AEROBIOTIX®

ILLUVIA® SENSE

INSTRUCTIONS FOR USE

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INSTRUCTIONS FOR USE / PACKAGE INSERT

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THIS PRODUCT IS NOT MARKETED IN THE UNITED STATES FOR THE DIAGNOSIS, TREATMENT OR PREVENTION OF ANY DISEASE.

Aerobiotix® reserves the right to change specifications contained in this document at any time without prior notice. If you have questions about the use of this product, contact Customer Service. Refer to the Customer Support section of this manual. For the most current version of the Instructions for Use document, visit the Aerobiotix website.

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GENERAL AND SAFETY INFORMATION

About this Instructions For Use

Congratulations on your choice of this Illuvia® Sense high-performance air handling system. Please study this Instructions For Use carefully to familiarize yourself with the special features and functions of your system prior to use and keep it in a safe place for future reference.

General Information

The Illuvia® Sense is an intraoperative air decontamination system that continuously cleans Operating Room air during occupancy and surgeries for the purpose of reducing airborne microorganisms. The system is an FDA regulated class 2 medical device with the product code FZH, air handling, room, under regulation 878.5070.

Indications For Use

The Illuvia® Sense is an air handling apparatus for surgical operating rooms intended to produce a directed, non-turbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient. The system also contains an internal germicidal ultraviolet system for additional efficacy.

Supplemental Sanitization Claim

The use of this device is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces.

Explanation of Product Symbols

SYMBOL	REFERENCE	TITLE	DEFINITION
	ISO 7010-M002	Refer to Instruction Manual/Booklet	To signify that the instruction manual/booklet must be read.
	ISO 7010-W001	General Warning Sign	To signify a general warning.
	ISO 7000-0434A	Caution	To signify a general caution.
	ISO 7010-W027	Optical Radiation (UV, Visible Radiation, IR)	Take care to avoid injury to eyes and skin when in the vicinty of optical radiation.
	IEC 60417-5019	Protective Conductor Terminal	To signify protective grounding terminal.

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WARNINGS AND CAUTIONS

WARNING: NOT SUITABLE FOR USE WITH SOLID-STATE SPEED CONTROLS.

AVERTISSEMENT: NE CONVIENT PAS A DES REGULATEURS DE VITESSEA SEMI CONDUCTEURS.

WARNING: TO REDUCE THE RISK OF ELECTRIC SHOCK DO NOT EXPOSE TO WATER OR RAIN.

AVERTISSEMENT: POUR RÉDUIRE LE RISQUE DE CHOC ÉLECTRIQUE NE PAS EXPOSER À L'EAU OU À LA PLUIE.

WARNING: TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT EXPOSE TO WATER OR RAIN.

AVERTISSEMENT: AFIN DE RÉDUIRE LE RISQUE DE CHOC ÉLECTRIQUE, NE PAS EXPOSER A L'EAU OU LA PLUIE.

CAUTION: UV lamps contain Mercury. Refer to UV Lamps – Handling and Disposal in the Additional Information section of this manual.

ATTENTION: Les lampes UV contiennent du mercure. Reportez-vous à Lampes UV - Manipulation et élimination dans la section Informations supplémentaires de ce manuel.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

ATTENTION: L'utilisation de commandes ou de réglages ou l'exécution de procédures autres que celles spécifiées ici peuvent entraîner une exposition à des rayonnements dangereux.

General Cautions & Electrical Safety

- Always disconnect the power from this air cleaner by unplugging the power cord before servicing, adding or removing parts and before cleaning.
- DO NOT use the unit in wet environments. If, for any reason, the unit gets moisture of any kind inside stop use and contact Customer Service.
- DO NOT operate in the presence of flammable gasses or liquids.
- DO NOT use the unit for the abatement of asbestos or other hazardous materials.
- Shock and mechanical hazard: Be certain to unplug the unit before performing any service or opening the cabinet.
- Prior to changing the filter or UV-C lamps be sure to turn the unit off, then unplug the power cord.
- The system has an electrical interlock mechanism that automatically shuts the system power off if the cabinet is opened during use.
- DO NOT operate the unit with the filters removed.
- DO NOT operate the unit with the cover removed.
- If visible light (more than a soft blue glow in a dark environment) is detected emanating from the unit, turn off immediately and contact Customer Service.
- If unit is powered on and fan is not operational, excessive or strange noises are heard, smell or smoke is observed or no air movement is detected, turn off and unplug the unit and contact Customer Service.
- DO NOT insert any objects in any of the vent holes on the machine.
- DO NOT exceed the power rating of the unit; this may damage or destroy unit.
- DO NOT use adapters or extension cords.
- DO NOT use this air cleaner as sole protection against harmful pollutants.
- DO NOT operate the unit and unplug the power cord if it has a damaged cord or plug, if the fan fails to rotate, if it is not working properly, if it was dropped or damaged or if it has contacted water.
- Only use this unit for its intended purpose of air cleaning in non-industrial environments.
- DO NOT use this unit in areas with very high concentrations of dust or powder to prevent the danger of dust explosions.
- DO NOT operate the unit with the front panel removed.

