Tuttnauer

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T-Top Autoclave

Data Sheet

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1. Introduction

T-Top 10” is a Class B Tabletop Steam Sterilizer. The autoclave is fully automatic, a computerized control unit ensures a fully automatic sterilization cycle, control and monitoring of physical parameters and a clear documentation of the sterilization cycle.

Drying is performed with the door closed.

This autoclave uses steam as a sterilizing agent. The steam is produced by warming up a controlled amount of water inserted into a pipe heating element, and then to the chamber. This technique saves energy and water consumption. The autoclave is equipped with a pipe heating element and with chamber heaters to maintain the steam inside the chamber.

The autoclave is equipped with a vacuum system which supports and improves:

- Removal of residual air from packs and porous load and most kinds of tubes (rubber, plastic etc.) by vacuum at the first stage of the cycle.
- Steam penetration into the load; resulting in effective sterilization.
- Temperature uniformity.
- Post sterilization drying phase.

Intended Use

The T-Top 10 tabletop autoclave is designed for the sterilization of medical and surgical goods such as wrapped and unwrapped, solid, hollow, and porous products that are found in dental, medical, first aid rooms, hospitals, and laboratories.

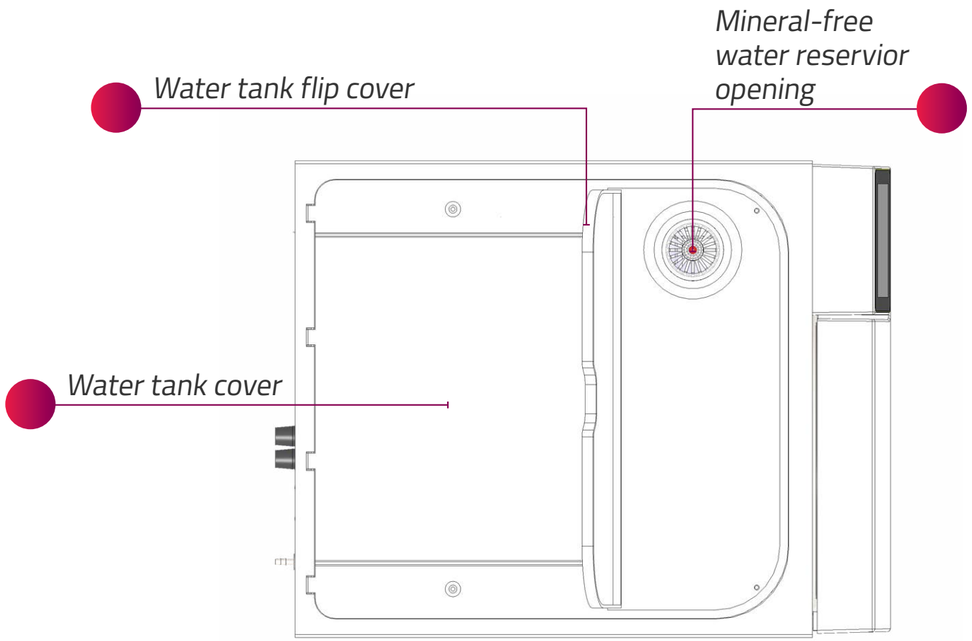
It is intended for use by hospitals, medical personnel. All autoclave users must receive training in the proper usage from an experienced employee.

