RESTEC Solutions LLC

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The first automated disinfection device to registered with FDA under product code MEC to use Hydrogen Peroxide with PAA to disinfect reusable medical items.

A Validated Disinfection Process...

- Meets ANSI/AAMI/ISO 11138-11140 standards for cycle validation
- Achieves >log⁶ (99.9999%) reduction of *G-stearo* spores¹ on a biological indicators for gaseous H₂O₂ sterilizers
- Chemical indicator confirming the appropriate level of PAA is present
- Ultra-fine vapor using EPA registered, food grade H₂O₂ PAA disinfectant ²
- Vaporized H₂O₂ PAA is an effective sporicidal agent³ against C-diff and Cauris⁵

Hydrogen Peroxide with PAA is a common EPA/FDA approved cold sterilant used in healthcare and food industries.

The <u>SONOPRO</u> patented system⁶ generates ultra fine particle aerosol with gas like performance providing excellent antimicrobial efficacy and coverage.



Environment and Safety...

- <u>5 minute total cycle time</u>, items are dry and available for immediate use
- For terminal disinfection of precleaned reusable medical items
- Designed for use by trained staff in critical care hospital areas
- Excellent material compatibility, safe on elastomers, plastics, medical electronics
- Meet OSHA PEL safety threshold limits ⁴
- 1. Geobacillus stearothermophilus 12980 for gaseous hydrogen peroxide sterilization validation (SBC-327 Mesa Labs, Bozeman MT).
- 2. EPA Reg. No.10324-214 LIST-N https://www.epa.gov/sites/default/files/2020-05/documents/052120_tagalog_051520_pdf_list_n.pdf
- 3. https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19 (List N)
- Testing in chamber upon cycle complete measured below OSHA PEL TWA STEL for H₂O₂ and HC₂H₃O₂ tested with Dragger Accuro system
- 5. AJIC, Efficacy of a multi-purpose high level disinfection cabinet against Candida auris and other health care-associated pathogen, CJ Donskey et.al.
- 6. United States Patent No.: US 11,160,192 B2 Issue Date Nov. 2, 2021 ULTRASONIC STANDING WAVE NEBULIZATION SYSTEM

SONOPRO

SPECIFICATIONS

Power Input

120/240VAC 550 Watts 60/50Hz

Operating Conditions

Temp 55°-95°F - Humidity 10%-90% RH

Weight - 77lbs/34kg

External Dimensions

Height 25" X Width 20" X Depth 22"

Treatment Chamber Dimensions

Height 24" X Width 13" X Depth 18"

HMI – 4.3" Color Touch Screen

Cycle Validation Products(biological/chemical)

11138 Mesa Labs – Apex® G-Stearo

11140 Millipore Sigma - PAA 500-2000 mg/L

Configurable Shelving

304 stainless steel

Lighting – White/Blue LED cycle indication

Liquid Servicing Intervals

SONOCHEM®A – replace every 250 cycles SONOCHEM®B – replace every 25 cycles

CHEMISTRY DATA

SONOCHEM® – "food grade" PAA cold sterilant

SONOCHEM®A – Disinfectant Solution H₂O₂ PAA Stabilized, 1 year shelf life 250ml HDPE <u>round white</u> containers

SONOCHEM®B – Diluent Solution pH Buffered Diluent, 1 year shelf life 200ml PET square clear containers







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