

OPERATION & MAINTENANCE MANUAL

Electronic Table - top Autoclave

models 2540, 3870 EHS

CAT. No. MAN205-0034-005E Rev. B COPYRIGHT ©





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Electronic Table-Top Pre and Post Vacuum Autoclave

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🖃 Tuttnauer U.S.A., 25 Power Drive, Hauppauge, NY, 11788 U.S.A. 🛈 +1-631-737 4850, 🗀 Fax: +1-631-737 0720

TABLE OF CONTENTS

	PARAGRAPH		
1.	GEN	ERAL	
	1.1	Incoming Inspection	4
	1.2	Warranty	4
	1.3	Warranty Statement	4
<i>2</i> .	GEN	ERAL INFORMATION	6
	2.1	Introduction	6
	2.2	Operating Conditions	8
	2.3	Stand – by heating mode	8
	2.4	Utilities	8
	2.5	Overall Dimensions for the 2540 model	11
	2.6	Overall Dimensions for the 3870 model	12
	2.7	Technical Specifications	13
	2.8	Electrical Specifications	13
	2.9	Construction	14
	2.10	Water quality	14
	2.11	Water for the vacuum system and the Drain Cooling	15
	2.12	Environment Emission Information	15
	2.13	Symbol Description	15
	2.14	Directives and Standards	16
3.	STER	RILIZATION PROGRAMS	19
	3.1	Program 1 - Unwrapped Instruments (1 - Flash 273)	19
	3.2	Program 2 (2- WDry 273)	20
	3.3	Program 3 (3 - WDry 250)	21
	3.4	Program 4 - (4 - Fast 273)	22
	3.5	Program 5 (5 - B&D Test)	24
	3.6	Program 6 (6 - Leakage Test)	25
4.	KEYE	BOARD (keys and display)	26
	4.1	Description and Functions of the Front Panel Keyboard	27
	4.2	Description of the Operational Messages	30
	4.3	Description of Displayed Error Messages and Safety Measure	s 31
5.0	PRIN	TER	35
	5.1	Printer Operation	35
	5.2	Printer Handling	37
6.	PREF	PARATION BEFORE STERILIZATION	38
7.	DEN	TAL HANDPIECE STERILIZATION	41

7. DENTAL HANDPIECE STERILIZATION

TABLE OF CONTENT	ΓS	(Cont.)
------------------	----	---------

	PARA	GRAPH	PAGE NO.
8.	OPE	RATION	43
	<i>8.1</i>	Operating Instructions	43
	<i>8.2</i>	Lifting and carrying	44
	8. 3	Loading and unloading the Device	44
9.	MAI	NTENANCE INSTRUCTIONS	46
	9.1	Preventive and Scheduled Maintenance	46
	9.2	Draining the Reservoir	47
	<i>9.3</i>	Replacing the Air Filter	48
	9.4	Replacing the Door Gasket	<i>49</i>
	9.5	Replacing the Cartridge Fuse	50
	9.6	Checking the Safety Valve	51
	9. 7	Cleaning water outlet strainer	52
<i>10</i> .	TRO	UBLESHOOTING	53
<i>11</i> .	SP A	RE PARTS LIST	56
<i>12</i> .	ACC	ESSORIES	56

TABLE OF CONTENT (Cont.)

PAGE NO.
10
17
18
26

1. GENERAL

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

1.1 Incoming Inspection

Upon receiving your Tuttnauer Autoclave carefully inspect the outside of the shipping carton for signs of damage. If any damage to the carton is found note the location with respect to the autoclave and check that area of the autoclave carefully once it is fully unpacked. 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 any damage is found contact your dealer as soon as possible so that they can file a claim with the shipping carrier and also notify Tuttnauer.

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.

Note: Lifting and carrying should always be done by two people.

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.

This warranty does not include routine cleaning and preventive maintenance to be performed according to instructions in

section 9.1 (Preventive and Scheduled Maintenance).

Tuttnauer warrantees all new EHS autoclaves for a period of one full year, covering both parts and labor. This one-year warranty covers defects in materials and workmanship on <u>every</u> part in the autoclave.

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 autoclaves that have been repaired or altered outside the factory without prior authorization from Tuttnauer.

Tuttnauer's obligation is limited to the repair or replacement of parts for the autoclave. This warranty will be void if the unit is not purchased from an authorized Tuttnauer dealer. No other warranties or obligations are expressed or implied.

The Autoclave should only be used in a manner described in this manual!

1.3 Warranty Statement

To activate the warranty, the registration card must be completed and returned to Tuttnauer within fourteen (14) days of purchase or you may call our customer service department at the number listed below.

For service on this product contact your dealer or Tuttnauer USA Co. No product will be received or accepted for repair without prior return authorization from Tuttnauer. All transportation charges to and from Tuttnauer must be paid by the owner of the autoclave. During the first 90 days after purchase of an autoclave, Tuttnauer will pay shipping costs on an individually evaluated basis and **ONLY** with pre-approval.

Note:

If you have any questions or there are any difficulties with this instrument and the solution is not covered in this manual, please contact your dealer or Tuttnauer USA Co.. **Do not attempt to service this instrument yourself**.

Tuttnauer USA Co. 25 Power Drive Hauppauge, NY, 11788, USA (800) 624 5836, (631) 737 4850, Fax: (631) 737 0720 e-mail:info@tuttnauer.com

2. GENERAL INFORMATION

2.1 Introduction

The EHS is a high speed, high vacuum, high capacity, hospital grade sterilizer with FDA cleared flash cycle. A built in vacuum pump and steam generator allows for increased load size and dramatically reduces total cycle time. The closed door drying system provides a faster and more thorough drying cycle. Seven automatic cycles are available. Five sterilization cycles and two test cycles. EHS models are available in a 10" or 15" chamber.

The EHS autoclave, models 2540 and 3870 are designed for the sterilization of wrapped and unwrapped instruments and related items found in dental, medical and veterinary clinics, first aid rooms, hospitals, laboratories etc. They are electrically – heated pre and post vacuum sterilizers, using steam as the sterilizing agent. A computerized control unit ensures a fully automatic sterilization cycle, and the control and monitoring of physical parameters.

The EHS pre / post vacuum sterilizer has the following features:

- ▶ It is a Class B sterilizer in accordance with the European standard prEN 13060-2
- It has a pre-vacuum conditioning stage
- ➢ It has a post-vacuum drying phase.
- ➢ It has a jacketed chamber
- ▶ It has a dual compartment water reservoir
- ▶ It has a complete water discharge system
- ➢ It has a PC friendly communication system

The advantages of this pre / post vacuum sterilizer are:

- Dramatically faster overall cycle time
- Better and deeper steam penetration into loads
- Increased load size
- More thorough and efficient drying of materials
- Automatically maintained water reservoirs
- Immediate availability of steam for sterilization
- Non recycled water reduces maintenance

The Vacuum pump:

The pre and post vacuum stages are achieved with the use of a high volume liquid ring vacuum pump.

The advantage of the <u>pre-vacuum</u> stage is felt during the sterilization stage. Vacuum removal of at least 99.5% of the air in the chamber allows the steam to penetrate deeper into packed materials. Deeper penetration allows for larger loads to be sterilized, thus saving time by having to run fewer cycles.

The advantage of the <u>post-vacuum</u> stage is an efficient and thorough drying of bagged and wrapped items. This is accomplished by the combined use of a heated chamber and the vacuum removal of residual moisture.

The Jacketed chamber:

This autoclave has a jacketed stainless steel chamber. The space between the walls of the chamber and jacket is used to generate and provide the steam required by the autoclave. The heating elements are located inside this cavity as is the mineral free water supplied by the reservoir. Steam is produced and maintained here as long as the unit is turned on, thereby eliminating waiting time and making possible steam on demand.

This autoclave's reservoir is divided into two compartments:

The front compartment is for supplying the steam generator with mineral free water. It is replenished from a mineral free water source and is maintained automatically by high and low sensors and a computer controlled solenoid valve.

The rear compartment is for supplying the liquid ring vacuum pump with tap water. It is replenished from a tap water source and is maintained automatically by high and low sensors and a computer controlled solenoid valve.

Printer option:

This autoclave can be equipped with an optional printer that prints the preset and actual parameters of each cycle (temperature, pressure and vacuum with respect to time).

Computer interface:

An outstanding feature of this autoclave is the communication system. This system allows interfacing with a personal computer for control and monitoring of the autoclave by means of a special software program. This communication system also enables the transmission of data from the autoclave through a modem - to a remote center for data logging or subsequent processing.

This manual is intended for the user. It gives the user a general understanding of the instrument and the best ways to operate and take care of it, in order to obtain optimum effective results.

After reading this manual, operating and maintaining the autoclave will be simple and easy. However since this instrument is built with 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 and holding technical documentation (including a technician manual) and adequate information are authorized to service the apparatus.

2.2 **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 $104^{\circ}F$ (40 °C) and a relative humidity of 85% respectively.

For optimal results from the first sterilization cycle, it is recommended to perform a B & D cycle (cycle # 5) at the beginning of each working day.

2.3 Stand – by heating mode

While the autoclave is in the jacket heating stage, "St.By" is displayed in the upper right corner of the LCD screen. This announcement is maintained until the jacket reaches it's working pressure, at which time the message will change to "READY". When the unit is first turned on it will take approximately 10 - 20 minutes for the jacket to reach its working pressure and temperature.

