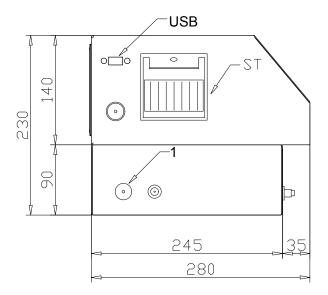


NOTE - NOTES

- La macchina deve essere livellata orizzontalmente. - L'alimentazione elettrica di ogni macchina deve essere protetta con un interruttore differenziale (30 mA, tipo "AC").
- Tutte le connessioni dei servizi per la macchina devono
- rispettare tutte le normative e pratiche locali applicabili. - Il fabbricante si riserva il diritto di apportare modifiche al prodotto che possono non essere riportate nel disegno.
- The machine shall be horizontally levelled. - The electrical supply of each machine must be protected with a ground fault interrupter (30 mA, "AC" type).

 - All services connections to the machine must comply with all
- applicable local codes and practices.

 The manufacturer reserves the right to make product changes that may not be reported in the drawing.



SPECIFICA CONNESSIONI - CONNECTION DETAILS			
1. ELETTRICA - ELECTRICAL			
Tensione - Voltage:	230-240V / 1~+N+PE / 50Hz		
Potenza - Power: 250W / 1,5 A			
Fusibili - Fuse rating: 1 x 2 A			
Cavo e sezione min Cable and min. section: 3 x 1.5 mm ²			
Colori dei cavi - Cable colours:			
N: Blu - Blue PE: Giallo/Verde - Yellow/Green	n L1: Marrone - Brown		

PESI - WEIGHTS	
Netto totale - Total Net:	13 daN (kg)
ALTRE SPECIFICHE - OTHERS	BETAILS
AMBIENTE - ENVIRONMENT	
Temperatura -Temperature:	+5+40°C (+41+104°F)
Umidità relativa - Relative humidity:	Max 80%(531°C); 50% (40°C)
Liv. pr. sonora - Eq. noise pr. lev. (Leq)	< 70 dB(A)
CONFIGURAZIONE - CONFIG	GURATION
A) Risc. in circolazione-Circulating heating type:	E: ELETTRICO-ELECTRICAL
B) Risc. in asciugatura-Air drying heating type:	X: N.A.
C) Risc. in taniche-Tanks water heating type:	X: N.A.
ACCESSORI INSTALLATI - INSTALLED OPTI	ONALS
ST) Stampante - Printer	

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Installation manual **Service** manual

EPW 100 S:

Manual Cleaning Phase Assistance for flexible endoscopes

Serial N°:











Via Balegante, 27 31039 Riese Pio X (TV) **ITALIA**

Manufacturer:

STEELCO S.p.A.

Via Balegante, 27 31039 Riese Pio X (TV) **ITALIA**





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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.

Follow 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.





1. GENERAL RULES

1.1 Limits of manufacturer's liability

The manufacturer shall not be held liable for failures or problems arising from tampering and/or incorrect applications and/or improper use of the machine.

The purchaser must follow all the instructions set forth in the user's manual, and in particular he must:

- Always work within the allowable limits for the use of the machine;
- · Always carry out constant and diligent maintenance;
- Allow the use of the machine only to skilled and trained personnel;
- · Use only manufacturer original spare parts.

Modifications and adaptations made on machines which will be placed on the market do not oblige the manufacturer to intervene on previously supplied machines, nor to consider the machine and the related user 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 have to be considered in addition to employer requirements, in order to be compliant to safety standards.

In case of serious accident that has occurred in relation to the device, it must be reported by the user and/or patient to the manufacturer and the competent authority of the Member State, in which the user and/or patient is established.

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 it is valid for the entire life cycle of the machine.

The manufacturer is available to give further information and/or to receive suggestions to make the manual more compliant to customers needs.

In order to prevent possible accidents to persons or property due to an incorrect translation of the instructions, the client must:

- Not perform any operation in case of doubts or uncertainties about the operation to be performed;
- Ask technical service for clarification of the instruction.
- Ask for a new copy of the manual if it has been lost.

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 to learn how to use and manage the device.

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 protect the user according to the following Regulations and "Technical Product Standards":

- Regulation (EU) 2017/745 (Medical Devices);
- 2014/35/UE (Low Voltage Directive);
- 2014/30/EU (EMC Electromagnetic compatibility directive);
- EN 61010-1 (Safety);
- EN 61010-2-040 (Safety);
- 2011/65/EC (RoHS II);
- 2012/19/EC (WEEE);
- · 2006/42/EC (Machine Directive);
- IEC 61000 (Electromagnetic compatibility);
- · IEC 61326-1 (Electromagnetic compatibility);
- ISO 14971 (Medical devices risk analysis);
- ISO/TS 15883-5 (Soil test A soil test method to prove the effectiveness of cleaning activities);
- IEC 60529 (IP Grade).





2. SAFETY INFORMATION

The compliance to safety standards allows the operator to work safely, without the danger of harming himself or others.

Before using the EPW 100 S, operators must be completely familiar with the functions and the operations of the machine.

They must read the user manual and be trained on the machine functions.



2.1 Intended purpose, improper use

INTENDED PURPOSE:

The use of this device is intended only and exclusively as system of automatic support for the manual washing of flexible endoscopes and relative components.

IMPROPER USE:

The improper use of this device is any other use than the intended use.

WARNING



Any other use than the intended use is forbidden.

An improper use of this unit may be hazardous to the operator and may seriously damage the machine itself

If the appliance is used without following the manufacturer instructions, the protection of the appliance may be compromised.

2.1.1 Application fields

• General flexible endoscopes (gastroscopes, bronchoscopes, colonscopes, etc..)





2.2 Important warnings and suggestions

For proper use of the machine, and in order to protect the personnel, carefully follow the general and specific rules below.

THE OPERATOR MUST:

- Carefully follow the instructions provided by the employer, managers and supervisors for individual and group safety.
- Use safety devices appropriately and carefully, as well as group and individual safety gear provided by the
 employer.
- Immediately inform the employer, the manager or the supervisor about deficiencies in the aforementioned
 devices, as well as any hazardous conditions which they may become aware of. In urgent cases, the operator
 shall take actions according to his responsibilities and abilities in order to eliminate or to reduce the deficiencies or
 the 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.

2.3 Safety recommendations

- · If the new machine looks 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 used only by trained persons;
- · This machine is intended as manual washing assister for flexible endoscopes.
- · Any use other than the intended use is forbidden.
- Keep chemical cleaning products out of the reach of children and people who have not been trained to use them properly.
- The user is not allowed to carry out any action or repair on the machine.
- The technical maintenance should be carried out by qualified and authorised operators only.
- The equipment should be installed by authorised people only.
- Do not install the equipment in rooms where the risk of explosion (ATEX) is present.
- Do not expose the equipment to extremely cold temperatures.
- · The electrical safety of machine is only guaranteed if it is connected to an efficient ground system.
- Be very careful while handling detergents and additives: avoid direct contacts, 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 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.

- Do not wash the machine externally using high-pressure jets of water.
- Disconnect the machine from the electrical supply before carrying out maintenance work.
- The acoustic pressure of the machine is below 40 dB(A).







2.4 Recommendations to ensure high quality performance

- The user must supervise the machine during the cycle.
- When the machine is running do not interrupt the cycle since this jeopardises cleaning efficacy.
- · Use recommended 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 recommendation of chemical additives does not make the manufacturer responsible for any damage to the materials and objects treated.
- Follow the manufacturer's chemical products indications.
- · Check that the chemical product is suitable for the washing programme as well as the material to be treated.
- The machine is designed to be used with water and chemical additives. Do not use organic or other types of solvent as they may cause a risk of explosion or the rapid deterioration of certain machine parts.
- Residues of solvents or acids (as in particular "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 chemical powder.
- · Do never use foaming detergent.
- · Use original components only.
- · The machine has to be used only with the components provided by the manufacturer.
- Components which are not approved by the manufacturer may compromise the results as well as user safety.
- Do not use chemical products chlorides based (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.

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 warranty.





2.4.1 Inlet water quality

The quality of the water used in all stages of cleaning is important for good results.

The water used in each stage must be compatible with:

- · The material of which the washer disinfector is made of.
- · The chemicals used in the process.
- · Process requirements for the various stages of the process.

The main factors that affect the good inlet water quality in relation to the washing efficacy are:

HARDNESS	The high hardness of the water generates a detergent inactivation, reducing its efficacy. It also causes limescale deposits in the machine, jeopardizing the clean of the instruments and the machine, especially on hot parts (ex. heating elements).	
IONIC CONTAMINANTS	A high concentration of ionic contaminants may cause corrosion of steel, manganese or copper instruments.	
MICROBIAL CONTAMINANTS	Microbial contaminants can increase the microbial contamination of the instruments at the end of the wash.	

The manufacturer recommends therefore that the water used should be softened and of drinkable quality in accordance with the "Guidelines for drinking water quality 3rd edition" published by WHO".

Further advice should also be obtained from the manufacturers of chemical and medical equipment. Where local standards are stricter than these recommendations, please follow local rules.

Note: it is the user's responsibility to supply the machine with suitable 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. / 58 pH

Chemical Properties

	Iron	min 0 mg/l (ppm)	max 2 mg/l (ppm)
Llegar metal ione	Manganese	min 0 mg/l (ppm)	max 2* mg/l (ppm)
Heavy metal ions	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)
	Phosphates (P ₂ O ₅₎	min 0 mg/l (ppm)	max 0,2 mg/l (ppm)
Others ionic contaminants	Nitrates (N _i)	min 0 mg/l (ppm)	max 20* mg/l (ppm)
	Silicates (SiO 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





2.5 Residual risks

The appliance includes a series of controls to prevent the access to hazardous internal parts or zones. It is however considered that the **EPW 100 S** includes some residual risks. Hereunder, the risks and the countermeasures that should be taken are shown:

PHASE	BASKET LOADING
RISK	Bruises caused by accidentally falling or bumping into the equipment itself.
MEASURE	Assign staff that is instructed and equipped with work equipment and appropriate clothing and individual protection gear (e.g. shirts and protective gloves).

PHASE	OBTAINING DETERGENTS/CHEMICAL ADDITIVES
RISK	Contact of body parts with chemical products.
MEASURE	The staff shall be trained 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 clothing which has been contaminated or soaked by the product. If the substances come into contact with the skin, wash off the areas immediately and rinse with water.
RISK	Inhalation of vapours of chemical wash products.
MEASURE	The staff shall be trained and equipped with appropriate clothing and individual protection gear. Be compliant to 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.
Ţ.	IN CASE OF CONTACT WITH BODY PARTS 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 due to the contact with hot parts of the appliance.
MEASURE	The maintenance must be performed only by trained personnel, equipped with appropriate clothing and individual protection gear. They must 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.				





2.6 Safety signals used

Safety signals (as set forth by 92/58 EEC) are sticked to the machine and closed to the working area, to inform the personnel of behaviour obligations and residual risks.

GENERIC SAFETY SIGNALS:

In particular, the most common labels with obligations, prohibition and danger signals, are:







Biological risk

INDIVIDUAL SAFETY WEAR:

The risk and the residual risk evaluation for the workers health and safety, is carried out in the working area and on any equipment. This allows the employer to adopt the individual protection gears which are most suitable and appropriate to be provided to workers.





2.7 Training

The instructions for use of the machine will be provided during the start-up phase by the AUTHORIZED INSTALLATION TECHNICIANS to MACHINE OPERATORS and MAINTENANCE TECHNICIANS.

The EMPLOYER must control if the staff is properly trained for the assigned duties.

2.7.1 Staff qualification

According to installation and maintenance procedures, some professional profiles are identified as follows:

IS INSTALLATION and REPAIR TECHNICIAN:

Specialized installation and maintenance operator. He is capable of machine positioning and installation, of the connection of the electrical and the hydraulic systems and of the machine start-up procedure. He also performs routine and special maintenance operations. This operator is responsible for staff training, for machine operation and for testing the machine.

AS RESPONSIBLE AUTHORITY FOR THE MACHINE IN THE WORKPLACE:

Specialized staff that must verify safety devices and procedures in order to use the machine without any hazard.

The responsible authority is personally responsible for training courses to users and maintenance operators.

He must ensure that staff assigned to operation has acquired all information for the use and the 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 the personnel about safety standards, actions to be avoided and the first aid interventions related to the use of the machine and the chemical wash agents it contains.

The responsible authority must be aware of the proper procedures and maintenance activities, as well as all procedures for the disposal of pollutants residuals and manufacturing wastes.

He must always be present during extraordinary or routine maintenance. He must approve all the operations or routine or special maintenance.

The responsible authority is responsible for the right functioning of the command, controls and safety devices in the machines.

He shall carry out scheduled verification of those devices in order to ensure their continued functioning over time.

AC MACHINE OPERATOR:

Skilled personnel who operate with the machine.

The machine operator must be perfectly aware of all the machine's command and control devices.

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

- Commissioning and start-up of the machine;
- · Connection of the endoscopes to be washed;
- · Operation of the machine in the various possible working modes.
- Programming and setting data from the operator panel and starting or resetting of work functions.
- Be capable of performing some routine maintenance such as cleaning inside the machine. All these operations must be performed using individual protection gear and following adequate safety measures.





2.8 Indication of sound level

The value shown below refers to a sound level measurement performed at a height of 1,5 m and at a distance of 1 m from the machine.

AVERAGE SOUND PRESSURE LEVEL: < 60 dB (A)

2.9 Transport and storage

Environment conditions:

- Temperature range -5 ... +40 °C;
- Relative Humidity range Max 80% (5 ÷ 31°C); 80...50% (31...40°C);
- Ventilation: Air exchange not required (it is required only if chemical tanks are installed).

2.10 Table of symbols

Symbols installed on the machine:

4	Electrical risk				
<u></u>	Warning - hot surface				
***	Manufacturer				
~~ <u> </u>	Manufacturing date				
\triangle	Attention! See the enclosed documentation for important warnings, such as warnings and precautions.				
i	See instruction for use				
	Protective conductor terminal				
CE	CE mark. It is reported on the serial number label.				
	WEEE waste disposal				
MD	Medical device indication*				
COD	It indicates the final product code of the medical device. It is reported in the serial number label. The "COD" corresponds to the article code in the system (AS 400) and in the sales invoice. This code can be variable depending on the model/specifications required by the customers. The machine model requested by the customer is in line with the model reported inside the technical documentation "DT-8051520DSXX2A" and in the DD 8051520DSXX2A medical device description document.				





REP	Authorized Local Representative.				
#	It indicates the model number of the product. It is reported on the serial number label.				
UDI	It indicates the unique device identifier of the product. It is reported on the serial number label.				





3. INSTALLATION (FOR THE INSTALLER ONLY)

3.1 Activity to be done before the installation

PREPARATION OF THE INSTALLATION SITE:

The connection arrangements to the electrical and hydraulic systems must be provided by the customer before the installation of the machine.

Connections must be compliant to the standards in the country of installation.

They also must be compliant to the instructions reported in the documentation, which is provided, on request, before the machine installation.

Environment conditions:

- Temperature range -5...+40°C;
- Relative Humidity range Max 80% (5 ÷ 31°C); 80...50% (31...40°C);
- Visibility: the brightness of the environment has to be between 100 lux and 1500 lux (in case of more restrictive standards in the country in which the equipment will be installed, these standards prevail).

3.2 Positioning

3.2.1 Movement, unpacking and placing

The machine reaches the customer completely packed and protected by cardboard packaging.

LIFTING AND MOVEMENT:

The handling of the machine does not foresee the use of particular vehicles since the entire package does not exceed 15 kg.

UNPACKING AND PLACING:

Unpack the machine, close to the installation area, carefully following these steps:

- · All the packaging materials can be recycled.
- · Open the packaging carefully.
- Do not turn the machine upside down since this may cause irreparable damage.
- Cut the strap, open the box and remove the expanded polystyrene angular protections.
- Remove the box and then the nylon bag.
- · Caution: the bag represents a serious hazard for children: disposed it immediately.
- · Place the machine on the work surface and level it by adjusting the feet.
- The machine must be placed horizontally with a maximum inclination of 1÷2°.
- Do not place the machine on surface which a fire or fume may occur.

3.2.2 Maximum Load for shelf positioning

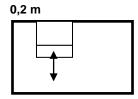
In case that the machine needs to be installed on a shelf, the shelf must be dimensioned to bear a minimum load of:

20 daN/m² ca. 20 kg

3.2.3 Positioning of the machine

The minimum dimensions needed for a standard installation, both in case of single and multiple installations, are given. For different installation ask to the distributors.

EPW 100 S







3.3 Electrical connection

- · The connection of the machine to the electrical supply mains must be made by qualified and skilled personnel.
- Power supply cable: the retailer and/or the installer must adapt the insulation class of the power supply cable to the working environment in order to be compliant to the Current Technical Regulations.
- · The electrical connection must be carried out in compliance with current technical regulations.
- Make sure that the measured voltage corresponds to the voltage indicated on the machine type plate.
- Check that the power supply voltage does not differ by more than 5% from its value.
- The frequency of the power supply voltage must not differ by more than 1% from its value.
- The connection of the machine to the electrical network must be equipped with a ground connection and an equipotential circuit as established by the regulations in force.
- Make sure that the electrical systems are efficiently grounded.
- The machine is built according to class II criteria.



- Connect the machine and the dedicated safety device (not supplied) using a power cable compatible with the electrical characteristics of the machine.
- In case the machine will not be used for a long time, it is suggested to perform the disconnection procedure of the electrical connection by placing the dedicated safety device in the OFF position.
- · The electrical network must be dimensioned and protected in accordance with current local regulations.

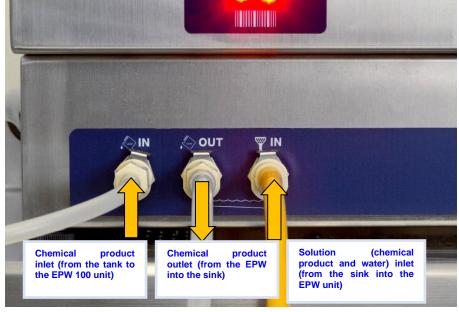
The dedicated safety device must be placed in an accessible place, free and not covered from other machines or anything that could obstruct the switch control.

 The dedicated safety device must be provided with quality markings and must be indicated as an electrical shut-off device for the machine.

3.4 Connection to the chemical product (if activated)

The chemical product dosing system can be activated/deactivated by a software with a password. It is composed of:

- Dosing pump for the chemical products.
- Sensor of presence for the chemical.
- Flow sensor to determine the exact quantity of chemical dispensed.
- Quick couplings for chemical tank/EPW connection and EPW/sink connection.





ATTENTION

In order to guarantee the right treatment of the medical devices, we suggest the use of specific products. In the case it is needed, ask for advises to the seller or the producer.





3.4.1 Presence sensor of chemical product

Each dosing pump is combined with a level sensor that checks the presence of chemical product inside the tank. If the product level is low, the electronic control system of the machine sends a message on the video for the lack of product.

3.4.2 Chemical product quantity check

Each individual pump is linked to volumetric sensor in order to measure the quantity of chemical product dispensed. The electronic control unit checks the value of the minimum quantity needed and, if necessary, it interrupts the cycle.

3.4.3 Replacement of chemical product container

To replace the chemical product tank, perform the following procedure:

- Take the new product tank.
- Wear appropriate PPE.
- Change the chemical product tank removing the level sensor from the empty tank and putting it into the new one.
- Close the cap and place the tank in the area where chemical substances are stored.

ATTENTION



The used chemical product can be dangerous if touched or inhaled. Before the use, carefully read the safety information supplied by the manufacturer of the chemical product and the label on the package.

While replacing the chemical product tank, use the appropriate devices for individual protection (chemical protective gloves, face masks for breathing, etc.).

The access to the technical compartment, where the chemical products are located, is permitted only to the authorized personnel and it is key protected.





3.4.4 Warning

- Check if the chemical is suitable for the washing program.
- Follow the chemical manufacturer instructions for dilution and contact time.
- The quantity of product delivered can be calibrated by the technician.
- To ensure the efficiency of the chemical dosing system it is recommended to perform the calibration procedure every 6 months.
- To ensure the efficiency of the chemical delivery pumps, it is important to perform the maintenance as described in chapter 6.
- · Use only liquid chemical products.
- Dispose the product following environmental, waste disposal legislation and any regional local authority requirements.
- · Place the chemical tank at a lower height level than the machine, do not place the chemical tank upon the machine.



ATTENTION

Before undertaking any sort of special maintenance or movement of the machine, empty tanks and chemical dosing circuit from the chemical. It is suggested 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.





PRELIMINARY CHECKS 4_

Introduction 4.1

The preliminary adjustments and controls are performed by a skilled technician.

Checks of safety systems

Here below, an indicative list of adjustments and checks of safety systems and devices that needs to be carried out:

- Check the mains supply voltage;
- Check the efficiency of the emergency and machine shutdown devices;
- Check the functionality of machine controls, especially the START and STOP commands.

4.3 **General controls**

Here below, an indicative list of general adjustments and checks:

- Check the correct functioning of general supplies of the machine (electrical and hydraulic);
- Be sure that the **MACHINE OPERATOR** is trained for the use of the machine.





5. CONTROL PANEL AND RELATED SYMBOLS

5.1 Machine components



REFERENCE	DEVICE	REFERENCE	DEVICE
1	Printer	7	Endoscope Channels Connection System
2	Barcode reader	8	Solution (chemical product and water) inlet (from the sink into the EPW unit)
3	Display	9	Chemical product outlet (from the EPW unit into the sink)
4	Start button	10	Chemical product inlet (from the tank to the EPW unit)
5	Stop button	11	USB Port
6	Reset button		





5.2 Control panel

The control panel simplifies the use of the machine since it indicates the cycle stages during the washing procedure; moreover, any fault is signalled by error messages. There are also some controls. The LED lights that identify the input have different colours.

The functioning of each input is showed on the display.



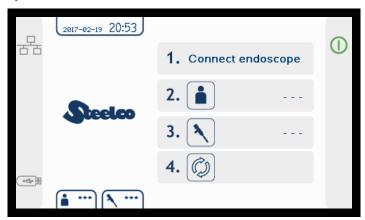
ATTENTION

Each field is active only if the corresponding LED light is switched on.

BUZZER

There is a buzzer that makes a sound every time that a key is pressed and intermittently in case of alarm.

MAIN PAGE (STAND-BY)



SYMBOLS

FIELD	DESCRIPTION
2017-06-22 11:15	Date and time
1. Connect endoscope	Connect the endoscope to the device – image shows a 4-stage sequence
2. 👛	User identification (OPTIONAL) - image showing a 4-stage sequence
3. 🔪	Endoscope identification (OPTIONAL) - image showing a 4-stage sequence
4. 🔘	Start the cycle - image shows a 4-stage sequence
	Leak test
	Time left to the end of the cycle
1 1	Operator and endoscope ID





FIELD	DESCRIPTION
	Start button placed on the side of the display
\bigcirc	Stop button placed on the side of the display
	Reset button placed on the side of the display
	Cycle in progress
	Chemical dosage – value shown on the side of the display
W	Purging of the endoscope channels –flow values and left time are shown on the side of the display
	When in movement, it indicates that the machine is flushing the endoscope channels for the rinse phase.
0≠≡≡≡	Drying of the endoscope internal channels— the time left is shown on the side of the display
	Connection to the ETHERNET network not active.
○€₽	Connection to the USB key active.
Cycle completed Disconnect endoscope	Cycle successfully completed
Alarm 09 Alr pump pressure switch	An alarm occurred. The code and a short description of the alarm are shown.
WARNING Chemical tank empty	Empty chemical canister. Please replace it with a new one.
ACTION	It indicates that an operator action is required. The operator has to manually clean the internal surfaces of the endoscope (if parameter "PAUSE EN" is set to 1). Press START after having carried out the endoscope brushing.
ACTION	Warning concerning the connection of the endoscope flush channels.





FIELD	DESCRIPTION
1. 2. 3. © 1	The machine requires a sequence of actions after the flushing phase: 1. Drain the water from the sink 2. Fill the sink with water up to the pre-set level 3. Press START to continue
1. 2. © ①	The machine requires a sequence of actions after the rinsing procedure with clean water: 1. Drain the water from the sink 2. Press START to continue
ACTION 1. 1.	Start the second flush phase.
STATE STATE	The operator can select how to continue the cycle: 1. Fill the sink with water 2. Empty the sink 3. Confirm water level





5.3 Menu

To enter the menu, use the SERVICE card placing it in front of the machine barcode reader.



The following menu will automatically appear:



In order to scroll through the menu items, press the arrows, while to access the menu, confirm the selection by using the central button.





MENU	DESCRIPTION
TIME/DATE	Time and date configuration
MACHINE	Machine settings. It also includes the section dedicated to the calibration of the flowmeters.
LEAK TEST	Section for the configuration of the leak test values.
CHEMICAL	Section for the configuration of the chemical products.
WASHING	Section for the configuration of the washing cycle values.
INPUT	Input status.
OUTPUT	Output activation/deactivation.
UPLOAD	Uploading of: • Machine settings; • Operator's list; • Endoscope's list; Here it is possible to reset the cycle history. Here it is possible to reset and update the firmware of the machine.
DOWNLOAD	Downloading of:
NETWORK	IP address settings.
BARCODE	Barcode reader settings.





5.3.1 Parameter list

5.5.1 Parame	<i>-</i>	1151				
CATEGORY	SECTION	PARAMETER	DESCRIPTION	MIN	MAX	U.o.M.
IP	1	1	Local IP address (first number)	0	255	YES_NO
IP	1	2	Local IP address (second number)	0	255	YES_NO
IP	1	3	Local IP address (third number)	0	255	YES_NO
IP	1	4	Local IP address (fourth number)	0	255	YES_NO
IP	1	5	Subnet mask (first number)	0	255	YES_NO
IP	1	6	Subnet mask (second number)	0	255	YES_NO
IP	1	7	Subnet mask (third number)	0	255	YES_NO
IP	1	8	Subnet mask (fourth number)	0	255	YES_NO
IP	1	9	IP gateway address (first number)	0	255	YES_NO
IP	1	10	IP gateway address (second number)	0	255	YES_NO
IP	1	11	IP gateway address (third number)	0	255	YES_NO
IP	1	12	IP gateway address (fourth number)	0	255	YES_NO
IP	1	13	Remote IP address (first number)	0	255	NUM
IP	1	14	Remote IP address (second number)	0	255	NUM
IP	1	15	Remote IP address (third number)	0	255	NUM
IP	1	16	Remote IP address (fourth number)	0	255	NUM
MACHINE	2	1	Back light	1	10	MSG
MACHINE	2	2	Acoustic signal	0	1	YES_NO
MACHINE	2	3	Chemical dosing value	1	999	milliLITER
MACHINE	2	4	Water dosing value	1	99	LITER
MACHINE	2	5	Language	1	13	MSG
MACHINE	2	6	Machine ID	10000	99999	NUM
MACHINE	2	7	Automatic sink presence	0	1	YES_NO





MACHINE	2	8	Automatic washing cycle	0	2	SELECT
MACHINE	2	9	Printer	0	1	YES_NO
MACHINE	2	11	ocs	0	1	YES_NO
MACHINE	2	12	Client ID string (char. 1)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 2)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 3)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 4)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 5)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 6)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 7)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 8)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 9)	,	~	CHAR_STR
MACHINE	2	12	Client ID string (char. 10)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 1)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 2)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 3)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 4)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 5)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 6)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 7)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 8)	,	~	CHAR_STR
MACHINE	2	13	Service ID string (char. 9)	,	~	CHAR_STR





MACHINE	2	13	Service ID string (char. 10)	,	~	CHAR_STR
MACHINE	2	14	Network connection type	0	2	SELECT
MACHINE	2	15	SteelcoData ARES	0	1	YES_NO
SEAL	3	1	Stabilization time (set point 1)	0	300	SEC
SEAL	3	2	Leak test check time (set point 1)	0	300	SEC
SEAL	3	3	Stabilization time (set point 2)	0	300	SEC
SEAL	3	4	Leak test check time (set point 2)	0	300	SEC
SEAL	3	5	Leak test check time during the cycle	0	300	SEC
SEAL	3	6	Leak test check (set point 1)	0	300	milliBAR
SEAL	3	7	Gasket integrity check (set point 2)	0	300	milliBAR
SEAL	3	8	Maximum pressure loss during check phase	0	300	milliBAR
SEAL	3	9	Maximum pressure loss during cycle	0	300	milliBAR
SEAL	3	10	Maximum pressure measurable by the air pressure switch	0	9999	milliBAR
SEAL	3	11	Minimum pressure measurable by the air pressure switch	0	9999	milliBAR
SEAL	3	12	Timeout to reach setpoint 1	20	300	SEC.
CHEMICAL	4	1	Enabling chemical agent	0	1	YES_NO
CHEMICAL	4	2	Chemical agent dose value	0	999	milliLITRI
CHEMICAL	4	3	Maximum duration of the chemical dosage phase	0	300	SEC
CHEMICAL	4	4	Minimum level of chemical agent in the tank	0	999	milliLITRI
CHEMICAL	4	5	Enable manual brushing phase	0	1	YES_NO
CHEMICAL	4	6	Milliliter pulses for the chemical flow meter calibration.	0	9,999	IMP_mLITRES
WASHING	5	1	Minimum flow alarm	0	9999	milliLITER
WASHING	5	2	Maximum flow alarm	0	9999	milliLITER
WASHING	5	3	Washing stage duration	0	999	SEC
WASHING	5	4	Delay for washing flow check	0	300	SEC
WASHING	5	5	Duration of drying stage or duration of protein residue test stage	0	300	SEC





WASHING	5	6	Rinsing stage duration	0	300	SEC
WASHING	5	7	Pulse/litre value for the calibration of the water flow meter.	0	999,9	IMP_LITER
WASHING	5	18	Internal channels purging time during the disinfection	0	1800	SEC
WASHING	5	19	Internal channels rinsing time after the disinfection	0	600	SEC
WASHING	5	20	Channels purging time during the protein test	0	300	SEC
WASHING	5	21	Pulse/litre value for the calibration of tank water flowmeter	0	999,9	IMP_LITER
WASHING	5	22	Enabling of the second flushing phase	0	1	YES_NO





5.3.2 Barcode reader programming procedure

In case the barcode reader needs to be replaced or it has lost its programming data, follow the instructions below:

1 – Start the procedure	
2	
3	
4	
5	
6	
7	
8	
9	





10 11- Finish the procedure

- 1. Switch off the machine;
- 2. Connect the new barcode reader to the main board;
- 3. Switch the machine on and while the data is uploading, press the lower button, then the central one and in the end the upper one. Keep them pressed and then let them go all together at the same time.
- 4. Wait until the display is completely switched on (approx. 10 seconds);
- 5. The technical menu will be displayed;
- 6. Select the barcode box by scrolling with the lower blue button;
- 7. Access the barcode window by pressing the central **red button**;
- 8. Put the "START" barcode card in front of the reader;
 9. Press the blue led "scan" button repeatedly over the 6 barcodes (Make sure that these are read. When the reader reads the code correctly, it switches off);
- 10. Repeat operations 7 and 8 for five times until the "procedure end" is reached;
- 11. The reader must stay switched on if it has been correctly programmed.



5.4 Key access

To access the machine menu, use the following barcode cards:

START COMMAND



STOP COMMAND



RESET COMMAND



SANIFICATION PROGRAM







SERVICE PROGRAM



PROTEIN TEST PROGRAM







6. INSTRUCTIONS FOR USE

6.1 Checks

- · Check the status of the machine on the display and ensure that no alarm messages are present;
- Check the quantity of the chemical product and if necessary, replace the tank.

6.2 Endoscope preparation and cycle start

- Place the endoscope in the dedicated sink;
- · Carry out user and endoscope identification for traceability purposes;
- · Remove buttons and valves from the device, to do follow the instructions at par. 6.3 and 6.4.

ATTENTION

- To avoid contamination, it is advisable to disinfect the connectors of the endoscopes periodically. The frequency is selected by the customer on the basis of the internal risk analysis.
- Disinfection of the connectors inside in instrument washers;
- · Disinfection by cold immersion with disinfectants.
- Sterilization in plasma, vaporized hydrogen peroxide, ETO sterilizers or in steam sterilizers using the 121°C rubber cycle.
- · Make sure the leak test connectors and tubes are completely dried before re-using them.



ATTENTION

If the leak test is not connected to the device or it is connected when the endoscope is already completely immersed, liquid can penetrate inside the instrument. Therefore, always connect the endoscope before submerging it in the sink.





6.3 Cycle start

• Enter the user ID using the right barcode card (OPTIONAL). The user ID will appear on the display;



• Enter the instrument ID using the right barcode card (OPTIONAL). The instrument ID will appear on the display;





ATTENTION

It is NOT possible to enter or change the user ID or instrument ID when the cycle is running.

 Press the "-START-" button on the side of the display or use the "-START-" barcode card placing it in front of the machine barcode reader.







• Follow the instructions given on the display during the cycle.





6.4 Washing cycle stages sequence

FOREWORD – It is possible to stop the cycle in any phase pressing the red dedicated button or using the STOP barcode cards.

• STAGE 1 – Instrument leak test.

During this stage, the machine carries out two types of test and it shows pressure values. This test controls the integrity of the instrument and the glued gaskets.

The endoscope is kept under pressure all over the cycle: if an alarm occurs - leak detected - only the user can interrupt the test that automatically brings the instrument back to atmospheric pressure.



ATTENTION

Do not disconnect the leak test connector while the device is still immersed. Liquid could penetrate inside the instrument.



STAGE 2 – Chemical dosage in the washing sink (it can be deactivated)

The machine doses the quantity of detergent set by the installation technician, according to the quantity of water contained in the washing sink and according to the parameters of the detergent producer.





ATTENTION

For the dosage and the contact time, follow the instructions given by the chemical manufacturer. Higher contact time and concentration could damage the endoscopes and the system.

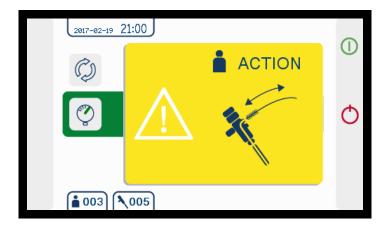




STAGE 3 – Brushing of the endoscope channels

After having dosed the detergent, the machine switches to a stand-by mode to allow the operator to manually carry out the cleaning of the endoscope channels. (Parameter 4.5 must be set to 1).

After having carried out the endoscope brushing operation, press START.



STAGE 4 - Connection of the endoscope channels to the device.



