

# OPERATION & MAINTENANCE MANUAL

Electronic Table-top Autoclave
(with cooling option)
Model 2840 EL-D

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# 1 GENERAL



Read the Operating Instructions carefully, before beginning any operation on the autoclave!

# 1.1 Incoming Inspection

The autoclave should be unpacked and inspected for mechanical damage upon receipt. Observe packing method and retain packing materials until the unit has been inspected. Mechanical inspection involves checking for signs of physical damage such as: scratched panel surfaces, broken knobs, etc. If damage is apparent, contact your dealer or point of purchase, so that they may notify the manufacturer and file a claim with the appropriate carrier. All Tuttnauer products are carefully inspected prior to shipment and all reasonable precautions are taken in preparing them for shipment to assure safe arrival at their destination.

# 1.2 Warranty

We certify that this instrument is guaranteed to be free from defects in material and workmanship for one year against faulty components and assembly with the exception of the heaters.

The warranty does not include and does not replace routine treatment and preventive maintenance to be performed according to instructions in sec. 1 .1 (Preventive and Scheduled Maintenance).

Our obligation is limited to replacing the instrument or parts, after our examination, if within one year after the date of shipment they prove to be defective. This warranty does not apply to any instrument that has been subjected to misuse, neglect, accident or improper installation or application, nor shall it extend to products that have been repaired or altered outside the factory without prior authorization from us.

The Autoclave should not be used in a manner not described in this manual!

# 1.3 Warranty Statement

The warranty registration must be completed and returned to our service departments; within fourteen (14) days of purchase or the warranty will be void.

Our Technical Service Depts can be reached at:

**Tuttnauer Europe** b.v., Hoeksteen 11, 4815 PR, Breda, P.O. Box 7191, 4800 GD Breda, Netherlands. ②+31/76-5423510, □Fax: +31/76-5423540, E-mail: info@tuttnauer.nl

# Note:

If there is any difficulty with this instrument, and the solution is not covered in this manual, contact our representative or us first. Do not attempt to service this instrument yourself. Describe the difficulty as clearly as possible so we may be able to diagnose the problem and provide a prompt solution.

If the autoclave is equipped with a printer, send along a copy of the last printout for our inspection. If replacement parts are needed, stipulate the model and serial number of the machine.

No autoclaves will be accepted for repair without proper authorization from us. All transportation charges must be paid both ways by the owner. This warranty will be void if the unit is not purchased from an authorized full service **Tuttnauer** dealer.

# 2 SAFETY INSTRUCTIONS

The autoclave has unique characteristics. Please read and understand the operation instructions before first operation of the autoclave. The following issues may require instructions guidance provided by the manufacturer: how to operate the autoclave, the door safety mechanism, the dangers involved in circumventing safety means, how to ensure that the door is closed, and how to select a correct sterilization program.

Make sure that you know where the main power switch is, where the water cut-off valve is and where the compressed air disconnection valve is located.

Autoclave maintenance is crucial for the correct and efficient function of the device. We enclose a log booklet that includes maintenance recommendations, with every device.

The weekly spore test is part of the preventive maintenance plan, along with the annual validation of the sterilization processes that ensures appropriate temperature dispersion within the chamber.

Never use the autoclave to sterilize corrosive products, such as: acids, bases and phenols, volatile compounds or solutions such ethanol, methanol or chloroform nor radioactive substances.

- 1. Never start using a new autoclave or a new steam generator, before the safety, licensing and authorization department has approved it for use.
- 2. All autoclave users must receive training in proper usage from an experienced employee. Every new employee must undergo a training period under an experienced employee.
- 3. A written procedure must be established for autoclave operation, including: daily safety tests, seal inspection and door hinge inspection, smooth action of the closing mechanism, chamber cleaning, prevention of clogging and preservation from corrosion, what is permitted and what is prohibited for sterilization and choosing a sterilization program.
- 4. Liquids may be sterilized only with the "liquids" program. The container must be covered but not sealed. Sealed bottles may only be sterilized using a special program. The bottle must be either Pyrex or a Borosilicate glass bottle.
- 5. When sterilizing plastic materials, make sure that the item can withstand sterilization temperature. Plastic that melts in the chamber is liable to cause a great deal of damage.
- 6. Individual glass bottles may be placed within an appropriate container that will be placed on a tray. Never place glass bottles on the floor of the autoclave. Never fill more than 2/3 of the bottle volume.
- 7. On closing the autoclave's door, make sure it is properly locked before activating.
- 8. Before withdrawing trays, wear heat resistant gloves.
- 9. Before opening the door, verify that there is no pressure in the chamber.
- 10. Open the door slowly to allow steam to escape and wait 5 minutes before you remove the load. When sterilizing liquids, wait 10 minutes.
- 11. Once a month, ensure that the safety valves are functioning, and once annually a certified tester must conduct pressure chamber safety tests.

- 12. Once annually, or more frequently, effective tests must be performed, i.e., calibration and validation.
- 13. Examine the condition of assemblies on a regular basis. Make sure there are no leaks, breaks, blockages, whistles or strange noises.
- 14. It is required to conduct maintenance operations as instructed.
- 15. Immediately notify the person in charge of any deviation or risk for the proper function of the device.

# 3 TECHNICAL DATA

# 3.1 Introduction

Model 2840 ELC is a table-top sterilizer designed especially for the sterilization of instruments, liquids, and other materials in hospital laboratories, medical laboratories, research institutes, food laboratories and pharmaceutical facilities.

A computerized control unit ensuring a fully automatic sterilization cycle controls the autoclave.

The temperature and pressure are controlled through sensors placed inside and outside the media container or bottles.

A special feature of the ELC series is the option of a fast cooling stage for liquids. In this stage pressure in the chamber is increased by means of compressed air to compensate the fast decreasing of pressure due to the fast cooling. The fast cooling shortens the time required for safe handling of bottles.

Five automatic sterilization programs are available, according to the material to be sterilized.

The sterilizer has multiple built - in safety devices, which provides adequate protection to ensure the safety of operating personnel.

On all models, a printer is an optional addition to the autoclave. The printer prints the preset and actual parameters of the cycle (temperature, time and pressure/vacuum).

The pressure scale, printer option and cooling method can be set up at any time by a technician.

### NOTE:

After operating the sterilizer, brown stains might appear on the bottom of the chamber. These stains are a result of the heating elements that are located at the lower external part of the chamber. The brown color is a common phenomenon, can easily be removed, and will not have any effect on the sterilized goods.

This manual is intended to give the user a general understanding of how the autoclave works and indicates the best ways to operate and take care of it in order to obtain optimum results and a trouble-free operation. After reading this manual, operating the autoclave should be straightforward. However, since the autoclave is built using high technology sensitive components, no attempt should be made by the user or any other unauthorized person to repair or recalibrate it.



Only technical personnel having proper qualifications, holding technical documentation and adequate test instrumentation are authorized to undertake repair or service.

# 3.2 Storage Conditions



The packed or unpacked autoclave shall be retained in indoor conditions!

# 3.3 Operating Conditions



This device is for indoor use only!

The sterilizer should be loaded only with autoclavable material!

The environment shall not exceed an ambient temperature of 40°C and a relative humidity of 85% respectively.



The operation altitude shall not be over 2000 meters (6561 feet) (ambient pressure shall not be lower than 80 kPa (11.6 psi)).

The autoclave shall not be used in a manner not specified in this manual!

Do not use the autoclave in the presence of dangerous gases.

Operate the autoclave only in the manner specified in the manual. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

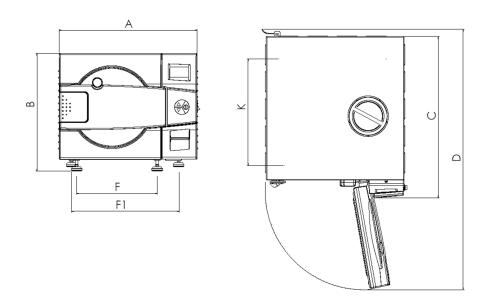
Caution!

Waste water should be brought into the public net in accordance with the local rules or requirements i.e ONLY NON-HAZARDOUS LIQUIDS SHALL BE DISPOSED IN PUBLIC SEWAGE!

# 3.4 Specifications

Property		Value	
Chamber	Dia.	280 mm (11")	
Chamber	Depth	504 mm (19.8")	
Chamber volume		28.5 lit. (7.5 US gal)	
	Width (A)	530 mm (20.8")	
External dimensions	Height (B)	444 mm (17.4")	
	Length (C)	605 mm (23.8")	
Maximum dimensions (door open)	D	950 mm (37")	
Distance between	K	415 mm (16.3")	
supporting legs F - front legs	F	315 mm (12.4")	
F1 - rear legs	F1	400 mm (15.7")	

# **Overall Dimensions**



Property	Value	
Weight	55 kg (121.3 lb)	
Overall Weight	67 kg (147.7 lb)	
Weight per support area	According to overall weight and floor	
(max. load)	loading requirements	
Shipping weight	60 kg (132 lb)	

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Property			Value	
Chinning	Width		63 cm (24.8")	
Shipping dimension	Height		71 cm (28.0")	
S	Lengtl	1	80 cm (35.8")	
3	Volum		0.36 m3 (14.5 ft³)	
Mineral- free water	Max. v	e	5 lit. (1.1 US gal)	
reservoir	Min. water volume		1.5 lit. (0.4 US gal)	
Maximum d (door open)		ons	950 mm (36.6")	
Maximum lo	oad per	item	0.5 kg (1.1 lb)	
Maximum lo	oad per	tray	2.0 kg (4.4 lb)	
Maximum s	olid loa	d	5.4 kg (12.0 lb)	
		W	212 mm (8.3")	
	Small	Н	21 mm (0.8")	
Tray		L	350 mm (13.7")	
dimension s	Big	W	_	
5		Н	_	
		L	_	
Max. Allowable Working pressure (MAWP)			2.8 bar (40 psi)	
No. of trays			5	
IMS cassettes (optional)			4 full & 4 half	

# 3.5 Electrical Data

Specifications	Value
Total Power	2200W
Voltage	208/230VAC / 1 ph
Amperage	10A
Protection against electrical shock	Class I (IEC 60601-1)
Mains supply fluctuation	+/- 10%
Degree of protection by enclosure	IP31

# Note:



In order to avoid any injury by electrical hazard, it is recommended that a ground fault protection device be installed in the electrical panel feeding the autoclave (local codes may make this mandatory).

### 3.6 Utilities

Specifications	Value	
Mineral free water	See table in sec. 3.9.	
Power supply	* 1 phase, 208/230VAC ±10%, 60Hz	
Recommended circuit breaker	15A	

<sup>\*</sup> According to the local network.



### **Attention:**

- A switch or circuit-breaker must be included in the building installation.
  This switch or circuit-breaker shall be in close proximity to the
  equipment, within easy reach of the operator; and marked as the
  disconnecting device for the equipment.
- The electrical net must be protected with a current leakage safety relay.
- The electrical network must comply with local rules or regulations.
- Verify that there is an easy access to the main power switch, to the water cut-off valve and to the current leakage safety relay.

# 3.7 Environment Emission Information

- 1. The peak sound level generated by the autoclave is 65dBa with background noise of 48 dBa.
- 2. The total heat per hour transmitted by the autoclave is <200Wh.

