



Brightening Ideas

2022

LIGHTING EMERGENCY

What makes a surgical lamp?

RIMSA

The purpose of this pamphlet is to present the state of the art in operating theatre illumination. This text provides the reader with an accessible, easily navigated, in-depth and concise guide to surgical illumination. It presents the principal characteristics of operating theatre lighting making ample reference to existing literature whilst comparing, with an academic approach, the principal issues related to operating theatre illumination.

Despite references to the available academic literature this text is not intended as an academic paper. Nevertheless, this publication should not be seen as a commercial brochure.

2019, Rimsa P. Longoni SRL

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INTRODUCTION

CHARACTERISTICS OF SCIALYTIC LAMPS

The main characteristic of scialytic lamps or surgical lamps is to be found in their name. The term scialytic originally derives from Greek and means 'devoid of shadow'; scialytic lamps are therefore shadowless i.e.: they are medical grade devices capable of creating a beam of light that neutralises the shadow of any object placed between the light source and the operating field.

Other than the ability to neutralise shadow, scialytic lamps must have other characteristics, including the capacity to create in-depth light and prevent temperature increases in the operating field. Since the end goal of these lights is obtaining optimal vision in cavities during surgery it is imperative that the lamps be designed to offer in-depth light. Similarly, to avoid complications during operations, it is necessary for scialytic lamps to generate as little heat as possible in order to reduce the risk of tissue desiccation.

Another essential characteristic of a scialytic lamp is purity of light: the lamp must be able to generate white light. Thanks to technological advancement and the introduction of LEDs into the medical lighting field, these lamps are now capable of generating white light whilst also having the added advantage of being able to create light with diverse colour temperatures and hues.

“Surgical luminaries are supposed to provide high quality, bright, comfortable and true colour illumination of a wound, even in difficult situations like deep cavities, and with the surgeon’s head and hands situated between the light source and the surgical sight.” (Knulst 2009: A, p.38)

In this report we will refer to the most relevant papers – or lack thereof – found in scientific literature relating to scialytic lamps.

1. MONOCHROMATIC WHITE LEDs

According to regulation CEI 60601-2-41, scialytic lamps must be able to guarantee a minimum value on the Colour Rendering Index (CRI).

When LEDs had just been introduced in the market, in order to reach the minimum CRI value stipulated by the regulation, it was necessary to use LEDs of different colours (RGB LED) as producers were never able to reach the minimum value required using only white LEDs. Therefore many producers opted for this solution and maintained this over time despite it being less than ideal: *"it is observed that the use of colored LEDs has its drawbacks because it introduces colored shadows on the surgical field. As the color appearance of objects is dependent on the color of the light [...] the appearance of tissue colors within these colored shadows might be compromised as well"* (Knulst: 2009 B, p.323). Today's producers are now implementing the use of only white LEDs.

The main identifiable problem with the use of RGB LEDs is the light diffraction caused by these. When an obstacle comes between the light source and the operating field, the shadow is split into the light's coloured components: *"light color variations in the illuminated field were noticed when using luminaires that contain differently colored LEDs, either as separate LED units or as differently colored chips in one LED unit. The color variations were noticed with bare eye, showing reddish and bluish areas within the illuminated field"* (Knulst. 2009 A, p.44).

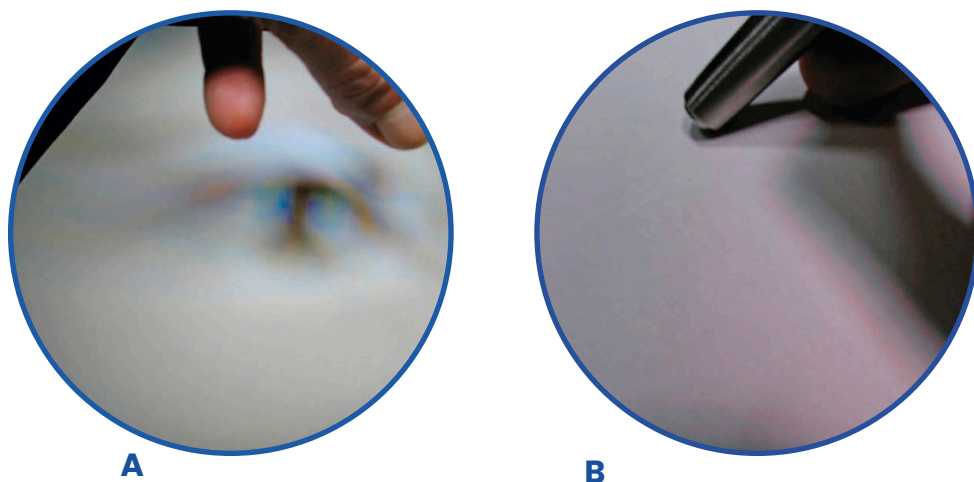


Fig. 1: Knulst et al. 2009, p.47

It has therefore been identified by the literature how coloured LEDs create coloured areas in the surgical focus area when objects are introduced between the light source and the operating field. We should also take into account that the head and hands of the surgeon operate under the light source for the entire length of the procedure, as this lets us understand the magnitude of the problem.

Another issue caused by the use of RGB LEDs is the declining luminosity curve, which is different for each colour: *"Different color LEDs have different efficiency, voltage, temperature dependence and rate of degradation"*(Bergh: 2004, p. 2746). Because of these different rates of degradation an RGB LED, powered light that today seems to be pure white, could have a greenish or pinkish hue tomorrow. This isn't a problem found in scialytic lamps that are solely powered by white LEDs as these have the same rate of degradation and will therefore always generate white light.

RIMSA uses solely white LEDs for all of its lamps, therefore immediately resolving the issue of coloured shadows. Even in 2002 when the world's first LED powered scialytic lamp was created (Bergh: 2004, p.2747), only white LEDs were used despite the huge technological difficulties present at the time. The LEDs used by RIMSA emit a light that can reach a temperature of colour equal to 5,000K – a light so purely white that it is close to that emitted by the sun at its Zenith – and an excellent Colour Rendering Index (CRI) value.



2.

