STERLINK™

FPS-15s Plus

User Manual

Low Temperature Plasma Sterilizer

Plasmapp Co., Ltd.

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FPS-15s Plus Sterilization System

User Manual

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Plasmapp International Customer Support

(Contact your local Plasmapp Customer Support Representative)

http://plasmapp.com

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Chapter 1. Introduction

1.1. How to Use This Manual

A user of the STERLINK™ FPS-15s 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™ FPS-15s 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™ FPS-15s 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. Manufacturer

Company Name	Plasmapp
Add.	(41061) 102, Cheombok-ro, Dong-gu, Daegu, Republic of Korea
Phone	+82-1544-0508
Website	http://plasmapp.com

1.3.2. Customer Service Center

Company Name	Plasmapp
Add.	(06611) 59, Seocho-daero 77-gil, Seocho-gu, Seoul, Republic of Korea
Phone	+82-1544-0508
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.

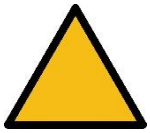
At the end of a cycle, the interior of the sterilizer may be hot. Do not touch the inside of the chamber or door with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.

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™ FPS-15s Plus Sterilizer System.

2.4. 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™ FPS-15s Plus Sterilization System is a Low Temperature Plasma Sterilizer for inactivating microorganisms that remain in metal and non-metal medical appliances and surgical instruments at low temperature. It is effective, safe, fast, affordable, easy to use, and reliable by providing a variety of sterilization solutions.

When using the sterilizer in accordance with the instructions specified in this user manual, be sure to carefully read 'Chapter 4 Preparation of Medical Devices', which describes allowable medical device materials and lumen sizes. When choosing a reusable medical device to be operated on this sterilizer system, you should obtain the information from the manufacturer in accordance with International Norms (ISO 17774 or AAMI TIR 12).

▌Product Ratings and Specifications

Item	Specifications/Conditions
Voltage	220 ~ 240 VAC
Rated frequency	50 / 60 Hz
Max. power consumption	1.0 kVA
Operating temperature	10 ℃ ~ 40 ℃
Humidity	Relative humidity of 30 ~ 85%
Atmospheric Pressure	70 ~ 106 kPa
Replaceable fuse	Fuse 250V / 10A

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™ FPS-15s 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 chambers or pouches. 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™ FPS-15s Plus Sterilization System is designed to operate in two different process modes, each of which is the sterilization cycle that combines Smart Ready (SR™) and Sterilization, Smart Complete (SC™) processes. This sterilizer system is designed to operate only in STERPACK™, STERPACK™ Plus, and STERLOAD™ Sterilization Cassette modes. Each 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 for each mode.

Sterilization cycle and minimum time by mode

Mode	Sterilization Cassette	Cycles and Minimum Process Time (in minutes)		
		SR™ / SC™	Sterilization process	Total
POUCH	STERPACK™	3	4	7
POUCH Plus	STERPACK™ Plus	6	8	14
CHAMBER	STERLOAD™	21	15	36

Sterilization process – Step 1

- Injection: Hydrogen peroxide is injected and vaporized from the cassette into the vaporizer, and fed into chambers or pouches. Specifically, the POUCH mode enables the rapid completion of the sterilization process within 10 minutes by feeding hydrogen peroxide directly into the pouch, thus maximizing sterilization efficiency.
- Diffusion: As the sterilant (Hydrogen Peroxide Vapor) 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 chamber and in the pouch of the sterilizer. The removed sterilant is purified through plasma treatment to ensure user safety. Particularly, the POUCH mode enables the rapid completion of the sterilization process by removing the sterilant directly from the pouch.

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™ FPS-15s Plus Sterilization System. The following figure shows the sterilizer system including the sterilizer cart and label-printer accessories.

Fig. 3.1 STERLINK™ FPS-15s 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).

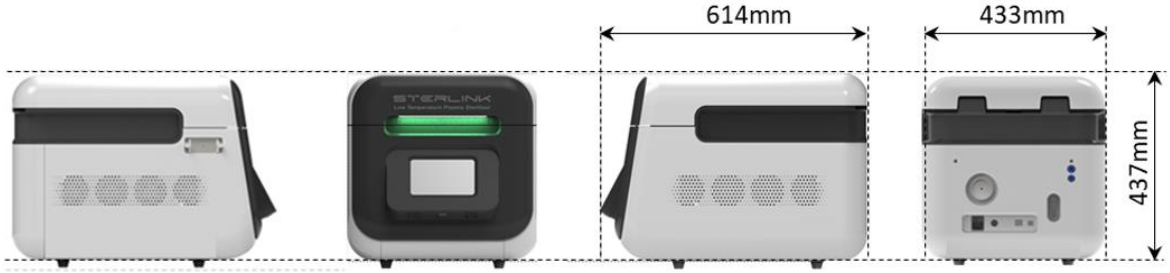


Fig. 3.2 STERLINK™ FPS-15s Plus Sterilization System

The STERLINK™ FPS-15s 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.

Fig. 3.3 Label Printer & Label Sticker Roll for the STERLINK™ FPS-15s 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™ FPS-15s Plus Sterilization System has three modes to automatically recognize barcodes that are printed on each Sterilant Cassette: STERPACK™, STERPACK™ Plus, and STERLOAD™. The barcode contains the information about the type and the manufacturing date of Sterilant Cassettes.

Fig. 3.4 Pouch Mode of STERPACK™ Sterilant Cassette

Fig. 3.5 Pouch Plus Mode of STERPACK™ Plus Sterilant Cassette

Fig. 3.6 Chamber Mode of the STERLOAD™ Sterilant Cassette

Each 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.

