

TECHNICAL REPORT



ALFA-FLEX

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REQUIREMENTS

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- 5; 6 • Examination lamp with flexible or articulated arm on mobile support
- 11 • Power supply 220V, 50Hz.
- 9 • Luminous field size ≥ 120 mm
- 9 • Color temperature 4000 - 5500 K
- 5 • Adjustable height 1500-1800 mm (range)
- 6 • Vertically adjustable support with anti-corrosion coating
- 6 • Base with anti-corrosion coating
- 6 • Technology Lighting based on LED technology
- 10; 11 • LED life time $\geq 50,000$ h
- 5; 6 • Mandatory flexible arm
- 8 • Illumination level at a distance of 50 cm minimum 35,000 lux
- 5; 6 • Mobile on support with minimum 5 wheels mandatory

THE COMPANY

RIMSA, established in 1936 by Palmino Longoni, was initially a mechanical workshop dedicated to repairing typewriters and the like; hence, the acronym R.I.M.S.A. (Riparazione di Macchine da Scrivere e Affini).

The transition from repair workshop to production facility took place in the **1940s**, when Mr. Palmino decided to give shape to a product of his own. Since then, RIMSA dedicated itself to the design and development of balanced arm lamps. Company growth resulted in an expansion of the product range with the introduction of magnifying and fluorescent lamps. Starting in the post-war period, RIMSA began making a name for itself in the electronics, goldsmithery, dentistry and industrial sectors.

In the **80s**, RIMSA began focusing closely on the **surgical lighting** sector and, in April 1983, the Milan Trade Fair Authority awarded RIMSA the prize for the design of a halogen surgical lamp. Research in the medical field continued and in March 1992 the Milan Chamber of Commerce awarded the company the prestigious "Technological Innovation" qualification certificate for the design of the Stellare open-spoke surgical lamp for operating theatres with laminar air flow.

In **2002**, RIMSA developed the **world's first LED operating light**, at a time when this technology was still in its infancy.

In **2017**, RIMSA patented "**UNICA**" the world's first surgical light with **no glare**.

The company is **certified ISO 9001**, **ISO 13485** and **ISO 14001**; and all our products are marked **CE**.

1936
Establishment

1943
Palmino Longoni becomes
a member of the Italian
Inventors Guild

1945
Rimsa's first
balanced arm lamp

1956
Historical Company
certificate

1971
Purposely designed
CNC and lathe light

1983
Rimsa's first
surgical light

1992
Technological
Innovation Award

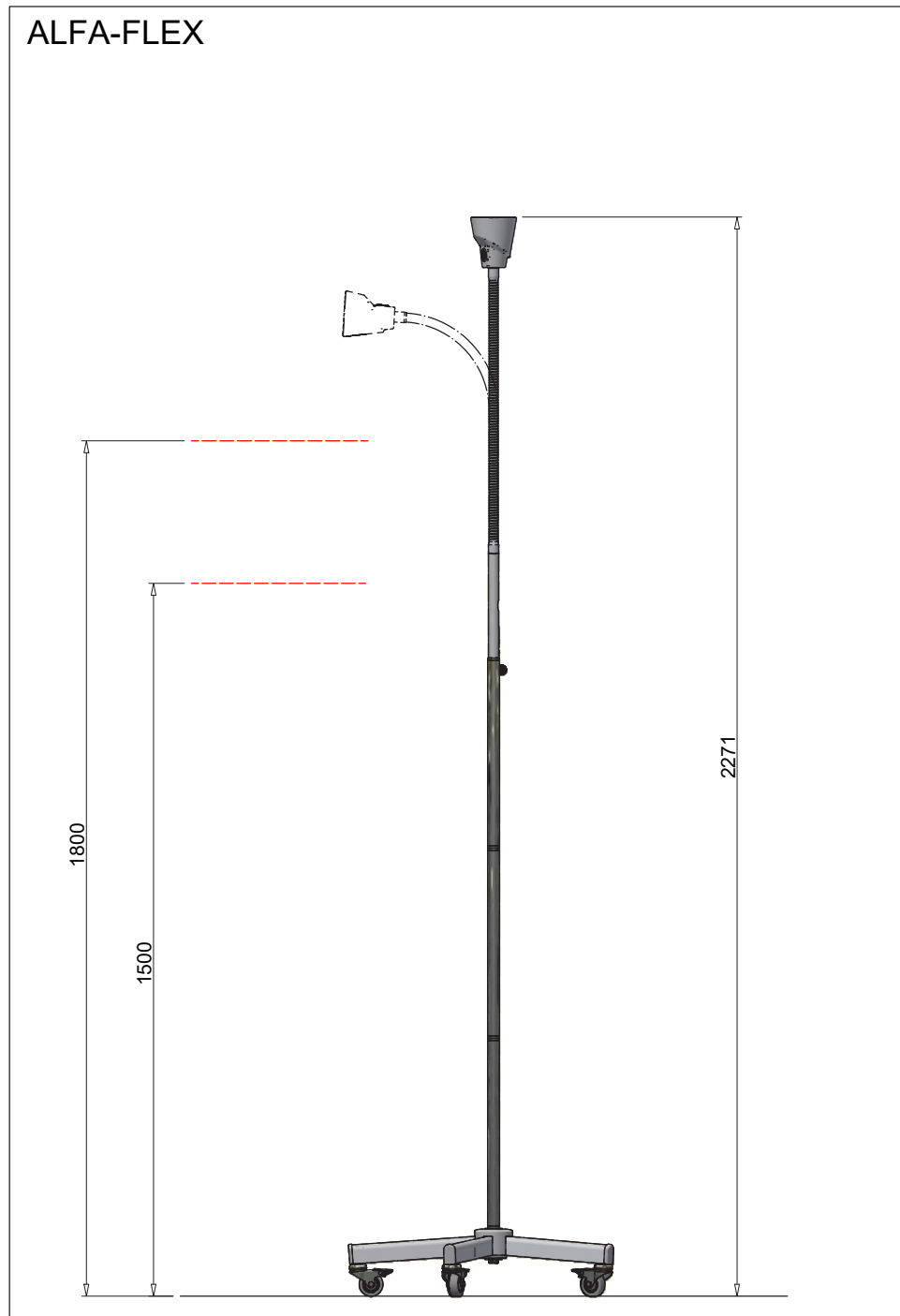
2002
Rimsa pioneers
the first LED surgical light

