User Manual

RENO-S130

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Renosem

Low Temperature Hydrogen Peroxide Sterilizer

RENO-S130 User Manual

RENOSEM Co., Ltd.

REOM-004-Rev.22

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Chapter 1. Introduction

1. About user manual

The user manual is to provide detailed information required to operate RENO-S130 Low temperature Hydrogen peroxide sterilization system.(Hereinafter "RENO-S130") Please read the manual and abide by user guideline to properly employ RENO-S130.

2. Intended use

RENO-S130 is used to sterilize the medical products including surgical instruments using Sterilization Agents in low temperature. RENO-S130 is suitable for heat and moisture sensitive instruments as the operation temperature of the sterilizer is low. The end-user can conveniently employ the sterilizer as the process data is displayed on the touch panel in real-time and print paper after the completion of process.

3. RENO-series sterilization system

RENO-series sterilizer disperses hydrogen peroxide gas to sterilize medical instruments during vacuum state of chamber through initializing stage. All stage of sterilization process is operated in dry, low temperature environment, which prevents the heat and moisture sensitive medical instrument from damage and leaving no toxic residue. For safe work environment, H2O2 gas is diffused into pure water and oxygen using plasma generator and vented outside through filter.
RENO-series sterilizer guarantees the sterility assurance level(SAL) of 10-6 defined by International Standard Organization(ISO), given understanding that the sterilizer is used in abiding by the user manual and, the material and structure of the medical instrument is compatible.

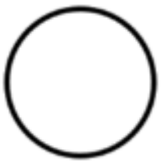
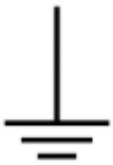
4. Inquiry

In case of query regarding RENO-S130 or compatibility of the item to be sterilized, please contact your local distributor or visit RENOSEM website at www.renosem.com

Chapter 2. Safety Information

The chapter contains information for safe use of RENO-S130 sterilizer. Carefully read the safety information of the user manual and its warning, caution and reference in prior to its usage.

1. Safety symbols

Definitions of Symbols found on RENO Sterilizer			
On(power) IEC 417, No.5007	 Off(power) IEC 417, No.5008	 Earth(ground) IEC 417, No.5017	 Protective earth IEC 417, No.5019
 Caution, hot surface IEC 417, No.5041	 Caution, risk of electric shock IEC 417, No.6042	 Direct current IEC 417, No.5031	 Alternating current IEC 417, No.5032
 Danger Revolving Objects	 Danger, Strong Oxidizing Agent	 Danger, Corrosive Substances	 Danger, Hands cutting in
 Danger, High Volage	 Caution, risk of radio frequency shock	 Wear Protective Gloves	 Wear Protective Goggles
 Type B applied part IEC 417, No.5840	 Caution, refer to accompanying documents	 Do not Disassemble	 Do not Touch with Hands

2. Personal Safety and First Aid

1) Hydrogen peroxide used for Sterilization Agent(Hereinafter “SA”) is easy to permeate and irritative to skin, eye, nose, neck, lung and gastrointestinal tract When using SA, use protective(latex or plastic) or waterproof glove. Empty cassettes must be discarded in designated place depending on hospital waste disposal regulation.
2) Hydrogen Peroxide is strong oxidizer and potentially dangerous with fire, explosion or damage of container. Prevent H2O2 from exposure to inflammable material such as paper, linen, wood or organics. Do not use or store H2O2 near heat or fire. In case of H2O2 exposure to clothes or other inflammable substances, rinse with running water immediately.
3) When H2O2 was exposed to skin with improper usage, rinse it with running water to prevent serious irritation. When H2O2 was exposed to eye, it may cause tissue damage. Rinse it with running water at least 10 minutes and follow doctor’s instruction. If H2O2 was inhaled, it may cause serious irritations to neck, lung and bronchitis. Move to the location with fresh air. If the patient is unbreathing, conduct emergency treatment and cardiopulmonary resuscitation. Contact emergency service and follow paramedic or doctor instruction. H2O2 may be life threatening if intake. Drink a lot of water immediately and follow doctor’s instruction. Do not vomit unless instructed by doctor. If the patient is unconscious, do not drink any water and follow doctor’s instruction after moving the patient to the hospital.
4) In case of dust or smoke fuming from sterilizer vent, it may be caused by trouble of filter or vacuum pump. Suspend the operation immediately and contact your customer service.

3. Precautions

1) Sterilization Agents(SA)

If the operation stopped due to anomaly or malfunction during sterilization or, remaining moisture on sterilized instruments after process complete, there may be H2O2 residue on surface or inside of the medical instruments. When handling such items, wear protective or waterproof gloves and do not touch eyes or face with wearing glove.

If the operation failed during the procedure due to the user cancellation or malfunction of the sterilizer, there may be H2O2 remaining in the SA cassettes. Wear protective glove to remove the cassettes.

SA cassettes must be exchanged for each cycle. Do not reuse SA.

2) Installation

Service personnel in knowledge and experience must install the sterilizer.

To initially install or relocate the sterilizer, service personnel approved by RENOSEM must do so.

After long suspension of its operation and usage, contact RENOSEM and take adequate advice before reusing.

3) Preparation of medical instrument

Medical instruments to be sterilized must be completely washed and dried. If there are organic or foreign matters on surface due to improper washing, it may be the cause of ineffective sterilization. The large quantity of moisture on medical instrument may be cause of extended operation time, and may lead to operation failure. If moisture exists on medical instrument, the sterilization efficacy cannot be guaranteed.

For sterilization instruction, follow the user guideline of instrument manufacturer.

The user guideline does not supersede that of the instrument manufacturer. In prior to use RENO-S20, check whether the material of the instrument is compatible with the sterilizer and select adequate cycle mode. The compatible materials are listed in the user manual. If information is unknown, please contact the instrument manufacturer or RENOSEM.

4) Consumables

Use of self-controlled biological indicator(Hereinafter “BI”) or chemical indicator(Hereinafter “CI”) strip and tape, pouch, wrap and tray must be provided or validated from RENOSEM for sterilization efficacy.

For each cycle, CI strip must be inserted with medical instrument to check sterility. BI must be used once in a week at minimum, in order to check sterilization performance is normal.

5) Miscellaneous

① Do not turn off circuit breaker or unplug the power cord during operation.
② Do not touch the sterilizer with wet hands.
③ Do not cause shock to the sterilizer.
④ Always close the chamber door except when loading and unloading the medical instruments.
⑤ If any anomaly is detected during use, suspend the operation immediately. and contact your administrator.
⑥ Do not disassemble, repair and modify the sterilizer unless authorized by RENOSEM.

Chapter 3. Description

1. Component

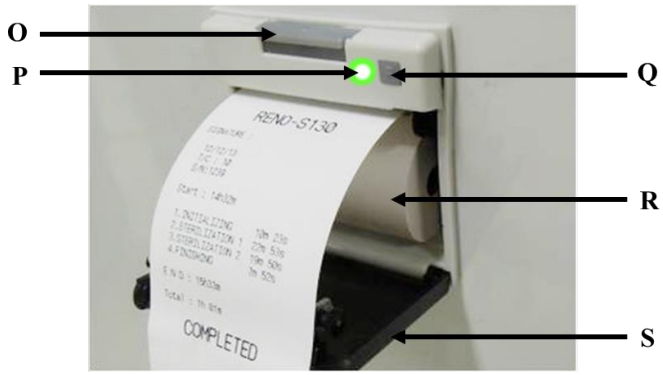
1) Exterior

No	Item	Function (Specification)
A	Touch panel	The component can control and monitor operation, and manage the function of the sterilizer.
B	Sterilant lamp	The blue LED lamp turns on when the sterilant is inserted into the Sterilant injection hole, so user can check whether the sterilant is present.
C	Door ON/OFF lamp	The red LED lamp turns on when the door is closed, so user can check whether the door is open or not.
D	Printer	Printer displays print out of the status of sterilization including results and errors.
E	Power Switch	The component is used to turn on and off of the machine.
F	Sterilizer Door	The door is used not only for loading and unloading the sterilizer, but also concealment for vacuuming and pressurizing chamber.
G	Power cord	It is used to connect plug to outlet.
H	Main switch	User can switch on and off the power to main system.
I	Ventilating fan	It is used to discharge heat.
J	Vent Grill	It is used to circulate the air inside sterilizer.