- DO NOT use attachments or filters not recommended for Illuvia® Sense.
- DO NOT use outdoors.
- DO NOT obstruct the air inlet and air outlet or sensor panel of the unit or place the unit such that it obstructs external wall, floor or ceiling air vents.
- DO NOT orient the unit side air intake within 3 feet (1 meter) of a doorway.
- DO NOT place the unit on a soft surface such as a bed or other soft furnishings.
- Only use this air cleaner in an upright position.
- DO NOT place next to a humidifier.
- Keep the power cord away from heated surfaces.
- DO NOT stack heavy objects on the power cord; this may result in electric shock or fire.
- Turn the power switch to off before unplugging the power cord.
- Unplug the unit prior to moving to avoid putting strain on the power cord.
- When moving the unit, make sure not to tip or move over uneven surfaces.
- DO NOT stack items on top of the unit.
- Use only on correctly grounded circuits.
- DO NOT allow children or others to climb or sit on unit. Falling of the unit can result in injury.
- DO NOT hang objects from the unit or power cord.
- DO NOT use the unit in a window.
- Use and store the unit in typical indoor settings with standard environmental conditions. Avoid excessive temperature, pressure and humidity.
- Transport the unit in intended shipping container.
- DO NOT modify the unit in any way. Modifications may result in underperformance, inoperability or cause injury to the user.
- UV Lamps, like all fluorescent lamps, contain mercury and must be handled and disposed of properly. Refer to: https://www.epa.gov/cfl for additional information on disposal and recycling of used lamps.
- DO NOT position the unit in a way that is difficult to disconnect the power cord from the wall outlet.
- If used in a manner not specified by Aerobiotix the protection provided by the equipment may be impaired.

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WARNING

The Illuvia® Sense contains four 16-watt ultraviolet lamps. The lamps are designed to decontaminate the airstream from viruses, spores, and bacteria*. The lamps automatically turn on when the system is turned on. NEVER OPERATE THE SYSTEM WITHOUT THE COVER IN PLACE, WITH THE CABINET DAMAGED, OR WITHOUT THE FILTER IN PLACE. PROLONGED EXPOSURE TO ULTRAVIOLET RAYS CAN RESULT IN SKIN OR EYE IRRITATION.

*

Microbes	Type
Bacteria	Staphylococcus epidermidis (S. epidermidis)
Bacteria	Mycobacterium tuberculosis (MTB)
Virus	MS2
Virus	SARS CoV-2
Spore	Bacillus atrophaeus (B. atrophaeus)

WARNING: Skin or eye damage may result from directly viewing the light produced by the lamps in this apparatus. Always disconnect power before re-lamping or servicing. Replace lamp with lamp P/N L1-0040-1, sold by Aerobiotix®.

AVERTISSEMENT : Des dommages à la peau ou aux yeux peuvent résulter de la visualisation directe de la lumière produite par la lampe dans cet appareil. Débranchez toujours l 'alimentation avant de remplacer ou de réparer. Remplacez la lampe par la lampe Référence L1-0040-1, vendue par Aerobiotix®.

You may notice a soft blue glow from the grilles of unit in dark environments. This is normal, and this blue light does not contain ultraviolet rays. Significant ultraviolet exposure can result from ***DIRECT*** exposure to the UV lamps themselves.

OVERVIEW OF INDOOR AIR QUALITY

The Illuvia® Sense is designed to remove contaminants from the air using a combination of filtration and an ultraviolet decontamination system to deactivate microbes from the air.

In order to get the best performance from your system, certain factors should be considered:

- The larger the room, the more time it will take for the unit to complete a full delivery cycle of treated air.
- The sources of air contamination should be considered and reduced as much as possible.
- Ventilation is important to air quality, and a source of fresh air for the room should be available.
- As the unit's filter becomes saturated, soiled or obstructed, the treatment efficiency will decrease. In unusually dirty or dusty environments, filter changes will need to be more frequent.

PACKAGING, LABELING AND STORAGE

Illuvia® Sense and accompanying cartridges are supplied clean. The unit and cartridges are boxed and individually labeled. Boxes and/or pouches should be inspected for damage that may affect the integrity of the packaging prior to use. Use care in handling and storage of the unit and cartridges.

