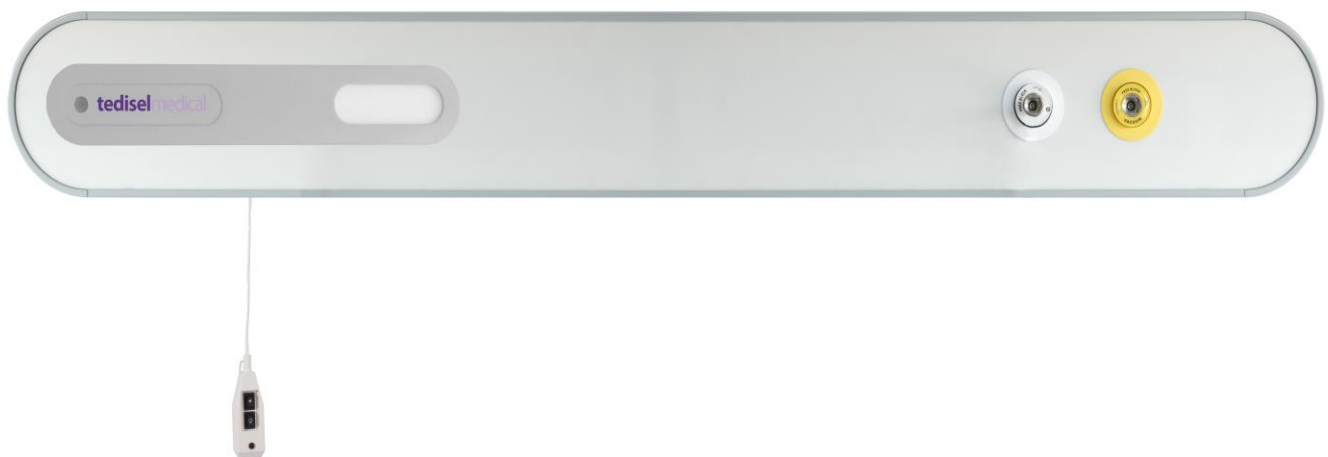


**tedisel**medical

# ICARUS

MAINTENANCE MANUAL



**CE** 0197

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# ICARUS

## Maintenance Manual

## 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

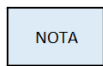


Explosion hazard: warns of ignition of explosive gas mixtures.



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

### 2.4. Indication of additional information



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.

#### 3.5. Essential Performance and Basic Safety Considerations

To ensure the BASIC SAFETY and ESSENTIAL PERFORMANCE, the following conditions are expected during the intended use:

- the electrical outlets work properly
- the light modules work properly

However, due to external unexpected EM disturbances, the ESSENTIAL PERFORMANCE can be degraded producing:

- Risk for the user/patient

- Cessation or interruption the power on the electrical outlets

### 3.6. EM Interference



WARNING: portable RF communications equipment, including antennas, can affect the systems. These types of devices should be used no closer than 30 cm (12 inches) to any part of the system, including cables”.

## 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 symbol



Product code



Unique identification code



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 ICARUS 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.

No special instructions are needed for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.

## 5.4. Purpose of the product

These systems have three main distinct functions within the hospital:

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

They consist of a chassis made of aluminium profiles, which integrates the electrical equipment, call, voice and data systems, and installation and channelling of medical gas outlets.

# 6. Maintenance

## 6.1. Training

Personnel performing maintenance must be trained and qualified by the customer. Persons who:

1. have received the training and are duly registered (at those levels where legal provisions make such registration necessary).
2. have been instructed in the maintenance 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.

## 6.2. Removal and installation of covers

For maintenance of the equipment, the outer covers must be removed.

### 6.2.1. Removal of diffusers

- Using a flat-nosed tool, remove the light diffusers ① as shown in figure 1, taking care not to scratch the paintwork on the top and bottom covers ②.
- Put the diffusers back on the equipment and press them into position until the clipping sound is heard.

### 6.2.2. Removal of top and bottom covers

- Using a flat-nosed tool, remove the top and bottom covers ② as shown in figure 1 taking care not to scratch other areas of the enclosure and leave them in a safe place.
- Place the upper and lower covers ② back on the device by pushing them into position and pressing them together until the clipping sound is heard.

