

MO092-EN	13/04/22	<b>E K I</b>
Rev.1	Page 1 of 17	

# **USER MANUAL FOR ME EQUIPMENT**

# **FONTE LUCE FL200K**

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.

This User manual is valid for the following model: FONTE LUCE FL200K

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: <u>info@rimsa.it</u>

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

The contents of this Manual may be amended by RIMSA, without prior notice or any further obligations, in order to make changes and improvements. The reproduction and translation, including partial, of any part of this manual is forbidden without the written permission of RIMSA.

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.



MO092-EN	13/04/22	ENI
Rev.1	Page 2 of 17	LIA

# **CONTENTS**

1 G	eneral information	4
1.1	Operator qualification	4
1.2	Packaging, transport, storage and characteristics of installation premises	5
1.3	Graphic symbols used on the Product	5
1.4	EU Declaration of conformity	6
1.5	Warranty Certificate	7
2 In	nportance of personal safety	8
2.1	Intended use	8
2.2	Safety conditions (secondary effects)	8
2.3		8
2.4	Controls to be performed every time before the lamp is used	8
3 Pi	roduct installation	9
3.1	First switch-on	9
3.2	Check the result of Product installation and testing before use	9
4 D	escription and operation	10
5 C	leaning and disinfecting	10
5.1	Cleaning the Product	10
5.2	Disinfecting	11
6 A	djustments	12
6.1	Yearly inspections by operator	12
6.2	Repairs	12
6.3	Troubleshooting	12
6.4	Routine maintenance	12
7 Te	echnical properties	13
	MC Declaration	14



MO092-EN	13/04/22	ENI
Rev.1	Page 3 of 17	LIA

BG За да поискате наръчника на този език, изпратете имейл на адрес info@rim	nsa.it.
---	---------

- CS Chcete-li si vyžádat příručku v tomto jazyce, zašlete e-mail na adresu info@rimsa.it.
- DA Hvis du ønsker at få manualen på dette sprog, bedes du sende en e-mail til info@rimsa.it.
- DE Um das Handbuch in dieser Sprache anzufordern, senden Sie bitte eine E-Mail an info@rimsa.it.
- EL Για να ζητήσετε το εγχειρίδιο σε αυτή τη γλώσσα, στείλτε μήνυμα ηλεκτρονικού ταχυδρομείου στη διεύθυνση info@rimsa.it.
- ES Para solicitar el manual en este idioma, envíe un correo electrónico a info@rimsa.it.
- ET Selles keeles käsiraamatu tellimiseks saatke palun e-kiri aadressile info@rimsa.it.
- FI Jos haluat käsikirjan tällä kielellä, lähetä sähköpostia osoitteeseen info@rimsa.it.
- FR Pour demander le manuel dans cette langue, veuillez envoyer un e-mail à info@rimsa.it.
- GA Chun an lámhleabhar sa teanga seo a iarraidh, seol r-phost chuig info@rimsa.it.
- HR Da biste zatražili priručnik na ovom jeziku, pošaljite e-mail na info@rimsa.it.
- HU A kézikönyv ezen a nyelven történő igényléséhez kérjük, küldjön e-mailt a info@rimsa.it címre.
- LT Norėdami prašyti vadovo šia kalba, siųskite el. laišką adresu info@rimsa.it.
- LV Lai pieprasītu rokasgrāmatu šajā valodā, lūdzu, sūtiet e-pastu uz adresi info@rimsa.it.
- 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.



MO092-EN	13/04/22	ENI
Rev.1	Page 4 of 17	

## 1 General information

The ME (Medical Electrical) EQUIPMENT to which this manual refers is a light generating light source for endoscopic instruments. 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 light source.

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	
Comply with applicable laws on waste disposal. This produce be disposed of in standard waste disposal bins. To avoid environment and health deriving from the dispersion substances in the environment, separate the various component parts such as iron, aluminium, plastic an material, and dispose of these through authorized channel ensure correct recycling, once the equipment has reached the useful life (10 years).		



MO092-EN	13/04/22	ENI
Rev.1	Page 5 of 17	CIA

## 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.

## Graphic symbols used on the Product

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



CE marking indicating the Product conforms to REGULATION (EU) 2017/745 and subsequent amendments and supplements



Date of manufacture (year/month)



Manufacturer's address



RECYCLING! The Product must be recycled separately



Stand-By



ON power



Top side of packaging



Protect from rain



Humidity to be complied (indicate max limit at top right and min limit at bottom left)



Limit temperature (indicate max limit at top right and min limit at bottom left)



General warning signal



Manual reading obligation



**Medical Device** 



Model reference



Serial number



Functional earth



CLASS II equipment



OFF power



Fragile packaging



Max number of stackable boxes



Pressure to complied be (indicate max limit at top right and min limit at bottom left)



