# tediselmedical ATLAS

# **MAINTENANCE MANUAL**



tediselmedical.com

**( €** 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.
	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



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.

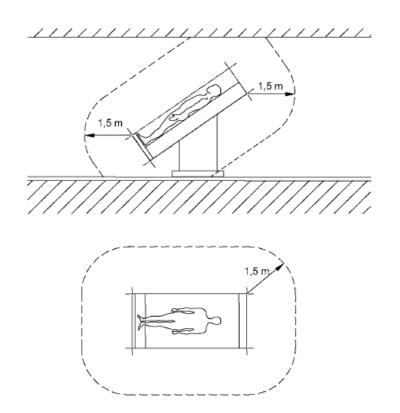


Fig. 1 Minimum extent of the PATIENT ENVIRONMENT

### 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.



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 also be de-energised.

3.3. Fire risk



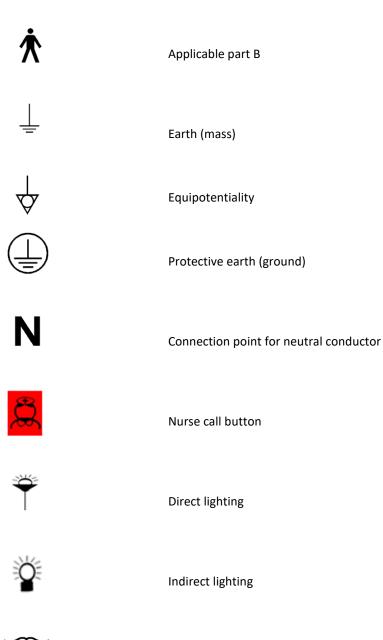
Plug-in connections for the supply of medical gases must not come into contact with oil, grease or flammable liquids.

### 3.4. Danger of electric shock



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

### 4. Symbols used



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Operating instructions

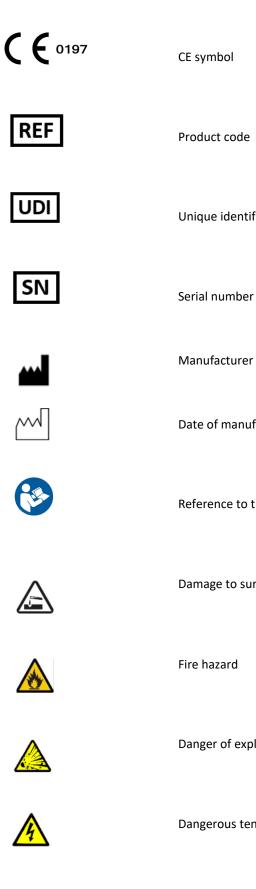


Health Product



Waste electrical equipment

Maintenance Manual ATLAS



Product code

UDI

Unique identification code

SN

Serial number

 $\sim$ 

Date of manufacture

Reference to the instruction manual

Damage to surfaces



Danger of explosion



Dangerous tension



Notice



### 5. Product data

This manual refers to the ATLAS 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 prevent reconnection.
- Ensure that all devices connected through the main body of the equipment 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

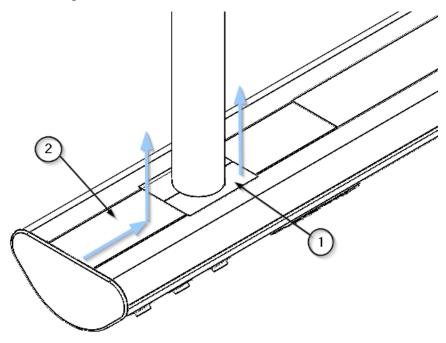
The main body of the ATLAS is supplied finished, so for on-site installation, the side walls and top covers must be removed in order to be able to connect to the downpipes and, if necessary, to fit other accessory equipment (trolleys).

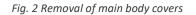


Disconnect the equipment electrically before proceeding with the disassembly of covers and end caps.

#### 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 move the upper covers of the main body ②, which are also press-fitted, by hand, first in the direction of the main body and, once the side wall has been cleared, by pulling them upwards. See figure 1.





- 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, slide it until it makes contact with the side wall. 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 6.3.1 of this manual.

