

OPERATOR MANUAL

Pre-vacuum Steam Heated Autoclave with one Vertical Sliding Door & with a prep. for Sussman Generator

Model L5596-1V-EP (5596 ECP-V)

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Safety Instructions

The autoclave has unique characteristics. Please read and understand the operation instructions provided by the manufacturer before the first operation of the autoclave. The following issues may require clarification: The operation of the autoclave; the door safety mechanism; the door closing mechanism; the dangers involved in circumventing safety means; and finally, the selection of an appropriate sterilization program.

Make sure that you know the placement of the main power switch, the position of the water cut-off valve, and where the steam and compressed air disconnection valves are located.

Autoclave maintenance is crucial for the correct and efficient function of the device. We recommend a daily B&D test and the weekly spore test as part of the preventive maintenance plan, along with the annual validation of the sterilization processes that ensures appropriate temperature dispersion within the chamber.



Only use the autoclave for products approved for sterilization in an autoclave. Never use the autoclave to sterilize corrosive products or chemicals, such as: acids, bases and phenols, volatile compounds or solutions such ethanol, methanol or chloroform nor radioactive substances.

Safety Operating Instructions:

- 1. NEVER start a new autoclave or a new steam generator, before the safety, licensing, and authorization department, has approved it for use.
- 2. All autoclave users must receive training in proper usage from an experienced employee. Every new employee should undergo a training period under an experienced employee.
- 3. A written procedure should be established to ensure safe autoclave operation, including: Daily safety tests; seal inspection and door hinge inspection; smooth action of the closing mechanism; chamber cleaning; prevention of clogging; preservation from corrosion; and finally, what is permitted and what is prohibited for sterilization and choosing a sterilization program.
- 4. If there is a steam generator drain it daily.
- 5. If there is an air compressor drain it daily.
- 6. Before use, check inside the autoclave chamber to ensure that no items have been left from a previous cycle.
- 7. Before loading the autoclave, clean the strainer on the chamber floor.
- 8. Load trays in such a way as to allow steam to move freely among all items.
- 9. Liquids may be sterilized only with the "liquids" program. The container must be covered but not sealed. Sealed bottles may only be sterilized using a special program. The container must be able to withstand the pressure and temperature of the autoclave.
- 10. 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.



- Individual glass bottles may be placed within an appropriate container that will be placed on a tray. Never place glass bottles on the floor of the autoclave. Never fill more than ²/₃ of the bottle volume.
- 12. On closing the autoclave door, make sure that it is properly locked before starting a cycle.
- 13. Verify once again that you have chosen the appropriate sterilization program.
- 14. Before withdrawing trays, wear heat resistant gloves.
- 15. Before opening the door, verify that there is no pressure in the chamber (chamber pressure gauge is located on the autoclave's front panel).
- 16. Open the door slowly to allow steam to escape and wait 5 minutes before you remove the load. When sterilizing liquids, wait 10 minutes, or until the temperature reaches 5° C above atmospheric temperature.
- 17. Once a month, ensure that the safety valves are operating.
- 18. Once annually, or more frequently, effective tests must be performed, i.e., calibration and validation.
- 19. Check the condition of assemblies on a regular basis. Make sure there are no leaks, breaks, blockages, whistles or strange noises.
- 20. Perform maintenance operations as instructed.
- 21. Notify the person in charge immediately of any deviation or risk of proper function of the device.
- 22. It is strictly forbidden for any person to enter the autoclave's chamber. If, for any reason (for cleaning, maintenance or if something falls down), it is necessary to enter the chamber, the person must lock and take the key out of the system, keeping the key on him, and shut OFF all utilities, (steam, water, compressed air, and electricity), to prevent accidents and injuries.

Instructions for Contaminated Waste

- 1. Verify that the contaminated waste at the sterilization station is packed in the correct bags/containers.
- 2. Verify that there are no leaks and that the package is correctly marked.
- 3. Large containers with a narrow spout may "behave" like a sealed bottle.
- 4. It is preferable to sterilize solutions in small containers rather than in differentlysized containers or in large containers.
- 5. It is recommended not to stand in front of the door when it opens, because steam may be discharged when the door is opened.
- 6. It is recommended to support sterilization bags at the bottom especially when they are hot.

