

ALFA-FIX
ALFA-FLEX
L88-LED-TW-M
GIMANORD-TW
PRIMA-FIX
PRIMA-FLEX

OPERATING MANUAL

LUMINAIRES FOR DIAGNOSIS

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Introduction

Please read this manual carefully and thoroughly before using the Product in order to protect the **“TECHNICAL SERVICE PERSONNEL”** and the **“OPERATOR”** from damage.

CE Marking

This device is a Class I medical device within the meaning of REGULATION (EU) 2017/745 concerning medical devices (Annex VIII) as amended and supplemented.

Compliance

The manufacturer declares that this Product is in conformity with Annex I (General Safety and Performance Requirements) of REGULATION (EU) 2017/745 as amended and supplemented by IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41 and documents this conformity by affixing the CE marking.

Manual validity

This manual is valid for the following models:

- ALFA-FIX
- ALFA-FLEX
- L88-LED-TW-M (GIMANORD-TW)
- PRIMA-FIX
- PRIMA-FLEX

Customer service

Customer service is at your disposal for clarification of the Product, its use, locating spare parts, for service and/or warranty issues, and for any other questions.

- RIMSA P. LONGONI SRL
- Via Monterosa, 18/20/22 - 20831 - Seregno (MB) - Italia
- Tel.: ++39 0362 325.709
- Fax: ++39 0362 328.559
- E-mail: info@rimsa.it

If the device causes the death or serious deterioration of the health of the patient and/or user, contact the manufacturer and the competent state authority where the event occurred.

Copyright

No part of this manual may be reproduced or translated without the written consent of RIMSA.

Translations

The original language of this manual is ITALIAN. For any translations, the original language of the manual shall prevail.

1 Legend

PRODUCT

The EM (electro-medical) EQUIPMENT to which this manual refers is a **LUMINAIRE FOR DIAGNOSIS**. For ease of description in this manual, this EM EQUIPMENT will be referred to as **“Product**.

OPERATOR

Professional medical personnel (e.g. professional health personnel, experienced patient caregiver).

RESPONSIBLE ORGANISATION

Entity responsible for the use and maintenance of EM equipment or an EM system (e.g. a hospital, an individual physician or an inexperienced person). Preparation and competence are included in the use.

TECHNICAL SERVICE PERSONNEL

Personnel (individuals or entities responsible to the RESPONSIBLE ORGANISATION) performing installation, assembly, maintenance or repair of the Product. In certain circumstances, their safety in accessing hazardous parts depends in part on their knowledge and competence to take appropriate precautions.

By way of example, but not limited to, the following professionals are considered TECHNICAL SERVICE PERSONNEL:

- Building Engineer, Surveyor, Building Contractor duly registered in the professional register (for construction work)
- Electrical Engineer, Electrical Technician qualified to practise as an electrician (for electrical works)

2 General safety information

This manual is an integral part of the Product as required by REGULATION (EU) 2017/745 as amended and supplemented. Please read and keep this manual close to the Product.



Risk of explosion.

The Product is not suitable for use in the presence of flammable anaesthetic agents.

RIMSA accepts no liability for any damage to persons or property resulting from the INSTALLATION/MANAGEMENT of the Product by anyone other than TECHNICAL SERVICE PERSONNEL or from the use of the Product by anyone other than the OPERATOR.

The installation of the Product is at the total expense and care of the RESPONSIBLE ORGANISATION; no burden or responsibility relating to the installation and/or commissioning of the Product can therefore be traced back to and/or in any way attributed to RIMSA.

The construction work to prepare the slab or wall, for Product to be installed on the ceiling or wall respectively, and the electrical work to prepare the electrical system to power the Product must be carried out in a solid and safe manner according to the rules of the art by the TECHNICAL SERVICE PERSONNEL.



Risk of electric shock.

To avoid the risk of electric shock, the Product must only be connected to a power supply network with protective ground.



Risk of electric shock.

The electrical layout of the room must comply with IEC 60364-7-710 and any national standards. A main switch with fuse protection or thermal-magnetic circuit breaker must be installed to ensure that the Product is de-energised.

3 Importance of personal safety

3.1 Intended use

LUMINAIRES FOR DIAGNOSIS

The Product is a medical device intended to be used in operating rooms within the OPERATING FIELD, with short-term duration, active, non-invasive, designed to locally illuminate the patient's body for treatments and diagnosis that can be interrupted without DANGER to the PATIENT in the event of a lack of light.

The optical radiation emitted by this Product complies with the exposure limits for reducing photobiological risk as specified by the IEC 60601-2-41 standard.

FIELD OF WORK

The Product provides good light intensity between 70 and 140 cm from the operating field.

3.2 Safety conditions (side effects)

Optical security

This product emits possibly hazardous optical radiation. Do not stare at the light emitted from the surgical luminaire. Eye injury may occur.

- Do not direct the light source into the eyes of the patient and OPERATOR.
- When the use of the Product is limited to the face (e.g. maxillofacial surgery, cosmetic surgery, ENT), it is mandatory to cover the patient's eyes with appropriate protection.



Possibility of glare and injury.

Failure to do so may result in glare and damage to the retina.

Electromagnetic interference

To avoid any significant risk of mutual interference due to the presence of the Product during specific examinations or treatments, please refer to the EMC declaration section in the user and maintenance manual.

Misuse

Do not place objects on the Product.

- Do not place and/or hang any object on the Product. Failure to comply with this prescription may cause objects to fall into the operating area.
- Do not cover the Product during operation to avoid overheating.
- Avoid collisions between parts of the Product or with nearby equipment. An impact may cause detachment of plastic parts or paint from the Product, which could fall into the operating field.

Undesirable effects due to overlapping light fields

Overlapping the light fields of several lamp heads could lead to a temperature increase in the operating field and thus to a risk of dehydration and/or tissue damage.



Possibility of dehydration and tissue damage.

In the case of reduced blood supply with the principle of tissue dehydration, reduce the light intensity.

Power Supply

To reduce the risk of burns, fire, electric shock, or injury to persons or animals:

- Use the power supply exclusively for its intended use as described below.
- Do not use outdoors; the power supply is intended for indoor use only.
- Do not allow it to be used as a toy. Pay special attention when the power supply is used by or near children.
- Use only accessories recommended by the manufacturer.
- Do not use the power supply if the cord or plug is damaged, if it has fallen or is damaged, or if it has fallen into water. In such cases, return the power supply to an authorized dealer or contact the service center.
- Do not drop or insert objects into openings.
- Do not use in the presence of spray products or where oxygen is administered.
- It is recommended to use the power supply near a convenient and easily accessible power outlet.
- Always unplug the power supply from the power outlet immediately after use.

3.3 Environmental conditions



Risk of explosion.

The Product is not suitable for use in the presence of flammable anaesthetic agents.

During operation:

- the ambient temperature must be between 10 °C and 40 °C;
- relative humidity must be between 30% and 75%;
- atmospheric pressure must be between 700 and 1060 hPa;
- the altitude must be less than or equal to 2000 m.

4 General Information

4.1 Qualification of employees

Qualification of personnel to carry out Product operations:

Installation

Qualified installer and/or technician.

Use

Professional medical staff.

Cleaning

Thoroughly trained medical and paramedical staff.

Ordinary maintenance

Qualified technician in possession of the technical-professional requirements.

Extraordinary maintenance

RIMSA or TECHNICAL SERVICE PERSONNEL.

Assistance

RIMSA or authorised dealer.

Disposal

Comply with current waste disposal regulations. This Product must not be disposed of in normal waste bins. To avoid risks to the environment and health resulting from the dispersion of pollutants into the environment, separate the various internal components (e.g. iron, aluminium, plastic and electrical material) and take them to the appropriate centres for proper recycling.

4.2 Target population and interactions

Target population

The intended use makes the Product suitable for any population without constraints of age, weight, health or medical conditions.

Patients may be awake or unconscious, under local or general anaesthesia.

The reference population can also consist of animals.

Patient interaction

An active patient can only touch the Product's lighthouse and swinging/pantograph arm accidentally, whereas such contact is excluded in the case of an unconscious or incapacitated patient.

Interaction with OPERATOR

The OPERATOR necessarily touches the Product's handle and keyboard, and occasionally the frame.

4.3 Packaging, transport, storage and installation site characteristics

Packaging

Cardboard boxes containing the Product. Dispose of in accordance with current national waste disposal directives.

Transport

Product is transported by ground, sea or air in accordance with the following specifications:

Temperature (°C): -15 / +60

Humidity (%): 10 / 95

Atmospheric pressure (hPa): 500 / 1060

Storage

Storage (warehousing) of the packaged Product must take place in a dry place and in compliance with the following specifications:

Temperature (°C): -15 / +60

Humidity (%): 10 / 95

Atmospheric pressure (hPa): 500 / 1060

Installation location

The room designated for Product application must have the following characteristics:

Temperature (°C): +10 / +40

Humidity (%): 30 / 75

Atmospheric pressure (hPa): 700 / 1060

4.4 Explanation of the graphic symbols used in this manual

To emphasise their importance, some safety precautions are highlighted using the graphic markers below. Safety measures must be observed during installation, use and maintenance of the Product.



General warning sign.



General mandatory behavioural signal.











Generic prohibition signal.

Follow safety precautions before using or servicing the Product. Strictly following safety precautions improves the ability to safely and properly use the Product and helps prevent improper maintenance that can be dangerous and cause damage. The safety measures are indicative but not exhaustive; the OPERATOR, the RESPONSIBLE ORGANISATION and the TECHNICAL SERVICE PERSONNEL must develop their own skills in order to improve and supplement them.






4.5 Graphic symbols used on packaging









Description of any graphic symbols on packaging boxes:

	Side up
	Fragile
	Shelter from the rain
	Maximum number of stackable boxes
	Humidity to be complied with (indicated in the upper right-hand corner as the maximum limit and in the lower left-hand corner as the minimum limit)
	Pressure to be adhered to (indicated in the upper right-hand corner as the maximum limit and in the lower left-hand corner as the minimum limit)
	Temperature limit (indicated in the upper right-hand corner as the maximum limit and in the lower left-hand corner as the minimum limit)
	Materials and composition

4.6 Graphic symbols used on the Product

Description of graphic symbols possibly present on the Product:

	CE marking proving the Product's compliance with REGULATION (EU) 2017/745 and subsequent amendments and integrations
	IMQ mark
	Date of manufacture (month and year)
	Manufacturer's address
	Follow the instructions for use

	Medical device
	Model reference
	Serial number
	Unique device identifier
	National representative
	Disposal
	CLASS II equipment
'N'	Connection point for neutral conductor
'L'	Connection point for line conductor
'I'	On
'O'	Off
	Stand-by and power on

5 Warnings for the Product Manager

5.1 Staff competence obligation

The RESPONSIBLE ORGANISATION must instruct the OPERATOR in the use, cleaning and maintenance of the Product. The instructions must be provided in written form on the basis of this manual.

