OPERATION & MAINTENANCE MANUAL

Full Manual

PlazMax

Hydrogen Peroxide Low Temperature Sterilizer with Automatic Vertical Sliding Door(s)

This device is not a medical device and not intended for medical use

Models: P50, P110, P160

Cat. No. MAN205-0560006EN Rev. D Sliding door full manual April 2022

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Tuttnauer
Innovation · Legacy · Partnership

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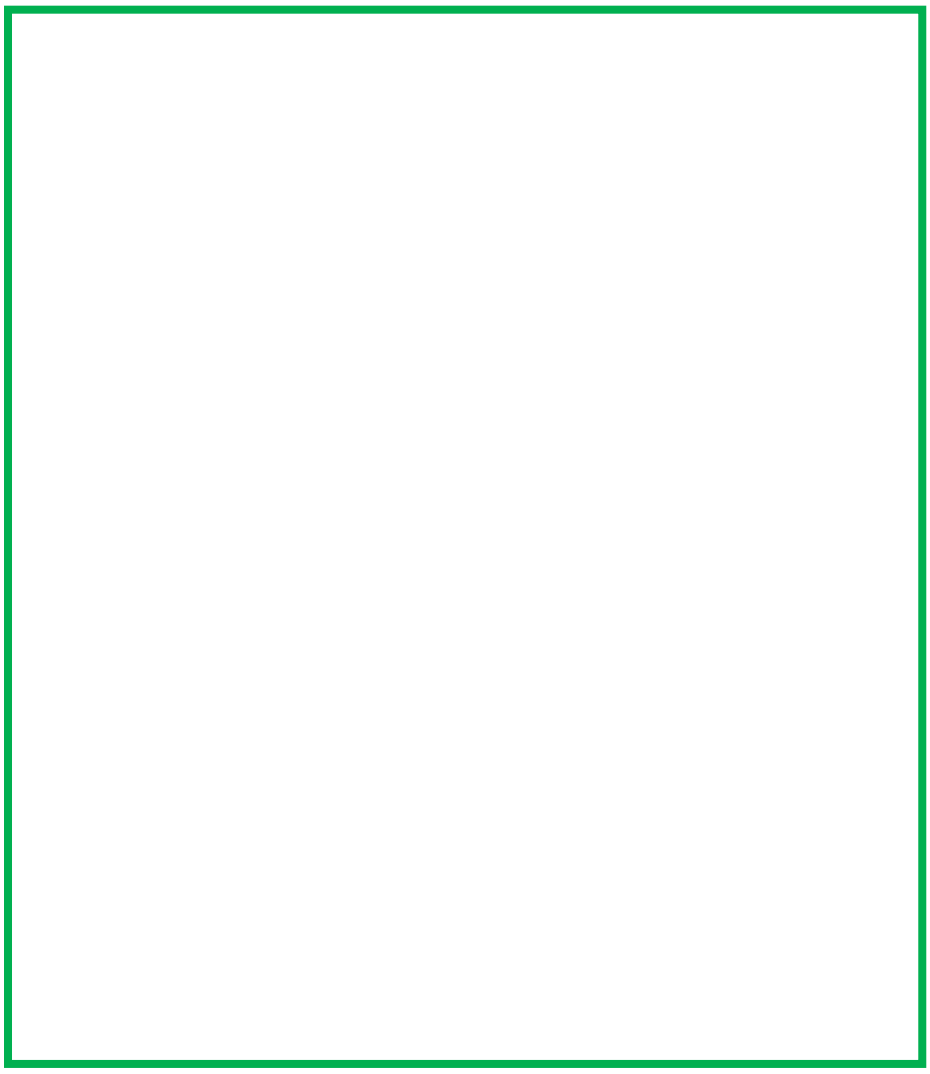
S.N.:



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INCOMING INSPECTION

The sterilizer should be unpacked and inspected for mechanical damage upon receipt. 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 damage is apparent, contact your dealer or point of purchase, so that they may notify the manufacturer and file a claim with the appropriate carrier.

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.

WARRANTY

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

The warranty does not include and does not replace routine treatment and preventive maintenance to be performed according to instructions in the Preventive and Periodical Maintenance paragraph.

Our obligation is limited to replacing the device or parts, after our examination, if within one year after the date of shipment they prove to be defective. This warranty does not apply to any device that has been subjected to misuse, neglect, accident or improper installation or application, nor shall it extend to sterilizers that have been repaired or altered by an un-authorized person.

The Sterilizer should not be used in a manner not described in this manual!

Do not attempt to service this instrument yourself.

WARRANTY STATEMENT

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

The warranty does not include and does not replace routine treatment and preventive maintenance to be performed according to instructions in the Preventive and Periodical Maintenance paragraph.

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 Technical Service

The PlazMax sterilizers are manufactured by:

Tuttnauer Ltd., Located Har – Tuv B
Industrial Zone, P.O. Box 170, Beit Shemesh 9910101, Israel. Tel: +972-2-9904611

The US Official Correspondence is:

Tuttnauer U.S.A. Co, Ltd. 25 Power Drive Hauppauge, NY, 11788, USA.
Tel (631) 737 4850, (800) 624 5836, Fax: (631) 737 0720

Note:

If there is any difficulty with this instrument, and the solution is not covered in this manual, contact our representatives 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 sterilizer 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 sterilizers 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.

STERILIZATION IN PLAZMAX STERILIZERS

Devices processed by the PlazMax sterilizer will be sterile if processed in accordance with the instructions in this Manual.

The manual does NOT provide Information on the functionality of sterilized devices.

The manual does NOT advise users of the PlazMax sterilizer whether the functionality of a particular device will be impaired if it is processed in vapor of Hydrogen Peroxide H_2O_2.

The user must contact the manufacturer of the device in order to determine whether the functionality of a particular device may be adversely impacted by processing it in a vapor of Hydrogen Peroxide H_2O_2.

In some cases, the device manufacturers have indicated that the functionality of certain devices may be impaired if processed in a vapor of Hydrogen Peroxide H_2O_2. Such devices may be impaired even though they may be made of materials and have dimensional characteristics that have been cleared for processing in vapor of Hydrogen Peroxide H_2O_2.

Because materials, manufacturing and repair processes may change, you are encouraged to contact the manufacturer of devices intended to be processed in vapor of Hydrogen Peroxide H_2O_2 for the most up to date information about processing particular devices in vapor of Hydrogen Peroxide H_2O_2.

GENERAL INFORMATION

Introduction

We appreciate your decision to purchase a “Tuttnauer” PlazMax sterilizer. The sterilizer you purchased is built of the best materials and components. They are approved for their safety as well as for their performance and quality.

The below operation and maintenance instructions checklist required from the operator and the technicians are minimized for good operation practice. This instruction list is intended to instruct the operator and the technician how to maintain the sterilizer and thus to lengthen its working life and ensure efficient and reliable sterilization.

We strongly recommend that the operator will read, understand and follow the operation and maintenance instructions of this manual and especially the safety information presented in chapter 2 and throughout this guide. The safety information is provided for your benefit and for the benefit of your instruments and equipment.

Using This Manual

Read the manual carefully, before beginning any operation on the sterilizer!

This manual is designed to provide useful information about the safety, the operation, sterilization process, installation, routine maintenance and troubleshooting of the “Tuttnauer” PlazMax Sterilizer.

The manual guide contains 12 chapters: Chapters 1 and 3. - *Introduction & System Overview* explains the features and parts of the sterilizer; Chapter 2. - *Safety Information* Gives Safety Information Instructions; Chapter 4. - *Load Preparation* explains how to prepare and package the items before and for sterilization, it also in (*Sterilization Operation)* explains how to effectively operate the PlazMax sterilizers; Chapter 5. - *Sterilization Cycles* describes the sterilization/*test* cycles and phases process;. Chapter 6 - *Indicators* provides information on the various indicators;. Chapter 7 - *Display Control Touch Screen explains the PlazMax* main screens and all users, operator and technician users screens. Chapter 8 - *Operating Instructions* provides *PlazMax* operating instructions including sterilization cycles selection and tests selection. Chapter 9 -.*Maintenance* – provides the preventive and replacement maintenance plan that periodically conduct verifying or replacing parts in the PlazMax sterilizer. Chapter 10 -. *MESSAGES* – provides Touch Screen Stand by Error Messages, Start cycle error messages, and cycle error messages. Chapter 11 - *PlazMax STERILIZER INSTALLATION provides* instructions for unpacking and the installation on site of the newly shipped & received PlazMax sterilizer. Chapter 12 - *FAQ* provides the frequently asked questions and answers concerning the PlazMax sterilizer.. *APPENDICES* provide with you with references, and *with ANNEX 1: INSTALLATION PLANS*, and *ANNEX 2: PREVENTIVE MAINTENANCE PLAN*. *APPENDIX 1* provides Electrical Control Drawings. *APPENDIX 2* provides Special Lubrication Oil For Vacuum Pump;. *APPENDIX 3* provides manual for TRIVAC D25B Vacuum Pump.

The chapters of this manual are:

- **General Information-** This section gives the user important information about using this manual and on how to make the best use out of this manual.
- **Chapter 1. Introduction** - This chapter is an introduction and contains general and important details about the "Tuttnauer" PlazMax Sterilizer, including some of the main parts of the sterilizer basic process and operating information.
- **Chapter 2. Safety Information Instructions** - This is an important chapter in the manual. You should read this chapter thoroughly, understand the information, and follow all the safety procedures. The safety procedures include: recommendations to the operator safe handling of the loads and how to use, store, handle and dispose of the Sterilizing agent.
- **Chapter 3. System Overview** - This chapter describes the major system components, it details the components and their function which includes: the Sterilant agent tank, Sterilant agent dosing, Electrical Safety features, Ventilation, Sterilization chamber, ON/OFF Button, Doors, Vaporizer Heating, Printer, Vaporizer Heating, Plasma Generator, Peristaltic and vacuum pumps, air filter and Warning Messages.
- **Chapter 4. - Load Preparation** - This chapter contains information regarding the preparation of Load items for Sterilization. The chapter briefly describes the materials and devices that can be sterilized by the PlazMax Sterilizer. The correct handling and storage of the PlazMax Sterilizing Agent is also briefly discussed. The chapter also provide sterilization operation information on how to effectively operate the PlazMax sterilizer.
- **Chapter 5. Sterilization Cycles -** PlazMax sterilization cycles and cycle reports are described in this chapter, including monitoring and test cycles.
- **Chapter 6. Indicators –** chemical indicator (CI), biological indicator (BI), lumen test – PCD as well as How to use the lumen kit PCD are also detailed in the chapter.
- **Chapter 7. Display Control Touch Screen –** This chapter explains the PlazMax main screens and all users, operator and technician users screens.
- **Chapter 8. Operating Instructions –** The chapter gives a step by step operating instructions. including sterilization cycles selection and tests selection.
- **Chapter 9. Maintenance –** The chapter gives the preventive plan and replacement maintenance plan that the user periodically conduct verifying or replacing parts in the PlazMax sterilizer.
- **Chapter 10. CONTROLLER MESSAGES –** Provides controller Touch Screen Stand by Error Messages, Start cycle error messages, and cycle error messages.
- **Chapter 11. PlazMax Sterilizer Installation -** This chapter provides instructions for unpacking and the installation on site of the newly shipped received PlazMax sterilize.
- **Chapter 12 – FAQ -** This chapter provides the most frequently asked questions and answers concerning the PlazMax sterilizer.
- **ANNEX 1, 2 and Appendix 1,2 and 3. -** Annex 1, 2 includes installation plans,and preventive maintenance plan. Appendix 1 provides PlazMax Electrical Control Drawings, Appendix 2 provides special lubrication oil for vacuum pump information. Appendix 3 provides manual for the maintenance TRIVAC D25B Vacuum Pump.

1. INTRODUCTION

1.1 Overview

Attention!
This device is not a medical device and not intended for medical use.

The design and development of the PlazMax series was preformed in compliance with the ISO14937/ 2009.

The PlazMax is a low temperature sterilizer designed to sterilize a broad range of devices rigid & flexible materials, solid & hollow devices. It is especially appropriate for the sterilization of heat and humidity sensitive devices.

The PlazMax inactivates micro-organisms with Vaporized Hydrogen Peroxide (VH_2O_2). The PlazMax diffuses H_2O_2 into the chamber and the vapor acts as the sterilizing agent.

The sterilization occurs inside the chamber by means of H_2O_2 saturation. The PlazMax utilizes the bacterium killing power of free radicals in the H_2O_2 atoms released by applying heat to the H_2O_2 gas in the vaporizer.

The use of VH_2O_2 vapor safely and rapidly sterilizes instruments and materials without leaving residue. The PlazMax sterilizer offers an effective, safe, fast, reliable, economical, easy to use, and flexible sterilization method.

The control system of the sterilizer is based on microcomputer technology, ensuring a highly reliable and safe automatic operation. This sterilizer has a controller which includes a Touch Screen (TS), on the front panel.

The TS enables the users to select a sterilization program, and start/stop a cycle. It also enables to set up the system, set parameters changes, and calibration. The cycle phases time and the set points for all process parameters are also automatically controlled by microcomputer software.

All stages of the sterilization cycle, including the exhaust stage, operate within a dry environment at a low, (less than 131ºF), temperature.

The PlazMax Sterilizer can be used for both metal and nonmetal devices, and can also sterilize instruments that have difficult-to-reach diffusion restricted spaces, such as hinges on forceps. (For details see Chapter 4).

The system consistently provides a sterility assurance level (SAL), of $X*10^{6}$, (as defined by FDA and international standards), when used in accordance with the directions in this manual.

The PlazMax sterilizer new design also offers unique features which enhance system operation & safety. These include:

- Automatic sterilizer refilling which ensure continuous system operation
- The sterilant agent tank is designed specifically to store the sterilant safely
- Fast sterilization cycles and a system that allows the dosing into the vaporizer in a complete absence of air
- Dosing system and perforating unit system, Sterilizing Agent Dosing.
- Electrical components which enhance safety
- Ventilation Safety. H_2O_2 Sterilization is completely secure and environment friendly

The sterilizer main external components are described in the following paragraph.

1.2 PlazMax Sterilizer General View

The PlazMax sterilizer external front view is shown below. The ON/OFF button and the printer are located behind the cover and are exposed when you swivel the cover up and open the cover.This sterilizer contains one or two Automatically operated Vertical Sliding door(s).

PlazMax main external components include:

- Touch Screen Monitor 7" Multi-color touch screen pane
- Service Side Panel
- Sliding Door
- Service Access Panel
- Sterilizing Agent Bottle Holder Drawer (H_2O_2)
- Kick Switch
- Sterilizer Rolling Wheels
- Service Side Panels
- ON/OFF Button USB Port & Printer

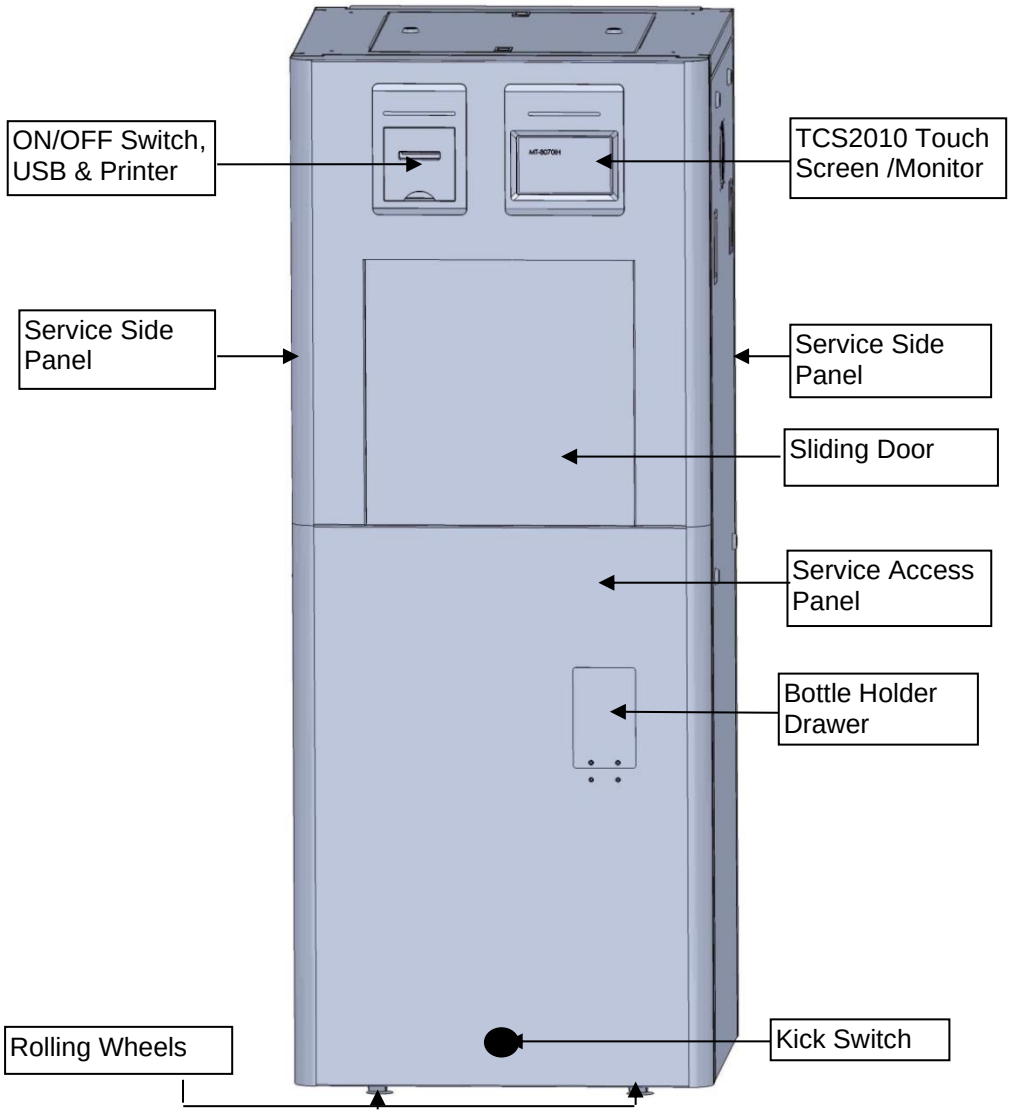


Figure 1- PlazMax Sterilizer exterior view

1.3 TECHNICAL DATA

MODELS		P50	P110	P160
Doors		1	1	1
Total volume		12 gal 47 Lt	29 gal 110 Lt	43 gal 162 Lt
Chamber Dimensions (mm)	W	16.5" 420mm	16.5" 420 mm	16.5" 420 mm
	H	7.0" 180mm	16.5" 420 mm	16.5" 420 mm
	D	24.5" 624 mm	24.5" 624 mm	36.2" 920 mm
Sterilizer External Dimensions (mm)	W	27.5" 700 mm	27.5" 700 mm	27.5" 700 mm
	H	60.2" 1530 mm	60.2" 1530 mm	70.8" 1800 mm
	D	28.7" 730 mm	28.7" 730 mm	37" 940 mm
Device Weight		518 Lbs 235 Kg	650.3 Lbs 295 Kg	760.5 Lbs 345Kg
Total Weight with crate		705.4 Lbs 320 Kg	870.8 Lbs 395 Kg	992 Lbs 450Kg
Power Supply (fluctuations +/-10%)	Voltage	3 X 208 V	3 X 208 V	3 X 208 V
	Frequency	50/60 Hz	50/60 Hz	50/60 Hz
	Power	2.8 kW	4.3 kW	4 kW

1.4 Warranty

PlazMax sterilizers are covered by a warranty against manufacturing defects.

To keep the warranty valid, the PlazMax must be used under the recommendations instructed by Tuttnauer, in the User and Maintenance Manuals. Only trained and authorized technicians should perform service and maintenance

1.5 Intended Use

This device is not a medical device and is not intended for medical use, it is intended for laboratory or veterinarian use only.

- The PlazMax Sterilizer is intended for use on various loads: for terminal sterilization of cleaned, rinsed and dried reusable materials. The materials contain a broad range of metals or non-metals, hollow or non hollow, rigid or flexible, and instruments that have inaccessible diffusion restricted spaces, such as hinges on forceps for laboratory and veterinatian device loads
- The PlazMax is used for sterilizing flexible tubes ≥4000mm length 1mm diameter when tube is opened in two ends or flexible tubes ≥1400mm length 1mm diameter when tube is opened in one end.
- The approved maximum loads per model:

P-50: Normal Cycle- 346 Lbs (157 Kg), Advanced Cycle- 15 Lbs (7 Kg), Heavy Duty Cycle- 24 Lbs (11 Kg), Endoscope Cycle- 1 Hollow Piece
P-110: Normal Cycle- 22 Lbs (10 Kg), Advanced Cycle- 22 Lbs (10 Kg), Heavy Duty Cycle- 28 Lbs (13 Kg), Endoscope Cycle- 2 Hollow Pieces
P-160: Normal Cycle- 28 Lbs (13 Kg), Advanced Cycle- 28 Lbs (13 Kg), Heavy Duty Cycle- 33 Lbs (15 Kg), Endoscope Cycle- 2 Hollow Pieces

1.6 Intended Users

- Laboratory and Veterinarian laboratory personnel

- Laboratory and Veterinarian professionals

Note- For all authorised users, the responsible body should ensure:

a) That all personnel who operate or maintain the equipment is trained in its operation and in its safe use;

b) That the regular training of all personnel concerned with the operation and maintenance of the equipment. Records of attendance at training are maintained and evidence of understanding demonstrated.

1.7 Environment

This device is for indoor use only!

The ambient temperature range shall be 41ºF to 86ºF and a relative humidity of 80%.

The operation altitude shall not be over 6562 ft (2000m). (ambient pressure shall not be lower than 11.6 psi (80 kPa).

1.8 Sterilization Operation Process

The basic general PlazMax sterilization process is as follows:

1. Turn the sterilizer on using the ON/OFF button or the .
2. Choose the intended cycle on the Touch Screen.
3. Wait twenty minutes for the machine to warm up, or if the serilizer is already warm and ready, continue to the next step.
4. Open the door and place the load on the shelf inside the chamber.
5. Shut the door by pressing on the 

tab on the main screen.
6. Press the "**Start Cycle**" on the touch screen. *When conditions are right the cycle starts automatically. The sterilization process runs now and is completed when an alarm notifies you that the process is completed.

*If the conditions are not right to start the cycle, the Program messages will be displayed on the screen. This shows that the sterilizer is waiting for the proper conditions. (For detailed sterilization procedures see Chapters 5 and 8).

2. SAFETY INFORMATION INSTRUCTIONS

This chapter provides information and instructions for the operator on how to safely use PlazMax sterilizer. You must read, understand, and strictly follow and use the information in this chapter before operating the sterilizer. Always pay attention to the warnings, cautions, and notes throughout this manual. This information is provided for your safety and in order to ensure that you receive the most benefit from the safe operation of your PlazMax Sterilization System. Only trained, experienced technicians, who are fully familiar with this sterilizer, should repair or adjust the PlazMax Sterilization System.

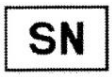
2.1 Warnings, Cautions, and Notes

Warning!
Warnings indicate events or conditions that can result in serious injury or death.

Caution!
Cautions indicate events or conditions that can result in severe damage to the equipment.

Note: Notes are in bold; they highlight specific information about the proper use and maintenance of the PlazMax Sterilization System.

2.1.1 Symbol Descriptions

Symbol	Standard Reference	Symbol Title	Descriptions
	ISO 15223- 1:2016 Reference no. 5.1.7. (ISO 7000-2498)	Serial number	Serial Number Indicates the manufacturer's serial number.
	ISO 15223- 1:2016 Reference no. 5.1.3. (ISO 7000-2497)	Date of manufacture	Date of Manufacture (Year Month) Indicates the original manufacture date for this device.
	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)	Manufacturer	Manufacturer Indicates the name and address for the manufacturer of this device. It may also include the date it was manufactured.
	ISO 15223-1:2016 Reference no. A.15	Consult instructions for use or consult electronic instructions for use	Consult Instructions for Use Consult the operating instructions.
	EN ISO 7010	Warning:electricity	Electric shock
	GHS Reference no. 1.4.10.4.2.3 A1.7	Highly flammable	flamable
	GHS	Corrosive	corrosive
	iso_grs_7010_WOO1	General warning sign	warning
	PAO	Period after opening	The sterilant bottle is valid for 30 days after opening.

2.1.2 Symbols used by the vacuum pump manufacturer

In addition there are Safety symbols used by the vacuum pump manufacturer shown in the vacuum pump manual.

2.2 Health and Safety Information

The PlazMax devices are considered as pollution degree 2 (PD2) environments according to safety standards and certification bodies.
The Plazmax complies with environmental occupational standards.

2.2.1 Warnings and Notes

Warnings and Notes for– Low temperature PlazMax sterilization agent

a. **Safety gloves**

When directly handling the sterilizing agent, you should use safety chemical resistant gloves (for example- latex, PVC (vinyl) or nitrile).

b. **Inhalation**

Long exposure to the sterilizing agent can be dangerous. The sterilizing agent vapour inhalation can cause burning and irritation of the respiratory tract. If vapour is inhaled, you should breathe fresh air and if there was a prolonged inhalation, seek for medical advice.

c. **Contact with the eyes**

The long exposure to the sterilizing agent can cause irritation and damage to the eyes. The sterilizing agent is not poisonous but can cause irritation. The vapour causes discomfort to the mucous membrane and to the eyes. The contact of the eyes with the sterilizing agent can be very dangerous because it can burn the cornea. If necessary see a doctor.

d. **Contact with skin**

The sterilizing agent can cause skin irritation and itching. In case of contact with skin, immediately rinse with plenty of water and seek medical advice.

e. **Accidental ingestion**

Sterilizing agent ingestion can cause serious damages and even death. You must prevent the contact of your mouth with the sterilizing agent. If the sterilizing agent is ingested drink water to dilute it; do not induce vomit and seek medical advice.

f. **Storage**

Store H_2O_2 at room temperature (59 to 86ºF) or in a cooler place if you are located where the room temperature is higher.

2.2.2 PlazMax Sterilizing agent

Sterilizing agent safety

The sterilizing agent safety is assured due to the following PlazMax safety measures:

- Using “Tuttnauer” sterilizing agent only
- Avoiding contact with the sterilizing agent, verify the expired date on the bottles
- Automatic sterilizing agent refilling

Only the use of “Tuttnauer” sterilizing agent is allowed as the system only recognizes the “Tuttnauer” bottle for PlazMax Sterilizing Agent.

Warning!
The operator must check carefully the Warning labels On the bottle before using . The label shows: the Date of Manufacturer, Expiry Date & Lot Number.
Once opened, the sterilant bottle is valid for 30 days. Do not exceed usage after the expiry date.

Any contact of the operator with the sterilizing agent is avoided since the sterilizer recharged drawer can only be opened after the operator receives a signal (from the sterilizer system) that indicates that additional new agent supply is required.
The supply of sterilizing agent is possible only after placing of a new bottle.
The refilling begins automatically after the operator’s gives instruction on the touch screen.
The refilling process of the sterilizer is completely automatic, avoiding any accidental contact with the operator.

Warning!
Under no circumstance the user shall manually perforate the sterilant agent bottle
The refilling process of the sterilizer is completely automatic, avoiding any accidental contact with the operator.
The sterilizing agent is not toxic but it is corrosive as it is hydrogen peroxide (H_2O_2).
The sterilizing agent should be stored away from the sun light, at room temperature, preferably in a dry and cool place.
Each recharge box includes instructions and recommendations on the proper and safe handling of the sterilizing agent. Follow the instructions.

After the automatic emptying of the bottle the drawer opens, allowing the closure of the bottle with the lid supplied within the bottle, and then its removal from the drawer. The bottle can be disposed in the domestic waste, or can be sent to the residual circuit recommended by the hospital’s infection control.

The new designed PlazMax sterilizer systems, provide unique automatic features that enhance the operation & safety by minimizing sterilant agent contact with the operator, the systems include:

- Dosing system and perforating unit system
- Sterilant agent tank
- Sterilizing Agent Dosing
- Electrical components Safety
- Ventilation Safety

2.2.3 Dosing system and perforating unit system safety

The Dosing system and perforating unit system enhance the operation safety of the PlazMax sterilizer:
The dosing system operation is ensured by an assembly of components that include the drawer for the bottle placing, the perforating unit and the bottle identification unit.

A peristaltic pump takes the sterilant agent into the sterilizer tank. (For detailed description refer to paragraph 3.1.2)

2.2.4 Sterilizing Agent Dosing system safety

The sterilizing agent dosing system and perforating unit, enhance the operation safety by minimizing sterilant agent contact with the operator.

The Sterilizing Agent Dosing features are detailed in chapter 3 paragraph 3.1.5.

2.2.5 Electrical components Safety

PlazMax design provides a high level of electrical safety to the operator and the technician. (For detailed description refer to chapter 3)

2.2.6 Ventilation Safety

For the ventilation detailed description, refer to chapter 3.

2.3 Handling and Storage of the PlazMax Sterilizing Agent

Warning!

Important: The correct handling and storage of the PlazMax Sterilizing Agent is extremely important for ensuring the safety of personnel and equipment.

For your own protection , always wear safety gloves and protective glasses when handling H_2O_2 .

In order to prevent Sterilizing agent leakage:

Make sure that the sterilizing agent used is the recommended for the PlazMax sterilizer. The use of wrong bottles of sterilizing agent may cause leakage. In case of leakage, use protection gloves and clean with abounding water.

Only the use of recommended sterilizing agent is allowed as the system will only recognize the recommended bottle of PlazMax Sterilizing Agent.

PlazMax Sterilizing Agent product can be stored at room temperature (59 to 86ºF).This applies only if the product is stored in the upright position.

Note:
If the bottles are not stored in the correct position there is a risk of an eventual leakage of liquid inside the boxes especially if the temperature is high. This could start a fire of the materials stored close to the Sterilizing Agent as it is a chemical product and an oxidizing agent.

2.3.1 Properties, Handling and Storage of the Sterilizing Agent

The Sterilizing Agent is H_2O_2 also commonly called Hydrogen peroxide in a concentration of approximitly 50% water and approximitly 50% H_2O_2.

The H_2O_2 is not defined as TOXIC but is defined as corrosive and in contact with the skin can cause skin burn; therefore it is recommended not to get in contact with the packaging / bottle only when wearing gloves and protective glasses.

The Boiling temperature of this liquid is at 239º F.

The PlazMax sterilizing agent is clear, color less and it looks like water and has a proper odour filter. It is not flammable; it is soluble with water independently of the sterilizing agent concentration.

The H_2O_2 substance shall be stored in a dark and clean place which is not exposed to sun light and the surrounding temperature is not higher than 77ºF. No papers, leaves or wood shall be present in the substance proximity.

When placing a new charge of sterilizing agent bottle, the system will recognize it automatically, due to the RFID installed in each bottle.

The RFID on the bottle contains information about the expiry date, lot number and packaging date.

When passing on the refilling system, the RFID will change its program preventing the use of the same bottle again.

The Hydrogen peroxide substance must be placed with the arrows facing upward.

Sort and verify that the **RFID** tag at the bottom of the bottle is not damaged.

Do not throw bottles that contain liquid, only defective packaging.

2.3.2 Sterilizing Agent Storage Safety Instructions

Warning!

<u>For your own protection , always wear safety gloves and protective glasses when handling H_2O_2 .</u>

The correct handling and storage of the PlazMax Sterilizing Agent is extremely important for ensuring the safety of personnel and equipment.

To ensure safety perform the following instructions:

1. Check the products immediately as soon as you receive them. Open the boxes by peeling back the label that contains the batch data, and confirm that boxes and bottles are completely dry.
2. If there is a leakage and depending on the damage, act according to the instructions of use inside the box. Then close the box again putting the label in its place and store it.
3. Open the box (If you are going to use the product) by pulling the handle out. (See the Figure below).

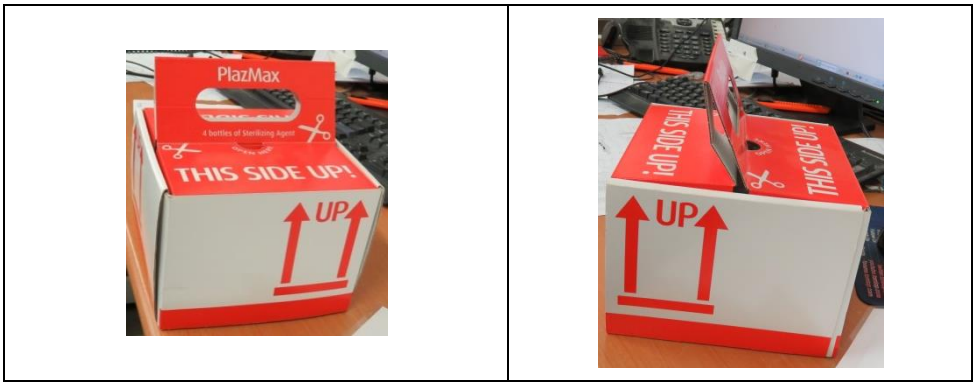


Figure 2 - PlazMax Sterilizer Agent Box

4. Transport and store the boxes/bottles in the upright position as indicated by the arrows of the packaging.
5. Store H_2O_2 at room temperature (59 to 86ºF) or in a cooler place if you are located where the room temperature is higher; make sure that the product is not stored together with inflammable materials.
6. Check the stored product regularly. Refer to the Material Safety Data Sheet attached, especially to point 7. Handling and Storage.

2.3.3 How to Handle the Sterilizing Agent Boxes

Warning!

<u>Important</u>: It is extremely important to handle and keep the PlazMax Sterilizing Agent Boxes in the correct position always with the arrows as shown on the boxes facing upward (See paragraph 2.3.2), in order to prevent leakage and thus to ensure the safety of personnel and equipment.

<u>Always wear safety gloves and protective glasses when handling H_2O_2.</u>

In order to prevent Sterilizing agent leakage:

Make sure that the sterilizing agent used is the recommended for the PlazMax sterilizer. The use of wrong bottles of sterilizing agent may cause leakage. In case of leakage, use protection gloves and clean with plenty of water.

Only the use of recommended sterilizing agent is allowed as the system will only recognize the recommended bottle of PlazMax Sterilizing Agent.

PlazMax Sterilizing Agent product can be stored at room temperature (59º to 86ºF). This applies only if the product is stored in the upright position.

If the bottles are not stored in the correct position there is a risk of an eventual leakage of liquid inside the boxes especially if the temperature is high. This could start a fire of the materials stored close to the Sterilizing Agent as it is a chemical product and an oxidizing agent.

To ensure safety handle of the PlazMax new Sterilizing Agent package boxes according to the signs and instruction on the boxes as shown in the figure below:

To open the box containing the 4 bottles

1. PlazMax new packages master box loaded with 6 boxes x 2 layers for a total of 12 boxes (A).
2. The internal box package (1), must be placed on the table with arrows facing up as indicated on the box (2).
3. Lift handle up, The cover can be ripped off (3) to open the box or, see step 4.
4. Open the side of the box at lower side cover (4) to lift the box open as shown in (5).
5. The nylon protected bottles can now be removed. (6).
6. Label on box that indicates that opened bottle can be used for only one month.

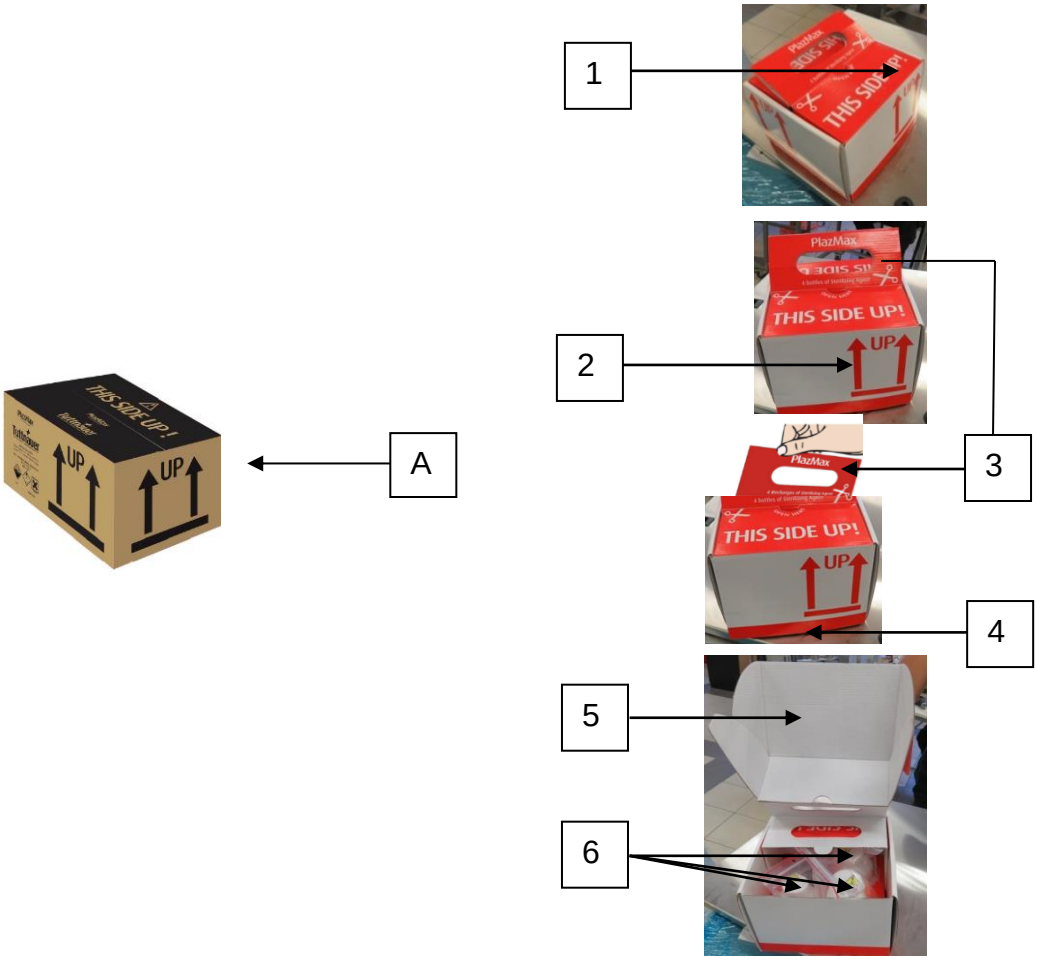


Figure 3 - PlazMax Sterilizer Agent Package

2.3.4 Expiry date of the bottle

The disposal should be in accordance with applicable regional, national and local laws and regulations. **Once opened, the sterilant bottle is valid for 30 days. Do not exceed usage after the expiry date.**

Sterilizing Agent Label on each H2O2 Bottle

2.3.5 Plazmax Sterilizing Agent direction for use

Warning!

<u>Important</u>: Read carefully the instruction label (see below) that is attached to the 4 pack H2O2 box.

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PlazMax

Sterilizing Agent

Directions for use:
It is necessary to use gloves and protective eye glasses before handling the bottles

- Before removing the bottle from the plastic bag, verify that there are no drops of liquid inside the bag. In case of drops in the plastic bag, do not use the bottle
- Remove the bottle from the plastic bag
- Place the bottle in the sterilizer drawer
- Remove the bottle cap after placing in the drawer

Important:
Do not use this Sterilant Agent if you notice any change. The special seal on the bottle should be intact and undamaged.

Under no circumstances should the seal be punched manually.

Do not use the bottles with expired validity.

In case of skin contact, rinse with plenty of water.

In case of accident, seek medical help and show the product label.

Use bottle within one month after opening.

Labeling Symbols:

LTR231-0019 V.02

3. SYSTEM OVERVIEW

3.1 Major System Features/Components

The PlazMax Sterilization System (Sterilizer) includes the following major systems and components:

- Touch Screen
- Dosing system and perforating unit
- Sterilant agent tank
- Peristaltic Pumps
- Sterilizing Agent dosing
- ON/OFF switch
- Electrical Safety components
- Doors
- Printer
- Vaporizer
- Vacuum Pump
- Oil filter
- Sterilization chamber
- Air Filter

The PlazMax Sterilizer Component/Features are detailed in the following pages.

3.1.1 Touch Screen

The touch screen is placed on the Loading Side panel. The screen allows you to select by touching the screen the selection of the desired cycles and provide you with visualization of all the cycle phases.

The sterilizer displays information and accepts commands through a color touch screen. By touching buttons displayed on the screen, you can enter letters and numbers, make selections, and start and stop the sterilizer.

3.1.2 Dosing system and perforating unit

The Dosing and perforating unit system consist of an assembly of components that include the following:

- Drawer for placing the bottle
- The perforating unit assembly
- Bottle identification unit
- Peristaltic pump

The dosing system is an assembly of components that include the drawer (Driven by Servo Motor Assembly) for placing the bottle (Figure 4, 5), the perforating unit and the bottle identification unit. A peristaltic pump takes the sterilant agent ,(H_2O_2), into the sterilizer tank.

The support where the H_2O_2 recharge is placed is made of nylon. When required the drawer opens to allow the bottle insertion. This bottle is automatically transported to the perforation unit and the H_2O_2 is pumped into the tank.

In order to know whether the bottle was placed correctly there is a detector that checks the validity and makes its authentication.

The perforator is an electric or pneumatic system which actuates a needle that perforates the bottle and removes the sterilizing agent from its interior.

To ensure that no sterilizing agent remains in the tubes, the system injects air into the aspiration circuit.

The perforator has an electric or pneumatic cylinder with sensors which determines the position of the movements related to the feeding of the sterilizing agent, and informs the operator of any possible malfunction.

All the control system is a 24V DC. All the places which can result in electric risk are signaled.

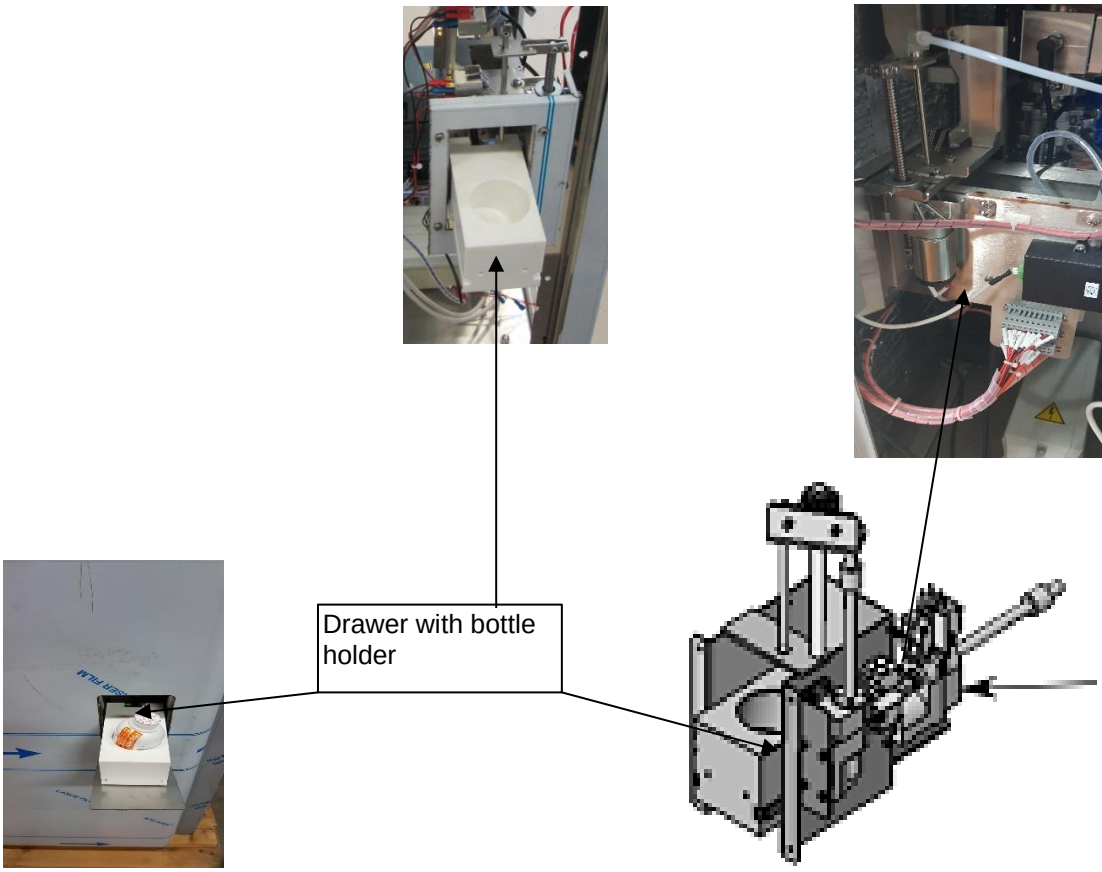
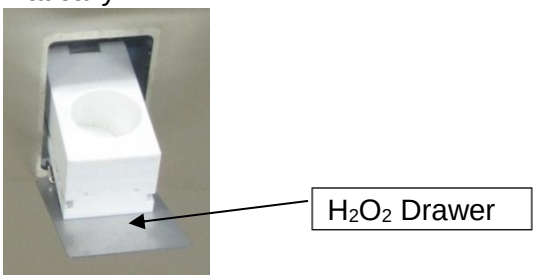


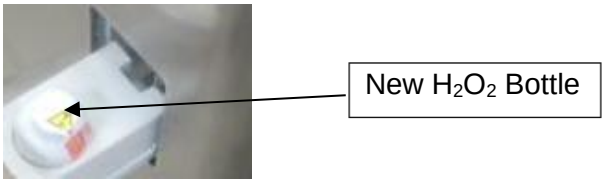
Figure 4 - Drawer with H_2O_2 bottle holder

Figure 5 - Drawer Driven by Servo Motor Assembly

1. The new H_2O_2 drawer opens automatically**.**



2. Place a new H_2O_2 bottle in the drawer and remove the bottle cover.
A message appears on the Touch Screen to confirm the bottle cover removal.
IMPORTANT: Remove the bottle cover only after placing the bottle in the drawer.

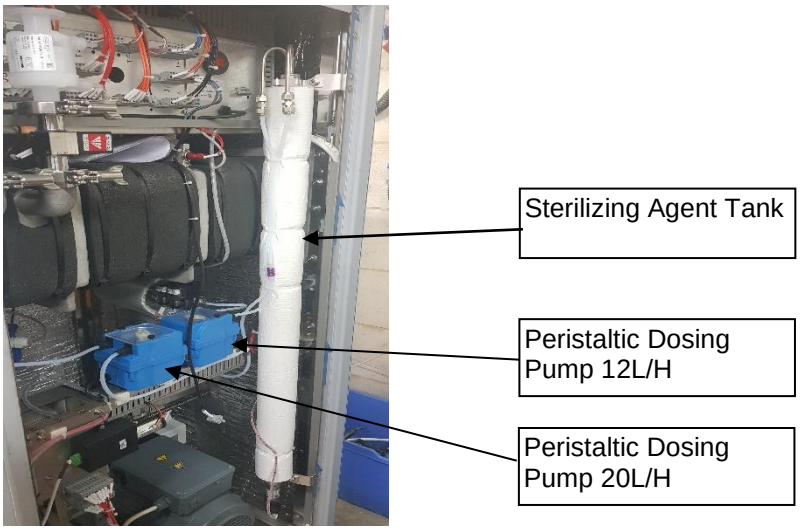


3.1.3 Sterilant Agent Tank

The sterilizing agent tank is designed to store the PlazMax sterilizing agent. Inside the tank there is an electronic reader that indicates to the PLC and the operator (on the touch screen) about the available H_2O_2 level in the tank.