PRE-OPERATION

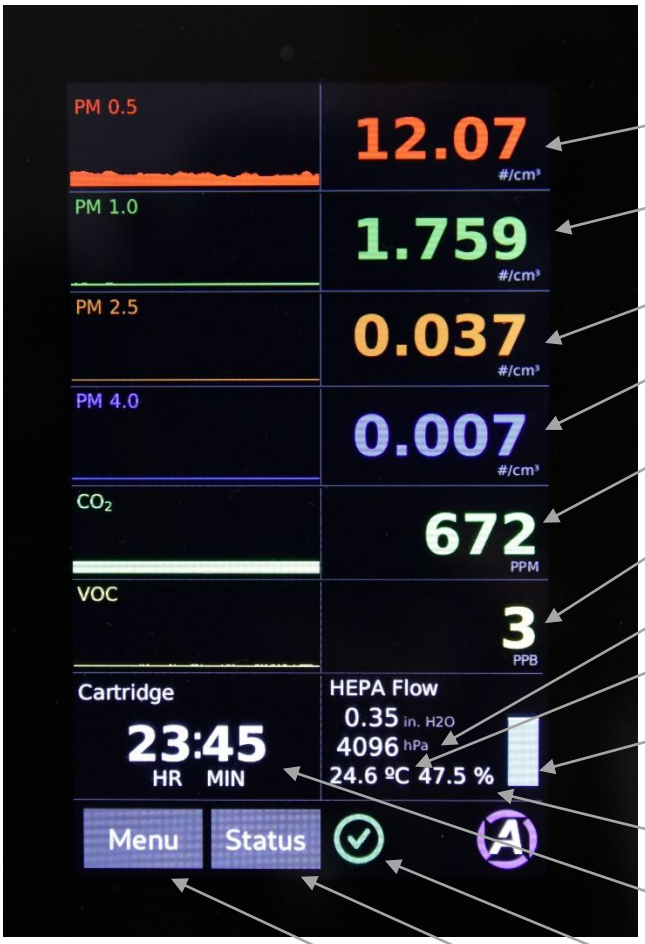
OPERATION

1. Plug the unit into a standard grounded 115 volt AC outlet.
2. Confirm that the unit or cord is not blocking activity/access areas or room vents.
3. Confirm that the unit is placed a minimum of 6 feet (2 meters) from any sterile surface.
4. Confirm that the power cord can easily be accessed for removal from the outlet.
5. The unit has two operation modes, a “STANDBY” mode and an “ON” mode.
6. Depress the power button on the front panel to toggle between the two modes.
7. The unit continues to monitor and record data whenever connect to an outlet, even when in “STANDBY” mode.
8. Ensure cartridges are changed per labelled cartridge requirements.
9. The unit is intended to be active for all times a room is occupied and active including continuous use.
10. Utilize “STANDBY” mode when not actively using the unit for short periods of time. If not being used for an extended period of time, unplug the unit from the outlet.
11. The unit will not be connected to a facility network by default, but only if specifically enabled during setup.

CONTROLS AND DISPLAYS

Main Panel:

POWER
BUTTON



MAIN DISPLAY

0.5 micron particulates count

1.0 micron particulates count

2.5 micron particulates count

4.0 micron particulates count

CO_2 count

VOC count

Barometric Pressure

Temperature

HEPA Differential Pressure

Humidity

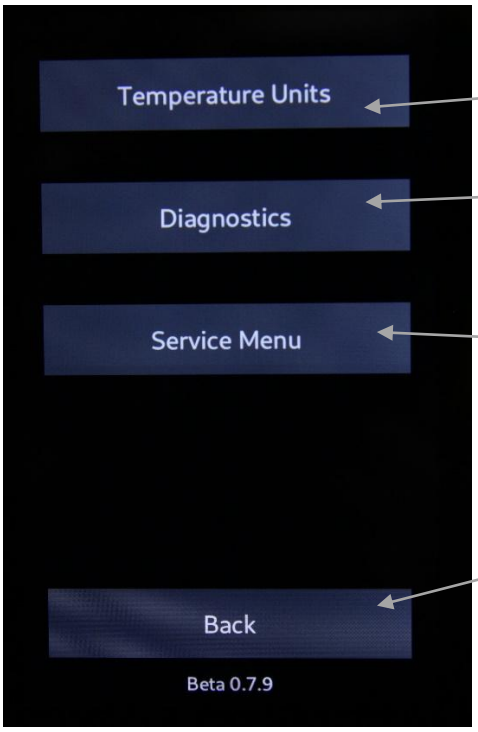
Cartridge Life Remaining

Status Indicator

Status Button

Menu Button

NOTE: Data displayed is for qualitative trend and device function monitoring only. It is not intended to provide diagnostic data for clinical decision making.



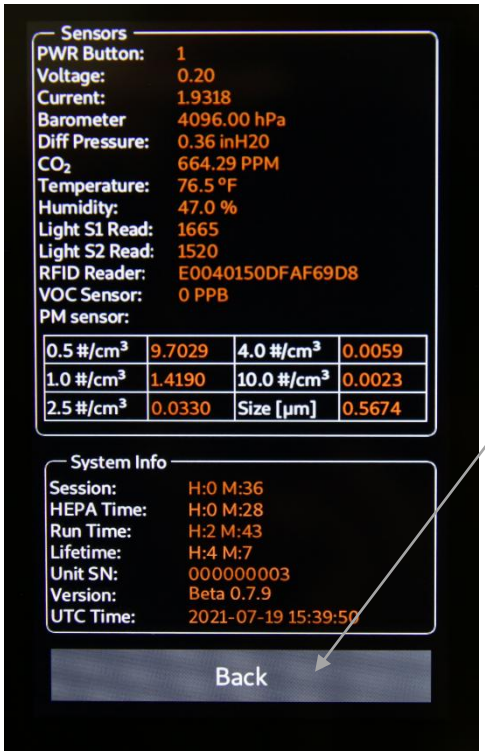
MENU DISPLAY

Temperature Unit Select (F/C)

