plasmapp

GC STERLINK™ mini

User Manual

Low-temperature plasma sterilizer

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GC STERLINK mini Sterilization System

User Manual

Plasmapp Co., Ltd.
102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea

Plasmapp International Customer Support
(Call your local Plasmapp Customer Support Representative)

Plasmapp Customer Center +82-1544-0508

https://plasmapp.com/eng/

Content

Chapter 1. Introduction

1.1. How to use this User manual

If you are a user or operator of the GC STERLINK mini sterilizer, you must read the “Safety information”, “Load preparation”, and “Operation” chapters prior to operating the sterilizer system. This “Introduction” (Chapter 1) describes configuration of this manual. “Safety information” (Chapter 2) provides information on safety using the sterilizer. “Sterilizer overview” (Chapter 3) describes the brief information on the sterilizer and component. “Load preparation” (Chapter 4) explains how to prepare and package instruments for processing. “Operation” (Chapter 5) explains how to operate the sterilizer and obtain optimal results.

If you are a supervisor, you also need to pay attention following chapters. “Access levels and supervisor level tasks” (Chapter 6) describes the tasks and options that are only available through the supervisor level access. “Reports and files”(Chapter 7) explains the management of sterilization information from the sterilizer. The chapters on “Maintenance” (Chapter 8), “Troubleshooting” (Chapter 9) and “Attachment” are provided as references. Keep this user manual available so that if any question arises, you can quickly locate the information you need.

1.2. If you have questions

If you have any question about operating the GC STERLINK mini sterilizer or what kind of items may be safely sterilized, please call our customer service center at +82-1544-0508 in Korea. Internationally, call your local Plasmapp customer support representative. You may also wish to visit our website at http://www.plasmapp.com/eng/

1.3. Contact information

1.3.1. Manufacturer

Company	**Plasmapp Co., Ltd.**
Address	102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea
Tel	+82-1544-0508
Website	https://plasmapp.com/eng/

1.3.2. Customer service center

Company	**Plasmapp Co., Ltd.**
Address	59, Seocho-daero 77-gil, Seocho-gu, Seoul, Republic of Korea
Tel	+82-1544-0508
Email	cs@plasmapp.com

Chapter 2. Safety information

Your safety is the primary concern of Plasmapp Co., Ltd. This chapter provides information on safely using the GC STERLINK mini sterilizer system. You must read and understand the safety information and instruction given in this chapter before operating the sterilizer. Always pay attention to the warnings, cautions and notes throughout this User manual. This information is for your safety and will make sure that you receive the best result from the safe operation of your sterilizer system.

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 mist can cause severe irritation of lungs, throat, and nose. If you inhale it, move to fresh air. Please consult a doctor immediately if the symptoms are severe or persist.

WARNING! CONCERTRATED 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.

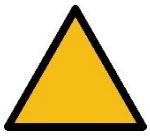
At the end of a cycle, the interior of the sterilizer may be hot. Do not touch the inside of the chamber or door with your bare or gloved hands. Allow the sterilizer to cool before touching interior surfaces.

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.

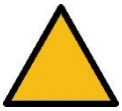
2.3. Warnings, cautions, and notes



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 GC STERLINK mini sterilizer system.

2.4. Symbols

	**WEAR SAFETY GLOVES**
	**WARNINGS AND CAUTIONS** Warnings and cautions are indicated in the triangle symbol
	**WARNING SIGNS**
	**HOT SURFACES PRESENT** Do not touch without protection
	**HAZARDOUS CHEMICAL PRESENT** Use personal protective equipment
	**TOXIC CHEMICAL PRESENT** Avoid exposure, contact, or ingestion

	**HAND CRUSH HAZARD** Keep hands clear while operating
	**ELECTRIC SHOCK HAZARD** Danger of electric shock without an electrical safety device
	**NO PUSHING**
	**NO SITTING**
	**NO STEPPING ON SURFACE**
	POWER ON
	**POWER OFF**
	**PROTECTIVE EARTH (GROUND)**
	**MANUFACTURER**
	**DATE OF MANUFACTUR**
	**EXPIRY DATE**

	**SERIAL NUMBER**
	**TEMPERATURE LIMIT**
	**HUMIDITY LIMIT**
	**CONSULT INSTRUCTION FOR USE**
	**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. Sterilizer overview

3.1. Intended use

The GC STERLINK mini sterilizer system is a low temperature sterilizer using sterilant of hydrogen peroxide to inactivate microorganisms for the metal and nonmetal medical devices to cover a broad range of surgical instruments. This product is effective, safe, fast, reasonable, easy to use, reliable, and offers a variety of sterilization methods.

Before operating the sterilizer, please review the Chapter 4 “Load preparation” in which recommended materials and lumen sizes are described. When selecting reusable medical devices to be processed in this sterilizer system, reprocessing information should be obtained from the manufacturer of the medical device in accordance with international norms (such as ISO 17774 or AAMI TIR 12).

- **Power ratings and specifications**

Classification	Description / Range
Rated power	100 VAC
Rated frequency	50-60 Hz
Maximum power consumption	1.5 kVA
Operating temperature	10 ℃ ~ 40 ℃
Operating humidity	Relative humidity 30 % ~ 85 %
Atmosphere pressure	70 ~ 106 kPa
Replaceable fuse	Fuse 250V / 12A (5mm x 20mm)

3.2. Sterilization procedure

You may already be familiar with general sterilization principles. It is noteworthy that the GC STERLINK mini sterilizer has unique feature, and it requires special attention to the ways in which it differs from other conventional sterilizers.

The GC STERLINK mini system sterilizes medical devices by using hydrogen peroxide vapor which will be diffused into the chamber or pouch, and the vaporized sterilant is exposed to the medical instruments and materials without leaving toxic residues. All stages of the sterilization cycle are not damaged to the compatible instruments which are sensitive to heat and moisture.

The GC STERLINK mini sterilizer can be used for metal and non-metal medical devices and it can sterilize instruments that have difficult-to-reach (diffusion-restricted) spaces, such as hinges on forceps. Please refer to “Load preparation” chapter for more information.

The sterilizer consistently provides the Sterility Assurance Level (SAL) of 10^{-6}, as defined by U.S. Food and Drug Administration (FDA) and international standards, for clinical use on all allowed substrates within the limits of the claims for materials and geometries when used in accordance with the directions in this User manual.

The devices have been pre-validated to the SAL of 10^{-6} based upon worst-case conditions, including lumens within the claim lengths and mated surfaces. If additional technical information concerning validation is needed, please contact Plasmapp or your local Plasmapp customer support representative.

3.3. Sterilization cycle

The GC STERLINK mini sterilizer is designed to be operated at two different modes of the sterilization cycle, and each mode is a combined cycle of the Smart Ready (SR™), Sterilization and Smart Complete (SC™) process. The sterilizer is designed to operate only with the sterilant cassettes of STERPACK™ and STERLOAD™ mini. Each cassette has individual barcode which will be scanned by the sterilizer to start the sterilization cycle automatically according to the barcode identifying the type of the cassettes. This automatic scan step reduces the user error and reliability of sterilization.

The optimized heating and drying process is provided in the SR™ process by measuring volume of the medical devices and residual water left on the devices in which the pressure of the pouch and chamber is independently controlled to obtain the venting and pumping pressure curves.

The sterilization process consists of the two consecutive identical sterilization phases, and the critical process parameters are controlled to be identical. The validation of the sterilization process is performed by using the half-cycle overkill method to demonstrate the 10^{-6} SAL. In the SC™ process the sterilizing

agent is removed before using the sterilized medical devices to maintain the asepsis. To ensure user safety, an independent pressure sensor of the sterilizer to measure the residual sterilant and perform an optimized completion process. The following table provides a brief description for each cycle mode.

