STERLINK™

STERLINK plus (110V)

User Manual



Low Temperature Plasma Sterilizer

plasmapp

STERLINK plus Sterilization System

Language: EN

User Manual

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Chapter 1. Introduction

1.1. How to Use This Manual

A user of the STERLINK plus Sterilization System must read the ‘Safety Information, Preparation of Medical Devices,’ and ‘Operation’ sections before using it. ‘Chapter 1 Introduction’ describes the components of this user manual. ‘Chapter 2 Safety Information’ provides information on safety and stability when using the sterilizer. ‘Chapter 3 Overview of the Sterilizer’ summarizes the information on the sterilizer and its components. ‘Chapter 4 Preparation of Medical Devices describes the method of preparing and packing medical devices. ‘Chapter 5 Operation’ describes how to use the sterilizer properly, and how to ensure optimum sterilization performance.

If you are responsible for controlling and supervising the STERLINK plus Sterilization System, you must read the entire user manual. It is recommended that you carefully read the sections after Chapter 5. ‘Chapter 6 Access Privileges and Tasks Performed with Administrative Privileges’ describes the tasks and options available only to administrators with access privileges. ‘Chapter 7 Reports and Files’ describes how to manage the sterilization information provided by the sterilizer. ‘Chapter 8 Maintenance’ and ‘Chapter 9 Troubleshooting’, and ‘Attachments’ are included for your reference. Be sure to keep this manual in a location where you can quickly and easily find the information you need just in case a problem arises.

1.2. Contact Us

If you have any questions about the operation of the STERLINK plus Sterilization System or would like to know whether certain types of medical devices are sterilized safely, please contact our customer service center at +82-1544-0508 in Korea. Internationally, contact your local Plasmapp customer support representative. You may also visit our website at http://plasmapp.com.

1.3. Contact Information

1.3.1. Legal Manufacturer

Plasmapp Co., Ltd.	
Address.	A-1005, 10F, 670, Daewangpangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13494, Republic of Korea
Phone	+82-1544-0508
Website	http://plasmapp.com

1.3.2. Customer Service Center

Plasmapp America Inc.	
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Phone	+1 786-218-7579
e-mail	cs@plasmapp.com

Chapter 2. Safety Information

Plasmapp places the highest importance on user safety, and this chapter provides the information that can help you use the sterilizer system safely. Before using the sterilizer, you should read and understand the safety information and instructions specified in this chapter. You should be well acquainted with the warnings, cautions, and notes stated in this user manual. The information set forth herein will help ensure your safety and achieve the best performance from the sterilizer.

2.1. Personal Safety and First Aid



WARNING! HYDROGEN PEROXIDE IS CORROSIVE.

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always wear latex, PVC (vinyl), or nitrile gloves while removing items from the sterilizer following any cancelled cycle or error occurrence. Residual hydrogen peroxide may be present. If the contact occurs, immediately flush skin with large amounts of water. If symptoms are severe or persist, consult a doctor immediately.



WARNING! HYDROGEN PEROXIDE IS AN OXIDIZER.

Avoid allowing hydrogen peroxide to contact organic materials, including paper, cotton, wood, or lubricants. Concentrated hydrogen peroxide is a strong oxidizer and may react with organic materials, causing ignition and fire.



WARNING! RISK OF EYE INJURY.

Direct hydrogen peroxide contact with eyes can cause irreversible tissue damage. If there is a contact with eyes, immediately rinse eyes thoroughly with a large amount of water. Consult a physician immediately.



WARNING! RISK OF SKIN INJURY.

Direct contact between the skin and hydrogen peroxide can cause severe irritation. If the contact occurs, immediately flush skin with large amounts of water. If symptoms are severe or persist, consult a physician immediately.



WARNING! RISK OF RESPIRATORY IRRITATION.

Inhalation of hydrogen peroxide vapor may cause severe irritation to the lungs, throat, and nose. If inhaled, move to a location with fresh air for breathing. If your symptoms are severe or if they persist, contact your doctor immediately.



WARNING! CONCENTRATED HYDROGEN PEROXIDE IS TOXIC.

Ingestion of hydrogen peroxide may be life-threatening. If swallowed, drink plenty of water immediately to dilute. Do not try to induce vomiting. Please consult a doctor immediately if the symptoms are severe or persist.



WARNING! STERILIZATION SURFACES.

At the end of a cycle, the interior of the sterilizer may be hot. Do not touch the inside of the chamber or door with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.

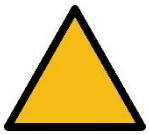
2.2. Personal Protective Equipment



CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

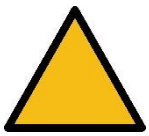
2.3. Warnings, Cautions and Notes



Warnings and cautions are accompanied by symbols surrounded by a triangle and are printed in the text in boldface italics. Warnings indicate events or conditions that can result in serious injury or death. Cautions indicate events or conditions that can result in severe damage to the equipment.

Note are accompanied by a check mark and are printed in italics. Notes highlight specific information about the proper use and maintenance of the STERLINK plus Sterilizer System.

2.4. Emergency Power-Off



In the event of smoke, unusual odor, liquid leakage, or any abnormal operation, immediately disconnect the sterilizer from the power supply by:

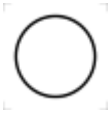
1. Pressing the main power switch located at the rear of the device, or
2. Unplugging the power cord from the wall outlet.

The power switch and plug must remain easily accessible at all times after installation.

Do not block access with furniture, walls, or other equipment.

2.5. Symbols

	**REFER TO INSTRUCTION MANUAL**
	**WEAR SAFETY GLOVES**
	**WARNINGS AND CAUTIONS** Warnings and cautions are indicated in the triangle symbol
	**WARNING SIGNS**
	**HOT SURFACES PRESENT** Do not touch the surface without any suitable protective equipment
	**HAZARDOUS CHEMICAL PRESENT** Be sure to wear personal protective equipment
	**HAZARDOUS CHEMICAL PRESENT** Be sure to wear personal protective equipment
	**HAND CRUSH HAZARD** Keep your hands away from the device during the operation
	**ELECTRIC SHOCK HAZARD**
	**NO PUSHING**
	**NO SITTING**
	**NO STEPPING ON SURFACE**

	POWER ON
	**POWER OFF**
	**PROPECTIVE EARTH (GROUND)**
	**MANUFACTURER**
	**DATE OF MANUFACTURING**
	**EXPIRY DATE**
	**SERIAL NUMBER**
	**TEMPERATURE LIMIT**
	**HUMIDITY LIMIT**
	**CAUTION**
	**THE EQUIPMENT SHOULD NOT BE DISPOSED OF IN THE NORMAL WASTE STREAM**
	**UNIQUE DEVICE IDENTIFIER**

	**BATCH CODE**
	**KEEP AWAY FROM SUNLIGHT**
	**DO NOT RE-USE**

Chapter 3. Overview of the Sterilizer

3.1. Intended Use

The STERLINK plus sterilizer is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.

The STERLINK plus can sterilize*:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless-steel lumen with:
  - o STERPACK™ plus: An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter
  - o STERLOAD™: An inside diameter of 2.4 mm or larger and a length of 280 mm or shorter

*The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 1 lb and 3.97 lbs with STERPACK™ plus and STERLOAD™, respectively.

▌Product Ratings and Specifications

Item	Specifications/Conditions
Voltage	100 - 120 VAC
Rated frequency	50 / 60 Hz
Max. power consumption	1.5 kVA
Operating temperature	10 ℃ - 40 ℃
Humidity	Relative humidity of 30 - 85%
Atmospheric Pressure	80 - 106 kPa
Replaceable fuse	Fuse 125V / 15A
Environmental	Indoor use
Pollution degree	II
Altitude	≤ 2000m
The degree of protection against harmful ingress of water	IPX0

3.2. Sterilization Processes

As a healthcare professional, you are probably already familiar with the general principles of sterilization. However, special attention is required when handling the STERLINK plus Sterilizer System, which adopts its own method that is different from other existing sterilizers.

It sterilizes medical devices by diffusing hydrogen peroxide vapor into chamber. It can quickly sterilize medical devices and materials without leaving toxic residues and does not damage the medical devices that are sensitive to heat and moisture.

It can be used on both metallic and non-metallic medical instruments, and it can also sterilize medical instruments with hard-to-reach spaces (limited diffusion spaces), such as forceps. For more details, refer to ‘Chapter 4 Preparation of Medical Devices’.

The sterilizer consistently guarantees a Sterility Assurance Level (SAL) of 10^{-6} as defined by the US Food and Drug Administration (FDA) and International Standards, provided that the materials and geometrical requirements in accordance with the instructions in this user manual are met.

The pre-validation has shown that this sterilizer can reach a SAL of 10^{-6}, including lumens, under worst-case conditions. For additional technical information related to validation, please contact Plasmapp or your local Plasmapp Customer Support Representative.

3.3. Sterilization Cycle

The STERLINK plus Sterilization System is designed to operate in pouch plus mode and chamber mode, which are the sterilization cycle that combines Smart Ready (SR™), Sterilization, and Smart Complete (SC™) processes. This sterilizer system is designed to operate only with the sterilant cassette, STERPACK™ plus and STERLOAD™. The cassette has a barcode printed on it. At the start of the process, the sterilizer scans the barcode to recognize the validity of the cassette, and automatically selects the sterilization mode based on the barcode system. This allows the system to reduce user errors and provide improved ease of use and sterilization reliability.

In the SR™ process, the moisture remaining in the medical devices is measured with an independent pressure sensor of the sterilizer, and the optimized heating and drying processes are conducted. The same sterilization process is performed twice in a row, and the process parameters are managed in the same way. It has been validated for 10^{-6} SAL with a half cycle of sterilization. The SC™ process completely removes the residual sterilant and ensures the Sterility Assurance Level before using sterilized medical devices. Particularly, to ensure user safety, an optimized completion process is carried out by measuring the remaining sterilant with an independent pressure sensor of the sterilizer.