2) Interior

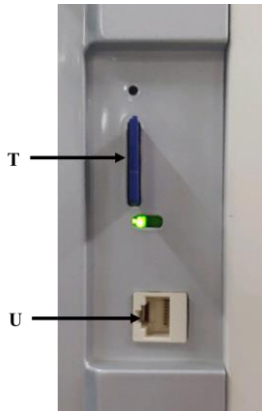
No	Item	Function (Specification)
K	Chamber	It is a vessel to contain the medical instruments for sterilization.
L	Shelf	It enables the user to place the medical instruments in dual layer. It can be removed if unused.
M	Sterilant injection hole	It is to insert the cassettes to supply H2O2 into the chamber.
N	Sterilant injection hole button	It is a button to open the sterilant injection hole.

3) Printer



No	Item	Function (Specification)
O	Printer cover open button	If pressed, the printer cover will open.
P	Printer Power lamp	User can check the printer status.
Q	Print paper button	The button enables user to pull out the print paper without opening printer cover.
R	Print paper	After the sterilization cycle is complete, the result is printed on the paper.
S	Printer cover	It is to be opened / closed to exchange the print paper.

4) SD card & LAN cable port

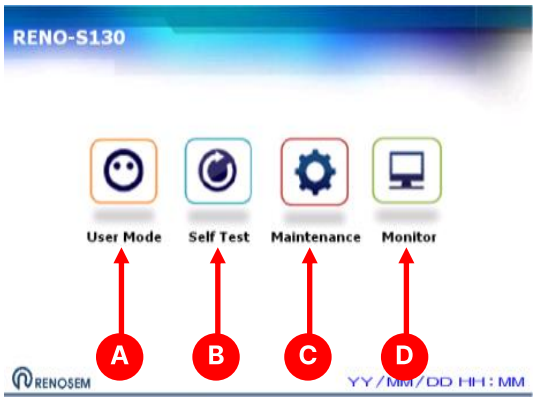


No	Item	Function (Specification)
T	SD card slot	It is a port for SD card to export print out information to PC.
U	LAN cable port	It is used to monitor or remotely control the sterilizer by connecting the sterilizer to a computer.

2. Touch Screen

1) Main screen

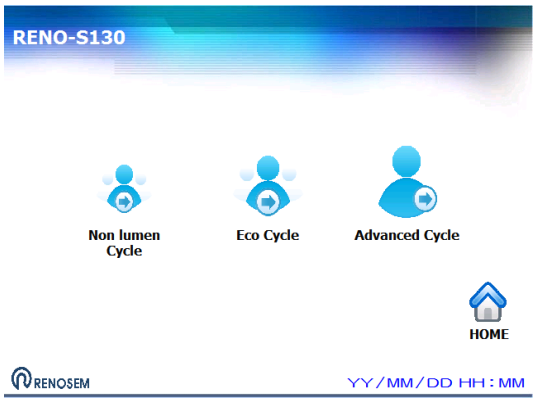
When the sterilizer power is turned on, main screen will pop up after loading(10 seconds).



No	Item	Function (Specification)
A	User Mode	User can select sterilization cycle.(Non-lumen cycle, Eco cycle, Advanced cycle)
B	Self Test	User can conduct self-test for the sterilizer maintenance.
C	Maintenance	Service engineer can conduct maintenance to the sterilizer.
D	Monitor	User can check the status for sterilization cycle.

2) Sterilization cycle

Press “User Mode” to enter selection screen for sterilization cycle.
To return to main screen, press [ ] icon on the bottom right.

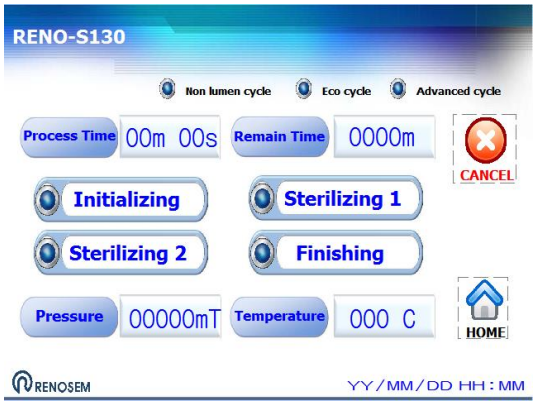


(1) Start sterilization cycle

Select each sterilization cycle button to enter “start” screen. Tap the start button to initiate sterilization cycle. To return to previous screen, press the arrow button in the lower right corner. And to return to main screen, press [ ] icon.

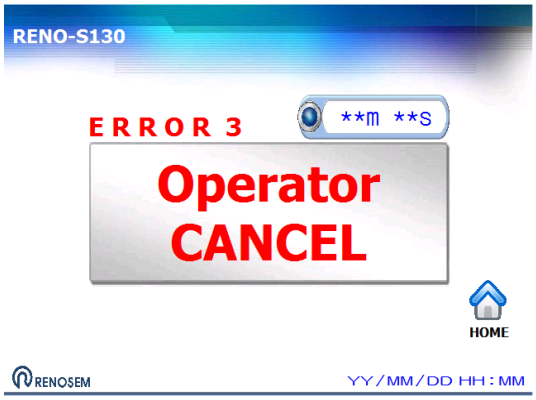
(2) Sterilization cycle process

Sterilization cycle process screen shows the current status for the on-going cycle.
User can check selected sterilization cycle, remaining time, real time pressure and temperature inside chamber, sterilization stage.
If user wants to cancel the operation before it is complete, tap “CANCEL” on the top right corner to stop the operation. If user wishes to return to the main screen, tap [ ] icon bottom right corner. The touch screen displays the main screen, but the sterilization cycle is operating. If user wishes to return to the process screen, tap [ ] icon in main screen.



(3) Cancel sterilization cycle

User can cancel the on-going cycle by pressing "CANCEL"] button. However, the sterilization cycle would only be cancelled after the finishing stage is completed to diffuse and vent the sterilization agent within the chamber.



(4) Sterilization cycle complete

When the sterilization cycle is complete, it will display the "process is completed" is completed screen. The visual and sound alarm would last for 10 seconds and, the result would be printed out. Press [ ] icon on the bottom right to return to the main screen.

3) Self-Test

Before daily use, the user can conduct self-test cycle to check the function of the sterilizer. Tap the "self-test" button on the main screen to enter start screen. Press the "Start" button to begin the sterilizer check-up. The result screen will pop up when the self-test is complete. To return to main screen, press [ ] icon on the bottom right corner.

3. Sterilization Cycle

To maximize the sterilization efficacy to the medical instruments, user must employ the appropriate sterilization cycle for the medical instruments. The load of the medical instrument must not exceed the maximum validation load for the sterilization cycle. If it is hard to select sterilization cycle for a specific medical instrument, contact the manufacturer or RENOSEM for inquiry.

1) General

The sterilization cycle of RENO-S130 consists of Advanced cycle, Eco cycle, Non-lumen cycle. Each cycle mode can be selected based on the sterilization time and configuration of the instrument to be sterilized. Each cycle is comprised of four stages: initializing stage, sterilizing 1 stage, sterilizing 2 stage and finishing stage.

Before daily use, the user can conduct self-test cycle to check the function of the sterilizer.

2) Sterilization process

(1) Four stages of sterilization cycle

① Initializing Stage

Start selected sterilization cycle after inserting medical instrument in the chamber. In the initializing stage, the chamber is being vacuumed for the dispersion of SA gas into the chamber.

② Sterilizing I Stage

Sterilizing I Stage is the earliest phase when the actual sterilization of medical instrument is being done. SA is injected, dispersed and condensed into the chamber for the sterilization of the instruments.