Sterilization cycle and minimum time by mode (60 Hz)

Mode	Sterilant cassette	Cycle and minimum cycle time (unit: min)		
		SR™ / SC™	**Sterilization**	**Total Cycle Time**
POUCH	STERPACK™	3	**4**	**7**
CHAMBER	STERLOAD™ mini	8	**10**	**18**

Sterilization process – Phase 1

- Injection: The hydrogen peroxide is transferred from the cassette into the vaporizer and the sterilant is vaporized and diffused into the chamber or pouch. The Pouch mode is unique function of this sterilizer in which the vaporized sterilant is directly provided into the pouch of STERPACK™, which maximizes sterilant efficiency and enables quick and reliable sterilization cycle within 10 minutes.
- Diffusion: As the vaporized sterilant is provided and the pressure is increased, the sterilization process proceeds as the surface and the inside of the medical device are exposed.
- Plasma purification / Vacuuming: The residual sterilant is pumped out by the vacuum pump of the sterilizer system, and the plasma is discharged in the plasma source which is installed in the piping line to purify the hydrogen peroxide vapor. The Pouch mode has unique feature in this process in which the residual sterilant is directly eliminated from the pouch of STERPACK™ through the direct connection port which is also used for injection.

Sterilization process – Phase 2

The steps in the Phase 1 are repeated.

3.4. Sterilizer system and accessories

The GC STERLINK mini sterilizer system is composed with the main sterilizer and pump module as shown in the following figure.

Figure 3.1 GC **STERLINK mini sterilization system (front)**

The STERLINK mini sterilization system 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.

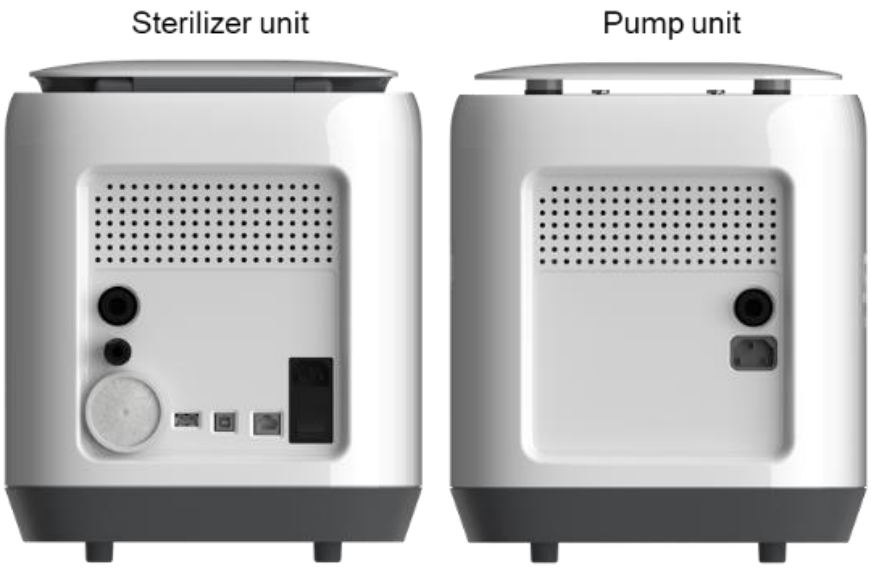


Figure 3.2 GC STERLINK mini sterilizer system (back)

Figure 3.3 GC STERLINK mini power cable

This GC STERLINK mini sterilization system can be used with a sticker type label-printer as an accessory which is for user convenience in managing the history of sterilization cycle information. The printer is designed to be connected to the USB print connector on the rear side of the sterilizer. For the detailed information about the report, please refer to the Chapter 7 featuring “Reports and Data”.

Figure 3.4 Label-printer for GC STERLINK mini sterilization system (Optional)

Figure 3.5 Cart for STERLINK mini sterilization system (Optional)

3.5. Sterilant cassettes

The GC STERLINK mini system has two different modes of POUCH and CHAMBER mode which are automatically initiated by the sterilizer according to the barcoded printed on the sterilant cassettes of STERPACK™ and STERLOAD™ mini, respectively.

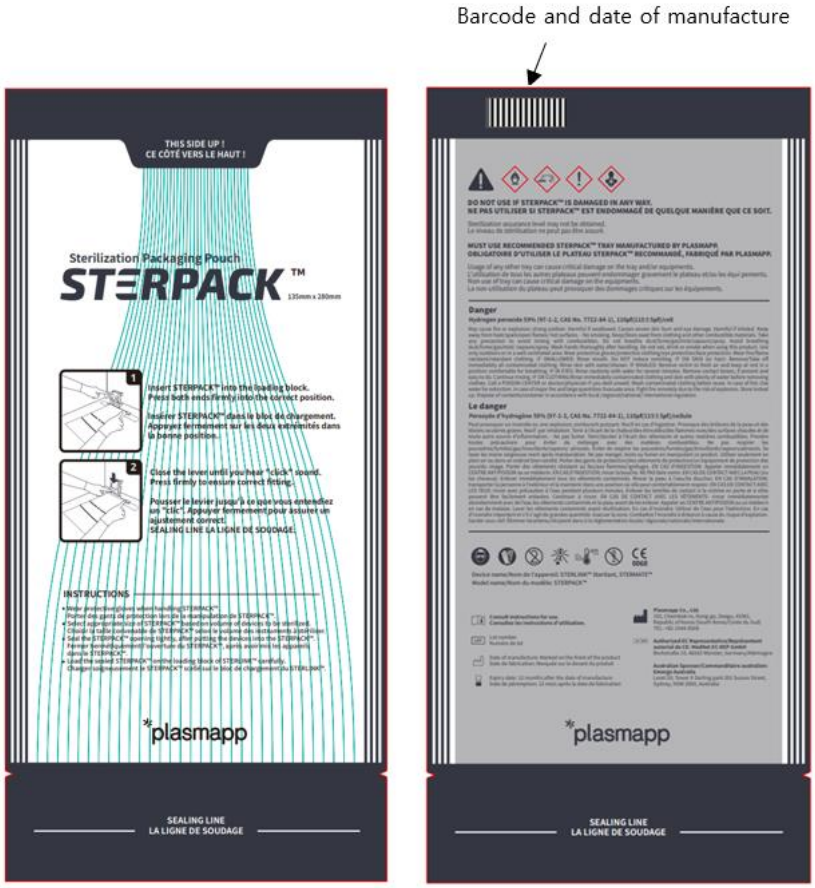


Figure 3.7 Sterilant cassette of STERPACK™ for POUCH mode

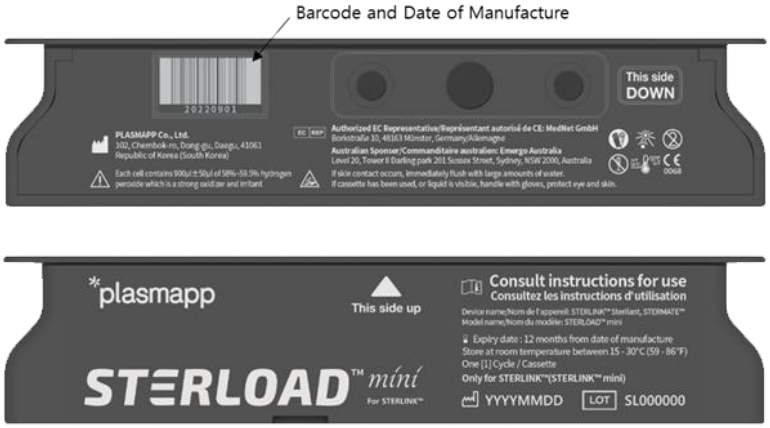


Figure 3.8 Sterilant cassette of STERLOAD™ mini for CHAMBER mode

Each cassette has two cells of sterilant which each cell contains precisely measured amount of hydrogen peroxide solution, and the two cells are used for repeating the same sterilization phases for one sterilization cycle. When the sterilization cycle is completed or stopped, the used cassettes should be handled with wearing protective gloves and be disposed according to the right regulation. Please refer to the Chapter 5 featuring “Operation” to have more information on how to use the cassette.

CAUTION! CHECK EXPIRY DATE.

When you use the sterilant cassettes (STERPACK™, STERLOAD™ mini), check the expiry date. If the date is expired, dispose and use new available sterilant cassettes.

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.

Chapter 4. Load preparation

4.1. Indications for use

The GC STERLINK mini sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The sterilization cycle is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma purification to complete the sterilization cycle.

The sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with the following materials and dimensions can be processed in the GC STERLINK mini sterilization cycles:

- Single-channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter.
- Single-channel stainless steel lumens with an inside diameter of 2 mm or larger and a length of 1,500 mm or shorter.
- Single-channel Teflon/PTFE lumens with an inside diameter of 1 mm or larger and a length of 2,000 mm or shorter.

CAUTION! KNOW WHAT YOU CAN PROCESS.

Before processing items in the sterilizer, make sure you know how the GC STERLINK mini sterilization process will affect the items. 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.

CAUTION! RISK OF WARRANTY VIOLATION.

Improper processing may limit liability for damage to processed instruments. The manufacturer cannot warrant the damage of the instruments due to improper use.

The GC STERLINK mini sterilizer is compatible for sterilizing the non-invasive and invasive medical devices, such as denture, endoscopes, ocular prosthesis, intraosseous transcutaneous amputation prosthesis, and surgical equipment.

4.2. What can be sterilized

There are a wide variety of materials and devices that can be sterilized in the GC STERLINK mini sterilizer. As more manufactures complete testing of their products with the sterilizer, the list of compatible items continues to expand. Information will be updated as new information becomes available. If the user has any doubt, please contact the medical device manufacturer or your local Plasmapp customer support representative.

CAUTION! RISK OF DAMAGE ON THE LOAD OR STERILIZER.

Do not attempt to sterilize items or materials that do not comply with the guidelines specified in this User manual. Consult the medical device manufacturer's instructions or call your local Plasmapp customer support representative to determine whether an item can be sterilized by the GC STERLINK mini sterilization system.

4.3. Items not to be processed

The following items should not be processed by the GC STERLINK mini sterilization system.

- Single use items for which the manufacturer does not recommend re-use.
- Liquid and powders.
- Items or materials that absorb liquids.
- Items made of materials that contain cellulose, such as cotton, paper or cardboard, linens, buck towels, gauze sponges, or any item containing wood pulp.
- Paper instrument count sheets or lot stickers.
- Items with mated Nylon® surfaces.

- Instruments and devices that cannot withstand a vacuum and are labeled for steam sterilization method only.
- Instruments and devices with potential surface deformation due to vacuum.
- Dead-end lumens must not be processed.
- Other instruments for which the manufacturer has not specifically recommended sterilization in the GC STERLINK Sterilizer.

4.4. Guidelines for preparing items to be sterilized

All items must be cleaned, rinsed, and thoroughly dried before being placed in the GC STERLINK mini sterilizer. Loads containing too much moisture may result an automatic cycle cancellation.

4.5. Cleaning, rinsing, and drying

The cleaning and sterilization are two separated processes. As with all sterilization methods, proper cleaning of instruments and devices is a critical and necessary step prior to sterilization. All items must be cleaned, rinsed, and thoroughly dried before loading into the sterilizer.

Carefully inspect all instruments and devices for cleanliness and dryness and for flaws or damage prior to packaging. If visible soil or moisture is present, the item must be re-cleaned and dried prior to sterilization. Devices and instruments with flaws or damages should be replaced or repaired before using.

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

Notes.

- Remove all blood, tissue, and soil from items by following the device manufacturer’s instructions using an appropriate detergent or cleanser.

- Rinse items thoroughly to remove detergent or cleanser residue.
- Dry all items thoroughly. An acceptable method for drying is to blow compressed gas through the lumen until no moisture exits the distal end of the device. Please ensure that any method used to dry the devices is in accordance with the manufacturer's instructions for use or contact the device manufacturer to obtain appropriate and safe procedures. It is necessary to remove moisture from all parts of the items. Only dry items should be loaded into the sterilization chamber to prevent cycle cancellation.
- Some complex re-usable medical devices may require disassembly for proper cleaning and sterilization. It is very important that you follow the device manufacturer's recommendations concerning cleaning and sterilization.
- Periodic careful inspection of items after repeated exposure to disinfectant / cleaner / sterilant is necessary, regarding the potential damage of the chemical agent to the items.

4.6. Packaging and loading

If you choose to package the instruments, proper preparation of trays, pouches, and instruments can minimize the possibility of the 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.

4.6.1. Instrument trays

Only GC STERLINK mini instrument trays and accessories are recommended for use in the GC STERLINK mini sterilizer. These instrument trays specially designed to allow diffusion of hydrogen peroxide. If you don't use the vacuum-designed tray in Pouch mode, the sterilization cycle can be cancelled due to the damage of pouch film.

4.6.2. Tray mats

Instrument trays should only be padded with polypropylene sterilization wrap. Never use linen, cellulose, or any materials in the "4.3. Items not to be processed" section. The foam

pads should not be used in instrument trays since they may absorb the hydrogen peroxide.

4.6.3. Packaging

Packaging should be performed as follows.

- Use only STERPACK™ for POUCH mode according to the size of the medical instrument.
- Use only polypropylene sterilization wrap or Tyvek® pouches for the CHAMBER mode operation.
- 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 materials on the "4.3 Items not to be processed" section.
- Arrange the items in a tray to ensure proper diffusion of hydrogen peroxide throughout the load.
- Place peel pouches on edge, if possible. Arrange them so that the transparent side of pouch faces the opaque side of the next pouch. Do not stack pouches on top of each other.
- Do not stack instruments inside the trays. Do not stack trays. Do not stack trays within trays.
- Place chemical indicator strips inside trays and pouches as needed.

4.6.4. Loading

The cassette should be precisely installed onto the loading block of the GC STERLINK mini sterilizer. For the CHAMBER mode operation, the packaged devices are recommended to be loaded inside the chamber after loading the cassette (STERLOAD™ mini) for your convenience.

WARNING! DO NOT USE IF PACKAGING IS DAMAGED.

Do not use if the package has been damaged or has not been properly sealed. If the sealing is not perfect, it's difficult to have confidence of asepsis, and the sterilization process can be cancelled.

CAUTION! INSERT CI (CHEMICAL INDICATOR).

Insert the CI in the packaging together with the product. After the sterilization cycle is completed, you can check if the product is working properly and the CI color has been changed properly.

CAUTION! BE CAREFUL, THE CHAMBER MAY BE HOT!

The temperature of the chamber may be hot. Wear protective gear and be careful when working inside the chamber and be careful of burns.

Chapter 5. Operation

5.1. Before you start

Each time you use the GC STERLINK mini sterilizer, follow the instructions provided in the Chapter 4 “Load preparation.” It is the operator’s responsibility to be familiar with the load preparation and safety information provided in this User manual.

Notes.

- The sterilizer shall be installed on the table. When the sterilizer is relocated from the initial place, it shall be relocated by the authorized person from the manufacturer.
- When the user reactivates the sterilizer after long term stop, the user shall contact the manufacturer and take proper instruction.
- The LAN connector is used only expert of manufacture. It is intended use for S/W update or diagnosis of product status.
- When installing the product, install it on a flat (within 3 degrees) place and the equipment should have a space of at least 5 cm away from the back and top part.

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 a cancelled cycle or error occurrence. Hydrogen peroxide residue may remain.

WARNING! HYDROGEN PEROXIDE DISPOSAL.

Hydrogen peroxide is designated as dangerous and hazardous medical wastes by American environment protection association and shall be disposed in accordance with the local regulation

CAUTION! USE ONLY CORD BY SUPPLIER.

If you use a power code/use cable code other than the one provided by our company, there is a risk of equipment malfunction or electric shock.

5.2. Start and warm-up

1. Turn on the main power switch which is located at the rear side of the sterilizer.
2. When power switch is on, sterilizer automatically go into preheating process.
3. Close the door during preheating process for warm up. The preheating process can take up to 30 minutes.
4. After the preheating process, a complete statement will appear instead of the “Preheating”.

Figure 5.1 GUIs for the preheating and preparation process

Number	Name	Description
1	Configuration	The display can be moved into the sterilizer’s configuration setup by touching this configuration icon.
2	Preheating	For components that require temperature control of chamber or vaporizer, to make the product ready the product will be preheat.
3	Time	The current configurable time is displayed in Configuration menu.
4	Preheating progress	This section displays the present status of preheating.
5	Sterilize	The sterilizer starts the sterilization cycle by touching this icon.

