MAS-00257
Range of Bedhead Panels
User Manual

Revision: 18

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Index

I. USER INSTRUCTIONS

1. Introduction

Each device manufactured by OXIGENOTERAPIA NORTE SRL comes with accompanying documentation, including this manual, its advisory notes (AWN), and the Safety Labels (SSP) attached to each panel. This information offers identification of the device and any relevant safety and performance information for the user or any other individuals, as appropriate. This manual is included in the device's packaging and on the Company's website. Particularly, labels and instructions are provided in a human-readable format in the country language in which the device is sold.

The residual risks are informed at the user using the internationally recognized risk symbols or identification colors used conforming to the harmonized standards.

This manual was written according to MDR Chapter III and has two sections:

- User Instruction section
- Device Installation Instructions section
- *The IFU must be provided to users in electronic PDF format.*
- *label indicating how to access the electronic version of the IFU must be attached to the device. The use of a QR code is required to facilitate access from a mobile phone*
- *After a customer request for an IFU, it must be delivered in PDF format within seven days.*
- *The accessibility and readability of the IFU must be validated (this will be done during 2026).*
- *When switching from paper to PDF format, a change notification form must be issued.*

2. Important overall safety notes (AWN) and labels (SSP) *(According to MDR Chapter III Section 23.2, bullet "m")*

2.1. As a result of the device risk management process, it is concluded that consulting the user manual has become a crucial risk control measure, making its consultation mandatory. Consequently, operating the equipment without reviewing the user manual, which serves as an essential accompanying document, presents a significant operational risk**.** *(Label SSP 286 attached to panel)*

2.2. Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel**.** *(AWN 32)*

2.3. **Important:** Any serious incident that may occur in relation to the device shall be reported to Oxigenoterapia Norte and the competent authority of the member state in which the user and/or patient is established. *(AWN1)*

3. Device and Manufacturer Identifications: *(According to MDR Chapter III Section 23.2, bullet "a")*

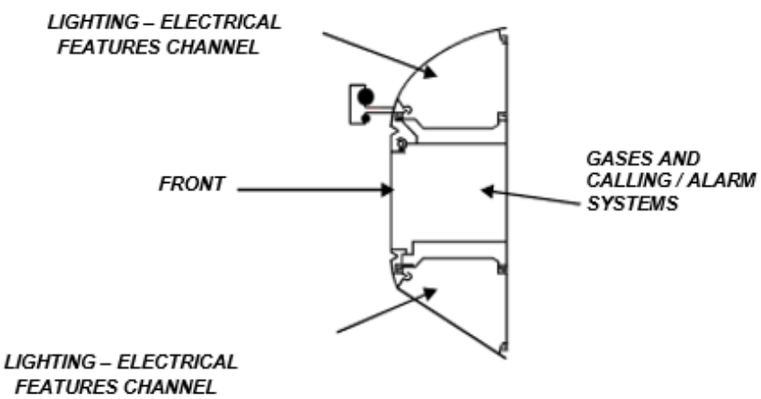
The following data can be found on a striker label attached to the device:

- Legal manufacturer name: Oxigenoterapia Norte S.A.C.I.F.I.A.
- Address: Coronel José Félix Bogado 1954, Castelar, Buenos Aires, Argentina
- The device covered by this manual: **MAS-00257**
- SRN: AR-MF-000034989
- Basic UDI-DI: ++G462MAS0257PM
- Person responsible for regulatory compliance: Carlos G. Barbieri
- E-mail: gbarbieri@oxigenoterapia.com.ar
- Phone: +5411-4629-6665 ext. 115
- Fax: +5411-4629-6665 ext. 114
- Authorised representative (if applicable): Arazy Group GmbH
- Address: The Square 12, Am Flughafen, 60549 Frankfurt am Main, Germany
- Contact person: Miki Melech
- E-mail: germany@arazygroup.com
- Phone: +49 (0) 69 95932-5090

Identification Label

UDI

4. Device's Intended Purpose.



Lateral View of a device of MAS-00257 Head Panel Family

Safe supply of single-phase electricity of 220 VCA in frequency requested by the customer, medical gases (oxygen, air, vacuum), feeble signals (telephony, data, etc.) ambient and reading light as well as the support for the necessary accessories for the normal medical practice, meeting the normative and medical professionals' requirements applicable to this type of device.

Additionally, to ensure the safe connection of the devices and accessories, the electrical connections are standardized and the medical gases outlets are indexed defining a unique univocal position in their connection.

The physical and functional configuration meets the operational requirements of the different medical areas where they are to be installed.

5. The clinical benefit to be expected.

The clinical benefits using the device is increasing safety condition of health professional works when attending patients of different pathologies because it acts as a very safe interface element between the hospital's supply network for medical gas, single-phase electrical power, and telephone signals, and various medical devices, including their corresponding hoses and wiring connection systems that health professionals use to obtain the necessary supplies (specific gas and electricity) for performing medical treatments on patients of different ages and pre-existing conditions, while the device is no in direct contact with the patients.

The panel device has been designed for this function to:

- Prevent changes of any kind or nature to gases and electrical signals that flow through it by applying the corresponding harmonized standards.
- Block the possibility of cross connections in the supply of medical gases through an unambiguous and secure identification of the gas couplings, and electrical connectors which are designed to block cross connections, providing a redundant security system in the connection operation.

To fulfill the performance and tightness requirements, defined by the harmonized standards listed in point 4, for different possible connections that provide the device, with a useful life of ten years.

Between the features we can find in these products there are;

- Medical Gases (Oxygen, Air, Vacuum)
- Lighting. (Ambient, night reading)
- Electrical sockets for the connection of medical devices. (With voltage and frequency as user requirements)
- Feeble signals, (Telephone, Data).
- Calling Systems. (Nurse, Doctor, Maid).
- Accessories Supports, (IV bag supports, Infusion pump supports, lamps, etc.)

6. Patient Target Group

The intended patient population consists of any human individual of any age and gender who suffers from an illness or disability that requires lying in a hospital bed that must have a panel in its vicinity for the supply of medicinal gases, vacuum, ambient and reading lighting and nurse call system.

7. Summary of safety and clinical performance

7.1. The identification of the device and the manufacturer, including the Basic UDI-DI, and the SRN.

Refer to point 3 above

7.2. The intended purpose of the device and any indications, contraindications and target populations.

- The intended purpose is defined in point 4,
- The target population is defined in 6 above.
- The device does not have any special indications and clinical benefit to be expected are described in point 5.
- The device does not have contraindications

7.3. Device description

The Oxigenoterapia Norte S.A. range of MAS-00257 bedhead panels is a safe, aesthetic and efficient means to fulfill the needs of the patients and medical staff.

The modularity and flexibility of the different characteristics allow user to access to products which satisfy the requirements of the equipment used in the different practices and also the aesthetic and functional needs of the patients, their families and hospital staff reducing the installation and maintenance jobs and consequently their costs.

Their main features are:

- Sturdy and modular design.
- Smooth external surfaces defined by gentle curves which ensure safety and cleaning ease.
- Totally built with aluminium extrusions designed by us.
- Installation flexibility for gases outlets and electrical services of different origins, (European or American).
- Isolated channels for different services, (gases, signals and electricity), see pic a.
- All the internal connections for gases, signals, alarms and electricity are factory made and tested.
- The fronts can be easily removed allowing maintenance and/or servicing jobs without having to affect the rest of the functions.
- Upper and lower indirect lighting features covered by a translucent faceted polycarbonate extrusion.

- Normalized 10 x 25 accessories rail, manufactured in anodized aluminium which supports most of the clamps used in the market.
- Easy installation thanks to the supplied support system
- Wide range of accessories.
- Most of the existing calling and alarm systems can be installed during the manufacturing process.
- Sound Level.
    - Audible Level: 64.9 dBA
    - Impulsive Level: 74.4 dBC
- The device complies with the electromagnetic emission and immunity tests and the rest of those specified by each standard in the following list defined in point 5.2.2.1 a) of the IEC 60601-1-2 Ed. 3.0 (2014) standard.

CISPR 11 Ed. 6.0 (2015) + A1 (2016) + A2 (2019)	Industrial, scientific, and medical equipment – Radio frequency disturbance characteristics – Limits and measurement methods.
IEC 61000-3-2 Ed. 5.0 (2018) + A1 (2020)	Electromagnetic compatibility (EMC) – Part 3-2: Limits. Limits for harmonic current emission (equipment with input current ≤ 16 A per phase).
IEC 61000-3-3 Ed. 3.0 (2013) + A1 (2017)	Electromagnetic compatibility (EMC) – Part 3-3: Limits. Limitation for voltage changes, voltage fluctuations, and flicker in public low-voltage power systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection.
IEC 61000-4-2 Ed. 2.0 (2008)	Electromagnetic Compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test.
IEC 61000-4-3 Ed. 4.0 (2020)	Electromagnetic Compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated radio-frequency electromagnetic field immunity test.
IEC 61000-4-4 Ed. 3.0 (2012)	Electromagnetic Compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient and burst immunity test.
IEC 61000-4-5 Ed. 3.0 (2014) + A1 (2017)	Electromagnetic Compatibility (EMC) – Part 4-5: Testing and measurement techniques – Immunity test to shock waves.
IEC 61000-4-6 Ed. 4.0 (2013)	Electromagnetic Compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity test to conducted disturbances induced by radio frequency fields.
IEC 61000-4-8 Ed. 2.0 (2009)	Electromagnetic Compatibility (EMC) – Part 4-8: Testing and measurement techniques – Immunity test to power-frequency magnetic fields.
IEC 61000-4-11 Ed. 3.0 (2020)	Electromagnetic Compatibility (EMC) – Part 4-11: Testing and measurement techniques – Immunity test to voltage dips, short interruptions, and voltage variations.

Bedhead Panels Family MAS-00257 are “Medical Supply Units”, with the possibility of vertical or horizontal installation to be mounted on or near to vertical surfaces, which may be solid or hollow (e.g., window frames).

These devices do not come with accessories they act only as an interface between gases and electricity hospital network and the devices to be used by heath professional.

The MAS-00257 is a family of configurable legacy bedhead panels which derive from a reference model which is the one that gives name to the family (leading device) featuring the same aluminium structure. The only distinction is the number of gas and electrical outlets, enabling us to cover them in one PSUR.

