Belimed
Infection Control

Belimed Steam Sterilizer TOP 5000

USER'S MANUAL

Series 9
Standard design
26" x 42.5" x 41"
(660 x 1080 x 1040)

Series 12
Standard design
26" x 42.5" x 55"
(660 x 1080 x 1400)

Series 15
Standard design
26" x 42.5" x 67"
(660 x 1080 x 1700)

Series 18
Standard design
26" x 42.5" x 79"
(660 x 1080 x 2000)

Series GR 9
Floor flush design
26" x 48.5" x 43"
(660 x 1230 x 1100)

Series GR 12
Floor flush design
26" x 48.5" x 55"
(660 x 1230 x 1400)

Series GR 15
Floor flush design
26" x 48.5" x 67"
(660 x 1230 x 1700)

Series GR 18
Floor flush design
26" x 48.5" x 79"
(660 x 1230 x 2000)

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IMPORTANT: A SUMMARY OF THE SAFETY PRECAUTIONS TO BE OBSERVED WHEN OPERATING THIS EQUIPMENT CAN BE FOUND ON PAGE 7 OF THIS MANUAL AND BEHIND THE SERVICE DOOR OF THE UNIT. DO NOT OPERATE THE STERILIZER UNTIL YOU HAVE BECOME FAMILIAR WITH THIS INFORMATION.

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1 Introduction

1.1 Become familiar with the system

This manual contains important information on proper use and maintenance of this sterilizer. All operators and departments heads are urged to carefully review and become familiar with the warnings, cautions and instructions contained herein. This sterilizer is specifically designed to process goods using only the cycles as specified in this manual. If there is any doubt about a specific material or product, contact the manufacturer of the product for the recommended sterilization technique.

1.2 Intended use

The Belimed Steam Sterilizer TOP 5000 is designed to be used for the terminal sterilization of porous and non porous, heat and moisture stable materials in the healthcare facilities.
The sterilizer is factory equipped with standard cycles: their applicability is insured only under the specified conditions. Depending of the chosen cycle, materials as different as textiles, glassware, unwrapped or wrapped instrument trays with single or multiple instruments can be sterilized.
The Belimed Steam Sterilizer TOP 5000 is factory equipped with cycles which has been tested in accordance with AAMI/ANSI ST-8 as well as EN285 Standards under defined load conditions. The cycles parameters can be easily modified to perform the sterilization under optimized conditions. A modification of the parameters of the standard cycles is under the responsibility of the user. BELIMED can offer assistance or quote complete validation procedures to the relevant standards.

WARNING

This sterilizer is not designed to process flammable liquids nor liquids in containers that are not designed for sterilization.

CAUTION

Any alteration of the sterilizer which affects its operation will void the warranty and could violate state and local regulations and jeopardize insurance coverage.

CAUTION

Use only original SAUTER AG replacement parts for maintenance purposes: in all other cases the manufacturer can no more guaranty the specified performances of the equipment nor apply the warranty conditions.

CAUTION

In order to ensure the proper function of the sterilizer, run a vacuum leak test cycle daily.

CAUTION

The Bowie-Dick/ DART Test Cycle has to be performed daily.

2 Summary of safety precautions

The following is a summary of safety precautions to be observed when operating or servicing this unit. WARNINGS indicate the potential for danger to personnel and CAUTIONS indicate the potential for damage to equipment. The precautions may be repeated where applicable throughout the manual. The following is a list of all safety precautions to be taken. Carefully read them before proceeding to use or service the unit.

WARNINGS

- **BURN HAZARD: The chamber door surface can be hot (>70°C/158°F), if the ambient temperature is above 30°C/86°F.**

- **BURN AND SHOCK HAZARD: Repairs and adjustments should be attempted only by authorized persons fully acquainted with this equipment. Use of inexperienced, unqualified persons to work on the equipment or the installation of unauthorized parts could cause personal injury or result in costly damage!**

- **Observe the label "Dangerous voltage": turn off main switch before opening**

- **BURN HAZARD: Allow sterilizer, generator (if applicable) and accessories to cool to room temperature before performing any cleaning or maintenance procedures.**

- **This sterilizer is not designed to process flammable liquids nor liquids in containers that are not designed for sterilization.**

- **BURN HAZARD: Sterilizer and rack/shelves will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.**

- **FALL HAZARD: To prevent falls keep floors dry by immediately wiping up any liquids or condensation in sterilizer loading or unloading area.**

- **EXPLOSION HAZARD: This sterilizer is not designed to process flammable liquids.**

- **BURN HAZARD: When sterilizing liquids, to prevent personal injury or property damage resulting from bursting bottles and hot fluid, you must observe the following procedure:**

- **It is inappropriate for a health care facility to sterilize liquids for direct patient contact.**
- **Use LIQUIDS cycle only. No other cycle is safe for processing liquids.**
- **Use only vented closures- do not use screw caps or rubber stoppers with crimped seal.**
- **Use only Type I borosilicate glass bottles- do not use ordinary bottles or any container not designed for sterilization.**
- **Avoid sudden opening of door at end of cycle. Wait at least 10 minutes before door opening and unloading the sterilizer.**
- **Do not allow hot bottles to be jolted. This can cause hot-bottle explosions! Do not move bottles if any boiling or bubbling is present.**
- **Allow bottles to cool to touch before attempting to move them from sterilizer shelf to storage area.**

- **BURN HAZARD: A steam supply malfunction may cause the sterilizer chamber to fill with scalding water. Do not open chamber door if the unit fails to complete an automatic cycle or if water leaks past the door gasket upon unlocking the door.**

- **STERILITY ASSURANCE HAZARD: Load sterility may be compromised if the chemical or biological indicator or the Bowie-Dick Test (or DART) indicate a potential problem.** If these indicators show a potential problem, refer the situation to a qualified maintenance technician before using the sterilizer further.
- **STERILITY ASSURANCE HAZARD: According to AMMI standards, a measured leak rate greater 1mmHg/minute indicates a problem with the sterilizer.** Refer the situation to a qualified maintenance technician before using the sterilizer further.
- **STERILITY ASSURANCE HAZARD: The Express cycle is only intended for use with a single instrument in a single wrapped instrument tray.**
- **STERILITY ASSURANCE HAZARD: The Express cycle is not intended for processing porous items (except the tray wrapper).**
- **STERILITY ASSURANCE HAZARD: The Flash cycle is not intended for processing porous items.**

C A U T I O N S

CAUTION: Avoid letting moisture get into chamber insulation, as it will cause rusting of the outer jacket.

CAUTION: Never use sharp tools to push gasket into groove.

CAUTION: Never use wire brush or steel wool on door and chamber assembly.

CAUTION: Observe the Electrostatic Precautions outlined in the maintenance manual. Always wear a grounding wrist strap when removing or replacing PC boards or ICs.

CAUTION: Solenoid valves are equipped with a special material which can be attacked by oils and grease. When replacing entire valve, wipe threads clean of cuttings oils and use Teflon tape to seal pipe joints.

CAUTION: Handle siphon and bellows assembly gently to avoid damage.

CAUTION: Keep the movement area of the door unobstructed during door opening and closing.

CAUTION: Any alteration of the sterilizer which affects its operation will void the warranty and could violate state and local regulations and jeopardize insurance coverage.

CAUTION: Use only original SAUTER AG replacement parts for maintenance purposes: in all other cases the manufacturer can no more guaranty the specified performances of the equipment nor apply the warranty conditions.

CAUTION: In order to ensure the proper function of the sterilizer, run a vacuum leak test cycle daily.

CAUTION: The Bowie-Dick/ DART Test Cycle has to be performed daily.

CAUTION: Sterilize only goods which are declared to be steam-sterilizable by their manufacturer and compatible with the chosen cycle parameters (maximum temperature)

CAUTION: Respect the maximum number of sterilization's given by the manufacturer of the goods to be sterilized. Check their proper function according to the manufacturer's information of the goods (e.g. instruments)

3 Installation

3.1 Sterilizer sizes

The Belimed steam sterilizers are available in the following sizes (Table 3-1):

Model	Configuration	Chamber size (H x W x D) (inch)	(mm)	Overall Dimensions (H x W x D) (inch)	(mm)
9-6-9 HS1	1 door	42"x 26"x 41"	1080 x 660 x 1040	79" x 67" x 50"	2000 x 1700 x 1280
9-6-9 HS2	2 doors	42"x 26"x 41"	1080 x 660 x 1040	79" x 67" x 50"	2000 x 1700 x 1300
9-6-12 HS1	1 door	42"x 26"x 55"	1080 x 660 x 1400	79" x 67" x 65"	2000 x 1700 x 1640
9-6-12 HS2	2 doors	42"x 26"x 55"	1080 x 660 x 1400	79" x 67" x 65"	2000 x 1700 x 1660
9-6-15 HS1	1 door	42"x 26"x 67"	1080 x 660 x 1700	79" x 67" x 76"	2000 x 1700 x 1940
9-6-15 HS2	2 doors	42"x 26"x 67"	1080 x 660 x 1700	79" x 67" x 76"	2000 x 1700 x 1960
9-6-18 HS1	1 door	42"x 26"x 79"	1080 x 660 x 2000	79" x 67" x 88"	2000 x 1700 x 2240
9-6-18 HS2	2 doors	42"x 26"x 79"	1080 x 660 x 2000	79" x 67" x 88"	2000 x 1700 x 2260
GR 9-6-9 HS1	Floor flush design, 1 door	48"x 26"x 43"	1230 x 660 x1100	79" x 75" x 63"	2000 x 1900 x 1600
GR 9-6-12 HS1		48"x 26"x 55"	1230 x 660 x1400	79" x 75" x 75"	2000 x 1900 x 1900
GR 9-6-15 HS1		48"x 26"x 67"	1230 x 660 x1700	79" x 75" x 87"	2000 x 1900 x 2200
GR 9-6-18 HS1		48"x 26"x 79"	1230 x 660 x2000	79" x 75" x 98"	2000 x 1900 x 2500
GR 9-6-9 HS2	Floor flush design, 2 doors	48"x 26"x 43"	1230 x 660 x1100	79" x 75" x 63"	2000 x 1900 x 1600
GR 9-6-12 HS2		48"x 26"x 55"	1230 x 660 x1400	79" x 75" x 75"	2000 x 1900 x 1900
GR 9-6-15 HS2		48"x 26"x 67"	1230 x 660 x1700	79" x 75" x 87"	2000 x 1900 x 2200
GR 9-6-18 HS2		48"x 26"x 79"	1230 x 660 x2000	79" x 75" x 98"	2000 x 1900 x 2500

Table 3-1: Sterilizer sizes

3.2 Required building system utilities

Unless otherwise specified in the contract the utilities (refer to Table 3-2 and Table 3-3) must be provided by the customer to the connection points (refer to Figure 3-1 and Figure 3-2).

3.2.1 Utility connections

Model		**9-6-9 HS1, GR 9-6-9 HS1, 9-6-9 HS2 GR 9-6-9 HS2**					**9-6-12 HS1, GR 9-6-12 HS1, 9-6-12 HS2 GR 9-6-12 HS2**				
Symbol	**Medium**	**Pressure in bar g**	**Pressure in psig**	**Customers supply**	**Peak**	**Consumption per batch with normal oad**	**Pressure in bar g**	**Pressure in psig**	**Customers supply**	**Peak**	**Consumption per batch with normal oad**
Standard-Supply lines											
SD	Sterilizing Steam	2.7-4.5	40- 65	1 ¼ " NPT	120 kg/h	30 kg	2.7-4.5	40- 65	1 ½ " NPT	160 kg/h	40 kg
KW	Tap water for vacuum pump, 15 °C (60°F)	2 - 5	25-75	¾ " NPT	2 m^3/h	400 l	2 - 5	25-75	¾ " NPT	2.5 m^3/h	550 l
DL	Compressed air, oil-free	5 - 7	75-100	¼" NPT	10 Nm^3/h	0.5 Nm^3	5 - 7	75-100	¼" NPT	10 Nm^3/h	0.5 Nm^3
EL1	Electric supply: 3 phase, 60 Hz, nominal current 13 A, fuse 20 A Wire dimension: AWG14			208 V	3.2 kW	1.5 kWh			208 V	3.2 kW	1.5 kWh
ZL	Air inflow to service room coming through customer's ventilation duct or from operating room.										
Standard-Waste line											
ALP	Free air exhaust of vacuum pump										
A	Floor drain (waste water open)			2 " NPT	max. 35 l/min				2 " NPT	max. 45 l/min	
GU	Floor drain			2"					2"		
AL1	Air outflow from service room: heat flow of 1 kW to be dissipated, temperature in service room <30°C (<86°F)				900 Nm^3/h at T app. 10 K					1200 Nm^3/h at T app. 10 K	
Option waste steam line upwards											
AD1	Waste steam, chamber	max. 2.7	max. 40	1 ¼" NPT	350 kg/h		max. 2.7	max. 40	1 ¼" NPT	350 kg/h	
AD2	Waste steam, jacket	max. 2.5	max. 37	1 " NPT	210 kg/h		max. 2.5	max. 37	1 " NPT	210 kg/h	
Option Cooling water circuit											
KWV	Cooling water forward: T1 10 °C, ΔT 15K (T1 50 °F, ΔT 60°F)	2 - 5	25-75	1 ¼" NPT	4 m^3/h	1000 l Discharge	2 - 5	25-75	1 ¼" NPT	5 m^3/h	1300 l Discharge
KWR	Cooling water backward			1 ¼" NPT					1 ¼" NPT		

Table 3-2: Utilities for chamber size 9-6-9 and 9-6-12

Model		9-6-15 HS1, GR 9-6-15 HS1,		9-6-15 HS2 GR 9-6-15 HS2			9-6-18 HS1, GR 9-6-18 HS1,		9-6-18 HS2 GR 9-6-18 HS2		
Symbol	Medium	Pressure in bar g	Pressure in psig	Customers supply	Peak	Consumption per batch with normal	Pressure in bar g	Pressure in psig	Customers supply	Peak	Consumption per batch with normal
Standard-Supply lines											
SD	Sterilizing Steam	2.7-4.5	40- 65	1 ½ " NPT	200 kg/h	50 kg	2.7-4.5	40- 65	1 ½ " NPT	240 kg/h	60 kg
KW	Tap water for vacuum pump, 15 °C (60°F)	2 - 5	25-75	1 " NPT	3 m^3/h	700 l	2 - 5	25-75	1" NPT	3.5 m^3/h	850 l
DL	Compressed air, oil-free	5 - 7	75-100	¼" NPT	10 Nm^3/h	0.5 Nm^3	5 - 7	75-100	¼" NPT	10 Nm^3/h	0.5 Nm^3
EL1	Electric supply: 3 phase, 60 Hz, nominal current 19.5 A, fuse 30 A Wire dimension: AWG12			208 V	4.8 kW	2.5 kWh			208 V	4.8 kW	2.5 kWh
ZL	Air inflow to service room coming through customer's ventilation duct or from operating room.										
Standard-Waste line											
ALP	Free air exhaust of vacuum pump										
A	Floor drain (waste water open)			2 " NPT	max. 60 l/min				2 " NPT	max. 65 l/min	
GU	Floor drain			2"					2"		
AL1	Air outflow from service room: heat flow of 1 kW to be dissipated, temperature in service room <30°C (<86°F)				1500 Nm^3/h at T appr. 10 K					1800 Nm^3/h at T appr. 10 K	
Option waste steam line upwards											
AD1	Waste steam, chamber	max. 2.7	max. 40	1 ¼" NPT	350 kg/h		max. 2.7	max. 40	1 ¼" NPT	350 kg/h	
AD2	Waste steam, jacket	max. 2.5	max. 37	1 " NPT	210 kg/h		max. 2.5	max. 37	1 " NPT	210 kg/h	
Option Cooling water circuit											
KWV	Cooling water forward: T1 10 °C, ΔT 15K (T1 50 °F, ΔT 60°F)	2 - 5	25-75	1 ¼" NPT	5 m^3/h	1600 l Discharge	2 - 5	25-75	1 ¼" NPT	6 m^3/h	2000 l Discharge
KWR	Cooling water backward			1 ¼" NPT					1 ¼" NPT		

Additional information			
	Batch time according EN 285	Textiles app. 50 min.	Instruments app. 55 min.
	Sound level according ISO 3746: 1995	65 dBA	

Table 3-3: Utilities for chamber size 9-6-15 and 9-6-18

3.2.2 Utility connection positioning

The customer shall provide all supply connection lines with a built in manual stop-cock. All connections assemblies between the sterilizer and supply/exhaust lines (customer's supply) are designed with flexible, pressure-resistant tubes made of 316L material: in that way, mechanical tolerances of ± 25 mm in any direction can be easily compensated which results in short assembly times. Only exception is the steam supply <SD> which is realized in a rigid manner.

When the exhaust line will be neither connected nor led outside the tubing ends up in a bend oriented upwards. The dimensions in Figure 3-1 and Figure 3-2 are mm, the medium symbols are defined in chapter 3.2.

Additional stainless steel panelling from 2000mm up to the ceiling can be provided by Belimed.

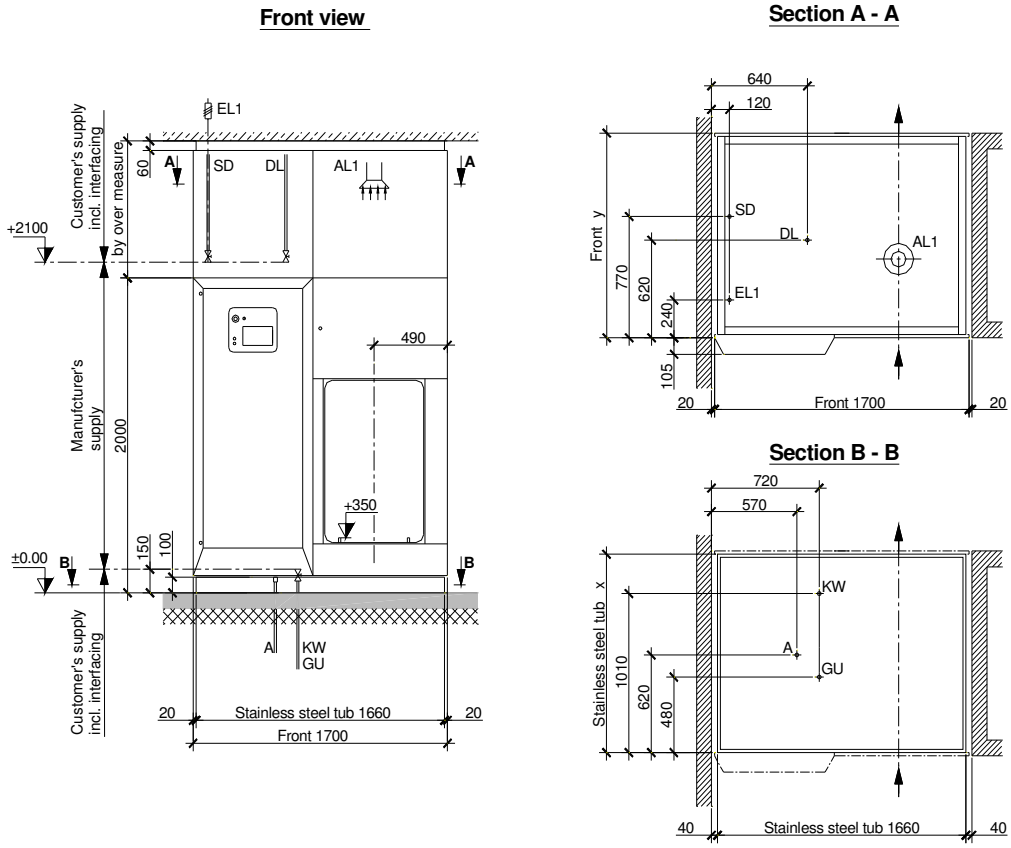


Figure 3-1: Utility position of standard sterilizer

Model	Front width **y** (mm)	Stainless steel tub width **x** (mm)	Operation weight (kg)	Floor safe load (N/m^2)
9-6-9 HS1/HS2	1280 /1300	1260 /1260	1680 /2110	2700 / 3400
9-6-12 HS1/HS2	1660	1620	1900 / 2330	2700 / 3300
9-6-15 HS1/HS2	1960	1920	2120 / 2550	2700 / 3200
9-6-18 HS1/HS2	2260	2220	2340 / 2770	2700 / 3200

Table 3-4: Front and tub width of standard sterilizer

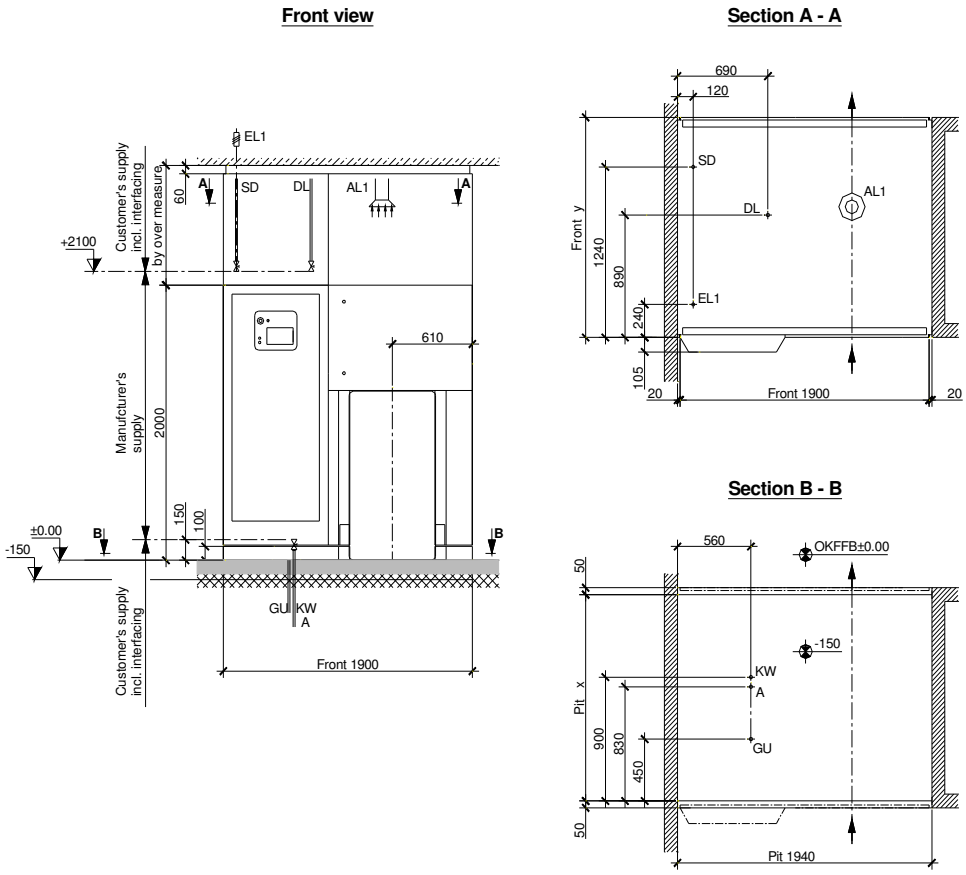


Figure 3-2: Utility position of floor flush sterilizer

Model	Front width **y** (mm)	Pit width **x** (mm)	Stainless bottom plate 1) (mm)	Operation weight (kg)	Floor safe load (N/m^2)
GR 9-6-9 HS1/HS2	1600	1500	1500 x 800	2090 / 2450	3000 / 3500
GR 9-6-12 HS1/HS2	1900	1800	1800 x 800	2390/ 2750	3100 / 3500
GR 9-6-15 HS1/HS2	2200	2100	2100 x 800	2690 / 3050	3100 / 3600
GR 9-6-18 HS1/HS2	2500	2400	2400 x 800	2990 / 3350	3200 / 3600

1) between chamber and left end of pit (below service area)

Table 3-5: Front and tub width of floor flush sterilizer

3.3 Installation instructions

3.3.1 Introduction

The installation of the sterilizer will generally be performed by Belimed technicians. They received a detailed training on all aspects of the installation, running and maintenance of the Belimed Sterilizers. Those details of the installation are part of their specific know how and will not be written down here. If the customer requires to perform the installation himself, Belimed will provide the necessary information and at least insure the supervision of the installation. This is required in order to be able to insure the warranty of the system for the accepted duration.

Each installation drawing pertains to the sterilizing equipment as specified or purchased by the customer. The general notes and recommendations are intended to complete the installation drawings.

Note: Installation must comply with local fire protection code!

3.3.2 Space considerations

Clearance in front of sterilizer, for comfortable loading and unloading operations, should be about twice the length of the loading cart or transfer carriage unless otherwise specified on installation drawing.

3.3.3 Mounting details

3.3.3.1 Illumination

Illumination of the service area should be provided to afford 50 to 100 foot-candles of total illumination.

3.3.3.2 Service power

One convenience outlet (110-120V) is required for power tools.

3.3.4 Utility service requirements

3.3.4.1 Terminal Fittings

Unless otherwise specified in the contract piping, shutoff valves and other appurtenances between terminal fittings on the equipment and wall or floor outlets are not furnished by Belimed.

Note: "Supply lines are to be safeguarded and separable in accordance with connection ratings"

3.3.4.2 Pipe sizes

Pipe sizes listed in paragraph 3.2 indicate the equipment termination sizes only. Size of supply piping is dependent on length of pipe run from pressure regulation station for steam line and main water headers to ensure adequate supply service pressure and demand flow at equipment terminals. Effect of coincident draw of multiple unit installations must also be considered.

3.3.4.3 Backflow preventer

If local codes require a reduced pressure principle device on water supply line it shall be provided by the customer.

3.3.4.4 Pressure relief valves

Belimed recommends piping all chamber relief valves to a vented manifold outside the equipment service area .

Caution: Do not reduce the discharge capacity of the safety relief valve.

Recommended piping practices for relief valve piping can be found in ASME Boiler and Pressure Vessel Code (Section VIII, UG-135).

3.3.4.5 Blow down piping

Blow down building steam, water and compressed air supply lines before final connection to equipment.

3.3.4.6 Steam and water pressure

Sterilizer is equipped to operate on pressures listed in Table 3-2 and Table 3-3. If supply pressure exceeds those shown, provide reducing valves. Unless otherwise specified in the contract reducing valves are not furnished by Belimed.

3.3.4.7 Steam quality

Steam should be condensate free and 100% saturated vapor (dry, not superheated) to ensure proper goods drying.
It has to fulfill the requirements of AAMI ST 46.

3.3.4.8 Water quality

Water is used for vacuum pump and heat exchangers. Refer to Table 3-6 for recommended water quality.

Condition	Nominal conditions	Maximum conditions
Temperature	4-16°C (40-60°F)	21°C (70°F)
PH	6.5-8	6-8.5
Total hardness as Ca^{2+}	0.2-2.5 mmol/l	3mmol/l
Total dissolved solids	50-200mg/l	400mg/l
Chloride	10-70mg/l	80mg/l

Table 3-6: Recommended feed water quality for sterilizers

3.3.4.9 Wiring Terminals

It is the responsibility of the customer to provide proper electrical disconnect device and branch circuit protection in accordance with applicable codes and regulations .
Wiring between disconnect device and junction box is not furnished by Belimed.
Connect the supply line on the terminal block (refer to Figure 3-3 and Figure 6-1):

Wire (cable)		Box connector no
Phase L1	to	L1
Phase L2	to	L2
Phase L3	to	L3
Protective Conductor to	⏚	

Figure 3-3: Junction box

The electrical installation must be carried out by an installer in the field. The free length of a lead inside the junction box shall be at least 6 inches.