6	Help	This section shows the current status.

5.3. Preparing the load

The load preparation is one of important part of the sterilization process. A biological indicator is generally used ensure that the system sterilizes the prepared load. Place a biological indicator in the STERPACK™ or sterilizer chamber for the POUCH or CHAMBER mode, respectively. This biological testing is recommended to be performed at least once per day or specified by your facility's policy. While the sterilizer is warning up, you can use this time to prepare the load.

※ The sterilization performance test should use a BI containing more than 1 x 10^6 *Geobacillus stearothermophilus* spores (ATCC 7953).

Mode	Item description
POUCH	Total mass of the items should be less than 0.5 kg.
CHAMBER	Total mass of the items should be less than 2.5 kg.

WARNING! POSSIBLE NON-STERILE DEVICE.

Improper sealing of the STERPACK™ for the POUCH mode may result in either a non-sterile device or cycle cancellation. Seal tight the STERPACK™ by using a recommended sealing machine.

CAUTION! DO NOT REUSE.

The products (STERPACK™, STERLOAD™ mini) are intended for single use only. Do not reuse. If you reuse the product, an error will occur.

CAUTION! CHECK EXPIRY DATE.

When you use the sterilant cassettes (STERPACK™, STERLOAD™ mini), check the expiry date. If the date is expired, dispose the cassette, and use new available sterilant cassettes. The use of expired date cassette will occur an error.

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.

5.4. Cassette loading

The GC STERLINK mini sterilizer has two different modes which are operated by using the cassette of the STERPACK™, STERLOAD™ mini. Place the cassette in the loading block as depicted in the following figure.

Figure 5.2 Loading cassettes of the STERPACK™ and STERLOAD™ mini

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! HAND CRUSH HAZARD.

The door of the sterilizer is designed to be manually opened and closed, and your hand can be injured by the door. Keep hands clear when opening or closing the door.

5.5. Starting sterilization cycle

1. Check whether the door is closed when the load has been properly placed in the chamber.
2. Touch “Sterilize” icon to start sterilization cycle.
3. The sterilizer automatically scans the barcode printed on the cassette to check validity of the loaded cassette and determine the operation mode.
4. The sterilizer automatically check the door status and start the sterilization cycle.
5. When sterilizer start process, the inside of the chamber maintains a vacuum status.

   User cannot force the door open due to vacuum status of chamber during sterilization process.

Figure 5.3 GUIs for the initializing and sterilization process

Number	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	Progress	This section displays the progress of the sterilization process.
11	Stop	This icon is for stopping the cycle which is determined by the user.

Notes.

- If a reused cassette is detected, the cycle will be cancelled.
- If an expired cassettes is detected, confirm whether to proceed with the sterilizer disposal cycle.
- Improper loading of the cassette may result in scanning error, and the cycle will be cancelled.
- When the chamber door is not properly closed, it results in cycle cancellation.
- Cycle stop may not obtain sterility assurance level and users can be exposed to residual sterilant which can be left in the cassette. Ensure protective gloves are worn when handling the used cassette.

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.

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. Cycle completion

When the sterilization cycle is completed, the sterilizer displays the cycle information such as the sterilization date, time and results of the mode. Click “confirm” button to return to “main” screen for the ready state.

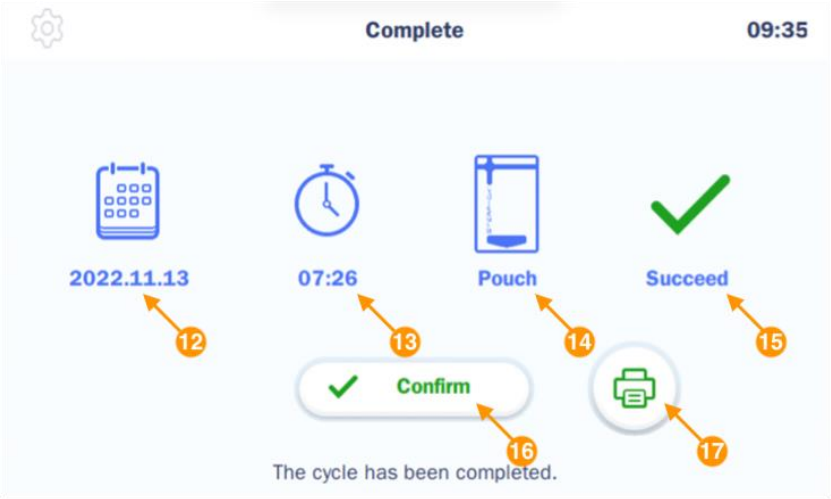


Figure 5.4 GUIs for completed sterilization cycle

Number	Name	Description
12	Date	This section displays the date of the sterilization cycle.
13	Cycle time	This section displays time for overall cycle time.
14	Mode	This section displays the mode of the finished sterilization cycle.
15	Result	This section displays the result of sterilization cycle.
16	Confirm	When the user clicks on “Confirm” button, the screen moves to ready state.
17	Print	When the user clicks on “Print” button, the label printer will print out the summary of the sterilization cycle information.

5.7. Cancelling sterilization cycle

There may be occasions when the user needs to cancel a cycle before it is completed. Touch the "STOP" button, and the screen displays a confirmation message. It is noteworthy that cancellation process cannot be stopped or cancelled when the user confirms the cycle cancellation.

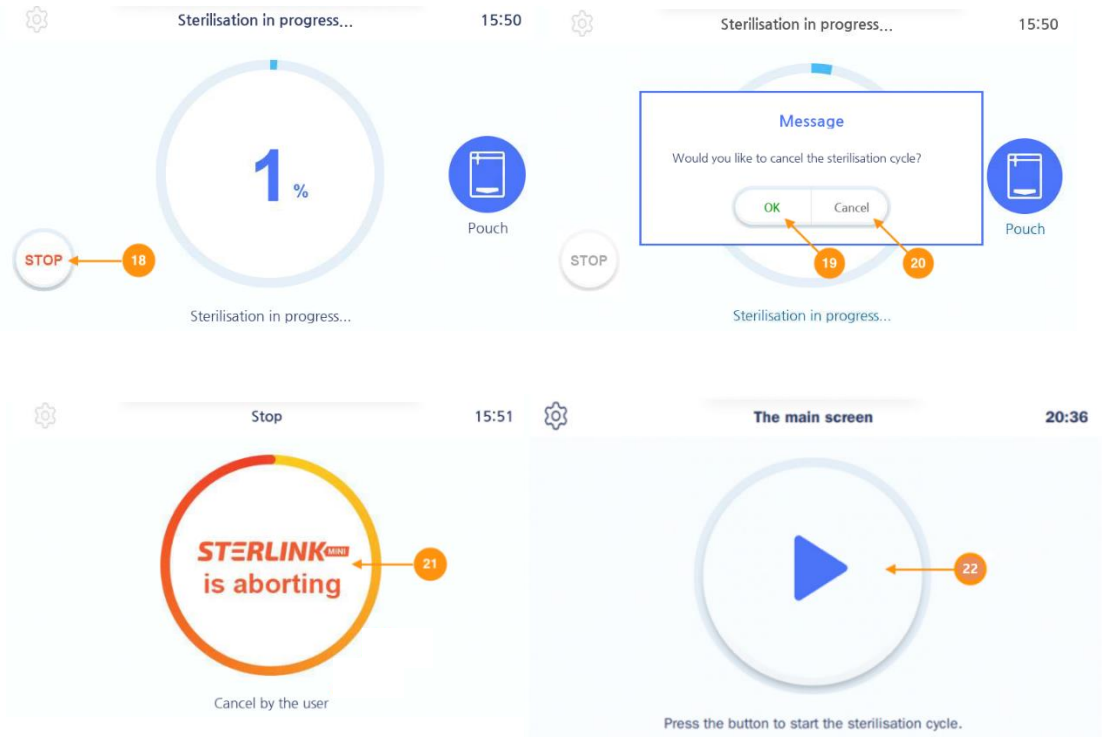


Figure 5.5 GUIs for canceling sterilization cycle

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	The main screen	When the sterilization cycle cancellation is complete, the screen returns to the ready state.

