tediselmedical

AURA

INSALLATION 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. 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.

3.5. Risk of equipment falling into the anchorage

WARNING: If during the operation of anchoring the equipment to the mounting surface there is no element to support the equipment, it may fall on the person/s performing the installation of the equipment.

3.6. Risk of burns

During the gas connection operation, the operator may suffer burns due to the welding process, as well as damage to the equipment or other surrounding equipment.

WARNING: Personal injury and material damage may occur.

3.7. Fire risk

If the working atmosphere is not sufficiently ventilated, volatile substances (e.g. oxygen) may have concentrated in the working atmosphere and could cause a fire when in contact with the heat source used for welding.

FIRE HAZARD: Failure to comply with this point can cause serious damage.

3.8. Risk of electrical contact

During assembly of the equipment, it may come into contact with any live wiring in the installation, which may cause the metal parts of the equipment to become live and therefore reach the operator.

DANGEROUS VOLTAGE: Failure to comply with this point may result in personal injury.

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. Installation requirements

5.1. Anchoring on the mounting surface. Minimum requirements

DANGER: Failure to comply with this point may result in personal injury.

Hardware for mounting the equipment is not included, the method of anchoring will depend on the surface.

	AURA 100	AURA 200	AURA 300
Maximum weight [kg]:	35	45	50
Maximum torque [Nm]:	126	162	180

Maximum weight: Maximum weight per metre of equipment length.

Maximum torque: Only for DIN rail equipment. Maximum torque per metre of equipment length.

5.2. Training

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

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

2. have been instructed in the installation 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. Installation and connection

This section of the manual describes how to install and connect the Aura devices. It should be noted that these operations will require the removal of parts of the enclosure.

NOTA

Before proceeding with the installation, the installation plans must be checked in order to locate the inputs arranged in the equipment to supply the different systems of the equipment, both for the distribution of medical gases and for the different electrical circuits, nurse call and voice and data.

There are two possibilities as to the location of these inputs, they can be located at the rear of the equipment (1), or they can enter from the sides (2). See Fig.1.

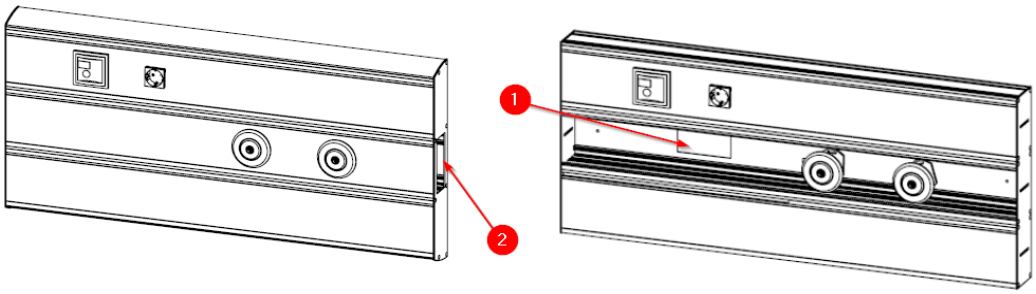


Fig. 1

(1) Supply connections at the rear of the equipment

(2) Supply connections on the sides of the equipment

6.1. Surface mounting

For the installation of the equipment there are rows of anchor points depending on the version. Thus the Aura 100 will have one row of anchor points, the Aura 200 will have two and the Aura 300 will have three.

The number and distance of these anchorage points will vary according to the length of the equipment and is defined in the corresponding installation plan that accompanies the equipment.

See installation drawing of the equipment.

An example for surface mounting of the Aura 300 is shown below.

To anchor the equipment, first remove the front covers of the enclosure (1, 2 and 3) with the help of the plastic suction cup (4) (see Fig. 2).