If an external steam generator (ELD) is connected, cable W980 is to connect to the control panel:(refer to Figure 3-4):

ELD wire no. - Control panel pin	
1	X11.10
2	X11.20
3	
4	X35B.3
5	

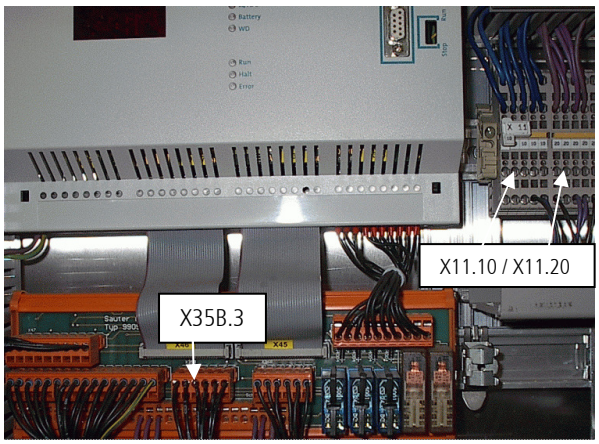


Figure 3-4: Control panel ELD connection

3.3.5 Preparation

Note: Installation must comply with local fire protection code!

3.3.5.1 Standard sterilizers

- Check the sterilizer placement according to installation drawing.
- Measure overall height on the wall opening.
- Mark the center lines of the sterilizer chamber on the floor with a color marker
- For correct positioning refer to installation drawing
- Check the position and carrying out of the floor drains (A and GU)
- Put the stainless steel tub on place (if required).
- Place the chamber on the stainless steel tub or, if no tub required, on the floor.
- Adjust the chamber high using the adjusting screws (refer to Figure 3-5) . Refer to the installation drawing.
- Lower surface of the frame must be leveled to +145 mm form final floor level.
- Remove door locking bolts and carefully open slide doors (refer to Figure 3-6).
- (operating end). Adjust the chamber high with a spirit level along x and y axis by using the 4 adjustment screws on the feeds. The upper surface of the guiding rails must be leveled to +350mm from the final floor level.
- If height and level are correct, lock the screws wit the lock nuts.
- Measure chamber level in x and y axis again by using a spirit level.
- Close chamber doors

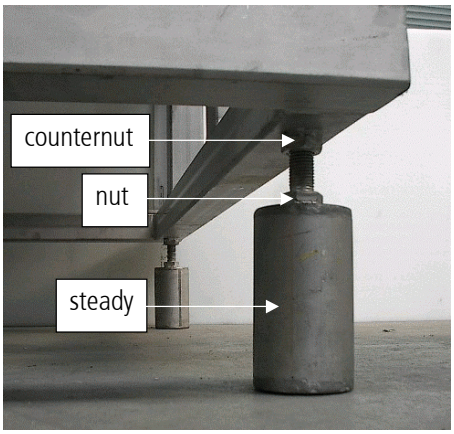


Figure 3-5: steady with adjusting screws

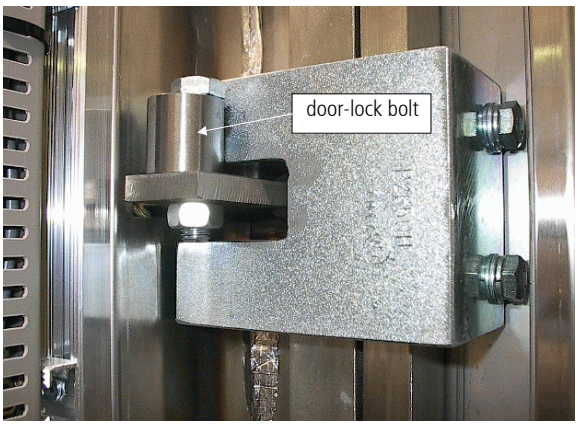


Figure 3-6: door lock bolt for transportation

4 Labeling

4.1 Type and Model Designation

The Belimed Steam Sterilizer TOP 5000 is available in the standard or in the floor flush configurationTable 4-1 hereafter resumes size and designation. Each size is offered in both 1 and 2 doors configuration.

Model	Configuration	Chamber size (H x W x D) (inch)	(mm)	Overall Dimensions (H x W x D) (inch)	(mm)
9-6-9 HS1	1 door	42"x 26"x 41"	1080 x 660 x 1040	79" x 67" x 50"	2000 x 1700 x 1280
9-6-9 HS2	2 doors	42"x 26"x 41"	1080 x 660 x 1040	79" x 67" x 50"	2000 x 1700 x 1300
9-6-12 HS1	1 door	42"x 26"x 55"	1080 x 660 x 1400	79" x 67" x 65"	2000 x 1700 x 1640
9-6-12 HS2	2 doors	42"x 26"x 55"	1080 x 660 x 1400	79" x 67" x 65"	2000 x 1700 x 1660
9-6-15 HS1	1 door	42"x 26"x 67"	1080 x 660 x 1700	79" x 67" x 76"	2000 x 1700 x 1940
9-6-15 HS2	2 doors	42"x 26"x 67"	1080 x 660 x 1700	79" x 67" x 76"	2000 x 1700 x 1960
9-6-18 HS1	1 door	42"x 26"x 79"	1080 x 660 x 2000	79" x 67" x 88"	2000 x 1700 x 2240
9-6-18 HS2	2 doors	42"x 26"x 79"	1080 x 660 x 2000	79" x 67" x 88"	2000 x 1700 x 2260
GR 9-6-9 HS1	Floor flush design, 1 door	48"x 26"x 43"	1230 x 660 x1100	79" x 75" x 63"	2000 x 1900 x 1600
GR 9-6-12 HS1		48"x 26"x 55"	1230 x 660 x1400	79" x 75" x 75"	2000 x 1900 x 1900
GR 9-6-15 HS1		48"x 26"x 67"	1230 x 660 x1700	79" x 75" x 87"	2000 x 1900 x 2200
GR 9-6-18 HS1		48"x 26"x 79"	1230 x 660 x2000	79" x 75" x 98"	2000 x 1900 x 2500
GR 9-6-9 HS2	Floor flush design, 2 doors	48"x 26"x 43"	1230 x 660 x1100	79" x 75" x 63"	2000 x 1900 x 1600
GR 9-6-12 HS2		48"x 26"x 55"	1230 x 660 x1400	79" x 75" x 75"	2000 x 1900 x 1900
GR 9-6-15 HS2		48"x 26"x 67"	1230 x 660 x1700	79" x 75" x 87"	2000 x 1900 x 2200
GR 9-6-18 HS2		48"x 26"x 79"	1230 x 660 x2000	79" x 75" x 98"	2000 x 1900 x 2500

Table 4-1: Size and Designation

4.2 Marking

The sterilizer can be identified through following two metal marking plates

Chamber/jacket ratings (Figure 4-1) are located just above the chamber door on the operating end

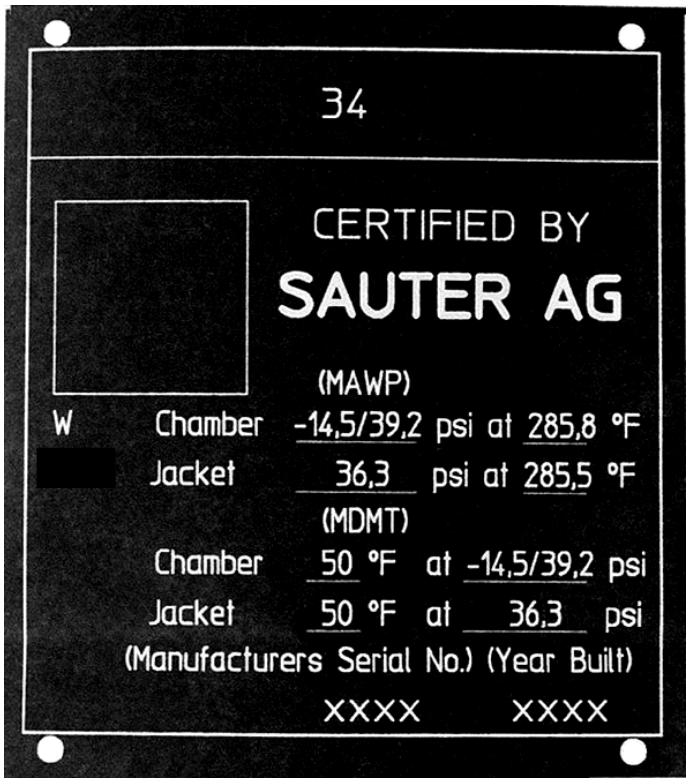


Figure 4-1: Chamber labeling

- Electrical ratings (Figure 4-2) are given on the label located in the upper part inside the servicing door of the operating end

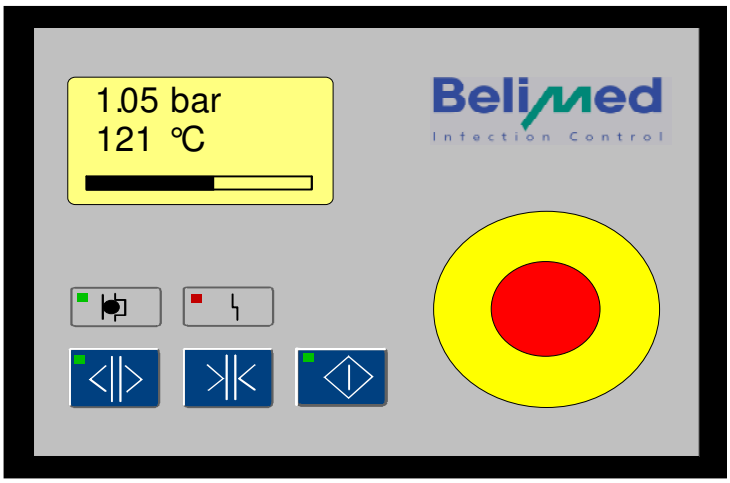


Figure 4-2: Labeling Electrical Ratings

4.3 Warning labels

Those labels are placed close to the respective parts which represent a potential hazard:
DANGER OF SCALDING !

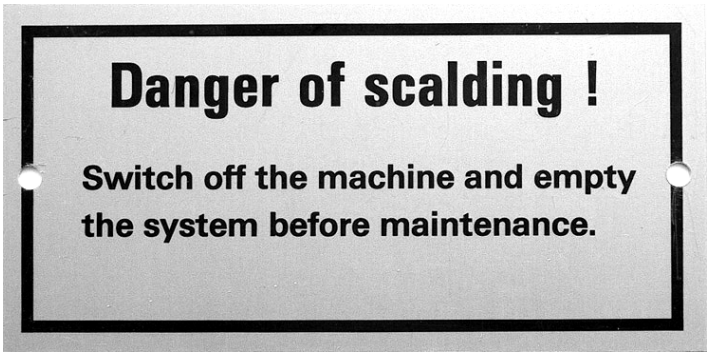


Figure 4-3: Label "DANGER OF SCALDING !"

- DANGER: OVERPRESSURE !

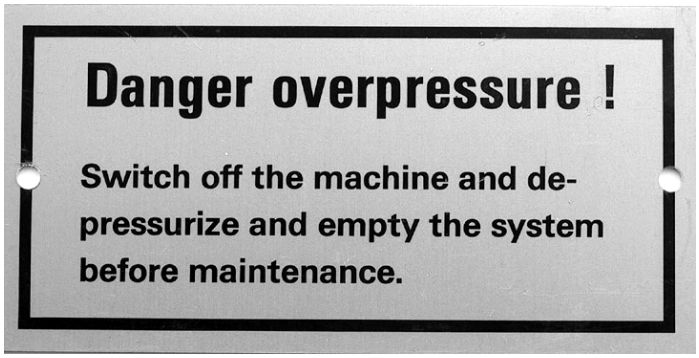


Figure 4-4: Label "Danger overpressure !"

- DANGEROUS VOLTAGE !

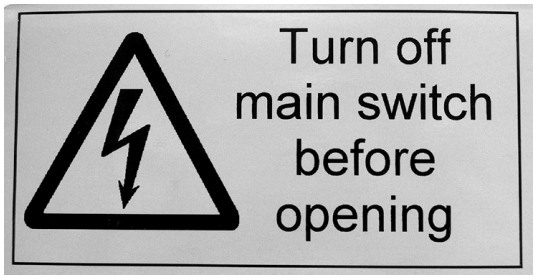


Figure 4-5: Label „DANGEROUS VOLTAGE !“

- Danger of Squeeze hand

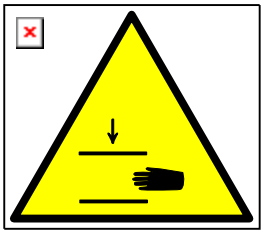


Figure 4-6: Label „Danger of squeeze hand" while closing chamber door

- BURN HAZARD

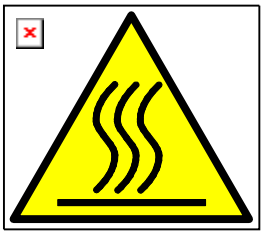


Figure 4-7: Label „Burn Hazard"

- CAUTION refer to accompanying documents

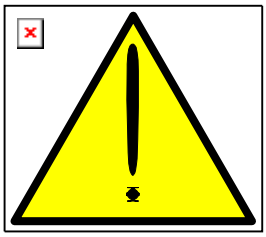


Figure 4-8: Label „CAUTION"

5 General description of the components and functions

5.1 General view

Figure 5-1 shows the main components or control elements which are accessible to the user from the operating end. The number of control elements of the sterilizer is reduced to the absolute minimum in order to maximize the simplicity and security of use.

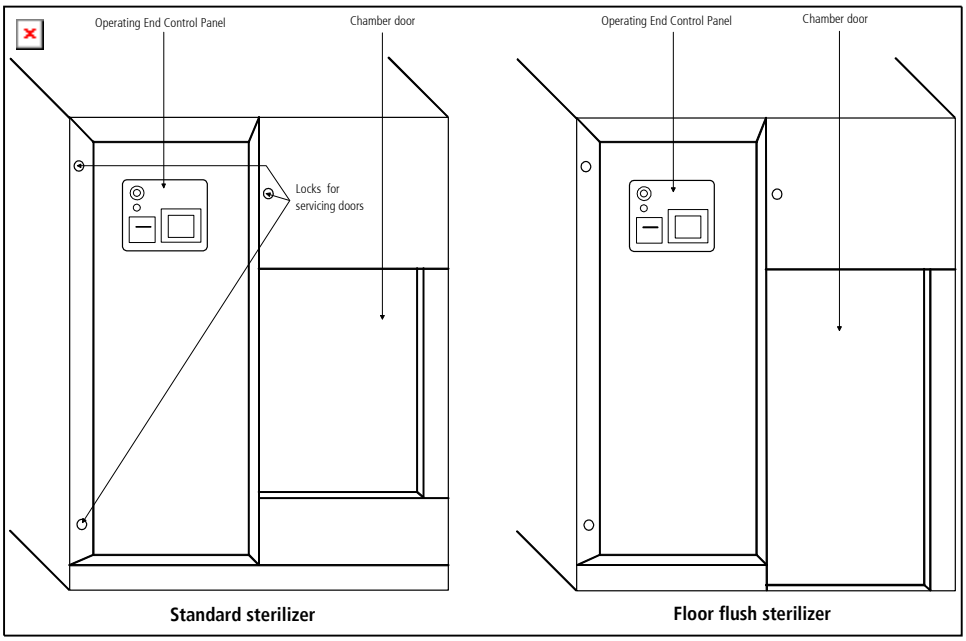


Figure 5-1: Control elements from the operating end

Figure 5-2 shows the main components or control elements which are accessible to the user from the non operating end.

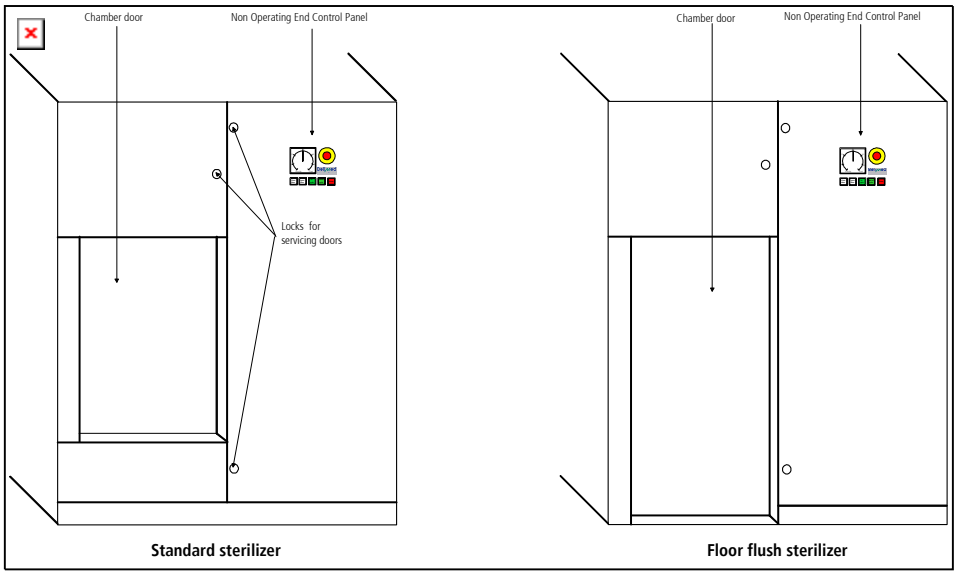


Figure 5-2: Control elements from the non operating end

5.2 Indicators and gauges

The system offers two types of indicators and gauges:

- The process indicators are all located on the display of the operating end control panel and of the non operating end control panel (see section 5.3 and 5.4)
- The service indicators and gauges are all located within the service area (see service and maintenance manual). The pressure gauges in the service area scaled with a double scale:

  1. **bar** gauge / 2. **psi** gauge for pressure / **in.Hg** for vacuum

The gauges shall show :

Pressure indication	Nominal conditions bar (*in.Hg* .. psig)	Maximum conditions bar (*in.Hg* ..psig)
Steam supply	2.7-3 (40-44)	2.7-4.5 (40-65)
Chamber	-0.95-2.3 (*28in.Hg*-0-33psig)	-1..+2.7 (*29.5in.Hg* -0-39 psig)
Jacket	-0.95-2.3 (*28in.Hg*-0-33psig)	-1..+2.5 (*29.5in.Hg* -0-36 psig)
Door seal (door locked)	3 (43.5)	2.8-3.2 (40.5-46.5)
Compressed air	5-7 (75-100)	5-7 (75-100)
Cooling water	2-5 (25-75)	2-5 (25-75)

Table 5-1: Pressure indicators in service area

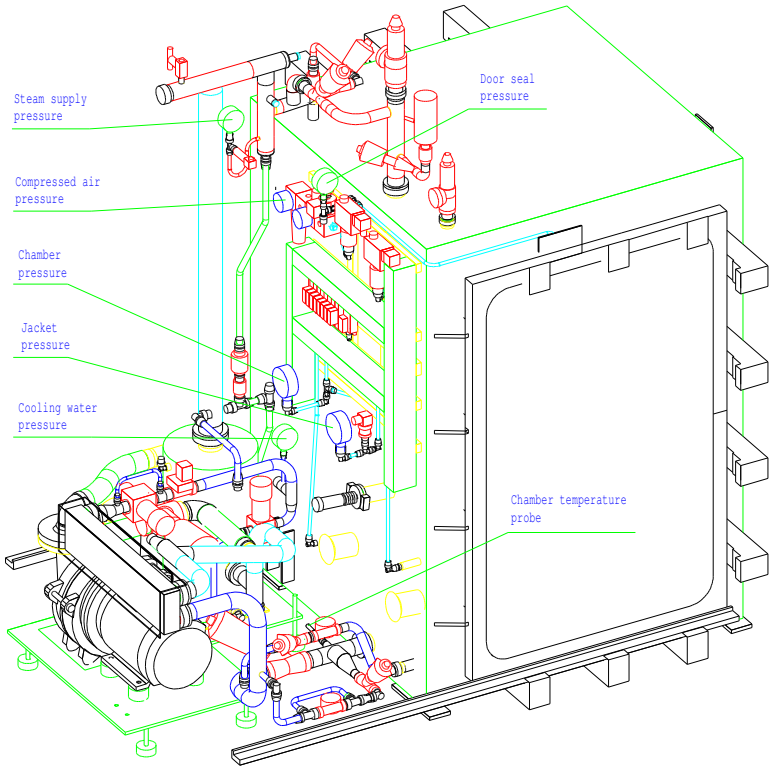


Figure 5-3: Instrumentation

5.3 Operating End Control Panel

Figure 5-4 shows the arrangement of the control elements on the operating end.
The user's control panel with the interactive touch-screen display is described with more details in Figure 5-5 and Figure 5-6 hereafter.
The chamber temperature indicator can be configured in °F or °C.
The chamber pressure indicator can be configured in mbara, bar*g*, kPa*a*, psi*a*, psig/in.Hg

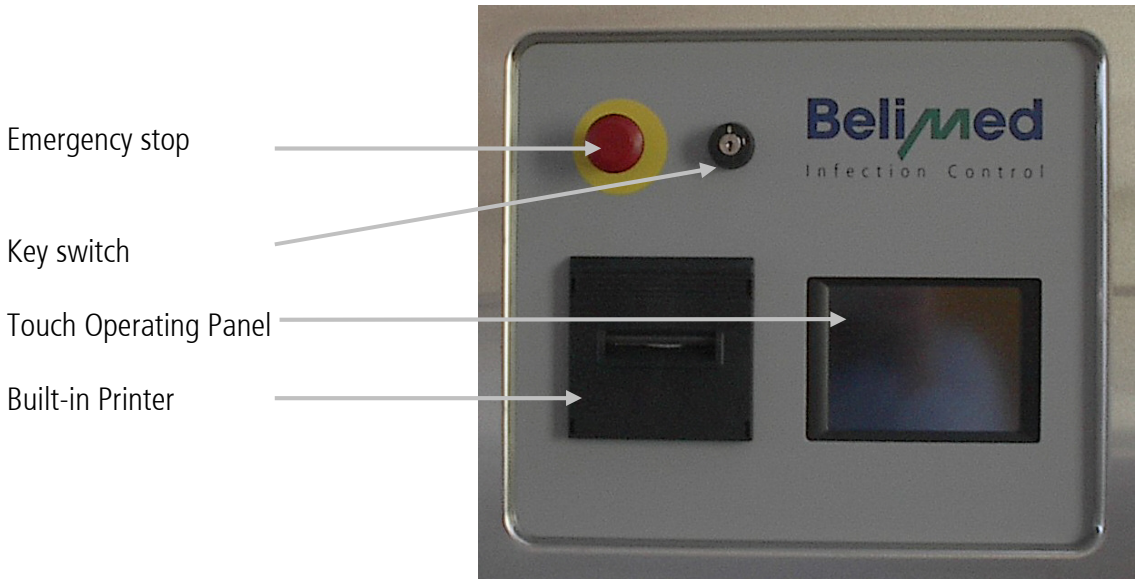


Figure 5-4: Operating end control panel

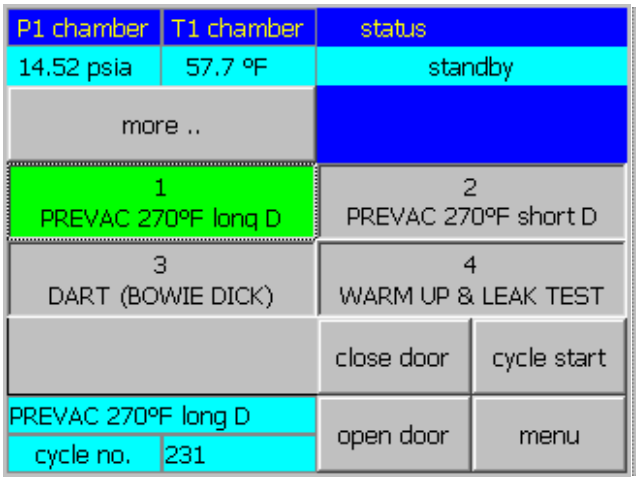


Figure 5-5: Out-of-cycle display

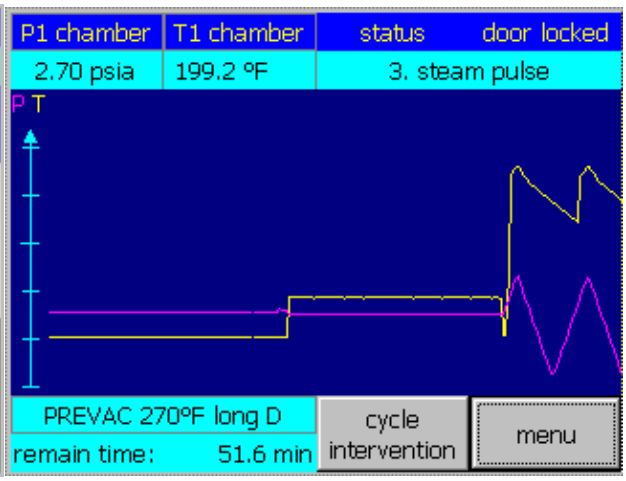


Figure 5-6: In-cycle display

5.4 Non-Operating End Control Panel (option)

Sterilizers with 2 doors are equipped with the non-operating end control panel.

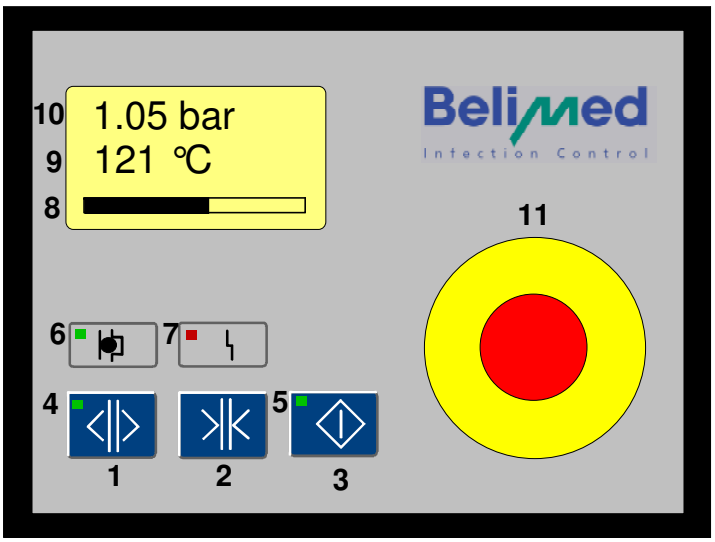
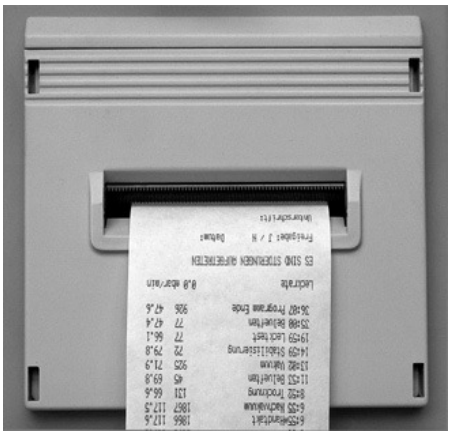


Figure 5-7: Non operating end control panel

No.	*Item*	*Name*	*Function*
1	Push button	Open door	Open chamber door at end of cycle
2	Push button	Close door	Close chamber
3	Push button		n/a
4	LED	Open door	Lights up, when the door on the non operating end can be opened
5	LED	In cycle	Lights up while a cycle is running
6	LED	Door locked	Lights up, when doors are locked
7	LED	Alarm	Lights up while an alarm is active
8	Bar Graph	Cycle progress	Shows the progress of a cycle (0...100%)
9	Display	Temperature	Chamber temperature Indicator or remain process time
10	Display	Pressure	Chamber pressure Indicator
11	Push button	Emergency stop	Emergency stop button

5.5 Printer

The built built-in cycle documentation printer is a is a panel mount printer (refer to Figure 5-8).



General Specifications:

Technology: impact dot matrix
Columns: 42 column
Paper with: 57.5mm
Paper roll diameter 38mm

For replacing paper roll or ribbon refer to chapter 11

Figure 5-8: Panel mount printer

5.6 Printouts (example)

```
BELIMED CYCLE DOCUMENTATION
Hospital      : Charity
Department    : CSSD
Machine-Type  : 12-6-12HS2    No:  045556
Run number    : 345679
Operator      : Brown
Cycle         : 4: Leak Test
Version       : PR: 13.03.2001  SW:   2.2
Cycle start   : 24.03.2001 / 13:35

Set-Values    : Leak rate   <1.3 mbar/min
                Test time       15.0 min

Time  Phase                Press. Temp.
 m:s                       mbara    °C
-----------------------------------------
 0:00 Vacuum                995   28.5
 2:20 Stabilize              70   25.5
 7:20 Air Leak Test          72   27.9
22:20 Air Break              79   28.3
24:03 Complete              980   29.1

Leak rate                  0.5 mbar/min

CYCLE PASSED
Cycle approved: Y / N      Date:

Signature:
```

Figure 5-9: Printout of a Leak Test cycle

5.7 Door operation

The doors of the Belimed Steam Sterilizer TOP 5000 are motorized: they can be activated by pressing the control buttons "open door" and "close door" on the control panel of the operating or non-operating end: the corresponding door will be activated when the sterilizer status allows the opening or closing procedure. The doors themselves are equipped with pressure sensitive switches which stop door closing if an object is in the door area.

