



MOBILE AIR DECONTAMINATION UNIT







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

WARNING

We strongly recommend that you fully read these instructions before operating the **PLASMAIR**^{$^{\text{m}}$} for the first time (see section 2 – Use).

This user manual is divided into 4 sections:

- Section 1: General information.
- Section 2: Operating instructions for the end user.
- Section 3: Technical information for maintenance personnel.

For **IMMUNAIR™** Fixed Deployable Plenum (FDP) or Mobile Deployable Plenum (MDP) configuration types, please see the corresponding instructions.



PACKING LIST

- **PLASMAIR**[™] Guardian **Unit**.
- 1 reactor set of 4 HEPA-MD modules.
- 1 HQ prefilter packaged in sealed protective film.
- Power supply cable.
- User Manual.
- Storage cover.
- Transport case (optional)

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GENERAL INFORMATION

1.1 SAFETY INSTRUCTIONS

- **READ THESE INSTRUCTIONS THOROUGHLY** and strictly follow the chronological order of installation, operation, storage and maintenance steps.
- Do not incline the device without support at an angle greater than 10° in relation to the floor. **Caution, it may topple over.**
- When storing or transporting the machine in cold conditions, wait at least 2 hours before operating the device and then run it alone an additional hour before using it with a patient.
- The unit should be used at room temperature and humidity, with dust levels below 0.1 mg/m3.
- In case of intense bio-cleaning of the room where the equipment is installed, it is strongly recommended to temporarily stop its operation to prevent potential release of bad smells from stage 4 of the HEPA-MD technology induced by relative humidity peaks.
- Do not let any liquid penetrate the system.
- Do not place the device near a heat source.
- Do not use the device in the presence of flammable gas.
- Never obstruct or cover the equipment 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 equipment and unplug the mains supply before opening the front door. 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.
- Plug the device exclusively into outlets that meet safety regulations, have been regularly inspected and are grounded.
- Unplug the device when not in use for extended periods.

ATTENTION : BEFORE ANY INTERVENTION CONCERNING AN ELECTRICAL ELEMENT, TURN OFF THE DEVICE AND UNPLUG IT.

ATTENTION : WORK ON THE PLASMAIR[™] (ELECTRIC CIRCUIT, ELECTRONIC CARDS, FAN, REACTOR MODULES IN PARTICULAR) MUST ONLY BE CARRIED OUT BY airinspace[®] PERSONNEL OR DULY QUALIFIED PERSONNEL.

ANY DAMAGE CAUSED BY THE DEVICE TRIPPING OVER OR FAILURE TO RESPECT INSTRUCTIONS FOR USE AND SAFETY RULES ARE THE SOLE RESPONSIBILITY OF THE USER.

1.2 REGULATORY STANDARD

PLASMAIR[™] Guardian equipment carry CE marking and comply with European regulations:

(F

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

1.3 NORMATIVE STANDARDS

- NF EN 61010-1 (2011 + A1 2019). Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements.

- EN 61326-1 (2021). Electrical equipment for measurement, control and laboratory use - EMC requirements. Part 1: General requirements

1.4 CLASSIFICATION

Type of protection against electrical shocks	Class I according to the standard NF EN 61010-1 Ground protection for all accessible metallic elements and internal metallic elements.
Degree of protection against water and solids	IP 40
Operational mode	Continuous Service Normal use operating for unlimited period, without running over the temperature limits.
Electromagnetic interference	EN 61326-1 class A gauge. PLASMAIR [™] Guardian 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	Painted steel chassis
2	Hinged front door (tailgate opening) for HEPA-MD [™] modules access
3	Control panel + LED
4	Mains plug with double-pole switch and fuses
5	Electrical connector USB / RJ45
6	Pivoting castor (the front castors are fitted with brakes)
7	Prefilter access flap
8	Removable housing
9	Opening door lock + handle



1.5.3 MARKINGS AND WARNINGS

Label	Wording	Position
Product	PLASMAIR TM Guardian Model: T2006-G P/N: CP21000 S/N: 2006-TG-72?? made in France airinspace ^W - 14 rus Jean Monnet Elancourt 78990 - FRANCE	On the right side of the unit, near the mains socket
Electrical characteristics (according to country)	airinspace () CE 230 V 50/60 Hz IP 40 600 VA max	On the right side of the mains socket (different label depending on the country's tension)
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
Ground connection during assembly warning		On the mains socket protective cover located in the ventilation chamber
High voltage connexion to reactor modules warning	ні-рот	On module 1
Ground connexion to reactor modules		On reactor modules 1, 2, 3 and 4
Prefilter	Made in France airinspace SE FR HQ Prefilter CP04237-N°?????	On the prefilter
Reactor module type identification	airinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspaceairinspace <td>On reactor modules 1, 2, 3 and 4</td>	On reactor modules 1, 2, 3 and 4
Mains socket fuse	F1 - 5 x 20mm 2 x 3.15 AT	Near the mains socket

1.5.4 PICTOGRAMS

Wording	Designation	Wording	Designation
\bigwedge	Electrical hazard		Danger! Fan
A.	Danger! High voltage		Protective Earth - equipotential ground connection

1.6 FUNCTIONAL DESCRIPTION OF THE DEVICE

1.6.1.1 Intented use

The PLASMAIR[™] Guardian is a mobile air decontamination unit, effective on moulds, bacteria, viruses and spores. As a mobile unit designed to control air quality and fight health-care acquired infections, the PLASMAIR[™] Guardian is positioned at neuralgic points of the hospital, anywhere where the risk of airborne contamination must be controlled.

