tediselmedical

ABITUS

MAINTENANCE MANUAL

CE 0197

tediselmedical.com

Content

1. Manufacturer

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2. Security information

Important notes in these operating instructions are marked with graphic symbols and signal words.

2.1. Injury risk warnings

Signal words such as DANGER, WARNING or CAUTION describe the degree of risk of injury. The different triangular symbols visually emphasise the degree of danger.

	WARNING	Refers to a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	CAUTION	Refers to a potential hazard which, if not avoided, may result in minor or slight injury.
	DANGER	Refers to an immediate danger which, if not avoided, will result in death or serious injury.
		Risk of finger entrapment

2.2. Warnings of risk of damage

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

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

NOTICE

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

2.3. Additional symbols used in the safety instructions

Fire hazard

Explosion hazard: warns of ignition of explosive gas mixtures.

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

Failure of the roof support system

Risk of collision

2.4. Indication of additional information

NOTA

A NOTE provides additional information and useful tips for safe and efficient use of the device.

2.5. Proper use of oxygen.

2.5.1. Oxygen explosion

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

Compressed oxygen presents an explosion hazard:

- Make sure that oxygen and gas outlets are free of oil, greasy materials and lubricants!

- Do not use cleaning agents containing oil, grease or lubricants.

2.5.2. fire hazard

DANGER: Escaping oxygen is combustible:

- Open fire, red-hot objects and open light are not allowed when working.

with oxygen!

- Don't smoke!

2.6. Patient environment

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

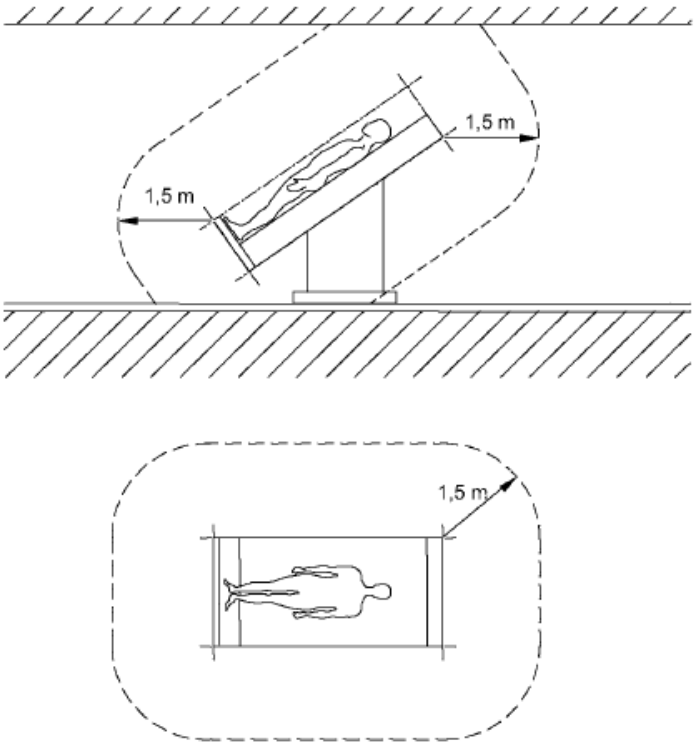

Fig. 1 Minimum extent of the PATIENT ENVIRONMENT

2.7. Combination with products from other manufacturers.

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

See point 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. Fire risk

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

3.4. Danger of electric shock

Signal cables (network, audio, video, etc.) must be electrically isolated from equipment and building connection ends to prevent contact with currents that can cause serious injury or death.

4. Symbols used

Applicable part B

Earth (mass)

Equipotentiality

Protective earth (ground)

Connection point for neutral conductor

Nurse call button

Direct lighting

Indirect lighting

Operating instructions

Health Product

Waste electrical equipment

CE 0197	CE symbol
REF	Product code
UDI	Unique identification code
SN	Serial number
	Manufacturer
	Date of manufacture
	Reference to the instruction manual
	Damage to surfaces
	Fire hazard
	Danger of explosion
	Dangerous tension
	Notice

	NOTICE	
		Risk of finger entrapment
	WARNING	Warning
	CAUTION	Caution
	DANGER	Danger

5. Product data

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

5.1. Storage conditions

The individual packaging of this type of product consists of a bubble wrap on the inside and a cardboard box on the outside. Non-stackable packaging.

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

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

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

Recommended humidity range: 10 % to 75 %.

Atmospheric pressure: 500 hPa to 1,060 hPa

5.2. Operating conditions

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

Recommended temperature range: -10 °C to 40 °C

Recommended humidity range: 30 % to 75 %.

Atmospheric pressure: 700 hPa to 1,060 hPa

5.3. Service life

The service life of the SICS family of products is determined by the service life of the medical gas intakes it incorporates, which is 8 years.

5.4. Purpose of the product

These systems have three main distinct functions within the hospital:

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

They consist of a chassis made of aluminium profiles, which integrates the electrical equipment, call, voice and data systems, and installation and channelling of medical gas outlets.

6. Maintenance

Re-inspection shall be carried out in accordance with EN 62353.

6.1. Training

The personnel doing the MAINTENANCE must be properly trained and qualified by the customer. Persons who:

1. have been instructed in the maintenance of this device by means of this instruction manual as a basis.

2. are able to assess the tasks they perform on the basis of their own professional experience and training in relevant safety standards and can recognise the potential hazards involved in the work.

6.2. Previous actions

- Disconnect all poles of the pendant system and the Service Head from the mains and prevent reconnection.
- Ensure that all devices connected via the service header are de-energised.
- Wait until the terminal device (e.g. high frequency surgical device, flat panel display, etc.) has cooled down.

The necessary maintenance work must be carried out as specified in the inspection plan in this manual.

NOTA

Built-in components from third party manufacturers must be inspected and maintained as prescribed in the corresponding Operating Instructions.

6.3. Disassembly and assembly of covers

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

NOTA

In the case of equipment fitted with service heads, these are already mounted on the main body.

6.3.1. Disassembly and assembly of upper decks

- Using a flat-nosed tool and taking care not to damage the paint on the top covers, remove the bottom covers of the downpipes ①, these are press-fitted. See figure 1.
- Now remove the upper covers of the main body ② which are also snapped on by hand. See figure 1.

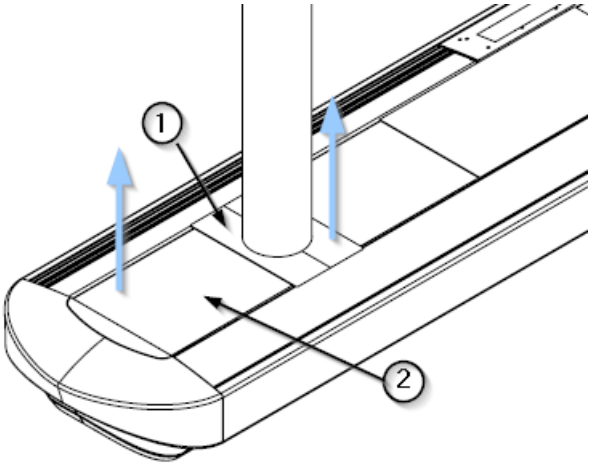

Fig. 2 Removal of main body covers

- To reassemble these covers, carry out the above steps in reverse order.
- First attach the top covers ②. You will hear a sound when the clipping is done. Check that the covers are securely fastened.
- Then fit the lower downpipe covers ① and press them in until you hear them click into place. Check that they are properly secured.

6.3.2. Disassembly and assembly of side walls

- Remove the top cover from the main body as described in section 6.5.1 of this manual.

