



Miele Group
Member



User manual

EPW 100 S:

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

Serial N°:





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ITALIA**

Manufacturer:

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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 incorrect translation of the instructions, the client must:

- 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 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 a 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 manufacturer instructions, the protection of the appliance may be compromised.

2.1.1 Application fields

- General flexible endoscopes (gastrosopes, bronchoscopes, colonoscopes, 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 disinfectant 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 CaCO ₃)
Max. conductivity / Ph:	n.a. / 5...8 pH

Chemical Properties

Heavy metal ions	Iron	min 0 mg/l (ppm)	max 2 mg/l (ppm)
	Manganese	min 0 mg/l (ppm)	max 2* mg/l (ppm)
	Copper	min 0 mg/l (ppm)	max 2* mg/l (ppm)
	Total heavy metal ions	min 0 mg/l (ppm)	max 10 mg/l (ppm)
Halides	Chloride	min 0 mg/l (ppm)	max 50 mg/l (ppm)
Others ionic contaminants	Phosphates (P 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 (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 **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.

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	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.
	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 stuck 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:



Electrical risk



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.

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 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:

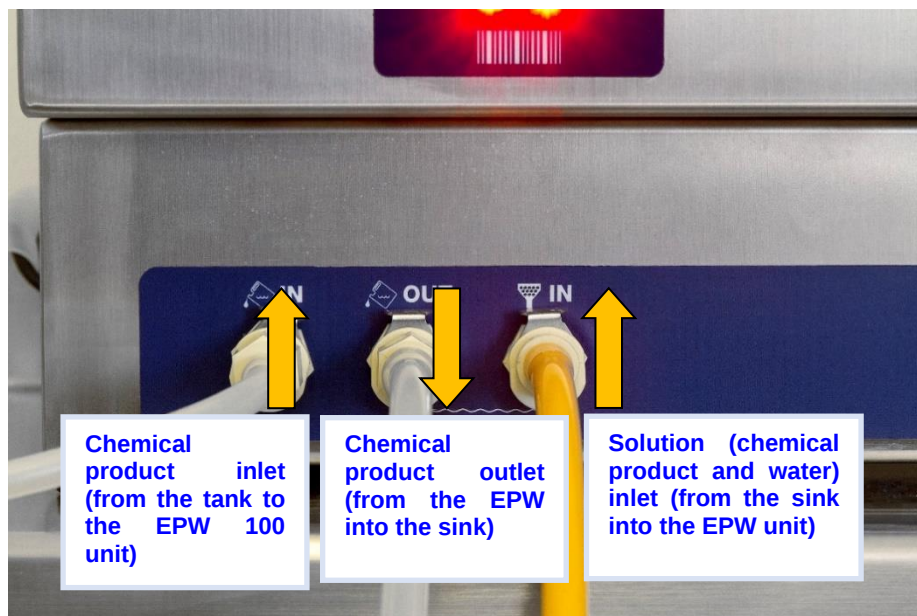
	Electrical risk
	Warning - hot surface
	Manufacturer
	Manufacturing date
	Attention! See the enclosed documentation for important warnings, such as warnings and precautions.
	See instruction for use
	Protective conductor terminal
	EC Mark
	WEEE waste disposal
	Medical device indication*
	It indicates 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

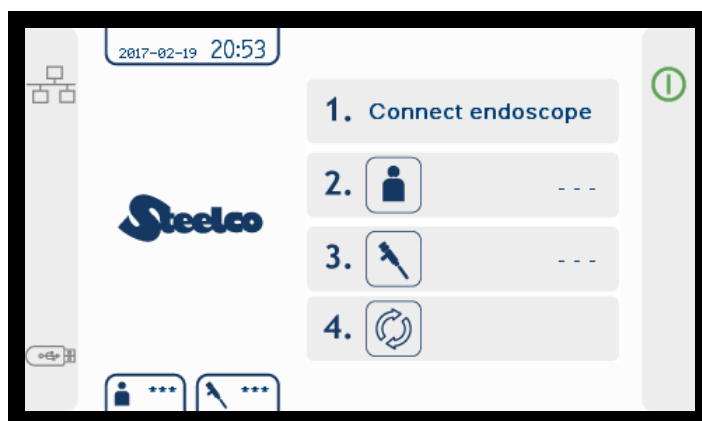
This control panel simplifies the use of the machine because it indicates the cycle stages during the washing procedure; moreover, any fault is signalled by error messages. There are controls. LED lights that identify the input have different colours. The function of each input is showed on the display.