The tank is fully insulated and is designed to prevent pressure generation in the tank.

Figure 6 – Sterilizing Agent Tank



3.1.4 Peristaltic Pumps

The H_2O_2 is pumped from the bottle to the tank by the Peristaltic Tank Dosing Pump.

The H_2O_2 is pumped from the tank into the vaporizer by the Peristaltic Vaporizer Dosing Pump.

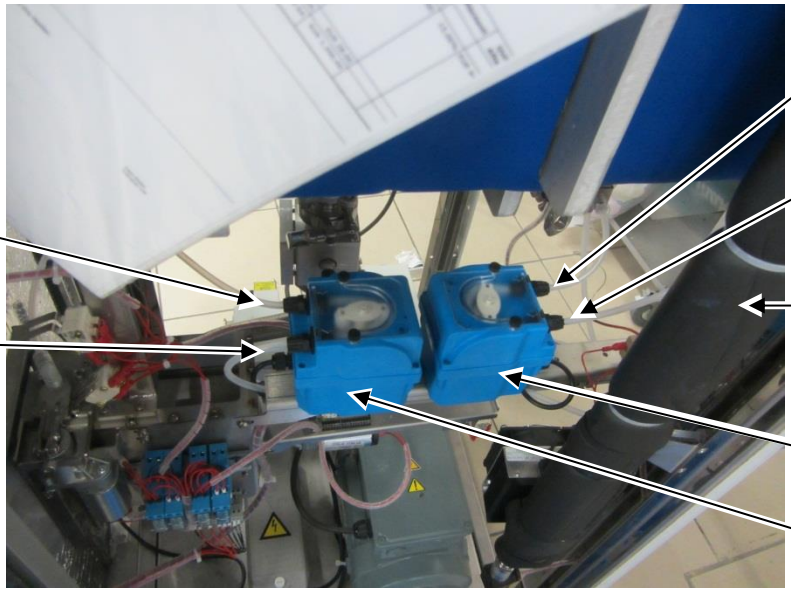


Figure 7 – Peristaltic Pumps

3.1.5 Sterilizing Agent Dosing

The sterilizer has a tank which stores the sterilizing agent, from the tank the H_2O_2 is dosed into the sterilization chamber. When sterilizing agent is missing in the tank, a message is displayed on the touch screen.

The operator must supply the sterilizer with sterilizing agent whenever the screen indicates that. The sterilizer does not work if there isn't enough sterilizing agent for the processing of one cycle.

The sterilizing agent feeding can only be done before the cycle start and when the "Refill Sterilizing Agent" button is active.

If the recommended bottle is inserted, the system will allow the drawer to close, the bottle is punched and the refill of the sterilizing agent into the tank is accomplished. At the end of the operation, the information is transmitted to the operator on the screen.

For additional security, you can use safety gloves when placing the recharges in the drawer.

The bottle containing the sterilant agent has a programmed microchip including the validity and packaging date of the bottle.

When the bottle passes through the refilling unit, the chip program is updated, preventing the reutilization of the same bottle. At the end of the refilling process, the system prints the related data (lot number, validity, cycle number, etc.).

If eventually an error occurs during refilling, a warning will appear on the screen.

IMPORTANT:

Sterilizing agent leakage prevention

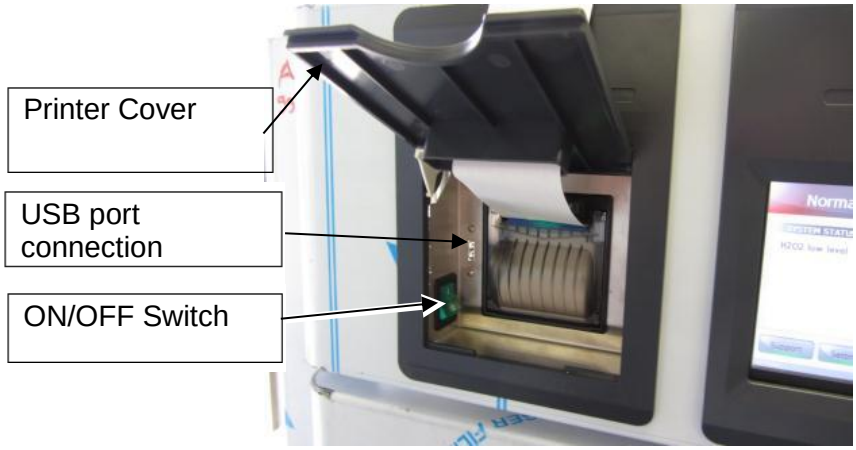
Ensure that only the recommended Sterilizing Agent for PlazMax is used. The use of wrong Sterilizing Agent bottles may cause leakage. In case of leakage, use protective gloves and clean with plenty of water.

3.1.6 ON/OFF Switch

The ON/OFF switch is located behind the printer cover in the front panel and is used for connecting and disconnecting the PlazMax sterilizer.

Once turned ON, it takes around 25 - 35 minutes for the sterilization chamber and the doors to warm up and keep at a predefined temperature.

If minimum conditions do not occur, then the cycle will not run and a message will be displayed on the touch screen warning the operator of it. When minimum conditions are attained the cycle will run automatically.



3.1.7 Electrical Safety components / Features

Note- Use equipment only according to instructions. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

PlazMax design provides a high level of electrical safety to the operator and the technician.

All the control system is a 24V DC. All the places which can result in electric risk are signaled.

All the PlazMax components are with the ratings of 24V DC, besides the following components: heating elements, and vacuum pump that are with the ratings of 208V.

The PlazMax contains protection and safety components such as circuit breakers and relays. There is also a tap on the electric switchboard to avoid accidental contact.

The devices have FCC approval that there is no electromagnetic noise.

It is recommended that user has a facility Circuit Breaker for overcurrent protection according to facility policy.

3.1.8 Doors

The doors are made from full aluminium resistant to corrosion and are warmed up to a controlled temperature.

The doors temperature is around 55ºC. Avoid touching the doors. It is requiered to use gloves for unloading material from the chamber, especially if you have sensitive skin.

The doors ensure the proper PlazMax operation and provide a sanitary barrier due to the micro switches and electromagnetic sealers that inhibit both doors from opening at the same time.

At the end of the cycle, the operator is informed that the cycle has been concluded and the door is now ready to open in order to unload the material from the chamber.

The operator can choose the door (in case of sterilizer with two doors) through which he selects to do the unloading. The two doors cannot be opened simultaneously; only one door at a time can be open.

The door(s) contain **safety bar(s)**. The Safety Bar prevent the door from trapping any object while closing. In a 2 doors system the two **Safety Bars** prevent the doors from trapping any object while closing.

Figure 8 –Chamber and Vertical Door

3.1.8.1 Door Gasket

Instructions to replace the door gasket (Figure 9).

1. Open the door. (The door is lowered to the bottom of the sterilizer)
2. Check and clean the gasket , if damaged proceed with the next steps.
3. Remove the door gasket.
4. Clean the gasket rail in order to remove the glue waste.
5. Place a silicone glue thread in the centre of the rail.
6. Place the gasket without stretching or shrinking.
7. Close the door and wait the silicone glue to dry before using the sterilizer.

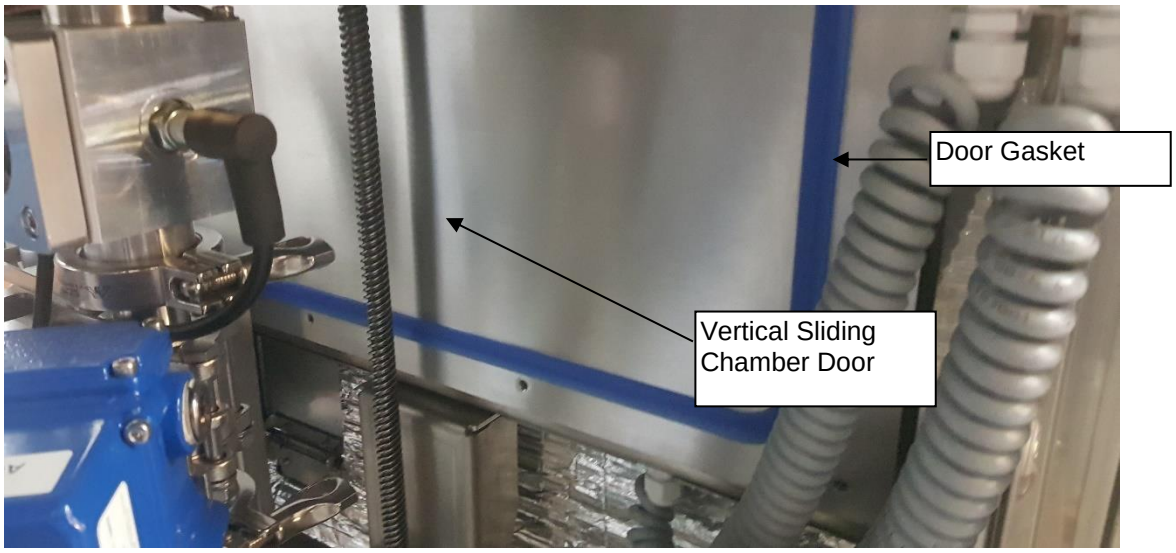


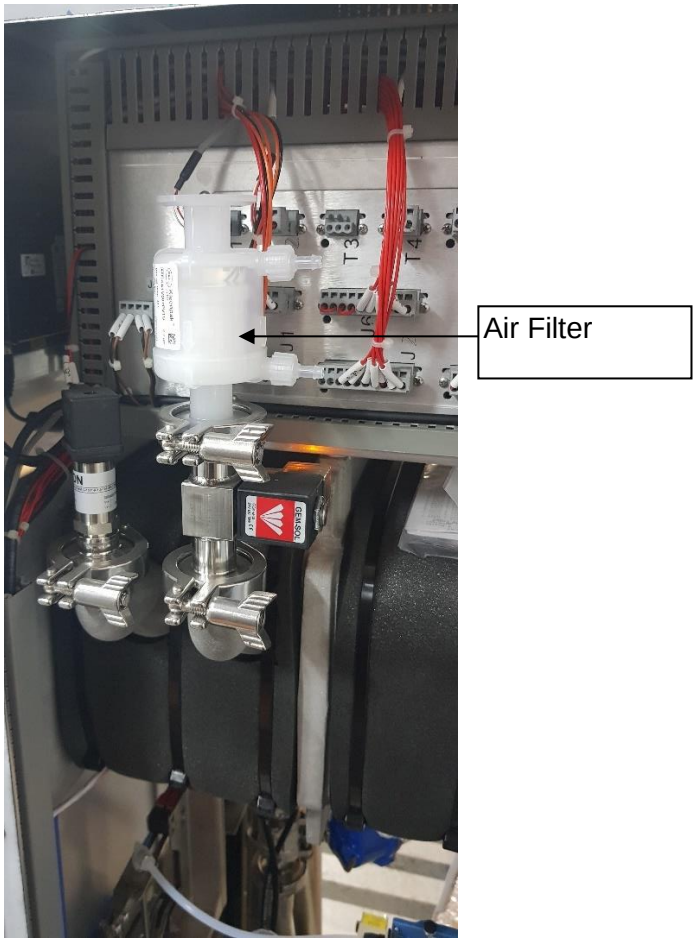
Figure 9 – Vertical Sliding Chamber Door

3.1.8.2 Air Filter

After an initial vacuum, air is injected into the chamber through the air Aeration filter in order to remove any possible humidity from the devices in the chamber.

Also during the sterilization phases air is injected to the chamber via this filter.

Periodically, the filter must be cleaned or replaced.



3.1.9 Printer

3.1.9.1 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:

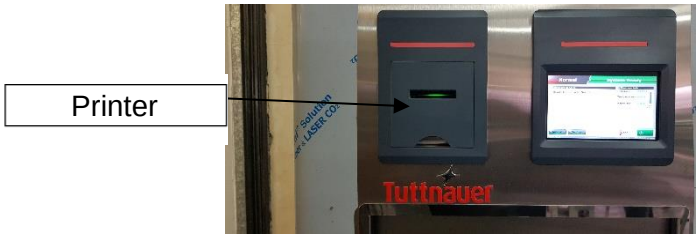
- Date:
- Time:
- Ser. Num:
- Model:
- Version:
- Cycle Num:
- Cycle Name:
- Ster Temp:
- Ster Time:
- Dry Time:
- End Temperature

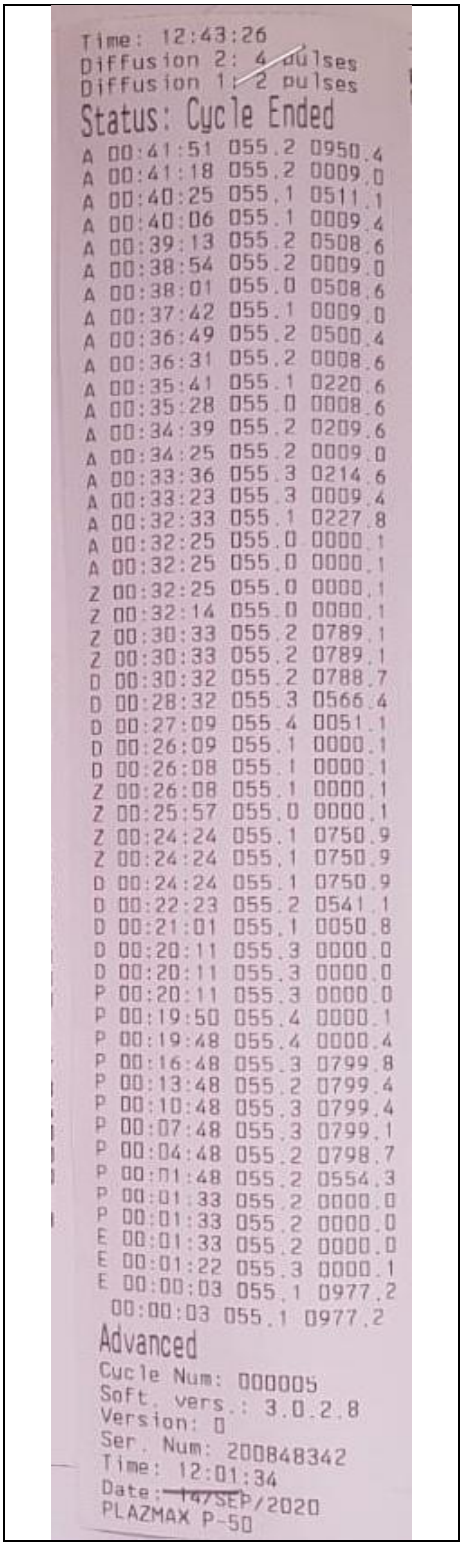
When the sterilization cycle begins the printer starts printing the above data.

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 the next page.




Time: 12:43:26
Diffusion 2: 4 pulses
Diffusion 1: 2 pulses
Status: Cycle Ended
A 00:41:51 055.2 0950.4
A 00:41:18 055.2 0009.0
A 00:40:25 055.1 0511.1
A 00:40:06 055.1 0009.4
A 00:39:13 055.2 0508.6
A 00:38:54 055.2 0009.0
A 00:38:01 055.0 0508.6
A 00:37:42 055.1 0009.0
A 00:36:49 055.2 0500.4
A 00:36:31 055.2 0008.6
A 00:35:41 055.1 0220.6
A 00:35:28 055.0 0008.6
A 00:34:39 055.2 0209.6
A 00:34:25 055.2 0009.0
A 00:33:36 055.3 0214.6
A 00:33:23 055.3 0009.4
A 00:32:33 055.1 0227.8
A 00:32:25 055.0 0000.1
A 00:32:25 055.0 0000.1
Z 00:32:25 055.0 0000.1
Z 00:32:14 055.0 0000.1
Z 00:30:33 055.2 0789.1
Z 00:30:33 055.2 0789.1
D 00:30:32 055.2 0788.7
D 00:28:32 055.3 0566.4
D 00:27:09 055.4 0051.1
D 00:26:09 055.1 0000.1
D 00:26:08 055.1 0000.1
Z 00:26:08 055.1 0000.1
Z 00:25:57 055.0 0000.1
Z 00:24:24 055.1 0750.9
Z 00:24:24 055.1 0750.9
D 00:24:24 055.1 0750.9
D 00:22:23 055.2 0541.1
D 00:21:01 055.1 0050.8
D 00:20:11 055.3 0000.0
D 00:20:11 055.3 0000.0
P 00:20:11 055.3 0000.0
P 00:19:50 055.4 0000.1
P 00:19:48 055.4 0000.4
P 00:16:48 055.3 0799.8
P 00:13:48 055.2 0799.4
P 00:10:48 055.3 0799.4
P 00:07:48 055.3 0799.1
P 00:04:48 055.2 0798.7
P 00:01:48 055.2 0554.3
P 00:01:33 055.2 0000.0
P 00:01:33 055.2 0000.0
E 00:01:33 055.2 0000.0
E 00:01:22 055.3 0000.1
E 00:00:03 055.1 0977.2
00:00:03 055.1 0977.2
Advanced
Cycle Num: 000005
Soft. vers.: 3.0.2.8
Version: 0
Ser. Num: 200848342
Time: 12:01:34
Date: 14/SEP/2020
PLAZMAX P-50

3.1.9.2 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

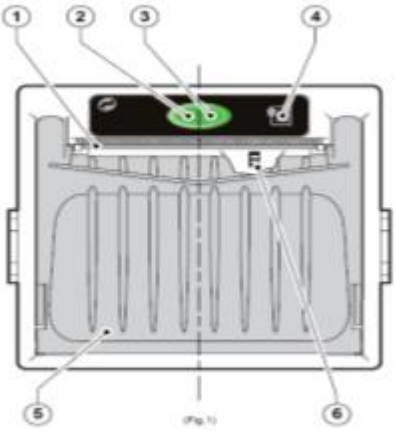


Figure 10 **– Printer model PLUS II view**

7. Open the printer cover door (3) by pulling it at the left bottom corner (2)
8. Press the OPEN key to open the printer cover as shown (see Fig. 11/1). Handle the paper cutter carefully not to cut your hand.
9. Place the paper roll making sure it unrolls in the proper direction as shown (see Fig.10, 11).
10. The paper should roll off the top of the roll.
11. Hold the loose end of the paper with one hand and re-close the cover with the other hand as shown (see Fig. 11/3) the printer cover is locked.
12. Tear off the exceeding paper using the jagged edge (see Fig. 11/4).

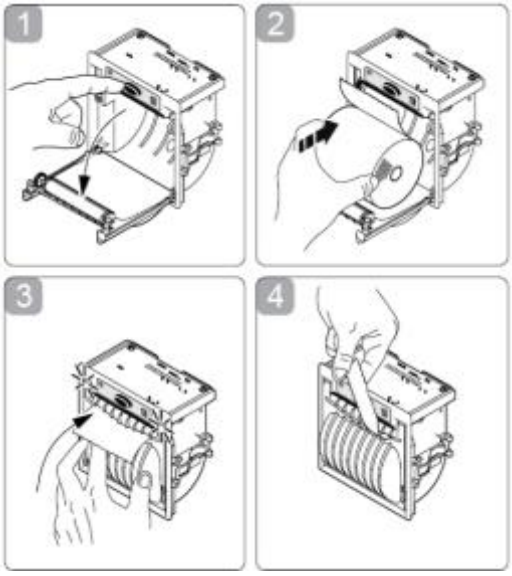


***Figure 11* – Printer loading paper**

13. Close the printer cover door (3) by pressing corner (2), with the tip end of the paper emerging from the slot (1). See Fig. 2 on previous page.

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.

Cautions!

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.

Warning!

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

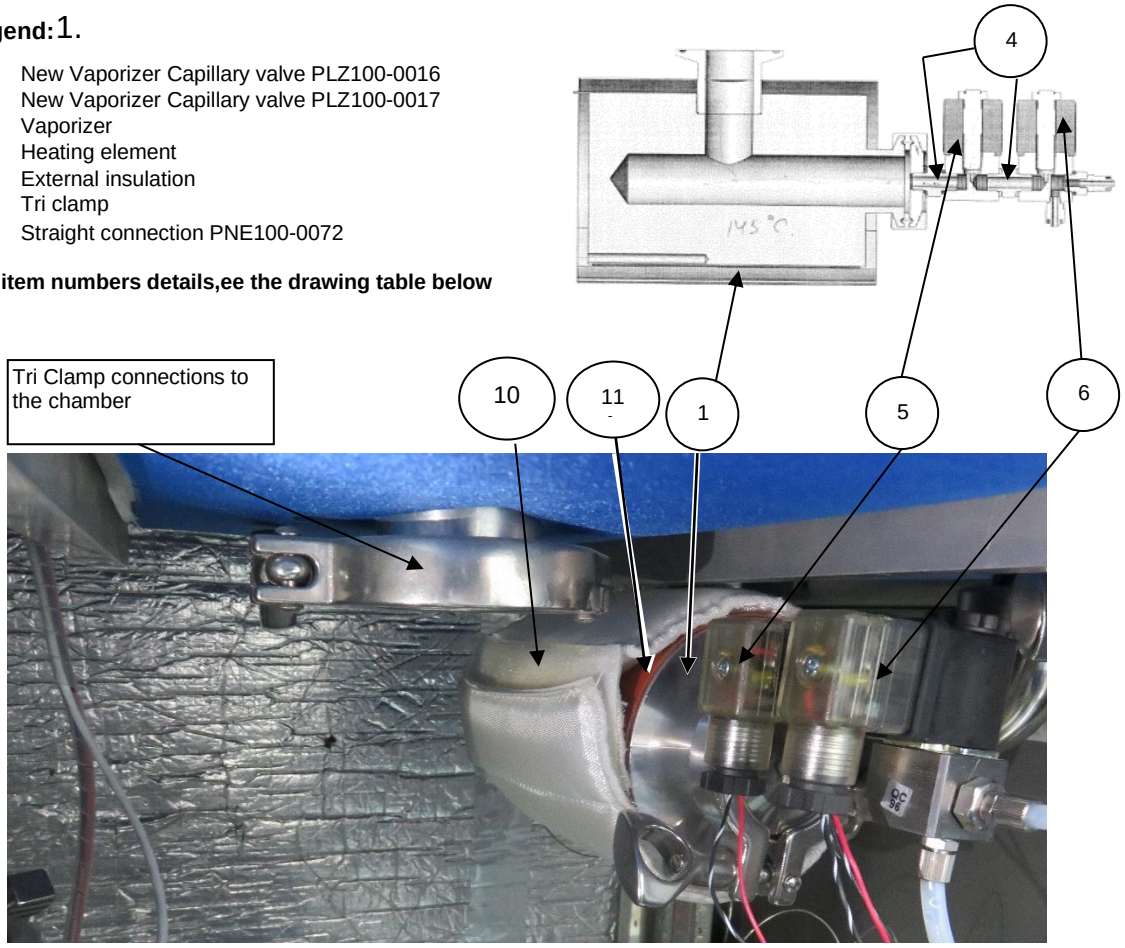
3.1.9.3 Vaporizer

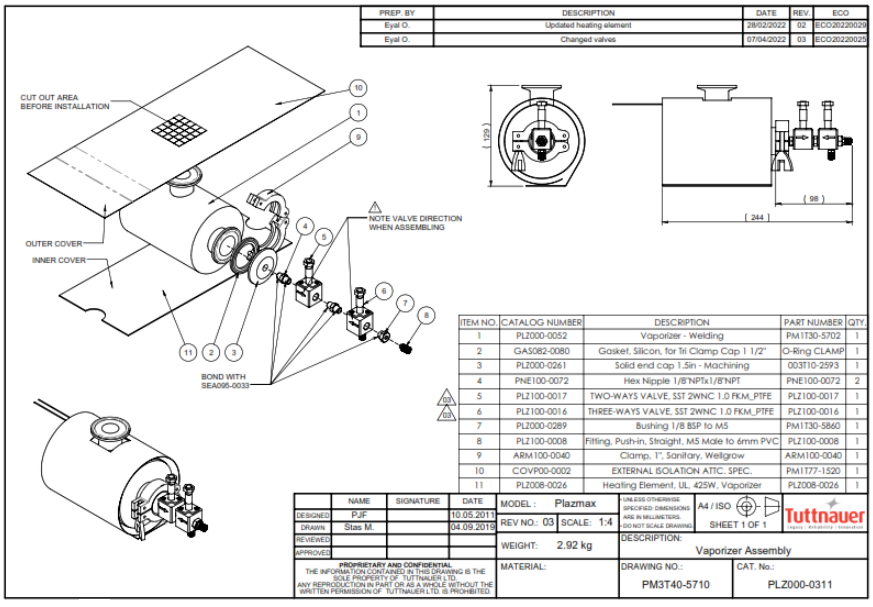
The vaporizer unit is a cylinder with a clamp connection .It is mounted on one of the exits on the bottom of the sterilizer chamber. The vaporizer is controlled by the internal software installed on the bottom of the sterilizer chamber.

Legend:1.

- New Vaporizer Capillary valve PLZ100-0016
- New Vaporizer Capillary valve PLZ100-0017
- Vaporizer
- Heating element
- External insulation
- Tri clamp
- Straight connection PNE100-0072

For item numbers details,ee the drawing table below





The vaporizer has an opening to the chamber and there is no valve between the vaporizer and the chamber, so that the vaporizer is part of the same chamber.

The figure above shows the vaporizer and the two H_2O_2 valves feeding process assembly, in which the hydrogen peroxide flow to the vaporizer and to the sterilizer chamber.
The H_2O_2 feeding system main componets include two valves (1) and (2), two straight connections (8) and the vaporizer assembly.

The operation of the the H_2O_2 flow to the sterilizer chamber is controlled by the software controller which controls the operation of valve 1 (Item 13) and valve 2 (Item 3).
The two valves works in pair, by alternating "Open-Closed", opening and closing simultaneously providing the required dose amount of hydrogen peroxide that passes from liquid to vapor and plasma state to the vaporizer and the plazmax chamber.
The hydrogen peroxide enters the heated (to 145 degrees C) evaporator. The hydrogen peroxide passes from liquid state to a vapor and plasma state. At this state it is sucked to the sterilizer chamber that is in vacuum. This process continue until 50 mbar is obtained.

The vaporizer is made of solid stainless steel (3) and contains a heating element (4) sleeve wrapped around its exterior cylindrical surface . The heating element is of a type that never flames up by itself, even when submitted to excessive temperatures. If the temperature will exceed 20ºC above normal operating conditions, the Main Switch will disconnect.

The external surface of the vaporizer is insulated (5) and protected to prevent accidental contact. Temperature is controlled by the control system.

In the beginning of each cycle, PlazMax will check the heating and temperature of the sterilizer heating components, including the vaporizer heater.
All the electrical and mechanical connections have rapid dismantling connections. The following elements are part of the Vaporizer: Heater, Vaporizer Valve,Two valves system, Probe, and Filter.

Note**:** Figure 12 also shows the new vaporizer used in Plazmax.

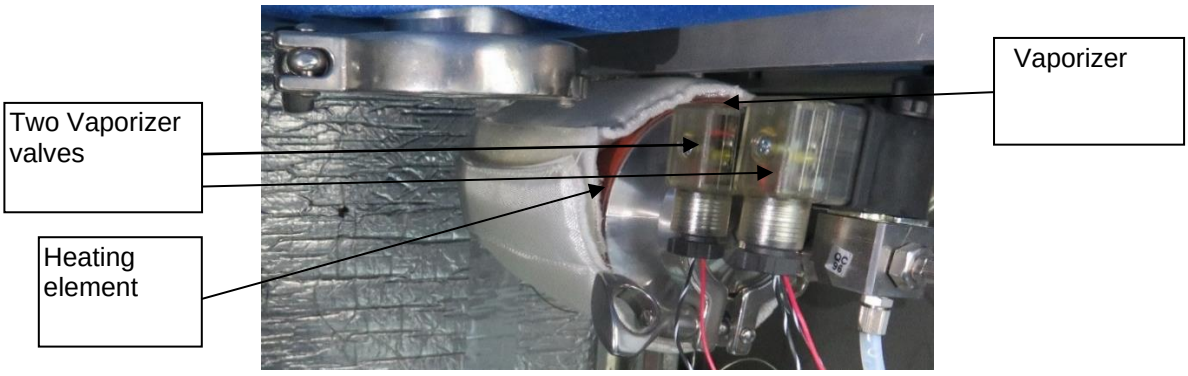


Figure 12 – The Vaporizer Assembly

3.1.9.4 Vaporizer Heater

The vaporizer has a heating element wrapped and banded around the vaporizer. (see vaporizer figure in par. 3.1.10).

The vaporizer contains a temperature probe linked to the software control.

3.1.9.5 Replacing the Vaporizer Heating Element

1. Remove the vaporizer isolation.
2. Disconnect the heater connectors.
3. Remove the heater and place the new one.
4. Connect the heater connectors.
5. Reassemble the vaporizer isolation and the fixers.

3.1.10 Vacuum Pump

For the generation of vacuum in the sterilizer, the PlazMax autoclave is equipped with an oil-sealed two-stage rotary vane vacuum pump – Trivac D25B. The pump is responsible for continuous operation, and for the generation of high vacuum in the sterilizer.

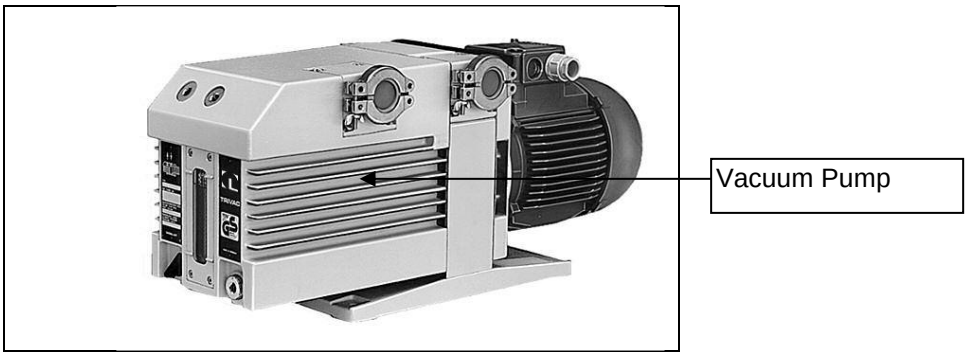


Figure 13 – PlazMax Vacuum Pump

The drive motor of the TRIVAC B is directly flanged to the pump at the coupling housing. The pump and motor shafts are directly connected by a flexible coupling. The bearing points of the pump module are force lubricated sliding bearings.
All controls as well as the oil-level glass and the nameplate are arranged on the front. All connections are to be found at the sides of the pump. The oil-level glass is provided with prisms for better observation of the oil level.
The pump module consists of assembly parts which are pin-fitted so as to allow easy disassembly and reassembly. The pump module can be easily removed without special tools.
Note:

1. After servicing the vacuum pump, make sure to reconnect the grounding earth connection.
2. Verify the vacuum pump oil level; the oil must be at the normal level.
3. Refer to the Vacuum Pump operation and maintenance instruction in this manual and in the appendix.

The mechanical oil filter function is the make the separation of fine particles from the pump's oil (sizes between 5 and 10 µm (OF)) and thus it protects and prevents mechanical damage to the vacuum pump.

The filter is installed without on the vacuum pump, and provides longer service life for the oil.

3.1.11 Oil Filter

The oil pump B draws in the oil and then after pumping it through the oil filter facility, only then the cleaned oil will arrive to the lubricating points of the pump. Thus the oil filter facility will not only extend the service life of the oil, but it will also extend the service life of the entire pump.

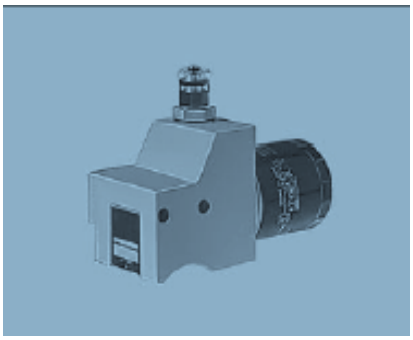


***Figure 14* – OF 4-25 mechanical oil filter**

3.1.12 Sterilization Chamber

The sterilization chamber is made of a material resistant to corrosion. Inside the chamber there are Teflon rails that ensure that there is enough space between the chamber and the basket, providing a correct circulation of the sterilizing agent.

It is rerequiered to use gloves to unload the chamber. The chamber heating is made electrically and the temperature is controlled by the control system.

The heating elements are installed around the chamber as a coat and are made of a high quality and safe silicone with fibre glass material.

***Figure 15* – Sterilization Chamber**

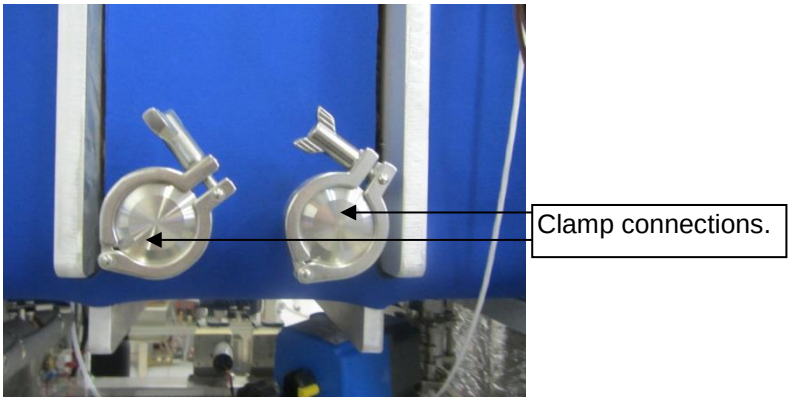
The temperature of the chamber walls is around 131ºF; therefore direct contact must be avoided. If you have sensitive skin, it is highly recommended to use safety gloves to unload the chamber.

The chamber heating is made electrically and the temperature is controlled by the control system.

The heating elements are installed around the chamber as a coat and are made from high quality safe silicone with fibre glass material.

3.1.13 Chamber Access Openings

It is possible to Access the chamber with probes and Transducers trough the clamp connections.



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4. LOAD PREPARATION

4.1 Overview

This chapter briefly describes the materials and devices that can be sterilized by the PlazMax Sterilizer. It also provides information on how to prepare items for sterilization.

However, there are a few important exceptions. Please review this chapter carefully; it contains details on recommended materials and lumen sizes.

Important: The correct handling and storage of the PlazMax Sterilizing Agent is extremely important for ensuring the safety of personnel and equipment.

Warning!
Do not attempt to sterilize items or materials that do not comply with the directions specified in this manual. In addition you should read the device manufacturer's instructions or call the manufacturer center to determine whether an item can be sterilized by this sterilizer. It is also stongly recommended to refer to the European Norm: EN17664.

4.2 Material and Items for Sterilization

Recommended Items & Materials that can be sterilized by PlazMax

Metals

- Any material manufacturers recommend that can to be sterilized by Hydrogen Peroxide (H_2O_2).
- Titanium
- Aluminium 6000 series
- Stainless steel 300 series

Non Metals

- Acrylonitrite butadiene styrene (ABS)
- Delerin
- EVA (Etheyl vinyl acetate)
- Fluorinated ethylene propylene (PTFE)
- Glass, USP type I borosilicate
- Low density polyethylene
- Latex
- Monel
- Neoprene rubber (polychloroprene)
- Silicone
- Nylon
- Phenolic resin
- Polyethylene terephthalate (PET)
- Poly (methyl methacrylate (PMMA)
- Poly (phenyl sulfone)
- Polypropylene
- Polysulfone
- Teflon (PTFE)

- Polyurethane
- Polyvinyl chloride (PVC)
- Silicone

Items and Material which cannot be Sterilized

- Absorbent materials (cellulose)
- Wood, linen, paper, spongeous materials
- Liquids
- Powder
- Oil
- Copper
- Bronze

4.3 Cleaning, Rinsing, and Drying

Cleaning of instruments and devices is a critical step required prior to sterilization.

The process of cleaning is necessary to remove organic and inorganic soil and debris from equipment. In this process, many microorganisms are removed from the surface of the items. The process of sterilization inactivates all remaining spores and live microorganisms.

Note:
All items must be cleaned, rinsed, and thoroughly dried before being placed in the PlazMax Sterilizer. Loads containing moisture may cause cycle cancellations.

It is necessary to perform careful periodic inspection of the items after repeated exposure to disinfectant/cleaner/sterilant, due to the potential damaging effects of the chemical agents on the items.

- Carefully inspect all instruments and devices for flaws or damage prior to packaging. Devices and instruments with flaws or damage should be replaced or repaired before using.
- Clean the devices according to the device manufacturers' instructions. You must remove all blood, tissue, and soil from items using appropriate detergents, cleansers and/or methods.
- All items including trays must be thoroughly cleaned, rinsed, and dried before loading into the sterilizer.
- Rinse items thoroughly to remove detergent or cleaner residue. Use treated water that is of a quality that ensures that hard water stains do not occur. Failure to remove all organic materials or detergents may result in the formation of light-colored residue on the devices. If residue is visible, you should clean, rinse, dry, and re sterilize the device prior to use.
- Dry all items thoroughly. An acceptable method for drying is to blow compressed gas through the lumen until no moisture exits at the distant end of the device. Please ensure that any method used to dry the devices is in accordance with the manufacturers' instructions for use, or contact the device manufacturer to obtain appropriate and safe procedures.
- It is necessary to remove moisture from all parts of the items. Only dry items should be loaded into the sterilization chamber to prevent cycle cancellation.

Warning!
Possible non-sterile device! Loads containing moisture may result in either a non-sterile device or cycle cancellation. Wear chemical resistant gloves when handling items from any load containing moisture.

4.4 Packaging and Loading

If you select to package the instruments, proper preparation of tray pouches and instruments can minimize or prevent cycle cancellations and biological indicator (BI) results due to load-related problems. All instruments must be cleaned, rinsed, and thoroughly dried before loading into sterilizer.

4.1.1 Packaging

- Use PlazMax Sterilizer-compatible polypropylene sterilization wrap and tyvek® pouches.
- Do not use any wraps or packaging that are not approved by PlazMax or materials that are not approved for use in this section.
- Arrange the items in a tray to ensure proper diffusion of H2O2 throughout the load.
- Place peel pouches on edge, if possible arrange them so that the transparent side of a pouch faces opaque side of the next pouch. Do not stack pouches on top of each other.(see Figure 18)
- Do not stack instruments on the trays. Do not stack trays within trays. Do not wrap instruments within a wrapped tray.
- If you are using rigid containers cleared by the FDA for use in the PlazMax Sterilizer, follow the instructions recommended by the instrument manufacturer. Do not stack containers within containers. Do not wrap instruments within the container.
- Place chemical Indicator Strips inside trays and pouches as needed.
- Do not allow any item to touch the walls of the sterilization chamber.

4.1.2 Loading

Full loads for model:

Warning! do not exceed from weight listed here:
Normal cycle is designated for full load weights, for:
P50 – 7kg, P110 – 10kg, P160 – 13kg.

Advanced cycle is designated for full load weights, for:
P50 – 7kg, P110 – 10kg, P160 – 13kg.

Heavy Duty cycle is designated for heavy load weights, for:
P50 – 11kg, P110 – 13kg, P160 – 15kg.

Flexible Endoscope:

P50- 1 pieace in maximum length of 4000mm with double open ends or 1400mm with one side opening

P-110 & P160- 2 pieaces in maximum length of 4000mm with double open ends or 1400mm with one side opening

Caution!

Ensure that metal objects do not come into contact with the walls of the chamber, contact with the door, or electrode can cause a cancellation, and/or damage item or the sterilizer. Provide at least 1 inch (25 mm) between the top of the load and the electrode.

4.5 Before You Start Sterilization

4.6.1 Loading the PlazMax Sterilization Chamber

The PlazMax chamber has 4 Teflon (PTFE) guiding rails designed to provide low friction sliding rails for trays, and make space between the chamber walls and the materials, allowing free circulation of sterilizing agent.

We recommend that all sterilization material should be packed in polypropylene or tyvek® pouches.

Do not use cellulose variations or tissue for the packaging of the devices, because these materials are sterilizing agent absorbent and make the ventilation more difficult.

The materials to be sterilized must be properly processed. They must be clean and completely dry.

Note: It is very important that the temperature of the materials to be sterilized is not lower than room temperature.

4.6.2 Start and Warm-up operation

Before you START go to Load Preparation and the Operation (Chapter 4).

4.6.3 Loading Item Preparation

Proper preparation of items, trays, pouches, and instruments can minimize or prevent cycle cancellation due to load-related problems.

A brief overview of load preparation is given below.

Arrange the items in a tray to ensure that the hydrogen peroxide and plasma can surround them.

- Place peel pouches loosely on edge, if possible.
- Arrange them so that the transparent side of a pouch faces the opaque side of the next pouch.
- **Do not stack pouches on top of each other.**
- Do not allow any item to touch the walls or door of the sterilization chamber or electrode. Provide at least 25 mm (1 inch) of space between the electrode the load.
- Place the PlazMax Biological Indicator or other approved biological indicator in the sterilization chamber.

Caution!
Metal objects must not come into contact with the chamber walls, door, or electrode. Contact with the walls, door or electrode can cause a cycle cancellation and/or damage the items or the sterilizer.

Note:
Do not stack instrument inside the trays. Do not stack trays. Do not stack trays within trays. Do not wrap instruments within the trays. If you are using rigid containers cleared by the FDA for use in the PlazMax System, follow the same procedures that are recommended for use with the PlazMax Instrument Trays.

1. Load the items to be sterilized (**for maximum loads see 4.4.2.**).
2. Press START to initiate the desired process cycle.

Note:
Pay attention to the placement of the items (sterilization material packed in polypropylene or tyvek® pouches).

4.6 Sterilization Operation

4.6.1 Before Starting

Prior to starting the PlazMax sterilizer read carefully and follow (chapter 2 and 4) load preparation and the materials/items devices that can be sterilized. It is the operator responsibility to be familiar with the information of this manual.

Warning!
Do not attempt to sterilize items or materials that do not comply with the directions specified in this manual. In addition you should read the device manufacturer's instructions or call the manufacturer center to determine whether an item can be sterilized by this sterilizer. It is also stongly recommended to refer to the European Norm: EN17664.

PlazMax Important Notice
Before processing any item in the PlazMax Sterilizer, make sure that you know how the PlazMax Sterilization Process will affect the items. Read, understand, and follow the device manufacturers' instructions for their respective products.

This manual lists the types of items and materials that can be safely processed in the sterilizer (Paragragh 4.2), also it is strongly recommended to consult the European Norm: EN17664.

This manual is not intended to replace any manufacturers' instructions. If you have questions, or if you are in doubt about the materials in your devices, contact the device manufacturer or your PlazMax Customer Representative for more information.

4.6.1.1 Preparing PlazMax for Operation

1. Remove the touch screen protection;(upon receiving a new sterilizer for the first time)
2. Take out the screw caps on the sterilizing supply drawer. Unscrew the drawer panel & remove it. Remove the lower front panel (Figure 1), and verify the vacuum pump oil level. The oil must be between the minimum and maximum level marks ;(Figure 16).

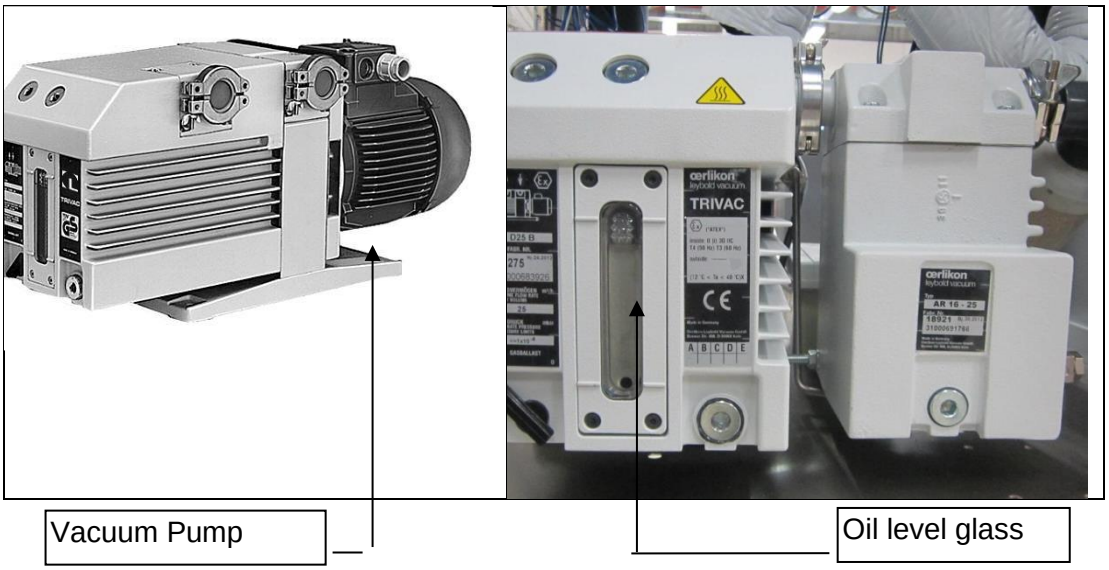


Figure 16 –Vacuum Pump

ATTENTION:
The doors are blocked for transport/shipping.

To unblock the doors proceed as follows:

1. Connect the sterilizer to the electric power.
2. Start the sterilizer, by Pressing on the ON/OFF button, (see chapter 8).
3. Supply the sterilizer with sterilizing agent, (follow the instructions in paragraph 8.2).
4. Select one of the programmes and the unclean side door will be unblocked. Open the door and remove the User Manual and any other items that have been placed inside the chamber (follow the instructions in chapter 4)

4.6.1.2 Before Starting Procedure

Before Starting Remove the touch screen protection.

Note:
This is done once after the first installation of the sterilizer. (See chapter 11)

PlazMax Important Notice
Never use sharp or marking instruments to touch the screen, as this could damage the screen.

