



# OPERATION & MAINTENANCE MANUAL

Prevacuum Table-top Autoclave Model 2540 NOVA-3



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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 glassware, lamps and heaters.

The warranty does not include and does not replace routine treatment and preventive maintenance to be performed according to instructions in paragraph 10.1 (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:

<b>Tuttnauer Europe</b> b.v., Paardeweide 36, P.O. Box 7191, 4800GE Breda, Netherlands. ೨+31/76-5423510, □Fax: +31/76-5423540, Email: info@tuttnauer.nl
■ <b>Tuttnauer USA Co.</b> , 25 Power Drive Hauppauge, NY, 11788,USA ①: (800) 624 5836, (631) 737 4850, □Fax:(631)737 07 20, Email info@tuttnauer.com

- **Rudolf Gunz & Co. PTY LTD**: Service Departments:
- 26-34 Dunning Avenue, Ros 2018, Sydney, Australia.
- Locked bag 690, Beaconsfield, NSW 2014, Australia.

#### 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 products 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.

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.

- 1 Make sure that you know where the main power switch is.
- 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
- Never start using a new autoclave, before the safety, licensing and authorization department has approved it for use.
- 4 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.
- 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.
- 6 Use protective equipment and clothes. Implement other safety instructions in accordance with local and national regulations and/or rules!
- 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.
- 8 Individual glass bottles may be placed within an appropriate container that will be placed on a tray.
- 9 On closing the device door, make sure it is properly locked before activating.
- 10 Before withdrawing trays, wear heat resistant gloves.
- Before opening the door, verify that there is no pressure in the chamber (chamber pressure gauge is located on the autoclave's front panel).
- Once a month, ensure that the safety valves are functioning, and once annually a certified tester must conduct pressure chamber safety tests.
- Pay attention to any leaks, breaks, blockages, whistles or strange noises. Inform, immediately, you supervisor upon noticing anything that may indicate a malfunction.
- 14 Immediately notify the person in charge of any deviation or risk for the proper function of the device.

# 3 GENERAL INFORMATION

#### 3.1 Introduction

This table-top autoclave is designed for sterilization of medical and surgical materials such as unwrapped and wrapped, solid, hollow, porous products and goods that are defined as hollow A in ophthalmic, dental and medical clinics, first aid rooms, small laboratories etc.

This autoclave model is an electrically heated sterilizer using steam as a sterilizing agent.

The autoclave is designed as Type B in accordance with EN13060. This model is a prevacuum sterilizer having the following features;

- An air removal stage (prevacuum), before starting the sterilizing stage.
- A post-sterilization drying phase, based on the combined operation of heat and vacuum with air inlet pulses.

In order to improve the efficiency of the vacuum pump – capability and speed – a heat exchanger is installed on the outlet piping of the chamber.

The steam and condensate evacuated from the chamber pass through a cooling coil immersed in the water reservoir and accumulated in a waste-water reservoir. This reservoir is emptied manually when the water level reaches a maximum pre-set level. The waste-water reservoir accumulates also the drain from the vacuum pump.

# 3.1.1 Displayed Pressure

The autoclave is equipped with two pressure measuring devices:

- 1. A <u>relative</u> analogue manometer that is used for indication purposes only. The manometer displays the pressure in kPa and psi.
- 2. An <u>absolute</u> digital display that is used for monitoring and control purposes. This device displays the pressure in kPa or in psi, according to the operator's requirement, and the absolute zero is displayed as "0".

The analogue pressure gauge is used as a guide only. Should there be a power failure during the operation of the autoclave, the pressure gauge indicates to the operator that there is pressure in the chamber.

The advantages of the prevacuum sterilizer are as follows:

- Removal of air pockets from packs and porous load and most kinds of tubes (rubber, plastic etc.) by vacuum at the first stage of the cycle.
- More efficient steam penetration into the load; assuring effective sterilization.
- Improved temperature uniformity.
- Better drying of materials due to the vacuum achieved in the chamber at the end of the sterilization cycle.

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).

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

After reading this manual, operating the autoclave will be 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.

#### 3.2 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 40°C and a relative humidity of 85% respectively.

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

It is recommended to perform a test cycle at the beginning of each working day. If the sterilized loads will include hand pieces – perform a Helix test. If the sterilized loads will include only porous or any material that does not include hand pieces – perform a B & D test cycle.

#### **CAUTION!**



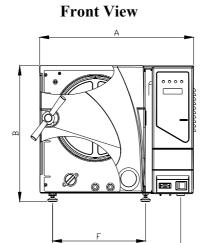
Waste water should be brought into the public net in accordance with the local rules or requirements

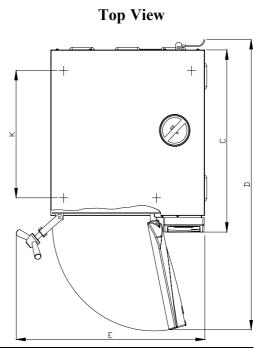
i.e. ONLY NON-HAZARDOUS LIQUIDS SHALL BE DISPOSED IN PUBLIC SEWAGE!

# 3.3 Specifications

Property		Value
Chamber	Dia.	254 mm (10")
Chamber	Depth	475 mm (18.7")
Chamber volume		23 lit. (6.1 gal)
	Width (A)	51 cm (20.1")
External dimensions	Height (B)	42.5 cm (16.7")
	Length (C)	56 cm (20.0")
Distance between	K	40 cm (15.75")
supporting legs	F	32 cm (12.6")
F - rear legs F1 - front legs	F1	42.6 cm (16.8")

# **Overall Dimensions**





Property		Value
Weight		55 kg (121 lb)
Weight per support area (max. load)		45 N/m2 (0.94 lb/ft2)
Shipping weight		65 kg (143 lb)
	Width	63 cm (24.8")
Shipping dimensions	Height	71 cm (28.0")
	Length	80 cm (35.8")
	Volume	0.36 m3 (14.5 ft3)
Minoral frag victor recomicin	Max. water volume	6 lit. (1.58 US gal)
Mineral-free water reservoir	Min. water volume	2 lit. (0.5 US gal)
Used (waste) water reservoir	Max. water volume	3.6 lit. (0.95 US gal)

Property		Value
Maximum dimensions (door	D	93 cm (36.6")
open)	E	65 cm (25.6")
Maximum load per item		0.5 kg (1.1 lb)
Maximum load per tray		2.0 kg (4.4 lb)
Maximum solid load		6.0 kg (13.2 lb)
Maximum textile load		2.0 kg (4.4 lb)
Max. Allowable Working pressure (MAWP)		2.76 bar (40 psi)
	W	17 cm (6.7")
Tray dimensions	Н	2 cm (0.8")
	L	41.5 cm (16.3")
No. of trays		4
IMS cassettes (optional)		3

# 3.4 Utilities

Utility	Value
Mineral free water	See table in para 3.9. On autoclaves with automatic mineral free water filling the Min. flow rate: 4lit/hr.
Drain	Must withstand 80°C
Power supply	1ph, 14.5A/230V, 50 Hz
Protection against electrical shock	Class I (IEC 60601-1)

# 3.5 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 < 200 Wh.

# 3.6 Electrical Data

Property	Value
Heaters Power	3000W
Total Power	3200W
Voltage (V)	1 ph / 230
Amperage (A)	14.5
Frequency (Hz)	50/60
Protection against electrical shock	Class I (IEC 60601-1)

#### 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).

# 3.7 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 LLDPE.
- Door handle is made of hard plastic material, which is safe to touch and thermo-insulated.

# 3.8 Symbol Description



Caution! Consult accompanying documents



Caution! Hot surface.



Caution! Hot steam.



**Protective earth (Ground)** 



On-Off

# 3.9 Water Quality

# 3.9.1 Physical characteristics and contaminants levels

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:

Physical characteristics and acceptable contaminants levels in water, for sterilizers		
Evaporate residue	≤ 15 mg/l	
Silica	≤ 2 mg/l	
Iron	≤ 0.2mg/l	
Cadmium	≤ 0.005 mg/l	
Lead	≤ 0.05 mg/l	
Rest of heavy metals	≤ 0.1 mg/l	
Chloride	$\leq$ 3 mg/l	
Phosphate	≤ 0.5 mg/l	
Conductivity	≤ 50 μs/cm	
pH	6.5 to 8	
Appearance	colourless, clean, without sediment	
Hardness	≤ 0.1 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.

#### 3.9.2 Reverse Osmosis

A Reverse Osmosis system may be used to improve the quality of the water used to generate steam in the autoclave chamber. The use of mineral free will contribute to better performance and longer life of the autoclave.

#### 3.10 Directives and Standards

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

#### 3.10.1 Technical Directives

- 1. Medical Device Directive 93/42/EEC.
- 2. Pressure Equipment Directive 97/23/EEC.

