

Updated information – April 1, 2020 0730 PT.

Ozone Disinfection and Decon for Covid PPE and Equipment Reuse

The following was submitted to the FDA-HHS for an Emergency Use Authorization in response to their 7:30 PM request for additional information to my earlier proposal.

Just giving you the most current info. Here is the request submitted 033120 at 8:00PM PT.

<https://presari.com/files/media/94/fdahhsemergencyuseauthorizationproposal040120.pdf>

Paul Krupin, BA MS, JD
509-531-8390

I'm trying to help alleviate the covid PPE shortage problems. I believe this can be done with ozone gas generators. They are readily available nationwide and work very similar to the H2P2 generator systems that have recently been greenlighted.

I would very much appreciate an rsvp letting me know you receive this reply with the additional information.

The information provided below contains the information requested in the [FDA's Guidance on Emergency Use Authorization of Medical Products and Authorization](#) items A through H list cited in the FDA's email response.

This is not a product. There is no commercialization in this proposal.

It is a request for a green light on a disinfection method using ozone to decontaminate covid contaminated PPE and equipment for reuse.

Critical Issue: Covid – 2 Kill Data is required. To substantiate the process covid-2 kill data using ozone in a small desktop chamber under controlled conditions is needed asap.

In my Thursday conference call, Steven Elliot stated that the number one most important data was the covid-2 kill data. It is totally lacking. [Steven Elliott, MS, Scientific Reviewer, THT4B1: Sterility Devices Team, DHT4B: Division of Infection Control and Plastic Surgery Devices, OHT4: Office of Surgical and Infection Control Devices, Center for Devices and Radiological Health, U.S. Food and Drug Administration. Phone: 301 796 5285 EM - Steven.Elliott@fda.hhs.gov]

I reached out and contacted several professionals and asked them how to do this. The feedback is that this can be done in a few hours with the right people and laboratory.

You need some covid positive blood and a desktop ozone sanitation chamber and an ozone meter, temperature meters, and humidifiers and humidity sensors. You test the five or more positive samples.

You split the samples and treat some of them with ozone. You test the treated and base reference samples again. Then compare the results.

We need to identify a virology laboratory capable of doing covid kill tests. The FDA – HHS has the contact, authority and capability to make this happen quickly.

With even the tiniest bit of covid-2 kill data that shows that the efficacy is similar to the covid-1 data documented prior research (provided below), then this can and should be issued to the public.

The existing cov-1 data shows 3 log 10 inactivation of bacteria and viruses at 25 ppm, for 22 minutes with a one-time burst dose of 90 percent humidity (references provided below).

Overview:

Research indicates that ozone disinfection can help an enormous number of people quite readily. Ozone generators are available on the market in sizes suitable from small CPAP disinfection to medium units designed for odor control to commercial units designed for ocean going cargo containers.

These can all be adapted for covid decon.

Right now, the US Navy could use this simple procedure to decontaminate the vessels and sanitize the ships off of San Francisco Bay and in port with sick sailors in Guam.

This could be used by the Army Corps of Engineers with trailers, tents, and truck storage containers in every city in the country.

It is readily deployable with guidance that allows people to do it themselves. Any disinfection is better than no disinfection.

The container storage disinfection is safer than room disinfection with lower risk to people from ozone gas inhalation.

I had a 10g/hour ozone generator delivered to my house. I have yet to procure or identify an ozone meter capable of telling me the PPM that can be achieved using it. Good ones cost \$500 and up, and delivery times are out to May.

Action: Conduct a controlled study to develop simple, easy to use, operational process specifications similar to the CDC 2008 guidance.

Ozone Disinfection and Decon for Covid PPE and Equipment Reuse

Action plans and references below.

Please take a look and forward this to people who can review it and take appropriate action.

