Miele Group Member

Steelco VS G2 Series
4 - 6 - 8 - 10 - 12

User Manual

Contents

1. INTRODUCTION 6
1.1. Dear Customer 6
1.2. Purpose of the manual 6
1.3. General notices 6
1.3.1. Clauses of supply 6
1.4. Warning list 7
2. PRODUCT INFORMATION 8
2.1. Intended use 8
2.2. Steelco VS G2 series performances 8
2.3. Model Identification 8
3. CONSTRUCTIONAL CHARACTERISTICS 10
3.1. Technical characteristics 10
3.1.1. Chamber dimensions 10
3.1.2. Footprint dimensions 10
3.1.3. Weights 10
3.1.4. Electrical specification: 400V - 50Hz - with vacuum pump 11
3.2. Autoclave Optionals 11
3.2.1. Clean Steam supply system 11
3.2.2. Number of doors 11
3.2.3. Technical Compartment 11
3.2.4. Other options 11
3.3. Autoclaves accessories 12
3.4. Environmental conditions 13
3.4.1. Unit classification (for all versions) 13
3.4.2. Characteristics of storage and conservation 13
3.4.3. Noise/Vibrations 13
3.4.4. Heat loss of the unit 13
3.5. Residual risks 14
3.5.1. Personal Protective Equipment (PPE) 14
3.6. Parts Identification 15
3.7. Autoclave labelling 16
3.7.1. Warning plates on remote vacuum pump (optional) 17
3.8. Table of symbols 18
4. ACCESS LEVEL TREE 19
4.1. Operator permissions 19
4.2. Supervisor permissions 20
5. OPERATOR MANUAL 21
5.1. Sterilization: general guidance 21
5.1.1. Load essentials 21
5.2. Operator position 21
5.3. Main menu page 22
5.4. User Login 23
5.5. Cycle management 24
5.5.1. How to start a cycle 24
5.5.2. Cycle completion 26
5.5.3. Electric feeding interruption 26
5.5.4. Emergency button 26
5.6. Emergency procedure for load extraction 27
5.6.1. Printout management 28
5.7. Last cycle menu 29
5.8. Alarms Manage 30

5.9. Legenda 31
6. SUPERVISOR ACCESS LEVEL 32
6.1. During a cycle 32
6.2. UTILITY Menu 33
6.2.1. Machine data 34
6.2.2. Special functions 34
6.2.3. Manual control 34
6.2.4. Generator drain 35
6.2.5. Printer 35
6.2.6. Automatic setup 35
6.2.7. Heating 36
6.2.8. Load / Unload 36
6.2.9. Local / Remote 36
6.2.10. Steelco Test 37
6.3. State menu 37
6.3.1. Synoptic 38
6.3.2. Analog input 38
6.3.3. Digital input 38
6.3.4. Hardware diagnostic 39
6.3.5. SD-CARD diagnostic 39
6.3.6. Digital output 39
6.3.7. Maintenance 40
6.4. Archive menu 40
6.4.1. Basic programs 40
6.4.2. Preferred programs 41
6.4.3. Test programs 41
6.4.4. Operators menu 41
6.4.5. Special programs 42
6.4.6. Basket managements 42
6.5. Historic archives 42
6.5.1. Alarms 43
6.5.2. Work cycles 43
6.5.3. Maintenance 43
6.6. Settings 44
6.6.1. Work 44
6.6.2. Base 44
6.6.3. Configurations 45
6.6.4. System save settings 46
6.6.5. Clock 46
6.7. Properties of sterilization program steps 47
6.7.1. Seal control 47
6.7.2. Air removal 47
6.7.3. Sterilization 48
6.7.4. Drying 49
6.7.5. Vacuum test 49
6.7.6. Heating 50
6.8. Basic Cycles: Settings and Graphs 51
6.8.1. Bowie & Dick test 51
6.8.2. Vacuum test 51
6.8.3. Instrument program 52
7. TROUBLESHOOTING 53
7.1. Alarms 53
7.2. Warnings 61
8. MAINTENANCE 62

8.1. Routine maintenance 62
8.1.1. Control measures/validation for sterility assurance 62
8.1.2. Printer paper roll replacement 63
8.2. Periodic Cleaning 64
8.2.1. External paneling cleaning 64
8.2.2. Sterilization chamber cleaning 64
8.2.3. Chamber strainer cleaning 66
8.2.4. Generator Drain (if applicable) 66
9. AFTER SALES SERVICE 67
10. QUALIFIED PERSONNEL MAINTENANCE SCHEDULING 68
10.1. Annual maintenance or 1000 cycles 68
10.2. Every 2 years or 2000 cycles 69
11. GLOSSARY 71
12. DISMANTLING, DEMOLITION AND DISPOSAL 72
12.1. Dismantling 72
12.2. Demolition and disposal 72
13. APPLICABLE STANDARDS 73

WARNINGS

Please note: use of this manual and attached documents is exclusively for authorized and trained personnel and for specific location where the autoclave is installed.

Information in this document is for the use of the addressee only, is confidential and may be legally privileged. Any further dissemination, distribution, copying or use without prior permission of the sender is strictly prohibited.

Steelco S.p.A. Reserves the right to act under the law should these warnings not be complied with.

Steelco S.p.A. warns that all operations concerning software and hardware must be carried out with the utmost care. Such operations can lead to the machine not behaving as required, to be damaged or to treat the load in a different way.

Any exception must have the authorization of Steelco S.p.A.

Please Note: images and pictures on this manual are for illustrative purposes only.

REFERENCE NOTES

Warning conditions are highlighted in the following way:

WARNING!

Description of warning

All usefull information/hints are highlighted in the following way:

Information and suggestion text.

With term:

- *Operator* is meant the trained and authorized person, who usually works on the machine and/or performs the following tasks:
  - Loading and picking up the product;
  - Cycle selection;
  - Cycle start and cycle reset;
  - Alarms reset;
  - Activation of Emergency Stop button.
- *Supervisor* is meant the person who supervise and validate all sterilization process
- *Qualified Maintenance Technician* is the technician who regularly performs maintenance in the facility, and properly trained for sterilizer maintenance.
- *Steelco SpA Representative* is the technician Authorized or properly trained by Steelco S.p.A. to perform Service.

This manual is required to be always accessible by the operator.

For other technical terms, please refer to chapter *11. GLOSSARY*

1. INTRODUCTION

1.1. Dear Customer

Thank you for placing your trust in Steelco S.p.A. We hope that the performance of this product will exceed your expectation.

Our first concern is that this equipment is operated and maintained with safety of all personnel involved in mind. To assure more safe and reliable operation:

- Read and understand this manual before install or operate sterilizer;
- Make sure that personnel is properly informed on contents of this manual;
- Assure that this manual is located near the sterilizer or if applicable, permanently affixed to the sterilizer.

1.2. Purpose of the manual

The purpose of this manual is to provide instructions for:

- Operation;
- Maintenance.

WARNING!

Information found in this manual is subject to modifications without prior notice.

Steelco S.p.A. is not liable for direct, indirect, accidental or other damages regarding the issue and use of this information.

Reproduction, adaptation or translation of this document or any part of it without prior written consent by Steelco S.p.A. is strictly forbidden.

1.3. General notices

The product and/or its accessories must always be used in compliance with the procedures set forth in this manual. They must never be used for other than their intended purposes.

1.3.1. Clauses of supply

Manufacturer shall not be liable in case of:

- Use parts other than Steelco authorized parts,
- Acts of God,
- Utility malfunction,
- Error in installation of the equipment by non-authorized personnel,
- Accidents,
- Abuse, misuse, tampering, alteration, modification,
- Improper service.
- Chlorides and corrosive chemicals,
- Lack of documented preventive maintenance as specified by maintenance manual.

1.4. Warning list

In order to prevent hazardous situations, with possible damage to individuals and/or property, please observe the following precautions:

WARNING!

Any alteration of the sterilizer not authorized or performed by Steelco Service Representative which could affect its operation will void the warranty, could adversely affect sterilization efficacy, could violate national, state and local regulations and jeopardize your insurance coverage.

Installation Area, proper Electrical, steam, compressed air and water services are under purchaser responsibility.

User facilities must report a device-related serious injury to the manufacturer.

Healthcare professionals within a user facility should familiarize themselves with their institution procedures for reporting any adverse events.

Do NOT pour water or other liquids on the unit.

Do NOT pour flammable liquids onto the machine.

Do NOT apply alcohol or any substance containing it on the Plexiglas panels.

Do NOT use the equipment in presence of explosive or flammable gases or vapors.

Do NOT remove any label or tag from the machine. If worn, damaged or unreadable this is necessary, ask for new ones contact your Steelco Service Representative.

Before carrying out any maintenance or cleaning, always disconnect and tag out the electrical all utilities supply.

Make sure the electrical system is provided with an earth connection in compliance with current laws and/or standards.

Use only original spare parts.

Failure to comply with the measures outlined above, shall void the warranty and may lead to dangerous operating conditions.

Make sure that all material used to wrap instruments is suitable for autoclave: working temperature 140°C (284°F) and pressure 2.5 bar (36.26Psig).

Avoid use of addictive and/or chemical solvent.

The access door to the technical compartment must remain locked while the autoclave is in use. Access to the technical compartment by the operator is prohibited: the keys to the compartment door must be kept and used ONLY by suitably trained maintenance technicians.

The use of sterilizing autoclaves must be entrusted to responsible personnel.

Improper use of the autoclave relieves the manufacturer of any liability.

In the event of water, compressed air and/or steam leaks, switch off the machine immediately and make it safe, close all the utilities that supply the machine and contact Steelco authorized technical assistance.

2. PRODUCT INFORMATION

2.1. Intended use

The Steelco VS G2 series autoclaves are designed for medical devices sterilization in healthcare environment;

Our autoclaves are suitable to operate on porous and rubber materials, on surgical instruments, on pre-packaged into bags materials, which withstand working temperatures up to 140°C and maximum pressure of 2.5 bar, with a maximum weight of 15 kg per STU.

WARNING!

It is preferable to avoid sterilizing materials that include additives and/ or chemical solvents.

2.2. Steelco VS G2 series performances

The Steelco VS G2 series sterilizers are designed to meet the performance requirements defined by standard EN285. The structural warranty on the chambers is 25.000 cycles or an operational life of 20 years, whichever comes first.

Next to the structural warranty follow local regulations for pressure vessel testing to ensure the integrity of the chamber to prologue the use of the sterilizer.

2.3. Model Identification

The machine model described in this manual is identified as the following example:

VS		4	/	1		E		G2
a		b		c		d		e

a) Machine model

b) Capacity of the sterilization chamber (in STU – Sterilization Units)

- 4 = 4 STU
- 6 = 6 STU
- 8 = 8 STU
- 10 = 10 STU
- 12 = 12 STU

c) Number of doors (1 single front door; 2 doors, one opposite the other)

d) The letters indicate the type of steam supply:

- E = internal generator with **E**lectric heating
- V = direct centralized steam ("**V**apour") without internal generator
- I = internal generator with **I**ndirect steam heating
- EV = internal generator with **E**lectric heating + direct steam ("**V**apour")

- EI = internal generator with **E**lectric heating + **I**ndirect steam

e) G2 serie

3. CONSTRUCTIONAL CHARACTERISTICS

3.1. Technical characteristics

3.1.1. Chamber dimensions

		MODEL									
		VS 4 G2		VS 6 G2		VS 8 G2		VS 10 G2		VS 12 G2	
Door number		1	2	1	2	1	2	1	2	1	2
	U.M.										
Width	mm inch	670.0 26.4									
Height	mm inch	700.0 27.6									
Depth	mm inch	686 27.0	710 28.0	986 38.8	1010 39.8	1286 50.6	1310 51.6	1760 69.3		2060 81.1	
Sterilization units	N°	4		6		8		10		12	
Usable volume	litres Cft m^3	322 11.4 0.322	333 11.8 0.333	462 16.3 0.462	474 16.7 0.474	603 21.3 0.603	614 21.7 0.614	810 28.6 0,810	825 29.1 0.825	925 32.7 0.925	966 34.1 0.966

Table 1 – Chamber dimensions

3.1.2. Footprint dimensions

	U.M.	MODEL				
		VS 4 G2	VS 6 G2	VS 8 G2	VS 10 G2	VS 12 G2
Width	mm inch	950 37.4				
Height	mm inch	2400 94.5				
Depth	mm inch	992 39.1	1292 50.9	1592 62.7	2042 80.4	2342 92.2

Table 2 – Footprints dimensions

3.1.3. Weights

	U.M.	MODEL									
		VS 4 G2		VS 6 G2		VS 8 G2		VS 10 G2		VS 12 G2	
		E - EV EI - I	V	E - EV EI - I	V	E - EV EI - I	V	E - EV EI - I	V	E - EV EI - I	V
Net weight (2 doors version)	Kg lb	830 1830	750 1653	1050 2315	950 2094	1300 2866	1200 2645	1650 3638	1550 3417	1900 4189	1800 3968
Hydraulic Test Weight (2 doors version)	Kg lb	1183 2608	1103 2432	1524 3360	1424 3139	1914 4220	1814 3999	2475 5456	2375 5236	2866 6318	2766 6098

Table 3 – Overall Weights

3.1.4. Electrical specification: 400V - 50Hz - with vacuum pump

	U.M.	MODEL									
		VS 4 G2		VS 6 G2		VS 8 G2		VS 10 G2		VS 12 G2	
		E - EV EI	V - I	E - EV EI	V - I	E - EV EI	V - I	E - EV EI	V - I	E - EV EI	V - I
Power	kW	36	4	52	4	52	6.5	70	5.5	70	5.5
Current	A	52	8	75	8	75	12	100	11	100	11

Table 4 – Electrical Specs

3.2. Autoclave Optionals

Below is a brief explanation of the various options that can be installed on the autoclave.

3.2.1. Clean Steam supply system

The Steelco VS G2 series includes several steam supply configurations:

- Built-in electrically heated steam generator (**E**): it creates clean steam by heating water via electric heating elements;
- Indirect generator (**I**): it uses industrial steam to transform water into clean steam ;
- Direct Line Steam (**V**): it uses external steam supply and this steam is used to heat the jacket and to the chamber;
- Electric generator + Direct Line Steam (**EV**): it has both an electric steam generator (E) and an external steam supply (V);
- Electric generator + Indirect Line Steam (**EI**): It has both electrical steam generator and indirect generator;

EV and **EI** configurations allow to shift from one steam supply to the other when needed.

3.2.2. Number of doors

The autoclave can be equipped with one door (**1**) or two doors (**2**).

3.2.3. Technical Compartment

The technical compartment can be placed:

- Front and/or rear (in case of through version)

This request must be made during negotiation of the contract.

