tediselmedical

AURA

USER AND CLEANING MANUAL

AURA 100

AURA 200

AURA 300

tediselmedical.com

CE 0197

Content

1. Manufacturer

Manufacturer: TEDISEL IBÉRICA S.L.
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2. Security information

Important notes in these operating instructions are marked with graphic symbols and signal words.

2.1 Injury risk warnings

Signal words such as DANGER, WARNING or CAUTION describe the degree of risk of injury. The different triangular symbols visually emphasise the degree of danger.

	WARNING	Refers to a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	CAUTION	Refers to a potential hazard which, if not avoided, may result in minor or slight injury.
	DANGER	Refers to an immediate danger which, if not avoided, will result in death or serious injury.
		Risk of finger entrapment

2.2 Warnings of risk of damage

The signal word WARNING describes the degree of risk of material damage. The triangular symbol visually emphasises the degree of danger.

Damage to surfaces: warns of damage to surfaces due to unsuitable cleaning agents and disinfectants.

NOTICE

Refers to a potential hazard which, if not avoided, may cause damage to the equipment.

2.3 Additional symbols used in the safety instructions

Fire hazard

Explosion hazard: warns of ignition of explosive gas mixtures.

Dangerous voltage: warns about electric shocks that can cause serious injury or death.

2.4 Indication of additional information

NOTA

A NOTE provides additional information and useful tips for safe and efficient use of the device.

2.5 Proper use of oxygen.

2.5.1 Oxygen explosion

Oxygen becomes explosive when it comes into contact with oils, greases and lubricants.

Compressed oxygen presents an explosion hazard:

- Make sure that oxygen and gas outlets are free of oil, greasy materials and lubricants!

- Do not use cleaning agents containing oil, grease or lubricants.

2.5.2 Fire hazard

DANGER: Escaping oxygen is combustible.

- Open fire, red-hot objects and open light are not allowed when working with oxygen!

- Don't smoke!

3. Risks

3.1 Gas explosion

Oxygen becomes explosive when it comes into contact with oils, greases and lubricants.

When in contact with oxygen in the air, medical gases may form an explosive or easily flammable gas mixture. The equipment is not suitable for use in environments containing flammable mixtures of anaesthetics with high concentrations of oxygen or nitrous oxide.

If such high concentrations of flammable mixtures of anaesthetics with oxygen or nitrous oxide occur in the environment of the device, there is a risk of ignition under certain conditions.

3.2 Risk of device malfunction

CAUTION: If one device is connected to the equipment and trips the protection mechanism of the corresponding circuit in the health care facility, other devices connected to the equipment will also be de-energised.

3.3 Fire risk

Plug-in connections for the supply of medical gases must not come into contact with oil, grease or flammable liquids.

3.4 Danger of electric shock

Signal cables (network, audio, video, etc.) must be electrically isolated from equipment and building connection ends to prevent contact with currents that can cause serious injury or death.

4. Symbols used

	Applicable part B
	Earth (mass)
	Equipotentiality
	Protective earth (ground)
	Connection point for neutral conductor
	Nurse call button
	Direct lighting
	Indirect lighting
	Operating instructions
	Health Product
	Waste electrical equipment

CE 0197	CE symbol
REF	Product code
UDI	Unique identification code
SN	Serial number
	Manufacturer
	Date of manufacture
	Reference to the instruction manual
	Damage to surfaces
	Fire hazard
	Danger of explosion
	Dangerous tension
 NOTICE	Notice

	Risk of finger entrapment
 WARNING	Warning
 CAUTION	Caution
 DANGER	Danger

5. Product data

This manual refers to the AURA model. This model is part of the SICA family.

5.1. Storage conditions

The individual packaging of this type of product consists of a bubble wrap on the inside and a cardboard box on the outside. Non-stackable packaging.

Under no circumstances should the product be stored with open or damaged packaging. If the product is inspected on receipt and installation is not carried out within 1 day, the product packaging must be resealed.

 NOTICE: Failure to follow these instructions may result in damage to the equipment.

