

tediselmedical

ATLAS

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.



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

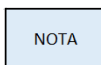


Failure of the roof support system



Risk of collision

2.4. Indication of additional information



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.

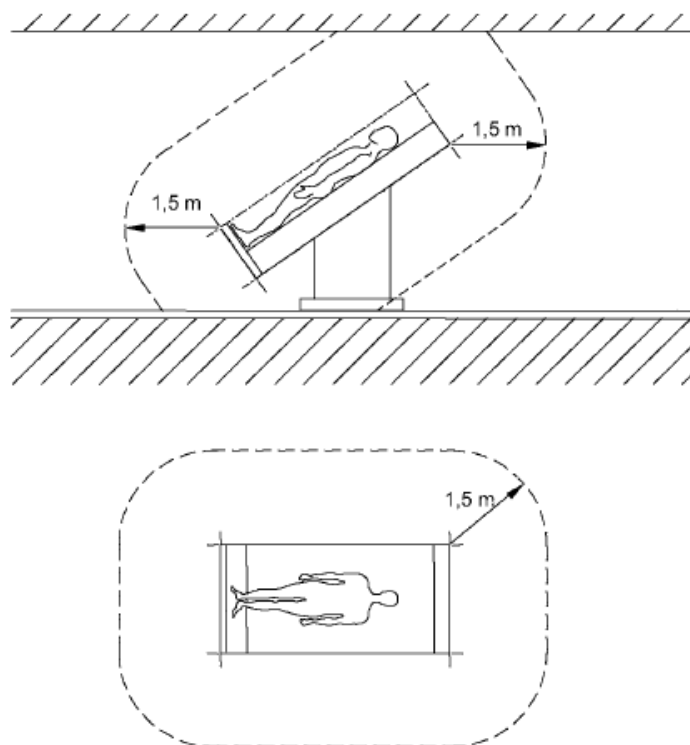


Fig. 1 Minimum extent of the PATIENT ENVIRONMENT

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 explosions



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 the materials, alcoholic content greater than 60 % may cause the plastic materials to become brittle. Dislodged particles may fall into open wounds. If liquid cleaning agents are allowed to penetrate into the hanging system and fittings, excess cleaning fluid may drip into open wounds. Strong acids, bases and agents with a high degree of corrosion resistance are not allowed to penetrate.

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.

4. Symbols used



Applicable part B








Earth (mass)















Equipotentiality



Protective earth (ground)

N	Connection point for neutral conductor
	Nurse call button
	Direct lighting
	Indirect lighting
	Operating instructions
MD	Health Product
	Waste electrical equipment
CE 0197	CE symbol
REF	Product code
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 ATLAS 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 headboard (structural part of the equipment) and the second one corresponding to the trolleys.

The packaging consists of a cardboard box and bubble wrap inside and can be stacked up to two high.

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 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 ATLAS units consist of two distinct parts, the structural part (downspouts), which is responsible for positioning the unit at the desired height, and the suspended header, which serves as a supply interface for energy consumers. The trolleys can also be used to house, store and store other devices without supplying them with power. See figure 2.