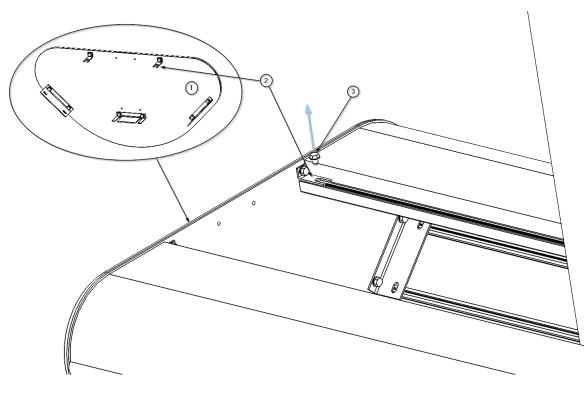


Fig. 3 Disassembly/assembly of end caps on ATLAS main body

- Using a hexagonal tool, remove the 8 M4 x 6 screws ③ securing the 5 side flanges ② of the side wall ①, as shown in figure 2.
- Carefully remove the side panel ① and place it in a safe place.
- To reassemble the end caps, carry out the above steps in reverse order.
- First attach the end cap ① by supporting the side tabs ② in the threaded slots of the main body and secure it with the 8 M4 x 6 screws ③.
- Check that the side wall ① is properly fixed.

#### 6.4. Replacement of LED strips and drivers in the indirect light module

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



Disconnect the equipment electrically before replacement.

- Unscrew the 2 M4 x 10 countersunk screws ①DIN 935 using a Phillips screwdriver as shown in figure 3.
- Remove the polycarbonate cover (2) and store it in a safe place. The lighting module is visible.
- Remove the 4 socket head cap screws M5 x 10 (3) DIN 912 using an Allen tool. The lighting module is now loose.

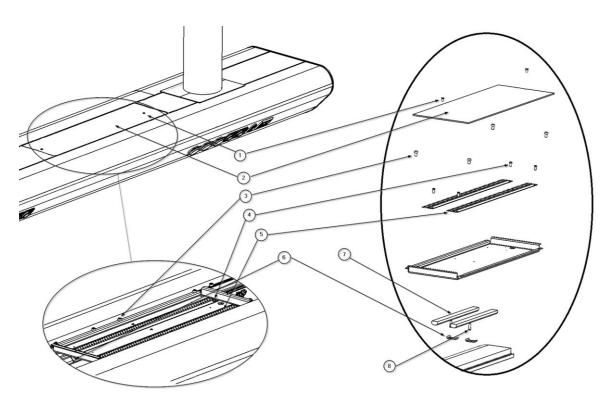


Fig.4 Indirect light substitution

- Disconnect the quick connector from the LED strips (5). The module can now be turned over and the controllers (7) and their terminal strip can be seen.
- Disconnect the power supply to the controllers ⑦ from the terminal strip.
- Unscrew the M4 x16 hex screws (8) DIN 933 by releasing the tabs (6) holding the controllers
  (7).
- Fit the new controllers (7) and secure them with the tabs (6) by screwing in the hexagonal screws (8).
- Connect the power supply of the controllers back to the terminal strip.
- Unscrew the M4 x16 hex screws ④ DIN 933 releasing the LED strips ⑤.
- Fit the new LED strips and secure them with the hexagonal screws (4).
- Connect the power supply cable of the newly installed LED strips.
- Re-attach the module by screwing in the 4 M5 x 10 socket head cap screws ③ DIN 912 using a hexagon socket tool. 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 (2) and screw in the 2 M4 x 10 countersunk screws (1) DIN 935.

### 6.5. Replacement of LED strips and drivers in the direct light module

If the direct light module of the ATLAS 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 drivers (2) and its terminal strip are visible.



See section 6.3.1 of this manual.

If, due to the configuration of the equipment, the indirect light module does not allow manipulation of the direct lighting module, remove it as indicated in the previous point.



See section 6.4 of this manual

- Disconnect the power supply of the controller (2) from the terminal strip.
- Unscrew the 2 M4 x 8 hex screws ① DIN 7500 and release the lighting module. The LED strip
  ⑤ and its quick connector are visible. See figure 4.

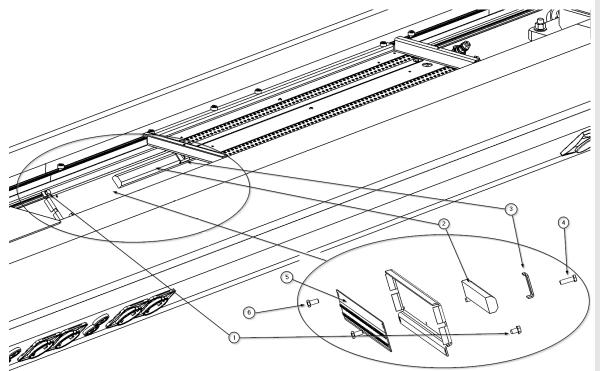


Fig.5 Substitution of direct light

- 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).

ATLAS

ATLAS

Maintenance Manual

- Unscrew the M4 x16 hex screw 4 DIN 933 by 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

• Refit 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 that the limit switches for the system carriages are properly secured.
- Check that the brakes on the trolleys are working properly and that the trolleys can be moved comfortably into the desired position.
- Adjust, if necessary, the friction brakes.

