



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 25, 2022

Matthew Schneider
Authorized Representative for
Sterifre Medical, Inc.
4020 Lake Washington Blvd. N.E., Suite 300
Kirkland, WA 98033

Subject: PRIA Label Amendment – Adding label claims for 7 pathogens with a small number of changes in the optional label statements.
Product Name: Aura-D™ Cartridge
EPA Registration Number: 93728-2
Received Date: 12/3/2021
Action Case Number: 00337043

Dear Matthew Schneider:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

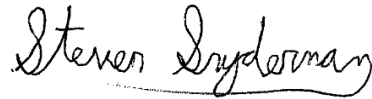
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

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Action Case No. 00337043

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Aidan Fife by phone at 202-566-0822, or via email at fife.aidan@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510M)
Office of Pesticide Programs

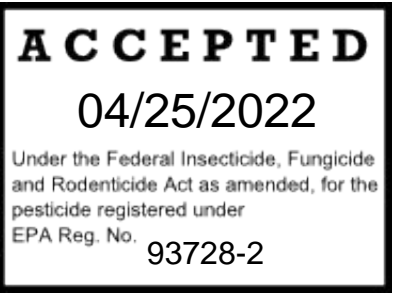
Enclosure: Stamped Final Label

Label Identification

AURA-D™ Cartridge

EPA Reg. No. 93728-2

April 21, 2022



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 production 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™ 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/PELIGRO:

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

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

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

Active Ingredient:

Hydrogen Peroxide 50.0%

Other Ingredients:..... 50.0%

Total: 100.0%

[Net] [W[EIGHT]]_____

Package will bear the actual net contents in milliliters and ounces

[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
<i>Staphylococcus aureus</i>	[ATCC 6538]
<i>Pseudomonas aeruginosa</i>	[ATCC 15442]
<i>Methicillin-resistant Staphylococcus aureus [(MRSA)]</i>	[ATCC 33592]
<i>Vancomycin-resistant Enterococcus faecalis [(VRE)]</i>	[ATCC 51575]
Virus Enveloped[◇]	ATCC and/or Strain
Hepatitis B Virus (tested as Duck Hepatitis B Virus)	[Strain 9/1/15]
Hepatitis C Virus (tested as Bovine Viral Diarrhea Virus)	[ATCC VR-1422]
Human Coronavirus	[Strain 229E] [ATCC VR-740]
Influenza A Virus (H1N1)	[Strain A/PR/8/34] [ATCC VR-1469]
Virus Large Non-Enveloped[◇]	ATCC and/or Strain
Adenovirus (Type 5)	[Strain Adenoid 75] [ATCC VR-5]
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*, *Methicillin-resistant Staphylococcus aureus [(MRSA)]*, *Vancomycin-resistant Enterococcus faecalis [(VRE)]*, Hepatitis B Virus, Hepatitis C Virus, Human Coronavirus, Influenza A Virus (H1N1), Adenovirus (Type 5), and Norovirus (Feline calicivirus).

[◇] When used according to disinfectant directions for use

[‡] *Methicillin-resistant Staphylococcus aureus [(MRSA)]* and *Vancomycin-resistant Enterococcus faecalis [(VRE)]*

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
- Convenient disinfecting
- Daily defense against germs[†] -and/or- pathogens on treated surfaces
- Deodorizes by disinfecting
- Disinfecting formula
- Disinfects -and/or- Kills flu virus
- Disinfects -and/or- kills germs[†]
- Disinfects odor-causing bacteria
- Effective against Multidrug Resistant Organisms [MDROs]][‡]
- Effective against -and/or- Kills Influenza A (H1N1) [Flu Virus]
- Effective against -or- Kills **insert emerging viral pathogens**
- Effective against tough non-enveloped viruses of concern, including Norovirus and Adenovirus
- Hard, non-porous multi surface disinfectant
- Helps reduce cross contamination on hard, nonporous surfaces
- Hospital disinfectant
- Hydrogen peroxide works by oxidizing microorganisms for disinfection
- Kills Germs[†] -and/or- Bacteria -and/or- Viruses[◇]
- Kills -and/or- disinfects -and/or- destroys -and/or- attacks bacteria -and/or- germs[†] -and/or- viruses[◇] on **insert use surface(s) from Table 1**
- Kills - -or- disinfects -or-destroys -or- attacks bacteria[:.] [in **insert use location(s) from Table 2**]
- Kills -or- disinfects -or-destroys -or- attacks viruses[◇] [[:.] [in **insert use location(s) from Table 2**]
- Kills bacteria -and/or- germs[†] -and/or 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 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
- Cold plasma technology[¶]
- 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* on surfaces
- Easy* to use
- Effective [disinfection -or- disinfectant] [formula]
- 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- non-critical clinical equipment
- For use in **insert use location(s) from Table 2**
- For use on high-touch hard non-porous surfaces
- 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
- Labor saving no-rinse formula
- [Leaves] no residue
- Lint free
- 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 wasted wipes
- Non-abrasive
- Non-[chlorine] bleach
- Non-flammable
- [Odor and exposure free] disinfection
- Patented technology
- Portable size
- Prevents formulation errors
- Reduce wipe waste
- Replace[s] up to 22 canisters of wipes
- Sealed and non-refillable cartridge
- [The product is] [always] ready to use when used with the AURA Automated Disinfection System
- [Touch free] disinfection
- Versatile
- [Wipe free] disinfection

