



# BSL3 and BSL4 Autoclaves



# **BSL3 and BSL4 Autoclaves**



In today's society the need for **safe bio-containment systems** is increasingly important. This is especially true in the sterilization process where standard autoclaves cannot deal with the threat posed by **harmful pathogens** and other contaminated materials that are emitted from BSL3/4 laboratories.

Tuttnauer is at the front lines, continuously creating new standards in the field of bio containment. With years of experience in the market, **Tuttnauer produces reliable and safe bio-containment systems.** 



# **BSL Considerations**

The Tuttnauer range of BSL autoclaves is designed to meet stringent **Bio Safety Level requirements for BSL3 and BSL4 facilities.** These include a hermetically sealed barrier between the different risk level zones and effective sterilization and disposal of all effluent and gases.

Special autoclave design consideration is given to:

- Autoclave and piping components
- Biological seal (Bio-shield)
- Effluent sterilization cycle
- Filter sterilization
- Safety valves and expansion vessel



## **Autoclave Piping and Components**

Specifically designed for use with steam systems that demand the highest safety conditions. 316L grade stainless steel is used for the chamber, piping and fittings. The inner chamber walls have a mirror like polished finish ( $Ra < 0.4\mu m$ ) to create a smooth surface.

#### Chamber Drain Valve Area

The chamber drain valve area is the coldest spot in the chamber. Tuttnauer BSL autoclaves resolve this problem by applying steam directly to the chamber drain valve area.

#### Hot-Well

The hot-well is a stainless steel water reservoir in which the feed water is heated to 80-90°C prior to entering the steam generator. The hot-well facilitates the removal of non-condensable gases.

#### Safety Valve

A safety valve is fitted to the chamber. Steam blasts from the safety valve are captured and condensed in an expansion vessel (optional) and then decontaminated before discharge to drain. Any remaining gases are treated via a microbiological sanitary air filter (optional).

#### **Diaphragm Valves**

Separate diaphragm valves (optional) for steam to the jacket and chamber prevent contamination from entering the valve mechanism.

#### Tri-clamp fittings

Tri-clamp fittings (optional) provide uniformly smooth and crevice free self-aligning joints for non-contaminating steam flows. They minimise the possibility of external contamination penetration through the valves and piping connection areas.

#### Separate Jacket and Chamber Connections

Separate jacket and chamber connections (optional) prevent contamination from entering the jacket. With this option the jacket is completely separated from the chamber.

## **Biological Seal**

The bio-shield provides a complete **hermetic seal for maximum biological containment** between the differently qualified zones. The bio-shield system meets BSL3 and BSL4 bio-safety levels using a combination of stainless steel plates and flexible neoprene wall seal to prevent micro-organisms from passing between zones.

- Jacket Frame A fully welded metal flange with threaded studs surrounds the jacket. A counter plate is attached to the flange using the nuts provided. Any necessary fittings for electrical connections pass through this section of the bio-shield via specially sealed conduits.
- Wall Frame A wall frame is built into the concrete wall of the building. Continuous neoprene sealing is used to seal the sterilizer completely in the aperture in the wall.



## **Prevacuum Air Sterilization**

All air that leaves the chamber prior to sterilization is treated as highly infectious and passes through a stringent **biological decontamination system that renders the air sterile.** 

### **Thermal Sterilization**

Prevacuum air leaves the chamber and makes contact with high temperature steam and is then passed through a high temperature heat exchanger which greatly increases the heat applied to the air making the air sterile and safe. The sterilized air is then cooled and any condensate is discharged to the drain.

### **Sterilization by Filtration**

#### **Double Filter Option**

For BSL 4 facilities a double filter system is recommended. Air from the chamber is passed through a double filtration system that ensures the air is decontaminated before discharge. The double filtration system uses two double-jacketed 0.2 µm filters sequentially mounted for added security. The filters are sterilized during the sterilization process.

#### Single Filter Option

Prevacuum air is sterilized by passing it through a 0.2  $\mu$ m biological filter. In order to maintain proper and effective filtration, the filter is sterilized in-place during every sterilization cycle.





