Belimed
Infection Control

Belimed Steam Sterilizer MST-V TOP 5000

USER'S MANUAL

Model 6-6-6 VS1 / VS2
660 x 660 x 700 mm

Model 6-6-9 VS1 / VS2
660 x 660 x 1000 mm

Model 6-6-12 VS1 / VS2
660 x 660 x 1300 mm

Model 6-6-18 VS1 / VS2
660 x 660 x 2000 mm

Table of contents

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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.

Manufacturer:

Belimed Sauter AG
Zelgstrasse 8
CH- 8583 Sulgen Switzerland
Phone +41 71 644 85 00
Fax + 41 71 644 86 01

Sales and Service:

2 Introduction

2.1 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.

2.2 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 EN285 standards under defined load conditions. The cycles parameters can be easily modified to perform the sterilization under optimised 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 liquids.

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 BELIMED 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 WARM-UP & LEAK TEST cycle daily.

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

2.3 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 authorised persons fully acquainted with this equipment. Use of inexperienced, unqualified persons to work on the equipment or the installation of unauthorised 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 liquids.**

- **BURN HAZARD: Sterilizer and rack/shelves will be HOT after cycle is run. Always wear protective gloves and apron 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 or any liquids at all.**

- **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 EN285 a measured leak rate greater 1,3mbar/minute indicates a problem with the sterilizer.** Refer the situation to a qualified maintenance technician before using the sterilizer further.

- **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.**

- **When closing the door, no person is to be inside the chamber. The operator is responsible for the observation of this safety precaution.**

CAUTIONS

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 jeopardise insurance coverage.

CAUTION: Use only original BELIMED 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 Test Cycle has to be performed daily.

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

CAUTION: Respect the maximum number of sterilisation'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	No. of sterile units 3)	Chamber volume (litres)	Chamber size (H x W x D) (mm)	Overall Dimensions (H x W x D) (mm) 1)	Weights (kg) 2) *Transport / Operation / Inspection*
6-6-6 VS1	1- door	4	305	660 x 660 x 700	1970 x 980 x 960/1040	700 / 780 / 1000
6-6-6 VS2	2- doors	4	305	660 x 660 x 700	1970 x 980 x 960/1040	750 / 830 / 1050
6-6-9 VS1	1- door	6	440	660 x 660 x 1000	1970 x 980 x 1260/1340	800 / 910 / 1240
6-6-9 VS2	2- doors	6	440	660 x 660 x 1000	1970 x 980 x 1260/1340	850 / 960 / 1290
6-6-12 VS1	1- door	8	565	660 x 660 x 1300	1970 x 980 x 1560/1640	900 / 1040 / 1465
6-6-12 VS2	2- doors	8	565	660 x 660 x 1300	1970 x 980 x 1560/1640	950 / 1090 / 1515
6-6-18 VS1	1- door	12	880	660 x 660 x 2000	1970 x 980 x 2260/2340	1100/ 1240/ 1865
6-6-18 VS2	2- doors	12	880	660 x 660 x 2000	1970 x 980 x 2260/2340	1150/ 1290/1915

1) without / with control panel above chamber

2) Weight with internal steam generator

3) 1 Sterile unit = (H x W x D) 300x600x300mm

Table 3-1: Sterilizer sizes

3.2 Required building system utilities

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

3.2.1 Utility connections

Model		6-6-6 VS1, 6-6-6 VS2				6-6-9 VS1, 6-6-9 VS2			
Symbol	Medium	Pressure in bar g	Customers supply	Peak	Consumption per batch with normal load	Pressure in bar g	Customers supply	Peak	Consumption per batch with normal load
Standard-Supply lines									
SD	Sterilizing Steam	2.5- 3	¾"	50 kg/h	13 kg	2.5- 3	¾"	60 kg/h	16 kg
KW	Tap water for vacuum pump, 15 °C (60°F) Option cooling water circuit	2 - 5	½"	1 m^3/h	190 l (10 l)	2 - 5	½"	1.2 m^3/h	280 l (10 l)
VE	Deionised water 15-80°C for internal steam generator only Conductivity: ≥1µS/cm and ≤15µS/cm	2 - 5	¼"	0.1 m^3/h	14 l	2 - 5	¼"	0.1 m^3/h	17 l
DL	Compressed air, oil-free	5 - 7	¼"	5 Nm^3/h	0.3 Nm^3	5 - 7	¼"	5 Nm^3/h	0.3 Nm^3
EL1	Electric supply: external steam 3N ~ 380-400V 50 Hz		4A (10A)	1.7 kW	0.5 kWh		4A (10A)	1.7 kW	0.6 kWh
EL1	Electric supply: intern. steam generator 3N~ 380-400V 50 Hz		48A (50A)	32 kW	10 kWh		69A (80A)	47 kW	12.5 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)		1 ¼"	max. 15 l/min			1 ¼"	max. 20 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			1.5 kW				1.8 kW	
Option waste steam line upwards									
AD1	Waste steam, chamber	max. 2.7	1" nipple	240 kg/h		max. 2.7	1" nipple	240 kg/h	
AD2	Waste steam, jacket	max. 2.7	1" nipple	240kg/h		max. 2.7	1" nipple	240kg/h	
AD3	Waste steam, steam generator	max. 3.5	1" nipple	290 kg/h		max. 3.5	1" nipple	290 kg/h	
Option Cooling water circuit									
KWV	Cooling water forward: T1 10 °C, ΔT 15K Cooling energy required	2 - 5	¾ "	2 m^3/h 8kW	400l 26000kJ	2 - 5	¾ "	2m^3/h 10kW	500l 32000kJ
KWR	Cooling water backward		¾ "				¾ "		

Table 3-2: Utilities for chamber size 6-6-6 to 6-6-9

Model		6-6-12 VS1, 6-6-12 VS2				6-6-18 VS1, 6-6-18 VS2			
Symbol	Medium	Pressure in bar g	Customers supply	Peak	Consumption per batch with normal load	Pressure in bar g	Customers supply	Peak	Consumption per batch with normal load
Standard-Supply lines									
SD	Sterilizing Steam	2.5- 3	¾"	70 kg/h	19 kg	2.5- 3	¾"	100 kg/h	25 kg
KW	Tap water for vacuum pump, 15 °C (60°F) Option cooling water circuit	2 - 5	½"	1.2 m^3/h	380 l (10l)	2 - 5	½"	1.2 m^3/h	430 l (10l)
VE	Deionised water 15-80°C for internal steam generator only Conductivity: ≥1µS/cm and ≤15µS/cm	2 - 5	¼"	0.1 m^3/h	20 l	2 - 5	¼"	0.1 m^3/h	26 l
DL	Compressed air, oil-free	5 - 7	¼"	5 Nm^3/h	0.3 Nm^3	5 - 7	¼"	5 Nm^3/h	0.3 Nm^3
EL1	Electric supply: external steam 3N ~ 380-400V 50 Hz		4A (10A)	1.7 kW	0.5 kWh		6A (10A)	2.6 kW	0.9 kWh
EL1	Electric supply: intern. steam generator 3N~ 380-400V 50 Hz		83A (100A)	56 kW	15 kWh		94A (100A)	65 kW	19 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)		1"	max. 20 l/min			1"	max. 25 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			2 kW				3kW	
Option waste steam line upwards									
AD1	Waste steam, chamber	max. 2.7	1" nipple	240 kg/h		max. 2.7	1" nipple	240 kg/h	
AD2	Waste steam, jacket	max. 2.7	1" nipple	240kg/h		max. 2.7	1" nipple	240kg/h	
AD3	Waste steam, steam generator	max. 2.7	1" nipple	290 kg/h		max. 2.7	1" nipple	290 kg/h	
Option Cooling water circuit									
KWV	Cooling water forward: T1 10 °C, ΔT 15K Cooling energy required	2 - 5	¾ "	2 m^3/h 12kW	Discharge 600l 36000kJ	2 - 5	¾ "	2.5 m^3/h 16kW	discharge 800l 45000kJ
KWR	Cooling water backward		¾ "				¾ "		
Additional information									
	Batch-time by full charging EN 285		textiles ca. 45 min. Instruments ca. 60 min.				textiles ca. 55 min. Instruments ca. 60 min.		
	Noise-level ISO 3746: 1995		65 dBA				75 dBA		

Table 3-3: Utilities for chamber size 6-6-12 to 6-6-18

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 realised in a rigid manner.

1 EL1 Electric supply, main switch

2 SD Steam connection models without steam generator

3 KW Tap water supply

4 DL Compressed air supply

5 VE Deionised water supply models with steam generator

6 A Drain

7-12: Gauges, refer to chapter 5.2

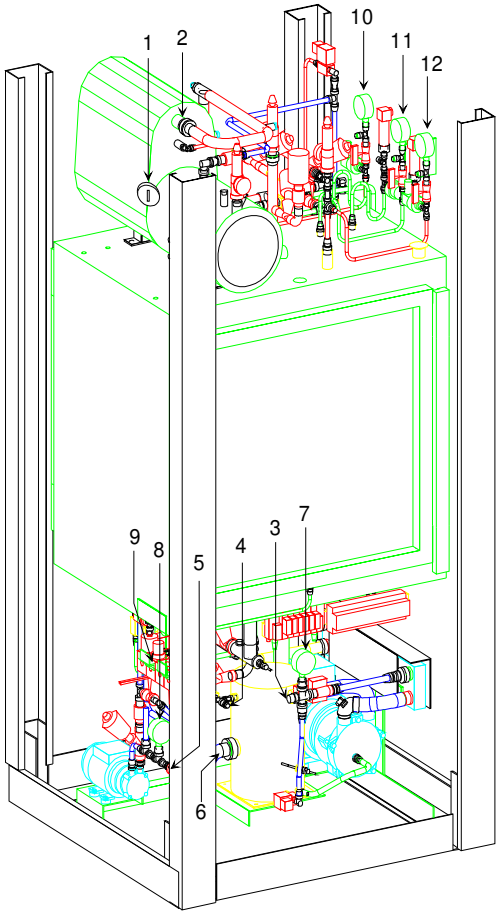


Figure 3-1: Utility connections

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.

3.3.2 Space considerations

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

3.3.3 Mounting details

3.3.3.1 Service power

One convenience outlet (230V) is required for power tools next to the sterilizer.

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 Pressure equipment directive 97/23/EG.

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 vapour to ensure proper goods drying.
It has to fulfil the requirements of EN285.

3.3.4.8 Water quality

Water is used for vacuum pump and heat exchangers. Refer to Table 3-3 for recommended water quality. It has to fulfil the requirements of EN285.

Condition	*Nominal conditions*	*Maximum conditions*
Temperature	4-16°C (40-60°F)	21°C (70°F)
Degree of acidity (PH)	6-8.5	5.5-9.5
Calcium and magnesium	<200 mg/l	<300 mg/l
Total hardness as $CaCO_3$	0.2-1.8 mmol/l	2 mmol/l
Residue on evaporation	<500 mg/l	<1500 mg/l
Conductivity at 20°C	<1000 µS/cm	<1500 µS/cm

Table 3-3: Recommended feed water quality for sterilizers

3.3.4.9 Demonized water quality for steam generator

Feed water has to fulfill the requirements of EN285 Annex B, Table B1.
The **conductivity** (at 20°C) must be **≥1µS/cm** and **≤15µS/cm**.

3.3.4.10 Wiring Terminals

Wiring between junction box (contains main power switch) and building service lines are not furnished by Belimed. Connect the main supply line on the terminals as shown in Figure 3-2:

Wire no.	Box connector no.
Phase L1 to	1
Phase L2 to	3
Phase L3 to	5
Neutral to	N
Protective Conductor to	⏚

Figure 3-2: Junction box

3.3.5 Preparation

3.3.5.1 Standard sterilizers

- Check the sterilizer placement according to installation drawing.
- Measure overall height on the wall opening.
- Mark the centre lines of the sterilizer chamber on the floor with a colour marker
- For correct positioning refer to installation drawing
- Check the position and carrying out of the floor drains (A [waste water] and GU [gully])
- Put the stainless steel tub on place (if required).
- Remove transportation screws from all door-counter weights.
- Place the chamber on the stainless steel tub.
- Adjust the chamber high using the adjusting screws. Refer to the installation drawing.
- Open chamber door
- Remove door locking bolts (below chamber) an insert the bolt 90° turned again.
- Adjust the chamber high with a spirit level along x and y axis by using the 4 adjustment screws on the feeds. The chamber floor must be levelled to 785mm above ground.
- Close chamber door.
- Tighten the gap between steel tub and sterilizer ground frame with silicone compound.
- Install the 4 pressure sensors.
- Fill 5 litres of water into the vacuum pump circulation tank.

4 Labelling

4.1 Type and Model Designation

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

Model	Configuration	No. of sterile units 3)	Chamber volume (litres)	Chamber size (H x W x D) (mm)	Overall Dimensions (H x W x D) (mm) 1)	Weights (kg) 2) *Transport / Operation / Inspection*
6-6-6 VS1	1- door	4	305	660 x 660 x 700	1970 x 980 x 960/1040	700 / 780 / 1000
6-6-6 VS2	2- doors	4	305	660 x 660 x 700	1970 x 980 x 960/1040	750 / 830 / 1050
6-6-9 VS1	1- door	6	440	660 x 660 x 1000	1970 x 980 x 1260/1340	800 / 910 / 1240
6-6-9 VS2	2- doors	6	440	660 x 660 x 1000	1970 x 980 x 1260/1340	850 / 960 / 1290
6-6-12 VS1	1- door	8	565	660 x 660 x 1300	1970 x 980 x 1560/1640	900 / 1040 / 1465
6-6-12 VS2	2- doors	8	565	660 x 660 x 1300	1970 x 980 x 1560/1640	950 / 1090 / 1515
6-6-18 VS1	1- door	12	880	660 x 660 x 2000	1970 x 980 x 2260/2340	1100/ 1240/ 1865
6-6-18 VS2	2- doors	12	880	660 x 660 x 2000	1970 x 980 x 2260/2340	1150/ 1290/ 1915

1) without / with control panel above chamber

2) Weight with internal steam generator

3) 1 Sterile unit = (H x W x D) 300x600x300mm

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 labelling (example)

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

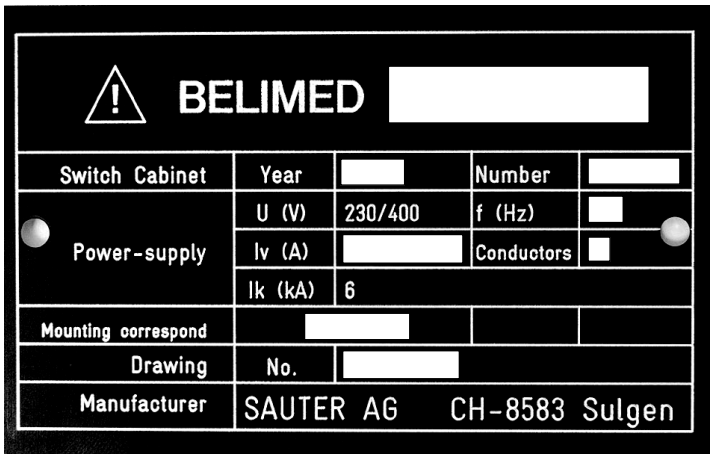


Figure 4-2: Labelling Electrical Ratings

4.3 Warning labels

Those labels are placed close to the respective parts which represent a potential hazard:

- DANGER OF SCALDING!

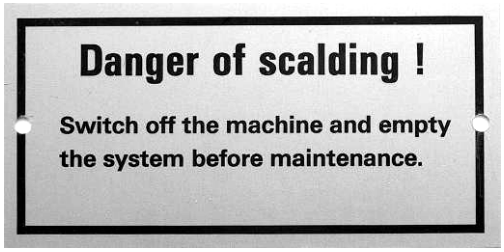


Figure 4-3: Label "DANGER OF SCALDING!"

- DANGER: OVERPRESSURE!

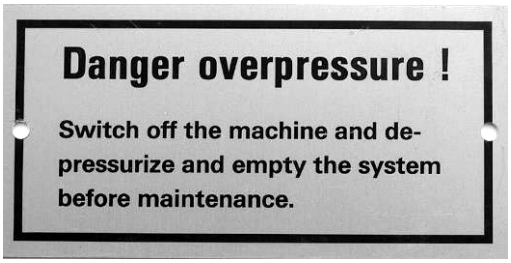


Figure 4-4: Label "Danger overpressure!"

- DANGEROUS VOLTAGE!

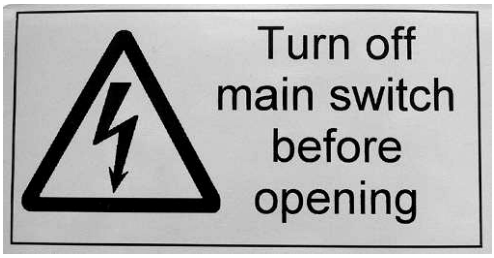


Figure 4-5: Label „DANGEROUS VOLTAGE!"

- 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 - REFER TO MANUAL"

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 maximise the simplicity and security of use.