Even this cancellation process also includes the purification process, the sterilant can be left on the loads or cassette. It is very important to wear protective gloves when handling the load and used cassettes. It is also noteworthy that the sterility assurance level may not be obtained for the cancelled cycle, and it requires to restart a new sterilization cycle with rewrapping using new packaging material.

WARNING! POSSIBLE NON-STERILE DEVICE.

Cycle cancellation may result in a non-sterile device, and it requires to restart a new sterilization cycle with rewrapping using 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. Processing a sterilized load

When you confirm the completed cycle, the sterilized load can be processed by inspecting the chemical indicators and by 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 and repackage and reprocess the load.

5.8.2. Processing self-contained biological indicator

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.

5.9. Sterilant disposal cycle

1. Check whether the door is closed when the expired cassette has been properly mounted in the chamber.
2. Touch “Sterilize” icon to start sterilant disposal cycle.
3. The sterilizer automatically scans the barcode printed on the cassette to check validity of the loaded cassette and determine the sterilant disposal mode.
4. When the “Cancel” button is selected, it returns to the main screen without progress. When the “OK” button is selected, it automatically checks the door status and starts the sterilant disposal cycle.
5. When the disposal process begins, the inside of the chamber maintains a vacuum state.

User cannot force the door open due to vacuum state of chamber during disposal process.

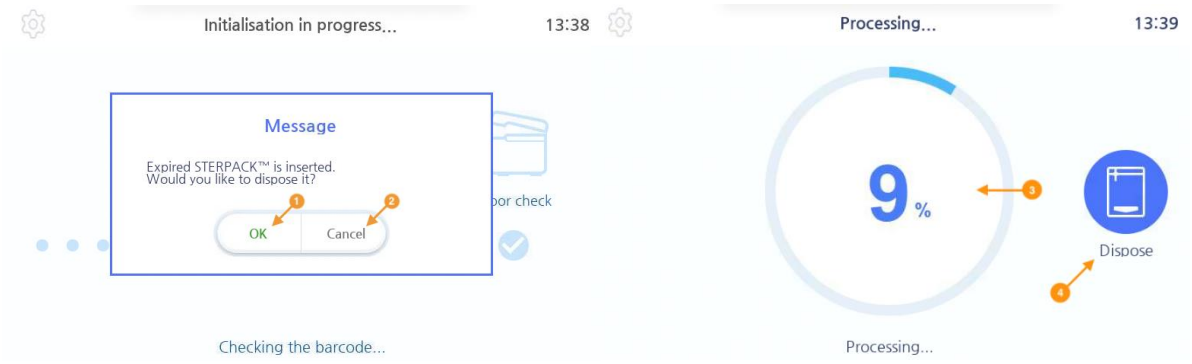


Figure 5.5 GUIs for confirmation of disposal and disposal process screen

Number	Name	Description
1	OK	This icon is for confirming the sterilant disposal cycle.
2	Cancel	This icon is for confirming the cancellation. When the “Cancel” button is selected, it returns to the main screen.
3	Disposal progress	This icon displays the progress of the disposal process.
4	Mode	This icon displays the mode in progress.

Notes.

- If a reused cassette is detected, the cycle will be cancelled.
- Improper loading of the cassette may result in scanning error, and the cycle will be cancelled.
- When the chamber door is not properly closed, it results in cycle cancellation.
- Cycle stop cannot guarantee sterilant disposal and users can be exposed to residual sterilant which can be left in the cassette. Ensure protective gloves are worn when handling the used cassette.

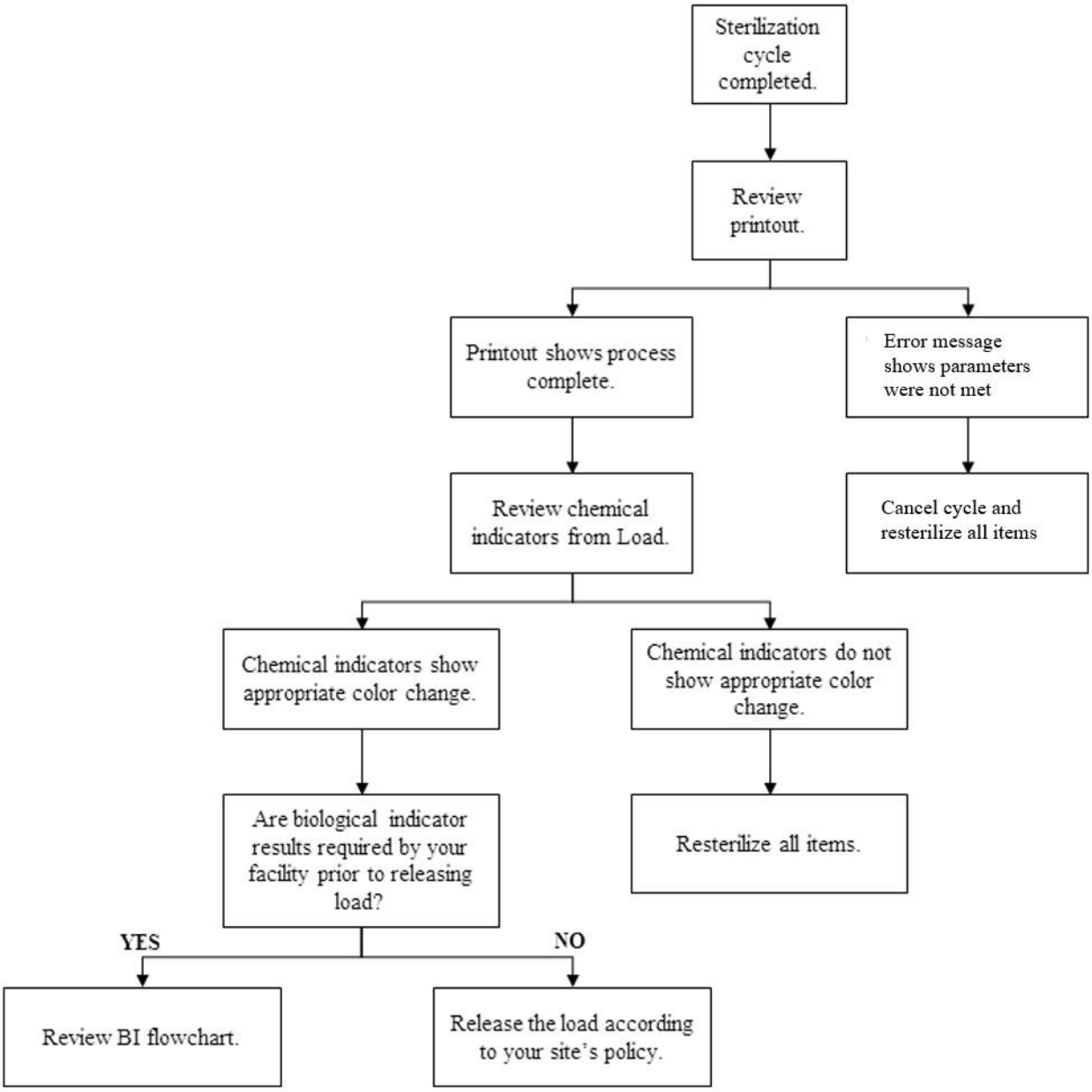
WARNING! POSSIBLE NON-STERILE DEVICE.

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.

