

**STANDARD CONFIGURATION SUMMARY**

- Chamber volume from 120 to 310 liters
- Working pressure meets ASME and PED requirements
- Working at pressures of 0-350 kPa absolute
- Temperature range 105 °C (221 °F) to 138 °C (280 °F)
- 18 kW / 27kW integral electrical steam generator or external steam source
- User friendly control system with touch screen display on loading side
- 10 factory set programs, 2 test programs, 18 programmable cycle programs
- Built-in printer
- Ethernet connection port for PC access via network
- USB port to download cycle data to memory device
- Independent pressure gauges on front panel
- 316L stainless steel chamber and door
- Chamber has a mirror-like finish
- Conforms to PED 97/23 EC, FDA Clearance
- Conforms to standards: ASME, AAMI/ANSI-ST8, EN 285
- Company approved for 21 CFR 820, ISO 9001:2008 and ISO 13485:2012 (Medical Devices)
- Optional configurations available

**OPTIONAL FEATURES SUMMARY**

- 316 Ti stainless steel chamber and/or jacket
- Sanitary pipe and valves
- Stainless steel bottom frame
- F<sub>0</sub> feature for sensitive loads and reducing cycle time
- Streaming steam cycles
- Bio-Hazard system for decontaminating discharged condensate/waste from the sterilizer
- Bio-Shield barrier system (BLS3 and BLS4 bio-safety level)
- RTD Load Probes / PT100
- Rapid cooling by use of internal cooling coil or jacket spray cooling
- Advanced steam generator options for quality steam
- Air detector
- Diaphragm valve for sanitary piping to prevent bio-burden
- Separate steam channels for chamber and jacket

**PRODUCT DESCRIPTION**

This autoclave series is designed to be highly customizable in order to cover a large range of applications for laboratories, research institutes and biotechnology facilities.

The autoclave series has a chamber volume range from 120 liters to 310 liters. The autoclave operates with saturated steam as the sterilizing agent with a temperature range from 105 °C (221°F) to 138 °C (280 °F) and a working pressure that meets ASME and PED requirements. The autoclave can be equipped with an 18kW or 27kW (model 55120) integral electrical steam generator which supplies the necessary steam for the sterilization process. External steam source may also be used.

**APPLICATIONS**

- Laboratory
- Research Institutes
- Biotech Facilities
- Food laboratories

**DEVICE PICTURE**



44/55 Compact Series with Manual Hinged Door



44/55 Vertical Sliding Door - Control Panel on Side

Information furnished by Tuttnauer is believed to be accurate and reliable. However, no responsibility is assumed by Tuttnauer for its use. This specification is subject to change without notice.

**PRODUCT SPECIFICATION**

**CHAMBER VOLUME & SIZE**

| MODEL | CHAMBER DIMENSIONS (mm) |        |       | VOLUME (liter) |
|-------|-------------------------|--------|-------|----------------|
|       | Width                   | Height | Depth |                |
| 4472  | 408                     | 408    | 730   | 120            |
| 4496  |                         |        | 970   | 160            |
| 5596  | 508                     | 508    | 970   | 250            |
| 55120 |                         |        | 1210  | 310            |

**DOOR SELECTION**

- Single door
- Double door (pass through)
  
- Manual right hinged
- Manual left hinged
  
- Automatic vertical sliding (door on left, control on right)
- Automatic vertical sliding (door on right, control on left)

All automatic doors have a robust hydraulic mechanism for operating doors.

**SERVICE ACCESS**

From loading side and left or right side.

**INSTALLATION SELECTIONS**

- Installed in a wall [Single Door]
- Cabinet enclosure [Single Door]
- Cabinet enclosure through one wall [Double Door]
- Installed through two walls [Double Door]

**ELECTRICAL SAFETY AND COMPONENTS**

The sterilizer meets the International Protection Level IPx4.

The following parts are located in the electric boxes:

- Solid State Relays for the command of the vacuum pump, and the water pump.
- Circuit Breakers for protection of all power circuits.
- Power supplies for powering of electronic circuitry and solenoid valves.
- Overload switch is used to protect the device from high overload currents.

The connection elements (sockets, plugs, etc) and components have a degree of protection conforming to the IPX4 protection level and conform to the EN 60529:1991 standard.

**VOLTAGE SUPPLY**

Three phase or one phase electricity supply is available.

- 415V 3 Phase with Neutral
- 380V / 400V 3 Phase with Neutral
- 230V 3 Phase with Neutral
- 208V 3 Phase without Neutral
- 220V / 230V 1 Phase (not 55120 model)
- 110V / 115V 1 Phase \*

\* For 18kW with building steam supply and vacuum by ejector

Frequency: 50 Hz or 60 Hz

| MODEL | STEAM GENERATOR POWER (kW) |
|-------|----------------------------|
| 4472  | 18                         |
| 4496  |                            |
| 5596  |                            |
| 55120 | 27                         |

Customized electrical specifications are available (additional cost).

**LANGUAGE**

The operator display is available in 26 languages including: English, Spanish, German, Dutch, Russian and Chinese.