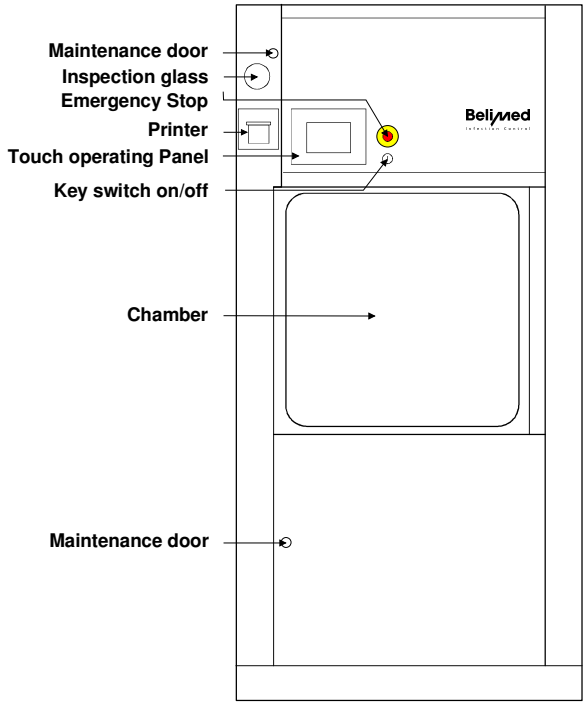


Figure 5-1: Control elements operating end

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

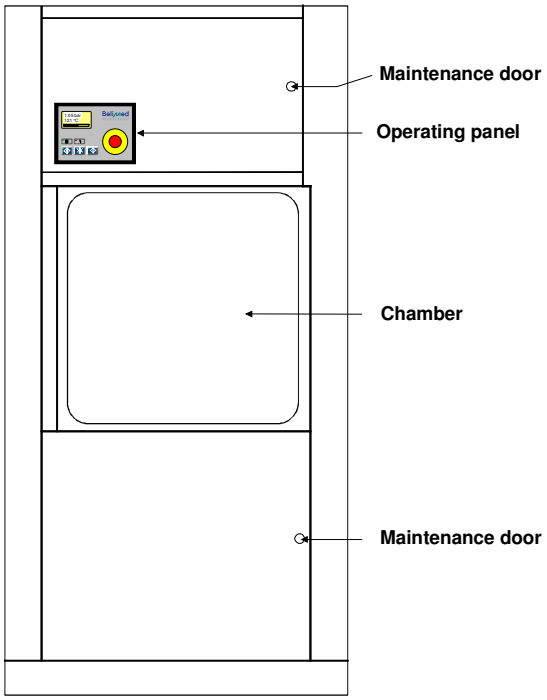


Figure 5-2: Control elements non operating end

5.2 Indicators and gauges

3.7

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 in bar gauge:

The gauges shall show :

Pressure indication	Nominal conditions bar	Maximum conditions bar
Steam supply	2.5-3	2.5-3.5
Chamber	-0.96-2.3	-1..+2.7
Jacket	-0.96-2.3	-1..+2.7
Door seal (door locked)	2.9-3.2	2.8-3.5
Compressed air	5-7	5-7
Tap water	2-5	2-5
Deionised water	2-5	1.5-5

Table 5-1: Pressure indicators in service area

3.9.3

1-6 Utilities, refer to chapter 0

7 Tap water pressure gauge

8 Deionised water (for optional steam generator)

9 Compressed air gauge

3.7.7 10 Steam supply gauge

3.7.2 11 Chamber pressure gauge

3.7.4 12 Jacket pressure gauge

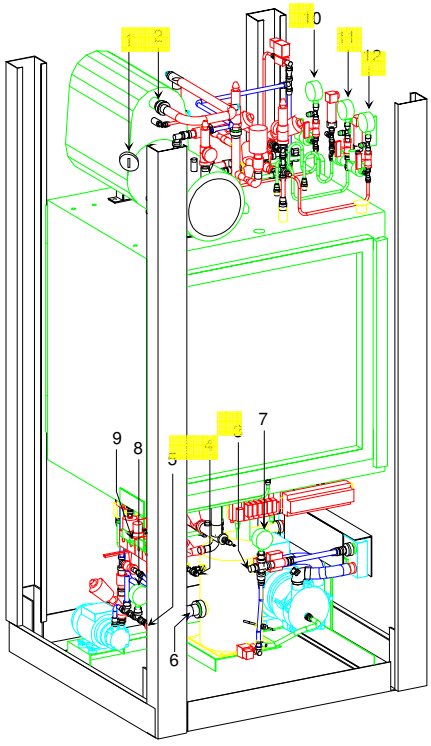


Figure 5-3: Instrumentation

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 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

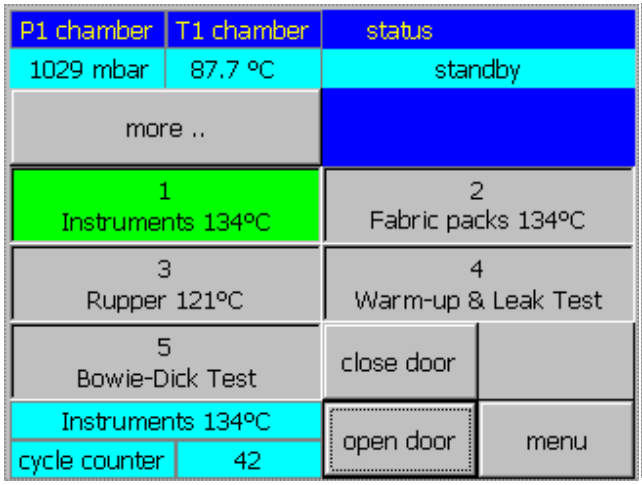


Figure 5-5: Out-of-cycle display

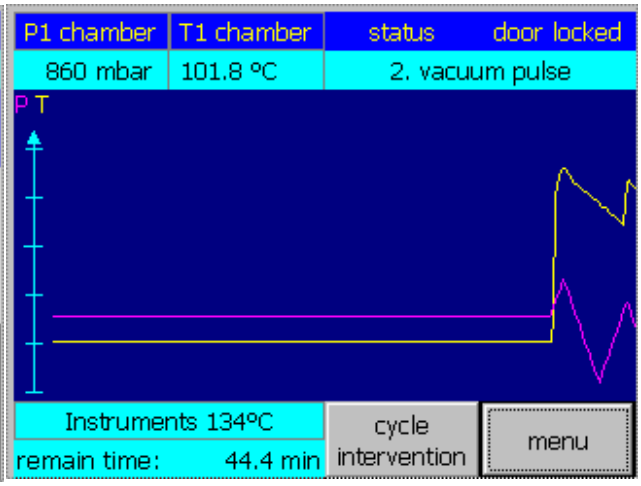


Figure 5-6: In-cycle display

5.4 Non-Operating End Control Panel (option)

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

Figure 5-7 shows the panel on the non operating end.

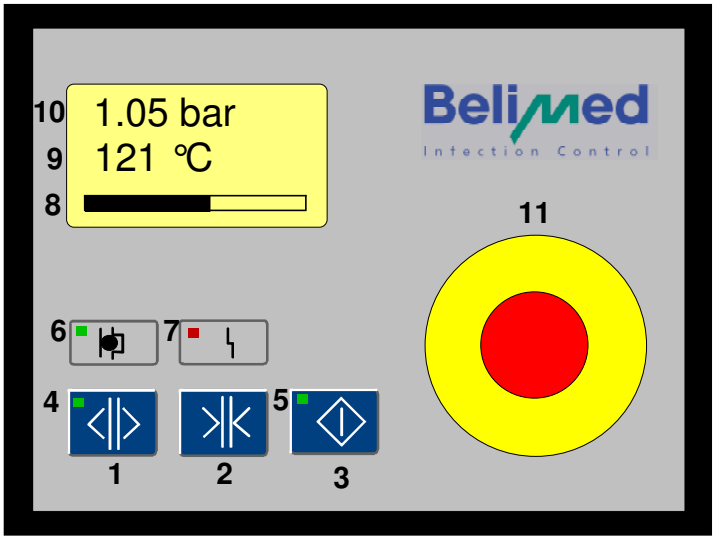
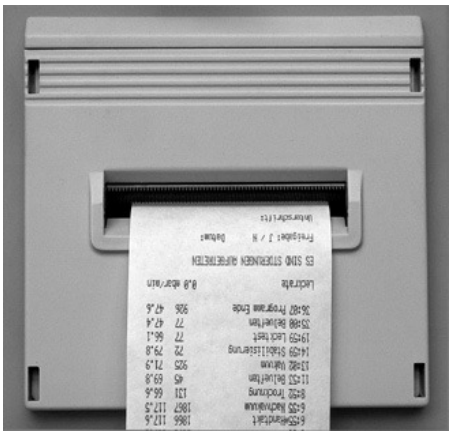


Figure 5-7: Non operating end control panel

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



General Specifications:

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

Figure 5-8: Panel mount printer

For replacing paper roll or ribbon refer to chapter 11

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 m:s	Phase	Press. mbara	Temp. °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 door motor is equipped with a safety clutch, which stops the door if the closing force is >150N.

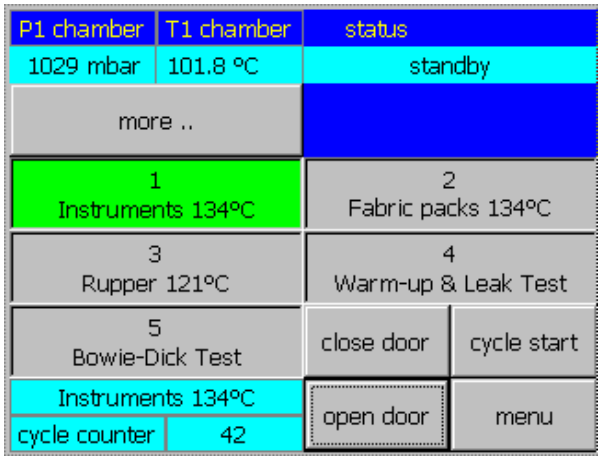


Figure 5-10: Door operation buttons operating end

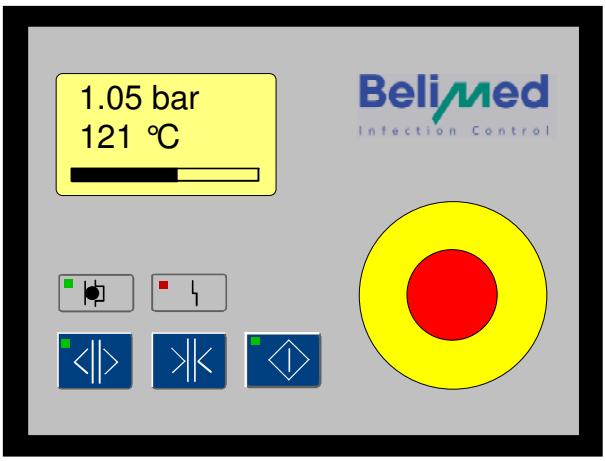


Figure 5-11: Door operation buttons non operation end

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 therefore: 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 for Textiles and max. 10 kg for Instrument load.
- 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 load can be the following:
    - Porous materials and textiles together
    - Single or small amount of instruments
    - Baskets of instruments together
    - Rubber goods 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 5 cm (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 shut-off valve** (refer to Figure 6-1) is located behind the access door on the top . Ensure this valve is in the open position before trying to operate the sterilizer.

The **Tap water shut-off valve** is located behind the lower maintenance door. Ensure this valve is open.

The **Deionized water shut-off valve** (option internal steam generator) is located behind the lower maintenance door on the left side. Ensure this valve 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).

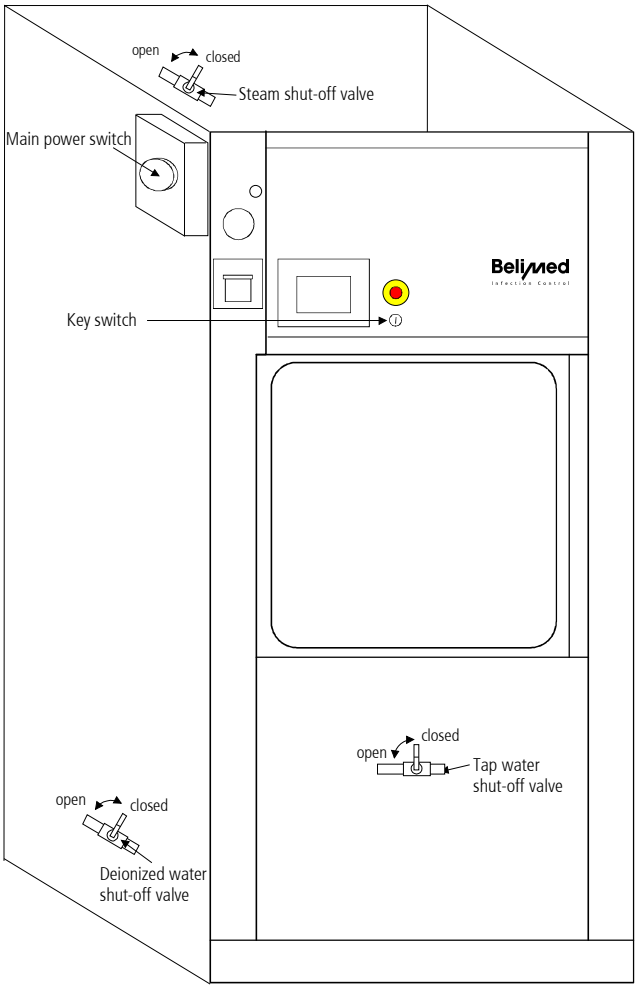


Figure 6-1: Utility locations

6.2 Log on

To operate the sterilizer a user must be logged on. The operator has to enter his password (refer to Figure 6-3 to Figure 6-4).

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)

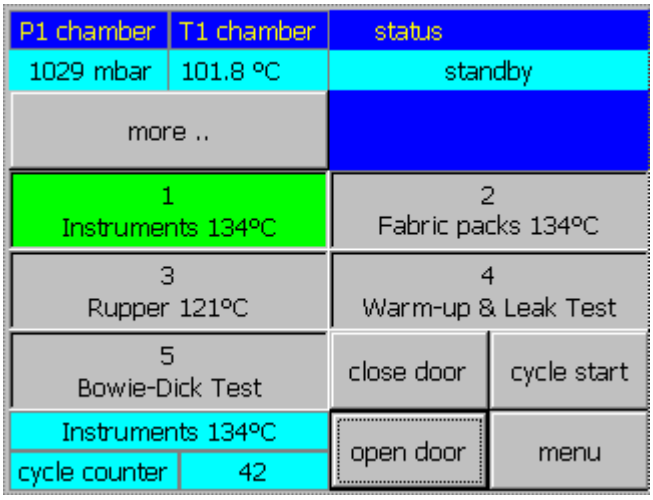


Figure 6-2: Out-of-cycle display

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

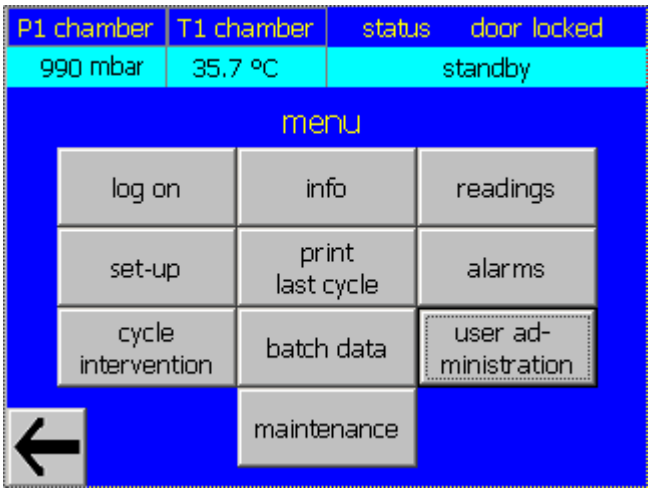


Figure 6-3: Menu display

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

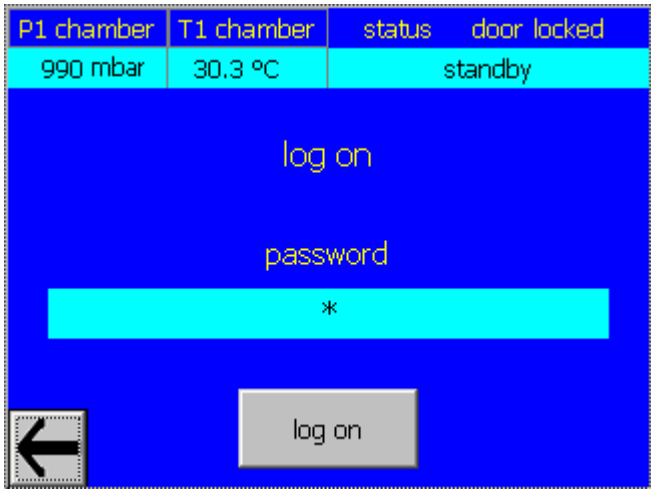


Figure 6-4: Log on display

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

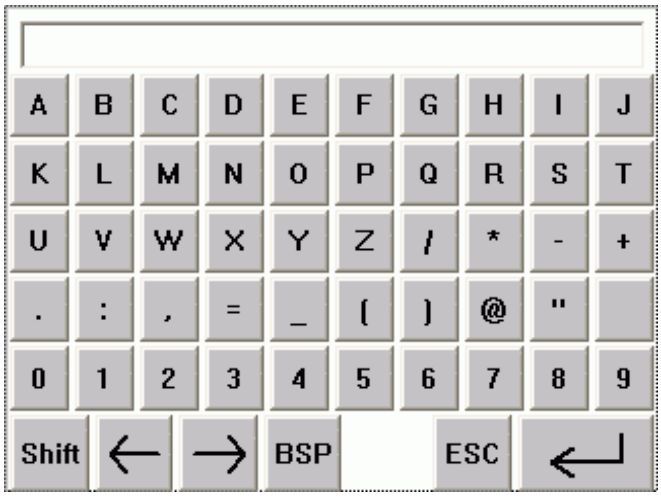


Figure 6-5: Alphanumeric keyboard

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 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 sterilizer

If you want to enter batch data manually select the 'Batch data' menu (refer to chapter 9.8.1).
If the optional documentation system ICS 8535-BC is installed, enter batch data with the barcode scanner first before loading the sterilizer (refer to chapter 9.8.2).

- Open the chamber door by pressing the 'open door' button.
- Verify that loading cart is securely fastened to the transfer carriage.
- Align the front end of the transfer carriage with the end of the sterilizer (refer to Figure 6-6)
- Move carriage forward until lever latches with lock bolt .
- Verify that transfer carriage is latched with chamber by pulling transfer carriage backwards (transfer carriage must remain stationary).
- Unlock loading cart by pushing unlock handle and pushing the cart into the sterilizer chamber.
- Disengage transfer carriage:
  - Push transfer carriage in chamber direction
  - Pull transfer carriage unlock lever
  - pull transfer carriage away from the sterilizer chamber
- Close the chamber door by pressing the 'close door' button, until door is closed.

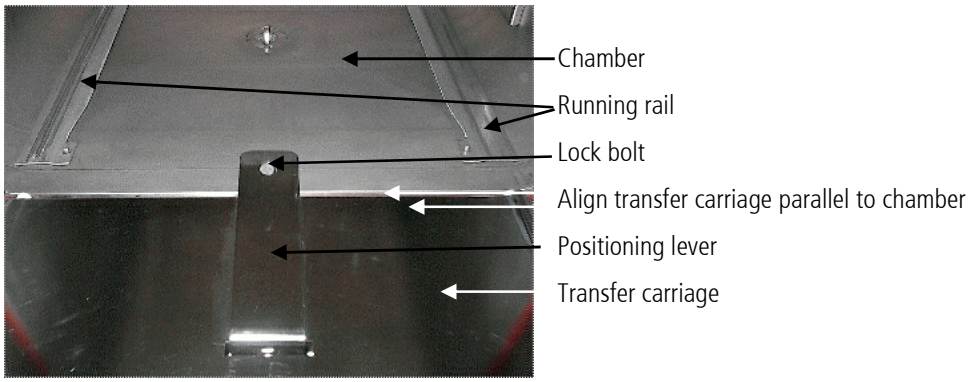


Figure 6-6: Align transfer carriage with chamber

Figure 6-7: Loading sterilizer

6.4 Select a cycle

6.4.1 Factory-set cycles and cycle values

The predefined programs of the Belimed MST-V TOP 5000 steam steriliser are described in Chapter 7.1.

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 6-8). These buttons display the cycle number, the cycle name and the sterilization exposure temperature.