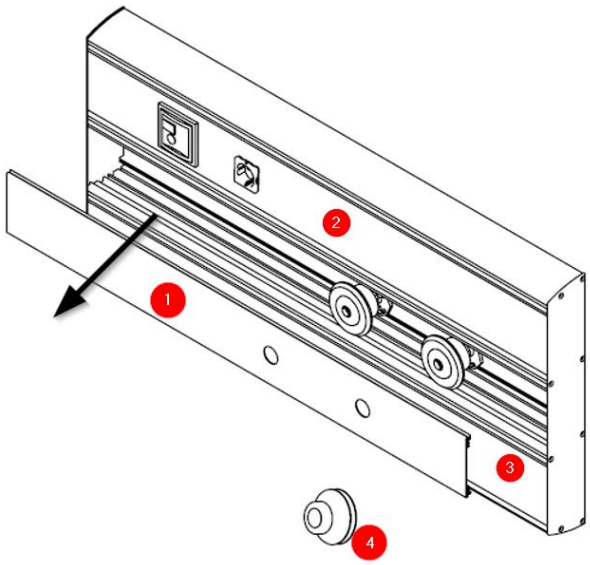


Fig. 2 Removal of front coverings

NOTA

In cases where the equipment has been ordered with PVC end caps, at least one end cap (1) must be removed before removing the gas circuit cover (2) (see Fig. 3).

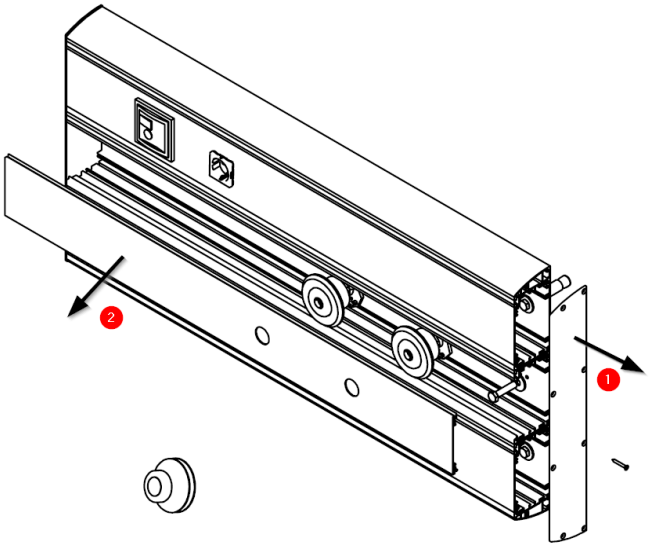


Fig.3 Removal of the side wall

Locate the anchorage points of the equipment indicated in the installation plan that accompanies it, in the case of the Aura 3, we will find 3 rows of anchorage points (See Fig.4).

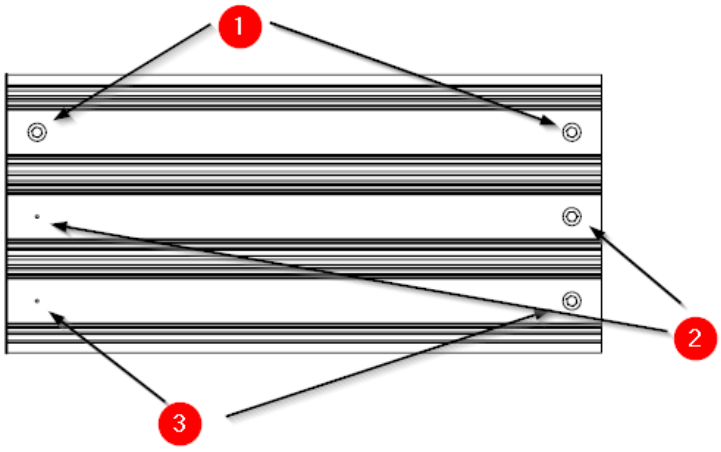


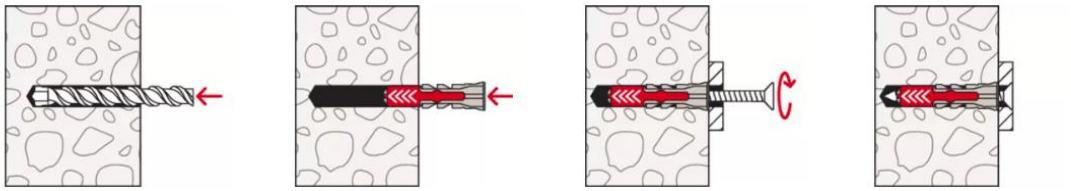
Fig.4 Anchor points of the AURA equipment

Once the equipment is in position, we must fix it by the two upper anchorage points (position 1 in figure Fig.4) without tightening it definitively, only to secure the equipment. Subsequently, we can make the rest of the joints to make the final tightening of all of them once they are all in place.