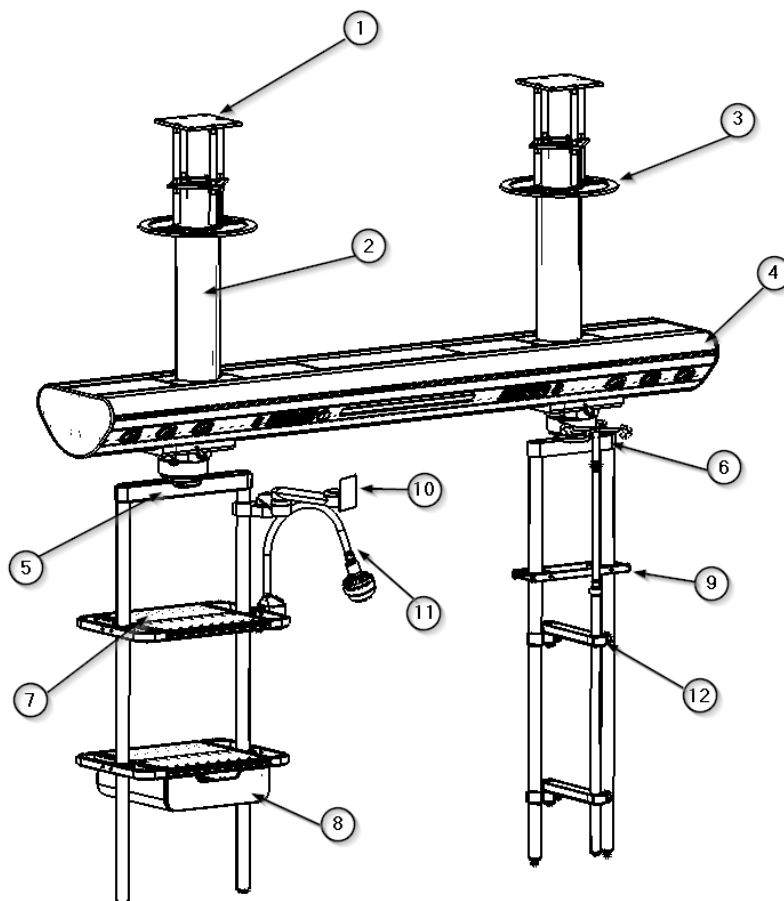


Fig.2 Parts of the equipment

- 1) Interface board
- 2) Roof lowering package
- 3) Ceiling trim
- 4) Suspended headboard (main body)
- 5) Trolley with 700mm trapeze (Optional)
- 6) 300mm trapeze element trolley (Optional)
- 7) 700mm trolley tray (optional)
- 8) Single drawer for 700mm trolley (Optional)
- 9) Double DIN rail for 300mm trolley (Optional)
- 10) Monitor bracket (Optional)
- 11) Scanning spotlight (Optional)
- 12) Dripper holder (Optional)

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

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.

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 2. 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.

NOTA

The variable length L as shown in figure 3 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.

