



ZERONITEC PURE 120

Operating Manual



Low Temperature Plasma Sterilizer



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The world best Plasma Sterilizer Company

Chapter 1. Theory of Operation

1. Health and Safety Information



Users must first understand all Health & Safety Information when using ZERONITEC PURE 120 prior to usage for the safety of not only the safety of the product but also the user's safety. 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 ZERONITEC PURE Plasma Sterilizers.

1.1. Safety Symbols



Hot surfaces present.
Do not touch without protection.



Hazardous chemical present.
Use personal protective equipment.



Toxic chemical present.
Avoid exposure, contact, or ingestion.



High voltage hazard.



Safety Goggles



Safety Gloves

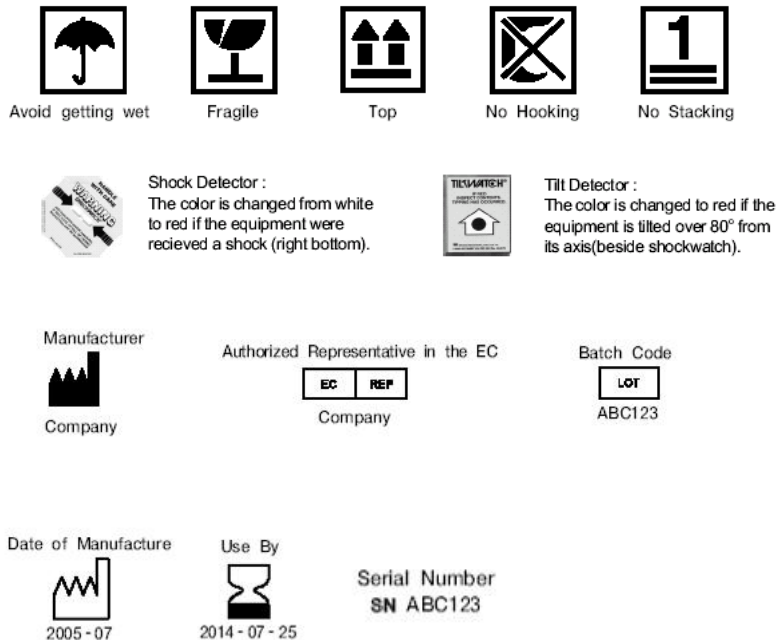


Ground



Touch Prohibition of Wet
hand

1.2. Outer Box Symbols



1.3 Danger, Warnings and Notes - Hydrogen Peroxide Plasma Sterilization

1.3.1. Safety Glasses or Goggles



Safety glasses or goggles (preferred) should always be worn when handling hydrogen peroxide. Vinyl gloves should also be worn.

1.3.2. Inhalation

Exposure to hydrogen peroxide gas or its by-products for periods exceeding 15 minutes may pose a significant danger.

Inhalation of hydrogen peroxide vapors can cause irritation and inflammation of the respiratory tract. If hydrogen peroxide vapor is inhaled, fresh air should be sought at once. If inhalation has been prolonged, a physician should be consulted immediately.

1.3.3. Eye Contact

Hydrogen peroxide may cause severe injury if it comes into contact with the eyes.

Prolonged exposure of hydrogen peroxide to the eyes may cause severe eye irritation and injury.

While hydrogen peroxide and by-products associated with its decomposition may not be lethal, contact with hydrogen peroxide can cause irritation and discomfort in the mucous membranes and the eyes. It is particularly dangerous if the hydrogen peroxide comes into contact with the eyes as corneal burns can occur very quickly

1.3.4. Skin Contact



Hydrogen peroxide may cause skin irritation and blistering.

If it comes into contact with skin, hydrogen peroxide may cause a prickling sensation. If skin contact occurs, flush the area of contact with water for a minimum of 15 minutes and see a physician.

1.3.5. Accidental Swallowing

Ingestion of hydrogen peroxide may cause severe injury or even death.

Contact with the membranes of the mouth must be avoided.

If hydrogen peroxide is swallowed, drink water immediately to dilute and contact a physician. Do not attempt to induce vomiting.

1.3.6 Fire risks for hydrogen peroxide



Hydrogen peroxide itself is not combustible or flammable, but when decomposition occurs, simultaneous heat and oxygen are formed, therefore if there is any flammable materials are present, fire may occur .

Since Hydrogen peroxide creates oxygen through decomposition, it must be store in specially designed containers, like the PURE hydrogen peroxide cassette which has small quantity in the capsule of the cassette. The Hydrogen Peroxide cassettes must avoid contact with flammable materials.

1.3.7 Leakage risk for hydrogen peroxide



In case hydrogen peroxide leakages, dilute it with a large amount of water immediately. Be sure to wear protective gloves to work with hydrogen peroxide.

Avoid getting it contact with wooden material, paper, cloth and other flammable material around, if there is contact with hydrogen peroxide, wash with enough water.

1.3.8. Storage

Hydrogen peroxide containers must be stored away from sources of direct sunlight or heat. It is recommended that containers are stored in a refrigerated area (2~8 °C) as the decomposition of hydrogen peroxide causes the release of oxygen and heat.

1.3.9. Transportation

Hydrogen peroxide should be transported at room temperature or refrigerated.

1.3.10. Shelf Life



The shelf life is the period of time that hydrogen peroxide is effective as a sterilizing agent. Depending upon storage conditions, the shelf life of hydrogen peroxide is as follows:

- In a refrigerated area ⇒ 24 Months
- At room temperature ⇒ In a package without direct sunlight, at 10~25°C ⇒ 6 Months.
- In the system(after load) ⇒ 45 days

1.4 Precautions When Inserting a Hydrogen Peroxide Injector into the Sterilizer

1.4.1. Proper Bar Code Identification

The Cassette Injector has a distinctive symbol in the shape of a red circle. The hydrogen peroxide cassette designed for use with the ZERONITEC PURE 120.

When placing the cassette in the Cassette Injector, be sure to align the two symbols to ensure the hydrogen peroxide cassette fits securely into the sterilizer. If placed incorrectly, the “Bar Code” button will not function.



1.4.2. Hydrogen Peroxide for ZERONITEC PURE 120 Use Only

To ensure proper sterilization, use only hydrogen peroxide sold specifically for the PURE 120. Hydrogen peroxide manufactured for use with the ZERONITEC PURE 120 has been designed specifically to optimize the system's unique sterilization process. If a different hydrogen peroxide is used, problems with sterilization power and other related equipment damage may occur. There is also an increased risk of injury for those handling the hydrogen peroxide.



To ensure this problem does not occur, a bar code system has been installed to ensure proper identification of the hydrogen peroxide to be used with the PURE 120. Hydrogen peroxide cassette other than those designed specifically for use with the PURE 120 will not be accepted. Carefully check that the hydrogen peroxide cassette is of the correct type before attempting to insert it into the INJECTOR.

1.5. Precautions When Removing a Hydrogen Peroxide cassette from the Sterilizer

1.5.1. Safety Wear (goggles and latex / vinyl gloves)



It is vitally important that protective goggles and vinyl gloves are worn when handling hydrogen peroxide. After the hydrogen peroxide has been used, the empty cassette will automatically pop-up in readiness for removal. When removing the cassette it is important that protective goggles and gloves are worn as some hydrogen peroxide may remain in the capsule. Be careful to ensure that hydrogen peroxide does not come into contact with the skin. Areas coming into contact with hydrogen peroxide should be rinsed immediately.

1.5.2. Ejecting Excess Hydrogen Peroxide

Hydrogen peroxide that has passed its expiry date should not be used.

If the hydrogen peroxide in the INJECTOR has passed its expiry date it should be ejected and disposed of.

1.5.3. Ejector Cassette

If it becomes necessary to remove any hydrogen peroxide that has passed its expiry date, or when the number of Hydrogen Peroxide Injection left 1 or 3 and the Alarm-17 displays with the following messages, "Sterilant cassette is empty, please replace with new cassette.", replace the Cassette with a new one.



Before installing or removing the Cassette in the sterilizer, it is vital that protective goggles and vinyl gloves are worn whenever handling the cassette.

1.6. High Temperature Warning



Caution should be exercised as some parts of the system are too hot to be touched.

For safety and to ensure a consistent sterilization process, do not open the side, back or top covers except when troubleshooting. If it becomes necessary to open the cover, wait until the components have cooled sufficiently before handling.

In order to provide proper sterilization, some parts of the sterilizer must be heated to set temperatures.

1.6.1. Sterilization Chamber

The main switch located on the lower part of the back cover should be left on at all times to ensure that the equipment is ready for use at any time. When in the "on" position, the wall of the sterilization chamber will remain at its optimal operating temperature.

For proper sterilization the inside of the chamber should be heated to over 40 °C.

The temperature inside the chamber can be calibrated by adjusting the wall temperature.



When the equipment's main switch is turned on, it takes approximately 10~30 minutes for the chamber to heat up and for the temperature inside the chamber to stabilize. Since the temperature is higher than 55°C, be sure to minimize or avoid touching the sterilization chamber when loading or unloading.

1.6.2. Vaporizer Heater

The injection flange is heated when the sterilization process begins. When the temperature exceeds 90°C the hydrogen peroxide vaporizes completely.

Be sure to minimize or avoid handling the heater housing until it has completely cooled.

1.7. High Voltage Warning

High voltage poses the risk of injury or even death due to electrical shock.

High voltage is required to initialize the plasma in the plasma chamber. It is dangerous to touch the equipment when high voltage is applied to it.

Check whether high voltage is applied to the equipment or not before doing any troubleshooting associated with high voltage.

1.8. Device Safety



WARNING: RISK OF INJURY OR DAMAGE TO STERILIZER

The ZERONITEC PURE Sterilizers should not be used stacked with other equipment.



CAUTION: RISK OF DAMAGE TO STERILIZER

Regularly scheduled, or Preventive Maintenance (PM) must be performed at the interval specified on the system. Make sure you schedule a service call in a timely manner when notified that a PM is due.



IMPORTANT! IMPORTANT CLEANING CHAMBER WALL

If white residue is visible on the load; this may be residue from the hydrogen peroxide stabilizer. Wear chemical resistant latex, PV (vinyl), or nitrile gloves when removing a load with visible white residue. **White residue can be minimized when Regular Cleanings are performed on your Sterilizer.**

**CAUTION: RISK OF VIOLATION OF WARRANTY**

Improper processing may limit our liability for damage to processed instruments. Improper processing may also violate your instrument warranty.

**KNOW WHAT YOU CAN PROCESS**

Before processing any item in the ZERONITEC PURE Sterilizer; make sure you know how the Sterilization Process will affect the item. Read, understand, and follow the medical device manufacturers' instructions for their products. The certain types of items and materials can be checked in Chapter 1. This guide is not intended to replace any medical device manufacturers' instructions.

If you have questions, or if you are in doubt about the materials in your devices, contact the medical device manufacturer or your Zeronitec Customer Service Center for more information.

**CAUTION: RISK OF DAMAGE TO LOAD – VENTING CAPS**

Take special care to confirm that venting caps are placed according to the manufacturers' instructions. Venting caps are intended to prevent damage to flexible scopes that are being exposed to a vacuum, regardless of the sterilant used.

**CAUTION: RISK OF DAMAGE TO LOAD-IMMERSION CAPS**

You *must remove* the water-resistant immersion cap (if present) prior to processing in the Sterilizer. If the immersion cap is not removed prior to processing in the Sterilizer, it will damage the flexible scope due to the inability to properly vent.

**CAUTION: KNOW WHAT YOU CAN PROCESS- FLEXIBLE ENDOSCOPES**

Prior to processing flexible endoscopes in the ZERONITEC PURE Sterilizer, you must read, understand, and follow the medical device manufacturer's instructions for use for the particular scope to be processed. Please contact the medical device manufacturer for more information on what can be processed in the ZERONITEC PURE Sterilizers.

1.9. Intended Use

The purpose of this device is to sterilize medical devices using low temperature plasma.