- **Do not attempt to open the door before the sterilizer is plugged in and the ON/OFF main switch on the front panel is turned on.**
- **Remove the right and left side panels.**

- **Unblock the door manually, and remove all items that might be inside the chamber.**
- **Verify the vacuum pump oil level; the oil must be at the normal level.**
- **Check that the pump tubes are disconnected. Remove the leads sealing the inlet and outlet of the vacuum pump, connect the tubes and tighten the clamps.**
- **Connect the molecular sieve on the outlet of the oil separator (molecular sieve must be leaning on the base steel plate).**
- **Switch ON the vacuum pump.**
- **Replace the external panels.**
- **Supply the sterilizer with the sterilant agent if needed (follow the touch screen instructions).**
- **Select one of the programs.**

4.6.1.3 Checklist

- **Make sure to warm up the unit with the tools for at least 15 minutes before start cycle.**
- **In the beginning of every new working week and before turning on the machine, make sure to press the drain button. Pressing this button is important to maintain the vacuum pump in proper operation mode.**

4.7 Loading and Warm-up

Prior to starting the PlazMax sterilizer read carefully and follow chapter 4, load preparation and the materials/items devices that can be sterilized. It is the operator responsibility to be familiar with the information of this manual.

1. Load the PlazMax Sterilization Chamber, according to the instructions in chapter 4.
2. Start and Warm-up according to the next paragraph.

4.7.1 Start and Warm-up

1. Turn on the main power switch which is located at the front of the sterilizer, above the printer.
2. Close the door. The sterilizer now begins warming up. The warm up can take up to 30 minutes.
3. Select the desired program.
4. Load the items to be sterilized. **for maximum loads see 4.4.2.** Note: Pay attention to the placement of the items (sterilization material packed in polypropylene or tyvek® pouches).
5. Arrange and always keep the opaque paper side of one pouched item attached and facing that of the transparent side of the next pouched item. Do not stack pouches on top of each other. (See Figure 17)

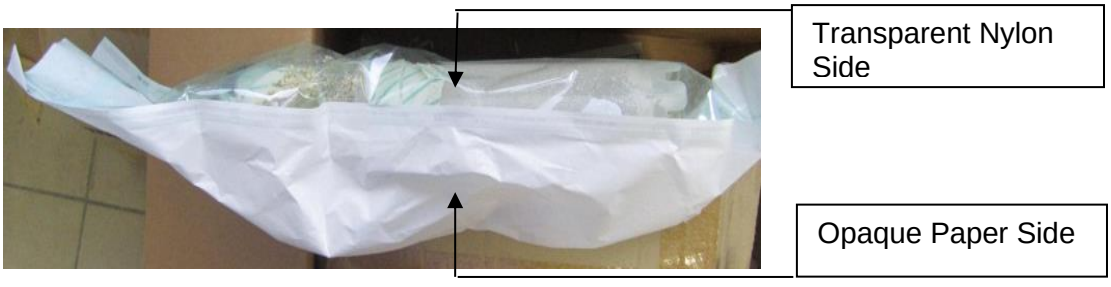


Figure 17 – Loading pouched items

6. Press **START** to initiate the desired process cycle.

5. STERILIZATION CYCLES

5.1 Overview

The PlazMax enables fast sterilization cycles of devices and lumen with H_2O_2 vapor as the sterilizing agent.

The sterilization cycles run in high vacuum in the chamber created and maintained by advanced vacuum pump technology.

5.1.1 PlazMax New Generation Sterilization Method

The PlazMax sterilizer features improved sterilization method based on the following parameters:

- Fast Sterilization Process
- Safety
- Environment Friendly
- Low Cost

Fast Sterilization Process:

The process takes in average about 40 minutes for the normal sterilization cycle, approximately 45 minutes for the advanced cycle, and 40 minutes for the endoscope cycle:

- The sterilization method only requires electrical supply
- The ventilation is not necessary, no gas is emitted
- The temperature of the materials is low, less than 55ºC
- PlazMax sterilization process duration time depends on the load weight placed into the process up to a maximum load (see 4.4.2.), as shown in the table below.

Table 1 – Plazmax Sterilization Cycle Time & maximum load

Load / Cycle	Non–hollow rigid loads	Hollow Flexible loads	Time (minutes)
Advanced*	approved	approved	**40**
	approved	approved	**50**
	approved	approved	**55**
Normal	approved	Not-approved	**35**
	approved	Not-approved	**45**
	approved	Not-approved	**50**
Endoscope	Not-approved	approved	**28**
	Not-approved	approved	**30**
	Not-approved	approved	**45**
Heavy Duty*	approved	approved	**46**
	approved	approved	**48**
	approved	approved	**63**

* Non hollow and hollow can be mixed

Maximum Loads Per model:

	Normal (kg)	Advanced (kg)	Heavy Duty (kg)	Endoscope
P-50	15.4 Lbs 7 kg	15.4 Lbs 7 kg	24.2 Lbs 11 kg	1 Piece
P-110	22 Lbs 10 kg	22 Lbs 10 kg	28.6Lbs 13 kg	2 Pieces
P-160	28.6Lbs 13 kg	28.6Lbs 13 kg	33Lbs 15 kg	2 Pieces

Safety:

The safety of the system is improved since:

- The operator has no contact with the sterilant agent
- Greater suitability to lumen sterilization
- The injection system controls the quantity of sterilant agent required inside the chamber based on the load, allowing a safe sterilization in every possible loading
- PlazMax performs self-testing cycles

Environment friendly:

- The packaging material is cellulose free
- The process does not consume water
- The steriliz
- ing agent is not toxic

Low cost:

PlazMax cycles are very economical:

- The cycle process takes approximately 40 minutes in average.
- The sterilization method requires electrical supply only
- Ventilation is not necessary, no gas is emitted
- Low process temperature of less than 55ºC

5.1.2 Sterilizing Agent Instructions

Refer to the Sterilizing Agent properties described in detail in this manual.
The Hydrogen Peroxide substance must be placed with the arrows facing upward.

Sort and verify that the RFID tag at the bottom of the bottle is not damaged. The PlazMax sterilizing agent is clear, colorless and looks like water. It is not flammable; and is soluble with water independently of the sterilizing agent concentration.

Before taking the bottle out of the plastic bag, verify that there are no liquid drops or leakage inside this bag (In case of sterilizing agent leakage, use safety gloves to take the bottle off the plastic bag and clean it before putting it onto the drawer holder).

1. Take the bottle of the plastic bag.
2. Place the bottle on the drawer holder.
3. **Take the bottle cover off**, only after placing the bottle on the holder.

Warning!

In case of skin contact with the sterilizing agent, wash immediately with plenty of water.

In case of injury or feeling unwell, seek medical advice, and if possible, show the product label.

5.2 Sterilization Cycles Description

General

PlazMax sterilization process is based on the hydrogen peroxide, (H_2O_2), vapor injection in a sterilization chamber at a controlled temperature and deep vacuum.

PlazMax sterilizer has four pre-established sterilization cycles. The pre-established sterilization cycles are:

- Cycle I – Advanced
- Cycle II – Normal
- Cycle III – Endoscopes
- Cycle IV – Heavy Duty

Sterilization Programs Process Stages

The sterilization programs are composed of the following process stage phases:

- Phase 1: Air removal
- Phase 2: Pre diffusion
- Phase 3: Diffusion 1
- Phase 4: Exhaust 1
- Phase 5: Diffusion 2
- Phase 6: Exhaust 2
- Phase 7: Aeration
- Confirm cycle

A theoretical typical sterilization cycle is shown in Figure 19.

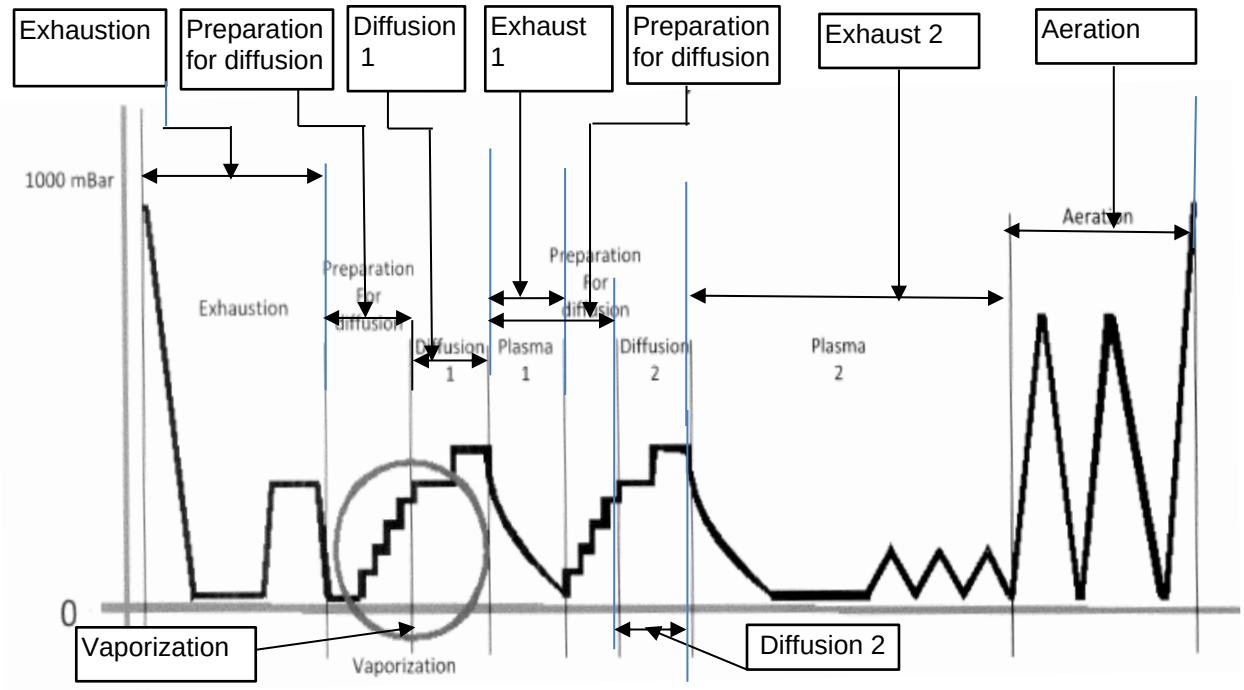


Figure 18 – Theoretical Cycle Graph

The sterilization cycles are designed to run in deep vacuum (in the chamber). The deep vacuum is achieved by the advanced vacuum technology and the double stage vacuum pump.

After an initial air removal phase & getting to a vacuum, an aeration is performed (to remove air from the chamber), in the pre diffusion phase air is injected into the chamber through the filter and the chamber is warmed up in order to remove any possible humidity from the instruments to be sterilized.

After the second vacuum phase, the H_2O_2 vapor is injected by pulsing into the chamber, and the diffusion (diffution 1) phase and micro-organisms inactivation begins. The sterilization chamber is filled with H_2O_2 after the relative humidity inside the chamber has been reduced. The sterilization process occurs after reaching vacuum of approximately 1 mbar pressure in the vaporizer.

Following the Diffusion phase comes the exhaustion and the sterilizing agent burning phases.

After the first diffusion and exhaustion phases comes the second diffusion and exhaustion phases (which are similar to the first diffusion & exhaustion phases), followed by the sterilizing agent burning phases.

Finally comes the chamber ventilation phase and the cycle is concluded.

Sterilization process is achieved by the capillary tube inside the vaporizer which transforms the H_2O_2 liquid into vapor gas. The controller continually monitors the H_2O_2 injection rate based on inputs from the system pressure and temperature sensor probes.

PlazMax enable fast sterilization cycles and a system that allows the dosing into the vaporizer in a complete absence of air.

5.3.1 Cycle I – Advanced Cycle

The Advanced cycle is used for general device sterilization, including hollow rigid instruments, in Tyvek pouches.
Intended use: Loads per model:
P50 – 7kg, P110 – 10kg, P160 – 13kg.
The advanced cycle process takes approximately 45 minutes, and 55 minutes maximum.

The Advanced Cycle is composed of the following phases:

- One Air removal phase
- One Pre-Diffusion phase
- Two phases of Diffusion (Diffusion 1 and Diffusion 2)
- Two phases of Exhaust (Exhaust 1 and Exhaust 2)
- One phase of Aeration
- Confirm cycle

This cycle is similar to the Normal Cycle, but the Diffusion phases are longer. The actual Advanced cycle graph is shown in Figure 20 below.

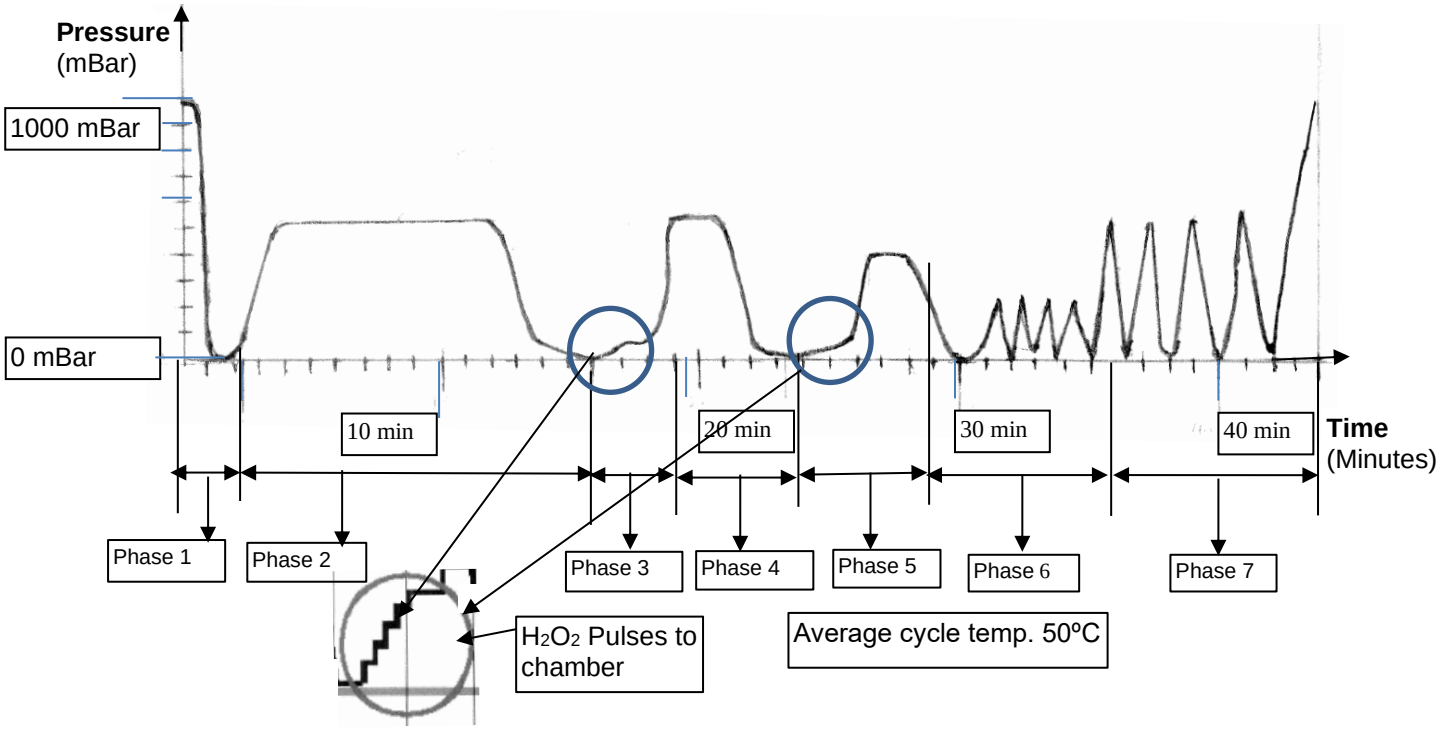


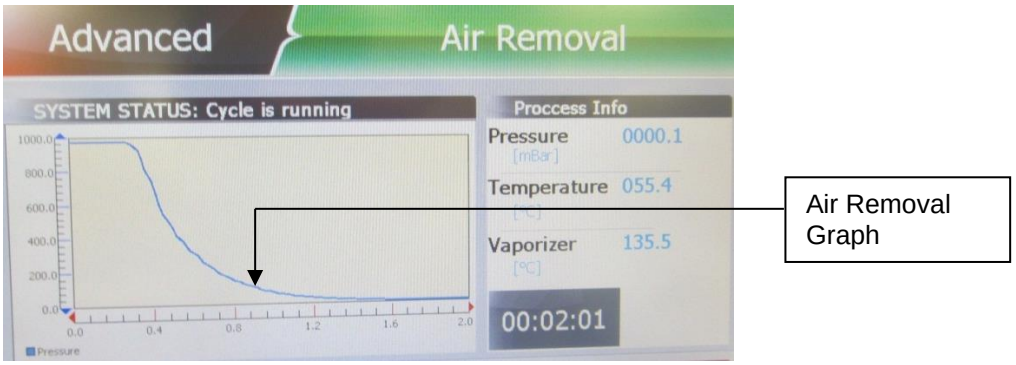
Figure 19 – Advanced Cycle Actual Graph

The Advanced cycle runs as follows:

5.2.1.1 Phase 1: Air removal:

In phase 1, air is removed from the chamber; the pressure in the chamber is reduced from atmospheric to vacuum.

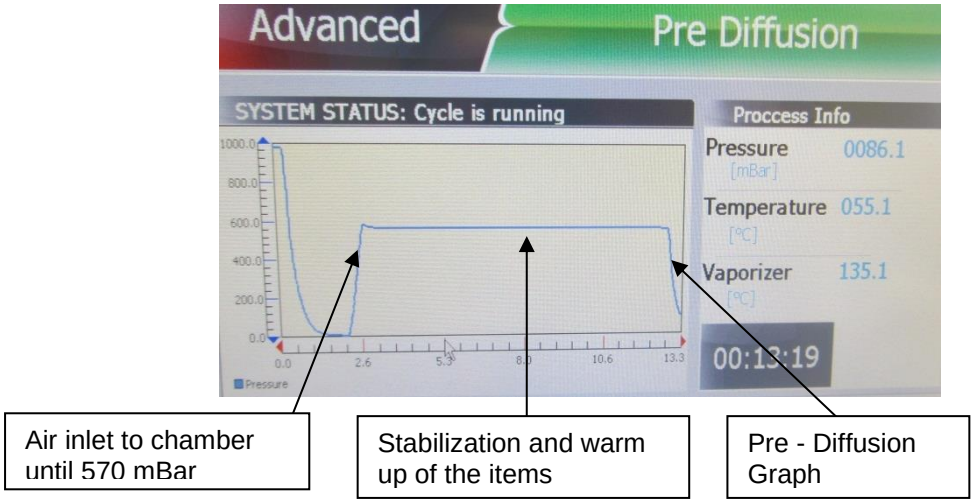
In phase 1 the system checks that there are no leaks in the chamber and it also monitors the performance of the vacuum pump. If the checks are satisfactory the system proceeds with the sterilization process.



5.2.1.2 Phase 2: Pre - Diffusion: (Preparation for Diffusion)

This phase consists of creating in the chamber and vaporizer conditions for the diffusion. Air is injected to push moisture, pressure is reduced to vacuum to remove all air. This phase includes the following:

- A heating mode to warm up the load.
- Evacuation of all the free air in the chamber.
- Run the vaporizer dozing pump to eliminate air bubbles inside the tubes.



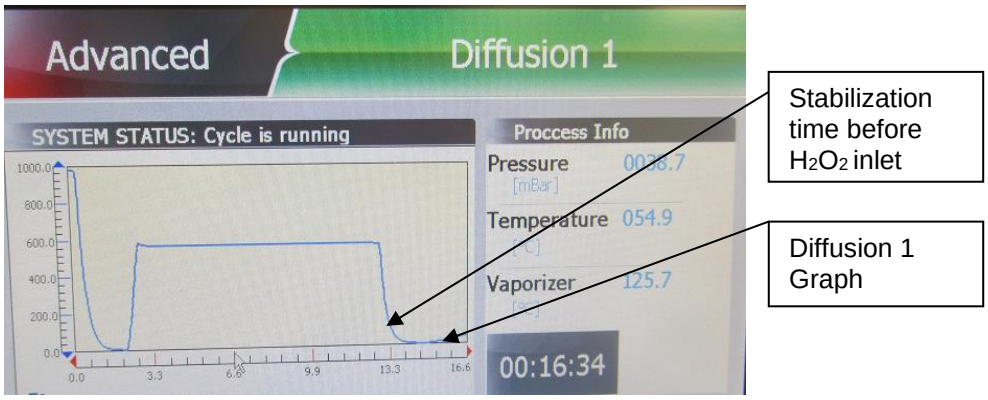
5.2.1.3 Phase 3: Diffusion 1 (Diffusion):

In this phase, under vacuum H_2O_2 is injected by pulses into the chamber and is diffused after being vaporized starting the items sterilization & micro-organisms inactivation. Air is also introduced to the chamber to push H_2O_2 to surround all the items to be sterilized.

In this process, three parameters occur as follows:

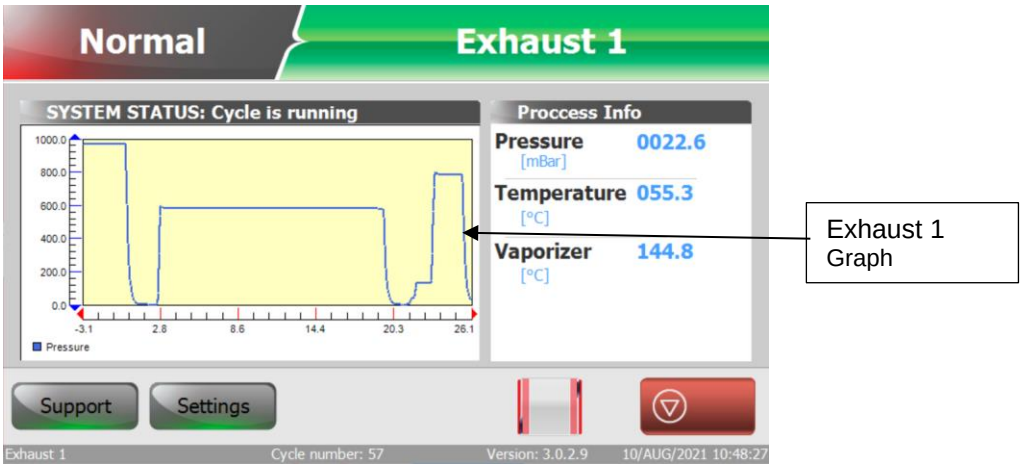
- Hydrogen Peroxide H_2O_2 vapor
- The vaporizer produces water vapor

All the H_2O_2 is diffused into the chamber and surround the items to be sterilized, starting the inactivation of micro-organisms.



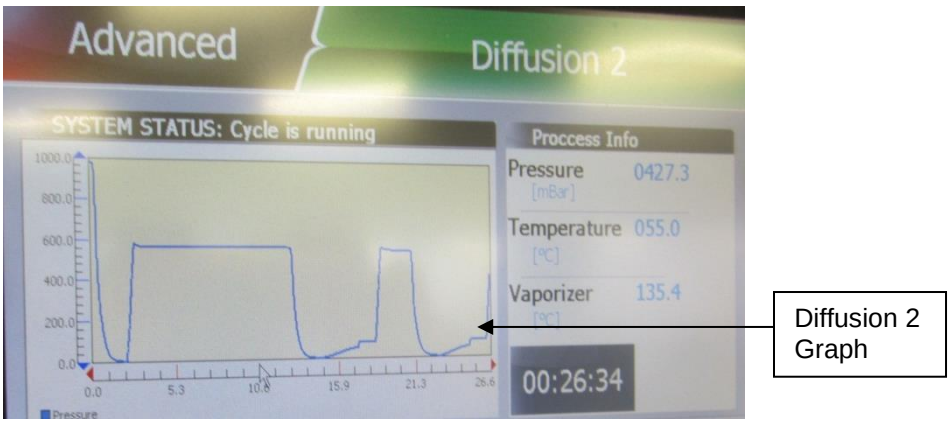
5.2.1.4 Phase 4: Exhaust 1

After the diffusion stage comes the Exhaust 1 mode phase, all the H_2O_2 gases are removed to filter.



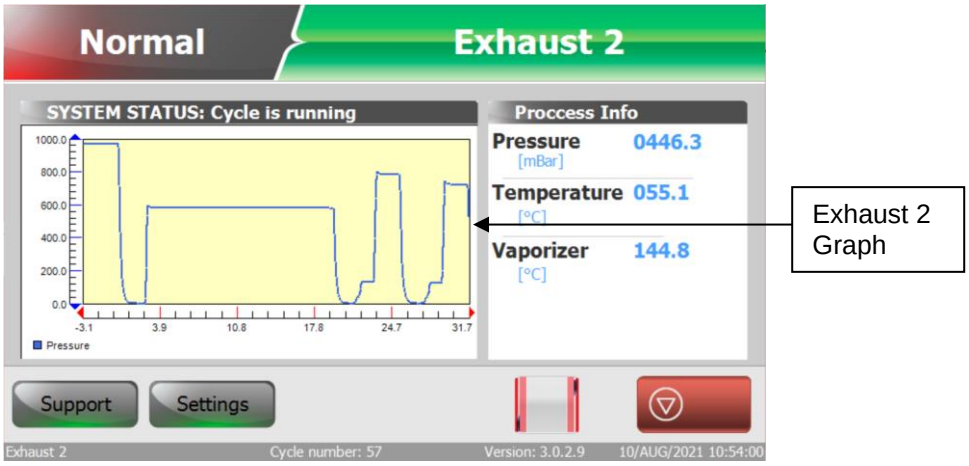
5.2.1.5 Phase 5: Diffusion 2 (Preparation for Diffusion 2)

(Similar to phase 3)



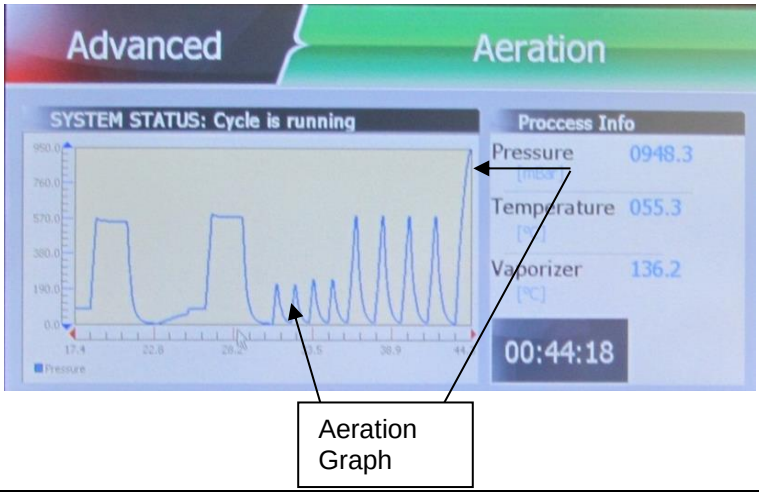
5.2.1.6 Phase 6: Exhaust 2

(The same as phase 4)



5.2.1.7 Phase 7 Aeration (Ventilation):

In this phase the chamber is ventilated with atmospheric air drawn through the air filter, so that no sterilant residue remains on the items and in the chamber.



5.2.1.8 End of Program: (Confirm Cycle):

At the end of a sterilization cycle, a buzzer sounds, and the cycle complete message appears.

A report of the cycle phases is printed, and the operator is informed if the cycle was successfully completed or if it failed. In the report, a space is available for the operator to sign and validate the report. At this stage it is possible to open the door.

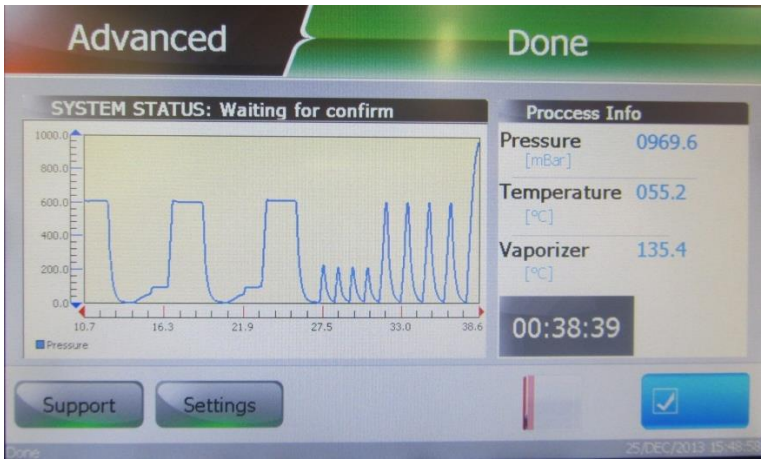


Figure 20 – Advanced Cycle Screen

Notes:

The PlazMax specified cycle time is related to the load inside the chamber. The operator can place up maximum load (see 4.3).

Experiments made with the PlazMax PCDs (Lumen Kit) confirm that Advanced Cycle has the capacity to sterilize the following lumen:

- Diameter ≥ 1 mm and extension ≤ 1.4 meters, with one closed end.
- Diameter ≥ 1 mm and extension ≤ 4 meters, with both ends opened.

5.3.2 Cycle II – Normal Cycle

The Normal Cycle is used for fast superficial sterilization process which can be used for rigid-solid instruments sterilization. **Remark:** If hollow and rigid are mixed together, please use the advanced cycle program
Intended use: Load of 10 kg maximum. The Normal cycle process takes approximately 40 minutes, the maximum cycle time is 50 minutes.

The Normal Cycle consists of:

- One air removal phase
- One Pre diffusion phase
- Two phases of Diffusion (Diffusion 1 and Diffusion 2)
- Two phases of Exhaust (Exhaust 1 and Exhaust 2)
- One phase of Aeration
- Confirm cycle

5.2.2.1 Phase 1: Air removal: (Exhaustion):

In phae 1, air is removed from the chamber; the pressure in the chamber is reduced from 1000 mbar to nearly 0 mbar vacuum.

In phase 1 the system checks that there are no leaks in the chamber and it also monitors the performance of the vacuum pump. If the checks are satisfactory, the system proceeds with the sterilization process.

5.2.2.2 Phase 2: Pre diffusion: (Preparation for Diffusion):

This phase consists of creating, in the chamber and in the vaporizer conditions for the diffusion. The purpose of this phase consists of the following:

- A heating mode which is required to warm up the load.
- Evacuate all the free air in the chamber.
- Running the vaporizer dozing pump in order to eliminate air bubbles inside the tubes.

5.2.2.3 Phase 3: Diffusion 1 (Diffusion):

In this phase, sterilizing agent H_2O_2 is injected into the chamber and is diffused after being vaporized. In this phase, 2 parameters occur as follows:

- The vaporizer produces water vapour.
- Hydrogen Peroxide H_2O_2 vapour.

All the sterilant agents are diffused into the chamber and surround the items to be sterilized. This starts the inactivation of micro-organisms.

5.2.2.4 Phase 4: Exhaust 1:

In the Exhaustion mode gases are removed through the filter- evioronment friendly.

5.2.2.5 Phase 5: Diffusion 2 (Preparation for Diffusion 2):

(The same as phase 3).

5.2.2.6 Phase 6: Exhaust 2:

(The same as phase 4)

5.2.2.7 Phase 7: Aeration (Ventilation):

In this phase the chamber is ventilated with atmospheric air drawn through the air filter, so that no sterilant residue remains on the items and in the chamber.

5.2.2.8 End of Program: (Confirm Cycle):

At the end of a successful sterilization cycle, a buzzer sounds, and the cycle complete message appears.

A report of the cycle phases is printed, and the operator is informed if the cycle was successfully completed or if it failed. At this stage it is possible to open the door.

Notes:

Tests made with the PlazMax PCDs (Lumen Kit) confirm that Normal Cycle has the capacity to sterilize the following lumen:

Diameter ≥ 1 mm and extension ≤ 1.4 meters, with one closed end.

- Diameter ≥ 1 mm and extension ≤ 4 meters, with both ends opened.
- The process takes approximately 40 minutes, depending on the type of load.

5.3.3 Cycle III – Endoscopes Cycle

Note: This cycle refers to Endoscopes not used for medical purposes, and only for laboratory or veterinarian purposes.

The Endoscopes Cycle is used for the sterilization of **Flexible Endoscopes only**. It sterilizes one or two endoscopes.
Note: if the endoscope is rigid, please, use the Advanced cycle program.

Endoscopes Cycle is similar to Advanced Cycle, besides the exposure to the sterilant & the heating stage are reduced.

Intended use: Load of **one or two endoscopes** (depending on model), one on the upper and one on the lower shelf. The Endoscopes cycle process takes approximately 30 minutes and it depends on the load, the maximum cycle time is 45 minutes.

Notes:

Endoscopes must be washed and disinfected prior to sterilization. Ensure that the endoscopes are completely dry before sterilization.

The experiments and tests made with the PlazMax PCDs (Lumen Kit) confirm that this cycle has the ability to sterilize the following lumen:

- Diameter ≥ 1 mm and extension ≤ 1.4 meters, with one closed end
- Diameter ≥ 1 mm and extension ≤ 4 meters, with both ends opened.

ATTENTION!

Endoscopes can be subjected to sterilization in the PlazMax sterilizer, only if the endoscopes manufacturer has indicated that the functionality of the devices may not be impaired if processed in a vapor of H_2O_2.

5.3.4 Cycle IV – Heavy Duty Cycle

Heavy Duty Cycle is used for complex / heavy load when hydrogen peroxide residue may remain on the load products.

The warming time in this cycle becomes longer and is aroung one hour.
The drying time is 30 minutes.

The Heavy Duty Cycle is composed of the same phases as the previous cycles, except for a longer drying and cycle time, the following are the Heavy Duty Cycle phases:

- One Air removal phase
- One Pre-Diffusion phase
- Two phases of Diffusion (Diffusion 1 and Diffusion 2)
- Two phases of Exhaust (Exhaust 1 and Exhaust 2)
- One phase of Aeration

Intended use: Heavy Duty cycle is designated for heavy load weights for:
P50 – 11kg, P110 – 13kg, P160 – 15kg.
The heavy load cycle process takes approximately 60 minutes.

5.3 Test Cycles

In addition to the sterilization cycles above, PlazMax sterilizer also perform Test Cycles:

5.3.1 Cycle V – Penetration Test

The Penetration Test consists of:

- One phase of Air removal
- One phase of Pre diffusion
- One phase of Diffusion 1
- One phase of Exhaust 1
- One phase of Aeration
- Confirm cycle

The penetration cycle is an extreme severe test. It is validated by the operator placing lumen Process Challenge Device (PCDs) with Biological Indicators indicators with population of $X*10^6$ CFU, inside the sterilization chamber.

The operator then incubates the Biological Indicators for results (according to manufacturer instructions), proving that the micro-organisms are destroyed, at the end of the cycle.

It is recommended to perform this test at a predetermined intervals.

In this cycle you must use the following PCDs:

- One single ended PCD (1400 mm) inside the sterilizer chamber.
- One double ended PCD (4000 mm) inside the sterilizer chamber.

The Penetration Test is composed of the following phases:

- Phase 1: Air removal
- Phase 2: Pre diffusion
- Phase 3: Diffusion 1
- Phase 4: Exhaust 1
- Phase 5: Aeration
- Confirm cycle

(See Figures 21 and 22 below).

***Note**- The penetration cycle has only one stage of Diffusion, thus the chamber is exposed half of the time to sterilant. For this reason it is forbidden to use this cycle as a sterilising cycle.*

5.3.1.1 Phase 1: Exhaustion

This is a vacuum and humidity exhaustion phase runs during a few minutes.

5.3.1.2 Phase 2: Preparation for Diffusion

This phase consists of creating in the chamber and vaporizer, conditions for the diffusion.

5.3.1.3 Phase 3: Diffusion

In this phase sterilant agent is injected into the chamber and is diffused after being vaporized.

5.3.1.4 Phase 5: Aeration

In this phase the chamber is ventilated so that no sterilant residue remains on the items and in the chamber.

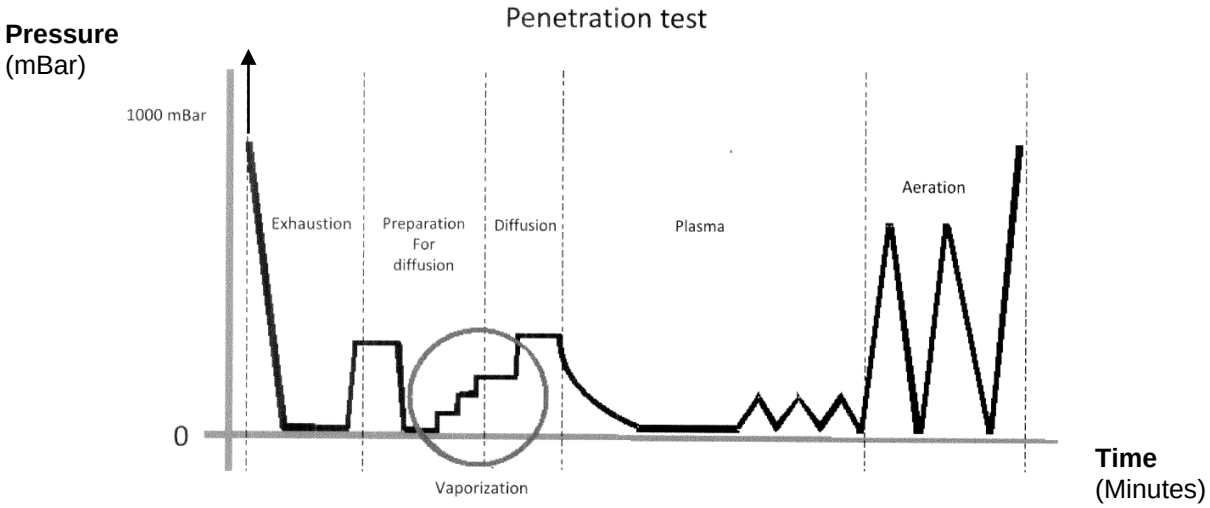


Figure 21 – Penetration Test Graph Description

5.3.1.5 End of Program: (Confirm Cycle):

At the end of the cycle after the buzzer sound signal, a report of the Penetration Test is printed out and the operator is informed if the test was successfully completed or if it failed.

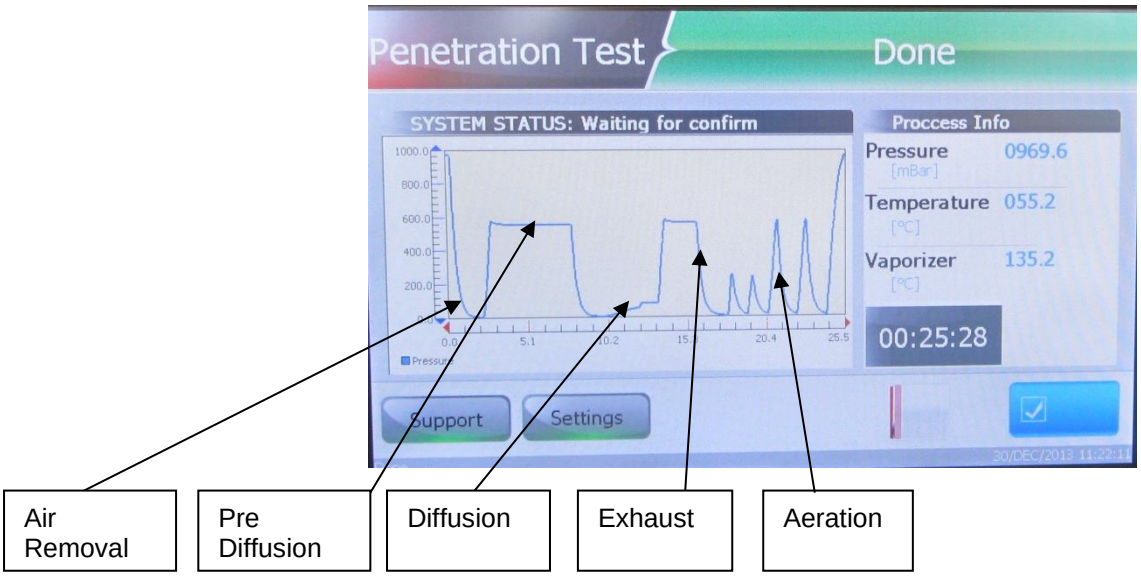


Figure 22 – Penetration Test Completed

5.3.2 Cycle VI – Leakage Test

The purpose of Leakage Test is to check the sterilizer chamber tightness. The system checks that the chamber is sealed and is monitored for leaks.

The test consists of the following:

- Subjecting the chamber to a deep vacuum.
- Closing of the Drain Valve, and stopping the Vacuum Pump.
- Verification in real time of the pressure variations inside the chamber.
- On line real time counting.

If there is a leakage in the sterilization system and chamber, this test will detect it. If the test is successfully completed the system can proceed to the other cycles.

The Leakage test runs as follows:

- Phase 1: Air removal
- Phase 2: Aeration

See Figures 16 and 17 below.

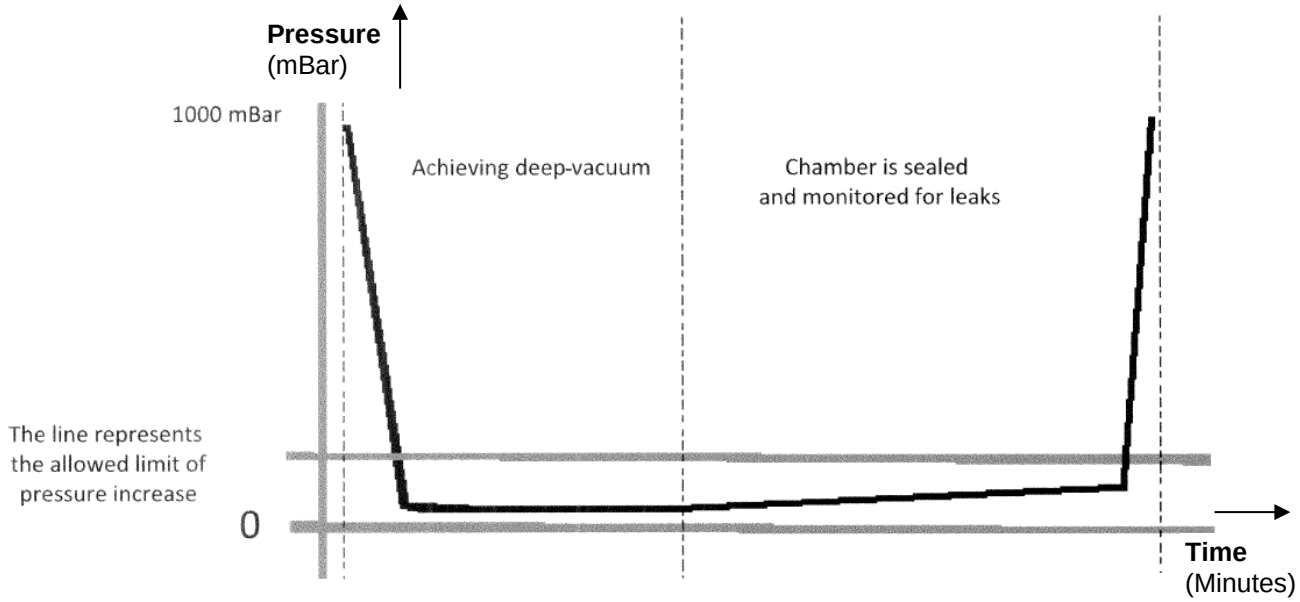


Figure 23 – Leak Test Graph Description

IMPORTANT:

THIS TEST CAN BE PERFORMED ONLY IN AN EMPTY CHAMBER AND WITHOUT ANY LOAD INSIDE THE CHAMBER.

5.3.2.1 End of Program: (Confirm Cycle):

At the end of the cycle after the buzzer sound signal, a report of the Leak Test is printed, and the operator is informed if the test was successfully completed or if it failed.

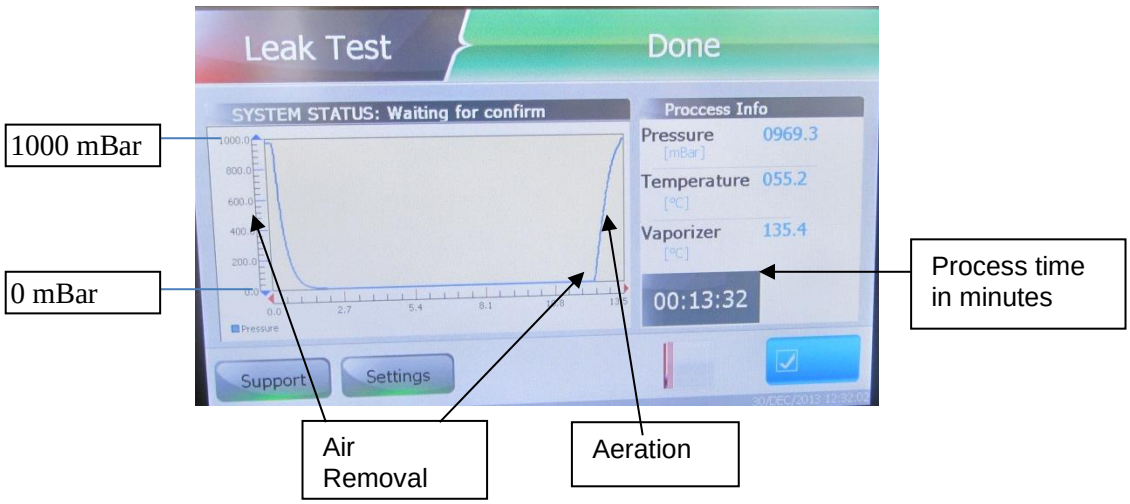
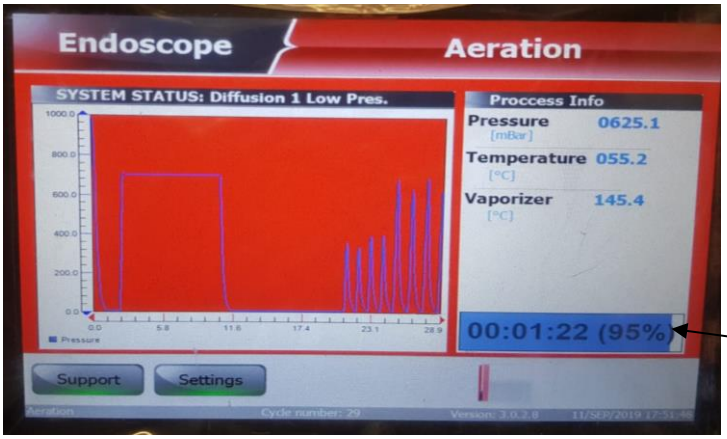


Figure 24 – Leak Test Completed



Progess bar display the progress of the cycle in percent according to statstics of the last cycles.

5.4 Unloading devices sterilized on PlazMax

When the cycle is completed successfully, the operator is informed that one of the doors can be opened (in case of 2 doors). The operator has the possibility to select which door will open, knowing that only one door can be opened at a time and opening one of the doors prevents the opening of the opposite one.

In case of a failed cycle it is possible to open the loading door only (Dirty Side).