**STANDARDS AND CODES**

Tuttnauer products meet the following provisions and standards:

**Europe:**

EN285: 2006+A2:2009 for Large Autoclaves

**USA:**

ANSI/AAMI - ST 8: 2008 – Hospital Sterilizers

**Directives & Guidelines:**

- DIN 58951-2:2003 Steam Sterilizers for Laboratory
- 97/23/EC - Pressure Equipment Directive
- 2004/108/EC - Electromagnetic compatibility
- 2006/95/EC - Electrical equipment
- 2006/42/EC - Machinery Directive

**Safety and EMC Standards:**

- EN 285: 2006+A2: 2009 “Large Steam Sterilizer”
- EN 61010-1: 2010
- EN 61010-2-040: 2005
- EN 61326-1: 2006
- EN 17665-1: 2006

**Pressure Vessel and Steam Generator Construction Standards:**

ASME Code, Section VIII, Division 1, unfired pressure vessels  
 ASME Code, Section I and Section VIII. Div. I

**Good Practice Standards:**

- ISO 17665-1: 2006
- ANSI/AAMI – ST 8: 2008

**Quality System Standards:**

- ISO 9001:2008 (Quality Management Systems)
- ISO 13485:2012 (Quality Systems for Medical Devices)
- Compliance with FDA QSR 21 CFR part 820 & part 11
- Canadian MDR (CMDR) SOR/98-282 (2006) consolidated

## CHAMBER CONSTRUCTION

### Materials

The sterilizer chamber is constructed from solid, high quality materials. Chamber and door thickness is no less than 6 mm.

### Standard Configuration Materials:

|                 |                      |
|-----------------|----------------------|
| Chamber + Door: | 316L stainless steel |
| Jacket:         | 304L stainless steel |

### Optional Materials (Stainless Steel):

|         |      |
|---------|------|
| Jacket: | 316L |
|---------|------|

### Chamber Design

The chamber is **fully jacketed**. The chamber floor is slightly sloped towards an internal drain to facilitate drainage. A stainless steel mesh strainer protects the drain port from blockage by debris. The chamber is mounted on a steel framework which is height adjustable.

### Door Gasket

Manual hinged door gasket: a silicone gasket is permanently fixed in the door.

Automatic sliding door gasket: a silicone gasket is fixed in a groove in the door frame and the gasket is forced against the door by means of steam and/or compressed air pressure.

### Surface Treatment

A passivation layer is applied to the internal surface through an electro-chemical treatment which results in a smooth and shiny stainless steel. The resultant surface is polished to an Ra value < 0.8 µm which is highly protected against corrosion. The internal corners are rounded to aid cleaning.

### Chamber Heating

The fully jacketed chamber is pre-heated by steam in the jacket.

### Stand Construction

Made of 304 stainless steel.

### Insulation

The sterilizer jacket and door are completely insulated with a 1" chloride free glass wool thereby keeping the autoclave cool on the outside. Customized thicker insulation is optional. The insulation is completely enclosed within a stainless steel cover.

The insulation reduces the energy consumption by keeping the heat inside the jacket and chamber.

## SAFETY FEATURES

### Door Safety Systems:

- A pneumatic safety component (pressure switch) is installed in the autoclave which prevents opening of the doors until pressure in the chamber reaches room (atmospheric) pressure.
- Door chamber cannot be opened when chamber is pressurized.
- Steam is not allowed into the chamber when the door is open.
- A cycle cannot start if the door is open or not properly locked.
- The sliding door movement will stop if the automatic sliding door detects any obstruction.
- Double door safety is implemented through interlocks which prevent both doors from being opened simultaneously.

**Safety Valves:** Both chamber and jacket are equipped with pressure relief safety valves. If the pressure exceeds the allowed limit then the safety valves will discharge.

**Built-in Steam Generator Safety:** A water level control system maintains a constant water level that ensures safe operation of the heaters. Furthermore, a sensor ensures that the heater does not operate without a sufficient amount of water in the generator.

**Emergency Shut-Off:** Easily accessible emergency switches for immediate cycle shut-off.

**Double Independent Monitoring:** The combined digital and mechanical monitoring systems provide a cross-reference and guarantee accurate results. The operator can view the pressure readings by means of the analog and digital displays.

## WATER RING VACUUM PUMP

The vacuum pump effectively removes more than 99% air from the chamber. The pump is mounted on a damping mechanism to minimize vibration.

During vacuum action the flow path of the fluids is through the condenser (heat exchanger) and the vacuum pump/ejector to drain. This protects the vacuum system from excessive temperatures.

## PIPES & COMPONENTS

The piping system of the autoclave consists of air-operated ball valves, which control the condensate and steam flow in and out of the chamber, operates the vacuum, and the air inlet valve.

### Standard configuration:

|                      |                              |
|----------------------|------------------------------|
| Piping and fittings: | 304 threaded stainless steel |
| Components*:         | Brass                        |

### Optional configuration (stainless steel):

|   |
|---|
| Primary piping & fittings **: 316 + triclamp fittings |
| Primary components: 316 triclamps or 316 threaded     |

\* Components – Manual valve, non-return valve, pressure regulator, pneumatic valves, steam trap, etc.

\*\* Primary piping system that connects to the chamber up to and including the first valve.

## PRESSURE GAUGES

The single door configuration has two pressure gauges located on the front panel (loading side) that indicate the pressure in the chamber and in the jacket.

The double door configuration has two additional pressure gauges on the unloading side that also indicate the pressure in the chamber and in the jacket.

Both configurations have another two pressure gauges in the service area that indicate the pressure in the steam generator and the door(s) gasket(s).

A steam generator pressure gauge can be placed on the front panel upon request.

## VALIDATION PORTS

The chamber is provided with two 1" threaded connections for optional vacuum/pressure gauges and test sensors. The Validation Ports are each found on the right and left side of the sterilizer from the control side.

**AIR FILTER**

A disposable microbiological air filter is provided to filter all atmospheric air introduced into the chamber for "disease free" air. The air is used to equalize the chamber pressure to atmospheric pressure at the end of the sterilization cycle. The filter is rated for a particle size of 0.01 µm.

