

tediselmedical

TOR

INSTALLATION MANUAL



tediselmedical.com

CE 0197

Content

1.	Manufacturer.....	4
2.	Security information.....	4
2.1.	Injury risk warnings.....	4
2.2.	Warnings of risk of damage	4
2.3.	Additional symbols used in the safety instructions.....	5
2.4.	Indication of additional information.....	5
2.5.	Proper use of oxygen.....	5
2.5.1.	Oxygen explosion.....	5
2.5.2.	Fire hazard	5
2.6.	Patient environment.....	6
2.7.	Combination with products from other manufacturers.....	6
3.	Risks.....	7
3.1.	Gas explosion	7
3.2.	Risk of device malfunction	7
3.3.	Risk of patient contamination and infection.....	7
3.4.	Fire risk.....	7
3.5.	Danger of electric shock.....	7
3.6.	Risk of collision	8
3.7.	Risk of system crash due to overload	8
3.8.	Risk of system crash due to poor installation	8
4.	Symbols used	8
5.	Installation requirements	11
5.1.	Equipment required for installation	11
5.2.	Training	11
6.	Installation and connection	12
6.1.	Installation recommendations	12
6.2.	Installation references.....	13
6.3.	Loading data.....	14
6.4.	Mounting of threaded bolts on the interface plate	16
6.4.1.	Installation without false ceiling.....	16
6.4.2.	Installation with false ceiling	17
6.5.	Mounting the downpipe on the interface plate.....	18

6.6.	Disassembly and assembly of covers	19
6.6.1.	Disassembly and assembly of side walls	19
6.6.2.	Disassembly and assembly of upper decks	20
6.7.	Installation of a section of the main body on two downpipes.....	21
6.8.	Assembly of a trolley	22
6.9.	Cable / hose routing	23
6.9.1.	Preparation of supply lines.....	23
6.9.2.	Installation of air exhaust pipes and ducts.....	25
6.9.3.	Connection of the different electrical circuits	26
6.10.	Limit switch adjustment for element carriages.....	27
7.	Installation checks.....	28
7.1.	Check the technical characteristics of the equipment.	28
7.2.	Mechanical test	28
7.3.	Mechanical crash test	28
7.4.	Gas circuit test.	29
7.5.	Electrical circuit tests.	29
8.	Regulations	30
8.1.	Team ranking.....	30
8.2.	Reference standards.....	30

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.



Hazardous voltage: warns of electric shock that can cause serious injury or death.



Failure of the roof support system



Risk of collision

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!

2.6. Patient environment

The dimensions in the figure below illustrate the minimum extent of the patient environment in an unrestricted area according to IEC 60601-1.

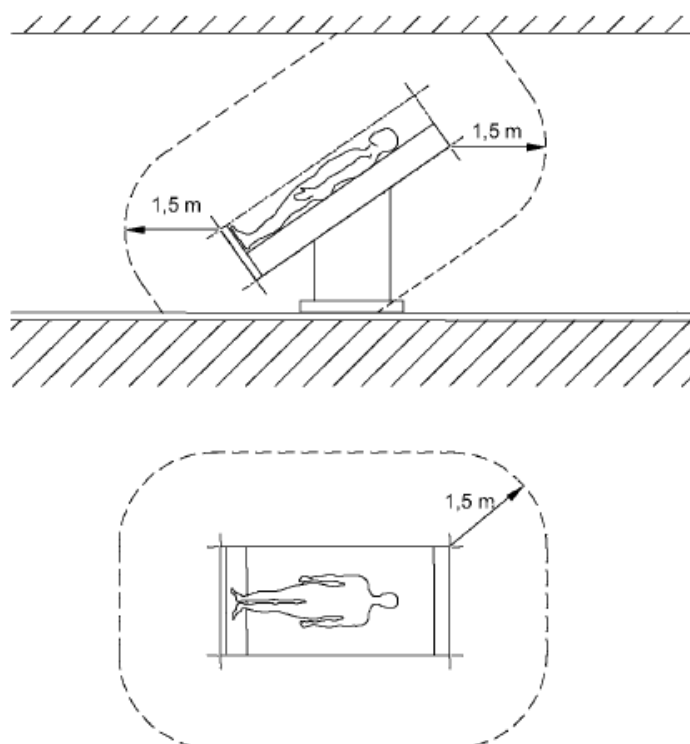


Fig. 1 Minimum extent of the PATIENT ENVIRONMENT

2.7. Combination with products from other manufacturers.

The suspension system is combined with the service head. To avoid dangerous overloads, which can damage or cause collapse of the service head and the pendant system, the specified maximum load capacity must be observed.



See section 6.7 of the user and cleaning manual supplied with the equipment.

Power supply packages intended to supply power to end devices must ensure electrical isolation and provide two protective measures according to IEC 60601-1.

NOTA

The party putting the device into operation is responsible for the validation of the whole system. If necessary, a conformity assessment procedure shall be performed and a

declaration of conformity with Article 22 of the Medical Devices Regulation (EU) 2017/745 shall be provided.



Read the Operating Instructions provided by the external manufacturer to obtain the necessary information for the operation of the end device.

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 not receive power.

3.3. Risk of patient contamination and infection



WARNING: Parts of the pendant system and adaptations are made of plastic. Solvents can dissolve plastic materials. Strong acids, bases and agents with an alcohol content of more than 60 % can cause plastic materials to become brittle. Dislodged particles may fall into open wounds. If liquid cleaning agents are allowed to penetrate the suspension system and fittings, excess cleaning fluid may drip into open wounds.

3.4. Fire risk



Plug-in connections for the supply of medical gases must not come into contact with oil, grease or flammable liquids.

3.5. 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.

3.6. Risk of collision



In the event of a collision with other devices, walls or ceilings, the pendant system and service head may be damaged and important patient care systems may fail, after a collision, the service head and pendant system should be inspected for damage.

3.7. Risk of system crash due to overload



The dead weights of all attached components and the weight of the attached loads must not exceed the maximum load weight of the base support unit.



If the maximum load capacity has been exceeded, there is a risk that the suspension system or components of the suspension system may become detached from the securing device and fall.



- The maximum load capacity of the suspension system and its components must not be exceeded!

See point 6 of the user and cleaning manual supplied with the equipment.

- Do not attach or mount any additional loads on the extension arms, service head and end devices.

3.8. Risk of system crash due to poor installation








If the fasteners of the individual parts of the system are not correctly positioned or if the tightening torques of the fasteners are not observed, the suspension system may come loose from its fastenings and fall down.

4. Symbols used



Applicable part B

	Earth (mass)
	Equipotentiality
	Protective earth (ground)
N	Connection point for neutral conductor
	Nurse call button
	Direct lighting
	Indirect lighting
	Operating instructions
MD	Health Product
	Waste electrical equipment
CE 0197	CE symbol
REF	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

TOR

Installation manual



WARNING

Warning



CAUTION

Caution



DANGER

Danger

5. Installation requirements

5.1. Equipment required for installation

- Lifting device or forklift with a permissible payload of at least 250 kg. Alternatively, a lifting winch with a permissible payload of at least 250 kg can be used if space is limited:



CAUTION

Check that the suspension system is sufficiently secured before lifting.



WARNING

During the lifting movement, be sure to avoid collisions with other suspension systems, devices, ceilings or walls and other assemblies.