1.6.1.2 PLASMAIR[™] Operating principles

The PLASMAIR[™] Guardian sucks in, treats and diffuses back the air of the room. Through the combined action of 3 principles, PLASMAIR[™] Guardian quickly abates ambient contamination and maintain it to a low level thus preventing nosocomial infection risk.

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.

Inside the PLASMAIR[™] Guardian, the airflow passes through a HEPA-MD[™] technology decontamination reactor. This innovative technology, which equips all airinspace[®] devices, combines the destruction of airborne microorganisms with very high efficiency particulate filtration through the joint action of non-thermal plasmas and electrically active collection media.

By sucking low to the floor and blowing close to the ceiling, the 1.95m PLASMAIR[™] Guardian ensures an optimal aeraulic sweep of the room by the "Coanda" effect and eliminates undecontaminated dead zones. The risk of increasing contamination by mixing the ambient air during periods of activity (care or other) is thus minimised.

AIRFLOW DIRECTION IN THE plasmair[™]



1.6.2 PHYSICAL CHARACTERISTICS

Electrical supply	~ 100 V, ~ 110/120 V, ~ 230 V; 50/60 Hz		
Maximum electrical power	600 VA / 600 W		
Power at 1000 m ³ /h (new prefilter and reactors)	160 W		
Electrical protection	 Isolated by removable power of Fused Ph + N bipolar switch 	cable	
Air flow rates	ventilation speeds continually adjustable 500 m ³ /h and 2500 m ³ /h (maximum out	e between put with new prefilter)	
Device noise levels according to standard NF-EN ISO 3744:2012 at 1m / 2m (new prefilter)	 - 500 m³/h 30 dB(A) / - 1000 m³/h 39 dB(A) / - 1500 m³/h 47 dB(A) / - 2000 m³/h 53 dB(A) / - 2500 m³/h 58 dB(A) / 	<30dB(A) 35dB(A) 43dB(A) 49dB(A) 54dB(A)	
Average velocity of air exiting diffusion grid	0.87 m/s at 1000 m ³ /h - equivalent outlet surface = 0,3	2 m²	
Air treatment capacity (room volume) Potentially all volumes according to desired level of efficient 150m ³ room for a ARH* of 17 vol/h.		sired level of efficiency.	
Aerosol filtration efficiency at 1000 m ³ /h (new pre-filter and reactors).	> 99.999% Particles Ø≥ 0,3 µm		
Bacteriological classification	Total flora: <10CFU/m ³ from an ARH of	f 18 vol/h	
Airborne Particulate Cleanliness Class	ISO 7 based on an ARH of 12 vol/h		
Time to achieve 90% particulate decontamination kinetic in minutes for particles of diameter ≥0.5µm - < 7 min at an ARH of 30 vol/h		1	
Water/aslid protection index	All equipment	IP40	
water/solid protection index	Control panel	IP40	
Overall dimensions	H 1940 x L 912 x P 690 mm		
Footprint	Short side	from 475 to 635 mm	
(pivoting castors with offset)	Long side	from 685 to 845 mm	
PLASMAIR [™] weight (see specific instructions for IMMUNAIR [™] CFP and CMP)	191 kg		
Maximum ground loading	587 kg/m ² (footprint 475 x 685 mm)		
Environmental conditions for operation (optimium)	Temperature	0°C to +45 °C	
	Relative humidity	Between 20% and 90%	
	Temperature	0°C to 45°C	
Environmental conditions for storage	Relative humidity	20% to 90%	
	Total dust	< 1 mg/m ³	

^{*} ARH = Air recycling rate of air per hour (e.g.: 750 m³/h in a 100 m³ room = ARH 7.5 vol/h).

1.7 SETTING UP INSTRUCTIONS

NOTA: If the device is delivered without carrying case, skip to step 3.

Unpacking (optional)

- 1. Move the transport case as close as possible to a clean, flat floor space.
- 2. Remove the unit from the transport case:
 - remove the side panels and the cover,
 - fit the case access ramp,
 - carefully remove the unit from the case.

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

THE UNIT IS HEAVY (191 KG) HANDLING AND UNLOADING MUST BE CARRIED OUT BY TWO PERSONS.

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

Reception

3. Only move the unit by means of the handle (1) and, if necessary, by the gripping areas (2) 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.



ATTENTION : USE A RAMP TO CROSS BLOCKS MORE THAN 1 CM HIGH.

- 4. Once the unit is in the area where it will be used, lock the front wheel brakes.
- 5. Carefully examine the device on delivery and make sure all the items on the packing list are present.
- 6. Open the front door and remove the reactor modules stored inside and packed in protective sachets. Remove the prefilter by lifting the prefilter access flap.
- 7. Carry out internal and external biocleaning of the unit with hospital disinfection products used in the establishment (see Section 3.8.- Maintenance Biocleaning).

