tediselmedical

N270

MAINTENANCE MANUAL

tediselmedical.com

Content

1. Manufacturer

Manufacturer: TEDISEL IBÉRICA S.L.
Address: C/ Sant Lluc, 69-81. 08918 - Badalona (Barcelona) SPAIN
Tel. +34 933 992 058
Fax +34 933 984 547
tedisel@tedisel.com
www.tediselmedical.com

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 a 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 the ends of building connections 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 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 N270 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. 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 fitting of external covers

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

6.2.1. Removal of diffusers

- Remove the light diffusers ① as shown in Fig. 1. Use a flat-bladed screwdriver with care not to scratch the paint on the side covers.

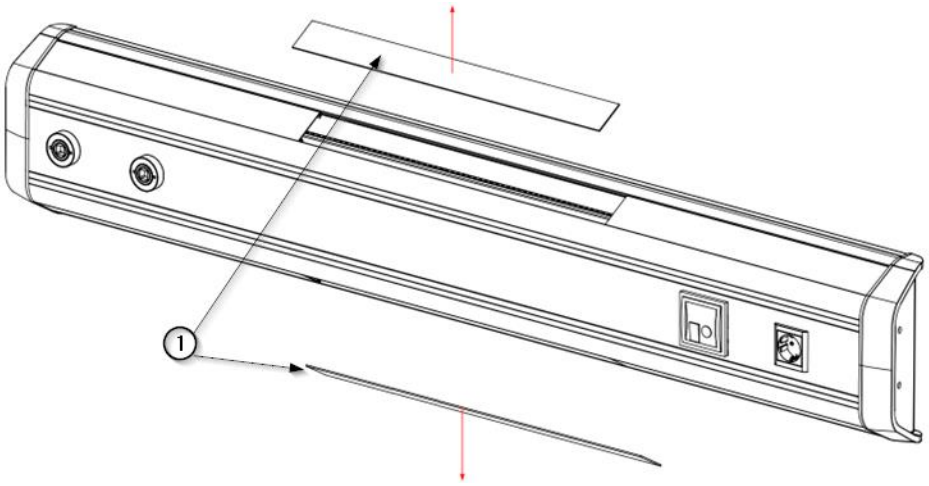

Fig.1 Removal of upper and lower diffusers

- 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

- Remove the diffusers as described in the previous chapter. You now have access to the side of the upper ① and lower ② covers.
- Remove the top covers ① and bottom covers ② as shown in figure 2 and leave them in a safe place.

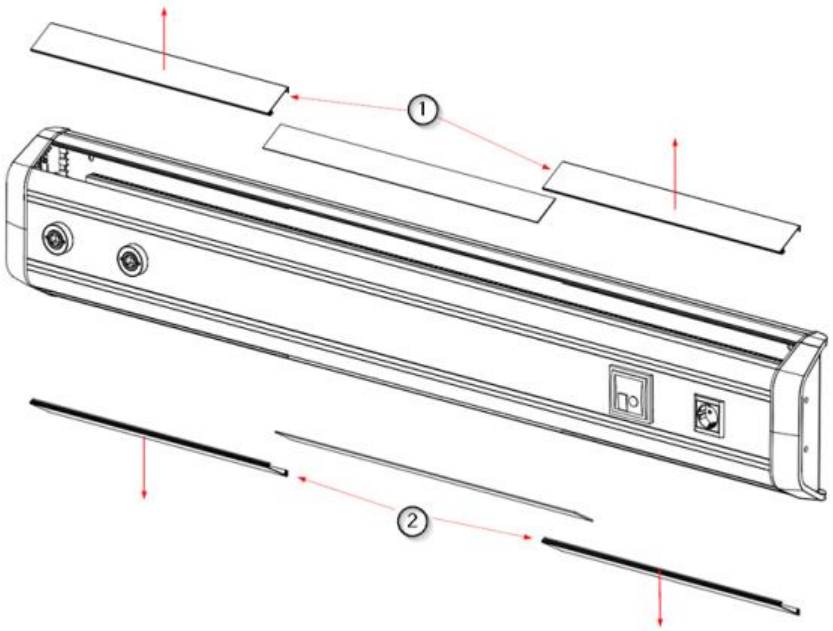

Fig.2 Removal of top and bottom coverings

- Place the top and bottom covers back on the equipment by bringing them into position and pressing them together until the clipping sound is heard.

6.2.3. Removal of central cover

- Remove the front cover ② using the suction cup ① as shown in figure 3 to reveal the pre-installed gas inlets on the device.

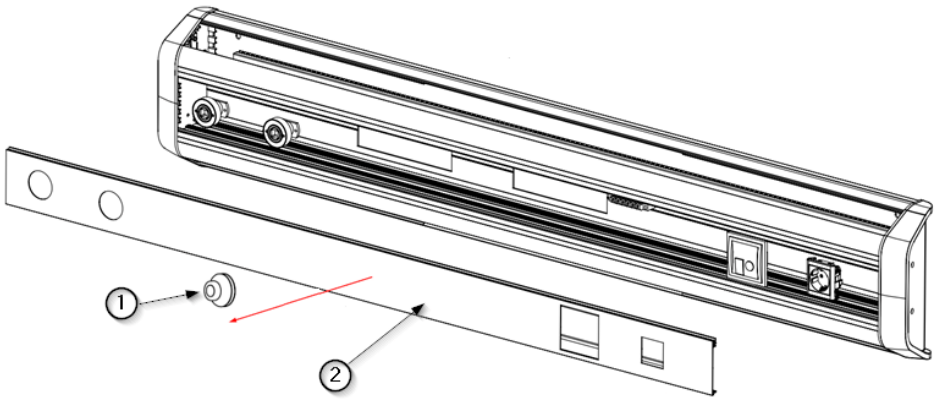

Fig.3 Removing the central cover of the gas rail

- Place the central cover on the device and press it into position until the clipping sound is heard.