The following table represents a brief description of the sterilization cycle modes

Sterilization cycle and minimum time by mode

Mode	Sterilization Cassette	Cycles and Minimum Process Time (in minutes)		
		SR™ / SC™	Sterilization	Total
Pouch plus	STERPACK™ plus	6	8	14
Chamber	STERLOAD™	21	15	36

Sterilization process – Step 1

- Injection: Hydrogen peroxide (sterilant) is injected and vaporized from the cassette into the vaporizer and fed into chamber.
- Diffusion: As the sterilant vaporizes and pressure increases, it diffuses into the surface and in the interior of the medical devices to proceed with the sterilization process.
- Plasma Purification: In this process, the used sterilant is removed, creating a vacuum in the STERPACK™ plus and chamber of the sterilizer. The removed sterilant is purified through plasma treatment to ensure user safety.

Sterilization Process – Step 2

The processes in Step 1 above are repeated.

3.4. Sterilizer Systems and Accessories

Optional accessories are available for use with the STERLINK plus Sterilization System. The following figure shows the sterilizer system including the sterilizer cart and label-printer accessories.



Figure 3.1 STERLINK plus Sterilization System

This product has a power supply plug (with cord) and a power supply connector on its back and is connected to a grounding conductor for protection against electric shock. In addition, the USB port on the back of the main body is connected to the USB port on the back of the label printer through a USB cable. The label printer connected to the sterilizer is supplied with power through the printer power adapter (insulated).

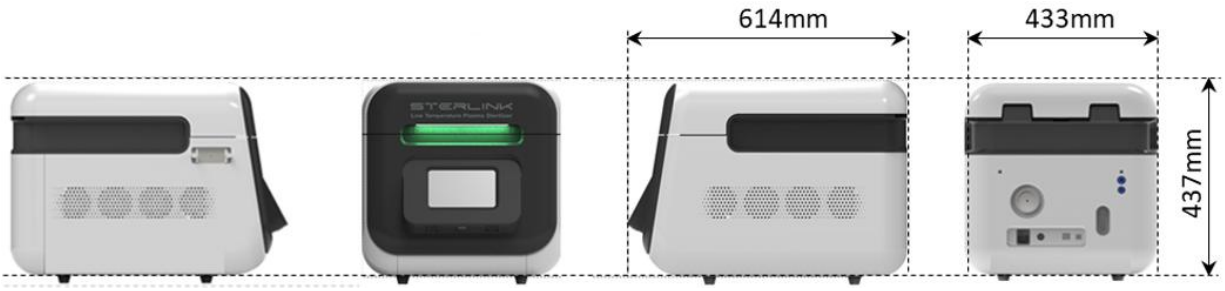


Figure 3.2 STERLINK plus Sterilization System



Figure 3.3 STERLINK plus dedicated power cable

The STERLINK plus Sterilization System provides an optional label printer that allows a user to print a report that summarizes sterilization information. To help a user manage the history with ease, this label printer prints a sticker type report.



Figure 3.4 Label Printer & Label Sticker Roll for the STERLINK plus Sterilization System

WARNING! ELECTRIC SHOCK HAZARD.

To avoid the risk of electric shock, this product must only be connected to a power supply with protective ground.

WARNING! USE OF PRINTER & CABLE.

Use of accessories, cables other than those specified or provided by the manufacturer of this equipment could result in decreased electromagnetic compatibility of this equipment and result in improper operation.

WARNING! INSTALLATION POSITION.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

3.5. Sterilant Cassette

The STERLINK plus Sterilization System has two modes (pouch plus mode and chamber mode) which is automatically initiated by scanning the barcode printed on the STERPACK™ plus or STERLOAD™ sterilant cassette. The barcode contains the information about the type and the manufacturing date of Sterilant Cassettes.

The cassette has two built-in cells containing the same amount of sterilant (hydrogen peroxide), so one complete sterilization cycle can be performed while repeating the same sterilization process using each cell. When the sterilization cycle is completed or aborted, you need to remove the used cassette from the sterilizer with protective gloves on and dispose of it according to applicable regulations. For more details about how to use the cassette, refer to ‘Chapter 5 Operation’.

The sterilant cassette is fixed and mounted by the fixing bar and the hook of the needle part inside the main body. The Barcode Scanner mounted inside the needle part automatically recognizes the barcode printed on the sterilant cassette and proceeds with the sterilization process.



(a) STERPACK™ plus (b) STERLOAD™

Figure 3.5 Sterilant cassettes



CAUTION! CHECK EXPIRY DATE.

Before using the sterilant cassettes (STERPACK™ plus and STERLOAD™), check the expiry date. If the cassette is expired, do not use. Dispose of the expired cassette and use an available unexpired sterilant cassette.



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

Chapter 4. Preparation of Medical Devices

4.1. Indications for Use

The STERLINK plus sterilizer is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.

The STERLINK plus can sterilize*:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless-steel lumen with:
  - o STERPACK™ plus: An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter
  - o STERLOAD™: An inside diameter of 2.4 mm or larger and a length of 280 mm or shorter

*The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 1 lb and 3.97 lbs with STERPACK™ plus and STERLOAD™, respectively.



WARNING! BE SURE TO UNDERSTAND THE STERILIZATION PROCESSES.

Before processing item(s) in the sterilizer, make sure you know how the STERLINK plus sterilization process will affect the item(s). If you have questions, or if you are in doubt about the materials in your device, contact the medical device manufacturer or your local Plasmapp customer support representative for more information.



WARNING! BREACH OF WARRANTY.

Improper use may cause damages to the equipment, and such damages will not be covered by the manufacturer's warranty.

The STERLINK plus Sterilization System is also suitable for the sterilization of both non-surgical and surgical instruments such as dentures, endoscopes, orbital implants, prostheses for bone marrow percutaneous amputation and surgical equipment, etc.

4.2. Items Applicable to the Sterilizer

The STERLINK plus Sterilization System is classified as 'Class II' in accordance with section 513(a) of the Federal Food, Drug, and Cosmetic Act and is intended to be used to sterilize medical instruments, including surgical instruments.

There are many types of materials and equipment that can be sterilized with this sterilizer. As more product tests are completed, the list of compatible items will continue to increase. It will be updated if there is any new information. If you have any questions, please contact the medical device manufacturer or your local Plasmapp customer support representative.



CAUTION! RISK OF DAMAGE TO MEDICAL INSTRUMENTS OR THE STERILIZER.

Do not sterilize the items or materials that are not permitted for use in this sterilizer. To determine what items can be sterilized with the STERLINK plus Sterilizer System, refer to the medical device manufacturer's instructions or contact your local Plasmapp customer support representative.

4.3. Things that Cannot Be Processed by the Sterilization System

The following items cannot be processed with the STERLINK plus Sterilization System:

- Disposable items for which re-sterilization is not recommended by the manufacturer.
- Liquids and powders
- Items or materials that absorb liquids
- Items made of fiber-containing materials such as cotton, paper or cardboard, linen, towels, gauze and sponges or wood pulp, etc.
- Medical instruments with paper labels such as stickers
- Items with the surface made of Nylon®
- Instruments that cannot withstand vacuum, and can only be sterilized by steam sterilization
- Instruments with a possibility of surface deformation due to vacuum
- Lumens blocked at one end
- Other tools that are not recommended for use with the STERLINK plus sterilizer by manufacturers

4.4. Material compatibility

As a reference, the result of material compatibility test is described below.

Type		Cosmetic change	Physical properties
Metal materials	Aluminium 5052	None	No change
	Aluminium 6061	None	No change
	Stainless Steel 304	None	No change
	Stainless Steel 316L	None	No change
	Titanium	Yellowness increased slightly	No change
Non-metal materials	High Density Polyethylene (HDPE)	None	No change
	Polypropylene (PP)	None	No change
	Polytetrafluoroethylene (PTFE)	None	No change
	Silicone (Hardness: 50)	None	No change

4.5. Instructions for Preparing the Items to Be Sterilized

All items should be cleaned, rinsed, and thoroughly dried before being put into the STERLINK plus sterilizer. If a medical device with too much moisture is put into the sterilizer, the cycle may be automatically canceled.

4.6. Cleaning, Rinsing, and Drying

Cleaning and sterilization are two separate processes. As with normal sterilization processes, it is important and essential to properly clean instruments and devices before sterilization. All items should be cleaned, rinsed, and thoroughly dried before being put into the sterilizer.

Before packing, be sure to check all instruments and devices carefully for cleanliness and dryness, and scratches or damages. If visible stains or moisture are found before sterilization, the instrument should be cleaned and dried again. Devices and instruments with defects or damages should be replaced or repaired before use.

Cleaning is a necessary process to remove organic·inorganic matters, and debris from the medical device. In this process, most microorganisms are removed from the surface. Sterilization inactivates all remaining spores and living microorganisms that still remain after the cleaning process.

Note:

- Be sure to remove all blood, tissues, and stains from the instrument with an appropriate cleaning agent in accordance with the manufacturer's instructions.
- Rinse the instrument thoroughly to remove any residues of the cleaning agent completely.
- The methods of drying the instrument should be in accordance with the manufacturer's instructions. Otherwise, you should contact the manufacturer for proper and safe procedures. Be sure to remove moisture from all instrument parts thoroughly. Put only fully dried instruments into the sterilizer's chamber to prevent the cycle from being cancelled.
- Some reusable medical devices may require dismantling for proper cleaning and sterilization. When it comes to cleaning and sterilization, it is very important to follow the instrument manufacturer's recommendations.
- The instruments that have been repeatedly exposed to disinfectants/cleaning agents/sterilants require regular inspections for potential damages from chemicals.

4.7. Packing and Loading

4.7.1. Packing and Loading for Pouch Plus Mode (STERPACK™ plus)

Proper preparation of pouches and instruments can minimize the possibility of cycle cancellations and positive biological indicator (BI) results due to load-related problems. All instruments must be cleaned, rinsed, and thoroughly dried before loading into the sterilizer.

4.7.1.1. Packaging

Packaging should be performed as follows.