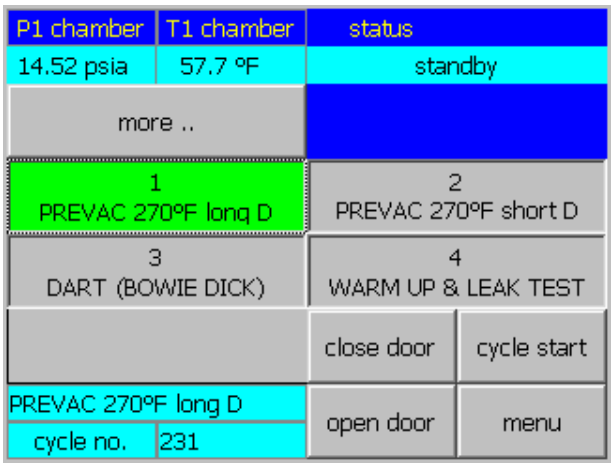


Figure 5-10: Door operation buttons operating end

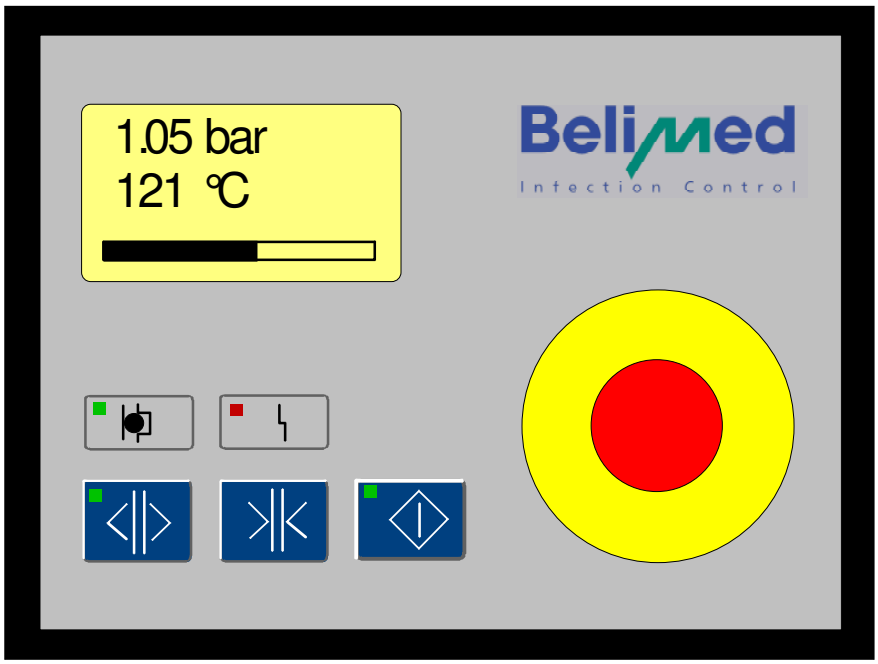


Figure 5-11: Door operation buttons non operation end

5.8 General precautions for the sterilization procedure

The sterilization performances in terms of cycle duration, level of dryness and water/steam consumption can only be achieved when the loading prescriptions are respected. Following aspects are to be followed:

- The goods to be sterilized must be placed on the loading racks especially designed therefor: avoid placing the goods directly onto the chamber floor.
- Each shelf of the loading rack must be loaded individually: do not stack trays.
- Containers may be stacked only if their steam openings are remain free. Some container types can only be stacked for transportation but not during sterilization.
- When wire baskets are stacked , pay attention that the goods of the underlying basket shall not be compressed. The package must be able to expand during the sterilization process.
- Heavy sterilization items shall always be placed in the lower part of the unit.
- Overfilled baskets and trays can cause problems. Loading of baskets has to be achieved in such a way that a hand can easily fit between the packs without compressing them. Container weight shall be limited to 7-8 kg.
- Foil/ paper packaging has to be stacked in an oblique way to each other, the paper side located downwards.
- Textiles have to be placed vertically whenever possible.
- Instruments shall be equally distributed among the tray
- Loading has to be performed with similar instruments or goods to be processed. A recommended
- can be the following:
- Porous materials and textiles together
- Single or small amount of instruments
- Baskets of instruments together
- Goods to be sterilized shall be packaged in a loose way. Sufficient room shall remain free in order that the steam can reach the surface of the goods to be sterilized without hindrance.
- Keep at least 2" distance - horizontally and vertically - between the goods to be sterilized and the chamber walls.
- Insure that the goods to be sterilized are placed in a stable way on the transportation cart and that they can't move or fall down during the process.
- Open containers, cups and tubes shall be placed in such a way that the condensed water will easily drain.

6 Operating the sterilizer

6.1 Turn on the sterilizer

The **Main Power Disconnect Switch** (refer to Figure 6-1) is located behind the access door on the main control box. This switch disconnects power to the control. Under normal operation, this switch is left in the **On** position at all times.

The **Steam Supply Valve** (refer to Figure 6-1) is located behind the access door on the top . Ensure this is in the open position before trying to operate the sterilizer.

The Water Supply Valve (refer to Figure 6-1) is located behind the access door between vacuum pump and chamber. Ensure this is in the open position before trying to operate the sterilizer.

The **Key Switch** (refer to Figure 6-1) is located on the Operating End Control Panel. Turn the key in the **I** position (on).

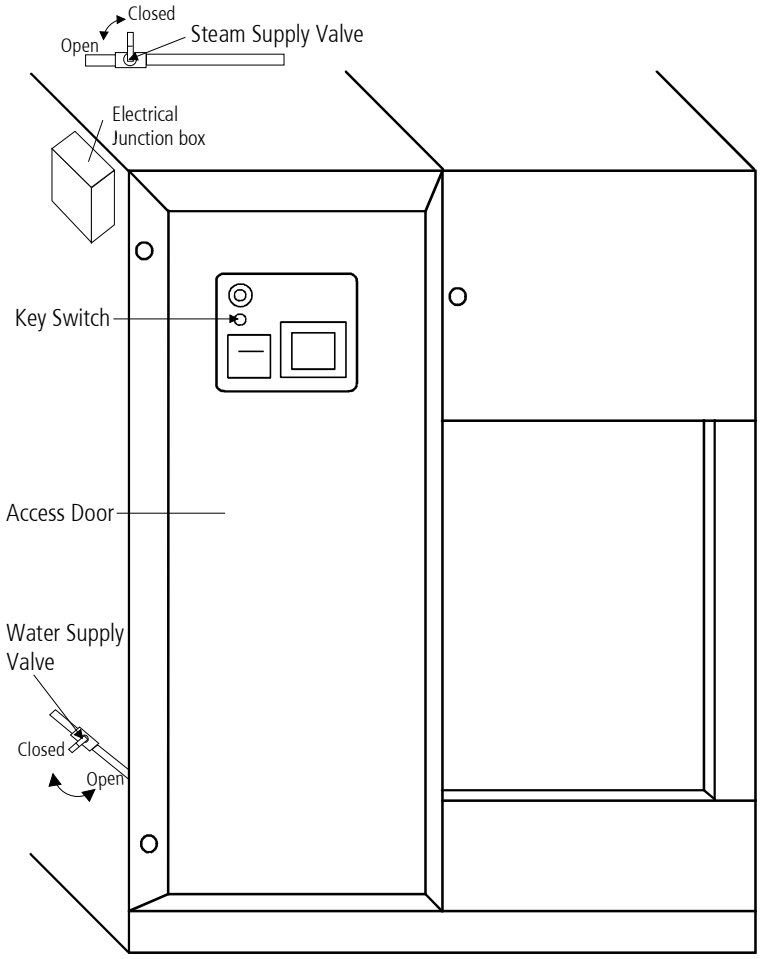


Figure 6-1: Utility locations

6.2 Log on

To operate the sterilizer a user must be logged on. The operator has to enter his password (refer to Figure 6-2 to Figure 6-5).

Note:

The Belimed service personnel can configure the system that a 'common' user is automatically logged on. The 'common' user can select and start a cycle and can operate the door. User 'System' is entered in the batch log. In this configuration, it is not possible to trace back to the user who started the program

Press the 'menu' button in the out-of-cycle display (refer to Figure 6-2)

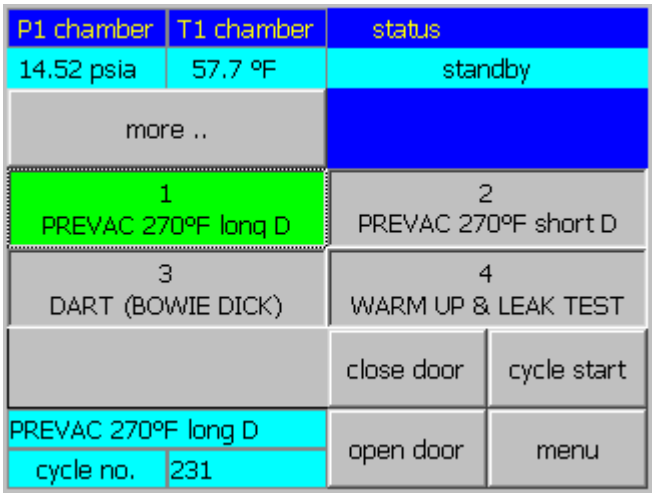


Figure 6-2: Out-of-cycle display

Then press the 'log on' button in the 'menu' display (refer to Figure 6-3)

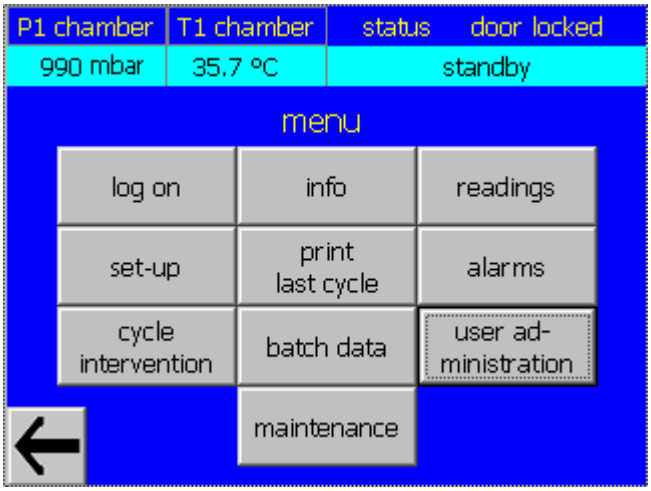


Figure 6-3: Menu display

The log on display shows the entry-field for the password. (refer to Figure 6-4)

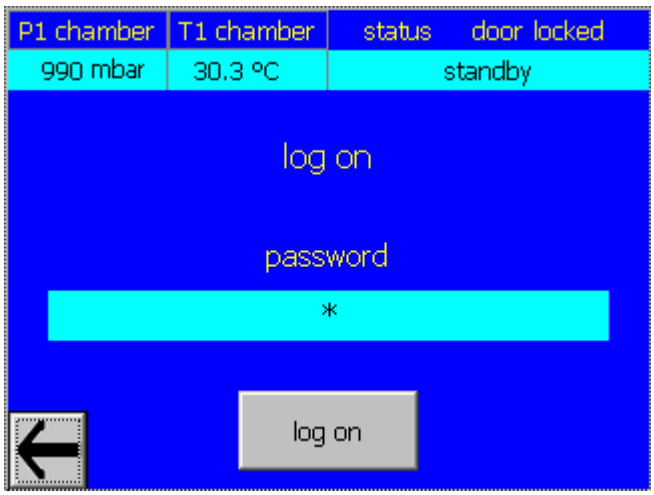


Figure 6-4: Log on display

To enter a password, press the field below 'password'.
The alphanumeric keyboard is shown (refer to Figure 6-5):

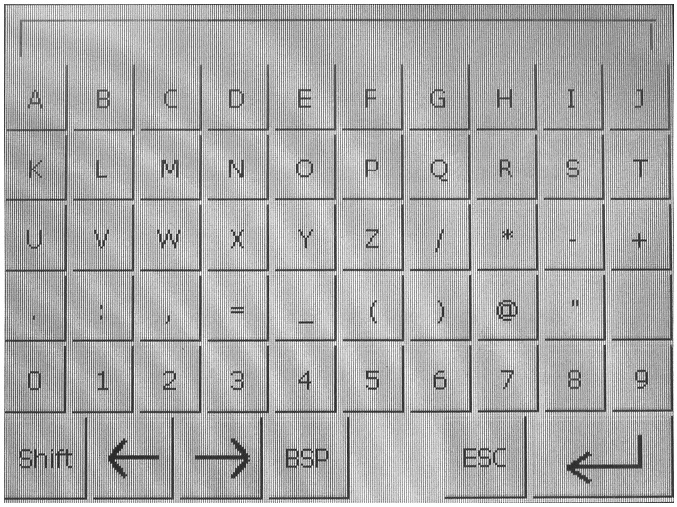


Figure 6-5: Alphanumeric keyboard

Enter the password and press the ↵ button. After entering the Password, press the **'Login'** button (Figure 6-4)
You will see message 'Invalid Password' if you have entered an incorrect Password.
If the Password is correct, the display switches to the Menu display.

6.3 Loading the sterilizer

WARNING - BURN HAZARD:

Sterilizer and rack/shelves will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

WARNING - FALL HAZARD

To prevent falls keep floors dry by immediately wiping up any liquids or condensation in sterilizer loading or unloading area.

Prepare the load as described in chapter 8 Techniques of sterilization.

CAUTION: Keep the movement area of the door unobstructed during door opening and closing.

6.3.1 Loading standard sterilizer

Open the chamber door by pressing the 'open door' button.
Verify that loading cart is securely fastened to the transfer carriage sterilizer.
Align the front end of the transfer carriage with the end of the sterilizer (refer to Figure 6-6)
Move carriage forward until latches agree with track inside chamber.
Lock the carriage by pulling the carriage lock lever to the left side an then push forward. The carriage latches to track inside chamber. (refer to Figure 6-7)
Verify that transfer carriage is latched to track inside chamber by pulling transfer carriage backwards (transfer carriage must remain stationary).
Carefully push the loading cart off the transfer carriage and fully into the sterilizer chamber.
Disengage transfer carriage latches from track inside chamber by pulling carriage lock lever (the carriage lever locks into place).
Back the transfer carriage away from the sterilizer
Close the chamber door by pressing the 'close door' button

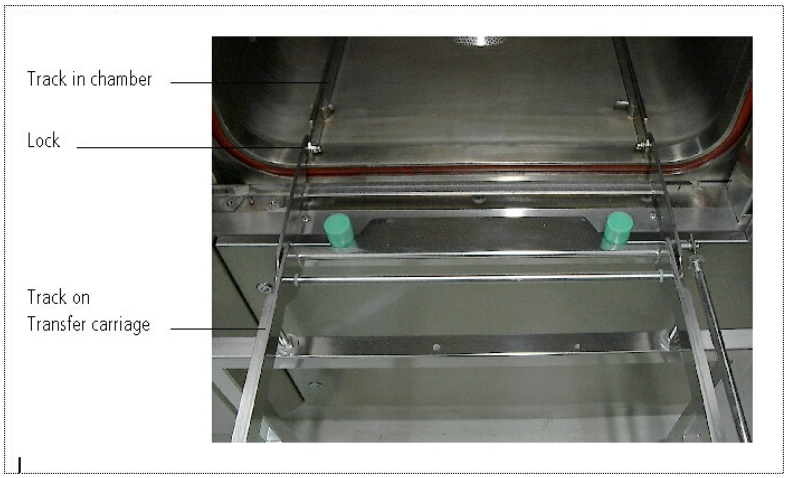


Figure 6-6: Align transfer carriage with chamber

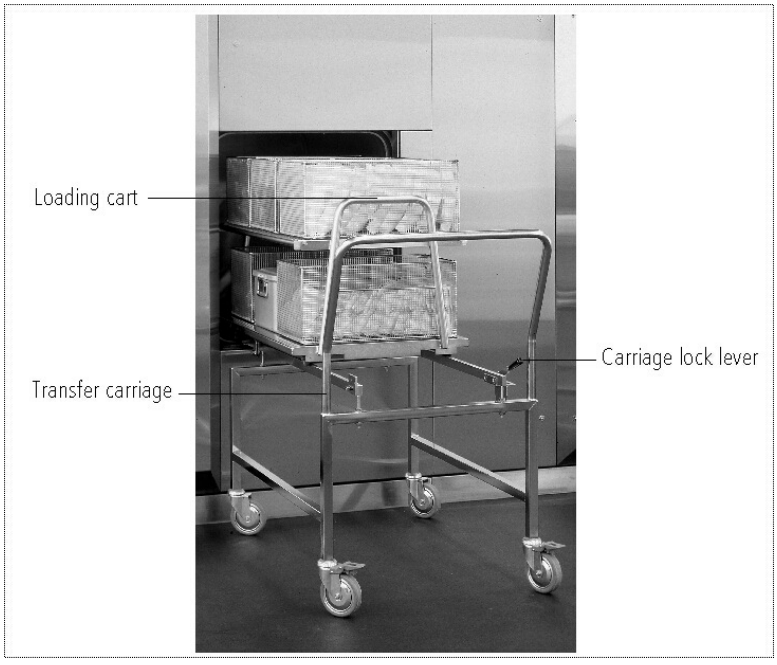


Figure 6-7: Loading standard sterilizer

Loading floor flush sterilizer

Open the chamber door by pressing the 'open door' button.

Push the loading cart into the chamber (refer to Figure 6-8). The loading cart must not touch the chamber walls or the unloading door. The distance between cart and the chamber walls and doors should be at least one inch.

Close the chamber door by pressing the 'close door' button.

Figure 6-8: Align Loading cart with floor flush sterilizer

6.4 Select a cycle

6.4.1 Factory-set cycles and cycle values

Belimed steam sterilizers TOP5000 are shipped with the factory-set cycles and cycle values listed in Table 6-1:

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	PREVAC 270°F	270°F	4 minutes	20 minutes	Double-Wrapped Instrument Trays, maximum weight of 17lbs each. Fabric Packs.
2	PREVAC 270°F	270°F	4 minutes	5 minutes	Fabric Packs
6	LIQUID 250°F	250°F	45 minutes	--	Max 1000ml of Liquid per bottle. Use only vented Type I borosilicate glass bottles.
7	EXPRESS 270°F	270°F	4 minutes	3 minutes	Single Wrapped Instrument Tray with non porous single instrument
8	FLASH 270°F	270°F	3 minutes	1 minute	Unwrapped Instrument Tray with a single instrument
9	FLASH 270°F	270°F	10 minutes	1 minute	Unwrapped Instrument Tray with non porous multiple instruments (maximum weight of 17lbs)
3	DART / Bowie Dick Test	273°F	3.5 minutes	1 minute	One DART or Bowie-Dick Test Pack
4	WARM UP & LEAK TEST	270°F	3 minutes	3 minutes	EMPTY CHAMBER

Table 6-1: Factory-set cycles

6.4.2 Select a cycle

Ensure that the load is suitable for the intended sterilization temperature (temperature resistant) before selecting a cycle.

Five cycle selection buttons (P1..P5) are shown on the screen (refer to Figure 6-9). These buttons display the cycle number, the cycle name and the sterilization exposure temperature.

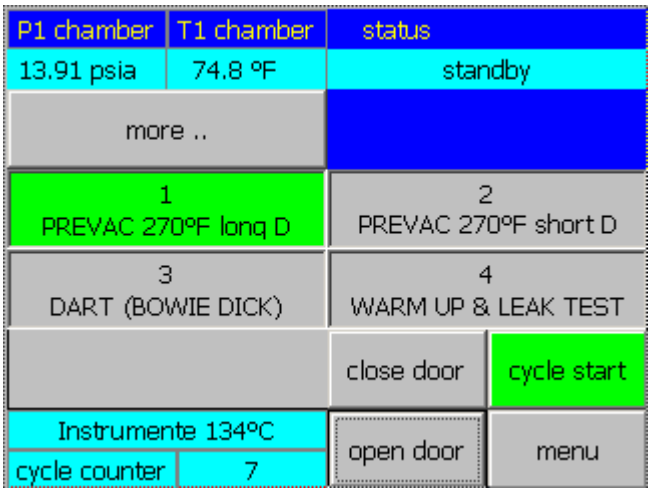


Figure 6-9: Cycle selection buttons with cycle start button

6.5 Start a cycle

The green Start button (Figure 6-9) lights when the sterilizer is at start standby.

The selected program is started after you press the Start button if:

- a cycle is selected
- chamber doors are closed
- no alarms are pending
- the minimum steam pressure is exceeded

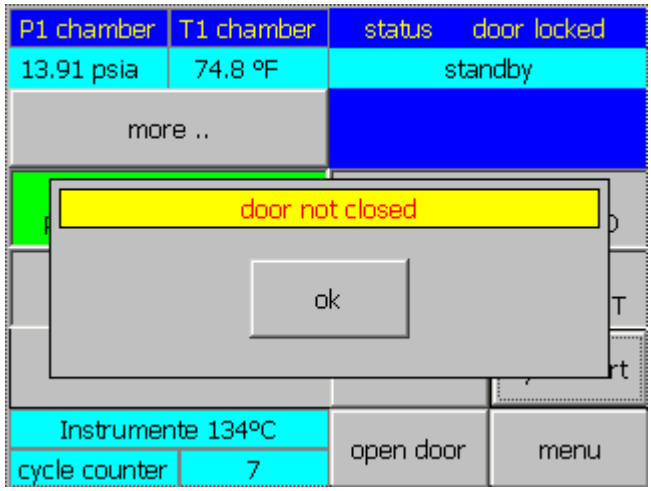


Figure 6-10: Cycle selection with "dialog box"

If the sterilizer is not at start standby, the cause is displayed with a dialog box (Figure 6-10) when you press the Start button.

6.6 In-cycle

During a cycle the following information is displayed:
Chamber pressure P1
Chamber temperature T1
Cycle graph
Cycle status (phase)
Cycle intervention button
Menu button

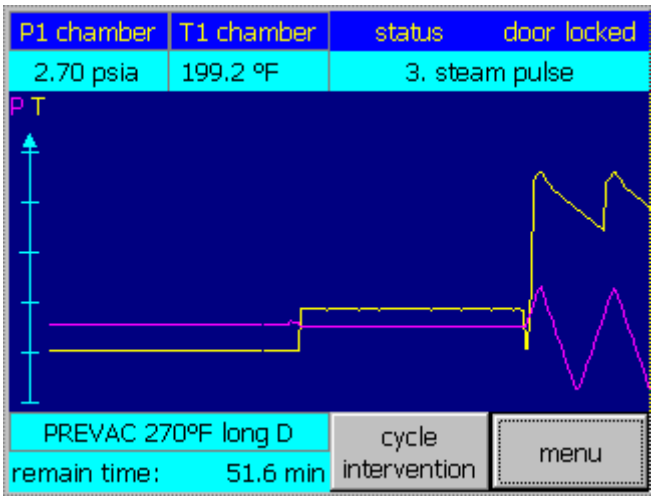


Figure 6-11: In-cycle display

6.7 Cycle failed

If there was an injurious alarm during a cycle, the door on the non operating end is locked.
On the operating end panel the message 'cycle failed' is displayed (refer to Figure 6-12).

If the user must press the 'ok' button. Only the door on the operating end can be opened. Unload the sterilizer. The load must be wrapped again with dry material before sterilizing.

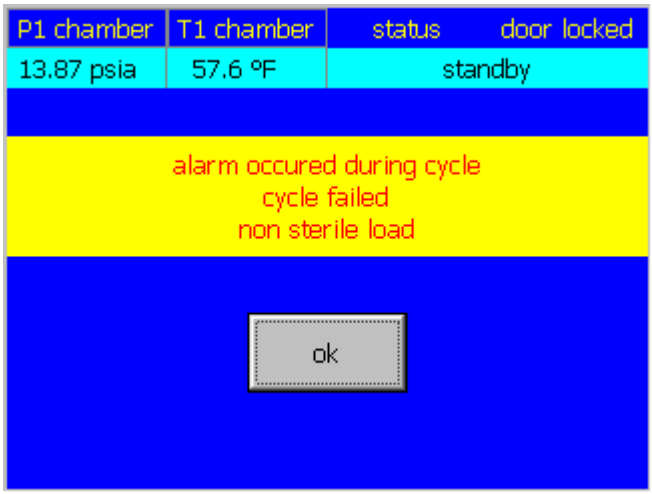


Figure 6-12: Cycle failed display

6.8 Unloading the sterilizer

WARNING - BURN HAZARD:

Sterilizer and rack/shelves will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

WARNING - FALL HAZARD

To prevent falls keep floors dry by immediately wiping up any liquids or condensation in sterilizer loading or unloading area.

The door on the non operating end (double-door sterilizers) can be opened if:

- The sterilization cycle is completed (Test cycles: door can be opened on the operating end only)
- The cycle passed (no injurious alarms during cycle)
- The difference between chamber pressure and atmospheric pressure does not exceed ±80mbar.

CAUTION: Keep the movement area of the door unobstructed during door opening and closing.

6.8.1 Unloading standard sterilizer

Open the chamber door by pressing the 'open door' button.
Move transfer carriage forward until latches agree with track inside chamber.
Lock the carriage by pulling the carriage lock lever to the left side an then push forward. The carriage latches to track inside chamber. (refer to Figure 6-7)
Verify that transfer carriage is latched to track inside chamber by pulling transfer carriage backwards (transfer carriage must remain stationary).
Carefully pull the loading cart from chamber onto transfer carriage until transfer carriage latch engages to loading cart.
Disengage transfer carriage latches from track inside chamber by pulling carriage lock lever (the carriage lever locks into place).
Back the transfer carriage away from the sterilizer.
Close the chamber door by pressing the 'close door' button

6.8.2 Unloading floor flush sterilizer

Open the chamber door by pressing the 'open door' button.
Carefully pull the loading cart from chamber
Close the chamber door by pressing the 'close door' button

6.9 Cycle documentation

At cycle end the cycle documentation is printed on the built-in printer (refer to Figure 6-13).
The Panel Mount printer uses impact dot matrix technology.
For a detailed description of the printer see instructions in chapter 5.5.
For printout examples see in chapter 5.6.

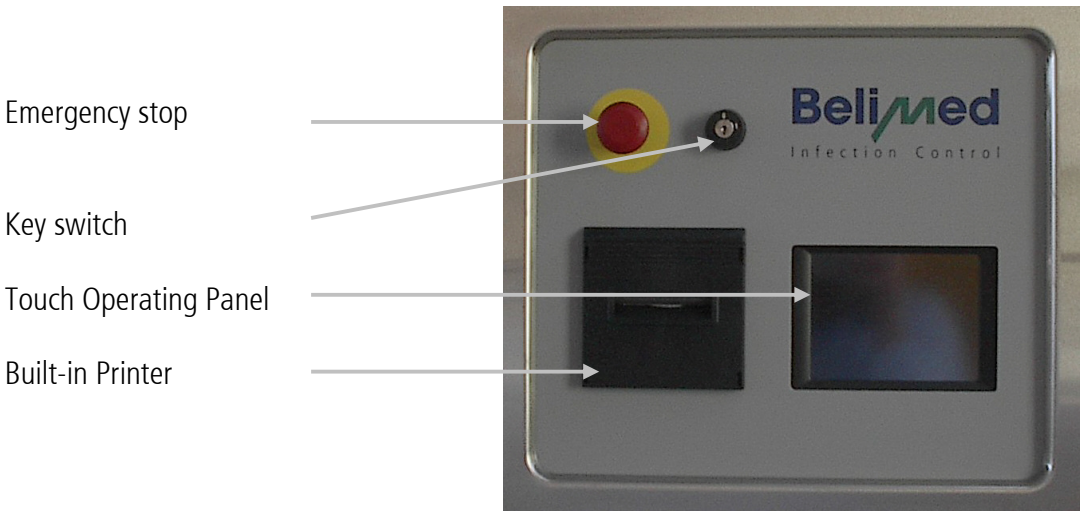


Figure 6-13: Operating panel with built-in printer

6.10 Log off

After using the sterilizer the user should log off to prevent that unauthorized persons can handle the sterilizer. Press first the 'menu' button on touch screen and then press the 'log off' button in the 'menu' display (refer to Figure 6-14).