Attention:

IF THE UNIT IS USED IN MANNER NOT SPECIFIED BY THE MANUFACTURER, THE PROTECTION PROVIDED BY THE EQUIPMENT MAY BE IMPAIRED.

KEEP THE DOOR CLOSED DURING THE DAY OR SHIFT. WHEN THE AUTOCLAVE IS NOT OPERATING, AT NIGHT OR ON THE WEEKEND, LEAVE THE DOOR OPEN.



Symbol Description

Symbol	Description
	Caution! Consult accompanying documents
	Caution! Hot surface.
	Caution! Hot steam.
	Protective earth (Ground)



1. GENERAL DESCRIPTION

1.1 Introduction

This autoclave is a sterilizer designed to cover a large field of applications for hospitals and medical centers as well as pharmaceutical and biotechnological industries.

The autoclave operates with saturated steam as the sterilizing agent, and has a temperature range of up to 279° F, (137° C), and pressure up to 34 psi, (2.3 bar).

The autoclave is equipped with an "Emergency Stop" push-button and key lock, mounted on the front panel. This feature is designed to prevent hazards to humans, and accidents due to equipment breakdown in compliance with the European standards EN-285 requirements.

When the emergency switch is activated, the key must be used to allow the switch to return to the operating position.

This autoclave is equipped with one vertical sliding door, operated by two hydropneumatic cylinders mounted laterally on both sides of the door. Each cylinder contains an integrated and separated oil system. The operation of the cylinders is performed by air pressure and the oil system acts as a speed control system. An adjustable restrictor controls the flow of oil from one side to the other side on each cylinder, controlling the speed movement of the door.

The touch screen and printer are installed on the Front Panel.

The sealing of the chamber is achieved through a heat resistant silicone gasket, located in a groove around the door opening of the autoclave.

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.
- A door cannot be opened at the end of the cycle if, the chamber temperature is higher than the preset final temperature, or

The electronic circuitry and software programming of the programmable control system are designed to operate 10 sterilization programs. In addition there are two test programs: Bowie & Dick Test and the Leakage Test.

The control system of the sterilizer is based on microcomputer technology, ensuring a highly reliable and safe operation. The computerized control unit ensures a fully automatic operation through the entire cycle; hence, after setting the pre-selected parameters and starting the operation, no further operator intervention is necessary.

The autoclave has an automatic shutdown system. If there are no operations for four hours, the autoclave goes into SLEEP mode.

The selected program, the main phases of the cycle and the status of the machine are controlled and displayed on digital readouts. For process documentation, the important information concerning operation is printed.

The Remote PC Reporting application, (R.PC.R), is used to generate Data and Trends reports on cycle data. This application is described in the separate manual provided.



Note:

The Touch Screen is manufactured from sensitive material. Press gently with a finger or use a special stylus. Do not use a fingernail or any other sharp implement to operate the Touch Screen.

Caution!

Do not operate the autoclave in the presence of dangerous gases and vapors.

It is strictly forbidden to enter the autoclave chamber!

If, for any reason (for cleaning, maintenance or if something falls down), it is necessary to enter the chamber, the person must lock the system by pressing the emergency switch and take the key with him to prevent accidents and unauthorized use.

Warnings!

Do not operate the autoclave in the presence of dangerous gases and vapors.

It is strictly forbidden to enter the autoclave chamber!

It is strictly forbidden for any person to enter the service area behind the service access panels, except the trained technician.

If, for any reason it is necessary to open the service access panel, the person must shut the system by pressing the emergency switch, withdrawing the key and keeping the key on him, and shut OFF all utilities, (steam, water, compressed air, and electricity), to prevent accidents and injuries.

The technician must follow the instructions in the SERVICE INSTRUCTIONS, "Working with power ON in Service Area" Section.



1.2 Front Panel

The operation and controlling of the autoclave is performed through the Touch Screen.

An Emergency Stop push-button incorporated with a key lock is installed on the front panel and is designed to prevent hazards to humans, and accidents or equipment breakdown.

The Service Access Door on the lower part of the Rear panel enables service under the chamber.



