Instructions for Healthcare Facilities and Personnel: Preparation of Compatible N95 Respirators for Bioburden Reduction and Installation and Operation of a Semi-Automated Bioburden Reduction Module for Emergency Use of Compatible N95 Respirators	

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease 2019(COVID-19) Public Health Emergency which covers the use of the SoMD Loves You, Inc.'s Semi-Automated Bioburden Reduction Module. This is applicable in bioburden reduction of compatible N95 or N95-equivalent respirators, not to include K95 respirators or filtering facepiece respirators (FFRs) that do not have exhalation valves, do not incorporate a duck-bill design and do not contain antimicrobial/antiviral agents and that 1) have been FDA-cleared, or 2) have been FDA-authorized under the EUA for CDC's National Institute for Occupational Safety and Health (NIOSH)-approved FFRs, or 3) have been FDA-authorized under the EUA for imported, non-NIOSH-approved FFRs that are not manufactured in China (hereafter referred to as "compatible N95 respirators") for single-user reuse by healthcare personnel. After bioburden reduction, follow CDC recommendations for Decontamination and Reuse of Filtering Facepiece Respirators, Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings, and Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, for loading and unloading N95 respirators into the Semi-Automated Bioburden Reduction Module.

This guide provides instructions and procedures to be followed by Healthcare Facility Personnel to collect, heat-treat, and distribute compatible N95 respirators for sanitization in the Bioburden Reduction Module. This guide also provides instructions for the operation and care of the Module.

Note: All personnel involved in the operation of this system and those using a heat-treated respirator from this system should be regularly screened for signs and symptoms of COVID-19 and other respiratory infections in accordance with the healthcare facility's procedures.

- Personnel operating the Semi-Automated Bioburden Reduction Module should be familiar with procedures and instructions outlined in the Instructions for Healthcare Personnel and Facilities Document.
- Compatible N95 Respirators subjected to bioburden reduction are not sterile. Use proper hand hygiene and gloves when removing or handling potentially used N95 respirators.

Contact Info: Website: https://www.somdlovesyou.org/ Email: info@somdlovesyou.org

- This bioburden reduction strategy should only be used in conjunction with a CDC recommended strategy for Reuse of Filtering Facepiece Respirators.
- Compatible N95 Respirators may be subjected to bioburden reduction up to 5 times.
- Compatible N95 Respirators should be discarded after 5 bioburden reduction cycles.
- If the name of the respirator's owner and/or the number of bioburden reduction cycles becomes illegible, the respirator should be discarded.
- Compatible N95 respirators must be free of visible damage and soil/decontamination (eg., blood, dried sputum, bodily fluids, makeup) should be discarded and not reused.
- Storage containers used for transporting respirators to and from the Semi-Automated Bioburden Reduction Module should be disposed of or cleaned regularly (eg., once per day) using soap and water and decontaminated using bleach or at least 60% alcohol.
- Compatible N95 Respirators should be placed in a breathable paper bag for a minimum of five days between each use.

DISCLAIMER:

Bioburden reduction strategies have not demonstrated the FDA recommendations to achieve decontamination. However, information on bioburden reduction shows this method may be effective against SARS-CoV-2 and should be used to supplement the recommendations from the CDC. Please refer to the CDC recommendations for Decontamination and Reuse of Filtering Facepiece Respirators, Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings, and Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response.

General Information for Compatible N95 Respirators:

- Discard N95 respirators following use during aerosol-generating procedures.
- Discard N95 respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Discard N95 respirators following close contact with any patient co-infected with an infectious disease requiring contact precautions.
- Discard N95 respirators that are damaged, discolored or visibly soiled.
- Consider use of a cleanable face shield (preferred) over an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls), when feasible to reduce surface contamination of the respirator.
- Use a pair of clean (non-sterile) gloves when donning a used N95 respirator and performing a user seal check. Discard gloves after the N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.
- Clean hands with soap and water before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit). If soap and water are not readily available, use a hand sanitizer that contains at least 60% alcohol. Cover all surfaces of your hands and rub them together until they feel dry.

Contact Info: Website: https://www.somdlovesyou.org/ Email: info@somdlovesyou.org

- Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and perform hand hygiene as described above.

Examples of Engineering Controls and Practices to Implement **in addition to** the use of the Bioburden Reduction module.

