S-COLUMN

USER AND CLEANING MANUAL



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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. |

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.



Refers to a potential hazard which, if not avoided, may cause damage to the equipment.

NOTICE

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.



Failure of the roof support system



Risk of collision

2.4. Indication of additional information



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

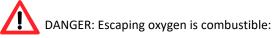


Oxygen becomes explosive when it comes into contact with oils, greases and lubricants.

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



- 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.

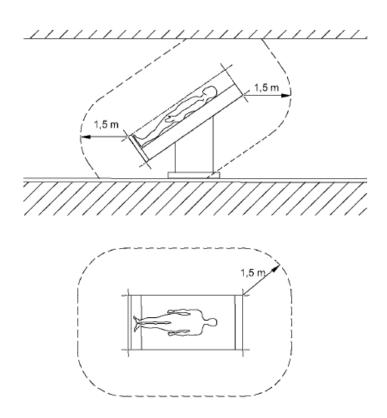


Fig. 1 Minimum extent of the PATIENT ENVIRONMENT

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. Ga explosion s



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.

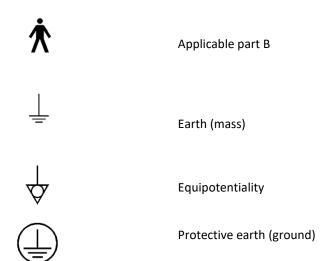
• Do not attach or mount any additional loads on the extension arms, service head and end devices.

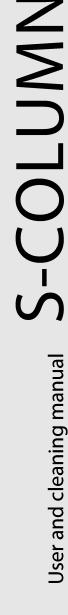
3.8. Risk of system crash due to poor installation



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





Connection point for neutral conductor



Ν

Nurse call button



Direct lighting

Indirect lighting





Operating instructions



Health Product



Waste electrical equipment

C € 0197

CE symbol



Product code



Unique identification code



Serial number

S-COLUMN User and cleaning manual



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



Caution



Danger

5. Product data

This manual refers to the S-COLUM model, suspended equipment with medium/low load capacity. This model belongs to the UMOS family.

5.1. Storage conditions

The packaging of this type of product consists of two parts, a first part containing the mobile arm (structural part of the equipment) and a second part corresponding to the service head.

The first consists of a cardboard box with a sturdy wooden structure and cardboard reinforcements inside the box to immobilise the arm. This packaging can be assembled in two heights.

The second consists of 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: -5 °C to 40 °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 service life of the UMOS family of products is determined by the service life of the distribution hoses and the medical gas inlets they incorporate, which is 8 years.

5.4. Product description

These systems have three main differentiated functions within the hospital and according to the area for which they are intended:

- Medical gas services
- Electrical, voice and data services
- Nurse call

S-COLUMN devices consist of two distinct parts, the structural part (drop tubes and/or arms), which is responsible for bringing the device to the desired point, and the service head, which serves as a supply interface for energy consumers and also for the housing, storage and storage of medical devices and accessories. See figure 2.

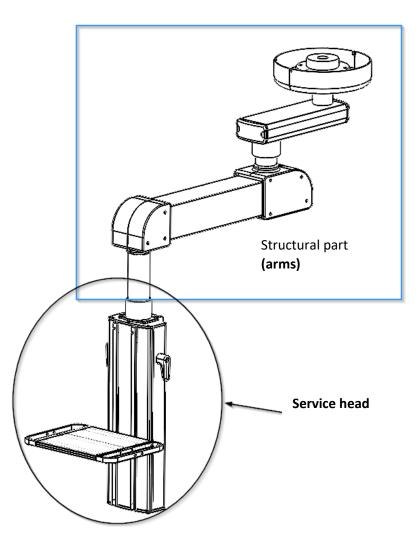


Fig.2 Parts of the equipment

Only S-COLUMN accessories supplied by Tedisel (platforms, device holders, etc.) attached to the system head can be used to pick up loads. For this purpose, the different loading conditions of a base support unit and the individual accessories must be considered:

- The load capacity of the base support unit is defined by the maximum equipment load (see rating plate on the system head). When attaching pick-up accessories, the equipment load is reduced by the weight of the accessories themselves.

Exceeding the maximum capacity of the equipment may result in injury to personnel or the patient, as well as damage to property.

5.4.1. Types of suspended structure

S-COLUMN systems can be segmented according to the mechanical fastening system used for the suspension of the service head:

(A) Depending on the type of brake: Electromagnetic (EM) or friction (F) depending on the mechanism used to lock the rotation of the arms and the service head.

The extension arms and the drop tube are equipped with brakes to keep them stable in any adjusted position. There are two types of brake, the mechanical or friction brake always present and electromagnetic brakes managed by the corresponding buttons (A), (B) located on the service head.

Additional mechanical brakes (friction brakes) ensure that the outriggers remain stable at the bearing point to the roof tube and between the outriggers in the event of a failure of the pneumatic brake. The mechanical brake can be adjusted as described in point 8.4 of this manual.

- (B) Depending on whether the movement is assisted: Non-motorised (NM) and motorised (M).
- **(C) Depending on the number of arms:** Single (S), double (D), single neck (rotating) (R) depending on the need to move the media column in reference to the vertical axis from the anchorage point of the equipment.
- (D) According to column orientation: Vertical (V) or Horizontal (H)
- (E) Depending on the number of service heads: Single (I) or tandem (T)

Below is a summary of the different features and configurations that the S-COLUMN model allows:

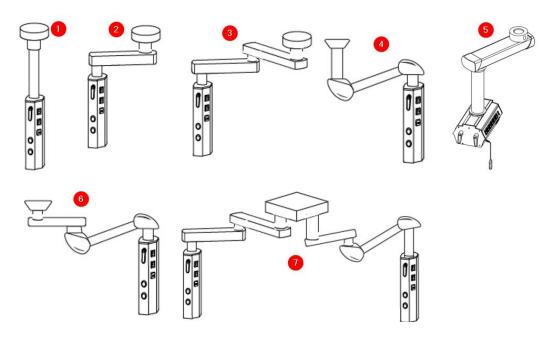


Fig.3 Typology scheme. Variants

1. Direct ceiling fixing via downpipe

This configuration consists of a downcomer that only allows rotation of the service head around the vertical axis of the equipment.

2. Attachment via single non-motorised arm

This configuration allows rotation around two axes in order to bring the service head closer to the point of application. Working space depending on the arm length.

3. Attachment via non-motorised double arm

This configuration allows rotation around three axes in order to bring the service head closer to the point of application. Working space depending on the combined lengths of the two arms.

