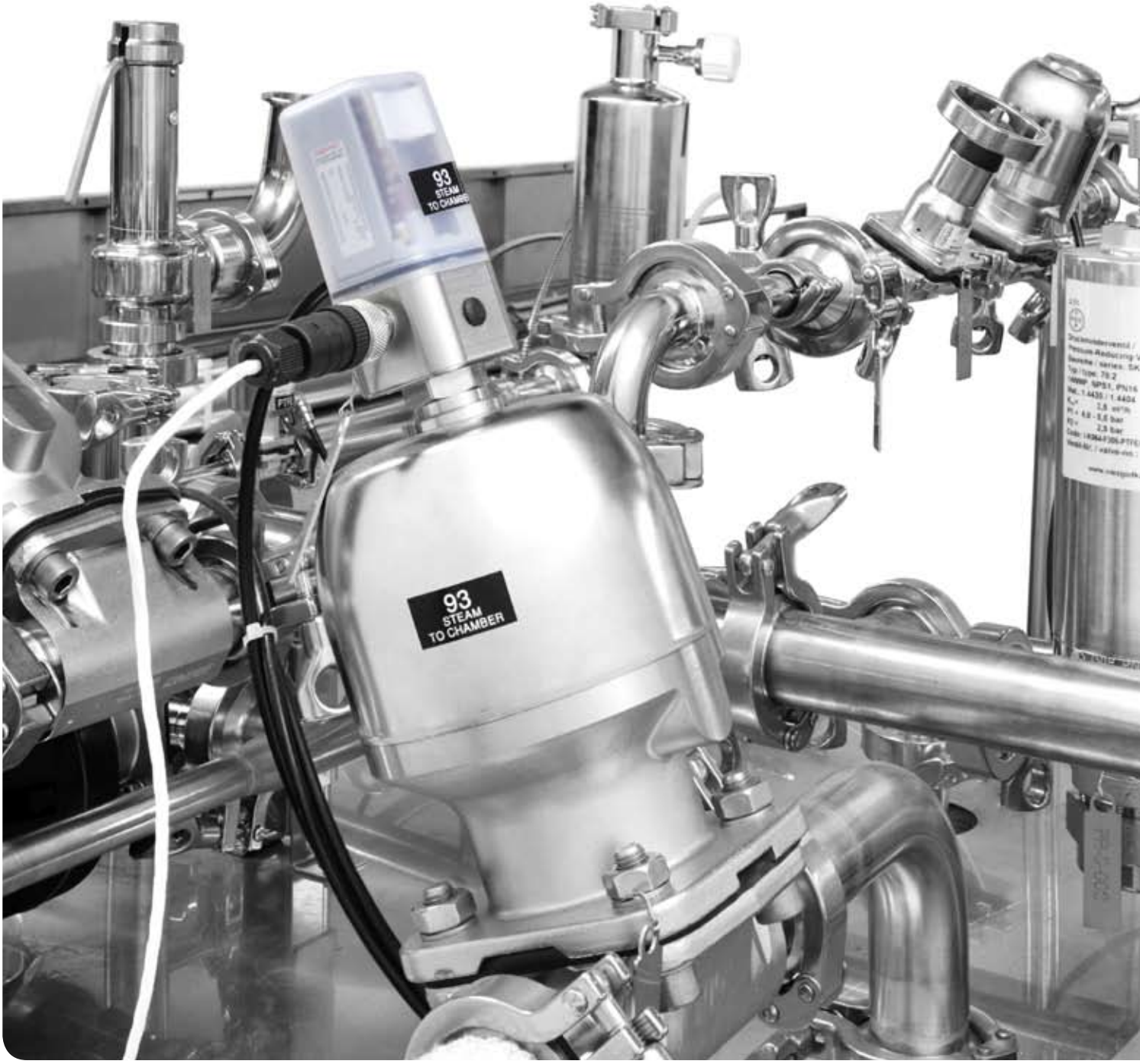
Tuttnauer
Your Sterilization & Infection Control Partners

Pharmaceutical Autoclaves



Pharma Line

Pharmaceutical Autoclaves

Tuttnauer pharmaceutical autoclaves have been engineered and manufactured in compliance with the cGMP regulations to meet the technical challenges of the pharmaceutical and biotech industries. Your products will be reliably and consistently sterilized according to the highest international standards with every cycle when using a Tuttnauer pharmaceutical autoclave. Tuttnauer provides high quality & safe autoclaves made from reliable long lasting components, and designed to conform to end-user requirements (URS) for production and quality assurance processes.