2. Contact ZERONITEC Customer Service Center

If you have any questions about using the ZERONITEC PURE Sterilizers or practicing ZERONITEC Process, please call our Customer Service Center at +82-32-811-8890 or email to info@zeronitec.com.

3. General Description of ZERONITEC PURE 120

3.1. ZERONITEC PURE 120 Sterilizer System

- Article : Low Temperature Plasma Sterilizer
- Grade : Class IIb
- Name : ZERONITEC PURE 120

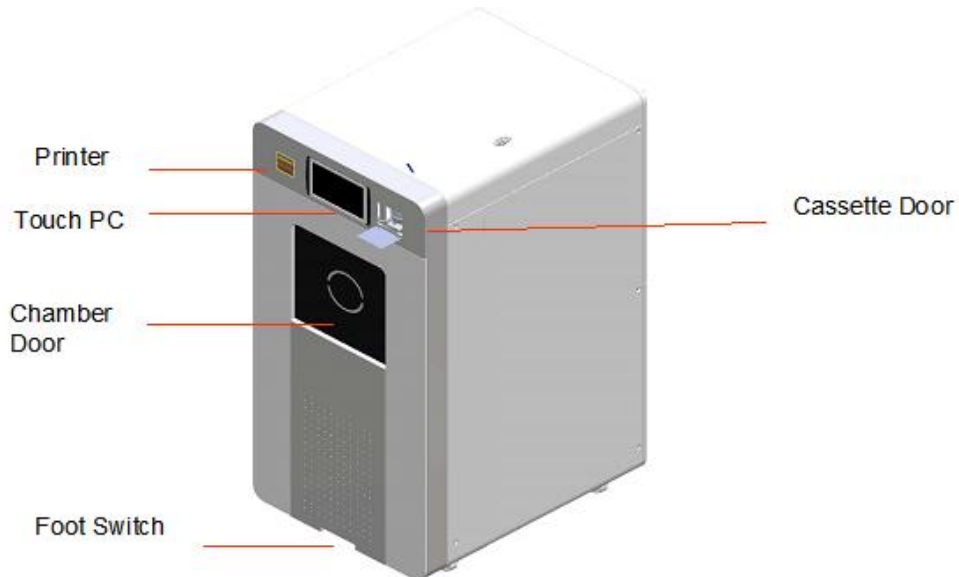
3.2 General Purpose of ZERONITEC PURE 120 Sterilizer System

ZERONITEC PURE 120 Sterilizer System has a primary purpose to inactivate microorganisms on a broad range of medical devices and surgical instruments as a low temperature plasma Sterilizer.

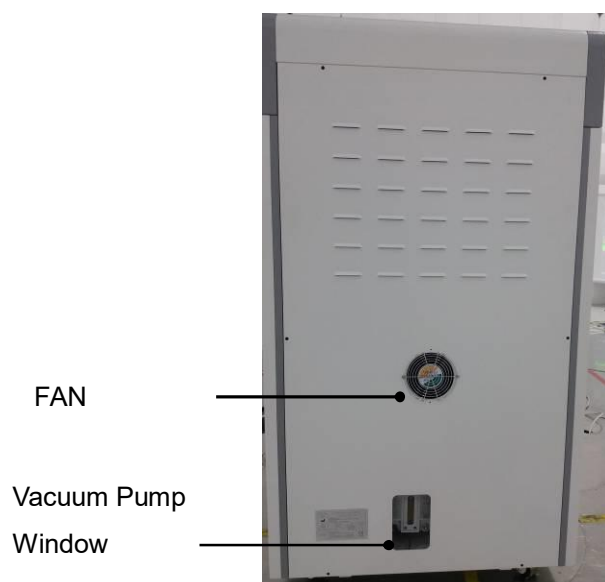
3.3 Specifications

System Total Size(W,H,D)	System	750mm X 1,670mm X 1,000mm
Chamber Dimension(W,H,D)	Total	410mm X 410mm X 840mm (140 L)
	Maximum Load Wt.	30Kg / Tray
Chamber	Insulation	Heat insulator (Flame-retardant foam)
	Capacity	1.2 kW
Door	Operation	Vertical Sliding Door
	Safety	2 x Safety Door Sensors
Weight	Main System	350 Kg
Optimum Voltage		220-230V~50/60 Hz, Single phase
Power Consumption		3.5 kW
Fuse		600 V~, 20 A (Size: 9.4 x 31.75 mm)
Cycles / cassette		8 cycles (Short)
		4 cycles (Standard, Advanced)
Sterilization Process Time		35 ~ 60 min
Maximum Vacuum		0.3 Torr (39.9 Pa)

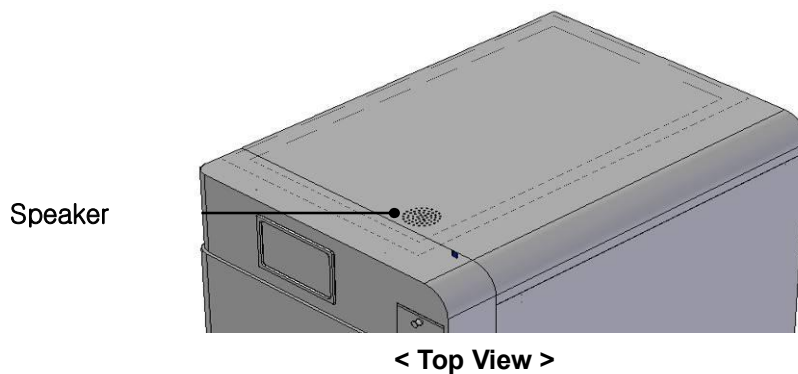
3.4 Exterior Description of ZERONITEC PURE 120



<Front / Side View>



< Rear View>



3.4.1. Touch PC Screen

This displays the status of the sterilization process and enables mode selection.

3.4.2. Chamber Door

It is used to load and unload items for sterilization.

3.4.3. Power Cord (AC)

It is a power supply Cord to the sterilizer.

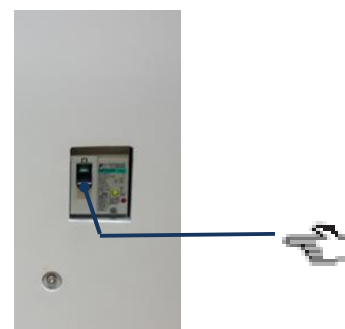
Type: AC 250V, 16A



Users must not use any cords other than the AC cords of ZERONITEC PURE 120. For local power cord, please contact ZERONITEC SERVICE CENTER.
: info@zeronitec.com

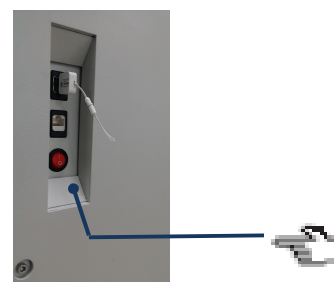
3.4.4. Main Power Switch

The power switch controlling the electric power supply to the sterilizer is located on the right side cover of the sterilizer.

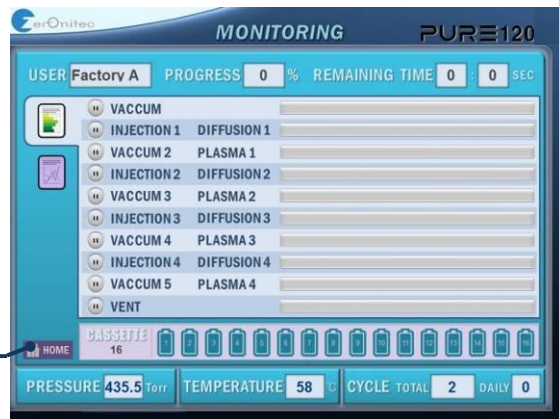


3.4.5. Control function

- ① ON : If main switch button is ON, the sterilizer system is activated.
- ② OFF: If main switch button is OFF, the sterilizer system is deactivated.



- ③ STOP Button is used to interrupt the sterilization cycle at any time and functions as an emergency button.



Sterilizer is ready to be used when the main power switch is turned on and ON button on the control panel is pressed.

3.4.6. Fans (Rear)

The Fan is a device to cool down the temperature of the sterilizer. It is located in the bottom of the rear of frame.

3.5. Interior Description of ZERONITEC PURE 120

3.5.1. High Voltage Transformer

It is a high voltage provider for creating plasma.

3.5.2. Vacuum Solenoid Valve

It controls the vacuum of the interior chamber.

3.5.3. Cracking Plasma Housing

It is located in an exhaust line between the bottom of the sterilization chamber and the rotary pump. Created plasma in the Cracking remains after sterilization.



3.5.4. INJECTOR unit

It is a device to hold the H₂O₂ cassette in the Supply Pot and supply quantitative Hydrogen Peroxide solution to the interior chamber.

3.5.5. Sterilization Chamber (Sterilization reactor)

It is a chamber to sterilize items, containing bottom and top trays.

3.5.6. Vacuum Pump

It is used to form and maintain vacuum pressure.

3.5.7. Vaporizer

It is an airtight container to form hydrogen peroxide vapor.

3.5.8. Vaporizer heater

It is a heater to heat up the container.

3.5.9. Fuse

It prevents damages from an electric over-current to the sterilizer system

3.5.10. Circuit Breaker

It blocks the power at the time of over current.

3.5.11. Chamber Heater Pad

It functions to raise the temperature of the chamber.

4. ZERONITEC PURE 120 Sterilizer Process

4.1. Plasma Sterilizer

The chamber temperature is always ON as a standby.

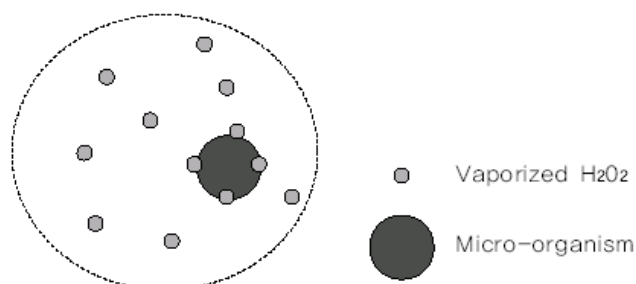
So, user can start sterilizing process immediately after operation switch ON.

The Plasma Sterilizer uses hydrogen peroxide vapor to render micro-organisms inactive without leaving any toxic residues. Hydrogen peroxide is an essential element to inactivate micro-organisms. Plasmas help dissociate the molecule structure of any remaining hydrogen peroxide after the sterilization process has taken place. This technology can be used to sterilize a wide range of medical devices and is particularly well suited for use with heat-and moisture sensitive instruments.

The Sterilizer consistently achieves a Sterility Assurance Level (**SAL**) of 10^{-6} , as defined by U.S. Food and Drug Administration (FDA) and international standards.

The Plasma Sterilizer is often referred to as the “next generation” of sterilization tool for the following reasons:

- It leaves no harmful residues and is environmentally friendly. The plasma sterilization process produces only water vapor and oxygen.
- The processing time is 35-60min.
- Only electricity is required for sterilization.
- Unlike gas sterilization, outside ventilation system is not required.
- The maximum operating temperature is less than 55°C.



The vaporized hydrogen peroxide surrounds each micro-organism and inactivates it in the vacuum chamber.

4.2. Properties of Hydrogen Peroxide (H₂O₂)

Hydrogen peroxide (H₂O₂) is clear, colorless, water like substance in appearance. It has a pungent odor and is non-flammable itself, It can be mixed with water in any proportion and is handled as a water solution, and has a boiling point of 114°C and a freezing point of -50°C.

4.3. Plasma

Plasmas refer to a group of positive ions and electrons with an electric charge created by an electrical field. Plasma is used to dissociate remaining residual gas after sterilization.

5. ZERONITEC PURE 120 Sterilization Cycle

The ZERONITEC PURE 120 has a process time of approximately 35~60 min per cycle.

It consists of four(4) consecutive and equal sterilization phases and the process occurs in the following stages:

5.1. Vacuum Stage

When items to be sterilized are placed in the sterilization chamber, the chamber is closed and evacuation begins. Once a sufficiently low pressure is achieved, the process moves on to the next stage.