5.2 Warranty and liability

RIMSA assumes no liability for unreliable operation of the Product if:

- The installation, authorised modifications and/or repairs are not carried out by TECHNICAL SERVICE PERSONNEL.
- The Product is not used in accordance with its intended use and with the user and maintenance manual.
- The room is not fit for use as a sanitary facility.
- The room is not constructed in accordance with the laws and/or regulations in force.
- The electrical installation of the premises does not comply with the appropriate regulations.

5.3 Checks to be carried out on Product before use



Carry out the electrical verification of the Product.

Before putting into service, carry out the electrical tests and the requirements specified in IEC 62353.

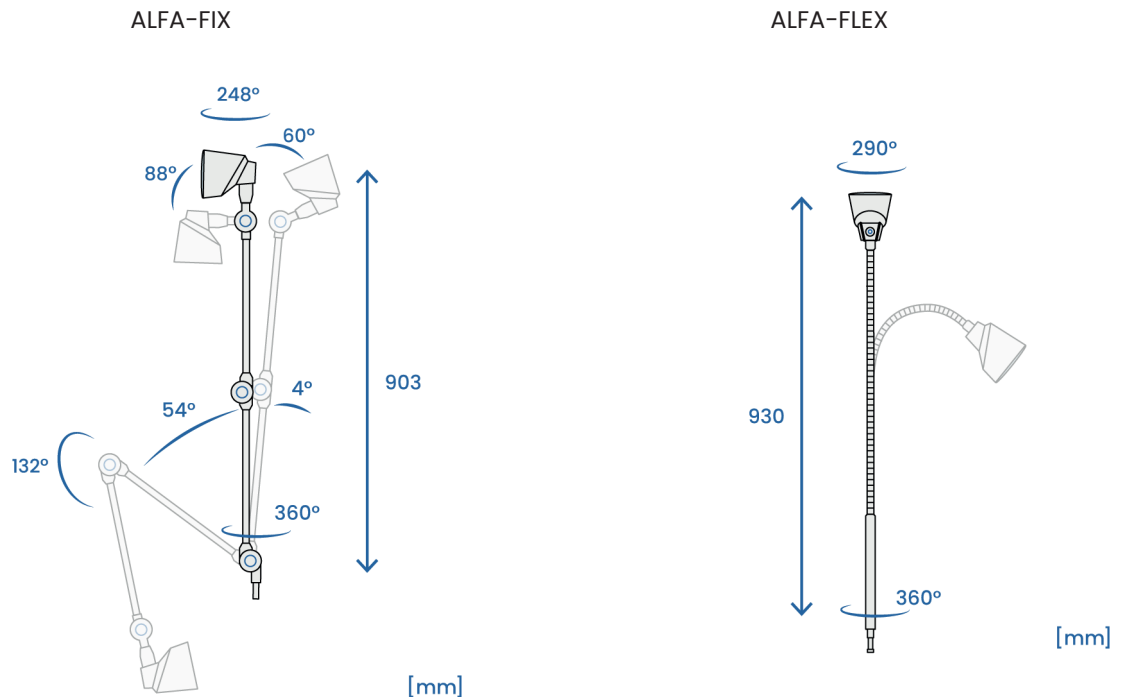
Before each use, in order to ensure Product safety and proper functionality, the OPERATOR must:

- clean/disinfect the Product in accordance with the provisions laid down by the competent national commission;
- check that the light emitted is stable and of adequate intensity;
- check that the lighthouse holds its position correctly;
- check that the swinging/pantograph arm holds its position correctly;
- check that there are no pieces or fragments of paint that can detach and fall onto the operating field. If they are present, remove them manually;
- check that the light source's protective shields are not damaged.

If one or more of these requirements are not met, please contact customer service.

6 Description and operation of the Product

6.1 Description and operation ALFA-FIX/ALFA-FLEX



The Product locally illuminates the patient's body thanks to the light produced by 3 LEDs focused through specific lenses. The positioning of the light beam is easy thanks to the articulated arm (present in ALFA-FIX) or flexible (present in ALFA-FLEX), and is performed manually.

On the reflector, there is a touch-sensitive key that allows turning the Product on/off and managing the light intensity. A short touch allows turning the lamp on and off; a prolonged touch, on the other hand, allows gradually increasing or decreasing the light intensity.

At the end of use, to turn off the Product safely, briefly touch the touch key; for disconnection from the network, unplug the power cord.

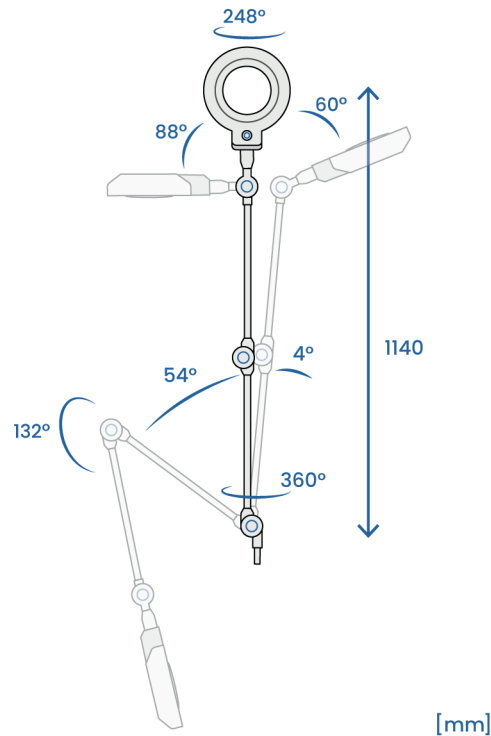


IMPORTANT: PRESS THE TOUCH KEY GENTLY!

To activate the intended functions, it is sufficient to touch the key lightly.

6.2 Description and operation L88-LED-TW-M (GIMANORD-TW)

L88-LED-TW-M (GIMANORD-TW)



The Product locally illuminates the patient's body thanks to the light produced by 256 LEDs protected by an acrylic profile. It is also equipped with a biconvex magnifying lens with a diameter of 120 mm and a magnification power of 3 diopters. The positioning is easy thanks to the articulated arm and is performed manually.

On the upper part of the reflector, there is a touch-sensitive key that allows turning the Product on/off, managing the light intensity, and selecting the desired color temperature:

- by briefly clicking the touch key, the Product turns on/off;
- with the lamp on, holding the touch key for a prolonged time adjusts the light intensity;
- with the lamp off, holding the touch key for a prolonged time adjusts the color temperature from 2700 K to 6000 K or vice versa. To reverse the direction of CCT change, briefly release the touch and press it again within 3 seconds. Once the desired CCT is selected, wait at least 3 seconds to save the setting.

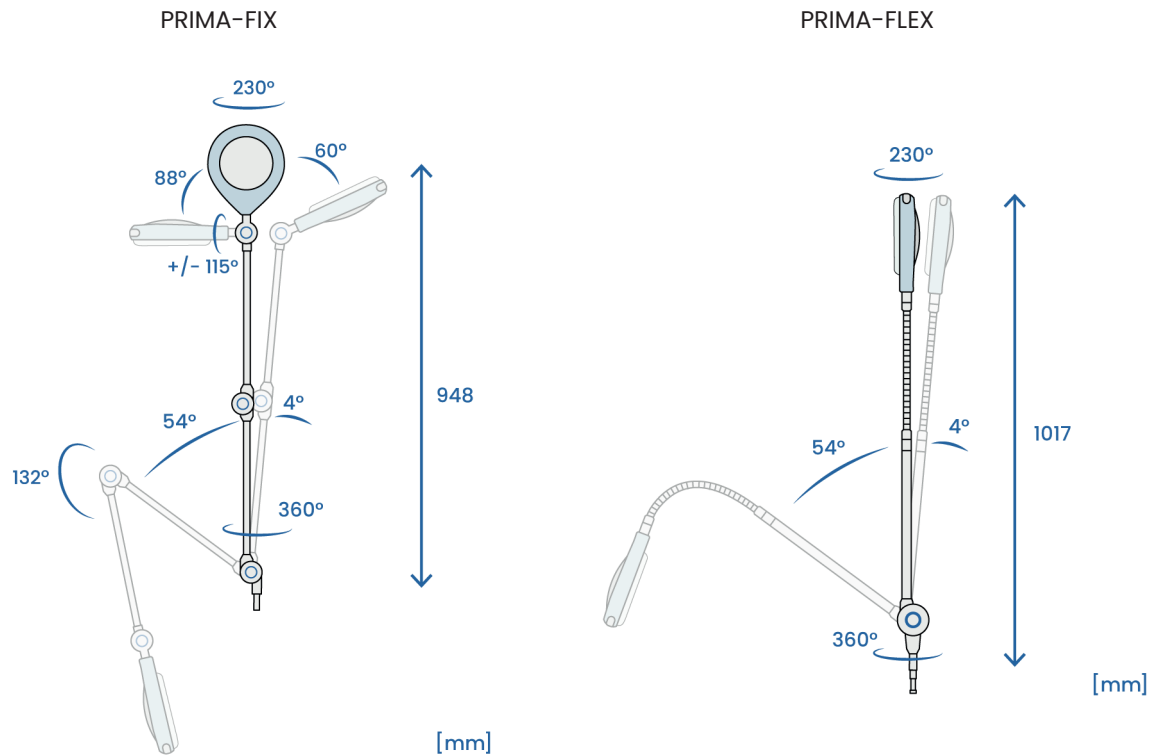
At the end of use, to safely turn off the Product, briefly touch the touch key; to disconnect from the network, unplug the power cord.



IMPORTANT: PRESS THE TOUCH KEY GENTLY!

To activate the intended functions, it is sufficient to lightly touch the key.

6.3 Description and operation PRIMA-FIX/PRIMA-FLEX

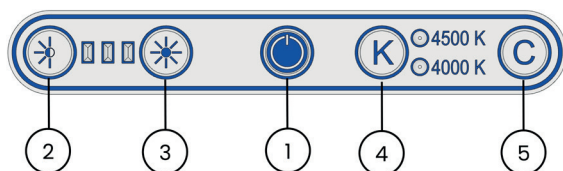


The Product locally illuminates the patient's body thanks to the light produced by 9 LEDs focused through specific lenses. There are also 3 non-focused LEDs to allow the use of courtesy or reading light. The positioning of the light beam is easy thanks to the articulated arm (present in PRIMA-FIX) or flexible (present in PRIMA-FLEX), and is performed manually.

The models PRIMA-FIX/PRIMA-FLEX are supplied with a sterilizable handle. To move the lamp, use the appropriate sterilizable handle.

To mount the handle, rotate it clockwise into the threaded hole located under the reflector until it reaches the stop and its rotation is locked.

By pressing the keys on the keyboard located on the reflector, the following functions can be adjusted:



- on/off via key (1);
- increase/decrease light intensity via keys (2) and (3), with display of the intensity level reached through 3 green position micro-LEDs;
- color temperature selection via key (4), with display through 2 green micro-LEDs;
- courtesy light selection via key (5), which allows the activation of the 3 LEDs without lens, not to be used for observation. To select it, the lamp must be off. In courtesy position, only the light intensity adjustment is allowed. To return to normal operating position, press key (1).

The light field is not adjustable.

At the end of use, to safely turn off the Product, press key (1); to disconnect from the network, unplug the power cord.