CAUTION! CHECK EXPIRY DATE.

Before using the sterilant cassettes (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™ FPS-15s Plus Sterilization System is designed for the sterilization of metallic and non-metallic medical devices at low temperatures. The process involves multiphase sterilization that combines the exposure to hydrogen peroxide vapor and plasma to complete the process.

The sterilizer is capable of sterilizing the instruments with limited diffusion space, such as the hinged part of forceps. You can use the STERLINK™ FPS-15s Plus sterilization cycle to sterilize the following medical instruments made from the acceptable materials, with specific dimensions.

- Single-channel stainless steel lumens with an inner diameter of 0.7 mm or more and a length of 500 mm or less
- Single-channel stainless steel lumens with an inner diameter of 2 mm or more and a length of 1,500 mm or less
- Single-channel PTFE lumens with an inner diameter of 1 mm or more and a length of 2,000 mm or less

WARNING! BE SURE TO UNDERSTAND THE STERILIZATION PROCESSES.

Before processing item(s) in the sterilizer, make sure you know how the STERLINK™ FPS-15s 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™ FPS-15s 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™ FPS-15s Plus Sterilization System is classified as 'Class IIb' 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™ FPS-15s 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™ FPS-15s 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™ FPS-15s Plus sterilizer by manufacturers

4.4. Instructions for Preparing the Items to Be Sterilized

All items should be cleaned, rinsed, and thoroughly dried before being put into the STERLINK™ FPS-15s Plus sterilizer. If a medical device with too much moisture is put into the sterilizer, the cycle may be automatically canceled.

4.5. 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.

4.6. Packing and Loading

By preparing appropriate trays, pouches, 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.

4.6.1. Sterilization Trays

It is recommended that you use only the manufacturer's dedicated trays and accessories for the STERLINK™ FPS-15s Plus Sterilization System. The sterilization tray is specially designed to facilitate the diffusion of hydrogen peroxide. Particularly, if you do not use a vacuum tray optimized for the POUCH mode, it may damage the pouch film, and eventually lead to cancellation of the sterilization cycle.

4.6.2. Tray Mat

Only sterilization wraps made of polypropylene can be inserted into the sterilization tray. Do not use linen, cellulose, or other materials specified in '4.3 Things that cannot be processed by the sterilization system'. Do not use foam pads because they can absorb hydrogen peroxide.

4.6.3. Packing

Packing should be done according to the following guidelines.

- In POUCH and POUCH Plus modes, you can select the one according to the size of the medical device to be packaged, and only the STERPACK™ or STERPACK™ Plus pouches are available.
- 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 tray carefully to ensure that hydrogen peroxide

diffuses evenly between the loaded items.

- If possible, keep the pouch upright. Arrange the pouches with the transparent side of the pouch facing the opaque side of the next pouch. Do not stack pouches on top of each other.
- Do not stack medical instruments inside the tray. Do not stack trays. Do not stack trays inside trays.
- If necessary, add some chemical indicators in the trays and pouches.

4.6.4. Loading

The cassette should be correctly mounted on the loading block of the STERLINK™ FPS-15s 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.

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, the Sterility Assurance Level cannot be guaranteed, and the sterilization cycle may be canceled in the POUCH Mode.

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™ FPS-15s 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 generated.
- 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™ FPS-15s 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 'Sterilize' icon will be displayed instead of 'Preheating' as shown below.

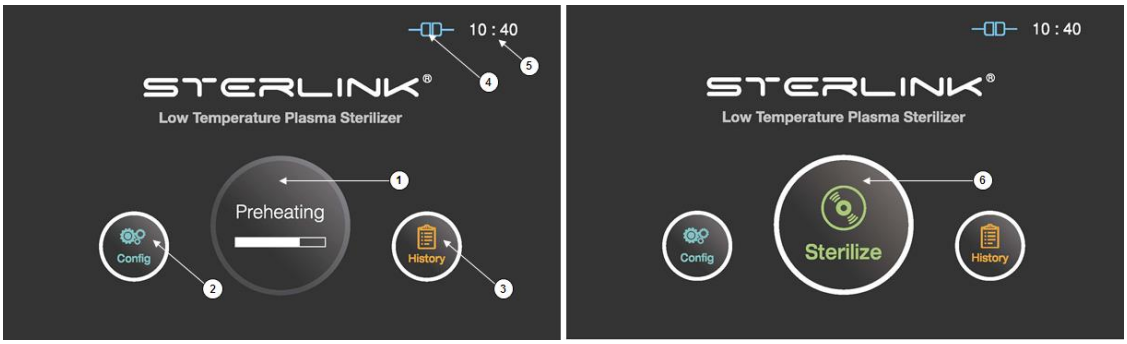


Fig. 5.1 Preheating and preparation processes displayed on the screen

No.	Name	Description
1	Preheating	For components that require temperature control of chamber or vaporizer, to make the product ready the product will be preheat.
2	Configuration	The display can be moved into the sterilizer's configuration setup by touching this configuration icon.
3	History	The display can be turned into the sterilization management window by touching this history icon.
4	ITS™ connection	This section displays the present status of ITS™ connection.
5	Time	The current configurable time is displayed in Configuration menu.
6	Sterilize	The sterilizer starts the sterilization cycle by touching this icon.

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.

Insert the biological indicators into the STERPACK™, STERPACK™ Plus, or STERLOAD™ chambers for the Pouch, Pouch Plus, or Chamber mode, respectively. 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	The total mass should be less than 0.5 kg.
POUCH Plus	The total mass should be less than 1.5 kg.
CHAMBER	The total mass should be less than 5.0 kg.

WARNING! FAILURE TO STERILIZE.

