Steelco

Miele Group Member

Instructions manual

Operating manual

LOW TEMPERATURE HYDROGEN PEROXIDE STERILIZERS

PL 130/1 - PL 130/2
PL 70/1 - PL 70/2 – PL40/1

Serial N°:

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Steelco Miele Group Member

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

Manufacturer:

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

CONTENTS

Thank you for purchasing this appliance.

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

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.

ATTENTION	**DISREGARD, 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 GUIDELINES

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 indicated in the user's manual, and he must in particular:

- Always work in accordance with the limits indicated for the use of the equipment;
- Always carry out constant and diligent maintenance;
- Allow the use of the machine by persons with proper skills and abilities needed for this job who have been properly trained and instructed;
- Use only manufacturer original spare parts.

Any modifications, adaptation or other 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.

It is possible to obtain specific knowledge on these topics by attending training courses held by Steelco Academy dedicated to service engineers.

The instructions in this manual do not replace but rather complete employer obligations as regards 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 incorrect translation of the instructions, the client must:
  - not perform operations or manoeuvres with the machine in case of any doubts or uncertainties about the operation to be performed;
  - ask after-sale service for clarifications on the instruction.
- If lost, ask the manufacturer for a new copy.

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 owner or user in order to allow him to become aware with its operation and the relative warnings.

Read the instructions carefully before installing and using the machine.

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

*The period may change according to the import country.

1.3 Regulations

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

- 93/42/CEE and s.m.i. (Directive on Medical Devices);
- 2006/42/EC (Machine directive);
- EN 61010-1 (Safety);
- EN 61010-2-040 (Safety);
- EN 61326-1 (Electrical equipment for measurement, control and laboratory use. Requirements of electromagnetic compatibility);
- EN ISO 14971 (Medical devices – Application of the risks management to the medical devices);
- EN ISO 14937 (Sterilization of healthcare products);
- EN 62304 (Medical device Software).

2. SAFETY INFORMATION

Compliance with safety standards allow the operator to work in safety, without the risk of causing damages to himself or to others.

Before start operating, the operator must be completely familiar with the functions and the proper operation of the machine and he must know the precise function of all machine command and control devices.

PL 130

PL 70

PL 40

2.1 Device description

The devices PL40, PL 70 and PL 130 are sterilizers which use vaporized hydrogen peroxide to eliminate micro-organisms from the surfaces and on the lumens of metal and non-metal medical devices previously washed, dried and packaged. This type of sterilization, performed in dry environment and at low temperature, is ideal for thermolabile and humidity-sensitive equipment.
The sterilisation is carried out by diffusing hydrogen peroxide vapour inside the chamber under vacuum obtained from a liquid solution, composed of 58% sterilizing agent.

INTENDED USE:

Low temperature hydrogen peroxide sterilization of packaged medical devices suitable to the treatment.

IMPROPER USE:

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

WARNING
Any use other than that for which the machine is intended is forbidden.
Improper use of this device can be dangerous for the health and the safety of the operator and can cause serious damage to the machine itself.
If the device is used in a manner not specified by the manufacturer, the protection of the device may be compromised.

2.2 Technical data

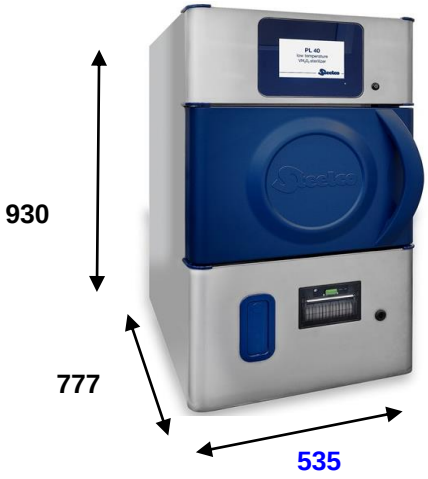
	PL40/1 single door	PL70/1 single door	PL70/2 double door	PL130/1 single door	PL130/2 double door
External dimensions (mm) WxDxH	535 x 777* x 930	642 x 920** x 1630	642 x 990*** x 1630	770 x 1040 x 1685	770 x 1070 x 1685
Chamber dimensions (mm) WxDxH	350 x 640 x 230	450 x 825 x 220	450 x 850 x 220	450 x 795 x 400	450 x 820 x 400
Chamber dimensions (mm^3)	350 x 640x230 (51,5 lt)	450x825x220 (81,7 lt)	450x850x220 (84,1 lt)	450x795x400 (143,1 lt)	450x820x400 (147,6 lt)
Shelves dimensions (mm) WxDxH	Higher: 333x510x120 Lower: 328x600x15	Higher: 380 x 510 x 105-120 Lower: 370-430x760x5		Higher: 370-430 x 760 x 50 Lower: 370-430 x 760 x 50	
Usable chamber capacity (lt)	45 lt	80 lt		140 lt	
Weight (net)	205 kg	270 kg		520 kg	
Voltage, connection and fuse rating (standard version)****	220/240V 50/60Hz 3 kw 1F+N+PE Fuse: 1x16A	380/415V 50/60Hz 4 kw 3F+N+PE Fuse: 3x8A		380/415V 50/60Hz 5 kw 3F+N+PE Fuse: 3x10A	
Overvoltage category (according to IEC EN 60664 rule)	II				
Sound emissions in dB (A)	< 70 dB (A)				
CE mark	Medical Device Directive Class IIb				
Manufacturer's address	Steelco S.p.a. Via Balegante, 27 31039 Riese Pio X (TV), Italy				

** PL70/1 single door: 970 mm including door handles.

*** PL70/2 double door: 1090 mm including door handles.

*** Voltage, connection and fuse rating: in case of special machine configuration, refer to the documentation attached to the machine.

FRONT VIEW	
	
PL 130	***PL 70***

FRONT VIEW

PL 40

2.3 Advice and important warnings

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

THE OPERATOR MUST:

- **Carefully follow the provisions and instructions provided** by the employer, the managers and the supervisors for individual and group safety.
- **Use safety devices** and group and individual safety gear provided by the employer **appropriately and with care**.
- **Immediately report to the employer,** the manager and the supervisor the deficiencies in the aforementioned devices and means, as well as any hazardous conditions which he/she may become aware of, directly taking action in case of urgency, within the scope of his/her responsibilities and abilities to eliminate or reduce these deficiencies or hazards.

THE OPERATOR MUST NEVER:

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

2.4 Safety recommendations

- If the new machine appears to be damaged, contact your dealer before operating.
- Any modification of the electrical and hydraulic systems needed to install the machine must be carried out by qualified and authorised persons only.
- This machine must be operated only by qualified and trained staff.
- The intended use of this device is solely and exclusively for the sterilization of medical equipment, using a sterilizing agent at low temperature.
- Any use other than the one for which the machine was intended is forbidden.
- The user is forbidden to carry out any repair.
- Technical Assistance for this machine must only be performed by qualified and authorised operators.
- The equipment should be installed by authorised persons only.
- Do not install the equipment in premises where there is a risk of explosion.
- Do not expose the equipment to intense cold.
- The electrical safety of this machine is only guaranteed if it is connected to an efficient earthing system.
- The operators must work in healthy conditions and follow the prescriptions of personal hygiene, and the requirements for maintaining of the environment and equipment. Use the PPE (protection of hands and face for the respiratory tract) and cloths in accordance with the guidelines applicable to the Central Sterile Supply Departments (CSSDs).
- Be very careful when handling chemicals. Avoid contact, wear rubber gloves and observe the safety requirements specified by the manufacturer of chemicals.
- Avoid inhaling the chemicals.

ATTENTION: Chemical products are irritating to the eyes, in case of contact, wash thoroughly with water and consult a doctor. In case of contact with the skin, wash thoroughly with water.

- Do not lean on the door and do not use it as a step.
- Pay attention, there may be risk of burning.
- Do not wash the machine with a high-pressure water jet.
- Disconnect the machine from the electrical supply before carrying out maintenance work.

2.5 Attention

- **The operator must monitor the machine during the cycle.**
- **In case of cycle interruption, this will not be validated. The relative information will be reported on the printout.**
- **It is necessary to ensure the correct sterilisation with periodic checks using chemical and biological indicators and corresponding PCD (process challenge devices)..**
- **Use recommended chemicals only. The use of other products may damage the machine.**
- **The use of appropriated PPE is mandatory during the manipulation of the instruments to be treated in order to prevent contact with infected material and the risk of contamination.**
- **The machine is designed to work with dedicated chemical products.**
- **Do not use solvents or acids for the cleaning of the machine.**
- **Use original components only.**
- **The machine must only be used with the baskets and/or components recommended by the manufacturer.**
- **Components which are not approved by the manufacturer may compromise the results achieved as well as user safety**
- **Never use chlorides based chemical products (bleaches, sodium hydrochloride, hydrochloric acid and so on) to clean the machine**

The manufacturer declines any liability for accidents to persons or things arising from failure to comply with the above-mentioned rules.

The failure to comply with the rules produces the immediate and total 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 machine includes some residual risks. Below are given appropriate measures to be taken for each phase or significant intervention of work:

PHASE	BASKET LOADING
RISK	**Contusions and cuts to the upper limbs,** due to accidental contact due to falling or collision against tools and instruments, mainly while loading and handling the basket.
MEASURE	Assign staff that is trained and equipped with appropriate work equipment and appropriate clothing and PPE (e.g. shirts and protective gloves).

PHASE	HANDLE H2O2
RISK	**Direct contact with hydrogen peroxide**
MEASURE	Assign staff that is trained and equipped with appropriate clothing and PPE. Wear protective clothing, gloves and glasses and comply with the safety requirements specified by the manufacturer of chemicals.
FIRST AID MEASURE	• Immediately remove clothes that have been contaminated or soaked with the product; • If the substances come into contact with the skin, wash off affected areas immediately and rinse with water. If the symptoms are severe or persist, immediately contact a doctor.
RISK	**Inhalation of vapours**
MEASURE	Assign staff that is trained and equipped with appropriate clothing and PPE. Comply with the safety requirements specified by the manufacturer of chemicals and in case it is foreseen, wear a protective mask suitable for the protection of the respiratory tract.
RISK	**Accidental release**
MEASURE	Not to disperse the concentrated chemical into drains or directly on surfaces; Collect any spilled fluid with absorbent material (e.g., sand, earth, sawdust); Rinse the residue quantity of chemical with plenty of water.
	**IN THE EVENT OF CONTACT WITH THE BODY OR RELEASE OF CHEMICAL PRODUCTS ALWAYS LOOK AT THE SAFETY MEASURES INDICATED IN THE PRODUCT TECHNICAL DATASHEET.**

PHASE	MAINTENANCE OF INTERNAL EQUIPMENT
RISK	**Burns of body parts by hot parts of the appliance.**
MEASURE	Only allow maintenance operations to be carried out by trained and qualified staff, wearing protective clothes and PPEs; Wear suitable clothing and protective gloves.
RISK	**Electric shock to the operator**
MEASURE	Only allow maintenance operations to be carried out by trained and qualified staff, wearing protective clothes and PPEs; Wear suitable clothing and protective gloves.

PHASE	CONTACT WITH HOT SURFACE
RISK	Burns of body parts by contact with hot surface of the machine.
MEASURE	The operator must not touch the surfaces, where are the safety labels relative to the hot temperature. 

PHASE	HIT THE MACHINE
RISK	Possible operator injury (contusions or cuts) in case of hitting the machine edge.
MEASURE	Check the integrity of the machine during the periodic maintenance.

2.7 Safety signs adopted

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

GENERIC SAFETY SIGNALS:

In particular, the labels with signals of obligation, prohibition and danger contained in this manual, relevant to this machine and most commonly used are:

Electrical risk

Warning! See the attached documentation

Caution hot surface

PERSONAL PROTECTIVE EQUIPMENT:

The evaluation of risks for the health and safety of workers carried out in the workplace and on any other equipment used, as well as the evaluation of residual risks as indicated, allows the Employer to evaluate the need to adopt the Personal Protective Equipment (PPE) which are most suitable and appropriate to be provided to workers.

Considering the type of machine, it is believed that PPE should be provided to the staff.

2.8 Staff training

The Instructions for use of the machine will be provided by the STEELCO TECHNICIAN during the start-up phase to MACHINE OPERATORS and MAINTENANCE TECHNICIANS for their areas of responsibility, who will be thus instructed and trained. It will be the duty of the EMPLOYER to ensure that the degree of staff training is suitable for assigned duties.

2.8.1 Qualified personnel

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

Tec ***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 site, as well as all routine and special maintenance operations. This operator is responsible for training staff for machine operation and for testing the machine.

Sup ***AUTHORITY RESPONSIBLE FOR THE MACHINE IN THE WORKPLACE:***
Skilled staff assigned to the verification of safety devices and procedures for a proper use of the machine in complete absence of hazards.

The *"Responsible Authority"* is personally responsible for training courses and training of personnel assigned to machine operation and maintenance.
He/she must ensure that staff assigned to operation have acquired all information required for use and routine maintenance of the machine, with attendance registration and documenting comprehension.

The *"Responsible Authority"* must have a perfect understanding of all command, control and safety devices of the machine.
He/she must inform all personnel assigned to machine operation and maintenance of the instructions relating to *"Safety"*, the *"Actions to be avoided"* and the *"First Aid Measures"* connected with use of the machine and the chemical agents contained in it.

The *"Responsible Authority"* must be aware of all the correct procedures for carrying out in absolute absence of danger the operation and maintenance of the machine and all the procedures for disposal of any residual polluting materials and manufacturing wastes.
He/she must always be present during extraordinary or routine maintenance and give his/her *"approval to proceed"* to staff assigned to routine or extraordinary maintenance.

The *"Responsible Authority"* will be responsible for the functionality of all the command, control and safety devices of the plant machinery and must perform all the scheduled checks on these devices in order to ensure their optimal functionality over the time.

Op ***MACHINE OPERATOR:***
Trained personnel responsible for the operation of the machine.
The *"Machine operator"* must be perfectly aware of all of the machine's command and control devices.
Only after having received the approval by the *"Safety Supervisor", the "Machine operator"* must be able of performing the commands provided:

- commissioning and start-up of the machine;
- loading and unloading of material to be sterilized;
- operation of the machine in the various possible working modes, such as the start of various programmed sterilization cycles.
- programming and setting data from the operator panel, adjusting single control devices during working phases, starting or resetting work functions.
- In addition, the *"Machine operator"* must, by making use of all required personal protection gear and following appropriate safety measures, be able of performing some routine maintenance such as cleaning the inside of the machine, cleaning clogged, discharging processing wastes polluting materials.

2.9 Sound level indications

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 and a distance of 1 m from the machine.

AVERAGE SOUND PRESSURE LEVEL: < 70 dB (A)

2.10 Storage

Before the commissioning and in the event of a prolonged inactivity of the machine the storing temperature must be between 5 ÷ 40 °C.

2.11 Device lifetime

The device has been designed for a period of 10 years with the scheduled maintenance service.

2.12 Table of symbols

Symbols installed on the machine:

	Electrical risk
	Manufacturer
	Manufacturing date
	Attention! See the enclosed documentation for important warnings, such as warnings and precautions.
	See instruction for use
	Protective conductor terminal
	CE mark issued by the notified body: 0051 identifies IMQ Indicated 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 (ONLY FOR THE INSTALLER)

3.1 Activity before installation

PREPARATION OF INSTALLATION SITE:
The arrangements for the connections to the electrical and plumbing systems and for the possible predisposition of the connection to the compressed air line must be provided by the client before the installation of the machine.
The devices are equipped with standard incorporated air compressor (Advanced pack configuration).
The connections must comply with the directives in force in the country of installation and follow with the instructions contained in the documentation (provided on request) prior to machine installation.

ENVIRONMENT CONDITIONS:

- Operating temperature 18 ÷ 35 °C;
- Relative humidity range Max 80% (5 ÷ 31°C); 80…50% (31…40°C);
- Maximum altitude: 2,000 m a.s.l. (for higher altitudes are available special versions of the device);
- The room must have at least 15 air changes/hour;
- Visibility: brightness of the environment from 100 lux to 1500 lux (in the case of more restrictive technical rules in force in the country where the machine is installed, refer to these rules).

3.2 Positioning

EQUIPMENT REQUIRED FOR INSTALLATION

- Transpallet;
- Safety goggles;
- Helmet;
- Safety shoes;
- Gloves;
- Complete instrument box;
- Spirit level.

3.2.1 Movement, unpacking and placing

The equipment is delivered to the client packed in a wooden box.
Front panel: can be opened and turned over to become an inclined plane (to slide down the machine by wheels).
Shipping by sea: additional moisture barrier bag is provided.

LIFTING AND HANDLING:
The handling and movement of the machine and its separate components must be carried out by trained personnel using appropriate lifting and transport equipment and this must comply with the following indications:

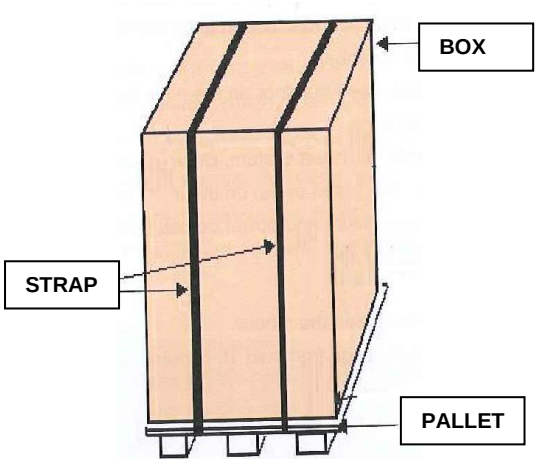
- Unload all the machine crates from the lorry and put all the parts together;
- Put all the machine parts together in a clean, safe and covered area in order to avoid damage;
- The lifting capability of the transpallet must be greater than the total weight of the machine to be moved;
- The machine must be kept as close as possible to the ground during handling;
- Stack up: not allowed;
- Rotation: do not turn upside down.

Failure to comply with the above requirements may cause serious damage to the equipment.

The transpallet operator must perform the displacement only when there are no persons or objects in the manoeuvring area.

	ATTENTION
	During the lifting procedure, the area must be considered a risk area. For this reason, nobody must stay nearby that area.
	The passage must be marked by special panels and barriers.
	Ropes and hooks must be CE marked.

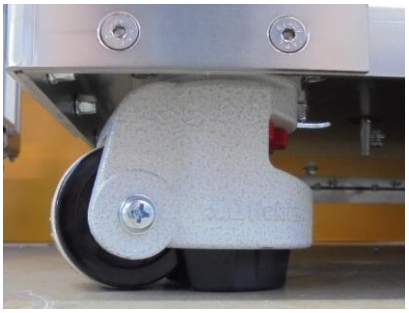
UNPACKING AND PLACING:
Near the place of installation, unpack the machine following carefully the following steps:
All the packaging materials can be recycled.



- Cut the straps;
- Unscrew and remove all wood panels;
- The front panel can be removed and turned over to become an inclined plane, on which it is possible to slide down the machine by wheels.
  ATTENTION: Do not move the panel while you slide down the machine.
- Unblock the front and rear wheels (PL130) or the feet (PL70/PL40);
- Slide down the machine onto the floor.
- Do not overturn the machine as this may cause irreparable damage.
- Place the machine onto the final installation position and level it as follow indicated:
- PL40: place the appliance on the target surface or on the optional trolley equipped with a movement system with lockable rollers.

- PL70: adjust the frontal feet.

- PL130: turn the red gear and the back rubber will block the wheels



- It is a plug-and play installation.

	ATTENTION
	The machine must be placed horizontally with a maximum inclination of 1÷2°.
	Do not place the machine on surface which could cause a fire or fume hazard.

The installation of the machine must be carried out by authorised technicians by complying with the site layout provided by the client.

	ATTENTION
	In order to protect the health and safety of personnel, the operator must wear the PPE (Personal Protective Equipment) described in the directives currently in force in the country in which the machine is installed.
	Some operations must be carried out with the protection panels removed from the machine; pay attention so as to avoid accidents and do not allow unauthorised personnel to enter the installation area.
	Make sure that the floor of the working area can bear the weight of the machine.

3.2.2 Maximum floor load

For the installation of the machine, the floor must be able to bear a minimum load of:

PL 40/1: 400 daN/m^2

PL 130/1 – PL 130/2 : 550 daN/m^2

PL 70/1 – PL 70/2 : 450 daN/m^2

3.2.3 Positioning the machine

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

Minimum distance from the left wall for the maintenance: + 0,40 m

Note: as the appliances are equipped with n.4 wheels (PL 70 e PL 130) or optional trolley (PL 40), it is possible to remove them from the final destination for the maintenance operations.

3.3 Electrical Connection

The connection of the machine to the electrical mains must be performed by qualified, skilled staff.

Power supply cable: The dealer and/or importer and/or installer has the obligation to adapt the insulation class of the power supply cable to suit the working environment in compliance with the technical rules in force in the country where the appliance is installed.

- Check that the electrical specifications match those shown in the label.
- The electrical connection must be carried out according to the technical regulations in force.
- Ensure that the measured value of the mains voltage 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.
- The device must be powered by an electrical distribution network with maximum impedance of 0,326+J0.204 Ω.
- The connection of the machine to the mains must be equipped with an earth connection and an equipotential circuit as established by current regulations.
- Make sure that the electrical systems are efficiently earthed.

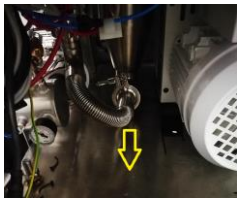
- The earth conductor must be connected to the earth terminal identified by the standard symbol.

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

- The positions of the proper terminals are the following:

PL 130

PL 70



PL 40

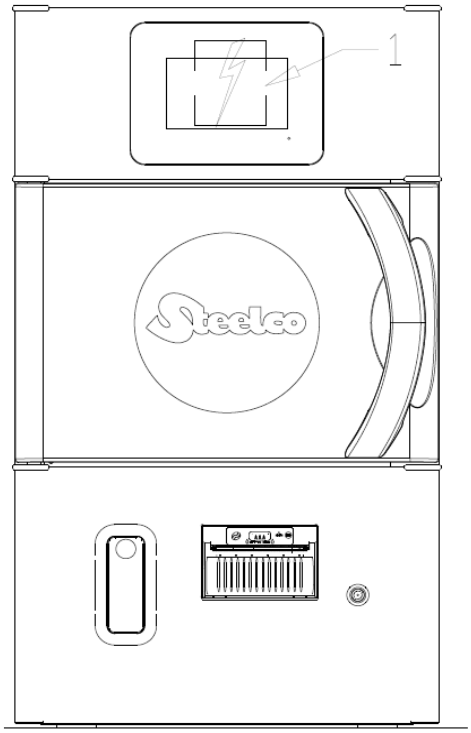
- Connect the machine and the relative dedicated safety device (not supplied) using a power cable compatible with the electrical characteristics of the machine.
- In the event of a prolonged inactivity of the machine it is advisable to perform the disconnecting procedure of the electrical connection by placing the dedicated safety device in an "OFF" state.
- The protection of the upstream line must be performed in accordance with local legislation in force.

	**ATTENTION**
	The dedicated safety device must be positioned as close as possible to the appliance. It must be easily accessible and located in a free area, not covered by other machines or anything that may hinder the switch.

- The dedicated safety device must be of adequate size for the power and with quality labels and must be flagged as a power interrupting device for the machine

- There must be a sign placed close to the dedicated safety device. See the following pictures:

EXAMPLE OF DEDICATED SAFETY DEVICE POSITIONING



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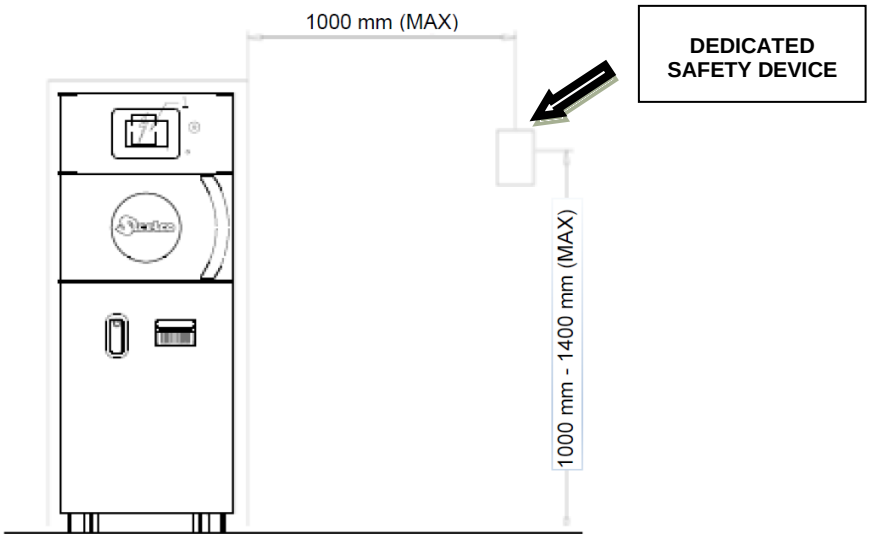
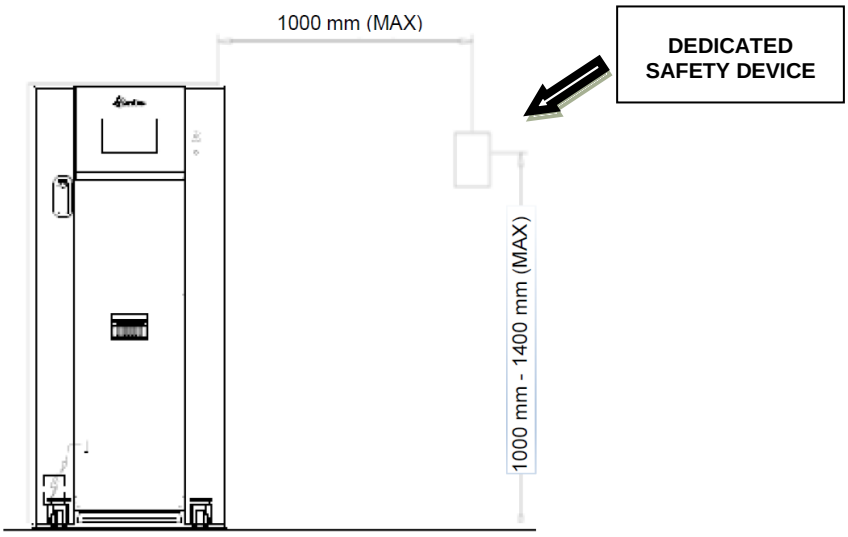


PL 70



PL 130

	**ATTENTION**
	With regards to specifications concerning the safety device and the cable cross sections, please refer to the electrical diagram.

3.4 Fuses

The fuses are used to protect the electrical circuits of machine from possible failure due to overload or short circuits. If a fuse fails, the components connected downstream and their functions are no longer available.

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

3.4.1 Replacing the fuse

ATTENTION

The replacement of the fuse must be carried out by authorized operators only.
Before fuse replacement procedure, determine and eliminate the cause of the fault.
If necessary, contact the manufacturer's technical assistance service.

Fuse replacement procedure:

- Switch off the machine from the main power supply switch making sure that the machine is in safety condition.
- Access to the electrical box.
- On the basis of the electrical diagram, identify fuse to be replaced.
- Remove the relevant fuse from the fuse holder compartment.
- Replace the defective fuse with a new one with the same characteristics. The correct values of the fuses are shown in the wiring diagram.

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

ATTENTION

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

3.5 External compressed air connection (Optional)

The appliances must be equipped with standard incorporated compressor (Advanced Pack configuration).

- The machine can be connected to the compressed air supply.
- The connection must comply with the safety regulations and the characteristics indicated on the installation layout.
- For the connection it is recommended to use a Ø 6mm pipe suitable for the compressed air pressure level.

3.6 Environment ventilation requirements

In order to ensure a comfortable and safe environment for the operator, with a constant temperature and humidity, it is necessary to set up an air-conditioning system capable to perform the specified air changes per hour.

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 emergency equipment and machine shutdown devices (circuit breaker);
- Check the efficiency of the door opening safety micro switch;
- Check the functionality of the machine controls with particular attention to the commands to **START** and **STOP**.

4.3 General Checks

Indicative list of general adjustments and checks to perform:

- Verify the correct execution of the electrical power supply of the machine;
- Ensure that the MACHINE OPERATOR is trained for its use;

5. DEVICE GENERAL DESCRIPTION

5.1 Operation description for PL70 and PL 130

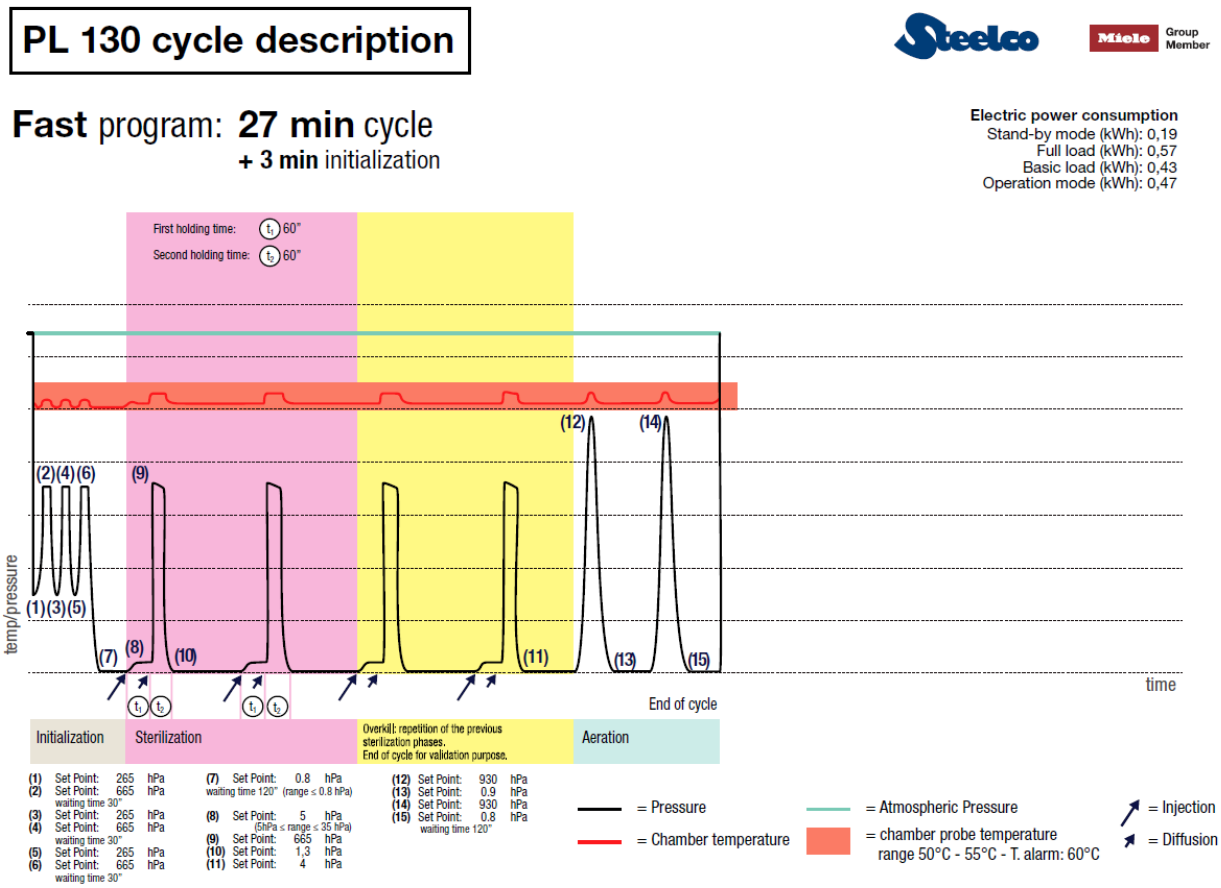
This device is designed for the terminal sterilization of packaged medical devices such as surgical instrumentation sensitive to heat and humidity.
It is suitable for surgical instruments in metal, metal alloys, delicate non-metallic alloys, micro-surgery instruments and hollow instruments with a maximum length up to 2200mm.