**LABORATORY SPECIFIC  
F<sub>0</sub> FEATURE OPTION**

F<sub>0</sub> feature enables reduced media exposure to high temperatures thereby reducing cycle time and preventing damage to temperature sensitive media. Provisions are made to control the sterilization process by insertion of a temperature sensor (PT100) in the load. The exposure time measure is calculated using algorithm based software from the time the temperature sensor in the load has reached a predetermined set point until the end of the sterilization stage. The F<sub>0</sub> value is recorded in the sterilization printout after the cycle completes.

**GRAVITY CYCLE**

Non-porous goods, liquids and media in closed vented glass containers are suitable to be sterilized by a gravity cycle. The gravity cycle implements the gravity air displacement principle.

**PREVACUUM CYCLE**

The prevacuum cycle is a fast and effective cycle for removing more than 99% of the air from the chamber. It also ensures good penetration. The vacuum system uses either a water ring vacuum pump or ejector to extract air from the chamber.

**RTD LOAD PROBE / PT100 OPTION**

In addition to the numerous other temperature sensors in the sterilizer, a number of optional movable PT100 temperature sensors for the chamber can be provided to monitor load temperature, particularly useful with sensitive liquid loads which require precise temperature control.

**BIO-SHIELD FRAME OPTION**

The Tuttnauer bio-shield frame meets the BSL2 bio-safety level. The sterilizer is surrounded by a stainless steel frame with holes that serves as a placeholder for a cross-contamination seal made of Neoprene sheet. The Neoprene sheet is placed between the frame and wall at site.

**BIO-SHIELD BARRIER SYSTEM OPTION**

The Tuttnauer bio-shield system meets BSL3 and BSL4 bio-safety levels using a wall seal (type 3).

**Jacket Frame** - This system includes a fully welded metal strip surrounding the jacket. It is equipped with threaded studs, counter plate, nuts and necessary pass through fittings for wiring or tube paths.

**Wall Frame** - The frame is equipped with anchors to hold it in a concrete wall, studs, counter plate, nuts and sealing neoprene sheets to seal the gap between the wall and the frame.

**BIO-HAZARD SYSTEM OPTIONS**

Tuttnauer's Bio-Hazard system provides an effluent sterilization cycle that sterilizes contaminated laboratory or medical waste.

While all the drain valves are close, the steam and gases from the air removal stage are exhausted through the side of the chamber wall and passed to the bio-hazard system.

**Filtration System** - This system provides a bio filtration during the air removal stage to ensure bio-containment. This jacketed hydrophobic filter is 0.003 µm for air and gases. Any condense will vaporize into steam by the jacket. The system allows for safe replacement and service of the filter. The filter is validated and is heat & pressure resistant. The filter is sterilized during every cycle (In situ) (SIP). (Filter Produced by Pall UK)  
This option is an alternative to the thermal Bio Hazard system.

**RAPID COOLING OPTIONS**

**Importance of Cooling** – Safe rapid cooling prevents breaking, deforming, damaging loads and reducing high temperature exposure time. Also, more sterilization cycles per day can be performed.

In both rapid cooling options steam in the chamber is replaced with compressed air to equalize pressure and then the chamber is cooled with one of the rapid cooling options mentioned below.

**COMPRESSED AIR FOR RAPID COOLING**

| Chamber Size (liters) | Air Pressure (Bar) | Flow Rate (liters/min) |
|-----------------------|--------------------|------------------------|
| 120 to 310            | 6 to 8             | 400                    |

In addition to the compressed air required for the sterilizer's valve system, the installation site must also include a separate compressed air utility to operate the cooling system.

Compressed air pressure for pneumatic valves must always be above 5 Bar. It is recommended to have a separate compressed air line for the pneumatic valves.

**1) Internal Cooling Coils** – Rapid cooling is achieved by passing water through the internal cooling coils thereby reducing cooling time by as much as 75%. Before passing water into the cooling coils the chamber steam in the chamber is replaced with compressed air to equalize pressure.

**RAPID COOLING WATER TABLE**

| Chamber Size (liters) | Cooling Water Pressure (Bar) | Temperature | Flow Rate (liters/cycle) |
|-----------------------|------------------------------|-------------|--------------------------|
| 120 to 310            | 3 to 5                       | 15 °C       | 300                      |

**2) Jacket Water Spray Cooling** – Rapid cooling is achieved by spraying RO water from nozzles in the jacket onto the internal jacket walls rapidly cooling the jacket and chamber. RO water is used to prevent any damage to the jacket. The jacket spray cooling does not use any space inside the chamber, and ensures clean chamber walls with no place for bacteria to buildup. Before jacket spraying the chamber steam in the chamber is replaced with compressed air to equalize pressure.

**STEAM SUPPLY**

The autoclave is supplied with either a standalone steam generator or an option to connect to building steam supply. A combined option of steam generator and building steam supply is also available.

Additional specialized steam supply configurations are listed in the Special Options and Accessories section below.

**Stand Alone Steam Generator:** supplies steam for the sterilization process. The stainless steel steam generator is an



electrically heated type generator equipped with immersion heaters, divided in three-phases. The electrical system of the steam generator is located in a separate electric box.

Water to the steam generator is supplied by a single-phase pump, from a water reservoir, which is connected to demineralized or RO water.

#### **Clean Steam Generator (Optional)**

An external 54kW stainless steel steam generator can be applied for clean steam. All generator components, including the heaters and piping, are built from 316L grade stainless steel.

#### **Steam to Steam Generator (Optional)**

The steam to steam generator is a highly advanced clean steam generator which produces pure steam by heating pure water. It uses steam as the energy source which can be supplied from building steam. It is constructed from 316L grade stainless steel.