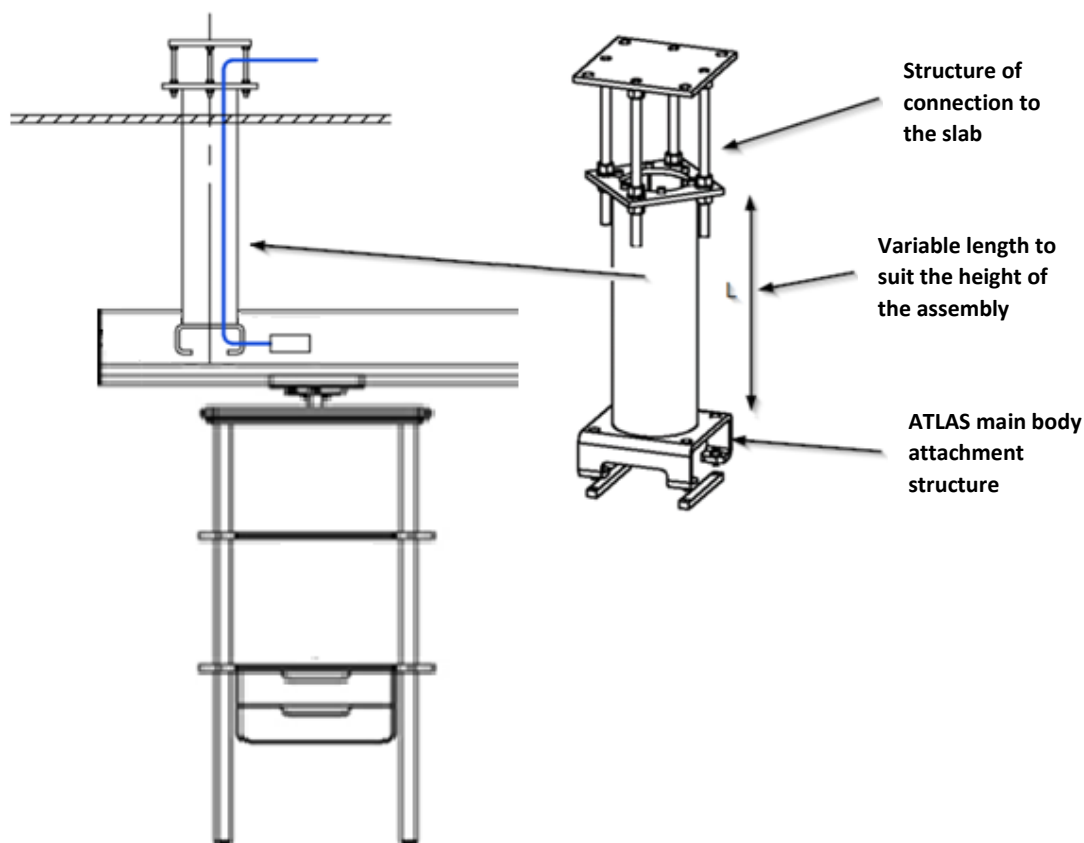


Fig.3 Parts. Downpipe

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

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.

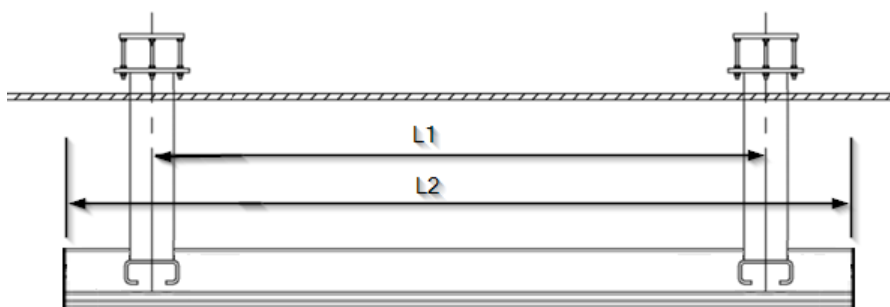


Fig. 4 Parts. Suspended headboard

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 3.



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 downpipes as shown in figure 4.

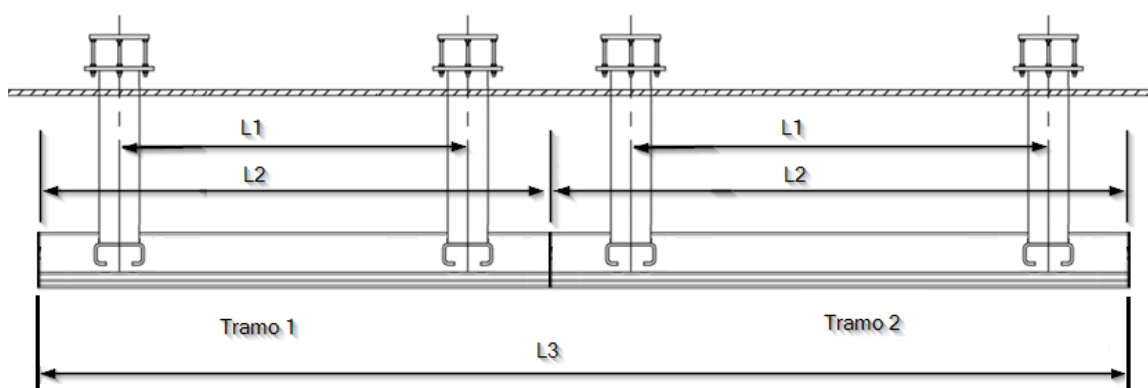


Fig. 5 Parts. Joining of two suspended headboard sections



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

A movable element that moves along a defined length within a section of ATLAS with one or two 38 mm diameter structural tubes on which other accessory elements can be supported. The tube may be positioned on the axis of rotation or on a trapezoid at a fixed distance. The distance between the tubes (L) can be 300mm, 500mm and 700mm. Figure 5 shows the variant with a 300mm and 700mm trapeze and the variant with the tube on the axis of rotation.