If the STERPACK™/STERPACK™ Plus is not completely sealed in POUCH and POUCH Plus Modes, the sterilization cycle may be canceled. Ensure a perfect sealing of STERPACK™/STERPACK™ Plus with a sealer that is supplied or recommended by Plasmapp.

CAUTION! DO NOT REUSE.

Sterilant Cassettes (STERPACK™, STERPACK™ Plus, STERLOAD™) are 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™, STERPACK™ Plus, 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. Mounting Cassettes

The STERLINK™ FPS-15s Plus sterilizer has three operating modes: STERPACK™, STERPACK™ Plus, and STERLOAD™ Sterilization Cassette. Mount the Sterilization Cassette on the loading block as shown in the figure below.

Fig. 5.2 Loading in STERPACK™ and 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. Place the medical instruments to be sterilized properly in the chamber, and make sure that the door is closed.
2. Press the 'Sterilize' 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.

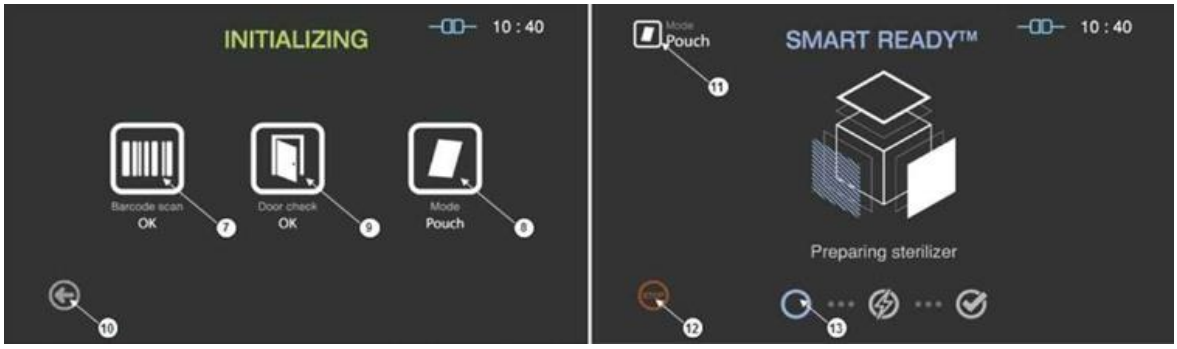


Fig. 5.3 Screen showing initialization and sterilization process

No.	Name	Description
7	Barcode	This section displays the barcode scanning result for the cassette loaded.
8	Mode	This represents the sterilization mode determined by the barcode.
9	Door	This section displays the door status.
10	Back	This icon is for cancelling the cycle.
11	Mode	This represents the mode of the sterilization cycle.
12	Stop	This icon is for stopping the cycle which is determined by the user.
13	Progress	This section displays the progress of the SR™ process.

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 canceled.
- 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

In the Smart Ready (SM)™ process, residual water, drying and heating, are measured and displayed as part of the load condition.

Fig. 5.4 Screens showing the drying and sterilization process.

No.	Name	Description
14	SR™ status	The status image will be blinking during the drying process.
15	Sterilization status	The status image will be blinking during the sterilization pr ocess.
16	Sterilization time	The remaining sterilization process time is displayed.

When the sterilization process has successfully completed, the smart complete(SC™) process is performed to ensure there is no residual sterilant remaining on the sterilized instruments. After the SC™ process, the sterilization cycle in finished, and a summary of the cycle result will be displayed. Press the confirm icon to return to the ready state.

Fig. 5.5 Screens showing the SC™ process and completed summary stage

No.	Name	Description
17	SR™ status	The status image will be blinking during the drying process.
18	Date	This section displays the date of the sterilization cycle.
19	Cycle time	This section displays time for overall cycle time (in minutes and seconds).
20	Mode	This section displays the mode of the finished sterilization cycle.
21	Result	This section displays the result of sterilization cycle.
22	Confirm	When the user presses the 'Confirm' icon, the screen moves to ready state.
23	Print	When the user presses the "Print" icon, the label printer will print out a summary of the sterilization cycle information.

5.7. Cancellation of the Sterilization Cycle

To cancel a cycle before it has been completed, touch the "STOP" icon. The screen will display a message to "confirm" or "cancel". Press the "confirm" icon to stop the sterilization cycle. Press the "cancel" icon to resume the sterilization cycle.

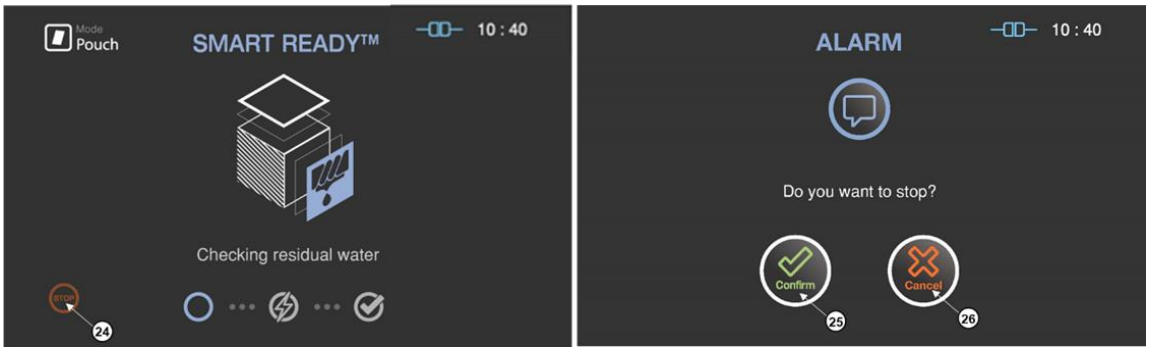


Fig. 5.6 Screen for one of the sterilization process and user confirm

No.	Name	Description
24	STOP	This icon is for cancelling the cycle.
25	Confirm	This icon is for confirming the cancellation.
26	Cancel	This icon is for withdrawing the cancellation.

