



User manual



LED surgical light

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Certifié ISO 9001 – ISO 13485

Summary

1. LEGAL INFORMATIONS:	4
1.1. Copyright, translation and property:	4
1.2. Staff competencies:	4
1.2.1. Operating staff:	4
1.2.2. Cleaning staff:	5
1.2.3. Technical staff:	5
1.3. Safe operation:	6
1.4. Obligation of information:	6
2. WARNINGS:	7
3. GENERALITIES:	9
3.1. Symbols:	9
3.2. Concerned products:	10
3.3. Manufacturer:	11
3.4. After sale service:	11
3.5. Concerning the product use:	11
3.6. Concerning this manual:	11
4. PRODUCT DESCRIPTION:	13
4.1. Surgical light system:	13
4.2. Surgical light:	15
5. Using:	17
5.1. Surgical light:	18
5.1.1. First start:	18
5.1.2. Positioning:	18
5.1.3. Light setting:	19
5.1.3.1. Starting:	20
5.1.3.2. Surgical light identification:	20
5.1.3.3. Lighting level:	20
5.1.3.4. Endo mode:	21
5.1.3.5. Color temperature:	21
5.1.3.6. Light field diameter:	22
5.1.4. Emergency supply:	22
5.1.5. Wall report (option):	24
5.1.5.1. Surgical light selection:	24

5.1.5.2.	Adjustment of the surgical light setting:	24
5.2.	HD / HR Camera (option):.....	25
5.2.1.	Synchronization:.....	25
5.2.2.	Starting:	25
5.2.3.	Camera dismount:	29
5.2.4.	Zoom adjustment:	30
5.2.5.	Focus adjustment:	30
5.2.6.	Exposure adjustment:.....	31
5.2.7.	Preset / Memorization:	31
5.2.8.	White balance:	31
6.	CLEANING, DISINFECTION, STERILIZATION:	32
6.1.	Cleaning, disinfection:	32
6.2.	Sterilization:.....	34
7.	CONTROLS AND SETTINGS:	35
7.1.	Controls:	35
7.2.	Arm setting of a ceiling light:.....	37
7.2.1.	Balancing of the spring arm:.....	37
7.2.2.	Travel in maximum height:.....	38
7.3.	Front arm setting:.....	40
7.3.1.	Balancing of the spring arm:.....	40
7.3.2.	Travel in maximum height:.....	42
7.4.	Consumable:.....	43
8.	STORAGE, USING CONDITIONS AND RECYCLING:	44
8.1.	Storage:	44
8.2.	Using condition:.....	44
8.3.	Recycling:.....	44
9.	TECHNICAL DATA:.....	46
9.1.	Surgical light	46
9.2.	Camera technical data (option):.....	47
9.3.	Wall report (option):	48
9.4.	Emergency emergency power supply (option):	49
10.	INTERFERENCES ELECTROMAGNETIQUES :	51
11.	FAILURES CHART:.....	56
12.	COMPLIANCE CERTIFICATE:.....	58
13.	WARRANTY:	59

1. LEGAL INFORMATIONS:

1.1. Copyright, translation and property:

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Only the French version shall prevail in case of problems with translation into other languages.

SURGIRIS reserves the right to modify the content of this document without notice as and when required to incorporate technical product developments and updates.

The trademarks mentioned in this document are the property of SURGIRIS.

1.2. Staff competencies:

1.2.1. Operating staff:

The surgical light and its operating manual are intended for medical and technical staff. These members of staff must have the proper knowledge to use and maintain the surgical light in accordance with the requirements in the country where the surgical light is used.

Staff using the device must be familiar with this manual for safe use.

The owner can only switch on the lights if SURGIRIS or its authorized representatives have performed a functional test of the lights at the installation place, and have completed training for nursing staff users

of the light in accord with the operator's manual instructions on safety.

1.2.2. Cleaning staff:

The surgical light and its operating manual are intended for medical and technical staff. These members of staff must have the proper knowledge to use and maintain the surgical light in accordance with the requirements in the country where the surgical light is used.

The cleaning should be performed by personnel trained accordingly.

1.2.3. Technical staff:

The surgical light and its operating manual are intended for medical and technical staff. These members of staff must have the proper knowledge to use and maintain the surgical light in accordance with the requirements in the country where the surgical light is used.

Any corrective and preventative maintenance including calibration and adjustments must be performed by qualified technical personnel only.

1.3.Safe operation:

The owner can only switch on the lights if SURGIRIS or its authorized representatives have performed a functional test of the lights at the installation place, and have completed training for nursing staff users of the light in accord with the operator's manual instructions on safety.

The warranty becomes void should the user or any third party attempt to perform any maintenance procedures without the written consent of SURGIRIS or should they not use original spare parts.

SURGIRIS prohibits any modification of the lighting system made by the user or by third parties.

