USER MANUAL FOR OBSERVATION LAMP

OBSERVA SERIES

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

RIMSA P. LONGONI s.r.l. - Via Monterosa, 18/20/22 – 20831 SEREGNO (MB) ITALY
Tel. +39 0362 325.709 Fax +39 0362 328.559
http://www.rimsa.it e-mail: info@rimsa.it

Introduction

Dear User, you are kindly invited to read this manual carefully before proceeding to use the Product in order to safeguard yourself and other people from any injuries.
This appliance is a Class 1 medical device pursuant to REGULATION (EU) 2017/745 on medical devices (Annex VIII) as amended and integrated.
The manufacturer declares that this Product complies with Annex I (General Safety and Performance Requirements) of REGULATION (EU) 2017/745 as amended and integrated and certifies such conformity by affixing the CE marking.
The Product is classified in risk group 1 according to IEC 62471 standard (Photobiological Safety of Lamps).
This User manual is valid for the following models:

- **ALFA-FIX/ALFA-FLEX**
- **L88-LED-M (GIMANORD)**
- **PRIMA-FIX/PRIMA-FLEX**

The customer service is at your disposal in case of Product details, information concerning its use, identification of spare parts being required and for any other queries you might have concerning the appliance, for ordering spares and for matters relating to assistance and warranty.
RIMSA P. LONGONI SRL
Via Monterosa 18
I-20831 Seregno MB
Tel.: ++39 0362 325.709
Fax: ++39 0362 328.559
e-mail: info@rimsa.it

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RIMSA reserves the right to change, cancel or otherwise amend the data contained in this document at any time and for any reason without prior notice inasmuch as RIMSA is constantly seeking new solutions which lead to product evolution. RIMSA therefore reserves the right to make changes to the supplied Product in terms of shape, fittings, technology and performances.
With regard to translations into languages other than Italian, reference shall always be made to the Italian edition of this User manual.

CONTENTS

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MT	Biex titlob il-manwal f'din il-lingwa, jekk jogħġbok ibgħat e-mail lil info@rimsa.it.
NL	Om de handleiding in deze taal aan te vragen, kunt u een e-mail sturen naar info@rimsa.it.
PL	Aby zamówić podręcznik w tym języku, należy wysłać wiadomość e-mail na adres info@rimsa.it.
PT	Para solicitar o manual nesta língua, envie por favor um e-mail para info@rimsa.it.
RO	Pentru a solicita manualul în această limbă, vă rugăm să trimiteți un e-mail la info@rimsa.it.
SK	Ak chcete požiadať o príručku v tomto jazyku, pošlite e-mail na adresu info@rimsa.it.
SL	Če želite zahtevati priročnik v tem jeziku, pošljite e-pošto na naslov info@rimsa.it.
SV	Om du vill ha handboken på detta språk skickar du ett e-postmeddelande till info@rimsa.it.

1 General information

The ME (Medical Electrical) EQUIPMENT to which this manual refers is a LUMINAIRE for diagnosis or observation. For ease of description, in this manual this ME EQUIPMENT will be called "Product".
This manual is an integral part of the Product as indicated by REGULATION (EU) 2017/745 and subsequent amendments and supplements. Always keep this operator's manual close to the lamp.
RIMSA disclaims all liability for any injuries to persons or damage to things caused by the installation, maintenance or use of the Product by unqualified operators. By qualified operator is meant whosoever has attended a course relating to the installation, maintenance and use of the product organised by RIMSA or, alternatively, whosoever has carefully read this installation manual. RIMSA does not authorize third parties to perform special maintenance jobs. Should a problem arise, contact RIMSA.
The end user is entirely responsible for Product installation activities; no costs or responsibilities relating to the installation and/or commissioning of the Product may therefore be traced back and/or in any case attributed to RIMSA.
The wall masonry works for Products to be installed on walls, and the electrical works for supplying power to the Product shall be carried out in a workmanlike manner by suitably qualified personnel to ensure these are sturdy and safe.
By way of example only, the following professional figures are deemed as suitably qualified:

- ⇨ Construction Engineer, Draughtsman, Building firm duly registered in the professional Register (for the masonry works)
- ⇨ Electrical Engineer, Electro-technical expert qualified to work as an electrician (for the electrical works)

The Product is an ME Medical Electrical equipment and therefore falls within the field of application of the IEC 62353 standard. Consequently, any operation performed on the Product must be carried out in compliance with the IEC 62353 standard, where applicable.

1.1 Operator qualification

This paragraph describes the requirements and qualifications which the operators involved in the various stages of Product life and use must possess.

Installation	Installer and/or qualified technician
Use	Professional medical personnel
Routine maintenance	Qualified technician with required technical-professional skills
Special maintenance	RIMSA or authorized Dealer
Assistance	RIMSA or authorized Dealer
Cleaning	Properly trained medical and paramedical personnel
Demolition	Comply with applicable laws on waste disposal. This product must not be disposed of in standard waste disposal bins. To avoid risks for the environment and health deriving from the dispersion of polluting substances in the environment, separate the various internal component parts such as iron, aluminium, plastic and electrical material, and dispose of these through authorized channels so as to ensure correct recycling, once the equipment has reached the end of its useful life (10 years).

1.2 Packaging, transport, storage and characteristics of installation premises

Boxes containing the Product together with User manual.
Transport is made by RIMSA or any road-hauler as long as in compliance with the following characteristics:
Temperature (°C): -15 / +60; Humidity: 10 / 95 %; Atmospheric pressure (hPa): 500 / 1060.
The packaged Product must be stored (warehoused) in dry premises having the following characteristics:
Temperature (°C): -15 / +60; Humidity: 10 /95 %; Atmospheric pressure (hPa): 500 / 1060.
The premises where the Product is started up must have the following characteristics:
Temperature (°C): +10 / +40; Humidity: 30 / 75 %; Atmospheric pressure (hPa): 700 / 1060.

