Tuttnauer
Your Sterilization & Infection Control Partners

HORIZONTAL AUTOCLAVE LOG BOOK

Autoclave Type _____

Serial No. _____

Department _____

Cat. No. MAN205-0158000EN Rev. E

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Tuttnauer
Your Sterilization & Infection Control Partners

IMPORTANT INFORMATION

Purchased at: _____

Date of purchase: _____

Service point: _____

Address of service point: _____

Contact person: _____

Tel: _____

Mobile: _____

E-mail: _____

Dear customer,
We appreciate your decision to purchase a "Tuttnauer" Autoclave.

The autoclave you purchased is built of the best materials and components. They are approved for their safety as well as for their performance and quality.

Tuttnauer. Ltd. Company meets the provisions of the **Medical Device Directive 93/42EEC** and **PED 97/23EEC** and the following standards:

ASME	American Society of Mechanical Engineers Section VIII, Division 1, for unfired pressure vessels.
AAMI/ANSI-ST8	Hospital sterilizers
EN 285	Large Sterilizers.
EN 554	Validation and routine control.
UL	UL 61010-1
IEC	IEC 61010-2-040 Safety

Tuttnauer Ltd. is also approved for:
ISO 9001:2008 (Quality Systems)
ISO 13485:2003 (Quality Systems for Medical Devices)
ISO 17665-1:2006 (Validation and Routine Control)
The most efficiency use and the highest Sterilization Assurance Level (SAL) can be obtained by maintaining the Device in the correct way. It is designed to be as easy as possible.

IMPORTANT:
The Autoclave is a safe instrument if maintained properly. If autoclave maintenance is neglecting, or operated in a manner not specified in the operation manual, the Autoclave may become hazardous.

The maintenance operations required from the operator and the technician are minimized due to the Good Engineering and Manufacturing Practice.

This brochure contains the following:

1. Steam sterilization.
2. Water quality and its influence on Stainless Steel.
3. Recommended maintenance.
4. An annual maintenance report and autoclave log table.

IMPORTANT:
Approve and sign, in the Annual Maintenance Report, each maintenance operation and test performed according to the maintenance schedule. Log also every repair operation performed on the autoclave, each change of parameters and any non-routine operation.

This brochure is intended to instruct the operator how to maintain the autoclave and thus to lengthen its working life and ensure efficient and reliable sterilization.

This LOG BOOK is provided in addition to the Operation & Maintenance manual, but does not replace it.


Warning!
It is strictly forbidden for any person, to enter the service area behind the services panels except trained technician.

If for any reason it is necessary to open the service panel, the person must shut the system by pressing the emergency switch, withdrawing the key and keeping the key on him, to prevent accidents and injuries.
The technician must follow the Maintenance Manual Instructions, in the SERVICE OPERATIONS "Working with power ON in Service Area" section

Steam sterilization

The autoclave is a device intended for sterilization of non-wrapped instruments and utensils, wrapped, packed and contained instruments, porous loads, hollow instruments, liquids in open and unsealed closed vessels as defined in the introduction of the “Operation & Maintenance Manual”. This device is designed for use in operation theaters, veterinary clinics, Central Sterilization Supply Department (CSSD), pharmaceutics industry, Medical waste, laboratories etc.
The most efficient sterilization of microorganisms is performed in an environment in which the temperature, the moister and the process time are controlled and carefully monitored
The autoclave fulfils these conditions. It is built as a pressure cooker, in which the dry saturated steam provides the temperature to assure the destruction of the micro-organisms.

To ensure a successful sterilization you must verify that:

a. The load to be sterilized must be clean, de-contaminated and autoclavable.
b. The packaging shall meet standard packaging requirements (container, fabric or paper packaging, bags).
c. The correct cycle is selected.
d. The autoclave is properly maintained.
e. The sterilized loads is stored in a sterile environment.

Water Quality and its Influence on Stainless Steel

The pressure chamber, as well as all parts that are in contact with the steam, are manufactured from high grade stainless steel. The properties of the stainless steel are derived from the bonds of the steel molecules with the oxygen in the air. Therefore the metal must come in contact with the air.

As a result of the contact between the stainless steel and the air a chrome-oxide film is built on the steel surface. This film protects the steel.

Tap water has the following properties that may cause the destruction of the steel.