Only SURGIRIS or an authorized representative may make changes to the product.

SURGIRIS will not be liable for damages caused by the lighting system if it has been subject to alterations or repairs made by the user or any third parties without the written consent of SURGIRIS or if the light has been misused or abused or used for any purpose other than the identified use.

1.4.Obligation of information:

It is necessary to keep this manual as a source of information for queries relative to the use, maintenance or safety on the supplied product.

Anyone using the product should be able to access to the manual at any time.

2. WARNINGS:



Improper use and non observance of the precautions can cause serious accidents. That is why it is essential to learn to use your surgical light and familiarize yourself with its functions by reading this manual.



Remove general power of the surgical light before dismantling it; turn off the light and wait for its cooling before cleaning.



Do not operate lights near a water flow.



If the line voltage is not known before the light installation, please consult an authorized dealer or local power company.



Connect power to the earth to avoid any risk of electric shock.



Do not use SURGIRIS lights in an environment presenting risks of explosion.



Never look directly inside the light on and avoid inserting any object reflecting the light beam: risk of glare from the high light output.



To ensure efficient lighting, the distance between the surface emitting the light of the surgical light and the operative field must be more than 50 cm.



Do not place or hang objects on the surgical light or on the arm. This would compromise the stability of the lighting system and these objects might fall onto the operation field. In addition, the suspension of heavy objects (such as the body of a person) can permanently damage the mechanism.



Never cover the surgical light during operation, as this will prevent the heat exchange necessary, and thus could result in possible overheating of the lighting system.



Avoid direct contact with the hands above the surgical light, this area allows the heat exchange. Use the positioning handles to move the light.



Improper height setting of the stop arm can cause collisions between the arm and damage the lighting system.



Any intervention on the suspension system can cause a risk of falling.



Do not discard all or any part of the lighting system even if it is defective.



Before any surgical operation, check the condition of the sterilizable handle.



The sterilization of the handle is prohibited to warm air.





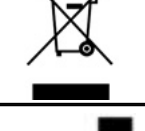



The using of the handle is strictly reserved for nursing staff that completed the disinfection requirements. Any staff who have not satisfied these requirements would compromise aseptic conditions of the handle. This staff member must use the position handles located on each side of the module.





3. GENERALITIES:

3.1.Symbols:

Symboles founded in the manual

	Warning danger, read carefully to use safely the device
	Danger, hot surface, read carefully to use safely the device
	Electrical danger, read carefully to use safely the device
	CE marking, the device is according to the european directive relative to medical devices 93/42/CEE
	Equipment should not be thrown away with household waste, equipment which is subject to separate collection for recycling
	Manufacturer adress

Symbols founded on the device

	Warning danger, see the user manual to use safely the device
	Danger, hot surface, see the manual user to use safely the device
	CE marking, the device is according to the european directive relative to medical devices 93/42/CEE
	Equipment should not be thrown away with household waste, equipment which is subject to separate collection for recycling

3.2.Concerned products:

This manual is for users of:

- X2

- X1
- HR / HD camera (option)

In versions:

- Ceiling version
- Wall version
- Mobile version

3.3.Manufacturer:



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3.4.After sale service:

If you have technical questions or need replacement parts, contact us at the following coordinates:

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Fax: (+33) 3 20 95 40 19
E-mail: sav@surgiris.com
Internet: www.surgiris.com

3.5.Concerning the product use:

The X1-X2-X3® lights are surgical lights which allow the local lighting of the patient body. They can be used as principal light with or without integrated emergency power supply back-up in case of a power failure, or as secondary light (Emergency light) with or without integrated emergency power supply back-up in case of a power failure .

They are intended to be used in operating theatre to provide local lighting of the patient in order to facilitate treatment and diagnosis interventions.

3.6.Concerning this manual:

This manual aims to provide a detailed description of the correct use of the surgical light.

Read it carefully to familiarize yourself with the use and operation of your device before using it in the operating theatre.

All checks must be performed by technicians trained by SURGIRIS and the equipment use must conform to the purpose for which it is intended.

SURGIRIS assumes no responsibility for damages due to misuse of the product.

To ensure reliable and sustainable use of the light, only original spare parts supplied by SURGIRIS may be used.

The company SURGIRIS would be liable for the consequences on safety, reliability and performance of the device if only the following conditions are complied with:

- The installation and the After Sales Service were performed by SURGIRIS or by an SURGIRIS authorized service centre or technician.
- The device is used according to instructions.

SURGIRIS products are quality products manufactured according to approved technical standards.

They left the factory in perfect working order and meet with all the required safety standards.

In order to ensure a lifetime of trouble-free use it is vital to perform an annual preventive maintenance and verification of wearing parts of the lights. This must be performed by SURGIRIS or by a SURGIRIS authorized service centre or technician.