STAGE 5 – Washing

During the washing stage, the machine checks and displays channels flow and residual time. Pressure control detects channels obstructions and disconnections.

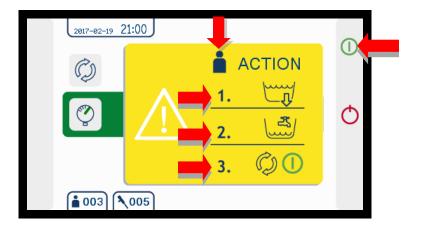






STAGE 6 – Wait for operator actions

During this stage, the machine asks the user to drain the washing water and to refill the sink with clean water before proceeding with the cycle by pressing the start button or by using the START barcode card.



STAGE 7 – Rinsing endoscope channels

During this stage, the machine removes detergent residuals inside endoscope channels; the user can also manually rinse the external surface of the device.



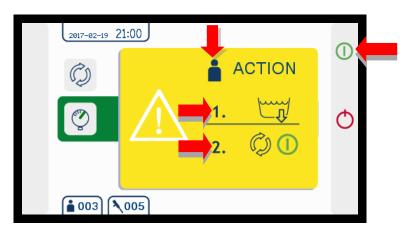
ATTENTION

Be aware that detergent residuals on the instrument can interfere with the endoscope washing cycle. Therefore, carefully wash the endoscope with clean water.



STAGE 8 – Wait for operator actions

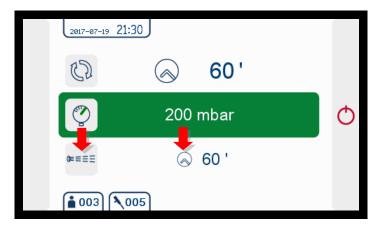
During this stage, the machine asks the user to drain the rinsing water before proceeding with the cycle pressing the start button or using the START barcode card.





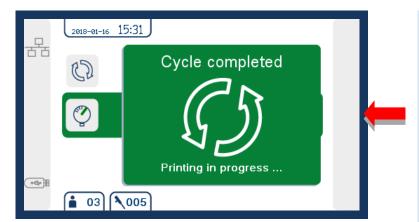


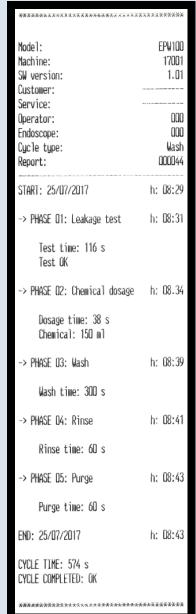
STAGE 9 – Channels Purging PhaseDuring this stage, the machine removes water residuals from the endoscope channels.





STAGE 10 – Printing process

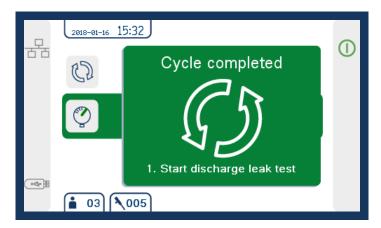








STAGE 11 - Start discharge leak test.





STAGE 12 - Disconnection of the endoscope.







7. SPECIAL CYCLE

7.1 Self-Disinfection cycle

It is possible to run self-disinfection cycle following this procedure:

1. Fill a tank with minimum 3 litres of water. Add 0,5% of Steelco Decon F (5ml for each litre of water). There's no need to mix the solution.



- 2. Close the leak test tube (the transparent tube of the OCS connector).
- 3. Enter operator ID.
- 4. Self-disinfection phase setup

Put the suction pipe (1) and the washing pipes <u>WITHOUT</u> the leak test (the transparent tube) (2) inside the tank with the solution.

The suction pipe's end (1) needs to be completely submerged into the solution, otherwise air will be pumped inside the machine.



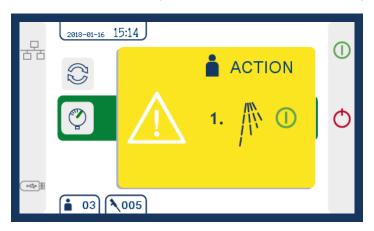




5. Start the self-disinfection cycle using the yellow RFID/barcode AUTO SANIFICATION card.



- 6. The machine will flush the hydraulic circuit for 10 minutes with the solution (water + disinfectant).
- 7. After the recirculation phase, the machine will go into standby mode and the following screen will appear:



8. Rinse phase setup

The operator must place the suction tube (1) into a clean tank with clean water, and the washing tubes (2) in the sink with the drain open. It is recommended to fill the tank with minimum 3L of clean water. The end of the suction pipe (1) needs to be completely submerged during the whole phase.



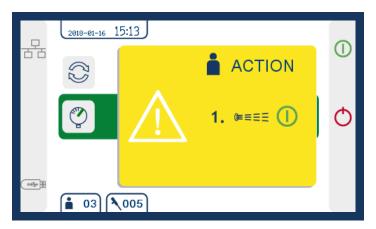




9. Use the START card to start the rinse phase.



- **10.** The machine will flush the hydraulic circuit for 30 seconds.
- 11. After the rinse phase, the following screen will appear.



12. Purging phase setup

Remove the suction tube from the tank with the clean water. Now the suction tube (1) needs to draw air in order to make an effective purge.

13. Start the purge phase using the START card and wait for the end of the cycle.



ATTENTION

The procedure must be repeated at the end of every working day of use or after 72 hours of machine downtime.





7.2 Protein removal test cycle

Using a dedicated barcode card, it is possible to start a protein test cycle in order to check the cleaning efficacy of the system. This test uses reagents that change colour when they come into contact with the proteins. Through the procedure described below, the liquid used for the test (saline solution, sterile solution, Tween 80) can be taken by the operator through the distal end of the endoscope.

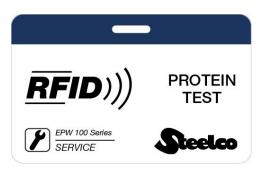
7.2.1 Proteins Test Procedure

- Place the endoscope to be tested in a dedicated container or on a clean surface.
- · Connect the endoscope to the OCS system and do not forget to connect the channel separator.





- Use low temperature systems to sterilize the suction tube connected to the machine.
- Enter the endoscope and operator ID using the built-in reader of the EPW unit.
- · Start the protein test using the correct barcode card.









• Place the distal part of the endoscope inside a second empty sterile container, without touching the walls, in order to avoid contaminations.



- · Wait for the end of the automatic leak test.
- After the leak test, start the flushing phase.
- After the flushing phase, extract the distal end of the endoscope and close the container. Raise the suction tube and start the purging cycle, in order to remove the water from the instrument.
- Take the printout with the traceability results of the test.
- Disconnect the endoscope using the START RFID card.
- Test the water according to the indications given by the protein test producer.

NOTE – At any moment of the cycle, at every stage, it is possible to reset or stop the cycle pressing the dedicated buttons or STOP and RESET barcode-cards.





8. MACHINE CONDITIONS

8.1 Preparation

Follow the preparation stage as described in the Paragraph.

8.2 Stand-by

The machine is ready to start.

The diagnostic is active.

Display showing warnings or alarms messages.

8.3 During the cycle

Start the cycle using the appropriate barcode Card or by the panel key.

The cycle is running properly.

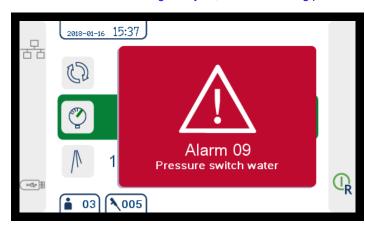
The diagnostic is active.

The user interface provides indications about the different cycle phases.

8.4 Alarms management

If the machine is locked in the standby mode, solve the cause of the alarm and do the unlocking procedure.

If the machine is locked during the cycle, do the unlocking procedure.



If a block occurs, a window appears providing the alarm code and a brief description of the cause. The user will be able to put in place the appropriate actions.



ATTENTION

If an alarm occurs the EPW 100 S stops to avoid and to prevent damages.





8.5 Alarms list

Here below, the list with the alarms, their description and the actions required is reported.

NUMBER	ALARM	DESCRIPTION	SOLUTION
01	Leakage test fail!	During the initial leak test the pression has dropped under the setpoint value P3 06 (or P3 07) of P3 07 (OR P3 09) mbar. During the cycle the pressure has dropped by P3 09 mbar from the setpoint value that was reached at the end of the initial leak test phase in less than 30 s. During the cycle the pressure has dropped by 50 mbar from the initial setpoint value P3 07.	Visual check of the device and then send it to maintenance.
02	High flow	During the flushing of the instrument's channels, the flow is higher than the max limit set by parameter P5 02.	Check the washing pump. Check the correct connection of the machine tube via the fast-connection connectors. Check the parameter setting.
03	Insufficient flow	During the flushing of the instrument's channels, the flow is LOWER than the min limit set by parameter P5 01.	Check the washing pump. Check the correct connection of the machine tube via the fast-connection connectors. Check the parameter setting.
04	Chemical lack	During the chemical product dosage, the level of the chemical in the tank is insufficient to reach the necessary dose set by parameter.	Change the chemical tank.
07	Chemical timeout	During the initial leak test, the setpoint P3 06 is not reached in the time set by parameter P3 12.	Check the operation of the chemical pump and the suction channel.
08	Air pump pressure switch	The pressure switch for the water control is not active, when the leak test pump is active.	Check the operation and the connection with the pressure transducer.
09	Water pump pressure switch	The pressure switch for the water control is not active when the cleaning pump is not active.	Check the operation of the purging pump and the suction channel.
10	Timeout leak test	During the leak test, the air pressure never reaches the preset value within the pre-set time.	Check that the tool is connected and no air leaks are present.
11	Flowmeters discrepancy	The chemical agent and water flowmeters have been swapped.	Check the connections.
12	Disconnected instrument	During the washing cycle the closing sensor of the OCS connection is not active. Disabled diagnostics if P2.18=1.	
13	Electrical interruption	During the cycle the power supply is disconnected from the machine. At the next start the alarm is displayed on the screen.	





15	FL1 impulses	During the dosage of the chemical product the chemical dosage flowmeter does not count any impulse in the time set by parameter P4 11.	
16	FL2 impulses	During the flushing of the instrument channels, the water flowmeter does not count any impulse in the time set by parameter P4 11.	
35	Keyboard communication	Keyboard communication failure	Check the keyboard operation and the connection with the electronic board.
36	Display communication	Display communication failure	Check the display operation and the connection with the electronic board.





8.6 Warning management

Warnings give some information to the user. Warnings don't stop the cycle. The user has to do the proper corrective actions in order to guarantee the safe use of the system.



In case of failure which does not lead to a block, a window appears indicating the warning with a short description as shown in figure.

8.7 Warning list

Below you can find a warnings list.

WARNING	DESCRIPTION	SOLUTION
Lower chemical level	The chemical product level is low.	Replace the chemical tank.
Disconnected instrument	At the start of the cycle, the endoscope is not connected.	Connect the endoscope.
Ares answer Timeout	Communication failure with SteelcoData ARES.	Check the connection to the net and restart Steelco-Data ARES.
Not authorised instrument	SteelcoData ARES cannot start a wash cycle for this endoscope.	Check the traceability of Steelco-Data ARES.





RESET PROCEDURE 9.

In case of block or alarm do the reset procedure:

- Keep the blue button pressed for 4 seconds;
- Press the red button when it lights up;
- Press the green button when it lights up;
- When the green button turns off, the alarm has been reset.

Otherwise pass the RESET barcode card on the reader.

The machine will return to the stand-by status.

10. SPECIAL FEATURES

10.1 Power failure

In case of a voltage drop during the stand-by mode, when the voltage restored, the system will return to the stand-by condition.

In case of a voltage drop during the cycle, when voltage is restored, the cycle will be interrupted and the machine will enter in stand-by mode.





11. WORK PROCEDURES

11.1 Introduction

The machine has been designed only and exclusively to wash flexible endoscopes channels therefore it is in contact with detergents and contaminated instruments.

For this reason it is necessary to provide operators instructions.

11.2 Users instructions

HEALTH CARE WORKERS, in normal operating conditions, are not subject to any risk if they use the proper PPE. The HEALTH CARE WORKERS must:

- · Carefully follow the instructions provided in this manual.
- Wear the appropriate PPE.
- · Inform in case of deficiencies or hazardous conditions

Maintenance technicians, in normal operating conditions, are not subject to any risk if they work wearing the proper PPF.

The maintenance technician must:

- · Carefully follow the instructions provided in this manual.
- · Wear the appropriate PPE.
- · Be really careful while reparing or replacing parts of machines which have not completed the cycle.





12. USB PORT

The USB port allows to upgrade the software and to save the cycle.

12.1 Software upgrades

Put the USB stick with the software upgrade into the USB port to load and update the board firmware.

WARNING: the USB stick must contain ONLY the upgrade file.

12.2 Cycle data saving

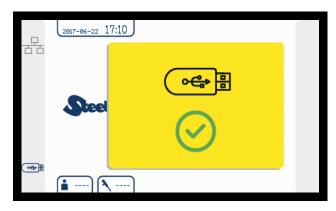
The device can save up to 100 cycles: if not downloaded, any extra cycle will be overwritten in the device memory capacity.

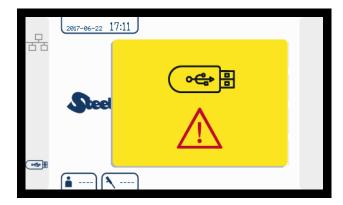
To download cycles data when the machine is in standby mode, put an empty USB memory stick into the dedicated port USB and follow the instruction:

1. The screen will be as the one shown on the right.



- 2. Press to save the data into the USB memory stick. If the saving procedure ends without any error, the screen will look like picture 14.1 otherwise it will look like picture 14.2.
- 3. Press to exit and do not save the cycle data.





Picture 14.1

Picture 14.2

WARNING: the USB memory stick must be empty in order to save data.





12.3 Modify the endoscope menu

1- Insert an empty USB stick



2 - Enter in the download menu using the technical card







3 - Enter in the downloads and select *Endoscopes*.



4- Press -"Endoscopes"- and download the list into the USB stick.



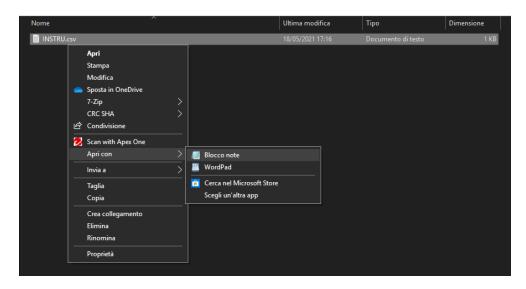




5 - Insert the USB stick into a PC USB port, rename the file removing the underscore.



6 - Open the file with the block notes.



7 - Fill it with the serial number, the model and the type of endoscope as shown below and save it.

```
INSTRU.csv - Blocco note
                                                                        \times
File Modifica Formato Visualizza ?
Instruments;
RC;
1;001;1234567;GIFH;OLYMPUS;
2;002;Serial2;Model2;Brand2;
3;003;Serial3;Model3;Brand3;
4;004;Serial4;Model4;Brand4;
5;005;Serial5;Model5;Brand5;
6;006;Serial6;Model6;Brand6;
7;007;Serial7;Model7;Brand7;
8;008;Serial8;Model8;Brand8;
9;009;Serial9;Model9;Brand9;
10;010;
11;011;
12;012;
13;013;
14;014;
15;015;
16;016;
17;017;
18;018;
19;019;
20;020;
```





8 – Insert again the USB stick in the device USB port.



9 - Enter using the technical card and select the upload menu.







10 - Enter and press *Endoscopes*.



11 - The upload will start.







13. PRINTER (OPTIONAL)

The machine can be equipped with a printer in order to print out the data of the washing cycle: on the printout also the endoscope and the user ID as well as events, such as alarms and warnings, are reported.



13.1 Last cycle printing

- 1. Enter in the device menu using the barcode (or RFID) card SERVICE;
- 2. Select DOWNLOAD
- 3. Select Historical cycle;
- 4. Keep the central button pressed for more than 3 seconds and then release it. The printing of the last cycle starts after having released the button.





FINE CICLO: OK
DURATA CICLO: DUm 36s

FINE: 12/04/2019 h: 15:58

Test superato
Durata test tenuta: 36s

-> FASE 01: Test di tenuta h: 15:58

AVVIO: 12/04/2019 h: 15:58

Humero report 000136
Tipo ciclo TENUIA

Endoscopio 000:
Operatore 00:
Servizio:
Cliente:
Versione software: 1.09
Seriale macchina: 19010 S

FINE CICLO: OK OURATA CICLO: D1m 28s	
FINE: 12/04/2019	h: 16:00
Durata spurgo: 20s	
-> FASE O2: Spurgo	h: 16:00
Chimico: 450mL Acqua: 30L Durata lavaggio: 30s	
-> FASE 02: Lavaggio	h: 15:59
Test superato Durata test tenuta: 38s	
→ FASE 01: Test di tenuta	h: 15;59
AVVIO: 12/04/2019	h: 15:59
Numero report Tipo ciclo	ODO137 PROTEINE
£	
Endoscopio 000:	
Operatore OO: Servizio: Cliente:	
Versione software: Seriale macchina: Hodello macchina:	1.09 19010 EPV100 S





13.2 Printer paper replacement

To replace the paper, follow the instruction below:

1. Press the green button and pull the cover to open the small door.





2. Place the paper as shown on the picture.







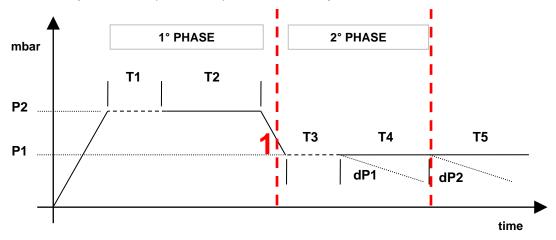
14. CALIBRATION PROCEDURE

14.1 Leak test setting

In the initial phase, the leak test controls that the endoscope has no leakages at a pressure P2. Then, the pressure drops to the pressure P1 and it is kept constant for the whole cycle.

The leak test continues during the whole cycle.

In the section 3 of the parameter list (LEAK TEST), there is the description of the variables included in the chart below.



If the machine cannot reach the pressure P1 within the time frame T3 a warning appears, calibrate the air venting using the valve indicated below by the red arrow.



REFERENCE	DESCRIPTION
1	Adjustment of the air that comes out of the endoscope.



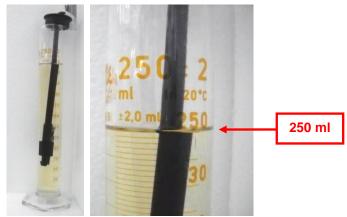


14.2 Chemical calibration

In order to calibrate the flowmeters, the chemical dosing system must be completely full.

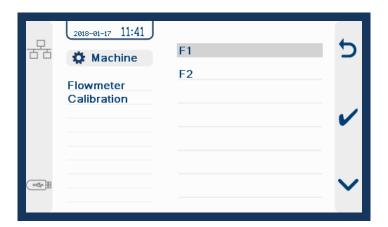
14.2.1 Calibration

Put the suction lance in the graduated cylinder for the calibration and fill it up to 250 ml with the chemical agent.



Chemical product

Enter in the menu: MACHINE FLOWMETER CALIBRATION



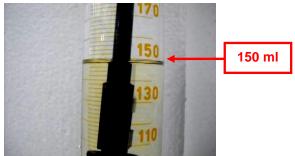
Select the flowmeter that needs to be calibrated by using the button and then press the central button ...





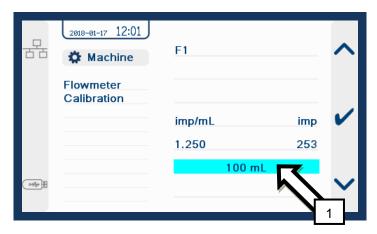


To start the procedure, press the button. To undo the procedure, press the button



Chemical product

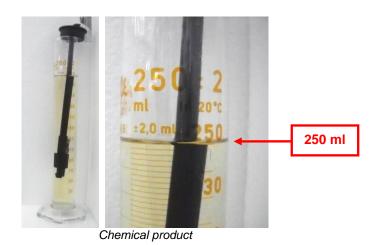
Press the button when the level of the chemical agent on the graduated cylinder has reached 150 ml. In field (1), highlighted in bright blue, insert the dosed quantity of 100 ml.



To confirm, press the central button.

14.2.2 Check

After the calibration, check if calibration has been performed correctly with the control procedure. Insert the suction lance in the graduated cylinder and fill it up to 250 ml with the chemical agent.



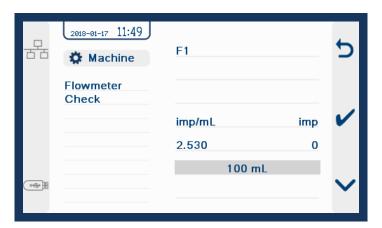
Enter in the menu: MACHINE FLOWMETER CHECK





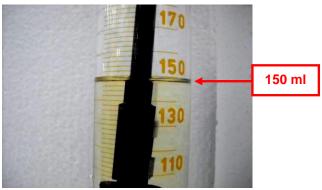


Select the flowmeter that needs to be checked and press the central button



To start the calibration test, press the central button.

Once the dosing phase has finished, the level of the chemical agent in the graduated cylinder should be of 150 ml.



Chemical product

If the levels do not match, a new calibration must be performed.





15. INSTALLATION AND OCS CONNECTION

Properly connect the OCS system to the instrument that needs to be treated and, if necessary, use the supplied caps to reduce the water flow of the disconnected tubes.

CODE	DESCRIPTION
C095019	1mm PERFORATED FEMALE LUER LOCK CAP
660037	QUICK MALE LUER COUPLING 3/16





16. MAINTENANCE

16.1 General recommendations on maintenance

The machine has been designed only and exclusively to wash flexible endoscopes channels therefore it is in contact with detergents and contaminated devices.

For this reason it is necessary to provide maintenance instructions.

Maintenance technicians are not exposed to any risk if they wea the proper PPE.

Technicians must:

- · Carefully follow the instructions set forth in this manual.
- Use PPE properly and with care.
- Be very careful while repairing or replacing mechanical parts (e.g. pump, etc.) on malfunctioning machines which have not completed the cycle.

Maintenance operations can be divided into Routine Maintenance and Special Maintenance.

GENERAL GUIDELINES:

MACHINE STATUS:

The machine must be switched off and the main switch must be in the OFF position.

Who will perform the maintenance must be sure that there nobody is closed to the machine during this operation.

SAFETY SYSTEMS TO BE ADOPTED:

The operation must be carried according to standards that regulate the use of disinfectant substances (see technical information), to the standards that regulate the contact with parts of the machine which may be contaminated by pathogenic materials and with the use of individual protection gear.

16.2 Procedure for routine maintenance work

Routine maintenance includes all operations that are needed to keep the machine components clean and functional. It must be performed regularly (see table of routine maintenance tasks) or when it is considered necessary due to an incorrect performance of treatment cycle.

Since these are simple cleaning operations, they are normally performed by the "health care workers" on his own liability.

16.3 Table of routine maintenance tasks

The following table shows the routine maintenance tasks, their frequency, who is in charge to perform them and the activities that has to be done.

Each activity is fully explained in the single reference forms.





TABLE OF ROUTINE MAINTENANCE TASKS

Osolos						ш	7	EPW 100 S	
-			-	rog	ran	l me	β	Programmed maintenance scheme	IME
	Step			months	ths			77; ;7* V	L
Components	make every	3	6 9	12	15	18 2	21 24	Activity	
The machine connection CPC O-ring connector	make every		×	×		×	×	Replace the oring.	15'
Instrument-machine connection pipes (external)	make every			×			×	Replace the pipes.	10,
Chemical product connection pipes (external)	make every			×			×	Replace the pipes.	10,
Internal connection pipes	make every						×	Replace the pipes.	30,
Electrical connections	make every		×	×		×	×	Check the integrity of the electrical connections.	52
Flowmeter	make every		×	×		×	×	Check the calibration of the flowmeters.	30,
Dosing pump	make every		×	×		×	×	Check for any leaks.	10,
Level sensor of chemical product	make every		×	×		×	×	Check the operation of and clean the suction filter.	5'
Female connectors of the OCS system O-Ring (inner O-Ring of each connector)	make every	×						Replace the O-Rings	,09
Replace the OCS tubes	make every			×				Replace the tubes	15'
Endoscope connectors	make every	×						Check the status of the connector and of the sealing O-Rings	
Washing pump	make every			×			×	Check for water leakage.	10,

N.B.: The time frames for the maintenance may vary by +/- 15 days from the period indicated in the table.

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, in particular if the supply water is very hard.

WARNING:

- DO NOT CLEAN THE MACHINE SURFACE WITH HIGH PRESSURE WATER.
- PLEASE CONTACT THE SUPPLIER OF YOUR CLEANING PRODUCTS FOR DETAILS METHODS AND PRODUCTS FOR THE ROUTINE SANIFICATION OF THE MACHINE.

		CLEANING OF SUCTION PUMP FILTER
	Worker: Is	Frequency of Intervention: 6 months
METH	OD OF INTERVENT	TION: Cleaning of the suction pump filters as described below:
Disass	emble the filter and	clean it.



WARNING

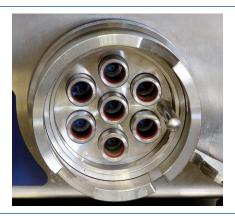
Maintenance activities can be performed only by trained, and qualified staff, equipped with adequate clothing and Individual Protection Devices. Always disconnect the machine before starting the maintenance operations.

		CHECK THE ENDOSCOPE CONNECTORS
	Worker: Is	Frequency of Intervention: 6 months
METH	OD OF INTERVENT	TION: Proceed as follows to check the endoscope connectors:
Check	the status of the co	nnector and of the sealing O-Rings. If necessary, replace them.

	REPLACE THE O-RING OF OCS CONNECTORS
Worker: Is	Frequency of Intervention: 6 months

METHOD OF INTERVENTION: Proceed as follows to replace the two O-Rings in each female connectors of the OCS system:

- · Disconnect the machine;
- · Replace the inner O-Ring of each connector.





ASSISTANCE

If a normal functioning of the machine is not achieved, even after interventions of ordinary maintenance, get in touch with our service assistance stating the defect, the model and the serial number of the machine.





17. PROBLEMS - CAUSES - SOLUTIONS

17.1 Introduction

This chapter lists some of the problems which may occur during machine operation, together with their cause and their solution.

Please refer to the attached assembly drawings, if the components are not identifiable by specific figures.

If all the instructions in this chapter have been followed and the problems persist or re-occur frequently, please contact our technical service.

17.2 Problems - Causes - Solutions

I. THE MACHINE DOES NOT WORK:

- C. The differential magneto-thermal switch has been deactivated.
- **R.** Check that the switch is in the ON position.
- R. Check that the display has been switched on.

I. THE USER PRESSED THE START BUTTON, BUT THE WASHING CYCLE DOES NOT START:

- **C.** The barcode reader does not read the cycle start code correctly.
- **R.** Start the washing cycle pressing the start button on the side of the display.
- R. Contact our technical service.

I. THE DETERGENT LOADING IS NOT PERFORMED CORRECTLY:

- **C.** The chemical product dosing pump is inefficient.
- **R.** Carry out the chemical product calibration procedure.
- R. Contact our technical service and ask for the intervention of an authorised technician.

I. THE WASHING PUMP IS NOT WORKING.

- **c.** The washing pump does not work properly. The machine returns the minimum flow alarm or the endoscope channel disconnection alarm.
- R. Check the correct endoscope connection and the connectors integrity. Contact our technical service and ask for the intervention of an authorised technician.

I. THE MACHINE DOES NOT PERFORM THE LEAK TEST:

- C. The instrument is not connected.
- R. Check that the instrument has been correctly connected.
- C. The compressor is not working properly.
- R. Contact the technical service and ask for the intervention of an authorised technician.





18. DECOMMISSIONING

18.1 How to disassembly the machine

Please note that the machine may contain contamination from blood and other bodily fluids, pathogens, facultative pathogens, genetically modified material, toxic or carcinogenic substances, heavy metals, etc., and must be decontaminated before disposal.

For environmental and safety reasons, dispose of all process chemical residues in accordance with safety regulations. Wear gloves and protective goggles.

Remove or disable the door lock prior to disposal of the machine, so that children cannot become trapped inside. Then make appropriate arrangements for safe disposal of the machine.

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

- Disconnect the machine from the electrical power and water supply. Disconnect also the drain. Once everything is disconnected, check that the water circuit is not pressurized.
- According to your country laws, contact the organization responsible for reporting and certifying machine demolition.
- Drain, store and dispose all the substances, such as oils and grease which may be in the lubrication tanks. Do it according to your country laws.
- During the disassembling of the machine, divide the materials according to their chemical composition (iron, aluminium, bronze, plastic, etc.).
- Ensure that the floor, where the machine (or any parts) is placed, is made of washable and non-absorbent materials.
 Ensure also that the floor has a proper drain as a protection against accidental oil leaks or rust.
 These drains must end into watertight collection containers.
- Cover the machine or parts of it with insulating covers in order to prevent damages to the structure, as oxidation or rust, due to rain or humidity.

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

18.2 Machine disposal



- Contact the manufacturer or the distributor, to dispose the equipment.
- Do not dispose this equipment as miscellaneous solid municipal waste.
- The re-using and the proper recycling of electronic and electrical equipment (EEE) is important in order to protect the environment and people health.
- According to the European Directive WEEE 2012/19/EC, arranged areas are available to throw out electrical and electronic equipment. Otherwise, the equipment can be managed by a distributor, when a new machine is purchased.
- The public administration and producers of electrical and electronic equipment are involved in facilitating the processes of the re-use and recovery.
- · Unauthorized disposal of waste electrical and electronic equipment is punishable by law.





Installation manual

COMPACT WASHER-DISINFECTOR-STERILIZER FOR ENDOSCOPE EQUIPMENT

EW 1

Serial N°:









Via Balegante, 27 31039 Riese Pio X (TV) ITALY

Manufacturer:

STEELCO S.p.A.

Via Balegante, 27 31039 Riese Pio X (TV) ITALY



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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).

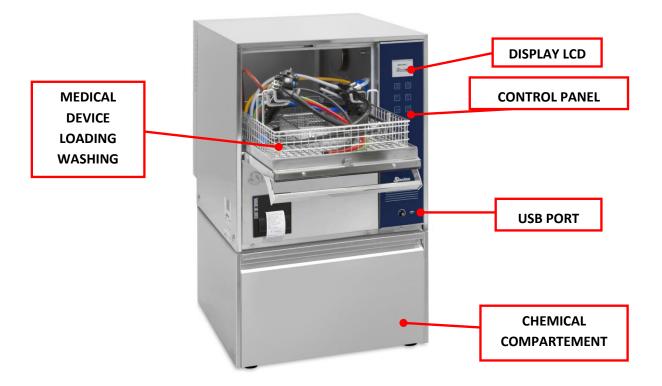


2. SAFETY INFORMATION

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 commands 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.

2.2.1 Application fields

This device is intended only and exclusively for the medical devices treatment, 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
	SteelcoXide-DT (detergent)
HYDROGEN PEROXIDE	SteelcoXide-A (component A)
	SteelcoXide-B (component B)
PERACETIC ACID	Neodisher SC (detergent)
PERACETIC ACID	Neodisher Septo PAC (paracetic acid)
GLUTARALDEHYDE	Neodisher SC
	Neodisher Septo GDA

STERILISATION CYCLES	CHEMICALS
	SteelcoXide-DT (detergent)
HYDROGEN PEROXIDE	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 thermaldisinfection 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. / 58 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 ₂ O 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 _i O 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 / 58 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 ₂ O 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 _i O 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.
- 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.	
Ţ.	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:







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 Table of symbols

Symbols installed on the machine:

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



3. INSTALLATION

3.1 Activity prior to installation

PREPARATION OF INSTALLATION SITE:

Arrangements for connections to the electrical and plumbing systems must be provided by the client prior to machine installation.

Connections must be compliant with current directives in the country of installation.

They must comply with the instructions contained in the documentation (provided on request) prior to machine installation.

Environment conditions:

- Temperature range +5...+40°C;
- Relative Humidity range 20...90% without condensation.
- Maximum altitude: 2.000 m MSL (for higher altitudes are available special versions of the device).

3.2 Positioning

3.2.1 Movement, unpacking and placing

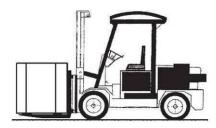
Movement of the machine is provided using transport and lifting equipment and must be observed the following indications:

LIFTING AND MOVEMENT:

Movement of the machine to the work site is carried out by means of a pallet truck or forklift, with special attention given to the following:

- The lifting capability of the forklift must be greater than the total weight of the machine to be moved.
- The machine must be kept as close as possible to the ground during movement;
- Stack up: not allowed;
- · Rotation: do not turn upside down.

The forklift operator must perform movement only when there are no persons or objects in the movement area.



UNPACKING AND PLACING:

Near the place of installation, unpack the machine following carefully these steps:

- All the packaging materials can be recycled.
- Open the packaging carefully.
- Do not overturn the machine as this may cause irreparable damage.
- Cut the strap or open the box and remove the expanded polystyrene corner guards.
- Remove the box followed by the nylon bag.

Caution: the bag represents a serious hazard for children and should be disposed of immediately.

- Place the machine on the work surface and level it by adjusting the feet.
- The machine must be placed horizontally with a maximum inclination of 1÷2°.
- Do not position the machine on surface which could cause a fire or fume hazard.



3.2.2 Maximum floor load

For machine installation, the floor must be rated for a minimum load of:

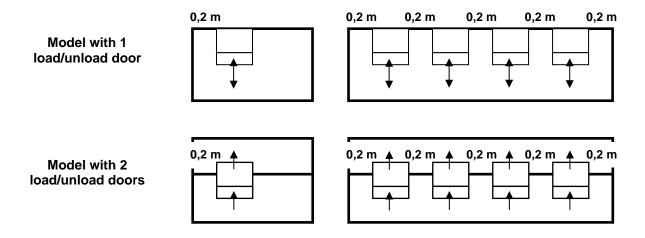
190 daN/m²

3.2.3 Positioning of the machine

In normal conditions, the minimum dimensions are suggested for the use of the machine in a single installation or with the coil nearby.

For different installation ask for the distributors.