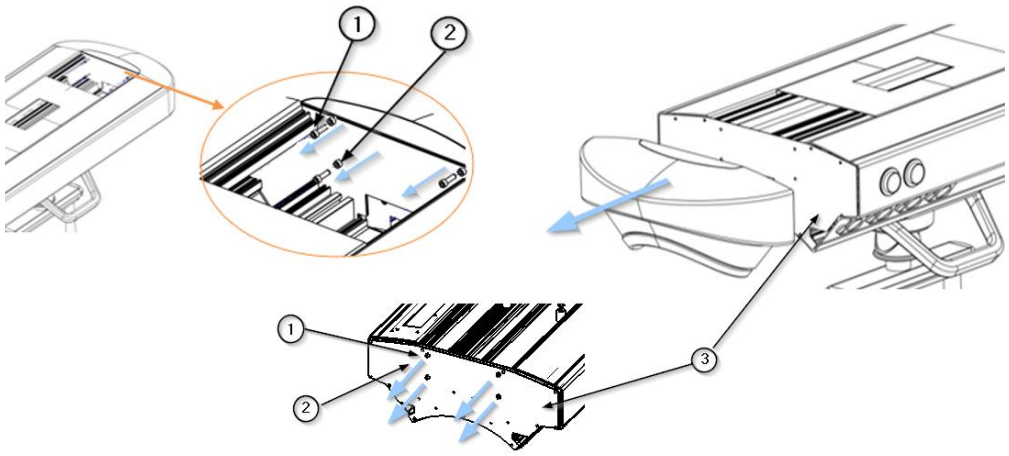

Fig. 3 Disassembly/assembly of end caps on ABITUS main body

- Using a hexagonal tool, remove the 4 M6 x 25 screws ① and the 4 corresponding washers DIN 9021 ② as shown in figure 2.
- Carefully remove the side panel and place it in a safe place.
- The end cap bracket ③ is now visible. Remove it by removing the 4 M6 x 25 screws ① and the 4 corresponding washers DIN 9021 ② using the same tool as shown in figure 2.
- To reassemble the end caps, carry out the above steps in reverse order.
- First attach the end bracket ③ and secure it with 4 M6 x 25 screws ① and 4 corresponding washers DIN 9021 ②.
- Then place the end cap in position and secure it with 4 M6 x 25 screws ① and 4 corresponding washers DIN 9021 ②.

6.3.3. Removal of trims on the carousels

To gain access to the extension arm pivot adjustment screws, the rear trims of the carousel must be removed.

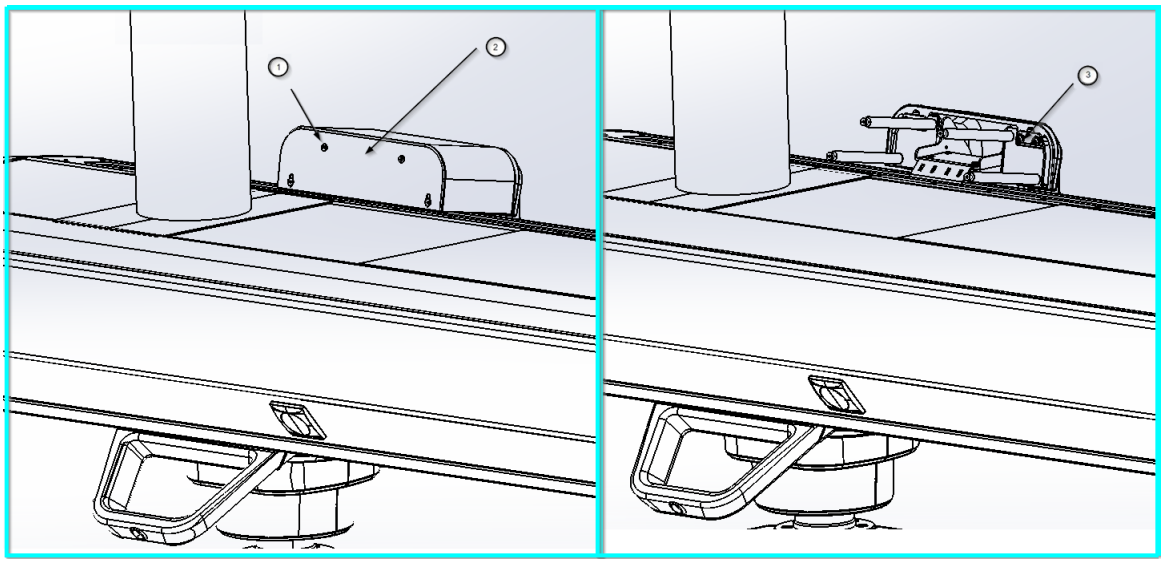

Fig.4 Removal of the top trim

- Unscrew the fixing screws ① holding the upper trim ② as shown on the left in figure 3.
- Remove the top trim ②
- Unscrew the Allen fixing screws ③ from the top of the rear trim ④ as shown on the right in figure 4.
- Unscrew the Allen screws ⑥ securing the trim plates ⑦ and the Allen screws securing the lower part of the rear trim as shown in figure 4.
- Remove the rear trim ④.

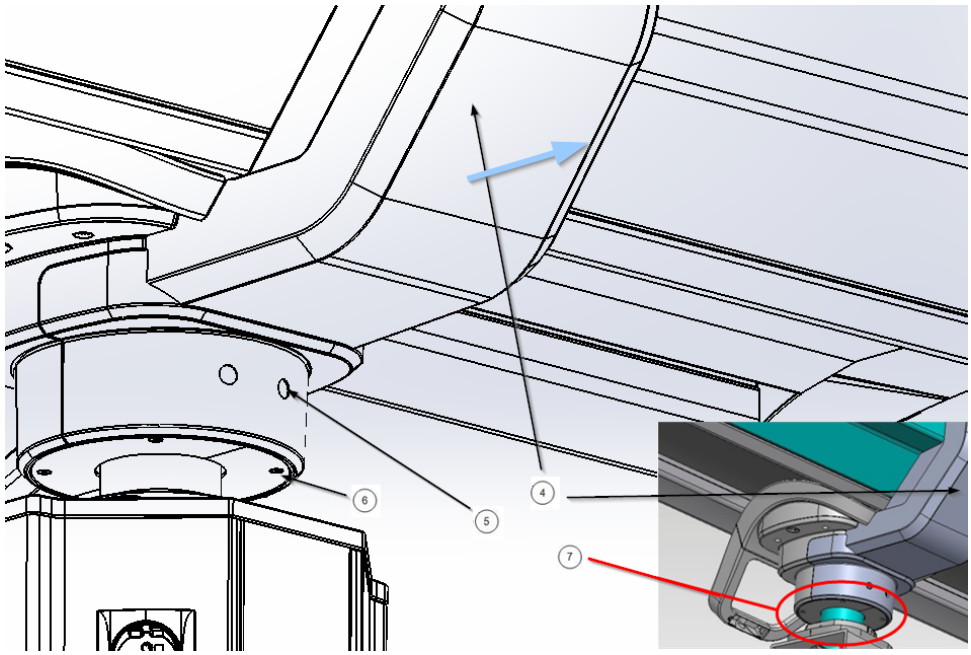

Fig.5 Rear trim removal

6.3.4. Opening of the side covers of a service head.

To carry out the operations described in sections 6.4 and 6.5 of this manual, you will need to fold down the service head covers.

- Open the side covers of the service head ① by removing the M4x16 socket head cap screws ④ at the top and bottom. The side cover can now be opened as shown in figure 5, revealing the inside of the service head.