# 3.8 Construction

The main parts of the autoclave are made of materials as indicated below:

- Chamber is built of stainless steel.
- Door is made of stainless steel.
- Trays are made of stainless steel.
- Water reservoir is made of hard plastic material.
- Door handle is made of hard plastic material, which is safe to touch and thermo-insulated.

# 3.9 Loading Capacities

# 3.9.1 Erlenmeyer Flasks

Size	250 ml	300 ml	500 ml	1000 ml
Qty	8	8	4	2

# 3.9.2 Medium Flasks (Schott)

Size	250 ml	500 ml	1000 ml
Qty	10	8	4

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# 3.10 Safety Features

This autoclave includes built-in safety features such as:

- Error message display.
- Temperature dependent door locking system according to European standards.
- Electronic pressure and temperature measurement.
- Safety relief valve to avoid build-up of excessive pressure.
- Door switch enabling operation to be started only when the door is closed.
- Water level safety device.
- Excess temperature protection.

# 3.11 Symbol Description



**Caution!** Consult accompanying documents



Caution! Hot surface.



Caution! Hot steam.



**Protective earth (Ground)** 

# 3.12 Water Quality

The distilled or mineral – free water supplied to the autoclave should have the physical characteristics and maximum acceptable level of contaminants indicated in the table below:

# Characteristics and Maximum acceptable contaminants levels in steam for sterlizers

(According to EN 13060:2004).

(recording to Livisous.2004).				
Element	Condensate – allowable content			
Silicium oxide. SiO <sub>2</sub>	≤0.1 mg/kg			
Iron	≤0.1 mg/kg			
Cadmium	≤0.005 mg/kg			
Lead	$\leq 0.05$ mg/kg			
Rest of metals except iron, cadmium, lead	≤0.1 mg/kg			
Chloride (Cl)	≤0.1 mg/kg			
Phosphate (P <sub>2</sub> O <sub>5</sub> )	≤0.1 mg/kg			
Conductivity (at 20°C)	≤3 μs/cm			
pH value (degree of acidity)	5 to 7			
Appearance	Colourless clean without sediment			
Hardness ( $\Sigma$ Ions of alkaline earth)	≤0.02 mmol/l			

Compliance with the above data should be tested in accordance with acknowledged analytical methods, by an authorized laboratory.

# **Attention:**



We recommend testing the water quality once a month. The use of water for autoclaves that does not comply with the table above may have severe impact on the working life of the sterilizer and can invalidate the manufacturer's guarantee.

# 3.13 Directives and Standards

Every autoclave meets the provisions of the following Directives and is constructed in compliance with the following Standards:

# 3.13.1 Technical Directives

- 1. Pressure Equipment Directive 97/23/EC.
- 2. Council Directive for low voltage equipment 73/23/EEC.

# 3.13.2 Technical Standards

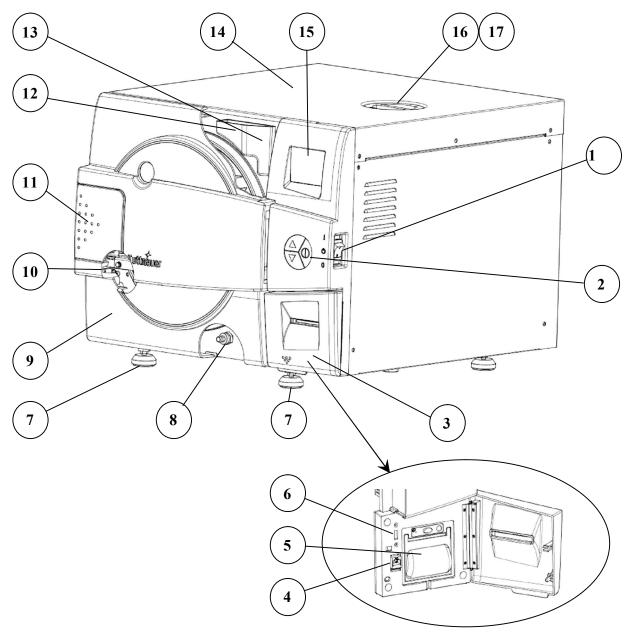
- 1. ASME code
- 2. EC-61010-1 & IEC-61010-2-040 Safety requirements for medical device.
- 3. EN 61326 EMC Requirements.

# 3.13.3 Quality standards

The manufacturing plant meets the following quality standards:

- 1. EN ISO 9001:2008– Quality System
- 2. ISO 13485:2003 Quality systems Medical devices.

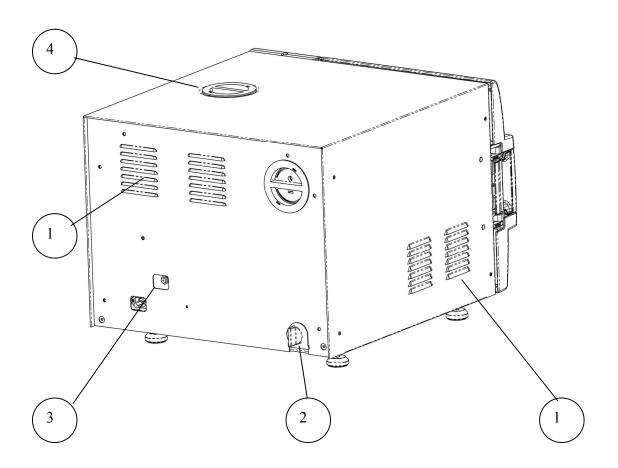
# FRONT VIEW



No.	Description	No.	Description
1	Main switch circuit breaker	9	Door cover
2	Operating keyboard	10	Door switch
3	Printer cover	11	Door closing device
4	RJ 45 connection	12	Water reservoir funnel
5	Printer (option)	13	Water level gauge
6	USB connection	14	Autoclave cover
7	Legs	15	Display
8	Mineral-free water reservoir drain valve	16	Mineral-free water reservoir cover
		17	Safety valve

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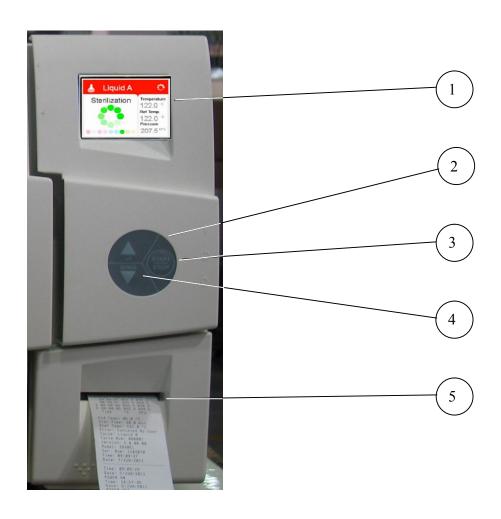
# REAR VIEW



No.	Description
1	Ventilation grills
2	Drain line water strainer
3	Main power electric cable socket
4	Mineral-free water reservoir cover

# 4 CONTROL PANEL

# 4.1 Control Panel Drawing



No.	Description
1	Display
2	Keypad: Up Button
3	Keypad: Start/Stop Button
4	Keypad: Down Button
5	Printer

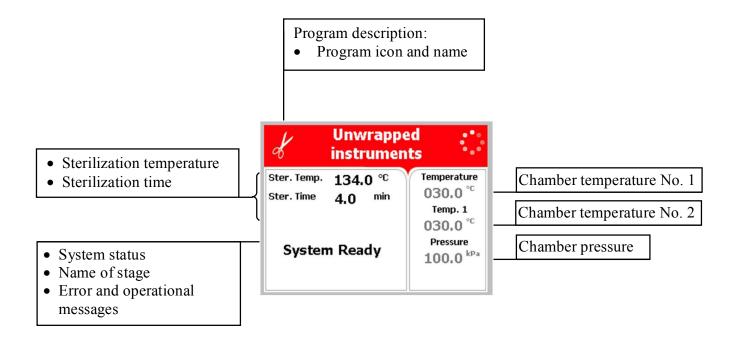
# 4.2 Description and Functions of the Front Panel Keyboard

The front panel is composed of 3 sections:

- 1. Display screen.
- 2. Keypad.
- 3. Printer

# 4.2.1 Display screen

The display is a LCD panel used to display the current status of the autoclave while using Operational Messages and Error Messages.



# *4.2.2 Keypad*

The keypad consists of three keys as described below:



# UP key

This key has the following functions:

- In the menu directories:
  - This key enables the operator to browse through the cycles.
- In the directories available:
  - When the cursor is blinking on a number, the UP ▲ key increases its value.
  - o When the cursor is blinking on a menu selection, the UP ▲ key allows browsing backward through the menu.
  - When adjusting a parameter and the cursor is blinking on "SET" or "EXIT" the UP ▲ key activates that procedure."



# DOWN key

This key has the following functions:

- In the menu directories:
  - This key enables the operator to browse through the cycles.
- In the directories available:
  - When the cursor is blinking on a number, the DOWN ▼ key decreases its value.
  - When the cursor is blinking on menu selection, the DOWN ▼ key allows browsing forward through the menu.
  - When adjusting a parameter and the cursor is blinking on "SET" or "EXIT" the **DOWN** ▼ key activates that procedure.



# START/STOP key

This key has the following functions:

- In the main screen:
  - Starts the process when the required program was chosen.
  - Stops the current process.
  - o Cancels the ERROR message displayed on the screen and opens the electric door lock.
- In the menu directories:
  - When the cursor is blinking on a number, the **START/STOP** © key enables moving to the next position.
  - When the cursor is blinking on a menu selection, the **START/STOP** key activates that selection.

# 4.2.3 Printer

The printer is an optional device.

It prints the detailed history of each cycle performed by the autoclave. The printing is on thermal paper with 24 characters per line and records the sterilization cycle information for subsequent consideration.

# 4.3 Displayed Error Messages / Symbols

The failures are divided into two categories.

- 1. Failure that occur before completing the sterilization stage, which in this case will leave the load unsterilized
- 2. Failure that occur after completing the sterilization stage, which in this case will leave the load sterilized

For the list of *Displayed Error Messages / Symbols* 

see sec. 14 TROUBLESHOOTING

# 4.4 Displayed operational messages / Symbols

Message / Symbol Name	Message / Symbol Description	Required Action	
	This symbol is displayed when the door is open.	Close the door.	
Door is open (during stand by)	This message is displayed when the door is opened:	Close the door to perform a new cycle.	
Cycle Ended	This message is displayed when the cycle ended successfully.	Press <b>START/STOP</b> in order to perform a new cycle.	
Test Ended	This message is displayed when the test ended.	Press <b>START/STOP</b> in order to perform a new test	
	This symbol is displayed when Cycle by Clock mode is performed.	Enter the Admin menu as described in this manual to change the time or to cancel this option.	
Cycle by clock	This message is displayed if the user presses  START/STOP key while the "cycle by clock" mode is active.	Enter the Admin menu as described in this manual to change the time or to cancel this option.	
Atmospheric pressure not set	This message id displayed in order to set the atmosphere pressure by opening the door for 5 minutes.	Open the door for 5 minutes in order to set the Atmospheric pressure.	
Critical settings have been updated, Please restart machine in order for changes to be updated	If a change of the autoclave setting was made, a restart operation is required.	Restart the autoclave in order for changes to be updated.	
	This message is displayed if the electrode in the chamber senses water.	Perform a new cycle to drain the chamber.	