5.2. Injection Stage

Once sufficient pressure is achieved, an aqueous solution of hydrogen peroxide is injected into the vaporizer and sterilization chamber. In the Injection Stage, any hydrogen peroxide vapor after the injection is broken apart into free radicals.

These free radicals move from the plasma chamber to the sterilization chamber in order to react with the micro-organisms.

5.3. Diffusion Stage

The hydrogen peroxide diffuses throughout the chamber, coating the items to be sterilized and causing the inactivation of micro-organisms.

5.4. Plasma Stage

After the Diffusion Stage, pressure in the chamber is reduced to a level suitable to initiate the production of plasma, during which time the plasma causes the remaining hydrogen peroxide to break down into oxygen and water vapor.

This constitutes one-half of the total sterilization process, which is then completed with the repetition of the above steps. The sterilization process consists of two consecutive,

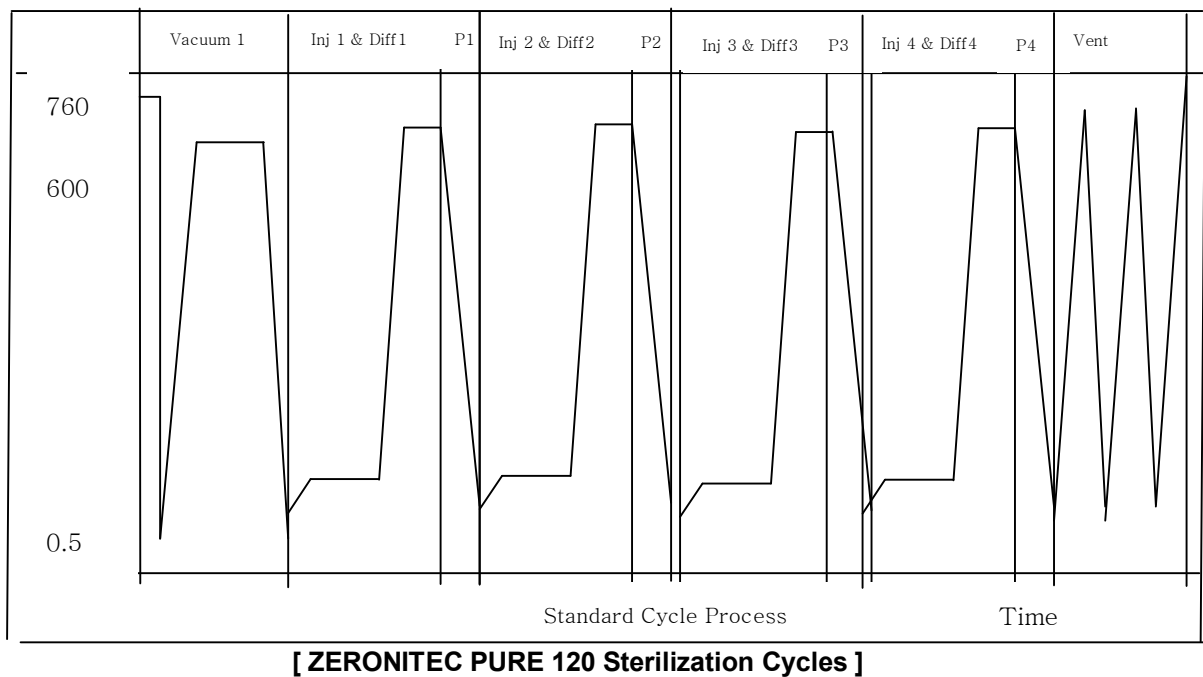
equal and distinct half cycles, the second of which is the Vent/Dry Stage.

5.5. Vent Stage

The sterilization chamber is cleaned by introducing HEPA filtered air (Air Filter HEPA 0.3 micron, 99.999%) at a specific pressure. The pressure in the chamber is again reduced, after which the sterilizer is again returned to normal atmospheric pressure with the introduction of HEPA-filtered air.



Pressure (Torr)



6. ZERONITEC PURE 120 Sterilizer Accessories

6.1 Biological Indicator (SCBI, Self-Contained Biological Indicator)

Biological indicators help users to monitor sterilizing conditions during sterilization cycles. It consists of microorganism and media. After completing a sterilization cycle, users can check whether the sterilizing conditions have been properly met by checking the color change of BI.

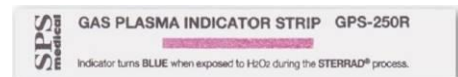


6.2 Chemical Indicator (CI)

It is a chemical Indicator to monitor whether there are any malfunctions that occur during the course of exposure of hydrogen peroxide. If the indicator has been exposed to the Hydrogen Peroxide, the color changes from blue to pink, which allows you to determine whether the sterilization process has been successful.

6.2.1 Chemical Indicator Strip

A Chemical Indicator Strip is placed in a package inside of the items to be sterilized, and discoloration of the strip after sterilization can determine the effectiveness of the sterilization.



6.2.2. Chemical Indicator Tape

Since the color changes during the sterilization process, users can immediately determine whether the sterilization process has been successful. Chemical Indicator Tape can be excluded if a Chemical Indicator Strip is contained inside an item.



6.3 Pouch

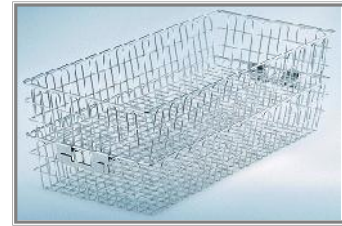
Pouches are used long-term after the sterilization, and composed of polyethylene, polyester and a special material (Tyvek-mylar) that passes through the sterilizing agent.

Size: 75,100,150,250, 300,400mm x 70m



6.4 Basket

Basket is used to load Sterilization items.



6.5 Sterilizing agent [Sterilant, Hydrogen peroxide H₂O₂]

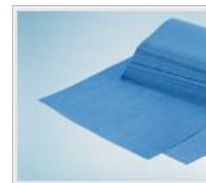
ZERONITEC PURE Sterilization agent cassettes are used for PURE series Plasma sterilizers.



6.6 Non-Woven Sheet

Non Woven Sheets are used to wrap items and cases containing sterilization items.

Material: Polypropylene (75mm~400mm)



6.7 Incubator

Incubators are used to culture Biological Indicators that have passed through the sterilization process.



Other accessories other than ZERONITEC PURE-Sterilizer Accessories (ex, Hydrogen Peroxide, Biological Indicator, Chemical Indicator Strip, Chemical Indicator Tape, Baskets, Pouch) must not be used.

7. Material Compatibility

7.1. Materials that Can Be Sterilized Using the Plasma Sterilizer

ZERONITEC PURE 120 can sterilize various medical instruments made of metal and nonmetal material including those with inner channels at low-temperature.

Metals

Stainless Steel 300series
Aluminum 6000series
Titanium

Non Metals

Acrylonitrile butadiene styrene(ABS)	Polycarbonate
Delrin	Polyetherimide
EVA(Ethyl vinyl acetate)	Polyethylene terephthalate(PET)
Fluorinated ethylene propylene(PFTE)	Poly(methyl methacrylate(PMMA)
Glass, USP Type I borosilicate	Poly(phenyl sulfone)
High density polyethylene	Polypropylene
Kraton	Polystyrene
Latex	Polysulfone
Low density polyethylene	Polytetrafluoroethylene(PTFE)
Monel	Polyurethane
Neoprene rubber(Polychloroprene)	Polyvinyl chloride(PVC)
Nylon	Silicone
Phenolic resin	

Items and the material which are not compatible with PURE-sterilizers must not be sterilized. Before operating the sterilizers, users must check manufacturer's instructions regarding disinfection and sterilization first. If users can not identify whether the medical instruments are compatible with the sterilizers or not, they should contact the ZERONITEC customer service center. : <http://www.zeronitec.com>

7.2. Materials that cannot be sterilized by using the Plasma Sterilizer

7.2.1. Absorptive materials (Cellulose)

Wood, linen, paper (count sheet), sponge, disposable suture materials

7.2.2. Liquids (Moisture)

7.2.3. Powders

7.2.4. Oils

7.3 PURE-Series Compatible Medical Device List

As a reference data for users, there is a PURE-series Compatible Medical Device List which contains various medical instruments lists so please inquire about periodically revised lists by contacting the ZERONITEC customer service center. Website : <http://www.zeronitec.com>

8. Lumen guide

8.1 Rigid Lumen (Single Channel Stainless Steel Lumen)

Cycles	Inside Diameter	Length (mm)	Remark	Per Load
Standard (45 min)	1 Ø	500	Tubing	5 lumens
	2 Ø	500	Tubing	
	3 Ø	500	Tubing	
Advanced (55 min)	1 Ø	500	Tubing	6 lumens
	2 Ø	500	Tubing	
	3 Ø	500	Tubing	

- The validation testing for this lumen size was conducted using a maximum of 6 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing.

8.2 Flexible Lumen (Single Channel Teflon / Polyethylene Lumens)

Cycles	Inside Diameter	Length (mm)	Remark	Per Load
Standard (45 min)	1 Ø	2,000	Tubing	7 lumens
	1 Ø	10,000	Tubing	5 lumens
Advanced (55 min)	1 Ø	2,000	Tubing	10 lumens
	1 Ø	10,000	Tubing	7 lumens

- Sterilize without any additional load. Up to 10 pieces of tubing may be sterilized at one cycle.
- If the lumens do not conform to these dimensions, please call the medical device manufacturer for information on how to properly sterilize this device. Lumens not
- conforming to these dimensions should not be processed in the ZERONITEC PURE Sterilizer.
- Inside Lumen Diameters
: 1 Ø = 1mm = 0.039 inch = 3 French = 20 Gauge

9. Cleaning, Rinsing, and Drying

Cleaning is necessary to remove organic and inorganic soil and debris from equipment. This process also removes many microorganisms from the surface of the items. Sterilization then inactivates all remaining spores and live microorganisms.

- All items including trays must be **thoroughly** cleaned, rinsed, and **dried** before loading into the Sterilizer.



Remaining moisture could interrupt the sterilization process.

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

Note: *Periodic careful inspection of the items after repeated exposure to disinfectant/cleaner/sterilant is necessary, due to the potential damaging effects of the chemical agents on the items.*

- **Clean** your devices according to the medical device manufacturers' instructions. You must remove all blood, tissue, and soil from items using appropriate detergents, cleansers and/or methods.
- **Rinse** items thoroughly to remove detergent or cleanser residue. Use treated water that is of a quality that ensures hard water stains do not occur. Failure to remove all organic materials or detergents may result in the formation of light-colored residue on the devices. If residue is visible, you should clean, rinse, dry, and sterilize the device again prior to use.
- **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 manufacturers' instructions for use or contact the device manufacturer to obtain appropriate and safe procedures. It is necessary to remove moisture from all parts of the items. **Only dry items should be loaded into the sterilization chamber to prevent cycle cancellation.**

WARNING! POSSIBLE RESIDUAL HYDROGEN PEROXIDE CONTACT!



Failure to ensure that instruments are completely dry before they are processed in the ZERONITEC PURE 120 sterilizer may result in residual hydrogen peroxide being present on the outer surface of the load. This may cause contact burns when the surface of the load is handled.

- Some complex reusable medical devices may require disassembly for proper cleaning and sterilization. It is very important that you follow the device manufacturers' recommendations concerning cleaning and sterilization

WARNING! POSSIBLE NON-STERILE DEVICE!



Loads containing moisture may result in either a non-sterile device or cycle cancellation. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves when handling items from any load containing moisture.

10.. Packaging & Loading the basket using BI and CI

Wrap the items to be sterilized using only PURE pouches and wraps.

Wrap the items with non-woven sheets or pouches with a chemical indicator strip inside.

Fix the non-woven sheet with the chemical indicator tape.

Pouch packages are placed on their edge with the plastic side of one pouch facing the paper or Tyvek side of the next pouch to maximize H₂O₂ gas penetration during sterilization and its removal during aeration. Pouch packages can be placed flat in the basket with the paper side down for the same reason.

Follow the manufacturer's instructions for the proper loading of items to be sterilized.