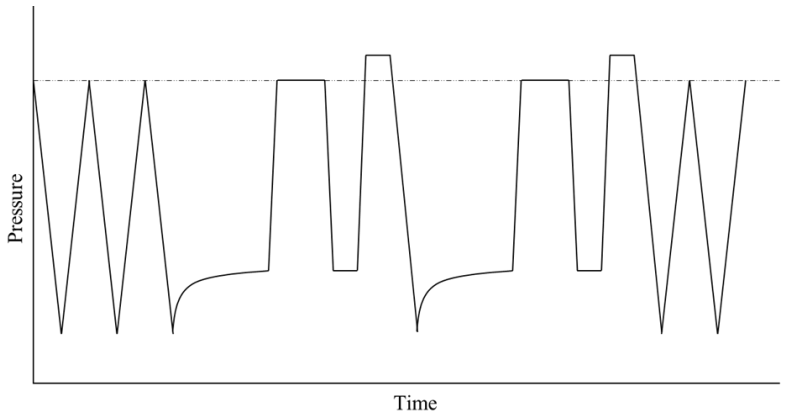
③ Sterilizing II Stage

Sterilizing II Stage is secondary phase for the sterilization. Identical process to that of sterilizing I stage is conducted.

④ Finishing Stage

Finishing Stage is to remove the existing SA gas within the chamber. After sterilizing I and II stage is complete, the pressure of the chamber returned to atmospheric level, in order to remove the sterilized items from the chamber.

(2) Advanced Cycle

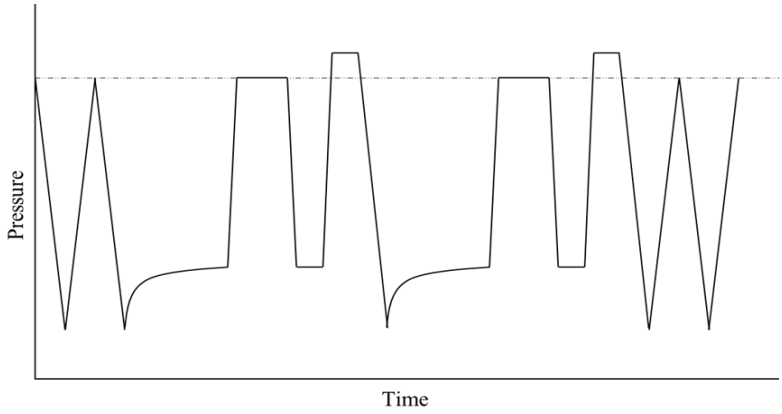


Advanced cycle of RENO-S130 can sterilize the medical instrument with hard-to-access areas such as long tube type instrument and adjunction of scissors, etc.

Tube type with the specification below can be sterilized in RENO-S130 advanced cycle.

- ✓ **Single channel Teflon lumens with**
  Inside diameter ≥ 1mm and length ≤ 1,000mm
- ✓ **Single channel Stainless steel lumens with**
  Inside diameter ≥ 0.7mm and length ≤ 500mm

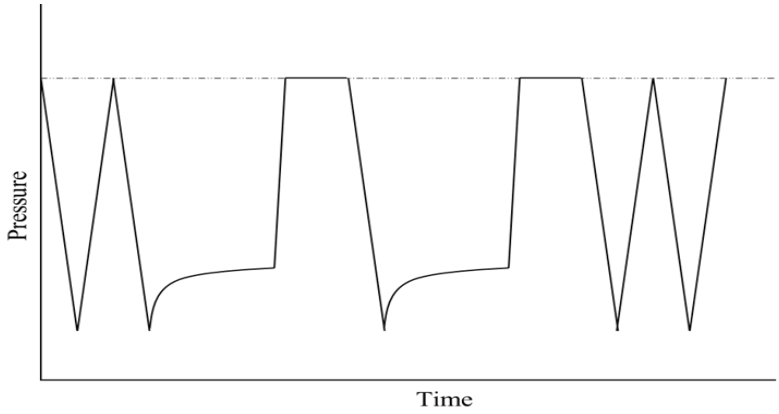
(3) Eco Cycle



Eco cycle of RENO-S130 can sterilize up to two endoscopes and can sterilize general surgical instruments or short tube type instruments.

- ✓ **Single channel Teflon flexible endoscope with**
  Inside diameter ≥ 1mm and length ≤ 900mm
- ✓ **Single channel Teflon lumens with**
  Inside diameter ≥ 1mm and length ≤ 400mm
- ✓ **Single channel Stainless steel lumens with**
  Inside diameter ≥ 1mm and length ≤ 200mm

(4) Non-Lumen Cycle



Non Lumen cycle of RENO-S130 can sterilize non-lumened instruments and instruments that require sterilization of surface. Also, using only the upper shelf of dual shelf of RENO-S130 chamber will maximize the sterilization efficacy.

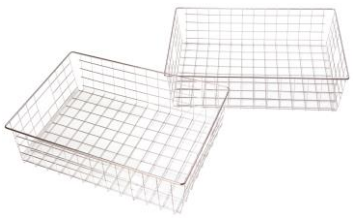
4. Sterilization load weight

To maximize the sterilization efficacy, the weight of medical instruments must not exceed the maximum load weight for each cycle. The maximum load weights are as table below and, one of two shelfs in the chamber may be limited for use depending on the selected cycle.

Sterilization cycle	Weight	Shelves
Advanced cycle	12kg or less	Top/bottom shelf usable
Eco cycle	8kg or less	Top/bottom shelf usable
Non-Lumen cycle	5kg or less	Top shelf usable only

5. Accessories and consumables

Accessories and consumables must be verified for its compatibility by RENOSEM. Always use the accessory and consumable provided by RENOSEM. Otherwise, sterilization efficacy cannot be guaranteed.

Item	Image	Function (Specification)
Sterilization Agent (RENO-SA10)		Sterilization agent is a hydrogen peroxide solution used for sterilization process. 1 cassette per 1 cycle. • Storage : room temperature or refrigerated at 5 ~ 30°C • Expiration date : 12 months from the manufacturing date, displayed in product label
Chemical Indicator Strip & Tape		Chemical indicator is to indicate sterilization efficacy indirectly by level of dispersion of SA within the chamber. • Storage : room temperature avoiding sunlight. • Expiration date : displayed in the product label
Pouch		Tyvek pouch is used to pack the medical instrument, which prevents contamination of instrument and guarantee longer sterility. • Dimension : 75, 100, 150, 200, 250, 300, 400mm • Storage : Room temperature avoiding direct sunlight and humid environment. • Expiration date: 60 months from the manufacturing date
Non-Woven Sheet		Non-woven sheet is used to pack a large sized medical instrument. it prevents contamination of instruments and guarantees longer sterility. • Storage : Room temperature avoiding direct sunlight and humid environment. • Expiration date : 36 months from the manufacturing date.
Biological Indicator		Biological indicator is used to indicate the sterilization performance of steril. • Storage : room temperature avoiding sunlight. • Expiration date : displayed in the product label.
Sterilization tray		Sterilization tray is used for easy loading and unloading of the instruments into the chamber. Two trays are included as standard accessories.

Item	Image	Function (Specification)
BI Incubator		BI incubator is used for the incubation of biological indicator. • Used temperature : 58~60°C(incubation temperature of *Geobacillus stearothermophilus*)

Chapter 4. Sterilization Preparation

1. Sterilizer checkup before use

1) Check if the sterilizer door is closed. The door must be closed even when idle.
2) Check if power cord is plugged into socket, and main power switch is on. If installed initially, power cord was unplugged or main power switch was down, connect the power cord and turn on the main power switch. 2 to 3 hours of pre-heating time after power supply is required for sterilizer chamber.
3) Turn on the power button located on the upper right corner adjoining with the right side of the chamber door when closed. If the power is on, the light comes on around the button.(**Note/**Refer to the sterilizer exterior photo in Chapter 3 for the actual power button location.)
4) Check if touch panel is on and main screen is displayed.