Recommended temperature range: -20 °C to 60 °C

Recommended humidity range: 10 % to 75 %.

Atmospheric pressure: 500 hPa to 1,060 hPa

5.2. Operating conditions

 NOTICE: Failure to follow these instructions may result in damage to the equipment.

Recommended temperature range: -10 °C to 40 °C

Recommended humidity range: 30 % to 75 %.

Atmospheric pressure: 700 hPa to 1,060 hPa

5.3. Service life

The useful life of the SICA family of products is determined by the useful life of the medical gas intakes it incorporates, which is 8 years.

5.4. Product description

These systems have three main differentiated functions within the hospital and according to the area for which they are intended:

- Medical gas services
- Electrical, voice and data services
- Lighting
- Nurse call

The Aura model consists of a chassis made from aluminium profiles that allows the integration of electrical equipment, lighting, call, voice and data systems, and the installation and channelling of medical gas outlets.

For equipment fitted with DIN rail for attachment of accessories:

WARNING: Exceeding the maximum capacity of the equipment may result in injury to personnel or patient as well as damage to property.

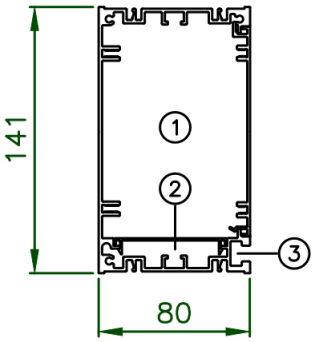
- Maximum weight on rail: 25Kg/m
- Maximum torque over one metre of rail: 50 Nm

There are 3 possible versions of the Aura model: Aura 100, Aura 200 and Aura 300.

5.4.1. General characteristics. Aura 100

Chassis consisting of 1 single cavity sharing electricity and gases, together with 2 internal separations for the passage of weak signals, and for the physical separation, in accordance with regulations, between gas components and electrical mechanisms.

Main section: (flush-mounted wall-mounting unit, Aura 100 WW)



1. Location of electrical and medical gas mechanisms*.
2. Wiring location for weak signals
3. Mounting location for DIN rail
4. LED strip placement

*This cavity can rotate its position

Fig. 1 Main chassis section of the Aura 100 wall-mounted chassis

Options with additional curved profile:

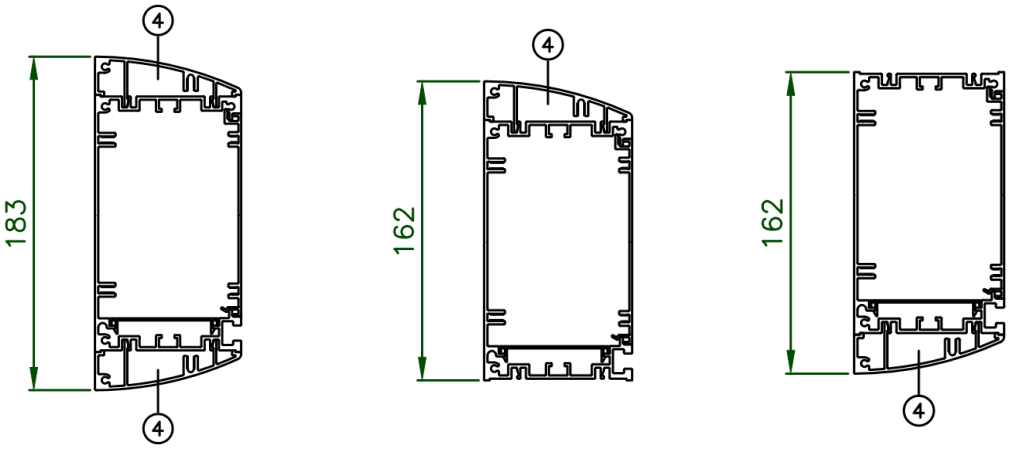


Fig. 2 Sections with additional curved profile of Aura 100

These options are given depending on how the equipment is to be mounted, so the first one corresponds to surface mounting (Aura 100 SS) and the next two correspond to semi-flush mounting (Aura 100 WS).

