



Pre-vacuum Steam Sterilizer with Generator Model 5075 GS-2A, 50125 GS-2A

Cat. No. MAN205-1000000EN Rev B

Tuttnauer Europe B.V., ■ Hoeksteen 11 4815 PR P.O. Box 7191 4800 GD Breda, The Netherlands ③ Tel: 31 (0) 765423510, □ Fax: 31 (0) 765423540

CE0344



Operation and Maintenance Manual

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General

1

Read the Operating Instructions carefully, before beginning any operation on the autoclave!

1.1. Incoming Inspection

Upon receiving your Tuttnauer Autoclave, carefully inspect the outside of the shipping carton for signs of damage. If any damage to the carton is found, note the location with respect to the autoclave and check that area of the autoclave carefully once it is fully unpacked. Observe packing method and retain packing materials until the unit has been inspected. Mechanical inspection involves checking for signs of physical damage such as: scratched panel surfaces, broken knobs, etc.

If any damage is found, contact your dealer as soon as possible so that they can file a claim with the shipping carrier and also notify Tuttnauer.

All Tuttnauer products are carefully inspected prior to shipment and all reasonable precautions are taken in preparing them for shipment to assure safe arrival at their destination.

Note: Lifting and carrying should always be done by two people.

1.2. Warranty Description

We certify that this instrument is guaranteed to be free from defects in material and workmanship for two years against faulty components and assembly with the exception of glassware, lamps and heaters.

This warranty does not include routine cleaning and preventive maintenance, to be performed according to instructions in 10.1 (Preventive and Scheduled Maintenance).

Tuttnauer warrantees all new GS-2A autoclaves for a period of one full year, covering parts (except door gaskets and HEPA filters -- they are considered wear items).

Tuttnauer warrantees all chambers for a period of ten (10) years against defects in materials and workmanship. This chamber warranty went into effect January 1997.

This warranty does not apply to any instrument that has been subjected to misuse, neglect, accident or improper installation or application, nor shall it extend to autoclaves that have been repaired or altered outside the factory without prior authorization from Tuttnauer.

Tuttnauer's obligation is limited to the repair or replacement of parts for the autoclave. This warranty will be void if the unit is not purchased from an authorized Tuttnauer dealer. No other warranties or obligations are expressed or implied.

The Autoclave should only be used in a manner described in this manual!

1.3. Warranty Statement

The warranty registration must be completed and returned to our service departments; within fourteen (14) days of purchase or the warranty will be void. Our European Representative's Technical Service Department can be reached at: Tuttnauer Europe B.V., Hoeksteen 11 4815 PR P.O. Box 7191 4800 GD Breda,

The Netherlands

Tel: 31 (0) 765423510,
Fax: 31 (0) 765423540

Note: If there is any difficulty with this instrument, and the solution is not covered in this manual, contact our representative or us first. Do not attempt to service this instrument yourself. Describe the difficulty as clearly as possible so we may be able to diagnose the problem and provide a prompt solution.

If the autoclave is equipped with a printer, send along a copy of the last printout for our inspection. If replacement parts are needed, stipulate the model and serial number of the machine.

No autoclaves will be accepted for repair without proper authorization from us. All transportation charges must be paid both ways by the owner. This warranty will be void if the unit is not purchased from an authorized full service Tuttnauer dealer.

Safety Instructions

2

The autoclave has unique characteristics. Please read and understand the operation instructions before first operation of the autoclave. This manual includes instructions of operation, the door safety mechanism; dangers involved in circumventing safety means, how to ensure that the door is closed, and how to select a correct sterilization program.

Never use the autoclave to sterilize corrosive products, such as: acids, bases and phenols, volatile compounds or solutions such ethanol, methanol or chloroform nor radioactive substances.

2.1. Safety features

The autoclave has the following features for hazard protection:

The pressure vessel chamber door has the following features protecting personnel from hazards:

- 1. Two door switches that indicate that the door is closed and locked. Without this indication steam is not introduced to the chamber.
- 2. A pressure switch that blocks door opening if the pressure is higher than 20% above the ambient pressure.

These features are implemented in the following devices (limiters):

For the chamber:

- a. Electrical door lock
- b. Mechanical membrane door lock
- c. Mechanical safety valve (1 for chamber and 1 for generator).

For the generator:

- a. Cut-off pressure switch
- b. Cut-off thermostat

The main power is shut off if there is lack of water or the pressure is above the safe level.

Below are the safety instructions:

2.2. Safety Instructions

- 1. All autoclave users must receive training in proper usage from an experienced employee. Every new employee must undergo a training period under an experienced employee.
- 2. When sterilizing plastic materials, make sure that the item can withstand sterilization temperature. Plastic that melts in the chamber is liable to cause a great deal of damage.
- 3. On closing the device door, make sure it is properly locked before activating. Verify

that DOOR OPEN symbol is replaced by the load number.

- 4. When withdrawing trays, wear heat resistant gloves.
- 5. Before opening the door, verify that the pressure in the chamber equals the atmospheric pressure (chamber pressure is displayed on the screen).
- 6. Unlock the door properly: see 8.3.
- 7. Open the door the minimum required to let the residual steam to escape from the chamber. Only after there is no vapor, open the door widely.and remove the load.
- 8. Once a month, ensure that the safety valve is operating, and once a year certified inspector must perform pressure chamber safety test.
- 9. Once a year, or more frequently, effective tests must be performed, i.e., calibration and validation.
- 10. Make sure there are no leaks, breaks, blockages, whistles or strange noises.

- 11. Perform maintenance operations as instructed. The owner of the autoclave is responsible to perform the maintenance operations.
- 12. Notify the person in charge immediately of any deviation from the proper function of the device.
- 13. Protective equipment and clothes and other safety instructions should be implemented in accordance with local and national regulations and/or rules!
- 14. This autoclave equipped with rear and front wheels, when moving the autoclave all utilities must be disconnected, at least 2 persons shall move the autoclave with caution. When the autoclave located in the required place, the wheels have to be locked. For further information see FRONT/REAR VIEW of the autoclave.

2.3. Operating Conditions

- 1. This device is for indoor use only!
- 2. The sterilizer should be loaded only with autoclavable material!
- 3. Do not use the autoclave in the presence of dangerous gases.
- 4. Minimum room ventilation shall be 10 cycles per hour.
- 5. The environment shall not exceed an ambient temperature range of from 5°C (41°F) to 40°C (104°F) and a relative humidity of 85% respectively.
- 6. The operational altitude shall not be over 2000 meters (6562 feet) (ambient pressure shall not be lower than 80 kPa (11.6 psia)).
- 7. Operate the autoclave only in the manner specified in the manual. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Caution!

3

Waste water should be brought into the public net in accordance with the local rules or requirements

ONLY NON-HAZARDOUS LIQUIDS SHALL BE DISPOSED IN PUBLIC SEWAGE!

General Information

3.1. Introduction

The GS-2A autoclave is designed for sterilization of wrapped and unwrapped instruments, and related items found in dental, medical, and veterinary clinics, first aid rooms, hospitals laboratories etc.

This autoclave is a steam-heated sterilizer using steam as the sterilizing agent. A computerized control unit ensures a fully automatic sterilization cycle, control and monitoring of physical parameters and a clear documentation of the sterilization cycle.

