



Mobile air decontamination unit



USER MANUAL

HEPA Sentinel



European Low Voltage Directive (LVD) 2014/35/EU European Electromagnetic Compatibility Directive (EMC) 2014/30/EU

WARNING

We strongly recommend that you fully read these instructions before operating the HEPA Sentinel for the first time (see section 2 – Use).

To make it easier for different types of users to access more detailed information, these instructions consist of 3 sections:

- Section 1: general information.
- Section 2: end user instructions for use.
- Section 3: technical information for servicing and maintenance personnel.

PACKING LIST

- 1 HEPA Sentinel unit.
- 1 HEPA filtration module.
- 1 HQ prefilter packaged in sealed protective film.
- 1 Power supply cable.
- 1 User manual.
- 1 Storage cover.
- Transport case (optional).

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SECTION 1 - GENERAL INFORMATION

1.1 SAFETY INSTRUCTIONS

- **READ THESE INSTRUCTIONS THOROUGHLY** and strictly follow the chronological order of installation, start-up and maintenance steps.
- Do not incline the device to an angle of more than 10° from level ground without support. **Caution**, **risk of tipping over**.
- If stored or transported at low temperatures, wait at least 2 hours before turning on the equipment.
- The device must be used at temperatures from +5°C to +35°C, with relative non-condensing humidity lower than 99%, with dust levels of less than 0.1 mg/m³.
- Do not allow any liquid to penetrate the device.
- Do not place the device near a heat source.
- Never obstruct or cover the device inlet (intake) or outlet (exhaust grille) during operation.
- Do not operate the device without the prefilter.
- Strictly use airinspace[®] supplies to replace the prefilter (see Section 3 §3.9.1 Prefilter management).
- Switch off the device and unplug the mains supply before opening the upper part. Do not place your hands near the fan before it has come to a complete stop.
- Do not twist, stretch or damage the power supply cable.
- Only connect the device to earthed sockets that meet legal requirements and are inspected periodically.
- Unplug the device when not in use for extended periods.

ATTENTION: BEFORE CARRYING OUT ANY WORK ON AN ELECTRICAL COMPONENT, SWITCH OFF THE DEVICE AND DISCONNECT IT FROM THE MAINS.

ATTENTION: WORK ON HEPA SENTINEL (INCLUDING ELECTRICAL CIRCUITS, ELECTRONIC CARDS, FANS, REACTOR MODULES) MUST ONLY BE CARRIED OUT BY **airinspace®** MAINTENANCE PERSONNEL OR DULY TRAINED PERSONNEL.

THE USER IS LIABLE FOR ANY DAMAGE, REGARDLESS OF ITS NATURE, CAUSED BY THE TIPPING OF THE DEVICE OR FAILURE TO COMPLY WITH USAGE RULES AND SAFETY INSTRUCTIONS.

1.2 REGULATORY STANDARD

HEPA Sentinel devices are CE-marked and comply with European regulations:



European Low Voltage Directive (LVD) 2014/35/EU European Electromagnetic Compatibility Directive (EMC) 2014/30/EU

1.3 NORMATIVE STANDARDS

- NF EN 61010-1 (2011). Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements.
- EN 61326-1 (2013). Electrical equipment for measurement, control and laboratory use EMC requirements Part 1: General requirements
- - NF S 90351 (2013). Healthcare establishments Clean rooms and associated controlled environments. Requirements relating to the control of airborne contamination.

1.4 CLASSIFICATION

Type of protection against electric shocks	Class I Earthing for all accessible metallic elements and internal metallic elements.
Level of protection of applied parts against electric shocks	No applied parts
Degree of protection against water and solids	IP 40
	Continuous service
Operating mode	Operation under normal conditions of an unlimited duration without exceeding operating temperature limits.
	Device not suitable for use with flammable anaesthetics mixed with air, oxygen or nitrous oxide.
el of safety when used in the presence of nmable anaesthetics mixed with air, gen or nitrous oxide	HEPA Sentinel is not an AP or APG category medical device. It should always be kept more than 25 cm away from a source of flammable anaesthetics mixed with air, oxygen or nitrous oxide. The user is therefore responsible for positioning HEPA Sentinel accordingly in the room to be treated.
	EN 61326-1 class B standard for conducted and radiated disturbances.
Electromagnetic interference	HEPA Sentinel is suitable for operation in an environment consisting of devices which respect equivalent criteria.

1.5 DESCRIPTION OF THE DEVICE

1.5.1 OVERVIEW



1	Flip-top cover to access the filtration module
2	Control screen + indicator lights
3	Removable faceplate
4	Prefilter access flap
5	Pivoting castor (the front castors are fitted with brakes)
6	Mains plug with double-pole switch and fuses
7	Painted steel chassis
8	Gripping area / handle
9	Electrical connector USB / RJ45

1.5.2 INTERNAL ACCESS



1	Removable outlet grille
2	Filtration module
3	Removable faceplate
4	Ventilation chamber access panel
5	Prefilter

1.5.3 MARKINGS AND WARNINGS

Label	Caption	Position
Product	HEPA Sentinel P/N: CP25000 S/N: HEPA-S-???? made in France airinspace™ - 14 rue Jean Monnet Elancourt 78990 - FRANCE	On the left side of the machine, near the mains socket
Electrical characteristics (according to country)	airinspace () 230 V 50/60 Hz 250 VA max airinspace () 115 V 50/60 Hz 250 VA max IP 40 250 VA max	On the left side of the mains socket (different label depending on the country's voltage)
Fan danger warning	DANGER! VENTILATEUR / FAN Débrancher et attendre arrêt avant intervention Disconnect and wait complete stop before intervention	On the ventilation chamber access panel
Electrical hazard warning	DANGER! Accès réservé maintenance Acces reserved to maintenance	On the ventilation chamber access panel as well as the transformer housing
Earth connection during assembly warning	SERRER / TIGHTEN	On the transformer housing located in the ventilation chamber
Prefilter	airinspace SE made in France HQ Prefilter CP11200-N°	On the prefilter
Reactor module type identification	airinspace 1 HS14-CP01065 N°	On the module
Mains socket fuse	F1 - 5 x 20mm 2 x 3.15 AT	Near the mains socket

1.5.4 SYMBOLS





1.6 FUNCTIONAL DESCRIPTION OF THE DEVICE

1.6.1 INTENDED USE

HEPA Sentinel is a high-performance mobile air filtration unit which captures microorganisms and particles. It is generally positioned in moderate risk areas such as corridors, airlocks and to protect installations while work is being carried out, for example. It significantly reduces contamination and may constitute an initial air purification stage before air is directed to a higher risk area.

1.6.2 OPERATING PRINCIPLES

HEPA Sentinel sucks in, treats and recirculates the air in the room. It quickly abates ambient contamination and maintains it at a low level, thus preventing the risk of hospital-acquired infection.

Its important air recycling rate, 10 to 20 folds the room volume per hour, enables a quick abatement of the average contamination level through dilution process. Typically, a pollution peak generated by a door opening is reduced by 90% in less than 10 minutes.