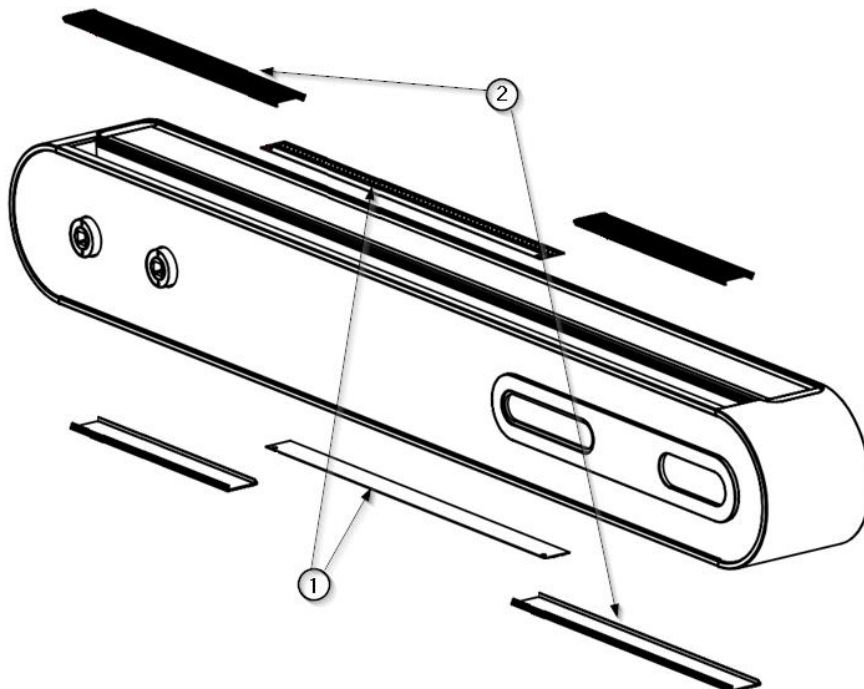


Fig. 1 Removal of diffusers and top and bottom covers

### 6.2.3. Withdraws from the front

- Remove the top covers as described in the previous point.

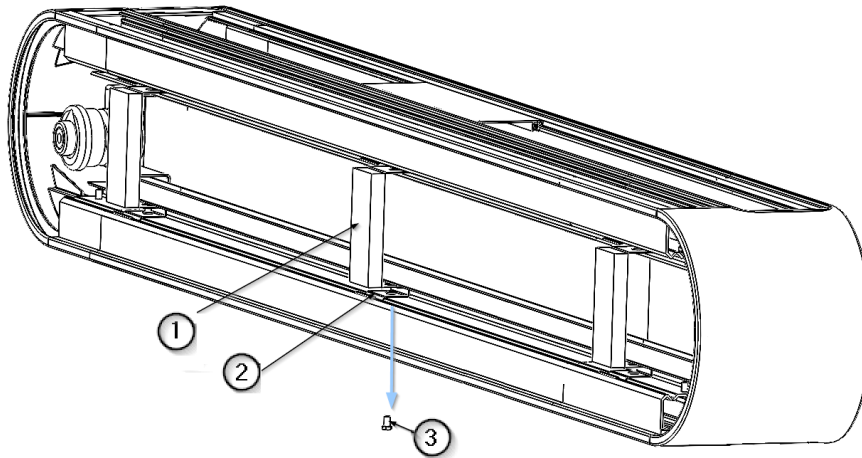


Fig. 2 Removing the front panel hardware

- Remove the M4 x 8 DIN 7505 screws (3) securing the front panel clamping tabs (2). The bracket (1) is fixed to the front panel.
- Remove the front cover (5) using two suction cups (4) as shown in figure 3 to reveal the pre-installed gas inlets on the device.

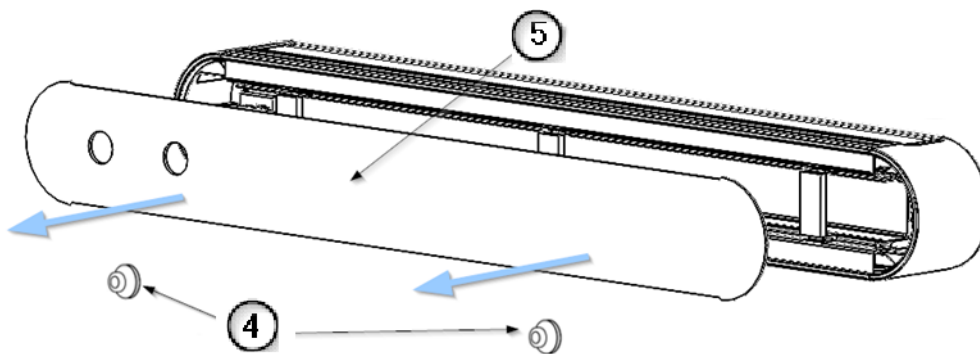


Fig. 3 Removal of the front panel

- To put the central cover back on the device, move it into position and press it until you hear the clipping sound.

