# **Tuttnauer**

# **FEATURE SUMMARY**

- Chamber volume from 120 to 310 liters
- Design pressure meets ASME and PED requirements
- Temperature range 105 °C (221 °F) to 138 °C (280 °F)
- 18 kW / 27 kW integral electrical steam generator or external steam source
- User friendly control system with touch screen display
- 30 Programs: 8 factory set programs, 2 test programs, 20 programmable cycle programs
- Built-in printer
- Ethernet connection port for PC access via network
- USB port to download cycle data to memory device
- Pressure gauges on front panel
- 316L stainless steel chamber and door
- Chamber has a mirror-like finish
- Stainless steel piping
- Conforms to Medical Device Directive 93/42 EEC and PED 97/23 EC, FDA Clearance
- Conforms to standards: ASME, AAMI/ANSI-ST8, EN 285, UL
- Company approved for 21 CFR 820, ISO 9001:2008 and ISO 13485:2003 (Medical Devices)
- Optional configurations available

# PRODUCT DESCRIPTION

This autoclave series is designed to cover a large field of applications for hospitals, CSSD and medical centers.

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 is equipped with an 18kW or 27kW integral electrical steam generator which supplies the necessary steam for the sterilization process. The sterilizer may also be connected to an external steam source.

# **APPLICATIONS**

Central Sterilizing Supply Department (CSSD) Operating Theater Out Patient Clinic

# **DEVICE PICTURE**



44 Compact Series with Hinged Door



44 Compact Series with Vertical Sliding Door

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	СНАМВЕ	VOLUME (liter)		
	Width	Height	Depth	
4472			730	120
4480	408	408	845	140
4496			970	160
5596	<b>500</b>	500	970	250
55120	508	508	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 COMPONENTS**

The following parts are located in the electric boxes:

- The Solid State Relays for the command of the vacuum pump, and the water pump.
- The Circuit Breakers for protection of all power circuits.
- The power supplies for powering of electronic circuitry and solenoid valves.
- An 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 electrical power supply is available.

## Voltage:

- 415V 3-Phase with Neutral
- 380V / 400V 3-Phase with Neutral
- 230V 3-Phase with Neutral
- 208V 3-Phase with or without Neutral
- 220V / 230V 1-Phase (not 55120 model)
- 110V / 115V 1-Phase \*
- \* For 18kW with building steam supply (optional vacuum by ejector)

Frequency: 50 Hz or 60 Hz

MODEL	STEAM GENERATOR POWER (kW)		
4472			
4480	18		
4496	10		
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, Chinese, Arabic.

#### STANDARDS AND CODES

Tuttnauer products meet the following provisions and standards:

### Europe:

EN285: 2006+A2:2010 for Large Autoclaves

#### USA:

ANSI/AAMI - ST 8: 2008 - Hospital Sterilizers

# **Directives & Guidelines:**

97/23/EC - Pressure Equipment Directive

2002/95/EC - RoHS Directives

2004/108/EC - Electromagnetic compatibility

2006/95/EC - Electrical equipment 2006/42/EC - Machinery Directive

# Safety and EMC Standards:

EN 61010-1: 2001 EN 61010-2-040: 2005 EN 61326-1: 2006 EMC Directive 89/336

EN 60529:1991 - Degrees of Enclosure Protection (IPX4)

# Pressure Vessel and Steam Generator Construction Standards:

ASME Code, Section VIII, Division 1, unfired pressure vessels ASME Code, Section I, for boilers

# **Good Practice Standards:**

ISO 17665-1: 2006

ANSI/AAMI - ST 8: 2008 Quality System Standards:

ISO 9001:2008 (Quality Systems)

ISO 13485:2003 (Quality Systems for Medical Devices)

Compliance with 21 CFR 820

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### **CHAMBER CONSTRUCTION**

#### **Materials**

The sterilizer chamber is constructed from solid, high quality materials. Chamber and door thickness is no less than 5 mm.

Standard Configuration Materials:

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

Optional Materials (Stainless Steel):

Chamber + Door: 316Ti

Jacket: 316L or 316Ti

### **Chamber Design**

The chamber is **fully jacketed**. 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 sealed against the door by means of steam 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 less than 0.8  $\mu$ m 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.

#### 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 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 immediately if an object is detected in front of the closing door
- 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 minimum water intake.