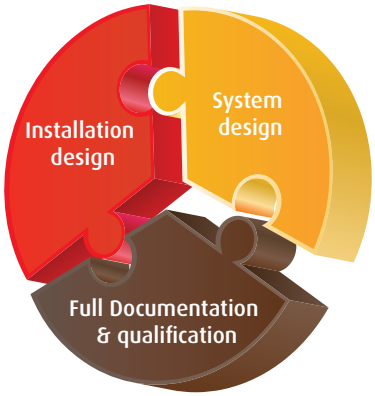
For over 87 years, Tuttnauer's sterilization and infection control products have been trusted at thousands of sites throughout the world. Tuttnauer has invested in the pharamceutical industry since 1925 supplying some of the most trusted pharmaceutical and biotech companies.

Pharmaceutical Line

Support for Your Investment

Tuttnauer understands the time and financial investment in Pharmaceutical projects and we provide the assistance needed to make your project installation and qualification successful.

With Tuttnauer Pharmaceutical autoclaves you receive support that will save you time, effort and expense.



Adherence to the cGMP Guidance

Specification, Documentation & Acceptance Testing

In general, Tuttnauer adheres to the cGMP in order to satisfy your requirements for documentation and qualification of pharmaceutical autoclaves.

In order to give our customers the confidence that they are using safe high quality cGMP pharmaceutical autoclaves, Tuttnauer comprehensively documents the design specifications, components, software, manufacturing process, and acceptance testing in order to prove that the autoclaves meet the customer's requirements.

GAMP

In order to ensure quality manufacturing, Tuttnauer applies GAMP guidelines at various stages of the manufacturing process.

Acceptance Testing

Tuttnauer has an advanced testing laboratory for acceptance testing of each autoclave before it leaves the factory. Each autoclave is subjected to Factory Acceptance Testing (FAT) which includes IQ - OQ documentation. In order to facilitate site validation, Tuttnauer provides a Site Acceptance Testing (SAT) service which includes IQ - OQ documentation.

Deliverable Documentation

Depending on customers requirements the following documentation can be supplied:

- DQ, IQ, OQ (including document templates for SAT)
- List of materials and components (with ID tagging)
- Data sheets and certificates for components and subsystems
- Certification of calibration
- Conformity certification
- Dimensions and location drawings
- Installation instructions
- Operations/technical manual

Standards and Directives

Tuttnauer manufactures autoclaves according to necessary international and local standards/directives required by our customers.