# 5 DESCRIPTION OF PROGRAMS

The sterilization cycle has a few stages in order to perform effective sterilization, i.e. destroying the required amount of bacteria according to the relevant standards.

### 5.1 Water Inlet

Water is injected into the chamber until the water level electrode detects that the required level is reached. Some time is added for a certainty before proceeding to the heating stage.

### 5.2 Heat

After a cycle has been initialized, steam is produced within the chamber. The temperature and pressure in the chamber increase until appropriate levels are reached. Sensors located inside the chamber control the temperature and pressure levels.

### 5.3 Sterilization

The sterilization temperature is factory set at 134°C (273°F) for instruments and at 121°C (250°F) for liquids and other materials for which this temperature is appropriate. These settings may be modified before each cycle. When sterilization temperature is reached, the timed sterilization cycle begins.

# 5.4 Exhaust

When the timed sterilization cycle is complete, the unit enters into the exhaust stage, provided that a program other than the liquid program was selected. The steam is exhausted from the chamber, bringing the internal pressure down to atmospheric pressure.

# 5.5 Cooling

The autoclave is designed to operate two liquid cooling cycles, as follows:

# 5.6 Sealed bottles (cooling with compressed air)

After completing the sterilization stage, feed water starts flowing through the cooling coil mounted around the outer side of the chamber.

Compressed air is injected inside the chamber and keeps a constant air pressure to balance the internal pressure of the liquids inside the bottles. Compressed air is passed through a  $0.2\mu$  microbiological filter. When the temperature of the liquids reaches the final set temperature, the cooling stage is completed, flowing water and compressed air is stopped and pressure in the chamber goes down to atmospheric pressure.

At this stage, the door of the autoclave can be opened and the sterilized materials can be taken out of the chamber.

# 5.7 Unsealed bottles (cooling without compressed air)

On completion of sterilization, steam is exhausted from the chamber at a slow rate. When the chamber pressure decreases to atmospheric pressure, water starts flowing through the cooling coil mounted around the outer side of the chamber. On conclusion of the cycle the water flow is stopped automatically, the process is completed and it is possible to open the door and take the sterilized goods out of the chamber.

# 6 STERILIZATION PROGRAMS

The autoclave offers six sterilization programs as follows:

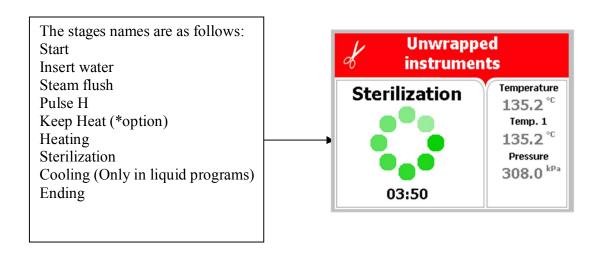
Ster	ilization Programs		Sterilizati	Screen Example	
Program			on time (minutes)		
1	Unwrapped instruments: For unwrapped instruments and materials, when the manufacturer recommends autoclaving at temperatures of 134°C	134°C	4	Unwrapped instruments  Ster. Temp. 134.0 °C Ster. Time 04.0 min. Temperature 030.0 °C Temp. 1 030.0 °C	
2	Unwrapped pouches: For Unwrapped pouches, when the manufacturer recommends autoclaving at temperatures of 134°C	134°C	7	Tunwrapped pouches  Ster. Temp. 134.0 °C Ster. Time 07.0 min.  System Ready  Temprature 030.0 °C Temp. 1 030.0 °C Pressure 100.0 kPa	
3	Unwrapped Delicate instruments: For unwrapped delicate instruments, when the manufacturer recommends autoclaving at temperatures of 121°C	121°C	20	Ster. Time 20.0 min.  System Ready  Unwrapped delicate instruments  Temperature 030.0 °C Temp. 1 030.0 °C Te	
4	Liquid A: For liquids in unsealed bottles when the manufacturer recommends autoclaving at temperatures of 121°C	121°C	20	Ster. Temp. 121.0 °C Ster. Time 20,0 min.  System Ready  System Ready  Control of the properties of th	
5	Liquid B: For liquids in sealed bottles when the manufacturer recommends autoclaving at temperatures of 121°C	121°C	30	Ster. Temp. 121.0 °C   Ster. Time 20.0 min.   Temperature 030.0 °C   Temp. 1 030.0 °C   Temp. 1 030.0 °C   Temp. 1 030.0 °C   Pressure 100.0 kPa	



# Note:

The sterility of instruments processed in unwrapped cycles cannot be maintained if exposed to non-sterile environment.

During the process, the stages of the cycle will be displayed on the screen:



\* Display can be activated only by an authorized person.

# 6.1 Operations Sequence

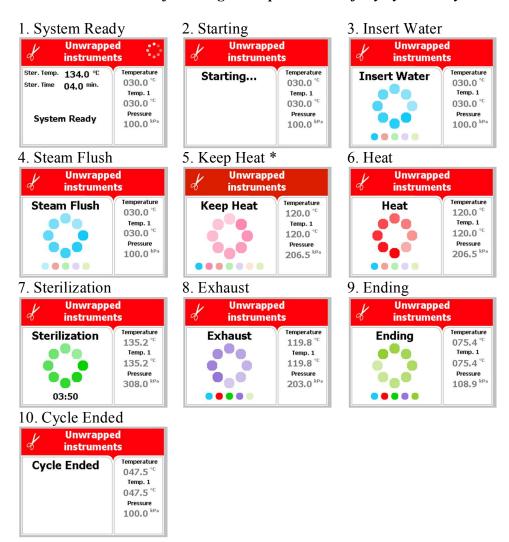
- Insert water into the chamber and heat by actuation of electrical heaters until reaching the high preset air pulse.
- Heating by actuation of electrical heaters until the sterilization temperature is reached.
- Sterilization temperature is maintained constant during the sterilization time.

# For Liquids Only:

• Slow exhaust; steam is slowly exhausted from the chamber, until it reaches the required end temperature (approx. 95°C) and the pressure equals the atmospheric pressure.

# 7 SCREENS

# 7.1 Screens following a complete successfully cycle – "Cycle Ended"



\* Display can be activated only by an authorized person.

In order to open the door press **START / STOP** key

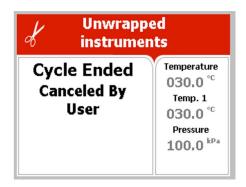
# 7.2 Screens following aborted cycles after complete sterilization stage

The sterilization phase ended successfully – cycle ended and the reason of failure is displayed

For example the next two scenarios:

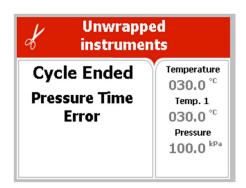
# 7.2.1 Canceled by user after complete sterilization stage

The cycle ended successfully, the reason for aborted cycle is displayed.



# 7.2.2 Pressure Time Error Failure occurrence after complete sterilization stage

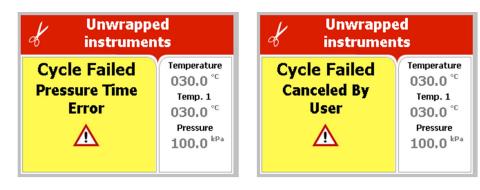
The cycle ended successfully, the reason of failure is displayed.



# 7.3 Screens following a fail cycle:

In this case, the display becomes yellow, a warning sign  $\bigwedge$  and the reason of failure will be displayed. For example the next two scenarios:

# 7.3.1 Failure according to Pressure Time Error



# 7.3.2 Failure according to Cancellation by user before complete sterilization stage

When "Cycle Failed" appears on the screen, the user shall press **START/STOP** key in order to delete the "Cycle Failed" message

An example for all displayed warnings according to Cycle Failed:



# 8 PRINTER

# 8.1 Printer Output

The printing is on thermal paper with 24 characters per line and contains the following information:

- Date:
- Time:
- Ser. Num:
- Model:
- Version:
- Cycle Num:
- Cycle:
- Ster Temp:
- Ster Time:

When the sterilization cycle begins the printer starts printing the above data.

After the preliminary printing, the autoclave starts performing the sequence of operations of the cycle. The measured values of temperature and pressure are printed at fixed time intervals, according to the phase of the process, as shown in the table on the next page.

The data is printed from the bottom up, beginning with the date and ending with "Cycle Ended". For an aborted cycle, "Cycle Failed" and the Error message are printed (refer to "Displayed Error Messages/Symbols"). For an example of a typical printout, see next page.

Note: Please note that the print out goes from the bottom upwards.

PRINTEI	R OUTPUT		DESCRIPTION	
Operator:			To be filled in manually by operator	
Time: 12:14:47			Time sterilization cycle ended	
Status: Cycle Ended				
00:24:43	101.3	099.7	Cycle finished time	
E 00:23:43	107.0	107.4	The time, temperature and pressure during exhaust	
E 00:22:08	134.5	311.9	The time, temperature and pressure during exhaust	
CLK 2:	12:12:10:0			
CLK 1:			Sterilization Process End time as registered by two clocks	
S 00:22:07	134.5	311.6	The time, temperature and pressure during sterilization	
S 00:22:06	134.5	311.6	The time, temperature and pressure during sterilization	
S 00:21:06	134.6	311.0	The time, temperature and pressure during sterilization	
S 00:20:06	134.5	310.1	The time, temperature and pressure during sterilization	
S 00:19:06	134.8	311.1	The time, temperature and pressure during sterilization	
S 00:18:06	134.5	315.8	The time, temperature and pressure during sterilization	
CLK 2:	12:08:08:0			
CLK 1:	12:08:08:0		Sterilization Process Start time as registered by two clocks	
H 00:18:04	134.4	315.1	The time, temperature and pressure during heating	
H 00:16:35	128.9	268.4	The time, temperature and pressure during heating	
H 00:13:35	116.3	180.9	The time, temperature and pressure during heating	
K 00:13:04	107.0	162.9	The time, temperature and pressure during Keep Heat	
K 00:12:22	115.1	200.4	The time, temperature and pressure during Keep Heat	
K 00:11:10	113.7	162.5	The time, temperature and pressure during Keep Heat	
A 00:11:04	107.0	162.9	The time, temperature and pressure during Air removal	
A 00:10:22	115.1	200.4	The time, temperature and pressure during Air removal	
A 00:10:00	113.7	162.5	The time, temperature and pressure during Air removal	
A 00:07:00	098.7	200.5	The time, temperature and pressure during Air removal	
A 00:06:45	097.6	165.4	The time, temperature and pressure during Air removal	
A 00:03:45	080.2	200.4	The time, temperature and pressure during Air removal	
A 00:00:45	053.7	154.4	The time, temperature and pressure during Air removal	
A 00:00:04	046.5	097.0	The time, temperature and pressure during Air removal	
F 00:10:18	092.8	096.6	The time, temperature and pressure during Steam Flush	
F 00:07:18	074.7	096.4	The time, temperature and pressure during Steam Flush	
F 00:04:18	047.4	096.3	The time, temperature and pressure during Steam Flush	
F 00:01:18	025.4	101.4	The time, temperature and pressure during Steam Flush	
W 00:00:05	029.3	096.0	The time, temperature and pressure during Water inlet	
TIME	°C	kPa	The time, temperature and pressure during where mee	
End Temp:	120.0 °C			
Ster Time:	4.0min		Sterilization time for selected program	
Ster Temp:	134.0°C		Sterilization time for selected program  Sterilization temperature in chamber for selected program	
Cycle:	Unwrappe	d instru	Cycle name	
Cycle Num:	000001		Cycle number	
	1.0.00.00		Version A.B.CC.DD = 1.0.00.00	
			A: Door Type: Single Manual = 1	
Version:			B: Vacuum Type = 0	
			C: Total number of Input/Output functionality that are not as default = 00	
			D: Total number of parameters values that are not as default = <b>00</b>	
Model: 2840ELC		0001	Model name	
Ser. Num:	000000000001		Model Serial number	
Time:			Time sterilization cycle started	
Date: 9/FEB/2010		10	Date sterilization cycle started	
			Total Asia A	
Time: 08:51:39		1.0	Time of turning on	
Date:			Date of turning on	
POWER ON	00.00.55		The device is turned on	
	Time: 00:00:00		Time of turning off	
Date:	9/FEB/201	10	Date of turning off	
POWER OFF			The device is turned off	