Additionally, the entire MAS-0257 is also called as the worst-case scenario (reference model), because it is equipped with a wide variety of gas and electrical power outlets in all possible designs, due to its complexity, no client would typically request this configuration, as it includes gas outlets and electrical sockets used in different markets. Nevertheless, since it has passed all the tests required by the applicable harmonized standards to validate its safety performance, we can claim that any other device derived from it, having a less complex equipment configuration, can also successfully pass the tests based on it. Then we are not obligated to conduct those tests on each device we manufacture with the same structural design, but with fewer features

7.4. Frequent Variants Required in the Market

GCR Panel with American gases outlets and Chile / Brazil / Italy electric sockets

Panel with American outlets and a combination of American and Chilean sockets GCR model

GCR Panel with AFNOR outlets and SCHUKO sockets.

Vertical GCRpanel with DIN outlets and Schuko sockets.

2 GCR channel panel with American outlets and Chilean and Schuko sockets

8. Possible diagnostic or therapeutic alternatives.

No Applicable.

9. Other Applicable Standards

The “Medical Supply Units” have been designed and manufactured under strict Quality and Safety standards. In particular they comply with the guidelines of the following standards:

- ISO 7396-1:2016 Piped medical gases distribution systems. Part 1: Terminal units for compressed medical gases and vacuum. + Amd1:2017
- ISO 9170-1:2017 Terminal units for medical gases
- ISO 11197:2019 Medical supply units.
- ISO 13485:2016 Sanitary Products, Quality Management Systems, Regulatory Requirements
- EN ISO 13485:2016/A11:2021 Sanitary Products, Quality Management Systems, Regulatory Requirements (Annexes ZA & ZB – Relationship between this European Standard and the Requirements of Regulation (EU) 2017/745 aimed to be covered)
- ISO 14971:2019 Medical Devices. Application of Risk management to medical devices.
- EN ISO 14971:2019/A11:2022 Medical Devices. Application of Risk management to medical devices. (Annexes ZA & ZB – Relationship between this European Standard and the Requirements of Reulation (EU) 2017/745)
- ISO 15223-1:2021 Graphical Symbols for use in the labelling of medical devices.
- ISO 19054:2005/Amd 1:2016 Rail systems for affixing medical equipment.
- IEC 60598- 1:2020 Lighting devices. Part 1: General requirements and testing.
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Electro medical equipment. Part 1: general requirements for safety.
- IEC 60601-1-2:2015+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
- IEC 62366-1:2015+AMD1:2020 Medical Devices Application of usability engineering to medical devices.
- Directive 2011/65/EU Restrictions in the use of certain dangerous substances in electrical and electronic devices (RoHs) amended in its Annex II by the Delegate Directive (UE) 2015/863
- In particular, the requirements of Regulation (EU) 2017/745

10. Summary of clinical evaluation and relevant information on post-market clinical follow-up;

The clinical evaluation based on the analysis of the collected and examined data from and Post-Market Clinical Follow-Up in our Last Periodic Safety Update Report PSUR-001 it was concluded that the device's benefit-risk profile has remained unchanged.

To enhance the reliability of the PSUR data based on the PMS report, we have incorporated a survey targeting a sample of users in domestic and international markets where our devices are sold. The survey was conducted using statistical methods to establish the sample size, its random selection process, and the results analysis technique.

The final PSUR results can be summarized as follows:

- All resultant device's performance indicators of our endpoints are lower enough and are statistically predictable and are under statistical control.
- As the analysis is related to the probability of faults during the lifetime of our devices, we have revalidated the lifetime obtained in 2014 of ten years.
- We could validate, using statistical tools, that our device can fulfill its intended use during its documented 10-year lifetime with adequate security and a favourable benefit-risk ratio, which is our most crucial target.
- Applying the well-known 80/20 rule, at the beginning of a device's life, 80% of faults are attributed to manufacturing errors, while only 20% are due to design errors. However, after several years of use, the situation has changed. Most failures are now attributed to design errors, as manufacturing errors are fixed during servicing activities. Then, based on the good results of the survey, the product design and usability can be revalidated.
- No new risks were detected based on hazardous situations based on wrong safety performance or intended purpose/use of the device, so there are no reasons for an additional updating of the Risk Analysis, PMS, CER reports of our QMS or the risk benefit balance which in that way would provide further clinical evidence support.
- We detected similar/equivalence devices already CE MDR certificated, the data is summarized in PMCF and CER reports.

11. Intended Users and Training Requirements

The intended users are health professionals with recognized academic and professional training; no additional training is specified.

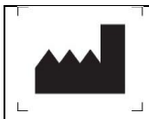
12. Any residual risks, contraindications, and any unwanted side effects, including information that should be conveyed to the patient in this regard. *(According to MDR Chapter III Section 23.4, bullet "g")***.**

Our bedhead panel does not have any contraindications or unwanted side effects and the information that should be conveyed to the patient in this regard are shown in the following points I-12.1 and I-12.2

12.1. Warnings or precautions that need to be taken and must be brought to the immediate attention of the device user and any other person, taking into account the intended user definition:

Some labels attached to device use the following alert symbols:

	Ground Connection		Equipotential Point
	Temperature Range		Use no Oil or Grease
	Date of manufacture		Risk of electrical shock
	Reading light		Do not mount on commonly
	"B" Type Applied Part		Maid Call
	Nurse Call		Read Instructions
	Alternating Current		Caution
	Authorized Representative in the European Community		Non-Sterile

	Manufacturer		Serial number

	Catalog number		Batch code
	Unique Device Identifier		CE Marking
	Medical Device		Country of manufacture
	Model number		

The user must also follow the following Advising and Warning Notes *(AWN)*

AWN1- Any serious incident that may occur in relation to the device shall be reported to Oxigenoterapia Norte and the competent authority of the member state in which the user and/or patient is established

AWN2- Since the device lacks a built-in electrical switch that isolates it from the electrical network, the network must furnish it with a safety disconnection system that includes fuses, a thermomagnetic switch, and a single-phase electrical differential switch with sufficient electrical selectivity to avoid interrupting the power supply to other areas of the hospital during a short circuit or electrical overload originating from the head panel. The fuses and the remaining electrical safe components must come from CE, UL, etc., manufacturers. No other requirements, such as the maximum permissible apparent impedance of the supply main, are required

AWN3- Connecting a medical electrical device (ME) to the panel forms an electromedical. system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connections.

AWN4 Please turn off electrical power before performing any maintenance activity.

AWN5 The panels must be frequently cleaned to remove dust and strange substances using a piece of cloth dampened in a solution of Sodium Hypochlorite in water at a 20% concentration. It is advised no using an ethanol, iodized bactericide substance or trichloroethylene for cleaning. After blowing or brushing, no additional cleaning is necessary inside the device during maintenance activities related to the durability of its electrical and electromagnetic parts

AWN6 Summary of symbol usage on labels attached to the device and in the advising and warning notes included in the instructions for use manual (IFU).

AWN7 It is recommended that the electrical integrity of the device components be checked at least once a year and that they not be exposed to high voltages exceeding the specified standard level for the country where the device was sold.

AWN8 Do not let the ground connection of the panel be disconnected (Its wire connection cross-section must be 4 mm²)

AWN9 The results of the production final checkouts regarding the device's electrical and gas quality levels are available upon explicit request from the customer and/or regulatory authorities for a minimum period of five years.

AWN10 The device's oxygen provision must be handled carefully and cautiously due to its chemical reactivity. It can be obtained through the proper use of gas connections without altering, eliminating, or forcing the indexed connection system provided. Other ambient risks can arise from the improper use of the other medical gas outlets supplied by the device.
Only plug in equipment that has a plug matching the outlets of the device's gas outlets; do not use adapters or interfaces.Do not force the gas connection on the wrong outlet because crossed connection of medical gases can result in fatal injury, therefore do not alter and/or eliminate the indexation system of the device gases outlets and the equipment connected to them.

AWN11 To avoid the obstruction of the vacuum outlets or the vacuum network of the hospital, loose hoses should not be left connected, unattended or open, to the vacuum outlets. If you use receptacles in operating rooms add 10/15 cm3 of water or ethanol in the bottle of the vacuum traps to avoid the filtration of powder to the outlets which may cause their obstruction and also keep the vacuum traps in good working order, to avoid their overflow causing fluids to pass to the vacuum outlet eventually clogging them. (Do not use the vacuum system as a domestic vacuum appliance)
The vacuum must be closed from the vacuum trap or the micrometric regulator once the procedure is finished.

AWN 12 All the device's circuit diagrams, components list and their description are available by explicit requirement of the customer and/or regulatory authorities, for a minimum period of five years.

AWN13 It is stated that the 10 x 25 accessories rail system is for light-weight use only. Ensure you do not exceed the maximum load of 40 kg per linear meter of rail and a maximum torque of 5 kgm per linear meter of rail, because due to the nature of the forces applied to the rail, its maximum capability is not only a result of the maximum allowed load per unit of length but is primarily influenced by the torque applied to the system as a whole. This tends to deform the structure, posing a consequent risk. To Determine the applied torque, follow these steps. Calculate or measure the distance from the front of the rail to the center of gravity of each of the loads expressed in meters. Weight each of the loads including the support system (monitor support, infusion pump support, IV bags holder, etc.), expressed in kg. Multiply each of the loads per their distances to the corresponding centres of gravity in order to obtain their torques. Add all the torques applied to each sector, determining their lengths. Finally verify that the former result does not exceed 5 kgm per linear meter of rail or equivalent fraction. Note: The aluminium structure of the device was designed with a safety factor of 2.5 to establish the allowable tensile stress, considering table 21 of the current standard IEC 60601-1 for a known load condition and for parts that are not exposed to wear.

AWN14 It is recommended that the device not be used in areas such as ICU, CCU, etc.

AWN15 As a result of the device risk management process, it is concluded that consulting the user manual has become a crucial risk control measure, making its consultation mandatory. Consequently, operating the equipment without reviewing the user manual, which serves as an essential accompanying document, presents a significant operational risk**.** *(Label SSP 286 attached to panel)*

AWN16 States that device installations must be done only by trained staff.

AWN17 This alerts users that when the device is installed outside a wall, it must follow the instructions and elements supplied for that purpose.

AWN18 Advises the installation staff to read standard ISO 7396-1 and states that the new installation point connections must be tested according to this standard.

AWN19 Alerts that gas pipes are not grounded.

AWN20 The lifespan of the product is 10 years, if you pretend to continue using the product beyond its lifespan, we recommend to send it to our factory for full inspection and refurbishing. At the end of its lifespan dispose of the unit and/or any of its components (packaging and electrical/electronic components included) according to the local regulations in force for the disposal of the different materials.

AWN21 States that the soldered connection points introduced during the installation must be checked.

AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities.

AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden.

AWN24 Alerts that an oxygen concentration greater than 25% produced by leaks can cause some materials to self-ignite, posing a fire risk.