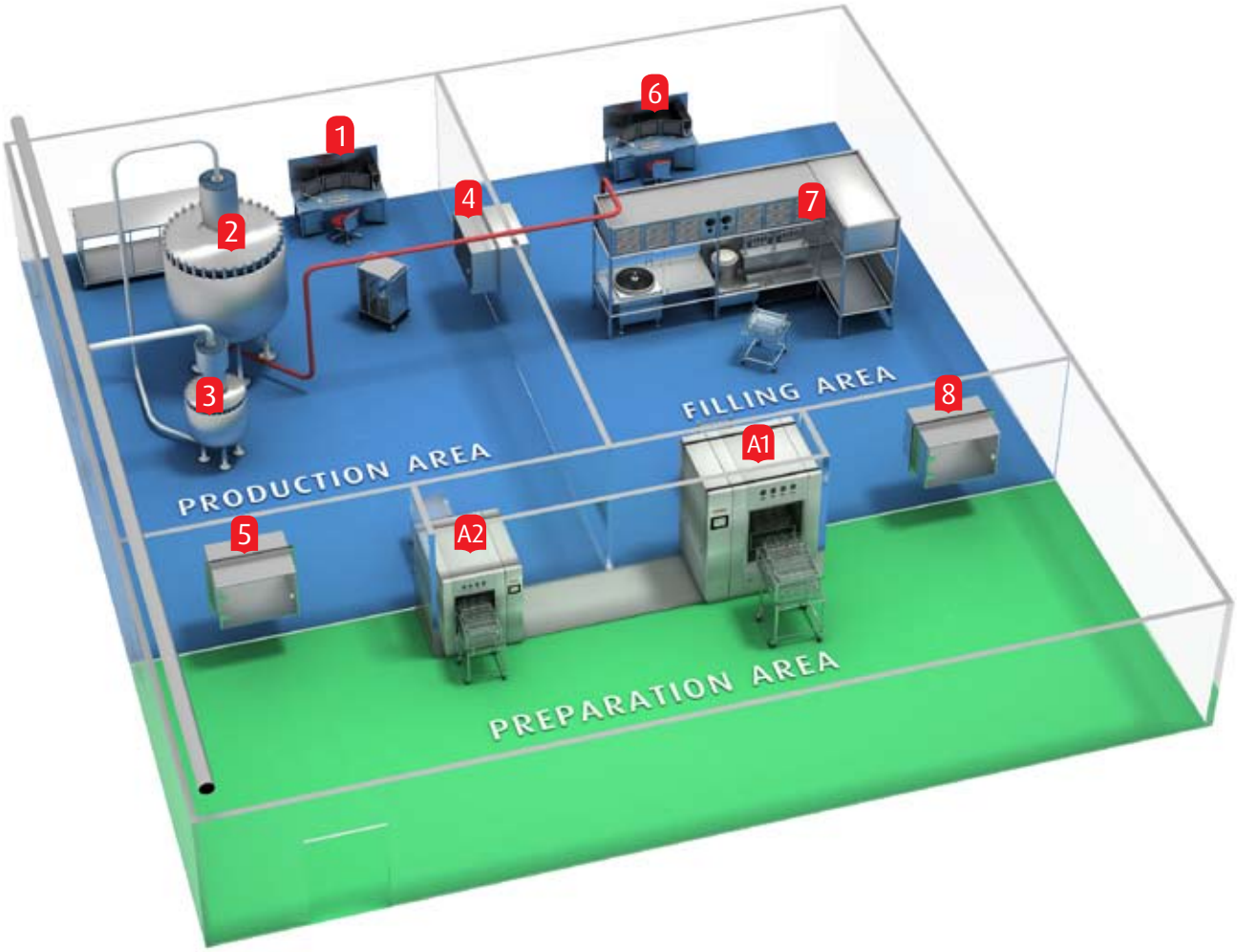
cGMP | FDA for LVP and SVP | GAMP | BPE2009 | ISPE BASELINE GUIDES | ISO 13845 | ISO 9001 | 21 CFR Part 11 | UL61010A ASME Code | ISO17665-1 | EN 285:2006

Production Sterile Processing

Bulk capacity autoclaves are ideal for pharmaceutical and biotech production lines where they are easily integrated with cleaning and sterilization systems used in pharmaceutical production.

Tuttnauer autoclave sterilization cycles will preserve the integrity of your products, packaging and instruments, while killing all micro-organisms. The pharmaceutical autoclaves have been developed to be used for many common applications in the pharmaceutical industry