- 8. Unpack the reactor modules and the prefilter. Fit them in the PLASMAIR[™] (see § 3.9.1 Prefilter management and § 3.9.2 Changing a reactor).
- 9. Connect the unit to a secure electric plug. (see § 1.6.4 Physical specifications)
- 10. Switch on the unit and check that it starts up correctly (see Section 2.2 Starting).
- 11. Note anomalies and any damage on the delivery sheet 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) When the room is already fitted with built-in mechanical ventilation of the unidirectional flow type, we recommend that you avoid pointing the PLASMAIR[™] unit towards this flow as much as possible to avoid any disruption to it.
- NOTA : 2) When the room is already fitted with built-in mechanical ventilation of the turbulent flow type, we recommend that you position the PLASMAIR[™] 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 equipment.
- 2. Tidy the power supply cable.
- 3. Protect the device by using the zipped 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, sunlight, heat, frequent changes in temperature and humidity, chemicals or other corrosive products.

Storage temperature: from 0°C to +45°C.

Relative humidity level : from 20% to 90%.

Dustiness : lower than 1 mg/m³.

1.9 TRANSPORT

Before transporting it, protect the unit from shocks and abrasion.

Transportation should be carried out by personnel instructed and qualified to do so.

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

Moving the equipment 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).

Respect the handling direction of the transport box:

1.10 DISPOSAL

This product is covered by the European Directive 2012/19/EU of 4 July 2012 on waste electrical and electronic equipment (WEEE):

- France: disposal is carried out by our partner ECOLOGIC. To find out about collection points or take-back procedures, visit www.e-dechet.com.

- Outside France: the disposal of this product and the recovery of the resulting waste must comply with the regulations arising from the application of the European directive by the various member states, as well as any local regulations that may supplement it.

SECTION 2 - OPERATION

2.1 OPERATING PRINCIPLES

The PLASMAIR[™] unit has been programmed to offer simple, user-friendly interface to its many levels users. On the basis of a single software, it therefore presents different display levels, adapted to everyone's expectations.

2.1.1 USERS AND ACCESS LEVELS

Two levels of intervention are defined for this material:

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

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

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

- starting up,
- changing the ventilation speed,
- handling warnings and alarms,

and for N2 level persons, which entices:

- reading the initialization parameters,
- reading the operating parameters,
- time counters reading,
- programming ventilation speeds,
- prefilter and reactor modules replacement.

2.1.2 USER INTERFACE

	main screen		
4 5 1 2			$ \begin{array}{c} \\ \hline \\ $
			LEDs
	1	Green led	4 Active decontamination
	2	Yellow led	5 Warning
r	3	Red led	6 Alarm
C	DK		This icon indicates that the device is working correctly
	~		This icon indicates a warning
	Ĵ		This icon indicates an alarm
2	- X -		This icon indicates the ventilation speed: DAY/NIGHT
5	-	m³/h	These icons indicate the actual air flow and the programmed room volume
	₽ -	m ³	
0	¢		Access key to the Setup Menu
(S		Signal that automatic night-time programmer is activated
1	¹		Signal that manual mode is activated

2.2 STARTUP

Connect the **PLASMAIR**^{$^{\text{M}}$} to a power outlet ~ 100 V, 110/120V, 230 V – 50/60 Hz using the 2P+T 10 A power supply cable provided.

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

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

The PLASMAIR[™] loads the operating program. This sequence lasts about 30 seconds. The initialization screen appears (decontamination is not active).



Once the software initialization is completed, the main screen is displayed,



NOTA: Without action on the buttons, the backlight of the screen will decrease after 3 min and turn off after an additional 30s when in Night mode.

2.3 CHANGING THE VENTILATION SPEED

The PLASMAIR[™] is programmed with two ventilation modes: Day/Night

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



Day mode on:



You can set the machine to automatically switch from day to night speed and vice versa (see \$3.5)

2.4 HANDLING WARNINGS AND ALARMS

2.4.1 DEFINITIONS

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

NOTA : The warning situation is indicated by the yellow backlight of the key, the ventilation still works but the filtering performance may be degraded. The green led shuts down and is replaced by the following pictogram:

example:



An **alarm** message is sent by the unit's system when personal or property safety are at stake. An alarm is systematically accompanied by the fan and the high voltage power supply being shut down. No further decontamination function is ensured. The controller remains switched on.

- NOTA : The alarm is indicated by the extinction of the green led, the lighting of the red led offer and the red backlight of the **L** key.
- NOTA : example:



2.4.2 PROCESSING

- 2.4.2.1 Displaying an alert or warning
 - Press the L key to display the default.

example:



Press the V key to go back to the previous screen.

2.4.2.2 Deleting an alert or warning

Keep the device in operation.

Remove default (e.g., close the front door left open).

In the case of an alarm, press the **L** icon and in the case of a warning, press the **L** icon. 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 🤍 key to go back to the main screen.

Alternate Method:

- Switch off the equipment.
- Remove default.
- Restart the equipment.

Example - Prefilter alarm:

- Prefilter not present (or prefilter positioned incorrectly), the system goes on alarm. The machine stops, ok is replaced by OFF, the alarm led lights up.
- Display the message by pressing the **L** icon. The following screen pops up:



- Remove default by inserting the prefilter more deeply in the back in its drawer.
- Press the 🤝 button. The machine will check whether the fault has been corrected.
- If no other fault or warning is present, the machine restarts: OK LED reappears.

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

NOTA: Refer to the annexes for the list of alerts and warnings.

