When used in medical or healthcare facilities pursuant to FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, please follow these supplemental instructions.

Guidance for Industry and Food and Drug Administration Staff: *Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*. March 2020

Molekule 1301 Folsom St. San Francisco CA 94103

Coronavirus Disease 2019 (COVID-19) Public Health Emergency Supplemental Labeling

Molekule Air Pro RX, Molekule Air and Molekule Air Mini

Indications for Use

Molekule, Inc. (Molekule) is providing this supplemental labeling in accordance with the FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency with respect to three of its ultraviolet air purifiers: Molekule Air Pro RX, Molekule Air and Molekule Air Mini (Molekule air purifiers). Based on this guidance:

"The Air Pro RX, Air and Air Mini air purifiers are intended for use in medical and healthcare facilities to destroy, by exposure to UV radiation, novel coronavirus (SARS-CoV-2) entrained on the device filter."

Serious or Life-Threatening Disease or Condition

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019. Chinese authorities identified a novel coronavirus (SARS-CoV-2), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases on all continents except Antarctica. The virus has been named "SARS- CoV-2" and the disease it causes has been named "coronavirus disease 2019" (abbreviated "COVID-19"). On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens and that involves the SARS-CoV-2.

Support for the Effectiveness of Molekule Air Purifiers

The Molekule air purifiers filter the air in a room several times per hour (depending on variables such as fan speed selected and room size). These devices have been demonstrated to kill selected

bacteria, viruses and molds (see tested organisms in the table below) entrained on the device's catalytic filter. This functionality may be effective in destroying the SARS-CoV-2 virus once removed from the air and entrained on the filter. These
devices are intended to be placed in medical and healthcare facilities as a medical countermeasure (MCM). These devices are not intended to replace personal protective equipment (PPE) or other similar MCMs.

Model	Organisms/Pollutant Tested (name, class, size)	Summary of results
Molekule Air Mini (MiniMo)	Coliphage φX174 Virus, 0.0025 µm	Room Chamber test (1000ft^3) Aerosolized microbial reduction of 98.7% in 2 hours. Filter media swatch elution after 24 hours of operation Filter viral phage counts non-detectable.
	MS2 bacteriophage, virus, 0.027 µm	Room Chamber (562ft^3) Average MS2 log reduction: 3.48 net log reduction in 60 minutes 4.18 net log reduction in 90 minutes 5.09 net log reduction in 120 minutes
Air Pro RX Air Air Mini	MS2 bacteriophage, virus, 0.027 µm	Filter Swatch Test Average log reduction in (24H): 45 °F:4.13 72 °F: 4.25 110 °F: 5.51
	Phi-X174 bacteriophage, virus, 0.025 µm	Filter Swatch Test Average log reduction (24H): 45 °F:4.37 72 °F:4.37 110 °F: 4.37
	Staphylococcus epidermidis, bacteria, 0.5-1.5 µm spheres	Filter Swatch Test Average log reduction (24H): 45 °F:4.88 72 °F:4.70 110 °F: 5.18
	Escherichia coli, bacteria, 0.5D x 2L µm Rods	Filter Swatch Test Average log reduction (24H): 45 °F:4.31 72 °F:4.79 110 °F: 4.79
	Aspergillus Niger, mold endospore, 2-5 µm	Filter Swatch Test Average log reduction (72H): 45 °F:3.91 72 °F:3.99 110 °F: 4.22

Model	Organisms/Pollutant Tested (name, class, size)	Summary of results
	Bacillus globigii, bacterial endospore, 0.5D x 1.125L µm Rods	Filter Swatch Test Average log reduction (72H): 45 °F: 4.11 72 °F: 4.41 110 °F: 4.41
Air Pro RX Air Air Mini	Methicillin-resistant Staphylococcus epidermidis, bacteria, 0.5-1.5 µm spheres	Filter Swatch Test Average log reduction in 20 minutes: 3.82
Air Pro RX Air Air Mini	MS2 bacteriophage, virus, 0.027 µm	Single pass average log reduction: 4.19 ±0.23
	Phi-X174 bacteriophage, virus, 0.025 µm	Single pass average log reduction: 4.19 ±0.51
	Staphylococcus epidermidis, bacteria, 0.5-1.5 µm spheres	Single pass average log reduction: 4.33 ±0.22
	Escherichia coli, bacteria, 0.5D x 2L µm Rods	Single pass average log reduction: 4.91 ±0.24
	Aspergillus Niger, mold endospore, 2-5 µm	Single pass average log reduction: 5.07 ±0.13
	Bacillus globigii, bacterial endospore, 0.5D x 1.125L µm Rods	Single pass average log reduction: 4.86 ±0.23