The autoclave offers a choice of automatic programs designed to match the material to be sterilized. The autoclave is equipped with a vacuum pump (GS-2A models only) that during the drying stage draws air through a HEPA filter (0.2μ m) and pushes that air through the heated chamber to remove moisture and facilitate the drying operation. **Drying is performed with the door closed.**

This autoclave is equipped with a vacuum system. The advantages of the prevacuum sterilizer in comparison to the regular gravity displacement steam sterilizer are as follows:

- Removal of air pockets from packs and porous load and most kinds of tubes (rubber, plastic etc.) by vacuum at the first stage of the cycle.
- Better steam penetration into the load; resulting in effective sterilization.
- Better temperature uniformity.

The autoclave is equipped with two Automatic Hinged doors. The doors are closed manually, and then locked by an automatic pneumatic mechanism. Similarly, at the end of a cycle, the doors are un-locked, and can be opened manually. The autoclave is mounted through a recessed wall. The two doors are located in two

The autoclave is mounted through a recessed wall. The two doors are located in two separate rooms, completely isolated.

The front door, on the side of the master control panel is in the preparation area, from where the autoclave is operated and serves for loading the material into the sterilization chamber. This area is known as the "dirty side." The rear door is located on the "clean side" and serves for unloading the sterilized material from the autoclave. This side of autoclave is equipped with secondary control panel (slave). The interlock system of the door is based on the following opening conditions:

- The door cannot be opened while the autoclave is in operation.
- The door cannot be opened if the chamber is under pressure.
- The door cannot be opened if there is liquid in the chamber.
- The door cannot be opened at the end of the cycle if the chamber temperature is higher than the preset final temperature.

The sealing of the chamber is achieved through heat resistant silicone gaskets, located in grooves around the doors openings of the autoclave .

An 18kW built-in steam generator supplies the steam for the sterilization process.

The GS-2A series features a digital display for monitoring and control purposes. The device is capable of displaying the pressure in psia, psig, or in kPa according to the operator's requirements. When the pressure is displayed in psig, the atmospheric pressure is shown (at sea level) as 0 psig. If the pressure is defined in psia or kPa the absolute zero is displayed as "0" and the atmospheric pressure is shown (at sea level) as 14.7 psia or 100 kPa respectively. The GS-2A can display temperature in °F or °C. A printer is a standard addition to the autoclave. The printer prints the preset and actual parameters of the cycle (temperature, time and pressure).

The GS-2A features built-in memory to record up to 100 sterilization cycles. These can be reprinted on the printer or exported to a USB device to be transferred to a PC.



Caution!

Only technical personnel having proper qualifications and holding technical documentation (including a technician manual) and adequate information are authorized to service the apparatus.

3.1. Front Panel and Rear Panel

Front Panel Loading ("Dirty") Side

The operation and controlling of the autoclave is performed through the Touch screen Interface. The Service Access Door on the lower part of the front panel enables service under the chamber.

Rear Panel Un-Loading ("Clean") side

The operation and controlling of the autoclave is performed through the Touch screen and Keypad.. The Service Access Door on the lower part of the Rear panel enables service under the chamber.

3.2. Specification

		5075	50405
Property		5075	50125
Chamber	Diam.	49.4cm	49.4cm
Chambol	Depth	75.0cm 125cm	
Chamber volume	·	160 liters, usable 250 liters volume 144 liters	
Max. Allowable Working pressure (MAWP)		2.8bar	
Net weight			520kg
Shipping weight			
Floor loading requirements		According to the Overall weight and floor requirements	According to the Overall weight and floor requirements
Max load		24 kg solid load or 12 kg textile	30 kg solid load or 22 kg textile
Trav dimensions	Big	(47.3 x 70 x 2 cm)	
	Small	(30.3 x 70 x 2 cm)	
No. of trays	2		
Load No. counter	Counting from 0 to 9999 and nullifies.		

3.3. Generator's Steam Data

Property	18kW
Max. working pressure	3 BarG
Safety relief valve	5 Bar

3.4. Generator's Electrical Data

Property	Value
Voltage	3 ph, 400V
Frequency (Hz)	50/60 Hz, depending on your country standard
Generator Consumption	27A (18kW)
Heaters	18kW

3.5. Autoclave's Electrical Data (the Generator is Not Included)

Property	5075	50125
Voltage	1 ph, 230V	1 ph, 230V
Frequency (Hz)	50/60 Hz	50/60 Hz
Consumption (the generator is not included)	6A	6A
Total power	400W	400W
Degree of protection by enclosure	IP31	IP31

Property		Value
	Power Supply	3Ph, 400V,50/60Hz depending on your country standard
Electric Power	Recommended circuit breaker	32A (18kW)
Suppry	Line current	30A(18kW)
	Protection against electrical shock	Class I (IEC 60601-1)
Mineral-free water	· inlet	1/2", 1-3 Barg
Tap water inlet		1/2", 2-5 Bar
Drain		3/4", withstanding temp. of 80°C

3.6. Utilities

- A switch or circuit-breaker must be included in the building installation. This switch or circuit-breaker shall be in close proximity to the equipment, within easy reach of the operator; and marked as the disconnecting device for the equipment.
- The electrical net must be protected with a current leakage safety relay.
- The electrical network must comply with local rules or regulations.
- Verify that there is an easy access to the main power switch, to the water cut-off valve and to the current leakage safety relay.
- Make sure while placing the autoclave, to leave space around the machine, to give the technician access to service the machine.
- All water connections to autoclave must be performed through "BACK FLOW PREVENTION SYSTEM" only, as per IEC 61770.

Cautions!

In order to avoid any injury by electrical hazard, it is recommended that a ground fault protection device (GFCI) be installed in the electrical panel feeding the autoclave (local codes may make this mandatory).

∕!∖

The electrical network must comply with local rules or regulations. Verify that there is an easy access to the main power switch and to the current leakage safety relay (GFCI). The voltage supplied to the device must comply with the label ± 5%.

Note: The electrical network must comply with local rules or regulations. Verify that there is an easy access to the main power switch and to the current leakage safety relay (GFCI). The voltage supplied to the device must comply with the label ± 5%.

3.7. Environmental Emission Information

- 1. The peak sound level generated by the autoclave is 70dBa with background noise of 60dBa.
- 2. The total heat per hour transmitted by the autoclave is <300Wh.

3.8. Construction

The main parts of the autoclave are made of materials as indicated below:

- Chamber is built of stainless steel 316 L.
- Door is made of stainless steel 304.
- Pressure vessel is made of stainless steel 316L.
- Cabinet is made of stainless steel 304
- Trays are made of stainless steel 316L.
- Generator's vessel is made of stainless steel 304/316L.
- Door closing handle is made of aluminium material, which is safe to touch and thermo-insulated.

