U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

March 2020

Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. Guidance for Industry and Food and Drug Administration Staff

Contains Non-binding Recommendations
June 1, 2020 FDA submission in process. Claims ARE NOT FDA approved.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[2]

SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to significant impacts on health care systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. To respond effectively to the COVID-19 outbreak, appropriate clinical management and infection control in conjunction with implementation of community mitigation efforts are critical.

FDA believes the policy set forth in this guidance will help address these urgent public health concerns by helping to increase the availability of sterilizers, disinfectant devices, and air purifiers during this public health emergency. Increased access to these devices may facilitate rapid turnaround of sterilized or disinfected medical equipment and reduce the risk of viral exposure for patients and health care providers to SARS-CoV-2.

Scope

The enforcement policies described in this guidance apply to the following devices and their accessories during the COVID-19 public health emergency. This enforcement policy applies to devices that already have FDA marketing authorization, as well as devices that are not currently marketed but would fall under one of the classification regulations set forth below.

Air Purifiers

Air purifying devices are intended for medical purposes to kill pathogens/microorganisms in the air by exposure to UV radiation or remove them through filtration. The classification regulations and associated product codes for air purifying devices, to which the policy in this guidance applies, are listed in Table 3:

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 880.5045	Medical recirculation air cleaner	FRF	II
21 CFR 880.6500	Medical UV air purifier	FRA	II

Policy

In the context of the COVID-19 public health emergency, it is necessary to maintain an adequate supply of sterilizers, disinfectant devices, and air purifiers that can facilitate rapid turnaround of sterilized or disinfected medical equipment and that help reduce the risk of viral exposure for patients and health care providers to SARS-CoV-2. FDA believes that certain sterilizers, disinfectant devices, and air purifiers falling within the scope of this guidance (see Section III) may help reduce this risk of viral exposure based on our current understanding of these devices and SARS-CoV-2.

Coronaviruses are RNA viruses enveloped in a lipid bilayer.[9,10] SARS-CoV-2 is a type of coronavirus. As depicted in Figure 1, lipid viruses are the least resistant microorganisms on the scale of descending order of resistance to germicidal chemicals.[11] Because sterilization processes render devices free from viable microorganisms including bacterial spores, and because disinfection kills most recognized pathogenic microorganisms, it can generally be inferred that sterilization and disinfection should minimize the viability of SARS-CoV-2 (as one of the least resistant microorganisms) on surfaces and in the air in confined spaces. Moreover, air purifiers can be designed to filter out virus-sized particles.

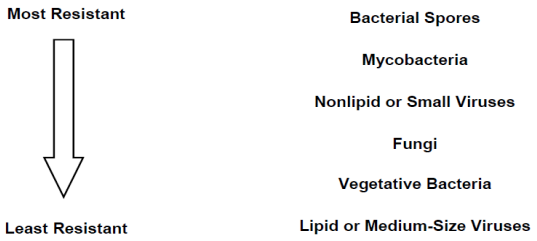

Figure 1. Descending Order of Resistance of Microorganisms to Germicidal Chemicals.

Modified from Favero, M.S. and Bond, W.W., Chemical Disinfection of Medical and Surgical Materials. In: Disinfection, Sterilization, and Preservation, 5th Ed Phila: Lippincott Williams & Wilkins 2001: 881-917.

In general, manufacturers of sterilizers, disinfectant devices, and *air purifiers* are required to submit a marketing application to FDA when seeking to market these devices. When these devices are previously approved or cleared, modifications to the indications or functionality of the devices would also generally require premarket authorization.

However, to help ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, during the declared public health emergency, FDA does not intend to object to limited modifications to the indications or functionality of FDA-cleared or FDA-approved sterilizers, disinfectant devices and air purifiers pertaining to a device's virucidal effectiveness against SARS-CoV-2, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a Premarket Approval Application (PMA) Supplement under section 515 of the FD&C Act and 21 CFR 814.39, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20. FDA believes such devices will not create such an undue risk where the performance and labeling elements in Sections IV.A and IV.B, respectively, are met. As an example, this would apply to a manufacturer that previously received 510(k) clearance for a steam sterilizer that is intended for sterilization of medical devices in health care settings, where the manufacturer would like to include a statement in the labeling that the device is effective in killing SARS-CoV-2 when used in accordance with the validated sterilization processes identified in the labeling.

