U.S. ENVIRONMENTAL PROTECTION AGENCY	**EPA Reg. Number:**	**Date of Issuance:**
Office of Pesticide Programs Antimicrobials Division (7510P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460	93728-2	11/30/21

NOTICE OF PESTICIDE:
  _ X _ Registration
  ___ Reregistration
  (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Aura-D™ Cartridge

Name and Address of Registrant (include ZIP Code):

Gen Minor
VP, Quality & Regulatory Affairs
Sterifre Medical, Inc.
4020 Lake Washington Blvd
Suite 300
Kirkland, WA 98033

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	**Date:**
Steven Snyderman Steven Snyderman, Product Manager 33 RMB2, Antimicrobials Division (7510P)	11/30/21

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCI identified below:

   a. Hydrogen Peroxide GDCI-000595-1127

   You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

4. Make the following label changes before you release the product for shipment:

   • Revise the EPA Registration Number to read, "EPA Reg. No. 93728-2."

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

   • Basic CSF dated 9/20/2019

If you have any questions, you may contact Perri Moeller at (202) 566-0813 or via email at moeller.perri@epa.gov.
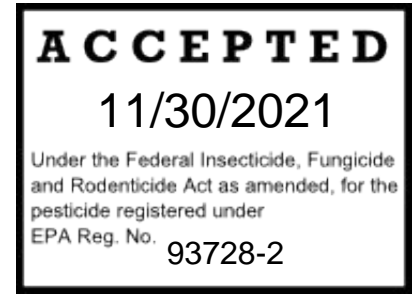

Enclosure: Stamped Master Label

Label Identification

AURA-D^{TM} Cartridge

EPA Reg. No. 93728-E

Nov. 24, 2021

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┌─────────────────────────────┐
│         ACCEPTED            │
│         11/30/2021          │
│ Under the Federal Insecticide, Fungicide │
│ and Rodenticide Act as amended, for the  │
│ pesticide registered under               │
│ EPA Reg. No.   93728-2                    │
└─────────────────────────────┘
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Formatting Notes (applicable for all claims):

Now[!] -and/or- New[ly][!] -and/&/or- **Improved[!]** may be added anywhere to a claim and will only be used for the first 6 months of producton shelf.

Optional text may be placed anywhere on the label -and/or- container.

Bold, italicized text is information for the reader and is not part of the label.

Bracketed information is optional text.

The word "and" may be substituted with "&". Plural words may be used in their singular form or singular words may be used in their plural form unless otherwise specified in 40 CFR.

All directions may be written in numbered form or in paragraph form.

All use surfaces and/or use locations on the label may be listed in conjunction with an image of the use surface and/or use location.

Highlighted text is new. Strike-through text means removed.

AURA-D^{TM} CARTRIDGE

For institutional use only – Not for food contact or household use

Note to Reviewer: In accordance 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the label.

KEEP OUT OF REACH OF CHILDREN

DANGER:

Active Ingredient:

Hydrogen Peroxide 50.0%
Other Ingredients: 50.0%
Total: 100.0%

SEE [SIDE -or- BACK] LABEL -or-
PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS.

[Net] [W[EIGH]T]_____
Package will bear the actual net contents in milliliters and ounces

AURA-D™ Cartridge is only for use in conjunction with the AURA™ Automated Disinfection System.

[Lot Number -or- No. -or- # _____]

[Expiration Date _____]

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER. Corrosive; causes eye and skin damage. Harmful if inhaled or swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapors or spray mist. Wear goggles or face shield and rubber gloves when handling [open container]. Wash thoroughly with soap and water after handling.

FIRST AID:

If in eyes: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor immediately for treatment advice.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor immediately for treatment advice.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor immediately for treatment advice.

If swallowed: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.

In case of emergency, call a poison control center [at 1-800-222-1222] or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL OR CHEMICAL HAZARDS: Strong oxidizing agent. This product is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

For labels with veterinary uses
ENVIRONMENTAL HAZARDS: This pesticide is toxic to birds, fish, and aquatic invertebrates.

For more [product -and/or- ingredient] information, visit www.sterifre.com.
Manufactured -or- Mfd. for [-and/or- © YYYY] Sterifre Medical, Inc., 4020 Lake Washington Blvd. NE, Suite 300, Kirkland, WA 98033
[1-(___) ____-_____ *Insert Sterifre Medical toll free number*.].
[*Insert trademark* -and/or- Sterifre Medical [is a [registered] trademark of Sterifre Medical, Inc.]
[*Insert trademark* -and/or- AURA-D [is a [registered] trademark of Sterifre Medical, Inc.]
[*Insert trademark* -and/or- AURA [is a [registered] trademark of Sterifre Medical, Inc.]
Made in [the] U.S.A. [of global -and/or- domestic components -and/or- ingredients.]
EPA Reg. No. 93728-___ *Insert dash number*
EPA Est. No. _____ *Insert EPA establishment number*
Visit us at www.sterifre.com.

[Patents: www.sterifre.com [/patents]]

Additional optional text
[Sterifre [Medical] Customer Assistance] [1-(___) ____-_____ *Insert Sterifre Medical toll free number*.] Any Questions? [The experts at Sterifre are standing by to answer any of your questions.] -or- Questions or Comments? Call [toll-free] [1-(___) ____-_____ *Insert Sterifre Medical toll free number*.] For [M]SDS information, please go to www.sterifre.com.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For Use with the AURA™ Automated Disinfection System Only: This product is only to be used in conjunction with the AURA™ Automated Disinfection System to disinfect pre-cleaned hard nonporous surfaces.

Refer to the AURA™ Automated Disinfection System User Manual for detailed AURA-D™ Cartridge installation, replacement, and product use directions -and/or- instructions.

Interior surfaces are not disinfected by the AURA™ Automated Disinfection System with the AURA-D™ Cartridge.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream, or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

Do not use an expired AURA-D™ Cartridge.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

[PESTICIDE] STORAGE: Keep product in its original packaging. Avoid damage to cartridge. Keep cartridge out of direct sunlight. Store at temperatures below 86°F (30°C).

[PESTICIDE] DISPOSAL: Hydrogen peroxide to be discarded should be disposed of as hazardous waste in accordance with local, state, and federal agency procedures.

CONTAINER HANDLING: Non-refillable cartridge. Do not reuse or refill this cartridge. Cartridge is designed to be empty after full use in the AURA™ Automated Disinfection System. Discard empty cartridge [per facility policy].

This product [is effective] [kills] [the following] [bacteria] [viruses] in 10 minutes:

Organism Table

Bacteria	ATCC and/or Strain
Staphylococcus aureus	[ATCC 6538]
Pseudomonas aeruginosa	[ATCC 15442]

Virus◇ [Small Non-Enveloped]	ATCC and/or Strain
Norovirus (tested as Feline calicivirus)	[Strain F-9] [ATCC VR-782]

Note to Reviewer*: These footnotes are used when the appropriate symbols are listed on label.*

† *Staphylococcus aureus, Pseudomonas aeruginosa*, and Norovirus (Feline calicivirus).