A typical Aura 100 configuration with additional curved top and bottom profiles is shown below, together with standard electrical and gas fittings:

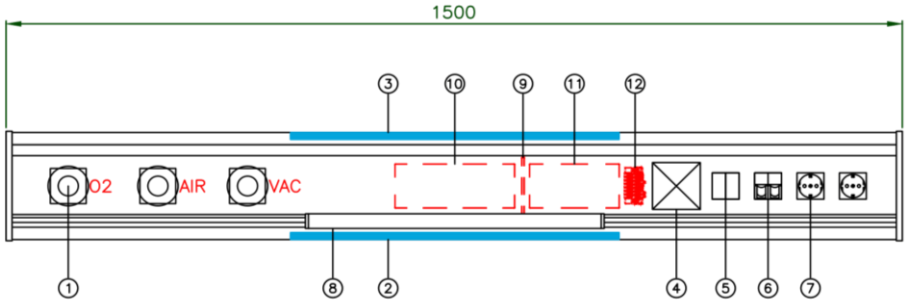


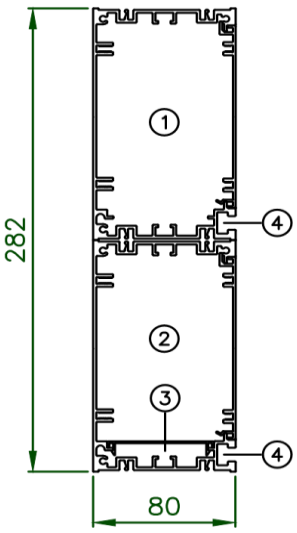
Fig. 3 Typical configuration for Aura 100

1. Gas intakes
2. LED strip for direct or reading light
3. LED strip for indirect or ambient lighting
4. Nurse call
5. Double switch for lighting actuation
6. Double RJ45 socket
7. Electrical outlets for power supply of equipment
8. DIN-rail or technical bar to support drippers, baskets and other elements.
9. Internal separator in accordance with separation regulations between gas elements and electrical mechanisms
10. Rear inlet for connection of gas pipes to the system
11. Rear entry for electrical connections to the installation and weak signals
12. Terminal block

5.4.2. General characteristics. Aura 200

Chassis consisting of 2 cavities, one for gases and the other for electricity, together with an internal separation for the passage of weak signals.

Main section: (wall mounted unit, Aura 200 WW)



1. Location of medical gases
2. Location of electrical mechanisms *
3. Wiring location for weak signals
4. Mounting location for DIN rail
5. LED strip placement

*Both cavities can be interchanged or rotate their position

Fig. 4 Main chassis section of Aura 200 wall-mounted chassis

Options with additional curved profile:

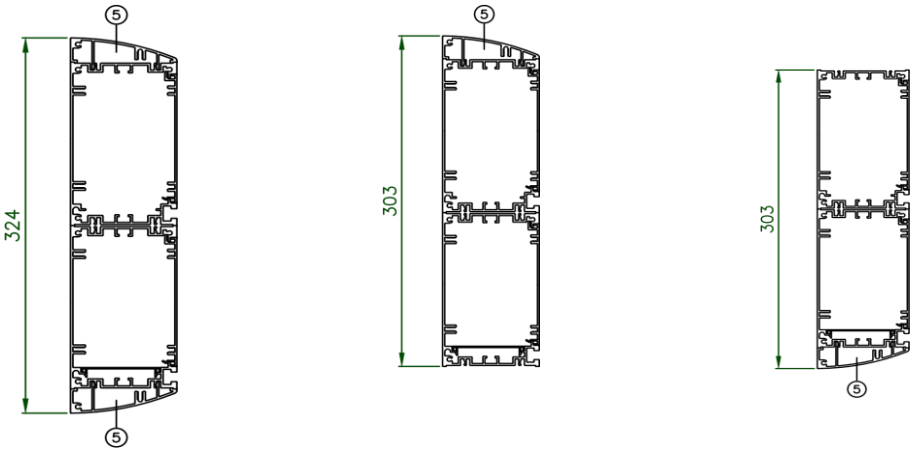


Fig. 5 Sections with additional curved profile Aura 200

These options are given depending on how the equipment is to be mounted, so the first one corresponds to surface mounting (Aura 200 SS) and the next two correspond to semi-flush mounting (Aura 200 WS).

