

tediselmedical

ABITUS

USER AND CLEANING MANUAL



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CE 0197

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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.

2.2. Warnings of risk of damage

The signal word WARNING describes the degree of risk of material damage. The triangular symbol visually emphasises the degree of danger.



Damage to surfaces: warns of damage to surfaces due to unsuitable cleaning agents and disinfectants.



NOTICE

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

2.3. Supplementary symbols used in the safety instructions



Fire hazard



Explosion hazard: warns of ignition of explosive gas mixtures.



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

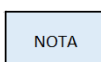


Failure of the roof support system



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



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.

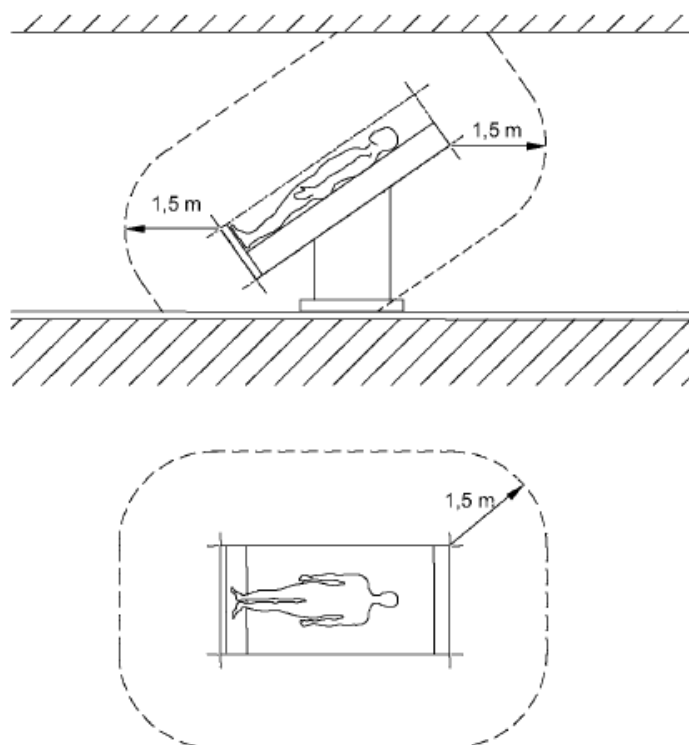


Fig. 1 Minimum extent of the PATIENT ENVIRONMENT

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 the ends of building connections 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.

3.9. Essential Performance and Basic Safety Considerations

To ensure the BASIC SAFETY and ESSENTIAL PERFORMANCE, the following conditions are expected during the intended use:

- the electrical outlets work properly
- the light modules work properly

However, due to external unexpected EM disturbances, the ESSENTIAL PERFORMANCE can be degraded producing:

- Risk for the user/patient
- Cessation or interruption the power on the electrical outlets

3.10. EM Interference



WARNING: portable RF communications equipment, including antennas, can affect the systems. These types of devices should be used no closer than 30 cm (12 inches) to any part of the system, including cables”.

4. Symbols used



Applicable part B



Earth (mass)



Equipotentiality



Protective earth (ground)

N

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. Product data

This manual refers to the ABITUS model. This model is part of the SICS family.

5.1. Storage conditions

The packaging of this type of product consists of two parts, the first one containing the suspended headrest (structural part of the equipment) and the second one corresponding to the service heads and/or trolleys.

The packaging consists of a cardboard box with a sturdy wooden structure. In the case of equipment fitted with service heads, the packaging has cardboard reinforcements inside the box to immobilise the extension arm (if applicable) and/or the service head. This packaging can be removable in two heights.

Under no circumstances should the product be stored with open or damaged packaging. If the product is inspected on receipt and installation is not carried out within 1 day, the product packaging must be resealed.



NOTICE: Failure to follow these instructions may result in damage to the equipment.

Recommended temperature range: -20 °C to 60 °C

Recommended humidity range: 10 % to 75 %.

Atmospheric pressure: 500 hPa to 1,060 hPa

5.2. Operating conditions



NOTICE: Failure to follow these instructions may result in damage to the equipment.

Recommended temperature range: 10 °C to 40 °C

Recommended humidity range: 30 % to 75 %.

Atmospheric pressure: 700 hPa to 1,060 hPa

5.3. Service life

The service life of the SICS 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

The ABITUS units consist of three distinct parts, the structural part (downspouts), which is responsible for positioning the unit at the desired height, the suspended headrest and the service heads, which serves as a supply interface for energy consumers and also for the housing, storage and storage of medical devices and accessories. Trolleys can also be used for the accommodation, storage and storage of other devices without supplying them with power. See figure 2.

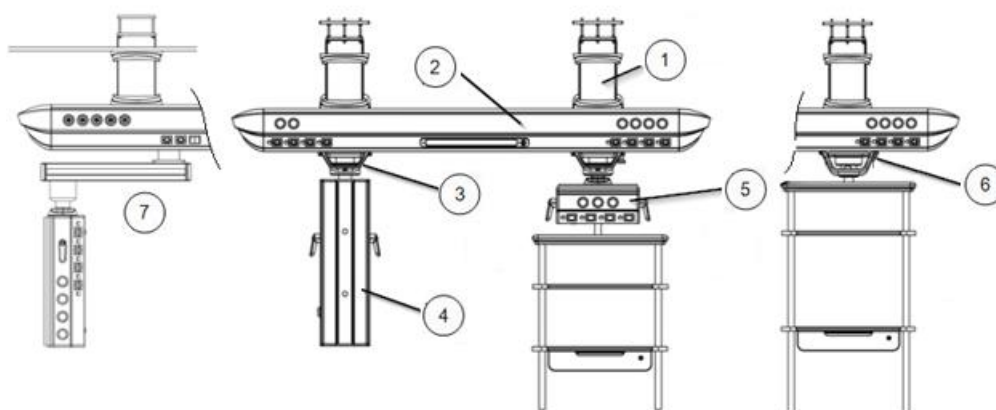


Fig.2 Parts of the equipment

- 1) Roof lowering package
- 2) Suspended headboard (main body)
- 3) Service head carousel
- 4) Wet supply column (wet service header)
- 5) Dry supply column (dry service head)
- 6) Trolley pota elements
- 7) Carousel + extension arm (optional)

Only pick-up attachments (platforms, device holders, etc.) attached to the service heads may be used for picking up loads. For this purpose, the different loading conditions of a base support unit and the individual accessories must be considered:

NOTA

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 staff or patient, as well as damage to property.

Cables and accessories may be provided by the facility.



WARNING: The use of external cables or accessories not provided by Tedisel may negatively affect EMC performance.

5.4.1. Parts and control elements.

5.4.1.1 Downpipes

Structural element that joins the main body of the equipment to the ceiling of the room in which the equipment is to be installed. See figure 3. In addition to the supply passage to the equipment, these downpipes define the height at which the equipment is installed with respect to the floor and, therefore, the relative position of each of its parts with respect to the operators. Separation can be requested for gas and electrical circuits through the same downpipe.

NOTA

The variable length L as shown in figure 1 of this assembly ranges from a minimum of 300mm to a maximum of 1500mm. If the destination premises have a greater distance to the point of connection to the floor slab, an intermediate structure (not supplied by Tedisel) will be required.

