

5075TLC-PVG-2A AND 50100 TLC-PVG-2A

The 5075TLC-PVG-2A and 50100TLC-PVG-2A horizontal pass through laboratory autoclaves are designed to provide high quality repeatable performance and accountability for a wide range of applications used in modern laboratories which include:

- Liquid sterilization with various cooling options (using two flexible PT100 probes, as indicated on IEC 61010-2-040 art. 7.106/3)
- Tips and Glass sterilization
- Instrument sterilization (wrapped or unwrapped)
- Biohazard and Waste sterilization
- Agar preparation
- Specialized customized cycles

the 5075TLC-PVG-2A and 50100TLC-PVG-2A use steam from an internal steam generator as the sterilizing agent. The autoclaves have a computerized control unit which ensures a fully automatic sterilization cycle, control and monitoring of physical parameters and a clear documentation of the sterilization cycle.

The autoclaves have automatic doors on both loading and unloading sides of the machine.

PRODUCT FEATURES

- Hinged doors with automatic locking (doors locked and released automatically with electric-motor system)
- 7" Touch Screen on both sides, with full color display in multiple languages
- 316L Stainless Steel Chamber
- Built in 9Kw Steam Generator, which provides fast heat-up for efficient cycles
- Incorporated Vacuum Pump for an efficient air removal and complete drying
- Coiled Jacket, which keeps the chamber warm during cycles and supports cooling
- Fast Cooling System by external cooling coil
- Built-in Printer that documents detailed history of each cycle
- USB Data Connection, for saving cycle data files on a PC with no additional software or specialized hardware
- Optional high-speed paperless chart recorder
- Pressure Gauges
- Delivered with Wheels, for convenient autoclave mobilization, installation and service.
- Delivered with a base tray

SAFETY FEATURES

Door Safety Systems

The laboratory autoclaves are designed with a number of independent mechanical and electronic safety features.

- 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 controller will not allow the door to be unlocked until liquid temperature reaches the predetermined end temperature

- The controller will not allow the door to be opened until chamber pressure reaches room pressure

General Safety Features

- Safety Valves: The stainless steel chamber is equipped with 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.



VALVES

The piping system of the autoclave uses electrical solenoid valves to control the condensate and steam flow in and out of the chamber, to control the vacuum, and to control the air inlet valve.

VALIDATION PORT

The chamber is provided with one threaded ½” connection for optional vacuum/pressure gauges and test sensors.

VACUUM PUMP

Prevacuum Air Removal & Post vacuum Moisture Removal

The vacuum pump effectively removes up to 99% air and moisture from the chamber. The pump is mounted on a shock absorber (damping mechanism) to minimize vibration.

DRYING

Complete Drying with Chamber Heating and Post Vacuum

Highly efficient drying is achieved by uniformly heating the chamber wall. This is achieved by heating the chamber from steam passed through a coiled pipe around the chamber. The post vacuum stage reduces the boiling point which speeds up drying. This results in fast and complete drying, and guarantees that even the most difficult loads such as textiles, porous loads, hollow instruments and tips, will dry.

PREVACUUM CYCLE

The prevacuum cycle is a fast and effective cycle for removing more than 99% of the air from the chamber in order to ensure good steam penetration and fast heating up.

BIO-HAZARD SYSTEM (OPTION)

The Bio-Hazard system provides an effluent sterilization cycle. Prior to sterilization, during the air removal stage, all effluent is passed through a 0.2µm biological filter that filters the exhaust air. During the sterilization phase, condensate does not leave the autoclave chamber where it is sterilized during the cycle together with the biological filter. After sterilization the sterilized effluent is cooled to a safe temperature before being discharged to drain.

F₀ CALCULATION (OPTION)

F₀ calculation enables reduced media exposure to high temperatures thereby reducing cycle time and preventing damage to temperature sensitive media. Provisions are made to control the sterilization process by insertion of a temperature sensor (PT100) in the load. The exposure time measure is calculated using algorithm based software from the time the temperature sensor in the load has reached a predetermined set point until the end of the heat up stage. The F₀ value is recorded in the sterilization printout after the cycle completes.

DISINFECTION/ISOTHERMAL CYCLE (OPTION)

This cycle is designed to enable disinfection (“low” temperature isothermal treatment) typically used for preparing agar and other biological media. The temperature range setting is flexible within 60°C to 94°C.