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

**Double Independent Monitoring:** The digital monitoring system provides a cross-reference and guarantees accurate results. The operator has two means of monitoring temperature and pressure.

### **WATER RING VACUUM PUMP**

The vacuum pump effectively removes air from the chamber. The pump is mounted on vibration absorbers to minimize vibration.

During vacuum action the flow path of the media 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 four pressure gauges that indicate the pressure in the chamber, jacket, door gasket, and the steam generator.

These pressure gauges are located on the autoclave's front panel (loading side).

The double door configuration has two additional pressure gauges at the unloading side that indicate the pressure in the chamber and the pressure in the gasket of the second door.

### **VALIDATION PORTS**

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

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### **AIR FILTER**

A disposable microbiological air filter is provided to filter all air entering the sterilizer chamber. 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 0.2 µm.

## STEAM SUPPLY

The autoclave is supplied with either a 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.

**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 feed water reservoir, which is connected to a source of mineral-free water.

#### 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 < 50 µS/cm</li>
- Maximum consumption: 12 liters per standard load cycle

**Note:** Soft water should <u>not</u> 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

# **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 (ISO/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.

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.

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### **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 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 an 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.
- Text and color wheel indicates the stage of the cycle

#### **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 is equipped with a printer on the loading side, 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:

### Cycle Start:

- Date
- Time
- Serial number
- Model name
- Software version
- Cycle number
- Cycle name

# Sterilization Parameters

- Sterilization temperature
- Sterilization time
- End temperature
- Dry time (models with pre vacuum and steam generator)

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 tilting over or rolling off.

# **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 rails of the loading cart with the tracks in the sterilizer chamber and enable the loading cart to roll in and out of the chamber.

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

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# 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.

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## **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
- For autoclave model 55120: 3-Phase, 208 / 220 / 230 / 380 / 400 / 415 Volt, with or without neutral, 27 kW

#### Without generator (all models)

Note: must have building steam supply (optional vacuum by ejector)

- 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, optional vacuum by ejector (not for 55120 model)
- 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 Feed Water for Steam Generator

- Water intended for the steam generator must have a water quality in accordance with EN 285:2006+A2:2009
- 2. Install 1/2" pipe with a shut-off valve at its end
- 3. Regulations may require a Back-Flow protection device
- 4a. Supply: 25 **ℓ**/h for sterilizers using 18 kW steam generators
- 4b. Supply: 37 **ℓ**/h for sterilizers using 27 kW steam generators

# **Tap Water**

- 1. Intended for vacuum pump and cooling.
- 2. Install 3/4" pipe with shut-off valve at its end.
- Supply pressure 2 5 bar at approximately 15°C temperature
- 4. Local regulations may require a Back-Flow protection device
- Hardness (free of alkaline earth ions) should be between 0.7 mmol/l and 2.0 mmol/l
- 6. Supply: approximately 17 ℓ/min

# **Compressed Air**

- 1. At least 3/8" hose to supply the compressed air
- 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.