[¶] This claim describes a key component of the AURA System, a cold plasma generator that produces ozone. Ozone is used in the system to pre-condition in the beginning of the cycle, then decompose the residual hydrogen peroxide at the end of the cycle.

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

Anesthesia equipment	External surfaces of [medical] equipment -or- [medical] equipment surfaces	Nurse-call devices -and/or- buttons -and/or- cords
Animal equipment	External surfaces of pneumatic tubes	Ophthalmoscope
Apnea monitor/sensor pad	External surfaces of [respiratory] equipment -or- respiratory equipment surfaces	Orthopedic & PT/OT equipment
Athletic equipment	External surfaces of ultrasound transducers and probes	Otoscope handle
Automatic feeders	External surfaces of [veterinary] equipment -or- veterinary equipment surfaces	Oximeter probes
Badges	Fiberglass [sealed] surfaces	Paddles
Bed-call button	Glucometers	Pagers
Bed-position control	Hard, nonporous hospital -and/or- medical -and/or- dental -and/or- veterinary surfaces	Patient monitoring equipment
Bilirubinometer	Hard non-porous mouse pads	Patient phone
Bladder scanner	Headsets	Patient support equipment
Blood analyzer, point of care [(iStat)]	High touch surfaces	Pens
Blood glucose monitors	IV Pumps/poles/warmers	Phlebotomy trays
B[lood] p[ressure] monitors	Key[s]	Physical therapy [(PT)] equipment [surfaces]
Bottle warmer	Keyboards	Plastic surfaces
Cast saw-motorized handpiece	Laminated surfaces	Pulse oximeters
Cell[ular] -or- wireless -or- mobile -or- digital phone	Lamps	Reflex hammer
Charging station[s]	Laptops	Rehab[ilitation] equipment
Chart cover	Leads	Remote controls
Clippers [(handpiece not head)]	Light Laryngoscope handle	Resuscitation cart-defib[rillator] paddles
[Computer] monitors	Light lens covers	Scales
[Computer] mouse	Loupes	Scales [(diaper/other)]
[Computer] peripherals	Mammography equipment	Stainless steel surfaces
[Computer] [Portable] keyboards	Mammography paddles	Staplers
[Computer] screens	Mobile devices	Stethoscopes
C[omputerized] T[omography] equipment	Mobile electronic equipment	Syringe pump
Cord[s]	MRI -or- Magnetic Resonance Imaging equipment	Tablet PCs
Dental unit instrument trays		Telecommunication equipment [surfaces]
Diagnostic equipment		[Tele]phones
Dictating equipment [surfaces]		Thermometer-temporal
Docking stations		Transducers
Doppler probes		Toys (hard non-porous surfaces)
Doppler transducers		[TV] remote [control]s
Electrocardiogram cables		Ultrasound transducers [and probes] [(external)]
Electric razor body		