1.3 Graphic symbols used on the Product

Description of the symbols on plates, product and in manual:

CE	CE marking indicating the Product conforms to REGULATION (EU) 2017/745 and subsequent amendments and supplements		IMQ mark
	Date of manufacture (year/month)	MD	Medical Device
	Manufacturer's address	REF	Model reference
	RECYCLING! The Product must be recycled separately	SN	Serial number
	Stand-By	CH REP	Swiss authorised representative
	Functional earth		CLASS II equipment
'I'	ON power	'O'	OFF power
'L'	Line lead connection point	'N'	Neutral lead connection point
	Top side of packaging		Weight of packaging
	Fragile packaging		Protect from rain
	Do not stack packaging		Limit temperature (indicate max limit at top right and min limit at bottom left)
	Humidity to be complied with (indicate max limit at top right and min limit at bottom left)		Pressure to be complied with (indicate max limit at top right and min limit at bottom left)
	General warning signal		General mandatory code of conduct signal
	Manual reading obligation		

1.4 EU Declaration of conformity

In accordance with 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 S.r.l.**
Address of registered place of business: Via Monterosa, 18/20/22 – 20831 SEREGNO (MB) – ITALY
Single registration number (SRN): IT-MF-000009224

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

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

Product and trade name: **ALFA-FIX, ALFA-FLEX, L88-LED-M, PRIMA-FIX, PRIMA-FLEX**
Model reference: ALFA-FIX, ALFA-FLEX, L88-LED-M, PRIMA-FIX, PRIMA-FLEX

Intended purpose: LUMINAIRE FOR DIAGNOSIS

Risk class of the device in accordance with the rules set out in Annex VIII of REGULATION (EU) 2017/745: **CLASS I**
Explanation: 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, par. 4.1 Rule 1)
Active medical device (Annex VIII, CHAPTER III, point 6. ACTIVE DEVICES, par. 6.2 Rule 10)

The manufacturer declares that the device is in conformity with 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 and with the following standards:

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

The conformity assessment procedure is developed with reference to premise (60) and Article 52 of REGULATION (EU) 2017/745.

RIMSA Quality System complies with UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards and is certified by CSQ (CSQ certificate no. 9120.RMS1 and 9124.RMS2).

Name: Paolo Longoni
Position: Managing Director

1.5 Warranty Certificate

1. The Product is covered by an 18-month warranty, including electrical parts.
2. The warranty begins on the date of product shipment from the RIMSA warehouse to the buyer.
3. In case of disputes, the date indicated on the "transport document" attached to the goods shall be deemed valid.
4. The warranty only covers the sending of Product spare parts to the buyer or, in the event of RIMSA considering the replacement of spare parts not feasible, the replacement of the entire product, after fabrication faults have been properly ascertained at the undisputable judgement of RIMSA. The warranty does not therefore cover any other costs or expenses (including, by way of example but without limitation, labour costs, packaging costs and transport costs, etc.).
5. The guarantee does not include the components subject to normal wear, such as halogen bulbs, LEDs, fuses, relays, ball bearings, etc.)
6. The warranty does not cover:
   - malfunctions due to failure to comply with the instruction manuals;
   - malfunctions due to installation and/or maintenance errors;
   - malfunctions or faults caused by carelessness, negligence, incorrect use or other causes not attributable to RIMSA;
   - malfunctions or faults due to the fact that the electrical system of the premises where the device is installed is not in compliance with IEC 60364-7-710 standard (standard for electrical systems in premises used for medical purposes) and similar standards.
7. RIMSA shall repay direct damages suffered by the buyer and which are documented as attributable to its product, caused within the warranty period, for an amount not above 40% of the net value of the product as indicated on the buyer's invoice. RIMSA's liability is expressly ruled out for indirect damages or consequential damages (including cases of the lamp not being used) deriving from the supply.
8. This warranty certificate replaces legal warranties for faults and non-conformities and rules out any other possible liability of RIMSA originating from the supplied products.
9. The payment of any damages to persons or things due to product malfunction or faults shall be limited to the maximum amount of RIMSA's insurance coverage for civil liability.
10. The warranty shall be automatically invalidated in the event of:
    - the Product having been tampered with or modified by the buyer or third parties;
    - the Product having been repaired by the buyer or third parties, without following the instructions in the instruction manuals;
    - the Product serial number having been cancelled, defaced or removed;
    - the buyer not being up to date with payments.
11. For jobs to be done under warranty, the buyer shall contact RIMSA only.
12. The component parts replaced under warranty must only be returned to RIMSA, if so requested by RIMSA, carriage free and suitably packed.
13. In case of failure to return a part requested by RIMSA, the cost of the component part will be charged.
14. RIMSA cannot accept returns from end users or in any case from parties other than the buyer.
15. Products returned to RIMSA must be complete with documentation authorising such return and another document describing the malfunction.
16. For everything not indicated on this warranty certificate, reference shall be made to the laws of Italy.
17. For all disputes deriving from or related to the orders to which this warranty certificate applies and which cannot be amicably settled between the parties, the only competent law court shall be that of Milan.

2 Importance of personal safety

2.1 Intended use

The Product has been designed to light up the area of the patient undergoing observation and diagnosis and is intended for use in doctors' surgeries.
The Product correctly lights up the operating field from a minimum distance of 40 cm and a maximum distance of about 70 cm, from the point of light emission.
The Product, in conformity with the IEC 60601-2-41 standard, is defined as a luminaire for diagnosis:

- luminaire for diagnosis is a luminaire to illuminate the body of the PATIENT locally in order to support diagnosis or treatment which could be interrupted without any hazard for the PATIENT in case of failure of the light. (The Product is not intended for use in operating theatres).