HEPA Sentinel draws air at floor level and blows it back towards the ceiling, guaranteeing an optimal airflow pattern and reducing stagnant contaminated air zones in the treated room, thanks to the "Coanda" effect. Furthermore, contamination accumulation during activity (nursing or others) is minimized by the proper mixing of the ambient air.



1.6.4 PHYSICAL CHARACTERISTICS

Electrical supply	~ 230 V; 50 Hz or ~110 V; 60 Hz (depending on the version)	
Maximum electrical power	250 VA / 190 W	
Electrical power at rated speed (600 m³/h)	61 VA / 38 W	
Electrical protection	 Isolated by removable power cable Fused Ph + N bipolar switch (3.15A) 	
Volume output	ventilation speeds continually adjustable from 300 m³/h to 1,400 m³/h (maximum output with new prefilter)	
Device noise level according to standard NF-EN ISO 3744:2012 at 1 m / 2 m (new prefilter)	- 400 m³/h 27 dB(A) / < 25 dB(A) - 600 m³/h 32 dB(A) / 28 dB(A) - 850 m³/h 39 dB(A) / 35 dB(A) - 1,200 m³/h 45 dB(A) / 41 dB(A) - 1,400 m³/h 49 dB(A) / 45 dB(A)	
Average velocity of air exiting diffusion grid	1.26 m/s at 1,000 m³/h - equivalent outlet surface = 0.22 m²	
Aerosol filtration efficiency at 850 m³/h (with new reactors and prefilter).	> 99,998% Particle ∅ ≥ 0.3 μm	
Bacteriological cleanliness class	Total flora: M10 from an ACH of 11 vol/h, M1 for an ACH > 23 vol/h <1UFC Fungal flora: from an ACH of 11 vol/h	
Particle cleanliness class	ISO 7 from an ACH of 11 vol/h	
Particle decontamination kinetics class	 CP_{0,5}10 at an ACH of 15 vol/h CP_{0,5}6 at an ACH of 30 vol/h 	
Air treatment capacity (room volume)	Potentially all volumes according to desired level of efficiency. 120 m³ room for an ACH* of 12 vol/h.	
Water/adida wastastina inday	Complete device IP40	
Water/solids protection index	Control panel IP40	
Overall dimensions	H 1,510 x W 750 x D 520 mm	
Footprint	Short side from 355 to 480 mm	
(pivoting castors with offset)	Long side 595 to 720 mm	
HEPA Sentinel weight	114 kg	
Maximum ground loading	543 kg/m² (footprint 355 x 595 mm)	
	Temperature +5 °C to +35 °C	
Environmental operating range	Relative humidity < 95% non-condensit	
	Temperature 0°C to 45°C	
Environmental storage range	Relative humidity 20% to 90%	
	Dust level < 1 mg/m ³	

NOTA: The information contained in this table is for information only. For any information on measurements and tolerance intervals, please contact **airinspace**® at the address given at the end of this document.

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1.7 **INSTALLATION INSTRUCTIONS**

NOTA: if the device is supplied without a carrying case, skip directly to step 3.

Unpacking (optional)

- Move the carrying case as close as possible to a clean, flat floor space.
- 2. Remove the unit from the transport case:



- fit the case access ramp,
- carefully remove the unit from the case.

ATTENTION: DO NOT PULL ON THE FRONT OF THE UNIT.

TO AVOID ANY RISK OF TIPPING WHEN REMOVING FROM THE TRANSPORT CASE, HOLD THE UPPER PART OF THE UNIT WHEN DESCENDING THE RAMP.

Reception

Only move the unit by means of the gripping areas (1) situated on either side at the front of the machine (aluminium profile sections).

Generally, one person is sufficient to move the unit, since it has been sized to fit most doors and lifts.



USE A RAMP TO CROSS BLOCKS ATTENTION: HIGH.

MORE THAN 1 CM

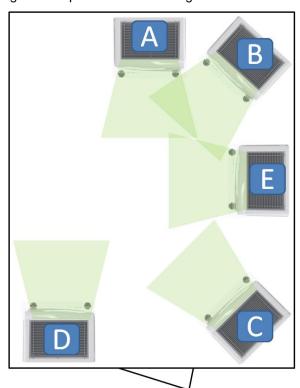
- Once the unit is in the area where it will be used, lock the front wheel brakes.
- 5. Carefully examine the device delivered and check that the items on the packing list are present.
- Remove the prefilter by lifting the prefilter access flap, and unpack it from its plastic bag

- 7. Put the prefilter back in place in the HEPA Sentinel unit (see §3.9.1 Prefilter management).
- 8. Connect the unit to a secure electrical socket. (see §1.6.4 Physical characteristics)
- 9. Switch on the unit and check that it starts up correctly (see §2.2 Start-up).
- 10. Write down any anomalies and damage on the delivery note and notify the distributor or **airinspace**[®]. If you wish to contact the manufacturer or distributor, please make sure to provide the serial number and date of purchase.

Position in the room

For an optimum position, favour the locations shown in the diagram below in the preferred order: A, B,..., E.

Generally, **airinspace**® recommends positioning the unit so that the blown airflow faces the length of the room and covers the largest area possible when taking into account a 90° open coverage range.



NOTA: 1: If the room is already fitted with built-in, unidirectional-flow mechanical ventilation, we recommend that you avoid pointing the HEPA Sentinel unit towards this flow, to the extent that it is possible, to avoid disrupting this flow.

NOTA: 2: If the room is already fitted with built-in mechanical ventilation of the turbulent flow type, we recommend that you position the HEPA Sentinel unit using the previously stated recommendations rather than considering a relative direction to the built-in flow (identical or opposite direction).

1.8 INSTRUCTIONS FOR REMOVAL AND STORAGE

- 1. Switch off and unplug the device.
- 2. Arrange the power supply cable.
- 3. Protect the device using the storage cover.
- 4. Release the brakes on the two front pivoting castors.
- 5. Push the unit to its storage area.
- 6. Lock the brakes on the two front pivoting castors.
- 7. The unit must be stored in a clean area with an atmosphere not polluted by industrial activities.

The unit must be protected from dust, direct sunlight, heat sources, frequent changes in temperature and humidity, potentially corrosive chemicals or other products.

Storage temperature : 0°C to +45°C.

Relative humidity level : 20% to 90%.

Dust level : less than 1 mg/m³.

1.9 TRANSPORT

Before transporting, protect the unit from shocks and scratches.

Transport must be carried out by duly trained and qualified personnel.

Equipment used to handle or lift the unit, alone or in its original case, must comply with applicable legislation (equipment used by the carrier or the user).

Moving the device alone without its original case must only be done using the castors fitted to it. Do not lift using straps or a fork lift.

When transporting, the unit (or the case) must remain vertical, firmly anchored and kept in an enclosed area (not transported in the open air on a platform, for example).

Follow the instructions regarding the transport crate direction:

1.10 DISPOSAL

This product is covered by European Directive 2012/19/EU of 04 July 2012 on waste electrical and electronic equipment (WEEE) and falls within category 6 "Electrical and electronic tools (with the exception of large-scale stationary industrial tools)" as defined in Appendix I to this directive.

Disposal of this product and the recovery of the resultant waste must respect regulations arising from the application of the European directive by the different member states, as well as any local regulations that complement it.