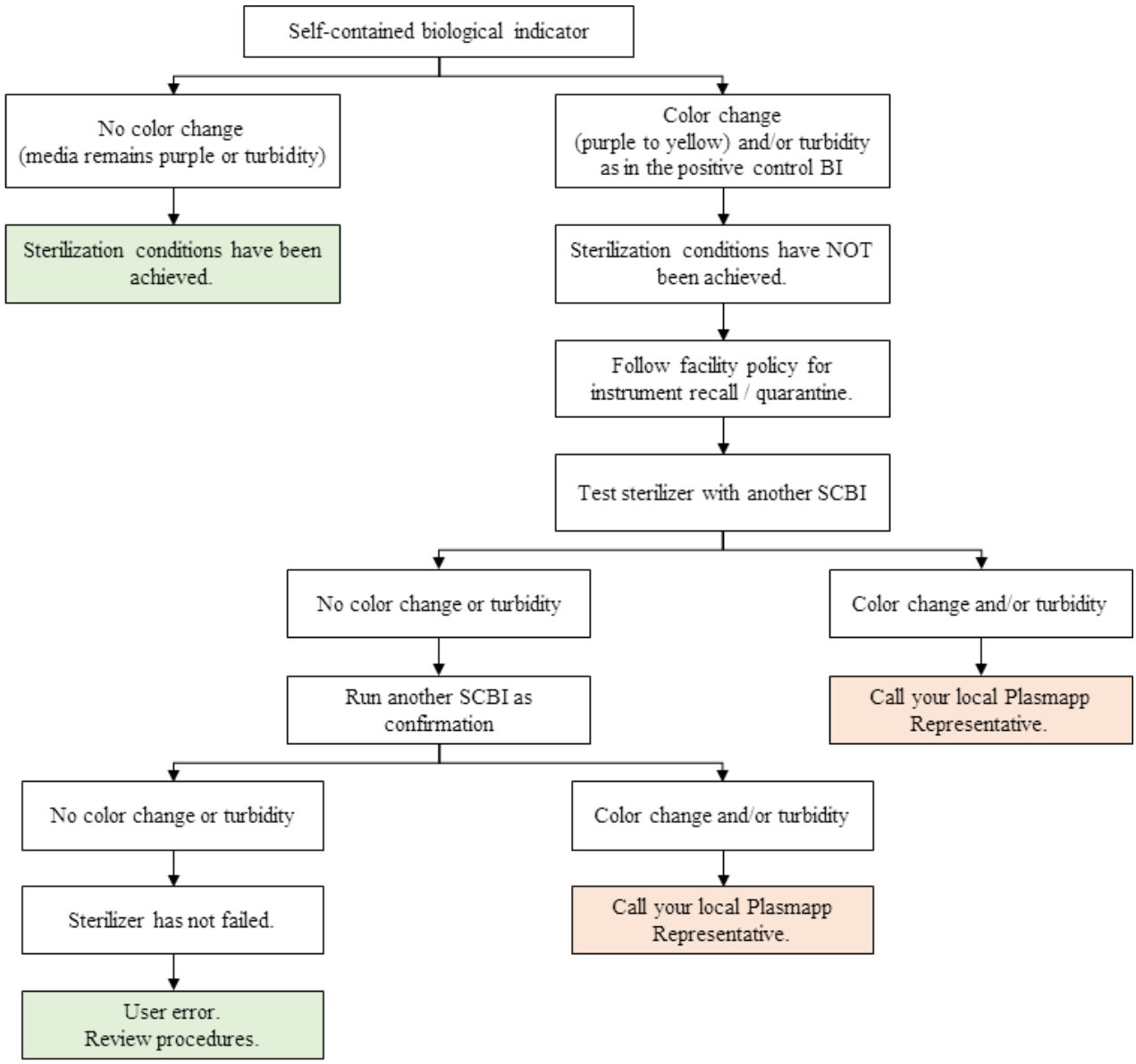
CAUTION! HYDROGEN PEROXIDE MAY BE PRESENT.

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.

Cycle completing flowchart



Biological indicator processing flowchart



Chapter 6. Access levels and supervisor tasks

6.1. Overview

The GC STERLINK mini sterilizer utilizes the embedded software for automated implementation of GC STERLINK sterilization process. This chapter contains how to control the configuration GC STERLINK mini low temperature plasma sterilizer.

Users with supervisor-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 some of them are designed to control access, manage system records, and perform advanced diagnostic functions.

6.2. Access levels

The GC STERLINK mini 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 tasks associated with the daily operation of the sterilizer. These authorities allow a user to:

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

Supervisor-level access includes all of the 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 utility menu

The Additional utilities menu in the “System configuration menu” is available to users with Supervisor or Service-level access authorities. The Additional utilities menu allows supervisors to configure the time setting, sterilizer system setting, and diagnostic test.

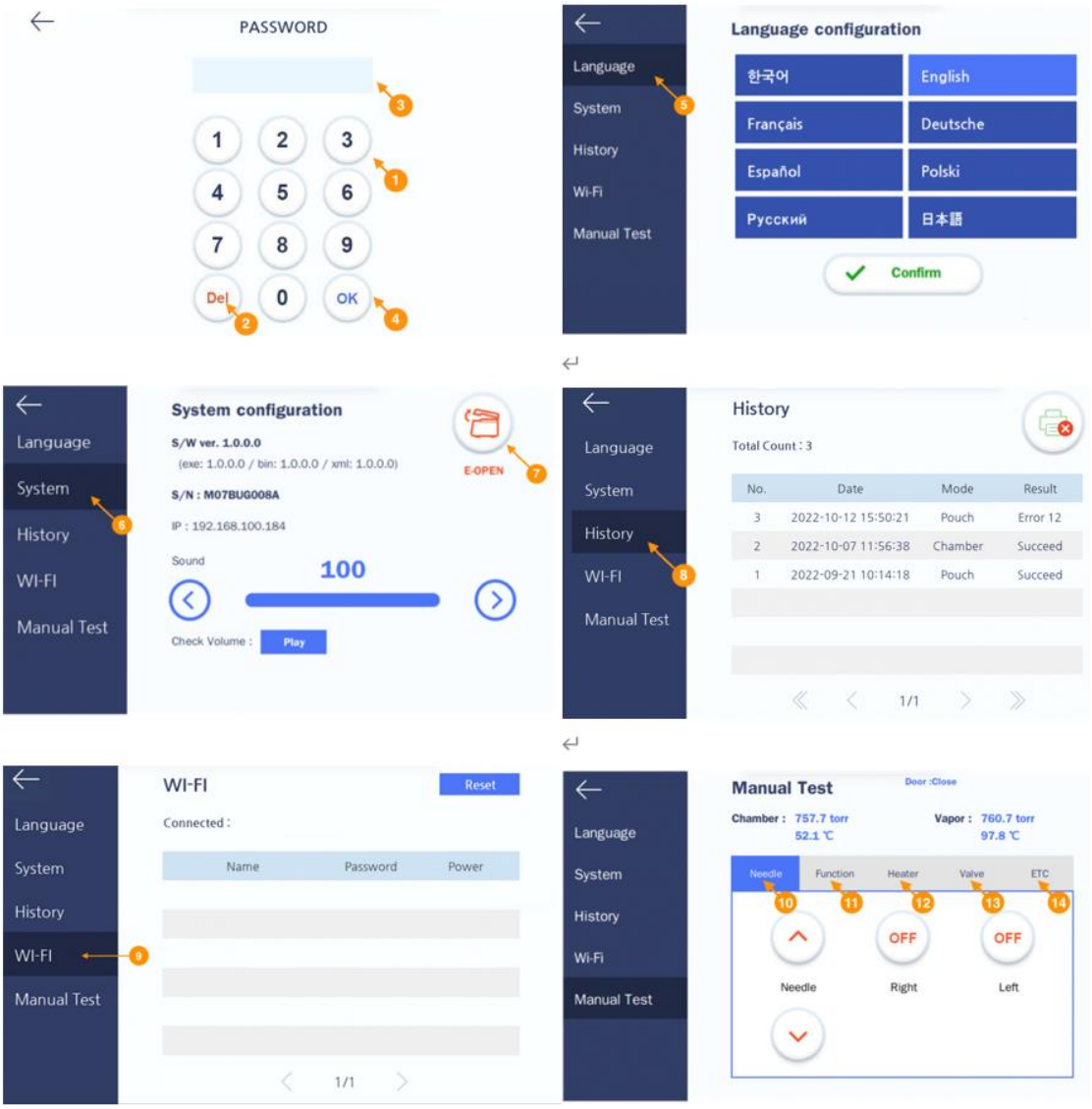


Figure 6.1 GUIs for system setting

Number	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 entered. The default setting for the password is “1111”.
4	OK key	The key is for confirming the 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.
9	Wi-Fi	The key is for setting up a wireless router. Displays the name of connected wireless network and shows the networks can connect.
10	Manual Test (Needle)	The key is for operating manually of vaporizer.
11	Manual Test (Function)	Pump, CPS, barcode can be operated manually.
12	Manual Test (Heater)	Turn each heater on and off and check the temperature.
13	Manual Test (Valve)	Open and close the valve of the equipment.
14	Manual Test (ETC)	Initialize the pressure sensor of the chamber and the vaporizer.