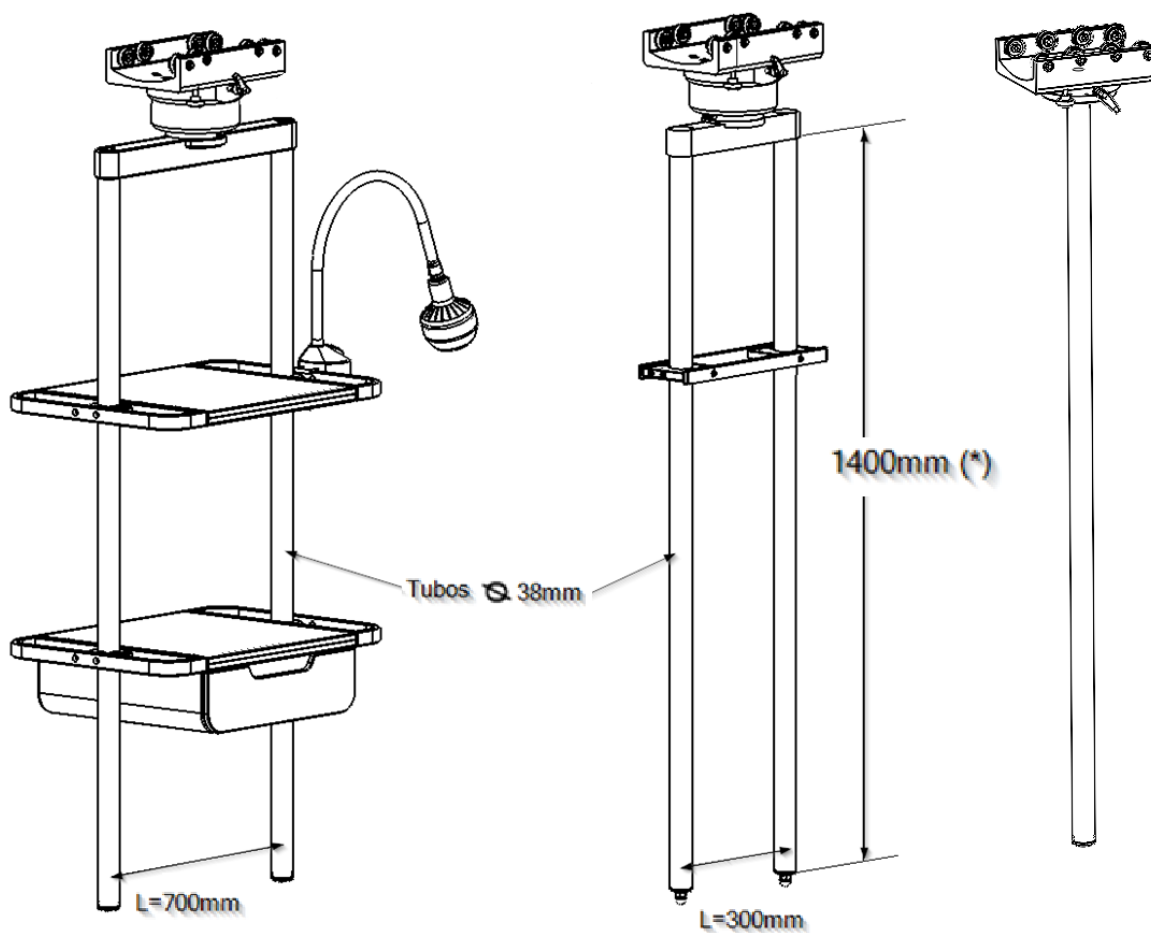


Fig. 6 Detail of trolleys for ATLAS



See Atlas accessories catalogue

The example in figure 5 shows a technical rail assembly on the structural tubes (middle picture in figure 5) and two trays, one with an individual drawer unit (picture on the left in figure 5). The image on the right shows the trolley with a single tube on the axis of rotation.