Place a biological indicator in the middle on the top shelf. The biological indicator is generally placed in a Tyvek pouch.



Frequency of biological testing should be performed at least once per day or in accordance with the users' hospital policy in order to monitor the effectiveness of the sterilization process.

Make sure Items to be sterilized are compatible with the ZERONITEC PURE 120.



Users should not use any material inside the basket for the purpose of protecting items.

11.. Placing Loaded Baskets in the Chamber

Place the loaded baskets in each shelf of the chamber. After loading the chamber, close the door tightly.

If the door is open, the “Alarm 09 : Check the Chamber Door Open “, will alarm.



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Chapter 2. System Installation

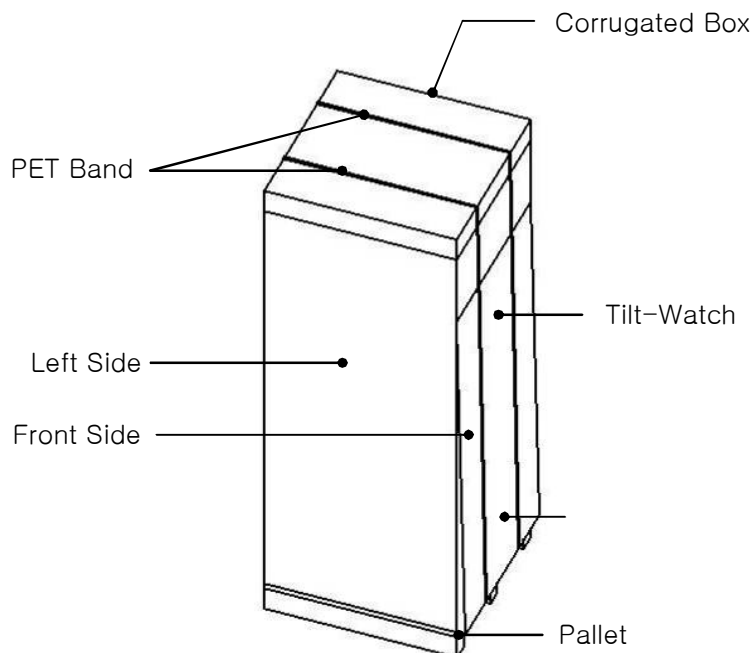
1. Unpacking

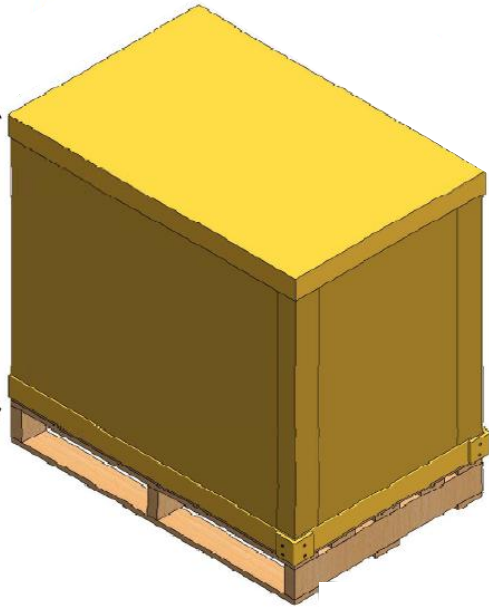
- 1.1. Check the “TiltWatch” and “Shock-Watch” labels before unpacking.
- 1.2. Unpack the equipment in an open space.

When the ZERONITEC PURE 120 is delivered, inspect it for damage that may have occurred during shipping. If any shipping damage is found when unpacking the sterilizer, immediately file a damage claim with the transportation company and notify ZERONITEC Co., Ltd immediately by emailing:

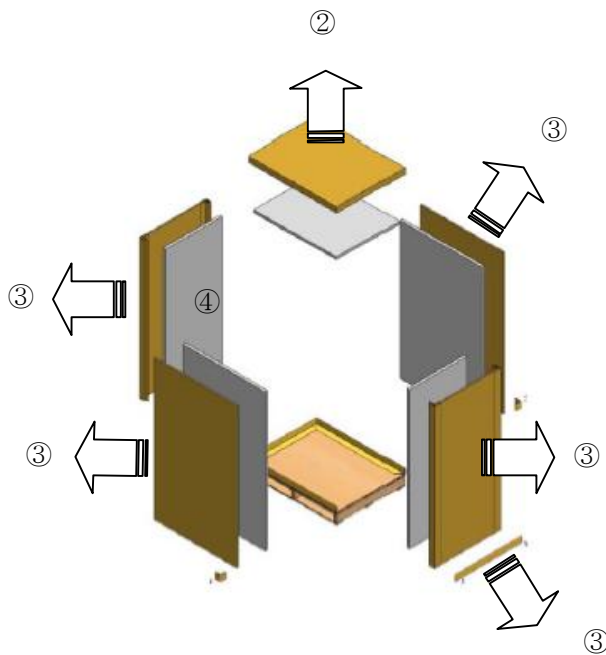
Website : <http://www.zeronitec.com>

- ① Cut the PET band.
- ② Uncover the cap of the triple corrugated box.
- ③ Remove the 4 side walls of the box.
- ④ Remove PF form on 5 sides for internal protection.
- ⑤ Slide down the machine with attached sliding panel.





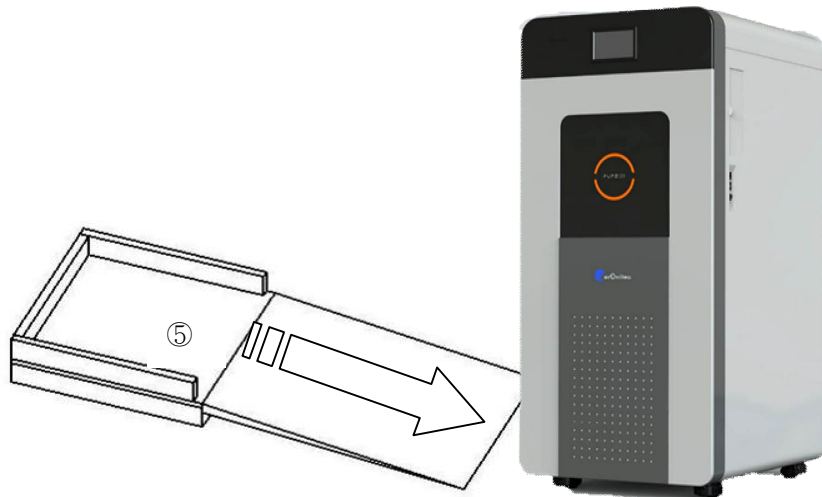
< Unpacking of Box >



< Removal of cardboard and protection FOAM >

Packaging Materials

1. Corrugated Cardboard
2. PF-FOAM
3. Wood Palette



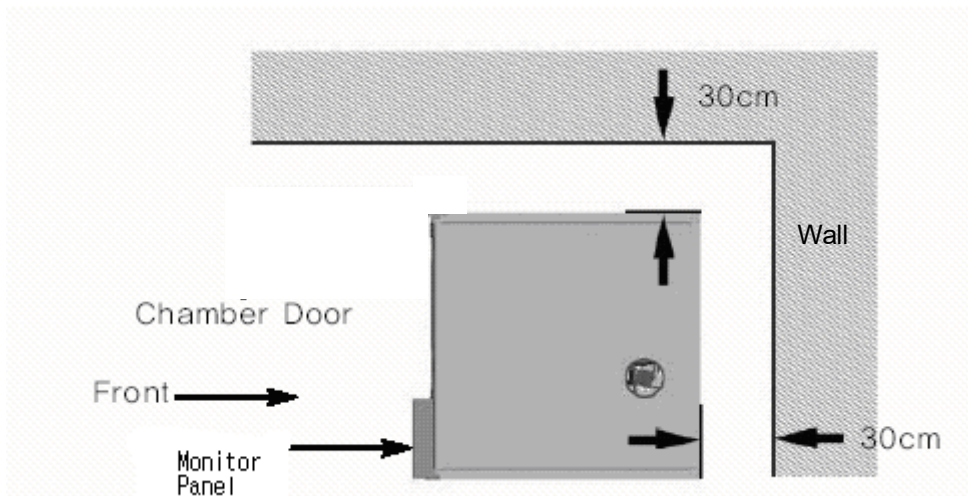
< Unloading of machine from pallet>

2. Utility Requirements

- 2.1. ZERONITEC PURE 120 can operate on 220-230V~ Single phase (frequency 50/60 HZ). The supplied voltage must meet the system's voltage requirements.
- 2.2. The power consumption of the sterilizer is approximately 3.5 kW.
The power supply available at the installation site should be over 3.5kW.

3. Preparing Areas for Installation

- 3.1. The PURE 120 can only be installed indoors and must be kept away from inclination, vibration and shock.
- 3.2. The input voltage should be maintained within 10%.
- 3.3. One phase of the power supply line must be grounded. If not, the AC ground should be suspended.
- 3.4. Under normal conditions, a temperature between 5 and 40°C should be maintained to ensure optimal sterilization performance.
- 3.5. To improve the sterilization efficacy, humidity should be controlled.
If the temperature is 5°C ~ 30°C, 80 % humidity is desirable.
Where temperatures range between 30°C ~ 55°C, humidity should be approximately 50%.
- 3.6. A minimum of 300mm clearance between the wall and the sterilizer is required for maintenance and servicing.
- 3.7. Move the sterilizer to its location by utilizing the casters.
Once in position, lock the casters so the unit remains in place.



4. Moving the Sterilizer

The ZERONITEC PURE 120 is designed to be easily moved using the casters. Pull out the hook and turn it 90° into deep hole position in order to lock the wheel.



[Wheel Locking]

5. Installation

- 5.2.1. Move the sterilizer to its place of installation.
- 5.2.2. Remove the vinyl wrapping.
- 5.2.3. Lock the casters by turning in up direction.
- 5.2.4. Connect the AC power cable to the power source. (220-230V~, single phase).
- 5.2.5. Turn on the power switch located on the right side cover of the sterilizer.

The power switch controls the power supply of the sterilizer.



This Unit should be left on at all times in order that sterilization may be performed as needed. The chamber wall is heated by turning on the power. For sterilization, the inside of the chamber should be heated to over 50°C. If heated from room temperature, it takes approximately 2 hour for the sterilizer to reach its optimal operating temperature.

- 5.2.8. Turn the switch button push in order to enable the micro-processor to communicate with the Touch Screen PC. The power supply to the Touch Screen PC is now on.

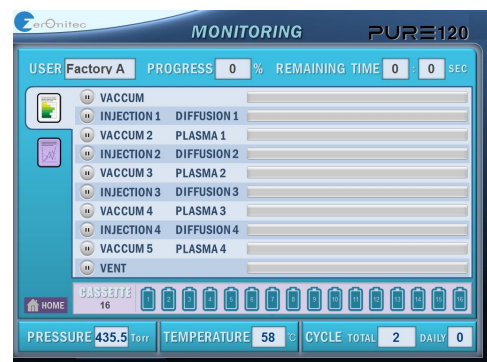


Check initial ZERONITEC PURE 120 screen on the touch screen. Program is automatically booted. Users can now operate the sterilizer from the main screen.



STOP Button

This button is used to interrupt the automatic cycle at any time. If this button is pressed during the automatic cycle, the sterilizer is advanced to Vacuum 5 & Plasma 4 Stage followed by Aeration & Venting, and removes the hydrogen peroxide gas from the chamber before opening the door.





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Chapter 3. Operating Procedure

The ZERONITEC PURE 120 is a compact unit designed to sterilize heat/moisture sensitive devices. It utilizes a fully automatic control system to ensure that proper sterilization conditions are met. The normal process time is 35~55 minutes.

3.1 Overview of the ZERONITEC PURE 120

Chamber Dimension

Total (W x H x D) : 410mm X 410mm X 760mm

Process Time

Standard : 35 ~ 60 min

Hydrogen Peroxide Usage

1.875 cc x 2 times = 3.7cc / 1 cycle (Short cycle)

1.875 cc x 4 times = 7.5cc / 1 cycle (Standard, Advanced cycle)

3.2. User Precautions for operating the sterilizer



Non-trained users must not operate the sterilizers.