❖When used according to disinfectant directions for use.

Antimicrobial Claims

- [Automated] disinfection technology
- Bacteria -and/or- virus -and/or- germ† fighting formula
- Bactericide -or- Bactericidal
- Broad spectrum disinfectant
- Broad spectrum no-rinse disinfectant for non-food contact surfaces
- Can help reduce cross contamination between treated hard nonporous surfaces
- Contains hydrogen peroxide
- Daily defense against germs† -and/or- pathogens
- Deodorizes by disinfecting
- Disinfecting formula
- Disinfects -and/or- kills germs†
- Disinfects odor-causing bacteria
- Easy⁕ [and] convenient disinfecting
- Effective against -or- Kills *insert emerging viral pathogens*
- Effective against tough non-enveloped viruses of concern, including Norovirus
- Hard, non-porous multi surface disinfectant
- Helps reduce cross contamination on hard, nonporous surfaces
- Hospital disinfectant
- Hydrogen peroxide works by oxidizing microorganisms for [complete] disinfection
- Kills Germs† -and/or- [up to 99.9% of] Bacteria -and/or- [up to 99.9% of] Viruses◊
- [Kills -and/or- eliminates -and/or- disinfects -and/or- destroys -and/or- attacks] [up to 99.9% of] *must remove brackets when "eliminates" in claim* bacteria -and/or- germs† -and/or- viruses on *insert use surface(s) from Table 1*
- [Kills -or- eliminates -or- disinfects -or-destroys -or- attacks] [up to 99.9% of] *must remove brackets when "eliminates" in claim* bacteria[:] [in *insert use location(s) from Table 2*]
- [Kills -or- eliminates -or- disinfects -or-destroys -or- attacks] [up to 99.9% of] *must remove brackets when "eliminates" in claim* viruses◊ [:] [in *insert use location(s) from Table 2*]
- Kills [up to 99.9% of] bacteria -and/or- germs† -and/or- [up to 99.9% of] viruses◊ from toys
- Kills *insert number up to the total listed in Organism Table* pathogens -or- organisms
- Kills Norovirus
- Kills odor causing bacteria
- Kills viruses◊ -and/or- bacteria] [in 10 min[utes]]
- [One button push] kills [up to 99.9% of] bacteria
- Oxidizing agent to provide disinfection
- Ready to use [hospital] disinfectant when used with the AURA Automated Disinfection System
- Simplifies -or- Simplify disinfecting
- Simply disinfect
- This product -or- *product name* is a ready to use [broad spectrum -and/or- germicidal† -and/or- disinfectant] designed for disinfecting [of] hard, nonporous surfaces when used with the AURA Automated Disinfection System
- This product -or- *product name* disinfects hard, nonporous hospital -and/or- medical surfaces [with no rinsing required]
- This product -or- *product name* disinfects hard, nonporous surfaces. Its non-abrasive formula is designed for use on -or- [Use daily on] [Use daily to disinfect] hard, nonporous surfaces found in animal housing facilities
- This product -or- *product name* is a [hospital-use] germicidal† [disinfectant] designed for disinfecting [of] hard, nonporous surfaces
- This product -or- *product name* is formulated to disinfect hard, nonporous, surfaces[:] *insert surfaces from Table 1* -and/or- *insert surface material(s) from Table 3*
- Use when you are concerned about bacteria -and/or- viruses◊ -and/or- germs†
- Use -or- disinfects [on] healthcare surfaces [on *insert surface(s) from Table 1]* -and/or- [*insert hard, non-porous surface material(s) from Table 3*]
- Using AOAC approved test methods (under Good Laboratory Practices, [(GLPs)], this product -or- *product name* kills the following organisms on hard, nonporous surfaces: *insert organism(s) from Organism Table*
- Versatile disinfectant
- Virucide◊
- Virucidal◊
- When used as directed, this product -or- *product name* [is] effective against bacteria -and/or- viruses◊ on hard nonporous surfaces

Emerging Viral Pathogen Claims

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels when used in accordance with the appropriate use directions for use indicated below".

Product name -or- this product meets the criteria to make claims against emerging pathogen claims from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an..	..follow the directions for use for the following supporting organism(s) on the label :
Enveloped virus	Norovirus (Feline calicivirus) (VR-782)
Large, non-enveloped virus	Norovirus (Feline calicivirus) (VR-782)

Product Name -or- this product has demonstrated effectiveness against viruses similar to *insert name of emerging virus* on hard, nonporous surfaces. Therefore, *product name* -or- this product can be used against *insert name of emerging virus* when used in accordance with the directions for use against *insert name of supporting virus(es)* on hard, nonporous surfaces. Refer to the CDC -or- OIE website at *insert pathogen-specific website address* for additional information.

Insert name of illness/outbreak is caused by *insert name of emerging virus. Product name* -or- this product kills similar viruses and therefore can be used against *insert name of emerging virus* when used in accordance with the directions for use against *insert name of supporting virus(es)* on hard, nonporous surfaces. Refer to the CDC -or- OIE website at *insert pathogen-specific website address* for additional information.

General/Miscellaneous Claims

- Automated disinfection system [at the point of care]
- Clear drying formula
- Compatible with a variety of hard non-porous surfaces. . See Table 1 in label.
- Convenient
- [Convenient and] easy* to use
- Delivers consistent [amount of solution] concentration every time
- Deodorizes odors caused by bacteria
- Designed for disinfection of non-critical items in healthcare environments
- Designed -or- Ideal for daily use
- Disinfection you know, used in a new way
- [Easy] enough for everyday use
- Easy* on surfaces
- Easy* to use
- Easy* to use around patient [areas]
- Effective [disinfection -or- disinfectant] [formula]
- Effortless disinfection
- Eliminates [daily] mixing and measuring
- Everything [you need] is already in the system
- [Exposure free] disinfection
- For healthcare use
- For hospital use
- For hard non-porous surfaces of medical -and/or- hospital -and/or- clinical equipment
- For use on hospital surfaces [in *insert location(s) from Table 2*]
- Formulated with hydrogen peroxide
- Formulated with [patented] hydrogen peroxide technology
- Fragrance free
- Great for -or- use on the -or- your [*insert use surface(s) from Table 1* -and/or- *insert hard non-porous surface material(s) from Table 3*] [in *insert use location from Table 2*] [!]
- [Hands free] disinfection
- Ideal for use in *insert use location(s) from Table 2*
- Ideal for use on high-touch hard non-porous surfaces
- Labor saving no-rinse formula
- [Leaves] no residue
- Lint free
- Makes disinfecting easier
- No fragrance added
- No [harsh] [alcohol] smell
- No harsh chemical fumes -or- smell -or- odor -and/or- build-up -and/or- residue
- No linting
- No lint left behind
- No mixing, measuring, or rinsing required
- No pinched fingers!
- No rinsing
- No VOCs
- No wasted wipes
- Non-abrasive
- Non-[chlorine] bleach
- Non-flammable
- [Odor and exposure free] disinfection
- Patented technology
- Portable size
- Prevents formulation errors
- Easy* - and/or- convenient -and/or- versatile
- Reduce wipe waste
- Replace[s] up to 22 canisters of wipes
- Safe to -or- for use on [the following surface [material]s:] *insert hard non-porous surface material(s) from Table 3*
- Sealed and non-refillable cartridge
- [The product is] [always] ready to use when used with the AURA Automated Disinfection System
- [Touch free] disinfection
- VOC free
- [Wipe free] disinfection