#### 6.6.1. 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 5.
- To reduce the braking force on the rotating shaft, turn the rotation brake lever counterclockwise, in the opposite direction to that shown in figure 5.
- To increase the braking force on the drive shaft, turn the rotation brake lever clockwise as shown in figure 5.
- To reduce the braking force on the drive shaft, turn the rotation brake lever counterclockwise, in the opposite direction to that shown in figure 5.

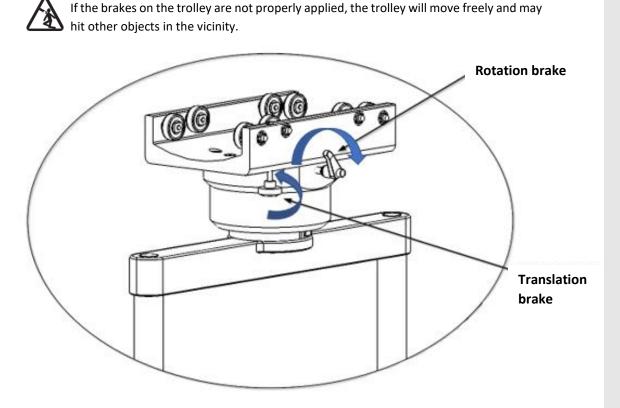


Fig.6 Adjustment of friction brakes on element carrier trolleys

#### 6.6.2. Limit switch adjustment for element 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 6 and 7.

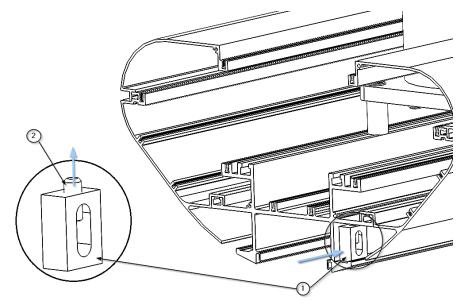


Fig.7 Adjustment of the travel limit switches.

- 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 7 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.

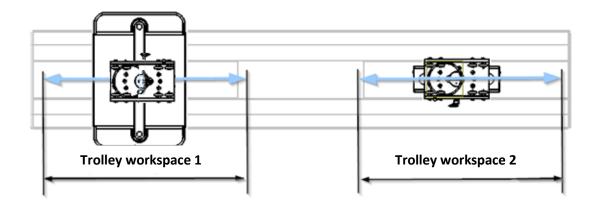


Fig.8 Adjusting the travel limit switches. Maximum stroke

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



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

#### 6.7. Checking of medical gas supply circuits

It is recommended to disconnect the equipment electrically before proceeding with the revision.

Passage	Descrip	tion	Periodicity	Tools/supplies
1	Detailed A) B)	d Visual Inspection: Remove the top covers to access the inside of the equipment following the steps specified in section 6.3.1 Removing and fitting the top covers. Perform a thorough visual inspection of all interior ductwork for signs of wear or damage.	Annual	Screwdriver set, protective gloves, torch, torch, etc.
2	Leak De	tection: Prepare a soap solution in a container.	Biannual	Soap solution, brush or paintbrush

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	B)	With a brush or paintbrush, apply the		
		solution to the junction points of the		
		piping to the gas terminal units, and other		
		soldered connections.		
	C)	Observe if bubbles form, indicating the		
		presence of a leak.		
	D)	If a leak is detected, mark the area for		
		later correction.		
3	Verifica	tion of gas terminal brackets:	Annual	Hand tools,
	A)	Physically assess the condition and		protective gloves
		integrity of the trunking supports. Check		
		for wear or structural damage.		
	B)	Ensure that the brackets are firmly fixed		
		to the profile and that there is no		
		movement or play in the brackets.		
4	Mainte	nance Register:	Always	Maintenance log
	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.		
	В)	Keep this record organised and accessible		
		for future reference and audits.		

**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.

### 6.8. 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)
Service Head	Ensure that the service head is held firmly in position*.	Annual	Visual inspection and stability check
Trolleys	Check mobility and fixation with the skid*. Check movement and rotation restriction stops. Check end stops.	Annual	Visual inspection and functional test Robustness check (1) See section 6.6.1 Adjustment of the mechanical brakes of the element carriers and 6.6.2 Adjustment of the limit switch 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