In addition, during the declared public health emergency, FDA does not intend to object to the distribution and use of sterilizers, disinfectant devices, and air purifiers that are intended to be effective at killing the SARS-CoV-2 virus but do not already have FDA marketing authorization, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a PMA Supplement under section 515 of the FD&C Act and 21 CFR 814.39, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20.

FDA believes such devices will not create such an undue risk where the performance and labeling elements in Sections IV.A and IV.B, respectively, are met. As an example, this would apply to a manufacturer of a new medical air purifier that has not been approved or cleared and that is effective in filtering out dust particles and bacteria, where the manufacturer would like to modify the filter mesh size in order to filter out viruses, including the SARS-CoV-2 virus.

The enforcement policies set forth in this guidance do not apply to sterilizers, disinfectant devices, and air purifiers that are intended to prevent or reduce the risks of hospital acquired infections (HAI) or COVID-19.

Air Purifiers

For the purposes of this guidance, FDA recommends that manufacturers of air purifiers evaluate or perform the following:

1) Demonstration of a 4 log reduction (through a combination of capture or destruction) of claimed particulates. (See https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-10-S400-Viable-Lab-Micro-Chem-Pathogen-Only.pdf)
2) If intended for use against bacteria, effectiveness against representative gram positive and gram negative species. (See https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-9-S400-Viable-Lab-EDL-Pathogens-Only.pdf)
3) If intended for use related to **SARS-CoV-2, effectiveness against a representative virus**. (See https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-10-S400-Viable-Lab-Micro-Chem-Pathogen-Only.pdf)
4) If the device generates ozone, the maximum acceptable level of ozone per 21 CFR 801.415. (See Non-Ozone UL 867 Standard Testing attached)
5) If intended for use in areas that have a sterile field or controlled air flow, a risk assessment to address turbulent air flow and/or potential site contamination. (See HVAC testing: https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-6-S400-Non-Viable-Hospital-HVAC-2019.pdf)

Labeling

In addition, FDA recommends that the devices described above include labeling that helps users better understand the device modifications, such as:

1) A clear description of the available data on the device's new indications or functions related to SARS-CoV-2 or co-existing conditions, such as:
   a) Device performance; (See: https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-5-S400-Pathogen-Testing-Summery-Revised-08112020.pdf)
   b) Potential risks (e.g., risk of UV exposure) (See attachment below)
2) A clear distinction delineating FDA-cleared or FDA-approved indications from those that are not FDA-cleared or FDA-approved. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA. (See heading)
3) For all disinfectant devices, a clear statement of the level of disinfection. (N/A)
4) For UV disinfecting devices:
   a) A caution that UV disinfection will reduce the number of pathogens on the device, but it will not eliminate them completely. (See https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-10-S400-Viable-Lab-Micro-Chem-Pathogen-Only.pdf)
   b) A statement that the device is an adjunct to currently existing reprocessing practices and not a replacement or modification to such practices. (NA)

Labeling (continued) ...

In addition, FDA recommends that the devices described above include labeling that helps users better understand the device modifications, such as:

c) A statement regarding the time, distance, and maximum area over which the device has been evaluated for effectiveness. (See https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-10-S400-Viable-Lab-Micro-Chem-Pathogen-Only.pdf)

d) An appropriate UV hazard warning label. (See Below Label Illustration)
e) Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed. (See Operators Manual https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-4-S400-Operators-Guide-2020.pdf)
f) Procedures to follow if the UV lamp malfunctions or fails. (See Service Guide https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-1-S400-Service-Guide-2020-REDUCED-.pdfhttps://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-1-S400-Service-Guide-2020-REDUCED-.pdf)
g) Description of the preparation of equipment or the room for disinfection (See Operators Manual https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-4-S400-Operators-Guide-2020.pdf))
h) A statement that the equipment intended to be disinfected is UV compatible. (NA) i) Identification of the UV dose. (See Operators Manual https://scientificairmanagement.com/wp-content/uploads/2020/08/PDF-4-S400-Operators-Guide-2020.pdf)