Table 1 Exterior Use Surfaces
[of]
Hard Non-Porous Surfaces

Anesthesia equipment
Animal equipment
Apnea monitor/sensor pad
Athletic equipment
Automatic feeders
Badges
Bed-call button
Bed-position control
Bilirubinometer
Bladder scanner
Blood analyzer, point of care [(iStat)])
Blood glucose monitors
B[lood] p[ressure] monitors
Bottle warmer
Cast saw-motorized handpiece
Cell[ular] -or- wireless -or- mobile -or- digital phone
Charging station[s]
Chart cover
Clippers [(handpiece not head)]
[Computer] monitors
[Computer] mouse
[Computer] peripherals
[Computer] [Portable] keyboards
[Computer] screens
C[omputerized] T[omography] equipment
Cord[s]
Dental unit instrument trays
Diagnostic equipment
Dictating equipment [surfaces]
Docking stations
Doppler probes
Doppler transducers
Electrocardiogram cables
Electric razor body

External surfaces of [medical] equipment -or- [medical] equipment surfaces
External surfaces of pneumatic tubes
External surfaces of [respiratory] equipment -or- respiratory equipment surfaces
External surfaces of ultrasound transducers and probes
External surfaces of [veterinary] equipment -or- veterinary equipment surfaces
Fiberglass [sealed] surfaces
Glucometers
Hard, nonporous hospital -and/or- medical -and/or- dental -and/or- veterinary surfaces
Hard non-porous mouse pads
Headsets
High touch surfaces
IV Pumps/poles/warmers
Key[s]
Keyboards
Laminated surfaces
Lamps
Laptops
Leads
Light Laryngoscope handle
Light lens covers
Loupes
Mammography equipment
Mammography paddles
Mobile devices
Mobile electronic equipment
MRI -or- Magnetic Resonance Imaging equipment

Nurse-call devices -and/or- buttons -and/or- cords
Ophthalmoscope
Orthopedic & PT/OT equipment
Otoscope handle
Oximeter probes
Paddles
Pagers
Patient monitoring equipment
Patient phone
Patient support equipment
Pens
Phlebotomy trays
Physical therapy [(PT)] equipment [surfaces]
Plastic surfaces
Pulse oximeters
Reflex hammer
Rehab[ilitation] equipment
Remote controls
Resuscitation cart-defib[rillator] paddles
Scales
Scales [(diaper/other)]
Stainless steel surfaces
Staplers
Stethoscopes
Syringe pump
Tablet PCs
Telecommunication equipment [surfaces]
[Tele]phones
Thermometer-temporal
Tourniquet
Transducers
Toys (hard non-porous surfaces)
[TV] remote [control]s
Ultrasound transducers [and probes] [(external)]

Table 2 Use Locations

Acute Care Facilities
Airports [Clinic]
Ambulances -or- [Emergency Medical] Transport Vehicles
Ambulatory Surgical Centers [(ASC)]
Amusement Parks [Clinic]
Animal Hospitals
Animal housing facilities
Animal Life Science Laboratories
[Animal -and/or- Pet] Grooming Facilities
Anesthesia Rooms or Areas
[Assisted Living -and/or- Full Care] Nursing
Beauty Salons -or- Shops
Blood Banks
[Blood -and/or- Plasma -and/or- Semen -and/or- Milk -and/or- Apheresis] Donation Centers
CAT Lab[oratories]
Central Service Areas
Central Supply Rooms -or- Areas
Colleges
Correctional Facilities
C[ritical] C[are] U[nits]
Cruise Ships
Day Care [Centers]
Dental Clinics
Dental Operatories
Dental -or- Dentist's Offices
Dialysis Clinics -and/or- Facilities
Doctors' Offices
Dormitories
E[mergency] R[oom]s
Emergency Vehicles
Equine farms
Exam[ination] Rooms
[Eye] Surgical Centers
Farms/Factories
Funeral Homes -or- Mortuaries

Gym(nasiums)
Health Care Settings -or- Facilities
Health Club[s] Facilities
Home Health Care Facilities
Hospices
Hospitals
Hotels
Industrial Facilities
Intensive Care Units -or- ICU [areas]
Isolation Areas
Kennels
Labs -or- Laboratory -or- Laboratories
Laundromats
Laundry Rooms
Livestock -and/or- Swine -and/or- Poultry Facilities
Locker rooms
Long Term Care Facilities
Manufacturing plants -or- facilities
[Massage -and/or- Facial -and/or- Hair -and/or- Nail] Salons -and/or- Spas
[Medical] Clinics
Medical Facilities
Medical -or- Physician's -or- Doctor's Offices
Military Installations
Motels
Newborn -or- Neonatal [Nurseries -and/or- Intensive Care] Units [NICU]
Nurseries
Nursing -or- Nurses' Stations
Ophthalmic Offices -and/or- Clinics
Orthopedics Offices -and/or- Clinics
Out-Patient Clinics
Out-Patient Surgical Centers [(OPSC) -and/or- Clinics -and/or- Facilities]
Patient [Care] Areas
Patient Restrooms

Patient Rooms
[Pediatric] Exam[ination] Rooms -or- Areas
Pediatric Intensive Care Units [PICU]
Pet Areas
Pet Shops -or- Stores
Pharmacies
Physical Therapy Rooms -and/or- Areas
Physicians' Offices
[Police -and/or- Fire] Facilities
Psychiatric Facilities
Public Areas
Radiology -or- X-ray Rooms -or- Areas
Reception Areas
Recovery Rooms
Recreational centers -or- facilities
Rehabilitation Centers
Respiratory Therapy Rooms -or- Areas
Restrooms
Restroom[s] [Areas]
Schools
Shelters
Shower Rooms -or- Areas
Storage Rooms -or- Areas
Surgery Rooms -or- O[perating] R[oom]s
Tattoo Parlors
Trains
Transportation Terminals
Transport Vehicles
Universities
Veterinary -and/or- Animal Hospitals
Veterinary Clinics -and/or- Facilities
Veterinary Exam[ination] Rooms
Veterinary Offices -and/or- Waiting Rooms
Veterinary O[perating] R[oom]s
Veterinary X-ray Rooms
Waiting Rooms -and/or- Areas
Wellness Centers
Work Stations
X-Ray Rooms -and/or- Areas