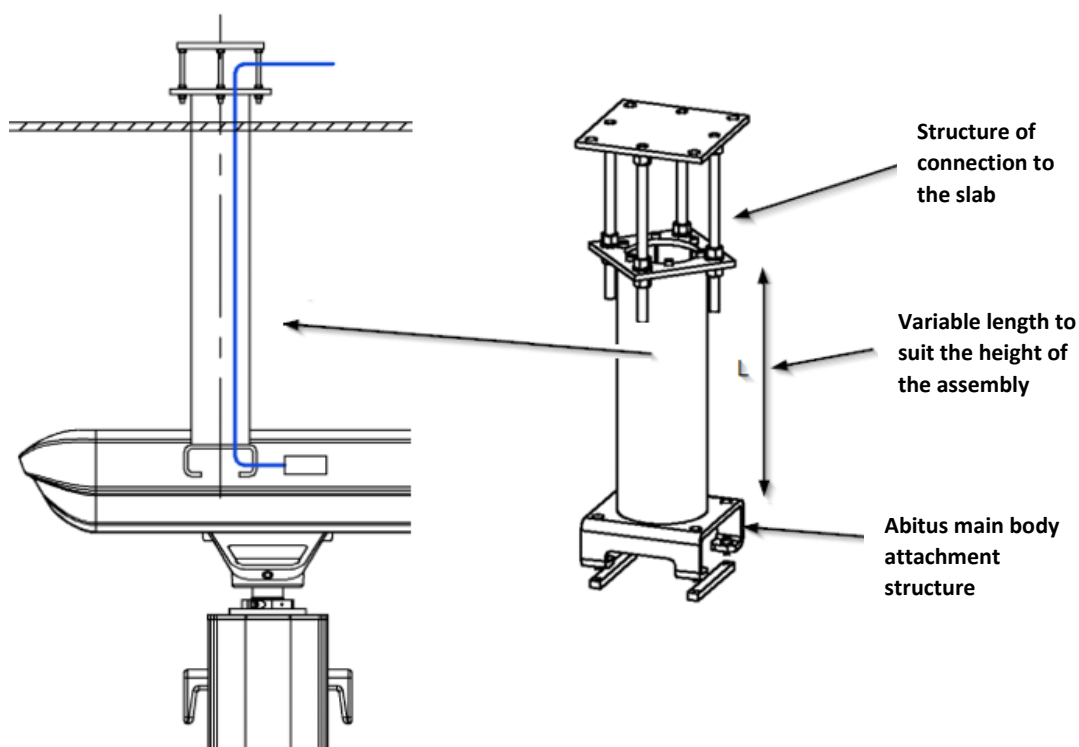


Fig.3 Parts. Downpipe

For lengths up to 1.5m, a maximum pure tensile load of 4,500 kg per downpipe is defined.

5.4.1.2 Suspended headboard. Main body.

Structural and functional element, attached to the downcomer, it is the chassis on which other accessory elements such as columns or trolleys can be fixed. It can also be used to house other elements such as lighting, terminal units for medical gases and vacuum, electrical sockets, etc.

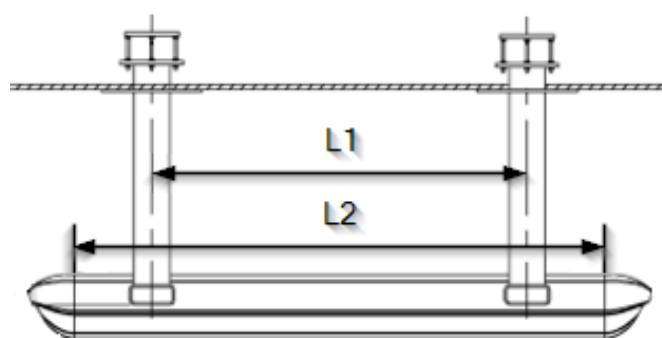


Fig. 4 Parts. Suspended headboard

In order to ensure that possible equipment that can be suspended in turn from the suspended header, a minimum spacing length between downspouts of $L1 > 1.2\text{m}$ is defined for suspended headers with chassis above $L2 > 2.5\text{m}$, see figure 4.



See product and installation drawing supplied with the equipment.

This distance L1 may be less for sections of length $L2 < 2.5\text{m}$. The specific distances for each unit depend on the final provision of fittings suspended from the main body and are detailed in the manufacturing and installation drawings accompanying the unit. The maximum length L2 per section is 3m, for longer suspended systems, the desired length L3 will be achieved by joining sections of maximum 3m, anchoring each of them to the slab by means of two downspouts as shown in figure 5.

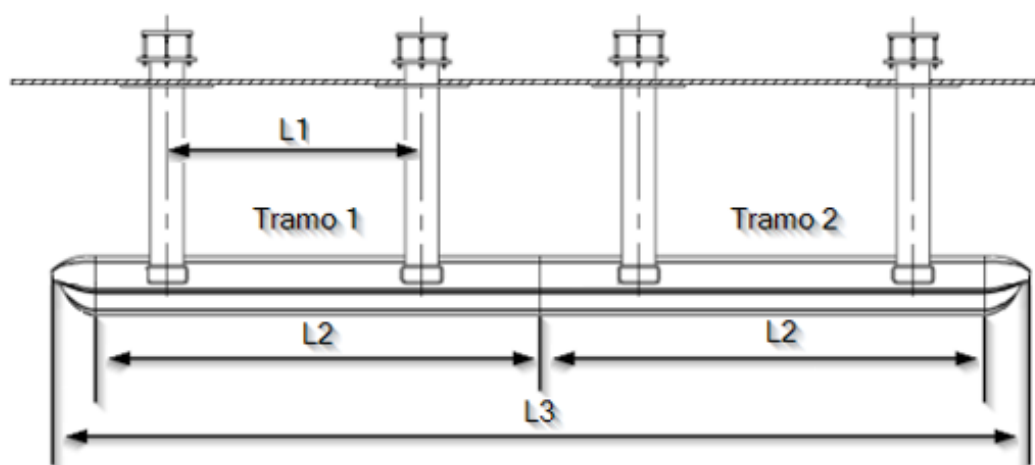


Fig. 5 Parts. Joining of two suspended headboard sections



The maximum load per main head section is 600 kg. Exceeding the maximum capacity of the equipment may result in injury to personnel or patient as well as damage to property.



See point 5.5 of this manual

5.4.1.3 Element carrier trolleys

Movable element that moves along a defined length within an ABITUS section with two 38mm diameter structural tubes on which other accessory elements can be supported. The distance between the tubes (L) can be 300mm, 500mm and 700mm. Figure 6 shows the 300mm and the 700mm variant.

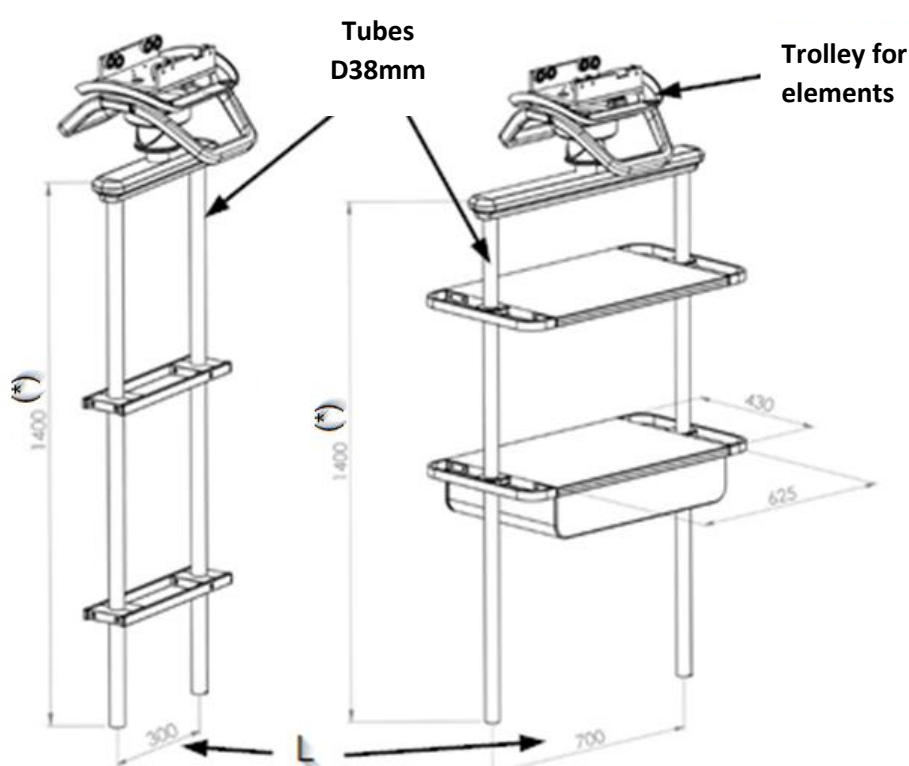


Fig. 6 Trolley detail for ABITUS



See Abitus accessories catalogue

In the example in figure 6 you can see two sets of technical rails on the structural tubes (picture on the left in figure 6) and two trays, one with individual drawers (picture on the right in figure 6). The standard length of the tubes is 1400mm, for special lengths please contact the manufacturer.