#### 3.10.2 Technical Standards

- 1. EN 13060:2004 Small Steam Sterilizers.
- 2. ASME Code, section VIII division 1 for pressure vessels.
- 3. EN 61010-1:01 Safety of electrical equipment ...General requirement.
- 4. EN 61010-2-041:96 Particular requirement for steam autoclaves.
- 5. EN 50081-01 (EMC) Emission compatibility...
- 6. EN 61000-1:97 (EMC) Immunity compatibility...

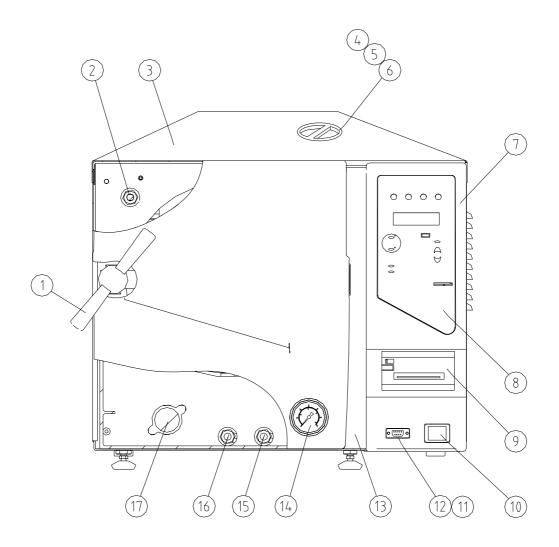
# 3.10.3 Quality standards

The manufacturing plant meets the following quality standards:

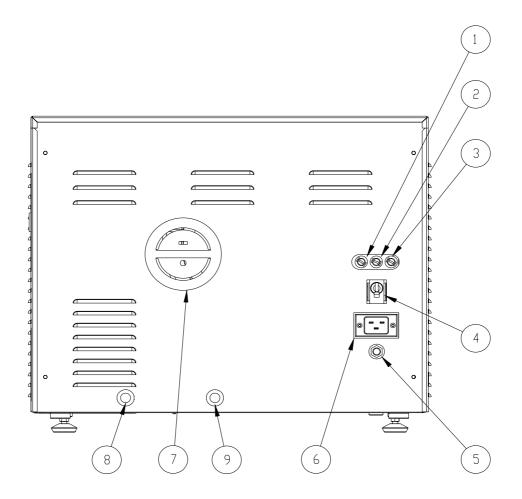
- 1. EN ISO 9001:2000- Quality System
- 2. ISO 13485 Quality systems Medical devices Particular requirements for the application of ISO 9001.

The manufacturer retains all supporting documentation.

# FRONT VIEW



No.	Description	No.	Description
1	Door closing device	10	Main switch
2	Door switch	11	RS232 communication port
3	Autoclave cover	12	RS232 port cover
4	Water reservoir cover	13	Completion to panel
5	Water reservoir – assembly	14	Pressure gauge
6	Safety valve	15	Clean water reservoir drain valve
7	Panel base	16	Waste water reservoir drain valve
8	Front panel key board	17	Water strainer
9	Printer (option)		



No.	Description				
1	Transformer fuse				
2	Water pump fuse				
3	Vacuum pump fuse				
4	Circuit breaker				
5	Cut-off thermostat				
6	Main power electric cable socket				
7	Air filter service cover				
8	Drain outlet (option). Mandatory on autoclaves with automatic mineral free water filling).				
9	mineral free water inlet (on autoclaves with automatic mineral free water filling)				

# 4 STERILIZATION PROGRAMS

The autoclave offers 6 sterilization programs, 2 test programs and one optional dry program. For changing any parameter refer to the Technician Manual.

# 4.1 Program 1 - (Flash 134)

Program 1 is recommended for sterilizing unwrapped instruments. Load weight shall not exceed 6 kg.

#### **Nominal Parameters**

• Sterilization temperature: 134°C (273°F).

• Temperature band:  $-0^{\circ}C + 3^{\circ}C$ .

• Sterilization time: 4 minutes.

• Dry time: 1 minute.

• Max. cycle time: 15 minutes.

• Average cycle time: 12 minutes.

# **Operation Sequence**

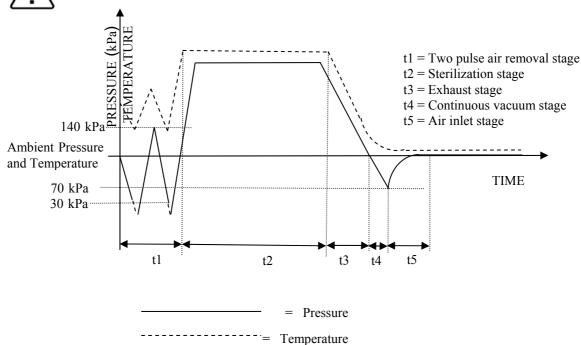
- Air-removal phase; Two vacuum pulses as described in the diagram below. Saturated steam is introduced into the chamber until the sterilization temperature is reached.
- Sterilization phase; temperature and pressure are maintained constant at the pre-set level for the sterilization time.
- Fast exhaust phase; steam is rapidly exhausted from the chamber, followed by a continuous vacuum pulse (0.5 minute) followed by vacuum break (air inlet), until pressure equalizes atmospheric pressure.

The cycle was validated with a 6 kg unwrapped solid load.

#### Note:



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



# 4.2 Program 2 - (WDry 134)

Program 2 is recommended for sterilizing porous wrapped and Hollow A (e.g. dental hand pieces, suction pipes) loads at temperatures of 134°C/273°F with 15 minutes drying stage.

Load weight shall not exceed 6 kg.

# **Nominal parameters**

• Sterilization temperature: 134°C (273°F).

• Temperature band:  $-0^{\circ}\text{C} + 3^{\circ}\text{C}$ .

• Sterilization time: 7 minutes.

• Dry time: 15 minutes.

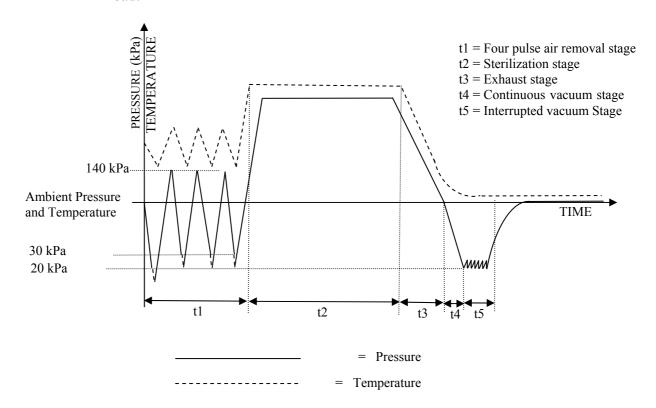
• Max. cycle time: 45 minutes.

• Average cycle time: 35 minutes.

# **Operation Sequence**

- Air removal phase; four vacuum pulses as described in the diagram below. Saturated steam is introduced into the chamber until the sterilization temperature is reached.
- Sterilization phase; temperature is maintained constant at the pre-set level for the sterilization time.
- Fast exhaust phase; steam is rapidly exhausted from the chamber, followed by a continuous vacuum pulse (5 minutes) followed by 10 minutes of interrupted vacuum pump operation, until pressure equalizes atmospheric pressure.

The cycle was validated with a 6 kg wrapped solid and 2 kg textile load.



# 4.3 Program 3 - (Prion 134)

Program 3 is recommended for sterilizing porous wrapped and Hollow A (e.g. dental hand pieces, suction pipes) loads at temperatures of 134°C/273°F with 15 minutes drying stage. This sterilization time is recommended for sterilization of prion.

Load weight shall not exceed 6 kg.

#### **Nominal parameters**

• Sterilization temperature: 134°C (273°F).

• Temperature band:  $-0^{\circ}\text{C} + 3^{\circ}\text{C}$ .

• Sterilization time: 18 minutes.

• Dry time: 15 minutes.

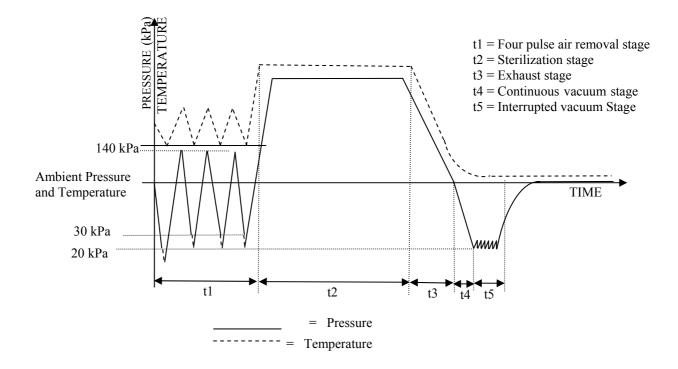
• Max. cycle time: 60 minutes.

• Average cycle time: 46 minutes.