2. Sterilization material

RENO-S130 is a medical device used for the sterilization of metal or non-metal made medical instrument in low temperature. RENO-S130 can sterilizer heat and moisture sensitive instrument in low temperature and humidity environment. RENO-S130 maximized the sterilization efficacy using hydrogen peroxide, and the SA(H_2O_2) is diffused into safe substances and vented.

1) Compatible materials

(1) Metal
- ① Aluminum
- ② Stainless steel
- ③ Titanium

(2) Plastic
- ① Acrylonitrile butadiene styrene : ABS
- ② Kraton polymer
- ③ Polyethylene
- ④ Polycarbonate
- ⑤ Polypropylene
- ⑥ Polystylene
- ⑦ Polyethylene terephthalate : PET
- ⑧ Polytetrafluroethylene : PTFE
- ⑨ Polymethyl methacrylate : PMMA
- ⑩ Polyether ether ketone : PEEK

(3) Glass

(4) Rubber
- ① Silicone elastomer

(5) Ceramic

(6) Lumen
- ① Hard-lumen
  a tube with an inside diameter of ≥ 0.7mm and a length of ≤ 500mm
- ② Soft-lumen
  a tube with an inside diameter of ≥ 1mm and a length of ≤ 12,000mm
- ③ One end blocked lumen
  a tube with an inside diameter of ≥ 2mm and a length of ≤ 1,500mm with one end blocked
- ④ Flexible endoscope
  an endoscope with an inside diameter of ≥ 1mm and a length of ≤ 900mm
- ⑤ Da Vinci endoscope: 8mm endoscope Xi

2) Incompatible materials

(1) Liquid

① Oil
② Water
③ Bubble

(2) Powder

(3) Absorptive material or material that contains water

① Paper
② Cellulose based material
③ Textile: Gauze, linen, towel, sponge
④ Wood/pulp

(4) Instrument or device that cannot be in vacuum state

(5) Others

① Acetal
② Buna N(Nitrile)
③ Brass
④ Hypalon
⑤ Copper and Zinc

3) Cautionary materials

(1) Disposables that reuse of the item are not recommended.
(2) Instrument that can be bleached or discolored due to surface painting.
(3) Cables : some of cables may stick to the plastic side of Tyvek pouch. Use non-woven sheet for packing.
(4) Instrument or device in which the manufacturer does not recommend sterilization by low temperature H2O2 gas sterilizer.
(5) Instrument or device that can be damaged by vacuuming or vacuum state.
(6) Instrument which confined space exists.

3. Washing and drying

The instrument to be sterilized must be washed and dried in prior to loading to the sterilizer. Complete washing and drying will enhance the sterilization performance.

1) Washing and Rinsing

- Wash the medical instrument based on the guideline of the manufacturers.
- Remove the blood or foreign object on the instrument with the adequate detergents. Remaining contamination may lower the sterilization efficacy.
- Rinse the instrument to remove the remaining detergent or contaminant after washing. Remaining contamination may lower the sterilization efficacy.

2) Drying

- Dry the medical instrument based on guideline of the manufacturer.
- Medical instrument must be fully dried in prior to the sterilization.
- Unless the instrument is fully dried, it may be a cause of lower sterilization quality, delayed operation time or sterilizer error. Remaining water on the medical instrument may cause user to experience sting or contact burns due to the remaining H2O2 in the chamber, although the sterilization cycle is complete.

4. Packaging

- In prior to packaging, inspect instrument for any damage or defect of the medical instrument and its parts. If so, the instrument must be repaired and replaced in prior to the sterilization.
- The packaging must be done by Tyvek pouch or non-woven sheet designed to be used for low temperature plasma or H2O2 sterilization. The packaging products for steam or EtO sterilization cannot be used.
- Medical instrument must be packaged using sterilization tray, Tyvek pouch and non-woven sheet provided by RENOSEM to guarantee of sterilization efficacy.
- Packaging medical instrument with CI strip is also recommended. However, the CI strip cannot be an alternative to using BI, as it is a mere chemical indication of the exposure to SA(H2O2)

5. Loading

- Packaged medical instrument must be vertically placed on sterilization tray. If the instrument is packaged with pouch, place it in unidirectional way in order to avoid transparent side facing each other.
- Packaged medical instrument must not be stacked. This caution applies to sterilization container specifically designed for the instrument.
- If there is a container specifically designed for sterilization of the medical instruments, package it on the surface of container after placing instrument inside, in order to avoid double packaging of the item.
- The weight of medical instrument must not exceed the sterilization validation load of the sterilization cycle.
- The weight of medical instrument varies on the length and number of lumen device. Refer to lumen guideline.
- BI must be used 1 vial per day, or in abiding by indigenous hospital regulation. Only use BI provided by RENOSEM to guarantee the sterilization efficacy.

◀ Tray loading of medical instrument

Chapter 5. Sterilizer Operation

In prior to use of medical device, check for the preparation of medical devices based on the guideline before using RENO-S130. User is responsible for the issues occurred due to incomplete understanding of safe information and weight of maximum loads for sterilizer.

1. Insert Sterilization Agent

1) After wearing the protective glove, take out the new SA from SA box.
2) Inspect if there are any defects (wet, broken, etc.) and check expiration date is valid.
3) Open the sterilizer door and press the sterilant injection hole button on the bottom right of the sterilizer chamber to take out the sterilant injection hole.
4) Insert SA cassette into the sterilant injection hole.
5) Check if blue LED lamp on the top right by door and push the sterilant injection hole until it clicks. This will complete the procedure for how to insert SA before sterilizer use.

▲ **Sterilant injection hole**

Caution

- ✓ Always use protective gloves when handling SA.
- ✓ Sterilization agent is hydrogen peroxide, and it may cause a burn or stimulation to skin in case of contact.
- ✓ When in contact with SA, rinse the contact point with running water.
- ✓ Used SA cassettes must be disposed in abiding by waste disposal policy of the user or hospital.
- ✓ When sterilization cycle is complete, remove and dispose SA cassettes from sterilizer.
- ✓ Close the sterilizer door at all times except when loading and removing sterilization items.

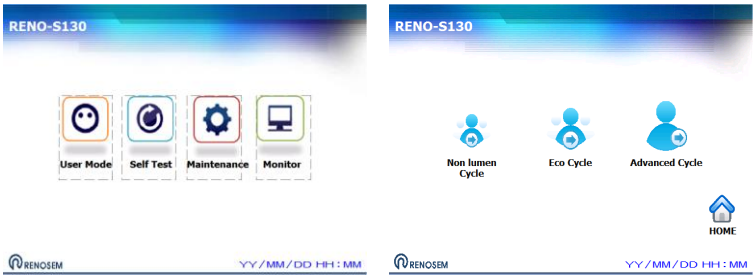
2. Loading the chamber

1) **Open the door and place medical instruments packaged in Tyvek pouch or sterilization tray on shelf in chamber.**
   - Use of sterilization tray is recommended. If unused, take caution packaged instrument are not in contact with the rear wall of the chamber. It may lead to blockage of vacuum vent, causing vacuum failure(error 1).
   - If required, upper shelf in the chamber can be removed to support large sized medical instruments.
   - When using non-lumen cycle, use upper shelf only.
2) **When loading is complete, close the sterilizer door. If the door is fully closed, red lamp on upper right of the chamber will be lighted.**
   - Check if a foreign object is stuck between door gap before closing the door. Object such as pouch or non-woven sheet may be caught, which lead to lower sterilization quality.
   - Use and wipe the door gap of the chamber with clean linen and alcohol once every week.

◀ Chamber loading

3. Selecting and starting a sterilization cycle

1) When all preparations are complete, press user mode button and select the sterilization cycle.



2) Select the desired cycle and press start button. User can check the progress of selected cycle on next page.