The four work cycles and the vacuum test cycle are programmed at the factory, validated and available for running from the control panel. The optional cycle can be available to be carried out on demand.

The data shown may differ by ± 10% depending on the physical conditions and environment of device installation.

Work cycles:

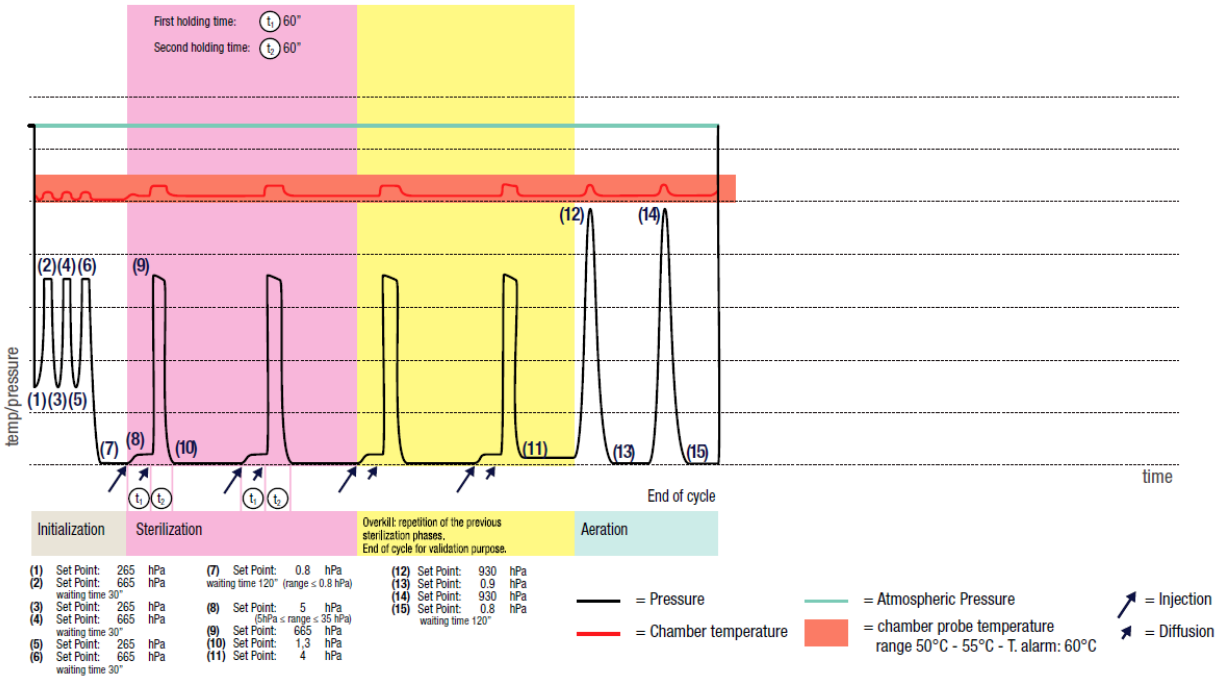
- **Fast cycle - Duration about 30 min (PL130) / about 32 min (PL 70)**
  For sterilizing generic reusable medical devices, rigid scopes without lumen and micro-surgery kits, with the exclusion of hollow instruments (surface sterilization). Max load: 19,5 Kg (PL130) / 13,5 kg (PL 70).
  See examples of load on page 38-40.



PL 70 cycle description

Fast program: **29 min** cycle
+ 3 min initialization

Electric power consumption
Stand-by mode (kWh): 0,15
Full load (kWh): 0,43
Basic load (kWh): 0,33
Operation mode (kWh): 0,40

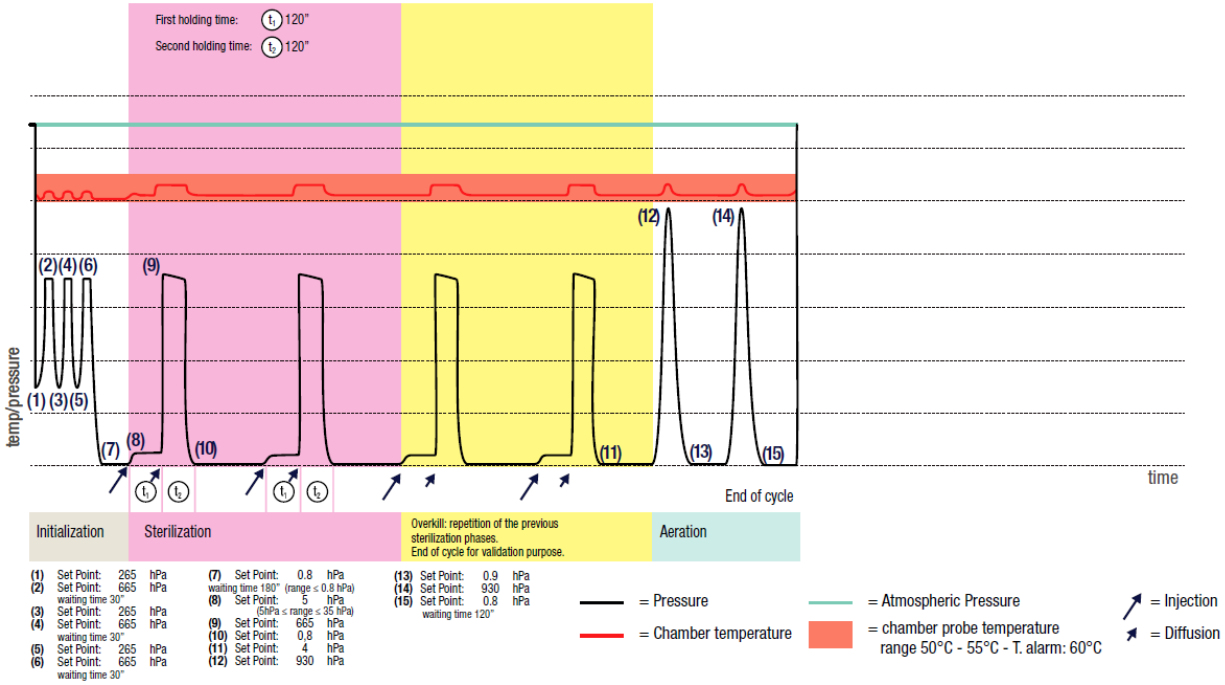


➢ **Flex cycle - Duration about 40 min (PL130) / about 42 min (PL 70)**
For sterilizing single and dual channel flexible lumens. Flexible endoscope with diameter from 1mm and length up to 1050 mm (depends on the load). Max load: 10,5 Kg (PL 130) / 5,5 Kg (PL 70).
See examples of load on page 38-40.

PL 130 cycle description

Flex program: **37 min** cycle
+ 3 min initialization

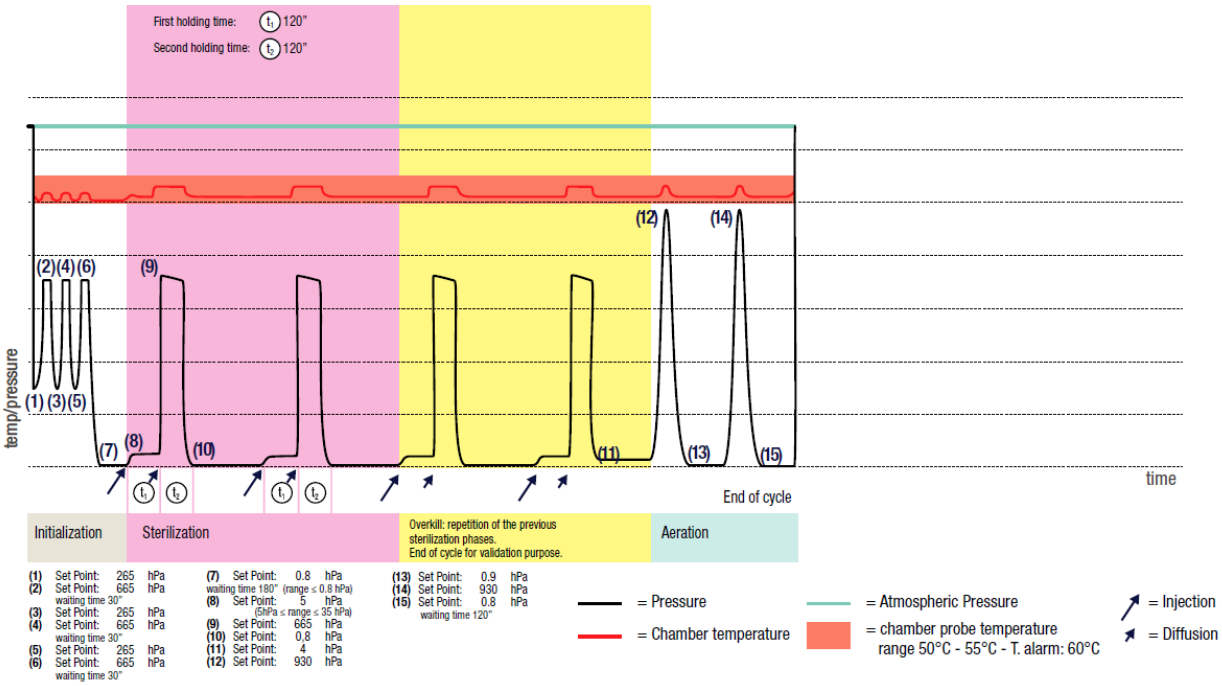
Electric power consumption
Stand-by mode (kWh): 0,19
Full load (kWh): 0,65
Basic load (kWh): 0,54
Operation mode (kWh): 0,47



PL 70 cycle description

Flex program: **39 min** cycle
+ 3 min initialization

Electric power consumption
Stand-by mode (kWh): 0,15
Full load (kWh): 0,46
Basic load (kWh): 0,38
Operation mode (kWh): 0,40



(1) Set Point: 265 hPa
(2) Set Point: 665 hPa
waiting time 30"
(3) Set Point: 265 hPa
(4) Set Point: 665 hPa
waiting time 30"
(5) Set Point: 265 hPa
(6) Set Point: 665 hPa
waiting time 30"
(7) Set Point: 0.8 hPa
waiting time 180" (range ≤ 0.8 hPa)
(8) Set Point: 5 hPa
(5hPa ≤ range ≤ 35 hPa)
(9) Set Point: 665 hPa
(10) Set Point: 0,8 hPa
(11) Set Point: 4 hPa
(12) Set Point: 930 hPa
(13) Set Point: 0.9 hPa
(14) Set Point: 930 hPa
(15) Set Point: 0.8 hPa
waiting time 120"

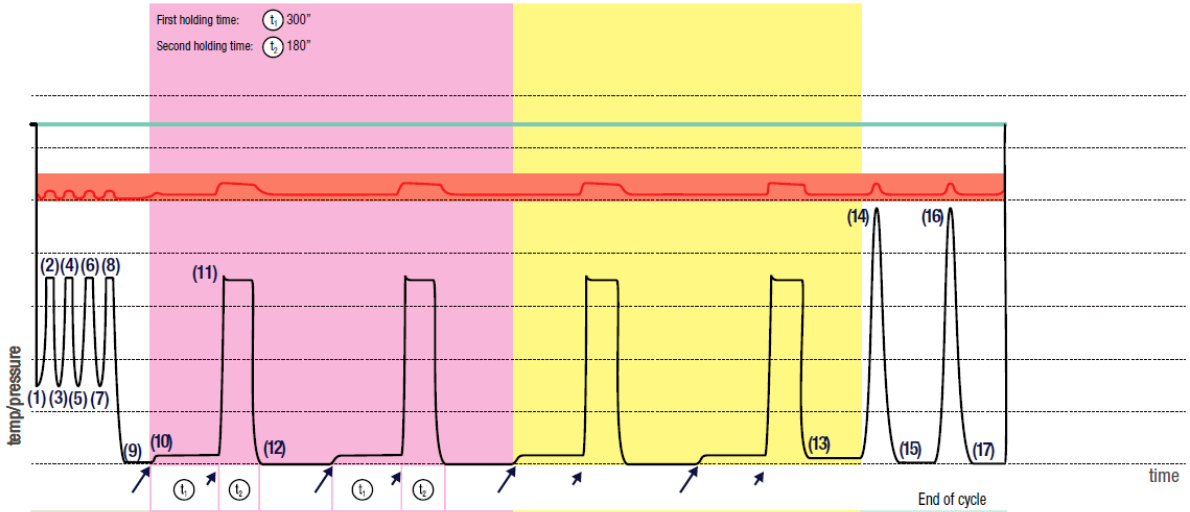
= Pressure
= Chamber temperature
= Atmospheric Pressure
= chamber probe temperature range 50°C - 55°C - T. alarm: 60°C
= Injection
= Diffusion

➢ **Standard Cycle - Duration about 52 min (PL130) / about 60 min (PL70)**
For sterilizing hollow rigid, semi-rigid and flexible instruments with diameter from 0,7 mm and length up to 750 mm (depends on the load). Max load: 10,3 Kg (PL 130) / 3,5 Kg (PL 70).
See examples of load on page 38-40.

PL 130 cycle description

Standard program: **48 min** cycle
+ 4 min initialization

Electric power consumption
Stand-by mode (kWh): 0,19
Full load (kWh): 0,75
Basic load (kWh): 0,63
Operation mode (kWh): 0,47



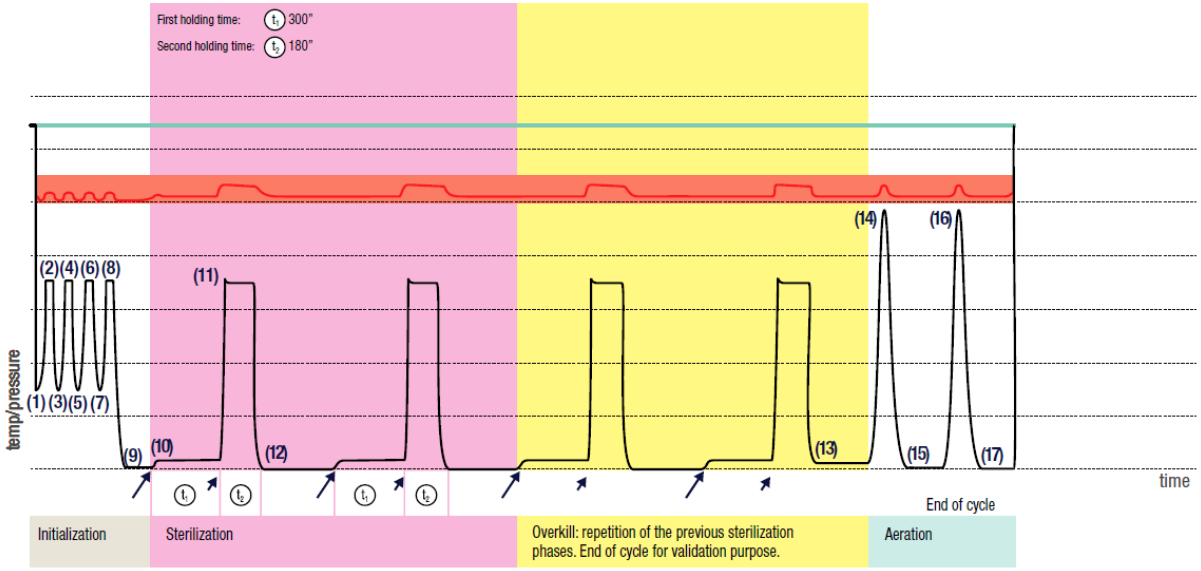
(1) Set Point: 265 hPa
(2) Set Point: 665 hPa
waiting time 30"
(3) Set Point: 265 hPa
(4) Set Point: 665 hPa
waiting time 30"
(5) Set Point: 265 hPa
(6) Set Point: 665 hPa
(7) Set Point: 265 hPa
(8) Set Point: 665 hPa
waiting time 30"
(9) Set Point: 0.8 hPa
waiting time 120" (range ≤ 0.8 hPa)
(10) Set Point: 5 hPa
(5hPa ≤ range ≤ 35 hPa)
(11) Set Point: 665 hPa
(12) Set Point: 0,8 hPa
(13) Set Point: 4 hPa
(14) Set Point: 930 hPa
(15) Set Point: 0,9 hPa
(16) Set Point: 930 hPa
(17) Set Point: 0,8 hPa
waiting time 120"

= Pressure
= Chamber temperature
= Atmospheric Pressure
= chamber probe temperature range 50°C - 55°C - T. alarm: 60°C
= Injection
= Diffusion

PL 70 cycle description

Standard program: **56 min** cycle
+ 4 min initialization

Electric power consumption
Stand-by mode (kWh): 0,15
Full load (kWh): 0,46
Basic load (kWh): 0,39
Operation mode (kWh): 0,40



(1) Set Point: 265 hPa
(2) Set Point: 665 hPa
waiting time 30"
(3) Set Point: 265 hPa
(4) Set Point: 665 hPa
waiting time 30"
(5) Set Point: 265 hPa
(6) Set Point: 665 hPa
waiting time 30"

(7) Set Point: 265 hPa
(8) Set Point: 665 hPa
waiting time 30"
(9) Set Point: 0.8 hPa
waiting time 120" (range ≤ 0.8 hPa)
(10) Set Point: 5 hPa
(5hPa ≤ range ≤ 35 hPa)
(11) Set Point: 665 hPa

(12) Set Point: 0,8 hPa
(13) Set Point: 4 hPa
(14) Set Point: 930 hPa
(15) Set Point: 0,9 hPa
(16) Set Point: 930 hPa
(17) Set Point: 0,8 hPa
waiting time 120"

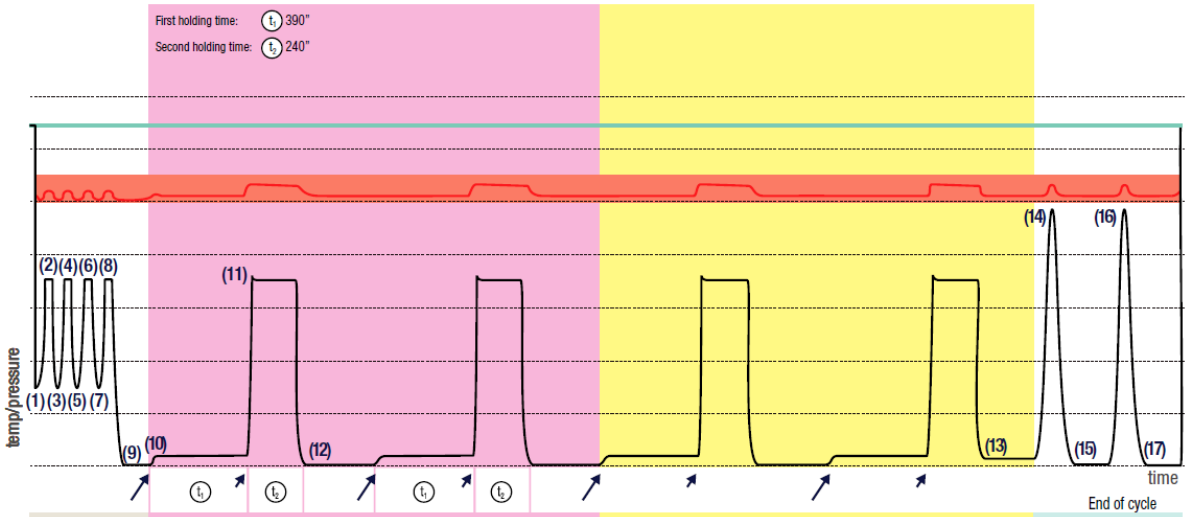
= Pressure
= Chamber temperature
= Atmospheric Pressure
= chamber probe temperature range 50°C - 55°C - T. alarm: 60°C
= Injection
= Diffusion

➢ **Intensive cycle - Duration about 64 min (PL130) / about 66 min (PL70)**
To sterilize hollow instrumentation single channel, dual channel and triple channel with diameter from 0,5 mm and length up to 2200 mm (depends on the load). Max load: 6,5 Kg (PL 130) / 4,5 Kg (PL 70).
See examples of load on page 38-40.

PL 130 cycle description

Intensive program: **60 min** cycle
+ 4 min initialization

Electric power consumption
Stand-by mode (kWh): 0,19
Full load (kWh): 0,90
Basic load (kWh): 0,78
Operation mode (kWh): 0,47



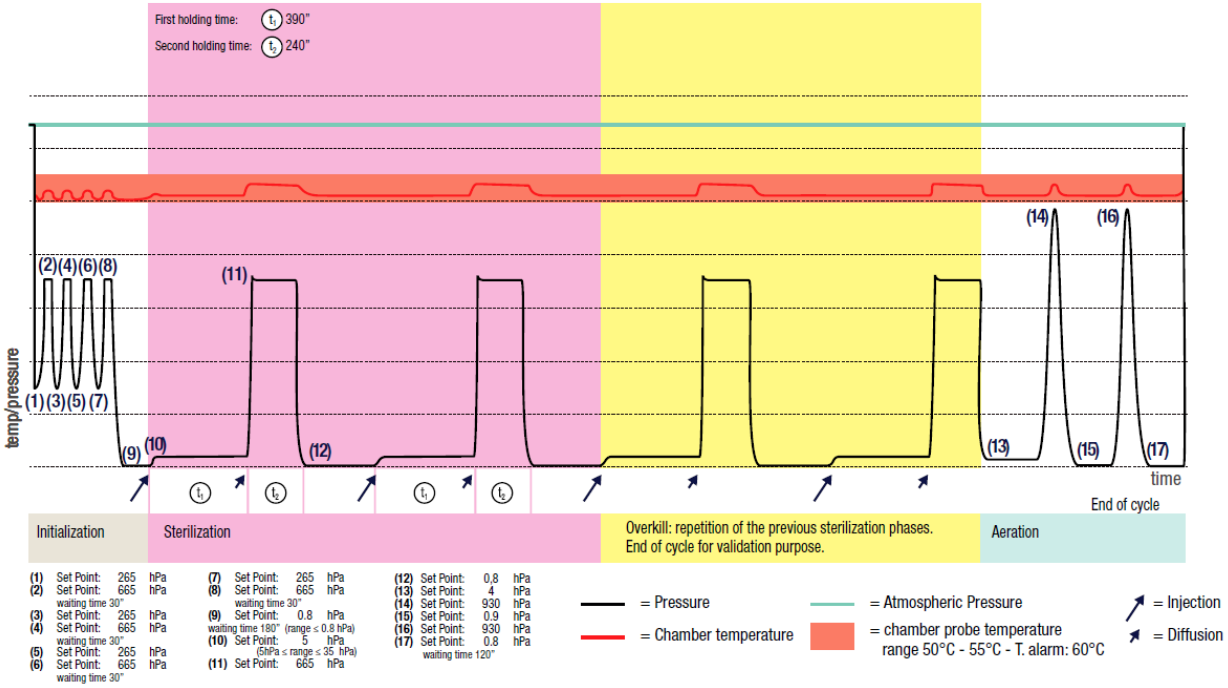
(1) Set Point: 265 hPa
(2) Set Point: 665 hPa
waiting time 30"
(3) Set Point: 265 hPa
(4) Set Point: 665 hPa
waiting time 30"
(5) Set Point: 265 hPa
(6) Set Point: 665 hPa
waiting time 30"
(7) Set Point: 265 hPa
(8) Set Point: 665 hPa
waiting time 30"
(9) Set Point: 0.8 hPa
waiting time 180" (range ≤ 0.8 hPa)
(10) Set Point: 5 hPa
(5hPa ≤ range ≤ 35 hPa)
(11) Set Point: 665 hPa
(12) Set Point: 0,8 hPa
(13) Set Point: 4 hPa
(14) Set Point: 930 hPa
(15) Set Point: 0.9 hPa
(16) Set Point: 930 hPa
(17) Set Point: 0.8 hPa
waiting time 120"

= Pressure
= Chamber temperature
= Atmospheric Pressure
= chamber probe temperature
range 50°C - 55°C - T. alarm: 60°C
= Injection
= Diffusion

PL 70 cycle description

Intensive program: **62 min** cycle
+ 4 min initialization

Electric power consumption
Stand-by mode (kWh): 0,15
Full load (kWh): 0,93
Basic load (kWh): 0,81
Operation mode (kWh): 0,40



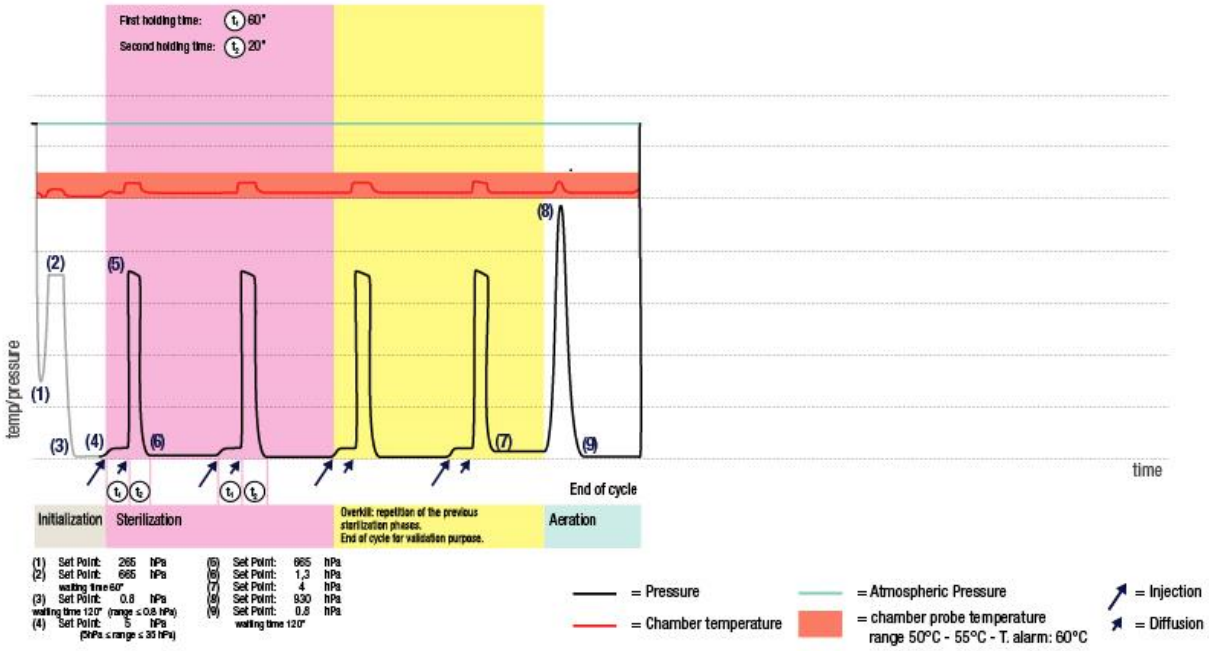
- During the sterilization cycle, the minimum temperature (alarm set point) is equal to 40°C; the maximum temperature (alarm set point) is equal to 60°C.
- During the injection phase, the pressure range is equal to: 5÷35 hPa (PL130) / 5÷35 hPa (PL70).

➢ **Superfast cycle (optional)- Duration about 22 min (PL130) / about 24 min (PL70)**
To sterilize generic reusable medical devices, rigid optics without any lumens and microsurgical kits except from cable tools (surface sterilization). Max load: 5,5 Kg (PL 130) / 2,2 Kg (PL 70).
See examples of load on page 38-40.