7 Accessories and Installation



Before proceeding with the installation phase, verify that all packages are present and in good condition, without transport damage, and that the contents match what is listed.



Claims are considered only if the seller or the shipper are immediately notified. Each claim must be made in writing. The goods always travel at the buyer's risk. Keep the original packaging in case there is a need to return the Product.

Depending on the usage needs, different support systems are available for the installation of the Product:

- S11 - clamp for table mounting
- S12 / S12 MED - clamp for vertical mounting
- Z400075 + Z400819 - rail bar + clamp for wall mounting
- RLBI - mobile version with locking system
- RLALFA (only for model ALFA-FLEX) - mobile version with locking system

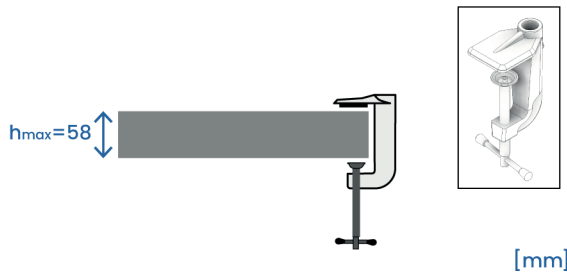


Do not position the Product in such a way that it is difficult to reach and unplug the power cord in case of emergency.



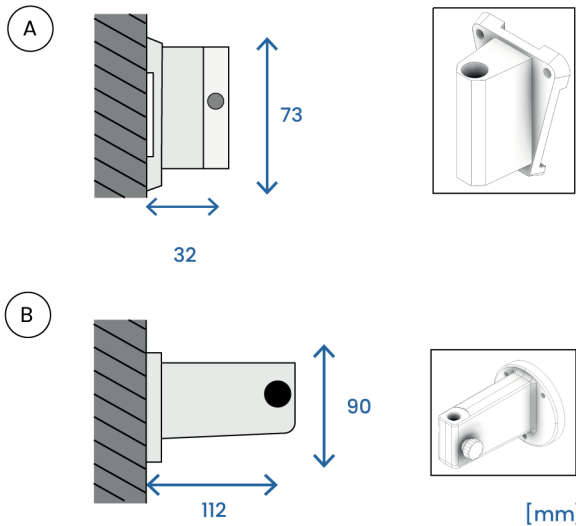
To avoid the risk of electric shock, the Product must be connected only to power networks with protective ground.

7.1 S11 - clamp for table mounting



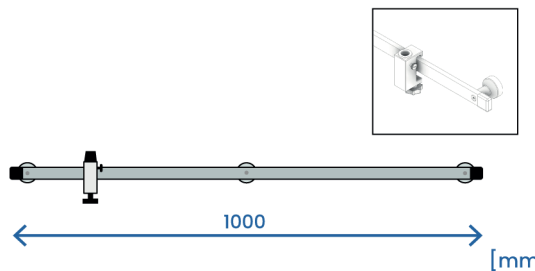
- Attach the S11 clamp to the table by tightening the threaded pin.
- Insert the lamp into the hole located at the top of the S11 clamp.
- With the aid of a screwdriver, tighten the screw on the back of the clamp.

7.2 S12 / S12 MED – clamp for vertical mounting



- Attach the S12 (A) / S12 MED (B) clamp to the wall with 3 expansion screws. RIMSA does not provide the screws.
- The wall must be load-bearing and constructed of solid bricks. Installation on hollow bricks and drywall is allowed only with the application of a plate on the opposite side of the wall (sandwich closure). RIMSA suggests using M5 screws.
- Insert the lamp into the hole located at the top of the S12 (A) / S12 MED (B) clamp.
- Tighten the threaded knob ensuring it fits into the groove of the lamp pin to prevent accidental dislodging.

7.3 Z400075 + Z400819 – rail bar + clamp for wall mounting



- Secure the rail bar as per the instructions provided below. Then insert the clamp onto the bar and tighten the lower knob.
- Insert the lamp into the hole located on the clamp. Tighten the threaded knob, ensuring it fits into the groove of the lamp pin to prevent accidental dislodging.

Safety instructions

- It is advisable to check the wall supports of the Bar every six months. It is also recommended to check the tightening of the support screws. Any technician or medical personnel who has read the next section can perform this operation.
- The maximum applicable load is 25 kg/m evenly distributed.
- The maximum torque moment is 80 N/m.
- The bars installed on the wall can withstand a vertical force of 150 N and a tensile force of 150 N applied simultaneously, without breakage or permanent deformation of the bar or any of its components.
- The maximum distance between spacers is less than the recommended maximum of 60 mm.

Supplied parts



Before proceeding with the assembly of the Product, ensure that the packaging is in good condition and without damage due to transport. Claims are considered only if the seller or the shipper is immediately notified. Each claim must be made in writing. Goods always travel at the risk and peril of the buyer. Keep the original packaging in case it is necessary to return the Product.

The package contains the following parts:



n.1 Z400075 - rail bar with rubber caps at the ends



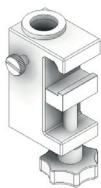
n. 3 spacers for accessory rail bar



n.3 M6 steel screws



n.3 wall plugs Ø12 mm



n.1 Z400819 - clamp

If even one component is missing, contact customer service immediately.

Assembly procedure



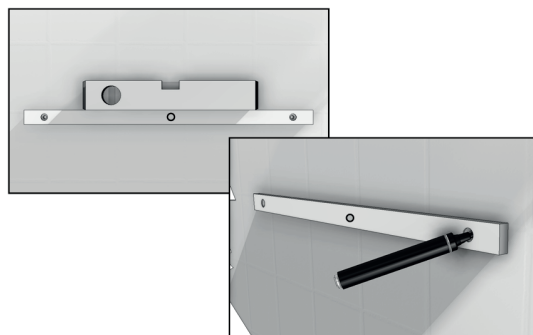
Before proceeding with the assembly, verify that the wall is load-bearing and made of solid bricks. Installation on hollow brick and drywall walls is allowed only with the application of a plate on the opposite side of the wall (sandwich closure).

1



Take the Rail Bar and position it at the desired height corresponding to the established fixing point.

2



Use a level to check the parallelism of the Bar and, using a marker, mark the points corresponding to the fixing holes.

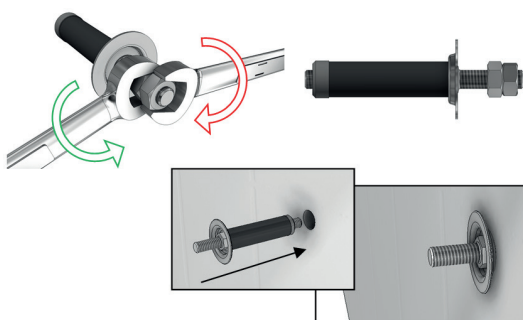
3



Use a drill to make three holes corresponding to the two marks.

Diameter and depth of holes: diameter 12 mm, depth 55 mm.

4



Take the anchor plugs and tighten the nut and locknut provided together. Then insert the plugs into the newly drilled holes, ensuring the washer is flush with the wall.

5



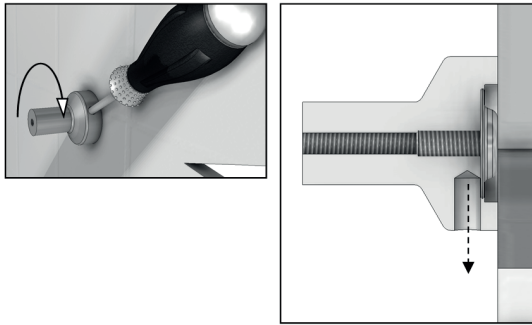
Using a wrench, turn the locknut clockwise to secure the anchor inside the hole. Then, unscrew and remove the nut and locknut.

6



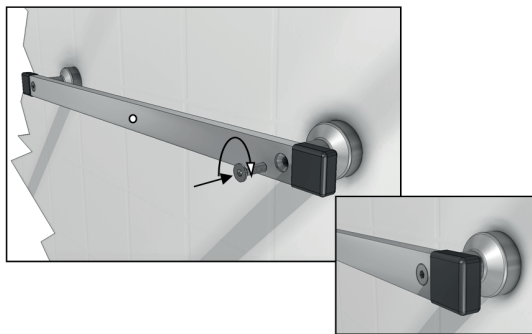
Take the rail supports and, after applying a drop of LOCTITE threadlocker on the threaded pins of the anchors, screw them onto the pins (use a screwdriver or pin inserted into the support's hole to assist).

7



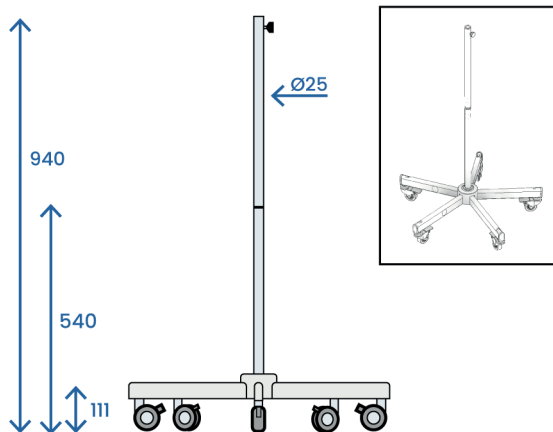
Tighten the supports until they are well secured; then continue rotating until the support holes are facing downward.

8

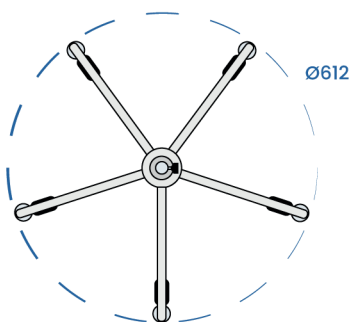


Take the Rail Bar and position it so that the mounting holes align with those of the supports. Slightly screw in the two mounting screws to center the bar on the supports; then fully tighten the screws.

7.4 RLBI / RLALFA - base with locking system



- Assemble the mobile version as per the instructions below.
- Then insert the Product into the hole located at the top of the mobile version rod.
- Tighten the threaded knob ensuring it fits into the groove of the lamp pin to prevent accidental dislodging.



[mm]



In the mobile version, engage all 5 wheel brakes during the operation of the equipment to ensure stability.



Do not hang on the Product with your weight. Do not climb, hang, lean, push, or lie on the Product. Failure to comply with this prescription may lead to damage to the Product, nearby devices, and personnel present.

Supplied parts



Before proceeding with the assembly of the Product, ensure that the packaging is in good condition and without transport damage.

The package contains the following parts:



n.5 100381 / 100382 - spoke



n.5 Z401148 - wheel with pin and brake



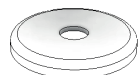
n.1 100361-R9003L - white central tube



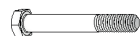
n.1 101552 - cross cover



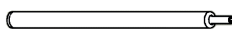
n.2 Z400812 - galvanized washer



n.2 100397-ZI - galvanized cap



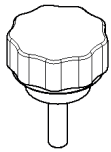
n.1 Z400813 - galvanized screw M12x90



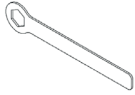
n.1 100612 - lower RL rod



n1 100611 - upper RL rod



n.1 101421 – knob with pin



n.1 100411 – hex key size 18

If even one of the components is missing, contact customer service immediately.