Minimum room ceiling height: Machine height (in m) + 0,3 m





3.3 Water connection

To perform proper installation, account of following regulations:

- The machine has been connected to the water distribution network following the in force rules;
- Use only the tubes supplied with the machine;
- Don't cut short the rubber tubes supplied with the machine;
- Make sure that mains water pressure is between 200 kPa (2 bar g) and 300 kPa (3 bar g);
 If it is below 200 kPa (2 bar g) dynamic pressure, you will need to install a pressure increase pump.
 If the pressure is higher than 300 kPa (3 bar g) a pressure reducer must be installed.
- If the average hardness of the water is higher than 7 °f, decalcified water must be used;
- For connection use cocks with an attachment of 3/4", located in an easily accessible location as near as possible to the machine:
- Make sure that the general feeding tube is sufficient for the flow rate required from the machine and equipped with a general closing valve.



ATTENTION

For the specifications for water connections, refer to the plant installation.

During the machine installation, the installer must take the following step:

- 1. Identify the tubes supplied with the machine and make sure they are free from damages;
- 2. Identify the correspondence of the connection of flexible tubes to the water supply taps arranged in site, according to the references of the following chart.

CONNECTION	COLOUR
COLD WATER / MIXED (WASH)	BLUE
DEMI WATER (RINSE)	WHITE

- 3. Screw and tighten up the pipe sleeve to the connection arranged in site.
- 4. Remove any debris in the pipes or in the taps. To perform this operation, open the tap and let the water flow in a pail.
- **5.** Check the water temperature according to the specifications of the installation diagram.
- 6. Identify the correspondence of the connection of flexible tubes to the solenoid valve water supply of the machine
- 7. Screw and tighten up the pipe sleeve to the connection arranged in site.
- **8.** Open gradually the water supply taps and check the connections seal.
- 9. Terminated the connection, in case of water leaks repeat the procedure.



ATTENTION

The threaded connections can be easily damaged, therefore, before to apply the maximum clamping, screw manually the locking sleeve for some threads.

Information:

- The back syphonage prevention system is already installed inside the machine concurring with IEC 61770;
- If it isn't available the double connection to hot and cold water, the two supply pipes must be connected together;
- The manufacturer declines all responsibility for damage or injury caused by noncompliance of the rules relating the supply installations.
- . If you don't comply with the conditions above, the deriving damages will not warranty.



ATTENTION

When the machine is not in operation, always close the supply cocks.



3.4 Electrical connection

Connection of the machine to the electrical mains must be made by qualified, skilled personnel.

Power supply cable: It is compulsory for the retailer - installer to adapt the insulation class of the power supply cable to suit the working environment in compliance with Current Technical Regulations.

- The machines are normally equipped with a mono-phase 220/230/240 vac 50hz power supply. For the specific voltage, please refer to the label on the machine.
- The electrical connection must be carried out in compliance with current technical regulations.
- Make sure that the mains voltage reading corresponds to the voltage indicated on the machine plate.
- Check that the power supply voltage does not differ by more than 10% from its nominal value.
- The frequency of the power supply voltage must not differ by more than 1% of its value.
- Connection of the machine to the mains must be provided with an earth connection and an equipotential circuit as set forth by current standards.
- Make sure that the electrical systems are efficiently earthed.
- The earth conductor is to be connected to the earth terminal identified by the standard symbol.



 The machine is equipped with a terminal identified by the relative symbol for equipotential connections between appliances (see rules for electrical plants).

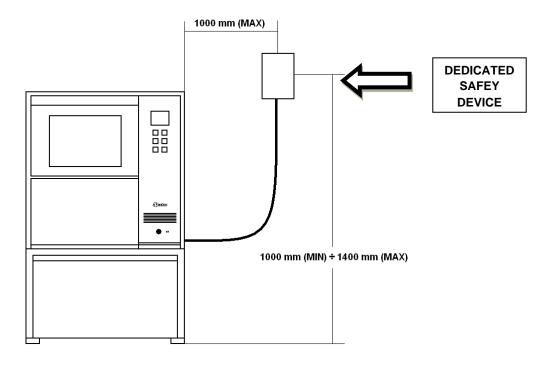


- Connect the machine and the relative dedicated safety device (not supplied) by using a power cable compatible
 with the electrical characteristics of the machine.
- In case of prolonged unused of the machine is recommended that you execute the disconnection procedure of the electrical connection by placing the dedicated safety device in "OFF" state.
- The upstream electrical power line must be dimensioned and protected in accordance with current local regulations.

The dedicated safety device must be positioned in an accessible place, free and not covered from other machines or anything that could obstruct the switch control.

- The dedicated safety device must be provided with quality markings and must be indicated as an electrical shutoff device for the machine.
- Near the dedicated safety device, a sign must be placed which reads:

EXAMPLE OF DEDICATED SAFETY DEVICE POSITIONING





3.5 Fuses

The fuses are used to protect the electrical circuits of machine from possible failure as overload or short circuits. If fuse takes action the downstream connections and their function are no longer available.

The fuses must respect the characteristics (size, dimensions and tripping characteristic) indicated in the wiring diagram.

3.5.1 Replacement of fuse



ATTENTION

The replacement of fuse must be done from authorized operators only.

Before making the replacement procedure of fuse, establish and remove the cause of the fault. If necessary, contact our technical assistance service.

Replacement procedure of fuse:

- Log off the machine in safety condition by dedicated safety device.
- Access at the electrical panel.
- Identify the fuse subjects to replacement, based on the wiring diagram.
- Remove the related fuse from electrical panel.
- Replace failure fuse with another fuse with same characteristics. The correct value of fuses is in the wiring diagram.

If at the reactivation of electrical devices the new fuse intervenes, repeat the diagnosis and replacement procedure as described previously.



ATTENTION

Use only fuses with the amperage and characteristics indicated in the wiring diagram. The use of fuses other than those specified in the wiring diagram, void the warranty and can cause the risk of damage the machine.



3.6 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.



3.6.1 Presence sensor of chemical product

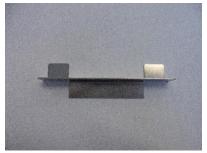
Each dosing pump is combined with a sensor that confirm the presence of chemical product inside the container. If the product is scarce, the electronic control system of the machine sends a message on video of lack of product.

3.6.2 Meter 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.

3.6.3 Container block

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







3.6.4 Replacement 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.





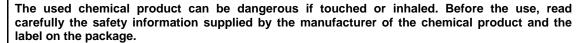
 Close the topper of the chemical product container and place it in the area for the storage of chemical substances.





Close the chemical compartment.

ATTENTION





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.

3.6.5 Warning

- For the maximum amount of product which can be used for washing cycle, follow the instructions for the product you are using.
- The quantity of supplied can be adjusted by following the directions given in paragraph 10.6.
- To ensure the efficiency of the chemical dosing system it is recommended to perform the calibration procedure every 6 months.
- To ensure the efficiency of the dispenser pumps for chemical products it is important to service them regularly as described in chapter 18.
- Use liquid chemical products only machine cannot function with powder detergent.
- For the dispose of the chemical detergent and his tank follow the instruction indicated on the technical and safety data sheet provided by the manufacturer.
- Check that type of chemical product is suitable for the specific washing program used.
- Don't place the chemical tank upon the machine.







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.

3.6.6 Information

- The machine has been validated in accordance with the provisions of Standard UNI EN ISO 15883.
- The type test was carried out using specific chemical products, concerning the type of chemical products, the concentrations and the cycle parameters used you can ask the Manufacturer for details.

3.7 Connecting the discharge pipe

- The discharge pipe connection should be checked carefully.
- Use a discharge pipe suitable for organic and chemical materials and hot liquids.
- This model is fitted with a drain pipe connection which has a diameter equal to that specified in the installation plant.

CAUTION: if the discharge pipe is clogged take great care when processing the water and avoid contact with hands, eyes, etc. In the case of contact rinse the parts concerned with plenty of water.

CONNECTING DRAINPIPE:

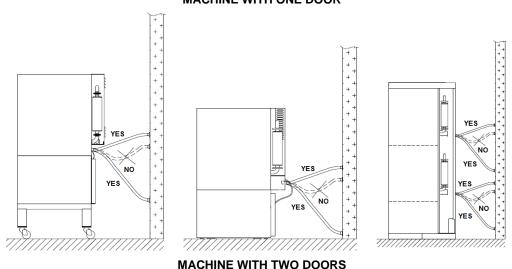
The drainpipe is connected to the sewer network in the following manner:

- Identify the drainpipe and relative fittings (green python pipe).
- Identify the drain manifold: connect the hose via the clamp.
- Insert the other end of the hose into the drain unit, fitting it properly and locking it in position.

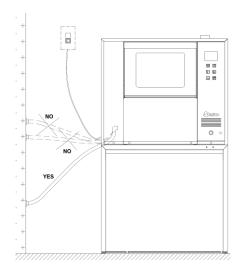
IT IS NECESSARY TO FOLLOW THESE INSTRUCTIONS FOR DRAIN CONNECTION:

- Drainpipe must be connected by using a clamp.
- Drainpipe must not present angles or irregular curving in its course.
- Drain point must be placed at the same height of the machine drain point or on the floor.
- Flexible drain hose must not have siphons or water retention zones (see following pictures).

MACHINE WITH ONE DOOR







Follow carefully these instructions as a wrong drain connection can cause the block of machine.

- The diameter of the drainpipe must be equal to that specified in the installation plant.
- Avoid drainpipe extension.

ATTENTION



- Drain must be done following International rules.
 The manufacturer cannot be held responsible if an inaccurate use of machine causes pollution.
- If the discharge pipe is clogged take great care when processing the water and avoid contact with hands, eyes, etc. In the case of contact, rinse the parts concerned with plenty of water.
- When the machine is connected to an exhaust ventilation system, the drainpipe should be
 positioned externally of the building, protected from any animal access, and make sure
 that it does not cause any hazard.

3.8 Drying air filtration

The machine is standard equipped with an air filter of class 5 following rules EN 779.

The filter's replacement is suggested after 100 working hours.

The machine is equipped also with a further absolute filter "HEPA H14" fallowing rules EN 1822.

The filter's replacement is suggested after 300 working hours.

3.9 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 Glutaraldhyde, connect the exhaust air connection to an external air evacuation system or put the machine under an extraction hood.



3.10 Medical compressed air connection (Optional)

- The machine can be equipped with the connection to medical compressed air.
- The connection must be in compliance with safety regulations and in accordance with features indicated on the installation plant.
- For the connection it is recommended to use PA 6 pipe suitable for pressure of medical compressed air system.

ATTENTION

- Empty the medical compressed air circuit of machine before performing the maintenance.
- The maximum inlet pressure must be lower than 2 bar. For this reason, it is necessary to install the pressure reducer external to the machine (not provided by manufacturer).



A detail of the machine connections is shown on the installation plant and electrical wiring.

3.11 Water intake filter connection

1. Unscrew the upper purge valve of the 0.45 μm filter



2. Screw on the purge fitting



The second secon

3. Fasten the 0,1 µm filter

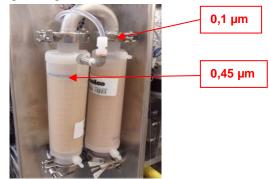


4. Fasten the 0,45 µm filter



5. Connect the purge pipe to the purge fitting





WARNING: Turn the fitting to face outwards



4. CHECKS PRIOR TO START-UP

4.1 Introduction

The preliminary adjustments and controls are performed by a skilled technician, who has been specifically trained for this purpose.

4.2 Checks of safety systems

Indicative list of adjustments and checks of safety systems and devices to be carried out:

- Check the mains supply voltage;
- Check the efficiency of the emergency and machine shutdown devices (circuit breaker);
- Check the efficiency of the door opening safety micro switch;
- Check the operation of machine controls, especially the START and STOP commands.

4.3 General controls

Indicative list of general adjustments and checks to be made:

- Check proper execution of general supplies of the machine (electrical and plumbing);
- Ensure that the MACHINE OPERATOR is trained for its use;



5. USING THE MACHINE (for the user)

5.1 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 sections 3.6.3.

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.

5.2 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 treatment cycle must be repeated.

5.2.1 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:

- Identify the hole between the door and the cover panel (see the picture).
- 2. Insert the dedicated instrument.
- 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 peracetic acid could be present inside the machine.



5.3 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.

5.4 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 Prevention 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 Program - 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.

5.4.1 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.

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

The Endoscope washer-disinfector must perform a daily thermal self-disinfection (regardless the chemical products used).

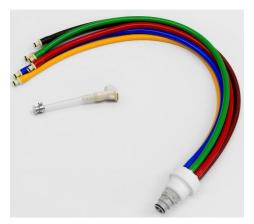
It is recommended to run the thermal self-disinfection program daily, to minimize contamination risk. This cycle can be performed automatically at a defined time: in case the endoscope washer-disinfector is not used during the weekend, make sure that the automatic self-disinfection is conducted.

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.



5.6 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:

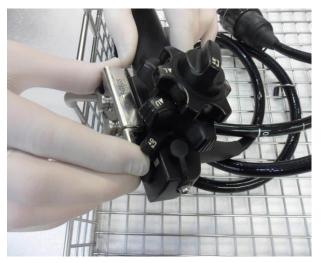
PUT THE ENDOSCOPE CAREFULLY INTO THE BASKET USING THE APPROPRIATE SUPPORTS (SEE PHOTO);





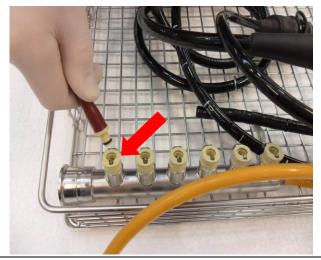
INSERT THE CHANNEL SEPARATOR, ACCORDING TO THE ENDOSCOPE TYPE (SEE PHOTO);

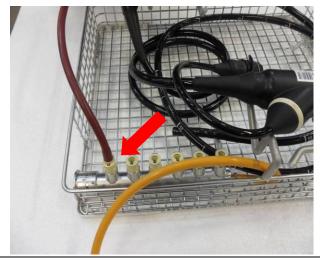




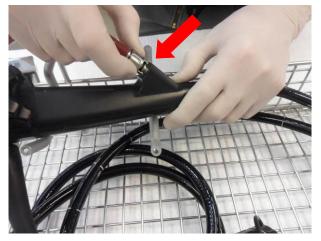
COUPLE THE CONNECTION PIPES TO BE USED FOR CONNECTION TO THE ENDOSCOPE WHICH ARE DIFFERENT DEPENDING ON THEIR BRAND AND MODEL (SEE PHOTO);

EXAMPLE OF BIOPSY CHANNEL CONNECTION



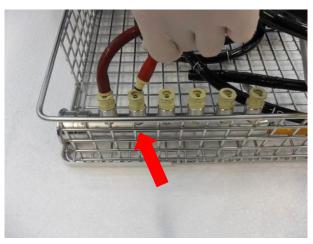


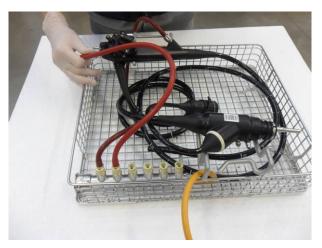






EXAMPLE OF "WATER JET" CHANNEL CONNECTION



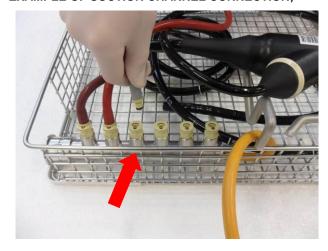




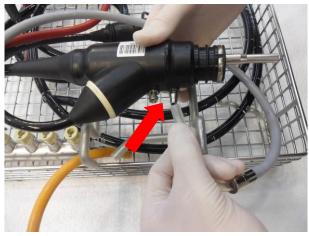




EXAMPLE OF SUCTION CHANNEL CONNECTION;









EXAMPLE OF A WATER CONNECTON POINT;











EXAMPLE OF AN AIR CONNECTION POINT





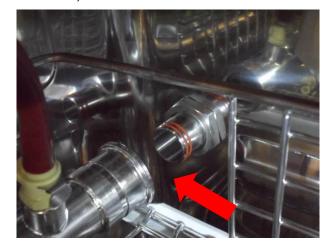
EXAMPLE OF A LEAK TEST CONECTION POINT







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.
- Non observance, even in part, of the rule here indicated, can cause dangerous leakage of water from the door.



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

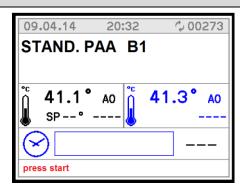
Select the washing cycle and press START



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

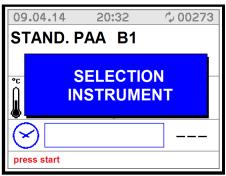






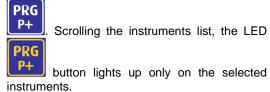








Select the instrument or instruments by pressing

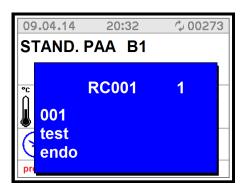


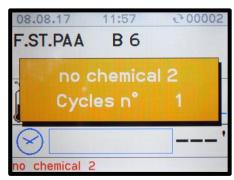
Press **START** button to start the washing cycle.

 If the chemical product is about to finish a popup appears as well as the number of cycles remaining.

While the pop-up is still on the display, press the

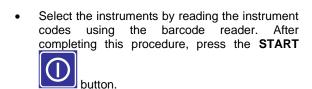


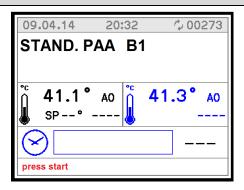


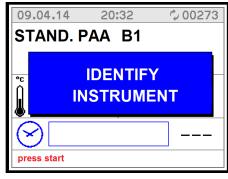


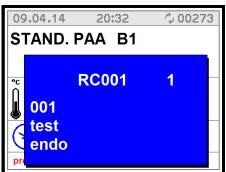
WITH BARCODE (Optional)

• Select the washing cycle and press START button.





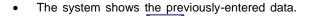






 Enter the operator code using the barcode reader and confirm this information by pressing





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

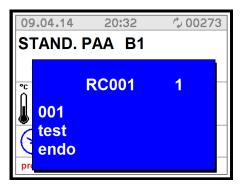
 If the chemical product is about to finish a popup appears as well as the number of cycles remaining.

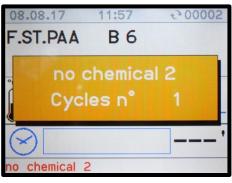
While the pop-up is still on the display, press the











5.7.1 Endoscope requirements

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

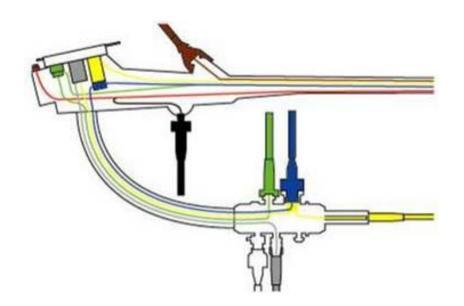
- Resistance to a temperature between +10°C and +60°C;
- Resistance of the endoscope channels to a maximum pressure of 1,5 bar;
- Resistance to a pressure of max. 300 mbar during the leak test;
- Resistance to the detergents and disinfectants used;
- Presence of connections where to attach each of the 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



5.8 Instruction to remove the load from the machine

At the end of the reprocessing cycle – done successfully- it will be possible to remove the endoscope from the basket by disconnecting all the connectors dedicated to the flowing canals from the instrument and proceeding then with the reuse, following the internal protocols and the national guidelines.



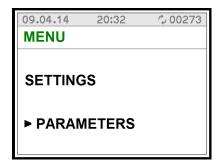
5.9 Instruction in case of 24h stop of the machine

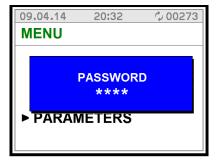
It is advisable to execute a sanitation cycle every day.

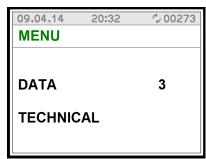
If the machine has not been used for more than 24 hours, it is advisable to carry out a sanitation cycle prior to using the machine.

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 5.5.4.
- II. The machine have to be left with the door shut.



6. CONTROL PANEL AND SYMBOLS USED

6.1 Switches (loading side)

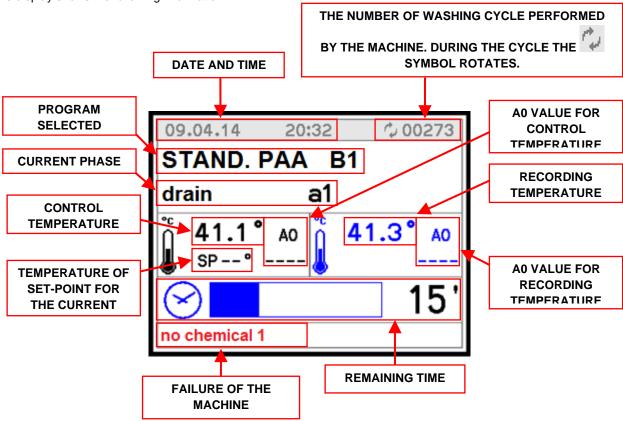
There are 6 switches with the following functions:

BUTTON	DESCRIPTION	665-6
	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.	
P1 D	Select "STANDARD PAA" cycle.	PRG P+
P2 O	Select "SELF-DISINFECTION 80" cycle.	
222	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).	Steelco
PRG P+	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.	



6.2 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.

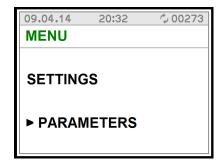
LED

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

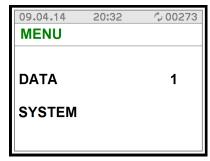


BUZZER

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.







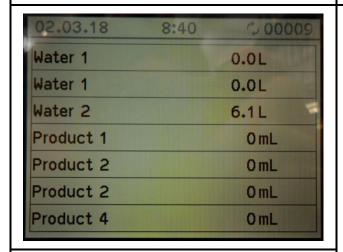


PRG

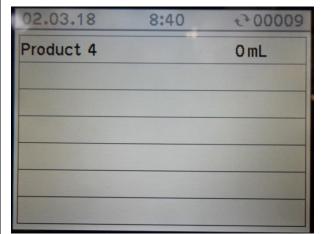
PIC. 2

02.03.18	8:37	\$ 00009
tank probe		23.0°C
tank probe 2		23.3°C
sump probe		17.7°C
press.sensor LT	1	0.244Bar
Wash pump		0.000 Bar
Wash flow		OmL/
purge pressure		0.038Bar

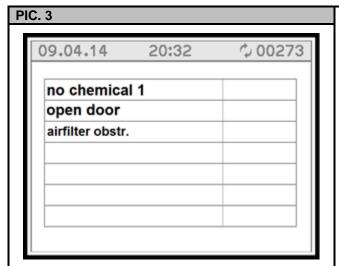
During the cycle, by pressing the switch **PRG** it will be displayed the various temperatures of the device and the values associated to the pressure transducers (Pic. 2).



It will be displayed also the water quantity filled and the chemical product quantity for each phase, pressing twice

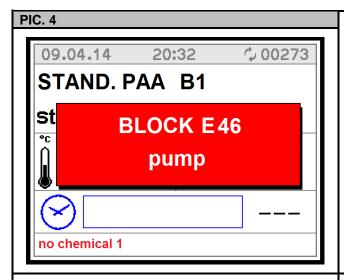


the PRG P+ switch.

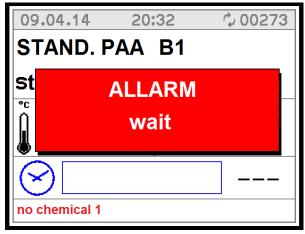


Pressing **PRG**a third time it display the screen with the list of alarms and warnings appears during the cycle (Pic.3).

PRG



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. "Restore procedure"), 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.

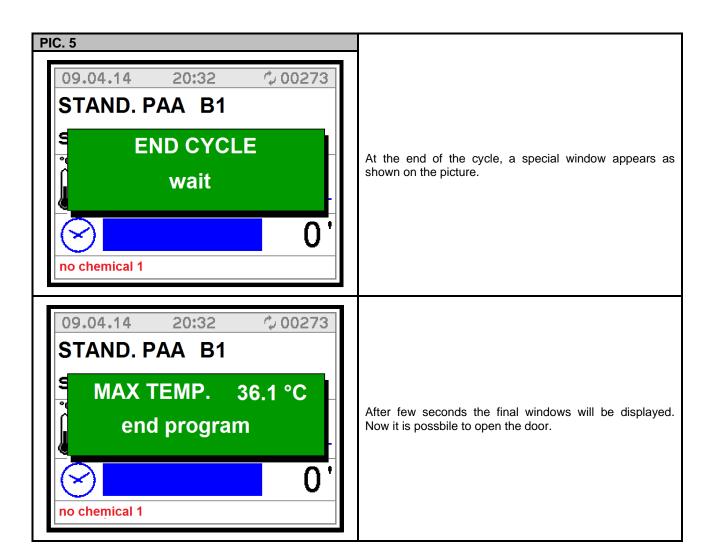
After the door unlocking the **ALARM** picture will be shown open the door and after few seconds the message will be re

In case of failure, which does not lead to a block, (lack of chemical) a message is shown at the bottom of the screen

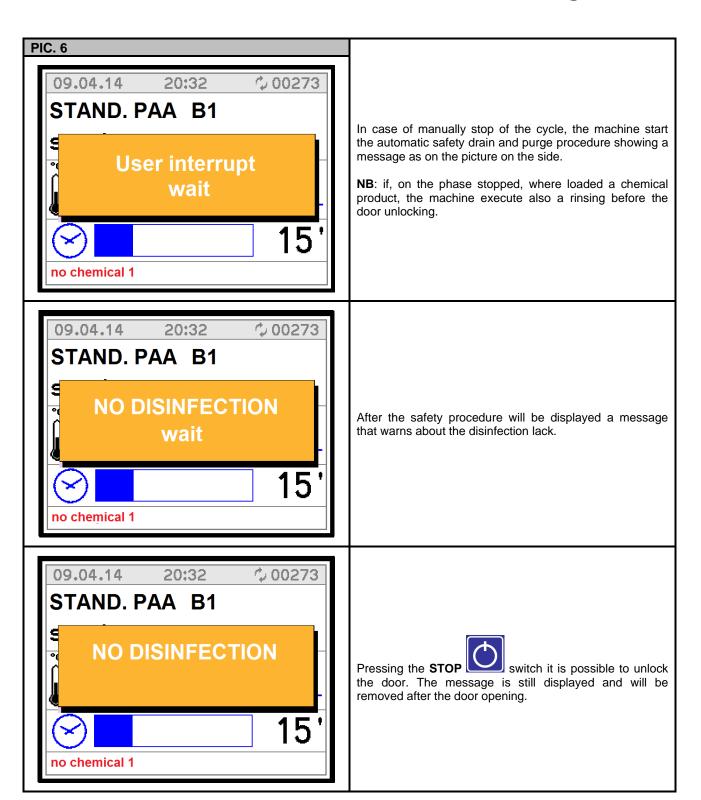
(Pic.1 point 11) or by pressing the **PRG** switch twice as shown in **Pic.3**.

PRG











6.3 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" barcodes;
- -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" barcode:

Anyway, you exit automatically by 60 sec. timeout.





6.4 Control panel (unloading side – if present)

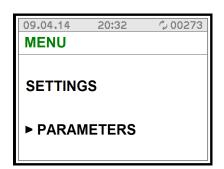
The display shows the following information: THE NUMBER OF WASHING CYCLE PERFORMED BY THE MACHINE. DURING THE CYCLE THE SYMBOL ROTATES. **DATE AND TIME PROGRAM A0 VALUE FOR SELECTED** 09.04.14 20:32 00273 CONTROL TEMPERATURE STAND. PAA **CURRENT PHASE** RECORDING a1 drain **TEMPERATURE** CONTROL **TEMPERATURE** 41.3 A0 A₀ **A0 VALUE FOR TEMPERATURE OF** RECORDING **SET-POINT FOR TFMPFRATURF** THE CURRENT o chemical 1 **REMAINING TIME FAILURE OF THE MACHINE**

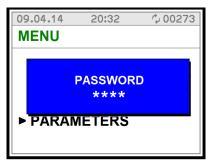
LED

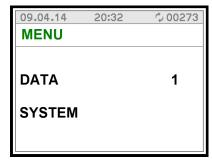
The keys of the glass display are touch-sensitive and backlit.

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.









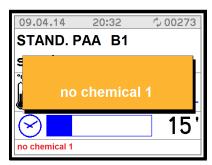
7. MACHINE CONDITIONS

The machine has three possible statuses:

7.1 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.





7.2 On cycle

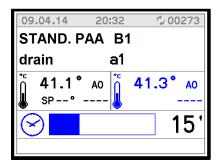
You can reach this point in the procedure by selecting the desired cycle and by pressing the **START** the machine up.



The cycle is running according to its phases.

The diagnostic and the regulators are active.

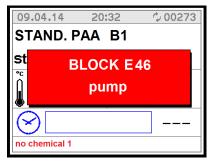
The user interface gives all indications about the different phases and about the chamber temperature.



7.3 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 8.2).



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



8. SPECIAL FEATURES

8.1 Power failure

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

8.1.1 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.

8.1.2 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:

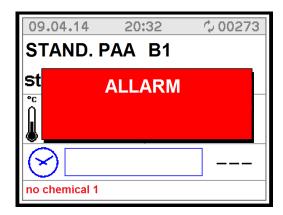
- The items inside the machine could be very hot and contaminated.
- The entire treatment cycle must be repeat.
- Material contaminated with peri acetic acid could be present inside the machine.

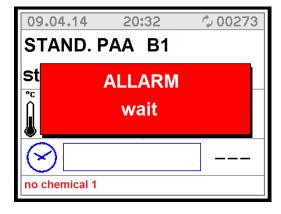
8.2 Reset procedure

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 "switchesSequence".
- 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.

9. WORK PROCEDURES

9.1 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.

9.2 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.

9.3 Decontamination procedures

In the event of repair or substitution of mechanical parts (e.g. drain pump, heating element etc.), before carrying out any type of maintenance operation on the internal parts of the machine, it is necessary to run a self-disinfection cycle and use appropriate PPEs to prevent any risks of infection.



9.4 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.

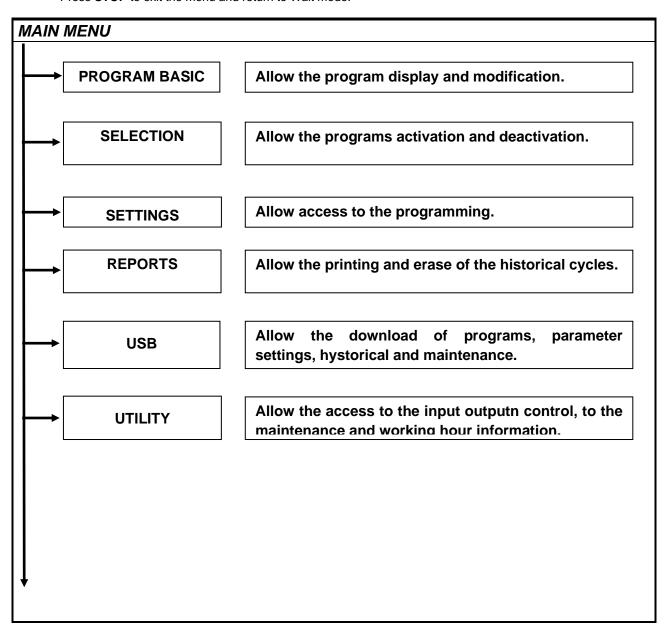


10. MENU

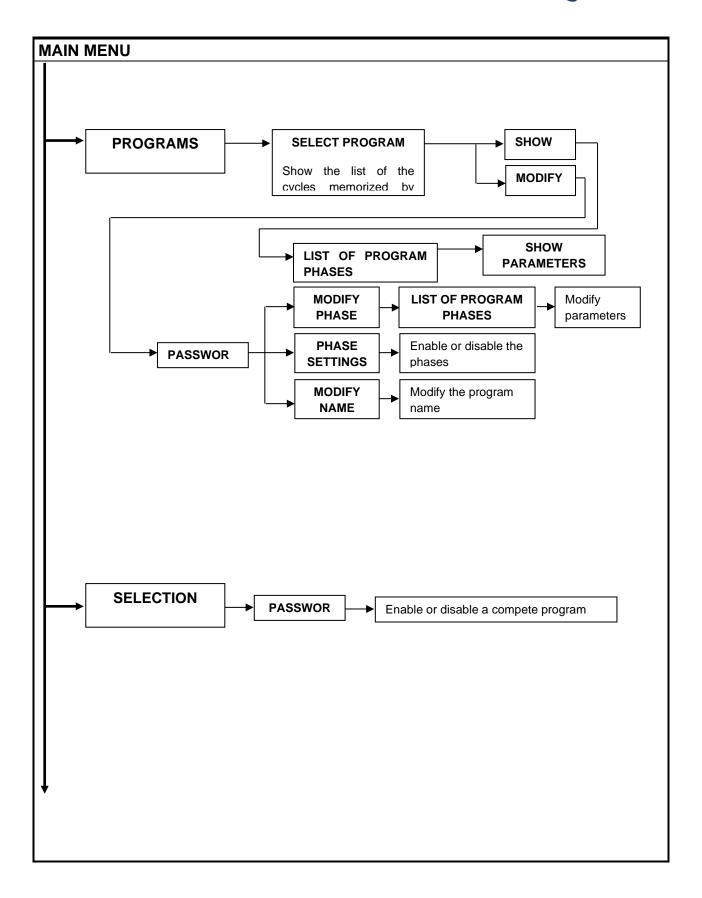
10.1 Menu plan

To enter the menu, keep the PRG key pressed for five seconds

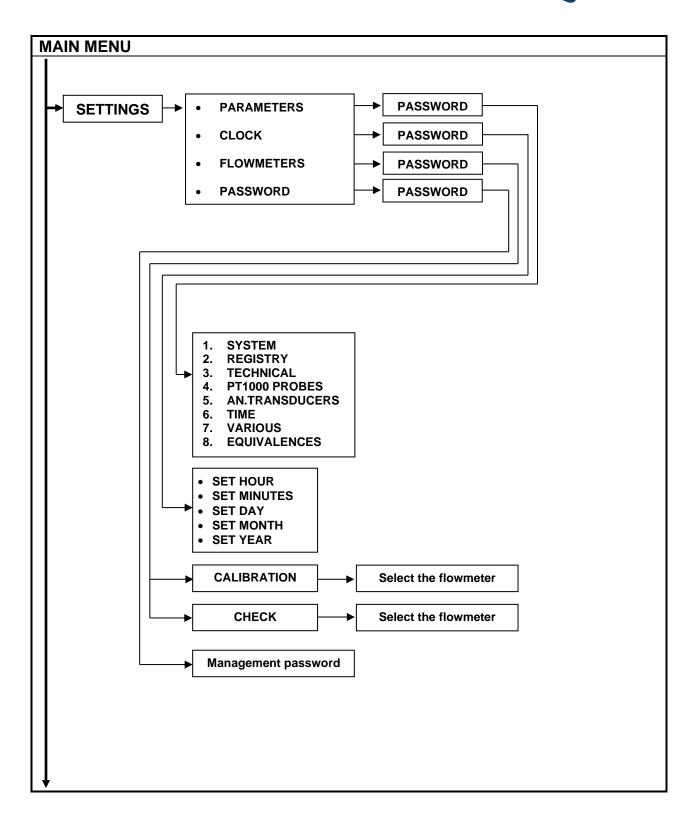
- Press **P1** programme switch to scroll through the menu.
- Press **START** to confirm selection.
- Press **STOP** to exit the menu and return to Wait mode.