PL 130 cycle description

SuperFast program: **20 min** cycle
+ 2 min initialization

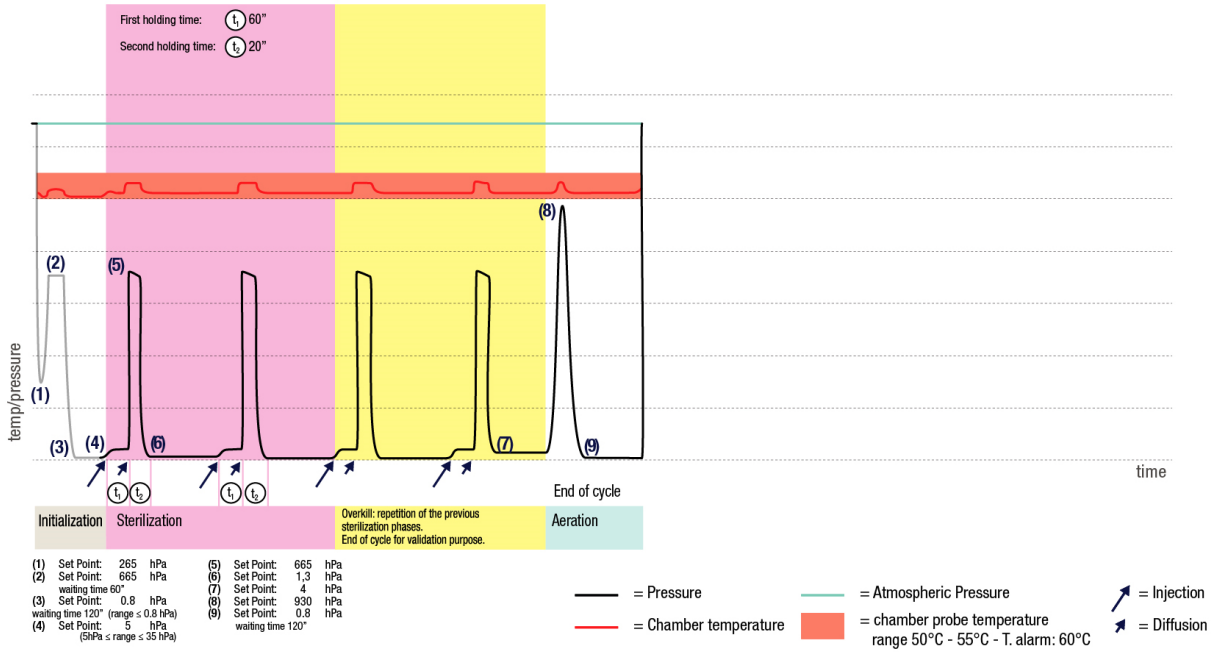
Electric power consumption
Stand-by mode (kWh): 0,19
Full load (kWh): 0,50
Basic load (kWh): 0,37
Operation mode (kWh): 0,47



PL 70 cycle description

SuperFast program: **22 min** cycle
+ 2 min initialization

Electric power consumption
Stand-by mode (kWh): 0,19
Full load (kWh): 0,50
Basic load (kWh): 0,37
Operation mode (kWh): 0,47



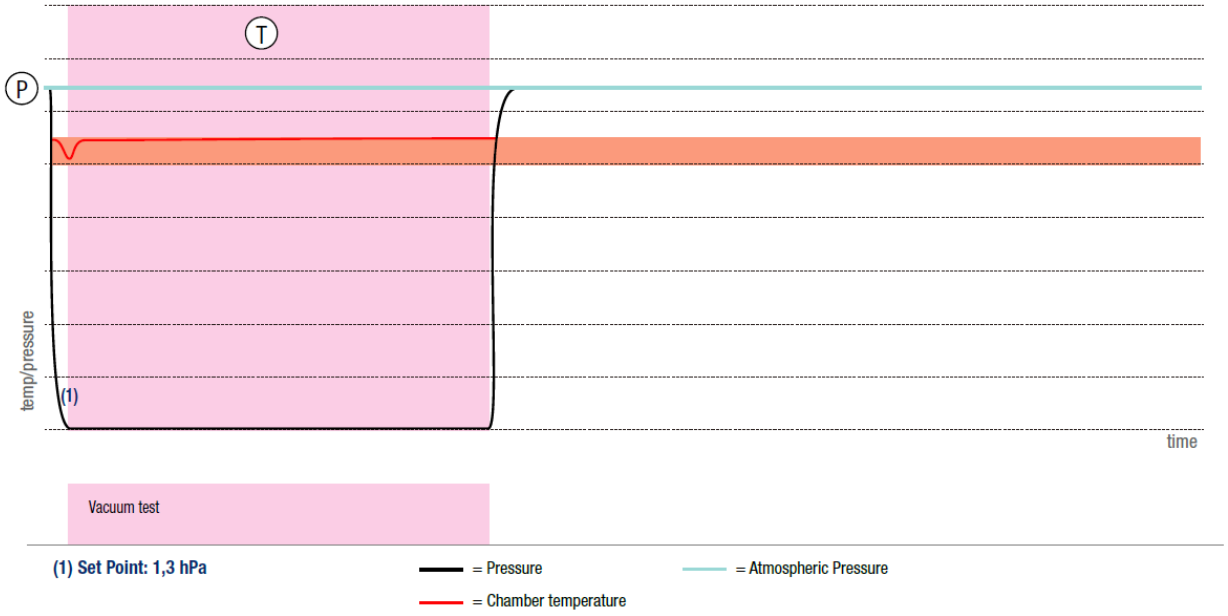
TEST CYCLE:

- **VacuumTest: Duration about 17 min (PL 130 and PL 70)**
  In order to test the system seal. The test consists of the achieving of a vacuum threshold and of the keeping of itself for a prefixed period of time. It is recommended to daily carry out the test before performing the work cycles.
  Initial vacuum value: 1,3 hPa.
  Vacuum seal time: 600 sec.
  Maximum leak: 2 hPa.

Cycle description

Vacuum test:
17 min cycle (PL 130 - PL 70 - PL 40)

Ⓟ = Atmospheric Pressure
Ⓣ = Vacuum holding time: 600 sec
Maximum Loss: **2 hPa**



(1) Set Point: 1,3 hPa

= Pressure
= Atmospheric Pressure
= Chamber temperature

PL 130

Ciclo FAST (30' appr.)

Per la sterilizzazione delle sole superfici esterne di dispositivi medicali anche accoppiate in acciaio inossidabile e titanio.

Strumenti: inclusi ma non limitati a:
- ***Endoscopi rigidi e semirigidi senza lumi***
- ***Endoscopi flessibili senza lumi (es. sonde ORL)***
- ***Telecamere e cavi***
- ***Batterie ricaricabili***
- ***Strumenti per oculistica senza lume***
- ***Lame laringoscopiche***
- ***Sonde ad ultrasuoni e trasduttori***
- ***Strumenti di chirurgia generale senza lume***

Peso massimo : 19.5 kg
(distribuito sui due ripiani)

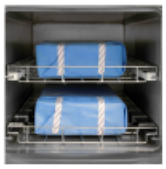
Lumi: NO
Solo superfici esterne

Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

Ciclo FLEX (40' appr.)

Per endoscopi flessibili con:
- Canale singolo: ø interno min: 1 mm, lunghezza max: 1050 mm;
- Canale doppio: canale A: ø interno min: 1 mm, lunghezza max: 1050 mm; canale B: ø interno min: 1 mm, lunghezza max: 1000 mm.

Strumenti: inclusi ma non limitati a:
- ***Endoscopi flessibili, come cistoscopi, isteroscopi, uretroscopi, coledocoscopi***
- ***Broncoscopi flessibili***
- ***Endoscopi chirurgici flessibili***
- ***Toracoscopi flessibili***
- ***Fibroscopi per intubazione flessibili***
- ***Batterie, fotocamere, cavi luce***
- ***Dispositivi senza Lumi***
- ***Endoscopi chirurgici Intuitive Surgical daVinci®***



Peso massimo : 10.5 kg
(distribuito sui due ripiani)

Max: 2 endoscopi con canali

Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

PL 130

Ciclo STANDARD (52' appr.)

Per strumenti chirurgici generici con lumi dotati di canali rigidi, semi-rigidi e flessibili (lumi flessibili in Teflon e lumi rigidi in acciaio) fino a tre canali:
- Lumi rigidi: con Ø ≥ 0.7 e lunghezza ≤ 550 mm.
- Lumi flessibili: con Ø ≥ 0.7 e lunghezza ≤ 750 mm

Strumenti: inclusi ma non sono limitati a:
- ***Endoscopi rigidi e semirigidi***
- ***Set di strumenti laparoscopici (cistoscopi, uretroscopi, artroscopi)***
- ***Strumenti per oculistica***
- ***Lumi flessibili in teflon***
- ***Batterie ricaricabili***
- ***Trapani ortopedici, seghe e sistemi di rasatura***
- ***Manipoli ad ultrasuoni***
- ***Cavi doppler e piastre del defibrillatore***
- ***Telecamere e cavi luminosi***
- ***Dispositivi senza lume***

Peso massimo : 10.3 kg
(distribuito sui due ripiani)

Max: 22 lumi

Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

Ciclo INTENSIVE (64' appr.)

Per strumenti chirurgici generici critici con lumi dotati di canali flessibili, semi-rigidi e rigidi (lumi flessibili in Teflon e lumi rigidi in acciaio) fino a tre canali:
- Lumi: con Ø ≥ 0.5 e lunghezza ≤ 2200 mm. flessibili, semi-rigidi e rigidi (canale singolo, doppio canale e triplo canale)

Strumenti: inclusi ma non sono limitati a:
- ***Endoscopi chirurgici flessibili***
- ***Uretroscopi flessibili***
- ***Toracoscopi***
- ***Broncoscopi***
- ***Cistoscopi***
- ***Isteroscopi***
- ***Coledocoscopi***
- ***Fibroscopi per intubazione***
- ***Lumi flessibili in teflon***
- ***Dispositivi senza lumi***
- ***Dispositivi trattati nel ciclo Standard***

Peso massimo : 6.5 kg
(distribuito sui due ripiani)

Max: 3 lumi con le caratteristiche riportate

Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

PL 130

SUPER FAST Cycle (22' approx.)
optional

For general medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces (no lumens)

Instruments : included but not limited to:

- ***Rigid and semi-rigid scopes without lumens***
- ***Flexible non lumen scopes, such as ENT scopes***
- ***Cameras and cables***
- ***Rechargeable batteries***
- ***Eye instruments without lumens***
- ***Laryngoscope blades***
- ***Ultrasound probes and transducers***
- ***General surgery instruments without lumens***

Max weight : 5.5 kg
(only lower shelf)

Lumens: NO
Only external surfaces

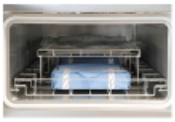
Packaging: container or packaging suitable for vaporized H2O2 sterilization, Tyvek bags or rolls, SMS sheets. For correct loading operations also refer to the User Manual or ask the Steelco representative

PL 70

Ciclo FAST (32' appr.)

Per la sterilizzazione delle sole superfici esterne di dispositivi medicali anche accoppiate in acciaio inossidabile e titanio.

Strumenti: inclusi ma non limitati a:
- ***Endoscopi rigidi e semirigidi senza lumi***
- ***Endoscopi flessibili senza lumi (es. sonde ORL)***
- ***Telecamere e cavi***
- ***Batterie ricaricabili***
- ***Strumenti per oculistica senza lume***
- ***Lame laringoscopiche***
- ***Sonde ad ultrasuoni e trasduttori***
- ***Strumenti di chirurgia generale senza lume***



Peso massimo : 13.5 kg
(distribuito sui due ripiani)

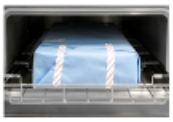
Lumi: NO
Solo superfici esterne

Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

Ciclo FLEX (42' appr.)

Per endoscopi flessibili con:
- Canale singolo: ø interno min: 1 mm, lunghezza max: 1050 mm;
- Canale doppio: canale A: ø interno min: 1 mm, lunghezza max: 1050 mm; canale B: ø interno min: 1 mm, lunghezza max: 1000 mm.

Strumenti: inclusi ma non limitati a:
- ***Endoscopi flessibili, come cistoscopi, isteroscopi, uretroscopi, coledocoscopi***
- ***Broncoscopi flessibili***
- ***Endoscopi chirurgici flessibili***
- ***Toracoscopi flessibili***
- ***Fibroscopi per intubazione flessibili***
- ***Batterie, fotocamere, cavi luce***
- ***Dispositivi senza Lumi***
- ***Endoscopi chirurgici Intuitive Surgical daVinci®***



Peso massimo : 5.5 kg
(distribuito sui due ripiani)

Max: 1 endoscopio con canali

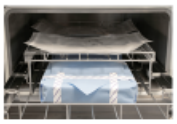
Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

PL 70

Ciclo STANDARD (60' appr.)

Per strumenti chirurgici generici con lumi dotati di canali rigidi, semi-rigidi e flessibili (lumi flessibili in Teflon e lumi rigidi in acciaio) fino a tre canali:
- Lumi rigidi: con Ø ≥ 0.7 e lunghezza ≤ 550 mm.
- Lumi flessibili: con Ø ≥ 0.7 e lunghezza ≤ 750 mm

Strumenti: inclusi ma non sono limitati a:
- ***Endoscopi rigidi e semirigidi***
- ***Set di strumenti laparoscopici (cistoscopi, uretroscopi, artroscopi)***
- ***Strumenti per oculistica***
- ***Lumi flessibili in teflon***
- ***Batterie ricaricabili***
- ***Trapani ortopedici, seghe e sistemi di rasatura***
- ***Manipoli ad ultrasuoni***
- ***Cavi doppler e piastre del defibrillatore***
- ***Telecamere e cavi luminosi***
- ***Dispositivi senza lume***



Peso massimo : 3.5 kg
(distribuito sui due ripiani)

Max: 9 lumi

Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

Ciclo INTENSIVE (66' appr.)

Per strumenti chirurgici generici critici con lumi dotati di canali flessibili, semi-rigidi e rigidi (lumi flessibili in Teflon e lumi rigidi in acciaio) fino a tre canali:
- Lumi: con Ø ≥ 0.5 e lunghezza ≤ 2200 mm. flessibili, semi-rigidi e rigidi (canale singolo, doppio canale e triplo canale)

Strumenti: inclusi ma non sono limitati a:
- ***Endoscopi chirurgici flessibili***
- ***Uretroscopi flessibili***
- ***Toracoscopi***
- ***Broncoscopi***
- ***Cistoscopi***
- ***Isteroscopi***
- ***Coledocoscopi***
- ***Fibroscopi per intubazione***
- ***Lumi flessibili in teflon***
- ***Dispositivi senza lumi***
- ***Dispositivi trattati nel ciclo Standard***

Peso massimo : 4.5 kg
(distribuito sui due ripiani)

Max: 3 lumi con le caratteristiche riportate

Confezionamento: container o packaging adatto alla sterilizzazione a H_2O_2 vaporizzato, buste o rotoli in Tyvek, fogli SMS. Per le corrette operazioni di carico consultare anche il Manuale Utente o chiedere al rappresentante Steelco.

PL 70

SUPER FAST Cycle (24' approx.) optional

For general medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces (no lumens)

Instruments : included but not limited to:

- ***Rigid and semi-rigid scopes without lumens***
- ***Flexible non lumen scopes, such as ENT scopes***
- ***Cameras and cables***
- ***Rechargeable batteries***
- ***Eye instruments without lumens***
- ***Laryngoscope blades***
- ***Ultrasound probes and transducers***
- ***General surgery instruments without lumens***

Max weight : 2.2 kg
(only lower shelf)

Lumens: NO
Only external surfaces

Packaging: container or packaging suitable for vaporized H2O2 sterilization, Tyvek bags or rolls, SMS sheets. For correct loading operations also refer to the User Manual or ask the Steelco representative

5.2 Operation description for PL40

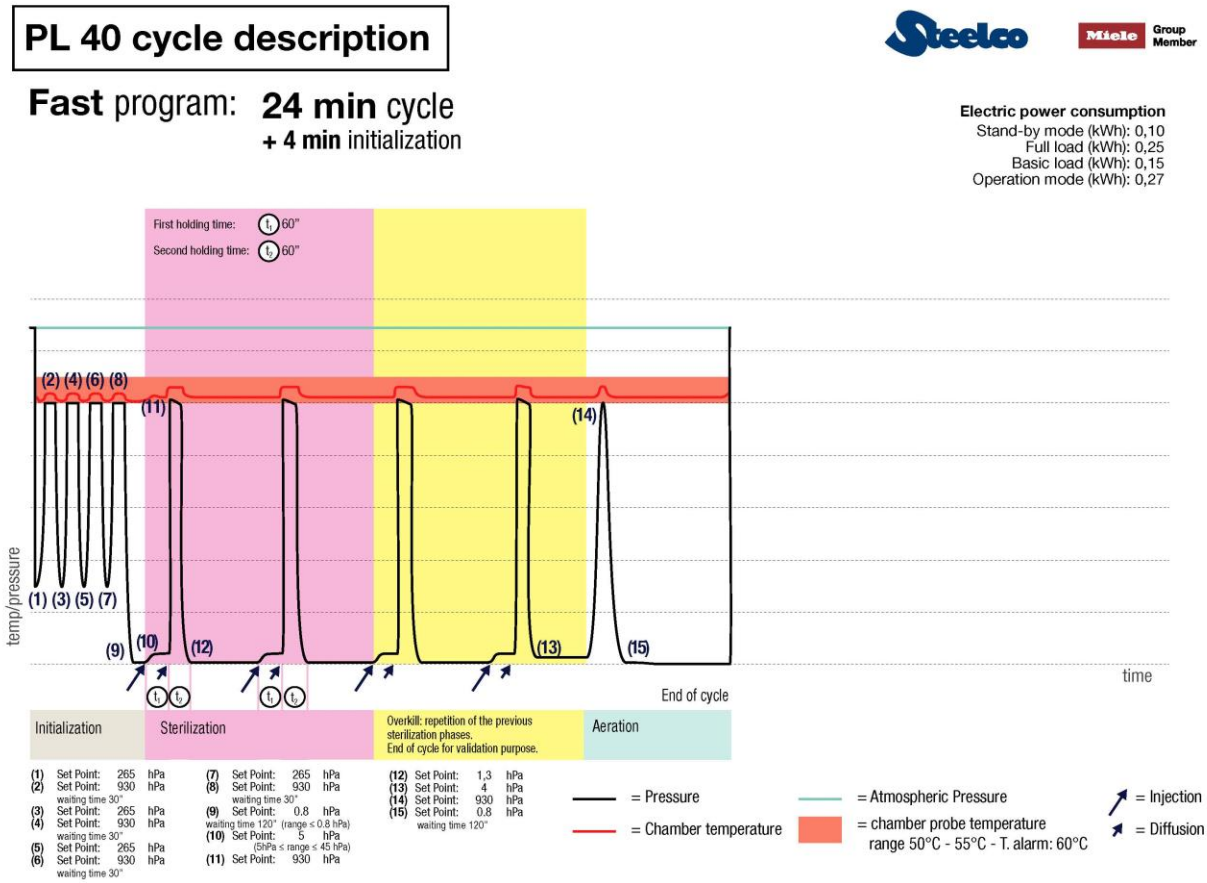
This device is designed for the terminal sterilization of packaged medical devices such as surgical instrumentation sensitive to heat and humidity.
It is suitable for surgical instruments in metal, metal alloys, delicate non-metallic alloys, micro-surgery instruments and hollow instruments.

The four work cycles and the vacuum test cycle are programmed at the factory, validated and available for running from the control panel. The optional cycle can be available to be carried out on demand.

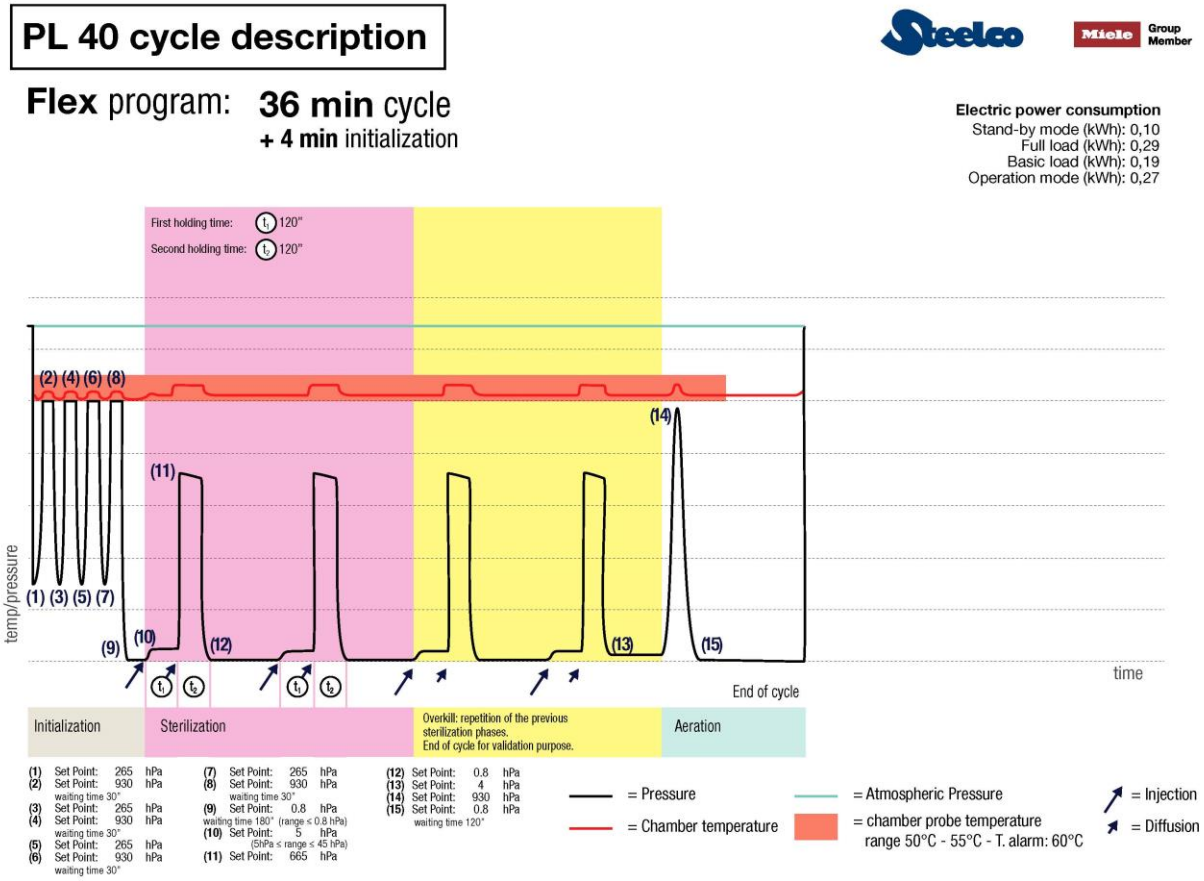
The data shown may differ by ± 10% depending on the physical conditions and environment of device installation.

Work cycles:

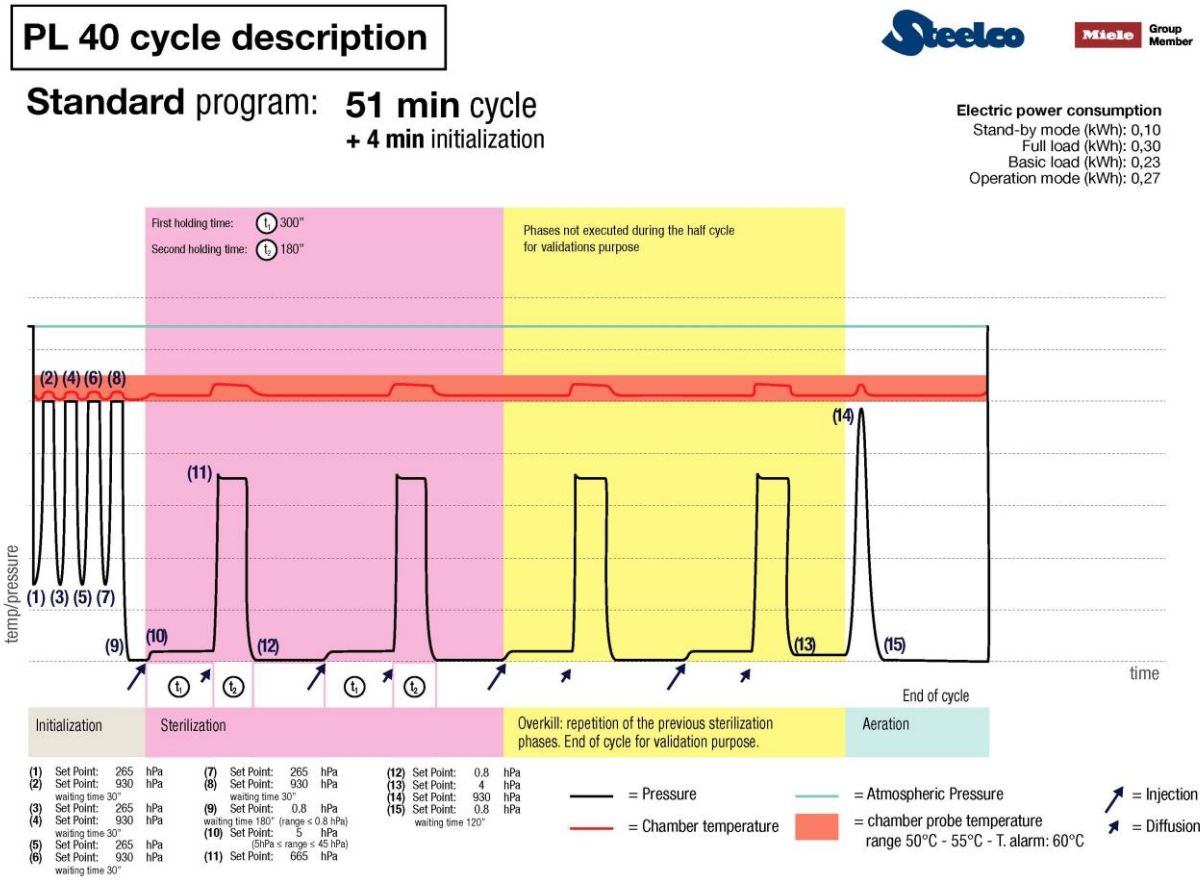
- **Fast cycle - Duration about 28 min**
  For sterilizing generic reusable medical devices, rigid scopes without lumen and micro-surgery kits, with the exclusion of hollow instruments (surface sterilization). Max load: 11,8 kg. See examples on page 48.



➢ **Flex cycle - Duration about 40min**
For sterilizing single and dual channel flexible lumens. Flexible lumens with a diameter of 0,7 mm and length until 1050 mm, flexible endoscopes with single and double channel. Max load: 3,5 kg. See examples on page 48.

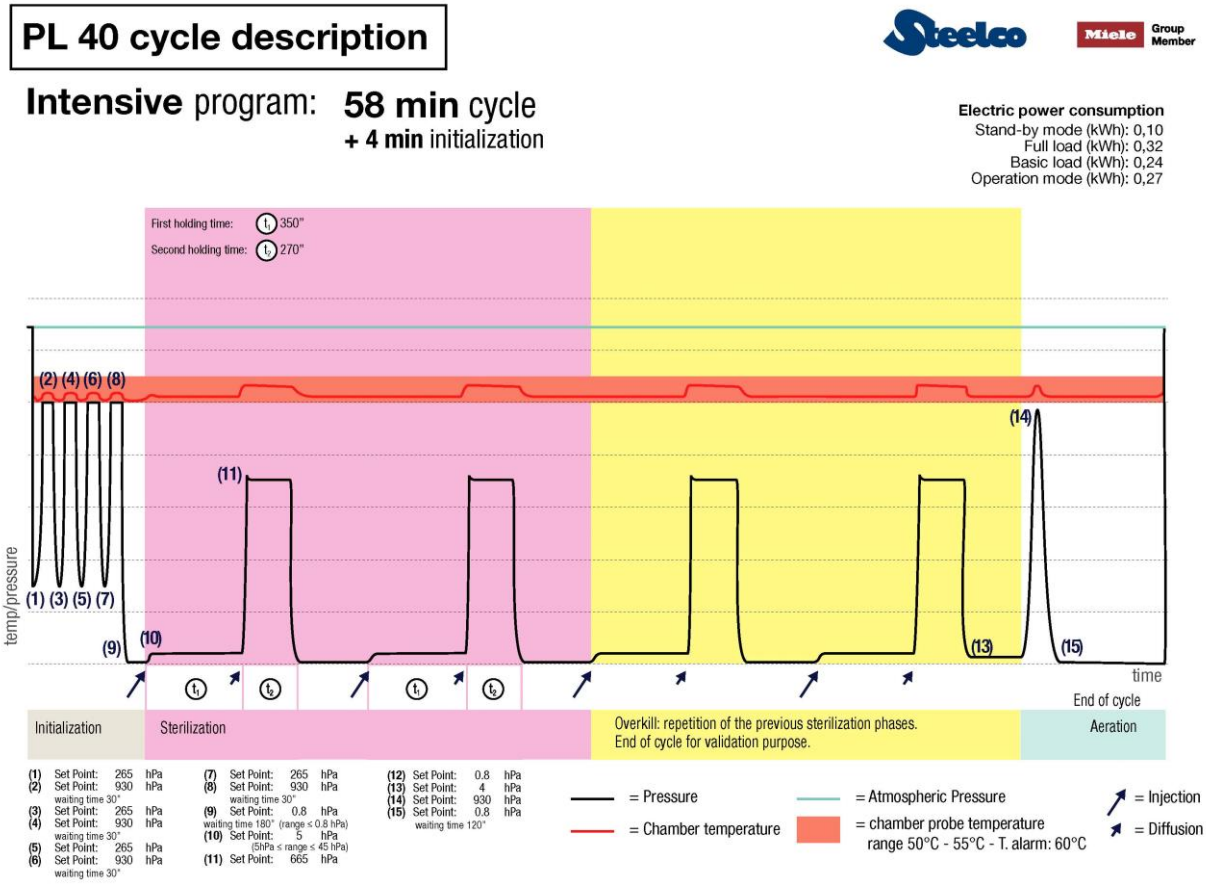


➢ **Standard Cycle - Duration about 55 min**
For sterilizing hollow rigid, semi-rigid and flexible instruments with single, double and triple channel with a diameter of 0,7 mm and length until 3000 mm (depending on the load). Max load: 5,5 kg. See examples on page 48.



➢ **Intensive cycle - Duration about 62 min**

To sterilize hollow instrumentation single channel, dual channel and triple channel with a diameter of 0,5 mm and length until 2200 mm (depending on the load). Max load: 3,5 kg. See examples on page 43.



- During the sterilization cycle, the minimum temperature (alarm set point) is equal to 40°C; the maximum temperature (alarm set point) is equal to 60°C.
- During the injection phase, the pressure range is equal to: 5÷45 hPa.

