

tediselmedical

ANTEA

MAINTENANCE MANUAL



CE 0197

tediselmedical.com

Content

1.	Manufacturer	3
2.	Security information.....	3
2.1.	Injury risk warnings.....	3
2.2.	Warnings of risk of damage	4
2.3.	Supplementary symbols used in the safety instructions	4
2.4.	Additional information	4
2.5.	Proper use of oxygen.....	4
2.5.1.	Oxygen explosion	4
2.5.2.	fire hazard.....	5
3.	Risks.....	5
3.1.	Gas explosion	5
3.2.	Risk of device malfunction.....	5
3.3.	Fire hazard	5
3.4.	Danger of electric shock	5
3.5.	Essential Performance and Basic Safety Considerations	5
3.6.	EM Interference	6
4.	Symbols used.....	6
5.	Product data.....	8
5.1.	Storage conditions	8
5.2.	Operating conditions	9
5.3.	Service life.....	9
5.4.	Purpose of the product.....	9
6.	Maintenance	9
6.1.	Training	9
6.2.	Removal/assembly of main or front cover	10
6.3.	Medical gas supply circuits	10
6.4.	Electrical and voice and data circuits, lighting.....	12
6.5.	Envelopes and structural elements	12
6.6.	Maintenance plan.....	12
7.	Cleaning.....	14
8.	Waste management	15
9.	Regulations.....	15
9.1.	Team ranking	15

9.2.	Reference standards.....	15
9.3.	Electromagnetic compatibility.....	16

1. Manufacturer

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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 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 symbols visually emphasise 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. Supplementary symbols used in the safety instructions



Fire hazard

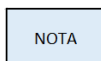


Explosion hazard: warns of ignition of explosive gas mixtures.



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

2.4. Additional information



A NOTE provides additional information and useful tips for the 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:

- Ensure 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



Escaping oxygen is fuel:

- Naked flame, red-hot objects and open lights are not allowed when working
- Do not 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 anaesthetic mixtures with high concentrations of oxygen or nitrous oxide.

If such high concentrations of flammable anaesthetic mixtures with oxygen or nitrous oxide occur in the vicinity 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 not receive power.

3.3. Fire hazard



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 connection points of the building's wiring 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 shall be met during intended use:

- the electrical outlets operate properly

- the light modules operate properly

However, due to external unexpected EM disturbances, the ESSENTIAL PERFORMANCE may be degraded, resulting in:

- Risk for the user/patient
- Cessation or interruptions to the power in 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



Hazardous voltage



NOTICE

Notice



Risk of finger entrapment



WARNING

Warning



CAUTION

Caution



DANGER

Danger

5. Product data

This manual refers to the ANTEA 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 inlets 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
- 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 the installation must be properly 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 in accordance with this instruction manual.
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/assembly of main or front cover

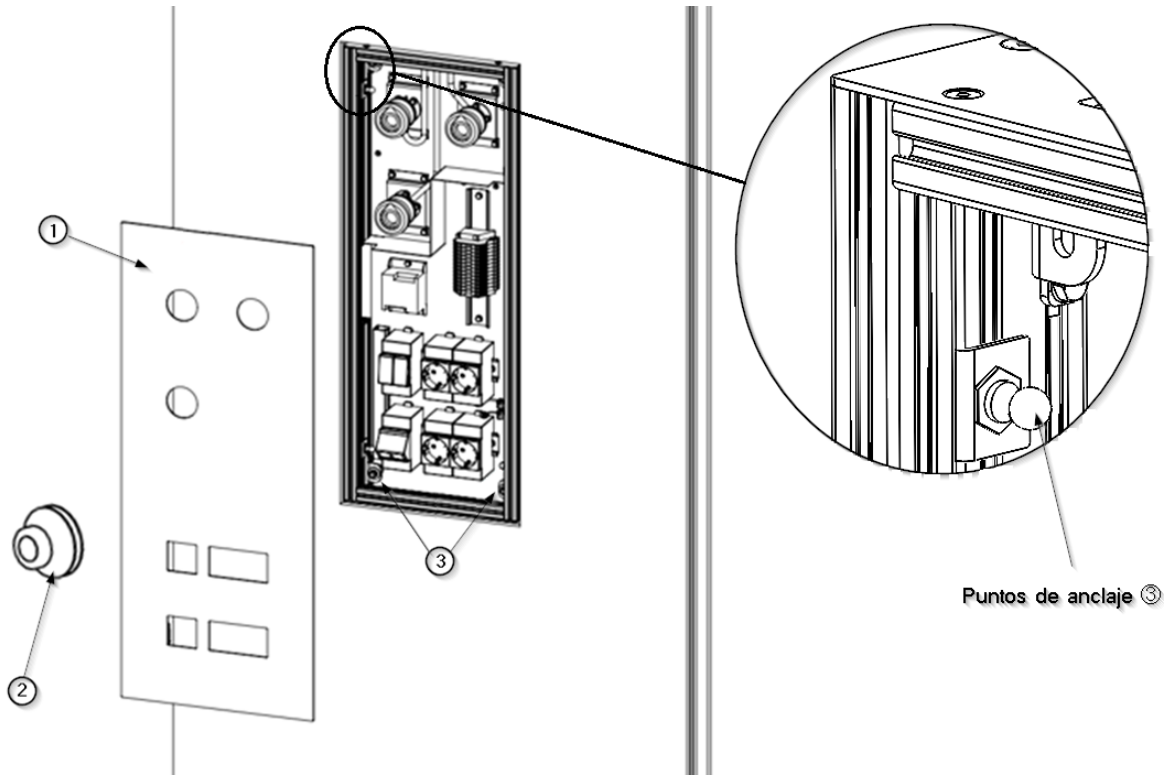


Fig. 1 Removal of the front of ANTEA

- Remove the cover ① using the suction cup ②. All gas, electrical, voice and data circuits will be exposed.
- To refit, present the cover and locate the anchorage points ③.
- Press on the cover in the area of the anchor points ③ until you hear the clipping sound.