- Protective gloves
- Digital spirit level
- Torque spanner
- Multimeter
- Standard tool kit
- Spanner 36
- 1 set of telescopic magnet pick-up tools
- Working platform (e.g. pedestal ladder) in accordance with country-specific occupational safety and health standards

5.2. Training

The personnel performing the installation must be properly trained and qualified by the customer. The equipment must only be **INSTALLED** by authorised personnel. 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 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

6.1. Installation recommendations

The figure shows a configuration of the equipment. The most common measuring ranges for each of the dimensions specified in the figure are given below.

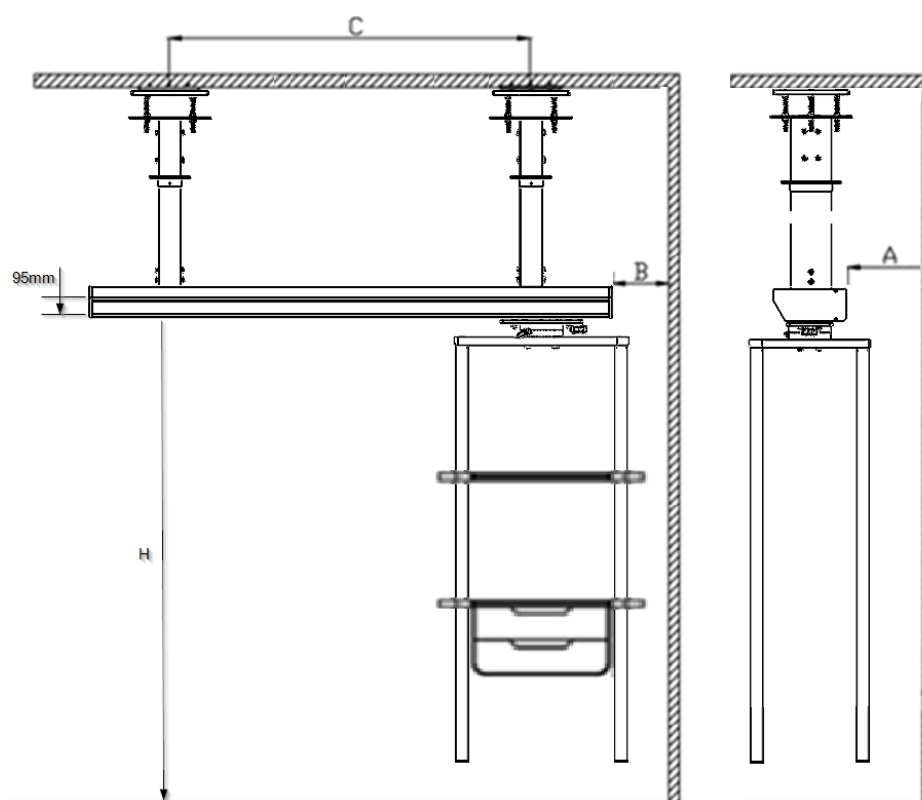


Fig. 2 Recommendations for installation

Measure	Description	
A	Wall clearance parallel to the main body of the equipment (mm)	Min 276
B	Wall clearance perpendicular to the main body of the equipment (mm)	Min 350
C	Distance between supports to ceiling per bed (mm)	Max 1500
H	Ground clearance (depending on the project)	Recommended 1900

The location of the headrest inside the box depends on the requirements of the project, and this section only shows the recommendations of minimum distances to be respected to ensure proper ergonomics and maintenance.

- Check that the position of the TOR anchor point does not impede any other installation or component between the suspended ceiling and the floor slab.

The anchor plate must be fixed to the slab as previously defined in the project drawings.



See the installation drawings supplied with the equipment.

6.2. Installation references

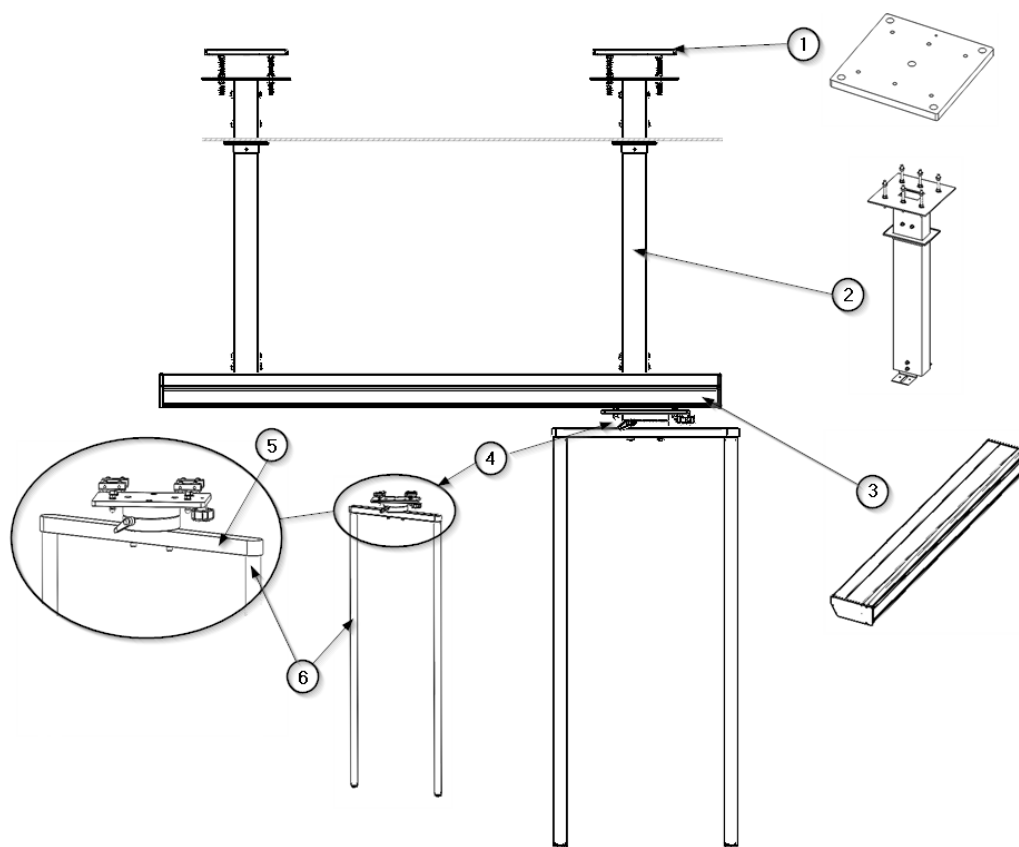





Fig. 3 Installation references

1	Interface plate - pre-assembled (one per downpipe)
2	Downpipe (Including trim) - (two per main body section)
	See point 6.5 of this manual
Material included:	6 rod M10 8.8 (length 150mm) 18 nut DIN934 for M10 18 washer DIN125 for M18

18 washer Grower DIN127 for M18	
3	Main body (suspended head section)
	See section 6.7 of this manual
Material included:	<ul style="list-style-type: none"> - Main body chassis (as many as sections) - Side walls (pre-assembled) quantity depending on the project. - 8 Cylindrical screws M8x25 8,8 - 8 spring washer NFE 25511 for M8 (8.2 x 18 x 1.4) - 4 Downpipe anchor rings
4	Trolley - depending on version (not including accessories)
	See manufacturing drawing accompanying the equipment and point 6.8 of this manual.
Material included:	<ul style="list-style-type: none"> - 1 element carrier (length of trapezoid specified in the order) - 1 tube carrier trapeze ⑤ (on request) - 2 tubes diameter 38 ⑥ element holder (on request) - 2 limit switches (pre-mounted on main body) - Other accessories not included

6.3. Loading data

The data required for the calculation of the ceiling load are given in the following tables. When mounting the suspension system, the vertical weight force of the ceiling assembly (the values correspond to the maximum load) must be added to the corresponding values of the suspension system to determine the ceiling load.