AWN25 Alerts that, as the gas connectors have double valve cut-offs, installation and maintenance activities can be done without withdrawing them from the supply lines.

AWN26 Danger: Use no oil or grease in any gas outlet and/or pipeline, such practices imply the risk of fire or explosion.

AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. Do not introduce unauthorized electrical changes in the panel circuit.

AWN28 Alerts customer and installation staff that the device must be connected to an electrical power meeting the Volts and Frequency defined in the Stricker label attached to the device.

AWN29 The device should not be used with supply voltages and frequencies other than those specified by its manufacturer defined in the label attached to the device

AWN30 Using the device for a purpose not described by the manufacturer involves a risk for the patient and related third parties and for the durability of the equipment and its electromagnetic immunity. .

AWN31 The device must be connected to a supply main with a protective earth through a thermomagnetic and differential relay protected by fuses with adequate electrical selectivity to avoid domino effects in the hospital's electrical main in case of an electrical short circuit or overload. These protective devices must be UL or VDE certified or equivalent. Do not connect external appliances with a consumption of more than 10 amperes

AWN32 Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. Care should be taken when using ME devices with antennas or with long cables that can work like them, to prevent impacting the device's electromagnetic immunity

AWN33 Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device’s features, the customer must connect only a qualified ME to the panel with adequate ground connection.

AWN34 Electrical shock protection: Class I Operation Mode: Continuous.
Protection Grade against liquids entry: No protection.
Mobility Grade: Permanently installed. Protection Grade: Type B
Protection grade for flammable anaesthetic mixtures: No protection

AWN35 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm^2)

AWN36 Care must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 cm

AWN37 The distance from the illumination system to the floor must 1590 mm

AWN38 If the installation is not made directly on a wall, follow the instructions supplied with the product and use the elements supplied to that end

AWN39 According to specific standard IEC 60601-1-2-2015 The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

12.2. List of security labels attached to the device

STRIKER LABEL TO BE ATTACHED TO EACH HEAD PANEL	
Code	**DESCRIPTION**
SSP0049	Label next to LED small spotlight indicating the on/off condition of the nurse call system (on remote control)
SSP0050	Label next to LED small spotlight indicating the on/off condition of the maid call system (on remote control)
SSP0053	Indicates where the LED lighting, nurse call, maid, call is activated/disactivated (located in remote control)
SSP0054	Label next to LED small spotlight indicating the on/off condition of the calling system to go to the bathroom
SSP0071	Indicates the location of the ground connection and the equipotential reference of the equipment
SSP0085	CE Indication label of the equipment
SSP0093	Indicates the electrical connection location for the cardiac arrest call
SSP0094	Indicates the location for the equipment's electrical power outlet
SSP0095	Indicates the AC power locations with an indication of frequency, AC voltage, and maximum AC current.
SSP0097	Indicates the location of the electrical connection for the LED lighting system
SSP0100	Indicates the grounding bar
SSP0105	Indicates the maximum admissible pressure in Kg/cm2 in the equipment
SSP0106	Indicates where the cardiac arrest call is activated
SSP0108	Cancel button of calls
SSP0109	Indicates where an external phone can be connected
SSP0110	Tube LED electrical specification (8 / 16 w)
SSP0111	Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm
SSP0112	Indicates the location of the electrical connection for the nurse call
SSP0113	Indicates the connection of the line to the telephone to the device
SSP0253	Safe distance between bed and panel
SSP0281	Do not use oil in gas outlets
SSP0282	On/off switch of LED tubes (Light)
SSP0283	Customer Data Connections (RJ45)
SSP0284	For safe operation, it is **mandatory** to read the user manual.
SSP0285	Defines on electrical outlets the allowed maximum continuous output in amperes
SSP0286	Connecting a medical electrical device (ME) to the panel creates an electromedical system. From this resulting group, the customer must only connect to qualified ME (Electromedical Equipment) on the panel.
SSP0287	Do not introduce unauthorized replacement parts in maintenance repair activities

12.3. List of residual Risks

Following a thorough risk analysis and implementation of control measures, the following residual risks remain. These residual risks are communicated to users through relevant warning notes and safety labels, as outlined in the table below.

Code	***FAILURE MODES***	***RELATED WARNING NOTE CODES (AWN) AND SECURITY LABEL ATTACHED TO DEVICE CODES (SSP)***
S-5-1	*Inadequate supply of feeble/weak signals, data transmission, nurse calling system, etc., due to noise or interference from other energy and data supply sources.*	***a) The following warnings in the MAS-00257 IFU manual*** *related to electrical security were recently reviewed; almost all are applicable to this risk. - AWN15 Advise customer to read the IFU manual. - AWN4 Advise cutting off electrical power before doing any maintenance activity. - AWN7 Advise that the electrical integrity of the device components must be controlled at least once a year and that they should not be exposed to high voltages exceeding the specified level. - AWN2 State that all electrical circuits must be externally protected against short circuits and overloads by fuses and/or breakers according to specifications. - AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters. AWN16 States that device installations must be done only by trained staff. - AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities. - AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN32 Advise Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. AWN33 Advise that Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising th**e electromagnetic device's fe**atures, the customer must connect only a qualified ME to the panel with adequate ground connection. AWN32 Advise Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. AWN39 The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment* ***b) In turn for adding additional safet****y in each device, we attached the following labels: - SSP0071 Indicates the location of the ground connection and the potential reference of the equipment. - SSP00100 Indicates the grounding bar, - SSP0105 Indicates the connection of the line to the telephone to the device, - SSP0109 Indicates where an external phone can be connected. SSP0284 Defines that for safe operation is mandatory to read the manual, SSP0285 Defines on electrical outlets the allowed maximum continuous output in amperes SSP0286 State that connecting a medical electrical device (ME) to the panel creates an electromedical system. From this resulting group, the customer must only connect to qualified ME (Electromedical Equipment) on the panel. SSP0287 Advise do not introduce unauthorized replacement parts in maintenance repair activities*
S-5-2	*Unsuitable light flow (excessive or poor) that can disturb the patient or hinder the health professional work*	***a) The following Alarm/Warning notes in*** *MAS-00257 IFU manual are used to increase the security level. - AWN7 advises that controlling the electrical integrity of the device components at least once a year is necessary and that they should not be exposed to high voltages exceeding the specified level. - AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters - AWN16 States that device installations must be done only by trained staff.- AWN22 advises maintaining the integrity of the internal grounded connections-AWN27 advises that when a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN32 Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. AWN33 Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connection, AWN35 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm2), AWN36 Care must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 compare must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 cm, AWN39 According to standard IEC 60601-1-2 The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment* ***b) For safety in each device, we place the following labels,*** *- SSP0094 Indicates the location for the equipment's electrical power outlet, SSP0097 Indicates the location of the electrical connection for the LED lighting system, SSP0100 Indicates the grounding bar, SSP0110 Tube LED electrical specification (8 / 16 w) SSP0284 For safe operation, it is mandatory to read the user manual. SSP0285 Defines on electrical outlets the allowed maximum continuous output in amperes, SSP0286 Connecting a medical electrical device (ME) to the panel creates an electromedical system. From this resulting group, the customer must only connect to qualified ME (Electromedical Equipment) on the panel. SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities*
S-5-3	*Electromagnetic disturbances due to the use of LED lamps associated with photobiological effects or exposure to electromagnetic fields*	

Code	FAILURE MODES	RELATED WARNING NOTE CODES (AWN) AND SECURITY LABEL ATTACHED TO DEVICE CODES (SSP)
S-5-4	*The supports do not have the necessary mechanical resistance and stiffness that compromise the proper use and durability of the device*	***a) Alert and Warning Notes**: The AWN13 Advise / Warning Note in MAS-00257 IFU According to point 201,982 of standard 1197 Ed,4 029, it is stated that the 10 x 25 accessories rail system is for light-weight use only. Ensure you do not exceed the maximum load of 40 kg per linear meter of rail and a maximum torque of 5 kgm per linear meter of rail, because due to the nature of the forces applied to the rail, its maximum capability is not only a result of the maximum allowed load per unit of length but is primarily influenced by the torque applied to the system as a whole. This tends to deform the structure, posing a consequent risk. To Determine the applied torque, follow these steps. Calculate or measure the distance from the front of the rail to the center of gravity of each of the loads expressed in meters. Weight each of the loads including the support system (monitor support, infusion pump support, IV bags holder, etc.), expressed in kg. Multiply each of the loads per their distances to the corresponding centres of gravity in order to obtain their torques. Add all the torques applied to each sector, determining their lengths. Finally verify that the former result does not exceed 5 kgm per linear meter of rail or equivalent fraction. Note: The aluminium structure of the device was designed with a safety factor of 2.5 to establish the allowable tensile stress, considering table 21 of the current standard IEC 60601-1 for a known load condition and for parts that are not exposed to wear.* ***b) Safety Label** to be attached at each device: SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm, SSP0253 Safe distance between bed and panel, SSP0284 For safe operation, it is mandatory to read the user manual, SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities.*
S-5-5	*Noncompliance with regulations in force or safety specific requirements makes the intended use hazardous*	***a) Alarm/Warning notes** which can be found in MAS-00257 IFU manual are the following:AWN2 Since the device lacks a built-in electrical switch that isolates it from the electrical network, the network must furnish it with a safety disconnection system that includes fuses, a thermomagnetic switch, and a single-phase electrical differential switch with sufficient electrical selectivity to avoid interrupting the power supply to other areas of the hospital during a short circuit or electrical overload originating from the head panel. The fuses and the remaining electrical safe components must come from CE, UL, etc., manufacturers. AWN3-Connecting a medical electrical device (ME) to the panel forms an electromedical. system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connections.- AWN7 advises that controlling the electrical integrity of the device components at least once a year is necessary and that they should not be exposed to high voltages exceeding the specified level, - AWN10: The warning is related to the device's oxygen handling.- AWN11: Advice on how to avoid obstructions in the vacuum system. - AWN18: Advise the installation staff to read standard ISO 7396-1. - AWN19: Alert that gas pipes are not grounded. - AWN20: Alert installation staff that the new point connection must be tested. - AWN22 advises maintaining the integrity of the internal grounded connections. - AWN23: To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden.* *- AWN24: Alert that an oxygen concentration greater than 25% produced by leaks can cause the self-ignition of some materials, leading to a fire risk. - AWN 26: Advises use no grease or oil in any gas outlets to avoid fire risk. - AWV 27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN32 Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. AWN33 Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connection. AWN35 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm2), AWN36 Care must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 cm, AWN38 If the installation is not made directly on a wall, follow the instructions supplied with the product and use the elements supplied to that end, AWN39 According to specific standard IEC 60601-1-2-2015 The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment**b) Safety Labels:** SSP0285 Defines on electrical outlets the allowed maximum continuous output in amperes, SSP0286 Connecting a medical electrical device (ME) to the panel creates an electromedical system. From this resulting group, the customer must only connect to qualified ME (Electromedical Equipment) on the panel. SSP0287 Do not introduce unauthorized replacement parts in maintenance, SSP0094 Indicates the location for the equipment's electrical power outlet,SSP0100 Indicates the grounding bar, SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment, SSP0110 Tube LED electrical specification (8 / 16 w) SSP0253 Safe distance between bed and panel, SSP0281 Do not use oil in gas outlets.*
S-5-6	*It does to satisfy the intended use*	
S-5-8	*In the manufacturing process, parts and components that do not fulfill the requirements of the original design may be assembled.*	***a) Alert and Warning Notes** which can be found in MAS-00257 IFU manual.* *- AWN7 advises that controlling the electrical integrity of the device components at least once a year is necessary and that they should not be exposed to high voltages exceeding the specified level. - AWN22 advises maintaining the integrity of the internal grounded connections. - AWN23: To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden - AWV 27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN15 As a result of the device risk management process, it is concluded that consulting the user manual has become a crucial risk control measure, making its consultation mandatory. Consequently, operating the equipment without reviewing the user manual, which serves as an essential accompanying document, presents a significant operational risk. (Label SSP 286 attached to panel)* ***b) Security Labels:** SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities, SSP0284 For safe operation, it is mandatory to read the user manual., SSP0281 Do not use oil in gas outlets*
S-5-9	*Non-Compatible with the use in medical environments because some material will be noncompatible with medical gases or some of them will be degradable or contaminants*	***a) Alert/Warning notes** which can be found in MAS-00257 IFU manual. AWN15 As a result of the device risk management process, it is concluded that consulting the user manual has become a crucial risk control measure, making its consultation mandatory. Consequently, operating the equipment without reviewing the user manual, which serves as an essential accompanying document, presents a significant operational risk. (Label SSP 286 attached to panel), - AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden - AWV 27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected* ***b) We attached the following security labels** , SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities, SSP0284 For safe operation, it is mandatory to read the user manual.*