4. Fixing via single motorised arm with rotation

This configuration allows rotation around two axes in order to bring the service head closer to the point of application and also allows it to move vertically with an associated load (accessories). Working space depending on the length of the arms.

5. Horizontal Column Layout

This is a configuration in which the service head is positioned horizontally. It allows an alternative arrangement of the service points. It can be fixed to the ceiling via all existing arm configurations or via the downpipe.

6. Fixing via motorised double arm with rotation

This configuration allows rotation around three axes in order to bring the service head closer to the point of application and also allows vertical displacement of the associated load. Working space depending on the length of the arms.

7. Tandem

This configuration allows two of the above options to be combined in the same anchor point. Working space depending on the combined lengths of the different pieces of equipment.

A summary table with the nomenclatures of the individual variants is shown below.

| | NO. ARMS | | MOTOR | | Brake type | |
|-------------------|----------|---|-------|----|------------|----|
| Model | S | D | Μ | NM | F | MS |
| S-COLUMN ROTATION | - | - | - | х | x | - |
| S-COLUMN | х | Х | - | Х | x | х |
| S-COLUMN MOTOR | x | х | x | - | x | х |

Table 1 Types of suspended structure. Summary

5.4.2. Parts and control elements

5.4.2.1 Drop tube

The length of the downpipes is variable according to each project and varies between 400 and 1000mm. The downpipes can rotate 340^o horizontally. The permissible load will be 135Kg for the drop tube variant with rotation. The length of the drop tube compensates for different ceiling heights to ensure that the service head is positioned at the desired working height.

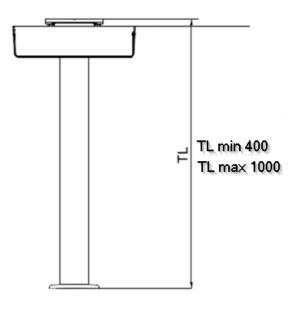


Fig.4 Drop pipes

To avoid collisions with other components or walls, the swivel range of the drop tubes can be limited by means of internal end stops. The end stops are pre-set at the factory.

See section 8.4.3 of this manual for the setting of rotation stops.

The brakes shall in any case be mechanical brakes and are located at the top of the drop tubes.

5.4.2.2 Non-motorised arms

The length of the arms is variable according to each project and varies between 600 and 1000mm. They can be combined up to a maximum of 18000mm between the anchorage point of the equipment and the vertical axis of the service head. Double arm pictured above and single arm pictured below in figure 5.

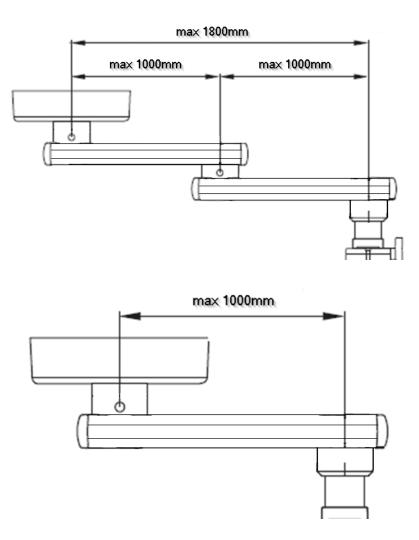


Fig.5 Non-motorised arms

Depending on the length configuration chosen, the permissible loads range from 130Kg to 165Kg. The extension arms can rotate 340° horizontally. The length of the drop tube compensates for different ceiling heights to ensure that the service head is positioned at the desired working height. The service head can rotate 340° horizontally.

To avoid collisions with other components or walls, the swivel range of the extension arms (2) and the drop tube (3) can be limited by means of internal end stops. The end stops of the extension arms (2) and the drop tube with roller bearing (3) are preset at the factory.

See section 8.4.3 of this manual for the setting of rotation stops.

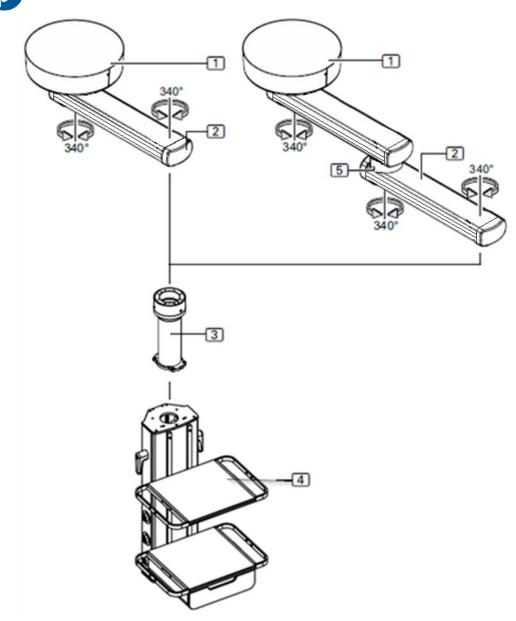


Fig.6 Non-motorised arm versions

Please note that your individual suspended system may differ from these illustrations.



See product and installation drawing supplied with the equipment.

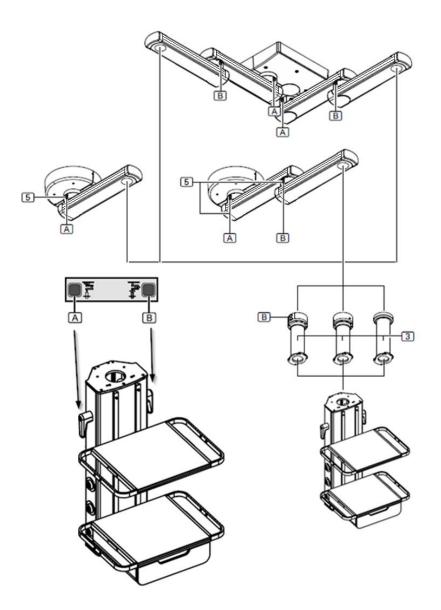
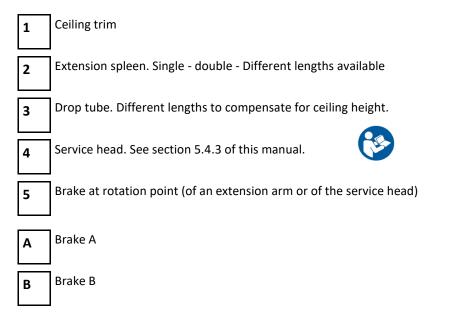


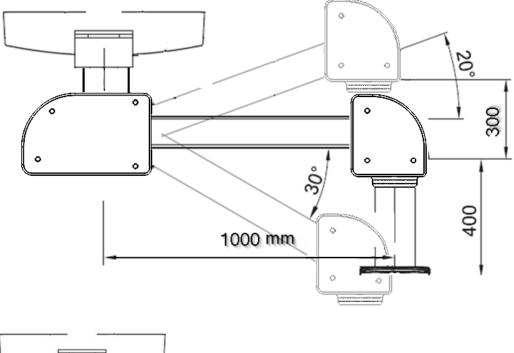
Fig.7 Location of brakes on non-powered arms



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5.4.2.3 Motorised arms

The length of the arms is variable according to each project. The motorised arm has a length of 1000mm, it can be combined with another one (forming a double arm) without motor whose length varies between 600 and 800 mm, giving a maximum of 1800mm between the anchorage point of the equipment and the vertical axis of the service head. See figure 8.