2.4 Utilities

For proper operation, these are the required utilities that need to be supplied:

Site requirements for installation of a 2540 EHS

- 1. <u>Counter top</u> able to support a minimum 200 lb. * (the unit is shipped with a suitable stand 26"W x 33"D x 34"H)
- 2. <u>Counter space</u> minimum 20"W x 32"D x 20"H * (see unit dimensions below)
- 3. <u>City water</u> supply 15 58 psi with shut off valve having ½" NPT male end. Higher rates of pressure will require the installation of a pressure reducer (58 psi max) The minimum flow rate required is 0.66 gal/min. (2.5 lit./min.). Installation of the valve should be 2" above counter height at the rear of the unit.
- 4. <u>Mineral Free water</u> supply 8 30 psi with shut off valve and ½" NPT male end. If the water pressure, at the autoclave inlet, is higher then 58 psi (4 bar), adjust the shut off valve for a low water flow into the mineral free water reservoir. The minimum rate of flow is 0.26 gal/min (1 lit/min). Installation of the valve should be 2" above counter height at the rear of the unit. * (an optional R.O. water system is available).
- 5. <u>Electrical power</u> 20A 208V <u>single</u> phase (voltage not to exceed 230V). Connection required; flush mount receptacle 6-20R, within 1 foot of the rear of the unit.
- 6. **Drainage** should be to a 4" high 4" diameter air break, reducing down to a 1 ¹/₂" vented line with a trap. All drainage components must be able to withstand a non-continuous temperature of 140°F (60°C). Drain opening should be within 1 foot of the rear of the unit. The use of two ¹/₂"x 6" Milford Type Copper Coated Hangers is required for the positioning of the two drain hoses over the center of the air break and a 4" metal worm gear clamp to secure the hangers. The hangers will need to be bent at a 90° angle to allow for proper positioning and securing with the clamp. * (see attached drawing)

Site requirements for installation of a 3870 EHS

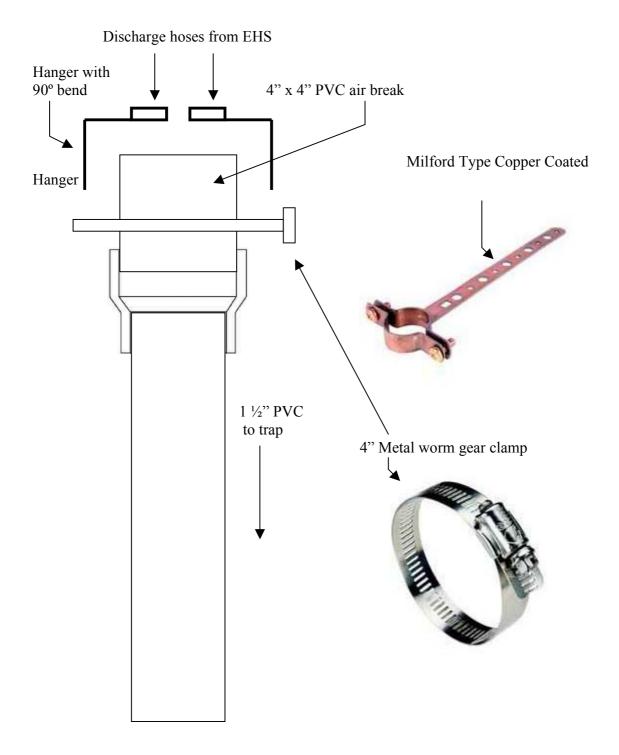
- 1. <u>Counter top</u> able to support a minimum 400 lb. * (the unit is shipped with a suitable stand 26"W x 33"D x 34"H)
- 2. <u>Counter space</u> minimum 26"W x 39"D x 24"H * (see unit dimensions below)
- 3. <u>City water</u> supply 15 58 psi with shut off valve having ½" NPT male end. Higher rates of pressure will require the installation of a pressure reducer (58 psi max) The minimum flow rate required is 0.66 gal/min. (2.5 lit./min.). Installation of the valve should be 2" above counter height at the rear of the unit.
- 4. <u>Mineral Free water</u> supply 8 30 psi with shut off valve and ½" NPT male end. If the water pressure, at the autoclave inlet, is higher then 58 psi (4 bar), adjust the shut off valve for a low water flow into the mineral free water reservoir. The minimum rate of flow is 0.26 gal/min (1 lit/min). Installation of the valve should be 2" above counter height at the rear of the unit. * (an optional R.O. water system is available)
- 5. <u>Electrical power</u> 20A 208V three phase, three power lines plus a ground (voltage not to exceed 230V). Connection required; flush mount receptacle or drop line with NEMA # L15-20R, this is a twist lock connector, within 1 foot of the rear of the unit.
- 6. **Drainage** should be to a 4" high 4" diameter air break, reducing down to a 1 ¹/₂" vented line with a trap. All drainage components must be able to withstand a non-continuous temperature of 140°F (60°C). Drain opening should be within 1 foot of the rear of the unit. The use of two ¹/₂"x 6" Milford Type Copper Coated Hangers is required for the positioning of the two drain hoses over the center of the air break and a 4" metal worm gear clamp to secure the hangers. The hangers will need to be bent at a 90° angle to allow for proper positioning and securing with the clamp. * (see attached drawing)

Caution!

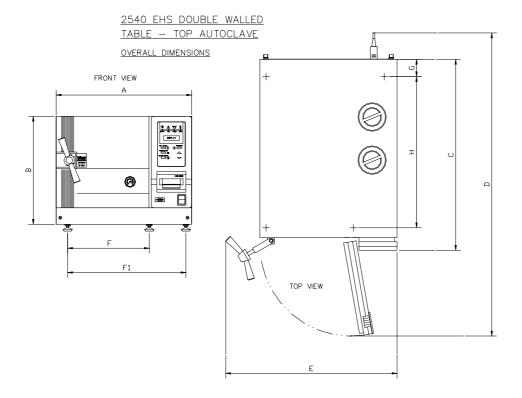


Wastewater should be brought into the public sewage network in accordance with the local rules or requirement i.e. only non-hazardous liquids shall be disposed in public sewage!

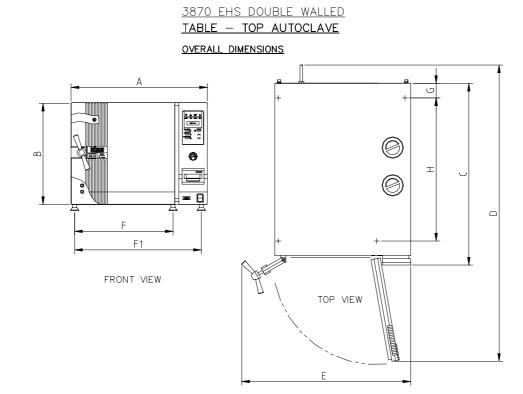
Suggested Site Drain Drawing



2.5 Overall Dimensions for the 2540 model



Dimensions	2540 EHS		
Dimensions	inches	mm	
Α	20.0	510	
В	16.7	425	
С	28.1	715	
D	43.3	1110	
Е	25	635	
F (Front legs)	11.8	300	
F1 (rear legs)	17.1	435	
G	2.0	50	
Н	21.6	550	



2.6 Overall Dimensions for the 3870 model

Dimensions	3870 EHS		
Dimensions	inches	mm	
Α	26.0	660	
В	20.7	525	
С	34.5	875	
D	55.0	1400	
Ε	32.0	815	
F (Front legs)	17.8	451	
F1 (rear legs)	24.0	610	
G	2.0	50	
Н	28.6	725	

2.7 Technical Specifications

Prope			Value			
Поре	ny		2540		3870	
Chamber		Dia.	10" (254 mm)	15'	' (380 mm)	
Chamber		Depth	18.7" (475 mm)	30" (760mm)		
Chamber volume			6.1 gal (23 lit.)	22.2	gal (84 lit.)	
Jacket volume			2.3 gal (8.5 lit.)	4.0	4.0 gal (15 lit.)	
Shipping weight			165 lb (75 kg)	313	lb (142 kg)	
Shipping volume			$21.5 \text{ ft}^3 (0.6 \text{ m}^3)$	27.2	$ft^3 (0.77 m^3)$	
Reservoir volume	Vacuum pump		0.7 gal (2.5 lit.)	0.7	gal (2.5 lit.)	
(upper float switch)	Jacket		0.7 gal (2.5 lit.)	0.7	gal (2.5 lit.)	
Max. Allowable Working pressure (MAWP)			40 psi (2.76 bar)	40 p	si (2.76 bar)	
		W		4 -	14" (35 cm)	
		Н			1" (2.5 cm)	
Tray dimensions		Н			26" (67 cm)	
(Internal)		W	6.7" (17 cm)		11" (28 cm)	
		Н	0.8" (2 cm)	Small	1" (2.5 cm)	
		L	16.3" (41.5 cm)		26" (67 cm)	
No. of trays			2	2		
IMS cassettes (opt	tional)		3 full & 3 half		15 full	
Load No. counter		Counting from 0 to 9999 and nullifies.				

2.8 Electrical Specifications

Proparty	Value		
Property	2540	3870	
Heaters Power	3000W	6000W	
Total Power	3200W	6200W	
Voltage (V)	1 ph / 208	3 ph / 208	
Amperage (A)	15	15	
Frequency (Hz)	50/60	50/60	
Protection against electrical shock	Class I (IE	C 60601-1)	

2.9 Construction

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

- Chamber is built of stainless steel 316 L.
- Door is made of stainless steel 304.
- Trays are made of stainless steel 316.
- Water reservoir is made of hard plastic material.
- Door handle is made of hard plastic material, which is safe to touch and thermoinsulated.

2.10 Water quality

The distilled or mineral – free water supplied to the steam generator shall be according to the table below:

Evaporate residue	$\leq 15 \text{ mg/l}$
Silica	$\leq 2 \text{ mg/l}$
Iron	$\leq 0.2 mg/l$
Cadmium	$\leq 0.005 \text{ mg/l}$
Lead	$\leq 0.05 \text{ mg/l}$
Rest of heavy metals	$\leq 0.1 \text{ mg/l}$
Chloride	$\leq 3 \text{ mg/l}$
Phosphate	≤ 0.5 mg/l
Conductivity	$\leq 50 \ \mu s/cm$
pН	6.5 to 8
Appearance	colorless, clean, without sediment
Hardness	$\leq 0.1 \text{ mmol/l}$

Mineral Free Water qualifications

(In compliance with ISO 11134 and ISO 13683)

Attention:

The use of water in the autoclave 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 warranty.

The suitability of the mineral free water to be used should be verified by testing in accordance with the above table, at an authorized laboratory using acknowledged analytical methods.