3.9. Stickers Description

Symbol	Meaning	Part Number	Location
\triangle	Caution! Consult accompanying documents	LAB048-0024	Near the cut-off
	Caution! Hot steam.	LAB048-0058	Near the safety valve
	Caution! Hot surface.		
	Protective earth (Ground)	LAB048-0020	Near the on/off switch
ON	On-Off	LAB048-0018	Near the Power switch
OFF			

3.10. Water Quality

Physical Characteristics and Contaminants Levels

The distilled or mineral–free water supplied to the autoclave should have the physical characteristics and maximum acceptable level of contaminants indicated in the table below:

Physical Characteristics and Maximum acceptable contaminants levels in steam for sterilizers (According to EN 13060: 2010)

Element	Condensate – allowable content
Silicon dioxide SiO ₂	≤0.1 mg/kg
Iron	≤0.1 mg/kg
Cadmium	≤0.005 mg/kg
Lead	≤ 0.05 mg/kg
All other metals except iron, cadmium, lead	≤0.1 mg/kg
Chloride (Cl)	≤0.1 mg/kg
Phosphate (P ₂ O ₅)	≤0.1 mg/kg
Conductivity	≤3 µs/cm
pH value (degree of acidity)	5 to 7
Appearance	Colorless clean without sediment
Hardness (Σ lons of alkaline earth)	≤0.02 mmol/l

Compliance with the above data should be tested in accordance with acknowledged analytical methods, by an authorized laboratory.

Attention: We recommend testing the water quality once a month. The use of water for autoclaves that do not comply with the table above may have severe impact on the working life of the sterilizer and can invalidate the manufacturer's guarantee.

Cautions!



Tap Water supply

Maximum hardness value 0.7-2.0 mmol/l

The use of soft water is strictly forbidden! Please consult a water specialist! Compliance with the above data should be tested in accordance with acknowledged analytical methods, by an authorized laboratory.

3.11. Directives and Standards

Every autoclave meets the provisions of the following Directives and is in compliance with the following Standards:

Tuttnauer. Ltd. company meets the provisions of the following standards:

ISO	13485:2003	(Quality Systems for Medical Devices)
ISO	9001:2008	(Quality Systems)
MDD	93/42/EEC	(Medical Device Directive)

Tuttnauer. Ltd. company also works in conjunction with and refers to:

ANSI/AAMI ST55 American Society of Mechanical Engineers

EN 12060	Section VIII, Division 1, for unfired pressure vessels.
EN 13000	
UL	UL 61010-1
PED	97/23EEC
IEC	IEC 61010-2-040 Safety
ISO	17665-1:2006 (Validation and Routine Control)







3.13. Overall Dimensions 50125GS-2A

3.14. Rear Panel Un-Loading ("Clean") Side View -- 5075GS-2A



No.	Description	No.	Description
1	Touch screen	4	On/off switch
2	Chamber Door	5	Service door
3	Wheel		



No.	Description	No.	Description
1	Printer	11	Network cable
2	Touch screen	12	Chamber and generator safety valve s
3	Chamber pressure gauge	13	Fast exhaust strainer
4	Generator pressure gauge	14	Power cable socket
5	Chamber door	15	Tap water inlet for drain cooling
6	Tap water reservoir. Left opening - overflow, leave open. Right opening – inlet, to be connected.	16	Service door
7	Tap water drain	17	Mineral-free water reservoir. Left opening - overflow, leave open. Right opening – inlet, to be connected.
8	Wheels	18	Chamber drain
9	Fan	19	Mineral-free water drain
10	Air filter opening		

3.16. Rear Panel Un-Loading ("Clean") Side View -- 50125GS-2A



No.	Description	No.	Description
1	Touch screen	4	On/off switch
2	Chamber Door	5	Service door
3	Wheel		

3.17. Front Panel Loading ("Dirty") Side View – 50125GS-2A



No.	Description	No.	Description
1	Printer	11	Chamber and generator safety valve s
2	Touch screen	12	Power cable socket
3	Chamber pressure gauge	13	Service door
4	Generator pressure gauge	14	Mineral-free water inlet, to be connected
5	Chamber door	15	Mineral-free water overflow, leave open
6	Tap water inlet, to be connected	16	Drain
7	Tap water overflow, leave open	17	Drain
8	Wheels	18	Chamber drain
9	Fan	19	Mineral-free water drain
10	Network cable		

Control Panel

4.1. Description and Functions of the Control panel

Touch screen

4

Touch screen is used for user interface including data output and input. This screen shows the program number and name, sterilization temperature, sterilization time, and dry time parameters of the current cycle, current cycle status (upper-right corner flag), current temperature and pressure. There are buttons allowing to start/stop cycles, to open and close doors, to enter quick options and to login.

The screenshot below shows the real-time display fields and buttons of the Touch screen.



No.	Function	No.	Function
1	Program name	9	Dry time
2	Program selector key	10	Door opening button
3	System status/Name of the cycle stage	11	"Clean" side door status
4	Sterilization temperature	12	Start/stop button
5	Login button	13	Chamber pressure
6	Quick options button (Quick options are available without login)	14	Chamber temperature
7	Sterilization time	15	Status alarm flag
8	"Dirty" side door status		

Printer

The printer prints the detailed history of each cycle performed by the autoclave. The printing is on thermal paper with 24 characters per line. It records the sterilization cycle information for subsequent consideration.

The printing is on thermal paper with 24 characters per line and contains the following information:

- Date:
- Time:
- Ser. Num:
- Model:
- Version
- Cycle Num:

- Cycle:
- Ster Temp:
- Ster Time:
- Dry Time:
- End Temperature

When the sterilization cycle begins the printer starts printing the above data.

After the preliminary printing, the autoclave starts performing the sequence of operations of the cycle. The measured values of temperature and pressure are printed at fixed time intervals, according to the phase of the process from the bottom up, beginning with the date and ending with "Cycle Ended". For an aborted cycle, "Cycle Failed" and the Error message are printed (refer to "Displayed Error Messages/Symbols").

Printer Handling

Maintenance

Wipe off any soiling on the printer surface with a dry soft cloth with a weak neutral detergent. After that, wipe the printer with a dry cloth. **Setting paper**



Printer model PLUS II Front view

1-Paper mouth
2-STATUS Led
3-OPEN key (for paper roll compartment opening)
4-FEED key
5-Paper roll compartment
6-Paper end sensor



1. Open the printer's cover door by pulling it at the bottom (see fig. 2).



Fig. 2

- 2. Press the OPEN key to open the printer cover as shown (see Fig. 3/1). Handle the paper cutter carefully not to cut your hand.
- 3. Place the paper roll making sure it unrolls in the proper direction as shown (see Fig. 3/2).
- 4. The paper should roll off the top of the roll.
- 5. Hold the loose end of the paper with one hand and re-close the cover with the other hand as shown (see Fig. 3/3) the printer cover is locked.
- 6. Tear off the exceeding paper using the jagged edge (see Fig. 3/4).



7. Close the printer's cover door (3) by pressing corner (2), with the tip end of the paper emerging from the slot (1). See Fig. 2.

Notes on treatment of thermal papers:

- Store the papers in a dry, cool and dark place.
- Do not rub the papers with hard substance.
- Keep the papers away from organic solvent.



Never disassemble the printer. Failure to follow this instruction may cause overheating or burning of the printer or the AC adapter. Or an electric shock, which may lead to fires or accidents.



Cautions!

Never use the printer in a place of extreme humidity or any place where it can possibly be splashed by any liquids. If any liquids get into the printer, it could

lead to fire, electric shock, or other serious accidents. Never touch the thermal head immediately after printing because it becomes very hot. Make sure that the thermal head is cool before setting papers or cleaning the thermal head.