I am a retired environmental scientist and attorney, with 27 years with the federal government, and another 20 years in industry. I've been trained as an EMT, nuclear emergency team member, wilderness first aid responder, and was a county civil defense director in Idaho. I worked for the Oregon

Department of Ecology Water Quality Division in 1977 MS Oregon State JD Willamette, USFS, USBLM, USDOE and more. I live in Kennewick WA.

Bottom line:

Commercially available ozone generators can be used to generate many times the needed 25 PPM ozone for less than one hour to decon covid contaminated small to medium size masks, clothes, PPE and rooms as long as people are protected from ozone inhalation. This can be done in small to medium contained units outside of buildings and facilities or in rooms with strict ventilation control to direct exfiltration of ozone gas to the outdoors, by trained professional personnel with appropriate PPE.

The CDC has approved ozone for the decon of medical equipment, but the approval does not go far enough. (reference and quote below).

I got to brief one of Dr. Fauci's teams on Thursday. I hope we are close to getting this green lighted. But I do not know whether they will release any new guidance. The Governor of any state can of course use this and decide to share the information and guidance any time. It is consistent with guidance being provided to people lower the risks as best they can every way they can.

Below:

1. Fast Track Proposal to Get the FDA-HHS Greenlight
2. Ozone Generator Calculations
3. Working Paper on the Ozone Disinfection and Decon for Covid PPE and Equipment Reuse

Contact me any time by phone or email if you have any questions at all.

Appreciatively,

Paul Krupin, BA MS JD
Kennewick WA 99337
509-531-8390

Fast Track Proposal – can be adapted for management decisions as needed anywhere.

This is a fast track proposal to getting FDA to approve ozone treatment standards for decon of covid contaminated equipment for reuse.

Craft a simple straightforward guideline that and approval, describing what the research indicates, what the ppm and duration needs to be, how to do the best job to achieve it.

This reference by a James B. Howard, PhD Virologist at UBC in Vancouver Canada indicates that a concentration of 25 ppm for 20 minutes, a 90 percent humidity can be 99.37 percent effective on bacteria and viruses:

<https://www.sciencedirect.com/science/article/abs/pii/S0196655308000965>

American Journal of Infection Control 2008 Ozone gas is an effective and practical antibacterial agent

An ozone dosage of **25 ppm for 20 minutes, with a short burst of humidity in excess of 90% relative humidity**, was able to inactivate more than 3 log₁₀ [colony-forming units](#) of most of the bacteria, including [Acinetobacter baumannii](#), [Clostridium difficile](#), and methicillin-resistant *Staphylococcus aureus*, in both in a laboratory test system and simulated field conditions. In many cases, complete eradication was achieved. Dried and wet samples were equally vulnerable to the ozone. Inactivation of bacterial samples dried onto soft surfaces (eg, fabric, cotton, filter paper) were comparable with that observed for samples on plastic.

Explain what it means to people and how it makes covid decon easy with the right commonly available equipment.

Use the CDC approval of ozone for disinfection from 2008 as a base, and then bring in the best studies from James Howard and other researchers, use the latest FDA greenlights as a guide, and build the approval document and support for ozone decon for equipment reuse.

Here it is:: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf>

Page 72 – quote with the existing measures bolded:

Ozone. Ozone has been used for years as a drinking water disinfectant. Ozone is produced when O₂ is energized and split into two monatomic (O₁) molecules.

The monatomic oxygen molecules then collide with O₂ molecules to form ozone, which is O₃. Thus, ozone consists of O₂ with a loosely bonded third oxygen atom that is readily available to attach to, and oxidize, other molecules. This additional oxygen atom makes ozone a powerful oxidant that destroys microorganisms but is highly unstable (i.e., half-life of 22 minutes at room temperature).

A new sterilization process, which uses ozone as the sterilant, was cleared by FDA in August 2003 for processing reusable medical devices. The sterilizer creates its own sterilant internally from USP grade oxygen, steam-quality water and electricity; the sterilant is converted back to oxygen and water vapor at the end of the cycle by a passing through a catalyst before being exhausted into the room. **The duration of the sterilization cycle is about 4 h and 15 m, and it occurs at 30-35°C.** Microbial efficacy has been demonstrated by achieving a SAL of 10⁻⁶ with a variety of microorganisms to include the most resistant microorganism, *Geobacillus stearothermophilus*.

