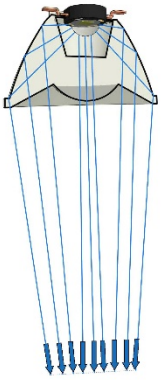
LAMP MODEL ALFA-LED

Light plays a major role in the medical field, being required to provide a faithful image of what the doctor sees during observation.
ALFA Led is an examination lamp in compliance with Directives 93/42 EEC and 2007/47 EC and bear the CE mark as Class 1 medical devices. It is in conformity with the general **IEC 60601-1** standard and with the specific **IEC 60601-2-41** standard and are therefore also usable in intensive-care wards, as well as in all medical surgeries.

Design: each lamp has been shaped to make the product ergonomic, making it suitable for all types of application and easy to clean.



Components, assistance, Italian spares: the availability of spare parts is guaranteed over the years and technical assistance is provided by carefully-selected distributors. Professionalism and quality have distinguished RIMSA products for over seventy years.

Thanks to three independent light sources, shadows can be reduced and provide a deep cylindrical light with highly reduced heat irradiation. Each LED integrates a resistance to ensure the continuous operation of the lamp even in the rare case of a LED fault. Medical power supply unit integrated in the base with double safety fuse, lead retainer with spiral protection and bipolar light switch with green indicator light, all features required to conform to medical standards. The flexible arm, for easy light adjustment, is 60 cm long and is covered by a smooth white shrink-wrap sheath for easier cleaning and disinfection. Voltage 100÷240V 50-60Hz. Especially suitable for: gynaecology surgeries, intensive-care units, bed headboard modules, ear, nose and throat surgeries, medication rooms and check-up rooms.

PERFORMANCES		
Light intensity at 0,5 m distance (Ec)	Klx	35.000 lux
Color temperature	K	4.200K
Color rendering index (CRI)	Ra	95
R9		≥ 90
Light field size at 50cm	mm	140 mm
ELECTRICAL DATA		
Primary alternating voltage (a.c.)	V	100 - 240
Frequency	Hz	50 / 60
Absorbed power	VA	20
Light head diameter	Cm	8,6
No. of LED	Led	3
Average LED life	hours	>60.000

AVAILABLE FIXING SYSTEMS:

- **TABLE CLAMP S11**
- **WALL CLAMP S12MED**
- **MOBILE BASE ON WHEELS RLALFA**
- **RAIL CLAMP Z40072**

Compulsory requirements of general medical standard IEC 60601-1:

§ 15.4.4 luminous bipolar switch
§ 8.11.3.6 safety cord
§ 8.11.5 double fuse
§ 9.2 no mechanical hazards
§ 9.3 shaped edges
§ 8.11.3.3 cord section
§ 9.4.2.2 tilting test 10°

Luminous bipolar switch 15.4.4

15.4.4 Indicators

Unless it is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided to indicate that ME EQUIPMENT is ready for NORMAL USE. The marking of 7.4.1 is not sufficient for this purpose.

.....Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.

Safety cord 8.11.3.6

8.11.3.6 Cord guards

POWER SUPPLY CORDS of other than STATIONARY ME EQUIPMENT shall be protected against excessive bending at the inlet opening of the equipment or of the MAINS CONNECTOR by means of a cord guard of insulating material or by means of an appropriately shaped opening in the ME EQUIPMENT.

(If a power cord were not adequately protected against excessive bending, there would be a high probability of breakage of power-carrying conductors, giving a RISK of fire, and with CLASS I ME EQUIPMENT, a high probability of breakage of the PROTECTIVE EARTH CONDUCTOR.)

Double fuse 8.11.5

8.11.5 Mains fuses and over-current releases

A fuse or OVER-CURRENT RELEASE shall be provided in each supply lead for CLASS I ME EQUIPMENT and for CLASS II ME EQUIPMENT having a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT.

No mechanical hazards 9.2

9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

9.2 HAZARDS associated with moving parts

9.2.1 General

ME EQUIPMENT with moving parts shall be designed, built and laid out so that, when PROPERLY INSTALLED and used as indicated in the ACCOMPANYING DOCUMENTS or under reasonably foreseeable misuse, the RISKS associated with those moving parts are reduced to an acceptable level.

The RISK from contact with the moving parts shall be reduced to an acceptable level by use of protective measures, bearing in mind the ease of access, the ME EQUIPMENT'S function, the shape of the parts, the energy and speed of the motion and the benefits to the PATIENT.

9.2.2.2 Gaps

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the gaps of the TRAPPING ZONE comply with the dimensions specified in Table 20.

Table 20 – *Acceptable gaps (a)*

Part of body	Adult gap (a) mm	Illustration
Finger	> 25 or < 8	

Shaped edges 9.3

9.3 HAZARD associated with surfaces, corners and edges

Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK shall be avoided or covered. In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Cord section 8.11.3.3

8.11.3.3 Cross-sectional area of POWER SUPPLY CORD conductors

The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than that shown in Table 17.

Compliance is checked by inspection.

Table 17 – *NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD*

RATED current (I) of ME EQUIPMENT A	NOMINAL cross-sectional area mm2 Cu
I ≤ 6	0,75
6 < I ≤ 10	1
10 < I ≤ 16	1,5
16 < I ≤ 25	2,5
25 < I ≤ 32	4
32 < I ≤ 40	6
40 < I ≤ 63	10

Tilting test 10° 9.4.2.2

9.4.2.2 Instability – overbalance

ME EQUIPMENT or its parts shall not overbalance when placed in any transport position of NORMAL USE on a plane inclined at an angle of 10 ° from the horizontal plane.

Compliance is checked by the following test: Prior to the test the ME EQUIPMENT is prepared as indicated in the ACCOMPANYING DOCUMENTS (or, if not specified, as in 9.4.2.2). The ME EQUIPMENT or its parts is placed on a plane inclined at an angle 10 ° from the horizontal plane. If the ME EQUIPMENT or its parts overbalances, it constitutes a failure.

ALFA LED