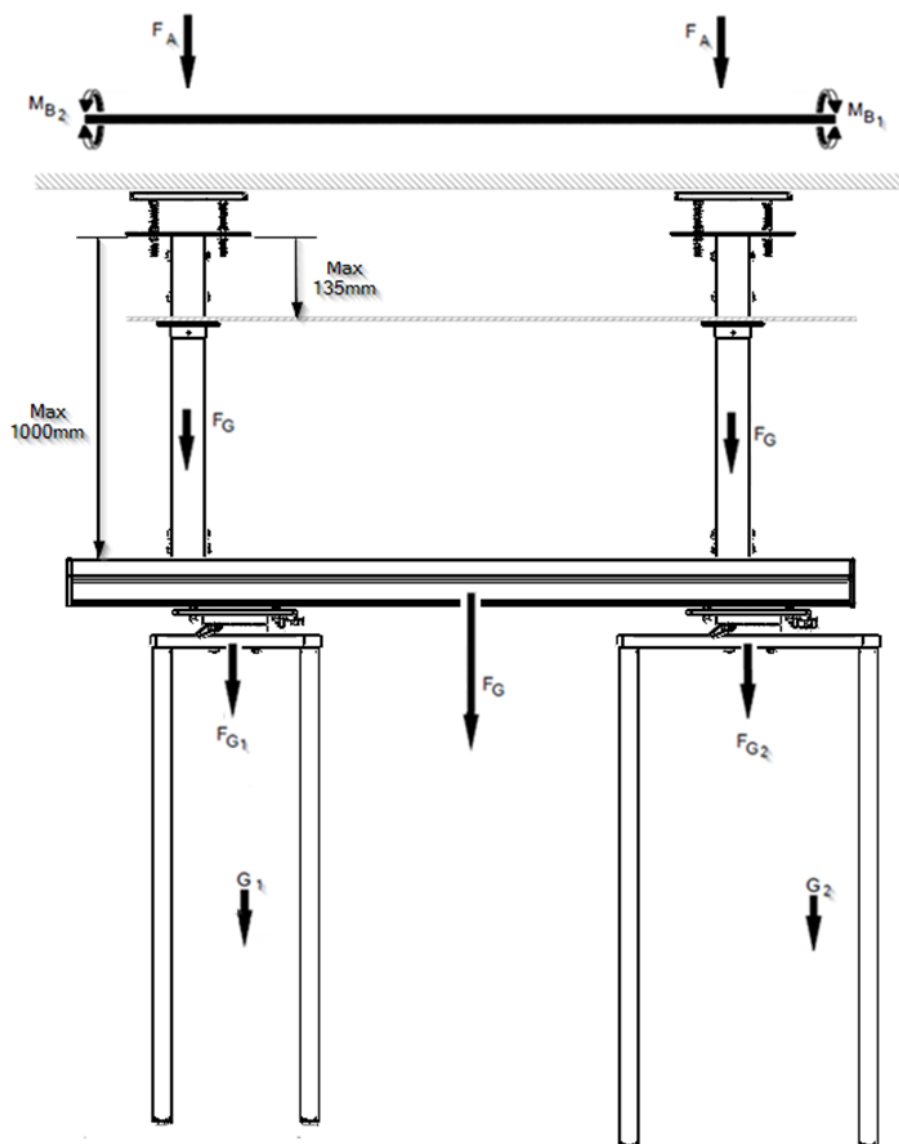


Fig. 4 Load calculation scheme for TOR

The table shows the values for the maximum permissible load capacity of the suspension system. The



...a of a version can be calculated from the sum of the individual versions.

The safety factors prescribed in the individual regions must be taken into account when calculating the maximum load data!

Suspended headboard	Weight (FG) [N] [N]	Weight (FA) [N] Anchor kit	Max. bending moment MB [Nm] [Nm] [Nm]	Load G [kg]
Downspout. Connecting elements	-	167	-	-
Downspout. Vertical section (L=1000mm)	36	-	-	-
Main body. Chassis length 1000mm	85	-	-	300
Main body. End walls	5	-	-	0
Trolley for elements	Weight (FG) [N] [N]	Weight (FA) [N] Anchor kit	Max. bending moment MB [Nm] [Nm] [Nm]	Load G [kg]
Trapeze trolley 300m	59	-	147 (*)	100
Trapeze trolley 500m	64	-	245 (*)	100
Trapeze trolley 700m	73	-	343 (*)	100

NOTA

(*) It considers the maximum load of a trolley applied on one of its tubes and the longitudinal axis of the trapezium perpendicular to the axis of the main body.

6.4. Mounting of threaded bolts on the interface plate

6.4.1. Installation without false ceiling

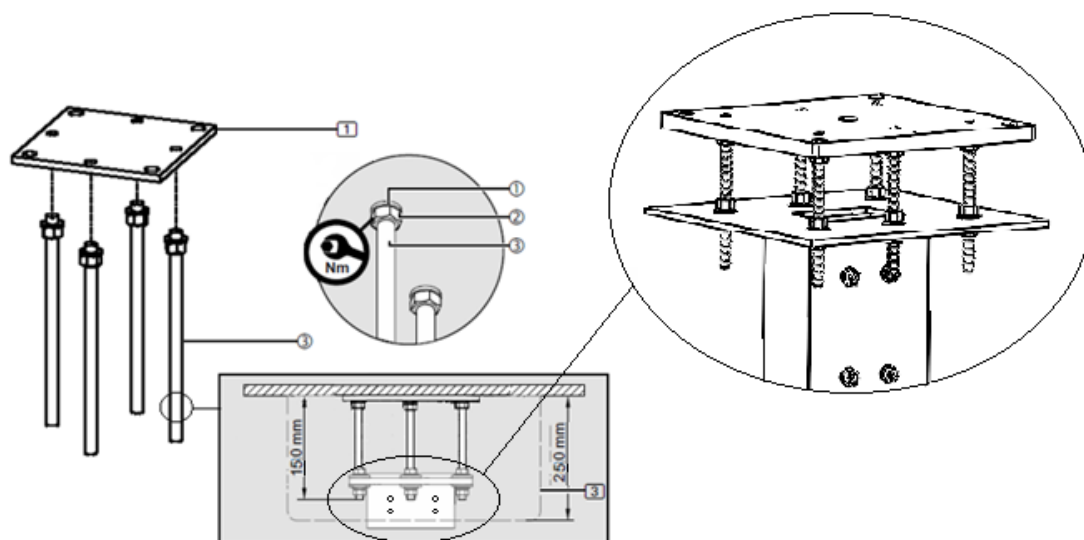


Fig. 5 Mounting of interface plate without false ceiling

- Thread 1 M10 hex nut (2) (2) each onto the M10 x 150 threaded bolts (3) (3) and then fit 1 spring washer (1) (1) each.
- The ceiling trim (3) is later mounted flush with the false ceiling. It covers the entire area of the connecting screws as shown in the detail in figure 5.