Improper use and non-observance of precautions can cause serious accidents. Therefore it is essential to learn how to use your SURGIRIS lighting and familiarize yourself with its functions by reading this manual.

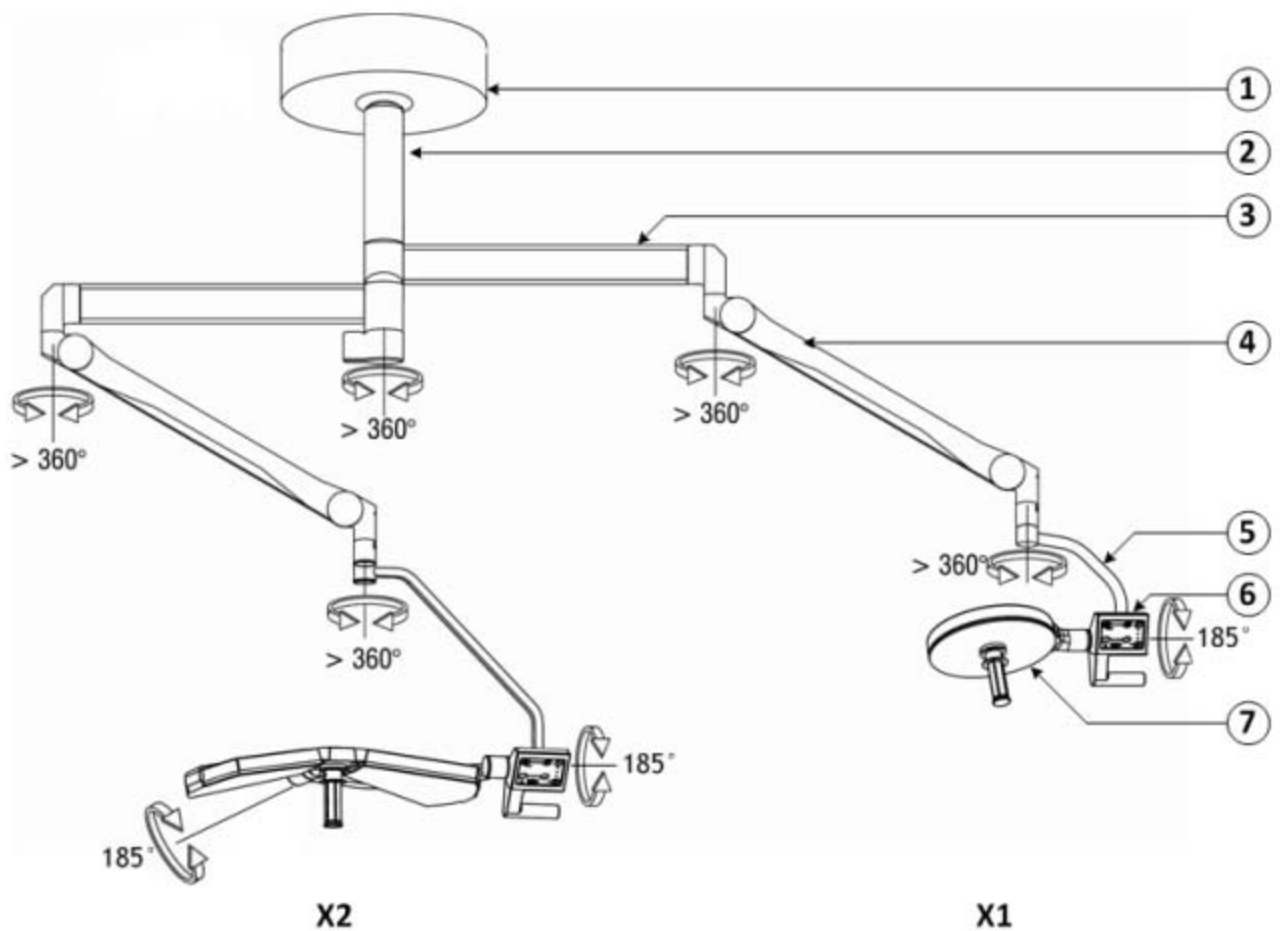
4. PRODUCT DESCRIPTION:

4.1.Surgical light system:

X3®, X2® and X1® lights are innovative surgical lights based on the new patented FOCUSMATIC® optics.

They are made of aluminum for good heat exchange and are viewed from an open body for proper integration into operating theaters with a blasting cap.