6.1.1. Wall mounting

The connecting elements to be used when installing Aura on a conventional masonry surface are as follows (see Fig. 5).

Position	Description
1	Screw DIN 571 for 8 mm socket, hexagon head, zinc plated
2	Wide washer DIN 9021 M6 zinc plated
3	Fischer DuoPower Bicomponent Cue



Loads

DuoPower

Highest recommended loads[1] for a single anchor.

The given loads are valid for wood screws with the specified diameter.

Type			5 x 25	6 x 30	6 x 50	8 x 40	8 x 65	10 x 50	10 x 80	12 x 60	14 x 70
Wood screw diameter		[mm]	4	5	5	6	6	8	8	10	12
Min. edge distance concrete	c_{min}	[mm]	30	35	35	50	50	65	65	80	100
Recommended loads in the respective base material F...[2]											
Concrete	≥ C20/25	[kN]	0,40	0,95	1,65	1,10	2,30	2,15	4,20	3,30	5,30
Solid brick	≥ Mz 12	[kN]	0,30	0,50	0,55	0,62	0,69	1,20	1,45	1,30	1,35
Solid sand-lime brick	≥ KS 12	[kN]	0,50	1,00	1,60	1,25	2,25	2,20	3,85	2,80	4,50
Aerated concrete	≥ AAC 2 (G2)	[kN]	0,05	0,10	0,15	0,10	0,16	0,20	0,30	0,24	0,35
Aerated concrete	≥ AAC 4 (G4)	[kN]	0,25	0,38	0,55	0,42	0,60	0,60	1,10	1,00	1,45
Vertically perforated brick	≥ Hlz 12 ($\rho \geq 0.9$ kg/dm³)	[kN]	0,13	0,15	0,17	0,25	0,40	0,25	0,40	0,35	0,40
Perforated sand-lime brick	≥ KSL 12 ($\rho \geq 1.6$ kg/dm³)	[kN]	0,40	0,60	0,60	0,70	1,00	0,70	2,00	0,75	1,50
Gypsum block	($\rho \geq 0,9$ kg/dm³)	[kN]	0,10	0,18	0,37	0,25	0,50	0,35	0,65	0,50	0,50
Gypsum fibreboard	12.5 mm	[kN]	0,24	0,33	0,35	0,35	-	0,50	-	-	-
Gypsum plasterboard	12.5 mm	[kN]	0,12	0,15	0,15	0,15	-	0,15	-	-	-
Gypsum plasterboard	2 x 12.5 mm	[kN]	0,13	0,15	0,24	0,20	0,32	0,30	-	-	-
Mattone Forato Typ F8		[kN]	0,30	0,30	-	0,25	-	0,25	-	-	-
Tramezza Doppio UNI 19		[kN]	0,15	0,15	0,23	0,15	0,30	0,20	0,52	0,35	0,35
Sepa Parpaing		[kN]	0,30	0,45	0.25[3]	0,45	0.45[3]	0,45	0.45[3]	0.60[3]	0.60[3]

[1] Required safety factors are considered.
[2] Valid for tensile load, shear load and oblique load under any angle.
[3] Load determination on plastered wall.