4. Sterilization cycle complete

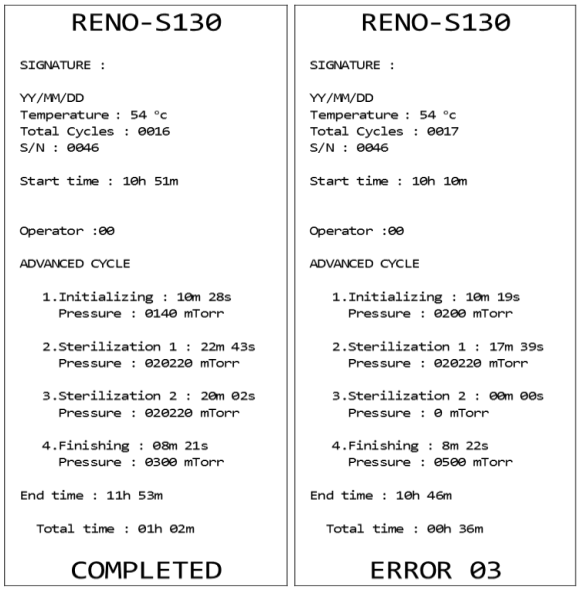
1) When sterilization cycle is complete, the visual and sound alarm will pop up. If error is caused, the cause must be determined and solved to restart the sterilization cycle.

2) Open chamber door and remove sterilized instruments.
3) Close the chamber door and remove the used SA from the insertion point. SA must be discarded based on waste disposal regulation of user or hospital.(Note/Before using the sterilizer, conduct self-test on daily basis to check the operational status of the sterilizer.)

5. Sterilization cycle record

1) Print out information

- When sterilization cycle is complete, the detailed cycle result is printed out.
- Always check the result of the sterilization cycle as the successful operation will display 'COMPLETED,' or 'ERROR' with designated number if unsuccessful.
- Printer paper is thermal paper and heat sensitive material, and storage under direct sunlight or high temperature location will blur the content of print paper. The validity of printer material is 5 years from the printing date. If longer period of storage is needed, printed material should be copied and stored.
- It is recommended to store the printed material as it is important for maintaining the record of sterilizer usage and post-sterilization management of medical instruments.



RENO-S130

SIGNATURE :

YY/MM/DD
Temperature : 54 °c
Total Cycles : 0016
S/N : 0046

Start time : 10h 51m

Operator :00

ADVANCED CYCLE

1.Initializing : 10m 28s
Pressure : 0140 mTorr

2.Sterilization 1 : 22m 43s
Pressure : 020220 mTorr

3.Sterilization 2 : 20m 02s
Pressure : 020220 mTorr

4.Finishing : 08m 21s
Pressure : 0300 mTorr

End time : 11h 53m

Total time : 01h 02m

COMPLETED

RENO-S130

SIGNATURE :

YY/MM/DD
Temperature : 54 °c
Total Cycles : 0017
S/N : 0046

Start time : 10h 10m

Operator :00

ADVANCED CYCLE

1.Initializing : 10m 19s
Pressure : 0200 mTorr

2.Sterilization 1 : 17m 39s
Pressure : 020220 mTorr

3.Sterilization 2 : 00m 00s
Pressure : 0 mTorr

4.Finishing : 8m 22s
Pressure : 0500 mTorr

End time : 10h 46m

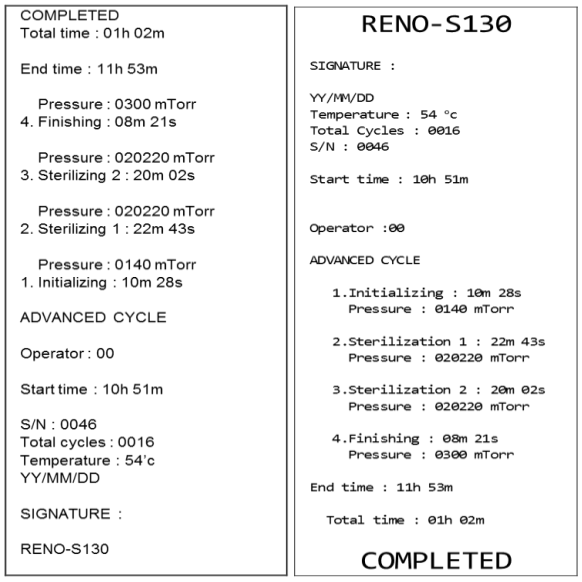
Total time : 00h 36m

ERROR 03

◀ Print out information after sterilization cycle complete

2) SD card Slot

- Sterilization cycle data can be stored on SD card, which is saved in name and format of 'Logfile.txt' in DATA folder. The file will open with the program that support txt format.(**Note/**txt file will open with "notepad" program most of time.)
- The green lamp will be lighted if SD card is properly inserted. The saved information is identical to that which was printed with thermal paper but upside down.
- The information saved in SD card is latest from top to bottom.



COMPLETED
Total time : 01h 02m

End time : 11h 53m

Pressure : 0300 mTorr
4. Finishing : 08m 21s

Pressure : 020220 mTorr
3. Sterilizing 2 : 20m 02s

Pressure : 020220 mTorr
2. Sterilizing 1 : 22m 43s

Pressure : 0140 mTorr
1. Initializing : 10m 28s

ADVANCED CYCLE

Operator : 00

Start time : 10h 51m

S/N : 0046
Total cycles : 0016
Temperature : 54'c
YY/MM/DD

SIGNATURE :

RENO-S130

RENO-S130

SIGNATURE :

YY/MM/DD
Temperature : 54 °c
Total Cycles : 0016
S/N : 0046

Start time : 10h 51m

Operator :00

ADVANCED CYCLE

1.Initializing : 10m 28s
Pressure : 0140 mTorr

2.Sterilization 1 : 22m 43s
Pressure : 020220 mTorr

3.Sterilization 2 : 20m 02s
Pressure : 020220 mTorr

4.Finishing : 08m 21s
Pressure : 0300 mTorr

End time : 11h 53m

Total time : 01h 02m

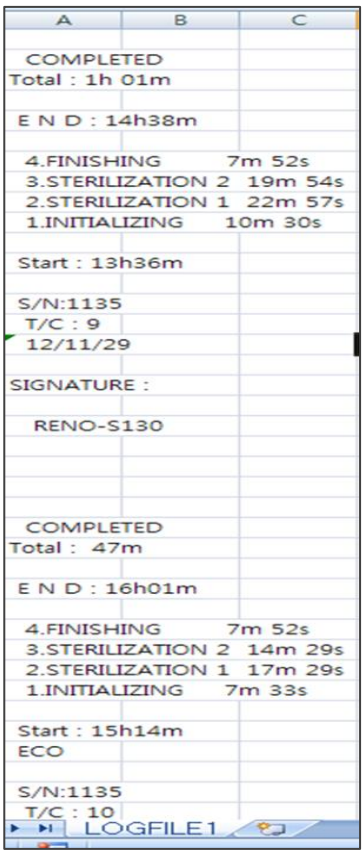
COMPLETED

◀ text file format saved in SD card / Printed material

• User can save the txt file into Microsoft excel format(xlsx). Follow the instruction below.

① **Run Microsoft Excel → File –Select Open → Select extension to "All" → Select Logfile.txt**
② **Text wizard screen will automatically appear. → In 1-1 screen, Select "Delimited", Select Start import at row – "1", Select File Origin "852 : Central European(DOS)" → Go to Next**
③ **In 1-2 screen, Select Delimiters "Other –"→ Go to Next**
④ **In 1-3 screen, Select Column data format "General" → Go to Finish**

• If you follow the instructions above, the file will be opened as shown in the picture on the right.
• To save as, select excel extension(xlsx) to save file in excel format.

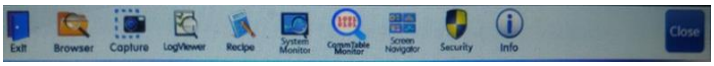


6. Remote monitoring

User can connect RENO-S130 sterilizer and personnel computer to remotely monitor the sterilizer. If connected, the touch screen of RENO-130 sterilizer will appear in computer screen identical to that of the sterilizer.
RENO-S130 Sterilizer can be remoted controlled, and user can use the connected computer to operate the sterilizer.

