



T-EDGE 10 & T-EDGE 11 DATA SHEET

Table Top Steam Sterilizer





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1. GENERAL DESCRIPTION



The T-Edge autoclave is a state-of the art 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 to 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.

A touchscreen is used for monitoring and control purposes.

The device has a built -in USB port to enable the operation of an external optional barcode printer:

- The barcode printer can print labels with a unique cycle ID barcode, operator name, sterilization, and expiry dates.
- One barcode printer can be connected to the machine.
- The printer connection to the machine, by using a USB socket, with a dedicated cable.
- Barcode printer power supply voltage can range between 100-240V.
- A barcode printer is an optional addition to the autoclave.

The device features built-in memory to record up to 999 sterilization cycles. These can be exported to a USB device to be transferred to a PC.

The device has a built-in Network Port for use with optional Tuttnauer's R.P.C.R software when connected to your local network.



The autoclave has two optional configurations (available upon request):

- Basic: Demineralized water is supplied by a manually filled reservoir, demineralized water overflow outlet on the rear cover (device catalog number: AMS10-230-PED-T, AMS11-230-PED-T)
- Automatic: Demineralized water direct inlet from the water supply system, demineralized water overflow, and wastewater outlet on the rear cover (device catalog number: AMS10-230-W-PED-T, AMS11-230-W-PED-T)

Note: This Data Sheet includes information on the following T-Edge models:

- 1. T-Edge 10 for 230V reference models AMS10-230-PED-T, AMS10-230-W-PED-T.
- 2. T-Edge 11 for 230V reference models AMS11-230-PED-T, AMS11-230-W-PED-T

All information in this document applies to all models unless indicated otherwise.

1.1. Intended Use & Users

The T-Edge 10 & T-Edge 11 tabletop autoclaves are designed for the sterilization of medical and surgical goods such as wrapped and unwrapped, solid, hollow, and porous loads used in healthcare facilities (e.g., hospitals, nursing homes, extended care facilities, freestanding surgical centers, clinics, and medical and dental clinics).

It is intended for use by hospitals and medical personnel.

All autoclave users must receive training in the proper usage from an experienced employee. Every new employee must undergo a training period under an experienced employee.

1.2. Configuration Summary

- Chamber volume
 - T-Edge 10 23 liters
 - T-Edge 11 27.2 liters
- Working pressure meets ASME (USA) and PED (Europe) requirements.
- Working pressure 15 to -335 kpa / 2.17-48.5 psi.
- Sterilization temp. range 121 °C to 134 °C (according to the sterilization program).
- USB, Ethernet and WIFI communication ports
- User friendly control system with a high-resolution 131mm x 84.5 mm tactile touchpad
- PT100 sensors
- Stainless steel chamber



1.3. Printers (Optional)

The printer(s) are optional and can be purchased/ordered from Tuttnauer by the customer; the printers can easily be installed and connected to the autoclave following the instructions given in the T-Edge Manuals. Printer details: Date, Time: Ser. Num: Model: Version: Cycle Num: Cycle Name: Ster. Temp: Ster. Time: Dry Time: End Temperature Cycle Ended".

The options include:

- One printer connected to the autoclave that can be loaded with thermal paper roll, or with label roll. The user can direct the printer to switch between printing on thermal paper roll or label roll.
- Two printers connected to the autoclave, one loaded with thermal paper roll, and the second printer with label roll.



example of a typical printout



Printer printing barcodes



Printer with thermal paper

1.4. Environment

This device is for indoor use only!

The ambient temperature range shall be 5°c - 40°c and the relative humidity of up to 80% - 85%.

1.5. Environment Emission Information

- 1. The peak sound level generated by the autoclave is 67 dBA with background noise of 48 dBA during sterilization stage, and 65 dBA during drying stage.
- 2. The total heat per hour transmitted by the autoclave is < 200 W/h. (172 kcal)



1.6. Electrical Utility Requirements

Power supply:

• Check and verify a 1 phase, 230VAC ±10%, 50/60Hz, 9A -1960W supply.

Electrical net: Check and verify that the electrical net is protected by a current leakage safety relay.