3.2.4. Other options

- Water saving
- Compressed air gaskets
- 4d sensor: sensor to measure the steam saturation within the chamber during the cycle
- Air detector: for measuring the presence of air inside the chamber during the sterilization cycle
- C14 option
- Degasser System: Degassing of incoming water for generation steam

- Measurement of steam quality according to EN285
- Non-condensable gas sensor
- Water inlet pressure switch
- Steam reducer (I, V version)
- Visual level of the generator
- Removable operator panel: can be installed in alternative positions to the one in the autoclave
- Remote vacuum pump
- Barcode reader
- Steelco Data

3.3. Autoclaves accessories

Below are the accessories available for the autoclaves Steelco VS G2 series

- Water softener
- Silenced air compressor
- Droplet collection tank

LOADING RACKS WITH SHELVES		
	Loading rack made of AISI 316L	Models: all models

LOADING SHELVES		
	Loading shelves made of AISI 316L	Models: all models

TRANSPORT TROLLEY		
	Transport trolley made of AISI 316 with fixed height	Models: all models

AUTOMATIC LOADING/UNLOADING SYSTEM		
	Automatic loading/unloading system made of AISI 304	Models: all models

Table 5 – Accessories detail

3.4. Environmental conditions

3.4.1. Unit classification (for all versions)

Design pressure	3 bar + vacuum
Operating temperature	max 134° C
Operating pressure	2.3 bar + vacuum
Use	Indoors
Altitude (max.)	2000 m
Relative humidity	5% to 85%
Temperature	+ 5 to + 40 °C
Degree of pollution (According to IEC EN 60950)	2
Overvoltage category (According to IEC EN 60664)	II
Resistance to mechanical stress (According to IEC EN 62262)	IK06, 1J

Table 6 – Classification as standard EN 61010-1

3.4.2. Characteristics of storage and conservation

The Steelco VS G2 series sterilization autoclaves must be stored in closed areas with the following characteristics:

Altitude (max.)	≤ 2000 m
Relative humidity	5% to 85%
Temperature	0 to + 60 °C
Time	12 month

Table 7 – Environmental characteristics

3.4.3. Noise/Vibrations

The average weighted level of sound pressure A is lower than or equal to 76 dB(A).

The declared values are measured and calculated in compliance with standard ISO 3746.

If the machine is properly installed, vibration is practically non-existent.

3.4.4. Heat loss of the unit

Values have been calculated/measured in the worst temperature condition from the admitted ambient temperatures, during exercise temperature peak.

MODEL	Heat dissipation in the technical compartment	Frontal heat loss (each door) in kW
VS 4 G2	2	0.3
VS 6 G2	2.6	0.3
VS 8 G2	3	0.3
VS 10 G2	3.8	0.3
VS 12 G2	4.1	0.3

Table 8 – Heat loss

3.5. Residual risks

Risk of use and maintenance by unskilled or untrained personnel.	Clear indications in the operating manual	This machine must be operated by trained persons only. The user is forbidden to carry out any work or repairs on the machine. Customer care available by authorized service. The equipment should be installed by authorized personnel only.
Risk of burns due to contact with hot objects at the end of the cycle.	In O&M manual, Operator is required to wear proper PPE during the loading/unloading phase.	GENERIC SAFETY SIGNALS: In particular, the labels with obligation signal, prohibition and danger shown on the manual, are  "Operator must wear proper PPE during loading and unloading phase, due to high temperature of the equipment".
Risk of hand crushing; moving parts. Sliding doors	Above the sliding door(s) there is an anti-crushing device.	

3.5.1. Personal Protective Equipment (PPE)

Equipment to protect against burns include:

- Heat-insulating gloves (usually provide complete coverage of hands and forearms)
- Lab coat
- Eye protection
- Closed-toe footwear

3.6. Parts Identification

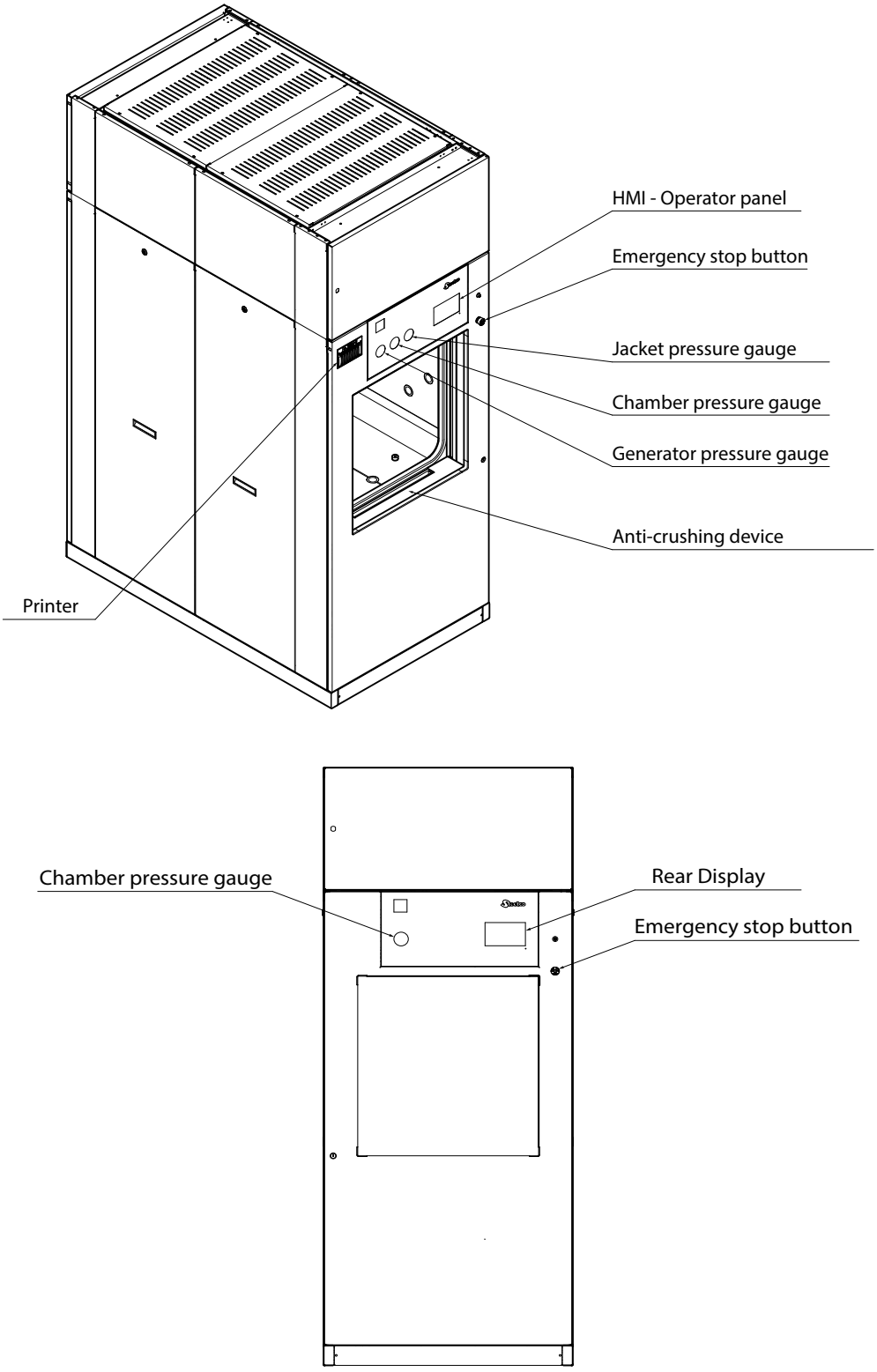
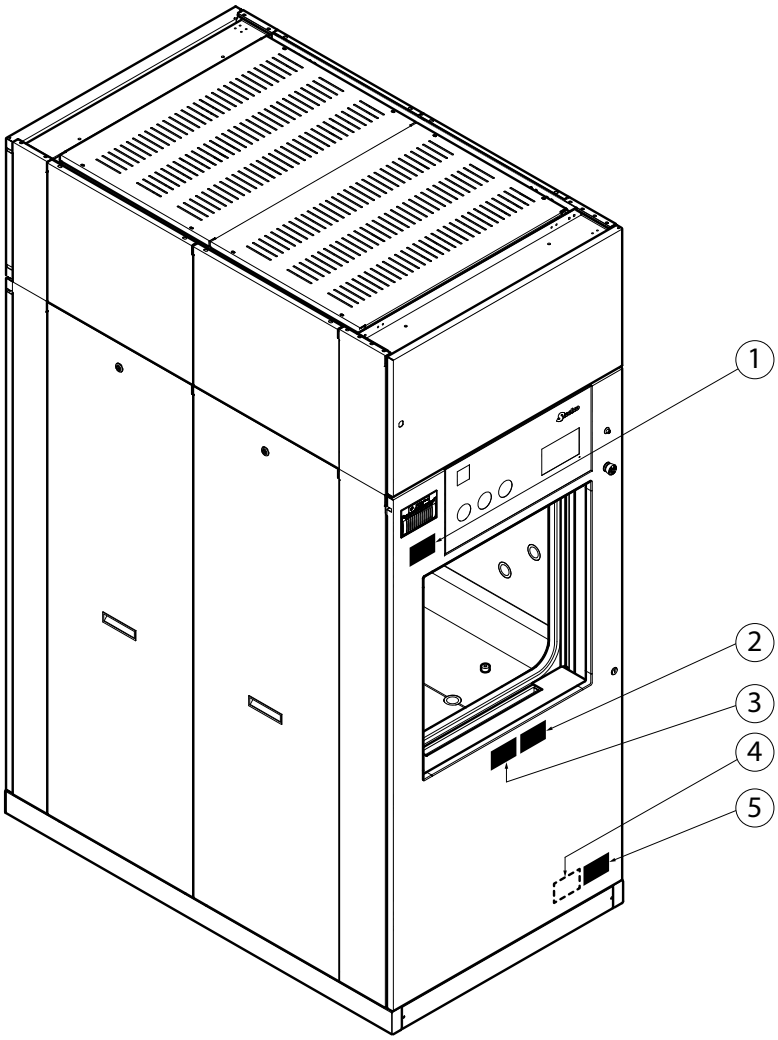


Figure 1 – Identification of front and rear parts

3.7. Autoclave labelling

Legenda and position of labels applied as detailed in below Figure 2.



POSITION	DENOMINATION
1	"Warning - hot surface" tag
2	"Be careful with hands" tag
3	“Read instructions for use”
4	"PED EC" group tag (internal side)
5	"Autoclave EC" tag

Figure 2 – Labelling design

WARNING!

Do NOT remove any label or tag from the machine. If worn, damaged or unreadable contact your Steelco Service Representative.

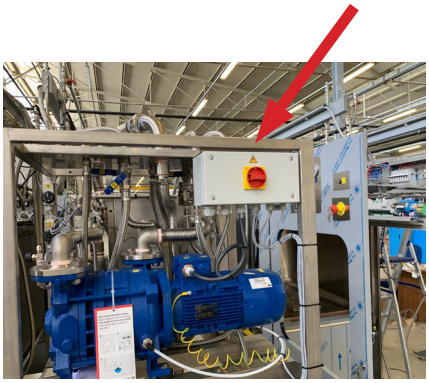
WARNING!

The use of sterilizing autoclaves must be entrusted to responsible personnel.

3.7.1. Warning plates on remote vacuum pump (optional)

In the case of a remote vacuum pump, a warning plate with the serial number and year of manufacture of the autoclave to which the pump is connected is affixed to the support frame of the remote vacuum pump.

Steelco	STEELCO S.P.A. VIA BALEGANTE, 27 31039 RIESE PIO X (TV) - ITALIA	Equipment referred to Steam Sterilizing Unit Serial Number: Year of Manufactuer:



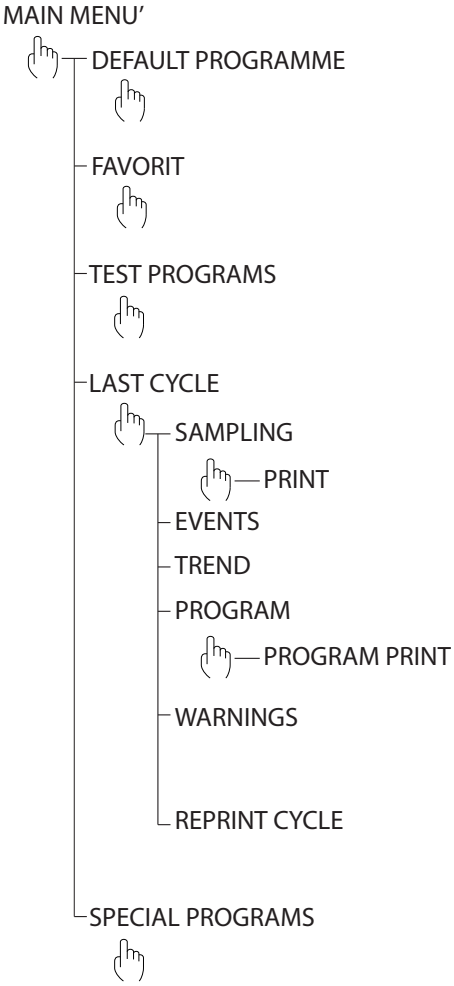
3.8. Table of symbols

Symbols installed on the machine

	Warning - hot surface
	Be careful with hands
	Equipotential terminal
	Warning - risk of electrical shock
3 ~	Tri-phase alternating current
~	Alternating current
	Ground terminal
	Warning - carefully read instructions
CE 0051	EC mark issued by notified agency: 0051 identifies IMQ
CE 0398	EC mark issued by notified agency: 0398 identifies CPM APAVE
	In position of a bi-stable push control
	Out position of a bi-stable push control

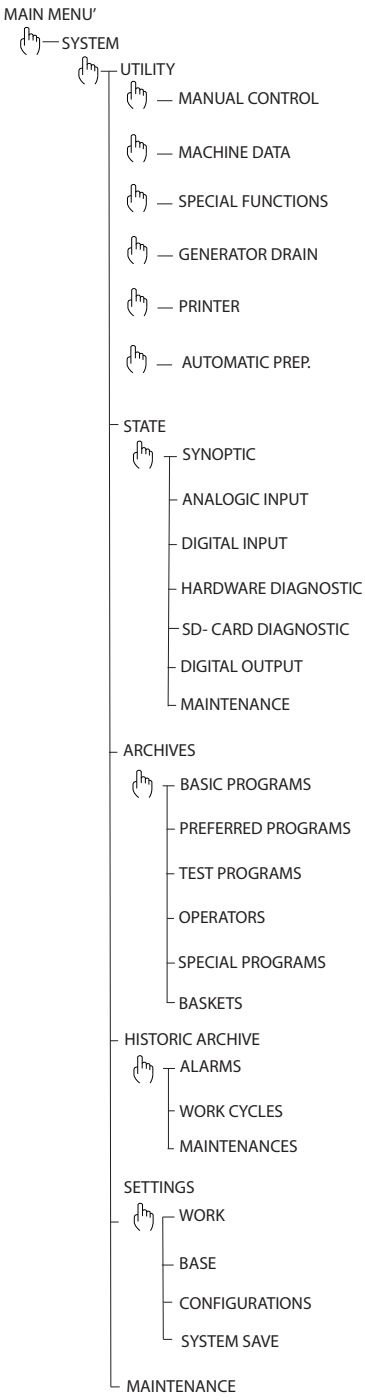
4. ACCESS LEVEL TREE

4.1. Operator permissions



4.2. Supervisor permissions

Besides the permissions of the operator access level, the supervisor access level includes the followings:



5. OPERATOR MANUAL

5.1. Sterilization: general guidance

Below is a brief and general guidance to steam sterilization techniques.

WARNING!

Following guidance does not superseed any of local procedures.

5.1.1. Load essentials

Below hints are information only, they do not supersede Local regulation or procedures in place.