	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
	Date and time
	Connect the endoscope to the device – image shows a 4-stage sequence
	Identify the user (OPTIONAL) - image showing a 4-stage sequence
	Identify the endoscope (OPTIONAL) - image showing a 4-stage sequence
	Start the cycle - image shows a 4-stage sequence
	Leak test
	Time left to the end of the cycle
	Operator and endoscope ID

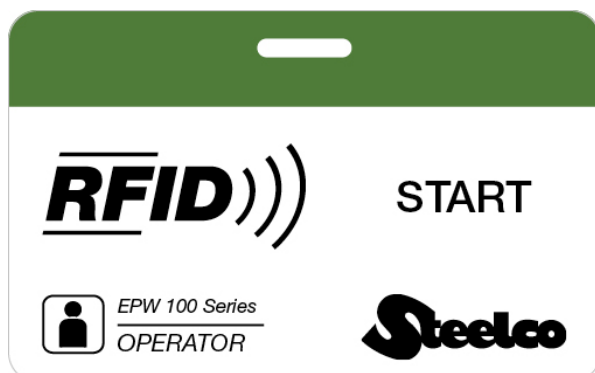
FIELD	DESCRIPTION
	Start button placed on the side of the display
	Stop button placed on the side of the display
	Reset button placed on the side of the display
	Cycle in progress
	Chemical dosage – value shown on the side of the display
	Purging of the endoscope channels –flow values and left time are shown on the side of the display
	When in movement, it indicates that the machine is flushing the endoscope channels for the rinse phase.
	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.
	It means that the cycle has been successfully completed
	It is that an alarm occurred. The code and a short description of the alarm are shown.
	Empty chemical canister. Please replace it with a new one.
	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.
	Warning concerning the connection of the endoscope flush channels.

FIELD	DESCRIPTION
 ACTION 1.  2.  3. 	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
 ACTION 1.  2. 	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. 	Start the second flush phase.
 STATE 1.  2.  3. 	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.

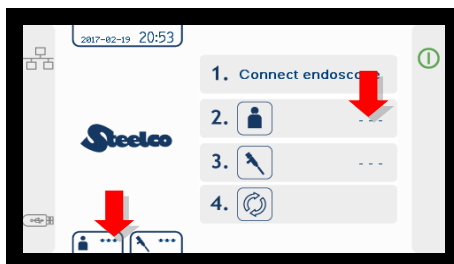


ATTENTION

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;



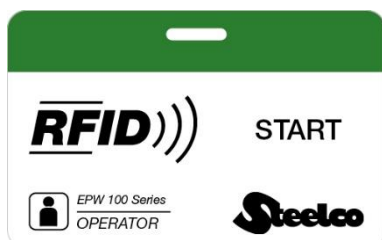
- Enter the instrument ID [using the right](#) barcode Card (OPTIONAL). [The instruments](#) ID will appear on the display;



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.**

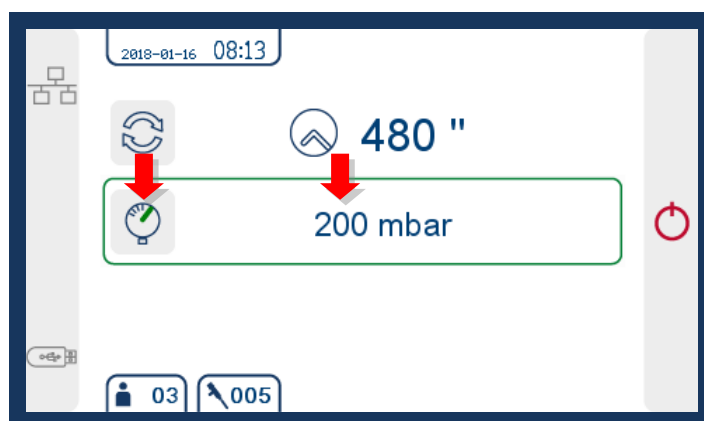
During this stage, the machine carries out two types of test and it shows the pressure values. This test controls the integrity of the instrument and the glued gaskets.

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.