SECTION 2 - USE

2.1 OPERATING PRINCIPLES

The HEPA Sentinel unit has been designed to provide users with a simple and user-friendly interface, regardless of their clearance level. Based on a single software program, it presents different display levels, adapted to everyone's expectations.

2.1.1 USERS AND ACCESS LEVELS

Three levels of intervention are defined for this material:

- N1 level: end user.
- N2 level: technician/maintenance.
- N3 level: manufacturer.

NOTA: Access levels N1 to N3 are protected by access codes.

This manual describes the use of the device for N1 level persons, which involves:

- · starting up,
- · changing the ventilation speed,
- · handling warnings and alerts.

and for N2 level persons, which involves:

- reading the initialisation parameters,
- reading the operating parameters,
- · reading the time counters,
- programming ventilation speeds,
- · replacing prefilters and reactor modules.

2.1.2 USER INTERFACE

main screen



LEDs

1 Green LED Filtration active

2 Yellow LED Warning

3 Red LED Alert

ОК	This icon indicates that the device is working correctly
>	This icon indicates a warning
	This icon indicates an alert
*	This icon indicates ventilation mode: DAY/NIGHT
m³/h	These icons indicate the programmed air flow and room volume
%	Setup Menu Access
Q	Signal that automatic night-time programmer is activated
*	Signal that manual mode is activated
×	Signal that the audible alarm is deactivated

2.2 START-UP

Connect the HEPA Sentinel unit to a power outlet using the 2P+T 10 A power supply cable provided. Make sure the supply voltage matches that of the electrical characteristics label (see table §1.5.3).

ATTENTION: THE ELECTRICAL SUPPLY PLUG MUST COMPLY WITH REGULATORY TEXTS AND BE PERIODICALLY CHECKED.

Toggle the stop-start switch to "1" (see §1.5.1). The switch lights up.

The HEPA Sentinel unit loads the operating programme. The initialisation screen appears (decontamination is not active).



When the HEPA Sentinel unit is booted for the first time, a succession of specific screens appears, where the parameters described hereafter must be adjusted. Otherwise, the main screen comes up directly and decontamination is activated.

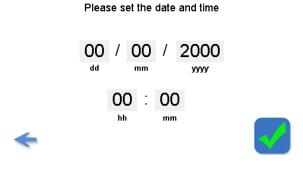
NOTA: Validate the current screen and move to the next screen by pressing the can return to the previous screen by pressing the can.

NOTA: You can reactivate the display of the first boot menu in the machine parameters (see §3.6.2). Once this reactivation has been selected, the first boot menu appears when you next restart the unit.

Interface language selection



Time and date selection



Once the different settings have been saved, the main screen comes up,



NOTA: If no buttons are pressed, the backlight of the screen will decrease after 3 min and turn off after an additional 30s when in Night mode.

NOTA: When restarting after a power cut, the device will automatically run at the previously selected speed.

2.3 RECOMMENDATIONS FOR USE

2.3.1 CHANGE AND CHOICE OF VENTILATION MODE

The HEPA Sentinel unit is programmed with two ventilation modes (Day/Night).

To switch from one mode to another, simply press the icon:



DAY mode on:



NIGHT mode on:



You can set the device to automatically switch from Day to Night mode and vice versa (see §3.5). To effectively eliminate microbiological contamination in a room, the air recirculation rate per hour

(ARH) must be around 20 vol/h in DAY mode



and 15 vol/h in NIGHT mode



(see §

1.6.4 - Physical characteristics).

When starting up, let the unit run in DAY mode for at least one hour in the closed room before the patient arrives.

The device is generally used in DAY mode



NIGHT mode is used to reduce the noise of the device with a view to improving the patient's sleeping comfort or when there are no visits within the area of use.

DAY mode is recommended during biocleaning operations and, more generally, for all activities involving external personnel in the patient's room. When the agitation stops, we recommend



2.3.2 FRESH AIR INTAKE

It is important to minimize the room's door openings to reduce the possible intrusion of contaminants into the protected area. However, a minimum intake of fresh air is recommended, both for patient comfort and the operation of the HEPA Sentinel unit.

ATTENTION:

THE HEPA SENTINEL UNIT HELPS ABATE AIRBORNE CONTAMINATION (PARTICULATE, MICROBIOLOGICAL, VOCS) IN A ROOM. IT CANNOT HOWEVER BE USED TO CONTROL THE TEMPERATURE, RELATIVE HUMIDITY OR SUPPLY OF OXYGEN IN THE ROOM. THIS IS WHY WE RECOMMEND AN INTAKE OF 2 TO 3 VOLUMES OF OUTDOOR AIR PER HOUR.

2.3.3 USE FOR THE CONTAINMENT OF INFECTIOUS PATIENTS

ATTENTION: WHEN THE HEPA SENTINEL UNIT IS USED TO ISOLATE INFECTIOUS PATIENTS OR IS USED IN EXPOSURE TO A HIGHLY INFECTIOUS AGENT, WE STRONGLY RECOMMEND LIAISING WITH THE INFECTION CONTROL DEPARTMENT TO DEFINE THE FRAMEWORK OF THE DEVICE'S DEPLOYMENT.

Applying the precautionary principle to the potential risk of cross-contamination, it is recommended to explicitly label the unit for this type of use in order to prevent a transfer of the material to another application.

However, if an application change is necessary (e.g. for the protection of an immunocompromised patient), it is imperative to contact the Infection Control Department for approval and to define the appropriate prior biocleaning procedure to be performed on the unit. Any intervention by **airinspace**® with regard to this biocleaning operation shall be outside the scope of the manufacturer warranty or service agreement entered into by the establishment for the device in question, if necessary, and subject to a commercial offer issued by **airinspace**®.

2.4 HANDLING WARNINGS AND ALERTS

2.4.1 DEFINITIONS

A **warning** message is displayed when a malfunction leads to degradation of the device's performance (decontamination, pressure drop, sound level) or when a filter needs to be replaced.

NOTA: The warning is indicated by the yellow backlight of the button; ventilation still works but filtration performance may deteriorate. The green LED is no longer on and is replaced with the following pictogram:

Example:



An **alert** message is displayed in the event of a malfunction likely to affect the safety of people or property. An alert systematically causes the fan to shut down. No further filtration function is ensured. The device remains switched on.

NOTA: The alert is indicated by the switching off of the green LED, the lighting of the red LED and the red backlight of the button.

Example:



2.4.2 PROCESSING

2.4.2.1 Displaying an alert or warning

- Press the button to display the warning.
- Press the button to display the alert and stop the audible alarm.
 Example:



Press the button to return to the previous screen.

2.4.2.2 Deleting an alert or warning

Keep the device in operation.

Correct the error (e.g. close the front door left open).

In the event of an alert, press the icon, and in the event of a warning, press the message is displayed. This operation aims to ensure that users are informed of incidents. In case of multiple incidents, various messages will scroll sequentially.

Press the button to return to the main screen.

Alternate Method:

- · Switch off the device.
- · Correct the error.
- · Restart the device.