Legend					
W	Insert Water	S	Sterilization stage		
F	Steam Flush	С	Cooling stage		
A	Air removal stage	CLK 1	Real Time Clock		
Н	Heating stage	CLK 2	Software clock		
K	Keep Heat (Optional)	E	Exhaust stage		

# 8.2 Printer Handling

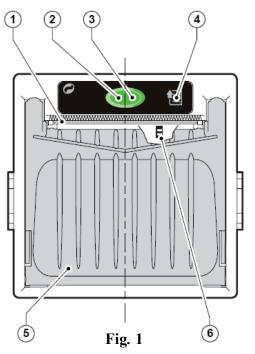
# 8.2.1 Maintenance

Wipe off the soiling on the printer surface with a dry soft cloth with a weak neutral detergent. After that, wipe the printer with a dry cloth.

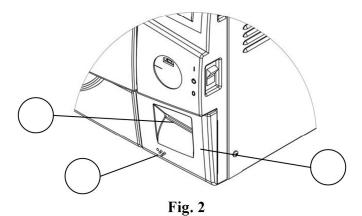
# 8.2.2 Setting paper

# **PLUS II Front view**

- 1-Paper mouth
- 2-STATUS Led
- 3-OPEN key (for paper roll compartment opening)
- 4-FEED key
- 5-Paper roll compartment
- 6-Paper end sensor



1. Open the printer's cover door (3) by pulling it at the left bottom corner (2).



- 2. Press the OPEN key to open the printer cover as shown (see Fig. 3/1). Handle the paper cutter carefully not to cut your hand.
- 3. Place the paper roll making sure it unrolls in the proper direction as shown (see Fig. 3/2).
- 4. Take out the paper and re-close the cover as shown (see Fig. 3/3) the printer cover is locked.
- 5. Tear off the exceeding paper using the jagged edge (see Fig. 3/4).

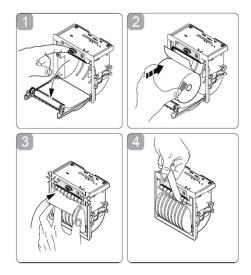


Fig. 3

6. Close the printer's cover door (3) by pressing corner (2), with the tip end of the paper emerging from the slot (1).

# 8.2.3 Notes on treatment of thermal papers:

- Store the papers in a dry, cool and dark place.
- Do not rub the papers with hard substance.
- Keep the papers away from organic solvent.

### Cautions!



Never disassemble the printer. Failure to follow this instruction may cause overheating or burning of the printer or the AC adapter. Or an electric shock, which may lead to fires or accidents.

Never use the printer in a place of extreme humidity or any place where it can possibly be splashed by any liquids. If any liquids get into the printer, it could lead to fire, electric shock, or other serious accidents.

Never touch the thermal head immediately after printing because it becomes very hot. Make sure that the thermal head is cool before setting papers or cleaning the thermal head.

# Power OFF the printer in any of the following cases:

- The printer does not recover from an error.
- Smoke, strange noise or smells erupt from the printer.
- A piece of metal or any liquid touches the internal parts or slot of the printer.

# 9 INSTALLATION

# 9.1 Placing

# **CAUTION:**



The sterilizer is not portable or hand-held equipment; it is a fixed device so it is forbidden to move it.

The sterilizer must be placed on a rigid and leveled surface. The stand must be able to withstand the load of the device and loaded material.

# 1. Counter top

Able to support a minimum of 70 kg (154 lb).

# 2. Counter space

Min. 55cmW x 65cmD (22"W x 25"D) \* (see unit dimensions).

When changing the autoclave location the door should remain open for at least 5 minutes in order to set the atmospheric pressure

# 9.1.1 Placing the Autoclave

Keep the back and the sides of the autoclave approximately 50 mm (2") away from the wall to allow ventilation and to facilitate the device disconnection.

If placed in a cabinet, verify that the rear of the cabinet is open to allow ventilation.

Insufficient space for ventilation may result in an increase of the autoclave's temperature that may damage the instrument.

It is recommended that enough space be left around the autoclave to give a technician access for servicing the machine.

# 9.1.2 Connections to Utility Supplies

Plug the power cord into the power supply output as specified in sec. 3.5 (Utilities).

# 9.2 Lifting and carrying



# CAUTION:

Before moving the autoclave, Make sure that the electric cord is disconnected from the power, and there is no pressure in the chamber and in the generator.

To avoid injuries, lifting and carrying should be done with at least two persons or by using a fork-lift or any other mechanical aid.

Do not drop the device!

### 9.3 Filling the Mineral-Free Water Reservoir.



Before filling the reservoir, verify that the autoclave is idle and there is no pressure in the chamber.

- 1. Open the door (1).
- 2. Pour water, gently, into the front funnel (5) until it reaches the required level (3) on the side gauge. It is preferable to use a carafe.

Please note that the side gauge is divided into three sections. The bottom red section (4) indicates that the water level in the reservoir is too low. The middle blue section (3) shows that there is sufficient amount of water. The upper red section (2) indicates that the water level in the reservoir is too high.



### Caution!

Under no circumstance should water be filled above the top sign level (the line between section 2 and 3) on the side gauge.



3. If the reservoir is empty, it is recommended to add water directly into the reservoir, as follows:

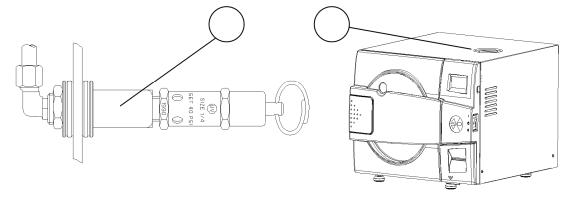
Before filling the reservoir, verify that the autoclave is idle, disconnected from the electrical supply and there is no pressure in the chamber.

- Remove the water reservoir cover (6).
- Pour distilled water into the reservoir through the opening on top of the autoclave until it reaches the base of the safety valve holder (7).



### **Caution:**

Under no circumstance should water be filled above the safety valve holder.



In case more water is added accidentally above the top sign level on the side gauge, decrease the water level by draining the reservoir before starting a cycle (see sec. 12.2).



#### **Caution:**

Use only water having the characteristics as per table in sec. 3.9. Tap water may clog the system and using them can invalidate the manufacturer's guarantee.

**USE DISTILLED WATER ONLY**. The impurities in tap water will create the need for more frequent cleaning and maintenance.

#### 10 PREPARATION BEFORE STERILIZATION

The purpose of packaging and wrapping of items for sterilization is to provide an effective barrier against sources of potential contamination in order to maintain sterility and to permit aseptic removal of the contents of the pack. Packaging and wrapping materials should permit the removal of air from the pack, penetration of the sterilizing water vapor into the pack and removal of the sterilizing vapor.

The basic principle determining the size, mass and contents of instrument and hollowware packs is that the contents are sterile and dry immediately on completion of the cooling cycle and removal of the pack from the sterilizer chamber

Instruments to be sterilized must be clean, free from any residual matter, such as debris, blood, pads or any other material. Such substances may cause damage to the contents being sterilized and to the sterilizer.

- 1. Before use, check inside the autoclave chamber to ensure that no items have been left from the previous cycle.
- 2. Immediately after use, clean instruments thoroughly to dispose of any residue.
- 3. It is recommended to wash instruments with an ultrasonic cleaner, using detergent and mineral-free water.
- 4. Launder textile wraps prior to reuse.
- 5. After cleaning, rinse instruments for 30 seconds. (Follow manufacturer's instructions on the use of products for cleaning and lubricating instruments after using the ultrasonic cleaner).
- 6. Materials, including materials used for inner wraps, shall be compatible with the item being packed and the sterilizing method selected.
- 7. Do not place materials to be sterilized directly on the chamber's wall. Place the material only on trays, rack, etc.

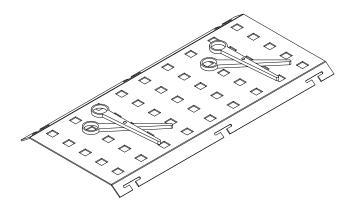
#### 10.1 Instruments

- 1. Before placing an instrument on the sterilizer tray, make sure that instruments which are not of the same metal, (stainless steel, carbon steel, etc.) are separated and placed on different trays.
- 2. Place empty containers upside down to prevent accumulation of water.

#### Note:

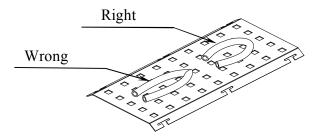
#### Check manufacturer's instructions for the sterilization of each item.

In case carbon steel instruments are placed on the stainless steel tray, the tray should be lined with a towel or paper wrap before placing the instruments on the tray. There should be no direct contact between the carbon steel and the stainless steel tray.



- 1. All instruments must be sterilized in an open position.
- 2. Use single-use wraps only once and discards them after use.
- 3. Place a sterilization indicator strip in each tray.
- 4. Place instruments with ratchets opened and unlocked or clipped on the first ratchet position.
- 5. Disassemble or sufficiently loosen multiple-part instruments prior to packaging to permit the sterilizing agent to come into contact with all parts of the instrument.
- 6. Tilt on edge items prone to entrap air and moisture, e.g. hollowware, so that only minimal resistance to removal of air, the passage of steam and condensate will be met.
- 7. Load items within the boundaries of the tray so that they do not touch the chamber walls, or fall off when the tray is moved.
- 8. The operator may use racks to allow adequate separation of packaged instruments.
- 9. Load trays in such a way as to allow steam to move freely among all items.
- 10. Once a week, use a biological spore test indicator in any load to make sure sterilization is performed.
- 11. Make sure that all instruments remain apart during the sterilization cycle.
- 12. Empty canisters should be placed upside-down, in order to prevent accumulation of water.

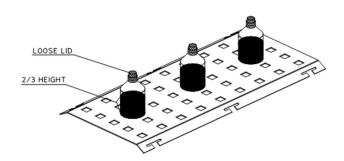
## 10.2 Tubing



When placing in a tray, Make sure that both ends are open, without sharp bends or twists.

### 10.3 Liquids

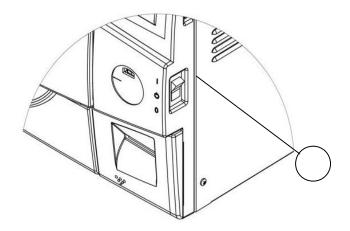
- 1. Use only heat-proof glass, filled 2/3 full.
- 2. Ensure that the glass container is covered but not sealed to prevent pressure build-up.
- 3. Place the two temperature sensors into two separate liquid containers. These are used to control the program temperature and ensure the safety of the operating cycle.