S-5-10	*Presence of Dangerous Substances in the materials.(RoHs)*	***a) Alarm/Warning notes*** *which can be found in MAS-00257 IFU manual.* *- AWV 27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected, AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden* ***b) Labels:*** *We also attached the following security labels: SSP0284 For safe operation is mandatory to read the user manual,*
Code	***FAILURE MODES***	***RELATED WARNING NOTE CODES (AWN) AND SECURITY LABEL ATTACHED TO DEVICE CODES (SSP)***
S-5-11	It can produce a final faulty product by using hazardous materials, using a wrong wiring design, and providing unacceptable accompanying documentation that will prevent the devices from meeting their intended purpose.	***a)*** *The following alert/warnings notes were included in the MAS-00257 IFU manual - AWN4 Advise cutting off electrical power before doing any maintenance activity, - AWN7 Advise that the electrical integrity of the device components must be controlled at least once a year and that they should not be exposed to high voltages exceeding the specified level, - AWN2 State that all electrical circuits must be externally protected against short circuits and overloads by fuses and/or breakers according to specifications. - AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters. AWN15 As a result of the device risk management process, it is concluded that consulting the user manual has become a crucial risk control measure, making its consultation mandatory. Consequently, operating the equipment without reviewing the user manual, which serves as an essential accompanying document, presents a significant operational risk. (Label SSP 286 attached to panel) - AWN19 Alerts that gas pipes are not grounded. - AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities. - AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. - AWN28 Alerts customer and installation staff that the device must be connected to an electrical power meeting the Volts and Frequency defined in the sticker label attached to the device, AWN32 Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. AWN33 Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connection. AWN34 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm2), AWN35 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm2), AWN36 Care must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 cm, AWN38 If the installation is not made directly on a wall, follow the instructions supplied with the product and use the elements supplied to that end, AWN39 According to specific standard IEC 60601-1-2-2015 The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment****b) Labels:*** *To add extra security, the following stickers label are installed on the device: - SSP094 Indicates the connection location for the equipment's electrical power outlet, - SSP095 Defines the frequency in Hz and the supply voltage in volts for the user, - SSP0097 Indicates the location of the electrical connection for the LED lighting system, - SSP0071 Indicates the location of the ground connection and the potential reference of the equipment, - SSP0100 Indicates the grounding bar, - SSP0105 Indicates the connection of the line to the telephone to the device, SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities, SSP0286 Connecting a medical electrical device (ME) to the panel creates an electromedical system, from this resulting group, the customer must only connect to qualified ME (Electromedical Equipment) on the panel.. SSP0285 Defines on electrical outlets the allowed maximum continuous output in amperes, SSP0286 SSP0110 Tube LED electrical specification (8 / 16 w)*
S-5-12	*Operative Failures*	***a) Alert and warning notes:*** *The MAS-00257 IFU manual included the following alarm/warning notes for the correct electrical use of the device.* *- AWN15 note advises the user to read the IFU manual carefully before using it, and the AWN15 note advises the installation staff to do the same. - AWN4 Advise cutting off electrical power before doing any maintenance activity. - AWN7 Advise that the electrical integrity of the device components must be controlled at least once a year and that they should not be exposed to high voltages exceeding the specified level. - AWN2 State that all electrical circuits must be externally protected against short circuits and overloads by fuses and/or breakers according to specifications.* *- AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters. - AWN16 states that the device installations must be done only by trained staff.* *- AWN19 alerts that these pipelines are not grounded. - AWN22 states that all the device's components are grounded, and their integrity must be protected. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN32 Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. AWN33 Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connection. AWN35 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm2). AWN36 Care must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 cm, AWN39 According to specific standard IEC 60601-1-2-2015 The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment* ***b) Safety Labels:*** *The MAS-00257 IFU manual included the following alarm/warning notes for the correct gas connections use of the device.* *AWN10 The warning is related to the device's oxygen handling and the correct use of gas connections without altering or eliminating the indexed connections system, AWN11 Advice on how to avoid obstructions in the vacuum system, leaving loose hoses connected to vacuum outlets and other related warning, AWN19 Alerts that gas pipes are not grounded. AWN21 States that the connection points introduced in the installation must be checked. AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden. AWN24 Alerts that an oxygen concentration greater than 25% produced by leaks can cause some materials to self-ignite, posing a fire risk. AWN25 Alerts that, as the gas connectors have double valve cut-offs, installation and maintenance activities can be done without withdrawing them from the supply lines. AWN26 Advises not to use oil or grease in any outlet to avoid fire risks.*

S-5-13	*Breakings, deformations and wear of rail to translate load*	***a) Alarm/Warning notes*** *which can be found in Annex 1 of the MAS-00257 IFU manual. - AWN13 Note Alerts the user that the supported rail was designed for light weight only the maximum load is indicated on the device ang give additional help to define the maximum torque for cantilever height conditions. AWN27 When a device component must be replaced for maintenance,* ***b) Safety Alerts: B) Safety Labels:*** *For safety in each device, we attach the following label: the SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm, SSP0253 Safe distance between bed and panel, SSP0284 For safe operation, it is mandatory to read the user manual.; SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities.*
Code	***FAILURE MODES***	***RELATED WARNING NOTE CODES (AWN) AND SECURITY LABEL ATTACHED TO DEVICE CODES (SSP)***
S-5-20	*Unsuitable Fixation or Installation in non suitable areas.*	***a) Alert and warning notes:*** *As explained, the Technical Office provides the assigned installation staff with all the necessary information regarding where to position a device and how to do so correctly from the very beginning of the installation process. Nevertheless, we added the following alert/warning notes to the MAS-00257 IFU manual: AWN15 Advice to installation staff to read the manual. AWN16 States that device installations must be done only by trained staff. AWN17 Alerts that when the device installation is not made on a wall, it must follow the instructions and elements supplied for that purpose. AWN18 Advises the installation staff to read standard ISO 7396-1 and states that the new installation point connection must be tested. AWN19 Alerts that gas pipes are not grounded. AWN21 States that the connection points introduced in the installation must be checked. AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities. AWN23* To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden. *AWN24 Alerts that an oxygen concentration greater than 25% produced by leaks can cause some materials to self-ignite, posing a fire risk. AWN25 Alerts that, as it is common, the gas connectors have double valve cut-offs, installation and maintenance activities can be done without withdrawing them from the supply lines. AWN26 Advises not to use oil or grease in any outlet to avoid fire risks.* ***b) Safety Notes:*** *And also the following label are attached to the device: SSP0253 Safe distance between bed and panel. SSP0281 Do not use oil in gas outlets SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment , SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities, SSP0285 Defines on electrical outlets the allowed maximum continuous output in amperes, SSP0284 For safe operation, it is mandatory to read the user manual.*