The ozone process is compatible with a wide range of commonly used materials including stainless steel, titanium, anodized aluminum, ceramic, glass, silica, PVC, Teflon, silicone, polypropylene, polyethylene and acrylic. In addition, rigid lumen devices of the following diameter and length can be processed: internal diameter (ID): > 2 mm, length ≤ 25 cm; ID > 3 mm, length ≤ 47 cm; and ID > 4 mm, length ≤ 60 cm.

The process should be safe for use by the operator because there is no handling of the sterilant, no toxic emissions, no residue to aerate, and low operating temperature means there is no

danger of an accidental burn. The cycle is monitored using a self-contained biological indicator and a chemical indicator.

The sterilization chamber is small, about 4 ft³ (Written communication, S Dufresne, July 2004).

A gaseous ozone generator was investigated for decontamination of rooms used to house patients colonized with MRSA.

The results demonstrated that the device tested would be inadequate for the decontamination of a hospital room 946.

Update the guidance to state what is needed for people to use ozone decontamination for the reuse of covid contaminated equipment.

More detailed information is provided in the linked pdf file.

Paul Krupin, BA, MS, JD
509-531-8390 Paul@Presari.com

Ozone Disinfection and Decon for Covid PPE and Equipment Reuse

Ozone generator equipment calculations – some are provided below.

In lieu of real cov-19 kill data, we all may be forced to use the best we can infer from all the prior data with other bacteria and viruses, and see what that can tell us with regard to the necessary ozone concentration and the related kill rate and efficacy.

The following research provides medical evidence that shows that bacteria and viruses can be killed:

<https://www.sciencedirect.com/science/article/abs/pii/S0196655308000965>

American Journal of Infection Control 2008

Ozone gas is an effective and practical antibacterial agent

Results

An ozone dosage of **25 ppm for 20 minutes, with a short burst of humidity in excess of 90% relative humidity**, was able to inactivate more than 3 log₁₀ [colony-forming units](#) of most of the bacteria, including [Acinetobacter baumannii](#), [Clostridium difficile](#), and methicillin-resistant *Staphylococcus aureus*, in both in a laboratory test system and simulated field conditions. In many cases, complete eradication was achieved. Dried and wet samples were equally vulnerable to the ozone. Inactivation of bacterial samples dried onto soft surfaces (eg, fabric, cotton, filter paper) were comparable with that observed for samples on plastic.

To determine what the commercial ozone units are capable of I started running the ozone conversion calculations.

Source <https://www.physicsforums.com/threads/mg-hr-into-ppm.91648/>

Assume that in 1 hr, you produce 1200 mg of Ozone. In order to find ppm, you need to know the mass of the air into which these 1200 mg of Ozone will be spread. This is where the measurements come in.

Let's say the room is $4 \times 5 \times 2.5 = 50 \text{ m}^3$.

The mass of the air in the room will be its Volume x Density = $50 \text{ m}^3 \times 1.25 \text{ g/l} \times 1000 \text{ l/m}^3 \times 1000 \text{ mg/g} = 62,500,000 \text{ mg}$.

If you divide the mass of the ozone by the mass of the air, you'll get the mass fraction of ozone.

Multiply that number by 1 million, and you've got ppm/hr: $1200 / 62,500,000 \times 1,000,000 = 19.2 \text{ ppm/hr}$.

Now all you've got to do is multiply that number by the time you run the machine and you've got ppm.

For example, after 1 hour you'll have $19.2 \text{ ppm/hr} \times 1 \text{ hr} = 19.2 \text{ ppm}$.

The ozone unit in the photo below is 8000 mg/h which is more than six times the above calculation.