Pharmaceutical Production Facility



Preparation Area
A1. Tuttnauer Autoclave
A2. Tuttnauer Autoclave

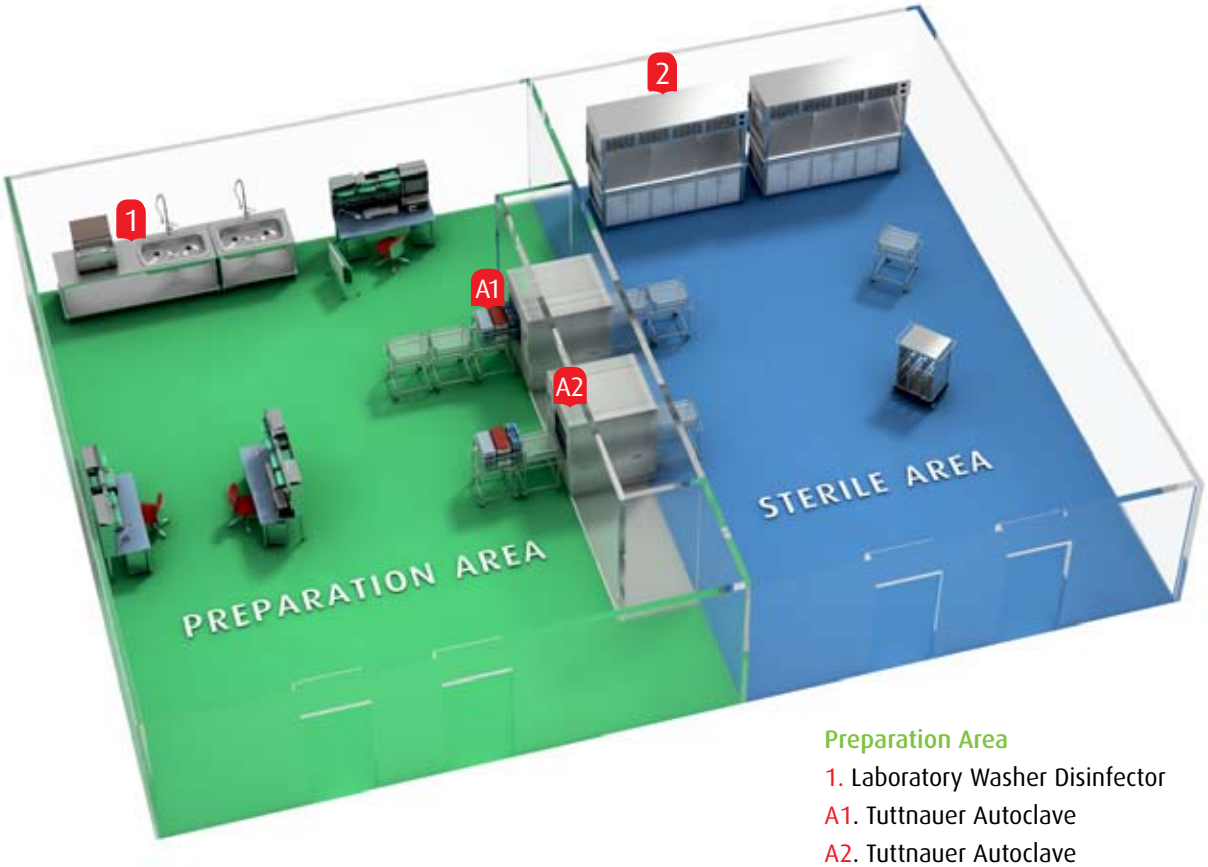
Production Area
1. Control Station
2. Reactor 1
3. Reactor 2
4. Pass Through Window
5. Pass Through Window

Filling Area
6. Control Station
7. Filling Machine
8. Pass Through Window

QA Laboratory Sterile Processing

Tuttnauer's small capacity autoclaves are well suited for R&D departments and QA laboratories where they integrate with quality management processes and conform with QA policies that required accurate monitoring and documentation, and precise control.

Pharmaceutical Quality Assurance Facility



Preparation Area

1. Laboratory Washer Disinfector

A1. Tuttnauer Autoclave

A2. Tuttnauer Autoclave

Sterile Area

2. Laminar Hood

Supporting Products for Production and QA

Tuttnauer also provides:

- Steam generators
- Clean steam generators

Loading Equipment:

- Pull-out trays (stainless steel) equipped with rails for easy loading and unloading.
- Loading Carts and Transfer Carriages. The loading cart is designed to roll from the transfer carriage onto the chamber rails.
- The carriage is equipped with a lock that prevents sliding, and swivel wheels with wheel breaks.

Design and Construction

The pharmaceutical autoclave line is designed and constructed for sanitary pharmaceutical applications which require strict compliance with cGMP. All machine components exposed to steam are made from 316L stainless steel.

Diaphragm Valves

Diaphragm valves and gauges are used to allow maximal drainability and minimise the risk of contamination.

Specialized Piping

To meet the high sanitary requirements of the cGMP the pharmaceutical-grade sanitary line (primary piping) to the chamber steam inlet is orbital welded.

Sanitary Air Filter

A 0.2 µm air filter ensures that bacteria free air enters the chamber. A SIP provision is available for the sanitary filter.