Table 2 Use Locations

Acute Care Facilities	Gym(nasiums)	Patient Rooms
Airports [Clinic]	Health Care Settings -or- Facilities	[Pediatric] Exam[ination] Rooms -or- Areas
Ambulances -or- [Emergency Medical] Transport Vehicles	Health Club[s] Facilities	Pediatric Intensive Care Units [PICU]
Ambulatory Surgical Centers [(ASC)]	Home Health Care Facilities	Pet Areas
Amusement Parks [Clinic]	Hospices	Pet Shops -or- Stores
Animal Hospitals	Hospitals	Pharmacies
Animal housing facilities	Hotels	Physical Therapy Rooms -and/or- Areas
Animal Life Science Laboratories	Industrial Facilities	Physicians' Offices
[Animal -and/or- Pet] Grooming Facilities	Intensive Care Units -or- ICU [areas]	[Police -and/or- Fire] Facilities
Anesthesia Rooms or Areas	Isolation Areas	Psychiatric Facilities
[Assisted Living -and/or- Full Care] Nursing	Kennels	Public Areas
Beauty Salons -or- Shops	Labs -or- Laboratory -or- Laboratories	Radiology -or- X-ray Rooms -or- Areas
Blood Banks	Laundromats	Reception Areas
[Blood -and/or- Plasma -and/or- Semen -and/or- Milk -and/or- Apheresis] Donation Centers	Laundry Rooms	Recovery Rooms
CAT Lab[oratories]	Livestock -and/or- Swine -and/or- Poultry Facilities	Recreational centers -or- facilities
Central Service Areas	Locker rooms	Rehabilitation Centers
Central Supply Rooms -or- Areas	Long Term Care Facilities	Respiratory Therapy Rooms -or- Areas
Colleges	Manufacturing plants -or- facilities	Restrooms
Correctional Facilities	[Massage -and/or- Facial -and/or-Hair -and/or- Nail] Salons -and/or- Spas	Restroom[s] [Areas]
C[ritical] C[are] U[nits]	[Medical] Clinics	Schools
Cruise Ships	Medical Facilities	Shelters
Day Care [Centers]	Medical -or- Physician's -or- Doctor's Offices	Shower Rooms -or- Areas
Dental Clinics	Military Installations	Storage Rooms -or- Areas
Dental Operatories	Motels	Surgery Rooms -or- O[perating] R[oom]s
Dental -or- Dentist's Offices	Newborn -or- Neonatal [Nurseries - and/or- Intensive Care] Units [NICU]	Tattoo Parlors
Dialysis Clinics -and/or- Facilities	Nurseries	Trains
Doctors' Offices	Nursing -or- Nurses' Stations	Transportation Terminals
Dormitories	Ophthalmic Offices -and/or- Clinics	Transport Vehicles
E[mergency] R[oom]s	Orthopedics Offices -and/or- Clinics	Universities
Emergency Vehicles	Out-Patient Clinics	Veterinary -and/or- Animal Hospitals
Equine farms	Out-Patient Surgical Centers [(OPSC) -and/or- Clinics -and/or- Facilities]	Veterinary Clinics -and/or- Facilities
Exam[ination] Rooms	Patient [Care] Areas	Veterinary Exam[ination] Rooms
[Eye] Surgical Centers	Patient Restrooms	Veterinary Offices -and/or- Waiting Rooms
Farms/Factories		Veterinary O[perating] R[oom]s
Funeral Homes -or- Mortuaries		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 Al2O3
Ceramic magnet
Chemraz
CPVC
EPDM
FKM (fluoroelastomers)
Fluorosilicone
Glass
Hastelloy-C
HDPE
NORYL
Norprene
PCTFE
PEEK

Polybutylene Terephthalate(PBT)
Polyethylene Terephthalate(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™ 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 pre-cleaned 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 issue***



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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 pre-cleaned 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	External surfaces of [medical] equipment -or- [medical] equipment surfaces	Ophthalmoscope
Animal equipment	External surfaces of pneumatic tubes	Orthopedic & PT/OT equipment
Apnea monitor/sensor pad	External surfaces of [respiratory] equipment -or- respiratory equipment surfaces	Otoscope handle
Athletic equipment	External surfaces of ultrasound transducers and probes	Oximeter probes
Automatic feeders	External surfaces of [veterinary] equipment -or- veterinary equipment surfaces	Paddles
Badges	Fiberglass [sealed] surfaces	Pagers
Bed-call button	Glucometers	Patient monitoring equipment
Bed-position control	Hard, nonporous hospital - and/or- medical -and/or- dental -and/or- veterinary surfaces	Patient phone
Bilirubinometer	Hard non-porous mouse pads	Patient support equipment
Bladder scanner	Headsets	Pens
Blood analyzer, point of care [(iStat)]	High touch surfaces	Phlebotomy trays
Blood glucose monitors	IV Pumps/poles/warmers	Physical therapy [(PT)] equipment [surfaces]
B[lood] p[ressure] monitors	Key[s]	Plastic surfaces
Bottle warmer	Keyboards	Pulse oximeters
Cast saw-motorized handpiece	Laminated surfaces	Reflex hammer
Cell[ular] -or- wireless -or- mobile -or- digital phone	Lamps	Rehab[ilitation] equipment
Charging station[s]	Laptops	Remote controls
Chart cover	Leads	Resuscitation cart-defib[rillator] paddles
Clippers [(handpiece not head)] [Computer] monitors	Light Laryngoscope handle	Scales
[Computer] mouse	Light lens covers	Scales [(diaper/other)]
[Computer] peripherals	Loupes	Stainless steel surfaces
[Computer] [Portable] keyboards	Mammography equipment	Staplers
[Computer] screens	Mammography paddles	Stethoscopes
C[omputerized] T[omography] equipment	Mobile devices	Syringe pump
Cord[s]	Mobile electronic equipment	Tablet PCs
Dental unit instrument trays	MRI -or- Magnetic Resonance Imaging equipment	Telecommunication equipment [surfaces]
Diagnostic equipment	Nurse-call devices -and/or- buttons -and/or- cords	[Tele]phones
Dictating equipment [surfaces]		Thermometer-temporal
Docking stations		Transducers
Doppler probes		Toys (hard non-porous surfaces)
Doppler transducers		[TV] remote [control]s
Electrocardiogram cables		Ultrasound transducers [and probes] [(external)]
Electric razor body		