Open Diagnostic Page

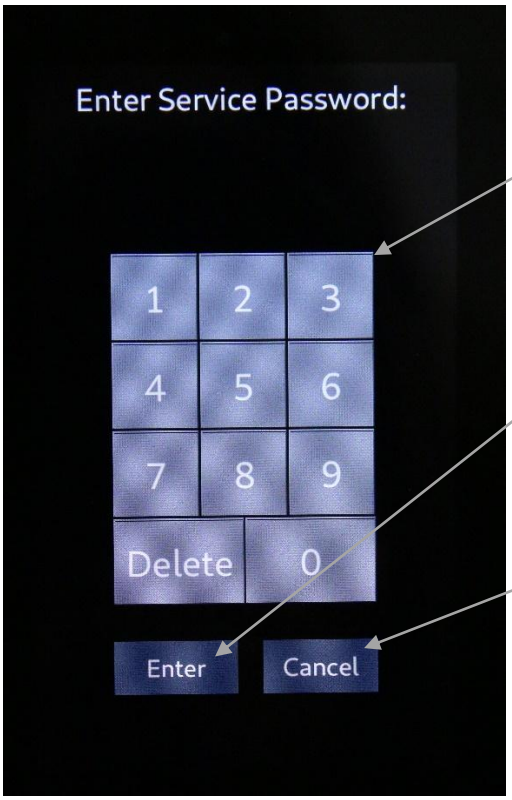
Enter Service Menu

Return to Main Display



DIAGNOSTIC PAGE

Return to Main Display

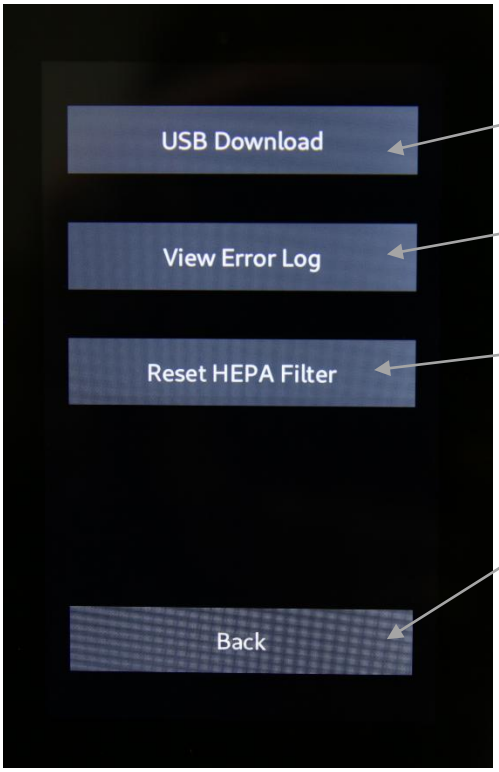


ENTER SERVICE MENU

Numeric Keyboard

Enter Service Menu

Cancel (Return to Menu Display)



BASIC SERVICE MENU

Open USB Download Page

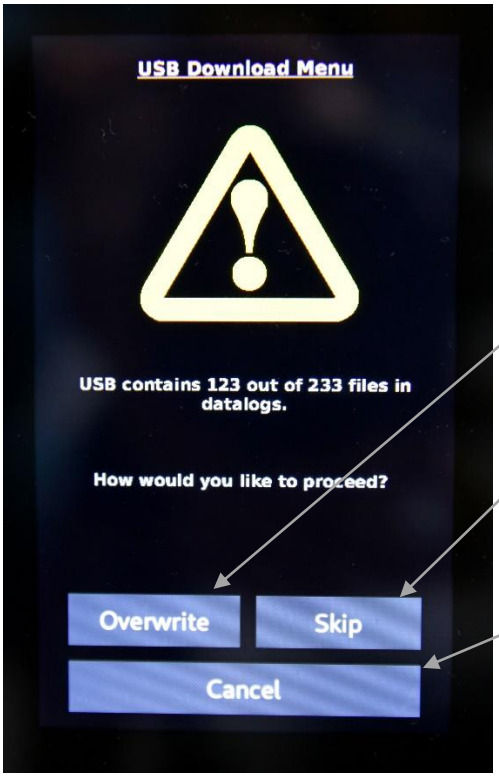
Open Error Log

Filter Reset for HEPA

Return to Main Display

USB DOWNLOAD MENU (No USB)

Return to Service Menu

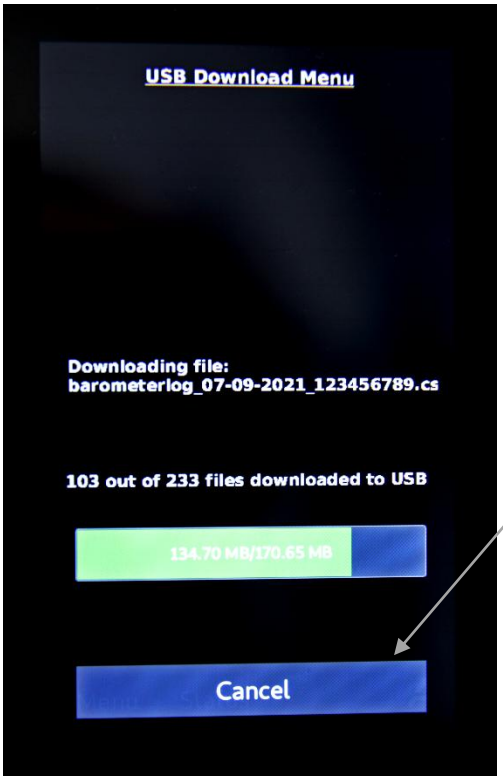


USB DOWNLOAD MENU (Warning)