### 11 OPERATING INSTRUCTIONS

## 11.1 Turning on the autoclave

• To start the system, turn on the main white switch (1), located on the right side of the autoclave.



### 11.2 Opening the door

- 1. Place your thumb on the plastic door cover (1) and the other fingers in the handle (3).
- 2. Pull the handle (2) until the locking of the door is released.
- 3. Open the door.



### 11.3 Loading

• Load the autoclave properly according to instructions in sec. 9

Please Mind:

- Compatible material
- Proper weight

### 11.4 Operations

- 1. Select the program.
  - **UP** key: next program.
  - **DOWN** key: previous program.



#### Attention:

Selecting a program is possible only when the door is open.

- 2. Verify that you chose the required cycle.
- 3. If the autoclave is equipped with a printer verify that a paper roll is inserted in the printer. If not insert as per para. 5.2.

### 11.4.1 Closing the door

- 1. Hold the opening handle in open position, while pushing the door until it comes to closed position, then release the handle.
- 2. The open door symbol is replaced by the message "System Ready".

### 11.4.2 Starting cycle

1. Start the cycle by pressing the START/STOP key.

The autoclave starts performing sequence of operations. The actual measured values of pressure and temperature are displayed continuously and printed every minute at STE stage, and every 5 minutes at the other stages. The phase in progress is displayed at the right side of the upper line as WATER, HEAT, STER., and EXH.

If the operator presses the START key and the door is not completely closed, the process will not start and the DOOR indicator will flash twice then turn off and the buzzer will sound four times.



#### **CAUTION**

Do not touch the strainer's cover, mounted on the exhaust line, during and short after operation.

Touching the hot strainer's cover may cause severe injuries.

#### 11.5 Unloading

- When the cycle ended successfully (including pressing the START/STOP key, or any failure, after completing the sterilization stage) message "Cycle Ended" (and the relevant failure message, if applicable) is displayed on the screen.
- Verify than there is no pressure in the chamber, according to the reading on the display. Only then you may open the door.



#### Warning

To avoid sever injuries from hot steam when opening the door:

- It is strictly forbidden to lean on the autoclave.
- It is strictly forbidden to place your hand or any part of your body over the door.
- Wear heat-resistant gloves or use the tray handle to remove the load from the autoclave
- On completion of the cycle, the load shall be visual inspected to ascertain that the load is dry, and that sterilization indicators have made the required color change.

### 11.6 Stopping the process and canceling the ERROR message

- It is possible to stop the program while the autoclave is operating. Pressing the **START/STOP** key at any stage of the process stops the operation. If the cycle was aborted before completing the sterilization stage, it will leave the load unsterilized.
- At the end of the aborted process (before completing the sterilization stage), "Cycle Failed" message, error message and a warning symbol are displayed on the screen. Refer to "Displayed Error Messages/Symb \(\hat{\Lambda}\)'.
- Pressing the **START/STOP** key cancels the displayed message and enables opening the door.



### Warning

The load has not completed a sterilization cycle, therefore it is not sterile. Handle it as contaminated load.

#### 11.7 Cycle by Clock mode (Start Cycle by Clock)

 This mode enables the operator to define the time of the beginning of the cycle. The maximum possible delay is 24 hours.
 For more information, see sec. 7.7.1. <u>Start Cycle by Clock</u>

### 12 CHECKING AND CHANGING PARAMETERS AND OTHER DATA

The control system prevents changing programs if the door is closed. This protection is intended to avoid program changes if the autoclave is loaded. If the operator for example inserts the load into the chamber, closes the door and leaves the room and another operator/user tries to change the program, the operator/user will not be able to do this unless the door is opened and the load inside the chamber can be seen.

### 12.1 Directories and subdirectories

The operator (Admin) may perform the following:

DIRECTORY	SUBDIRECTORY	
Cycle Parameters – applicable only for Custom programs	See sec. 7.4 "Cycle Parameters (Custom Program)"	
	Print Rate All	
System Parameters	Print Rate Sterilization	
	Screen Saver	
	View old cycle history	
History	Export history to USB	
	Clear history files	
	Set date and time	
	Export gain offset to USB	
Maintenance	Reset atmosphqaeric pressure	
	Printer test	
	Print all gain and offset	
Advanced entions	Start cycle by clock	
Advanced options	Export all settings to USB device	
	View current version information	
Version information	View factory default version information	
	View previous version information	

# 12.2

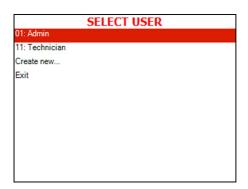
**Table of parameters**The parameter default depends on the selected program. The following table is an example to Custom 1 program.

Parameters	Description	Default	Unit	Range	Resolution
Pulse A Count	Define the number of pulses in the first pulses group		#	0-10	1
Pulse A Stay Time	Define the additional time that the vacuum pump will continue to operate or slow/top exhaust valve will remain open after reaching the preset pressure in the first pulses group		Second	1-100	1
Pulse A Low Pressure	Define the minimum vacuum/pressure level in the first pulses group	130.0	kPa	5-200	1
Pulse A High Pressure	Define the maximum vacuum/pressure level in the first pulses group	180.0	kPa	5-200	1
Pulses B Count	Define the number of pulses in the second pulses group	0	#	0-10	1
Pulse B Stay Time	Define the additional time that the vacuum pump will continue to operate or-slow/top exhaust valve will remain open after reaching the preset pressure in the second pulses group	2	Second	1-100	1
Pulse B Low Pressure	Define the minimum vacuum/pressure level in the second pulses group	160.0	kPa	5-200	1
Pulse B High Pressure	Define the maximum vacuum/pressure level in the second pulses group		kPa	5-200	1
Sterilization Temperature	Define the sterilization temperature		°C/°F	80-137	0.5°
Sterilization Time	Define the sterilization time		Minute	0-9999	0.5
F0Mode	This parameter calculates the time that the load is exposed to temperature according to F0 table. The printer prints out the values before sterilization and at the end of this cycle		#	0-1	1
End Temperature	Define the temperature at the end of the cycle, the cycle will not end before reaching the preset temperature		°C/°F	30-120	1
Multiple Cycles			#	1-50	1
Multiple Cycles Gap	Define the interval between repeated cycles in case that Multiple Cycles parameter is defined		Minute	1-60	1
Print Rate All	All Defines the printing rate during the cycle except sterilization stage		Minute	1-30	1
Print Rate Sterilization	Defines the printing rate during the sterilization stage		Minute	1-30	1
Screen Saver	Defines the interval from the last use of the Keypad until activating the screen saver	90	Minute	0-600	1

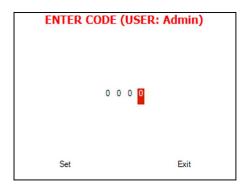
### 12.3 Entering the main menu

1. Enter the **SELECT USER** screen by pressing the **UP** and **DOWN** keys simultaneously. (To exit the **SELECT USER** screen move the cursor to **Exit** by pressing **UP** or **DOWN** keys and then press **START/STOP** key).

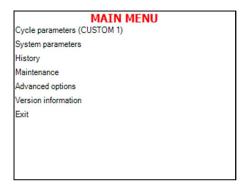
**SELECT USER** screen will be displayed:



2. Enter the Enter Code screen by moving the cursor to **Admin** and pressing **START/STOP** key. (In order to exit the **ENTER CODE** screen move the cursor to **Exit** by pressing **START/STOP** Key. When **Exit** is blinking press **UP** or **DOWN** keys). The following screen will be displayed:

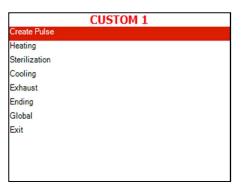


- 3. 0000 is displayed on the screen with the cursor blinking on the right digit.
- 4. To increase or decrease the digits, press the **UP** or **DOWN** keys.
- 5. After changing the code to 0001 move the cursor to **Set** by pressing the **START/STOP** key.
- 6. When **Set** is blinking, press the **UP** or **DOWN** keys to enter the **MAIN MENU** of the autoclave.
  - The following screen will be displayed:



- 7. To browse through the directories, use the **UP** or **DOWN** keys.
- 8. When the required directory is blinking, press the **START/STOP** key. The required screen will be displayed.
- 9. In order to exit this screen:
  - Move the cursor to **Exit** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
    - or -
  - Press the **UP** and **DOWN** keys simultaneously.

The parameters display for Custom 1 program appears:



### 12.4 Cycle Parameters (Custom program = duplicate program)

This directory applicable only for custom program

Subdirectory	Property
	Pulse A Countq
	Pulse A Stay Time
	Pulse A Low Pressure
Consta Della	Pulse A High Pressure
Create Pulse	Pulse B Count
	Pulse B Stay Time
	Pulse B Low Pressure
	Pulse B High Pressure
Heating	Sterilization Temperature
	Cool Mode
Cooling	Cool End Temperature
	Cool Exhaust Rate
Exhaust	Exhaust Mode
Ending	End Temperature
Enumg	Exhaust Mode
	Dry Tqaime
	Dry Exhaust Mode
	Dry Heat On 1
Drying	Dry Heat Off 1
	Dry first stage time
	Dry Heat On 2
	Dry Heat Off 2
Ending	End Temperature
Ending	Exhaust Mode
Global	F0 Mode

This directory includes seven subdirectories

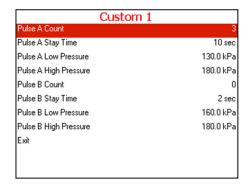
These subdirectories enable to see and change the cycle parameters. Therefore it is necessary to choose the required cycle before entering the "MAIN MENU".

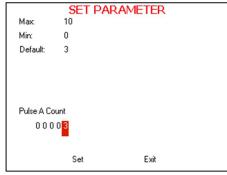
For seeing or changing the parameters proceed as follows:

Choose and enter cycle parameters

The following screen will display:

### 12.5 Cycle Parameters -- Create Pulse

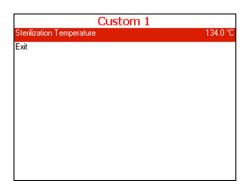


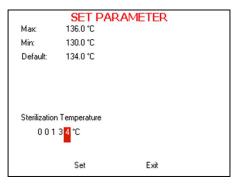


Typical display for **Create Pulse** subdirectory

- 1. Choose and enter Pulse A Count
- 2. **SET PARAMETER** screen will be displayed
- 3. Set the required value, move to **Set** and press **UP** or **DOWN** keys to confirm the parameter value.
- 4. In order to exit move the cursor to **Exit** and press **UP** or **DOWN** keys.
- 5. Repeat steps 1 4 for the following parameters: Pulse A Stay Time, Pulse A Low Pressure, Pulse A High Pressure, Pulse B Count, Pulse B Stay Time, Pulse B Low Pressure, Pulse B High Pressure.