It is recommended to position yourself on a large, flat surface and place a cloth or bubble wrap to avoid scratching/damaging the already painted parts during assembly.

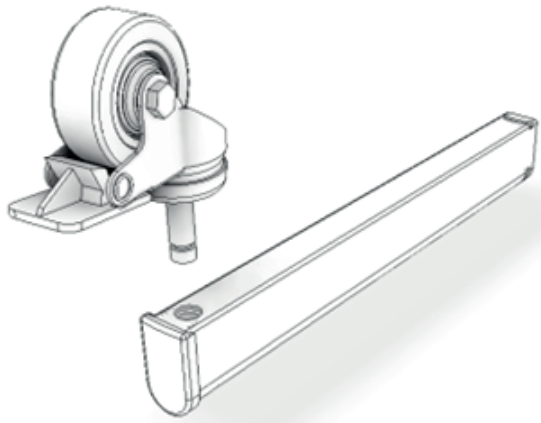


To assemble the Product, only one person is needed; the necessary tools are a hex key size 18, provided with the base, and a hammer. Follow these instructions carefully.

Assembly procedure

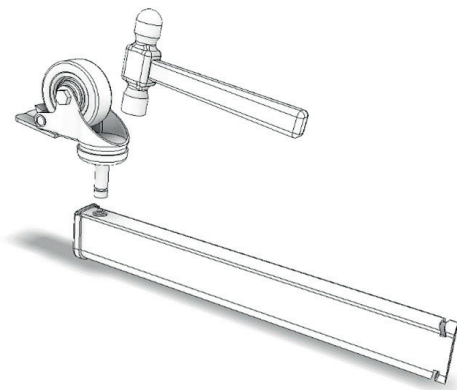
Assembly of the base of the mobile version

1



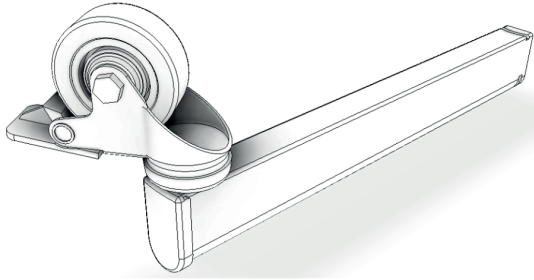
Place the spoke on a flat surface with the hole facing upwards. Position the wheel pin in the hole of the spoke.

2



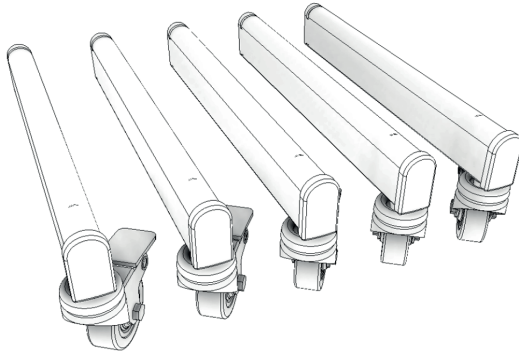
With the help of a hammer, secure the wheel pin into the spoke, aiming at the edge of the wheel as shown in the figure.

3



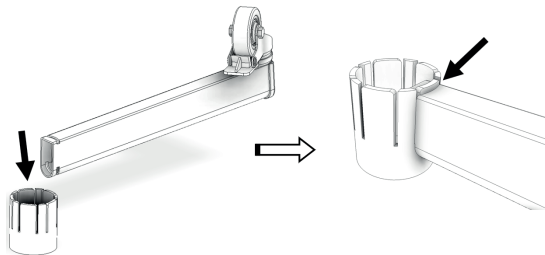
For correct insertion, you should hear the “CLICK” of the pin engaging in the spoke. Proceed with the other 4 wheels.

4



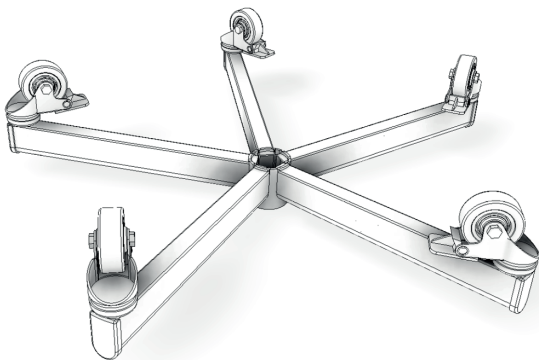
WARNING: Ensure that each wheel is firmly inserted into the spoke and that all wheels are free to rotate.

5



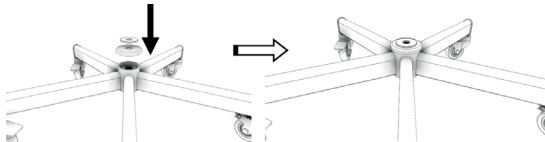
Slide the spoke with wheel onto the central tube at the groove. Proceed with the other 4 spokes.

6



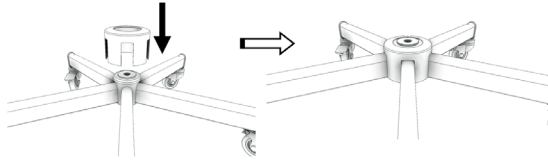
WARNING: Ensure that each spoke is inserted all the way into the groove of the tube.

7



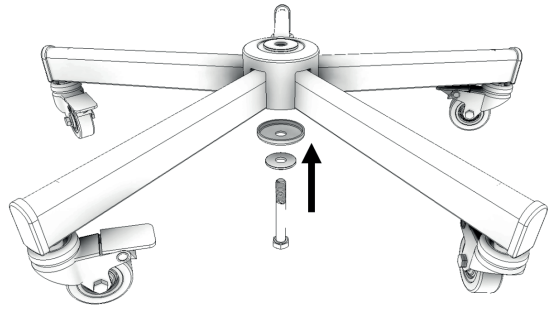
Turn the mobile version over and first insert the cap and then the washer on the end of the tube.

8



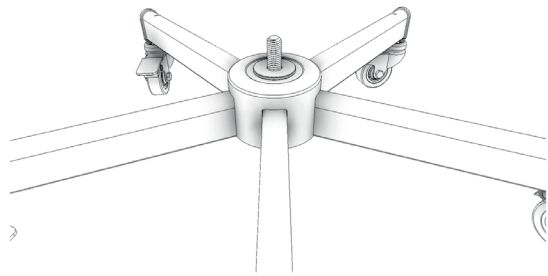
Position the cross cover and slide it onto the mobile version.

9



Slide the washer and cap onto the galvanized screw M12x9. Then insert the screw into the hole at the center of the base from bottom to top.

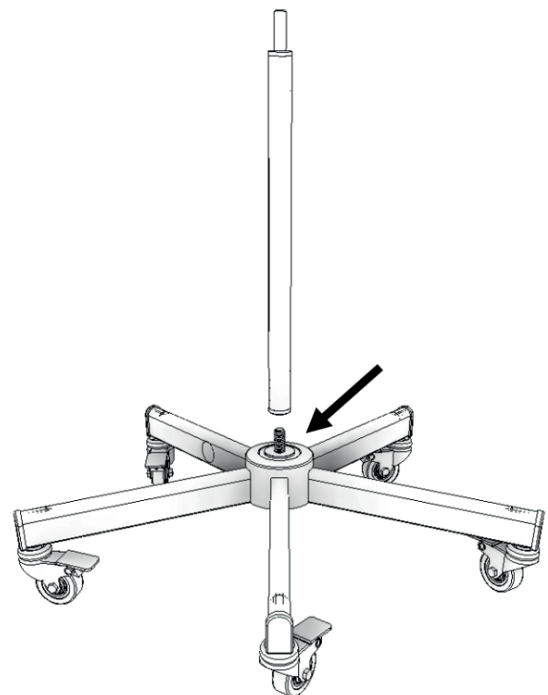
10



WARNING: The galvanized screw M12x90 must pass through washer, cap, tube, cap, and washer as shown in the figure.

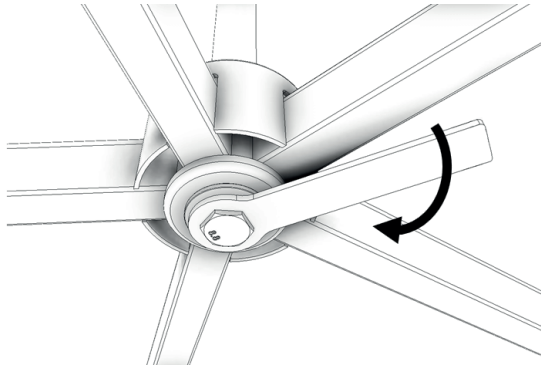
Assembly of the stems

11



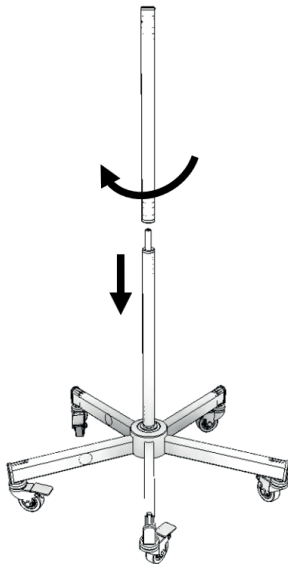
Now position the lower stem of the mobile version at the M12x90 screw.

12



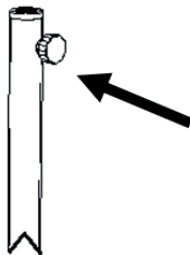
Hold the lower stem of the mobile version steady and tighten the M12x90 screw with the help of the hex key, ensuring it is fully seated.

13



Position the upper stem on the lower one and screw it until fully seated.

14



Screw the knob with pin onto the side hole of the upper stem.

15



WARNING: Verify that the stem is tightly secured and that the mobile version is stable and parallel to the floor. Ensure that all wheels rotate freely.

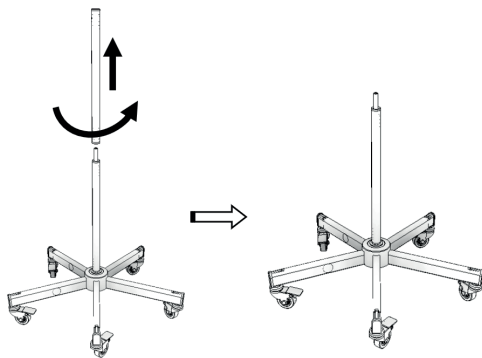
Optional: power supply support plate

Upon request, to facilitate the movement of the Product installed on the mobile version, an accessory can be added to allow the support of the power supply.



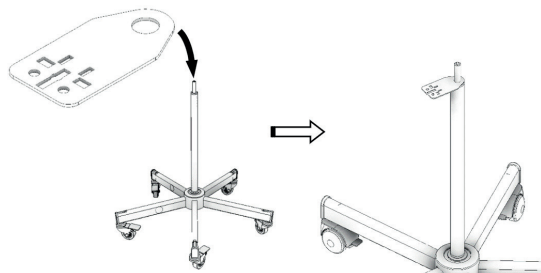
To assemble the Product, only one person is needed, without the necessity of additional tools. Strictly adhere to these instructions.