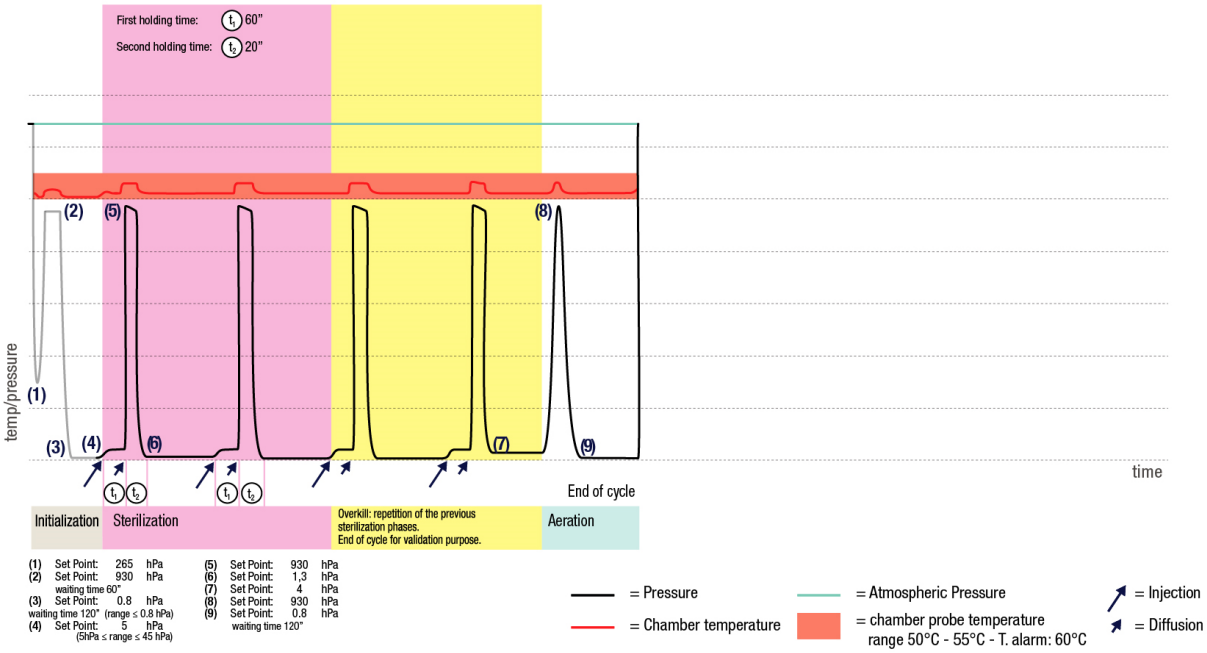
➢ **Superfast cycle (optional)- Duration about 25 min**

To sterilize generic reusable medical devices, rigid optics without any lumens and microsurgical kits except from cable tools (surface sterilization). Max load: 1,5 Kg.
See examples on page 48.

PL 40 cycle description

SuperFast program: **21 min** cycle
+ 4 min initialization

Electric power consumption
Stand-by mode (kWh): 0,19
Full load (kWh): 0,50
Basic load (kWh): 0,37
Operation mode (kWh): 0,47



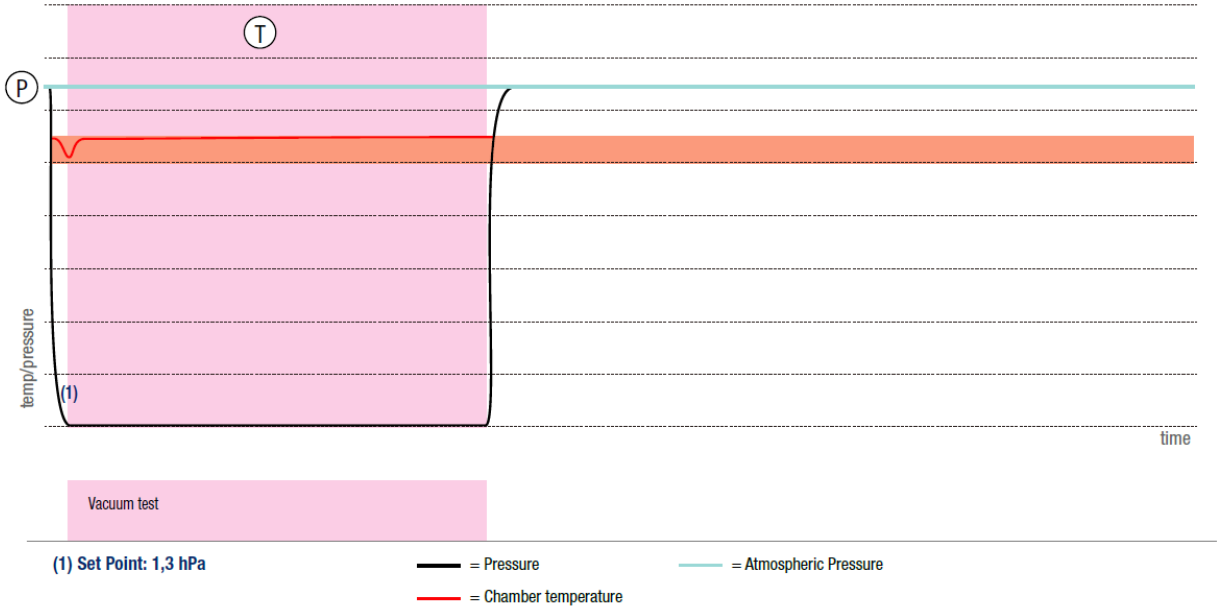
TEST CYCLE:

- **VacuumTest: Duration about 17 min (PL 40)**
  In order to test the system seal. The test consists of the achieving of a vacuum threshold and of the keeping of itself for a prefixed period of time. It is recommended to daily carry out the test before performing the work cycles.
  Initial vacuum value: 1,3 hPa.
  Vacuum seal time: 600 sec.
  Maximum leak: 2 hPa.

Cycle description

Vacuum test:
17 min cycle (PL 130 - PL 70 - PL 40)

Ⓟ = Atmospheric Pressure
Ⓣ = Vacuum holding time: 600 sec
Maximum Loss: **2 hPa**



PL 40

SUPER FAST Cycle (25' approx.) optional

For general medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces (no lumens)

Instruments : included but not limited to:

- ***Rigid and semi-rigid scopes without lumens***
- ***Flexible non lumen scopes, such as ENT scopes***
- ***Cameras and cables***
- ***Rechargeable batteries***
- ***Eye instruments without lumens***
- ***Laryngoscope blades***
- ***Ultrasound probes and transducers***
- ***General surgery instruments without lumens***

Max weight : 1.5 kg
(only lower shelf)

Lumens: NO
Only external surfaces

Packaging: container or packaging suitable for vaporized H2O2 sterilization, Tyvek bags or rolls, SMS sheets. For correct loading operations also refer to the User Manual or ask the Steelco representative

5.3 General description of the sterilization cycle

Once a program is started, the sterilizer automatically processes the load through a predefined combination of the standard phases below mentioned.
The cycles are factory programmed and validated, cannot be modified by the operator and include the following typical steps:

1. **PREPARATION:**
   control of the chamber temperature, detection and control of the humidity. This phase is executed to reach the optimal conditions needed for a sterilization cycle as well as for a testing cycle.

2. **INIZIALIZATION:**
   the system generates a fractional vacuum, eliminates the residual humidity, detects the humidity value and afterwards maintains the chamber at an absolute pressure of about 0,8 hPa.

3. **STERILIZATION:**
   Injection of a quantity of 1.1 ml (PL 40) / 1.5 ml (PL 70) / 2.5 ml (PL 130) of hydrogen peroxide (vacuum chamber). The temperature and the pressure of the chamber must be kept constant for a variable duration in minutes depending on the cycle (first waiting time). After the first waiting time the system carries out an injection of filtered air in the chamber maintaining the chamber to the new pressure condition for a variable duration in minutes depending on the cycle (second waiting time). Neutralization of the residual hydrogen peroxide per suction and simultaneous activation of the plasma generator. Subsequent passage through the platinum catalyst to guarantee the culling of the hydrogen peroxide residuals. Final step thanks to an active carbon filter.
   The described sterilization phase is repeated 4 times. The last two repetitions are implemented to obtain the "overkill" effect.

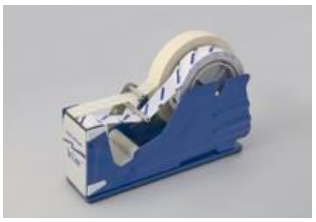
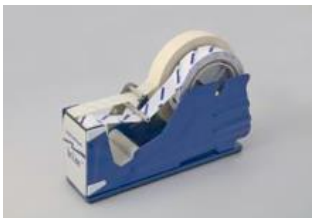
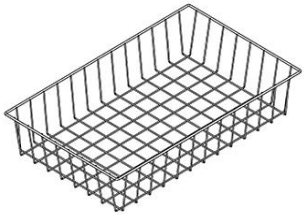
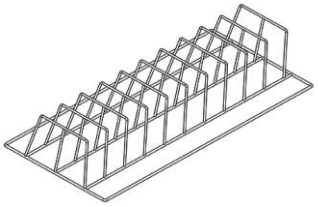
4. **CYCLE COMPLETION (VENTILATION)**
   Through fractionated vacuum in the chamber for a predetermined time, the end of which the atmospheric pressure is re-established inside the chamber. At the end of the cycle the load does not have any residue, does not require ventilation and can be used immediately.

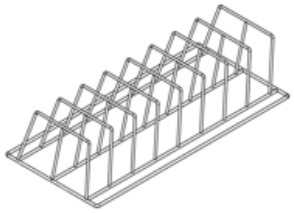
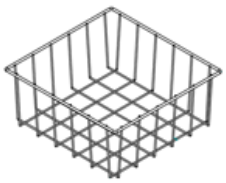
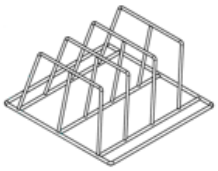
TESTS

Vacuum Leak Test: this cycle is used to verify the vacuum integrity of the sterilizer. During a predetermined time interval, the system verifies that there is no loss of vacuum above the value set by the parameter.

5.4 Components and process indicators

DESCRIPTION	CODE	IMAGE
VH202 – 24hr Biological indicator self-contained 1 box of 50 ampoules each	9992268P	
Steam Incubator of 37°C/55°C for 13 indicators and EO for 24hr indicators cod. 9992268P	9992093	
Ultra-rapid biologic incubator VH202 – 30 min. 1 box of 50 ampoules each It requires a rapid reading incubator	9992266P	
Rapid reading incubator for 30 min. indicators cod. 9992266P. Traceability software included	9992267P	
Paper roll 57mm x 7mt, 3 pcs. For rapid reading incubator cod. 9992267P	9992518	
VH202 type 4 indicator-1 box of 250 stripes	9992269P	
VH202 type 1 indicator-1 box of 250 stripes	9992270P	
VH202 indicator type of type 1 - 19mm x 50mt -1 roll	9992271P	

Tape process support - 1 unit	9992091P	
Tape process support - 1 box of 6 units	9992091P	
Paper roll for thermal printer, 112 mm x 30 mt	088500500	
LOADING BASKET (for PL70 and PL130) Stainless steel AISI 304: • Max n.1 for PL 70 • Max n.2 for PL 130 • Dimensions: 420x685x132H mm	C1683	
INSERT FOR POUCHES (for PL70 and PL130) Stainless steel AISI 304: • Max n.1 for PL 70 (in combination with C1683) • Max n.2 for PL 130 (in combination with C1683) • Nr. 10 spaces of 60 mm	C1682	
INSERT FOR POUCHES (for PL70 and PL130) • Stainless steel AISI 304: • Max n.1 for PL 70 (in combination with C1683) • Max n.2 for PL 130 (in combination with C1683) • Nr. 6 spaces of 103 mm	C1706	
LOADING BASKET (for PL40) Stainless steel AISI 304: Dimensions: 310x600x132H mm	C1722	

INSERT FOR POUCHES (for PL40) Stainless steel AISI 304: To use in combination with C1722 Nr. 8 spaces of 67 mm	C1723	
LOADING BASKET (for PL40) Stainless steel: Dimensions: 310x300x132H mm	C1724	
INSERT FOR POUCHES (for PL40) Stainless steel AISI 304: • To use in combination with C1724 or C1722 • Nr. 3 spaces of 67 mm	C1725	
PCD rigid, metal support D=12mm L=250mm one open side - for **VH202 24hr biological indicator self-contained cod: 9992268P and VH202 30min indicator** **Ultra rapid biological cod: 9992266P**	99912723	
PCD flexible D=2mm L=1500mm one open side - for VH202 24hr indicator **Biological self-contained cod: 9992268P**	99913504	
PCD flexible D=2mm L=750mm one open side - for VH202 24hr indicator **Biological self-contained cod: 9992268P**	99913505	
PCD rigid D=2mm L=275mm one open side - for VH202 24hr indicator **Biological self-contained cod: 9992268P**	99913506	
PCD flexible D=2mm L=1500mm one open side – for VH202 30min indicator **Ultra rapid biological cod: 9992266P**	99913508	

PCD flexible D=2mm L=750mm one open side – for VH202 30min indicator **Ultra rapid biological cod: 9992266P**	99913509	
PCD rigid D=2mm L=275mm one open side – for VH202 30min indicator **Ultra rapid biological cod: 9992266P**	99913510	

ATTENTION

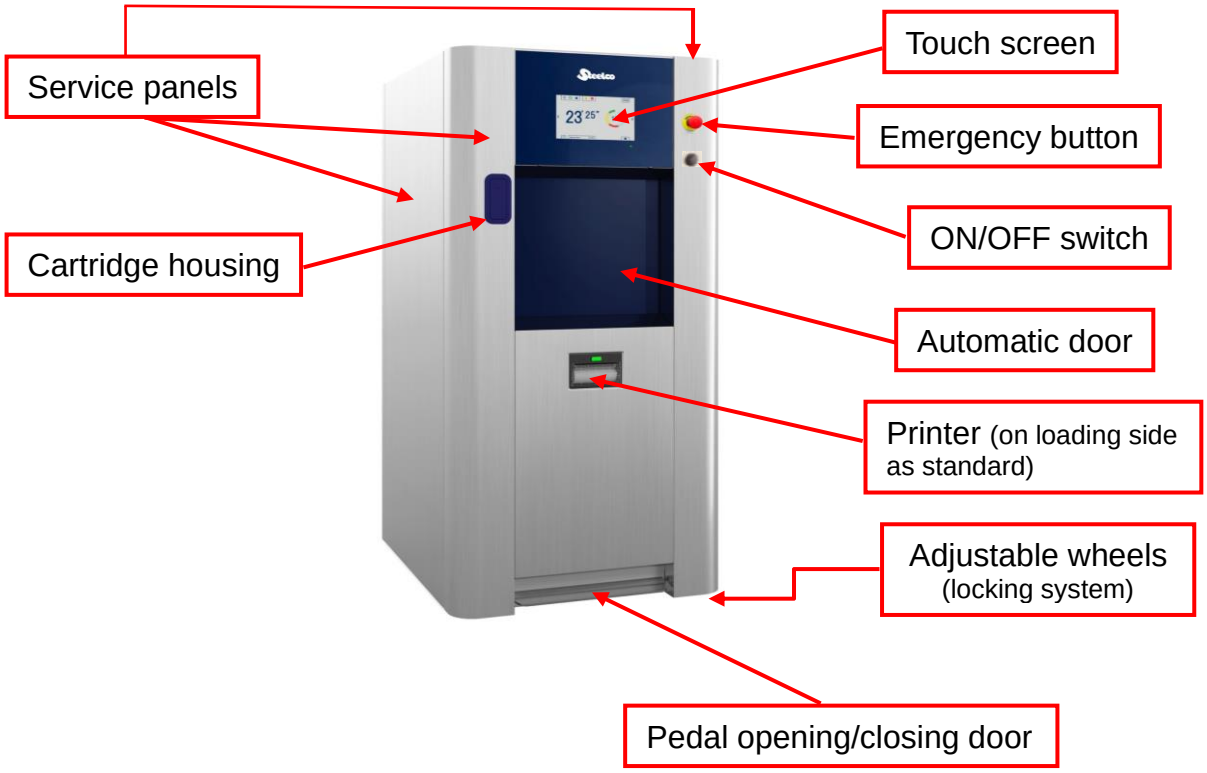
Steelco recommends the use of original components only.

5.5 Consumables

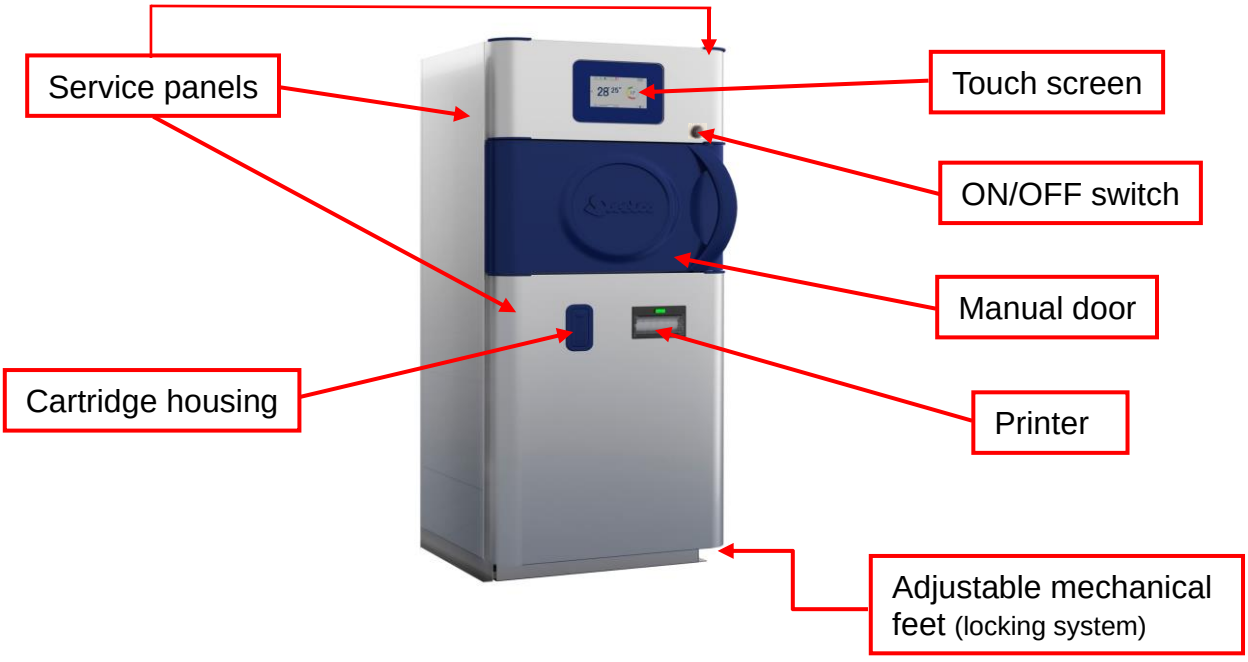
9992537	Steelcopro PL 40: box with 10 cartridges
9992536	Steelcopro PL 70: box with 10 cartridges
9992118	Steelcopro PL 130: box with 20 cartridges
9992535	Steelcopro PL 130: box with 10 cartridges

5.6 Machine description

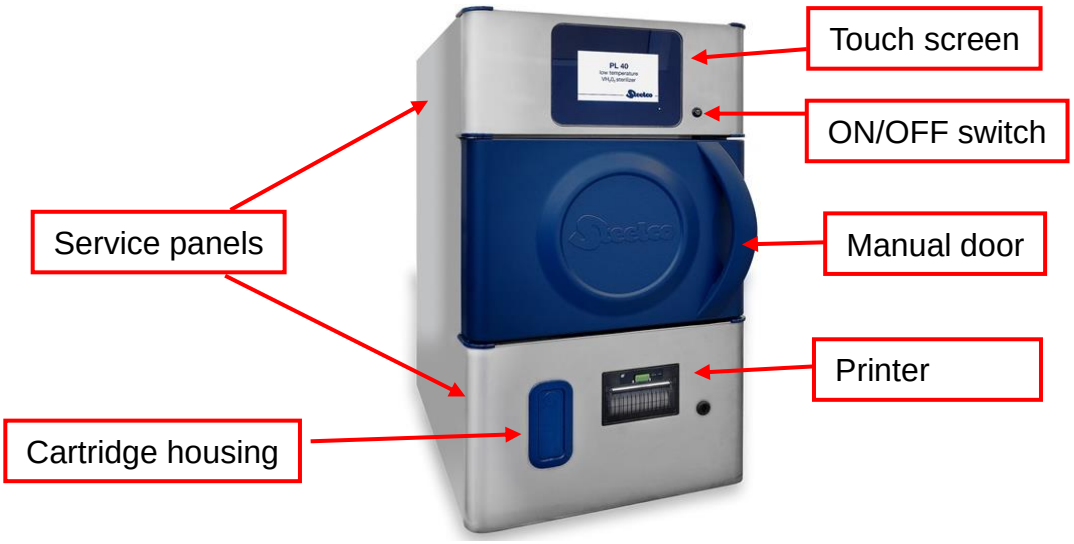
PL 130



PL 70



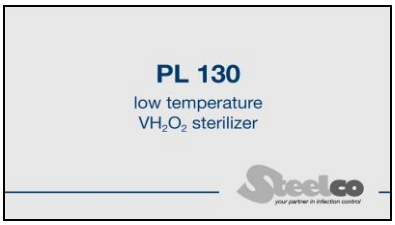
PL 40

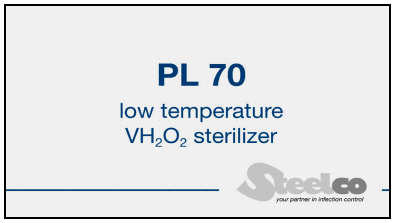


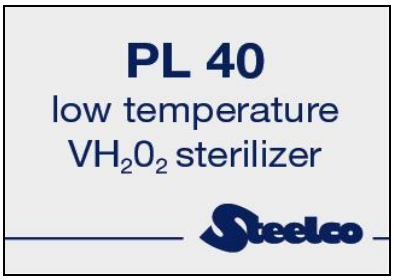
5.6.1 Touch screen

The operator panel allows to:

- Select the appropriate cycle;
- Start a cycle;
- Monitor the cycle parameters.







5.6.2 Cartridge

One cartridge has a liquid solution of concentrated hydrogen peroxide (58%), containing the right amount for one cycle (PL 130 and PL70), for two cycles (PL 40).
Each cartridge is marked with the batch and the expiry date.
It is also equipped with an RFID system to prevent reuse and to identify the expiry. If the cartridge is expired or has already been used, it will be rejected for one cycle (PL 70 and PL 130) or for two cycles (PL 40) its use is denied, and the corresponding message will appear on the panel.
Each machine has a cartridge identification system, which avoids the usage of a different cartridge dedicated to another equipment.
The cartridge is restored empty at the end of its use: 1 cycle (PL 70, PL 130), 2 cycles (PL 40).

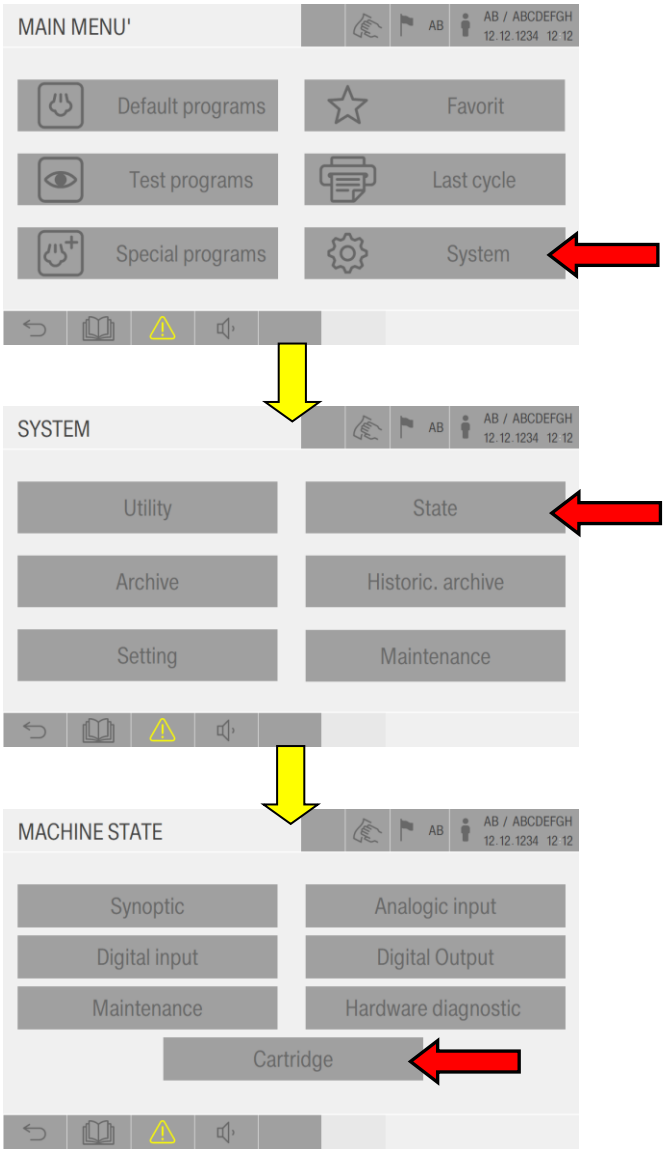
	**ATTENTION**
	The cartridges should be stored at a temperature between +5°C and +30°C. **The hydrogen peroxide is corrosive to the skin, eyes, nose, throat, lungs and gastrointestinal tract.** **Always wear chemical resistant gloves when removing devices from the sterilizer.** **As a result of a wrong procedure, if at the end of the cycle the devices loaded clearly show the presence of humidity or liquids, hydrogen peroxide may be present.** **The shelf life is 12 months (5°C ÷ 30°C).**

HOW TO USE A NEW CARTRIDGE (PL 130 and PL 70)

Generally, the cartridge slot is always open.
If you have closed it, perform the following procedure to open it and to be able to insert a new cartridge.

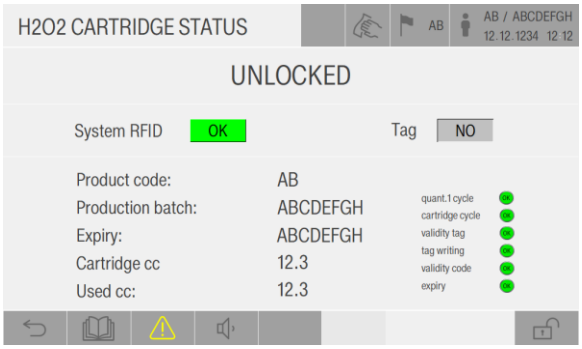
	**ATTENTION**
	Wear protective gloves when replacing the cartridge.
	The chemical substance may burn or irritate the skin and eyes.
	Promptly rinse the skin in case of contact with the chemicals.
	Always close the cartridge slot even when the machine is not in use.
	Remove the empty cartridge when the display indicates that the sterilization process is completed and the slot automatically opens.

1. Open the cartridge compartment by pressing the key  in the page “**H2O2 CARTRIDGE STATUS**”.



2. Insert the cartridge into the cartridge slot;

3. Close the cartridge slot. Check the deadline of the cartridge.



4. Start the cycle;
5. Once the sterilization cycle ends, an acoustic signal will be activated and the panel message "**CYCLE END OK**" or "**CYCLE END NOT OK**" will appear (in case of alarm). If an alarm occurs, see on page 76.

(If an error occurs, identify the causes that generated it, take the necessary precautions before working on the machine and repeat the process.)

6. Open the door, remove the devices and close the door;
7. At the end of the cycle the door cartridge holder opens automatically. Remove the cartridge and dispose it in accordance with the hospital waste disposal policies.

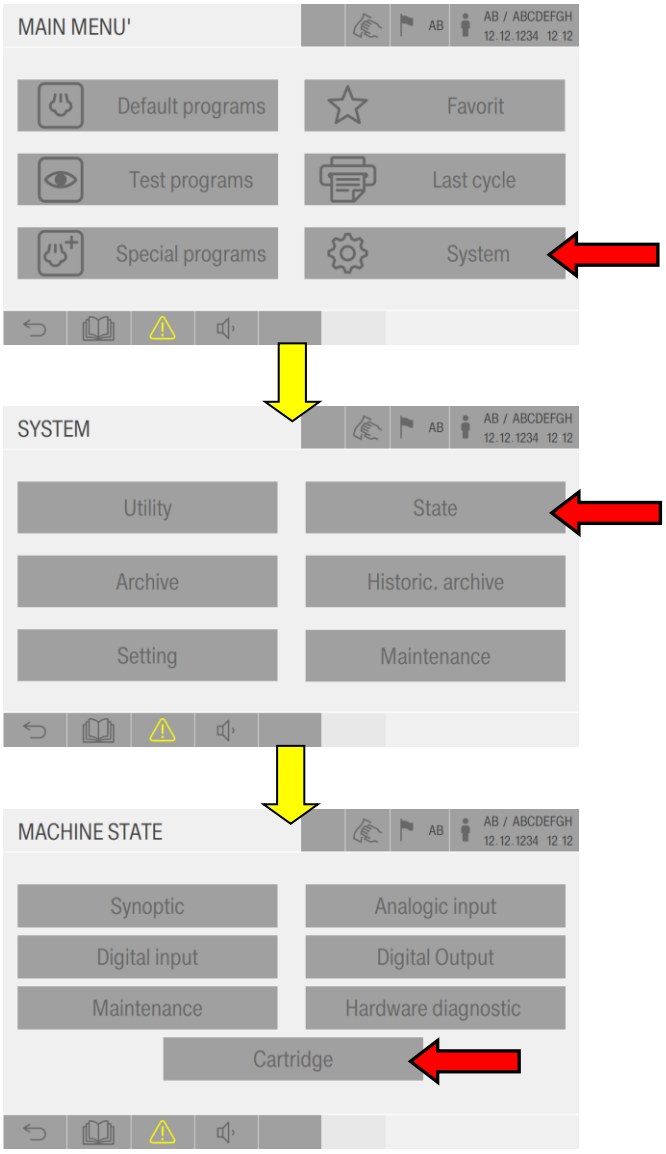
	ATTENTION
	With regards to the safe disposal of chemical products or their containers, please refer to regulations in force in the country where the appliance is installed.

	ATTENTION
	THE USE OF PERSONAL PROTECTION EQUIPMENT IS VERY IMPORTANT: THE USER IS RESPONSIBLE FOR THE MACHINE SAFETY. IN NO CASE STEELCO WILL BE HELD RESPONSIBLE IN THE EVENT OF ACCIDENTS (FOR EXAMPLE, EXPOSURE OF THE OPERATOR TO A HIGH CONCENTRATION OF H2O2).