Once the cycle cancellation has been initiated, it cannot be stopped by the user.

Fig. 5.7 Screen for one of the sterilization process and user confirm

No.	Name	Description
27	Caution for door handling	It highlights that door should not be handled by the user during the stopping process.
28	Caution for sterility	The status image will be blinking during the sterilization process.
29	User confirm	When the user confirm is selected, the screen moves to rea dy 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 materi

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.

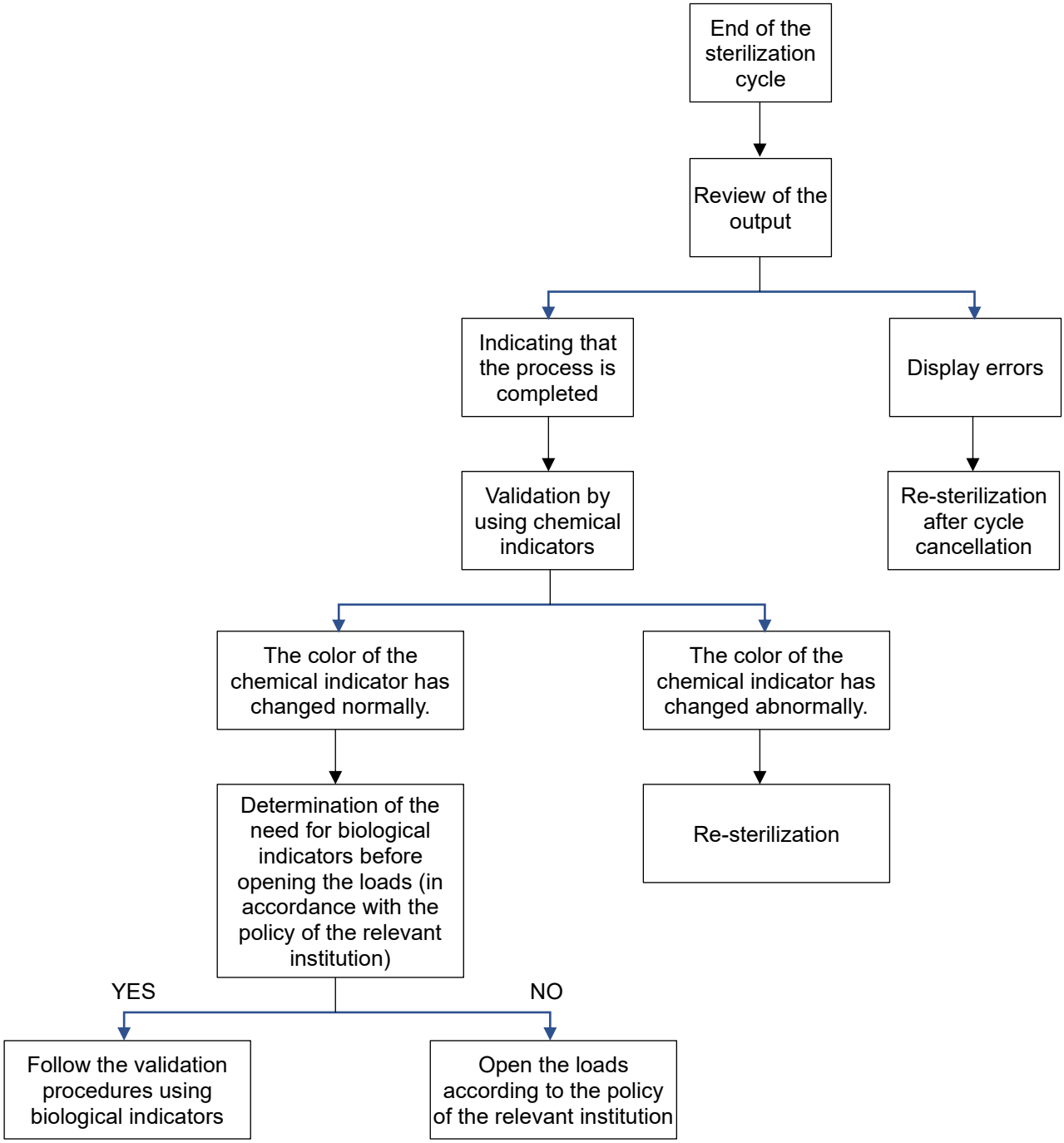
5.8.1. Inspecting chemical indicator

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.