WARMING CYCLE (OPTION)

The warming cycle has a temperature range from 95°C to 104°C .

TWO PT100 SENSORS

Two flexible PT100 temperature sensors inside the chamber are provided to monitor load temperature for sensitive liquid

loads which require precise temperature and heat exposure control.

Safety is an important concern. Safety is ensured by using two PT100's to compare liquid temperatures between liquids in two vessels. If the temperature is different then it means a glass vessel may have broken.

Furthermore, two PT100s ensure glass vessels of different volumes in the chamber are sterilized and reach specified end temperature.

BACSOFT 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 (EN 61010-2-040).

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

The operators control panel includes a 7 inch touch screen and printer.

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.

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 7-inch 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.

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 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: | Sterilization Parameters |
| ▪ Date | ▪ Sterilization temperature |
| ▪ Time | ▪ Sterilization time |

- Serial number
- Model name
- Software version
- Cycle number
- Cycle name
- End temperature
- Dry time

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.

R.P.C.R. SOFTWARE

Automatic recording software (optional) for recording cycle information to any PC on your network via Ethernet. R.P.C.R generates reports such as graphs of cycle data, numeric cycle data, cycle print-outs, and more.

CYCLE PROGRAMS

30 program cycles are available with each autoclave. Up to 8 cycle programs are factory set according to optional features. The remaining 22 cycles are fully customizable by the user.

Standard Cycles:

- Pre and Post vacuum cycles
- Solid and glassware loads at 134°C or 121°C for delicate loads (plastics)
- Liquid loads and waste liquids at 121°C
- Hollow, porous and textile loads at 134°C
- Waste: hollow, porous and textile at 121°C

Optional Cycles:

Media Processing Cycles

Isothermal Processing: For preparing agar and other biological media with a temperature range from 60°C to 95°C that allows for gentle heating and cooling down of agar.

Holding Temperature: Special program with programmable holding temperature at the end of the cycle to prevent cooling of media.

Biohazard Air Filter

- During air removal all exhaust air is filtered through a 0.2µm biological filter to prevent contamination of the laboratory
- Biohazard solid loads at 134°C
- Biohazard liquid loads at 121°C

Special Custom Cycles

Tuttnauer is able to provide specifically customized cycles upon request. These may include material stress test, ageing test, varnish test, and others.

Test Cycles

- Air leakage test cycle
- Bowie & Dick steam penetration test at 134°C

FAST LIQUID COOLING

Importance of Cooling - The chamber construction includes external water coils which rapidly reduce the liquid temperature by the injection of cold water into these coils. This feature is

particularly useful for sterilizing sensitive liquid loads requiring reduced heat exposure time.

Cooling Process - Fast cooling is achieved by replacing steam with compressed air to equalize pressure and passing water through the cooling coils thereby reducing cooling time by as much as 75%. This results in safe cooling preventing breaking, deforming, damaging loads and reducing high temperature exposure time. Also, more sterilization cycles per day can be performed.

The installation site must include a separate compressed air utility to operate the cooling system.

INDEPENDENT PAPERLESS CHART RECORDER

A high-speed paperless chart recorder (optional), with independent microprocessor control and power supply. The unit operates independently of the autoclave and is suitable for independent cycle documentation. Includes two additional sensors (temperature & pressure). Has multi-range input and can record up to 4 analog input signals, producing analog trend records. Data can be exported to a USB memory device or transferred via an Ethernet connection. The recorder is operated manually by a switch button to start and stop recording. The unit includes installation CD and viewer software.

BIOLOGICAL SEAL

** Only for 50100TL model*

The bio-shield provides a complete hermetic seal for maximum biological containment between the differently qualified zones.

The bio-shield system meets the BSL3 bio-safety level 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.

LOADING EQUIPMENT (OPTION)

Loading carts and transfer carriages on rails to assist the loading and unloading process. Constructed of high quality,

durable stainless steel. The adjustable loading cart rolls from the transfer carriage onto the interior chamber tracks for easy handling of heavy loads.

UTILITY DATA / REQUIREMENTS

Drainage (Sewage)

1. At least 1/2" sewage pipe.
2. The sewage shall be able to withstand continuous temperature of 80 °C. The drain/sewage system should be able to withstand 120 °C in case of malfunction.

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.