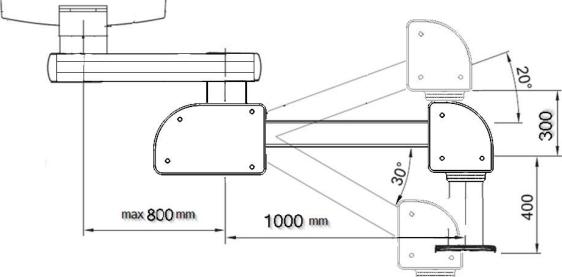


Fig.8 Motorised arms

The arms can rotate 340° horizontally and, in addition, the motor arm can be adjusted vertically 20° upwards and 30 degrees downwards. The length of the drop tube compensates for different ceiling heights to ensure that the service head is positioned at the desired working height. The service head can rotate 340° horizontally.

On the service head there is a double push button for activating the motors that raise or lower the system as shown in figure 9.

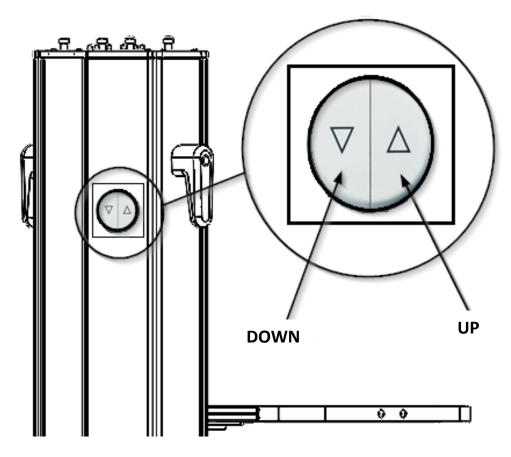


Fig.9 Motorised arm drive

To avoid collisions with other components or walls, the swivel range of the arms and the roller bearing drop tube (4) can be limited by means of internal end stops. The end stops of the arms and the roller bearing drop tube are preset at the factory.



See section 8.4.3 of this manual for the setting of rotation stops.

Depending on the length configuration chosen, the permissible loads range from 140Kg to 160Kg.

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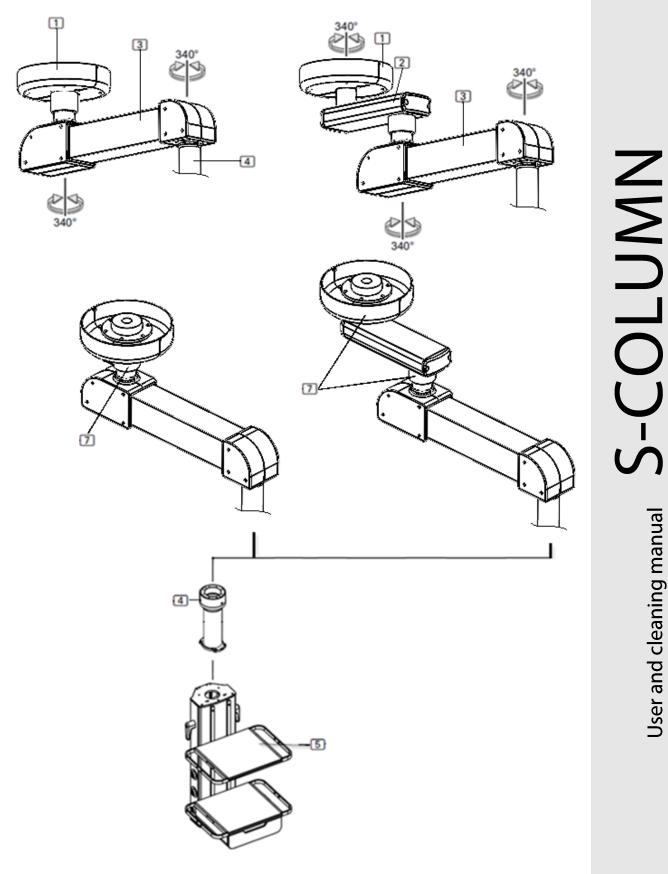


Fig.10 Motorised arm versions

Please note that your individual suspended system may differ from these illustrations.

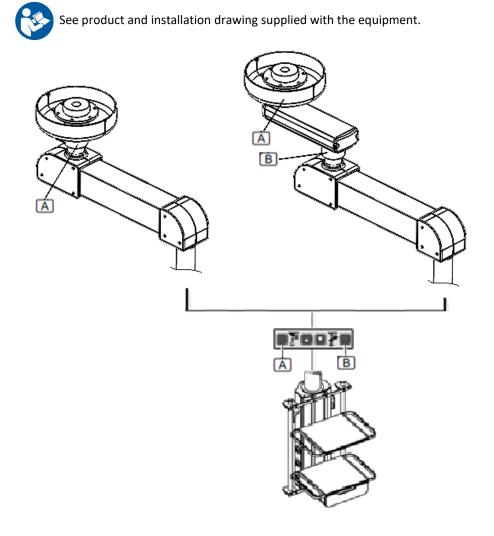
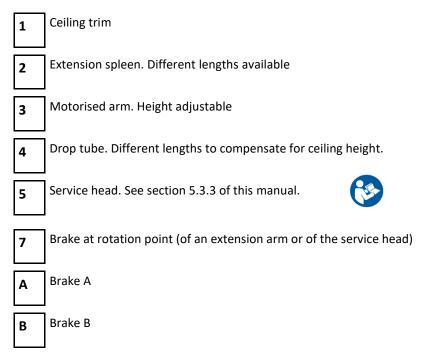


Fig.11 Location of the brakes on the motorised arms



5.4.3. Types of service heads

There are two possible configurations for the media or service head, the most common of which is vertical, shown left in figure 12, where the media head is parallel to the downpipe axis. In the second configuration it is horizontal, right image in figure 12.