A typical Aura 200 configuration with additional curved top and bottom profiles is shown below, together with standard electrical and gas fittings:

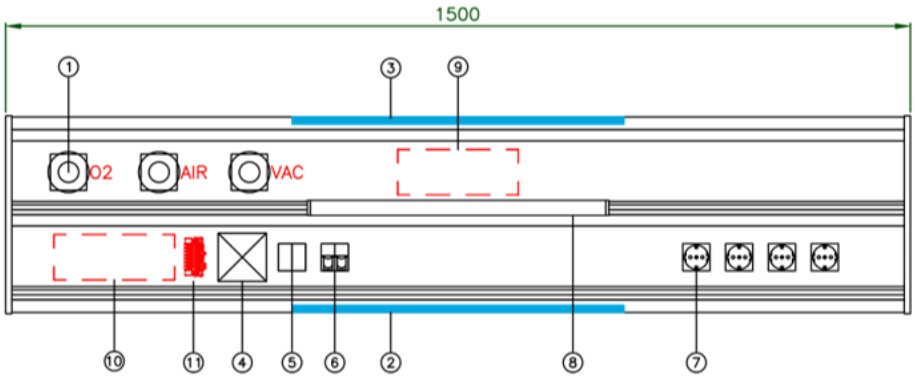


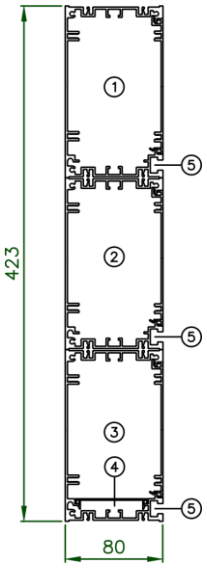
Fig. 6 Typical configuration for Aura 200

1. Gas intakes
2. LED strip for direct or reading light
3. LED strip for indirect or ambient lighting
4. Nurse call
5. Double switch for lighting actuation
6. Double RJ45 socket
7. Electrical outlets for power supply of equipment
8. DIN-rail or technical bar to support drippers, baskets and other elements.
9. Rear inlet for connection of gas pipes to the system
10. Rear entry for electrical connections to the installation and weak signals
11. Terminal block

5.4.3. General characteristics. Aura 300

Chassis made up of 3 cavities, one for gases, another for electricity, and the third with the option of one of the two previous ones depending on the needs of the project. Additionally, there is an internal separation for the passage of weak signals in the relevant cavity.

Main section: (wall mounting unit, Aura 300 WW)



1. Location of medical gases
2. Location of medical gases or electrical mechanisms *
3. Location of electrical mechanisms*.
4. Wiring location for weak signals
5. Mounting location for DIN rail
6. LED strip placement

*These cavities can be interchanged or rotated in position.

Fig. 7 Main chassis section of Aura 300 wall-mounted chassis

Options with additional curved profile:

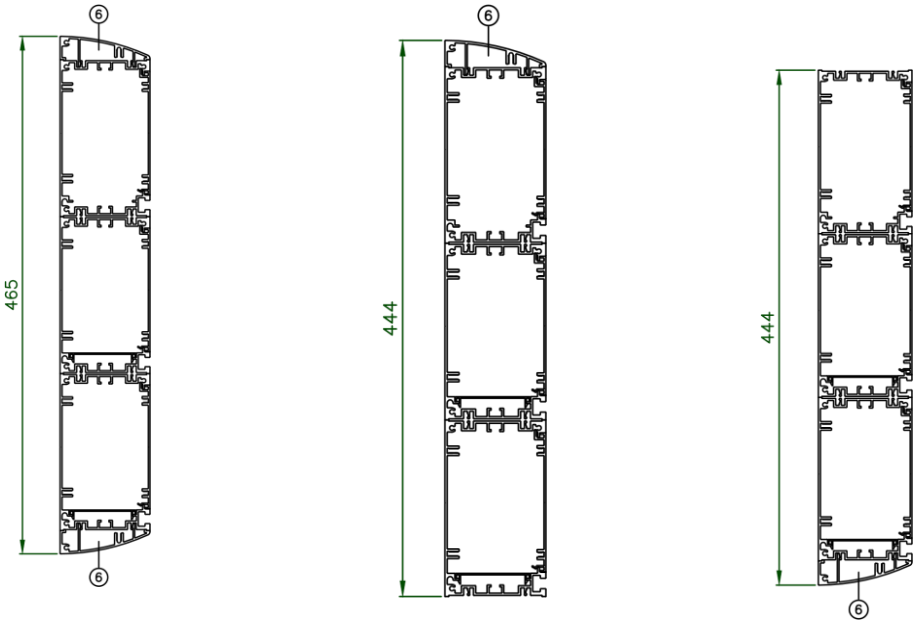


Fig. 8 Sections with additional curved profile Aura 300

These options are given depending on how the equipment is to be mounted, so the first one corresponds to surface mounting (Aura 300 SS) and the next two correspond to semi-flush mounting (Aura 300 WS).

A typical Aura 300 configuration with additional curved top and bottom profiles is shown below, together with standard electrical and gas fittings:

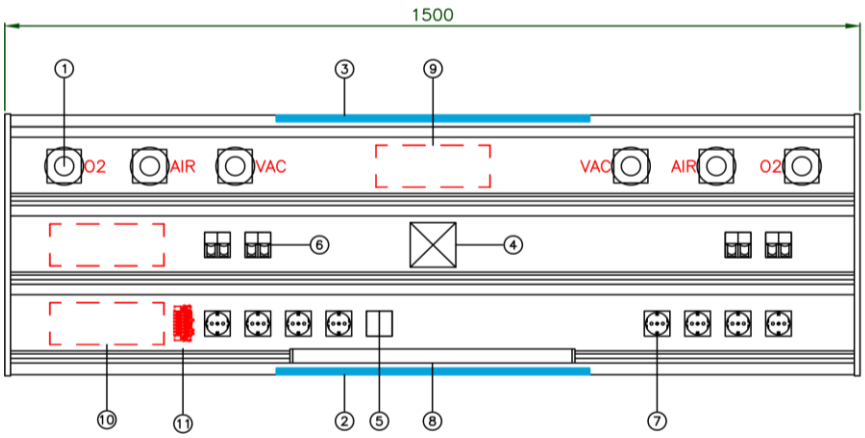


Fig. 9 Typical configuration for Aura 300

1. Gas intakes
2. LED strip for direct or reading light
3. LED strip for indirect or ambient lighting
4. Nurse call
5. Double switch for lighting actuation
6. Double RJ45 socket
7. Electrical outlets for power supply of equipment
8. DIN rail or technical bar for the support of drippers, baskets and other elements.
9. Rear inlet for connection of gas pipes to the system
10. Rear entry for electrical connections to the installation and weak signals
11. Terminal block

5.4.4. Other features and configurations

Below is an overview of the different features and configurations that the Aura model allows:

1. Assembly

The headboard can be surface-mounted or recessed in the wall. Recessed mounting does not allow for curved profiles and therefore the headboard cannot be fitted with direct or indirect lighting.

2. Chassis length and orientation

The length of the chassis is variable according to each project. The maximum length per section is 3000 mm, subject to possible extensions depending on the requirements of the project or installation. In the case of continuous headboards for the supply of more than one bed, adjacent sections are assembled to form a longitudinal headboard with multiple sections.

The orientation of the chassis can be either horizontal (the most common) or vertical.