Power OFF the autoclave in any of the following cases:

- The printer does not recover from an error.
- Smoke, strange noise or smells erupt from the printer.
- A piece of metal or any liquid touches the internal parts or slot of the printer.

4.2. Displayed Error Messages / Symbols

The failures are divided into two categories:

- Failures that occur before completing the sterilization stage, which in this case will leave the load unsterilized
- Failures that occur after completing the sterilization stage, which in this case will leave the load sterilized

For the list of *Displayed Error Messages / Symbols* see 11 <u>TROUBLESHOOTING</u>

Message / Symbol Name	Message / Symbol Description	Required Action
	This symbol displays when the door is closed.	To open the door tap the door open button To run the cycle tap START/STOP key
	This symbol displays when door 1 is open.	Tap the door open button to close door 1.
	This symbol displays when door 2 is open.	Tap S the door open button to close door 2.
"Door is open"	This message is displayed when the door is opened: In stand–by, if start key is pressed.	Close the door to perform a new cycle. If the problem persists, call the technician.
"Cycle Ended"	This message is displayed when the cycle ended successfully.	Tap START/STOP in order to perform a new cycle.
"Test Ended "	This message is displayed when the test ended.	Tap START/STOP in order to perform a new test
	This symbol is displayed when Cycle by Clock mode is active.	Enter the main menu as described in this manual to change the time or to cancel this option.
"System is not ready to run a cycle. Cycle by clock is active"	This message is displayed if the user presses START/STOP key while the "start cycle by clock" mode is active. Starting another cycle is not allowed.	Enter the main menu as described in this manual to change the time or to cancel this option.
"Atmospheric pressure not set"	This message is displayed in order to set the atmospheric pressure by opening the door for 2 minutes.	Open the door for 2 minutes in order to set the Atmospheric pressure.
"Please restart machine in order for changes to be updated"	Changes to the system software require that the autoclave be restarted.	Restart the autoclave in order for changes to be updated.

4.3. Displayed Operational Messages/ Symbols

Wait Door Closing	This message is displayed while the door closing mechanism is closing or locking the door.	Wait until the door is completely locked.
Wait Door Opening	This message displays while the door open mechanism is open or unlocking the door.	Wait until the door is unlocked

5

Sterilization Programs

5.1. Program Parameters

Program	lcon	Name	Тетр	Sterilization time (minutes)	Dry time (minutes)
1	Ľ	Unwrapped 134	134°C (270°F)	4	1 (default) Range: 1-99
2	Ľ	Wrapped 134	134°C (270°F)	7	20 (default) Range: 20-99
5	¥	Unwrapped 121	121°C (250°F)	20	1 (default) Range: 1-99
6	¥	Wrapped 121	121°C (250°F)	20	20(default) Range: 20-30
7	1	Prion	134°C (273°F)	18	20(default) Range: 0-99
8		Vacuum test		Vacuum test	
9		Bowie & Dick test	134°C	3.5	2

During the process, the stages of the cycle will be displayed on the Touch screen:

The stages names are as follows: Start Pulse L Pulse H Heating Sterilization Exhaust Drying Ending	01 Unwrapped 134	Run
	Starting Ster. Temp. Ster. Time Dry Time 134.0 4.0 1	Temperature 040.8 [°C] Pressure 103.7 [kPa]
	6/UL/2016 11:10:34	Version: 3.0,2.106

Note: The control system incorporates a safety feature that prevents changing programs if the door is closed .

This protection is intended to prevent running an inappropriate program if the autoclave is loaded, but the cycle is not immediately started .

If the operator for example inserts the load into the chamber, closes the door and leaves the room and another operator/user tries to change the program, the operator/user will not be able to do this unless the door is opened and the type of load inside the chamber can be seen. The autoclave offers four preprogrammed sterilization programs

5.2. Cycle Process Description

- Air-removal stage; vacuum pulses are performed .
- Heating stage: steam is inserted into the chamber until the sterilization temperature is reached.
- 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.
- For Wrapped 134 and Wrapped 121. Drying by heating of chamber and air circulation to remove leftover moisture from the instruments and wraps.

5.3. Vacuum Test Process Description

- Vacuum is produced in the chamber, down to P1=7 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 printer 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 printer 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. If the vacuum test failed, the screen color changes from purple to yellow. If the vacuum test is completed, the screen color will remain purple. Even if the vacuum test is completed, the operator shall check the test results and consider whether the test results are acceptable or not

5.4. Bowie and Dick Test Process Description

- 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.
- **Note:** If the B&D test cycle ended successfully "Test Ended" message will display.

6

Installation Instruction

6.1. Placing

Make sure while placing the autoclave, to leave space around the machine, to give the technician access to service the machine. Keep the back and the right side of the autoclave approximately 2" (50mm) away from the wall to allow for ventilation. At the time of installation or anytime the unit is relocated the atmospheric pressure parameter needs to be reset. (See 9.4).

Connect the power cord to the socket on the rear side of the autoclave; plug it into the supply outlet. The autoclave must be connected to a properly grounded outlet.

6.2. Setup

Make sure all the feet are on the autoclave and none of them has been lost
The unit is ready to operate.

6.3. Utilities connection

- If the autoclave is intended to operate with water inlet and drain outlet connected to the facility's utilities, connect the following:
- a. Connect the autoclave to the source of mineral-free water through a flexible ½" hose. Mount a manual valve on the source of the water supply, in order to enable closing the water inlet for maintenance or servicing purposes.
- b. Connect the feed water supply to the tap water inlet. The supplied water pressure shall be set to 2-4bar. Mount a manual valve on the source of the water supply, in order to enable closing the water inlet for maintenance or servicing purposes.

6.4. Lifting and Carrying

Cautions!

Before moving the autoclave, Make sure that the electric cord is disconnected from the power, and there is no pressure in the chamber.

1. Disconnect the power supply cord.

2. Drain the water from the reservoir and the chamber (open the water drain valve (see "Dirty" Side View) and pour the water to a bucket) Do not drop the device!

6.5. Generator

After installation and prior to putting the machine into operation, the following preparing and checkout procedure for the generator is to be fulfilled: **Warning!**



When servicing the autoclave, disconnect all the electrical power supplies to the unit. This is done by switching OFF the main power supply switch, or by unplugging the electrical power main supply cords.

- Check the connection to local sewage. Check that the sewage pipeline is not clogged. (Pour water for this task).
- Check the connection to compressed air, pay attention to the door, set the pressure to 6-8 bar.
- Check the connection to tap water. Open the water valve. Manually test the water valves by over-riding the appropriate solenoid valve. If there are no leaks rotate backwards the solenoid by-pass. Leave the manual inlet taps open.
- Check the connection to mineral-free water. Open the water valve. Test manually the water valves by over-riding the appropriate solenoid valve. If there are no leaks, rotate backwards the solenoid by-pass. Leave the water manual inlet taps open.
- Open the generator electric box, switch ON the 3 Phase circuit breaker with its Trip Coil, and ensure all the other circuit breakers are ON.
- Switch ON the 3 Phase circuit breaker with its Trip Coil, and ensure all the other circuit breakers are ON.
- Check that the Microbiological Filter Cover is removed.
- Check the connection to electricity To be performed by an authorized electrician only!