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.

- Check the welding points of the pipeline by wetting these areas with a soapy solution (welding test foam).
- Check the condition of the brackets to ensure that they are securely attached to the gas profile.
- Check the condition of the gas intakes, their actuators, etc.

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 section 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 push buttons 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 module s

If the lighting modules of the N270 system are malfunctioning, both the LED strips ② and the controllers ① 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 strip ②.
- Disconnect the power supply of the controller ① from the terminal strip.
- Unscrew the M4 x16 hex screws ④ DIN 933 releasing the tab ③ holding the controller ① and LED strip ②.

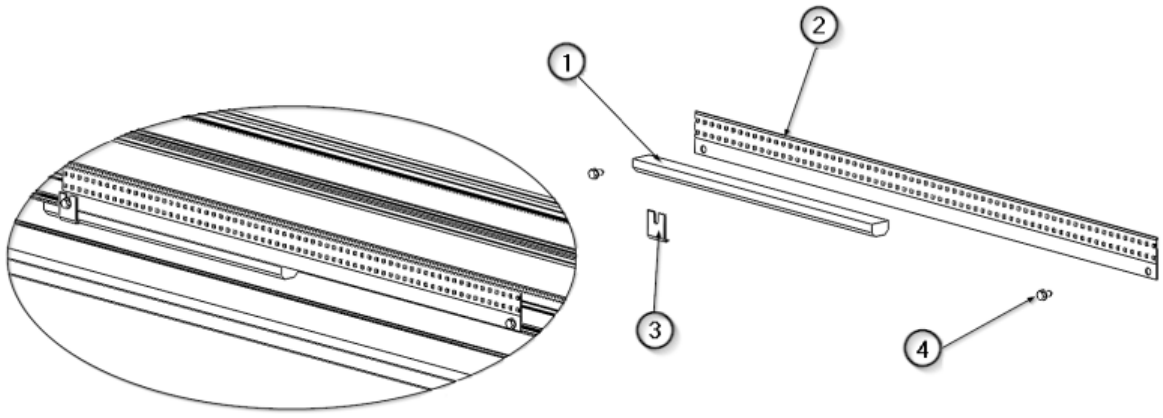

Fig.4 Replacing LED strips and controllers

- Attach the LED strip ② and secure it with an M4 x16 hex screw ④ (the one that is not used to secure the tab ④ that holds the driver).
- Fit the new controller ① and secure it with the tab ③ by screwing in the second hexagonal screw ④.

- Connect the power supply of the controller ① back to the terminal strip.
- Connect the power supply quick connector of the newly installed LED strip ②.
- 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.

Put the covers back in place.

6.6. Envelopes and structural elements

- Perform a visual inspection to detect if any items are not properly secured.

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

6.7. Inspection plan

Inspection plan		
Important information		
• Inspection intervals must be observed •The attached system must be checked by Tedisel or a company authorised by Tedisel. Following the points and intervals described below.		
Visual Inspection (annual)	NOK	OK
• The parts of the bonded system are not deformed and do not show any damage (scratches, cracks, etc.)*.		
• The system is free of paint defects*.		
• Covers are available and correctly fitted*		
• All rating plates and labels are available and legible		
• All electrical and/or voice and data cables must be inspected for damage and replaced if necessary**		
• All copper conduit for medical gases and vacuum must be inspected for damage and replaced if necessary**.		
Functional check (annual)	NOK	OK
• The system is securely in place;		
• All sockets (if any) are fixed and working properly**.		
• Tested protective conductor resistance** (EN 62353)		
• Gas intakes (if any) were fixedly mounted and are working properly**.		
• Inspection of copper piping for medical gases and vacuum (if any) **		
•The lighting (if any) is switched on when the switch is operated.		
Observations		
Confirmation of the inspection		
The above-mentioned work, including the necessary adjustments and security testing, has been carried out:		
Date	**Name (in capitals)**	**Signature**
* Damaged, deformed or missing components should be replaced as a precautionary measure. In this case, please contact the supplier of the suspension system. ** If one of the above items is found to be non-compliant during the inspection, the attached system must be shut down immediately as a precautionary measure to ensure that avoid further damage to persons and equipment. Notify the system supplier immediately.		

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** concerning 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	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 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) 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 UN drop for 0.5 period 100% of UN drop for 1 period 30% of UN drop for 25 periods Remark: UN is the AC mains voltage before applying the test level.	100% UN drop for 0.5 period 100% of UN drop for 1 period 30% of UN 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: 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.

<table>
<tr><th>Interference resistance</th><th>Level of verification according to IEC 60601</th><th>Level of compliance</th><th>Environment/Guidelines</th></tr>
<tr><td>HF interference induced by IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz
6 Vrms ISM band</td><td>3 Vrms
6 Vrms</td><td>AM 1KHz modulation
Depth 80% Depth 80%
Depth 80% Depth</td></tr>
<tr><td>HF interference induced by IEC 61000-4-3</td><td colspan="3">
<table>
<tr><th>RANGE</th><th>FREQUENCY</th><th>MODULATION</th><th>STEP</th><th>LEVEL</th></tr>
<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>
</table>
</td></tr>
</table>

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