NOTA

(*) The standard length for structural tubes is 1,400mm. Consult the manufacturer for special lengths.

5.5. Maximum load capacity

The maximum load capacity is the maximum weight that can be carried by the suspended headboard. The example in figure 6 shows a configuration with two trolleys. The maximum load is counted on one of the tubes of each trolley.

The maximum load per main head section is 600 kg. This load includes the payload capacity of the trolleys and their own weight.

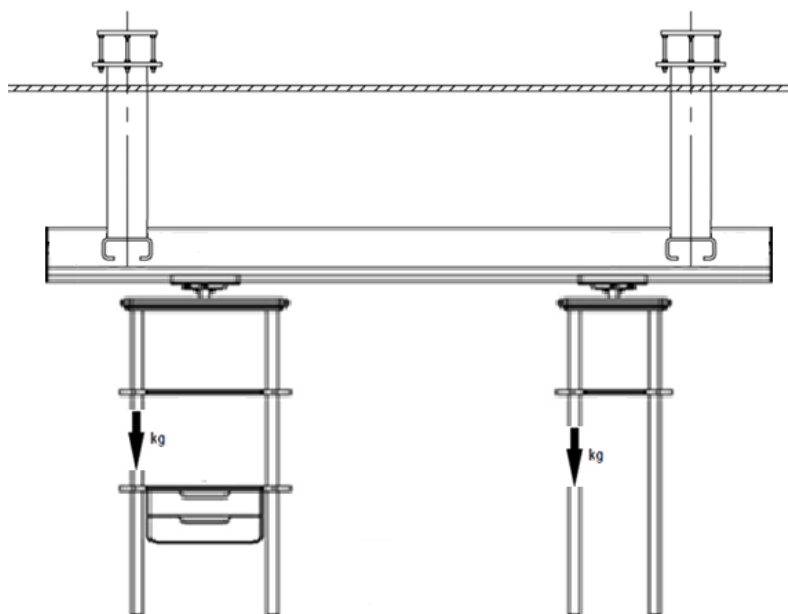


Fig.7 Load application point on trolleys

5.6. Maximum payload capacity

The dead 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.

NOTA

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

In the example shown in figure 6, there is an ATLAS assembly with two trolleys. The maximum payload of a trolley is 150 kg and is indicated on a visible sticker on the corresponding trapezoid.



See section 6.3 of this manual

6. Technical data

6.1. Overall dimensions

Below is an illustration of an ATLAS hanging system with two trolleys and some accessories. Please note that the configuration of your hanging system may differ from this illustration.