Overwrite Warning to Continue to Download

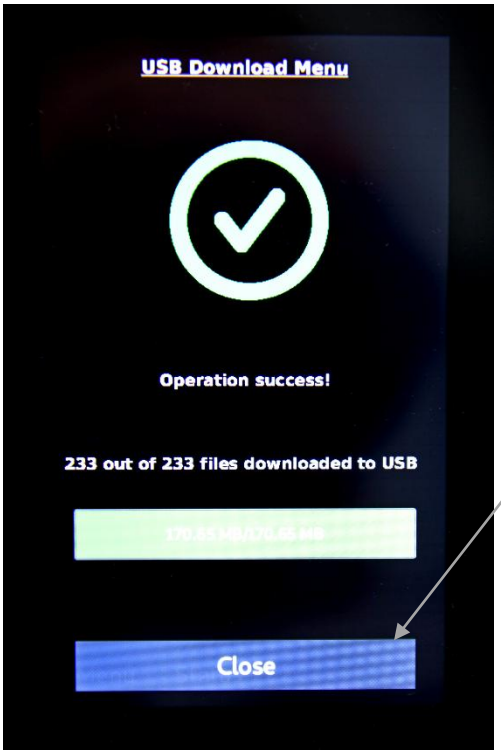
Skip and Return to Main Display

Cancel and Return to Service Menu



USB DOWNLOAD MENU (USB Downloading)

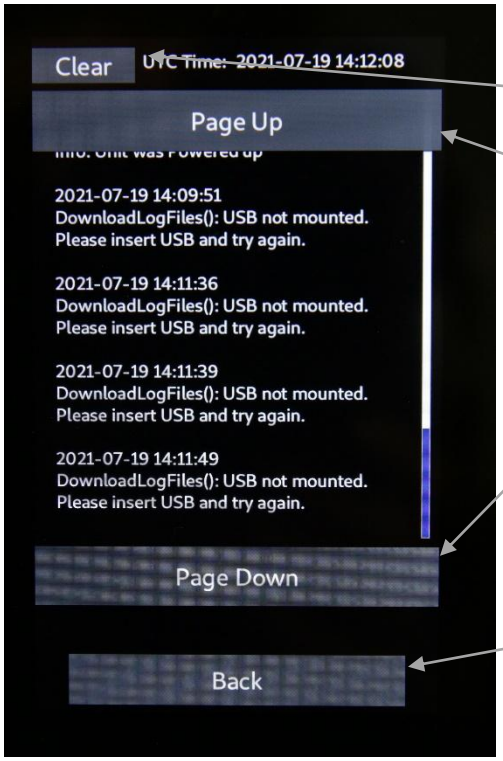
Return to Service Menu



USB DOWNLOAD MENU (USB Download Success)

Close (return to Main Display)