If the M10 threaded bolts (3) (3) are not completely screwed in, they may come out of the interface plate (1) and cause the system to fall down.

- Check that the shortened M10 threaded bolts (3) are securely fastened at the correct distance from each other and fully screwed into the interface plate 1.



The M10 hex nuts (2) must be tightened to 195 Nm.

6.4.2. Installation with false ceiling

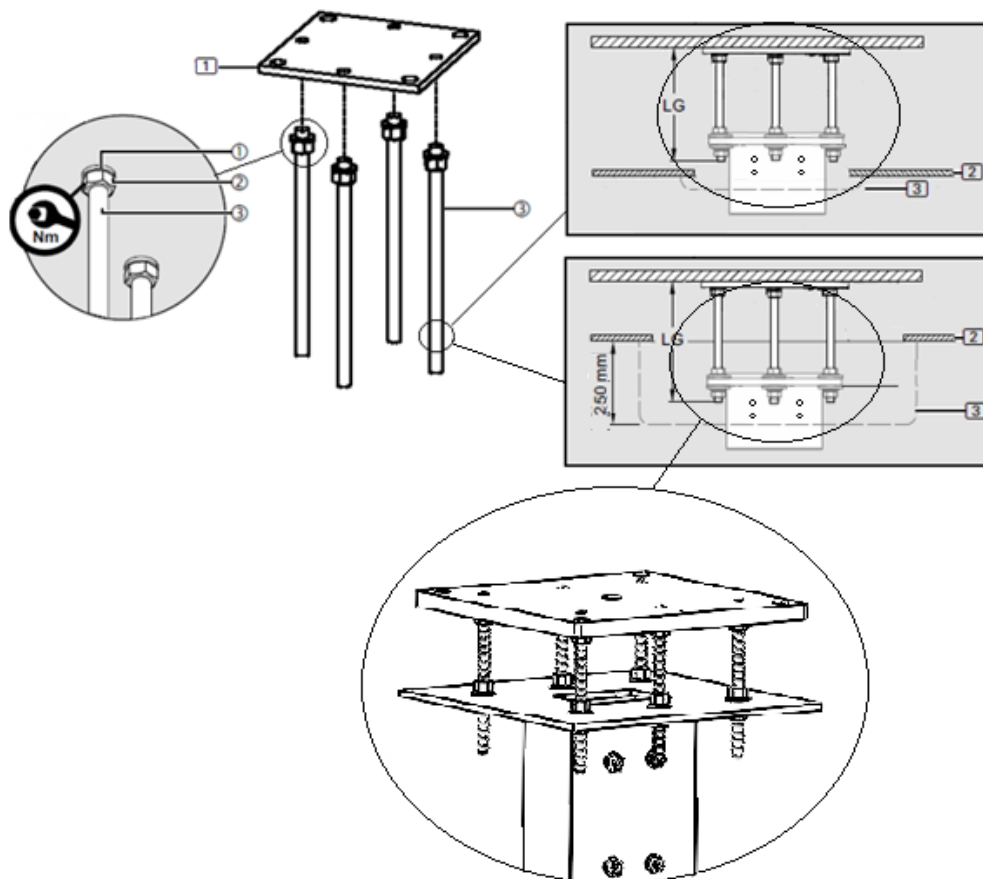


Fig. 6 Installation of interface plate in room with false ceiling

There are two different configurations if a downpipe is installed in a room with a false ceiling. One possibility is that the distance between the floor slab and the false ceiling completely covers the LG length of the threaded bolts (3), in this case a flat ceiling trim with a height of less than 10mm is

supplied as shown in the top right of figure 6. The other possibility is that the distance between the slab and the false ceiling is not sufficient for a correct installation and energy supply, in this case a 250mm high trim can be ordered (optional) as shown in the lower right part of figure 6.

- The ceiling trim (3) is later mounted flush with the false ceiling. It covers the entire area of the connecting screws as shown in the detail in figure 6.
- Fit 1 spring washer (1) and screw 1 M10 hex nut (2) each onto the M10 threaded bolts (3).



If the M10 threaded bolts (3) (3) are not completely screwed in, they may come out of the interface plate (1) and cause the system to fall down.

- Check that the M10 threaded bolts (3) are securely fastened at the correct distance from each other and fully screwed into the interface plate 1.



The M10 hex nuts (2) must be tightened to 195 Nm.

6.5. Mounting the downpipe on the interface plate

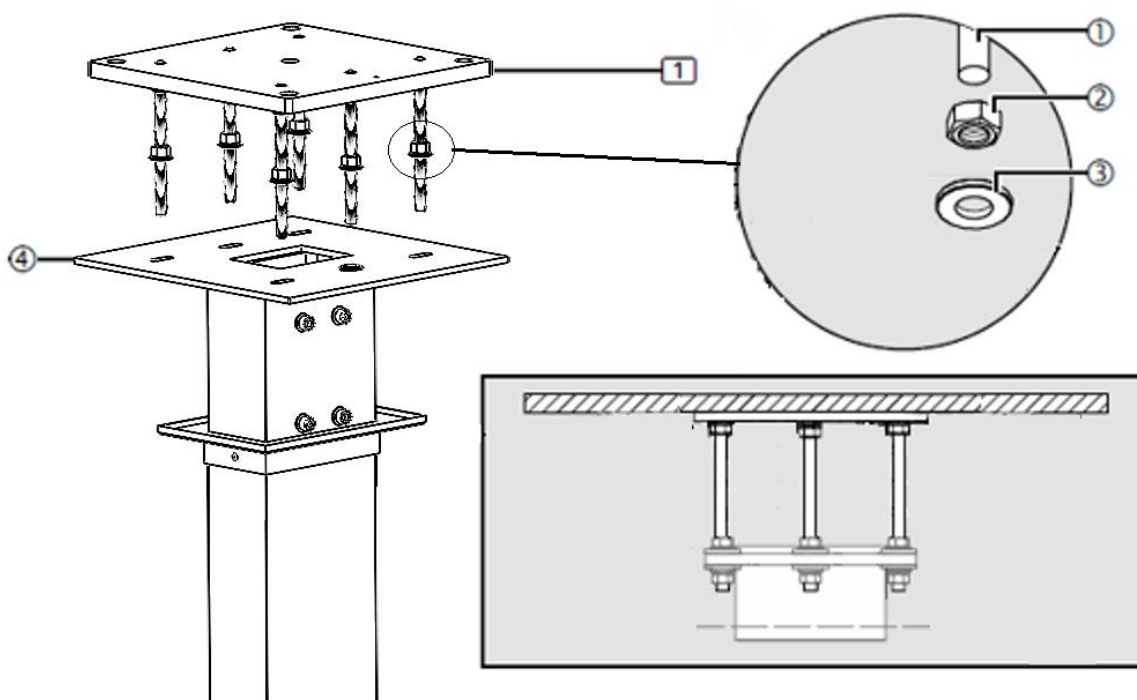


Fig. 7 Mounting of the downpipe on the interface plate

- For each M10 threaded bolt (1) screw on an M10 hexagon nut (2).