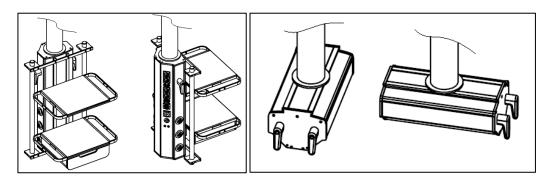


Fig.12 Service head types

5.4.3.1 Vertical service head TDSHV and TDSHV XL

In this configuration, two areas can be distinguished in the media head, the main one being the front side (loading area), on the left in figure 13, where there are two DIN rails on which different accessories can be mounted. On the rear side, in the centre of figure 13, we find the sockets or terminal units that serve as the supply interface for the power consumers that can be connected to the equipment. Depending on the height of the chassis, there are 4 standard sizes, shown on the right in figure 13. For special lengths please consult the manufacturer (*).

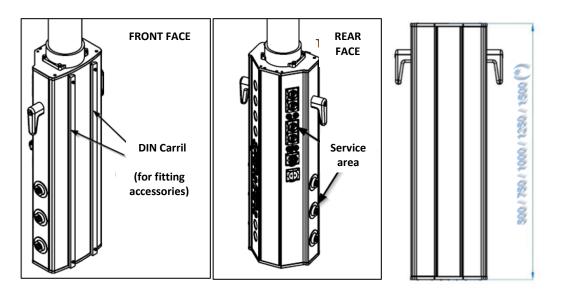


Fig.13 Vertical service heads

5.4.3.2 Horizontal service head TDSHH

In this configuration, two zones can be distinguished in the media head. On the two side faces there is the service area where the sockets for power, voice and data supply and gases are located, which serve as a supply interface for the energy consumers that can be connected to the device. On the underside there are two tubes on which various accessories can be attached. Depending on the length of the chassis, there are 3 standard sizes for the horizontal service heads, as shown in the lower part of figure 14. For special lengths please contact the manufacturer (*).



See Accessories section 5.3.3.4 of this manual.

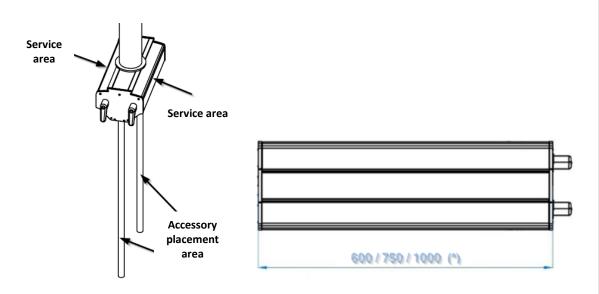


Fig.14 Horizontal service head

5.4.3.3 Other service head features

1. Treatment and finishing

Aluminium profiles can be processed either raw and then polished or anodised.

Finishes can be epoxy paint or antibacterial paint.

The standard colour used is matt white, but any other colour is possible according to the project specifications.

2. Lighting

Installation of 18 W LED strips, length 600 mm and colour temperature 4500 °K, in the upper part of the arms. Both 120 V and 230 V power supply.

Possibility of strips of different power and colour temperature subject to specific requests per project.

Possibility of installing a 3.2 W LED spotlight in the lower part of the column, for position or vigil lighting.

3. Drives

Possibility to control and manipulate the lighting by means of different actuators: switches, push buttons, nurse calls, potentiometers or dimmers and switches.

4. Electrical outlets

Possibility of installation of electrical sockets type A and B (Standard and Hospital Grade), type C, D, E, F, G, H, H, I, J, K, L, M, N, O, and multi standard sockets.

Possibility of colour variation of the electrical socket in accordance with the regulations of the region and the needs of the project.

5. Voice & data sockets and weak signals

Possibility of installing RJ45 Cat. 5/6/6A/7/7A sockets, RJ12 sockets and RJ11 sockets.

Possibility of installing call systems compatible with the hospital, either supplied by the hospital itself, or foreseeing and adapting modules supplied by third parties.

Possibility of installing relays, remote switches and a 24V control system for switching and manipulation of the lighting via the call system.

6. Protection mechanisms and land

Earthing and equipotential bonding busbars can be installed.

7. Video & audio & data sockets

HDMI, S-VIDEO, 3G BNC, 4K SDI, VGA and DisplayPort sockets can be installed.

USB 2.0/3.0/3.1 sockets can be installed.

Possibility of installing USB chargers for recharging mobile devices and *tablets*.

8. Future forecasts and/or enlargements

Possibility of installing blind covers to provide for elements and their future expansion.

9. Gas intakes

Possibility of installation and supply of gas inlets with ISO and USA standards. ISO standards include the following types: DIN 13260-2, AFNOR NF S 90-116, SS 875 24 30, BS 5682:2015, CM, CZ, ENV 737-6 EN 15908, UNI 9507, SDEGA EN ISO 9170-2.

Within the US standards are the following standards: ALLIED/CHEMETRON, DISS, OHIO/OHMEDA, PURITAN/BENNETT and OXEQUIP/MEDSTAR.

Possibility of installation of different gas intakes: O2, Medical Air, Vacuum, N2O, CO2, Air 800, N2, Motive Air, Heliox and EGA intakes (Passive or with Venturi system).



See the instructions for use of the gas inlets installed.

5.4.3.4 Accessories



When placing electrical devices in the deposition areas of the system head, be sure to maintain a safety distance of at least 20 cm from the power plug and/or on/off switch of the deposited device to the nearest oxygen (O2) or nitrous oxide (N2O) outlet point on the system head. See figure 15.

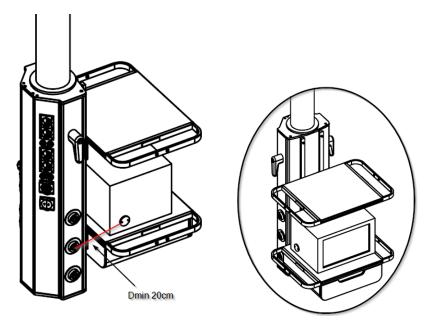


Fig.15 Minimum distance from a voltage point

See section 2.2 of this manual.

The service heads of the S-COLUMN family of devices are equipped with two DIN rails on which various accessories can be attached to support other medical devices.

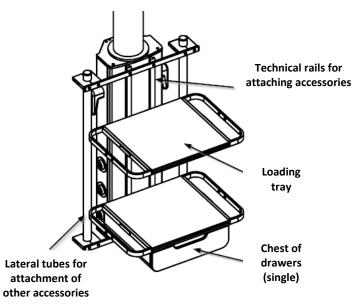


Fig.16 Accessories on vertical service head

Figure 16 shows an example of an element tray and another tray with an individual drawer unit and two vertical tubes which, in turn, will hold more accessories.