Materials and composition



General mandatory code of conduct signal



Do not stare directly at the light source



MO092-EN	13/04/22	ENI
Rev.1	Page 6 of 17	

### 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.I.

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: FONTE LUCE FL200K

Model reference: FL200K

Intended purpose: LIGHT-GENERATING SOURCE FOR ENDOSCOPIC INSTRUMENTS

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

RYANS A PLONGONISH ONE

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:

EN 60601-1 (Part 1: General requirements for basic safety and essential performance)

• EN 60601-1-2 (Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)

• EN 60601-2-18 (Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment)

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



MO092-EN	13/04/22	ENI
Rev.1	Page 7 of 17	LIN

## 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.



MO092-EN	13/04/22	EVI
Rev.1	Page 8 of 17	

## 2 Importance of personal safety

#### 2.1 Intended use

The Product is used to generate cold light for transfer to endoscopy instruments.



The Product is not intended for use in emergency rooms or 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 cover the Product during operation.
   Failure to comply could prevent heat exchange with the
  - Failure to comply could prevent heat exchange with the environment and the Product could overheat.
- Place the Product on a stable and horizontal support, free from vibrations.
- All operations must be performed by qualified personnel only.
- The light source contained in this appliance must be replaced only by the manufacturer or by his service assistance or by such qualified personnel.
- To avoid any significant risk of reciprocal interference due to the presence of the Product during specific exams or treatments, see section 8 of the manual.

#### 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<sub>2</sub>O (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, 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.



MO092-EN	13/04/22	ENI
Rev.1	Page 9 of 17	

## 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 installation of the Product must be carried out in an environment for medical use in compliance with the instructions in this manual. The electrical system of the (local) environment in which the installation is carried out must comply with the IEC 60364-7-710 standard (standard for electrical systems for rooms used for medical use) and similar standards.



The Product is not intended for use in emergency rooms or operating theatres.



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

#### 3.1 First switch-on

To verify the correct functioning of the Product, follow the steps below:

- 1. Check that the switch (I / O) on the front panel is in position O;
- 2. Connect the jack coming from the device cable with that of the power supply;
- 3. Insert the power plug into the socket;
- 4. Insert the LED handpiece cable (not supplied) into the connector on the front panel;
- 5. Turn the switch (I/O) to position I and check that the fan turns on;
- 6. Touch the touching key on the front panel;
- 7. Check the correct operation of the LED and of all functions.

## 3.2 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

DE	ticked.	
1.	Verify that the environment of use is suitable and complies with the national provisions in force.	
2.	Check that the Product is placed on a stable and horizontal support, free from vibrations.	
3.	Check the connection between the cable coming from the Product and the one coming from the power supply.	າe □
4.	After switching on, the Product must emit light.	
	Installer's stamp and signature:	



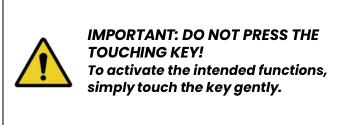
MO092-EN	13/04/22	EVI
Rev.1	Page 10 of 17	

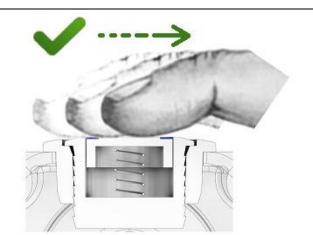
## 4 Description and operation

The Product is equipped with 16 cold light LEDs focused through a special lens. The light source then passes through an additional spherical biconvex lens.

On the front of the Product there is a switch that allows you to power up and activate the cooling fan. On the front of the Product there is also 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 and then turn off the switch; 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.

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 indications shown on the manufacturer's technical sheet, being careful that no liquids penetrate into the joints of the various Product parts.



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.



MO092-EN	13/04/22	ENI
Rev.1	Page 11 of 17	

### 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.

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.

Dilute the disinfectants strictly according to the percentage indications shown on the manufacturer's technical sheet, being careful that no liquids penetrate into the joints of the various Product parts.



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.



MO092-EN	13/04/22	<b>E</b> KI
Rev.1	Page 12 of 17	

## 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 Troubleshooting

No.	Problem	Solution
1	The Product does not turn on	Make sure that the power cord plug is inserted into the mains socket and that the socket supplies voltage. Make sure that the I/O switch is in position O. Disconnect the power plug, wait a few minutes and reconnect it. If the problem persists, contact assistance.
2	light (the fan is on but no	Make sure that the power cord plug is inserted into the mains socket and that the socket supplies voltage. Make sure that the LED handpiece cable is connected correctly and that the I/O switch is in position O. Disconnect the power plug, wait a few minutes and reconnect it. If the problem persists, contact assistance.

## 6.4 Routine maintenance

No.	. Internal Action	
1 Once a year power cable is not damaged/ worn of touching key are working properly.  Check the condition of the Product pair paint pieces that could fall in the power cable is not damaged/ worn of touching key are working properly.		Check the general condition of the Product. Check that the power cable is not damaged/ worn and that the switch and touching key are working properly.
		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 assistance.