Preparation before Sterilization. Loading

7

The most important stage begins with removing debris by <u>cleaning</u> and rinsing. Effective cleaning is affected by several factors: Water quality, type, concentration and quality of a cleaner, an effective washing method and adequate rinsing and drying.

Cleaning dried <u>blood</u> is especially difficult because it flows and dries in difficult-toclean locations. It must be washed away. Mechanically scrubbing, high pH detergents, enzymatic solutions and water spray at high pressure will clean this contamination.

<u>Attention:</u> Consult the Medical Device manufacturer relating adequate and most effective cleaning method and cleaning agents.

Instruments which are composed of several components shall be dismantled.

Disinfection is the next step. It is important for safe handling. There are various methods and means for disinfection like soaking in liquid chemical disinfectants or hot water disinfection.

<u>Packaging.</u> The target in packing medical items is to assure that the contained goods are sterile and maintaining them sterile till opening the package.

There are various methods and techniques used in preparation and packaging of surgical instruments.

7.1. General rules to be considered:

- 1. The packaging materials should be held in the room ambient conditions (temperature and humidity) for at least 2 hours.
- 2. The packaging materials should be examined regularly for defects.
- 3. Procedures should be established to assure that packaging is consistent with the manufacturer's recommendations.
- 4. Policy whether to warp in single or double layer, woven or non-woven should be established.
- 5. Container systems should be scientifically proven to suit the specific sterilization program.
- <u>Paper-paper bags</u> are used for safe post sterilization handling. Usually as single wrap. Intended for small, lightweight and low profile instruments.
- <u>Paper-plastic pouches</u>, single or double packing is intended for longer storage period. In case of double packing, two sequentially sized packs should be used. No folding is permitted. They should be placed so that plastic faces plastic and paper faces paper. Paper-plastic pouches shall not be wrapped or contained.
- <u>Textile packs.</u> The barrier properties of new textile wrap are diminished by repeated laundering and sterilization cycles. They shall be inspected for holes, worn spots breaks, stains or separation of the fabric.
- <u>Non-woven.</u> Unique materials like paper or Polypropylene as single layer or as "Double wrap single layer. It is tear resistant and is for single use.
- 6. Immediately after surgery use, clean instruments thoroughly to dispose of any residue or immerse it in enzymatic disinfectant.
- 7. It is recommended to wash instruments with an ultrasonic cleaner, using detergent and mineral-free water.
- 8. Launder textile wraps prior to reuse.
- 9. After cleaning, rinse instruments for 30 seconds. (Follow manufacturer's instructions on the use of products for cleaning and lubricating instruments after using the ultrasonic cleaner).
- 10. Materials, including materials used for inner wraps, shall be compatible with the item being packed and the sterilizing method selected.
- 11. Do not place materials to be sterilized directly on the chamber's wall. Place the material only on trays, rack, etc.
- 12. Before placing an instrument into the sterilizer tray, make sure that instruments which are not of the same metal, (stainless steel, carbon steel, etc.) are separated and placed on different trays.



- 13. Place empty containers upside down to prevent accumulation of water.
- 14. Before use, check inside the autoclave chamber to ensure that no items have been left from the previous cycle.
- 15. Do not overload the chamber or the trays.
- 16. Use only autoclavable products. Please refer to the manufacturer instructions for sterilization of unknown materials or instruments.
- **Note:** Check manufacturer's instructions for the sterilization of each item.
- 17. Observe maximum weight limits as referenced in the table in 3.2
- 18. All instruments must be sterilized in an open position.
- 19. Use single-use wraps only once and discards them after use.
- 20. In case carbon steel instruments are placed on stainless steel trays, the trays should be lined with a towel or paper wrap before placing the instruments on the trays. There should be no direct contact between the carbon steel and the stainless steel trays.
- 21. Verify that the packaging method is in accordance with good practice approach and the packaging materials are in accordance with the applicable standards (e.g. EN868 series).
- 22. Place a sterilization indicator strip (Class 4) in each tray.
- 23. Place instruments with ratchets opened and unlocked or clipped on the first ratchet position.
- 24. Disassemble or sufficiently loosen multiple-part instruments prior to packaging to permit the sterilizing agent to come into contact with all parts of the instrument.
- 25. Tilt on edge items prone to entrap air and moisture, e.g. hollowware, so that only minimal resistance to removal of air, the passage of steam and condensate will be met.
- 26. Load items within the boundaries of the tray so that they do not touch the chamber walls, or fall off when the tray is in move.
- 27. The operator may use racks to allow for adequate separation of packaged instruments.
- 28. Load trays in such a way as to allow steam to move freely among all items.
- 29. Allow a distance of approximately 2.5 cm (1") between trays to permit steam circulation.
- 30. Once a week, use a biological spore test indicator in any load to make sure sterilization is performed.
- 31. Make sure that all instruments remain apart during the sterilization cycle.
- 32. Empty canisters should be placed upside-down, in order to prevent accumulation of water.

7.2. Packs

- 1. Place packs upright on trays, side by side.
- 2. Packs should not touch the chamber walls.
- 3. Pack instrument sets in a manner that prevents damage to delicate items.
- 4. Pack hollowware sets so that all openings face the same direction and so that the contents cannot move inside the pack.
- 5. Load packs of folded operating room drapes with layers vertical, allowing air to be removed from the packs rapidly.
- 6. Do not place packs of hollowware and trays of instruments above textile packs or soft goods in order to avoid wetting caused by condensation from items above.
- 7. Do not stack pouches. It is recommended that a Tuttnauer[™] Pouch Rack be used. This will allow the operator to place pouches on their side, which will increase

capacity and provide proper spacing to ensure steam penetration and promote adequate drying.

8. Load items packed in flexible packaging materials on edge with paper to laminate, or flat with the paper surface upwards.



Note: The manufacturer's recommendations shall be observed, concerning the sterilization data for each type of material.

7.3. Tubing

Rinse tubing after cleaning with pyrogen free water. When placing in a tray, Make sure that both ends are open, without sharp bends or twists.



7.4. Wrapped Instruments

- 1. Wrapped instruments should be packed in material that promotes drying such as autoclave bag, autoclave paper.
- 2. Use single-use wraps once only and discard after use.
- 3. It is highly recommended to utilize the Tuttnauer[™] Pouch Rack. This rack allows the operator to place pouches on their side, thus increasing the capacity of the autoclave significantly and promoting better drying of the instruments. Contact your dealer for details.
- 4. Verify that the packaging method is in accordance with good practice approach and the packaging materials are in accordance with the applicable standards. We recommend using plastic-paper pouches.

7.1. Loading

Every autoclave is supplied either with two (or more) stainless steel shelves, or with rails for loading a loading cart from transfer carriage (see the figure below).

The transfer carriage (2) is made of stainless steel and is adjustable to balance the height of the loading cart to rails in the sterilizer chamber. The loading cart (1) is designed to slide smoothly off the carriage into the sterilization chamber.

The carriage moves on four heavy-duty castors, which are mounted on its base.

To load the autoclave from the cart:

1. Maneuver the Transfer Carriage into position to line up its rails with the rails of the autoclave (as shown on the figure below).

- 2. Turn the handle (3) to the right.
 - The pin (4) will lock the transfer carriage to the chamber
- 3. Roll the loading cart into the chamber.
- 4. Turn the handle (3) to the left

Now the transfer carriage is released from the chamber.