Make sure not to place fingers near the sides of the ANTEA cover.

- Check that the cover is securely in place and that all electrical and gas elements are correctly positioned.

6.3. Medical gas supply circuits



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

- Remove the front cover of the equipment as described in the previous point.



See point 6.2 of this manual

Passage	Description	Periodicity	Tools/supplies
1	<p>Detailed Visual Inspection:</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>Leak Detection:</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 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>	Biannual	Soap solution, brush or paintbrush
3	<p>Verification of gas terminal brackets:</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
4	<p>Maintenance Register:</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

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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 front cover of the equipment as described in section 6.2 of this manual.



See point 6.2 of this manual

- Sockets: Check voltage at each of the equipment's sockets.
- Lighting: On/off check from push buttons on the equipment and/or from the call control.
- Voice and data: Checking of each of the mechanisms of the equipment and call control by the centre's IT and communications staff.
- Replace the front cover of the equipment



6.5. 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.

6.6. Maintenance plan

Item to be inspected	Description	Periodicity	Method of inspection
Gas outlets	Inspection of medical gas inlets*.	Annual	Visual inspection and functional test Ease of connection and disconnection manoeuvres Wear and tear or damage Marking and labelling
Copper gas connection I	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> 

Copper gas connections II	<p>Overhaul and status check*.</p> <p>It is recommended to disconnect the equipment electrically before proceeding with the overhaul.</p> 	Biannual	<p>Leak detection</p> <p>See point 6.3 <i>Medical gas supply circuits</i></p> 
Nurse call	Operation of the call system	Biannual	Simulation of call and system response. Ensure effective communication with nursing
Switches	Checking of the lighting actuation	Annual	Functional test. Check operability
RJ45 sockets	Inspection of voice and data sockets	Annual	Connecting to devices and testing data transfer
Electrical outlets	Verification of equipment power supply*.	Biannual	Use of a multimeter to check supply voltage and continuity (3), and connection of devices
Electrical and data cabling	<p>Review and check of status and functionality*.</p> <p>It is recommended to disconnect the equipment electrically before proceeding with the overhaul.</p> 	Annual	<p>Visual inspection and functional test. Check connections, and correct signalling.</p> <p>Check according to applicable regulations</p> <p>See section 6.4 <i>Electrical, voice and data circuits, lighting, etc.</i></p> 
Inputs (gas and electrical)	Checking pipe and electrical connections*.	Annual	Visual inspection. Check connections, absence of obstructions and correct marking.
Video & audio outlets	Operation of HDMI and USB sockets, etc.	Annual	Device connection and data/video/audio transfer
Protection mechanisms	Verification of earths and protections*.	Annual	Use of a multimeter (3) for continuity tests

Treatment and finishing	Check paint condition	Annual	Visual inspection and tactile test (4)
Vinyls and phenolics	Check condition of vinyls and plates	Annual	Visual inspection and tactile test (4)
Front	Inspection of the front end and its condition	Annual	Visual inspection and tactile test (4)
Ball retainers	Inspection of ball retainers securing the front end to the frame*.	Annual	Visual inspection and tensile test
Chassis and Structure	Inspection of the tubular profile and sheet aluminium structure	Annual	Visual and tactile inspection (4) to detect deformities

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:

- 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.
- The test shall be considered successful if, to the touch, the surface is uniform, with no perceptible irregularities and no signs of flaking or deterioration.

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 Aid 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 using 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 93/42/EEC** regulation on medical devices, this product group is classified as:

- Class IIb, according to Annex II, with the exception of section 4, rule 11.
- IP20 protection class according to IEC 60529.

Equipment designed for continuous operation.

9.2. Reference standards

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

ISO11,197 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	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	Class A	The ceiling 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. 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.
Harmonic emissions according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/transients according to IEC 61000-3-3	In accordance with	

Interference resistance	Test level according to IEC 60601	Level of compliance	Environment/Guidelines
Electrostatic 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-earth voltage	±1 kV phase-to-phase voltage ±2 kV phase-to-earth voltage	The quality of the supply voltage should be typical of a commercial or hospital environment.
Voltage dips and fluctuations of the supply voltage according to 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 Comment: UN is the AC mains voltage before applying the test level.	100% UN drop for 0.5 period 100% drop in UN for 1 period 30% drop in UN for 25 periods	The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the ceiling supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the ceiling supply unit from a device with an uninterruptible power supply or a battery.
Short interruptions of the supply voltage in accordance with the standard IEC 61000-4-11	100% for 5 s Comment: UN is the AC mains voltage before applying the test		The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the ceiling supply unit requires continuous