So with the same space, the calculation looks like this:

$8000 / 62,500,000 \times 1,000,000 = 128 \text{ ppm/hr}$.

4 meters by 5 meters by 3 meters = 13.12 ft by 16.40 ft by 6.5 ft which is the size of a large trailer storage container.

So if this is right, the commercial ozone generators will produce the ppm needed quite easily for small to medium size containers.

It also appears that even the small plastic shoe box size CPAP ozone sanitation units can hit a sufficient concentration as well.

Any ideas or suggestions or feedback would be very much appreciated.

Paul Krupin
509-531-8390 Paul@Presari.com
www.Presari.com

URGENT – Please forward to the right people for review and action.

Ozone Disinfection and Decon for Covid PPE and Equipment Reuse

My name is Paul Krupin. I am a retired environmental scientist and attorney, with 27 years with the federal government, and another 20 years in industry. I've been trained as an EMT, nuclear emergency team member, wilderness first aid responder, and was a county civil defense director in Idaho. I worked for the Oregon Department of Ecology Water Quality Division in 1977 MS Oregon State JD Willamette, USFS, USBLM, USDOE and more. I live in Kennewick WA.

I have developed information describing how to use ozone generators small and large) to disinfect large quantities of surgical masks, N 95 masks, and other contaminated equipment, and even food, and other materials. This can be done quickly and readily.

The result is that the equipment available can be quickly and easily disinfected and reused.

Action Requested: Immediate technical and management review of the soundness of this approach. With the State Health / Emergency management concurrence, this could be deployed easily to people everywhere.

In particular it needs the best possible medical references for the time/concentration duration kill times for temperature and humidity.

We can speed up the kill time with moist ozone laden air and this would be an additional help to achieve the needed level of effectiveness.

We need desktop covid kill test data. I believe it can be acquired at the state labs very quickly with official action.

The information below describes how to do this practically with readily available equipment. References are also provided.

Please hit reply and let me have full contact information so I can continue communications with you. Here is mine.

Paul J. Krupin – pikrupin@gmail.com 509-531-8390

Ozone sanitation and disinfection for covid.

The concept is quite simple. Ozone kills the covid virus at concentrations of 5 to 10 ppm in about one hour. In moist ozone laden air, the effectiveness is even higher.

Procedure:

Place a portable ozone generators and an electric fan in a small confined space. These can be placed in small totally self-enclosed trucks, trailers, and other containers.

Place used, contaminated masks and other equipment on racks, shelves, so that the ozone can reach all surfaces.

Turn the generators on, close the door.

Wait for sufficient time – one hour at 5 to 10 ppm.

Open the door, let the fresh air in and let the ozone laden air dissipate.

Some illustrations:

Depending on the size of the ozone generator, this can be easily done in a variety of situations from small to large.

Small ozone generators can be used to build shoe box size disinfection chambers.

Here is a photo and a link to one such device:

<https://drosolutions.com/product/ozone-disinfection-sterilization-box/>



Ozone Disinfection Sterilization Box

O3 – is a universal and MOST POTENT KNOWN DISINFECTING AGENT!!! This is an excellent Ad-On item to your at-home Ozone Package and has many uses for Ozone Therapy Items or Baby Feed Bottles or Medical Multi-use items or any other usages.

SKU: ODB-2.0.

Categories: All Products, Ozone Disinfection Tag: Disinfection-Sterilization

\$ 35.00

[Like 1](#) [Tweet](#) [Share](#)

1

[+ ADD TO CART](#)

Here is a photo of a device created by a Richland Washington High School teacher with a portable ozone generator and an old refrigerator.



Mobile Alternatives

Mobile ozone generators can be placed inside cars, trailers and portable storage units outside hospitals and emergency facilities.

Ozone generators are available at home remediation and restoration companies and medical equipment suppliers businesses.

These can be enlisted for deployment in communities with a systematic outreach communications.