The M10 hex nuts (2) must be mounted on the M10 threaded bolts (1) at exactly the right distance from each other.

- Set the distance between the M10 hex nuts (2) and the interface plate (1).
- Using a digital spirit level, align the M10 hex nuts (2) horizontally.

- Fit 1 washer ③.
- Secure the washer ③ with adhesive or elastic tape on the threaded bolts ①.
- Fit the downpipe by passing the threaded bolts through the through-holes of the counter plate ④.
- Fit a flat washer ③.
- For each M10 threaded bolt ① screw on an M10 hexagon nut ② to secure the downpipe.

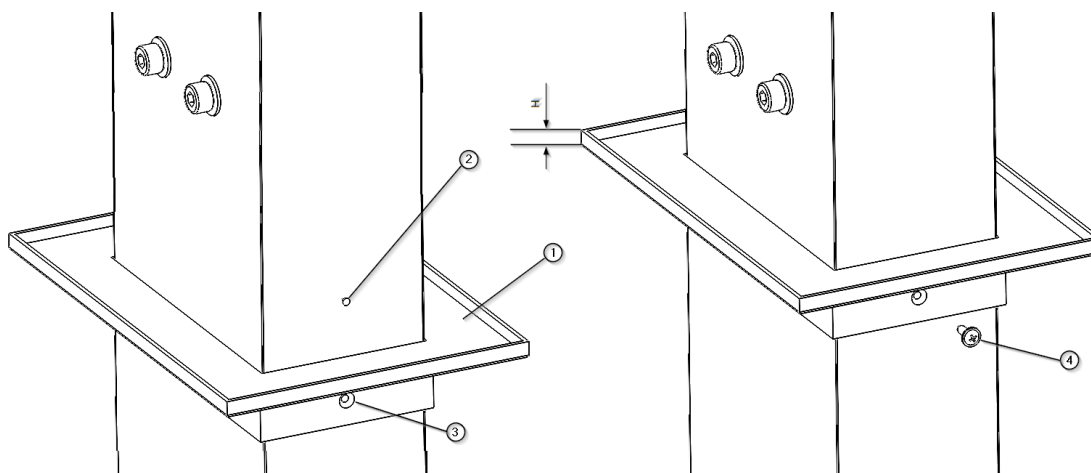


Fig. 8 Fitting the downpipe roof trim

- Present the downpipe trim ① (pre-assembled) in the final position and mark the hole ② for the self-tapping screw ④ by resting it in the hole of the trim ③. Drill a hole with a 3 mm drill bit.
- Finally fix the downpipe trim ① by screwing in the self-tapping screw ④ as shown in figure 8.

NOTA

There are two different models of ceiling trim. One with height H= 10mm and the other with height H= 300mm.

6.6. Disassembly and assembly of covers

The main body of the TOR is supplied finished, so for on-site installation, the side walls and top covers must be removed in order to be able to connect the downpipes and, if necessary, fit other accessory equipment (trolleys).

6.6.1. Disassembly and assembly of side walls

- Using an Allen tool, remove the 2 M4 x 16 screws ① and release the side tabs ③ from the side panel ②, as shown in figure 9.

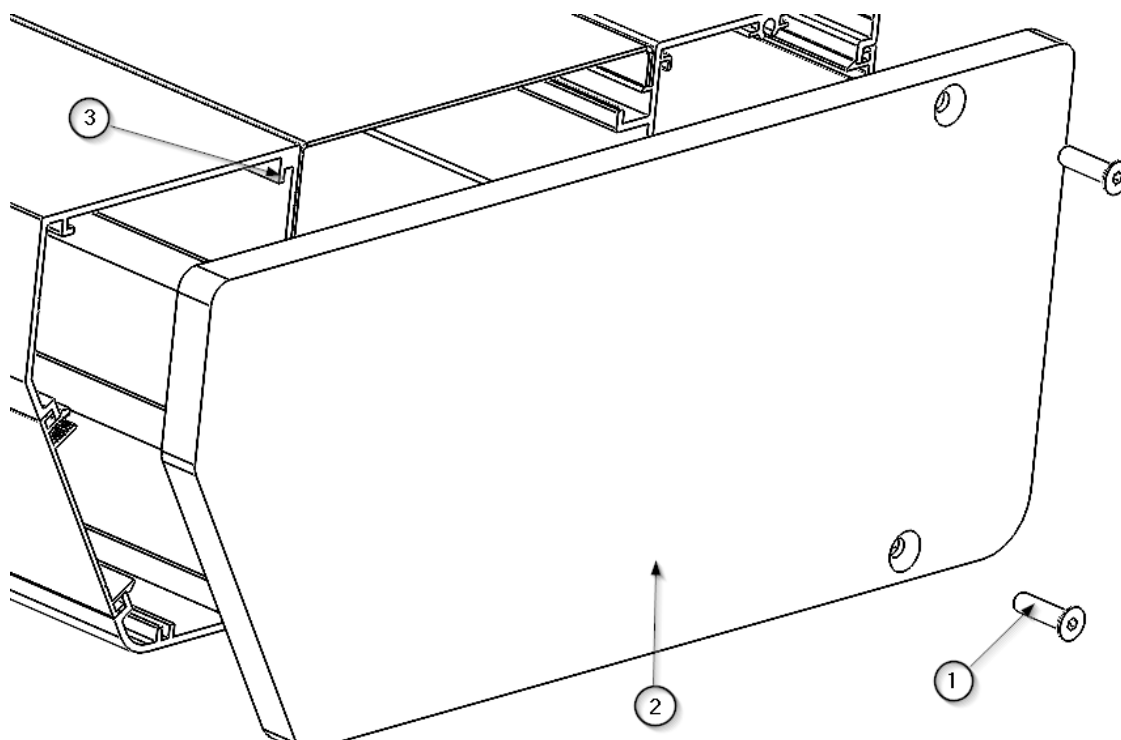


Fig. 9 Disassembly / assembly of end caps on main body TOR

- Carefully remove the side panel ② and place it in a safe place.
- To reassemble the end caps, carry out the above steps in reverse order.
- First attach the end cap ② by supporting the side tabs ③ in the slots of the main body and secure it with the 2 M4 x 16 hexagon socket screws ①.
- Check that the side wall ② is properly fixed.

6.6.2. Disassembly and assembly of upper decks



- Remove the side wall as described in the previous chapter of this manual.
- See section 6.6.1 of this manual.
- Now move the upper covers of the main body ① closest to the pressure sides with your hands, first moving them in the direction of the main body and, once the downpipe ② has been saved, pulling them upwards. See figure 10.