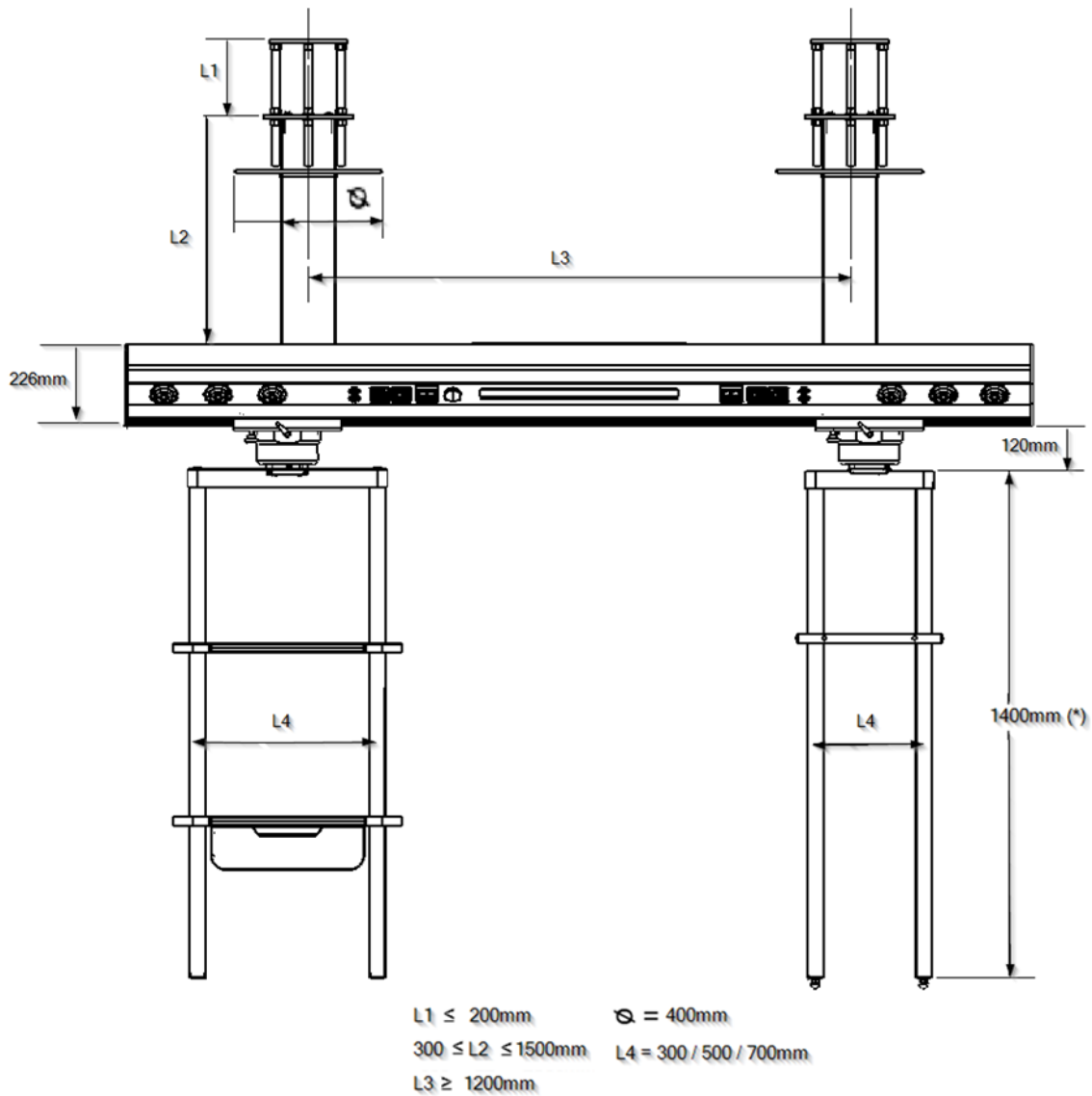


Fig.8 Diagram of suspended ATLAS with different elements

NOTA

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

6.2. Weight of the hanging system

The weight of the system does not include gas pipes, inserted power cables or 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)	2kg/Ud
Chassis (span).....	34kg/m



(*) See section 5.4.1.2 of this manual.

6.2.3. Accessories

Item trolley (trapeze 300mm)	17Kg
Element carrier (trapeze 500mm)	17Kg
Item trolley (trapeze 700mm)	19Kg
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
Item trolley (trapeze 300mm)	150 Kg
Item trolley (trapeze 500mm)	150 Kg
Element carrier trolley (trapeze 700mm)	150 Kg
Trolley tray with 700mm trapeze.....	50kg
Single drawer on trolley tray with 700mm trapeze.....	40kg
Technical double rail set on 38mm diameter tube (L=300mm)	25kg
Technical double rail set on 38mm diameter tube (L=500mm)	25kg
Technical double 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)	up to 60W

6.5. Noise level

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

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.

8. Use of equipment

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

- Electrical, voice and data circuits.
- Nurse call
- Lighting
- 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 main body.
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

8.3. Training

Personnel using ATLAS 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 the mechanical brakes of the element carrier trolleys

The mechanical brakes keep the trolleys stable. Adjust the braking force in such a way that they remain stable in any position and can still be conveniently adjusted.