2.2 Safety conditions (secondary effects)

- Do not direct the light source into the patient's and/or operator's eyes.
- Obligation to adequately protect the patient's eyes.
  Failure to follow such precautions could cause glare and potential damage to the retina.
- Never place and/or hang anything on the Product.
  Unless this precaution is taken, positioning will not be reliable and the danger exists of such objects falling in the operating area.
- Never hang on the Product with the body weight of a person.
  Failure to follow such precaution could damage the Product structure.
- Never cover the head of the Product during operation.
  Failure to comply could prevent heat exchange with the environment and the Product could overheat.
- Avoid knocking the rocker arms and Product head.
  A violent knock could damage the Product and pieces of paint could chip off and fall onto the operating field in the patient area.
- To avoid any significant risk of reciprocal interference due to the presence of the Product during specific exams or treatments, see section 9 of the manual.

Power supply

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

- Use the power supply only for its intended use as described below.
- Do not use outdoors, the power supply is intended for indoor use only.
- Do not allow to be used as a toy. Pay close attention when this power supply is used by, or near children.
- Use only attachments recommended by the manufacturer.
- Never operate the power supply if it has a damaged cord or plug, if it has been dropped or damaged or if it has fallen into water. In such cases return the power supply to an authorised dealer or contact the customer service.
- Never drop or insert an object into any openings.
- Do not operate where aerosol (spray) products are being used or where oxygen is being administered.
- The power supply should be used near to a convenient and easily accessible mains socket.
- Always unplug the power supply from the mains socket immediately after using.

2.3 Environmental conditions

- The Product is not suitable for use in explosion-risk areas.
- The Product is not suitable for use wherever there are flammable mixes of anaesthetics with air, oxygen or N_2O (laughing gas).
- The Product is not suitable for use in environments rich in oxygen and use is not intended in the presence of flammable 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 1060hPa.

2.4 Controls to be performed every time before the lamp is used

To make sure the Product is safe and provides a correct diagnosis, every time before use, the operator must:
- Clean/disinfect the Product according to the rules laid down by the relevant national commission;
- Check the emitted light is stable and of adequate intensity;
- Check the flexible arm remains in the selected position, without falling.

3 Product installation

Before proceeding to install the Product, first of all check the presence of all the packaging and that this is in good condition and has not been damaged during transport. Claims will only be taken into consideration if the seller or carrier has been immediately notified. All claims must be made in writing. Goods always travel under the responsibility and at the risk of the buyer.
Keep the original packaging in case the Product has to be re-dispatched.

The Product is supplied with different support systems, to be selected as required:
- 'S/11' wing-nut vice for fastening to table;
- 'S/12 MED' wall-fastening clamp;
- 'Z400819' rail bar clamp, 'Z400075' rail bar supplied with 1 metre bar length, 3 spacers, 3 wall anchors and 3 screws for fastening the anchors to the bar;
- 'RL' ('RLALFA' only for ALFA-FLEX model) floor lamp consisting of upright and 5 wheels with pedal-operated lock system.

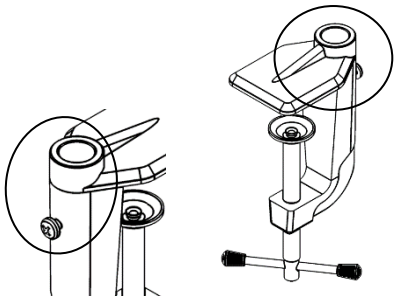
For PRIMA-FIX/PRIMA-FLEX model the package also contains a sterilizable handpiece.

Do not position the device so it is hard to reach and remove the power plug in case of an emergency.

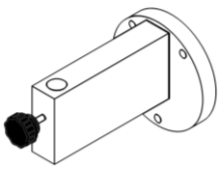
To avoid the risk of electric shocks, this appliance must only be connected to mains supplies with earth connection.

3.1 Installation in table version (S/11 fastening)

- Fasten the clamp S/11 to the table and tighten the threaded pin.
- Fit the lamp in the hole located in the top part of the clamp S/11.
- With the aid of a screwdriver, tighten the screw on the back of the clamp.

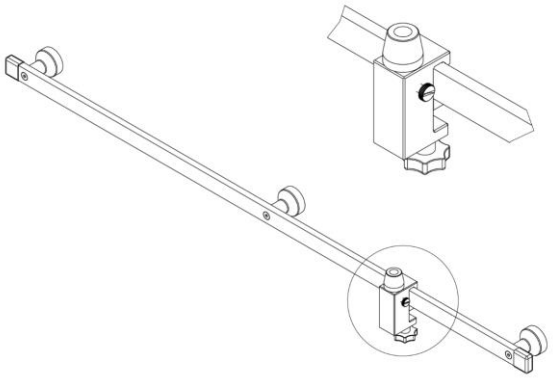


3.2 Installation of wall version (S/12 MED fastening)



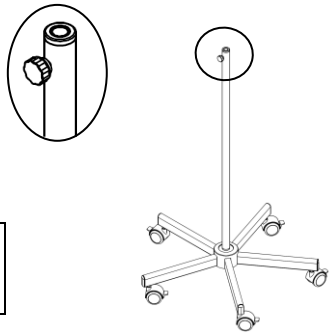
- Fasten the clamp S/12 MED to the wall with 3 expansion screws. RIMSA does not supply screws.
- The wall must be a supporting wall and be made of solid brick. Installation on walls of perforated bricks and plasterboard is only allowed with the fitting of a plate on the opposite side of the wall (sandwich closing). RIMSA suggests using M5 screws.
- Fit the lamp in the hole located in the upper part of the clamp S/12 MED.
- Screw up the threaded knob, making sure this fit into the mill hole of the lamp pin in such a way as to prevent it accidentally coming out.