1) Touch screen setting

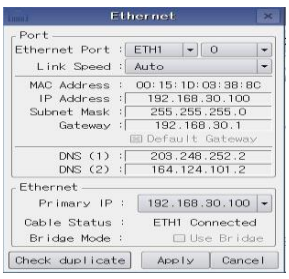
(1) Load system menu from the main screen. The system menu will appear by sliding down the upper center of the touch panel.



(2) Press 'Exit' icon on the bar. The sterilizer menu will close and transit to touch screen menu.

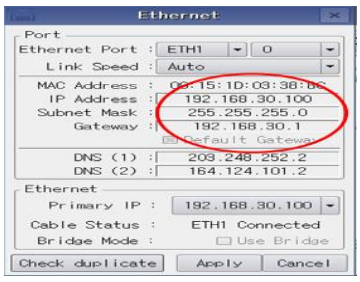
(3) Open Control Panel window by pressing the icon in the menu. Press Ethernet on the system section.

▲ Control panel

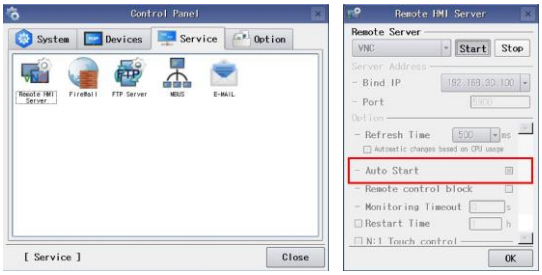


▲ Ethernet

(4) Configure each network on the Ethernet screen. Inquire set value of each network to the administrator.



(5) Return to control panel, and select start automatically on Remote HMI server in the service section.

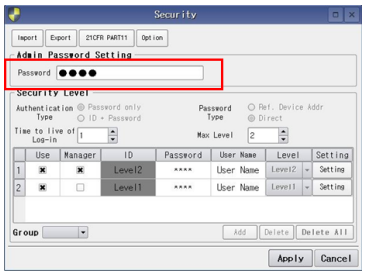


- ✓ Auto Start : Remote HMI server will automatically start when touch screen reboots.
- ✓ Remote control block : Remote control is disabled and remote monitoring is enabled upon selection.
- ✓ Bind IP : IP value selected in 6.1.4 will be default VNC server IP.

- For remote monitoring, touch screen setting and PC setting is required. Identical IP address is required for both touch screen and PC.

(6) Set admin password on the security in the system section.

- The password can be maximum 8 letters in numbers, upper- and lower-case letter. Upper- and lower-case letters are distinguished.
- Set password is required for all system configurations including networking.



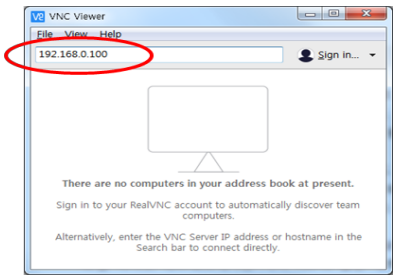
- Do not change other preset value. It may cause serious error to the system operation.

2) PC Setting

(1) Download and install latest version of VNC-Viewer program.

- ✓ Download Link
  https://www.realvnc.com/en/connect/download/viewer/
- ✓ The program may be changed or required to be purchased depending on terms and condition of the proprietor of the program.

(2) Execute VNC-Viewer, insert IP address identical to VNC server IP on touch screen and press enter.



(3) During gaining access to VNC server, password authentication screen will open. Insert the password set on the admin password setting.(touch screen).

(4) Connect PC and sterilizer with LAN cable.

- ✓ Direct connection : Gateway-IP-Address of PC and touch screen must be identical.
- ✓ Indirect connection(HUB) : Gateway-IP-Address of touch screen must be identical to that of AP(Access point).

- In case of public network environment, configure touch screen and PC IP address with assistance of network administrator.
- Admin password must be set and protected in intranet or internet to maintain security.

3) Remote monitoring

(1) Return to sterilizer main screen by pressing “Run” icon in the touch screen menu screen.

(2) If connected to PC, “eye” icon will be displayed on the upper right corner of touch screen and VNC viewer. The connected sterilizer can be monitored and controlled from the PC.

(3) To discontinue remote monitoring, click “eye” icon to close the program on both touch screen or VNC viewer.

7. Sterilization check : Indicators

1) Chemical Indicator(CI)

Chemical indicator or CI is recommended to be included for each sterilization cycle run. However, unlike Biological indicator or BI, CI cannot check sterilization efficacy of sterilizer but diffusion of SA.

CI strip is recommended to be inserted into Tyvek pouch before packaging, and CI tape is recommended to be taped to non-woven sheet or pouch for packaging.

(1) CI Color

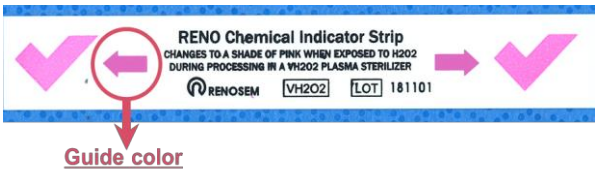
① Pre-sterilization color

- ✓ CI Tape : Blue
- ✓ CI Strip : Purple
- ✓ If the color of CI is changed, do not use the CI as it may have been exposed or expired.

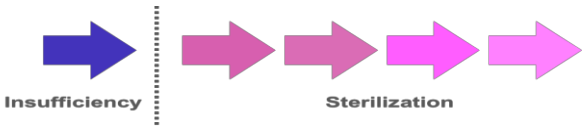
② Post-sterilization color

- ✓ CI Tape : Pink
- ✓ CI Strip : Pink
- ✓ Check the sterilization by the following instruction to observe level of color change.

(2) How to check CI color change



- If CI is exposed by H2O2, the color of CI will change into pink from blue or purple.
- The color change of CI strip can be easily observed thanks to guide color. If color change of CI strip is brighter or similar to guide color, the medical instrument is sufficiently sterilized and ready for use.
- If the color change of CI is darker than guide color or stained, medical instrument must be re-sterilized.
- Insufficient color change of CI may be related to the absorptive material or amount of water or oil in the chamber. Check medical instrument again and re-sterilize.



- If insufficient color change of CI is repeated 3 times or more, contact local distributor or RENOSEM customer service for overhaul of the sterilizer.
- Use CI supplied by RENOSEM for guaranteeing to sterilization check.

2) Biological Indicator(BI)

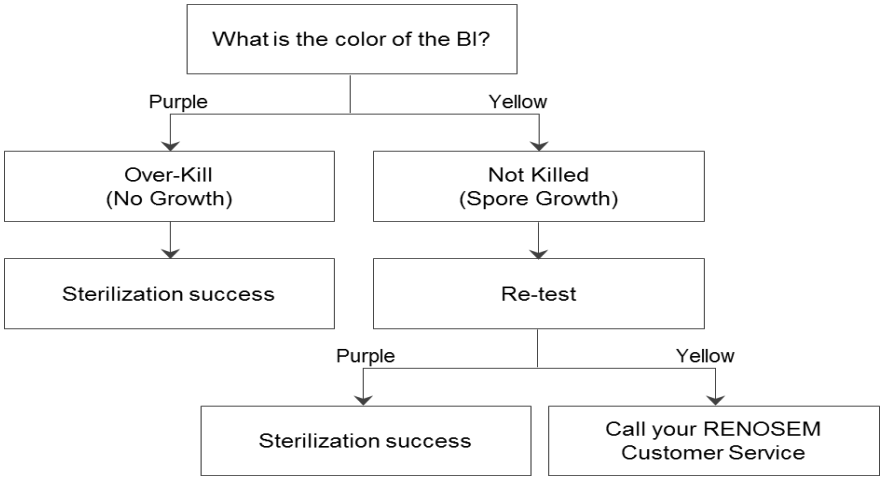
Biological indicator or BI can check sterilization efficacy of sterilizer. It is recommended to use BI to check the performance of sterilizer once a week at minimum, or abiding by hospital regulation.
BI supplied by RENOSEM uses microorganism that is resistant to hydrogen peroxide sterilizer, and can verify performance of the sterilizer.