1. **Chlorides** These are alkaline materials that neutralize the protection film. The chlorides are destructive especially in stainless steel since they accelerate development of stress cracks.
2. **Water hardness** The Magnesium and the Calcium produce a white scale film on the metal that prevents oxygen from contacting the steel surface. The scale reduces significantly the heat conductivity.
3. **Dirt or contaminants** Dirt or contaminants may prevent contact of the steel with oxygen.

Therefore only distilled water or mineral free water may be used to produce steam.

Physical Characteristics and Maximum acceptable contaminants levels in water or steam, for steam generator and sterilizers

According to EN 1360:2004

	Contaminants in water supplied to generator	Contaminants in condensate at steam inlet to sterilizer
Evaporate residue	≤ 10 mg/l	N/A
Silicate (SiO_2)	≤ 1 mg/l	≤ 0.1 mg/l
Iron	≤ 0.2mg/l	≤ 0.1mg/l
Cadmium	≤ 0.005 mg/l	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l	≤ 0.05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0.1 mg/l	≤ 0.1 mg/l
Chloride (Cl)	≤ 2 mg/l	≤ 0.1 mg/l
Phosphate (P_2O_5)	≤ 0.5 mg/l	≤ 0.1 mg/l
Conductivity (at 25°C)	≤ 5 µs/cm	≤ 3 µs/cm
pH value (degree of acidity)	5 to 7.5	5 to 7
Hardness (Σ ions of alkaline earth)	≤ 0.02 mmol/l	≤ 0.02 mmol/l
Appearance	Colorless, clean, without sediments	

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

Attention:

Using water 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.

Summary:

Use only distilled (not pure) water or mineral free water. Water source to create distilled or mineral free water may be:

1. Di-ionization column	
2. Reverse osmosis device	
3. Water distiller	
4. Rain water	

Do not use tap water or "soft water".

Soft water contain 0-60 mg/l (0-3.5 gpg) dissolved calcium and magnesium

If the autoclave is equipped with a liquid ring vacuum pump, the feed water supplied to the pump must meet the following requirements:

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

Horizontal autoclave Preventive Maintenance (maintenance procedure is provided in the operation manual)

Caution!

Only authorized electricians are allowed to install or attend the electrical system!

When servicing the autoclave, disconnect the all electrical power supplies to the unit. This is done by switching OFF the main power supply switch, or by un-plugging the electrical power main supply cords. Before starting, ensure there is no pressure in the autoclave.

Keep the autoclave and its surroundings clean.

Before each cycle

1. Clean the strainer at the bottom of the chamber.
2. Verify that the door gasket and the surface that the gasket is pressed on are clean.
3. Keep the door closed between sterilizing cycles.

Daily

1. Clean the door gasket every day with a soft cloth.
2. Before the first operation of the day, if the unit is cold, warm up the jacket for at least 20 minutes with the door closed, even if the READY LED is lit up.
3. Keep the door closed between sterilizing cycles.
4. Carry out a BOWIE & DICK test at the beginning of each day after warm up.
5. Drain the compressor tank before starting operation (if applicable).
6. If sterilizing liquids, clean the chamber at the end of every day.
7. At the end of the day leave the door open.

Weekly (shall be performed only when the autoclave is cold)

1. Clean the cabinet and door parts, the internal walls of the autoclave, the shelves and the shelf rails with a soft cloth and household detergent. Clean the chamber while the autoclave is cold. The detergent shall be flushed away with water.

   If you used tap water, for the final flush use distilled or mineral-free water.

Caution!

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

2. Place several drops of oil on all the door spindles and pins (if applicable).
3. Drain the generator (if applicable) as follows:
   a. Switch OFF the power.
   b. Wait until the pressure decreases to 0.5 bar (watch the pressure gauge).
   c. Open the drainage manual valve for a few seconds till the glass tube becomes empty, and then close the valve.
   d. Drain the water level tube by opening the tube valve located at the bottom elbow connecting the tube to the vessel.
4. At the end of the week, or if the autoclave will stand for a prolonged period, clean the chamber when it is cold, and leave the door open.

Monthly

1. Once a month before the weekend, follow these steps:
   a. Remove the door gasket, and thoroughly clean the door gasket groove.
   b. Remove any stains or corrosion from the door gasket groove, and blow out all traces of dirt with compressed air.
   c. Thoroughly clean the door gasket.
   d. Leave the door gasket out for the weekend.
   e. Before start of day/shift after the weekend, re-place the door gasket according to the instructions in the “Replacing the Door Gasket“ section.