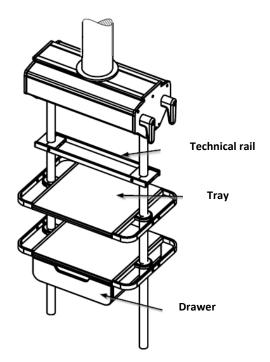
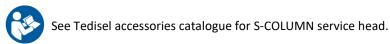


Fig.17 Accessories on horizontal service head

Figure 17 shows an example of an element tray, a tray with individual drawer unit and two technical rails for further accessories.



5.5. Maximum load capacity of the structural part

The maximum load capacity is the maximum weight that can be supported by the arm or set of arms, in the case of the example shown in Figure 18 a configuration with one extension arm (2) and one motorised arm (3) is shown. The maximum load is counted as applied on the vertical axis about which the service head will rotate.

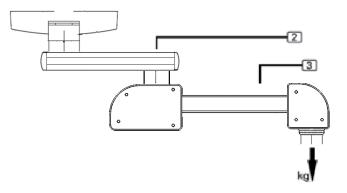
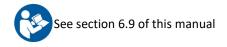


Fig.18 Load application point



5.6. Maximum payload capacity

The dead weight of the drop tube (4) and the service head (5) must be subtracted from the maximum load capacity of the suspension system. This value corresponds to the maximum load capacity (payload). In the example illustrated in figure 19, there is an extension arm and motorised arm assembly with a load capacity of 120 kg, the maximum payload is 95 kg after subtraction of the dead weight of the service head and is indicated on the sticker (1) on the service head.

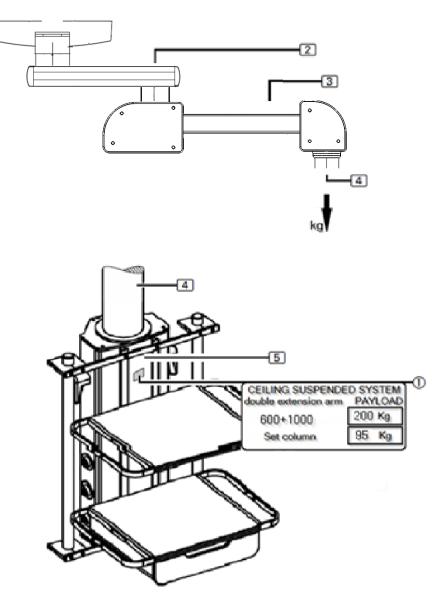


Fig.19 Location of the payload label

ΝΟΤΑ

If the drop tube (4) or the service head (5) is replaced, the maximum load capacity (payload) must be recalculated and indicated on the label (1) on the service head (5).

6. Technical data

6.1. Drop tubes

A diagram of the drop tubes is shown below. A friction brake is used to lock the rotation of the service head. Please note that the configuration of your hanging system may differ from this illustration.

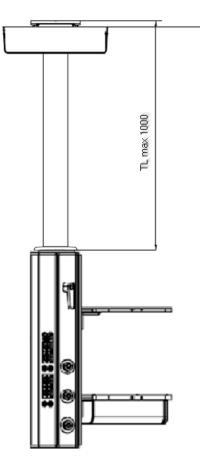


Fig.20 S-COLUMN ROTATION: Friction brake

6.2. Non-motorised arms

Various diagrams of non-motorised arms are shown below. An electromagnetic brake is used to lock the rotation of the service head. Please note that the configuration of your pendant system may differ from this illustration.

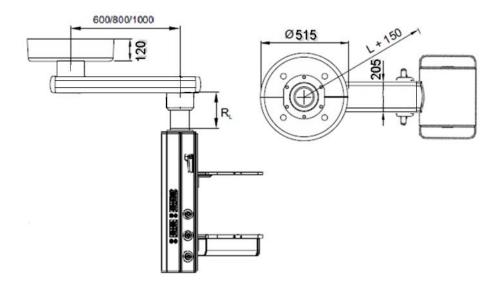


Fig.21 S-COLUMN: single arm, electromagnetic brake

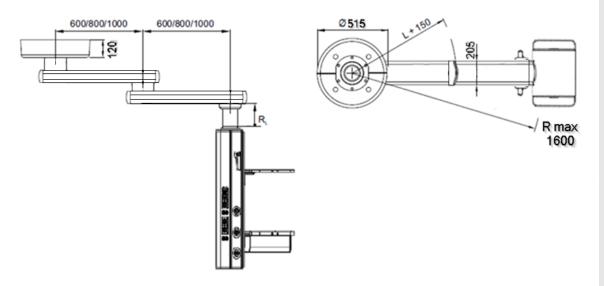


Fig.22 S-COLUMN: double arm, electromagnetic brake

6.3. Motorised arms

Various diagrams of motorised arms are shown below. An electromagnetic brake is used to lock the rotation of the service head. Please note that the configuration of your pendant system may differ from this illustration.

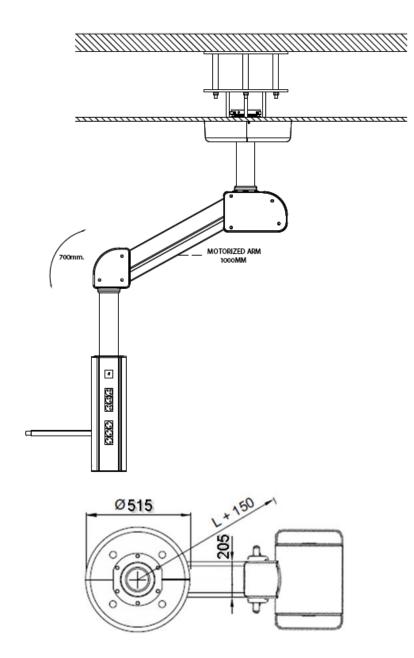


Fig.23 S-COLUMN MOTOR: single arm, electromagnetic brake

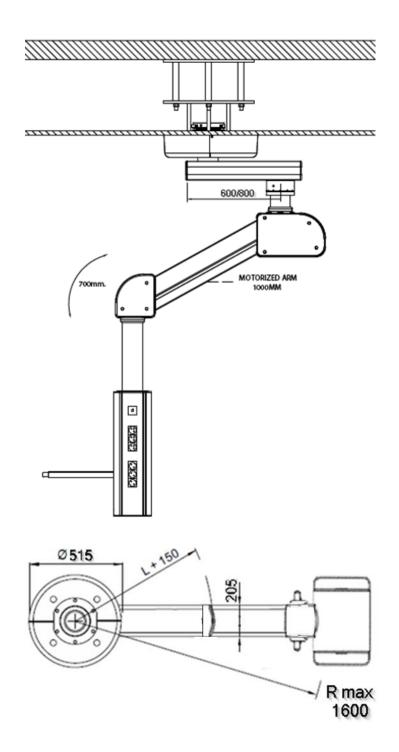


Fig.24 S-COLUMN MOTOR: double arm, electromagnetic brake

6.4. Duty cycle of electromagnetic brakes

- The maximum duty cycle of electromagnetic brakes shall not exceed 1 minute.