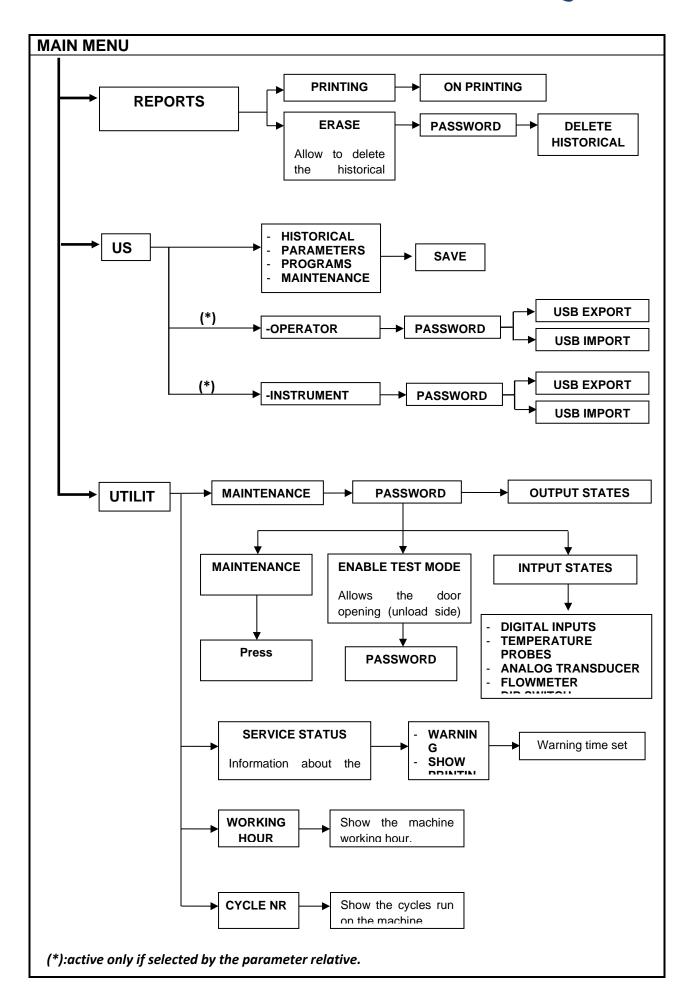














10.2 Parameter settings

To set the parameters will be requested a password (2nd or 3rd level), that will be entered using **P1** and **P2** buttons. If the password entered is wrong, you will quit the menu immediately.

Pressing P1 and P2 buttons it is possible to select the parameter to be changed and pressing P1 and P2 buttons increase or decrease the value of the various parameters.

If the parameters are not modified, it is possible to quit the parameters menu keeping pressed the **STOP** button for 5 seconds.

ATTENTION:

The access to the programming mode is restricted only to authorized and skilled technicians which are supplied with the password.

The password must be obtained from the manufacturer.

10.3 Parameters list

SW version 7.10			Legen	d: char=c	character, sel=sele	ction, nu	m=number
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX
MACHINE	1	1	User name	char		,	~
CYCLE	1	2	Operator identification (0: no, 1: with keyboard, 2: with barcode reader).	sel		0	2
PRINT	1	4	Graphic print out at the end of the cycle; 0 = no print out. 1 = print graph. 2 = table print out. 3 = print only on USB.	num		0	3
PRINT	1	5	Print out results of the cycle being carried out (events, consumption,). (0:no, 1: complete printing (all phases), 2: reduced printing (only event header)	sel		0	2
KEYBOARD	1	7	Buzzer volume key tone loading side (0 = buzzer switched off).	num		0	50
KEYBOARD	1	8	Buzzer volume end of cycle warning loading side (0 = buzzer switched off).	num		0	50
KEYBOARD	1	9	Buzzer alarm volume loading side (0 = buzzer switched off).	num		0	50
KEYBOARD	1	10	Buzzer volume key tone unloading side (0=buzzer switched off).	num		0	50
KEYBOARD	1	11	Buzzer volume end of cycle warning unloading side (0=buzzer switched off).	num		0	50
KEYBOARD	1	12	Buzzer alarm volume unloading side (0=buzzer switched off).	num		0	50
KEYBOARD	1	13	Show the A0 value on the display.	sel		0	1
KEYBOARD	1	14	Enable acoustic signal to warn about chemical product lack (sound level as for the alarm)(0=NO, 1=YES)	sel		0	1



SW version 7.10		Legend: char=character, sel=selection, num=number							
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX		
CYCLE	1	16	Enable warning for full historical cycle; 0 = no warning. 1 = warning without cycle start disabled. 2 = warning and cycle start disabled. The warning will be reset if the historical cycle will be printed or downloaded on USB.	num		0	2		
CYCLE	1	17	Instrument ID (1: manually before the cycle start 2: with barcode scanner before the cycle start)	num		1	2		
KEYBOARD	1	18	Nr. of errors insertion password to access into the protected menù, to visualize the warning on the working screen. (0: function disabled)	num		0	100		
PRINT	1	19	Number of repetition tickets header and cycle's result in the appendix to the printout of the cycle completed ok (for cycles with endoscope instruments)	num		0	10		
INSTRUMENT	1	20	Doctor identification (1=with keyboard, 2= with barcode reader)	sel		1	2		
INSTRUMENT	1	21	Patient identification (1=with keyboard, 2= with barcode reader)	sel		1	2		
INSTRUMENT	1	22	Abbreviation for doctor codes (for identification with barcode reader)	char		А	Z		
SUPERVISOR	1	23	Connection to supervisor system (0=no, 1=SteelcoData, 2=SteelcoData Ares, 3=SteelcoData not Ares with ID unloading machine operator)	sel		0	2		
SUPERVISOR	1	24	Machine IP address	num		0	255		
SUPERVISOR	1	25	Gateway IP Address	num		0	255		
SUPERVISOR	1	26	IP Netmask	num		0	255		
SUPERVISOR	1	27	Supervisor IP address	num		0	255		
CYCLE	1	28	Request of operator identification (if P1.02 > 0) (0 = to start the cycle, 1 = to start and to end the cycle)	num	PSW 1	0	1		
CHEMICALS	1	29	Number of cycles threshold from which the low-level chemical popup will be displayed (0 = pop-up never shown)	num	PSW 1	0	99		
MACHINE	2	1	Machine model	char		,	~		
MACHINE MACHINE	2	3	Machine serial number Test date (day-month-year).	char		0 1/1/10	9 31/12/99		
KEYBOARD	2	4	Select language.	num sel		0	7		
MACHINE	2	5	Station number.	num		0	99		
MACHINE	2	6	Client/distributor (16 characters).	char			~		
KEYBOARD	2	7	Select font group; 0 = European. 1 = European + Japanese. 2 = European + Cyrillic.	num		0	2		



SW version 7.10		Legend: char=character, sel=selection, num=number							
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX		
KEYBOARD	2	8	Unit of measurement. 0 = International. 1 = American.	sel		0	1		
DOORS	3	1	Double door machine	sel		0	1		
PT1000	3	2	Activate redundancy probe (chamber probe 2); 0 = no. 1 = on an indipendent board. 2 = on main board.	sel		0	1		
PRINT	3	3	Printer on board; 0 = none. 1 = on board 1. 2 = on both board 1 and 2 (Redundant print for machine that manage it).	sel		0	1		
CYCLE	3	4	Activate after cycle has been interrupted due to energy failure; 0= when phase restarts; 1= from the beginning of the cycle; 2= from when cycle failed.	sel		0	2		
DOORS	3	7	Enable the pass through function.	sel		0	1		
BREAK TANK	3	9	Presence of break tank.	sel		0	1		
INSTRUMENT	3	10	Instrument number in the chamber	num		0	2		
BOILER	3	11	Presence of water tank 3	sel		0	1		
DRYER	3	20	Activate dryer; 0 = no. 1 = normally selected. 2 = normally not selected. 3 = always activated.	num		0	3		
WATER	3	25	(4-20 mA) analogue electrical conductivity probe	sel		0	1		
WATER	3	30	Presence of water 2.	sel		0	1		
DOORS	3	31	Door safety switches presence for UL conformity.	sel		0	1		
PT1000	3	33	Presence of drying probe; 0 = no probe. 1 = only control probe. 2 = control probe + redundancy probe.	num		0	2		
CYCLE	3	34	Number of automatic repetitions of cycle for washing test (0 = no repetition)	num	PSW 2	0	100		
CHEMICALS	3	36	Presence of chemical product 3 dosing pump.	sel		0	1		
CHEMICALS	3	37	Presence of chemical product 4 dosing pump.	sel		0	1		
CHEMICALS	3	38	Number of additional rinsing phases on the cycle to fill the chemical circuit.	num		0	3		
INSTRUMENT	3	39	Enable channels purging.	sel		0	1		



SW version 7.10		Legend: char=character, sel=selection, num=number							
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX		
CYCLE	3	42	Enable cycles validation test (0= NO, 1= stop cycle enabled in the whole cycle, 2= stop cycle enabled only in the phase of last rinse, 3= stop cycle enabled only in the phase before the disinfection)	sel		0	3		
CYCLE	3	43	Automatic sanitation cycle selection: 0 = disabled 1= cycle B4 (Sanif.80)	Sel		0	1		
CYCLE	3	44	Hours for automatic sanitation cycle start.	h		0	23		
CYCLE	3	45	Minutes for automatic sanitation cycle start.	m		0	59		
INSTRUMENT LEAK	3	47	Enable instrument leak test.	sel		0	1		
PUMPS	3	48	Enable channels control.	sel		0	1		
PT1000	3	49	Presence of sump probe.	sel		0	1		
INSTRUMENT	3	50	Purge type medical air.	sel		0	1		
PT1000	4	1	Offset calibration for chamber probe 1 at a 0°C – ZERO.	°C		-9,9	9,9		
PT1000	4	2	Offset calibration for chamber probe 1 at a 100°C – SPAN.	°C		-9,9	9,9		
PT1000	4	3	Offset calibration for chamber probe 2 at a 0°C – ZERO.	°C		-9,9	9,9		
PT1000	4	4	Offset calibration for chamber probe 2 at a 100°C – SPAN.	°C		-9,9	9,9		
PT1000	4	5	Offset calibration for dryer probe 1 at a 0°C – ZERO.	°C		-9,9	9,9		
PT1000	4	6	Offset calibration for dryer probe 1 at a 100°C – SPAN.	°C		-9,9	9,9		
PT1000	4	7	Offset calibration for dryer probe 2 at a 0°C – ZERO.	°C		-9,9	9,9		
PT1000	4	8	Offset calibration for dryer probe 2 at a 100°C – SPAN.	°C		-9,9	9,9		
PT1000	4	9	Offset calibration for sump probe at a 0°C – ZERO (water inlet in the machine).	°C		-9,9	9,9		
PT1000	4	10	Offset calibration for sump probe at a 100°C – SPAN (water inlet in the machine).	°C		-9,9	9,9		
LEAK TEST	5	1	Lower pressure limit during leak test.	bar		0	P 5.02		
LEAK TEST	5	2	Upper pressure limit during leak test.	bar		P 5.01	1		
PUMPS	5	3	Auxiliary instrument channel pump pressure scale – lower limit	bar		0	P 5.04		
PUMPS	5	4	Auxiliary instrument channel pump pressure scale – upper limit	bar		P 5.03	2,5		
PUMPS	5	5	Lower pressure limit for washing pump.	bar		-1	P 5.06		
PUMPS	5	6	Upper pressure limit for washing pump.	bar		P 5.05	2,5		



SW version 7.10		Legend: char=character, sel=selection, num=number							
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX		
INSTRUMENTS	5	7	Lower pressure limit for purge (draining phase)	bar		0	P 5.08		
INSTRUMENTS	5	8	Upper pressure limit for purge (draining phase)	bar		P 5.07	6		
INSTRUMENTS	5	9	Electrical conductivity scale – lower limit	bar	μS/cm	0	P 5.10		
INSTRUMENTS	5	10	Electrical conductivity scale – upper limit	bar	μS/cm	P 5.09	20006		
CHAMBER	6	1	Max time for 1°C increase in the chamber.	s		0	999		
DRAIN	6	3	Maximum drainage time.	s		0	999		
BREAK TANK	6	4	Maximum drainage time of break tank.	s		0	999		
WATER	6	5	Maximum waiting time for cold water filling in the chamber (diagnostic water loading too slow) (0= diagnostics deactivated).	S		0	999		
WATER	6	6	Maximum waiting time for water filling in the break tank.	s		0	999		
WATER	6	7	Maximum waiting time to pulses of water circulation flowmeter (diagnostic washing arm flow).	S		0	99,9		
LEAK TEST	6	8	Test safety time for leak test and pressure stabilization in leak test control for "fast" program	s		0	99		
LEAK TEST	6	9	Check time for leak test for "fast" program.	S		0	99		
WATER	6	10	Delay time after water loading to check the min. temperature in "fast" program	S		0	50		
WATER	6	11	Maximum waiting time for water flowmeter impulse.	s		0	99,9		
CHEMICALS	6	12	Maximum waiting time for chemical products flowmeter impulse.	S		0	99,9		
DOORS	6	13	Maximum door lock opening time.	S		0	99,9		
DOORS	6	14	Maximum door lock closing time.	S		0	99,9		
INSTRUMENTS	6	16	Bleed drain valve opening time delay to diagnose pressure reduction.	s		0	99,9		
EQUIPMENT	6	18	Delay on over temperature cut-out reading or heating elements feedback reading; (0 = diagnostic disabled).	S		0	99,9		
DRYER	6	19	Delay on blower pressure switch reading; (0 = diagnostics deactivated).	S		0	99,9		
CHEMICALS	6	20	Chemical product 1 filling time.	S		0	999,9		
CHEMICALS	6	21	Chemical product 2 filling time.	S		0	999,9		
CHEMICALS	6	22	Chemical product 3 filling time.	S		0	999,9		
CHEMICALS	6	23	Chemical product 4 filling time.	S		0	999,9		
PUMPS	6	26	Time for auxiliary channel water flow outside threshold level alarm	S		0	99,9		



SW version 7.10			Legen	d: char=c	character, sel=sele	ction, nu	m=number
ТҮРЕ	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX
PUMPS	6	27	Time for auxiliary channel water pressure outside threshold level alarm	S		0	99,9
PUMPS	6	28	Fractional pump OFF time.	S		0	99,9
PUMPS	6	29	Fractional pump ON time.	s		0	99,9
DRAIN	6	30	Draining cycle OFF time (N.C.).	S		0	99,9
DRAIN	6	31	Draining cycle ON time (N.C.).	S		0	99,9
DRAIN	6	32	Draining cycle OFF time. (fast program)	S		0	99,9
DRAIN	6	33	Draining cycle ON time. (fast program)	s		0	99,9
WATER	6	34	Water filter bleed valve opening OFF time cyclicity during sanitisation cycle.	S		0	999
WATER	6	35	Water filter bleed valve opening ON time cyclicity during sanitisation cycle.	s		0	999
DRYER	6	38	Blower cooling time (post-ventilation).	S		0	999
DOORS	6	40	Door 1 lock opening delay after the limit switch.	S		0	9,9
DOORS	6	41	Door 1 lock closing delay after the limit switch.	S		0	9,9
DOORS	6	42	Door 2 lock opening delay after the limit switch.	S		0	9,9
DOORS	6	43	Door 2 lock closing delay after the limit switch.	S		0	9,9
REGENERAT.	6	44	Pause time during regeneration.	S		0	999
REGENERAT.	6	45	Water loading time for regeneration.	S		0	999
REGENERAT.	6	46	Cold water loading time for regeneration rinsing.	S		0	999
PRINT	6	47	Sampling time for chamber temperature and pressure trends.	s		5	99
CYCLE	6	48	Time in months to warn about forthcoming maintenance service since the last one carried out.	num		1	99
CYCLE	6	49	Machine hours number to warn about the next maintenance service since the last one carried out.	h		1	9999
BREAK TANK	6	50	Extra time to drain completely break tank under the minimum level.	S		0	99
WATER	6	52	Delay on pressure switch reading for sanitation circuit (0 = diagnostic disabled).	S		0	99,9
DRYING	6	53	Pause time of heating element 2 in tank during the resistive drying process.	S		0	999
LEAK TEST	6	54	Max time to reach the pressure set- point during the leak test.	S		0	99
LEAK TEST	6	55	Time for initial safety leak test (N.C.).	S		0	99
LEAK TEST	6	56	Initial leak test time (N.C.).	S		0	99



SW version 7.10			Legen	d: char=c	character, sel=sele	ection, nui	m=number
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX
LEAK TEST	6	57	Scan time of leak test during cycle.	S		0	99
LEAK TEST	6	58	Drain time for leak test at end cycle. (Cycle OK or cycle interrupted by event).	S		0	99
INSTRUMENTS	6	59	Max time to reach pressure setpoint for purge	s		0	99
DRYING	6	60	Time heating OFF for fractioned drying	s		0	99,9
DRYING	6	61	Time heating ON for fractioned drying	S		0	99,9
LEAK TEST	6	62	Delay time for opening the leak test valve after compressor activation	s		0	2
LEAK TEST	6	63	Time for initial Leak Test and Pressure stabilization of the Safe Case	Ø	PSW	0	99
LEAK TEST	6	64	Extra delay washing pump activation during the sanitization cycle after water 1 loading ended (for water leaks diagnostics from water 1 loading valve). The extra delay counts after 10 s from the last pulse detected by the water 1 flowmeter after water 1 valve closing.	s		0	99
LEAK TEST	6	65	Time water loading in tank beyond which visualizing the filters clogging warning (0: warning disabled)	S		0	999
DRAIN	7	1	Number of fractioned draining cycles (N.C.).	num		1	99
DRAIN	7	2	Number of fractioned draining cycles (fast program).	num		1	99
INSTRUMENTS	7	3	Pressure setpoint for purge (draining phase) (fast program)	bar		0	4
DRYER	7	5	Max difference between air probes.	°C		0	99
DRYER	7	6	Min. temperature for air temperature probes disparity control.	°C		0	120
CHAMBER	7	7	Min. quantity of water in the chamber.	L		0	P 7.08
CHAMBER	7	8	Max. quantity of water in the chamber.	L		P 7.07	99
WATER	7	9	Amount of water on tank for the activation of tank level switch (for disparity diagnostic between the water amount measured by flowmeter and the tank level sensor).	L		0	9,9
WATER & CHEMICALS	7	10	Maximum percentage error in the water and chemical dosing. (Comparison with redundancy flowmeter or with redundancy equivalent dosing time).	%		1	50
CHAMBER	7	11	Max. chamber probe temperature disparity.	°C		0	99



SW version 7.10			Legen	d: char=c	character, sel=sele	ction, nui	m=number
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX
CHAMBER	7	12	Min. temperature for chamber temperature probes disparity control.	°C		0	95
DRYER	7	13	Min temperature to be reached during drying phase (ventilated).	°C		0	100
PREWASH	7	14	Max. permitted temperature on prewashing phase.	°C		0	95
PUMPS	7	15	Lower washing water flow limit for selection of three bronchoscopes (lt/min).	num		0	P7.16
PUMPS	7	16	Upper washing water flow limit for selection of three bronchoscopes (lt/min).	num		P7.15	9999
PUMPS	7	17	Lower limit for pump pressure for selection of three bronchoscopes.	bar		-1	P7.18
PUMPS	7	18	Upper limit for pump pressure for selection of three bronchoscopes.	bar		P7.17	2,5
WATER	7	19	Min. temperature for water of fast program	°C		30	55
WATER	7	20	Max. water impulses excess after the water valve deactivation (for water flowmeter) or after the washing pump switch off (for washing arms water flowmeter).	num		0	99
CHEMICALS	7	21	Max. chemical impulses excess after dosing pump switch off.	num		0	99
CHAMBER	7	22	A0 temperature interval.	°C		0	99
CHAMBER	7	23	A0 temperature reference.	°C		0	99
CHAMBER	7	24	A0 lower temperature limit.	°C		0	99
PRINT	7	25	Horizontal graphics resolution (pixel/hour).	num		240	1000
REGENERATION	7	26	Regeneration (value/displayed value/cycles completed after the last regeneration: 1/10/never, 2/15/30, 3/20/25, 4/25/21, 5/30/18, 6/35/15, 7/40/12, 8/45/9, 9/50/6, 10/55/3, 11/60/1).	sel		1	11
REGENERAT.	7	27	Regenerations number before a "salt lack" warning	num		1	18
KEYBOARD	7	28	Programme selected in position 1 (P1 switch).	num		1	5
KEYBOARD	7	29	Programme selected in position 2 (P2 switch).	num		1	5
KEYBOARD	7	30	Program selected in position 3 (P3 button).	num		1	8
CHAMBER	7	31	Temperature emergency value during the working cycles (machine with endoscopes).	°C		0	70
CHAMBER	7	32	Temperature emergency value during the sanitation cycles (machine without endoscopes inside the chamber).	°C		0	99
CHAMBER	7	33	Max water temperature in chamber during the drying phase on working cycles (machine with endoscopes inside the chamber).	°C		0	P 7.31



SW version 7.10			Legen	d: char=c	character, sel=sele	ction, nu	m=number
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX
CHAMBER	7	34	Max water temperature in chamber during the drying phase on sanitation cycles (machine without endoscopes inside the chamber).	°C		0	P 7.32
DRYER	7	35	Air temperature emergency value (drying probe).	°C		0	120
PUMPS	7	36	Lower washing water flow limit for selection of two bronchoscopes (lt/min).	L		0	P 7.37
PUMPS	7	37	Upper washing water flow limit for selection of two bronchoscopes (lt/min).	L		P 7.36	999,9
LEAK TEST	7	38	Maximum pressure limit for leak test.	bar		0	0,999
LEAK TEST	7	39	Air pressure set-point for leak test.	bar		0	0,999
LEAK TEST	7	40	Max air pressure loss during the leak test on initial control.	bar		0	0,099
LEAK TEST	7	41	Max air pressure loss during the leak test on cycle.	bar		0	0,099
LEAK TEST	7	42	Max air pressure loss during the leak test after drain.	bar		0	0,099
LEAK TEST	7	43	Tolerance of air pressure loss in leak test during cycle.	bar		0	0,099
PUMPS	7	44	Lower washing water flow limit without instruments (lt/min).	L		0	P 7.45
PUMPS	7	45	Upper washing water flow limit without instruments (lt/min).	L		P 7.44	999,9
PUMPS	7	46	Lower limit for pump pressure for selection of two bronchoscopes.	bar		-1	P 7.47
PUMPS	7	47	Upper limit for pump pressure for selection of two bronchoscopes.	bar		P 7.46	2,5
PUMPS	7	48	Lower limit for pump pressure without instruments.	bar		-1	P 7.49
PUMPS	7	49	Upper limit for pump pressure without instruments.	bar		P 7.48	2,5
CHAMBER	7	50	Temperature over the set point to switch off the heating elements or probe test (without instrument).	°C		P7.51	3
CHAMBER	7	51	Temperature over the set point to switch on again the heating elements or probe test (without instrument).	°C		0,1	P7.50
CHAMBER	7	52	Temperature over the set point to switch off the heating elements (only for working cycles).	°C		P7.53	3
CHAMBER	7	53	Temperature over the set point to switch on again the heating elements (only for working cycles).	°C		0	P7.52
INSTRUMENTS	7	54	Pressure setpoint for purge (draining phase) (N.C.).	bar		0	4
DRYING	7	56	Heating inertia for the drying (span of temperature below the setpoint for the heating ON-OFF)	°C		0	30
INSTRUMENTS	7	57	Upper limit pressure for residual purge (when purge activity is not in progress)	bar		0	2,5



SW version 7.10	Legend: char=character, sel=selection, num=num						m=number
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX
INSTRUMENTS	7	58	Max. activation in cycle of leak test instrument valve (0 = diagnostic disabled).	num		0	99
INSTRUMENTS	7	59	Lower limit pressure for residual purge (when purge activity is not in progress)	bar		0	1
WATER	7	60	Program selected in position 3 (P3 button).	μS/cm		0	20000
WATER	7	61	Minimum pressure difference below the purge setpoint after 3 seconds following the start of the machine purge system drainage procedure.	bar		0	2
WATER	7	62	Temperature threshold for water filter bleed valve cyclical opening during the sanitisation cycle	°C		0	99
LEAK TEST	7	63	Air Pressure Set Point for Safe case Leak Test	bar	PSW 2	0	999,9
LEAK TEST	7	64	Air Pressure Leak tolerance for Safe Case	bar	PSW 2	0	999,9
LEAK TEST	7	65	Temperature set point of the rinse phase of the chemical installation loading cycle	bar		0	95
WATER	8	1	Water 1: Impulse/litre (flowmeter).	imp/l		0	999,9
WATER	8	2	Water 2: Impulse/litre (flowmeter).	imp/l		0	999,9
WATER	8	4	Reference for automatic water flowmeter calibration. If P2.08=YES, the value is interpreted in gallons/10.	L		1	99
CHEMICALS	8	5	Chemical product for dosing pump 1: impulse/millilitre (flowmeter).	imp/ml		0	9,999
CHEMICALS	8	6	Chemical product for dosing pump 2: impulse/millilitre (flowmeter).	imp/ml		0	9,999
CHEMICALS	8	8	Chemical product for dosing pump 4: impulse/millilitre (flowmeter).	imp/ml		0	9,999
CHEMICALS	8	9	Chemical product for dosing pump 1: sec/millilitre (timed control).	s/ml		0	9,999
CHEMICALS	8	10	Chemical product for dosing pump 2: sec/millilitre (timed control).	s/ml		0	9,999
CHEMICALS	8	11	Chemical product for dosing pump 3: sec/millilitre (timed control).	s/ml		0	9,999
CHEMICALS	8	12	Chemical product for dosing pump 4: sec/millilitre (timed control).	s/ml		0	9,999



SW version 7.10			Legen	d: char=c	character, sel=sele	ection, nu	m=number
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX
CHEMICALS	8	13	Number of cycles that can be performed with the chemical product in dosing unit 1 below the reserve threshold (minimum active level)	num		1	99
CHEMICALS	8	14	Number of cycles that can be performed with the chemical product in dosing unit 2 below the reserve threshold (minimum active level)	num		1	99
CHEMICALS	8	15	Number of cycles that can be performed with the chemical product in dosing unit 3 below the reserve threshold (minimum active level)	num		1	99
CHEMICALS	8	16	Number of cycles that can be performed with the chemical product in dosing unit 4 below the reserve threshold (minimum active level)	num		1	99
CHEMICALS	8	17	Reference for automatic calibration of chemical flowmeter; If P2.08=YES, the value is interpreted in liquid ounce/10.	ml		1	999
WATER	8	18	Circulation washing pump water: impulses/litres (flowmeter).	imp/l		0	999,9
WATER	8	19	Redundancy flowmeter water 1: impulses/litres (redundancy flowmeter).	imp/l		0	999,9
WATER	8	21	Auxiliary instrument channel water pump circulation: pulses/litre (flow meter)	imp/l		0	9999
CHEMICALS	8	22	Dosing 1 chemical product: impulses/milliliter (redundancy flowmeter).	imp/ml		0	9,999
CHEMICALS	8	23	Dosing 2 chemical product: impulses/milliliter (redundancy flowmeter).	imp/ml		0	9,999
CHEMICALS	8	25	Dosing 4 chemical product: impulses/millilitre (redundancy flowmeter).	imp/ml		0	9,999
WATER	8	26	Water 1 control: 0= with flowmeter and redundancy flowmeter 1= with only one flowmeter	sel		0	1
CHEMICAL	8	27	Chemical product 1 control: 0=time dosing with redundancy flowmeter 1= dosing with only one flowmeter 2= timed dosing 3= dosing with flowmeter and redundancy flowmeter	sel		0	3
CHEMICAL	8	28	Chemical product 2 control: 0= dosing with flowmeter and redundancy flowmeter 1= dosing with only one flowmeter 2= timed dosing	sel		0	2



SW version 7.10		Legend: char=character, sel=selection, num=number							
TYPE	SEC.	PAR.	DESCRIPTION	UoM	CUSTOMER SETTINGS	MIN	MAX		
CHEMICAL	8	30	Chemical product 4 control: 0= dosing with flowmeter and redundancy flowmeter 1= dosing with only one flowmeter 2= timed dosing	sel		0	2		



10.4 Details of the electronic boards

The electronic card was designed for the control of the endoscope washer.

Any use other than that specified above.

The electronic card was designed following the indications given in the standards below:

EN 60335	Low voltage	
EN 61000-6-1	Immunity	
EN 61000-6-3	Emissions	

10.5 Features of the electronic boards

SERIAL INTERFACE

CT - Com1:

Asynchronous serial interface for bidirectional communication with the keyboard card.

S-232 - Com2:

Asynchronous serial interface type RS 232 foreseen for connection to PC or printer.

S-CAN - Com3:

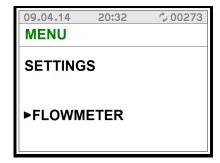
Bus serial connection for the connection between the electronic boards (main and slave).

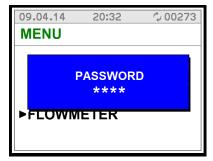
10.6 Chemical flowmeters setting

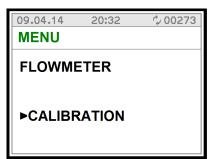
In order to set the flowmeters it is necessary to control that the chemical products dosing system is completely filled.

10.6.1 Calibration

Enter the menu: SETTINGS → FLOWMETERS → Insert 2nd level password → CALIBRATION.

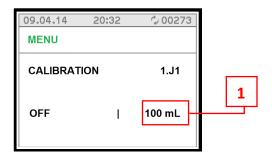






Insert the suction lance of the chemical to be calibrated into a graduated cilinder and fill it with the chemical up to 250 ml.

After selecting the flowmeter to calibrate (see the input output section 10.7) push **START** to start the procedure and **CONFIRM** it.



Press **START** when the level on the ml-graduated cylinder have reached the displayed quantity (1). If you want to shut off the procedure press **STOP**.

The calibration allow the setting of both control and redundancy flowmeters calibrating only the control one. For example: to calibrate both control and redundancy flowmeter for chemical 2, calibrate only 1.J2 flowmeter.

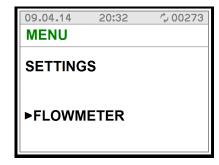


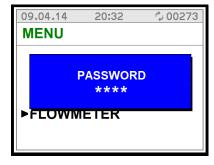
It is mandatory to perform the calibration of the dosing flowmeters with the chemical product at the same room temperature of the endoscope washer. If chemical canisters are stored at different temperatures, wait a proper period of time to stabilize the temperature before starting the calibration. Viscosity strongly affects calibration results.

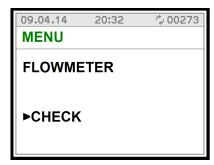
10.6.2 Check

After the calibration it is necessary to control the calibration efficacy by the CHECK procedure.

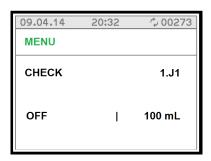
Enter the menu: SETTINGS → FLOWMETERS → Insert 2nd level password → CHECK







Select the chemical flowmeter to check and press START to begin the calibration verification.



Once finished the dosing, the level of product in the graduated cylinder should be the same of that one shown in the display.

Whether the levels do not correspond, a new setting must be executed. The quantity of product to execute the setting can be changed using 8.17 parameter.

The check procedure have to be executed for both control and redundancy flowmeters.

AFTER THE CHEMICAL CALIBRATION IT IS NECESSARY TO RUN A RINSING CYCLE WITHOUT INSTRUMETNS INSIDE THE CHAMBER.

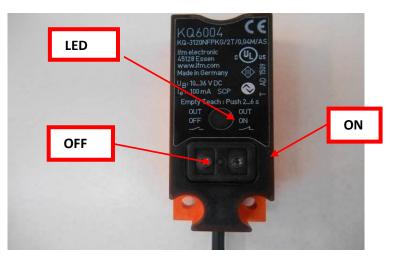


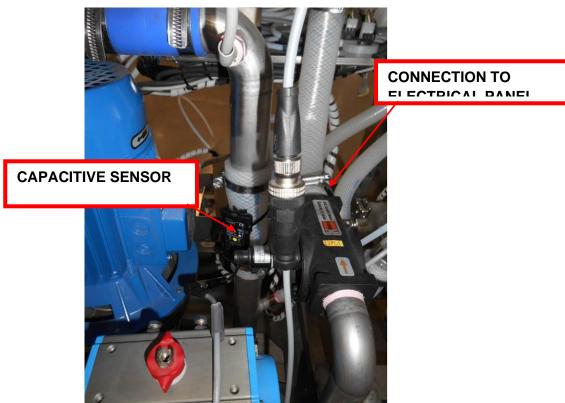
10.7 Setting of the capacitive sensor ifm for the detection of the presence of water into the chamber

The purpose of calibration is to display the LED on with presence of water into the chamber, and the LED off with absence of water.

OPERATION TO BE CARRIED FOR CALIBRATION:

1. The sensor is installed on the sump ramp of the machine (without water into the chamber) and connected to electrical panel. The LED lights up automatically for the sensor contact with the surface on which it is placed.





- 2. Press and hold the OFF button from 4 to 6 seconds, keeping the LED off VERIFY THE LED IS OFF.
- 3. Loading water into chamber and verify the LED is on VERIFY THE LED IS ON.
- 4. Drain the water from the chamber and verify the LED is off VERIFY THE LED IS ON.