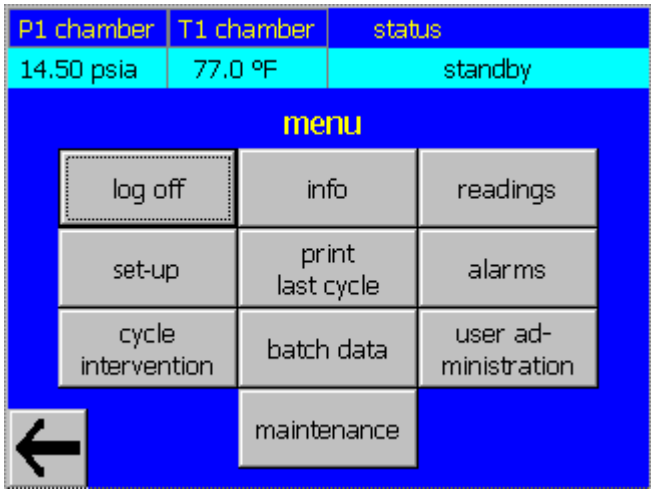


Figure 6-14: Menu display

6.11 Turn off the sterilizer

After unloading the last cycle (in the evening) turn off the sterilizer with the key switch (refer Figure 6-13).

6.12 Automatic Unloading Device

6.12.1 General

The automatic unloading device unloads the loading cart out of the chamber after the cycle is finished.

WARNING

For sterilizers with loading and unloading from the same side (1-door operation) never place a loading cart on the automatic unloader while a process is running!

6.12.2 Overview

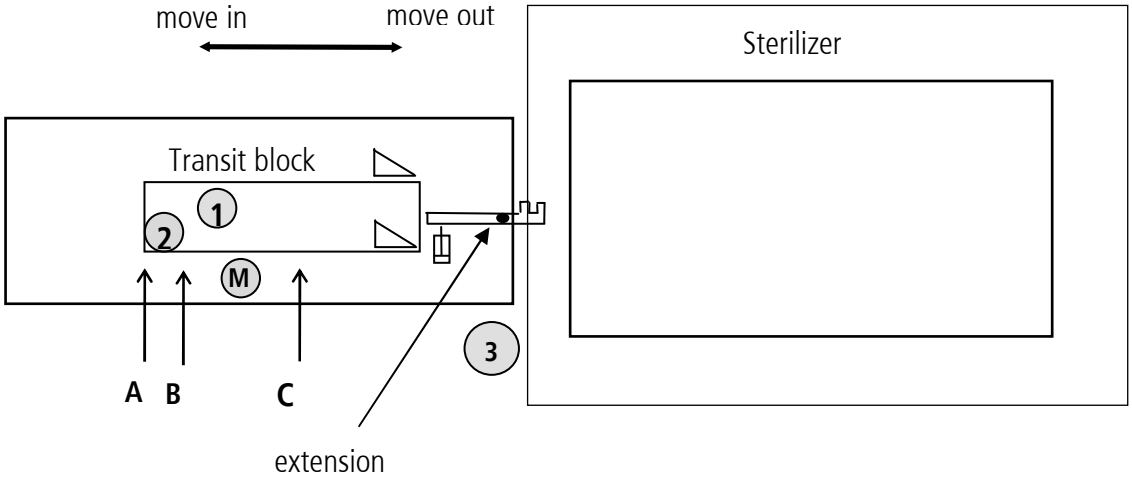


Figure 6-15: Unloading device overview

Positions

A: Initial position: Proximity switch (1) and (2) covered, light barrier (3) not covered

B: Ground position move in: Proximity switch (1) covered

C: End position move out: Proximity switch (2) covered

6.12.3 Automatic operation

6.12.3.1 Initialize

If the unloading device is set to "automatic" on the operating panel TOP5000, the transit block moves to initial position automatically.

6.12.3.2 Conditions for the automatic unloading sequence

- Cycle has to be finished and the door unlocked.
- No cycle "warm up" and "leak test" selected
- The unload device is set automatic on the TOP5000

6.12.3.3 Sequence

1. door opens completely
2. transit block moves out in to the chamber until end position is reached
3. the extension couples on
4. transit block moves back out of the chamber until ground position is reached
5. monitoring extension is coupled, if not: an alarm will be set
6. repetition point 2 an 4 until loading cart is completely out of the chamber
7. transit block moves out in to the chamber for 4 seconds
8. the extension couples off
9. transit block moves back out of the chamber until ground position is reached
10. door is closing completely
11. waiting in ground position until loading cart is taken away (light barrier (3) not covered)
12. transit block moves back until Initial position is reached

6.12.4 Manual operation

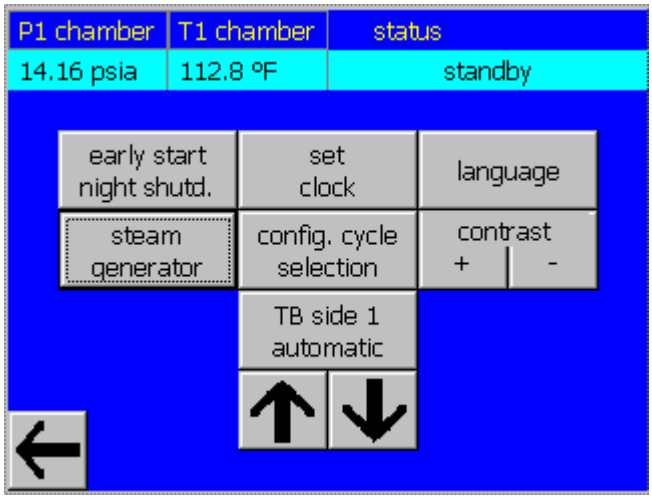


Figure 6-16: Unloading device overview

If the transit block is not set in automatic mode, it can be moved forwards and backwards by pressing the arrow button below the automatic function button. The proximity switches (1) and (2) and the light barrier are monitored in manual mode as well.

6.12.5 Possible alarms from the unloading device

Alarmtext	Description / condition	comment
Coupling extension unloading system	automatic unloading system is in process AND proximity switch "extension TB 2 coupled" at begin of the unloading process is not covered OR Proximity switch "extension TB 2 coupled" at the end of the enlacing process is not covered	Automatic unloading process will be switched off
Time overrun unloading system	System is in end or start position AND automatic unloading system is in process AND end-position of the unloading system is not reached within 20 seconds.	Automatic unloading process will be switched off

7 Sterilizer Factory Cycles Settings

Belimed steam sterilizers TOP5000 are shipped with the factory-set cycles and cycle values listed in Table 7-1:

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	PREVAC 270°F	270°F	4 minutes	20 minutes	Double-Wrapped Instrument Trays, maximum weight of 17lbs each. Fabric Packs.
2	PREVAC 270°F	270°F	4 minutes	5 minutes	Fabric Packs
6	LIQUID 250°F	250°F	45 minutes	--	Max 1000ml of Liquid per bottle. Use only vented Type I borosilicate glass bottles.
7	EXPRESS 270°F	270°F	4 minutes	3 minutes	Single Wrapped Instrument Tray with non porous single instrument
8	FLASH 270°F	270°F	3 minutes	1 minute	Unwrapped Instrument Tray with a single instrument
9	FLASH 270°F	270°F	10 minutes	1 minute	Unwrapped Instrument Tray with non porous multiple instruments (maximum weight of 17lbs)

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
3	DART / Bowie Dick Test	273°F	3.5 minutes	1 minute	One DART or Bowie-Dick Test Pack
4	WARM UP & LEAK TEST	270°F	3 minutes	3 minutes	EMPTY CHAMBER

Table 7-1: Factory-set cycles and cycle values

7.1 270°F Pre-vacuum Cycles

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	PREVAC 270°F	270°F	4 minutes	20 minutes	Double-Wrapped Instrument Trays, maximum weight of 17lbs each. Fabric Packs.
2	PREVAC 270°F	270°F	4 minutes	5 minutes	Fabric Packs

Table 7-2: 270°F Pre-vacuum Cycles

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Pre-vacuum Cycles

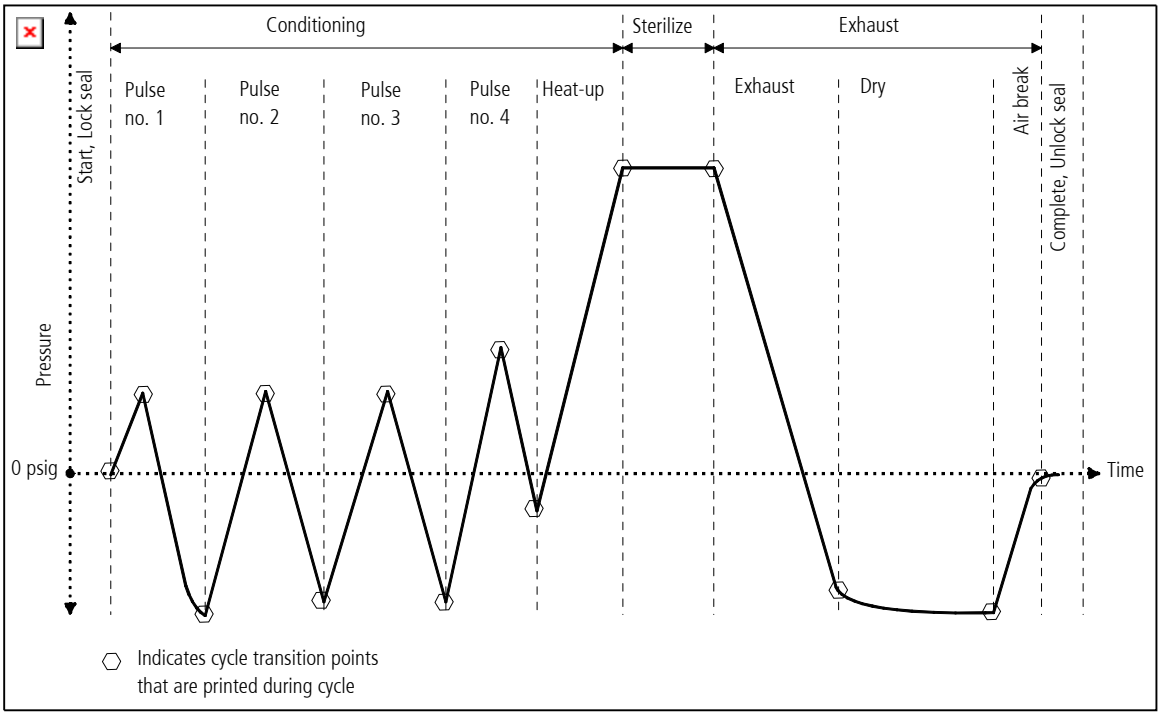


Figure 7-1: Cycle Graph - 270°F Pre-vacuum cycles

7.2 250°F Liquid Cycle

WARNING - EXPLOSION HAZARD:

This sterilizer is not designed to process flammable compounds

WARNING - BURN HAZARD:

When sterilizing liquids, to prevent personal injury or property damage resulting from bursting bottles and hot fluid, you must observe the following procedures:
It is inappropriate for a health care facility to sterilize liquids for direct patient contact.
Use Liquid cycle only; no other cycle is safe for processing liquids
Use only vented closures; do not use screw caps or rubber stoppers with crimped seal.
Use only Type I borosilicate glass bottles, do not use ordinary glass bottles or any container not designed for sterilization.
Do not allow hot bottles to be jolted; this can cause hot-bottle explosions. Do not move bottles if any boiling or bubbling is present.

This sterilizer is not designed to process flammable liquids nor liquids in containers that are not designed for sterilization.

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
6	LIQUID 250°F	250°F	45 minutes	--	Max 1000ml of Liquid per bottle. Use only vented Type I borosilicate glass bottles.

Table 7-3: 250°F Liquid Cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 LIQUID Cycles (refer to Figure 7-2):

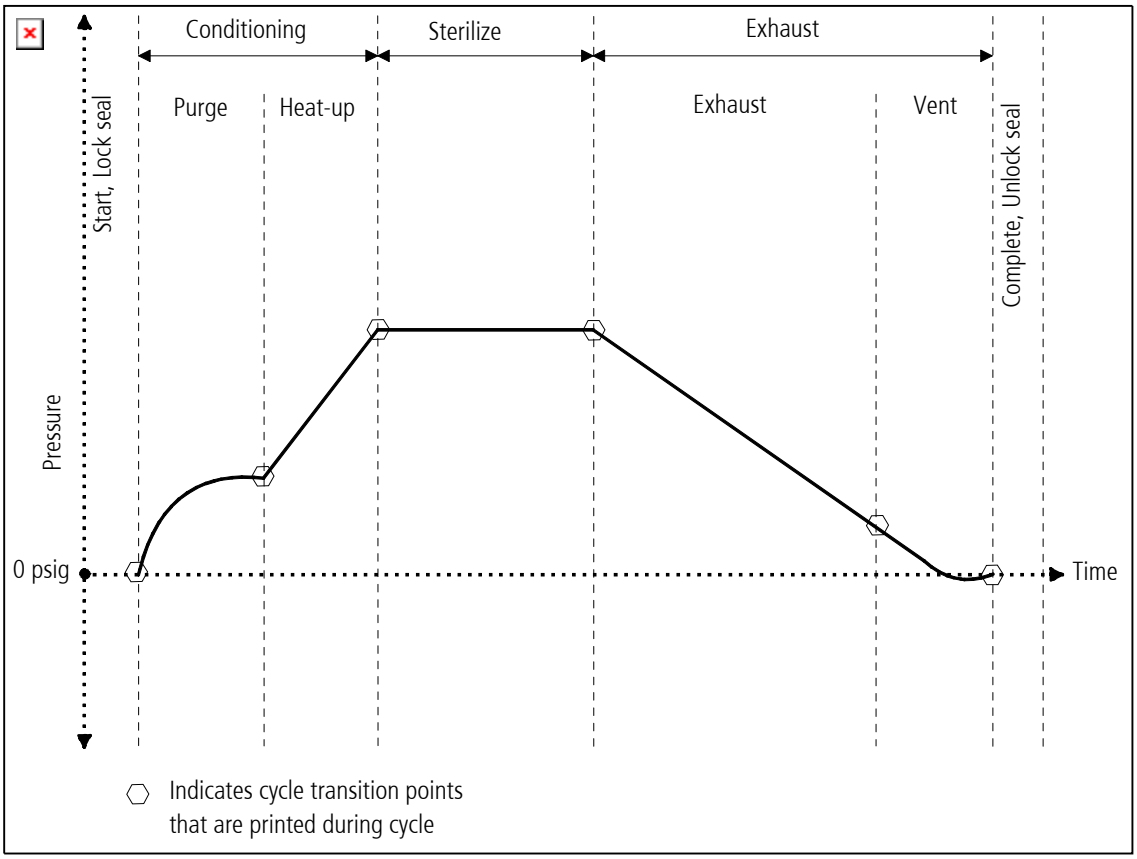


Figure 7-2: Cycle Graph - Liquid cycle

7.3 270°F Express Cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
7	EXPRESS 270°F	270°F	4 minutes	3 minutes	Single Wrapped Instrument Tray with non porous single instrument

Table 7-4: 270°F Express Cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Express Cycles (refer to Figure 7-3):

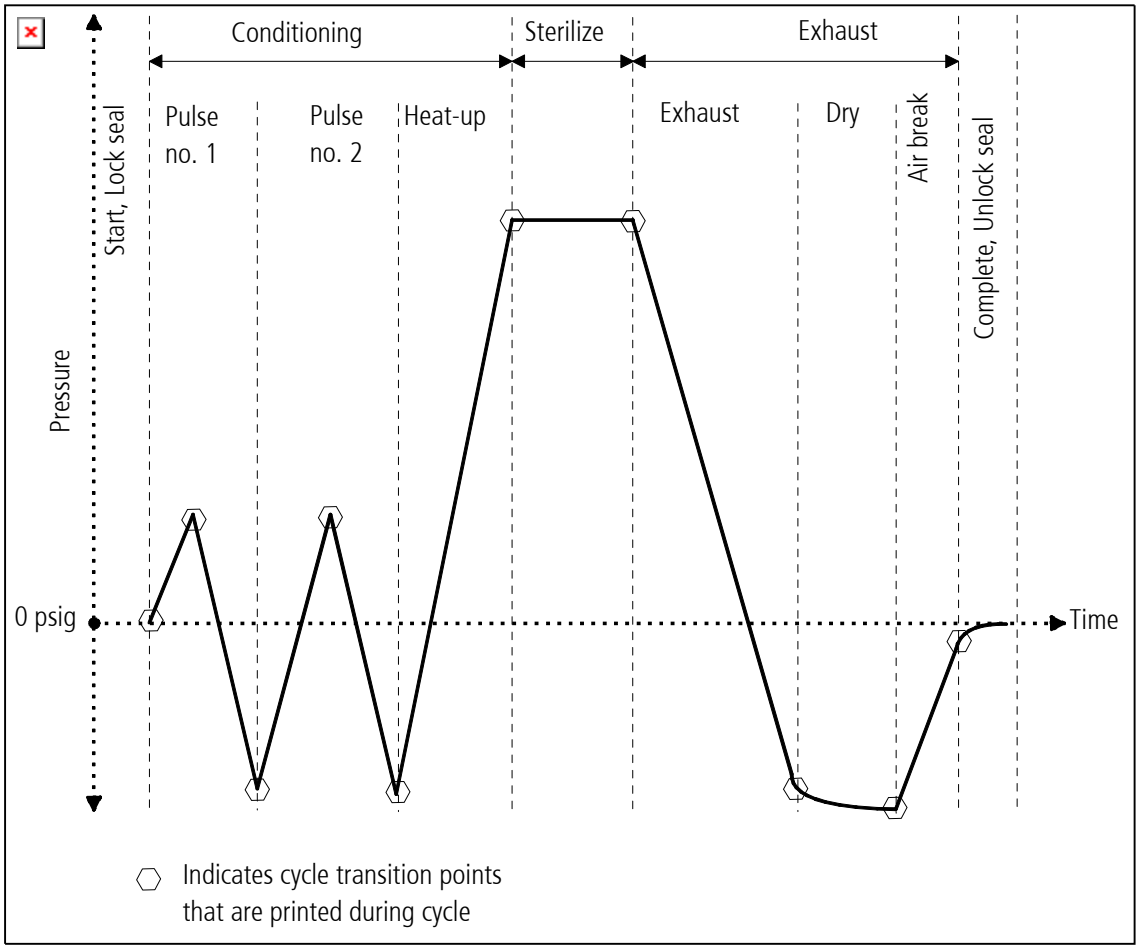


Figure 7-3: Cycle Graph - Express cycle

7.4 270°F Flash Cycles

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
8	FLASH 270°F	270°F	3 minutes	1 minute	Unwrapped Instrument Tray with a single instrument
9	FLASH 270°F	270°F	10 minutes	1 minute	Unwrapped Instrument Tray with non porous multiple instruments (maximum weight of 17lbs)

Table 7-5: 270°F Flash Cycles

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Flash Cycles (refer to Figure 7-4):

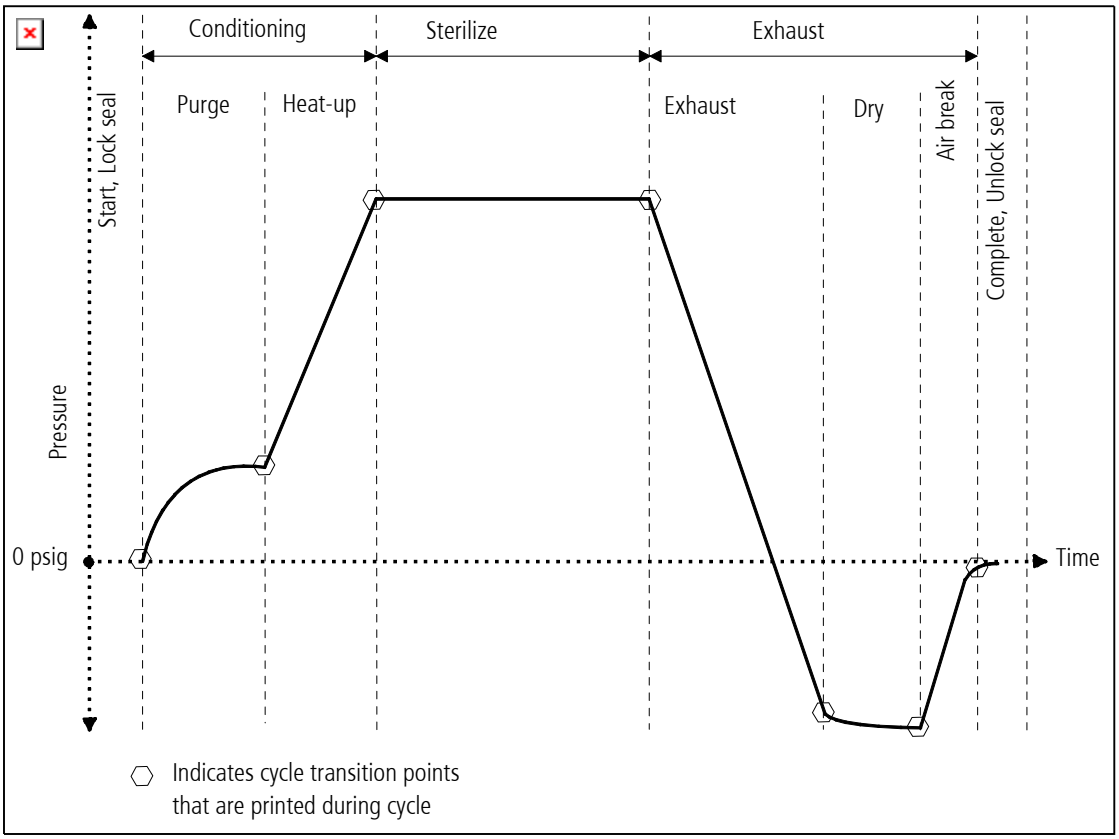


Figure 7-4: Cycle Graph - Flash cycles

7.5 DART / Bowie-Dick Test cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
3	DART / Bowie -Dick Test	273°F	3.5 minutes	1 minute	One DART or Bowie-Dick Test Pack

Table 7-6: DART / Bowie-Dick Test cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 DART / Bowie-Dick Test Cycles (refer to Figure 7-5):

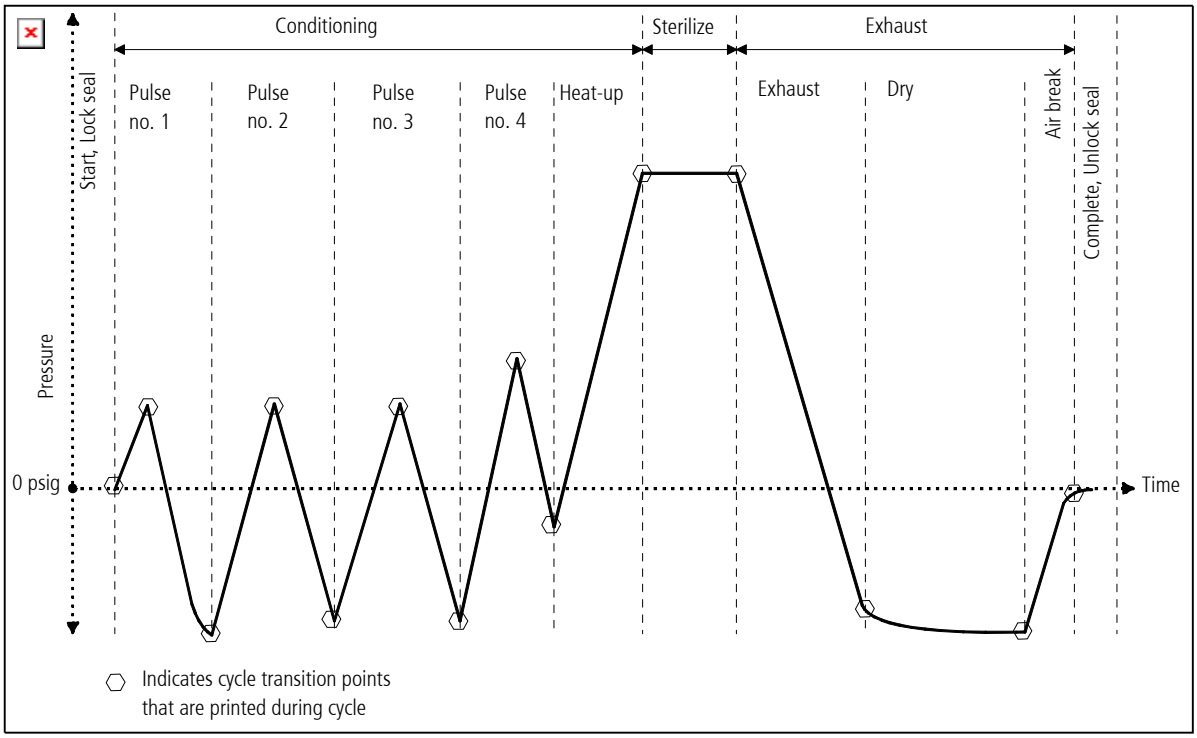


Figure 7-5: Cycle Graph - DART / Bowie-Dick Test cycle

CAUTION

The Bowie-Dick/ DART Test Cycle has to be performed daily.

7.6 Warm-up & Leak Test cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
4	WARM UP & LEAK TEST	270°F	3 minutes	3 minutes	EMPTY CHAMBER

Table 7-7: Warm-up & Leak Test cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Warm-up & Leak Test Cycles (refer to Figure 7-6):

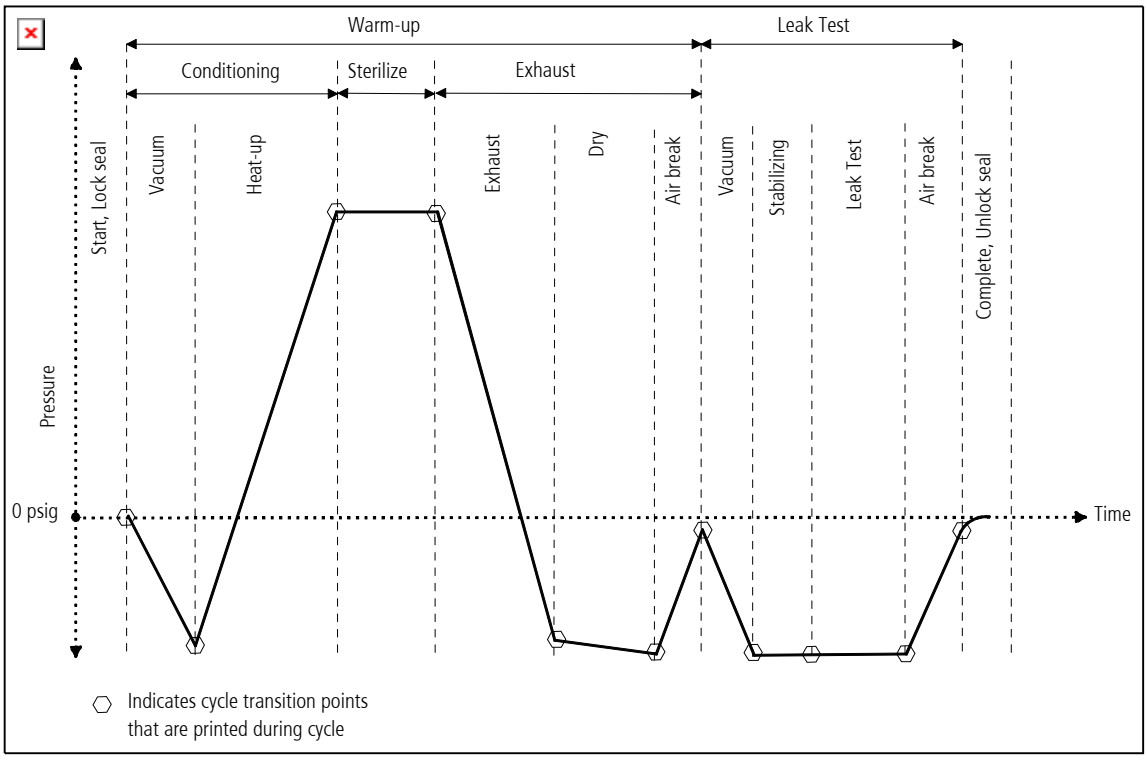


Figure 7-6: Cycle Graph - Warm-up & Leak Test cycle

CAUTION

In order to ensure the proper function of the sterilizer, run a vacuum leak test cycle daily.