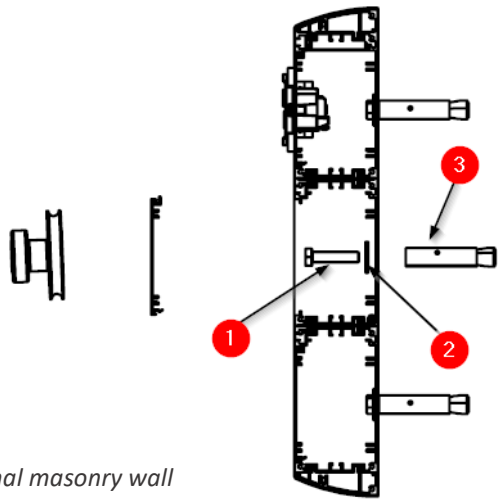


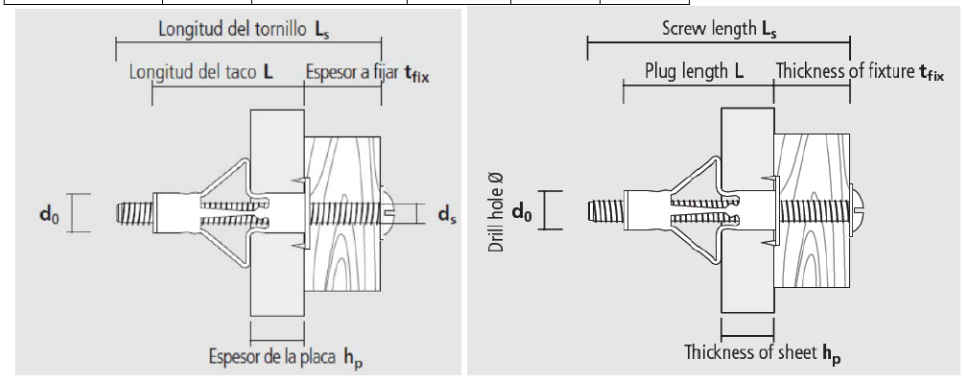
Fig.5 Fixing the equipment on a conventional masonry wall

6.1.2. Mounting on plasterboard panels.

The recommended connecting elements when installing Aura on a conventional masonry surface are as follows (see Fig. 6).

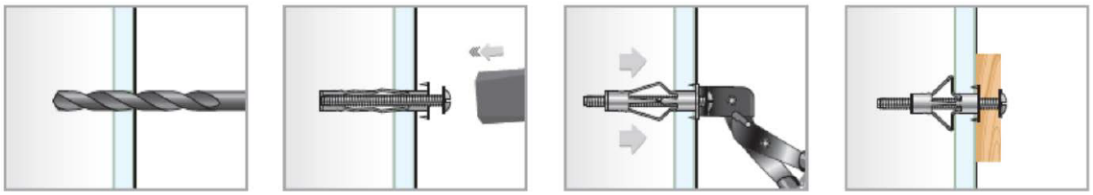
Position	Description
1	Metal expansion plug for gypsum plasterboard (incl. screw)
2	Washer M6 zinc plated

REF	do [mm]	$h_{p\ min-max}$ [mm]	Rosca- ***thread***	Ls [mm]	L [mm]
HRM 4-20	8	3-18	M4	52	46
HRM 4-24	8	18-24	M4	58	52
HRM 4-38	8	32-38	M4	72	66
HRM 5-16	11	3-16	M5	58	52
HRM 5-32	11	14-32	M5	71	65
HRM 5-45	11	32-45	M5	88	80
HRM 6-16	13	3-16	M6	58	52
HRM 6-32	13	14-32	M6	71	65
HRM 6-45	13	32-45	M6	88	80
HRM 8-16	13	3-16	M8	61	53
HRM 8-32	13	16-32	M8	73	66



PROCEDIMIENTO DE INSTALACIÓN / ***INSTALLATION PROCEDURE***

Instalación con pinza / ***Mounting with installation pliers***



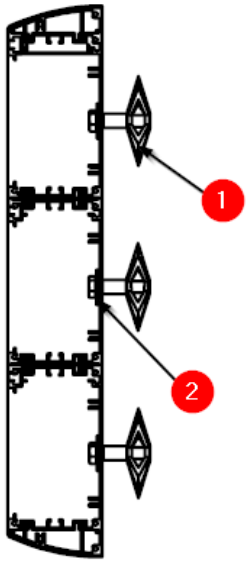


Fig.6 Fixing the equipment to a plasterboard wall

6.1.3. Flush mounting

For the installation of the equipment there are rows of anchor points depending on the version. Thus the Aura 100 will have one row of anchor points, the Aura 200 will have two and the Aura 300 will have three.

In the case of embedding the equipment in a wall, there are two possibilities for the anchoring, the first one is if the fixing is done on the bottom of the surface, in this case the indications of the previous point must be followed.