# **Operation Sequence**

- Air removal phase; four vacuum pulses as described in the diagram below. Saturated steam is introduced into the chamber until the sterilization temperature is reached.
- Sterilization phase; temperature is maintained constant at the pre-set level for the sterilization time.
- Fast exhaust phase; steam is rapidly exhausted from the chamber, followed by a continuous vacuum pulse (5 minutes) followed by 10 minutes of interrupted vacuum pump operation, until pressure equalizes atmospheric pressure.

The cycle was validated with a 6 kg wrapped solid and 2 kg textile load.



# 4.4 Program 4 - (NoDry 121)

Program 4 is recommended for sterilizing unwrapped delicate instruments at temperatures of 121 °C / 250 °F without drying stage. Load weight shall not exceed 6 kg.

# **Nominal parameters**

• Sterilization temperature: 121 °C (250 °F).

• Temperature band:  $-0^{\circ}\text{C} + 3^{\circ}\text{C}$ .

• Sterilization time: 20 minutes.

• Max. cycle time: 40 minutes.

• Average cycle time: 35 minutes.

# **Operation Sequence**

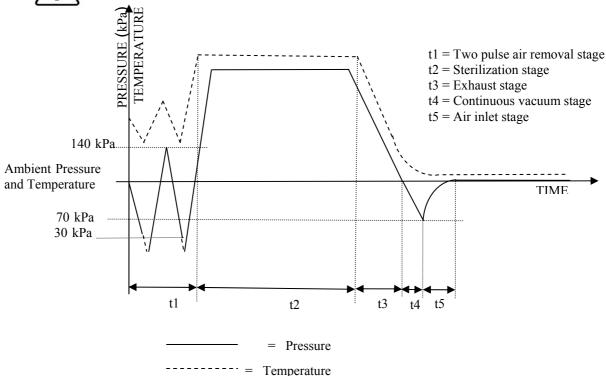
- Air removal phase; two vacuum pulses as described in the diagram below. Saturated steam is introduced into the chamber until the sterilization temperature is reached.
- Sterilization phase; temperature is maintained constant at the pre-set level for the sterilization time.
- Fast exhaust phase; steam is rapidly exhausted from the chamber, followed by a continuous vacuum pulse (0.5 minute) followed by vacuum break (air inlet), until pressure equalizes atmospheric pressure.

The cycle was validated with a 6 kg unwrapped solid load.

#### Note:

 $\triangle$ 

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



# 4.5 Program 5 - (WDry 121)

Program 5 is recommended for sterilizing porous wrapped and Hollow A (e.g. dental hand pieces, suction pipes) loads as well as delicate instruments at temperatures of 121°C/250°F with 15 minutes drying stage.

Load weight shall not exceed 6 kg.

#### **Nominal parameters**

• Sterilization temperature: 121 °C (250 °F).

• Temperature band:  $-0^{\circ}\text{C} + 3^{\circ}\text{C}$ .

• Sterilization time: 20 minutes.

• Dry time: 20 minutes.

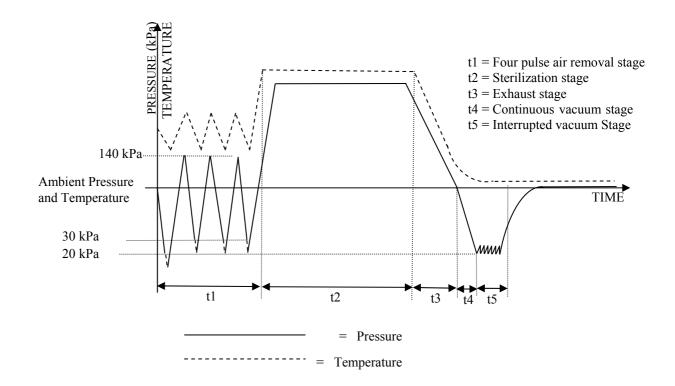
• Max. cycle time: 65 minutes.

• Average cycle time: 55 minutes.

# **Operation Sequence**

- Air removal phase; four vacuum pulses as described in the diagram below. Saturated steam is introduced into the chamber until the sterilization temperature is reached.
- Sterilization phase; temperature is maintained constant at the pre-set level for the sterilization time.
- Fast exhaust phase; steam is rapidly exhausted from the chamber, followed by a continuous vacuum pulse (5 minutes) followed by 15 minutes of interrupted vacuum pump operation, until pressure equalizes atmospheric pressure.

The cycle was validated with a 6 kg wrapped solid and 2 kg textile load.



# 4.6 Program 6 - (Slow 121)

Program 6 is recommended for sterilizing delicate and unwrapped instruments that need a slow exhaust at temperatures of 121°C/250°F without drying stage.

# Nominal parameters

• Sterilization temperature: 121 °C (250 °F).

• Temperature band:  $-0^{\circ}\text{C} + 3^{\circ}\text{C}$ .

• Sterilization time: 20 minutes.

• Max. cycle time: 45 minutes.

• Average cycle time: 37 minutes.

# **Operation Sequence**

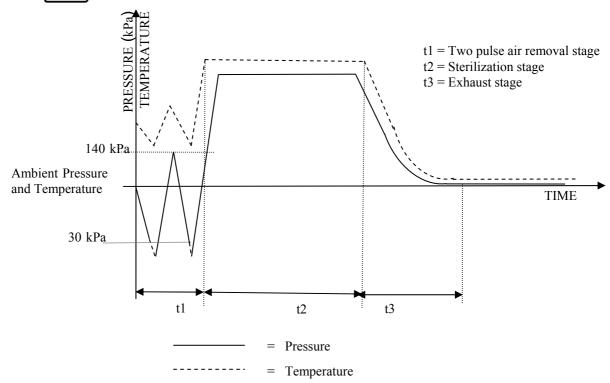
- Air removal phase; two vacuum pulses as described in the diagram below. Saturated steam is introduced into the chamber until the sterilization temperature is reached.
- Sterilization phase; temperature is maintained constant at the pre-set level for the sterilization time.
- Slow exhaust phase; steam is slowly exhausted from the chamber, until pressure equalizes atmospheric pressure.

The cycle was validated with a 6 kg unwrapped solid load.

#### Note:



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



# 4.7 Program 7 - (BD Test)

Program 7 is the Bowie & Dick test program, with fixed sterilization parameters 134°C and 3.5mins, which cannot be modified by the operator or the technician.

# **Nominal parameters**

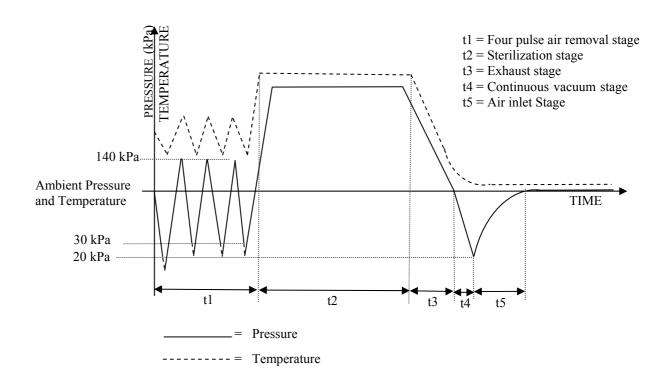
• Sterilization temperature: 134°C

• Sterilization time: 3.5 minutes.

• Dry time: 1 minutes.

# **Operations Sequence**

- Air removal phase; four vacuum pulses as described in the diagram below. Saturated steam is introduced into the chamber until the sterilization temperature is reached.
- Sterilization phase; temperature is maintained constant at the pre-set level 134°C for sterilization time 3.5 minutes.
- Fast exhaust phase; steam is rapidly exhausted from chamber until pressure equalizes atmospheric pressure.
- Drying phase; vacuum in chamber for 1 minute while chamber is heated at reduced power.



# 4.8 Program 8 - (VacTest)

Note:

Before performing this test, verify that the autoclave is cold and that the autoclave is dry (not humid and no water drops).

Vacuum is produced in the chamber down to  $P_1$ =17 kPa. 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  $P_2$ . 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  $P_3$ . The rate of change of  $P_3$ - $P_2$  shall not exceed 0.13 kPa/min. If  $P_3$ - $P_2$  exceed 1.3 kPa the printer will print "TEST FAIL". If  $P_3$ - $P_2$  is within the required value, the cycle will end normally.

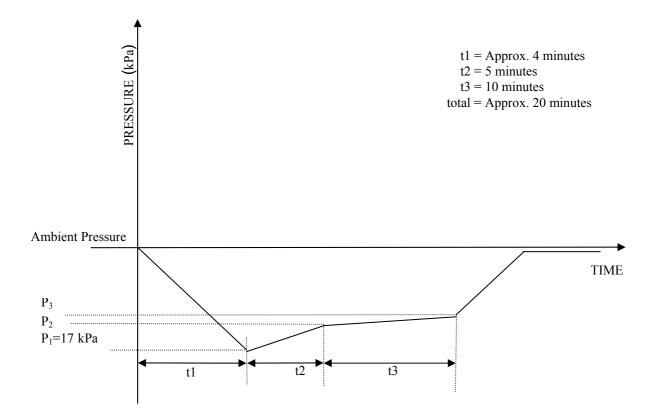
# **Operations Sequence**

• Vacuum is produced into the chamber down to 17 kPa.