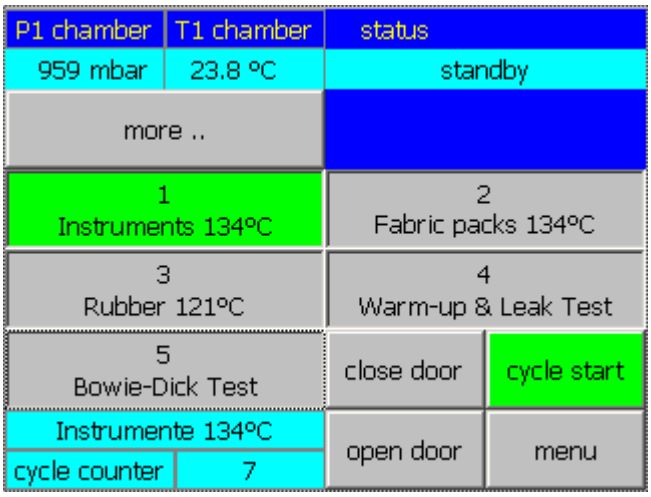


Figure 6-8: Cycle selection buttons with cycle start button

6.5 Start a cycle

The green Start button (Figure 6-8) 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

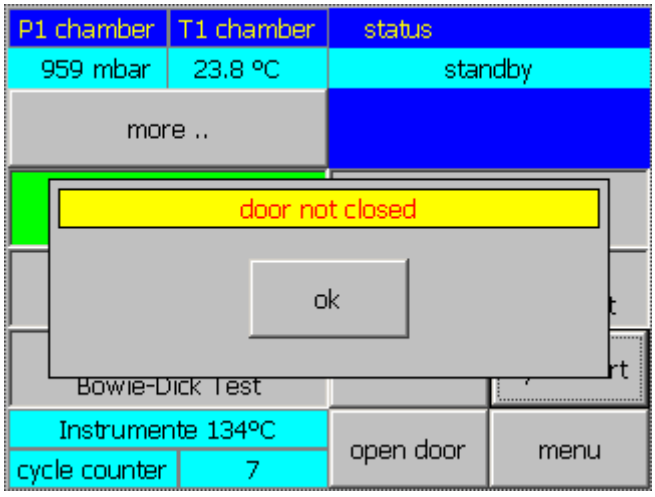


Figure 6-9: Cycle selection with "dialog box"

If the sterilizer is not at start standby, the cause is displayed with a dialog box (Figure 6-9) 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

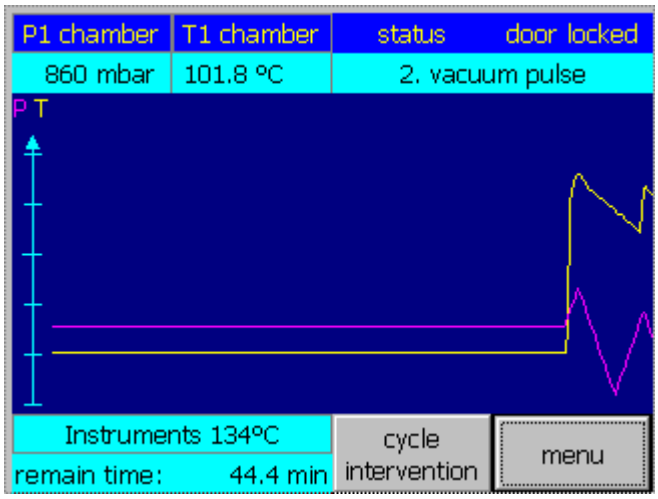


Figure 6-10: In-cycle display

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 6-11).
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.

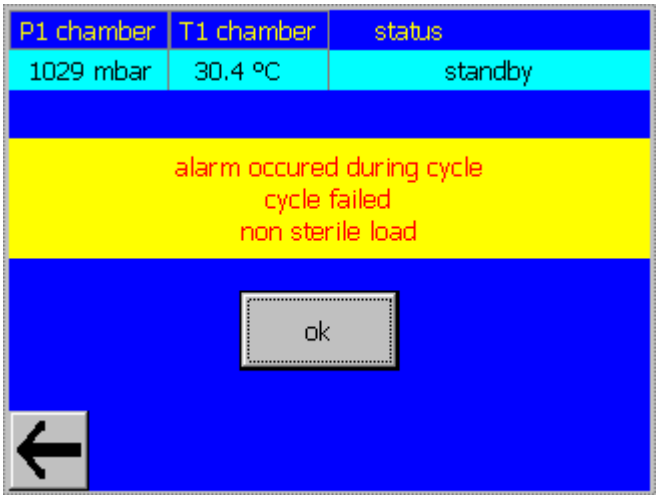


Figure 6-11: Cycle failed display

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 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 sterilizer

- Open the chamber door by pressing the 'open door' button.
- Align the front end of the transfer carriage with the end of the sterilizer (refer to Figure 6-6)
- Move carriage forward until lever latches with lock bolt .
- Verify that transfer carriage is latched with 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:
  - Push transfer carriage in chamber direction
  - Pull transfer carriage unlock lever
  - pull transfer carriage away from the sterilizer 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 6-12).
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.

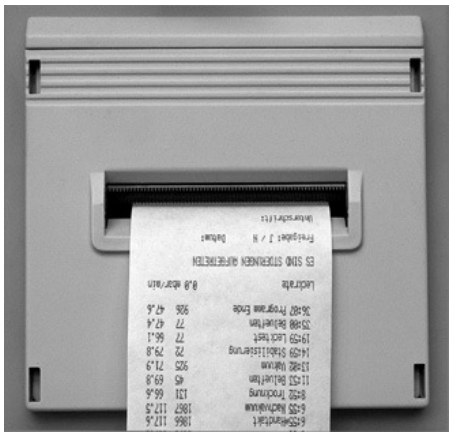


Figure 6-12: Built-in printer

6.10 Log off

After using the sterilizer the user should log off to prevent that unauthorised 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 6-13).

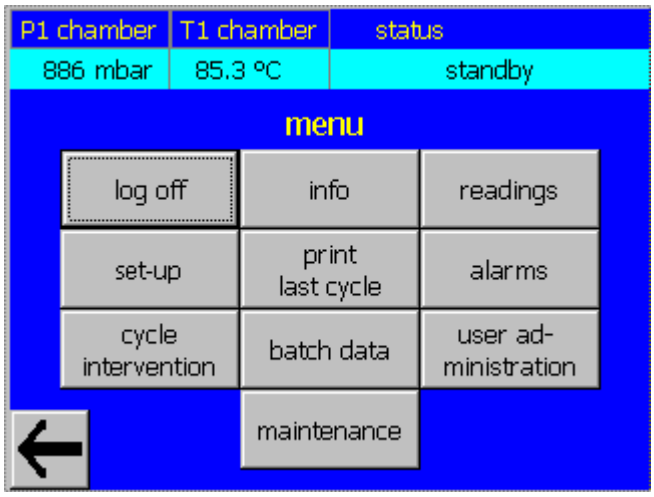


Figure 6-13: Menu display

6.11 Turn off the sterilizer

After unloading the last cycle of a day turn off the sterilizer with the key switch (refer to Figure 6-1).

6.12 Cycle intervention

The cycle intervention touch screen button is used to

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

Pressing Abort causes the sterilizer chamber to depressurise (if pressurised), evacuate the chamber (to dry if possible) and to air break. The door opening deactivates, the control prompts the operator to acknowledge the 'cycle aborted' message (refer to Figure 6-11).

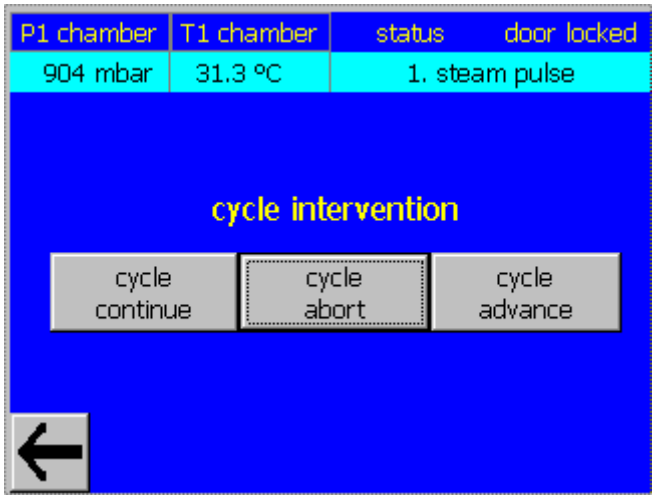


Figure 6-14: cycle intervention display

7 Cycle description

7.1 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	Instruments 134°C	134°C	5 Min	11 + 2*3 Min	Instrument in trays or containers max. 7-8kg / tray or container
2	Fabric packs 134°C	134°C	5 Min	6 Min	Fabric Packs max. 7.5kg / pack
3	Rubber 121°C	121°C	20 Min	6 Min	Rubber, Porous load max. 7.5kg / pack
4	WARM UP & LEAK TEST	134°C	5 Min	3 Min	EMPTY CHAMBER max. Leak rate 1.3mbar/Min
5	Bowie-Dick Test	134°C	3.5 Min	3 Min	Bowie-Dick Test pack
6	LEAK TEST	-	-	-	EMPTY CHAMBER max. Leak rate 1.3mbar/Min
7*)	Heavy Instruments 134°C	134°C	5 Min	11 + 4*3 Min	Heavy instruments in stainless steel containers, max. 14kg / container (gross weight)
8*)	Porous load	125°C	20 Min	6 Min	Fabric Packs max. 7.5kg / pack
9*)	Gravity	121°C	20 Min	0 Min	single items, not vacuum proof
10*)	Special	134°C	60 Min	6 Min	porous load max 7.5kg / pack

*) Special cycles, selectable on demand

Table 7-1: Factory set cycles

7.2 Changes to program parameters

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 EN285 guidelines for validating sterilization cycles to assure the proper Sterility Assurance Level (SAL) as well as moisture retention acceptance criteria.

7.3 Differences in pre-treatment with the Air Detector option

Three fractions are set by default in the case of fractionated pre-treatment FRVV. The Belimed MST-V steam steriliser is delivered with 8 fractions instead of 3 in the case of sterilisers with the "Air Detector" option. The following pressure-time diagrams show the differences with respect to pre-treatment FRVV:

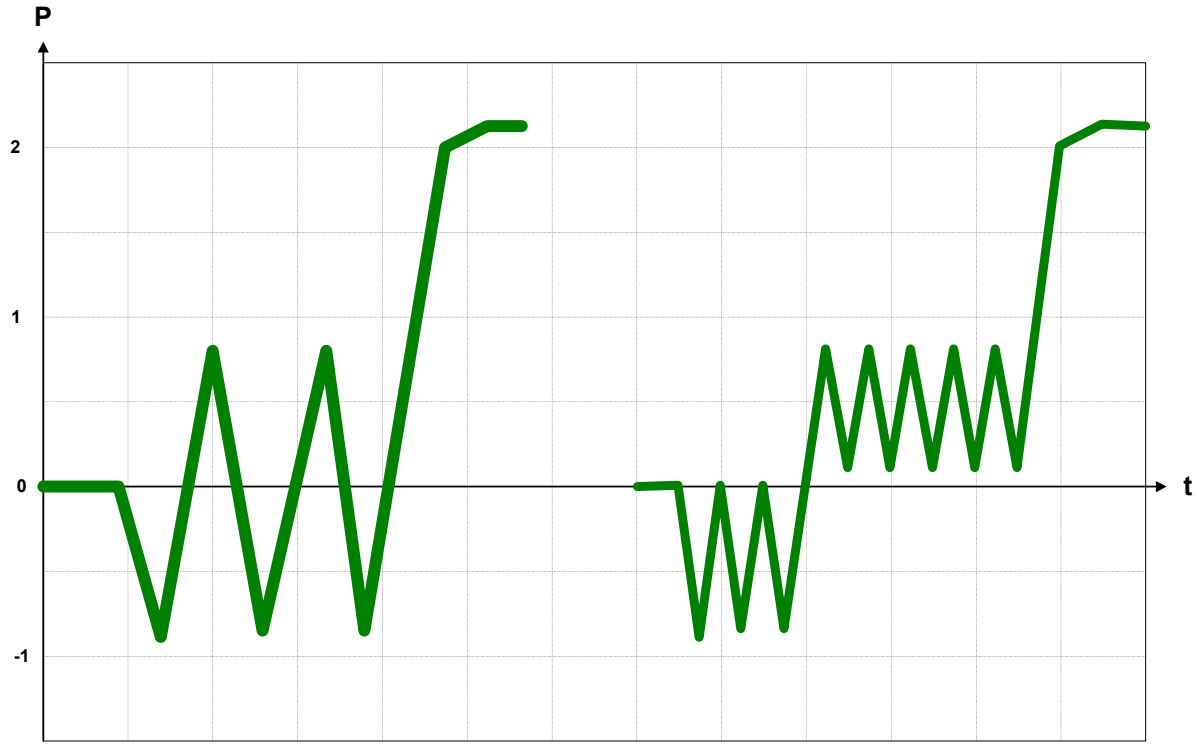


Figure 7-1: Pre-treatment FRVV default

Figure 7-2: Pre-treatment FRVV with Air Detector option

7.4 Pressure-time diagrams of default programs

The Chapters which follow show the pressure-time diagrams in the form of a general graph for the steam steriliser without the Air Detector option. Changes as a result of program parameters are reserved.

7.4.1 Legend further to the process sections:

The process sections are identified with the following abbreviations in the pressure-time diagrams:

1: Pre-treatment: venting and increase phase

2: Sterilisation: plateau time

3: After-treatment: suction, drying and venting phase

4: Test phase

7.5 134°C Instrument cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	Instruments 134°C	134°C	5 Min	11 + 2*3 Min	Instrument in trays or containers max. 7-8kg / tray or container

Table 7-2: 134°C Instrument cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 134°C Instrument cycle.

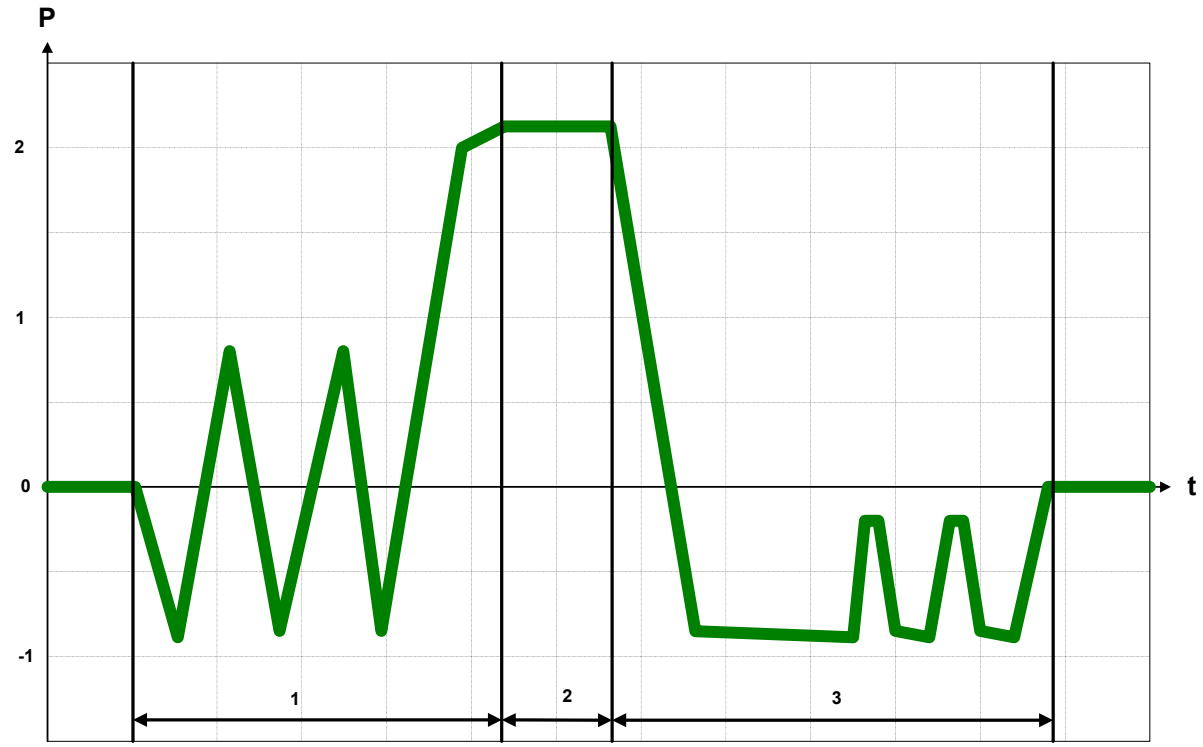


Figure 7-3: Cycle Graph - 134°C Instrument cycle

7.6 134°C Porous Load cycles

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
2	Fabric packs 134°C	134°C	5 minutes	6 minutes	Fabric Packs max. 7.5kg / pack
10	Special	134°C	60 minutes	6 minutes	porous load max 7.5kg / pack

Table 7-3: 134°C Porous load cycles

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Porous Load Cycles 134°C .

3.6.1

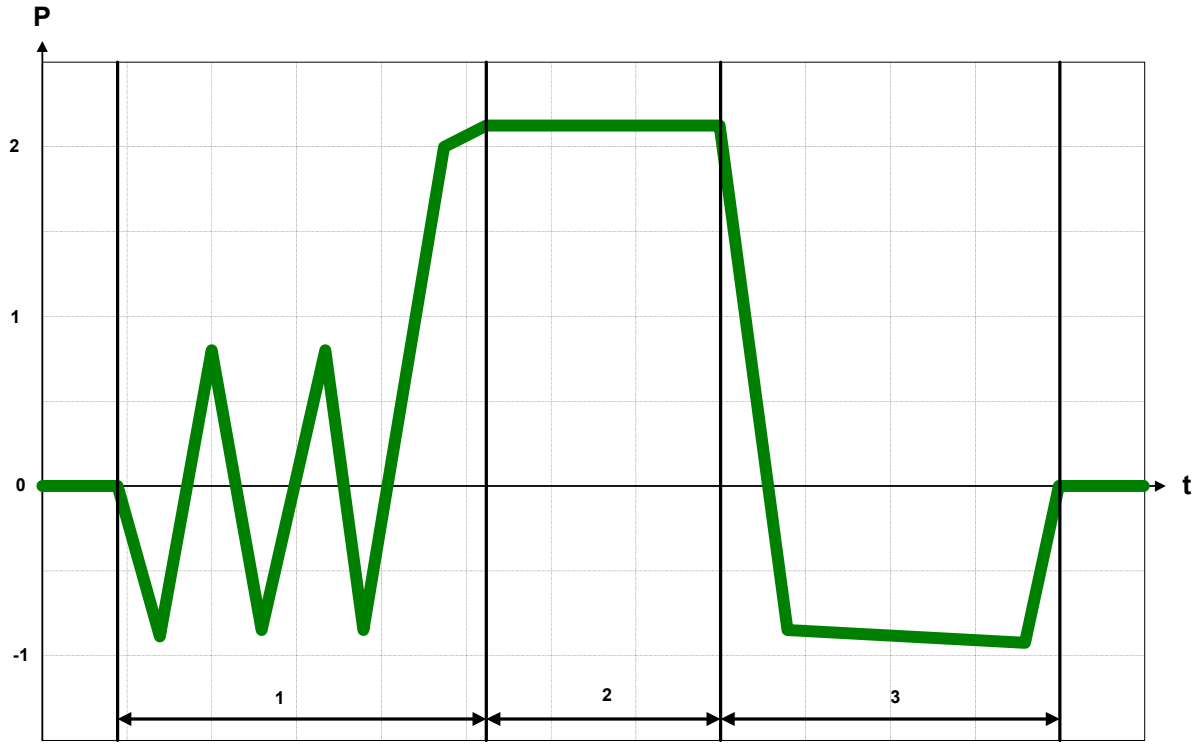


Figure 7-4: Cycle Graph - 134°C Porous load cycle

7.7 121°C RUBBER Cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
3	Rubber 121°C	121°C	20 min.	6 minutes	Rubber, Porous load max. 7.5kg / pack

Table 7-4: 121°C Rubber cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Rubber Cycle