- To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers should be disposed of or cleaned regularly.
- Extend the use of N95 respirators by wearing the same N95 for repeated close contact encounters with several different patients, without removing the respirator per recommended guidance on the implementation of extended use.
- Implement limited re-use of N95 respirators by one HCP for multiple encounters with different patients, but remove it after each encounter. See additional guidance on potential methods for decontamination.
- Exclude HCP at higher risk for severe illness from COVID-19 such as those of older age, those with chronic medical conditions, or those who may be pregnant from contact with known or suspected COVID-19 patients.
- Designate convalescent HCP for provision of care to known or suspected COVID-19 patients (those who have clinically recovered from COVID-19 and may have some protective immunity) to preferentially provide care).
- For example, the healthcare worker may wear one respirator each day and store it in a breathable paper bag at the end of each shift. The order of FFR use could be repeated with a minimum of five days between each FFR use.

Chain of Custody for N95 Respirators

It is recommended that healthcare workers follow the instructions below at the end of a respirator's use to bag their own respirators for bioburden reduction, and write their name or other identifier on both the respirator and the bag. Markings can be made using permanent markers.

Remove and Prepare N95 Respirators

Please follow the steps listed below to prepare your respirators for collection and bioburden reduction:

1. Remove respirator per manufacturer instructions. If visibly soiled, damaged or wet, please discard the respirator per hospital protocol.
2. If not soiled, damaged or wet, place a tick mark on the exterior surface of the respirator using a permanent marker. The respirator can be reused up to 5 times. If there are 5 tick marks, discard the respirator.

Contact Info: Website: https://www.somdlovesyou.org/ Email: info@somdlovesyou.org

3. Place the respirator in a breathable paper bag for a minimum of five days between each use. (approved/provided by the healthcare facility) labeled with your name and department/organization.
4. Place the bagged respirator into a designated collection receptacle or hand to appropriately protected personnel for collection. The container is closed and transported to a designated area for safekeeping and storage until ready for the bioburden reduction.
5. The bagged respirators are moved to the Bioburden Reduction Module in sealed containers labeled with a biohazard safety symbol by designated personnel.

NOTE: No items other than N95 respirators should be placed in the collection bags for bioburden reduction. This method is only intended to be used for N95 respirators, and not for other personal protective equipment, such as gowns, gloves, etc.

Bioburden reduction of N95 Respirators

Appropriately protected, designated facility personnel open the containers and place the bagged N95s on the racks in the Bioburden Reduction Module. The operator of the Semi-Automated Bioburden Reduction Module will mark the bioburden reduction cycle count on the bag during this process. At the end of the bioburden reduction cycle, the bagged respirators are placed in a sanitized container and returned to a designated holding area to be returned to your department and to you for reuse.

Receive and Reuse N95 Respirators

1. Check to see if the bagged respirator you received has your name on it. If not, do not use the respirator inside of the bag, and ask designated decontamination personnel for help locating your respirator.
2. Remove the respirator from the bag and check it for obvious signs of physical damage. If at any time the labeling is not legible or there is visible soil or damage, discard the respirator.
3. Don the respirator in accordance with your facility's policy. Use a pair of clean (non-sterile) gloves when donning a used N95 respirator and performing a user seal check. Perform the User Seal Check for N95 respirators as outlined by NIOSH every time the respirator is worn to ensure an adequate seal is achieved (https://www.cdc.gov/niosh/docs/2018-130/pdfs/2018-130.pdf).
4. Discard gloves after the N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.

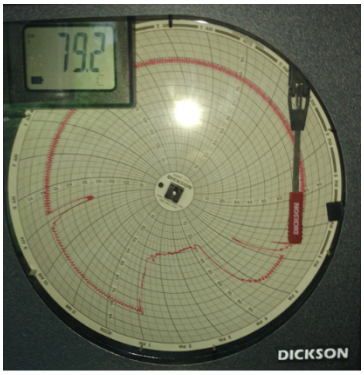
Contact Info: Website: https://www.somdlovesyou.org/ Email: info@somdlovesyou.org

5. Consider the use of a cleanable face shield (preferred) in addition to an N95 respirator and/or other steps (e.g., masking patients, use of engineering controls), when feasible to reduce surface contamination of the respirator.
6. Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the respirator (if necessary for comfort or to maintain fit).
7. Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and perform hand hygiene as described above.