Air Detector

An optional air detector detects insufficient air removal and non-condensable gases in the steam.

Chamber and Jacket Construction

The 316L Stainless Steal chamber inner walls have a mirror like surface level polish less than 0.4 µm (specific polishing values are available upon request). The chamber is constructed to be drainable with smooth, rounded and sloped surfaces to enable proper drainage and cleaning.

The jacket is constructed from 316L stainless steel. The chamber is cooled through jacket water cooling.

Advanced Control System

Take advantage of Tuttnauer's sophisticated user-friendly PLC control system based on the advanced Allen-Bradley platform in all pharmaceutical autoclaves.

Standard Features

- 7" Multi-color touch screen for easy access to controls and information via the panel
- Stores the last 200 cycles in built-in memory
- 4 access levels and 11 user passwords to control access/operation of the autoclave
- In/Out test (enables technician to check each system component separately)
- Sterilization Temperature range 110°C to 137°C
- Ethernet connection for remote monitoring, remote maintenance, and software updates
- Filter replacement notifications based on the number of cycles
- 21 CFR part 11

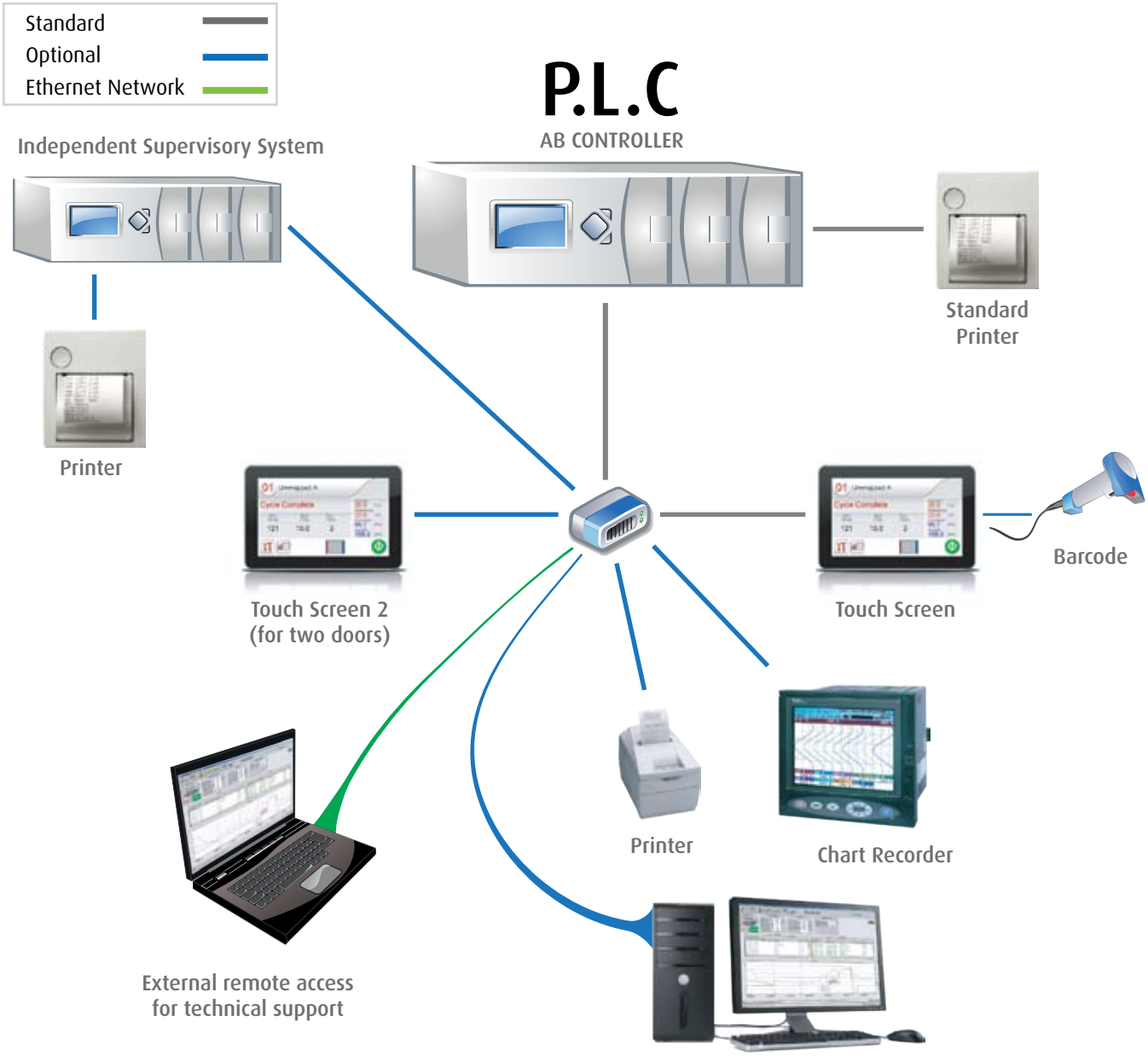
Optional Features

- 10" Multi-color touch screen
- F_0 software control
- Up to 16 different Barcodes

Sophisticated Touch Screen HMI

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

- Multi-color display for easy reading
- Easy operation
- Quick access to important information
- 26 Multiple languages
- Built-in view of historical cycle data
- Graphical display of Temperature and Pressure trend graphs



SCADA Software & Hardware