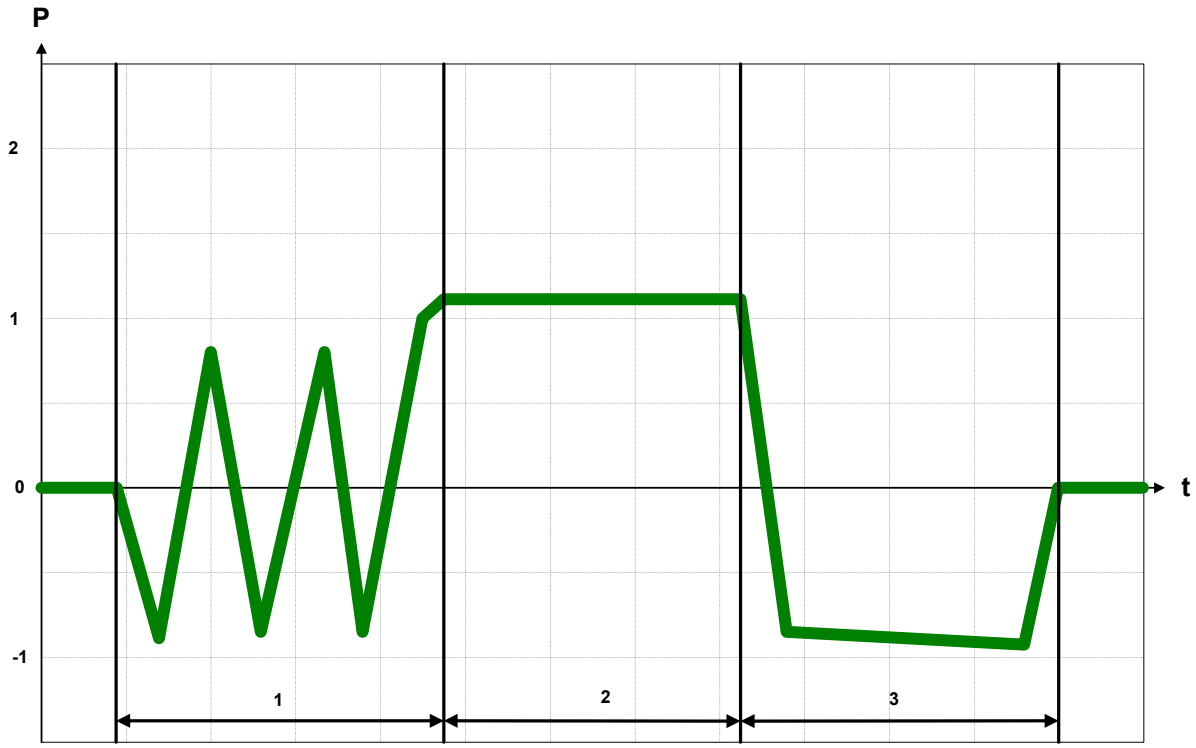


Figure 7-5: Cycle Graph - 121°C Rubber cycle

7.8 134°C WARM-UP & LEAK TEST Cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
4	WARM UP & LEAK TEST	134°C	4 minutes	3 minutes	EMPTY CHAMBER max. Leak rate 1.3mbar/Min

Table 7-5: 134°C Warm-up & Leak Test cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Warm-up & Leak Test Cycle:

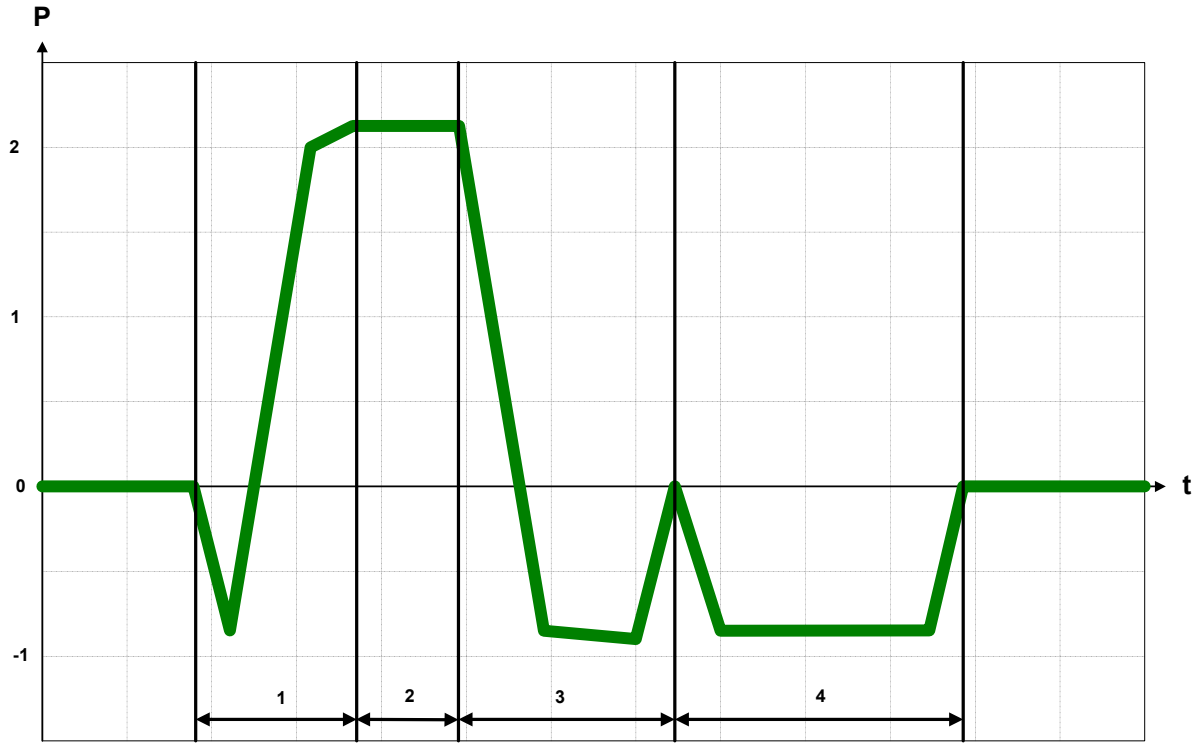


Figure 7-6: Cycle Graph - Warm-up & Leak Test cycle

CAUTION

In order to ensure the proper function of the sterilizer, run a WARM-UP & LEAK TEST cycle daily.

7.9 134°C Bowie-Dick Test

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
5	Bowie-Dick Test	134°C	3.5 minutes	3 minutes	1 Bowie-Dick Test Pack

Table 7-6: Bowie-Dick Test cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Bowie-Dick Test Cycle 134°C .

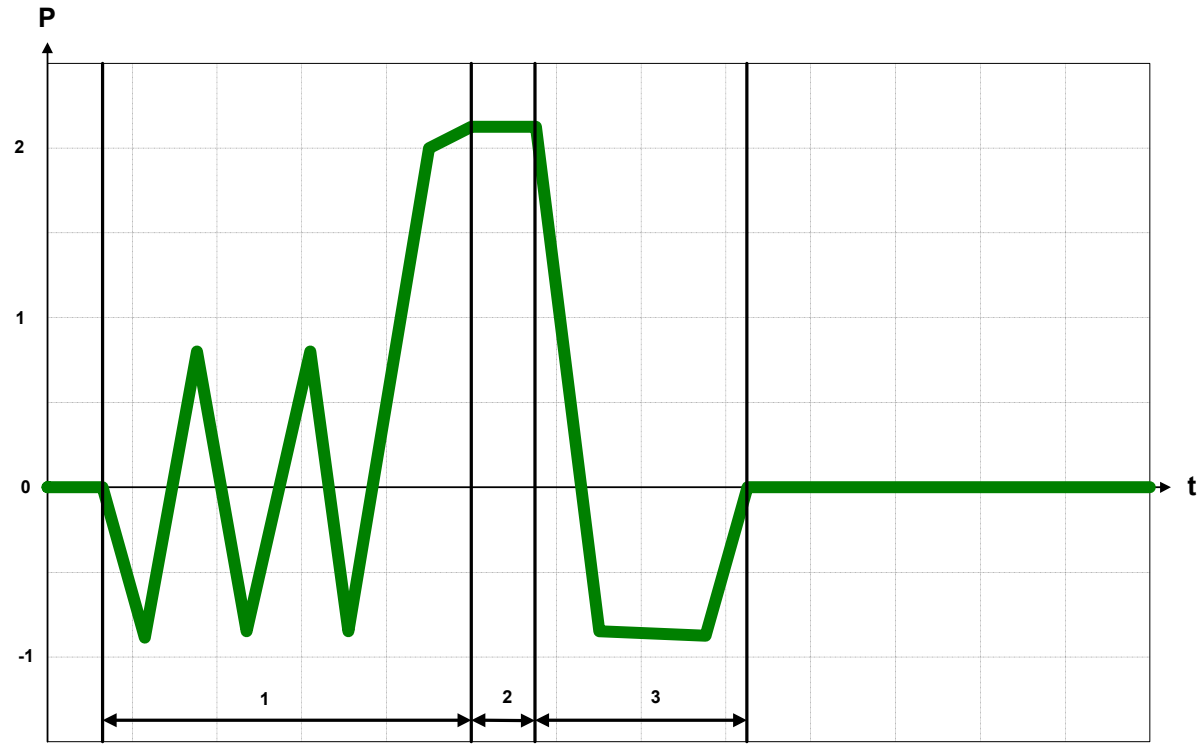


Figure 7-7: Cycle Graph - 134°C Bowie-Dick Test cycle

CAUTION

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

7.10 Leak Test Cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
6	LEAK TEST	-	-	-	EMPTY CHAMBER max. Leak rate 1.3mbar/Min

Table 7-7: Leak Test cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Leak Test Cycle :

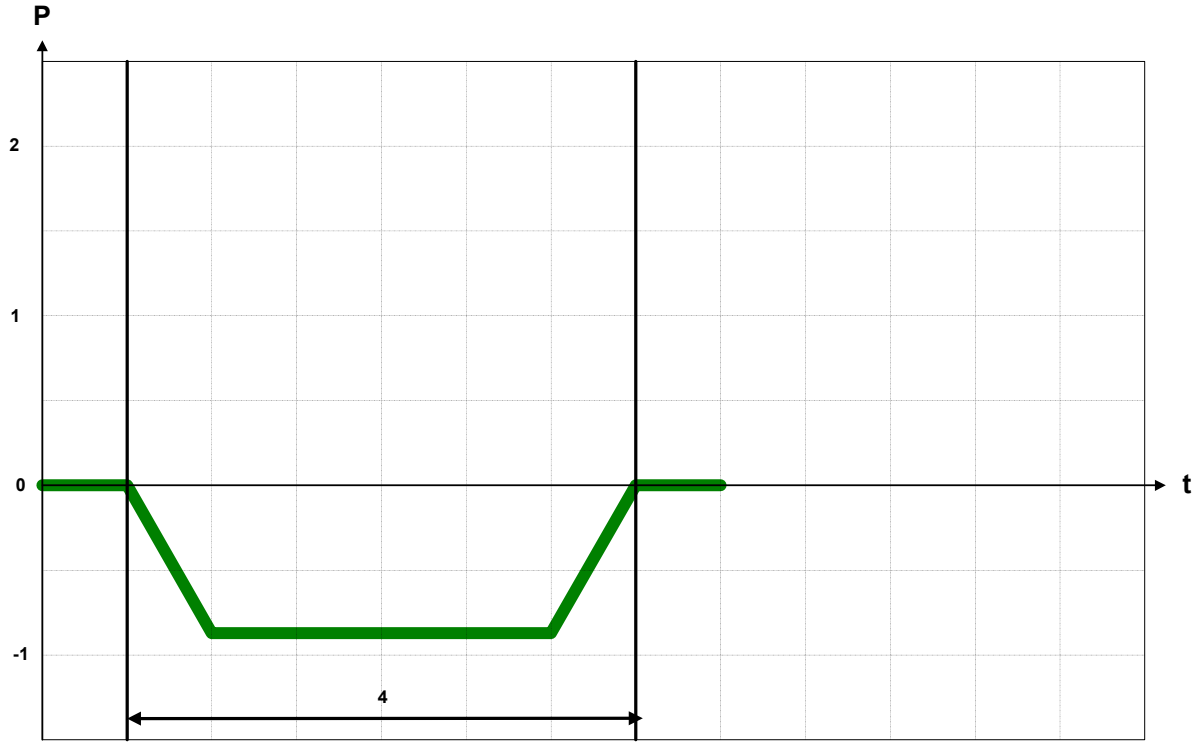


Figure 7-8: Cycle Graph - Leak Test cycle

7.11 134°C Heavy Instruments cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
7	Heavy Instruments 134°C	134°C	5 minutes	11 min. + 4*3 min	Heavy instruments in stainless steel containers, max. 14kg / container (gross weight)

Table 7-8: 134°C Heavy Instruments cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 Heavy Instruments Cycle :

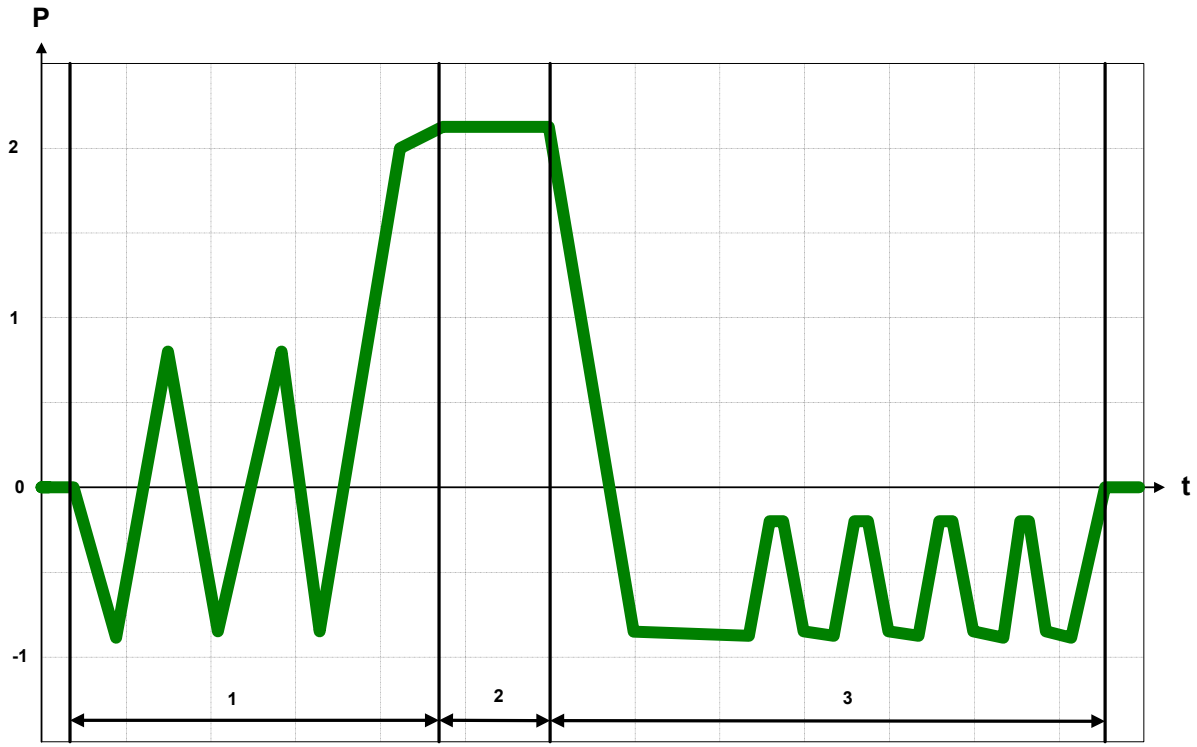


Figure 7-9: Cycle Graph - 134°C Heavy Instruments cycle

7.12 125°C Porous Load Cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
8	Porous load	125°C	20 minutes	6 minutes	Fabric Packs max. 7.5kg / pack

Table 7-9: 125°C Porous Load cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 125°C Porous Load Cycle

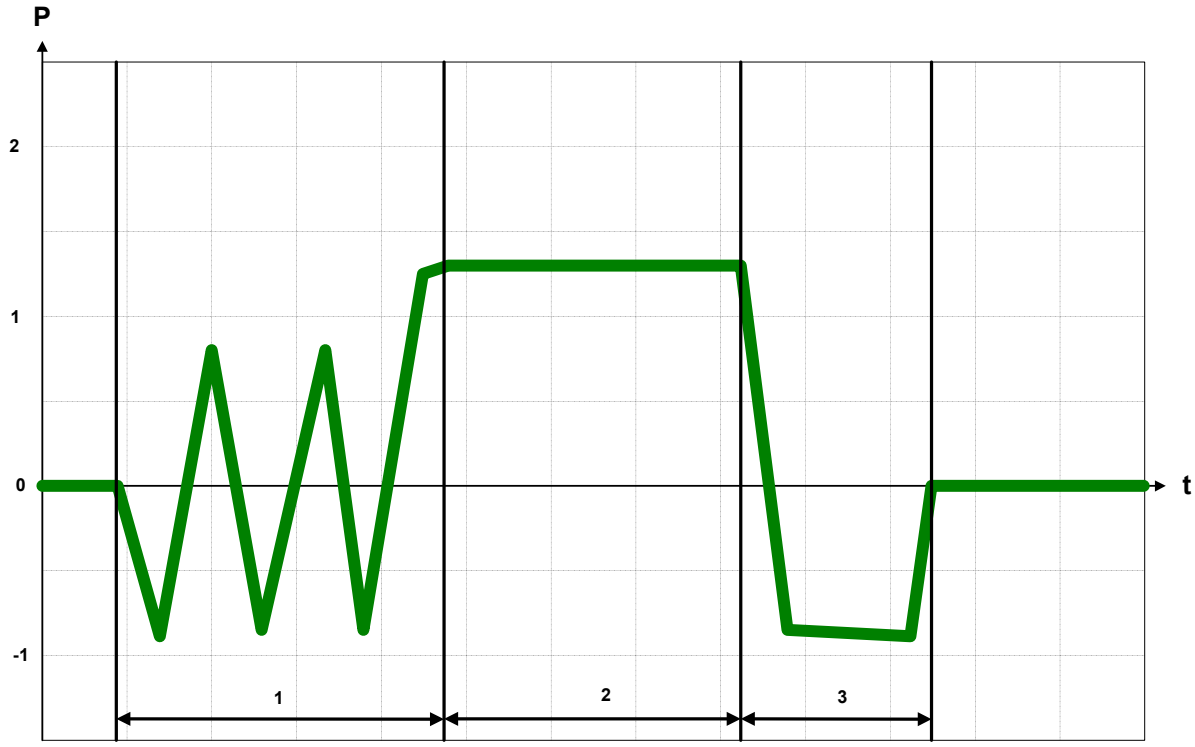


Figure 7-10: Cycle Graph - 125°C Porous Load cycle

7.13 121°C Gravity Cycle

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
9	Gravity121°C	121°C	20 minutes	-	single items, not vacuum proof

Table 7-10: 121°C Gravity cycle

The cycle graph provides a visual representation of the Belimed Steam Sterilizer TOP 5000 121°C Gravity Cycle

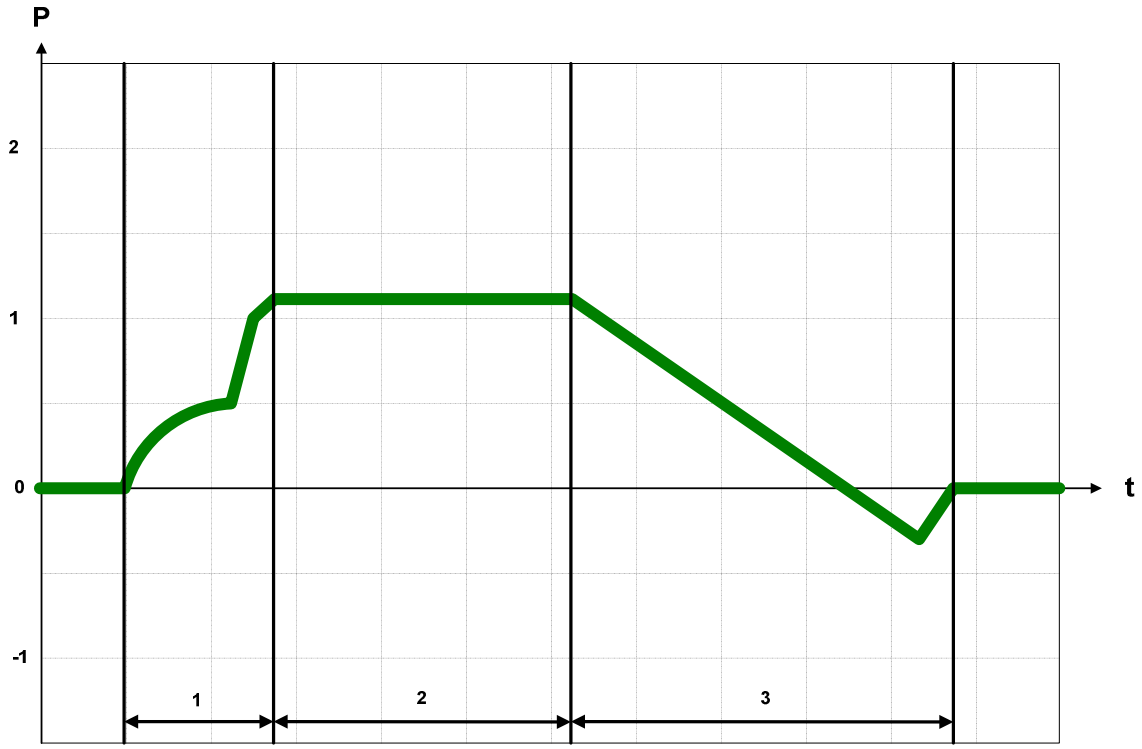


Figure 7-11: Cycle Graph - 121°C Gravity cycle

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 when removing a processed load. Protective gloves and apron should also be worn when reloading sterilizer following previous operation

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 (15°C-25°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 centre 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 8 kg , density factor: not in excess of 0.47kg/dm3, and the size must be limited to 250x500x250mm.
- Single Fabric Test Pack (for validation) should weigh approximately 7 kg and the size must be limited to 220x300x250mm.