3. Treatment and finishing

Aluminium profiles can be processed either raw and then polished or anodised.

The finishes can be epoxy paint or antibacterial paint.

The standard colour used is matt white, but any other colour is possible according to the project specifications.

4. Vinyls and phenolics

Possibility of gluing vinyl on the front covers.

Possibility of gluing phenolic boards from 0.5 to 1 mm thick.

The designs or motifs of the vinyl and phenolic panels are subject to the specifications of each project.

Possibility of digital printing on the front covers.

5. Endwall options

Installation of headwalls made of different materials: PVC and Aluminium.

6. Lighting

Installation of 10 W and 20 W LED strips, length 550 mm and colour temperature 4500 ºK. Both 120 V and 230 V power supply.

Possibility of strips of different wattage and colour temperature subject to specific requests per project.

7. Drives

Possibility to control and manipulate the lighting by means of different actuators: switches, push buttons, nurse calls, potentiometers or dimmers and switches.

Possibility of installing pushbuttons or switches to control blinds.

Possibility of installing emergency mushroom pushbuttons.

8. Electrical outlets

Possibility of installation of electrical sockets type A and B (Normal and Hospital Grade), type C, D, E, F, G, H, H, I, J, K, L, M, N, O, and multi standard sockets.

Possibility of colour variation of the electrical socket in accordance with the regulations of the region and the needs of the project.

9. Voice & data sockets and weak signals

Possibility of installing RJ45 Cat. 5/6/6A/7/7A sockets, RJ12 sockets and RJ11 sockets.

Possibility of installation of hospital-compatible call systems, either from own supply, or provision and adaptation of modules supplied by third parties.

Possibility of installing relays, remote switches and 24V control system for switching and manipulation of the lighting via the call system.

10. Protection mechanisms and land

Earthing and equipotential bonding busbars can be installed.

11. Video & audio & data sockets

HDMI, S-VIDEO, 3G BNC, 4K SDI, VGA and DisplayPort sockets can be installed.

USB 2.0/3.0/3.1 sockets can be installed.

Possibility of installing USB chargers for charging mobile devices and *tablets*.

12. Future forecasts and/or enlargements

Possibility of installing blind covers to provide for elements and their future expansion.

13. Wakefulness pilots

Possibility of installing a 1W LED signalling lamp.

14. Gas intakes

Possibility of installation and supply of gas inlets with ISO and USA standards. ISO standards include the following types: DIN 13260-2, AFNOR NF S 90-116, SS 875 24 30, BS 5682:2015, CM, CZ, ENV 737-6 EN 15908, UNI 9507, SDEGA EN ISO 9170-2.

Within the US standards are the following standards: ALLIED/CHEMETRON, DISS, OHIO/OHMEDA, PURITAN/BENNETT and OXEQUIP/MEDSTAR.

Possibility of installation of different gas intakes: O2, Medical Air, Vacuum, N2O, CO2, Air 800, N2, Motive Air, Heliox and EGA intakes (Passive or with Venturi system).

15. Accessories

DIN rails of different lengths can be installed. The maximum permissible length will be the length of the header, and this will depend on the project requirements. The number of DIN rails to be installed will depend on the configuration or version of Aura.

DIN rails can be manufactured in stainless steel or aluminium.

When placing electrical devices in the deposition areas of the system head, be sure to maintain a safety distance of at least 20 cm from the power plug and/or on/off switch of the deposited device to the nearest oxygen (O2) or nitrous oxide (N2O) outlet point at the system head.

See section 2.2 of this manual.

6. Intended use

Aura belongs to the SICA family, systems designed to be fixed to the wall above the bed in hospital rooms, Emergency Box, ICU Box, URPA Box, etc. for the supply of medical gases, electric current and communication access points, direct and indirect nurse call device, lights and support bar for hanging other medical devices.

7. Use of equipment

The specifications of each of the functional elements of the equipment must be taken into account when using the equipment.