Legend:

- 1. Pressure Gauges
- 2. Touch Screen
- 3. Printer
- 4. Emergency STOP Switch
- 5. Chamber Door
- 6. Service Access Panel



2. PRINTER

2.1 Printer Output

The autoclave is equipped with a character printer, which prints a detailed history of each cycle performed. (This can be used for the record or 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 Name:
- 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, as shown in the table on the next page.

The data is printed 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").

For an example of a typical printout, see next page.



Date: 23/JUN/2019 Time: 12:24:45 Ser. Num: 14110412 Model: 5596 - 1V-SP Version: 2 Cycle Num: 000001 Bowie and Dick Ster. Temp. 134.4 °C Ster. Time 10.0 min* Dry Time 15 min* End Temp: 134.4 °C °C kPa Time A 00:00: 09 039.7 103.9 A 00:00: 10 040.7 103.9 A 00:00: 11 040.7 103.5 A 00:00: 37 043.1 164.8 A 00:03: 37 088.0 074.5 A 00:06: 37 078.6 047.6 A 00:09: 37 077.6 035.2 A 00:12: 37 077.2 026.2 A 00:13: 11 077.2 024.5 A 00:14: 18 099.3 160.6 A 00:16: 20 074.3 021.9 A 00:17: 12 112.1 161.0 A 00:18 : 37 073.2 021.5 A 00:19: 28 112.9 160.9 A 00:20: 54 070.7 020.9 H 00:21: 44 113.1 161.0 H 00:24: 44 133.9 294.4 H 00:25: 38 135.7 308.8 CLK 1: 12:50:25 CLK 2: 12:50:24 S 00:25: 40 135.8 309.4 S 00:26: 40 136.5 314.8 S 00:27: 40 136.5 315.0 S 00:28: 40 136.5 314.8 S 00:29: 40 136.5 315.2 S 00:30: 40 136.6 315.0 S 00:31:40 136.6 315.1 S 00:32: 40 136.7 315.8 S 00:33: 40 136.6 315.2 S 00:34:40 136.6 315.1 S 00:35:40 136.6 315.5 S 00:35:40 136.6 315.8 CLK 1: 13:00:25 CLK 2: 13:00:25 E 00:35:41 136.6 315.8 E 00:36:36 108.1 107.9 D 00:36:36 108.1 107.9 D 00:39:36 093.9 003.6 D 00:42:36 093.2 003.1 D 00:45:36 087.0 003.1 D 00:48:36 079.5 003.1 D 00:51:36 073.3 003.1 D 00:51:41 073.1 003.1 00:51:45 073.0 003.1 00:52:49 071.7 095.5 Status: Test Ended Time: 13:17:35 Operator: _

Legend

- A Air removal stage (Pulse L & Pulse H)
- H Heating stage
- S Sterilization stage
- E Exhaust stage
- W Water Filling
- D Drying stage
- CLK1 Real Time Clock
- CLK2 Software clock
- F Steam Flush



2.2 Printer Handling

Maintenance

Wipe off any dirt 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 cover door (3) by pulling it at the left bottom corner (2)
- 2. Press the OPEN key to open the printer cover as shown (see Fig. 2/1). Handle the paper cutter jagged edge carefully to avoid cutting your hand.
- 3. Place the paper roll making sure it unrolls in the proper direction as shown (see Fig. 2.2).
- 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. 2/3) the printer cover is locked.
- 6. Tear off the exceeding paper using the paper cutter jagged edge (see Fig. 2/4).





Fig. 2

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

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.

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 printer 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.



3. STERILIZATION PROGRAMS

Cycles Parameters: Gravity 1

- Sterilization temperature 250° F
- Sterilization time 15 minutes
- Dry time 2 minutes

Cycles Parameters: Gravity 2

- Sterilization temperature 250° F
- Sterilization time 15 minutes
- Dry time 2 minutes

Cycles Parameters: Gravity 3

- Sterilization temperature 275° F
- Sterilization time 4 minutes
- Dry time 2 minutes

Cycles Parameters: Gravity 4

- Sterilization temperature 273° F
- Sterilization time 4 minutes
- Dry time 2 minutes

Cycles Parameters: Pre-Vacuum 1

- Sterilization temperature 250 F
- Sterilization time 15 minutes
- Dry time 30 minutes

Cycles Parameters: Pre-Vacuum 2

- Sterilization temperature 250 F
- Sterilization time 20 minutes
- Dry time 30 minutes