COLOUR RENDERING INDEX

The Colour Rendering Index (CRI) measures the capacity of a light source to reproduce colours faithfully. Due to their specific use and importance, scialytic lamps must guarantee a particular minimum value on this scale which is measured in Ra.

Although international regulations require a minimum CRI value of 85 Ra, the values on offer in the market are far superior. Nevertheless, a high CRI value of a light is not a guarantee of quality - values greater than 85 Ra are not perceptible to the naked eye - the Colour Rendering Index offers a valuable tool for determining the ability of a lamp to faithfully reproduce colour.



CRI: 51



CRI: 80



CRI: 96

Fig. 2: Demonstration of the Colour Rendering Index (CRI)

The method used to measure colour rendering capacity, introduced by the CIE (Commission Internationale de l'Éclairage) in 1937 and revised in 1974, is a quantitative evaluation method based on the comparison of 8 samples of standard colours illuminated by the tested light source and a control light source. The average score over the 8 examples is then the tested light source's final score and is typically between 1 and 100 Ra.

Although the measurement offered by the CRI is highly regarded by the IEC (International Electrotechnical Commission), over time two other methods of measurement have been added: R9 which specifically measures the light source's ability to reproduce the colour red faithfully – imperative for the visibility of blood and internal organs – and R13 which represents the colour pink and measures the faithful reproduction of skin tones.

The CRI, alongside the R9 and R13 values, offers a trustworthy measurement. However, in the last few years many have questioned the validity of this test and for this reason the IES (Illuminating Engineering Society) developed its own method of measuring colour rendering capacity called TM30-15. This method is made up of three indicators designed to measure the accurate reproduction of colour. The Fidelity Index (measured in R_f and the sun is used as the control light source), the Gamut Index (used to measure colour saturation) and the Colour Vector Graphic (a visual representation of saturation of colours and shades).

At present the TM30-15 method is used alongside the CRI method but with time it will replace the CRI as it is considered the more extensive measurement – it uses 99 colour samples to measure the light source's capacity compared to the CRI's 8. The use of a far greater number of colour samples renders the TM30-15 more reliable and representative.

3.

LUX

International law sets the maximum level of illumination a medical device can have and when it comes to scialytic lamps – a Class 1 medical device – the limit is 160,000 lux.

Similarly to the CRI, and light intensity, it is not always necessary for a device to output the maximum level available. Some surgeons have indeed underlined how the illumination created by a scialytic lamp can create risk and discomfort: *“Some of the operating lamps gave too much illuminance which resulted in glare and made it harder to see” (Hemphälä, 2009).*

160,000 lux is, to all intents and purposes, a hugely elevated value of light intensity, so distant from normal requirements of professional illumination that the scientific community is questioning the legitimacy of such a high value. In an operating theatre the risk of glare caused by scialytic lamps is already reasonably common and there are no advantages over the use of a light with a more measured output.

The study on illumination presented by Professors Bougaud and Grosjean intends to promote light intensity values below 160,000 lux. It analyses the light absorbency of tissue and blood in order to show that scialytic lamps of 100,000 lux are preferable compared to those of 160,000 lux.

As highlighted in the document, flesh absorbs 92% of light that illuminates it whilst blood absorbs 96% of light. This extraordinarily high level of absorption therefore determines the necessity of such high values of light intensity for scialytic lamps.

ABSORPTION OF LIGHT:

Example:

$\lambda = 560 \text{ nm}$	<i>Fresh pork flesh: absorbs 92%</i>
	<i>Fresh pork blood: absorbs 96%</i>
$\lambda = 490 \text{ nm}$	<i>Fresh pork flesh: absorbs 87%</i>
	<i>Fresh pork blood: absorbs 95%</i>

Fig. 3: Bougaud A. & Grosjean E., éclairage opératoire

Therefore, considering the light absorption values for flesh, the difference in lux between the two light sources (60,000 lux) – during surgical use – is greatly reduced to a negligible difference (3,000 lux). With this negligible variation in mind, we must take into consideration the amount of light that is blocked by the surgeon’s body. During an operation surgeons regularly find themselves between the light source and the operating field. Taking into account the light blocked by the surgeon (approximately 20%) the difference between the two light sources becomes 2,000 lux.

Remaining conscious of the risks associated with an elevated level of illumination – direct glare and indirect glare, i.e., light reflected by surgical equipment – and taking into account the advantages offered by a more moderate level of light intensity, the International Electrotechnical Commission has proposed to lower the maximum level of lux from 160,000 to 150,000 lux.



4.

LIGHT AND TECHNOLOGY



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Over the course of the years many new technologies have been developed and implemented. In 1919, electromechanical professor Louis François Verain created a lamp that finally permitted in-depth illumination of the operating field, eliminating shadow.

More than a century has passed since the first prototype of the lamp that Verain called scialytic was created and since then many improvements have been made to the scialytic lamp that we know today: manoeuvrable arms to hold the cupola instead of a chain, light sources capable of facilitating heat dispersion and the introduction of different types of smaller lamps containing neon, argon, helium, krypton, halogen, and sulphur plasma. (Crestanello, 2011, p.181)

Over the decades many different lighting technologies have been adopted. Many different experiments have led to the creation of modern LED powered scialytic lamps, relegating other light sources to specific roles.

For years halogen powered scialytic lamps have resisted the advancement of technology thanks to their reliability. This dominance received a setback when xenon was introduced. Despite the initial interest in this technology, it was proven that xenon powered light sources emitted far more retina-harming ultraviolet rays compared to other light sources (Cutan Ocul Toxicol, 2014; p. 195). Therefore, despite initial acceptance by the market, this technology was eventually excluded in favour of halogen bulbs.

To enjoy a further technological advancement, we must wait until 2002 when RIMSA, after having extensively studied its potential, presented (at the MEDICA trade fair in Düsseldorf) the first LED powered scialytic lamp in the world.

The introduction of LEDs in operating theatre had a destabilising effect on the field, causing a substantial change in the concept of light whilst also setting a new standard.

The advent of the LED revolutionised lighting systems: in place of one single beam of light emanating from a halogen bulb, scialytic LED powered lamps produce multiple beams of light that converge in one place.