Fold down the cover of the enclosure with the help of a plastic suction cup ②.

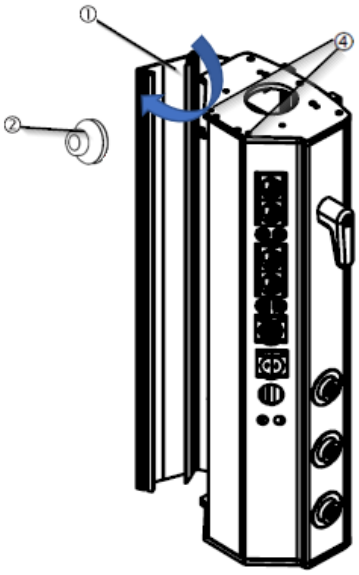

Fig. 6 Opening the sides of a service head

The figure illustrates a vertical service head, the most common, for the horizontal service head the procedure is identical.

6.4. Replacement of LED strips and controllers in indirect lighting

If the indirect light module of the ABITUS system malfunctions, both the LED strips ⑤ and the drivers ⑦ must be replaced.

Disconnect the equipment electrically before replacement.

- Unscrew the 4 M6 x 16 countersunk screws ②DIN 935 using an Allen tool as shown in figure 6.
- Remove the polycarbonate cover ① and store it in a safe place. The lighting module is visible.

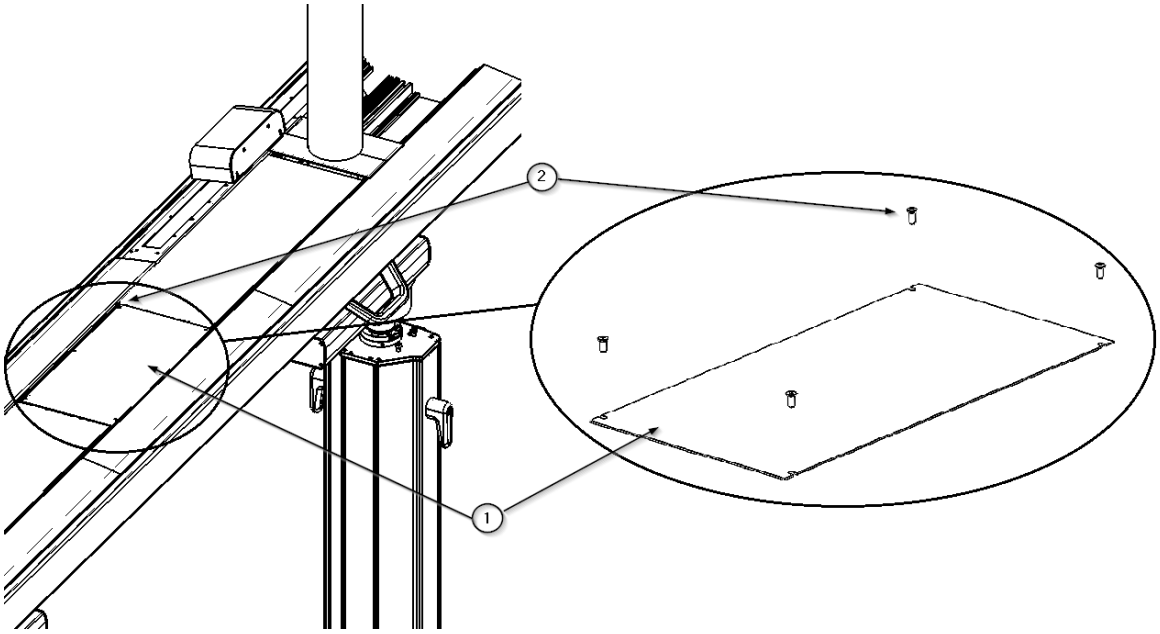

Fig. 7 Removing the polycarbonate diffuser

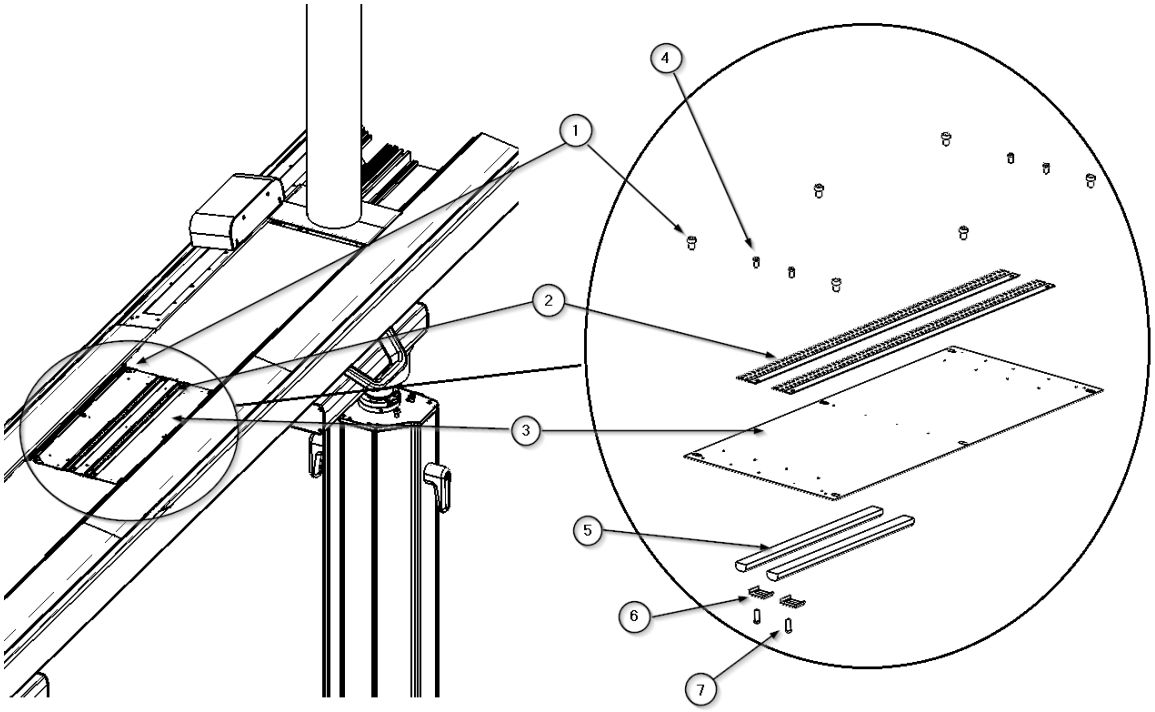

Fig. 8 Replacing indirect light

- Remove the 4 M6 x 10 socket head cap screws ① DIN 912 using an Allen tool. The bracket for the lighting module ③ is now loose.
- Disconnect the quick connector from the LED strips ②. The module can now be turned over and the controllers ⑤ and their terminal strip can be seen.
- Disconnect the power supply to the controllers ⑤ from the terminal strip.

- Unscrew the M4 x16 hex screws ⑦ DIN 933 by releasing the tabs ⑥ holding the controllers ⑤.
- Fit the new controllers ⑤ and secure them with the tabs ⑥ by screwing in the hexagonal screws ⑦.
- Connect the power supply of the controllers back to the terminal strip.
- Unscrew the M4 x10 hex screws ④ DIN 933 releasing the LED strips ②.
- Fit the new LED strips ② and secure them with the hexagonal screws ④.
- Connect the power supply cable of the newly installed LED strips ②.
- Reattach the module holder ③ using an Allen tool by screwing in the 4 M6 x 10 socket head cap screws ① DIN 912. Check that the lighting module is fixed in position.
- Power up the lighting circuit and perform a test run to check that the lighting module switches on and off.