### 12.6 Cycle Parameters -- Heating





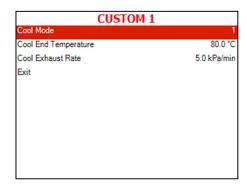
Typical display for **Sterilization Temperature** subdirectory

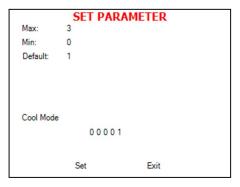
- 1. Choose and enter **Sterilization Temperature**
- 2. **SET PARAMETER** screen will be displayed
- 3. Set the required value, move to **Set** and press **UP** or **DOWN** keys to confirm the parameter value.

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- 4. In order to exit move the cursor to **Exit** and press **UP** or **DOWN** keys.
- 5. Repeat steps 1 4 for the following parameters: Sterilization temperature, Sterilization Time.

### 12.7 Cycle Parameters -- Cooling

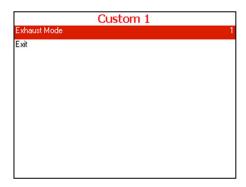


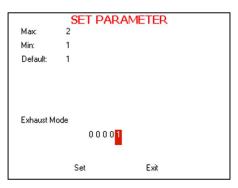


Typical display for Cool Mode subdirectory

- 1. Choose and enter **Cool Mode**
- 2. **SET PARAMETER** screen will be displayed
- 1. Set the required value, move to **Set** and press **UP** or **DOWN** keys to confirm the parameter value.
- 2. In order to exit move the cursor to **Exit** and press **UP** or **DOWN** keys.
- 3. Repeat steps 1 4 for the following parameters: Cool Mode, Cool End Temperature, Cool Exhaust Rate.

### 12.8 Cycle Parameters -- Exhaust



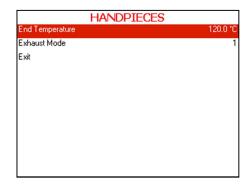


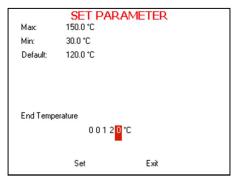
Typical display for Exhaust Mode subdirectory

- 1. Choose and enter **Exhaust Mode**
- 2. **SET PARAMETER** screen will be displayed

- 3. Set the required value, move to **Set** and press **UP** or **DOWN** keys to confirm the parameter value.
- 4. In order to exit move the cursor to **Exit** and press **UP** or **DOWN** keys.

### 12.9 Cycle Parameters -- Ending

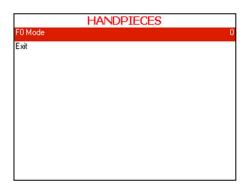


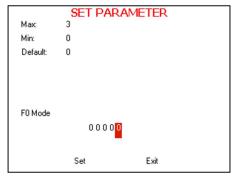


Typical display for End Temperature subdirectory

- 1. Choose and enter **End Temperature**
- 2. **SET PARAMETER** screen will be displayed
- 3. Set the required value, move to Set and press **UP** or **DOWN** keys to confirm the parameter value.
- 4. In order to exit move the cursor to Exit and press **UP** or **DOWN** keys.
- 5. Repeat steps 1 4 for Exhaust Mode.

### 12.10 Cycle Parameters -- Global





Typical display for **F0 Mode** subdirectory

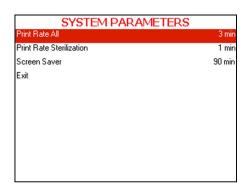
- 1. Choose and enter **F0 Mode**
- 2. **SET PARAMETER** screen will be displayed

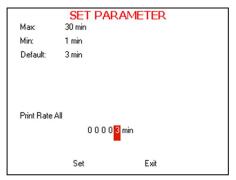
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- 3. Set the required value, move to **Set** and press **UP** or **DOWN** keys to confirm the parameter value.
- 4. In order to exit move the cursor to **Exit** and press **UP** or **DOWN** keys.

### 12.11 System Parameters

This directory includes three subdirectories
The following screen will be displayed when entering **SYSTEM PARAMETERS** directory:



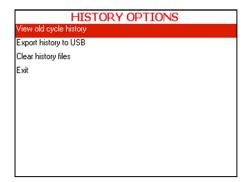


- 1. Choose and enter **Print Rate All** (printing rate during the whole cycle except sterilization stage).
- 2. **SET PARAMETER** screen will be displayed
- 3. Set the required value, move to **Set** and press **UP** or **DOWN** keys to confirm the parameter value.
- 4. In order to exit move the cursor to **Exit** and press **UP** or **DOWN** keys.
- 5. Repeat steps 1 4 for the following parameters: Print Rate Sterilization (printing rate during sterilization stage), Screen Saver (0 600 minutes, the default is 90 minutes).

### *12.12 History*

This directory includes two subdirectories

The following screen will be displayed when entering **HISTORY** directory:



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- In order to enter to the sub directories move the cursor by pressing UP or DOWN keys to the required item and press START/STOP key
- 2. In order to exit this screen follows one of the next:
  - Move the cursor to **Exit** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
  - Press the **UP** and **DOWN** keys simultaneously.

### 12.12.1 View old cycle history

This subdirectory enables to print the 100 previous cycles. The following screen will be displayed when entering **View old cycle history** subdirectory:

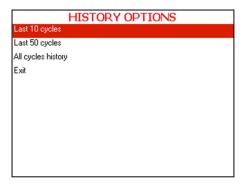
	HISTORY
cycle_000100	31/DEC/2009 11:43:17
cycle_000099	31/DEC/2009 11:43:10
cycle_000098	31/DEC/2009 11:42:47
cycle_000097	31/DEC/2009 11:42:43
cycle_000096	31/DEC/2009 11:42:39
cycle_000095	31/DEC/2009 11:42:35
cycle_000094	31/DEC/2009 11:42:30
cycle_000093	31/DEC/2009 11:42:27
cycle_000092	31/DEC/2009 11:42:22
cycle_000091	31/DEC/2009 11:42:16
cycle_000090	31/DEC/2009 11:42:13

- 1. Choose the required cycle according to cycle number, date and time with the **UP** or **DOWN** keys
- 2. Press the **START/STOP** key. The printer will print the printout of the required cycle
- 3. In order to exit this screen follows one of the next:
  - Move the cursor to **Exit** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
  - Press the **UP** and **DOWN** keys simultaneously.

### 12.12.2 Export history to USB

This subdirectory enables to Export history to USB device.

- 1. Insert the USB device into the USB Socket
- 2. Move the cursor to Export history to USB
- 3. Press the **START/STOP** key.
- 4. The following screen will be displayed:



- 5. Move the cursor to the required item and press **START/STOP** key
- 6. The following screen will be displayed:



- 7. Remove the USB device from the USB Socket
- 8. In order to exit this screen and return to **HISTORY OPTIONS** screen press **START/STOP** key.
- 9. In order to exit the **HISTORY OPTIONS** screen:
  - Move the cursor to Exit with the UP or DOWN keys and select it by pressing the START/STOP key.
    - or -
  - Press the **UP** and **DOWN** keys simultaneously.

### 12.12.3 Clear history files

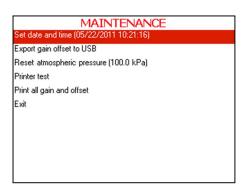
This sub directory enables to delete all history files. In order to delete all history files move the cursor to Clear history files and press **START/STOP** key The following screen will be displayed:



In order to exit this screen press START/STOP key

#### 12.13 Maintenance

This directory includes five subdirectories
The following screen will be displayed when entering **MAINTENANCE** directory:



- 1. In order to enter the sub directories move the cursor by pressing **UP** or **DOWN** keys to the required item and press **START/STOP** key
- 2. In order to exit this screen:
  - Move the cursor to **Exit** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
  - Press the **UP** and **DOWN** keys simultaneously.

### 12.13.1 Set date and time

This **SET DATE AND TIME** screen will be displayed when entering the subdirectory:

#### SET DATE AND TIME

Time: 1 2 : 1 3 : 4 4
Date: 3 1 / DEC / 2 0 0 9

Set Exit

When entering the **SET DATE AND TIME** screen, the time and date are displayed. The cursor is blinking on the "second" digit.

The time is displayed in the upper row in the form "HH:MM:SS". The hour range is 24 hour (i.e. from "0" to "24")

The date is displayed in the lower row in the form "DD:MMM:YYYY".

- 1. To increase or decrease the time or the date use the **UP** or **DOWN** keys.
- 2. To move the cursor from one digit to another press the **START/STOP** key.
- 3. After changing the time and the date move the cursor to **Set.**
- 4. Confirm the new time and date by pressing **UP** or **DOWN** keys.
- After saving is completed, **SET DATE AND TIME** screen is still displayed, move the cursor to **Exit** and press **UP** or **DOWN** keys to return to **MAINTENANCE** screen.

### 12.13.2 Export gain offset to USB

This subdirectory enables to Export gain offset to USB device.

- 1. Insert the USB device into the USB Socket
- 2. Move the cursor to **Export gain offset to USB**
- 3. Press the **START/STOP** key
- 4. The following screen will be displayed:



- 5. Remove the USB device from the USB Socket
- 6. In order to exit this screen and return to **MAINTENANCE** directory press **START/STOP** key.
- 7. In order to exit the **MAINTENANCE** directory follows one of the next:
  - Move the cursor to **Exit** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
  - Press the **UP** and **DOWN** keys simultaneously.

### 12.13.3 Reset atmospheric pressure

This sub directory enables to reset the atmospheric pressure. In order to reset the atmospheric pressure move the cursor to **Reset the atmospheric pressure** and press **START/STOP** key The following screen will be displayed:



In order to exit this screen press **START/STOP** key

### 12.13.4 Print Test

This subdirectory enables the operator to test the printer.

When pressing START/STOP key on the Printer Test item the printer will print out the following print out:

Cycle errors:

None

Canceled By User

Door is open

Analog Input Error

I/O Card Failed

Power Down

No Water

Heat Time Error

Vacuum Time Error

Pressure Time Error

Heat Time Error (Keep)

Heat Time Error

Low Pressure

High Pressure

Low Temp

High Temp

Time Error

High Pressure (Dry)

High Pressure (Ending)

Air Error

High Temp. (Ending)

Error Open Door

Error Close Door

Accessory Timeout

**Emergency Stop** 

Bio Filter Time Out

Purge Time Out

And the following screen will be displayed.



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In order to exit this screen and return to **MAINTENANCE** directory press **START/STOP** key.

In order to exit the **MAINTENANCE** directory follows one of the next:

- Move the cursor to **Exit** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
- Press the **UP** and **DOWN** keys simultaneously.

### 12.13.5 Print All Gain and Offset

This subdirectory enables the operator to print all the gain and offset values.

When pressing **START/STOP** key on the **Print all gain and offset** item the printer will print out the following:

Drain Temperature
G:000.0400;O:-004.0000
Chamber Temperature
G:000.0400;O:-004.0000
Ref Temperature 1
G:000.0400;O:-004.0000
Chamber Pressure
G:000.1250;O:-100.0000
Chamber Water Level
G:001.0000;O:000.0000
Mineral Free Water Level
G:001.0000;O:000.0000

And the following screen will be displayed.



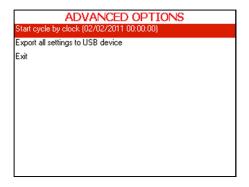
In order to exit this screen and return to MAINTENANCE directory press START/STOP key.