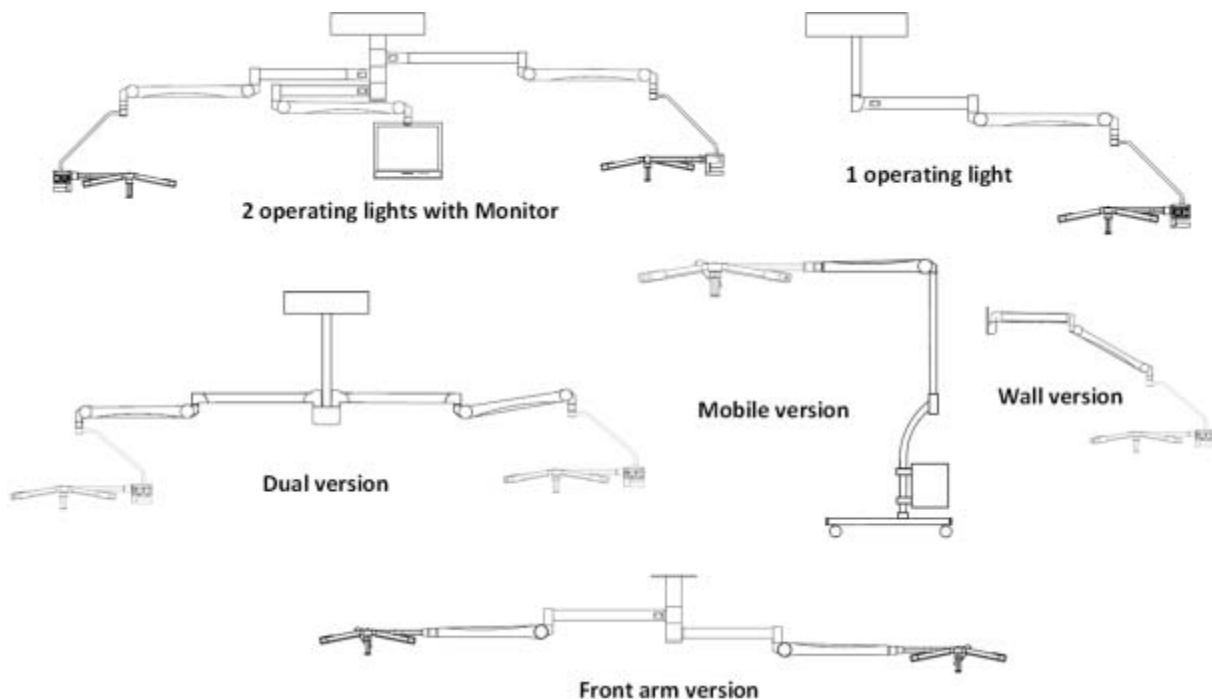
No phthalates was used for the design and the manufacture of surgical lights.



- ① Ceiling cover
- ② Drop tube
- ③ Extension arm
- ④ Spring arm

- ⑤ Simple / double yoke
- ⑥ Control handle
- ⑦ Lighting system

Others configurations available:



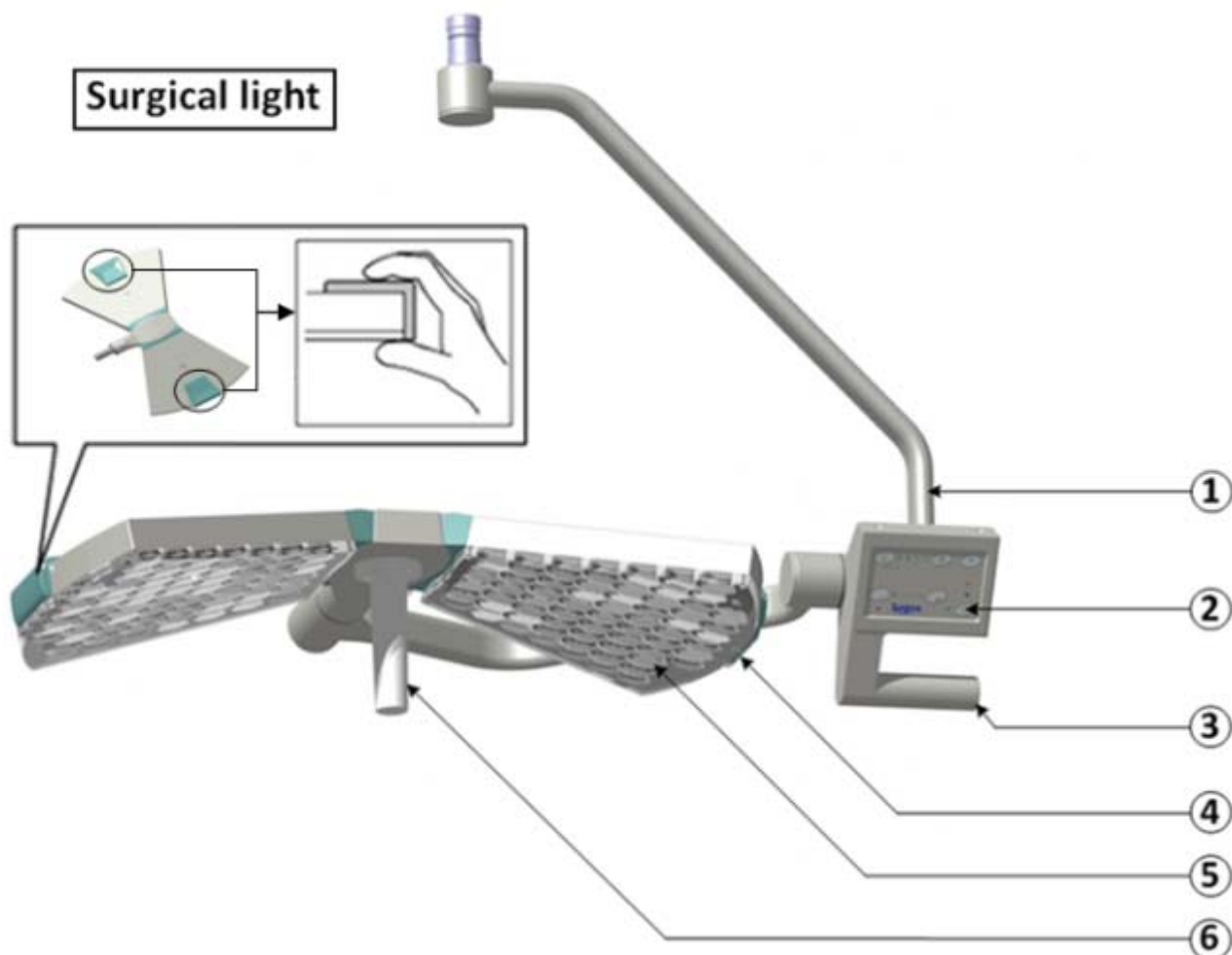
The lighting system is secured to the ceiling with a **drop tube** ② integral with the roof and the concrete fixation kit is concealed by a **ceiling cover** ①. The **drop tube** ② adjusts the height of surgical lights from the floor of the theatre.