Note: A “single pass” refers to reduction of particulates from the air stream after a single pass through a test unit.

The technology has been demonstrated to destroy the listed microorganisms in the stated time periods. The Molekule UV air purifiers have not been specifically tested against the SARS-CoV-2 virus and may have different efficacy against the specific virus.

Use in Surgical Suites and Other Critical Care Sites

The Molekule Air Pro RX is recommended for use in the operating room or other critical care sites, due to its large fan size and ability to rapidly cycle air. The Air Pro RX has the ability to turn over the operating room air at a frequency higher than the other Molekule products. 6-9 ACH may be achieved in a room with 4000 cubic foot volume (standard operating room size) with a flow rate ranging from 400-600 cubic feet per minute (CFM).

The Air Pro RX's recommended placement within these critical sites varies depending on the nature of the room

Positively pressurized rooms aimed at keeping dirty particles out of the room should have the Air Pro RX's outlet facing towards the door. This will support the designed leakage path and help keep dirty particles out during instances when the door is opened. Conversely, in negatively pressurized rooms, Air Pro RX should be positioned away from doors and towards exhaust vents. This will help entrain any dirty particles to the room's exhaust and work in concert with the designed air leakage scheme.

The Molekule Air and Air Mini can be used in smaller rooms, patient suites, or partitions (600 ft^2 and 250 ft^2, respectively). Multiple Molekule Air and Molekule Air Minis may be used in larger rooms, as required. It is recommended that Air and Air Mini should be as close to the patient as possible. It is recommended that units be elevated, and the purifier inlet placed near the patient's exhalation zone, see notes below. Units should be operated at the highest fan setting tolerable (from a noise perspective) to maximize effectiveness. Molekule Air and Air Mini are not engineered for surgical suites.

Warning: The Air and Air Mini are not recommended for use in surgical suites, because they may disrupt laminar flow.

Filter Lifetime and Device Placement Justification

Molekule Air Pro RX

Room Type	Pressure Type	Guidelines: Device Placement Filter Replacement Qty per room/ patient	Justification or Reasoning
Surgery and Critical Care Rooms	Negative	Both Filters Replaced Weekly Device exhaust placed towards room air exhaust and away from doors Per 1000 sq ft of room Minimum 1 Maximum 2	Weekly Filter replacement is recommended to allow optimum oxidation of infectants and contaminants in these critical environments Air Pro RX shall be placed away from doors and with the outlet facing towards the flow exhaust of the room. This follows a principle, wherein Air Pro RX placement works in concert with the existing air flow path of the room. Air Pro RX's outlet shall never cross the laminar air flow supply. Units shall be placed with all device outlets towards the air exhaust(s) of the room. Limit of two devices per air exhaust outlet.