- Use Tyvek® pouches for the pouch plus mode operation.
- Insert a chemical indicator and medical instruments to be sterilized inside the Tyvek® pouches.
- In the pouch plus mode, the STERPACK™ plus maintains vacuum condition after sterilization. Therefore, do not use fragile medical instruments that are easily damaged by vacuum or sharp instruments that can pierce the pouch.
- Do not use paper pouches or sterilization wraps containing cellulose or cotton.
- Do not use any wraps or packaging that are not approved by Plasmapp Co., Ltd. or that contain materials in the "Things that cannot be processed" section.
- Arrange the Tyvek®-sealed items in the STERPACK™ plus pouch to ensure proper diffusion of hydrogen peroxide throughout the load.
- Arrange them so that the transparent side of a Tyvek® pouch faces the opaque side of the STERPACK™ plus pouch.
- Place process challenge device (PCD) with biological indicator inside the STERPACK™ plus pouch as depicted in Fig. 4.1, if needed.



Figure 4.1 Location of PCD with SCBI in the STERPACK™ plus pouch

4.7.1.2. Loading

The cassette should be precisely installed onto the loading block of the STERLINK plus sterilizer, as described in Fig. 4.2.



Figure 4.2 Loading STERPACK™ plus in the chamber

4.7.2. Packing and Loading for Chamber Mode (STERLOAD™)

By preparing appropriate trays and devices when packing medical instruments, you can minimize the possibility of cycle cancellations caused by loading-related issues and a positive test for biological indicators. Be sure to clean, rinse, and dry all instruments thoroughly before loading them into the sterilizer.

4.7.2.1. Packing

Packing should be done according to the following guidelines.

- Only the polypropylene sterilization wraps and Tyvek™ pouches are available for the Chamber Mode.
- Do not use paper pouches, sterilization wraps containing cellulose, or cotton.
- Do not use the wraps or packaging not approved by Plasmapp or the materials specified in '4.3 Things that cannot be processed by the sterilization system'.
- Place medical instruments on the chamber carefully to ensure that hydrogen peroxide diffuses evenly between the loaded items.
- Place peel pouches 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 poches on top of each other.

4.7.2.2. Loading

The cassette should be correctly mounted on the loading block of the STERLINK plus Sterilization System. For the Chamber Mode, it is recommended to load the cassette (STERLOAD™) first, and then put the packaged medical instrument into the chamber. Place the process challenge device (PCD) including a biological indicator at the front side of the chamber as depicted in Fig. 4.3, if needed.



Figure 4.3 Location of PCD with SCBI



WARNING! DO NOT USE IT IF PACKAGING IS DAMAGED.

Do not use it if packaging is even slightly damaged. If the packaging is not perfectly sealed.



CAUTION! INSERT CI (CHEMICAL INDICATOR).

Insert the CI in the packaging together with the product. After the sterilization cycle is completed, verify that the product is working properly, and the CI color has changed color accordingly.



CAUTION! BE CAREFUL! MAY BE CHAMBER HOT!

The temperature in the chamber may be very high. Therefore, when working in the chamber, be sure to wear protective gloves, and be careful of burns.

Chapter 5. Operation

5.1. Before Use

When using the STERLINK plus Sterilization System, follow the instructions specified in 'Chapter 4 Preparation of Medical Devices', and be sure to read and understand the operating instructions and precautions provided in this user manual.

Note:

- This sterilizer should be placed on a table in the designated area for use. It should be installed on a flat floor (inclination of 3 degrees or less) with a space of at least 5 cm from the back and top surfaces.
- Do not apply unspecified voltage to the sterilizer. If you need to use unacceptable power for urgent sterilization under special circumstances, please contact your nearest distributor or our head office. The damages to the product resulting from the use of unspecified voltage will void the warranty.
- When preheating the sterilization chamber, be sure to connect the power cord and turn on the power switch 15 minutes before starting the sterilization process. Starting the sterilization process without preheating may cause failure.
- The LAN connector is used for S/W updates or diagnosing the product status.
- Do not use the sterilizer in close proximity to the equipment that generates plenty of electromagnetic waves.
- Keep the sterilizer away from fire or a location where steam is generate
- When restarting a sterilizer that has not been used for a long time, a user should contact the manufacturer to get appropriate instructions.
- This equipment can only be operated by people who have been trained by the manufacturer or a manufacturer-delegated company.



WARNING! HYDROGEN PEROXIDE IS CORROSIVE.

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Always were latex, PVC (vinyl), or nitrile gloves while removing items from the sterilizer following a cancelled cycle or error occurrence. Following hydrogen peroxide may be present.



WARNING! DISPOSAL OF HYDROGEN PEROXIDE.

Hydrogen peroxide is designated as a dangerous and hazardous medical waste by the American Environment Protection Association and should be disposed of in accordance with applicable local regulations. (U.S. Waste Disposal Regulations: U.S. EPA 40 CFR 262)



CAUTION! USE MANUFACTURER SUPPLIED POWER CORD ONLY.

To avoid risk of equipment malfunction or electrical shock, use the power cord supplied by the manufacturer with the STERLINK plus sterilizer only.



WARNING! DO NOT MODIFY THIS EQUIPMENT.

No modification of this equipment is allowed.

5.2. Start-up and Preheating

1. Turn on the main power switch on the back of the sterilizer.
2. When the power is turned on, the sterilizer will be automatically preheated.
3. Close the door during the preheating process. Preheating may take up to 40 minutes.
4. After the preheating process, the ‘ ▶ ’ icon will be displayed instead of ‘Preheating’ as shown below.

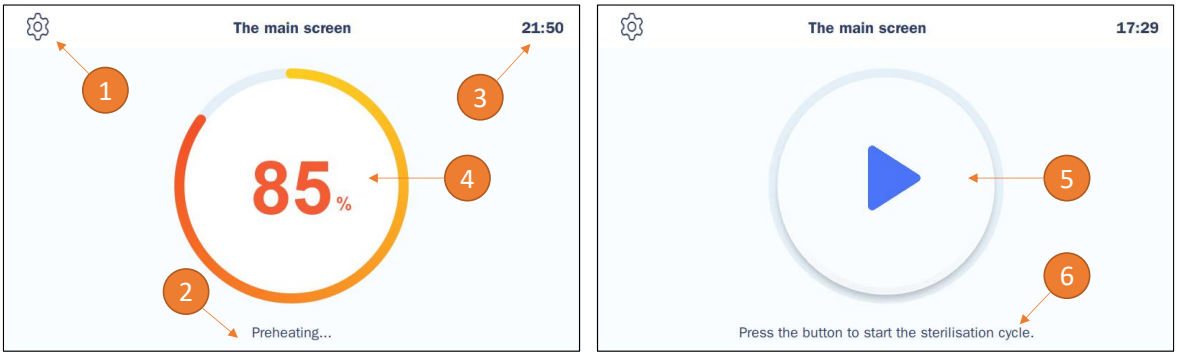


Fig. 5.1 Preheating and preparation processes displayed on the screen

No.	Name	Description
1	Configuration	Click the ‘Configuration’ icon to go to the Configuration settings of the sterilizer.
2	Description	The current status of the sterilizer is displayed.
3	Time	The current time that can be set in the ‘Configuration’ is displayed.
4	Preheating progress	Displays the progress status of the current preheating.
5	Sterilization button	Click this icon to start the sterilization cycle.
6	Help	This section shows the current status.

5.3. Preparations for Loading

Ensuring that sterilization conditions are met during the sterilization cycle is one of the most important issues in sterilization. Using Biological Indicators (BI) is one way of ensuring that the sterilizer is working properly.

Place a biological indicator in the STERPACK™ plus pouch for pouch plus mode or in the chamber for chamber mode. It is recommended that this biological test be performed once a day, or in accordance with your facility's policy. While the sterilizer is preheated, you can prepare the loads.

Mode	Description
Pouch plus	The total mass should be less than 1 lb (450 g)
Chamber	The total mass should be less than 3.97 lbs (1.8 kg)



CAUTION! DO NOT REUSE.

Sterilant Cassette (STERPACK™ plus and STERLOAD™) is intended for single use only, and cannot be reused. When reused, an error will occur and will affect the performance of the product.



WARNING! CHECK THE EXPIRATION DATE.

When using the Sterilant Cassette (STERPACK™ plus and STERLOAD™), check the expiration date first. If the date has expired, discard it, and use a new Sterilant Cassette. A cassette that has expired may cause errors.



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

5.4. Cassette Loading

The STERLINK plus sterilizer has one operating mode which is operated by using the cassette of the STERPACK™ plus and STERLOAD™. The figure below shows the STERLOAD™ cassette placed in the loading block as an example.



Figure 5.2 Mounting cassette of the STERLOAD™



WARNING! BEWARE OF HOT SURFACES IMMEDIATELY AFTER STERILIZATION.

Immediately after the sterilization cycle, the interior of the sterilizer may be hot. Never touch the chamber and the interior of the sterilizer with your bare hands or gloved hands.



WARNING! WATCH OUT FOR HAND INJURIES.

The door of the sterilizer is designed to be opened and closed manually, which may cause injury to your hands. Be careful not to hurt your hands when opening and closing the door.

5.5. Starting the Sterilization Cycle

1. After placing the STERPACK™ plus or STERLOAD™ in the loading block and the load in the chamber, confirm the door is closed.
2. Press the ‘ ▶ ’ icon to start the sterilization cycle.
3. Then, the sterilizer automatically scans the barcode printed on the cassette to validate the loaded cassette and determines the operating mode.
4. The sterilizer automatically checks that the door is closed and starts the sterilization cycle.
5. When the sterilization process starts, the door cannot be opened during the process because the interior of the chamber is kept in a vacuum state.