5.4.1.4 Service head carousel

A movable element that moves along a defined length within an ABITUS section and supports service heads and their accessories. These can be attached directly to the carousel (left image in figure 6) or

via a 0.6m extension arm (right image in figure 6). The stroke of this carousel is defined by placing stops to limit its displacement and thus prevent it from coming into conflict or colliding with other elements of the room or the ABITUS equipment itself. See figure 8.

Also, the rotation of the arms should be limited to prevent the service heads hanging from them from hitting the patient and/or other equipment that may be in the patient's vicinity.



See the manufacturing and installation drawing supplied with the equipment for the range of rotation of the extension arms.

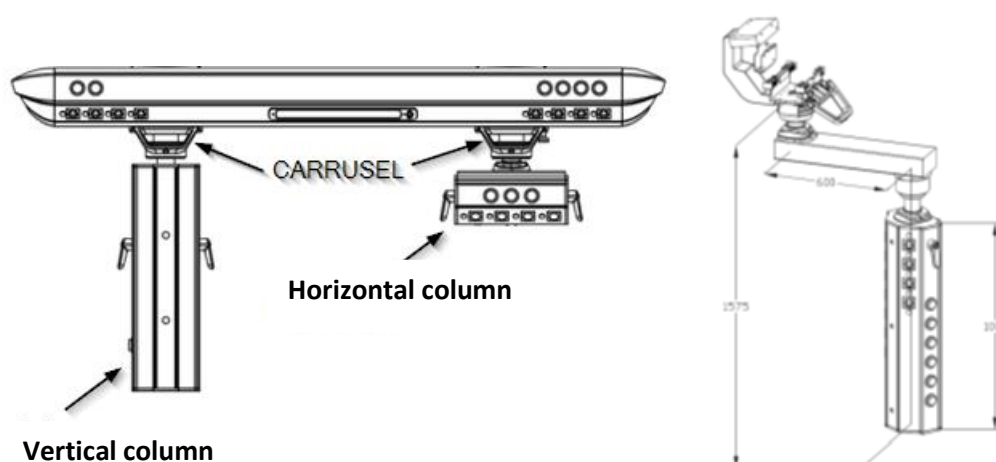


Fig. 7 Carousel detail for ABITUS with two columns and carousel with arm

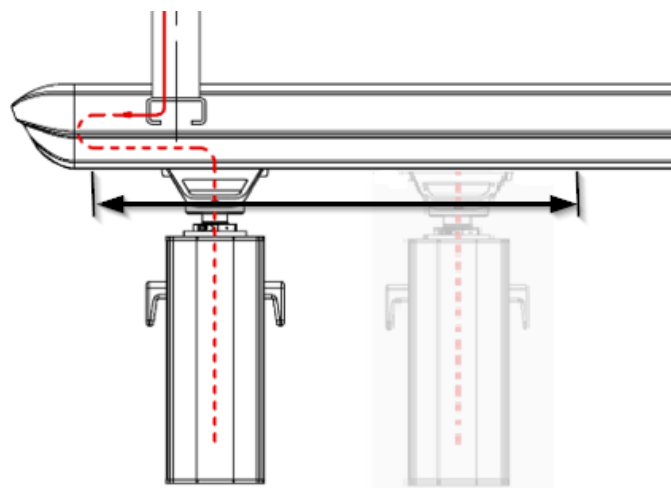


Fig. 8 Displacement of a carousel on ABITUS main body

The actuators for the different brakes are located on the handles of the service head. See figure 9. For those configurations with direct service head on carousel, i.e. without extension arm, actuators A/B release both the travel brake and the swing brake. For those configurations with an extension arm,

actuator A unlocks the travel brake, while actuator B unlocks the pivot brake at both pivot points, leaving the arm free, the rotation of the arm being limited only by the pivot stops.



See section 8.4.4 of this manual.

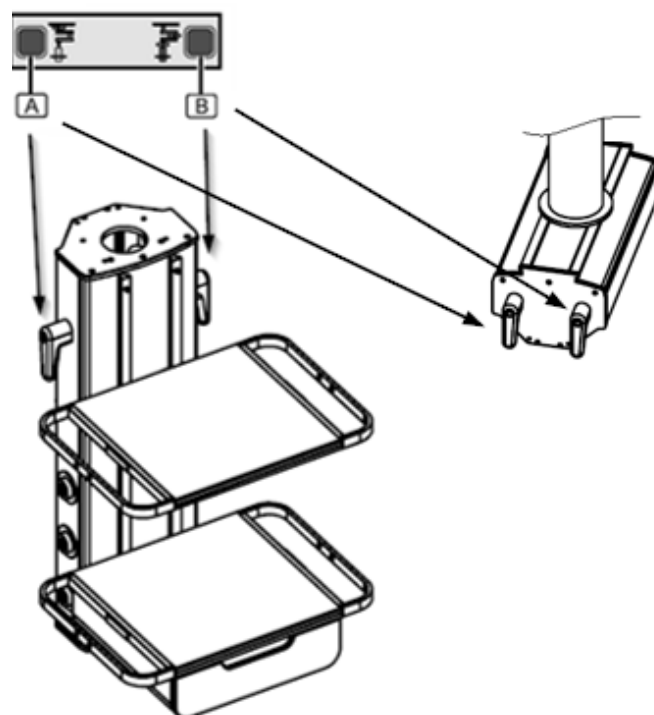


Fig. 9 Position of brake actuators on a service head

The above figure shows the location of the brake actuators in a vertical service head (left picture in figure 9) and in a horizontal service head (right picture in figure 9).

5.4.1.5 Service heads

There are two possible configurations for the media or service head, the most common of which is vertical, shown left in Fig. 10, where the media head is parallel to the downpipe axis. In the second configuration it is horizontal, right image in Fig. 10.

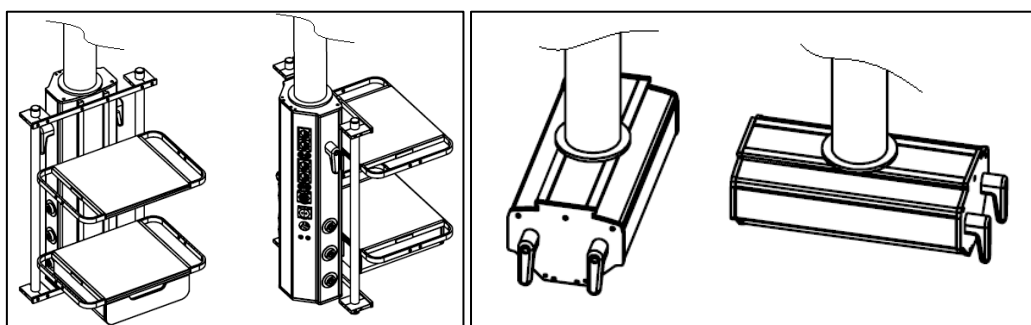


Fig.10 Types of service heads

For the vertical configuration, two zones can be distinguished on the media head, the main one being the front side (loading area), on the left in figure 11, where there are two DIN rails on which various accessories can be mounted. On the rear side, in the centre of figure 11, are the sockets or terminal units that serve as the supply interface for the power consumers that can be connected to the device. Depending on the height of the chassis, there are 3 standard sizes, on the right in figure 11. Please consult the manufacturer for special heights (*).