ERROR LOG



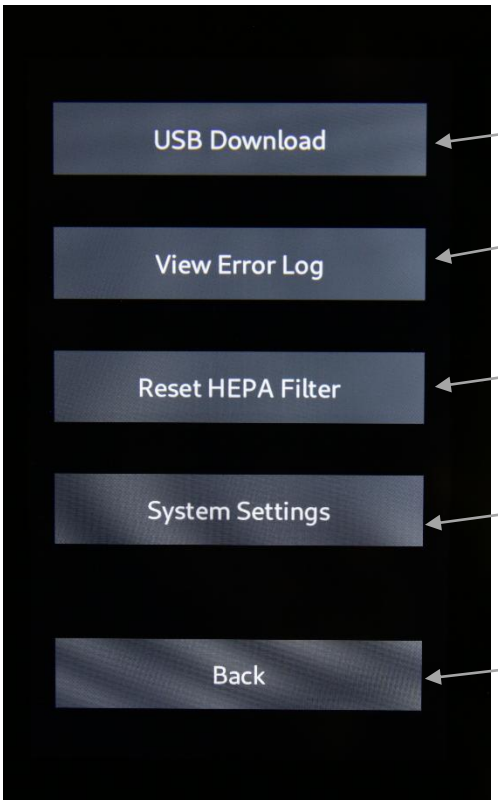
Clear Error Log

Move Page Up

Move Page Down

Return to Service Menu

ADVANCED SERVICE MENU



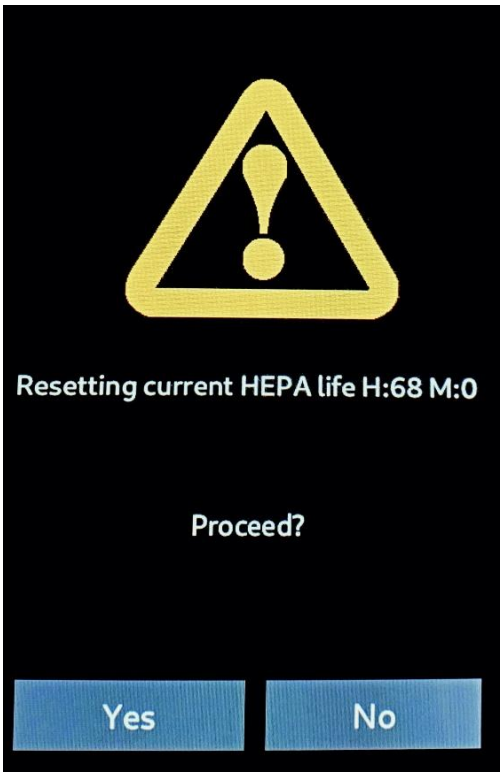
Open USB Download

Open Error Log

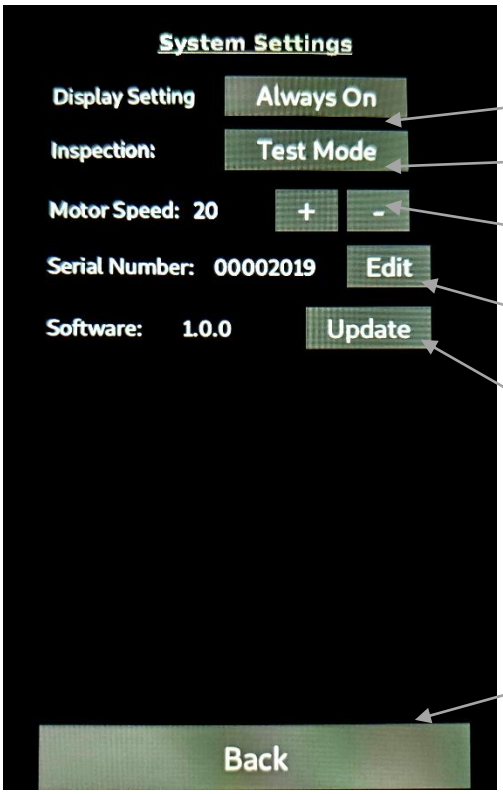
Filter Reset for HEPA Filter

Enter System Settings

Return to main display



RESET HEPA FILTER (Basic and Advanced Menus)



SYSTEM SETTINGS (Advanced Service Menu Only)

Display Setting Select (on with fan/always on)

Enter Test Mode Page

Motor Speed Scale (0 to 20)

Serial Number Editor

Software Update

Return to Service Menu

TEST MODE (Advanced Service Menu Only)

Return to System Settings

Start Test

TEST IN PROGRESS (Advanced Service Menu Only)

Back (return to System Settings)

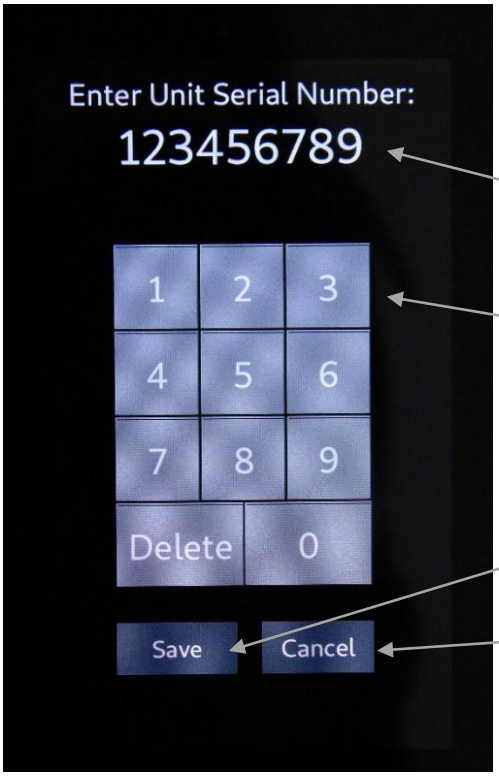
Stop Test (return to Test Mode)

Real Time Clock

File System Version

UV On/Off Toggle

Motor On/Off Toggle



SERIAL NUMBER EDITOR

(Advanced Service Menu Only)

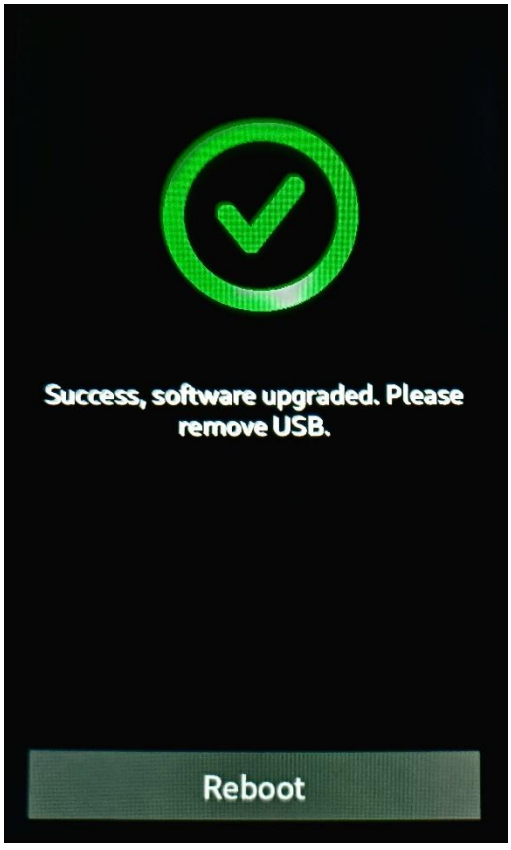
Current Serial Number

Numeric Keyboard

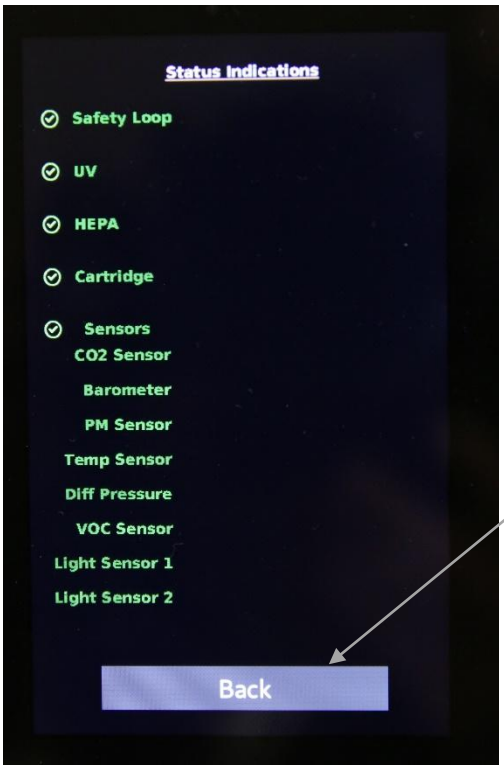
Save Edited Serial Number

Return to System Settings

SOFTWARE UPDATE



SOFTWARE UPDATE (Success)