	-	
Status area display	Warning definition	Fault condition(s)
	Module stage 1 low current warning	I < Intensity warning threshold
	High voltage low level warning	HV < High voltage warning threshold
	Prefilter saturated or clogged warning	Prefilter end of life/prefilter partially or totally blocked.
····	Level 1 module replacement	Time counter > 4 years of operation
···	Level 2 module replacement	Time counter > 4 years of operation
 <u>></u>	Level 3 module replacement	Time counter > 4 years of operation
 <u>></u>	Level 4 module replacement	Time counter > 1 year of operation
··· /2	Saturated or clogged filtering module warning	Module 2 end of life or outlet grille blocked

2.4.2.3 Warnings list

2.4.2.4 Alarms list

Status area display	Alarm definition	Fault condition(s)
OFF >	Fan not rotating (Error A)	Fan likely to fail or blocked
	Module stage 1 weak current alarm (Error B)	I < Intensity minimum threshold
OFF >	Module stage 1 weak tension alarm (Error D)	HV < High voltage minimum threshold
OFF J	Module stage 1 high current alarm	I > Intensity maximum threshold
OFF >	Missing or misplaced prefilter alarm	Miniswitch sensor opened
OFF >	Missing or mispositioned reactor alarm	Miniswitch sensor opened
	Front door alarm	Miniswitch sensor opened

2.5 RECOMMENDATIONS FOR USE

2.5.1 CLEANING

Follow the recommendations of Chapter 3.8 §.

2.5.2 CHOICE OF VENTILATION SPEEDS

To effectively eliminate all microbiological contamination of a room, there must be a

recirculation per hour (ARH) in the range of 20 vol/h on DAY mode and of 15 vol/h on

NIGHT mode

(see section 1.6.4 - Physical specifications)

When starting the machine, let the system run on DAY mode at least one hour in the closed room before the patient arrives.

Generally the machine is used in DAY mode



The NIGHT speed is used to reduce the noise of the machine in order to improve patient sleeping comfort when there are no visits within the protective zone.



2.5.3 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 fresh air intake is recommended both for patient comfort and the operation of the PLASMAIR[™] unit.

ATTENTION : IN ORDER TO KEEP CLIMATIC CONDITIONS COMPATIBLE WITH THE OPERATING RANGE OF THE PLASMAIR[™] UNIT (RELATIVE HUMIDITY < 90% HR) WE RECOMMEND A FRESH AIR INTAKE OF 2 TO 3 VOLUMES PER HOUR.

2.5.4 USE FOR THE CONTAINMENT OF INFECTIOUS PATIENTS

ATTENTION : AS PART OF **PLASMAIR**[™] UNIT OPERATION FOR THE CONTAINMENT OF INFECTIOUS PATIENTS OR INVOLVING EXPOSURE TO A HIGHLY INFECTIOUS AGENT, IT IS STRONGLY RECOMMENDED TO COORDINATE WITH THE INFECTION CONTROL DEPARTMENT TO DEFINE THE FRAMEWORK OF THE UNIT'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. An intervention of airinspace® to ensure this biocleaning will be taken outside the framework of the manufacturer's warranty contract or the service contract subscribed by the establishment for the device concerned, if necessary and subject to a commercial offer issued by Airinspace.

SECTION 3 - SOFTWARE MANAGEMENT – CLEANING - MAINTENANCE

3.1 AVIGATION MENU

Navigating the PLASMAIR[™] setting menu is done by pressing the setup key from the main screen:

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

		×
1	2	3
4	5	6
7	8	9
	0	-
Clear	En	ter

• If the entered access code corresponds to level 1 (User level – default password : 0001) the following parameter display screen pops up:



	This button allows you to select the language of the user interface: French, English, German, Spanish or Chinese.
Ħ	This button is used to set the size of the room and adjust the ventilation speed depending on the air renewal rate (or select the Immunair mode)
8	This button allows you to set different passwords.
3	This button is used to enable or disable the automatic switching between DAY and NIGHT modes and to set the corresponding hours.

-^/-•	This button provides access to the machine's settings (read only mode).
	This button provides access to the recorded data of the unit.
G	This button allows you to go back to the previous screen.

• If the entered access code corresponds to level 2 (Technician level – default password : 1234) the following parameter supervision screen pops up:



This screen is identical to the main screen except for the Maintenance key that replaces the parameters display key.



This button provides access to the machine's settings (editable mode).

NOTA : You can return to the main screen at any time by pressing the return key \mathbf{F} .

3.2 LANGUAGE SETUP

From the maintenance screen, press the language selection button, **U** the flag changes along with all the texts of the user interface. A subsequent press scrolls through the different languages: English, German, Spanish, Chinese or French.



SETTING PROCEDURES FOR THE ROOM SIZE AND VENTILATION 3.3

screen pops up:

B This screen allows you to select 3 different flow setting modes: Room volume : -- m3 Night mode : -- V/h $\text{Day mode}: - \cdot \text{V}/h$ Night mode : --- m3/h Day mode : --- m3/h Automatic mode by pressing the button. The user enters the room size and the unit automatically adjusts its speed to ensure an Air Recycling rate per Hour set by default at Room volume : -- m3 20 volumes/h in DAY mode and 15 Night mode : -- V/h Day mode : -- V/h volumes/h in NIGHT mode. Night mode : --- m3/h Day mode : --- m3/h

From the maintenance screen, press the room size and flow setting button 4. the following

NOTA: It is possible to change these renewal rates with a level 2 access code (see §3.6)

Manual mode by pressing the button. •

Room volume : m3 Night mode : V/h Day mode : V/h Night mode : m3/h Day mode : m3/h	Γ		
Day mode : V/h Night mode : m3/h		Room volume : m3 Night mode : V/h	
Night mode : m3/h		Day mode: V/h	
Day mode m5/m		Night mode : m3/h Day mode : m3/h	

The user enters the desired air flow in m3/h for the DAY/NIGHT mode or the volume of the room and the renewal rates in DAY/NIGHT modes.