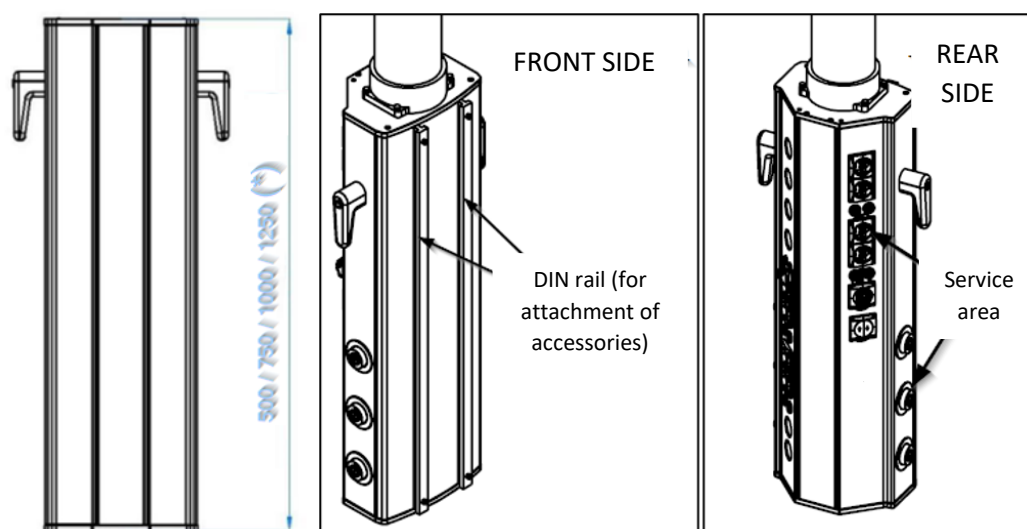


Fig. 11 Vertical service head

For the horizontal configuration, two zones can be distinguished in the media head as shown in figure 12. 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 the 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 Fig.12. Please consult the manufacturer for special lengths (*).



See Accessories section 5.4.1.6 of this manual.

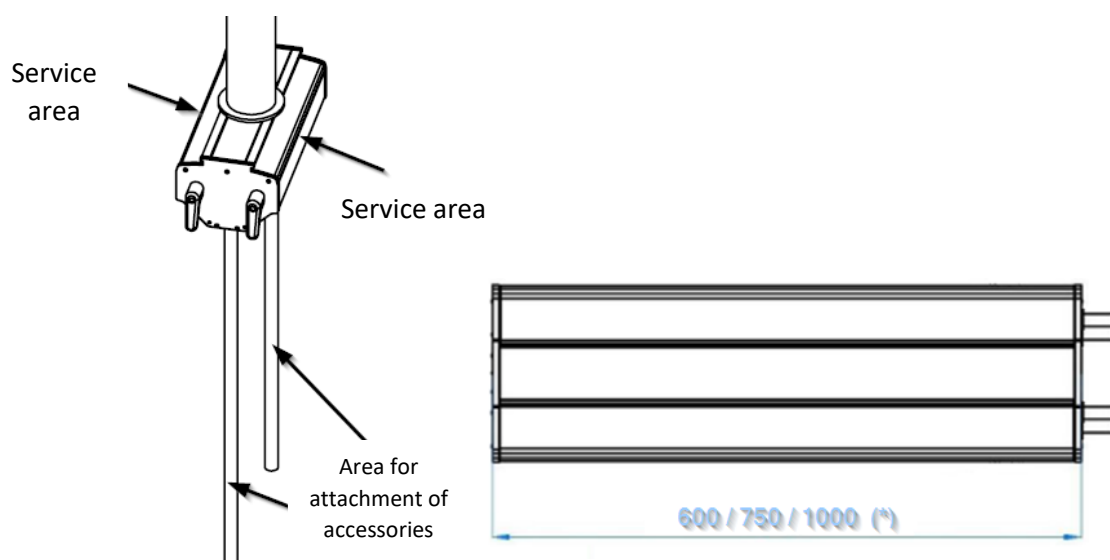


Fig. 12 Horizontal service head

5.4.1.6 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 project specifications.

2. Drives

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

3. Electrical outlets

Possibility of installation of electrical sockets type A and B (Standard and Hospital Grade), type C, D, E, F, G, 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.

4. 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 24V control system for switching and manipulation of the lighting via the call system.

5. Protection mechanisms and land

Earthing and equipotential bonding busbars can be installed.

6. 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*.

7. Future forecasts and/or enlargements

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

8. Gas intakes

Possibility of installation and supply of gas inlets with ISO/EN and NFPA/CGA standards. ISO/EN standards include the following types: DIN 13260-2, AFNOR NF S 90-116 / FD S 90-119, SS 875 24 30, BS 5682:2015, CM, CSN 85 2762, ENV 737-6, EN 15908, UNI 9507, SDEGA EN ISO 9170-2.

Within the NFPA/CGA 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.

5.4.1.7 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 Fig. 13.

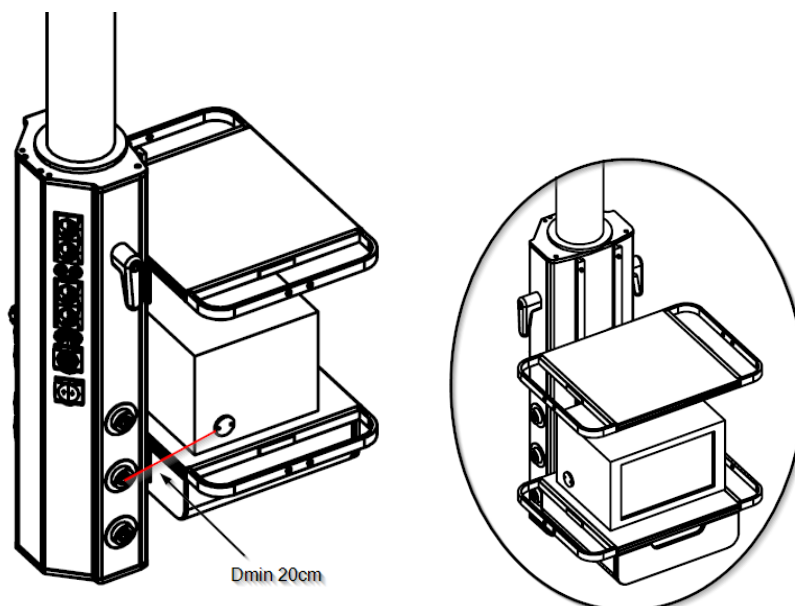


Fig.13 Minimum distance from a stress point



See section 2.2 of this manual.

The service heads are fitted with two DIN rails on which various accessories can be attached to support other medical equipment.

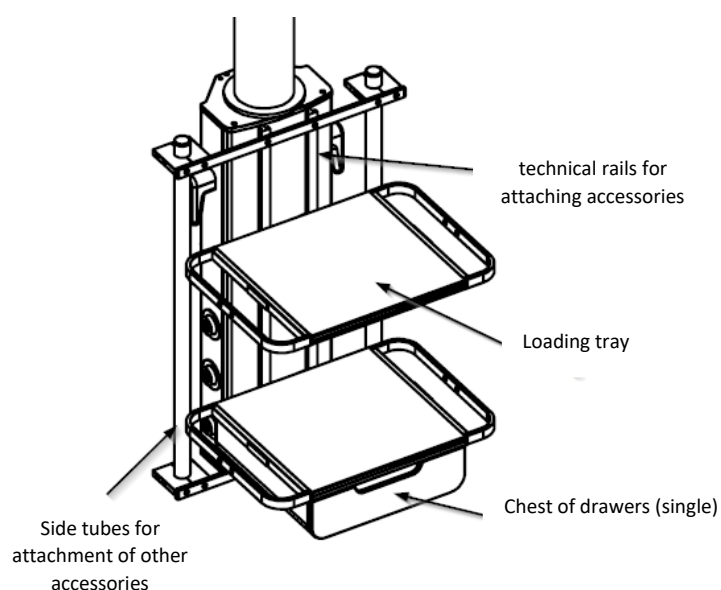


Fig.14 Fittings on vertical service head

Figure 15 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.

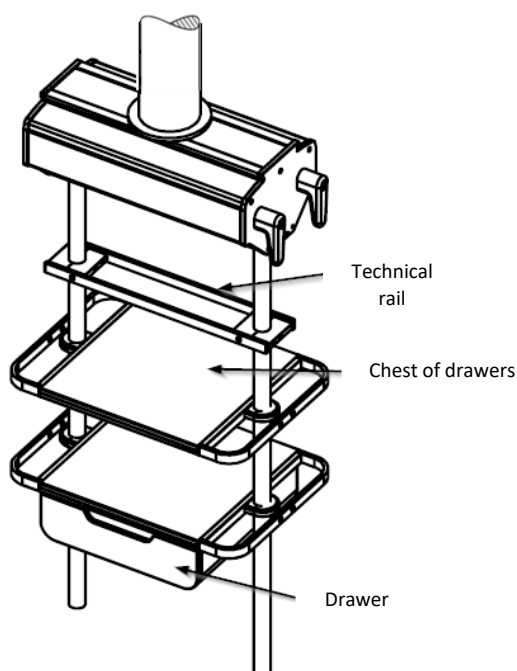


Fig.15 Fittings on horizontal service head



See Tedisel accessories catalogue for service head

5.5. Maximum load capacity

The maximum load capacity is the maximum weight that the suspended headboard can support. The example shown in figure 16 shows a configuration with an extension arm (3) and a horizontal column without an extension arm (2).