- 5. Take the transfer carriage aside to let the door be closed.
- 6. Close the door.
- **Notes:** When loading the materials to be sterilized into the chamber, observe the rules described in this chapter. Do not overload the cart or the shelves as this can have adverse effects on the results of the sterilization and drying. Leave space between the packs or wrapped instruments to allow complete removal of air pockets in the air removal stage, and for free penetration of steam in the heating and sterilization stages.



Operating Instructions

8

8.1. Water Supply

If the autoclave is connected to external water supply, open the manual valves of the tap water supply and mineral-free water supply.

8.2. Turning on the Autoclave

- 1. Plug the power cord into the back of the autoclave and into the wall outlet (see the dirty side view).
- 2. Turn on the rocker switch (1), located on the left service door.





GS-2A 50125

3. When running the autoclave for the first time, set date and time (see 9.1 Quick Options Screen, Set Date and Time).

8.3. Starting a cycle

Load the autoclave properly (see 7)

Selecting the program is as follows:

- 1. Tap on the screen to wake up the system.
- 2. Check the Touch screen for any Stand by Error or Cycle Error messages.
- 3. If any messages appear on the Touch screen, take the Corrective Action recommended in 4.2.

The Touch screen is used to select sterilization programs. You can only select programs from the Touch screen if the autoclave door is open. Door open is shown

by the triangle symbol

	Unwrapped 13	4	🖡	
Program Selector Key	Not Ready		Temperature 040.8 [°C] Pressure	Status Alarm Flag
	Ster. Temp. Ster. Time 134.0 4.0	Dry Time 1	103.7 [kPa]	
	6/JUL/2016 10:55:31		Version: 3.0.2.106	

If the status alarm flag is yellow, it means that there are open alarms.

4. Tap on the alarm status flag to open the active alarms list. The Active Alarm screen appears.

	Active alarms
Date & Time	Error
15/MAY/2014 10:37:30	Mineral free water reservoir empty
e [

- 5. Make the necessary corrections.
- To select a sterilization program, tap the 'Program Selector Key' (top left-hand corner of screen, see the screenshot in step 3). The Program Select screens appear.
- **Note:** Screen program names in this manual are provided for illustrative purposes ONLY. The options available on your autoclave depend on its configuration and may differ from those shown in these illustrations.

Select program	
Unwrapped 134	
Wrapped 134	
Unwrapped 121	
Wrapped 121	
Prion 134	
Vacuum Test	
1 2	()

- To find the desired sterilization program, search through the screens by tapping or etc.. (Up to 8 pages are possible).
- 8. Open the door.
- 9. If open need to close the door and then re-open it, tap



The door will unlock, and you can pull it open again.

To re-close the door, repeat step 14.

- Note: You cannot select a new program while a program is running or if the door is closed.
- 10. To select a sterilization program from the list, tap the desired program.
- 11. Tap when done to return to Home screen.

The Autoclave Control Screen re-appears. Make sure that you selected the correct program. 12. If the autoclave is equipped with a printer verify that a paper roll is inserted in the printer. If not - insert as shown in 4.1.

Note: The program can only be changed when the door is open.

13. Push the door closed and hold it in that position for 10 seconds.

The door will automatically lock, and the Close Door message appears.

If the System Ready appears and the yellow flag turns green , it means that the autoclave is ready to run a cycle.

14.

15.

Тар

on the Autoclave Control screen to run the selected program.

A confirmation screen appears asking the user to approve starting a new cycle.



If you do not want to start the cycle, (for example to re-arrange the load), tap



During a running cycle, the screen displays the program name and number.



The alarms status flag appears on a green color background to indicate that a cycle is running.

8.4. Malfunctions (Stop by User or Controller)

If a malfunction occurs during a cycle run:

• The alarm status flag will display



The Alarm screen appears.

	Active alarms
Date & Time	Error
15/MAY/2014 12:20:04	High Pressure
•	
	e

The start button changes to The buzzer sounds 3 times. •



waiting for user confirmation.

- •
- The autoclave enters Abort Cycle sequence. •

If the reason for the alarm no longer exists, tap

to reset the alarm.

Warning! The load has not completed a sterilization cycle, therefore it is not sterile. Handle it as contaminated load
--

8.5. Cycle End

At end of a successful sterilization cycle there is a long buzzer sound and the Status shows



Tap the

to release the door locking mechanism.

The door locking mechanism will release only if these conditions are fulfilled:

- The chamber pressure is below 115 kPa, (2.1psig).
- There is no liquid in the chamber.
- The chamber temperature is below the END TEMP parameter.

Open the door and remove the sterilized material from the loading cart following the steps indicated in the 'Un-loading' paragraph.

Warnings! Loading or unloading of material from the chamber can only be done if the door is completely open. It is forbidden to put any part of the body inside the chamber whilst the door is closing. Do not operate the autoclave in the presence of dangerous gases and vapors. Verify that the pressure in the chamber is atmospheric pressure. Do not attempt to open the door if the pressure in the chamber is above atmospheric pressure.

Note: If cycle failed in a 2-door autoclave, only the front door can be opened.

		01 Unwrapped ir	nstruments	Run
		Starting		Temperature 040.5 [°C]
		Ster. Temp. Ster. Time 134.0 0.5		Pressure 099.8 [kPa]
Durina	a cycle the start	button becomes red	\bigcirc	
Duning				
1.	Tap 💙 to a	abort the cycle.		
Nata	The autoclave a The autoclave w the operator wh	automatically goes thro vill signal the operator ien the door can be op	bugh a shut that the cyc ened. (See	down seque cle has beer above)

8.6. Aborting a Cycle

Note: After aborting a cycle in a 2-door autoclave, only the <u>front door</u> can be opened.

Warning!

The load has not completed a sterilization cycle, therefore it is not sterile. Handle it as contaminated load.

Do not attempt to open the door until notified that the abort sequence is complete. If the controller does not indicate that the sequence is complete, do not attempt to open the door. Contact your Tuttnauer trained and certified autoclave technician.



Caution!

Warning!

Do not touch the strainer's cover, mounted on the exhaust line, during and short after operation.

Touching the hot strainer's cover may cause severe injuries

8.7. Ending the Cycle. Unloading

When the cycle has ended successfully (including the user pressing the START/STOP key after the sterilization stage has finished) the message "Cycle Ended" is displayed.

In the event of a failure, after completing the sterilization stage, the message "Cycle Ended" and the relevant failure message are displayed on the Touch screen.

Pressing the START/STOP key will clear the "Cycle Ended" message or any error message and unlock the door.

Verify that there is no pressure in the chamber, according to the reading on the 1. display, and that "System Ready" is displayed. Only then may the door be opened.

2. To release the door locking at the end of operation, tap the door button on the Touch screen (see 4.1). The same applies at power up after fail. Unlock the door properly. Open the door the minimum required to let the residual steam to escape from the chamber. Only after there is no vapor, open the door widely.



To avoid severe injuries from hot steam when opening the door: it is strictly forbidden to lean on the autoclave. It is strictly forbidden to place your hand or any part of your body over the door.