Contact with live parts can cause an electric shock.

- Replace the polycarbonate cover ① and screw in the 4 M6 x 16 countersunk screws ② DIN 935 as shown in figure 7.

6.5. Replacement of LED strips and controllers in direct illumination

If the direct light module of the ABITUS system malfunctions, both the LED strips ⑤ and the drivers ② must be replaced.

Disconnect the equipment electrically before replacement.

- Remove the top covers as described in section 6.3.1 of this manual. The lighting module, the controllers ② and their terminal strip are visible.

See section 6.3.1 of this manual.

- Disconnect the power supply of the controller ② from the terminal strip.
- Unscrew the 2 cylinder screws M6 x 12 ① DIN 912 and release the lighting module. The LED strip ⑤ and its quick connector are visible. See figure 8.

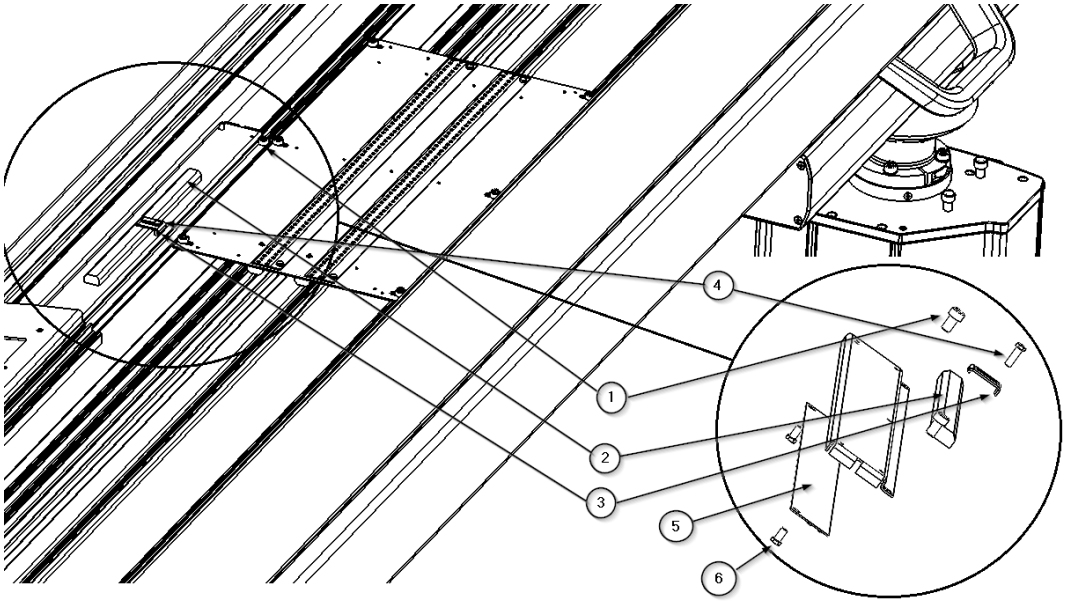

Fig.9 Substitution of direct light

- Disconnect the quick connector from the LED strip ⑤.
- Unscrew the M4 x10 hex screws ⑥ DIN 933 releasing the LED strip ⑤.
- Fit the new LED strip ⑤ and secure it with the hexagonal screws ⑥.
- Connect the quick connector of the LED strip ⑤.
- Unscrew the M4 x16 hex screw ④ DIN 933 releasing the tab ③ holding the controller ②.
- Fit the new controller ② and secure it with the tab ③ by screwing in the hexagonal screw ④.
- Re-attach the module by screwing in the 2 M4 x 8 hex screws ① DIN 7500. Check that the lighting module is fixed in position.
- Connect the power supply of the controller ② back to the terminal strip.
- Power up the lighting circuit and perform a test run to check that the lighting module switches on and off.

Contact with live parts can cause an electric shock.

- If it was necessary to remove the indirect light module, refit and reconnect it as described in point 6.4 of this manual.

See section 6.4 of this manual

- Replace the top covers as described in section 6.3.1 of this manual.

See section 6.3.1 of this manual.

6.6. Structural and movement check

A complete inspection of the entire suspension system shall be carried out, adjusting all parameters that deviate from those initially foreseen.

- Carry out a visual inspection to detect if any item is not properly fixed and there are no deformed or damaged items.
- Check the pivot stops on each pivot point.
- Check that the limit switches for the carousels or carriages of the system are properly secured.
- Check that the air brakes function correctly, i.e. that they release when the corresponding push buttons are operated.
- Check that the extension arms, if any, can be comfortably brought into the desired position.
- Check that the gas hoses are not kinked or kinked, if necessary, release and reconnect them without tension and check the system's swivel stops to ensure that they are not re-tensioned / kinked.
- Adjust, if necessary, the friction brakes of the individual pivot points.

6.6.1. Adjustment of the rotary stops

The extension arm and the drop tube on which the service head rotates are equipped with at least 1 ball stop that prevents the internal cables from being destroyed. With 1 ball stop installed, the swivel range is restricted to a maximum of 330 degrees. With 2 ball 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 9.

See the manufacturing and installation drawing accompanying the equipment.

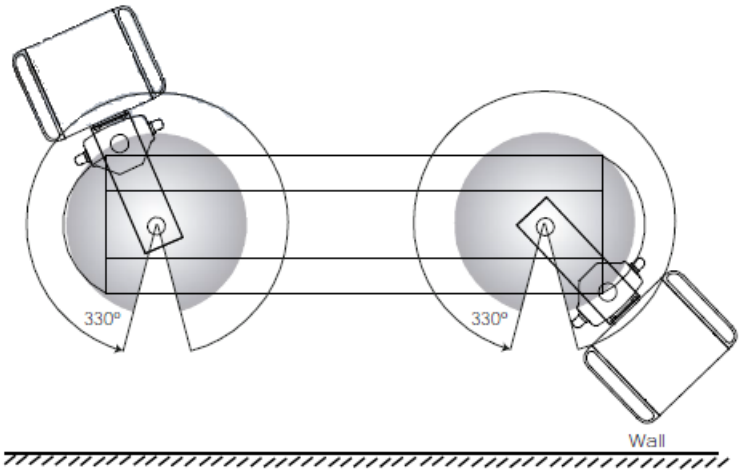

Fig.10 Swivel range for extension arms on an ABITUS section

- Remove the carousel trims as described in section 6.3.3 of this manual.
- Once the rear trim has been removed, the steps (1) for adjusting the carousel swivel angle limited by the Allen screws (2) are visible. The following figure shows the rotation of a column with extension arm, the case for a column without extension arm is identical.