In the case of equipping the suspended headboard with trolleys, the load is always counted as applied on the axis of rotation of the trolleys as shown in figure 17.

The maximum load per main head section is 600 kg. This load includes the payload capacity of the systems suspended from the suspended head end body as well as their own weight.

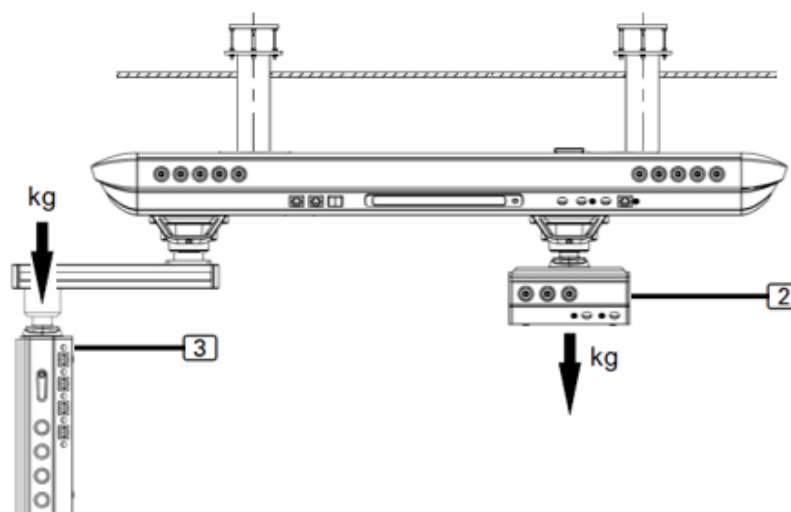


Fig.16 Load application point on service heads

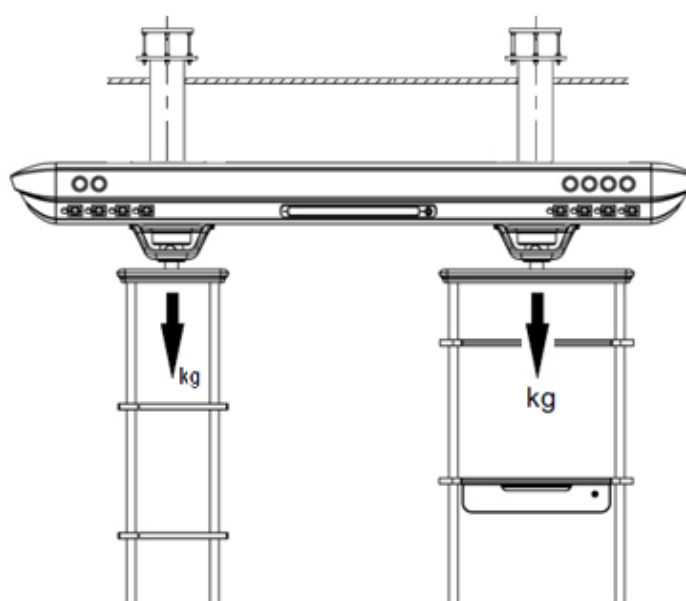


Fig.17 Point of application of the load on trolleys

5.6. Maximum payload capacity

The dead weight of the carousel (extension arm if applicable) and the service head as well as the weight of the trolleys must be subtracted from the maximum load capacity of the suspension system. This value corresponds to the maximum load capacity (payload).



The maximum loads for the system in question are defined in the manufacturing and installation drawings. If any elements are included retrospectively, the calculations must be redone.

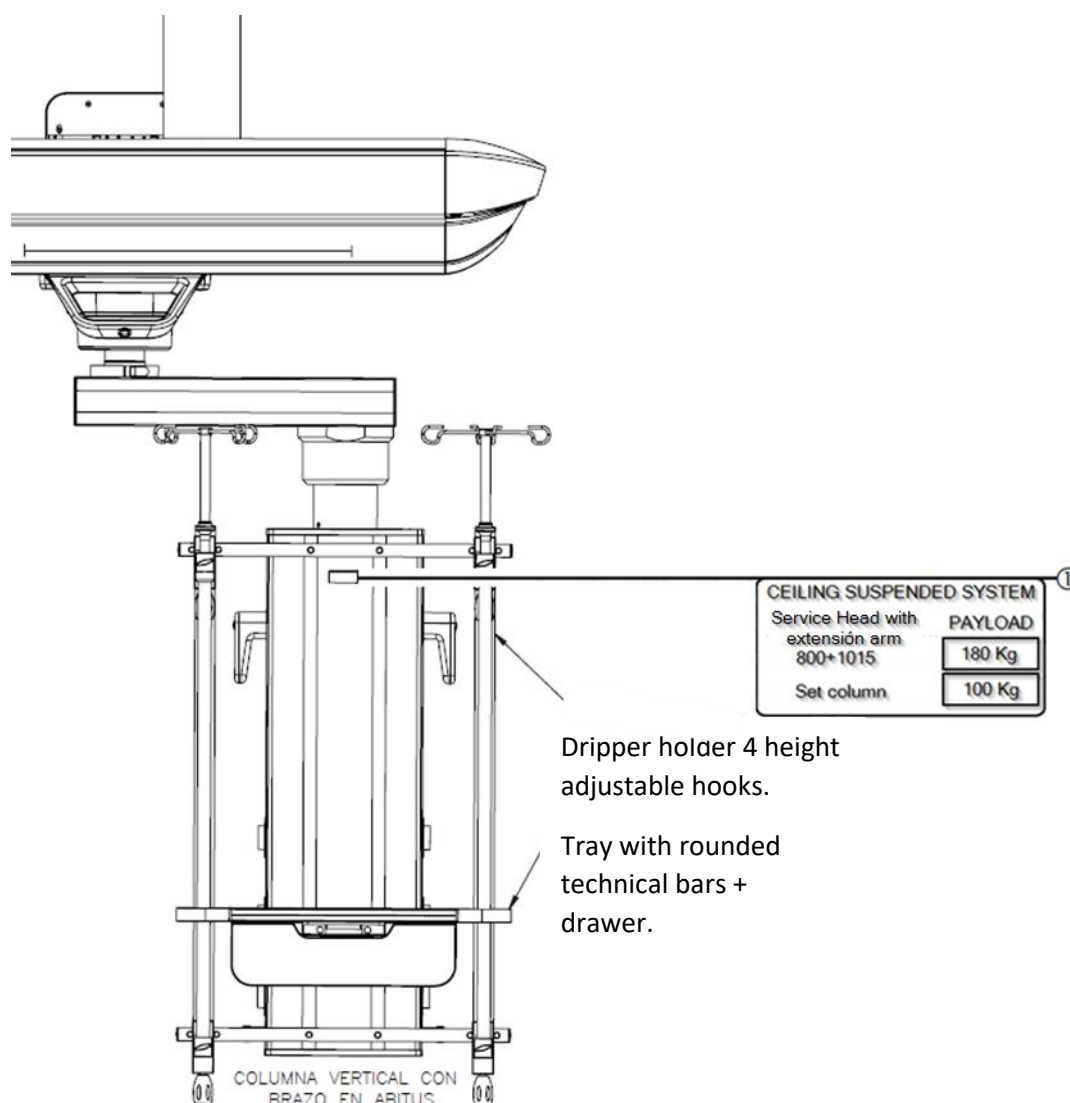


Fig.18 Location of the payload label on a service head

NOTA

Not including own weight of trays and/or drawers or other accessories intended to hold

more items.

In the example illustrated in figure 18, there is an ABITUS assembly with column and extension arm. The maximum payload is 100 kg after subtracting the dead weight of the extension arm and the service head and is indicated on the sticker (1) on the service head. In the case of trolleys, the label is visible on the corresponding trapezoid.