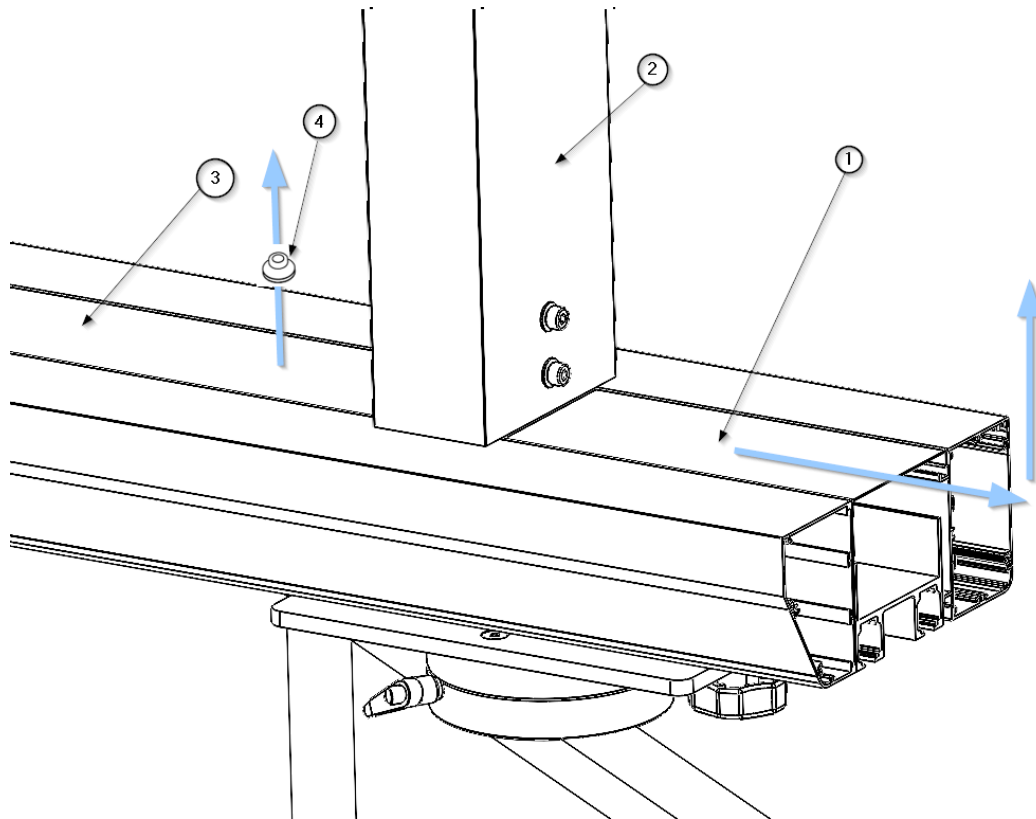


Fig. 10 Removing the main body covers

- Use the suction cup ④ to remove the upper cover between the two downpipes. This cover is snapped on.
- To reassemble these covers, carry out the above steps in reverse order.
- First attach the top covers ①. You will hear a sound when the clipping is done. If it is the cover on the side, slide it until it makes contact with the downpipe ② and then clip it on.
- Check that the covers are securely fastened and in the correct position.

6.7. Installation of a section of the main body on two downpipes

Inside each suspended head section ⑤ (main body) there are brackets ①, M8 x 25mm Allen screws ④ and S10 lock washers ③ for connection to the plates ② that come on the downpipes ⑥. See figure 11.

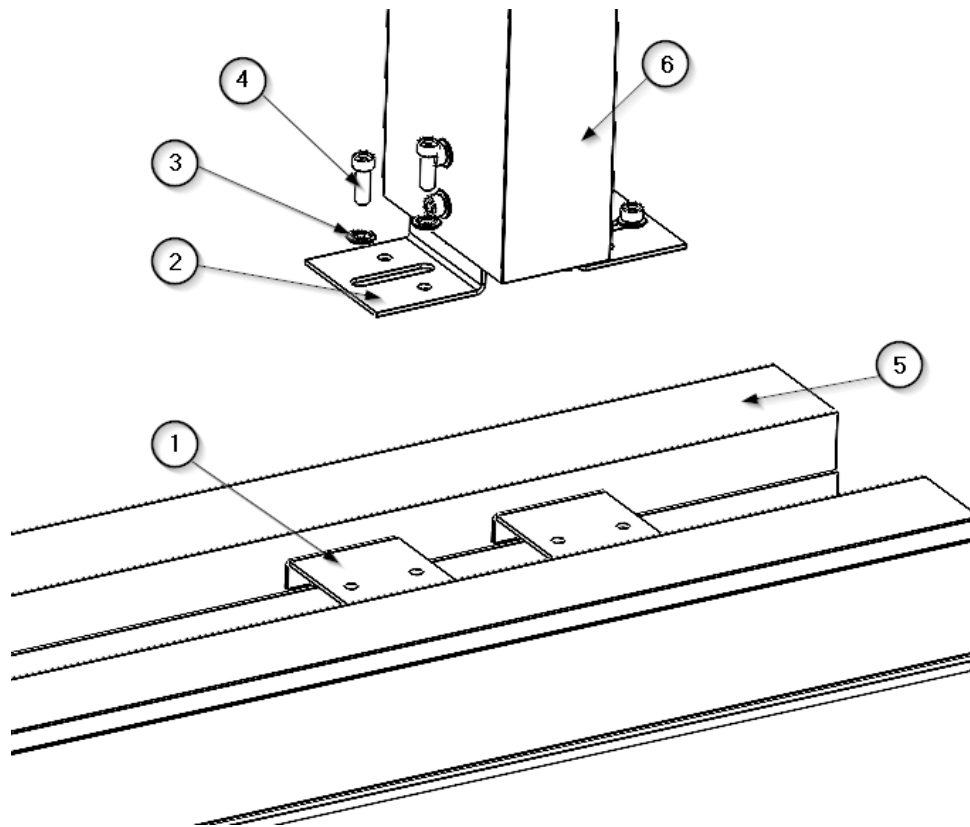


Fig. 11 Anchoring diagram of an ATLAS main body section on a downpipe

- Remove the side walls and top covers from the main body.
- See section 6.6.1 and 6.6.2 of this manual.
- Remove the M8 x 25mm socket head cap screws (4) and the S10 lock washers (3) and store them in a safe place.
- Align the brackets (1) with the brackets (2) and connect them with the M8 x 25mm socket head cap screws (4) and the S10 lock washers (3) without tightening them completely.
- Make sure that the equipment is aligned and level. Then tighten the M8 x 25mm socket head cap screws (4) of all downpipes to a torque of 40 Nm.
- The M8 x 25mm socket head cap screws (4) must be tightened to 40 Nm.
- Finally, fit the previously removed covers and side walls to the main body following the steps described in section 6.6.1 and 6.6.2 of this manual.

6.8. Assembly of a trolley

This section shows the assembly of a trolley. This element is not pre-assembled, it must be installed once the main body has been installed in the room where it is to be used.

- Remove the side wall as described in section 6.6.1 of this manual.



See section 6.6.1 of this manual.

- Position the first carriage limit switch (the one furthest from the head end) as described in section 6.10.2 of this manual.
- Insert the carriage with the bearings ② into the guide in the centre of the main body ① as shown in figure 12.