The second possibility is to anchor from the sides.

First we will remove each of the front covers of the equipment (1), in this configuration it will not be necessary to remove the side panels (3), which will always be made of aluminium.

The equipment can now be pre-positioned in the housing (2) and the anchoring of the equipment can be completed using the screws (4) that correspond to the mounting surface (see points 4.2.1 and 4.2.2 of this manual). (See Fig. 7).

NOTA

The number and distance of these anchorage points will vary according to the length of the equipment and is defined in the corresponding installation plan that accompanies the equipment.

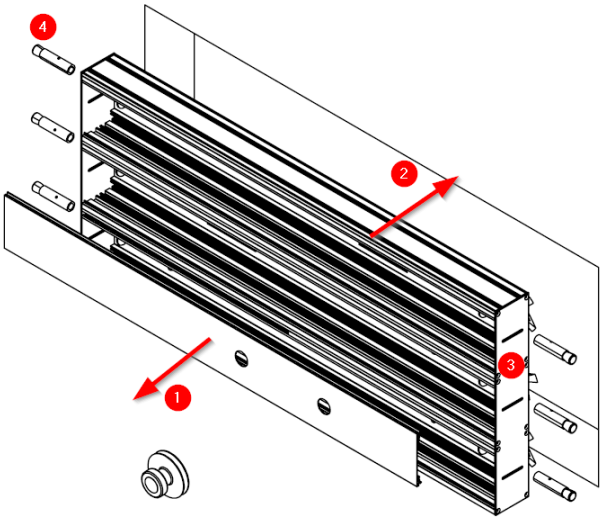


Fig.7 Mounting the equipment in the housing

See installation drawing of the equipment.

6.2. Electrical and voice/data connection:

The electrical, voice and data circuits enter the equipment through a window (1), the dimensions and location of which are detailed in the installation plan of the equipment. The electrical circuits terminate in a common terminal block (2), except for voice and data, whose connection is direct to the corresponding mechanism (3). (See Fig.8).

The equipment must be installed by qualified personnel taking into account national regulations.

To avoid the risk of electric shock, the equipment must be connected to a protective earth. Failure to do so may result in personal injury.

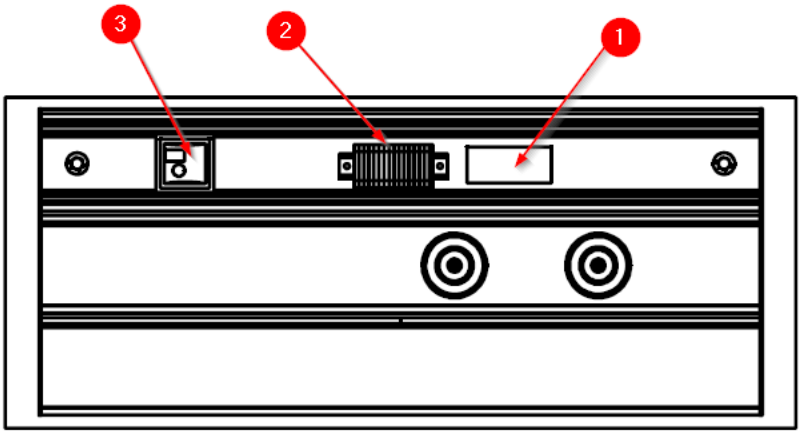


Fig.8 Detail of electrical connection points on AURA

See installation drawing of the equipment.

6.3. Gas connection:

The medical gas circuits enter the equipment through a window whose size and location are detailed in the installation plan of the equipment. The connection of the medical gas circuits shall be carried out in accordance with the applicable standards, UNE EN ISO 7396-1_2016 and UNE EN ISO 7396-2_2007 by qualified personnel.