See section 6.3 of this manual

6. Technical data

6.1. Overall dimensions

Below is an ABITUS suspension system with a vertical service head with extension arm, a horizontal service head and a trolley. Please note that the configuration of your hanging system may differ from this illustration. Please consult the manufacturer for special lengths (*).

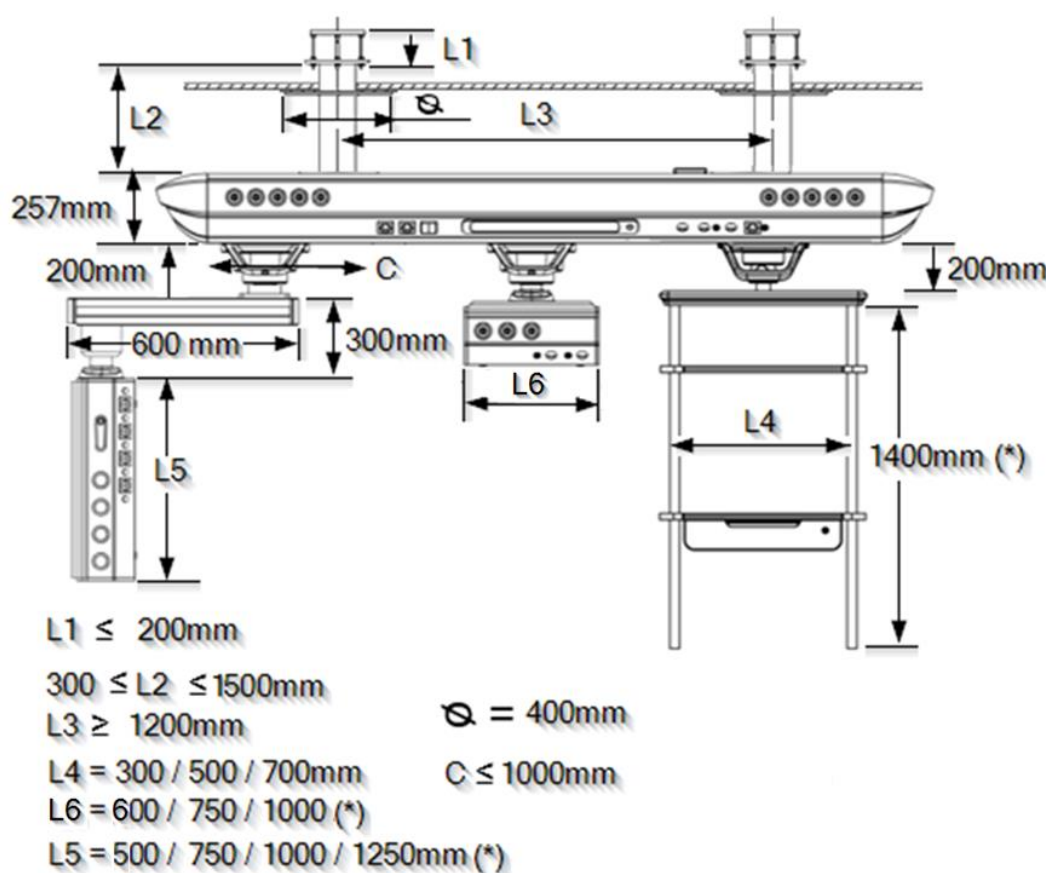


Fig.19 Diagram of ABITUS suspension with various elements

NOTA

(*) Please consult the height possibilities for the element-holding tubes for a specific project.

The extension arm and the drop tube on which the service head rotates 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 330 degrees. With 2 stops installed, the swivel range can be further restricted. The swivel range of these two elements is factory fitted and must be defined for each project. If no restriction is specified, they are configured as shown in figure 20.



See the manufacturing and installation drawing accompanying the equipment.

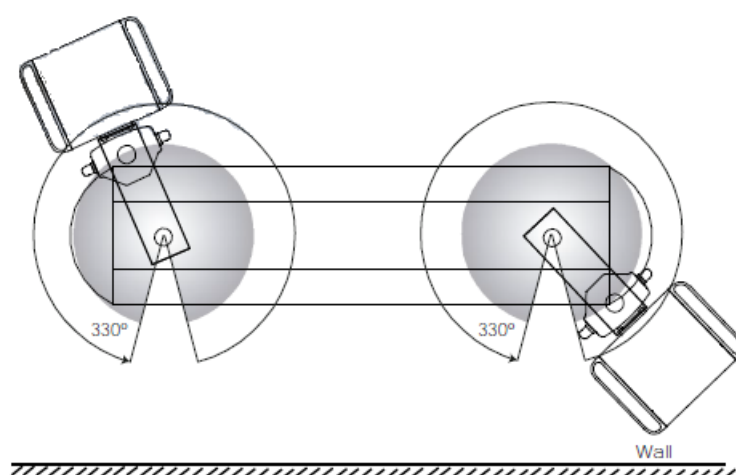


Fig.20 Swivel range for extension arms on an ABITUS section

6.2. Weight of the hanging system

The weight of the system does not include gas hoses, inserted power cables, ceiling plates, drop pipes and optional accessories.

6.2.1. Downpipes

Forged structure.....	12.0kg
Straight section (*)	86.1kg/m
Suspended headboard structure.....	4.0kg



(*) See section 5.4.1.1 of this manual.

6.2.2. Suspended headboard. Main body

End cap (side cover)	3.5kg/Ud
Chassis (span).....	41kg/m



(*) See section 5.4.1.2 of this manual.

6.2.3. Carousel. Extension arm

Carousel	18kg
Carousel with extension arm	33kg

6.2.4. Service head

TDSHV vertical service head (750mm)	18kg
TDSHV vertical service head (1000mm)	21kg
TDSHV vertical service head (1250mm)	25kg
TDSHH horizontal service head (600mm)	18kg

6.2.5. Accessories

Item trolley (trapeze 300mm)	16Kg
Item trolley (trapeze 500mm)	16.5Kg
Item trolley (trapeze 700mm)	17Kg
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
Stainless steel double technical rail set on 38mm diameter tube (L=300mm)	1,2kg
Stainless steel double technical rail set on 38mm diameter tube (L=500mm)	1.5kg
Stainless steel double technical rail set on 38mm diameter tube (L=700mm)	1,8kg

6.3. Load-bearing capacity of the suspension system

Downpipes up to 1500mm	4.500kg
Suspended headboard. Main body.....	600kg
Carousel	220kg
Carousel + Extension Arm 600mm.....	220kg
Vertical service head TDSHV.....	100kg
Horizontal service head TDSHH.....	100kg

Element trolley (trapeze 300mm)	100Kg
Element carrier (trapeze 500mm)	100Kg
Item trolley (trapeze 700mm)	100Kg

Tray on vertical service head	50kg
Drawer in vertical service head	40kg
38mm diameter tube up to 1.4m for attachment of accessories.....	50kg
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

6.4. Electrical data

Rated voltage.....	AC 230V
Nominal frequency	50Hz
Nominal power (2 lighting modules + solenoid valves)	up to 80W

6.5. Noise level

Noise energy level	65db(A) (EN ISO 3746) not exceeded
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6.6. Brakes

Brake torque with pneumatic brake applied	approx. 50Nm
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6.7. Dynamic torque (with brake released)

DYNAMIC TORQUE (with brake released)	3.5 to 40 Nm
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NOTA

Depending on position and payload

7. Intended use

SICS 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.

7.1. Incorrect use

The maximum load bearing capacity of the ceiling pendant system and its components as specified in Chapter 6.3 Load capacity of the suspension system, must not be exceeded.



See point 6.3 of this manual.

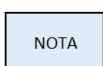
7.2. Contraindications

- The pendant system must not be used close to strong magnetic fields.
- No BF or CF application parts in accordance with IEC 60601-1 may be directly connected to the ceiling pendant system

8. Use of equipment

ABITUS devices are intended for continuous operation. The specifications of the individual functional elements of the equipment must be observed when using the equipment.

- (A) Electrical, voice and data circuits.
- (B) Nurse call
- (C) Lighting
- (D) 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

Ambient temperature: 10°C to 40°C.