2.11 Water for the vacuum system and the Drain Cooling

The feed water supplied to the liquid ring vacuum pump must meet the following requirements:

- Hardness: 0.7 2 mmol/l.
- Water temperature: shall not exceed 59°F (15°C).

Note:

The use of hard water in the vacuum pump may invalidate the warranty for the vacuum pump, since it can cause blocking of the rotor, which can damage the pump.

2.12 Environment Emission Information

- A. The peak sound level generated by the sterilizer is < 70 / dBA with background noise of 60 dBA.
- B. The total heat transmitted by the sterilizer is:
 - <100 W / h (341 btu) for 2540 EHS
 - < 150 W / h (512 btu) for 3870 EHS.

2.13 Symbol Description



Caution! Consult accompanying documents



Caution! Hot surface.



Caution! Hot steam.



Protective earth (Ground)

Stand by

2.14 Directives and Standards

2.14 Directives and Standards

Every autoclave meets the provisions of the following Directives and is designed, manufactured and tested in compliance with the following Standards:

2.14.1 Technical Directives

1. Medical device directive MDD/93/42/EEC.

- 2.14.2 Technical Standards
 - 1. A.S.M.E. Code, section VIII division 1 for pressure vessels.
 - 2. UL3101-1 for Laboratory use Electrical Equipment.
 - 3. ANSI/AAMI ST-8, Hospital Steam Sterilizer (model 2540 EHS).
 - 4. ANSI/AAMI ST-37, Flash Sterilization: Steam sterilization of Patient Care Items for Immediate Use
 - 5. ANSI/AAMI ST-55 Table-Top Steam Sterilizer (model 3870 EHS).

2.14.3 Quality standards

The manufacturing plant meets the following quality standards:

- 1. EN ISO 9002 (7.94) Quality System
- 2. EN 46002 (8.96) Quality System Medical device Particular requirements.
- 3. ISO 13488 Quality systems Medical devices Particular requirements for the application of ISO 9002.

The autoclave is UL listed E206879, FDA cleared and notified by 0123 Notifying Body in compliance with directive MDD/93/42/EEC. The manufacturer retains all supporting documentation.

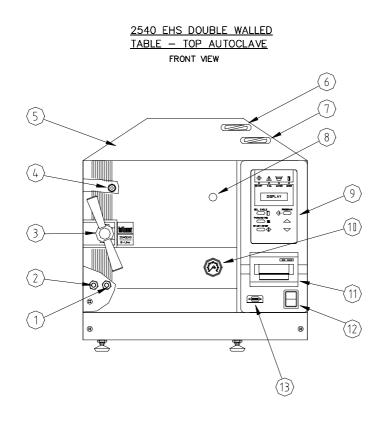
The 2540 EHS was tested in accordance with, manufactured in accordance with, and meets all of the requirements of ANSI/AAMI ST-8.

The 3870 EHS was tested in accordance with, manufactured in accordance with, and meets all of the requirements of ANSI/AAMI ST-55.

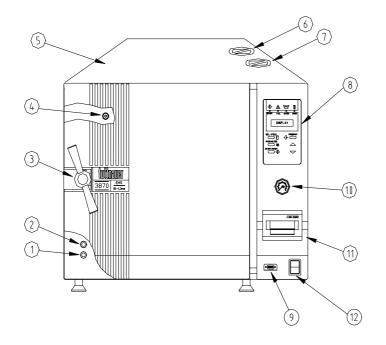
Both models were tested in accordance with ANSI/AAMI ST-37.

In addition, each model meets applicable ANSI/AAMI standards. The 2540 EHS has been tested in accordance with ANSI/AAMI ST-55, the 3870 EHS has been tested in accordance with ANSI/AAMI ST-8, and the flash cycles for both models have been tested in accordance with ANSI/AAMI ST-37.

Front View



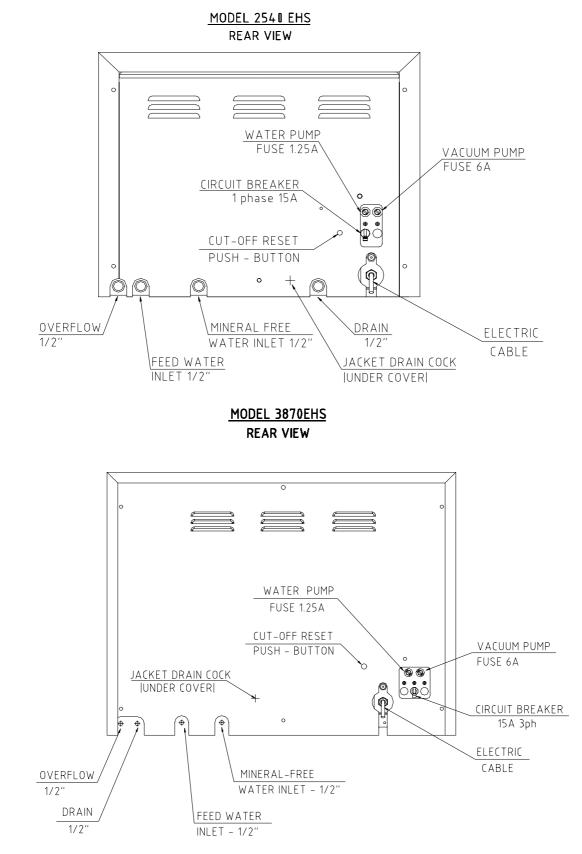
3870 EHS DOUBLE WALLED TABLE - TOP AUTOCLAVE FRONT VIEW



- 1 MINERAL FREE WATER RESERVOIR DRAIN VALVE
- VACUUM PUMP WATER RESERVOIR 2 DRAIN VALVE
- 3 DOOR TIGHTENING BOLT
- 4 DOOR SWITCH
- 5 AUTOCLAVE COVER
- 6 FEED WATER RESERVOIR COVER (VACUUM PUMP)
- MINERAL FREE WATER 7
- RESERVOIR COVER 8 - VALIDATION PORT COVER
- 9 KEYBOARD
- 10 JACKET PRESSURE GAUGE
- 11 PRINTER
- 12 MAIN SWITCH 13 CONNECTOR TO PC

- 1 VACUUM PUMP WATER RESERVOIR DRAIN VALVE
- 2 MINERAL FREE WATER RESERVOIR DRAIN VALVE
- 3 DOOR TIGHTENING BOLT
- 4 DOOR SWITCH
- 5 AUTOCLAVE ENCLOSURE
- 6 FEED WATER RESERVOIR COVER (VACUUM PUMP)
- 7 MINERAL FREE WATER RESERVOIR COVER
- 8 KEYBOARD
- 9 CONNECTOR TO PC
- 10 JACKET PRESSURE GAUGE
- 11 PRINTER
- 12 MAIN SWITCH

Rear View



3. STERILIZATION PROGRAMS

The autoclave offers 4 sterilization programs, with or without a drying stage and 2 test programs.

3.1 Program 1 - Unwrapped Instruments (1 - Flash 273)

Program 1 is recommended for a single unwrapped instrument and other materials intended for immediate use and for the prevention of cross contamination, when the manufacturer recommends autoclaving at temperatures of 273°F (no drying cycle is required).

Nominal Parameters

- Sterilization temperature: 273°F 279°F.
- Sterilization time: 3.5 minutes.

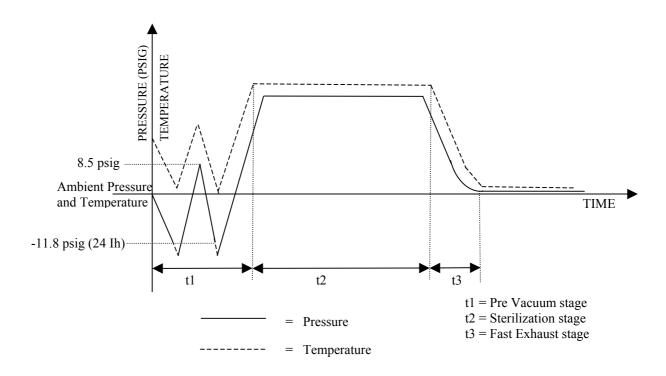
Operations Sequence

- ♦ Pre Vacuum stage; two vacuum pulses remove air by drawing the chamber down to -11.8 psig (24 lh). At the end of the pre vacuum stage steam enters the chamber from the jacket until the sterilization temperature and pressure is reached.
- Sterilization stage; temperature and pressure are maintained constant at the preset level for the programmed sterilization time by periodic injection of steam from the jacket.
- Exhaust stage; steam is rapidly exhausted from the chamber allowing the chamber pressure to reach 0 psig (atmospheric pressure).



Note:

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



3.2 Program 2 (2 - WDry 273)

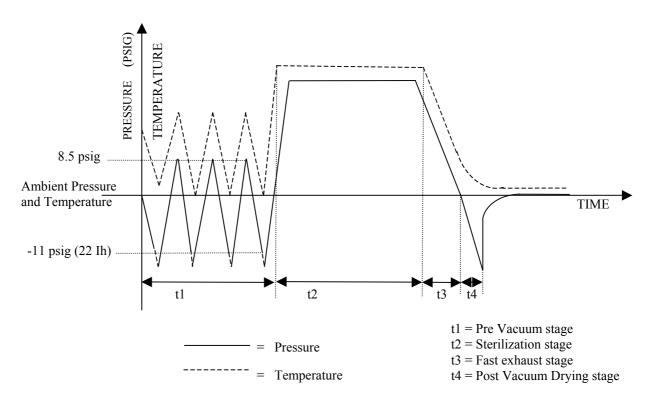
Program 2 is recommended for wrapped instruments, porous load and other materials when the manufacturer recommends autoclaving at temperatures of up to 273°F with a drying stage.

Nominal parameters

- Sterilization temperature: 273°F 279°F.
- Sterilization time: 8 minutes.
- Dry time: 20 minutes.