- Load the sterlizer with items properly cleaned, disinfected and dried.
- Cycles must be selected evaluating always the type of load.
- Items for sterilization must be visibily cleaned.
- Any contamination or debris can affect the sterilization success.
- Observe the manufacturers' instructions.
- Maintain the instruments as instructed by the manufacturer.
- Textile must be washed and dried prior sterilization.
- Ensure that no acid or solvent residues are introduced into the chamber.
- Jointed instruments (forceps, scissors, ...) must be sterilized open and according to manufacturer's instructions.
- Possibly, sterilize different material separately - in different containers or trays
- The items must NOT touch the sterilization chamber or the door
- Never place items for sterilization in the sterilizer without suitable packaging. always place wrapped items in a proper carrier.
- Arrange the envelope properly, to prevent air pockets forming.

WARNING!

Follow the instruments/textile manufacturer's instructions regarding reprocessing and sterilization.

Observe the relevant standard and guidelines.

5.2. Operator position

The operator is required to stand in front of the autoclave only for start-up, loading, unloading and shut off operations.

WARNING!

Operator must wear proper Personal Protective Equipment (PPE) during loading and unloading phase, due to high temperatures of the equipment.

WARNING!

It is not possible to open the door(s) till chamber pressure is “zero”. Do not force the door.

WARNING!

The level indicators must remain closed during the operating period.

A safe area (Respect zone) must be established to avoid sterilizer room occupants get injured during regular activities.

Room occupants must always respect the “respect zone” when sterilizer is working (exposed parts can reach more than 50°C (122° F).

To reduce slippery conditions, keep floors dry by immediately wiping up any spilled liquids or condensation in sterilizer loading or unloading area.

WARNING!

Loading and unloading of sterilized material must only be carried out by operators assigned to sterilization.

5.3. Main menu page

The control system described in the following pages may be indicative. The HW and SW configuration chosen by the client may introduce some changes. For additional information refer to Steelco Assistance Service.

Below figure represents the main control panel:

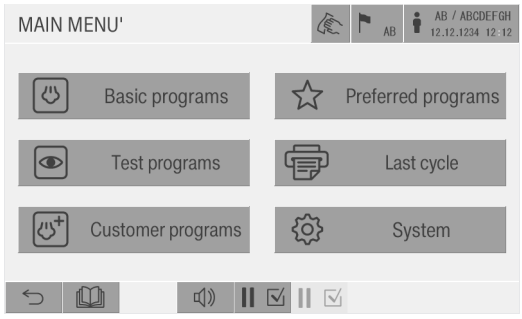
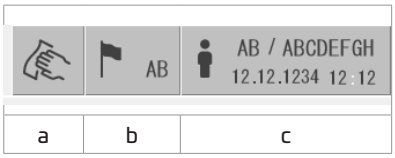


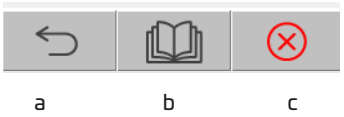
Figure 1 – Main menu page

The following table shows the main icons and navigation buttons on the touchscreen display:



a) Function that disables the on-screen functions and allows them to be cleaned
b) Function that allows you to select the language of the screen
c) Function that allows login/logout

The bottom bar contains the following icons for quick navigation:



a) Allows you to go to the previous screen
b) Return to the main page
c) If the symbol is red then there are alarms present, press to display the list.

5.4. User Login

The device is equipped with a multilevel access control to protect the system data and the functions with different security levels.

Any action requested in the system must be validated by entering a password assigned to the operator.

When a menu command is tapped, the system displays the log-in interface.

Figure 2 – User login

On the upper bar of Main Menù page tap the icon as shown above

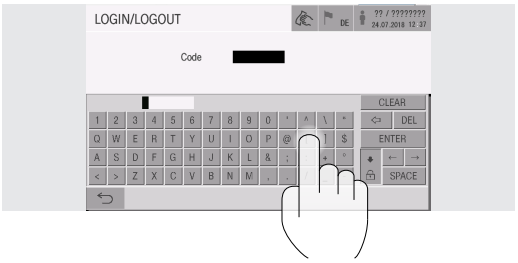


Figure 3 – Login keyboard

Usefull keyboards keys:

⇦	Deletes the character before the cursor
DEL	Deletes the character that follows the cursor
⮌	Hides the keyboard
ENTER	Validate the entered data

5.5. Cycle management

5.5.1. How to start a cycle

1. Switch-ON the machine using the proper button, below the display on the loading side.

User shall be compliant with Local regulation or procedure on Bowie & Dick test, Vacuum Test and Helix test performance.

WARNING!

Operator must wear proper Personal Protective Equipment (PPE) during loading and unloading phase, due to high temperatures of the equipment.

2. Press *BASIC PROGRAMS* or *PREFERRED PROGRAMS* or *CUSTOMER PROGRAMS* on the touchscreen to access the cycle start menu.

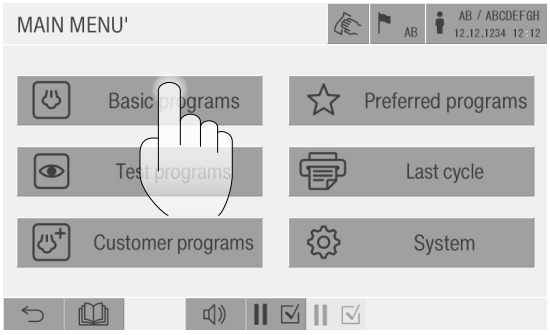


Figure 4 – Main menu

3. Select the cycle to start. Press *Start* to confirm.

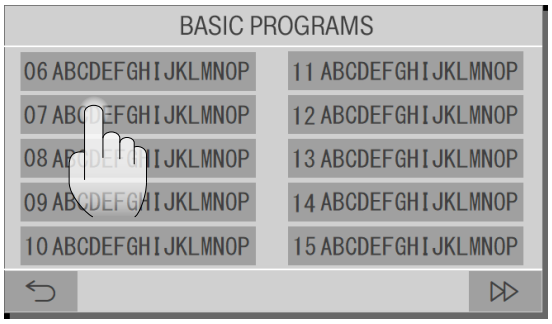


Figure 5 – Cycle selection

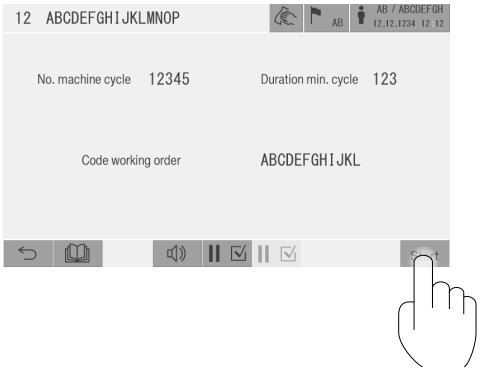


Figure 6 – Cycle start

During the cycle, the machine automatically positions itself on the *CYCLE STATUS* page.

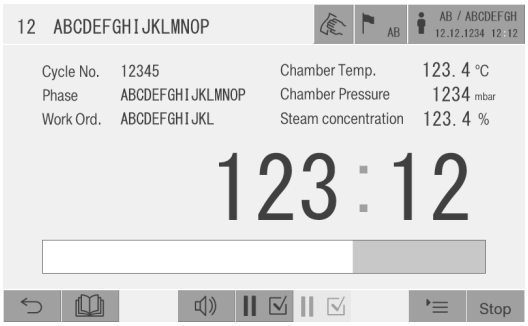


Figure 7 – Sterilization

5.5.2. Cycle completion

When sterilization process is completed the autoclave returns to *MAIN MENU* page.

The sterilizer condition will appear as *FINISHED CYCLE* - once the door will be opened the condition will turn to *OUT OF CYCLE*.

5.5.3. Electric feeding interruption

If there is a power failure, the screen will appear as follows:

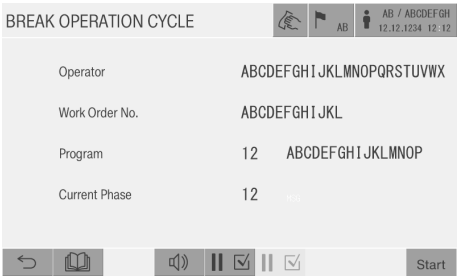


Figure 8 – Cycle interrupted

By pressing the START button the cycle skips to the drying phase. The cycle will be completed with a negative result and identified as *CYCLE NOT OK*. The supervisor must be informed.

5.5.4. Emergency button

The emergency button is an emergency device which “freeze“ completely any action that the machine was performing.

To reset the emergency button insert the key into the red button and turn it.

Press the *Reset* button at the bottom right of the screen to reset all alarms.

The autoclave will conclude the cycle.

Cycle outcome could be “*NOT OK*”.

5.6. Emergency procedure for load extraction

WARNING!

This procedure must be carried out by the supervisor only.

WARNING!

Operator must wear proper Personal Protective Equipment (PPE) during unloading phase, due to high temperatures of the equipment.

Should the control system (PLC) be defective, it is possible to extract the load from the unit via a three-position selector and a key, which are located internally behind the front panel, identified by the tags 26SA1 and 26A2.

Then proceed as follows:

1. Press the emergency push button.
2. Open the inspection door of the technical compartment.
3. Insert the keys into the selectors 26SA1 and 26SA2.
4. Rotate the selector "26SA1" into "position 1" and keep it rotated.
5. Wait until the pressure inside the sterilizer chamber reaches the atmospheric pressure. This may take some time in relation to the pressure existing into the chamber.
6. Rotate the selector "26SA1" into "position 2" to de-pressurize the seal of the door.
7. Rotate the selector "26SA2" into the "position 1") and keep it in position for at least 20 seconds to retract the seals of the door. Release the selector "26SA2".
8. Rotate the selector "26SA2" into the "position 2" and keep it in position to open the front door. When the door is completely opened it stops automatically. Then release the selector "26SA2".
9. Wait some time until the load is cooled enough to extract it from the chamber.
10. Then proceed with unloading the material, using appropriate protection against high temperatures that may be present.
11. Remove the keys from the selectors.
12. Close the inspection door of the technical compartment and call the Steelco Service Representative.

5.6.1. Printout management

Printout management is greatly important to identify the status of the process and machine.

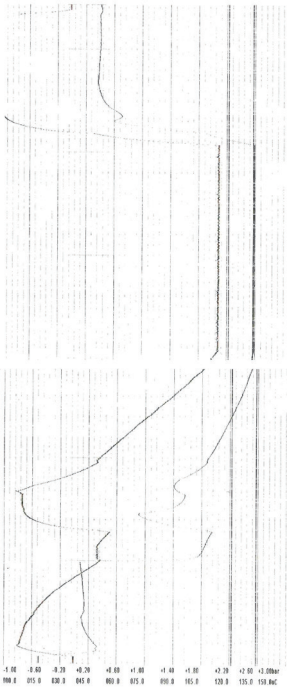
Relevant information contained in the printout are detailed below:

EVENTS LIST

Time (hh:mm:ss), counting (in seconnds), temperature (°C), pressure (bar), event list, phase name.

CYCLE RESULT

Cycle result (OK/NON OK), FO value (from the recording and from the control), date and time of cycle completion.

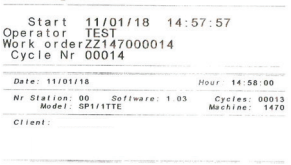


REPORT TREND

Graphic trend of cycle analogical signals (°C, bar).

PHASE SEQUENCE AND VALUES

Details of phase sequences, temperature and/or pressure and/or duration and the program executed.



MACHINE DATA

Start time, operator name, work order number, cycle progressive number, software version, machine model and customer name.

WARNING!

The data shown in the graphic representation depends on the parameters set up on *PRINTER OPTION* menu.

5.7. Last cycle menu

MAIN MENU>LAST CYCLE

This menu allows to display and print the information related to the latest performed cycle.

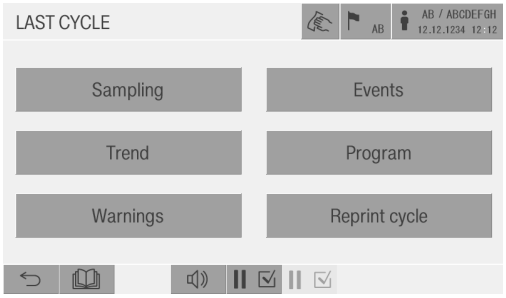


Figure 9 – Last cycle

The available options are:

- *SAMPLING*: it displays the events occurred during the last cycle, by sampling the data; user can choose the sampling time (1, 10, 60, 600 seconds)
- *EVENTS*: it prints relevant events occurred during the last cycle;
- *TREND*: it displays the diagram relating to the last cycle. Using the arrows on the screen user is able to move back and forward the diagram. Tap the rectangular icon to go back. The diagram shows both the control and recording data (temperature and pressure).
- *PROGRAM*: View and print the settings of the last executed program
- *WARNINGS: Displays any warnings that may have appeared in the last cycle.*
- *REPRINT CYCLE*: it reprints the last cycle printout.

5.8. Alarms Manage

If the trouble persists for second though the alarm will switch off.

Any alarm condition will switch off all activities, such as valve operation, motors, buzzer, etc...

Cycle result will be changed

Any alarm condition is signaled on the state bar.

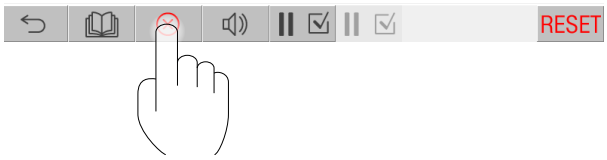


Figure 10 – Alarm

Tap the blinking ALARM to enter the page with the list of the active alarm conditions.

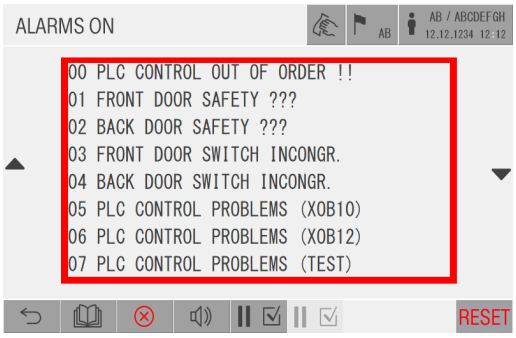


Figure 11 – Active alarms

Once the alarm conditions have been resolved, press Reset to return to the current cycle.

If an alarm condition occurs during a sterilization cycle, the control system will stop the cycle and activate the following page.

If the causes of the alarm have been eliminated, the sterilizer restarts by pressing the *RESET* button. In any case the sterilization process is identified as a *NOT OK CYCLE*.

WARNING!

The generator only stops when the emergency button is pressed.

The result of the cycle will be printed on the final report.

Every alarm that interrupts the cycle is recorded and counted by the system.