5.5 Sterilization Process Monitoring

PlazMax sterilization process can be monitored by four different means:

- Cycle Report Printout
- Chemical Indicators
- Biological Indicators
- Lumen Test - PCD

IMPORTANT:

It is the user's responsibility to check the sterilizer efficiency.

The user must place chemical indicator, in every load, according to the directives of the organization regulations.

It is highly recommended to place one biological indicator by using the PCD (Lumen Kit) at least once a week, and according to the directives of the organization.

5.5.1 Cycle Report

At the end of a successful sterilization cycle, a buzzer sounds, and the cycle complete message appears.

At the end of the completed cycle, the finished sterilization process data is printed out. The operator must check the print out report cycle result, in order to ensure that the cycle was successfully concluded.

If the PlazMax sterilizer requires maintenance, a warning message will appear in the cycle report print.

After each H_2O_2 refilling, the system will print the refilling data. At the end of the cycle remove the printout from the printer. See an example of a printout report below.

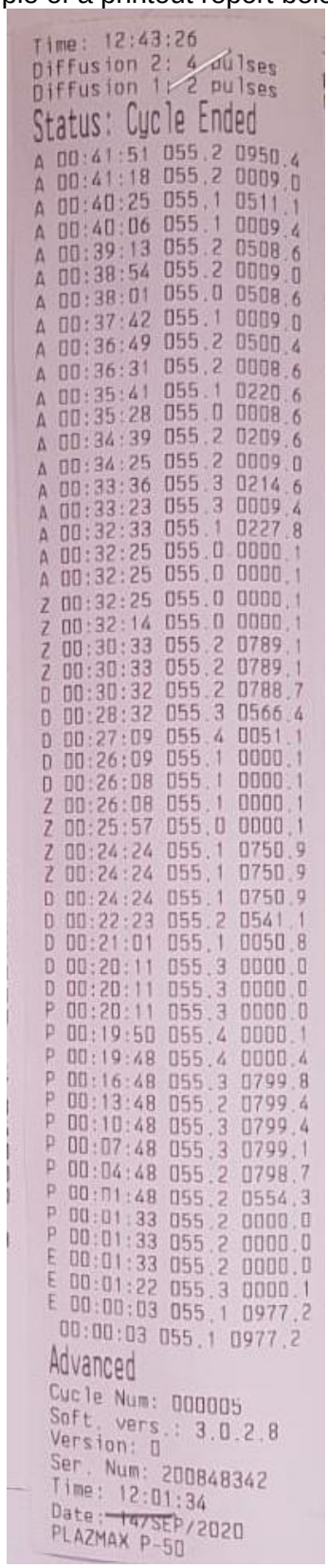


Figure 25 – Typical Cycle Print out Report Example

The Report data includes the type and number of cycle, the various phases, and the result, total time of the cycle, and space for the operator signature.

5.6 Empty Tank

Before any batch of H_2O_2 bottle replacement change, a system message appears that request from the user to empty the hydrogen peroxide H_2O_2 tank, before entering H_2O_2 from a new batch.

To empty the tank perform the following:

- Perform Air removal unil the pressure reaches 0.3 mbar.
- The diffusion process starts until the pressure reaches 70 mbar
- Empty the chamber until 0.3 mbar is reached
- Increase the pressure to the required settings until the system recognize that there is no further rise in pressure, the system goes to aeration stage, and.
- End of process

6. INDICATORS

6.1 Chemical Indicator (CI)

The Chemical Indicators (CI) are used to detect if there was enough sterilizing agent inside the packs, and it shows the integrity result of the medical devices processing.

The CI used in the PlazMax fully reveals, reflects and responds to the period of exposure to H_2O_2, and is an indicator that can provide assurance as to the process efficiency and success.

We recommend placing one strip of Tuttnauer chemical indicator inside each pack to be sterilized.

Other brands can be used according to the protocol of the institution.

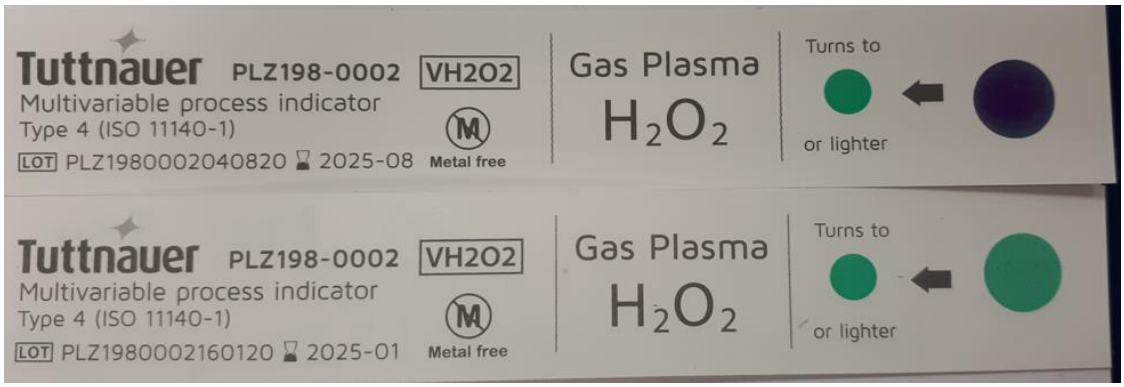


Figure 26 – Chemical indicator for Hydrogen Peroxide

In cases where the CI does not change its color in a pack, the sterilization of this pack shall be repeated, and an investigation shall be done to determine whether the load has been correctly processed.

6.2 Biological Indicator (BI)

The Biological Indicators (BI) are used for sterilization process monitoring purpose. Place at least one BI inside the sterilization chamber for each cycle. (Perform a Penetration test at least once a week).

Note:The BI must be placed in a sealed pouch before being placed in the chamber.

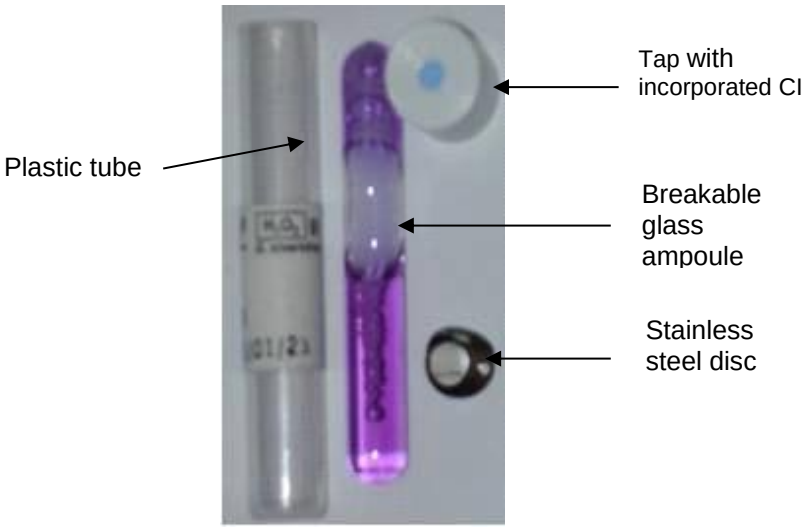


Figure 27 – Biological Indicator (BI) *(for example)*

The BIs have a defined quantity of inoculated spores in a small stainless steel disc placed inside a plastic tube with a breakable glass ampoule, (which includes a culture media).

We recommend the use of FDA approved biological indicators for VH_2O_2 sterilization processes, and contain Geobacillus Stearothermophilus spores.

The culture media changes its color from purple to yellow when the culture is positive (Growth).

After the sterilization process, the BI must be incubated according to the manufacturer instructions.

If the sterilization process **fails,** the BI changes its color from purple to **yellow**, (Growth).

If the BI remains purple it means that the sterilization was successful. (Not Growth).

The BI cap has a CI which turns from blue to pink when exposed to the sterilizing agent.

Note- With every incubation add an ampule of Bis that did not overgo the sterilization process, as a control. This ampule should change its color from purple to yellow to indicate growth of micro-organisms.

No colour change, there is no bacteriological grow. (Not Growth)

Change of colour to yellow. It means that the sterilization process failed (Growth).

Figure 28 – Growth and Not Growth results

Note- you can find in the FAQ section details of Tuttnauers recommended indicators

6.3 Lumen Test – Process Challenge Device (PCD)

a. Lumen Kit

The sterilization process monitoring can be performed with flexible lumen kits.

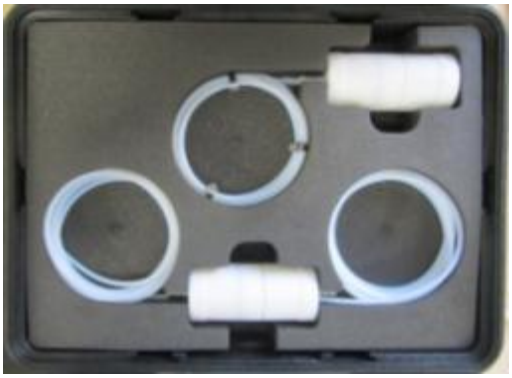
In the kit, there are two types of lumen: opened on both sides and opened only on one side. The difference is only in the total length of the lumen.

- 4000mm Lumen:

Consists of a chamber for the indicators positioning, and of a capillary (2000mm long with 1 mm of diameter) on each side of the chamber

- 1400mm Lumen:

Consists of a chamber for the indicators positioning, (sealed on one of the sides), and having a capillary, (1400mm long with 1 mm of diameter), on the other side.



b. How to use the lumen kit (PCD)

1. Prepare the PCD;
2. Verify if the lumen is cleaned (free of water drops and/or dust);
3. Place BI & CI into the PCD housing.

IMPORANT:

Place the PCD with the indicators inside the sterilizer chamber at least once a week.

4. Process the cycle;

Note:

The PCDs in the table below must be used for the following cycles:

Cycle Name	PCDs placement
Advanced Cycle:	Place 2 PCD's (1400 mm and 4000 mm) inside the sterilizer chamber.
Normal Cycle:	Place 1 PCD's (4000 mm) inside the sterilizer chamber
Endoscopes Cycle	Place 2 PCD's (1400 mm and 4000 mm) inside the sterilizer chamber
Penetration Test	Place 1 PCD's (1400 mm) inside the sterilizer chamber
Heavy Duty	Place 2 PCD's (1400 mm and 4000 mm) inside the sterilizer chamber.

IMPORTANT:

It is important to perform these verifications only with the chamber empty and free from any load. The PCD test shows to the end user whether the sterilizer is performing properly or not.

5. Remove the PCD from the chamber;

6. Verify the chemical indicator result, and incubate the biological indicator in a suitable incubator according to manufacturer instructions.

c. What to do in case of lumen test failure

If the chemical indicator does not show color change, repeat the cycle, if the failure remains, contact your PlazMax distributor for technical assistance.

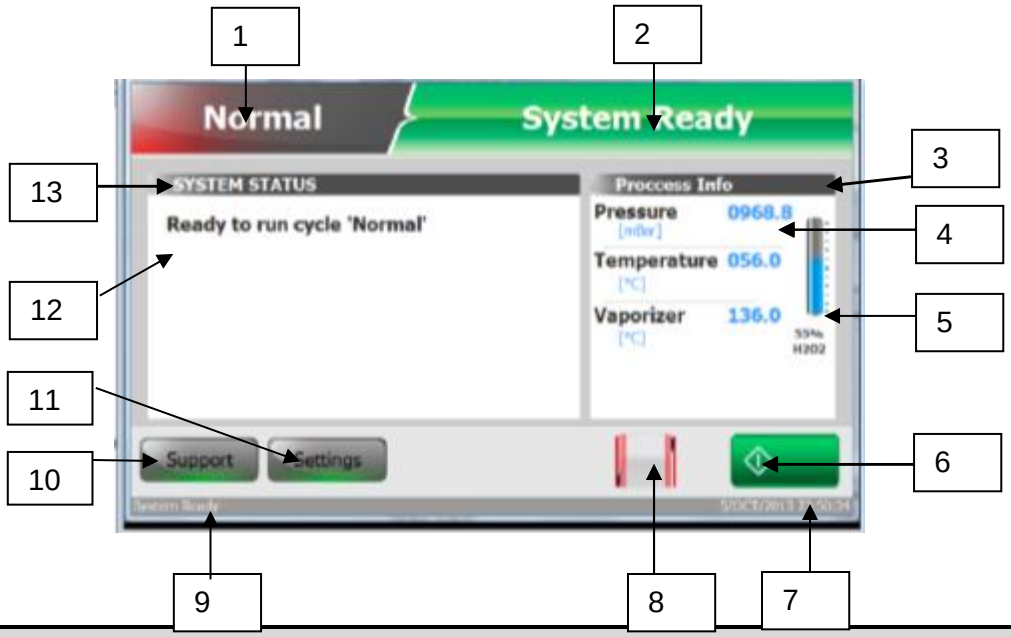
7. DISPLAY CONTROL TOUCH SCREEN

After switching the system ON, the following PlazMax screens are displayed.

Note:
To get to the main screen , see section 9 for detailed step by step operating procedure.
The loading progress bar display the progress of the cycle according to statistics of the last cycles

7.1 Display Main Touch Screen

Description and Functions



No.	Description
1	**Program Name**. Displays the name of the present running program
2	**System Status**. Displays the present stage of the program, errors or operation messages/symbols
3	**Process Info.** The sub window of heading 4 below
4	**Process Info. Display.** This area displays the variable system data, actual chamber pressure, chamber temperature and vaporizer temperature in real time
5	**H_2O_2 Status**. Displays the actual H_2O_2 percentage quantity in the sterilizer system
6	**System Activation Button.** Start the cycle system
7	**Date and Time.** Shows the actual date and time
8	**Door Status Symbol**. Displays the doors status whether open or closed
9	**System Status**. Displays the present stage of the program, errors or operation messages/symbols
10	**Support Button**. Pressing it displays the system technical support screen
11	**Settings Button.** Displays the Quick Options screen
12	**Message Status Zone**. Displays the system status and messages in real time
13	**System Status.** Shows system status zone headings

The Display Screen is mainly composed from four major sections:

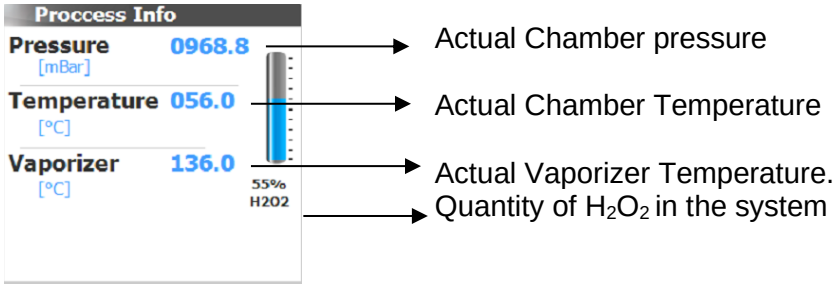
1. Head Line Section.
2. Process information and reporting Area.
3. Message zone System status area.
4. Footer line section.

1. Head Line Section

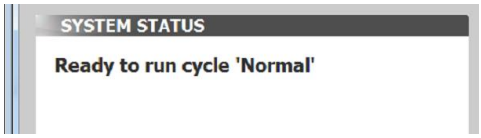
The Head Line Section is divided to two. When the chosen program is selected, the name and the icon of the program is displayed in this section.
After activating the program and through all cycles, the System status is displayed.

2. Process information and reporting Area

During the stages, this area displays the variable system data in real time.



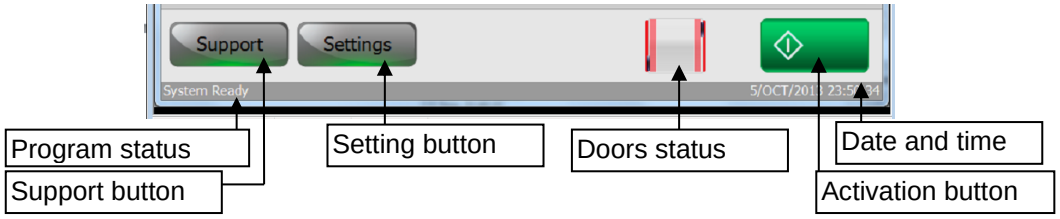
1. System status area



This area displays the system status in real time and the error messages, parameter names and values for chosen program.

During the cycle process the stages and time, (sterilization and drying), will be show in this area.

2. Footer line section



The footer line section contains:

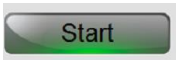
The buttons that activates the support and setting screens, the doors status (whether open or closed). It also indicates the present system state, date and time.

3. The Display screens

The display indicates the current status of the unit at all times: the current stage of the sterilization cycle, the temperature in the chamber, the temperature in the vaporizer ,the pressure in the chamber, the cycle start time and the cycle estimated end time.

7.1.1 Touch Screen Icon Symbols

Symbol	Description
	Home (to the main screen)
	Return (to previous screen menu)
	Select
	Logout
	Set
	Doors
	Support
	Settings (brings the Quick Options screen)
	Start cycle

Symbol	Description
	Abort Cycle
	Confirm cycle
	New User
	H_2O_2
	Start
	Endo. ID

7.2 Displayed Operational Touch Screens

The TCS2010 software is designed to provide user friendly operation for all PlazMax users.

The software contains:

- All Levels Users screens
- Operator Level screens
- Technician Level screens
- Manufacturer screens

This section describes the displayed operational Touch Screens of the PlazMax sterilizer.

The All Users screens in paragraph 7.2.1 provides information for important functions such as:

Settings, Quick Options, export to USB, printing cycles, adjusting Date and Time, Software version information, handle H_2O_2, , Login, New User, HMI settings, Select Cycle, Handle Endoscope, and Import HMI Application.

The Operator Level touch screens are presented for the user information only, and are in para. 7.2.2.

The Technician Level touch screens are also presented for the user information only, and are in paragraph 7.2.3.

The step by step sterilization operating Instructions explaining how to operate the sterilizer with the Touch Screens is described in section 8.

7.2.1 All Users Displayed Touch screens

These screens are used by all PlazMax users and include the following screens:

1. Quick Options. Export data
2. Print Cycles
3. Version Info.
4. Set Time
5. Handle H_2O_2
6. Login
7. New User
8. HMI settings
9. Select Cycle
10. Handle Endoscope
11. Import HMI Application

The All Users screens in this section provide instructions for important functions such as: Settings, Quick Options, Export to USB, printing cycles, Adjusting Date and Time, etc.

Quick Options

1. Export Data

1. Press on the **"Settings"** tab from the main screen below

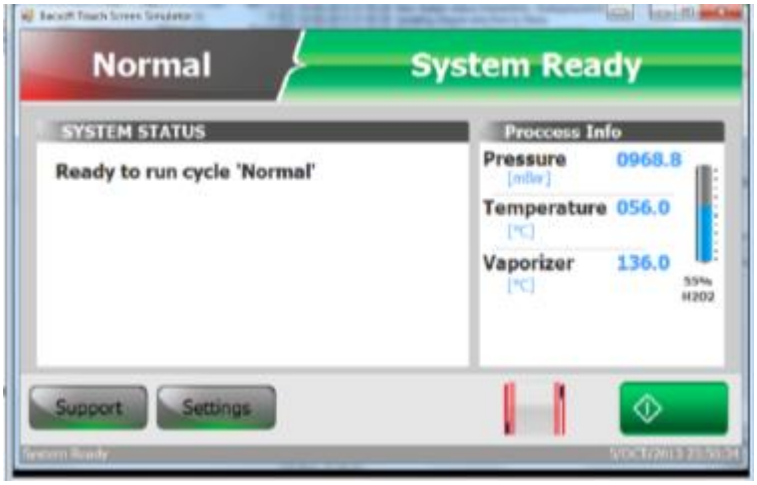
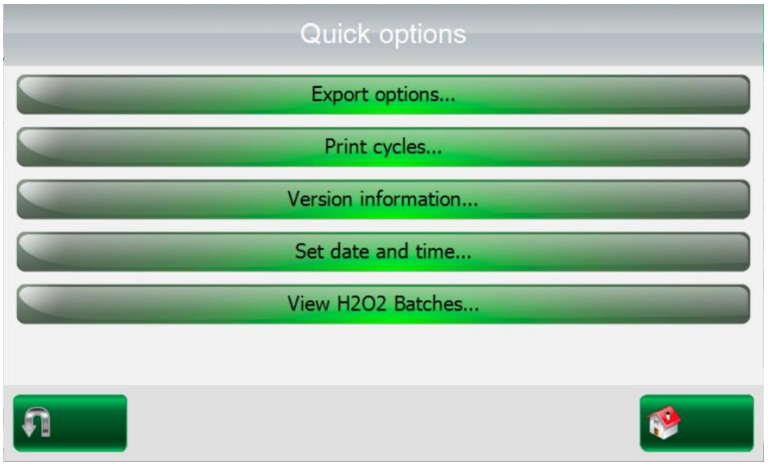


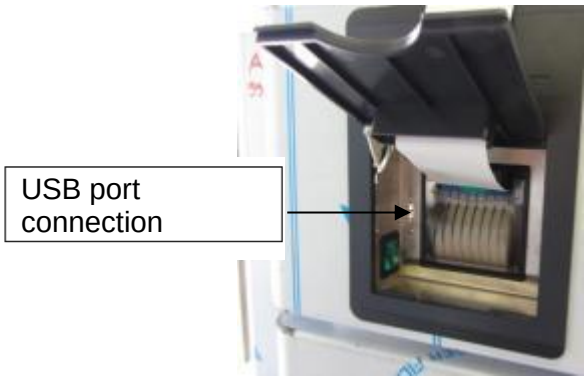
Figure 29 – Main Sceen

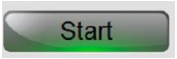
The Quick Options screen will be displayed.



2. Press **"Export options "** tab on the Quick Options Menu above.The following screen will be displayed

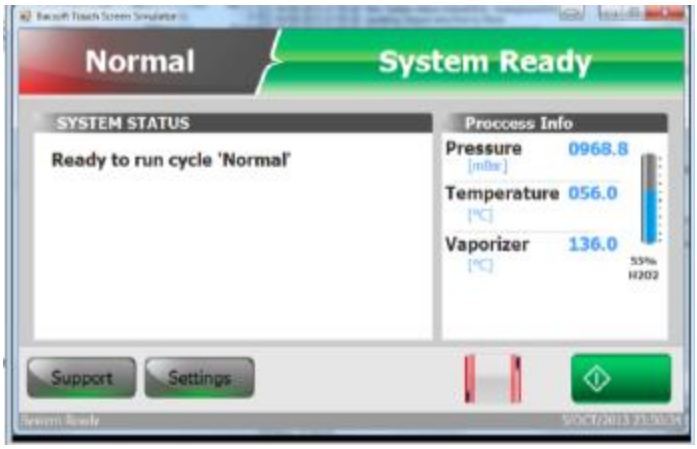
You can select from the number of cycles and application, settings or history. Insert the USB to the PLC outlet in the USB port.



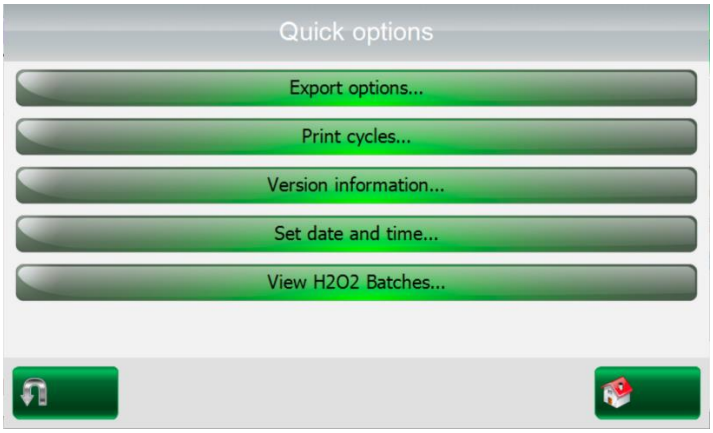
3. Press 

2. Print Cycles

1. Press the **"Settings"** tab from the main screen below



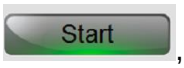
The Quick Options screen will be displayed.



2. Press **"Print Cycles"** tab on the Quick Options Menu above;

The following screen will be displayed

You can select from the number of cycles to print.

Press 

, and the printer will start printing the report.

3. Version Information

1. Press on the **"Settings"** tab from the main screen as above.
2. Press **"Version information"** tab on the Quick Options Menu above;

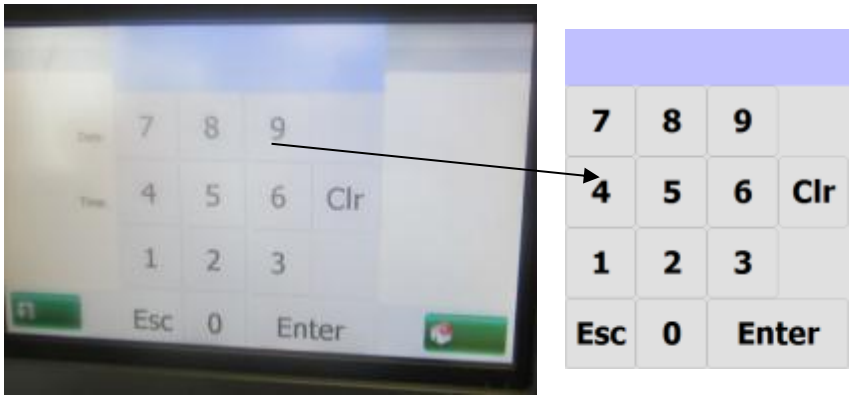
The following screen will be displayed.

4. Adjusting Date and Time

1. Press on the **"Settings"** tab from the main screen as above.
2. Press **"Date & Time"** tab on the Quick Options Menu above;

The following screen will be displayed.

1. Press on the day/month/and year. The following screen pop up which allows you to adjust the date. Press 

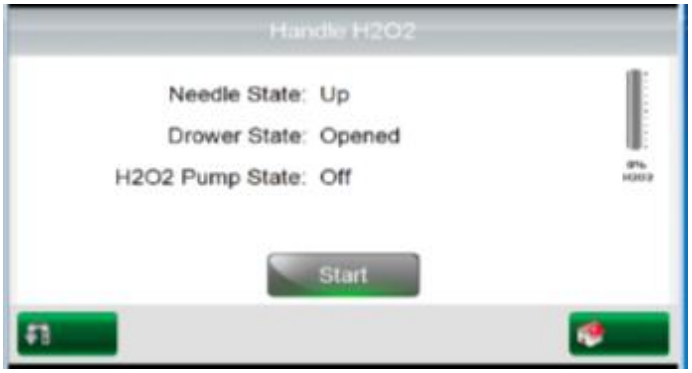


After setting date and time the application will perform Auto-Restart.

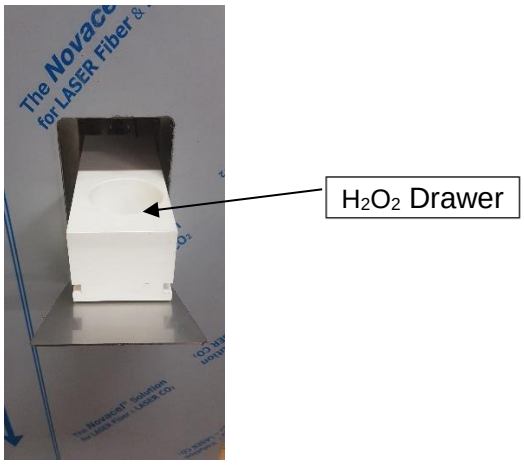
5. Handle H_2O_2

When H_2O_2 is at low level

1. Press on the H2O2 button from the **Not Ready** main screen above



2. Place in the drawer a new H_2O_2 bottle. Remove the bottle cover.
A message appears on the Touch Screen to confirm the bottle cover removal.
The Autoclave H_2O_2 Drawer is extended out.



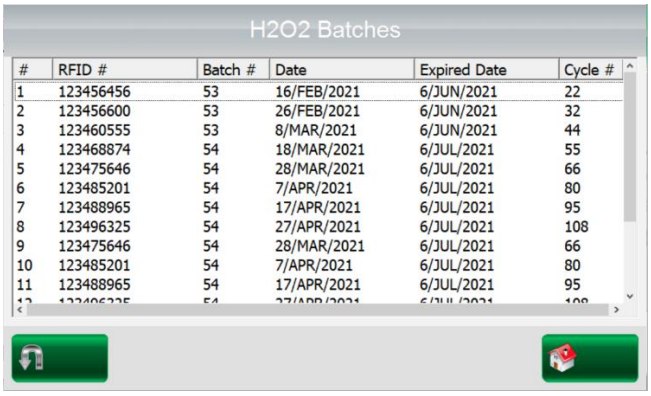
3. The following screen showing empty H_2O_2 appears:

4. Press Start tab, and the process of H_2O_2 filling from the bottle starts.
At the end of this process a message will appear. Remove the H_2O_2 bottle.

6. View H2O2 Batches

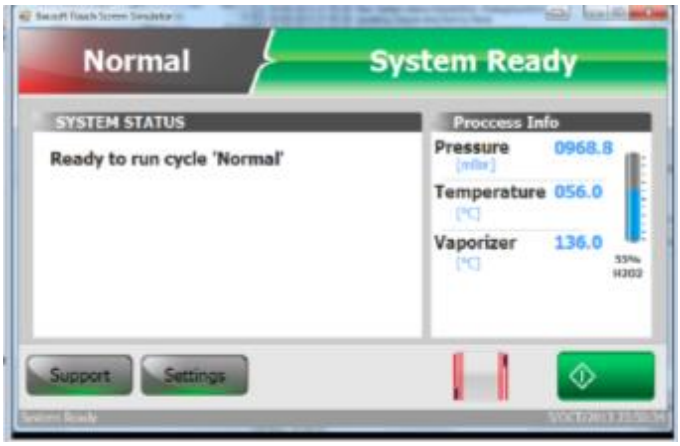
1. Press on the **"Settings"** tab from the main screen as above.
2. Press **"View H2O2 Batches"** tab on the Quick Options Menu above;

The following screen appears, displaying the consumption per bottle:

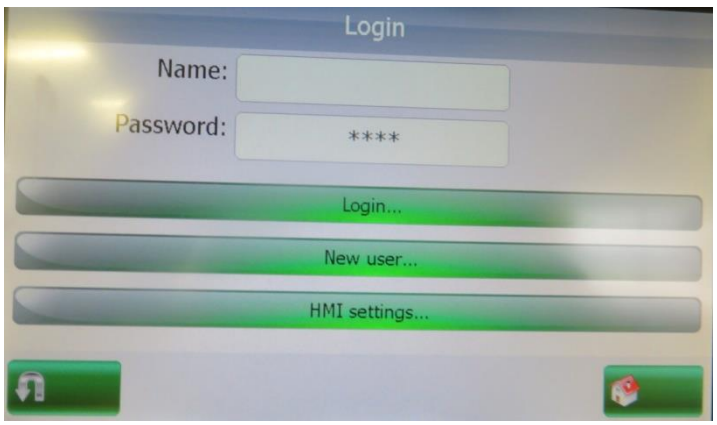


7. Login

From the main screen below.



Tapping on **Support** button will display the Login screen below.



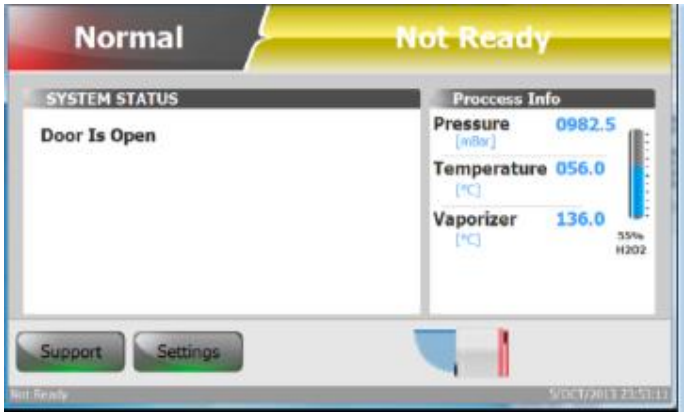
8. New User

A new user can be created , the system support user factory code.

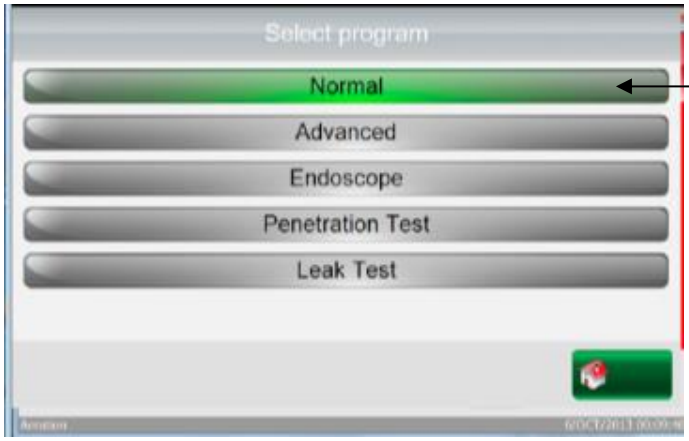
9. HMI settings

10. Select Cycle

1. Open the door. Place the items load on the shelf inside the chamber. The **Main** screen will show the door is open.

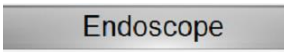


2. Press on **Normal** on the touch screen of the **Main screen. T**he PlazMax **Select program** screen showing the sterilization programs list will be displayed. Select the required cycle, close the door and press "**Start Cycle**" on the touch screen.



3. Press on the **Home**  tab to return to the main screen.

11. Handle Endoscope

If Endoscope cycle is required, press 

tab and follow the above. The following screen appears.

1. Press on **"Intro. ID"** button.

The screen below is displayed.

The operator can change and enter new endoscope ID, name, quantity, etc.

2. Press 

To return to the previous screen press on  .

12. Import HMI Application

7.2.2 Displayed Operator Level Touch screens

The Operator screens are used by the Operator Level users and include the following screens:

1. Main menu
2. System Parameters
3. Set parameter
4. Maintenance
5. Handle Counters
6. Advance Options
7. View IP Address
8. View Machine Setup

Notes:
The Operator Level operating instructions are detailed in paragraphs 9. The Operator Level screens are shown in this section,

1. Main menu

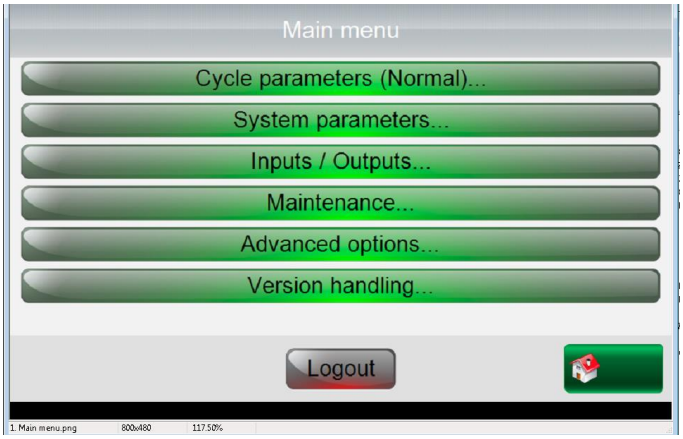
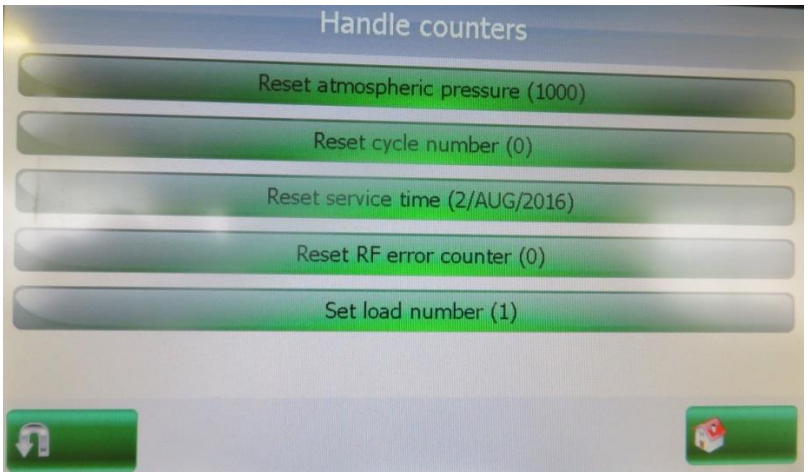


Figure 30 – Main Menu

2. Handle Counters

1. Press on the Handle counters... button from the **Main menu** screen above

The following screen will be displayed



3. Advanced Options

1. Press on the Advanced options... button from the **Maint Menu** screen above (figure 30).

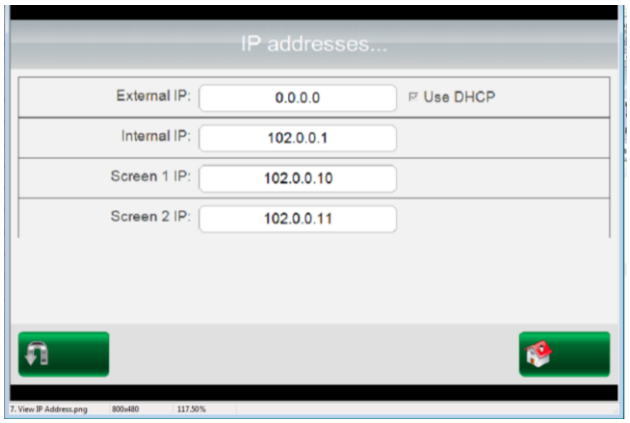
The following screen will be displayed.

***Figure 31* – Advanced Options**

4. View IP Address

1. Press on the IP addresses... button from the **Advanced Options** screen above (figure 31).

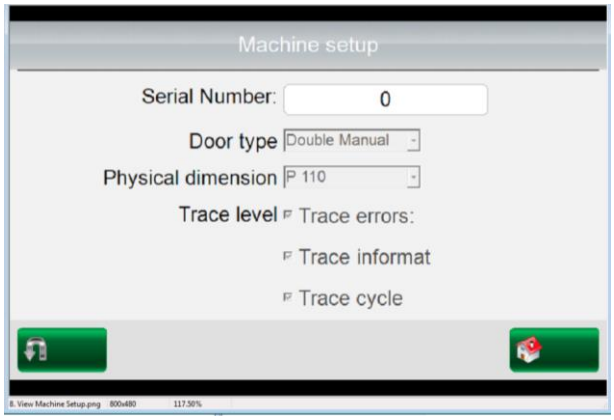
The following screen will be displayed



5. View Machine Setup

1. Press on the Machine setup... button from the **Advanced Options** screen above (figure 31).

The following screen will be displayed


Machine setup
Serial Number:
0
Door type
Double Manual
Physical dimension
P 110
Trace level
Trace errors:
Trace informat
Trace cycle

7.2.3 Displayed Technician Level Touch screens

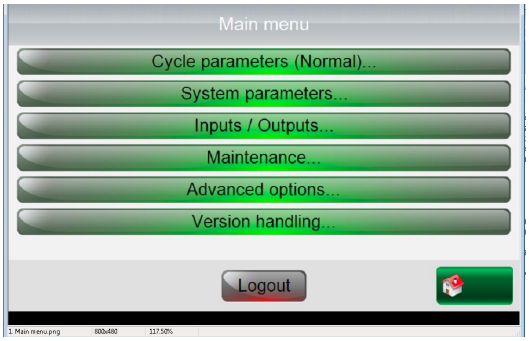
These screens are used by Technician Level users and include the following screens:

1. Main menu
2. System Parameters
3. Set parameter
4. Inputs Outputs
5. Digital Inputs
6. Digital Outputs
7. Temperature Sensors
8. Calibrate analog Input
9. Pressure sensors
10. Maintenance
11. Handle Counters
12. Advanced Options
13. Enable cycles
14. IP addresses
15. Units Settings
16. Machine Setup
17. Version Handling

Main menu

1. Main menu selection

1. Press on the **"Settings"** tab from the main screen below



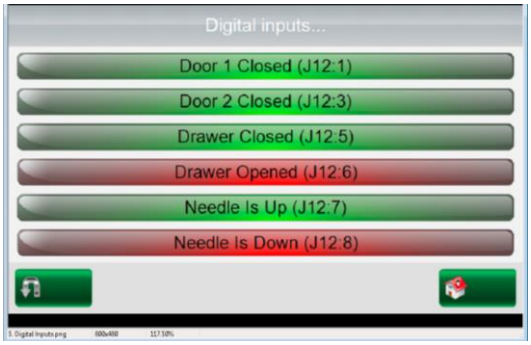
The Quick Options screen will be displayed.

2. System Parameters

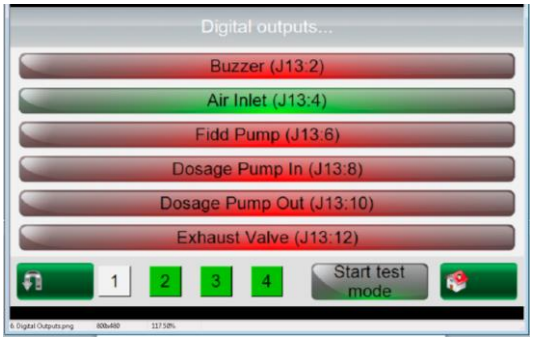
3. Set parameter Screens Selection

4. Inputs Outputs Screens Selection

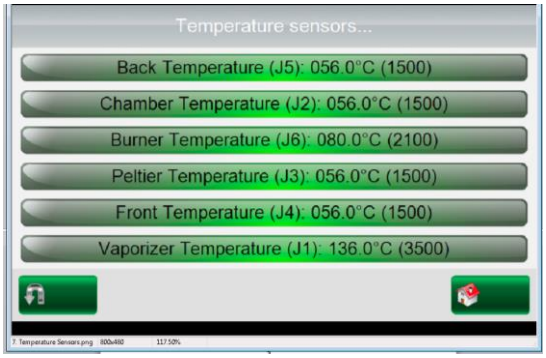
5. Digital Inputs Screens Selection



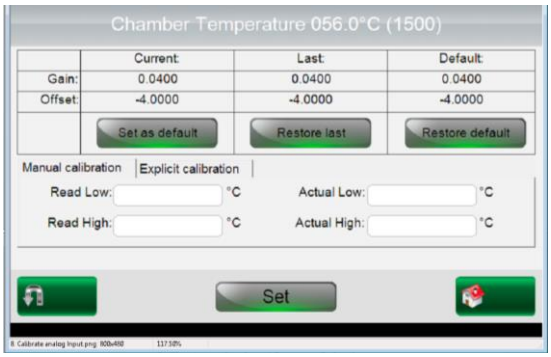
6. Digital Outputs Screens Selection



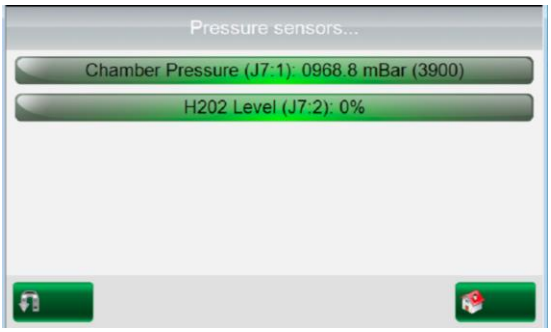
7. Temperature Sensors Screens Selection



8. Calibrate analog Input Screens Selection

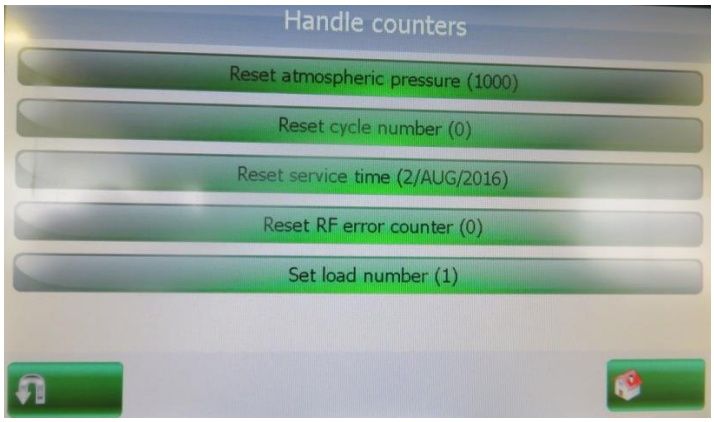


9. Pressure sensors Input Screens Selection

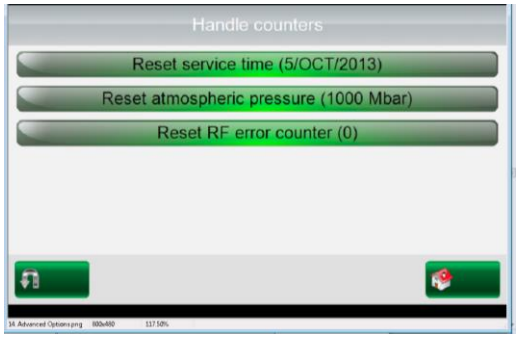


10. Maintenance Screens Selection

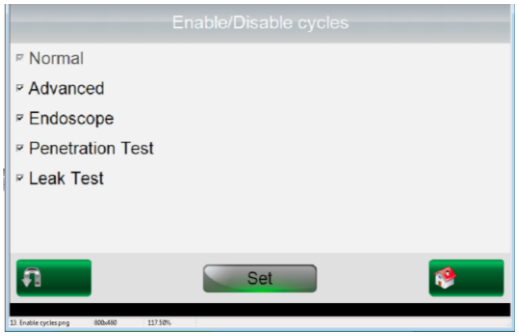
11. Handle Counters Screens Selection



12. Advanced Options Screens Selection

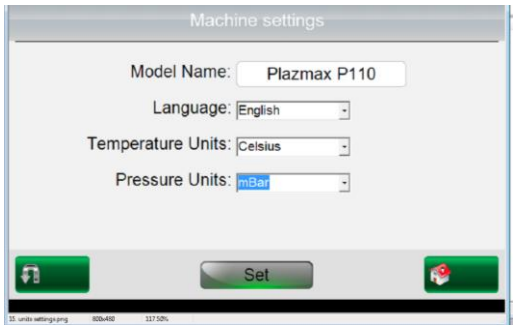


13. Enable cycles Screens Selection

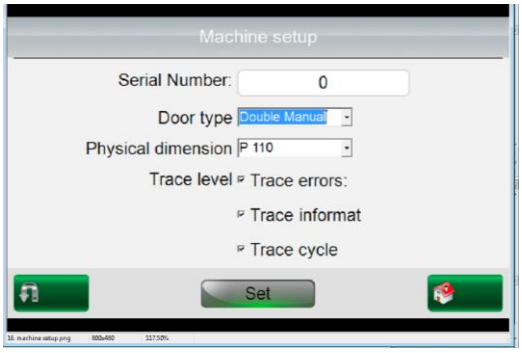


14. IP Addresses Screens Selection

15. Units Settings Screens Selection



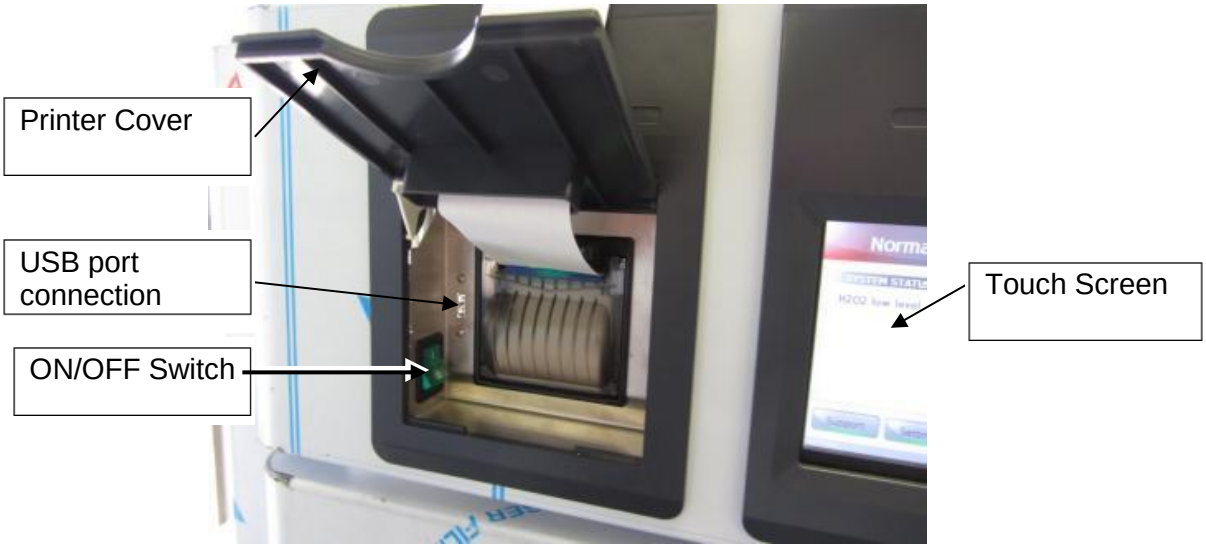
16. Machine Setup Screens Selection



17. Version Handling Screens Selection

8. OPERATING INSTRUCTIONS Before Starting Autoclave Sterilization:

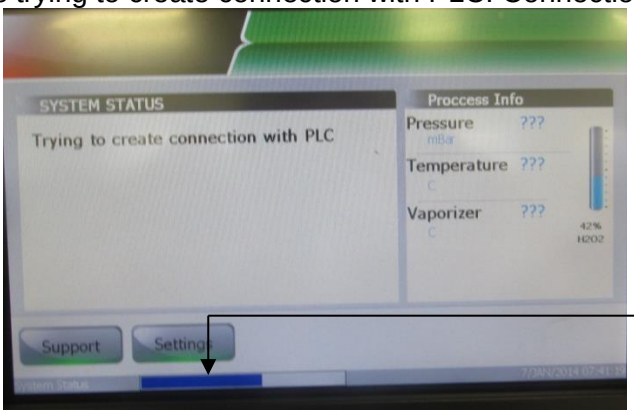
1. Ensure that the sterilizer is connected to an electrical (230V) power source.
2. Lift the printer cover. Press 1 on the ON/OFF switch push Button to start the PlazMax.



