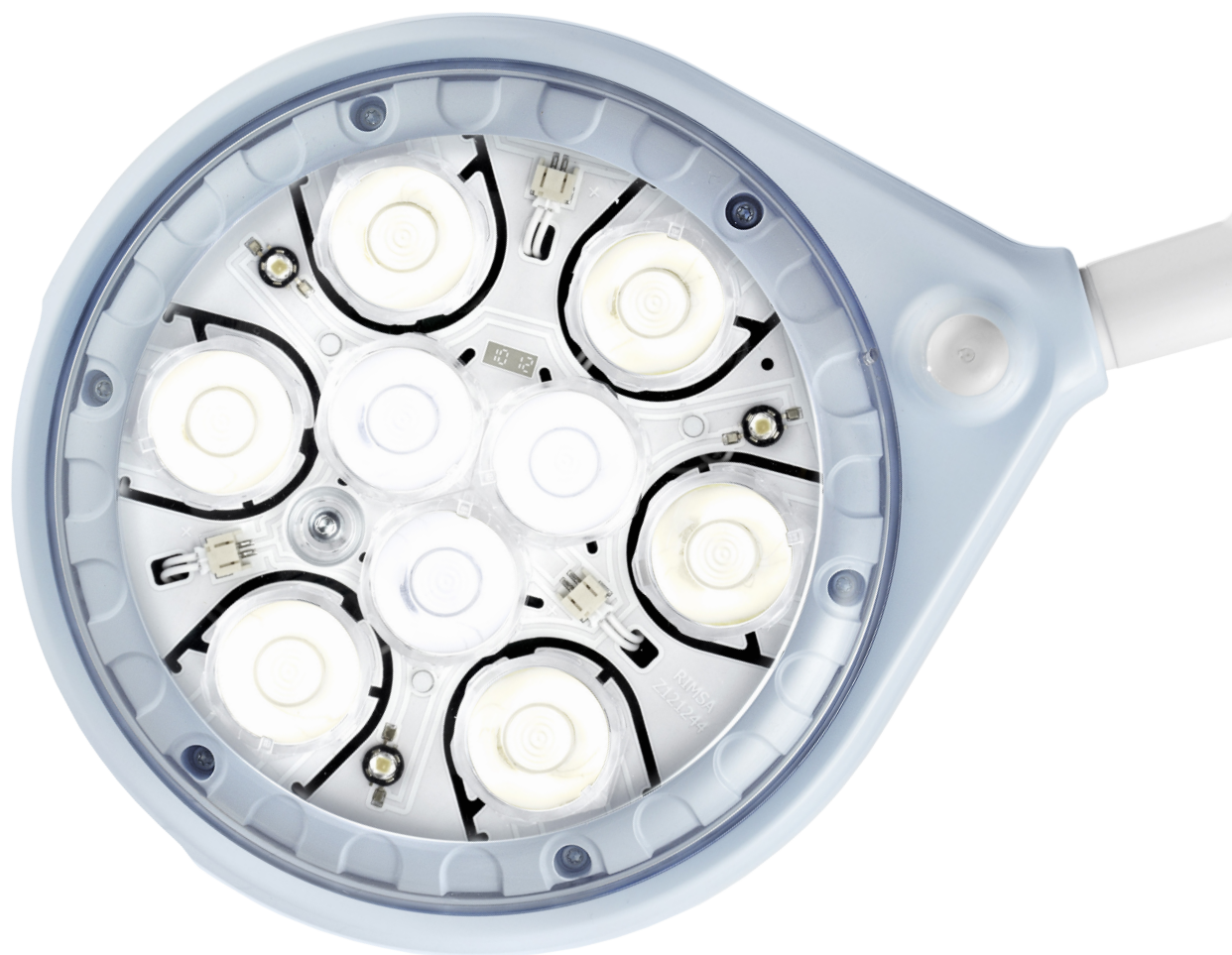


TECHNICAL REPORT



PRIMA LED

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REQUIREMENTS

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- 5; 6 • Examination lamp with articulated arm on mobile support
- 11 • Power supply 220V, 50Hz.
- 9 • Luminous field size ≥ 150 mm
- 9 • Color temperature 4000 - 5500 K
- 8 • Light intensity adjustment mandatory
- 5 • With adjustable height minimum range 1400-1900 mm
- 6 • Support with anti-corrosive coating vertically adjustable
- 6 • Base with anti-corrosive coating
- 6 • Technology Lighting based on LED technology
- 10; 11 • LED life time $\geq 50,000$ h
- 6 • Temperature increase in the light field ≤ 1 degree
- 6 • Articulated arm mandatory
- 8 • Illumination level at a distance of 50 cm minimum 60,000 lux
- 5; 6 • Mobile on support with at least 5 wheels mandatory
- 10 • "Handle for adjusting the inclination of the lamp reflector" mandatory

