tediselmedical

AURA

MAINTENANCE MANUAL

AURA 100

AURA 200

AURA 300

CE 0197

tediselmedical.com

Content

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 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 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 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 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 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 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 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 Medical gas supply circuits

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

Remove the gas circuit enclosure cover (1) using the plastic suction cup (2) (see Fig. 1).

NOTA

For surface-mounted units where the unit is ordered with PVC end caps, at least one end cap (1) must be removed before removing the gas circuit cover (2) (see Fig. 2).

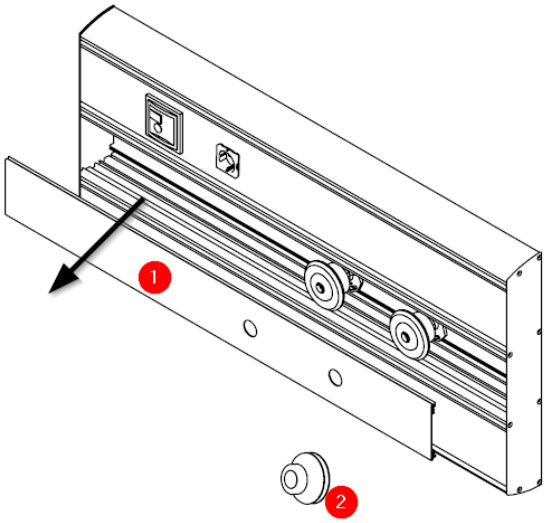

Fig. 1 Removal of front gas cover

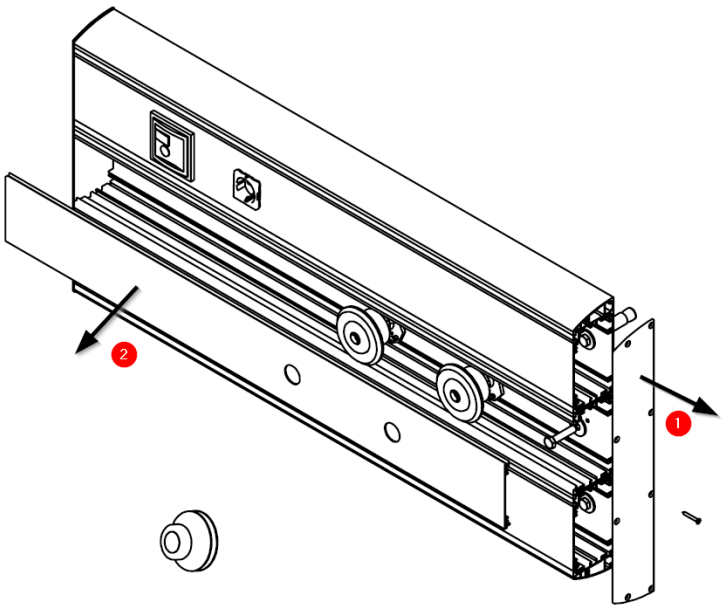

Fig.2 Removal of the side wall and subsequently of the front gas cover

Passage	Description	Periodicity	Tools/supplies
1	**Detailed Visual Inspection**: A) Perform a thorough visual inspection of all interior ductwork for signs of wear or damage.	Annual	Screwdriver set, protective gloves, torch, torch, etc.
2	**Leak Detection:** A) Prepare a soap solution in a container. 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. C) Watch for bubbles to form, indicating the presence of a leak. D) If a leak is detected, mark the area for later correction.	Biannual	Soapy solution, brush or paintbrush
3	**Verification of gas terminal brackets:** A) Physically assess the condition and integrity of the trunking supports. Check for wear or structural damage. B) Ensure that the brackets are firmly fixed to the profile and that there is no movement or play in the brackets.	Annual	Hand tools, protective gloves
4	**Maintenance Register**: 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. B) Keep this record organised and accessible for future reference and audits.	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.

6.3 Electrical and voice and data circuits, lighting

A visual inspection is recommended before starting the checks.

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

6.4 Replacement of LED strips and lighting controllers

If the lighting modules of the AURA system malfunction, both the LED strips ② and the controllers ① must be replaced.

Disconnect the equipment electrically before replacement.