STATUS DISPLAY

Return to Main Display

CARTRIDGE REPLACEMENT

1. Cartridge replacement is required when the operating room or procedural room is being utilized.
2. Only use an Aerobiotix® cartridge.
3. To remove a used filter cartridge, first turn off the fan and ultraviolet lamps by depressing the button on the front panel. Pull outward on the loop attached to the front part of the cartridge (see arrow, below). If the unit has not been powered down, it will automatically do so when the cartridge is removed.
4. To insert a new cartridge, place the cartridge into the cartridge slot in the front of the unit until it stops. The cartridge should be flush with the device surface. If the device fails to power up after cartridge replacement, confirm that the cartridge is fully seated in the unit.
5. Discard the used cartridge, see Additional Information section for more details.

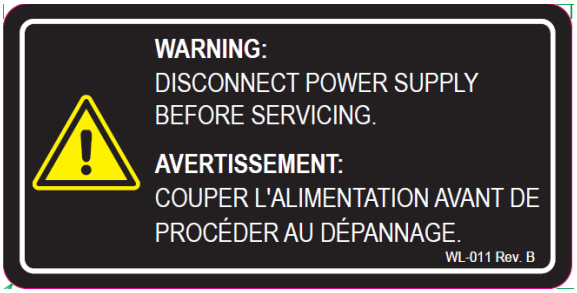
CLEANING

For safe cleaning of the unit, the following is recommended.

1. Power off unit and unplug from the power outlet.
2. Wear PPE as required by facility Infection Prevention and Control procedures.
3. Wipe down the exterior surfaces of the unit following each case with a hospital approved, EPA registered, hospital-grade disinfectant.
4. Follow the manufacturer's instructions for use of the disinfectant.
5. Visually inspect the unit. Repeat cleaning if needed.
6. Do not allow liquids to enter the unit.

MAINTENANCE AND SERVICE

1. DO NOT service any part of the unit while it is in use.
2. All service on the unit must be performed by an Authorized Aerobiotix technician.
3. Prior to each use check the power cord for damage. Do not use if the power cord is cracked, frayed, or has exposed wires. If power cord maintenance is required, contact Customer Service.
4. For service or maintenance needs, contact Customer Service.
5. No routine preventive maintenance is required for the safe operation of the Illuvia Sense.


WARNING:
DISCONNECT POWER SUPPLY BEFORE SERVICING.
AVERTISSEMENT:
COUPER L'ALIMENTATION AVANT DE PROCÉDER AU DÉPANNAGE.
WL-011 Rev. B

WARNING
UV light hazard. Avoid looking directly at light.
UV
AVERTISSEMENT
Risque de lumière UV. Évitez de regarder directement la lumière.
WL-002 Rev.D

WARNING
You MUST read and understand technical manual before servicing this machine.
AVERTISSEMENT
Vous DEVEZ lire et comprendre le manuel technique avant de réparer cette machine.
WL-003 Rev.C

ADDITIONAL INFORMATION

Technical Specifications

Unit

- Width 18 in (460 mm)
- Depth 18 in (460 mm)
- Height 54 in (1,375 mm)
- Weight 150 lbs (68 kg)
- Power 120 VAC / 60 Hz / Single Phase / 8.74 Amps
- Power Consumption 1.0 kW/hr Max
- Power cord length 92 in (2,335 mm)
- Wheel size 4 in (102 mm) Locking Casters
- Airflow rate 450 CFM (765 m^3/hr)
- Decibel level <65 dBA

HEPA Filter

- Width 12 in (305 mm)
- Depth 11.5 in (292 mm)
- Height 24 in (610 mm)
- Media 99.97% HEPA filtration efficiency

Pre-filter Cartridge

- Width 18 in (457 mm)
- Depth 1 in (25.4 mm)
- Height 17 in (432 mm)
- Media MERV 11
- RFID cartridge identifier
- Clear plastic pull tab
- Multi-layer technology: MERV 11 Filter Media / Carbon

Blower / Motor

- Power 1/2HP / 120/208-240 VAC / 50/60 Hz / Single phase / 7.7/5.0-4.3 Amps
- Width 10.6 in (269 mm)
- Diameter 10.4 in (264 mm)
- Airflow sufficient to support 450 CFM unit output

Display

- 2.6 in (65 mm) x 4.3 in (109 mm) TFT LCD, resistive touch screen
- Internal real time air quality monitor:
  - Particle quantity per cm^3 by size
  - Particle size in µm: 0.5 / 1.0 / 2.5 / 4.0 / 10.0 (not displayed)
  - Average particle size in µm
- Temperature / Humidity / Barometric Pressure / Differential Pressure / CO_2 / VOC
- UV-C lamp operation indicator
- HEPA life indicator
- Lifetime run hours
- Session minutes

UV-C Technology

- Patented Photolytic UV-C technology
- UV-C germicidal wavelength of 254 nm

- UV-C is contained within the unit and does not create exposure to staff and patients in the room
  (ASHRAE Airborne Microorganism Testing & UL 61010-1 Testing)
- 4 UV-C lamps for a total 64 W

Input/Output Connections

There are two input/output connections on the Sense Unit, one USB port and one micro SD port. They are located on the right-hand side of the unit.