	Positive	Both Filters Replaced Weekly	Weekly Filter replacement is recommended to allow optimum oxidation of infectants and contaminants in these critical environments
		Device exhaust placed towards doors or room exhaust.	Air Pro RX shall be placed facing towards doors or secondarily room exhaust. This is based on the previously stated simulation in a positive pressure surgery suite. Air Pro RX's outlet shall never cross the laminar air flow supply.
		Per 1000 sq ft of room Minimum 1 Maximum 2	First Unit: Unit shall be placed with its outlet facing towards the entry door. Additional Units: Units shall be placed with outlets facing towards room air exhausts. Limit 2 devices per outlet
	Not Required	Both Filters Replaced Weekly	Weekly Filter replacement is recommended to allow optimum oxidation of infectants and contaminants in these critical environments
		Device exhaust placed towards room air exhaust and away from doors	Air Pro RX shall be placed away from doors and with the outlet facing towards the flow exhaust of the room. This follows a similar principle, wherein Air Pro RX placement works in concert with the existing air flow path of the room, under the assumption the room's air is compromised relative to adjoining rooms.
		Per 1000 sq ft of room Minimum 1 Maximum 2	Units shall be placed with all device outlets towards the air exhaust(s) of the room. Limit of two devices per air exhaust outlet.
Inpatient Nursing and General Nursing Facilities AND Radiology and Diagnostic Rooms	Negative	Both Filters Replaced Weekly	Weekly Filter replacement is recommended to allow optimum oxidation of infectants and contaminants in these critical environments. These environments generally have fewer internal air changes than nonsurgical suites.
		Device exhaust placed towards room air exhaust and away from doors	Air Pro RX shall be placed away from doors and with the outlet facing towards the flow exhaust of the room. This follows a similar principle, wherein Air Pro RX placement works in concert with the existing air flow path of the room.
		Per 1000 sq ft Minimum 1 Maximum 2	Units shall be placed with all device outlets towards the air exhaust(s) of the room. Limit of two devices per air exhaust outlet.

Positive	Both Filters Replaced Weekly	Weekly Filter replacement is recommended to allow optimum oxidation of infectants and contaminants in these critical environments.
	Device exhaust placed towards doors or room exhaust. Per 1000 sq ft Minimum 1 Maximum 2	Air Pro RX shall be placed facing towards doors or secondarily towards room exhaust. This is based on the previously stated simulation, showing the benefit of placing the exhaust facing towards the door. First Unit: Unit shall be placed with its outlet facing towards the entry door. Additional Units: Units shall be placed with outlets facing towards room air exhausts. Limit 2 devices per outlet
Not Required	Both Filters Replaced Weekly	Weekly Filter replacement is recommended to allow optimized oxidation in these critical environments
	Device exhaust placed towards doors or room exhaust.	Air Pro RX shall be placed away from doors and with the outlet facing towards the flow exhaust of the room. This follows a similar principle, wherein Air Pro RX placement works in concert with the existing air flow path of the room, under the assumption the room is compromised.
	Per 1000 sq ft Minimum 1 Maximum 2	Units shall be placed with all device outlets towards the air exhaust(s) of the room. Limit of two devices per air exhaust outlet.

Molekule Air

Room Type	Pressure Type	Guidelines: Device Placement Filter Replacement Qty per room/patient	Justification or Reasoning
Surgery and Critical Care Rooms	Negative	Not Recommended. See Air Pro RX	Air Pro RX was designed for the surgical suites and critical care environments featuring laminar flow curtains. Air's vertical outlet, when placed near a patient, may disturb laminar flow.
	Positive	Not Recommended. See Air Pro RX	Air Pro RX was designed for the surgical suites and critical care environments featuring laminar flow curtains. Air's vertical outlet, when placed near a patient, may disturb laminar flow.
	No Required	Not Recommended. See Air Pro RX	Air Pro RX was designed for the surgical suites and critical care environments featuring laminar flow curtains.

Inpatient Nursing and General Nursing Facilities AND Radiology and Diagnostic Rooms	Negative Positive & Not Required	Filters Replaced Monthly Molekule Air should be placed on tables, stands, cabinets, raised from the floor if possible. Close to patient(s) and away from doors. Within 2.5 feet of the patient's mouth/ nose. Minimum One Device per 4 patients No Maximum	Monthly Filter replacement is recommended to allow optimum oxidation of infectants and contaminants in these critical environments. It is recommended that units be elevated, and the purifier inlet placed near the patient's exhalation zone, specifically within 2.5 feet[1] of the patient's mouth/nose, to allow the purifier entrain and oxidize released aerosols. This may help reduce overall aerosol concentration in the room. This is particularly important during aerosol generating procedures[2], such as intubation associated procedures, endotracheal aspiration, suction of body fluids, bronchoscopy, nebulizer treatments, etc. Placement away from doors ensures that any pressurization air flow requirements are not impacted.