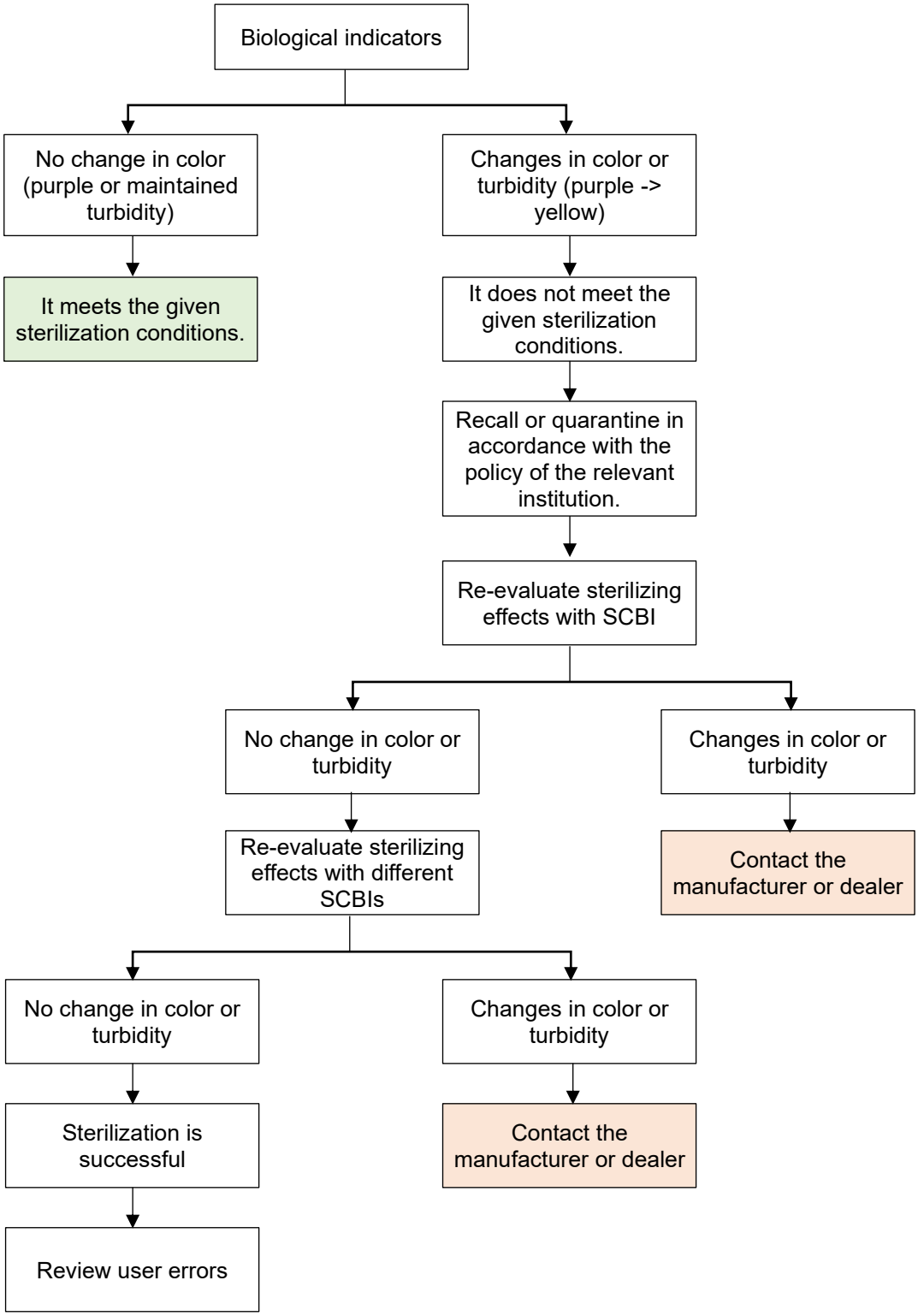
5.8.2. Disposal of biological indicators

Remove the biological indicator from the load 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™ FPS-15s Plus Sterilizer utilizes the embedded software for automated implementation of STERLINK™ FPS-15s Plus sterilization process. This chapter contains how to control the configuration of the STERLINK™ FPS-15s 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™ FPS-15s 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 configuration and system setting

No.	Name	Description
1	Number key	The number keys are provided for entering password and system setting.
2	Del key	The key is for deleting the number entered.
3	Password display	This section displays the password digit as '*'. The default setting for the password is "1111".
4	OK key	The key is for confirming the password.
5	Back	This icon is for going back to the user screen for ready.
6	Display selection	The display time for the screen saver can be selected by touching the circle icon.
7	Minus key	The sound volume can be decreased by touching this minus key.
8	Plus key	The sound volume can be increased by touching this plus key.
9	Sound bar	The sound bar displays the established volume.
10	Door open	When the door of the sterilizer cannot be opened, this function can open the door urgently.
11	Pump Heating	When the ambient temperature is low or the product is not used for long time, this function can start the preheating of vacuum

		pump.

Warning! PRODUCT MANAGER ACCESS AUTHORIZATION

Only administrators who had training on the sterilizer product can use the functions "Door open" and "Pump Heating" if the door cannot be opened or the pump doesn't work.

Note:

- The lifetime of the touch screen backlight is considerably increased by the screen protection function in which the sterilizer automatically will be turned off when it is not in use during the setting time.
- The time required to turn off the power is 15 minutes which is the factory default setting.
- When the venting filter is contaminated or blocked with other object, the venting process can fail, resulting in the door not opening. If this occurs, the "Door open" can be used to open the door. Note that this key is activating additional venting and can take about 10 seconds to complete. It the problems persist, contact Plasmapp or the local Plasmapp customer support representative.
- If the vacuum pump oil is not replaced regularly, or if the unit has not been used for a long period time or the frequency of use is lower than the standard mentioned is Chapter 8 "Maintenance" the unit may not function properly. The "Pump heating" function can be used to resolve this problem, which can take approximately 10 minutes to complete. If the problem persists, please contact Plasmapp or the local Plasmapp customer support representative.

Chapter 7. Reports and Data

7.1. Reports

Upon completion of the sterilization cycle, the STERLINK™ FPS-15s 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.

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

No.	Name	Description
1	Date	This section displays the date of the sterilization cycle.
2	Cycle time	This section displays the overall cycle time.
3	Mode	This section displays the mode of the finished sterilization cycle.
4	Result	This section displays the result of the sterilization cycle.
5	User confirm	When the user selects “confirm”, the screen moves to ready state.
6	Print	When the print icon is selected, the label printer will print out the summary of the sterilization cycle information.
7	Caution	This section describes caution information when the sterilizat ion fails.