Front View

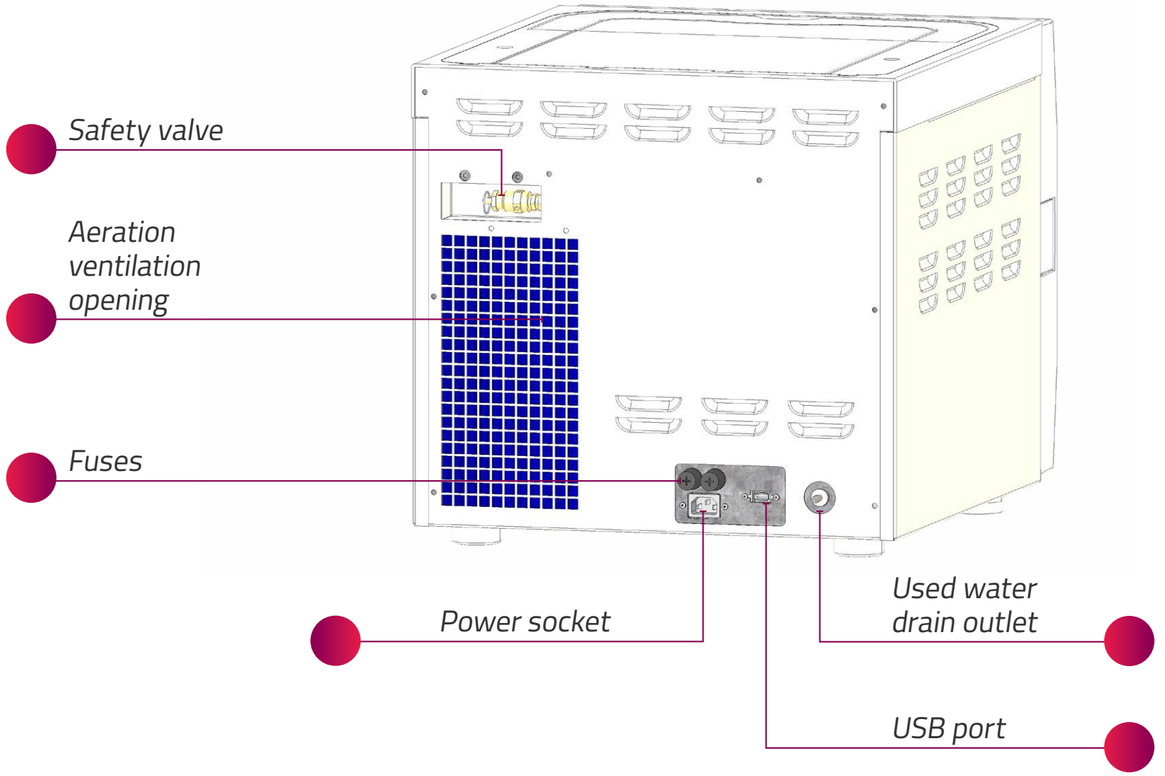

Air filter
Chamber
Door gasket
Door switch (close)
Door switch (locked)
USB port
ON/OFF switch
Waste water drain
Clean water drain


Touch screen
Tuttnauer
T-Top
Door handle

Top View



Rear View



2. Features and Advantages

Features

- High-resolution touchscreen.
- Built in memory (up to 500 cycles).
- Connectivity to R.PC.R.
- The device is Wi-Fi compatible enabling remote tracking and monitoring via the T-Connect software
- 2 USB ports
- Chamber volume 22 liters (Stainless steel)
- Working pressure 15 to 335 kpa / 2.17 to 48.5 psi.
- Sterilization temp. range 121 °C/249.8 °F to 134 °C/273.2 °F (according to the sterilization program).
- Safety feature prevents premature opening of the door.
- Service and maintenance plan included.

Advantages

- Plug-and-play readiness
  - Small footprint.
  - Requires only a power source to begin operation.
- The cylindrical design makes it easier to load, and offers many years of reliable performance.
- Versatile:
  - Designed for the sterilization of medical and surgical instruments such as wrapped and unwrapped, solid, hollow, and porous products
  - Low cost
- Meets international regulations and standards, and is PED certified.

3. Facility Requirements

The facility must meet the following requirements for the T-Top to operate properly:

Placement

- The autoclave is intended to be operated in indoor conditions only.
- The environment shall not exceed an ambient temperature range of 5°C (41°F)-40°C (104°F) and 85% relative humidity.
  To allow proper ventilation and easy device disconnection, keep the back and the sides of the autoclave approximately 10 mm away from the wall and facilitate the device disconnection.
- The autoclave must be stored in indoor conditions only.

CAUTION:
Insufficient ventilation space may result in system malfunction or damage due to overheating.

Electrical Connectivity

- The power supply must meet the following specifications:
  - 1 phase, 230VAC ±10%, 50Hz

4. Control System

The main board controls all autoclave functions, performs the operation sequence according to the user-selected program, and monitors operation.

The control system includes the following features:

- PID (Proportional Integral Differential) temperature control.
- Digital inputs and outputs for sterilizer control.
- Analog inputs allowing for control and reading of temperature and water level.
- 2 USB ports for external devices such as an external printer, a barcode reader, or a USB memory stick.
- Flash memory and real-time clock backup to store cycle data of the last 500 cycles.
- Data is stored even if there is a power failure.
- In/Out test.
- Visual indication of temperature and water levels.
- Visual alert of cycle malfunctions.
- Temperature sensors: The temperature measuring circuits are linear and manufactured using high-precision components.
- The control system enables temperature calibration to be performed digitally

Sterilization Programs

Icon	Name	Temp	Sterilization Time (min)	Dry Time (min)	Load Type	Type of Use
	Unwrapped 134	134°C	4	2 (default) Range: 0-99	Unwrapped instruments (Unwrapped Solid)	Immediate use only
	Wrapped 134	134°C	4	22 (default) Range: 0-99	Handpieces, Wrapped instruments (wrapped solid), Textile (fabric packs), porous	For storage
	Wrapped 134|2Kg	134°C	4	15 (default) Range: 0-99	Handpieces, Wrapped instruments (wrapped solid), Textile (fabric packs), porous	For storage
	Unwrapped 121	121°C	20	2 (default) Range: 0-99	Unwrapped instruments (Unwrapped Solid)	Immediate use only
	Wrapped 121	121°C	20	25 (default) Range: 20-99	Handpieces, Wrapped instruments (wrapped solid), Textile (fabric packs), porous	For storage
	Prion 134	134°C	18	22 (default) Range: 30-99	Solid / Porous load	For storage
	Prion 134|2Kg	134°C	18	15 (default) Range: 30-99	Solid / Porous load	For storage
	Bowie and Dick	134°C	3.5	2 (default) Range: 0-99	Chemical Indicator in a product challenge device	Periodic testing as referred to in ISO 17665-1
	Vacuum Test	N/A	N/A	Vac. Time stable 1 = 5min Vac. Time stable 2 =10min	Empty	Not Applicable
	System Clean	N/A	N/A	N/A	Empty	Periodic cleaning