The vacuum pump stops.

#### Note:

# During the test period the autoclave is not heated.



# 4.9 Program 9 - (Dry Only)

(OPTION - This program is not applicable for autoclaves sold in Europe)

Program 9 enables the operator to perform a drying operation.

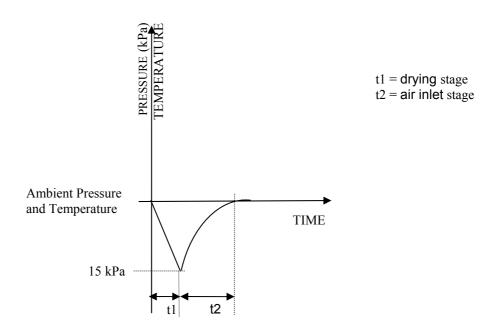
# **Nominal parameters**

• Drying temperature: 134°C

• Dry time: 5 minutes.

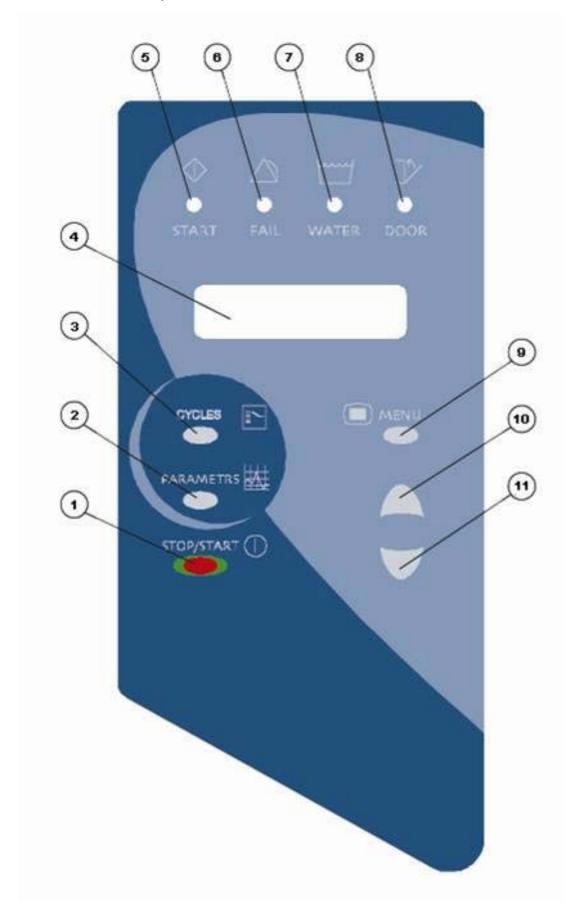
# **Operations Sequence**

• Vacuum is produced in the chamber for 5 minutes. During this period the vacuum reaches 15 kPa while chamber is heated. This is followed by an interrupted air inlet until pressure equals atmospheric pressure.



# 5 KEYBOARD (keys and display)

# Front Panel Keyboard



# 5.1 Description and Functions of the Front Panel Keyboard

The command panel is divided in 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. 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.

# **Starting the process:**

It is active while the autoclave is in READY position, if the door is closed and water level in the reservoir is normal. Pressing this key starts the selected process.

# **Stopping the process:**

It is active while the autoclave is in process. Pressing this key at any stage of the process stops operation.

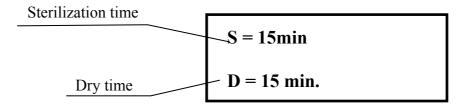
# Canceling the FAIL message

At the end of an aborted process, 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.

#### 2. Parameters key

This key displays for 5 seconds the three parameters of the program. After selecting the program, it is possible to have the parameters displayed by pressing this key; the top line reads the following data:



The data is erased automatically after 5 seconds, or if the parameter key is pressed again during these three seconds.

# 3. Cycles key



This key enables selecting the desired program out of 8 programs. Pressing this key advances the selected program to the next (e.g. from program 2 to 3).

If the system is set to program 8, pressing the key returns to program 1.

This autoclave has the following available programs:

- 1. Unwrapped instruments without drying. 134°C (273°F)/ 4 minutes.
- 2. Porous, wrapped and Hollow A loads. 134°C (273°F)/ 7 minutes with 15 minutes drying.
- 3. Porous, wrapped and Hollow A loads. 134°C (273°F)/ 18 minutes with 15 minutes drying.
- 4. Unwrapped delicate instruments without drying. 121°C (250°F)/20 minutes.
- 5. Porous, wrapped and Hollow A loads. 121°C (250°F)/20 minutes with 20 minutes drying.
- 6. Delicate and unwrapped instruments that need a slow exhaust, at 121°C (250°F)/20 minutes without drying.
- 7. Bowie & Dick Test + Helix test.
- 8. Vacuum Test.

# 4. Display

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

#### 5. Start led indicator



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

#### 6. Fail led indicator



When the "FAIL" LED indicator is on; it indicates that the cycle has failed either as a result of exceeding the allowable limits or the STOP key has been pressed.

#### 7. 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 (generator).

#### 8. Door led indicator



If the "Start" key is pressed and the door is unlocked the light will remain on and the buzzer will sound six times.

If a cycle is in progress and fails on door unlocked "FAIL" LED indicator will be lit and a message "Door Open" will be displayed.

# 9. Menu key



This key is designed for entering changes in the programs. The operator can perform the following:

- 1. Change the date.
- 2. Change the time.

#### Note:

Access to other programming level is possible only through a special code and may be performed only by authorized personnel.

# 10. UP key



This key enables increasing the value displayed above the cursor, at the clock programming and for setting of certain parameters by the technician.

# 11. DN key



This key enables decreasing the value displayed above the cursor, at the clock programming and for setting of certain parameters by the technician.

# 5.2 Description of the Operational Messages

The display is divided in 2 rows, each row has 16 characters.

# 5.2.1 The upper row:

On the right side of the upper row, 6 characters are allotted for displaying the stage in progress

•	ST. BY	-	Autoclave in stand by mode.
•	VACUM	-	Vacuum stage.
•	HEAT	-	Heating stage.
•	STER	-	Sterilization stage.
•	EXH	-	Exhaust stage
•	DRY	-	Dry stage
•	P(n)V	-	Air-removal stage. (n) is the number of the vacuum pulse.
•	P(n)H	-	
•	TEST	-	T7
•	WAIT 1	-	Stabilization stage (t2) during Vac test
•	WAIT 2	-	Test stage (t3) during Vac test
•	READY	-	Autoclave is ready to begin a cycle.

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

		Europe	USA
• Program 1	-	Flash 134	Flash 273
• Program 2	-	Wdry 134	Wdry 273
• Program 3	-	Prion 134	Prion 273
• Program 4	-	NoDry 121	NoDry 250
• Program 5	-	Wdry 121	Wdry 250
• Program 6	-	Slow 121	Slow 250
• Program 7	-	BD Test	BD Test
• Program 8	-	VacTest	VacTest

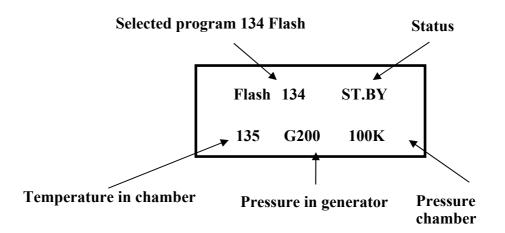
When the PARAMETERS key is pressed; the parameters of the selected program are displayed.

#### 5.2.2 The lower row:

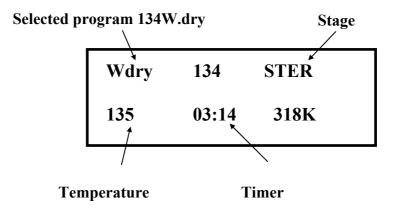
- On the right side of the lower row, 5 characters are allotted for chamber pressure display.
- The actual pressure is continuously displayed at all stages of the process and between processes (standby).
- On the left side of the lower row the temperature is displayed; 5 characters are allotted for the display of temperature in °C or °F, in the form 134.3 or 273.4.
- In case the process is aborted, the diagnosis of the fail is displayed on the left side of the lower row, instead of the temperature. 11 characters are allotted for this error message.
- On completion of the process, the 'CYCLE END' message is displayed on the left side of the lower row.
   For BD Test and VacTest the message on completion of the cycle will be 'TEST ENDED'.
- At the sterilization and dry stage, the countdown of the time left to the completion of the stage will be displayed between the readouts of temperature and pressure. The format of the display will be MM: SS (two digits for minutes and two digits for seconds).
- During the stand-by stage, the pressure in the generator will be displayed between the readouts of temperature and pressure. The format of the display will be "G200" (G for generator and 200 the pressure in kPa)
- At the heating and exhaust stages, the pressure in the generator and the temperature in the coil will be displayed, alternately, between the readouts of temperature and pressure. The format of the pressure display will be "G200" (G for generator and 200 the pressure in kPa) and that of the temperature will be "C085" (C for coil and 085 the temperature in °C)
- When a cycle is started by means of pressing the START key, the load number is displayed for 2 seconds on the left of the lower row.