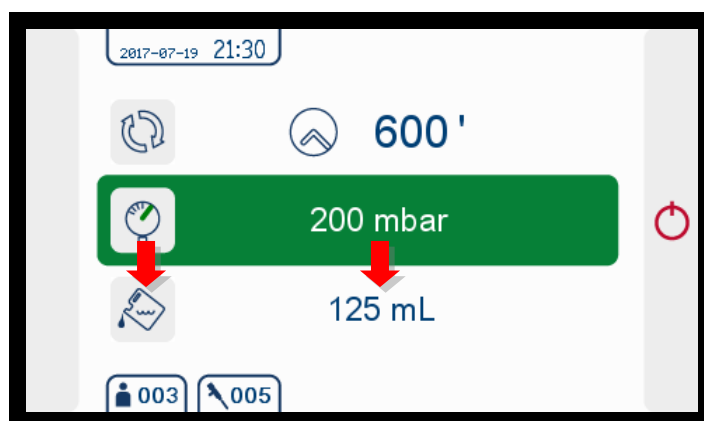
ATTENTION

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.

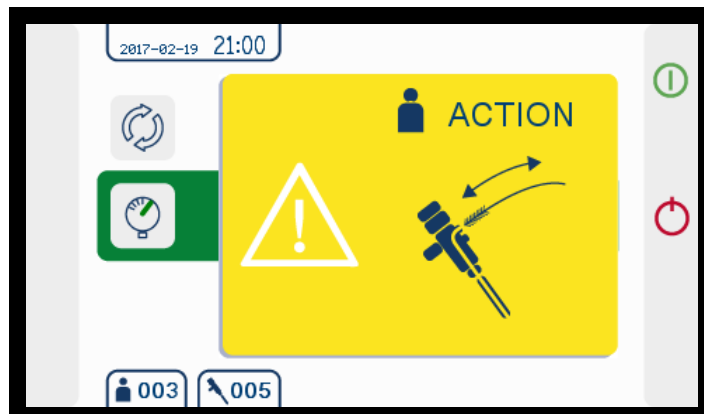


ATTENTION

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.