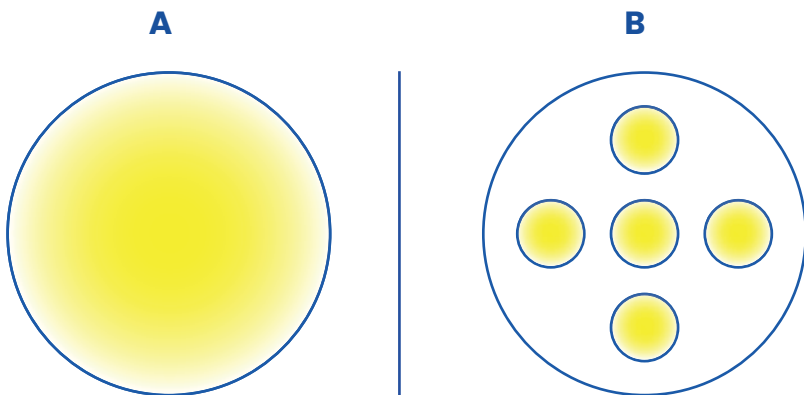


Fig. 4: Halogen light compared to LED light

A : Halogen

B : LED

This conceptual revolution of light reflection had a huge impact. The introduction of LEDs into operating theatres, especially in the beginning, meant that the parameters by which a scialytic lamp is judged had to be changed due to the fact that LEDs present several disadvantages compared to halogen solutions.

The first disadvantage of using LEDs is the reduction of the emitting surface area of light which subsequently leads to a reduction in the capacity of shadow elimination i.e. the scialytic effect. The scialytic effect is of course a feature of the emitting surface area of the lamp itself: if this surface area is reduced then the scialytic effect is also reduced. (Fig 4)

Comparing an LED lamp to a halogen lamp there is a notable reduction in light emitting surface area. Therefore, an LED light has a lesser scialytic effect than its halogen counterpart. In a scialytic lamp powered by halogen, the light emitted by the bulb is intercepted by the parabola that is installed in the reflector. This allows light rays to coincide within the area between the light emitting surface and the cupola of the bulb. In an LED powered lamp this incidence is structurally impossible. An LED lamp is made up of different light sources positioned on the surface of the reflector and the spaces found between each light source are incapable of emitting light (shadow zones). Therefore, a halogen lamp has a greater area of light emission than an LED because halogen lamps do not have shadow zones and for this reason a halogen powered scialytic lamp has a greater light emitting surface area. (Fig 5)

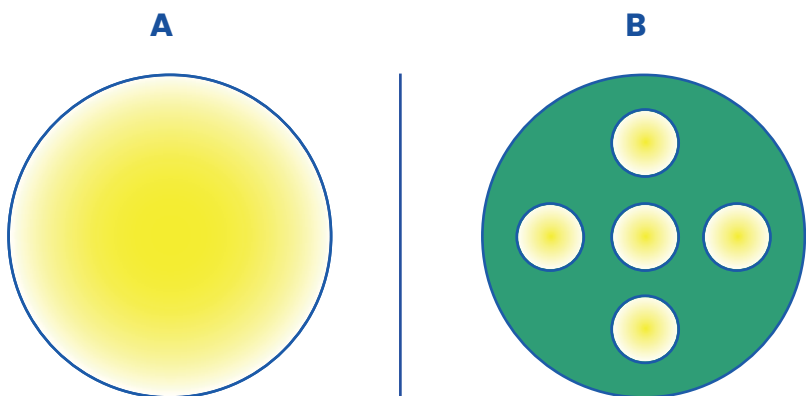


Fig. 5: Shadow zones

A : Halogen

B : LED

By increasing the number of light sources and bringing them closer to each other it is possible to reduce shadow zones. This decision brings with it severe imbalances, not only in energy and consumption but also in performance. Although light from an LED is cold, the LED itself emanates heat and the concentration of a high number of LEDs without adequate space to allow cooling and dissipation considerably impacts on lighting performance. The high number of LEDs in such a close proximity also causes an overheating of the illuminated area, thus eliminating one of the key advantages of LED technology.

Prima facie then, halogen technology would be preferable to LED, however LEDs guarantee lower temperatures on the operating field and therefore also guarantee a reduction in both tissue desiccation and visual stress.

The advantages of LED technology outweigh the disadvantages. These benefits offered by LED technology have allowed it to take halogen's place.



5. DIRECT LIGHT VS INDIRECT LIGHT



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Now that we have established the benefits of LEDs compared to halogen solutions, we will explore how it is possible to obtain an optimal surgical level illumination from an LED lamp.

The LED is a light source that is incapable of generating a pin-point light; it is therefore necessary to add an external element which captures the broad ray of light and channels it to a fixed point.

Within the system of LED illumination there are two variations of illumination technology: reflected LED light and direct LED light. Direct LED light technology requires that a lens be positioned over each diode; thus merging the beams of light produced into one single beam. Compared to LED lamps that use indirect light, the beam of light that is produced by the diode is in this case intercepted by a parabola that reflects the beams, merging them into one. Almost all scialytic lamp producers have adopted direct light technology; RIMSA on the other hand decided from the outset to study and focus on reflected or indirect light.

DIRECT LIGHT

INDIRECT LIGHT

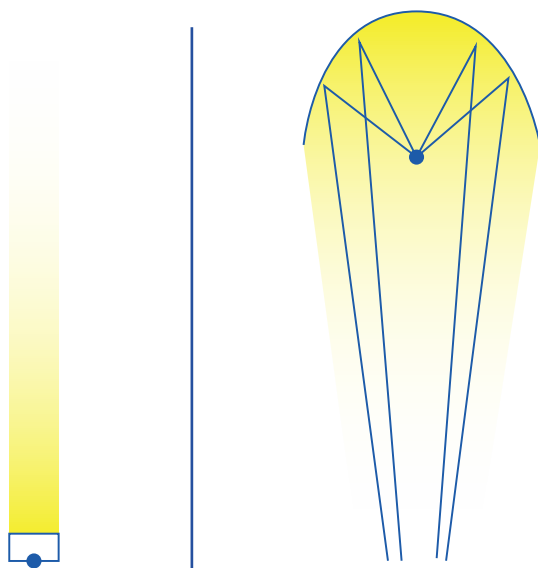


Fig. 6: Functional principles of direct light vs indirect light

The two reflection systems, direct and indirect light, are therefore deeply different. Despite their differences however, the two systems share the most relevant disadvantage of LED illumination when compared to halogen illumination – they both have a reduced light emitting surface area.