The handling is facilitated by an **extension arm** ③ associated with a **spring arm** ④, offering a wide range of mobility in the horizontal and vertical.

The joints **drop tube** ②/ **extension arm** ③, **extension arm** ③ / **spring arm** ④ and **spring arm** ④/ **yoke** ⑤ allow rotations completely free with no angle restriction.

X3®, X2® and X1® surgical light is secured by a **double yoke** ⑤. This system provides to the light high mobility and maneuverability and comfortable use.

4.2.Surgical light:



- | | |
|----------------------|------------------------------|
| ① Yoke | ④ Lateral positioning handle |
| ② Control keyboard | ⑤ Side module |
| ③ Positioning handle | ⑥ Sterilizable handle |

The combination of red, cyan and white LEDs provides adjustment in color temperature from 3500°K to 5000°K in maintaining a CRI (Color Rendering Index) above 95.

The X3®, X2® and X1® surgical light can be manipulated thanks to the **sterilizable handle** ⑥ or with the **lateral positioning handle** ④ located on each module. So you can choose the angle or the best position.



The use of the sterile handle is strictly reserved for nursing staff that completed the disinfection requirements. Any staff member who has not satisfied these requirements would compromise the aseptic conditions of the handle. This staff member must use the position handles located on each side of the module.

5. Using:



Do not use the X1 and X2 surgical lights in a MRI room



The superposition of multiple surgical lights on the same operative field has the effect of increasing light intensity and can dry out the tissues. Adapt the lighting level accordingly.



Do not use the light near a water flow.



Do not use SURGIRIS lights in an environment presenting risks of explosion.



Never look directly inside the light on and avoid inserting any object reflecting the light beam: risk of glare from the high light output.

5.1. Surgical light:

5.1.1. First start:

The owner can switch on the lights if the manufacturer or supplier has:

- Performed an operational test of the surgical light system at the installation location,
- Trained user of the surgical light according to the instructions in the manual.



Improper use and non observance of precautions can cause serious accidents.

5.1.2. Positioning:

1. Position the surgical light in the **middle of the field**.
2. Adjust the **height** with the **handle of prepositioning**③ or with **sterilizable central handle**⑥.
3. Adjust the **angle** with the **sterilizable handle**⑥ or with the lateral positioning handles on each **side module**④.

The position of the lamps depends on the operation type and user preferences. This is a suggestion of settings.