Notes:

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

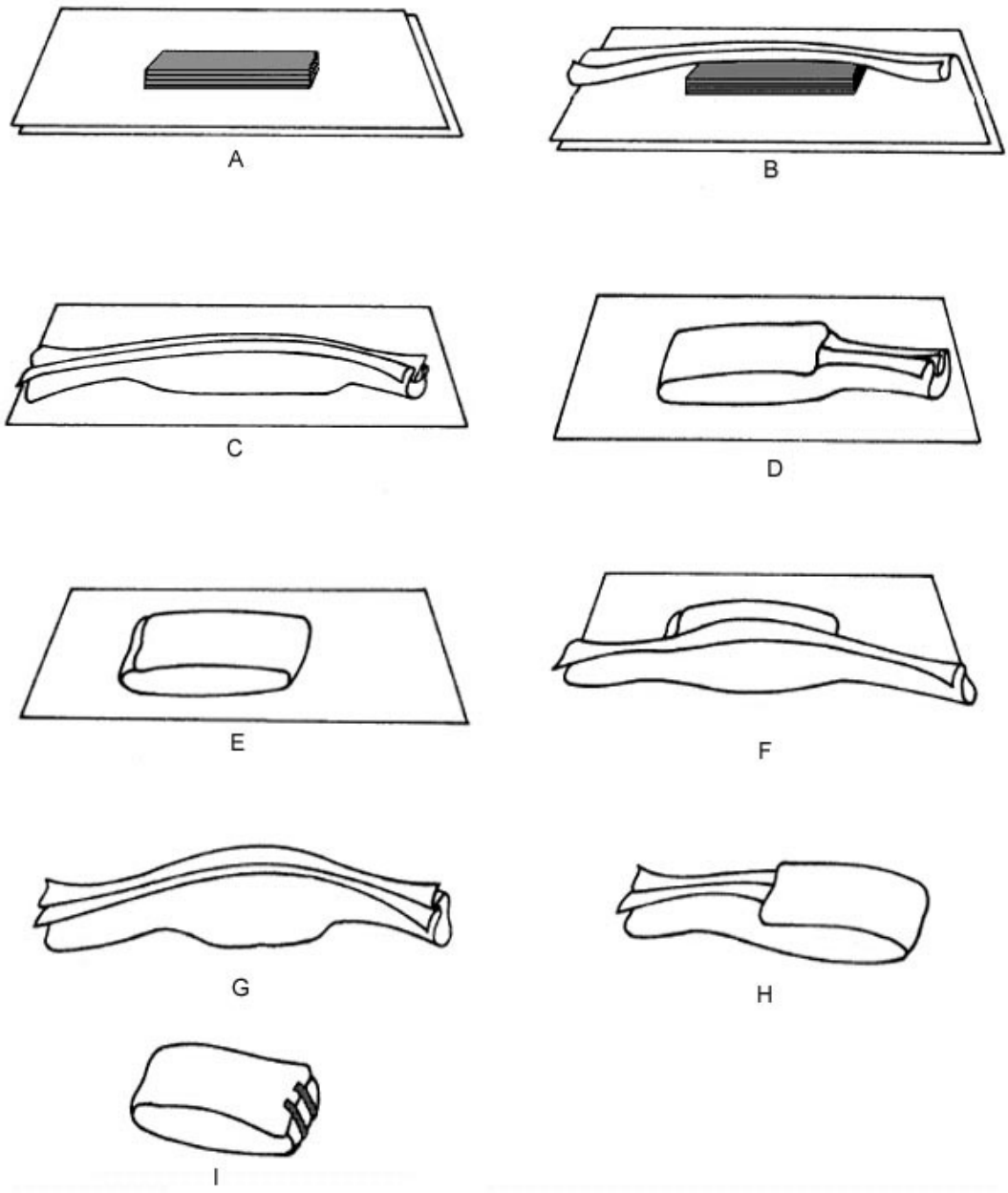


Figure 8-1: Double-wrapping: Square fold

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 5-8 kg for minimising moisture retention. The maximum weight must not exceed 10kg.

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 6-8 kg for minimising moisture retention.

Note:

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

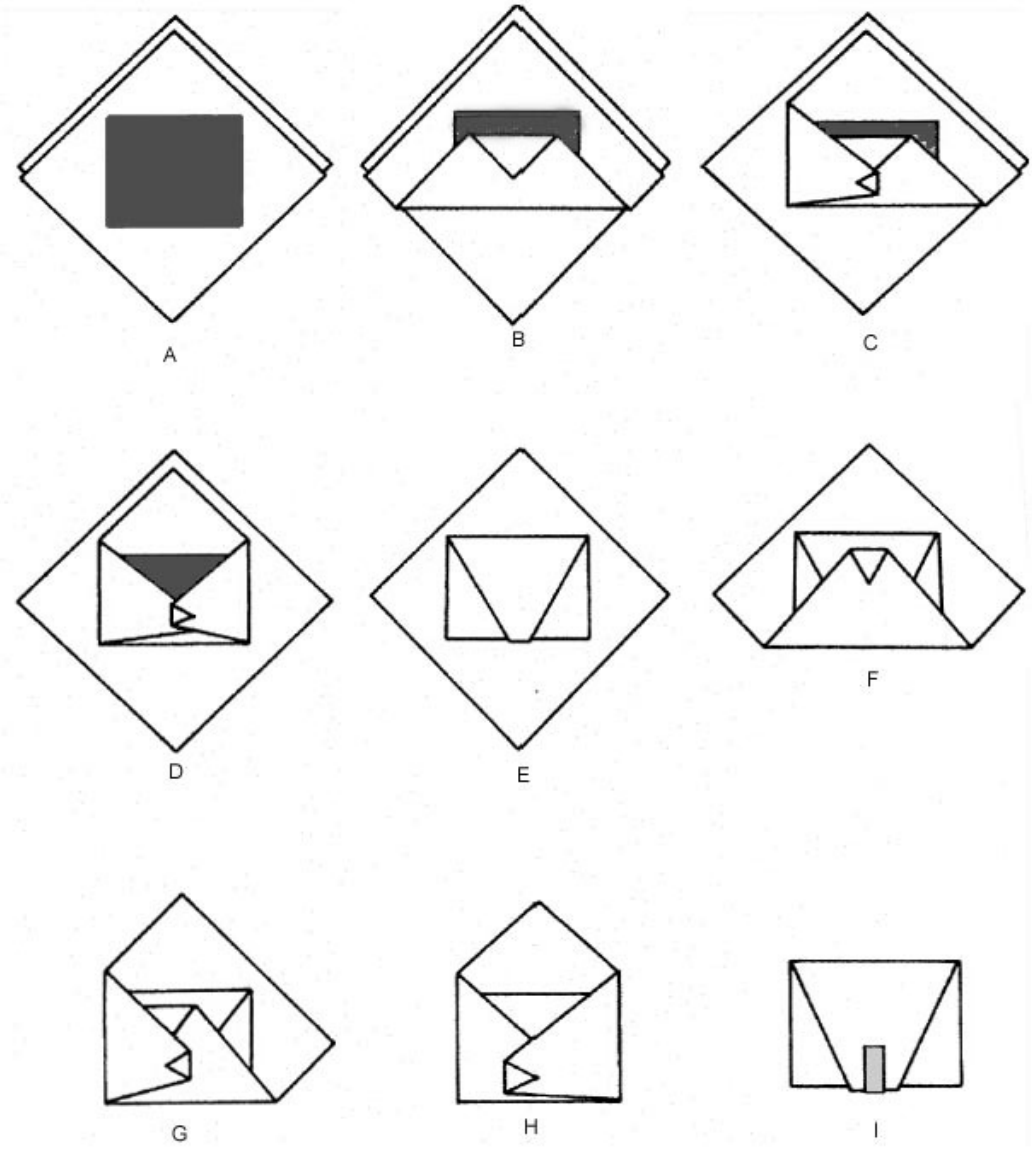


Figure 8-2: Double-wrapping: Envelope fold

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).

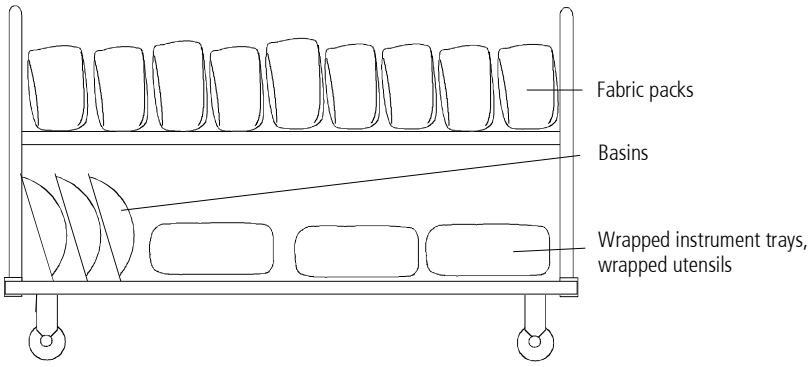


Figure 8-3: Loading cart with combined (solid) load

8.1.6 Steam sterilization cycles

Cycle no. 1 and 2 is recommended for full load fabric packs, instrument trays, utensils.
Cycle no. 3 for is recommended for rubber load.

No.	CYCLE	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
1	Instruments 134°C	134°C	4 minutes	25 minutes	Instrument Trays 7-8kg / StE
2	Fabric packs 134°C	134°C	4 minutes	6 minutes	Fabric Packs
3	Rubber 121°C	121°C	20 min.	6 minutes	Rubber

Table 8-1: Recommended solid cycles

Model	Sterilizer Chamber Size W x H x D (mm)	Wrapped Instrument Trays up to 14 kg each (gross weight) No. of sterile units (StE)	Fabric Packs 250x550x250mm up to 7.5 kg each No. of sterile units (StE)
6-6-6	660 x 750 x 740	4	4
6-6-9	660 x 750 x 1040	6	6
6-6-12	660 x 750 x 1400	8	8
6-6-18	660 x 750 x 2000	12	12

Table 8-2: Recommended solid load

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 134°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 134°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 (e.g. rubber) refer to the manufacturers recommendations and restrictions (steam, temperature, max. sterilization time).
For rubber use only 121°C Rubber cycle

8.2 Guideline for Determining wet packs

8.2.1 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.

8.2.2 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

8.2.3 Moisture retention acceptance criteria

The EN285 1994 sets the following acceptance criteria:

8.2.3.1 Fabric packs

Moisture retained by the fabric test pack must cause no more than 1% 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 in the load must cause no more than a 0.2% increase in pre-sterilization weight.

8.2.3.2 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 and 50% relative humidity) for a minimum of one hour following unloading from the sterilizer.

8.2.4 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

8.3 Sterility maintenance

8.3.1 Cooling

All items removed from the sterilizer should remain on transfer carriage 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

8.3.2 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

8.3.3 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.

8.3.4 Expiration dating

Each item should be labelled 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 labelled with a clearly identifiable expiration date that takes this degradation into account and/or that is based on the device manufacturer's instructions.

9 Operator device TOP 5000

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

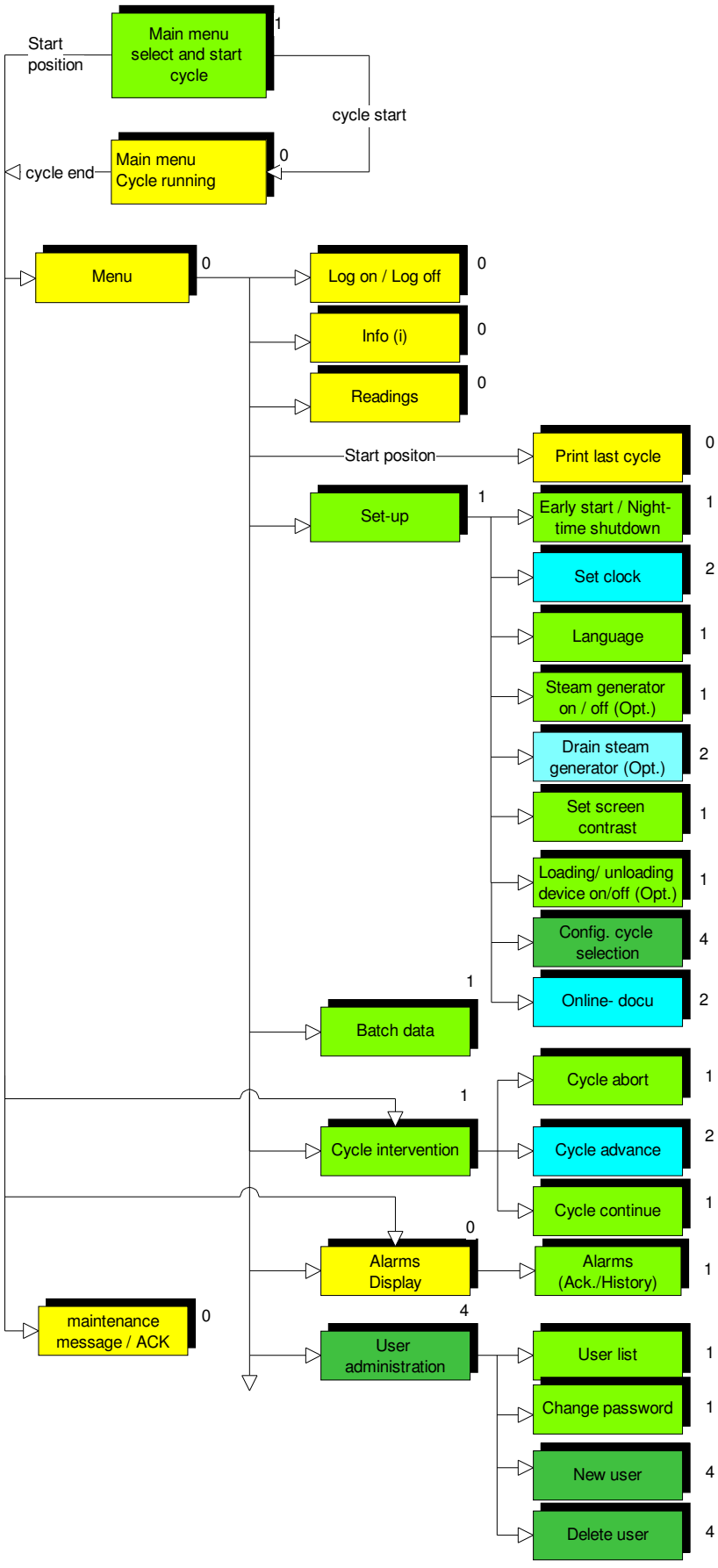
Level 4: Administrator

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.

Table 9-1 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

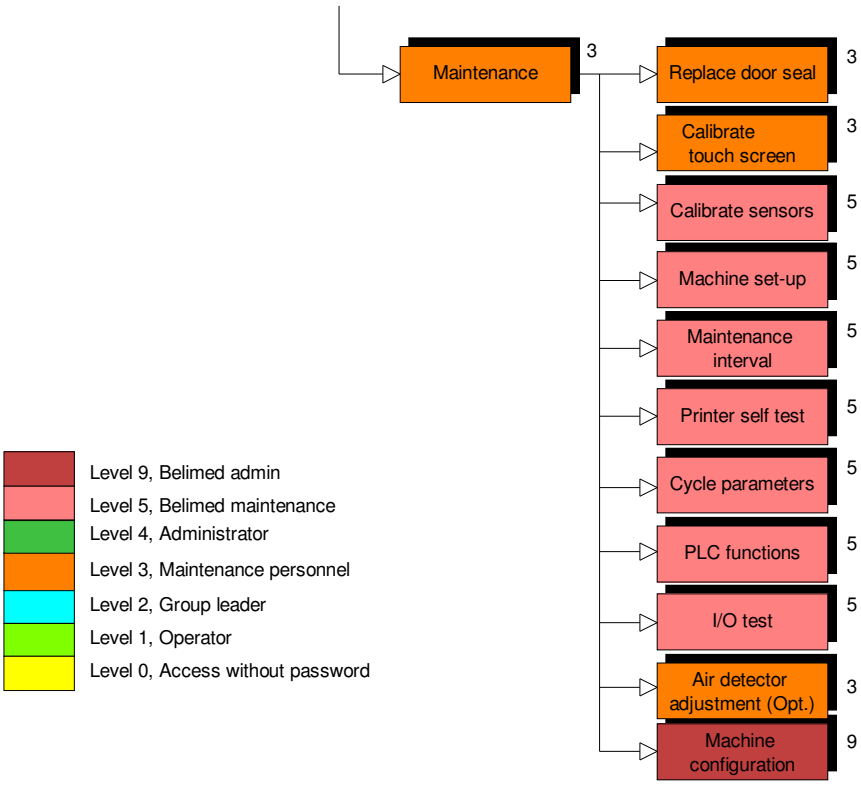


Table 9-1: User menus and rights

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.