(1) How to use BI

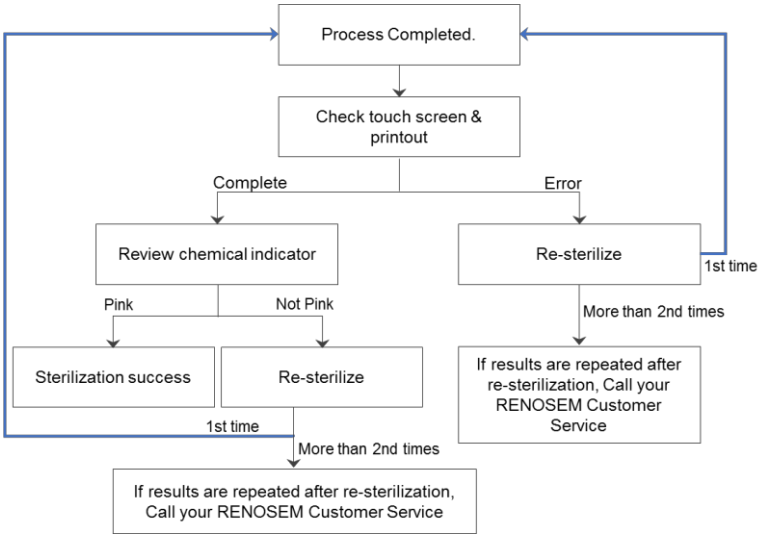
① Prepare BI and package with CI in Tyvek pouch. RENO-Check Kit offered by RENOSEM can be alternated for pouch.
② Place BI in the worst zone inside chamber for sterilizer. For RENO-S130, it is rear side of the upper shelf.
③ Start sterilization cycle.(To use RENO-Check kit, distinguish advance and eco cycle based on lengths. RENO-Check kit cannot be used for non-lumen cycle.)
④ Upon completion of sterilization cycle, break the ampoule in BI. Check if ampoule is properly broken.
⑤ Mark required information including date, time, user etc., and incubate for 24 hours using BI incubator.
⑥ Check the color of BI after 24 hours. If the color remains purple, sterilization is completed normally. If the color changed to yellow, sterilizer is incomplete and must be conducted again.(If BI color changed to yellow after re-sterilization, contact local distributor or RENOSEM customer service for overhaul of the sterilizer.)
⑦ Dispose used BI in abiding by user or hospital regulation.

◀ BI Color change
Successful sterilization(Purple),
Failed Sterilization(Yellow)

(2) BI Flow chart



8. Flow Chart

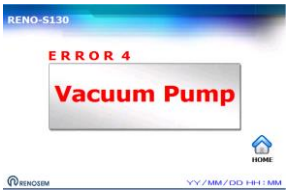
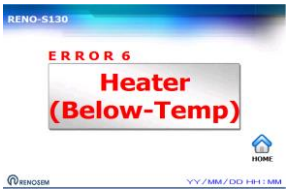


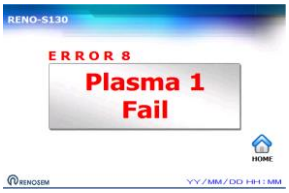
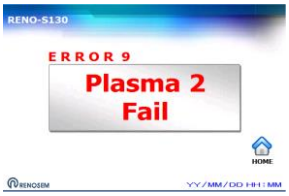
Chapter 6. Troubleshooting

1. Error Code

If trouble occurred during sterilization cycle, the finishing stage of the cycle will be proceeded. The corresponding error code and expected problem will appear on the touch screen.
Finishing stage will last 6 to 7 minutes, and result includes error code and expected problem will be printed out. Do not open the door immediately and wait until finishing stage is complete and result is printed out.

Code	Error	Cause	Solution
Error 01		• It is caused when incompatible material(paper, gauze, linen, etc.) or not completely dried item is loaded and sterilized. • It is caused when vacuum level does not reach 600mTorr during certain amount of time in the initializing stage.	• Check if any incompatible or not completely dried item is loaded into the chamber • Remove incompatible material, completely dry medical instrument and restart sterilizer. • Check if item in chamber exceeded the validation load, and remove some items to meet the requirement. • If error recurs, contact local distributor or RENOSEM customer service.
Error 02		• It is caused when used SA was reused in the sterilizer. • It is caused if the pressure value does not reach the set value in certain amount of time during sterilization stage.	• After completion of finishing stage, examine SA is used or not. • If SA is not inserted, mount new SA and restart. • Even if remaining SA is inserted, discard it and insert new SA. • If error recurs after having taken all the procedures above, contact local distributor or RENOSEM customer service.
Error 03		• It is caused when user manually presses cancel button to suspend operation of the sterilizer.	• If cancel button is pressed during sterilization, the finishing stage must be completed to fully stop sterilizer operation and restart.

Code	Error	Cause	Solution
Error 04		• It is caused by malfunction or overcurrent of rotary pump.	• Upon occurrence of the error, contact local distributor or RENOSEM customer service.
Error 05		• It is caused when surface temperature of chamber exterior is overheated more than 60°C. • It is caused when vaporizer temperature reaches more than 200°C.	• Contact your local distributor or RENOSEM customer service.
Error 06		• It is caused when chamber temperature fails to reach more than 40°C. • It is cause when vaporizer temperature does not reach more than 130°C.	• It is caused by lack of preheating of the sterilizer. The sufficient preheating time must be met in prior to use. Lack of preheating in initial installation, Failure to power supply, blackout may result in such error. • If error recurs, contact local distributor or RENOSEM customer service.
Error 07		• It is caused when pressure gauge is defect or not functional. • Value of pressure gauge is displayed as 0 Torr at normal state.	• Contact your local distributor or RENOSEM customer service.

Code	Error	Cause	Solution
Error 08		• It is caused when Plasma 1 is not functional.	• Contact your local distributor or RENOSEM customer service.
Error 09		• It is caused when Plasma 2 is not functional.	• Contact your local distributor or RENOSEM customer service.
Error 10		• It is caused when pressure value does not reach the set pressure value during sterilizing 2 stage in certain period of time.	• Check and remove if absorptive materials (Paper, cotton, gauze, linen, etc.) and restart the cycle. Exchange SA cassette. • If error recurs after having taken all the procedures above, contact local distributor or RENOSEM customer service.
Error 11		• It is caused when self-test mode is failed.	• If error recurs after having taken all the procedures above, contact local distributor or RENOSEM customer service.

2. ARARM Code

Code	Error	Cause	Solution
ALARM 01		• It is caused when user presses “start” button to initiate sterilization cycle without mount SA cassette.	• Insert unused SA cassettes and resume operation. • If the alarm recurs in spite of inserting SA cassette, contact your local distributor or RENOSEM customer service.
ALARM 02		• It is caused when user starts self-test mode with inserted SA cassette in the system.	• Start self-test after removing the SA cassette. • If the alarm recurs, contact your local distributor or RENOSEM customer service.
ALARM 03		• It is caused when user pressed “start” button to initiate sterilization cycle while front door is unclosed.	• Check if door is closed properly and resume operation. • If the alarm recurs, contact your local distributor or RENOSEM customer service.
ALARM 04		• It is caused when the parts on the sterilizer is not ready to start.	• Turn off and restart the sterilizer. • If the alarm recurs, contact your local distributor or RENOSEM customer service.

3. PM(Preventive Maintenance) ALARM

Code	Error	Cause	Solution
ALARM PM 01		• It is caused when PM Kit 1 schedule for maintenance and replacement of spare parts in PM Kit 1 is due after 600 sterilization cycle run. • It is triggered when sterilization cycle is initiated.	• Contact your local distributor or RENOSEM customer service. • Despite the occurrence of alarm, the sterilization cycle will be initiated normally. Press “monitor” icon on bottom right of touch screen to return to process run page.
ALARM PM 02		• It is caused when PM Kit 2 schedule for maintenance and replacement of spare parts in PM Kit 2 is due after 1200 sterilization cycle run. • It is triggered when sterilization cycle is initiated.	• Contact your local distributor or RENOSEM customer service. • Despite the occurrence of alarm, the sterilization cycle will be initiated normally. Press “monitor” icon on bottom right of touch screen to return to process run page.
ALARM PM 03		• It is caused when PM Kit-3 schedule for maintenance and replacement of spare parts in PM Kit 3 is due after 2400 sterilization cycle run. • It is triggered when sterilization cycle is initiated.	• Contact your local distributor or REBNOSEM customer service. • Despite the occurrence of alarm, the sterilization cycle will be initiated normally. Press “monitor” icon on bottom right of touch screen to return to process run page.