Quarterly

1. Clean water strainers on pipelines while autoclave is not operating, (idle).

2. Verify sewage pipe is not clogged ensuring free drainage of sewage liquids. It is important that sewage liquids do not overflow at the working site.
3. Disassemble the steam –traps and clean them. The cleaning operation requires cleaning of the strainer inside the steam-trap. This can be done by rinsing and removing any dirt, which causes blockage.
4. Check the piping connections and tighten where necessary to avoid leakage.
5. De-scale the generator (if applicable).
6. Verify that the water quality complies with the requirements as detailed in the Water Quality paragraph.
7. Check the vacuum pump inlet/outlet for scale build up and de-scale if necessary.

Every 6 month

1. Replace the 0.01μ air filter

On Autoclaves with Manual Doors

1. Every six months before the weekend, follow these steps:
   a. Remove the door gasket, and thoroughly clean the door gasket and the groove.
   b. Leave the door gasket out for the weekend.
   c. Before start of day/shift after the weekend, re-place the door gasket according to the instructions in the "Replacing the Door Gasket" section.

Yearly

1. Perform an overall check of the locking system and replace worn parts.
2. Check and tighten where necessary the electrical connections in the electrical board, connection box, motors, electrical valves, locking device screws and instrumentation.

3. Clean the electronic control unit, using a vacuum cleaner.
4. Check the door gasket and replace if damaged.
5. Ensure periodical tests are done on time.
6. Check the steam-traps and replace if worn.
7. Calibrate the control system
8 Validate the applicable cycles
9. Check and verify tight closing of all tightening bolts of the side guides, as well as top and bottom guides (if applicable). Replace worn bolts if necessary (on horizontal or vertical door).
10. Check and verify tight closing of all tightening bolts of the bronze strips. Replace worn bolts if necessary (on horizontal or vertical door).
11. Check and verify tight closing of all tightening bolts of the door guide rail (including the door wheels). Replace worn bolts if necessary (on horizontal or vertical door).
12. Check the hydraulic piston including oil level. Check the hydraulic system for leakage, worn or loose component (on horizontal or vertical door).
13. Disassemble the door cover, check and tighten all locking mechanism bolts (on manual or automatic hinged doors).See MOD205-0021EN or Automatic Door Preventive Maintenance section in Maintenance Manual, for procedure.
14. Check operation of the micros-witches. Verify that they are placed tightly as required.
15. Check the safety valve. Allow the safety valve to blow off by letting the pressure increase until it reaches the working pressure + 10%. This verifies that the safety valve operates as required and the valve seats is kept free of mineral deposits.

Note:

Yearly maintenance should always be accomplished by a trained sterilizer service technician.

Every 12 months or after performing a significant change (refer to local law)

1. An Authorized Inspector must perform a safety test on the steam generator.

Every 24 months or after performing a significant change (refer to local law)

1. An Authorized Inspector must perform a safety test on the autoclave.

Log all maintenance and repair operations in the autoclave LOG BOOK.

Maintenance Schedule

	Test and Maintenance Operations	Before each cycle	Daily	Weekly	Monthly	Quarterly	Every 6 Months	Yearly
Operator	Clean the strainer at the bottom of the chamber.	X						
	Clean the door gasket	X						
	Drain the compressor tank before starting operation (if applicable).		X					
	If sterilizing liquids, clean the chamber at the end of every day.		X					
	Clean the cabinet and door parts, the internal walls, the shelves and the shelf rails			X				
	Oil the door hinges (if applicable)			X				
	Drain the generator (if applicable)			X				
Technician	Check the safety valves							X
	Check the water quality				X			
	Clean water strainers on pipelines.					X		
	Verify sewage pipe is not clogged.					X		
	Disassemble and clean the steam–traps.					X		
	Check the piping connections and tighten where necessary.					X		
	De-scale the generator (if applicable)					X		
	Replace the 0.01μ air filter						X	
	Check and tighten where necessary the electrical connections.							X
	Clean the electronic control unit.							X
	Check the door gasket and Replace if damaged.							X
	Perform an overall check of the locking system and replace worn parts.							X