All information in the Sterilizer manual must be fully understood.

Check whether the door is opened or not before sterilization.

After push the ON switch, check the Touch screen PC and the chamber temperature is over 50℃.

Maintaining appropriate temperature(50~60℃) of the sterilization chamber is necessary.

⇒ **ON switch Main power is kept to turn on at all times.**

The vacuum pump is then checked to make sure of correct operation.



In the event of an emergency in the middle of sterilization process, the program is automatically terminated. At this time, do not try to open sterilizer covers, or initiate any repairs. Please contact the ZERONITEC customer service center.

Any violation of the guidelines in the ZERONITEC manual may lead to failure or damage to the sterilizer.

Avoid shock to the sterilizers at all costs.

It is important to keep the AC cord of the sterilizer plugged in during sterilization process to avoid sterilization interference. Users must not open the covers.

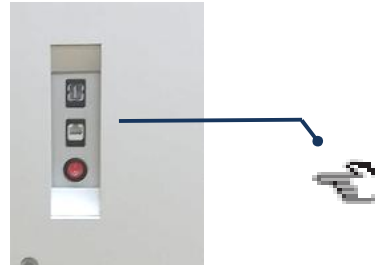
After completing the sterilization process, the following should be checked;

- If the sterilizer malfunctions, stop using it immediately and contact the ZERONITEC Co., Ltd customer service center.

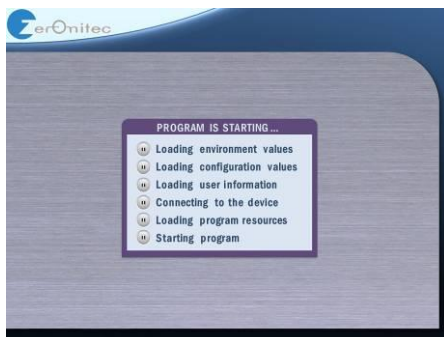
- Only PURE accessories (ex, Biological Indicator, Chemical Indicator Strip, Chemical Indicator Tape, Pouch) are used for the ZERONITEC PURE 120.

3.3. Preparation for sterilizer operation

3.3.1. ON switch pushed. The power supply to the Touch screen PC is now on.

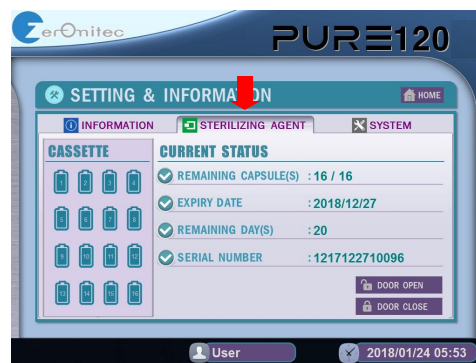
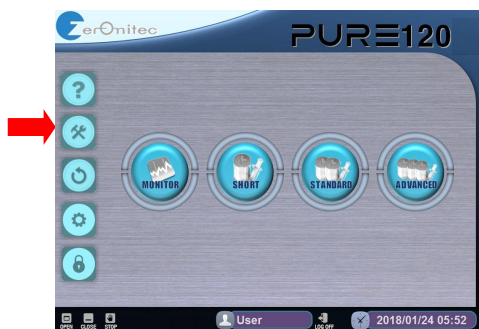


3.3.2. Users can then see the screen displaying ZERONITEC PURE 120..

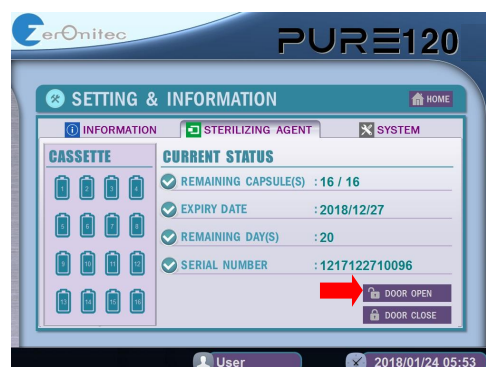


3.3.3. Insert a Hydrogen Peroxide Cassette into the Supply inlet

3.3.3.1. Press “Setting” -> “SETTING&INFORMATION” -> “Sterilizing Agent” menu on Main screen.



3.3.3.2. Press “DOOR OPEN” button to open cassette supply door .



3.3.3.3. The INJECTOR door open automatically and the Container automatically come out and set the home position to load cassette.

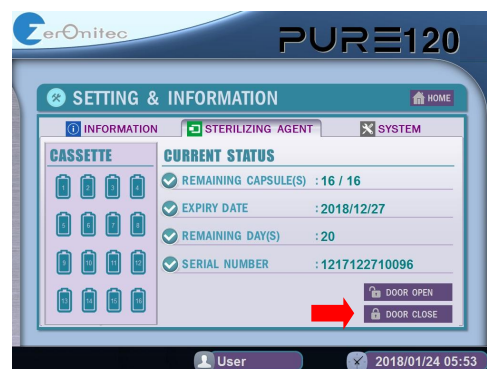
Insert a hydrogen peroxide Cassette(use only H₂O₂ specifically designed for use with ZERONITEC PURE 120) into the Supply inlet from the right side(◀).

When inserting a hydrogen peroxide cassette, ensure that **Red Dot** symbol on the cassette and **Red Dot** on the supply inlet align correctly. Otherwise, sterilant cassette can't be loaded.



Load cassette
from the right side

3.3.3.4 Within 15 seconds after pressing “DOOR CLOSE” button, barcode of cassette is scanned automatically and the Remaining Capsule is set at “16”. Users can now see the Remaining Capsule changes from 0 to 16 on the STERILIZING AGENT Screen.

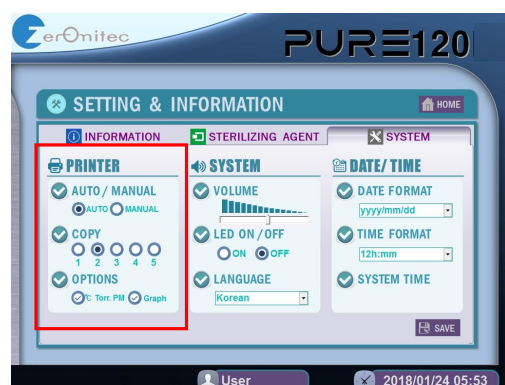


The figure for Remaining Capsule will be reduced by 4 counts during a full cycle. (4 Hydrogen Peroxide injections per a full cycle). A total 4 cycles can be processed with one Cassette .

3.4. Setting the Printer

Press SETTING button from HOME Screen and move to “SETTING&INFORMATION” screen ->”SYSTEM” tab-> “PRINTER”.

User can set Printer configuration as follow.



3.4.1 MODE

- AUTOMATIC : After cycle is complete, printout come out automatically.
- MANUAL : After cycle is complete, printout come out manually.

On the cycle complete message windows, press "PRINTER" icon.

3.4.2 COPY: For both AUTOMATIC mode, it sets how many printout will come out automatically.

3.4.3 OPTION

- °C /Torr/PM ON: When printouts come out, Temperature and Pressure parameters and PM cycle are displayed.
- °C /Torr/PM OFF : When printouts come out, Temperature and Pressure parameters and PM cycle are not displayed.
- GRAPH ON: When printouts come out, cycle graph is displayed.
- GRAPH OFF: When printouts come out, cycle graph is not displayed.

3.5. Starting the Sterilization Cycle

3.5.1. Sterilization Process

The sterilization cycle consists of two consecutive and equal sterilization phases.

The sterilization process lasts approximately 35~60 minutes per cycle with no validation load.

The sterilization cycle can be monitored by the Touch Panel located on the cover.

Vacuum Stage 1 ⇒ Injection 1 & Diffusion 1 ⇒ Vacuum 2 & Plasma 1 ⇒ Injection 2 & Diffusion 2 ⇒ Vacuum 3 & Plasma 2 ⇒ Injection 3 & Diffusion 3 ⇒ Vacuum 4 & Plasma 3 ⇒ Injection 4 & Diffusion 4 ⇒ Vacuum 5 & Plasma 4 Vent Stage ⇒ Return to Atmospheric Pressure

3.5.2. Auto Processing for Sterilization Cycles

3.5.2.1. When sterilization cycle is started,

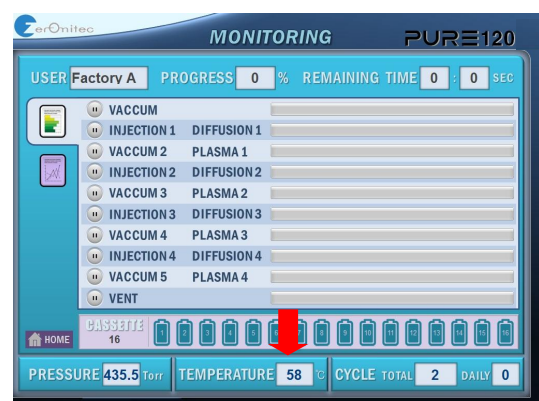
system check the Chamber Temperature and Sterilizing agent count automatically.

If the chamber temperature is less than 50 °C, Alarm 8 "Check the temperature" message appears.

Please check the real temperature value on the MONITORING screen and wait until it reaches 54~55 °C before commencing the sterilization process

3.5.2.2. On MONITORING screen, when the temperature reach °C, it is ready for sterilization processing.

Open the chamber door and load the basket with sterilizing items in the chamber.



3.5.2.3. Close the chamber door.

3.5.2.4. Select a sterilization cycle “SHORT/STANDARD/ADVANCED” button on the main screen.
When “SHORT, STANDARD and ADVANCED” cycle is selected, confirm message

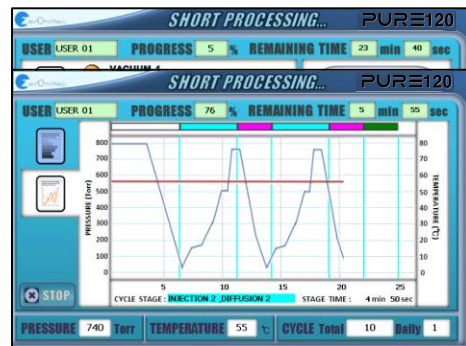


“Process Start ?” appears.

Then press YES button. The cycle is started.



3.5.2.5. The “MONITOR” screen will appear automatically and allow monitoring of the sterilization process including each stage with total remaining time, real-time chamber temperature and pressure, stage time
During the sterilization process, if “Graph” button is selected, the operator can monitor the process pressure in a graph format .



3.5.2.6. Completing the Auto process.

The sterilization process takes between 35~60 minutes depending on selected program.

A “Completed” message will confirm completion of cycle successfully , if CI colors are changed normally, use sterilized goods”.



3.6. Unloading sterilized items

Once sterilization is completed, remove the baskets containing sterilized items from the chamber.

3.7. Monitoring the Sterilization Process

3.7.1. Printer

Immediately after “Complete” message announces the completion of the cycle, sterilization process records are printed. Sterilizer printouts from the thermal printer show the process records as shown in the picture.

```

Sterilant Remaining Cycle : 1 / 14
Date : 2014-08-08
Start Time : 오후 11:18:09
End Time : 오후 11:41:13
Vacuum Time : 342
Injection1 Time : 210
Diffusion1 Time : 303
Vacuum2 / Plasma1 Time : 318
Injection2 Time : 6
Diffusion2 Time : 12
Vacuum3 / Plasma2 Time : 12
Vent Time : 181
Cycle Time : 1384
CYCLE STATUS : Complete
STERILIZER S/N : 1
Facility Name : Zeronitec
Department Name : Zeronitec
OPERATOR ID : Supervisor
Approved By :
  
```

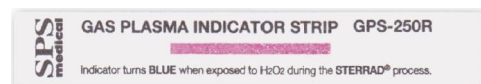
3.7.2 Sound Alarm

Immediately after “Complete” message announces the completion of the cycle, Complete alarm rings.