Table 3 Hard Non-Porous Surface Materials

304 Stainless steel
316 Stainless steel
440 C Stainless steel
ABS plastic
Aluminum
Butyl
Ceramic AI203
Ceramic magnet
Chemraz
CPVC
EPDM
FKM (fluoroelastomers)
Fluorosillicone
Glass
Hastelloy-C
HDPE
NORYL
Norprene
PCTFE
PEEK

Polybutylene Terephthalthe(PBT)
Polyethylene Terephthalthe(PET)
Perfluoroalkoxy alkanes(PFA)
Polycarbonate
Polypropylene
Polyurethane, Millable
PP-363 (plasticized vinyl) 2
PTFE
PVC
PVDF
Sapphire Glass
Santoprene
Silicone
Titanium3
TPE (thermosplastic elastomers)
Tritan Copolyester
Tygon
Vamac
Viton A2

Not Recommended For Use With
-or- Avoid Contact With:

Brass
Clothing
Copper
Galvanized steel
Painted wood
Paper surfaces
Porous surfaces
Porous painted surfaces
Silver

User Manual

AURA^{TM} Automated Disinfection System

AURA Automated Disinfection System

For Institutional Use Only - Not for Food Contact or Household Use

AURA Automated Disinfection System is for use only with the AURA-D™ Cartridge.

AURA Automated Disinfection System is intended to disinfect hard nonporous surfaces.

Read directions for use and precautions on the AURA-D Cartridge label.

Formatting notes:

 Bold, italicized text is information for the reader and is not part of the labeling.

 Bracketed information is optional text.

 The word "and" may be substituted with "&". Plural words may be used in their singular form or singular words may be used in their plural form unless otherwise specified in 40 CFR.

 All directions may be written in numbered form or in paragraph form.

 All use surfaces and/or use locations on the labeling may be listed in conjunction with an image of the use surface and/or use location.

 Highlighted text is new. Strike-through text means remove

Sterifre Medical, Inc.
4020 Lake Washington Boulevard N.E.
Suite 300
Kirkland, WA 98033
1-800-____ - _____ ***Insert Sterifre toll free number***

EPA Establishment No.: _____ ***Establishment number will be added upon approval***

Table of Contents

1. Introduction

This manual describes the safety precautions, functions, features and methods of use and care for the AURA Automated Disinfection System to be referred to as the AURA System herein. The AURA System is for use only with the AURA-D Cartridge.

Review this manual entirely before using the system.

Note: For ordering AURA-D Cartridges, please contact your Sterifre Representative.

The graphics, figures, and images used in this user manual are examples only. The actual display and design of these may be slightly different on your system.

Only trained personnel who have reviewed the manual in its entirety should operate the AURA System.

Important notes, warnings, or cautions are italicized and segregated from the body of the text. If the warning or caution is safety-related or could result in significant damage if it is not heeded, an additional warning/caution symbol will be displayed in the margin to further alert the reader.

2. Use of Symbols

Safety Notice	Meaning
	A yellow **CAUTION** symbol is used to identify conditions or actions for which a potential hazard may exist. These conditions or actions may cause minor personal injury or property damage if the instructions are not followed

3. **Indications for Use**

The AURA Automated Disinfection System is intended to disinfect hard, nonporous surfaces in a variety of environments. Refer to Table 1 for Exterior Use Surfaces [of] Hard Non-Porous Surfaces and Table 2 for Use Locations where this product can be utilized.

Table 3 Hard Non-Porous Surface Materials can be used as a reference for materials that are compatible with the AURA System.

⚠️ *CAUTION: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.*

⚠️ *CAUTION: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.*

⚠️ *CAUTION: The AURA System is not intended for disinfection of the inside space of tubular structures.*

⚠️ *CAUTION: Interior surfaces are not disinfected by the AURA™ Automated Disinfection System with the AURA-D™ Cartridge.*

Table 1 Exterior Use Surfaces
[of]
Hard Non-Porous Surfaces

Anesthesia equipment
Animal equipment
Apnea monitor/sensor pad
Athletic equipment
Automatic feeders
Badges
Bed-call button
Bed-position control
Bilirubinometer
Bladder scanner
Blood analyzer, point of care [(iStat)])
Blood glucose monitors
B[lood] p[ressure] monitors
Bottle warmer
Cast saw-motorized handpiece
Cell[ular] -or- wireless -or- mobile -or- digital phone
Charging station[s]
Chart cover
Clippers [(handpiece not head)]
[Computer] monitors
[Computer] mouse
[Computer] peripherals
[Computer] [Portable] keyboards
[Computer] screens
C[omputerized] T[omography] equipment
Cord[s]
Dental unit instrument trays
Diagnostic equipment
Dictating equipment [surfaces]
Docking stations
Doppler probes
Doppler transducers
Electrocardiogram cables
Electric razor body

External surfaces of [medical] equipment -or- [medical] equipment surfaces
External surfaces of pneumatic tubes
External surfaces of [respiratory] equipment -or- respiratory equipment surfaces
External surfaces of ultrasound transducers and probes
External surfaces of [veterinary] equipment -or- veterinary equipment surfaces
Fiberglass [sealed] surfaces
Glucometers
Hard, nonporous hospital - and/or- medical -and/or- dental -and/or- veterinary surfaces
Hard non-porous mouse pads
Headsets
High touch surfaces
IV Pumps/poles/warmers
Key[s]
Keyboards
Laminated surfaces
Lamps
Laptops
Leads
Light Laryngoscope handle
Light lens covers
Loupes
Mammography equipment
Mammography paddles
Mobile devices
Mobile electronic equipment
MRI -or- Magnetic Resonance Imaging equipment
Nurse-call devices -and/or- buttons -and/or- cords

Ophthalmoscope
Orthopedic & PT/OT equipment
Otoscope handle
Oximeter probes
Paddles
Pagers
Patient monitoring equipment
Patient phone
Patient support equipment
Pens
Phlebotomy trays
Physical therapy [(PT)] equipment [surfaces]
Plastic surfaces
Pulse oximeters
Reflex hammer
Rehab[ilitation] equipment
Remote controls
Resuscitation cart-defib[rillator] paddles
Scales
Scales [(diaper/other)]
Stainless steel surfaces
Staplers
Stethoscopes
Syringe pump
Tablet PCs
Telecommunication equipment [surfaces]
[Tele]phones
Thermometer-temporal
Tourniquet
Transducers
Toys (hard non-porous surfaces)
[TV] remote [control]s
Ultrasound transducers [and probes] [(external)]