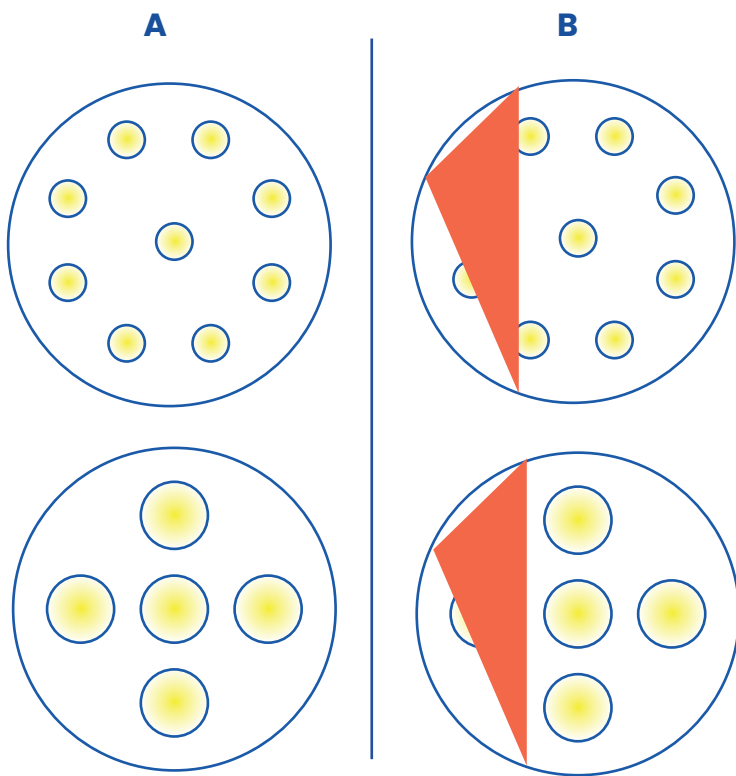


Fig. 7: Left shows direct LED light and indirect LED light without an obstacle; right shows direct LED light and indirect LED light with an obstacle.

In both cases multiple light sources must be installed into the diameters of the reflector and in both cases shadow zones are created thus reducing the light emitting surface area. However, with indirect LED technology, the illuminating surface area of each LED is greater, and this reduces the perception of LED technology's proprietary disadvantage. In short, using indirect LED technology increases the light emitting surface area.

Indirect reflection therefore allows for a greater illuminated surface area whilst using fewer LEDs. Alongside that also comes the added benefit of lower temperature generated on the printed circuit board, guaranteeing a longer service life, a lower luminous degradation and a greater scialytic effect than that of a direct reflection solution.

The number of LEDs, despite often being considered a fundamental value, is actually meaningless in regards to the quality of a lamp. The maximisation of the light emitting surface area is physically impossible if many LEDs are placed along the reflecting surface of the lamp. On the other hand, it is hugely important to highlight the effective value of the light emitting surface.

RIMSA, conscious of the disadvantages caused by direct illumination, whilst creating the world's first scialytic LED powered lamp in 2002, were designing a solution using indirect light for its own product.

Further developing the advantages of indirect reflection, in 2017 RIMSA patented 2R technology (Double reflection technology) which guarantees the maximisation of the light emitting surface area.

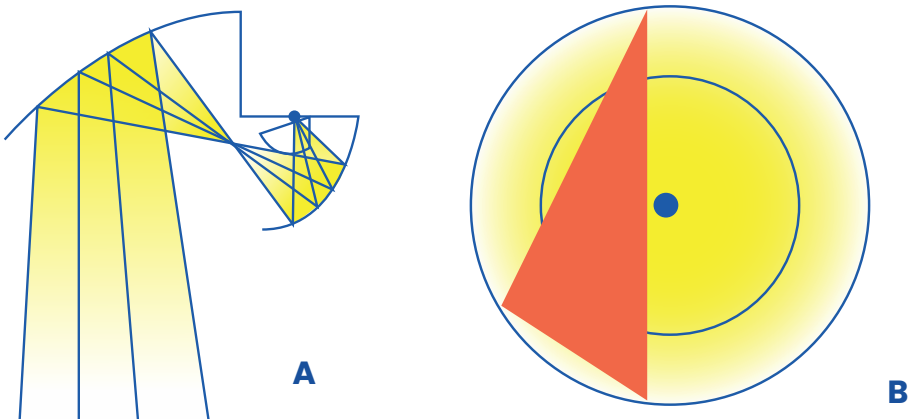


Fig. 8: representation of double reflection technology



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The presence of LEDs along two circumferences positioned at the extremity of two modules of mirrors, creates a double reflection illumination capable of obtaining a light emitting surface area that is incomparable to any other type of reflection.

With the patented 2R technology, the light emitting surface area matches the area of the reflector.



6.

GLARE



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When discussing surgical illumination we must always consider how the quality of the illumination impacts on the eyes of the surgeon. Their visual comfort is of prime importance. Considering the length of time required for some operations and the potential gravity of a human error in these situations, one of the most important factors in surgical illumination is that of creating a beam of light that doesn't stress, tire, or blind the surgeon. The most irritating effect that scialytic lamps can create is glare: the sensation of being blinded.

There can be many different causes that result in glare and the consequential visual irritation for the surgeon. The first cause of glare blindness is direct exposure to an intense light source and scialytic lamps have very high levels of luminous intensity, up to 160,000 lux, and if a surgeon were to inadvertently look at the light source they would be blinded:

"A veiling glare is produced by all high illuminative light sources" (Mathew, 2017, p.30). "Some of the operating lamps gave too much illuminance which resulted in glare and made it harder to see" (Hemphälä, 2009).

Two types of glare exist: direct glare and indirect glare. The first is the sensation of blindness created by looking at a highly luminous surface like a scialytic lamp. The second refers to glare created by areas that have a marked difference in luminous intensity (see chapter 9).