Sample UVC Warning Label Affixed to Each Device

Environmental Diagnostics Laboratory

Monitoring of Ozone Emission from Scientific Air S400

PACS ID#: 07175

Work Order#: 026151

Customer: Scientific Air Management LLC

Dates of Testing: 9/8/2020-9/10/2020

Date Completed: 9/10/2020

Date of Report: 9/10/2020

Environmental Diagnostics Laboratory

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EDL
Environmental Diagnostics Laboratory

PURE AIR
CONTROL SERVICES INC.

September 10, 2020

To Dana Leonaggeo
1301 West Copans Toad Suite D1
Popano Beach, FL 33060

Reference: PACS ID 07175 Work Order 026151 Monitoring of Ozone Emission from Scientific Air S400

Dear Dana Leonaggeo,

We appreciate the opportunity to provide you with our professional, environmental microbiology services. EDLab is pleased to submit this report that describes ozone emission from Scientific Air S400.

This report summarizes the findings and other relevant data as per your request. A test certificate is also issue based on the findings.

Please call me at 1-800-422-7873, ext. 301 should you have any questions. We look forward in assisting you in future projects.

Respectfully Submitted,

Joiya Mendez
QC Analyst

Dr. Rajiv R. Sahay, CIAQP, FIAS
Laboratory Director

Héctor Rivera
Analyst

1.0 Background

Dana Leonaggeo contacted the EDLab at Pure Air Control Services, Inc. to conduct an ozone emission test on Scientific Air S400 to comply with California State ozone regulations. The manufacturer believes that this device will not produce ozone in a concentration that surpasses California State ozone regulations of 0.050 parts per million (ppm). Upon request, a "Scope of Work" was developed by the laboratory and executed after the approval of Dana Leonaggeo. The laboratory report after the experiment provides ozone reading produced from Scientific Air S400.

2.0 Test Design

This study comprises a pre- and post-assessment of the ozone levels within a closed environmental chamber alongside the baseline under the prevailing environmental conditions. The ozone level was recorded using Aeroqual Ozone Monitor 500 with an ozone sensor range of 0.001-0.500 ppm. Pressure around the test site were closely monitored.

3.0 Processing

EDLab's team of analyst collected 1 set of ozone emission data within the test chamber without the device (Scientific Air S400) running and 3 sets of ozone emission data with the device running. All data obtain during the experiment are recorded at 1-minute interval during an 8-hour duration.

4.0 Control Samples, Data, and Images

Experimental findings are recorded in the corresponding observation ***Table 1.*** Photographs of important stages of the experiment are presented in ***Figure 1***.

5.0 Results

All data, statistical analysis and photographs are presented under the following ***Table 1*** and ***Graph 1.***

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Table 1. Net ozone emission from Scientific Air S400

Time Interval	***60 min.***	***120 min.***	***180 min.***	***240 min.***	***300 min.***	***360 min.***	***420 min.***	***480 min.***	***Remark ≤ 0.050***
Trail	***Avg. (ppm)***	***Avg. (ppm)***	***Avg. (ppm)***	***Avg. (ppm)***	***Avg. (ppm)***	***Avg. (ppm)***	***Avg. (ppm)***	***Avg. (ppm)***	
Scientific Air S400 Off	0.002	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Yes
Scientific Air S400 On (I)	0.000	0.000	0.001	0.001	0.002	0.003	0.003	0.003	Yes
Scientific Air S400 On (II)	0.004	0.004	0.004	0.005	0.004	0.004	0.005	0.005	Yes
Scientific Air S400 On (III)	0.006	0.005	0.006	0.007	0.007	0.008	0.009	0.007	Yes