- To increase the braking force on the rotation axis, turn the rotation brake lever clockwise as shown in figure 8.
- To reduce the braking force on the rotating shaft, turn the rotation brake lever counterclockwise, in the opposite direction to that shown in figure 8.
- To increase the braking force on the drive shaft, turn the rotation brake lever clockwise as shown in figure 8.

- To reduce the braking force on the drive shaft, turn the rotation brake lever counterclockwise, in the opposite direction to that shown in figure 8.



If the brakes on the trolley are not properly applied, the trolley will move freely and may hit other objects in the vicinity.

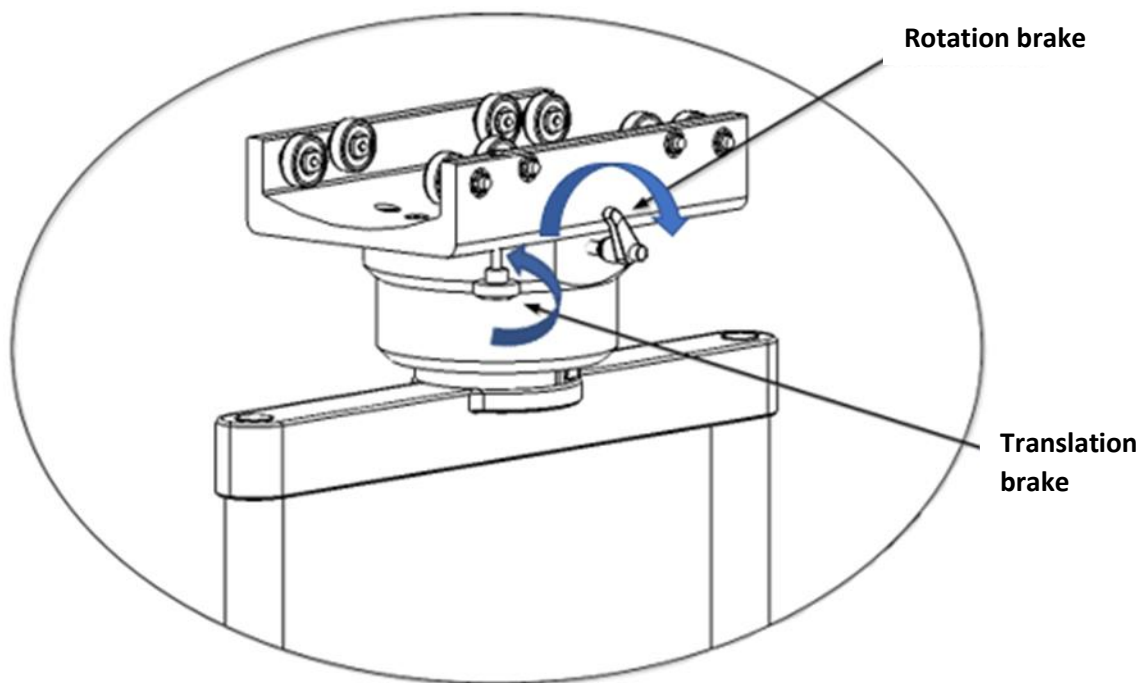


Fig.9 Adjustment of friction brakes on element carrier trolleys

8.4.2. Limit switch adjustment for element carrier carriages

ATLAS equipment trolleys can slide freely along the entire length of the main body section on which they are installed. It is necessary to limit their travel to ensure that these elements do not conflict with patient and operator space. See figure 9 and 10.