The default values displayed are the last

saved values and the K button is for erasing the data in order to re-enter

them, or to get rid of the interdependent fields,

(Regime = Volume x ARH). The minimum ventilation speed should be greater than 300 m3/h.

When the manual mode is activated the appears on the main screen

Immunair mode by pressing the button. •

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

3.4 SETTING VENTILATION FOR IMMUNAIR CONFIGURATION

As described in the previous section 3.3 § for the setting of the ventilation, the screen offers a third option when the PLASMAIR[™] unit is associated to the IMMUNAIR[™] Fixed Deployable Plenum (FDP) or Mobile Deployable Plenum (MDP). In this case, the Immunair mode needs to be selected to adapt the airflow within the IMMUNAIR[™] system for optimal efficacy and confort.



The DAY/NIGHT ventilation modes will be set at 1100 and 500m3/h - standard settings for optimum performance with

PASSWORDS SETTING PROCEDURE 3.5

From the maintenance screen, press the password button,

The following screen appears when the level 1 access mode (User) is selected

	 User password	¢	It is then possible to reset the password for level 1 (User – default password : 0001).
1			The following screen appears when the level 2 access mode (Technician- default password : 1234) is selected
	User password	C*	It is then possible to reset the passwords for levels 1 (User) and 2 (Technician).
_			NOTA : You can return to the main screen at any time by pressing the return key

3.6 NIGHT TIME PROGRAMMER SETTING PROCEDURE

From the maintenance screen, press the programmer button

The following screen pops up:

Automa	atically switches	s to night mode	₽
Start :	lime	End time	

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

You can disable the automatic switching from DAY to NIGHT mode by pressing the following screen appears:

	Automatically switches to night mode	
Press	off icon to switch back to automatic mod	le.

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

3.7 PARAMETERS ACCESS

NOTA: The solution and arrows on the bottom of the screen allow you to scroll through the parameters pages.

3.7.1 ON DISPLAY MODE (LEVEL 1-USER)



From the maintenance screen, press the parameters display

button 🚰 the following screen pops up:

This screen allows you to view the software version of the user interface and the operation counters of the different reactors modules (stages 1, 2, 3, 4), the prefilter counter and the total counter.

		E
Fan setpoint :	V	
Pressure sensor 1 :	Pa	
Pressure sensor 2 :	Pa	
Current setpoint (HV) :	µA	
Current feedback :	µA	
Voltage feedback :	KV	
*	->	

This screen displays:

- the fan steering setpoint in Volts
- the differential pressure at the fan inlet nozle (probe 1) and the reactors differential pressure (probe 2) in Pascal
- the current steering setpoint of the High Voltage Power

Supply Unit in µA

- The stage 1 current value in µA
- The stage 1 tension value in KVolt
- the state of the prefilter (L), door (P), prefilter pressure switch (S) and reactor (U) sensors

Setting	ate and time
. / mm / a	aa HH ;mm
Aud	le alarm
+	→

This screen allows you to set the date and time, and to enable or disable the audible alarm

3.7.2 ON SUPERVISION MODE (LEVEL 2-TECHNICIAN)

From the maintenance screen, press the parameters supervision button *the following screen pops* up:

This screen allows you to view the software version of the user interface and the operation counters of



The stage 1 tension value in KVolt

the state of the prefilter (L), door (P), prefilter pressure switch (S) and reactor (U) sensors



This screen allows you to view and edit:

the warning threshold in μA "stage 1 module current low"

the alarm threshold in μA "stage 1 module current insufficient"

the alarm threshold in µA "stage 1 module current high"

the warning threshold in KV "high voltage low"

the alarm threshold in KV "stage 1 module insufficient voltage"

the delay before thresholds detection (faults appearance)

the state of the prefilter (L), door (P), prefilter pressure switch (S) and reactor (U); their activation (green) / desactivation (red).

CAUTION: MODIFICATION OF THE SUPERVISION MODE SETTINGS IS RESTRICTED TO THE INITIATIVE OF THE AIRINSPACE® MANUFACTURER OR A DULY TRAINED TECHNICAL PERSON FOR MORE THAN DIAGNOSTIC OR TRANSIENT FUNCTIONS

3.8 DISPLAY AND UPLOADING OF RECORDED DATA

 Ioading ...

 ♥



The following screen pops up:

This screen displays the events (alarms or warnings) and frequency (operating parameters recorded every hour) recorded.



Pressing the key enables the downloading of all recorded data to a USB stick inserted previously in the Datalog port (A) on the unit side (see §1.5.1 marker No. 5)

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

3.9 MAINTENANCE – BIOCLEANING

The following recommendations should not replace the procedures and frequency of biocleaning defined by the EOH for the department where the PLASMAIR™ Guardian unit is used.

airinspace[®] strongly recommends users to keep aware and, if necessary, to strengthen the frequencies presented here in accordance with the practices of the department.