1



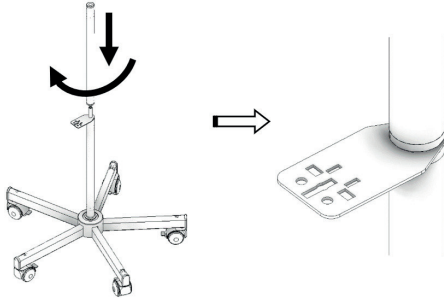
Unscrew and remove the upper stem.

2



Take the plate and insert it onto the fixing screw of the upper stem.

3

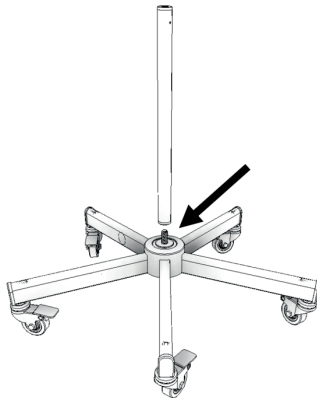


Screw back and secure the upper stem, locking the support plate.

7.4.1 Application in gynecology and podiatry

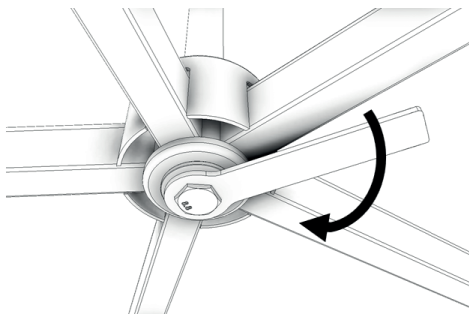
Using only the upper base stem, the lamp is also applicable in gynecological and podiatric fields as it reaches a lower height that facilitates movement and direction.

1



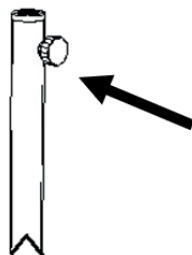
After assembling the base, position the upper base stem in correspondence with the M12x90 screw.

2



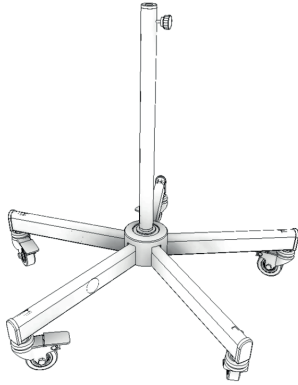
Hold the upper base stem steady and tighten the M12x90 screw with the help of a hex key, ensuring it is fully seated.

3



Screw the knob with pin into the side hole of the upper stem.

4



WARNING: Ensure the stem is tightly secured and that the base is stable and parallel to the floor. Verify that all wheels rotate freely.

7.5 First power-on

- 1 Connect the cable exiting the Product to that of the power supply;
 - 2 Insert the power supply plug into the power outlet;
- Models ALFA-FIX/ALFA-FLEX and L88-LED-TW-M (GIMANORD-TW) are set to turn on when connected to power without needing to press the touch on/off key.



For models ALFA-FIX/ALFA-FLEX and L88-LED-TW-M (GIMANORD-TW), wait at least 5 seconds before pressing the touch key.

- 3 For models PRIMA-FIX/PRIMA-FLEX, press the I/O key on the keyboard located on the front of the reflector to turn on the Product.
- 4 Verify the correct operation of all LEDs and the functions of the Product.

7.6 Verification of installation and Product testing operations before use

The following prescriptions are mandatory during the installation verification phase, as they prove the correct execution of all the points outlined. For this reason, each individual point must be checked off when addressed.

1	Verify the suitability of the wall/surface for the installation of the Product.	()
2	Verify the correct insertion of the stem pin into its respective fixing.	()
3	Check that the movement mechanics function perfectly. Check the mechanical operation through orientation and rotation movements.	()
4	Check the connection between the cable coming from the Product and the one coming from the power supply.	()
5	After turning on, the Product must emit light from the reflector.	()

Stamp and signature of the TECHNICAL SERVICE PERSONNEL:

8 Batteries

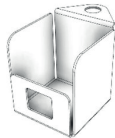
8.1 Description

Upon request, the Product mounted on RL can be equipped with a battery pack to allow operation even in case of a power outage on the main line.



Before proceeding with the assembly of the Product, ensure that the packaging is in good condition and without damage due to transport.

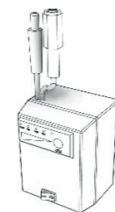
In addition to the product, the package contains the following components:



n.1 100429-R9003L - battery support box



n.1 100432 battery charger power supply 24Vdc, or
n.1 100433 battery charger power supply 12Vdc



n.1 100437 Battery pack 24Vdc, or
n.1 100438 Battery pack 12Vdc

If even one of the components is missing, contact customer service immediately,



To assemble the Product, only one person is needed, without the necessity of additional tools. Strictly adhere to these instructions.

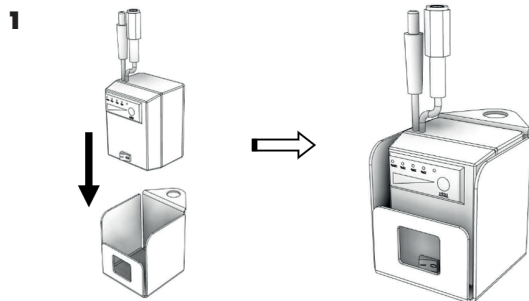
Specifications

- Nominal voltage: 12 V or 24 V
- Capacity: 3.3 Ah
- Composition: Lithium-Ion

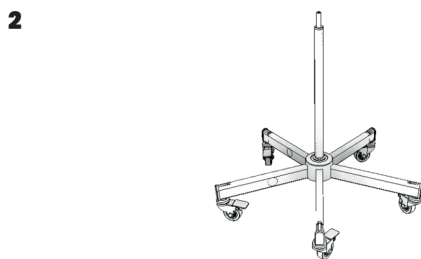
Storage warnings

- Store the batteries at a temperature between -20 °C and +30 °C.
- The battery ages even during storage, so it is recommended to use it as soon as possible.

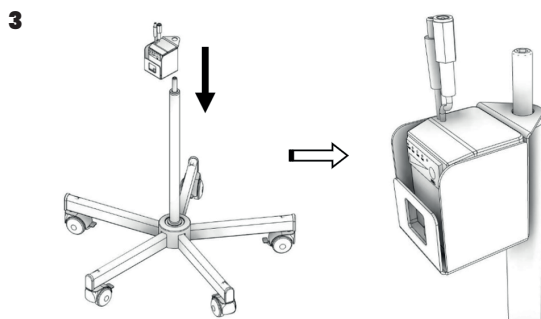
8.2 Assembly procedure



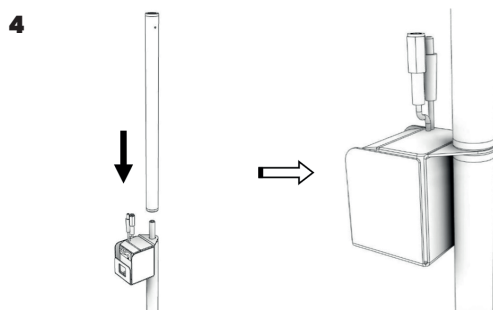
Insert the battery pack into its support, orienting it with the connection cables upwards and the control panel/switch towards the open side of the box.



Proceed with the assembly of the RL base following steps 1-9, up to the tightening of the lower stem.



Insert the battery support onto the lower stem of the RL base.



Screw the upper stem and tighten, locking the battery-support group.

8.3 Battery life

The estimated battery life is as follows:

Model	Duration [h]
-------	--------------

ALFA-FIX / ALFA-FLEX	12
L88-LED-TW-M (GIMANORD-TW)	8
PRIMA-FIX / PRIMA-FLEX	8

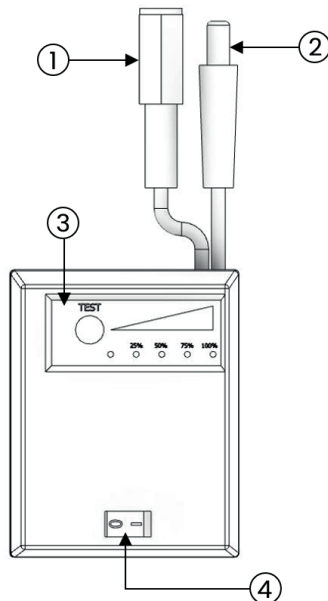
8.4 Charging and use procedure



The battery pack is provided **NOT** charged; before the first use with the lighting product, perform a complete charging cycle.



Charge the battery pack **ONLY** using the power supply provided in conjunction with it.



Charging procedure

Connect the male Jack connector (2) of the battery charger to the female Jack connector (1) of the battery pack; then connect the battery charger to the 100-230 Vac mains socket.

Usage procedure

Connect the male Jack connector (2) of the battery pack to the female Jack connector (1) of the wiring coming from the lighting device; then set the I/O switch (4) to 'I'.

Charge status check procedure

Press the 'TEST' button on the interface panel (3); the lighting of the indicator LEDs will show the remaining charge percentage of the battery pack.



During both the charging phase and the usage phase, the remaining charge level of the battery pack is **NOT** displayed; to know it, perform the 'charge status check procedure' described previously.

9 Cleaning and disinfection

The RESPONSIBLE ORGANISATION must comply with the prescriptions (standards and guidelines) on hygiene, disinfection and sterilisation laid down by the competent national commission.

9.1 Application method



Before cleaning/disinfecting the Product, disconnect the power supply.



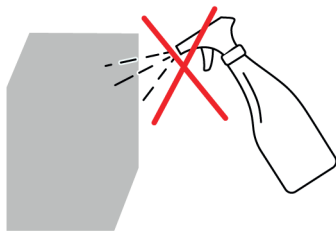
Allow the Product to cool down and only proceed with cleaning/disinfection when it is completely cold.



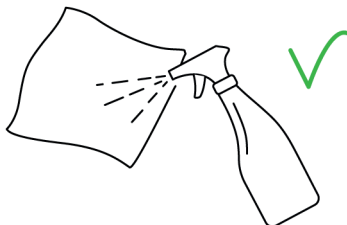
Possible damage to the Product.

To avoid damaging the Product, follow the instructions in this section.

These instructions are valid for the cleaning/disinfection of all parts of the Product.



Do not spray the cleaner/disinfectant or other liquids directly onto the Product.



Moisten a cloth with the cleaner/disinfectant without saturating it.

It is recommended not to use a paper towel as, once moistened, it could disintegrate and some fragments could enter the crevices of the Product.



Wipe the cloth over the Product.

Failure to comply with the above prescriptions could result in:

- the detachment of the paint with possible accidental fall of the same into the operating field;
- premature aging of the plastics with consequent weakening and possibility of breakage;
- the opacification of the protective screens and glasses.