## **Advanced Control System for Your Laboratory**

Take advantage of Tuttnauer's sophisticated user-friendly control system Bacsoft control system for repeatable high performance (standard). Allen Bradley PLC is also available (optional)

#### **Standard Features**

- 7" Multi-color touch screen panel
- Keypad control panel on second door of two door autoclaves with Bacsoft controller
- Stores the last 200 cycles in built-in memory (Bacsoft)
- Multiple access levels and user passwords to control access/ operation of the autoclave
- Diagnostic In/Out test (enables technician to check each system component separately)
- Sterilization Temperature range 105°C to 138°C
- PID (Proportional Integral Differential) pressure control
- Filter replacement notifications

**Optional Features** 

- 10" Multi-color touch screen
- Up to 8 different barcode readers
- Independent Recording for cross-checking cycle measurements
- Disinfection/Isothermal Temperature range from 70°C to 95°C
- F<sub>o</sub> software control
- 21 CFR part 11



## Sophisticated Touch Screen HMI

The HMI (Human Machine Interface) has been designed with the following considerations:

- Multi-color display for easier reading from a distance
- Multilingual (26 languages)
- Graphical display of Temperature and Pressure trend graphs

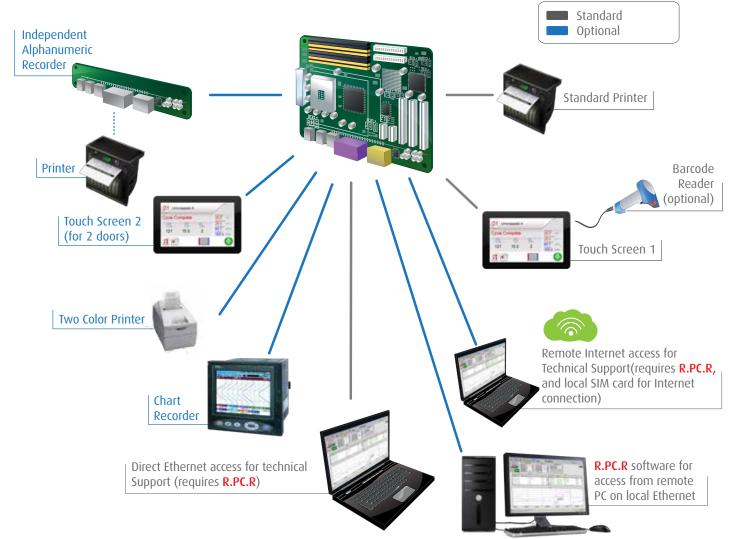
## **Documentation Package**

An optional full documentation package is available:

- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Performance Qualification (PQ)



## **Bacsoft Controller**



## **R.PC.R Software**

Automatic Recording of Cycle Information to Your PC

Reporting You Can Rely On

- Automatic recording of cycle information to any PC on your network
- Convenient access to graphs and tables that are easy to understand
- Easily generate PDF reports
- No need to file printouts, saving you time

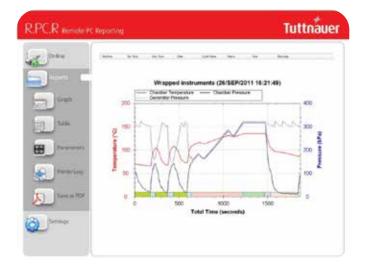
Be in Control with Real-Time Remote Monitoring

- $\boldsymbol{\cdot}$  See the real-time autoclave display on your PC
- Monitor all activity for up to 8 autoclaves

With R.PC.R you can see: Graphs of the cycle data, Numeric cycle data, cycle print-outs, measured values table, parameter table. Note:

• R.PC.R is available with Allen Bradley controller but without monitoring feature

• Optional SCADA system is available with Allen-Bradley controller



# A Wide Range of BSL Autoclaves

Tuttnauer offers an unmatched range of BSL Autoclaves that are available with chamber volumes ranging in size from 250 Liters to 9500 Liters. Each model is available with either single or double doors.

## The 55 BSL Series

Available with the following door options:

- Fully automatic vertical sliding door
- Manual door

Model	Chamber Dimensions (WxHxD) mm	Chamber Volume (Liter)
5596	508 x 508 x 970	250
55120	508 x 508 x 1210	310



Manual Hinged Door



## The 66 Mid Range BSL Series

Tuttnauer medium size BSL autoclaves with chamber volumes ranging in size from 450 Liters to 920 Liters.