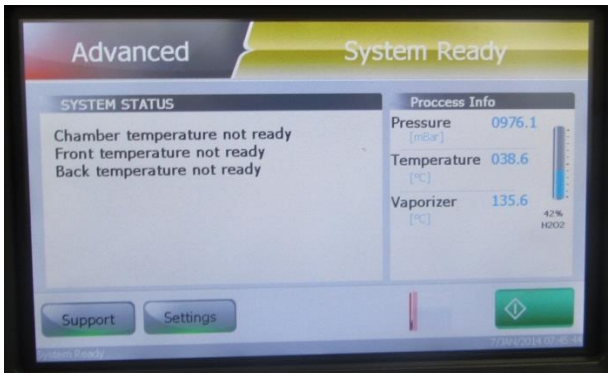
The following screens are displayed.

Warning!
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.

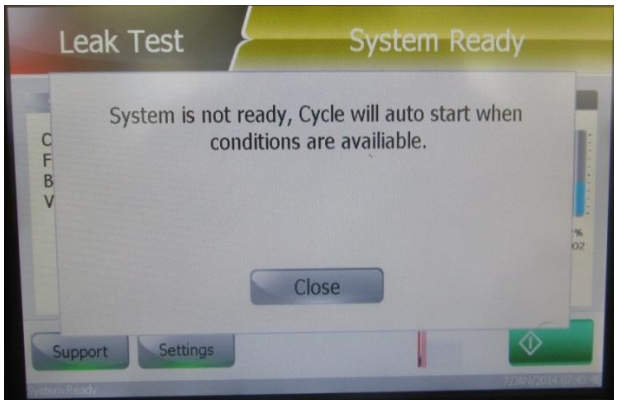
Wait while the system is trying to create connection with PLC. Connection with PLC is in progress now.



After the system completes connecting with the PLC, the following screen is displayed.



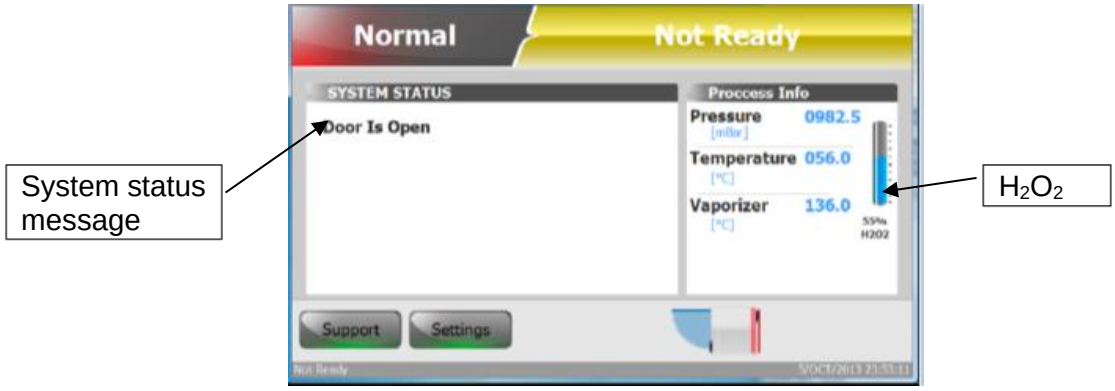
The system is not ready, the sterilizer is waiting for the conditions to be right (chamber temperature around 50ºC, vaporiser temperature135ºC, etc.). When the conditions will be right the cycle will start automatically.



Notes:
The next screen shows a system “Not ready screen “since the door is open. (See p. 8.1)
When Connection with the PLC is completed the following screen is displayed.

8.1 Preparation before sterilization - Door Is Open

1. Not ready screen

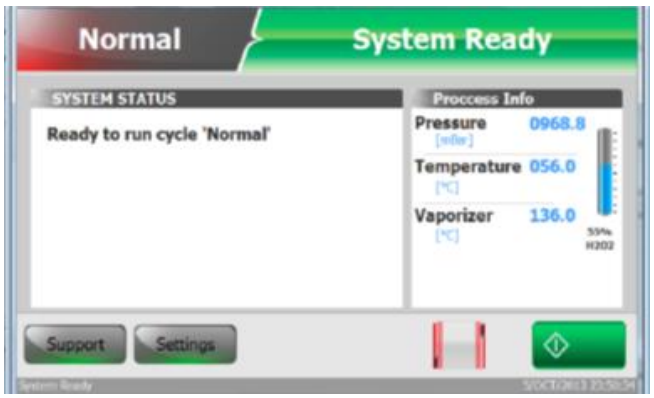


System status message indicates **Door Is Open**.

At this stage, open the door and place the items load (Load up to 15 items maximum, or 2 Endoscopes maximum) on the shelf inside the chamber.

Close the door manually. The **ready to run cycle Normal** screen is displayed**.** (See screen below)

2. System ready screen



When there is sufficient H_2O_2 (the quantity of H_2O_2 is 55% in the screen shown), the PlazMax is ready for the selection of sterilization programs. (Go to paragraph 8.3).

If there is not enough H_2O_2 in the autoclave the system will not start. (Go to paragraph 9.2).

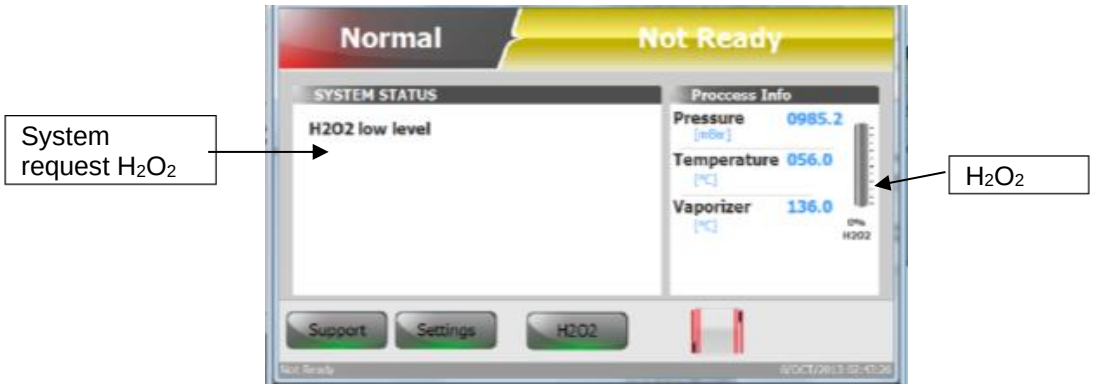
8.2 Preparation before sterilization - System Missing H2O2

3. Filling H2O2 Procedure

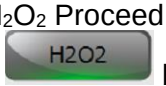
If there is not enough H_2O_2 in the autoclave the system will not start. The screen below will be displayed, indicating that the system request H_2O_2.

The sterilizer will not be ready until H_2O_2 is introduced, for PlazMax H_2O_2 filling procedure, follow this procedure.

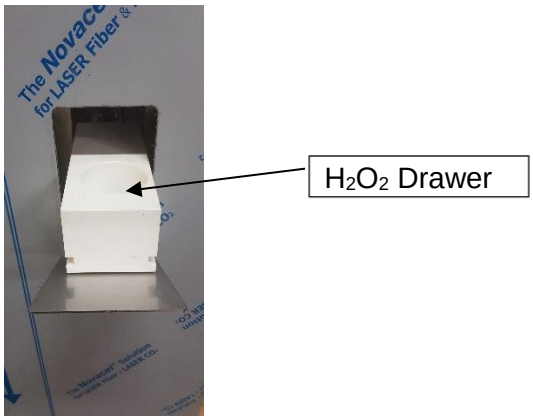
Note: If there is sufficient H_2O_2 in the system, proceed with section 9 procedure.



To fill PlazMax with H_2O_2 Proceed as follows:

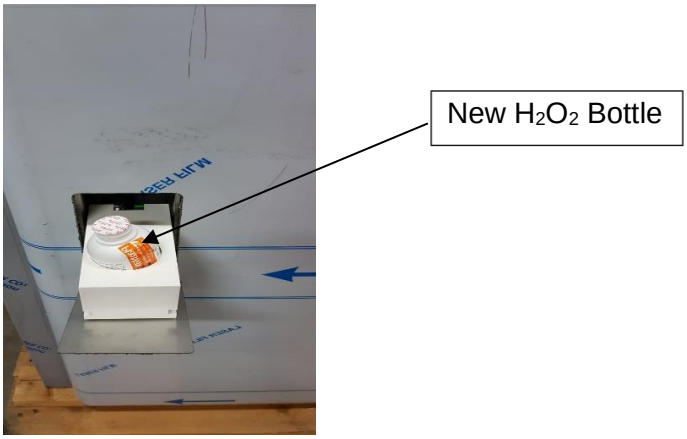
1. Press on 

button on the above screen to start the H_2O_2 filling process. The Autoclave H_2O_2 Drawer is extended out.



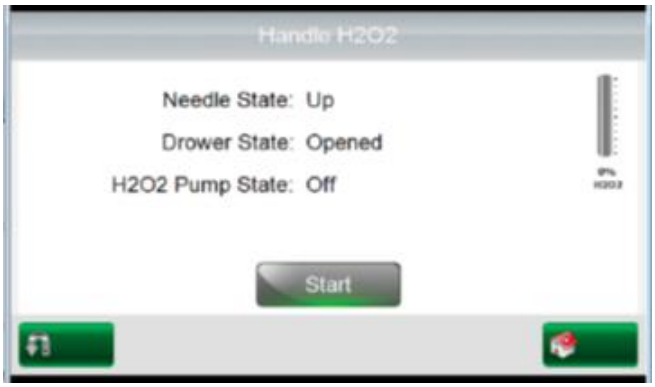
The following screen showing empty H_2O_2 appears:

2. Place a new H2O2 bottle in the drawer. Remove the bottle cap. **IMPORTANT: Remove the bottle cap only after placing the bottle in the drawer.**



3. Press the “Start” 

button (on Handle H2O2 screen below), the syringe mechanism system is lowered inside the bottle and the pump starts to suck the H2O2 liquid. After approximately 1 minute the following screen will appear.



4. Remove the empty H2O2 bottle. close with the lid & throw the old bottle to the disposal waist container.

5. Press “Home”  button, the drawer will retract and return to its closed position. The MAIN SCREEN will be displayed. Note: The screen below shows 55% H2O2, (with a new full bottle the screen will show around 100 % H2O2).

8.3 OPERATING INSTRUCTIONS - Sterilization Programs Selection

8.3.1 Starting the Sterilizer

Notes:
When starting the autoclave for the first time, adjust and set the Time and Date. (See paragraph 7.2.1, 4)

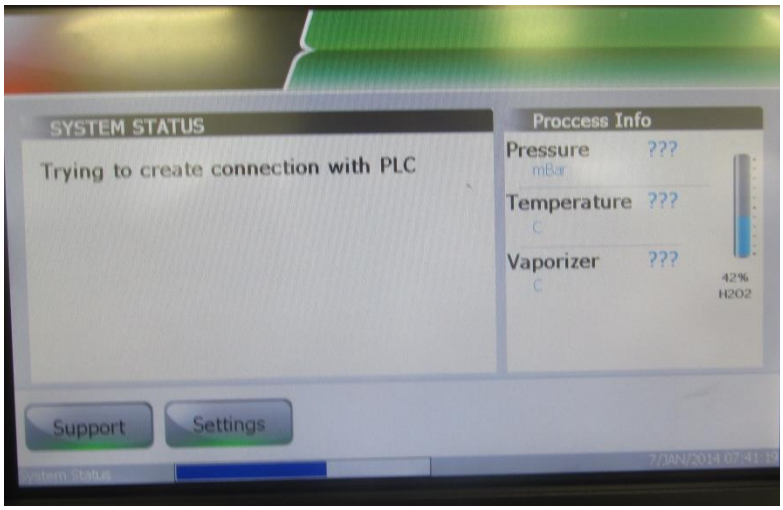
The Touch screen is used to select sterilization programs. In order to choose a sterilization program, the PlazMax door must be open. Door open is shown by this  symbol.
Screen captures shown in this manual are provided for illustrative purposes ONLY. The options available on your autoclave depend on its configuration and may differ from those shown in these illustrations.
Check the Touch Screen for any Stand by Error or Cycle Error massages.
If any messages appear on the Touch Screen, take the Corrective Action recommended in the "ERROR MESSAGES" section.

Warning!
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.

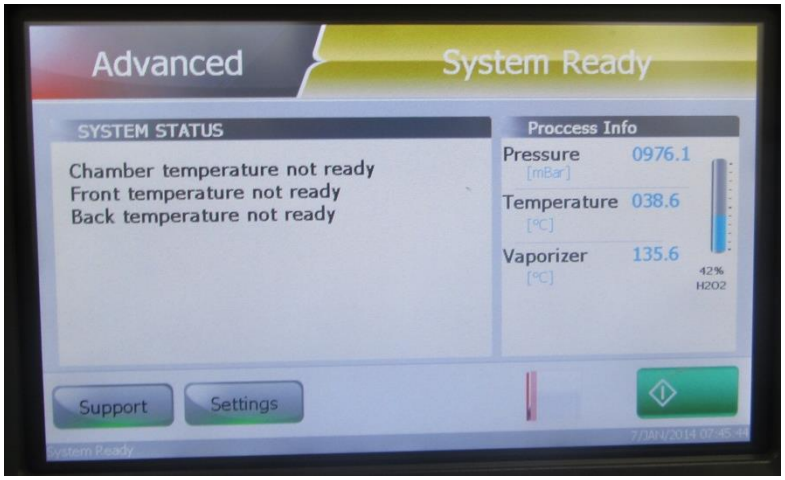
1. Ensure that the sterilizer is connected to electrical (230V) power source.
2. Lift the printer cover. Press 1 on the ON/OFF switch push Button to start the PlazMax .

The following screens are displayed.

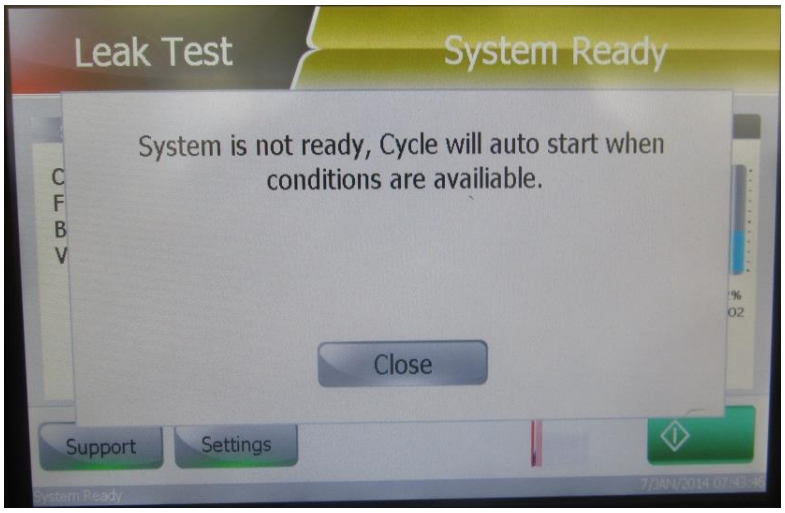
Wait while the system is trying to create connection (in progress now) with PLC.



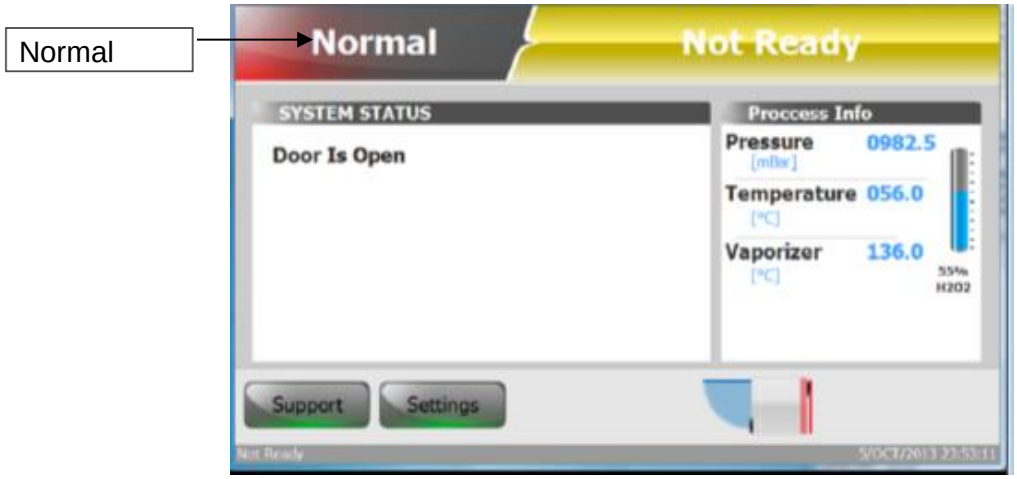
After the system completes connecting with the PLC, the following screen is displayed.



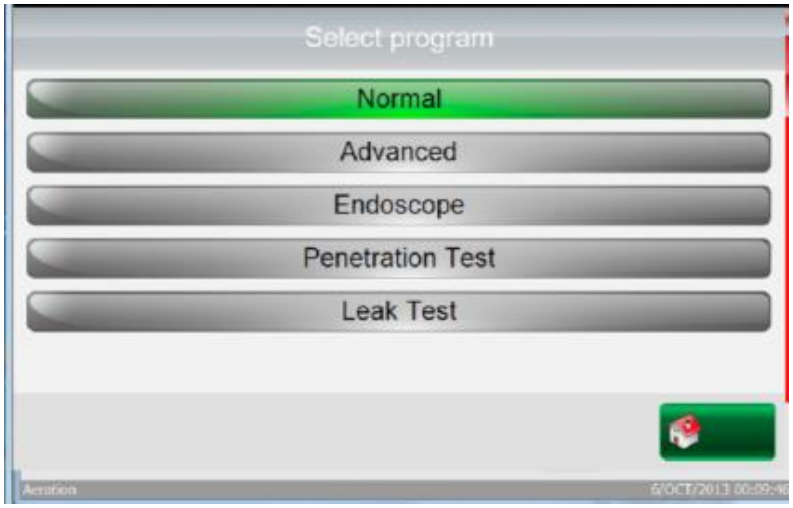
The system is not ready, the sterilizer is waiting for the conditions to be right (chamber temperature around 50ºC, vaporizer temperature135ºC, etc.). When the conditions will be right the cycle will start automatically.



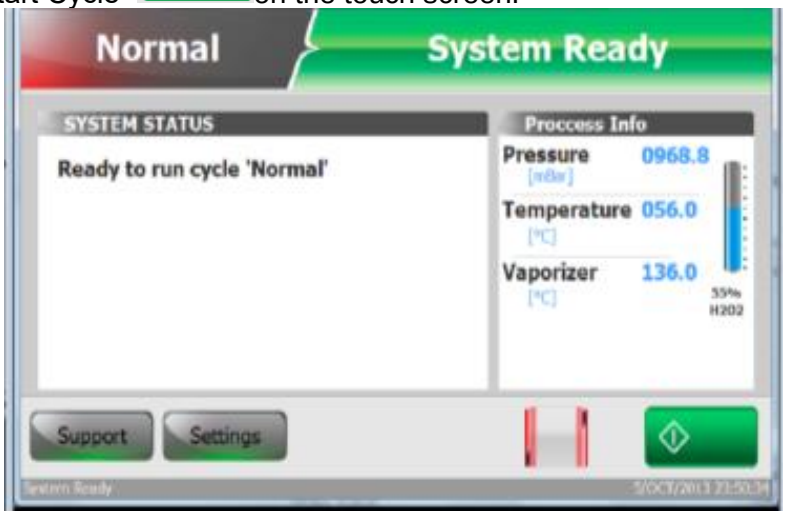
6. Open the door manually and place the items load (up to 15 items maximum, or 2 Endoscopes maximum) on the shelf inside the chamber .The screen below shows that the door is open.



7. Press on **Normal** on the touch screen below, the PlazMax **Select program** screen showing the sterilization programs list will be displayed.



8. Select the cycle **Normal**  from the screen above, close the door and press "Start Cycle"  on the touch screen.



If you wish to select another sterilization program continue to the next paragraph 8.3.2.

8.3.2 How to select a Sterilization Program

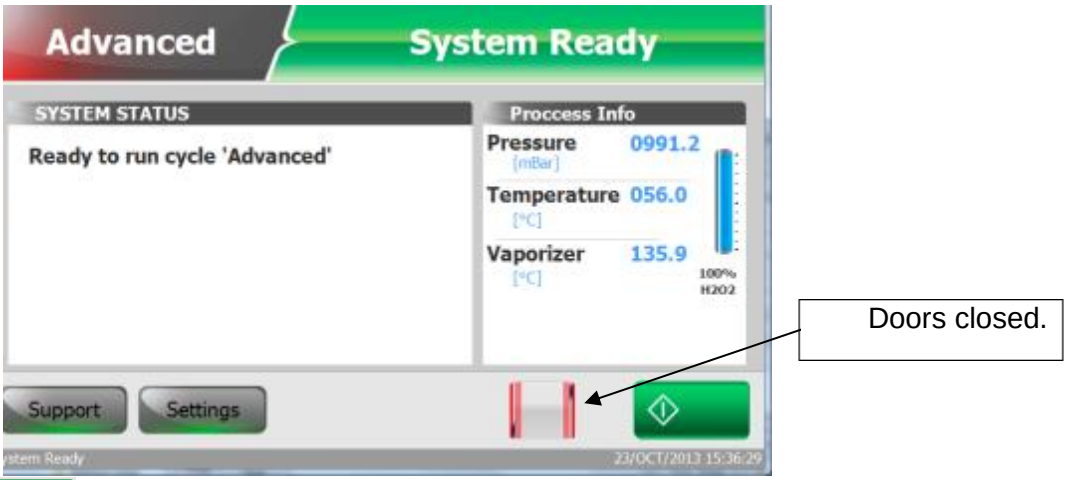
The **Select program** screen allows the user to select Normal, and Endoscope sterilization programs. It also allows the user to select Penetration and leak tests.

1. Open the door and place the items load (up to 15 items maximum, or 2 Endoscopes maximum) on the shelf inside the chamber.
2. Select a sterilization program from the list, if **Advanced** sterilization program is required, select **Advanced** Advanced program, by pressing on Advanced.

Figure 32 – Select Program Screen

The Advanced **Not Ready** screen appears:

1. Close the door. The following Advanced screen appears showing **"Ready to run cycle Advanced"**, and doors closed.



2. **Press**  button, the **Advanced Start cycle** sterilization program appears.

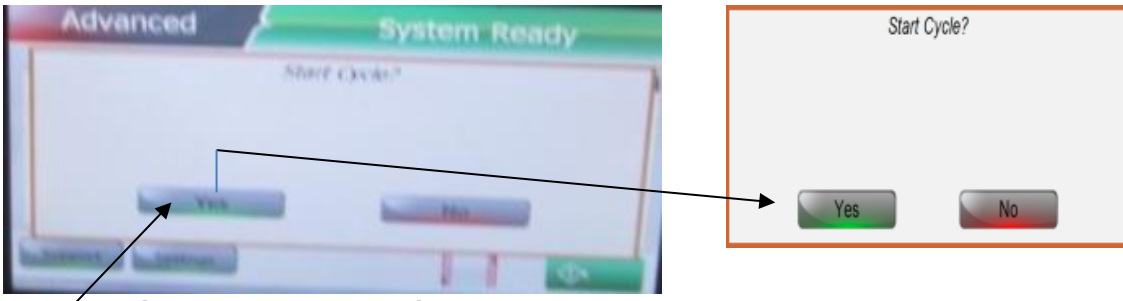
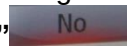


Figure 33 – Start Cycle screen

Press "**Yes**"  button, the advanced sterilization program starts by the Air Removal stage screen (see Figure 34 below). The Air Removal sterilization phase will be automatically followed through by all the stages as shown below.

Pressing on "**No**"  button will not start the sterilization cycle.

3. Continue to paragraph 8.3.3.

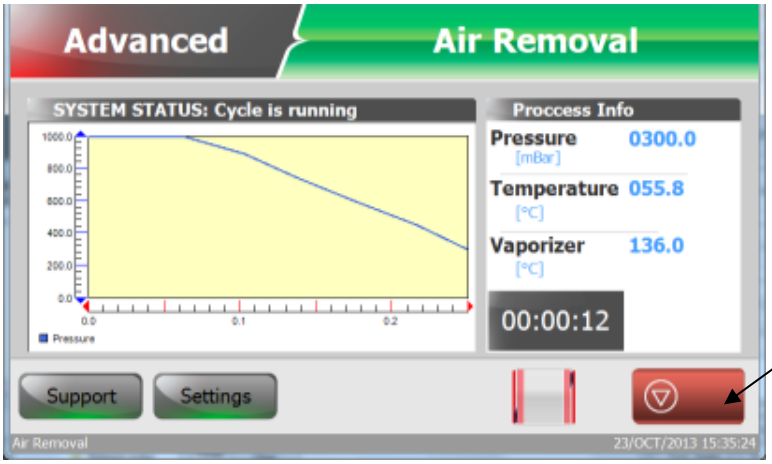
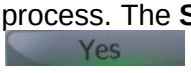
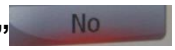


Figure 34 – Advanced Air Removal Phase Screen

Press "Yes"  button, the advanced sterilization program starts by the Air Removal stage screen.

8.3.3 Aborting Cycle During Sterilization Process

Pressing on  Abort Cycle button from the screen above (Figure 32) during the sterilization process will end the process. The **Stop Cycle?** Screen will be displayed (see below) asking for **Yes** or **No.** Press **"Yes"**  button, the process will end.

Pressing on "**No**"  button will continue the Advanced sterilization program **Air Removal** sterilization cycle phase. The Air Removal sterilization phase will be automatically followed through all the sterilization program stages shown for Normal program in the next paragraph 8.3.4.

Note:
The Advanced sterilization program is similar to the Normal sterilization program except for the diffusion duration time. The following paragraph shows a Normal sterilization program phases which are also similar to the advanced sterilization program.

8.3.4 Sterilization Programs Process Stages

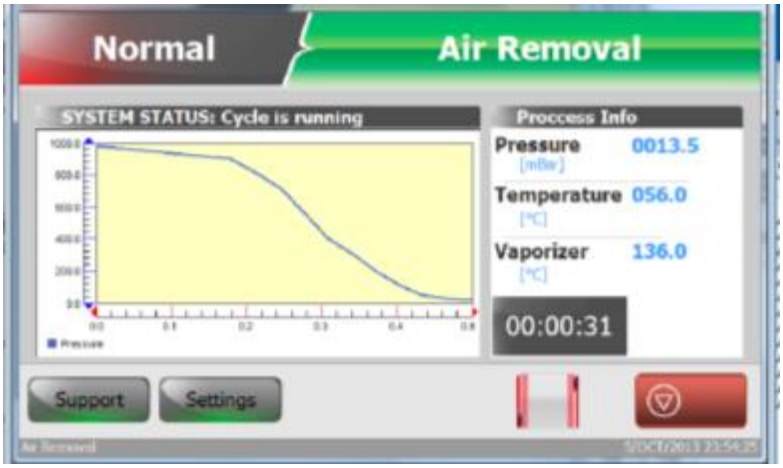
The Advanced, Normal and Endoscope sterilization programs are composed of the following process stage phases:

- Air removal
- Pre diffusion
- Diffusion 1
- Exhaust 1
- Diffusion 2
- Exhaust 2
- Aeration
- Confirm Cycle

Note:

The following screens are the normal sterilization cycle stage phases screens, the advanced sterilization cycle stage phases screens are similar to the normal, except for the longer diffusion duration time, therefore the same procedure is valid for the advanced cycle.

1. **Air Removal**



After the air removal phase, the following sterilization onsecutive phases continue automatically:

2. Pre diffusion
3. Diffusion 1
4. Exhaust 1
5. Diffusion 2
6. Exhaust 2
7. Aeration
8. Confirm Cycle

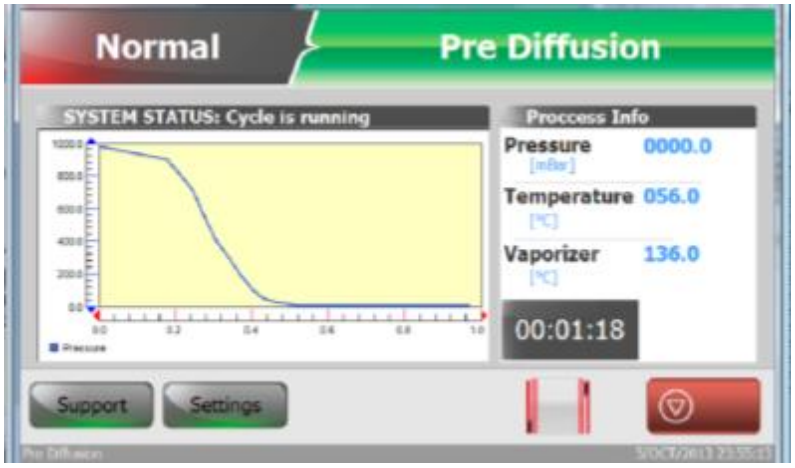
Cycles run automatically. At the end of a Cycle properly concluded you will hear a continuous sound alarm, and the printer will printout a report with the cycle data.
The length of all cycle phases and the setpoints for all critical process

The parameters are controlled the devices software.

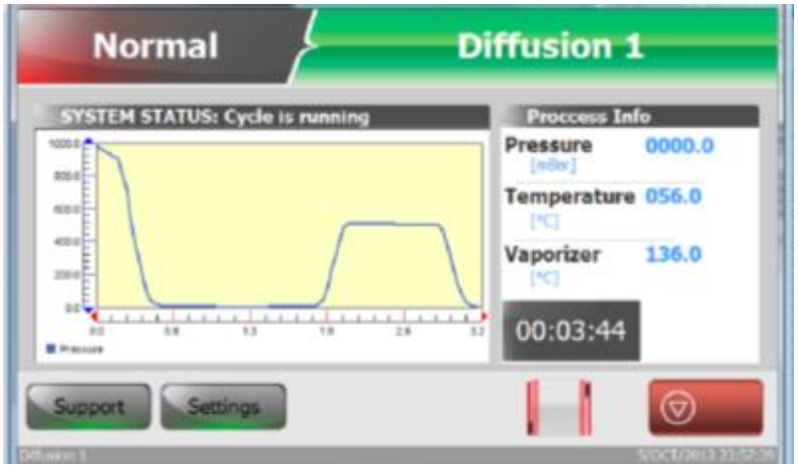
The display indicates the status of the unit at all times: the current stage of the sterilization cycle, the temperature in the chamber, the temperature in the vaporizer ,the pressure in the chamber, the cycle start time and the cycle estimated end time.

Each load goes through eight consecutive stages: Air Removal, Pre Diffusion, Diffusion 1, Exhaust 1, Diffusion 2, Exhaust 2, and Aeration.

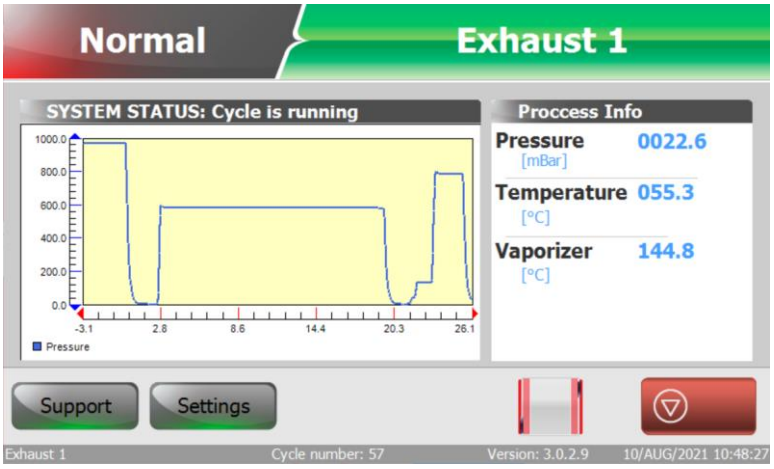
2. Pre Diffusion



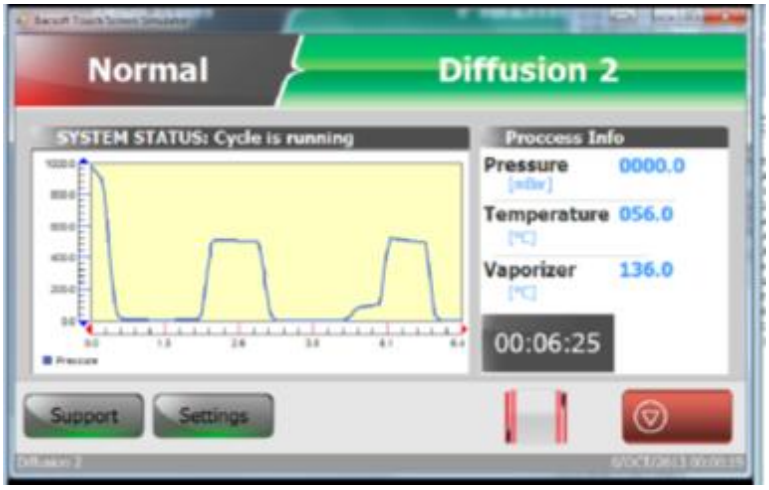
3. Diffusion 1



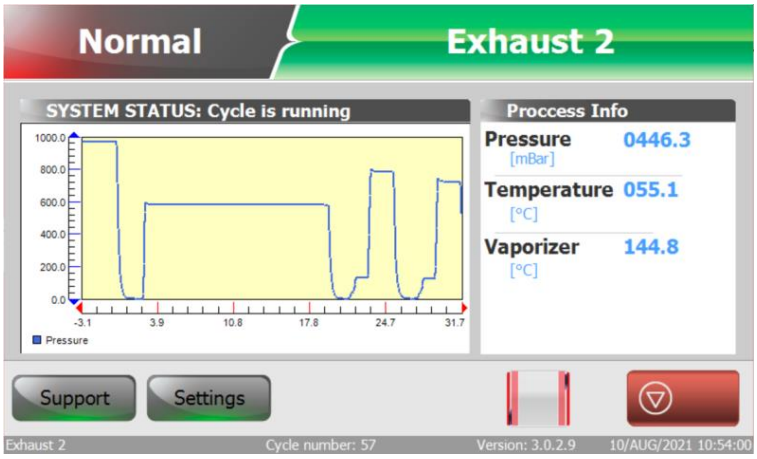
4. Exhaust 1



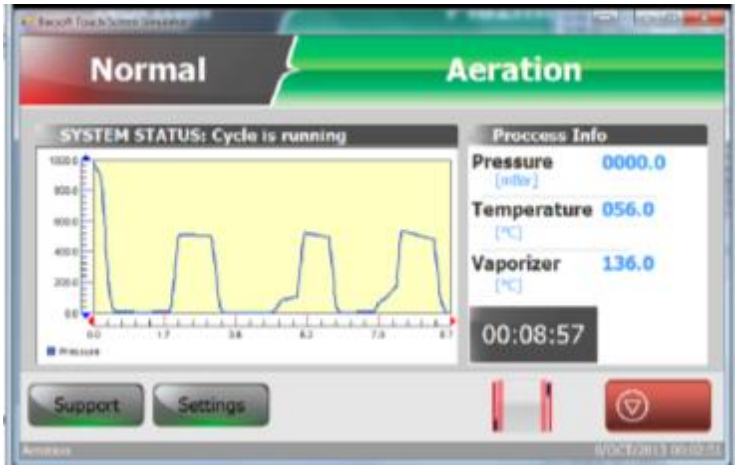
5. Diffusion 2



6. Exhaust 2



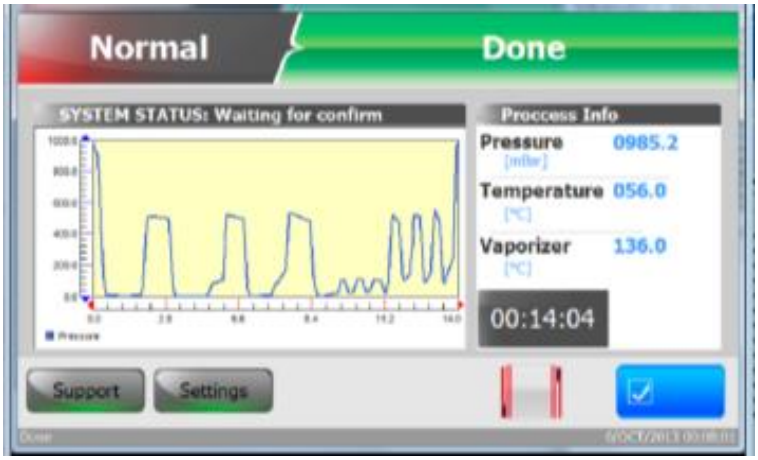
7. Aeration



8. Confirm Cycle-End of Cycle Process

Notes:
A process ends only after the evacuation of all the H_2O_2 gas from the system chamber. If the process fails before the admission of H_2O_2 gas to the chamber there is no need for gas evacuation.

At the end of the successful normal sterilization cycle the following screen is displayed.



1. Press  button.

The Normal sterilization program is now complete and the items load inside the PlazMax chamber can be removed.

2. Open (manually) the door. The items load from inside the PlazMax chamber can now be removed.

Note**:**

If at any time during the above cycle phases you wish to end the cycle. Pressing on  button on any of the phases above will end the sterilization process.

A **Stop Cycle?** Screen will be displayed (see "Stopping **a Cycle During Sterilization Process", paragraph 10.3.**) asking for **Yes** or **No**. Press **"Yes"** button, the process will end. Pressing on **"No"** will continue the cycle.

8.3.5 Sterilization Failed Cycle

In the event **of** malfunction during a sterilization program, a **Failed Cycle** red screen as shown in (Figure 35) below appears:

1. Cycle Fail Aeration screen

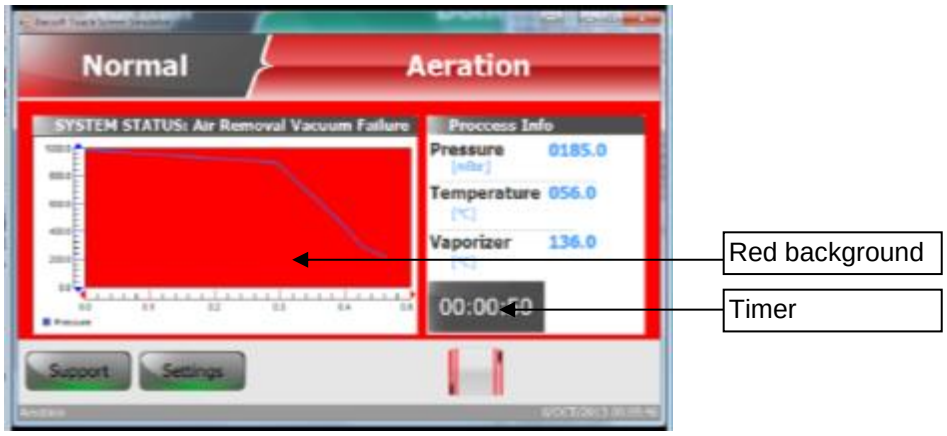


Figure 35 – Normal Aeration Fail Phase Screen

You have to wait for the cycle to end and confirm Cycle **Fail,** the blue button appears on the screen. This indicates that the cycle ends and the condition are safe to open the door. The following screen appears:

1. Press on the blue  bottom**.**

Notes:
A process ends only after the evacuation of all the H_2O_2 gas from the system chamber. If the process fails before the admission of H_2O_2 gas to the chamber there is no need for gas evacuation.

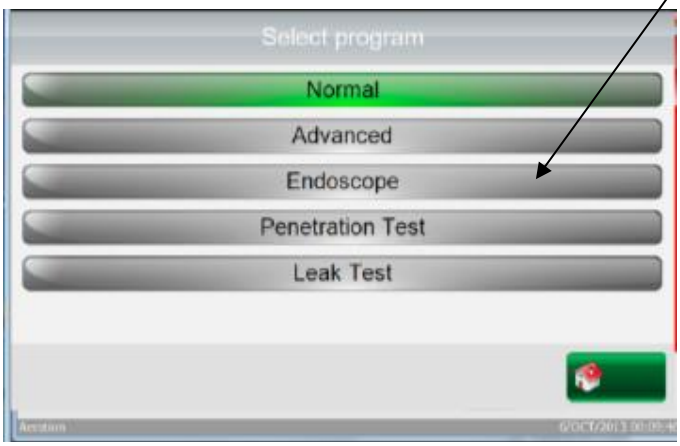
Warning!
The items inside the sterilizer chamber are presently not sterilized. You must re-start the sterilization cycle again.
hydrogen peroxide may be present. if there is a cycle cancellation and the items in the load appear wet, hydrogen peroxide may be present. wear chemical resistant gloves while removing the items from the chamber, and to wipe off the items with a damp cloth.

8.4 Selecting Endoscope Sterilization Program

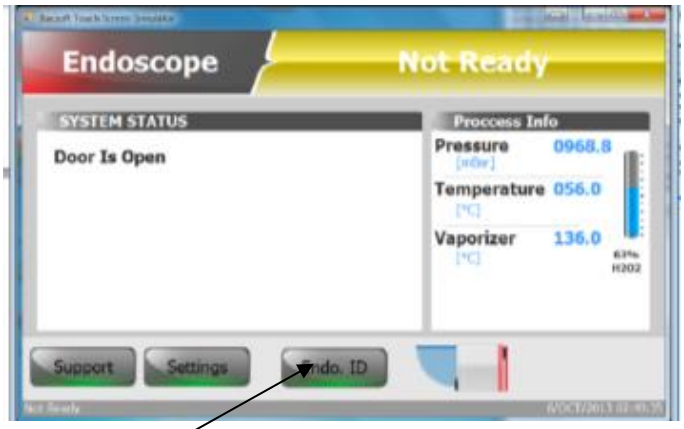
From the **Select Program** Screen you can select **Normal**, **Advanced**, or **Endoscope** sterilization programs, proceed as described below.

To select **Endoscope** program**,** select from the **Select Program** screen:

1. Open the door, select Endoscope cycle by pressing on Endoscope tab,



The following screen appears:



2. Press on **"Endo. ID"** button. The screen below is displayed

The operator can change and enter new endoscope ID, name, quantity, etc. (Place two Endoscopes maximum).

To go to the previous screen, press  return. Press 

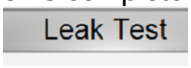
8.5 Leak Test Selection

This test is designed to check the sterilization chamber tightness integrity. It consists on submitting the chamber to a vacuum, with a stop of the Vacuum Pump, and with the drain valve closed.

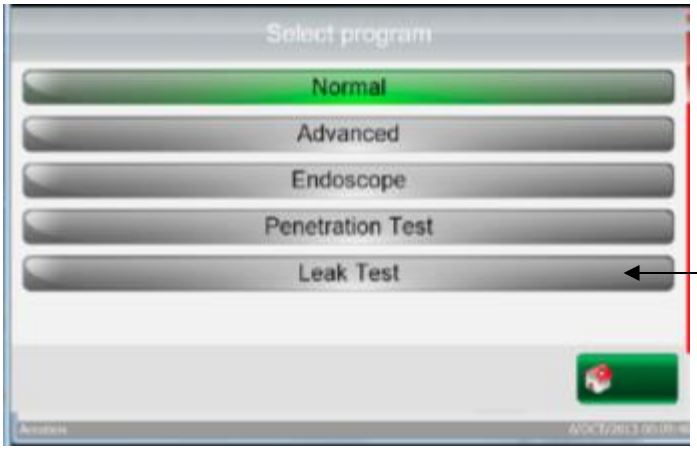
The test process is monitored, on a time counting, and a continuous verification of the pressure variations inside the chamber is performed.