Cycles Parameters: Pre-Vacuum 3

- Sterilization temperature 250 F
- Sterilization time 30 minutes
- Dry time 30 minutes



Cycles Parameters: Pre-Vacuum 4

- Sterilization temperature 270 F
- Sterilization time 10 minutes
- Dry time 30 minutes

Cycles Parameters: Liquid 1

- Sterilization temperature 250 F
- Sterilization time 15 minutes

Cycles Parameters: Liquids 2

- Sterilization temperature 250 F
- Sterilization time 20 minutes

Cycles Parameters: Liquid 3

- Sterilization temperature 250 F
- Sterilization time 30 minutes

Cycles Parameters: Liquids 4

- Sterilization temperature 250 F
- Sterilization time 45 minutes

Cycles Parameters: Vacuum Test

Cycles Parameters: Bowie and Dick

- Sterilization temperature 274° F
- Sterilization time 3.5 minutes
- Dry time 2 minutes



4. PREPARATION BEFORE STERILIZATION

Warning!

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

Instruments to be sterilized must be clean, free from any residual matter, such as debris, blood, pads or any other material. Such substances may cause damage to the contents being sterilized and to the sterilizer, and prevent sterilization.

1. Wash instruments immediately after use, to dispose of any residue. Follow manufacturer's instructions on the use of instruments/washing etc., for cleaning and lubricating. Before placing an instrument into the sterilizer tray, make sure that instruments composed of different material-types (stainless steel, carbon steel, etc.) are separated and placed in different trays.

Note:

Check manufacturer instructions for sterilization of each item.

In General

- 1. If carbon steel instruments are used with stainless steel trays, the tray should be lined with a towel or paper wrap before placing the instrument. There should be no direct contact between the carbon steel and the stainless steel trays.
- 2. Biohazard material, chemicals, agar solutions or any others aggressive materials that can damage the 316 stainless steel chamber must be placed in bags or containers to avoid spill to the chamber. In an event of contact, the chamber must be cleaned or passivated to maintain proper condition of the chamber.
- 3. Before placing an instrument into the sterilization tray, make sure that carbon steel instruments are not in contact with stainless steel instruments. These instruments should be separated and placed in different trays.
- 4. All instruments must be sterilized in an open position.
- 5. Place a sterilization indicator strip in each tray.
- 6. Once a week use a biological spore test indicator in any load to ensure sterilization.
- 7. Make sure that all the instruments remain apart during the sterilization cycle.
- 8. Empty canisters should be placed upside-down in order to prevent accumulation of water.
- 9. Do not overload sterilizer trays. Overloading will cause inadequate sterilization and drying.
- 10. Allow a distance of approximately 25 mm, (1"), between trays to permit circulation of steam.
- 11. Wrapped instruments should be packed in material which promotes drying, such as: Autoclave bags, autoclave paper and muslin towels.



Note:

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).

4.1 Loading

Note:

Liquids can only be sterilized in an autoclave with two temperature sensors in the chamber.

Every machine is supplied either with two (or more) stainless steel shelves, or with rails for loading a loading cart from transfer carriage.

The transfer carriage is made of stainless steel and comes with adjustable legs to balance the height of the loading cart to rails in the sterilizer chamber. The cart 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. The two castors on the rear of the carriage are equipped with brakes. When the transfer carriage is put in position for loading or un-loading the cart from the autoclave, the brakes must be applied.



It is strictly forbidden to load or un-load the loading cart, if the transfer carriage is not connected by the hooks to the autoclave, and the brakes are not applied.

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.





4.2 Un-loading

- 1. When the buzzer signals the successful completion of a cycle, open the door and let the load cool down for several minutes.
- 2. Maneuver the Transfer Carriage into position to line up the rails with the rails of the autoclave, lock the two locking wheels.
- 3. Remove the loading cart (or the containers) onto the Transfer Carriage and place aside to cool down.
- 4. 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.). Do not touch the hot load. Hot loads absorb moisture and may absorb bacteria from the hand.
- 5. 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.



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 autoclave's chamber.

If, for any reason (for cleaning, maintenance or if something falls down), and it is necessary to enter the chamber, the person must shut the system by actuating the emergency switch and withdraw the key from the system, keeping the key on him, to prevent accidents and injuries.