When a user selects the 'Print' button, the label printer will print a summary report that shows the details on the device status, sterilization cycle, and cassette information. This summary report is useful for record keeping, and the label printing allows for convenient tracking of information on sterilized loads. The figure below shows an example of a summary report.

Fig. 7.2 Short format report for passed and failed cycle

Printer paper used is thermal transfer paper that is prone to fade due to exposure to sunlight or high temperatures. The shelf life of the printer paper is approximately 5 years. For long-term records storage, it is advised that a copy or scan of the report be made. The history can also be printed out by using the Instrument Tracking System (ITS™). The cycle information which is available at the history page of the ITS™ can be printed out in the short or long format depending on user purpose and choice. The long-format report is useful for detailed cycle quality control and contains valuable diagnostics information for customer service. The report includes the detailed information about the sterilization cycle, and operation parameters. Examples of the long-format report are illustrated in the

following figure.

Fig. 7.3 Long-format report for passed and failed cycle

7.2. Data

The STERLINK™ FPS-15s 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 STERLINK™ FPS-15s Plus sterilizer. The sterilizer shows the data for the last 50 cycles. After the 50 cycles have been completed, the oldest cycle record is replaced with the new record of the 51st 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™ FPS-15s 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™ FPS-15s 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

Note:

- Repairs and adjustments should only be attempted by experienced technicians who are fully trained to maintain and repair the STERLINK™ FPS-15s 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 c ancellation 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 sterilizer, disengage the front cover to reveal the label-printer roll.
2. Remove by pulling out the roll.
3. Insert new label-printer roll and close the 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.

8.2. Sterilization Cassette

Hydrogen peroxide (formula: H_2O_2) contained in the cassettes of STERPACK™, 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™ FPS-15s 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	30 – 85%
Atmosphere pressure	70 – 106 kPa
Temperature	10 – 40℃

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 40℃, and the humidity level should be kept below 85%.

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™ FPS-15s 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

Fig. 9.1 Sterilizer status with difference LED colors

9.2. User Errors

The STERLINK™ FPS-15s 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.

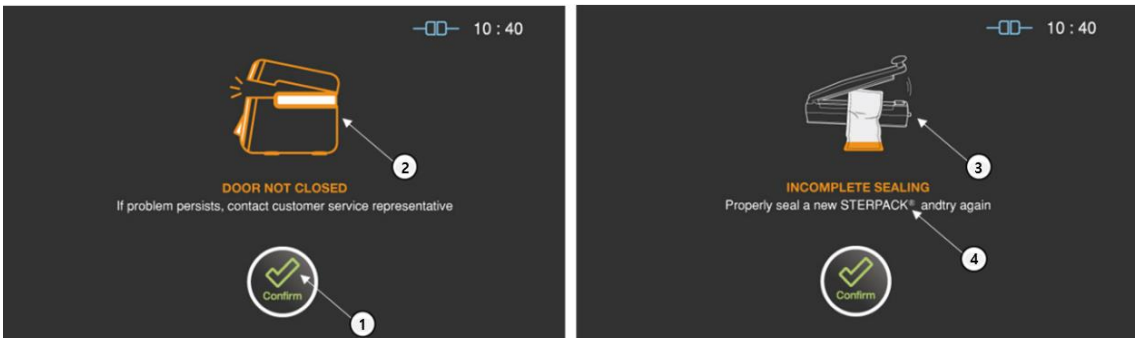


Fig. 9.2 Screen showing user errors

No.	Name	Description
1	Confirm	The user should confirm the error when the source of the problem is checked and understood.
2	DOOR NOT CLOSED	Probable cause: The door is not closed. Suggestion: Check door closing and try again.
3	INCOMPLETE SEALING	Probable cause: STERPACK™ is not comletely sealed. Suggestion: Seal a new STERPACK™ completely and try again.
4	Description	This section describes the cause and solution of the problem.

- The "Incomplete sealing" error may occur if the pouch is damaged by sharp medical instruments in POUCH mode, and it is recommended to use a dedicated tray.

9.3. Sterilant Cassettes Errors

The STERLINK™ FPS-15s 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.

Fig. 9.3 Screen showing the errors related with the sterilant cassettes

No.	Name	Description
5	Confirm	The user should confirm the reason of the error and press Confirm button.
6	USED CASSETTE	Probable cause: The cassette has been previously used. Suggestion: Try again with a new cassette.
7	EXPIRED CASSETTE	Probable cause: The cassette is expired. Suggestion: Try again with a new cassette or check time settin g.
8	INVALID CASSETTE	Probable cause: The barcode of the cassette is invalid. Suggestion: Try again with a new cassette.

9	BARCODE NOT DETECTED	Probable cause: The cassette is not detected. Suggestion: Clean the barcode window or try again.

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. Other system errors

While system errors may be a result of problems with the load, they can also arise from a component failure. If the problem persists, contact Plasmapp or the local Plasmapp service representative.