8 Techniques of sterilization

8.1 Guidelines for preparing and sterilizing wrapped packs

WARNING - BURN HAZARD:

BURN HAZARD: Sterilizer and rack/shelves will be HOT after cycle is run. Always wear protective gloves and apron (also face shield if processing liquids) when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation

Refer to AAMI ST-46 Chapter 5 for Processing considerations.

8.1.1 Preparing load:

- Before sterilization, materials must be thoroughly cleaned.
- Wrappers may be made of 100% cotton, 140 thread count, two-ply fabric, and freshly laundered.
- Reusable wrappers should be laundered between sterilization cycles
- Before wrapping, packaging materials must be dry and should be under room temperature (20°C-23°C) and at a relative humidity ranging from 30%-60% for at least 2 hours.

8.1.2 Wrapped fabric packs

- Place two wrappers on work surface
- Place contents on wrappers. Fabrics should be folded flat, with each succeeding layer placed crosswise to the one below to promote free steam circulation.
- Place internal chemical indicator in the center of the pack
- Wrap contents sequentially in two wrappers (refer to Figure 8-1).
- Secure with sterilizer tape and identify
- The maximum weight must not exceed 18 pounds, density factor: not in excess of 10.7 lb/ft^3, and the size must be limited to 23"x11"x11".
- Single Fabric Test Pack (for validation) should weigh approximately 3.3 pounds and should have a density of approximately 11.3 lb/ft^3 (refer to AAMI-ST8 recommendations in section 5.5.1.1).

Notes:

- Wrapper size should be adequate for the desired method of wrapping. Excessive size wrappers may cause drying problems
- Do not wrap too tightly

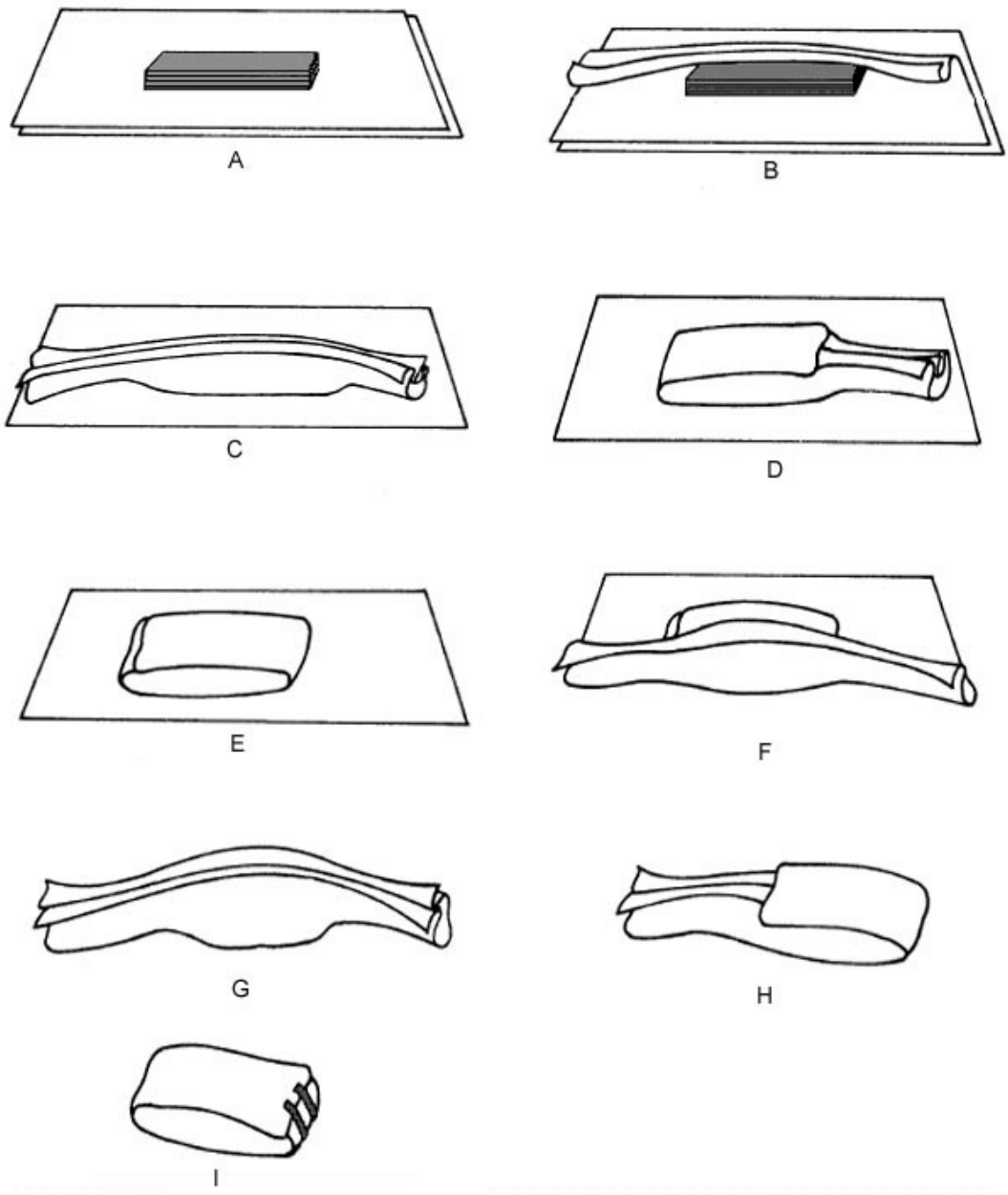


Figure 8-1: Double-wrapping: Square fold

8.1.3 Wrapped instrument sets

- Inspect instruments to make sure they are functioning properly, they are clean and dry.
- Open, disassemble or unlock instruments to permit steam contact to all surfaces.
- Use mesh-bottom tray or wire-mesh or equivalent trays.
- Place a fully opened huck towel in the bottom of the tray. This will assist drying.
- Place instruments on towel, distributing them as much as possible. Using an adequate size tray will allow optimal distribution of the instruments.
- Fold the towel excess over the instruments
- Place internal chemical indicator on instruments. Ink side should not come in contact with metal surface.

- Wrap instrument tray sequentially in two wrappers (refer to Figure 8-1).
- Secure with sterilizer tape and identify.
- Recommended weight of each wrapped instrument set is 17 pounds for minimizing moisture retention (refer to AAMI-ST8 recommendations in section 5.5.3.1). The maximum weight must not exceed 25 pounds.

Notes:
- Instrument trays must be designed for effective sterilization and drying
- Use a towel which covers the tray with minimum excess overhang.
- Wrapper size should be adequate for the desired method of wrapping. Excessive size wrappers may cause drying problems.

8.1.4 Wrapped utensils

- When placing utensils in a set, separate each clean, dry basin from the one beneath it by a huck towel.
- Open towel to fully cover the metal surface.
- Arrange utensils so that the bottom of each is parallel to the one beneath it. This allows air to escape from the utensils and helps drying.
- Place internal chemical indicator in an area of the package where steam penetration is worst. Ink side should not come in contact with metal surface.
- Wrap utensils sequentially in two wrappers (refer to Figure 8-2).
- Secure with sterilizer tape and identify
- Recommended weight of each wrapped utensil set is 7 pounds for minimizing moisture retention.

Note:
- Wrapper size should be adequate for the desired method of wrapping. Excessive size wrappers may cause drying problems.

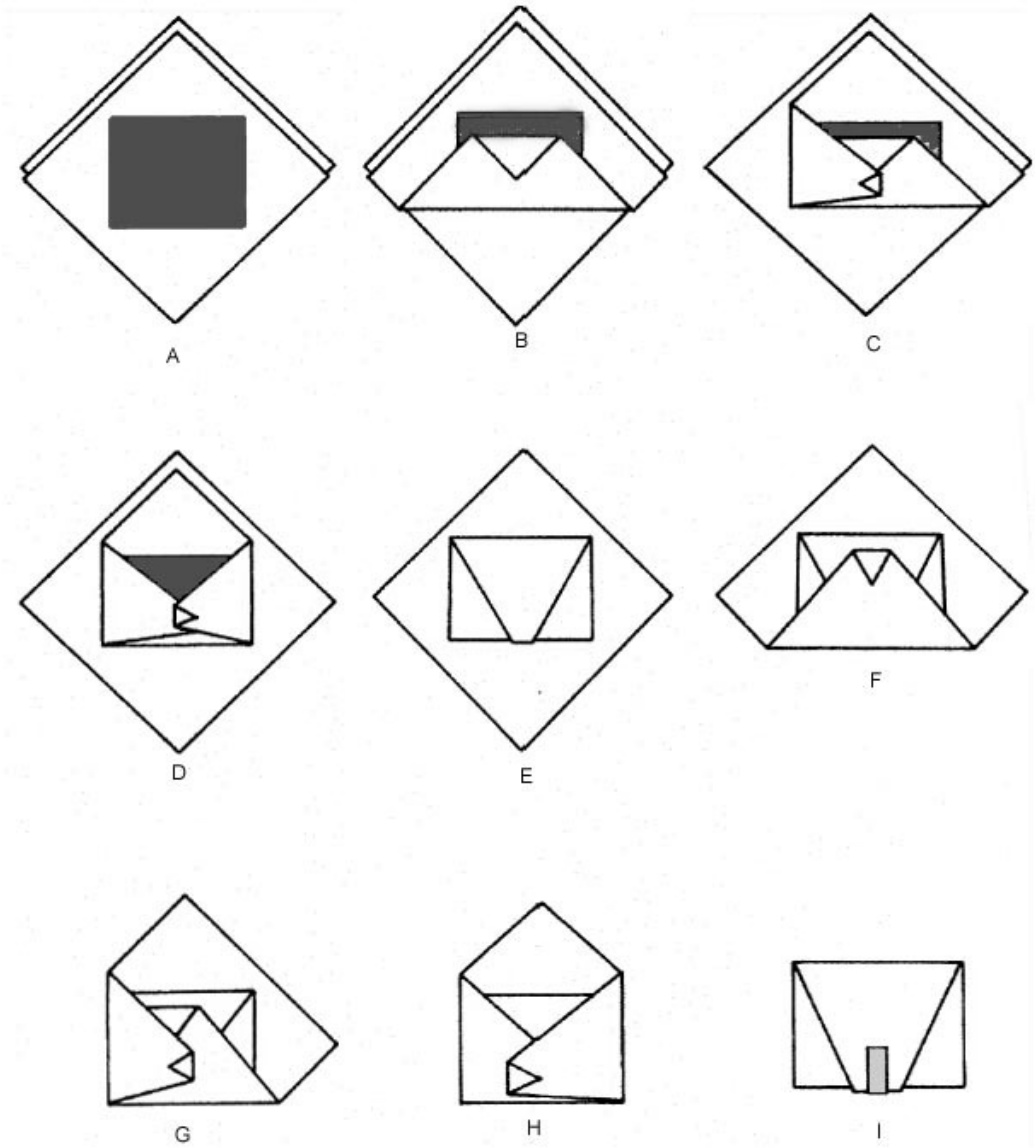


Figure 8-2: Double-wrapping: Envelope fold

8.1.5 Loading the cart:

- In loads which combine fabrics and hard goods (instruments, utensils), place fabric packs on the upper shelves (refer to Figure 8-3).
- Place fabric packs on edge to promote passage of steam through the pack
- Do not overload shelves
- Do not compress packages
- Provide at least 2 inches between the chamber walls and the packages (the load should be within the cart)
- Place packages on sterilizer shelves, do not staple packages
- Never place utensil sets or packages outside of the cart (e.g. chamber floor).

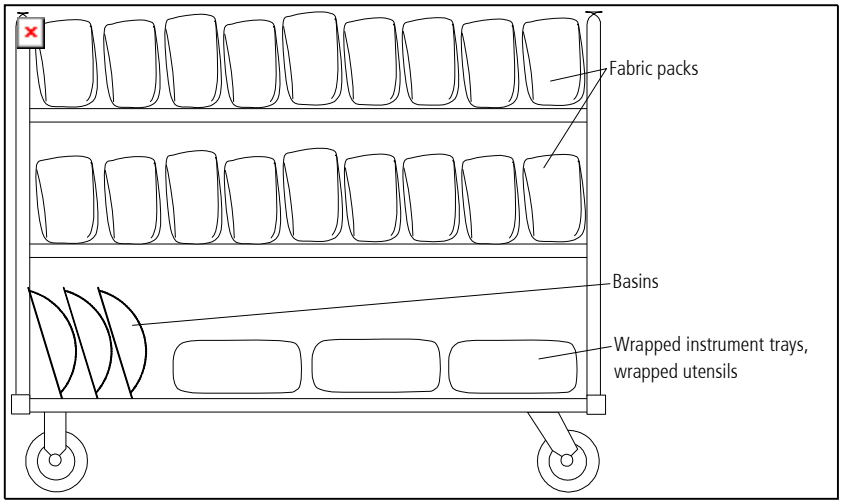


Figure 8-3: Loading cart with combined (solid) load

8.1.6 Steam sterilization cycles

Use cycle no. 1 is recommended for full load fabric packs, instrument trays, utensils.
Use cycle no. 2 for fabric packs (Table 8-1).

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	PREVAC 270°F	270°F	4 minutes	20 minutes	Double-Wrapped Instrument Trays, Fabric Packs, *For amount refer to table 8-1*
2	PREVAC 270°F	270°F	4 minutes	5 minutes	Fabric Packs *For max. amount refer to table 8-1*

Table 8-1: Steam sterilization cycles for porous load

Sterilizer Chamber Size (mm)	Wrapped Instrument Trays up to. 17lbs each	Fabric Packs 11*x11"x9" max.6.6 lbs each	Fabric Packs 23"x11"x11" max. 17 lbs each
26”x 42.5”x 41” (660 x 1080 x 1040)	9	18	9
26”x 42.5”x 55” (660 x 1080 x 1400)	12	30	12
26”x 42.5”x 67” (660 x 1080 x 1700)	15	36	15
26”x 42.5”x 79” (660 x 1080 x 2000)	18	42	18
26”x 48.5”x 43” (660 x 1230 x 1100)	9	18	9
26”x 48.5”x 55” (660 x 1230 x 1400)	12	30	12
26”x 48.5”x 67” (660 x 1230 x 1700)	15	36	15
26”x 48.5”x 79” (660 x 1230 x 2000)	18	42	18

Table 8-2: Recommended solid loads

Ensure that the load is suitable for the intended sterilization temperature (temperature resistant) before selecting a cycle.

8.1.7 Material qualification

Fabrics:
Use only fabrics designed for steam sterilization with 270°F (132°C).
Life time of fabrics depend mainly on washing and ironing the fabrics.
Please note the manufacturers declaration.

Instruments:
Use only instruments designed for steam sterilization with 270°F (132°C).
Instrument life time depends mainly on use and cleaning with chemicals.
100% ASTM 316 Stainless steel instruments can generally be used for steam sterilization.
For other materials note the manufacturers declaration.

Other materials:
Before sterilizing other materials refer to the manufacturers recommendations and restrictions (steam, temperature, max. sterilization time).

8.2 Guidelines for preparing and sterilizing liquids

WARNING - EXPLOSION HAZARD:

This sterilizer is not designed to process flammable compounds

WARNING - BURN HAZARD:

When sterilizing liquids, to prevent personal injury or property damage resulting from bursting bottles and hot fluid, you must observe the following procedures:
It is inappropriate for a health care facility to sterilize liquids for direct patient contact.
Use Liquid cycle only; no other cycle is safe for processing liquids
Use only vented closures; do not use screw caps or rubber stoppers with crimped seal.
Use only Type I borosilicate glass bottles, do not use ordinary glass bottles or any container not designed for sterilization.
Do not allow hot bottles to be jolted; this can cause hot-bottle explosions. Do not move bottles if any boiling or bubbling is present.
Avoid sudden opening of door at end of cycle. Wait at least 10 minutes before door opening and unloading the sterilizer.
Sterilizer and rack/shelves will be HOT after cycle is run. Always wear protective gloves, apron and face shield when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation.

WARNING - Restrictions

It is inappropriate for a health care facility to sterilize liquids for direct patient contact.

This sterilizer is not designed to process flammable liquids nor liquids in containers that are not designed for sterilization.

8.2.1 Preparing load

- Use only Type I borosilicate glass bottles, do not use ordinary glass bottles or any container not designed for steam sterilization
- The maximum allowed bottle size is 1000ml
- Do not use flammable liquids
- Use only vented closures; do not use screw caps or rubber stoppers with crimped seal.
- Place the bottles into baskets to prevent falling down from the cart during transportation
- Place chemical indicator in a hermetically sealed vial in the center of a bottle.

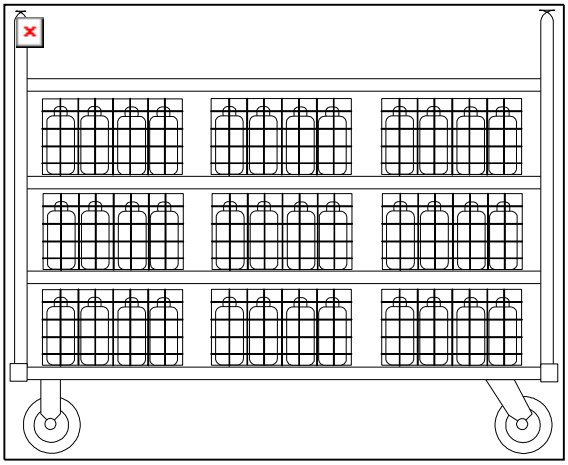


Figure 8-4: Loading cart with liquid load

8.2.2 Liquid cycle

Only use cycle no. 6 liquid cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
6	LIQUID 250°F	250°F	45 minutes	--	Max 1000ml of Liquid per bottle. Use only vented Type I borosilicate glass bottles. *For amount refer to Table 8-3*

Table 8-3: 250°F Liquid Cycle

Sterilizer Chamber Size (mm)	Volume of Liquid in one bottle	Number of bottles
26"x 42.5"x 41" (660 x 1080 x 1040)	1000 ml	126
26"x 42.5"x 55" (660 x 1080 x 1400)	1000 ml	168
26"x 42.5"x 67" (660 x 1080 x 1700)	1000 ml	210
26"x 42.5"x 79" (660 x 1080 x 2000)	1000 ml	252
26"x 48.5"x 43" (660 x 1230 x 1100)	1000 ml	126
26"x 48.5"x 55" (660 x 1230 x 1400)	1000 ml	168
26"x 48.5"x 67" (660 x 1230 x 1700)	1000 ml	210
26"x 48.5"x 79" (660 x 1230 x 2000)	1000 ml	252

Table 8-4: Recommended liquid loads

This sterilizer is not designed to process flammable liquids nor liquids in containers that are not designed for sterilization.

8.3 Appropriated use of Flash cycle

The express cycle is used to sterilize a single unwrapped instrument tray **for immediate** use (e.g. a dropped instrument). There is **no storage or shelf life** of Flash sterilized items.
This cycle may only be uses if the sterilizers non operating end is within the surgery theatre.

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
8	FLASH 270°F	270°F	3 minutes	1 minute	Unwrapped Instrument Tray with a single instrument
9	FLASH 270°F	270°F	10 minutes	1 minute	Unwrapped Instrument Tray with non porous multiple instruments (maximum weight of 17lbs)

Table 8-5: 270°F Flash Cycles

Note: The Belimed Steam Sterilizer TOP 5000 is usually installed in the Central Sterilization Supply Department CSSD.

8.4 Appropriated use of Express cycle

The express cycle is used to sterilize a **single wrapped** instrument tray with a non porous single instrument **for immediate** use. The Express cycle is useful in providing quick turnaround of an instrument using the wrapped technique for transport from sterilizer to the point of use. A single wrapped item sterilized with the express cycle does not have a shelf life.

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
7	EXPRESS 270°F	270°F	4 minutes	3 minutes	Single Wrapped Instrument Tray with non porous single instrument

Table 8-6: 270°F Express Cycle

8.5 Guideline for Determining wet packs

8.5.1 Introduction

Aseptic techniques for surgical procedures require that all supplies coming in contact with the surgical field have to be sterile.
An inherent, inseparable quality for sterility of supplies is a 'state of dryness'. Wet materials transmit bacteria; therefore, a 'state of wetness' would compromise the sterility of process packs and instruments presented to sterile field.

8.5.2 Evaluation of wet packs

A load must be examined for wet packs for three conditions:

- Water droplets on the exterior of a pack
- Water droplets within a pack
- Absorbed moisture in a pack

8.5.3 Moisture retention acceptance criteria

The AAMI ST-8 1994 sets the following acceptance criteria:
Fabric packs
'Moisture retained by the fabric test pack must cause no more than 3% increase in pre-sterilization test pack weight, and the pack must not exhibit wet spots'.
Wrapped instruments
'Upon completion of the recommended cycle, the wrapped instrument pack must have no wet spots on the outer wrappers. Moisture retained by the 100% cotton towel must cause no more than a 20% increase in pre-sterilization weight of the towel'.

Summary

- External droplets or visible moisture on the exterior pack, or on the tape, are unacceptable unless the wrap is completely impermeable to water.

Note: This should be inspected while unloading the sterilizer

- Water droplets on the interior of a wrap, or on the items within the pack, are unacceptable
- A pack is unacceptable if the pack is damp or wet when opened for use.
- A general guideline is that the pack be completely dry after cooling to room temperature (i.e., 21°C [70°F] and 50% relative humidity) for a minimum of one hour following unloading from the sterilizer.

8.5.4 Solving wet pack problems

If moisture is detected on the interior of the wrap, in the huck towel or on the item the causes can be:

- Insufficient drying time
- Chamber overloaded; size , density or weight of specific packs
- Excessively large hard goods items being sterilized
- No absorbent huck towel used

- Materials not being permitted to cool and equilibrate to room temperature
- Wet steam supply
- Defective vacuum drying system
- Air leak (perform leak rate test)

8.6 Sterility maintenance

Refer also to AAMI ST46

8.6.1 Cooling

All items removed from the sterilizer should remain on loading cart until adequately cooled.

- They should not be touched within cooling process
- A cooling time of 30-90 minutes is recommended
- During cooling the loading cart should be placed in a low-traffic area where there are no air-conditioning or other cold-air vents in close proximity

8.6.2 Inspection

As items are removed from loading cart, they should be visually inspected
Do not use:

- Any items with torn packaging
- Packaging that appears to be wet

8.6.3 Sterile storage

Sterile materials should be stored:

- at least 8-10 Inches above floor
- at least 18 inches below ceiling
- at least 2 inches from outside walls

Items should positioned so that packaging:

- is not crushed
- is not bent
- is not compressed
- can't become wet

Closed or covered cabinets are recommended for the storage of seldom-used supplies.

8.6.4 Expiration dating

Each item should be labeled with a control date for stock rotation and the following statement:
'Contents sterile unless package is open or damaged. Please check before using'.
If the product contains material that degrades over time, the product package should be labeled with a clearly identifiable expiration date that takes this degradation into account and/or that is based on the device manufacturer's instructions.

9 Operating device TOP5000

9.1 User administration

Each user is defined by a:

- user name (alphanumeric, max. 20 characters)
- user access level (numeric 1..4, for user rights see chapter 9.2)
- Password (alphanumeric, max.10 characters)

9.1.1 User's rights

Users with four different access levels can be defined on the TOP5000:

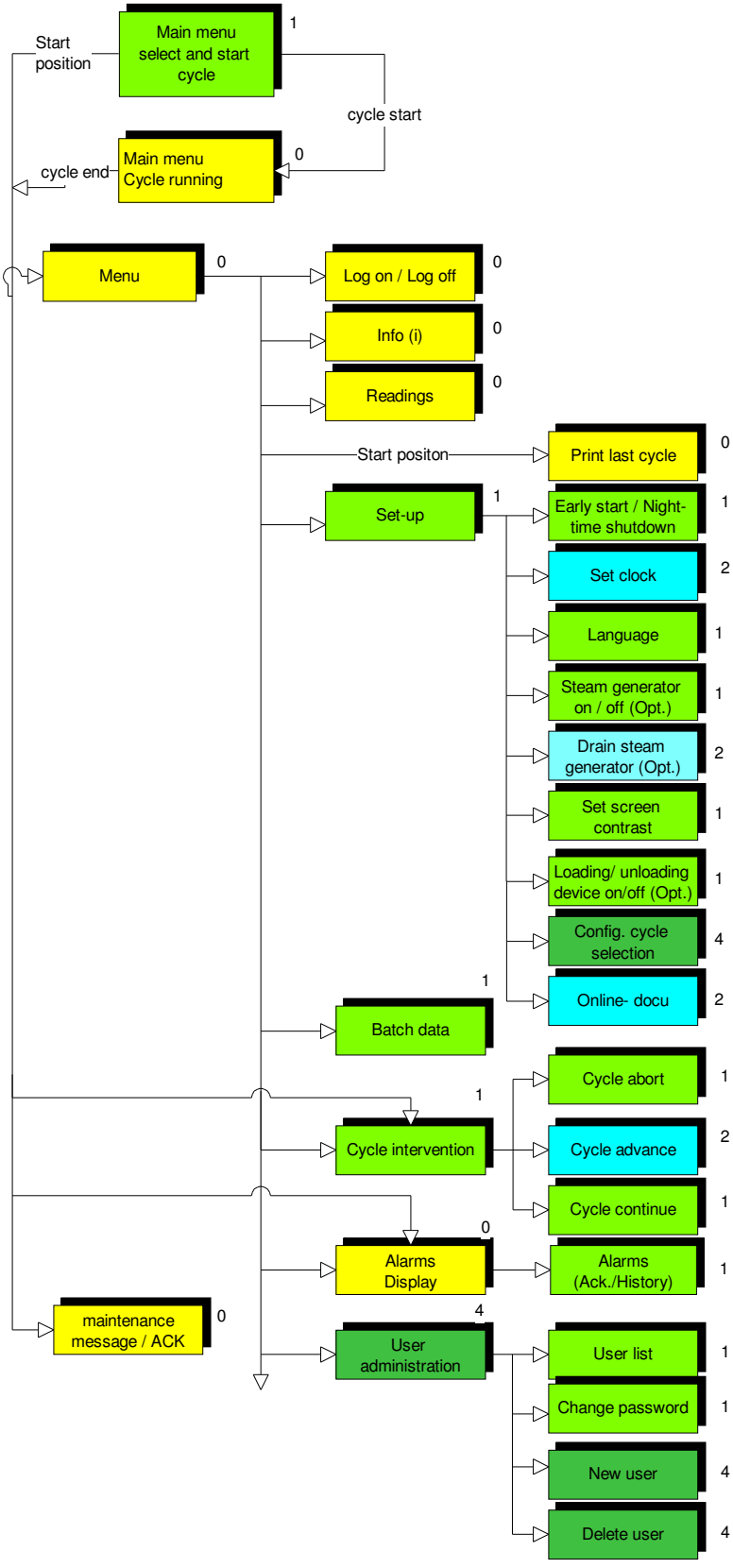
- Level 1: Operator
- Level 2: Group Leader
- Level 3: Maintenance personnel
- Level 4: Administrator

The Administrator only can define new users or delete users.