5.9. Legenda

	IN CYCLE
	The current cycle has been interrupted so the result will be negative
	IN ALARM
	Cycle successfully completed
	Cycle ended, but there was an interruption in the cycle
	Cycle not successfully completed

6. SUPERVISOR ACCESS LEVEL

6.1. During a cycle

When starting a cycle, with Supervisor access or any other higher Operator access, you can view the TREND and GRAPHIC as follows:

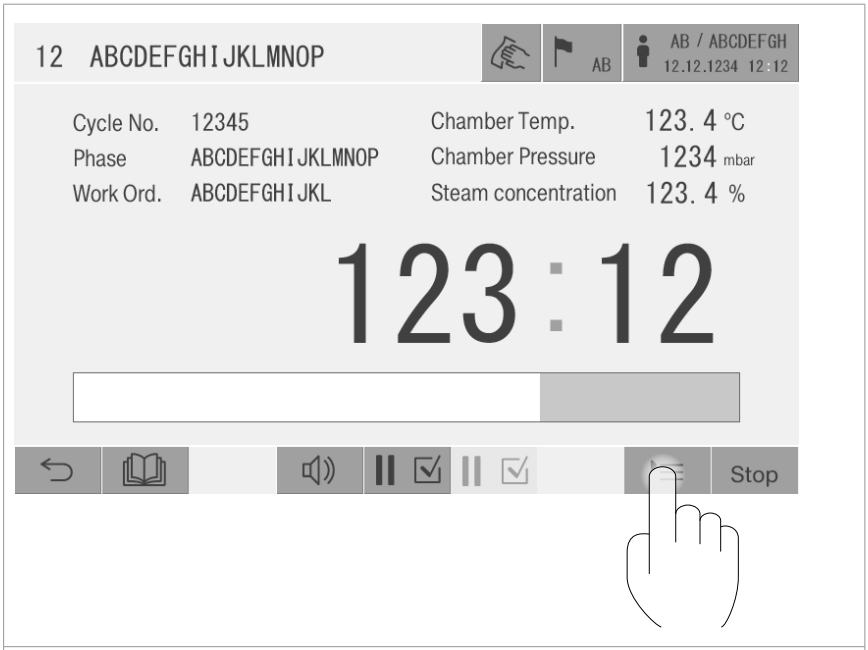


Figure 12 – Work status

By pressing the key several times, you can view the detail of the current phase:

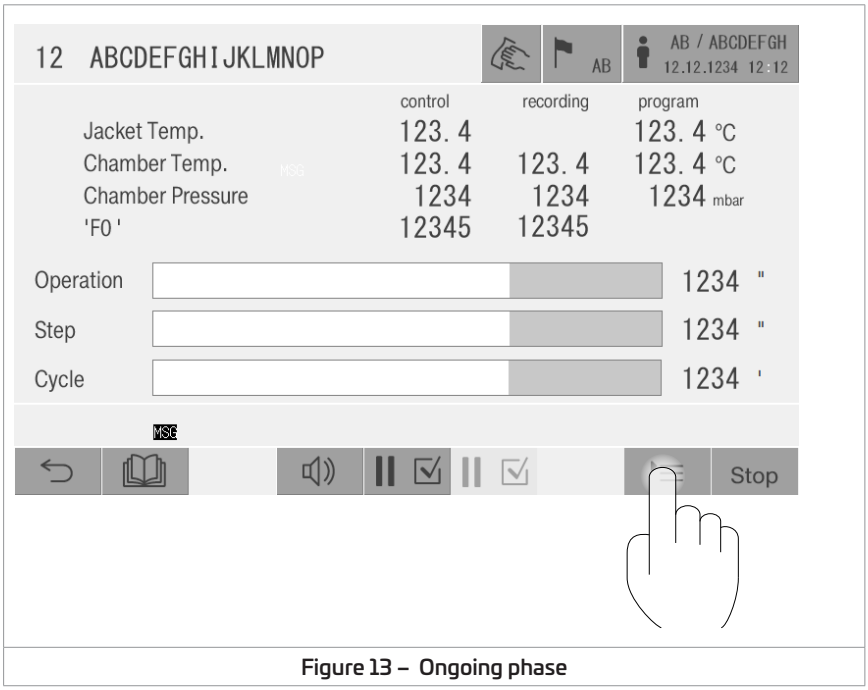


Figure 13 – Ongoing phase

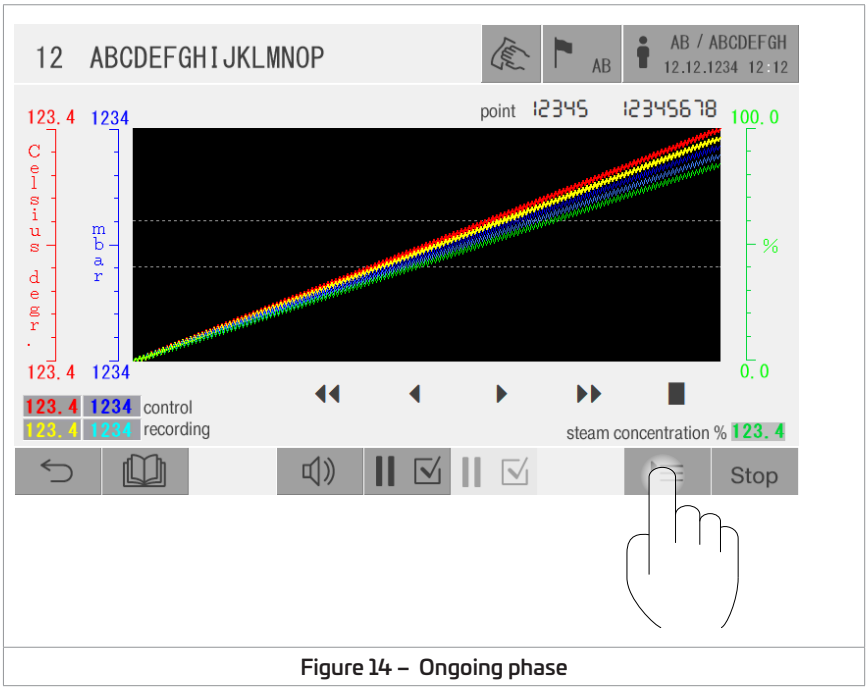


Figure 14 – Ongoing phase

6.2. UTILITY Menu

MAIN MENU>SYSTEM>UTILITY

This page displays and prints relevant information about the sterilizer.

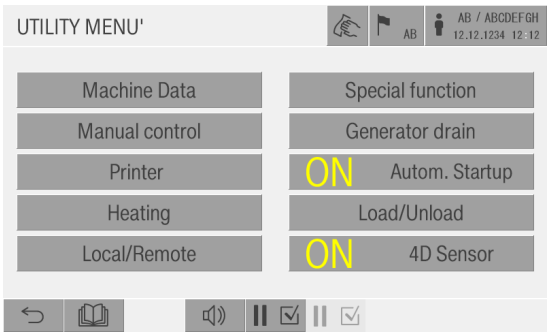


Figure 15 – Utility menu

* This menu item depends on the configuration of the machine.