Molekule Air Mini

Room Type	Pressure Type	Guidelines: Device Placement Filter Replacement Qty per room/patient	Justification or Reasoning
Surgery and Critical Care Rooms	Negative	Not Recommended. See Air Pro RX	Air Pro RX was designed for the surgical suites and critical care environments featuring laminar flow curtains. Air Mini's vertical outlet, when placed near a patient, may disturb laminar flow.
	Positive	Not Recommended. See Air Pro RX	Air Pro RX was designed for the surgical suites and critical care environments featuring laminar flow curtains. Air Mini's vertical outlet, when placed near a patient, may disturb laminar flow.
	No Required	Not Recommended. See Air Pro RX	Air Pro RX was designed for the surgical suites and critical care environments featuring laminar flow curtains.

Inpatient Nursing and General Nursing Facilities AND Radiology and Diagnostic Rooms	Negative Positive & Not Required	Filters Replaced Monthly Molekule Air Mini should be placed on tables, stands, cabinets, raised from the floor if possible. Close to patient(s) and away from doors. Within 2.5 feet of the patient's mouth/nose. Minimum One Device per 4 patients No Maximum	Monthly Filter replacement is recommended to allow optimum oxidation of infectants and contaminants in these critical environments. It is recommended that units be elevated, and the purifier inlet placed near the patient's exhalation zone, specifically within 2.5 feet[1] of the patient's mouth/nose, to allow the purifier entrain and oxidize released aerosols. This may help reduce overall aerosol concentration in the room. This is particularly important during aerosol generating procedures[2], such as intubation associated procedures, endotracheal aspiration, suction of body fluids, bronchoscopy, nebulizer treatments, etc. Placement away from doors ensures that any pressurization air flow requirements are not impacted. Placement away from doors ensures that any pressurization air flow requirements are not impacted.

Journal References:
1) https://www.sciencedirect.com/science/article/pii/S0012369215319619 -
2) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338532/ -
3) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6409895/#B22-pharmaceutics-11-00075 –

Additional Instructions for Use

These additional instructions supplement the User Manual provided with the Molekule air purifier when the device is used for the above Indications for Use. The soft goods handle of the Air and Air Mini devices can be removed and kept off under these Indications for Use.

Warning!

Prior to changing filters or cleaning the unit, don all Personal Protective Equipment (PPE) per your institution's standard biohazard handling protocol. In non-healthcare, closed quarantine facilities, this may include disposable gloves, masks, and/or eye protection.

Consult a qualified healthcare provider for a full list of PPE for your specific environment. The immediate area should be cleared of anyone not performing the filter change procedure.

Warning!

Failing to follow these cleaning instructions can increase the risk for electric shock, fire, and/or damage to the device. To reduce the risk of electric shock and fire, always unplug the device before performing any cleaning and ensure the device has completely dried before plugging in the device.

Replacing and Disposing of Filters

Follow your Molekule User Manual for instructions on replacing filters. Additional cleaning and disposal actions are required for closed quarantine areas and healthcare facilities in mitigating the risk of airborne virus transmission.

Discard the used filter per the biohazard removal process recommended by your healthcare provider. Contact your healthcare provider for biohazard bags and containment recommendations specific for your environment.

The outside surfaces of the Molekule air purifier should be cleaned and disinfected daily. Accessible interior surfaces should be cleaned and disinfected during filter changes. See Figure 1 below for cleaning and disinfection locations. Clean and disinfect all surfaces per instructions below:

How to Clean and Disinfect the Device

1. Use a clean, disposable cloth dampened with a water and detergent solution to wipe external and/or internal surfaces. The cloth should be damp, but not dripping. In a healthcare environment, follow your facility's standard surface cleaning procedure. For use in non-healthcare closed, quarantine areas, use dish soap or a cleaner recommended or provided by a qualified healthcare provider.

2. Use a clean disposable cloth (different from step 1) dampened with clean water to wipe the external and/or internal surfaces. The cloth should be damp, but not dripping.