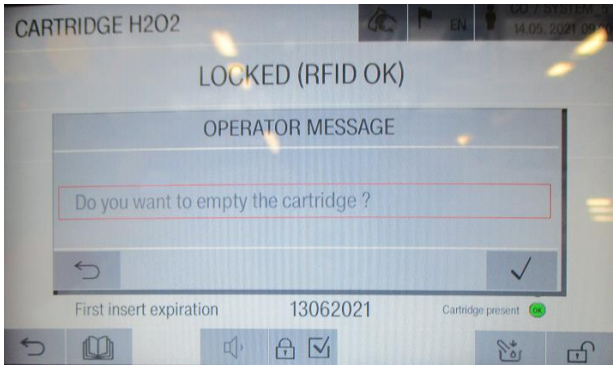
HOW TO USE A NEW CARTRIDGE (PL 40)

By using a cartridge PL 40 it is possible to perform two cycles.
The cartridge slot remains closed between the execution of the first and second cycle.
The cartridge slot automatically opens at the end of the cartridge use (after no. 2 cycles).
If you have closed the slot, perform the following procedure to open it and to be able to insert a new cartridge.

1. Open the cartridge compartment by pressing the key  in the page "**H2O2 CARTRIDGE STATUS**".



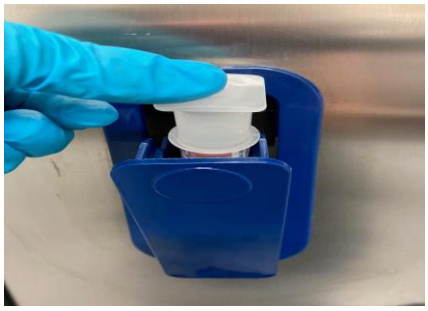
When the cartridge has been inserted, the duration is 30 days.
In case of expired cartridge into the machine, the system denies the use of it.
Proceed with the operation “empty the cartridge” to remove it.



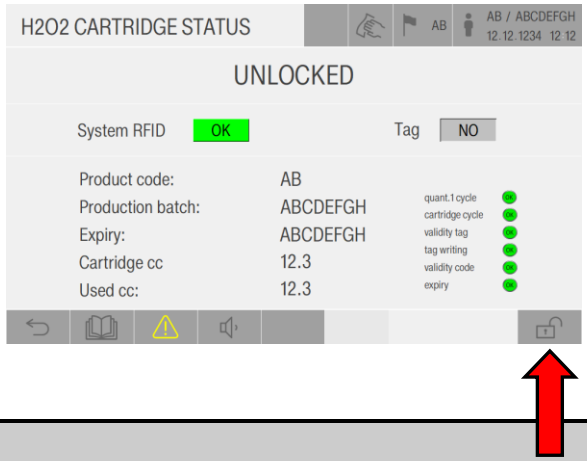
	ATTENTION
	Wear protective gloves when replacing the cartridge.
	The chemical substance may burn or irritate the skin and eyes.
	Promptly rinse the skin in case of contact with the chemicals.
	Always close the cartridge slot even when the machine is not in use.
	Remove the empty cartridge when the display indicates that the sterilization process is completed and the slot automatically opens.

	ATTENTION
	Do not empty the possible expired cartridge boxes by the operation “empty the cartridge” into the machine.

2. Insert the cartridge into the cartridge slot pushing it down.



3. Close the cartridge slot. Check the deadline of the cartridge;



	ATTENTION
	Do not empty the cartridge inserted before to proceed to its use. Once the cartridge has been inserted, immediately close the cartridge slot.

4. Start the cycle;
5. Once the sterilization cycle ends, an acoustic signal will be activated and the panel message "**CYCLE END OK**" or "**CYCLE END NOT OK**" will appear (in case of alarm). If an alarm occurs, see on page 76.

(If an error occurs, identify the causes that generated it, take the necessary precautions before working on the machine and repeat the process.)

6. Open the door, remove the devices and close the door;
7. At the end of the cycle the door cartridge holder opens automatically. Remove the cartridge and dispose it in accordance with the hospital waste disposal policies.

ATTENTION

With regards to the safe disposal of chemical products or their containers, please refer to regulations in force in the country where the appliance is installed.

ATTENTION

THE USE OF PERSONAL PROTECTION EQUIPMENT IS VERY IMPORTANT:
THE USER IS RESPONSIBLE FOR THE MACHINE SAFETY.
IN NO CASE STEELCO WILL BE HELD RESPONSIBLE IN THE EVENT OF ACCIDENTS (FOR EXAMPLE, EXPOSURE OF THE OPERATOR TO A HIGH CONCENTRATION OF H2O2).

5.6.3 Door

PL 130:

The machine is equipped with vertical sliding doors and it is made of 12 mm thick AISI 316L stainless steel, without welding and with a heating system.
The vertical movement of the door takes place thanks to a motorized drive chains system that guarantees silence and precision during the opening and closing phases. The thermal insulation ensures that the external temperature does not exceed 40°C.
The door is equipped with a “pinch guard” device which prevents the total closure in the presence of obstacles. The opening of the door can occur by foot pedal or from the control panel.
If the door remains open beyond the time set by the parameter, it will be notified by the acoustic signal and by a message on the display.
According to a pre-set parameter, the door will automatically close.

PL 70 – PL 40:

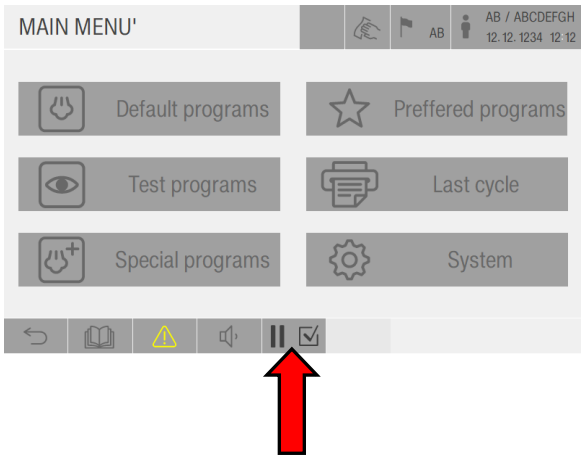
The hinged doors open manually and are made of AISI 316L stainless steel with a thickness of 12 mm. They are not welded and faired with carter in self-extinguishing expanded polyurethane.
They are equipped with heating system with electric resistances which distribute the temperatures homogeneously in the sterilization chamber and prevent points of potential condensation. The thermal insulation ensures that the external temperature does not exceed 40°C.
Unlocking of the doors opening occur by control panel.
If the door remains open beyond the time set by the parameter, it will be notified by the acoustic signal and by a message on the display.

	**ATTENTION**
	Regarding the PL 70 and PL 40, open and close the door only by acting on the handle.

	**ATTENTION**
	In the machine with pass-through doors, the simultaneous opening of both doors is not allowed. The sterile-side door opens only at the end of a cycle of treatment performed correctly.

Below are reported the cases of door locking/unlocking, according to the machine conditions:

MACHINE STATUS	SYMBOL	COL	POSSIBLE ACTIONS
OUT OF CYCLE	n.a.	n.a.	To open the doors, press the button on the control panel or the pedal (PL130); to open the doors press the button in the control panel and manually open it (PL70 e PL40).
ON CYCLE		green	During the cycle the doors remain closed.
CYCLE END NOT OK		red	In the passthrough version the door on the sterile side remains locked.
CYCLE END OK		green	In the passthrough version, unloading occurs only on the sterile side.



The symbol set for the door status representation is composed of two symbols.

The first symbol indicates the actual door status, while the second one indicates the enabled door.

Not closed door. It is possible to open and close the door.

Opened door. It is possible only the closure.

Closed door. It is possible only the opening.

Blocked door.

Opening door (flashing yellow).

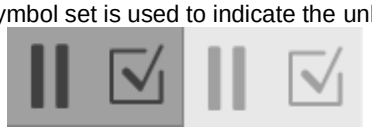
Closing door (flashing yellow).

Enabled door.

Disabled door due to running program.

Disabled door due to alarm.

In case of doble door machine, the same symbol set is used to indicate the unloading door status.



Push the door opening button:
-PL130 the door automatically opens;
-PL70 manually open the door;
-PL40 manually open the door.

5.6.4 Sterilization chamber

The chamber and doors are entirely surrounded by a bundle of electrical resistances which ensure homogeneous distribution of heat and a reduction of areas potentially subjected to condensation.
The load can be positioned in the two wire steel shelves, inserted on rails which make them extractable to facilitate the loading of the machine.

It is also possible to use the optional components (baskets and grids).

	ATTENTION
	Steelco recommends using only original components.

5.6.5 Printer

The sterilizer has a built-in printer located on the front.
It is possible to print reports on the cycle and the other information on thermal paper.
Paper loading is easy and does not require ink cartridges.

6. USE OF THE MACHINE (FOR THE USER)

6.1 Compatibility of materials – Sterilization warnings

Compatibility is defined as the ability of materials to withstand exposure to **vaporized hydrogen peroxide** without significant changes in their physical or chemical properties (i.e. without variations of resistance, flexibility, chemical composition, colour, etc.).
The following classifications are based on the experience of working with the materials.

MACHINE COMPATIBLE MATERIALS
METALS
• Stainless Steel • Aluminium • Titanium
NON-METALS
• Delrin • Latex • Nylon • Monel • Kraton • Teflon • Silicon • Phenolic resins • Glass • Neoprene • Acrylonitrile butadiene stirene (ABS) • Ethylene Vinyl Acetate (EVA) • Borosilicate Glass • Polyvinyl chloride (PVC) • Polyethylene (PE) • Polymethylmethacrylate (PMMA) • Polyetheretherketone (PEEK) • Polyetherimide (ULTEM) • Polycarbonate (PC) • Polypropylene (PP) • Polyetherimide (PEI) • Polyethylene terephthalate (PET) • Polysulfone • Polystyrene • Polyphenyl sulphone • Polyolefin • Polyurethane (PU)

MATERIALS NOT TO BE PROCESSED IN THE MACHINE

- Disposable devices for which the manufacturer does not recommend sterilization
- Liquids and powders
- Oils
- Wadding
- Items or materials which absorb liquids
- Objects made of materials which contain cellulose, such as for example: cotton, paper or cardboard, fabrics, raw cloth, gauze or any item containing wood pulp
- Equipment counting sheets or batch labels made of paper
- Articles with coupled Nylon surfaces
- Tools and devices that cannot withstand the vacuum and which can be sterilized exclusively with gravity steam methods
- Items with a structure which causes their surfaces to adhere to one another, unless there is a method to keep the surfaces separate.
- Devices containing internal parts, such as sealed supports, may present not efficient sterilization.

6.2 Instruments preparation

In order to be correctly re-processed inside the PL 40, PL 70 and PL 130 systems, the instruments must first be cleansed and washed manually or by automated washing process.

	**ATTENTION**
	<u>Handle</u> the instruments following the manufacturer's instructions. ***Disassemble them if necessary and allowed. Subsequently remove the organic material manually or mechanically.***
	<u>Rinse</u> well to remove soap residue. ***If all organic materials and soap are not removed, it may affect the process.***
	<u>Dry</u> the instruments completely with compressed air. ***The chamber must contain only dry instruments.*** ***If the machine detects a high humidity, the machine will abort the cycle.***

	**ATTENTION**
	Wear chemical-resistant gloves when handling unloaded instruments containing humidity.
	A careful periodic inspection of the items after repeated exposure to the sterilizing agent is necessary because of the potential harmful effects of the chemical agent on the items.

6.3 Packaging and loading

PACKAGING:

- For packaging use envelopes in Tyvek and/or sheets of non-woven fabric SMS/SMX type.
  It is also possible to use containers dedicated to the vaporized hydrogen peroxyde sterilization.

Tyvek roll

SMS sheets

- Do not use paper bags or packaging sheets containing cellulose or cotton;
- Do not use any material listed in the section "Materials not to be processed" (see chapter 6.1).
- Correctly arrange the items in the basket/tray to ensure an adequate diffusion of the vaporized hydrogen peroxide to the entire load;
- If possible, arrange the bags sideways. Arrange them so that the transparent side of one bag is facing the transparent side of the next one. The hydrogen peroxyde penetrates inside the envelope from the matt side.
- Do not stack envelopes one above the other.
- When possible, place the heavy load on the lowest shelf.
- Place strip chemical indicators inside the bags (one for envelope).

	**ATTENTION**
	Always refer to the manufacturer instruments packaging requirements of the instruments treated.

LOADING:

The user is responsible of his/her own knowledge concerning the preparation of loads and the safety information provided in this operational manual.

1. Turn on the ON/OFF switch located on the right side front panel of the sterilizer.
2. The sterilizer will start the warm-up phase, which may take up to 30 minutes.
3. While the sterilizer is warming up, you can use this time to prepare the load. For information on preparing the load, please read the corresponding chapter 6.2.
4. At the end of the warm-up phase, open the door and arrange the devices on the shelves. It is possible to load the machine also during the warm-up (see chapter 8.2).
   If necessary, the upper shelf can be removed to accommodate a large load on the lower surface.
5. Check that the load is positioned in the centre of the shelves to allow the gas to circulate correctly inside the chamber and into the containers.
6. Do not place the loading close to the walls.
7. Do not overload the chamber.

ATTENTION

Respect the maximum acceptable load for each cycle indicated in chapter 5.1.

8. Once the chamber is loaded, close the door. Make sure that nothing is stuck by its door seal.

6.4 Indicators

LOAD VALIDATION

Check each cycle through the appropriate chemical indicators (one for each pack and pouch Type 1 or Type 4) and test the device with biological tests at least on a weekly basis and in accordance with the guidelines applicable to the Central Sterile Supply Departments (CSSDs) (see chapter 5.4).

- **CHEMICAL INDICATOR**

Chemical indicators provide a method to verify that the load has actually been exposed to the hydrogen peroxide in the sterilizer.
Chemical indicators are not a substitute for biological indicators.

- **BIOLOGICAL INDICATOR**

Biological indicators help monitoring the sterilization cycle and correct functionality of the sterilizer.
For the test cycle with biological indicators, follow the instructions in paragraph BIOLOGICAL TEST without instrument (see chapter 6.4.2).

6.4.1 At each cycle – with instrument

For the control of the sterilization processes, insert chemical indicators inside the Tyvek bag or in the specific container/package.
At the end of the cycle check that the colour of the indicator changed from red to yellow (Type 1) and from purple to green (Type 4):

It is recommended to use also a biological indicator (type 24 h or 30 min) at each cycle previously bagged.

	ATTENTION
	IF THE TEST PROVE IS FAILED, THE CYCLE NEEDS TO BE REPEATED.

6.4.2 At least on a weekly basis – BIOLOGICAL TEST without instrument

Place a biological indicator in the chamber type 24h or 30 min (see on page 29), on the back of the bottom shelf. The biological analysis should be performed at least once a week or as specified by the procedures of your own healthcare facility.
Refer to the Instructions for use provided with the biological indicator to ensure proper usage.

1. **Prepare the biological indicator**
2. **Seal it within the Tyvek bag by inserting a chemical indicator**
3. **Process the biological indicator**
4. **Break the test tube**
5. **Incubate the test tube for 24 hours or 30 minutes following the type**
6. **Check that the liquid colour did not change (changing colour indicates the presence of bacterial growth) in case of biological indicator 24h or wait for the result printout ("NEGATIVE") in case of rapid biological indicator 30 min.**

	ATTENTION
	Check the validity of the indicators and biological tests before use.

6.5 End-of-cycle unloading

At the end of the *correctly* performed cycle, you can unload the instruments (from the sterile side in case of two doors machine version).
At the end of the *incorrectly* performed cycle you can unload the instruments only from the loading side.

	ATTENTION
	**The cartridges should be stored at a temperature between +5°C and +30°C.** **The hydrogen peroxide is corrosive to the skin, eyes, nose, throat, lungs and gastrointestinal tract.** **Always wear chemical resistant gloves when removing items from the sterilizer.** **As a result of a wrong procedure, if at the end of the cycle the items loaded clearly show the presence of humidity or liquids, hydrogen peroxide may be present.** **The shelf life is 12 months (5°C ÷ 30°C).**

After making sure that the chemical and biological indicators display the correct colour change and that the cycle report indicates that all necessary cycle settings were correctly observed, the sterilized load is will be ready for immediate use, in accordance with the procedures set by the healthcare facility where the machine is being used.
If the chemical and/or biological indicators do not display the right colour change, inspect the cause, re-package, and repeat the treatment of the load.

The sterilized material must be adequately treated and stored to maintain its sterile status until the next use. Inadequate storage conditions can cause a future contamination of the material.

7. WORKING PROCEDURES

7.1 Introduction

The machine has been designed built only and exclusively for low temperature vaporized hydrogen peroxide sterilisation of packaged medical devices suitable to the process.
It is therefore subject to continuous contact with a chemical agent and with contaminated instrumentation.
For this reason, it is necessary to provide some useful indications for the operators responsible for its use.

7.2 Instructions to personnel

The operator responsible for the use of the machine in normal operating conditions, is not exposed to risks if he/she works in safety using the appropriate means of protection.
In order to operate safely the operator must:

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

The personnel in charge of maintenance in normal working conditions, is not exposed to risks if they work in safety using the appropriate 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 and the group and individual safety gear provided in the workplace.
- Use special care and attention in the event of repair and replacement of mechanical parts on malfunctioning machines which have not completed the sterilization cycle.

8. CONTROL PANEL AND SYMBOLS USED

8.1 Emergencies

EMERGENCY BUTTON

The PL130 is equipped with two non-automatic reset emergency stop buttons:

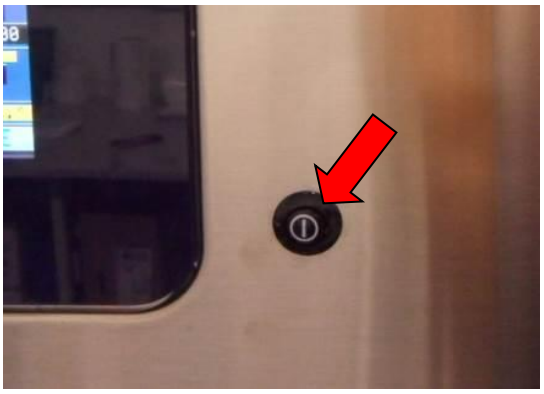
- No. 1 emergency button located on the loading side;
- No. 1 emergency button located on the unloading side (only pass-through machines);

The red emergency button is located in an easily accessible position, yet sufficiently protected from accidental actuations.

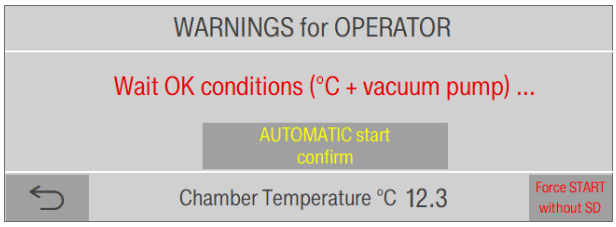
8.2 Power On/Off

Turn on the machine by following the procedure:

- Press the ON/OFF button as shown in the following figure.



- The control panel will automatically start.
- Login by typing the code and relative password. After the data entry, press the LOGIN button. If it is the first login, it will appear the change password pop-up.
- If the operator tries to start a cycle, the following message will appear.

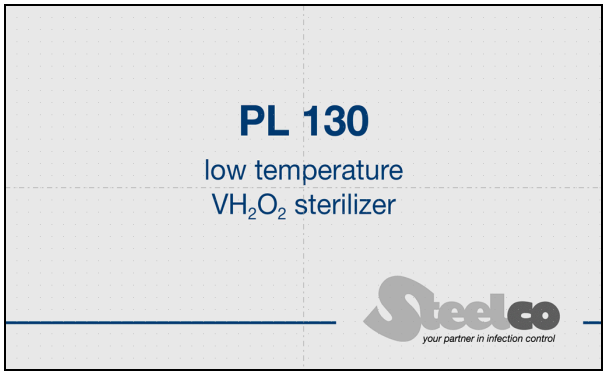


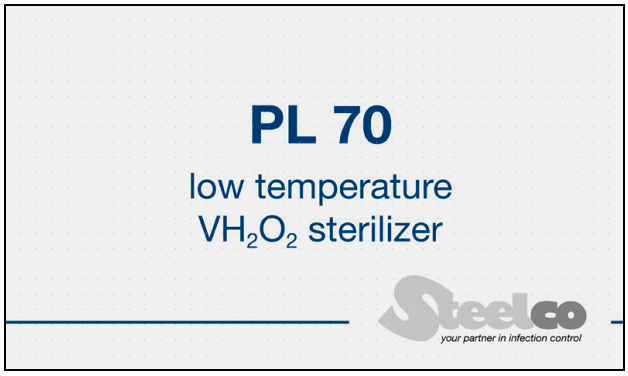
- The operator can prepare the load inside the machine and push the button “AUTOMATIC start confirm”. The cycle will automatically start when the fixed settings have been reached.
  The machine is checking the chamber temperature and pump conditions.
  These controls will take 30 – 40 minutes.
- Check that there are no alarm messages. If there are, remove them by pressing the button  and consequently “Reset”.

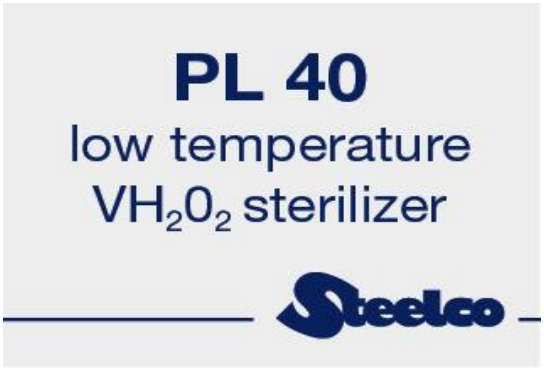
Switch off the machine by pressing the same button.

8.3 Control panel (loading side)

The control panel is composed of an LCD “Touch-screen” monitor.
The LCD monitor, depending on the program/management status position, displays keys that can be selected by pressing the display area and which control specific control functions.







8.4 Control panel unloading side (if present)

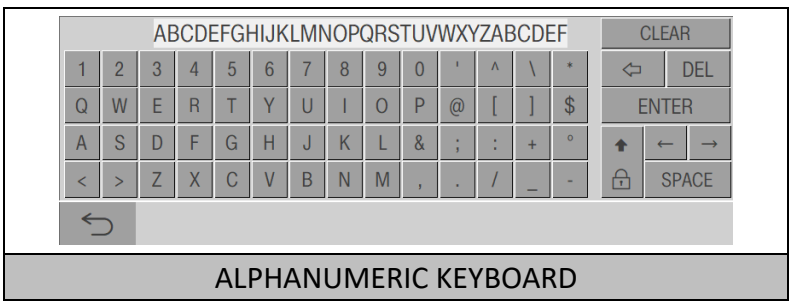
In case of double door unit, the machine is equipped with an additional control panel.
The displays and functions of this panel are limited compared to the loading side panel; by using this panel, the user can only:
- display the page of the current cycle;
- reset any active alarms;
- open and close the door at the end of the cycle.

8.5 Keyboards

The control system uses two types of keyboards: a keyboard for typing and a numeric keypad to enter numbers.

ALPHANUMERIC KEYBOARD

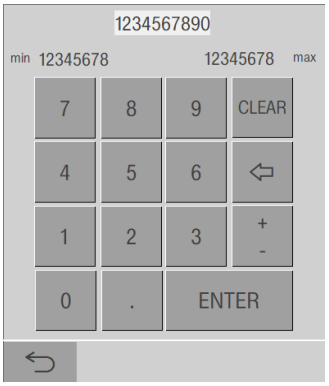
To type a text, press the key sequence you want and press the enter key.
The "BS" key deletes the character before the cursor, while the "DL" key deletes the character that follows the cursor. At the end of the insertion, press the “END” key to close the keyboard.



ALPHANUMERIC KEYBOARD

NUMERIC KEYBOARD

To type a number, press the key sequence you want and then press the button "ENT".
At the end of the insertion, press the “INPUT END” key to close the keyboard.
The values reported above the numeric keypad indicate the limit values accepted by the field in which you are entering the number.



NUMERIC KEYBOARD

9. LOGIN PASSWORD

Password protection prevents any unauthorized users from accessing critical functions and/or controls which may compromise the correct functioning of the machine and its safety conditions.
For safety reasons, some machine settings and/or functions can only be accessed by inserting the corresponding password.

The levels of security are the following:

- **Operator level**
- **Foreperson level**
- **Maintenance technician level**
- **Supervisor Level**
- **Manufacturer level**

10. OPERATION

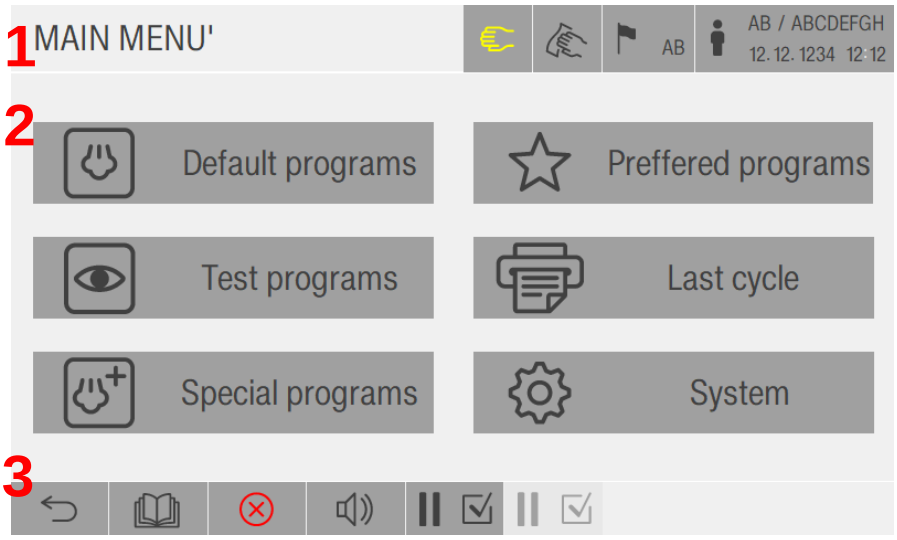
10.1 Home page

When the machine is switched on, it appears the main page.

The screen is divided in 3 sections: Rif.1 – upper section

Rif. 2 – main body

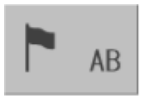
Rif. 3 – lower section



In the upper section there is the viewed screen title and a symbol set, which are described below:

The machine is in manual control.

Disable the screen function to allow the surface cleaning.



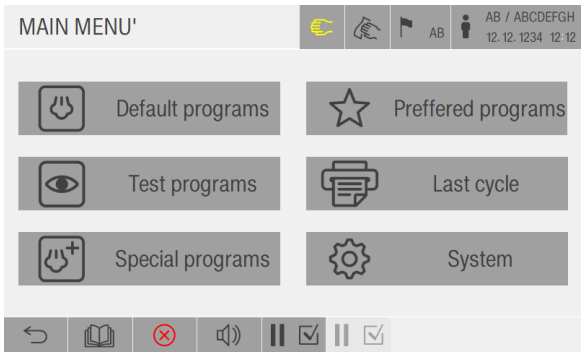
This function allows to choose the language.

This function allows the login/logout and it indicates the logged operator name with relative group. Indeed, it is indicated the date and hour.

In case of running program, the following symbol will appear:

SYMBL	COLOUR	DESCRIPTION
	green	WORKING CYCLE
	red	ALARM DURING A CYCLE
	yellow	The working program has been interrupted, therefore the result is negative.
	green	Program completed with success.
	red	Program not completed with success.
	yellow	Program finished, it has occurred a program interruption.

In the lower section there are different symbol set, which are described below:

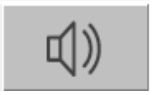


Allow to go back to the previous screen.

Allow to go back to the previous screen of the main menu.

Only in case of active alarm or warning

If the symbol is red, there are some alarms. Press to view the list.
If the symbol is yellow, there are some warnings. Press to view the list.



In case of alarm, it allows to switch off the buzzer, if this function is enabled by the parameter.

View the loading door status.

View the unloading door status (in case of double door machine).

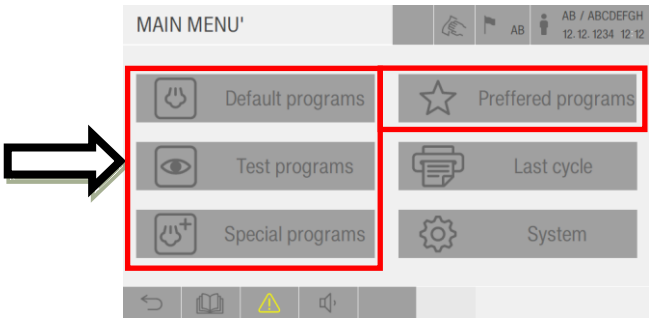
This button can have different functions based on the viewed screen.
In view pages or data input pages it has the confirm function.
In parameter pages it allows the save.

10.2 Sterilization

This menu allows the user to select the appropriate sterilization cycle and start it.

Follow the steps below:

1. Switch on the equipment by acting on the ON/OFF button (Ref. paragraph Power On/Off).
   The chamber preparation will take about 30 minutes.
2. In the screen MAIN MENU press the program you want to start.



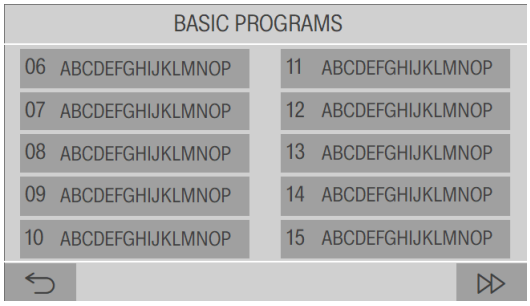
DEFAULT PROGRAMS Allow to select and execute a default program.

TEST PROGRAMS Allow to select and execute a test program.

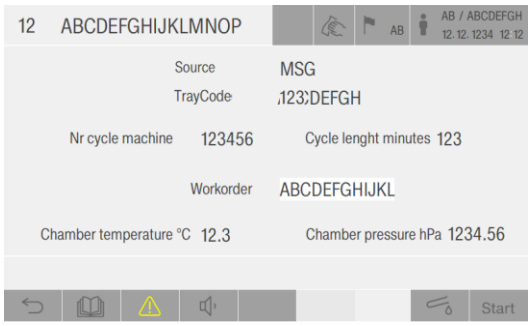
SPECIAL PROGRAMS Allow to select and execute a special program.

PREFERRED PROGRAMS Allow to select and execute a program from the group of preferred programs.

For example, if we choose “basic programs”, it will appear the following screen.



3. Press the desired program to access the start cycle screen



Source: It indicates the selection mode of the program that automatically appears:
-PROGRAM CHOICE selected by the operator
-CYCLE SCHEDULING automatic start
-PROGR.FROM BARCODE/RFID scan from barcode.