6.2.1. Machine data

MAIN MENU>SYSTEM>UTILITY>MACHINE DATA

Figure 16 – Machine data

6.2.2. Special functions

MAIN MENU>SYSTEM>UTILITY>SPECIAL FUNCTION

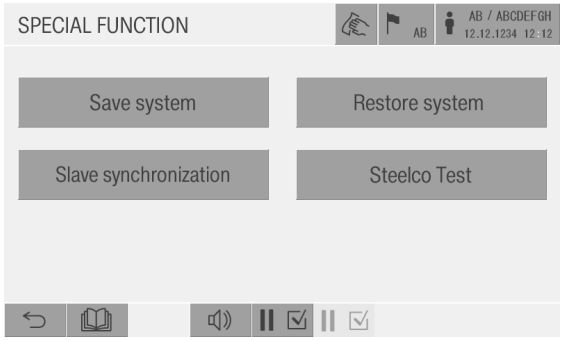


Figure 17 – Special function

6.2.3. Manual control

MAIN MENU>SYSTEM>UTILITY>MANUAL CONTROL

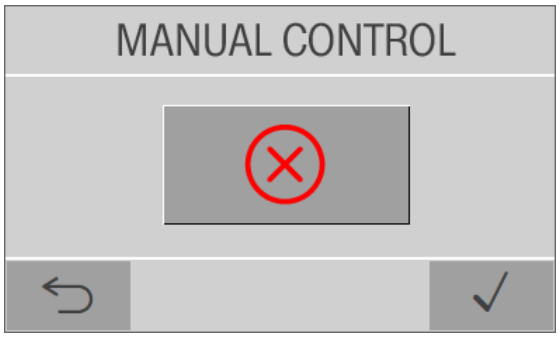


Figure 18 – Manual controls

6.2.4. Generator drain

MAIN MENU>SYSTEM>UTILITY>GENERATOR DRAIN

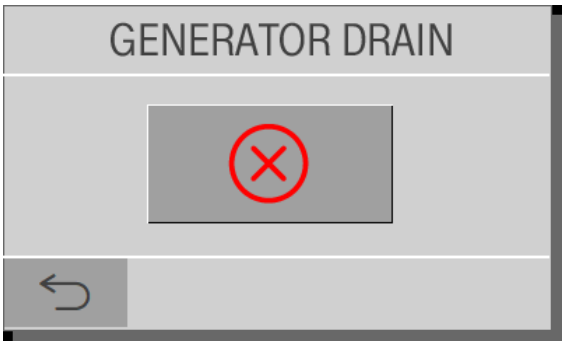


Figure 19 – Generator drain

6.2.5. Printer

MAIN MENU>SYSTEM>UTILITY>PRINTER UTILITY

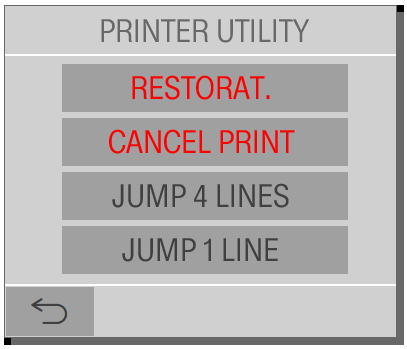


Figure 20 – Printer

6.2.6. Automatic setup

MAIN MENU>SYSTEM>UTILITY>AUTOMATIC SETUP

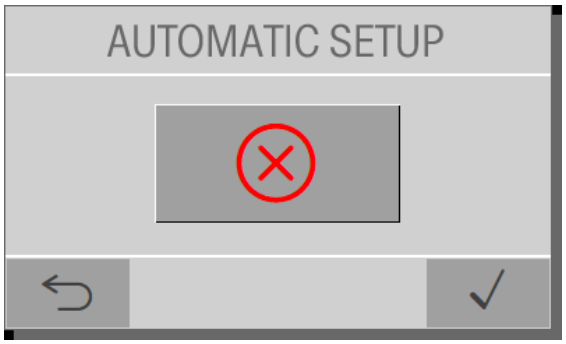


Figure 21 – Automatic setup

6.2.7. Heating

MAIN MENU>SYSTEM>UTILITY>HEATING

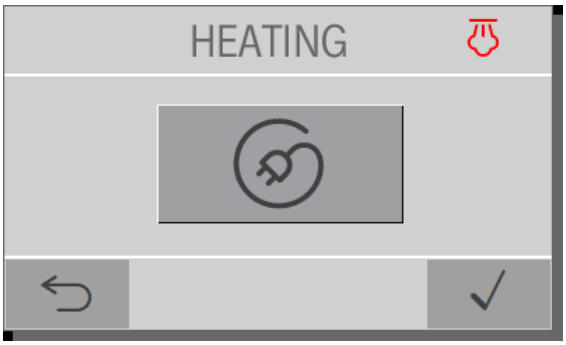


Figure 22 – Heating

6.2.8. Load / Unload

MAIN MENU>SYSTEM>UTILITY>LOAD/UNLOAD

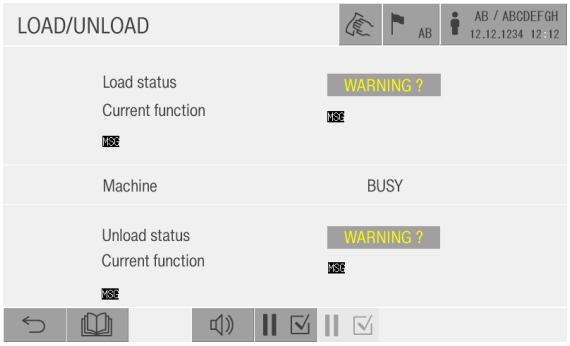


Figure 23 – Load / unload

6.2.9. Local / Remote

MAIN MENU>SYSTEM>UTILITY>LOCAL/REMOTE

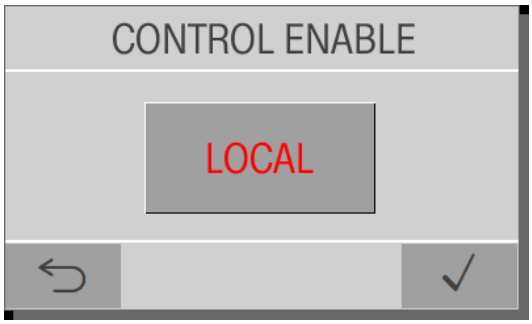


Figure 24 – Local/Remote

6.2.10. Steelco Test

MAIN MENU>SYSTEM>UTILITY>STEELCO TEST

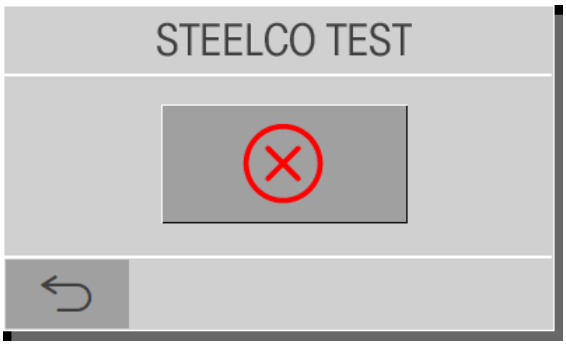


Figure 25 – Steelco test

6.3. State menu

MAIN MENU>SYSTEM>STATE MENU

This page displays the following information

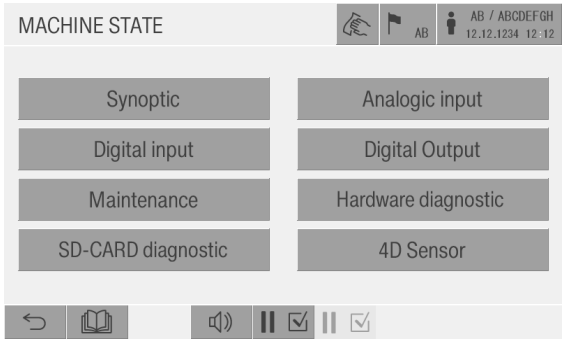


Figure 26 – Machine state menu

6.3.1. Synoptic

MAIN MENU>SYSTEM>STATE MENU>SYNOPTIC

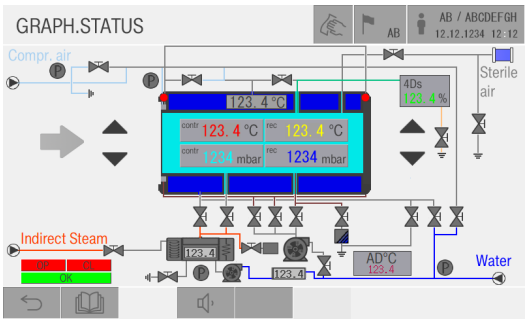


Figure 27 – Synoptic

6.3.2. Analog input

MAIN MENU>SYSTEM>STATE MENU>ANALOG INPUT

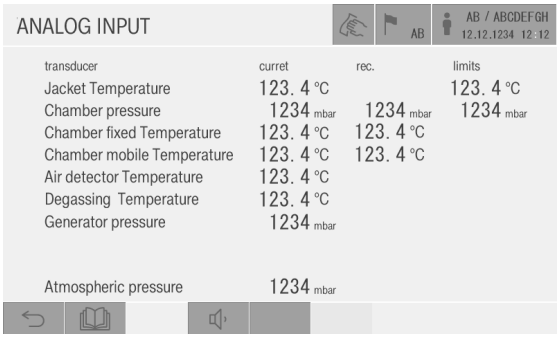


Figure 28 – Analog input

6.3.3. Digital input

MAIN MENU>SYSTEM>STATE MENU>DIGITAL INPUT

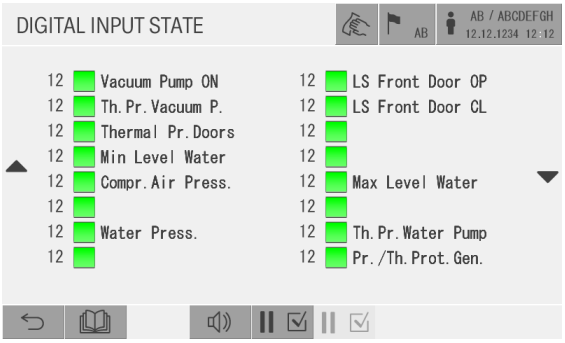


Figure 29 – Digital input

6.3.4. Hardware diagnostic

MAIN MENU>SYSTEM>STATE MENU>HARDWARE DIAGNOSTIC

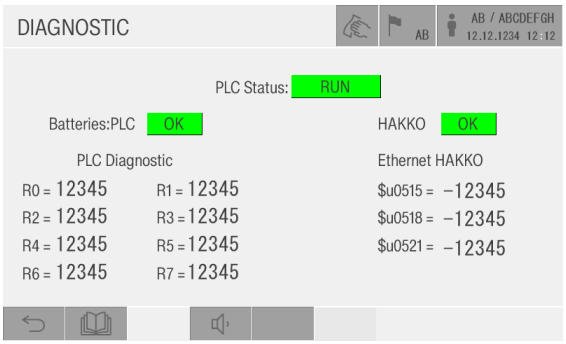


Figure 30 – Hardware diagnostic

6.3.5. SD-CARD diagnostic

MAIN MENU>SYSTEM>STATE MENU>SD-CARD DIAGNOSTIC

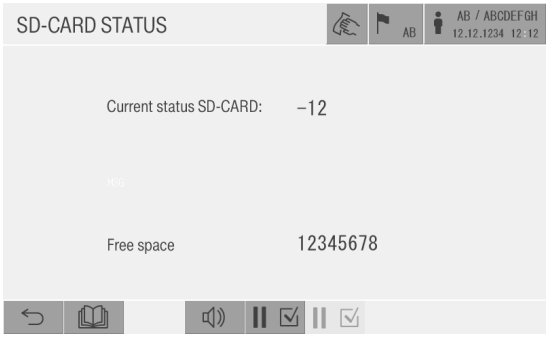


Figure 31 – SD-card Diagnostic

6.3.6. Digital output

MAIN MENU>SYSTEM>STATE MENU>DIGITAL OUTPUT

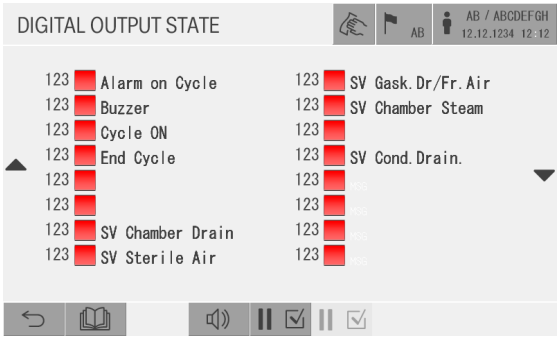


Figure 32 – Digital output

6.3.7. Maintenance

MAIN MENU>SYSTEM>STATE MENU>MAINTENANCE

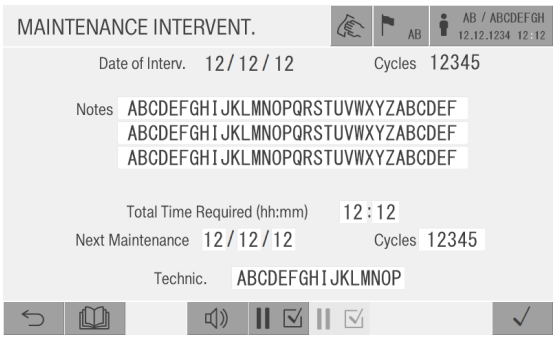


Figure 33 – Maintenance

6.4. Archive menu

MAIN MENU>SYSTEM>ARCHIVE

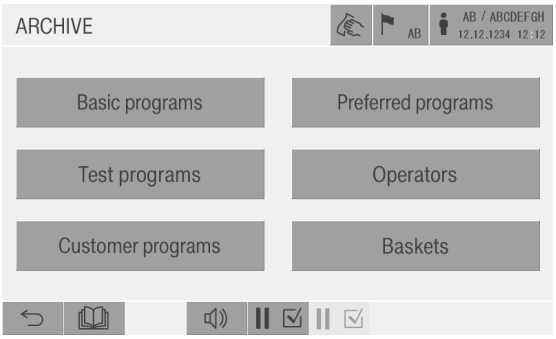


Figure 34 – Archive menu

6.4.1. Basic programs

MAIN MENU>SYSTEM>ARCHIVE>BASIC PROGRAMS

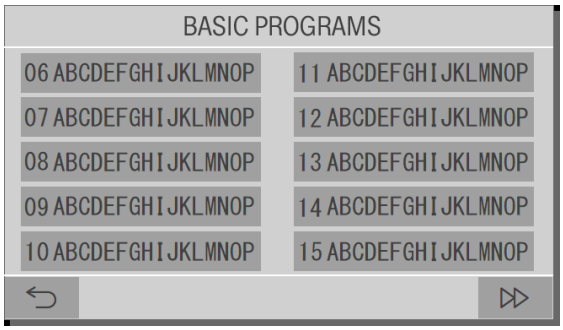


Figure 35 – Basic programs

6.4.2. Preferred programs

MAIN MENU>SYSTEM>ARCHIVE>PREFERRED PROGRAMS

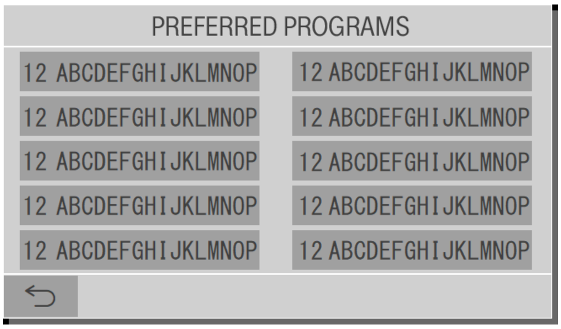


Figure 36 – Preferred programs

6.4.3. Test programs

MAIN MENU>SYSTEM>ARCHIVE>TEST PROGRAM

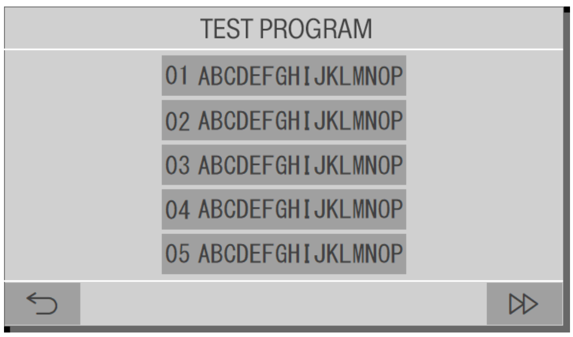


Figure 37 – Test program

6.4.4. Operators menu

MAIN MENU>SYSTEM>ARCHIVE>OPERATORS

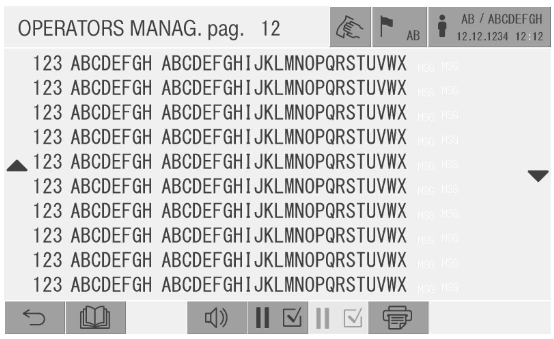


Figure 38 – Operators management list

6.4.5. Special programs

MAIN MENU>SYSTEM>ARCHIVE>SPECIAL PROGRAMS

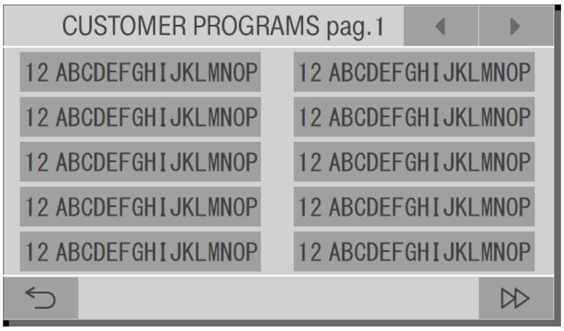


Figure 39 – Special programs

6.4.6. Basket managements

MAIN MENU>SYSTEM>ARCHIVE>BASKET

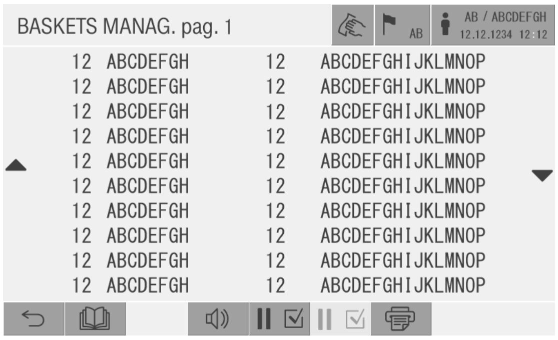


Figure 40 – Basket

6.5. Historic archives

MAIN MENU>SYSTEM>HISTORIC ARCHIVES

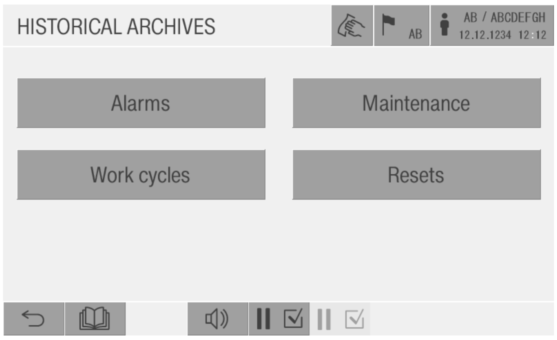


Figure 41 – Historic archives

6.5.1. Alarms

MAIN MENU>SYSTEM>HISTORIC ARCHIVES>ALARMS

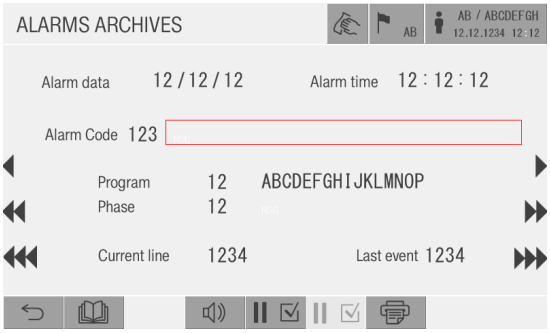


Figure 42 – Alarms

6.5.2. Work cycles

MAIN MENU>SYSTEM>HISTORIC ARCHIVES>WORK CYCLES

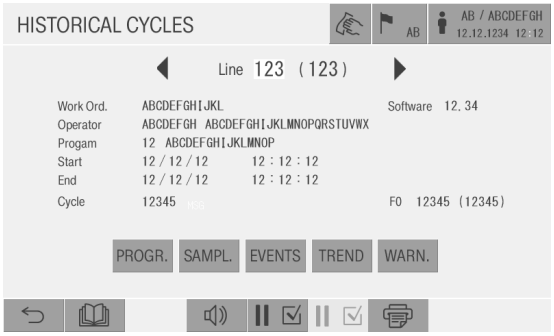


Figure 43 – Work cycles

6.5.3. Maintenance

MAIN MENU>SYSTEM>HISTORIC ARCHIVES>MAINTENANCE

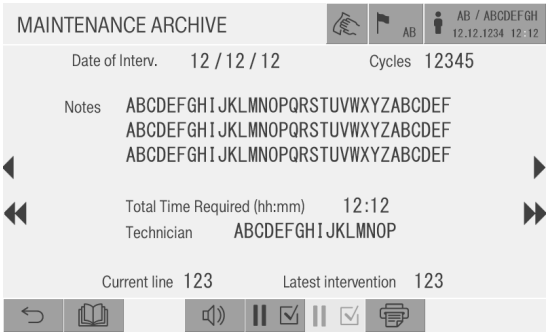


Figure 44 – Maintenance

6.6. Settings

MAIN MENU>SYSTEM>SETTINGS

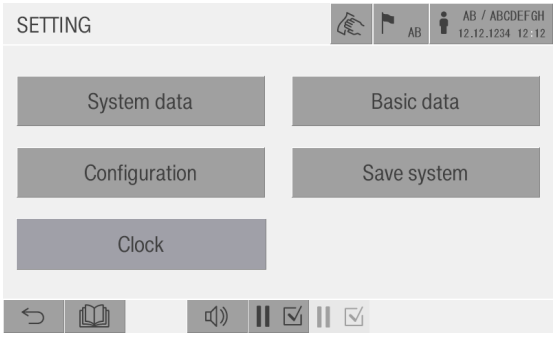


Figure 45 – Settings

6.6.1. Work

MAIN MENU>SYSTEM>SETTINGS>WORK

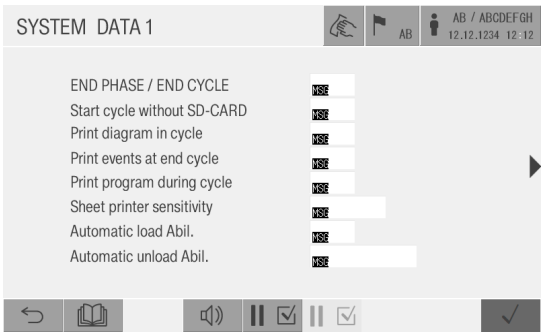


Figure 46 – Work

6.6.2. Base

MAIN MENU>SYSTEM>SETTINGS>BASE

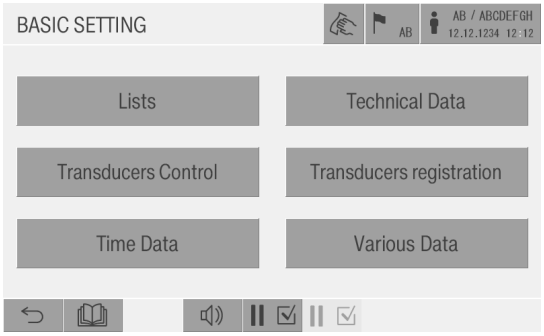


Figure 47 – Base

6.6.3. Configurations

MAIN MENU>SYSTEM>SETTINGS

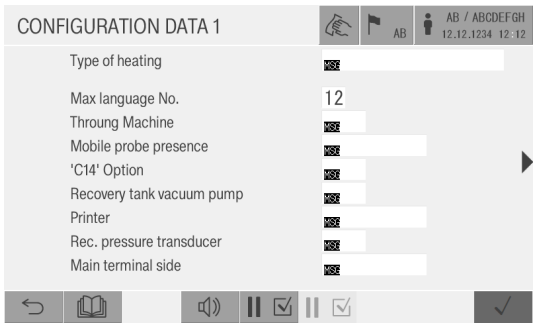


Figure 48 – Configuration 1

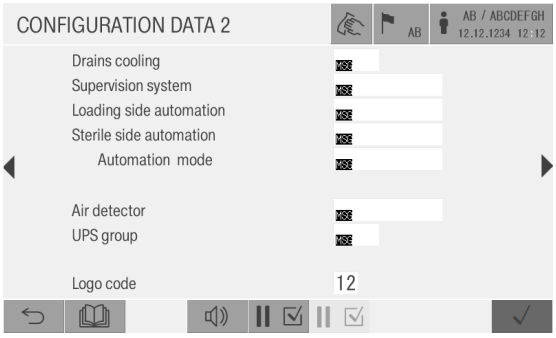


Figure 49 – Configuration 2

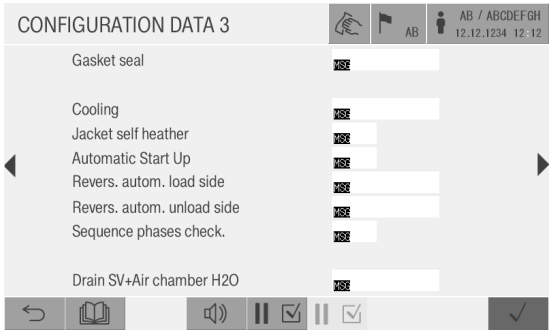


Figure 50 – Configuration 3

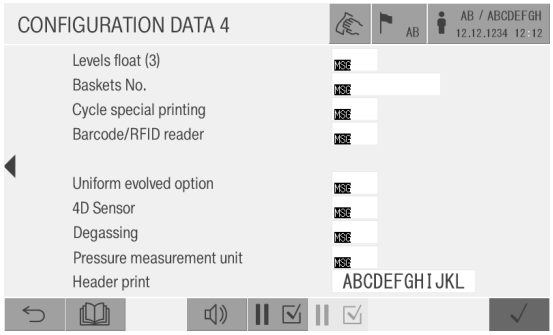


Figure 51 – Configuration 4

6.6.4. System save settings

MAIN MENU>SYSTEM>SETTINGS> SYSTEM SAVE

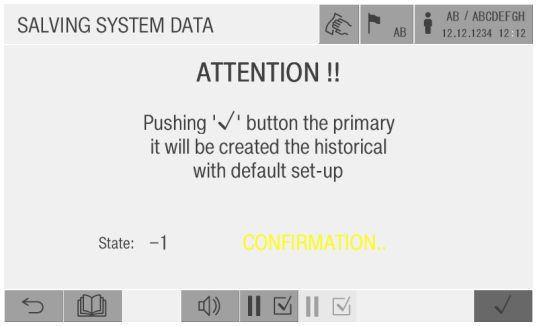


Figure 52 – System save

6.6.5. Clock

MAIN MENU>SYSTEM>SETTINGS> CLOCK

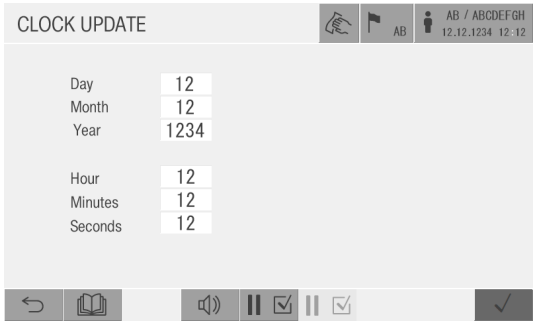


Figure 53 – Update clock

6.7. Properties of sterilization program steps

MAIN MENU > CONFIGURATION > PROGRAMS > Program name

6.7.1. Seal control

MAIN MENU > CONFIGURATION > PROGRAMS > Program name > SEAL CONTROL

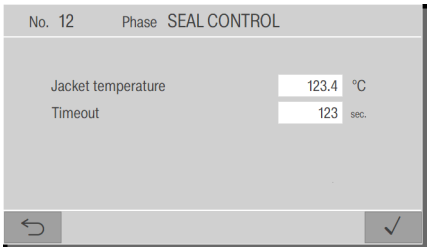


Figure 54 – Seal control

- *JACKET temperature*: allows to set the temperature to be reached by the jacket before activating the gasket seal.
- *TIMEOUT*: sets the time to be waited for, before generating an alarm indicating problems in the seal system.

6.7.2. Air removal

MAIN MENU > CONFIGURATION > PROGRAMS > Program name > AIR REMOVAL

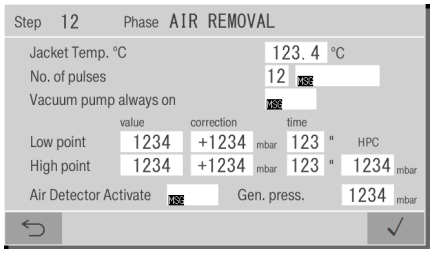


Figure 55 – Air removal

- *JACKET temperature*: allows to set the temperature to be maintained in the jacket during the whole phase.
- *No. of PULSES*: establishes the number of homogenization pulses to be done (during a pulse vacuum is created in the chamber and then the chamber is pressurized through steam injection. This is to grant that the air is removed from the load to be sterilized).
- *Vacuum pump always ON*: if YES, during the vacuum phase, after the set-points reached, the pump remains active for the set time.