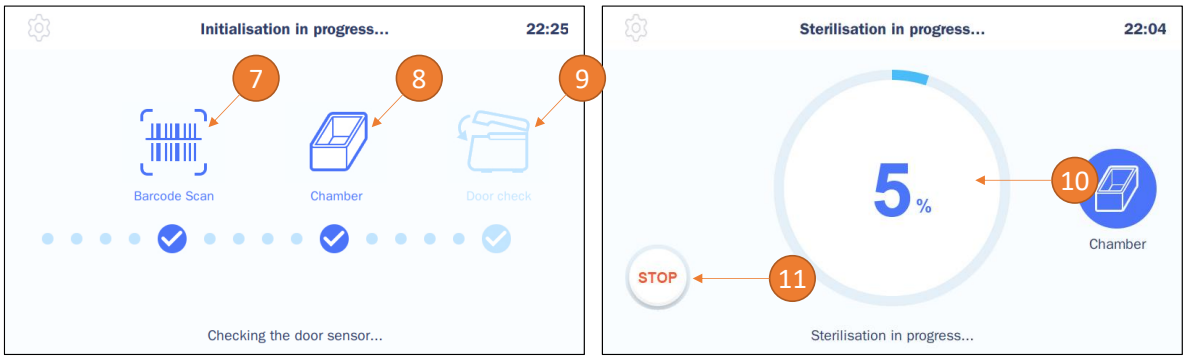


Figure 5.3 Screen showing initialization and sterilization process

No.	Name	Description
7	Barcode	The result of the barcode scanning of the loaded cassette is displayed.
8	Mode	It indicates the sterilization mode determined by the barcode.
9	Door	It indicates the status of the door.
10	Sterilization progress	Displays the progress status of the current sterilization.
11	Stop	This icon is used to cancel the sterilization cycle.

Note:

- When a cassette is reused or expired, the cycle will be cancelled.
- If a cassette is mounted incorrectly, an error occurs in barcode recognition, and the cycle will be canceled.
- If the chamber door is not tightly closed, the cycle will be cancelled.
- The cancellation of a cycle does not guarantee a Sterility Assurance Level, and a user may be exposed to sterile residues that remain on the cassette. Accordingly, make sure to wear protective gloves when handling used cassettes.



WARNING! POSSIBLE NON-STERILE DEVICE.

Improper loading of the cassette may result in either a non-sterile device or cycle cancellation. The cassette should be precisely loaded on the cassette loading block of the sterilizer and properly locked.

WARNING! ELECTROMAGNETIC DISTURBANCES.

A high voltage is used at the start of the sterilization cycle, which may cause minor disturbances to electronic devices outside the product. Also, portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in sterilization failure.



The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.



CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

5.6. Progress and Completion of the Cycle

Upon the completion of the sterilization cycle, the sterilization displays the cycle information such as the sterilization date, time, and the result of the mode. Click “confirm” button to return to “main” screen.

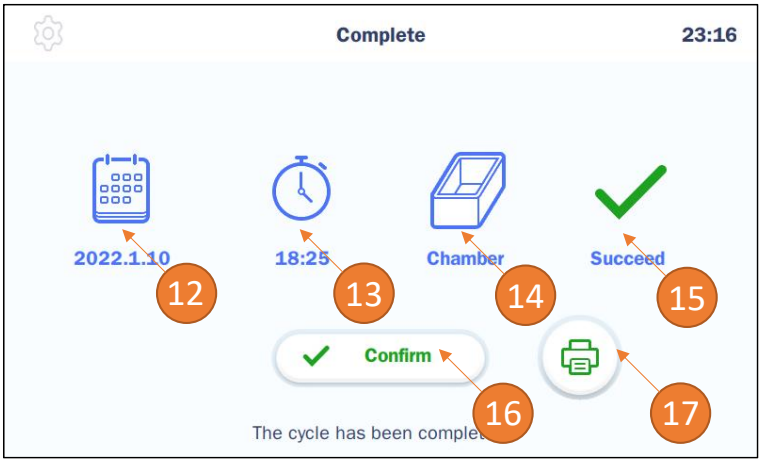


Figure 5.4 Screens showing the processes and completion of the sterilization cycle.

No.	Name	Description
12	Date	Displays the start date of the sterilization cycle.
13	Cycle time	Displays time for overall cycle time
14	Mode	Displays the mode of the finished sterilization cycle
15	Result	Displays the result of the sterilization cycle
16	Confirm	Clicks on “Confirm” button, the screen moves to ready state
17	Print	Clicks on “Print” button, the label printer will print out the summary of the sterilization cycle information

5.7. Cancellation of the Sterilization Cycle

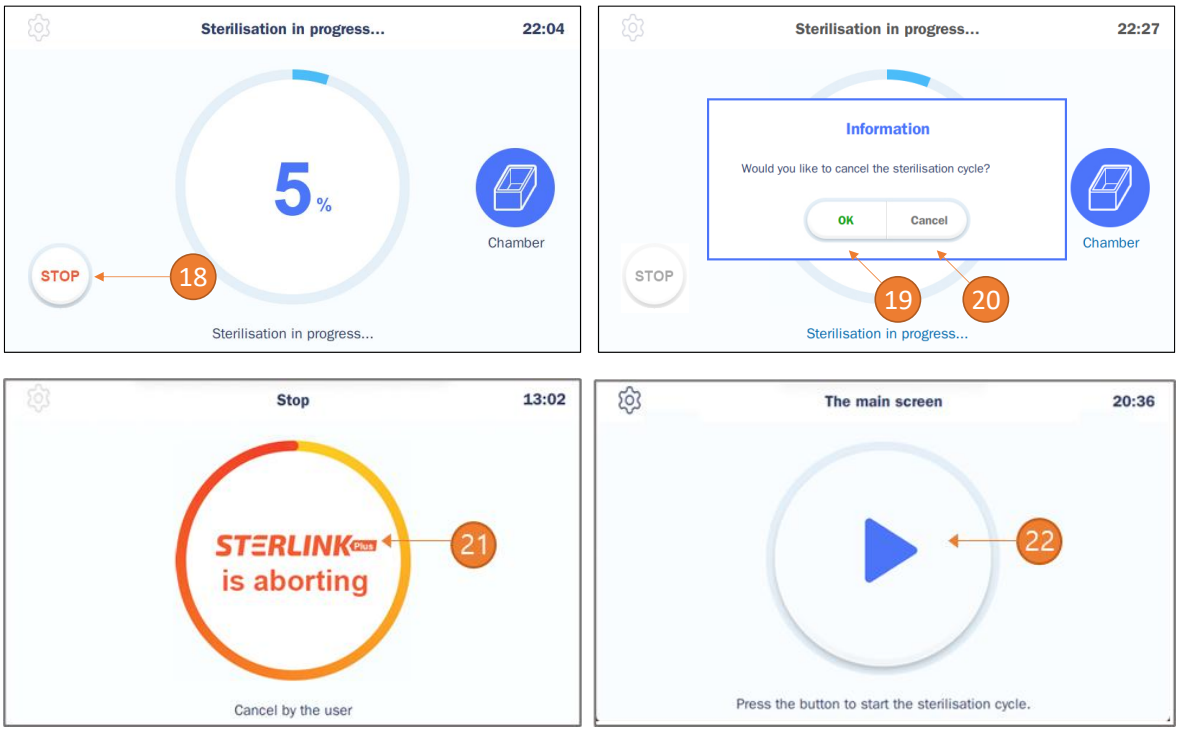


Figure 5.5 Screen for cancellation of sterilization cycle

Number	Name	Description
18	STOP	This icon is for cancelling the cycle.
19	OK	This icon is for confirming the cancellation.
20	Cancel	This icon is for withdrawing the cancellation.
21	Aborting	This section displays for removing residual sterilant when the user cancels the cycle.
22	Home	When the sterilization cycle cancellation is complete, the screen returns to the ready state.

A purification process is performed when the cycle is cancelled but may result in residual sterilant on the load. Protective gloves should be worn when handling the load and used cassettes. As the desired sterility assurance level may not be obtained, a new sterilization cycle should be performed after placing the device(s) in new packaging material.



WARNING! POSSIBLE NON-STERILE DEVICE.

Cycle cancellation may result in a non-sterile device and requires a new sterilization cycle to be performed after placing the device(s) in new packaging material.



CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

5.8. Handling Sterilized Loads

When the cycle has been confirmed as being completed, the sterilized load can be processed by inspecting the chemical indicators and processing the biological indicator.