The 66 series is available with the following door options:

- Fully automatic vertical sliding door
- Hinged door with automatic locking

Model	Chamber Dimensions (WxHxD) mm	Chamber Volume (Liter)
6690	610 x 610 x 915	340
66120	610 x 610 x 1215	450
6671130	660 x 710 x 1295	610
6671162	660 x 710 x 1620	760
6671197	660 x 710 x 1970	920









Automatic Hinged Door

## The 69 Large Capacity BSL Series

Tuttnauer Large BSL Autoclaves with chamber volumes ranging in size from 510 Liters to 1010 Liters.

The 69 series is available with two door options:

- Fully automatic horizontal sliding door
- Hinged door with automatic locking

Model	Chamber Dimensions (WxHxD) mm	Chamber Volume (Liter)
6990	610 x 910 x 915	510
69120	610 x 910 x 1215	680
69150	610 x 910 x 1515	840
69180	610 x 910 x 1815	1010



Automatic Hinged Door



#### Horizontal Sliding Door

## **Bulk BSL Series**

Tuttnauer offers Bulk BSL Autoclaves with chamber volumes up to 9000 Liters. Additional sizes are available.

The Bulk BSL autoclave series is available with fully automatic horizontal sliding doors.



Model	Chamber Dimensions (WxHxD) cm	Chamber Volume (Liter)		
Floor Mounted				
364853	91 x 122 x 136	1500		
364860	92 x 122 x 151	1700		
364872	92 x 122 x 182	2000		
3648100	92 x 122 x 252	2800		
3648144	92 x 122 x 363	4000		
Pit Mounted				
366260	92 x 158 x 152	2210		
368660	92 x 220 x 152	3000		
368686	92 x 220 x 220	4500		
428686	107 x 220 x 218.5	5145		
498686	125 x 220 x 218.5	6100		
728686	183 x 220 x 219.5	8840		

## **Loading Equipment**

Tuttnauer loading equipment assists with the loading and unloading process. The equipment is made of high quality, durable stainless steel.

**Pull-Out Trays:** Stainless steel trays equipped with rails for easy loading and unloading. The rails are designed to prevent the trays from rolling over.

**Loading Carts and Transfer Carriages:** The adjustable loading carriage rolls from the transfer trolley onto the interior chamber tracks for easy handling of heavy loads. The trolley is equipped with revolving wheels, maximizing mobility in limited space. The wheel breaks prevent the trolley from rolling and the carriage is equipped with a lock that prevents it from sliding.

**Automatic Loader:** Designed for loading/unloading baskets. The control of the loader is controlled by the autoclave controller.



### Technical Standards and Directives

- 2014/68/EU Pressure Equipment Directive
- EN 285:2015 Large Steam Sterilizers
- EN 61010-1: 2010, EN 61010-2-040: 2015, EN 61326-1: 2013
- ASME Sec. VIII Div.1 and Sec. I, ASME BPE
- EN 61326-1:2013 EMC Requirements for Electrical Equipment
- ANSI/AAMI/ST8:2013 (R2018)
- EU 2017/2102 Restriction of the use of certain hazardous substances (RoHS Directive)
- 2014/30/EU Electromagnetic Compatibility

### Quality Standards

Tuttnauer manufacturing plant meets the following quality standards:

- ISO 9001: 2015 Quality Management Systems
- ISO 13485: 2016 Quality Management Systems for Medical Devices
- Compliance with FDA QSR 21 CFR part 820 & part 11

## Your Sterilization & Infection Control Partners

#### **Company Profile**

For over 95 years, Tuttnauer's sterilization and infection control products have been trusted by hospitals, universities, research institutes, clinics and laboratories throughout the world. Supplying a range of top-quality products to over 140 countries, Tuttnauer has earned global recognition as a leader in sterilization and infection control.

#### More from Tuttnauer:

Featuring Tuttnauer's range of cleaning, disinfection and sterilization solutions





Vertical autoclaves for liquid, glassware, and biohazardous waste



Benchtop autoclaves for life science applications



International Sales and Marketing E-mail: info@tuttnauer-hq.com www.tuttnauer.com

Tuttnauer Europe b.v. Hoeksteen 11, 4815 PR PO Box 7191, 4800 GD Breda The Netherlands Tel: +31 765 423 510 Fax: +31 765 423 540 E-mail: info@tuttnauer.nl

Tuttnauer USA Co. 25 Power Drive, Hauppauge, NY 11788 Tel: +800 624 5836, +631 737 4850 Fax: +631 737 0720 E-mail: info@tuttnauerUSA.com



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