2017
Unica is the first LED
surgical light with no glare

2021
85th anniversary

Scialytic lamp model

ALFA-FLEX



This document is intended to highlight the necessary and desired characteristics of a operating light.

The document reviews the available literature on the subject in order to provide an up-to-date overview of the state of the art in operating theatre lighting technology. Divided into areas, the document specifies how the product offered by RIMSA meets every need.

ALFA

Examination lamp with flexible or articulated arm on mobile support. Vertically adjustable support with anti-corrosion coating and Base with anti-corrosion coating.

Mobile base RLBI with 5 wheels; each wheel with brake.

ALFA LED is an operating light suitable for gynaecology surgeries, intensive care units, head and bedside modules, otolaryngology outpatient clinics, dressing rooms and examination rooms.

Three LEDs are housed in the reflector to ensure bright, deep light with low power consumption and minimal heat radiation. Each LED is equipped with a resistor to ensure continuous use of the lamp even in the rare event that an LED should fail.

The flexible arm, for easy positioning of the lamp, is 60 cm long and is covered with a smooth white shrink sleeve for easy cleaning and disinfection.

The reflector is narrow and simple; optimal to save on space in the healthcare staff's work area. The lamp is very light and easy to move.

The lamp, which complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 – Standard **CEI 60601-2-41**, is a **Class I** medical device.

THE SCIALYTIC LAMP

The fundamental characteristic of the scialytic lamps, or surgical lamps, is to be found in the name itself. The term scialytic means “without shadows”; the surgical lamps are therefore lamps without shadows. ie: they are medical devices capable of generating a beam of light which neutralizes the shadow of the obstacle placed between the light source and the surgical field.

In addition to the ability to remove shadows, surgical lights must have other characteristics, including the ability to generate depth illumination and be designed to prevent temperature rise in the surgical area. In order to obtain an optimal vision in the cavities during surgery it is, in fact, necessary that the lamps are designed to offer deep light. Similarly, to avoid problems during operations, the operating lamp must generate the least amount of heat possible so as to reduce the risk of tissue dehydration. (Knulst 2009: A, p.38).

1919 —————> 2024

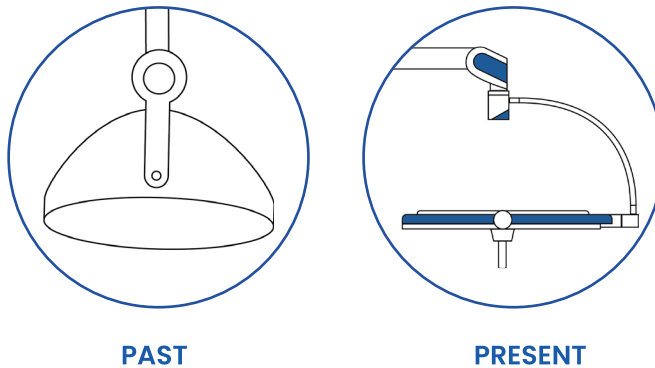


Figure 1:
Illustrated summary of
operating lights, from Verain
to UNICA

ILLUMINOTECHNICAL PROPERTIES

After having defined the nature of a surgical lamp, the illuminotechnical characteristics necessary for a surgical lamp are proposed.

Taking the **CEI 60601-2-41** standard as a reference, we highlight the necessary characteristics that every surgical lamp must possess. Without prejudice to the objective impossibility of appreciating some values in the absence of instruments, any positive variation of these limits is to be understood as a condition for improvement.

COLOR RENDERING INDEX (RA)

According to the CEI 60601-2-41 standard, surgical lamps must guarantee a minimum color rendering value which coincides with the maximum value perceptible to the naked eye (85 Ra). The Color Rendering Index (**CRI**) measures the ability of a light source to reproduce colors faithfully.