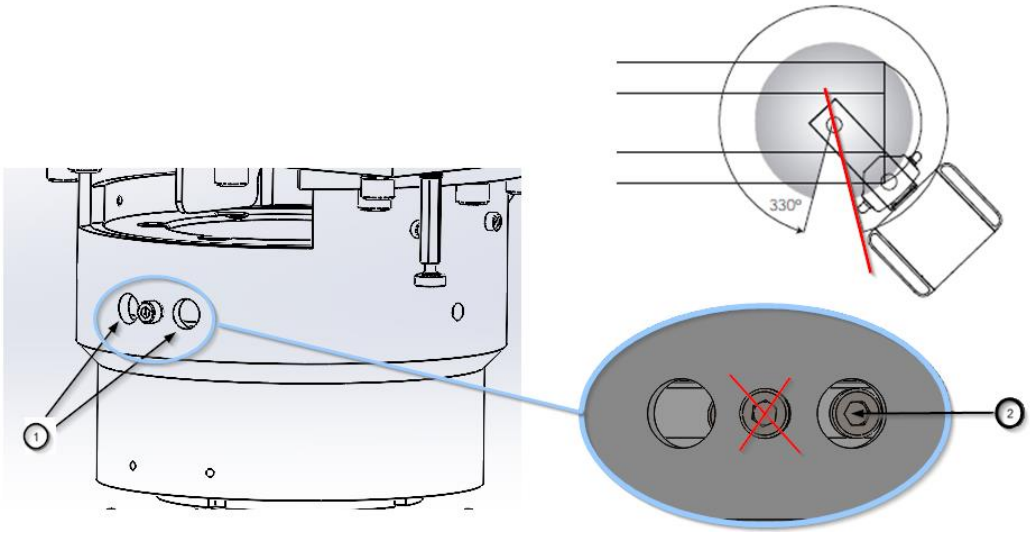

Fig.11 Schematic diagram of rotation control

Do not unscrew the central Allen screw (marked with a red cross in figure 4), otherwise the carousel will rotate freely and the rotation can no longer be limited.

- To adjust the right-hand pivot stop on the column, move the column to its maximum position as shown in the upper right-hand side of figure 10.

The stop socket head cap screw (2) will then appear as shown in the lower part of figure 4 (detail at the bottom right of the figure).

- Unscrew and remove the Allen screw (2).

As long as the Allen screw (2) is not in place, the extension arm rotates freely.

- Bring the column to the desired new maximum position giving sufficient clearance (the space of a fist) as shown in figure 11.

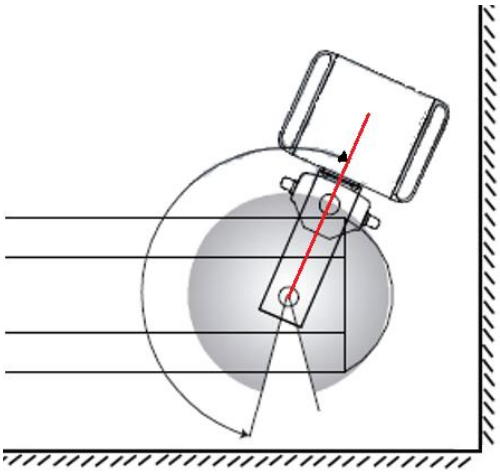

Fig.12 Fixing the right-hand pivot stop of a column with extension arm.

- Insert the Allen screw (2) and screw it back in. The right-hand pivot stop of the column is now complete.

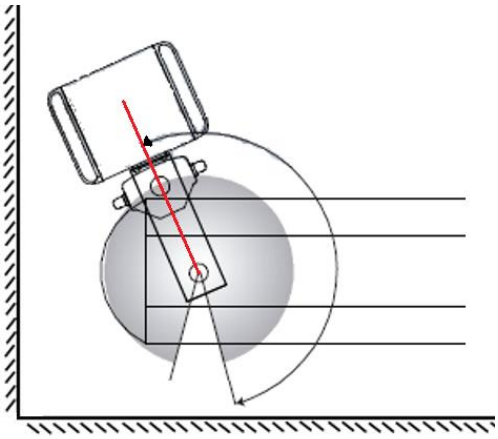

Fig.13 Fixing the left pivot stop of a column with extension arm.

- If necessary, adjust the left-hand rotation. To do this, follow the steps indicated in this point, bearing in mind that to set the left-hand stop you must bring the column to the maximum desired position for the left-hand turn and then fit the Allen screw (2) previously removed as shown in figure 12.
- Refit the rear trim and the upper carousel trim.

6.6.2. 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 at the factory, but must be moved to the desired position. See figure 13 and 14.

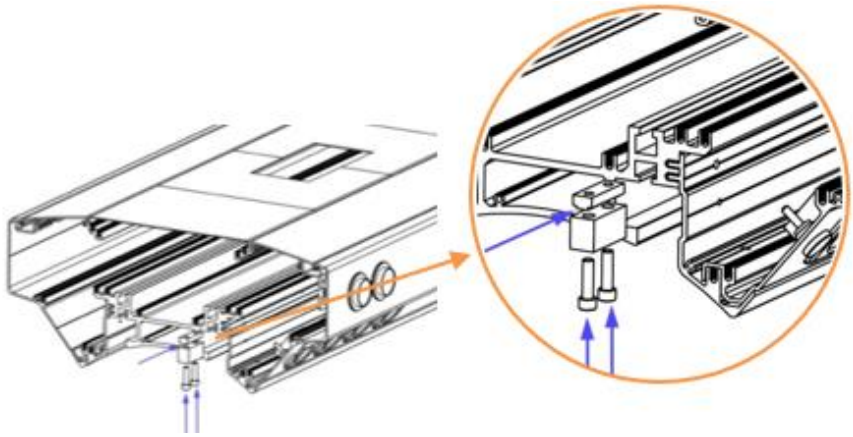

Fig.14 Adjusting the travel limit switches.

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

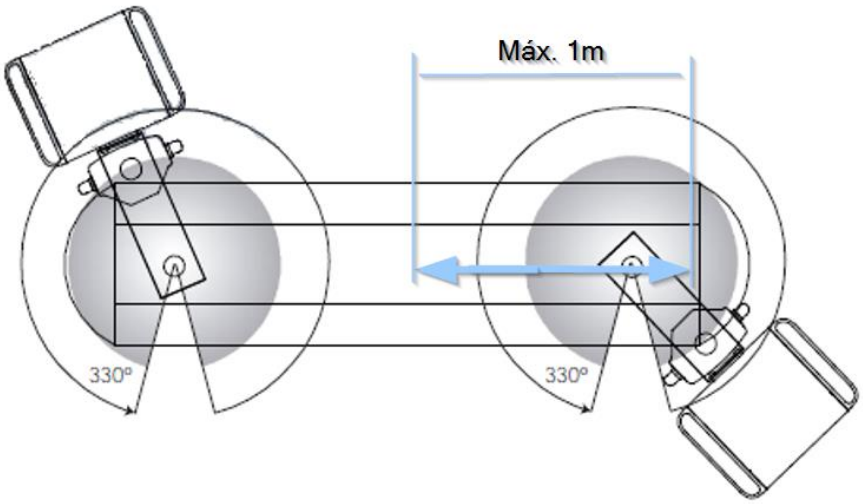

Fig.15 Adjusting the travel limit switches. Maximum stroke

6.6.3. 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.

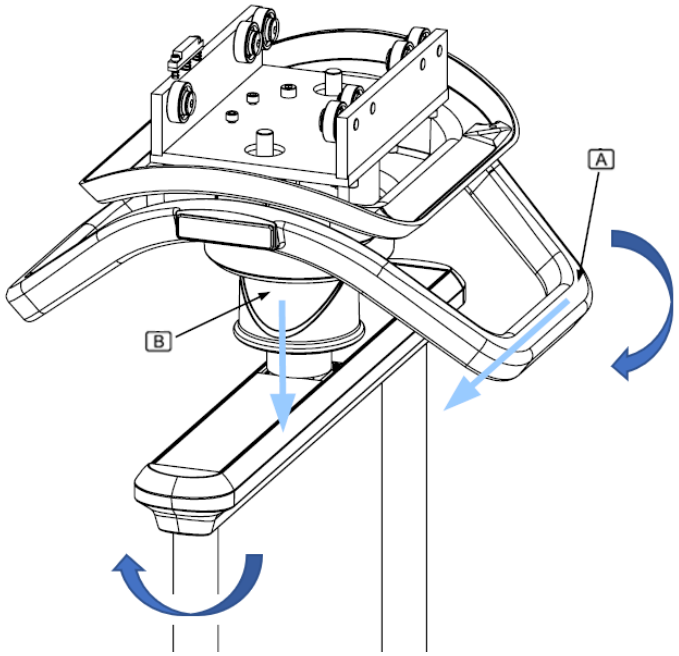

Fig.16 Carriage brake release actuators for ABITUS

- 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.