	Test and Maintenance Operations	Before each cycle	Daily	Weekly	Monthly	Quarterly	Every 6 Months	Yearly
Technician	Check the steam-traps and replace if worn.							X
	Calibrate the control system							X
	Validate the applicable cycles							X
	Check all bolts and nuts and fasteners are tight. Replace worn bolts, nuts, fasteners, shins, rails, bearings and any other worn part if necessary (on horizontal or vertical door).							X
	Check the hydraulic piston oil level. Check the whole hydraulic system for leakage, or any worn or loose components (on horizontal or vertical door).							X
	Disassemble the door cover, check and tighten all locking mechanism bolts (on manual or automatic hinged doors). See MOD205-0021EN or Automatic Door Preventive Maintenance section in Maintenance Manual for procedure.							X
	Check operation of the micro-switches. Check that the fasteners holding all micro-switches are tight.							X

Notes:

1. The procedures done by the "User" referred in the Preventive and Periodical Maintenance, must be performed by trained personnel only.
2. Keeping the inside of the autoclave clean will lengthen its life and its proper operation.
3. Ensure the chamber is empty and cold during all cleaning.
4. For all cleaning use ordinary household stainless cleaner, and rinse first with tap water, and then with distilled or mineral free water.

5. Use only mineral-free water for the steam generator as detailed in the Water Quality paragraph, (If applicable).
6. Keep the door closed between sterilizing cycles.
7. If you **see** or **hear** anything extraordinary, stop using the autoclave and call for service.

Periodical Tests

1. Once a year calibrate and validate the autoclave.
2. Periodical safety tests (pressure vessel and electricity) shall be performed by an Authorized Inspector at intervals as required by the local laws, rules or regulations.

Periodical safety tests should be performed by an authorized inspector at intervals as required by local law, rules or regulations.

Notes:

Ensure periodical tests are done on time!

LOG HISTORY

Annual Maintenance Log – first year: Year _____

	Test and maintenance operations	Performed by	Date	Signature
Monthly	Check the safety valve			
	Check the water quality			
Quarterly	Clean water strainers on pipelines.			
	Verify sewage pipe is not clogged.			
	Disassemble and clean the steam–traps.			
	Check the piping connections and tighten where necessary.			
	De-scale the generator (if applicable)			
6 Mont	Replace the 0.01μ air filter			
Yearly	Check and tighten where necessary the electrical connections.			
	Clean the electronic control unit.			
	Check the door gasket and Replace if damaged.			
	Check the steam-traps and replace if worn.			
	Calibrate the control system			
	Validate the applicable cycles			
	Check and verify all closing bolts of the side or top/bottom guides, (bronze strips), (if applicable), are tight. Replace worn bolts if necessary (on horizontal or vertical door).			
	Check and verify tight closing of all tightening bolts of the door guide rail (including the door wheels). Replace worn bolts if necessary (on horizontal or vertical door).			
	Check the hydraulic piston including oil level. Check the hydraulic system for leakage, worn or loose component (on horizontal or vertical door).			
	Disassemble the door cover, check and tighten all locking mechanism bolts (on manual or automatic hinged doors). See MOD205-0021EN or Automatic Door Preventive Maintenance section in Maintenance Manual for procedure.			
	Check operation of the micros-witches. Verify that they are placed correctly and all fasteners are tight..			
	Generator safety test (intervals as required by the local laws, rules or regulations).			
	Autoclave safety test (intervals as required by the local laws, rules or regulations).			

REMARKS

Annual Maintenance Log – second year: Year _____

	Test and maintenance operations	Performed by	Date	Signature
Monthly	Check the safety valve			
	Check the water quality			
Quarterly	Clean water strainers on pipelines.			
	Verify sewage pipe is not clogged.			
	Disassemble and clean the steam–traps.			
	Check the piping connections and tighten where necessary.			
	De-scale the generator (if applicable)			
6 Mont	Replace the 0.01μ A air filter			
Yearly	Check and tighten where necessary the electrical connections.			
	Clean the electronic control unit.			
	Check the door gasket and Replace if damaged.			
	Check the steam-traps and replace if worn.			
	Calibrate the control system			
	Validate the applicable cycles			
	Check and verify all closing bolts of the side or top/bottom guides, (bronze strips), (if applicable), are tight. Replace worn bolts if necessary (on horizontal or vertical door).			
	Check and verify tight closing of all tightening bolts of the door guide rail (including the door wheels). Replace worn bolts if necessary (on horizontal or vertical door).			
	Check the hydraulic piston including oil level. Check the hydraulic system for leakage, worn or loose component (on horizontal or vertical door).			
	Disassemble the door cover, check and tighten all locking mechanism bolts (on manual or automatic hinged doors). See MOD205-0021EN or Automatic Door Preventive Maintenance section in Maintenance Manual for procedure.			
	Check operation of the micros-witches. Verify that they are placed correctly and all fasteners are tight..			
	Generator safety test (intervals as required by the local laws, rules or regulations).			
	Autoclave safety test (intervals as required by the local laws, rules or regulations).			