Example - Prefilter alert:

- Prefilter not present (or prefilter positioned incorrectly), the system goes on alert. The device stops, ok is replaced with off and the alert LED lights up.
- Display the message by pressing the icon. The following screen appears:



- Correct the error by inserting the prefilter more deeply into its drawer.
- Press so that the machine can check whether the fault has been corrected.
- If there are no other faults or alerts, the machine restarts: the OK LED reappears.

NOTA: It is possible to simultaneously process multiple warnings and alerts.

Warnings list 2.4.2.3

Status area display	Warning definition	Fault condition(s)
	Prefilter saturated or clogged warning	Prefilter end of life / Prefilter partially or totally blocked
•••	Prefilter replacement	Time counter > 1 year of operation
5	Level 1 module replacement	Time counter > 4 years of operation
	Insufficient flow (Error V)	Flow 30% lower than the setpoint for 5 minutes
	Saturated or clogged filtering module warning	Module end of life or outlet grille blocked

2.4.2.4 List of alerts

Status area display	Alert definition	Fault condition(s)
	Fan not rotating (Error A)	Fan likely to fail or blocked
OFF	Prefilter missing or incorrectly positioned alert (Error S)	Miniswitch dry contact open
5	Reactor missing or incorrectly positioned alert (Error U)	Miniswitch dry contact open
	Front door alert (Error P)	Miniswitch dry contact open
	Module 1 disabled	Module 1 lifespan exceeded by 6 months
	Prefilter disabled	Prefilter lifespan exceeded by 6 months

SECTION 3 - SOFTWARE MANAGEMENT - CLEANING - MAINTENANCE

3.1 MENU NAVIGATION

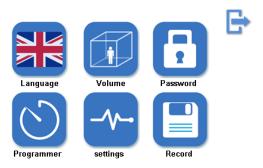
You can browse the settings menu on the HEPA Sentinel unit by pressing the from the main screen:



Access to parameters is protected by a password to be entered in the screen. Enter the access code using the keypad and confirm by pressing 'Enter'.



• If the access code entered (by default: "0001") corresponds with level 1 (User level), the following parameter display screen comes up:



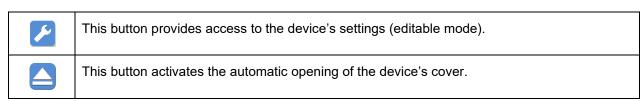
	This button allows you to select the language of the user interface: French, English, German, Spanish or Chinese.
	This button is used to set the size of the room and adjust the ventilation speed depending on the air renewal rate.
•	This button allows you to set different passwords.
$\boxed{\Diamond}$	This button is used to enable or disable the automatic switching between DAY and NIGHT modes and to set the corresponding hours.
- \\-	This button gives you access to the device parameters (read only mode).
	This button gives you access to the recorded data of the device.
	This button allows you to return to the previous screen.

• If the access code entered (by default: "1234") corresponds with level 2 (Technician level), the following parameter supervision screen comes up:



This screen is identical to the main screen, with the exception of:

- The maintenance button , which replaces the parameter display button
- The open cover button —, which is a new feature.



NOTA: You can return to the main screen at any time by pressing the Back key

3.2 LANGUAGE SETUP

From the maintenance screen, press the language selection button ; the flag changes along with all the text in the user interface. Press this button again to scroll through the different languages: English, German, Spanish, Chinese, French.



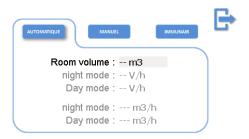
3.3 SETTING PROCEDURES FOR ROOM SIZE AND VENTILATION

From the maintenance screen, press the room size and flow setting button and the following screen comes up:



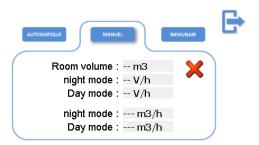
This screen allows you to select 3 different flow setting modes:

• Automatic mode by pressing the key.



The user enters the room size and the device automatically adjusts its flow to guarantee a recycling rate per hour set by default at 20 volumes/h in DAY mode and 15 volumes/h in NIGHT mode.

Manual mode by pressing the key.



The user enters the desired air flows in m³/h for the DAY mode and NIGHT mode, or the volume of the room and the renewal rates in DAY and NIGHT modes. The default values displayed are

the last saved values and the button allows you to delete the information so that you can re-enter it. The minimum ventilation speed must be higher than 300 m³/h. When the manual mode is activated the icon appears on the main screen.

• *IMMUNAIR*™ *mode* by pressing the key.



The screen allowing you to select ventilation modes offers a third option when the HEPA Sentinel unit is connected to an IMMUNAIR™ Fixed Deployable Plenum (FDP) or Mobile Deployable Plenum (MDP). In this case, the IMMUNAIR™ mode must be selected to adapt the ventilation speed of the HEPA Sentinel unit for optimal effectiveness and comfort.



DAY/NIGHT ventilations modes are set to 1,100 and 500m³/h. On the main screen, the icon is replaced with the icon.

3.4 PASSWORD SETTING PROCEDURE

From the maintenance screen, press the password button,

The following screen appears when level 1 access mode (User) has been selected:



You can then reset the password for level 1 (User, by default "0001").

The following screen appears when level 2 access mode (Technician) has been selected:



You can then reset the passwords for level 1 (User, by default "0001") and level 2 (Technician, by default "1234").

3.5 PROGRAMMER SETTING PROCEDURE

From the maintenance screen, press the programmer button.

Automatically switches to night mode

ON

Start time

End time

:

This screen allows you to turn the programmer on or off. If activated, the icon and mod switch times are displayed. The starting and ending hours of the NIGHT mode are editable.

You can disable the automatic switch from DAY to NIGHT mode by pressing the following screen comes up:

Automatically switches to night mode

OFF

Press the icon to switch back to automatic mode.

When the programmer is activated the icon appears on the main screen.

ACCESSING THE PARAMETERS 3.6

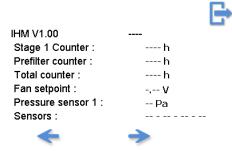
The and arrows at the bottom of the screen allow you to scroll through the parameters pages.

You can return to the main screen at any time by pressing the Back key NOTA:



3.6.1 IN DISPLAY MODE (LEVEL 1-USER)

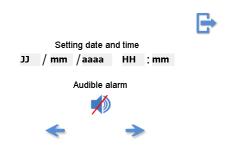
From the maintenance screen, press the parameters display button and the following screen comes up:



This screen displays the software version of the user interface as well as the operation counter of the filtration module (stage 1), the prefilter counter, the total counter, the fan steering setpoint in Volts, the differential pressure at the fan inlet nozzle in Pascals as well as the status of the sensors:

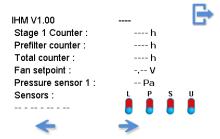
	L=0: Prefilter inserted
Prefilter Sensor (L)	L=1: Prefilter missing
D 0 (D)	P=0: Door closed
Door Sensor (P)	P=1: Door open
D (1) D (1)	S=0: Prefilter not obstructed
Prefilter Pressure switch (S)	S=1: Prefilter obstructed
	U=0: Reactor modules present
Reactor modules sensor (U)	U=1: Reactor module(s) missing

This screen is used to set the time and date. It is also used to activate or deactivate the audible alarm:

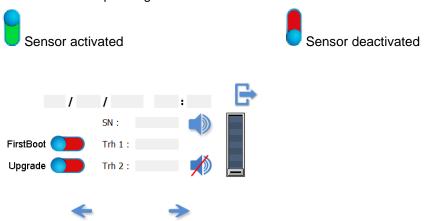


3.6.2 IN SUPERVISION MODE (LEVEL 2-TECHNICIAN)

From the maintenance screen, press the settings supervision button and the following screen pops up:



This screen displays the software version of the user interface as well as the operation counter of the filtration module (stage 1), the prefilter counter, the total counter, the fan steering setpoint in Volts, the differential pressure at the fan inlet nozzle in Pascals as well as the status of the sensors (see table §3.6.1 for details). You can also activate or deactivate the different sensors by pressing the button located under the corresponding letter.