# **Examples**

Example 1: Autoclave between processes, the program No.1 has been selected, the door is still open and START has not been pressed yet.



Example 2: The autoclave is in the sterilization stage, program No.3 is active and the time left to completion of sterilization phase 3 minutes and 14 seconds.



Example 3: The process failed due to temperature drop in the sterilization stage in program No.6.

Slow	121	Fail
LOW	178K	

in

# 5.3 Displayed Error Messages and Safety Measures

Low Temp. "Low Temp" message is displayed, FAIL indicator

lights and cycle is aborted, if the temperature drops for more than 5 seconds below the sterilization

temperature.

Low Heat "Low Heat" message is displayed and sterilization does

not start if the autoclave has not reached sterilization

temperature after heating for 20 minutes.

**High Temp.** "High Temp" message is displayed, FAIL indicator lights and the cycle is aborted in one of the following cases:

• If temperature rises 3°C (6°F) above sterilization temperature during the sterilization stage.

• If temperature sensor is damaged, this message appears during the HEAT stage.

Low Pres. "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.** "High Pres" message is displayed, FAIL indicator lights, and the cycle is aborted if pressure rises above the pressure correlated to the sterilization temperature

+3°C (6°F) for more than 5 seconds.

**Low Vacuum** "Low Vacuum" message is displayed and FAIL indicator lights if, in the vacuum stage, the required vacuum level is not reached during 20 minutes after the

cycle is started.

**Man. Stop** "Man. Stop" message is displayed and the FAIL indicator lights after the STOP key is pressed for longer

than 1 second.

**Power Dn** "Power Dn" message is displayed if a power failure occurred during sterilization stage. When power

of power failure. This message is displayed for several seconds and the printer prints POWER DN. If the temperature does not fall below the sterilization temperature, sterilization resumes automatically. When power returns, and temperature falls below sterilization temperature, the cycle will stop, exhaust will be performed according to the program requirements and POWER DN & FAIL messages will be displayed and printed. If a power failure occurs during the HEAT

resumes, the system automatically returns to the point

stage, heating resumes (provided there is enough water in the generator). If not, the cycle aborts. Dry and exhaust stages automatically resume operation once the

power is back on.

Not Ready Fill water "Not ready" message is displayed in the upper row in the display, "Fill water" is displayed in the lower row and the "WATER" LED indicator is lit in case of insufficient water in the water reservoir.

After water is added to the reservoir, the START/STOP indicator button must be pressed, to start the required sterilization cycle. If displayed on an autoclave with automatic water filling, it indicates faulty water supply.

**Door Open** 

"Door Open" message is displayed and the DOOR LED indicator is lit if the door is improperly closed. The START button should be pressed to start the desired cycle. If the door accidentally opens during any stage of the cycle, the same message and indicator appears, and the system reacts as if the START/STOP key was pressed.

**Empty Res L** 

"Empty Res L" message is displayed when the used water reservoir is full and has to be emptied. This message is displayed only after START/STOP push-button is pressed and before the cycle begins. If displayed on an autoclave with automatic water filling, it indicates clogged drain.

Stop Fill

"Stop Fill" message is displayed when the water level in the mineral free water reservoir reaches the level of the upper float switch. A buzzer will sound and the message "Stop Fill" will be displayed. This message is not applicable for autoclaves with automatic water filling.

Test Fail

"Test Fail" Message is displayed when there is a leakage during vacuum test or when there is a failure during B&D test.

Sleep

"Sleep" message is displayed if the autoclave has not been used for 4 hours and no push-button has been pressed during this period. The "Sleep" message will be displayed without backlight and the "START" LED will blink during the "Sleep" period. To exit the "Sleep" status, press any push-button.

# 6 CHECKING AND CHANGING PARAMETERS AND OTHER DATA

In order to set the autoclave's clock, check the main sterilization parameters (sterilization temperature sterilization time, and dry time) and to print the sterilization of one of the 10 previous cycles, you can enter three subdirectories and obtain the required data. Setting the clock can be done by the operator, the other functions are only accessible for authorized persons through an access code.

# 6.1 Setting the clock

This directory enables you to set the time and date.

- 1. Press **MENU** pushbutton.
- 2. **ENTER CODE** will be displayed.
- 3. If, at this point, **CYCLES** is pressed, **Set Clock** will be displayed.
- 4. To enter the **Clock settings** press **CYCLES** again.

When entering the set clock display the time and date are displayed. The curser is blinking on the digits for the hour.

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:MM:YY".

- 1. To increase or decrease the time or the date use the **UP** and **DOWN** pushbuttons.
- 2. To move the curser from one digit to another press the **PARAMETERS** pushbutton
- 3. After completing setting the time and the date press **CYCLES** to confirm the new time and date and to exit press **MENU** twice.

#### 7 PRINTER

The printer is an optional device. If the autoclave is not equipped with a printer paragraph 6 is not applicable.

#### 7.1 Printer Output

The autoclave is 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 plain paper with 24 characters per line and contains the following information:

- Software version
- Date and Time
- Selected program
- Sterilization pressure
- Sterilization temperature
- Sterilization time
- Summary of performed cycle and identification hints.

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 below.

The data is printed from the bottom up, beginning with the date and ending with "O.K." for a complete cycle or "FAIL" for an aborted cycle.

For an example of a typical printout, see next page.

# DESCRIPTION

			_	
Operator:			To be filled in manu	ually by operator
Time: Date: CYCLE EN	17:09:08 26/09/20		Time sterilization cy Date sterilization cy	•
00:50:46 D 00:48:46	076.8	034.5 036.2		are and pressure when cycle ended. are and pressure during drying.
*			Prints drying data ev	very 3 minutes.
D 00:30:46	104.8	109.2	The time, temperatu	are and pressure during drying.
E 00:30:07		211.6	The time, temperatu	are and pressure during exhaust.
S 00:30:07		311.3	The time, temperatu	are and pressure during sterilization.
*			Prints sterilization d	lata every 1 minute.
S 00:10:06	121.1	210.0	The time, temperatu	are and pressure during sterilization.
H 00:08:57		058.3	The time, temperatu	are and pressure during heating.
V 00:08:57		058.3	The time, temperatu	are and pressure during air removal.
* * *			Prints sterilization d lower peak (the short	lata every 3 minute or on upper and rter time)
V 00:00:00 Time	078.1 °C	095.0 kPa	The time, temperatu	are and pressure during air removal.
Dry Time: Ster Time: Ster Temp:	Ster Time: 020.0min		Drying time for sele Sterilization time fo Sterilization temper program Description of cycle	or selected program. ature in chamber for selected
WDry Load number: 0933 Param. Ver: 0030 Ver: Nova 1.40 Ser.Num: 02304101 Time: 16:18:22 Date: 26/09/2004			Cycle counter Version of parameter Program's name and Autoclave's serial number of the sterilization cycle.	ers setting I version. umber. ycle started.
Legend V H	Vacuum st Heating st		E D	Exhaust stage drying stage
S	Sterilization		D	ar ying stage

#### 7.2 Printer Operation

#### **CAUTION:**

# Do not perform the following operations, since they may be damage the printer.

- 1. Do not carry out blank printing without recording paper and no ink ribbon in the unit, this may damage the printing head.
- 2. Do not drop any foreign subjects as paper clips, or splits pins, etc. into the printer unit.
- 3. Do not pull the paper in printer forcibly by hand or pull the paper in opposite way to paper feed direction.
- 4. Do not operate the printer with a ribbon cassette that has run out completely. Replace the ribbon before it has been worn out. Ribbon damaged by excess use may result in printing problems. Do not apply ink on this ribbon cassette.

# 7.3 Opening/Closing the Front Panel

- 1. Press, with your finger, on the left side of the front panel and pull it forward when the lock is released. It opens about 180° around the fixed axis.
- 2. For closing, press the front panel, tightly close it until a click sound is heard. Also, confirm, on closing, that paper is not jammed.

#### 7.4 Opening/Closing the Ribbon Cover

- 1. When paper is out of the front cover, cut it off.
- 2. Press, with your finger, on the dent on the left side of the ribbon cover and pull it forward. It opens, approximately, 180° around the fixed axis.
- 3. For closing, press the ribbon cover and close it tightly.