- Electrical, voice and data circuits.
- Nurse call
- Lighting
- Gas intakes

NOTA There may be actuators for switching on modules of the lighting modules in the room in which the equipment is installed.


See product and installation drawing accompanying the equipment.


NOTICE: Details of the elements and their characteristics can be found in the product definition drawing.

7.1. Product preparation

Before COMMISSIONING, during MAINTENANCE, INSPECTION, SERVICE and after REPAIR, a functional test must be carried out at the installation site. This functional test must be carried out by the operator or a person authorised by the operator, and persons authorised by the operator must be properly instructed.

This requirement is considered fulfilled if:

1. The functional reliability of the system is assured.
2. The maximum permissible load capacity (payload) has been safely determined and is indicated on a label attached to the service head.
3. The correct functioning of the device has been approved by the operator during the first commissioning and documented by signing a test report according to Appendix G EN 62353.


See point 3 of this manual.


WARNING: To prevent unintentional actuation of the control elements, ensure that all cables and hoses are sufficiently far away from the control elements.

7.2. Environment. Environmental conditions

Ensure that the ambient conditions are within the prescribed range for proper operation of the equipment.


See section 5.2 of this manual.

7.3. Training

The personnel performing the installation must be properly trained and qualified by the customer. The equipment must only be USED by authorised personnel. Persons who:

1. have undergone medical training and are duly registered (at those levels where legal provisions make such registration necessary).

2. have been instructed in the use of this device by means of this instruction manual as a basis.

3. are able to assess the tasks they perform on the basis of their own professional experience and training in relevant safety standards and can recognise the potential hazards involved in the work.

8. Cleaning

Perform this operation with slightly moist cleaning instruments to ensure that no liquid enters the equipment. Since no part or component of the system is invasive, sterilisation is not necessary.

Do not use abrasive or very hard cleaning agents that may cause damage to the exterior coatings, such as disinfectants containing sodium hypochlorite, which is highly corrosive to aluminium.

WARNING: Damage to equipment may occur.

Formaldehyde-free disinfectants such as Saint Nebul Ald from Proder Pharma are recommended. Method of application:

4. Dilute 4 pulses of the valve supplied by the manufacturer per 5 litres of water.
5. Spray the compound on the product and let it react for 15 minutes.
6. Remove with water or soap solution with a wrung out cloth.

Switch off the power supply

Contact with live parts can cause an electric shock.

- Always disconnect the device from the main power supply before cleaning and disinfecting it.

- Do not insert objects into the openings of the device.

9. Waste management

Applies WEE2012/19 and RoHS directive 2011/65/EU, amendment 2015/863/EU. The equipment has electrical and electronic components, so it cannot be disposed of as organic waste, but as electrical/electronic waste.

10. User information on warnings

Under no circumstances should the user remove any part of the equipment enclosure to carry out checks.

10.1. Lighting problems

In the event of a fault or malfunction in the lighting systems, check the ignition from all intended actuators. If the problem persists, contact maintenance personnel.

10.2. Power supply problems

In the event of a fault or malfunction in any equipment connected to the supply unit, check this equipment by plugging it into another point of the equivalent supply unit. If the problem persists, contact service personnel.

10.3. Problems with the supply of medical gases

In the event of a failure or malfunction in the medical gas supply system, check the following:

- That you are trying to make the connection at the corresponding gas connection.
- That the gas inlet actuator is working properly and is not blocked.

If the problem persists, contact your service personnel.

11. Incident warning information

Any serious incident involving the product must be reported to Tedisel Ibérica and to the competent authority of the member state where the user and/or the patient are established.

See point 1 of this manual.

12. Regulations

12.1. Team ranking

According to the new **MDD** regulation **93/42/EEC** on medical devices, this product family is classified as:

- Class IIb, by Annex II, excluding section 4, regulation 11.
- Protection level IP20 according to IEC 60529

Equipment intended for continuous operation.

12.2. Reference standards

The device complies with the safety requirements of the following standards and directives:

ISO11197: Medical supply units

IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance.