Compressed Air (for fast cooling)

1. At least 1/2" hose to supply the compressed air
2. Compressed air pressure 6 – 8 Bar
3. Flow rate: 30l/min. for 2840 models; 50l/min. for 38xx and 50xx models
4. Building compressed air supply line requires shut-off valve
5. Pressure: 6 bar, free from liquid water droplets, filtered to 25 µm, free from oil droplets greater than 2 µm

Ambient Temperature

Room temperature should be in the range from 5 to 40 °C and 85% RH (relative humidity).

Mineral-Free Feed Water for Steam Generator

Water supplied to the steam generator should have the following hardness and conductivity requirements:

- Hardness (ions of alkaline earth) < 0.02 mmol/l
 - Conductivity < 15 µS/cm (at 20 °C)
1. Water intended for the steam generator must have a water quality in accordance with EN 13060 (only Annex C)
 2. Install 1/2" pipe with a shut-off valve at its end
 3. Regulations may require a Back-Flow protection device

Note: Soft water should not be used since its use may result in corrosion of the steam generator and chamber.

Tap Water

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

PRODUCT SPECIFICATION

5075TLC-PVG-2A TECHNICAL SPECIFICATIONS

Chamber	Diam.	500 mm
	Depth	810 mm
	Volume	155 liters
Overall Dimensions	Width	840 mm
	Height	2100 mm
	Depth	1010 mm
Max. Allowable Working Pressure	2.8 bar	

50100TLC-PVG-2A TECHNICAL SPECIFICATIONS

Chamber	Diam.	500 mm
	Depth	1050 mm
	Volume	205 liters
Overall Dimensions	Width	840 mm
	Height	2100 mm
	Depth	1250 mm
Max. Allowable Working Pressure	2.8 bar	

AUTOClave'S ELECTRICAL DATA

Power Supply	3 X 380 V
	3 x 208 V
	3 x 230 V
	230 V One Phase
Total Power	9 kW
Frequency	50/60 Hz
Protection against Electrical Shock	Class I (IEC 60601-1)
Degree of Protection by Enclosure	IP31

STEAM GENERATOR'S DATA

Max. Working Pressure	3 BarG
Safety Relief Valve	5 BarG

ERLENMEYER FLASKS LOADING CAPACITY (ml)

Model	250ml	500ml	1000ml	2000ml	5000ml
5075 TLC Standard	36	21	14	8	3
5075 TLC 2 Trays	67	40	11	8	3
50100 TLC Standard	48	28	17	12	4
50100 TLC 2 Trays	91	54	15	11	4

SCHOTT-DURAN FLASKS LOADING CAPACITY (ml)

Model	250ml	500ml	1000ml	2000ml	5000ml
5075 TLC Standard	49	36	23	15	8
5075 TLC 2 Trays	105	64	21	10	4
50100 TLC Standard	63	40	30	17	10
50100 TLC 2 Trays	137	82	29	14	7

Note: Standard Loading Capacity: 1 base tray. Optional: 2 trays.

STANDARDS AND DIRECTIVES

Tuttnauer pressure vessels are both ASME and PED certified.

- DIN 58951-2:2003 Steam Sterilizers for Laboratory Use

Directives & Guidelines:

- PED 97/23/EC Pressure Equipment Directive
- 2002/95/EC RoHS Directive
- 2006/95/EC Electrical equipment
- 2004/108/EC Electromagnetic compatibility
- 2006/42/EC Machinery Directive
- 2002/96/EC WEEE Directive
- ANSI / AAMI – ST55: 2010 Table Top steam sterilizer
- EN 13060: 2004+A2: 2010 Small steam sterilizer

Safety and EMC Standards:

- EN 61010-1: 2010 Safety requirements for laboratory use
- EN 61010-2-40: 2005 Safety requirements for sterilizers
- EN 61326-1: 2013 Electrical Equipment for EMC Requirements
- EN 17665-1: 2006 Sterilization of health care products – moist heat

Pressure Vessel and Steam Generator Construction Standards:

All ASME certified vessels are inspected by an independent authorized ASME inspector.

- ASME Code, Section VIII, Division 1, Unfired Pressure Vessels
- ASME Code, Section I, for Boilers

Quality System Compliance:

- ISO 9001:2008 (Quality Systems)
- EN ISO 13485: 2012 Quality Management System
- Canadian MDR (CMDR) SOR/98-282 (2015), consolidated
- In compliance with FDA QSR 21 CFR part 820 & part 11

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