Nr cycle machine: It indicates the counter of the progressive number of cycles performed.

Cycle length minutes: It indicates the length of the selected program.

Workorder: It indicates the workorder created for the program, after pressing the START button.

Chamber temperature °C Reached temperature inside the chamber.

Chamber pressure hPa Reached pressure inside the chamber.

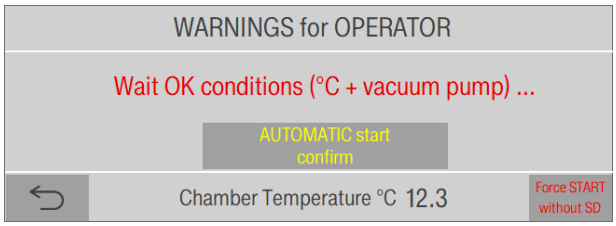
ATTENTION: in case of installed BARCODE reader or RFID reader (both optional), it will be possible to read the operator code in order to login and to read the sterilization cycle code for the cycle selection.

BARCODE READER

RFID READER

4. Press the button Start with the flashing writing.
   If the writing is grey, it is possible to create a workorder and do the checks for the cycle start.

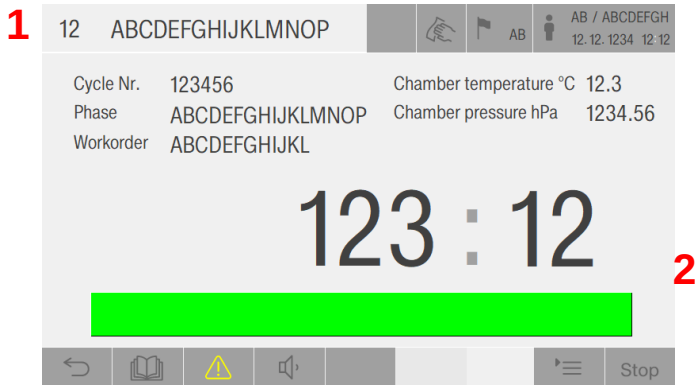
If there are conditions under which the program cannot be started, a popup displays a message for the operator.



Press the button with the writing “AUTOMATIC start confirm”.

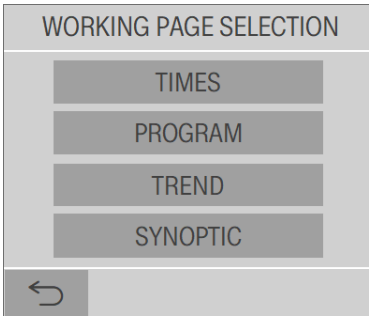
If there are no conditions under which the program cannot be started, after pressing the START button, the following popup appears. Then it will display the running program screen.

5. The screen “**WORK STATUS**” appears.

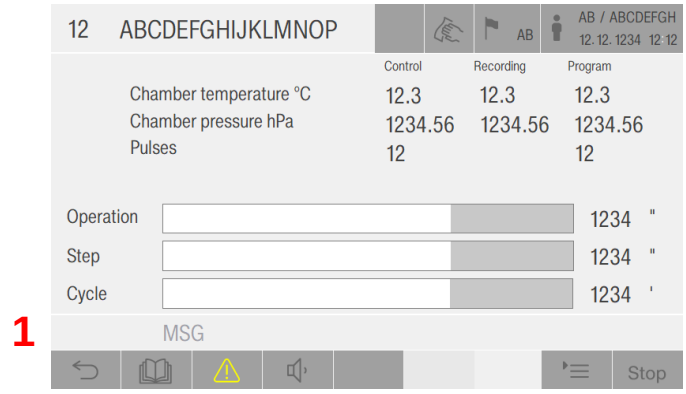


Rif. 1	It indicates the number and name of the selected program.
CYCLE NR	It indicates the counter of the progressive number of running program.
PHASE	It indicates the name of the running phase.
WORKORDER	It indicates the workorder code of the running program.
CHAMBER TEMPERATURE °C	It indicates the current chamber temperature.
CHAMBERA PRESSURE hPa	It indicates the current chamber pressure.
Rif. 2	It indicates the missing time and the elapsed time bar.

In the lower bar, the button  allows to scroll the pages, which display the data of running program.



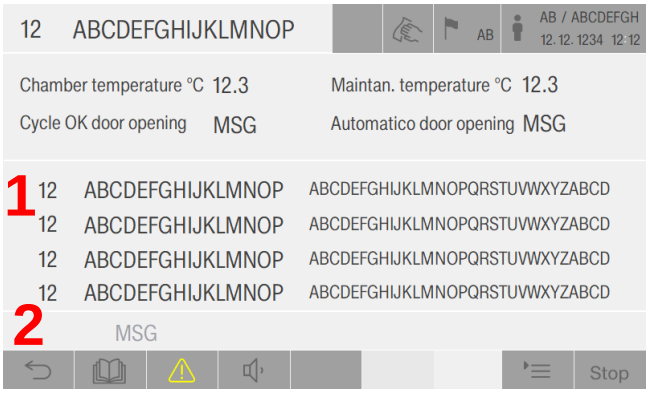
TIMES



This screen displays the machine status during the cycle.

CHAMBER TEMPERATURE °C	It indicates the current chamber temperature (registration and control) and the setpoint temperature.
CHAMBER PRESSURE hPa	It indicates the current chamber pressure (registration and control) and the setpoint pressure.
PULSES	It indicates the current number of pulses.
OPERATION	It indicates the missing time and the elapsed time bar for the operation ongoing.
STEP	It indicates the missing time and the elapsed time bar for the step ongoing.
CYCLE	It indicates the missing time and the elapsed time bar for the program.
Rif. 1	The message of the step ongoing.

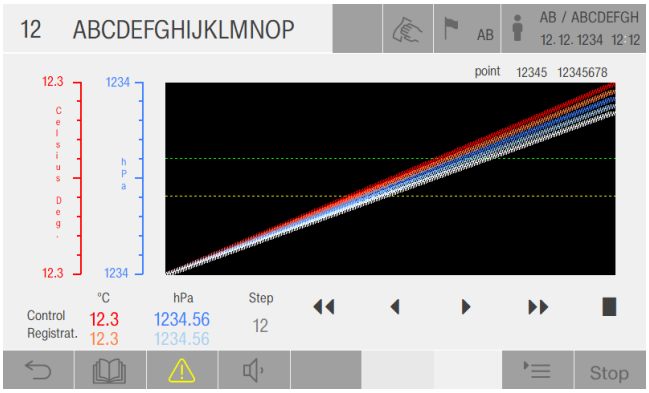
PROGRAM



CHAMBER TEMPERATURE °C **CYCLE OK DOOR OPENING** **MAINTAN. TEMPERATURE** **AUTOMATIC DOOR OPENING**	It indicates the parameters setting.
Rif. 1	It indicates the phases list composing the working program. The working phase is underlined and it is possible to enter the specifications of each single phase by pushing on it.
Rif. 2	It indicates the message of the working phase.

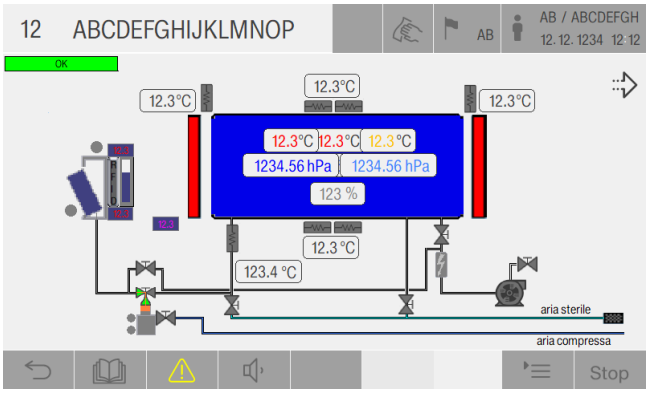
TREND

By pressing the button "**TREND**" the user will enter the page that shows in graphical form the data recorded by both the control system and the recording system.
By pressing on one of the arrows below the graph it is possible to move inside the same with a cursor.
By selecting the cursor, the user can display the temperature and pressure physical settings present in the chamber (data on the lower left-hand side). To reposition the cursor at the end of the graph press the button identified by a rectangle.
.

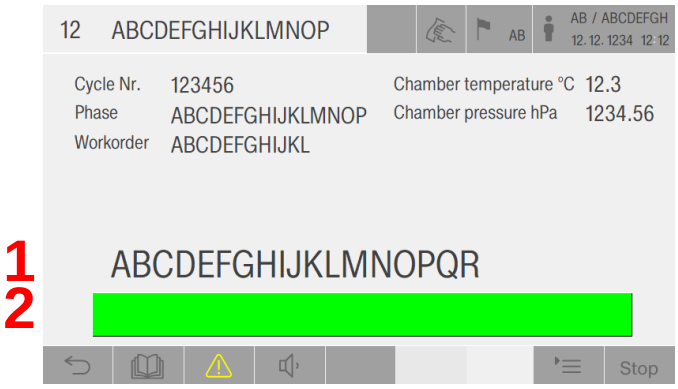


SYNOPTIC

The status of all the input and output channels is described in graphic form in the screen “SYNOPTIC”.



At the end of the working program, the following screen appears, showing the program result.

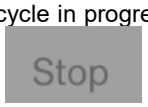


Ref. 1 It indicates the program result, which can be:
COMPLETED OK, COMPLETED NOT OK, INTERRUPTED

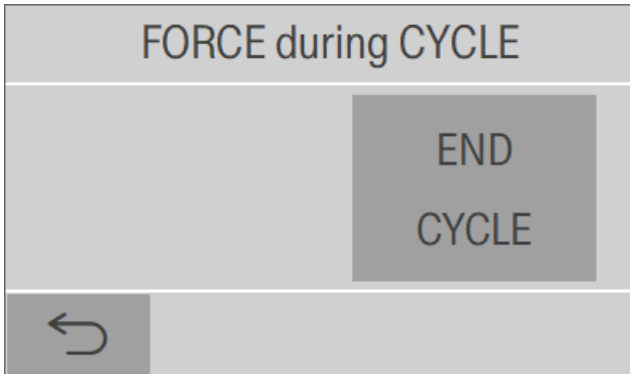
Ref. 2 It indicates graphically the program result, which can be:
GREEN for the result COMPLETED OK
YELLOW for the result COMPLETED NOT OK
RED for the result INTERRUPTED

If the cycle successfully ended, when the door is opened to perform the unloading, the control panel returns to the main page.

If during the execution of the cycle occurs a voltage drop, apply the procedure described in chapter 10.5 “Restore operation after voltage drop”.
In the event of an alarm during the cycle, refer to chapter 11 “Alarms and events list”.

In order to stop the cycle in progress, if the parameter “PHASE/CYCLE END” (SYST. DATA - 1) is set to YES, the user can press the button 

and the following popup will be displayed:

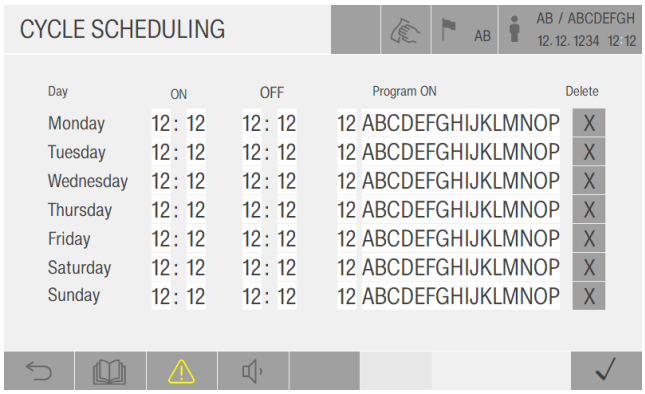


Press the button “END CYCLE”. In default conditions, the machine ends the cycle and starts aeration;

On the upper screen section, it appears the symbol 

10.2.1 Automatic preparation (Optional)

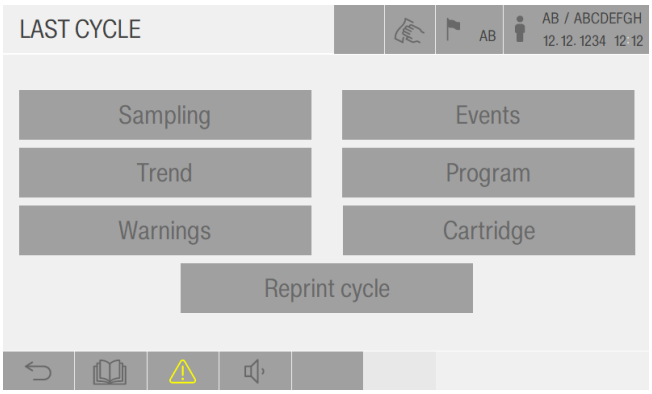
The automatic preparation function allows to set the automatic start time of selected cycle for each day of the week.
It is activated only if parameter “WORK Choice” (Syst. data – page 1) is set to “CYCLE SCHEDULING”.
To access the relative page: MAIN MENU → SISTEM → SETTING → Cycle scheduling



Press one time the button X to delate the selected program.
If this button is pressed twice, the time will be deleted.

10.3 Last cycle

To enter the “LAST CYCLE” menu, simply press the corresponding button from the main menu. This menu allows to display and print the information regarding the latest sterilization cycle performed by the machine.

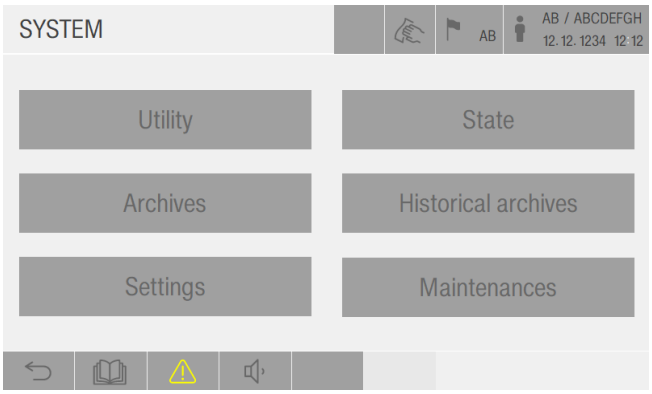


The options that can be activated are:

SAMPLING	Allows to print or check the samplings of the last cycle performed also establishing the sampling interval.
EVENTS	Allows to print or check the events relating to the last sterilisation cycle performed.
TREND	Allows to graphically visualize the data recorded by both the control and recording systems.
PROGRAM	Allows to view the cycle details.
WARNINGS	Allows to view the cycle warnings.
CARTRIDGE	Allows to view the cartridge information.
REPRINT CYCLE	Allows to choose to reprint the last sterilisation cycle recorded by the control or the recording system. Furthermore, this option allows to reprint the graphic chart with the pressure and temperature readings.

10.4 SYSTEM

To enter the “SYSTEM” menu, simply press the corresponding button from the main menu. This menu allows to access the configuration and management pages of the machine.



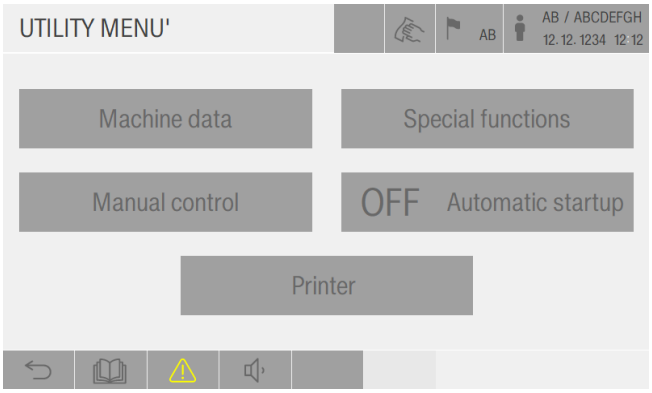
The options that can be activated are:

UTILITY	Allows the access to the utility functions of the machine.
STATE	Allows the access to the pages of the machine status.
ARCHIVES	Allows the access to the creation and management functions of the programs and operator archives.
HISTORICAL ARCHIVES	Allows the access to the alarms, programs, and service historical archives pages.
SETTINGS	Allows the access to machine setting parameters pages.
MAINTENANCE	Allows the access to machine management and service pages.

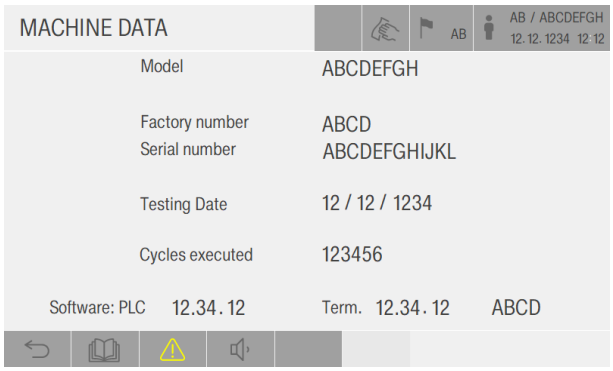
10.4.1 Utility menu

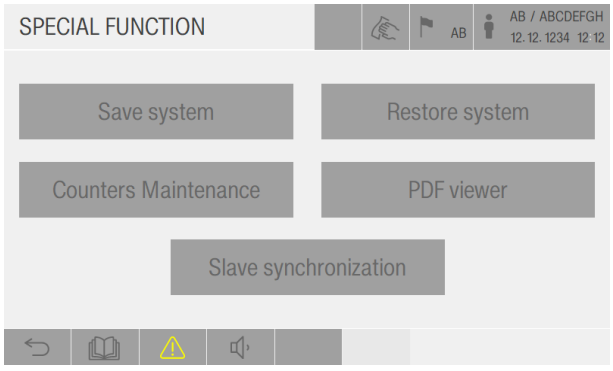
To enter the menu "**UTILITY**" press the SYSTEM button in the MAIN MENU.

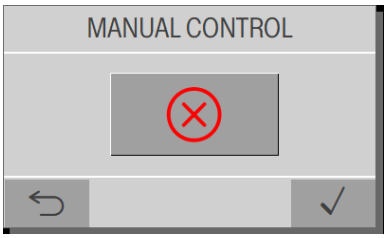
This menu allows you to display and print information regarding the sterilizer and its status, and allows to perform a series of useful operations for using the printer.



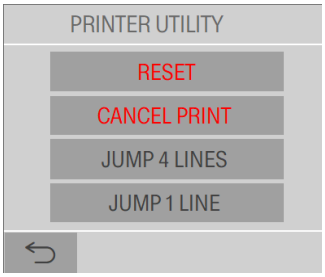
The options that can be activated are::

MACHINE DATA	Allows to display the sterilizer ID data.
The data displayed are: ➢ sterilizer model; ➢ serial number of the sterilizer; ➢ commissioning date of the sterilizer; ➢ software version installed on the PLC; ➢ software version installed on the Touch-screen terminal;	

SPECIAL FUNCTIONS	Allows to access the special function only to a high-level user.
➢ Save system; ➢ Restore system; ➢ Counters Maintenance; ➢ PDF viewer; ➢ Slave synchronization.	

MANUAL CONTROL	Allows to enable the manual control
By pressing this button, a popup is displayed, which allows the activation of the manual control, if the login level of the logged user allows it.	

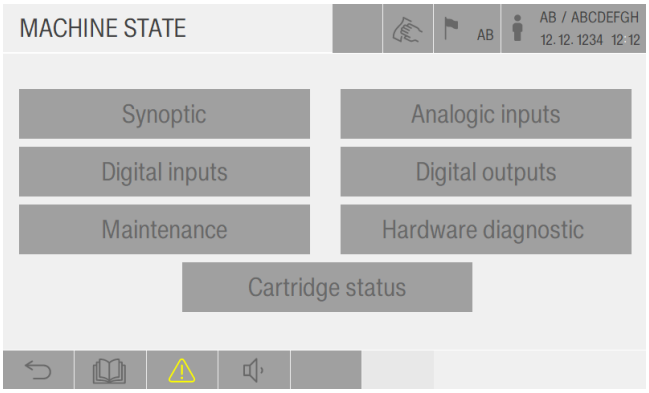
AUTOMATIC STARTUP	See chapter “Automatic preparation”.

PRINTER	It allows to execute some operation on the printer from the panel control. The possible actions are:
	➢ RESET: resets printer hardware and initializes the same (with this procedure the printer is set up to be used by the control system). ➢ CANCEL PRINT: cancels the current print job; ➢ JUMP 4 LINES: the printer will skip four lines; ➢ JUMP 1 LINE: the printer will skip one line.

10.4.2 Status

To enter the menu "**STATUS**" press the SYSTEM button in the MAIN MENU.

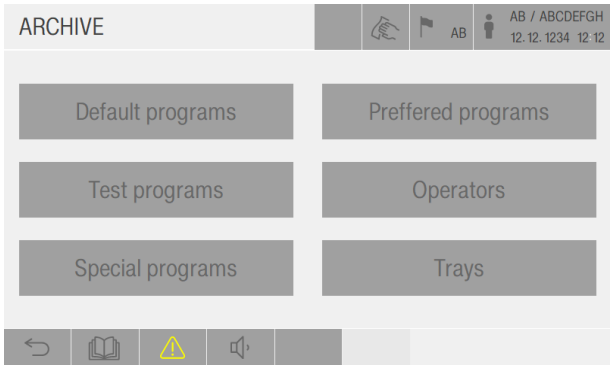
This menu allows you to access the machine status pages.



SYNOPTIC	Allows to view the machine synoptic, and if the manual control is active, to enable the different outputs.
ANALOGIC INPUTS	Allows to view the status of the different analogic inputs.
DIGITAL INPUTS	Allows to view the status of the different digital inputs.
DIGITAL OUTPUTS	Allows to view the status of the different digital outputs and, if the manual control is active, to enable them.
MAINTENANCE	Allows to view the data of the last performed maintenance work.
HARDWARE DIAGNOSTIC	Allows to view the results of the hardware diagnostic.
CARTRIDGE STATUS	Allows to view the data of used cartridge.

10.4.3 Archive

This page allows to access to the creation and management functions of programs and operators.



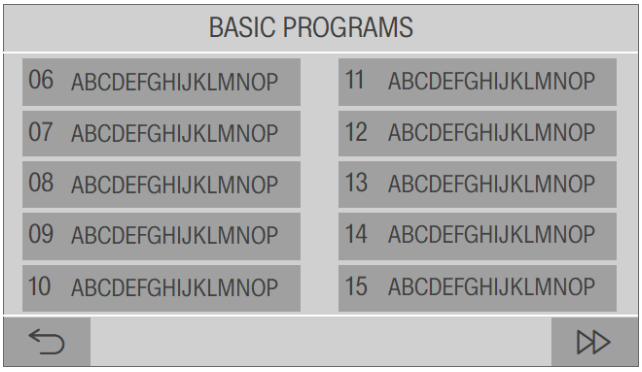
PROGRAMS

Select the group to be connect to the concerned program.

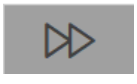
DEFAULT PROGRAMS	Allows to create the default programs.
TEST PROGRAMS	Allows to create the test programs.
SPECIAL PROGRAMS	Allows to create the special programs.
PREFERRED PROGRAMS	Allows to group a set of the most used programs.

After choosing the type of the new program, it is necessary to press the relative button.

It will be displayed a pop-up, which allows to select the position of the created program.

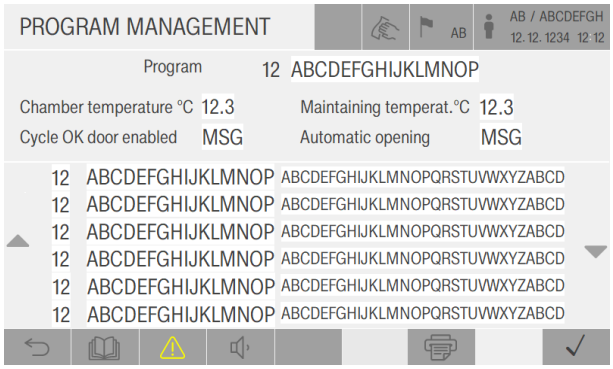


Go back to the previous page. The viewed pop-up disappears.



Not viewed during the program creation phase.

After defining the program saving position, the following page appears:



PROGRAM — Define the program name.

CHAMBER TEMPERATURE °C
MAINTAINING TEMPERAT. °C — These parameters define the temperature inside the chamber.

CYCLE OK DOOR ENABLED
AUTOMATIC OPENING — These parameters define the enabled doors according to the program result.


These arrows allow to move in the list of phases, which compose the program.

PHASES LIST — Allows to enter the different phases, which compose the program, indicating the phase type and some particular parameters.

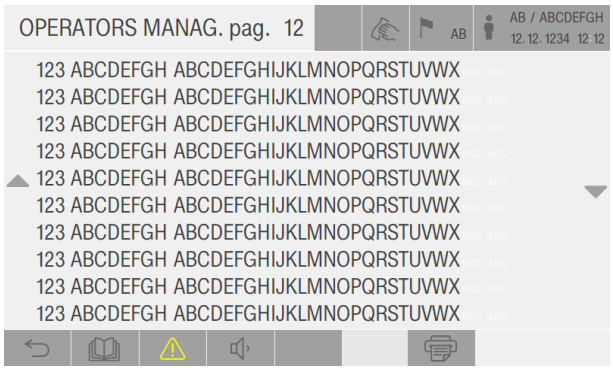
Allows to print the selected program, if a printer is present.

Save the program changes in the relative saving position.

After choosing the desired phase, it is necessary to press in the right section in order to access to the relative pop-up for entering the particular parameters of the selected phase.

OPERATORS

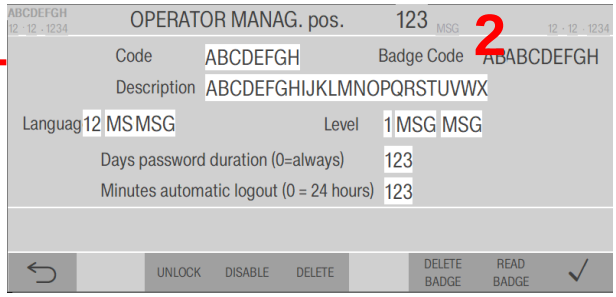
This page allows to manage the operators archive, being able to create new operators. It displays the name of the operator on each line.



The information given in the table:

- Operator code.
- Operator name.
- Level of membership of the operator.
- Operator status (QUALIFIED, DISABLED).

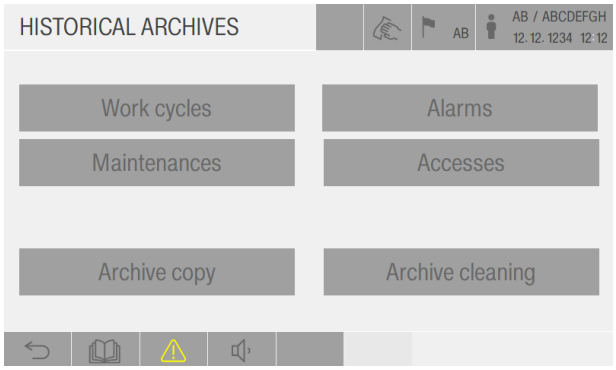
By clicking on a free field, you can enter a new operator, while clicking on a filled line, it is possible to change the data and delete the operator. In both cases, the following pop-up appears.



Ref. 1	It indicates the date of user creation.
Ref. 2	It indicates the operator status: QUALIFIED, DISABLED, STUCK.
CODE	It indicates the code linked to the created user. At the creation, it is linked to a generic password, which will be changed at the first log-in.
BADGE CODE	N.A.
DESCRIPTION	It indicates the operator name.
LANGUAG	It indicates the language linked to the operator.
LEVEL	It indicates the level of access to the various machine menu.
DAYS PASSWORD DURATION	It set the number of validity days for each new inserted password.
MINUTES AUTOMATIC LOGOUT	It set the minutes after which the operator will be automatically disconnected.
UNLOCK	It allows to unlock the operator. Allowed to a higher level of user.
DISABLE	It allows to disable the operator. Allowed to a higher level of user.
DELETE	It allows to delete the operator. Allowed to a higher level of user.

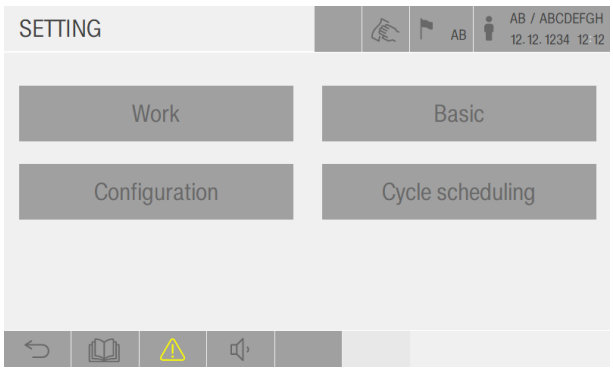
10.4.4 Historical Archives

This page allows the access to the historical archives of the alarms, work cycles, maintenances.



10.4.5 Setting

To enter the "**SETTING**" menu press in the SYSTEM button on the main menu.
This menu is protected by password; therefore, it is accessible only by responsible personal, which have got the password.