IMPORTANT:
This test can be performed only in empty chamber and without load inside the chamber.

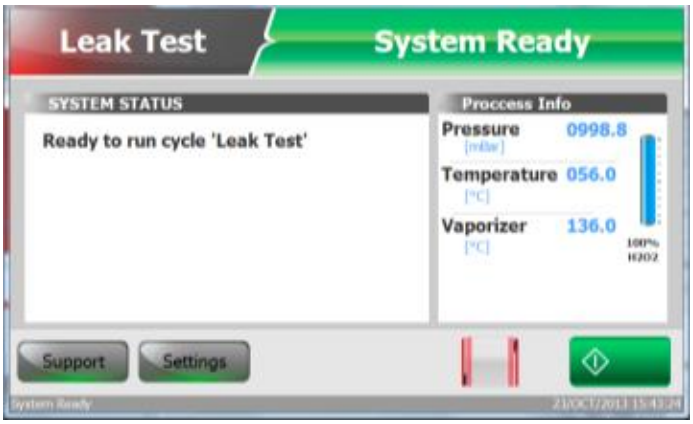
It is recommended to perform Leak test once a week.

1. Open the chamber door. Remove all items from the chamber; make sure that the chamber is completely empty.
2. Select 

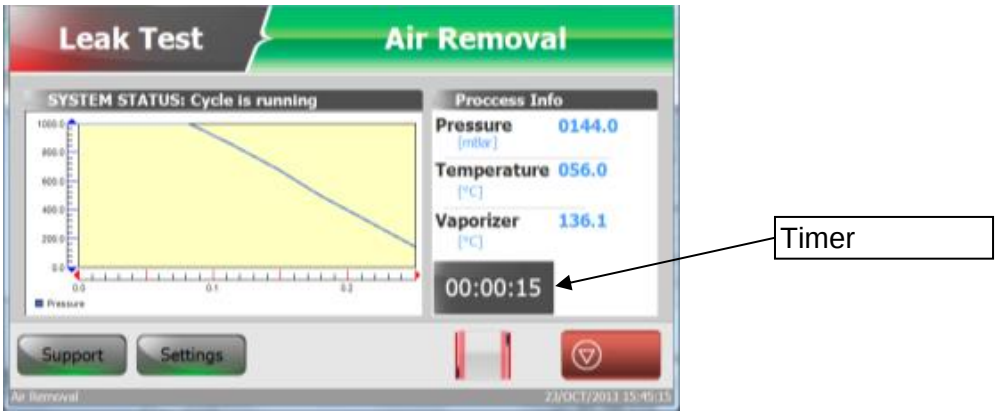
from the **Select Program** screen below.



3. The **Leak Test** system Ready screen appears:



4. **Press**  button. The Leak air removal screen appears:



The test is complete after approximately 10 minutes

At the end of the cycle after the buzzer sound signal, a report of the Leak Test is printed,and the operator is informed if the test was successfully completed (Figure 40) or if it failed (para. 8.5.1).

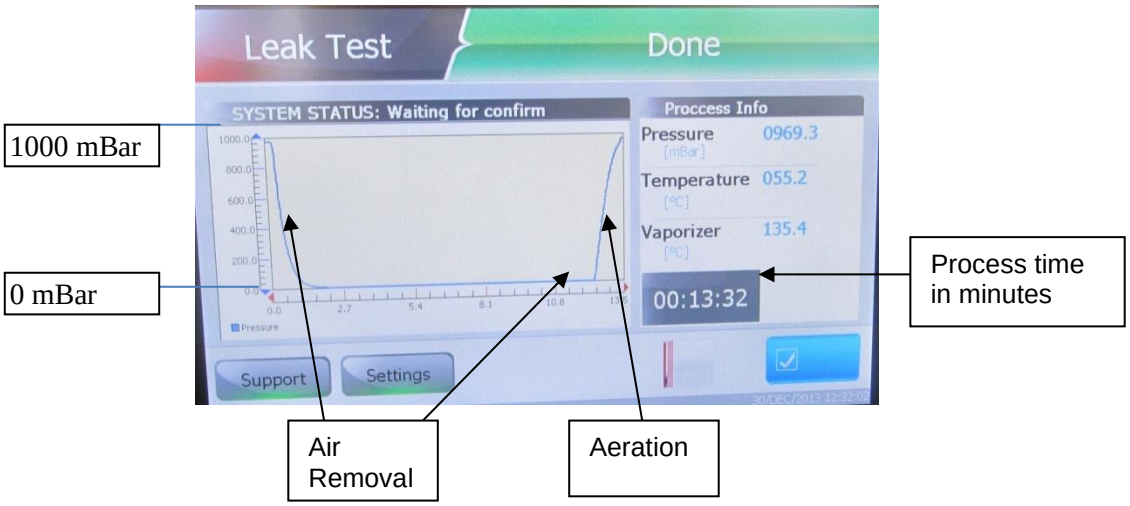


Figure 36 – Leak Test Completed

8.5.1 Leak Test Failure

3. Leak Test Cycle Fails

If the leak test fails, the following screen appears.

1. Open the door and check the door seal for tightness, clean the door.
2. Select Leak test from the Select Program screen.
3. Repeat the test
4. If the test fails again call service.

Cycles run automatically. At the end of a Cycle properly concluded you will hear a continuous sound alarm, and the printer will print a report with the cycle data.

The operator must check the message on the touch screen and the data on the printout. In case of failure, this message will be displayed on the screen and you will hear an intermittent sound alarm. The report will be printed out.

8.6 Penetration Test Selection

The penetration cycle test is an extreme test designed to validate the integrity of the sterilizer based on the result of the devices processing. The test is done by the operator placing Lumen Process Challenge Device (PCDs) with chemical indicator (CI) & Biological Indicator (BI), inside the sterilization chamber.

The operator is then checking the indicators results at the end of the cycle.

It is recommended to perform this test at predetermined scheduled intervals. In this cycle you must use the following PCDs:

- One PCD's (1400 mm) inside the sterilizer chamber.
- One double ended PCD (4000 mm) inside the sterilizer chamber.

To perform this test, proceed as in the leak test above.

The following screen (Figure 38) shows a successful penetration test.

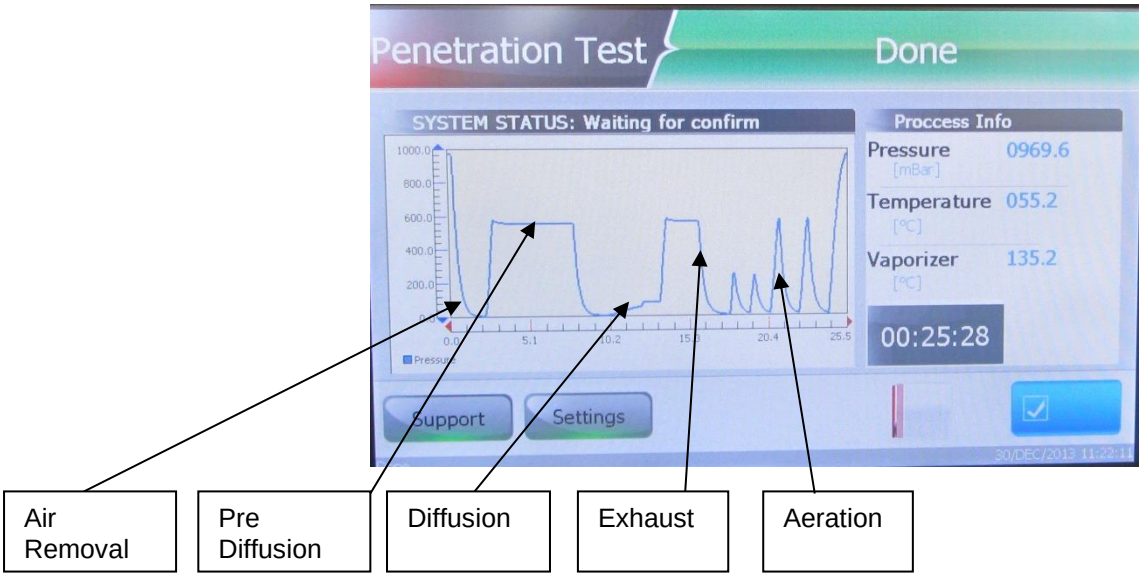


Figure 37 – Penetration Test Completed

In cases where the CI does not change its color in a pack or the BI's does not change the color to yellow, the test failed and shall be repeated, and verification must be done to determine if the load has been correctly sterilized.

If the Penetration test failure persists, call service

8.6.1 End of Program: (Confirm Cycle):

At the end of the cycle after the buzzer sound signal, a report of the Penetration Test is printed out and the operator is informed if the test was successfully completed or if it failed.

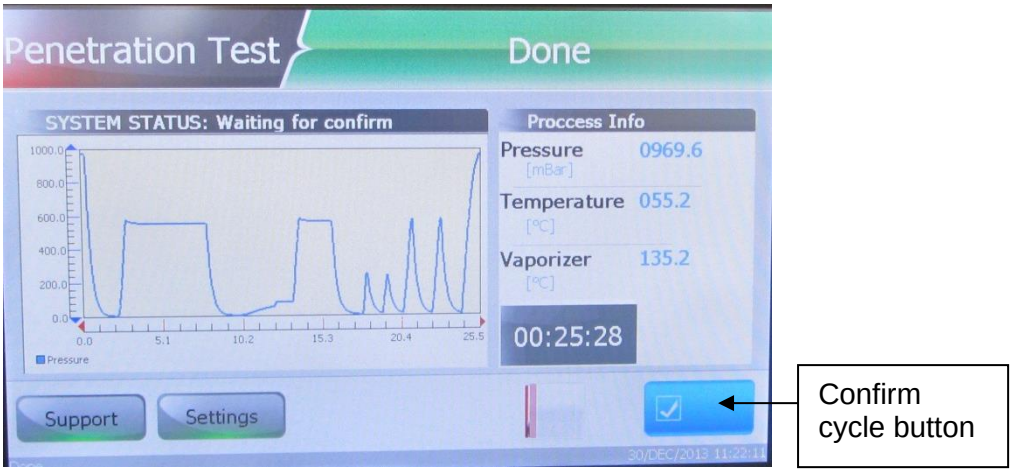


Figure 38 – Penetration Test Confirm Cycle

1. Press  button.

The Penetration Test program is now complete.

2. Open (manually) the door.

8.7 Malfunctions

If a malfunction occurs during the sterilization programs operation:

In the event of malfunction during a sterilization program, a Failed Cycle red screen as shown in (Figure 39) below appears:

1. Cycle Fail screen

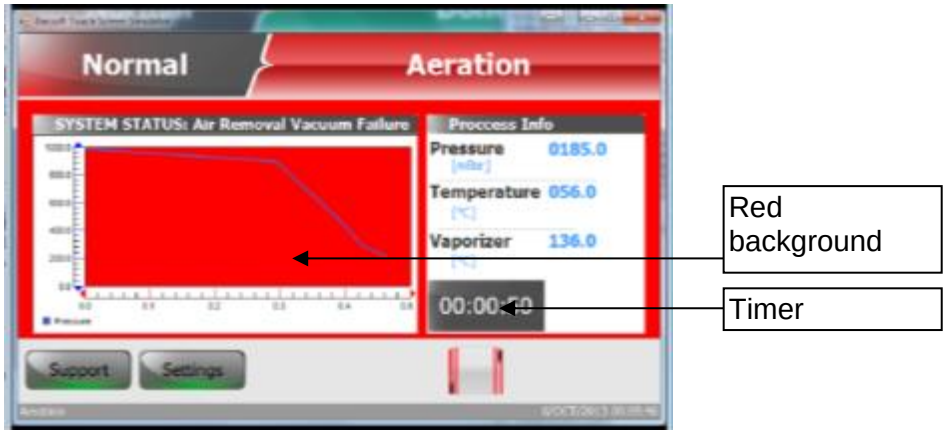
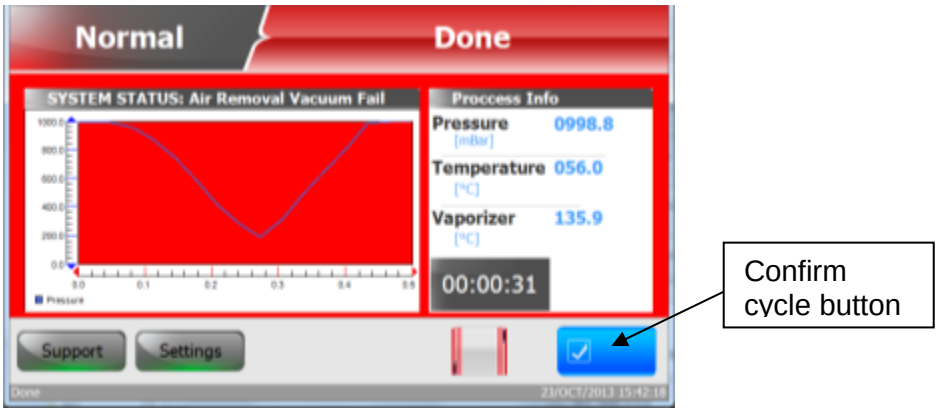


Figure 39 –Fail Phase Screen

You have to wait for the cycle to end and confirm Cycle **Fail,** the blue button appears on the screen. This indicates that the cycle ends and the condition are safe to open the door. The following screen appears:



2. Press on the blue  bottom**.**

Notes:
A process ends only after the evacuation of all the H_2O_2 gas from the system chamber. If the process fails before the admission of H_2O_2 gas to the chamber there is no need for gas evacuation.

Warning!
The items inside the sterilizer chamber are presently not sterilized. You must re-start the sterilization cycle again.

8.8 Cycle End

At the end of the **cycle** after the buzzer sound signal, a report of the Leak Test is printed and the operator is informed that the test was successfully completed or if it failed.

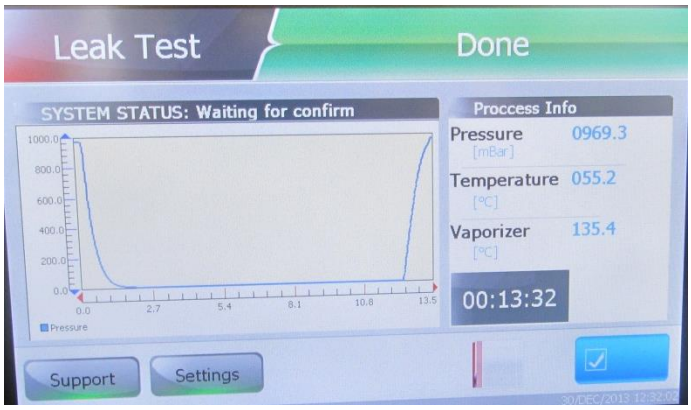


Figure 40 – Test Completed

8.8.1 Confirm cycle

A process ends only after the evacuation of all the H_2O_2 gas from the system chamber. If the process fails before the admission of H_2O_2 gas to the chamber there is no need for gas evacuation:

1. Press  button.

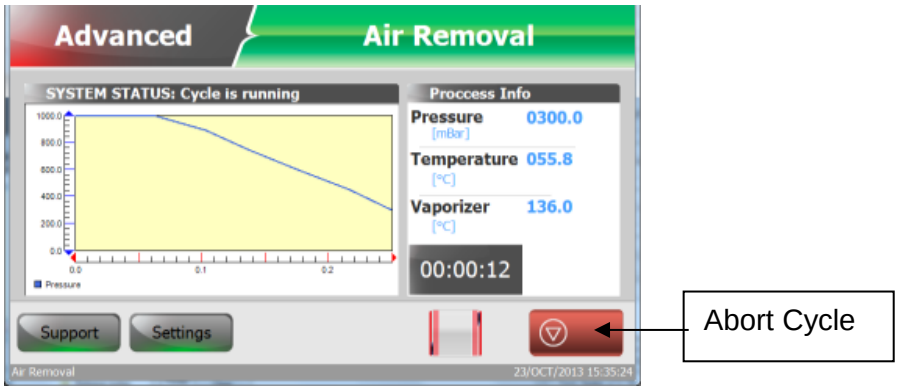
The Normal sterilization program is now complete and the items load inside the PlazMax chamber can be removed.

2. Open (manually) the door. The items load from inside the PlazMax chamber can now be removed.

8.9 Aborting a Cycle

The sterilizer 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).



1. Press on  Abort Cycle button from the screen above during the sterilization process. will end the process.

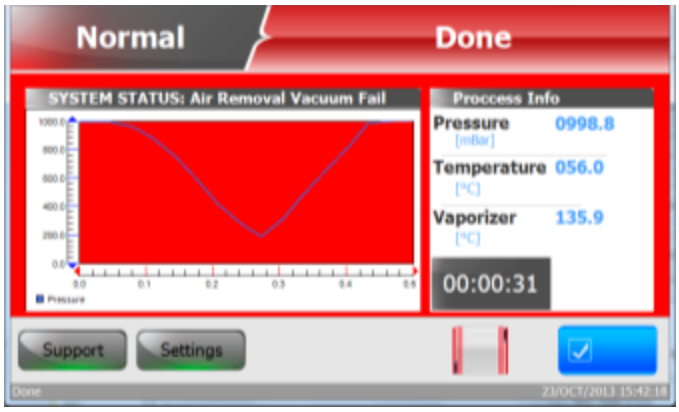
A **Stop Cycle?** Screen (Figure 42) will be displayed asking to stop cycle **Yes** or **No.**

2. Press **"Yes"** Yes button, the process will end.

Figure 41 – Stop Cycle Screen

Pressing on "**No"** No button will continue the **Air Removal** sterilization cycle phase.

You have to wait for the cycle to end and confirm Cycle**;** the blue button appears on the screen. This indicates that the cycle ends and the condition are safe to open the door. The following screen appears:



3. Press on the blue bottom**.**

Notes:
A process ends only after the evacuation of all the H_2O_2 gas from the system chamber. If the process fails before the admission of H_2O_2 gas to the chamber there is no need for gas evacuation.

Warning!
The items **inside the sterilizer chamber are presently not sterilized. You must re-start the sterilization cycle again.**

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.

9. MAINTENANCE

Warning!

These service instructions are for the use of qualified personnel only! Repairs and adjustments should only be done by authorized technicians who are fully trained to maintain and repair the PlazMax Sterilizer.

Use of unauthorized parts for maintenance or repair could cause personal injury, result in costly damage to equipment, or sterilizer malfunction and will void the warranty.

To avoid electric shocks, do not perform any servicing other than that specified in the operating instructions unless you are qualified to do so. Refer to all servicing to qualified service personnel.

When servicing the sterilizer, and/or opening any service panel, disconnect all electrical power supplies to the unit.

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

The purpose of the maintenance is to keep the sterilizer in good operating conditions.

Some maintenance procedures are performed automatically by the sterilizer software, other maintenance is periodically performed manually.

The maintenance consists of the following preventive maintenance and replacement maintenance plan that periodically conduct verifying or replacing parts in the PlazMax sterilizer.

Maintenance must be performed by authorized technicians, following the equipment manufacturers' instructions and this manual. When the maintenance is not periodically followed, a warning message will be printed out on the cycle report.

Preventive and replacement corrective maintenance

Before each cycle

1. Make sure to warm up the unit with the tools inside the compartment for at least 15 minutes before start cycle.
2. Verify that the door gasket and the mating surfaces that the gasket is pressed against are clean.
3. Keep the door closed between sterilization cycles.
4. See the table in the following pages.

Six months

Preventive Maintenance Plan.
Note: Perform all maintenance activities when the sterilizer and the pump are not operational.

Components that should be verified/replaced during the maintenance:

1. Check the oil level of the Vacuum pump (when the pump is not operational), the oil level should be higher than half. (see paragraph 9.1.9).
2. Remove the odor filter content, and clean the filter housing. Remove the stainless steel filter at the bottom of the housing, and clean the filter. Replace the filter mesh with a new one if needed (see paragraph 9.1.6).
3. Check the refill filter (every 6 months) which is located inside the housing of the oil separator filter. Replace it if required. (see paragraph 9.1.8).

Yearly

LEVEL 2 MAINTENANCE (Every year or after 1500 Cycles whichever comes first)

1. Check the H_2O_2 Vaporizer Filter Valve every twelve months or 1500 cycles. Replace the H_2O_2 Vaporizer Filter if required. (see paragraph 9.1.4).
2. Replace the vacuum pump oil every twelve months or 1500 cycles following the procedure in the manufacturer Vacuum Pump user manual, and this manual. (see paragraph 9.1.9).
3. The oil should be one of the following types:
   LVO-100 White oil
   LVO-600 White oil
4. Replace the oil separator filter every twelve months or 1500 cycles according to manufacturer manual instructions and this manual (paragraph 9.1.8.).
5. Replace the odor refill filter every twelve months or 1500 cycles according to instructions of this manual, and paragraph 9.1.6.
6. Replace the Fast Connections and Tubes of the Sterilizing agent circuit every twelve months or 1500 cycles. (see paragraph 9.1.3).
7. Replace Vaporizer valve every twelve months or 1500 cycles. (see paragraph 9.1.1).
8. Replace the HEPA Filter every twelve months or 1500 cycles. (see paragraph 9.1.5).
9. Check for damage and Clean the door Gasket every twelve months. (see paragraph 9.1.10).

Note: For detailed maintenance instructions see paragraph 9.1
Note: Battery Replacement when required: replace the battery with the same type and manufacturer.

IMPORTANT:
In an effort to better serve our customers, Tuttnauer LTD has established an automatic reminder to schedule your semi-yearly Prventive Maintenance to your PLAZMAX autoclave. Please make sure to follow all steps in the maintenance chapter.
This is to serve as confirmation that according to Tuttnaurer's operation and maintenance manual for the Plazmax autoclave – the requested preventive maintenance will and should be fully performed. Failure to perform periodical preventive maintenance shall be deemed as a violation of the operation and maintenance manual, and may result in damage to the unit, which shall consequently be executed from Tuttnaeuer's obligation to provide warranty and/or service coverage, if applicable.

MAINTENANCE summary

Note: For detailed maintenance instructions see paragraph 9.1

Component	Every 6 Months	Every Year or 1500 Cycles (whichever comes first)	P/N	Figure/Para.
Vacuum Pump Oil Level	Check the oil level (when the pump is not operational) (The oil level should be higher than half)	Replace the oil		**Figure 51 Paragraph 9.1.8**
H_2O_2 Vaporizer Filter Valve	Check the Filter Clean the Filter Replace the filter if needed	Replace the filter	PLZ175-0008	**Figure 45 Paragraph 9.1.4**
Oil Filter		Replace the filter if needed	PLZ000-0138	**Figure 43 Paragraph 9.1.2**
Door Gasket	Clean the gasket		PLZ000-0110	**Figure 52 Paragraph 9.1.9**
Fast Connections and Tubes of the Sterilizing Agent Circuit		Replace	PLZ000-0095	**Figure 44 Paragraph 9.1.3**
Vaporizer Valves		Replace	PLZ100-0016 PLZ100-0017	**Figure 42 Paragraph 9.1.1**
Airation Filter		Replace	PLZ175-0001	**Figure 46 Paragraph 9.1.5**
Odor Filter	Remove the odor filter content clean the filter housing Remove the S.S mesh filter. Replacethe filer if required	Replace the odor filter refill	-Housing PLZ175-0005 Filter PLZ175-0009	**Figure 47 Figure 48 Figure 49 Paragraph 9.1.6**
0il Separator Filter	Check the refill filter inside the housing of the oil separator filter Replace the filter if required	Replace		**Figure 50 Paragraph 9.1.7**

9.1 Preventive and replacement corrective maintenance Instructions

9.1.1 Vaporizer Filter valve

Instructions for the for maintenance or the replacement of the the Vaporizer valve .

1. Remove the Vaporizer valves, (Figures 42).
2. Install new Vaporizer valve.
3. Verify that all the tubes and fittings are properly connected.
4.

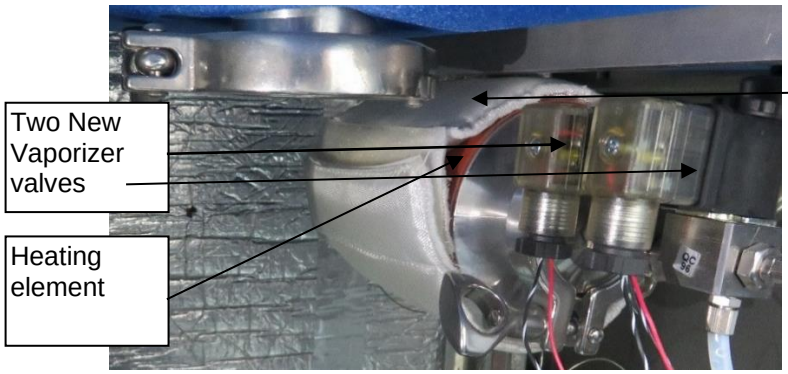


Figure 42 –Vaporizer Valve

9.1.2 Oil Filter

Instructions for the replacement of the Oil Filter (Figures 43).

1. Remove the old Oil Filter, (Figures 43).
2. Install the new Oil Filter.

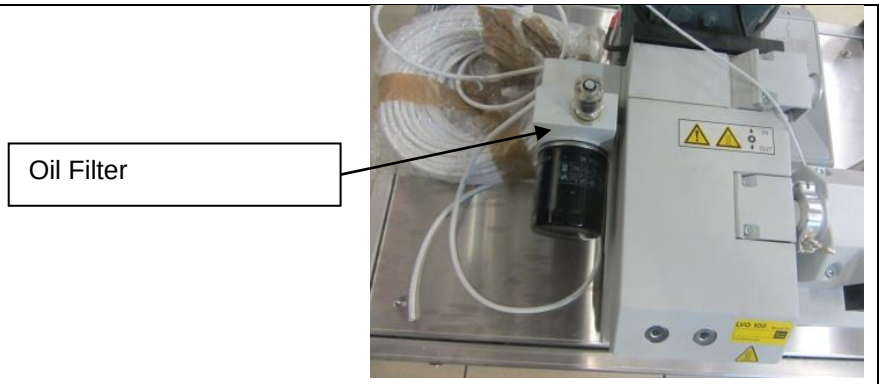
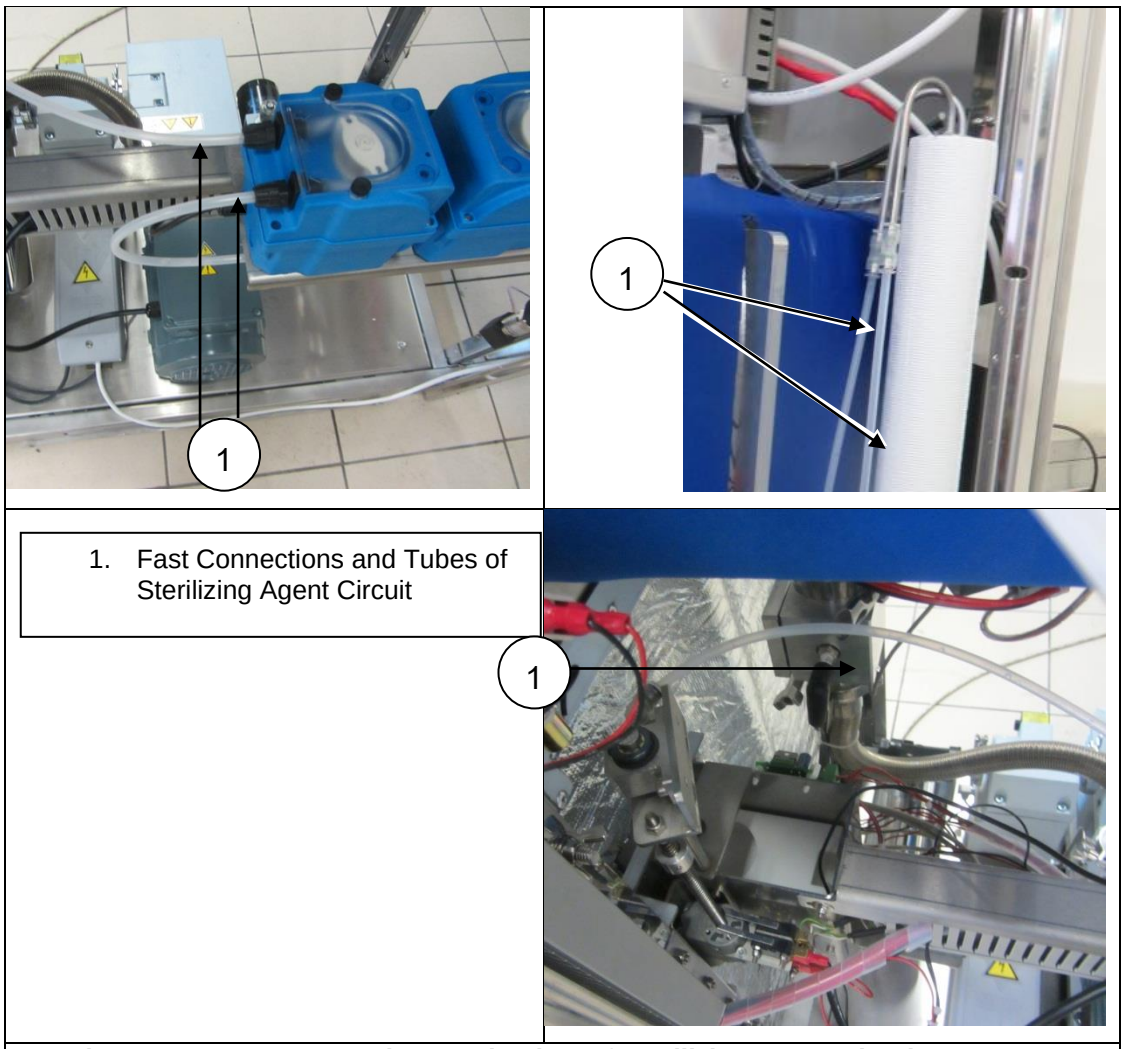


Figure 43 – Oil Filter

9.1.3 Fast Connections and Tubes of Sterilizing agent circuit

Instructions for the replacement of Fast Connections and Tubes of Sterilizing agent circuit (Figures 45):

1. Remove the old Fast Connections and Tubes of the Sterilizing agent circuit , (Figures 44).
2. Install the new Fast Connections and Tubes of the Sterilizing agent circuit kit (P/N: PLZ000-0095) .
3. Verify that all the Fast Connections, fittings and tubes are properly connected.



1. Fast Connections and Tubes of Sterilizing Agent Circuit

Figure 44 – Fast Connections and Tubes of Sterilizing Agent Circuit

9.1.4 H_2O_2 Vaporizer Filter Valve

Instructions for the for maintenance or the replacement of the the H_2O_2Vaporizer Filter valve:

1. Remove the H_2O_2Vaporizer Filter valve, (Figures 45).
2. Install a new H_2O_2Vaporizer Filter valve.
3. Verify that all the pipes and fittings are properly connected.

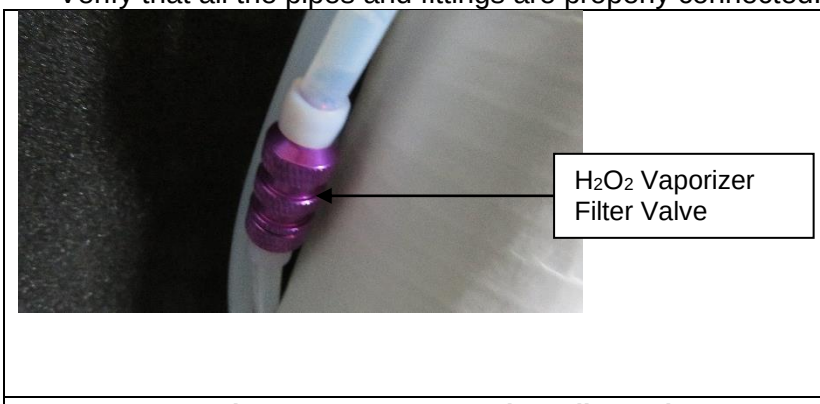


Figure 45 – H_2O_2 Vaporizer Filter Valve

9.1.5 Airation Filter

Instructions for maintenance or the replacement of the Hepa Filter (Figures 46):

1. pen the TRI clamp (1) , disconnect the old HEPA filter.
2. Replace the old Hepa Filter with a new Hepa Filter.
3. Close the TRI clamp (1), and check for leaks.

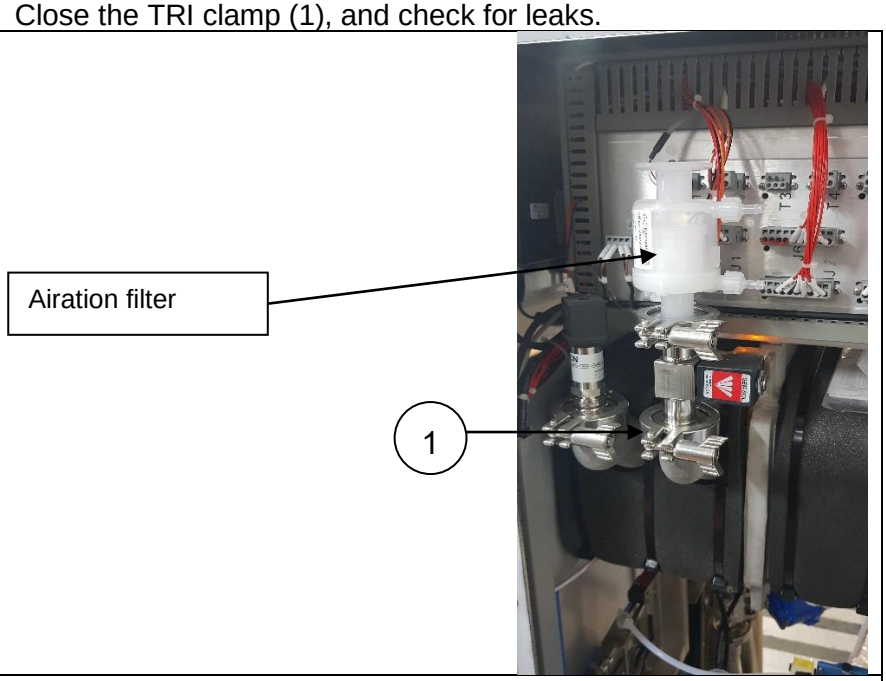


Figure 46 –-Airation filter

9.1.6 Odor Filter

Instructions for the maintenance or the replacement of the Odor Filter (Figures 47, 48 & 49).

1. Remove the TRI clamp (4),
2. Remove the odor housing cylinder cover(3), by opening the screws (2) Figure 47.
3. Release the housing cylinder Tightening Ring (1), by turning the ring counterclockwise using the screw driver rod tool inserted in the ring hole**.**
4. Remove the odor housing cylinder cover(3)
5. Remove the Odor Filter (5) bags inside the cylinder, Figure 48.
6. Remove the Odor Filter content, clean the filter housing. Remove the stainless steel (item 6, Figure 49) mesh filter at the bottom of the housing. Clean the mesh filter. Return the cleaned mesh filter.
7. Replace the Odor Filter (5) bags, Figure 48.
8. Re Installation of the Odor Filter is a reverse operation of the above steps

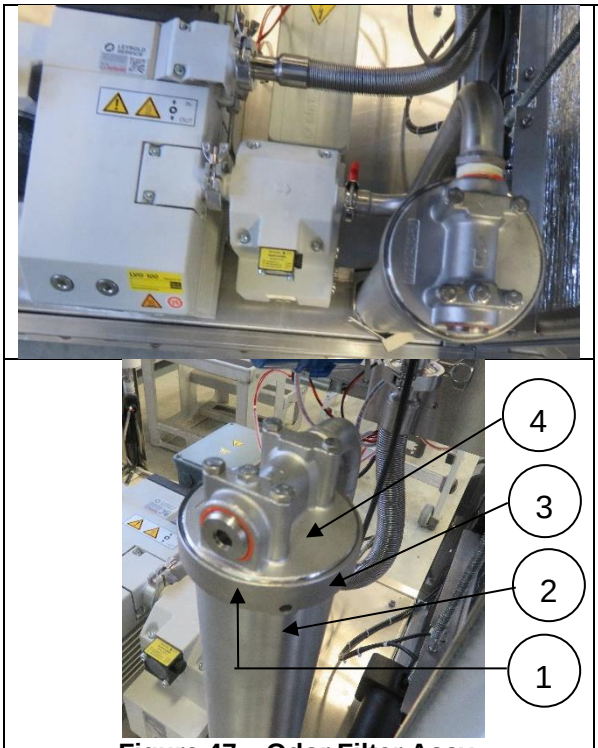


Figure 47 – Odor Filter Assy.

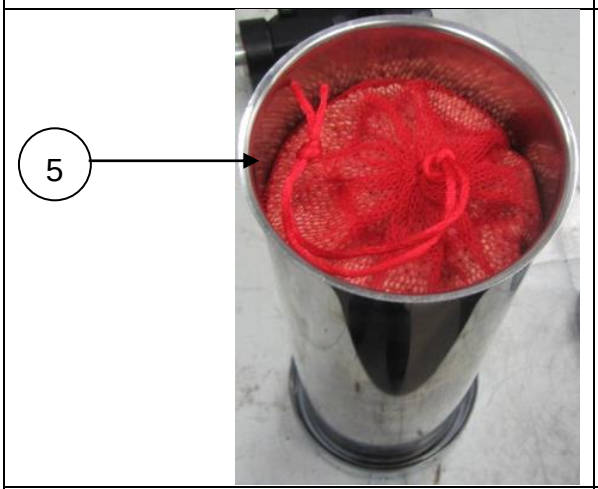


Figure 48 – Odor Filter

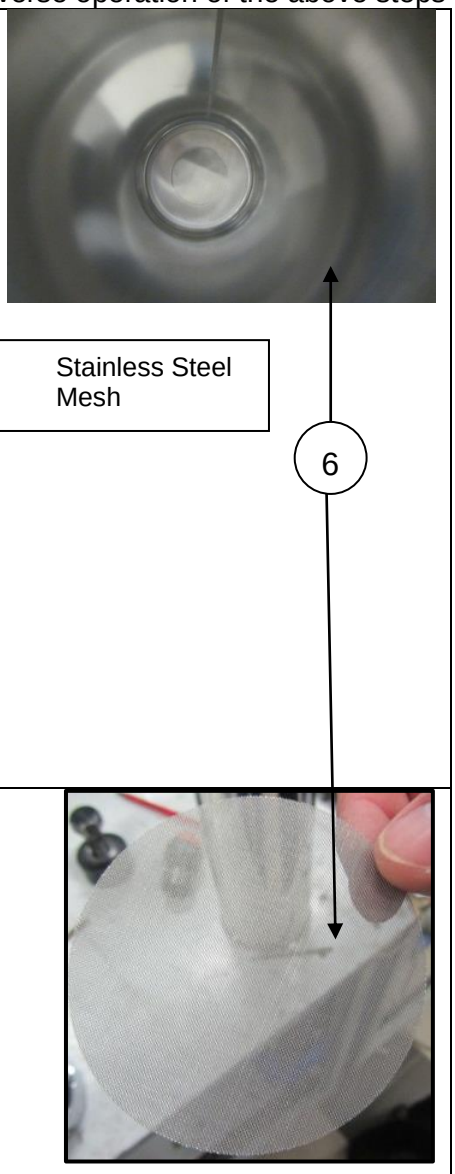


Figure 49 – Stainless Steel Mesh

9.1.7 0il Separator Filter

Instructions for the for the maintenance or the replacement of the the Oil Separator Filter:

1. Remove the 4 screws (1), (Figures 50).
2. Lift the oil separator filter cover (2).
3. Remove the old Oil Separator Filter.
4. Install the new Oil Separator Filter.
5. Place the oil separator filter cover (2) in its Proper position.
6. Tighthen the the 4 screws (1).

Figure 50 – Oil Separator Filter

9.1.8 Vacuum Pump Oil Level Indicator Gauge

1. Check the level of the Vacuum pump oil every six months, the oil level gauge should be higher than half.
2. Add Oil if required.
3. Replace the oil every twelve months

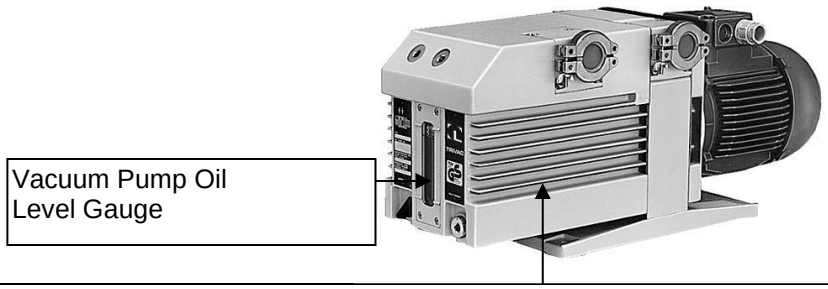


Figure 51 –Vacuum Pump Oil Level Indicator

9.1.9 Door Gasket

1. Check the gasket and verify that it is not damaged
2. Clean the gasket and the mating surfaces.

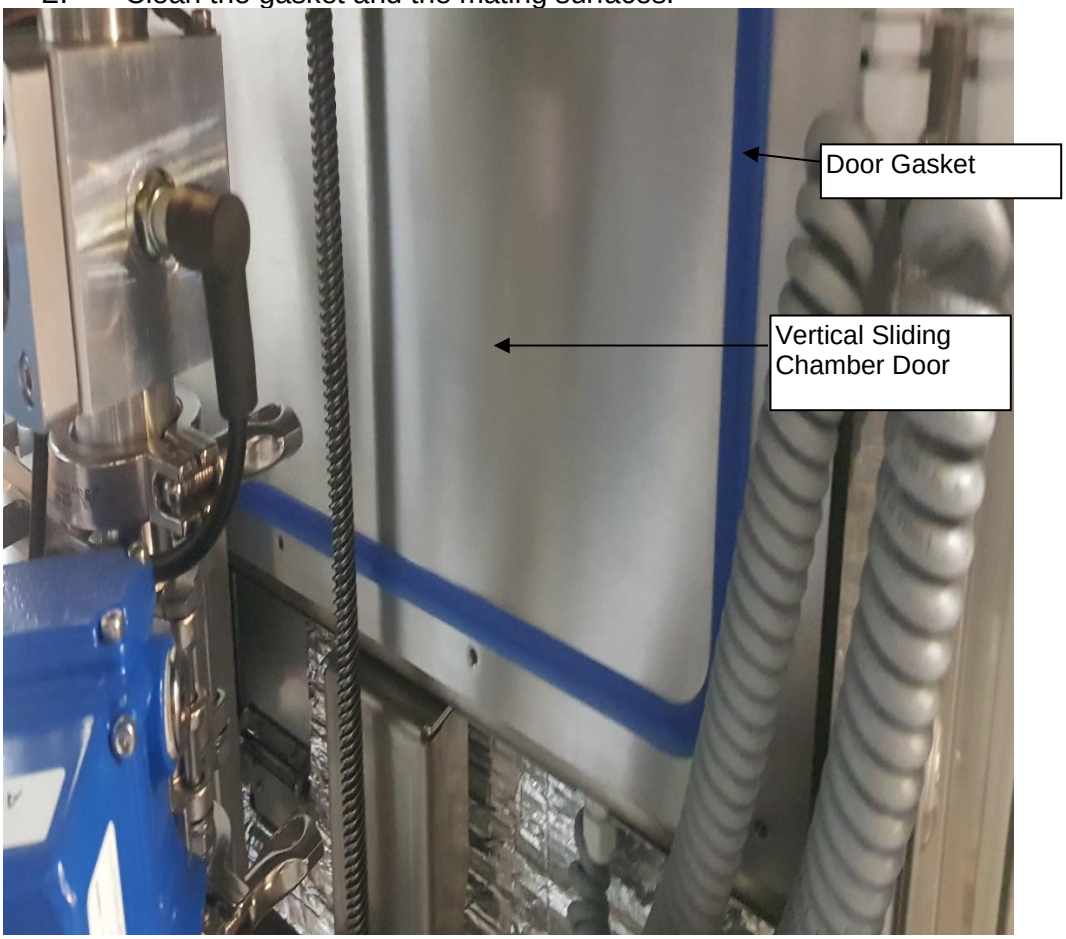


Figure 52 – Door Gasket

9.2 PlazMax Vacuum Pump Replacement Maintenance

The design concept of the TRIVAC B pump require very little maintenance when operated under normal conditions. The work required is described in the sections below. In addition to this, a maintenance plan is provided in tables below.

All work must be carried out by suitably trained personnel. Maintenance or repairs carried out incorrectly will affect the life and performance of the pump and will void any warranty claims.

If the TRIVAC B pump is used in ambient air which is very contaminated, make sure that the air circulation and the gas ballast valve are not adversely affected.

When the TRIVAC B pump has been pumping corrosive media, we recommend that whenever possible, a planned maintenance work be carried out immediately in order to prevent corrosion of the pump while it is at standstill.

 **Warning!**
Danger caused by High Electric Voltages. Death or severe injury caused by an electric shock! The electrical connections must be provided only by a trained electrician as specified, for example, by the regulations EN 50110-1.

Note:
The national regulations of the country in which the equipment is being operated. Disconnect the electrical connections before disassembling the pump.

Vacuum Pump Maintenance Plan

The Vacuum Pump Maintenance Plan is shown in the following tables.

No.	Maintenance Plan	Measurement/test quantity Operating/auxiliary materials	VE	VP	D	6M	A	N-A	Remarks
1.	Operate the pump for at least 1 h x with gas ballast.	Operate the pump for at least 1 h x with gas ballast			**X**				Condensed water is thus removed from the oil.
2.	Check the oil level, if required change the oil.	Oil: LVO 100 or special and The oil should be one of the following types: - ALCATEL A200 -DIF OIL-20 -HE200	**X**		**X**				Refill: Only after the pump has been switched off.
3	Check the quality of the oil, change the oil if required.	visually (all oils) **Chemically** **Mechanically**	**X**		**X**	 **X** **X**			**Visually:** normally light and transparent, oil change the oil if required. Change is required when discolorations increase. **Chemically:** to DIN 51558, when the neutralization number exceeds 2; then an oil change will be required. **Mechanically:** when viscosity is 20 % above the one of fresh oil; then an oil change will be required

Vacuum Pump Maintenance Plan

No.	Maintenance Plan	Measurement/test quantity Operating/auxiliary materials	VE	VP	D	6M	A	N-A	Remarks
4	Clean the inlet screen in the intake port, change it as required.	Suitable cleaning agent and compressed air				X			*Clean inlet screen with a cleaning agent and. blow it out with compressed air under a suction hood. *Replace the defective inlet screen. Use a cleaning agent which complies with the national/international specifications. Observe the safety regulations when using cleaning agents.
5.							X		Already clean before the maintenance interval has elapsed when the noise level increases. Clean internal demister with cleaning agent Replace the defective internal demister Dispose of the defective internal demister as special waste. Cleaning agent according to national/international specifications. **Observe the safety regulations when using cleaning agents.**

No.	Maintenance Plan	Measurement/test quantity Operating/auxiliary materials	VE	VP	D	6M	A	N-A	Remarks
6	Check the edges of the teeth on the coupling element for any damages; change the coupling element as required.	Suitable cleaning agent and compressed air					X		Change of the coupling element if required only by the manufacturer.
7.	Change the oil Oil And Clean the oil level glass	Oil: LVO 100 Suitable cleaning agent and compressed air					X		Oil change: First oil change after 100 operating hours. Pump switched off and cold. Clean the oil level glass with a cleaning agent and blow it out *with* compressed air under a suction hood Use cleaning agents only corresponding to the national/international specifications. **Observe the safety regulations when using cleaning agents.** **Quantity of oil:** see Technical data
8	Check the fan of the pump and motor as well as the cooling fins on the motor for deposits, and clean as required.	Brush and industrial vacuum cleaner.					X		Depending on the amount of dust check the pump and keep it clean **Caution:** switch off the pump and ensure that it cannot run inadvertently (disconnect from the mains).