NOTA: THE BIOCLEANING PROTOCOL FOLLOWS THE RECOMMENDATIONS OF THE HYGIENE DEPARTMENT OF THE ESTABLISHMENT.

RECOMMENDATION: TO PREVENT CHEMICAL IMPREGNATION OF THE MODULES, SWITCH OFF THE MACHINE DURING WET CLEANING OF THE FLOORS, THEN ALLOW TO DRY BEFORE RESTARTING, OTHERWISE THE PARTS WILL BE REPLACED QUICKLY.

3.9.1 PRODUCTS CHEMICALLY COMPATIBLE WITH AIRINSPACE® PRODUCTS

airinspace[®] devices are compatible with all cleaning and disinfection products commonly used in most hospitals. These include :

- Halogens (Chlorine and iodide based products)
- Biguanides (chlorhexidine) ;
- Alcohol (70° ethanol, 60° isopropyl alcohol);
- Quaternary ammonium compounds (benzalkonium chloride...);
- Oxidants (peracetic acid, hydrogen peroxide based products) ;
- Diamidines (hexamidine);
- Aldehydes ;
- Phenol derivatives

airinspace[®] strongly recommends its users to check the choice of disinfectants used, by carefully selecting the biocidal activity standards the product must comply with (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	Myco- bactericide	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	

3.9.2 STANDARD PROCEDURE

By default, the standard disinfection procedure applies for maintenance of the PLASMAIR[™] 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.

3.9.2.1 *Material 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]
- [8mm Allen key only for annual maintenance of the unit]
- [2.5mm Allen key only for annual maintenance of the unit]

3.9.2.2 Daily Biocleaning



- 1. Prepare the material needed and the Detergent Disinfectant solution;
- 2. Using the wipe suitably impregnated with 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 following a "forward march" principle (without overlapping round trips). Ensure that you regularly recharge 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 AND WRING OUT THE WIPE WELL BEFORE APPLICATION TO THIS AREA.

3. Leave to dry.

If the surface is very dirty:

First perform cleaning with a detergent: wet dust suppressant, detergent solution and rinsing.

3.9.2.3 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 by lifting using the handle built into the grille frame (dotted arrow above).

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.

Reposition the dry grille. Position the integrated handle in the cut situated in the front of the Plasmair and place the grille on the chassis built legs.

ATTENTION : DO NOT SPRAY OR DIRECTLY WIPE DD ONTO THE OUTLET GRILLE WHEN FITTED TO THE PLASMAIR[™] SINCE THIS MAY DAMAGE THE REACTORS.

3.9.2.4 Yearly biocleaning

2

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 **PLASMAIR[™]** UNIT, PLEASE TURN THE POWER OFF. UNPLUG AND TAKE ALL THE PRECAUTIONS NECESSARY TO ENSURE THAT THE EQUIPMENT CANNOT RESTART BY ACCIDENT.

Stop the PLASMAIR[™] using the I/O switch and disconnect from the mains by unplugging the electric cable (1).

Open the front door of the unit by unlocking the closure system (2):

- Using an 8mm Allen key unlock the **PLASMAIR**[™] front door by rotating counter-clockwise (a quarter turn) and then pulling the tailgate up front.

- Direction of rotation:

1





Remove the front panel:

Remove the 3 connecting screw from the lower front panel with a 2.5mm Allen key.

Take hold of the panel and lift it slightly to disengage the two guide pins located on the front side bottom.

To facilitate extraction, raise the pre-filter cover.



- 1. For parts (1) to (4), apply the daily biocleaning procedure;
- 2. For part (5), apply the biocleaning procedure used when a patient changes;
- 3. Disinfect internal parts (6) to (11). The fan is accessed from above, simply remove the reactors to clean the fan chamber.



3.9.3 OTHER PROCEDURES

The maintenance/biocleaning procedures recommended by **airinspace**[®], i.e. frequency and scope of cleaning, may depend on the nature of the germs encountered.

Transmission mode	Type of germ / Pathology	Necessary microbial activity of the disinfectant product	Applicable procedure	reference of the paragraph
	Vegetative bacteria	Postorioido		§ 2.3*
	BMR	Daciencide	Stondard	
Contact	Fungal	Fungicide	Stanuaru	
	Virus	Virucide		
	Bacterial spores (sp. C. difficile*)	Sporicide (* Bleach 2,6% diluted 1/5 th)	Spores	§ 2.4*
	Tuberculosis	Active mycobacteria		§ 2.5*
	Pertussis			
	Diphtheria			
	Bacterial meningitis	Bactericide		
	Scarlet fever			
"Air"-	Other bacteria			
Airborne	Measles		Air	
+ Droplets	Chickenpox			
	Flu			
	Adenovirus	Virucide		
	RSV			
	Viral meningitis			
	Other virus			

3.9.3.1 Selection of the applicable disinfection procedure:

3.9.3.2 Cleaning frequency:

Area concerned	Procedures "Standard" / "Spores"	Procedures "Air"	
Procedure Accessible external surfaces	daily	daily	
Removable grille	for each new patient	for each new patient	
Blowing pipework	once a year	for each new patient	
Prefilter hatch	ONCE a year + Long term stoppage or move (see section 2.3.3)	ONCE a year + Long term stoppage or move (see section 2.3.3)	
Internal parts	once a year	once a year	

3.10 MAINTENANCE

CAUTION: MAINTENANCE AND REPAIR OF THE UNIT DURING ITS LIFETIME IS THE RESPONSIBILITY OF THE MANUFACTURER OR HIS REPRESENTATIVE.