Graphic User Interface (GUI)

The control system is operated via a large color touchscreen, allowing the user to easily operate the autoclave, navigate through the menus, and select programs. It is password protected to prevent unauthorized access.

The system offers customizable access levels, with access controlled for the following functions:

Running test cycles, setting parameters, performing calibration, performing service and maintenance, selecting cycles, starting cycles, and controlling the door.

Further characteristics of the GUI include:

- Quick access to important information.
- Built-in view of historical cycle data.
- Graphical display of temperature graphs.
- Multiple languages.*
- Display of the following:
  - Temperature in the chamber.
  - Door status.
  - Sterilization time countdown.
  - Autoclave status: Standby, Ready, Air Removal, Pre-Vacuum, Heating Sterilization, Exhaust, Air Inlet, Cycle Ended

*Languages include:

English, German, Spanish, French, Italian, Portuguese, Dutch, Czech, Bulgarian, Polish, Hungarian, Croatian, Serbian, Romanian, Swedish, Danish, Turkish, Greek, Russian, Estonian, Latvian, Lithuanian

5. Specifications

T-Top 10” Technical Specifications

Characteristics	
Chamber Ø x D	249 Ø x 450 mm
External dimensions WxHxD	462x460x585 mm
Shipping WxHxD	620x540x735 mm
Weight	45 Kg
Chamber volume	22 lit
Water tank volume	3.6 lit
Wastewater tank volume	Up to float: 3.75 lit Overflow: 5.75 lit
Max allowable working pressure	2.8 bar

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Water Quality Specifications

Suggested maximum limits of contaminants in water for steam sterilization (per EN13060):

Substance / measurement	Feed Water	Condensate
Evaporate residue	≤ 10 mg/l	≤ 1.0 mg/l
SiO2	≤ 1 mg/l	≤ 0.1 mg/l
Iron	≤ 0.2mg/l	≤ 0.1mg/l
Cadmium	≤ 0.005 mg/l	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l	≤ 0.05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0.1 mg/l	≤ 0.1 mg/l
Chloride (Cl)	≤ 2 mg/l	≤ 0.1 mg/l
Phosphate	≤ 0.5 mg/l	≤ 0.1 mg/l
Conductivity (at 20°C)	≤ 15 µs/cm	≤ 3 µs/cm
pH value	5 to 7.5	5 to 7
Hardness	≤ 0.02 mmol/l	≤ 0.02 mmol/l

Substance / measurement	Feed Water	Condensate
Tap Water Supply	0.7-2.0 mmol/l (70- 200 mg/l CaCO3)	
Appearance	Colorless, clean, without sediments	

NOTES:

It is recommended to consult a water specialist prior to use.

It is recommended to test the water once a month.

Use only deionized water, having a maximum conductivity of 15 µs/cm. Conductivity greater than 15 µs/cm may cause failures.

CAUTIONS:

The use of water for autoclaves that does not comply with the table may severely impact the working life of the autoclave and can invalidate the manufacturer's warranty.

The use of soft water is strictly forbidden.

Electrical Specifications

Property	Value
Total Power	1800 W
Voltage	1Ph - 230 VAC
Amperage	10 A
Protection against electrical shock	IEC 61010-1
Main Supply Fluctuation	±10%
Frequency (Hz)	50 Hz
Pollution degree	Pollution degree 2
Over-voltage category	category II
Pollution degree of the intended environment	

Loading Capacities

Maximum Solid load	T-Top 10"
Unwrapped	6 kg
Wrapped	3.6 kg
Textile	1.5 kg

Regulations

The life cycle of Tuttnauer's T-Top is in compliance with the following regulation and quality standards:

Regulation (EU) 2017/745 (MDR)	
EN ISO 13485	Quality management system – Medical Devices
EN ISO 14971	Medical Devices – application of risk management for Medical Devices
PED	2014/68/EU
EN 13060	Small Steam Sterilizer
ISO 17665	Sterilization of Health care products – Moist heat
IEC 61010-1	Safety requirements for Electrical equipment for measurement, control, and laboratory use – Part 1: General requirements/
IEC 61010-2-040	Safety requirements for Electrical equipment for measurement, control, and laboratory use - Part 2-040: Requirements for sterilizers and washer–disinfectors used to treat medical materials
EN-613261-1	EMC Requirements for Electrical Equipment
IEC 62304	Medical Device Software – Software life cycle processes

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Thank you!