In order to exit the **MAINTENANCE** directory:

- Move the cursor to **Exit** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
  - or -
- Press the **UP** and **DOWN** keys simultaneously

### 12.14 Advanced Options

This directory includes two subdirectories



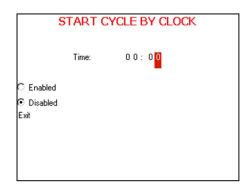
The following screen will be displayed when entering **ADVANCED OPTIONS** directory:

- In order to enter to the sub directories move the cursor by pressing UP or DOWN keys to the required item and press START/STOP key
- 2. In order to exit this screen:
  - Move the cursor to Exit with the UP or DOWN keys and select it by pressing the START/STOP key.
    - or -
  - Press the UP and DOWN keys simultaneously.

### 12.14.1 Start Cycle by Clock

This subdirectory enables the operator to postpone the operation by a pre-set time.

This **Start cycle by clock** screen will be displayed when entering the **START CYCLE BY CLOCK** subdirectory:

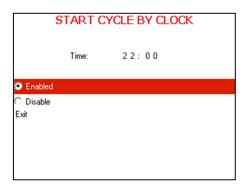


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When entering the **START CYCLE BY CLOCK** screen, the time is displayed. The cursor is blinking on the "minute" digit. The time is displayed in the form "HH:MM". The hour range is 24 hours (i.e. from "0" to "24").

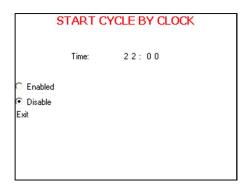
### 12.14.1.1 Enabling The Start Cycle By Clock

- To increase or decrease the time use the UP or DOWN keys.
- 2. To move the cursor from one digit to another press the **START/STOP** key.
- 3. After changing the time move the cursor to **Enabled**
- 4. Confirm the **START CYCLE BY CLOCK** by pressing **UP** or **DOWN** keys.
- 5. Move the cursor by pressing **START/STOP** key to **Exit** and press **UP** or **DOWN** keys to return to **ADVANCED OPTIONS** screen.



### 12.14.1.2 Canceling the START CYCLE BY CLOCK

- 1. To cancel the **START CYCLE BY CLOCK** move the cursor by pressing **START/STOP** key to **Disable** and press **UP** or **DOWN** keys.
- 2. Move the cursor to **EXIT** by pressing **START/STOP** key and press **UP** or **DOWN** keys, the **START CYCLE BY CLOCK** will be canceled



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### 12.14.2 Export all settings to USB device

This subdirectory enables the operator to export all settings to USB device.

- 1. Insert the USB device into the USB Socket
- 2. Move the cursor to Export all settings to USB device
- 3. Press the **START/STOP** key.
- 4. The following screen will be displayed:



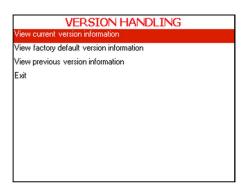
- 5. Remove the USB device from the USB Socket
- 6. In order to exit this screen and return to **ADVANCED OPTIONS** directory press **START/STOP** key.

In order to exit from the **ADVANCED OPTIONS** directory:

- Move the cursor to **EXIT** with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
  - or -
- Press the **UP** and **DOWN** keys simultaneously

### 12.15 Version information

This directory includes two subdirectories

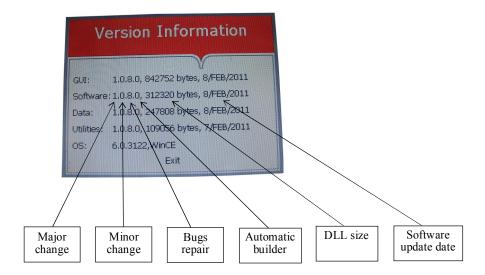


- 1. In order to enter to the sub directories move the cursor by pressing **UP** or **DOWN** keys to the required item and press **START/STOP** key
- 2. In order to exit this screen follows one of the next:
- 3. Move the cursor to Exit with the **UP** or **DOWN** keys and select it by pressing the **START/STOP** key.
- 4. Press the **UP** and **DOWN** keys simultaneously.

### 12.15.1 View current version information

In order to view this subdirectory press **START/STOP** key on the **View current version information** item. This subdirectory enables the operator to see the current version information as described below:

- 1. GUI Graphic user interface Holds the entire Human Machine interface including the main application screen and all the configuration screens, which enable the user to handle the machine.
- 2. Software Logic Holds all the application logic for running the machine.
- 3. Data Code section that handle the entire data storage in the application.
- 4. Utilities Utilities Holds general functionality which is used by the logic section and the GUI section e.g. converting function to display different pressure or temperature units, languages types etc.
- 5. OS Operation System Microsoft Windows CE. Version 6.0.



Major change Concept change eg: changing the operating system, Changed by the

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programmer in accordance with

the change sequence.

• Minor change Feature change or function change,

changed by the programmer in accordance with the change

sequence.

• Bugs repair Software bugs repair changed by

he programmer in accordance

with the change sequence.

• Automatic builder Changed (updated) automatically

after each source code

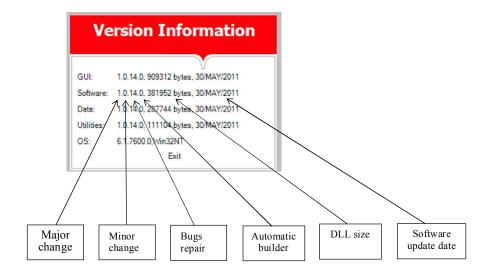
compilation.

• DLL size Dynamic-Link Library size

#### 12.15.2 View factory default version information

This subdirectory enables the operator to see the factory default version information.

In order to see this subdirectory press **START/STOP** key on the **View factory default version information** item. The following screen will be displayed:



### 12.15.3 View previous version information

This subdirectory enables the operator to see the previous version information.

In order to see this subdirectory press **START/STOP** key on the **View previous version information** item.

#### 13 SERVICE AND MAINTENANCE INSTRUCTIONS

#### 13.1 Preventive and Scheduled Maintenance

The maintenance operations described in this chapter have to be fulfilled periodically to keep the device in good condition and to reduce the breakdown time to a minimum.

The user can easily execute these operations in accordance with further instructions.

The owner of the autoclave is responsible to order an authorized technician to perform the periodical tests and preventive maintenance operations. Use only mineral-free water as detailed in sec. 3.9 (water quality).



### Warning:

Before carrying out any preventive maintenance operation, ensure that the electrical cord is disconnected and that there is no pressure in the autoclave.

### 13.1.1 Daily by the operator

Clean door gasket with a soft cloth. The gasket should be clean and smooth. A mild soapy solution may be used.

### 13.1.2 Weekly by the operator

1. Check the interior of the autoclave. If the autoclave is dirty it requires cleaning as follows:

Take out the tray holder and trays. Clean the tray holder, trays and chamber's interior (especially its bottom part) with a cleaning agent & water. Wipe off the sediments from the chamber bottom with a sponge. Immediately after cleaning, rinse the tray holder, trays and chamber's interior with water to avoid stains on the metal.



#### **CAUTION:**

Do not use steel wool or steel brush as this can damage the chamber!

- 2. Clean the outer parts of the autoclave with a soft cloth.
- 3. Replace mineral free water in the reservoir.

### Autoclaves without recycling of mineral free water

If the autoclave was not used, drain the water from the mineral free water reservoir once a week, and refill with fresh mineral-free water or distilled water (see sec. 12.2).

#### 13.1.3 Periodically

#### *13.1.3.1 By the operator*

- 1. Once a month, activate the safety valve (see sec. 12.5).
- 2. Once a month clean the strainer as per sec. 12.6. Cleaning frequency may be reduced according to experience.
- 3. Check the door gasket every 12 months and replace it if required (see sec. 12.4).

### 13.1.3.2 By a qualified technician

#### **Every 6 months**

- Tighten the screws of the heaters and the electrical connections at the heaters, valves and connectors in the control box.
- Replace the air filter, every 6 months or after 1000 cycles (the shorter period).

#### Once a year

This operation shall be done by an authorized technician.

- Check the continuity of the grounding connections.
- Calibrate the temperature and pressure.
- Perform validation of the autoclave.
- Checking the precise operation of the earth leakage relay.
- Checking that the autoclave is leveled.
- Checking the safety elements; safety valve, cut-off thermostat, door locking mechanisms.
- Checking the operation sequences, the sterilization parameters etc.
- Checking the water reservoir, piping, plastic parts and electric wires.
- Checking and tightening the piping joints to avoid leakage.
- Checking and tightening all screw connections in the control box, heaters and valves and instrumentation.

### 5 years

- Checking the door device for excessive wear.
- Performing safety tests: pressure vessel, efficiency, electrical, according to local rules or regulations.

To be performed only, by an authorized inspector.

### 13.2 Draining the Reservoirs

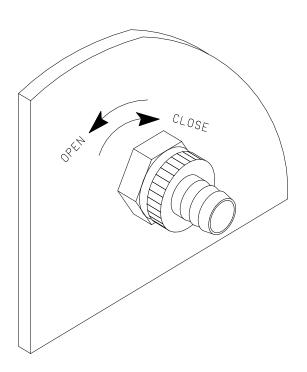


#### **CAUTION!**

Before starting, Make sure that the electric cord is disconnected and there is no pressure in the autoclave.

The drain valve is located on the front left side of the autoclave after the door is opened. The function of the drain valve is to drain the water reservoir.

- 1. Connect the silicone hose, supplied with the autoclave, to drain into a bucket.
- 2. Turn drain valve counterclockwise to the open position.
- 3. Fully drain the reservoir.
- 4. With a quart of tap water flush out the reservoir.
- 5. Turn drain valve clockwise to the close position.
- 6. Connect the electric cord to power source.
- 7. Fill the reservoir with distilled water to just below the safety valve (see sec 9.3).
- 8. Turn on the main power switch.
- 9. The autoclave is now ready for use.



#### 13.3 Cleaning the Air Jet

(Located in the water reservoir.)



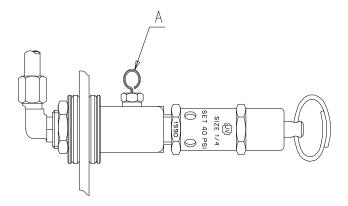
### A dirty air jet is the number one cause of failed spore tests

The elimination of air from the sterilization chamber during heat up is **critical** to the proper operation of the autoclave. Failure of the air removal system will be responsible for incomplete sterilization, indicator strips that do not turn, failed spore tests and aborted sterilization cycles. A clogged air jet will result in receiving the error message "Low Heat".

The air jet consists of a small orifice with a clean out wire inserted in it (wire is permanently installed and will not come out). It is required that the air jet be cleaned once per week or more often if necessary, to remove any accumulated dirt and debris.

It is preferred to clean the air jet when the unit is running a cycle and under pressure. Any loosened debris will be blown away, however, it can be done while the unit is idle.

- 1. Remove the water reservoir cover.
- 2. Clean the hole of the jet by manipulating the air trap wire back and forth 10 times.

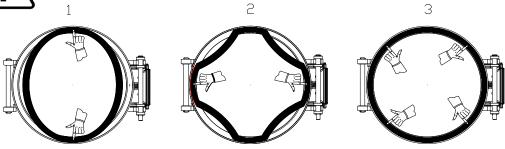


It is important to clean the hole of the air trap, as described at point 2 before starting operation of the autoclave, for the first time.