- *LOW point bar*: sets in the first field the pressure of the first vacuum value which the machine must reach, in the second field the variation of pressure that is added to every pulse to find vacuum values characterizing the following pulses, in the third field the period of time for which the machine remains at the vacuum value reached at every pulse.
- *High point bar*: sets in the first field the value of the pressure value which the machine must reach at the first pulse, in the second field the variation that is added to every pulse to find the value of the following pressure pulses, in the third field the period for time in which the machine remains at the pressure

value.

6.7.3. Sterilization

MAIN MENU > CONFIGURATION > PROGRAMS > Program name > STERILIZATION

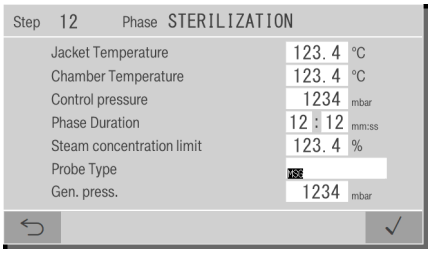


Figure 56 – Sterilization

- *JACKET Temperature*: allows to set the temperature to be maintained in the jacket during the whole phase.
- *CHAMBER Temperature*: allows to set the temperature value at which the counting of the sterilization time starts.
- *Control Pressure (mbar)*: sets the pressure of the sterilization plateau.
- *Phase Duration (mm:ss)*: sets the length of the sterilization plateau.
- *PROBE Type*: establishes the probe to be considered while surveying the temperature of the chamber: the fixed probe or the mobile (option) probe.
- Air
- Pump
- Press. gen. mbar

6.7.4. Drying

MAIN MENU > CONFIGURATION > PROGRAMS > Program name > DRYING

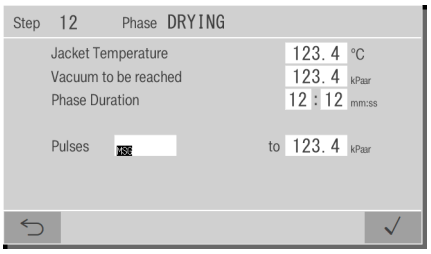


Figure 57 – Drying

- *JACKET Temperature*: allows to set the temperature to be maintained in the jacket during the whole phase.
- *Vacuum to be reached bar*: sets the vacuum value to be reached by the autoclave to grant the cooling.
- *Test time (mm:ss)*: sets the period of time for which the vacuum condition described before must be maintained.

6.7.5. Vacuum test

MAIN MENU > CONFIGURATION > PROGRAMS > Program name > VACUUM TEST

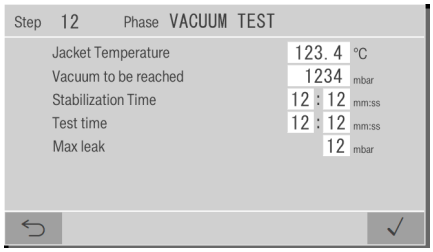


Figure 58 – Vacuum test

- *JACKET Temperature*: allows to set the temperature to be maintained in the jacket during the whole phase
- *Vacuum to be reached bar*: sets the vacuum value to be reached by the autoclave before the stabilization phase.
- *Stabilization Time (mm:ss)*: sets the duration of the stabilization phase (after the vacuum conditions set before have been reached, the autoclave stop the vacuum pump and closes all inlet and drain pipes of the autoclave and remains in this condition for the time set with this parameter.
- *Test Time (mm:ss)*: at the end of stabilization phase the actual vacuum test begins. During the period of time dimensioned with this parameter, the system checks that there is not no vacuum leak over 1,3 mmbar/min.
- *Max. leak (mbar)*: allows to set the value of the admissible loss beyond which vacuum test fails.

6.7.6. Heating

MAIN MENU > CONFIGURATION > PROGRAMS > Program name > HEATING

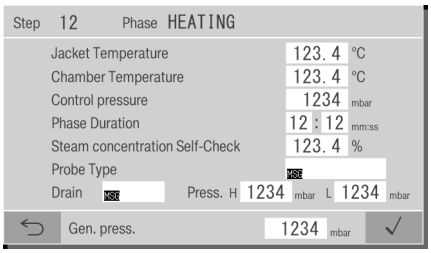


Figure 59 – Heating

- *JACKET Temperature*: allows to set the temperature to be maintained in the jacket during the whole phase;
- *CHAMBER Temperature*: allows to set the temperature value at which the counting of the time for which the temperature set must be maintained starts. If set to 000.0 the control is done exclusively in pressure
- *Control Pressure bar:* sets the pressure with which the heating phase is controlled. If set to Zero the phase is controlled exclusively by temperature. If a NEGATIVE value is set, adjustment is made on the temperature: "-1.00" has to be read as "<1.00 bar", defining the maximum pressure limit.
- *Phase duration (mm:ss)*: time cycle, the count starts when the temperature is reached (With temperature = 0 counting starts immediately).
- *Drain Chamber*:
  - *NO*: the chamber steam intake is activated; the chamber drain valve is disabled; the condensate is drain only by the steam trap;
  - *YES*: the chamber steam intake is enabled; the chamber drain valve is enabled;
  - *PUMP*: the chamber steam intake is enabled; the vacuum pump is enabled.

With options YES or PUMP, steam intake and drain/suction begin when the set temperature is reached. Phase time count also starts at this moment.

The discharge / suction activation points (on / off) are settable by means of the parameters: *PR. Bar High and Low*.

- *Probe type*: establishes the probe to be considered while surveying the temperature of the chamber: the fixed probe or the mobile (option) probe.

6.8. Basic Cycles: Settings and Graphs

Graphs are intended for indicative purpose only.

All cycles(called program in the SW), except for liquid cycle, are characterized by 4 phases. Each phase is configured differently to meet the cycle's purpose.

6.8.1. Bowie & Dick test

This cycle includes following phases:

1. Seal control;
2. Homogenization (3 times);
3. Sterilization;
4. Drying.

The frequency and duration of each phase may vary depending on sterilizer configuration, control selection and programming.

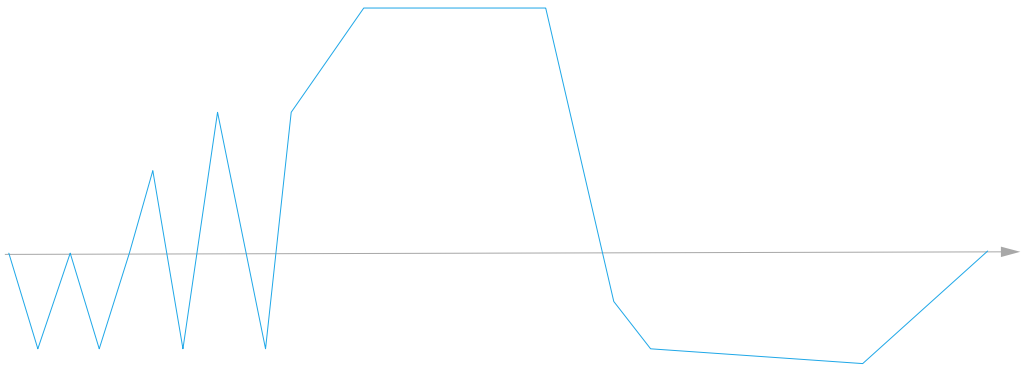


Figure 60 – Bowie & Dick test

6.8.2. Vacuum test

This cycle includes following phases:

1. Seal control;
2. Vacuum test.

The frequency and duration of each phase may vary depending on sterilizer configuration, control selection and programming.

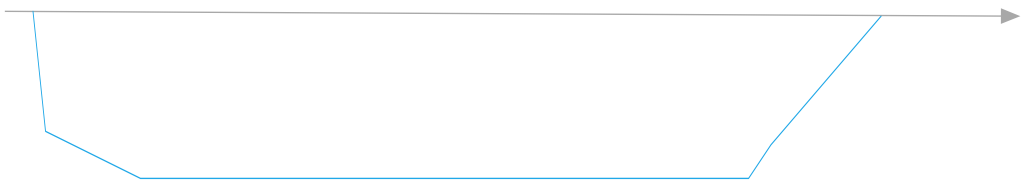


Figure 61 – Vacuum test

6.8.3. Instrument program

This cycle includes following phases:

1. Seal control;
2. Homogenization (3 times);
3. Sterilization;
4. Drying.

The frequency and duration of each phase may vary depending on sterilizer configuration, control selection and programming.

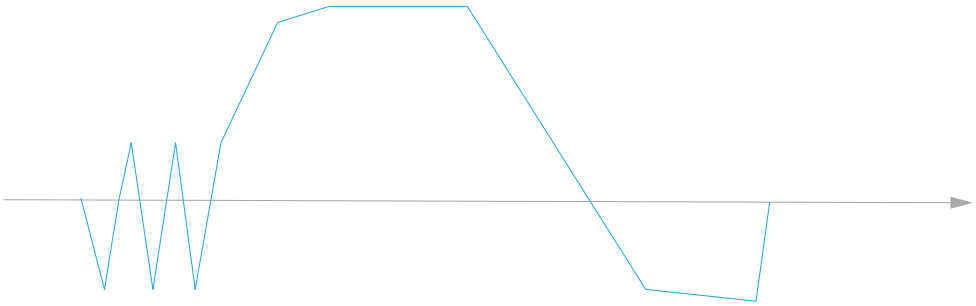


Figure 62 – Instruments Program at 134

7. TROUBLESHOOTING

7.1. Alarms

The following table provides a brief description of the meaning of each alarm and suggested actions.