Operations Sequence

- Pre Vacuum stage; four vacuum pulses remove 99.5% of the air by drawing the chamber down to -11 psig (22 Ih). At the end of the pre vacuum stage steam enters the chamber from the jacket until the sterilization temperature and pressure is reached.
- Sterilization stage; temperature and pressure are maintained constant at the preset level for the programmed sterilization time by periodic injection of steam from the jacket.
- Exhaust stage; steam is rapidly exhausted from the chamber allowing the chamber pressure to reach 0 psig (atmospheric pressure).
- Post Vacuum Drying stage; while the jacket is heated to maintain a high temperature environment within the chamber, a single vacuum pulse is created for 20 minutes in order to release and remove residual moisture from any items within the chamber.



3.3 Program 3 (3-WDry 250)

Program 3 is recommended for delicate wrapped or unwrapped instruments and other material which the manufacturer recommends autoclaving at temperatures of up to 250°F with a drying stage

Nominal parameters

- Sterilization temperature: 250°F 256°F
- Sterilization time: 30 minutes.
- Drying time: 20 minute.

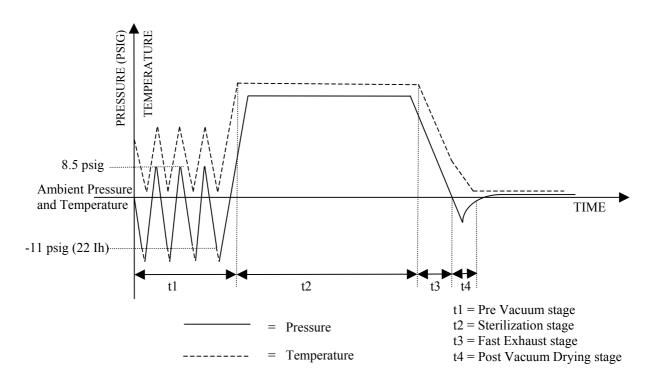
Operations Sequence

- Pre Vacuum stage; four vacuum pulses remove 99.5% of the air by drawing the chamber down to -11 psig (22 Ih). At the end of the pre vacuum stage steam enters the chamber from the jacket until the sterilization temperature and pressure is reached.
- Sterilization stage; temperature and pressure are maintained constant at the preset level for the programmed sterilization time by periodic injection of steam from the jacket.
- Exhaust stage; steam is rapidly exhausted from the chamber allowing the chamber pressure to reach 0 psig (atmospheric pressure).
- Post Vacuum Drying stage; while the jacket is heated to maintain a high temperature environment within the chamber, a single vacuum pulse is created for 20 minutes in order to release and remove residual moisture from any items within the chamber.



Note:

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



3.4 Program 4

3.4.1 Program 4 - (4 - Fast 273)

This program is available only in the 2540EHS

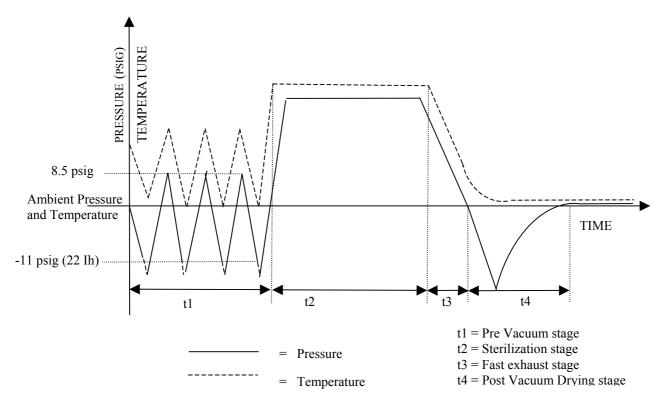
Program 4 is recommended for wrapped instruments, non-lumened and materials that the manufacturer recommends autoclaving at temperatures of up to 273 °F with a drying stage.

Nominal parameters

- Sterilization temperature: 273°F 279°F.
- Sterilization time: 4 minutes.
- Dry time: 20 minutes.

Operations Sequence

- Pre Vacuum stage; four vacuum pulses remove 99.5% of the air by drawing the chamber down to -11 psig (22 Ih). At the end of the Pre Vacuum stage steam enters the chamber from the jacket until the sterilization temperature and pressure is reached.
- Sterilization stage; temperature and pressure are maintained constant at the preset level for the programmed sterilization time by periodic injection of steam from the jacket.
- Exhaust stage; steam is rapidly exhausted from the chamber allowing the chamber pressure to reach 0 psig (atmospheric pressure).
- Post Vacuum Drying stage: while the jacket is heated to maintain a high temperature environment within the chamber, a single vacuum pulse is created for 20 minutes in order to release and remove residual moisture from any items within the chamber.



3.4.2 Program 4 - (4 - WDry 273)

This program is available only in the 3870EHS

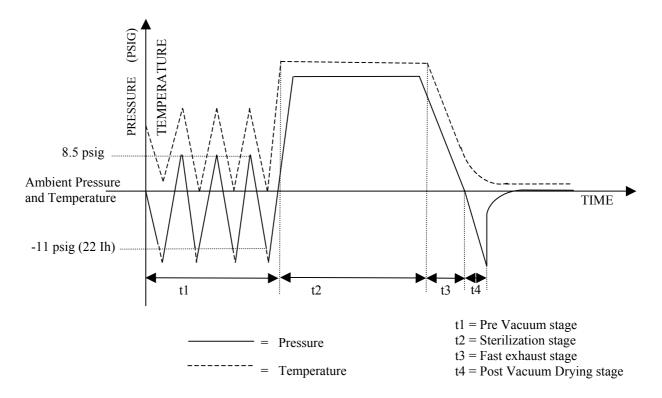
Program 4 is recommended for wrapped instruments, porous load and other materials when the manufacturer recommends autoclaving at temperatures of up to 273°F with a drying stage.

Nominal parameters

- Sterilization temperature: 273°F 279°F.
- Sterilization time: 8 minutes.
- Dry time: 20 minutes.

Operations Sequence

- Pre Vacuum stage; four vacuum pulses remove 99.5% of the air by drawing the chamber down to -11 psig (22 Ih). At the end of the pre vacuum stage steam enters the chamber from the jacket until the sterilization temperature and pressure is reached.
- Sterilization stage; temperature and pressure are maintained constant at the preset level for the programmed sterilization time by periodic injection of steam from the jacket.
- Exhaust stage; steam is rapidly exhausted from the chamber allowing the chamber pressure to reach 0 psig (atmospheric pressure).
- Post Vacuum Drying stage; while the jacket is heated to maintain a high temperature environment within the chamber, a single vacuum pulse is created for 20 minutes in order to release and remove residual moisture from any items within the chamber.



3.5 Program 5 (5 - B&D Test)

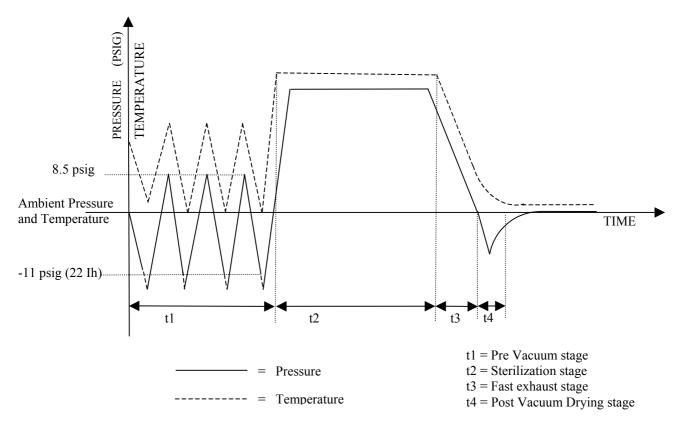
This is a test program, with fixed sterilization parameters 273°F and 3.5 minutes that cannot be modified by the operator.

Nominal parameters

- Sterilization temperature: 273°F 279°F.
- Sterilization time: 3.5 minutes.
- Dry time: 2 minutes.

Operations Sequence:

- Pre Vacuum stage; four vacuum pulses remove 99.5% of the air by drawing the chamber down to -11 psig (22 Ih). At the end of the Pre Vacuum stage steam enters the chamber from the jacket until the sterilization temperature and pressure is reached.
- Sterilization stage; temperature and pressure are maintained constant at the preset level for the programmed sterilization time, of 3.5 minutes, by periodic injection of steam from the jacket
- Exhaust stage; steam is rapidly exhausted from the chamber allowing the chamber pressure to reach 0 psig (atmospheric pressure).
- Post Vacuum Drying stage; while the jacket is heated to maintain a high temperature environment within the chamber, a single vacuum pulse is created for 2 minutes in order to release and remove residual moisture from any items within the chamber.



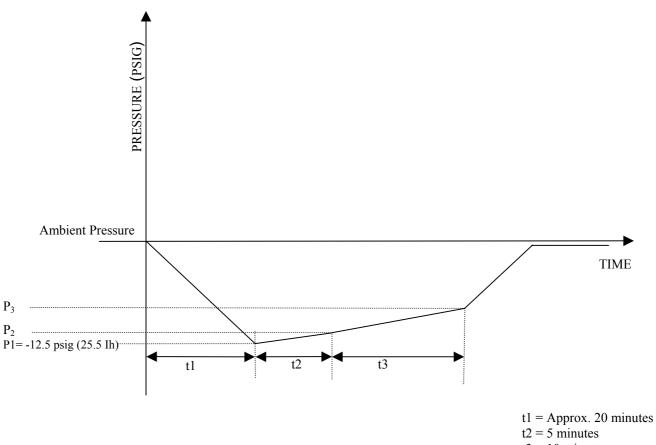
3.6 Program 6 (6 – Vacuum Leakage Test)

Vacuum is produced in the chamber down to (P_1) -12.5 psig (25.5 lh). At this stage all the valves close. The autoclave remains in this stage for 5 minutes. This period enables the condition in the chamber to reach equilibrium. After the 5 minutes have elapsed the printer records the pressure that is referred to as P₂. At this point the test begins and lasts 10 minutes. At the end of the test, the printer records the results. The pressure at the end of the test is referred to as P₃. The rate of change of P₃ to P₂ shall not exceed 0.02 psi/min. If P₃ to P₂ exceeds 0.02 psi/min the printer will print "FAIL". If P₃ to P₂ is within the required value, the cycle will end normally.