Mineral-free water inlet: Optional - 1/2"BSP automatic (option for automatic filling).

Drain water outlet: Waste outlet (may connect a fix connection).

1.7. Utility Requirements

1.7.1 Consumption

Ducinanti		Dimension		
	Property	T-Edge 10	T-Edge 11	
	Max. water volume	Overflow (up to the float) – 3.8lit	Overflow (up to the float) – 4.6lit	
Mineral-free	Min. water volume	1lit		
water reservoir	The volume used by the sterilization cycle/load having the highest steam consumption	Recorded 800ml were required to sterilize full load of porous type using "wrapped 121". 900ml for Wrapped 273F + protect		
Used (waste) water reservoir Max. water volume		Max vol. – 4.0lit Float –3.7lit max allowed for start cycle		

The steam is produced by warming up a controlled amount of water inserted to a pipe heating element, and then to the chamber. This technique saves energy and water consumption.



1.8. Water Quality Requirements

Suggested Maximum Limits of Contaminants in Water for Steam Sterilization per EN13060

Substance	Feed Water	Condensate
Evaporate residue	≤ 10 mg/l	≤ 1.0 mg/l
SiO ₂	≤ 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
Appearance	Colorless, clean, without sediments	

Tap water could contain chemicals and/or endotoxins and should not be recommended unless filtered or treated. Some chemicals that are used to treat tap water can be damaging to the sterilizer and/or load, and endotoxins, if present, could transfer to the load and compromise sterility assurance. Therefore, distilled water is recommended for tabletop sterilizers. Additional information about water quality is available in AAMI TIR34

2. DIRECTIVES AND STANDARDS

The T-Edge autoclave meets the provisions of the following Directives and is constructed in compliance with the following Standards:

- Medical Device Directive 93/42/EEC as amended by 2007/47/EC
- Medical Device Single Audit Program companion document, doc# MDSAP AU G0002.1.004 rev. 13-04-2017Ft
- MDSAP audit approach doc# MDSAP AU P0002.005
- FDA QSR 21 CFR part 820 & part 11
- Australian Therapeutic Goods (Medical Devices) Regulations 2002
- Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013, 67/2009, 56/2001, 23/2012)
- Japanese QMS Ordinance (MHLW MO 169)
- Canadian MDR (CMDR) SOR/98-282 (2018), consolidated
- Global Unique Device Identification Database (GUDID) Guidance for Industry and Food and Drug Administration Staff
- ISO 9001: Quality Management System
- EN ISO 13485: Quality Management System Medical Devices



- ISO 14001: Environmental management system
- **ISO 17025:** General requirements for the competence of testing and calibration laboratories
- EN ISO 14971: Medical devices Application of risk management for medical devices
- ASME Code Section Land Section VIII. Div. I.
- PED 2014/68/EU
- Chinese Regulations Special Equipment Licensing Office
- EN 13060: Small Steam Sterilizer
- ANSI/AAMI/ST55: Tabletop Steam Sterilizer
- ISO 17665: Sterilization of health care products Moist heat
- ANSI/AAMI/ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- IEC 61010-1 / UL 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

3. SAFETY FEATURES

The device safety features are independent as requested by ASME and PED standards. The chamber door has the following features protecting personnel from hazards:

- 1. Two door switches that indicate that the door is closed. Without this indication steam is not introduced into the chamber.
- 2. An electrical door locking pin that blocks door opening during operation.

The following safety devices are installed in the autoclave to optimize its safe operation:

- 1. Safety thermostat, to prevent over-heating of the chamber heating elements.
- 2. Safety cut-off switch to prevent over-heating of the pipe heating element.
- 3. A pressure safety valve to prevent over-pressurizing of the chamber.

3.1. Device Placement and Operating Conditions

- 1. Verify that the dimensions of the surface of the counter are at least 55cm x 60cm
- 2. Check and verify that the counter carrying the autoclave is a rigid and leveled surface and can carry a load of 75kg
- 3. If placed in a cabinet, verify that the rear of the cabinet is open to allow ventilation. Recommended cabinet sizes:
 - **T-Edge 10** Width 58-60cm; Height -56.5-57.5cm; Min. Depth 63.2-64cm
 - **T-Edge 11** Width 60-62cm; Height -56.5-57.5cm; Min. Depth 63.2-64cm
- 4. The operational altitude shall not be over 4000 (m) / 13123 feet.
- 5. Ambient pressure of 60.5 kPa / 8.8 psi or higher.