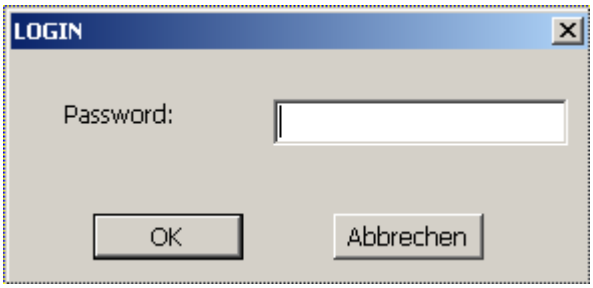


Figure 9-1: Password entry

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).

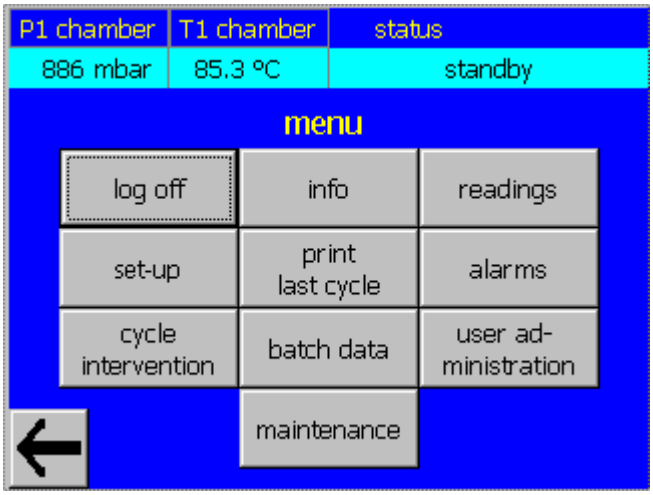


Figure 9-2: Menu display

Press the **'User Administration'** button (Figure 9-2). 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.

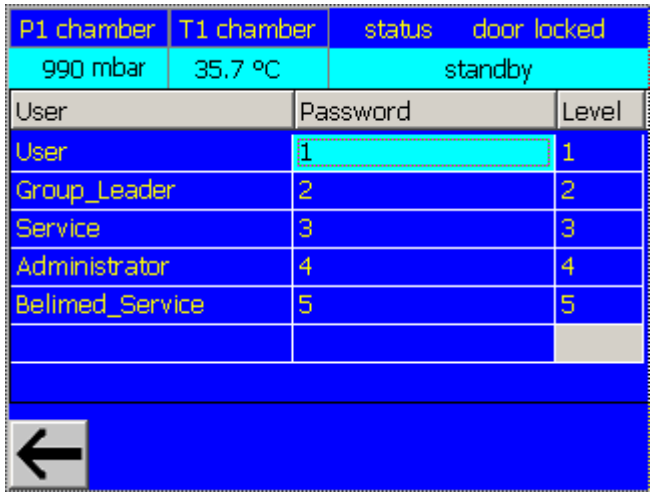


Figure 9-3: User administration

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):

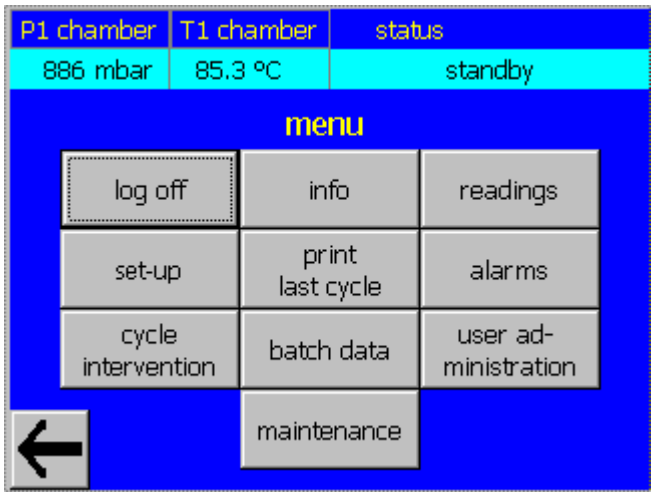


Figure 9-4: Menu display

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)

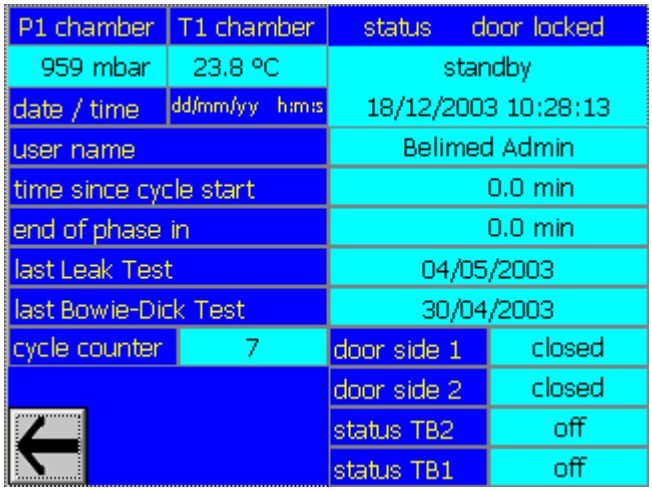


Figure 9-5: Info display

9.3 Readings

Each user can open the Readings display.

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

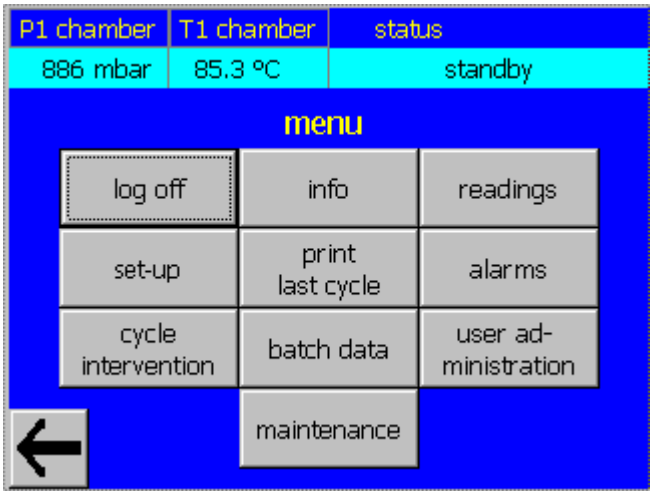


Figure 9-6: Menu display

Press **'readings'** button.

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

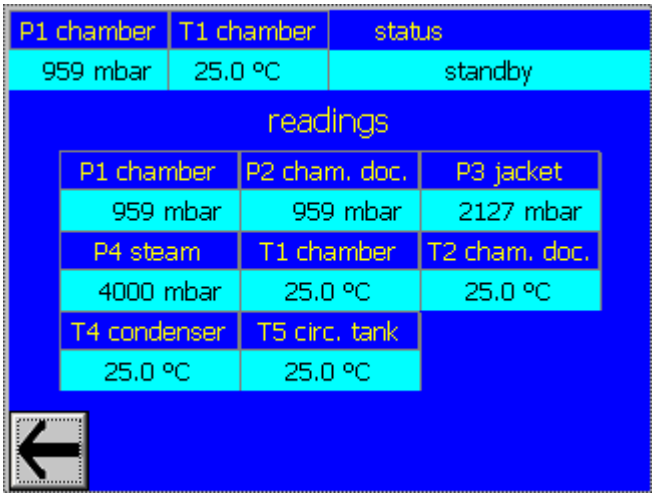


Figure 9-7: Readings display

P1	Chamber pressure - control	P2	Chamber pressure - documentation
P3	Jacket pressure	P4	Steam supply pressure
T1	Chamber temperature - control	T2	Chamber temperature - documentation
T3	Air detector temperature (option)	T4	Condenser temperature - chamber outlet cooling
T5	Circulation tank temperature - vacuum pump cooling		

9.4 Set-up

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

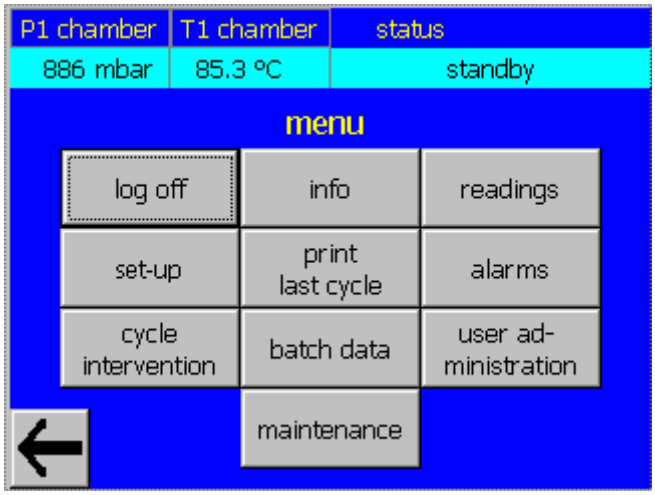


Figure 9-8: Menu display

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 steam generator connected)
- Drain steam generator (access level 2 / option: internal steam generator)
- Configure cycle selection (access level 2)
- Set screen contrast (access level 1)
- Activate on-line documentation
- Automatic loading / unloading device on/off (access level 1 / option)

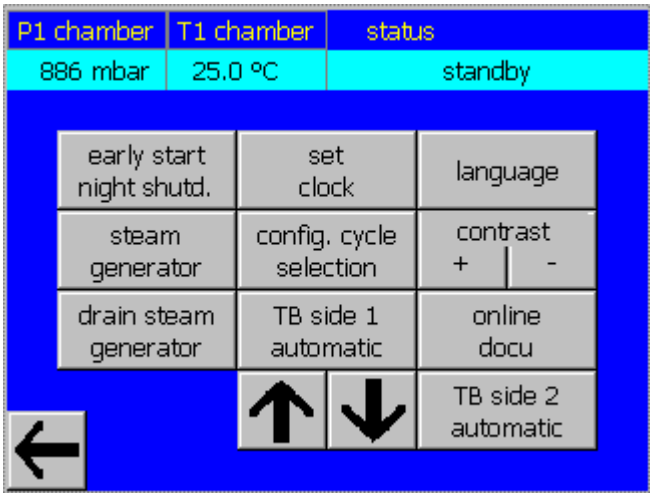


Figure 9-9: Set-up display

9.4.1 Early start / night-time shutdown

Press **'early start / night shutd.**' button. The display shows the input-mask (refer to Figure 9-11):

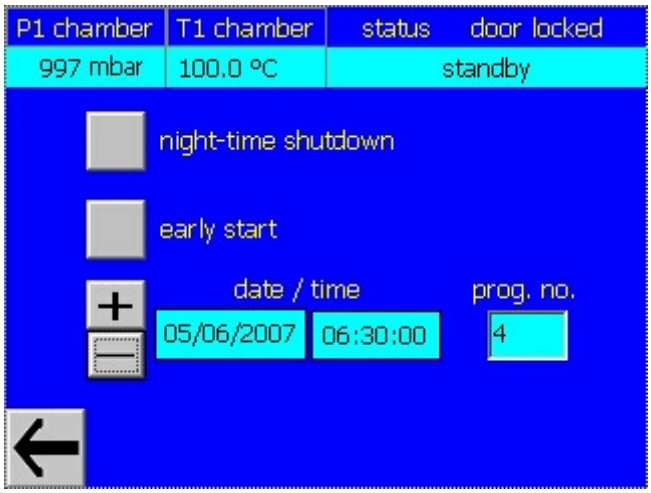


Figure 9-10: Early start / night-time shutdown display

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.

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 **'prog. no.'** and activate **'early start'** button (left side).
With the keys **+** and **-** the starting date can be selected gradually.

The sterilizer goes into a sleep mode (the display is turned off). At the pre-set early start time the sterilizer goes into an active mode, the operating panel display is turned on and the pre-selected cycle starts. The system suggests the date of the next day and the last pre-set time.
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: MM/DD/YY hh:mm:ss
Legend:

MM:	Month (1..12)	DD:	Day of the month (1..31)	YY:	Year (00..99)
hh:	hour 1..12	mm:	minute (0..59)	ss:	second (0..59) xx: AM or PM

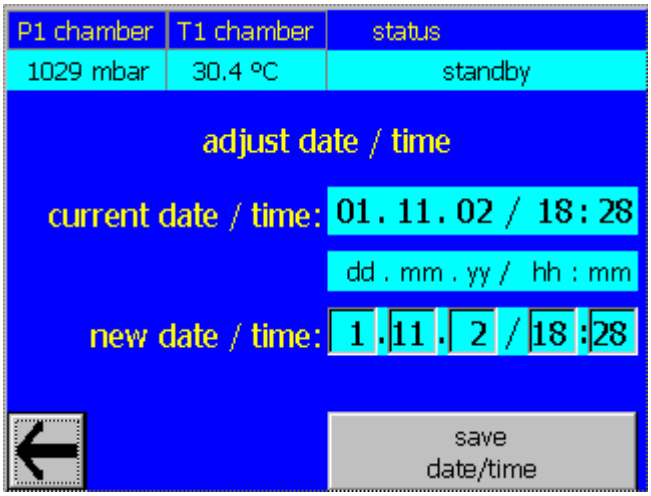


Figure 9-11: Set clock display

Press **'save date/time'** button to set the new date/time

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.

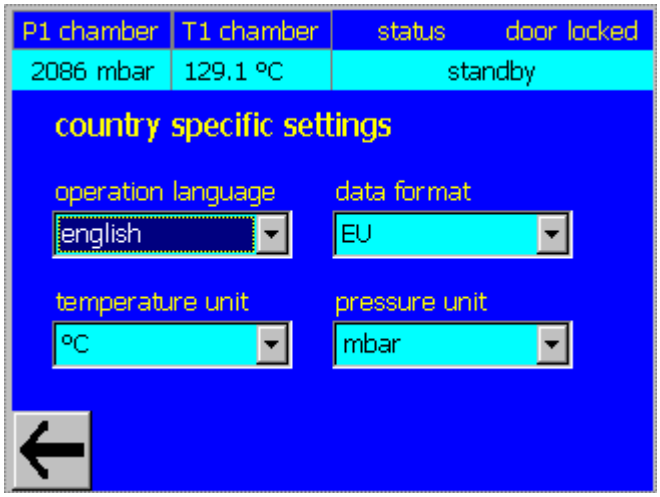


Figure 9-12: Language and units display

9.4.4 Steam generator

If the steam generator can be activated form the sterilizer (option) 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 selectable cycles by a user can be activated (green) or locked (red).
- Cycle start only after entering a password by the operator (set: yes)
- Automatic logon with user name 'Sytem' using level 1 (set: yes).

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

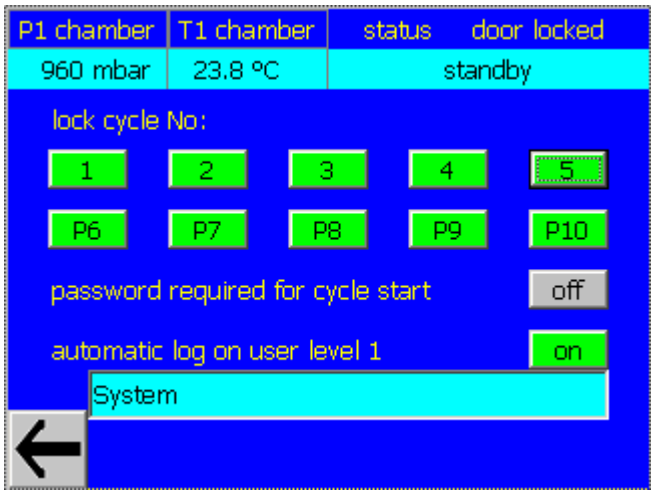


Figure 9-13: Configure cycle selection

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.

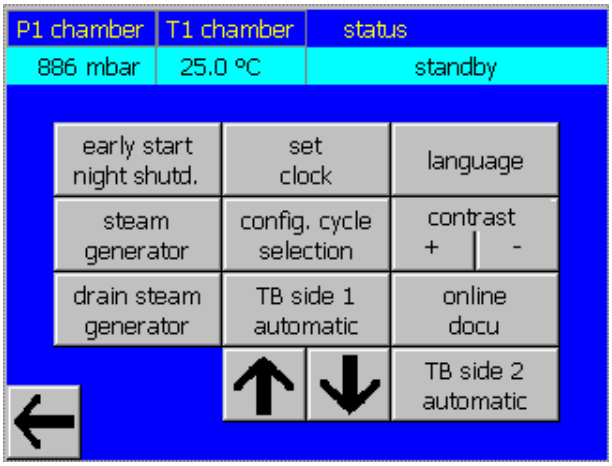


Figure 9-14: Set-up display

9.4.8 Online documentation

If there is an external PC- based documentation system ICS 8535 installed, the built-in printer can be turned off (refer to Figure 9-14). In case of a breakdown of the system ICS 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 9-15):
Press **'print last cycle'** button and a cycle documentation copy is printed.

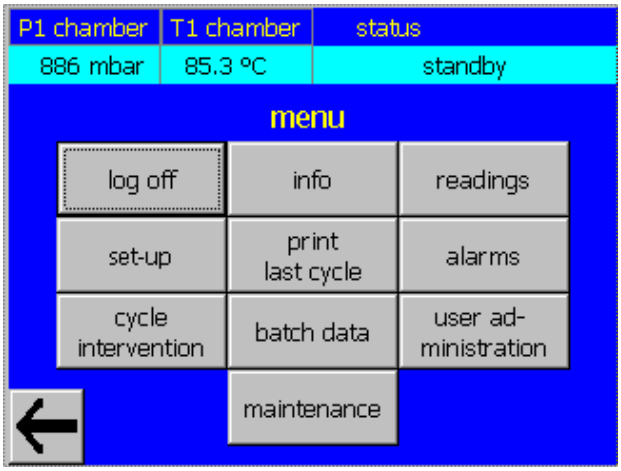


Figure 9-15: Menu print last cycle display

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).