PM alarm is displayed for 5 seconds and then disappears.

4. Power outage

1) Power outage during sterilization cycle run

(1) After power is restored, the information will not be printed due to unfinished sterilization cycle.

(2) Door of the sterilizer will not open. Vaporized Sterilization Agent(H2O2) may remain inside chamber, and it must be removed to open the door.

(3) Refer to the following instruction for removing Sterilization Agent and open the sterilizer door.

- Select desired sterilization cycle (anything) and press start.
- Press “cancel” button after 10 seconds to cancel operation.
- After pressing the button, finishing stage will be proceeded. Any remaining sterilization agent within chamber will be removed. After the completion of stage, open sterilizer door and replace SA cassette into new cassettes.

2) Power outage during idle mode

- Sterilizer function can be restored immediately after power is stored.

Chapter 7. Installation and Maintenance

1. Installation of sterilizer

In prior to installing sterilizer, the packaging must be removed. Prepare wide space for unpacking sterilizer. Even if the distance between unpacking and installation location is remote, RENO-S130 sterilizer is equipped with wheels to support easy movement.

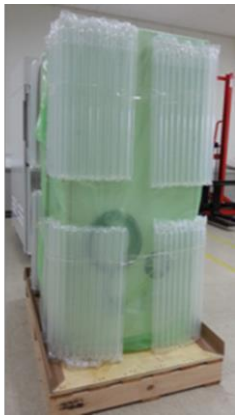
1) Unpacking

(1) In prior to unpacking, check tilt watch and shock watch indicator located respectively on the bottom right side and upper left side to detect any titling or shock to sterilizer package.(Note/If color of tilt watch and shock watch indicator is red, suspend unpacking the sterilizer and contact RENOSEM customer service.)

◀ **Tilt watch & Shock watch indicator**

◀ **Sterilizer exterior package**

(2) Remove PET band and dislocate cardboard.



◀ **Sterilizer interior package**

(3) Remove inner protection film.


◀ **Locked wheel(left), Unlocked wheel(right)**

(4) Moving wheels on bottom is initially locked. Press lever on the right to unlock. Press lever on the left to lock the wheel.
(5) Move to the installation location.
(6) If arrived to installation position, lock the moving wheels to fix the position. Follow the instruction to connect the power to RENO-S130. Turn on the main switch at the bottom of the rear of the sterilizer.(**Note/**After booting, put sterilizer in idle for 2 hours to preheat the device.)

2) Installation environment

- Sterilizer must be installed and used indoor.
- Rated voltage must be used and optimal error bound of input power source to be within 10%.
- Always conduct first class grounding.(grounding resistance less than 10Ω)
- Set installation temperature is from 15 to 30°C. Temperature below 15°C may result in error 4.
- Set humidity is below 80% R.H. in temperature from 15 to 30°C, below 50% R.H. from 31 to 40°C.
- The installation altitude is less than 2,000 m.
- Installation location must be safe from slope, vibration and shock.

3) Check after installation

- After installation, fix the power plug. The outlet must be connected to the ground wire.
- Check that the main switch at the bottom of the back of the sterilizer is turned on, and turn on the power switch to see if the power is on properly.
- Select Self-test on the main screen to start. After about 7 minutes, check if the self-test is completed and the alarm sounds. If it doesn't end normally and an error occurs, restart with the self-test again after solving the problem.

4) Precaution for installation

- Only person with expertise or training can install the sterilizer.
- The wall of installation location must be at least 30cm away. The floor of installation location must be in level.(slope less than 3°)
- Do not cause shock to sterilizer while moving to installation location.
- Do not install or use sterilizer in close with other equipment produce electromagnetic waves.
- Check power plug is tightly inserted into outlet. Single socket is recommended.
- After sterilizer usage, check all function is normal.
- Personnel whom RENOSEM did not authorize cannot disassemble, repair and modify sterilizer.
- Do not install sterilizer closely to the source of steam or fire.

2. How to change printer paper

Printer lamp will start to blink if refill is required.

1) Press “open cover” button to open the printer cover and check printer paper.
2) If printer paper is empty, refill printer paper. The empty roll of printer paper must be removed before refilling.
3) Place new printer papers with its end exposed and close the printer cover.
4) Close the cover and press the print button in the touch screen and draw the printer paper. If printer paper is not rolled out, open the cover and check if printer paper is properly mounted.

   ✓ Printer paper must be mounted as shown in the following picture. If printer paper is not properly mounted, information will not be printed out despite sterilization cycle complete.
   ✓ The printer paper button is displayed in picture of printer in component description of printer(Chapter 3, 1-3)).


▲ **Proper installation side of printer paper**

◀ **When properly installed to printer**

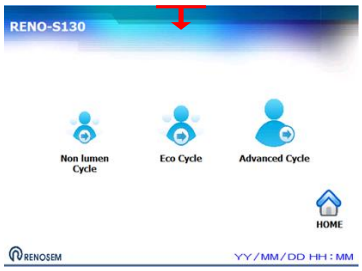
3. Sterilizer storage and management

1) Store sterilizer in location with minimal influence from air pressure, temperature, humidity, wind, sunlight, dust, salt and ion.
   (1) storage condition
      ▪ Humidity : 20~85% R.H.
      ▪ Air pressure : 70~106kPa
      ▪ Temperature : 10~40°C
2) Store sterilizer in location safe from slope, vibration and shock.
3) Do not store sterilizer in gas source or hazardous material.
4) Manage sterilizer in clean condition. Use soft linen with water or alcohol to wipe inside chamber and sterilizer exterior cover. Other detergent cannot be used.

4. Set date and time

Date and time of touch screen can be modified.

1) Go to main screen.
2) When the sterilizer is not in operation, touch and sliding down the upper center of the touch panel and press “EXIT” on the pop-up window to move to the desktop.



3) Press ① at the bottom right of the touch panel to set the date and time.

4) When the date setting is complete, press ② on the top left of the touch panel to return to the main screen.

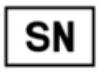
Chapter 8. Statement of Conformity

CE 1639

RENOSEM Co., Ltd. declares that this product conforms to the General Safety and Performance requirements and provisions of Medical Device Regulation (EU) 2017/745.
All supporting documentation is retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.
Product classification according to Medical Device Regulation 2017/745, Annex VIII Rule 16 Medical Device Classification is IIa.

Notified Body: SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
Manufacturers Registered Name: RENOSEM Co., Ltd.
Room 822, 823, 824, 301, Bupyeong-daero, Bupyeong-gu, Incheon, KOREA

Chapter 9. Labelling

SYMBOL	Explanation
	Do not reuse
	Batch code
	Date of manufacture
	Manufacturer
	Authorized representative in Europe
	Serial number
	Use by
	Caution, consult accompanying documents
	CE Mark

RENOSEM Co., Ltd Room 822, 823, 824, 301, Bupyeong-daero, Bupyeong-gu, Incheon, KOREA	EC REP **CMC Medical Devices & Drugs S.L** C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Renosem		CE 1639	
Product Name	**Low Temperature Hydrogen peroxide Sterilizer**		
How to Use	**User`s Manual Reference**	**Model (REF)**	**RENO-S130**
Rated Input Power	**3 KVA**	**Rated Input**	**200V~, 50/60Hz 230V~, 50Hz**
		SN	
RENOSEM Co., Ltd Room 822, 823, 824, 301, Bupyeong-daero, Bupyeong-gu, Incheon, KOREA **[www.renosem.com]**		EC REP **CMC Medical Devices & Drugs S.L** C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain	

www.renosem.com

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