SCADA software (optional) allows for control and monitoring of up to 16 sterilizers on an external PC. The software retrieves data, creates graphs, tables and printouts. Thousands of hours of cycle data can be stored in the cycle history.

Programs

The advanced control system allows for customization of each program which allows for a high degree of versatility, providing the flexibility of using the same autoclave for many types of loads and applications. The controller has up to 22 programs.

Tuttnauer thoroughly checks each program to ensure that they perform according to our customers requirements (URS).

Unwrapped & Solid

- Utensils
- Glassware
- Machine Parts

Wrapped & Porous Goods

- Textiles
- Filters & Filter Vessels
- Elastomers & Rubbers
- Ampoules & Vials
- Instruments & parts (wrapped)
- Glassware (Wrapped)

Liquids & Media (Optional)

- Liquids (open)
- Liquids (sealed)

Biohazard (Optional)

- Pathogens
- Biohazard Waste

Test & Control

- Leak Test
- Bowie & Dick Test
- Filter Sterilization
- Filter Integrity Testing Connections (optional)

Pre and Post Vacuum

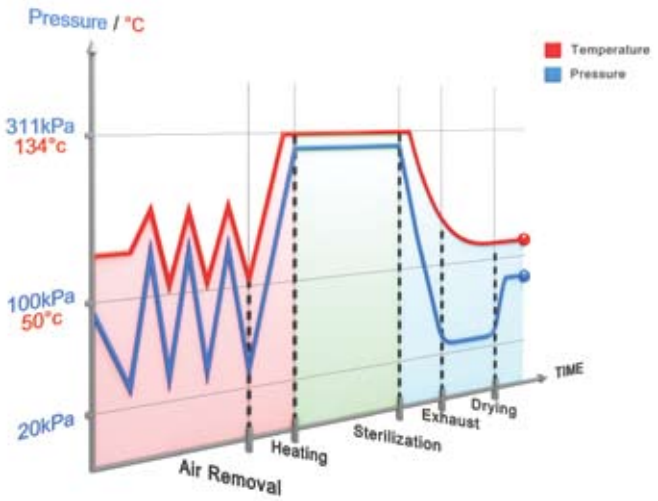
With the pre and post vacuum optional feature the following additional benefits are available:

Liquid Sterilization and Media Preparation

- Efficient forced air removal for media and liquids
- Water cooling in the jacket to reduce cooling times (chamber is pressurized with compressed air to prevent liquid loss)

Dry Goods and Porous Loads

- Adjustable vacuum and pressure rates, depth, and holding time in both pre and post conditioning phases for fast and efficient processing & preservation of product
- Suitable for items such as empty containers, filters and tubing



Control &Documentation

Features and Options

Standard ✓ Optional o

Validation and Support Documentation	
IQ/OQ Documentation (cGMP)	✓
DQ Documentation	o
Software Sequence of Operation (SOO)	o
FAT (Pre-qualification)	o
SAT (IQ/OQ)	o