CAUTION! PRODUCT MANAGER ACCESS AUTHORIZATION.

Additional utility functions, including the “Door open” and “Pump Heating” functions, which are used when the door is not opened or the pump does not work, are available only to trained administrators of this sterilizer.

Notes.

- 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 objects, the venting process can be failed and door cannot be opened. When it occurs, this “Door 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.
- If the oil of vacuum pump is not replaced regularly, not used for a long time or the use frequency is lower than the standard mentioned is Chapter 8 “Maintenance” it may not work properly, the function “Pump heating” can resolve this problem. It can take about 10 minutes. If the problems persist, please contact Plasmapp or your local Plasmapp customer support representative.

Chapter 7. Reports and files

7.1. Reports

The cycle report is automatically created and displayed by the GC STERLINK mini sterilizer when the sterilization cycle is completed. The displayed report summarizes the cycle information of the cycle date, time, process mode and the result of the sterilization cycle.

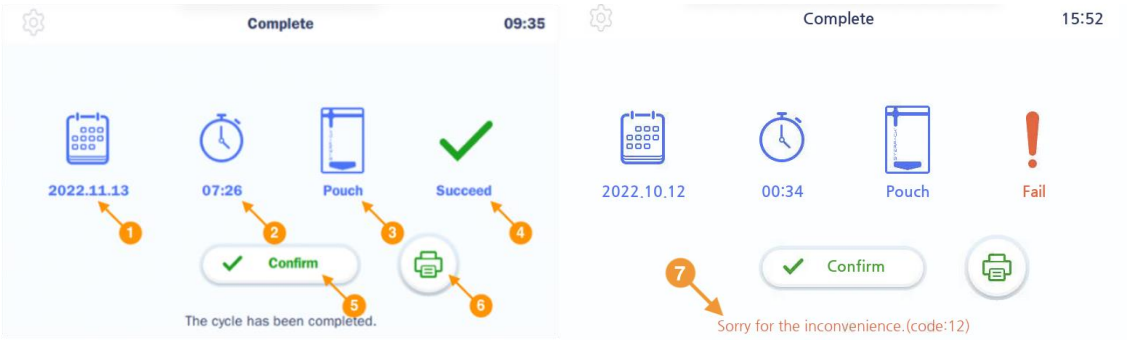


Figure 7.1 GUIs of cycle summary when the cycle is passed and failed

Number	Name	Description
1	Date	This section displays the date of the sterilization cycle.
2	Cycle time	This section displays time for overall cycle time.
3	Mode	This section displays the mode of the finished sterilization cycle.
4	Result	This section displays the result of sterilization cycle.
5	Confirm	Press “Confirm” button and the screen moves to ready state.
6	Print	Press “Print” button, the label printer will print out the summary of the sterilization cycle information.
7	Caution	This section describes caution information when the sterilization fails.

The information will be printed out by the label-printer when print button is selected by a user, and the label-printer will print out the short-format report that shows the device status, information of sterilization cycle, and cassette information. This short-format report is useful for record keeping purposes and label-print is convenient to provide traceability of sterilized loads. Examples of the short-format report are illustrated in the following figure.

Figure 7.2 Short format report for passed and failed cycle (Sample)

The printer paper is the thermal paper so that it can be faded under sunlight or high temperature. The shelf life of the printer paper is about 5 years. If you want to keep the record in long-term, please copy or scan the record paper and store it.

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.

Figure 7.3 Long format report for passed and failed cycle (Sample)

7.2. Data

The GC STERLINK mini sterilizer can create, store, display, and print the cycle data. When connected to internet, the sterilizer can upload the cycle history files to the ITS™ server. Cycle history data contains very detailed sterilization cycle information of each SR™, sterilization and SC™ process. The data includes identifying information about the sterilizer, time, date, cycle duration information, process data from the sensors of the sterilizer. Information is extracted from the cycle history data to produce the printed report.

The history file is stored in the GC STERLINK mini sterilizer. The sterilizer displays data from the previous 80 cycles. After completing 80 cycles, the oldest cycle record is replaced with the new record for the 81st cycle. If the sterilizer is connected to the ITS™ server and the internet, cycle history data is uploaded to the server periodically.

Chapter 8. Maintenance

The GC STERLINK mini sterilizer is the highest quality sterilizer that performs reliable sterilization cycles. As the sterilizer may be deteriorated by continuous usages, the sterilizer also needs proper maintenance to guarantee user safety and reliable sterilization cycle. This chapter describes what kind of works and parts are required for the maintenance of the GC STERLINK mini sterilization system.

8.1. Manual maintenance

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

- Cleaning sterilizer exterior and interior chamber
- Replacing printer paper
- Routine sterilizer maintenance

Notes.

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

8.1.1. Cleaning the sterilizer exterior and interior chamber

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

Notes.

- 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! HAND CRUSH HAZARD.

The door of the sterilizer is designed to be manually opened and closed, and your hand can be injured by the door. Keep hands clear.

CAUTION! POSSIBLE DAMAGE ON THE STERILIZER.

Do not use the steel brush (wire brush), steel foam (steel wool), compound and detergent containing chloride compound. They may damage the sterilizer or its electrodes. Please remove all detergent, fabric or thread left in the chamber after cleaning.

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.

8.1.2. Replacing label-printer paper

When the label-printer roll is empty, the roll is required to be replaced manually as following.

1. Holding the body push the top of the front cover to 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.

WARNING! ELECTRIC SHOCK HAZARD.

TURN OFF THE POWER WHEN REPLACING THE FUSE.

There is a risk of electric shock if the fuse is replaced without using the fuse specifications provided by Plasmapp Co., Ltd. or when the power is switched on.

8.2. Sterilant cassettes

Hydrogen peroxide (Chemical Formula: H_2O_2) in the cassettes of STERPACK™ and STERLOAD™ mini is designated as dangerous and hazardous waste by American Environment Protection Association and shall be disposed in accordance with the local regulation.

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. Moving, long term stop and disposal of the sterilizer

When the GC STERLINK mini sterilizer system is reinstalled from initial place to the another, the system shall be moved by the authorized technicians. If there is no continuous sterilization cycle, it is required to turn off the power switch of the sterilizer and pull out the power cord from the power outlet with following storage condition.

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.

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. User errors

The GC STERLINK mini sterilization system is designed to provide alarm messages with the intuitive figures representing the predictable source for the user errors. When the user confirms, the error should be checked and understood by the user. If the problems persist, please contact Plasmapp or local Plasmapp customer service representative

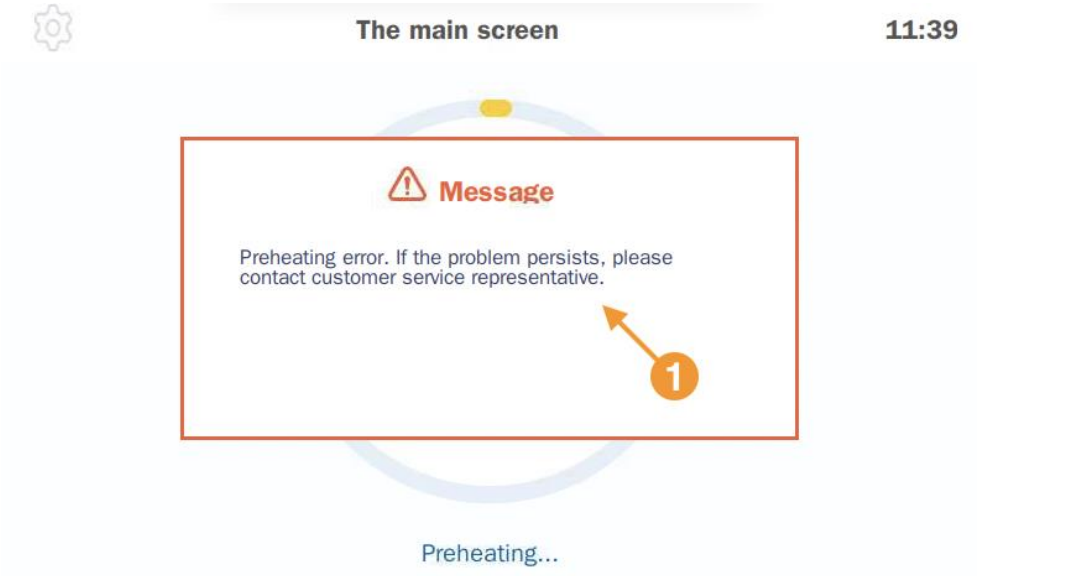


Figure 9.1 GUI for the display of Error Message

Number	Name	Description
1	Error Message	The message that appears if an error occurs.