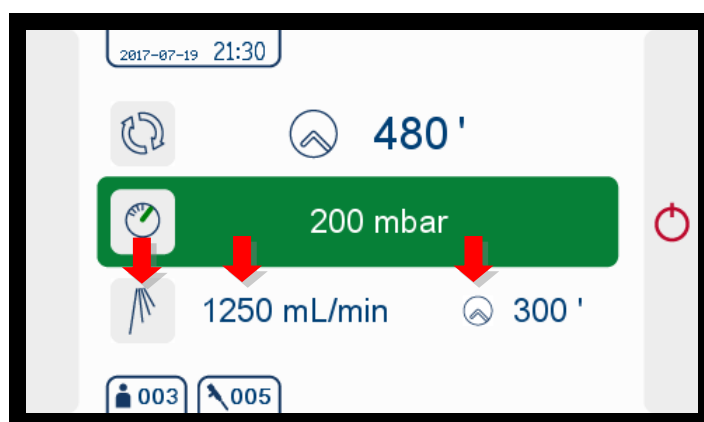


- **STAGE 4 – Endoscope flush channels connection.**



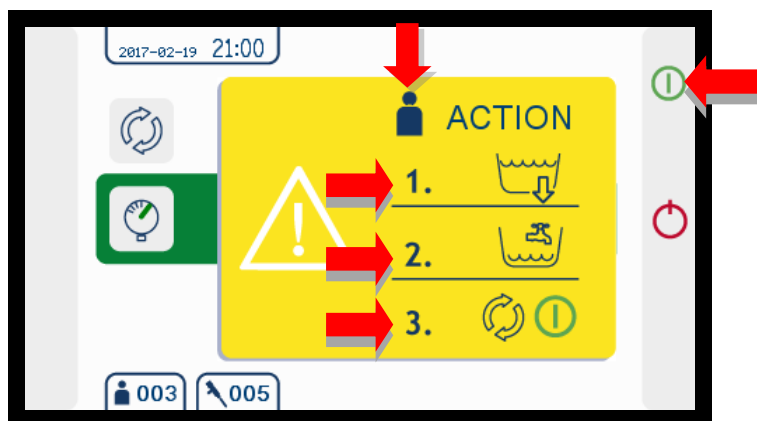
- **STAGE 5 – Washing**

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**

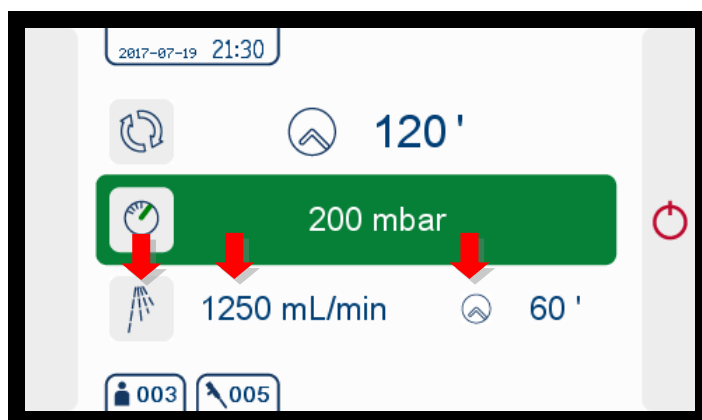
During this stage, the machine **asks** the user to drain the washing water and to refill the sink with clean water before proceeding with the cycle by pressing the start **button** or by using the START barcode card.



- **STAGE 7 – Rinsing endoscope channels**

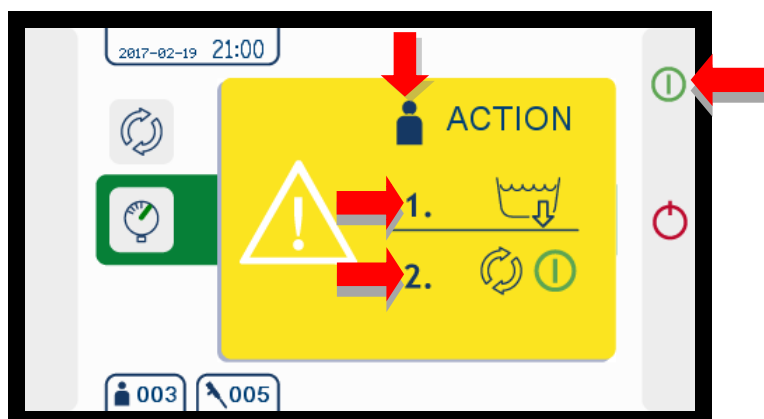
During this stage, the machine removes detergent residuals inside endoscope channels; **the user** can also manually rinse the external surface of the device.

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



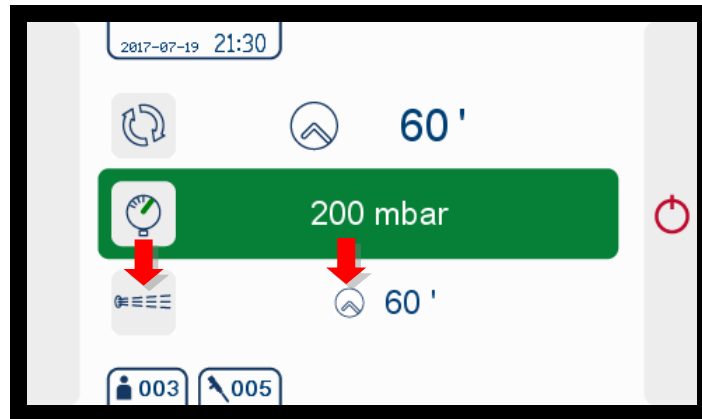
- **STAGE 8 – Wait for operator actions**

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.

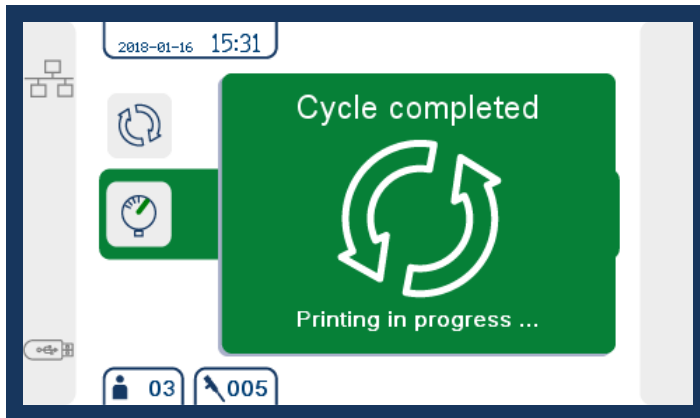


- **STAGE 9 – Channels Purging Phase**

During this stage, the machine removes water residuals from the endoscope channels.