3.3 Installation of wall version (bar rail fastening)



- Fasten the bar rail according to attached instructions MO002i.
- Fit the clamp on the bar and tighten the lower knob.
- Fit the lamp in the hole located on the clamp.
- Screw up the threaded knob, making sure this fit into the mill hole of the lamp pin in such a way as to prevent it accidentally coming out.

3.4 Installation of 5-spoke floor version (RL)



- Mount the stand as per the attached instructions Mod.RL.
- Then fit the lamp in the hole located in the top part of the stand rod.
- Screw up the threaded knob, making sure this fits into the mill hole of the lamp pin in such a way as to prevent it accidentally coming out.

In the floor version, operate all 5 wheel brakes during operation to ensure stability.

3.5 Handpiece fitting (only for PRIMA-FIX/PRIMA-FLEX model)

To fit the handpiece, turn it clockwise inside the threaded hole provided until it is up against the headpiece and rotation remains blocked.

3.6 First switch-on

At this point it's possible to check the Product works properly.
Follow the instructions below:

1. Connect the jack on the lamp cable to the jack on the power supply unit;
2. Insert the plug of the power supply in the power socket;
3. Touch the touching key on the reflector (for ALFA-FIX/ALFA-FLEX and L88-LED-M (GIMANORD) models);
4. Press the I/O keyboard located on the front part of the reflector (only for PRIMA-FIX/PRIMA-FLEX model);
5. Make sure all LEDs and functions are working properly.

3.7 Check the result of Product installation and testing before use

The following instructions are to be deemed mandatory during the installation inspection phase, as they prove that all the various jobs referred to have been correctly done. Hence each single step must be ticked.

1. Make sure the wall is suitable for Product installation. ☐
2. Make sure the stand pin has been correctly fitted in its fastening point. ☐
3. Make sure movement mechanisms are working properly. Check mechanical operation by means of direction and rotation movements. ☐
4. Check the connection between the cable coming from the Product and the cable coming from the power supply unit. ☐
5. After switch-on, the Product must emit light from the reflector. ☐

Installer's stamp and signature:

_____

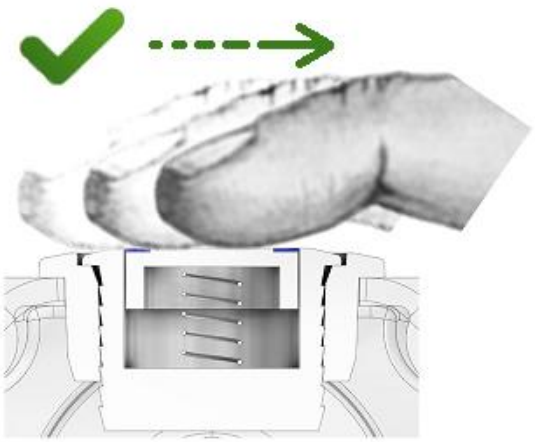
4 Description and operation

4.1 Description and operation ALFA-FIX/ALFA-FLEX

The Product locally lights up the patient's body thanks to 3 LEDs focalized by means of specific lenses. Positioning the light beam is made easy thanks to the articulated arm (ALFA-FIX) or flexible arm (ALFA-FLEX), and is done manually.

The Product does not have a keyboard to operate. On the reflector there is a touching key which allows to switch on/off the Product and manage the light intensity. A short touch allows to switch on and off the lamp; a prolonged touch, instead, allows to gradually increase and decrease the light intensity.
After use, to safely switch off the Product, touch shortly the touching key; to disconnect from the mains, remove the plug.

IMPORTANT: DO NOT PRESS THE TOUCHING KEY!
To activate the intended functions, simply touch the key gently.

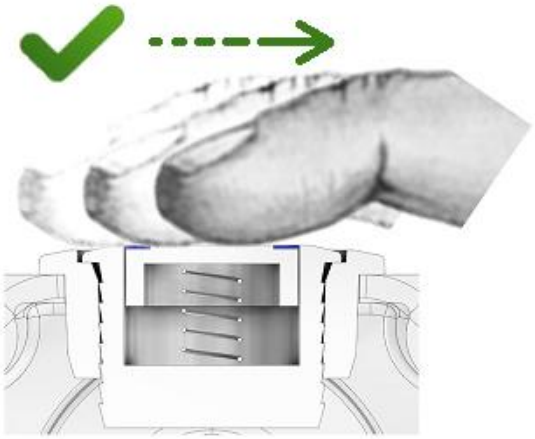


4.2 Description and operation L88-LED-M (GIMANORD)

The Product locally lights up the patient's body thanks to 128 LEDs. Positioning is easy thanks to the articulated arm and is done manually.

The Product does not have a keyboard to operate. On the reflector there is a touching key which allows to switch on/off the Product and manage the light intensity. A short touch allows to switch on and off the lamp; a prolonged touch, instead, allows to gradually increase and decrease the light intensity.
After use, to safely switch off the Product, touch shortly the touching key; to disconnect from the mains, remove the plug.