#### **STEAM GENERATOR WATER QUALITY**

Various water systems can be used to supply mineral-free water to the steam generator such as Reverse Osmosis (RO), distilled water, etc. Water supplied to the steam generator should be in compliance with the EN 285 standard which includes the following hardness and conductivity requirements:

- Hardness < 0.1 mmol/l
- Conductivity < 15 µS/cm
- Maximum consumption: 12 liter per cycle for standard load

**Note:** Soft water should not be used since its use may result in corrosion of the steam generator and chamber.

#### **VACUUM SYSTEM AND DRAIN COOLING WATER QUALITY**

City tap water supply:

- Hardness between 0.7 and 2 mmol/l
- The tap water pressure should be in the range of 3 – 5 bar (40 - 72 psi)
- Recommended temperature: 15°C
- Consumption: 160 liters per cycle average
- Bio-hazard system requires another 200 liters per cycle

#### **BACSOFT CONTROL SYSTEM**

The main board controls and monitors the physical parameters of the sterilization process and performs the operation sequence of the machine, according to a user selected program, and includes the following features:

- PID (Proportional Integral Differential) pressure control
- Digital inputs and outputs for sterilizer control
- Analog inputs for control and reading temperature and pressure
- A USB port for external devices and an optional barcode feature
- Direct connection to an internal thermal printer
- An Ethernet communication port for access via a network
- Measures chamber pressure and steam generator pressure
- FLASH memory stores cycle data for the last 200 cycles even if there is a power failure
- Two real-time clocks (RTC) for supervising cycle time errors
- In/Out test
- Preventative maintenance notification based on number of cycles or time period

The control system controls all system functions, monitors system operations, visually alerts the operator of cycle malfunctions and, on demand, provides visual indication of the chamber temperature and pressure.

**TEMPERATURE AND PRESSURE SENSORS**

The temperature and pressure measuring circuits are both linear and designed with components having a high precision. The PT100 sensors conform to Class A of the IEC751 standard (EN 61010-2-040).

When the exhaust temperature increases above 40°C (measured by a PT100 sensor at the exhaust drain) then tap water is mixed with the exhaust to drain.

The control system allows for the calibration of temperature and pressure to be performed digitally.

Each sensor circuit is calibrated with individual constants to correct the deviation in manufacturing and aging.

The system uses FLASH memory in which the offset and gain data of the sensors are stored.

**CONTROL PANEL ON LOADING SIDE**

The operators control panel is found on the loading side of the sterilizer and includes a 7 inch touch screen and printer.

The control system is operated via the Bacsoft fully automated menu driven multi-color touch screen display allowing the user to easily operate, browse programs or set the autoclave.

30 identification Codes and Passwords are provided to control access/operation of the machine preventing unauthorized access. These access levels are customizable. Access control can be applied to functions, such as running test cycles, setting parameters, calibration, service and maintenance, cycle selection, cycle start and door control.

With the standard factory configuration, calibration of the temperature circuits and calibration of the pressure circuits require an access code.

**MULTI-COLOR TOUCH SCREEN DISPLAY**

User interface (UI) has been designed with the following features:

- Multi-color touch display for easier reading from a distance
- Text and color wheel indicates the stage of the cycle
- Built-in view of historical cycle data
- Graphical display of temperature and pressure graphs
- Multilingual (26 languages)



The 7 inch touch screen gives easy access to all control features for operating the autoclave. With technician level password access there are further features available for maintenance, calibration and checking the autoclave.

**CONTROL PANEL ON UNLOADING SIDE**

The operators control panel found on the unloading side of the sterilizer is a keypad (standard) with a 3.5 inch LCD display. The

control panel can be upgraded to a multi-color touch screen display (optional).



The following information is displayed:

- Temperature and pressure in the chamber
- Door status
- Sterilization time count down
- Autoclave status: standby, ready, pre-vacuum, heating, sterilization, exhaust, dry time, air inlet, cycle ended.

**ALARMS**

The autoclave uses visual alarm indicators. Automatic process checking and failure detection are provided by the control system. In the event of a failure during the sterilization cycle, the system enters an alarm phase which will safely end the process automatically. The range of alarms includes:

- Temperature & pressure sensor failure
- Phase time-outs
- Door(s) not properly closed
- Power failure
- No water in the feed water reservoir
- Optional utility alarms: no water / no steam / no air

**CYCLE DOCUMENTATION - PRINTER**

The autoclave can be equipped with an optional printer which prints a detailed history of each cycle performed by the instrument. The printing format is 24 characters per line.

The following information is printed when the autoclave is turned on:

- Time & date when autoclave last turned off (powered down)
- Time & date when autoclave last turned on (powered up)

The following preliminary information and set parameters are printed when the sterilization cycle begins:

- |                     |   |
|---------------------|---|
| <b>Cycle Start:</b> | <b>Sterilization Parameters</b>                         |
| ▪ Date              | ▪ Sterilization temperature                             |
| ▪ Time              | ▪ Sterilization time                                    |
| ▪ Serial number     | ▪ End temperature                                       |
| ▪ Model name        | ▪ Dry time (models with pre vacuum and steam generator) |
| ▪ Software version  |   |
| ▪ Cycle number      |   |
| ▪ Cycle name        |   |

Thereafter, the autoclave starts performing the sequence of operations of the cycle. The measured values of temperature and pressure are printed at 1 minute time intervals. All interval times can be user defined (1 second to 10 minutes). Furthermore, the customer may request customized time intervals prior to order delivery.

The data is printed beginning with the date and ending with "CYCLE ENDED" for a complete cycle or "CYCLE FAILED" for an aborted cycle.