Sterifre
MEDICAL

Table 2 Use Locations

Acute Care Facilities
Airports [Clinic]
Ambulances -or- [Emergency Medical] Transport Vehicles
Ambulatory Surgical Centers [(ASC)]
Amusement Parks [Clinic]
Animal Hospitals
Animal housing facilities
Animal Life Science Laboratories
[Animal -and/or- Pet] Grooming Facilities
Anesthesia Rooms or Areas
[Assisted Living -and/or- Full Care] Nursing
Beauty Salons -or- Shops
Blood Banks
[Blood -and/or- Plasma -and/or- Semen -and/or- Milk -and/or- Apheresis] Donation Centers
CAT Lab[oratories]
Central Service Areas
Central Supply Rooms -or- Areas
Colleges
Correctional Facilities
C[ritical] C[are] U[nits]
Cruise Ships
Day Care [Centers]
Dental Clinics
Dental Operatories
Dental -or- Dentist's Offices
Dialysis Clinics -and/or- Facilities
Doctors' Offices
Dormitories
E[mergency] R[oom]s
Emergency Vehicles
Equine farms
Exam[ination] Rooms
[Eye] Surgical Centers
Farms/Factories
Funeral Homes -or- Mortuaries
Gym(nasiums)
Health Care Settings -or- Facilities
Health Club[s] Facilities

Home Health Care Facilities
Hospices
Hospitals
Hotels
Industrial Facilities
Intensive Care Units -or- ICU [areas]
Isolation Areas
Kennels
Labs -or- Laboratory -or- Laboratories
Laundromats
Laundry Rooms
Livestock -and/or- Swine -and/or- Poultry Facilities
Locker rooms
Long Term Care Facilities
Manufacturing plants -or- facilities
[Massage -and/or- Facial -and/or- Hair -and/or- Nail] Salons -and/or- Spas
[Medical] Clinics
Medical Facilities
Medical -or- Physician's -or- Doctor's Offices
Military Installations
Motels
Newborn -or- Neonatal [Nurseries -and/or- Intensive Care] Units [NICU]
Nurseries
Nursing -or- Nurses' Stations
Ophthalmic Offices -and/or- Clinics
Orthopedics Offices -and/or- Clinics
Out-Patient Clinics
Out-Patient Surgical Centers [(OPSC) -and/or- Clinics -and/or- Facilities]
Patient [Care] Areas
Patient Restrooms
Patient Rooms
[Pediatric] Exam[ination] Rooms -or- Areas
Pediatric Intensive Care Units [PICU]

Pet Areas
Pet Shops -or- Stores
Pharmacies
Physical Therapy Rooms -and/or- Areas
Physicians' Offices
[Police -and/or- Fire] Facilities
Psychiatric Facilities
Public Areas
Radiology -or- X-ray Rooms -or- Areas
Reception Areas
Recovery Rooms
Recreational centers -or- facilities
Rehabilitation Centers
Respiratory Therapy Rooms -or- Areas
Restrooms
Restroom[s] [Areas]
Schools
Shelters
Shower Rooms -or- Areas
Storage Rooms -or- Areas
Surgery Rooms -or- O[perating] R[oom]s
Tattoo Parlors
Trains
Transportation Terminals
Transport Vehicles
Universities
Veterinary -and/or- Animal Hospitals
Veterinary Clinics -and/or- Facilities
Veterinary Exam[ination] Rooms
Veterinary Offices -and/or- Waiting Rooms
Veterinary O[perating] R[oom]s
Veterinary X-ray Rooms
Waiting Rooms -and/or- Areas
Wellness Centers
Work Stations
X-Ray Rooms -and/or- Areas

Table 3 Hard Non-Porous Surface Materials

304 Stainless steel	Polybutylene Terephthalthe(PBT)	Not Recommended For Use With
316 Stainless steel	Polyethylene Terephthalthe(PET)	-or- Avoid Contact With:
440 C Stainless steel	Perfluoroalkoxy alkanes(PFA)	Brass
ABS plastic	Polycarbonate	Clothing
Aluminum	Polypropylene	Copper
Butyl	Polyurethane, Millable	Galvanized steel
Ceramic Al203	PP-363 (plasticized vinyl) 2	Painted wood
Ceramic magnet	PTFE	Paper surfaces
Chemraz	PVC	Porous surfaces
CPVC	PVDF	Porous painted surfaces
EPDM	Sapphire Glass	Silver
FKM (fluoroelastomers)	Santoprene	
Fluorosillicone	Silicone	
Glass	Titanium3	
Hastelloy-C	TPE (thermosplastic elastomers)	
HDPE	Tritan Copolyester	
NORYL	Tygon	
Norprene	Vamac	
PCTFE	Viton A2	
PEEK		

4. System Description

The AURA system is a fully automated disinfection system that utilizes 50% hydrogen peroxide as the active ingredient. The 50% hydrogen peroxide is packaged in a custom cartridge as the AURA-D Cartridge. The 50% hydrogen peroxide contacts the surfaces of the items in the chamber to inactivate the pathogens during the disinfection process. The system also produces ozone as part of the process. The air that exits the chamber is exhausted through a neutralizing filter that ensures only clean air leaves the system and is below OSHA permissible exposure limits.

The AURA system is a fully integrated system which consists of hardware, electronics, and software to operate and monitor the system. The system has a chamber with adjustable shelves on which items for disinfection are placed. The AURA system only requires a standard AC 120V power outlet.

Figure 1: AURA System general features

5. **System Specifications**

Those marked with an asterisk (*) will be updated to reflect final device specifications.

Chamber Volume: 14 liters

Chamber Inner dimensions: 31cm (12.2in) W x 23cm (9.1in) H x 20cm (7.9in) D

*System Outer Dimensions: 44.2cm (17.4in) W x 47.0cm (18.5in) H x 34.1cm (13.6in) D

*Weight: ~10 kg (~20lb)

Rated Mains Input Voltage: 120V

*Power Consumption: ~100W

Process Time: 10 mins

Installation: Countertop (Wall mount optional)

Environmental Operating Conditions	Minimum	Maximum
Ambient Temperature	20°C	27°C
Ambient Relative Humidity	35%	60%

6. **Display Screen Functions/Messages**

Screen Message	Definition
AURA Ready	System is ready to use for disinfecting items
Disinfecting	System is currently disinfecting items within the chamber
Stop	Stops the disinfection cycle when in progress
Settings Menu	Menu of options to configure or obtain additional information about your AURA System
Information	Provides information about the system, such as, device ID, manufacture date, firmware version, filter expiration, current cartridge age, system active for days, cartridges replaced, filters replaced, cycles started, cycles completed, number of startups, etc.
Brightness	Increases or decreases screen brightness as desired
Service	Provides a menu to install/replace cartridge and filters
Cartridge	Provides access to the cartridge door
Back	Takes user back to Settings Menu

7. AURA System Initial Installation

1) Plug the AURA System into a standard 120V outlet.

2) Turn system power on.

3) Wait for the SYSTEM CHECK to complete.

4) Once system check is complete, the screen will display INSTALL CARTRIDGE.

8. AURA-D Cartridge Initial Installation

1) Select SETTINGS.

2) Select SERVICE.