3.2. Electrical Components Safety

All components are safety approved and certified by national and international organizations like UL, CE, and others.

4. LANGUAGES

4.1. The operator display is available in the following languages:

English Spanish
French Portuguese
German Italian
Dutch Russian



5. TECHNICAL SPECIFICATIONS

5.1. Device Properties: Dimensions

Property			Dimension		
rioperty		T-Edge 10		T-Edge 11	
	Width		48cm		50cm
External size	Heigh	t		50cm	
	Depth		58 cm supporting co 60 cm countertop	58 cm supporting common install base carry a 60 cm countertop	
	Diame	eter	25 cm		28 cm
Chamber	Depth	1		46 cm	1
	volum	ne	23lit		27.2lit
Max. Allowable Wo	rking pr	essure (MAWP)		2.8 bar	
Safety relief valve				2.8 bar	
Net weight		53kg		56kg	
Shipping weight			66kg		69kg
Floor loading requir	rements	5	75kg		
		Solid /Unwrapped	6kg		9kg
Max load		Solid /Wrapped	3.5kg		5.4kg
		Textile	1.5kg		2kg
N 4 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -	4	Unwrapped	1.2kg		1.8kg
Maximum load per tray		Wrapped	0.72kg		1.08kg
Tray dimensions		42.1cm x 18.9cm x 2	.05cm	42.1cm x 20.7cm x 2.05cm	
No. of trays			5		
Load No. counter			Counting from 0 to 9	Counting from 0 to 999 and nullifies.	

5.2. Device Electrical Data

Property	Value
Voltage	1Ph / 230 VAC
Amperage	9A
Total power	1960W
Frequency (Hz)	50/60Hz
Protection against electrical shock	IEC 61010-1
Mains supply fluctuation	+/- 10%



5.3. Utilities

Property		Value
	Power Supply	1 phase, 230VAC ±10%, 50/60Hz
Electric Power Supply	Recommended circuit breaker	16A
	Line current	9A

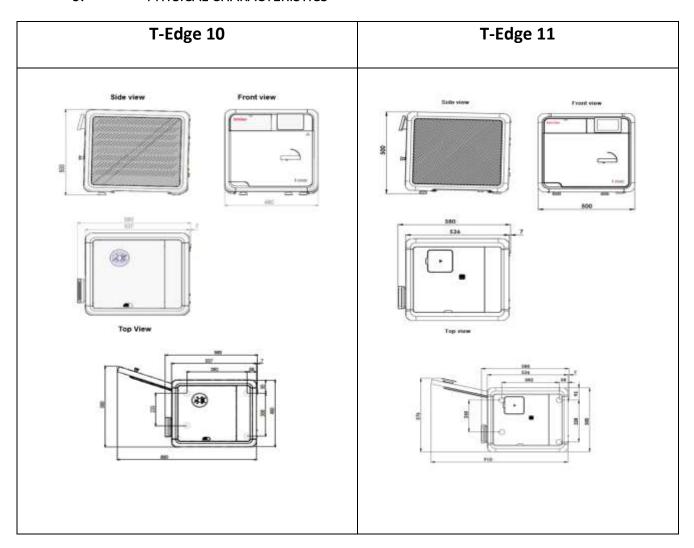
^{*}According to local network

5.4. Construction

Property	Value
Pressure vessel	Stainless steel 316 L
Trays	Aluminum
Door, frame, locking mechanism	Stainless steel 304 L
Locking handle	Polycarbonate
Covers	Polycarbonate
Water reservoirs (mineral free / waste)	Polycarbonate