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 technician must follow the instructions in the SERVICE INSTRUCTIONS "Working with power ON in Service Area" section



5. OPERATING INSTRUCTIONS



Do not operate the autoclave in the presence of dangerous gases and vapors.

Emergency Stop Push-Button in cooperative with key lock mounted on front panel switches OFF the autoclave operation.

When emergency switch is activated, the key must be used to allow the switch to return to the operating position.

Note:

The Touch Screen is manufactured from sensitive material. Press gently with a finger or use a special stylus. Do not use a fingernail or any other sharp implement to operate the Touch Screen.

5.1 Quick Options

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 press to display the 'Quick options' menu screen.



Extra Dry Time

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

To add extra dry time press

Add extra dry time...



The Add extra dry time screen appears.

		Add dry time		
	۰ 0		ି 20	
	∘ 5		° 25	
	ି 10		് 30	
	ୁ 15			
				_
ก		Set		1

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

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 To export to a USB device press

The Add Export options screen appears.



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 press



The Print cycles screen appears.



Select the desired Print cycle option. 1.





to return to Quick options menu screen. 3. Press Press

Version Information

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

to return to Home screen.

It includes:

4

- Control system application. ٠
- OS (Operating System).
- Cycle parameters checksum (Cycle checksum changes when a specific ٠ 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 press

The Version information screen appears.



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.

Set date and time To set date and time press



The set date and time screen appears.

	Set date and time	
Date	Day Month Year	
-	Hour Minute Second	
Time:	7 : 58 : 7	
	14/MAY/2014 07:58:08	
A	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. Press 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).

- 5. Set the desired time and date.
- Press Set
 Press to return to Quick options menu screen.
 Press to return to Home screen.

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 press Start cycle by clock...



The Start Cycle by Clock screen appears.

Start cycle by clock	
⊂ Enabled	
Set	1

- 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.

- 4. Press set to Enable 'Start cycle by clock'.
- 5. Press

to return to **Quick options** menu screen.

6. Press **b** to return to **Home** screen.



5.2 User Login

Tuttnauer Press screen to wake up

If the control is in sleep mode, this screen appears

1. Tap on the screen to wake up the system.

The Autoclave Control screen appears.

Bacsoft Touch Screen Simulator			
01 Por	ous 134		
Not Ready			Temp. 1 046.6 [°C]
Ster. Temp. 134.0	Ster. Time 5.0	Dry Time 1	044.9 [°C] Pressure 099.3 [kPa]
18/FEB/2015 11:15:08			Version: 3.0.0.5



5.3 Starting the Autoclave

Check the Touch Screen for any Stand by Error or Cycle Error messages.

If any messages appear on the Touch Screen, take the Corrective Action recommended in the "BACSOFT ERROR MESSAGES" section.

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

	Bacsoft Touch Screen Simulator	ous 134		•	
Program Selector Key	Not Ready			Temp. 1 046.6 [°C]	Status Alarm Flag
	Ster. Temp.	Ster. Time	Dry Time	044.9 [°C]	
	134.0	5.0	1	Pressure 099.3 [kPa]	
	18/FEB/2015 11:15:08			Version: 3.0.0.5	

The Yellow status alarm flag means there are open alarms.

1. Press 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
•	m
	1

- 2. Make the necessary corrections.
- 3. To select a sterilization cycle, tap the 'Program Selector Key' (top left-hand corner of screen).

Note:

If you change from a 134° C program to a lower temperature program, for example a 121° C program, you need to wait for the jacket to cool down and reach a pressure between 160–180 kPa. If you don't wait, you will get FAIL message.

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 instruments	
Wrapped instruments	
Unwrapped delicate instr	
Wrapped delicate instrum	
Prion	
Vacuum Test	
1 2	1

- 4. To find the desired sterilization cycle, search through the screens by tapping 1 2 or 3. (Up to 8 pages are possible).
- 5. Open the door.

Note:

Make sure that you select the correct cycle.

You cannot select a new program while a program is running.

You cannot select a new program if the door is closed.

- 6. To select a sterilization cycle from the list, tap the desired program.
- 7. Press



when done to return to Home screen.

The "Autoclave Control Screen" re-appears.