Alarm message	Description of the trouble and its possible cause	Suggested solution
--	Moving the key-selector on "I" the machine does not switch on Possible causes: 1) the machine has no voltage; 2) the main switch upside the machine is switched off ; 3) the main switch of the electric panel is switched off; 4) the machine safety devices intervened; 5) transformer or power feeder damage	Check: 1) for live voltage; 2) for the main switch upside the machine; 3) that the main switch of the electric panel is switched on; 4) for the intervention of the safety devices; 5) for the efficiency of the transformer and/or the power feeder
00 PLC CONTROL OUT OF ORDER !!	Control PLC malfunction	Switch off and switch on again the machine. If the problem persists, contact Steelco customer service
01 FRONT DOOR SAFETY ???	The anti-crushing plate on the indicated side is pushed	Reset the alarm, and repeat the operation of closing and opening the door
02 BACK DOOR SAFETY ???		
03 FRONT DOOR SWITCH INCONGR.	The door sensors are inconsistent: door shows that it is open and closed at the same time.	Switch off and switch on again the machine and check the integrity of the limit switch. If the problem persists, contact Steelco customer service
04 BACK DOOR SWITCH INCONGR.		
05 PLC CONTROL PROBLEMS (XOB10)	Problems in the autoclave management program	Switch off and switch on again the machine. If the problem persists, contact Steelco customer service
06 PLC CONTROL PROBLEMS (XOB12)		
07 PLC CONTROL PROBLEMS (TEST)	PLC functionality test failure	
08 HAKKO TERMINAL NOT OK	The HMI does not answer	Check the Ethernet cable from Hakko to PLC If the problem persists, contact Steelco customer service

Alarm message	Description of the trouble and its possible cause	Suggested solution
09 PLC CONTROL JACKET PROBE ?	The probe does not read or gives no data to the PLC. Possible causes: - Damaged probe; - Converter breakdown; - Analogical card breakdown	Switch off and switch on again the machine. If the problem persists verify the probe, the converter and the analogical card. To replace one of these components and to set again the measuring system contact Steelco customer service
10 PLC CONTROL FIXED PROBE ?		
11 PLC CONTROL MOBILE PROBE ?		
12 PLC CONTROL PRESS. TRANSD. ?	The transducer does not read or gives no data to the PLC. Possible causes: - Damaged transducer; - Analogical card breakdown	
13 PROBE AIR DETECT ?	The probe does not read or gives no data to the PLC. Possible causes: - Damaged probe; - Converter breakdown; - Analogical card breakdown	Switch off and switch on again the machine. If the problem persists verify the probe, the converter and the analogical card. To replace one of these components and to set again the measuring system contact Steelco customer service
14 INCORRECT PHASE SEQUENCE !!	Phase error in the 3-phase voltage supply	Check that the power supply cables are connected as specified in the wiring diagram. If the problem persists, contact Steelco customer service
16 READING FIXED TEMP. RECORD. ?	Incorrect data reading from the probe to the PLC	Replace the probe or its analog inputs card to the PLC. If the problem persists, contact Steelco customer service
18 READING RECORDING PRESSURE ?	Incorrect data read from pressure switch to the PLC	Replace pressure switch or its analog inputs card to the PLC. If the problem persists, contact Steelco customer service
19 CONTROL FRONT DOOR ?	The door does not open even though the command is sent	Check the settings of the cycle and the sliding guides. If the problem persists, contact Steelco customer service
20 CONTROL BACK DOOR ?		
21 GENERATOR OVER PRESSURE	Steam generator pressure too high. Possible causes: - Pressure switch failure; - Heating contactors jammed	Check the safety pressure switch and contactors (if faulty replace). If the problem persists, contact Steelco customer service
22 WATER PUMP SWITCH FAIL	Thermal protection of the water pump motor active	Check water line for blockage, reset the thermal protection. If the problem persists, contact Steelco customer service

Alarm message	Description of the trouble and its possible cause	Suggested solution
25 PLC RECORDING FIXED PROBE ?	The probe does not read or gives no data to the PLC. Possible causes: - Damaged probe; - Converter breakdown; - Analog card breakdown	Switch off the machine and switch on again. If the problem persists verify the probe, the converter and the analog card. To replace one of these components and to reset the measuring system contact Steelco customer service
27 PLC RECORDING PRESS. TRANSD.?	The transducer does not read or gives no data to the PLC. Possible causes: - Damaged transducer; - Analog card breakdown	Switch off the machine and switch on again. If the problem persists verify the transducer, the converter and the analog card. To replace one of these components and to reset the measuring system contact Steelco customer service
28 CONTRADICTION PROBE ON STER.	The two probes of the systems (registration, control) provide conflicting readings or one of the two does not provide data to the PLC Possible causes: - Damaged probe; - Converter breakdown; - Analog card breakdown	
29 PRESSURE TRASDUCTOR FAIL !		
31 MASTER/SLAVE CONTROL FAIL ?	Absence of communication between Master and Slave HMI	Check Ethernet cable connecting Master and Slave, and that the HMIs and PLC are in RUN mode
32 SLAVE/MASTER CONTROL FAIL ?	Absence of communication between Slave and Master HMI	
33 NO LINE STEAM !!	Steam pneumatic valve failure or absence of steam in-line	Check the presence of steam in line, and pneumatic valve. If the problem persists, contact Steelco customer service
34 NO LINE WATER !!	There is no water in the feed line. Possible causes: 1) there is no water in the circuit upstream of the machine; 2) the water pressure is not sufficient; 3) the water flow is not sufficient; 4) the pressure switch does not work correctly	Verify: 1) the presence of water in the feed circuit upstream of the machine; 2) that the water feed valve to the machine are open; 3) that the no return valve is not locked; 4) that the pressure and the water flow are according to the manufacturer's specifications; 5) the water in-line pressure switch is functioning and, if necessary, replace it

Alarm message	Description of the trouble and its possible cause	Suggested solution
35 COMPRESSED AIR FAILURE!	Signals there is no compressed air in the feed line. Possible causes: 1) there is no compressed air in the circuit delivered to the sterilizer; 2) the compressed air pressure is not sufficient; 3) the compressed air capacity is not sufficient; 4) the pressure switch does not work correctly	Verify: 1) the compressed air supply circuit delivers air to the sterilizer; 2) that the pressure and the compressed air capacity are according to manufacturer's specifications; 3) the compressed air in-line pressure switch is functioning and, if necessary, replace it.
36 THERMAL CUT-OUT !!	A motor safety thermal device cut out on the door motor is active	Open the electric panel and reset the thermal overload protection device. If the problem persists, contact Steelco customer service
37 EMERGENCY STOP!	The emergency stop button has been pushed	Reset to the normal state by unlocking the emergency button
38 FEED-WATER PROBLEMS !!	Water cannot be admitted to the machine. Possible causes: 1) the pump safety devices have intervened; 2) the water pump does not work; 3) the level monitoring relay does not work; 4) the tube or the strainer which takes water to the pump is obstructed; 5) the tube which comes out of the pump is obstructed; 6) the level control device does not work; 7) the level control probes are encrusted and cannot detect the presence of the water	Verify: 1) the fuses or the thermal device of the water pump are not blown or tripped; 2) the water pump output is sufficient; 3) no obstruction of the tube or the strainer which takes water to the pump 4) no obstruction of the tube which comes out of the pump; 5) the level control device is in working order; 6) the level control probes are clean and properly connected 7) clean or replace the level control probe
39 PROBLEMS WITH GASKET SEAL!!	The gasket is not pressurized / depressurized. Possible causes: 1) the door gasket is worn or damaged; 2) the gasket inlet pipe is obstructed; 3) the gasket steam inlet valve does not work; 4) there are some leaks in the gasket drain circuit	Verify: 1) the state of the gasket; 2) no obstruction in the gasket inlet pipe; 3) the function of the gasket steam valve; 4) the seal of the gasket drain circuit

Alarm message	Description of the trouble and its possible cause	Suggested solution
40 FRONT DOOR NOT CLOSED !!	The door is not closed or the door closed signal does not reach the control PLC. Possible causes: 1) the door has not been closed by the operator; 2) the door closing stop device is damaged and can not detect the door reaching its closed position; 3) the signal of the limit switch is not detected by the PLC input card; 4) the door is out of its guide; 5) the door is blocked from closing completely.	1) check the door has been closed; 2) Verify: - The function of the door stop limit switch; - The function of the PLC input device; - The door movement.
41 BACK DOOR NOT CLOSED !!		
42 PRESSURE CONTROL TRASD. FAIL	Failure of connection between the transducer and the PLC. Defective transducer or analog input card	Check and replace the pressure transducer or the analog input card
43 VACUUM PUMP FAIL !	PLC does not receive feedback from the vacuum pump: 1) The pump is not working; 2) The pump is working but there is a problem between the aux contact and the PLC	Contact Steelco customer service
44 VACUUM PUMP SWITCH FAIL	The thermal protection of the pump's motor cut out	Contact Steelco customer service
45 WATER LEVEL MISMATCH !!	Inconsistency between the maximum and minimum levels of water	Contact Steelco customer service
46 FAIL DOOR IN CYCLE ??	Pressure loss in the door gaskets during the cycle	Contact Steelco customer service
47 GENERATOR DISCHARGE FAIL !	Discharge pneumatic valve jammed	Contact Steelco customer service

Alarm message	Description of the trouble and its possible cause	Suggested solution
48 JACKET HEATING TIME??	The machine can not heat the jacket in the time allowed. Possible causes: 1) the steam line is closed; 2) wrong data setting; 3) problem in the circuit taking steam to the jacket; 4) the water in the generator is not sufficient to generate the quantity of steam that is necessary for heating; 5) there is too much water in the generator: it fills the jacket causing a fall in temperature; 6) problem in the heating device; 7) the jacket steam traps are obstructed and do not drain the air or the condensate present in the jacket/generator; the system surveying temperature is not calibrated	Contact Steelco customer service
49 TIMEOUT WATER COOLING PUMP !	Timeout when refilling the vacuum pump water	Contact Steelco customer service
50 CHAMBER VACUUM TIME ??	The machine cannot achieve the vacuum in the chamber in the allowed time. Possible causes: 1) wrong data setting; 2) problem in the chamber vacuum circuit; 3) the transducer and the analog card are not working correctly; 4) the vacuum pump liquid ring does not have enough/has too much water supplied; 5) leak in the gasket or in the hydraulic circuit	Contact Steelco customer service
51 CHAMBER PRESSURE TIME ??	The machine cannot reach the right pressure value in the chamber in the allowed time. Possible causes: 1) wrong data setting 2) the transducer and the analog card are not working correctly; 3) problem in the circuit taking steam in the chamber 4) the condensate drain system is not functional	Contact Steelco customer service

Alarm message	Description of the trouble and its possible cause	Suggested solution
52 OUT OF STERILIZING TIME ?	The sterilization phase lasted longer than the MAX time set. Possible causes: 1) during the phase there was a temporary power failure; 2) a problem in the heating element causes a fall in temperature and stops the counting of the sterilization time; 3) the MAX time set was shorter than the sterilization time	Contact Steelco customer service
53 OPENING CONDITION TIME ??	TIME-OUT returning to atmospheric pressure. Possible causes: 1) Chamber pressure transducer not working; 2) Air filter clogged or 3) Pneumatic valve air intake jammed	Contact Steelco customer service
55 STERILIZATION TEMPERAT.LOW ?	During the sterilization phase the temperature fell below the minimum value set. Possible causes: 1) the steam line has been closed; 2) during the sterilization phase condensate covered the drain probe (failed or blocked steam trap or plumbing); 3) the measuring system is not calibrated; 4) problem with the heating element; 5) leak in the chamber drain circuit	Contact Steelco customer service
56 STERILIZATION TEMPERAT.HIGH ?	During the sterilization phase the temperature went over the maximum value set. Possible causes: 1) the measuring system is not calibrated; 2) leak in the door gasket to the chamber	Contact Steelco customer service
57 VACUUM TEST FAIL !!	During the vacuum test the machine cannot keep the leak under the allowed limit. Possible causes: 1) Measuring system issue; 2) Leakage in the hydraulic circuit or connections to the chamber, seals, valves, etc..	Contact Steelco customer service

Alarm message	Description of the trouble and its possible cause	Suggested solution
58 ATMOSPHERE CONDITION TIME	TIME-OUT returning to atmospheric pressure. Possible causes: 1) Chamber pressure transducer not working; 2) Air filter clogged or 3) Pneumatic valve air intake jammed	Contact Steelco customer service
60 AIR DETECTOR TEST FAIL	The test detected a loss greater than the set one.	Contact Steelco customer service
61 GENERATOR SUPPLY FAIL	The heating of the generator was ON too long compared to the value of TIME-OUT set	Contact Steelco customer service
62 COOLING NOT POSSIBLE	Phase not executable	Check the settings of the cycle. Contact Steelco customer service
63 ENERGY LACK DURING CYCLE !!	Power supply was interrupted while the machine was in cycle	Push the start button
69 GENERATOR LEVEL ALARM !!	Generator water level has dropped below the critical level	Contact Steelco customer service
70 GENERATOR TRASD. FAIL !!	The transducer does not read or gives no data to the PLC. Possible causes: - Damaged transducer; - Analog card failure	Switch off the machine and switch on again. If the problem persists verify the function of the probe, the converter and the analog card. To replace one of these components and to reset the measuring system contact Steelco customer service.
71 PROBE DEGASSING FAIL !!	The probe does not read or gives no data to the PLC. Possible causes: - Damaged probe; - Converter breakdown; - Analog card breakdown	
79 TIMEOUT HEATING 4D SENSOR !	The temperature of the device is not reached in foreseen time	Contact Steelco customer service

7.2. Warnings

The following table provides a brief description of the meaning of each warning.

Warning message	Description
03 LOAD/UNLOAD SYSTEM ALARM	Warning or alarm from the Steelco conveyor Problem from Miele conveyor
04 WATCH-DOG LOAD/UNLOAD PLC ?	Communication problem between sterilizer and Steelco conveyor
05 LOAD/UNLOAD COMM.PLC FAIL ?	Steelco Conveyor PLC Problem
06 POWER SUPPLY FROM UPS	Power supply failure and UPS trip
07 AIR DETECTOR DISABLED	Air Detector is disabled
08 PRINTER DISABLED	Printer is disabled
09 RECORDING SYSTEM PROGR.FAIL	Problem with the chamber pressure and/or temperature reading from the recording system
10 SD-CARD NOT OK	HMI can't read SD card
11 PLC BATTERY NOT OK	PLC battery must be replaced or inserted
12 DRAIN GENERATOR STARTED UP	Sterilizer is perfoming the automatic generator discharge
13 CALL FOR MAINTENANCE	Scheduled maintenance is required
14 TERMINAL BATTERY NOT OK	HMI battery must be replaced or inserted
15 CHECKUP COMMUNICATION FAULT	Communication error with HMI CheckUp
16 4D:RS232 COMMUNICATION FAULT	Communication error with 4D Sensor
17 4D:INTERNAL SENSOR FAULT	4D Sensor hardware problem
18 4D:INSUFFICIENT STEAM CONC.	Steam concentration during sterilization phase is lower than expected
19 4D:CONDITIONING FAILED	Problem with the first vacuum pulse during the cycle. Consequently, the 4D sensor cannot set the "0 setpoint".
20 4D:CALIBRATION FAILED	4D Sensor, after 3 attempts, fails to calibrate
21 4D:SELF-CHECK FAILED	Steam concentration in Selfcheck program is too high than expected
22 4D:INSUFFICIENT STERILIZ.TIME	The set sterilization time is too short

8. MAINTENANCE

Preventive maintenance is an important key to ensure the longest useful life possible for your sterilizer.