- If the electromagnetic brakes are operated for a longer period of time, the power supply may automatically switch off as a protective measure against overheating.

- Once the power supply has been switched off, it should cool down for 10 minutes and then be disconnected from the mains for 10 seconds before being switched on again.

Normal operation of the system can only be resumed afterwards.

6.5. Duty cycle of the height adjustment mechanism

For motor-driven systems, the maximum duty cycle of the height adjustment mechanism on the motor arm must exceed 3 minutes.

- If the height adjustment mechanism is operated for a prolonged period of time, the electric motor of the motor arm may automatically switch off as a protective measure against overheating.
- To avoid overloading the electric motor, be sure to wait at least 30 minutes after operating the height adjustment mechanism before operating the height adjustment mechanism. Subsequently, the height adjustment mechanism can be operated once more for 3 minutes.

6.6. Weight of the hanging system

The weight of the system does not include gas hoses, inserted power cables, ceiling plates, drop tubes or optional accessories. Below are the weights of the service headers and accessories that can be placed on the structural part (drop tube or arm/s).

6.6.1. Service head

| TDSHV vertical service head (500mm) | 14kg | |
|---|-------|--|
| TDSHV vertical service head (750mm) | .18kg | |
| TDSHV vertical service head (1000mm) | .21kg | |
| TDSHV vertical service head (1250mm) | 25kg | |
| TDSHV vertical service head (*) for special dimensions please contact the manufacturer. | | |
| TDSHH horizontal service head (600mm) | 18kg | |
| Horizontal service head TDSHH (750mm) | .20kg | |
| Horizontal service head TDSHH (1000mm) | .23kg | |
| Horizontal service head TDSHH (*) for special dimensions please contact the manufacturer. | | |

6.6.2. Accessories

| Tray on vertical service head | 9kg |
|---|--------|
| Drawer in vertical service head | 16,5kg |
| 1m 38mm diameter tube set for attachment of accessories | 3kg |
| Tray on horizontal service head | 6kg |
| Drawer in horizontal service head | 14kg |
| Flange assembly for 38mm diameter pipe | 0,35kg |

| Double technical stainless steel rail set on 38mm diameter tube (L=500mm)1,6kg |
|--|
| Double technical stainless steel rail set on 38mm diameter tube (L=700mm)2kg |
| Double technical aluminium rail set on 38mm diameter tube (L=500mm)1,4kg |
| Double technical aluminium rail set on 38mm diameter tube (L=700mm)1,7kg |

6.7. Load-bearing capacity of the suspension system

6.7.1. S-COLUMN ROTATION system

| Maximum load on rotation axis220 Kg |
|-------------------------------------|
|-------------------------------------|

6.7.2. S-COLUMN single-arm system

| Extension arm 600mm | 250kg |
|----------------------|-------|
| Extension Arm 800mm | 220kg |
| Extension arm 1000mm | 210kg |

6.7.3. S-COLUMN double arm system

| Extension arm 600/800mm or 800/600mm | 200kg |
|--|-------|
| Extension arm 800/800mm | 185kg |
| Extension arm 1000/600mm or 600/1000mm | 185kg |

6.7.4. S-COLUMN MOTOR system

| Motor arm (1000 mm) | 200kg |
|--|-------|
| Extension arm, 600mm, with motor arm (1000 mm) | 200kg |
| Extension arm, 800mm, with motor arm (1000 mm) | 180kg |

6.7.5. Service head

| Horizontal service head TDSHH100k |
|-----------------------------------|
|-----------------------------------|

6.7.6. Accessories

| Tray on vertical service head | 50kg |
|---|-------|
| Drawer in vertical service head | 40kg |
| 1m 38mm diameter tube set for attachment of accessories | 150kg |
| Tray on horizontal service head | 50kg |
| Drawer in horizontal service head | 40kg |
| Stainless steel double technical rail set on 38mm diameter tube (L=300mm) | 25kg |

| Stainless steel double technical rail set on 38mm diameter tube (L=500mm)25kg |
|---|
| Stainless steel double technical rail set on 38mm diameter tube (L=700mm)25kg |

6.8. Electrical data

6.8.1. S-COLUMN System

| Rated voltage | AC 230V |
|--|--------------------------------|
| Nominal frequency | 50Hz |
| Rated power | up to 220W |
| Indirect light extension arm | DC 12V |
| 2 / 4 lighting modules (supply voltage 12 V DC, 2 lighting boards each c | onnected in series to 24 V DC) |

6.8.2. S-COLUMN MOTOR system

| Rated voltage | AC 230V |
|--|--------------------|
| Nominal frequency | 50Hz |
| Rated current at AC 230V | 5A |
| Indirect light extension arm | DC 12V |
| 2 / 4 lighting boards (supply voltage 12 V DC, 2 lighting boards each connected in | series at 24 V DC) |

6.9. Noise level

Noise energy level65db(A) (EN ISO 3746) not exceeded

6.10. Brakes

| Brake torque with pneumatic brake appliedapprox. 50Nm |
|---|
| Brake torque (electromagnetic brake actuated on motor arm) approx. 70Nm |
| Brake torque (electromagnetic brake actuated on extension arm)approx. 70 Nm |
| Brake torque (electromagnetic brake actuated on XL extension arm)approx. 150 Nm |

6.11. Dynamic torque (with brake released)

NOTA Depending on position and payload

7. Intended use

UMOS is a ceiling pendant system designed for the supply of medical gases, electrical power and access communication points from the ceiling to the workstation of medical specialists. It is used especially for equipping operating theatres, ARD and ICU.

8. Use of equipment

S-COLUMN devices are intended for continuous operation. The specifications of the individual functional elements of the device must be observed when using the device.

- (F) Electrical, voice and data circuits.
- (G) Nurse call
- (H) Lighting
- (I) Gas intakes

There may be actuators for switching on modules of the lighting modules in the room in which the equipment is installed.

See product and installation drawing supplied with the equipment.

NOTICE: Details of the elements and their characteristics can be found in the product definition drawing.