S-5-21	*a) Possible PMS feedback regarding gas and electrical failure modes.c) Does not meet the documented intended use.d) Claims associated with inadequate usability context.e) Failures mode related to a lack of final control or non-compliance with the ISO 7396-1 standard by third parties.f) Claims about electrical failures*	***a) Alert/Warning notes:*** *AWN3-Connecting a medical electrical device (ME) to the panel forms an electromedical. system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connections .AWN5 The panels must be frequently cleaned to remove dust and strange substances using a piece of cloth dampened in a solution of Sodium Hypochlorite in water at a 20% concentration. It is advised no using an ethanol, iodized bactericide substance or trichloroethylene for cleaning. AWN7 It is recommended that the electrical integrity of the device components be checked at least once a year and that they not be exposed to high voltages exceeding the specified standard level for the country where the device was sold. AWN10 "The device's oxygen provision must be handled carefully and cautiously due to its chemical reactivity. It can be obtained through the proper use of gas connections without altering, eliminating, or forcing the indexed connection system provided. Other ambient risks can arise from the improper use of the other medical gas outlets supplied by the device. Only plug in equipment that has a plug matching the outlets of the device's gas outlets; do not use adapters or interfaces. Do not force the gas connection on the wrong outlet because crossed connection of medical gases can result in fatal injury, therefore do not alter and/or eliminate the indexation system of the device gases outlets and the equipment connected to them. AWN11 "To avoid the obstruction of the vacuum outlets or the vacuum network of the hospital, loose hoses should not be left connected, unattended or open, to the vacuum outlets. If you use receptacles in operating rooms add 10/15 cm3 of water or ethanol in the bottle of the vacuum traps to avoid the filtration of powder to the outlets which may cause their obstruction and also keep the vacuum traps in good working order, to avoid their overflow causing fluids to pass to the vacuum outlet eventually clogging them. (Do not use the vacuum system as a domestic vacuum appliance). The vacuum must be closed from the vacuum trap or the micrometric regulator once the procedure is finished. AWN15 As a result of the device risk management process, it is concluded that consulting the user manual has become a crucial risk control measure, making its consultation mandatory. Consequently, operating the equipment without reviewing the user manual, which serves as an essential accompanying document, presents a significant operational risk. (Label SSP 286 attached to panel. AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities. AWN18 Advises the installation staff to read standard ISO 7396-1 and states that the new installation point connections must be tested according to this standard. AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden. AWN26 Advises not to use oil or grease in any outlet to avoid fire risk AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. Do not introduce unauthorized electrical changes in the panel circuit. AWN29 The device should not be used with supply voltages and frequencies other than those specified by its manufacturer defined in the label attached to the device AWN30 Using the device for a purpose not described by the manufacturer involves a risk for the patient and related third parties and for the durability of the equipment and its electromagnetic immunity. Care should be taken when using ME devices with antennas or with long cables that can work like them, to prevent impacting the device's electromagnetic immunity. AWN31 The device must be connected to a supply main with a protective earth through a thermomagnetic and differential relay protected by fuses with adequate electrical selectivity to avoid domino effects in the hospital's electrical main in case of an electrical short circuit or overload. These protective devices must be UL or VDE certified or equivalent. Do not connect external appliances with a consumption of more than 10 amperes AWN32 Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity. AWN33 Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connection. AWN35 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm2) AWN36 Care must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 cm AWN38 If the installation is not made directly on a wall, follow the instructions supplied with the product and use the elements supplied to that end.* ***b) Safety Notes:*** *In turn, the following safety stickers attached to each device may also be useful: SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment SSP0281 Do not use oil in gas outlets, SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities, SSP0284 For safe operation, it is mandatory to read the user manual.SSP0100 Indicates the grounding bar.*

Code	***FAILURE MODES***	***RELATED WARNING NOTE CODES (AWN) AND SECURITY LABEL ATTACHED TO DEVICE CODES (SSP)***
S-5-24	*Connection to network with wrong frequency and voltage in the customer site*	***a) The AWN notes and security label d****efined in Section S-5-12 are also applicable to this case; we will only highlight the most crucial ones for it: - AWN4 Advise cutting off electrical power before doing any maintenance activity. - AWN7 Advise that the electrical integrity of the device components must be controlled at least once a year and that they should not be exposed to high voltages exceeding the specified level. - AWN2 State that all electrical circuits must be externally protected against short circuits and overloads by fuses and/or breakers according to specifications. - AWN9 Advise to only plug in devices that meet electrical regulations without the use of adapters. - AWN15 Advice to installation staff to read the manual. - AWN16 States that device installations must be done only by trained staff. - AWN19 Alerts that gas pipes are not grounded. - AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities. - AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected.* ***b) Safety Labels.*** *To add extra security, the following stickers are installed on the device:* *- SSP094 Indicates the connection location for the equipment's electrical power outlet. - SSP095 Defines the frequency in Hz and the supply voltage in volts for the user. - SSP0097 Indicates the location of the electrical connection for the LED lighting system. - SSP0071 Indicates the location of the ground connection and the potential reference of the equipment* *- SSP0100 Indicates the grounding bar. - SSP0105 Indicates the connection of the line to the telephone to the device. - SSP0109 Indicates where an external phone can be connected*
S-5-25	*Lack of connections tightness.*	***a) For safety, the warning/alert notes and labels mentioned in*** *the previous point also apply to this risk (These are the more critical AWN notes for this point of those point out in section S-5-18 above, that are also applicable)* *- AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters. - AWN10 The warning is related to the device's oxygen handling and the correct use of gas indexed connections. - AWN11 Advice on how to avoid obstructions in the vacuum system. - AWN16 States that device installations must be done only by trained staff. - AWN21 States that the connection points introduced in the installation must be checked. - AWN23 Advises against using intermediate or unauthorized gas connections. - AWN24 Alerts that an oxygen concentration greater than 25% produced by leaks can cause some materials to self-ignite, posing a fire risk. - AWN25 Alerts that, as the gas connectors have double valve cut-offs, installation and maintenance activities can be done without withdrawing them from the supply lines. - AWN26 Advises not to use oil or grease in any outlet to avoid fire risks. -*

S-5-26	*Lack of indexation in the connections that can produce non conform supply of medical gases*	*AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected.* ***b) Labels** attached to the device: SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment.*
S-5-27	*Use for non intended uses or device use in medical procedures for which the product was not conceived*	***1) The following warnings/alert notes** in the user and maintenance manuals IFU Coded MBPU-001 and labels attached to device help on defining the medical, physical and chemical properties of the gases for which the device has been designed and correct use of the device:* *3) Warning/alert notes: Several of the AWN notes and Safety Labels listed in sections S-5-26 and 27 are applicable in this section. The more crucial ones are as follows:* *AWN3 Advise customer to read the IFU manual. AWN6 Show a summary of symbol usage in the label attached to the device and in the IFU manual. AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters. AWN10 The warning is related to the device's oxygen handling and the correct use of gas connections without altering or eliminating the indexed connections system AWN11 Advice on how to avoid obstructions in the vacuum system. AWN14 States that the device must not be used in areas such as ICU, CCU, etc. AWN16 States that device installations must be done only by trained staff. AWN17 Alerts that when the device installation is not made on a wall, it must follow the instructions and elements supplied for that purpose. AWN21 States that the soldered connection points introduced in the installation must be checked. AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden. AWN24 Alerts that an oxygen concentration greater than 25% produced by leaks can cause some materials to self-ignite, posing a fire risk. AWN26 Advises not to use oil or grease in any outlet to avoid fire risks.. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected.* ***2) Stricker labels**: SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm*
S-5-28	*Supply of gases at unsuitable pressures*	
S-5-29	*Lack of correct installation/maintenance*	***1) The following warnings/alert** notes in the user and maintenance manuals IFU Coded MAS-00257* *AWN7 Advise that the electrical integrity of the device components must be controlled at least once a year and that they should not be exposed to high voltages exceeding the specified level. AWN2 State that all electrical circuits must be externally protected against short circuits and overloads by fuses and/or breakers according to specifications. AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters. AWN10 The warning is related to the device's oxygen handling and the correct use of gas connections without altering or eliminating the indexed connections system AWN11 Advice on how to avoid obstructions in the vacuum system. AWN13 Defines the rail weighting resistance in kg and the resistant torque in kgm. AWN14 States that the device must not be used in areas such as ICU, CCU, etc. AWN16 States that device installations must be done only by trained staff. AWN18: Advise the installation staff to read standard ISO 7396-1. AWN19 Alerts that gas pipes are not grounded. AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities. AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden. AWN26 Advises not to use oil or grease in any outlet to avoid fire risks. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN28 Alerts customer and installation staff that the device must be connected to an electrical power meeting the Volts and Frequency defined in the Stricker label attached to the device* *2) Stricker labels: SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment. SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm. SSP0022 Recommendation label for the user not to force the indexed pneumatic connections. SSP0253 Safe distance between bed and panel. SSP0281 Do not use oil in gas outlets. SSP0094 Indicates the location for the equipment's electrical power outlet. SSP0095 Indicates the AC power locations with an indication of frequency, AC voltage, and maximum AC current. SSP0097 Indicates the location of the electrical connection for the LED lighting system SSP0071 Indicates the location of the ground connection and the equipotential reference of the equipment. SSP0100 Indicates the grounding bar. SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm. SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment. SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities, SSP0286 Connecting a medical electrical device (ME) to the panel creates an electromedical system. From this resulting group, the customer must only connect to qualified ME (Electromedical Equipment) on the panel. SSP0285 Defines on electrical outlets the allowed maximum continuous output in amperes SSP0284 For safe operation, it is mandatory to read the user manual.*

Code	***FAILURE MODES***	***RELATED WARNING NOTE CODES (AWN) AND SECURITY LABEL ATTACHED TO DEVICE CODES (SSP)***
S-5-31	*a) Connection to an incorrect gas line supply incompatible with the device's intended use.* *b) Internal flow of particles and bacteria may result from the device operating in a generally dirty state or improper use of the vacuum system.* *c) The gas supply is contaminated.*	***a) For safety, the following warnings/alert** note in the user and maintenance manuals, IFU Coded MAS-00257,.* *in AWN10 The warning is related to the device's oxygen handling and the correct use of gas connections without altering or eliminating the indexed connections system AWN11 Advice on how to avoid obstructions in the vacuum system, leaving loose hoses connected to vacuum outlets and other related warning. AWN3 Advise to only plug in devices that meet electrical regulations without the use of adapters. AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden AWN24 Alerts that an oxygen concentration greater than 25% produced by leaks can cause some materials to self-ignite, posing a fire risk. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN30 When the device is not in operation, to avoid the entry of particles and bacteria, keep it pressurized with gas.* ***b) Security Labels:** SSP0281 Do not use oil in gas outlets. SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment, SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities, SSP0284 For safe operation, it is mandatory to read the user manual.*

S-5-32	*Gas leaks at the outlet connections or at the internal connections of the device*	*a)* ***The following warnings/alert notes*** *and security labels are documented in MAS-00257 IFU manual: AWN10 The warning is related to the device's oxygen handling and the correct use of gas connections without altering or eliminating the indexed connections system. AWN21 States that the connection points introduced in the installation must be checked. AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden AWN24 Alerts that an oxygen concentration greater than 25% produced by leaks can cause some materials to self-ignite, posing a fire risk. AWN26 Advises not to use oil or grease in any outlet to avoid fire risks. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected.****Labels attached to the device:*** *SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment. SSP0022 Recommendation label for the user not to force the indexed pneumatic connections*
S-5-33	*Degradation of components (breaking rust, etc.)*	***a) Warning/alert notes in the IFU:*** *AWN30 Using the device for a purpose not described by the manufacturer involves a risk for the patient and related third parties and for the durability of the equipment. AWN28 Alerts customer and installation staff that the device must be connected to an electrical power meeting the Volts and Frequency defined in the Stricker label attached to the device. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN25 Alerts that, as the gas connectors have double valve cut-offs, installation and maintenance activities can be done without withdrawing them from the supply lines. AWN26 Advises not to use oil or grease in any outlet to avoid fire risks. AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden. AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities. AWN16 States that device installations must be done only by trained staff. AWN11 Advice on how to avoid obstructions in the vacuum system, leaving loose hoses connected to vacuum outlets and other related warning.* ***b) Labels attached to device.*** *SSP0095 Indicates the AC power locations with an indication of frequency, AC voltage, and maximum AC current. SSP0105 Indicates the maximum admissible pressure in Kg/cm2 in the equipment, SSP0284 For safe operation, it is mandatory to read the user manual. SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities.*
S-5-34	*Interference with other devices in the use environment.*	***a) The following warnings/alert notes AWN*** *defined in the user and maintenance manuals IFU Coded MAS 027: AWN13 Defines the rail weighting resistance in kg and the resistant torque in kgm. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected.* ***b) Labels attached to the device:*** *SSP00111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm. SSP0253 Safe distance between bed and panel, SSP0284 For safe operation, it is mandatory to read the user manual. SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities*
S-5-35	*Use after the specified lifespan*	***1) Warning/alert notes:*** *AWN16 States that device installations must be done only by trained staff. AWN20 Alerts that the device at the end of its lifespan must be disposed of according to regulations in force. .AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden. AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. AWN28 Alerts customer and installation staff that the device must be connected to an electrical power meeting the Volts and Frequency defined in the sticker label attached to the device.* ***2) Security Labels:*** *SSP0284 For safe operation, it is mandatory to read the user manual. SSP0287 Do not introduce unauthorized replacement parts in maintenance repair activities,SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm, SSP0095 Indicates the AC power locations with an indication of frequency, AC voltage, and maximum AC current, SSP0111 Indicates the maximum load on the front load rail in Kg and the maximum torque resistance in Kgm.*