10.4.6 Parameter list

DESCRIZIONE - DESCRIPTION	NOTE - NOTES
Programma lavoro *Work program*	Nota: per entrare nel menu cliccare su "???" *Note: to enter the menu click on "???"*
Fine fase / Fine ciclo Abilita il pulsante di fine fase/fine ciclo ***End phase/End cycle*** *Enable the button to force the end of the phase or of the cycle*	
Avvio ciclo senza SD-CARD Permesso di avvio ciclo anche se la SD Card non è presente o è in allarme ***Start without SD CARD*** *Allow to start a cycle without SD Card or with CF Card damaged*	
Stampa grafico in ciclo ***Print cycle graph***	
Stampa eventi a fine ciclo ***Print events at end cycle***	
Stampa programma in ciclo ***Print program body in cycle***	
Sensibilità carta stampante ***Printer paper sensibility***	
Abilitazione blocco RFID Abilita il blocco RFID ad avvio ciclo che controlla la validità del tag per consentire l'avvio del ciclo ***Enable RFID block*** *Enable the check of the RFID tag before the cycle start and do not allow the cycle start if the code is not valid*	
Temperatura bassa riferimento °C ***Low reference temperature °C***	
Temperatura alta riferimento °C ***High reference temperature °C***	
Riscaldamento immediato ***Immediate heating***	
Abilitazione stampante ***Enable printer***	
Abilitazione sistema registrazione ***Enabling registration system***	
Spegnimento display ***Display switching off***	
Programmi a tempo Abilita l'avvio automatico del ciclo	

DESCRIZIONE - DESCRIPTION	NOTE - NOTES
Timed programs *Enable the automatic start of the cycle*	
Abilitazione igrometro **Enabling hygrometer**	
Abilitazione segnali acustici ***Enable acoustic signals***	
Numero commessa automatico ***Automatic job number***	
Ora solare / Legale ***Legar/Solar time***	
Numero stazione ***Station number***	
Cliente ***Customer***	
Ubicazione ***Place***	
Gestione allarmi in ciclo Gestione in caso di allarme in ciclo ***Alarms management on cycle*** *Action to be taken if an alarm occurs during the cycle*	
Sistema stampa ciclo ***Cycle printout system***	
Blocco automatico porta ***Automatic door lock***	
Massimo numero tentativi login ***Maximum number of login attempts***	0=nessun limite *0 = no limit*
Minimo numero caratteri codice e password ***Minimum number of code and password characters***	
Durata operatore cancellato (giorni) ***Duration of canceled operator (days)***	
Default minuti LOGOUT ***Default minutes LOGOUT***	
Default validità password (giorni) ***Password validity default (days)***	
Minimo numero tipi di carattere per password **Minimum number of characters' types for password**	
Default tastiera alfanumerica ***Default alphanumeric keyboard***	
Operatore automatico all'accensione ***Automatic operator at power on***	
Operatore fittizio di Sistema ***System dummy operator***	
Limiti funzionali camera (°C) ***Chamber functional bounds (°C)***	
Limiti funzionali iniezione (°C) ***Injection functional bounds (°C)***	
Limiti di stampa (°C) ***Printout limits (°C)***	

	TOLL -	ZERO	SPAN
Camera (°C) ***Chamber (°C)***	9.0	0.0	0.0
Basso camera (°C) ***Lower heating (°C)***	0.5	0.0	0.0
Iniezione H2O2 (°C) ***Injection heating (°C)***	0.5	0.0	0.0
Porta carico (°C) ***Loading door heating (°C)***	0.5	0.0	0.0
Alto camera (°C) ***Higher heating (°C)***	0.5	-1.0	0.0

DESCRIZIONE - DESCRIPTION	NOTE - NOTES
Limiti funzionali trasduttore pressione alta H (hPa) ***High pressure transducer functional limits H (hPa)***	
Limiti funzionali trasduttore pressione alta H (hPa) ***High pressure transducer functional limits H (hPa)***	
Limiti stampa pressione (hPa) ***Pressure print limits (hPa)***	
Limiti funzionali igrometro % ***Functional limits hygrometer %***	
Correzione trasduttore pressione alta H (hPa) ***Correction of high pressure transducer H (hPa)***	
Correzione trasduttore pressione bassa L (hPa) ***Correction of low pressure transducer L (hPa)***	
Correzione temperatura camera (°C) ***Chamber temperature correction (° C)***	
Correzione trasduttore pressione alta H (hPa) ***Correction of high pressure transducer H (hPa)***	
Correzione trasduttore pressione bassa L (hPa) ***Correction of low pressure transducer L (hPa)***	
Tempo massimo 1 °C riscaldamento basso camera (") ***Maximum heating time for the lower chamber heating (")***	
Tempo massimo 1 °C riscaldamento iniezione (") ***Maximum heating time for injection heating (")***	
Tempo massimo 1 °C riscaldamento porta carico (") ***Maximum heating time for loading door (")***	
Tempo massimo 1 °C riscaldamento alto camera (") ***Maximum heating time for the higher chamber heating (")***	
Tempo massimo condizionamento apertura (") ***Maximum time for chamber conditioning (")***	
Tempo massimo comando porte (") ***Door control maximum time (")***	
Stand-by riscaldamento (') ***Heating stand-by activation (')***	
Tempo campioni TREND Tempo tra un campionamento e l'altro per il grafico in stampa **(")** ***Trend sampling time*** *Sampling time for the printed/shown graph* **(")**	
Tempo campioni ARCHIVI Tempo tra un campionamento e l'altro per l'archivio **(")** ***Data base sampling time*** *Sampling time for the saved data* **(")**	
Tempo sicurezza apertura porte (") ***Safety time for door opening (")***	
Tempo avviso porta aperta (") ***Door open warning time (")***	
Ritardo finecorsa cartuccia sbloccata (") ***Delay after the unlocking of the cartridge (")***	
Tempo sicurezza pressione punti bassi Extratempo di vuoto dopo il raggiungimento del valore di set **(")** ***Safety time for the low pressure points*** *Extratime to maintain ON the vacuum pump after the set point reaching* **(")**	
Tempo attivazione plasma (") ***Plasma activating time (")***	
Tempo massimo pressione assoluta bassa (") ***Maximum time to reach the low pressure value (")***	
Tempo massimo pressione assoluta alta (") ***Maximum time to reach the high pressure (")***	
Tempo controllo compressore (") ***Compressor control time (")***	

DESCRIZIONE - DESCRIPTION	NOTE - NOTES
Tempo riempimento circuito di dosaggio (“) **Dosing circuit filling time (“)**	
Tempo stabilizzazione °C stand-by (“) Tempo di attesa per la stabilizzazione della temperatura ***Stabilization time for temperature during stand-by mode (“)*** *Waiting time for temperature stabilization*	
Tempo attivazione pompa start-up (“) Tempo di accensione pompa per riscaldamento all’accensione macchina ***Activation time for vacuum pump (“)*** *Switch-on time of the heating pump when the machine is switched on*	
Tempo sicurezza dosaggio H2O2 (“) ***Dosage safety time for H2O2 (“)***	
Tempo sicurezza iniezione H2O2 (“) ***Injection safety time for H2O2 (“)***	
Tempo Massimo riscaldamento camera (‘) Tempo massimo riscaldamento macchina per il raggiungimento del set point ***Maximum chamber heating time (‘)*** *Maximum heating time to reach the set point*	
Tempo attivazione EV filtro olio (“) ***Oil filter activation time (“)***	
Tempo Svuotamento H2O2 plasma emerg. (“) Tempo Svuotamento H2O2 attraverso il plasma in fase di emergenza ***Emptying time for H2O2 on plasma emerg. (“)*** *Time H2O2 emptying through the plasma in the emergency phase*	
Tempo livello basso areazione emergenza (“) ***Emergency ventilation low level time (")***	
Tempo apertura elettrovalvola circuito lavaggio H2O2 *(“)* ***H2O2 washing circuit solenoid valve opening time (“)***	
Tempo chiusura elettrovalvola circuito lavaggio H2O2 *(“)* ***H2O2 washing circuit solenoid valve closing time (“)***	
Tempo sicurezza aria sterile *(“)* ***Sterile air safety time (“)***	
Tempo blocco porta – tempo massimo blocco porta *(“)* ***Door lock time - maximum door lock time (“)***	
Tempo sblocco porta – tempo massimo sblocco porta *(“)* ***Door unlock time - maximum door unlock time (“)***	
Tolleranza - apertura porta (hPa) Valore sotto il setpoint per l’apertura della porta ***Tolerance - door opening* (hPa)** *Value below the set point to allow the door opening*	
Tolleranza + apertura porta (hPa) Valore sopra il setpoint per l’apertura della porta ***Tolerance + door opening* (hPa)** *Value over the set point to allow the door opening*	
Temperatura camera fuori ciclo (°C) ***Chamber temperature out of cycle*** (°C)	
Temperatura iniezione fuori ciclo (°C) ***Injection temperature out of cycle*** (°C)	
Temperatura iniezione in ciclo (°C) ***Injection temperature during cycle*** (°C)	
Offset riscaldamento basso camera (°C) ***Offset lower chamber heating*** (°C)	
Offset riscaldamento porta carico (°C) ***Offset loading door heating*** (°C)	
Offset riscaldamento alto camera (°C) ***Offset higher chamber heating*** (°C)	
Numero cicli lavaggio iniezione H2O2 ***Number of H2O2 injection washing cycles***	
Limite minimo emergenza temperatura camera (°C) Temperatura cui cominciare a eseguire il controllo ***Emergency check minimum chamber temperature*** (°C) *Temperature to start the emergency temperature check*	
Limite minimo temperatura emergenza iniezione (°C)	

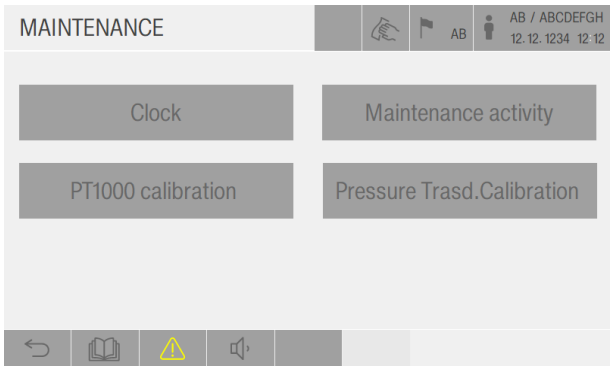
DESCRIZIONE - DESCRIPTION	NOTE - NOTES
Temperatura cui cominciare a eseguire il controllo ***Emergency check minimum injection temperature*** (°C) *Temperature to start the emergency temperature check*	
Limite minimo pressione atmosferica (hPa) **Minimum atmospheric pressure limit (hPa)**	
Massima incongruenza temperatura camera (°C) Massima incongruenza tra temperatura di controllo e registrazione ***Maximum chamber temperature disparity*** (°C) *Maximum disparity between control and recording temperature*	
Emergenza: numero impulsi aerazione ***Emergeny: impulses number areation***	
Emergenza: livello basso 1° impulso pressione (hPa) ***Emergency: low level 1st pressure impulse (hPa)***	
Emergenza: livello alto pressione (hPa) ***Emergency: high level pressure*** **(hPa)**	
Emergenza: livello basso pressione (hPa) ***Emergency: low level pressure*** **(hPa)**	
Massima incongruenza trasduttore pressione alta H (hPa) **Maximum inconsistency high pressure transducer H (hPa)**	
Massima incongruenza trasduttore pressione bassa L (hPa) **Maximum inconsistency low pressure transducer L (hPa)**	
Punto di scambio trasduttore L↔ H (hPa) ***Transducer exchange point L ↔ H (hPa)***	
Banda morta in scambio (hPa) ***Exchange dead band (hPa)***	
Minima pressione per allarmi trasduttori L (hPa) ***Minimum pressure for transducer alarms L (hPa)***	
Minima pressione per allarmi trasduttori H (hPa) ***Minimum pressure for transducer alarms H (hPa)***	
Numero attivazioni EV dosaggio ***Number of EV dosage activations***	
IP PLC	
Subnet mask	
Default router	
IP RFID	
Modello sterilizzatrice ***Sterilizer model***	
Numero fabbrica macchina ***Machine factory number***	
Numero matricula macchina ***Machine serial number***	
Data di Collaudo ***Test date***	
Codice logo ***Logo code***	
Massimo numero lingue ***Maximum number of languages***	
Stampa range pressione ***Print pressure range***	
Range inferiore pressione per stampa ***Lower pressure range for printing***	
Range superiore pressione per stampa ***Higher pressure range for printing***	
Intestazione stampa ***Print header***	
Macchina passante ***Double door machine***	
Stampante Tipo di stampante: a pannello o A4 ***Printer*** *Printer type: panel or A4*	
Controllo sequenza fasi ***Phase sequence check***	
Lettore barcode/RFID	

DESCRIZIONE - DESCRIPTION	NOTE - NOTES
Barcode/RFID reader	
Gruppo UPS ESTERNO ***EXTERNAL UPS group***	SI solo in presenza di gruppo UPS esterno collegato YES only in the presence of an external UPS group connected
Stampa range temperatura ***Print temperature range***	
Range inferiore temperatura per stampa ***Lower temperature range for printing***	
Range superiore temperatura per stampa ***Higher temperature range for printing***	
Sistema di registrazione ***Recording device***	
Stampa speciale ciclo ***Cycle special printout***	
Numero programma svuotamento cartuccia ***Cartridge emptying program number***	
Programmi a tempo ***Timed programs***	
Sistema di supervisione ***Supervisor system***	
Numero iniezioni per ciclo ***Injection number for each cycle***	
Capacità nominale cartuccia (ml) ***Full cartridge quantity(ml)***	
Quantità singola iniezione (ml) ***Single injection quantity (ml)***	
Igrometro ***Hygrometer***	
Giorni validità cartuccia da 1° inserimento ***Cartridge validity days from 1st insertion***	
Massimo numero iniezioni per cartuccia ***Maximum number of injections per cartridge***	
Massimo nr caratteri barcode cesto ***Maximum characters number basket barcode***	
Pressione vuoto finale su inizializzazione hPa ***Pressure final empty on hPa start-up***	

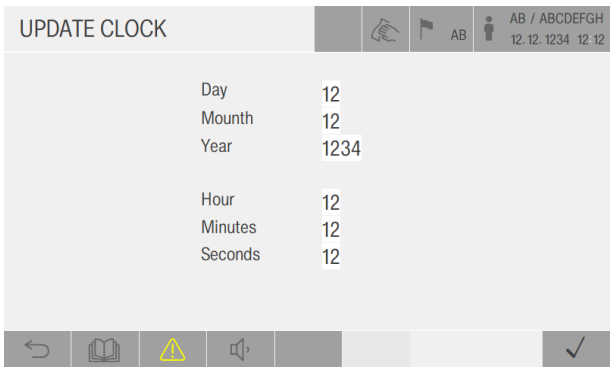
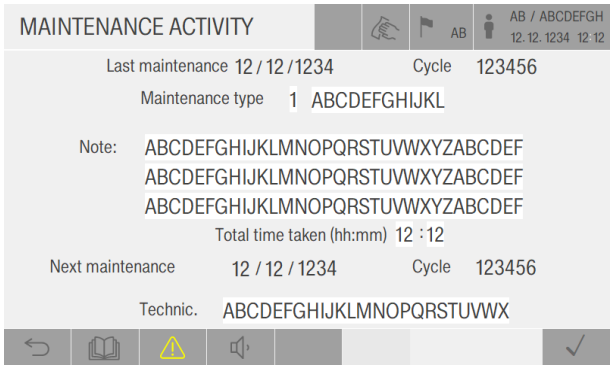
	TIPO *TYPE*
	CICLI *CYCLES*
1	600
2	1200
3	2400
4	0000

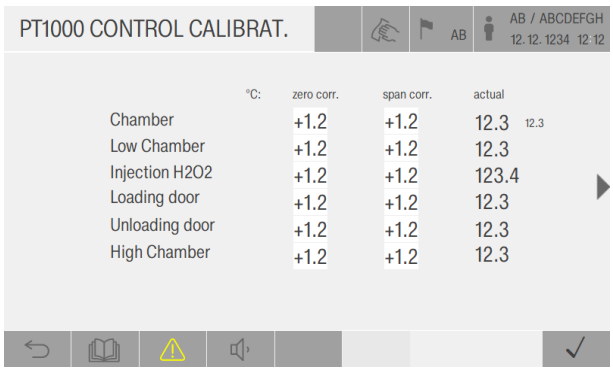
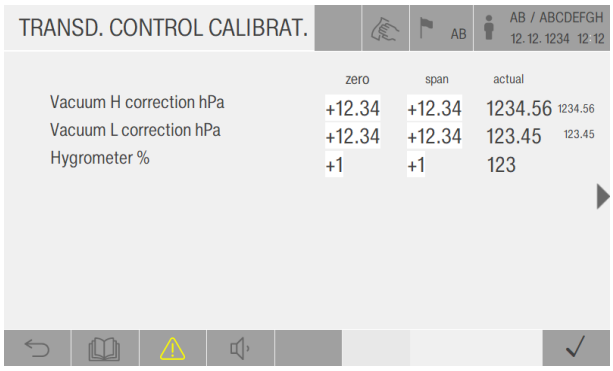
10.4.7 Maintenance

The “**MAINTENANCE**” menu is protected by password; therefore, it is accessible only by responsible personal, which have got the password.



From the main page of this menu it is possible to start the following activities:

“**UPDATE CLOCK**”: it allows to change the actual date and hour;	
“MAINTENANCE ACTIVITY” allows the operator to enter the date and the number of cycles provided for the next maintenance. Upon the occurrence of one of the two conditions, it will generate the service request. **Last maintenance:** Date of last maintenance. **Cycles:** N. of performed cycles from the last maintenance. **Maintenance type**: it indicates the type of maintenance intervention. **Note:** Maintainer notes relating to the maintenance carried out. **Total Time Taken (hh:mm):** Time spent for the maintenance. **Next maintenance:** Enter the date since the machine will generate the service request. **Cycles:** Enter the number of cycles that will generate the service request. **Technic.:** The name of the technician who has performed the maintenance.	

“PT1000 CONTROL CALIBRAT.” it allows the temperature probes calibration.	
“TRASD. CONTROL CALIBRAT.” it allows the control pressure probes calibration.	

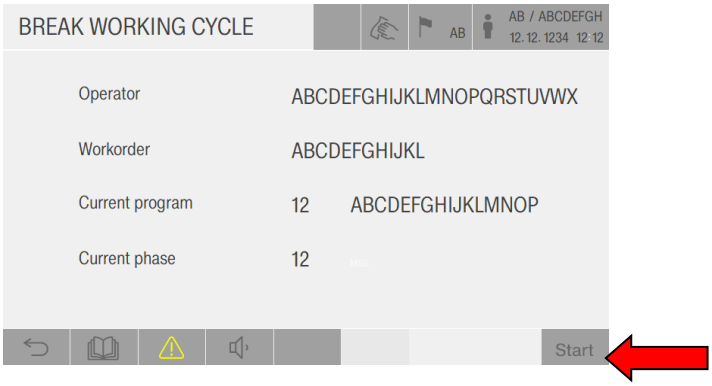
10.5 Restoring operation after voltage drop

10.5.1 Voltage drop in stand-by status

If a voltage drop occurs while in the machine is in stand-by, the machine returns to the standby status upon return of the voltage.
In this case it is necessary to remove the alarm.

10.5.2 Voltage drop during the execution of a cycle

If during the execution of the cycle occurs a voltage drop, the machine will show the screen "**BREAK WORKING CYCLE**" upon subsequent restoration of the voltage.



By pressing on the **START** button the cycle restart from the beginning of the phase that was running at the time of the interruption of the electrical supply.

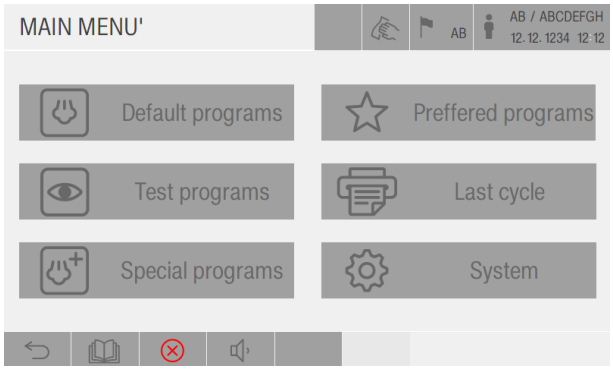
The result of the sterilisation process is identified by the END status in red colour, program not completed with success.

	**ATTENTION** **The hydrogen peroxide is corrosive to the skin, eyes, nose, throat, lungs and gastrointestinal tract.** **Always wear latex or PVC chemical resistant gloves when removing items from the sterilizer after a cancelled cycle.** **As a result of a cancelled cycle, if the items loaded clearly show the presence of humidity or liquids, hydrogen peroxide may be present.**

11. ALARMS AND EVENTS LIST

11.1 Alarms

In case an alarm condition occurs during the sterilisation cycle, the control system stops the sterilisation cycle and shows the following screen:



Press the button  . It appears the screen which describes the alarms.

	**ATTENTION** **In the presence of an alarm the machine stops, in this way the risk of causing breakages and/or malfunctions that could affect the functioning of the system is prevented or at least reduced.**

There are two pages of alarms: it is possible to switch from one page to another by pressing the arrows located at the bottom left. Once the active alarm conditions have been analysed and the causes that generated the alarms have been eliminated, it is possible to restore the system by pressing the "**RESET**" button.

By pressing the "RESET" button the sterilizer resumes its operation. In any case the result of the sterilisation process is identified by the symbol 

in red colour, program completed without success.

	**ATTENTION** **The hydrogen peroxide is corrosive to the skin, eyes, nose, throat, lungs and gastrointestinal tract.** **Always wear latex or PVC chemical resistant gloves when removing items from the sterilizer after a cancelled cycle.** **As a result of a cancelled cycle, if the items loaded clearly show the presence of humidity or liquids, hydrogen peroxide may be present.**

The following table lists the machine alarms

ALARM	MESSAGE	DESCRIPTION	SOLUTION
0	**PLC CONTROL OUT OF ORDER!!!**	Malfunction of the plc control	Turn the machine off and on again.
3	**LOAD.DOOR LIM.SWITCH INCONGR.**	The limit switch reports a different status from the actual door status.	Turn the machine off and on again, check the integrity of the limit switch.
4	**UNLOAD.DOOR LIM.SWITCH INCONGR.**	The limit switch reports a different status from the actual door status.	Turn the machine off and on again, check the integrity of the limit switch.
5	**PLC CONTROL PROBLEMS (XOB10)**	Problems with the autoclave management program.	Turn the machine off and on again.
6	**PLC CONTROL PROBLEMS (XOB12)**	Problems with the autoclave management program	Turn the machine off and on again.
7	**PLC CONTROL PROBLEMS (TEST)**	PLC functionality test failed	Turn the machine off and on again.
8	**HAKKO TERMINAL NON OK!**	The analogic card is not responding.	Check the Ethernet cable connecting HAKKO and PLC.
9	**LOW CHAMBER HEAT.TEMP. OUT-OF-RANGE**	Lower part of chamber temperature out of range.	Check: - the corresponding probe; - the W340 analogic card; - the contactor.

10	**CHAMBER CONTR. TEMP. OUT-OF-RANGE**	Chamber temperature is out of range.	Check: - the corresponding probe; - the W340 analogic card; - the contactor.
11	**H202 INJ. TEMP. OUT-OF-RANGE**	H2O2 injector temperature is out of range.	Check: - the corresponding probe; - the W340 analogic card; - the static relay.
12	**CHAMBER CONTR. PRESS. OUT-OF-RANGE**	Chamber pressure is out of range.	Check: - the pressure transducer; - that the vacuum pump is not in use; - the W340 analogic card;
13	**LOADING DOOR TEMP.OUT-OF-RAN.**	Loading door temperature is out of range.	Check: - the temperature probe; - the W340 analogic card; - the contactor;
14	**UNLOADING DOOR TEMP.OUT-OF-RANGE**	Unloading door temperature is out of range.	Check: - the temperature probe; - the W340 analogic card; - the contactor;
15	**INCORRECT PHASE SEQUENCE**	The three phases sequence is not correct.	-Check the supply power lines. -switch the phases.
16	**PLASMA SYSTEM NOT OK**	PLASMA system does not work.	Check: - the electrodes; - the functionality of the power supply unit;
17	**SAFETY LOADING DOOR**	Loading door safety micro-switch triggered	Loading door blocked; micro-switch damaged; cable damaged; E165 inputs card damaged.

18	**SAFETY UNLOADING DOOR**	Unloading door safety micro-switch triggered.	Unloading door blocked; micro-switch damaged; cable damaged; E165 inputs card damaged.
19	**CONTROL LOADING DOOR???**	The door does not open despite the command	Check: - cycle settings and status of the guides - door motors power fuse; - check the door open/close contactor and the corresponding analogic card.
20	**CONTROL UNLOADING DOOR???**	The door does not open despite the command	Check: - cycle settings and status of the guides - door motors power fuse; - door open/close contactor and corresponding analogic card.
21	**NO AUX. CIRCUITS**	Emergency button triggered	Release the loading and unloading emergency buttons.
22	**THERMAL/MAGNETOTH TRIGG.**	Thermal switch triggered.	Check: - the PLC input card; - the thermal switch
23	**% HUM. OUT-OF-RANGE**	Humidity reader out of range.	Check: - the W340 analogic card; - the humidity sensor
24	**CONTROL PRESS.TRANS.'H' FAILURE**	Defective or disconnected upper pressure transducer.	Check the upper control pressure transducer.
25	**CONTROL PRESS.TRANS.'L' FAILURE**	Defective or disconnected lower pressure transducer.	Check the lower control pressure transducer.
26	**% HUM. TRANS. FAILURE**	Humidity reader out of range.	Check: - the W340 analogic card; - the humidity sensor.
27	**RECORD.PRESS.TRANS.'H' FAILURE**	Defective or disconnected upper pressure transducer.	Check the upper recording pressure transducer.

28	**RECORD.PRESS.TRANS.'L' FAILURE**	Defective or disconnected lower pressure transducer.	Check the lower recording pressure transducer.
29	**COMPRESSED AIR FAILURE**	No compressed air	Check: - the pressure switch; - the compressor - the inputs card.
30	**UPP.CHAM.HEAT.TEMP OUT-OF-RANGE**	Upper part of the chamber temperature is out of range.	Check: - the corresponding probe; - the W340 analogic card; - the contactor.
32	**LOADING DOOR NOT CLOSED IN CYCLE**	The loading side door is open during the cycle. Possible causes: 1) the door closing limit switch is damaged and does not react to the door movement; 2) the PLC inputs card fails to manage the limit switch signal;	Check: - the correct functioning of the limit switch; - the correct functioning of the PLC inputs card; - the door movement.
33	**UNLOADING DOOR NOT CLOSED IN CYCLE**	The unloading-side door is open during the cycle. Possible causes: 1) the door closing limit switch is damaged and does not react to the door movement; 2) the PLC inputs card fails to manage the limit switch signal;	Check: - the correct functioning of the limit switch; - the correct functioning of the PLC inputs card; - the door movement.
34	**UPP.CHAM.HEAT.TIME**	The temperature did not increase by 1°C in the pre-set time frame.	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the resistance; - the thermal probe; - the correct operation of the
35	**LOW CHAMBER HEATING TIME**	The temperature did not increase by 1°C in the pre-set time frame.	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the resistance; - the thermal probe; - the correct operation of the

36	**H2O2 INJECTION HEATING TIME**	The temperature did not increase by 1°C in the pre-set time frame.	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the resistance; - the thermal probe; - the correct operation of the
37	**LOADING DOOR HEATING TIME**	The temperature did not increase by 1°C in the pre-set time frame.	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the resistance; - the thermal probe; - the correct operation of the
38	**UNLOADING DOOR HEATING TIME**	The temperature did not increase by 1°C in the pre-set time frame.	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the resistance; - the thermal probe; - the correct operation of the
39	**EMERG. CHAMBER HEATING (GLOBAL)**	The temperature exceeds the pre-set emergency temperature	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;
40	**LOWER CHAMBER HEATING EMERGENCY**	The temperature exceeds the pre-set emergency temperature	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;
41	**H2O2 INJECTION HEATING EMERGENCY**	The temperature exceeds the pre-set emergency temperature	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;
42	**LOADING DOOR HEATING EMERGENCY**	The temperature exceeds the pre-set emergency temperature	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;
43	**UNLOADING DOOR HEATING EMERGENCY**	The temperature exceeds the pre-set emergency temperature	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;

44	**CARTRIDGE RELEASING PROBLEMS**	The cartridge is not locked in the pre-set time frame.	Check: - the settings of the corresponding parameter; - the cartridge unlocking motor; - the motor control relay; - the micro-switch; - the correct operation of the
45	**CARTRIDGE EJECTION PROBLEMS**	The cartridge was not ejected in the pre-set time frame	Check: - the settings of the corresponding parameter; - the cartridge unlocking motor; - the motor control relay; - the micro-switch; - the correct operation of the
46	**H2O2 INJECTION NEEDLE POSITION PROBLEM**	The needle is not in the position required by the unit.	Check: - the micro-piston; - the valves; - all pneumatic connections; - the correct operation of the inputs/outputs card;
47	**EXCESSIVE HUMIDITY**	The humidity in the chamber is too high	Check: - the humidity level reader; - the correct operation of the inputs/outputs card; -the load (dry load required).
48	**H2O2 INJECTION NOT OK (PRESS.)**	The peroxide was not loaded.	Check: - the peroxide loading system; - the correct functioning of the solenoid valves.
49	**INJECTION NEEDLE LIMIT SWITCH INCONS.**	Both sensors of the piston are simultaneously active or inactive.	Check: - the sensors; - the correct operation of the inputs/outputs card
50	**CARTRIDGE EJECT (LIMIT SWITCH)**	The cartridge was not ejected in the pre-set time frame.	Check: - the cartridge ejection motor; - the correct operation of the inputs/outputs card; - the motor relay; - the cartridge unlocking system.
51	**LOW ABSOLUTE PRESSURE TIME**	The pre-set pressure level was not reached in the pre-set time frame.	Check: - the vacuum pump; - the vacuum valve; - check the vacuum seal via vacuum test; - check the humidity levels of the materials;

52	**UPP. ABSOLUTE PRESSURE TIME**	The pre-set pressure level was not reached in the pre-set time frame.	Check: - the vacuum pump; - the vacuum valve; - check the vacuum seal via vacuum test;
53	**H2O2 INJECTION NOT OK IN CYCLE**	The peroxide injection system is not functioning correctly during the cycle.	Check: - the piston position sensors; - the pneumatic valves; - the correct operation of the inputs/outputs card;
54	**CHAMB. ABS. PRESSURE L INCONGRUENCE**	The value between the lower pressure transducer of the control chamber and the recording exceeds the set value.	Check the functioning of the lower pressure transducers and in case carry out the calibration.
55	**UPP. CHAMBER HEATING EMERGENCY**	The temperature exceeds the pre-set emergency temperature	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;
56	**REG. SYS. COMM. PROBL.**	Problems communicating with the system	Check: - the communication cables; - the control PLC;
57	**VACUUM TEST FAILURE!!**	During the vacuum test, the machine cannot contain the loss within the pre-set time frame. Possible causes: 1) incorrect setting of the measure system; 2) loss on the hydraulic circuit. 3) leakage from the	Perform the calibration of the system; check the correct operation of the valves of the circuit in question. Check the door and chamber seal.
58	**OPENING COND. TIME (PRESS.)**	Atmospheric conditions re-balancing TIME-OUT. Chamber pressure transducer not working, air filter or pneumatic suction valve blocked.	Check and eventually de-block the air filter or the suction valve. Calibrate the transducer.
59	**CHAM. REG. TIME OUT-OF-RANGE**	The chamber temperature exceeds the pre-set values	Check the temperature probe, check the W340 analogic card;

60	**CHAMBER ABS. REGIS. PRESS. OUT-OF-RANGE**	The chamber pressure exceeds the pre-set values	Check: - the pressure transducer; - that the vacuum pump is not in use; - the W340 analogic card;
61	**CHAMBER TEMPERATURE INCONSISTENCY**	The value between chamber probe and recording probe exceeds 2°C	Check the correct functioning of the temperature probes and re-calibrate them if necessary;
62	**CHAMBER ABS. PRESS. INCONGRUENCE**	The value between the high control chamber pressure exceeds the set value.	Check the correct functioning of the pressure transducers and re-calibrate them if necessary
63	**NO ENERGY IN CYCLE!!!**	The power supply was interrupted during a cycle.	Press the start button
66	**DOSING PISTON FAILURE**	-The sensor doesn't work -Solenoid valve doesn't work	-Check the sensor -Check the solenoid valve -Check the electrical connection
67	**LOW TEMPERATURE CHAMBER**	The temperature exceeds the pre-set emergency temperature	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;
68	**CHAMBER HEATING PROBLEMS (TIME)**	The temperature did not increase in the pre-set time frame.	Check: - the settings of the corresponding parameter; - the correct operation of the contactor; - the thermal probe; - the correct operation of the inputs/outputs card;

11.2 Warnings

Warnings alert the user that a specific functionality condition has changed.
Unlike alarms, warnings do not influence the machine's functionality: the machine will continue its cycle.
When warnings appear, the user is required to intervene in the shortest possible time, in order not to compromise the correct operation of the machine.