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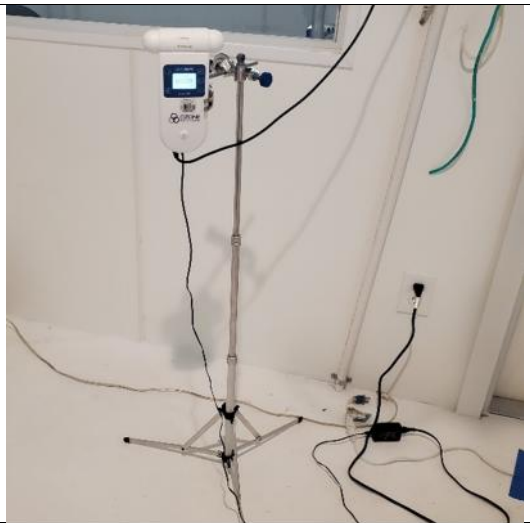
6.0 Photographs and Figures

The following section contains photos and figures of some important observations as well as other experimental stages, including graphs based off the experimental findings.

Figure 1: Experimentation Site

A. Experimental Room Set Up

B. Scientific Air S400



C. Sensor Stand

D. Sensor Close-up

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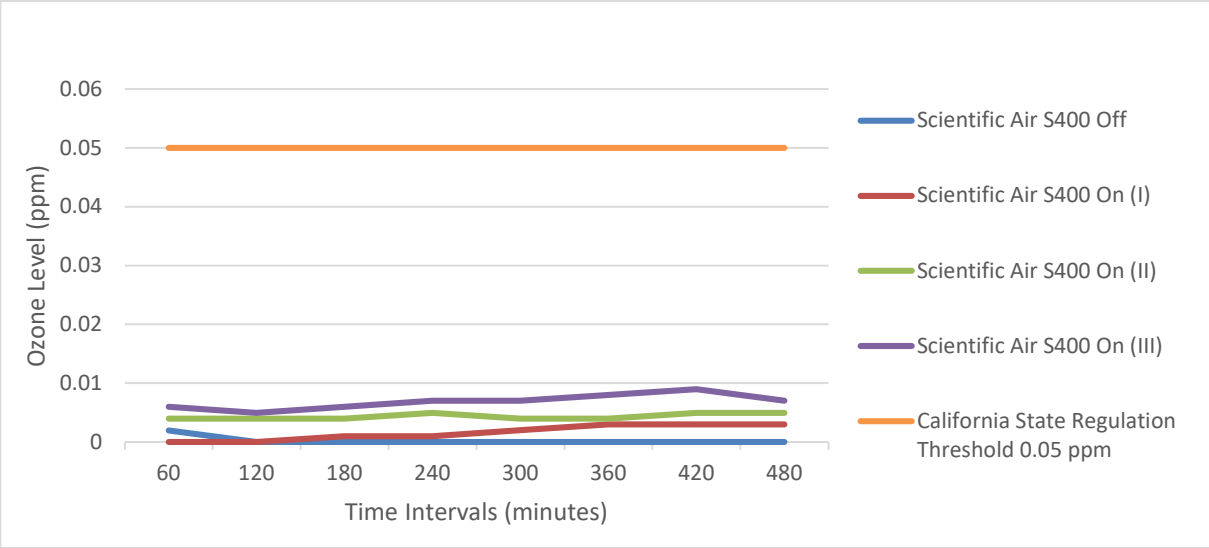
Graph 1. Ozone Emission from Scientific Air S400



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7.0 Conclusion

The goal of this study was to examine if the Scientific Air S400 complies with California State ozone level regulations. Three sets of 8-hour ozone monitoring were conducted by operating the Scientific Air S400 unit inside the environmental chamber. A set of data was also collected after conditioning the environmental chamber and placing the equipment inside. The ozone emitted by the Scientific Air S400 was below the 0.050 ppm threshold set by the California State ozone level regulation. This unit meets or exceeds the UL 867 requirements.

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END OF REPORT

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