9.2 Product Cleaning

Frequency

We recommend cleaning the Product daily.



Possible damage to the Product.

To avoid damaging the Product, follow the instructions in this section.

- Do not use sharp, pointed or abrasive objects to avoid the risk of damaging surfaces.
- Do not spill liquids directly onto the Product.
- Clean the Product with a damp but not wet cloth.
- Use appropriate low-alkaline and chlorine-free cleaning agents. Do not use abrasive and/or harmful products (e.g. petrol, paint thinners, alkaline, acidic or alcohol-containing cleaners or aldehydes).
- Dose the cleaning agents scrupulously observing the percentage indications in the manufacturer's technical data sheet, taking care that no liquids penetrate into the crevices of the various parts of the Product, paying particular attention to the lighthouse and support structure.

9.3 Product Disinfection

Frequency

We recommend disinfecting the Product before each use.

Disinfectants may contain substances that are harmful to health; use disinfectants established by the competent national commission for hygiene and disinfection, in compliance with the hygiene standards adopted by the RESPONSIBLE ORGANISATION.



Possible damage to the Product.

To avoid damaging the Product, follow the instructions in this section.

- Do not use sharp, pointed or abrasive objects to avoid the risk of damaging surfaces.
- Do not spill disinfectant liquids directly onto the Product.
- Disinfect the Product with a damp but not wet cloth.
- Use appropriate low-alcohol disinfectants.
- To avoid damage to stainless steel and aluminium parts, use only disinfectants that do not contain chlorine or halogens.
- Dilute the disinfectants scrupulously observing the percentage indications given in the manufacturer's technical data sheet, taking care that no liquid penetrates into the cracks of the various parts of the Product, paying particular attention to the lighthouse and support structure.

9.4 Cleaning, disinfection and sterilisation of the handle

The sterilizable handle is provided only with PRIMA-FIX and PRIMA-FLEX.

Frequency

The handle must be sterilised before use and can withstand about 200 sterilisation cycles.



Danger to the patient.

The OPERATOR must comply with the requirements laid down by the competent national commission for hygiene, disinfection and sterilisation.

The handle is made of polysulphone (PSU), a heat- and impact-resistant plastic material.

Replace the handle as soon as it is cracked or deformed, as it could fall into the operating field.

Mounting/dismounting the handle

- rotate the handle counterclockwise and remove it;
- rotate the handle clockwise until it reaches the stop on the head and its rotation is blocked.

Cleaning

Before disinfection and sterilisation, clean the handle. It is recommended to use medium alkaline detergents free of active chlorine. Dose the detergents strictly according to the percentage specifications on the manufacturer's data sheet.

Both manual and automated cleaning are permitted.

- For manual cleaning, soak the handle in cleaning solution and clean it with a soft brush or lint-free cloth. After cleaning, rinse off the detergent residue with plenty of water.
- For automated cleaning, use a machine/scrubber that complies with the requirements of ISO 15883-1.

Disinfection

Before sterilisation, disinfect the handle. It is recommended to use alcohol- or aldehyde-based products. Disinfectants must be approved by the disinfectant manufacturer for use on Polysulphone (PSU). Dilute disinfectants strictly according to the percentage specifications on the manufacturer's data sheet.

Both manual and automated disinfection are allowed.

- For manual disinfection, follow the instructions on the manufacturer's data sheet/instructions for use. After disinfection, rinse disinfectant residues thoroughly with water.
- For automated disinfection, use a washer-disinfector complying with the requirements of ISO 15883-1.

Sterilisation

Polysulphone (PSU) is tested for gamma-ray, steam and ethylene oxide (ETO) sterilisation procedures. The result of other sterilisation procedures is not guaranteed.

RIMSA, based on the design of the handle and its own experience, suggests steam sterilisation.

Before sterilising the handle, place it in a suitable sterilisation pack (e.g. plastic/paper bags; single or double pack).

When inserted into the autoclave, take care that the open side of the handle is facing downwards.

The handle must be free and must not be encumbered by other material to be sterilised.

The handle can withstand about 200 steam sterilisation cycles while respecting the following parameters:

- steam sterilisation at 121 °C and 1.3 bar for 25 to 30 minutes;
- steam sterilisation at 134 °C and 2.3 bar for 4 minutes.



Danger to the patient.

Do not exceed the sterilisation temperature of 134 °C. Damaged handles must not be used. Strictly follow ISO 17665-1 and ISO 17665-2.

10 Adjustments

10.1 Annual checks by the manager

Respect the annual intervals and check the Product in compliance with IEC 62353 standards.

10.2 Repairs

The Product must be opened and repaired exclusively by the manufacturer. Contact customer service in case of any need.



No modification of this equipment is allowed.

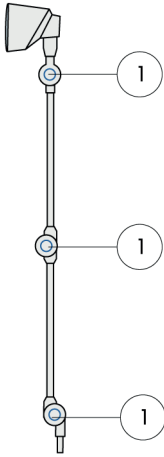
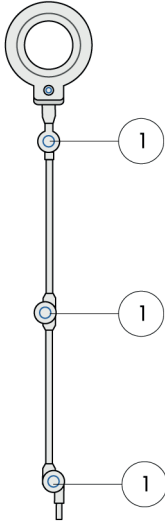
10.3 Friction adjustment

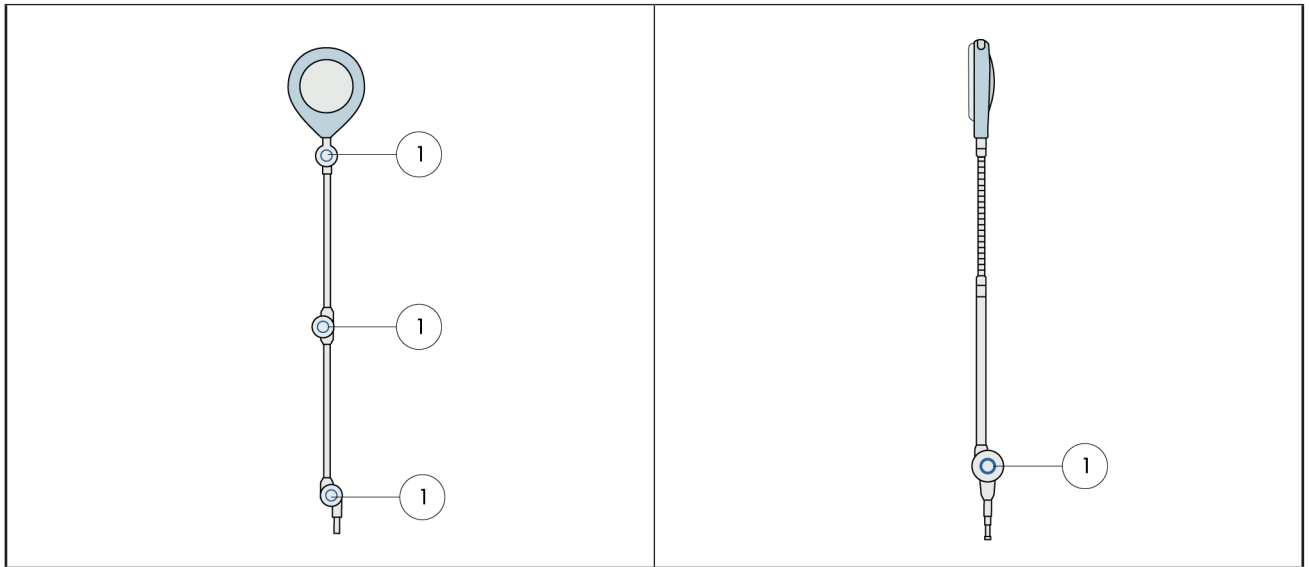
The Product is supplied balanced and does not require further adjustments; however, in the case of a Product with an articulated arm, if over time the movement of the arms around the rotation joints becomes too stiff or too loose, preventing the Product from maintaining its position, it is possible to adjust the different friction systems to restore the correct balance.

Use the hex key to adjust the friction force at the rotation joints and, consequently, the movement of the mobile arms.

Rotation joints

Depending on the versions of the Product, there is a different number of joints (1) and therefore of frictions:

ALFA-FIX	L88-LED-TW-M (GIMANORD-TW)
	
PRIMA-FIX	PRIMA-FLEX



Adjustment procedure



Remove the sticker to access the relevant joint. Using a hex key, adjust the screw located on the side of the joint. Turn clockwise to increase the friction force and thus stiffen the movement. Turn counterclockwise to decrease the friction force and make the movement lighter. At the end of the adjustment, the movement should still be smooth and even.

10.4 Troubleshooting

N°	Problem	Solution
1	The Product does not work	Contact support.
2	The Product does not hold position	See Friction adjustment section. If after adjustments the Product still does not maintain position, contact support.
3	The light flickers	Contact support.
4	The light beam is not focused	Contact support.

10.5 Ordinary maintenance

N°	Period	Intervention
----	--------	--------------

1	Once a year	Perform complete movements of all the joints of the Product and verify that there are no difficulties in movement. If the Product does not hold its position or is stiff in movements, contact technical assistance. See also the section on Friction Adjustment.
2	Once a year	Verify that the clamp fixing screws are correctly tightened. If they are not securely fastened, tighten them adequately.
3	Once a year	Check the condition of the Product's paint. Ensure that there are no paint chips that could fall into the operating field. If there are parts of paint deemed hazardous, contact assistance.

10.6 Spare parts list

Description	Order code
Sterilizable handle PRIMA-FIX and PRIMA-FLEX	Z100848
Battery pack 24Vdc	100437
Battery pack 12Vdc	100438
Charger power supply 24Vdc	100432
Charger power supply 12Vdc	100433



Use only original parts RIMSA.