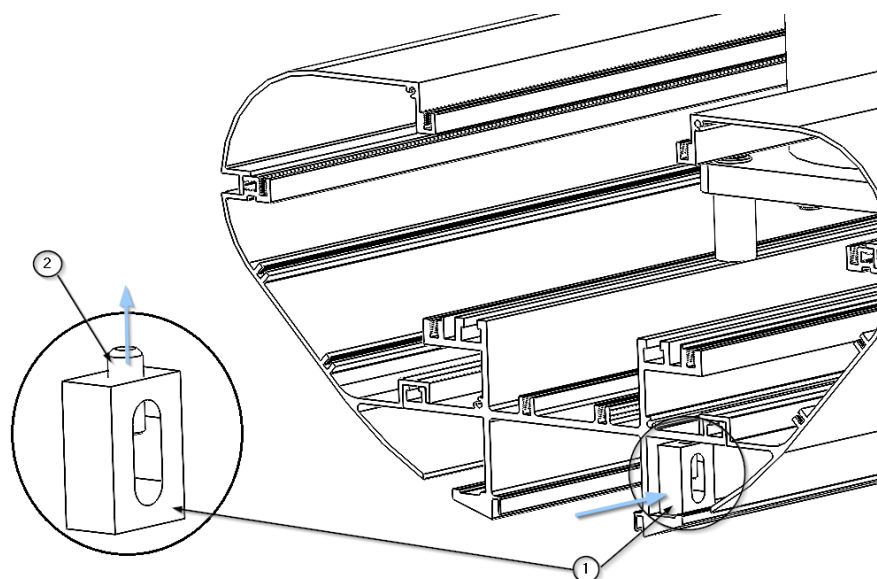


Fig.10 Adjustment of the travel limit switches.

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

The example in figure 10 shows an ATLAS unit with two element carriages, the limit switches must ensure that the element carriages do not collide with the other elements in the environment.

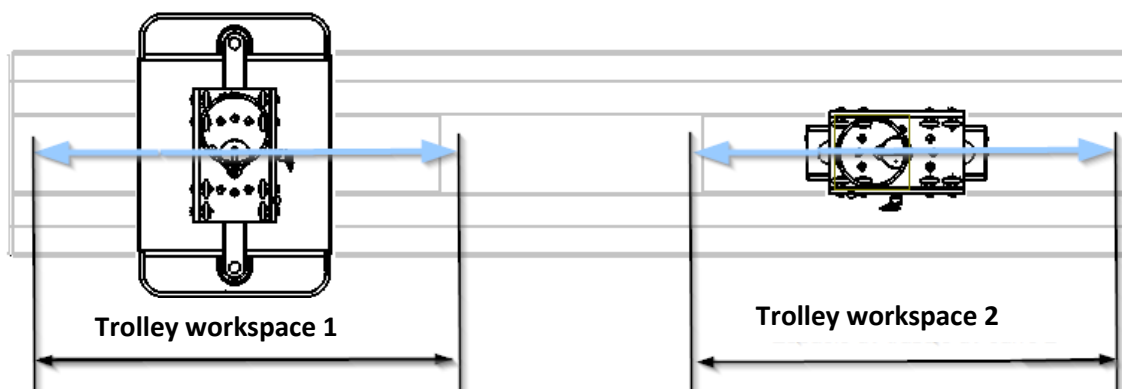


Fig.11 Adjustment of the travel limit switches.

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



The hexagon socket bolts (2) M8 - DIN 913 must be tightened to 40 Nm.

9. Cleaning

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



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



WARNING: Damage to equipment may occur.

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

Method of application:

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



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

Switch off the power supply



: 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 should the user remove any part of the equipment enclosure to carry out checks.

11.1. Lighting problems

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

11.2. Power supply problems

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

11.3. Problems with the supply of medical gases

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

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

If the problem persists, contact your service personnel.

12. Incident warning information

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



See point 1 of this manual.

13. Regulations

13.1. Team ranking

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

- Class IIb, by Annex II, excluding section 4, regulation 11.
- IP20 protection level 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	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 in accordance with 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.

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

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 border="1"> <thead> <tr> <th>RANGE</th> <th>FREQUENCY</th> <th>MODULATION</th> <th>STEP</th> <th>LEVEL</th> </tr> </thead> <tbody> <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> </tbody> </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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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