#### 7.5 Paper Feeding

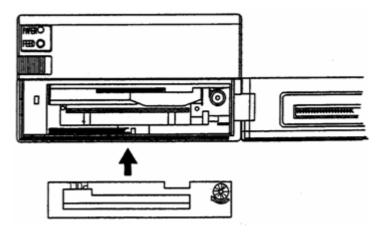
- 1. With the Feed switch pressed once, paper is fed by one line.
- 2. Paper is fed continuously while it is continuously pressed.
- 3. To feed paper, do not pull it forcibly. Use the Feed switch.
- 4. During pressing the Feed switch, the data can not be received.

#### 7.6 Replacing Ribbon Cassette

- 1. Turn off the power.
- 2. In case the paper is out from front cover, cut the paper or remove this paper.
- 3. Open the ribbon cover.
- 4. Remove the old ribbon cassette by pulling it out by the edge marked with "PULL".
- 5. Insert ribbon between the printing head and the platen, verifying that the new ribbon cassette is in the correct direction. Press cassette down from the knob side.
- 6. Turn the ribbon cassette knob clockwise (see arrow) to cancel slack.

#### **Notes:**

- a. In case the ribbon cassette is kept in the printer too long, the printing paper may be contaminated.
- b. Continuous printing under low temperature may result in light-color characters due to the characteristics of the ink.
- c. Do not attempt to print without the ribbon cassette since this may damage the printer's head.
- d. Replace ribbon cassette before wearing out completely.
- e. Use original ribbon cassette.



# 7.7 Printing Paper

# 6.7.1 The Paper Roll

Before inserting paper into the printer verify that the beginning of roll paper to the inner core must be as follows.

- 1. No folds. Paper must be rolled on the inner core
- 2. No flap
- 3. Do not stick the paper to the core. (If an inner core is available)

#### 6.7.2 Recommended paper:

Only use the type of paper suitable to this printer. To order additional paper please contact your distributor or local dealer.

#### 6.7.3 Replacing the Paper Roll

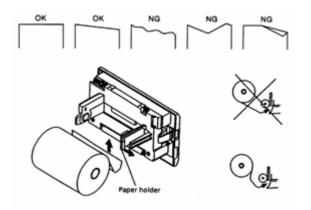
- 1. Open the front cover.
- 2. Press outwards the arms of the paper-roll clip (see drawing) and remove the roll's core. Remove, at this time, excessive paper by using the Feed switch.
- 3. Cut the edge of the Printing Paper according to the following drawing.

- 4. Insert the new paper into the paper-roll clip of the printer mechanism.
- 5. When auto-loading function is specified, paper is loaded automatically.
- 6. When auto-loading function is not specified, push the LF switch until the paper enters the printer mechanism.
- 7. Press slightly the paper holder in the direction marked with an arrow (see drawing) and insert paper roll. Verify that the paper holder holds the roll's core.
- 8. After canceling the slack of the printing paper, close the front panel.
- 9. After setting the paper, press LF switch once. The printer turns to data input printing mode.

#### Note:

- a. Verify that the paper winding direction is correct.
- b. Do not replace paper while the autoclave is operating.
- c. Do not pull the paper in reverse direction of paper feed. This may damage the printing head.
- d. If the paper strip is not perpendicular to the printer, the printer may be jammed.

In case the printer is jammed, turn OFF the power switch immediately and pull out, slowly, the excessive paper. Pulling the paper must be done perpendicular to the printing head.



#### 7.8 PaperNearEnd

When the paper roll is near the end, the paper-near-end is detected and printing is stopped. Power supply to the printing solenoid and motor is immediately stopped and the Paper led is lit.

When data still exists in the input buffer, the remaining data in the buffer is printed before stopping.

Discharge remaining paper with the Feed switch, set new paper and push the Feed switch.

#### 7.9 PaperEnd

This feature detects that there is no paper in the printer. When there is no printing paper, printing stops and the Paper led is lit. The paper led will be lit.

Printing is also stopped in case data remains in the input buffer.

Install a new paper roll as described in para. 6.5 Then the Paper led will go off.

When auto loading function is available, printer automatically feeds recording paper a few lines by inserting the recording paper into the paper inlet.

#### 7.10 Mechanical Alarm

When trouble in the mechanism results in locking of the motor, power supply to the printing solenoid and motor is stopped and the Paper led goes on. To recover from alarm state, after correcting causes for the malfunction, re-supply power.

For severe trouble, turn power off and call for service.

# 7.11 Auto Loading Function

This printer is equipped with a function that can automatically load paper. With paper inserted, it is automatically fed a few lines. When printing paper is not perpendicular to the printing head or not properly fed, take out paper gently and insert it once again.

#### 8 INSTALLATION

#### 8.1 Placing

#### **CAUTION:**



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.
- 2. <u>Counter space</u> minimum 51cmW x 60cmD (20.1"W x 20"D) \* (see unit dimensions)

#### 7.1.1 Placing the Autoclave

The autoclave has an inclination of approx. 2° towards the rear. This ensures that water is completely drained out of the chamber through the opening at the bottom rear of the chamber.

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

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.

#### 7.1.2 Connections to Utility Supplies

Plug the power cord into the supply socket.



Attention! The pressure of the generator does not decrease immediately when the equipment is turned off. Wait approx. ½ an hour to verify that the pressure decreased to atmospheric pressure.

#### 8.2 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.

- 1. Disconnect the power supply cord.
- 2. Drain the water from both reservoirs.

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 this device!

#### 8.3 Loading and unloading the Device

#### 7.3.1 *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; please refer to the manufacturer instructions for sterilization of unknown materials or instruments.

#### 7.3.2 Loading

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

For detailed loading instructions, see para. 8 (Preparation before sterilization)

#### 7.3.3 Unloading

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 colour change.

# 8.4 Filling the Mineral-Free Water Reservoir (for autoclaves not equipped with automatic water filling)

Remove the water reservoir cover. Pour distilled water into the reservoir through the opening on top of the autoclave until it reaches the level of the upper float switch, approximately 6.5 liters (1.72 gallons). If the water level reaches the upper float, a 4-seconds intermittent beep will sound to indicate that the reservoir is full. In case more water is added **accidentally above the level of the safety valve**, decrease the water level by draining the reservoir before starting a cycle (see para. 11.2).

#### Note:

Minimum water quantity required for a sterilization cycle is 2.6 liters. Use only water having the characteristics as per table in para. 3.9.

#### Caution!



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

Use mineral free water only. Tap water may clog the system.

#### 9 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.

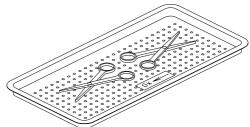
The basic principle determining the size, mass and contents of instrument and hollowware packs is that the contents are sterile and dry immediately on completion of the drying cycle and removal of the pack from the sterilizer chamber

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 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. Before placing an instrument into 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.

#### **Note:**

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

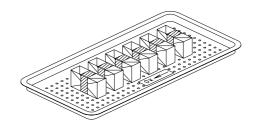


- 8. In case carbon steel instruments are placed on stainless steel trays, the trays should be lined with a towel or paper wrap before placing the instruments on the trays. There should be no direct contact between the carbon steel and the stainless steel trays.
- 9. All instruments must be sterilized in an open position.
- 10. Use single-use wraps only once and discard them after use.
- 11. Place a sterilization indicator strip in each tray.

- 12. Place instruments with ratchets opened and unlocked or clipped on the first ratchet position.
- 13. 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.
- 14. 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.
- 15. Load items within the boundaries of the tray so that they do not touch the chamber walls, or fall off when the tray is in move.
- 16. The operator may use racks to allow adequate separation of packaged instruments.
- 17. Load trays in such a way to allow steam to move freely among all items.
- 18. Load trays loosely to capacity.
- 19. Once a week, use a biological spore test indicator in any load to make sure sterilization is performed.
- 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 2.5 cm (1") between trays to permit steam circulation.

#### 9.1 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 paper surface downwards.

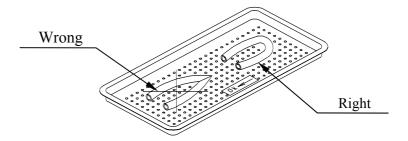


Note:

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

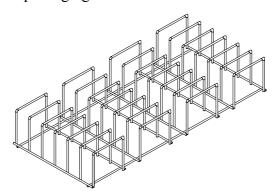
# 9.2 Tubing

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



#### 9.3 Wrapped Instruments

- 1. Wrapped instruments should be packed in material that promotes drying such as autoclave bag, autoclave paper, and muslin towels.
- 2. It is highly recommended to utilize the Tuttnauer<sup>™</sup> Pouch Rack. This rack allows the operator to place pouches on their side, thus increasing the capacity of the autoclave significantly and promoting better drying of the instruments. Contact your dealer for details.
- 3. 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). We recommend to use plastic-plastic or plastic-paper pouches.