When OK button is confirmed for Cycle complete message, The Alarm is turned off.

3.7.3. Chemical Indicator

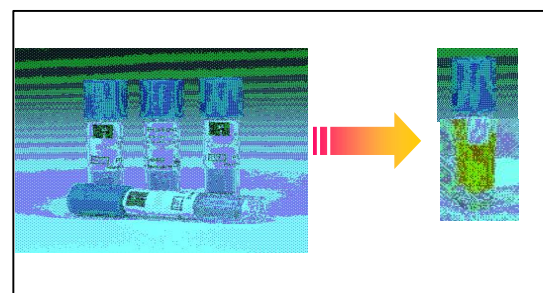
Chemical Indicators (CI) are used to detect some sterilization process failures.



Most Chemical Indicators consist of a sensitive chemical that changes color depending on one or more parameters of the sterilization process. CIs used for the ZERONITEC PURE 120 sterilizer will respond to temperature, hydrogen peroxide exposure, and exposure time. The color of strip changes Blue to Pink

3.7.4. Biological Indicator (SCBI, Self-Contained Biological Indicator)

Biological Indicators (BI) used to monitor the sterilization process containing *Geobacillus-Stearothermophilus* spores. It is reported *Geobacillus Stearothermophilus* spores are the most resistant for plasma hydrogen peroxide sterilization.



[No Color Change (Red or range) Color Change (Yellow)]

[No Growth]

[Growth]

Upon completion of the sterilization process, the BI will need to be incubated for 24 hours]

If the sterilization process fails, it changes color from red or orange to yellow.

If it remains red or orange, sterilization has been performed successfully.

Frequency of biological testing should be at least once per day or in accordance with hospital policies. ZERONITEC SCBI contains microorganisms that are known to be resistant to the

sterilization process and the best way to verify proper processing.

3.8. How to define sterilization efficacy.

Lumen PCD kit is used for sterilization efficacy test, and the way of performing the test is as follows.

3.8.1. Lumen PCD Test

Lumen PCD Test is to check if sterilization parameters meet the optimal sterilizing conditions using chemical indicators. Frequency of Lumen PCD test is recommended to perform once per week or in accordance with user's hospital policy. It is also performed after the following occasions such as preventative maintenance or calibration and in case of fixing and repairing.

3.8.1.1. Soft and Hard Lumen PCD

Sterilization monitoring systems include soft and hard lumen kits, each containing two types of lumen. Each lumen has a diameter of 1mm and is open on both sides, differing only in length and material:

Length of the soft lumen (made from Teflon) is 10,000mm

Length of the hard lumen (made from stainless steel) is 500mm

3.8.1.2. Using the Lumen Kit

Lumen Kit consists of a hard lumen (1 Ø x500mm) and two soft lumens (1 Ø x10,000mm, 2Ø x1,500mm).

The following illustrates the procedures for lumen testing in the PURE-series:

- 1) Cutting CI strip in 6mm x 40mm length.
(Check the length and diameter of the lumen)
- 2) Put CI Strip inside Lumen. And seal up.



[[Soft Lumen]



[Hard Lumen]

- 3) Put the soft lumen into the pouch roll cut in 32^{cm} length and seal up.
Put the hard lumen into the pouch roll cut in 60^{cm} length and seal up.



[Soft Lumen]

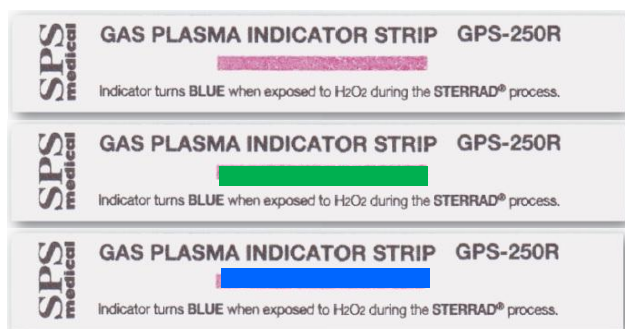


[Hard Lumen]

- 4) Load pouched two hard lumens and soft lumens in the chamber.
Run the Auto cycle once with the pouch roll in the chamber of the sterilizer.



- 5) Blue bar changes to pink (or lighter) when exposed in sterilizer.



3.9. How to remove an Empty Hydrogen Peroxide Cassette

- 2.1. Users can start the Auto process by pressing the “SHORT, STANDARD and ADVANCED” button. If the H₂O₂ capsule count reaches “0” or “3” for standard and advanced cycle, if the H₂O₂ capsule count reaches “0” or “1” for short cycle, the touch screen automatically display ALARM 5 with the following message before starting cycle:

“Cassette is empty, please replace with new cassette” on the screen. Users then need to replace the H₂O₂ cassette with a new one.

As each cycle runs, the count will decrease by 4(four). Users need to change the H₂O₂ cassette only when the alarm message appears on the screen.

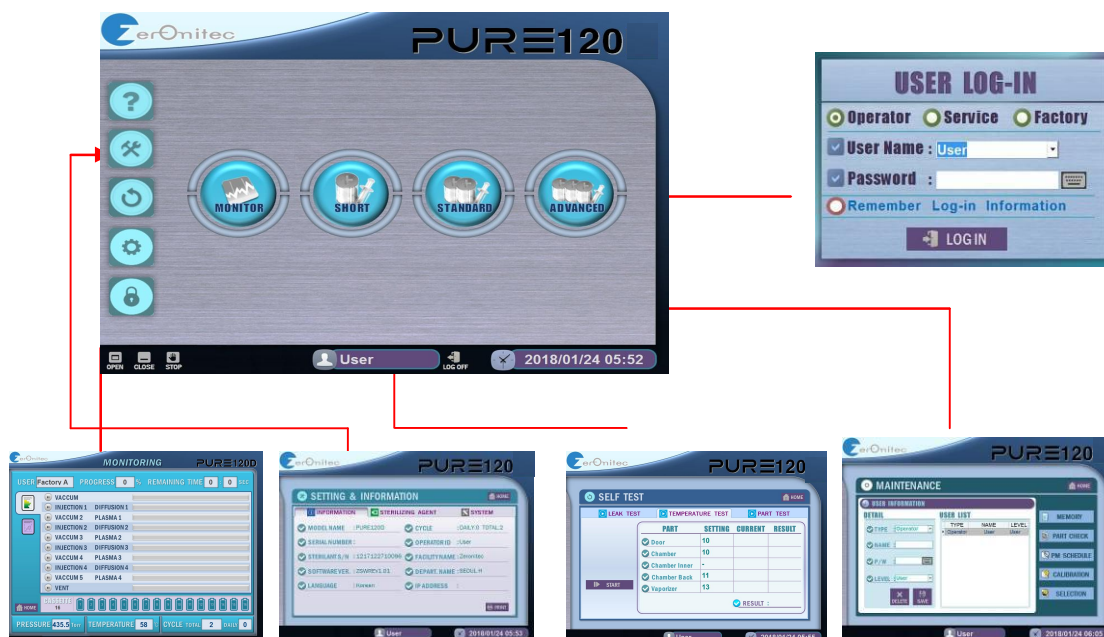




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Chapter 4. Additional Functions

4.1 System Information



- ① Choose the **SETTING** icon on **HOME** screen -> **Information** tab button to display **SYSTEM INFORMATION**.

If necessary, touch the **"PRINT"** button to print out the information.



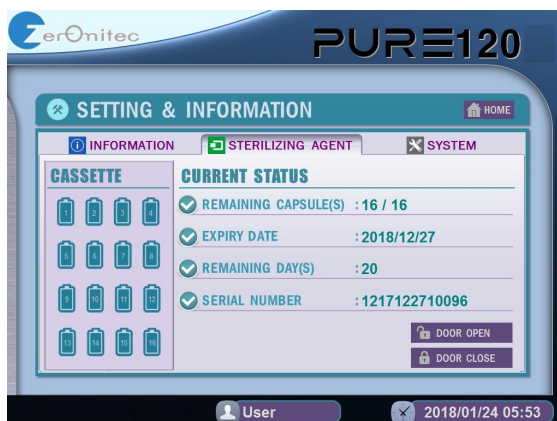
4.2 SETTING

- ① Choose the SETTING Icon on Home screen. There are three parts for system setting.
After setting is changed, setting should be saved with SAVE button.
 - Sterilization Agent
 - Printer, Date & Time, Volume , LED display.
 - PRINTER



Sterilizing Agent

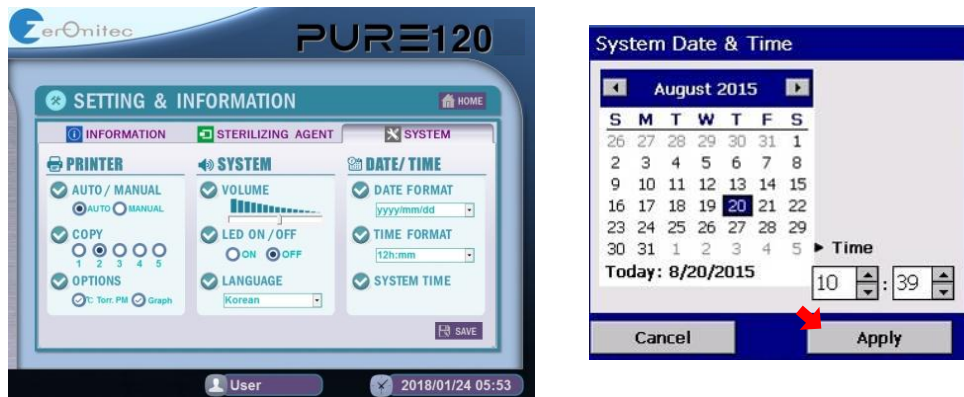
- In Sterilizing agent menu, when touch DOOR OPEN button, Sterilant supply door open and loading tray come out automatically. After loading sterilant, when touch DOOR CLOSE button, Barcode reader reads the sterilizing agent barcode information. Serial number, Remaining cassette capsule, and Remaining expiry date of current sterilization agent cassette can be checked.



I

Date and Time

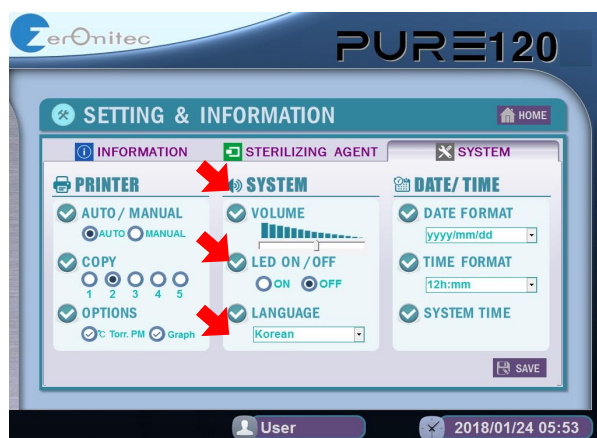
- Choose "Date and Time" button to set the date and time formats and "SETTING" button to set new time and date and to start the local time zone.



- After choosing the system time, press OK button to confirm this setting.
- After setting the date and time format and System time, setting should be saved by SAVE button before leaving the screen.

Volume & Display (Door LED , Language)

- Choose SYSTEM to set the volume of the alarm loudspeaker.
- Adjust the volume with adjust button.



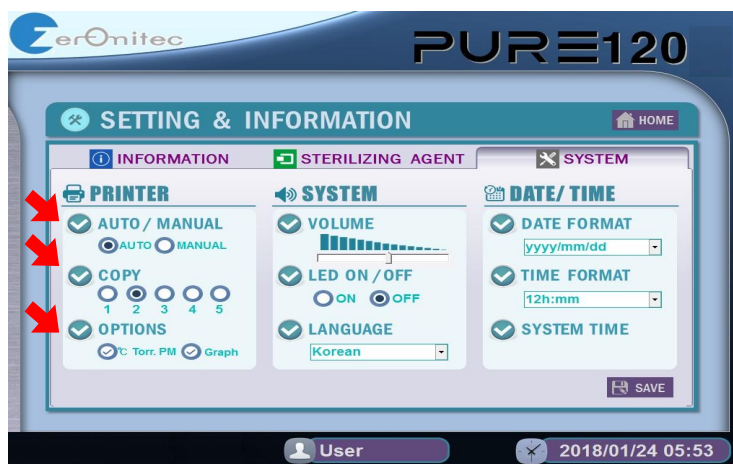
To turn off LED indicator on the front door, inactive LED by set to "OFF".
To change display language, select the desired language.