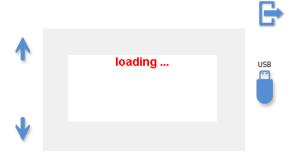


This screen is used to set the time and date, adjust the volume of the audible alarm and/or deactivate this alarm and set the renewal rates per hour for day and night modes. It also allows you to reset the FirstBoot menu and upgrade the programme of the electronic card.

3.7 DISPLAY AND UPLOADING OF RECORDED DATA

From the maintenance screen, press the datalog button

The following screen comes up:



This screen displays the events recorded (alarms or warnings). The operating parameters are also recorded every operating hour.

Press the button to download all recorded data to a USB key that has been inserted into the Datalog port on the side of the device (see §1.5.1 marker no. 9)



NOTA: It is possible to make 10,000 frequency recordings and 1,000 event recordings. Beyond that, the oldest data is overwritten by the most recent.

3.8 MAINTENANCE - BIOCLEANING

We should reiterate that these recommendations are to be compared with any **specific biocleaning** frequencies defined by internal staff for the department in which the HEPA Sentinel unit is used.

airinspace® strongly recommends that users be aware of and, where necessary, increase the frequencies presented herein in accordance with the practices of the department.

NOTA: The biocleaning protocol follows the recommendations for use of the establishment's infection control service.

3.8.1 MAINTENANCE PRODUCTS COMPATIBLE WITH airinspace® equipment

The device is compatible with common disinfectant cleaning products used in hospitals:

- Halogens (chlorinated and iodine products);
- Biguanides (chlorhexidine);
- Alcohol (70° ethanol, 60° isopropyl alcohol);
- Quaternary ammonium compounds (benzalkonium chloride, etc.);
- Oxidising agents (peracetic acid, hydrogen peroxide-based compounds);
- Diamidines (hexamidine);
- Aldehydes;
- Phenolic derivatives, etc.

airinspace® strongly recommends that users verify the choice of disinfectants used, by carefully selecting the biocidal activity standards with which the product must comply (by default, the product is expected to at least comply with the testing standards under standard conditions - phase 1 and in the presence of interfering substances – phase 2.1):

Validation stage	Bactericide	Fungicide	Sporicide	Mycobactericid e	Virucide
Standard – phase 1	EN 1040	EN 1275	EN 14347		
Suspension with interfering substances - phase 2.1	EN 13727 EN 1276	EN 13624 EN 1650	EN 13704	EN 14348	EN 14476 +A1
Areas – phase 2.2	EN 14561 EN 13697	EN 14562 EN 13697		EN 14563	

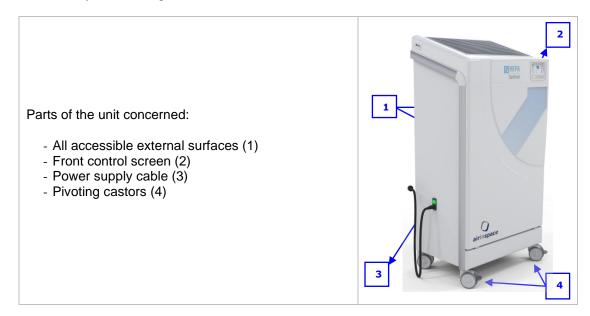
3.8.2 STANDARD PROCEDURE

By default, the standard disinfection procedure applies for maintenance of the HEPA Sentinel unit. In particular it is suitable for maintenance of the unit in the event of exposure to any pathogenic agent other than bacterial spores and germs at risk of airborne droplet transmission.

3.8.2.1 Equipment required

- Single use or recyclable wipes (to be changed after each room)
- Detergent-Disinfectant (DD) graded as Bactericide Fungicide Virucide, in bucket or spray container
- [Step only for annual maintenance of the unit]
- [2.5mm Allen key only for annual maintenance of the unit]

3.8.2.2 Daily Biocleaning



- 1. Prepare the equipment required and the **D**etergent **D**isinfectant solution;
- Using a wipe that has been soaked in the solution or after spraying **DD** directly onto the unit, wipe the disinfectant solution over the relevant parts of the device (see table above), preferably working from top to bottom. Make sure you regularly re-soak the wipe with product, if the disinfectant solution is in a bucket, or spray more **DD** onto the surface if it does not appear sufficiently moist;

ATTENTION: DO NOT SPRAY DD DIRECTLY ONTO THE CONTROL SCREEN. WRING OUT THE WIPE WELL BEFORE APPLICATION TO THIS AREA.

3. Leave to dry.

NOTA: If the surface is very dirty, it should be cleaned with a detergent first: dust with a damp cloth, wash with a detergent solution and rinse.

3.8.2.3 Patient's shifts Biocleaning:

Parts of the unit concerned:

- All accessible external surfaces (1)
- Front control screen (2)
- Power supply cable (3)
- Pivoting castors (4)
- Removable outlet grille (5)



- 1. For parts (1) to (4), apply the full daily biocleaning procedure;
- 2. Disinfect the removable outlet grille (5).

Remove the removable outlet grille and immerse it in the **DD** bucket for 15 minutes. Leave the grille to dry and, if necessary, wipe it with a dry, soft, lint-free cloth. Reposition the dry grille.

ATTENTION: DO NOT SPRAY OR DIRECTLY WIPE DD ONTO THE OUTLET GRILLE WHEN FITTED TO THE **HEPA** SENTINEL UNIT AS THIS COULD DAMAGE THE FILTRATION MODULE.

3.8.2.4 Yearly biocleaning

ATTENTION:

SINCE YEARLY BIOCLEANING OF THE UNIT REQUIRES ACCESS TO INTERNAL PARTS OF THE UNIT, IT MUST BE CARRIED OUT BY DULY AUTHORISED MAINTENANCE PERSONNEL.

BEFORE ACCESSING THE INTERNAL PARTS OF THE HEPA SENTINEL UNIT, SWITCH OFF THE DEVICE. UNPLUG THE EQUIPMENT AND TAKE ALL THE PRECAUTIONS NECESSARY TO ENSURE THAT IT CANNOT RESTART BY ACCIDENT.

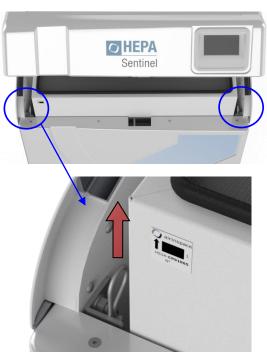


Stop the HEPA Sentinel unit using the I/O switch and disconnect from the mains by unplugging the power cord (1).