8.1. Product preparation

Before COMMISSIONING, during MAINTENANCE, INSPECTION, SERVICE and after REPAIR, a functional test must be carried out at the installation site. This functional test must be carried out by the operator or a person authorised by the operator, and persons authorised by the operator must be properly instructed.

This requirement is considered fulfilled if:

- 1. The functional reliability of the suspension system and the service head is ensured.
- 2. The maximum permissible load capacity (payload) has been safely determined and is indicated on a label attached to the service head.
- 3. The correct functioning of the device has been approved by the operator during the first commissioning and documented by signing a test report according to Appendix G EN 62353.



See point 3 of this manual.

WARNING: To prevent unintentional actuation of the control elements, ensure that all cables and hoses are sufficiently far away from the control elements.

8.2. Environment. Environmental conditions



8.3. Training

Personnel making USE of the equipment must be properly trained and qualified by the customer. The equipment must only be USED by authorised personnel. Persons who:

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

2. have been instructed in the use 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.

8.4. Adjustments



Disconnect the equipment electrically, as well as any equipment supplied through the service head, before making adjustments to prevent live system cables leading to the equipment from coming into contact with live parts of the system.

8.4.1. Adjustment of the mechanical brake on the arms

In case of failure of the pneumatic (compressed air operated) brakes, additional mechanical brakes (friction brakes) keep the extension arm and motor arm stable. Adjust the braking force in such a way that the motor arm or extension arm remains stable in any position and can still be adjusted conveniently.

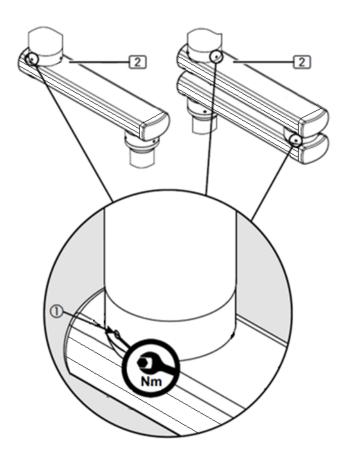


Fig.25 Friction brake adjustment

The mechanical brakes (friction brakes) hold the extension arm (2) in any set position. Adjust the braking force in such a way that the extension arm (2) remains stable in any position and can still be adjusted conveniently. If the brakes are not adjusted correctly, the extension arm may automatically move in an uncontrolled manner.

NOTA

Observe the end stop recommendation in chapter 8 and make sure to tighten the brake bolts of the Unit on the roof tube more than at the bearing point of the lower extension arm. This facilitates the bending of the lower extension arm and allows the bearing unit on the lower extension arm to rotate freely.



See section 8.4.3 of this manual.

Use a suitable torque spanner to adjust the brake.

- 1. To increase the braking force, tighten the brake Allen screws ① by turning them evenly to the right (clockwise). Tighten to 1.6 Nm.
- 2. To reduce the braking force, unscrew the brake Allen screws ① by turning them evenly to the left (counterclockwise).
- 3. Carrying out a test run

8.4.2. Adjustment of the mechanical brake on the drop tube

The brake screw (friction brake) is adjusted in the same way for all different versions of the suspension system. Adjust the braking force of the respective end device so that the end device remains stable in any set position and can still be adjusted comfortably. In the figure below you can see the adjustment scheme for the service head.

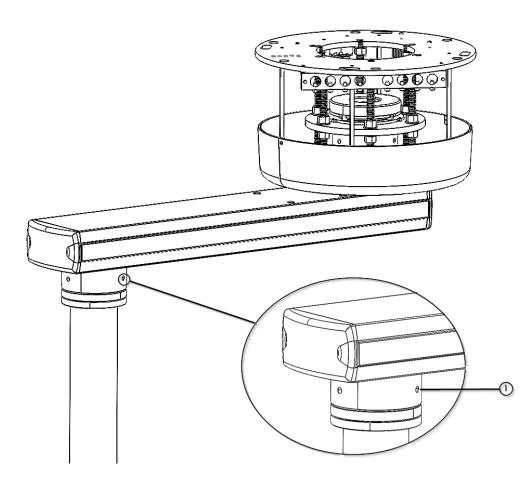


Fig.26 Adjusting the friction brake on the drop tube

Use a suitable Allen screwdriver.

- 4. To increase the braking force, insert the flat screwdriver into the brake screws ① and turn it clockwise to the right.
- To reduce the braking force, insert the flat screwdriver into the brake screws ① and turn it to the left (counterclockwise).
- 6. Carry out a test run.

8.4.3. Adjustment of the rotary stops

The extension arm and drop tube are equipped with at least 1 swivel stop that prevents the internal cables from being destroyed. With 1 stop installed, the swivel range is restricted to a maximum of 340 degrees. With a second stop the swivel can be further restricted.

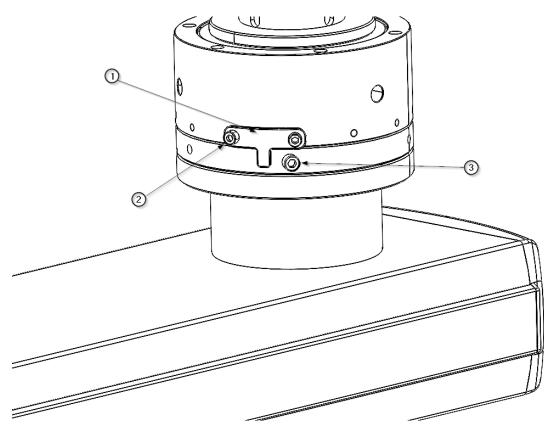


Fig.27 Adjustment of the rotary stops

1. Rotate the extension arm or console tube to the desired end stop position and then insert the pivot stop (1) and secure it by means of the M5x16 DIN 912 socket head cap screws (2).

Make sure that the stopper is firmly in place. The extension arm or drop tube can be rotated until the stop ① touches the limiting screw ③.

The first turning limit is already defined.

2. Rotate the extension arm or console tube to the desired position for the second end stop and then insert an additional end stop.

- 4. Tighten the fixing screws 2 to 40 Nm.
- 5. Check that the swivel range of the arms is as desired.

9. 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.

The use of **formaldehyde-free** disinfectants such as Proder Pharma's Saint Nebul Ald. or a mild soap solution with a standard dishwashing product is recommended.

Method of application:

- 1 Dilute 4 pulses of the valve supplied by the manufacturer per 5 litres of water.
- 2. Do not spray the compound on the product, wipe the surface with a moderately damp cloth and let it react for 15 minutes.
- 3. Remove with water or soap solution with a clean, wrung out cloth.