6.6.4. Pneumatic brake release for carousels

The pneumatic brakes for the carousels of ABITUS equipment 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 16.

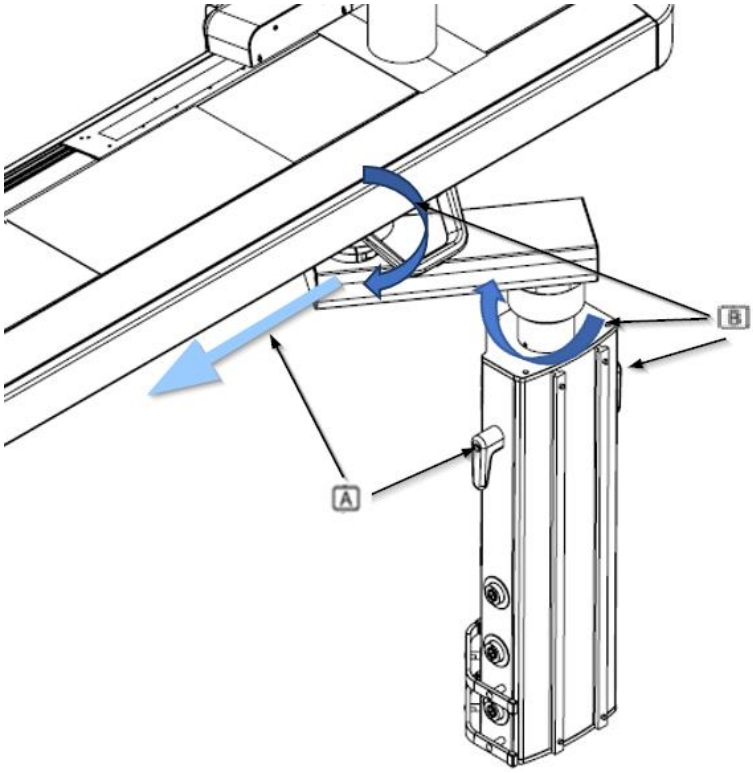

Fig.17 Unlocking the pivoting and traversing brakes of the ABITUS column-mounted traversing columns

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 17.

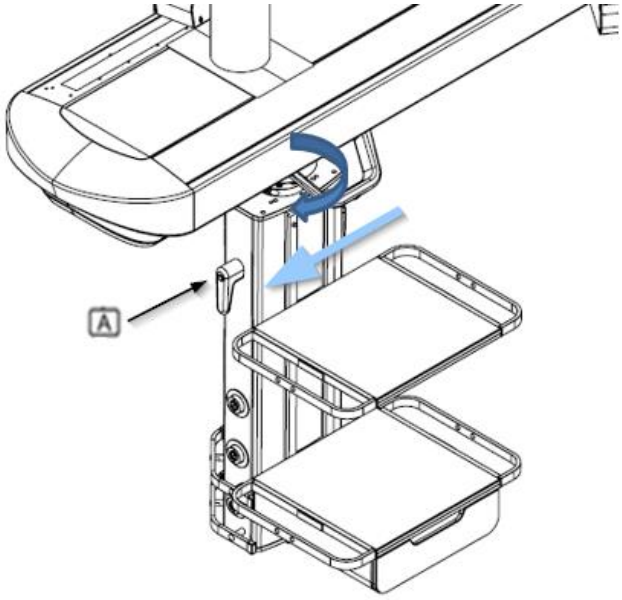

Fig.18 Unlocking the swing and travel brakes of ABITUS armless columns

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 and damaged.

6.7. Procedure for Inspection and Replacement of Flexible Hoses for Medical Gases

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

Passage	Description	Periodicity	Tools/Supplies needed
1	**Detailed Visual Inspection**: A.1) Open the service head by following the steps specified in *paragraph 6.2.1 Opening the side covers of a previously specified service head.*  A.2) Open the main body top cover following the steps specified in *6.3.1 Disassembly and assembly of top covers* (if applicable).  B) Observe every inch of the flexible hoses, paying attention to signs of discolouration, hardening, cracking, bulging or general wear and tear. C) Also inspect the area where the hoses connect to other components for signs of wear at the joints.	Annual	Torch or spotlight, protective gloves
2	**Clamp Verification**: A) Examine all rim clamps for signs of rust, wear or deformation. B) Check that the clamps are firmly holding the hoses and that there is no slippage.	Annual	Torch or spotlight
3	**Connection Check**: A) Inspect each hose connection at the grooved nipple and at the tee.	Annual	Protective gloves

	B) Make sure that the connections are tight, with no looseness. C) Feel the connections to confirm that there is no slippage or unnecessary movement.		
4	**Leak Detection:** A) Prepare a soap solution in a container. B) Using a brush, apply the solution to the hose connections. C) Observe if bubbles form, indicating the presence of a leak. D) If a leak is detected, mark the area for later correction.	Biannual	Soap solution, brush or paintbrush
5	**Hose replacement**	Every 8 years	-
5.1	**Hose Replacement** See section *6.7.1 Replacement of flexible hoses for medical gases.* 	-	Spare hose, adjusting tools, new clamps
5.2	**Post-Substitution Test** See section *6.7.1 Replacement of flexible hoses for medical gases.* 	-	Soap solution, brush or paintbrush
6	**Maintenance Register**: A) After each inspection or intervention, record in a document or management system all details, such as date, findings, actions taken, name of technician, and parts replaced. B) Keep this record organised and accessible for future reference and audits.	Always	Maintenance log

Additional note: Be sure to follow all relevant safety regulations and recommendations. It is essential that personnel involved in these tasks are properly trained and wear personal protective equipment.

6.7.1. Replacement of flexible hoses for medical gases

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

The gas hoses are pre-assembled on the Service Head and on the Main Body of the Equipment, if applicable. They must be replaced every 8 years in order to guarantee the correct operation of the equipment.

- Shut off the power supply and the medical gas supply to the equipment.
- Open the top covers as shown in section 6.3 of this manual.

Release the connections of the hoses to be replaced both at the source (interface plate) and at the terminal unit inside the service head, or body of the equipment.

If we focus on the Service Head. To do this, open the side covers of the service head as described in point 6.3.4 of this manual.

See section 6.3.1 and 6.3.4 of this manual.