Table 2 Use Locations

Acute Care Facilities	Home Health Care Facilities	Pet Areas
Airports [Clinic]	Hospices	Pet Shops -or- Stores
Ambulances -or- [Emergency Medical] Transport Vehicles	Hospitals	Pharmacies
Ambulatory Surgical Centers [(ASC)]	Hotels	Physical Therapy Rooms -and/or- Areas
Amusement Parks [Clinic]	Industrial Facilities	Physicians' Offices
Animal Hospitals	Intensive Care Units -or- ICU [areas]	[Police -and/or- Fire] Facilities
Animal housing facilities	Isolation Areas	Psychiatric Facilities
Animal Life Science Laboratories	Kennels	Public Areas
[Animal -and/or- Pet] Grooming Facilities	Labs -or- Laboratory -or- Laboratories	Radiology -or- X-ray Rooms -or- Areas
Anesthesia Rooms or Areas	Laundromats	Reception Areas
[Assisted Living -and/or- Full Care] Nursing	Laundry Rooms	Recovery Rooms
Beauty Salons -or- Shops	Livestock -and/or- Swine -and/or- Poultry Facilities	Recreational centers -or- facilities
Blood Banks	Locker rooms	Rehabilitation Centers
[Blood -and/or- Plasma -and/or- Semen -and/or- Milk -and/or- Apheresis] Donation Centers	Long Term Care Facilities	Respiratory Therapy Rooms -or- Areas
CAT Lab[oratories]	Manufacturing plants -or- facilities	Restrooms
Central Service Areas	[Massage -and/or- Facial -and/or- Hair -and/or- Nail] Salons -and/or- Spas	Restroom[s] [Areas]
Central Supply Rooms -or- Areas	[Medical] Clinics	Schools
Colleges	Medical Facilities	Shelters
Correctional Facilities	Medical -or- Physician's -or- Doctor's Offices	Shower Rooms -or- Areas
C[ritical] C[are] U[nits]	Military Installations	Storage Rooms -or- Areas
Cruise Ships	Motels	Surgery Rooms -or- O[perating] R[oom]s
Day Care [Centers]	Newborn -or- Neonatal [Nurseries -and/or- Intensive Care] Units [NICU]	Tattoo Parlors
Dental Clinics	Nurseries	Trains
Dental Operatories	Nursing -or- Nurses' Stations	Transportation Terminals
Dental -or- Dentist's Offices	Ophthalmic Offices -and/or- Clinics	Transport Vehicles
Dialysis Clinics -and/or- Facilities	Orthopedics Offices -and/or- Clinics	Universities
Doctors' Offices	Out-Patient Clinics	Veterinary -and/or- Animal Hospitals
Dormitories	Out-Patient Surgical Centers [(OPSC) -and/or- Clinics -and/or- Facilities]	Veterinary Clinics -and/or- Facilities
E[mergency] R[oom]s	Patient [Care] Areas	Veterinary Exam[ination] Rooms
Emergency Vehicles	Patient Restrooms	Veterinary Offices -and/or- Waiting Rooms
Equine farms	Patient Rooms	Veterinary O[perating] R[oom]s
Exam[ination] Rooms	[Pediatric] Exam[ination] Rooms -or- Areas	Veterinary X-ray Rooms
[Eye] Surgical Centers	Pediatric Intensive Care Units [PICU]	Waiting Rooms -and/or- Areas
Farms/Factories		Wellness Centers
Funeral Homes -or- Mortuaries		Work Stations
Gym(nasiums)		X-Ray Rooms -and/or- Areas
Health Care Settings -or- Facilities		
Health Club[s] Facilities		