- **5.** To verify the accuracy of the calibration, follow the steps:

 - a) Load water into the chamber: verify that the LED is onb) Drain water from the chamber: verify that the LED is off

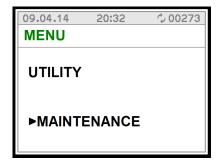
If this condition is met, the sensor calibration is ok.



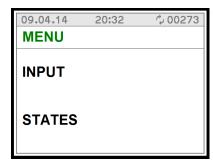
10.8 Input/output - devices status

On EW1 machine it is possible to display the state of the devices.

Enter the menu: UTILITY → MAINTENANCE → Insert 3rd level password → INPUT.



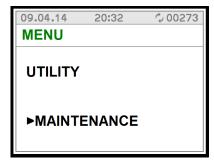


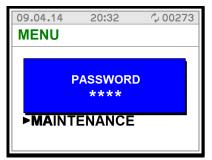


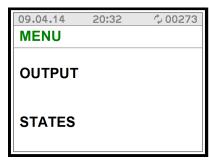
Use switch **P1** and **P2** to select the input to show; the machine will display the actual device status. Whether the input is not active, the writing **OFF** appears, otherwise, when active, appears ON.

It is also possible to modify the devices status.

Enter the menu: UTILITY → MAINTENANCE → Insert 3rd level password → OUTPUT.







Use switch **P1** and **P2** to select the output to show; the machine will display the actual device status. Press **START** switch on the device you need to activate/deactivate and with **P1** and **P2** modifiy the output status. Whether the output is not active, the writing **OFF** appears, otherwise, when active, appears ON. If a contractor is not possible to activate you will see on the display the writing "**FORBIDDEN**".



WARNING

For input and output's specification see the wiring diagram.



10.9 Password management

The programmation access and the menu are protected by three password levels:

- 1st level: operator password allow the access to the programs selection, historical and USB menu access (view and printing, not historical deletion).
- 2nd level: technician password allow the access to all menu but with limited modification possibility.
- 3rd level: manufacturer password allow the complete access to all menu and settings of the machine.

The password is made up of from four characters. Every character can be chosen between:

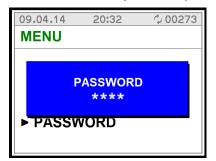
- Number digits: from "0" to "9";
- Uppercase alphabet: from "A" to "Z";
- Lowercase alphabet: from "a" to "z";
- Space " ";
- Minus sign "-";
- Full stop ".".

10.9.1 Password change

To set the password follow the procedure:

Enter the menu: SETTINGS → PASSWORD → Insert 3rd level password (currently)







Select the password that you want to change pressing **START** button.

During the insertion, the four characters are displayed with four stars ****. The selected character to be changed is flashing.

Pressing **P1** and **P2** buttons it is possible to set the value of character while pressing **START** button it is possible to confirm the selection and proceed with other character.

To confirm the insertion of new password, press **START** button.

It will be required to insert new password: if the inserted password coincides with the one just set it will display the **MODIFY - DONE -** message otherwise, in case of incorrect insertion, it will display **ERROR** message.

In case of **ERROR** or exit from menu by pressing **STOP** button, the password will not be modified and remains valid the value in force.



ATTENTION

In case of you forgot the password it is not possible to recover it.

Contact the manufacturer that will provide a temporary password. This password only allows the access to password menu to set new password.

10.9.2 Warning about unauthorized access

The alarm "WARNING PASSWORD" warns about any attempt to access at menu by unauthorized personnel. It will be displayed every time it is exceed the number of password entries set by parameter P1.18 (P 1.18=0 the alarm function is disabled).

To reset the alarm, enter at password menu and insert the password.



10.10 **Barcode reader setting**

In case of barcode replacement or memory loss, set the barcode reader by reading the following codes.



RS-232 Serial Interface Quick Set Command



Host Interface Selection



for Gold/Jade/Diamond series





END (Exit)





PROGRAM

Record Suffix









PROGRAM









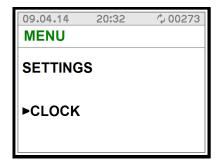


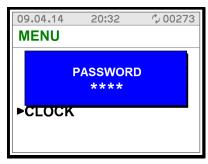


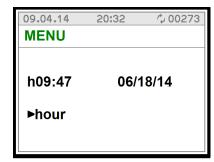
11. CLOCK

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

SETTINGS \rightarrow CLOCK \rightarrow set date and hour.







The time shown is also to qualify the events historical.



12. HISTORICAL DATA and PRINTOUT

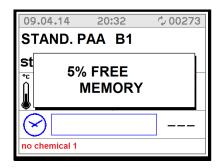
During the working cycle, the machine memorizes on a RAM all the working data of the wash cycles that have been

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 GASTROSCO	PE
	STORZ	
B 6 F. ST. PAA	Record	: 00002
START:	07/06/14	h: 10:14
-> 1: drain T1= 35.9°C	C T2= 36.1°C	h: 10:14
-> leak test		h: 10:14
-> 2: prewash T1= 35.4°C	C T2= 35.3°C	h: 10:15
Water 2	programm. 6 L	executed 6 L
-> 3: drain T1= 35.4°C channel dry	C T2= 35.4°C ying	h: 10:16
-> 4: treatment T1= 37.2°C	T2= 37.1°C	h: 10:21
Water 2 Product 1= OK T>= 35°C (T1= 35.8°	programm. 6 L 30 mL t= 300 s t= 2°C) (T2= 35.8°	6 L 32 mL 300 s
-> 5: drain T1= 37.2°C channel dry	T2= 37.1°C	h: 10:22
-> 6: rinsing 1 T1= 36.4°C		h: 10:23
Water 2	6 L	6 L

- ←Customer/distributor (value set by parameter P2.06)
- ←Username (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

←Water consumption

20 s

←Chemical consumption

+=

36.4°C) (T2=

20 s t=

36.4°C)

0°C

Т>=



1	1
-> 7: drain h: T1= 36.4°C T2= 36.4°C channel drying	: 10:24
-> 8: disinfect. h: T1= 37.3°C T2= 37.3°C	xecuted 6 L 61 mL
-> 9: drain h: T1= 37.3°C T2= 37.3°C channel drying	: 10:29
-> 10: rinsing 4 h: T1= 36.4°C T2= 36.4°C	xecuted
-> 11: drain h: T1= 36.4°C T2= 36.4°C channel drying	: 10:31
end program: 07/06/14 h:	÷ 10:31 ←Date and hour of the cycle end (standard cycle 17 min)
<><><><><><><><><><><><><><><><><><><>	←Alarm/warning description (if present)
Doctor	←Doctor signature
Patient	←Patient signature
><	><

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

*****	******	
	********** : ******** : EW 1 : 12001 : 0 : 7.00 : 13	←Customer/distributor (value set by parameter P2.06) ←Username (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=nc
INSTRUMENT 1	: RC001 GD900123 GASTROSCOPE STORZ	←Endoscope information
B 6 F. ST. PAA	Record: 00002	←Cycle name and cycle number on historical
end program:	07/06/14 h: 10:14 07/06/14 h: 10:31 >>>>>>>>>	←Date and hour of cycle start (standard cycle 17 min) ←Date and hour of the cycle end (standard cycle 17 min)
E1	ND CYCLE OK ><><><>	←Alarm/warning description (if present)
Doctor		←Doctor signature
Patient		←Patient signature
><	><	



13. PC INTERFACE

The main board have a communication channel RS 232 on Modbus file. With this channel it is possible to print the historical events by setting the printer as follows:

baud rate: 2400 baud,flow control XON XOFF,

data bits: 8bits,parity: none,stop bit: 1 bit,column: 40

14. 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.



14.1 Programming

It is sufficient to insert the USB key on the port and switch OFF and switch ON the control panel board using the ON/OFF button.

The display will ask about the new files installation allowing the selection between APPEND (add only the new parts) and OVERWRITE (delete the existing files and install the new one).

It is possible to program:

- Parameters
- Cycles
- Control panel FW
- Language file

14.2 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

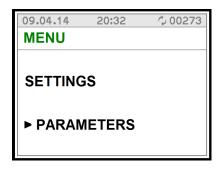
The cycle and parameter files can be used to program another machine or as back-up of the machine.

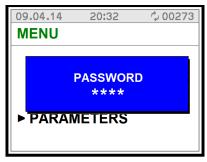


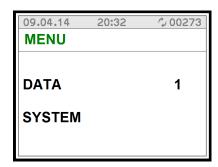
14.3 Data saving during the cycle

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorized 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.







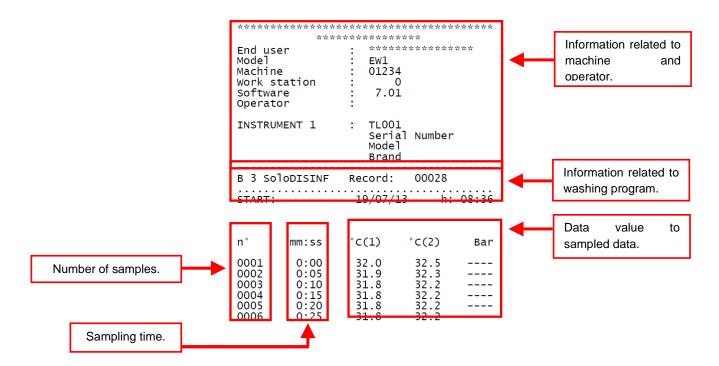
- Start the washing program;
- At the end of the cycle the machine creates the file with the samples of temperature and pressure probes with the information of every washing program phases.

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



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

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

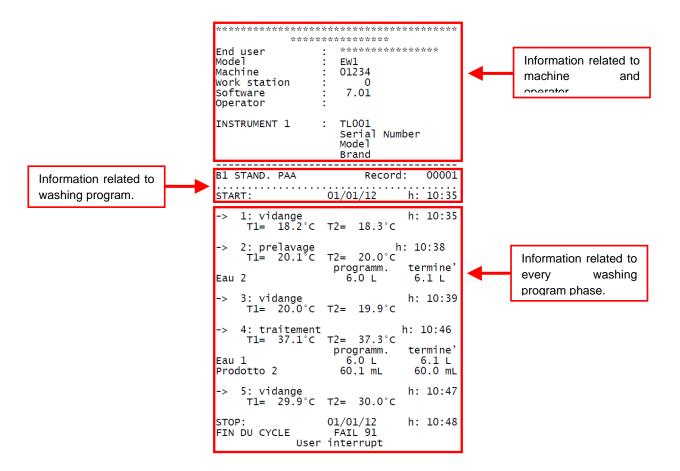






The file *****C.TXT contains:

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.



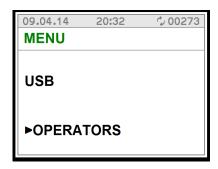


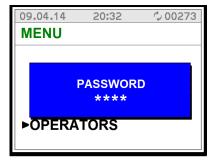
14.4 Operator archive management

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorized 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.

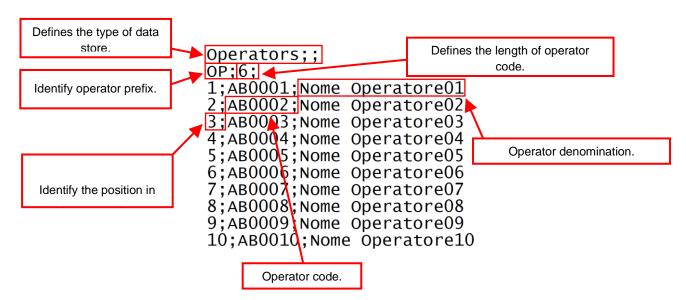
Enter menu: USB → OPERATOR → Insert 3rd level password → USB EXPORT → Press START button.







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: 09 number digits, "AZ" uppercase alphabet, "az" 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: 09 number digits, "AZ" uppercase alphabet, "az" lowercase alphabet, " space, "-" minus sign, "." full stop.			
Operator denomination	Length ≤ 16 (can be empty) Allowable characters: 09 number digits, "AZ" uppercase alphabet, "az" 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: $USB \rightarrow OPERATOR \rightarrow Insert 3^{rd}$ level password $\rightarrow USB$ IMPORT $\rightarrow Press$ START button.







ATTENTION



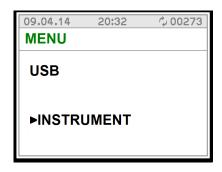
- To modify the operator archive file, it is recommended use a text editor (ex. Notepad).
- If the file contains an operator with the field "OPERATOR CODE" null (no character), the file is considered valid up to the previous operator. All subsequent elements are ignored.
- If the file contains values 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.

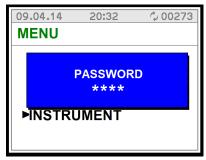


14.5 Instrument archive management

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 the 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

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;

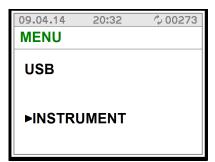
If it is set to 0=not activated channels pump (When there are small instruments);

If it is set to 1= activated channels pump.

FIELD	FIXED CHARACTERISTICS			
Type of data store	Nothing			
Instrument prefix	Length = 2 Allowable characters: 09 number digits, "AZ" uppercase alphabet, "az" 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: 09 number digits, "AZ" uppercase alphabet, "az" lowercase alphabet, " space, "-" minus sign, "." full stop.			
Serial number	Length ≤ 16 (can be empty) Allowable characters: 09 number digits, "AZ" uppercase alphabet, "az" lowercase alphabet, " "space, "-" minus sign, "." full stop.			
Instrument denomination	Length ≤ 16 (can be empty) Allowable characters: 09 number digits, "AZ" uppercase alphabet, "az" lowercase alphabet, " "space, "-" minus sign, "." full stop.			
Instrument manufacturer	Length ≤ 16 (can be empty) Allowable characters: 09 number digits, "AZ" uppercase alphabet, "az" 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: $USB \rightarrow INSTRUMENT \rightarrow Insert 3^{rd}$ level password $\rightarrow USB$ IMPORT $\rightarrow Press$ 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 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.



15. ALARMS and EVENTS LIST

15.1 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.

15.2 List of alarm messages

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

N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
E1	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): Overtime lock door ref. P6.14 (problems on the door lock motor). 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 has 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)
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 has 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 \neq 0)
E24	fan problem	 Diagnostic enabled if P6.19 ≠ 0, in these cases: the fan pressure switch is open with the fan running at maximum speed the fan pressure switch is closed with the fan off



N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
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)
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)



N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION					
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 counted 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 redundance flowmeter higher than P7.10. (DISINFECTANT – bi-component). (Diagnostic active if P8.30=0)					
E61	no water 1	During water 1 filling in the break tank, the water level has not reached level within time set by P6.06.					
E62	break tank	Emergency level is active.					
E63	break tank	Lower level is deactivated 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;					
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 \neq 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 have a leakage. (Diagnostic is active if 3.47≠0) 					



N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION					
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 have a 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 has 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)					
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 $P3.49\neq0$)					
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) measuran excess of impulses higher than P7.21 with dosing pump OFF. (Diagnosti 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)					



N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION				
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 $P3.39 \neq 0$)				
E99	Min. air pressure	The air pressure measured from the purge transducer (when the purge activity in progress) has exceeds the minimum limit set by P7.59. (Diagnostic is active 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.				
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.				



N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
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).

15.3 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	General 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 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. 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 remain 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 new washing cycle.					



DISPLAY MESSAGE	DESCRIPTION			
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)			

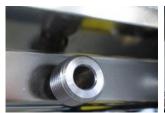
15.4 List of historical events

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

16. VALIDATION PROCEDURES

16.1 Thermometric tests

The machine is equipped with a hole on the chamber for the thermometric test probes:

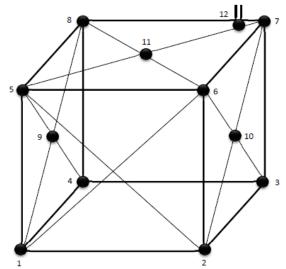




It is located under the door.

To open it it is sufficient to remove the under door panel and unscrew the cap.

The probes have to be placed inside the chamber following a defined scheme, as indicated on standard ISO 15883-1:



- One probe on each corner (1, 2, 3, 4, 5, 6, 7, 8)
- One probe on the two wall side (9, 10)
- One on the center of the roof (11)
- One adiacent to the control probes (12)



17. 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 reprocessable devices in the EW 1 system in favor of those recommended by the manufacturer).

18. 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.



19. MAINTENANCE

19.1 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.

19.1.1 Maintenance request

The machine displays the "MAINTENANCE" warning after a specified time or after a specified number of working hours according to parameter P6.48. This warning doesn't affect the normal use of machine.

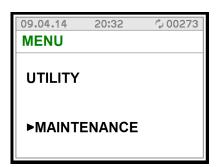
The service technician must do the maintenance operations in the shortest possible time.

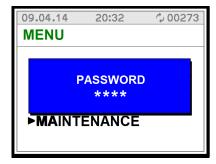


To clear the "MAINTENANCE" warning, follow the procedure:

- 1. Do the general maintenance of machine;
- 2. Enter at the MENU':

 $\textbf{UTILITY} \to \textbf{MAINTENANCE} \to \textbf{Insert 3}^{\text{rd}} \ \textbf{level passord} \to \textbf{MAINTENANCE REGISTER} \to \textbf{Press START button}.$









19.2 Procedure for routine maintenance work

Routine maintenance includes all operations aimed at keeping various parts of the machine clean and functional. They must be performed on a regular basis (see table in paragraph 18.3) or when considered necessary due to incorrect performance of washing cycle.

Since these are simple cleaning operations, they are normally performed by the machine operator on his own liability.

19.3 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

Pooleo	ENDOSCOPES WASHER (EW 1) Programmed maintenance scheme										GE
O recto											RIFERENECE
Components	Step				mo	nths				Activity	RIFE
Components	make every	3	6	9	12	15	18	21	24	Activity	
Chamber filters	make every day									Take off filters and cleaning.	M1
Water solenoid filter	make every				x		x			Check, clean and if necessary replace.	M4
Water filter 0,1-0,45 µs	make every				x					Replace.*	
Pre filter dryer F5	make every 100 hours									Replace.	M5
Dryer HEPA filter	make every 300 hours									Replace.	M5
Temperature probes	make every				x				х	During periodic validation, check the sensor status.	M2
Safety thermostat	make every				x				х	Verify the sensor.	
Chemical dosing pump	make every		x		x		x		х	Check the presence of leakage.	
Chemical tank level sensor	make every		x		x	v	×		x	Check and clean the suction filter.	
Connection pipe of dosing pump	make every	5	×		×		x		x	Check of crashing, any leakage or hardening.	
Washing arms	every week									Check for free rotation. Open the cleaning caps and wash inside: check and in case cleaning the nozzle.	M 3
Door gasket	make every		x		x		x		x	Verify the gasket and replace after 1000 cycles.	
Washing pumps	make every		x		x		x		x	Check for water leakage from the arm seal.	
Water heating element	make every				x				х	Check for water leakage fro the gasket.	
Water solenoid valves	make every				x				x	Check for any leaks, if necessary remove and clean the membrane seat.	
Drain pump	make every				x				x	Check for any leaks, if necessary remove and clean the membrane seat.	
Pressure switches	make every				x				х	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.	
Pipe of unloading water	make every				x				х	Check the situation of pipe and the seal.	
Pipes of loading water	make every				x				x	Check the situation of pipe and the seal.	



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.



CLEANIN	IG OF WASHING CHAMBER DRAIN FILTERS

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.

Worker: Ac

M1

• 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 AND DISINFECTION OF 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.

METHOD OF DISINFECTION OF EXTERNAL SURFACES

It is not possible to use corrosive products or products with chlorine.

The disinfection procedure has to be carried out following the hospital guidelines.

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.

19.4 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.



19.5 Table of special maintenance

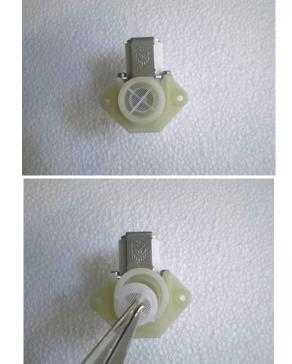
See scheduled maintenance table.

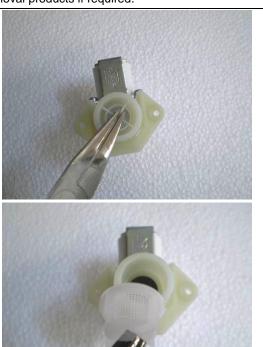
CLEANING OF WATER SOLENOID VALVES INLET FILTERS

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

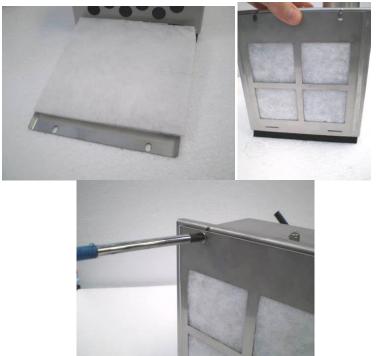
M5 Worker: Is Frequency of Intervention: 100 hours

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.

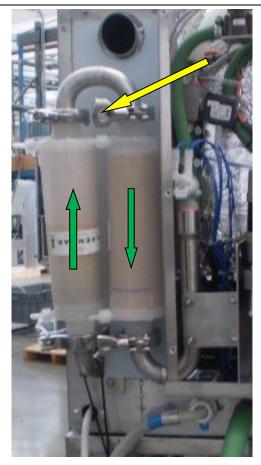




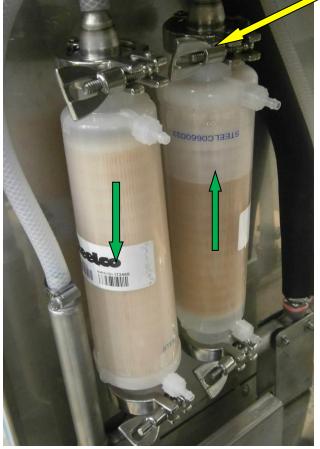
M7 Worke	er: Is	Frequency of Intervention: every year

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	

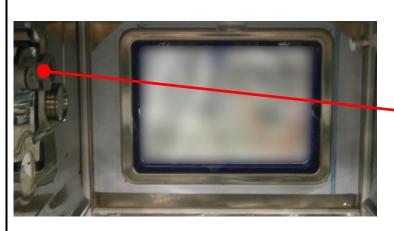
METHOD OF INTERVENTION: check the self-disinfection connector into the washing chamber as described below:

- 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).

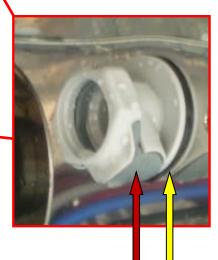
ATTENTION:

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

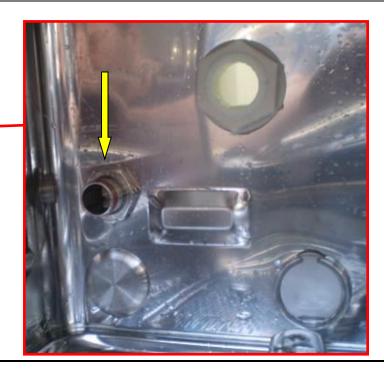
METHOD OF INTERVENTION: check of integrity of gasket for the connection between machine and basket, as described below:

• 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.





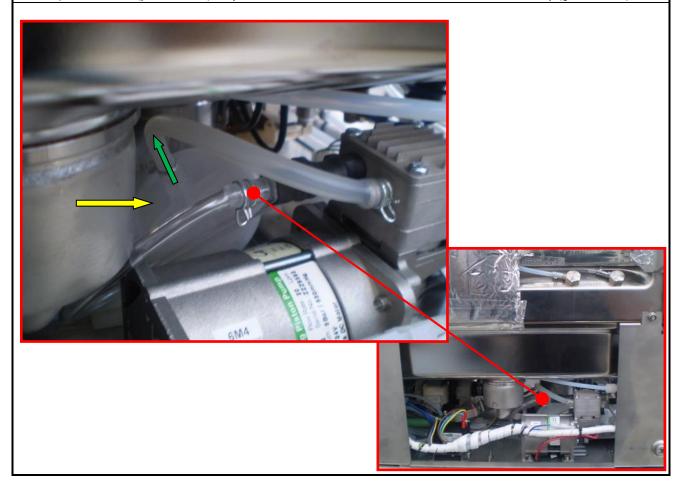


REPLACEMENT OF AIR FILTER FOR LEAK TEST			
M10	Worker: Is	Frequency of Intervention: every year	

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).





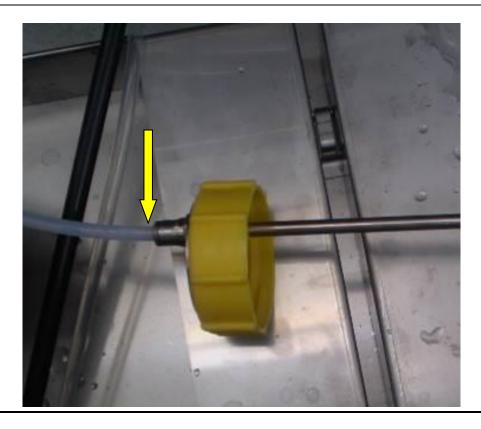
CHECKING THE SUCTION LANCE OF CHEMICAL PRODUCT 2 (DESINFECTANT)

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.

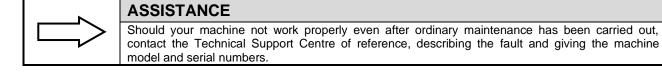
Check the suction pipe is not damaged throughout its length.





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.





20. PROBLEMS - CAUSES - SOLUTIONS

20.1 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.

20.2 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 washing chamber, performing the routine maintenance described in chapter 18 (Form M2) of this manual.

P. MACHINE DOES NOT PROPERLY RUN WASHING CYCLE:

- **C.** The nozzles of the washing arms are clogged by deposits or lime.
- S. Clean the washing arms by carrying out the routine maintenance set forth in chapter 18 (Form M3) of this manual.
- **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 18 (form M1) of this manual.

P. DETERGENT FILLING PHASE DOES NOT OCCUR CORRECTLY:

- C. Chemical dispensing pump not very efficient.
- S. Perform the routine maintenance set forth in chapter 18 of this manual.
- 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 18 (Form M5-M6) of this manual.
- **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.



21. DECOMMISSIONING

21.1 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.

21.2 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





Certificate N° 569

Training Certificate

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

EW'

Riese Pio X, 17/10/2013

Person in charge for training

D. Ales

Steelco S.p.A.

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"For the Environmentally conscious"

D 18#10 Rev



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)

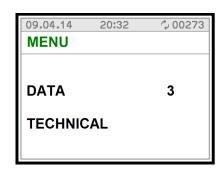
Endoscopes can be re-processed in the cycle dedicated to biological sampling. The only difference compared to a normal disinfection cycle refers to the interruptions during the final rinsing phase.

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

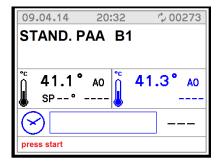
The sample must be taken during the final rinsing stage.

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.



ATTENTION

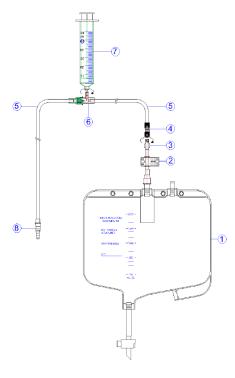


- Adequate measures must be implemented to avoid contamination of the sample during the water sample-taking stage. It is recommended to use the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check).
- The water samples for the microbiological test must be taken only during the final rinsing 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:



- Insert the 80 cm PVC pipe (5) into the sump of the washing chamber;
- 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);
- 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 OF THE ENDOSCOPE

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. 	
	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).	
UNSATISFACTORY	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 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. 	
	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. 	
UNSATISFACTORY	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.





ED 150

Drying and storage cabinet for flexible endoscopes



After the reprocessing in an endoscope washer, the endoscope is ready to be used right away. If it is not used immediately, the latter should be dried and stored in controlled conditions in a drying and storage cabinet.

Steelco ED 150 dries and stores flexible endoscopes keeping them in controlled conditions while waiting for the next patient.

The aseptic storage time is **independently certified up to 720 hours**.

ED 150 allows to hung endoscopes vertically with dedicated supports to prevent their distal part from touching the bottom of the chamber. For the positioning and the withdrawal of the endoscopes, the operator is facilitated by the system of vertical sliding drawers that allows the almost total extraction of the drawers and the convenient access to the instruments.

The ED 150 model is available in different configurations as single or side-by-side combined module.

The double module version reduces the used space by sharing the central control module. The two cabinets are indeed configured in a more compact frame that combines two devices into a single frame despite being two independent units regarding all other aspects: mechanical, connections, control panels etc.

Models

Single device - 9 endoscopes capacity

ED 150/1 - Single door model

ED 150/2 – Double door model

Combined device - 18 endoscopes capacity

ED 150/3 - Single door model









Specifications

Dimensions

External dimension

ED 150/1 - 968 mm x 810 mm x 2270 mm

ED 150/2 – 968 mm x 845 mm x 2270 mm

ED 150/3 - 1713 mm x 810 mm x 2270 mm

Drying/storage chamber

ED 150/1 - 548 mm x 714 mm x 1700 mm

ED 150/2 - 548 mm x 752 mm x 1700 mm

ED 150/3 - 548 mm x 714 mm x 1700 mm

Sound level

< 50 dB

Drying

Endoscope channels purging with pressurized HEPA H14 filtered air.

The device is also equipped with an efficient warm air flow that dries both the chamber and the endoscopes external surface.

Certifications

ED 150 is classified class I, according to rule 13 of Annex VIII of the regulation EU 2017/745 (MDR).

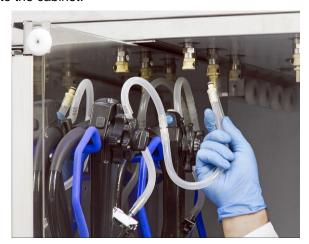
Cabinet/instrument connection

Steelco ED 150 is equipped with sliding panels, each one with three (3) hangers where the endoscopes are dried and stored vertically with dedicated supports to prevent their distal part from touching the bottom of the chamber.



The sliding panels allow the almost total extraction of the panels themselves and the simplified access to all the instruments.

The connection system of the endoscope channels is made of silicone pipes, completed with connectors dedicated to endoscope channels (different brands and models). Such tubes have CPC male connectors on the other side to allow the endoscope connection to the cabinet.







Construction

- External frame and panels in stainless steel AISI 304.
- Vertical panels in stainless steel AISI 304.
- Drying and storage chamber coating in polish stainless steel AISI 304.
- Vertical panels upper guides made of AISI 304 stainless steel and equipped with plastic wheels on bearings. The lower guides are made of AISI 304 with Teflon.
- Instrument hangers made of stainless steel AISI 304 with instrument protection system.
- Chamber thermal insulation made by mineral wool panels coating.
- Hinged reversible door, configurable for right or left opening, realized with a double HST (High Shock Tested) tempered glass.
- Three (3) 0,75 kW air drying heating elements.
- Safety lock for the end position of extraction of the drawers.





- Drying circuit, with a dedicated blower, for a homogeneous distribution of the heat inside the chamber, in order to prevent the creation of high temperature areas. The circuit is monitored by a pressure switch.
- Endoscope channels are purged through filtered compressed air (built-in air compressor).
- Alternatively, the cabinet can also be directly connected to external medical grade quality compressed air (air compressor not available).
- The filtration system is made up of a pre-filter and a HEPA H14 filter and it serves both the drying circuits.
- Easy filters maintenance with access from the frontal superior lifting panel.





- · Sensors to monitor the door opening.
- Panel-controlled door locking system.

Control system and connection interface

Control panel with 3-digit LED display.

Device settings, safety features

- Chamber temperature set at +40°C.
- Visual and acoustic alarm if the temperature is out of the pre-set working range.
- Visual and acoustic alarm in case of non-correct functioning of the air-drying flow system. This alarm cannot be removed until the flow is restored within the working range.
- Visual and acoustic alarm in case of non-correct instrument connection.
- Visual and acoustic warning when HEPA filter maintenance is needed.
- Visual and acoustic alarm in case one door is left opened for a longer period than a pre-set time.
- All acoustic alarms can be disabled through a general parameter.
- Interlocked doors in case of double door model to avoid the simultaneous door opening.

Standard configuration

Endoscope connectors up to cabinet capacity

Standard equipped with Olympus connectors.

If different connectors are needed, endoscope brands and models must be specified in the order.

HEPA H14 air filtering

Optional

Device main switch

Humidity detection system

Indirect UV drying air treatment

And others, to be verified with your local distributor/ agent.

Connections

For any connection detail, please refer to installation drawing of the selected model.

Electrical requirements

- The total power of the machine in the standard configuration is:
 - Single cabinet: 2,75 kW.
 - Combined cabinet: 5,5 kW.
- 230V/~/50Hz.
- Other electrical connections available to match electrical requirements of the installation site.





EPW 100 S

Semi-automatic device to support the manual cleaning phase of flexible endoscopes



EPW 100 S allows traceability, standardization, and semi-automation of the manual pre-cleaning phase of flexible endoscopes, taking care of the most stressing and repeated actions (syringe flushing & rinsing) and drastically reducing the risk of errors.

This compact benchtop device works in combination with any pre-washing sink or with Steelco dedicated sinks to provide a complete automatization of the process.

Main features:

- Barcode operator and endoscope ID recognition;
- Leak test at the beginning and throughout the cycle;
- Detergent single shot delivery;
- · Automatic channels flushing, rinsing, and purging;
- · Monitoring of channels flow and pressure;
- Channels detergent residuals washed away by the final rinsing and purging phases;
- Complete traceability of critical parameters
- · Cycle standardization;
- Dedicated protein test cycle;
- · Dedicated self-disinfection cycle.

Dimensions

Dimensions

450 x 280 x 230 mm

Certifications

Steelco EPW 100 S is classified class I, according to rule 13 of Annex VIII of the regulation EU 2017/745 (MDR).



Miele Group Member

Operation

The compact size of the system EPW 100 S allows its positioning in proximity of the sink normally used for the manual cleaning of the endoscope.

The endoscope is placed in the sink during all stages of the pre-wash and, according to its level of water filling, EPW 100 S doses precisely the required amount of concentrated detergent.

Steelco EPW 100 S guides the operator with graphic messages during the execution of the process:

 Recognition of instruments and operators by barcode/RFID reader or manual input (barcode/ RFID cards available for different cycles).



- Manual connection of the OCS connector.
- Manual connection of the leak test connector.
- Activation of leak test (leak test is active during all phases of the cycle until its completion).
- · Manual filling of the sink until it reaches the pre-

- set level (the level must be clearly identifiable by the operator).
- Activation of the automatic detergent dosing (concentrated with single shot delivery).
- The machine will switch to a stand-by mode to allow the operator to manually carry out the endoscope channels brushing.