- 3. Let the load cool down for several minutes.
- 4. Maneuver the Transfer Carriage into position to line up the rails with the rails of the autoclave (as shown on the figure below).
- 5. Turn the handle (3) to the right. The pin (4) will lock the transfer carriage to the chamber.
- 6. Roll the loading cart out of the chamber and onto the transfer carriage.
- 7. Once the loading cart is firmly on the transfer carriage and locked into place, turn the handle (3) to the left, and take the transfer carriage aside to cool down.
- 8. Allow the load to cool down in an area with minimum passing traffic (to avoid the possibility of touching the hot load), and without air movement (air conditioning, etc.).



Note: Do not touch the hot load. Hot loads absorb moisture and may absorb bacteria from a hand. Do not transfer a hot load to metal shelves for cooling. Perform a visual inspection to ascertain that sterilizing indicators have made the required color change, and that the load is dry.

The load is to be rejected if:

- a The package has been compressed.
- b. The package is torn.
- c. The load is wet (water droplets signs).
- d. The load fell on the floor.
- e. Condense can be observed on the lid.
- f. The PCD or other indicator present Faulty cycle.



Warnings:

During loading and unloading use safety gloves and glasses in accordance with local safety regulations and good practice.

Do not operate the autoclave in the presence of dangerous gases and vapors. It is strictly forbidden for any person, to enter the service area behind the services panels except trained technician. If for any reason it is necessary to open the service panel, the person must shut the system by pressing the emergency switch, withdrawing the key and keeping the key on him, to prevent accidents and injuries. The sterility of the instruments processed in unwrapped cycles cannot be maintained if exposed to non-sterile environment. Don't touch the strainer's cover, mounted on the exhaust line, during and shortly after operation. It will get very hot. To avoid severe injuries from hot steam when opening the door, it is strictly forbidden to lean on the autoclave or to place your hand or any part of your body over the door.

9. At the end of each working day close the main water valve.

8.8. Stopping the Process due to Cycle Failure

- The cycle can stop itself if the unit detects a problem
- If the cycle is aborted prior to completing the sterilization stage, a yellow caution screen is displayed with a caution symbol, the message "Cycle Failed", and an error message explaining the reason for the failure.
- Pressing the START/STOP key cancels the displayed message and unlocks the door so it can be opened.



Warning: The load has not completed a sterilization cycle, therefore it is not sterile. Handle it as contaminated load.

9

Checking and Changing Parameters

9.1. Quick Options Screen: Touch Screen

The autoclave controller offers quick options for the operator.

- 1. Extra Dry Time.
- 2. Export to USB Options.
- 3. Print Cycles.
- 4. Version Information.
- 5. Set Date and Time.
- 6. Start Cycle by Clock.

The **Quick options** menu is available without the need to login.

From HOME SCREEN menu tap

to display the 'Quick options' menu screen.

	Quick options	
	Add extra dry time	
	Export options	
	Print cycles	
	Version information	
	Set date and time	
	Start cycle by clock (Disabled)	
ก		۲

Extra Dry Time

Add extra dry time option is displayed only for programs that have a 'Dry time' parameter value greater than '0'.

To add	extra	dry	time	tap

Add extra dry time...

The Add extra dry time screen appears.

	Add dry time	
e	0	c 20
r	5	° 25
c	10	° 30
r	15	
ก	Set	*

1. Select the desired extra dry time.



Export Options

The Export menu offers the user options to export to a USB device. (User should first connect a USB device to the autoclave USB socket).

Export application

Exports the machine current software application to an attached USB device. A folder named "Application / New" will be created on the USB device, containing all the "dll" and "exe" files of the application.

Export settings

Exports the gain and offset of the machine. 2 folders named "Current" and "FactoryDefault" will be created on the USB device.

Export logs

Will create a folder named "Logs" on the USB device, containing "CfrPart11Log.txt" file (just in case system parameter 'Support CFR part 11' is not 0).

Export history

To export to a USB device tap

Exports data history of the last cycles run on the machine. User can choose to export all cycles, or last 10/50 Cycles. A folder named "History" on the USB device will be created. Two files are created for each cycle:

- cycle_[#].cyc
- cycle_[#].txt.

Export options...

The Add Export options screen appears.

	Export options	
	Export application	
	Export settings	
	Export logs	
	Export history	
	ୁ Last 10 cycles	
	ି Last 50 cycles	
	 All cycles 	
A	Start	1

1. Select the desired Export option.



Note: If the USB is plugged out during the export process – "File copy error" message will be displayed.

Print Cycles

The Print cycles menu sends to the machine printer cycle history reports for the last 10 cycles, 50 cycles, or all cycles.

	To print cycles tap
	The Print cycles screen appears.
	Print cycles
	∝ Print last cycle
	⊂ Print last 5 cycles
	⊂ Print last 10 cycles
	Start 🔮
1.	Select the desired Print cycle option.
2.	Tap
2	
э.	
4.	Tap Example to return to Home screen.

Version Information

This screen gives information about the current software version installed in the machine controller. It includes:

- Control system application.
- OS (Operating System).
- Cycle parameters checksum (Cycle checksum changes when a specific cycle parameter value is changed).

- System parameters checksum (System checksum changes when a specific system parameter value is changed).
- Serial number of the machine.

Version information...

To view Version information tap **EVEN** The Version information screen appears.

	Version information
	Serial number: 14031500
	Model Name: 6191197 2A SPBH
	Main card ID: 0
	IO card ID: 1 (Version 7.3)
	Cycle parameters checksum: 477263
	System parameters checksum: 26475
	Application: 3.0.0.5, 3302400 bytes 12/FEB/2015
	OS version: 6.1.7601.65536,Win32NT
	fi 🔮
1.	Tap to return to Quick options menu screen.
2.	Tap to return to Home screen.

Set Date and Time

Note: Date and time setting is one of the preconditions to run a cycle. This screen allows the user to set up the **Date** and the **Time** on the machine. The operator should perform **set Date and Time** when turning the machine on for the first time.

To set date and time tap Set date and time..

The set date and time screen appears.

	Set date and time	
I Date:	Day Month Year 14 / 5 / 2014	
H Time:	Hour Minute Second 7 : 58 : 7)
	14/MAY/2014 07:58:08	
F	Set	1

- 1. The Date is displayed in "DD: MM: YYYY" format.
- 2. The **Time** is displayed in the "**HH:MM:SS**" format. The hour range is 24 hours (i.e. from "0" to "23").]
- 3. Fill the current **Date and Time**
- 4. Tap Set to update.
- **Note:** If invalid date is entered, an error message will be displayed. Setting time from one screen should update the PLC and the screen on the other side of the autoclave as well, (for a two door autoclave).



Start Cycle by Clock

The operator can set the machine to start a cycle automatically at a pre-defined hour. Cycle will auto start on the time set only if conditions are available to start cycle. **Note:** Selecting another cycle is not allowed while 'Start cycle by clock' is enabled.

To Start Cycle by Clock tap

Start cycle by clock...

The Start Cycle by Clock screen appears.

	tart cycle by clock	
⊂ Enabled ∉ Disabled Start time:	Hour Minute	
ก	Set	%

- 1. The hour is displayed in "HH:MM" format. The hour range is 24 hours (i.e. from "0" to "23).
- 2. Set the required time you want to start the auto run.
- 3. Check Enabled.
- **Note:** An error message will be displayed on attempt to set invalid data: (hour > 23) or (minutes >59).