### 13.4 Replacing the Door Gasket



To avoid injuries replace the gasket while the autoclave is cold.



Pull off the gasket from the door groove and install the new gasket referring to the drawings as above points 1, 2 and 3.



### **CAUTION!**

See drawing below for the right direction of the gasket.

### 13.5 Checking the Safety Valve

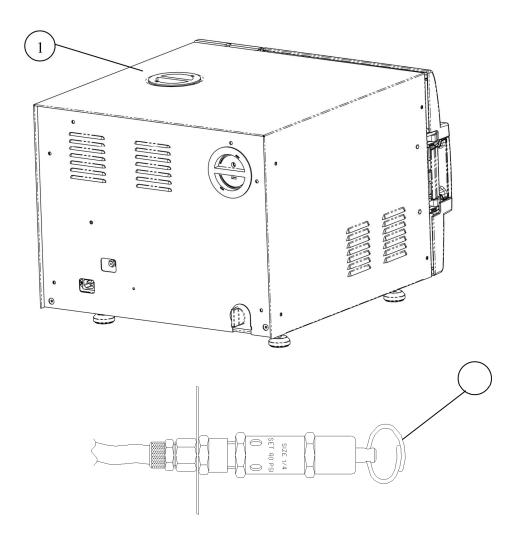
(Located in the water reservoir)

In order to prevent the safety valve from becoming blocked, it is necessary to allow the steam pressure to escape through it (every month).



To avoid injuries begin this check while the autoclave is cold.

- 1. Operate the sterilization cycle according to the manual.
- 2. Allow a pressure of approximately 200 kPa (29-psi) to build up in the chamber.
- 3. Remove water reservoir cover (1).
- 4. Pull the ring of the safety valve using a tool, i.e. screwdriver, hook etc and lift the safety valve ring for 2 seconds. Be careful not to burn your hands.
- 5. Press the STOP key to abort operation, and allow the steam to exhaust from chamber.
- 6. Wait until pressure goes down to zero, only then can the door be opened.



### 13.6 Cleaning the water outlet strainer



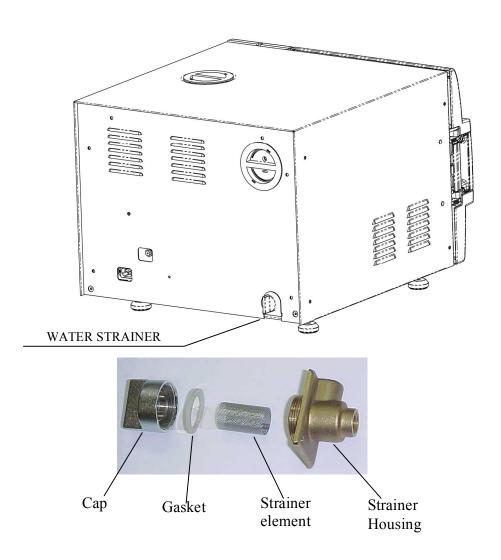
#### Caution!

Before proceeding, Make sure that the electric cord is disconnected and there is no pressure or water in the chamber.





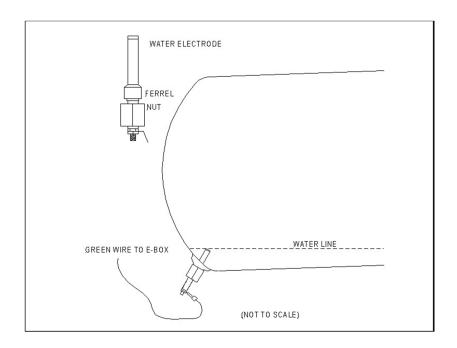
- 1. The strainer's cover is HOT
- Do not touch the strainer's cap, mounted on the exhaust line, during and shortly after operation. Touching the hot strainer's cap may cause severe injuries.
- 2. If maintenance operation is performed while strainer cap is hot, use heat resistant gloves to avoid injuries.
- 1. Open the strainer cap.
- 2. Remove the strainer element.
- 3. Rinse the strainer with water, using a brush if necessary.
- 4. Reinstall the strainer element.
- 5. Close the strainer cap



### 13.7 Water Sensor Cleaning

It is required that the water sensor be cleaned at least once per week. Cleaning the sensor will ensure that the water level in the chamber is properly reported to the microprocessor all during the cycle.

The water sensor is located in the rear of the chamber. It is easily cleaned using a damp cloth or sponge, you may use a mild soapy solution if you like. It is important to wipe the <u>sides</u> of the sensor as well as the tip, to remove any dirt or debris that may have built up.



## 14 TROUBLESHOOTING

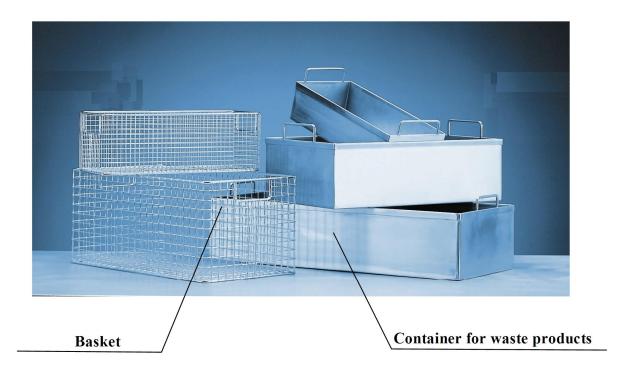
Only technical personnel having proper qualifications and holding technical documentation (including a technician manual) and adequate information are authorized to service the apparatus.

Problem/ Error Message	Message / Symbol Description	Corrective Action
Display is not activated	<ul> <li>The main switch is in the 'off position.</li> <li>the power cord is not connected properly to the machine and the power source.</li> <li>There is no electrical power in the main source.</li> </ul>	<ul> <li>Turn the main switch on.</li> <li>Make sure the power cord is properly connected to the machine and the power source.</li> <li>Fix the electrical power supply.</li> </ul>
The printer does not print	The paper is not inserted correctly in the printer.	<ul> <li>Make sure the paper is inserted in the printer correctly. See sec. 8.2.</li> <li>Switch the machine off then back on. If the printer prints the date and time, the printer is O.K.</li> </ul>
"Analog Input Error"	This message is displayed when any Temperature sensor or Pressure sensor is disconnected or out of range.	Call the technician.
"Chamber temperature not in range"	This message is displayed if the temperature in the chamber is too high or too low from the normal range.	Wait until the the chamber reaches the normal range temperature.
"Chamber pressure not in range"	This message is displayed if the pressure in the chamber is too high or too low from the normal range.	Wait until the the chamber reaches the normal range pressure.
"I/O Card Failed"	This message is displayed if I/O card is faulty (both while cycle is running or not).	Call the technician.
"I/O card is not connected"	This message is displayed if I/O card is disconnected (both while cycle is running or not).	Call the technician.
"Low Temp"	This message is displayed if the temperature drops for more than 1 second below the sterilization temperature during sterilization cycle.	Perform a new cycle.
"High Temp"	This message is displayed if the temperature raises 7°F (4°C) above sterilization temperature during the sterilization stage for 2 seconds during sterilization cycle.	Perform a new cycle.

Problem/ Error Message	Message / Symbol Description	Corrective Action
"High Temp. (Ending)"	This message is displayed if the system cannot reach the required temperature, in the chamber, within 10 minutes.	Perform a new cycle.
"Heat Time Error"	This message is displayed if the system cannot reach the required temperature, in the chamber, within the preset time.	Verify that the autoclave is not overloaded.
"Heat Time Error (Keep)"	This message is displayed if the system cannot reach the required temperature, in the chamber, during the optional "Keep Heat" stage, within the preset time.	Verify that the autoclave is not overloaded.
"Low Pressure"	This message is displayed if Chamber Pressure drops below the sterilization pressure (135°C = 313 kPa ,134°C = 304 kPa ,132°C = 286 kPa 121°C = 205 kPa) for 2 seconds during the sterilization stage.	Perform a new cycle.
"High Pressure"	This message is displayed if Chamber Pressure raises 4.2 psi-29 kPa above sterilization pressure (135°C = 313 kPa ,134°C = 304 kPa ,132°C = 286 kPa 121°C = 205 kPa) for 2 seconds during the sterilization stage.	Perform a new cycle.
"High Pressure (Ending)"	This message is displayed if the system cannot reach atmospheric pressure ± 5kPa during the ending stage.	Perform a new cycle.
"Pressure Time Error"	This message is displayed if the system cannot reach the required pressure conditions in the chamber, after preset time, during the air removal stage.	Verify that the autoclave is not overloaded.
"RTC Error - Please Set Current Date and Time"	This message is displayed in order to set the date and the time.	Set Current Date And Time. If the problem persists, call the technician.
"Time Error"	This message is displayed if the real time clock is faulty.	Call the technician.
"Door is open (During the cycle)"	This message is displayed when the door is open: During the cycle.	Close the door to perform a new cycle.
"Canceled By User"	This message is displayed after the START/STOP key is pressed and cycle aborted.	Wait until "cycle failed – canceled by user" or "cycle end – canceled by user" is displayed. Perform a new cycle.
"Cycle Failed"	This message and symbol are displayed if an error occurs before sterilization cycle is completed.	Perform a new cycle.

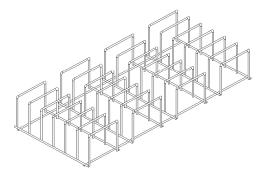
Problem/ Error Message	Message / Symbol Description	Corrective Action
"Air Error"	This message is displayed at the end of the cycle If the autoclave does not reach the atmospheric pressure after 10 minutes.	Wait until the autoclave reaches the atmospheric pressure and perform a new cycle.
"Periodical check time exceeded - Please call for service"	The periodical maintenance time has passed.	Call for service.
"Mineral free water reservoir empty"	This message is displayed if the water level electrode does not sense water.	Fill the mineral free water reservoir.
"Cycle counter exceeded - Please call for service"	Number of cycles, since last periodical maintenance, exceeded the preset number as defined by "cycle counter" parameter.	Call for service.
"Power Down"	This message is displayed if power down has occurred during the cycle. (this message will print out in the printer after the autoclave turns on).	Turn on the autoclave and wait until the autoclave is ready (reaches the safe condition) and perform a new cycle.
"No Water"	This message is displayed if the electrode in the chamber did not sense water within the preset time.	<ol> <li>check and fix the mineral free water supply.</li> <li>check and clean the water inlet filter.</li> <li>Clean the water level electrode.</li> </ol>

# **BASKETS AND CONTAINERS**



Stainless steel wire baskets		Stainless steel conta for waste produc	
L x D x H (mm)	Capacity	L x D x H (mm)	Capacity
400 x 180 x 160	1	400 x 190 x 160	1

# POUCH RACK ACS215-0008



# 15 SPARE PARTS LIST

PART NUMBER	DESCRIPTION
FIL175-0042	Filter, Air, 0.2 Micron, Model 50mm D
THE002-0066	Thermal paper for CUSTOM PLUSII printer roll 57mm, d=50mm

# 16 ACCESSORIES

PART NUMBER	DESCRIPTION
GAS084-0007	Drain P.V.C. Tube, 8x12
THE002-0052	Printer, PLUSII-S2B-0004
WIR040-0002	Cable, Electric, Plug + Socket 208/230V 10A, EUR