Installation of the Semi-Automated Bioburden Reduction Module

The Bioburden Reduction Module is delivered to a Healthcare Facility on a rollback truck. The driver unloads the Module and places it in the Facility's desired outdoor or accessible enclosed bay location. The Module is leveled and connected to a Facility electrical source using a 120V extension power cord, connected to a 15-amp circuit. When the cord is connected, the blower, thermostat and chart plotter automatically begin operation. The Module arrives onsite with 50 gallons of heating fuel pre-loaded in the tank. The wall switch inside the heater room doors is turned to the on position to start the furnace. This switch turns on the fuel nozzle blower and ignites the burner unit which sends heat into the heating chamber via the blower and chamber ceiling vents.

SOMD Loves You, Inc. Heat Sanitation Module



Dickson Chart Plotter

It normally takes twenty minutes for the Module to reach the preset temperature. The chart plotter records the temperature inside the heating chamber. When the chamber, as recorded on the chart plotter, has reached a stable temperature range between 75° C and 82° C, the Module is ready to be used for N95 respirator bioburden reduction. The burner and blower units only get turned off for scheduled, routine maintenance. The paper on the Chart plotter is changed every 24 hours, marked with the date and time removed, and stored in the metal rack below the plotter (where the plotter directions and specification manual are located) for later recall, if and when needed to verify temperatures during a heating cycle. The Module is shipped with a packet of spare plotter papers.

Operation of the Semi-Automated Bioburden Reduction Module

Contact Info: Website: https://www.somdlovesyou.org/ Email: info@somdlovesyou.org

The Bioburden Reduction Module is in continuous operation at the desired temperature of 75°C. There are two double doors at each end of the Module. The oil heater, oil tank, blower and chart plotter are on the back end. The front end is the heat chamber. The doors may be locked from the outside, but remain unlocked from the inside thereby preventing anyone from accidentally being locked inside the Module. The internal temperature is managed by a thermostat and recorded on the Dickson 8-inch chart recorder. Prior to placing any containers in the Module, the chart recorder is inspected to validate that the Module is operating at the desired

Module Oil Heater, Blower and Chart Plotter


Module Heat Chamber

temperature range between 75°C and 82°C. When the chamber door is opened, the temperature will immediately drop. It takes about four minutes for the interior to cool off enough to safely enter. The bags containing the N95 respirators are placed on the NSF wire racks for bioburden reduction. After the heat chamber, doors are closed and the temperature stabilizes between 75°C and 82°C again, the N95 respirators must remain in the closed chamber for 80 minutes to expose compatible N95 respirators to ≥ 75 ^{0}C for ≥ 60 min.

Collect and Prepare N95 Respirators

Please follow the steps listed below to prepare your respirators for collection and bioburden reduction:

1. Suitably PPE protected staff will collect the appropriately labeled containers holding the bagged and labeled compatible N95 respirators and move them to the Bioburden Reduction Module.
2. Prior to opening the Module, check the Module heat range as described above.
3. Open the containers and place the bagged N95s on the NSF wire racks in the Bioburden reduction Module. Be certain that the NSF wire racks are at least six inches away from any wall to allow for proper air circulation in the heat chamber. Up to 2000 masks may

be placed on the racks. Do not stack the bags. Keep the containers open and leave them in the Module to undergo the sanitation procedure.

4. Exit the Module and close the door. Record the time.
5. At the end of an 80-minute sanitation cycle, check the chart recorder again to be certain the temperature for the last hour ranged between 75° C and 82° C. If not, the bioburden reduction cycle should be extended until 60 minutes at temperature is reached. After the cycle completion, record the time, turn off the heater unit and open the Module door.

Distribute N-95 Respirators

After placing the bagged respirators in appropriate sanitized containers, take the containers to the designated storage room or take them directly to the healthcare unit/department from which they originated.

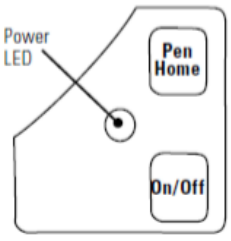
Record Keeping

1. The Paper Chart used for temperature recording must be replaced once daily.
    a. To replace paper first press the home button located on the chart
    b. Replace used paper with fresh paper
    c. Press home button again before continuing operation of the module
2. Personnel removing the old paper chart must print their name, date, and sign the log.
3. Personnel placing new paper into the recording system must also leave their printed name, date, and signature in the log.
4. The log must be retained for records.

Bioburden reduction Module Routine Maintenance

1. Chart Plotter

The Dickson Chart Plotter Model KT8P2 records the heating chamber temperature on a revolving sheet of paper. The paper records for 24 hours and must be changed each day. The Plotter has two buttons and an LED light on the front panel.