Operations Sequence

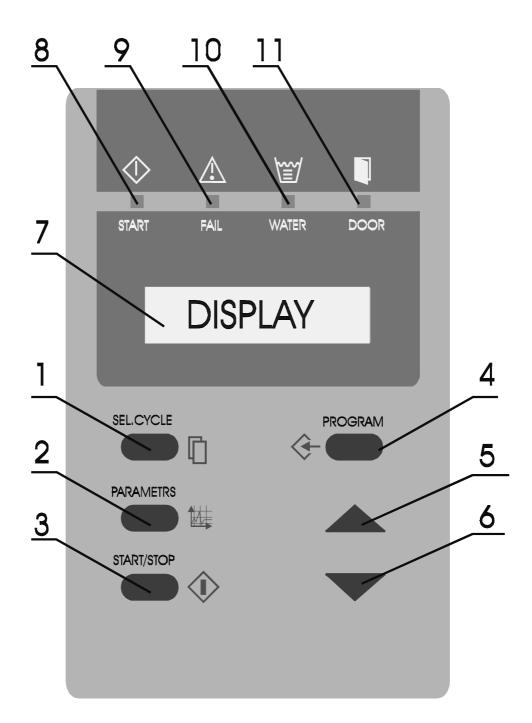
- Vacuum is produced in the chamber down to -12.5 psig (25.5 Ih).
- The chamber is allowed to stabilize for 5 minutes then a test is done to establish P2.
- A second test is done after 10 minutes to establish P3 and to determine the vacuum lost (P3 P2)
- The vacuum pump stops.

Note: During the test period the autoclave is not heated.



t3 = 10 minutes

4. *KEYBOARD* (keys and display)



Front Panel Keyboard

4.1 Description and Functions of the Front Panel Keyboard

The command panel is comprised of 3 sections, on the lower section there are 6 keys; 3 command keys and 3 programming keys.

The middle section consists of the LCD display with two rows and 16 characters on each line.

The top section consists of 4 signal lights that indicate the status of the autoclave.

1. Sel. Cycle (select cycle) key



Pressing this key selects, in order, one of the 6 programs listed below. Each time the key is depressed it advances to the next program (e.g. from program 2 to 3).

If the system is set to program 6, pressing the key returns to program 1.

This autoclave has the following available programs:

- 1. Flash for single unwrapped instruments at 273°F with 3.5 minutes of sterilization time and no drying.
- 2. Wrapped instruments and materials at 273°F with 8 minutes of sterilization and 20 minutes drying.
- 3. Wrapped or unwrapped instruments and materials at 250°F with 30 minutes of sterilization and 20 minutes of drying.
- 4. Wrapped non-lumened instruments and materials at 273°F with 4 minutes of sterilization and 20 minutes of drying.
- 5. Bowie & Dick Test
- 6. Vacuum Leakage Test

2. Parameters key



Pressing this key displays for 3 seconds the three parameters of the current program (except for the Bowie & Dick Test and the Vacuum Leakage Test). The information is displayed along the top row of the LCD screen and is as follows:

Sterilization Temp	Sterilization Time	Dry Time
273°F	S = 4m	D=1Øm

After 3 seconds, or if the parameter key is pressed again, the screen returns to it's original program display.

$\langle \mathbf{i} \rangle$

3. Start/ Stop key

This key commands the following 3 functions:

- Starting the process.
- Stopping the process.
- Canceling the FAIL message from the command panel and opening the electric door locking if available.

Starting the process:

For starting a program this key is active only when the autoclave is in the "Ready" mode. If the door is closed, the water level in the reservoir is normal and the "Ready" indicator is on the screen then pressing this key starts the selected program.

Stopping the process:

For stopping a program this key is active while the autoclave is running a program, pressing this key at any stage of the program stops the process.

Canceling the FAIL message

At the end of an aborted program, the FAIL light is turned on and an error message is displayed on the screen indicating the cause of the failure.

Pressing this key cancels the displayed message and switches off the FAIL light.

<

This key is designed for programming the date and time as well as setting system parameters. The date and time settings are readily available to the machine operator. System parameters are only accessible with the appropriate access code and should only be changed by a properly trained and qualified service technician.

When the PROGRAM key is pressed, the first to be displayed is the date with the cursor under the day. Each time the PROGRAM key is pressed the cursor advances to the next parameter, month, year, hour, minutes and then seconds. Using the UP (5) and DOWN (6) keys will change the value of the parameter above the cursor.

After the date and time have been set, pressing the PROGRAM key again will show CODE: 000. A technician's access code is required to proceed further and change system parameters. Information on all the system parameters can be found in the Technicians Manual.

5. UP key

4. Program key



This key will increase the value displayed above the cursor, for either programming the clock or for setting system parameters by the technician.

6. DN key



This key will decrease the value displayed above the cursor, for either programming the clock or for setting system parameters by the technician.

7. DISPLAY SCREEN

The screen is an LCD display that consists of two display rows each containing 16 characters. The top row shows the current program and READY status. The bottom row shows real time temperature and pressure in the chamber.

8. START LED INDICATOR



When the "START" LED indicator is on it indicates that the system is running a program.

9. FAIL LED INDICATOR



When the "FAIL" LED indicator is on it indicates that the cycle has failed either, because the system parameters have not been maintained or the STOP key has been pressed.

10. WATER LED INDICATOR



When the "WATER" LED indicator is on it indicates that there is a lack of water in the mineral free water reservoir.

11. DOOR LED INDICATOR



If the "Start" key is pressed and the door is unlocked the light will signal twice, the buzzer will sound four times and a message "Door Unlock" will be displayed.

If a cycle is in progress and fails because the door is unlocked the "FAIL" LED indicator will light and a message "Door Unlock" will be displayed.

4.2 Description of the Operational Messages

The display is comprised of 2 rows, each row consists of 16 characters.

4.2.1 The upper row:

On the left side of the upper row, 10 characters are allotted for the selected programs.

1 - Flash 273	fast sterilization, fast exhaust, no drying.
2 - WDry 273	lumened instruments, fast exhaust, with drying.

- 3 WDry 250 all instrumentation, fast exhaust, with drying.
- 4 Fast 273 fast sterilization, non-lumened instruments, fast exhaust, with drying.
- 5 B&D Test Bowie Dick Test.
- 6 Leakage Test vacuum leakage test.

On the right side of the upper row, 6 characters are allotted for the selected programs.

- St.By (Stand By) Jacket heating stage.
- READY Jacket heating stage completed
- Vacum (Vacuum) Pre Vacuum stage
- Heat (Heating) Heating stage.
- Ster (Sterilization) Sterilization stage.
- ◆ Exh (Exhaust) Exhaust stage
- ◆ Dry (Dry Stage) Post Vacuum Drying stage
- ◆ Test Vacuum test stage

When the PARAMETERS key is pressed the parameters of the selected program are displayed on the upper row.

4.2.2 The lower row:

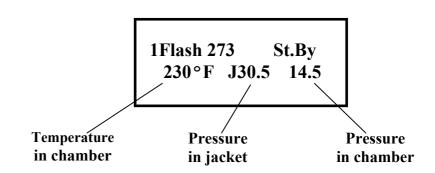
- On the left side of the lower row 5 characters are allotted for the display of temperature in ° F, in the form 273°F.
- On the right side of the lower row, 5 characters are allotted for display of the chamber pressure. The actual pressure is continuously displayed at all stages of the process and between processes (standby).
- In the center of the lower row 6 characters are allotted for the display of the jacket pressure. The jacket pressure is displayed continuously unless the area is needed for another message.
- In case the process is aborted, the reason for the failure is displayed on the left side of the lower row, instead of the temperature. 11 characters are allotted for this error message.

- During the sterilization and dry stages, the countdown clock showing the amount of time left to the completion of the stage is displayed in the screen area between the readouts of temperature and pressure.
- The format of the display is, MM:SS (two digits for minutes and two digits for seconds).
- On completion of the process, the END message is displayed in the screen area between the readouts of temperature and pressure.

The time between 2 complete cycles must be at least 10 minutes in order to give the machine time to cool down. If the machine is started within that 10-minute period, a countdown clock showing the time remaining will be displayed in the screen area between the readouts of temperature and pressure. Once the countdown is completed the second cycle will automatically begin.

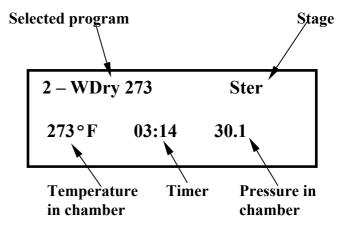
When a cycle is started by means of pressing the START key, the load number is displayed for 2 seconds on the left side of the lower row.

Example 1: The screen display showing the autoclave between processes and program No.1 has been selected.

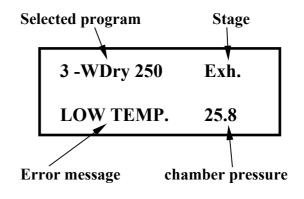


Example 2: The screen display showing the autoclave in the sterilization stage and program No.2 is running. The time left to completion

is 3 minutes and 14 seconds.



Example 3: The screen display showing a process that has failed due to temperature drop during the sterilization stage of program No.3.



4.3 Description of Displayed Error Messages and Safety Measures

- **Low Heat** Message is displayed and sterilization does not start if the autoclave has not reached sterilization temperature after heating for 30 minutes.
- **Low Temp.** Message is displayed, FAIL indicator lights and cycle is aborted, if the temperature drops for more than 5seconds below the sterilization temperature.
- **High Temp.** Message is displayed, FAIL indicator lights and the cycle is aborted in one of the following cases:
 - If temperature rises 6°F above sterilization temperature during the sterilization stage.
 - If temperature sensor is damaged, this message appears during the HEAT stage.
- **Low Pres.** Message is displayed, FAIL indicator lights, and the cycle is aborted if the pressure drops for more than 5 seconds below the pressure correlated to the sterilization temperature.
- **High Pres.** This message is displayed, FAIL indicator lights, and the cycle is aborted if pressure rises above the pressure correlated to the sterilization temperature by 6°F for more than 5 seconds.
- **Low Vacuum** Message is displayed and FAIL indicator lights if in the air removal stage a vacuum level of -11 psig (22 Ih) is not reached during 20 minutes after the cycle is started.
- **Man. Stop** Message is displayed and the FAIL indicator lights after the STOP key is pressed for longer than 1 second.
- **Power Down** No Message is displayed if a power failure occurs. An On message is printed on the printer with the date and time showing that there was a power interruption and when the power came back on. If the power is lost during the sterilization stage, then when power resumes, the system automatically aborts the cycle, exhaust will be performed according to the program requirements and a FAIL messages will be displayed and printed...