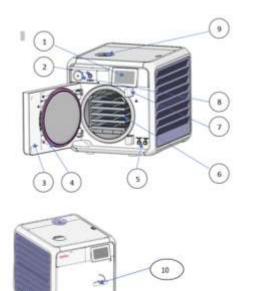


6. PHYSICAL CHARACTERISTICS



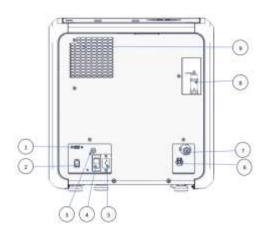


7.1. Depiction of Main System Parts:



No.	Description	No.	Description
1	Touch screen	6	Chamber
2	On/off switch	7	Door switches
3	Chamber Door	8	Air filter
4	Door Gasket	9	Mineral-free water reservoir opening
5	Mineral-free (left) and waste water (right) reservoir drains	10	Door Handle

7.2. Rear View



No.	Description	No.	Description
1	USB ports	6	Waste outlet
2	LAN socket	7	Mineral free inlet (available in AMS10- 230-W-PED-T, AMS11-230-W-PED-T)
3	Cut-off Thermostat	8	Safety valve
4	Circuit breaker on off switch	9	Aeration Ventilation opening
5	Power socket		



8. CONTENT OF THE DEVICE PACKAGE

8.1. **T-Edge 10**

Part Number	Part Description	Quantity Supplied
AMS10-230-PED-T/	T-Edge10 Autoclave	1
AMS10-230-W-PED-T		
DEV000-0663	Aluminum Tray for 10"	5
TRH511-0001	Wire Tray holder for trays or Cassettes	1
TRH511-0004	tray stoppers (to be assembled on tray	8
	holder)	
CMT240-0002	Tray Handle	1
PIP411-0042	Tube for Reservoir Drain	2
PIP511-0029	Tube for Auto reservoir drain+ Angular	1
	connector for the rear drain pipe	
WIR040-0003	Power cable 10A, 250V, EUR	1
MAN205-0502001EN	Operation and Maintenance Manual	1
MAN205-0502002EN	Technician Manual	1



8.2. **T-Edge 11**

Part Number	Part Description	Quantity Supplied
AMS11-230-PED-T/ AMS11-230-W-PED-T	T-Edge11 Autoclave	1
TRY510-0001	Aluminum Tray for 11"	5
TRH510-0001	Wire Tray holder for trays or Cassettes	1
CMT240-0002	Tray Handle	1
PIP411-0042	Tube for Reservoir Drain	2
PIP511-0029	Tube with Angular connector for Auto Reservoir Drain	1
FIL175-0176	Hose Seal With Filter, Mesh 60	1
GAS086-0102	Hose, Flexible, St. St, Nut End, RS331S12, Hydra ½"x200cm	1
WIR040-0003	Power cable 10A, 250V,	1
CLE096-0072	Chamber Clean for B&S-Class 6 tablets – sample kit	1
03-134-05	Autoclave Calibration Report	1
MAN205-1500000EN	Table- Top and Vertical autoclave log book	1
MAN205-0502027EN	Operation and Maintenance Manual	1
MAN205-0502028EN	Technician Manual	1



9. SYMBOLS APPEARING ON THE LABELS AND IN THIS MANUAL

***	Manufacturer				
EC REP	European Authorized Representative				
M	Year of Manufacturing				
MD	Medical Device				
#	Model Number				
SN	Serial Number				
Ţ <u>i</u>	Consult the Operation and Maintenance Manual (User Manual) before use				
CE 0344	European compliance Mark of compliance with the European Medical Device Directive (Number xxxx identifies the Notified Body that performed the examination)				
C€ 1155	European compliance Mark of compliance with the European Pressure Equipment Directive (Number xxxx identifies the Notified Body that performed the examination)				
*	Keep away from sunlight and protect from heat.				
	For Indoor Use Only				
*	Keep dry				
X	Disposal according to electronic scrap ordinance				
<u>tt</u>	This side up (during transport and shipment)				
Ţ	Fragile (during transport and shipment)				
OR	A warning or precaution as detailed in the Operation and Maintenance Manual (User Manual)				
OR OR	Caution! Hot Surface				