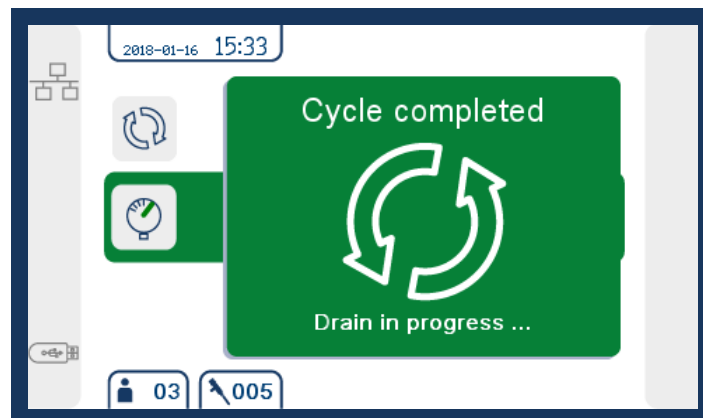
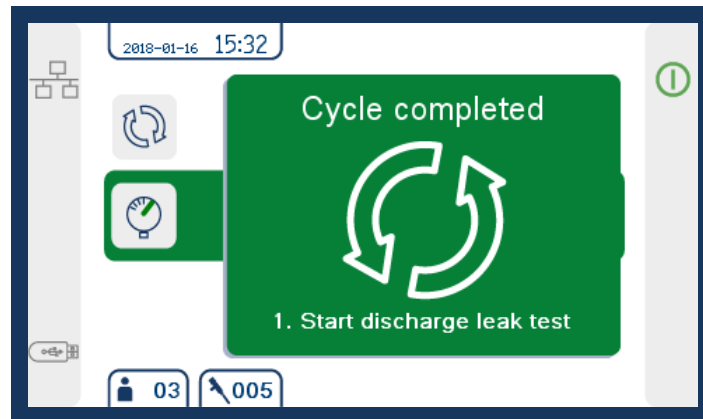


- **STAGE 10 – Printing process**

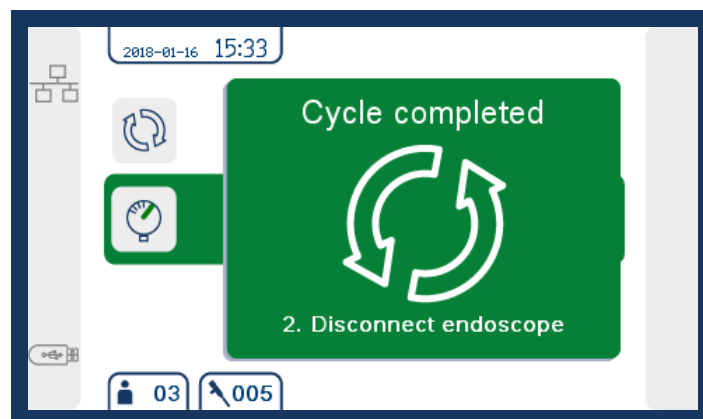


Model:	EPW100
Machine:	17001
SW version:	1.01
Customer:	-----
Service:	-----
Operator:	000
Endoscope:	000
Cycle type:	Wash
Report:	000044
START: 25/07/2017	h: 08:29
-> PHASE 01: Leakage test	h: 08:31
Test time: 116 s	
Test OK	
-> PHASE 02: Chemical dosage	h: 08:34
Dosage time: 38 s	
Chemical: 150 ml	
-> PHASE 03: Wash	h: 08:39
Wash time: 300 s	
-> PHASE 04: Rinse	h: 08:41
Rinse time: 60 s	
-> PHASE 05: Purge	h: 08:43
Purge time: 60 s	
END: 25/07/2017	h: 08:43
CYCLE TIME: 574 s	
CYCLE COMPLETED: OK	

- 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:

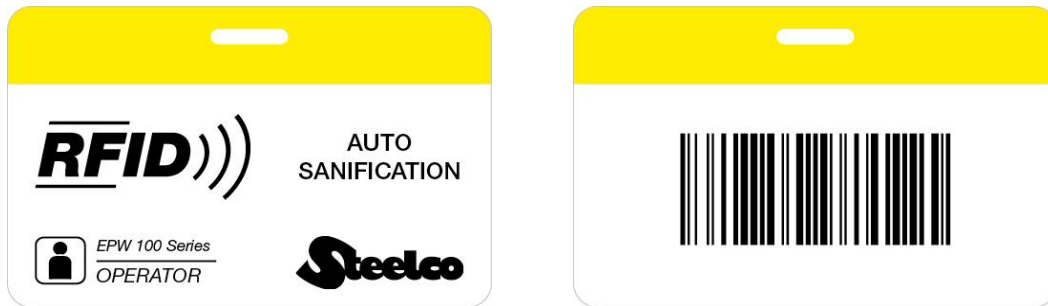
1. Fill a tank with minimum 3 litres of water. Add 0,5% of Steelco Decon F (5ml for each litre of water). There's no need to mix the solution.



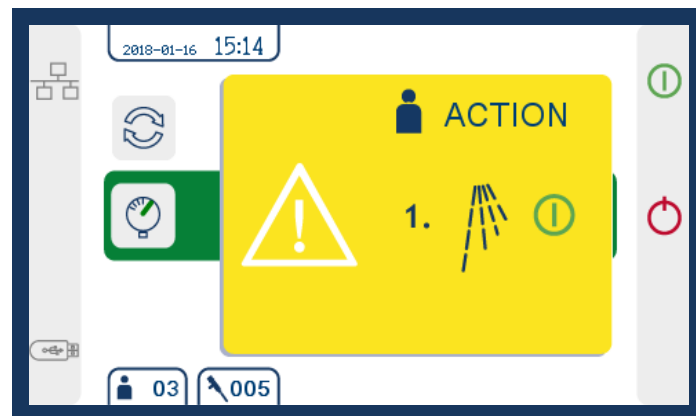
2. Close the leak test tube (the transparent tube of the OCS connector).
3. Enter operator ID.
4. **Self-disinfection phase setup**
Put the suction pipe (1) and the washing pipes WITHOUT the leak test (the transparent tube) (2) inside the tank with the solution.
The suction pipe's end (1) needs to be 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.

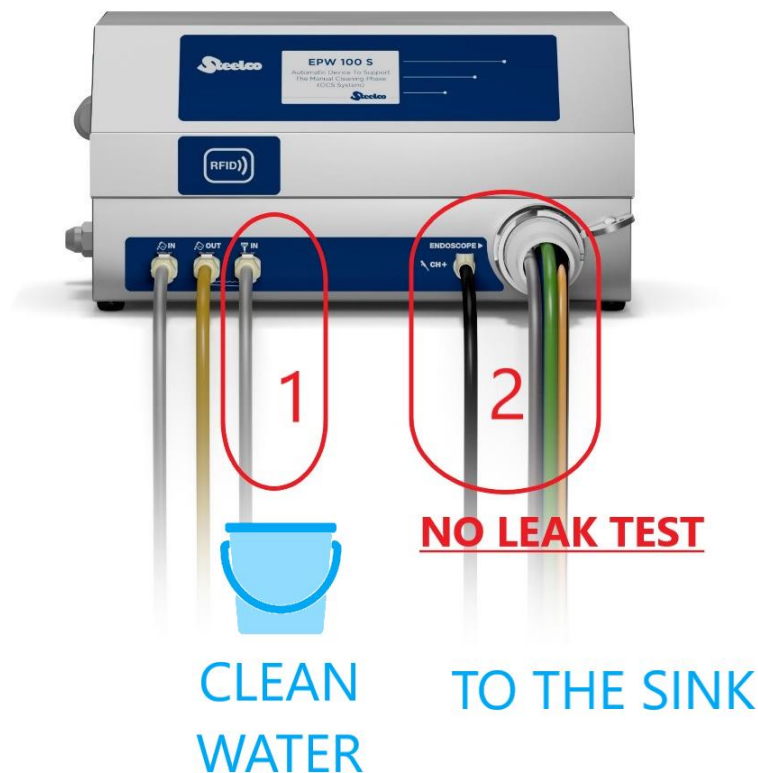


6. The machine will flush the hydraulic circuit for 10 minutes with the solution (water + disinfectant).
7. After the recirculation phase, the machine will go into standby mode and the following screen will appear:



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

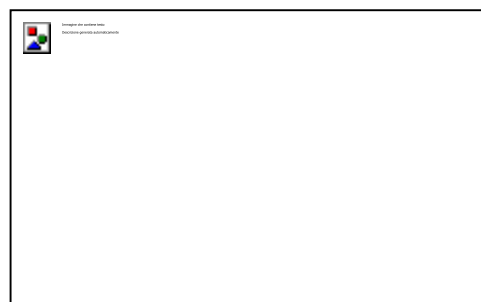
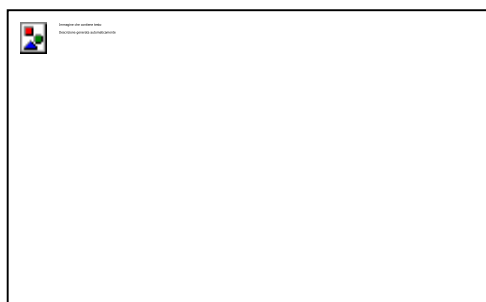
- Place the endoscope to be tested in a dedicated container or on a clean surface.
- Connect the endoscope to the OCS system and do not forget to connect the channel separator.



- 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 pressure 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 .

8. RESET PROCEDURE

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.

9. SPECIAL FEATURES

9.1 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.

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](#) PPE.

The maintenance technician must:

- Carefully [follow](#) the instructions provided in this manual.
- Wear the appropriate PPE.
- [Be really careful while](#) repairing 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

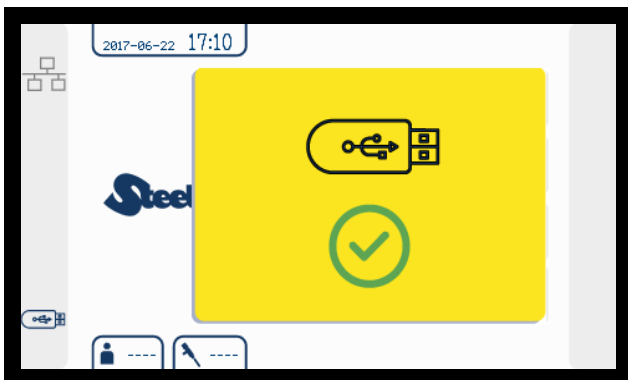
The device can save up to 100 cycles: if not downloaded, any extra cycle will be overwritten in the device memory capacity.

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:

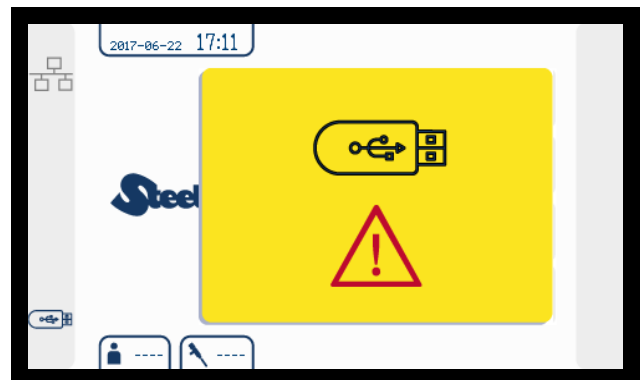
1. The screen will be as the one shown on the right.



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



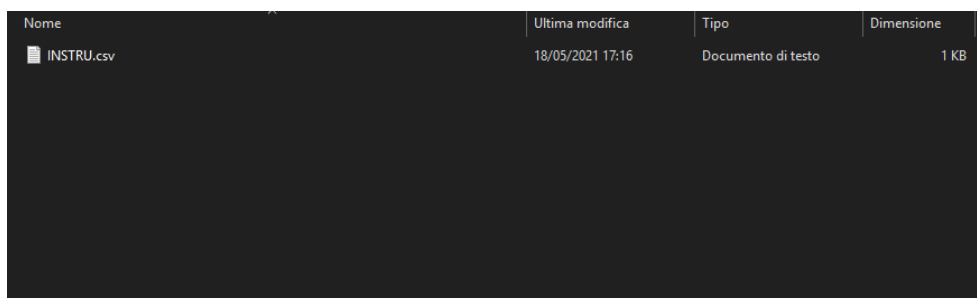
3 - Enter in the downloads and select *Endoscopes*.