Open the tilt door of the unit by unlocking the closing system (2):

- Remove the outlet grille from the HEPA Sentinel unit and pull on the tab located in the pipework (see arrow below):





Remove the front panel:

Remove the two pins holding the front panel by pulling them up.

Grab the panel and gently pull it forward to release the two guide tabs, then upward to release it from the two pins at the bottom of the façade.

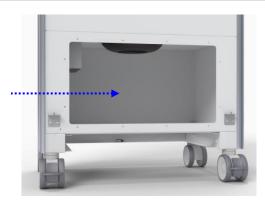
Parts of the unit concerned: - All accessible external surfaces (1) - Front control screen (2) - Power supply cable (3) - Pivoting castors (4) - Removable outlet grille (5) - Suction chamber (6) - Internal door surfaces (7) - Internal bodywork (8) - Blowing pipework (9) - Prefilter housing (10)

- 1. For parts (1) to (4), apply the daily biocleaning procedure.
- 2. For part (5), remove the removable outlet grille. Immerse the outlet grille in the **DD** bucket for 15 minutes. Leave the grille to dry and, if necessary, wipe it with a dry, soft, lint-free cloth.
- 3. Disinfect internal parts (6) to (10). The fan can be accessed from above; simply remove the filtration modules to clean the fan chamber (see §3.9.2.4).

10



Clean the inside surface of the front door, the modules cabinet and the newly accessible parts of the bodywork, then remove the suction chamber access panel using a 2.5 mm Allen key (x12 screws).



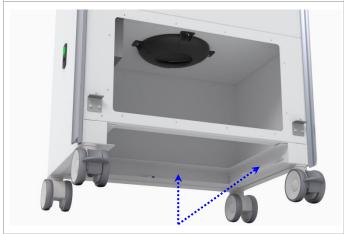
Clean the internal surface of the suction chamber access panel, then clean the walls of the internal cavities as well as the fan blades. The fan can be accessed from above, once the filtration modules have been removed.



Beware of danger: take care not to cut yourself on the fan blade ends.

Caution: do not spray any **DD** onto the prefilter of the unit at the base of the suction chamber or onto the foam pad underneath the fan.

Replace the access panel using screws and the 2.5 mm Allen key.



Clean the prefilter housing using a lint free soft cotton cloth or wipes soaked in disinfectant product.



After removing the removable outlet grille for maintenance, carry out cleaning on the outlet pipework. Where appropriate, use a step to facilitate access to this part of the HEPA Sentinel unit.

Caution: do not spray any DD directly into the outlet pipework as this may damage the filtration module (if there is one in the machine).

Put the grille back in place after cleaning.

3.8.3 OTHER PROCEDURES

The maintenance/biocleaning procedures recommended by ${\bf airinspace}^{\it @}$ depend on the nature of the germs encountered

3.8.3.1 Selection of the applicable disinfection procedure:

Transmission mode	Type of germ / Pathology	Necessary microbial activity of the disinfectant product	Applicable procedure	
Contact	Vegetative bacteria	Bactericide	Standard	
	BMR			
	Fungal	Fungicide		
	Virus	Virucide	1	
	Bacterial Spores (sp. C. difficile*)	Sporicide (* Bleach 2.6% diluted 1/5th)	Spores	
	Tuberculosis	Active mycobacteria	Air	
	Pertussis			
	Diphtheria	Bactericide		
"Air": Airborne + Droplets	Bacterial meningitis			
	Scarlet fever			
	Other bacteria			
	Measles			
	Chickenpox			
	Flu	Virucide		
	Adenovirus			
	RSV			
	Viral meningitis			
	Other virus			

3.8.3.2 Cleaning frequency:

Scope of biocleaning	Procedures "Standard" / "Spores"	Procedures "Air"
Accessible external surfaces	daily	daily
Removable grille	with each new patient	with each new patient
Blowing pipework	yearly	with each new patient
Prefilter hatch	yearly + Long term stoppage or move (see section 2.3.3)	yearly + Long term stoppage or move (see section 2.3.3)
Internal parts	yearly	yearly

3.9 MAINTENANCE

ATTENTION:

AS PART OF A SERVICE AGREEMENT, MAINTENANCE AND REPAIR OF THE DEVICE DURING ITS LIFETIME ARE THE RESPONSIBILITY OF THE MANUFACTURER OR AN AUTHORISED SERVICE CENTRE.

HOWEVER, THE PREFILTER, FILTRATION MODULES AND FUSES CAN ONLY BE REPLACED BY DULY AUTHORISED MAINTENANCE PERSONNEL.

To guarantee maximum efficiency at all times, the HEPA Sentinel unit's consumable parts (prefilter and filtration modules) have limited lifespans managed by time counters.

When the expected lifetime of a consumable part has been achieved, a warning message appears on the unit screen, indicating that it should be replaced (see image below for illustration). If the expired consumable part is not replaced within 6 months of the appearance of the message, the unit will default, making it impossible to use until the consumable part in question has been replaced and the corresponding counter has been reset.

Example:



Time remaining before the unit shuts down.

3.9.1 PREFILTER MANAGEMENT

3.9.1.1 Description of the prefilter stage

The prefilter, located at the base of the HEPA Sentinel unit, protects the device's internal components against airborne macroparticles and excessive dust accumulation.

To ensure this protection, **airinspace**® recommends and implements a prefilter with bespoke chemical filtration on all new HEPA Sentinel units (available by contacting **airinspace**®, product code CP11200).

3.9.1.2 Prefilter risk analysis

The prefilter has an exposed external surface through which air enters the HEPA Sentinel unit for treatment. Particles and macroelements are collected on the surface of the filtrating media, which is located at the base of the unit, 12 cm from the ground. It cannot therefore be accessed directly by healthcare personnel or patients. In addition, when the unit operates, the depression produced by suction makes it impossible for the accumulated elements to detach themselves.

To prevent the detachment of any hazardous materials from the surface of the prefilter when the unit is not in operation or during maintenance operations, airinspace® makes the following recommendations.

3.9.1.3 Prefilter replacement

a- Replacement procedure

To guarantee continued decontamination performance by the HEPA Sentinel unit over time, the prefilter should be replaced once the prefilter saturation warning appears on the control screen. This signal is managed by the unit according to the measured prefilter pressure drop as well as operating time. On average, it occurs after a period of 6 months to 1 year depending on the level of dust in the environment.

ATTENTION:

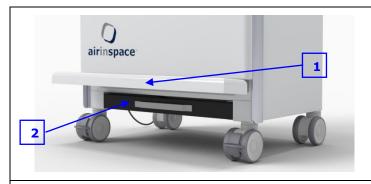
TO AVOID POTENTIAL EXPOSURE OF THE PATIENT TO MATERIAL FROM THE EXTERNAL SURFACE OF THE PREFILTER DURING THE REPLACEMENT PHASE, **airinspace**® RECOMMENDS MAKING THIS REPLACEMENT BETWEEN TWO PATIENTS WHENEVER POSSIBLE.