Environmental Conditions

- Indoor Use
- Temperature 5°-40°C
- Relative Humidity 0-93%
- Maximum Altitude 2000m
- Supply Voltage fluctuations +/- 10%
- Overvoltage Category II
- Pollution Degree 2

Installation Requirements

- No facility modification required
- Mobile unit that can be easily moved

Safety Certifications

- IEC/UL 61010-1 / CSA C22.2 61010-1-12
- IEC 61326-1
- CSA C22.2 #187 Clause 7
- FCC 47 CFR Part 15-C/E
- RSS-247
- ETSI EN 300 328
- ETSI EN 301 893
- ETSI EN 301 489-1 / 489-17
- ETL US/C Listed

Discarding Used Filters

Used filters can normally be discarded per standard institutional sanitation policies. Please refer to local regulations and laws as well as institutional policies for proper handling and disposal.

UV Lamps – Handling and Disposal

UV lamps, like most fluorescent lamps, contain mercury and must be handled and disposed of properly. The mercury is sealed inside of the lamp tube. There is no danger of mercury contact if the lamp tubes remain intact. If the lamp tubes are to break, they also have a protective durable PET outer shell to contain the mercury should it escape the lamp tube. Due to the hazardous nature of liquid mercury and mercury vapor any spill should be treated seriously and cleaned up immediately. Although the amount of mercury in the UV lamps is less than that found in a thermometer, **follow the EPA's suggested mercury thermometer cleaning procedure below.**

Before Cleanup

- Have people leave the room.
- Air out the room for 5-10 minutes by opening a window or door to the outdoor environment.
- Shut off the central forced air heating/air-conditioning system, if you have one.
- Collect materials needed to clean up broken bulb:
    - stiff paper or cardboard;
    - sticky tape;
    - damp paper towels or disposable wet wipes (for hard surfaces); and
    - a glass jar with a metal lid or a sealable plastic bag.

During Cleanup

- **DO NOT VACUUM.** Vacuuming is not recommended unless broken glass remains after all other cleanup steps have been taken. Vacuuming could spread mercury-containing powder or mercury vapor.
- Be thorough in collecting broken glass and visible powder. Scoop up glass fragments and powder using stiff paper or cardboard. Use sticky tape, such as duct tape, to pick up any remaining small glass fragments and powder. Place the used tape in the glass jar or plastic bag. See the detailed cleanup instructions for more information, and for differences in cleaning up hard surfaces versus carpeting or rugs.
- Place cleanup materials in a sealable container.

After Cleanup

- Promptly place all bulb debris and cleanup materials, including vacuum cleaner bags, outdoors in a trash container or protected area until materials can be disposed of. Avoid leaving any bulb fragments or cleanup materials indoors.
- Next, check with your local government about disposal requirements in your area, because some localities require fluorescent bulbs (broken or unbroken) be taken to a local recycling center. If there is no such requirement in your area, you can dispose of the materials with your household trash.
- If practical, continue to air out the room where the bulb was broken and leave the heating/air conditioning system shut off for several hours.

If you have further questions, please call your local poison control center at 1-800-222-1222.

Refer to https://www.epa.gov/cfl for additional information on cleanup of broken lamps or disposal and recycling of used lamps.

CUSTOMER SUPPORT

Call Aerobiotix® Monday through Friday 9AM to 5 PM ET at **888-978-7087.** If your call is made after business hours or on weekends, please leave your name, telephone number, and a brief description of the problem. A Customer Service representative will call back at the earliest opportunity or email info@aerobiotix.com.

You may also visit **aerobiotix.com**.

WARRANTY INFORMATION

Aerobiotix® warrants this Illuvia® Sense product to be free from defects in material, manufacture and design for a period of three years. If this product is defective in materials, manufacture or design during this warranty period, Aerobiotix® will, at its option, repair or replace the product. Repair parts and /or replacement products may be either new or reconditioned at the discretion of Aerobiotix®. This limited warranty does not include service to repair damage from improper installation, improper connections with external electrical fault, accident, disaster, misuse, abuse or modifications to the product not approved in writing by Aerobiotix®. Any service repair outside the scope of this limited warranty shall be at applicable rates and terms then in effect.

All other express and implied warranties for this product including the warranties of merchantability and fitness for a particular purpose are hereby disclaimed. Some states do not allow the exclusion of implied warranties or limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

If this product is not as warranted above, your sole and exclusive remedy shall be repair or replacement as provided above. In no event will Aerobiotix®, or any of its authorized sales and service representatives be liable to the customer or any third party for any damages in excess of the purchase price of the product. This limitation applies to damages of any kind including any direct or indirect damages, lost profits, lost saving or other special, incidental, exemplary or consequential damages whether for breach of contract, tort or otherwise or whether arising out of the use of or inability to use the product, even if Aerobiotix® or an authorized Aerobiotix® representative or distributor has been advised of the possibility of such damages or of any claim by any other party. Some states do not allow the exclusion or limitation of incidental damages for some products, so the above limitation or exclusion may not apply to you.

This warranty gives you specific legal rights, and you may also have other rights that may vary from state to state.

Prop. 65 Warning for California Residents

WARNING: This product may contain chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm.

Manufacturer

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EPA Establishment No.: 101682-OH-1

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Cert. to CAN/CSA Std. C22.2 No. 187