IEC 60601-1-2: Medical electrical equipment. Part 1-2. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic disturbances.

12.3. Electromagnetic compatibility

According to EN 60601-1-2:2015 this equipment is intended for use in the electromagnetic environment specified below. The user of this equipment must satisfy himself that it is being used in such an environment.

Interference emission measurements	**Compliance**	**Comment**
HF emissions according to CISPR 11 standard	Group 1	The supply unit uses HF energy exclusively for its internal OPERATION. Therefore, its HF emissions are minimal and interference with devices in its vicinity is unlikely.
HF emissions according to CISPR 11 standard	Class A	The roof supply unit is suitable for use in non-domestic installations and in installations that are directly connected to the PUBLIC SUPPLY NETWORK, which also supplies residential buildings.
Harmonic emissions according to the standard IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/transients according to the standard IEC 61000-3-3	In accordance with	

Interference resistance	Test level according to IEC 60601	Level of compliance	Environment/Guidelines
Static Electric Discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge 15 kV aerial discharge	±8 kV contact discharge 15 kV aerial discharge	Floors should be made of wood, concrete or ceramics. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Fast transient electrical interference amplitudes / bursts according to the norm IEC 61000-4-4	±2 kV for power supply cables ±1kV for input and output cables	±2 kV for power supply cables ±1 kV for incoming and outgoing cables	The quality of the supply voltage should be typical for a commercial or hospital environment.
Overvoltage (wave) according to IEC 61000-4- 5	±1 kV phase-to-phase voltage ±2 kV phase to ground voltage	±1 kV phase-to-phase voltage ±2 kV phase to ground voltage	The quality of the supply voltage should be typical for a commercial or hospital environment.
Voltage dips and fluctuations of the supply voltage according to the standard IEC 61000-4- 11	100% of U_N drop for 0.5 period 100% of U_N drop for 1 period 30% of U_N drop for 25 periods Remark: UN is the AC mains voltage before applying the test level.	100% U_N drop for 0.5 period 100% drop in U_N for 1 period 30% drop in U_N for 25 periods	The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the roof supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the roof supply unit from a device with an uninterruptible power supply or a battery.

Short interruptions of the supply voltage according to the standard IEC 61000-4- 11	100% for 5 s Remark: UN is the AC mains voltage before applying the test level.		The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the roof supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the roof supply unit from a device with an uninterruptible power supply or a battery.
Magnetic field for power supply frequencies (50/60 Hz) according to the standard IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields created by the mains frequency should be those of a commercial or hospital environment.

Interference resistance	**Level of verification according to IEC 60601**	**Level of compliance**	**Environment/Guidelines**
HF interference induced by IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM band	3 Vrms 6 Vrms	AM 1KHz modulation Depth 80% Depth 80% Depth 80% Depth
HF interference induced by IEC 61000-4-3			

RANGE	FREQUENCY	MODULATION	STEP	LEVEL
A	80-1000MHz	AM 1 kHz Prof: 80%	LOG 1%	10 V/m
B	1000-2000MHz	AM 1 kHz Prof: 80%	LOG 1%	10 V/m
C	2000-2700MHz	AM 1 kHz Prof: 80%	LOG 1%	10 V/m
D	385MHz	PM 18 Hz Cycle: 50%	-	27 V/m
E	450MHz	FM 1 kHz Desv:± 5 kHz	-	28 V/m
F	810-930MHz	PM 18 Hz Cycle: 50%	-	28 V/m
G	1720-1970MHz	PM 217 Hz Cycle: 50%	-	28 V/m
H	2450MHz	PM 217 Hz Cycle: 50%	-	28 V/m
I	5240-5785MHz	PM 217 Hz Cycle: 50%	-	9 V/m

Transmitter power rating	Safety distance depending on emission frequency Environment/Guidelines		
	150 kHz to 80 MHz $D = 1,2\ P$	80 MHz up to 800 MHz $D = 1,2\ P$	800 MHz up to 2.5 GHz $D = 2,3\ P$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23