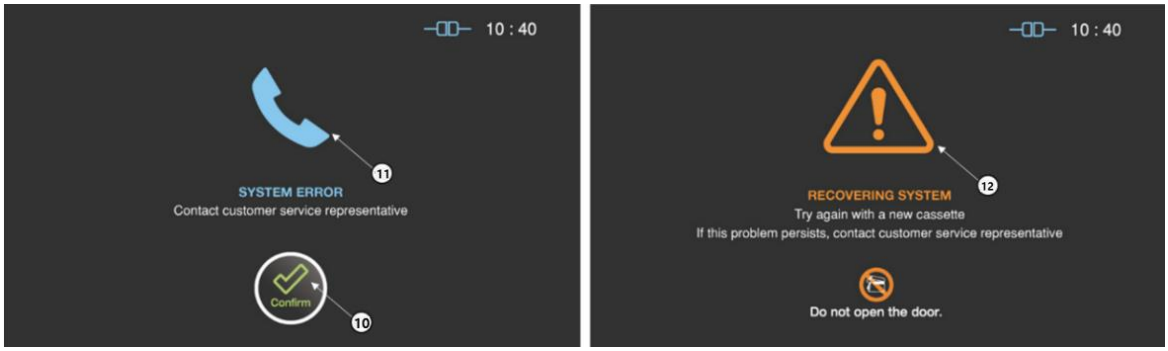


Fig. 9.4 Screen showing the system error

No.	Name	Description
10	Confirm	The user can confirm this system error after contacting customer service representative.
11	SYSTEM ERROR	Probable cause: A component failure results in preheating error. Suggestion: Contact the customer service or restart the system.

12	SYSTEM STABILIZING	Probable cause: A component failure results in completing the cycle. Suggestion: Wait until recovering system and try again.

Note:

▪ Repairs and adjustments should only be made by the trained and authorized personnel.

▪ If the door cannot be opened after the sterilization cycle has completed, refer to Section 6.3 for "Additional utility menu" options which can be used to temporarily open the door. If the problems persist, contact 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.

9.5. Self-Diagnosis Function

Problems can be caused by a malfunction of the STERLINK™ FPS-15s 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 door is not closed tightly
15	When STERPACK™ has a damaged pouch or poor sealing
21	When attempting to operate with reused STERLOAD™ / STERPACK™
22	Expired STERLOAD™ / STERPACK™ is used
23	When the barcode of STERLOAD™ / STERPACK™ is invalid
24	When the barcode recognition of STERLOAD™ / STERPACK™ is not good
30	Poor formation of a vacuum(standard)

40	Poor injection of the sterilant
50	Poor diffusion of the sterilant

Attachment A. Warranty

1. The manufacturer, Plasmapp Co., Ltd., warrants the STERLINK™ FPS-15s Plus Sterilization System to be free from any defects in materials and workmanship for one year from the date of delivery.

2. The warranty is limited to manufacturing defects or defects occurring in normal use. You should identify the defect, and notify the manufacturer to avail of a warranty.

3. The warranty does not cover the repairs or replacements caused by abnormal uses, including damage or breakage caused by a user's careless handling, neglect, non-compliance with the manufacturer's maintenance guidelines, etc.

4. In addition, each of the following will void the warranty: (i) any part that has been changed due to arbitrary disassembly, modification, or repair after delivery; (ii) the serial number is removed or changed after delivery; (iii) non-compliance with the manufacturer's recommended operating instructions and maintenance procedures; (iv) normal wear and tear over time; and, (v) breakage and damage caused by natural disasters or fire.

5. Even under the warranty period, if such problems are beyond the scope of the warranty requirements presented herein, repairs will be provided at a cost.

CEO of Plasmapp Co., Ltd., Lim Yu-bong

Attachment B. Cassettes, Consumables, Trays, and Accessories

B1. Sterilant Cassettes

Name	Descriptions/Specifications	Fig.
STERPACK™	Impermeable pouch containing the sterilant for the POUCH mode. Store at room temperature between 15-30℃(59-86℉). Keep away from sunlight. - Made of: PP/NY - Sterilant: Hydrogen peroxide (Concentration: 58~59.5%) - 1 pouch per cycle, 50 cassettes per box	
STERPACK™ Plus	Impermeable pouch containing the sterilant for the POUCH Plus mode. Store at room temperature between 15-30℃(59-86℉). Keep away from sunlight. - Made of: PP/NY - Sterilant: Hydrogen peroxide (Concentration: 58~59.5%) - 1 pouch per cycle, 30 cassettes per box	
STERLOAD™	Cassette containing the sterilant for the CHAMBER Mode. Store at room temperature between 15-30℃(59-86℉). Keep away from sunlight. - Made of: ABS - Sterilant: Hydrogen peroxide (concentration: 58~59.5%) - 1 pouch per cycle, 30 cassettes per box	

B2. Consumables

Name	Descriptions/Specifications	Fig.
Tyvek™ Pouch (W100)	STERILIZATION POUCH FOR CHAMBER MODE - Pouch Width: 100 mm - Total length: 400 mm - Made of: Tyvek™, Easy-Peel film - 1 pouch per cycle, 120 pouches per box	
Tyvek™ Pouch (W200)	STERILIZATION POUCH FOR CHAMBER MODE - Pouch Width: 200 mm - Total length: 400 mm - Made of: Tyvek™, Easy-Peel film - 1 pouch per cycle, 90 pouches per box	
Tyvek™ Pouch (W300)	Sterilization Pouch for CHAMBER mode - Pouch Width: 300 mm - Total length: 400 mm - Made of: Tyvek™, Easy-Peel film - 1 pouch per cycle, 60 pouches per box	

B3. Dedicated Trays

Name	Descriptions/Specifications	Fig.
STERPACK™ Tray	Dedicated vacuum tray optimized for high vacuum sterilization for STERPACK™ - Size: 195 mm (W) x 80 mm (D) × 30 mm (H) - Weight: 0.15 kg - Made of: Aluminum - For STERPACK™ only	
STERPACK™ Plus Tray	Dedicated vacuum tray optimized for high vacuum sterilization for STERPACK™ Plus - Size: 260 mm (W) x 160 mm (D) × 50 mm (H) - Weight: Approx. 0.6 kg - Made of: Aluminum - For STERPACK™ Plus only	
Chamber Tray	Tray inside the chamber - Size: 350 mm (W) x 250 mm (D) × 105 mm (H) - Weight: Approx. 0.4 kg - Made of: Aluminum	