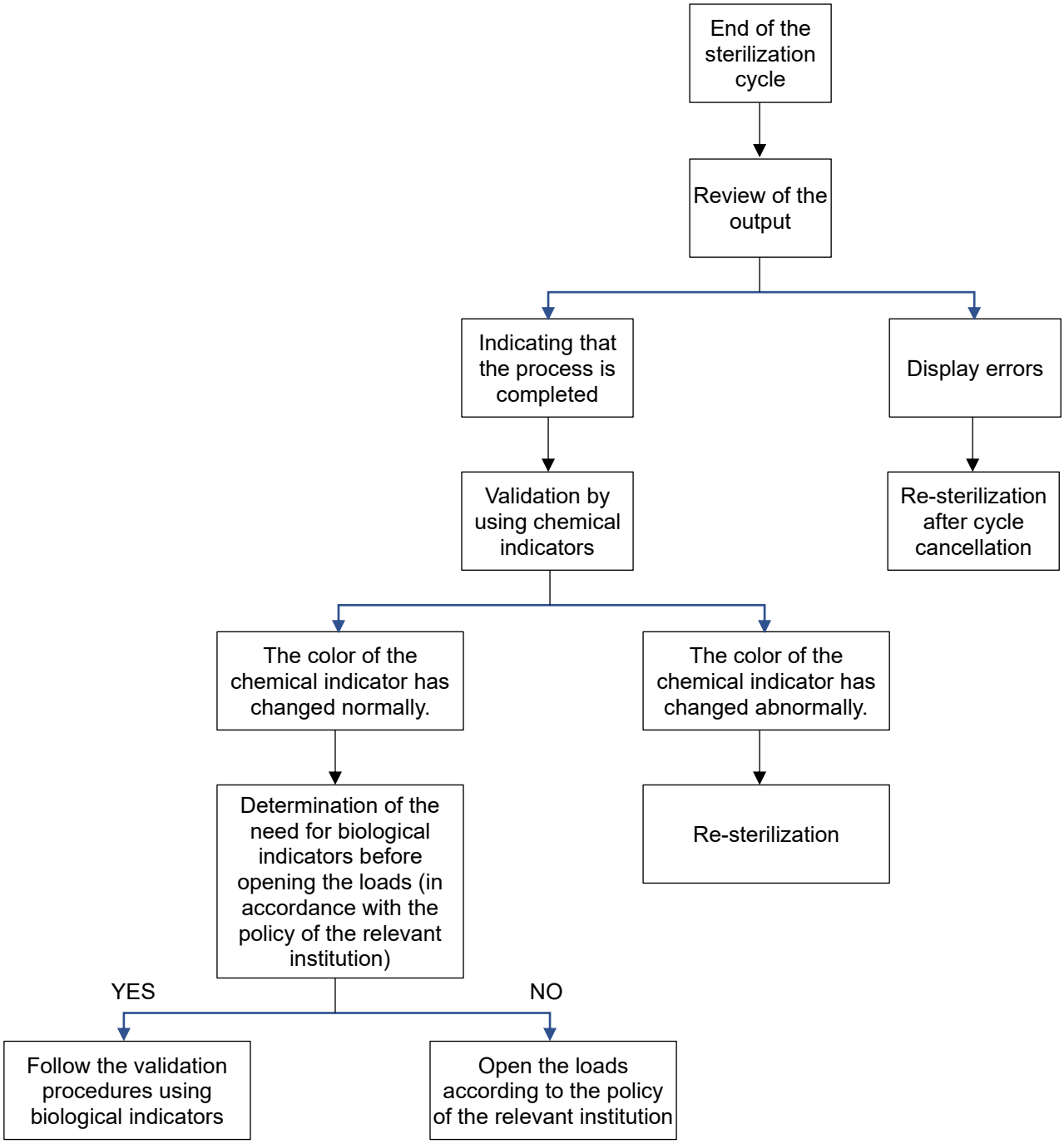
5.8.1. Inspecting chemical indicator

After ensuring that the chemical indicators exhibit the correct color change, and the cycle printout shows that all parameters were met, the sterilized load is ready for immediate use, following your facility's policy. If the chemical indicators do not exhibit the correct color change, investigate the cause. Then repackage and reprocess the load.

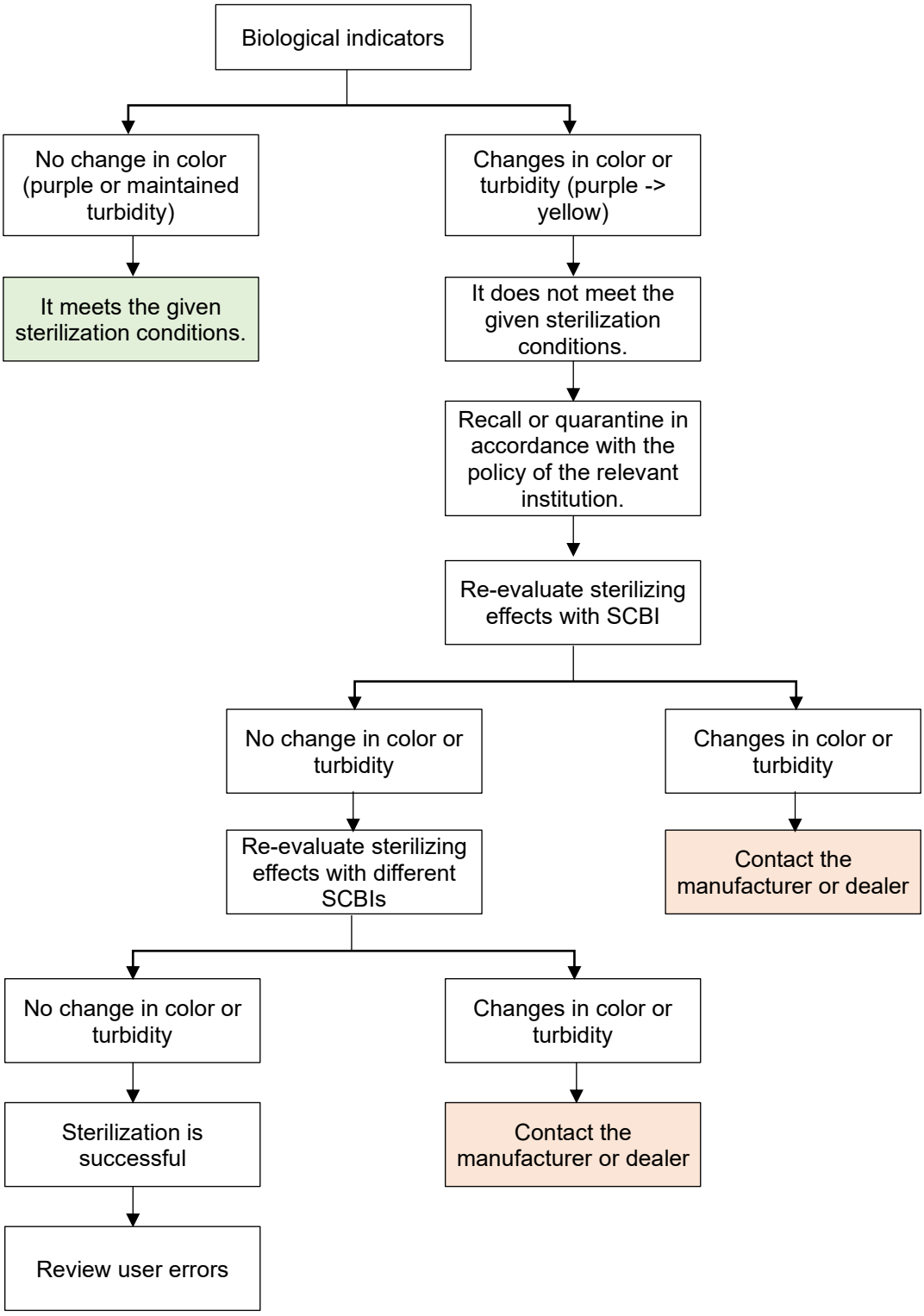
5.8.2. Processing biological indicators

Remove the biological indicator from the load /or PCD and process it according to its Instruction for use. Refer to the biological indicator flow chart on the following pages.

Cycle Completion Procedures



Procedures to Validate the Sterilization Cycles by Using Biological Indicators



5.9. How to Power Off Safely

In order to power the sterilizer off, turn off the main power switch on the backside after checking the chamber vented to the atmospheric pressure. If the chamber vented properly, the door could be opened.

Chapter 6. Access Levels and Administrator Tasks

6.1. Overview

The STERLINK plus Sterilizer utilizes the embedded software for automated implementation of STERLINK plus sterilization process. This chapter contains how to control the configuration of the STERLINK plus Low Temperature Plasma Sterilizer.

A user with administrator-level access authorities (see below) are permitted to perform a set of restricted sterilizer functions. These functions are not used in daily sterilizer operation and are designed to control access, manage system records, and perform advanced diagnostic functions.

6.2. Access Levels

The STERLINK plus sterilizer can be configured to require that the users enter a valid password in order to control the system configuration. There are three levels of access available. Each is associated with a different subset of permitted operations.

Operator-level access is designed to permit a user to perform the tasks associated with the daily operation of the sterilizer. These authorities allow a user to:

- Start and cancel the cycle
- Print a cycle history report and view cycle history files
- Setup the display and sound

Administrative-level access include all authorities of Operator-level access and additionally provides the ability to:

- Run diagnostic tests
- Perform calibration for the sensors
- Perform emergency action function
- Setup system time

Service-level access is only for use by the Plasmapp customer service representatives.

- Software update
- Modify the process parameters

6.3. Additional Utilities Menu

The additional utilities menu of 'Configuration' is only available to administrators, or users with service level access. The additional utility menus allow administrators to configure time settings, sterilization system settings, and diagnostic tests.

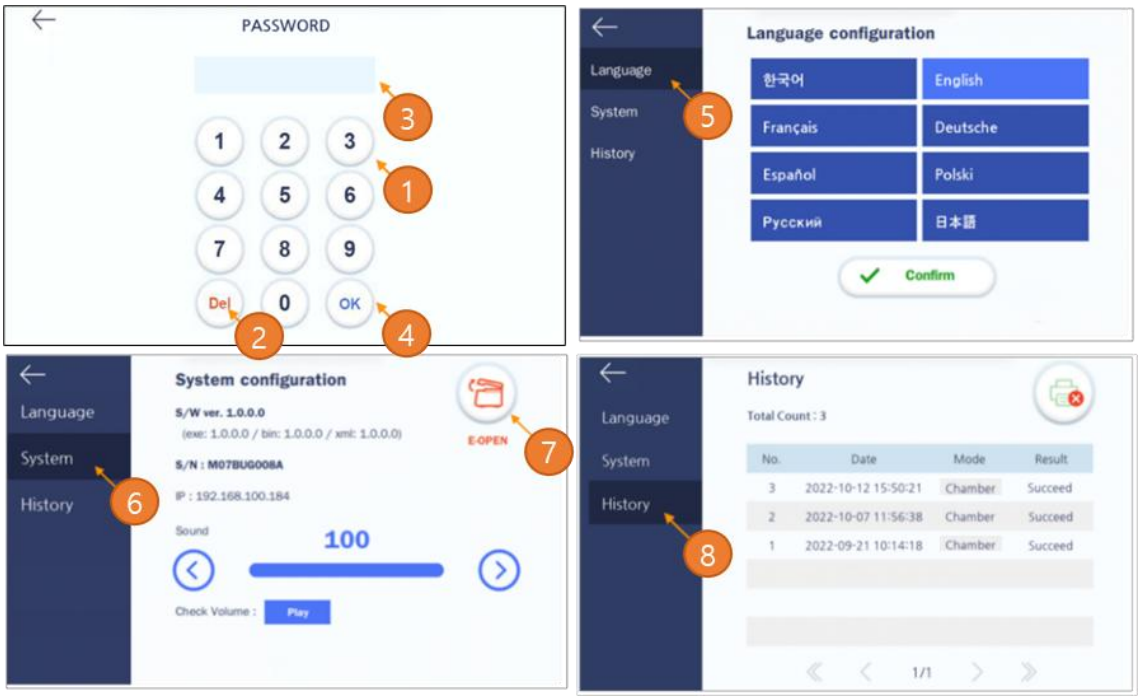


Fig. 6.1 Screens for system settings

No.	Name	Description
1	Number key	A number key is provided for entering the password and system settings.
2	Del key	It deletes the entered number.
3	Password display	It displays the entered password. The password is set to "1111" by default.
4	OK key	It confirms the entered password.
5	Language	The key is for changing the language. When the language changed, it will automatically reboot and the selected language will be applied.
6	System	The key is for viewing information on the device or adjusting the volume.
7	E-Open	If the chamber is not opened due to vacuum, the emergency vent button can be used to forced vent.
8	History	It shows the usage history of the equipment. Up to 80 usage histories are stored.