**OPTIONAL LOADING EQUIPMENT**

**Two Pull Out Trays**

Stainless steel trays equipped with tracks for easy loading and

unloading. The tracks are designed to prevent the trays from rolling over.

### Loading Cart and Transfer Carriage

The loading cart rolls off the transfer carriage onto the chamber rails for easy handling of heavy loads.

The transfer carriage uses heavy duty revolving wheels (castors) to maximize mobility in limited space, and wheel brakes to prevent rolling. There is a lock to prevent the loading cart from sliding. The legs of the transfer carriage are adjustable to match the height of the loading cart with the tracks in the sterilizer chamber.

Both the loading cart and transfer carriage are made of durable AISI 304 or AISI 316 stainless steel.

See Special Options and Accessories section for more options.

## STERILIZER DOCUMENTATION

Two copies of the manuals are provided. Operator and service manuals are in a selected language. Other manuals are in English. Manuals include electrical and piping diagram.

Furthermore, a CD is provided containing the following:

- Operators manual
- Technical manual
- Serial number of the specific autoclave
- Factory test report prior to shipping
- Optional - technical specifications for component, etc.

## MAINTENANCE / SERVICE PLAN

A global network of skilled service specialists can provide periodic inspections and adjustments to help assure low-cost peak performance. A detailed service and maintenance plan is included in the operator manual.

## PACKAGING FOR SHIPMENT

The sterilizer is packed in a wooden crate for shipping/transportation.

## WARRANTY

Tuttnauer warrants that each device is carefully tested, inspected and that it leaves the factory in proper working condition.

Tuttnauer certifies that the device is guaranteed to be free from defects in material and workmanship, for one year from installation date but not more than 18 months from shipping date, against faulty components and assembly. Extended warranty periods are optional.

The warranty does not include and does not replace routine treatment and preventive maintenance to be performed according to "Preventive and Periodical Maintenance" instructions mentioned in the device's accompanying manual.

**The user must ensure that all utilities used, including the water, meet all the specifications mentioned in the operator manual.**

The user is subject to the full warranty statement found in the documentation delivered with the equipment.

## UTILITY DATA / REQUIREMENTS

### External Steam Source

1. 97 – 100 % dry saturated steam

2. Steam rate 25 kg/h
3. Protected by certified safety valve (max 2.8 bar.)
4. Final steam pipe to the autoclave at least pipe 3/4" (ND 20)
5. Install a shut-off valve at end of steam pipe

### Electrical

#### With generator (all models)

- 3-Phase, 208 / 220 / 230 / 380 / 400 / 415 Volt, with or without neutral, 18 kW (Bio-Hazard system requires 24 kW)

#### Without generator (all models)

Note: must have building steam supply

- 3-Phase, 208 / 220 / 230 / 380 / 400 / 415 Volt, with or without neutral, not less than 10 A
- 1-Phase, 110 / 115 / 220 / 230 Volt, with neutral, not less than 10 A, vacuum by ejector
- 1-Phase (only 4472 and 4480 Models), 220 / 230 Volt, with neutral, not less than 10 A, vacuum by V6 vacuum pump

Additional customizable electrical specifications are available.

### Drainage (Sewage)

1. At least 2" sewage pipe
2. The sewage shall be able to withstand continuous temperature of 80 °C and for short time periods at 100 °C
3. Each autoclave will have a separate sewage line connected to a vertical vent pipe. Vertical pitch is 1000 mm.

Note: Local national regulations may require that the drain be tapped and vented, and not connected to other drains which may cause back pressure or obstruct flow. An air break may also be necessary.

### Mineral-Free Water

1. Water intended for the steam generator must have a water quality in accordance with ISO EN 285:2006+A2:2009.
2. Installation of 1/2" pipe with a shut-off valve at its end
3. Regulations may require a Back-Flow protection device
4. Supply: 25 ℓ/h

### Tap Water

1. Intended for vacuum pump and cooling.
2. Install 3/4" pipe with shut-off valve at its end.
3. Supply pressure 2 - 5 bar at approximately 15°C temperature
4. Local regulations may require a Back-Flow protection device
5. Hardness (free of alkaline earth ions) should be between 0.7 mmol/ℓ and 2.0 mmol/ℓ

### Compressed Air

1. At least 3/8" hose to supply the compressed air
2. The compressed air supply line coming from the building must have a shut-off valve
3. Pressure: 6 to 8 bar, free from liquid water, filtered to 25 µm, free from oil droplets greater than 2 µm

### Ambient Temperature

Plant room temperature should be in the range from 5 to 40 °C and 85% RH (relative humidity).