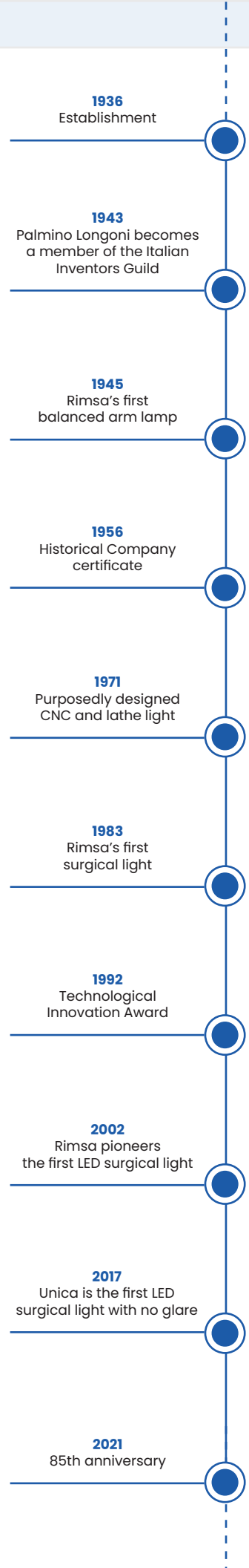
THE COMPANY

RIMSA, established by Palmino Longoni in 1936, began its history as a workshop for the repair of typewriters and similar products, hence the acronym RIMSA. The transition from a repair shop to a production reality took place in the 1950s, when Mr. Palmino decided to give shape to his own product. Since then, RIMSA has dedicated itself to the design and development of pantograph lamps.

The development of the company led to the expansion of the range of articles produced with the introduction of magnifying and fluorescent lamps. Starting from the post-war period, RIMSA therefore began to establish itself in the electronic, goldsmith, dental and industrial sectors. In the 1980s, RIMSA concentrated its energies in the surgical lighting sector and, in April 1983, the Ente Fiera di Milano awarded RIMSA the first recognition for the design of a halogen light operating lamp. Research in the medical field continued and in March 1992 the Milan Chamber of Commerce awarded the coveted "Technological Innovation" qualification certificate for the project of a stellar scalytic lamp with open shapes for laminar flow operating theatres.