Warning! PRODUCT MANAGER ACCESS AUTHORIZATION

Additional utility functions including the “E-OPEN” functions, which are used when the door is not opened, is available only to trained administrators of this sterilizer.

Note:

- If the drain filter is dirty or blocked by other objects, the draining process will fail, and the door cannot be opened. When it occurs, this “E-OPEN” can be used to open the door. Note that this key is activating addition venting and it can take about 10 seconds. If the problems persist, please contact Plasmapp or your local Plasmapp customer support representative.

Chapter 7. Reports and Data

7.1. Reports

Upon completion of the sterilization cycle, the STERLINK plus Sterilization System automatically creates a cycle report. The completed report summarizes the information of the cycle date, time, process mode, and the result of the sterilization cycle.

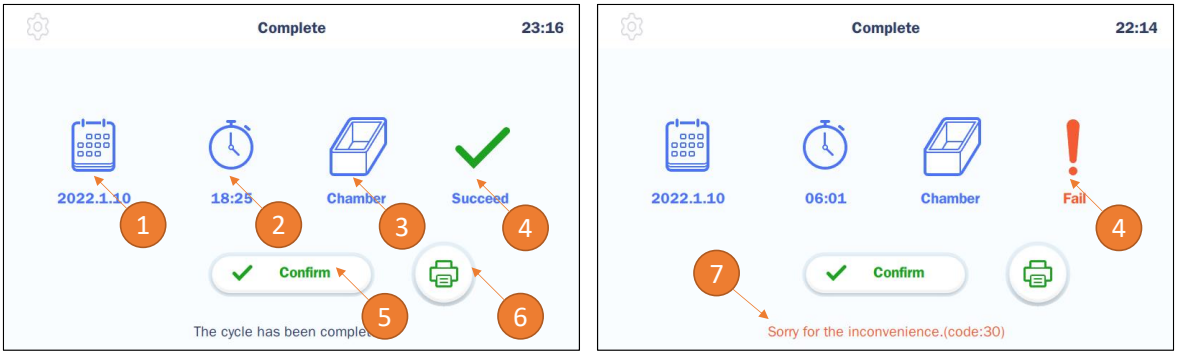


Figure 7.1 Screens for cycle report; succeed (left) and fail (right)

No.	Name	Description
1	Date	Displays the start date of the sterilization cycle.
2	Cycle time	Displays time for overall cycle time
3	Mode	Displays the mode of the finished sterilization cycle
4	Result	Displays the result of the sterilization cycle
5	Confirm	Clicks on “Confirm” button, the screen moves to ready state
6	Print	Clicks on “Print” button, the label printer will print out the summary of the sterilization cycle information
7	Description	The current status of the sterilizer is displayed.

When the user selects the Print button, the label printer prints a summary-format report that displays device status, sterilization cycle information, and cassette information. This summary report is useful for record keeping and label printing is convenient for tracking information by attaching it to sterile loads. The following figure is a sample of the sterilization cycle completion report.



Figure 7.2 report for passed and failed cycle

Printer paper is a heat transfer paper that can fade due to sunlight or high temperature exposure. To keep your records in the long run, copy or scan to keep a copy.

7.2. Data

The STERLINK plus Sterilizer System can create, store, display, and print the cycle data. When connected to the Internet, the sterilizer can upload the cycle history files to the ITS™ server. The cycle history file includes very detailed information on each SR™, sterilization cycles, and SC™. The information extracted from the cycle history file is used to print the report.

The history file is stored on the sterilizer. The sterilizer shows the data for the last 80 cycles. After the 80 cycles have been completed, the oldest cycle record is replaced with the new record of the 81st cycle. If the sterilizer is connected to the ITS™ server and the Internet, the cycle history data will be periodically uploaded to the server.

Chapter 8. Maintenance

The STERLINK plus is a top-class sterilizer for optimal sterilization cycles. The sterilizer can be damaged with continued use, so proper maintenance is required to ensure reliable sterilization cycles, including user safety. This chapter describes the functions and types of parts required to maintain the STERLINK plus sterilization system.

8.1. Manual Maintenance

The following maintenance procedures are performed by the user, when needed:

- Cleaning the exterior interior of the sterilizer
- Replacing printer paper
- Regular maintenance of the sterilizer

Replace if required for 3 months after new installation and regular replacement required every 12 months.

Note:

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERLINK plus sterilizer.
- Use of unauthorized parts for maintenance or repair could personal injury, result in costly damage, or sterilizer malfunction and voiding of the warranty.

8.1.1. Cleaning the exterior interior of the sterilizer

The sterilizer exterior can be cleaned with a soft cloth and a mild, nonabrasive detergent solution if necessary. When cleaning the sterilizer exterior, follow the guidelines:

1. Turn off the power to the sterilizer before cleaning the exterior.
2. Never allow cleaning solution or water to enter the interior or chamber. Moisten a cloth with nonabrasive detergent solution and use the damp cloth to clean the surfaces.
3. Do not spray cleaning solution directly on the touch screen. Use a dampened cloth to clean the screen.

The sterilizer interior chamber can be cleaned with a soft cloth or damp soft cloth with no running water. When cleaning the sterilizer interior chamber, follow the guidelines.

1. Turn off the power of the sterilizer before cleaning the interior chamber.
2. Wait until the interior chamber has cooled down.
3. Never allow cleaning solution or water to enter the interior or chamber. Use only dry or damp cloth to gently clean the surface of the interior chamber.
4. Wait until the interior chamber is completely dry before staring the sterilizer

Note:

- When a user attempt to clean the chamber, door, or interior surface, the user must wear gloves and follow the guidelines.
- Failure to follow the guidelines may result in damage to the sterilizer and may void the warranty.



WARNING! STERILIZATION SURFACES.

At the end of a cycle, the interior of the sterilizer may be hot. Do not touch the inside of the chamber or door with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.



WARNING! WATCH OUT FOR HAND INJURIES.

The door of the sterilizer is designed to be opened and closed manually, which may cause injury to your hands. Be careful not to hurt your hands when opening and closing the door.



CAUTION! POSSIBLE DAMAGE ON THE STERILIZATION.

Do not use a steel brush (wire brush), steel foam (steel wool), or compounds and detergents containing chloride. These may damage the sterilizer. Remove all detergent, fabric or thread left in the chamber after cleaning.



WARNING! HYDROGEN PEROXIDE MAY BE PRESENT.

Wear latex, PVC (vinyl), or nitrile gloves whenever handling a load after a cycle cancellation or error occurrence. Hydrogen peroxide liquid may be present on the load or in the chamber.

8.1.2. Replacing the label-printer paper

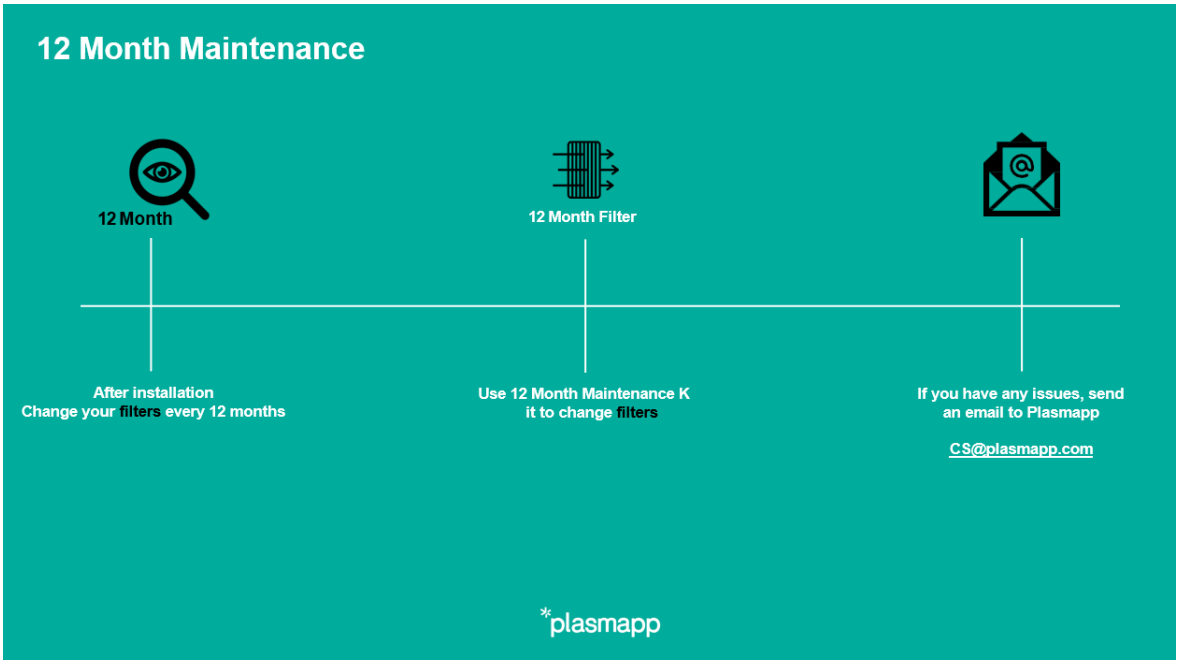
If the label printer roll is empty, replace the roll manually as follows:

1. While holding the body of the printer, press and open the front cover.
2. Press both sides of the middle cover to open it, revealing the label-printer roll.
3. Remove by pulling out the roll.
4. Insert new label-printer roll and close the middle cover and front cover.