Copper gas connection I	Overhaul and status check*. It is recommended to disconnect the equipment electrically before proceeding with the overhaul.	Annual	Visual inspection Verification of supports See section 6.7 Checking of medical gas supply circuits
Copper gas connections 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 Checking of medical gas supply circuits
LED lighting	Testing of LED strips for direct and indirect light	Half-yearly	Visual inspection and function test See points 6.4 and 6.5. Replacement of LED strips and drivers
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	Review and check of status and	Annual	Visual inspection and functional test.
data cabling	functionality*. It is recommended to disconnect the equipment electrically before proceeding with the overhaul.		Check connections, and correct signalling. Check according to applicable regulations See section 6.3.1 Disassembly and assembly of the upper shrouds
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

#### 9.1. 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.

#### 9.2. 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.

#### 9.3. Electromagnetic compatibility.

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

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

Interference	Test level according	Level of compliance	Environment/Guidelines
resistance	to IEC 60601		
Static Electric	±8 kV contact	±8 kV contact	Floors should be made of
Discharge (ESD)	discharge	discharge	wood, concrete or ceramics. If
according to IEC	15 kV aerial	15 kV aerial discharge	the floor is covered with a
61000-4-2	discharge		synthetic material, the
			relative air humidity should
			be at least 30%.
Fast transient	±2 kV for power	±2 kV for power supply	The quality of the supply
electrical	supply cables	cables	voltage should be typical for a
interference	±1kV for input	±1 kV for incoming and	commercial or hospital
amplitudes / bursts	and output cables	outgoing cables	environment.
according to the		outgoing cubics	
norm			
IEC 61000-4-4			
Overvoltages	±1 kV phase-to-	±1 kV phase-to-phase	The quality of the supply
(waves) according	phase voltage	voltage	voltage should be typical for a
to the standard	±2 kV phase to	±2 kV phase to ground	commercial or hospital
IEC 61000-4- 5	ground voltage	voltage	environment.
Voltage dips and	100% of <sub>UN</sub> drop for	100% <sub>UN</sub> drop for	The quality of the supply
fluctuations of the	0.5 period 100% of	0.5 period	voltage should be typical for a
supply voltage	UN drop for 1 period	100% of UN drop for 1	commercial or hospital
according to the	30% of UN drop for	period 30% of UN drop	environment.
standard	25 periods	for 25 periods	If the user of the roof supply
IEC 61000-4- 11			unit requires continuous
	Remark:		operation even in case of
	UN is the AC mains		power supply interruptions, it
	voltage before		is recommended to supply the
	applying the test		roof supply unit from a device
	level.		with an uninterruptible power
			supply or a battery.
Short interruptions	100% for 5 s		The quality of the supply
of the supply			voltage should be typical for a
voltage in	Remark:		commercial or hospital
			•

accordance with	UN	is the AC main	s			e	nvironment		
the standard	volt	age before				lf	the user of	the roof sup	oly
IEC 61000-4- 11 a		lying the test	ng the test			unit requires continuous			
	leve	·I.						en in case of	
							•	interruption	it
								-	
								ded to supply	
						r	oof supply u	nit from a de	vice
						W	vith an unint	erruptible po	ower
						S	upply or a b	attery.	
Magnetic field for	30 A	V/m	30 A/m			Tł	e magnetic	fields create	d
power supply						by	the mains f	frequency	
frequencies (50/60						sh	ould be tho	se of a	
Hz) according to						со	commercial or hospital		
the standard							vironment.	·	
						CI	ivii onniene.		
IEC 61000-4-8	-								
Interference resistance	Le	vel of verification	on according to		Level of		Environme	nt/Guidelines	
	IE	C 60601			compliance				
HF interference	21	Vrms 150 kHz			3 Vrms		AM 1KHz r	nodulation	
induced by	-						Depth 80%	6 Depth 80%	
IEC 61000-4-6		6 Vrms ISM band			6 Vrms		Depth 80% Depth		
HF interference		RANGE	EDEOLENCY	-	MODULATION		STEP	LEVEL	1
HF Interference		A	FREQUENCY 80-1000MHz	+	AM 1 kHz Prof: 80		LOG 1%	10 V/m	-
induced by		В	1000-2000MHz		AM 1 kHz Prof: 80	)%	LOG 1%	10 V/m	1
		C D	2000-2700MHz 385MHz		AM 1 kHz Prof: 80 PM 18 Hz Cycle: 5		LOG 1%	10 V/m 27 V/m	-
IEC 61000-4-3		E	450MHz	F	M 1 kHz Desv:± 51	kHz	-	28 V/m	]
		F	810-930MHz		PM 18 Hz Cycle: 50		-	28 V/m	-
		G H	1720-1970MHz 2450MHz		M 217 Hz Cycle: 5 M 217 Hz Cycle: 5		-	28 V/m 28 V/m	-
		I	5240-5785MHz		M 217 Hz Cycle: 5 M 217 Hz Cycle: 5		-	9 V/m	1

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