In the case ALFA, the value is **96 Ra**

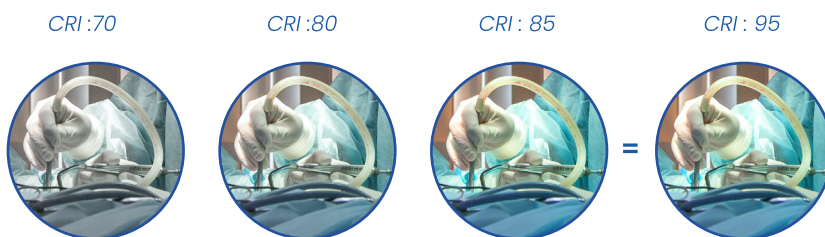


Figure 2:
Demonstration of the CRI

LIGHT INTENSITY

International legislation also establishes the maximum illuminance levels allowed for medical devices and in relation to scialytic lamps (Class I medical device), this limit is 160.000 Lux. Similarly to the color rendering index, even for the level of light intensity, it is not always necessary to have the maximum value available.

Some surgeons have in fact underlined how the illuminance from an operating lamp creates risks and annoyances: "Some of the operating lamps gave too much illuminance which resulted in glare and made it harder to see" (Hemphälä, 2009).

It is evident how literature suggests the abandonment of such high levels of light intensity and the evolution of international legislation is moving in this direction.

ALFA, is available at **70.000 lux**. However, it is recommended to use the lamp at a reduced intensity. It is possible to adjust the intensity **from 4 to 100%**.

TOUCH BOTTON

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.



COLOUR TEMPERATURE

The regulation of the colour temperature is an appreciated property even if it is defined as non-necessary by the literature. In fact, it has been proven that the first reason for appreciating this property is the possibility of replicating situations of illumination of the operating field similar to those offered by incandescent lamps (about 3,000K). Nonetheless, the literature demonstrates that a high temperature is preferable.

ALFA, comes with a colour temperatures of **4500 K**.

OPERATING FIELD

The operating field is set to 150 mm.

MANEUVERABILITY

RIMSA designs and manufactures each arm of the operating light structure according to ergonomic principles: the structures are completely in aluminum so as to reduce their weight while guaranteeing excellent stability. RIMSA is the only manufacturer of surgical lamps to make the support structures in-house. The lamp is always guaranteed to be stable.

GENERAL CHARACTERISTICS

Safety in case of failure: if a single LED is not working, this does not compromise the use of the lamp.

CLEANING Easily accessible parts subject to periodic maintenance and cleaning. Ease and ergonomics of use with particular regard to the cleaning and sanitizing operations of all parts.

CONSUMPTION extremely low consumption 7 W - 15 VA.

PRODUCT LIFE is a function of temperature. The LED, although capable of generating “cold” light, heats up and its useful life is a function of the temperature reached at the junction point or at the point where the LED is soldered to the printed circuit. The higher the temperature at the junction point, the shorter the useful life of the LED and therefore of the lamp. The ability to dissipate heat therefore allows to lengthen the useful life of the product. RIMSA products are entirely made in aluminium. Aluminum guarantees an excellent capacity to dissipate heat. The same printed circuit boards on which the LEDs are installed are made of three materials: copper, aluminum and ceramic. While copper allows for conduction and ceramic for insulation, aluminum allows for thermal transmission of the temperature at the junction point over a larger surface area, thus allowing for the reduction of this and resulting in an extended product life. Again to guarantee an extended useful life, RIMSA informs about the presence of a zener for each LED installed in the reflector. The function of this element is in fact to absorb the power of the relative LED should it stop working. These interventions therefore allow the product to guarantee a life of 60.000 + hours.

YEAR OF LAUNCH ON THE MARKET: 2021

ANTIMICROBIAL PAINT

The lamp is painted with antibacterial epoxy powder paint.

The painting department, which is internalised at Rimsa, features a 7-axis anthropomorphic unit that automatically recognises the component to be painted and independently initiates the consistent painting programme to ensure repeatable results.

The products are coated with antimicrobial epoxy powder paint to ensure perfect adhesion to components, resistance to cleaning and to reduce the presence of bacteria; this paint also has a low environmental impact when compared to other solutions. Discarded powder is filtered and reused, allowing us to reduce our environmental impact.

PERFORMANCES

Light intensity at 0,5 m distance (Ec)	Lux	70.000
Color temperature	K	4.500
Color rendering index (CRI)	Ra	96
d10 light field diameter where illuminance reached 10% of Ec	mm	150

ELECTRICAL DATA

Primary alternating voltage (ac)	V	100-240
Frequency	Hz	50/60
Absorbed power	W - VA	7 - 15
No. of LEDs	LED	3
Average LED life	hours	> 60.000
Light head diameter	cm	9,5
Control of illuminance	%	4-100

All technical light measurements are to be deemed with a tolerance of $\pm 6\%$ for metrological and manufacturing reasons



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