Make sure that you selected the correct cycle.



- 8. Load the autoclave following the steps indicated in the 'Loading' paragraph.
- 9. For liquid loads, choose the two containers that contain the most liquid, and insert the two flexible temperature sensors into both of them.



CLOSE

The door will close after you tap

Keep tools, hands or any other body parts clear of the door while the door is closing!



The door will close automatically and the Open Door message appears.

11. To re-open the door for any reason, tap

The door will open.

12. To re-close the door, repeat step 10.

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

13. Press 🥙 on the Autoclave Control screen to run the selected cycle.

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

		Start Cycle?
		Yes
14.	Press	to start the cycle.

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

No



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



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



5.4 Malfunctions (Stop by User or Controller)

If a malfunction occurs during a cycle run:

• The alarm status flag will display

Porous 134		Fai
Pulse L		Temp. 1 046.6 [°C]
Ster. Temp. Ster. Time 134.0 5.0	Dry Time 1	044.9 [°C] Pressure 099.3 [kPa
18/FEB/2015 11:22:06		Version: 3.

• Press or Fail to see the status alarm.

The Alarm screen appears.

	Active alarms
Date & Time	Error
15/MAY/2014 12:20:04	High Pressure
	m ,
	e 🖉 👘

The start button changes to

waiting for user confirmation.

- The buzzer sounds 3 times.
- The autoclave enters ABORT CYCLE sequence.

If the reason for the alarm no longer exists, tap



to reset the alarm.



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



5.5 Cycle End

At end of a successful sterilization cycle there is a long buzzer sound and the Status shows not and Please Confirm are displayed.



1. Tap V to release the door locking mechanism.

An "OPEN" message appears on the door icon.

2. Tap to open the door.

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



Loading or unloading of material from the chamber can only be done if the door is completely open and in the lowest position.

It is forbidden to put any part of the body inside the chamber whilst the door is closing.

It is strictly forbidden for any person to enter the autoclave's chamber.

If, for any reason (for cleaning, maintenance or if something falls down), it is necessary to enter the chamber, the person must shut the system by actuating the emergency switch and withdraw the key from the system, keeping the key on him, and shut OFF all utilities, (steam, water, compressed air, and electricity), to prevent accidents and injuries.

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 <u>front door</u> can be opened.



5.6 Aborting a Cycle

During a cycle, the screen displays the program name "Unwrapped instruments" and the program number.

The alarms status flag running.

A cycle stage is also displayed according the cycle progress.

Aborting a Cycle

During a cycle the start button becomes red



to abort the cycle.

The autoclave automatically goes through a shutdown sequence.

The autoclave will signal the operator that the cycle has been aborted and will advise the operator when the door can be opened. (See above)

Note:

1.

After aborting a cycle in a 2-door autoclave, only the front door can be opened.

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.

Warning!

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



6. MAINTENANCE OF AUTOCLAVE

6.1 **Preventive and Periodical Maintenance**

		1. Clean the strainer at the bottom of the chamber.
	Before each	2. Verify that the door gasket and the surface that the gasket is
	cycle	pressed on are clean.
		3. Keep the door closed between sterilizing cycles.
		1. Clean the door gasket every day with a soft cloth.
		2. Before the first operation of the day, if the autoclave was disconnected from power and not in STANDBY mode, start the autoclave and warm up the jacket for <u>at least 20 minutes</u> with the door closed. Even if READY messages appear, disregard them.
		3. Keep the door closed between sterilizing cycles.
	Daily	4. Carry out a BOWIE & DICK test at the beginning of each day after warm up.
		5. Drain the compressor tank before starting operation (if applicable).
		6. If sterilizing liquids, clean the chamber at the end of every day.
j.		7. At the end of the day leave the door open.
Use		8. Inspect the sight glass gauge of the generator for chips, scratches, cracks, nicks, or any other visible sign of damage.
		 Clean the cabinet and door parts, the internal walls of the autoclave, the shelves and the shelf rails with a soft cloth and household detergent. Clean the chamber while the autoclave is cold. The detergent shall be flushed away with water. If you used tap water, for the final flush use distilled or mineral-free water.
	Weekly	Caution!
		Do not use steel wool or steel brush as this can damage the chamber!
		2. At the end of the week, or if the autoclave will stand for a prolonged period, clean the chamber when it is cold, and leave the door open.
		3. Clean and spray the door gasket with silicon spray, (SEA095- 0014).