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 pouch is not completed sealed, an error message can be displayed to stop the sterilization cycle. Sealing errors can occur when the pouch is damaged by a sharp object medical instrument in the pouch, and it is recommended to use a dedicated tray.
- 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.

Most system errors are related to load issues. However, problems can arise due to malfunction of the GC STERLINK mini 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.

9.2. Self-diagnostic function

The problem could be caused by a GC STERLINK mini sterilization system malfunction, such as the above user error, sterilization cassette error, or other system errors. Error Code can be checked on the "History" screen by pressing the "History" button on the initial screen, and the necessary actions can be taken by referring to the Error List below. If the problems persist, please contact Plasmapp or your local Plasmapp customer support representative.

[Error List]

CODE	Description
10	Temperature of the chamber and vaporizer does not reach the appropriate range.
11	During the process, an abnormal power outage occurs.
12	Stopped by user.
13	The door to the chamber does not close properly.
15	STERPACK™ pouch is damaged or sealing is defective.
21	Using re-used STERLOAD™ mini / STERPACK™.
22	Using expired STERLOAD™ mini / STERPACK™.
23	The barcode validity of STERLOAD™ mini / STERPACK™ is flawed.
24	Poor barcode recognition on STERLOAD™ mini / STERPACK™.
30	Inadequate initial vacuum formation.
40	Sterilant injection is inadequate.
50	Sterilant diffusion is inadequate.

Attachment A. Warranty

1. The manufacturer of Plasmapp Co., Ltd. warrants the product of GC STERLINK mini sterilizer to be free from defects in materials and workmanship for a period of one year from the delivery date.

2. For any defects found in manufacturing or in normal use, the warranty can be applied. To be eligible for the warranty, the defects should be identified and notified to the manufacturer.

3. The warranty does not apply to repairs or replacements required because of accident, misuse, neglect, failure to maintain in accordance with the manufacturer's specification, or cause other than ordinary use.

4. For (i) any portion of the product modified after the delivery; (ii) where the serial numbers have been removed or altered after the delivery; (iii) where the recommended operating and maintenance procedures have not been followed; (iv) to normal wear and tear; (v) damage due natural disasters or fire, the warranty does not apply.

5. Even if the warranty period is available but not within the scope of the warranty, all reparations can be done with additional fees.

Plasmapp Co., Ltd.

Attachment B. Sterilant, consumables, trays and accessories

B1. Sterilant cassettes

Name	Description / Specifications	Figure
STERPACK™	Impermeable pouch containing sterilant for POUCH mode Store at room temperature between 15-30℃(59-86℉) Keep away from sunlight - Material: PP/NY - Sterilant: Hydrogen peroxide (concentration: 58 – 59.5%) - 1 cycle per pouch, 50 cassettes per box	
STERLOAD™ mini	Cassette containing sterilant for CHAMBER mode Store at room temperature between 15-30℃(59-86℉) Keep away from sunlight - Material: PC/ABS - Sterilant: Hydrogen peroxide (concentration: 58 – 59.5%) - 1 cycle per cassette, 30 cassettes per box	

B2. Consumables

Name	Description / Specification	Figure
Tyvek® pouch (100*400)	Device sterile packaging pouch for CHAMBER mode - Pouch width: 100 mm - Total length: 400 mm - Material: Tyvek®, Easy-Peel film - 1 cycle per pouch, 120 pouches per box	
Tyvek® pouch (200*400)	Device sterile packaging pouch for CHAMBER mode - Pouch width: 200 mm - Total length: 400 mm - Material: Tyvek®, Easy-Peel film - 1 cycle per pouch, 90 pouches per box	

B3. Special tray

Name	Description / Specifications	Figure
STERPACK™ Tray	Dedicated vacuum tray optimized for high vacuum sterilization with STARPACK™ - Size: 80 mm × 195 mm × 30 mm - Weight: 0.15 kg - Material: Aluminum - Dedicated for STERPACK™ (POUCH MODE)	

B4. Accessories

Name	Description / Specification	Figure
Label-Printer (Optional)	**External thermal printer** - Size: 120 mm × 102 mm × 146 mm - Weight: 0.5 kg - Thermal paper width: 56 mm	
Label Sticker Roll	**Label sticker roll for label-printer** - Roll width: 56 mm - Roll length: 49 labels - 6 rolls per box	
Chemical indicator tape (CI Tape)	**Chemical indicator for sterilization cycle monitor** - Tape width: 20 mm - Length: 50 m - Expiration date: Refer to the product notification date	
Chemical indicator strip (CI Strip)	Chemical indicator for sterilization cycle monitor - Size: 18 mm × 105 mm - Packaging: 250 strips per case - Expiration date: Refer to the product notification date	

Attachment C. Specifications

C1. General information

(1) Product name: Low temperature plasma sterilizer

(2) Model: GC STERLINK mini

(3) Manufacturer

Company	**Plasmapp Co., Ltd.**
Address	102, Cheombok-ro, Dong-gu, Daegu, 41061, Republic of Korea
Tel	+82-1544-0508
Website	http://plasmapp.com/eng/

C2. Technical specification

Classification	Description			Unit
Dimensions	Sterilizer: 275 (W) x 440 (D) x 330 (H) Pump unit: 275 (W) x 440 (D) x 330 (H)			mm
Chamber volume	7			liter
Safety Device	Physical	Opening prevention by door sensor and vacuum		
	Electrical	Insert rated fuse for overcurrent prevention		
Process variable	Cycle Temperature	< **60**		ºC
	Pressure range	0 – 760		torr
	Base pressure	< 3.0		torr
	Diffusion pressure	20 – 80		torr
	Process verification	Chemical indicator (CI)	Type 1 (Compliance: ISO 11140-1)	Process verification
Vacuum	Base pressure	< 3.0		torr
	Vacuum leakage	< 0.1		torr/sec
Sterilization	Sterilization Performance	LUMEN (Single-channel Stainless Steel)	Dia. 0.7, Length: 500 Dia. 2, Length: 1,500	mm
		LUMEN (Single-channel PTFE)	Dia.: 1, Length: 2,000	mm
	Sterilization process time	POUCH	**4**	min
		CHAMBER	**10**	min
	Full cycle time	POUCH	**7**	min
		CHAMBER	**18**	min
Sterilant	Hydrogen peroxide (H_2O_2 58 – 59.5%)			-
Purification	Plasma discharge treatment (Low frequency)			-
Display	Size	154.9 (W) x 89.0 (H)		mm
	Resolution	800 x 480		mm
Port	IEC-320 C14, RJ-45, USB type A, USB type B, cable connector			-
Electrical characteristic	Rated power	100 VAC, 12 A		-
	Rated frequency	50-60		Hz

User manual for the GC STERLINK mini sterilization system

Manufacturer: Plasmapp Co., Ltd.

102, Cheombok-ro, Dong-gu, Daegu, 41061

Republic of Korea

Website: https://plasmapp.com/eng/

TEL: +82-1544-0508

- This user manual is not for sale. -