Direct glare negatively impacts the eyes of the surgeon. However, the subsequent blindness is not the only consequence: glare also influences other aspects of our health.

When visibility is low, the body tends to modify its position in an attempt to find a more comfortable view, these modifications influence the posture of the surgeon (Matern, 2007, p. 198). It has also been proven how glare negatively impacts the posture of the surgeon:

"Unsatisfactory visual conditions often induce a strained posture, unconsciously, in an effort to improve vision. The eyes lead the body" (Anshel et al, 2005)

Similarly, it has been proved that glare influences the hydration of the eye causing dryness (Hemphälä, 2009). Whilst ocular dryness and incorrect posture can be seen as logical consequences of glare, another negative aspect has been linked to this. The third 'invisible' impact of glare on surgeons is the influence it has on their productivity: *"Glare can lower productivity" (Horgen, 2007).*

Boyce (2006) revealed the correlations between productivity and ocular fatigue (Hemphälä, 2009). Any discomfort can deeply influence the concentration of the surgeon in the execution of a surgical procedure and ultimately errors may occur, creating a risk for the patient.

It is evident how glare is a key problem in the operating theatre: *"The requirements for the visual environment in a surgery room are high. Surgery or assistants who are having any visual problems can make serious mistakes" (Hemphälä, 2009).*

Angle Lamp	90°	75°	60°	45°	30°	15°	0°
RIMSA UNICA520 Zero Glare Technology 2R double reflection	0 lx 	20 lx 	30 lx 	30 lx 	50 lx 	220 lx 	120.000 lx 
	0 lx 	90 lx 	130 lx 	170 lx 	500 lx 	1.100 lx 	120.000 lx 
RIMSA PENTALED E/N Indirect light	0 lx 	150 lx 	300 lx 	370 lx 	600 lx 	1.500 lx 	110.000 lx 
	0 lx 	150 lx 	300 lx 	370 lx 	600 lx 	1.500 lx 	110.000 lx 
RIMSA Direct light With polycar- bonate lenses	0 lx 	150 lx 	300 lx 	370 lx 	600 lx 	1.500 lx 	110.000 lx 

Fig. 9: In the above image we see the values in lux of the light that stresses the surgeon's retina when the scalytic lamp is positioned at different angles at the same distance. We can therefore compare the luminous intensity of three RIMSA lamps which utilise different technology. What is immediately apparent are the great advantages of indirect light and double reflection technology offered by UNICA.



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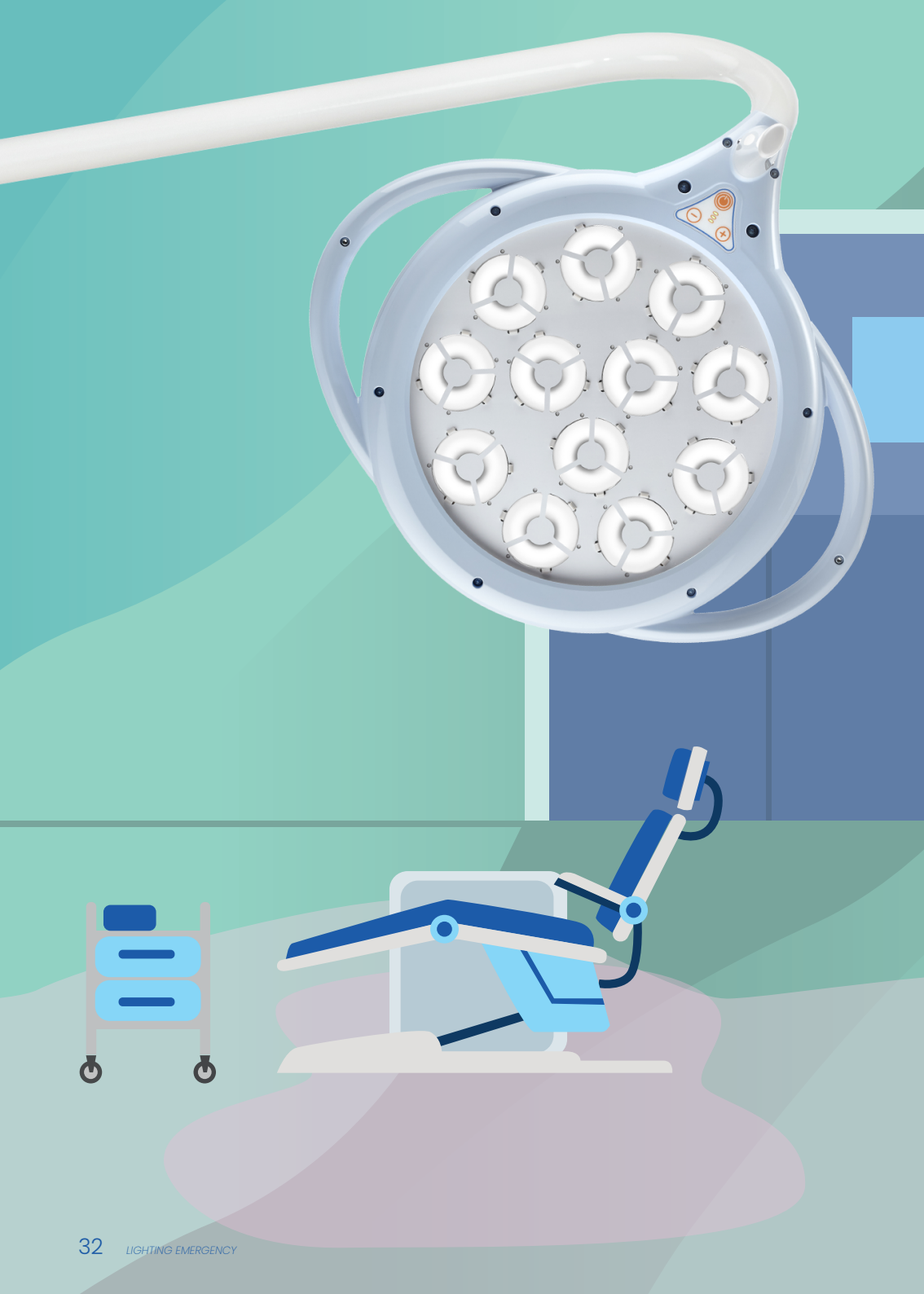
Glare in operating theatre represents a huge risk for surgeons, for the entire medical staff and for the patient, and it is also a danger to their health. For these reasons, producers of scialytic lamps should address this issue seriously.