Additionally one user (level 5) is reserved for Belimed Service and one user (level 9) is reserved for the Belimed Administrator.

Important: In some cases, only buttons for which the operator has read or write access are displayed.

shows the TOP5000 menus with the corresponding user rights.


Start position
Main menu select and start cycle
1
cycle start
Main menu Cycle running
0
cycle end
Menu
0
Log on / Log off
0
Info (i)
0
Readings
0
Start positon
Print last cycle
0
Set-up
1
Early start / Night-time shutdown
1
Set clock
2
Language
1
Steam generator on / off (Opt.)
1
Drain steam generator (Opt.)
2
Set screen contrast
1
Loading/ unloading device on/off (Opt.)
1
Config. cycle selection
4
Online- docu
2
Batch data
1
Cycle intervention
1
Cycle abort
1
Cycle advance
2
Cycle continue
1
Alarms Display
0
Alarms (Ack./History)
1
maintenance message / ACK
0
User administration
4
User list
1
Change password
1
New user
4
Delete user
4

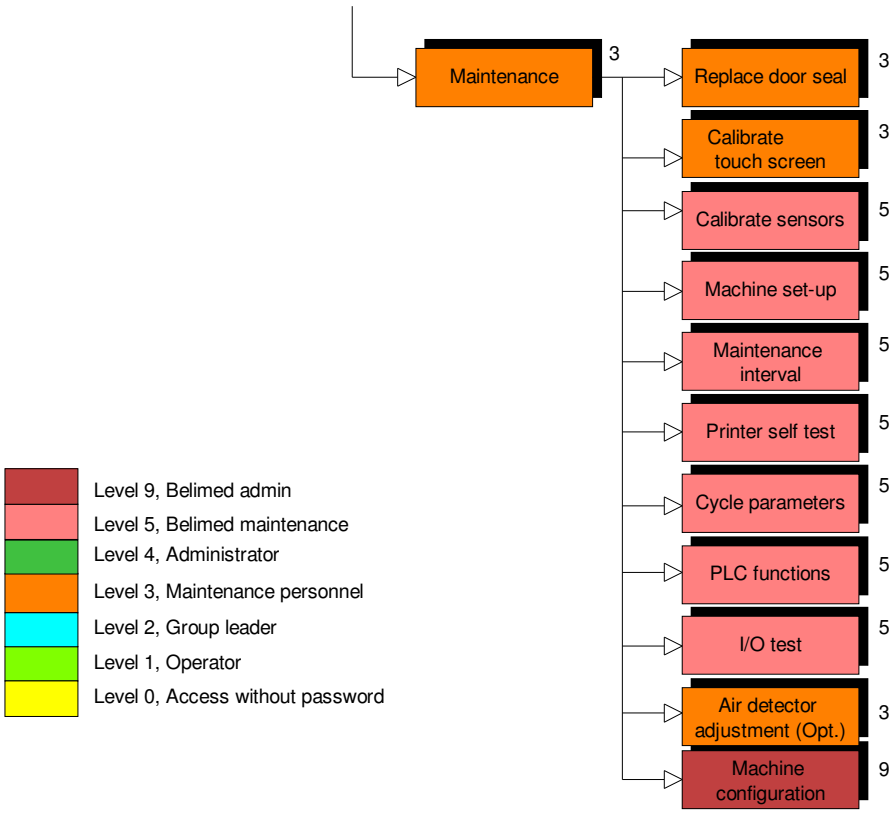


Table 9-1: user menus and rights

9.1.2 Direct login

In the case of visible buttons for which the user has no authorisation, the user is prompted directly to enter the Password. The user can log in with his or her Password and then receives access authorisation.

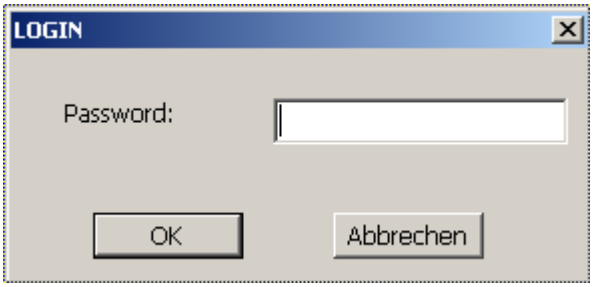


Figure 9-1: Password entry

9.1.3 Administrate user

The Administrator (Level 4) has permission to create new users, delete users or change Passwords. Press the **'Menu'** button. The Mask menu is then displayed (Figure 9-2).

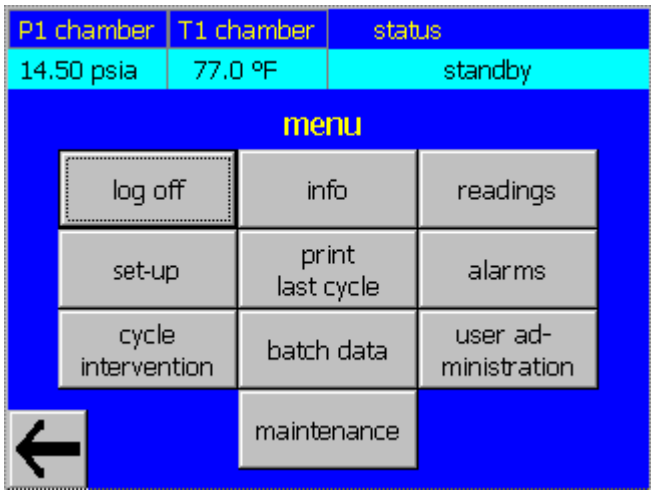


Figure 9-2: Menu display

Press the **'User Administration'** button (Figure 9-3). A list of all users with Password and Level is then displayed. Only users with Level equal to or lower than the user logged in are displayed.

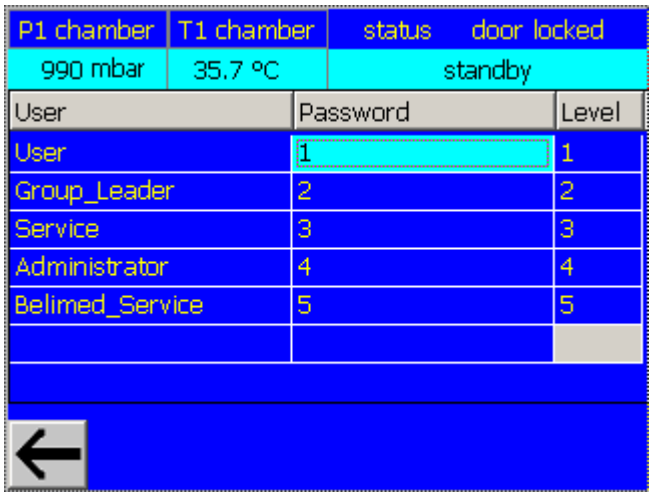


Figure 9-3: User administration display

Figure 9-3 shows the factory-default users with Password and Level.

9.1.3.1 Create New User

A new user can be defined by making entries in fields "User", "Password" and "Level". The user name may contain maximum 20 characters and the Password may contain maximum 10 characters. User names and Passwords may never be the same.

9.1.3.2 Delete User

Fields "User" and "Password" must be deleted in order to delete a user from the list. Button "BSP" can be used for this.

9.1.3.3 Change Password

The Password can be changed easily in field "Password".

9.2 Info

Each user can open the information display.

Press **'menu'** button. The menu functions are displayed (refer to Figure 9-4):

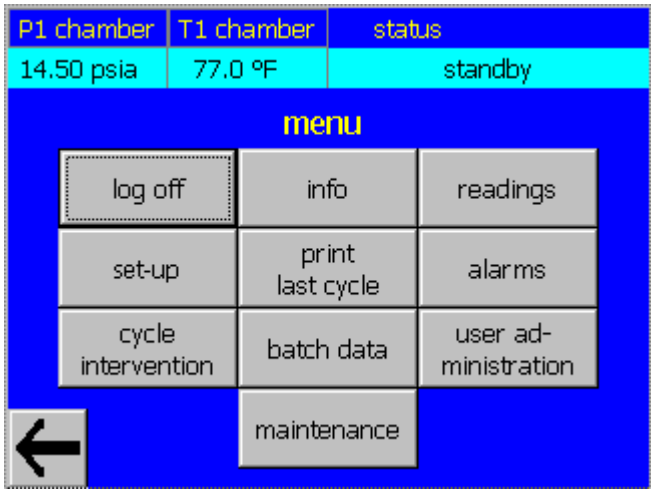


Figure 9-4: Menu display

Press **'info'** button

The display shows the following information (refer to Figure 9-5):

- actual time and date
- User name
- Time since cycle start
- Remaining time in the actual phase
- Date of last Leak Test and last Bowie Dick Test
- Cycle counter
- Status of doors and steam generator (if configured)
- Status of conveyor system TB (if configured)

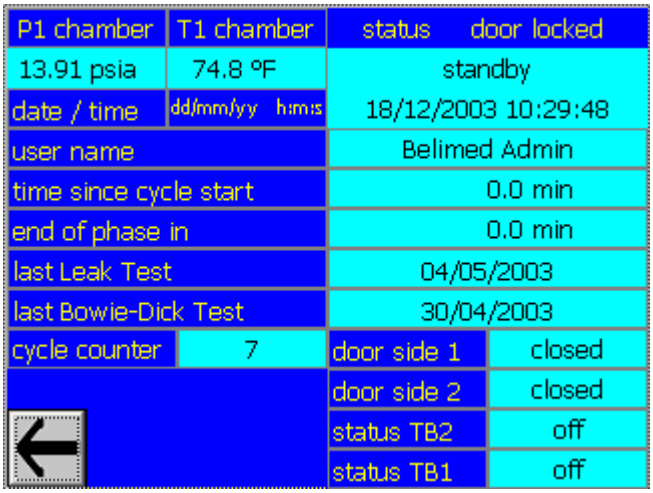


Figure 9-5: Info display

9.3 Readings

Each user can open the Readings display.

Press **'menu'** button. The menu functions are displayed (refer to Figure 9-6):

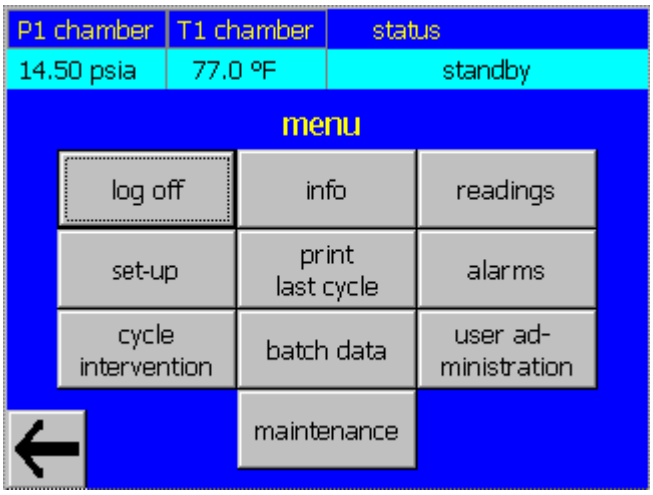


Figure 9-6: Menu display

Press **'readings'** button.

The display shows the actual readings of all temperature- and pressure sensors, used in the sterilizer (refer to Figure 9-7):.

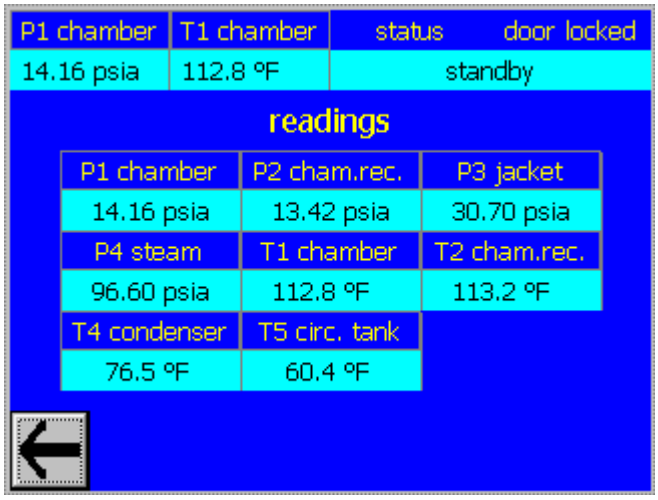


Figure 9-7: Readings display

9.4 Set-up

Press **'menu'** button. The menu functions are displayed (refer to Figure 9-8):

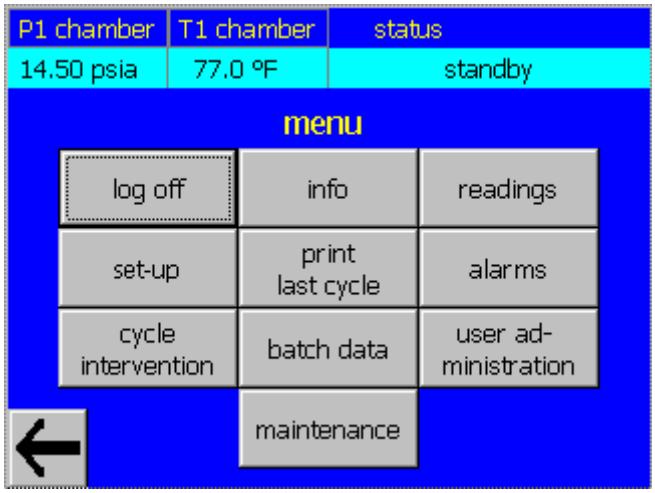


Figure 9-8: Menu display

Press **'set-up'** button.

The display shows the 'set-up' functions (refer to Figure 9-9):

- Early start and night-time shutdown (access level 1)
- Set clock (access level 2)
- Select Language (access level 1)
- Steam generator on/off (access level 1) / if connected
- Drain steam generator (access level 2) / option: internal steam generator
- Configure cycle selection (access level 2)
- Set screen contrast (access level 1)
- Activate loading (TB1) / unloading device (TB2) / (access level 1) / option
- Activate on-line documentation (access level 2)

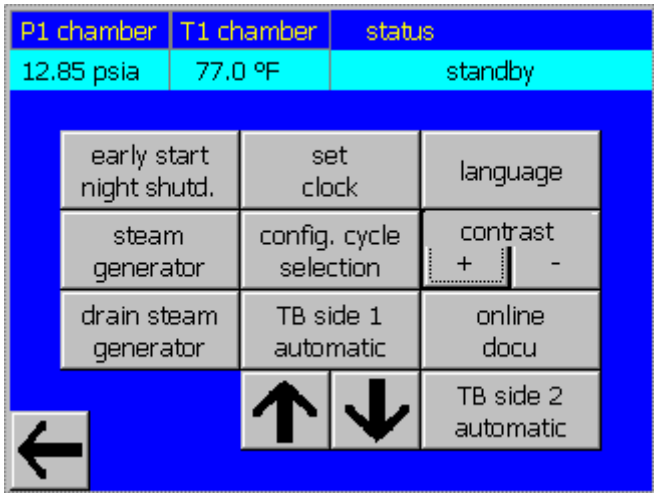


Figure 9-9: Set-up display

9.4.1 Early start / night-time shutdown

Press **'early start / night shutd**.' button. The display shows the input-mask (refer to Figure 9-10):

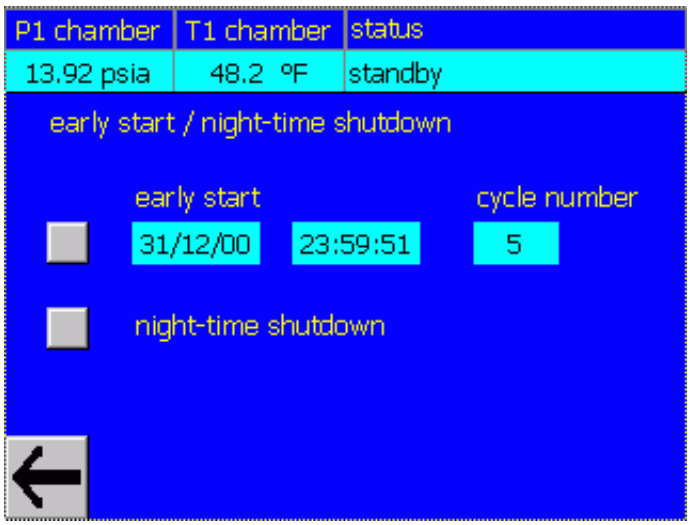


Figure 9-10: Early start / night-time shutdown display

9.4.1.1 Night-time shutdown

If you press **'night-time shutdown'** button, the sterilizer goes into a sleep mode at the end of the next cycle. All valves are closed, an optional connected steam generator is turned off.
To restart the sterilizer turn key switch off and on again.

9.4.1.2 Early start

Conditions for early start:
The Sterilizer must be in the initial position and the chamber doors must be closed.
If you want to start a cycle early in the morning (usually the warm-up and leak test cycle),
set **'early start'** date and time, enter **'cycle no.'** and activate **'early start'** button (left side).
The sterilizer goes into a sleep mode (the display is turned off). At the preset early start time the sterilizer goes into an active mode, the operating panel display is turned on and the pre-selected cycle starts.
If the sterilizer is in sleep mode (early start or night-time shutdown) and you want to operate, turn the key-switch off and on again. The early start and night-time shutdown are turned off.

9.4.2 Set clock

Usually twice a year (change of winter- to summertime and summer- to wintertime) the time has to be adjusted. Press **'Set clock'** button (refer to Figure 9-11).
Press the date/time button and enter the time and date in the format: dd/mm/yy hh:mm
Legend:

dd:	Day of the month (1..31)	mm:	Month (1..12)	yy:	Year (00..99)
hh:	hour 1..12	mm:	minute (0..59)		

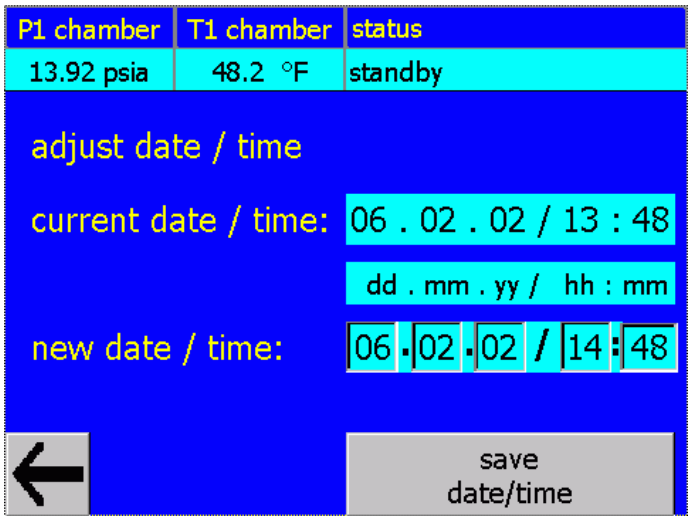


Figure 9-11: Set clock display

9.4.3 Language and units

Each operator (access level 1) can select the language he wants to have displayed.
Press **'language'** button in the set-up menu and then press the operation language select button **'⩛'** (refer to Figure 9-12). All predefined languages are displayed. Press the language you need in the display field. The display changes to the selected language.

The administrator (access level 4) has the right to change the units:
Temperature:

- Degree Celsius (°C
- Degree Fahrenheit (°F)

Press the temp. unit select button **'⩛'** and choose the temperature unit.
Pressure:

- Millibar absolute (mbara)
- Bar gauge (bar)
- Kilopascal absolute (kPa)
- Pounds/square inch absolute (psia)

- Pounds/square inch gauge for pressure (psig) and inches of Mercury for vacuum (in.Hg)

Press the pressure unit select button '⮟' and choose the pressure unit.

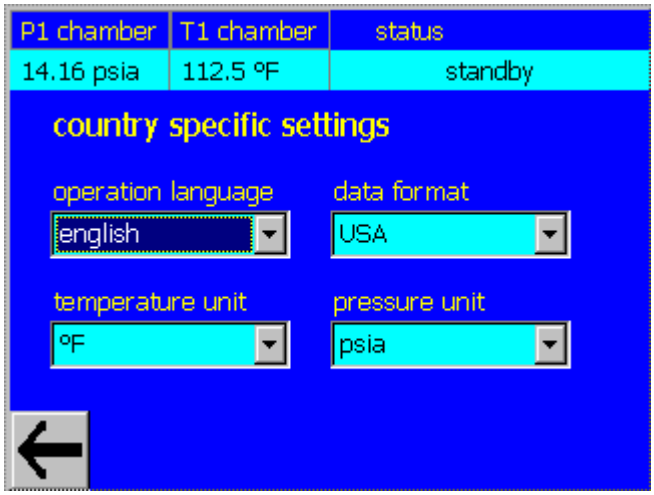


Figure 9-12: Language and units display

9.4.4 Steam generator

If the steam generator can be activated form the sterilizer (optional) you can turn on and off the steam generator by pressing the **'steam generator'** button (refer to Figure 9-9).

9.4.5 Drain steam generator

If an internal steam generator (option) is installed, it can be emptied by pressing the **'drain steam generator'** button (refer to Figure 9-9).

9.4.6 Configure cycle selection

The administrator (level 4) can define:
The active cycles (select all Cycle numbers which should be selectable by a user.
Cycle start only after entering a password by the operator (set: yes)
Automatic logon with user name 'System' using level 1 (set: yes).

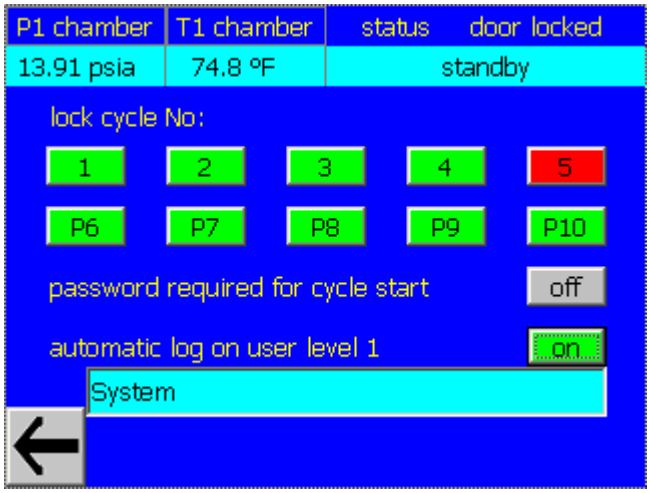


Figure 9-13: Configure cycle selection

To activate a cycle or a function or press corresponding button (refer to Figure 9-13).

9.4.7 Display contrast

All logged on users can adjust the display contrast (Refer to Figure 9-14).
To increase the contrast of the display, press **'contrast +'** button.
To decrease the contrast of the display, press **'contrast -'** button.

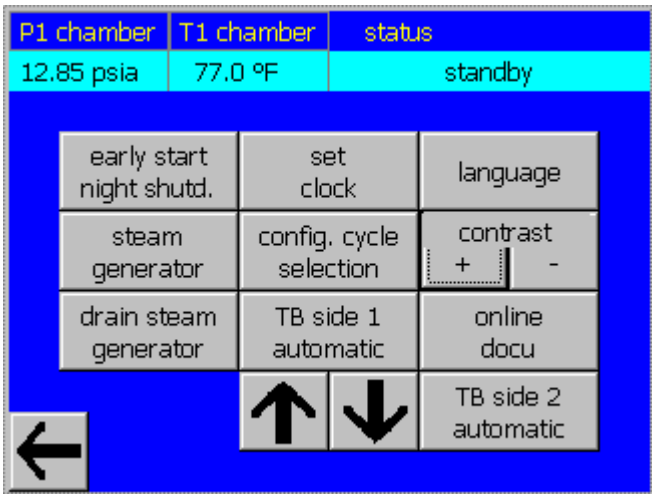


Figure 9-14: Set-up display

9.4.8 Online docu

If there is an external PC- based documentation system 8535 installed, the built-in printer can be turned off (refer to Figure 9-14). In case of a breakdown of the system 8535, the built in printer can be activated by the group leader (Active = green background).

9.4.9 Automatic loading and unloading device

The optional external loading (TB1) or unloading device (TB2) can be activated (refer to Figure 9-14).
With the buttons **'↑'** and **'↓'** the loading device can be moved manually.

9.5 Print last cycle

The cycle documentation is printed at the end of the cycle.
It is possible to print a copy of the cycle documentation until the next cycle is started.
Press **'menu'** button. The menu functions are displayed (refer to Figure 9-14):
Press **'print last cycle'** button and a cycle documentation copy is printed.

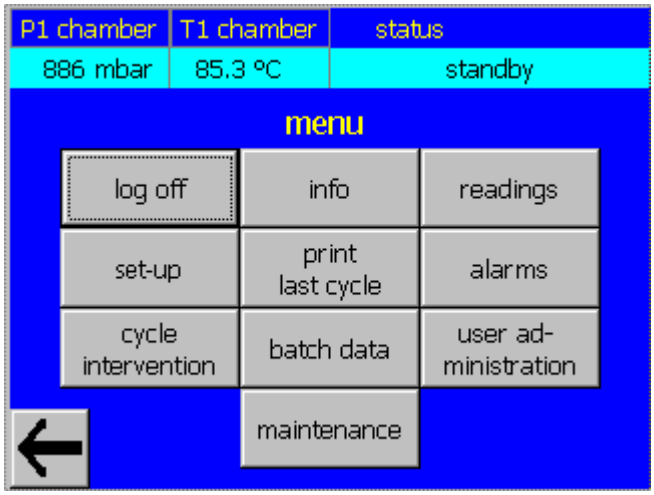


Figure 9-15: Menu print last cycle display

9.6 Alarm messages

All important process parameters are continuously monitored. If there is a deviation, an alarm button is displayed in the main mask.(refer to Figure 9-16).

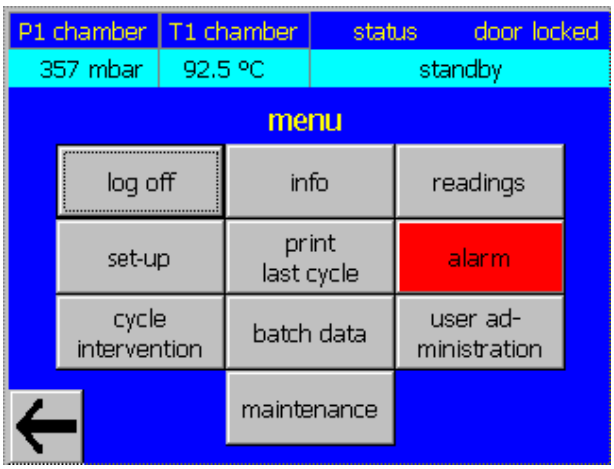


Figure 9-16: Out-of-cycle display with active alarm

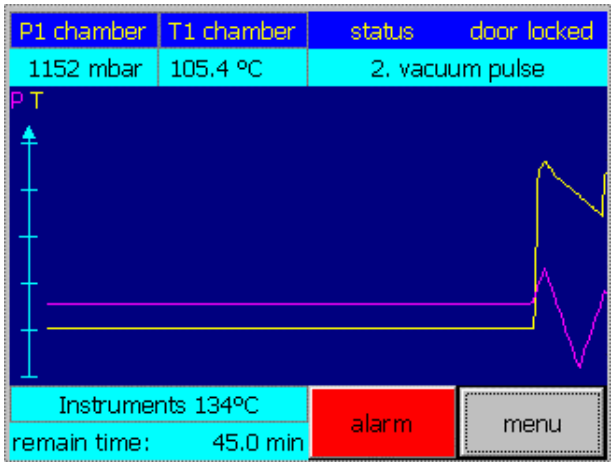


Figure 9-17: In-cycle display with active alarm

Press **'alarm'** button. All active alarms are displayed (refer to Figure 9-18).

The alarm mask has 3 buttons:

- Help
- ACK
- history

The alarm is displayed with time/date and the alarm message.

Each alarm must be acknowledged by an operator (access level 1)

- To acknowledge an alarm press the **'ACK'** button.
- To display the history of the last 250 alarms press **'history'** button
- To get more information about the active alarm press **'Help'** button.