Table 3 Hard Non-Porous Surface Materials

304 Stainless steel
 316 Stainless steel
 440 C Stainless steel
 ABS plastic
 Aluminum
 Butyl
 Ceramic Al2O3
 Ceramic magnet
 Chemraz
 CPVC
 EPDM
 FKM (fluoroelastomers)
 Fluorosilicone
 Glass
 Hastelloy-C
 HDPE
 NORYL
 Norprene
 PCTFE
 PEEK

Polybutylene Terephthalate(PBT)
 Polyethylene Terephthalate(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

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

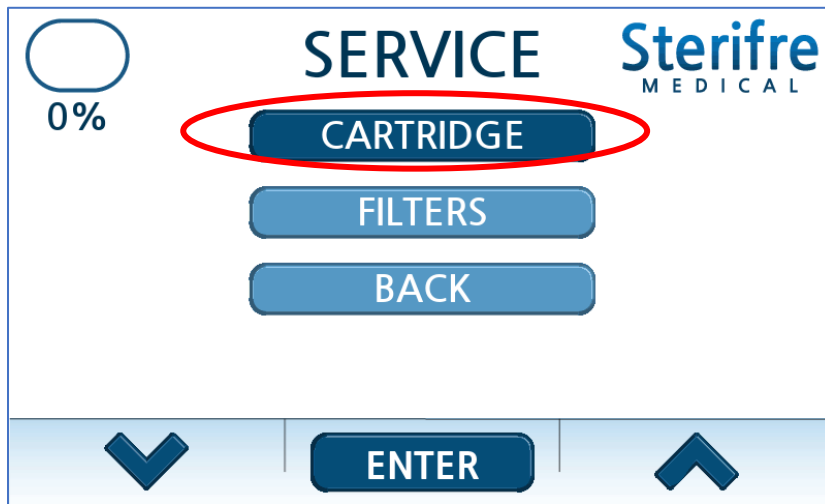
- 1) Select SETTINGS.



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

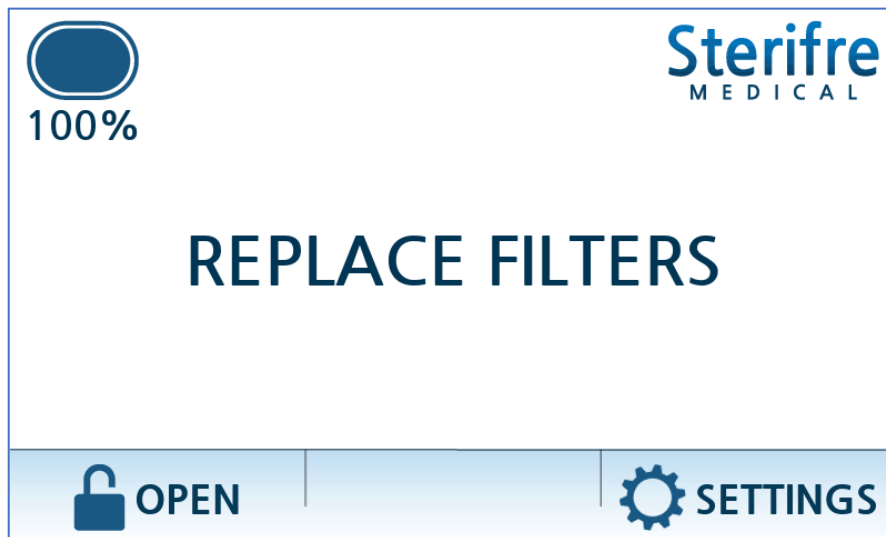
- 1) When the cartridge is empty, the display will show REPLACE CARTRIDGE.



- 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.

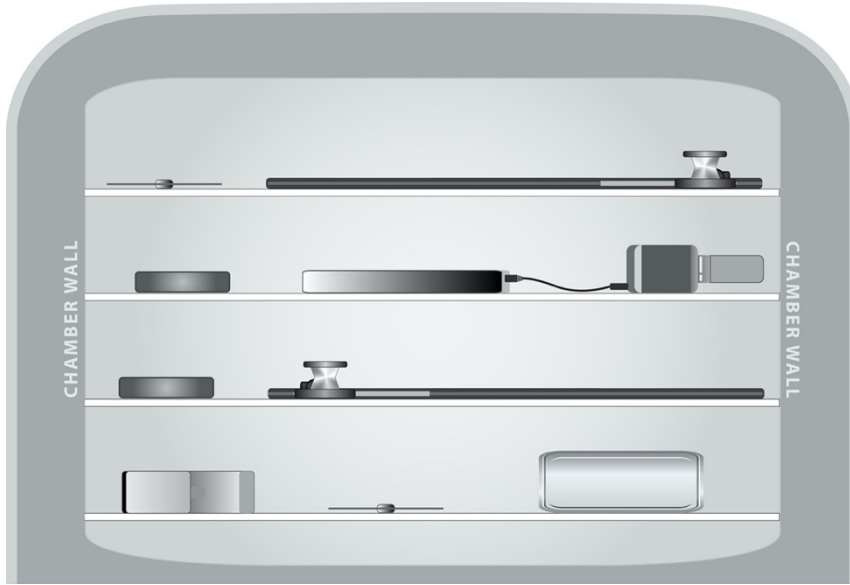


- 3) Multiple items may be disinfected at the same time.