### Floor

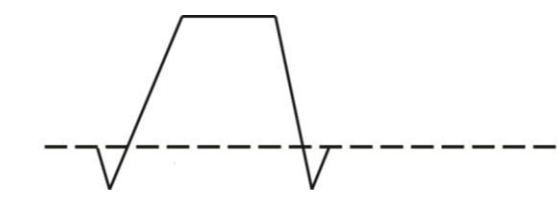
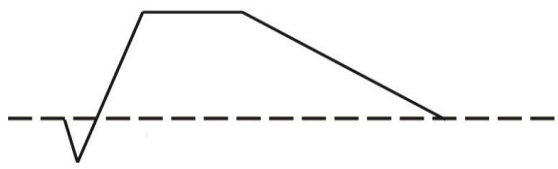
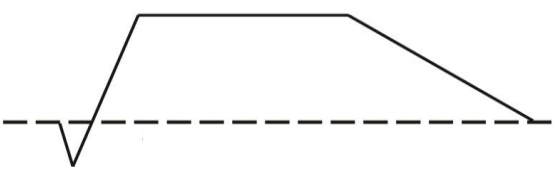
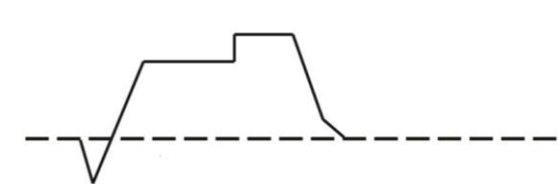
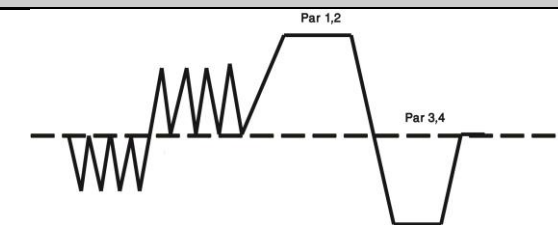
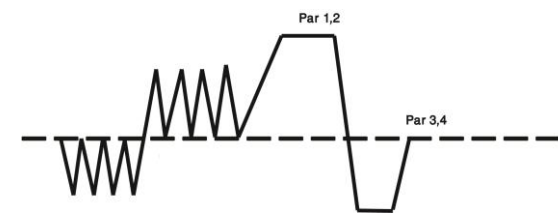
The unit mass shall be considered no less than 10000 N/m<sup>2</sup> according to the DIN 58949-7:2004 standard.

### Ventilation

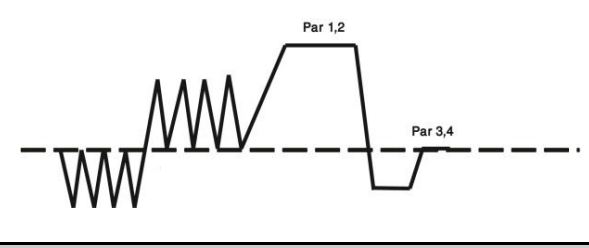
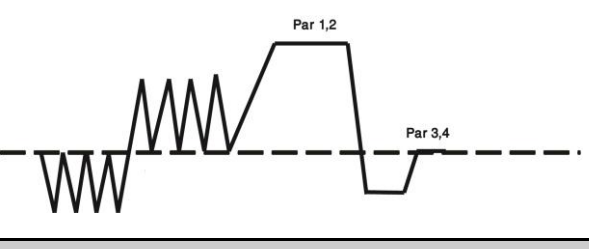
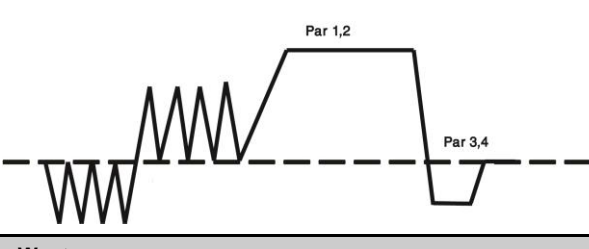
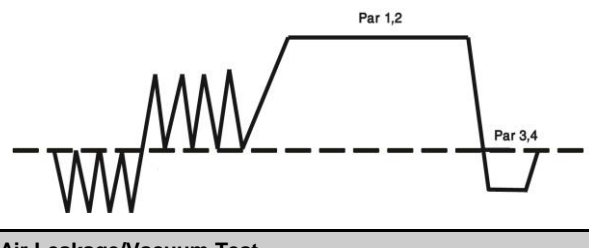
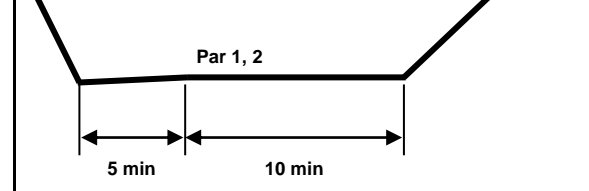
10 air replacements per hour.

**PROGRAM CYCLE DATA**

Note: All program cycles are customizable. Number of pulses, the depth & height of each pulse, and pulse profile (negative pulse, positive pulse, or mixed negative & positive) can be configured.