Note:

- 1. The procedures done by the "User" referred in the Preventive and Periodical Maintenance, must be performed by trained personnel only.
- 2. Biohazard material, chemicals, agar solutions or any others aggressive materials that can damage the 316 stainless steel chamber must be placed in bags or containers to avoid spill to the chamber. In an event of contact the chamber must be cleaned or passivated to maintain proper condition of the chamber.
- 3. Keeping the inside of the autoclave clean will lengthen its life and its proper operation.
- 4. If you **see** or **hear** anything extraordinary, stop using the autoclave and call for service.

Warning!

Do not operate the autoclave in the presence of dangerous gases and vapors.

It is strictly forbidden to enter the autoclave chamber!

It is strictly forbidden for any person to enter the service area behind the service access panels, except the trained technician.



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7. BACSOFT ERROR MESSAGES

7.1 BacSoft Touch Screen Stand by Error Messages

The following table describes the system error messages and corrective actions.

Message	Description	Corrective Action
System Ready	No error	For information only
Water in chamber	Water detected in the chamber	Call autoclave Technician
Door Is Open	Door is open	For information only
Cycle by clock is active	Stand by cycle is scheduled to be run	NA
Jacket is cool	Jacket is cool	Wait till jacket reaches working temperature
Steam generator low pressure	Steam generator pressure is too low	Wait 30 minutes. (Applicable for autoclaves with internal steam generators
Drain is hot	Drain is too hot	For information only
IO Extension device not connected	Io Extension Not Connected (if IO Extension is defined)	Call for service
High Start Temperature	Accessory Cycle High Start Temperature	
VHP Input Not Ready	VHP Accessory Cycle Is Not Ready	Call VHP Provider for service to check the VHP generator
Bio filter timeout	Unable to heat bio filter	Call for service to replace filter
Bio filter is cool	Thermo bio filter is too cold	Wait 20 minutes. If the message not disappear call for service
Printer port is not valid	Printer port is not valid	Call for service
WaitDoorOpening	Door is opening	For information only
WaitDoor Closing	Door is closing	For information only
Cool drain time out	Time out while trying to cool drain	Call for service
Jacket time out	Time out while trying to heat jacket	Call for service
Supply error	No supply is detected	Call for service
Supply water error	No tap water supply	Call for service



Message	Description	Corrective Action
Supply distilled water error	No distilled water supply	Call for service
Compressed air supply error	No compressed air supply	Call for service
Steam generator no water	No water in steam generator	Call for service
Chamber pressure not in range	Chamber pressure is out of range	Call for service
Chamber temperature not in range	Chamber temperature is out of range	Call for service
Atmospheric pressure not set	Atmospheric pressure is not set	Call for service
Door error	Invalid door state	Call for service
Emergency Stop	Emergency Stop button is pressed	Call for service
Analog input error	Analog input sensor is out of range	Call for service
Air detector is not connected	Air detector Extension Not Connected (If applicable)	Call for service
I/O Card Failed	This message is displayed if I/O card is faulty (both while cycle is running or not).	Turn OFF and ON the autoclave in order to restart the control system. If the problem persists, call for service.
I/O card is not connected	This message is displayed if I/O card is disconnected (both while cycle is running or not).	Turn OFF and ON the autoclave in order to restart the control system. If the problem persists, call for service.
Protocol port is not valid	I/O card protocol port is not valid	Call for service
Main panel not connected	Master Panel Not Connected	Call for service



7.2 BacSoft Touch Screen Cycle Error Messages

The following table describes the system error messages and corrective actions.