### 6.2.4. Removal of side walls

- Remove the top covers as described in section 6.1.2 of this manual. The screw (2) that fixes the end cap will be visible.

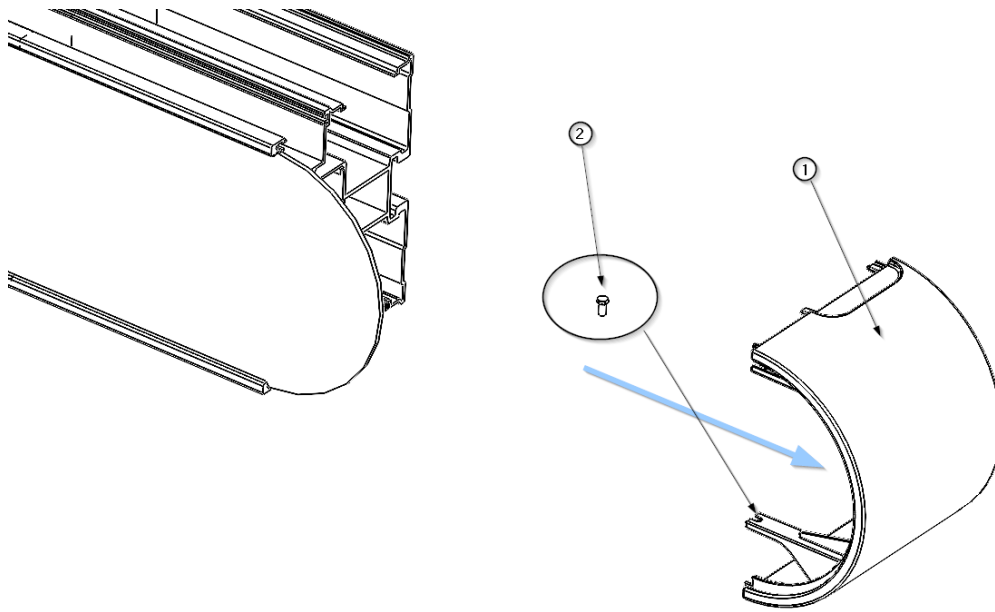


Fig. 4 Removal of side walls

- Remove the M4 x 10 screw ② DIN 7505 and slide the end cap ① in the direction of the equipment chassis to remove it as shown in figure 4.
- To refit the end cap ① simply push it into position in the direction of the chassis until the end cap stops and fit the fixing screw ②.

### 6.3. Medical gas supply circuits



It is recommended that the equipment be disconnected electrically before servicing.

- Remove the front cover protecting the gas pipes.



See section 6.1 of this manual.

Passage	Description	Periodicity	Tools/supplies
1	<p><b>Detailed Visual Inspection:</b></p> <p>A) Perform a thorough visual inspection of all interior ductwork for signs of wear or damage.</p>	Annual	Screwdriver set, protective gloves, torch, torch, etc.
2	<p><b>Leak Detection:</b></p> <p>A) Prepare a soap solution in a container.</p> <p>B) With a brush or paintbrush, apply the solution to the junction points of the piping</p>	Biannual	Soap solution, brush or paintbrush

	<p>to the gas terminal units, and other soldered connections.</p> <p>C) Watch for bubbles to form, indicating the presence of a leak.</p> <p>D) If a leak is detected, mark the area for later correction.</p>		
<b>3</b>	<p><b>Verification of gas terminal brackets:</b></p> <p>A) Physically assess the condition and integrity of the trunking supports. Check for wear or structural damage.</p> <p>B) Ensure that the brackets are firmly fixed to the profile and that there is no movement or play in the brackets.</p>	Annual	Hand tools, protective gloves
<b>4</b>	<p><b>Maintenance Register:</b></p> <p>A) After each inspection or intervention, record in a document or management system all details, such as date, findings, actions taken, name of technician, and parts replaced.</p> <p>B) Keep this record organised and accessible for future reference and audits.</p>	Always	Maintenance log

**Additional note:** Be sure to follow all relevant safety regulations and recommendations. It is essential that personnel involved in these tasks are properly trained and wear personal protective equipment.

#### 6.4. Electrical and voice and data circuits, lighting

It is recommended that the equipment be disconnected electrically before servicing.

- Remove the top and bottom covers protecting the conduits for electrical, voice and data components and lighting.



See point 6.1 of this manual

NOTA

For equipment in which an electrical element located on the central rail has been requested, the protective cover of this rail must be removed again.