Switch off autoclave utilities during preventive maintenance operations.

8.1. Routine maintenance

The autoclave is already programmed with test cycles, such as bowie & Dick, vacuum test and Helix, which can/shall be used as per procedure in-place or local regulation.

The routine maintenance operations are detailed in the following table:

FREQUENCY	ACTION
DAILY	- Visual checks for any leaks - Check for paper presence and replace roll if required. - Clean the inside of the sterilization chamber with a damp soft cloth (to be carried out when the chamber is cold); - Clean the external accessible parts; - Check the cleanliness of the chamber strainer.If clogged clean it properly using a soft cotton cloth or similar.
WEEKLY	- Check for leaks (we suggest to perform a vacuum test) - Generator Drain **

** if applicable

Never permit unqualified personnel to operate and/or service the sterilizer.

WARNING!

Test and preventive maintenance documentation must be conserved in compliance with current legislation.

Steelco SpA highly encourage to increase maintenance activities after life expectancy expiration.

Verify sterilizer proper operations after any maintenance.

8.1.1. Control measures/validation for sterility assurance

According to European and national legislation and guidelines, sterilization processes must be validated.

Validation is under equipment operator responsability and it is covered by international standards (e.g. EN ISO 17665-1).

Steelco SpA suggests to regularly monitor the equipment to evaluate its effectiveness. For further information, please contact Steelco Spa.

8.1.2. Printer paper roll replacement

1. Open the paper roll drawer by pushing up the green button then remove the empty reel.

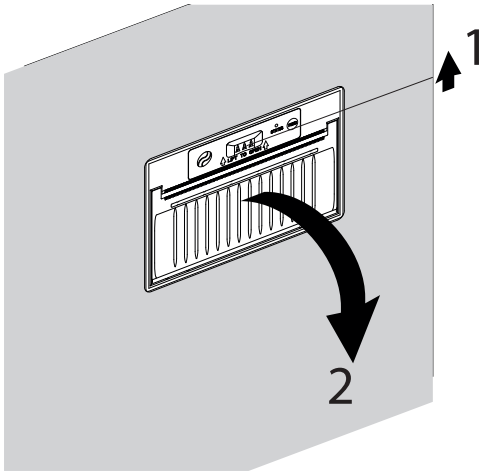


Figure 63 – Printer drawer

WARNING!

During maintenance, it is necessary to disconnect the unit from the power supply.

Removal of panels must be carried out ONLY by specialized personnel.

2. Place the new paper roll as shown in the figure below (thermal coat upside).

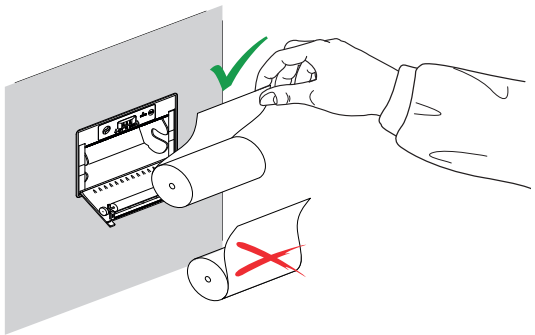


Figure 64 – Paper roll replacement

3. Close the drawer.

8.2. Periodic Cleaning

8.2.1. External paneling cleaning

WARNING!

Clean all stainless steel surface properly to keep its corrosion resistance.

Often clean steel surfaces, especially internal ones, using a damp cloth with soap and water or any common detergent that does not contain abrasive or chlorine substances.

Rinse with demineralized water.

Do not clean user interface and touch screen with alcohol, corrosive substances or substances containing them.

8.2.2. Sterilization chamber cleaning

All residue found in the chamber is cleanable using hot water. For harden residue use soap and water and a nylon brush. For stubborn residues use stainless steel wool (rubbing only in the direction of the satin finish).

Rust stains due to incorrect maintenance may be eliminated using specific products.

Lime deposits can be removed using cleaning products that do not contain chloride substances.

Stainless steel treatment is highly suggested to restore brightness and prevent any corrosion sign. This treatment need to be applied once chamber is clean and dry.

Cleaning of the sterilization chamber must be performed when all equipment is completely cold.

Carefully follow the below instructions:

1. Turn on the autoclave;
2. Open the loading door;
3. Switch off the machine using the power switch and tag it;
4. Clean the chamber;
5. Turn on the autoclave;
6. Close the loading door;
7. Switch off the machine using the power switch.

WARNING!

For autoclaves with two doors, with restrictive door management, it could be impossible to open the sterile side door after the power up. In this situation it is possible to leave the door open on the sterile side after the last sterilization cycle of the previous day and clean from that side before the power up.

Alternatively it is possible to clean all the chamber from the non sterile side.

8.2.3. Chamber strainer cleaning

Periodically clean the drain filter and make sure that there are no obstructions that could compromise the water drainage.

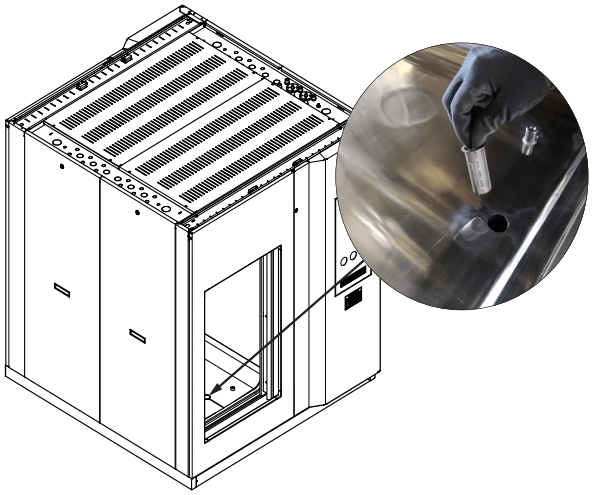


Figure 65 – Chamber drain filter

WARNING!

Never use sodium hypochlorite, hydrochloric acid or solutions that contain them.

Be especially careful to keep drops of water from getting into the unit. Never use direct jets of water to prevent infiltration and damage to the internal parts.

Avoid contact with purely ferrous materials which may contaminate the steel surfaces and create corrosion craters, permanently damaging the unit.

Do not clean the plexiglas panels or the touch screen with alcohol or corrosive substances.

8.2.4. Generator Drain (if applicable)

MAIN MENU > UTILITY > GENERATOR DRAIN >ON

The periodic drain of the generator is strongly recommended in the presence of mains water with high levels of hardness.

Drain the generator for at least 5 minutes, then switch OFF.

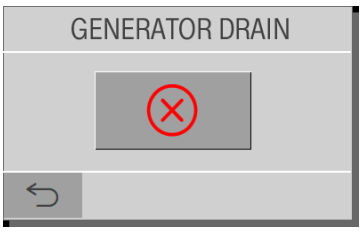


Figure 66 – Generator drain

9. AFTER SALES SERVICE

Contact your nearest Steelco Authorized Center.

All information required to identify the autoclave are contained in *UTILITY MENÙ>MACHINE DATA.*

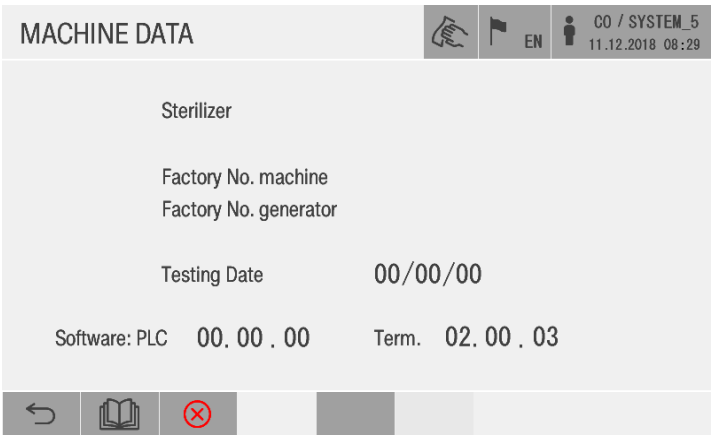


Figure 67 – Machine data screen

10. QUALIFIED PERSONNEL MAINTENANCE SCHEDULING

Never permit unqualified personnel to operate and/or service the sterilizer.

Contact your nearest Steelco Authorized Center to schedule your next maintenance.

WARNING - PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD

Repairs and adjustments to this equipment must be made only by fully qualified service personnel. Maintenance performed by inexperienced, unqualified persons or installation of unauthorized parts could cause personal injury, invalidate the warranty or result in costly equipment damage.

WARNING - SHOCK AND BURN HAZARD

Disconnect all utilities to sterilizer before servicing. Do not service the sterilizer unless all utilities have been properly locked out. Always follow all locally mandated Lockout-Tagout and electrical safety-related work practice standards.

WARNING - BURN HAZARD

Allow sterilizer and accessories to cool to room temperature before performing any cleaning or maintenance procedures.

WARNING

Any time the front door panel is opened for checks or maintenances (i.e. check on heating elements), insert the safety screws to prevent any movement of the chamber sliding door. Remove the screws just before closing the door.

10.1. Annual maintenance or 1000 cycles

- Verify the general conditions
- Drain the generator
- Check the electrical connections and tight the contacts
- Clean the chamber and verify the drain filter
- Replace door gaskets
- Check, clean or evenly change the fill water filter
- Replace TC chamber gasket
- Replace the pressure switch
- Check for obstruction in the steam inlet line
- Check, clean and if necessary replace the generator level probe
- Check the state of cleaning and if necessary clean the limestone deposits

from the generator
- Verify the integrity of the electrical resistance gaskets
- Check the tightening of the screws fixing the electrical resistances of the generator (if any) (tightening torque 14 Nm)
- Level relays functional test
- Verify operation and if needed replace it
- Check the supply voltage 230-500Vac 24Vdc
- Check the hydraulic connections and repair if needed
- Perform functional test
- Check no leaks on the safety valves
- Verify operation and eventual substitution of gauges
- Check the matching between temperature and pressure
- Check the printer
- Verify and calibrate if needed of chamber termperature probes.

10.2. Every 2 years or 2000 cycles

- Verify the general conditions
- Drain the generator
- Replace air filter
- Check the electrical connections and possibly tight the contacts
- Clean the chamber and verify the drain filter
- Replace door gaskets
- Check, clean or evenly change the fill water filter
- Replace TC chamber gasket
- Replace the pressure switch
- Check for obstruction in the steam inlet line
- Replace the safety valves
- Check, clean and if necessary replace the generator level probe
- Check the state of cleaning and if necessary clean the limestone deposits from the generator
- Verify the integrity of the electrical resistance gaskets
- Every two years replace the contactor resistance
- Level relays functional test
- Verify operation and if needed replace it
- Check the supply voltage 230-500Vac 24Vdc
- Check the hydraulic connections and repair if needed
- Perform functional test
- Check no leaks on the safety valves
- Verify operation and eventual substitution of gauges
- Check the matching between temperature and pressure
- Check the printer
- Verify and calibrate if needed of chamber termperature probes.

Verify sterilizer proper operations after any maintenance.

11. GLOSSARY

TERM	DESCRIPTION
Operator	Trained and authorized person, who usually works on the machine and/or performs the unloading/loading of the products, cycle selection, cycle start and reset, alarms reset, activation emergency stop button.
Alarm	It is intended the type of malfunction signal that derives from the process control.
Maintenance Technician	Technician who regularly performs maintenance in the facility and proper trained for sterilizer maintenance.
Qualified Maintenance technician	Technician authorized by Steelco S.p.A. to perform service.
Fo	It expresses the number of minutes of sterilization equivalent to a 121°C sterilization.
HMI	Acronym for Human Machine Interface, i.e. the software that acts as interface between the user and the machine, providing the right compromise between usability, functionality and feedback.
I/O	Acronym for Input/Output, i.e. digital or analog Input/ Output signals.
PID	Acronym for Proportional Integrative Derivative, it describes the behavior of an analog adjustment system used to control the injection of steam into the chamber.
PLC	Acronym for Programmable Logic Controller.
Process	Set of operations executed by the machine to reach its purpose (sterilization, heating, test).
Set Point	Boolean or numeric value that defines the behavior of a function within a sub-phase.
HW	Hardware
SW	Software

12. DISMANTLING, DEMOLITION AND DISPOSAL

12.1. Dismantling

To disassemble the machine correctly, take the following warnings into account:

- Generator (if any) shall be properly emptied
- The machine shall be completely cold
- All utilities (water, steam, compressed air, etc.) must be disconnected.

If the machine will be moved on another location the door screws must be installed (Contact your maintenance technician to receive assistance on this)

12.2. Demolition and disposal

The demolition and disposal of the machine are the exclusive responsibility of the owner, who must act in compliance with the laws in force in his country regarding safety, respect and protection of the environment.

Demolition and disposal may also be entrusted to third parties, provided that companies authorised to recover and dispose of the materials in question are always used.

Always comply with the regulations in force in the country where you operate for the disposal of the materials and, if necessary, for the report of disposal.

WARNING!

All dismantling operations for demolition must be carried out with the machine at a standstill and without power supply.

WARNING!

The responsibility for any damage to people and animals always falls on the owner.

Pursuant to art. 13 of Legislative Decree no. 151 of 15 July 2005 implementing Directive 2002/96/EC of 23 February 2003 on Waste Electrical and Electronic Equipment, known as WEEE, promoting reuse, recycling and other forms of recovery in order to reduce the amount to be sent for disposal and improving the intervention of those involved in the life cycle of such products.

13. APPLICABLE STANDARDS

The sterilizers dealt with by this document comply with directive:

- Pressure Equipment Directive (PED) 2014/68/EU
  - Entrusted to Notified Body 0398 CPM Apave Italy.
- Medical Device Directive 93/42/CEE e 2007/47/CE
  - It complies with all relevant European directives and standards, and bears the CE mark with the identifier 0051 IMQ

and their harmonized standards:

- EN 285 Sterilization - Steam sterilizers - Large sterilizers.
- ISO/TS 17665 Sterilization of health care products
- IEC EN 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – General requirements.
- IEC EN 61010-2-040 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.
- IEC EN 60204-1 Safety of machinery - Electrical equipment of machines - Part 1: General requirements.
- UNI EN ISO 14971 Medical devices - Application of risk management to medical devices
- IEC 62366-01 Application of usability engineering to medical devices.
- IEC 62304 - Medical Device Software.
- EN 61326-1 Electrical equipment for measurement, control and laboratory use EMC requirements - Part 1: General requirements.

The CE certification for Medical Devices Directive is entrusted to 0051 IMQ.

Other applicable directives are:

- 2006/42/CE (Machinery Directive).
- 2014/30/EU (EMC Directive).

SALES AND ASSISTANCE REFERENCES

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