Multilanguage can be selected.

- Before exit the setting menu, "SAVE" button should be touched to confirm this setting.

Printer

- Choose SYSTEM to set printer options.
 - **Auto:** every time a sterilization cycle is completed, the printer paper comes out automatically.
 - **Manual:** Printer paper doesn't come out automatically. When user touch "Printer" button in completed cycle message window, cycle information is printed out for set count .
 - **COPY :** the number of papers printed out can be set for AUTO mode.
 - **Tem/Pressure, PM, Graph:** the parameters for the printout can be set.
- After setting, press the SAVE button.



Printout with real-time values(Temp/Pressure)and PM cycle

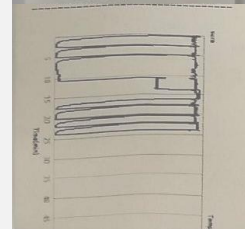
Printout format can be set by user.

Basic information.	Printout with real-time values(Temp/Pressure)and PM cycle	Printout with real-time values(Temp/Pressure),PM cycle and Graph.
☒ OPTION ☐ Torr. PM ☐ Graph	☒ OPTION ☒ Torr. PM ☐ Graph	☒ OPTION ☒ Torr. PM ☒ Graph

Selected program: SHORT
 Total Cycle : 16
 Daily Cycle : 1
 Sterilant Serial Number : 821404
 1111
 Sterilant Load Date : 2014-05-18
 Sterilant Expiry Date : 2014-05-22
 Sterilant Remaining Cycle : 1 / 14
 Date : 2014-08-08
 Start Time : 오후 11:18:09
 End Time : 오후 11:41:13
 Vacuum Time : 342
 Injection1 Time : 210
 Diffusion1 Time : 303
 Vacuum2 / Plasma1 Time : 318
 Injection2 Time : 6
 Diffusion2 Time : 12
 Vacuum3 / Plasma2 Time : 12
 Vent Time : 181
 Cycle Time : 1384
 CYCLE STATUS : Complete
 STERILIZER S/N : 1
 Facility Name : Zeronitec
 Department Name : Zeronitec
 OPERATOR ID : Supervisor
 Approved By :

Zeronitec Co., Ltd.
 CYCLE Information
 MODEL NO : PURE 120
 STERILIZER NO : DEMO
 FACILITY NAME : Zeronitec
 DEPART. NAME : SEOUL H
 Sterilant
 Serial No : 1217111010042
 Loading Date : 2018-04-23
 Expiry Date : 2018-05-13
 Rem. Capsule : 6/16
 Selected Cycle : Standard
 Total Cycle : 8
 Daily Cycle : 2
 Date : 2018-04-24
 Start Time : 17:27:59
 End Time : 18:13:54
 [VACUUM 1]
 Total Time : 07:03
 Temperature(Max) : 55 C
 Pressure(Max) : 756 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 1 & DIFFUSION 1]
 Total Time : 06:28
 Temperature(Max) : 55 C
 Pressure(Max) : 677 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 2 & PLASMA 1]
 Total Time : 02:26
 Temperature(Max) : 55 C
 Pressure(Max) : 667.9 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 2 & DIFFUSION 2]
 Total Time : 06:28
 Temperature(Max) : 55 C
 Pressure(Max) : 690 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 3 & PLASMA 2]
 Total Time : 02:26
 Temperature(Max) : 55 C
 Pressure(Max) : 673.2 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 3 & DIFFUSION 3]
 Total Time : 06:28
 Temperature(Max) : 55 C
 Pressure(Max) : 694.8 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 4 & PLASMA 3]
 Total Time : 02:26
 Temperature(Max) : 55 C
 Pressure(Max) : 689 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 4 & DIFFUSION 4]
 Total Time : 06:25
 Temperature(Max) : 55 C
 Pressure(Max) : 694.1 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 5 & PLASMA 4]
 Total Time : 01:31
 Temperature(Max) : 55 C
 Pressure(Max) : 682.7 Torr
 Pressure(Min) : 2 Torr
 [VENT]
 Total Time : 04:14
 Temperature(Max) : 55 C
 Pressure(Max) : 756 Torr
 Pressure(Min) : 4.1 Torr
 Cycle Time : 45:55
 Cycle Status : Completed
 OPERATOR ID : User
 APPROVED BY :

Zeronitec Co., Ltd.
 CYCLE Information
 MODEL NO : PURE 120
 STERILIZER NO : DEMO
 FACILITY NAME : Zeronitec
 DEPART. NAME : SEOUL H
 Sterilant
 Serial No : 1217111010042
 Loading Date : 2018-04-23
 Expiry Date : 2018-05-13
 Rem. Capsule : 6/16
 Selected Cycle : Standard
 Total Cycle : 8
 Daily Cycle : 2
 Date : 2018-04-24
 Start Time : 17:27:59
 End Time : 18:13:54
 [VACUUM 1]
 Total Time : 07:03
 Temperature(Max) : 55 C
 Pressure(Max) : 756 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 1 & DIFFUSION 1]
 Total Time : 06:28
 Temperature(Max) : 55 C
 Pressure(Max) : 677 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 2 & PLASMA 1]
 Total Time : 02:26
 Temperature(Max) : 55 C
 Pressure(Max) : 667.9 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 2 & DIFFUSION 2]
 Total Time : 06:28
 Temperature(Max) : 55 C
 Pressure(Max) : 690 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 3 & PLASMA 2]
 Total Time : 02:26
 Temperature(Max) : 55 C
 Pressure(Max) : 673.2 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 3 & DIFFUSION 3]
 Total Time : 06:28
 Temperature(Max) : 55 C
 Pressure(Max) : 694.8 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 4 & PLASMA 3]
 Total Time : 02:26
 Temperature(Max) : 55 C
 Pressure(Max) : 689 Torr
 Pressure(Min) : 0.5 Torr
 [INJECTION 4 & DIFFUSION 4]
 Total Time : 06:25
 Temperature(Max) : 55 C
 Pressure(Max) : 694.1 Torr
 Pressure(Min) : 0.5 Torr
 [VACUUM 5 & PLASMA 4]
 Total Time : 01:31
 Temperature(Max) : 55 C
 Pressure(Max) : 682.7 Torr
 Pressure(Min) : 2 Torr
 [VENT]
 Total Time : 04:14
 Temperature(Max) : 55 C
 Pressure(Max) : 756 Torr
 Pressure(Min) : 4.1 Torr
 Cycle Time : 45:55
 Cycle Status : Completed
 OPERATOR ID : User
 APPROVED BY :



USER LOG-IN (Operator login)

If your facility does not ask operator login information, just check "Remember Log-in information" with default "Operator user" ID and don't try to change the ID.

- ① When the "Remember Log-in information" is checked on USER LOG-IN windows , user don't have to log-in whenever system started. This mode is recommended to be used

when the sterilizer is used without operator restriction.

- ② When the "Remember Log-in information" is not checked, USER LOG-IN function is activated.

Whenever sterilizer system is started, USER must select user name and enter password. Once log-in is done, the user ID is recorded in the system information. Therefore, user can't use sterilizer system without log-in. Whenever operator run cycle mode, USER LOG-IN windows appears. The user ID is recorded and printed when cycle is completed. This mode is recommended to be used when all operator's information should be recorded by the system or when operator is restricted.



- ③ User can check the log-in status in the sterilizer.
- ④ To register a new ID and Password, log in with "User ADMIN" ID on HOME screen and choose MAINTENANCE mode. Only "User Admin" can change user's ID & password or create operators , other Admin ID information. After Create, Delete, press SAVE button before leaving the screen.

If admin want to change user information, select the detail information, after then Users are listed on the USER LIST window.



4.3 Self Test

Choose the Self-test Icon on Home screen, there are 3 parts of system test.

- Leakage test
- Temperature test
- Parts test

Vacuum and Leakage Test

Select "Leak Test" tab, press the START button to start automatic Vacuum and Leakage up rate test of the sterilizer.

-Vacuum and Leakage up Test takes about 10 minutes to be completed.



-Just in case this test needs to be stopped emergently, the CANCEL button can be used.

Touch the Printer icon to print out the result paper.

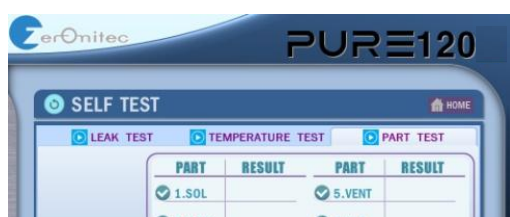
Temperature Test

- Press the "Temperature Test" tab to check each temperature status.
- Just in case this test needs to be stopped emergently, the CANCEL button can be used.
- Touch the PRINT button to print out the result paper.



Part Test

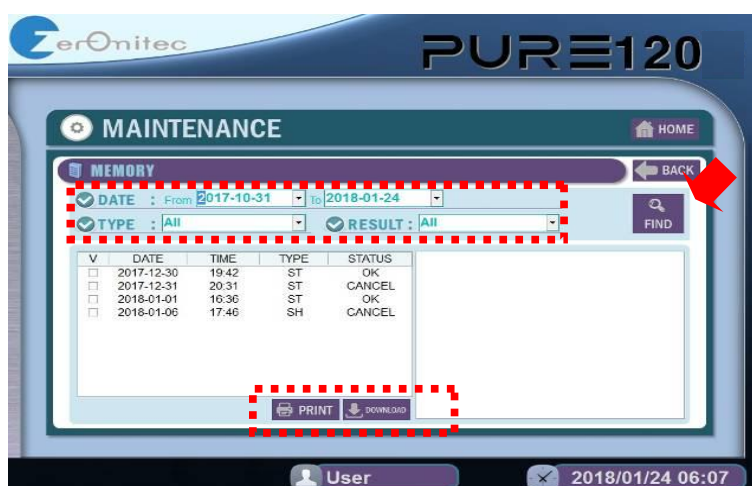
- Press the "Parts Test" tab to check each part's function.
- Just in case this test needs to be stopped emergently, the CANCEL button can be used.
- Touch the Printer icon to print out the result paper.



4.4 Reprint and Download of Cycle History

The sterilization history data are saved into hardware of sterilizer and it can be saved for more than 10,000 cycles. Choose the "MAINTENANCE" mode from HOME screen.

- ① Choose the **MEMORY** button.
- ② Search for the date or period, type, result to be reviewed by using FIND button. Check a cycle to be reviewed and the cycle result page that is the same with the printer paper is shown on right screen. If user want to print the cycle data, check necessary cycle data to be reprinted on left windows screen and touch the PRINT button. When multiple cycle data are checked(V), all data will be reprinted.



< MEMORY function>

- ③ If user want to save data to USB memory card, insert USB memory card into the system. On left windows screen, select cycles to be saved or select "Check All" button and touch the "DOWNLOAD" button. The checked data will be downloaded into USB memory card. It takes 1 to 3 minutes depending on being saved data.
After data download is finished, remove the USB memory card.
- ④ If USB memory card is not invalid or not connected, The warning message" USB Memory is not connected" is displayed when the "DOWNLOAD" button is pressed.
- ⑤ The saved data can be read as Text file format on lab-top computer.

4.5 PM(Preventive Maintenance) Alarm

Preventive Maintenance (PM) for ZERONITEC PURE Series is normally performed for Vacuum pump oil, Activated Carbon Filter, and Oil Mist Filter

PM 2 level is normally performed for Bacterial HEPA Filter and Plasma chamber assy.