3) Select CARTRIDGE.
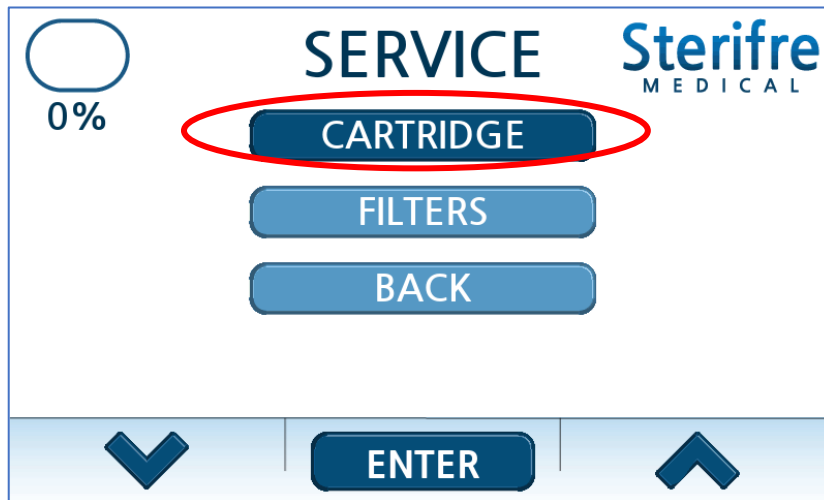
4) Chamber door will unlock.

5) Open the cartridge compartment door and insert cartridge as shown on the instructions affixed to the compartment door.

6) Close the compartment door and then the chamber door.

7) The system will initialize and when complete, the display screen will show AURA READY.

8) The AURA-D Cartridge level icon located on the top left of the screen will show 100%.

9. Replacing the Cartridge

1) When the cartridge is empty, the display will show REPLACE CARTRIDGE.

2) Follow steps in Section 8.

3) The system will initialize and when complete the display screen will show AURA READY.

10. Replacing Filters

1) If filters need to be replaced, the display will show REPLACE FILTERS. Select SETTINGS, then and select FILTERS.
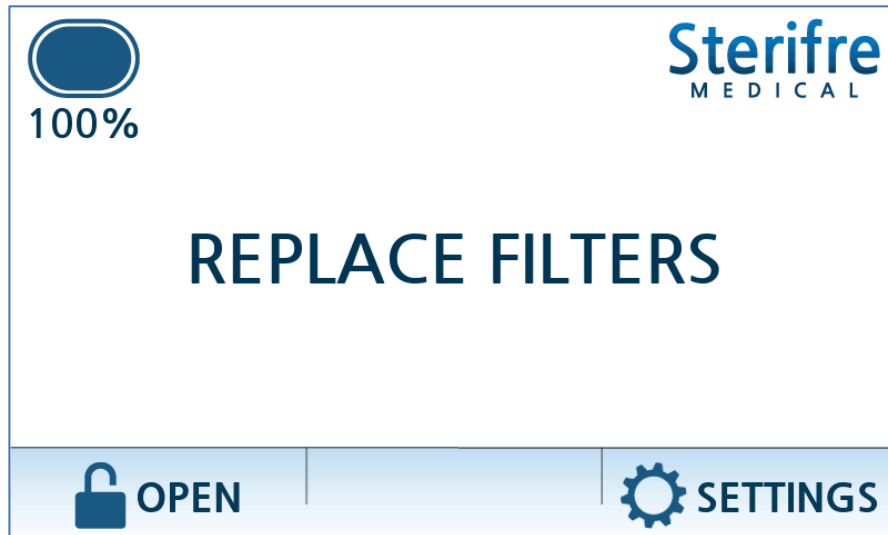
2) Follow the display instructions to replace filters.

11. Preparation of Items to be Disinfected

NOTE:

- Items to be disinfected are of hard non-porous compositions/surfaces.
- They may be varied in form and/or function.
- Pre-clean visibly soiled items prior to placing them into the AURA System.

12. System Operating Instructions

1) Ensure the display says READY and select OPEN to unlock the chamber door.

CAUTION: If it does not say READY, follow the screen message. If the READY message still does not appear, contact your Sterifre Representative.

2) Open the chamber door and place items on the shelves. Screen will display CHAMBER DOOR OPEN.

3) Multiple items may be disinfected at the same time.

CAUTION: Place items so they do not contact each other and no portion of an item overlaps with itself. Items should not touch the disinfection chamber walls.

4) Follow directions below for the proper placement of items in the AURA System.
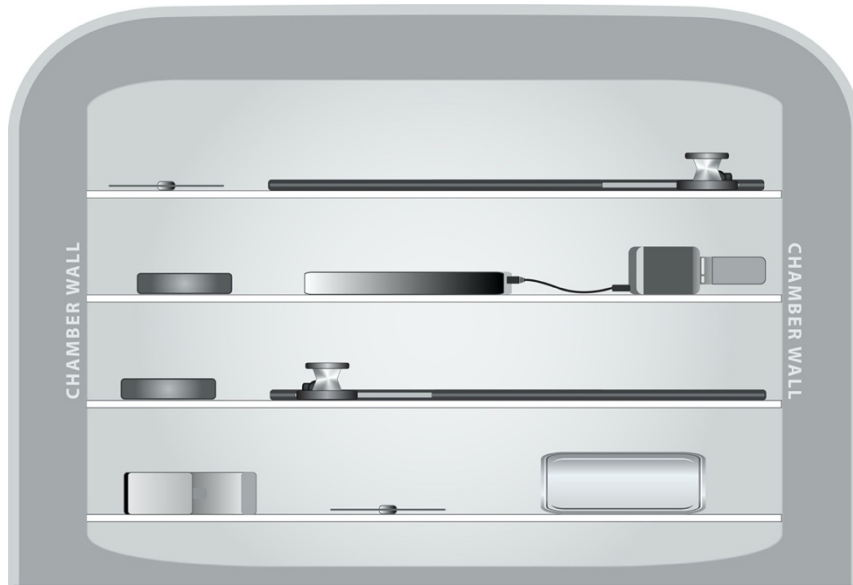
CORRECT LOADING – FRONT VIEW