If a power failure occurs during the Pre Vacuum or Heat stage, the cycle resumes and is continued until completion.

Dry and Exhaust stages automatically resume operation once the power is back on.

- **Door Unlock** Message is displayed and the DOOR LED indicator flashes if the door is improperly closed and the START button is pressed to start the desired cycle. If the door becomes ajar during any stage of the cycle, the DOOR UNLOCK message is displayed and the FAIL indicator lights.
- Add Water Message is displayed, the buzzer is activated four times and the "Water" LED illuminates if the water level switch indicates no water in the mineral free water reservoir and the START button is pressed. In this case the cycle will not begin until water is added and the START button is pressed.

- **Ready** Message is displayed if the autoclave is ready to begin a cycle. This will be when the pressure in the jacket has reached the proper pressure for the required cycle.
- **Not Ready** Message is displayed if the START key has been pressed before the pressure in the jacket has reached the proper pressure for the required cycle.
- **St. By** Message is displayed after the autoclave has been turned on and while the pressure in the jacket is rising to the pressure required to begin a cycle.
- **Gen. Error** Message is displayed, the buzzer is activated and the FAIL indicator illuminates when the water pump runs continuously for more than 10 minutes, attempting to fill the jacket. To cancel this alarm the main power switch must be turned off. After turning power back on, if the GEN.ERROR alarm occurs again after 2¹/₂ minutes, a service technician must be called.
- **Vac Water** Message is displayed when the low water level float, in the feed water reservoir, detects that the water level is too low.

If a printer is installed on the system, then the printer will print any ERROR messages that appear on the LCD Display

5.0 PRINTER

5.1 Printer Operation

The autoclave can be equipped with a character printer, which prints a detailed history of each cycle performed by the instrument (for the record or for subsequent consideration).

The printing is made on thermal paper with 24 characters per line and prints the following information each time a cycle is run.

- Software version
- Date and time
- Selected program (with the parameters for that program)
- Sterilization time
- Sterilization temperature
- Sterilization pressure
- Success or failure of the performed cycle.
- ◆ Load number (1 99999) for identification
- Autoclave identifier
- Space for the operator's signature

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

The data is printed from the bottom up, beginning with the software version number and ending with space for the operator's signature (see the example below).

PRINTER OUTPUT	DESCRIPTION	
Operator :	To be filled in manually by operator.	
Autoclave:001	Autoclave identifying number.	
02/03/2002 09:04:44	Date and time sterilization cycle ended.	
Load number: 00011	Load number. Useful for record keeping and	
	scheduling maintenance	
Cycle ended		
D30:17 187.5°F 26.2Ihg	The time, temperature and pressure during post vacuum drying	
E26:15 230.2°F 01.3Psig	The time, temperature and pressure during exhaust.	
S24:21 276.1°F 31.0Psig	The time, temperature and pressure during	
C C	sterilization.	
*		
*	Prints sterilization data every 1 minute.	
*		
S18:19 275.5°F 31.9Psig	The time, temperature and pressure during sterilization.	
S17:19 273.6°F 31.2Psig	The time, temperature and pressure during sterilization.	
H11:25 187.7°F 22.4Ihg	The time, temperature and pressure during heating.	
V09:34 232.4°F 08.8Psig	The time, temperature and pressure during pre vacuum.	
*		
V00:00 076.0°F 00.2Ihg	The time, temperature and pressure during pre vacuum.	
Dry time: 020min	Drying time for selected program.	
Ster time: 008.0min	Sterilization time for selected program.	
Ster Temp: 273°F	Sterilization temperature for selected program.	
PROGRAM: 2-WDry	Selected program: 2- 273°F with dry cycle	
02/03/2002 08:17:30	Date and time sterilization cycle began.	
EHSEn42-20USA	Software version number	

Legend

V	Vacuum stage	D	Drying stage
H	Heating stage	Psig	Pound per Square Inch
S	Sterilization stage	Ihg	Inch of Mercury
E	Exhaust stage		

5.2 Printer Handling

The printer is driven and controlled automatically by the control unit, while the autoclave performs a sterilization program.

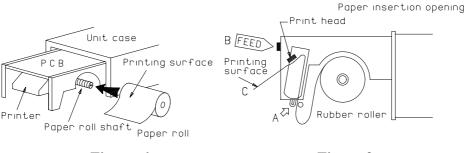


Figure 1

Figure 2

To set the paper roll in the printer perform the following steps:

- 5.2.1 Gently push the clips for removing the front panel, remove the panel and pull out the printer gently.
- 5.2.2 Set the paper roll on the shaft (See Figure 1). Since the outer and inner surfaces of the paper are different set the roll so that the printing surface is the outer.
- 5.2.3 Gently push the paper face down into insertion opening (A) in Figure 2. Keep pressing the feed switch (B) until the paper comes out from the print head (C).
- 5.2.4 When the paper emerges from the print head, insert it in the paper cutter (the slot in the front panel) and reassemble the front panel on the unit.

The paper roll is set inside the unit and the printer is ready for use..

NOTE: If the paper is not pulled in by the rollers even when you press the feed switch (B) push the paper in.

5.2.5 To ensure a reliable operation of the printer perform the following:

5.2.5.1 Turn the main switch to the OFF position.

5.2.5.2 Turn the main switch to the ON position; press the feed switch at the same time. Verify that the printer performs an operation test by printing all the built-in characters

The following precautions have to be taken ensuring the proper operation of the printer:

- Avoid contact between the paper and the hot parts of the autoclave, as the paper will be blackened.
- Do not pull out the paper roll from the paper insertion opening.
- Use only the 58mm. wide thermal paper rolls, supplied by your dealer.

6. **PREPARATION BEFORE STERILIZATION**

This section applies to the sterilization of all instruments [*except for dental handpieces*]. For the preparation of dental handpieces, please refer to the handpiece manufacture's instructions and see section 7 in this manual.

CAUTION: The liquid cycle is not meant for the sterilization of liquids intended for direct patient contact.

The purpose of packaging and wrapping items for sterilization is to provide an effective barrier against contamination during storage, once the items have been sterilized.

Packaging and wrapping materials should be approved for use in a steam sterilizer and permit the removal of air and penetration of the steam during the sterilization process.

The basic principle of determining the size, mass and contents of instrument and hollowware packs is that the contents are sterile and dry immediately upon completion of the drying cycle

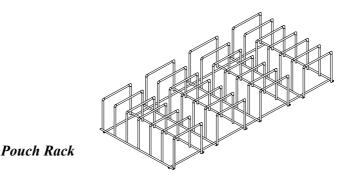
Instruments to be sterilized must be clean and free from any residual matter, such as debris, blood, pads or any other material. Such substances may cause damage to the instruments themselves or the sterilizer.

- 1. Clean instruments immediately after use. It is recommended that instruments be cleaned in Tuttnauer's **UltraWash** instrument washer or ultrasonically cleaned using Tuttnauer's **Clean and Simple** enzymatic cleaning solution.
- 2. After ultrasonic cleaning rinse under tap water for 30 seconds and pat dry to remove residual minerals. If your tap water has a high mineral content then rinse a second time in a bath of distilled water or alcohol to remove minerals.
- 3. Launder textile wraps prior to reuse, but **do not** use bleach.
- 4. Follow the instrument manufacturer's instructions for cleaning and lubricating instruments. For proper handpiece maintenance the use of Tuttnauer's **HandpieceSPA** is recommended.
- 5. Be sure that instruments of dissimilar metal (stainless steel, carbon steel, etc.) are separated. Carbon steel instruments should be bagged or placed on autoclavable towels and not directly on stainless steel trays. (Mixing will result in the oxidation of these metals).
- 6. Do not place materials to be sterilized directly on the chamber's wall. Place the material only on trays, rack, etc.
- 7. Check the manufacture's instructions as to the proper procedure for sterilizing each item.



- 8. Place a sterilization indicator in each tray or inside each wrapped pack.
- 9. All instruments **must** be sterilized in an open position.
- 10. Use single-use wraps once only and discard after use.

- 11. Verify that the packaging method is in accordance with good practice approach and the packaging materials are in accordance with the applicable standards (e.g. EN868 series).
- 12. At least once per week use a biological spore test (Bacillus Stearothermophilus) in any load to insure proper sterilization. (Be aware testing standard may vary).
- 13. Place instruments with ratchets opened and unlocked or clipped on the first ratchet position.
- 14. 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.
- 15. Tilt on edge items prone to entrap air and moisture, e.g. hollowware, so that only minimal resistance to air removal, the steam passage and condensate will be met.
- 16. Load items within the boundaries of the tray so that they do not touch the chamber walls, or fall off when the tray is inserted into the autoclave.
- 17. The operator may use racks to allow for adequate separation of packaged instruments.
- 18. Load trays loosely to capacity. Instruments should be loaded one level deep only
- 19. Do not overload the sterilizer trays. Overloading will cause inadequate sterilization and poor drying. Allow approximately 1 2 lbs. of instruments per tray.
- 20. Make sure that all instruments remain apart during the sterilization cycle.
- 21. Empty canisters should be placed upside-down, in order to prevent accumulation of water.
- 22. Allow a distance of approximately 1" (2.5 cm) between trays or cassettes to permit steam circulation.
- 23. Wrapped instruments should be packed in material that will allow steam penetration and promote drying, such as autoclave bag, autoclave paper, or muslin towels.
- 24. Do not stack pouches. It is recommended that a Tuttnauer[™] Pouch Rack be used. This will allow the operator to place pouches on their side, which will increase capacity and provide proper spacing to ensure steam penetration and promote adequate drying.