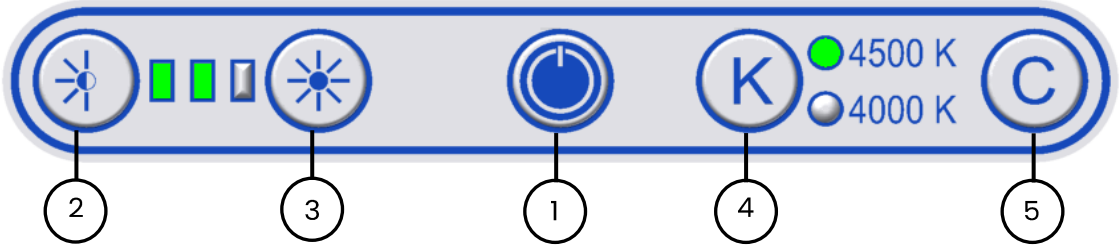
IMPORTANT: DO NOT PRESS THE TOUCHING KEY!
To activate the intended functions, simply touch the key gently.



4.3 Description and operation PRIMA-FIX/PRIMA-FLEX

The Product locally lights up the patient's body thanks to 9 LEDs focalized by means of specific lenses. 3 non-focalized LEDs are also fitted to permit using a courtesy or reading light. Positioning the light beam is made easy thanks to the articulated arm (PRIMA-FIX) or flexible arm (PRIMA-FLEX), and is done manually. By means of the membrane keyboard on the reflector, the various Product functions can be easily controlled.

The following functions can be controlled by means of the keyboard:
Switch the lamp on and off by means of the stand-by key (1). Adjust light intensity by pressing keys (2) and (3), with display of the level of intensity achieved by means of 3 green positions micro-LEDs.
Select the colour temperature by means of the "K" key (4) with display by means of 2 green micro-LEDs. Select the courtesy light by means of the "C" key (5), which permits switching on the 3 LEDs without lens, not to be used for observation. To select the courtesy light, the lamp must be switched off. In courtesy position, only the light intensity can be adjusted, while temperature change is not possible.
To return to normal operating position, the stand-by key (1) must be pressed.



The light field is not adjustable.
To move the lamp use the sterilisable handpiece.
After use, to safely switch off the Product, press the stand-by key (1); to disconnect from the mains, remove the plug.

5 Cleaning and disinfecting

5.1 Cleaning the Product

Before going ahead with cleaning operations switch off the Product by detaching the plug, make sure it cannot be switched back on and leave it to cool down. Only clean the Product when it is cold.

Protect the Product from water spray and detergents and do not clean it with liquids.
Do not spray detergent directly on Product but spray the detergent on a cloth so as to dampen it. Afterwards wipe the Product with the cloth. Clean the Product with a damp, but not wet, cloth.
The Product is best cleaned at least once a day when used. To clean the lamp, the support need not be removed.
Clean with suitable detergents with low alkaline content and chlorine free. Do not use abrasive products, petrol, paint thinners, alkaline detergents, acids, containing alcohol or aldehydes.
Dose the detergents strictly according to the percentage indica-tions shown on the manufacturer's technical sheet, being care-ful that no liquids penetrate into the joints of the various Product parts, with special care give to the lamp elements and into the support arm system.

Failure to comply with the instructions could cause the paint to come off with possible accidental dropping of such paint into the patient area, the early ageing of the plastic parts with consequent weakening, or the tarnishing of glass.

5.2 Disinfecting

Before going ahead with disinfecting operations switch off the Product by detaching the plug, make sure it cannot be switched back on and leave it to cool down. Only disinfect the Product when it is cold.

Protect the Product from water spray and detergents and do not disinfect it with liquids.
Do not spray detergent disinfectant directly on Product but spray the detergent disinfectant on a cloth so as to dampen it. Afterwards wipe the Product with the cloth. Disinfect the Product with a damp, but not wet, cloth.
The Product is best disinfected every time before use. To clean the lamp, the support need not be removed.
Clean with suitable detergents with low alkaline content and chlorine free.
Disinfectants can contain substances which are harmful for the health - only use disinfectants in accordance with the rules on hygiene established by the hospital; the Product operator must comply with the rules established by the national commission for hygiene and disinfection.
To prevent damaging parts in stainless steel or aluminium, only use disinfectants which are chlorine and halogen free; to prevent the plastic parts becoming fragile, use only disinfectants with low alcohol content; dose the disinfectants so no liquids penetrate inside the lamp elements and into the support arm system.

Failure to comply with the instructions could cause the paint to come off with possible accidental dropping of such paint into the patient area, the early ageing of the plastic parts with consequent weakening, or the tarnishing of glass.

Each Product, over time, is subject to a certain amount of wear. Product safety and operation must therefore be checked during inspection and maintenance intervals.

5.3 Handpiece sterilization (only for PRIMA-FIX/PRIMA-FLEX model)

Replace the handpieces as soon as these become cracked or deformed, as these could fall in the patient area.
The Product operator must comply with the rules established by the national commission for hygiene and disinfection.
Handpiece fitting / removal:
- turn the handpiece anti-clockwise and remove it;
- turn the handpiece clockwise until it is up against the headpiece and rotation is blocked.

Cleaning, disinfection and sterilization of the handpiece
Handpieces are made of plastic material resistant to heat and knocks (PPSU - Polyphenylsulphone).
They can be cleaned with a mild o mid-alkaline detergent free of active chlorine.
To disinfect the handpieces, we suggest using alcohol or aldehyde-based products. The disinfectants must be approved by the manufacturer for use on Polyphenylsulfone (PPSU).
Rinse the handpieces before sterilization.
Handpieces can withstand about 200 steam sterilization cycles in accordance with the following parameters:
- steam sterilization at 121°C and 1.3 bar from 25 to 30 minutes,

or
- steam sterilization at 134°C and 2.3 bar for 4 minutes.