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.

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.

9.1. Disinfection

Disinfectants may contain substances hazardous to health which, in contact with skin and eyes, can cause injury or affect the respiratory organs when inhaled. Observe protective measures:

- Observe hygiene rules.
- Follow the instructions of the disinfectant manufacturer.
- Carry out surface disinfection every working day and in case of contamination.

Wiping disinfection is the standardised disinfection method prescribed for the pendant system.

The operator must define the hygiene rules and safety instructions related to the disinfection methods to be applied.

- In case of contamination with potentially infectious material (e.g. blood, body secretions or excreta), surfaces must be immediately and specifically disinfected.
- Be sure to apply the disinfectant in the correct concentration.
- For surface disinfection, do not spray, but wipe surfaces.
- Cleaned surfaces may only be used after the disinfectant has dried.

10. 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.

11. User information on warnings

Under no circumstances shall the user remove any part of the equipment enclosure to carry out checks.

11.1. Lighting problems

In the event of a fault or malfunction in the lighting systems, check the ignition from all intended actuators. If the problem persists, contact maintenance personnel.

11.2. Power supply problems

In the event of a fault or malfunction in any equipment connected to the supply unit, check this equipment by plugging it into another point of the equivalent supply unit. If the problem persists, contact service personnel.

11.3. Problems with the supply of medical gases

In the event of a failure or malfunction in the medical gas supply system, check the following:

- That you are trying to make the connection at the corresponding gas connection.
- That the gas inlet actuator is working properly and is not blocked.

If the problem persists, contact your service personnel.

12. Incident warning information

Any serious incident related to the product must be reported to Tedisel Ibérica and to the competent authority of the member state where the user and/or the patient are established.



See point 1 of this manual.

13. Regulations

13.1. 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.

13.2. 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.

13.3. 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 | Compliance | Comment |
|----------------------------|---------------|---|
| Interference emission | Compliance | comment |
| measurements | | |
| HF emissions according to | Group 1 | The supply unit uses HF energy exclusively for its |
| CISPR 11 standard | | internal OPERATION. Therefore, its HF emissions are |
| | | minimal and interference with devices in its vicinity |
| | | is unlikely. |
| HF emissions according to | Class A | The roof supply unit is suitable for use in non- |
| CISPR 11 standard | | domestic installations and in installations that are |
| Harmonic emissions | Class A | directly connected to the PUBLIC SUPPLY NETWORK, |
| according to the standard | | which also supplies residential buildings. |
| IEC 61000-3-2 | | |
| Emissions of voltage | In accordance | |
| fluctuations/transients in | with | |
| accordance with the | | |
| standard | | |
| IEC 61000-3-3 | | |

| Interference | Test level according | Level of compliance | Environment/Guidelines |
|---------------------|----------------------|------------------------|---------------------------------|
| resistance | to IEC 60601 | | |
| Static Electric | ±8 kV contact | ±8 kV contact | Floors should be made of |
| Discharge (ESD) in | discharge | discharge | wood, concrete or ceramics. If |
| accordance with | 15 kV aerial | 15 kV aerial discharge | the floor is covered with a |
| the | discharge | | synthetic material, the |
| IEC 61000-4-2 | | | relative air humidity should |
| | | | be at least 30%. |
| Fast transient | ±2 kV for power | ±2 kV for power supply | The quality of the supply |
| electrical | supply cables | cables | voltage should be typical for a |
| interference | ±1kV for input | ±1 kV for incoming and | commercial or hospital |
| amplitudes / bursts | and output cables | outgoing cables | environment. |
| according to the | | | |
| norm | | | |
| IEC 61000-4-4 | | | |
| Overvoltages | ±1 kV phase-to- | ±1 kV phase-to-phase | The quality of the supply |
| (waves) according | phase voltage | voltage | voltage should be typical for a |
| to the standard | ±2 kV phase to | ±2 kV phase to ground | commercial or hospital |
| IEC 61000-4- 5 | ground voltage | voltage | environment. |

| Voltage dips and fluctuations of the supply voltage according to the standard IEC 61000-4- 11 | 100% of UN drop for 0.5 period 100% of UN drop for 1 period 30% of UN drop for 25 periods Remark: UN is the AC mains voltage before applying the test | 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 |
|--|---|--|---|
| | level. | | with an uninterruptible power supply or a battery. |
| Short interruptions of the supply | 100% for 5 s | | The quality of the supply |
| voltage according | Remark: | | voltage should be typical for a |
| to the standard | UN is the AC mains | | commercial or hospital environment. |
| IEC 61000-4- 11 | voltage before applying the test level. | | 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 | 30 A/m | 30 A/m | The magnetic fields created |
| power supply | | | by the mains frequency |
| frequencies (50/60 Hz) according to | | | should be those of a commercial or hospital |
| the standard | | | environment. |
| IEC 61000-4-8 | | | |

| tedisel | medical |
|---------|---------|
| | |

| Interference resistance | Level of verification according to | | Level of | Environme | nt/Guidelines |
|--|------------------------------------|--|---|----------------------------|--|
| | IEC 60601 | | compliance | | |
| HF interference induced by IEC 61000-4-6 | 3 Vrms 150 kHz 6 Vrms ISM ban | | 3 Vrms 6 Vrms | | modulation 6 Depth 80% 6 Depth |
| HF interference | RANGE | FREQUENCY | MODULATION | STEP | LEVEL |
| induced by IEC 61000-4-3 | A B C D E F G | 80-1000MHz 1000-2000MHz 2000-2700MHz 385MHz 450MHz 810-930MHz 1720-1970MHz | AM 1 kHz Prof: 80% AM 1 kHz Prof: 80% AM 1 kHz Prof: 80% PM 18 Hz Cycle: 50% FM 1 kHz Desv:± 5 kHz PM 18 Hz Cycle: 50% PM 217 Hz Cycle: 50% | LOG 1% LOG 1% LOG 1% | 10 V/m 10 V/m 27 V/m 28 V/m 28 V/m 28 V/m |
| | G H I | 1/20-19/0MHz 2450MHz 5240-5785MHz | PM 217 Hz Cycle: 50% PM 217 Hz Cycle: 50% PM 217 Hz Cycle: 50% | - | 28 V/m 28 V/m 9 V/m |

| Transmitter power rating | Safety distance depending on emission frequency Environment/Guidelines | | | | |
|--------------------------|--|--------------|---------------|--|--|
| | 150 kHz to 80 | 80 MHz up to | 800 MHz up to | | |
| | MHz | 800 MHz | 2.5 GHz | | |
| | D = 1,2 P | D = 1,2 P | 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 | | |