11 Technical data

11.1 Technical data ALFA-FIX/ALFA-FLEX

Photometric data	
Color temperature, CCT $\pm 10\%$ [K]	4000
Illuminance at center $E_{C,Ref} \pm 10\%$ [lux]	70,000
Reference distance D_{Ref} [cm]	50
Max illuminance at center $E_{C,MI} \pm 10\%$ [lux]	150,000
Max illuminance distance D_{MI} [cm]	20
Light field diameter $d_{10} \pm 10\%$ [mm]	139
Light field diameter $d_{50} \pm 10\%$ [mm]	81
d_{50} / d_{10} [%]	≥ 50
Color rendering index $R_a \pm 5$ [-]	96
$R_g \pm 5$ [-]	92
Total irradiance $E_{Total} (D_{Ref}) \pm 10\%$ [W/m ²]	307
Total irradiance $E_{Total} (D_{MI}) \pm 10\%$ [W/m ²]	638
Electrical connection data	
Primary alternating voltage [Vac]	100 – 240
Frequency [Hz]	50/60
Power consumption [VA]	23
Light source	n. 3 LEDs
LED light source lifespan [h] (this data may vary based on voltage spikes and usage frequency)	60,000

General data	
Regulation	REGULATION (EU) 2017/745
Product classification according to REGULATION (EU) 2017/745	Class I
Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41
Product classification according to IEC 60601-1	Class II
Operating conditions	Continuous operation
Means of electrical isolation from line voltage	Built-in electrical plug
Steam sterilization of the handle	N/A
Dimensions	
Diameter of light body [cm]	9.5
Light emission surface area [cm ²]	22
Product weight excluding supports [kg]	2
Markings	
CE	Compliant with REGULATION (EU) 2017/745
IMQ	
<p><i>Note 1: unless otherwise indicated, values are to be considered with a tolerance of $\pm 5\%$ due to metrological and construction reasons.</i></p> <p><i>Note 2: all tests were conducted in accordance with section 201.5.4 "General requirements for tests on EM EQUIPMENT - Other conditions" of IEC 60601-2-41. In particular, the Product was tested with maximum luminous intensity and color temperature of 4000 K.</i></p> <p><i>Note 3: the optical radiation emitted by this Product complies with the exposure limits for reducing photobiological risk as per IEC 60601-2-41.</i></p>	

11.2 Technical data L88-LED-TW-M (GIMANORD-TW)

Photometric data	
Color temperature, CCT $\pm 10\%$ [K]	2700 \div 6000
Illuminance at center $E_{C,Ref} \pm 10\%$ [lux]	2,250
Reference distance D_{Ref} [cm]	50
Max illuminance at center $E_{C,MI} \pm 10\%$ [lux]	2,250
Max illuminance distance D_{MI} [cm]	50
Diameter of light field $d_{10} \pm 10\%$ [mm]	200
Diameter of light field $d_{50} \pm 10\%$ [mm]	100
$d_{50} / d_{10} [\%]$	≥ 50
Color rendering index $R_a \pm 5$ [-]	95
$R_g \pm 5$ [-]	88
Total irradiance $E_{Total} (D_{Ref}) \pm 10\%$ [W/m ²]	8
Total irradiance $E_{Total} (D_{MI}) \pm 10\%$ [W/m ²]	8
Electrical connection data	
Primary alternating voltage [Vac]	100 – 240
Frequency [Hz]	50/60
Power consumption [VA]	38
Light source	n. 256 LEDs
LED light source lifespan [h] (this data may vary based on the occurrence of voltage spikes and frequency of use)	60 000

General Data	
Regulation	REGULATION (EU) 2017/745
Product Classification according to REGULATION (EU) 2017/745	Class I
Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41
Product Classification according to IEC 60601-1	Class II
Operating Conditions	Continuous operation
Means of electrical isolation from line voltage	Built-in electrical plug
Steam sterilization of the handle	N/A
Dimensions	
Lighthouse diameter [cm]	23
Light emission surface [cm ²]	/
Product weight net of supports [kg]	3
Markings	
CE	Compliant with REGULATION (EU) 2017/745
<p><i>Note 1: unless otherwise indicated, values are to be considered with a tolerance of ± 5% due to metrological and construction reasons.</i></p> <p><i>Note 2: all tests were conducted in accordance with section 201.5.4 "General requirements for tests on EM EQUIPMENT - Other conditions" of the IEC 60601-2-41 standard. In particular, the Product was tested with maximum luminous intensity and color temperature of 6000 K.</i></p> <p><i>Note 3: the optical radiation emitted by this Product complies with the exposure limits for reducing photobiological risk as per the IEC 60601-2-41 standard.</i></p>	

11.3 Technical Data PRIMA-FIX/PRIMA-FLEX

Photometric Data	
Color temperature, CCT $\pm 10\%$ [K]	4000 / 4500
Illuminance at center $E_{C,Ref} \pm 10\%$ [lux]	115 000
Reference distance D_{Ref} [cm]	50
Max illuminance at center $E_{C,MI} \pm 10\%$ [lux]	135 000
Max illuminance distance D_{MI} [cm]	20
Light field diameter $d_{10} \pm 10\%$ [mm]	149
Light field diameter $d_{50} \pm 10\%$ [mm]	75
d_{50} / d_{10} [%]	≥ 50
Color rendering index $R_a \pm 5$ [-]	96
$R_g \pm 5$ [-]	92
Total irradiance $E_{Total} (D_{Ref}) \pm 10\%$ [W/m ²]	570
Total irradiance $E_{Total} (D_{MI}) \pm 10\%$ [W/m ²]	600
Electrical Connection Data	
Primary alternating voltage [Vac]	100 – 240
Frequency [Hz]	50/60
Power consumption [VA]	32
Light source	no. 12 LEDs
LED light source duration [h] (this data may vary based on the occurrence of voltage peaks and frequency of use)	60 000

General Data	
Regulation	REGULATION (EU) 2017/745
Product classification according to REGULATION (EU) 2017/745	Class I
Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-41
Product classification according to IEC 60601-1 standard	Class II
Operating conditions	Continuous operation
Means of electrical isolation from line voltage	Built-in electrical plug
Steam sterilization of the handle	N/A
Dimensions	
Diameter of lamp body [cm]	19.5
Light emission surface (4000 K / 4500 K)[cm ²]	42 / 63
Product weight net of supports [kg]	3.5
Markings	
CE	Compliant with REGULATION (EU) 2017/745
IMQ	
<p><i>Note 1: unless otherwise indicated, values are to be considered with a tolerance of $\pm 5\%$ due to metrological and construction reasons.</i></p> <p><i>Note 2: all tests were performed in accordance with section 201.5.4 "General requirements for tests on EM EQUIPMENT - Other conditions" of the IEC 60601-2-41 standard. In particular, the Product was tested with maximum luminous intensity and color temperature of 4500 K.</i></p> <p><i>Note 3: the optical radiation emitted by this Product complies with the exposure limits for the reduction of photobiological risk provided by the IEC 60601-2-41 standard.</i></p>	

12 EU Declaration of Conformity

Drafted pursuant to Article 19 and Annex IV of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Manufacturer: **RIMSA P. LONGONI SRL**

Registered Office Address: **Via Monterosa, 18/20/22 - 20831 - Seregno (MB) - Italia**

Unique Registration Number (SRN): **IT-MF-000009224**

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Basic UDI-DI: **++B880LUMINAIREPM**

Product name, trade name, and model reference: ALFA-FIX

Product name, trade name, and model reference: ALFA-FLEX

Product name, trade name, and model reference: L88-LED-TW-M (GIMANORD-TW)

Product name, trade name, and model reference: PRIMA-FIX

Product name, trade name, and model reference: PRIMA-FLEX

Intended use: LUMINAIRES FOR DIAGNOSIS

Device risk class, in accordance with the rules of Annex VIII of REGULATION (EU) 2017/745: **CLASS I**

Justification:	Duration:	Short-term (Annex VIII, CHAPTER I, point 1. DURATION OF USE)
	Description:	Non-invasive medical device (Annex VIII, CHAPTER III, point 4. NON INVASIVE DEVICES, paragraph 4.1 Rule 1)
		Active medical device (Annex VIII, CHAPTER III, point 6. ACTIVE DEVICES, paragraph 6.2 Rule 10)

The manufacturer declares that the device complies with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 5 April 2017, concerning medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC and the following standards:

IEC 60601-1	(Part 1: General requirements for basic safety and essential performance)
IEC 60601-1-2	(Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests)
IEC 60601-2-41	(Part 2: Particular requirements for the basic safety and essential performance of surgical luminaires for diagnosis)

The conformity assessment procedure of the device is carried out according to recital (60) and Article 52 of REGULATION (EU) 2017/745.

The Quality and Environment System of RIMSA complies with UNI EN ISO 9001, UNI CEI EN ISO 13485, ISO 14001 and ISO/IEC 27001 standards and is certified by IMQ S.p.A. (certificates no. 9120.RMS1, no. 9124.RMS2, no. 0833.2023 and no. 1402.2024).

Name: Paolo Longoni

Position: CEO



13 EMC Declaration

The Product has been tested according to IEC 60601-1-2 to ensure correct electromagnetic compatibility.



Possibility of interference with neighbouring equipment

Portable and mobile communication equipment may affect the Product. The Product should not be used in the vicinity of another device and if use is necessary, the Product must be checked for functionality.

The use of accessories other than those supplied/recommended RIMSA may increase the emission level and lower the immunity level of the device.

The Product is designed for use in the electromagnetic environment described below.

It is the responsibility of the RESPONSIBLE ORGANISATION or OPERATOR to ensure that the Product is used in a compatible environment.

It may happen that the Product, when subjected to irradiation in the range 80 MHz - 1 GHz or to burst radiation, no longer responds to commands, neither for the lamp nor for the camera (if present).

In this case, essential performance will still be guaranteed, but to restore normal operation, it will be necessary to remove power from the main switch.

Immunity Testing	Compliance	Electromagnetic Environment - Guidelines
RF emissions CISPR 11	Group 1	The Product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Product is suitable for use in all environments and can be used in domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided that the following notice is observed:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	WARNING: The device/system is intended to be used only by healthcare professionals.

Immunity tests	Test level IEC 60601-1-2	Compliance level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV at contact ±2, ±4, ±8 kV, ±15 kV in air	± 8 kV at contact ±2, ±4, ±8 kV, ±15 kV in air	It is preferable for the floor to be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the moisture content must be at least 30%.
Fast-pulsing electrical transients IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	A mains quality typical of a commercial or domestic environment is recommended.
Shockwaves IEC 61000-4-5	± 0.5 kV, ± 1 kV Differential mode	± 0.5 kV, ± 1 kV Differential mode	A mains quality typical of a commercial or hospital environment is recommended.
Magnetic field at mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at mains frequency must be at levels characteristic of a typical location in a commercial or hospital environment.
Voltage dips, short interruptions and variations on power supply input lines IEC 61000-4-11	10 ms - 0% at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms - 0% at 0° 500 ms - 70% at 0° 5 s - 0%	10 ms - 0% at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 20 ms - 0% at 0° 500 ms - 70% at 0° 5 s - 0%	A mains power quality typical of a commercial or hospital environment is recommended. If the Product is to be used continuously even in the event of a power failure, connect the lamp to a mains supply capable of providing continuous power or to a battery.
NOTE: U_T is the AC mains voltage before application of the test level.			

Test frequency [MHz]	Band ^{a)} [MHz]	Service ^{a)}	Modulation ^{b)}	Maximum power [W]	Distance [m]	Immunity test level [V/m]
385	380-390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28
2450	2400-2750	Bluetooth, WLAN, 02.11, b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802-11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9

NOTE: If it is necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME medical device or ME SYSTEM must be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

^{a)} For some services only rising frequencies are included.

^{b)} The carrier must be modulated using a square wave signal at 50% duty cycle.

^{c)} As an alternative to FM modulation, a modulation of 50% of the pulse at 18 Hz may be used because, although it does not represent actual modulation, it would be the worst case.

**Proximity immunity to magnetic field in the frequency range 9 kHz - 13.56 MHz
IEC 61000-4-39**

Magnetic fields at mains frequency must be at characteristic levels caused by radio frequency fields from devices used in close proximity.