| Program 1 – Warm Up  |   | Warm Up  |                         |                                      |                        |
|--|---|--|-------------------------|--------------------------------------|------------------------|
| Atmospheric Pressure   |    | Parameters   | Units                   | Range                                | Factory Setting        |
|  |   | 1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode<br>4. Drying Time (Post-Vacuum) | °C<br>min<br>min<br>min | 105 - 137<br>1 - 99<br>1-6<br>0 - 99 | 121<br>3<br>fast<br>1  |
| Notes:<br>It is recommended to run this program once in the morning before regular use in order heat up the chamber surface and prevent excessive condensation for first cycle after the machine is turned on. |   |  |                         |                                      |                        |
| Program 2 – Liquid Short   |   | Liquid Short   |                         |                                      |                        |
| Atmospheric Pressure   |    | Parameters   | Units                   | Range                                | Factory Setting        |
|  |   | 1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode                                 | °C<br>min               | 105 - 137<br>1 - 99<br>1-4           | 121<br>15<br>Slow      |
| Notes:<br>Residual air is displaced by 1 vacuum pulses. Slow exhaust time is dependent on load volume and configuration of bottles/flasks.   |   |  |                         |                                      |                        |
| Program 3 – Liquid Long  |   | Liquid Long  |                         |                                      |                        |
| Atmospheric Pressure   |    | Parameters   | Units                   | Range                                | Factory Setting        |
|  |   | 1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode                                 | °C<br>min               | 105 - 137<br>1 - 99<br>1-4           | 121<br>30<br>Slow      |
| Notes:<br>Residual air is displaced by 1 vacuum pulses. Slow exhaust time is dependent on load volume and configuration of bottles/flasks.   |   |  |                         |                                      |                        |
| Program 4 – Liquid + Fast Cooling  |   | Liquid + Fast Cooling  |                         |                                      |                        |
| Atmospheric Pressure   |  | Parameters   | Units                   | Range                                | Factory Setting        |
|  |   | 1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode                                 | °C<br>min               | 105 - 137<br>1 - 99<br>1-4           | 121<br>15<br>cooling   |
| Notes:<br>Residual air is displaced by 1 vacuum pulses (down to 25 kPa). Compressed air is applied at the end of the sterilization stage to pressurize the chamber and enable safe fast cooling.               |   |  |                         |                                      |                        |
| Program 5 – Porous 121   |   | Porous 121   |                         |                                      |                        |
| Atmospheric Pressure   |  | Parameters   | Units                   | Range                                | Factory Setting        |
|  |   | 1. Sterilization Temperature<br>2. Sterilization Time<br>4. Drying Time (Post-Vacuum)                    | °C<br>min<br>min        | 105 - 137<br>1 - 99<br>1 - 99        | 121<br>15<br>15        |
| Notes:<br>Air is displaced by 4 negative vacuum pulses to remove the air followed by 4 positive steam pulses to improve heat distribution according to EN285. Followed by drying period.                       |   |  |                         |                                      |                        |
| Program 6 – Porous 134   |   | Porous 134   |                         |                                      |                        |
| Atmospheric Pressure   |  | Parameters   | Units                   | Range                                | Factory Setting        |
|  |   | 1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode<br>4. Drying Time (Post-Vacuum) | °C<br>min<br>min<br>min | 105 - 137<br>1 - 99<br>1-4<br>0 - 99 | 134<br>7<br>fast<br>15 |
| Notes:<br>Air is displaced by 4 negative vacuum pulses to remove the air followed by 4 positive steam pulses to improve heat distribution according to EN285. Followed by drying period.                       |   |  |                         |                                      |                        |



| Program 7 – Glassware              |   | Glassware   |                                  |  |   |
|------------------------------------|---|---|----------------------------------|--|---|
| Atmospheric Pressure               |    | <b>Parameters</b><br>1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode<br>4. Drying Time (Post-Vacuum)   | <b>Units</b><br>°C<br>min<br>min | <b>Range</b><br>105 - 137<br>1 - 99<br>1-4<br>0 - 99 | <b>Factory Setting</b><br>121<br>15<br>fast<br>15 |
|                                    |   | <b>Notes:</b><br>Air is displaced by 4 negative vacuum pulses to remove the air followed by 4 positive steam pulses to improve heat distribution according to EN285. Followed by drying period.                           |                                  |  |   |
| Program 8 – Tips and Plastics      |   | Tips  |                                  |  |   |
| Atmospheric Pressure               |    | <b>Parameters</b><br>1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode<br>4. Drying Time (Post-Vacuum)   | <b>Units</b><br>°C<br>min<br>min | <b>Range</b><br>105 - 137<br>1 - 99<br>1-4<br>0 - 99 | <b>Factory Setting</b><br>121<br>15<br>fast<br>15 |
|                                    |   | <b>Notes:</b><br>Air is displaced by 4 negative vacuum pulses to remove the air followed by 4 positive steam pulses to improve heat distribution according to EN285. Followed by drying period.                           |                                  |  |   |
| Program 9 – Cages                  |   | Cages   |                                  |  |   |
| Atmospheric Pressure               |   | <b>Parameters</b><br>1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode<br>4. Drying Time (Post-Vacuum)   | <b>Units</b><br>°C<br>min<br>min | <b>Range</b><br>105 - 137<br>1 - 99<br>1-4<br>0 - 99 | <b>Factory Setting</b><br>121<br>20<br>fast<br>20 |
|                                    |   | <b>Notes:</b><br>Air is displaced by 4 negative vacuum pulses to remove the air followed by 4 positive steam pulses to improve heat distribution according to EN285. Followed by drying period.                           |                                  |  |   |
| Program 10 – Waste                 |   | Waste   |                                  |  |   |
| Atmospheric Pressure               |  | <b>Parameters</b><br>1. Sterilization Temperature<br>2. Sterilization Time<br>3. Exhaust Mode<br>4. Drying Time (Post-Vacuum)   | <b>Units</b><br>°C<br>min<br>min | <b>Range</b><br>105 - 137<br>1 - 99<br>1-4<br>0 - 99 | <b>Factory Setting</b><br>134<br>30<br>fast<br>15 |
|                                    |   | <b>Notes:</b><br>Air is displaced by 4 negative vacuum pulses to remove the air followed by 4 positive steam pulses to improve heat distribution according to EN285. Followed by drying period.                           |                                  |  |   |
| Program 11 Air Leakage/Vacuum Test |   | Air leakage test to chamber through door and other seals  |                                  |  |   |
| Atmospheric Pressure               |  | <b>Parameters</b><br>1. Stabilizing Time<br>2. Test Time  | <b>Units</b><br>min<br>min       | <b>Range</b><br>-<br>-                               | <b>Factory Setting</b><br>5<br>10                 |
|                                    |   | <b>Notes:</b><br>Chamber vacuum is brought to 10 kPa. Thereafter all valves and motors are closed for 5 minutes enabling pressure stabilization. The acceptable pressure change over the following 10 minutes is 1.3 kPa. |                                  |  |   |

## SPECIAL OPTIONS AND ACCESSORIES

### ADVANCED CONTROL & MONITORING FEATURES

#### 7" TFT (LCD) Touch Screen

Upgrade from keypad to 7" touch screen on unloading side.