 After brushing, the system will switch to a standby mode to allow the operator to connect the channels to their dedicated connectors.



- Automatic start of the instrument flushing with the cleaning solution.
- Manual emptying of the sink.
- Manual filling of the sink with clean water until it reaches the pre-set level.
- Automatic start of the rinsing phase.
- Manual emptying of the sink.
- Automatic start of the purging of the endoscope channels to remove any residual of the cleaning solution.
- End of the prewashing cycle and consequent interruption of the leak test by approval of the operator (via barcode/RFID reading or manual input).

Using the dedicated cards, it is also possible to:

- Activate the cycle for organic sampling (protein test).
- Activate the self-disinfection of the device.

Construction

- Made of stainless steel AISI 304 (DIN 1.4301).
- Other components are made of stainless steel or materials resistant to aggressive chemicals.

Standard Features

Leak test

Membrane pump with double pressure check





device and mechanical safety valve against overpressure (over 400 mbar).

Leak test air is 0,2 micron filtered.

Flushing system

- Water recirculation pump for powerful channel flushing.
- Flowmeter to check flow quantity and to monitor disconnections.
- A water filtering system captures residues and prevents their re-circulation to grant excellent cleaning results.

Chemical dosing

- Automatic liquid detergent dosing single shot delivery (detergent volume has to be set according to the water volume of the sink at the desired filling level)
- One (1) membrane dosing pump precisely add the liquid chemical agent to the washing basin.
- Flowmeter to control chemical dosed quantity.
- Automatic chemical level control with low-level sensors.

Instrument connection

The OCS connector is made of silicone pipes which must be completed with connectors dedicated to all endoscope channels (different brand and models) for the connection to Steelco EPW 100 S. The OCS is equipped with a magnetic sensor to detect the proper connection and has:

- · Leak test connection.
- Six (6) channels connection.
- 7th channel connection built in the EPW 100 S.



Barcode reader

For the recognition of operators and instruments.

Control system

Microprocessor control system

Microprocessor for total checking and displaying of each single cycle phase with process residual time highlight.

Execution of 3 automatic programs

· Cleaning cycle.

- Organic residual sampling cycle (protein test)
- Self-disinfection cycle

System control panel

 Soft-touch control panel (touch function areas with led) for an optimal cleaning and disinfection of the display. This assures the operator a better protection against contamination when operating the machine and selecting functions.



- TFT4,3" QVGA (480x272px) LCD graphic color display.
- The system gives acoustic and visual alarms for every problem with detailed information.
- Integrated barcode reader for instrument and operator identification, cycle recognition, start and stop.

System monitoring

- Visual alarms provide quality control for each cycle, highlighting the phase being executed and the remaining time until cycle completion.
- USB port for the download and storage of historical cycle data.
- Connection to traceability software SteelcoData Live or SteelcoData ARES by Ethernet Port.

Optional features

Accessories for instrument connection

RFID hands-free system

For the recognition of operators and instruments.

Integrated thermal printer

For the validation of the pre-washing treatment.

SteelcoData Live software

Dedicated software for the traceability of all the information of the endoscope washing cycles.

SteelcoData ARES software

Dedicated software for the monitoring of the whole endoscope reprocessing system including the use, the manual prewashing, the automatic reprocessing,





the storage, the service and all the waiting times between any of these phases.

And others, please verify with your local distributor/ agent.

Chemicals

Steelco validated chemicals are available (ISO/TS 15883-5)

Connections

For any connection detail, please refer to installation drawing of the selected model.

Electrical requirements

- Power 0.25 kW
- Voltage 230V/~/50Hz
- Voltage 208V/~/60Hz
- Other electrical connections are available to match electrical requirements of the installation site.





EW 1

Compact automated endoscope reprocessor



The new Steelco EW 1 machine has been developed to comply to the ISO 15883 directives.

The EW 1 washer disinfector is capable to reprocess 1 flexible endoscope, up to 3 video fiberscopes/cystoscopes of all types and brands and up to 11 rigid endoscopes with dedicated wash carts

Highest flexibility is granted by the compact design, which assures low cycle costs by reduced consumption of water, chemicals and energy.

The integrated monitoring system assures a higher level of safety by checking flow and pressure of the instrument connection.

EW 1 endoscope reprocessor performs chemical disinfection cycle for instruments and a thermal disinfection cycle for device self disinfection.

EW 1 design provides an installation set for any facilty:

- Single door
- Double door pass through

The "rack" option set-up for two EW 1 unit allows asynchronous reprocessing of 2 flexible endoscopes on a small footprint

- Single door double unit on "rack"
- Double door pass through double unit on "rack"

Specifications

Dimensions:

Single door

External WxDxH: 600mm x 630mm x 945mm 23.62" x 24.80" x 37.20"

Chamber WxDxH: 415mm x 480mm x 375mm 16.33" x 18.90" x 14.76"

Door passage WxH: 415mm x 260mm 16.33" x 10.23"

Double door

External WxDxH: 710mm x 570mm x 1206mm 23.62" x 24.80" x 47.48"

Chamber WxDxH: 415mm x 480mm x 375mm 16.33" x 18.90" x 14.76"

Door passage WxH: 415mm x 260mm 16.33" x 10.23"

Water consumption:

(6 I) per chamber fill

Sound level:

< 40 dB standard configuration 56.2 dB with forced air drying system

Cycles:

3 pre programmed, 4 user defined

Drying:

Complete purging of the instrument channel by a built-in 0,2µm sterile air system.

Washing chamber and endoscope external surface warm air drying is also available as option.

Process chemicals:

Compatible and tested with **peracetic acid** (cold disinfection) and **glutaraldehyde**.

Dosing:

Automatic chemical dosing via membrane pumps controlled by double flowmeters





Standard features

Hinged drop down door

- Stainless steel door frame, stainless steel AISI 316L (DIN 1.4404) washing chamber side, high visibility HST tempered full glass door external side.
- The door acts as a loading platform for wash carts for a convenient instruments loading and unloading job.

Locking Door

 Door locking system during cycle execution grants operator safety and prevents interference with wash cycle.

Washing system

- Two separate hydraulic circuits and pumps for endoscope channel and washing chamber
- Two rotary spray arms, one on the bottom and one on the top of the chamber
- Spray arms made of AISI 316L stainless steel (DIN 1.4404)
- Easily disassemble washing arms for cleaning and maintenance
- The EW 1 drain system guarantees the complete emptying of the washing chamber and hydraulic circuit.

Water connections and filtration

- One (1) water line connection available for cold/mixed or demineralized water.
- Water line is equipped with two (2) flow meters for checking and validation of water quantity and with a water filtration system (one 0.45 µm and one 0.1 µm filter).
- Water level sensor into the washing chamber.

Channels treatment

 The channels treatment is guaranteed by a dedicated pump, a flow sensor and pressure transducer for the water circulation control.

Channels purging/drying system

 Built-in sterile air system, made up of 0,2µm filter for the air sterilization, that ensures the complete purging of the instrument channels.

Channels monitoring

Leakage test

- The leak test verifies the suitability of instruments to be treated into the machine preventing possible problems before they cause serious damages
- Leak test is executed during the whole wash/disinfection cycle with automatic cycle stop in case of anomaly

Channels check

- Endoscope channel flow and pressure monitoring during the whole cycle.
- Automatic stop of the operating cycle in case of alarm and automatic rinsing for the total removal of eventual chemical product residuals.

Circulation pumps

- 110W power pump, 90 l/min flow dedicated to endoscope channel washing
- 110W power pump, 90 l/min flow dedicated to washing chamber washing arms

Chemical dosing

The correct dosing quantity is essential for trustworthy disinfection results.

- Two (2) membrane pumps provide precise addition of liquid chemical agents.
- Volumetric check of the dosed chemicals by double, high accuracy flow meters for checking and validation of disinfectant and detergent quantity.

Chemical storage

EW1 endoscope reprocessor is endowed with a stainless steel base for the storage of process chemicals.

- Up to three (3) chemical tanks 5lt capacity.
- · Level sensor check.

Washing chamber heating element

- 2.6 kW electrical heating element
- Electronic thermostat
- Two (2) independent PT1000 temperature probes
- One (1) additional PT 1000 probe for the checking of inlet water temperature





Microprocessor Control System

- Possibility of up to 7 storable programs 3 standard programs, 4 user definable programs
- Pre memorized programs follow the chemicals used for the validation, are developed by Steelco and certified by microbiological hygienic report.
- Different programs are selectable from the control panel. Cycle start is possible only after the operator recognition.

System control panel

- · Soft touch control system on glass panel
- 3.5" graphic colour LCD display



System Monitoring

- Constantly informs the operator regarding machine status, cycle phase, remaining cycle time to the end of treatment and the chamber temperature.
- Audible and visual alarms provide quality control for each wash cycle.
- · Water level sensor for water sump load
- RS 232 Port for printer connection to monitor and validate washing cycle
- USB port for historical cycle data, machine parameters and washing programs download. Allows easy software upgrades.

Process washing and disinfection Cycles

EW1 is compatible and tested with peracetic acid (cold disinfection), glutaraldehyde and can perform thermodisinfection cycles.

By using Steelco process chemicals the EW 1 automatic endoscope reprocessor reaches the highest efficiency results proven by microbiological tests together with complete documentation and instruments maximum safety conditions.

 Washing and disinfection cycle phases are: prewash, detergent wash, rinse, low temperature disinfection and two final rinses

- Peracetic acid disinfection temperature 35°C/95°F, cycle phase time 5 min.
- Glutaraldehyde disinfection temperature 55°C/131°F, cycle phase time 5 min.
- Thermal disinfection cycle: 80°C/176°F washing phase (cycle phase time 10 min.), air drying

Process traceability

Steelco EW 1 gives a report for each disinfection cycle including:

- EW 1 serial number identification
- Id of the instrument (up to 3 intruments)
- Id of the operator who activated the cycle It also gives a report of all parameters in process:
- Cycle time
- · Water consumption
- · Chemical products dosing
- Phase details

At the end it points out that the cycle has been correctly processed.

Drain Pump

 Independently operated drain pump for efficiently pumping out waste water

Construction

Wash Chamber and door internal side

- Constructed using AISI 316L BA Ra<30μin (Ra<0.8μm)
- Designed and constructed with smooth edges and corners removing areas where dirt can accumulate and allow bacterial growth.

Exterior

 AISI 304 Scotch Brite finish Ra<40μin (Ra<1.2μm)

Components

 Constructed using stainless steel and other materials which are resistant against the effects of aggressive detergents

Insulation

 High performance melamine insulation guards against heat loss and reduces noise level





Optional features

Double door pass through version

Additional water connection

 Equipped with two (2) flow meters for checking and validation of water quantity. This option is normally required when demineralized water is available, in order to perform instrument disinfection and final rinse with that water.

Powered electrical heating elements

- 4.6 kW electrical heating element to reduce process total cycle time
- AER total power 5.05 kW

3rd chemical dosing pump

 Membrane pump providing precise addition of liquid chemical agents (i.e. instrument lubricant)

Water Softener

- Softens incoming water
- Programmable regeneration with low salt alarm

Compressed air additional tank

 3.5l additional tank for compressed air to improve channel drying

Connection for external compressed air medical quality

· Max inlet pressure 2 bar

Washing chamber warm air drying system

- forced HEPA H14 filtered warm air drying ensures perfect drying of the external surface of the endoscopes
- 0.75 kW electric heating element

Barcode reader

allows faster instrument and operator recognition

Printer

 External printer for validating washing phases with detailed information

Network connection

 Ethernet connection for the remote recording of cycle parameters through SteelcoData traceability software

Accessories

- A variety of basket trays for flexible endoscopes, videobronchoscopes/cystoscopes or 3 fiberscopes/cystoscopes with separate control, rigid scopes...
- Using the "rack" option, two EW 1 machines will be installed on the top of each other on a mobile shelf. This set up allows asynchronous reprocessing of 2 flexible endoscopes on a small footprint.

Cleaning chemicals

· Dedicated cleaning chemicals are available.

Required utilities

For connection details please refer to installation drawing of the selected model/version.

Water

Drain Connection

Electrical requirements

- Total power of the machine in standard configuration 3.05 kW
- 230V/~/50Hz
- other electrical connections are available to match electrical requirements of installation site.





EW 1 Automated endoscope reprocessor (AER)



Steelco EW 1 has been developed to be compliant with the standard UNI EN ISO 15883-4 and UNI EN ISO 14937.

EW 1 is an automatic device for the reprocessing of one (1) flexible endoscope or up to two (2) videobroncho/cystoscopes or up to four (4) single-channel fiber broncho/cystoscopes of the major brands.

It also allows the reprocessing of rigid endoscopes with dedicated washing carts.

EW 1 has been validated for low temperature high level disinfection and liquid sterilization processes and it can perform the thermal self-disinfection, as recommended by the standard UNI EN ISO 15883-4.

Highest flexibility is granted by the compact design, which assures low cycle costs reducing consumption of water, chemicals and energy.

Models

The AER is available as **single door** or **double door** pass through versions.

EW 1 is also available in a *Rack* configuration having two units installed one on top of the other in a unique frame structure, in order to exploit small spaces and enable the asynchronous treatment of two endoscopes.

The *Rack* configuration is available both with single and double door.

Specifications

Single unit dimensions

External dimensions

Single door: 600 mm x 630 mm x 945 mm Double door: 710 mm x 570 mm x 1206 mm

Washing chamber

415 mm x 480 mm x 375 mm

Loading height Single door: 683 mm Double door: 950 mm

Door passage 415 mm x 260 mm

Rack configuration dimensions

External dimensions

Single door: 750 mm x 690 mm x 1643 mm Double door: 860 mm x 570 mm x 1663 mm

Washing chamber

415 mm x 480 mm x 375 mm

Loading height

Single door – lower chamber – 712 mm Single door – upper chamber – 1322 mm Double door – lower chamber – 720 mm Double door – upper chamber – 1350 mm

Door passage 415 mm x 260 mm





Water consumption

6 liters per chamber fill

Sound level

< 60 dB

Certifications

EW 1 is classified class IIb, according to rule 15 of Annex IX, 93/42/EEC Medical Device Directive.

EW 1 is compliant with the standard EN ISO 15883 parts 1, 4 and 5.

EW 1 is compliant with the standard EN ISO 14937.

Construction

Exterior

- Main frame made of stainless steel AISI 304 (DIN 1.4301).
- Panels made of AISI 304 MS2 finish.

Hinged Door

- Stainless steel frame hinged door.
- The glass door grants total visual monitoring of the process and it is realized with a double HST (High Shock Tested) tempered glass.
- Interlocked doors in case of double door version.

Washing Chamber

- Constructed using AISI 316L BA Ra < 30μin (Ra < 0.8μm).
- Designed and constructed with smooth edges and corners to allow the total chamber draining at the end of the cycle and to avoid areas where dirt can accumulate and allow bacterial growth.

Components

 Manufactured using stainless steel and other materials which are resistant against the effects of aggressive detergents.

Insulation

 High performance melamine insulation guards for thermal and acoustic insulation.

Standard features

Loading/unloading doors

- Door locking system during cycle execution to guarantee operator safety and to prevent any interference with the washing cycle.
- The double door model is equipped with an automatic interlock system to keep the dirty/ clean areas separate.
- Open doors also work as a stand for the washing

cart during loading and/or unloading operations and as an anti-dripping surface, thus helping keep the floor dry, clean and safe.



Endoscope loading and connection to the AER

Steelco EW 1 is equipped with a removable washing cart made of stainless steel, with guiding rails to ease its pull-out and allow the ergonomic load of one big size flexible endoscope. Such washing cart can be similarly pulled out from the opposite side in double door versions at the end of the cycle.

Washing system

- · Washing circuits with two (2) dedicated pumps:
 - For the washing arms placed on the top and on the bottom of the washing chamber.
 They are set to grant an efficient dynamic washing flow which allows a thorough endoscope cleaning.
 - For the basket connection and endoscope channels.
- Spray arms, made of AISI 316L stainless steel, which can be easily disassembled for cleaning and maintenance operations.
- The drain system grants the complete emptying of the washing chamber and the hydraulic circuit.

Water connections and filtration

- Two (2) water line connections available for softened cold/mixed and demineralized water.
- Water line is equipped with two (2) flowmeters for the control and validation of water quantity introduced in the chamber.
- Water filtration system through a sequence of two filters (one 0.45 µm and one 0.1 µm filter).
- The dual stage water filtration system not only ensures the presence of a microbiologically adequate final rinse water, but it also filters and ensures the high quality of all the water used in the disinfection phase.
- Filters are automatically decontaminated during the thermal self-disinfection.





Channels treatment and monitoring

- The channels treatment is guaranteed by a dedicated pump, a flow sensor and a pressure transducer for the water circulation control.
- Endoscope channels flow and pressure are monitored during the whole cycle.
- Automatic stop of the cycle in case of alarm and automatic rinse (single or double) to remove chemical product residuals, when needed.

Channels purging/drying system

- Endoscope channels are purged through 0.2 μm filtered compressed air (built-in air compressor).
- Alternatively, the machine can also be directly connected to external medical grade quality compressed air (air compressor not available).
- An additional setup for the connection to external medical grade quality compressed air is available as an option. In this case, built-in air compressor and connection for external compressed air are both available, but the default functioning will be with built-in air compressor.
- A forced heated air-drying system is available as an option for the elimination of residual humidity inside the washing chamber and on the external surfaces of the endoscope.

Leakage test

- The leak test verifies the instruments suitability to be treated into the AER preventing possible problems before they can cause damages.
- Leak test check is active during the whole cycle with automatic cycle stop in case of anomalies.

Washing chamber heating elements

- 2.5 kW electrical heating element in the sump of the washing chamber
- Two (2) independent temperature probes (PT 1000) in the washing chamber
- Additional PT1000 probe to check the inlet water temperature and the temperature during the heating phase.

Chemical dosing system

The correct dosing quantity is essential for trustworthy disinfection results.

- Three (3) automatic membrane dosing pumps precisely add liquid chemical agents.
- Volumetric control of the dosed chemicals by double, high-accuracy flowmeters to control and validate the disinfectant and detergent quantity.

Chemical storage

The endoscope washer EW 1 allows the storage of chemical tanks inside its frame.

· Capacity of up to four (4) tanks equipped with

- protective caps to avoid any vapors emission.
- Collection tank in case of chemical leakages.
- The feeding system is equipped with low level sensors.

Drain pump

Control System

The control system allows the definition and the memorization of customized programs dedicated to the treatment of each single instrument according to the chemical products used.

- Three (3) electrical boards: one (1) master and two (2) slaves.
- Standard pre-memorized programs certified by microbiological hygienic reports carried out by certified laboratories.
- All different programs can be selected from the control panel. Cycle start is possible only after the operator recognition.

System control panel

- · Soft touch control system on glass panel.
- A 3,5" graphic color LCD display constantly informs the operator about the machine status: cycle phase, time left, chamber temperature, chemical and water quantities. The system registers all the sensible parameters to print and archive them.
- At the end of the cycle, the system highlights the correct instruments reprocessing.
- Acoustic and visual alarms provide quality control for each wash cycle.
- Printer connection to monitor and validate the washing cycles.
- USB port on frontal panel for cycle data, machine parameters and washing programs download. It also allows easy firmware update.
- Optional Ethernet RJ 45 connection via gateway for supervisor SW connection.

Process traceability

The identification of each single endoscope ensures that the cycle control information is closely related to the single instrument, thus granting its complete traceability.

EW 1 prints a final report for each cycle with:

- AER serial number identification
- ID of the instruments
- ID of the operator

It also reports all the process parameters as:

Cvcle time





- Water consumption
- Chemical products dosing
- Phase details
- Events

At the end, the cycle status is pointed out (pass/fail).

Built-in printer

Built-in printer for validating washing phases with detailed information

Reprocessing cycles

EW 1 is compatible and has been validated for low temperature high level disinfection (35°C) and liquid sterilization processes.

By using Steelco chemical products, EW 1 grants instruments maximum safety conditions as well as **efficient results proven by microbiological tests** together with complete documentation.

Validated high level disinfectant

The validation has been performed by a certified European microbiological laboratory to attest the conformity to UNI EN ISO 15883-4.

Validated liquid sterilant

The validation has been performed by a certified European microbiological laboratory to attest the conformity to UNI EN ISO 14937.

Self-disinfection cycles

- The device performs the thermal self-disinfection cycle: 80°C/176°F washing phase as requested by the standard UNI EN ISO 15883-4.
- Completely automatic and programmable selfdisinfection cycles.
- Self-disinfection of the hydraulic circuit and of the water filtration system.

Optional

Washing chamber forced warm air-drying system

- A forced HEPA H14 filtered air drying system ensures the drying of the external surface of the endoscopes.
- 0.75 kW electric heating element.

Extra heating elements

4 kW heating element to be used where there is only cold water available (to reduce the total cycle time without the installation of boilers).

Barcode reader

For the recognition of operators and instruments.

Stand on wheels (only for single door machine)

SteelcoData Live software

Dedicated software for the traceability of all the information of the endoscope washing cycles.

SteelcoData ARES software

Dedicated software for the monitoring of the whole endoscope reprocessing system including the use, the manual prewashing, the automatic reprocessing, the storage, the service and all the waiting times between any of these phases.

Light inside the chamber

And others, please verify with your local distributor/agent.

Accessories

- Complete range of connectors for endoscopes brands and models.
- Duodenoscope dedicated reprocessing support.
- Steelco Process Challenge Device (PCD) kit for the control of the cleaning efficacy.
- Trolleys for the transport and short time storage of contaminated and/or disinfected endoscopes and accessories.

Required utilities

For any connection detail, please refer to installation drawing of the selected model/version.

Demineralized and softened cold/mixed water

Drain connection

Electrical requirements

- The total power of the machine in the standard configuration is 3,05 kW.
- 230V 50Hz
- Other electrical connections are available to match electrical requirements of installation site.





User Manual

ENDOSCOPES DRYING CABINET

ED 150/1

ED 150/2

ED 150/3

Serial N°:









Via Balegante, 27 31039 Riese Pio X (TV) ITALY

Manufacturer:

STEELCO S.p.A.

Via Balegante, 27 31039 Riese Pio X (TV) ITALY



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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.



Miele Group Member

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.

In case of serious accident that has occurred in relation to the device, it must be reported by the user and/or patient to the manufacturer and the competent authority of the Member State, in which the user and/or patient is established.

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:

- Regulation (EU) 2017/745 (Medical Devices);
- 2014/35/EU (Low Voltage Directive);
- 2014/30/EU (EMC Electromagnetic compatibility Directive);
- EN 61010-1 (Safety);
- EN 61010-2-010 (Safety);
- 2011/65/EC (RoHS ||);
- 2012/19/EC (WEEE);
- 2006/42/EC (Machine Directive).

and recognized international standards:

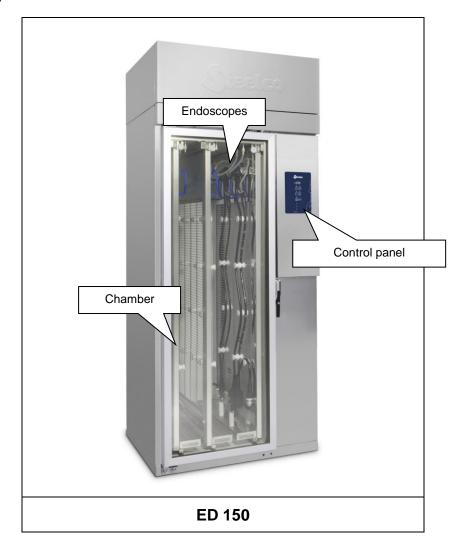
- IEC 61000 (Electromagnetic compatibility);
- IEC 61326-1 (Electromagnetic compatibility);
- IEC 60529 (IP Grade);
- ISO 14971 (Medical devices risk analysis);
- The device is compliant to the EN ISO 16442, controlled environment storage cabinet for disinfected thermolabile endoscopes. Aseptic storage time is **certified up to 720 hours by an independent laboratory**.



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 and he must know the precise function of all command and control devices of the machine.



2.1 Intended purpose, improper use

INTENDED PURPOSE:

The use of the machine is intended for the drying and the storage of the endoscopes.

Improper use of this unit may be hazardous to the operator and may seriously damage the machine itself.

WARNING:

If the appliance is used in a manner not specified by the manufacturer, protection of the appliance may be compromised.

IMPROPER USE:

Any use other than that for which the machine was intended is forbidden.

The machine is indeed for indoor use only.



2.2 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.

2.3 Safety recommendations

- If the new machine appears to be damaged, contact the retailer before starting it.
- Any modification of electrical and venting systems necessary to install the machine must be carried out by qualified, authorised persons only.
- This machine must be operated by trained persons only.
- The machine must be used for drying and for maintaining warm the endoscopes.
- 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 Laboratory dryer should be carried out by qualified and authorised operators only.
- The equipment should be installed by authorised persons only.
- The electrical safety of this Instrument dryer is only guaranteed if it is connected to an efficient earth system.
- 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.
- Do not lean on the door and do not use it as a step.
- Disconnect the machine from the electrical supply before carrying out maintenance work.



ATTENTION

The ED 150/3 model has got a double mains supply. For that reason, make sure to have unsticked the correct side before procedeeing with the maintenance.

• The acoustic pressure of the machine is below 50 dB (A).





2.4 Recommendations to ensure high quality performance

- The user must oversee the machine during the cycle.
- When the machine is running do not interrupt the cycle since this jeopardises the holding time on temperature programmed.
- While handling objects, it is required the use of the suitable PPEs in order to avoid contaminating devices to be stored/preserved.
- During cleaning of the machine do not use products that may damage steel and cause the rapid deterioration of certain machine parts; contact should be avoided.
- Repairs and servicing of this machine must be carried out by authorised persons only.
- · 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 included by the manufacturer.
- Accessories which are not approved by the manufacturer may compromise the results achieved as well
 as user safety.
- Wet location.
- Mains supply voltage fluctuations: +/- 10%.
- Overvoltage category: II.
- Pollution degree: 2.
- IP: 00.



ATTENTION

The manufacturer declines all responsibility for personal injury or material damage resulting from the non-observance of the above rules.

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





Residual risks 2.5

The appliance includes a series of fixed guards to prevent access to hazardous internal parts or zones.

It is however considered that the machine includes some residual risks.

Hereunder for each phase or significant work intervention are useful measures to be taken:

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.

Safety signals used 2.6

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









Control panel with double mains supply

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.





2.7 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.

It will be the duty of the EMPLOYER to check that the degree of staff training is suitable for assigned duties.

2.7.1 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.

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 dried;
- Operation of the machine in the various possible working modes, such as the start of various programmed 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.





2.8 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: < 50 dB (A)

2.9 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).

2.10 Table of symbols

Symbols installed on the machine:

4	Electrical risk
	Warning - hot surface
4	Manufacturer
{	Manufacturing date
\triangle	Attention! See the enclosed documentation for important warnings, such as warnings and precautions.
Ţ <u>i</u>	See instruction for use
	Protective conductor terminal
CE	EC Mark
X	WEEE waste disposal
MD	Medical device indication*
REF	It indicates the catalogue number of manufacturer.

^{*}According to the regulations in force in Canada, the products covered by this documentation do not qualify as medical devices.





3. USING THE MACHINE (FOR THE USER)

3.1 Checks

Check the machine status on the display and check that there are not any alarm messages.

3.2 Opening and closing the door/s

3.2.1 Stand by condition, one door model

In condition of stand-by it is possible open and close the door manually in every moment. The machine is equipped with key that allows to lock the door.

3.2.2 Machine in cycle, one door model

In condition of machine in cycle it is possible open and close the door manually in every moment. The machine is equipped with key that allows to lock the door.

If the door is opened during the cycle, remember that:

- The items inside the machine may be very hot.
- If the door is not re-closed within the time set by the relative parameter **P30**, the machine will show the warning message "**OPn**" on the display, accompanied by a beep. The message will be cleared once that the door is closed and the cycle will restart automatically from the point at which the door was opened.
- Otherwise, if the operator does not close the door in the time set by the parameter **P48**, the machine will show the alarm message "**Er4**" on the display and the cycle will be interrupted definitively.



ATTENTION

In this case the instruments inside the chamber are considered as contaminated and must be washed, disinfected and dried again.

3.2.3 Stand by condition, two doors model

In condition of stand-by it is possible open and close the door manually in every moment. The doors can not be opened simultaneously.

3.2.4 Machine in cycle, two doors model

The machine is equipped with a lock doors system. To open the doors during the cycle is necessary press the button 'STOP' on the control panel.

The doors can not be opened simultaneously.

If the door is opened during the cycle, remember that:

- The items inside the machine may be very hot.
- If the door is not re-closed within the time set by the relative parameter **P30**, the machine will show the warning message "**OPn**" on the display, accompanied by a beep. The message will be cleared once that the door is closed and the cycle will restart automatically from the point at which the door was opened.
- Otherwise, if the operator does not close the door in the time set by the parameter **P48**, the machine will show the alarm message "**Er4**" on the display and the cycle will be interrupted definitively.



ATTENTION

In this case the instruments inside the chamber are considered as contaminated and must be washed, disinfected and dried again.





In case of emergency and/or the door has locked due to a power cut, it is possible to open the door manually as described below:

Insert the screwdriver into the hole on the closing panel of the cabinet.



- Turn the screwdriver clockwise to unlock the door.





- Open the door.

3.3 Anti-contamination (if present)

Upon opening the door, the second fan speed is automatically enabled. This stage makes it possible to increase the chamber pressure, with the aim of preventing contaminations due to contact with the external environment.

ATTENTION: The second fan speed is enabled only if parameter P31 is set to 3.





3.4 Preparation

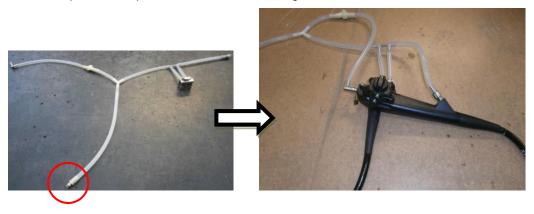
ATTENTION



BE SURE THAT THE DRYING CABINET HAS REACHED THE TEMPERATURE BEFORE INTRODUCE THE ENDOSCOPES.

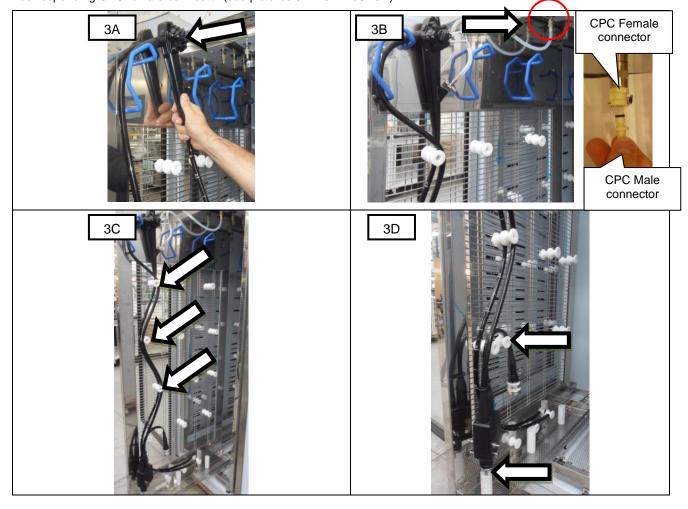
THE ROLLERS MUST BE POSITIONED ACCORDING TO THE TYPE INSTRUMENT TO BE INSERT INSIDE THE CABINET.

1-Connect the endoscope to the respective universal slide, leaving don't connected the other end.



2-Extract carts from the cabinet.

3-Place the endoscopes on the supports of the carts and insert the CPC male connector of the universal slide into the corresponding CPC female connector (see pictures 3A – 3B – 3C -3D).





Regarding the small dimension instrumentations (bronchoscope, cystoscopy, etc.), use the supplied support as shown on the picture:











ATTENTION

Make sure that nothing is blocking the holes and the air exit from the chamber.





3.5 Programs

		PROGRAM PHASES
PROGRAM NUMBER	PROGRAM NAME	DRYING
PROGRAM 01	RAPID	DRYING
	Duration (min)	120
	Temperature (°C)	40
	Holding Time (min)	120
PROGRAM 02	STANDARD	DRYING
	Duration (min)	240
	Temperature (°C)	40
	Holding Time (min)	240
PROGRAM 03	INTENSIVE	DRYING
	Duration (min)	Infinity
	Temperature (°C)	40
	Holding Time (min)	n.d.

PLEASE NOTE: If the machine is equipped with a humidity sensor, the length of the cycle is no longer determined by the parameters P1 – P4 – P7, but by the parameter P53 and the subsequent humidity threshold check set at P52.

3.6 Statement

By testing the endoscopes drying cabinet ED150, for 720 hours of storage in compliance with current regulations, all requirements were fulfilled.

3.7 Switching on

Activate the dedicated safety device.







- The control panel starts automatically.
- Check that there is no alarm message. In negative case remove it.



4. CONTROL PANEL AND SYMBOLS USED

4.1 Control panel/s

The cabinet is equipped with one or two control panels depending on the model (single door or double door). The control panel makes the machine easy to use and it indicates the programs, the actual chamber temperature and

The control panel makes the machine easy to use and it indicates the programs, the actual chamber temperature and fault messages.

If the machine is equipped with through passage doors, the control panel on load side allows to start cycles and to enter inside the menu, while the control panel on unload side only allows to interrupt the cycle and reset alarms.

DISPLAY LED

- Displays the various programmes, temperatures and any machine faults.
- During STAND-BY status, the type of programme selected is displayed.
- After pressing START, the display indicates the temperature of the air inside the chamber and when pressing the PRG button the temperature in the heater.
- In the event of a SHUTDOWN, the display indicated the shutdown status and the type of fault.