Position the handpieces in straight position with open side downwards.
Do not exceed a sterilization temperature of 134°C.
Avoid the handpieces coming into contact with other objects during the sterilization process.
Strictly keep to the ISO 17665-1 standard.

6 Adjustments

6.1 Yearly inspections by operator

Keep to the yearly inspection schedules and inspect the product according to IEC 62353 standard.

6.2 Repairs

The Product must only be opened and repaired by the manufacturer. Contact customer service as indicated on page 1 in case of need.

Making any changes to this appliance is forbidden.

6.3 Clutch adjustments

The Product is sold balanced and does not require further adjustment. Nevertheless, if the movements of the arms around the rotation joints becomes too stiff or too loose over time, such as to prevent the device remaining in position, the different clutch systems can be adjusted to restore correct stability.

Use the Allen key to adjust clutch force at the rotation joints and, therefore, the consequent movement of the small moving arms.

Rotation joints

The different device versions have a different number of joints and therefore of clutches:

ALFA-FIX

L88-LED-M
(GIMANORD)

PRIMA-FIX

PRIMA-FLEX

Adjustment procedure

Remove the adhesive to access the joint in question. Using the Allen key, adjust the screw alongside the joint.
Turn clockwise to increase the force of the clutch and stiffen movement.
Turn anti-clockwise to reduce the force of the clutch and loosen movement.
At the end of the adjustment, movement should still be smooth and uniform.

6.4 *Troubleshooting*

No.	Problem	Solution
1	The Product fails to work	Contact the after-sales service.
2	The Product does not remain in position	See par. 6.3. If, after adjustment, the product still fails to remain in position, contact the after-sales service.
3	The light flickers	Contact the after-sales service.
4	The light beam is not focalised	Contact the after-sales service.

6.5 *Routine maintenance*

No.	Internal	Action
1	Once a year	Perform complete movements of all Product joints and make sure movement is smooth. If the Product fails to maintain its position or its movements are hard, contact the after-sales service. See also par. 6.3.
2	Once a year	Make sure the retention screws of connections are tightened properly. If these are not properly fastened, adequately tighten.
3	Once a year	Check the condition of the Product paint. Make sure there are no paint pieces that could fall in the patient area. If any paint pieces deemed hazardous are found, contact the after-sales department.

6.6 *Spare parts list*

Use original RIMSA parts only.

Description	Order code
Sterilisable grip	Z100848

7 Technical properties

7.1 Technical properties ALFA-FIX/ALFA-FLEX

Technical properties	ALFA-FIX/ALFA-FLEX
Illumination E_c at 50cm distance ± 10% [Lux]	60,000
Colour temperature (±5%) [K]	4,500
Colour rendering index Ra [-]	94
R_9 [-]	55
Light range diameter d_{10} [mm]	130
Light range diameter d_{50} [mm]	75
Max irradiation [W/m²]	255
Irradiation / Illumination [mW/m²lx]	3.64
Max irradiation in UV [W/m²]	0.022
Power connection details	
Primary alternate voltage [Volt ac]	100-240
Frequency [Hz]	50/60
Power input [VA]	15
Current to LED module [A]	Max 1
Light source	N°3 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	4 - 100
General data	
Regulation	REGULATION (EU) 2017/745
Classification of Product according to REGULATION (EU) 2017/745	Class I
Standards	IEC 60601-1 and IEC 60601-2-41
Classification of Product according to IEC 60601-1	CLASS II
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use and the colour temperature and the colour rendering index are stable and are within the range 3,000K-6,700K and 85-100, respectively).
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance E_e in the lighted area does not exceed 1,000 W/m² at a distance of 500 mm).
Colour	RAL 9003
IP Classification	IP20
Operating conditions	Continuous operation
Mains power voltage insulation means	Integrated power plug
Dimensions	
Diameter of lamp body [cm]	9.6
Light field diameter [cm]	15
Lens diameter [cm]	3.2
Light emission surface [cm²]	22
Lamp weight [kg]	2
Markings	
CE	In conformity with REGULATION (EU) 2017/745

All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons.