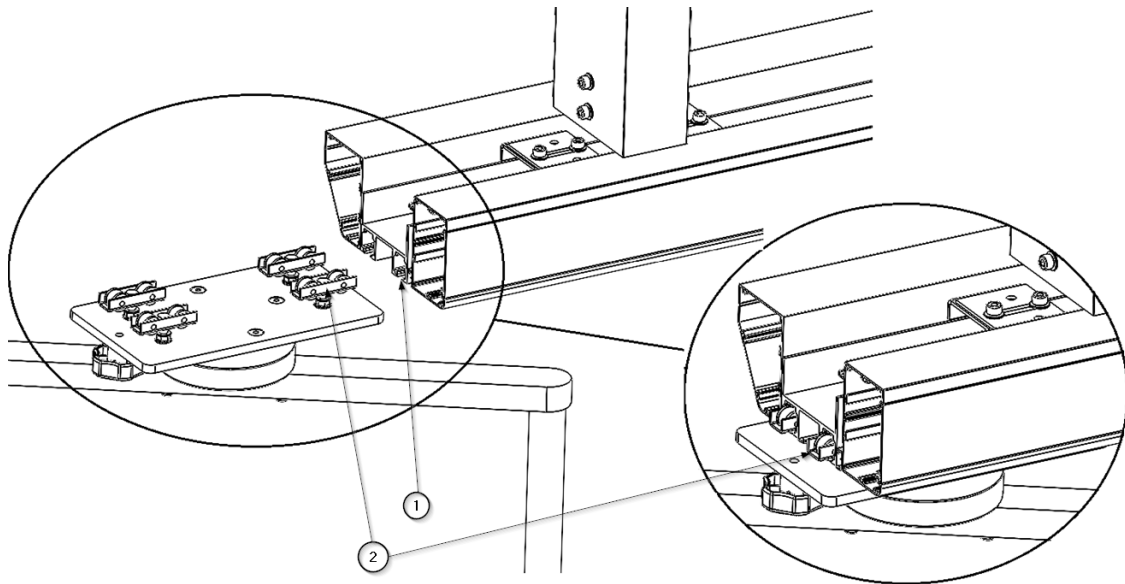


Fig. 12 Assembly of the trolley

- Fit the second limit switch as described in section 6.10.2 of this manual.
- Refit the side wall as described in section 6.6.1 of this manual.

6.9. Cable / hose routing



Before any installation and adjustment work, the pendant system must be disconnected from the mains.

6.9.1. Preparation of supply lines

In order to install the main body of the equipment, the supply lines to the equipment, which have previously been passed through the downpipes, must be prepared.

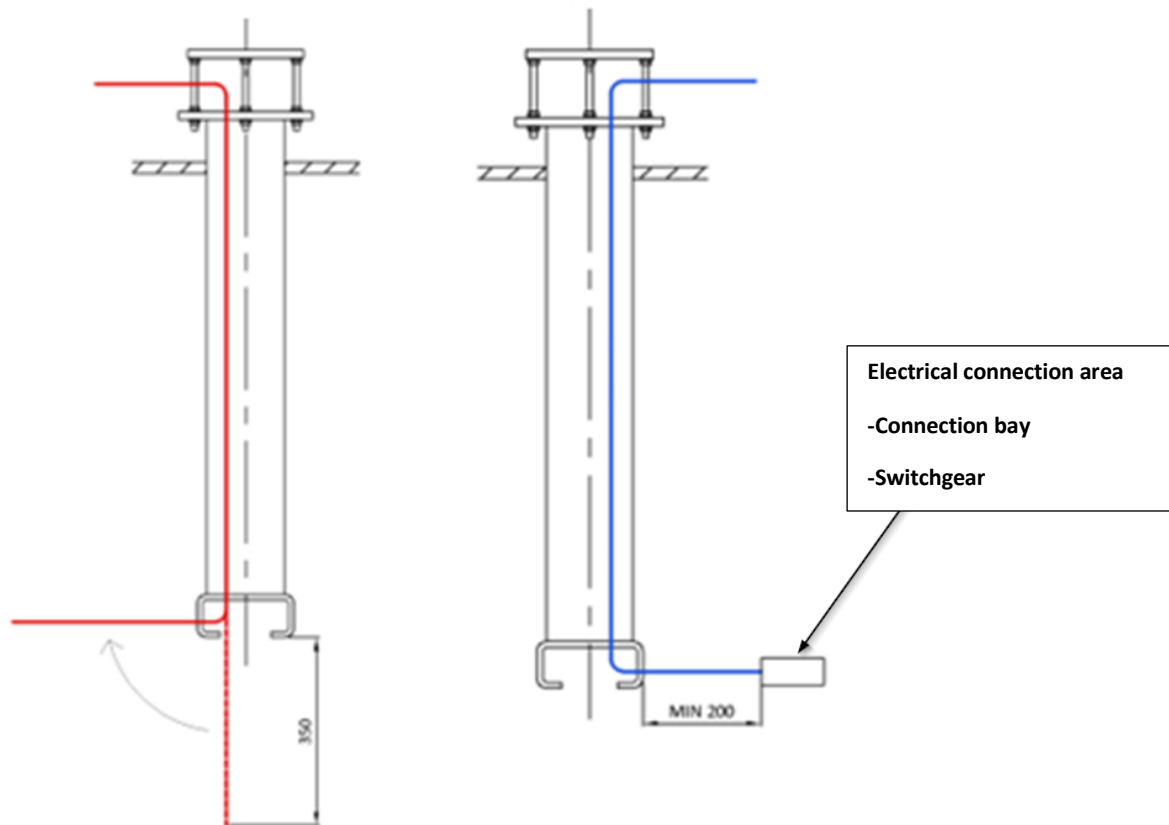


Fig. 13 Preparation of supply lines

In order to be able to work comfortably, the copper pipes should protrude about 350mm below the downpipe. At this point they should be bent in such a way that they are horizontal and above the lower face of the lower anchor of the downpipe. See picture on the left in figure 13.

The electrical cables should protrude about 200 mm from the bottom of the downpipe to ensure that the connection area (where the terminal block is located) can be reached without any problems. See picture on the right in figure 13.

Damaged power cables can carry 230 V electrical voltage that energises the pendant system, and supply gases can escape from damaged supply hoses:

- Check all cables and hoses for damage. Be sure to insert them carefully without the cables/hoses crossing each other, without loops and without kinks.
- Cables and pipes must be positioned in the suspension system in such a way that they are not exposed to tensile stresses.
- Cables and hoses must be routed straight up out of the flange to prevent damage (e.g. chafing of the sheathing) and to allow free rotation.
- Protruding cables and hoses must not be routed in the service head or on the flanges, but must be routed in the interface plate and secured against falling out with cable retainers.

- Electrical cables should be routed according to regional standards (in a spiral coiled tube if necessary).

Power and earthing cables as well as gas pipes are pre-installed in the service head and run through the pendant system. Order-specific cables, including telephone and nurse call cables, must be routed separately through the pendant system.

6.9.2. Installation of air exhaust pipes and ducts

To connect the gas circuits, remove the top cover of the main body.



See section 6.6.2 of this manual.

- Ensure that gas types are correctly assigned

The gas type is indicated by colour on the gas supply tubes. These tubes are fitted with a sealing plug which can only be removed during installation.

- Check the pipes and ducts for dirt and clean them with oil-free air.
- Ensure that cables, hoses and conduits are assigned to the correct supply outlets.