To work more comfortably, remove the service head as follows:

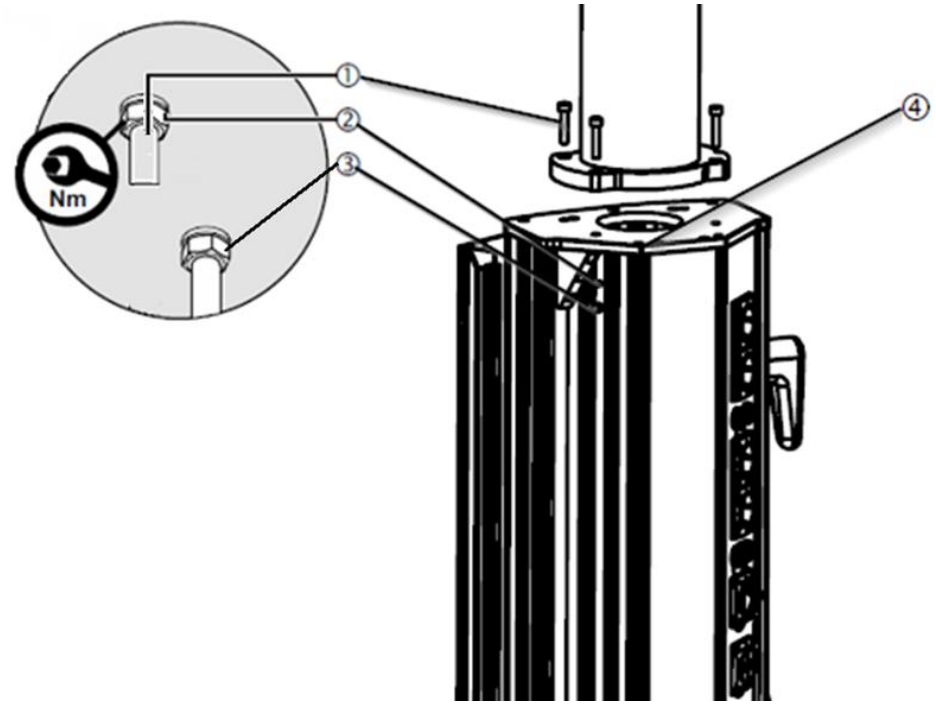

Fig. 19 Disassembly / assembly of the service head on the drop tube.

- Release the 4 M8 socket head cap screws ① that secure the service head.
- The service head is loose
- Remove the hoses to be replaced by loosening the hoses from the gas terminal units.
- Carefully pass the new hoses ① through the pendant system and onto the interface plate as shown in Figure 20.
- Check all hoses. Be sure to insert them carefully without crossing each other, without loops and without kinks.
- The hoses must be positioned in the suspension system in such a way that they are not exposed to tensile or torsional stresses.
- Protruding hoses must not be placed on the service head or flanges, but must be placed on the interface plate and secured against falling with cable retainers.

NOTA

For systems with air brakes, check air supply lines and brake valves for contamination and clean if necessary.

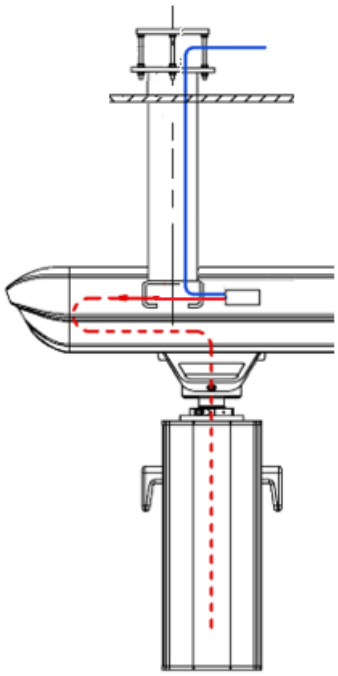

Fig. 20 Routing of gas hoses and evacuation of anaesthetic gases.

If we focus on the main body. To do this, open the top covers as described in section 6.3.1 of this manual.

See point 6.3.1 of this manual.

- Remove the hoses to be replaced by loosening the hoses from the gas terminal units.
- Carefully pass the new hoses ① through the pendant system and onto the interface plate as shown in Figure 20.
- Check all hoses. Be sure to insert them carefully without crossing each other, without loops and without kinks.
- The hoses must be positioned in the suspension system in such a way that they are not exposed to tensile or torsional stresses.
- Protruding hoses must not be placed on the main body or flanges, but must be placed on the interface plate and secured against falling with cable retainers.

NOTA

For systems with air brakes, check air supply lines and brake valves for contamination and clean if necessary.

6.7.2. Installation of the Flexible hoses for medical gases

- Ensure gas types are assigned correctly

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

- Check hoses and lines for dirt and clean them with oil-free air.
- Ensure that hoses and lines are assigned to the correct supply outlets.
- Attach a hose clamp to the gas supply hose, remove the sealing plug and push the hose into the correct gas supply outlet.
- Up to 3 gas supply hoses and up to 2 vacuum hoses can be connected to one gas valve using Y-connectors.
- Press the hose clamp and check that it is securely in place.
- Connect and secure the anaesthetic exhaust hoses.

Concerning the Service Head:

- Direct the service head without putting any stress on the supply hoses.
- Present the service head in front of the drop tube of the boom system(s) with the aid of the working platform.
- Pass the gas hoses through the upper hole of the service head. See figure 19.
- Fit the 4 M8 socket head cap screws ① into the 4 recesses provided in the upper part of the service head as shown in figure 18.
- For each M8 socket head cap screw ①, fit 1 S10 lock washer ② (as illustrated in figure 18) so that the flat washer is seated between the upper seal of the service head (on the inside) and the corresponding hexagon nut ③.

The M8 socket head cap screws ① - DIN EN ISO 10642 must be tightened to 40 Nm.

- Once the service head has been attached, connect the gas hoses to the appropriate gas terminal unit.
- Ensure that gas types are correctly assigned

Refer to Main Body (if applicable):

- Connect the gas hoses to the appropriate gas terminal unit.
- Ensure that gas types are correctly assigned

- Replace the top covers.

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

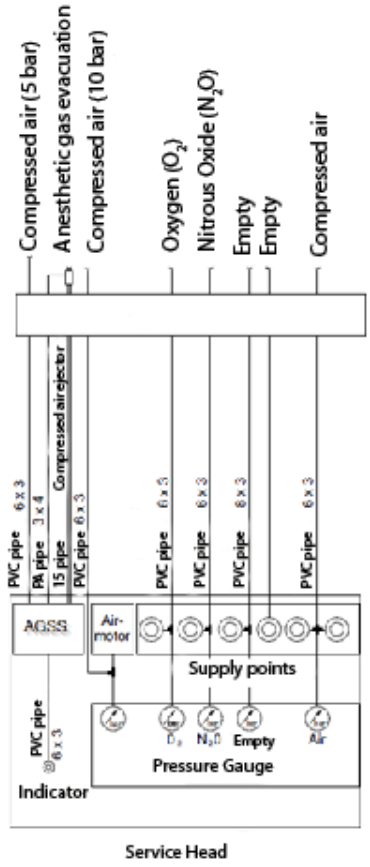

Fig. 21 Example of connection of gas hoses and exhaust air ducts to main body

- Perform a gas type test by following these 5 points:

  1. Gas outlets and marking according to EN ISO 9170-1 or EN ISO 9170-2
  2. Leakage according to EN ISO 11197
  3. Congestion according to EN ISO 7396-1 or EN ISO 7396-2
  4. Solid contamination according to EN ISO 7396-1 or EN ISO 7396-2
  5. Gas type according to EN ISO 7396-1 or EN ISO 7396-2