Facility Installations

If ozone generators are used inside buildings special precautions must be taken to control infiltration and exfiltration of ozone and prevent inhalation of ozone by people in the rooms and building.

Saunas, hyperbaric chambers, laundry rooms and other places with controlled ventilation, can all feasibly be converted into sanitation rooms, with the needed precautions for each one.

Workers gaining entry will need Personal Protective Equipment - carbon mask filtration -- to enter the rooms safely until the ozone laden air has been dissipated and/or vented to the outside.

Small confined space sanitization units located outside appear to be preferable and more easily managed by people without special equipment and skills.

Time duration data and references:

<https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf> - look on page 72 for ozone

https://sportsozone.com/files/3414/4121/2543/How_Ozone_Affects_Bacteria.pdf or this web site has a list of bacteria and viruses and time duration dosage times <http://www.mold-help.org/how-ozone-affects-bacteria/>

Covid Kill Data

I have not found any literature or references specifically identifying the best Covid kill data and time duration.

This data can be developed quickly by doing benchtop kill tests at the state laboratories doing the covid tests.

Action Requested:

Please review this information and forward it to the right medical professionals and authorities.

Please contact me If you have any questions at all.

I would welcome the chance to work with anyone to help make the case and guidance explicit and well supported so that it can be deployed to help alleviate the equipment shortages.

If you have any other suggestions or ideas please let me know.

Appreciatively,

Paul Krupin
509-531-8390 Paul@Presari.com

Responses to questions from a retired US Army Corps of Engineers Health Officer

1. Would there need to be signs posted outside the decontamination facility describing what equipment needed to be used to enter the space after the process has ended?

Yes – this is best done outside in a yard covered porch or opened garage in small to medium size trailers which can be opened and flushed to the outside in minutes. If this is room or an entire building of facility, then it is best to let no one in while the ozone generator is working. Workers will need PPE – carbon filter masks to enter. The room needs to have fresh air throughout to resume normal entry. One company report I identified uses an air catalytic convertor to speed up the conversion of residual ozone to oxygen so people can reenter and use the room.

2. Time to wait before entering? Varies on the size of the room and ventilation. A trailer with a fan? Maybe an hour. Home remediation and restoration companies usually require a day when using this technology for severe odor control. A desktop CPAP size box operating for an hour could flush with a window open and ventilation for fresh air in minutes.

Speed of getting ozone out of area safely after decon? **It varies**
How to do it?

Exhaust fans? **These could be used to reduce the time.**

3. Training needed to use the specific decon device?

A simple stepwise instructions is all that is needed for the small to medium containers size sanitation chambers.

If it is a room or facility, which would be best done by experienced professionals with the right equipment and PPE.

5. Is there a swab test available to test the decon'd equipment to ensure the process worked before reuse of the equipment?

Not that I am aware of. Ozone detectors and monitors are available to measure in concentration of ozone attained but they are expensive.

6. How do you mark the decon'd equipment to show cleaned for reuse?

Would have to be done by hand eye separation, and placed into clean containers or boxes, with hand marking or magic markers, pens etc.

7. What is the recommended minimum size container needed for decon of masks, ventilators, etc?

It varies by the output of the device. This is why we calculate carefully. The calculations show that even the CPAP disinfection equipment can work on a desktop for homemade masks, gowns and other equipment. The refrigerator unit in the picture is 30 cubic feet.

8. what savings in time will your proposal have over standard decon process?

A lot. The literature I've found states that ozone gas also decons better, is gaseous over liquid, and gets into nooks and crannies that liquids cannot get into.

9. Can duct tape or similar removable material be used to help seal the containers if not airtight.

Yes – and the gases inside the containers can be managed with small holes, plastic pipe or ducts, and hoses with fans, etc to evacuate the enclosures.

10. Will forcing ozone into a container disperse the virus to the outside of the container if not airtight?

Unlikely. But if the virus was in the air and not on surfaces, yes.