Legend for maintenance plan
VE = Maintenance before switching on the system
VP = Maintenance before starting production
D= Daily maintenance
6m = Six monthly maintenance
A = Annual maintenance
n-a = Maintenance every n years

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10 CONTROLLER MESSAGES

10.1 Controller Touch Screen Stand by Error Messages

Message	Description	
Door Is Open	Indicate that the door is open	Close the door to start the cycle.
H_2O_2 low level	Indicates that there is not sufficient H_2O_2 for the cycle	
Chamber temperature not ready	Indicates that the temperature of the chamber did not reach the required temp. for start cycle	Wait about 10 min.to warm up the chamber
Front temperature not ready	Front door did not reach the required temperature to run the cycle	Wait about 10 min. to warm up the door
Back temperature not ready	Back door did not reach the required tem. to run the cycle	Wait for about 10 min. to warm up the door .(Only in sterilizer with 2 doors)
Vaporizer temperature not ready	Vaporizer did not reach the required temp. to run the cycle	Wait about 10 min. to warm up the vaporizer
Temperature timeout	One of the parts above did not reach the required temp. in normal time.	Call Service
Wait for Door Opening	Door is in opening progress	N/A indication
Wait for Door Closing	Door is in closing progress	N/A indication
Chamber pressure not in range	Chamber pressure is out of range	Call service
Chamber temperature not in range	Chamber temperature is out of the normal range	Call service
Front temperature not in range	Door temperature is out of the normal range	Call service
Back temperature not in range	Door temperature is out of the normal range	Call service
Vaporizer temperature not in range	Vaporizer temperature is out of the normal range	Call service
Atmospheric pressure not set		
Door error	Invalid doors state	Call service
Drawer error	Invalid drawer state	Call service
Emergency Stop	Emergency stop button is pressed	Find out the reason why it was pressed. If it is safe to release it by key
Analog input error	One or more analog inputs are out of range	Call service
Digital output test mode is active	User selected 'Test Digital Outputs'	Massage is only for technician
I/O card is not connected	Failed creating communication with I/O card	Call service

10.2 Controller Start cycle error messages

The following table describes the system Start cycle error messages.

Message	Description	
Routine cycle service is recommended. Please call your service provider.	System parameter 'Cycle Service Counter' defines the number of cycles that can be issued before the error is displayed.	Call service
Routine service is recommended. Please call your service provider.	System parameter 'Time Service Counter' defines the number of days passed before the error is displayed.	Call service
Other Cycle Is Currently Running	Other Cycle Is Currently Running	
Door Open	Door is not closed	Informative
RTC Error - Please Set Current Date And Time.	System Date & time are not set.	Set date and time – see the operating instructions in chapter 7
Invalid Parameter value	Low Pressure' parameter value is higher than 'High Pressure' parameter value	Only for factory
Please open and close door before restarting a cycle.	Door has not been open after the previous cycle ended.	Informative, please Open door and close door before start cycle
System is not ready, Cycle will auto. start when conditions are available.	The massage appears if the cycle started when the conditions were not ready for starting a cycle	Informative, the cycle will start when conditions will be ready. It is done automatically.

10.3 Controller cycle error messages

The following table describes the system cycle error messages.

Message	Description	
Cycle Done	No error	Informative massage
Air Removal Vacuum Failure	Failed getting chamber pressure to 'Air Removal Requested Pressure' point	Call service
Leak	Pressure gap is higher than the value of parameter 'Max Allow Difference' in the Leak test cycle	Call service
Pre Diffusion Air Inlet Failure	Failed getting chamber pressure to 'Prepare High Pressure' point	Call service
Pre Diffusion Vacuum Failure	Failed getting chamber pressure to 'Prepare Low Pressure' point	Call service
Pre Diffusion Vac. Fail	Failed getting chamber pressure to 'Prepare Low Pressure' point	Call service
Diffusion 1 Low Pressure	Failed getting chamber pressure to 'Diffusion 1 Low Pressure' point	Call service
Diffusion 1 High Pressure	Chamber pressure was changed to more than the value of parameter 'Diffusion 1 Pressure Gap'	Call service
Diffusion 1 High Rate	Pressure change rate is higher than value of parameter 'Diffusion 1 Safe Pressure Rate'	Call service
Diffusion 1 Air Inlet Failure	Failed getting chamber pressure to 'Diffusion 1 High Pressure' point	Call service
Chamber pressure not in range	Failed getting chamber pressure to 'Diffusion 1 High Pressure' point	Call service
Exhaust 1 Vacuum Failure	Failed getting chamber pressure to ' Exhaust 1 Pressure'	Call service
Diffusion 2 Low Pressure	Failed getting chamber pressure to 'Diffusion 2 Low Pressure' point	Call service
Diffusion 2 High Pressure	Chamber pressure was changed to more than value of parameter 'Diffusion 2 Pressure Gap'	Call service
Diffusion 2 High Rate	Pressure change rate is higher than value of parameter 'Diffusion 2 Safe Pressure Rate'	Call service
Diffusion 2 Air Inlet Failure	Failed getting chamber pressure to 'Diffusion 2 High Pressure' point	Call service
Exhaust 2 Vacuum Failure	Failed getting chamber pressure to ' Exhaust 2 Pressure' point	Call service
Aeration Vacuum Failure	Failed getting chamber pressure to 'Aeration Low Pressure' point	Call service

Message	Description	
Aeration Air Inlet Failure	Failed getting chamber pressure to 'Aeration High Pressure' point	Call service
Normal Pressure	Failed getting normal pressure during Aeration stage	Call service
Canceled By User	User has pushed the stop button and canceled the cycle	Informative
Emergency Stop	Emergancy stop button has been pressed during the cycle	
I/O Card Not Connected	Connection with the I/O card has been lost	Call for service
Analog Input Error	Analog input has been detected and is out of range	Call for service
Power Down	Electric power down encountered while cycle was running	Call for service
Door Is Open	Call service	Call service
If 2 doors are open	2 doors cannot be open	Call service

11. PlazMax STERILIZER INSTALLATION

This chapter provides instructions for unpacking and the installation on site of the newly shipped received PlazMax sterilizer. It also supplies detailed installation and sterilizer moving and positioning on site information.

11.1 How to unpack the sterilizer

1. Inspect and verify that the PlazMax Sterilizer Wooden Packing Crate transport arrived undamaged. If the pack is damaged during transport, inform your supplier immediately. Inspect the PlazMax Sterilizer transport shipping Wooden Crate for signs of damage during transport. If arrived undamaged proceed with unpacking. If the pack is damaged during transport, inform your supplier immediately.

1. Unpack the machine in an ample space.

2. Remove the external packing.

3. Remove all the fixing screws that hold the 4 brackets that secure the machine to the pallet.(See Figure 54)

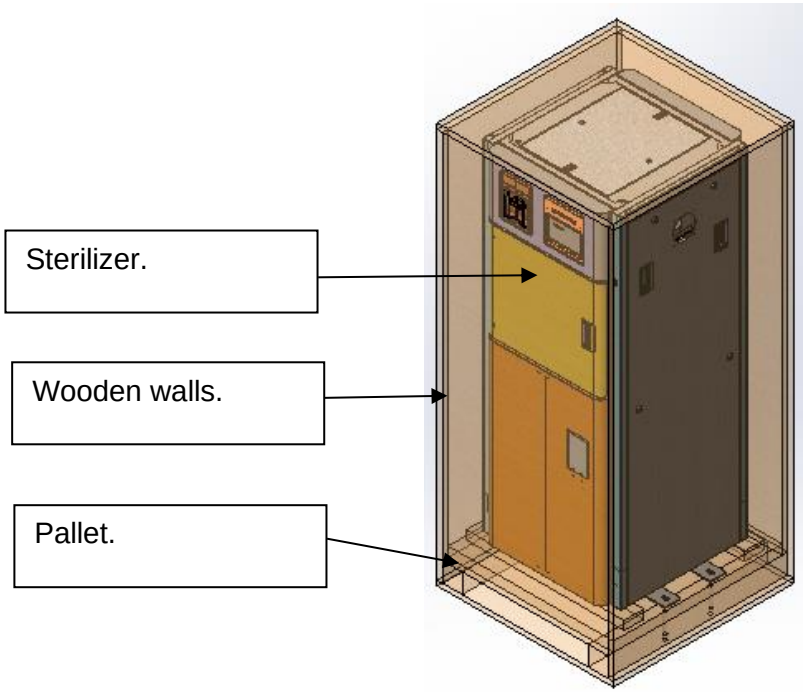


Figure 53 – PlazMax Sterilizer Wooden Packing (showing some panels removed)

4. Lift the machine using the pallet (see Figure 40).

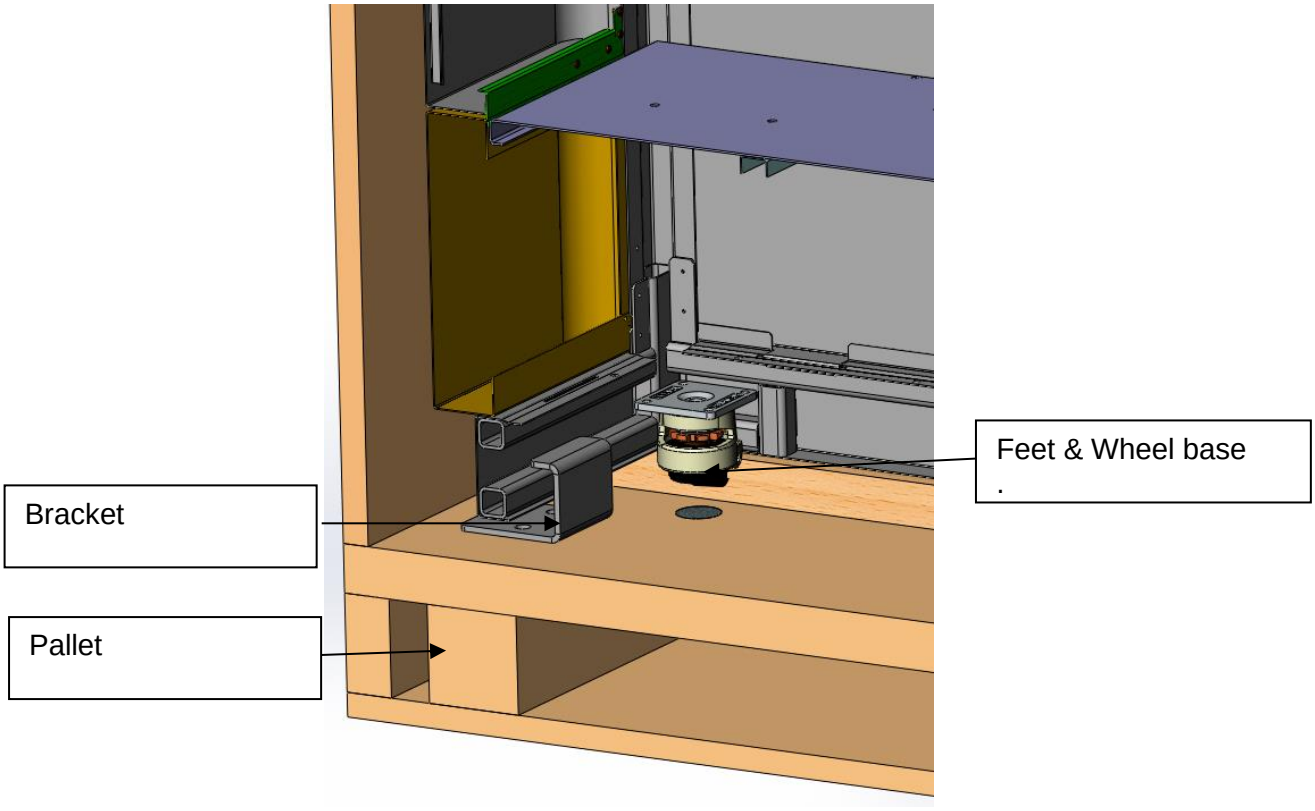


Figure 54 – PlazMax Sterilizer Hooking Bracket to Pallet

5. Before placing the machine on the ground check if the wheels are down and the feet are up. (See Figure 58).

Warning!
Do not tilt the sterilizer more than 45 degrees as it may result in injury to personnel and cause damage to equipment. The sterilizer shall be placed on a stable surface.

6. Once on the installation site, rotate the toothed wheel in the base of each one of the wheels counter-clockwise, to lift the wheels and leave the machine on the feet. Make sure that the sterilizer is levelled. (See Figure 57 and Figure 58).

Figure 55 – foot down

Figure 56 – Foot up and wheel down

Note: The feet are made of anti-skidding material.

11.2 Installation requirements

Installation plan:
The device must be installed in a socket that is connected to a 4 -Pole circuite breaker. The 4- Pole circuite breaker must be located in a reachable position and it must be marked as the disconnecting device for the equipment

PlazMax sterilizer must be installed according to the plans on **ANNEX 1** on this manual by a ttrained technichian.

Installation Qualification and Operational Qualification Checklist is on **ANNEX 2**.

11.3 Moving PlazMax Sterilizer

The levelling wheels makes it is very easy to move the sterilizer to its allocated destine place. The sterilizer must be installed first and then levelled.

The machine can easily be moved on its own base wheels to its final position.

When the sterilizer is at its allocated installation site, lower the sterilizer four feet, following the instructions of this Chapter.

Note:
Now that the sterilizer is leveled and at its final location, you can proceed with the installation of PlazMax operating instructions in chapter 11.

12. FAQ (Frequently Asked Questions)

This chapter provides the most frequently asked questions and answers concerning the PlazMax sterilizer

Can *I sterilize flexible endoscopes?*

Yes, but they must not be rolled inside the involucres and they must have the lumen ends open, according to the endoscope manufacturer recommendations (please refer to this manual).

Can I use common paper in the PlazMax?

Yes, but it must be in very small amounts, for example, very small labels, can be used, but it is not recommended because that limits the capacity of loading.
The common paper absorbs the sterilizing agent removing it from the chamber, especially near the labels, and will result in more sterilizing agent waste.

What kind of material should I use for the packaging?

For the packaging, you should use polypropylene or Tyvek, or other materials not containing cellulose.

You should use packaging methods prepared for this sterilization method, recommended by Tuttnauer.

What kind of indicators should I use?

You should use FDA approved VH_2O_2 biological indicators (BI) with a population of X* 10^6 *Geobacillus Stearothermophilus* & chemical indicators (CI). The BI is a container like the BI used in the steam sterilizers, but has the particularity of the *Geobacillus Stearothermophilus* being inoculated on a stainless steel disc.
Tuttnauer developed a FDA approved BI & CI for this use. The Bio-indicators carry a population of X*10^6 CFU which has been developed with the purpose to be placed inside a lumen PCD. The chemical indicator change the color in contact with vaporised Hydrogen Peroxide for.

Please contact Tuttnauer representative for further information and ask for Tuttnauers' Bio-Indicator CAT# WTL198-0059 & Chemical indicators CAT# PLZ198-0002

How can I validate the sterilizer?

Our Company’s service department has qualified personnel to validate the sterilizers.
The validation kit is a small equipment which can be mounted near the PlazMax. It is independent of the automation and validates independently all the cycle data, informing the operator if the cycle passed according to the manufacturer graphs and a complete executed cycle report is supplied.

How can I interpret the sterilizer report?

At the end of the cycle, the PlazMax prints out a report of the various cycle phases and the time spent in each phase. It records any fail during the cycle and a blank space is available so the operator can sign and validate the report.
If necessary, other print outs can be done by accessing saved data. In each report are included the cycle file name saved in the system (that will be year, month, day and cycle number processed in this particular day - e.g. 20070312001). This operation is only possible if no cycle is running at the moment.

Basically, the report informs that all the phases have been passed.

In case of phase failure, it will appear in the report. The report indicates if the cycle passed or not. The sterilizing agent refilling can also be recorded.

What is the danger level of this sterilizer?

The PlazMax **does not emit toxic gas. (Sterilizing agent is corrosive, but not toxic).**

What precautions should be considered on cleaning the PlazMax?

To clean the sterilizer chamber you must turn on the sterilizer and select one of the cycles, so the doors can be unlooked. Turn off the sterilizer until the cleaning is finished.
The sterilization chamber can be cleaned with a wet cloth and water. The water should not be placed directly into the chamber because it damages the vacuum pump. After the cleaning, the door should be kept open until the chamber is completely dry
Periodically, (each 6 or 8 months), the chamber exhaustion filter must be cleaned or replaced**.**
The chamber must be cleaned every week due to natural deposit of dust.
The outside surfaces can be cleaned with appropriated cleaners. In our PlazMax range of products we have the suitable cleaners.
All the cleaning actions must be done at the beginning of the day when the machine is cold.

Can I burn myself when operating the PlazMax?

No.
The chamber and doors temperature is around 55ºC which cannot lead to accidental burnings. Nevertheless, if you have a sensitive skin, you should use gloves when unloading the chamber at the end of the cycle as the material should still be hot.

How should I clean the touch screen?

First you have to turn the machine “OFF” and then you can clean it with a wet cloth or with some special product for cleaning PC screens.

Is there any risk of explosion?

There is no danger. The cycle runs in vacuum.

PlazMax is programmed to report any irregular situation

The equipment was developed with high concern about the personnel safety. When refilling the sterilizing agent, it is not possible to touch it directly.
If you have any question, please contact the production and manufacturing department for further information.

Who should do the PlazMax’s maintenance?

The maintenance should only be done by the manufacturer and recommended companies with a PlazMax training.
The PlazMax may have a tele maintenance service. This service is activated according to the agreement made between the manufacturer and the customer.
It’s possible, using an Ethernet connection, to verify from our facilities the entire PlazMax components and show all the information in the sterilizer screen and all the steps that should be followed. By these means, any qualified technician can replace the damaged parts that were recommended by the machine’s report.

Can I use some other kind of sterilizing agent in the PlazMax?

No.
You cannot use **any** product which is not recommended for use with this equipment.
PlazMax has been studied and developed together with the sterilizing agent PlazMax.
It is not possible to introduce any other kind of sterilizing agent in the sterilizer tank because the PlazMax has a calculation system that detects if any non-recommended sterilizing agent has been introduced.
Any attempt to refill manually the PlazMax tank will be detected and PlazMax will be blocked after some cycles until the authorized technician intervention.

Tuttnauer Company will not take responsibility for the use of other Sterilizing Agent that is not PlazMax, or for the resulting damages.

What should I do if there is an average?

You have to read and note any information given by the machine.
Refer to the user manual for any help. If you do not find the needed information, you should contact the manufacturer or the authorized agent.
Together with your user manual you will get a Non Conformity record sheet. Please record on it all verified malfunctions, breakdowns or strange situations. These must be reported to your PlazMax supplier or manufacturer. This information is very important and will support us on constant improvement of PlazMax equipment, and for customer's satisfaction.
You have to read and note any information given by the machine.
Refer to the user manual for any help. If you do not find the needed information, you should contact the manufacturer or the authorized agent.

Together with your user manual you will get a Non Conformity record sheet. Please record on it all verified malfunctions, breakdowns or strange situations. These must be reported to your PlazMax supplier or manufacturer. This information is very important and will support us on constant improvement of PlazMax equipment, and for customer's satisfaction.

How can I buy PlazMax products?

You can buy directly from the manufacturer, or from the exclusive distributors.

Who has developed the PlazMax?

PlazMax has been developed by a large and young team. The basis was the new method of using hydrogen peroxide as a sterilizing agent, which patent process is in registration phase. This team tried hard to make the machine performing, ergonomic, safe and also attractive.

Soon, you will find in our website the names of the elements that made this project possible.

If you have any opinion about the PlazMax, do not hesitate in sending it to the manufacturer and we will be pleased to take it in consideration.
Our customer's opinion is very important to us.

What is the best place to install the PlazMax?

The PlazMax should be placed in any ventilated room as the unit releases heat.
Furthermore, concerning the two doors units, it must be mounted in sanitary barrier zones, like CSSD.

The PlazMax does not require any specific connection it only requires an electrical power supply.

The PlazMax includes, as an option, stainless steel sections to fix the sterilizer to the wall.

How does the cycle run?

The sterilizer has been studied in order to have fast cycles and even to be able to sterilize lumen.

Basically, in the chamber, the cycle runs in high vacuum which is attained thanks to the most innovative vacuum technology and a double stage vacuum pump.

After an initial vacuum, air is injected into the chamber by a HEPA filter in order to remove any possible humidity from the instruments to be sterilized and to lead it to the drain trap by means of the vacuum system.

After the second vacuum phase, the sterilizing agent is injected into the chamber and the diffusion phase begins. After the Diffusion phase comes the exhaustion and the sterilizing agent burning (plasma process) phases.

After the burning phase (plasma), a chamber ventilation phase follows and the cycle is concluded. Finally a report is printed out.

13. SPARE PARTS LIST

Part No.	Description
ARM100-0006	Steam Trap 1/4 TKK41
ARM100-0039	Seal, Sanitary, 1"", EPDM, 40MP-E, 316L
ARM100-0040	Clamp, Single Pin, Heavy Duty, 1", Sanitary, 13LAH, Wellgrow
BOL191-0020	Pan Head Machine Screw, Phillips, M3x10, St. St. A2, DIN7985
BOL191-0140	Pan Head Machine Screw, Phillips, M4x12, St. St. A2, DIN7985
BOL191-0143	Pan Head Machine Screw, Phillips, M5x35, St. St. A2, DIN7985
BOL194-0330	Blind Rivets 4x10, Head 7.5 mm, Aluminium, DIN7337 A
CTP201-0218	Relay, Timer, Solid-state
CTP201-0271	Relay Socket
CTP201-0272	Miniature PCB relay, coil 24VDC, contact 250VAC, 8A, 2 pole
CTP201-0364	5-Port Unmanaged Industrial Enhernet Switch
ELC456-0126	Keypad Panel for Horizontal-Assy.
CPN064-0031	Keyboard, EZ 9"&11", EZ/3870-D & Hor.-D
CTP200-0138	Board, I/O Extension,
CTP200-0140	Board, Main Control
ELC258-0035	Shield, Control Unit Boards
ELE039-0048	Terminal, male, brass, w/o isolation, PC1L18704LR, K.S. Terminals
NUT192-0217	Hex Nut, 8-32UNC, Brass, Plain
NUT193-0291	Serrated Lock Washer External Teeth,M4(5/32),Steel,Zinc Pl.,DIN6798A
POL067-0048	Window, Clear for Control Sys. Screen
THE002-0061	Full Color graphical display 3.5"
THE002-0121	Industrial Computer with touch screen - UTC-307, 7" -Windows 10
WIR040-0180	Cord, extension, USB 2.0 type A - panel F to M, 35 cm
ELE032-0141	Plazma system braid
ELE035-0012	Switch, Panel, Rocker, 2-pole, ON-OFF, 250VAC, 16A
ELE039-1052	Female Connector,2 pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1053	Female Connector ,3 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1054	Female Connector,4 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1055	Female Connector, 6 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1057	Female Connector,10 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE034-0010	Circuit Breaker, 1ph, 10A
ELE034-0011	Circuit Breaker, 1ph, 2A
ELE034-0012	Circuit Breaker, 1ph, 16A
ELE034-0014	Circuit Breaker, 1ph, 20A
ELE034-0018	Circuit Breaker, 1ph, 6A, FAZ-C6
ELE034-0069	Contactor, 24VDC/ 20A, 2NO, 2-pole
ELE035-0129	PSU,DIN Rail,24VDC,4.2A,100W
ELE035-0136	PSU,DIN Rail,12VDC,4.5A,54W
ELE035-0170	Fuse, 5x20mm, Glass tube, 250V, 5A, SB
ELE035-0192	BUZZER, PIEZO, CONTINUOUS, 85dB@30cm/3-28VDC
ELE035-0192	BUZZER, PIEZO, CONTINUOUS, 85dB@30cm/3-28VDC
ELE035-0217	PSU,DIN Rail,24VDC,4.2A,100W
GAS082-0043	Gasket, EPDM, O-Ring, 7.8x1.8
GAS082-0080	Gasket, Silicon, for Tri Clamp Cap 1 1/2"
NUT192-0192	Hex Nut, M5X4, Stainless Steel A2, DIN934
NUT193-0271	Plain Washer Without Chamfer, M5 (3/16), Stainless Steel A2, DIN125
NUT193-0325	Spring Lock Washers With Square Ends, M5 (3/16), St. St. A2,DIN127B

PLZ000-0052	Vaporizer, Plazmax - Welding
PLZ000-0212	Linear actuator, 24VDC, HG, C1, HS 650mm
PLZ000-0224	Coil 3W,24VDC
PLZ000-0225	Connector CNE 24V
PLZ000-0289	Hex Bushing 1/8" BSP to M5
PLZ100-0016	Valve 3-way G80 2WNC DC 1 St.St. PTFE
PLZ100-0017	Valve 2-way G80 2WNC DC 1mm St.St. PTFE
PLZ239-0005	EM-324C, DC-MOTOR Controller 12-24V 3/4A
PNE100-0072	Hex Nipple, Equal, Pipe Size 1/8"NPTx1/8"NPT , 316 St. St.
THE039-0062	Ground Terminal, Feed-Through, 2-Conductor, 6 mm², Green/Yellow
THE039-0120	Push-In Type Jumpers Bar 2-Pole Nominal
WIR040-0215	Cord, extension, RJ45 connector, 1.0 M
ELE032-0152	Plazma Command Braid
ELE035-0012	Switch, Panel, Rocker, 2-pole, ON-OFF, 250VAC, 16A
ELE039-1052	Female Connector,2 pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1053	Female Connector ,3 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1054	Female Connector,4 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1055	Female Connector, 6 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1057	Female Connector,10 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE034-0010	Circuit Breaker, 1ph, 10A
ELE034-0011	Circuit Breaker, 1ph, 2A
ELE034-0012	Circuit Breaker, 1ph, 16A
ELE034-0014	Circuit Breaker, 1ph, 20A
ELE034-0018	Circuit Breaker, 1ph, 6A, FAZ-C6
ELE034-0069	Contactor, 24VDC/ 20A, 2NO, 2-pole
ELE035-0129	PSU,DIN Rail,24VDC,4.2A,100W
ELE035-0136	PSU,DIN Rail,12VDC,4.5A,54W
ELE035-0170	Fuse, 5x20mm, Glass tube, 250V, 5A, SB
ELE035-0192	BUZZER, PIEZO, CONTINUOUS, 85dB@30cm/3-28VDC
ELE035-0192	BUZZER, PIEZO, CONTINUOUS, 85dB@30cm/3-28VDC
ELE035-0217	PSU,DIN Rail,24VDC,4.2A,100W
NUT192-0192	Hex Nut, M5X4, Stainless Steel A2, DIN934
NUT193-0271	Plain Washer Without Chamfer, M5 (3/16), Stainless Steel A2, DIN125
NUT193-0325	Spring Lock Washers With Square Ends, M5 (3/16), St. St. A2,DIN127B
PLZ239-0005	EM-324C, DC-MOTOR Controller 12-24V 3/4A
THE039-0062	Ground Terminal, Feed-Through, 2-Conductor, 6 mm², Green/Yellow
THE039-0120	Push-In Type Jumpers Bar 2-Pole Nominal
WIR040-0215	Cord, extension, RJ45 connector, 1.0 M
ELE032-0152	Plazma Command Braid
ELE035-0012	Switch, Panel, Rocker, 2-pole, ON-OFF, 250VAC, 16A
ELE039-1052	Female Connector,2 pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1059	Male Connector,10 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1061	Male Connector,6 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE032-0173	Plazma Drawer Braid
ELE039-1052	Female Connector,2 pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1057	Female Connector,10 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1052	Female Connector,2 pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1056	Female Connector,8 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1058	Male Connector,8 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1060	Male Connector,4 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1061	Male Connector,6 Pole,5mm Pin Spacing with Cage Clamp Connection

ELE039-1062	Male Connector,2 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1063	Male Connector,3 Pole,5mm Pin Spacing with Cage Clamp Connection
PLZ000-0226	Air switch Latching 6871-ALT
PLZ000-0227	Piston for electric drawer, 120mm, 18.5mm/s, 12/24VDC
PLZ000-0228	Piston for electric drawer, 200mm, 18.5mm/s, 12/24VDC
PLZ040-0001	Ignition Cable with Connector, HI-TEMP, Silicone, C-J, Plazmax
PLZ040-0002	Vertical door spiral cable
THE003-0046	Sensor, Temperature,PT100,5x70,SiliconeCable 2m,3 wire,DIN43760 cl.A
THE003-0047	Sensor, Temperature,PT100,7x30,Teflon Cable 2m,3 wire,DIN43760 cl.A
THE005-0003	Thermostat, Safety, 180C, TY95/AC, Campini
BOL191-0020	Pan Head Machine Screw, Phillips, M3x10, St. St. A2, DIN7985
BOL191-0070	Flat Head Machine Screw, Phillips, M4x10, St. St. A2, DIN965
BOL191-0158	Pan Head Machine Screw, Phillips, M4x8, St. St. A2, DIN7985
BOL191-0245	Pan Head Machine Screw, Phillips, M5x16, St. St. A2, DIN7985
ELE036-0022	Limit Switch with cable, Roller Plunger, Parallel, SPDT, 6A 250VAC
GAS086-0016	Tube, Teflon, 4x6mm
NUT193-0269	Plain Washer Without Chamfer, M6, Stainless Steel A2, DIN125
NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
NUT193-0325	Spring Lock Washers With Square Ends, M5 (3/16), St. St. A2,DIN127B
PLZ000-0165	Transducer, Pressure, 1 BAR, 4-20mA.
PLZ000-0166	Pressure Transmitter Low Pressure 0-100mBAR
PLZ000-0188	Dosing Pump MP2-B 20L/H, (Silicone Pipe) Plazmax
PLZ000-0189	Dosing Pump MP2-B 12L/H, (Silicone Pipe) Plazmax
PLZ000-0291	Vacuum Pump, Two stage rotary vane, typ TRIVAC D16B - Kit
PLZ000-0133	Mechanical oil filter OF 4-25
PLZ008-0007	Heating Element, Center - CALESCO, 600W for P50 Chamber
PLZ008-0008	Heating Element, Front - CALESCO, 600W for P50 Chamber
PLZ082-0003	Silicone door gasket for PlazMax 50
PLZ082-0005	Silicone door gasket for PlazMax 110, 160
PLZ100-0012	Fitting, T, 6 Tube Dia. to 4
BOL191-0070	Flat Head Machine Screw, Phillips, M4x10, St. St. A2, DIN965
NUT193-0263	Plain Washer Without Chamfer, M6, Steel, Zinc Plated, DIN125-1A
NUT193-0317	Spring Lock Washers With Square Ends, 1/4, St. St. A2, DIN127B
SOL026-0045	Coil, Solenoid, 24VDC, 10W
SOL026-0087	.Solenoid valve, 1/4" BSP, NC, St. St
PLZ000-0104	Bushing Clamp for Transducer Joint - Welding
TUB152-0008	Round Tube 1" (25.04mm)x1.6 Fully annealed,304 St.St.,ASTM–A213
CMT196-0001	Bushing, water level electrode
NUT193-0317	Spring Lock Washers With Square Ends, 1/4, St. St. A2, DIN127B
BOL191-0158	Pan Head Machine Screw, Phillips, M4x8, St. St. A2, DIN7985
NUT193-0270	Plain Washer Without Chamfer, M4 (5/32), Stainless Steel A2, DIN125
NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
NUT193-0347	Plain Washer, 1.2X4.2X16, Stainless Steel A2
SKR203-0011	Shock Absorber, PLAZMA
BOL191-0140	Pan Head Machine Screw, Phillips, M4x12, St. St. A2, DIN7985
BOL191-0158	Pan Head Machine Screw, Phillips, M4x8, St. St. A2, DIN7985
BOL191-0245	Pan Head Machine Screw, Phillips, M5x16, St. St. A2, DIN7985
CMT240-0037	Multipurpose Valve Microswitches Spacer
ELE036-0012	Limit Switch, Snap-Action,Lever,Light,SPDT,21A/250VAC
ELE036-0036	Limit Switch,Snap-Action,Formed Lever,Light,SPDT,10A,125/250VAC
NUT192-0221	Nylon Insert Lock Hex Nut, M5, Stainless Steel A2, DIN985

NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
NUT193-0325	Spring Lock Washers With Square Ends, M5 (3/16), St. St. A2,DIN127B
PLZ100-0001	Elbow 90° Union , 6 Tube Dia.-Viton
PLZ239-0002	Card, RFID, 13.56Mhz HF02 Reader - 1 Antenna Channel, LogiTag
PLZ100-0008	Fitting, Push-in, Straight, M5 Male to 6mm PVC Tube With Nut St.St.
CTP201-0309	Fan, 120x120x38,24VDC,Ball
ELE036-0022	Limit Switch with cable, Roller Plunger, Parallel, SPDT, 6A 250VAC
ELE036-0034	Limit Switch with cable,Snap-Action,SPDT,6A 250VAC
LOK692-0039	Pin, Cotter, 2.0x16 mm
NUT193-0317	Spring Lock Washers With Square Ends, 1/4, St. St. A2, DIN127B
NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
NUT193-0325	Spring Lock Washers With Square Ends, M5 (3/16), St. St. A2,DIN127B
NUT193-0347	Plain Washer, 1.2X4.2X16, Stainless Steel A2
NUT193-0270	Plain Washer Without Chamfer, M4 (5/32), Stainless Steel A2, DIN125
NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
SPR177-0033	Spring, compression, door 5075-D
PLZ082-0003	Silicone door gasket for PlazMax 50
NUT192-0191	Hex Nut, M4X3.2, Stainless Steel A2, DIN934
NUT193-0291	Serrated Lock Washer External Teeth,M4(5/32),Steel,Zinc Pl.,DIN6798A
NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
PLZ000-0220	PVC Switch Foot or hand activated 6439-BLACK1
POL065-0082	Support, printer door, Hor. , 38XX-D , 50XX-D
SEA095-0015	SILICONE GLUE- ELESTOSIL E41(TUBES)
THE002-0066	Thermal paper for CUSTOM PLUSII printer roll 57mm d=50mm
THE002-0121	Industrial Computer with touch screen - UTC-307, 7" -Windows 10
HAN071-0009	Service door lock, Push to Close Latches - Slide Latch, Flush Style
PLZ175-0005	Odour filter housing (stainless steel)
PLZ175-0009	Molecular sieve refill for odour filter
ELE039-1059	Male Connector,10 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1061	Male Connector,6 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1052	Female Connector,2 pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1057	Female Connector,10 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1052	Female Connector,2 pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1056	Female Connector,8 Pole,5mm Pin Spacing with Coding Fingers Closed
ELE039-1058	Male Connector,8 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1060	Male Connector,4 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1061	Male Connector,6 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1062	Male Connector,2 Pole,5mm Pin Spacing with Cage Clamp Connection
ELE039-1063	Male Connector,3 Pole,5mm Pin Spacing with Cage Clamp Connection
PLZ000-0224	Coil 3W,24VDC
PLZ000-0226	Air switch Latching 6871-ALT
PLZ000-0265	Vacuum Pump, Two stage rotary vane, typ TRIVAC D25B
PLZ000-0290	Vacuum Pump, Two stage rotary vane, typ TRIVAC D16B
PLZ040-0001	Ignition Cable with Connector, HI-TEMP, Silicone, C-J, Plazmax
PLZ170-0003	Electric Actuator 24VACDCx6s + Valve, Manual, 3-Piece, Ball, 1"TC
THE005-0003	Thermostat, Safety, 180C, TY95/AC, Campini
BOL191-0020	Pan Head Machine Screw, Phillips, M3x10, St. St. A2, DIN7985
BOL191-0070	Flat Head Machine Screw, Phillips, M4x10, St. St. A2, DIN965
BOL191-0158	Pan Head Machine Screw, Phillips, M4x8, St. St. A2, DIN7985
BOL191-0245	Pan Head Machine Screw, Phillips, M5x16, St. St. A2, DIN7985
ELE036-0022	Limit Switch with cable, Roller Plunger, Parallel, SPDT, 6A 250VAC

GAS086-0016	Tube, Teflon, 4x6mm
NUT193-0269	Plain Washer Without Chamfer, M6, Stainless Steel A2, DIN125
NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
NUT193-0325	Spring Lock Washers With Square Ends, M5 (3/16), St. St. A2,DIN127B
PLZ000-0165	Transducer, Pressure, 1 BAR, 4-20mA.
PLZ000-0188	Dosing Pump MP2-B 20L/H, (Silicone Pipe) Plazmax
PLZ000-0189	Dosing Pump MP2-B 12L/H, (Silicone Pipe) Plazmax
PLZ000-0133	Mechanical oil filter OF 4-25
PLZ000-0309	Bracket + Spring for Vertical Door Lift
PLZ000-0326	Vacuum Pump, Trivac D25B - 3PH, 208V, UL -KIT
PLZ000-0328	Vacuum Pump, Trivac D16B - 3PH, 208V, UL -KIT
PLZ008-0007	Heating Element, Center - CALESCO, 600W for P50 Chamber
PLZ008-0008	Heating Element, Front - CALESCO, 600W for P50 Chamber
PLZ008-0016	Heating Element, 425W, Vaporizer
PLZ008-0018	Heater kit foam for 3 heater P110 Chamber
PLZ008-0019	Heating Element-3 heater kit for P110 Chamber 600W 230V
PLZ008-0020	Heater kit foam for 3 heater P50 Chamber
PLZ008-0021	Heating Element-3 heater kit for P50 Chamber 400W 230V
PLZ008-0022	Heater kit foam for 4 heater P160 Chamber
PLZ008-0023	Heating Element-4 heater kit for P160 Chamber 400W 230V
PLZ008-0024	Heater foam for Door -Plazma
PLZ008-0025	Heating Element-for door Plazma
PLZ082-0003	Silicone door gasket for PlazMax 50
PLZ100-0012	Fitting, T, 6 Tube Dia. to 4
BOL191-0070	Flat Head Machine Screw, Phillips, M4x10, St. St. A2, DIN965
NUT193-0263	Plain Washer Without Chamfer, M6, Steel, Zinc Plated, DIN125-1A
NUT193-0317	Spring Lock Washers With Square Ends, 1/4, St. St. A2, DIN127B
SOL026-0045	Coil, Solenoid, 24VDC, 10W
PLZ000-0104	Bushing Clamp for Transducer Joint - Welding
TUB152-0008	Round Tube 1" (25.04mm)x1.6 Fully annealed,304 St.St.,ASTM–A213
CMT196-0001	Bushing, water level electrode
NUT193-0317	Spring Lock Washers With Square Ends, 1/4, St. St. A2, DIN127B
BOL191-0158	Pan Head Machine Screw, Phillips, M4x8, St. St. A2, DIN7985
NUT193-0270	Plain Washer Without Chamfer, M4 (5/32), Stainless Steel A2, DIN125
NUT193-0323	Spring Lock Washers With Square Ends, M4 (5/32), St. St. A2,DIN127B
NUT193-0347	Plain Washer, 1.2X4.2X16, Stainless Steel A2
SKR203-0011	Shock Absorber, PLAZMA
BOL191-0140	Pan Head Machine Screw, Phillips, M4x12, St. St. A2, DIN7985
BOL191-0158	Pan Head Machine Screw, Phillips, M4x8, St. St. A2, DIN7985
BOL191-0245	Pan Head Machine Screw, Phillips, M5x16, St. St. A2, DIN7985
CMT240-0037	Multipurpose Valve Microswitches Spacer

SPARE PARTS LIST ELECTRICAL CONTROL BOX

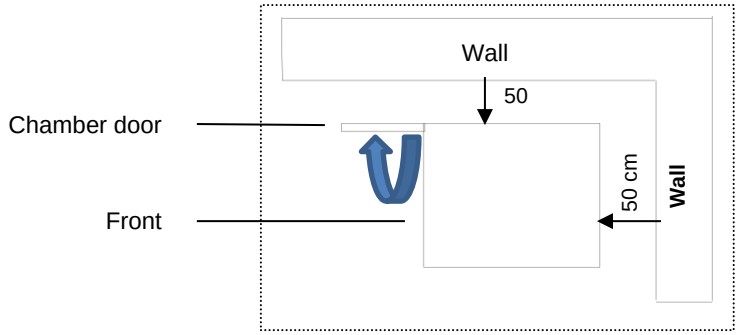
Part No.	Description
CTP201-0218	Relay, Timer, Solid-state
CTP201-0435	Industrial 5-port Mini Type Unmanaged Ethernet Switch, Stratix 2000
CTP201-0436	Relay, Overload, 140MP-A3E, 6.3A
ELC456-0126	.Keypad Panel for Bacsoft Horizontal-Assy
ELE032-0141	Plazma system Electric braids

ELE032-0201	Plazma system Electric extension braids
ELE034-0069	Contactor, 24VDC/ 20A, 2NO, 2-pole
ELE034-0076	Circuit Breaker, 3ph, 20A
ELE034-0077	Circuit Breaker, 2 pole, 10A
ELE034-0078	Circuit Breaker, 1 pole, 10A
ELE034-0079	Circuit Breaker, 1 pole, 2A
ELE034-0080	Contactor, 100-K12 24VDC
ELE035-0170	Fuse, 5x20mm, Glass tube, 250V, 5A, SB
ELE035-0192	BUZZER, PIEZO, CONTINUOUS, 85dB@30cm/3-28VDC
ELE035-0244	PSU,DIN Rail,24VDC,10A
CMT456-0022	DIN RAIL, Length 100 mm
PLZ000-0175	Electrical Box - PLAZMAX
PLZ239-0005	EM-324C DC-MOTOR CONTROLLER 12-24V 3/4A
WIR040-0215	Cord, extension, RJ45 connector, 1.0 M

14. ANNEX 1: INSTALLATION PLANS

Installation Plans

Single Door Model



Single door sterilizer – view from the

At first installation run a penetration test with Biological Indicator.