Relative humidity: min.30% max.: 75%.

Atmospheric pressure: 700hPa to 1060hPa

Altitude: up to 3,000 m above sea level

8.3. Training

Personnel using ABITUS 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 and manipulations



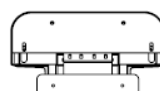
Disconnect the equipment electrically, as well as any equipment supplied through the service head, before making adjustments to prevent live system cables leading to the equipment from coming into contact with live parts of the system.

8.4.1. Adjustment of mechanical brakes

In case of failure of the pneumatic (compressed air operated) brakes, additional mechanical brakes (friction brakes) keep the extension arm and/or the service head stable. Adjust the braking force in



Mechanical brake



such a way that the extension arm and/or the service head remain stable in any position and can still be adjusted conveniently.

Fig.21 Adjustment of the friction brakes on service heads

Be sure to tighten the brake screws at the carousel more than at the pivot point of the service head. This facilitates the correct positioning of the service head in relation to the new position of the extension arm.

8.4.1.1 Adjustment of the swing brakes

1. To increase the braking force, turn the brake lever evenly to the right (clockwise).
2. To reduce the braking force, turn the brake lever evenly to the left (counterclockwise).
3. Carrying out a test run

8.4.1.2 Adjustment of the travel brake

1. Locate the cover on the bottom of the travel brake actuator and remove it using a flat-bladed tool such as a screwdriver. Picture on the left in figure 22.

This is a locknut system, each nut is loosened to the opposite side. The upper nut is loosened to the left and the lower nut is loosened to the right. the knob remains loose.

2. Loosen the two nuts as shown in the picture on the right in figure 22.

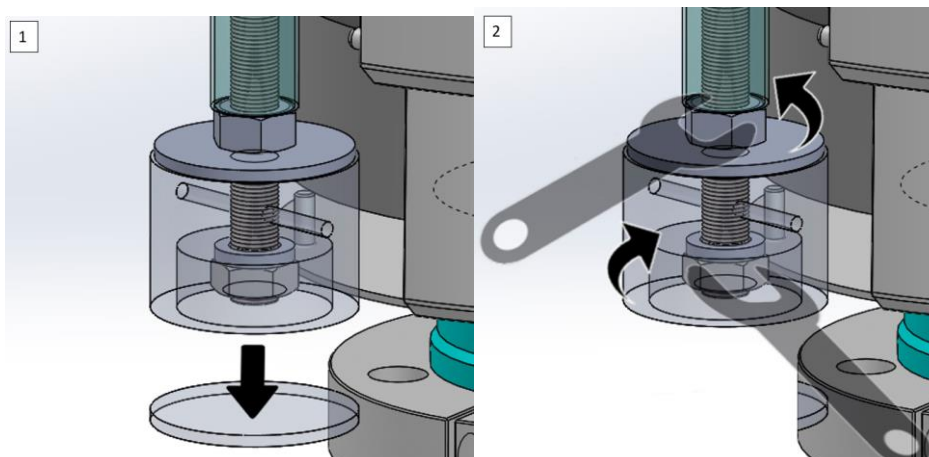


Fig.22 Adjusting the travel brake. Loosen elements and position

3. lower the knob minimally to get more bar travel, as shown in the picture on the left in figure 23, so you will have more friction and the brake will slow down. If, on the other hand, you want less resistance to travel, you will need to leave less bar travel.
4. Tighten each of the nuts until the system is fixed as shown in the picture on the right in figure 23. The upper nut tightened clockwise and the lower nut counterclockwise.

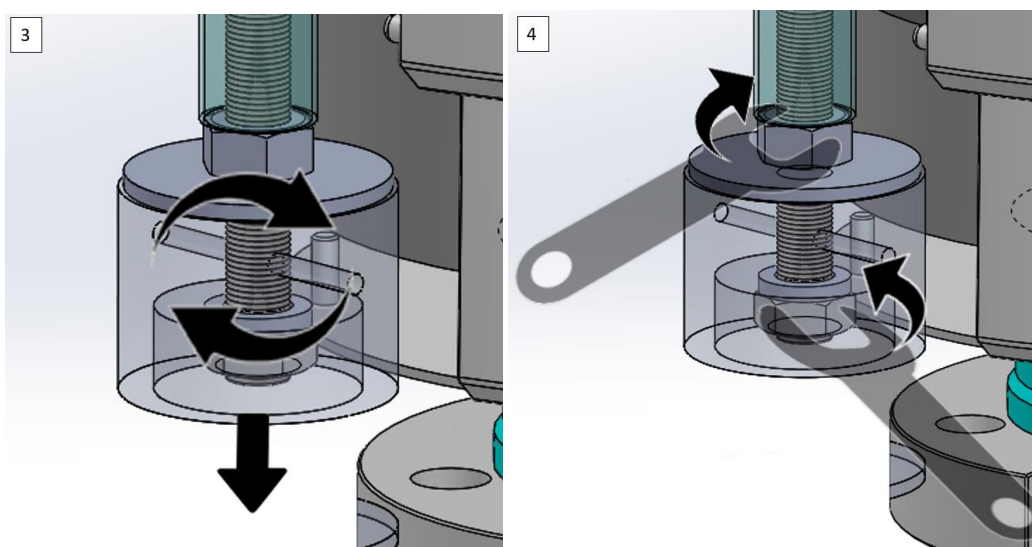


Fig.23 Adjustment of the travel brake. Adjustment.

5. Replace the knob cover to close the system as shown in figure 24.

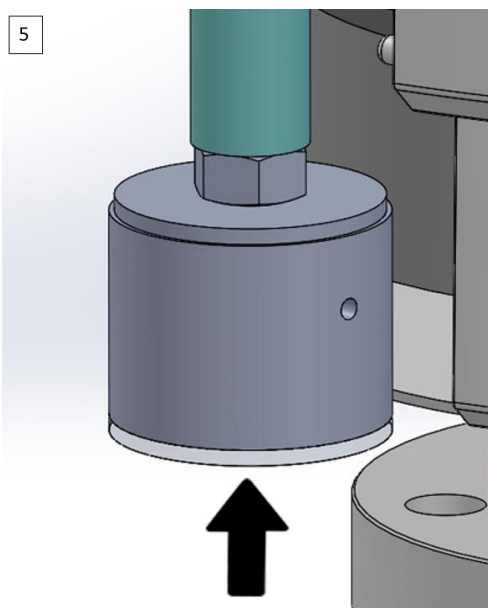


Fig.24 Adjusting the travel brake. Close the cover.

8.4.2. Adjustment of limit switches for carousels and carriages

The carousels and carriages of ABITUS 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 in order to ensure that these elements do not conflict with the patient and operator space. These elements are pre-installed in the factory, but must be moved to the desired position.

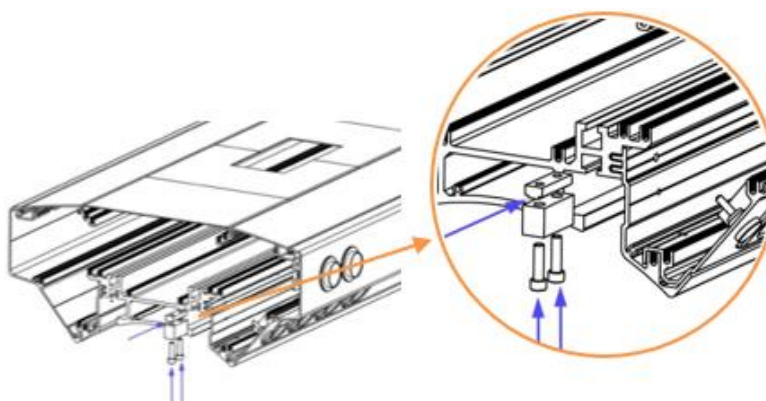


Fig.25 Adjusting the travel limit switches.



The socket head cap screws M8 - DIN EN ISO 10642 must be tightened to 40 Nm.



NOTICE: The total stroke of a carousel may not exceed 1m in length, otherwise the electrical, gas and/or voice and data hoses may be overstretched.