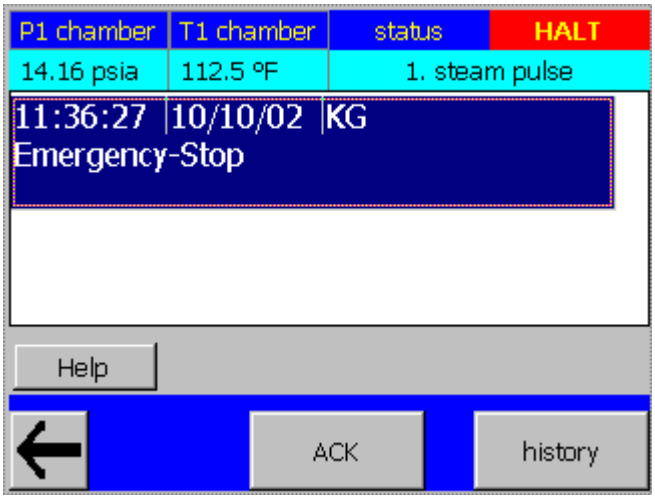


Figure 9-18: Alarm display

The operator should follow the Help instructions on the alarm Display. If these instructions fail to clear the alarm, consult your department supervisor or a trained service technician before using the sterilizer further.

9.6.1 Critical alarms

Only the critical alarms are printed out in the batch report. If a critical alarm has occurred during a cycle, the door can only be released on the operating end. A message 'cycle failed' is displayed on the operating panel and printed on the batch documentation. The start of a new cycle is not possible if a critical alarm is pending.

9.6.2 Alarm list

Table 9-2 shows the list of alarms and the possible causes.

No.	1st line: Alarm message text 2nd line: Cause	Critical alarm
1	Emergency-Stop	X
	Emergency-Stop button on the sterilizer has been pressed.	X
2	Vacuum pump	X
	Motor protection switch vacuum pump has tripped.	
3	Door motor	
	Motor protection switch of the door motors has tripped.	
4	Cycle aborted	X
	Function 'cycle abort' has been activated by an operator or by the system itself.	
5	Power failure	X
	Loss of electric power	
6	Manual advance	X
	The 'manual advance' button has been pressed by on operator	
7	Fault of PLC battery	
	PLC battery empty (do not switch-off electric power switch; change buffer battery)	
8	On-Off Key switch off	X
	The key switch was turned off during cycle running	
9	Too long in step	X
	The monitoring time of a cycle phase has been exceeded.	
11	Sensor T1 failed	X
	Temperature sensor T1 signal is out of range (0..150°C)	

No.	1st line: Alarm message text 2nd line: Cause	Critical alarm
12	Sensor T2 failed	X
	Temperature sensor T2 signal is out of range (0..150°C)	
14	Sensor T4 failed	X
	Temperature sensor T4 (condenser) signal is out of range (0..150°C)	
15	Sensor T5 failed	X
	Temperature sensor T5 (circulation tank) signal is out of range (0..150°C)	
18	Sensor P1 failed	X
	Pressure sensor P1 signal is out of range (4..20mA)	
19	Sensor P2 failed	X
	Pressure sensor P2 signal is out of range (4..20mA)	
20	Sensor P3 failed	X
	Pressure sensor P3 signal is out of range (4..20mA)	
21	Sensor P4 failed	
	Pressure sensor P4 signal is out of range (4..20mA)	
22	Undertemperature T1	X
	Chamber temperature T1 is below alarm set-point during sterilization phase	
25	Overtemperature T1	X
	Chamber temperature T1 is above max. alarm set-point during sterilization phase	
27	Overtemperature T5	X
	Temperature in circulation tank is >50°C	
28	Divergence T1-T2	X
	During sterilization phase the difference T1-T2 is >±1°C	
30	Max. chamber pressure	X
	Maximum chamber pressure exceeded, steam to chamber valve not closed / leaky	
31	Max. jacket pressure	X
	Maximum jacket pressure exceeded, steam to jacket valve not closed / leaky	
32	Low jacket pressure	X
	Jacket set pressure not reached within preset time, steam to jacket valve not open or low steam supply pressure	
33	Steam pressure low	
	Steam supply pressure is below set-point	

No.	1st line: Alarm message text 2nd line: Cause	Critical alarm
34	Correlation low temp.	X
	Temperature T1 is lower than the saturated steam temperature calculated from P1	
35	Correlation high temp.	X
	Temperature T1 is higher than the saturated steam temperature calculated from P1	
36	Leak rate test failed	X
	The chamber is leak or wet	
37	Divergence P1-P2	X
	During sterilization phase the difference P1-P2 is > ±100mbar	
38	Door 1 time overrun	
	Door on the operating end hasn't reached the end position within 20 seconds	
39	Door 2 time overrun	
	Door on the non operating end hasn't reached the end position within 20 seconds	
40	Door 1 safety-switch	X
	Safety limit switch door closed on operating end is actuated during a cycle	
41	Door 2 safety-switch	X
	Safety limit switch door closed on non operating end is actuated during a cycle	
42	Door 1 not closed	X
	Limit switch door closed on operating end is not actuated during a cycle	
43	Door 2 not closed	X
	Limit switch door closed on non operating end is not actuated during a cycle	
44	Safety-bar 1	
	Safety-bar on operating end was actuated during door closing	
45	Safety-bar 2	
	Safety-bar on non operating end was actuated during door closing	
46	Limit switches 1	
	The two limit switches on operating end door didn't change the position during door opening within 0.5 seconds	
47	Limit switches 2	
	The two limit switches on non operating end door didn't change the position during door opening within 0.5 seconds	
48	Door not unlocked	
	Door seal didn't unlock during door- unlock step	

No.	1st line: Alarm message text 2nd line: Cause	Critical alarm
49	Door not locked	X
	Minimum door seal pressure not reached	
50	Ext. steam generator	
	Alarm signal from external steam generator	
58	Atmospheric pressure monitoring	
	Atmospheric pressure switch difference to sensor P1	
59	Deviation from time base	X
	The real time clock deviates from the PLC time-base	
61	Overtemperature T4	X
	Temperature in condenser is >80°C -> lack of cooling water	
62	Lack of compressed air	X
	Compressed air pressure is <4 bar g	
65	Time overrun unloading system	
	Unloading system hasn't reached the end position within 20 seconds	
66	Coupling extension unloading system	
	The extension of the unloading system isn't coupled or uncoupled correct	
76	Connection to printer	
	The PLC doesn't receive telegram form printer interface	
78	No connection to system 8535	
	The PLC doesn't receive telegrams form documentation system 8535	

Table 9-2: Alarm list

9.7 Cycle intervention

The cycle intervention touch screen button is used to

- Abort a cycle before it is finished normally (by operator, access level 1)
- Advance the cycle into the next phase (for maintenance and qualification, access level 2) or
- Continue an interrupted cycle (by emergency stop or motor starter failure, access level 1)

Press **'menu'** button. The menu functions are displayed (refer to Figure 9-19):

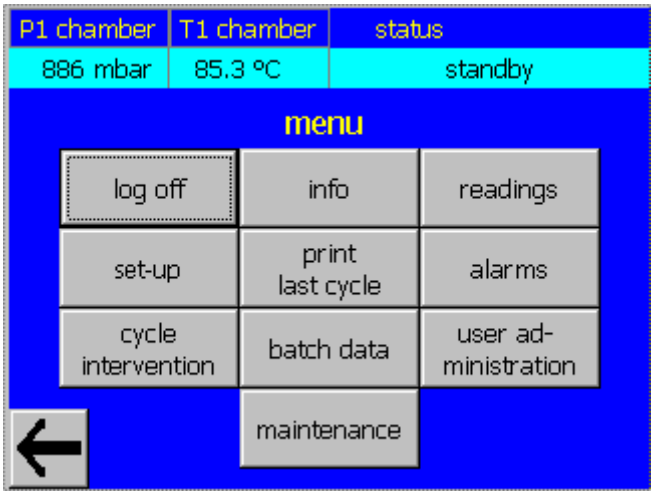


Figure 9-19: Menu display

Press **'cycle intervention'** button (refer to Figure 9-20).

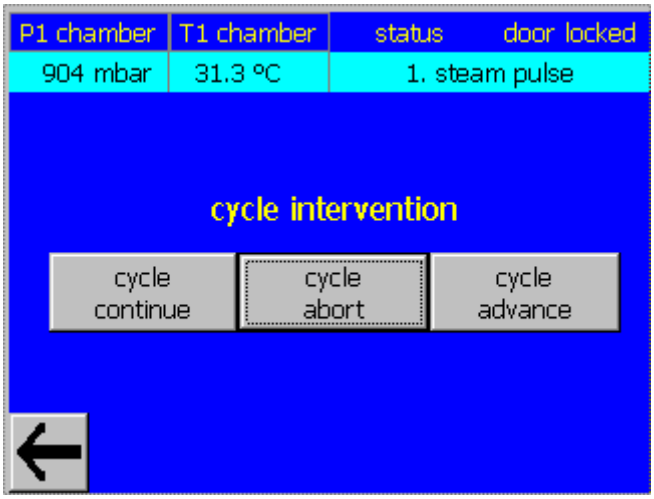


Figure 9-20: Cycle intervention display

9.7.1 Cycle advance

Press **'cycle advance'** button to advance the cycle into the next phase. An alarm message 'manual advance' is generated.

9.7.2 Cycle abort

Press **'cycle abort'** button. This causes the sterilizer-chamber to depressurise (if pressurised), evacuate the chamber (to dry) and to air break. The door opening deactivates, the control prompts the operator to acknowledge the 'cycle aborted' message and to Log on.

9.7.3 Cycle continue

Press **'cycle continue'** to continue an interrupted cycle. This function only works if the alarm has already gone.

9.8 Batch data

9.8.1 Manual data entry

Batch data entry must be activated in the set-up menu.
Press **'menu'** button and then **'batch data'** button (refer to Figure 9-19):
The following batch data can be entered (refer to Figure 9-21):
Load details (alphanumeric 12 characters).
batch No. (12 digits).
Batch data is printed on the cycle documentation printer.

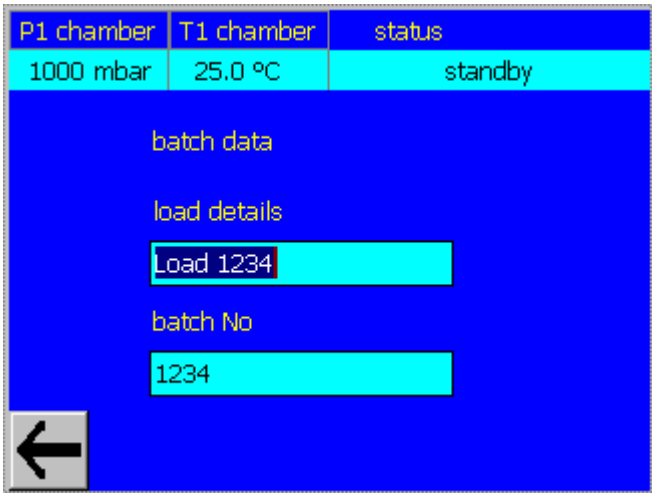


Figure 9-21: Manual batch data entry

9.8.2 Batch data entry with Documentation system 8535-BC

An optional PC- based cycle documentation system 8535-BC can be supplied for electronic batch data acquisition.
Before loading the sterilizer, the load ID- numbers are to be read with a barcode scanner.
A maximum of 18 items can be entered. The ID's are displayed on the display (refer to Figure 9-22).

The bar code type EAN13 is used, whereby 12 characters are displayed. The 13th character is the check sum an is not displayed. If necessary, the last or all entries can be deleted. At cycle start the data is transferred to the system 8535 and the table on the sterilizer is deleted afterwards.

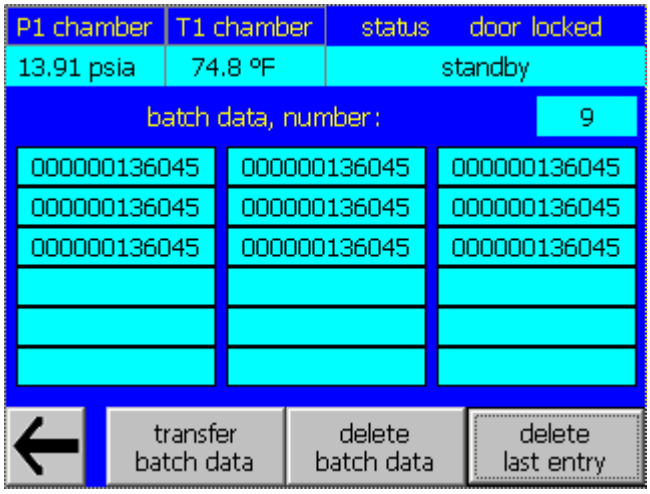


Figure 9-22: Scanner based batch data entry

At cycle start the data is transferred to the system 8535 and the table on the sterilizer is deleted afterwards.
The data can also be transferred several times to system 8535 with the **"transfer batch data"** button even before program start

9.8.3 Batch data input via scanner with ICS 8665 Documentation System

The data is **not** transferred automatically to system 8565 on program start. The data must be transferred to system 8565 before program start with the **"transfer batch data"** button. The program is then selected automatically by system 8565. This is indicated in a dialog box. After this, no other program may be selected.

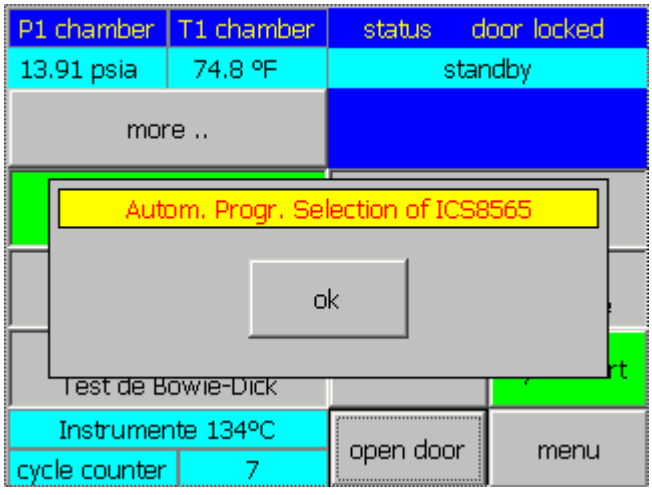


Figure 9-23: Automatic program selection by ICS 8565

9.9 Maintenance messages

After a predefined number of cycles a maintenance message is displayed in the Out-of-cycle display (refer to Figure 9-24).

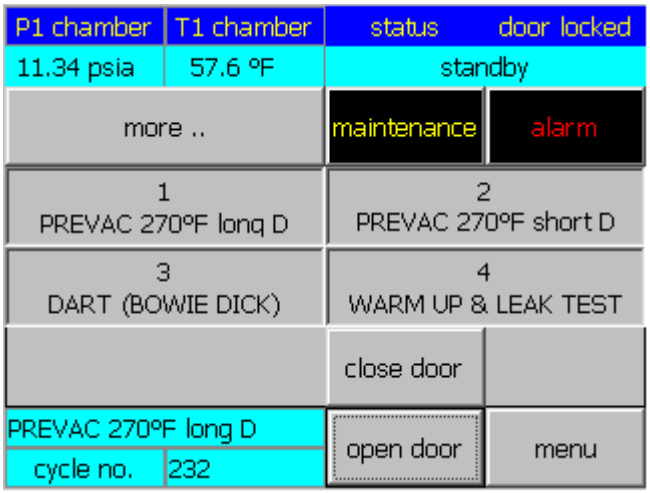


Figure 9-24: Out-of-cycle display with maintenance message.

The maintenance message can be acknowledged by maintenance personnel (access level 3).
Press **'maintenance'** button in the out-of cycle mask. If the maintenance has been done press **'ACK'** button in the maintenance mask (refer to Figure 9-25).

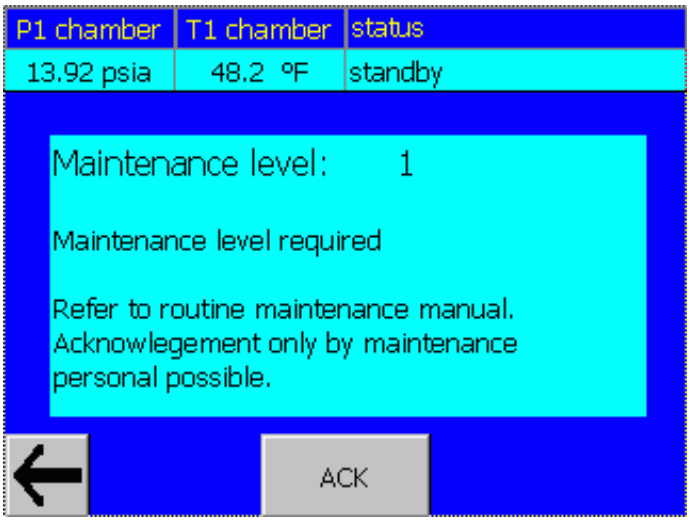


Figure 9-25: Maintenance message display.

9.10 Maintenance functions

Press **'menu'** button. The menu functions are displayed (refer to Figure 9-26):

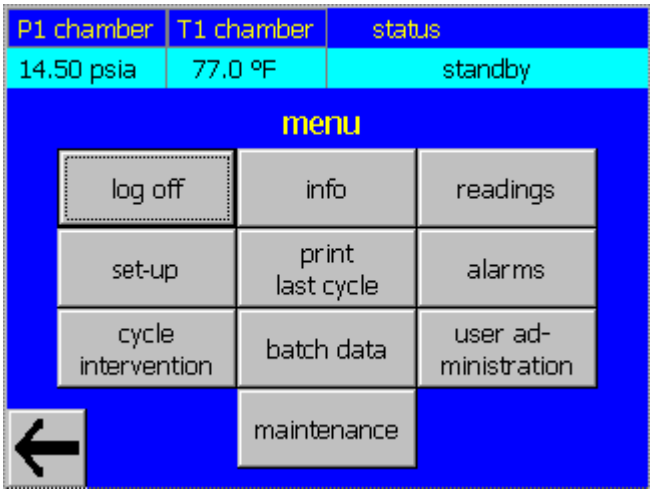


Figure 9-26: Menu display

Press **'maintenance'** button. The following functions can be selected (refer to Figure 9-27):

- Replace door seal at operating end (access level 3)
- Calibrate touch screen (access level 3)
- Calibrate sensors (access level 5)
- Machine set-up (access level 5)
- Define maintenance intervals (access level 5)
- Printer self test (access level 5)
- Cycle parameters (access level 5)
- PLC functions (access level 5)
- PLC Input-Output Test (access level 5)
- Air Detector (option, access level 5)

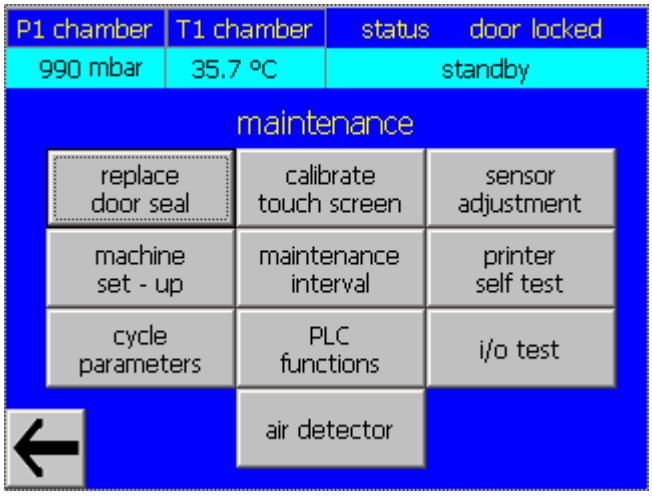


Figure 9-27: Maintenance menu display

9.10.1 Replace door seal

The maintenance personnel can replace the door seal. on the operating end by pressing **'replace door seal'** button while the chamber door is open (refer to Figure 9-28).
Press 'blow out door seal' button to remove door seal.
Press 'pull back door seal' button and the vacuum pump sucks a vacuum behind the door seal.

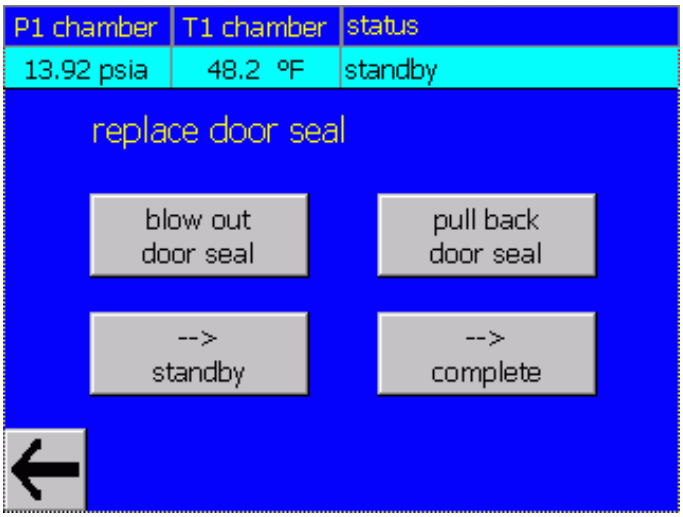


Figure 9-28: Replace door seal display

For replacing the door seal refer to 'maintenance manual'.

9.10.2 Calibrate touch screen

If the touch screen adjustment is inaccurate, adjust the touch screen. Press **'calibrate touch screen'** button and follow the instructions (refer to Figure 9-27).

9.10.3 Sensor adjustment

For sensor adjustment refer 'maintenance manual'

9.10.4 Machine set-up

The Belimed maintenance personnel must set the machine set-up before running the first cycle.

The first display (refer to Figure 9-29) must be adjusted:

- Enter hospital name into the **'hospital name'** field .
- Enter department name into the **'department'** field.
- Enter the machine number (serial number) into the **'machine No.'** field.
- Enter the ambient pressure (in mbar absolute) into the **'norm ambient pressure'** field.

The ambient (atmospheric) pressure depends on the altitude of the sterilizer. Enter the following values:

Altitude (m)	ambient pressure (mbar)	Altitude (m)	ambient pressure (mbar)
0	1013	1200	877
200	989	1400	856
400	966	1600	835
600	943	1800	815
800	921	2000	795
1000	898	2200	775

Table 9-3: Ambient pressure for altitudes up to 2200m.

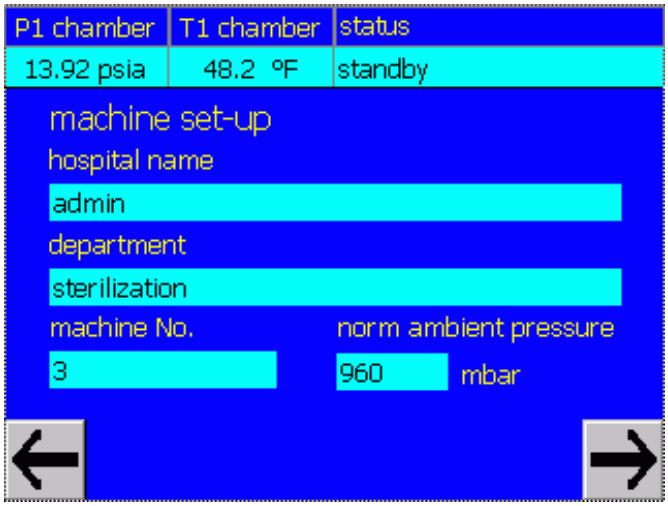


Figure 9-29: Machine set-up display 1

The second display (refer to Figure 9-30) functions are:

- The low steam pressure alarm delay time can be set (default: 300s)
- Pressure difference between set steam pressure and alarm pressure (default: 500mbar)
- Steam set pressure in out-of cycle position (default: 3900mbar)
- Steam set pressure in- cycle (default: 700mbar above chamber pressure during sterilize phase)

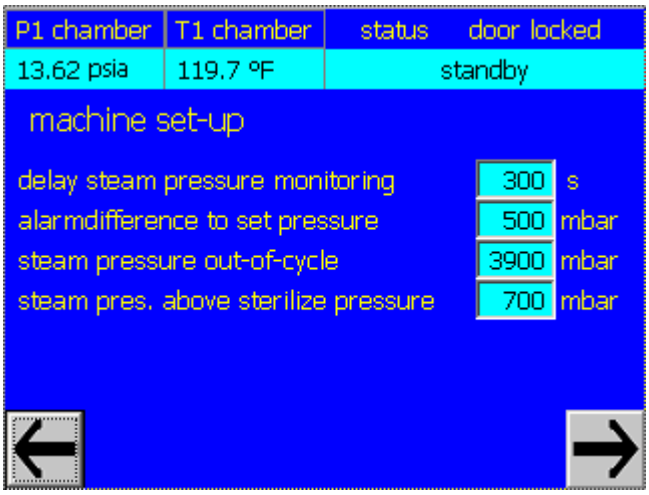


Figure 9-30: Machine set-up display 2

The third display (refer to Figure 9-31) functions are:

- The compensation time before the sterilization is started can be set (default: 4 seconds).
- The control temperature of the circulation tank (default: 40/40°C*)
- the control temperature of the circulation tank during vacuum steps (prevac, dry, default:21/30°C*)
- The control temperature of the condenser if the chamber pressure is >500mbar (default: 50/30°C*)
- The control temperature of the condenser if the chamber pressure is <500mbar (default: 35/15°C*)

*) without / with cooling water loop.