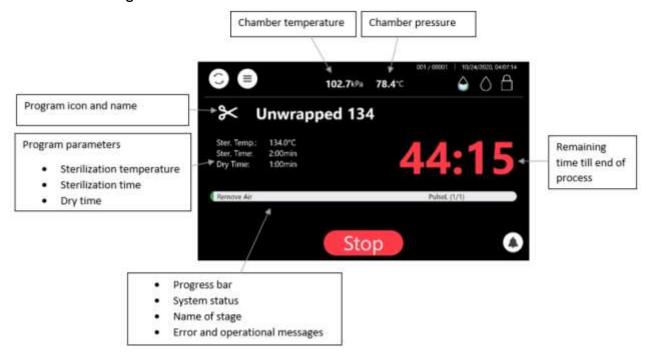


10. HUMAN MACHINE INTERFACE (HMI)

10.1. HMI

The HMI is based on a graphic Touch screen LCD panel. The screen is used to display the autoclave status, Operational or Error Messages and for operating the machine.

10.2. Program screen





10.3. Displayed Operational Messages / Symbols

Symbol	Message / Symbol Description	Required Action
	This symbol is displayed when the door is open	Informative symbol
	This symbol is displayed when the door is closed	Informative symbol
<u>←</u>	Full water level (Clean water tank)	Informative symbol
	Full water level (Waste water tank)	Fix water level (insert or drain water). If it is displayed at end of cycle, and the electrode in the chamber senses water, the door will be locked. Run a new cycle to drain the chamber.
	Alert	Press to watch alert description
Unanigoed legy 270F Can lym Can lym	The "Successful" message is displayed when the cycle ends successfully.	Informative message
too me di laman	The "Fail" message is displayed when the cycle failed due to either an intended cycle abort action by the user, or due to a run-time error.	Perform a new cycle to sterilize the load

10.4. Control Panel

The display is a graphic Touch screen LCD panel used to display the autoclave status, any Operational or Error Messages and for operating the machine.

For detailed information, please refer to the user manual.



11. AVAILABLE STERILIZATION PROGRAMS AND TEST PROGRAMS

			_	Sterilization	Dry time (minutes)			
#	Icon	Name	Temp	time (minutes)	T-Edge 10	T-Edge 11	Load type	Type of use
1	*	Unwrapped 134	134°C	4	2 (default) Range: 1-99	2 (default) Range: 1-99	Unwrapped Instruments (Unwrapped Solid)	Immediate use only
2	*	Wrapped 134	134°C	4	16 (default) Range: 16-99	16 (default) Range: 16-99	Handpieces, Wrapped Instruments (wrapped solid), Textile (fabric packs), porous	For storage
3	W	Unwrapped 121	121°C	20	2 (default) Range: 1-99	2 (default) Range: 1-99	Unwrapped Instruments (Unwrapped Solid)	Immediate use only
4	×	Wrapped 121	121°C	20	16 (default) Range: 20-99	25 (default) Range: 20-99	Wrapped Instruments (wrapped solid), Textile (fabric packs), porous	For storage
5	石	Prion	134°C	18	30 (default) Range: 30-99	30 (default) Range: 30-99	solid load/ Porous load	For storage
6		Bowie and Dick	134°C	3.5	2 (default) Range: 0-99	2 (default) Range: 0-99	Chemical Indicator in a product challenge device	Periodic testing as referred to in ISO 17665-1
7		Vacuum Test	N/A	Vac. Stable Time 1 = 5min Vac. Time stable 2 =10min			Empty	Not Applicable
8		Chamber Clean	134°C	N/A			Empty	Periodic cleaning

Notes:

1. Prion program requires the demineralized water level in the reservoir to be filled to the maximum level to start the program, otherwise an alert will be prompted "please fill water tank to full for start".



- 2. The sterilization program can be used for sterilizing lumen device of no longer than 230mm and no smaller than 3.4mm.
- 3. This sterilization program can be used in sterilizing up to five dental handpieces.