7.2 Technical properties L88-LED-M (GIMANORD)

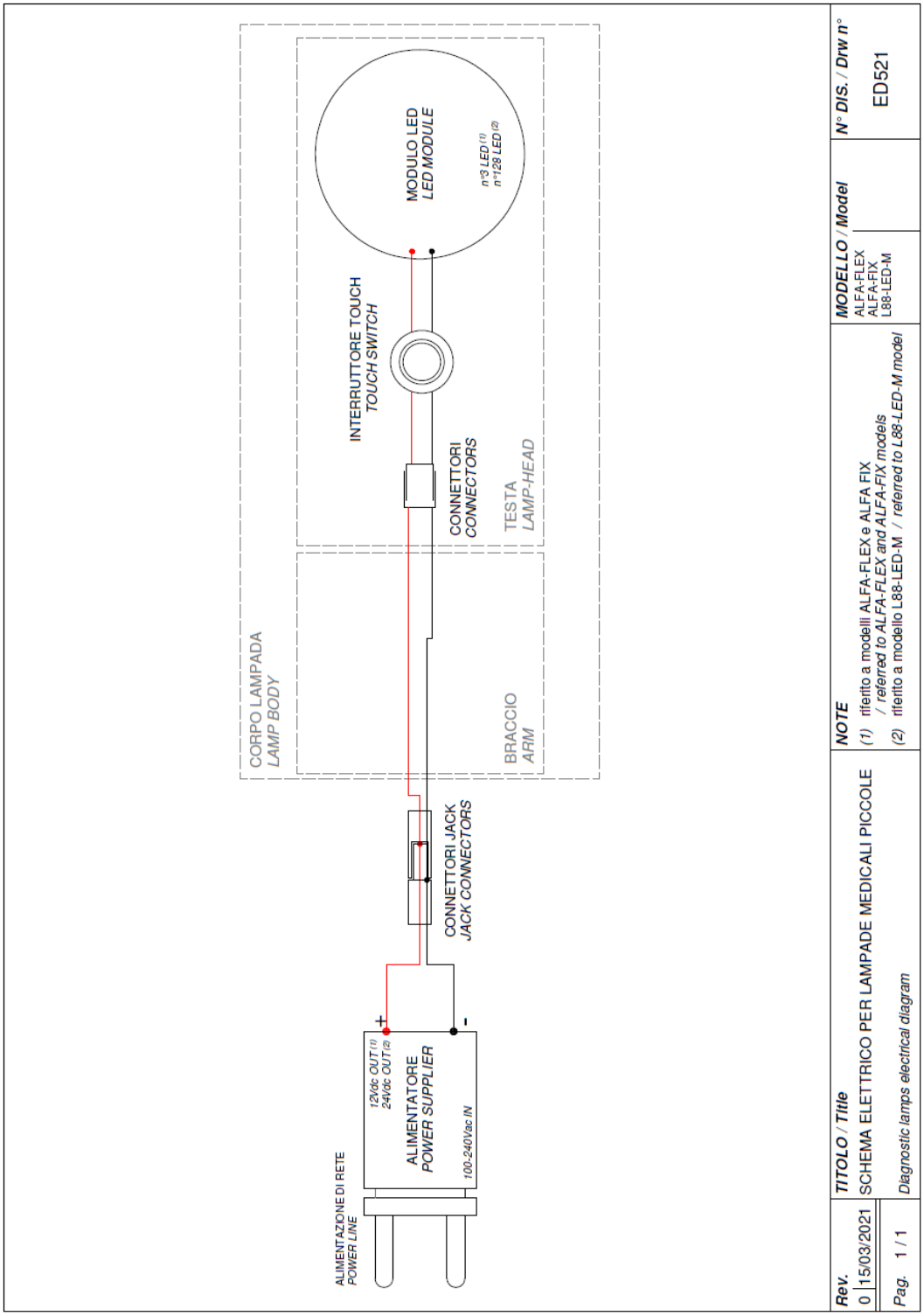
Technical properties	L88-LED-M (GIMANORD)
Illumination Ec at 50cm distance ± 10% [Lux]	2,250
Colour temperature (±5%) [K]	5,000
Colour rendering index R_a [-]	95
R_9 [-]	88
Light range diameter d_{10} [mm]	900
Light range diameter d_{50} [mm]	700
Max irradiance [W/m²]	7.65
Irradiation / Illumination [mW/m²lx]	3.4
Max radiation in UV [W/m²]	0.0003
Power connection details	
Primary alternate voltage [V ac]	100-240
Frequency [Hz]	50/60
Absorbed power [VA]	38
Current to LED module [A]	Max 0.75
Light source	N°128 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	5 - 100
General data	
Regulation	REGULATION (EU) 2017/745
Classification of Product according to REGULATION (EU) 2017/745	Class I
Standards	IEC 60601-1 and IEC 60601-2-41
Classification of Product according to IEC 60601-1	CLASS II
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use and the colour temperature and the colour rendering index are stable and are within the range 3,000K-6,700K and 85-100, respectively)
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance E_e in the lighted area does not exceed 1,000 W/m² at a distance of 500 mm).
Colour	RAL 9003
IP Classification	IP20
Operating conditions	Continuous operation
Mains power voltage insulation means	Integrated power plug
Dimensions	
Diameter of lamp body [cm]	23
Lamp weight [kg]	3
Markings	
CE	In conformity with REGULATION (EU) 2017/745
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons.	