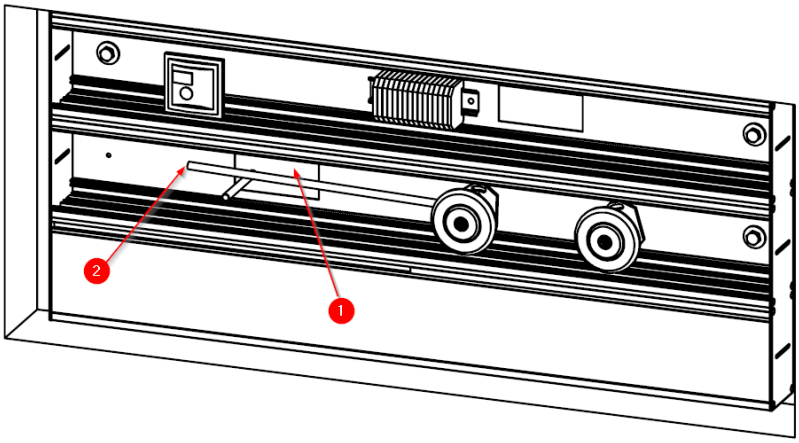


Fig.9 Medical gas and vacuum connection inlet

The gas circuits shall be connected in the inlet area of the pipes of the installation (1), and the installation plan shall be checked before starting the operation. The gas corresponding to the beginning of each circuit (2) is identified in the same way in each unit (see Fig. 9).

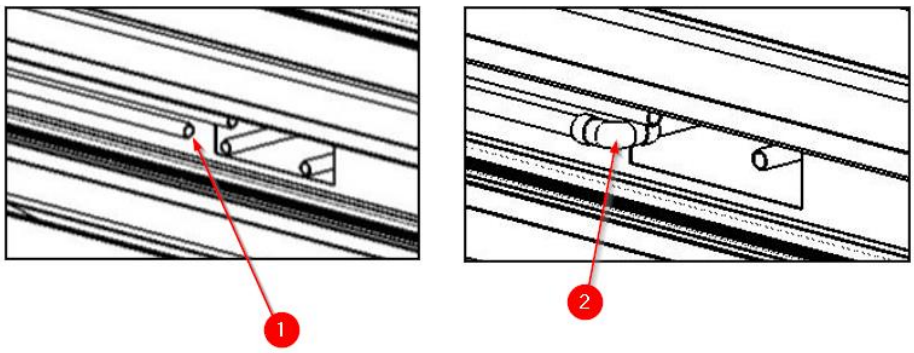


Fig.10 Cutting of pipes and fitting of copper fittings

Once the installation pipe and the equipment pipe have been identified and it has been verified that they correspond to the same circuit, both can be cut to the appropriate size (1) and the appropriate copper fitting can be added to make the joint (2). The soldering can now be carried out (See Fig. 10).

CAUTION: Failure to comply with this point will cause serious damage.

7. Installation checks

When making adjustments to the equipment, it is necessary:

- verify that the relevant medical gas shut-off valves are properly closed and ensure that the system cannot be reopened.
- verify that the system is electrically disconnected and take measures to ensure that the system cannot be reconnected.

CAUTION: Failure to comply with this point will cause serious damage.

7.1. Mechanical test

It must be checked that each of the anchorage points is properly fixed to the mounting surface and that there is no displacement of the equipment.

WARNING: Personal injury may result from dropping the equipment.

7.2. Electrical circuit tests.

Power must be supplied to each of the circuits provided and a test must be carried out to check that all the mechanisms provided in the circuit in question, and only these, are supplied with voltage.

- Check continuity of protective earth wiring.

DANGEROUS VOLTAGE: To avoid risk of electric shock, equipment must be connected to a protective earth. Failure to do so may result in personal injury.

7.3. Gas circuit test.

The equipment must be tested according to the current standards, EN ISO 7396-1_2016 and EN ISO 7396-2_2007 by qualified personnel.

The medical gas piping system shall be checked:

- Watertightness
- Integrity
- No crossovers between circuits.
- Good functioning of the gas intakes

These tests shall be carried out at operating pressure.

CAUTION: Danger of impact of a metallic element due to faulty disconnection, can cause serious personal injury.

7.4. Check envelope.

Check that each of the enclosure elements that have been removed to carry out the installation operations described in this manual are properly fixed and secured in their intended position.

- Checking of openings, closings, foldings, displacements.

WARNING: The use of gloves is recommended as minor personal injury may occur.

8. Regulations

8.1. 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.

8.2. 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.