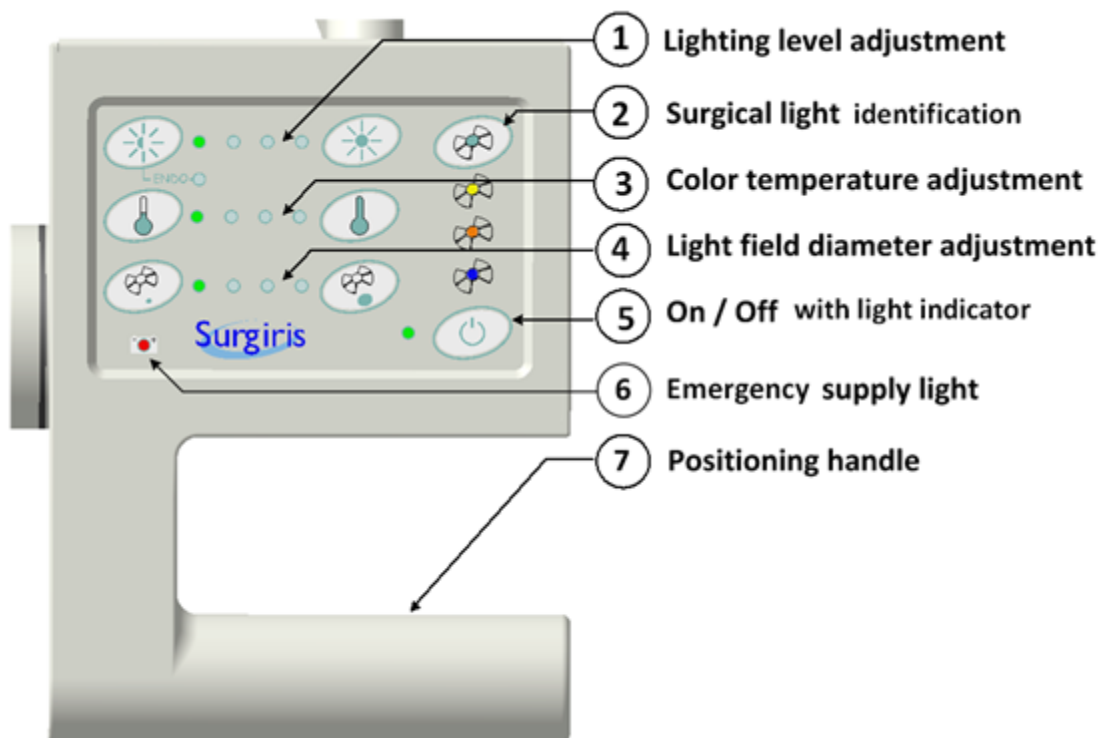
The sterilizable handle can only be manipulated during the operation by personnel that have complied with and met the necessary recommendations of sterilization.



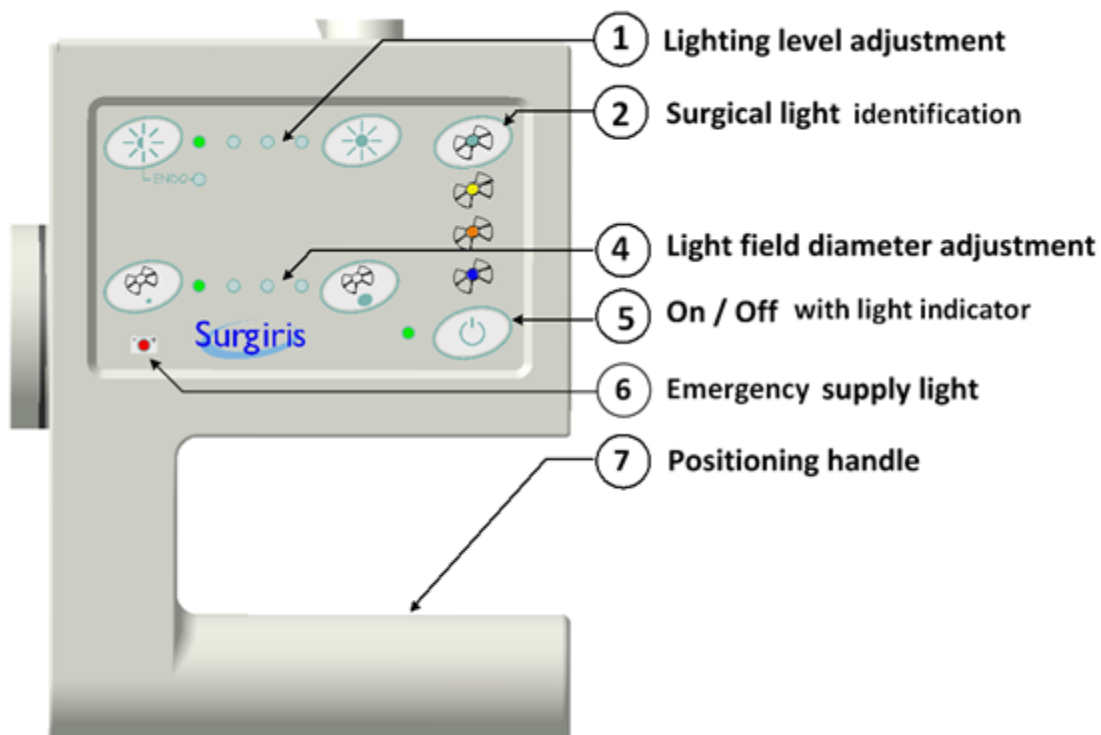
Avoid direct contact with the hands above the surgical lighting, this area allows the heat exchange. Use the positioning handles.