3. Use a clean disposable cloth (different from steps 1 and 2) and disinfectant to wipe external and/or internal surfaces. In a healthcare environment, follow your standard surface disinfecting procedure. For use in non- healthcare closed, quarantine areas, please contact your healthcare provider to recommend the appropriate disinfectant for your specific environment. The Centers for Disease Control and Prevention (CDC) recommends diluted household bleach solutions of approximately 0.7% bleach, alcohol solutions with at least 70% alcohol, and most common EPA-registered household

disinfectants. Avoid use of concentrated ammonia solutions on anodized aluminum (Molekule Air tube chassis). These solutions have been evaluated by Molekule for the purposes of cleaning its products and should not acutely affect their structural integrity nor their long-term performance.

4. Do not spray any liquid into the inlet or outlet of Molekule devices. Do not clean or contact LED lights or any exposed printed circuit boards.

Note: Molekule uses Sabic 945U on all User Accessible Plastic Surfaces. This material was chosen not only for its mechanical properties, but also due to its chemical compatibility against solvents. See the report referenced below which highlights Sabic's portfolio and recommended materials for Healthcare Enclosures and an assessment against environmental concerns. It includes testing for several resins, including 945AU, against cleaning agents and cleansing wipes used in a healthcare setting

TABLE 1
CHEMICAL RESISTANCE PERFORMANCE TESTING - HEALTHCARE RESINS, STANDARD RESINS

PRODUCT FAMILY	GRADE/SERIES	Exposure time (days)	Bleach sodium hypochlorite solution, 50%	Cidex[1] glutaraldehyde based disinfectant	Methyl ethyl ketone (MEK)	Virex[1] organic ammonium chloride based disinfectant	Betadine[1] microbicide: povidone-iodine solution	Ethanol (ethyl alcohol)	Hydrogen peroxide 3%	Isopropanol (isopropyl alcohol; ipa) 70%	Saline 10%	Lipid hydrocarbon-containing organic compounds; fatty acid derivatives	DEHP diethylhexylphthalate
LEXAN PC RESINS													
Healthcare products													
	HP1R	3	+	+	■	●	+	●	+	+	+		
	HPS2R	3	+	+	■	●	+	+	+	+	+		
	HPS7	3	+	●	■	●	+	+	7 days +	+	+	●	5 days +
	HPX4	3	+	+	■	▲	+	+	+	+	+		
	HPH4404	3	+	+	■	+	+	+	+	+	+		
	HPH4704	3	+	+	■	+	+	+	+	+	●		
Standard products													
	925	7	+	●	■	●	+	+	+	+	+		
	945	7	+	●⚠	■	●	+	+	+	+	+		
	925A	7	+	●	■	+	+	+	+	+	+		
	945AU	7	+	+	■	+	+	+	+	+	+		

Sabic 945AU outperforms just about every resin noted in any of the categories. It is exceptionally suited for a medical environment and is designed for healthcare enclosures. We recommend any of the below cleaners be used while following cleaning protocols outlined in this Supplemental Labeling, including: Bleach sodium mix, Cidex, Virex, Betadine, Ethanol, Hydrogen Peroxide, Isopropyl Alcohol, or Saline Solution. Molekule device enclosure materials, both metal and plastic, have been evaluated for performance in a healthcare environment.

References available on www.molekule.com

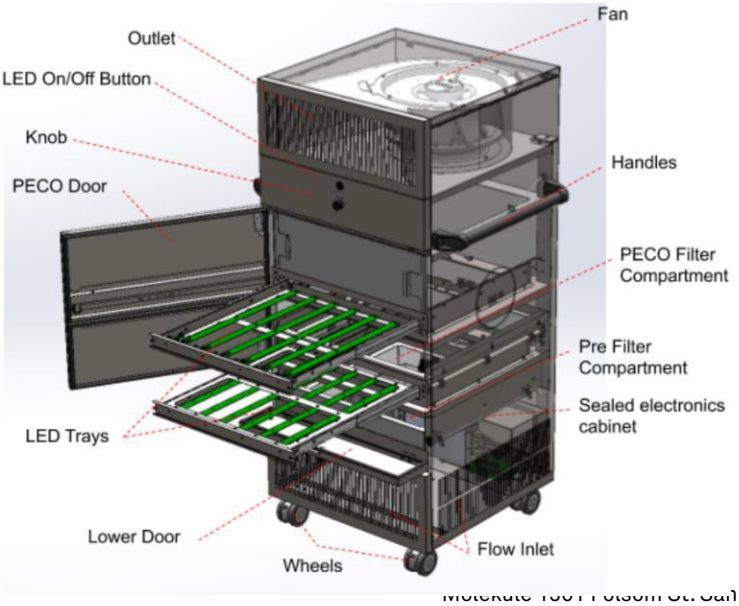
1. Sabic, Resistance + Durability Chemical Resistance Performance Testing for Healthcare Materials
2. Intertek, Molekule Inc. Test Report #104174335COL-001, 26-Dec-2019, Bioburden Testing