In order to solve the problem of glaring, in 2002, RIMSA had already developed its first surgical LED lamp with indirect light.

Comparing the values of illumination in lux of lamps that adopt the two different technologies on the retina of the user at different angles, the benefits offered by indirect reflection to counteract the risk of glare are clear.

After an undertaking of many years, in 2017, RIMSA patented UNICA, the only scialytic lamp that, thanks to its double reflection technology, is capable of completely removing glare caused by surgical illumination.





7.

MANOEUVRABILITY



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Manoeuvrability is another topic that scientific research has paid particular attention to. The report 'Indicating shortcomings in surgical lighting systems' (Knulst: 2011, p.269 – 270) presents the principal problems encountered in operating theatre regarding manoeuvrability of scialytic lamps.

One of the most serious issues reported in the operating theatre is that some surgeons have not been able to move the lamp using the handle. The lamp was either too heavy or the suspension system made the lamp impossible to move (Knulst: 2011, p.269 – 270).

When confronting this type of problem, it has been observed how surgeons have had to move the lamp with both hands, forcibly interrupting the operation. It seems evident then that being unable to move a scialytic lamp creates a double issue: to the inability of moving the lamp we must also add the risk of infection. Having to move the lamp using both hands causes the surgeon to come in contact with a non-sterile area.

In order to prevent these kinds of problems, RIMSA designs and produces their lamp arms according to the principles of ergonomics: they are made of aluminium to reduce weight whilst guaranteeing excellent stability.

RIMSA is the only producer of scialytic lamps to design and build their own support structures.



A second problem highlighted by the research is clutter: when the illumination device is moved it collides with other lamps, the heads of other medical staff in the operating theatre or even its own ceiling anchor.” (Knulst: 2011, p. 269 – 270).

By analysing the solutions put forward by scialytic lamp producers, a great standardisation in the illumination systems can be noted. This standardisation doesn’t account for the specific needs of each situation and is rarely able to adapt to any given situation. RIMSA, designing its own support structures internally, can better respond to any requirement, offering solutions that are customised to the dimensions of each installation. In addition to personalised support structures, RIMSA also offers two configurations of yoke: single yoke (**A**) or double yoke (**B**). Whilst the double yoke is the only configuration offered by all other producers, RIMSA also offers a single yoke solution in order to be able to fit the needs of installations where there is a low ceiling.

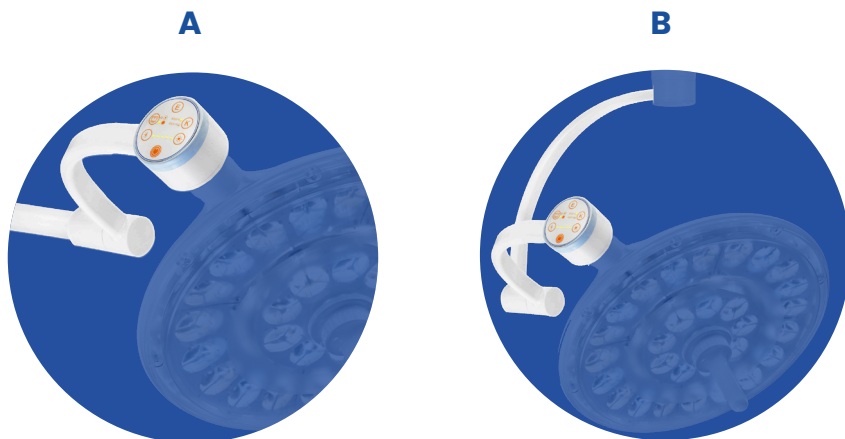


Fig. 10: Comparison between single yoke and double yoke.

It was also highlighted that nurses have repeatedly had to assist in the repositioning and set-up of lamps (Knulst: 2011, p. 269 – 270) unfortunately however, nurses are not always on hand to assist with this during surgery, causing the surgeon problems. RIMSA, wanting to address this issue, added to all its products the 'Always on Focus' technology: the reflection of light is designed so that it can guarantee a cone of light that is homogenous at any distance within 70-140 cm from the operating field. Thanks to 'Always on Focus' technology it is no longer necessary to adjust the focus and search for optimal illumination.

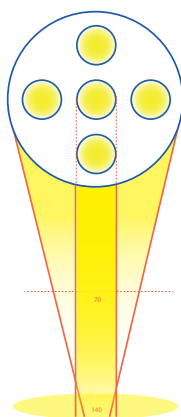
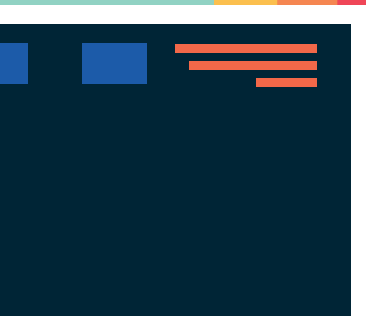


Fig. 11: Visualisation of the 'Always on Focus' technology.



8.

IMPACT ON LAMINAR AIR FLOW

In operating theatres, it is of great importance that a sterile environment is maintained in order to avoid infection. Despite the precautions, it remains difficult to combat the bacterial count that develops on the operating field. One of the methods used to maintain a low bacterial count is laminar air flow: *"A ventilation system in an operating theater (OT) is able to provide a clean surgical environment, and it plays an important role in the prevention of contamination through airborne particles"* (Traversari et al, 2016 p. 40). The laminar air flow is a constant flow of clean air that helps to minimise the risk of infection as much as possible.

"In the absence of perforation of surgical gloves, the principal causes of infection are bacteria remaining following preparation of the skin or airborne bacteria which inoculate the surgical site" (Refaie et al, 2017, p. 1061).

Laminar flow is not, however, a definitive solution since there are factors that can negatively affect its ability to function effectively: *"It has been revealed that the air current in the operating room with a vertical laminar airflow system is influenced, leading to the contamination of surgical field, surgical staffs, and door opening"* (Kay et al: 2019, p. 1).

Heat emitted by scialytic lamps disturbs the laminar air flow:
“the disturbance of laminar air flow by the surgical light is influenced by its electrical power, its surface area, its shape and position above the operating table and its angulation”
(Knulst: 2009 B, p. 322).

In an attempt to solve this problem, many producers modify the shape of their lamp, convinced that by doing so they can reduce the impact their lamps have on laminar air flow. However, this modification does not help towards their objective. The shape of the object struck by the laminar air flow, in this case a lamp, is uninfluential on the turbulence of air flow created. Uniquely shaped reflectors become even more unnecessary when regulatory requirements for measuring the turbulence caused are taken into account. The legislation DIN 1946-4, requires that the calculation of turbulence be made with the lamp at a 45° angle. Therefore, unique shapes (such as reflectors with holes in them) are rendered useless. What does have a great effect on laminar air flow is the temperature reached by the object placed under the flow of air: the greater the temperature, the greater the turbulence. A more effective approach to solve this problem is to reduce the heat dispersed by the cupola of the lamp. Heat has the greatest influence on laminar air flow.

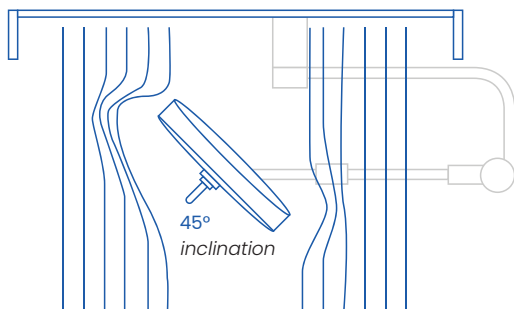
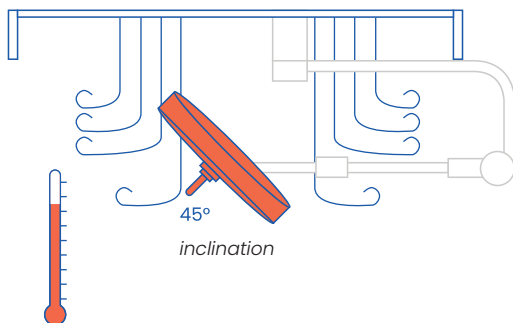
A**B**

Fig. 12: Comparison between two lamps of different temperatures at the required 45° angle and their effect on laminar air flow.

To reduce heat it is important to take into consideration the heat generated whilst the lamp is operational. It is for this reason that RIMSA, during the design phase prefers materials that aid heat dissipation: the body and the cupola of RIMSA lamps are made of die-cast aluminium, in this way heat radiated from the head of the lamp is effectively reduced. Moreover, the internal components of the lamp – the LED PCB – are made of aluminium, copper and ceramic, reducing at source the heat generated by the LEDs. This decision allows a reduction in temperature during LED use and consequently an increase in product service life whilst improving the lamp's interaction with the laminar air flow.

The impact of scialytic lamps on laminar air flow is part of the legislation of the regulatory standard DIN 1946-4 which states that the maximum intensity of turbulence is 37.5%. RIMSA has been certified as conforming to the standard thanks to a study that was done in collaboration with the Politecnico di Milano, which tested the values using RIMSA's UNICA model.

The results of the tests done to measure the intensity of turbulence completed on two different models of RIMSA's scialytic lamps were strictly below the maximum value (37.5%) (Standard Annex E DIN 1946-4). For the UNICA 520 model, whilst operational, the maximum level of turbulence measured was 15.4% and for the UNICA 860 model the maximum value measured was 15.8%. Therefore, this proves that the test for acceptable limit of turbulence (37.5% level of maximum turbulence) for satellites and surgical lamps is comfortably passed (Grassi, Report n. 934, October 2018) when using these two scialytic lamps in operating theatres that use laminar air flow systems.



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9.

FOCUS AND AUTOMATIC DIAMETER ADJUSTMENT

The irritation inflicted on surgeons by repositioning scialytic lamps also causes another problem: the beam of light being out of focus.

During surgery, the focus of the light is set before surgery begins.

However, it does happen that during surgery the lamp is moved and, in theory, every time that it is moved the focus must be adjusted to the new position. In practice however, in the critical moments of a surgery, adjusting the focus of the beam of light is not a top priority. Therefore, surgeons and medical staff tend to succumb to this lack of focus and move the lamp again or simply do nothing to address the issue.

During the observation of a 46-hour long surgery 346 LAs (moments where the scialytic lamp was adjusted) were identified. This gives an average of an adjustment every 7.5 minutes. [...] Neither the focus of the beam of light nor the levels of illumination were ever adjusted during the observation period" (Knulst: 2011, pp. 268–269).

RIMSA realised that surgeons were using the wrong light every time they moved the lamp and did not adjust the focus. In order to overcome this type of problem, RIMSA installed a system of optical lenses in its products so that the beams of light coincide and are always perfectly focused at any distance between 70–140 cm away from the surgical field.

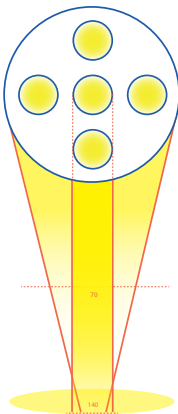


Fig. 13: Visualisation of the 'Always on Focus' technology.

10.

COMPENSATION AREA

The feeling of being blinded by glare doesn't only occur when the surgeon looks directly at the light source, it also happens when the eye deviates its gaze from the centre of the illuminated area to the edge of the surgical focus. In the centre, in most cases, the level of illumination reaches 160,000 lux. However, towards the edges of the illuminated area illumination is drastically reduced: *"Luminance contrast that it 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 through areas with different light intensity such as the passage from the illuminated surgical field to any other area in the operating theatre. This sudden change in intensity can cause numerous problems.

Firstly, this type of glare causes visual discomfort; surgeons would attempt to be more comfortable by continuously changing their positioning in order to improve their view but in doing so would sacrifice concentration: *"glare can lower productivity"* (Horgen et al; 2007).

Loss of concentration caused by glare can be harmful to patients: indeed the consequences of glare in operating theatres are presented in literature as direct and concrete risks to the health of the patients: *"Surgeons or assistants who are having any visual problems can make serious treatment mistakes"* (Hemphälä, 2009).

Conscious of this problem, producers have been trying to find a solution to indirect glare in operating theatres caused by scialytic lamps: the most effective solution for this discomfort was found in progressive illumination.

In 2013, Maquet S.A.S commissioned a study on the 'Comfort Light' functionality of their scialytic lamp - the *"Maquet Powerled 2 White Paper"* - designed to resolve this issue. The report highlighted the benefits of this feature: *"We can see from the figures that transitional lighting reduces the sensation of glare by 7% and the feeling of sleepiness by 15%."* (Maquet PowerLED II white paper. 2013).

This confirmation of the advantages of progressive illumination creates another reference point for other producers that offer the same concept of progressive illumination through different technology. The most recent scialytic lamp produced by RIMSA – the UNICA – is fitted with an area of compensation that allows for a “progressive and gradual adjustment of light intensity with the aim of removing glare between the central area of surgical focus and its perimeter” (UNICA catalogue, RIMSA, 2017).

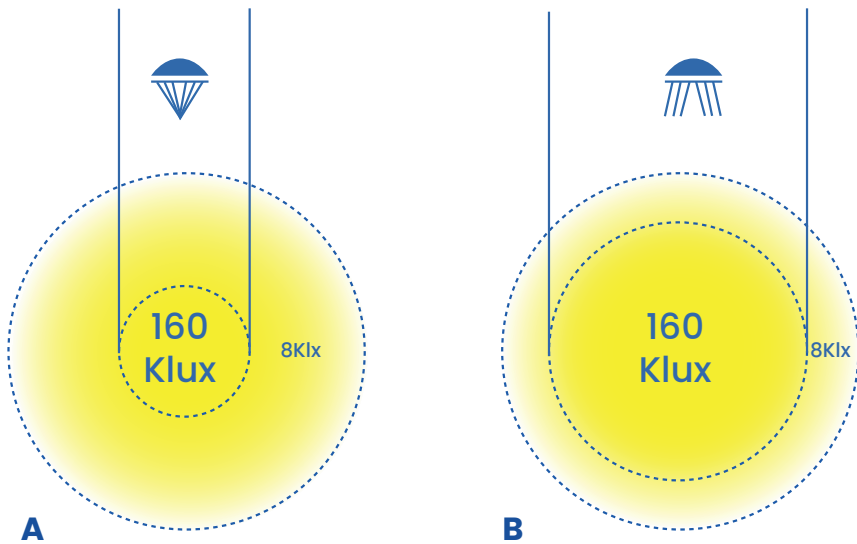


Fig. 14: Visualisation of the adjustment area

The area of adjustment designed by RIMSA consists of a light ring that is peripheral to the area of surgical focus and permits visual adjustment thus avoiding sudden transition from a shadowy area to an area that is highly illuminated.

This adjustment area guarantees the absence of glare and perception of black dots, the general feeling of being blinded – when the surgeon takes their eyes off the intensely illuminated surgical field: *“Particular attention has been devoted to visual impact. To avoid the feeling of blindness experienced when passing from a very well-lit area to a non-illuminated peripheral zone, an intermediate low-lit area has been created so the eye can adapt to light change” (Unica catalogue, Rimsa, 2017).*



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11.

“ENDOLIGHT”

Medical-scientific literature has focused greatly on the principal characteristics of scialytic lamps whilst it has neglected many of the features developed by producers designed to improve working conditions in operating theatres. This has resulted in an almost non-existent scientific coverage of a feature that the majority of producers call ‘endolight’ – light for endoscopy.

Light for endoscopy is a feature that allows surgeons to illuminate the surgical field with a soft light, whilst at the same time having the ability to illuminate the entire operating theatre with green or blue light.

Unfortunately there is no research that is capable of answering a very simple question: *“why exactly is a green light necessary during endoscopic surgeries?”*

Only within the producers’ commercial catalogues can we find the answer: *“green light is essential for endoscopic surgeries”* (*Dr. Mach, MachLED 5; Trilux, Aurinio wave*). The catalogues of Maquet, Merivaara and Steris have underlined the fact that green light helps the surgeon view both images and screens. This is the beginning of an explanation but there is no one that goes into detail as to exactly why green light is necessary.

The Nuvo catalogue addresses the issue stating that the human eye perceives more green tones than any other colour and therefore it is the best choice of light colour during operations that require a low level of light (Vu LED Surgical Light, Nuvo, www.nuvosurgical.com). However, no other sources are cited nor are any other scientific explanations provided.

The only true reference to the topic in scientific literature is presented in the Merivaara Q-FLOW catalogue where it is stated that the “green ambilite” is optimal: *“Due to the Purkinje effect it provides better definition to images and text”*.

Simply put, the Purkinje effect explains why, in dark conditions, the human eye sees very few colours: when light is dim, the human eye is more sensitive to the wavelengths of blue and green.

RIMSA designed a feature for UNICA called “endoled”, which allows the user to adjust the light intensity of the white light and the seven colour temperatures (between 3800 K and 5000 K): *“For endoscopy and concentrated operating field operation, the Endoled function is active, providing soft light, this too adjustable in intensity and tone, to light up the work area”* (Unica catalogue, Rimsa, 2017). The “endoled” also offers an ambient blue light achieved by a light ring positioned on the tip of the cupola.



Apparently, the only studies that support the use of a coloured ambient light are those relating to the Purkinje effect. The Purkinje effect considers blue and green the only alternatives when it comes to improving visibility of text and images. Blue however is to be preferred as it has been shown to have a calming and relaxing effect: *"To identify the best choice of interior conditions for buildings such as colour and light, there is a need to determine the physiological changes in people under these conditions when the exposure is long enough to allow the participants of the study to adapt to them"* (Abbas,2006 p. 1228).

"Blue can be considered relaxing" (Al-Ayash, 2015, p. 197).



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