

**TABLE-TOP AND VERTICAL
AUTOCLAVE LOG BOOK**

Autoclave Type _____

ID No. _____

Serial No. _____

Department _____

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 from the best materials and components. They are approved for their safety as well as for their performance and quality.

The autoclave complies with either American ANSI/AAMI Standards, thus listed by the ASME, UL and FDA or complying with the Medical Device Directive 93/42 EEC as amended by Directive 2007/47, thus complying with EN13060 and ISO17665-1 Standards.

Tuttnauer manufactures Autoclaves comply with Australian, Chinese, standard requirements and Laboratory, Pharmaceutical, Medical waste and industrial autoclaves.

The production site Quality System conforms to the requirements of ISO 9001:2008 and ISO 13485:2003.

The most efficiency use and the highest sterilization assurance level can be obtained by maintaining the Device in the correct way. It is designed to be as easy as possible.

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. Maintenance plan for Table top and laboratory autoclave.

In this booklet you will find the autoclave log Table. Please log in it every repair operation performed on the autoclave, each change of parameters and any non-routine operation.

Note: This log-book is provided in addition to the operation & maintenance and technician manuals, and does not replace it. For detailed maintenance and repair procedures please see the technician manual.

Steam sterilization

The autoclave is a device intended for sterilization of non-wrapped (exposed), wrapped (fabrics, paper, bags), packed (pouches, Cassetts, Containers), porous loads (fabrics, filters), hollows (bottles, Canisters), liquids in open and unsealed closed vessels as defined in the introduction of the “Operation & Maintenance Manual”. This device is designed for use in first aid rooms, dental clinics, operation rooms, veterinary clinics, pharmaceuticals industry, removal of medical waste, laboratories etc.

The most efficient sterilization of microorganisms is performed in an environment in which the temperature, the humidity and the process time are controlled and monitored in the adequate levels.

The autoclave fulfils these conditions. It is built as a pressure cooker, in which the dry saturated steam in the chamber provides the temperature and the humidity (the pressure enables maintaining the required temperature and humidity simultaneously)

To ensure a successful sterilization you must verify that:

- a. The load to be sterilized must be clean.
- b. The autoclave must be maintained well.
- c. The sterilized loads must be stored in a sterile environment.

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

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's 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 – Magnesium and Calcium produce a white scale film on the metal that prevents oxygen from contacting the steel's 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.

This water shall have the following characteristics and maximum contamination according to the following table

| | | | |
|---|--------------|--|--------------------------------------|
| Silicium oxide. SiO ₂ | ≤0.1 mg/kg | Chloride (Cl) | ≤0.1 mg/kg |
| Iron (Fe) | ≤0.1 mg/kg | Phosphate (P ₂ O ₅) | ≤0.1 mg/kg |
| Cadmium (Cd) | ≤0.005 mg/kg | Conductivity at 20°C | ≤ 3 µs/cm |
| Lead (Pb) | ≤ 0.05 mg/kg | pH value | 5 to 7 |
| Rest of metals except iron, cadmium, lead | ≤ 0.1 mg/l | Appearance | Colourless, clean, without sediments |
| Hardness (Σ ions of alkaline earth) | | ≤ 0.02 mmol/l | |

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



Attention:

We recommend monthly testing of the water quality. The use of 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 may be:

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

Do not use tap water neither "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.



Table-top autoclave Preventive Maintenance (maintenance procedure is provided in the operation manual)

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

Maintain the cleanliness of the autoclave and its surrounding.

Daily

2. Leave the autoclave's door open.

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.
2. Clean and descale the chamber, copper tubes and reservoir using a cleaning agent.



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.
6. Once a week, or after 20 cycles (whichever comes first), drain the water from the reservoir, and refill with fresh mineral-free water or distilled water*.
7. Clean the air jet (if applicable)*.

Monthly

3. Check the safety relief valve (if applicable).

Every six month

1. Replace the air filter (if equipped with an air filter).
3. Clean the water strainer located on side or rear wall of the autoclave*.
4. Clean the fan grid and the electronic control unit with a vacuum cleaner from the inside outward.
5. Clean door gasket with a soft cloth. The gasket should be clean and smooth.
Note: For Class B autoclaves, clean the gasket and its groove once in 6 months if so recommended by the service center.

Yearly

1. Check and verify the fastener assembly strength.
2. Check the door gasket and Replace if damaged.
3. Perform validation test of the process.

Every 12 months (or according to your regulations) or after performing a significant change

1. Perform a safety test by an authorized Inspector.

*Not applicable to Class B autoclaves.

Log all maintenance and repair operations in the autoclave’s logbook.