B4. Accessories (Optional)

Name	Descriptions/Specifications	Fig.
Cart	**Cart with locking wheels** - Size: 483 mm (W) × 660 mm (D) × 603 mm (H) - Weight: 43 kg - Made of: Stainless steel	

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	
Printer Roll	**Label sticker roll for a label printer** - Roll width: 56 mm - Roll Length: 49 labels - Packing unit: 6 roll/box	
Chemical Indicators (CI Tape)	**Chemical indicators for checking the sterilization cycles** - Tape width: 20 mm - Length: 50 m - Expiration date: Refer to the date indicated on the product	
Chemical Indicators (CI Strip)	**Chemical indicators for monitoring the sterilization cycle** - Size: 18 mm (W) x 105 mm (L) - Packing unit: 250 strips per case - Expiration date: Refer to the date indicated on the product	
Biological Indicators (BI)	**Biological indicators to determine whether or not the sterilization cycle is successful** - Size: Tube 50.4 mm (H) x Φ8.5 mm / Cap 16.4 mm (H) x Φ10.5 mm - Packing unit: 50 EA/box - Expiration date: Refer to the date indicated on the product label	
Biological Indicators' Incubator (BI Incubator)	**Incubator of biological indicators to determine whether or not the sterilization cycle is successful** - Size: 180 mm (H) x 154 mm (W) x 105 mm (D) - Voltage range: 100 ~ 240V AC - Power: 28 W	

Attachment C. Product Specifications

C1. General Information

(1) Product Name: Low Temperature Plasma Sterilizer

(2) Model: FPS-15s Plus

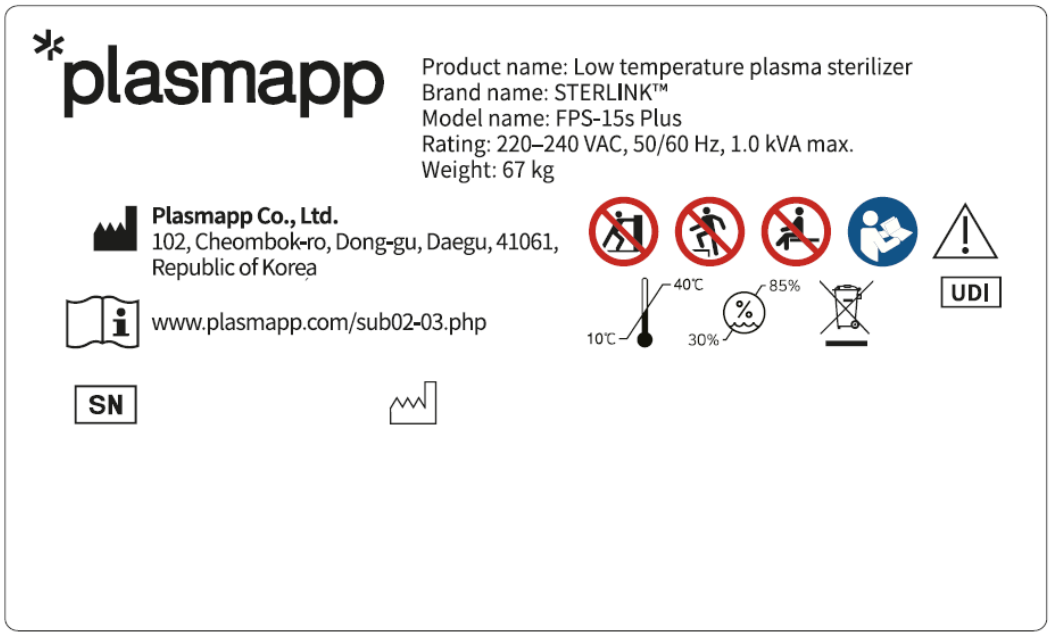
(3) Manufacturer

Company Name	Plasmapp
Add.	(41061) 102, Cheombok-ro, Dong-gu, Daegu, Republic of Korea
Phone	+82-1544-0508
Website	http://plasmapp.com

(4) Purpose: Plasma Sterilization of Medical Instruments at Low Temperature

(5) Label sticker: It should be attached at the back of the sterilizer (refer to the following Fig.)

Specification 1. FPS-15s Plus (sample)



*The countries list is not exhaustive and only provides examples where the system could be used. Please contact your local Plasmapp customer support representative.

C2. Technical specifications

	Description (Performance and Specifications)			Unit
Size	433 (W) × 614 (D) × 437 (H)			mm
Chamber capacity	14			liter
Min. time for the process cycle	Pouch Mode (STERPACK™)	SR™ / SC™ cycle	3	min
		Sterilization cycle	4	
		Full cycle	7	
	Pouch Plus Mode (STERPACK™ Plus)	SR™ / SC™ cycle	6	
		Sterilization cycle	8	
		Full cycle	14	
	Chamber Mode (STERLOAD™)	SR™ / SC™ cycle	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	≤ 0.1		torr/sec
Pressure range	0 - 760			torr
Temperature of the sterilization cycle	≤ 60			°C
Display	7-inch TFT LCD touch screen			-
Power supply	220~240 VAC, 50/60 Hz			-
Max. power consumption	1.0			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

User Manual for STERLINK™ FPS-15s Plus Sterilization System

 **Manufacturer: Plasmapp Co., Ltd.**

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