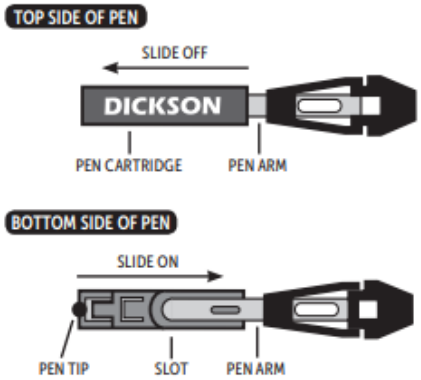
a. Paper Change

Replacement Paper for the Plotter is Dickson Product SKU C410, a 24 hour, temperature range 0-100 paper. It is specifically designed for the ink pen used in the Plotter not to cause ink blotting. To install the 24-hour chart, press the PENHOME key to move the pen(s) to the outside of the chart. The pen(s) is automatically raised

off the chart. Remove the old chart, place the new chart on the Chart Hub being certain that the edge of the chart slides under the Chart Guide Clips located at the outside of the chart.

b. Pen Change

See the adjoining figure for instructions on how to change the Chart Plotter pen. The pen typically lasts for one year and should be changed before it runs out.



1. Flip pen arm up
2. Slide used pen cartridge off pen arm
3. Slide new pen cartridge on pen arm
4. Make sure end of pen arm comes into contact with pen tip
5. Remove pen cap
6. Flip pen arm down

c. Battery Replacement

- The battery compartment is located on the back of the unit
- The recorder uses a standard AA battery for up to two years of battery life
- Insert new battery with positive end up

There are four AA batteries in the Chart Plotter that provide 24 hours of backup power. If the batteries require replacement, the LED indicator blinks red. The batteries are found in an enclosure on the rear of the plotter. To replace, open the enclosure and replace the batteries.

d. LED Indicators

The LED Indicator on the front panel has the following meanings:

- AC Power with Battery Backup - Solid Green
- AC Power with Low Battery or No Battery - Blinks Red
- Battery Only - Blinks Green

e. Sensor Replacement

The Chart Plotter does not require calibration. The sensor is the only device that requires recalibration and that is performed by replacing the sensor. The R400 Single-K Thermocouple Temperature sensor is carefully tested and calibrated before being shipped from the factory. For the greatest accuracy, it is recommended to

replace the sensor every 6-12 months. To order a Calibrated Replacement Sensor Call Dickson customer service at (630) 543-3747 or go to www.dicksondata.com. When the new Replaceable Sensor arrives, simply turn off the recorder, remove and discard the old sensor, plug in the new one and power the recorder back on. Your recorder will continue to record temperature without interruption. The KT856P2 Chart Plotter was carefully tested and calibrated before being shipped from the factory.

2. **Air Filter Replacement**

There is a standard, easily available, F100 series, MERV-11 or 13, 16 by 25 inch air filter that requires replacement every 6 months (or more frequent if the module is operating in a very dusty environment). The filter is available from most local hardware or home centers or online. It should be replaced every six months (or sooner if the Module is located in a very dusty environment).

The filter is located near the floor on the return air vent inside the heating chamber. It is easily accessible. Flip open the tabs, lift the cover, remove the old filter and replace the new filter with the air flow arrow pointing towards the rear of the chamber. Discard the old filter.

3. **Oil Refill, Oil Filter Replacement**

Contact your local heating oil supplier for routine fuel resupply. The delivery truck will fill the 275-gallon capacity tank in accordance with standard practices. The tank is located in the rear of the Module, left side door. The oil filter requires annual replacement and is normally performed by the fuel supply company.

4. **Thermostat Replacement**

The thermostat must be replaced every six months. The thermostat must also only be purchased through SoMDLY or BurchOil.

5. **Lightbulb**

Located inside of the module there is a standard high temperature rated light bulb that must be replaced every two months.

6. **Chamber Cleanliness**

It is recommended that the chamber be swept frequently and be kept free of loose debris. We recommend the walls, floors, and racks get wiped down periodically with an alcohol-based cleaner according to the Facility's standard operating procedures.

Note: N95 Respirators shall not be processed more than 5 times by this process, as currently available data suggest that N95 respirators can only be exposed to the intended bioburden reduction temperature-time exposure for up to 5 times without loss of functionality.

Contact Info: Website: https://www.somdlovesyou.org/ Email: info@somdlovesyou.org