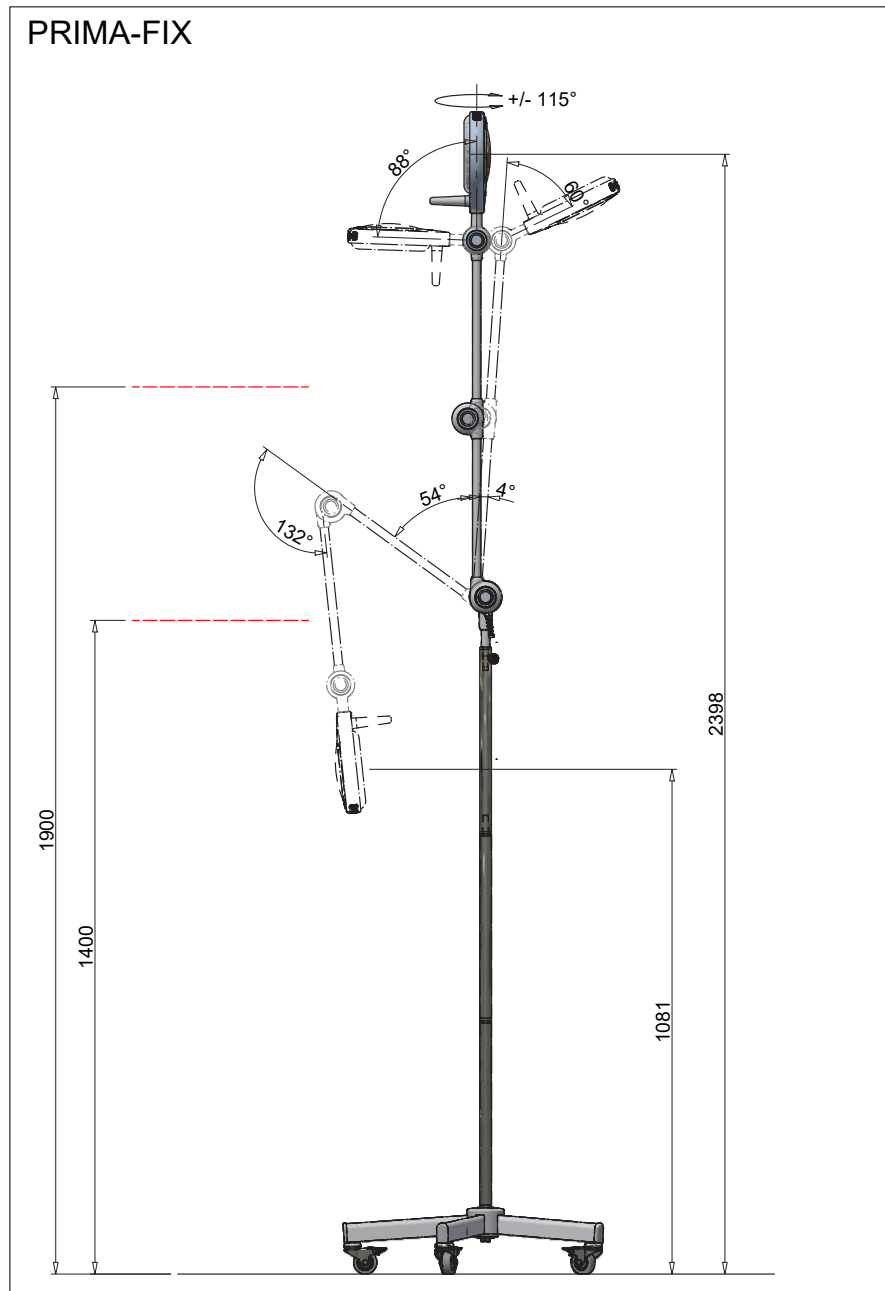
In **2002**, RIMSA developed the world's first LED operating room light when this technology was still in its infancy. Following a study that lasted several years and aimed at offering a product in line not only with the operational needs of surgeons, but also with the wishes of an entire operating team, in **2017** RIMSA made UNICA available, the only lamp in the world with Zero glare technology: no glare.

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



Scialytic lamp model

PRIMA LED



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.

PRIMA LED

With its attractive design, **PRIMA LED** is a concentrate of technology with unrivalled performance - the best for an observation lamp.

It consists of 9 LED optics divided into two separate circuits (6+3). The lamp's optics have been designed to provide focused and deep illumination. The diameter of the illuminated field is 16 cm at 0.50 m.

The radial arrangement of the optics and the large reflector diameter (195 mm) allow for shadow suppression and three-dimensional illumination.

Temperature increase in the light field ≤ 1 degree.

Examination lamp with articulated arm on mobile support. Support with anti-corrosive coating vertically adjustable. Base with anti-corrosive coating.

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

CCT: PRIMA LED, one of the first white LED lamps, is equipped with a colour temperature selector switch (4000 - 4500 Kelvin). The colour change takes place using only monochromatic LEDs to avoid colour shifts on the area to be observed.

Design: the circular and ultra-flat shape of the reflector makes the product ergonomic and suitable for any type of installation, from the surgery to the intensive care unit. The lamp is light and easy to move. The Ergo Spring balancing system gives PRIMA LED manoeuvrability and stability.

PRIMA-FIX - In this configuration, the reflector is mounted on a 3-jointed arm for even more precise positioning. The new design allows even easier handling, with an additional rotation of the reflector.

Courtesy light: The first and only examination lamp with the possibility of an ambient light in addition to the traditional focused light. The courtesy light is produced by 3 other LEDs. Via the membrane keyboard on the reflector, this function can be activated.

Cleaning and sterilisable handle: the first examination lamp to be equipped with a removable and sterilisable handle. PRIMA LED cares about asepsis. Quick and easy to clean aluminium construction; resistant to corrosion, wear and tear and disinfection.

Reduced weight and dimensions.