- Carry out a visual inspection before starting the checks.
- Sockets: Check the voltage at each of the equipment's sockets.
- Lighting: Check the switching on/off from the pushbuttons on the equipment and/or from the call control. If they do not work properly, see point 6.5 of this manual.
- Voice and data: Check each of the mechanisms of the equipment and call control. To be carried out by the centre's IT and communications staff.

### 6.5. Replacement of LED strips and drivers in lighting modules

If the lighting modules of the ICARUS system malfunction, both the LED strips ⑤ and the controllers ⑦ must be replaced.



Disconnect the equipment electrically before replacement.

- Remove the diffusers as described in paragraph 6.1.1 of this manual. The lighting module shall be exposed.
- Disconnect the quick connector from the LED strips ①.
- Disconnect the power supply to the controllers ③ from the terminal strip.
- Unscrew the M4 x16 hex screws ⑤ DIN 933 by releasing the tabs ④ holding the controllers ③.

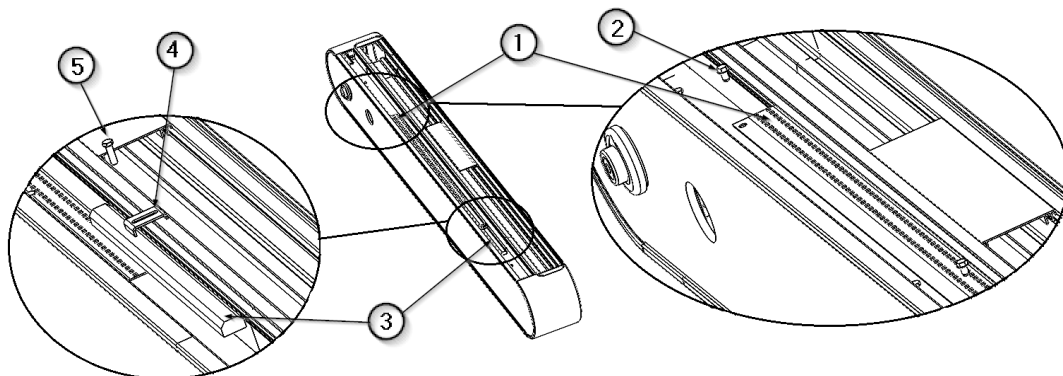


Fig.5 Replacement of LED strips and drivers

- Fit the new controllers ③ and secure them with the tabs ④ by screwing in the hexagonal screws ⑤.
- Connect the power supply of the controllers back to the terminal strip.
- Unscrew the two M4 x 8 hex screws ② DIN 7505 releasing the LED strips ①.
- Fit the new LED strips ① and secure them with the hexagonal screws ②.
- Connect the power supply quick connector of the newly installed LED strips ①.

- Check that the lighting module is fixed in position.
- Power up the lighting circuit and perform a test run to check that the lighting module switches on and off.



Contact with live parts can cause an electric shock.

- Replace the diffusers.





## 6.6. Envelopes and structural elements

Carry out a visual inspection to detect if any item is not properly fixed.



In case of suspicion, carry out a physical check of the elements and refasten them properly.

## 6.7. Maintenance plan

Item to be inspected	Description	Periodicity	Method of inspection
<b>Gas outlets</b>	Inspection of medical gas intakes*.	Annual	Visual inspection and functional test  Ease of connection and disconnection manoeuvres  Wear and tear or damage  Marking and labelling
<b>Copper gas connection I</b>	Overhaul and status check*.  It is recommended to disconnect the equipment electrically before proceeding with the overhaul.  	Annual	Visual inspection  Verification of supports  See point 6.3 <i>Medical gas supply circuits</i>  
<b>Copper gas connections II</b>	Overhaul and status check*.  It is recommended to disconnect the equipment electrically before proceeding with the overhaul.  	Biannual	Leak detection  See point 6.3 <i>Medical gas supply circuits</i>  