LEDS

There are 9 Leds:

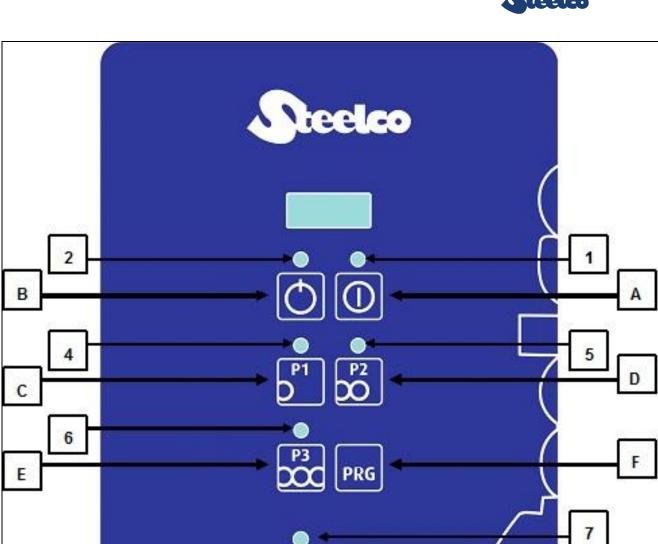
- one yellow Start led (1).
- one flashing red led to indicate that alarm happen (2).
- one green led to indicate a complete cycle (3).
- three yellow leds for indication of the various programme (4), (5), (6).
- three flashing yellow leds (7), (8), (9) to indicate that the cycle is on process.

BUZZER

• The buzzer sounds each time a key is pressed and intermittently in the case of a machine Shutdown.

4.2 Switches

BUTTON	REF.	DESCRIPTION	
		Press the button to select the program "Pr1". STAND-BY CONDITION: the button is used in the menu to increase the numerical values, scroll through the list of operator parameters and the list of Inputs/Outputs.	
P2 D STAND		Press the button to select the program "Pr2". STAND-BY CONDITION: the button is used in the menu to reduce the numerical values, scroll through the list of operator parameters and the list of Inputs/Outputs.	
P3	E	Press the button to select the program "Pr3".	
PRG F Keep the button pressed for 5 seconds to Press the PRG button to scroll through the CYCLE IN PROGRESS: Press the PRG		STAND-BY CONDITION: Press the button to scroll through the programs Pr1, Pr2, Pr3. Keep the button pressed for 5 seconds to visualize the menu. Press the PRG button to scroll through the list of menu sectors. CYCLE IN PROGRESS: Press the PRG button to visualize the temperature measured by the heaters. After a few seconds, the temperature of the air inside the cabinet it reappears.	
START	Α	STAND-BY CONDITION: Press the button to confirm the enter to the controls inside the menu. CYCLE IN PROGRESS: Press the button to begin the selected phase.	
	В	STAND-BY CONDITION : Press the button inside the menu to return at the previous or initial display state.	
STOP		CYCLE IN PROGRESS, ONE DOOR MODEL : press the button to stop definitively the cycle in progress.	
		CYCLE IN PROGRESS, TWO DOOR MODEL: Press the button to stop the cycle in progress. In this condition pressing START the cycle will be started again from the point at which it was interrupted, while pressing STOP the cycle will be stopped definitively.	





5. MACHINE STATUS

5.1 Preparation

Carry out the phase of preparation as described in Par 3.3.

5.2 Wait

The machine is ready to start a cycle.

The diagnostics are active.

If necessary, the display indicates that the door is open or gives warning messages.

5.3 Cycle

Cycle mode is entered by pressing the **START** key, this command is only accepted if the machine is in wait mode and the door is closed.

The diagnostics and regulators are active.

The user interface gives information concerning the cycle in progress and temperature chamber.

5.4 Shutdown

LOCK IN STAND BY:

In case of lock with machine in stand-by, reactivate the cause of the alarm occurred and perform the unlocking procedure.

Once reset the alarm, the machine will return at the previous state.

LOCK DURING THE CYCLE:

In case of lock during the cycle, reactivate the cause of the alarm occurred and perform the unlocking procedure. Once reset the alarm, the interrupted cycle starts from the beginning.

6. PROCEDURE OF RESET

In case of LOCK, reactivate the cause of the alarm occurred and perform a procedure on the keyboard which consists of the sequence below, to reset the alarm:

- 1. Press the **STOP** and **START** switch together and keep pressed for 5".
- 2. Press the programme switch P2 followed by the program switch P1.

7. SPECIAL FEATURES

7.1 Power failure

In case of dropout in stand-by condition, the board will recur in the previous stand-by condition, at the voltage reactivation.

In case of dropout during the performance of a cycle, at the voltage reactivation, the interrupted cycle will be managed according to the parameter setting P28.



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8. WORK PROCEDURES

8.1 Introduction

The machine was built only and exclusively for drying endoscopes that have already been handled/sterilized. For this reason, it is necessary to provide some useful instructions for the operators who will be using it.

8.2 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 cycle.

8.3 Decontamination procedures

When making repairs or replacing mechanical parts on malfunctioning machines that have not completed the cycle, before undertaking any sort of maintenance on the internal parts of the machine, the disinfection procedure must be carried out in order to eliminate any pathogenic residues and protect operators who come into contact with the machine from the risk of infection.

The decontamination procedure must be performed by the system operator, who must be equipped with all provided individual protection gear.

Carry out disinfection with a surface disinfectant or a disinfectant spray. The products used must be controller and approved according to European regulations. Watch contact time closely.

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, provided by the manufacturer), 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.

MODE OF INTERVENTION:

It is advisable to proceed with the disinfection of the machine as described in the chapter relating to maintenance.

When performing maintenance on parts of the machine which have not been reached by the disinfectant, take appropriate precautions and use suitable safety gear.





9. MENU

9.1 Accessing the menu

To enter the menu, keep pressed the **PRG** key for five seconds.

- Press **PRG** button to scroll through the menu.
- Press **START** to confirm selection, press **STOP** to return at the previous or initial display state.

WARNING:

Only authorized technicians with password are allowed to enter the programming menu.

The password must be required to the manufacturer.

Enter MENU to display the following fields:

FIELD	DESCRIPTION
PAr → Machine Parameters	Machine parameters setting.
CLo → Clock	Date/time setting. Activated if PLUG IN (printer board) is enabled. The date/time value is displayed if the historical cycles file is printed.
Prn → Print	Print the historical cycles. Activated if printer is enabled.
ErA → Erase	Delete the historical machine data. Activated if PLUG IN is enabled.
SEr →Service	Maintenance setting. Access to the service hours of the machine.
I_O → I/O PLC	Display inputs/outputs PLC and Enabling/Disabling outputs PLC.

Following is described the keys sequence to enter into menu fields.



KEYS SEQUENCE TO ENTER INTO "PARAMETER MENU" - PAr -:

ACTION	DESCRIPTION	DISPLAY			
USER - INSTALLER MENU					
Keep pressed PRG for 5 seconds	Access to the menu fields	PAr			
Press - START -	Confirm operation	PAS			
Press - P1/P2 -	Set password	xxx			
Press - START -	Confirm operation	"P"			
Press - P1/P2 -	Scroll through parameters and select the desired parameter.	"P"			
Press - START -	Confirm operation to enter into the desired parameter. Display and/or modify the parameter.	Parameter value: -Pressing START button the modified parameter is saved and the display return to the previous status -Pressing STOP button the display return to the previous status, and the modified parameter is not saved			

KEYS SEQUENCE TO ENTER INTO "CLOCK MENU" - CLo -:

ACTION	DESCRIPTION	DISPLAY
USER – IN	AN MENU	
Keep pressed PRG for 5 seconds	Access to the menu fields	PAr
Press - PRG -	Scroll through menu fields	CLo
Press - START -	Confirm operation	1
Press - P1/P2 -	Scroll through days number and select the desired value	1 31
Press - START -	Confirm the desired value	1
Press - P1/P2 -	Scroll through months number and select the desired value	1 12
Press - START -	Confirm the desired value	0
Press - P1/P2 -	Scroll through years number and select the desired value	0 99
Press - START -	Confirm the desired value	0
Press - P1/P2 -	Scroll through hours number and select the desired value	0 23
Press - START -	Confirm the desired value	0
Press - P1/P2 -	Scroll through minutes number and select the desired value	0 59
Press - START -	Confirm the desired value	Set values are stored and the display returns to the standby display status

KEYS SEQUENCE TO ENTER INTO "PRINT MENU" - Prn -:

ACTION	DESCRIPTION	DISPLAY		
USER - INSTALLER - MAINTENANCE TECHNICIAN MENU				
Keep pressed PRG for 5 seconds	Access to the menu fields	PAr		
Press - PRG -	Scroll through menu fields	Prn		
Press - START -	Confirm operation	Print the historical cycles		

If the message "FAIL 2" appears during printing, it means that the cycle has been interrupted manually.



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KEYS SEQUENCE TO ENTER INTO "ERASE MENU" - ErA -:

ACTION	DESCRIPTION	DISPLAY		
USER MENU				
Keep pressed PRG for 5 seconds	Access to the menu fields	PAr		
Press - PRG -	Scroll through menu fields	ErA		
Press - START -	Confirm operation	PAS		
Press - P1/P2 -	Set password	xxx		
Press - START -	Confirm operation	The display shows the "ErA" text, in which the historical cycles file is deleted. At the end of procedure the display returns to the standby display status.		

9.2 Details of the electronic card

The electronic card was designed following the indications given in the standards below:

EN 60335	Low voltage
EN 61000-6-3	Emission
EN 61000-6-1	Immunity

9.3 Features of master card

Serial interface

Com1

Low voltage bus bar for two-way communication with the keyboard card.

Com₂

Asynchronous serial interface type RS232 foreseen for connection to PC or printer(optional).

10. CLOCK

- The card has a real-time clock.
- Time readings are also used when recording historical data.

11. PC INTERFACE

The card has a communication channel RS232 with Modbus protocol.

The channel can be used to access the historical data records file by setting the printer as follows:

- Baud rate: 2400 Baud, X ON X OFF,
- · data bits: 8bits,
- · parity: none.





12. ALARMS AND EVENTS LIST

12.1 Logical description of alarm interventions

During machine operation, the operator is aided by **ALARMS** or **WARNING** which make use of visual signals on the operator display panel 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 to the operator by a message on the operator panel.

The alarm which appears on the panel remains active until the cause of intervention is removed. The intervention of an alarm stops the cycle currently in progress.

12.2 List of alarm messages

Possible alarms which may intervene during a work cycle are shown on the control panel display.

The message includes the number of the alarm that has intervened.

A complete list of possible alarm messages follows.

ALARM		DESCRIPTION
Er0	POWER FAILURE	This occurs when there is an electrical power failure during a work cycle.
Er1	FREE	-
Er2	FREE	-
Er3	UV LAMP FAULT	UV lamp fault for more than the time set by parameter P24 .
Er4	DOOR OPEN	Door being open for more than the time set by parameter P48.
		This occurs when the during the cycle the temperature inside the cabinet is over the value set by parameter P16 .
Er6	PROBLEMS ON CABINET PROBE (Probe n°1)	This condition happens when, with heaters ON, the temperature in the cabinet, does not increase of 1°C within the time setted by the parameter P19. This control is carried out only if the temperature is lower than the one set by parameter P18. Likely reasons of such a block could be either a problem on heating elements or a too low set time by the parameter.
Er7	FAULTY CABINET PROBE (Probe n°1)	This occurs when the temperature probe 1 (in the cabinet) is damaged.
Er8	FREE	-
Er9	FAULTY HEATER PROBE (Probe n°2)	This occurs when the temperature probe 2 (heater) is damaged.
E10	PROBLEMS ON HEATER PROBE (Probe nr.2)	This condition happens when, with heaters ON, the temperature in the heater, does not increase of 1°C within the time setted by the parameter P23 . This control is carried out only if the temperature is lower than the one set by parameter P22 . Likely reasons of such a block could be either a problem on heating elements or a too low set time by the parameter.
E11 FREE		-
E12	LIMIT °C HEATER PROBE (Probe n°2)	This occurs when during the cycle, the temperature inside the heater is over the value set by parameter P20 .
E13	PROBLEMS BLOWER 1 (COMPRESSOR)	Pressure switch fault SP3, fan failure.
E14	PROBLEM BLOWER 2 (MAIN BLOWER)	Pressure switch fault SP3, fan failure or clogged filter HEPA.
E15	FREE	-





E16	REDUNDANCY CHAMBER PROBE(OPTIONAL)	-
E17	CAN SERIAL CONNECTION (Double door cabinet)	Lack of CAN communication between the two boards.
E18	FAULTY DOOR 1 LOCKING SYSTEM	Failure in the locking system of the loading door. This happens when time set by parameter P39 for the opening and the closing of the locking system of the door is over, or the locking door system is open during the active phases of the drying cycle.
E19	FAULTY MOTOR DOOR 1(OPTIONAL)	-
E20	DOOR 1 OPEN DURING THE ACTIVE PHASES OF THE CYCLE	The door has remained open over the time set by parameter P30 .
E21	FAULTY DOOR 1 ENDSWITCH (Double door cabinet)	Contradiction in the status of the limit switch of the loading door.
E22	FAULTY DOOR 2 LOCKING SYSTEM	Failure in the locking system of the unloading door. This happens when time set by parameter P39 for the opening and the closing of the locking system of the door is over, or the locking door system is open during the active phases of the drying cycle.
E23	FAULTY MOTOR DOOR 2(OPTIONAL)	-
E24	DOOR 2 OPEN DURING THE ACTIVE PHASES OF THE CYCLE	The door has remained open over the time set by parameter P30 .
E25	FAULTY DOOR 2 ENDSWITCH (Double door cabinet)	Contradiction in the status of the limit switch of the unloading door.
E26	DOORS STATUS CONTRADICTORY (Double door cabinet)	Contradiction in the status of the doors.
E27	HYGROMETER	Hygrometer problems.



13. MAINTENANCE

13.1 General recommendations on maintenance

The machine was built only and exclusively for drying endoscopes that have already been handled/sterilized.

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.
- Be particularly careful and aware in case of maintenance for the replacement of potentially contaminated bacteriological filters.

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 behavioral rules, in compliance with standards regarding contact with parts of the machine which may be contaminated by pathogenic materials and with use of suitable PPEs.

The maintenance machine operations described in this manual are divided into "Routine maintenance works" and "Extraordinary maintenance works".

The **routine maintenance** works concern all the operations aimed to keep all the different parts of the machine cleaned and functional and they have to be executed in a periodical frequency or when it is considered necessary, as it is reported an uncorrect washing cycle execution.

The manufacturer and the dealer make available the preventive maintenance kits, called **PM KITS**, which provide for interventions effectued in a fixed frequency (1 year). The kits include the necessary components, in order to keep the optimal device performances.

Here below you could find the summarising table of the different maintenance works, the maintenance frequency and the staff in charge of each operation (**Ac**= Preposed to the machine use; **Is**= Installation and reparation Technician). Each single intervention is described more precisely in the following sheets.

All the **extraordinary maintenance** works must be executed only and exclusively by qualified and expert staff. If your machine presents a functional damage, for which you have to ask for an extraordinary maintenance work, you are kindly invited to contact the distributor/dealer.



ATTENTION

The ED 150/3 model has got a double mains supply. For that reason, make sure to have unsticked the correct side before procedeeing with the maintenance.



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TABLE OF ROUTINE MAINTENANCE TASKS

CLEANING AND CHECKING OPERATIONS		
FREQUENCY	ACTIVITY	WORKER
EVERY WEEK	-Blower: Check for free rotation.	
	-Cleaning and disinfection of the internal chamber walls and accessories.	Ac
EVERY 6 MONTHS	-Instrument and machine connectors: Check the state and if necessary replace.	
	-Door gasket: Check the state of the seal	
	-Compressor: Check for air leaks from the gasket.	ls
	-Compressor air filter unit (0,2 μ m cod. ED100085): Check the state of the compressor air filter unit. Replace it wheneven necessary and at least once a year.	
EVERY YEAR	-Temperature probes: During periodic validation, check the sensor status.	Is
	-Safety thermostat: Verify the sensor.	

PREVENTATIVE MAINTENANCE OPERATIONS*		
FREQUENCY	ACTIVITY	WORKER
	-Replace door gasket	ls
	-Replace UV-C light	
EVERY YEAR	-Replace drying F5 filter	
	-Replace HEPA filter	

^{*} The operational instructions are included in the machine documentation and in the PM Kit.

* The operative instructions are inclused in the machine documentation and in the PM KIT.

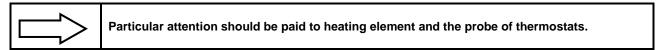
N.B.:

The time frames for execution of the maintenance programme may vary by +/- 15 days from the period indicated in the table.

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.

It is advisable to carry out a general check-up and to clean the appliance regularly.







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.

WARNING: IT IS NECESSARY TO MAKE A MAINTENANCE AT REGULAR INTERVALS AS DESCRIBED ON THE TABLE BELOW, IN ORDER TO GUARANTEE THE PERFECT FUNCTIONING.

DISINFECTION AND CLEANING OF THE CHAMBER		
	Worker: Ac	Frequency of Intervention: Recommended monthly
METHOD OF INTERVENTION:		

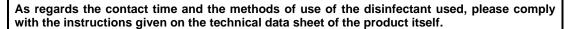
It is advisable to proceed with the disinfection of the machine as described below:

- Open the access door to the chamber and check that no equipment or instruments have been left inside.
- Remove baskets or boxes and clean them.
- Inside the chamber, evenly spray a disinfectant that is both compatible to be used on steel surfaces.
- All internal parts must be treated by this operation.

The approved STEELCO product for cleaning and disinfection of the chamber is called "STEELCO Surface Cleaner Disinfectant". -Annex A-

N.B.: "Steelco SCD" must be sprayed directly onto a low particle generation cloth that will then be used on all internal surfaces accessories. Contact must minutes. and time he 10 Should this product be sprayed directly onto the surfaces, following a 10-minute contact time, remove the product using the cloth.

ATTENTION





Always check the compatibility of the chemical product with the materials it will be used on; this information can be found on the technical data sheet of the chemical product used.

The application of the disinfectant inside the chamber must be carried out when the surfaces are cold in order to avoid harmful fumes coming from the product being inhaled.

CLEANING THE EXTERNAL BODY OF THE MACHINE		
	Worker: Ac	Frequency of Intervention: daily/weekly

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.

It is recommended to use chemical ("STEELCO SCD") compatible with external surface of the cabinet.

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.





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.		

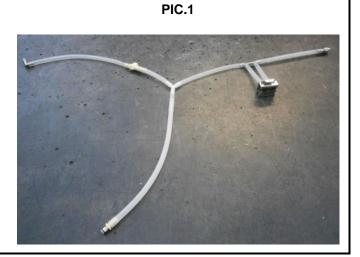




Treatment of endoscope connections

In order to avoid contamination, it is advisable to periodically carry out a cycle in which endoscope connections are disinfected.

- -Maximum resistance temperature 70°C;
- -Disinfectable by means of cycles thermostatically controlled material (e.g. plasma gas thermolabile materials in washer disinfectors).



PIC.2

It is advisable to replace pipes every year and to reprocess them on a weekly basis.







14. PROBLEMS - CAUSES - SOLUTIONS

14.1 Introduction

This chapter includes possible problems which may occur during machine operation, along with their cause and solution. All components, if not identified by specific figures, are referred to by the attached assembly drawings. If after following all instructions in this chapter the problems persist or re-occur frequently, please contact our technical service

14.2 Problems - Causes - Solutions

I. MACHINE WILL NOT START:

- C. Circuit breaker de-activated.
- R. Place it in the "ON" working position.
- C. Machine start switch de-activated.
- R. Press the start button.

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

- C. The door is not correctly closed or locked.
- R. Check door closure. Check that the door micro-switch is properly activated.
- C. Micro-switch failure.
- **R.** Check operation and replace as necessary.

MACHINE DOES NOT REACH SET TEMPERATURE FOR THE SELECTED WARMING:

- C. The heaters do not work correctly.
- **C.** The temperature probe do not work correctly.
- R. Check and replace as necessary.

I. MACHINE DOES NOT PERFORM WARMING PHASE:

- C. Air filter is dirty or clogged.
- R. Clean the filter by carrying out the routine maintenance set forth in chapter 13.5 (Form M2) of this manual.
- C. The fan of the warming system does not work.
- R. Check the electrical connections of the warming system.
- R. Contact our technical service and ask for the assistance of an **authorized workshop technician** for the repair or replacement of the motor.



15. DECOMMISSIONING

15.1 Instructions for disassembly and demolition of machine

Please note that the machine may contain contamination from blood and other bodily fluids, pathogens, facultative pathogens, genetically modified material, toxic or carcinogenic substances, heavy metals, etc., and must be decontaminated before disposal.

For environmental and safety reasons, dispose of all process chemical residues in accordance with safety regulations. Wear gloves and protective goggles.

Remove or disable the door lock prior to disposal of the machine, so that children cannot become trapped inside. Then make appropriate arrangements for safe disposal 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, nonabsorbent, 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.

15.2 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 equipments is punishable by law with the appropriate penalties.





ANNEX A





BINFTS:

16. STORAGE AND DRYING CABINETS: SANIFICATION PROCEDURE OF THE INTERNAL SURFACES AND ACCESSORIES

The rule EN 16442, at point 5.3, predicts that the internal cabinet surfaces and its accessories—storage cases and DM transport—could be submitted and resist to the cleaning processes and routine disinfection without being subject to degenerations.

For this aim the manufacturer must provide a procedure of validated cleaning and disinfection.

The tested and validated disinfectant by Steelco S.p.A. for the sanification phase of the cabinet walls and the storage boxes is Steelco SCD code 9992105.

Steelco SCD is ready to be used with a spectrum of biocid action for bacteria, fungus and virus. The product must be left in contact to the surface for 10 minutes and consequently removed with a proper cloth. No rinse is requested.

Sanification procedure

Steelco S.p.A. recommends to carry out the sanification procedure of the cabinet as described below at least once a month or to refer to the internal protocol of the structure.

It is recommended to clean the accessories of the cabinets after each procedure with a routine cadence or by following what indicated in the internal protocol of the structure. If the cabinet cases are used for the transport of the dirty endoscopes to the reconditioning area, the same must be sanitized after each procedure.

- 1. Disconnect the cabinet electrical power supply
- 2. Remove the endoscopes in stock from the internal part of the cabinet
- 3. Spray **Steelco SCD** on the cabinet walls and on the accessories (eventual baskets in the mesh, cases etc...)
- 4. Allow the product action for 10 minutes
- 5. Remove the product with a proper cloth allow particulate release





It is possible to use alternatively the following methods in order to sanitize the accessories.

Alternatives methods for accessories sanification

- Standard chemical disinfection cycle (35°C) in the endoscope washer Steelco model EW 2 Standard chemical disinfection cycle in washer disinfector with a temperature not higher than 45°C

Sanification of endoscopes connectors

The endoscopes connectors must be periodically disinfected or sterilized as well.

Here below some methods:

- Cycles for thermolabile material inside the endoscope washers or thermo-disinfectors;
- Terminale sterilization al low temperature (Plasma, hydrogene peroxide or Ethylene oxyd);
- Use of disinfectants that can be re-used and proper to thermolabile products.







User manual

EPW 100 S:

Semi-automatic device to support the manual cleaning phase of flexible endoscopes

Serial N°:











Via Balegante, 27 31039 Riese Pio X (TV) **ITALIA**

Manufacturer:

STEELCO S.p.A.

Via Balegante, 27 31039 Riese Pio X (TV) **ITALIA**





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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.

Follow 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.





1. GENERAL RULES

1.1 Limits of manufacturer's liability

The manufacturer shall not be held liable for failures or problems arising from tampering and/or incorrect applications and/or improper use of the machine.

The purchaser must follow all the instructions set forth in the user's manual, and in particular he must:

- Always work within the allowable limits for the use of the machine;
- Always carry out constant and diligent maintenance;
- Allow the use of the machine only to skilled and trained personnel;
- Use only manufacturer original spare parts.

Modifications and/or adaptations made on machines which will be placed on the market do not oblige the manufacturer to intervene on previously supplied machines, nor to consider the machine and the related user 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 have to be considered in addition to employer requirements, in order to be compliant to safety standards.

In case of serious accident that has occurred in relation to the device, it must be reported by the user and/or patient to the manufacturer and the competent authority of the Member State, in which the user and/or patient is established.

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 it is valid for the entire life cycle of the machine.

The manufacturer is available to give further information and/or to receive suggestions to make the manual more compliant to customers needs.

In order to prevent possible accidents to persons or property due to in correct translation of the instructions, the client

- Not perform any operations in case of any doubts or uncertainties about the operation to be performed;
- Ask technical service for clarification of the instruction.
- Ask for a new copy of the manual if it has been lost.

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 to learn how to use and manage the device.

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 protect the user in compliance with following Regulations and "Technical Product Standards":

- Regulation (EU) 2017/745 (Medical Devices);
- 2014/35/UE (Low Voltage Directive);
- 2014/30/EU (EMC Electromagnetic compatibility directive);
- EN 61010-1 (Safety);
- EN 61010-2-040 (Safety);
- 2011/65/EC (RoHS II);
- 2012/19/EC (WEEE);
- 2006/42/EC (Machine Directive);
- IEC 61000 (Electromagnetic compatibility);
- IEC 61326-1 (Electromagnetic compatibility);
- ISO 14971 (Medical devices risk analysis);
- ISO/TS 15883-5 (Soil test A soil test method to prove the effectiveness of cleaning activities);
- IEC 60529 (IP Grade).





2. SAFETY INFORMATION

The compliance to safety standards allows the operator to work safety, without the danger of harming himself or others.

Before using the EPW 100 S, operators must be completely familiar with the functions and the operations of the machine.

They must read the user manual and be trained on the machine functions.



2.1 Intended purpose, improper use

INTENDED PURPOSE:

The use of this device is intended only and exclusively as system of automatic support for the manual washing of flexible endoscopes and relative accessories.

IMPROPER USE:

The improper use of this device is any other use than the intended use.

WARNING



Any other use than the intended one is forbidden.

An improper use of this unit may be hazardous to the operator and may seriously damage the machine itself.

If the appliance is used without following the manufacurer instructions, the protection of the appliance may be compromised.

2.1.1 Application fields

• General flexible endoscopes (gastroscopes, bronchoscopes, colonscopes, etc..)





2.2 Important warnings and suggestions

For proper use of the machine, and in order to protect the personnel, carefully follow the general and specific rules below.

THE OPERATOR MUST:

- Carefully follow the instructions provided by the employer, managers and supervisors for individual and group safety.
- Use safety devices appropriately and carefully, as well as group and individual safety gear provided by the employer.
- Immediately inform the employer, the manager or the supervisor about deficiencies in the aforementioned
 devices, as well as any hazardous conditions which they may become aware of. In urgent cases, the operator
 shall take actions according to his responsibilities and abilities in order to eliminate or to reduce the deficiencies or
 the 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.

2.3 Safety recommendations

- If the new machine looks 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 used only by trained persons;
- This machine is intended as manual washing assister for flexible endoscopes.
- Any other use than the intended use is forbidden.
- Keep chemical cleaning products out of the reach of children and people who have not been trained to use them
 properly.
- The user is not allowed to carry out any action or repair on the machine.
- The technical maintenance should be carried out by qualified and authorised operators only.
- The equipment should be installed by authorised people only.
- Do not install the equipment in rooms where the risk of explosion (ATEX) is present.
- Do not expose the equipment to extremely cold temperatures.
- The electrical safety of machine is only guaranteed if it is connected to an efficient ground system.
- Be really careful while handling detergents and additives: avoid direct contacts, 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 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.

- Do not wash the machine externally using high-pressure jets of water.
- Disconnect the machine from the electrical supply before carrying out the maintenance.
- The acoustic pressure of the machine is below 40 dB(A).







2.4 Recommendations to ensure high quality performance

- The user must supervise the machine during the cycle.
- When the machine is running do not interrupt the cycle since this jeopardises cleaning efficacy.
- Use recommended 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 recommendation of chemical additives does not make the manufacturer responsible for any damage to the materials and objects treated.
- Follow the manufacturer's chemical products indications.
- Check that the chemical product is suitable for the washing programme as well as the material to be treated.
- The machine is designed to be used with water and chemical additives. Do not use organic or other types of solvent as they may cause a risk of explosion or the rapid deterioration of certain machine parts.
- Residues of solvents or acids (as in particular "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 chemical powder.
- Do never use foaming detergent.
- Use original accessories only.
- The machine has to be used only with the accessories provided by the manufacturer.
- Accessories which are not approved by the manufacturer may compromise the results as well as user safety.
- Do not use chemical products chlorides based (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.
- All OCS connectors shall be stored in a protected environment to avoid any risk of cross contamination.
 Moreover they shall also be routinely sterilized in a steam sterilizer using the 121°C rubber cycle with the
 frequency selected by each customer on the basis of his internal risk analysis. A visual check at the end of
 the cycle in the steam sterilizer is necessary in order to make sure that no residual humidity is left inside the
 OCS channels, and especially in the leak test channel.

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 warranty.





2.4.1 Inlet water quality

The quality of the water used in all stages of cleaning is important for good results.

The water used in each stage must be compatible with:

- The material of which the washer disinfector is made of.
- The chemicals used in the processes.
- Process requirements for the various stages of the process.

The main factors that affect the good inlet water quality in relation to the washing efficacy are:

HARDNESS	The high hardness of the water generates a detergent inactivation, reducing its efficacy. It also causes limescale deposits in the machine, jeopardizing the clean of the instruments and the machine, especially on hot parts (ex. heating elements).
IONIC CONTAMINANTS	A high concentration of ionic contaminants may cause corrosion of steel, manganese or copper instruments.
MICROBIAL CONTAMINANTS	Microbial contaminants can increase the microbial contamination of the instruments at the end of the wash.

The manufacturer recommends therefore that the water used should be softened and of drinkable quality in accordance with the "Guidelines for drinking water quality 3rd edition" published by WHO".

Further advice should also be obtained from the manufacturers of chemical and medical equipment.

Where local standards are stricter than these recommendations, please follow local rules.

Note: it is the user's responsibility to supply the machine with suitable water.

2.4.1.1 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. / 58 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 ₂ O 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 _i O 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





2.5 Residual risks

The device includes a series of controls to prevent the access to hazardous internal parts or zones. It is however considered that the **EPW 100 S** includes some residual risks.

PHASE	BASKET LOADING
RISK	Bruises caused by accidentally falling or bumping into the equipment itself.
MEASURE	The staff shall be trained and equipped with the proper equipment and with appropriate clothing and individual protection gear (e.g. shirts and protective gloves).

PHASE	OBTAINING DETERGENTS/CHEMICAL ADDITIVES
RISK	Contact of body parts with chemical products.
MEASURE	The staff shall be trained 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 clothing which has been contaminated or soaked by the product. If the substances come into contact with the skin, wash off the areas immediately and rinse with water.
RISK	Inhalation of vapours of chemical wash products.
MEASURE	The staff shall be trained and equipped with appropriate clothing and individual protection gear. Be compliant to 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.
Ţ.	IN CASE OF CONTACT WITH BODY PARTS, 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 due to the contact with hot parts of the appliance.
MEASURE	The maintenance must be performed only by trained personnel, equipped with appropriate clothing and individual protection gear. They must 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.	





2.6 Safety signals used

Safety signals (as set forth by 92/58 EEC) are sticked to the machine and closed to the working area, to inform the personnel of behaviour obligations and residual risks.

GENERIC SAFETY SIGNALS:

In particular, the most common labels with obligations, prohibition and danger signals, are:







Biological risk

INDIVIDUAL SAFETY WEAR:

The risk and the residual risk evaluation for the workers health and safety, is carried out in the working area and on any equipment. This allows the employer to adopt the individual protection gears which are most suitable and appropriate to be provided to workers.





2.7 Training

The instructions for use of the machine will be provided during the start-up phase by the AUTHORIZED INSTALLATION TECHNICIANS to MACHINE OPERATORS and MAINTENANCE TECHNICIANS.

The EMPLOYER must control if the staff is properly trained for the assigned duties.

2.7.1 Staff qualification

According to installation and maintenance procedures, some professional profiles are identified as follows:

IS INSTALLATION and REPAIR TECHNICIAN:

Specialized installation and maintenance operator. He is capable of machine positioning and installation, of the connection of the electrical and the hydraulic systems and of the machine start-up procedure. He also performs routine and special maintenance operations.

This operator is responsible for staff training for machine operations and for testing the machine.

AS RESPONSIBLE AUTHORITY FOR THE MACHINE IN THE WORKPLACE:

Specialized staff that must verify safety devices and procedures in order to use the machine without any hazard.

The responsible authority is personally responsible for training courses to users and maintenance operators.

He must ensure that staff has acquired all information for the use and the 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 the personnel about safety standards, actions to be avoided and the first aid interventions related to the use of the machine and the chemical wash agents it contains.

The responsible authority must be aware of all the proper procedures and maintenance activities, as well as all procedures for the disposal of pollutants residuals and manufacturing wastes.

He must always be present during extraordinary or routine maintenance. He must approve all the operations or routine or special maintenance.

The responsible authority is responsible for the right functioning of all the command, controls and safety devices in the machines.

He shall carry out scheduled verification of the devices in order to ensure their continued functioning over time.

AC MACHINE OPERATOR:

Skilled personnel who operate with the machine.

The machine operator must be perfectly aware of all of the machine's command and control devices.

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

- Commissioning and start-up of the machine.
- Connection of the endoscopes to be washed.
- Operation of the machine in the various possible working modes.
- Programming and setting data from the operator panel and starting or resetting of work functions.
- Be capable of performing some routine maintenance such as cleaning inside the machine. All these operations must be performed using individual protection gear and following adequate safety measures.





Indication of sound level

The value shown below refers to a sound level measurement performed at a height of 1,5 m and at a distance of 1 m from the machine.

AVERAGE SOUND PRESSURE LEVEL: < 60 dB (A)

2.9 **Transport and storage**

Environment conditions:

- Temperature range -5 ... +40 °C;
- Relative Humidity range 20...90% without condensation;
- Ventilation: Air exchange not required (it is required only if chemical tanks are installed).

2.10 Table of symbols

Symbols installed on the machine:

4	Electrical risk
	Warning - hot surface
4	Manufacturer
\mathbb{A}	Manufacturing date
\triangle	Attention! See the enclosed documentation for important warnings, such as warnings and precautions.
[]i	See instruction for use
	Protective conductor terminal
CE	EC Mark
X	WEEE waste disposal
MD	Medical device indication*
REF	It indicates the catalog number of manufacturer.

^{*}According to the regulations in force in Canada, the products covered by this documentation do not qualify as medical devices.

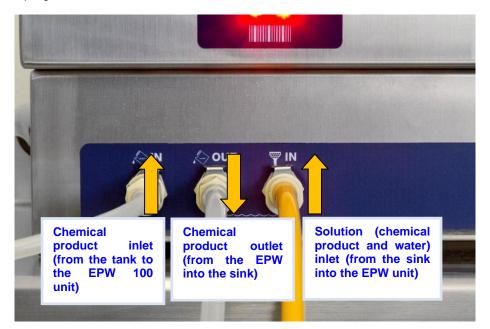




3. CONNECTION TO THE CHEMICAL PRODUCT (IF ACTIVATED)

The chemical product dosing system can be activated/deactivated by software with a password. It is composed of:

- Dosing pump for the chemical product.
- Sensor of presence for the chemical.
- Flow sensor to determine the exact quantity of chemical dispensed.
- Quick couplings for chemical tank/EPW connection and EPW/sink connection.