Note:

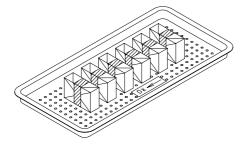
A table "Suitability of steam sterilization processes for various goods and method of packing" is added to the accompanying documents.

25. Packs

- 1. Place packs upright on trays, side by side.
- 2. Packs should not touch the chamber walls.
- 3. Pack instrument sets in a manner that prevents damage to delicate items.
- 4. Pack hollowware sets so that all openings face the same direction and so that the contents cannot move inside the pack.
- 5. Load packs of folded operating room drapes with layers vertical, allowing air to be removed from the packs rapidly.
- 6. Do not place packs of hollowware and trays of instruments above textile packs or soft goods in order to avoid wetting caused by condensation from items above.
- 7. Load items packed in flexible packaging materials on edge with paper to laminate, or flat with the plastic surface downwards.

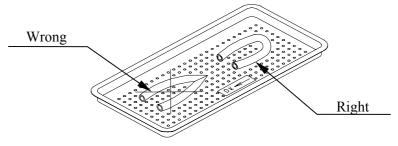
Note:

The manufacturer's recommendations shall be observed, concerning the sterilization data for each type of material.



26. Tubing

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



27. Cassettes

Instruments may be sterilized in cassettes. The advantage of the cassettes is that the sterilized instruments may remain organized in the cassettes ready for use, while stored in a sterile area.

If using model 2540 remove the trays and slide the cassettes into the chamber on the rack system.

If using model 3870 place the cassettes directly on the tray, either lying flat (but no stacking) or on edge.

7. DENTAL HANDPIECE STERILIZATION

Up to 5 dental handpieces may be sterilized concurrently in the autoclave in the wrapped or unwrapped mode. No additional articles should be sterilized concurrently with the dental handpieces. You should follow the handpiece manufacturer's instructions regarding cycle times and temperatures. Where those instructions have not been provided, you may use one of the automated programs for wrapped and unwrapped instruments as follows:

Cycle	Time (minutes	Temperature (°F)
Unwrapped Instruments (Program 1)	3.5	273
Wrapped Instruments (Program 2)	8	273

Caution: Some dental handpieces may be contraindicated for exposure to high sterilization temperatures. The electronic control system permits the sterilization temperature to exceed the set temperature by 6°F. Hence, when utilizing one of the automated programs, the sterilizer may reach a temperature as high as 279°F.

<u>Loading</u>: No more than 5 dental handpieces, and <u>only</u> dental handpieces, should be sterilized during the same sterilization cycle. This was the worst case scenario validated during testing.

Users selecting other load configurations should validate the process to ensure *effective sterilization*. When loading, sufficient space should be allowed between each handpiece to allow effective steam penetration.

Tuttnauer recommends the review of ANSI/AAMI publication ST-42-1998 entitled: "Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care, medical, surgical and dental facilities."

A. For Wrapped Cycles: (For unwrapped cycles, please skip to B).

- (1) Remove all trays, except for the bottom tray, from the sterilization chamber.
- (2) Place in the sterilization chamber a five position, stainless steel pouch divider specifically designed for paper/plastic pouches that will stand on edge during sterilization. The pouch divider should be placed in the center of the bottom tray level to the sterilizer.
- (3) Seal each handpiece in a 3.5" x 9" paper/plastic peel pouch.
- (4) Positioning the pouches in the pouch divider depends upon the number of dental handpieces being sterilized. No more than 5 handpieces should be sterilized during any single cycle. In all cases, the pouches should be positioned standing on edge and evenly distributed in the handpiece rack. The sides of the pouches should alternate, such that the paper side of one pouch stands next to the plastic side of the next pouch.

B. For Unwrapped Cycles:

Note: Trays need not be removed for unwrapped cycles.

- (1) Before placing a dental handpiece onto a sterilizer tray, make sure that the instruments that are not of the same metal (stainless steel, carbon steel, etc.) are separated and placed in different trays.
- (2) In case carbon steel instruments are used with stainless steel trays, the tray should be lined with a towel or paper-wrap before positioning the instrument. There should be no direct contact between the carbon steel and the stainless steel trays.
- (3) Place a sterilization indicator strip in each tray.

(4) Make sure the instruments do not touch each other during the sterilization cycle.

Warning: Unwrapped instruments should be considered not sterile after processing once exposed to a non-sterile environment.

8. **OPERATION**

8.1 *Operating Instructions*

- 1. Open the main feed-water supply valve.
- 2. Open the mineral-free water supply valve.
- 3. Ensure the drain is connected. The drainage hose must be fixed very securely to the drain when water is released to reduce the risk of injury to personnel.
- 4. Turn on the rocker switch mounted on the front panel to activate the control circuits.
- 5. Wait until "READY" appears in the display.
- 6. Set the clock for the proper date and time, by means of the PROGRAM key (4), UP (5) and DOWN (6); see paragraph 4.1.
- 7. Press the SELECT key (1) to select the required program .The name of the program is displayed indicating the program has been selected.
 - 7.1 It is recommended to run a B & D cycle as the first cycle each working day.
- 8. To check the program parameters prior to running the program press the Parameters key (2).
- 9. Load the material to be sterilized into the chamber, and close the door.

Note:

In order to ensure the door is fully sealed, tighten the door bolt until "hand-tight". Do not over - tighten the bolt as this may result in damage to the gasket.

Should the autoclave fail to reach the sterilizing temperature/pressure, always check if the door is fully sealed. If not, tighten the door bolt further, as described above, until completely sealed.

10. Press the START key (3) to put the autoclave in operation.

The autoclave starts performing the sequence of operations. The actual measured values of the clock, pressure and temperature are displayed continuously and printed every minute during sterilization stage and at the minimum and maximum pressure points for other stages.

The messages St.By, READY, Vacum, Heat, Ster., Exh, Dry and Test are displayed at the right side of the upper line.

If the operator presses the START key and the door is not completely closed, the process will not start and the DOOR light flashes for 4 seconds.

11. Drying is performed by means of the vacuum pump and heated chamber.

All programs have the ability to perform a vacuum assisted drying stage, to remove unwanted moisture from instruments or other material that has been sterilized. The drying time is adjustable depending on individual needs. Program 1 intended for unwrapped instruments comes set to 0 minutes, all other sterilization programs are set to 20 minutes. All drying stages begin after the steam exhaust stage.

12. At the end of the cycle a buzzer rings and the START light switches OFF. The message "END" is displayed. The exhaust value is opened to prevent formation of a vacuum, if the door is not opened immediately.

In the event of program failure, the exhaust valve is opened, a continuous sound followed by beeps is output, the FAIL indicator is lit and the appropriate error message is displayed.

- 13. Open the door and unload the sterilized material from chamber.
- 14. At the end of the day switch off the power by means of the rocker switch on the front panel.

Attention!

The pressure and temperature of the jacket decreases very slowly when the equipment is turned off.

8.2 Lifting and carrying

Caution:



Before moving the autoclave, Make sure that the electric cord is disconnected from the power, that all hoses are disconnected from water supply and drain and there is no pressure in the chamber.

- 1. Disconnect the power supply cord.
- 2. Disconnect the water and drain hoses.
- 3. Drain the water from the reservoir and vessel.

To avoid injuries, lifting and carrying should be done by at least two people.

Do not drop this device!

8.3 Loading and unloading the Device

8.3.1 Safety

Protective equipment and clothes and other safety instructions should be implemented in accordance with local and national regulations and/or rules!

For proper sterilization - Do not overload the chamber. Only autoclavable products shall be used; for sterilization of unknown materials or instruments please refer to the instructions of the manufacturer of these items

8.3.2 Loading

Correct loading of the autoclave is essential to successful sterilizing for several reasons. Efficient air removal from the chamber and the load will permit effective steam penetration and saturation, and allow proper drainage of condensate. Additionally, correct loading will reduce damage to packs and their contents and maximize efficient use of the sterilizer.

For detailed loading instructions, see para. 6 (Preparation before sterilization)

8.3.3 Unloading

On completion of the cycle, the load shall be immediately removed from the sterilizer and a visual inspection made to ascertain that the load is dry, and that sterilizing indicators have made the required color change.



Do not touch the strainer's cover, mounted on the left side of the autoclave, during or shortly after operation.

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

9. MAINTENANCE INSTRUCTIONS

9.1 Preventive and Scheduled Maintenance

The maintenance operations described in this chapter need to be followed as indicated to keep the device in good working condition.

The instructions that follow can easily be carried out by the office personnel and do not require a service technician.

Should the need arise, technical assistance or a service technician can be requested by either calling your dealer or Tuttnauer USA Co.



Warning:

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

9.1.1 Daily

- 1. Clean the door gasket with a mild detergent, water and soft cloth or sponge. The gasket should be clean and smooth
- 2. It is recommended to run a B & D test (program 6) as the first cycle each working day.

9.1.2 Weekly

1. Take out the tray holder and trays. Clean the tray holder and trays with detergent or a non-abrasive stainless steel cleaner and water, using a cloth or sponge. Rinse the tray holder and trays immediately with water to avoid staining the metal.



Caution

Do not use steel wool, steel brush or bleach as this can damage the chamber and trays!

- 2. Put a few drops of oil on the 2 door pins and door tightening bolt.
- 3. Clean the outer parts of the autoclave with a soft cloth.

9.1.3 Periodically

- 1. Once every month clean and check the safety valve (see para. 9.6).
- 2. Every 6 months or as needed replace the air filter, (see para. 9.3).
- 3. Every 6 months clean the electronic box with compressed air, from inside outward.
- 4. Check the door gasket every 12 months and replace it if required (see para. 9.4).
- 5. Clean the strainer once a month (see para. 9.7).

9.2 Draining the Reservoir

Caution!