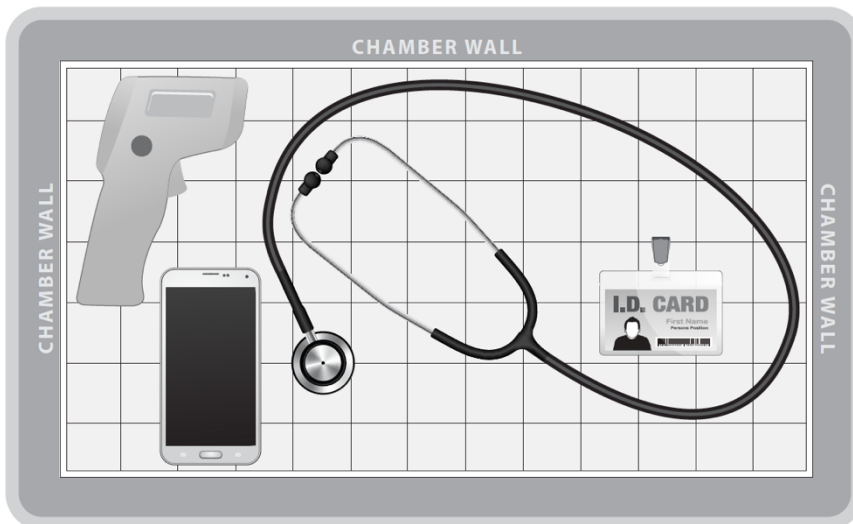
CAUTION: Place items so they do not contact each other and no portion of an item overlaps with itself. Items should not touch the disinfection chamber walls.

4) Follow directions below for the proper placement of items in the AURA System.