8.4.3. Mechanical brake release for trolleys for element carriers

The mechanical brakes for ABITUS equipment carriages are set at the factory. These brakes block both the travel movement of the carriages on the main body guides and the rotation around their trapeze axis with the element carrier tubes.

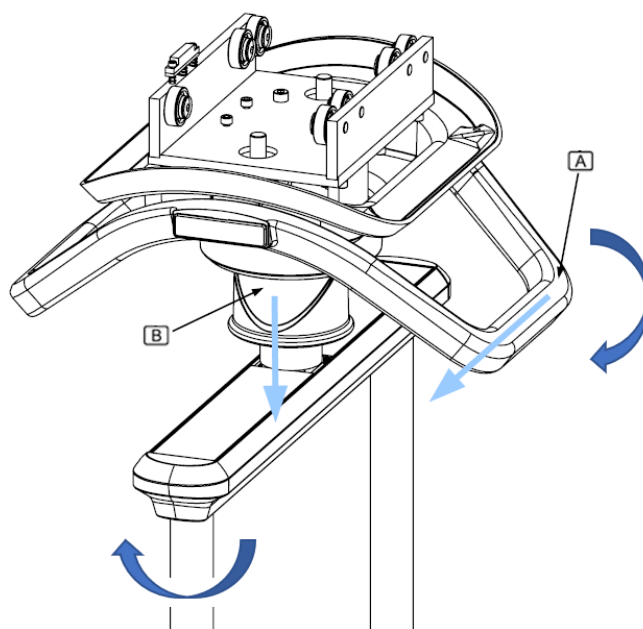


Fig.26 Carriage brake release actuators for ABITUS

- To move the trolley to another position within the main body section of the ABITUS, pull the handle (A) downwards to release the travel brake of the unit and, without releasing it, move the trolley to the desired position. Once in the desired position, release the handle (A) and the travel brake will lock again and the trolley will remain fixed in that position.
- To rotate the trolley trapezoid on its axis, pull down on the handle (B) and with the other hand grab one of the structural tubes to rotate the structure. Once the system is in the desired position, release the handle (B) and the rotation brake will lock again, leaving the trolley trapezoid fixed in that position.

8.4.4. Pneumatic brake release for carousel

The pneumatic brakes for the ABITUS carousels are factory set. These brakes stop the carousels from moving on the guides of the main body as well as the rotation of the extension arm and/or the service head around its axis.

For those configurations with an extension arm, actuator A releases the travel brake. Actuator B releases the pivot brake at the two pivot points, leaving the arm free, the rotation of the arm is limited only by the pivot stops. See figure 27.

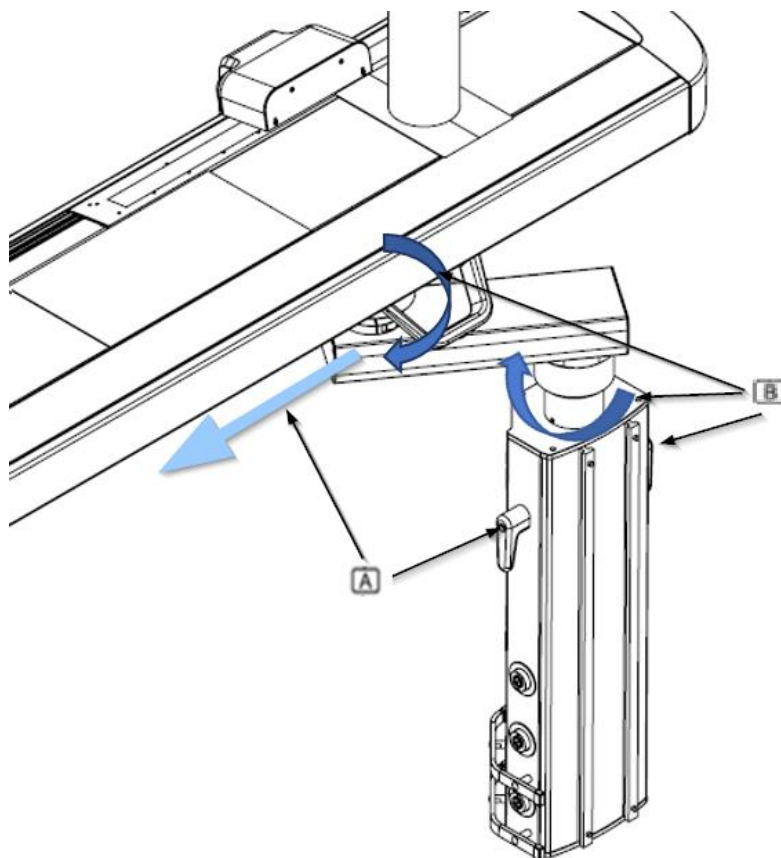


Fig.27 Unlocking the pivoting and traversing brakes of the ABITUS column brackets with arm

For configurations without an extension arm, only drive (A) is enabled and when actuated, both the travel brake and the rotation brake are released simultaneously as shown in figure 28.

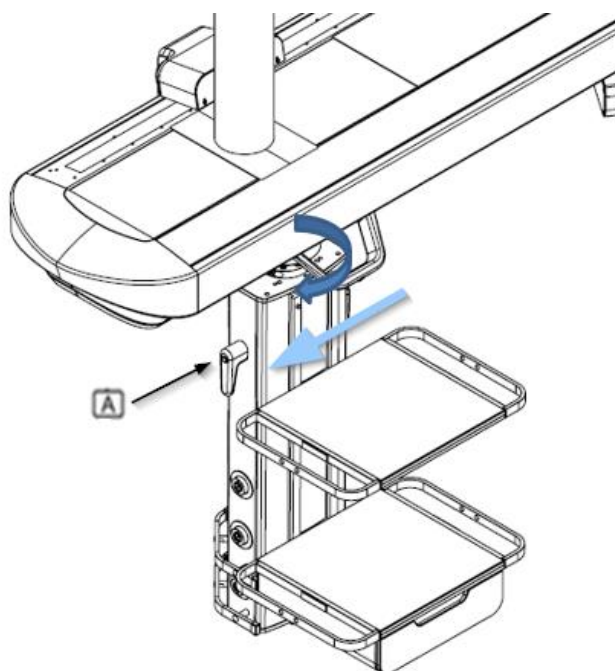


Fig.28 Unlocking the swing and travel brakes of ABITUS armless columns

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 adaptations, 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.

NOTA

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 involving 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 measurements	Compliance	Comment

HF emissions according to CISPR 11 standard	Group 1	The supply unit uses HF energy exclusively for its internal OPERATION. Therefore, its HF emissions are minimal and interference with devices in its vicinity is unlikely.
HF emissions according to CISPR 11 standard	Class A	<p>The roof supply unit is suitable for use in non-domestic installations and in installations that are directly connected to the PUBLIC SUPPLY NETWORK, which also supplies residential buildings.</p> <div> <div>NOTA</div> <p>The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential ENVIRONMENT (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment</p> </div>
Harmonic emissions according to the standard IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/transients according to the standard IEC 61000-3-3	In accordance with	

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

Voltage dips and fluctuations of the supply voltage according to the standard IEC 61000-4- 11	100% of U_N drop for 0.5 period 100% of U_N drop for 1 period 30% of U_N drop for 25 periods Remark: U_N is the AC mains voltage before applying the test level.	100% U_N drop for 0.5 period 100% of U_N drop for 1 period 30% of U_N drop for 25 periods	The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the roof supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the roof supply unit from a device with an uninterruptible power supply or a battery.
Short interruptions of the supply voltage in accordance with the standard IEC 61000-4- 11	100% for 5 s Remark: U_N is the AC mains voltage before applying the test level.		The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the roof supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the roof supply unit from a device with an uninterruptible power supply or a battery.
Magnetic field for power supply frequencies (50/60 Hz) according to the standard IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields created by the mains frequency should be those of a commercial or hospital environment.

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

Transmitter power rating	Safety distance depending on emission frequency Environment/Guidelines (m)		
	150 kHz to 80 MHz $D = 1,2 P$	80 MHz up to 800 MHz $D = 1,2 P$	800 MHz up to 2.5 GHz $D = 2, 3 P$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23



WARNING: stacking the device or installing the device close to other equipment may affect to the performance of the systems due to EMI disturbances.