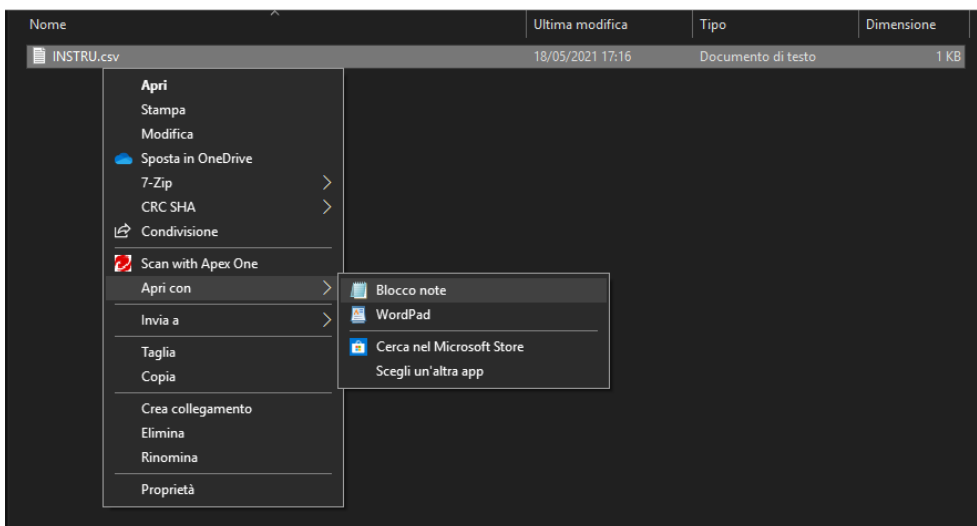
4- Press “Endoscopes” and download the list into the USB stick.



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	

Model:	EPW100
Machine:	17001
SW version:	1.01
Customer:	-----
Service:	-----
Operator:	000
Endoscope:	000
Cycle type:	Wash
Report:	000044

START: 25/07/2017	h: 08:29
-> PHASE 01: Leakage test	h: 08:31
Test time: 116 s	
Test OK	
-> PHASE 02: Chemical dosage	h: 08:34
Dosage time: 38 s	
Chemical: 150 ml	
-> PHASE 03: Wash	h: 08:39
Wash time: 300 s	
-> PHASE 04: Rinse	h: 08:41
Rinse time: 60 s	
-> PHASE 05: Purge	h: 08:43
Purge time: 60 s	
END: 25/07/2017	h: 08:43
CYCLE TIME: 574 s	
CYCLE COMPLETED: 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

	EPW 100 S																	TIME
	Programmed maintenance scheme																	
	Components	Step	months												Activity			
			3	6	9	12	15	18	21	24								
		make every		X		X		X									Replace the oring.	15'
	The machine connection CPC O-ring connector	make every				X											Replace the pipes.	10'
	Instrument-machine connection pipes (external)	make every				X											Replace the pipes.	10'
	Chemical product connection pipes (external)	make every															Replace the pipes.	30'
	Internal connection pipes	make every															Check the integrity of the electrical connections.	5'
	Electrical connections	make every		X		X		X									Check the calibration of the flowmeters.	30'
	Flowmeter	make every		X		X		X		X							Check for any leaks.	10'
	Dosing pump	make every		X		X		X		X							Check the operation of and clean the suction filter.	5'
	Level sensor of chemical product	make every		X		X		X		X							Replace the O-Rings	60'
	Female connectors of the OCS system O-Ring (inner O-Ring of each connector)	make every		X													Replace the tubes	15'
	Replace the OCS tubes	make every					X										Check the status of the connector and of the sealing O-Rings	
	Endoscope connectors	make every		X													Check for water leakage.	10'
	Washing pump	make every					X									X		

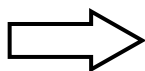
N.B.: The time frames [for the maintenance](#) may vary by +/- 15 days from the period indicated in the table.

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**

METHOD OF INTERVENTION: Clean the suction pump filters as described **below**:

Disassemble the filters and 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**

METHOD OF INTERVENTION: Proceed as follows to check the endoscope connectors:

Check the status of the connector and of the sealing O-Rings. If necessary, **replace** them.

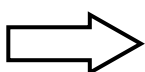
REPLACE THE O-RING OF OCS CONNECTORS

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 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.

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.