IF THE ESTIMATED PATIENT CHANGE IS MORE THAN THREE WEEKS AFTER THE APPEARANCE OF THE PREFILTER SATURATION WARNING, IT IS POSSIBLE TO ENVISAGE CHANGING THE PREFILTER IN THE PATIENT'S PRESENCE BUT THEY MUST BE PROTECTED BY A FACE MASK.

THEY MUST CONTINUE TO WEAR THE MASK THROUGHOUT THE REPLACEMENT PROCEDURE.

IN ADDITION, PERSONNEL CARRYING OUT THE PROCEDURE ARE ADVISED TO WEAR GLOVES AND A PROTECTIVE MASK DURING THE PREFILTER EXTRACTION OPERATION.

FINALLY, RUN THE HEPA Sentinel UNIT FITTED WITH A NEW PREFILTER FOR 30 MINUTES BEFORE RESUMING VENTILATION IN DAY MODE.



Leave the device running throughout the operation (the HEPA Sentinel unit will stop by itself once the prefilter has been extracted).

Lift the inspection hatch (1) at the bottom of the device to access the prefilter (2).



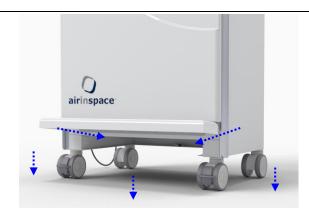
Place a Biohazard type bag [110 litres – 700 x 1,050 mm] around the inspection hatch of the HEPA Sentinel unit.

Cover the prefilter frame with the bag, hold the bottom of the bag and grab the flexible handle of the prefilter.

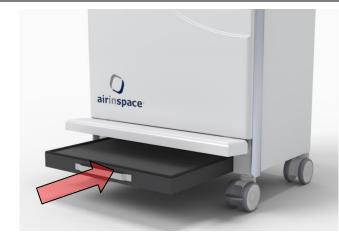
Slowly guide the prefilter into the bag.

Device ventilation stops and the "Alert: prefilter missing or incorrectly positioned" message is displayed on the control screen.

Close the Biohazard bag as soon as the entire prefilter is inside.



Clean the opening of the prefilter drawer housing, the inside of the prefilter inspection hatch and the floor around and under the unit (within a 30 centimetre radius of the equipment), using a lint-free, soft, cotton cloth or wipes soaked in disinfectant product.



Install the new prefilter while respecting the direction of airflow: foam gasket on top of the prefilter, arrow on the prefilter label showing the direction of airflow see §1.6.3).

Reset the prefilter counter (see §3.9.4 – Resetting a counter).

Dispose of the used prefilter in accordance with the regulations in force within the establishment (see c-Disposal)

b- Traceability

airinspace® recommends establishing a traceability document in which to record each prefilter change.

c- Disposal

ATTENTION: AS THE USED PREFILTER IS HIGHLY LIKELY TO CARRY DUST CONTAINING BIOLOGICAL CONTAMINANTS, airinspace® RECOMMENDS DISPOSING OF THIS PREFILTER IN ACCORDANCE WITH APPLICABLE REGULATIONS FOR THE TREATMENT OF SPECIAL WASTE (E.G. BIOHAZARDOUS MEDICAL WASTE TREATMENT).

The materials making up the prefilter are polystyrene for the frame, polyurethane for the foam gasket and glass microfibre with synthetic fibre and active charcoal for the filter medium.

3.9.1.4 Unit switched off, removal of a part or storage

When the HEPA Sentinel unit is stopped, the depression produced by suction is interrupted and elements collected on the external surface of the prefilter may become detached, in particular if the unit is handled.

airinspace® therefore recommends disinfecting surfaces potentially exposed to falling aggregates, using an appropriate solution (see §3.8 - Maintenance - Biocleaning), in accordance with the following instructions:



Spray **D**etergent-**D**isinfectant (DD) on the floor around and under the unit (within a radius of 30 centimetres around the device) - gently wipe the **DD** residue and inactive aggregate materials using a soft, lint free cotton cloth or wipes.

This deactivation step must be completed before the device is handled.

When the HEPA Sentinel unit must be removed from a room in the presence of a patient, this patient must be protected by a face mask. This protection must be maintained for the whole of the shutdown procedure described above as well as when the equipment is moved out of the room.

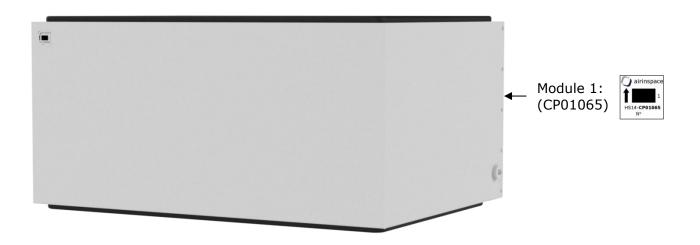
ATTENTION: IN SPECIFIC CASES WHERE THE UNIT MUST BE TRANSFERRED FROM A SEPTIC ZONE (ROOM WITH INFECTIOUS PATIENTS FOR EXAMPLE) TO AN ASEPTIC ENVIRONMENT, THE PREFILTER MUST BE CHANGED BEFORE THE DEVICE IS MOVED TO THE ASEPTIC ZONE.

NOTA: It should be pointed out that, when the unit is used for septic isolation or when it is exposed to highly infectious agents, airinspace® strongly recommends that users contact the establishment's hygiene department to define the scope of the device's deployment, notably with regard to any changes of area. In addition, in accordance with the principle of precaution with regard to any risk of cross contamination, we recommend that you explicitly label the unit if it is used for septic containment

3.9.2 CHANGING THE FILTRATION MODULE

The filtration module can only be changed by personnel with sufficient knowledge, duly trained and authorised by airinspace[®].

3.9.2.1 Description of the filtration module



3.9.2.2 Tools required:

• None.

3.9.2.3 Recommendations:

- Do not replace the filtration module in the presence of patients.
- Keep the new filtration module in its original packaging until installation. During installation, take every precaution to avoid damaging or soiling the new module: clean hands, clean storage medium, handle the module with the outside envelope only.
- Run the HEPA Sentinel unit in DAY mode (icon on screen:) for 30 minutes following the operation.
- Make sure the used module and associated packaging are disposed of in accordance with the environmental protection rules and special waste regulations in force within the establishment.

3.9.2.4 Removal procedure

ATTENTION:

DANGER! BEFORE WORKING ON THE HEPA SENTINEL UNIT, SWITCH OFF THE DEVICE, UNPLUG THE UNIT AND TAKE ALL NECESSARY PRECAUTIONS TO PREVENT ANY INADVERTENT RESTART.



Open the upper cover of the unit by pressing

the button, which can be accessed via the touchscreen in supervision mode (level 2 - technician), see §3.1.

Beware: as the cover opens automatically, do not stand above the machine during opening.

Stop the HEPA Sentinel unit using the I/O switch and disconnect from the mains by unplugging the power cord (1).



Remove the front panel:

Remove the two pins holding the front panel by pulling them up.

Grab the panel and gently pull it forward to release the two guide tabs, then upward to release it from the two pins at the bottom of the façade.