Figure 1. Molekule air purifier exterior cleaning locations

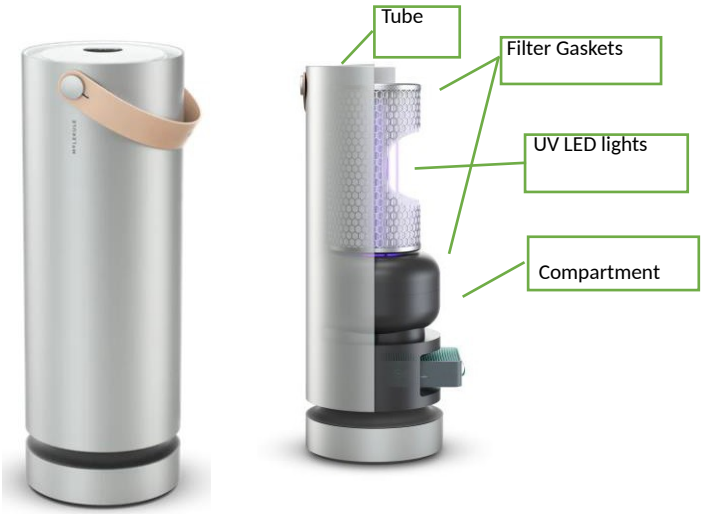
Molekule Air Pro RX

Clean and disinfect all external surfaces, including handles, inlet and outlet vents, knobs and wheels.

Clean and disinfect interior surfaces, including cabinet doors and compartment surfaces. Do not open or attempt to clean LED lights or fan.



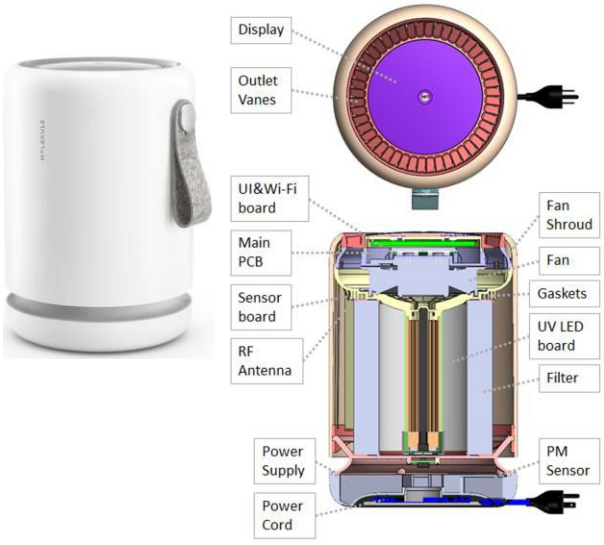
Molekule Air



With handle removed, clean and disinfect all external surfaces, including base, main tube and LED screen.

Clean and disinfect interior surfaces, including tube, covered compartments and filter gaskets. Do not open or attempt to clean LED lights, fan or other electrical components (boards, antenna, etc.)

Molekule Air Mini



With handle removed, clean and disinfect all external surfaces, including base, main tube and capacitive touch buttons on the top of the device.

Clean and disinfect interior surfaces, including tube and filter gaskets. Do not open or attempt to clean LED lights, fan or other electrical components (boards, antenna sensors, etc.)