11.1. Additional Sterilization Programs

#	Icon	Name	Description	
1	Ω	Custom	Duplicates a sterilization program and enables modifying the settings. Note: Requires validation by the user!	
2	S., S., S.	Virus Protect	The Virus Protect program is selected prior to a sterilization program to ensure that viruses are eliminated.	
3	(// +	Add Extra Dry Time	Enables the option of adding extra dry time to a program	
4		Start Cycle By Clock	Gives an option of starting a cycle by clock	

11.2. Maximum Load Weight per Load type

Load type	Maximum Load Weight		Suitable for programs	
	T-Edge 10	T-Edge 11		
Textile, porous	1.5kg	2.0kg	Wrapped Pouches	
Handpieces	5 un	its	Wrapped Pouches	
Solid Unwrapped	6.0kg	9.0kg	Unwrapped	
Solid Wrapped	3.5kg	5.4kg	Wrapped	

11.3. Description of the Sterilization Cycle Stages

- **Air-removal stage:** Pre vacuum pulses are performed. For wrapped cycles, there are 2-3 pulses, and the vacuum is deeper.
- **Heating stage:** Steam is inserted into the chamber until the sterilization temperature is reached



- **Sterilization:** Sterilization temperature is maintained constant during the sterilization time.
- Fast exhaust: Steam is exhausted out of the chamber at a fast rate until pressure decreases to ambient pressure.
- **Drying:** Performed with the door closed by pulling vacuum and using the accumulated heat in the chamber and the load to remove leftover moisture from the instruments and wraps.

11.4. Description of the Vacuum Test Stages

Vacuum is produced in the chamber, down to P1=2.17 psi (15 kPa.) At this stage all the valves close. The autoclave remains in this stage for 5 minutes. This period enables the condition in the chamber to reach equilibrium. After the 5 minutes have elapsed, the *cycle 'history record'* records the pressure that is referred to as P2. At this point the test begins and lasts 10 minutes. At the end of the test, the *cycle 'history record'* records the results. The pressure at the end of the test is referred to as P3.

Notes:

- During the test period the autoclave is not heated. Even if the vacuum test is completed, the operator shall check the test results and consider whether the test results are acceptable or not.
- Perform the Vacuum Test on a completely dry chamber, preferably following a cycle with a Drying procedure i.e., a Wrapped cycle, and after the chamber was cooled i.e., Sleep mode/Turned off.

11.5. Description of Bowie-Dick Test Stages

Air-removal stage: Vacuum pulses are performed.

Heating stage: Steam is inserted into the chamber until the sterilization temperature and pressure are reached.

Sterilization stage: Temperature and pressure are maintained constant at the pre-set level for sterilization time.

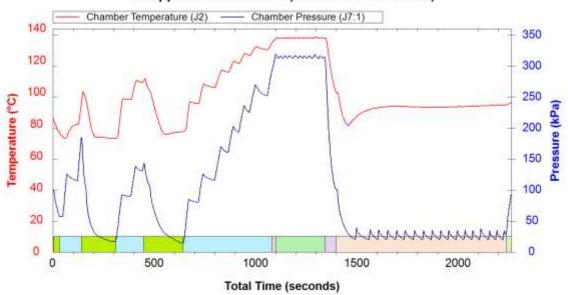
Fast exhaust stage: Steam is exhausted out of the chamber at a fast rate until pressure decreases to ambient pressure.

Drying stage: Heating of chamber followed by a vacuum break (air inlet) to remove leftover moisture from the instruments and wraps. Air inlet to reach atmospheric pressure.

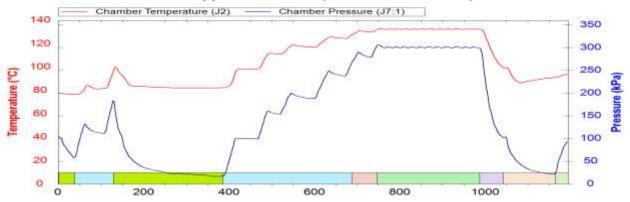


12. TYPICAL STERILIZATION CYCLES











Pricing on any accessories shown can be found by keying the part number into the search box on our website.

The specifications listed in this brochure are subject to change by the manufacturer and therefore cannot be guaranteed to be correct. If there are aspects of the specification that must be guaranteed, please provide these to our sales team so that details can be confirmed.

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