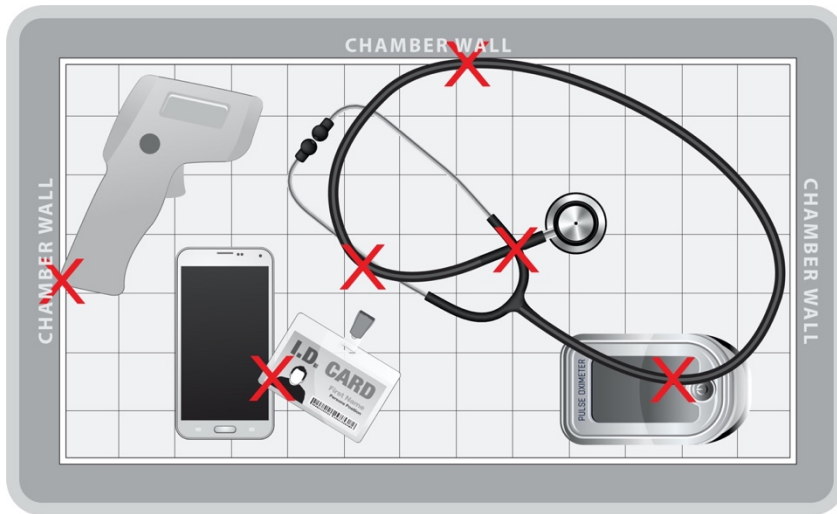
CORRECT LOADING – FRONT VIEW

Space items so they do NOT contact each other



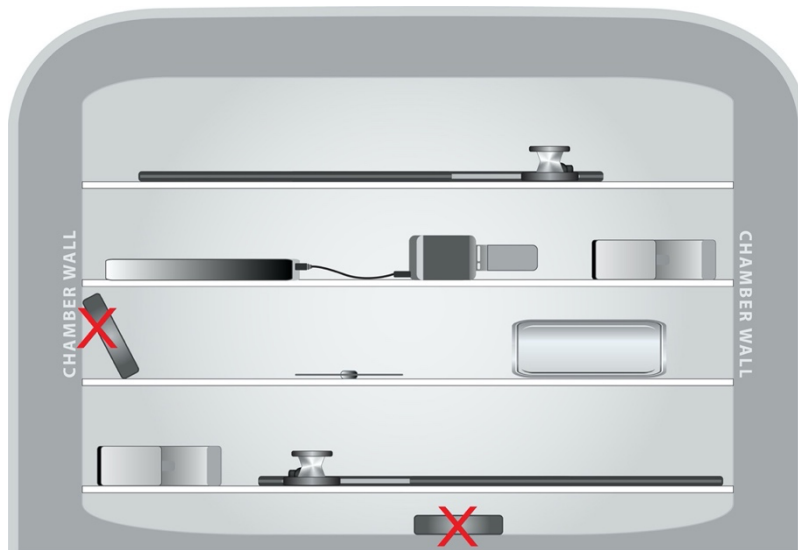
CORRECT LOADING – TOP VIEW

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.

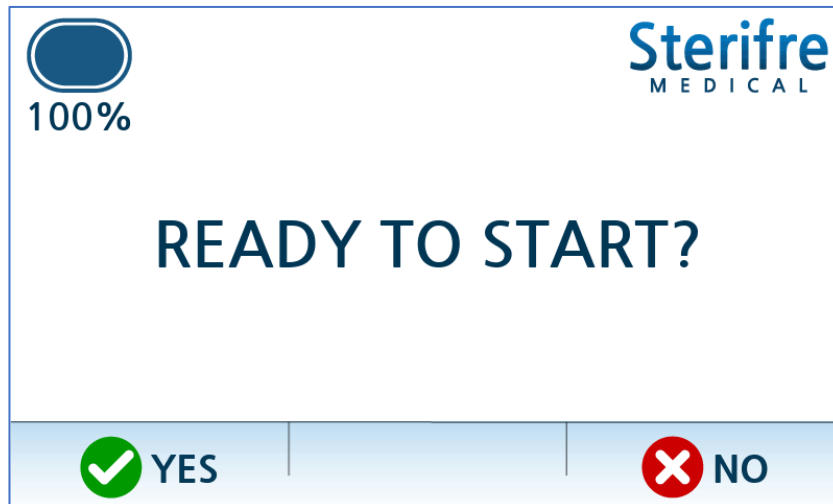


CAUTION: If door is not closed, system will not initiate next steps. First, verify there is no obstruction. If chamber door still cannot be closed properly, contact your Sterifre representative.

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



7) Select START then the display will show READY TO START?

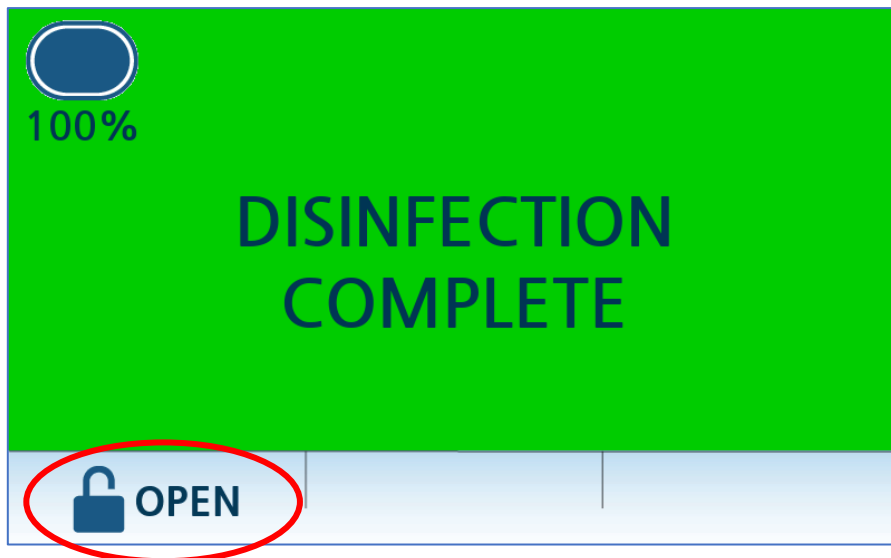


8) Select YES to initiate the system cycle.

- 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.