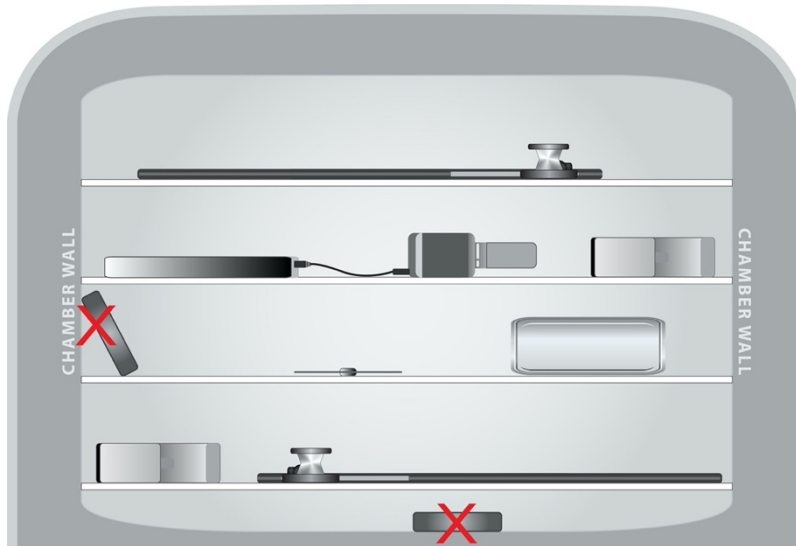*Space items so they do NOT contact each other*
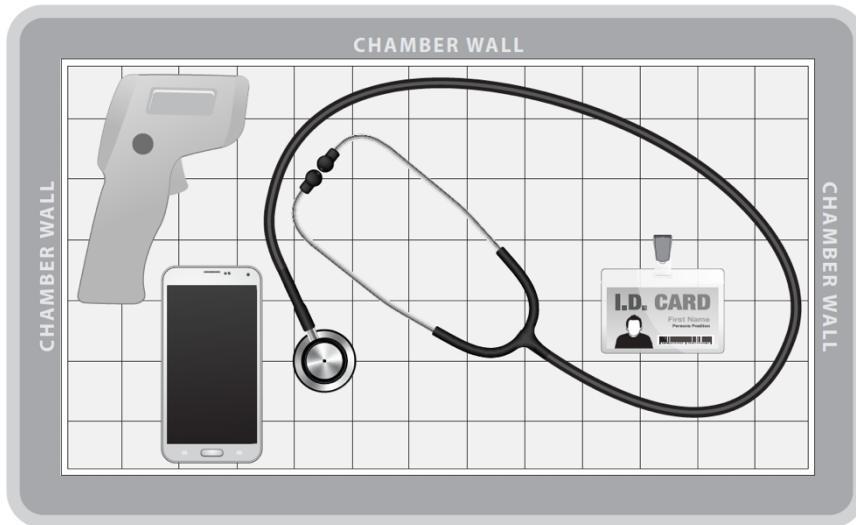
CORRECT LOADING – TOP VIEW

Space items so they do NOT contact each other
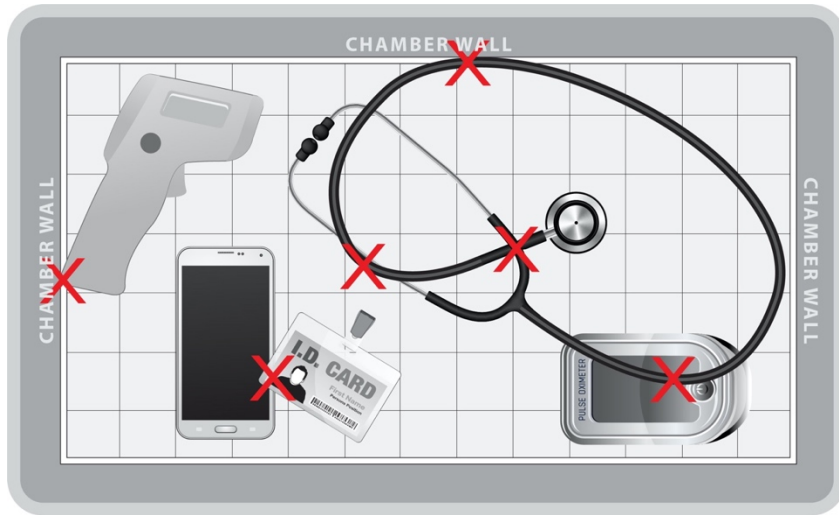
INCORRECT LOADING – TOP VIEW

Items must not overlap and/or touch chamber walls

INCORRECT LOADING – FRONT VIEW

Do NOT place items beneath bottom shelf

Do NOT place items touching the chamber walls

CORRECT LOADING OF LARGER ITEMS

Remove shelves for larger item placement

5) Close chamber door.

CAUTION: If door is not closed, system will not initiate next steps. First, verify there is no obstruction. If chamber door still cannot be closed properly, contact your Sterifre representative.

6) Once door is locked, the screen will display AURA READY.

7) Select START then the display will show READY TO START?
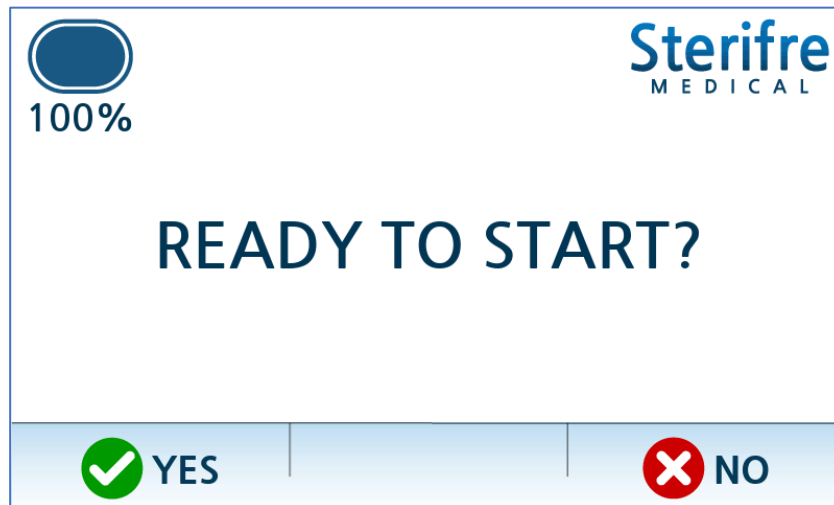
8) Select YES to initiate the system cycle.

9) Screen will display DISINFECTING and counts down the remaining processing time. The disinfection processing time is 10 mins.

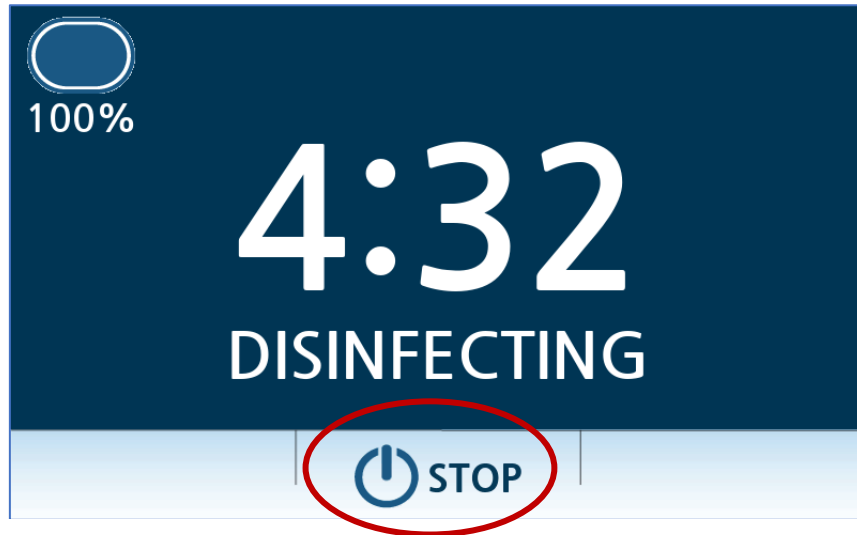10) The display screen background color changes to dark blue.