HOWEVER, REPLACEMENT OF THE PRE-FILTER, REACTOR MODULES AND FUSES CAN BE CARRIED OUT BY TECHNICAL PERSONNEL WHO HAVE READ THE INFORMATION BELOW.

In order to ensure maximum efficiency at all times, the consumables of the PLASMAIR[™] unit (prefilter and reactors modules) have limited lifetimes managed by time counters.

When the lifetime of a consumable is reached, a warning message appears on the unit screen indicating that it should be replaced. If the expired consumable is not replaced within a period of six months after the message first appears, the unit will default, impeding its use until the consumable is replaced and the corresponding counter reset.

3.10.1 PREFILTER MANAGEMENT

3.10.1.1 *Description of the prefilter stage*

The prefilter, located at the base of the PLASMAIR[™] unit, protects the equipment's internal components from airborne macroparticles and the excessive accumulation of dust.

To provide this protection, **airinspace[®]** recommends and uses a made to measure HQ high quality filter on all new PLASMAIR[™] units (available from **airinspace[®]**).

3.10.1.2 *Prefilter risk analysis*

The prefilter has an exposed external surface through which air enters the PLASMAIR[™] unit for treatment. Particles and macroelements are collected on the surface of the filtrating media, which is located at the base of the unit, 15 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.

3.10.1.3 Prefilter replacement

a- <u>Replacement procedure</u>

To guarantee continued decontamination performance by the PLASMAIR[™] unit over time, the prefilter must be replaced once the prefilter saturation warning appears on the control screen ("L" signal and yellow LED). This signal is generated by the unit's system according to the prefilter measured pressure drop and the actual operating time. On average it occurs after a period between 6 months and 1 year depending on the level of dust in the environment.

CAUTION: TO AVOID POTENTIAL PATIENT EXPOSURE TO MATERIAL FROM THE OUTER SURFACE OF THE PREFILTER DURING THE REPLACEMENT PHASE, AIRINSPACE RECOMMENDS THAT THE REPLACEMENT BE PERFORMED BETWEEN PATIENTS IF POSSIBLE.

CAUTION: IF THE ESTIMATED PATIENT DISCHARGE IS GREATER THAN SIX MONTHS AFTER THE PREFILTER WARNING APPEARS, THEN THE PREFILTER MAY BE CHANGED: - IN THE PRESENCE OF THE PATIENT OR BY TAKING THE Guardian PLASMAIR™ UNIT OUT OF THE ROOM TO MAKE THIS CHANGE. THE PATIENT MUST BE PROTECTED BY A FACE MASK.

THE MASK MUST BE WORN THROUGHOUT THE REPLACEMENT PROCEDURE. IN ADDITION, IT IS RECOMMENDED THAT THE PERSONNEL INVOLVED WEAR GLOVES AND A PROTECTIVE MASK WHEN REMOVING THE PREFILTER. FINALLY, RUN THE Guardian PLASMAIR™ UNIT EQUIPPED WITH A NEW PREFILTER FOR 30 MINUTES AFTER RESETTING IN DAY VENTILATION REGIME.





b- <u>Traceability:</u>

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

c- Disposal

CAUTION : SINCE THE USED PREFILTER IS HIGHLY LIKELY TO PRESENT DUST THAT CONTAINS BIOLOGICAL CONTAMINANT, AIRINSPACE RECOMMENDS DISPOSAL OF THE PREFILTER IN ACCORDANCE WITH THE APPLICABLE REGULATIONS FOR THE HANDLING OF SPECIAL WASTE (BIOHAZARD MEDICAL WASTE TREATMENT FOR EXAMPLE).

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

3.10.1.4 Unit switched off, removal of a part or storage

When the PLASMAIR[™] unit is stopped, the depression produced by sucking 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 falls of aggregates, using a suitable solution (see § 3.8), using the following instructions:



Spray Detergent-Disinfectant (DD) on the floor around and under the unit (to a radius of 30 centimetres around the equipment) - carefully wipe the DD residues and inactive aggregate materials using a lint free soft cotton cloth or wipes. This deactivation step must be completed before the device is handled.

When the **PLASMAIR**[™] unit must be removed from a room in the presence of a patient, they must be protected by a facial 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.

CAUTION : IN SPECIFIC CASES WHERE THE UNIT MUST BE TRANSFERRED FROM A SEPTIC ZONE (CONTAINING INFECTIOUS PATIENTS FOR EXAMPLE) TO AN ASEPTIC ENVIRONMENT, THE PREFILTER MUST BE CHANGED BEFORE THE EQUIPMENT IS MOVED INTO THE ASEPTIC ZONE.

Remember that when the unit used for septic isolation or when it is exposed to highly infectious agents, **airinspace**[®] strongly advises users to **get in touch with the establishment's Infection Control department** to define the scope of the equipment's deployment, **and in particular with respect to any changes of sector**. In addition, applying the principle of precaution with regard to any risk of cross contamination, we recommend that you explicitly label the unit if used for septic confinement.