13. The performance characteristic of the device. *(According to MDR Chapter III Section 23.4, bullet "e")*

The device's performance is defined according to its proposed use during its ten years documented life span, gathering a positive risk-benefit balance. To achieve this goal, the device´s design was carried out, tested, and validated according to the following standards:

General Standard:	IEC 60601-1 Ed. 3.0 (2005) + A1 (2012) + A2 (2020)
Specific Standards:	ISO 11197 Ed. 4 (2019)
Collateral Standards:	ISO 14971 Ed. 3 (2019) IEC 60601-1-6 Ed. 3.0 (2010) + A1 (2013) + A2 (2020) + IEC 62366-1 Ed. 1.0 (2015) + A1 (2020)

14. Information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories. *(According to MDR Chapter III Section 23.4, bullet "f", "h", and "i")*

- There are no residual risks, contraindications, or undesirable side effects, including the information to be conveyed to the patient regarding this matter. *(bullet "g")*
- Specifications the user requires to use the device appropriately, *(bullet "h")*
- The device does not have measuring functions *(bullet "h")*

Regarding electric devices, multiparameter monitors, defibrillators, infusion pumps and other standard equipment are usually connected to our panel.

The electric supply can provide a maximum AC of 10 amperes with an AC Voltage of 220 Volts which is equivalent to an AC total power of 2,20 KVA for each site with the following distribution strategy: 5 AC amperes (1,1 KVA) for general purposes that gives an electrical power reserve of 0,900 KVA to drive a defibrillator

Oxygen or medical air flowmeters or pressure regulators can be connected to the oxygen or medical air pipelines.

In turn vacuum regulators or vacuum traps can be connected to the vacuum pipelines.

Our device has been designed to work with the following pressure ranges:

Medical gas supply system / combination	***Rated distribution pressure range (kPa)***	***Distribution pressure range (kPa)***	***Test Pressure (kpa)***
Pipeline and/or pressure regulators for medical gases	*400 to 500*	*320 to 600*	*200*
Pipeline and/or flowmeters for medical gases	*400 to 500*	*320 to 600*	*200*
Vacuum pipeline and/or vacuum regulator or trap	*-40*	*-90 to -40*	*500*

- All the variables can be controlled with measurement class 5%.
- All these controls must be done by trained heath professional.
- The device after its installation can be used without any additional treatment. *(bullet "l")*

15. **The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer.** *(According to MDR Chapter III Section 23.4, bullet "k")*

    This information is given in Section II Installation Instructions and Section III Maintenance Instructions of this manual.

16. **Devices intended for use together with other devices and/or general-purpose equipment** *(According to MDR Chapter III Section 23.4, bullet "q")*

    These requirements are treated in next point I-20 of this manual.

17. **Safe alert to the user to use the device appropriately***(According to MDR Chapter III Section 23.4, bullet "h")*

    The Alert and Warning Note AWN 15 of this IFU states that as a result of the device risk management process, it is concluded that consulting the user manual has become a crucial risk control measure, making its consultation mandatory. Consequently, operating the equipment without reviewing the user manual, which serves as an essential accompanying document, presents a significant operational risk.

    Security Label SSP 286 attached to panel alert that connecting a medical electrical device (ME) to the panel creates an electromedical system, then the customer must only connect to qualified ME (Electromedical Equipment) on the panel.

18. **Warnings or precautions to be taken in order to facilitate the safe disposal of the device,** *(According to MDR Chapter III Section 23.4, bullet "v")*

    The Alert and Warning Note AWN 20 of this IFU manual states that the product's lifespan is 10 years. If the user pretends to continue using the product beyond its lifespan, we recommend sending it to our factory for full inspection and refurbishing. At the end of its lifespan, the final device disposal (and/or any of its components) must be done to meet local regulations in force for the disposal of different types of materials.

19. **Date of issue of the instructions for use, or if they have been revised, the date of issue and the identifier of the latest revision of the instructions for use;***(According to MDR Chapter III Section 23.4, bullet "y")*

    The IFU manual provides a list of applicable AWNs and another list for Safety Labels. The last revision identifier is the same as the IFU, so any change in these lists generates a new IFU level update definition.

20. **A notice to the user and/or patient related to any serious incident that occurred concerning the device use.;***(According to MDR Chapter III Section 23.4, bullet "z")*

    AWN1 alert user that any serious incident that may occur in relation to the device shall be reported to Oxigenoterapia Norte and the competent authority of the member state in which the user and/or patient is established (and also to DNV)

21. **The information needed to control the device installation to perform safely its intended purpose,** *. (According to MDR Chapter III Section 23.4, bullet "k")*

Considering that the device does not need consumable components or requirements of previous calibration, or special cleaning and disinfection control before its use, this IFU provides the following information, which was summarized from the information in section 12.2

AWN2- Since the device lacks a built-in electrical switch that isolates it from the electrical network, the network must furnish it with a safety disconnection system that includes fuses, a thermomagnetic switch, and a single-phase electrical differential switch with sufficient electrical selectivity to avoid interrupting the power supply to other areas of the hospital during a short circuit or electrical overload originating from the head panel. The fuses and the remaining electrical safe components must come from CE, UL, etc., manufacturers.

AWN3- Connecting a medical electrical device (ME) to the panel forms an electromedical. system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connections.

AWN5 The panels must be frequently cleaned to remove dust and strange substances using a piece of cloth dampened in a solution of Sodium Hypochlorite in water at a 20% concentration. It is advised no using an ethanol, iodized bactericide substance or trichloroethylene for cleaning.

AWN7 It is recommended that the electrical integrity of the device components be checked at least once a year and that they not be exposed to high voltages exceeding the specified standard level for the country where the device was sold.

AWN8 Do not let the ground connection of the panel be disconnected (Its wire connection cross-section must be 4 mm^2)

AWN16 States that device installations must be done only by trained staff.

AWN17 This alerts users that when the device is installed outside a wall, it must follow the instructions and elements supplied for that purpose.

AWN18 Advises the installation staff to read standard ISO 7396-1 and states that the new installation point connections must be tested according to this standard.

AWN19 Alerts that gas pipes are not grounded.

AWN21 States that the soldered connection points introduced during the installation must be checked.

AWN22 Advises maintaining the integrity of the internal grounded connections during installation or maintenance activities.

AWN23 To avoid the risk of fire, electric shock, and other hazards, such as gas leaks or electromagnetic compatibility, any change in the electrical and pneumatic device's integrity and the use of intermediate or unauthorized gas or electrical connections are forbidden.

AWN26 Danger: Use no oil or grease in any gas outlet and/or pipeline, such practices imply the risk of fire or explosion.

AWN27 When a device component must be replaced for maintenance, the specification of the one initially assembled in the factory must be respected. Do not introduce unauthorized electrical changes in the panel circuit.

AWN28 Alerts customer and installation staff that the device must be connected to an electrical power meeting the Volts and Frequency defined in the Stricker label attached to the device.

AWN32 Do not to use RF equipment and electromedical devices with long radiating cables or cellular devices closer than 30 cm from the panel to prevent impacting the device's electromagnetic immunity.

AWN33 Connecting a medical electrical device (ME) to the panel forms an electromedical system from the resulting group. To avoid compromising the electromagnetic device's features, the customer must connect only a qualified ME to the panel with adequate ground connection.

AWN35 When connecting a medical electrical device (ME) that requires an equipotential reference, the output marked with the following icon must be used. (Its internal wire cross section must be 4 mm^2)

AWN36 Care must be taken when using radiant medical electrical devices, they must be placed at a distance from the panel greater than 30 cm

AWN37 The distance from the illumination system to the floor must 1590 mm

AWN39 According to specific standard IEC 60601-1-2-2015 The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

22. Warnings or precautions to be taken in order to facilitate the safe disposal of the device. *(According to MDR Chapter III Section 23.4, bullet "v")*

The applicable warning is the Alert and Warning Note AWN20 that states:

The lifespan of the product is 10 years, if you pretend to continue using the product beyond its lifespan, we recommend to send it to our factory for full inspection and refurbishing. At the end of its lifespan dispose of the unit and/or any of its components (packaging and electrical/electronic components included) according to the local regulations in force for the disposal of the different materials

23. Warning to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established . *(According to MDR Chapter III Section 23.4, bullet "Z")*

The applicable warning is the Alert and Warning Note AWN1 that states:

Any serious incident that may occur in relation to the device shall be reported to Oxigenoterapia Norte and the competent authority of the member state in which the user and/or patient is established

24. No applicable bullets of MDR Chapter III Section 23.4:

Bullets from "l" to "p" are no applicable (except bullet "k"), and also bullets r, t, u, w, x aa

25. information that allows the user and/or patient to be informed of any warnings, precautions, contra- indications, measures to be taken and limitations of use regarding the device *(According to MDR Chapter III Section 23.4, bullet "s")*

This information is given in point I-12.2

26. Additional Warnings and Recommendations associated with the safety standards IEC 60601-1 Ed. 3.0 (2005) + A1 (2012) + A2 (2020) and ISO 11197 Ed. 4 (2019)