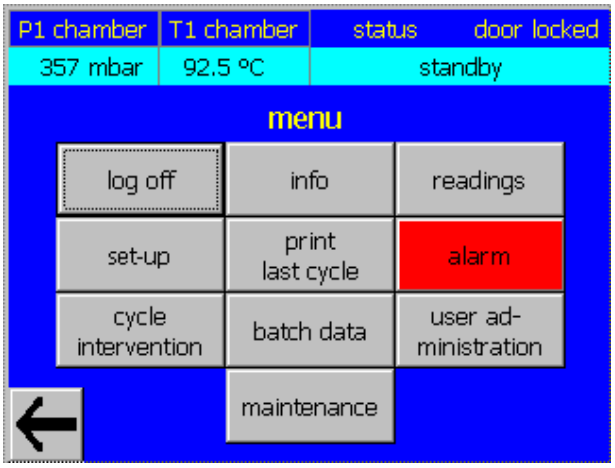


Figure 9-16: Out-of-cycle display with active alarm

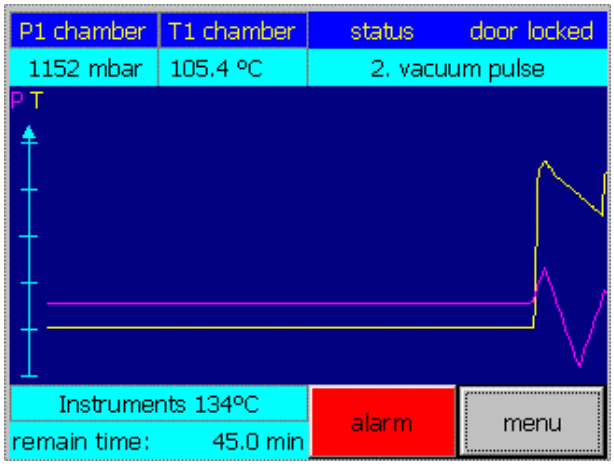


Figure 9-17: In-cycle display with active alarm

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 number/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

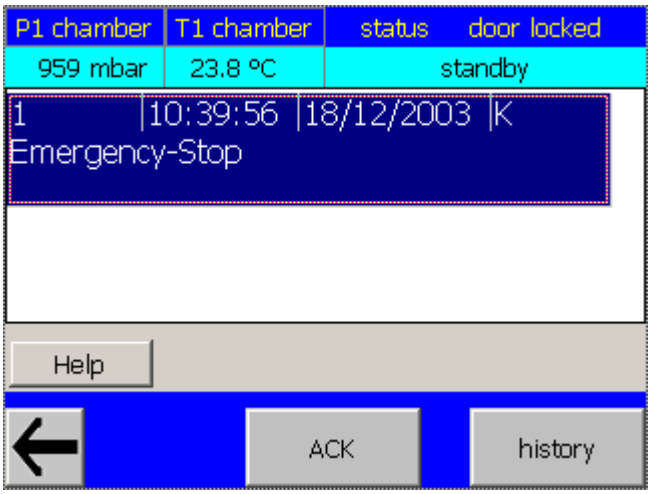


Figure 9-18: Alarm display

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.	
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)	
12	Sensor T2 failed	X
	Temperature sensor T2 signal is out of range (0..150°C)	
13	Sensor T3 failed (Option Air detector)	X
	Temperature sensor T3 signal is out of range (0..150°C)	
14	Sensor T4 failed	X
	Temperature sensor T4 signal is out of range (0..150°C)	
15	Sensor T5 failed	X
	Temperature sensor T5 signal is out of range (0..150°C)	

No.	1st line: Alarm message text 2nd line: Cause	Critical alarm
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	
23	Undertemperature T3 (Option Air detector)	X
	Air detector temperature T3 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	
29	Air Detector Test (Option Air detector)	X
	Air detector doesn't reach set- temperature or is below set-temp. during sterilize phase	
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 pre-set time, steam to jacket valve not open or low steam supply pressure	
33	Steam pressure low	
	Steam supply pressure is below set-point	
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	

No.	1st line: Alarm message text 2nd line: Cause	Critical alarm
39	Door 2 time overrun	
	Door on the non operating end hasn't reached the end position within 20 seconds	
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	
48	Door not unlocked	
	Door seal didn't unlock during door- unlock step	
49	Door not locked	X
	Minimum door seal pressure not reached	
50	Ext. steam generator	
	Alarm signal from external steam generator	
51	Feed pump (Option Internal steam generator)	
	Motor protection switch feed pump has released	
52	Thermo limiter (Option Internal steam generator)	
	Thermo limiter of internal steam generator has released	
53	WFI feed time overrun (Option Internal steam generator)	
	Feed pump monitoring time has exceeded	
54	Minimum water level (Option Internal steam generator)	
	Water level in the steam generator felt below minimum.	
55	Max. pressure steam generator (Option Internal steam generator)	
	Max. steam pressure in steam generator exceeded	
56	WFI supply (Option Internal steam generator)	
	The WFI supply pressure is low (<1bar g)	
57	Heating contactor (Option Internal steam generator)	
	A steam generator heating contactor didn't switch off	
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	
60	Lack of cooling water	
	Low cooling water pressure or cooling water tank empty	
61	Overtemperature T4	X
	Temperature in condenser is >80°C	
62	Lack of compressed air	X
	Compressed air pressure is <4 bar g	

No.	1st line: Alarm message text 2nd line: Cause	Critical alarm
64	Time overrun TB1	
	Loading device didn't reach end position within time-limit	
65	Time overrun TB2	
	Unloading device didn't reach end position within time-limit	
76	Connection to printer	
	The PLC doesn't receive telegrams form printer interface	
78	No connection to system ICS 8535	
	The PLC doesn't receive telegrams form documentation system ICS 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):

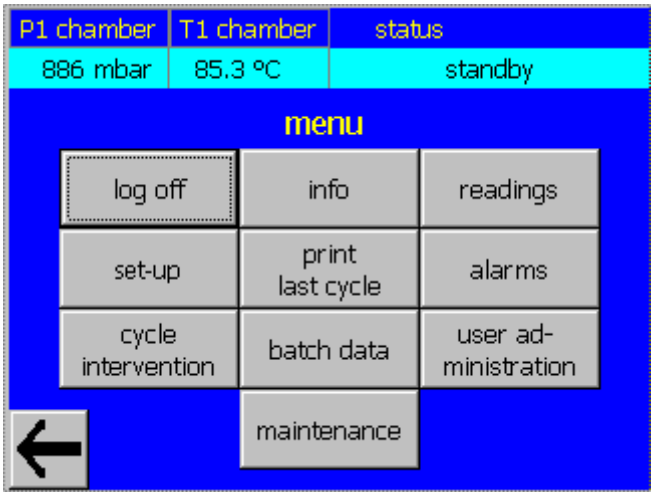


Figure 9-19: Menu display

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

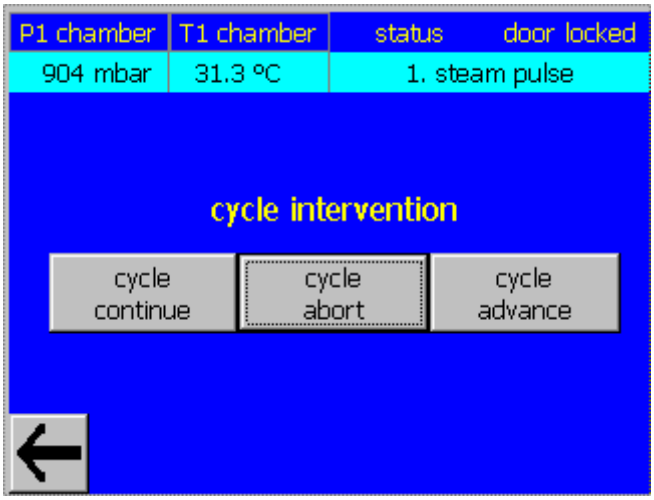


Figure 9-20: Cycle intervention display

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.

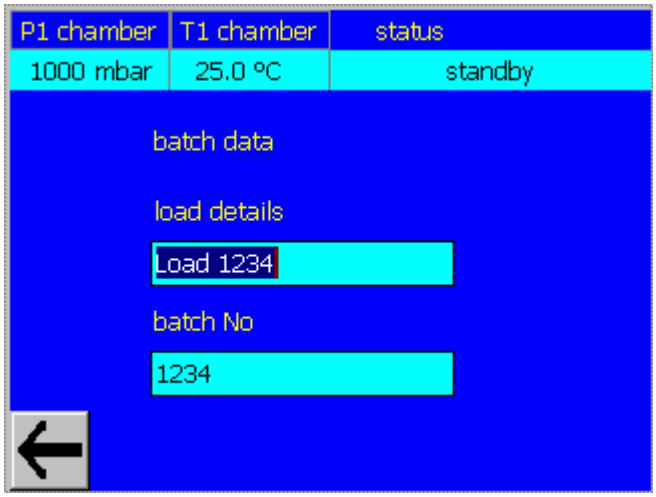


Figure 9-21: manual batch data entry

9.8.2 Batch data entry with Documentation system ICS 8535-BC

An optional PC- based cycle documentation system ICS 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.
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.

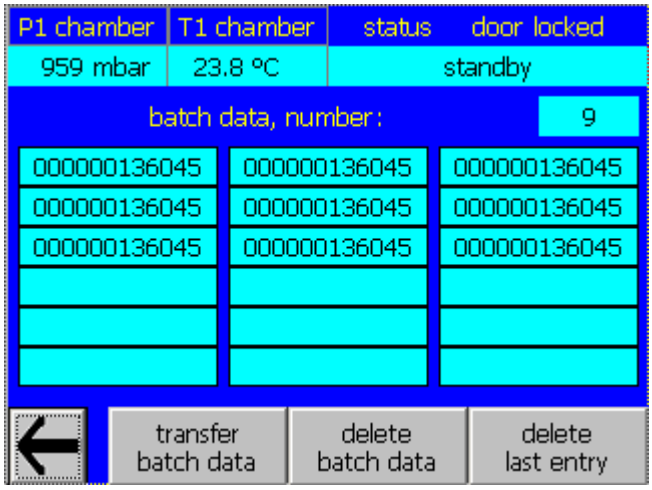


Figure 9-22: Scanner based batch data entry

At cycle start the data is transferred to the system ICS 8535 and the table on the sterilizer is deleted afterwards.
The data can also be transferred several times to system ICS 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.

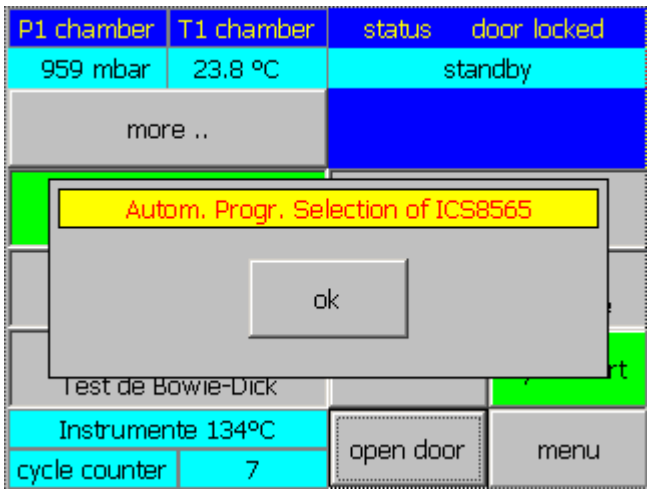


Figure 9-23: Automatic program selection by ICS 8565

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).

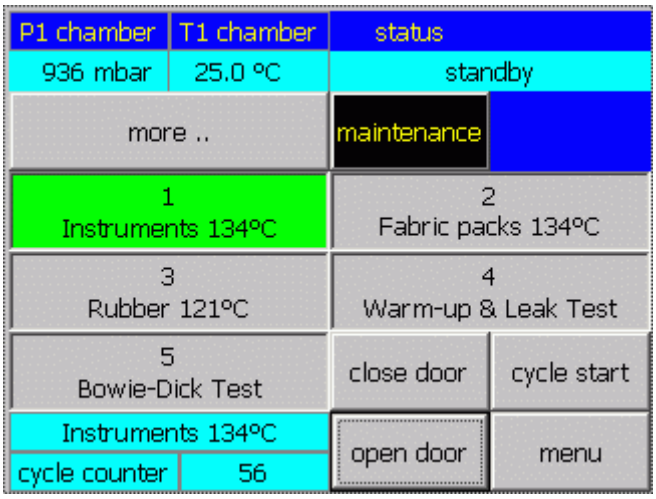


Figure 9-24: Out-of-cycle display with maintenance message

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).

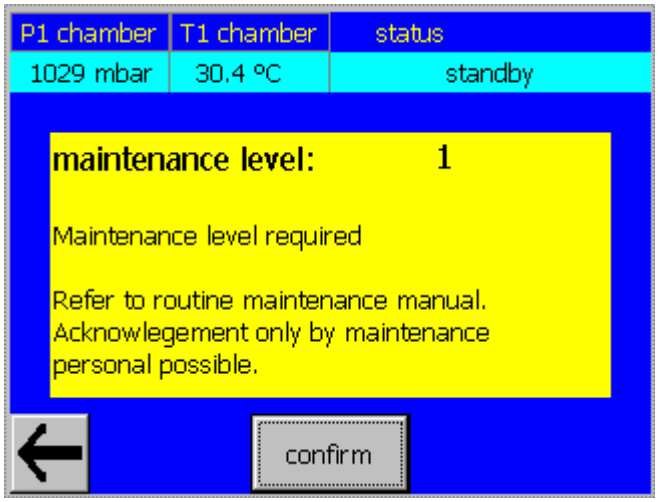


Figure 9-25: Maintenance message display

9.10 Maintenance functions

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

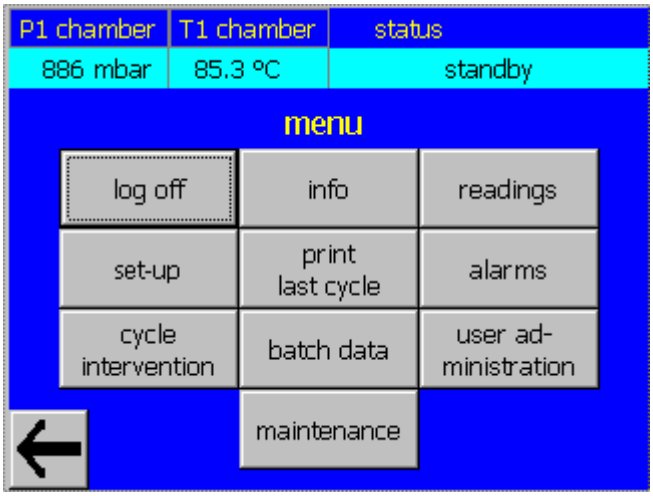


Figure 9-26: Menu display

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)
- Maintenance intervals (access level 5)
- Printer self test (access level 5)
- Cycle parameters (access level 5)
- PLC functions (access level 5)
- I/O Test (Level 5)
- Air Detector (option, access level 5)

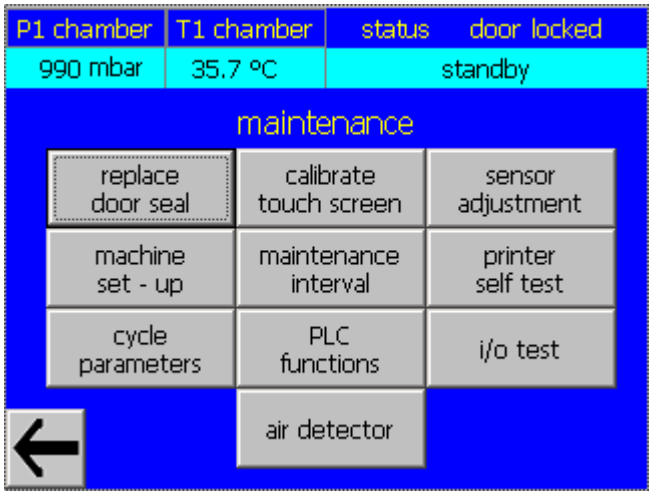


Figure 9-27: Maintenance menu display

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 on the operating end.
Press 'pull back door seal' button and the vacuum pump sucks a vacuum behind the door seal.
Press 'standby' button to set the sterilizer to initial (load) position
Press 'complete' button to set the sterilizer to 'complete' (unload) position to replace the door seal on the non operation end.
For replacing the door seal refer to 'maintenance manual'.

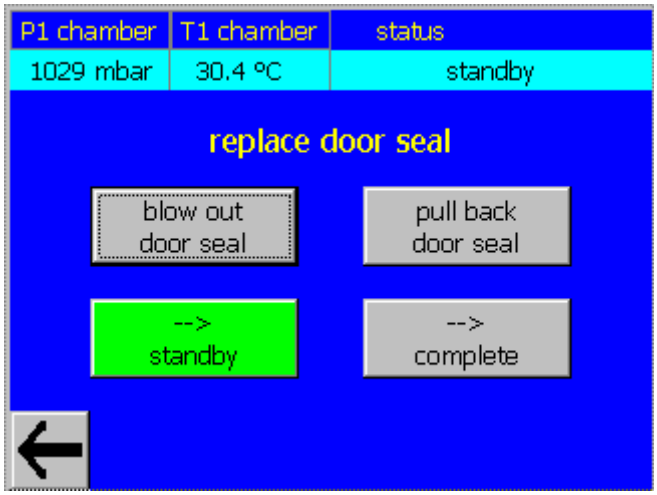


Figure 9-28: Replace door seal display

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 Sensors 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

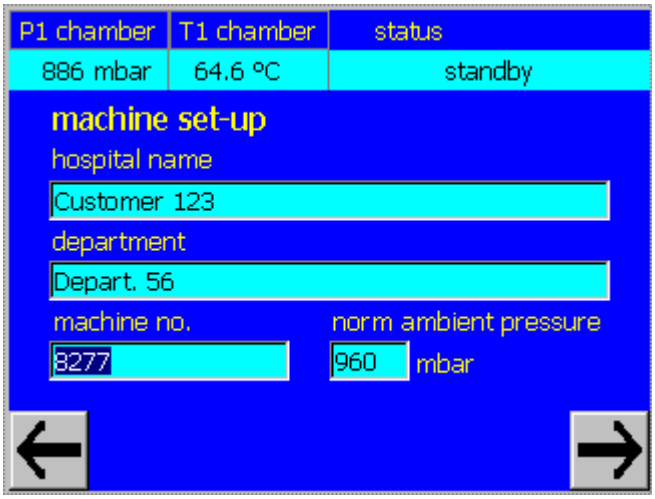


Figure 9-29: Machine set-up display 1

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)

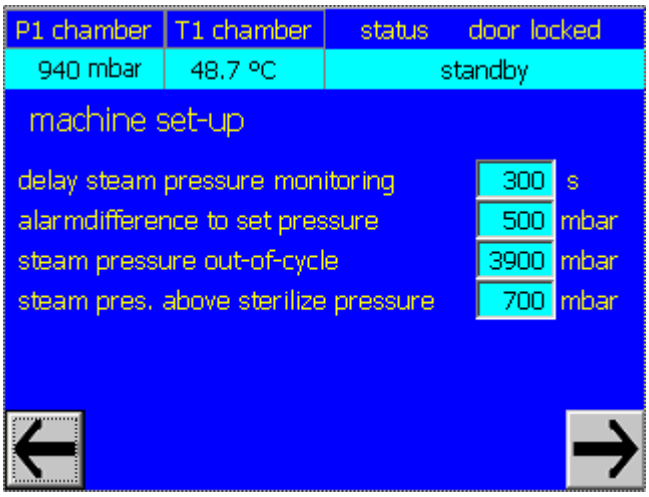


Figure 9-30: Machine set-up display 2

- 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.