Test Frequency	Modulation	Immunity test level [A/m]
30 kHz ^{a)}	CW	8
134.2 kHz	Pulse modulation ^{b)} 2.1 kHz	65 ^{c)}
13.56 MHz	Pulse modulation ^{b)} 50 kHz	7.5 ^{c)}

a) This test is only applicable to ME MEDICAL DEVICES or ME SYSTEMS intended for use in a healthcare home environment.

b) The vector shall be modulated using a square wave signal at 50% duty cycle.

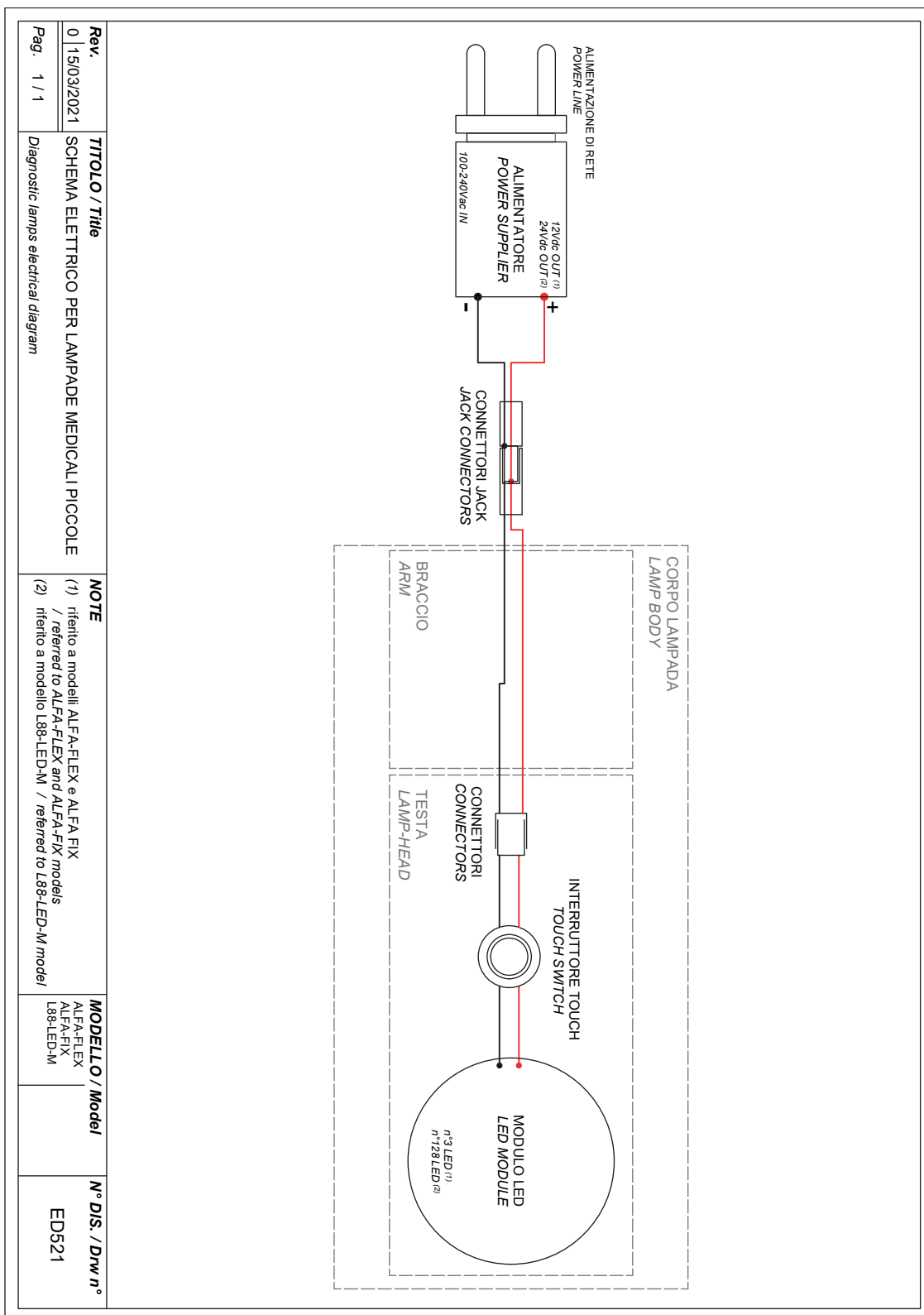
c) The mean square value shall be applied prior to modulation.

14 Certificate of Warranty

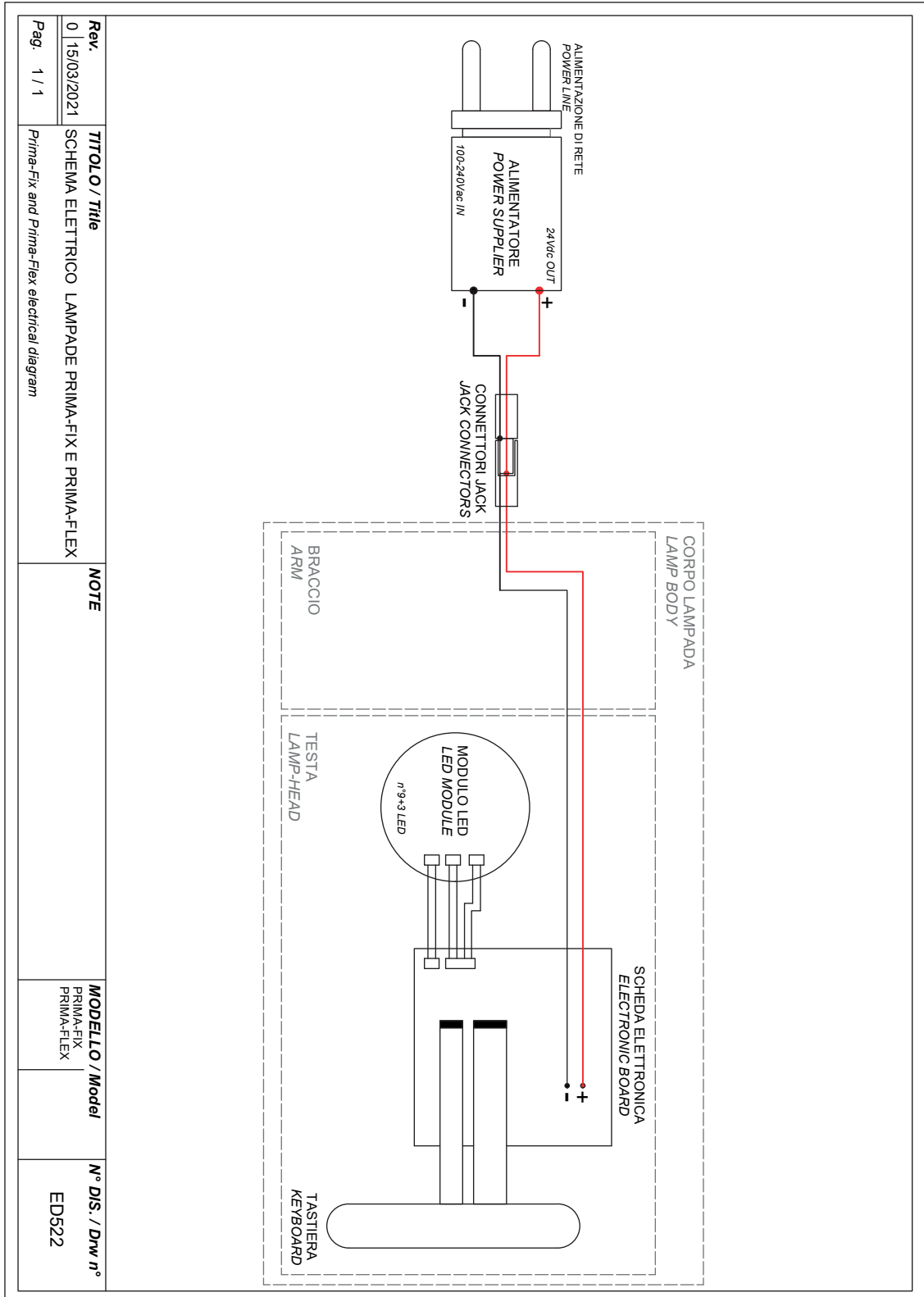
- 1** The Product is under warranty for a period of 18 months, including electrical parts.
- 2** The warranty begins on the date of dispatch of the Product from the RIMSA warehouse to the buyer.
- 3** In the event of a dispute, the date indicated on the 'transport document' accompanying the goods shall be deemed valid.
- 4** The warranty is limited to sending the buyer spare parts of the Product or, if RIMSA deems replacement of the parts to be impracticable, to replacing the entire Product, and is made for well established causes of manufacture and at RIMSA's sole discretion. The warranty does not therefore include any other costs or expenses (such as but not limited to labour costs, packaging and transport costs, etc.).
- 5** Excluded from the guarantee are components subject to normal wear and tear (e.g. halogen bulbs, LEDs, fuses, relays, ball bearings, etc.).
- 6** They are not covered by warranty:
 - malfunctions due to non-compliance with all instructions in the manuals
 - malfunctions due to installation and/or maintenance errors;
 - malfunctions or defects caused by neglect, negligence, misuse or other causes not attributable to RIMSA;
 - malfunctions or defects due to the fact that the electrical installation in the environment (room) in which the installation is carried out does not comply with IEC 60364-7-710 (standard for electrical installations for medical premises) and similar standards.
- 7** RIMSA shall indemnify direct damage to the buyer that is documented as being attributable to his Product, caused within the warranty period, in an amount not exceeding 40% of the net value of the Product as stated on the invoice to the buyer. RIMSA's liability for indirect or consequential damage (including loss of use of the Product) arising from the delivery is expressly excluded.
- 8** The guarantee in this certificate is in lieu of the legal guarantees for defects and non-conformities and excludes any other possible liability of RIMSA arising from the Products supplied.
- 9** Compensation for any damage to persons or property caused by the Product's malfunction or defects shall be limited to the amount of RIMSA's liability insurance coverage.
- 10** The purchaser automatically forfeits the guarantee if:
 - the Product has been tampered with or modified by the buyer or a third party;
 - the Product has been repaired by the Buyer or a third party without complying with the instructions contained in the Manuals
 - the serial number of the Product has been erased, blurred or removed;
 - the Buyer is not in good standing with payments.
- 11** For warranty work, the purchaser must only contact RIMSA.
- 12** Parts replaced under warranty must be returned to RIMSA, only if requested by RIMSA, carriage paid and properly packaged.
- 13** Failure to return the component at RIMSA's request will result in the cost of the component being charged.
- 14** RIMSA does not accept returns from end users or otherwise from parties other than the buyer.
- 15** Products returning to RIMSA must have the return authorisation documentation and a document describing the malfunction attached.
- 16** For anything not covered by this warranty certificate, please refer to Italian law.
- 17** For any dispute arising out of or in connection with orders to which this guarantee certificate applies that the parties have not been able to settle amicably, the Court of Milan shall have exclusive jurisdiction.

15 Electrical Schematics

15.1 Electrical schematic ALFA-FIX/ALFA-FLEX and L88-LED-TW-M (GIMANORD-TW)



15.2 Electrical schematic PRIMA-FIX/PRIMA-FLEX





RIMSA P. LONGONI SRL

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