The previously defined advising and Warning Notes AWN 1, 2, 3, 8, 9, 12, 14, 15, 22, from 27, to 36, and Secure Labels SSP from 0284 to 0286 (yellow colored in both tables) can be considered to meet the requirements of the general standard IEC 60601-1 Ed. 3.0 (2005) + A1 (2012) + A2 (2020) requirements, as well as those of the specific standard ISO 11197 Ed. 4 (2019). However, we must add the AWN29 according to Section 5.2.1.2 of IEC 60601-1-2-2015:

The emissions characteristics of our equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment

II. INSTALATION INSTRUCTIONS

1. Warning and alerts note for installations activities.

The general user warning and alert notes for point I-12 of the instructions regarding panel usage are still valuable for installation activities, particularly those summarized below:

a) Device installation should be carried out by trained personnel.

b) The device must be connected to an electrical power source meeting the voltage and frequency specifications defined in the sticker label attached to the device

c) It is recommended that the installation personnel read this manual carefully to obtain an optimum and safe installation of the product

d) Avoid using oil or grease in any gas outlet or pipeline; such practices pose a risk of fire or explosion.

e) Before doing any servicing inside the panel, ensure you have cut off the electrical supply

f) Do not use pure ethanol or iodized-based bactericides for cleaning.

g) It is necessary to periodically control (at least once a year) the integrity and safety of the power circuit's components, replacing them if necessary. Do not expose them to voltages exceeding the product's specifications. If you have any doubts, please consult our customer service department

h) At the end of its lifespan dispose of the unit and/or any of its components (packaging and electrical/electronic components included) according to the local regulations in force for the disposal of the different materials

i) Crossed connections of medical gases can result in fatal injury. Only work with one gas line at a time and ensure the line identification is correct throughout the source pipeline. The tests for detecting crossed connections are described in iso 7396-3. in case of doubt consult our customer service department.

j) the internal gases pipelines in this product are part of a piping system for gases of medical use, therefore they are designed, built and tested complying in iso 7396-1, being all the requirements of this standard extensive to its installation. for more information about the testing requirements please refer in detail to the contents of the standard

k) The internal gas pipelines in this product are part of a piping system for gases of medical use. Therefore, they are designed, built, and tested complying with ISO 7396-1, with all the requirements of this standard being extensive to its installation. For more information about the testing requirements, please refer in detail to the contents of the standard.

l) The internal gas pipelines are not grounded because the external distribution pipelines for medical gases must be grounded upstream.

m) All the panel's internal connections have been factory tested; only test the new welding points you make. Withdraw any flammable component (plastic, rubber, etc.) from the welding zone.

n) All the components in the structure near the powered wires and connection terminals are properly grounded. Ensure the integrity of these connections is maintained during installation and maintenance operations.

o) Avoid using intermediate connectors or unauthorized connections, as they may lead to significant issues in the proper functioning of the described systems.

p) The device can be used in standard ambient conditions of pressure and temperature with a relative humidity level up to 75%. However, the AWN 15 alert and advice note recommends not using the device in areas such as the ICU, CCU, or equivalent. The maximum storage stack height is 12 meters, and the storage ambient specifications are the same as those for use.

2. Qualification of the Installation Staff

According to the country where the product is to be installed. The installation personnel must have knowledge of the local standards related to:

- Identification of pipelines for medical gases
- Requirements for the installation of pipelines for medical gases
- Medical vacuum systems (in general)
- Threads and valves for medical gases cylinders

They are also required to read this manual previous to installation

3. Installation details and recommendations.

All the internal connections for gases are made and tested at the manufacturing facility following the guidelines of EN ISO 7396-1 “Medical Gases Piped Distribution Systems, Part 1 Medical Gases and Vacuum Networks”.

The following chart indicates the minimum required parameters for this type of terminal units

WORKING PRESSURE [kPa]	TESTING PRESSURE [kPa]	TESTING FLOW [l/min]	MAXIMUM PRESSURE DROP [kPa]
400-500	320	40	15
400-500	320	200	70
700-1000	560	350	70
VACUUM	40 (+)	25	15

Likewise, all the internal connections for signals, alarms, and electricity are also factory-made and tested. The following chart indicates the maximum parameters foreseen for the electrical socket’s circuits, according to standard EN-60601-1: Electromedical Equipment requirements. Part 1: general safety requirements

Number of Sockets per Circuit	Wire Cross Sections and Terminal Connectors	WARNING SIGN	
		Maximun Capacity per Circuit (A)	Maximum Capacity per Socket (A)
1 to 2	1.5	16	According to Specification Per Brand and Network Voltage
3 to 6	2.5	25	
7 to 8	4	32	

a) Previous to Installation - Checklist

Previous to installation verify the integrity of the protective packaging of the product controlling:

- Complete origin identification.
- Uncut packaging tapes.
- Inexistence of re-taping.
- Evidence of bumps in the cover.
- Signs of humidity.
- Internal noises indicating the breakage or detachment of any element.
- Missing items according to shipment documents.

If you have any doubts, contact the freight company or forwarder in order to evaluate the damage and put the corresponding claim.

b) Wall Installation

MAS-0257 MODELS

- ✓ Verify that the condition, composition and position of the installation vertical surfaces corresponds to the requirements of the product, especially their flatness.
- ✓ Verify if the existing connections, regarding to their position, correspond to the requirements of the product, if not proceed to their correction previous to installation.
- ✓ Verify the correct dimension and identification of the medical gas's pipelines, if not proceed to the correction previous to installation.
- ✓ Verify the correct dimension, number and identification of the connection cables in general (power, lighting, calling, alarms, etc) in case of differences, proceed to the correction previous to installation.
- ✓ Place the package in the position indicated by the symbols on a horizontal, firm and safe surface.
- ✓ Cut the tapes closing the packaging and open it.
- ✓ Open the packaging box. Remove the internal protection elements, such as spacers, end cap protectors, etc.
- ✓ Separate the supplied fixation elements.

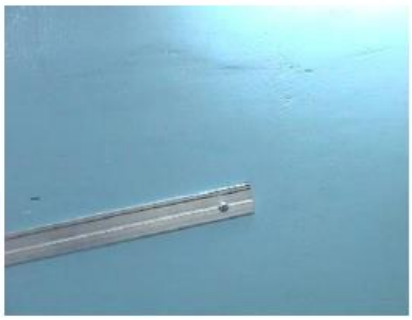
ONLY FOR HORIZONTAL MOUNTING (picture a)

- ✓ Remove the protective cover of the support profile.
- ✓ Select amongst the supplied fixation elements the ones suitable for the installation surface according to the following chart:

FIXATION	EXAMPLE	RECOMMENDED USE	DRILLING DIAMETER	EQUIPMENT TO MOUNT
NYLON PEG		MASONRY CONCRETE	**8 mm**	PANELS IN VERTICAL OR HORIZONTAL POSITION
SX NYLON PEG		MASONRY HOLLOW BRICK REINFORCED DRYWALL	**8 mm**	PANELS IN VERTICAL OR HORIZONTAL POSITION
TOGGLER BOLT		DRYWALL	**13 mm**	PANELS IN VERTICAL OR HORIZONTAL POSITION LIGHT CALL TERMINAL

- ✓ Identify or mark the referential axle of the connections.
- ✓ Place the support extrusion in reference to the axle, at the height indicated in supplied documentation.
- ✓ Proceed to mark on the wall one of the extreme perforations of the support.
- ✓ Drill and affix without tightening the support (picture 1), level the support using bubble level (picture 2) and mark the rest of the perforations of the support (picture 3).
- ✓ Turn the support extrusion without releasing it in order to drill the rest of the perforations.
- ✓ Put the support into position and fix it tightly.
- ✓ Withdraw the protective polyethylene wrapping just before installation

✓ Inspect the back part of the product in order to identify the position the openings and holes for connection and fixation (picture 4)



1

2

3

4

✓ Proceed to remove the panel fronts carefully in order to preserve their integrity and position (5,6,7)

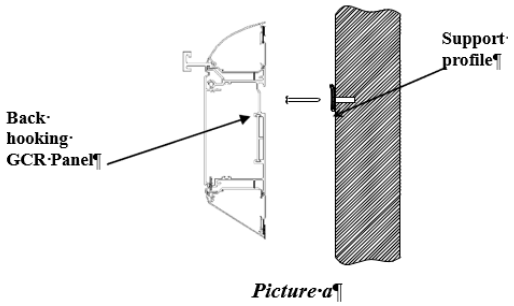
5

6

7

✓ Pass through the corresponding openings the gases pipes and electrical cables.

✓ Bring the panel near to the wall and hang it from the flange at the back side of the body by sliding the support profile inside it. (Picture “a” and pictures 8, 9)



Picture·a¶

8

9

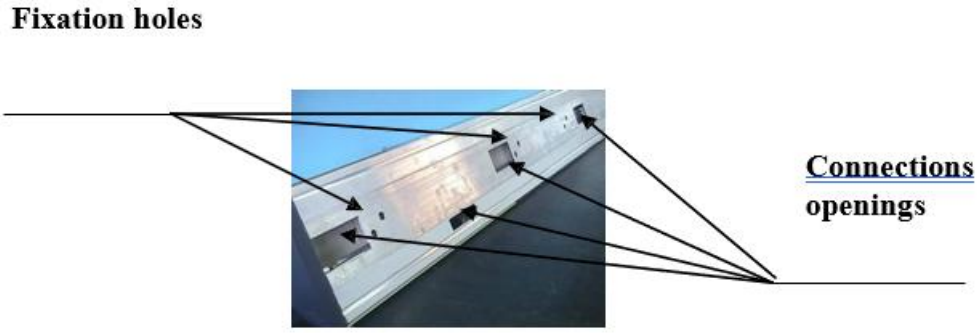
- ✓ Mark, drill and fix firmly the panel placing the fixations at not less than one per meter or section larger than 50 cm in length. (Picture 10)

10

- ✓ Control that the panel is properly fixed, firm and without movement with respect to the wall.
- ✓ Ensure you clean all possible dirt, specially inside the panel, that could have been generated during the operation.

c) Horizontal Mounting Without Support Profile

- ✓ Withdraw the protective polyethylene wrapping just before installation
- ✓ Inspect the back part of the product in order to identify the position of the openings and holes for connection and fixation. (Picture 11)



11

- ✓ Proceed to remove the panel fronts carefully in order to preserve their integrity and position. (Pictures 12, 13 and 14)

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14

- ✓ Place the panel against the wall matching the connection openings with their corresponding wall connections and then mark the fixation holes. Place a bubble level on top of the panel to ensure its perfect horizontal position. (Pictures 15, 16, y 17)

15

16

17

Bubble Level **Fixation Holes**

- ✓ Withdraw the panel, drill the wall and place the proper fixations in the wall.
- ✓ Place again the panel in mounting position. Pass through the corresponding openings the gases pipe and electrical cables. (Pictures 18 y 19)

18

19

- ✓ Proceed to fix the panel without tightening, using, if possible, one of the holes nearest to its axis.
- ✓ Level with a bubble level.
- ✓ Fix the panel firmly to the wall in that position, using for it the rest of the fixation holes if it is possible to drill the wall in those places without interfering with other existing networks (water, gas, etc.).
- ✓ Control that the panel is fixed, firm and without movement with respect to the wall.