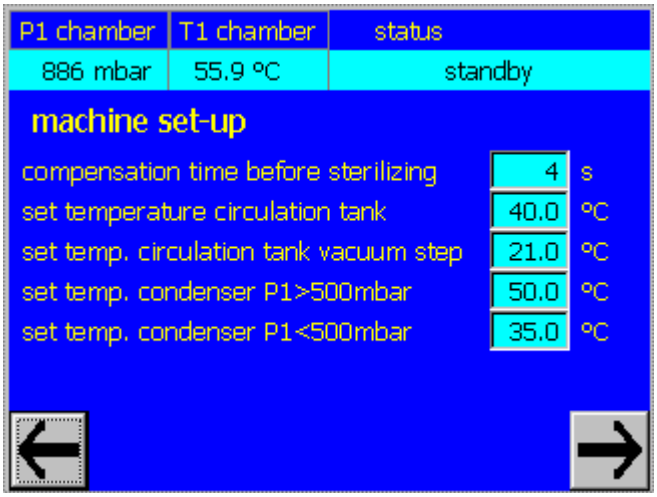


Figure 9-31: Machine set-up display 3

- 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

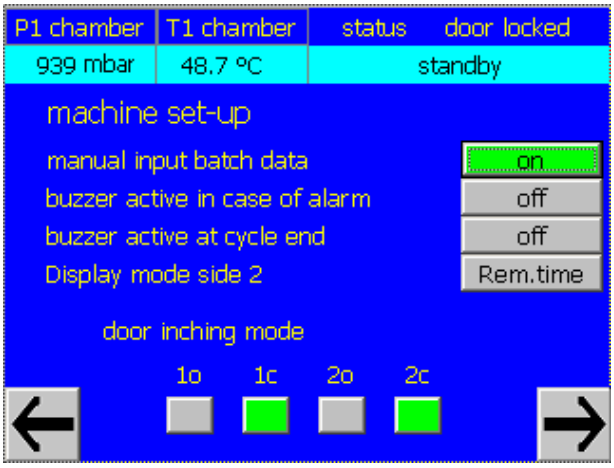


Figure 9-32: Machine set-up display 4

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)

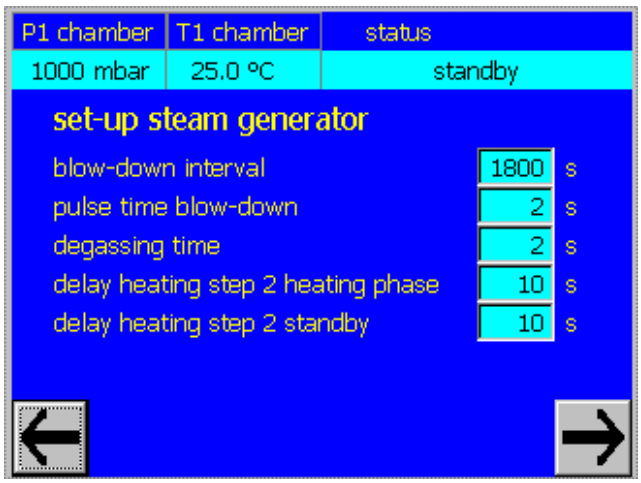


Figure 9-33: Machine set-up display 5

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 gravity: 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

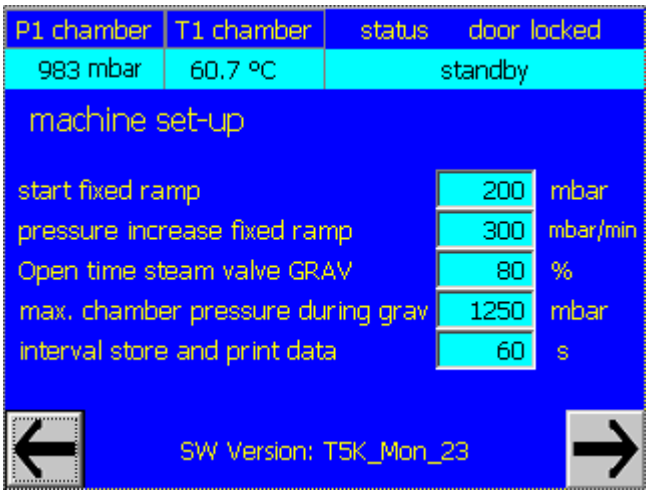


Figure 9-34: Machine set-up display 6

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 ICS 8535 is connected via serial interface (RS485), enter the sterilizer system address communication port address, range 3..20)

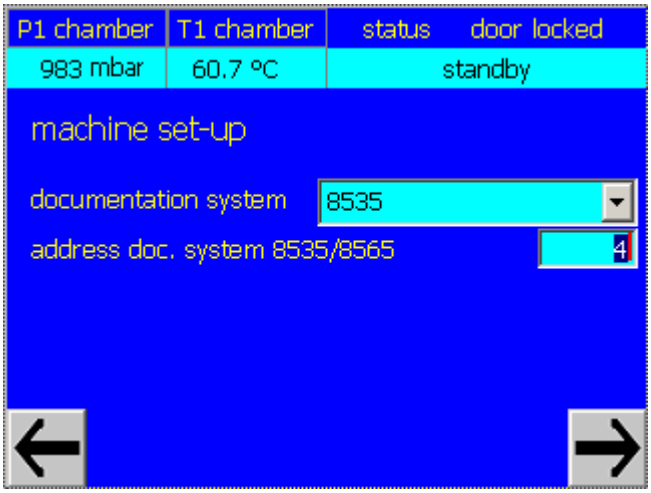


Figure 9-35: Machine set-up ICS 8535

- IP address, documentation system ICS 8535, with Ethernet connection: if the sterilizer is connected to an ICS 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.

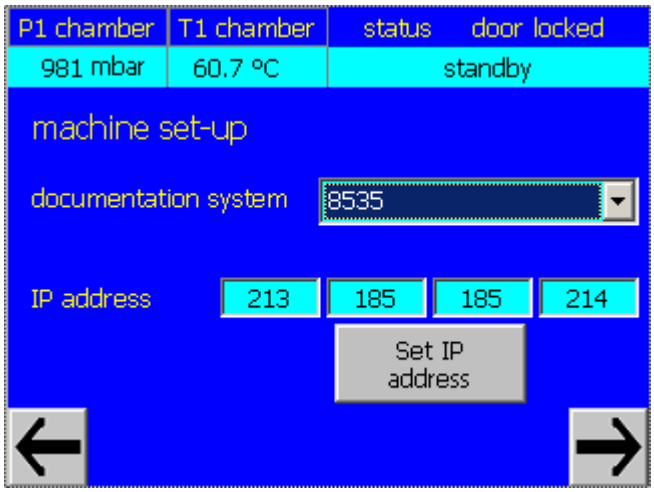


Figure 9-36: Machine set-up ICS 8535 TCP/IP

9.10.5 Maintenance interval

The factory-set maintenance intervals can be changed by Belimed maintenance personnel when special circumstances require shorter intervals (e.g. quality of utilities do not fulfil our specifications).
The standard settings are defined in the 'Maintenance Manual' (Refer to Figure 9-37). The current values are displayed at the right. You can reset the maintenance counters at any time by pressing the "reset" buttons.

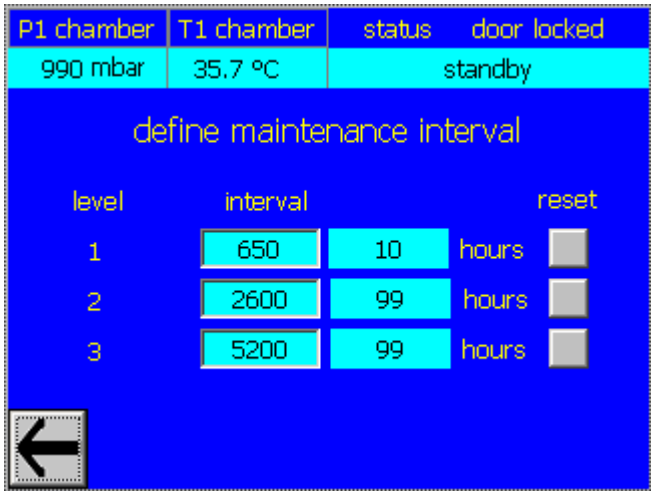


Figure 9-37: Maintenance interval display

9.10.6 Printer self-test

The printer system-test forces a printout (refer to Figure 9-38). 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.

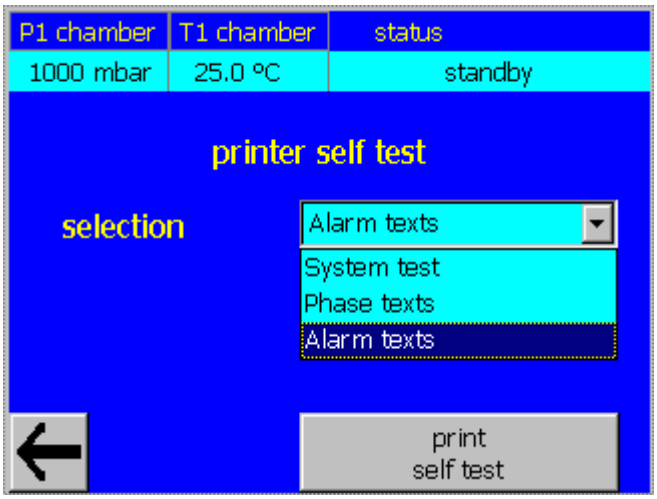


Figure 9-38: Printer self test

9.10.7 Modify Cycle Parameters and copy program

The Belimed maintenance personnel can modify the following cycle parameters (refer to Figure 9-39):

- Cycle name
- Sterilize time
- Dry time

IMPORTANT:

The cycles listed in Table 7-1 have been validated using the techniques documented in EN285. 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 EN285 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.

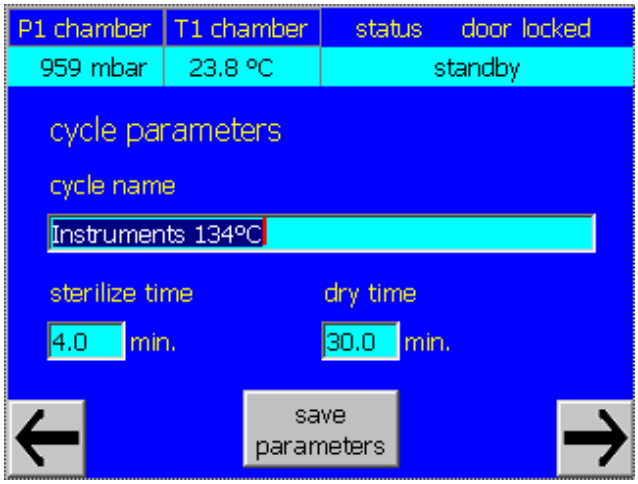


Figure 9-39: Modify cycle parameters display 1

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

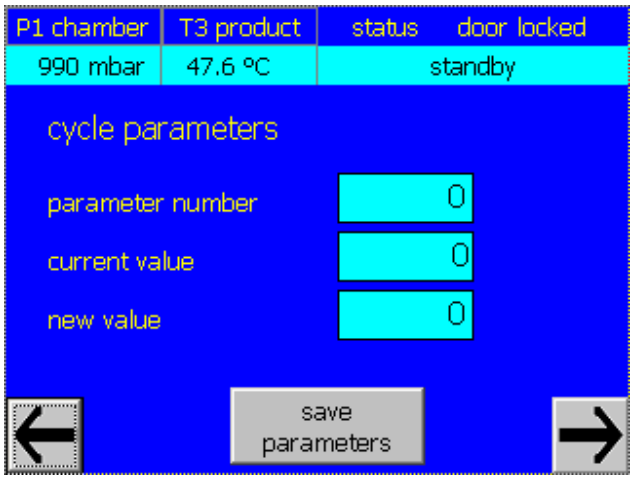


Figure 9-40: Modify cycle parameters display 2

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

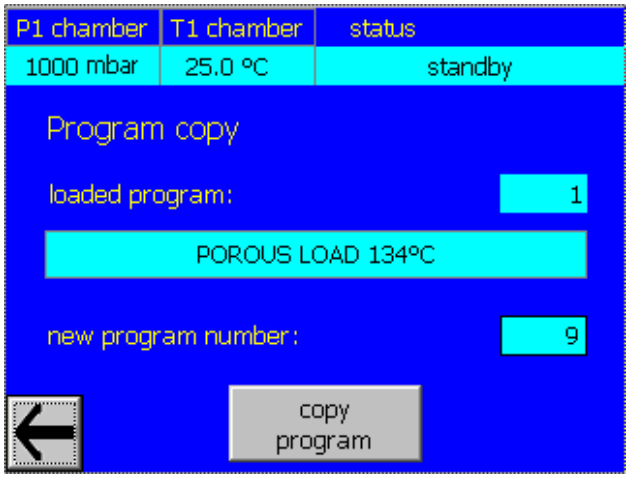


Figure 9-41: Copy program display

Guidance to copy a program:

1. Select the program to be copied. (See chapter 6.4.2 Select a cycle)
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.

9.10.8 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 9-42).

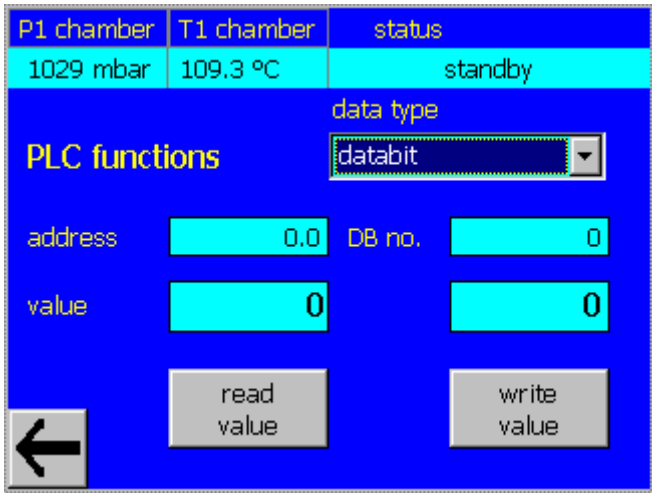


Figure 9-42: PLC functions

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.

9.10.9 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 9-43).
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.

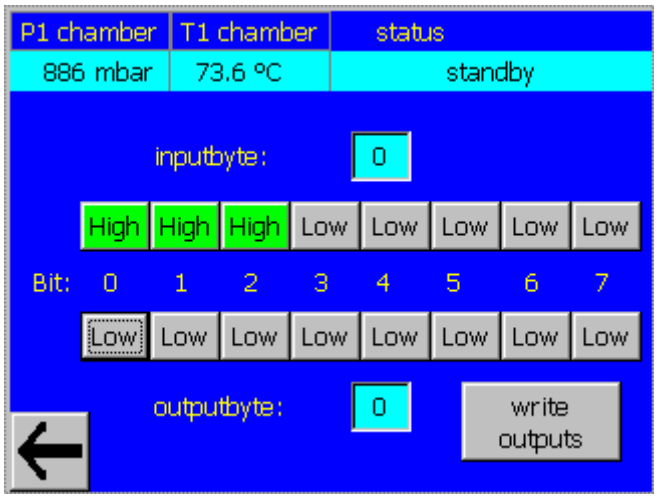


Figure 9-43: I-O Test

9.10.10 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.

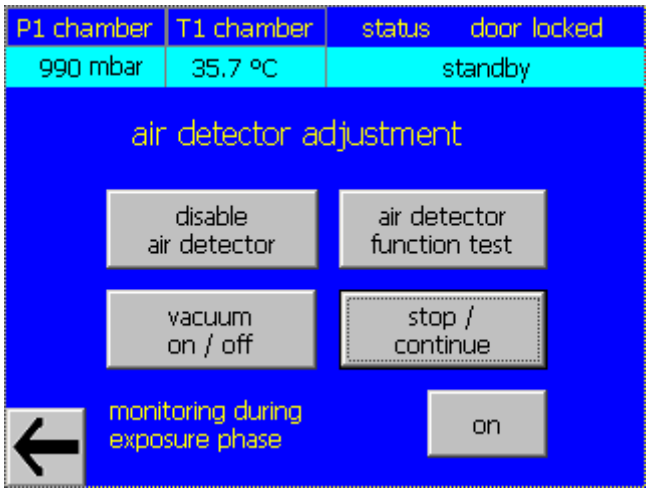


Figure 9-44: Air Detector adjustment

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 utilising B.stearothermophilus is the most reliable form of biological monitoring.
To verify the process insert the biological indicator in a test pack (refer to EN 285 / EN 554 / EN866-3 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

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

Daily run a Bowie-Dick Test 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 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 BELIMED 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).

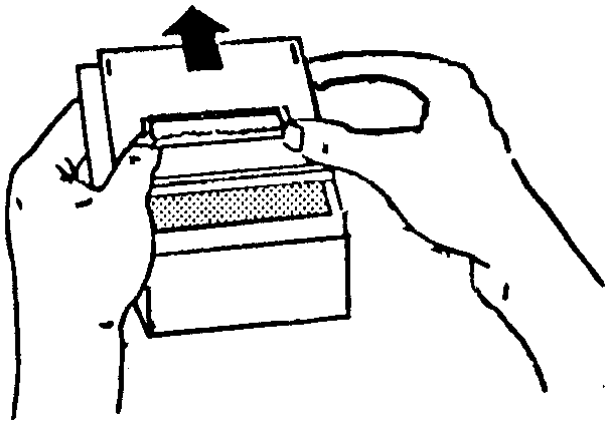


Figure 11-1: Remove printer cover

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)

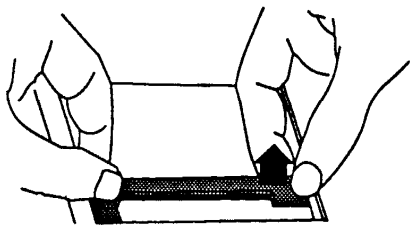


Figure 11-2: Replace ribbon cassette 1

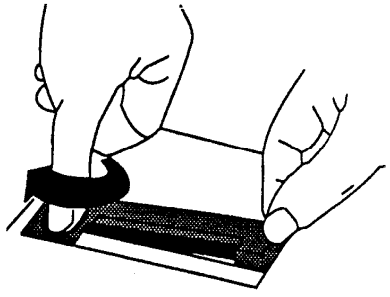


Figure 11-3: Replace ribbon cassette 2

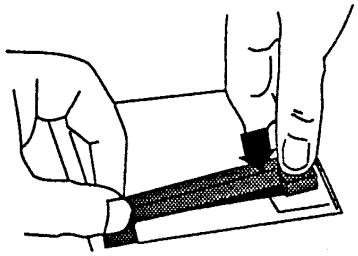


Figure 11-4: Replace ribbon cassette 3

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).

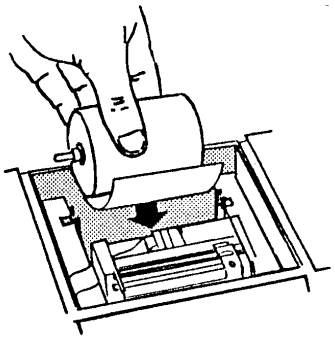


Figure 11-5: Replace paper roll 1

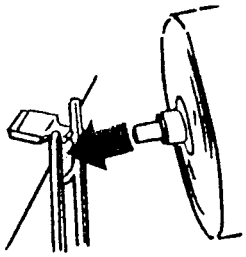


Figure 11-6: Replace paper roll 2

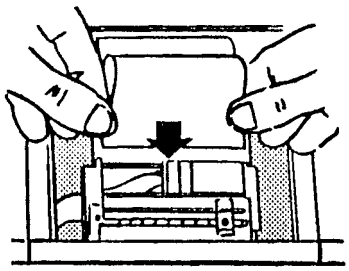


Figure 11-7: Replace paper roll 3

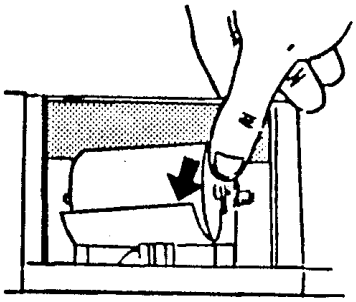


Figure 11-8: Replace paper roll 4

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).

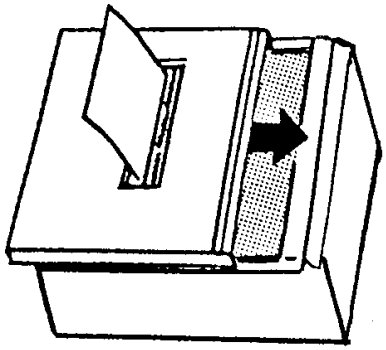


Figure 11-9: Printer: place the cover back

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 EAB TOP (Belimed part no. 3-175).

12 List of Figures

13 List of Tables