REMARKS

Annual Maintenance Log – third year: Year _____

	Test and maintenance operations	Performed by	Date	Signature
Monthly	Check the safety valve			
	Check the water quality			
Quarterly	Clean water strainers on pipelines.			
	Verify sewage pipe is not clogged.			
	Disassemble and clean the steam–traps.			
	Check the piping connections and tighten where necessary.			
	De-scale the generator (if applicable)			
6 Mont	Replace the 0.01μ air filter			
Yearly	Check and tighten where necessary the electrical connections.			
	Clean the electronic control unit.			
	Check the door gasket and Replace if damaged.			
	Check the steam-traps and replace if worn.			
	Calibrate the control system			
	Validate the applicable cycles			
	Check and verify all closing bolts of the side or top/bottom guides, (bronze strips), (if applicable), are tight. Replace worn bolts if necessary (on horizontal or vertical door).			
	Check and verify tight closing of all tightening bolts of the door guide rail (including the door wheels). Replace worn bolts if necessary (on horizontal or vertical door).			
	Check the hydraulic piston including oil level. Check the hydraulic system for leakage, worn or loose component (on horizontal or vertical door).			
	Disassemble the door cover, check and tighten all locking mechanism bolts (on manual or automatic hinged doors). See MOD205-0021EN or Automatic Door Preventive Maintenance section in Maintenance Manual for procedure.			
	Check operation of the micros-witches. Verify that they are placed correctly and all fasteners are tight..			
	Generator safety test (intervals as required by the local laws, rules or regulations).			
	Autoclave safety test (intervals as required by the local laws, rules or regulations).			

REMARKS

Annual Maintenance Log – fourth year: Year _____

	Test and maintenance operations	Performed by	Date	Signature
Monthly	Check the safety valve			
	Check the water quality			
Quarterly	Clean water strainers on pipelines.			
	Verify sewage pipe is not clogged.			
	Disassemble and clean the steam–traps.			
	Check the piping connections and tighten where necessary.			
	De-scale the generator (if applicable)			
6 Mont	Replace the 0.01μ air filter			
Yearly	Check and tighten where necessary the electrical connections.			
	Clean the electronic control unit.			
	Check the door gasket and Replace if damaged.			
	Check the steam-traps and replace if worn.			
	Calibrate the control system			
	Validate the applicable cycles			
	Check and verify all closing bolts of the side or top/bottom guides, (bronze strips), (if applicable), are tight. Replace worn bolts if necessary (on horizontal or vertical door).			
	Check and verify tight closing of all tightening bolts of the door guide rail (including the door wheels). Replace worn bolts if necessary (on horizontal or vertical door).			
	Check the hydraulic piston including oil level. Check the hydraulic system for leakage, worn or loose component (on horizontal or vertical door).			
	Disassemble the door cover, check and tighten all locking mechanism bolts (on manual or automatic hinged doors). See MOD205-0021EN or Automatic Door Preventive Maintenance section in Maintenance Manual for procedure.			
	Check operation of the micros-witches. Verify that they are placed correctly and all fasteners are tight..			
	Generator safety test (intervals as required by the local laws, rules or regulations).			
	Autoclave safety test (intervals as required by the local laws, rules or regulations).			

REMARKS

Autoclave Log Table

Date	Malfunction description, maintenance/repair operation	Performed by

Autoclave Log Table (cont.)

Date	Malfunction description, maintenance/repair operation	Performed by

Autoclave Log Table (cont.)

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Date	Malfunction description, maintenance/repair operation	Performed by

Autoclave Log Table (cont.)

Date	Malfunction description, maintenance/repair operation	Performed by

Autoclave Log Table (cont.)

Date	Malfunction description, maintenance/repair operation	Performed by

Note for user:

If an additional log book is required, please contact the dealer or Tuttnauer. Ltd. directly.