- ✓ Ensure you clean all possible dirt, specially inside the panel, that could have been generated during the operation.

During installation activities, keep in mind the following advice notes:

AWN37 The distance from the illumination system to the floor must 1590 mm

AWN38 The installation is not made directly on a wall, follow the instructions supplied with the product and use the elements supplied to that end

d) Threaded Connections

- ✓ Close the check valve to cut the supply of the gas you want to connect.
- ✓ Withdraw the supplied nuts and bushings in the internal gas's connection points of the panel.
- ✓ Identify the wall pipeline corresponding to the same gas.
- ✓ Bend it avoiding the reduction of the cross section.
- ✓ Approach it to the end of the connector where you want to unite it.
- ✓ Mark, in order to cut the pipeline surplus, being careful to leave one more centimetre as the pipe should enter the connector.
- ✓ Cut and eliminate the burr if any.
- ✓ Thread the nut and bushing withdrawn previously.
- ✓ Insert the end of the pipe into the connector (picture 15), till you feel both pieces snug (Picture 16).

15

16

17

- ✓ Keep that position and hand tighten the nut the most you can. The nut should turn freely if the elements are correctly aligned. During this operation never use wrenches as you could possibly damage the threads of the connector or the nut if the alignment is not correct (picture 17).
- ✓ Once you are sure the elements are aligned, you can tighten the connection firmly using for that purpose wrenches of the proper dimension avoiding displacements along the axis of the connection which may cause leaks.
- ✓ Open the check valve.
- ✓ Insert a test connector in the outlet letting a small quantity of gas to flow freely in order to allow the filling of the pipeline and the connection up to the outlet.
- ✓ Verify the absence of leaks in the connection using for it a paintbrush soaked in soapy water.
- ✓ Correct, if necessary, till you obtain zero leaks
- ✓ Dry the zone carefully.
- ✓ Verify that all the outlets corresponding to the gases not yet connected do not have pressure/vacuum (absence of crossed connections).

- ✓ Verify that the gas output through the outlet is free and continuous, if not you may be in presence of an obstruction or clogging.
- ✓ Verify the correct coupling and operation of the outlets corresponding to the same gas.
- ✓ Proceed to identify the connected gas using a previously controlled portable oximeter. We want to make clear that we do not pretend an accurate measure but to identify the gas, taking into account that in the common medical use gases it is enough with the following:
    - Negative pressure: it is a medical vacuum pipeline.
    - Positive pressure: if the oximeter reads near to 100%, it is an oxygen pipeline, near to 21% it is a medical air pipeline.
- ✓ Repeat completely the former sequence till you complete the correct connection of all the gases.
- ✓ Close the front that covers the connection, taking into account that to place it correctly it must be inserted in a 45º angle inside the hinge at the body of the panel till it snuggles and then turn and close it.

e) Welded Connection

- ✓ Close the check valve to cut the supply of the gas you want to connect.
- ✓ Identify the wall pipeline corresponding to the same gas.
- ✓ Bend it avoiding the reduction of the cross section.
- ✓ Approach it to the end of the connector where you want to unite it.
- ✓ Mark, in order to cut the pipeline surplus, being careful to leave one more centimetre.
- ✓ Cut and eliminate the burr if any.
- ✓ Insert the end into the expansion supplied in the pipe inside the panel to connect till you feel both parts snuggle and then keeping the position weld with a strong silver welding complying with ISO 17672. (Pictures 18 and 19)

18

19

- ✓ Open the check valve.
- ✓ Insert a test connector in the outlet letting a small quantity of gas to flow freely in order to allow the filling of the pipeline and the connection up to the outlet.
- ✓ Verify the absence of leaks in the connection using for it a paintbrush soaked in soapy water.
- ✓ Correct, if necessary, till you obtain zero leaks.
- ✓ Dry the zone carefully.
- ✓ Verify that all the outlets corresponding to the gases not yet connected do not have pressure/vacuum (absence of crossed connections).
- ✓ Verify that the gas output through the outlet is free and continuous, if not you may be in presence of an obstruction or clogging.
- ✓ Verify the correct coupling and operation of the outlets corresponding to the same gas.

- ✓ Proceed to identify the connected gas using a previously controlled portable oximeter.

Note: We want to make clear that we do not pretend an accurate measure but to identify the gas, taking into account that in the common medical use gases it is enough with the following:

- Negative pressure: it is a medical vacuum pipeline.
- Positive pressure: if the oximeter reads near to 100%, it is an oxygen pipeline, near to 21% it is a medical air pipeline.

- ✓ Repeat completely the former sequence till you complete the correct connection of all de gases.
- ✓ Close the front that covers the connection, taking into account that to place it correctly it must be inserted in a 45º angle inside the hinge at the body of the panel till it snuggles and then turn it and close it

All panels are internally wired up to a connection terminal placed near the connection openings. The panels have equipotential ground terminals, etc.

Note; Ensure to previously cut the power from the board which powers the panel.

- ✓ Identify the conductors at the service entrance (power circuits, lighting circuits, grounds, etc.)
- ✓ Cut them at a suitable length (allowing an easy connection with a surplus of 15 cm)
- ✓ Withdraw the insulation at the wire's end (approx. 6cm) and proceed to its tinning.
- ✓ Insert each wire in the corresponding terminal (indicated in the sign near the terminal connector) according to the technical documentation supplied with the product.
- ✓ Tighten the fixation screw firmly, verifying that the connection has been properly made.
- ✓ Close the front that covers the connection being careful that when executing that task, no interferences are produced with the rest of the conductors hampering it
- ✓ Connect the electrical power to the panel verifying that:

  - Power Circuit: All the electrical sockets must have the corresponding voltage and are connected to the corresponding circuit using to that end a tester with the adequate capacity. If there is more than one power circuit, you shall feed one at a time, verifying that the voltage in the disconnected sockets is 0 V.
  - Lighting Circuit: Verify that all the lights supplied in the panel work correctly. If there is more than one illumination circuit, you shall feed one at a time, verifying that the lights connected to the disconnected circuits do not turn on.
  - If in this last step you verify any difficulty, proceed to check the cause and repair it.

f) Calling System and Alarms Connection

Previous to the connection of calling or/and alarms systems you must have already installed if corresponds, the call repeaters, the door lights and/or the bathroom calling systems according to the instructions of the manufacturer of such systems.

Once you have done that:

- ✓ Ensure to previously cut the power from the power board.
- ✓ Identify the conductors at the service entrance (calling system circuits or alarm system circuits.)
- ✓ Cut them at a suitable length (allowing an easy connection with a surplus of 15 cm)
- ✓ Withdraw the insulation at the wire's end (approx. 6cm) and proceed to its tinning.
- ✓ Insert each wire in the corresponding terminal (indicated in the sign near the terminal connector) according to the technical documentation supplied with the product.

- ✓ Tighten the fixation screw firmly, verifying that the connection has been properly made.
- ✓ Close the front that covers the connection being careful that when executing that task, no interferences are produced with the rest of the conductors hampering it
- ✓ Connect the electrical power to the panel verifying the proper operation of the systems according to the indications of the manufacturer.

g) Data and Telephone Connections

- ✓ Ensure to previously cut the power from the power board.
- ✓ Identify the conductors at the service entrance (telephony circuits or data circuits.)
- ✓ Cut them at a suitable length (allowing an easy connection with a surplus of 15 cm)
- ✓ Withdraw the insulation at the wire's end (approx. 6cm) and proceed to its tinning.
- ✓ Connect firmly to the sockets at the front of the panel
- ✓ lose the front that covers the connection being careful that when executing that task, no interferences are produced with the rest of the conductors hampering it.
- ✓ Connect the electrical power to the panel verifying that the systems work properly

h) Complimentary Introductory Training Course

Once the final operation tests are completed, a complimentary introductory training course will be given to the user staff, the maintenance staff and any medical personnel the Medical Institution may consider appropriate. Although the use of the device is very intuitive it must be used by personnel previously trained by the Medical Institution.

III. MAINTENANCE INSTRUCTIONS

1. Warning and alerts note for installations activities.

The general user warning and alert notes for point I-12 of the instructions regarding panel usage are still valuable for maintenance activities, particularly those summarized below:

a) An oxygen concentration greater than 25% produced by leaks in the gases system can provoke the self-ignition of some materials (such as synthetic fibers) or the propagation of a spark generated by an electrical circuit failure and/or its unproper operation (e.g.: unplugging a device without turning it off), with the consequent risk of fire near the panel and the resultant life risk.

b) As all gas outlets are supplied with a double valve system, it is not necessary to cut the gas supply to the panel or withdraw it for service.

2. Generalities

The Oxigenoterapia Norte range of panels has been designed to operate with a minimum periodical and routinely maintenance in order to ensure a reliable performance.

Competent maintenance personnel, used to work with medical gases, must have previously read this manual to perform these tasks which do not require more than a hand tools kit.

Be sure to have all the spare parts before you start the job

You must weekly verify the absence of leaks in the gas system, specially at their external connections.

In the presence of leaks, you must proceed to their repair according to the instructions given in this manual.

Periodically, according to the instructions of the manufacturer, you must replace all of the O-rings of the outlets.

3. Replacement of a defective outlet for gases of medical use.

To access the failed gas outlet component, you first need to remove the aluminium cover. Insert a fine flat-point screwdriver between the aluminium cover and the plastic cover, applying slight pressure to unhook and withdraw it. Take care not to damage the paint. (As shown in picture 13).

Then, you can either replace the failed component or repair it according to the manufacturer's instructions, which can be found on the manufacturer's website.

4. Replacement of components of the lighting system

Insert a fine point long screwdriver between the cover and the aluminium extrusion (as shown in picture 13, making a slight pressure, unhook and withdraw the cover. (Picture 13 and 14)

13

14

If the element to replace is the led tube, it is in sight. Be assured that the replacement tube has the same specifications as the one in the panel (voltage, Hz, CE mark, etc.).

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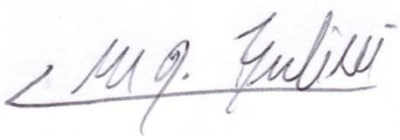
Written by:	Gustavo BARBIERI	
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