<b>LED lighting</b>	Testing of LED strips for direct and indirect light	Half-yearly	Visual inspection and function test  See points 6.5 <i>Replacement of LED strips and drivers in lighting modules</i>  
<b>Nurse call</b>	Operation of the call system	Half-yearly	Simulation of call and system response. Ensure effective communication with nursing
<b>Switches</b>	Checking of the lighting actuation	Annual	Functional test. Check operability
<b>RJ45 sockets</b>	Inspection of voice and data sockets	Annual	Connecting to devices and testing data transfer
<b>Electrical outlets</b>	Verification of equipment power supply*.	Half-yearly	Use of a multimeter to check supply voltage and continuity (3), and connection of devices
<b>Electrical and data cabling</b>	Review and check of status and functionality*.  It is recommended to disconnect the equipment electrically before proceeding with the overhaul.  	Annual	Visual inspection and functional test. Check connections, and correct signalling.  Check according to applicable regulations  See section 6.4 <i>Electrical, voice and data circuits, lighting, etc.</i>  
<b>Entrances (gas and electrical)</b>	Checking pipe and electrical connections*.	Annual	Visual inspection. Check connections, absence of obstructions and correct marking.
<b>Video &amp; audio outlets</b>	Operation of HDMI and USB sockets, etc.	Annual	Device connection and data/video/audio transfer
<b>Protection mechanisms</b>	Verification of earths and protections*.	Annual	Use of a multimeter (3) for continuity tests
<b>Treatment and finishing</b>	Check paint condition	Annual	Visual inspection and tactile test (4)

<b>Vinyls and phenolics</b>	Check condition of vinyls and plates	Annual	Visual inspection and tactile test (4)
<b>Headwalls</b>	Inspection of the headwalls and their condition	Annual	Visual inspection and tactile test (4)

Damaged, deformed or missing components must be replaced as soon as possible. In that case contact the supplier of the Equipment.

\*If one of the above points is found to be non-compliant during the inspection, the system must be shut down immediately as a precautionary measure to prevent further damage to persons and equipment. Notify the system supplier immediately.

### (3) Use of the multimeter:

- It shall be used to verify that electrical outlets and related components are operating correctly. With it, values such as voltage (to ensure that the sockets are providing the correct voltage), resistance (to identify possible faults or short circuits) and continuity (to ensure that circuits are complete and there are no interruptions) can be measured.

### (4) Tactile test:

- This refers to using touch to evaluate a surface or component. For example, by running the hand or fingers over the paint on a structure, one can determine if there are any irregularities, bumps or flaking.

## 7. 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:

1. Dilute 4 pulses of the valve supplied by the manufacturer per 5 litres of water.
2. Spray the compound on the product and let it react for 15 minutes.
3. 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.

## 8. 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.

## 9. Regulations

### 9.1. 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.

### 9.2. 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.

### 9.3. 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	<p>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.</p> <p><b>NOTA</b> The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.</p>
Harmonic emissions according to the standard IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/transients in accordance with 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)	±1 kV phase-to-	±1 kV phase-to-phase	The quality of the supply

according to IEC 61000-4- 5	phase voltage ±2 kV phase to ground voltage	voltage ±2 kV phase to ground voltage	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: $U_N$ is the AC mains voltage before applying the test level.	100% $U_N$ drop for 0.5 period 100% of $U_N$ drop for 1 period 30% of $U_N$ drop 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: $U_N$ 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
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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	<table border="1"> <thead> <tr> <th>RANGE</th> <th>FREQUENCY</th> <th>MODULATION</th> <th>STEP</th> <th>LEVEL</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>80-1000MHz</td> <td>AM 1 kHz Prof: 80%</td> <td>LOG 1%</td> <td>10 V/m</td> </tr> <tr> <td>B</td> <td>1000-2000MHz</td> <td>AM 1 kHz Prof: 80%</td> <td>LOG 1%</td> <td>10 V/m</td> </tr> <tr> <td>C</td> <td>2000-2700MHz</td> <td>AM 1 kHz Prof: 80%</td> <td>LOG 1%</td> <td>10 V/m</td> </tr> <tr> <td>D</td> <td>385MHz</td> <td>PM 18 Hz Cycle: 50%</td> <td>-</td> <td>27 V/m</td> </tr> <tr> <td>E</td> <td>450MHz</td> <td>FM 1 kHz Desv:± 5 kHz</td> <td>-</td> <td>28 V/m</td> </tr> <tr> <td>F</td> <td>810-930MHz</td> <td>PM 18 Hz Cycle: 50%</td> <td>-</td> <td>28 V/m</td> </tr> <tr> <td>G</td> <td>1720-1970MHz</td> <td>PM 217 Hz Cycle: 50%</td> <td>-</td> <td>28 V/m</td> </tr> <tr> <td>H</td> <td>2450MHz</td> <td>PM 217 Hz Cycle: 50%</td> <td>-</td> <td>28 V/m</td> </tr> <tr> <td>I</td> <td>5240-5785MHz</td> <td>PM 217 Hz Cycle: 50%</td> <td>-</td> <td>9 V/m</td> </tr> </tbody> </table>					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
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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 (m)		
	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



**WARNING:** stacking the device or installing the device close to other equipment may affect to the performance of the systems due to EMI disturbances.