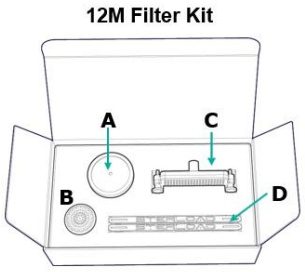
8.1.3. Routine sterilizer maintenance

The usage level of each registered sterilizer will be indicated in the user registered ITS™ system. When the usage level suggests for sterilizer maintenance, please contact your local Plasmapp customer support representative.

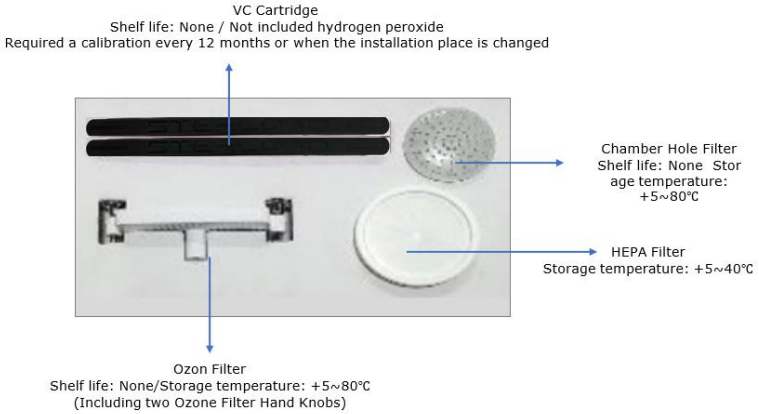
8.1.3.1 Routine sterilizer maintenance (Filter)



Maintenance Kits



A	HEPA Filter
B	Chamber Filter
C	Ozon Filter *(Two hand knobs)*
D	VC Cartridge





Filter Change Using Filter Kit

Changing HEPA Filter



1. Take out the new HEPA filter

2. Pull and remove existing HEPA filters

3. Slide the new HEPA filter into the h ole to replace it.

Changing Ozone Filter



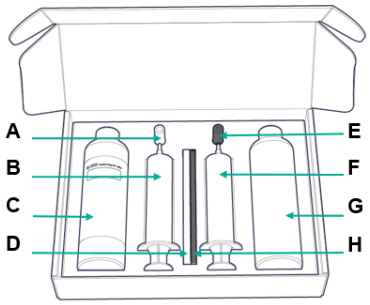
1. Ozone filter can be found on the left side of the product.

2. Remove the Knobs

3. Remove the Ozone filter and replace it with new Ozone filter

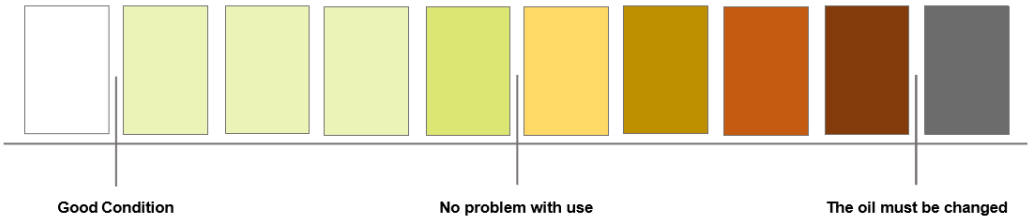
8.1.3.2 Routine sterilizer maintenance (Oil)

Oil Change Kit



A	New oil injection silicon adapter (white)
B	New oil injection syringe
C	New oil bottle
D	New oil injection tube (transparent)
E	Extracted oil injection silicon adapter (black)
F	Extracted oil syringe
G	Extracted oil bottle
H	Waste oil extraction tube (black)

※CAUTION: Even if the color of the oil has not changed murky, it must be replaced after a year.
For example, like engine oil in a car, the oil may oxidize and deteriorate over a certain period of time, causing problems with the operation of the device.



Oil Change Using Oil Kit



8.2. Sterilant Cassettes

Hydrogen peroxide (formula: H_2O_2) contained in the cassettes of STERPACK™ plus and STERLOAD™ is designated as a dangerous and hazardous medical waste by the American Environment Protection Association and should be disposed of in accordance with applicable local regulations. (U.S. Waste Disposal Regulations: U.S. EPA 40 CFR 262)



CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.

If a cycle cancels and the items in the load appear wet, hydrogen peroxide may be present. Wear latex, PVC (vinyl), or nitrile gloves while removing the items from the chamber and wiping off the items with a damp cloth.

8.3. Shipping, Long-Term Shutdown, and Disposal of the Sterilizer

8.3.1. Shipping, long-term shutdown, and disposal of the Sterilizer

The relocation of the STERLINK plus Sterilizer System is to be handled by authorized technicians only. If continuous sterilization is no anticipated, turn the power switch on the sterilizer off, and pull the power cord from the power outlet. The system should be stored under the conditions outlined in the table below:

Name	Value
Humidity	Below 90%
Atmosphere pressure	80 – 106 kPa
Temperature	Shipping: -29 – 50℃ Storage: 0 – 45℃

When the system is reactivated after long stop, the user shall contact the manufacturer of the sterilization system and the authorized person of the manufacturer to take a proper instruction. Moreover, the equipment shall not be reinstalled where the power cord is difficult to handle.

In the event that disposal of the system is necessary, the system may be return to the manufacturer, recycled with a local recycler, or disposed of in a local landfill. Disposal of infectious waste and electronic circuit boards are regulated by the U.S. Environment Protection Agency and most international environmental agencies. Please contact Plasmapp or your local Plasmapp customer support representative for additional information.

8.3.2. How to store the sterilizer

Be sure to store the product in a location that meets the following requirements:

- A location with adequate space in consideration of the movements of personnel who use the product.
- Keep the product out of contact with the floor.
- A well-ventilated location with lighting that is suitable for handling the product.
  - The lighting should be bright enough to ensure the proper functioning of the device.
  - When direct sunlight shines through the window, install curtains or blinds.
  - Ventilation greatly affects product quality and users' hygiene, so consider using an air conditioning device, if necessary.
- A location equipped with insect & rat repellent facilities and fire extinguishing facilities
  - Install traps in drains and seal areas that pass through the walls, install insect screens at exhaust and ventilation openings, etc.
- The temperature should be between -10℃ and 55℃, and the humidity level should be kept below 90%.

8.3.3. How to handle and distribute the sterilizer

Pay attention to the instructions below to avoid any damages and quality problems caused by carelessness in handling and distributing the sterilizer.

- Keep it away from direct sunlight during handling and distribution.
- Pay attention to safety conditions, such as inclination, vibration, shock, etc.
- . Keep it away from places where chemicals are stored, or where gases are generated.
- Load it with the arrow printed on the box side up.
- Do not stack them in more than 3 tiers in the distribution process.
- Do not use the hook when moving the product or moving it in the packaging box.



CAUTION! DO NOT CARRY ALONE.

Because this product is heavy, it should be carried and moved by two or more people.

Chapter 9. Troubleshooting

Most sterilizer operating problems are accompanied by a system message. These messages are useful in determining the source of the problem. In many causes you can take remedial actions to correct the source of the problem and thereby return the sterilizer to normal operation. If you are unable to identify the cause and solve the problem, please contact Plasmapp or your local Plasmapp customer support representative.

9.1. System Functions

The STERLINK plus sterilization system implements fully automatic sterilization cycles. The system indicates the status of the sterilizer with green, blue and orange LEDs, as follows:

LED color	Status
Green	Ready to sterilize (flashing during the preheating process)
Blue	Completion of the sterilization cycle (flashing during the sterilization cycle)
Orange	Light on when an error occurs



Figure 9.1 Sterilizer status with difference LED colors

9.2. User Errors

The STERLINK plus Sterilization System is designed to show intuitive figures of likely causes for user errors and provide warning messages. Therefore, the user should be able to identify and understand such errors. If the problem persists, please contact Plasmapp or your local Plasmapp Customer Support Representative.

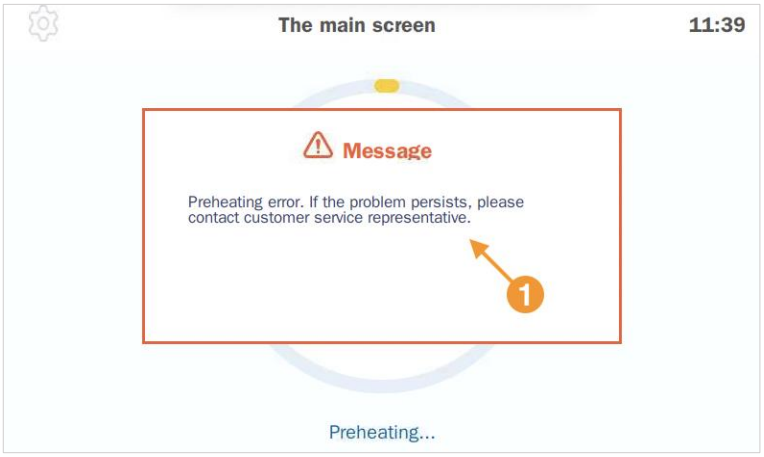


Figure 9.2 Screen showing user errors

No.	Name	Description
1	Error Message	Message appears if an error occurs

9.3. Sterilant Cassettes Errors

The STERLINK plus Sterilization System is designed to automatically initiate a sterilization cycle according to the barcode information provided on the sterilant cassettes. For barcode-related errors, the cause is visually displayed.

Notes.

- A Pre-heating error occurs if the unit is not warmed up to 40 minutes after booting.
- An Initializing error occurs if the cassette is re-used, expired, or invalid. Please check cleanliness of the scanner glass inside the sterilizer chamber and try again with a new cassette.
- Initializing error occurs if the chamber door is open.
- If the load prepared with too much moisture, an error message can be displayed to stop the sterilization cycle. The load should be dried and try again with a new cassette.