- Remove the side walls
- Use a flat screwdriver to prise the joint of the curved profile on the centre profile. The lighting module will be visible.
- 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 ③ DIN 933 releasing the tab ④ holding the controller ① and LED strip ②.

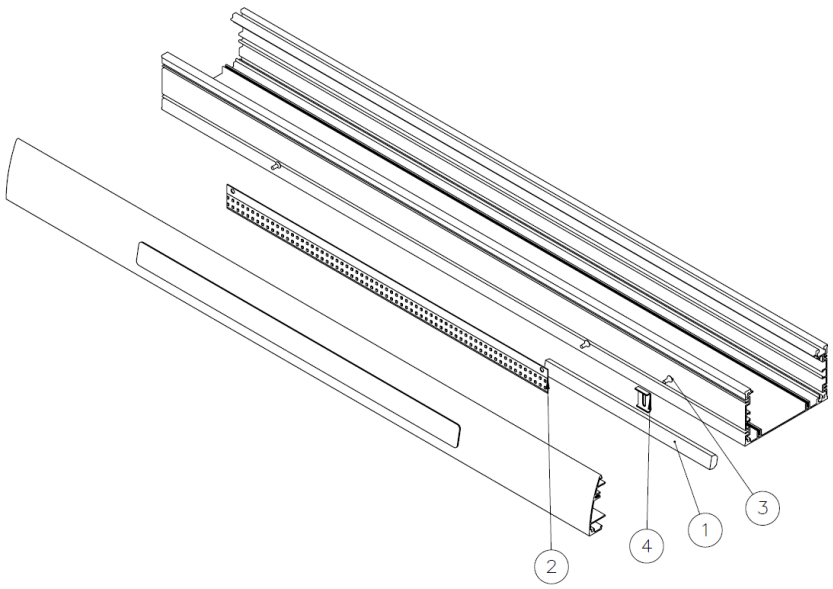

Fig.3 Replacement of LED strips and drivers

- Attach the LED strip ② and secure it with an M4 x16 hex screw ③ (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 ④ by screwing in the second hexagonal screw ③.
- 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

6.5 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 intakes*.	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 *6.2 Medical gas supply circuits* 

Copper gas connections II	Overhaul and status check*. It is recommended to disconnect the equipment electrically before proceeding with the overhaul. 	Biannual	Leak detection See point *6.2 Medical gas supply circuits* 
LED lighting	Testing of LED strips for direct and indirect light	Half-yearly	See points *6.5 Replacement of LED strips and drivers in lighting modules* 
Nurse call	Operation of the call system	Half-yearly	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*.	Half-yearly	Use of a multimeter to check supply voltage and continuity (3), and connection of devices
Electrical and data cabling	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 *6.3 Electrical, voice and data circuits, lighting, etc.* 
DIN rail	Inspection of dripper support and other elements	Annual	Visual inspection and dummy load (2) Check condition and robustness (1)

Entrances (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)
Headwalls	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.

(1) Check condition and robustness:

- This assessment is made through a detailed visual inspection, looking for obvious signs of damage, wear, or corrosion. To assess robustness, physical tests can be carried out, for example, by applying a manual force at different points to check its strength.
- For the specific structure or plate to be considered in good condition, it should not show visible signs of damage, excessive wear or corrosion. In addition, it should not deform or move beyond an acceptable range when force is applied to it.

(2) Dummy load:

- This refers to applying a weight or force that simulates the most extreme conditions of use to which the device might be subjected in practice. This load is used to assess whether the device can withstand the demands of day-to-day use in the operating theatre.
- The specific value of the load will depend on the specifications detailed in the Equipment.

(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. Elimination

The disposal of electrical and electronic devices is subject to special guidelines according to WEE directive 2002/96/EC. This device must be disposed of in accordance with national regulations.

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	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	In accordance	

fluctuations/transients in accordance with the standard IEC 61000-3-3	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 fall for 0.5 period 100% of UN fall for 1 period 30% of UN fall 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.

Interference resistance	Level of verification according to IEC 60601	Level of compliance	Environment/Guidelines
HF interference induced by	3 Vrms 150 kHz to 80 MHz	3 Vrms	AM 1KHz modulation

IEC 61000-4-6	6 Vrms ISM band	6 Vrms	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