7.3 Technical properties PRIMA-FIX/PRIMA-FLEX

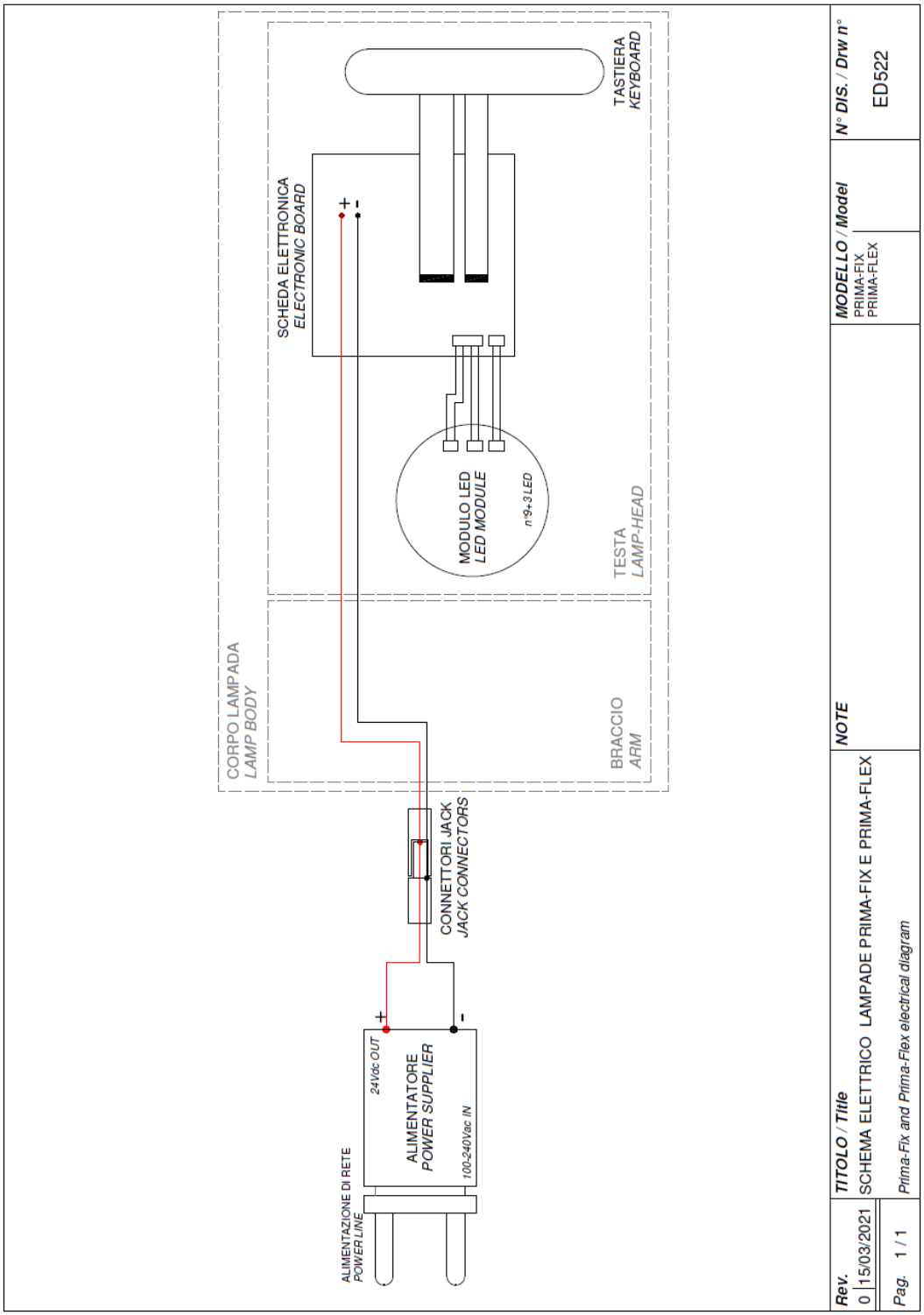
Technical properties	PRIMA-FIX/PRIMA-FLEX
Illumination E_c at 50cm distance ± 10% [Lux]	105,000
Colour temperature (±5%) [K]	4,000/4,500
Colour rendering index Ra [-]	95
R_9 [-]	61
Light range diameter d_{10} [mm]	150
Light range diameter d_{50} [mm]	82
Max irradiation [W/m²] *(4000K – 4500K)*	357 - 387
Irradiation / Illumination [mW/m²lx] *(4000K – 4500K)*	3.61 - 3.67
Max irradiation in UV [W/m²]	0.03
Focalization from grip	No
Power connection details	
Primary alternate voltage [Volt ac]	100-240
Frequency [Hz]	50/60
Power input [VA]	23
Current to LED module [A]	Max 0,75
Light source	N°9+3 LEDs
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	25 – 100
General data	
Regulation	REGULATION (EU) 2017/745
Classification of Product according to REGULATION (EU) 2017/745	Class I
Standards	IEC 60601-1 and IEC 60601-2-41
Classification of Product according to IEC 60601-1	CLASS II
Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the ME equipment does not vary by more than 20% during use and the colour temperature and the colour rendering index are stable and are within the range 3,000K-6,700K and 85-100, respectively).
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm does not exceed 10 W/m² and the total irradiance E_e in the lighted area does not exceed 1,000 W/m² at a distance of 500 mm).
Colour	RAL 9003
IP Classification	IP20
Operating conditions	Continuous operation
Mains power voltage insulation means	Integrated power plug
Handpiece steam sterilization	121°C and 1.3 bar from 25 to 30 minutes
Dimensions	
Diameter of lamp body [cm]	19.5
Lens diameter [cm]	3.2
Light emission surface [cm²] *(4000K – 4500K)*	42-63
Lamp weight (PRIMA-FIX / PRIMA-FLEX) [Kg]	3.5/3.3
Markings	
CE	In conformity with REGULATION (EU) 2017/745
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons.	

8 Wiring diagrams

8.1 Wiring diagram ALFA-FIX/ALFA-FLEX and L88-LED-M (GIMANORD)



8.2 Wiring diagram PRIMA-FIX/PRIMA-FLEX



9 EMC Declaration

The Product has been tested according to IEC 60601-1-2 standard to ensure correct electromagnetic compatibility.
Portable and mobile RF-communications equipment can affect the Product. The Product should not be used adjacent with other equipment and that if adjacent use is necessary the Product should be observed to verify normal operation.
The Product is intended for use in the electromagnetic environment specified below. The customer or the user of the Product should assure that is used in such an environment.

Emissions test	Conformity	Electromagnetic environment - directives
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 establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Product or shielding the location.
Harmonic emissions IEC 61000-3-2	Conforming	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Conforming	
NOTE: The EMISSIONS characteristics of this 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.		

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	± 2 kV For power supply unit ± 1 kV For input/output lines	± 2 kV For power supply lines ± 1 kV For input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV Differential mode ± 0.5 kV, ± 1 kV, ± 2 kV Common mode	± 0.5 kV, ± 1 kV Differential mode ± 0.5 kV, ± 1 kV, ± 2 kV Common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	<5% U_T (>95% dip in U_T) For 0,5 cycle 40% of U_T (60% dip in U_T) For 5 cycles 70% of U_T (30% dip in U_T) For 25 cycles <5% U_T (>95% dip in U_T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Product requires continued operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is is the a.c mains voltage prior to application of the test level.			

Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 Veff 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Product, included cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and *d* is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance leave in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the Product

The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people