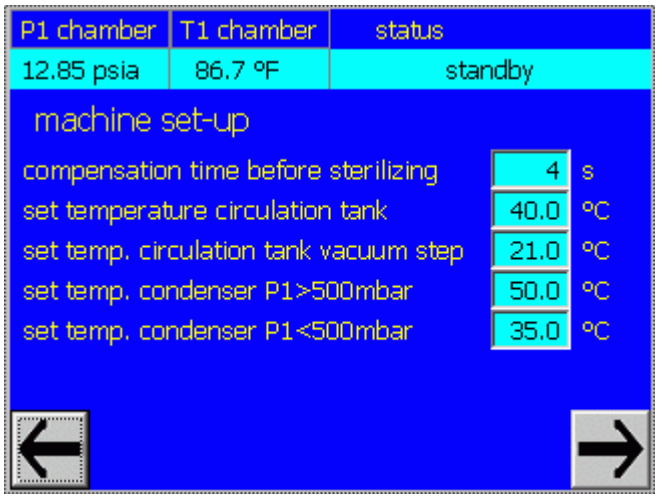


Figure 9-31: Machine set-up display 3

The fourth display (refer to Figure 9-32) functions are:

- The system can request batch data before a cycle is started
- A buzzer can be activated at an incoming alarm (until alarm is acknowledged)
- A buzzer can be activated at cycle end (until a chamber door is opened
- Display mode: The remain process time or the chamber temperature on side 2 will be displayed.
- The door opening / closing function can be set to an inching mode (door moves only as long as the door open or door close button is pressed)
  1o: open door on operating end
  1c: close door on operating end
  2o: open door on non operating end
  2c: close door on non operating end

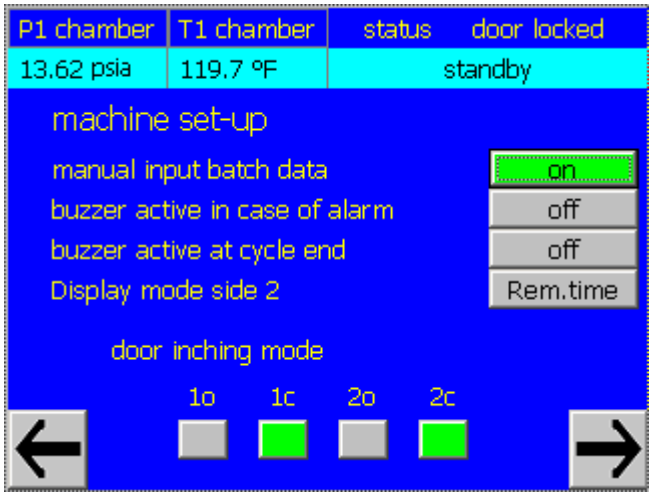


Figure 9-32: Machine set-up display 4

The fifth display (refer to Figure 9-33) functions are (only with internal steam generator):

- Blow-down interval (default 1800s)
- Blow down pulse (default 2s)
- degassing time (default 2 sec); depending on water quality.
- to reduce peak current, the second heater can be delayed.
- during heat-up phase (default =2 sec)
- during standby phase (default=20 sec)

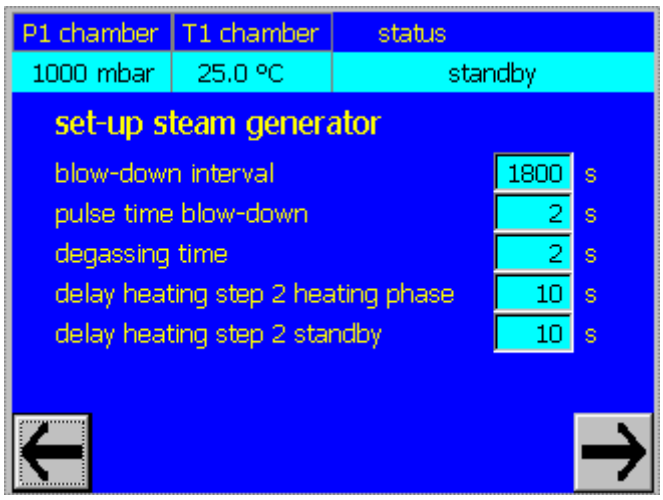


Figure 9-33: Machine set-up display 5

The sixth display (refer to Figure 9-34) functions are:

- Start point of the reduced steam pressure increase rate below sterilize pressure (default: 200mbar)
- Pressure increase rate before sterilization (reduced ramp, default: 200mbar/min) to prevent an over-temperature on the top of the chamber
- Open time steam valve gravitation: the steam inlet and, thus, also the steam outlet can be reduced by reducing the open time in the range between 10 and 100 %.
- Maximum chamber pressure during graviation: the chamber steam valve is closed when the maximum chamber pressure is exceeded.
- Print interval and data store during sterilize phase on built-in printer (default: 60 s)
- The software version of the panel is displayed

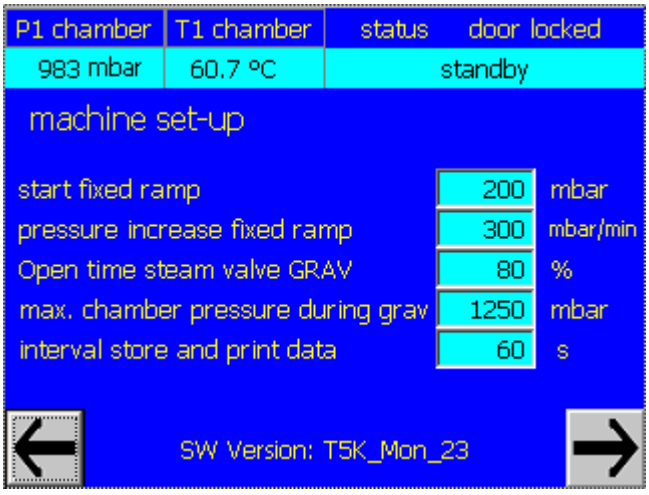


Figure 9-34: Machine set-up display 6

The seventh display (refer to Figure 9-35) functions are:

- Define the external documentation system (none / 8535 / 8535 BC/8565)
  (BC: Barcode reader for recording the load)
- If an external documentation system type 8535 is connected via serial interface (RS485), enter the sterilizer system address communication port address, range 3..20)

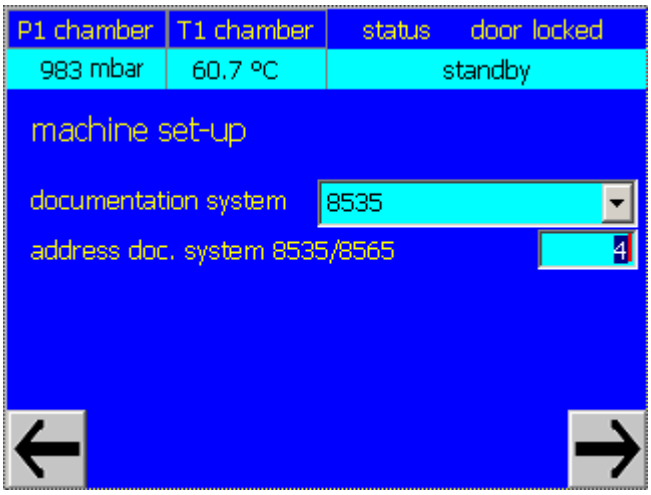


Figure 9-35: Machine set-up ICS 8535

- IP address, documentation system 8535, with Ethernet connection: if the sterilizer is connected to an 8535 documentation system, each unit must have a TCP/IP address. Click on the "Set IP address" button to accept this address after it has been set.

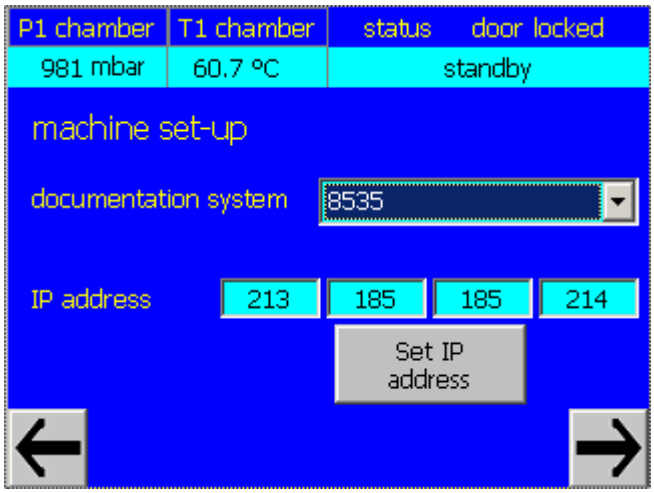


Figure 9-36: Machine set-up ICS 8535 TCP/IP

9.10.5 Printer self-test

The printer system-test forces a printout (refer to Figure 9-37). Thereby the following are tested:

- Serial communication between PLC and Printer interface
- Serial communication between Printer interface and printer
- Printer interface
- Accuracy of Sensor inputs on printer interface (T2, P2), if a reference RTD (T2=134°C) and a reference input current (P2= 12mA) are connected to the sensor inputs.
- Printer function

A record is printed out with machine type and no., date, time, set values , actual values, allowed tolerance and result.
Additionally to the system- test, a printout of the alarm texts and the cycle phase texts can be forced.

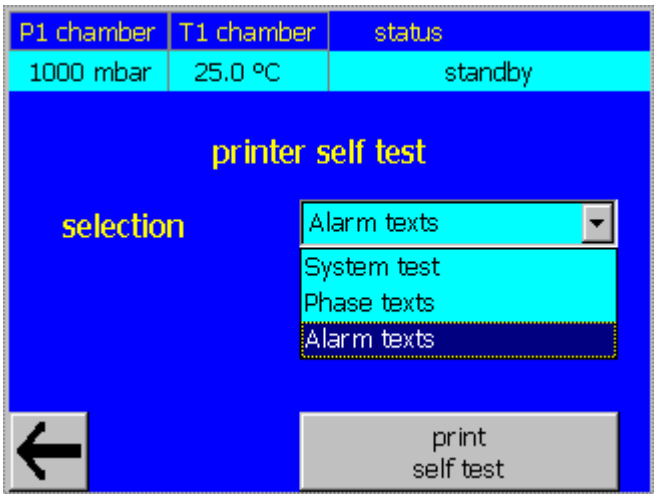


Figure 9-37: Printer self test

9.10.6 Modify Cycle Parameters and copy program

The Belimed maintenance personnel can modify the following cycle parameters (refer to Figure 9-38):

- Cycle name
- Sterilize time
- dry time

IMPORTANT:

The cycles listed in Table 6-1 / Table 7-1 have been validated using the techniques documented in AAMI ST-8 and ST-37. If different cycle parameters (sterilize time or dry time) are required, it is the responsibility of the health care facility to validate the cycle. Reference appropriate AAMI guidelines for validating sterilization cycles to assure the proper Sterility Assurance Level (SAL) as well as moisture retention acceptance criteria.

After modifying parameters press **'save parameters'** button. A new version is generated on the basis of the date if the parameters are changed.

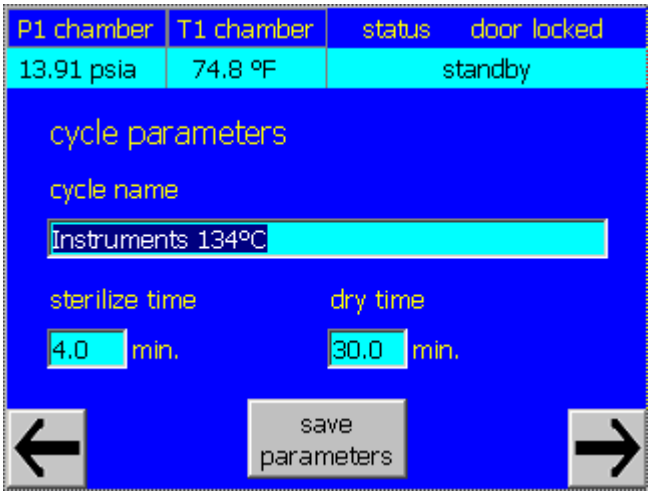


Figure 9-38: Modify cycle parameters display 1

All parameters can be displayed and modified in a further mask.

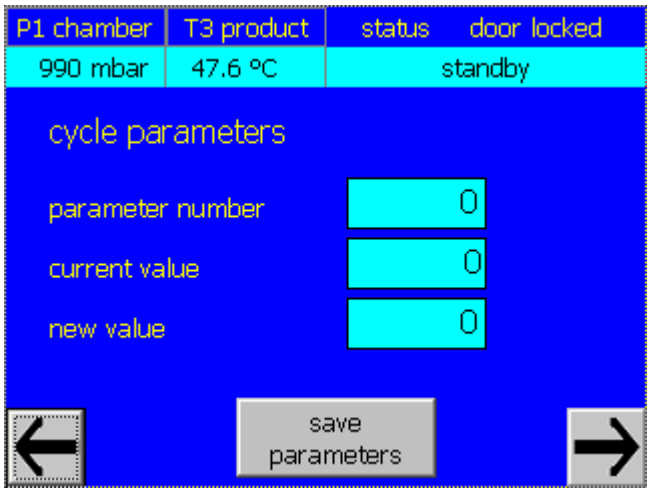


Figure 9-39: Modify cycle parameters display 2

Procedure for displaying or changing program parameters:

1. Enter the parameter number in the **"parameter number"** field. Belimed Service or the technician will be able to provide you with information on the corresponding number.
2. The current parameter is displayed without unit in the **"current value"** field
3. In the case of modification: enter the new value in the **"new value"** field.
4. In the case of modification: press the **'save parameters'** button. If the parameters are changed, a new version is generated on the basis of the date.
5. The new value is displayed immediately in the **"current value"** field.

None of the parameter values have a unit. This means:

- Temperatures are displayed in tenths of 1 °C
- Pressure is displayed in mbar absolute
  Times are displayed in tenths of a minute.

In a third screen a complete program can be copied under a new number

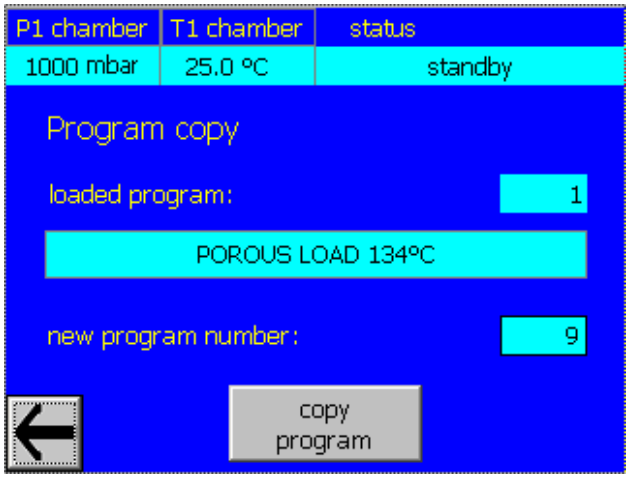


Figure 9-40: Copy program display

Guidance to copy a program:

1. Select the program to be copied. (See chapter.6.4.2)
2. Enter the number of the new program in field **'new program number'**

Warning: Any existing program under that number will be overwritten !

3. Press **'copy program'** button to copy the program.

To modify the program name and parameters, the new program needs to be selected.

9.10.7 PLC functions

The PLC functions allow the Belimed maintenance personnel to read any data from the PLC.

Warning:
Write entries are allowed only to Belimed maintenance personnel, who are authorised by the sterilizer manufacturer. The functions, and addresses must be announced by the manufacturer before.

The Belimed maintenance personnel has access to the PLC data memory (refer to Figure 9-41).

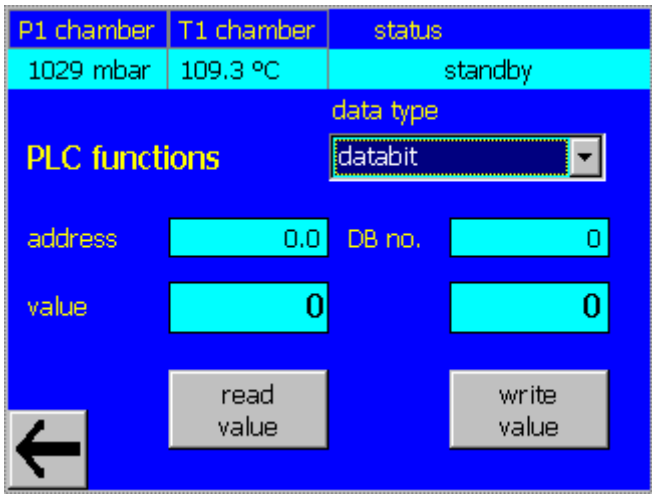


Figure 9-41: PLC functions

Reading a value from PLC:

- Select the data type
- Enter the PLC memory address and DB- No.
- Push button 'read value'

Change a value in the PLC:

- Read the value, you want to change as described above
- enter the new value in the field 'value'
- Press button 'write value'

The new value is displayed on the left side.

9.10.8 I/O- Test

The Belimed maintenance personnel can read the digital PLC inputs for diagnostics and wiring tests. He also can temporary set an digital output (refer to Figure 9-42).
Leaving the Mask resets the (manual set) outputs
Reading a digital input from PLC:

- Enter the Input byte address in the field 'input byte'

Values with 24V are displayed 'High' with green background

Writing a digital output:

- Enter the output byte address in the field 'output byte'
- Select the desired bit in the lower row. The button changes to 'high' with green background
- Push the 'write outputs' button. The corresponding output is set.

Warning:
Digital outputs are set without any conditions (not limit switches are checked). The outputs stay set until a reset command is set or the mask is closed. Only the emergency stop button stays in action.

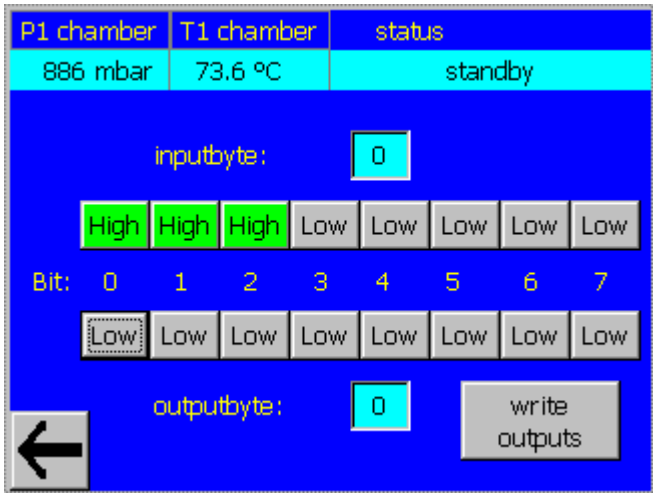


Figure 9-42: I-O Test

9.10.9 Air Detector Adjustment (optional)

The following settings can be made for the Air Detector option.

Air Detector inactive:

Monitoring of the Air Detector can be deactivated by pressing this button for a batch. The documentation is created with note "non-sterile". This function is reset automatically with the next batch.

Air Detector Function Test:

The function test can be activated by pressing this button for a batch. A needle valve is opened in order to create a leak in the next batch during pre-treatment. The documentation is created with note "non-sterile". This function is reset automatically for the next batch.

Vacuum On / Off, Halt / Continue:

Pressing button "Vacuum On / Off" allows the vacuum to be generated in the chamber in initial position. Pressing button "Halt / Continue" halts or continues the function respectively. This function is scheduled for setting the leakage rate of the needle valve.

Monitoring During Exposure Phase:

This button allows you to set whether the temperature of the Air Detector is to be monitored or not during the exposure phase.

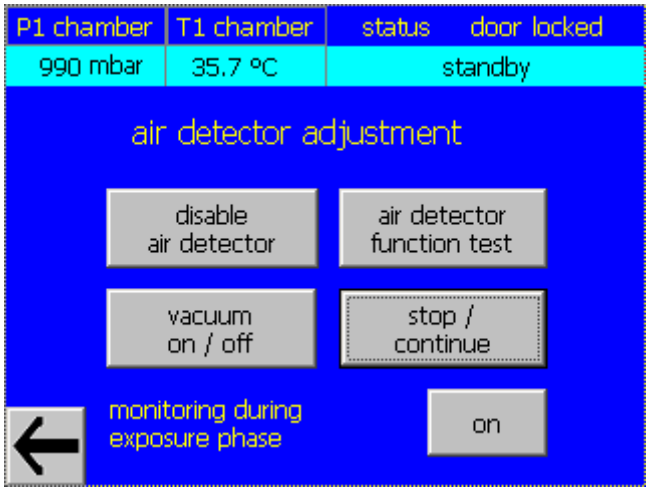


Figure 9-43: Air Detector adjustment

For Air Detector Adjustment refer 'maintenance manual'

10 Routine Monitoring

10.1 Biological monitoring

As part of the operator's verification of the sterilization process, biological indicators may be used to demonstrate that sterilization conditions have been met.
A live spore test utilizing B.stearothermophilus is the most reliable form of biological monitoring.
To verify the process insert the biological indicator in a test pack (refer to AAMI ST-8 guidelines) and place pack on the lowest shelf of the cart. Run test pack through a typical Pre-vacuum cycle (Cycle no. 1 or 2).
On completion, forward test pack and monitor to appropriate personnel for evaluation.

10.2 Testing for pre-vacuum efficiency

CAUTION
In order to ensure the proper function of the sterilizer, run a vacuum leak test cycle daily.

10.2.1 Leak Test

Daily run first a 'Warm-up & Leak-Test' or 'Leak-Test' cycle. This test measures the integrity of the sealed pressure vessel and associated piping to assure air is not being admitted to the sterilizer during vacuum steps.
After running a Leak Test, the leak rate is printed on the cycle documentation.
If the leak rate is out of range, additionally an alarm message is printed.
The malfunction must be reported to the supervisor, who will take appropriate action to determine the cause of the problem. Sterilizer should not be used during this time.
The leak rate value will help define a trend over a period of time if the integrity of the system begins to deteriorate.

10.2.2 Bowie-Dick Test

CAUTION

The Bowie-Dick/ DART Test Cycle has to be performed daily.

Daily run a Bowie-Dick Test (DART) cycle before processing any loads. This cycle should be used to test the adequacy of air removal from chamber an load, so that steam can penetrate the load. It is not a test for adequate exposure to heat in terms of time-at-temperature.

Tests such as Bowie-Dick or DART® (Daily Air Removal Test) are designed to document the removal of residual air from a sample challenge load.

In case of these tests, following exposure in a Bowie-Dick Test cycle, the pack is opened, the indicator examined and conclusions are drawn as to the pattern of residual air, if any, that remained in the pack during the sterilization cycle. Any indication of a malfunction must be reported to the supervisor, who will take appropriate action to determine the cause of the problem. Sterilizer should not be used during this time.

11 Routine Maintenance

CAUTION

Use only original SAUTER AG replacement parts for maintenance purposes: in all other cases the manufacturer can no more guaranty the specified performances of the equipment nor apply the warranty conditions.

11.1 Replacement of ribbon or paper roll

The printer is built in a strong plastic housing with removable cover. For replacing the ribbon or the paper roll, the cover must be removed from the housing.

Step 1: Remove the cover

Shift the cover while placing the two thumbs on the grooved rail and pressing into the opposite direction (Figure 11-1).

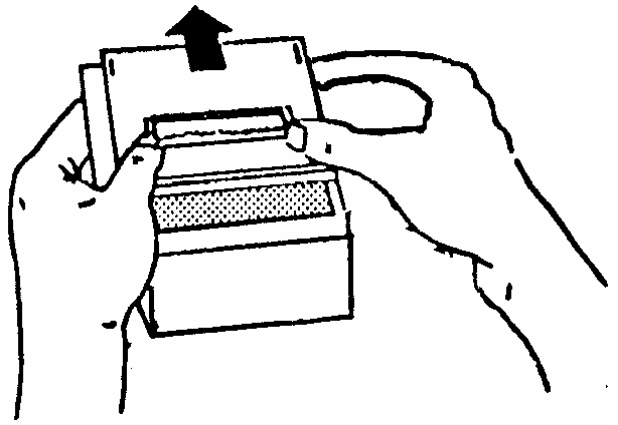


Figure 11-1 Replacement of ribbon or paper roll

Step 2: replace the ribbon cassette

For replacing the printing ribbon press onto the edge of the ribbon cassette, where the words „PUSH" and „EJECT" appear (Figure 11-2). After that the ribbon cassette is unlocked on the right hand side and it can be removed. Tighten the ribbon of the new cassette by turning the small wheel on the right hand side in the arrow-indicated direction (Figure 11-3). Place the ribbon cassette over the paper. The paper must be between the textile ribbon and the plastic rail. Place the cassette in its definitive location until it engages clearly (Figure 11-4)

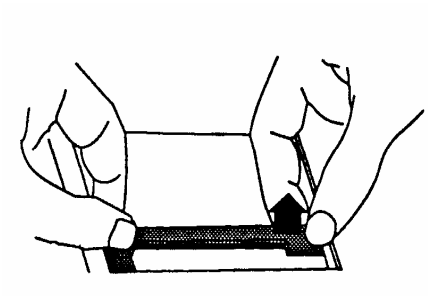


Figure 11-2: Replace ribbon 1

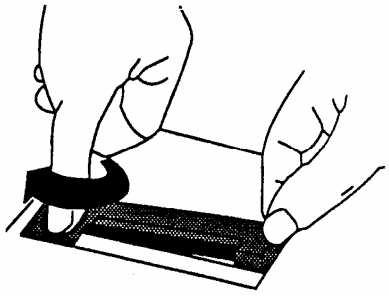


Figure 11-3: Replace ribbon 2

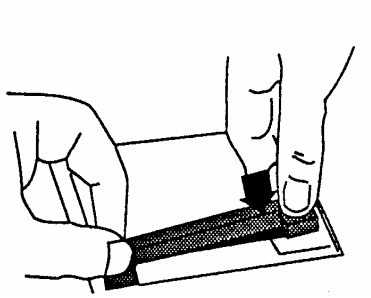


Figure 11-4: Replace ribbon 3

Step 3: replace the paper roll

Paper rolls with a diameter of 38mm (1.5") are compatible with the printer housing.
Remove the ribbon cassette according to step 2. Remove the spindle with the core of the empty paper roll and place it into the core of the new roll. Place the roll in this way that the paper will be carried down and forwards (Figure 11-5). If necessary cut off the paper end straightly. Introduce the end of the paper from underneath into the corresponding slot at the printer until there is a resistance. In order to get the paper in front of the textile ribbon press the paper advance button until about 5 cm come out of the printer.
Introduce the ribbon cassette in its location as explained in step 2 (Figure 11-6 to Figure 11-8).

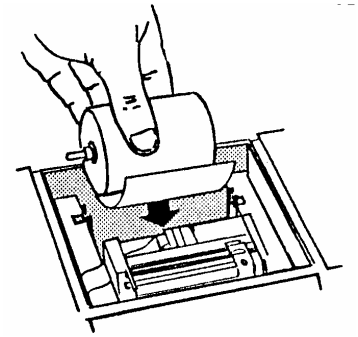


Figure 11-5: Replace paper 1

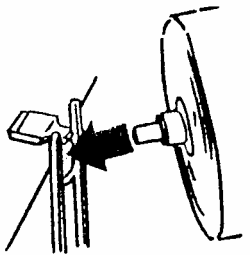


Figure 11-6: Replace paper 2

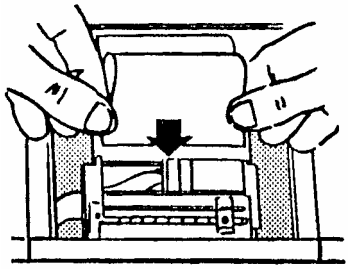


Figure 11-7: Replace paper 3

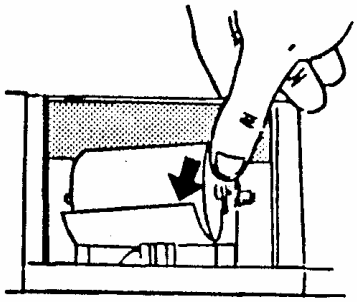


Figure 11-8: Replace paper 4

Step 4: Place the cover back in its position

Introduce the paper from the back side through the cover. Place the cover on the housing with a distance of about 1 cm from the edge and shift it as far as it goes (Figure 11-9).

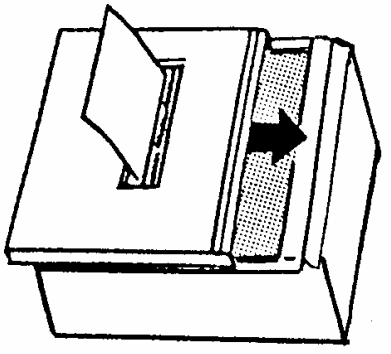


Figure 11-9: Place back printer cover

11.2 Cleaning of Chamber and Front panels

Clean chamber and front panels if dirty but at least once per week.

WARNING

Before entering the chamber (e.g. for cleaning) turn the key switch off (position '0') and keep the key in your pocket as long as you work in the chamber.

CAUTION

Clean the chamber in cold condition only.

Chamber: Clean with cotton towel or sponge. Use water or washing-up liquid. See to it that no residues are left.

Front panels: Clean with soft towel. Clean dry or use washing-up liquid or stainless steel cleaner (Belimed part no. 05 44308).

12 Update history

Revision	Date	Pages	Release		Description
			Date	Initials	
1.0	5.2.2002	1 - 100	12.2.2002	ABR	Operating Instructions produced by HST
1.1	15.03.2002	1-104	18.3.2002	ABR	Warnings added HST
1.2	3.5.2002	1-104	6.5.2002	ABR	Warnings / Cautions added by HST
1.3	15.10.2002	1 - 110	17.5.2002	HST	screen mask added, installation figures added MWE
1.4	15.10.2002	1 - 111	25.10.2002	HST	directory automated MWE
1.5	18.11.2002	1-113	18.11.2002	HST	Online-docu. and TB function description added
1.6	27.1.2003	1-113	27.1.2003	HST	Installation: Terminal block instead of disconnect switch, Alarm 62 added
1.7	17.2.2003	1-113	17.2.2003	HST	Table 3-3 - EL1: fuse 30A stainless steel bottom plate for GR models
1.8	4.4.2003	1-113	4.4.2003	HST	Installation: Additional text: panelling up to the ceiling
1.9	4.2.2004	1-114	4.2.2004	MWE	Operating Instructions updated for software version 1.5
2.0	16.9.2004	1-114	16.9.2004	MWE	Operating Instructions updated for software version 2.0 (New control panel on non operating end)
2.1	09.02.2006	1-115	09.02.2006	MWE	Operating Instructions updated for software version 2.1 Chapter 9.10.6 modified
2.2	3.05.2005	1-115	3.05.2005	MWE	Operating Instructions updated for software version 2.2
2.3	13.07.2005	90	13.07.2005	PHE	For Sensor adjustment refer maintenance guidelines
2.4	13.01.2006	1-108	13.01.2006	MWE	Extension machine set up for software version 23, insert automatically figure and table content, Critical alarms added, minor corrections

13 Appendix

13.1 List of Figures:

13.2 List of Tables