#### 10 OPERATING INSTRUCTIONS



To avoid possible damage, do not leave the autoclave un-attended while in operation

- 1. Remove the water reservoir cover. Pour distilled water into the reservoir through the opening on top of the autoclave until it reaches the level of the upper floatswitch, approximately 6.5 liters (1.72 gallons).
- 2. Insert the plug into the socket and switch on the circuit breaker on the backside of the machine.
- 3. Turn on the main switch mounted on the front panel to power the control circuits.
- 4. The autoclave will be ready for use within 10 minutes. This is the time needed to heat up the steam generator.
- 5. Set the clock for the proper date and time, by means of the MENU key (9), UP (10) and DOWN (11); see section 5.1 and 6.1.
- 6. Press the CYCLES key (3) to select the required program. The name of the program is displayed indicating the program has been selected.
- 7. Press PARAMETERS key (2) to monitor the nominal parameters of the program.
- 8. Load the material to be sterilized into the chamber, and close the door.

#### Note:

Due to inherent elasticity of the door gasket, the DOOR LED indicator may indicate that the door is closed before a complete seal is made between the door and the chamber.

Therefore, in order to ensure the door is fully sealed, continue to 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.

- 9. Verify once again that you have chosen the appropriate sterilization program.
- 10. Press the START/ STOP key to put the autoclave into operation. 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 2 minutes at the other stages. The phase in progress is displayed at the right side of the upper line as VACUM, HEAT, STER., EXH., and DRY. During the air removal stage the following is displayed at the middle of the bottom line: the pulse number followed by a letter indicating the operation in progress V-vacuum, H-heating, E-exhaust (Ex. P1V or P2H). If the operator presses the START key and the door is not completely closed, the process will not start and the DOOR light will remain on, DOOR OPEN will be displayed and the buzzer will sound six times.

#### **CAUTION:**



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



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

- 11. At the end of the cycle, the START light is put off, the END message is displayed and the buzzer will ring a continuous sound for 7 seconds. In case of a failed cycle, the diagnosis of the failure followed by the "FAIL!!!" message will be displayed and printed and the buzzer will output an interrupted sound.
- 12. Open the door and unload the sterilized material from chamber. In case of fail press the START/STOP key to cancel the locking of the door. For unloading hints see para. 8.3.3 (Unloading).

#### 11 MAINTENANCE INSTRUCTIONS

#### 11.1 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, as specified in para. 11.1.3.2.

Use only mineral-free water as detailed in para. 3.9 (water quality).

#### 11.1.1 Daily

Clean door gasket with a soft cloth. The gasket should be clean and smooth.

# 11.1.2 Weekly

- 1. 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. You may use diluted Chamber Brite<sup>TM</sup> solution as cleaning agent. To prepare this solution, pour one bag of Chamber Brite<sup>TM</sup> into 3/4 1 liter of warm mineral-free water. Immediately after cleaning, rinse the tray holder, trays and chamber's interior with water to avoid stains on the metal.
- 2. Once a week clean and descale the chamber and the reservoir using a cleaning agent as described above.



#### **CAUTION:**

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

- 3. Put a few drops of oil on the 2 door pins and door tightening bolts.
- 4. Clean the outer parts of the autoclave with a soft cloth.
- 5. Replacing mineral free water

# 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 or distilled water (see para.

11.2).

# Autoclaves with recycling of mineral free water (not available in Europe!)

Once a week, or after 20 cycles (whichever comes first), drain the water from the mineral free water reservoir once a week, and refill with fresh mineral-free water or distilled water (see para. 11.2).

6. Once a week or when "Empty Res L" is displayed (the shorter period) drain the water from the waste water reservoir (see para. 11.2).

#### 11.1.3 Periodically

#### 11.1.3.1 By the operator

- 1. Once a month activate the safety valve (see para. 11.6).
- 2. Once a month clean the strainer as per para. 11.8. Cleaning frequency may be reduced according to experience.
- 3. Replace the air filter, every 6 months or after 1000 cycles (the shorter period) according to para. 11.3.
- 4. Once every six months clean the fan grid with a vacuum cleaner from the outer side of the grid.
- 5. Check the door gasket every 12 months and replace it if required (see para. 11.4).

#### 11.1.3.2 By a qualified technician

#### 6 months

 Tightening the screws of the heaters and the electrical connections at the heaters, valves and connectors in the control box

#### Year

- Checking the continuity of the grounding connections.
- Calibrating the temperature and pressure.
- Performing 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, cutoff 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 closing device for excessive wear.

Performing safety tests (pressure vessel, efficiency, electrical) according to local rules or regulations. Only an authorized inspector may perform this.

#### 11.2 Draining the Reservoirs

(Applies to the clean-water reservoir and to the waste-water reservoir)

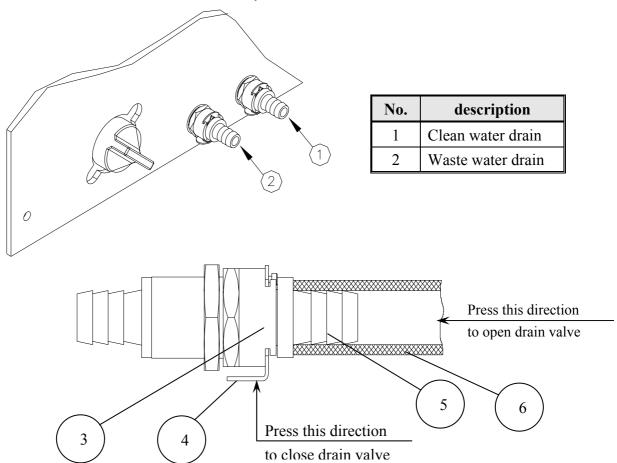


#### **CAUTION!**

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

- 1. To drain the reservoir, use item (5) with the plastic tube (6) attached to it (supplied with the autoclave).
- 2. Insert part (5) into valve (3) and press it until you hear a "click". The drain valve is open.
- 3. When the water reservoir is empty, press part (4). Item (5) will pop out approx. 3mm and the drain valve will be closed. Remove item (5) with the plastic tube.
- 4. If the drained reservoir is the clean-water reservoir, fill reservoir with distilled water until it reaches the level of the upper floatswitch, approximately 6.5 liters (1.72 gallons).
- 5. Connect the electric cord to the power source.

The autoclave is now ready for use.



#### 11.3 Replacing the Air Filter

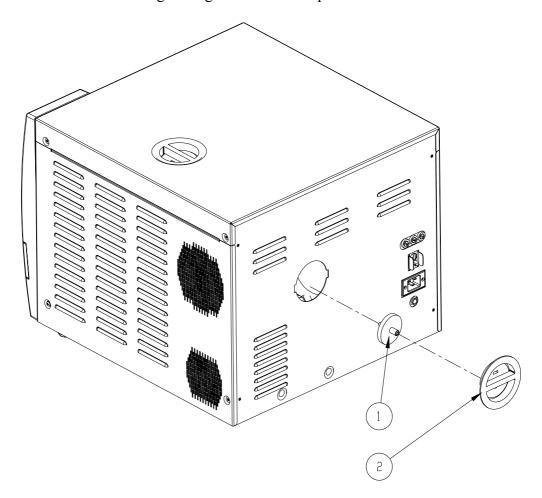
In order to "break" the vacuum, at the end of the dry phase, filtered atmospheric air enters the chamber via a solenoid valve. The filtration of the air is performed by the bacteriological filter that is placed at the inlet of the chamber.

The bacteriological filter is mounted at the inlet of the chamber, through a solenoid valve.

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

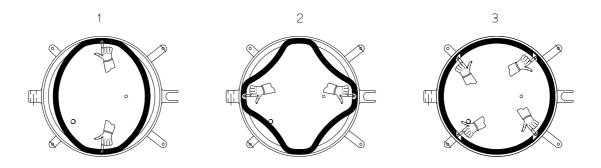
To replace the filter proceed as follows:

- 1. Remove the cover of the opening.
- 2. Cut the tie wrap connecting the filter to the flexible tubing.
- 3. Replace the filter with a new one connecting it with the flexible tube and tightening it with a tie wrap.



No.	description
1	Air filter
2	Air filter opening access cover

# 11.4 Replacing the Door Gasket



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.

# 11.5 Replacing the Cartridge Fuse



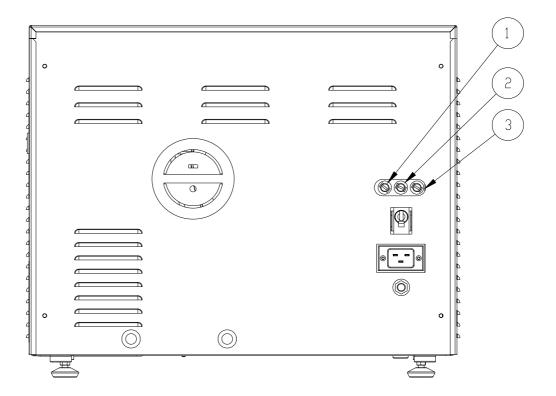
# **CAUTION!**

# Make sure that the electrical power cord is disconnected!

Use a screwdriver to unlock the fuse holder cover by turning it counter clockwise a little, and pull it out.