Control	
21 CFR part 11	✓
SCADA	o
Independent Recorder	o
10″ Touch Screen (7″ standard)	o
External Printer	o

Autoclave

Features and Options

Pressure Vessel	
AISI 316L stainless steel chamber	✓
ASME Code Section VIII, Division 1 or PED 97/23 EEC	✓
AISI 316L stainless steel jacket	o
Polished Surface (Ra less than 0.4 µm)	o
Insulation encased in stainless steel	✓
Jacket covering 100% of the chamber wall for uniform heat distribution.	✓
Jacket cooling	o
Bio-shield preperation	o
AISI 304 or 316L stainless steel base frame	o
Door(s)	
Automatic sliding door(s)	✓
Bi-directional door sequencing	o

Piping & Components	
Pharmaceutical grade sanitary piping and components (primary)	o
Pharmaceutical grade sanitary piping and components (primary & secondary)	o
PT100 temperature sensor in drain	✓
Sanitary 0.2 µm air admission filter	o
Chamber water level & alarm	✓
Isolated pressure (membrane) gauges	o
Videoboroscoping report for clean piping	o
Air detector	o
Other	
Clean steam generator	o
Biohazard system for waste treatment	o
Filter integrity testing connections	o

Pharmaceutical Autoclaves Models

Tuttnauer pharmaceutical autoclaves have fully automatic sliding doors and chamber volumes ranging in size from 250 liters to 2000 liters.

Model	Chamber Dimensions (Wx H x D) mm	Chamber Volume (Liter)	Door Options
5596	508 x 508 x 970	250	Vertical sliding - 1 or 2 doors
66120	610 x 610 x 1215	450	Vertical sliding - 1 or 2 doors
T-Max 12	660 x 1220 x 1295	1040	Horizontal sliding - 1 or 2 doors
364872	920 x 1220 x 1820	2000	Horizontal sliding - 1 or 2 doors

Autoclave Installation and Configuration

- Bi-Directional door sequencing controls on both sides of autoclave is standard on two door autoclaves
- Mounting can be recessed between two walls, in a wall, or stand alone
- Bio shield wall seal prevents airflow between different classified areas

Safety

Safety of personnel is an important issue. Tuttnauer autoclaves include numerous safety features/systems to ensure a safe work environment.

Door Safety

- The pharmaceutical autoclaves are designed with a number of independent mechanical and digital safety features:
- In case of failure the clean door remains closed in order to protect the clean area from contamination
- A safety device prevents the operator from opening the door when the chamber is pressurized
- Steam will not to enter the chamber when the door is open
- A cycle cannot start if the door is open or not properly locked
- The door cannot unlock until liquid temperature reaches the predetermined end temperature
- The door cannot unlock until chamber pressure reaches room pressure
- An air inflated door gasket creates a hermetic seal between the door and chamber

General Safety Features

- Double Independent Monitoring: The combined electronic and mechanical monitoring ensures that the operator has two independent means to monitor pressure
- Safety Valves: If the pressure exceeds the allowed limit the safety valves will discharge
- Built-in Steam Generator Safety: A water level monitoring system maintains a constant water level and ensures safe operation of the heaters

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Tuttnauer
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Global partnerships

At Tuttnauer we feel that business means people dealing with people. We pride ourselves on our reputation for having long-lasting relationships with our customers based on commitment and trust, spanning over decades and distances.

Our Flexibility is Your Advantage

Beyond our wide range of products and ability to customize products to customer requirements, we also manage complete turnkey solutions, including planning, design and installation of equipment, as well as consultation and feasibility studies, for projects of all sizes.

More from Tuttnauer:

Featuring additional Tuttnauer product's for laboratory and life science applications.

Vertical autoclaves for liquids, glassware, and biological waste

Vertical autoclaves for liquid, glassware, and biohazardous waste

Benchtop autoclaves for life science applications

Pharma Line

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

Tuttnauer Europe b.v.
Hoeksteen 11, 4815 PR
P.O.B. 7191, 4800 GD Breda
The Netherlands
Tel: +31 (0) 765 423 510, Fax: +31 (0) 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@tuttnauer.com

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