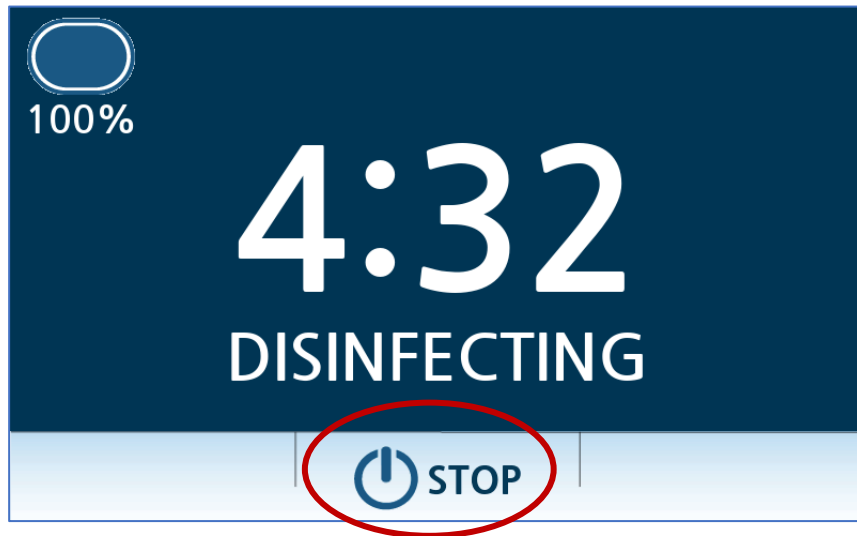
- 11) If cycle needs to be stopped, follow steps 15.a-f.
- 12) After the cycle is complete, the display screen background color changes to green. Screen will display DISINFECTION COMPLETE. Select OPEN to unlock the chamber door.



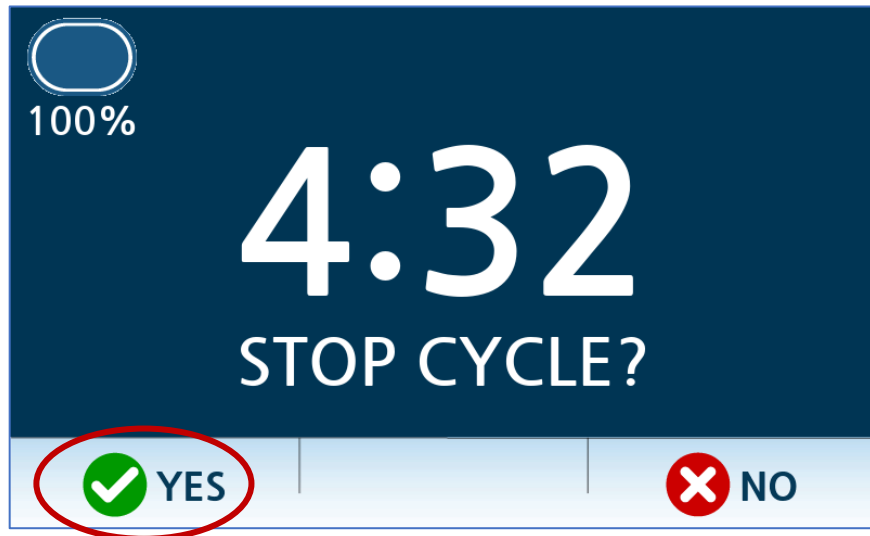
- 13) Open chamber door and remove items from chamber.
- 14) The items are disinfected and ready to use.

15) If cycle needs to be stopped:

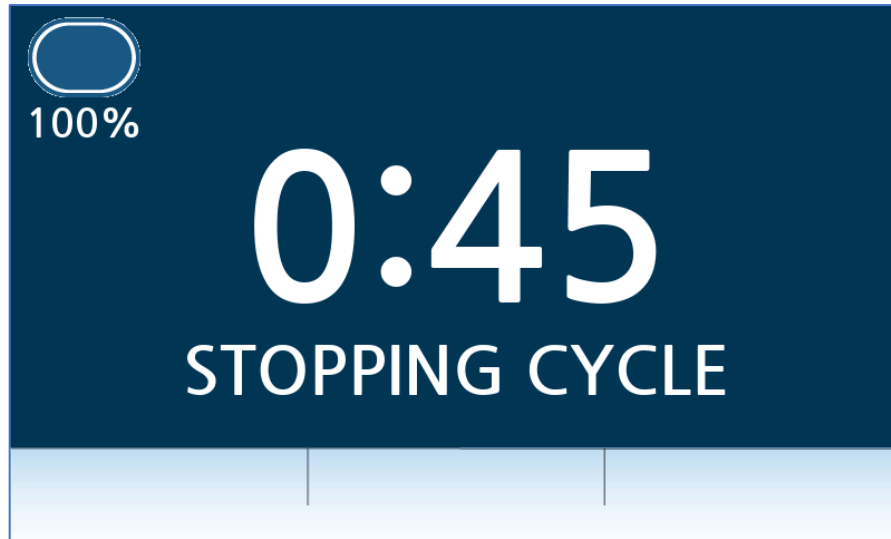
a. Select STOP.



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