3.10.2CHANGING A REACTOR

Changing reactor modules must only be carried out by personnel with sufficient knowledge, suitably trained and duly authorised by **airinspace**[®].

3.10.2.1 Composition of reactor modules

The reactor consists of four dedicated modules:



- 3.10.2.2 Tools required:
 - An 8mm Allen key.
- 3.10.2.3 Recommendations:
 - Carry out reactor module replacement in the absence of a patient.
 - Keep the new reactor modules in their original packaging until installation. During installation, take every precaution to avoid damaging or soiling the new modules (clean hands, clean storage media, handling modules with the outside envelope only...).
 - Operate the PLASMAIR[™] on DAY mode (on screen icon:) during 30 minutes after operation.
 - Ensure that used reactors and associated packaging are eliminated in accordance with environmental protection rules and special waste regulations current in the establishment.

CAUTION : MODULE 2 BEING HEAVY (OVER 20 KG), TWO PERSON ARE REQUIRED TO SAFELY HANDLE THIS SPECIFIC PART.

3.10.2.4 Removal procedure

CAUTION : DANGER! BEFORE OPERATING ON THE **PLASMAIR**[™], SWITCH OFF THE EQUIPMENT, UNPLUG AND TAKE ALL THE PRECAUTIONS NECESSARY TO ENSURE THAT THE EQUIPMENT CANNOT RESTART BY ACCIDENT.





3.10.2.5 *Fitting operation*

Carry out the fitting operation in the opposite order to removal. Please reset the replaced modules counters (see §3.10.3 – Resetting a counter).

3.10.3CHANGING A FUSE

Two fuses (6.3 AT) protect elements of the electric circuit. They are located in the base area (marker 4 §1.5.1).

3.10.3.1 *Tools required:*

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

3.10.3.2 Fuse Replacement procedure



3.10.4 RESETTING A COUNTER

3.10.4.1 Consumable replacement frequency

Reminder:

In order to ensure maximum efficiency at all times, the consumables of the PLASMAIR[™] unit (prefilter and reactors modules) have limited lifetimes managed by timers.

When the lifetime of a consumable is reached, a warning message appears on the unit screen indicating that it should be replaced. If the expiring consumable is not replaced within a period of six months after the message first appears, the unit will default, impeding its use until the consumable is replaced and the corresponding counter reset.

The following table indicates the replacement frequency of the PLASMAIR[™] unit consumables.

Consumable designation	Maximum lifespan
Stage 1 module - R41 - Plasma	4 years
Stage 2 module - R42 - Collector	4 years
Stage 3 module - R43 - Catalyst	4 years
Stage 4 module - R44 - Absorption	1 year
Prefilter	1 year

3.10.4.2 Counter reset procedure

Once the consumable is replaced (see §3.9.1 for the pre filter and §3.9.2 for a module), it is necessary to reset the associated timer. The reset procedure described below is applicable to every consumable of the unit.

example: prefilter time counter reset

The prefilter is expiring, the machine screen displays symbols and 2. However, the unit keeps operating and decontamination is still active. Pressing the button indicates that the prefilter should be replaced and the number of days above the 6 months before the unit defaults.





• Check the counter in the settings:



- Replace the prefilter (see §3.9.1)
- Open the unit front door (units on / door alarm on)
- Use the NFC reader to the left of the reactor modules to scan the prefilter label (simply touch the tag with the flat part of the reader). A "beep" indicates that the

reading worked. The *C* is no longer displayed on the screen.

NOTA : An ascending "beep" indicates that the machine has correctly recognized the consumable and that the counter has been reset. A descending "beep"indicates a problem with the consumable (part used in another machine, used, already scanned or incompatible).



- Store the NFC reader in the space provided
- Close the unit front door and reactivate the machine by pressing the key.



• Check the counter in the settings:



3.11 ELECTRICAL BLOCK DIAGRAM

Reference point	Désignation	Designation
A	Interrupteur bipolaire	Bipolar switch
В	Fusible F1	F1 Fuse
С	Filtre secteur	ECM filter
D	Transformateur isolement	Isolating transformer
E	Alimentation 24 Vdc	24 Vdc power supply
F	Ventilateur	Fan
G	Minirupteur porte avant	Front door switch
н	Minirupteur présence préfiltre	Prefilter switch
I	Minirupteur module	Module switch
J	Manostat différentiel préfiltre	Prefilter differential pressure switch
K	Interface utilisateur tactile	Tactile user interface
L	Lecteur NFC	NFC reader
М	Carte plateforme	Controller board
N	Alimentation 10kVdc	10kVdc H.V power supply
0	Sonde pression différentielle réacteur	Reactor differential pressure sensor
P Sonde pression différentielle ventilateur		Fan differential pressure sensor
X1	Réacteur étage 1	Stage 1 reactor
X2	Réacteur étage 2	Stage 2 reactor
X3	Réacteur étage 3	Stage 3 reactor
X4	Réacteur étage 4	Stage 4 reactor







3.12 DISTRIBUTOR WARRANTY

Please contact your local representative airinspace®.

Any problems resulting from unauthorized attempts at repairs, modifications, tipping over, use of inappropriate voltage or any operations contrary to the instructions in the User Manual are not covered by the present warranty. (see General Conditions of sales)

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3.13 UNIT IDENTIFICATION

In any correspondence with **airinspace[®]** or with an official sales representative, state the PLASMAIR[™] serial number and acquisition date:

