

PANTOGRAPH AND MEDICAL LAMP FACTORY



TECHNICAL REPORT

UNICA

RIMSA
Brightening ideas

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REQUIREMENTS

Pag.

- 5, 6 • Shadowless surgical lamp intended for illumination in major surgical investigations with ceiling mounting with 2 satellites
- 6 • Lighting system based on mandatory LED (Light Emitting Diodes) technology
- 6 • Number of satellites 2
- 9 • Color temperature 4,500 \pm 500 K
- 8 • Color index > 95
- 10 • Field size, cm Adjustable diameter min. 24-32 cm
- 11 • Depth \geq 80 cm
- 17 • Working distance 0.7-1.5 m
- 8 • Illumination level at 1 m distance satellite no. 1 \geq 130,000 lux, satellite no. 2 \geq 130,000 lux
- 5 • 330 degree rotation
- 5 • Vertical adjustment, cm \geq 70
- 20 • Temperature increase in the operative field <1° C
- 21 • Power Supply Electrical network 220V, 50Hz
- 20 • Average lifetime of LEDs min. 50000 h
- 20 • Removable sterilizable handles
- 9 • Control panel integrated in the main lamp
- 6 • Bridge height 3-4 m



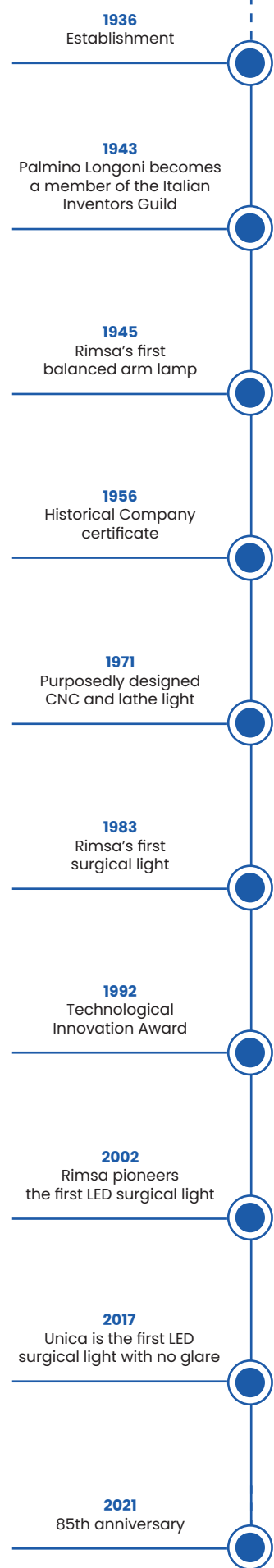
THE COMPANY

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.

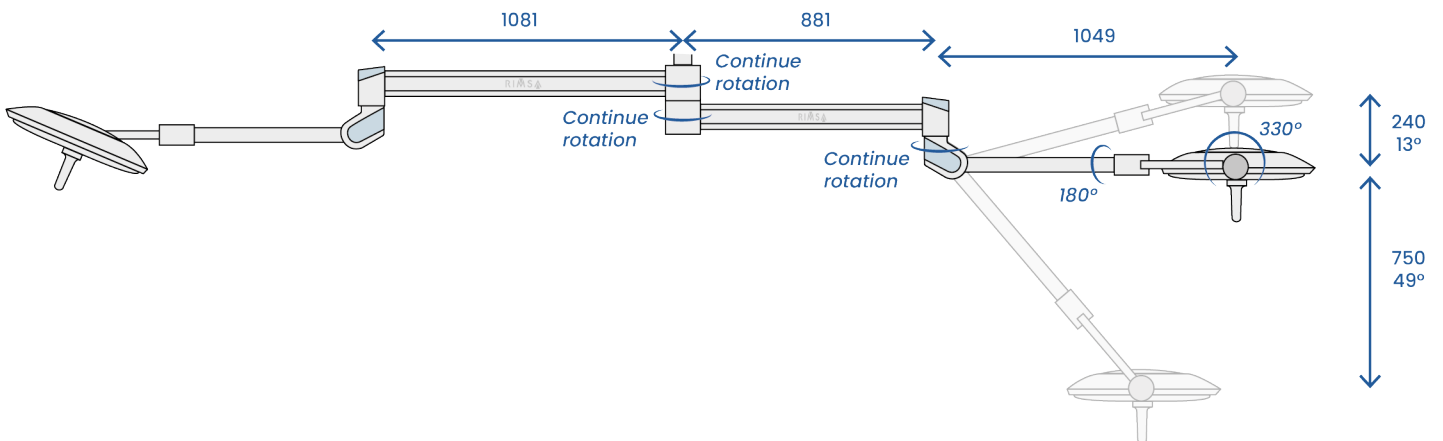
In **2002**, RIMSA developed the world's first LED operating room light when this technology was still in its infancy. Following a study that lasted several years and aimed at offering a product in line not only with the operational needs of surgeons, but also with the wishes of an entire operating team, 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

UNICA 520+520



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.

UNICA 520

UNICA 520 - surgical light with white LEDs - was born from the engineering imagination of a close-knit team of physicists, engineers and surgeons with the aim of providing **shadowless light** on the operating field while suppressing all forms of direct and indirect glare, creating the ideal conditions for **major surgeries**.

UNICA is a double reflection **LED** operating theatre light and it is thanks to this technology that two clear technical advantages can be achieved:

- The maximisation of the light emission surface area;
- The elimination of direct glare.

Besides presenting itself as a competitive product given its technical characteristics, UNICA, thanks to its **double reflection technology** that **eliminates glare**, is a safer solution for the patient and the medical team.

The joints are equipped with sliding contacts and allow a continuous rotation of the arms even in case of installation of a camera.

The vertical heeling arm has been subjected to mechanical testing of 40,000 continuous movements, guaranteeing maximum sturdiness, to reduce maintenance interventions to a minimum and to ensure the user the most complete safety during use.

The configuration proposed here is for a lamp with **two identical satellites** (UNICA 520), which can be installed in a room of 3-4 m in height.

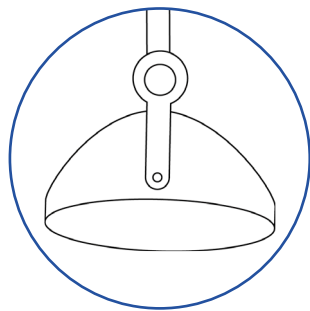
The lamp, which complies with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 - Standard **IEC 60601-2-41**, is a **Class I** medical device.

THE SCIALYTIC LAMP

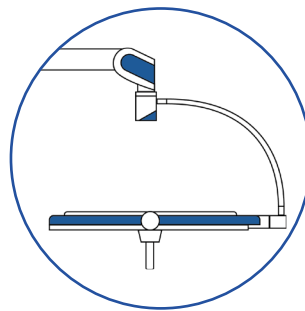
The fundamental characteristic of the scialytic lamps, or surgical lamps, is to be found in the name itself. The term scialytic means “without shadows”; the surgical lamps are therefore lamps without shadows. ie: they are medical devices capable of generating a beam of light which neutralizes the shadow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



PRESENT

Illustrated summary of operating lights, from Verain to UNICA

ILLUMINOTECHNICAL PROPERTIES

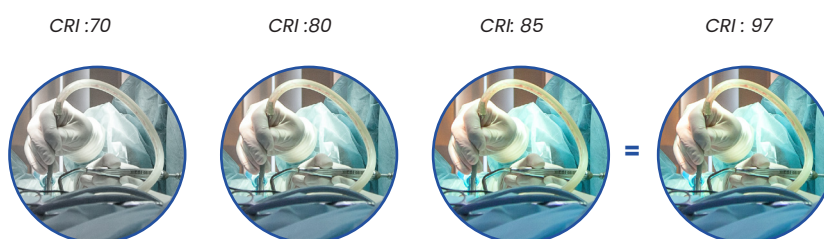
After having defined the nature of a surgical lamp, the illuminotechnical characteristics necessary for a surgical lamp are proposed.

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 UNICA, the value is **96 Ra** for the Unica 520 model.



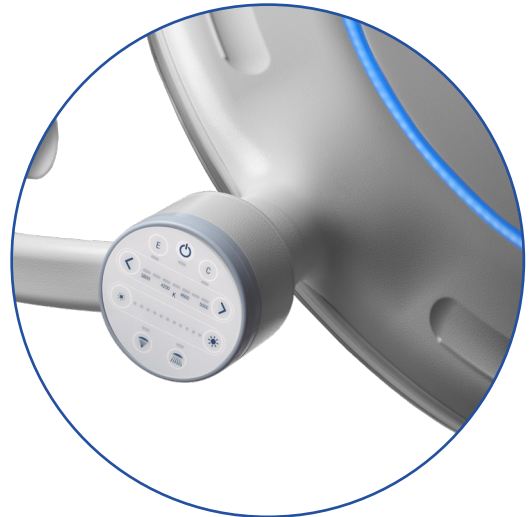
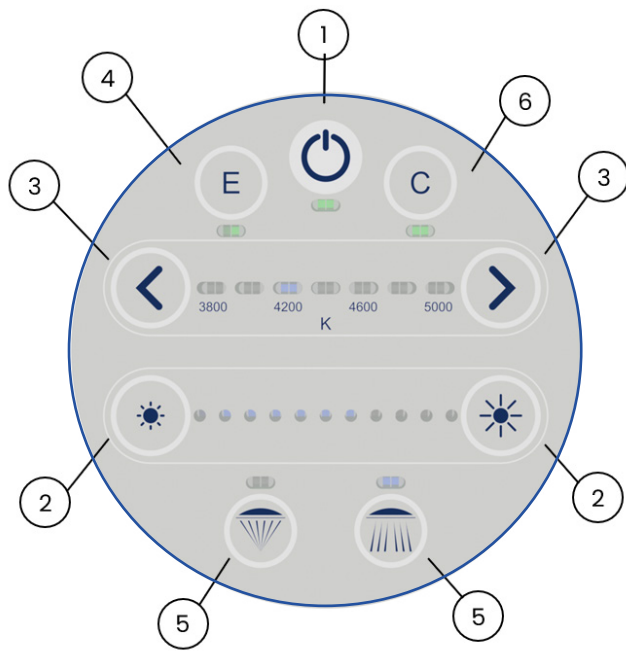
Demonstration of the CRI

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).

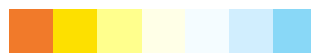
Although the literature suggests the abandonment of such high levels of light intensity and the evolution of international legislation is moving in this direction; the product offered: UNICA, is available at **160.000 lux**. However, it is recommended to use the lamp at a reduced intensity. It is possible to select the intensity, interacting with the **11 level of intensity from 25% to 100%** and selectable from the keyboard.



CONTROL KEYBOARD

The capacitive keyboard with touch technology is fitted on the Product yoke. By touching with your finger on the surface of the keyboard, the following functions can be activated:

- lamp switch-on and switch-off by means of the "I/O" key (1). With the lamp off, the green LED indicates the presence of power voltage;
- adjustment of light intensity by touching the sun symbol keys (2). The level of intensity achieved is indicated by means of 11 blue microleds;
- selection of colour temperature from among 7 values: 3800K, 4000K, 4200K, 4400K, 4600K, 4800K and 5000K by pressing the keys indicating the value (3). Press the key twice to select intermediate values;
- enabling the "Endoed" function, using the key with the letter E (4). This function is only available with lamp off;
- adjustment of light range (increase-decrease) by means of key (5) which increases or reduces the range;
- enabling of "Courtesy Light" by means of key C (6), to light up background.



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.

UNICA, allows you to select **7 colour** temperatures in the region **from 3800 to 5000 K**.

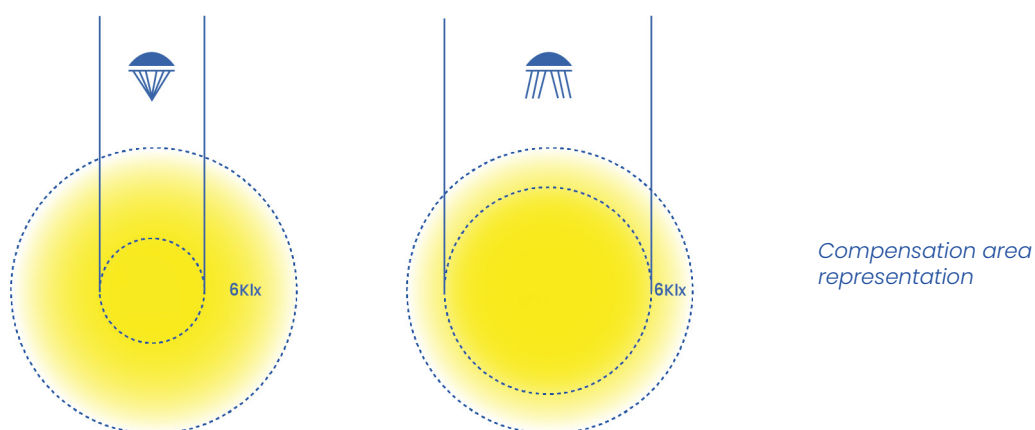
When the synchronization function is active, on lamp systems, the temperature variation occurs automatically on all domes. You can disable the sync function to allow different color temperatures on different domes of the same system.

OPERATING FIELD

The operating field is **electronically adjustable** in 3 levels by selecting from the keyboard placed on the structure of the lamp (wall control, remote control and room integration available as options):

- **Endoscopy**: the diameter of the operative field is **16 cm**;
- **Small**: the diameter of the operative field is **21 cm**;
- **Large**: the diameter of the operative field is **35 cm**.

A low illuminance area (**compensation area**) is added to the luminous area while using the small diameter and large diameter selections. The compensation area is described in the section: **EXCLUSIVE FEATURES**.



LIGHT EMITTING SURFACE AREA

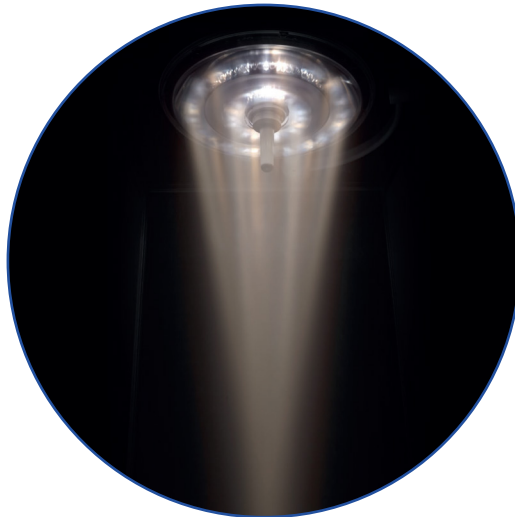
The need for a large dome does not necessarily mean a large diameter but a dome with a large light emitting surface area. The light emitting surface is the area of the dome where the light actually comes from.

The light emitting surface area must therefore be calculated net of any shadow areas (from which no light comes) such as the area between one lens and another. The light emitting surface area of the two versions of the offered product:

UNICA 520



107.300 mm²

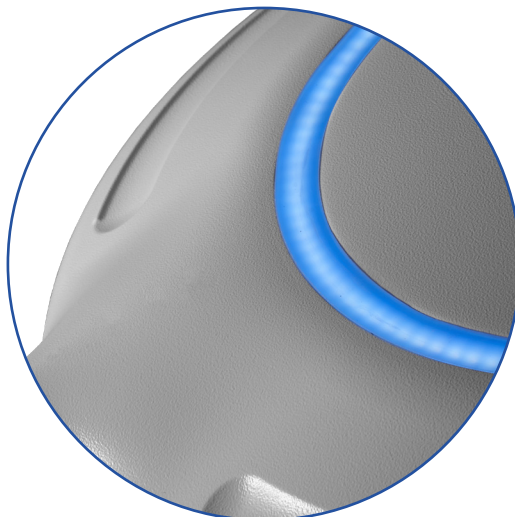


DEPTH OF FIELD

The **depth** of field (L1+ L2 at 20%) is of **1030 mm**.

ENDOLIGHT

The light for endoscopy is a function which allows the illumination of the operating field with soft, uniform illumination the possibility of illuminating the entire operating room with blue light coming from a small LED circle placed on the upper part of the reflector and which can be activated and deactivated on command.



A courtesy light is installed in the upper part of the dome; a silicone gasket protects the LED crown which, when switched on, creates a soft light effect.

EXCLUSIVE FEATURES

In this chapter we intend to present the exclusive properties and the improving characteristics of the offered product. The UNICA lamp, produced by RIMSA, was developed taking into account the needs of users, patient safety and the limitations made known and available in the literature; each technical and technological choice derives from an in-depth study of the medical-scientific literature on the subject and from direct comparison with surgeons.

The guiding idea behind the development of this lamp was to solve the problems highlighted by specialists during surgery: glare, difficulty in handling, excessive use of sensors.

After a study that involved the company for over four years, it was possible to patent UNICA: the only double reflection lamp capable of maximizing the surface area of light emission, eliminating glare and offering maximum freedom of settings to respond to the needs of each individual surgeon, without resorting to any sensor or electronic regulator but only thanks to physical and optical effects so as to avoid the risk of breakdowns.

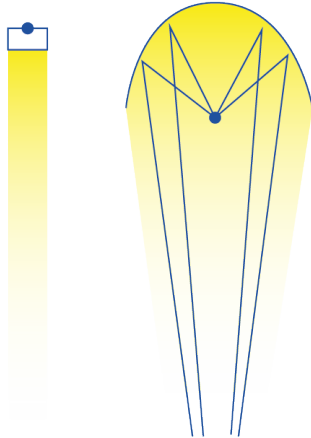
INDIRECT LIGHT

The LED is a light source that is incapable of generating punctiform lighting; it is therefore necessary to use an external element which conveys the diffused light beam and directs it to a fixed point. There are two lighting technologies: reflected light LED lighting and direct light LED lighting.

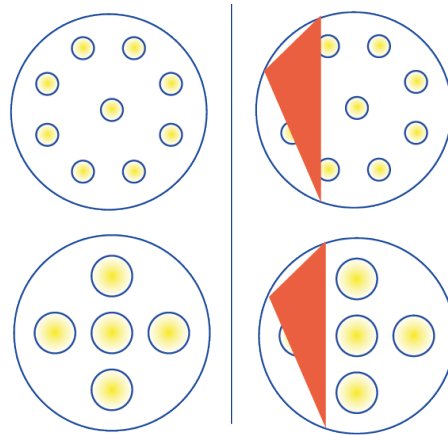
Direct light LED lighting systems provide for the application of lenses above the diode which converge the light beam. With regard to indirect light LED lamps, the light beam emitted by the diode is instead intercepted by a parabola which reflects the rays and conveys them to a point.

Indirect light offers two advantages: it increases the emission surface and reduces the glare effect. In the case of UNICA, the light emitting surface is maximized to coincide with the surface area of the reflector, while direct glare is completely neutralised.

Direct light and indirect light operating principle



On the left, LED direct light and indirect light without obstacle; on the right, LED direct light and indirect light with obstacle



GREATER LUMINOUS SURFACE

Indirect reflection allows for a greater luminous surface with a smaller quantity of LEDs compared to a direct light solution. This choice therefore makes it possible to reduce the temperature that is created on the printed circuit, guaranteeing a longer useful life for the product as well as resulting in less light degradation and a better operating effect compared to a direct reflection solution. The improvement of the scialytic effect coincides with the increase of the light emission surface (ie the area of the reflector net of the shaded areas); this means that, for the same obstacle, the incidence of this in an indirect light solution is lower than it could result with a direct light solution.



Lighting technologies
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ANTI-GLARE

Glare in the operating room represents a serious risk for surgeons, the entire medical staff and the patient, and is also a danger to their health. For these reasons, manufacturers of surgical lights should address this issue seriously.

Eager to find a solution to the problem of glare, RIMSA already in 2002 developed the first LED operating lamp with indirect reflection technology.

Angolo Lampada	90°	75°	60°	45°	30°	15°	0°
RIMSA UNICA520 Zero Glare Tecnologia 2R a doppia riflessione	0 lx 	20 lx 	30 lx 	30 lx 	50 lx 	220 lx 	120.000 lx
RIMSA PENTALED E/N Luce indiretta	0 lx 	90 lx 	130 lx 	170 lx 	500 lx 	1.100 lx 	120.000 lx
RIMSA Luce diretta con lenti in policarbonato	0 lx 	150 lx 	300 lx 	370 lx 	600 lx 	1.500 lx 	110.000 lx

The image shows the values in lux of the light which insists on the surgeon's retina when the operating lamp is at different degrees of angle at the same distance. The light intensity results of three different RIMSA lamps with different technologies can then be compared. The enormous advantage offered by the indirect double reflection lighting offered by Unica is immediately evident.

In fact, comparing the illuminance values in lux of lamps with the two different technologies that insist on the user's retina at different angles of inclination, the benefit offered by indirect reflection technology with respect to the risk of glare is evident.

After a commitment that lasted several years, in 2017 RIMSA patented Unica, the only surgical lamp which, thanks to its double reflection technology, is able to completely remove the glare caused by surgical lighting.



Glaring effect
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DOUBLE REFLECTION

Patented by RIMSA in 2017, this optical solution for collimating the light beam emitted by the LED allows the maximization of the light emission surface and the elimination of direct glare. Its operating principle is based on a double reflection: there are in fact two mirrors on the reflector which direct the light beam onto the operating field, guaranteeing a cone of light that is always in focus.

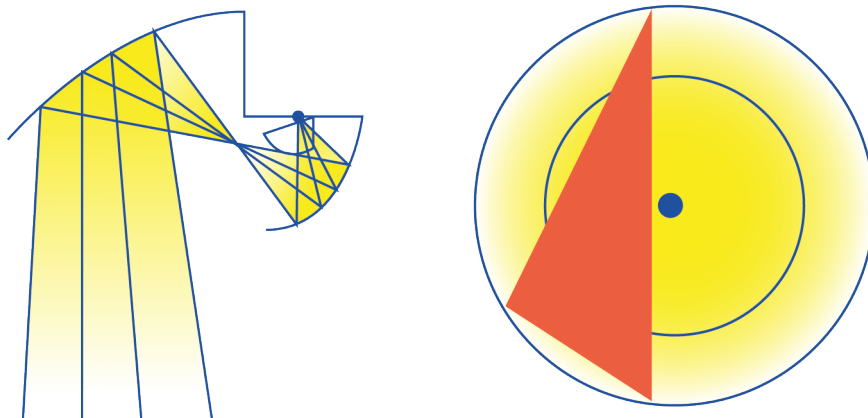


Figure 7: Representation of double reflection technology

The light rays of the LED, conveyed through an aspherical lens, are projected onto a first segmented elliptical mirror, which in turn reflects them onto a second smooth surface mirror, directing them onto the operating field

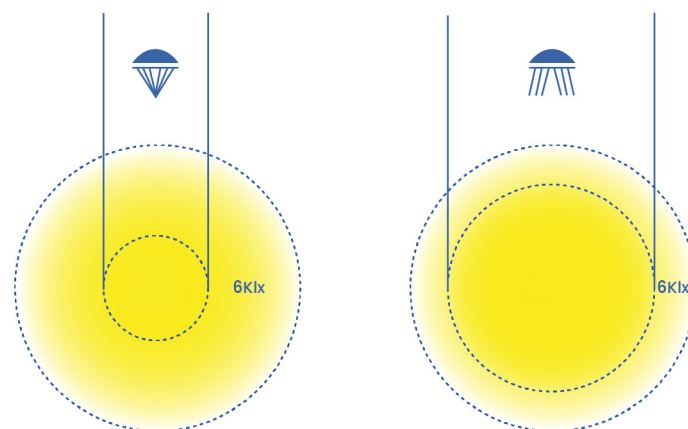


The double reflection system
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COMPENSATION AREA

The sensation of glare does not only occur when a surgeon looks directly at the light source, but also when the eye deviates from the center of the light field – where in most cases the illuminance level reaches 160,000 lux – towards the edges of the surgical focus, where illuminance is drastically reduced: “Luminance contrast that is too high will cause visual impairments due to continuous readaptation of the eyes” (Hemphälä, 2009).

This type of glare is called indirect glare and is caused by the passage of the eye over areas of different light intensities such as the passage between the surgical area and the rest of the room. This sudden change causes numerous problems.

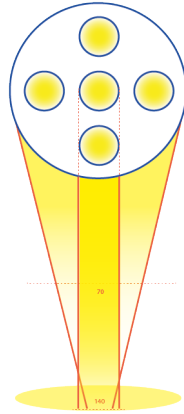


Representation of the compensation area

In order to solve this problem, UNICA has been equipped with the compensation area function which allows a “progressive and gradual adaptation of the light in order to remove the glare between the central area of the surgical focus and the peripheral one”.

ALWAYS ON FOCUS FUNCTION

With the “always on focus” technology, light reflection is designed to ensure a homogeneous light cone at any distance within a limit of **70-150 cm** from the operating field. Thanks to the Always on Focus technology, there is no more need to adjust the focus and search for the optimal lighting.



Visualization of Always on Focus technology

CONTROL OF THE LAMP AND LIGHTING PARAMETERS FROM A STERILE AREA

In order to allow the surgeon maximum customization, a capacitive light intensity adjustment system has been installed on the handpiece. Through this installation, the surgeon can independently adjust the level of light intensity directly from the sterilizable handpiece. An ergonomic guide along the body of the handpiece helps the surgeon in identifying the command, allowing him to adjust it without having to take his eyes off the operating field.



The sterilizable handle is equipped with a capacitive system for adjusting the light intensity, which can be operated by the surgeon in the sterile area. A longitudinal guide on the handle helps the surgeon locate the sensor location without taking his eyes off the work area



Laminar air flow
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LAMINAR FLUX COMPATIBILITY

Laminar flux compatibility does not depend on any particular shape of the reflector as much as on the temperature of the body in the laminar flux path. As is evident from reading the reference standard: **DIN 1946-4**, the laminar flow incidence tests, with reference to the operating light, are to be carried out with the reflector bent at 45 degrees. The uselessness of special shapes (see solutions with holes) in order to improve compatibility is therefore apparent.

What affects turbulence is in fact the heat reached by the body placed under the flow: the higher its temperature, the greater the turbulence. A more incisive approach to solve this problem is to reduce the heat dissipated by the lamp dome. The disturbing element of laminar flow is in fact heat.

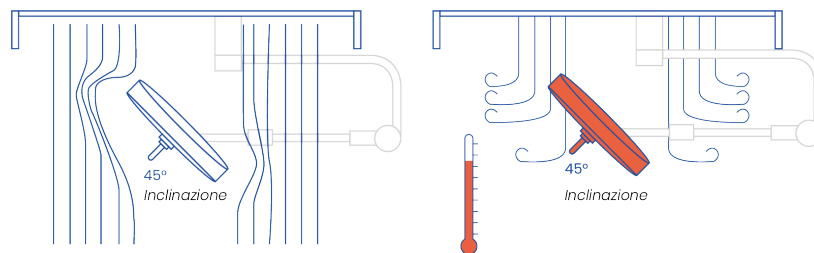


Figure 10: Comparison of two lamps at different temperatures positioned as required by the standard and effect on laminar flow

The data on the turbulence intensity measured during the test campaign of the two Rimsa operating light models are strictly below the maximum value (37.5%) (Standard Annex E DIN 1946-4). For the UNICA 520 model with the lamp switched on, the maximum turbulence level measured is **15.4%**.

It can be stated that by using these two operating lights in operating theatres equipped with laminar flow, the acceptability limit of the system test for satellites and surgical lights (37.5% maximum turbulence level) is largely exceeded.

*Values measured by the Milan Polytechnic's Department of Aerospace Safety and Technology.



Maneuverability
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MANEUVERABILITY (SINGLE AND DOUBLE FORK)

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.



Single fork and double fork compared

Analyzing the solutions proposed by the manufacturers of surgical lamps, we note an important standardization of the lighting systems. This standardization, which does not take into account the specifics of each situation, can hardly adapt to every circumstance.

RIMSA, by designing its own structures internally, is able to best respond to every type of requirement, offering solutions with suitable dimensions for each installation. In addition to the custom structures, RIMSA has two fork configurations: single fork **(A)** or double fork **(B)**.

While the double yoke is the only configuration made available by all manufacturers, RIMSA also offers a single yoke solution to meet the needs of low ceiling installations.

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. The modular study of the product allows easy replacement of the faulty light source.

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. 2 removable sterilizable handles** included

CONSUMPTION Extremely low consumption 75 W - 85 VA.

PRODUCT LIFE 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. This heat dissipation system also guarantees a **temperature increase in the operative field of less than 1° C.**

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.

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 1 m distance (Ec)	lux	160.000
Color temperature (7 selections)	K	3.800 to 5.000
Color rendering index (CRI)	Ra	96
Color rendering index (R9)	Ra	96
d10 light field diameter where illuminance reached 10% of Ec	mm	210
Diameter adjustment	-	Electronic
Light field diameter adjustable from-to	mm	210-350
Depth of illumination IEC 60601-2-41 (L1+L2) at 20%	mm	1030
Total radiated energy	W/m ²	580
Ratio between radiated energy and illuminance	mW/m ² lx	3,68
Compatibility with laminar flow (DIN 1946-4)	%	15,4

ELECTRICAL DATA

Primary alternating voltage (ac)	V	100-240
Frequency	Hz	50/60
Absorbed power	W - VA	75 - 85
No. of LEDs	LED	84
Average LED life	hours	> 60.000
Light head diameter	cm	52
Control of illuminance	%	25-100

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



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