6.8. Maintenance plan

Item to be inspected	Description	Periodicity	Method of inspection

Downpipe plate and structure	Ensuring strength and load-bearing capacity*.	Annual	Visual inspection for signs of wear or corrosion Check condition and robustness (1)
Downpipes	Ensure correct connections and check gas & electrical supply passages. Check height and relative position*.	Annual	Visual inspection and robustness check (1)
Carousel	Check mobility and fixation with the service head*. Check end stops	Annual	Visual inspection and functional test. Robustness check (1) See point *6.6.2 Adjustment of limit switches for carousels and carriages* 
Brakes	Functionality check and adjustment*. Check brake release	Annual	Functional testing and adjustment See section *6.6 Structural and movement check and 6.6.4 Release of pneumatic brakes for carousel.* 
Service Column	Ensure that the spine remains firm and in position*.	Annual	Visual inspection and stability check
Trolleys	Check mobility and fixation with the skid*. Check brake release Check end stops	Annual	Visual inspection and functional test. Robustness check (1) See point *6.6.2 Adjustment of limit switches for carousels and carriages and 6.6.3 Release of mechanical brakes for element carriers* 
Trays and Drawers	Ensuring functionality and cleanliness	Half-yearly	Visual inspection and dummy load (2) Check condition and robustness (1)
Other accessories	Inspection of dripper support and other elements	Annual	Visual inspection and dummy load (2) Check condition and robustness (1)

Gas outlets	Review and check of status and functionality*.	Annual	Visual inspection and functional test. Ease of connection and disconnection manoeuvres Wear and tear or damage Marking and labelling
Flexible gas hoses I	Review and check of status and functionality*.  It is recommended to disconnect the equipment electrically before proceeding with the overhaul.	Annual	Visual inspection. Verification of clamps. Checking connections. See section *6.7 Inspection and Replacement Procedure for Flexible Hoses for medical gases.* 
Flexible gas hoses II	Overhaul and status check*.  It is recommended to disconnect the equipment electrically before proceeding with the overhaul.	Biannual	Leak detection. See section *6.7 Inspection and Replacement Procedure for Flexible Hoses for medical gases.* 
Replacement of flexible gas hoses	Replacement of flexible gas hoses*.  It is recommended to disconnect the equipment electrically before proceeding with the overhaul.	8 years	See point *6.7.1 Replacement of Flexible Hoses for medical gases* 
LED lighting	Testing of LED strips for direct/indirect light on Main Body and LED spotlight for waking light on Column	Half-yearly	Visual inspection and function test See point *6.4 and 6.5. Replacement of LED strips and lighting controllers* 

Nurse call	Operation of the call system	Half-yearly	Simulation of call and system response. Ensure effective communication with nursing
Switches	Checking of the lighting actuation	Annual	Functional test. Check operability
RJ45 sockets	Inspection of voice and data sockets	Annual	Connecting to devices and testing data transfer
Electrical outlets	Verification of equipment power supply*.	Half-yearly	Use of a multimeter to check supply voltage and continuity (3), and connection of devices
Electrical and data hoses	Review and check of status and functionality*.  It is recommended to disconnect the equipment electrically before proceeding with the overhaul.	Annual	Visual inspection and functional test. Check connections, and correct signalling. Check according to applicable regulations See section *6.2.1 Opening of the side covers of a service head* 
Video & audio outlets	Operation of HDMI and USB sockets, etc.	Annual	Device connection and data/video/audio transfer
Protection mechanisms	Verification of earths and protections*.	Annual	Use of a multimeter (3) for continuity tests
Treatment and finishing	Check paint condition	Annual	Visual inspection and tactile test (4)
Headwalls	Inspection of the headwalls and their condition	Annual	Visual inspection and tactile test

Damaged, deformed or missing components must be replaced as soon as possible. In this case, please contact the supplier of the device.

*If one of the above points is found to be non-compliant during the inspection, the system must be shut down immediately as a precautionary measure to prevent further damage to persons and equipment. Immediately notify the System supplier.

(1) Check condition and robustness:

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

(2) Dummy load:

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

(3) Use of the multimeter:

- It shall be used to verify that electrical outlets and related components are operating correctly. With it, values such as voltage (to ensure that the sockets are providing the correct voltage), resistance (to identify possible faults or short circuits) and continuity (to ensure that circuits are complete and there are no interruptions) can be measured.

(4) Tactile test:

- This refers to using touch to evaluate a surface or component. For example, by running the hand or fingers over the paint on a structure, one can determine if there are any irregularities, bumps or flaking.
- The test shall be considered successful if, to the touch, the surface is uniform, with no perceptible irregularities and no signs of flaking or deterioration.

7. Cleaning

Perform this operation with slightly moist cleaning instruments to ensure that no liquid enters the equipment. Since no part or component of the system is invasive, sterilisation is not necessary.

Do not use abrasive or very hard cleaning agents that may cause damage to the exterior coatings, such as disinfectants containing sodium hypochlorite, which is highly corrosive to aluminium.

WARNING: Damage to equipment may occur.

Formaldehyde-free disinfectants such as Saint Nebul Ald from Proder Pharma are recommended. Method of application:

1. Dilute 4 pulses of the valve supplied by the manufacturer per 5 litres of water.

2. Spray the compound on the product and let it react for 15 minutes.
3. Remove with water or soap solution with a wrung out cloth.


Switch off the power supply

Contact with live parts can cause an electric shock.

- Always disconnect the device from the main power supply before cleaning and disinfecting it.
- Do not insert objects into the openings of the device.

8. 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.

9. Regulations

According to the new **MDD** regulation **93/42/EEC** concerning medical devices, this product family is classified as:

- Class IIb, by Annex II, excluding section 4, regulation 11.
- Protection level IP20 according to IEC 60529

Equipment intended for continuous operation.

9.1. Reference standards

The device complies with the safety requirements of the following standards and directives:

ISO11197: Medical supply units

IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance.

IEC 60601-1-2: Medical electrical equipment. Part 1-2. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic disturbances.

9.2. Electromagnetic compatibility.

According to EN 60601-1-2:2015 this equipment is intended for use in the electromagnetic environment specified below. The user of this equipment must satisfy himself that it is being used in such an environment.

Interference emission measurements	Compliance	Comment
HF emissions according to CISPR 11 standard	Group 1	The supply unit uses HF energy exclusively for its internal OPERATION. Therefore, its HF emissions are minimal and interference with devices in its vicinity is unlikely.
HF emissions according to CISPR 11 standard	Class A	The roof supply unit is suitable for use in non-domestic installations and in installations that are directly connected to the PUBLIC SUPPLY NETWORK, which also supplies residential buildings.
Harmonic emissions according to the standard IEC 61000-3-2	Class A	
Emissions of voltage 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 UN fall for 0.5 period 100% of UN fall for 1 period 30% of UN fall for 25 periods Remark: UN is the AC mains voltage before applying the test level.	100% UN drop for 0.5 period 100% of UN drop for 1 period 30% of UN drop for 25 periods	The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the roof supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the roof supply unit from a device with an uninterruptible power supply or a battery.
Short interruptions of the supply voltage according to the standard IEC 61000-4- 11	100% for 5 s Remark: UN is the AC mains voltage before applying the test level.		The quality of the supply voltage should be typical for a commercial or hospital environment. If the user of the roof supply unit requires continuous operation even in case of power supply interruptions, it is recommended to supply the roof supply unit from a device with an uninterruptible power supply or a battery.
Magnetic field for power supply frequencies (50/60 Hz) according to the standard IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields created by the mains frequency should be those of a commercial or hospital environment.

Interference resistance	Level of verification according to IEC 60601	Level of compliance	Environment/Guidelines

<table>
<tr><td>HF interference
induced by
IEC 61000-4-6</td><td>3 Vrms 150 kHz to 80 MHz
6 Vrms ISM band</td><td>3 Vrms
6 Vrms</td><td>AM 1KHz modulation
Depth 80% Depth 80%
Depth 80% Depth</td></tr>
<tr><td>HF interference
induced by
IEC 61000-4-3</td><td colspan="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></td></tr>
</table>

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