Disabling the 'Start cycle by clock' will return the system to normal state.



1. On the main screen, tap the Log in button (1)

1	01 Unv	vrapped 13	34	
	System Rea	ady		Temperature 040.8 [°C]
	Ster. Temp. 134.0	Ster. Time 4.0	Dry Time 1	Pressure 103.7 [kPa]
	11/JUL/2016 15:03:58		Open	Version: 3.0.2.106

The login screen will appear (see below).

	Login	
Name:		
Password:	****	
	Login	
	New user	
	HMI settings	
		1

2. On the login screen, enter your name (Admin is the default), and the password (0001 is the default), then tap the Login icon.

You will see the main menu screen (Admin version, see below).

Main menu	
Cycle parameters	
System parameters	
Maintenance	
Logout	

Note: If user already logged in, pressing will open the main menu screen.

9.3. **System Parameters**

This directory includes three subdirectories:

- Print Rate All
- Print Rate Sterilization
- Screen Saver •

Screen saver

Screen Saver—System parameter

Screen Saver parameter defines the time to wait before activate screen saver. 0 - screen saver is disabled.

Set parameter					
Min value: 0.	.0 min	Current value: 90.0 min			
Max value: 600.0 min					
Default value: 9	0.0 min				
Description: Time to wait before active	ate screen saver. 0 - se	creen saver is disabled			
	90				
f	Set				

Range 0-600 minutes Default 90 minutes

9.4. Maintenance

From Main menu screen, the Technician can enter the Maintenance menu. The available sub menus: Handle Counters Printer Test

Handle counters—Reset Atmospheric Pressure

The screen Handle counters offers the user the option to reset a counter from list of counters.

	Reset counters	
	Reset cycle counter	
	Reset bio hazard counter	
	Reset service time	
	Reset atmospheric pressure	
A		1

To reset the atmospheric pressure: Leave the door open for 2 minutes at least Ambient temperature should be less than 45°C.

Note: The atmospheric pressure should be reset when installing the autoclave for the first time, or after relocating, or calibrating the autoclave.

10

Maintenance Instructions

10.1. Preventive and Scheduled Maintenance

The maintenance operations described in this chapter need to be followed as indicated to keep the device in good working condition.

The instructions that follow can easily be carried out by the operating personnel and do not require a service technician.

Note: Technician manual describes the maintenance operations required from qualified technician, every two months and once a year. Should the need arise, technical assistance or a service technician can be requested by calling your dealer.

Daily

• Clean door gasket with a mild detergent, water and a soft cloth or sponge. The gasket should be clean and smooth.

Weekly by the operator

- Empty and refill the vacuum pump reservoir.
- Put a few oil drops on the 2 door pins and door tightening bolt.
- Clean the outer parts of the autoclave with a soft cloth.
- Clean and descale the chamber.

Periodically by the operator

- Once per month clean the water outlet strainer (see 10.3). Cleaning frequency may be reduced according to experience.
- Check the door gasket every 12 months and replace it if required (seeTechnician manual).
- Replace the air filter, every 6 months or after 1000 cycles (whichever comes first) according to sec. 12.3.

10.2. Cleaning the Water Outlet Strainer (GS-2A 5075 only)



Before proceeding, Make sure that the electric cord is disconnected and there is no pressure or water in the chamber.

Warnings!



1. The strainer's cover is HOT

Do not touch the strainer's cap, mounted on the exhaust line, during and shortly after operation. Touching the hot strainer's cap may cause severe injuries.

2. If maintenance operation is performed while strainer cap is hot, use heat resistant gloves to avoid injuries.

- 1. Open the strainer cap.
- 2. Remove the strainer element.
- 3. Rinse the strainer with water, using a brush if necessary.
- 4. Reinstall the strainer element.
- 5. Close the strainer cap.



10.3. Replacing the HEPA Air Filter (GS-2A 5075 only)

Caution!

Before proceeding, make sure that the electric cord is disconnected and there is no pressure in the autoclave.

The HEPA filter is located on the back of the autoclave. (See "Dirty" Side View).

- 1. Pull out the filter cover. The filter cover is held in place by plastic tabs. Rotate the cover until the tabs release, the cover will come off and the filter will come out.
- 2. The filter and cover are pressed together. Place two fingers between the filter and the cover and while supporting the cover pull the filter and cover apart.
- 3. Insert a new filter by pressing it into the filter seat.
- 4. Replace the filter cover.
- **Note:** make sure that the arrow on the filter body points inwards, toward the chamber. Make sure that you don't bend the filter pipe when reattaching the cover.



Note: It is recommended to replace the HEPA filter, every 6 months or after 1000 cycles (whichever is the shorter period).

11 Troubleshooting

Only technical personnel having proper qualifications and holding technical documentation (including a technician manual) and adequate information are authorized to service the apparatus.

Problem/ Error Message	Message / Symbol Description	Corrective Action
Display is not activated	The main switch is in the off position. The power cord is not connected properly to the machine and the power source. There is no electrical power in the main source.	Turn the main switch on. Make sure the power cord is properly connected to the machine and the power source. Fix the electrical power supply.
The printer does not print, or it prints, but nothing is printed on the paper	The paper is not inserted correctly in the printer.	Make sure the paper is inserted in the printer correctly. See 4.1, Printer handling Switch the machine off then back on. If the printer prints the date and time, the printer is O.K.
"Chamber temperature not in range"	This message is displayed if the temperature in the chamber is too high or too low from the normal range.	Wait until the the chamber reaches the normal range temperature.
"Chamber pressure not in range"	This message is displayed if the pressure in the chamber is too high or too low from the normal range.	Wait until the the chamber reaches the normal range pressure.
"RTC Error - Please Set Current Date and Time"	This message is displayed in order to set the date and the time.	Set Current Date And Time. If the problem persists, call the technician.
"Door is open (During the cycle)"	This message is displayed when the door is open: During the cycle.	Close the door to perform a new cycle.
"Canceled By User"	This message is displayed after the START/STOP key is pressed and cycle aborted.	Wait until "cycle failed – canceled by user" or "cycle end – canceled by user" is displayed. Perform a new cycle.
"Air Error"	This message is displayed at the end of the cycle If the autoclave does not reach the atmospheric pressure after 10 minutes.	Wait until the autoclave reaches the atmospheric pressure and perform a new cycle.
"Power Down"	This message is displayed if power down has occurred during the cycle. (this message will print out in the printer after the autoclave will turn on).	Turn on the autoclave and wait until the autoclave is ready (reaches the safe condition) and perform a new cycle.

The following messages require you to check that your autoclave is not overloaded:

- "Heat Time Error"
- "Heat Time Error (Keep)"
- "Pressure Time Error"

The following messages require you to perform a new cycle:

- "Low Temp"
- "High Temp"
- "Low Pressure"
- "High Pressure" "
- "High Pressure (Ending)"
- "High Pressure (Exhaust)"
- "High Pressure (Dry)"

- "Pressure Time Error"
- "Cycle Failed"

The following messages require you to call for service:

- "Analog Input Error"
- "Time Error"
- "Periodical check time exceeded Please call for service"
- "Cycle counter exceeded Please call for service"

The following messages require you to turn the autoclave off and on again, and if the problem persists, to call for service.

- "I/O Card Failed"
- "I/O card is not connected"

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