Furthermore, by pressing the specific icon, the user can recall the warnings window in any given moment.

In the presence of a warning, on the lower bar the symbol  appears.
Press this button to access the page "**ACTIVE WARNING**" and display the specific warning.

Page → "**ACTIVE WARNING**".

The "**ACTIVE WARNING**" page contains the warnings which arise during the machine's operations.

It allows the user to view a brief description of the alerts present in order to be able to intervene in the correct way for their removal.

After following the appropriate procedure to solve the cause of the warning in question, the short description that appeared in the management page alerts will disappear.

Press the button  to return to the previous page.

The following table lists all the machine's warnings

WARNING	MESSAGE	WARNING	MESSAGE
00	MASTER/SLAVE COMM. FAIL	09	RECORDING SYSTEM DISABLE
01	SLAVE/MASTER COMM. FAIL	10	SD-CARD NOT OK
02	RFID SYS.COMM.PROBL.	11	PLC BATTERY NOT OK
03	RFID SYS. PROBL.	14	TERMINAL BATTERY NOT OK
04	RFID CONTR. DISABLED	16	TYPE 1 MAINTENANCE REQUEST
05	HYGROMETER DISABLED	17	TYPE 2 MAINTENANCE REQUEST
06	POWER SUPPLY FROM UPS	18	TYPE 3 MAINTENANCE REQUEST
08	PRINTER DISABLED	19	TYPE 4 MAINTENANCE REQUEST

12. ELECTRONIC BOARD DATA

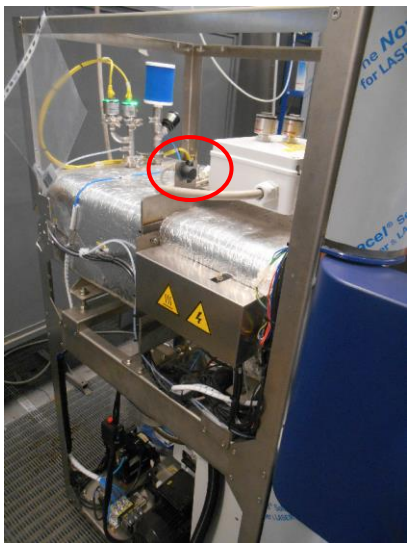
Electronic card designed to control a single machine.
No different use other than as specified above is permitted.
The electronic board has been designed in compliance with indications defined by the following reference standards:

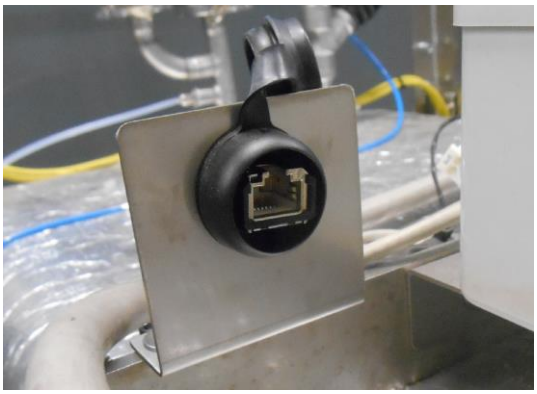
EN 60335	**Low voltage**
EN 61000-6-1	**Immunity**
EN 61000-6-3	**Emission**

13. ETHERNET CONNECTION

The machine is provided with Ethernet port for service purpose.

In the PL40 and PL70 there is an ethernet port located above the chamber.



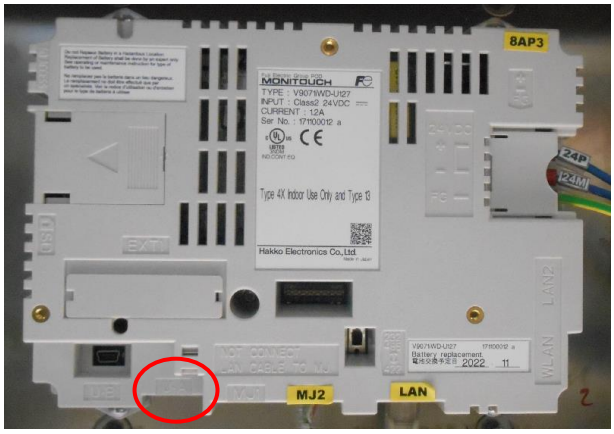


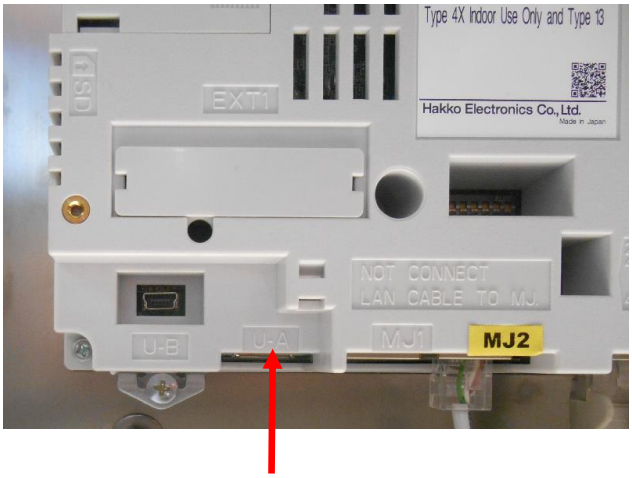
In the PL130 there is an ethernet port located under the chamber.

14. USB PORT

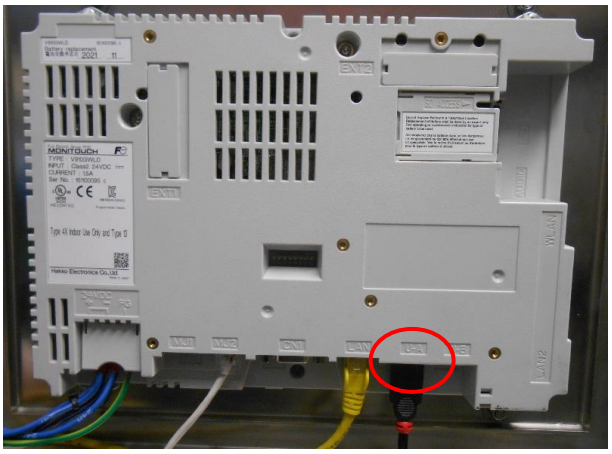
The USB port allows software upgrades and BACK-UP.
If the printer is connected to the USB port, disconnect it in order to use the port.

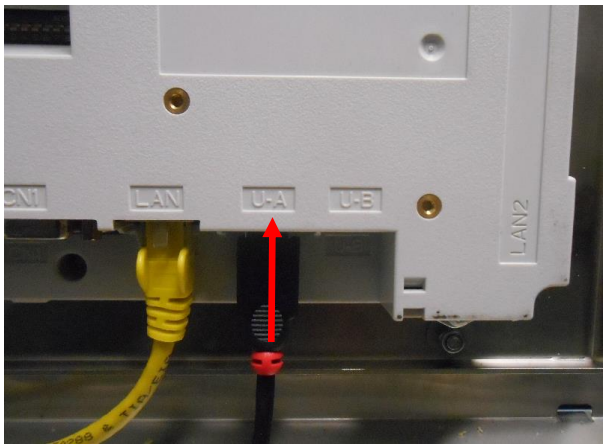
In the PL40 and PL70 the USB port (U-A) is on the bottom left side of the rear control panel.





In the PL130 the USB port (U-A) is on the bottom right side of the rear control panel.

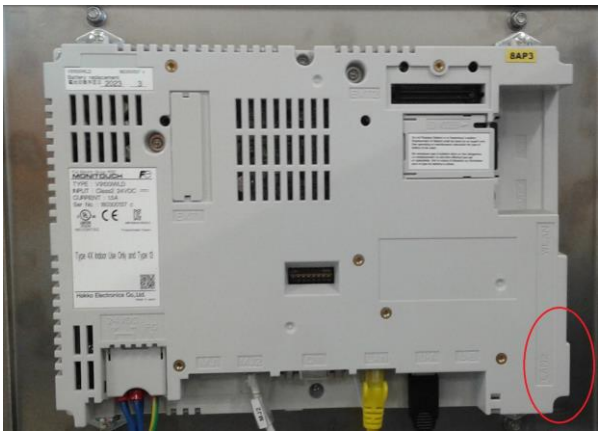




15. LAN CONNECTION

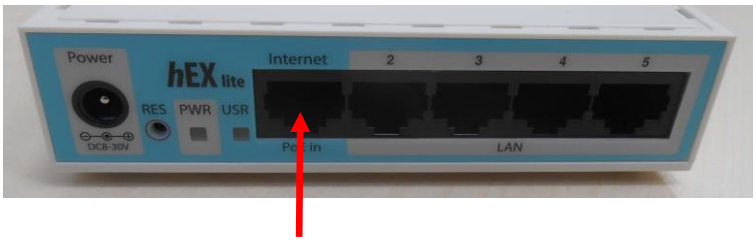
The machine is provided with LAN connection which allows you to connect to a traceability system. Connect the ethernet port to a NETWORK with an RJ-45 (ethernet) cable.

In the PL130 there is a dedicated LAN connection in the HMI (LAN2).



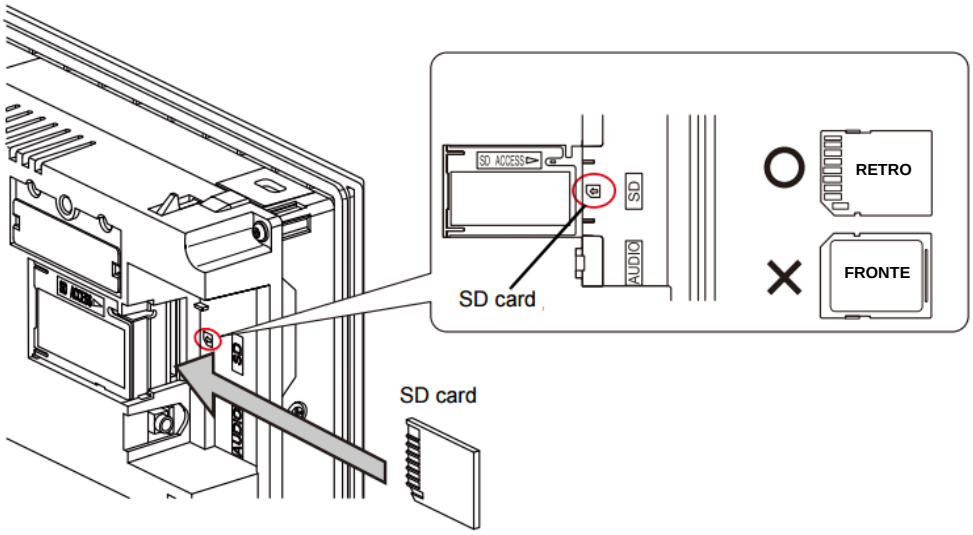
The IP setting must be done in the HMI. It is necessary to enter the programming menu of the HMI and modify the setting regarding the LAN2 connection.

In the PL 70 there is a dedicated device located above the chamber.



16. SD CARD

The machine is equipped with an SD card that can be used to perform a backup of the machine, to save the cycles, to transfer the programs screen, data and images.



17. PRINTOUTS

At the end of each cycle the machine automatically prints out a summary report.
The report contains:

- The machines identification data
- Program name
- Descriptions
- Name of the operator that starts the cycle
- Date and time of cycle start
- Date and time of cycle end
- Number of progressive cycles
- Process data recordings
- Summary of the phase duration times
- Cycle outcome
- Fields for operator and supervisor signatures
- Graph of the analogical signals during the cycle

18. MAINTENANCE

18.1 General recommendations on maintenance

The machine has been designed built only and exclusively for low temperature hydrogen peroxide sterilisation of packaged medical devices.
It is therefore subject to continuous contact with chemical agent and with contaminated instrumentation.
For this reason, it is necessary to provide some useful instructions for the technicians who will perform maintenance on it.

ATTENTION

The machine maintenance is allowed only to Steelco personnel or official distributor, who are properly trained.

The maintenance technicians, in normal working conditions, is not exposed to risks if they work in safety using the appropriate 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 and the group and individual safety gear provided in the workplace.
- Use special care and attention in the event of repair and replacement of mechanical parts (e.g. pump, etc.) on malfunctioning machines which have not completed the cycle.

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 suitable PPE.

Maintenance operations of the machine described in this manual can be divided into "**Routine Maintenance Operations**" and "**Extraordinary Maintenance Operations**".

Routine maintenance includes all operations aimed at keeping various parts of the machine clean and functional.
They must be performed on a regular basis or when considered necessary due to incorrect performance of cycle.
The manufacturer and the distributor provide preventative maintenance kits called **PM KITs** that envisage operations carried out at fixed intervals. The kits include the necessary components to maintain optimal device performance.
The following table shows the various routine maintenance tasks, their frequency and who is to perform them (**Op**= machine operator; **Tec**= installation and repair technician).
Each single task is more fully explained in the single reference forms.
All **special maintenance** work is to be performed only by qualified, skilled personnel.
If your machine should require special maintenance, please contact your retailer/distributor.

ATTENTION

In case of spare parts use only original components.

18.1.1 Maintenance Request

After a certain time or number of cycles depending on the setting, the machine will report the alert **'MAINTENANCE'**. This warning doesn't affect the normal use of machine.
The maintainer however must take action in the shortest possible time in order not to compromise the correct operation of the machine.

TABLE OF ROUTINE MAINTENANCE TASKS

Op= machine operator
Tec= installation and repair technician

CLEANING AND CHECKING OPERATIONS		
FREQUENCY	**FREQUENCY**	**FREQUENCY**
EVERY WEEK	-Chamber cleaning -External body cleaning.	**Op**
EVERY 6 MONTHS OR 600 CYCLES	-Pump oil: check the level and refill if necessary.	**Tec**
	-Door gasket: check and clean. -Door chain status check (for PL130). -Vacuum pump protection filter check and clean. -Condense outlet from the compressed air accumulation vessel. -Vaporizer: clean. -Check vacuum pump oil level. -Door chain check and lubricate (for PL 130). -Door lock lubricate (for PL 70 and PL40). -Cartridge lock/unlock system lubricate.	**Tec**

VACUUM PUMP OIL		
FREQUENCY	**FREQUENCY**	**FREQUENCY**
EVERY 4 YEARS OR 4800 CYCLES	-Pump oil: replace (code PL001037=1lt for PL 70 and PL 130). PL 70 uses 1 lt and PL 130 uses 2 lt. -Replace oil drain plug seal for vacuum pump (PL001099) for PL 70 and PL 130.	**Tec**
EVERY 2 YEARS OR 2400 CYCLES	-Pump oil: replace (code PL003029 = 2 lt for PL 40). - Replace oil drain plug seal for vacuum pump (PL003033) for PL40.	**Tec**

PREVENTATIVE MAINTENANCE OPERATIONS *		
FREQUENCY	**FREQUENCY**	**FREQUENCY**
EVERY 6 MONTHS OR 600 CYCLES	-Replace HEPA air filter (code 045566). -Replace exhaust filter (code PL001070) + active carbon filter (PL001101). -Replace humidity filter (code 013831) only for PL 70 and PL 130 advanced versions. -Replace seal gasket (code 021304). -Replace vaporizer adapter (code PL001073). -Replace injection system gasket (-PL003016; no. 2 PL001080)	**Tec**
EVERY YEAR OR 1200 CYCLES	- Replace vacuum pump oil filter (PL002032 for PL 40 and PL 70. PL001561R for PL 130). - Check oil status (colour) and replace if necessary. - Replace plasma generator inspection glasses (code 500180) only for PL70, PL130 advanced and PL40.	**Tec**

	- Replace plasma electrode gasket (no.2 PL001102). - Replace plasma generator O-rings (code 400064) only for PL 70, PL 130 advanced and PL 40. - Replace generator electrodes (code PL001921) only for PL 70, PL 130 advanced and PL 40.	
EVERY 2 YEARS OR 2400 CYCLES	- Replace door gasket (code PL70 → PL002035, PL130 → PL001075; PL 40→PL003030). - Replace PLC battery (code 010262) - Replace Touch screen battery (PL70, PL40 and PL130 basic → 010427, PL130 → 014508)	**Tec**

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

NOTE: The time frames for execution of the maintenance programme may vary +/- 15 days with respect to the period indicated in the table.

Note Routine maintenance operation must be carried out with the frequency described in the table; it is advisable to carry out single cleaning operation whenever it is necessary.

If the machine requires replacement of one or more components, refer to the manufacturer's spare part list.

ATTENTION:

- The machine is not protected against water jets, and it is therefore not advisable to use pressure-operated cleaning systems.

CHAMBER CLEANING		
	Worker: **Op**	Frequency of intervention: **every week**

METHOD OF INTERVENTION:

Open the door of the chamber and check that no instruments have been left inside.
The chamber must be cold.
In case of H2O2 residuals inside the chamber, clean with a cloth dampened with distilled water.
Uniformly spray a suitable detergent* (adequate for contact with stainless steel), involving all internal parts of the chamber and proceed with any further cleaning operations.
*As an alternative, it is possible to use a cloth dampened with distilled water.

	ATTENTION
	Follow the instructions on the product's technical file regarding time frames and modality for use.
	Always check the product's technical data sheet and its compatibility with the materials to be cleaned.
	The application of the detergent in the chamber must be performed on cold surfaces, to avoid the creation of hazardous fumes.

CLEANING THE EXTERNAL BODY OF THE MACHINE		
	Worker: **Op**	Frequency of intervention: **every week**

METHOD OF INTERVENTION CLEANING EXTERNAL BODY:

With the aid of a moist cloth, thoroughly clean the outer casing of the machine using a suitable detergent*.
Avoid using abrasive products and any type of solvent and/or diluent.
* We recommend using the "Steelco Shine" (code 9992078).
As an alternative, it is possible to use neutral detergent.

METHOD OF CLEANING LABEL:

Use a soft cloth to clean the surface of the label.
Use only water or isopropyl alcohol.
Do not use abrasive cleaners or solvents of any kind.

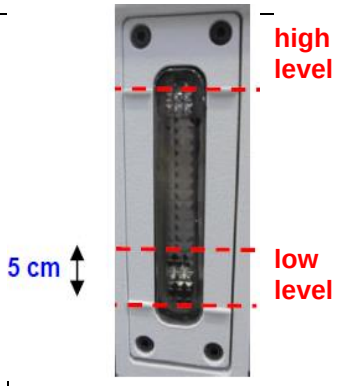
METHOD OF CLEANING TOUCH SCREEN:

Use a soft cloth to clean the surface of the touch screen.
Use only isopropyl alcohol.

CHECK OF VACUUM PUMP OIL		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**

MAINTENANCE METHOD:

- Every 6 months check the oil level. It must be about 5 cm above the low level.



DOOR GASKET CHECK		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**

MAINTENANCE METHOD: check the door gasket

Check that the door gasket is not damaged.
Clean it using a cloth dampened with tap water.

DOOR CHAIN STATUS CHECK AND LUBRICATE (FOR PL 130)		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**

MAINTENANCE METHOD: check the efficiency of operation as described:

Check the chain tension.
If the tension level is incorrect, fasten the chain.
Lubricate the chain by applying a layer of grease (code 040357).

LOCK DOOR LUBRICATE (FOR PL70)		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**

MAINTENANCE METHOD lubrificate as described

Apply oil as indicated on the components in door movements.

CARTRIDGE LOCK/UNLOCK SYSTEM LUBRICATE (FOR PL70 AND PL130)		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**

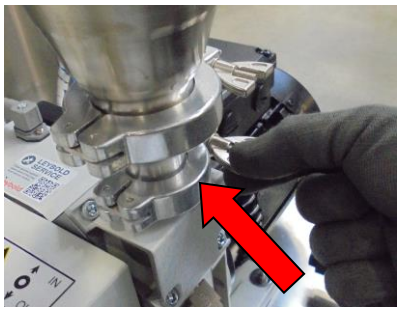
MAINTENANCE METHOD lubrificate as described

Apply oil as indicated on the components in cartridge compartment movement.

VACUUM PUMP PROTECTION FILTER CHECK

	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**

MAINTENANCE METHOD:



Coarse particles can cause the pump to slow down.

- Clear the filter from obstructions with a brush under tap water and check the seal (PL 70 code 022308; PL 130 and PL40 code 022309) and replace if necessary.
- Dry thoroughly and place the filter.

ATTENTION

IT IS IMPORTANT TO COMPLY WITH FILTER MAINTENANCE INDICATIONS, TO AVOID POTENTIAL H2O2 EMISSIONS.

VAPORIZER CLEANING

	Worker: **Tec**	Frequency of intervention: **6 months or 600 cycles**

MODE OF INTERVENTION:

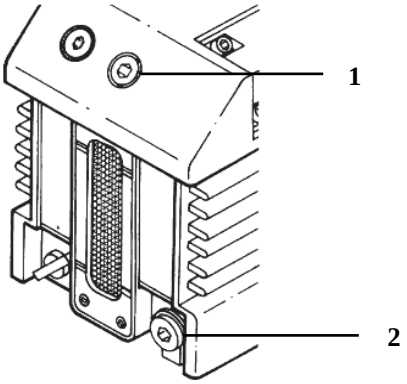
- Disassemble the vaporizer, take off the spiral and wash under demi water in order to remove the crystallized H2O2 residuals.
- Every 6 months replace the seal gasket (code 021304) and the diffuser sitting (code PL001073).

CHECK/REFILL OF VACUUM PUMP OIL

	Worker: **Tec**	Frequency of intervention: **Control: every 6 months or 600 cycles and replace every 4 years or 4800 cycles (PL70 and PL130); check every 6 months or 600 cycles and replace every 2 years or 2400 cycles (PL40)**

MAINTENANCE METHOD:

- Periodically check the state of the oil to see whether it is either cloudy or transparent. The oil is normally clear and transparent. If it is darkened, it needs to be replaced.



Vacuum Pump

- Remove the oil drain plug (2) and allow the oil to drain into an adequate container.
- When the oil flow slows, screw the drain plug and turn on the pump for a few seconds.
- Turn off the pump again.
- Remove the oil drain plug and drain the remaining oil.
- Check the oil status if dark replaces with new oil, replace the oil drain plug. Code: PL001099 (PL70 and PL130). Code PL003033 (PL40).
- Remove the oil filling cap (1) and fill with oil PFPE (LVO 400), code PL001037 (PL70 and PL130). The quantity is 1 litre for PL70 and 2 litres for PL130.
- Fill with oil, code PL003029 (PL40). The quantity is 2 litres for PL40.
- Retighten the plug.

ATTENTION

- **Change the oil when the pump is fully warmed up, to avoid condensation in the pump.**
- **Please comply with environmental regulations when disposing of used oils.**
- **When you need to check the oil, turn the pump off and allow the necessary quantity of oil to flow out into a glass or a similar container.**
- **When changing the oil, use the same type of oil as the one previously inside the pump. If the oil is replaced with mineral oil there is the risk of flame ignition.**

18.2 Procedure for preventive maintenance

All “preventive maintenance operations” must be performed by qualified and competent staff only.

AIR FILTERS REPLACEMENT		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**
MAINTENANCE METHOD: carry out the replacement of the filter.		
Unscrew the filter from the pipe. Screw a new filter (code 045566).		

EXHAUST FILTER		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**
MODE OF INTERVENTION: replace the exhaust filter		
Remove the cover. Replace the filter with a new one (code PL001070 + PL001101).		

	ATTENTION
	**Do not replace the filters in the proximity of operations/activities that generate dust.**
	Follow the safety and health regulations in loco and wear suitable protective clothing.
	Steelco recommends the use of original components only. The use of parts other than those prescribed, could affect the results obtained.

HUMIDITY FILTER REPLACEMENT		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**
MODE OF INTERVENTION: replace the humidity switch filter		
Replace the filter every 6 months (code 013831) only for PL70, PL130 advanced and PL40		

GASKET REPLACEMENT OF THE INJECTION SYSTEM		
	Worker: **Tec**	Frequency of intervention: **every 6 months or 600 cycles**
MODE OF INTERVENTION:		
• Replace the gaskets (code PL003016 and PL001080 x 2) every 6 months or 600 cycles		 

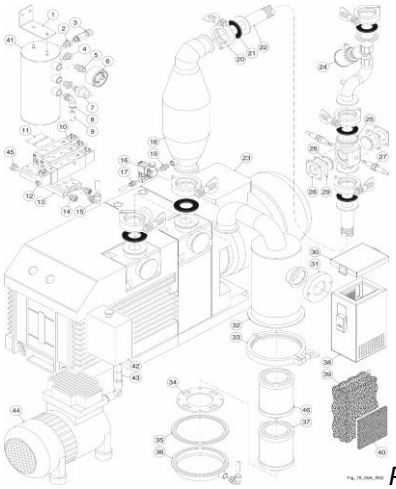
VACUUM PUMP OIL FILTER REPLACEMENT

M2	Worker: **Tec**	Frequency of intervention: **every year or 1200 cycles**

MAINTENANCE METHOD:

- Remove the clamp closing and remove the cover (4).
- Remove the flange by using the nuts.
- Replace the used filter elements (5) with new ones, code:
  PL 40/PL 70 → PL002032
  PL 130 → PL001561R following this procedure:
- Insert the filtering element;
- Fix using the flange and close the recipient by using the clamp closing.
- Fasten the base again with nuts, so that the filtering elements fit into the openings in the base and lid.
- Check the oil level after the first cycle and replace if necessary.

Please comply with environmental regulations when disposing of used parts.



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PL 130

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ATTENTION

IT IS IMPORTANT TO COMPLY WITH FILTER MAINTENANCE INDICATIONS, TO AVOID POTENTIAL H2O2 EMISSIONS.

DOOR GASKET REPLACEMENT		
	Worker: Tec	**Frequency of intervention:** Control: 6 months – Replacement: every 2 years or 2400 cycles
MODE OF INTERVENTION: replace the door gasket as described below:		
1. Bring the door in over stroke position. 2. Remove the old gasket. 3. Clean very well the groove with a Scotch-Brite cloth or with a cloth soaked in methylated spirit.		
4. Reseat the new seal in the housing of the door: PL 40 → PL003030 PL 70 → PL002035 PL 130 → PL001075 Place one end of the gasket in the middle of the top side of the seat and proceed with the insertion along the entire seat of the gasket until the two ends are joined.		
5. In order to weld the two gasket ends use a high temperature resistant silicone (code 040139), insert it between the two ends. Clean the silicone residuals using paper.		
6. Let the silicone dry for about 2 hours before to start a cycle.		

PLASMA GENERATOR COMPONENTS REPLACEMENT (ONLY FOR PL70 AND PL130 ADVANCED AND PL40)		
	Worker: **Tec**	Frequency of intervention: **once year or 1200 cycles**
MODE OF INTERVENTION: glass, O-Ring, sparking plug replacement		
The inspection glass tends to get dark. Once every two years replace: n.2 glasses (code 500180), n.2 O-Rings (code 400064) and n.2 generator electrodes (code PL001921) and n.2 plasma electrodes gaskets (code PL001102).		

	AFTER SALE SERVICE
	If your machine does not work properly even after ordinary maintenance has been carried out, contact the Technical Support Centre of reference, describing the fault and giving the machine model and serial numbers.

19. PROBLEMS – CAUSES – SOLUTIONS

19.1 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.

19.2 Problems - Causes - Solutions

I. MACHINE DOES NOT START:

C. Circuit breaker de-activated.

R. Bring it into the working position "ON".

C. Machine start switch de-activated.

R. Press the start button.

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

C. The door has not been closed or locked correctly.

R. Check the closing of the door ensuring that the microswitch of the door is correctly activated.

C. Micro-switch failure.

R. Check the operation and possibly replace it.

C. Cartridge missing or expired.

20. DECOMMISSIONING

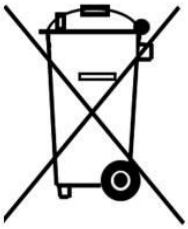
20.1 Instructions for disassembly of the machine

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

- Disconnect the machine from the mains.
- Consult the institution responsible for the verbalization and certification of demolition of the machine, as provided for by the laws in force 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
- Carry out the disassembly of the machine taking care to divide the materials that compose it according to their chemical nature (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 provisions of the law in force in the country of installation and use of the machine, dispose of all materials and substances resulting from removal of the same.

20.2 Machine disposal



- For disposal of the device please contact the manufacturer or distributor.
- Do not dispose of these apparatuses as municipal waste mixed solid but make a separate collection.
- The reuse or the correct recycling of EEE is useful to preserve the environment and human health itself.
- In accordance with European WEEE Directive 2012/19/EC are available specific collection centres which deliver waste electrical and electronic equipment, and it is also possible to return the equipment to the distributor at the time of purchase of a new equivalent.
- The public administration and the producers of AEE are committed to facilitate the processes of reuse and recovery of WEEE through the organization of collection activities and through the use of appropriate design measures.
- The law punishes with appropriate sanctions who illegally dispose the WEEE.