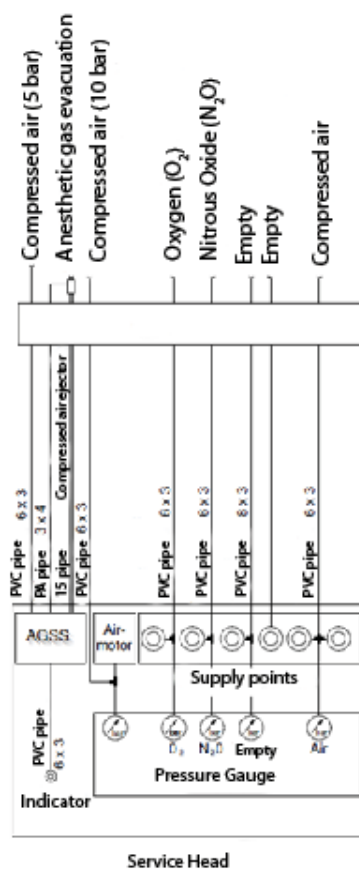


Fig. 14 Example of connection of gas lines and anaesthetic gas evacuation systems.

- Prepare the copper connections for each gas outlet.
- The gas connection is made in the central body of TOR.
- Check the diameter of the gas connections, which must be duly indicated, together with the type of gases (oxygen, vacuum, air, etc.).
- Perform the welding of each of the compressed medical gas and vacuum supply circuits according to EN ISO 9170-1 and anaesthetic gas evacuation systems according to EN ISO 9170-2.
- Perform a gas type test by following these 5 points:
 1. gas outlets and marking according to EN ISO 9170-1 or EN ISO 9170-2
 2. Leakage according to EN ISO 11197
 3. Congestion according to EN ISO 7396-1 or EN ISO 7396-2
 4. Solid contamination according to EN ISO 7396-1 or EN ISO 7396-2
 5. Gas type according to EN ISO 7396-1 or EN ISO 7396-2

6.9.3. Connection of the different electrical circuits

To connect the electrical circuits, remove the top cover of the main body.



See section 6.6.2 of this manual.

The electrical connection is always made in the connection area shown in figure 12. This is located on the main body, next to one of the downpipes. All electrical hoses are numbered to identify the circuit to which they belong. The colour of the cable will indicate whether it is an earth connector, a neutral or a phase.



Before any installation and adjustment work, the pendant system must be disconnected from the mains.

- Cut all green/yellow earthing wires (2.5 mm² and 10 mm²) to the correct length.
- Connect them to the 2.5 mm² or 10 mm² series terminals on the earth terminal block provided in the connection area.
- All earthing cables must be securely installed in the strain relief mechanisms.
- Connect the power wires to the terminal block as illustrated in the wiring diagram supplied with the equipment.



See installation drawing(s) accompanying the equipment.

- All power cables must be securely installed in the strain relief mechanisms.

- Carefully check that the power cables are not trapped or kinked during the entire translation and rotational movement of the service heads.

6.10. Limit switch adjustment for element carriages

The trolleys of the TOR equipment can slide freely over the entire length of the main body section on which they are installed. It is necessary to limit their travel to ensure that they do not conflict with patient and operator space. See figure 15 and 16.

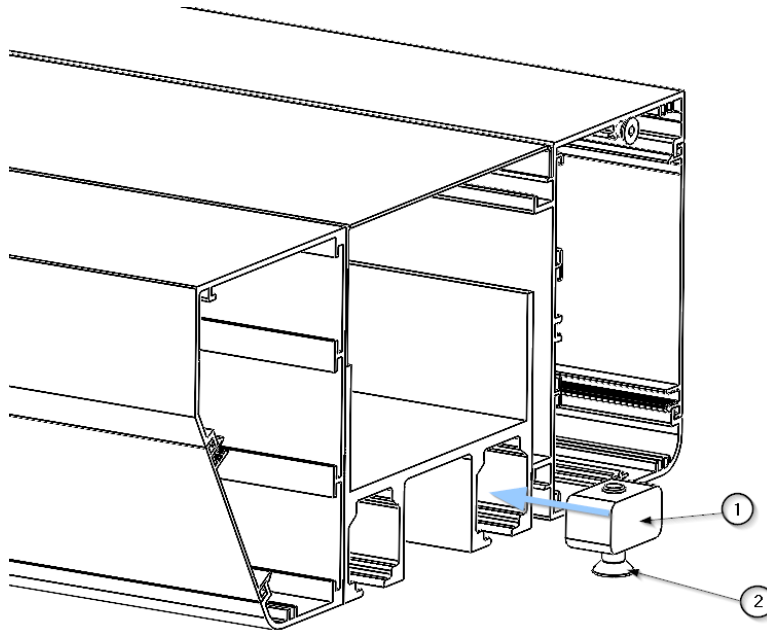


Fig.15 Adjustment of the travel limit switches.

- Use an Allen key to loosen the bolt (2) of the cross stop (1).
- Move the cross stop to the desired position on the TOR main body guide.

The example in figure 16 shows a TOR unit with two element carriages, the limit switches must ensure that the element carriages do not collide with the other elements in the environment.

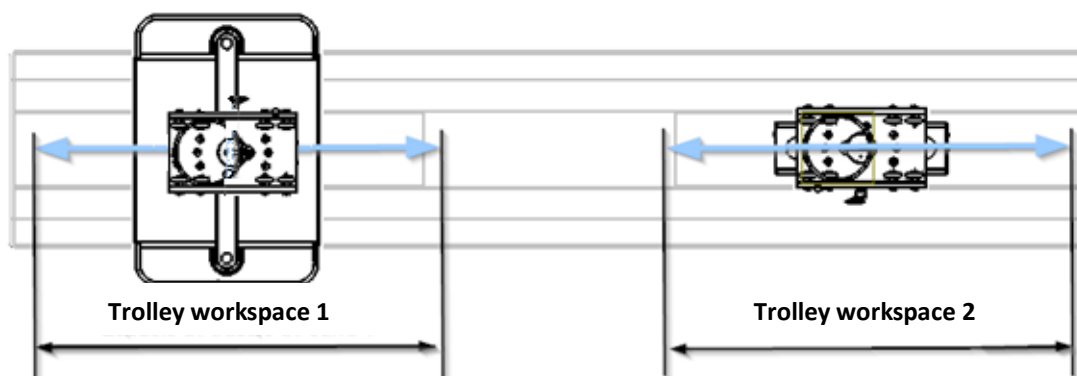


Fig.16 Adjusting the travel limit switches. Maximum stroke

- Tighten the Allen stud ② and check that the cross stop is fixed in this position.
- Do the same with the second crosscut fence.



The hexagon socket bolts ② M6 - DIN 913 must be tightened to 40 Nm.

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 measures must be taken to ensure that the system cannot be reconnected.



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



Before any installation and adjustment work, the pendant system must be disconnected from the mains.

7.1. Check the technical characteristics of the equipment.

Before proceeding with the installation of the equipment, it must be checked that the surface on which the equipment is to be installed meets the space and resistance requirements according to the characteristics of the equipment in question.



See point 6 of the user and cleaning manual supplied with the equipment.

7.2. 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.



Personal injury may result from falling equipment.



See section 6.4 of this manual.

7.3. Mechanical crash test

Once the system has been installed, it must be checked to ensure that no collisions can occur with:

- other hanging systems,
- ceilings or walls,
- other equipment

If it is necessary to adjust the stroke on the element carriages.



See section 6.10 of this manual.

7.4. 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.

7.5. Electrical circuit tests.

Once the equipment has been installed, 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.



See manufacturing drawing(s) accompanying the equipment.

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.