The number of cycles of operation can be altered followed by the operating conditions.

When this alarm occurs, please call to the engineers.

PM Alarms occur when user starts the cycle. Depending on the PM parts, or the set cycles by the engineers, the alarms will come together or each on the monitor.

Even though these alarms occur, the sterilizer will work normally. **When the PM Alarm is shown on the screen, confirm the alarm with "OK" button and then alarm window disappears. *The PM parts are recommended to be replaced or maintained by the authorized engineer in time. Therefore, if alarm appear, please contact customer service center.***

Chapter 5. Routine Maintenance

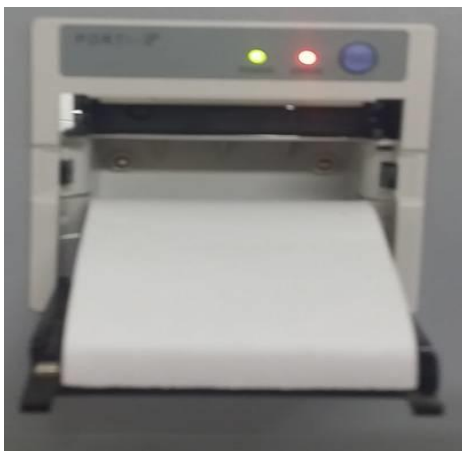
5.1. Replacing of Print paper

Replace the paper roll as follows;

5.1.1. Pull and open the cover on either side of the printer.



5.1.2. Remove any remaining paper and the roll.



5.1.3. Insert the new paper roll.

After the release is placed on the end of the paper,
close the cover

5.1.4. Push "FEED" to determine whether the roll has been correctly inserted.

5. 2. Safe keeping and maintenance

5.2.1 Storage Condition

Keep the sterilizer away from the effects of pressure, temperature, humidity, sunlight, dust, and high levels of salt or static electricity in the air.

Humidity: 30 – 85 %

Pressure: 70 - 106 KPa

Temperature: 10 - 40 °C

Keep away from inclination, vibration and shock.

Avoid places where unit can be exposed to chemicals or gases

After all the sterilization process, the 10^{-3} Torr of the reactor's internal pressure to maintain the pressure after vacuum, turn the sterilizer out by drawing the blocker down. At the event of a failure, stop using the sterilizer and call an expert.

The person inexperienced does not try to repair or convert the parts of sterilizers.

Only trained technicians should try to repair or make modifications to the parts of the sterilizers.

5.2.2 Cleaning the exterior of the sterilizers

A soft cloth is used to clean the exterior of sterilizers. If there are tough stains on the surface, a little acetone or alcohol soaked cloth can be used for cleaning.

5.2.3 Cleaning of the Inside the chamber

The Tray is removed from inside of the chamber.

Clean inside the chamber with a cloth with Alcohol periodically.

If clean inside the chamber with a wet cloth and distilled water, then clean with a dry cloth without remaining water or moisture inside the chamber.

If there are remaining water or humidity inside the chamber, system doesn't function for vacuum process.

Do not pour any detergent solution or cleaning material into the chamber. Any substance not recommended from ZERONITEC can affect the sterilizing process.

Trays are also cleaned in the same way.

Refrain from using the sterilizer until any remaining moisture in the chamber completely evaporates.



Do not clean the chamber door area with abrasives.

The sterilization chamber uses an O-ring vacuum seal to maintain a vacuum in the chamber. Never use rough cleaning tools, such as a wire brush or steel wool, on the door housing or chamber assembly. This could damage the seal.



If any other than recommended method for cleaning or decontamination method for ZERONITEC PURE 120 sterilizer is used, the sterilizers can be damaged. Therefore, users must check whether the cleaning method follows the guidelines supplied in this manual.

Chapter 6. Troubleshooting

Error Messages display on the touch screen after sterilization process is started.

The Error number is printed on printer paper after cycle is completed.

After this message, Vacuum 5 & PLASMA 4 and VENT phases will be automatically performed and terminated.

6.1. Error Messages

No	Displayed Message	Description	User's Action
ERROR 01	Cycle Cancel	By pressing the STOP button on the control panel, the process is immediately cancelled and the process automatically converts to Plasma II and Vent stages.	Wait for a few minutes until the cancel process finishes automatically. Users do not need to do anything during the process. After completion of cancel process, restart the sterilization process.
ERROR 02	Pump Current	There is an over current in the Rotary Pump. Please check vacuum pump or EOOR.	Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ERROR 03	Cassette Position	Checked the cassette position Cassette motor is not detected in the Home position sensor.	Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ERROR 04	Injector Position	Checked the Injector position Injector motor is not detected in the Home(Rear) position sensor.	Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ERROR 05	Chamber Temperature	Check the Chamber Temperature The temperature of the Chamber heater is out of normal range, setting $\pm 3^{\circ}\text{C}$.	Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ERROR 06	Vaporizer Temperature	The temperature of the Vaporizer heater is out of normal range, setting $\pm 10^{\circ}\text{C}$.	Check the Vaporizer Temperature. Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ERROR 07	Vacuum Failed	This error indicates that vacuum pressure has not reached a certain pressure by a definite time since Vacuum valve has been opened.	1. Check whether the items to be sterilized are overloaded or are wet. 2. Reduce load volume or dry items completely if wet. 3. Check the Self-test (Vacuum & Leak test) 4. Restart the sterilization process. 5. If the error continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com

No	Displayed Message	Description	User's Action
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ERROR 08	Injection Failure during Injection Stage	Chamber pressure doesn't reach to set value during injection stage. H2O2 was not injected or blocked.	Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ERROR 09	Diffusion Failure during Diffusion Stage	Chamber pressure doesn't reach to set value during diffusion stage.	Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ERROR 10	Plasma Failure	Plasma is not detected from plasma assembly.	Contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com

6. 2. Alarm Messages

Alarm Messages display only on the Screen prior to the sterilization process.

When user touch the Alarm message, the message disappears.

But, if the cause of alarm is not solved yet, the alarm appears again upon cycle start.

No	Displayed Message	Description	User's Action
ALARM 01	Can not sense the barcode	Can not sense the barcode Scanner is unable to sense the barcode for a certain period of time.	1. Match the red circles on the INJECTOR unit and the cassette correctly. 2. Repeat scanning process. 3. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 02	Duplicated barcode. Please insert new cassette	Duplicated barcode Inserted cassette is not new since the barcode of cassette was already read by scanner. Insert new cassette.	1. Verify the serial number of the barcode. 2. Replace the hydrogen peroxide cassette with new barcode. 3. Repeat the barcode scanning process again.
ALARM 03	Expired sterilant from manufacturing date. Please insert new cassette	Sterilant is expired from manufacturing date.	1. Discard the expired sterilant in accordance with the procedures for the disposal of hazardous waste. 2. Replace the hydrogen peroxide cassette with a valid cassette and restart the process.
ALARM 04	Expired sterilant after loaded Please replace with new cassette	Sterilant cassette was expired since the sterilant cassette has been loaded into sterilizer.	1. Replace the hydrogen peroxide cassette with a new cassette.
ALARM 05	Sterilant cassette is empty Please replace with new cassette	The remaining number of capsule is not enough to run selected cycle. Please replace with new cassette.	1. Replace the cassette. 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 06	Incorrect cassette Please insert correct cassette	The barcode of sterilant is not matched with sterilizer or invalid.	1. Insert correct cassette for the sterilizer model or undamaged barcode. 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 07	Check the Door Temperature	Door Heater does not work within the range of standby setting $\pm 5^{\circ}\text{C}$..	If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com

No	Displayed Message	Description	User's Action
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ALARM 08	Check the Chamber Temperature	Chamber Heater does not work within the range of standby setting $\pm 5^{\circ}\text{C}$.	If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 09	Check the Chamber Door Open	Chamber door is not closed completely.	1. Check the door up home sensor. 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 10	Check the Chamber Back Temperature	Chamber back temperature does not work within the range of standby setting $\pm 5^{\circ}\text{C}$.	1. Check the Chamber back heater 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 11	Check the Vaporizer Temperature	Vaporizer temperature does not work within the range of standby setting $\pm 5^{\circ}\text{C}$.	1. Check the Vaporizer heater 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 12	PM1 Change the Carbon Filter	PM1 Change the Carbon Filter	1. Change the Carbon Filter from PM 1 Kit. 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 13	PM1 Change the Oil mist Filter	PM1 Change the Oil mist Filter	1. Change the Oil mist Filter from PM 1 Kit. 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 14	PM1 Change the Pump Oil	PM1 Change the Pump Oil	1. Change the Pump Oil from PM 1 Kit. 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 15	PM2 Change the HEPA Filter	PM2 Change the HEPA Filter	1. Change the HEPA Filter from PM 2 kit 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 16	PM2 Change the Plasma Assembly	PM2 Change the Plasma Assembly	1. Change Plasma Assembly from PM 2 Kit. 2. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com

No	Displayed Message	Description	User's Action
ALARM 17	Check the Cassette Home	Check the Cassette Home position	If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 18	Check the Cassette detect sensor	Check the Cassette detect sensor	If the Alarm continues, contact the ZERONITEC Co., Ltd service Center. info@zeronitec.com
ALARM 19	Cassette door is opened	Check the cassette door	If the Alarm continues, contact the ZERONITEC Co., Ltd service Center. info@zeronitec.com
ALARM 20	Check the Supply Position	Check the cassette supply motor or sensor.	If the Alarm continues, contact the ZERONITEC Co., Ltd service Center. info@zeronitec.com
ALARM 21	Check the Injector position	Check the Injector motor or sensor.	If the Alarm continues, contact the ZERONITEC Co., Ltd service Center. info@zeronitec.com
ALARM 22	Power Outage occurred	Main power failure was occurred and system was rebooted.	1. If system was standby status, please just confirm the Alarm message. 2. If rebooted during sterilization process, please confirm the Alarm message and wait until the remaining process is finished on screen. 3. Repacking all items including changing C/I and B/I indicators and sterilize the items again. 4. If the Alarm continues, contact the ZERONITEC Co., Ltd. Service Center. info@zeronitec.com
ALARM 23	Print Error	Check the printer	If the Alarm continues, contact the ZERONITEC Co., Ltd service Center. info@zeronitec.com
ALARM 24	Check the Front Door	Check the front door	If the Alarm continues, contact the ZERONITEC Co., Ltd service Center. info@zeronitec.com
ALARM 25	Cannot open the door Please check the Pressure	Chamber pressure doesn't reach to atmospheric pressure.	Please check the Pressure If the Alarm continues, contact the ZERONITEC Co., Ltd service Center. info@zeronitec.com

Chapter 7. State of Conformity

7.1. State of Conformity



ZERONITEC Co., Ltd. with its registered office and its headquarters at **RM#917, Sicox Tower, 484, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea** is the manufacturer of the Low Temperature Plasma Gas Sterilizer.

ZERONITEC Co., Ltd. declares that this product conforms to the safety provisions as set out in Annex II (excluding Section 4), risk class IIb, following Council Directive 93/42/EEC as amended by Directive 2007/47/EC as certification Notified Body Number 1639.

Chapter 8. Labelling

8.1 Labelling

Explanation of Symbols:

SYMBOL	EXPLANATION
	Catalogue number
	Manufacturer
	Serial number
	rAuthorized representative in the European Community
	Date of manufactured
	Caution
	Consult instructions for use
	Do not dispose of with domestic waste

Product name	Low Temperature Plasma Sterilizer		
	ZERONITEC PURE 120		
	ZERONITEC CO., LTD. RM#917, Sicox Tower, 484, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea (Made in Korea). Tel : +82 (0)31 8039 6690, Fax: +82 (0) 31 8039 6601		
			
Weight	350 kg	Quantity	1 SET
Input Voltage	220V-230V~, 50/60Hz	Consumption Electricity	3.5 kw
	CMC MEDICAL DEVICES & DRUGS S.L. C/ Horacio Lengo, 18. 29006. Malaga. Spain Tel : +34 951 214 054 / Fax : +34 952 330 100 E-mail: info@cmcmedicaldevices.com		