#### 10" TFT (LCD) Touch Screen

Upgrade from 7" to 10" touch screen on loading side.

#### R.PC.R Software

Software that is installed on a network connected PC. Allows for remote monitoring and download of cycle data from an autoclave connect to same network. Software gives access to: cycle data graph, numeric cycle data, print-outs, measured values table, parameter table, and more.

#### Remote Automated Cycle Data Recording

- Automatic recording of cycle information to any PC on the same Ethernet network
- Convenient access to graphs and tables
- Generate PDF reports

#### Real-Time Remote Monitoring

- See real-time autoclave display on network connected PC
- Monitor all activity for up to 8 autoclaves

#### Two Color Printer

Printer IDP3550 Serial dot impact, two colors black/red, high speed printing 3.6 lines/sec, 7 X 9 matrix 40 columns, 76mm roll paper, paper auto loading. **DPU 3550 Paper Collector** Collects paper from printer.

#### Independent alphanumeric Recorder

Two Additional Sensors (Temperature & Pressure) for Secondary Measurements and Printing. The analog signal from the additional sensors are transferred to the controller (via an additional analog input extension board) and are printed by the control system printer.

#### Paperless Chart Recorder

A high-speed paperless chart recorder, with independent microprocessor control and power supply, is suitable for independent cycle documentation. This multi-range input recorder can record up to 4 analog input signals, producing analog trend records. Data can be exported to a USB memory or transferred via Ethernet connection. The unit includes installation CD and viewer software. The unit operates independently of the autoclave. The recorder automatically starts recording when cycle starts and stops when the cycle ends, following a signal from the controller. Dry contacts are available.

#### Independent Chart Recorder

A high-speed chart recorder, with independent microprocessor control and power supply, is suitable for independent cycle documentation. This multi-range input recorder can record up to 3 or 4 to 6 points at once from RTDs and DC voltage input signals, producing analog trend records and print-outs. Simple operation with an easy-to-view display allows one to key-in various items of set data. The unit operates independently of the autoclave.

#### Barcode Reader

The barcode reader allows identification and tracking of the material flow in the autoclave by reading the barcode on the container/basket. The data is stored in the Bacsoft controller and the list of barcodes is printed during cycle process. In the Bacsoft controller the barcode data is linked to sterilization cycle data. Barcode data is used in the reports generated by R.PC.R software (optional).

### ADVANCED OPERATION FEATURES

#### Multipurpose Valve

Compressed air operated control valve drains the water/steam and releases pressure in order to open the chamber if a cycle failure occurs due to electric power failure.

#### Dual Steam Source Valve Switch

To switch from central steam supply and backup steam generator and back.

#### Foot Pedal to Open Door

The foot pedal feature allows one to open the door by foot.

#### Automatic Restart and Shutdown

Feature enables a preprogrammed restart and/or complete shutdown of utilities at cycle end or set time, closing all utility valves, returning chamber and jacket to ambient temperature.

### ADVANCED STEAM RELATED OPTIONS

#### Automatic Blow Down

Automatic drainage of the steam generator can be accomplished through the use of a programmable timer.

#### Separate Connection to Jacket and Chamber

Enables reaching sterilization at a faster rate and improved temperature control when working with liquids, especially with disinfection cycle. This feature is recommended for clean steam systems.

### WATER RECYCLING

#### Water Recycling System (Radiator)

This system cools down and recycles water used by the heat exchanger to cool down the exhaust from the chamber. The system uses a radiator and fan to cool down the water. Tuttnauer's water saving system saves more than 50% of the tap water used. This system increases the heat emission in the room.

#### Water Recycling System (Building Chiller)

This option provides configuration of the autoclave for connection to building chiller. The chilled water is used by the heat exchanger to cool down the exhaust from the chamber before it reaches the vacuum pump. The output water from the vacuum pump is also cooled down by the chilled water and then recycled back to the vacuum pump. This option saves approx. 90% of the tap water used. Site must provide water chiller (water below 15 °C).

#### RO Water Recycling System for Jacket Cooling

This option includes jacket cooling and provides a configuration of the autoclave for connection to building chiller. Demineralized water that is used to cool down the jacket, will exit the jacket hot. This hot water will be cooled down by the chilled water and heat exchanger and then recycled back to the jacket. This option saves approx. 90% of the demineralized water used. Site must provide water chiller (temperature below 15 °C).

## **ACCESSORIES**

### **Hot Well**

The hot well heats water to about 80-90°C to remove non-condensable gases (de-gas) prior to being pumped to the steam generator or STS generator.

### **Silent Air Compressor**

Silent Air Compressor for operating the pneumatic valves and automatic door/s (must be ordered if there is no local source of compressed air).

### **Silent Air Compressor for Fast Cooling**

Silent Air Compressor used with the fast cooling option when building compressed air is not available. This compressor can also serve the pneumatic valves. Compressor, Air, Silent, 30L, 230V, 1 HP, Airbag, Fiac

In case the machine includes fast cooling and building compressed air is not available.

## **CONTACT INFORMATION**

### **International Sales and Marketing**

E-mail: [info@tuttnauer-hq.com](mailto:info@tuttnauer-hq.com)

Website: [www.tuttnauer.com](http://www.tuttnauer.com)

### **Tuttnauer Europe b.v.**

Hoeksteen 11

4815 PR Breda

The Netherlands

Tel: +31 (0) 765 423 510

Fax: +31 (0) 765 423 540

E-mail: [info@tuttnauer.nl](mailto:info@tuttnauer.nl)

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