Note: see *Maintenance and Replacement Procedures* in the Technician Manual for your model.

| | Test and maintenance operations | Daily | Weekly | 1 Month | 6 months | yearly | 5 years | |
|--|--|--------------|---------------|----------------|-----------------|---------------|----------------|--|
| To be performed by the operator | Cleaning the door gasket | X | | | | | | |
| | Cleaning the air jet* | | X | | | | | |
| | Cleaning the trays and the tray holder | As needed | | | | | | |
| | Cleaning the system with a cleaning agent | | | X | | | | |
| | Oiling the door hinges | | | | | X | | |
| | Replacing water (weekly or after 20 cycles) | | X | | | | | |
| | Cleaning the water level electrodes* | | X | | | | | |
| | Cleaning the water strainer* | | | | X | | | |
| | Cleaning the electronic box grid | | | | | X | | |
| | Checking the safety valve | | | X | | | | |
| To be performed by the technician | Replacing the air filter (if applicable) | | | | X | | | |
| | Checking the door gasket | | | | | X | | |
| | Checking and fastening piping joints | | | | | X | | |
| | Fastening screws | | | | | X | | |
| | Checking earth connection | | | | | X | | |
| | Checking the autoclave’s leveling | | | | | X | | |
| | Opening and Cleaning the valves | | | | | X | | |
| | Checking the locking device for wear (by authorized engineer only) | | | | | X | | |
| | Visual inspection of integrity of the water reservoir, piping, plastic parts and electrical wiring | | | | | X | | |
| Checking wear of the locking screw | | | | | | X | | |

Periodical safety tests shall be performed by an authorized inspector at intervals as required by the local laws, rules or regulations.

*Not applicable to Class B autoclaves.

LOG SECTION

Annual maintenance log – first year: year _____

| | Test and maintenance operations | Performed by | Date | Signature |
|--|---|---------------------|-------------|------------------|
| Monthly | Cleaning the water strainer* | | | |
| | Checking the safety valve | | | |
| | Checking the water quality | | | |
| 6 months | Cleaning the electronic box grid | | | |
| | Replacing the air filter | | | |
| Yearly | Checking the door gasket | | | |
| | Checking and fastening piping joints | | | |
| | Fastening screws | | | |
| | Checking earth connection | | | |
| | Performing validation | | | |
| | Checking the earth leakage relay | | | |
| | Checking the autoclave's leveling | | | |
| | Checking the valves | | | |
| | Checking the thermostats | | | |
| | Checking the locking device for wear | | | |
| | Verifying the cycles' parameters | | | |
| | Checking integrity of the water reservoir, piping, plastic parts and electrical wiring | | | |
| | Checking wear of the locking screw | | | |
| Checking calibration of temperature and pressure | | | | |
| | Periodical safety tests (at intervals as required by the local laws, rules or regulations). | | | |

*Not applicable to Class B autoclaves.

Annual maintenance log – first year: year _____

| REMARKS |
|---|
| Cleaning the water strainer |
| Checking the safety valve |
| |
| Cleaning the electronic box grid |
| Replacing the air filter |
| Checking the door gasket |
| Checking and fastening piping joints |
| Fastening screws |
| Checking earth connection |
| Performing validation |
| Checking the earth leakage relay |
| Checking the autoclave's leveling |
| Checking the valves |
| Checking the thermostats |
| Checking the locking device for wear |
| Verifying the cycles' parameters |
| Checking integrity of the water reservoir, piping, plastic parts and electrical wiring |
| Checking wear of the locking screw |
| Checking calibration of temperature and pressure |
| Periodical safety tests (at intervals as required by the local laws, rules or regulations). |

Annual maintenance log – second year: year _____

| | Test and maintenance operations | Performed by | Date | Signature |
|--|---|--------------|------|-----------|
| Monthly | Cleaning the water strainer* | | | |
| | Checking the safety valve | | | |
| | Checking the water quality | | | |
| 6 months | Cleaning the electronic box grid | | | |
| | Replacing the air filter | | | |
| Yearly | Checking the door gasket | | | |
| | Checking and fastening piping joints | | | |
| | Fastening screws | | | |
| | Checking earth connection | | | |
| | Performing validation | | | |
| | Checking the earth leakage relay | | | |
| | Checking the autoclave's leveling | | | |
| | Checking the valves | | | |
| | Checking the thermostats | | | |
| | Checking the locking device for wear | | | |
| | Verifying the cycles' parameters | | | |
| | Checking integrity of the water reservoir, piping, plastic parts and electrical wiring | | | |
| | Checking wear of the locking screw | | | |
| Checking calibration of temperature and pressure | | | | |
| | Periodical safety tests (at intervals as required by the local laws, rules or regulations). | | | |

*Not applicable to Class B autoclaves.