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

# Make sure that the right fuse is installed as marked below!



No.	Cat. No.	Description
1	ELE035-0074	Transformer fuse — 0.5A
2	ELE035-0055	Water pump fuse — 1.25A
3	ELE035-0055	Vacuum pump fuse — 1.25A

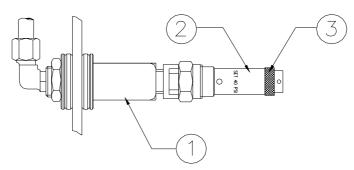
#### 11.6 Checking the Safety Valve

In order to prevent the safety valve from blockage, 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. Turn the pressure-relief-nut 2 turn counterclockwise.
- 2. Operate the autoclave on cycle 1, 2 or 3.
- 3. Verify that the safety valve discharges (steam escapes from the valve) when reaching maximum pressure.
- 4. Turn off the autoclave.
- 5. Wait until the pressure decreases to zero and the autoclave cools down. Turn the pressure-relief-nut 2 turn clockwise.



No.	Description
1	Safety valve base
2	Safety valve
3	Pressure relief nut

#### 11.7 Door Safety System

The door opening is ensured by two means:

- a. The closing device prevents an incidental opening of the door.
- b. A pull-type solenoid that in inactivated position locks the door and must be electrically powered to release the locking and enable the opening of the door.

#### 11.7.1 Solenoid locking device

The solenoid locks the door in the following situations:

- 1. When the control unit is not powered.
- 2. If power failed or has been turned off while the autoclave is in operation, even if power has been restored.
- 3. If operation was stopped before completion of the cycle as a result of a failure or a manual stop.

For cases described at points 2 and 3, press START/STOP key to cancel the door locking at the end of the operation. If, for any reason, the locking mechanism does not open, **do not use force to open the door**. Turn the closing device a quarter (1/4) turn clockwise (closing direction) and re-try to open the door. **Do not use force to open the door**.

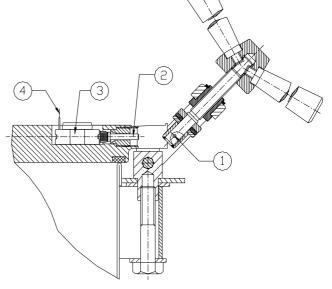
If, despite operating according to the instructions above, the door does not open, call an authorized technician.

#### 11.7.2 Emergency door opening (Authorized technician only!)

In order to facilitate initial installation, the door locking position is taped in this retracted position at the factory. On completion of all installation activities this tape must be removed.

If for any reason the door locking mechanism is permanently locked, it is possible to open the door and provide access for eventual repairs to the locking mechanism. The swing bolt has a drilled opening located in the lock catch. By pushing the piston back with a 2mm. pin, the swing bolt may be turned another 3/4 position until the position catches again. Repeat these steps until the bolt is swung and the door opened.

No.	Description
1	Opening for the release of
1	the locking screw
2	Solenoid pin
3	Solenoid
4	Electrical connection



# 11.8 Cleaning water strainer



#### **CAUTION!**

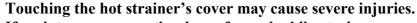
Before proceeding, Make sure that the electric cord is disconnected and there is no pressure in the autoclave.

- 1. Open the strainer cover.
- 2. Remove the strainer element.
- 3. Rinse the strainer with water. Use a brush if necessary.
- 4. Reinstall the strainer element.
- 5. Close the strainer cover.

#### **CAUTION!**

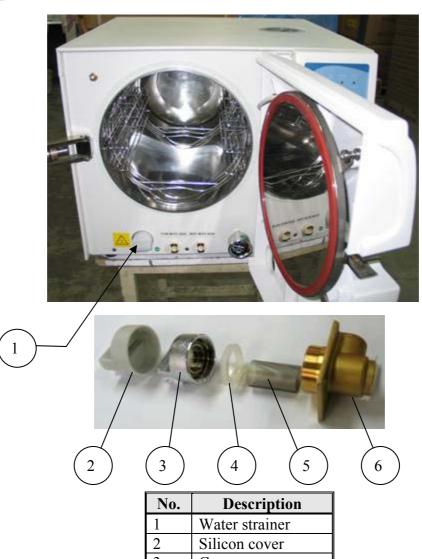


Do not touch the strainer's cover, mounted on the exhaust line, shortly after operation.





If maintenance operation is performed while strainer cover is hot, use heat resistant gloves to avoid injuries.



No.	Description
1	Water strainer
2	Silicon cover
3	Cap
4	Gasket
5	Strainer element
6	Strainer housing

# 12 TROUBLESHOOTING

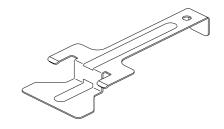
Only technical personnel having proper qualifications and holding technical documentation (including a technician manual) and adequate information are authorized to service the apparatus.

Problem	lem	Sol	Solution
12.1	12.1 display is not activated	1.1	<ul><li>1.1 Verify that the main switch is in the 'On' position.</li><li>(see front view drawing).</li><li>1.2 Make sure the power cord is properly connected to the machine and the power source. (see rear</li></ul>
		1.3	view drawing)  Check the reset button on the cut-out thermostat.
		1.4	(Section view diaming)  Make sure the circuit breaker has not tripped. Lift circuit breaker's lever if necessary. (See rear view drawing)
		1.5	1.5 Verify that there is electrical power in the main source.
12.2	12.2 'Low Vacuum' is displaved	2.1	2.1 Check the door for leakage and replace the door gasket, if necessary. (see para. 11.4, Replacing the Door Gasket)
	·	2.2	2.2 Make sure the pump is running. Check the pump fuse and replace it if necessary. (see para. 11.5, Replacing the Cartridge Fuse).
12.3	12.3 'Low Heat' is displayed 3.1 Make sure	3.1	Make sure the machine has the proper amount of sterilization load.
12.4	12.4 'Empty Res L' is displayed	4.1	4.1 The waste water reservoir has to be drained. In case the optional drain outlet is used, check that the outlet is not clogged.

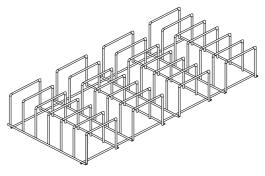
Problem	olem	Solution	tion
12.5	12.5 'Add water' is displayed	4.2	4.2 Verify that the mineral free water supply is O.K.
12.6	12.6 The printer prints, but nothing is printed on	5.1	Verify the ribbon is O.K. replace if required (see para. 7.6, Replacing Ribbon Cassette) Verify that the printing paper is inserted correctly (see para. 7.7 Printing Paper)
12.7	12.7 The printer does not print.	6.1	Make sure the paper is inserted in the printer. (see para. 7.7, Printing Paper) 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. Contact your dealer to solve the problem. If the printer does not print the test printout, there is a problem with the printer. Contact your dealer to solve the problem
12.8	12.8 When the machine is switched on, the printer feeds paper all the time.	7.1	Make sure the 'feed button' on the printer is not stuck.
12.9	12.9 The machine is leaking at the door	8.1	Make sure the door is tightened enough. Replace the door gasket. (see para. 11.4 Replacing the Door Gasket)

If the problem persists, contact your dealer or point of purchase for further assistance.

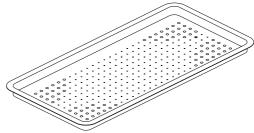
# TRAY HANDLE CMT240-0001



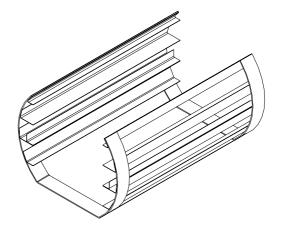
# POUCH RACK ACS215-0008



# TRAY TRY240-0001



# TRAY HOLDER TRH254-0001



# 13 SPARE PARTS LIST

PART NUMBER	DESCRIPTION
ELE035-0055	Fuse, Slow Blow, 1.25A, 6.3x32mm
ELE035-0074	Fuse, Slow Blow, 0.5A, 5x20mm
SRV000-0235	Screen, 400 Micron, For Strainer 1/4"
FIL175-0042	Filter, Air, 0.2 Micron, Model 50mm D
GAS080-0003	Gasket, Door, 2540
THE002-0010	Paper, Roll, Printer CBN-920
THE002-0020	Ribbon, Ink, Printer CBN-920

# 14 ACCESSORIES

PART NUMBER	DESCRIPTION
ACS215-0008	Pouch rack
CMT240-0001	Handle, Tray
GAS084-0007	Drain P.V.C. Tube, 8x12
THE002-0009	Printer, CBN-920, CITIZEN
TRH254-0001	Holder, Tray, 2540
TRH254-0009	Holder, Tray, Wire, 2540
TRY240-0001	Tray, perforated, St.St, 23/2540
WIR040-0002	Cable, Electric, Plug + Socket 230V 16A, EUR