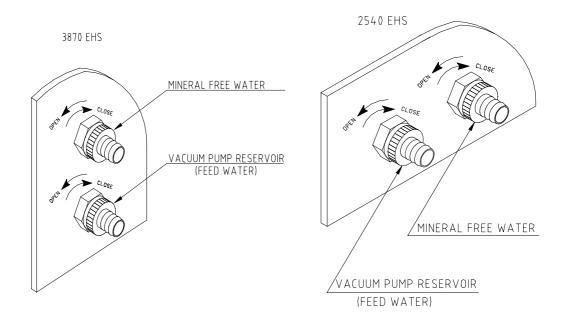
\triangle

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

The drain valves are located on the autoclave's front. Each compartment (jacket reservoir and vacuum pump water reservoir) is connected to a separate drain valve (see location drawing below).

- 1. Connect the supplied plastic tube to the relevant valve and turn drain valve counter clockwise (1 turn).
- 2. When the water reservoir is empty, turn drain valve clockwise to the closed position. Remove the plastic tube.
- 3. Connect the electric cord to power source.
- 4. Turn on the autoclave. Mineral free water / tap water will enter the relevant reservoir until it reaches the water level switch, approximately 2.5 liters (0.7 gallons) in each compartment

The autoclave is now ready for use.



9.3 Replacing the Air Filter

In order to "break" the vacuum, at the end of the dry phase, filtered atmospheric air enters the chamber via a solenoid valve. The filtration of the air is performed by the bacteriological filter that is placed at the inlet of the chamber, through a solenoid valve.

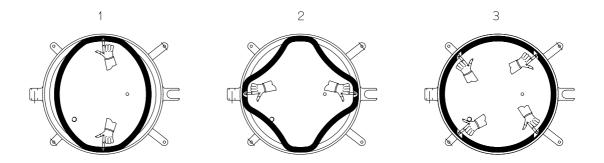
The filter is mounted near an opening on the left sidewall of the autoclave enclosure, to ease access for replacing it.

To replace the filter proceed as follows:

- 1. Remove the cover of the opening.
- 2. Remove the filter:
 - 2.1 On model 2540, disconnect the filter from the filter cover and the flexible tubing.
 - 2.2 On model 3870, cut the tie wrap connecting the flexible tubing to the filter. Disconnect the filter from the filter cover and the flexible tubing.
- 3. Replace the filter with a new one:
 - 3.1 on model 2540, connect the filter to the filter cover and the flexible tubing.
 - 3.2 On model 3870, connect the filter to the cover and to the flexible tubing and secure it with a tie wrap.



Service cover with air filter



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!

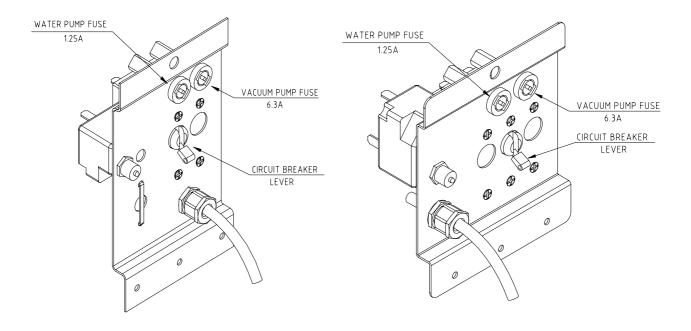
This gasket is designed with a trapezoidal cross section. The gasket should be placed with the widest side towards the door.

9.5 Replacing the Cartridge Fuse Caution Make sure that the electrical power cord is disconnected!

Use a screwdriver to unlock the fuse holder cover by turning it counter clockwise $\frac{1}{4}$ turn, and pull it out.

Insert a new cartridge into the holder and turn the cover clockwise until locked.

Make sure that the correct fuse is installed as specified in the drawings below:



Model 2540 EHS

Model 3870 EHS

9.6 Checking the Safety Valve

The safety valve is 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 the valve. This procedure should be done every month as follows:

- 1. Operate the sterilization cycle according to the manual.
- 2. Allow a pressure of approximately 30 psig to build up in the jacket.
- 3. Remove water reservoir cover

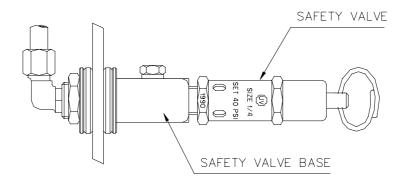
Caution!



This next step will expose you to HOT STEAM

To avoid being burned, by hot steam, do not place your face over the safety valve.

4. Pull the ring of the safety valve using a tool, i.e. screwdriver, hook etc and open the safety valve for 2 seconds then release it. Be careful not to burn your hands. The safety valve should close automatically within a few seconds, if not then turn the unit off and have a service technician replace the valve.



9.7 Cleaning water outlet strainer



Caution!

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

Warnings

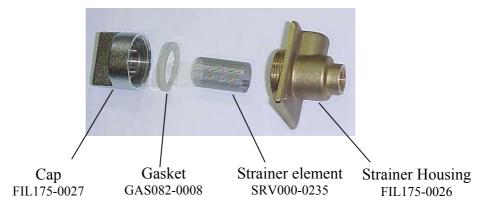


1. Do not touch the strainer's cover, mounted on the left side of the autoclave, during and shortly after operation. Touching the hot strainer's cover may cause severe injuries.

- 2. If maintenance operation is performed while strainer cover 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.



Water strainer



This Only and	This troubleshooting chart enables the us Only technical personnel having proper and adequate information are authorized	This troubleshooting chart enables the user to solve minor malfunctions, prior to requesting service Only technical personnel having proper qualifications and holding technical documentation (including a technician manual) and adequate information are authorized to service the apparatus.
	Problem	Solution
	The machine is not responding	 Verify that there is electric power in the electric network. Make sure the main switch is in the 'On' position. (see front view drawing). Make sure the power cord is properly connected to the machine and the mains. (see rear view drawing) Make sure the circuit breaker has not tripped. Reset circuit breaker if necessary. Cut-off thermostat may have been activated. Press the cut-off reset button.
Ċ	'Low Vacuum' is displayed	 2.1 Check the door for leakage and replace the door gasket, if necessary. 2.2 Make sure the pump is running. Check the pump fuse and replace it if necessary. 2.2 Make sure the pump is running. Check the pump fuse and replace it if necessary. 2.2 Make sure the pump is running. Check the pump fuse and replace it if necessary. 2.3 Make sure the pump is running. Check the pump fuse and replace it if necessary. 2.4 Verify that the vacuum pump water reservoir contains the adequate quantity of water. 2.5 if the above did not solve the problem – call for service.
ω.	'Gen. Error' is displayed	3.1 Water level electrode does not sense water for a period of 10 minutes. Check water level in the reservoir. If water level is low and lower float switch is not stuck – call for service.

10. TROUBLESHOOTING FOR THE OPERATOR

	Problem	Solution
4.	'Low Heat' is displayed	4.1 Make sure the machine has the proper amount of sterilization load.4.2 Check that there is no leakage of steam at the door. If yes, verify that the door is closed according to instruction in para. 8.1 if leakage continues, replace door gasket according to para.9.4.
		 4.3 If the above did not solve the problem – call for service. 4.4 Verify that there is enough mineral free water in the reservoir. 4.5 Check 1.25A fuse and replace if burnt. 4.6 Check electrical supply fuses. Replace or reset tripped fuse as needed.
5.	'Low Water' is displayed	 Check if there is water in the mineral free water reservoir. 5.1 If no water then possible faulty mineral free water supply. Fix water supply. 5.2 If there is water then possibly the water pump fuse in burnt. Replace fuse. 5.3 If the above did not solve the problem – call for service.
6.	'Low Pres' is displayed	 6.1 Check the door for leakage and replace the door gasket if necessary. (see para. 9.4 Replacing the Door Gasket) 6.2 If the above did not solve the problem – call for service.
Ч.	The printer does not print.	 7.1 Make sure the paper is inserted in the printer. (see para. 5.2, Printer handling) 7.2 Switch off the machine and switch it back on while pressing the feed button on the printer. If the printer prints a test printout, the printer is O.K. and there is a problem with the electronics. Call for service to solve the problem. If the printer does not print the test printout, there is a problem with the printer. Call for service to solve the problem.

10. TROUBLESHOOTING FOR THE OPERATOR

	Problem	Solution
×.	The printer prints, but nothing is printed on the paper.	 8.1 Make sure the paper is mounted in the right way. Only one side of the paper is printable. (see para. 5.2, Printer handling) 8.2 If paper is inserted correctly and problem persists – call for service.
9.	When the machine is switched on, the printer's paper is fed continuously.	9.1 Make sure the 'feed button' on the printer is not stuck.9.2 If button is not stuck and problem persists – call for service.
10	10. The machine is leaking at the door	 10.1 Make sure the door is tightened enough. Replace the door gasket. (see para. 9.4 Replacing the Door Gasket) 10.2 If problem persists - call for service.
11	 When running a cycle, the exhaust stage takes a very long time. 	11.1 Fast exhaust valve is faulty. Call for service

10. TROUBLESHOOTING FOR THE OPERATOR

If the problem persists, contact your dealer or Tuttnauer USA for further assistance.

11. SPARE PARTS LIST

DESCRIPTION	PART NUMBER		
	2540	3870	
1.25A fuse	01910106	01910106	
6.3A fuse	ELE035-0005	ELE035-0010	
2µ bacteriological filter	FIL175-0042	03140036	
Door gasket	02610023	02610019	
Printer paper	01610406	01610406	
Printer DPU20	01610100	01610100	
Cap for ¹ / ₄ " strainer	FIL175-0027	FIL175-0027	
Strainer element	FIL175-0020	FIL175-0020	
Teflon gasket 4 mm	GAS082-0008	GAS082-0008	

12. ACCESSORIES

DESCRIPTION		PART NUMBER	
		2540	3870
Tray	Big	CT520010	CC520010
IIay	Small	C1320010	CC520020
Tray handle		CT530020	-
Tray holder		CT510010	CC510010
Silicon drain tube		02620016	02620016