Many system errors are related to load issues. However, problems can arise due to malfunction of the STERLINK plus sterilization system. If the problems persist, please contact Plasmapp or your local Plasmapp customer support representative.



WARNING! POSSIBLE NON-STERILE DEVICE.

Any error may result in a non-sterile medical device, and it requires to restart a new sterilization cycle with rewrapping using new packaging material.



CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.

Any error may result in failure of removing hydrogen peroxide. Wear latex, PVC (vinyl), or nitrile gloves when handling the loads and cassette.

9.4. Self-Diagnosis Function

Problems can be caused by a malfunction of the STERLINK plus Sterilization System, including user errors, sterilization cassettes-related errors, and other system errors described above. If you click the “History” button on the initial screen, you can check the details of the malfunctions (Error Codes) on the “History” screen and take necessary actions by referring to the Error List below. If the problem persists, please contact Plasmapp or your local Plasmapp customer support representative.

[ERROR LIST]

CODE	Description
10	When the temperature of the chamber and vaporizer fails to reach the appropriate range
11	When the power is abnormally shut down during the process
12	When the system is stopped by a user
13	When the chamber’s door is not closed tightly
15	When the STERPACK™ plus is not sealed completely
21	When attempting to operate with reused the STERPACK™ plus and STERLOAD™
22	Expired the STERPACK™ plus and STERLOAD™ is used
23	When the barcode of the STERPACK™ plus and STERLOAD™ is invalid
24	When the barcode recognition of the STERPACK™ plus and STERLOAD™ is not good
25	When the barcode not compatible for STERLINK plus is recognized
30	Poor formation of a vacuum (standard)
40	Poor injection of the sterilant
50	Poor diffusion of the sterilant

Attachment A. Warranty

1. Purpose of warranty

This warranty certificate is issued by Plasmapp Co., Ltd. (″the Company″) to assure customers of the product quality and reliability. It guarantees the product against defects in materials or workmanship that occur under normal use conditions for a specified period of time.

2. Period of warranty

The Company warrants to the original end-use purchaser that, for a period of one (1) year from the date of installation, the Product will be reasonably free of defects in materials and workmanship. Upon expiration of the warranty period, any repair or replacement of parts shall be subject to a service charge to be borne by the customer

3. Scope and coverage

① If the product is used under normal operating conditions, the Company warrants that it will be free from defects in manufacturing or parts during the warranty period.
② The Company's warranty obligation is limited to the repair or replacement of defective components with new or equivalent parts that ensure equal performance.
③ The decision to repair or replace the defective part or product shall be at the sole discretion of the Company.

4. Exclusions

This warranty does not apply to the following cases;
① Malfunction or damage caused by user negligence, misuse, unauthorized modification, or improper repair.
② Damage due to mishandling, dropping, or transportation accidents.
③ Malfunction or damage caused by the use of consumables not supplied or approved by the Company.
④ Failure or damage resulting from the customer's refusal to allow inspection requested by the Company.
⑤ Malfunction caused by failure to comply with the Company's maintenance instructions or service conditions.
⑥ Normal wear and tear, aging, or deterioration of consumable parts under ordinary use.
⑦ Damage or malfunction caused by natural disasters such as fire, salt corrosion, harmful gases, abnormal voltage, lightning, or earthquake.
⑧ Malfunction or damage resulting from failure to follow the operating instructions or safety precautions provided in the user manual.

5. Other provisions

① This warranty certificate is provided at the time of product sale and will not be reissued.
② The content of this warranty is subject to change in accordance with applicable laws and the Company's quality assurance policy.

Plasmapp Co., Ltd.



Attachment B. Cassettes, Consumables, and Accessories

B1. Sterilant Cassettes

Name	Descriptions/Specifications	Figure
STERPACK™ plus	Cassette containing sterilant for pouch plus mode - Pouch material: CPP/Nylon® - Nozzle material: PP - Sterilant: Hydrogen peroxide (concentration: 58-59.5%) - Single-use, 30 cassettes per box	
STERLOAD™	Cassette containing the sterilant for the chamber mode. - Made of: ABS - Sterilant: Hydrogen peroxide (concentration: 58~59.5%) - Single-use, 30 cassettes per box	

B2. Consumables

Name	Descriptions/Specifications	Figure
Tyvek® Roll	Sterilization Pouch for CHAMBER mode - Pouch Width: 400 mm - Total length: 100 M - Made of: Tyvek®, and PET/LLDPE film - Customized cut per cycles, 100 M per box	

B3. Monitoring system

Name	Descriptions/Specifications	Figure
Test pack (PCD) for pouch plus mode	Process challenge device for sterilization cycle monitor - Material: Polycarbonate (PC) - Length: 77 mm	
Test pack (PCD) for chamber mode	Process challenge device for sterilization cycle monitor - Material: Polycarbonate (PC) - Length: 84 mm	
Self-Contained Biological Indicator	Biological indicator for sterilization cycle monitor (BT96, Terragene®) - Spore: *Geobacillus stearothermophilus* ATCC 7953 - Population: ≥ 10^6 - Spore carrier: Polyethylene fibers - Fluorescence readout available (30 min)/pH color change (48 h)	
Incubator	Incubator (Mini-Bio, Terragene®) - Size: 154 mm × 105 mm × 180 mm - Power: 28 W - Weight: 0.9 kg - Fluorescence readout (30 min)	
Chemical Indicator Tape	Chemical indicator for sterilization cycle monitor (CT40, Terragene®) - Tape width: 20 mm - Length: 50 M	
Chemical Indicator Strip	Chemical indicator for sterilization cycle monitor (CD42, Terragene®) - Size: 18 mm × 105 mm - Packaging: 250 strips per case	

B4. Accessories

Name	Descriptions/Specifications	Figure
Cart	**Cart with locking wheels** - Size: 483 mm (W) × 660 mm (D) × 603 mm (H) - Weight: 37 kg - Made of: Stainless steel	
Label-Printer	**External thermal transfer printer** - Size: 120 mm (W) × 102 mm (D) × 146 mm (H) - Weight: 0.5 kg - Width of thermal transfer paper: 56 mm	
Label sticker Roll	**Label sticker roll for a label printer** - Roll width: 56 mm - Roll Length: 49 labels - Packing unit: 6 roll/box	

Attachment C. Product Specifications

C1. General information

(1) Product name: Low temperature plasma sterilizer

(2) Model: STERLINK plus

(3) Life Cycle : 15 years

(4) Manufacturer

■ **Legal Manufacturer**

Plasmapp Co., Ltd.	
Address	A-1005, 10F, 670, Daewangpangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13494, Republic of Korea
Phone	+82-1544-0508
Website	http://plasmapp.com

■ **Contract Manufacturer**

Zero Hitech CO., LTD., Factory 2	
Address	42, Udeung-gil, Hyangnam-eup, Manse-gu, Hwaseong-si, Gyeonggi-do, Republic of Korea

C2. Technical specifications

Classification	Description (Performance and Specifications)			Unit
Dimensions	433 (W) × 614 (D) × 437 (H)			mm
Chamber volume	14			liter
Cycle time	Pouch plus mode	SR™ / SC™ Process	6	min
		Sterilization Process	8	
		Full Cycle	14	
	Chamber Mode	SR™ / SC™ Process	21	
		Sterilization cycle	15	
		Full cycle	36	
Sterilization method	Sterilant: Hydrogen peroxide (concentration: 58-59.5%) Injection/penetration, diffusion, and purification by plasma			
Sterilization pressure	Base Pressure	≤ 3.0		torr
	Pressure Leak-rate	≤ 6		torr/min
Maximum temperature of the sterilization cycle	≤ 60			ºC
Display	800×480 Resolution / 7-inch TFT LCD Touch Screen			-
Power supply	100-120 VAC, 50/60 Hz			-
Max. power consumption	1.5			kVA
Protection against electric shock	Class 1 (Protection against electric shock)			-
EMC standards	IEC 60601-1-2			-
Classification of test product	Type 1, Class A, non-life-sustaining devices or systems; Do not intentionally use RF electromagnetic energy, No RF transmission/reception, used in non-shielding locations, No control, monitoring, or measurement of physiological factors			-

Attachment D. Electromagnetic Compatibility Information

Phenomenon	Basic EMC standard or test method	Test level /requirement
Mains terminal disturbance voltage	CISPR 11 EN 55011	Group1, Class A
Radiated disturbance	CISPR 11 EN 55011	Group1, Class A
Electrostatic Discharge Immunity	IEC 61000-4-2 EN 61000-4-2	± 8 kV/Contact ± 2, ± 4, ± 8, ± 15 kV/Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3 EN 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3 EN 61000-4-3	Table 9 in IEC 60601-1-2: 2014 +A1:2020
Immunity to proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz	IEC 61000-4-39 EN 61000-4-39	134.2 kHz: 65 A/m, PM 2.1 kHz 13.56 MHz: 7.5 A/m, PM 50 kHz
Electrical Fast Transient/Burst Immunity	IEC 61000-4-4 EN 61000-4-4	± 2 kV, 100 kHz repetition frequency
Surge Immunity	IEC 61000-4-5 EN 61000-4-5	Line to Line ± 0.5 kV, ± 1 kV Line to Ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6 EN 61000-4-6	3 V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8 EN 61000-4-8	30 A/m 50 Hz and 60 Hz
Voltage dips	IEC 61000-4-11 EN 61000-4-11	0 % U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11 EN 61000-4-11	0 % U_T; 250/300 cycle

Revision

Revision No.	Revision History	Revision Date
00	Initial release	2023.06.17
01	- Reflect Website Address and US CS Information - Added Maintenance Kit for US users	2023.10.12
02	- Technical specifications Reflect on the latest	2023.10.16
03	- Address change - Add Legal Manufacturer, Contract Manufacturer	2025.09.24
04	- Address change - Warranty Update	2026.11.03

User Manual for STERLINK plus Sterilization System

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- This user manual is not for sale. -