# **OVERALL EXTERNAL DIMENSIONS**

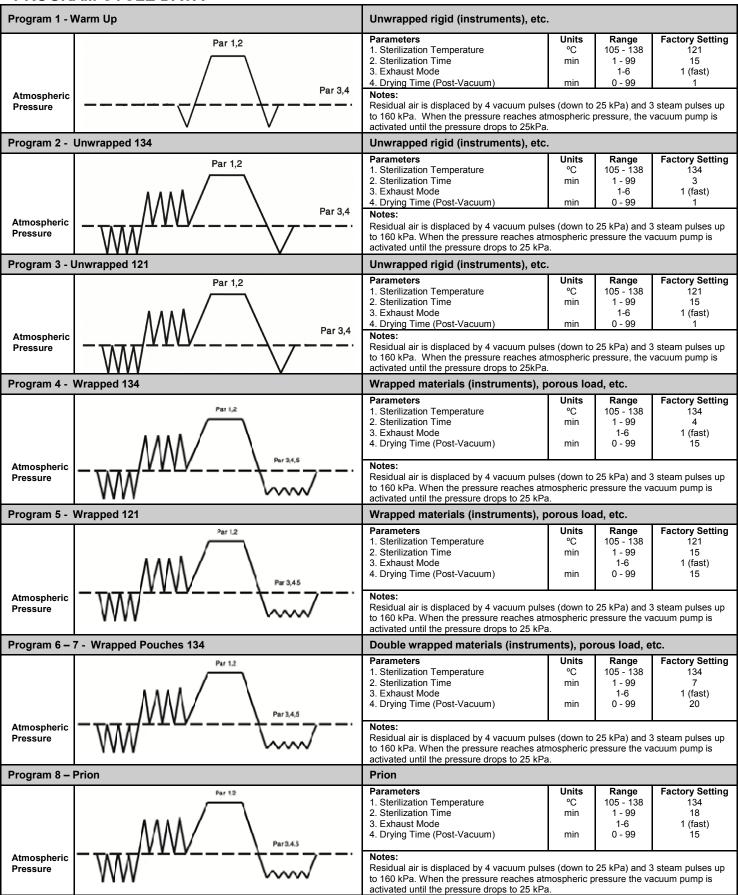
MODEL	DOOR CONFIGURATION		EXTERNAL DIMENSIONS (mm)		
	Door Type	No. of Doors	Width	Height	Depth
4470	Hinged	1	850	1630	1240
		2			1260
4472	Vertical Sliding	1	900	1630	1212
		2			920
	Hinged	1	850	1630	1330
4480		2			1350
	Vertical Clidina	1	900	1630	1302
	Vertical Sliding	2			1033
4496	Hinged	1	850	1630	1480
		2			1490
	Vertical Sliding	1	850	1630	1480
		2			1490
5500	Hinged	1	950	1600	1490
		2	950	1680	1520
5596 Vertical Sliding	1	1000	1000	1250	
	vertical Silding	2	1000	1680	1290
	Hinand	1	950	1680	1735
55120	Hinged	2			1755
	Vertical Sliding	1	1000	1680	1515
		2			1550

Note: Upon request Tuttnauer can provide special configuration so that the autoclave will fit through narrow passage-ways / elevators during transportation in and out of buildings.

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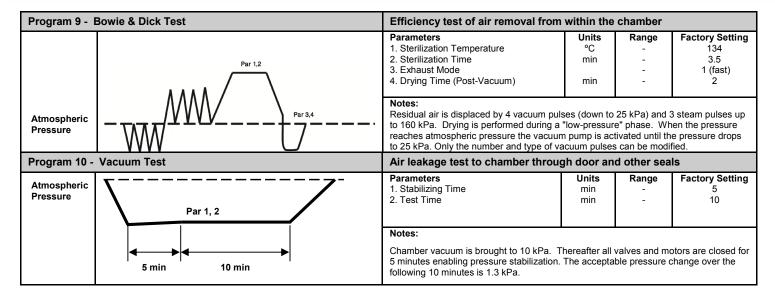


# **PROGRAM CYCLE DATA**



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# SPECIAL OPTIONS AND ACCESSORIES

# ADVANCED CONTROL & MONITORING FEATURES 10" TFT (LCD) Touch Screen

Upgrade from keypad to touch screen on unloading side.

### **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.

#### 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 connected to the 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

#### **Remote Access**

Provides technician ability to monitor autoclave via Internet (requires R.PC.R, and local SIM card for Internet connection).

# **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.

#### Chart Recorder (Independent Microprocessor Control)

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 12 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 (obligatory for meeting EN285).

#### **Barcode Reader**

The barcode reader allows identification and tracing 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 cycle sterilization data. Barcode data is used in the reports generated by R.PC.R software (optional).

### **Process Workflow Management Data Connection**

Provides real-time data to any process workflow management system supporting Modbus.

# **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**

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.

# 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 105<sup>0</sup>C and less.

### **ACCESSORIES**

#### **Air Compressor**

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

## **Hot Well**

The hot well heats water to about 80-90°C to remove noncondensable gases prior to being pumped to the steam generator.

## **Bio Shield Frame**

The sterilizer is surrounded by a frame which serves as a preparation for a cross-contamination seal made of Neoprene sheet that is attached between the frame and the wall at site.

### Water Recycling System

This system recycles water necessary for the heat exchanger to cool down the steam exhaust from the chamber. The water saving system recycles the water and reuses it. Tuttnauer's water saving system saves more than 50% of the tap water used

# **CONTACT INFORMATION**

# **International Sales and Marketing**

E-mail: info@tuttnauer-hq.com Website: www.tuttnauer.com Blog: www.tuttnauer.com/blog

# 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

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