The lamp, which complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 - Standard IEC 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).

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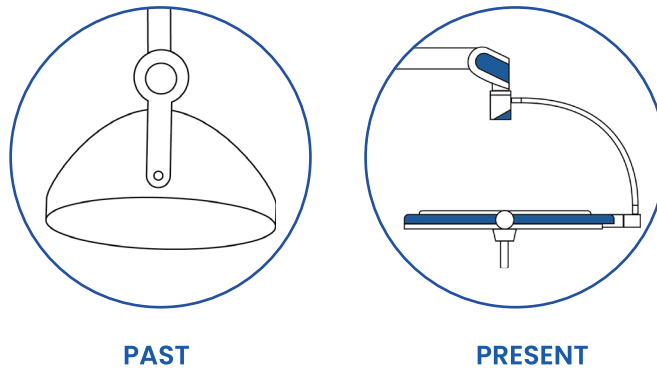


Figure 1:
Illustrated summary of
operating lights, from Verain
to UNICA

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 PRIMA LED, the value is **95 Ra**.

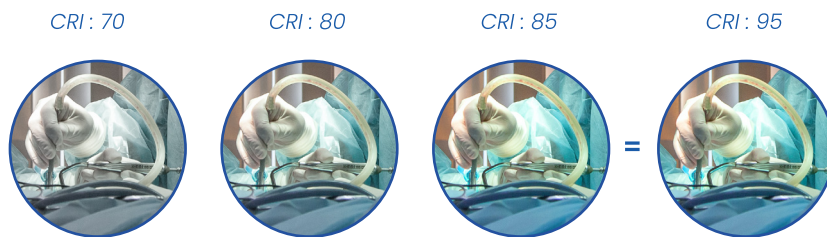


Figure 2:
Demonstration of the CRI

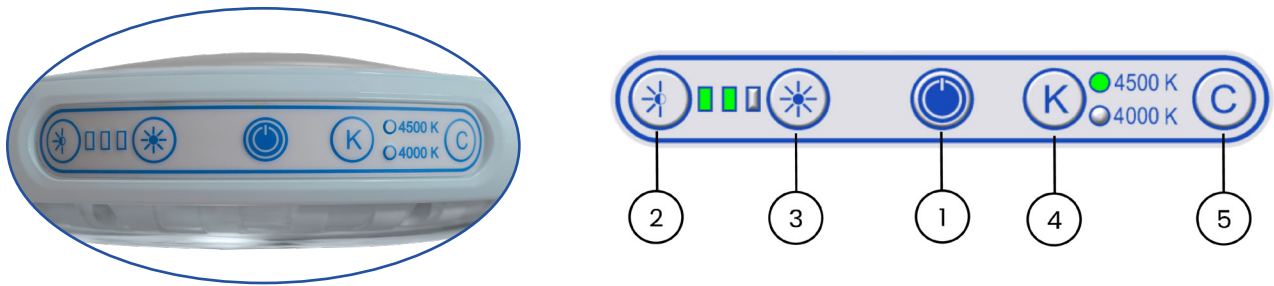
LIGHT INTENSITY

International legislation also establishes the maximum illuminance levels allowed for medical devices and in relation to scalytic 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.

PRIMA LED is available at **105.000 lux** at 50 cm. However, it is recommended to use the lamp at a reduced intensity. It is possible to select the intensity from the keyboard, **from 20 to 100 %**.



KEYBOARD

- on the left - light adjustment
- in the middle - on/off button
- on the right - "K" changes colour temperature 4000 or 4500 K
- on the right - press "C" when the lamp is switch off to light up only 3 LEDs.

The buttons, positioned on the light head, are very easy to press and reach.



COLOR TEMPERATURE

The regulation of the color 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.

PRIMA LED, allows you to select 2 color temperatures **4000 K** and **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. The unavailability of a LED is in fact not perceptible during use.

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.

HANDLES Each lamp is made available with n. 1 sterilizable handle included. The handle can be used to adjust the inclination of the lamp reflector.

CONSUMPTION extremely low consumption 10,5 W – 20 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	105.000
Color temperature (2 selections)	K	4.000 - 4.500
Color rendering index (CRI)	Ra	95
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	10,5 - 20
No. of LEDs	LED	9
Average LED life	hours	> 60.000
Light head diameter	cm	19,5
Control of illuminance	%	20-100

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



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