15. ANNEX 2: PREVENTIVE MAINTENANCE PLAN

Components that should be verified/replaced during the maintenance:

LEVEL 1 MAINTENANCE (Every 6 months or after 750 Cycles)

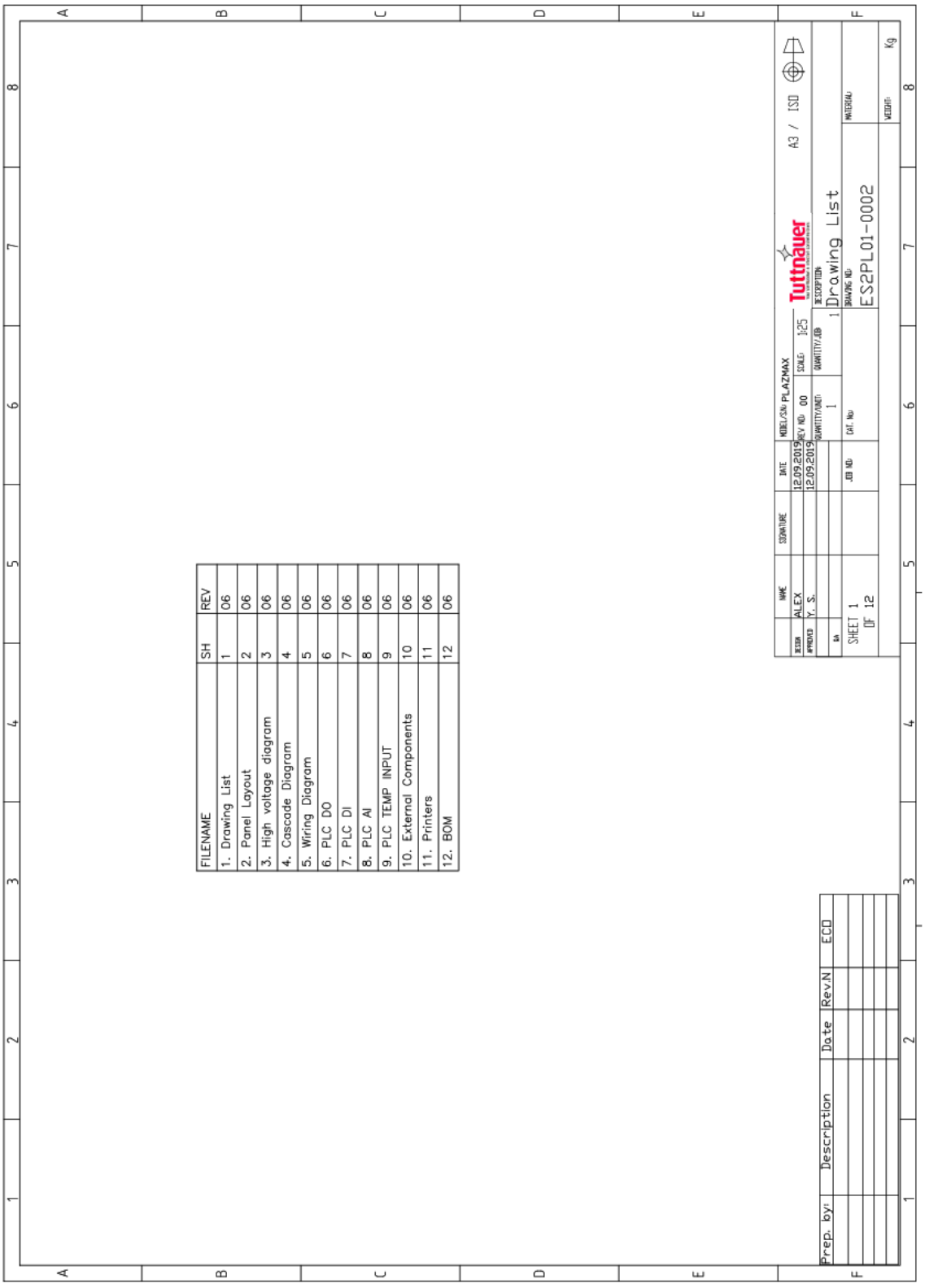
LEVEL 2 MAINTENANCE (Every year or after 1500 Cycles)

Other actions to take:

REFER TO THE TABLES IN CHAPTER 9

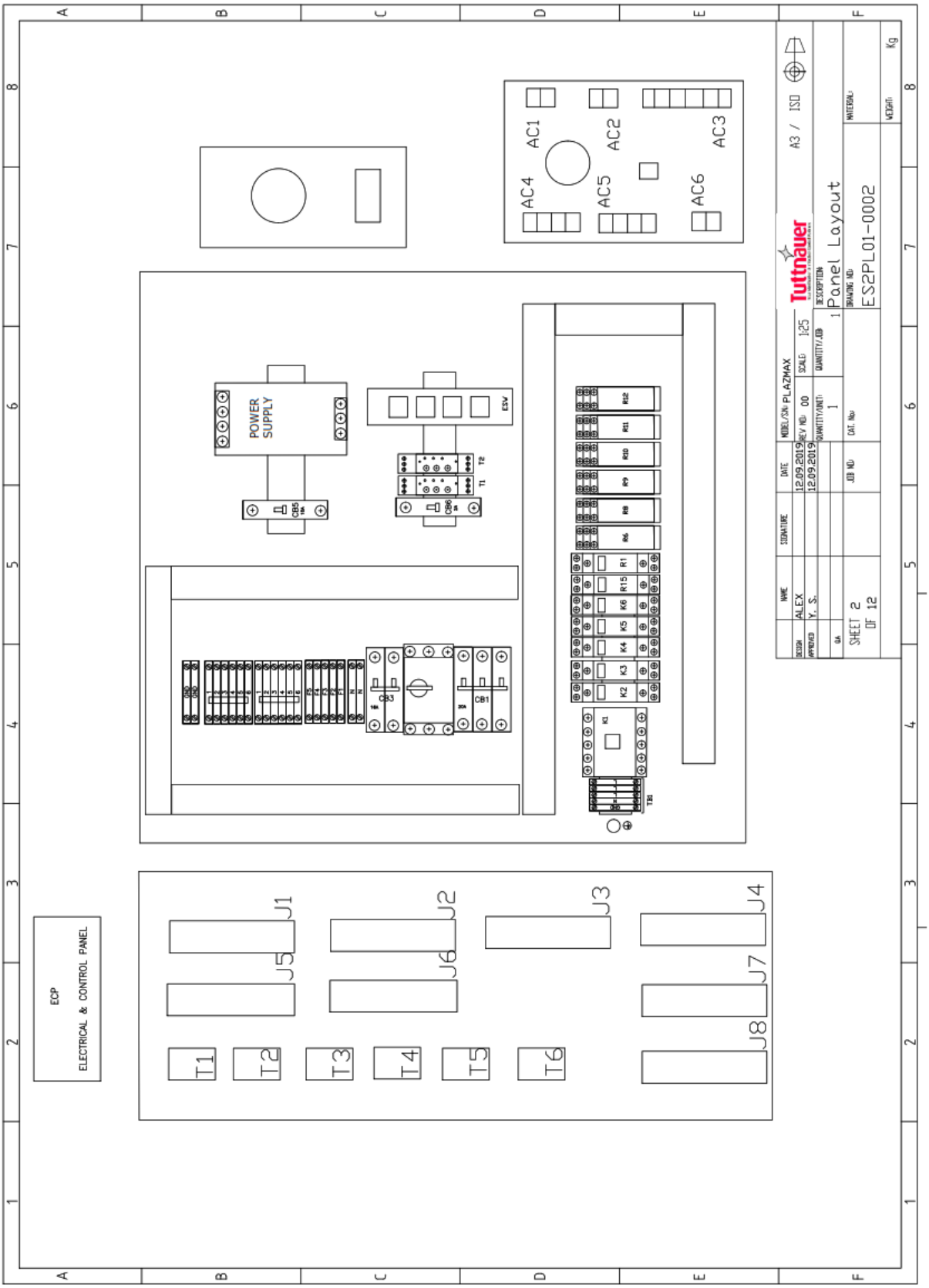
16. Appendix 1: Electrical Control Drawings

1. DRAWING LIST

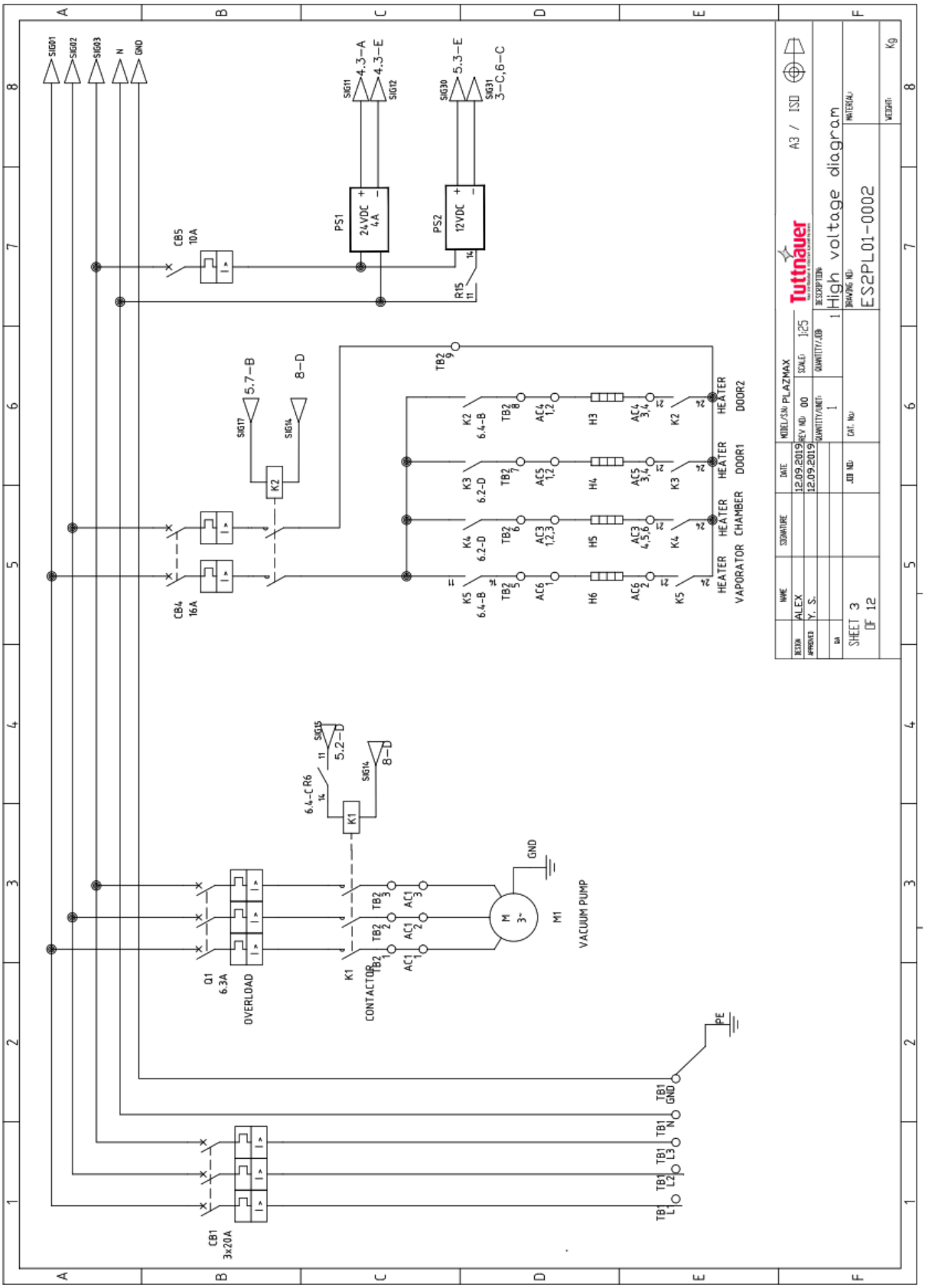


FILENAME	SH	REV
1. Drawing List	1	06
2. Panel Layout	2	06
3. High voltage diagram	3	06
4. Cascade Diagram	4	06
5. Wiring Diagram	5	06
6. PLC DO	6	06
7. PLC DI	7	06
8. PLC AI	8	06
9. PLC TEMP INPUT	9	06
10. External Components	10	06
11. Printers	11	06
12. BOM	12	06

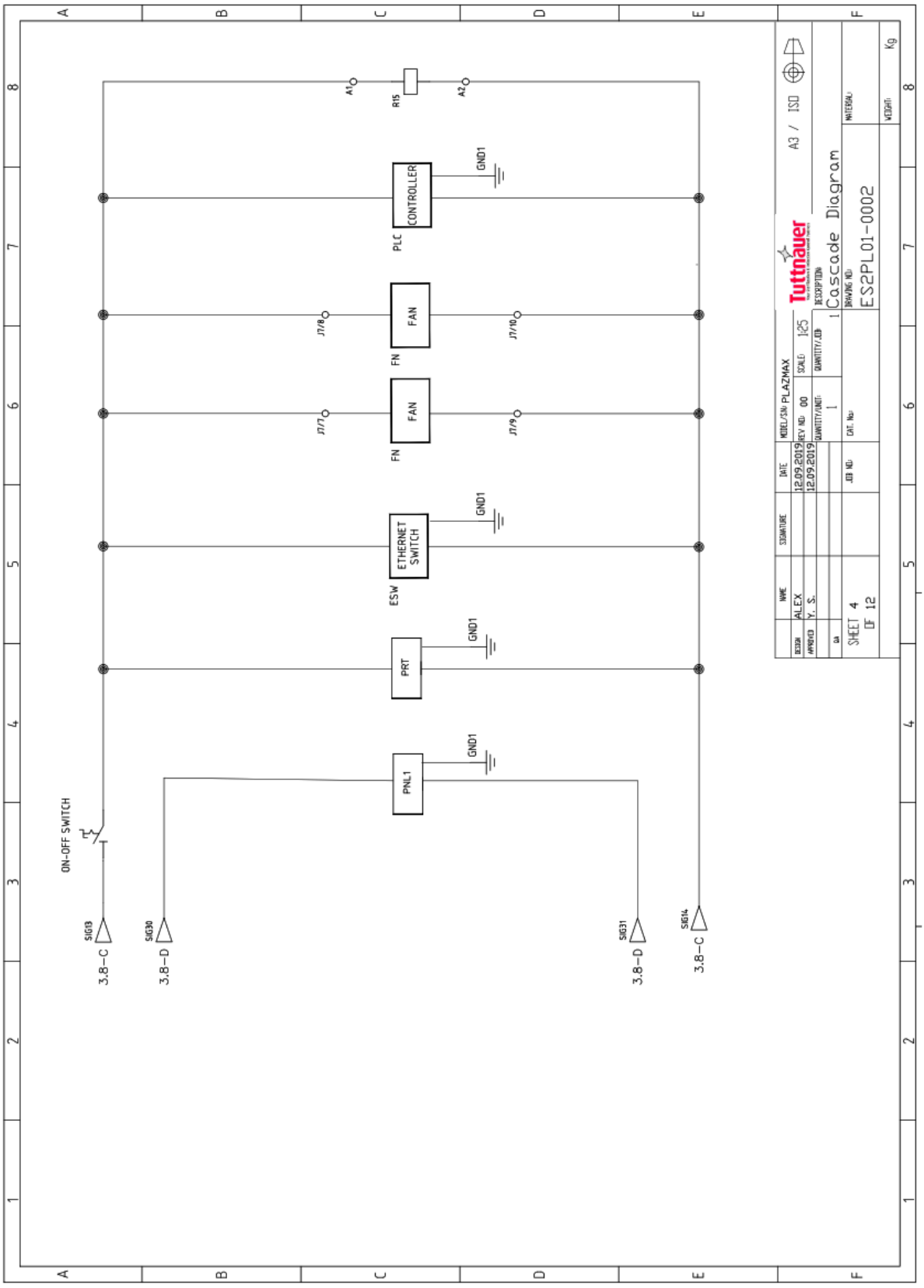
2. PANEL LAYOUT



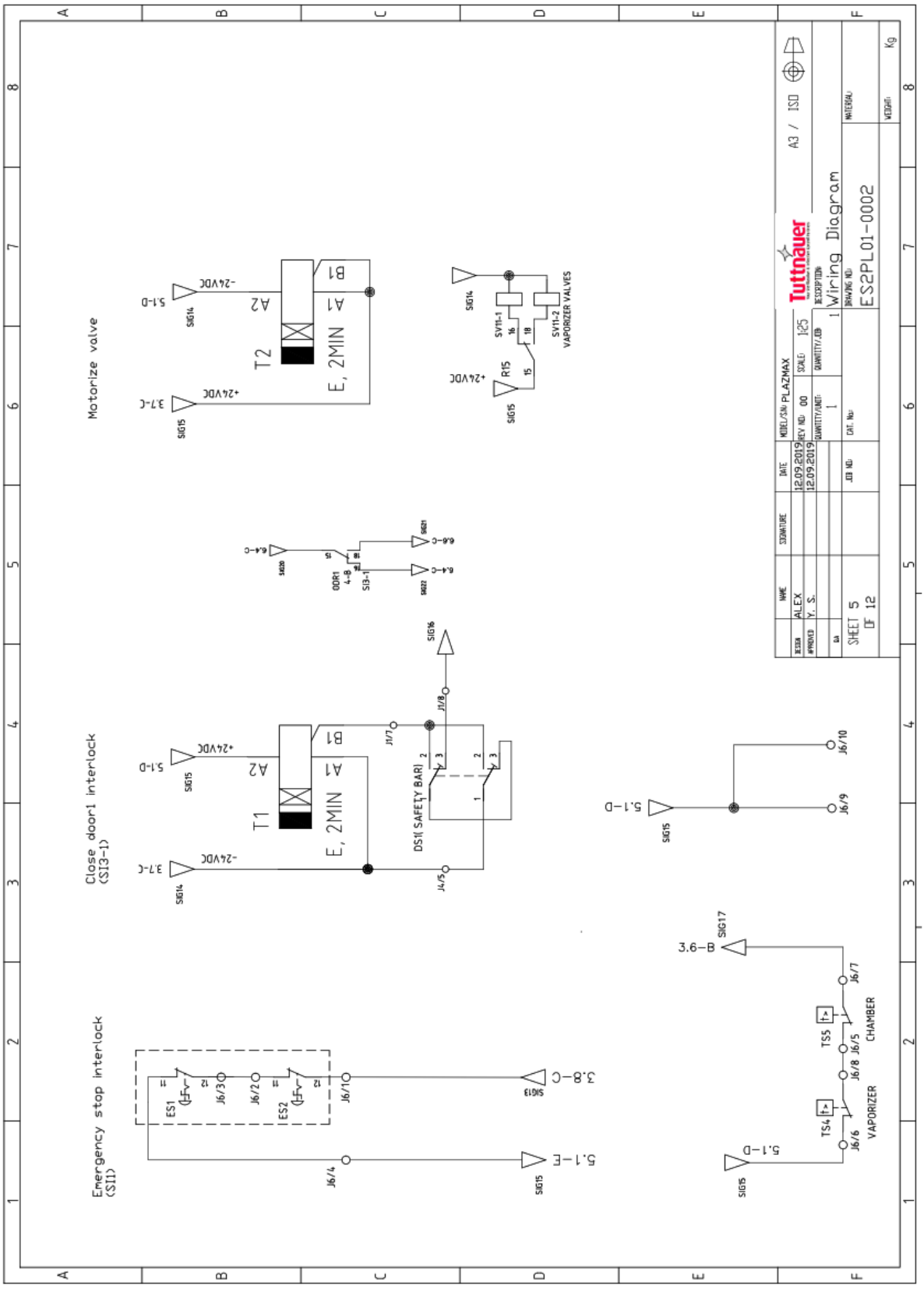
3. HIGH VOLTAGE DIAGRAM



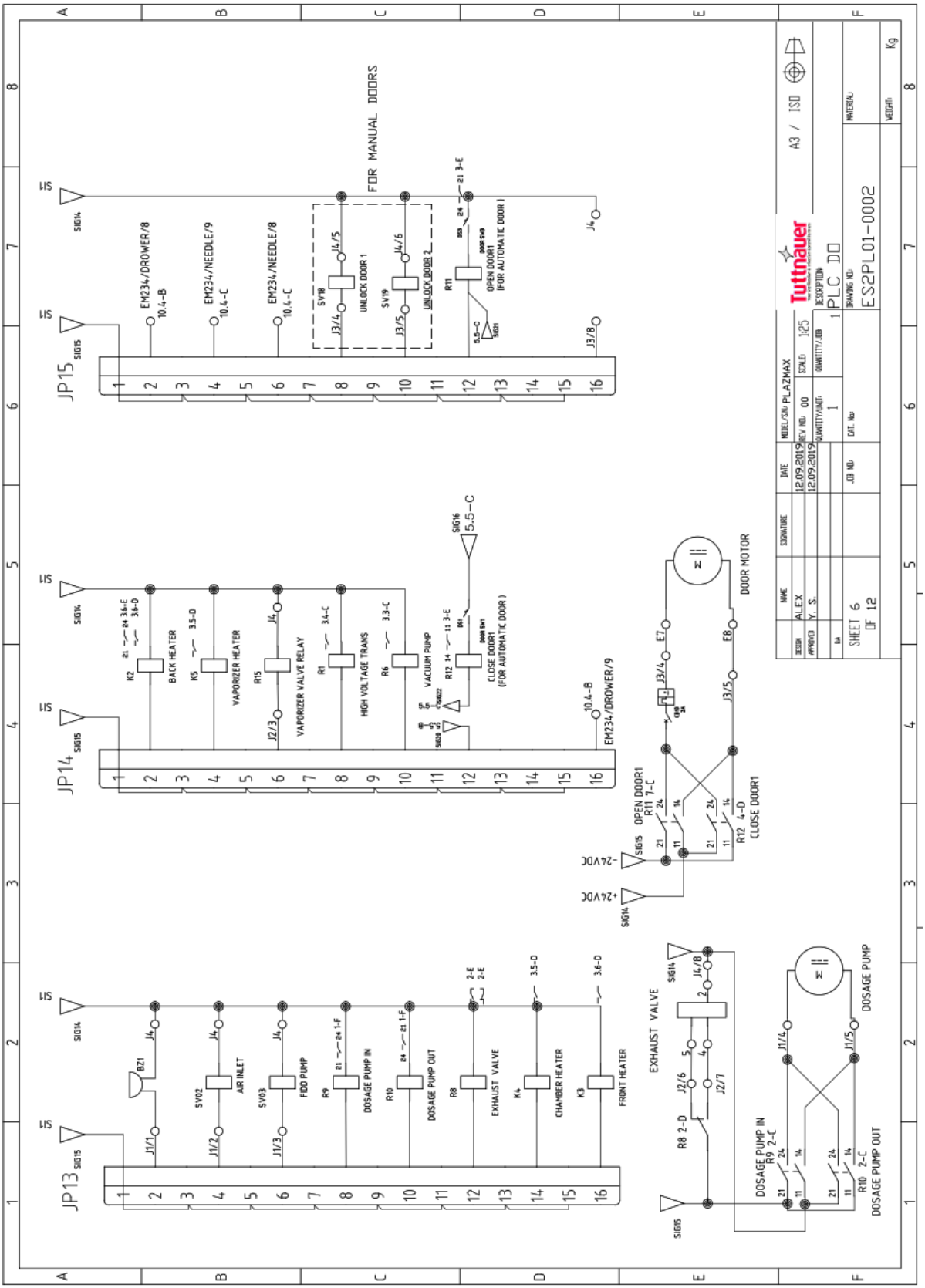
4. CASCADE DIAGRAM



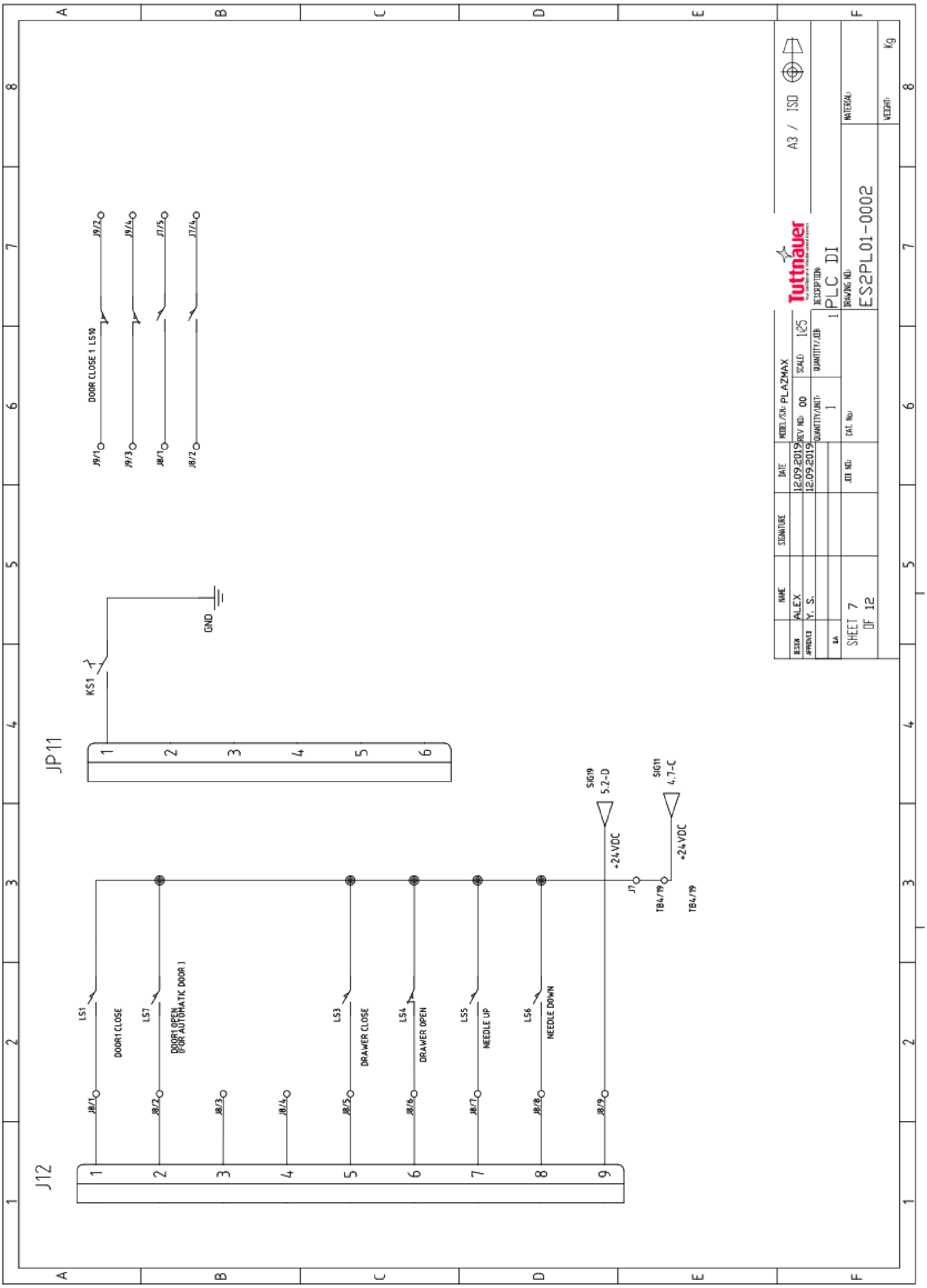
5. WIRING DIAGRAM



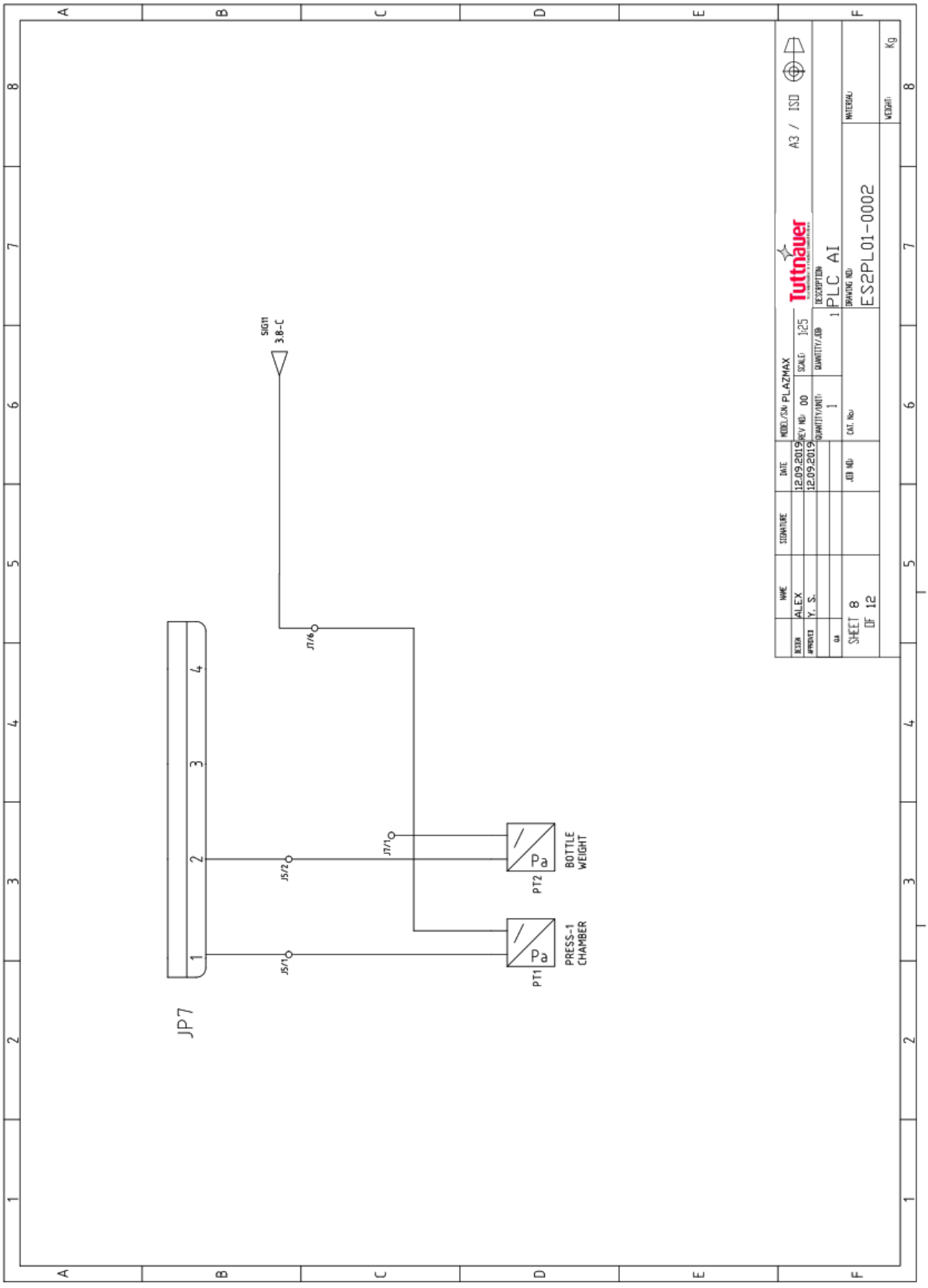
6. PLC DO-1


FOR MANUAL DOORS
JP15
JP14
JP13
EM234/DROWER/8
EM234/NEEDLE/9
EM234/NEEDLE/8
UNLOCK DOOR 1
UNLOCK DOOR 2
OPEN DOOR1 (FOR AUTOMATIC DOOR)
BACK HEATER
VAPORIZER HEATER
VAPORIZER VALVE RELAY
HIGH VOLTAGE TRANS
VACUUM PUMP
CLOSE DOOR1 (FOR AUTOMATIC DOOR)
DOOR MOTOR
OPEN DOOR1
CLOSE DOOR1
AIR INLET
FIDD PUMP
DOSAGE PUMP IN
DOSAGE PUMP OUT
EXHAUST VALVE
CHAMBER HEATER
FRONT HEATER
DOSAGE PUMP
+24VDC
-24VDC
PLAZMAX
PLC DO
ES2PL01-0002
SHEET 6 OF 12

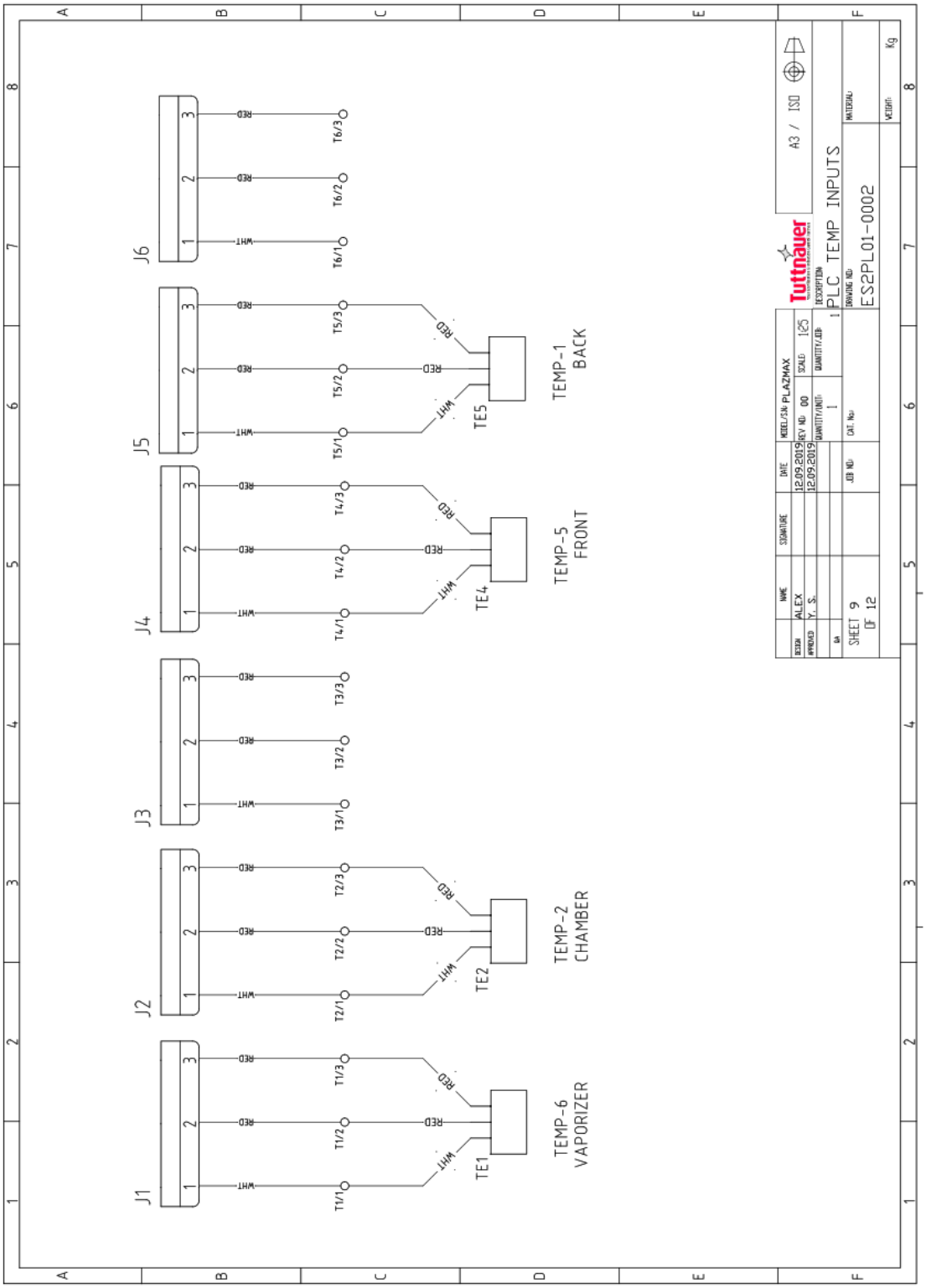
7. PLC DI


J12
JP11
DOOR CLOSE 1 LS10
J9/1
J9/2
J9/3
J9/4
J8/1
J7/5
J8/2
J7/4
KS1
GND
DOOR1 CLOSE
DOOR1 OPEN (FOR AUTOMATIC DOOR)
DRAWER CLOSE
DRAWER OPEN
NEEDLE UP
NEEDLE DOWN
LS1
LS7
LS3
LS4
LS5
LS6
SIG19 5.2-D
SIG11 4.7-C
+24VDC
TB4/19
MODEL/S.N: PLAZMAX
REV NO: 00
SCALE: 1:25
DESIGN ALEX 12.09.2019
APPROVED Y. S. 12.09.2019
DESCRIPTION: PLC DI
DRAWING NO: ES2PL01-0002
SHEET 7 OF 12
A3 / ISO

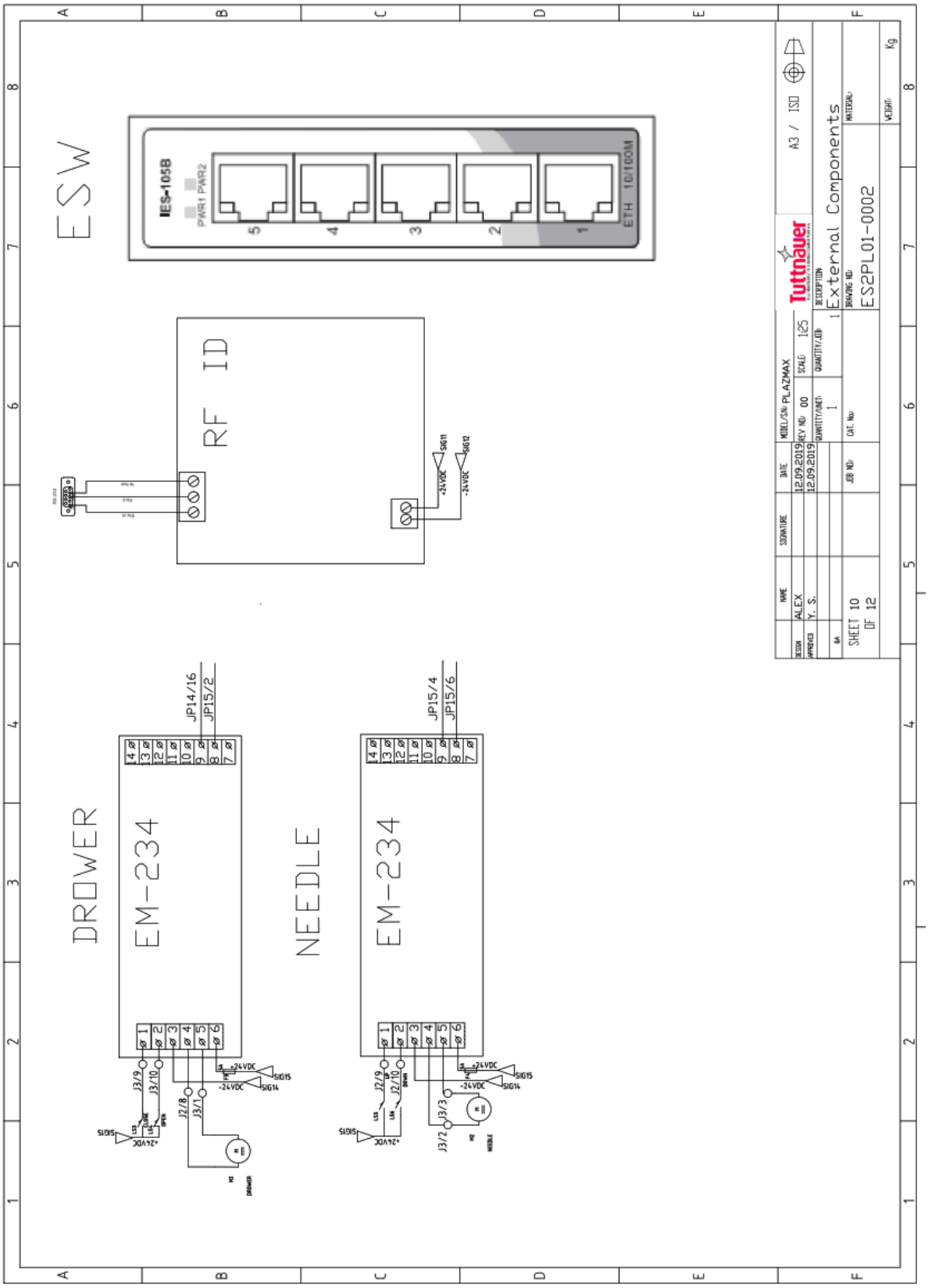
8. PLC AI


SIG11
3.8-C
J7/6
J7/1
J5/2
J5/1
JP7
Pa
PT2
BOTTLE WEIGHT
Pa
PT1
PRESS-1 CHAMBER
Tuttnauer
A3 / ISO
MODEL/SN PLAZMAX
DATE
12.09.2019
12.09.2019
REV NO: 00
SCALE: 1:25
QUANTITY/UNIT: 1
QUANTITY/JOB 1
DESCRIPTION
PLC AI
CAT. No:
DRAWING NO:
ES2PL01-0002
JOB NO:
MATERIAL:
WEIGHT: Kg
NAME
SIGNATURE
DESIGN ALEX
APPROVED Y. S.
QA
SHEET 8 OF 12

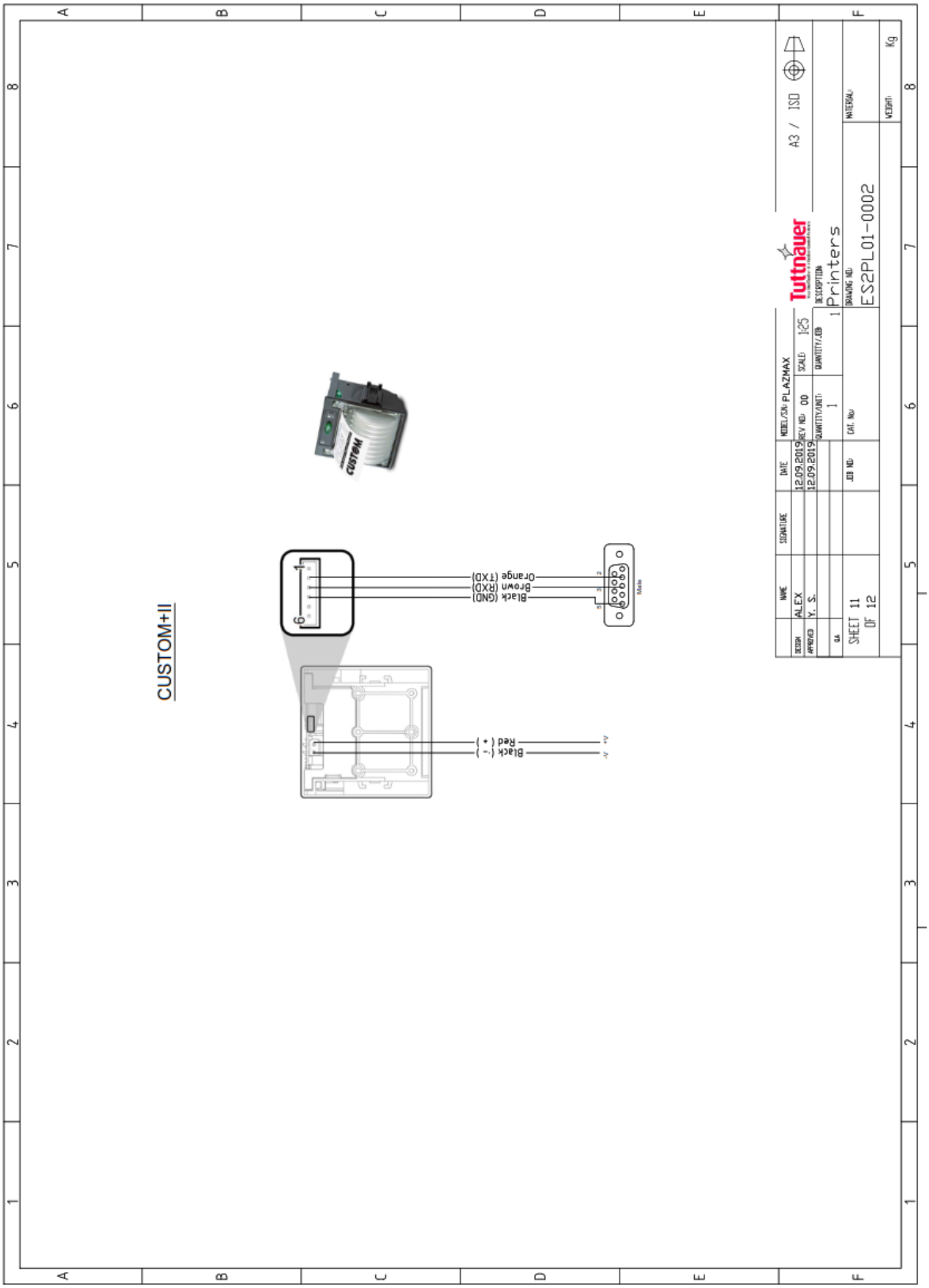
9. PLC TEMP INPUTS



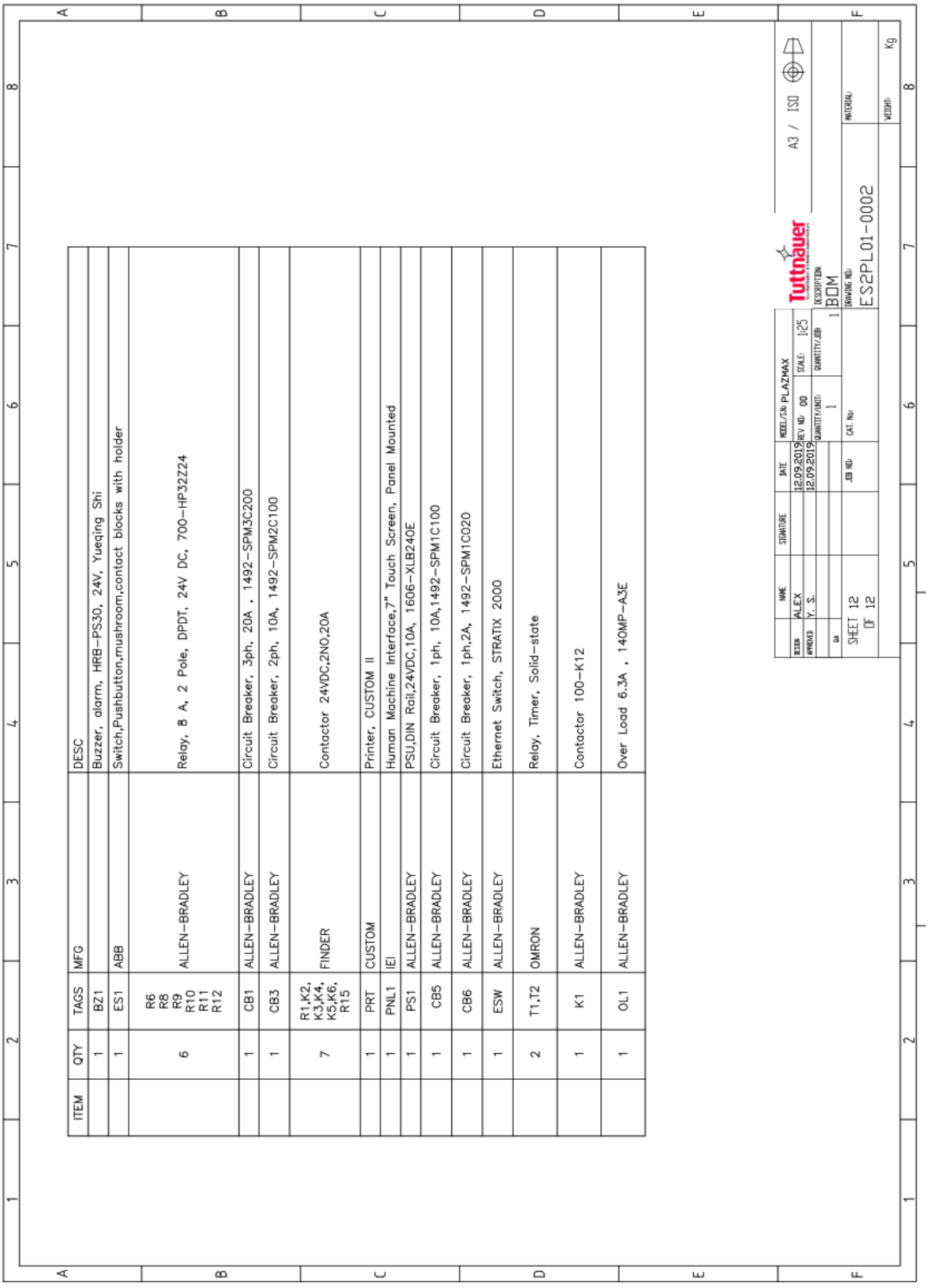
10. EXTERNAL COMPONENTS



11. PRINTERS


CUSTOM+II
Orange (TXD)
Brown (RXD)
Black (GND)
Red (+)
Black (-)
Tuttnauer
PLAZMAX
Printers
ES2PL01-0002
A3 / ISO
SHEET 11
OF 12

12. BOM



ITEM	QTY	TAGS	MFG	DESC
	1	BZ1		Buzzer, alarm, HRB-PS30, 24V, Yueqing Shi
	1	ES1	ABB	Switch,Pushbutton,mushroom,contact blocks with holder
	6	R6 R8 R9 R10 R11 R12	ALLEN-BRADLEY	Relay, 8 A, 2 Pole, DPDT, 24V DC, 700-HP32Z24
	1	CB1	ALLEN-BRADLEY	Circuit Breaker, 3ph, 20A , 1492-SPM3C200
	1	CB3	ALLEN-BRADLEY	Circuit Breaker, 2ph, 10A, 1492-SPM2C100
	7	R1,K2, K3,K4, K5,K6, R15	FINDER	Contactor 24VDC,2NO,20A
	1	PRT	CUSTOM	Printer, CUSTOM II
	1	PNL1	IEI	Human Machine Interface,7" Touch Screen, Panel Mounted
	1	PS1	ALLEN-BRADLEY	PSU,DIN Rail,24VDC,10A, 1606-XLB240E
	1	CB5	ALLEN-BRADLEY	Circuit Breaker, 1ph, 10A,1492-SPM1C100
	1	CB6	ALLEN-BRADLEY	Circuit Breaker, 1ph,2A, 1492-SPM1C020
	1	ESW	ALLEN-BRADLEY	Ethernet Switch, STRATIX 2000
	2	T1,T2	OMRON	Relay, Timer, Solid-state
	1	K1	ALLEN-BRADLEY	Contactor 100-K12
	1	OL1	ALLEN-BRADLEY	Over Load 6.3A , 140MP-A3E

17. APPENDIX 2: Vacuum Pump

See TRIVAC D25B (for the P-110 & P160 models) or D16B (for the P50 models) vacuum pump Maintenance manual.