11) If cycle needs to be stopped, follow steps 15.a-f.

12) After the cycle is complete, the display screen background color changes to green. Screen will display DISINFECTION COMPLETE. Select OPEN to unlock the chamber door.
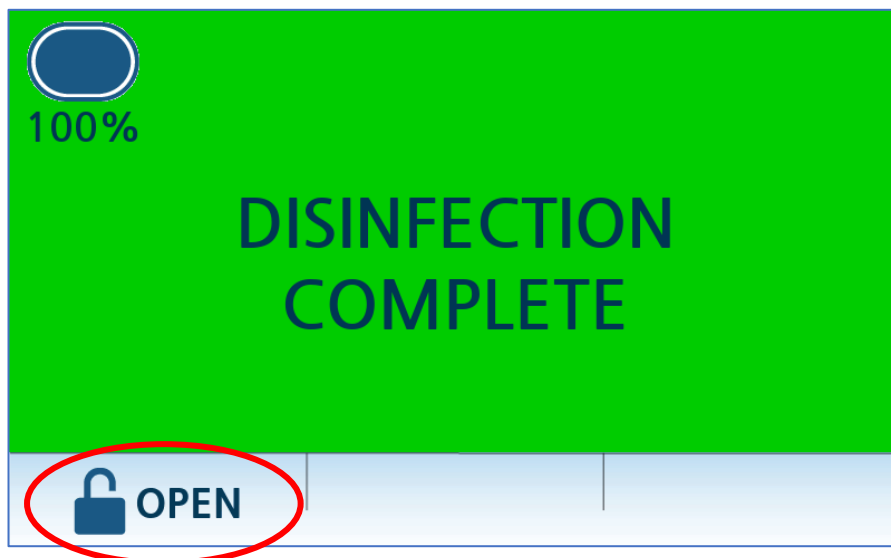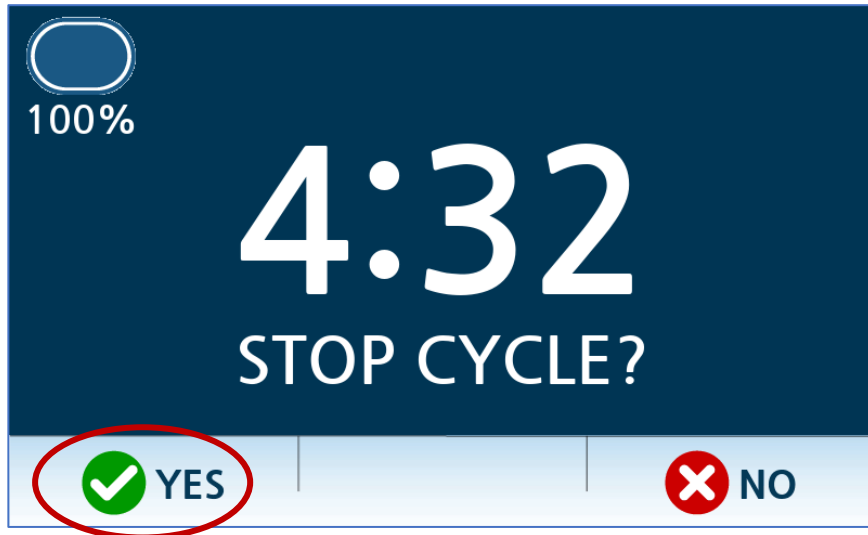

13) Open chamber door and remove items from chamber.

14) The items are disinfected and ready to use.
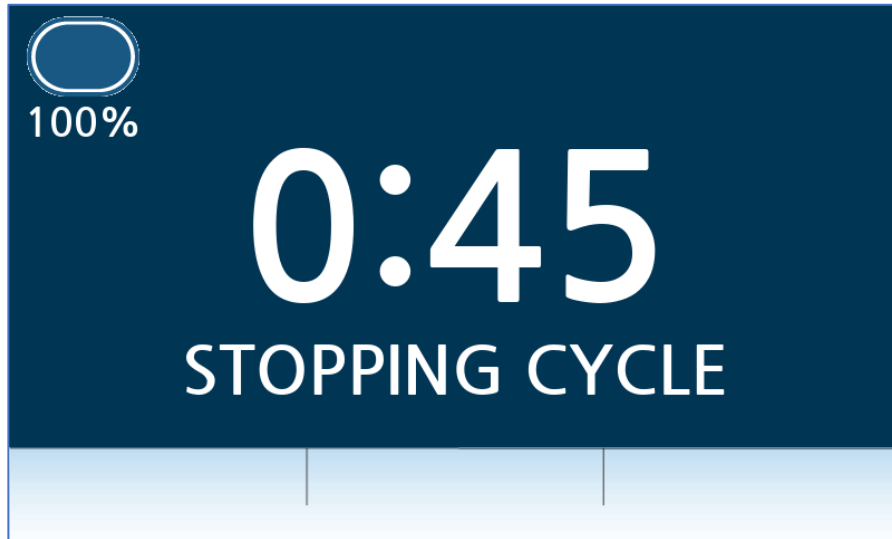
15) If cycle needs to be stopped:

    a. Select STOP.

    b. Display screen will show STOP CYCLE, then confirm by selecting YES.

c. System will display STOPPING CYCLE and countdown the remaining
    time.

d. The system will then display INTERRUPTED, ITEMS NOT DISINFECTED.
    The display screen background color changes red.

e. Select OPEN to unlock chamber door.

f. After the chamber door is closed, the display screen will show AURA
    READY.

13. **System Error**

1) If an error message appears on the display screen, please contact your Sterifre Representative for assistance.

(Example error message screen)

14. **System Error Codes and Resolutions**

Final error codes will be listed in the table below

CODE	DESCRIPTION	RESOLUTION
S01	System check failed	Contact Sterifre Representative
S02	Ozone (O3) generator not present	Contact Sterifre Representative
S03	Nebulizer not present	Contact Sterifre Representative
D01	Nebulizer error	Contact Sterifre Representative
D02	O3 generator error	Contact Sterifre Representative
D03	H2O2 fluid delivery system error	Contact Sterifre Representative
D04	Pressure falls outside limits	Contact Sterifre Representative
C01	Circulating fan over-temp	Contact Sterifre Representative
C02	O3 generator over-temp	Contact Sterifre Representative
M01	External O3 sensor over limit	Contact Sterifre Representative

15. System Cleaning

The AURA system is a disinfection system and therefore the interior surfaces and shelves are disinfected with each use. If the shelves, or interior or exterior system surfaces are visibly soiled, clean with a mild, soapy solution or an all-purpose cleaner.

16. System Servicing

Contact your Sterifre Representative for system repair and maintenance in accordance with your facility's policy.

END OF DOCUMENT