ATTENTION

In order to guarantee the right treatment of the medical devices, we suggest the use of specific products. In the case it is needed, ask for advises to the seller or the producer.

3.1 Presence sensor of chemical product

Each dosing pump is combined with a level sensor that check the presence of chemical product inside the tank. If the product level is low, the electronic control system of the machine sends a message on the video for the lack of product.

3.2 Chemical product quantity check

Each individual pump is linked to volumetric sensor in order to measure the quantity of chemical product dispensed. The electronic control unit checks the value of the minimum quantity needed and, if necessary, it interrupts the cycle.

3.3 Replacement of chemical product container

To replace the chemical product tank, perform the following procedure:

- Take the new product tank.
- · Wear appropriate PPE.
- Change the chemical product tank removing the level sensor from the empty tank and putting it into the new one.
- Close the cap and place the tank in the area where chemical substances are stored.





ATTENTION



The used chemical product can be dangerous if touched or inhaled. Before the use, carefully read the safety information supplied by the manufacturer of the chemical product and the label on the package.

While replacing the chemical product tank, use the appropriate devices for individual protection (chemical protective gloves, face masks for breathing, etc.).

The access to the technical compartment, where the chemical product tanks are placed, is permitted only to the authorized personal and it is key protected.

3.4 Warning

- Check if the chemical is suitable for the washing program.
- Follow the chemical manufacturer instructions for dilution and contact time.
- The quantity of product delivered can be calibrated by the technician.
- To ensure the efficiency of the chemical dosing system it is recommended to perform the calibration procedure every 6 months.
- To ensure the efficiency of the chemical delivery pumps it is important to perform the maintenance as described in chapter 6.
- Use only liquid chemical products.
- Dispose the product following environmental requirements, waste disposal legislation and any regional local authority requirements.
- Do not place the chemical tank upon the machine.

ATTENTION



Before undertaking any sort of special maintenance or movement of the machine, empty tanks and chemical dosing circuit from the chemical. It is suggested 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.



4. CONTROL PANEL AND RELATED SYMBOLS

4.1 Machine components



REFERENCE	DEVICE	REFERENCE	DEVICE
1	Printer	7	Endoscope Channels Connection System
2	Barcode reader	8	Solution (chemical product and water) inlet (from the sink into the EPW unit)
3	Display	9	Chemical product outlet (from the EPW unit into the sink)
4	Start button	10	Chemical product inlet (from the tank to the EPW unit)
5	Stop button	11	USB Port
6	Reset button		





4.2 Control panel

This control panel simplifies the use of the machine because it indicates the cycle stages during the washing procedure; moreover, any fault is signalled by error messages. There are controls.

LED lights that identify the input have different colours.

The function of each input is showed on the display.



ATTENTION

Each field is active only if the corresponding LED light is switched on.

BUZZER

There is a buzzer that makes a sound every time that a key is pressed and intermittently in case of alarm.

MAIN PAGE (STAND-BY)



SYMBOLS

FIELD	DESCRIPTION
2017-06-22 11:15	Date and time
1. Connect endoscope	Connect the endoscope to the device – image shows a 4-stage sequence
2. 👛	Identify the user (OPTIONAL) - image showing a 4-stage sequence
3. 🔪	Identify the endoscope (OPTIONAL) - image showing a 4-stage sequence
4. 🔘	Start the cycle - image shows a 4-stage sequence
	Leak test
	Time left to the end of the cycle
▲ ↑	Operator and endoscope ID





FIELD	DESCRIPTION
(1)	Start button placed on the side of the display
O	Stop button placed on the side of the display
(I _R	Reset button placed on the side of the display
	Cycle in progress
	Chemical dosage – value shown on the side of the display
	Purging of the endoscope channels –flow values and left time are shown on the side of the display
/M	When in movement, it indicates that the machine is flushing the endoscope channels for the rinse phase.
¢≡≡≡≡	Drying of the endoscope internal channels— the time left is shown on the side of the display
	Connection to the ETHERNET network not active.
○€₽ ⊞	Connection to the USB key active.
Cycle completed Disconnect endoscope	It means that the cycle has been successfully completed
Alarm 09 Air pump pressure switch	It is that an alarm occurred. The code and a short description of the alarm are shown.
WARNING Chemical tank empty	Empty chemical canister. Please replace it with a new one.
ACTION	It indicates that an operator action is required. The operator has to manually clean the internal surfaces of the endoscope (if parameter "PAUSE EN" is set to 1). Press start after having carried out the endoscope brushing.
ACTION	Warning concerning the connection of the endoscope flush channels.





FIELD	DESCRIPTION
1. 2. 3. 00 1	The machine requires for a sequence of actions after the flushing phase: 1. Drain the water from the sink 2. Fill the sink with water up to the pre-set level 3. Press start to continue
1. 1. 2. 0 1	The machine requires for a sequence of actions after the rinsing procedure with clean water: 1. Drain the water from the sink 2. Press start to continue
ACTION 1. 1.	Start the second flush phase.
STATE	The operator can select how to continue the cycle: 1. Fill the sink with water 2. Empty the sink 3. Confirm water level

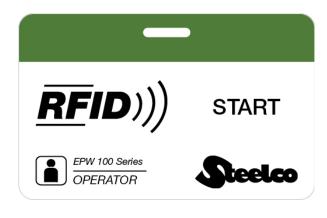




4.3 Key access

To access the machine menu, use the following barcode cards:

START COMMAND





STOP COMMAND



RESET COMMAND







SANIFICATION PROGRAM







5. INSTRUCTIONS FOR USE

5.1 Checks

- Check the status of the machine on the display and ensure that no alarm messages are present;
- Check the quantity of the chemical product and if necessary, replace the tank.

5.2 Endoscope preparation and cycle start

- Place the endoscope in the dedicated sink;
- Carry out user and endoscope identification for traceability purposes;
- Remove buttons and valves from the device. To do it, follow the instructions at par. 5.3 and 5.4.

ATTENTION

- To avoid contamination, it is advisable to disinfect the connectors of the endoscopes periodically. The frequency is selected by the customer on the basis of the internal risk analysis.
- Disinfection of the connectors inside instrument washers;
- Disinfection by cold immersion with disinfectants.
- Sterilization in plasma, vaporized hydrogen peroxide, ETO sterilizers or in steam sterilizers using the 121°C rubber cycle.
- Make sure the leak test connectors and tubes are completely dried before re-using them.



ATTENTION

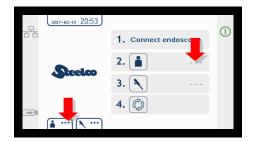
If the leak test is not connected to the device or it is connected when the endoscope is already completely immersed, liquid can penetrate inside the instrument. Therefore, always connect the endoscope before submerging it in the sink.





5.3 Cycle start

• Enter the user ID using the right barcode Card (OPTIONAL). The user ID will appear on the display;



• Enter the instrument ID using the right barcode Card (OPTIONAL). The instruments ID will appear on the display;





ATTENTION

It is NOT possible to enter or change the user ID or the instrument ID when the cycle is running.

Press the "-START-" button on the side of the display or use the "-START-" barcode card placing it in front of the
machine barcode reader.







• Follow the instructions given on the display during the cycle.





5.4 Washing cycle stages sequence

FOREWORD – It is possible to stop the cycle in any phase pressing the red dedicated button or using the STOP barcode cards.

• STAGE 1 – Instrument leak test.

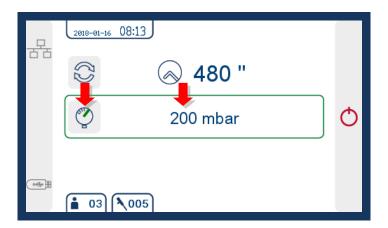
During this stage, the machine carries out two types of test and it shows the pressure values. This test controls the integrity of the instrument and the glued gaskets.

The endoscope is kept under pressure all over the cycle, if an alarm occurs - leak detected - only the user can interrupt the test that automatically brings the instrument back to atmospheric pressure.



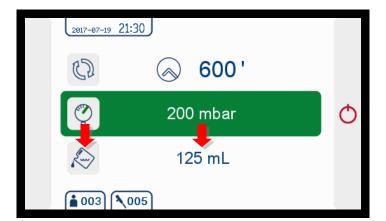
ATTENTION

Do not disconnect the leak test connector while the device is still immersed. Liquid could penetrate inside the instrument.



STAGE 2 – Chemical dosage in the washing sink (It can be deactivated).

The machine doses the quantity of detergent set by the installation technician, according to the quantity of water contained in the washing sink and according to the parameters of the disinfectant producer.





ATTENTION

For the dosage and the contact time, follow the instructions given by the chemical manufacturer. Higher contact time and concentration could damage the endoscopes and the system.

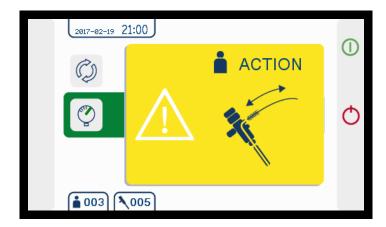




• STAGE 3 – Brushing of the endoscope channels

After having dosed the detergent, the machine switches to a stand-by mode to allow the operator to manually carry out the cleaning of the endoscope channel. (Parameter PAUSE EN must be set to 1).

After having carried out the endoscope brushing operations, press START.

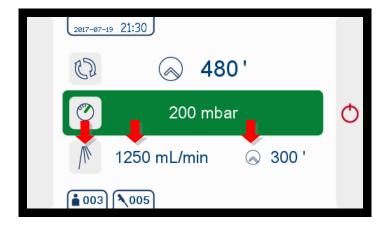


• STAGE 4 – Endoscope flush channels connection.



• STAGE 5 – Washing

During the washing stage, the machine checks and displays channels flow and residual time. Pressure control detects channels obstructions and disconnections.

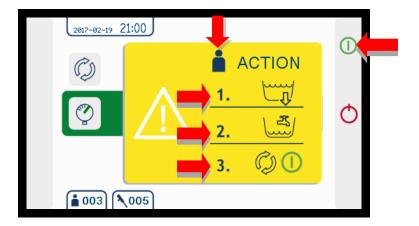






• STAGE 6 - Wait for operator actions

During this stage, the machine asks the user to drain the washing water and to refill the sink with clean water before proceeding with the cycle by pressing the start button or by using the START barcode card.



STAGE 7 – Rinsing endoscope channels

During this stage, the machine removes detergent residuals inside endoscope channels; the user can also manually rinse the external surface of the device.



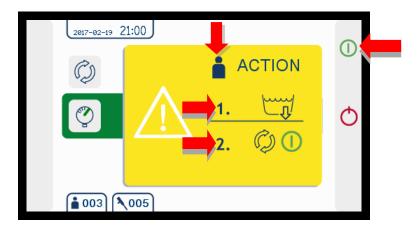
ATTENTION

Be aware that detergent residuals on the instrument can interfere with the endoscope washing cycle. Therefore, carefully wash the endoscope with clean water.



• STAGE 8 – Wait for operator actions

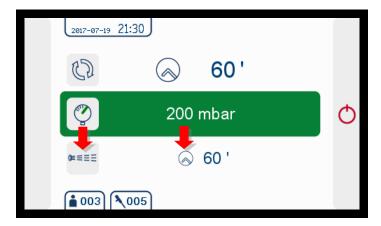
During this stage, the machine asks the user to drain the rinsing water before proceeding with the cycle by pressing the start button or by using the START barcode card.





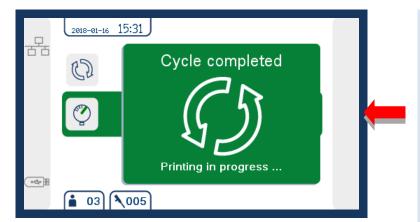


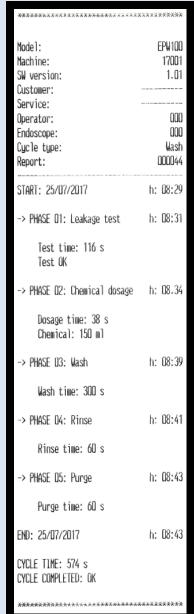
STAGE 9 – Channels Purging PhaseDuring this stage, the machine removes water residuals from the endoscope channels.





• STAGE 10 - Printing process

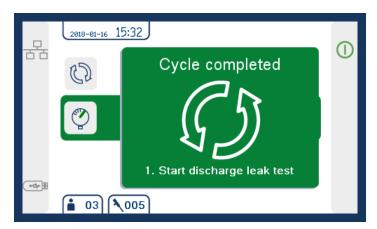






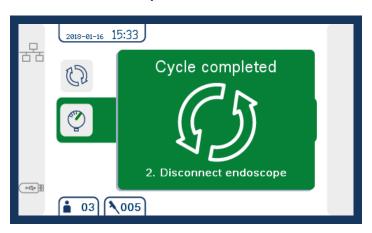


STAGE 11 - Start discharge leak test.





STAGE 12 - Disconnection of the endoscope.







6. SPECIAL CYCLE

6.1 Self-Disinfection cycle

It is possible to run a washing pump Self-Disinfection cycle following this procedure:

1. Fill a tank with minimum 3 litres of water. Add 0,5% of Steelco Decon F (5ml for each litre of water). There's no need to mix the solution.



- 2. Close the leak test tube (the transparent tube of the OCS connector).
- 3. Enter operator ID.
- 4. Self-disinfection phase setup

Put the suction pipe (1) and the washing pipes <u>WITHOUT</u> the leak test (the transparent tube) (2) inside the tank with the solution.

The suction pipe's end (1) needs to be completely submerged into the solution, otherwise air will be pumped inside the machine.





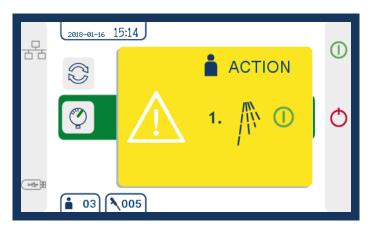


5. Start the self-disinfection cycle using the yellow RFID/barcode AUTO SANIFICATION card.





- 6. The machine will flush the hydraulic circuit for 10 minutes with the solution (water + disinfectant).
- 7. After the recirculation phase, the machine will go into standby mode and the following screen will appear:



8. Rinse phase setup

The operator must place the suction tube (1) into a clean tank with clean water, and the washing tubes (2) in the sink with the drain open. It is recommended to fill the tank with minimum 3L of clean water. The end of the suction pipe (1) needs to be completely submerged during the whole phase.



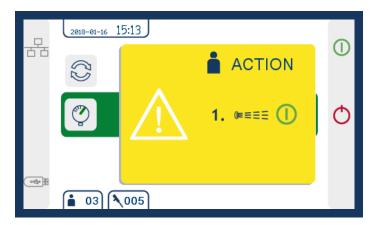




9. Use the START card to start the rinse phase.



- 10. The machine will flush the hydraulic circuit for 30 seconds.
- **11.** After the rinse phase, the following screen will appear:



12. Purging phase setup

Remove the suction tube from the tank with the clean water. Now the suction tube (1) needs to draw air in order to make an effective purge.

13. Start the purging phase using the START card and wait for the end of the cycle.



ATTENTION

The procedure must be repeated at the end of every working day or after 72 hours of machine downtime.





6.2 Protein removal test cycle

Using a dedicated barcode card, it is possible to start a protein test cycle in order to check the cleaning efficacy of the system. This test uses reagents that change colour when they come into contact with the proteins.

Through the procedure described below, the liquid used for the test (saline solution, sterile solution, Tween 80) can be

taken by the operator through the distal end of the endoscope.

6.2.1 Proteins Test Procedure

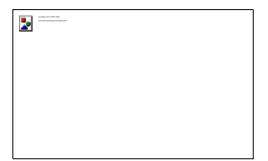
- Place the endoscope to be tested in a dedicated container or on a clean surface.
- Connect the endoscope to the OCS system and do not forget to connect the channel separator.

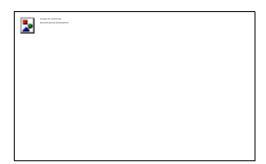
 Dry the exterior of the endoscope with a sterile cloth to avoid water residues contaminating the test by entering the container.



Use low temperature systems to sterilize the suction tube connected to the machine.

- Enter the endoscope and operator ID using the built-in reader of the EPW unit.
- Start the protein test using the correct barcode card.





 Place the distal part of the endoscope inside a second empty sterile container, without touching the walls, in order to avoid contaminations.







- Wait for the end of the automatic leak test.
- After the leak test, start the flushing phase.
- After the flushing phase, extract the distal end of the endoscope and close the container.
- Raise the suction tube and start the purging cycle, in order to remove the water from the instrument.
- Take the printout with the traceability results of the test.
- Disconnect the endoscope using the START RFID card.
- Test the water according to the indications given by the protein test producer.

NOTE – At any moment of the cycle, at every stage, it is possible to reset or stop the cycle pressing the dedicated buttons or STOP and RESET barcode-cards.





7. MACHINE CONDITIONS

7.1 Preparation

Follow the preparation stage as described in the Paragraph 7.2.

7.2 Stand-by

The machine is ready to start.
The diagnostic is active.
Display showing warnings or alarms messages.

7.3 During the cycle

Start the cycle using the proper barcode card or using the panel key.

The cycle is running properly.

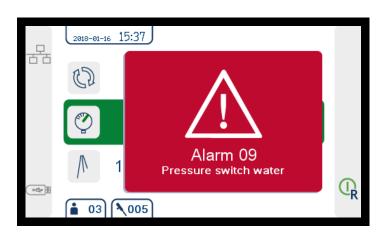
The diagnostic is active.

The user interface provides indications about the different cycle phases.

7.4 Alarms management

If the machine is locked in the standby mode, solve the cause of the alarm and do the unlocking procedure.

If the machine is locked during the cycle, do the unlocking procedure.



If a block occurs, a window appears providing the alarm code and a brief description of the cause. The user will be able to put in place the appropriate actions.



ATTENTION

If an alarm occurs the EPW 100 S stops to avoid and to prevent damages.





7.5 Alarms list

Here below, the list with the alarms, their description and the actions required is reported.

NUMBER	ALARM	DESCRIPTION	SOLUTION
01	Leakage test fail!	During the initial leak test the pression has dropped under the setpoint value P3 06 (or P3 07) of P3 07 (OR P3 09) mbar. During the cycle the pressure has dropped by P3 09 mbar from the setpoint value that was reached at the end of the initial leak test phase in less than 30 s. During the cycle the pressure has dropped by 50 mbar from the initial setpoint value P3 07.	Visual check of the device and then send it to the maintenance.
02	High flow	During the flushing of the instrument's channels, the flow is higher than the max limit set by parameter P5 02.	Check the washing pump. Check the correct connection of the machine tube via the fast-connection connectors. Check the parameter setting.
03	Insufficient flow	During the flushing of the instrument's channels, the flow is LOWER than the min limit set by parameter P5 01.	Check the washing pump. Check the correct connection of the machine tube via the fast-connection connectors. Check the parameter setting.
04	Chemical lack	During the chemical product dosage, the level of the chemical in the tank is insufficient to reach the necessary dose set by parameter.	Change the chemical tank.
07	Chemical timeout	During the initial leak test, the setpoint P3 06 is not reached in the time set by parameter P3 12.	Check the operation of the chemical pump and the suction channel.
08	Air pump pressure switch	The pressure switch for the water control is not active, when the leak test pump is active.	Check the operation and the connection with the pressure transducer.
09	Water pump pressure switch	The pressure switch for the water control is not active when the cleaning pump is not active.	Check the operation of the purging pump and the suction channel.
10	Timeout leak test	During the seal test, air pressure never reaches the pre-set value within the pre-set time.	Check that the tool is connected and no air leaks are present.
11	Flowmeters discrepancy	The chemical agent and water flowmeters have been swapped.	Check correctness of connections.
12	Disconnected instrument	During the washing cycle, the closing sensor of the OCS connection is not active. Disabled diagnostics if P2.18=1.	
13	Electrical interruption	During the cycle the power supply is disconnected from the machine. At the next start the alarm is displayed on the screen.	





15	FL1 impulses	During the dosage of the chemical product the chemical dosage flowmeter does not count any impulse in the time set by parameter P4 11.	
16	FL2 impulses	During the flushing of the instrument channels, the water flowmeter does not count any impulse in the time set by parameter P4 11.	
35	Keyboard communication	Keyboard communication failure	Check the keyboard operation and the connection with the electronic board.
36	Display communication	Display communication failure	Check the display operation and the connection with the electronic board.





7.6 Warning management

Warnings give some information to the user. Warnings don't stop the cycle. The user has to do the proper corrective actions in order to guarantee the safe use of the system.



In case of failure which does not lead to a block, a window appears indicating the warning with a short description as shown in figure.

7.7 Warning list

Below a list with the possible warnings is reported.

WARNING	DESCRIPTION	SOLUTION
Lower chemical level	The chemical product level is low.	Replace the chemical tank.
Disconnected instrument	At the start of the cycle, the endoscope is not connected.	At the start of the cycle, the endoscope is not connected.
Ares answer Timeout	Communication failure with SteelcoData ARES.	Communication failure with SteelcoData ARES.
Not authorised instrument	SteelcoData ARES cannot start a washing cycle for this endoscope.	SteelcoData ARES cannot start a washing cycle for this endoscope.





RESET PROCEDURE 8.

In case of block or alarm do the reset procedure:

- Keep the blue button pressed for 4 seconds;
- Press the red button when it lights up;
- Press the green button when it lights up;
- When the green button turns off, the alarm has been reset.

Otherwise, pass the RESET barcode card on the reader.

The machine will return to the stand-by status.

SPECIAL FEATURES

Power failure 9.1

In case of a voltage drop during the stand-by mode, when the voltage restored, the system will return to the stand-by condition.

In case of a voltage drop during the cycle, when voltage is restored, the cycle will be interrupted and the machine will enter in stand-by mode.





10. WORK PROCEDURES

10.1 Introduction

The machine has been designed only and exclusively to wash flexible endoscopes channels therefore it is in contact with detergents and contaminated instruments.

For this reason it is necessary to provide operators instructions.

10.2 Users instructions

HEALTHCARE WORKERS, in normal operating conditions, are not subject to any risk if they use the proper PPE. The HEALTH CARE WORKERS must:

- Carefully follow the instructions provided in this manual.
- Wear the appropriate PPE.
- Inform in case of deficiencies or hazardous conditions

Maintenance technicians, in normal operating conditions, are not subject to any risk if they work wearing the proper PPF.

The maintenance technician must:

- Carefully follow the instructions provided in this manual.
- Wear the appropriate PPE.
- Be really careful while reparing or replacing parts of machines which have not completed the cycle.





11. USB PORT

The USB port allows to upgrade the software and to save the cycles.

11.1 Software upgrades

Put the USB stick with the software upgrade into the USB port to load and update the board firmware.

WARNING: the USB stick must contain ONLY the upgrade file.

11.2 Cycle data saving

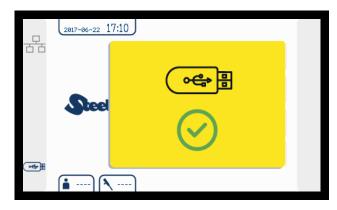
The device can save up to 100 cycles: if not downloaded, any extra cycle will be overwritten in the device memory capacity.

To download cycles data when the machine is in standby mode, put an empty USB memory stick into the dedicated port USB and follow the instruction:

1. The screen will be as the one shown on the right.



- 2. Press to save the data into the USB memory stick. If the saving procedure ends without any error the screen will look like picture 14.1 otherwise it will look like picture 14.2.
 - Press to exit and do not save the cycle data.





Picture 14.1

Picture 14.2

WARNING: the USB memory stick must be empty in order to save data.





11.3 Modify the endoscope menu

1 - Insert an empty USB stick.



2 - Enter in the download menu using the technical card



3 - Enter in the downloads and select *Endoscopes*.





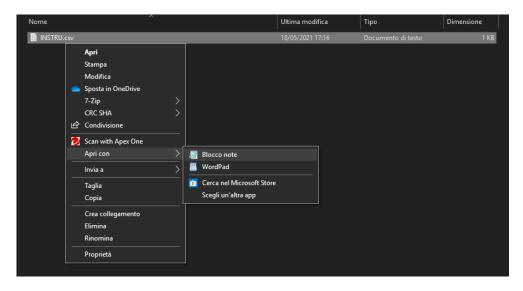
4- Press "Endoscopes" and download the list into the USB stick.



5 - Insert the USB key into a PC, rename the file removing the underscore.



6 - Open the file with the block notes.



7 - Fill it with the serial number, the model and the type of endoscope as shown below and save it.





```
INSTRU.csv - Blocco note
File Modifica Formato Visualizza ?
Instruments;
RC;
1;001;1234567;GIFH;OLYMPUS;
2;002;Serial2;Model2;Brand2;
3;003;Serial3;Model3;Brand3;
4;004;Serial4;Model4;Brand4;
5;005;Serial5;Model5;Brand5;
6;006;Serial6;Model6;Brand6;
7;007;Serial7;Model7;Brand7;
8;008;Serial8;Model8;Brand8;
9;009;Serial9;Model9;Brand9;
10;010;
11;011;
12;012;
13;013;
14;014;
15;015;
16;016;
17;017;
18;018;
19;019;
20;020;
```

8 – Insert again the USB stick in the device.



9 - Enter using the technical card and select the upload menu.







10 - Enter and press *Endoscopes*.



11 - The upload will start.







12. PRINTER (OPTIONAL)

The machine can be equipped with a printer in order to print out the data of the washing cycle: on the printout also the endoscope and the user ID as well as events, such as alarms and warnings are reported.

CYCLE OK







12.1 Printer paper replacement

To replace the paper, follow the instruction below:

1. Press the green button and pull the cover to open the small door.







2. Place the paper as shown on the picture.





13. INSTALLATION AND OCS CONNECTION

Properly connect the OCS system to the instrument that need to be treated and, if necessary, use the supplied caps to reduce the water flow of the disconnected tubes.

CODE	DESCRIPTION
C095019	1mm PERFORATED FEMALE LUER LOCK CAP
660037	QUICK MALE LUER COUPLING 3/16





14. MAINTENANCE

14.1 General recommendations on maintenance

The machine has been designed only and exclusively to wash flexible endoscopes channels therefore it is in contact with detergents and contaminated devices.

For this reason it is necessary to provide maintenance instructions.

Maintenance technicians are not exposed to any risk if they wear the proper PPE.

Technicians must:

- Carefully follow the instructions set forth in this manual.
- Use PPE properly and with care.
- Be very careful while repairing or replacing mechanical parts (e.g. pump, etc.) on malfunctioning machines which have not completed the cycle.

Maintenance operations can be divided into "Routine Maintenance" and "Special Maintenance".

GENERAL GUIDELINES:

MACHINE STATUS:

The machine must be switched off and the main switch must be in the OFF position.

Who will perform the maintenance must be sure that nobody is closed to the machine during this operation.

SAFETY SYSTEMS TO BE ADOPTED:

The operation must be carried out according to standards that regulate the use of disinfectant substances (see technical information), to the standards that regulate the contact with parts of the machine which may be contaminated by pathogenic materials and with the use of individual protection gear.

14.2 Procedure for routine maintenance work

Routine maintenance includes all operations that are needed to keep the machine components clean and functional. It must be performed regularly (see table of routine maintenance tasks) or when it is considered necessary due to an incorrect performance of treatment cycle.

Since these are simple cleaning operations, they are normally performed by the "health care workers" on their own liability.

14.3 Table of routine maintenance tasks

The following table shows the routine maintenance tasks, their frequency, who is in charge to perform them and the activity that has to be done.

Each activity is fully explained in the single reference forms.





TABLE OF ROUTINE MAINTENANCE TASKS

Chooles						Ш	D	EPW 100 S	
			4	rog	ran	me	пр	Programmed maintenance scheme	IME
	Step			months	ths				L
Components	make every	9 €	6	12	15	18 2	21 24	ACTIVITY	
The machine connection CPC O-ring connector	make every	×		×		×	×	Replace the oring.	15'
Instrument-machine connection pipes (external)	make every			×			×	Replace the pipes.	10,
Chemical product connection pipes (external)	make every			×			×	Replace the pipes.	10,
Internal connection pipes	make every						×	Replace the pipes.	30,
Electrical connections	make every	×		×		×	×	Check the integrity of the electrical connections.	2
Flowmeter	make every	×		×		×	×	Check the calibration of the flowmeters.	30,
Dosing pump	make every	×		×		×	×	Check for any leaks.	10,
Level sensor of chemical product	make every	×		×		×	×	Check the operation of and clean the suction filter.	5'
Female connectors of the OCS system O-Ring (inner O-Ring of each connector)	make every	×						Replace the O-Rings	,09
Replace the OCS tubes	make every			×				Replace the tubes	15'
Endoscope connectors	make every	×						Check the status of the connector and of the sealing O-Rings	
Washing pump	make every			×			×	Check for water leakage.	10,

N.B.: The time frames for the maintenance may vary by +/- 15 days from the period indicated in the table.

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, in particular if the supply water is very hard.

WARNING:

- DO NOT CLEAN THE MACHINE SURFACE WITH HIGH PRESSURE WATER.
- PLEASE CONTACT THE SUPPLIER OF YOUR CLEANING PRODUCTS FOR DETAILS ABOUT METHODS AND PRODUCTS FOR THE ROUTINE SANIFICATION OF THE MACHINE.

		CLEANING OF SUCTION PUMP FILTER
	Worker: Is	Frequency of Intervention: 6 months
METH	OD OF INTERVENT	FION: Clean the suction pump filters as described below:
Disass	emble the filters and	d clean them.



WARNING

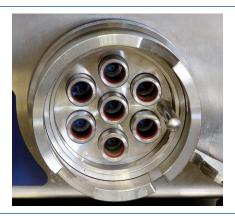
Maintenance activities can be performed only by trained and qualified staff, equipped with adequate clothing and Individual Protection Devices. Always disconnect the machine before starting the maintenance operations.

		CHECK THE ENDOSCOPE CONNECTORS
	Worker: Is	Frequency of Intervention: 6 months
METH	OD OF INTERVENT	FION: Proceed as follows to check the endoscope connectors:
Check	the status of the co	nnector and of the sealing O-Rings. If necessary, replace them.

REPLACE THE O-RING OF OCS CONNECTORS	
Worker: Is	Frequency of Intervention: 6 months

METHOD OF INTERVENTION: Proceed as follows to replace the two O-Rings in each female connectors of the OCS system:

- Disconnect the machine;
- Replace the inner O-Ring of each connector.





ASSISTANCE

If a normal functioning of the machine is not achieved, even after interventions of ordinary maintenance, get in touch with our service assistance stating the defect, the model and the serial number of the machine.





15. PROBLEMS - CAUSES - SOLUTIONS

15.1 Introduction

This chapter lists some of the problems which may occur during machine operation, together with their cause and their solution.

Please refer to the attached assembly drawings, if the components are not identifiable by specific figures.

If all the instructions in this chapter have been followed and the problems persist or re-occur frequently, please contact our technical service.

15.2 Problems - Causes - Solutions

I. THE MACHINE DOES NOT WORK:

- C. The differential magneto-thermal switch has been deactivated.
- **R.** Check that the switch is in the ON position.
- R. Check that the display has been switched on.

I. THE USER PRESSED THE START BUTTON, BUT THE WASHING CYCLE DOES NOT START:

- C. The barcode reader does not read the cycle start code correctly.
- R. Start the washing cycle pressing the start button on the side of the display.
- R. Contact technical service.

I. THE DETERGENT LOADING IS NOT PERFORMED CORRECTLY:

- **C.** The chemical product dosing pump is inefficient.
- **R.** Carry out the chemical product calibration procedure.
- R. Contact technical service and ask for the intervention of an authorised technician.

I. THE WASHING PUMP IS NOT WORKING:

- **c.** The washing pump does not work properly. The machine returns the minimum flow alarm or the endoscope channel disconnection alarm.
- R. Check the correct endoscope connection and the connectors integrity. Contact our technical service and request the intervention of an authorised technician.

I. THE MACHINE DOES NOT PERFORM THE LEAK TEST:

- C. The instrument is not connected.
- R. Check that the instrument has been correctly connected.
- **C.** The compressor is not working properly.
- R. Contact the technical service of reference and request the intervention of an authorised technician.





16. DECOMMISSIONING

16.1 How to disassembly the machine

Please note that the machine may contain contamination from blood and other bodily fluids, pathogens, facultative pathogens, genetically modified material, toxic or carcinogenic substances, heavy metals, etc., and must be decontaminated before disposal.

For environmental and safety reasons, dispose of all process chemical residues in accordance with safety regulations. Wear gloves and protective goggles.

Remove or disable the door lock prior to disposal of the machine, so that children cannot become trapped inside. Then make appropriate arrangements for safe disposal of the machine.

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

- Disconnect the machine from the electrical power and water supply. Disconnect also the drain. Once everything is disconnected, check that the water circuit is not pressurized.
- According to your country laws, contact the organization responsible for reporting and certifying machine demolition.
- Drain, store and dispose all the substances, such as oils and grease which may be in the lubrication tanks. Do it accordingly with your contry laws.
- During the disassembling of the machine, divide the materials according to their chemical composition (iron, aluminium, bronze, plastic, etc.).
- Ensure that the floor where the machine (or any parts) is placed is made of washable and non-absorbent materials. Ensure also that the floor has a proper drain as a protection against accidental oil leaks or rust. These drains must end into watertight collection containers.
- Cover the machine or parts of it with insulating covers in order to prevent damages to the structure, as oxidation or rust, due to rain or humidity.

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

16.2 Machine disposal



- Contact the manufacturer or the distributor, to dispose the equipment.
- Do not dispose this equipment as miscellaneous solid municipal waste.
- The re-using and the proper recycling of electronic and electrical equipment (EEE) are important in order to protect the environment and people health.
- According to the European Directive WEEE 2012/19/EC, arranged areas are available to throw out electrical and electronic equipment. Otherwise, the equipment can be managed by a distributor when a new machine is purchased.
- The public administration and producers of electrical and electronic equipment are involved in facilitating the processes of the re-use and recovery.
- Unauthorized disposal of waste electrical and electronic equipment is punishable by law.