Message	Description	Corrective Action
Cycle Done	No error	For information only
Canceled By User	User has pushed the stop button and canceled the cycle	For information only
Door is open	Door has been manually opened during cycle	Call for service
Analog Input Error	an analog input has been detected to be out of range	Call for service
I/O Card Failed	This message is displayed if I/O card is faulty (both while cycle is running or not).	Turn OFF and ON the autoclave in order to restart the control system. If the problem persists, call for service.
I/O card is not connected	This message is displayed if I/O card is disconnected (both while cycle is running or not).	Turn OFF and ON the autoclave in order to restart the control system. If the problem persists, call for service.
Power Down	Electric power down while cycle was running	Call autoclave Technician
No Water	If water has not been detected (water level sensor is bigger than value of system parameter 'Water Level Detection Value') after X seconds as defined in cycle parameter 'Water Time Error'	Not applicable for this autoclave
Heat Time Error	If chamber temperature does not reach X°c as defined in cycle parameter 'Exhaust Top Temperature' after X minutes as defined in cycle parameter 'Heat Time Error'	Check utilities or Call for service
Vacuum Time Error	If chamber pressure does not reach X kPa as defined in cycle parameter 'Pulse [A,B,C,D] Low Pressure' after X minutes as defined in cycle parameter 'Pressure Time Error'	Check utilities or Call for service
Pressure Time Error	If chamber pressure does not reach X kPa as defined in cycle parameter 'Pulse [A,B,C,D] High Pressure' after X minutes as defined in cycle parameter 'Pressure Time Error'	Check utilities or Call for service



Message	Description	Corrective Action
Heat Time Error (Keep)	If chamber temperature does not reach X°c as defined in cycle parameter 'Temperature [1,2] Stay' after X minutes as defined in cycle parameter 'Heat Time Error'	Check utilities or Call for service
Heat Time Error	If chamber temperature does not reach X°c as defined in cycle parameter 'Sterilization Temperature' after X minutes as defined in cycle parameter 'Heat Time Error'	Check utilities or Call for service
Low Pressure	If during sterilization stage, the chamber pressure goes below the minimum valid sterilization pressure	Check utilities or Call for service
High Pressure	If during sterilization stage, the chamber pressure goes above the maximum valid sterilization pressure.	Check utilities or Call for service
Low Temp	If during sterilization stage, the chamber temperature goes below the sterilization temperature as defined in cycle parameter 'Sterilization Temperature'	Check utilities or Call for service
High Temp	If during sterilization stage, the chamber temperature goes above the maximum valid sterilization temperature	Call for service
Time Error	If there is a gap in sterilization time of more than 3 seconds between the two clocks of the machine	Call for service
Low Pressure (Cooling)	If chamber pressure does not reach X kPa as defined in cycle parameter 'Cool Pressure' after X minutes as defined in cycle parameter 'Cool Pressure Time Error'	Check and fix the compressor air supply.
High Temp. (Cooling)	If chamber temperature does not goes below X°c as defined in cycle parameter 'Cool End Temperature' after X minutes as defined in cycle parameter 'Cool Error'	Call for service
High Pressure (Exhaust)	If chamber pressure does not goes below atmospheric pressure + 10 kPa after x minutes as defined in cycle parameter 'Exhaust Time Error'	Perform a new cycle.



Message	Description	Corrective Action
High Pressure (Dry)	If chamber pressure is above atmospheric pressure + 10 kPa when staring dry stage	Call for service
High Pressure (Ending)	This message is displayed if the system cannot reach atmospheric pressure ± 0.73psi (5kPa) during the ending stage.	Call for service
Air Error	If chamber pressure is below atmospheric pressure - 5kpa X minutes (as defined in cycle parameter 'Normal Pressure Time Out) after the end stage begins	Call for service
High Temp. (Ending)	If chamber temperature does not reach X°c as defined in cycle parameter 'End Temperature' X minutes (as defined in cycle parameter 'Normal Temperature Time Out) after the end stage begins	Perform a new cycle.
Accessory Timeout	In Accessory test cycle - If Digital input 'Acc Operate' value is 0 after x minutes as defined in cycle parameter 'Accessory Time Out'	Call for service
Emergency Stop	If emergency stop has been pushed during cyle (If Digital input 'Emergency Stop' value is '0')	Call for service
Bio Filter Time Out	If bio hazard filter is not ready after 2 minutes from the start of stage 'Purge'	Call for service
Purge Time Out	If chamber temperature drops below "X°C" (as defined in cycle parameter 'Purge Temperature') during X Minutes (as defined in cycle parameter 'Purge Time Out) after the purge stage begins	Call for service
Air Detector	if value of 'Air Detector Pressure' is bigger than value defined in cycle parameter 'Air Detector'	Call for service