MO092-EN	13/04/22	EVI
Rev.1	Page 13 of 17	

# 7 Technical properties

Technical properties	FONTE LUCE FL200K
Illumination E <sub>c</sub> at 2.5cm distance ± 10% [Lux]	147,000
Colour temperature (±5%) [K]	5,000
Colour rendering index Ra [-]	89
R <sub>9</sub> [-]	54
Max irradiation [W/m²]	488
Irradiation / Illumination [mW/m²lx]	3.32
Power connection details	
Primary alternate voltage [Volt ac]	100-240
Frequency [Hz]	50/60
Power input [VA]	34
Power input [W]	max 18
Light source	Nº16 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 60601-2-18
Standards  Classification of Product according to IEC 60601-1 standard	IEC 60601-1 and IEC 60601-2-18  CLASS II
Classification of Product according to IEC 60601-1	
Classification of Product according to IEC 60601-1 standard	CLASS II
Classification of Product according to IEC 60601-1 standard Colour	CLASS II RAL 9003
Classification of Product according to IEC 60601-1 standard Colour IP Classification	CLASS II RAL 9003 IP20
Classification of Product according to IEC 60601-1 standard  Colour  IP Classification  Operating conditions	CLASS II  RAL 9003  IP20  Continuous operation
Classification of Product according to IEC 60601-1 standard  Colour  IP Classification  Operating conditions  Mains power voltage insulation means	CLASS II  RAL 9003  IP20  Continuous operation
Classification of Product according to IEC 60601-1 standard  Colour  IP Classification  Operating conditions  Mains power voltage insulation means  Dimensions	CLASS II  RAL 9003  IP20  Continuous operation  Integrated power plug
Classification of Product according to IEC 60601-1 standard  Colour  IP Classification  Operating conditions  Mains power voltage insulation means  Dimensions  Product weight [kg]	CLASS II  RAL 9003  IP20  Continuous operation  Integrated power plug
Classification of Product according to IEC 60601-1 standard  Colour  IP Classification  Operating conditions  Mains power voltage insulation means  Dimensions  Product weight [kg]  Dimensions [cm]	CLASS II  RAL 9003  IP20  Continuous operation  Integrated power plug



MO092-EN	13/04/22	ENI
Rev.1	Page 14 of 17	LIN

### 8 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.

<b>Emissions test</b>	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 A	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
Harmonic emissions IEC 61000-3-2	Not Applicable	buildings used for domestic purposes, provided the following warning is heeded:  WARNING: This equipment/system is intended for use
Voltage fluctuations/flicker emissions IEC 61000-3-3	Conforming	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 reorienting or relocating the Product or shielding the location.

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.



MO092-EN	13/04/22
Rev.1	Page 15 of 17



Immunity test	Test level to IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge	± 8 kV contact	± 8 kV contact	Floors should be wood, concrete or ceramic tile.  If floors are covered with synthetic
(ESD) IEC 61000-4-2	± 15 kV air	± 15 kV air	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	± 2 kV For power supply lines ± 1 kV	Mains power quality should be that of a typical commercial or residential environment.
	For input/output lines	For input/output lines	
Surge IEC 61000-4-5	± 1 kV Differential mode	± 1 kV Differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 01000-4-5	± 2 kV Common mode	± 2 kV Common mode	
	<5% U <sub>τ</sub> (>95% dip in U <sub>τ</sub> ) For 0,5 cycle	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) For 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Product requires continued
Voltage dips, short interruptions and voltage variations on	$40\%$ of $U_T$ (60% dip in $U_T$ ) For 5 cycles	$40\%$ of $U_T$ (60% dip in $U_T$ ) For 5 cycles	operation during power mains interruptions, it is recommended that the Product be powered from an uninterruptible power supply or
power supply input lines IEC 61000-4-11	70% of $U_T$ (30% dip in $U_T$ ) For 25 cycles	$70\%$ of $U_T$ (30% dip in $U_T$ ) For 25 cycles	battery.
	$<5\% U_T$ (>95% dip in $U_T$ ) For 5 sec	$<5\% U_T$ (>95% dip in $U_T$ ) For 5 sec	
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.



MO092-EN	13/04/22	EN
Rev.l	Page 16 of 17	

Immunity test	Test level to	Conformity	Electromagnetic environment -
	IEC 60601-1-2	level	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 $d = 1.2\sqrt{P}  150 \text{ KHz to } 80 \text{ MHz}$ $d = 1.2\sqrt{P}  80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P}  800 \text{ MHz to } 2.7 \text{ GHz}$ 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.



MO092-EN	13/04/22	С
Rev.1	Page 17 of 17	

# 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 $d = 1.2\sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = 1.2\sqrt{P}$	<b>800 MHz to 2.7 GHz</b> $d = 2.3\sqrt{P}$	
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