Remove the module to be replaced by holding it by its sides and pulling forward.

3.9.2.5 Fitting operation

Carry out the fitting operation in the opposite order to removal. Reset the replaced module's counter (see §3.9.4 – Resetting a counter).

3.9.3 CHANGING A FUSE

Two fuses (3.15A T) protect the elements of the electric circuit. They are located near the mains socket (marker 6 §1.5.1 - Overview).

3.9.3.1 Tools required:

- A multimeter to measure resistance and voltage.
- A small flat screwdriver to facilitate the opening of the drawer and removing fuses.

3.9.3.2 Fuse Replacement procedure



3.9.4 RESETTING A COUNTER

3.9.4.1 Consumable part replacement frequency

Reminder:

To guarantee maximum efficiency at all times, the HEPA Sentinel unit's consumable parts (prefilter and filtration module) have limited lifespans managed by time counters.

When the lifespan of a consumable part is reached, a warning message appears on the unit screen indicating that it should be replaced. If the expired consumable part is not replaced within 6 months of the appearance of the message, the unit will default, making it impossible to use until the consumable part in question has been replaced and the corresponding counter has been reset.

The following table indicates the replacement frequency of the HEPA Sentinel unit's consumables.

Consumable part designation	Maximum lifespan
Stage 1 module - HS14 - Filtration	4 years
Prefilter	1 year

3.9.4.2 Counter reset procedure

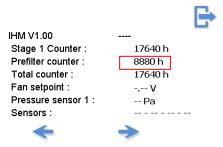
Once the consumable part has been replaced (see §3.9.1 for the prefilter and §3.9.2 for a module), the associated time counter must be reset. The reset procedure described below is applicable to each of the unit's consumable parts.

Example: resetting the prefilter time counter

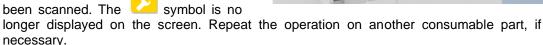




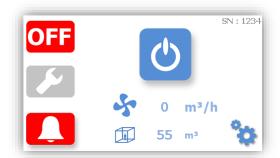
Check the counter in the settings:



- Replace the prefilter (see §3.9.1)
- Open the upper cover of the unit using the found in the parameters, technician level (see §3.1).
- Extract the NFC reader located inside the flip-top cover, by rotating it slightly to release it from its holder.
- Use the NFC reader to scan the prefilter label (simply apply the flat part of the reader onto the label for 2 seconds). An audible beep indicates that the label has

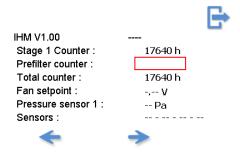


- NOTA: An ascending beep indicates that the machine has correctly recognised the consumable part and that the counter has been reset. A descending beep indicates a problem with the consumable part (part used in another machine, well-worn, already scanned or incompatible).
- Store the NFC reader in the space provided for this purpose by securing it back on its holder.
 Carefully replace the spiral cord of the NFC reader to avoid any pinching when closing the cover.
- Close the tilt door of the unit and restart the machine by pressing the button



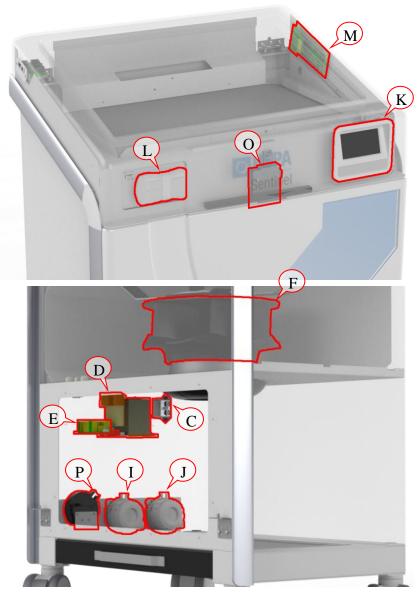


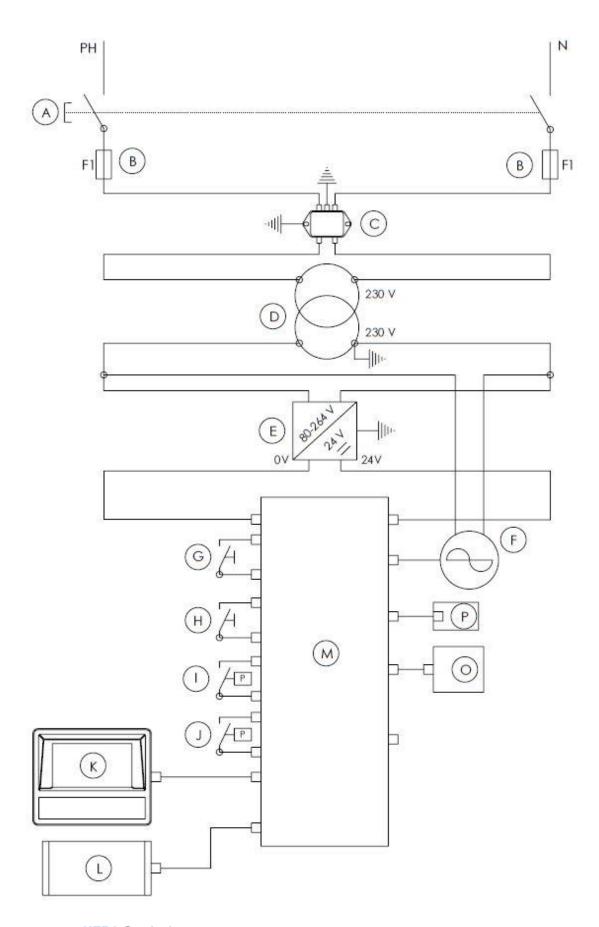
• Check the counter in the settings:



3.10 FUNCTIONAL ELECTRICAL DIAGRAM

Reference	Description	Description
Α	Power supply socket	Power supply socket
В	Fuses	Fuses
С	EMC power-line filter	EMC power-line filter
D	Isolating transformer	Isolating transformer
Е	24 VDC power supply	24 VDC power supply
F	Fan	Fan
G	Prefilter switch	Prefilter switch
Н	Reactor sensor	Reactor Sensor
I	Reactor differential pressure switch	Reactor differential pressure switch
J	Prefilter differential pressure switch	Prefilter differential pressure switch
K	Tactile user interface	Tactile user interface
L	NFC reader	NFC reader
M	Controller board	Controller board
0	Electromechanical rotary lock	Electromechanical rotary lock
Р	Fan differential pressure sensor	Fan differential pressure sensor





3.11 DISTRIBUTOR WARRANTY

Contact your local airinspace® dealer.

Note: any problems arising from an unauthorised repair attempt, modification, fall, use at incorrect voltage or operations that do not comply with the instructions in the User Manual are not covered by the warranty.

3.12 MODEL IDENTIFICATION

If you wish to contact **airinspace**® or a dealer, please make sure to provide the serial number of the HEPA Sentinel unit and its date of purchase:



CONTACT airinspace®

airinspace® S.E.

14, Rue Jean Monnet 78990 Elancourt France +33 1 30 07 01 01

= +33 1 30 07 01 02

contact@airinspace.com
www.airinspace.com