Annual maintenance log – first year: year _____

| REMARKS |
|---|
| Cleaning the water strainer |
| Checking the safety valve |
| |
| Cleaning the electronic box grid |
| Replacing the air filter |
| Checking the door gasket |
| Checking and fastening piping joints |
| Fastening screws |
| Checking earth connection |
| Performing validation |
| Checking the earth leakage relay |
| Checking the autoclave's leveling |
| Checking the valves |
| Checking the thermostats |
| Checking the locking device for wear |
| Verifying the cycles' parameters |
| Checking integrity of the water reservoir, piping, plastic parts and electrical wiring |
| Checking wear of the locking screw |
| Checking calibration of temperature and pressure |
| Periodical safety tests (at intervals as required by the local laws, rules or regulations). |

*Not applicable to Class B autoclaves.

Annual maintenance log – third year: year _____

| | Test and maintenance operations | Performed by | Date | Signature |
|--|---|--------------|------|-----------|
| Monthly | Cleaning the water strainer* | | | |
| | Checking the safety valve | | | |
| | Checking the water quality | | | |
| 6 months | Cleaning the electronic box grid | | | |
| | Replacing the air filter | | | |
| Yearly | Checking the door gasket | | | |
| | Checking and fastening piping joints | | | |
| | Fastening screws | | | |
| | Checking earth connection | | | |
| | Performing validation | | | |
| | Checking the earth leakage relay | | | |
| | Checking the autoclave's leveling | | | |
| | Checking the valves | | | |
| | Checking the thermostats | | | |
| | Checking the locking device for wear | | | |
| | Verifying the cycles' parameters | | | |
| | Checking integrity of the water reservoir, piping, plastic parts and electrical wiring | | | |
| | Checking wear of the locking screw | | | |
| Checking calibration of temperature and pressure | | | | |
| | Periodical safety tests (at intervals as required by the local laws, rules or regulations). | | | |

*Not applicable to Class B autoclave.

Annual maintenance log – first year: year _____

| REMARKS |
|---|
| Cleaning the water strainer |
| Checking the safety valve |
| |
| Cleaning the electronic box grid |
| Replacing the air filter |
| Checking the door gasket |
| Checking and fastening piping joints |
| Fastening screws |
| Checking earth connection |
| Performing validation |
| Checking the earth leakage relay |
| Checking the autoclave's leveling |
| Checking the valves |
| Checking the thermostats |
| Checking the locking device for wear |
| Verifying the cycles' parameters |
| Checking integrity of the water reservoir, piping, plastic parts and electrical wiring |
| Checking wear of the locking screw |
| Checking calibration of temperature and pressure |
| Periodical safety tests (at intervals as required by the local laws, rules or regulations). |

Annual maintenance log – fourth year: year _____

| | Test and maintenance operations | Performed by | Date | Signature |
|--|---|--------------|------|-----------|
| Monthly | Cleaning the water strainer* | | | |
| | Checking the safety valve | | | |
| | Checking the water quality | | | |
| 6 months | Cleaning the electronic box grid | | | |
| | Replacing the air filter | | | |
| Yearly | Checking the door gasket | | | |
| | Checking and fastening piping joints | | | |
| | Fastening screws | | | |
| | Checking earth connection | | | |
| | Performing validation | | | |
| | Checking the earth leakage relay | | | |
| | Checking the autoclave's leveling | | | |
| | Checking the valves | | | |
| | Checking the thermostats | | | |
| | Checking the locking device for wear | | | |
| | Verifying the cycles' parameters | | | |
| | Checking integrity of the water reservoir, piping, plastic parts and electrical wiring | | | |
| | Checking wear of the locking screw | | | |
| Checking calibration of temperature and pressure | | | | |
| | Periodical safety tests (at intervals as required by the local laws, rules or regulations). | | | |

*Not applicable to Class B autoclave.

Annual maintenance log – first year: year _____

| REMARKS |
|---|
| Cleaning the water strainer |
| Checking the safety valve |
| |
| Cleaning the electronic box grid |
| Replacing the air filter |
| Checking the door gasket |
| Checking and fastening piping joints |
| Fastening screws |
| Checking earth connection |
| Performing validation |
| Checking the earth leakage relay |
| Checking the autoclave's leveling |
| Checking the valves |
| Checking the thermostats |
| Checking the locking device for wear |
| Verifying the cycles' parameters |
| Checking integrity of the water reservoir, piping, plastic parts and electrical wiring |
| Checking wear of the locking screw |
| Checking calibration of temperature and pressure |
| Periodical safety tests (at intervals as required by the local laws, rules or regulations). |