5.1.3. Light setting:

X3^{COLOR} and X2^{COLOR} control keyboard



X3^{FIX}, X2^{FIX} and X1 control keyboard



5.1.3.1. Starting:

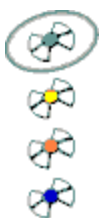


To **start** the device,

- Press the **On/Off button ⑤**, the indicator on the left of the button illuminates.
- To stop the device, press the On/Off button ⑤, the indicator on the left is extinguished.

Similarly for stopping the device, press this button also.

5.1.3.2. Surgical light identification:





Each cupola in a surgical light system is identified by its proper color. This color is established during the surgical light manufacturing and cannot be changed by the user.

This identification is only used in the case of the piloting with the wall report. (See chapter 5.1.5. Wall report).

5.1.3.3. Lighting level:



At the top of the remote control, you can adjust the **lighting level ①** to 7 possible levels.

- To **decrease** the lighting level, press the **left button** .
- To **increase** the lighting level, press the **right button** .

To adjust a setting from a low value to high value quickly, keep the right button pressed till you achieve the desired level of intensity.

For a change of setting from a high value to a low, it is possible to keep the left button pressed till you reach the desired level of intensity.



The superposition of multiple surgical lights on the same operative field has the effect of increasing


light intensity and can dry out the tissues. Adapt the lighting level accordingly.

5.1.3.4. Endo mode:




The “ENDO” mode provides you a lighting ambience for endoscopic operations.

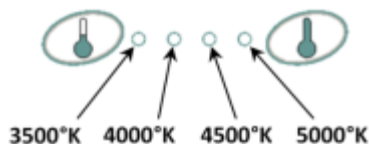
Activation:

- Keep the lower button  pressed to decrease the minimum illumination and keep the button depressed for **3 seconds** to enter the “ENDO” mode.



Deactivation:

- Press the higher  button, the lighting level returns to the minimum level.

5.1.3.5. Color temperature:



In the middle of the control panel, you can adjust the **color temperature** ③ (Only for the X3^{COLOR} and the X2^{COLOR}).

- To **decrease** the color temperature (accentuates to the red), press the **left button** .
- To **increase** it (accentuates the white and blue), press the **right button** .

You can choose between 4 color temperatures: 3500, 4000, 4500, 5000°K. This change allows you to enhance the contrast depending on the type of the operation and the surgeon's preferences.



Synchronization:

If you have at least two SURGIRIS lights, the change of the color temperature of one surgical light causes an automatic change of it on the other's lights.

This is the only setting that is synchronized between the surgical lights.

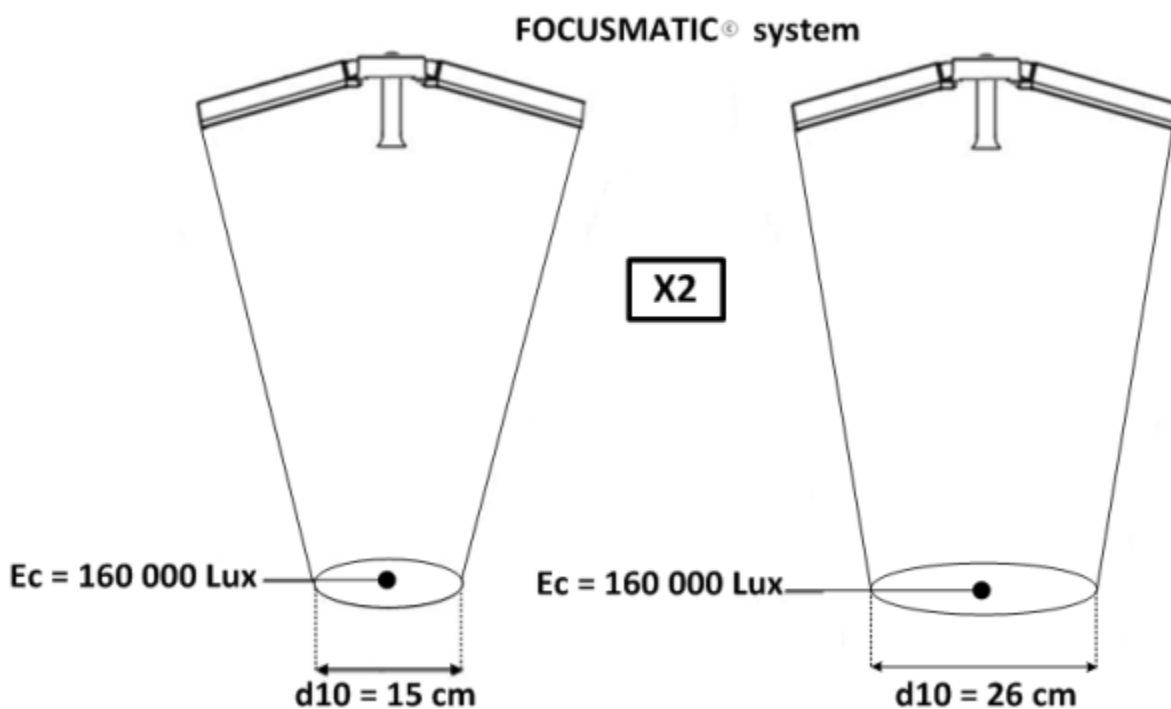
5.1.3.6. Light field diameter:



Below the control keyboard, you can electronically adjust the **diameter of the light field**④ and this without mechanical movement of the surgical light.

- To **decrease** the diameter, press the **left button**.
- To **increase** it, press the **right button**.

The X3®, X2® and X1® surgical lights are equipped with the new **FOCUSMATIC®** system.



This system allows maintaining the light intensity level irrespective of the diameter of illuminated field.

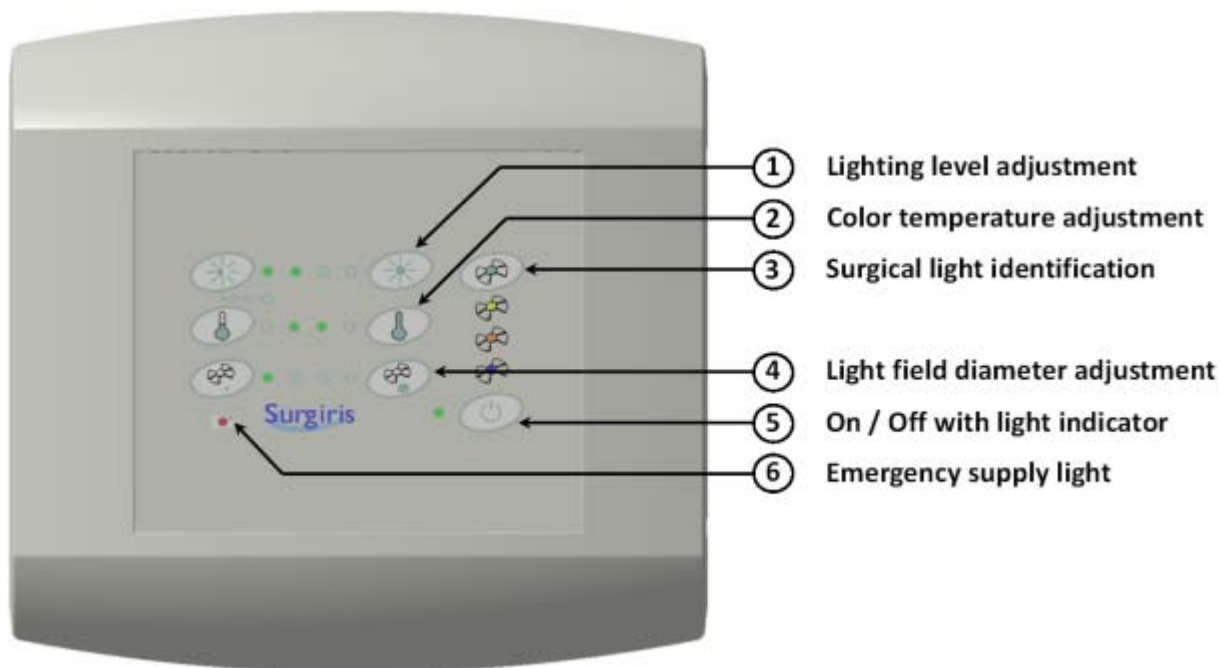
5.1.4. Emergency supply:

The X3®, X2® and X1® surgical lights could be equipped with an emergency supply in case of main power failure during the light using.

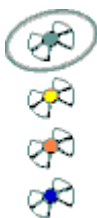


Transition to the emergency supply is automatic and is symbolized by the intermittent lighting of the battery symbol.

5.1.5. Wall report (option):




5.1.5.1. Surgical light selection:



The selection of the **surgical light** ② is available if you have one or many SURGIRIS lights equipped with a wall report. **This is only active on the wall report.**

Each lighting operation is identified by a color. This identification is determined during the surgical light manufacturing and cannot be changed. Thus the surgical lights can be controlled by the wall report due to a wireless connection.

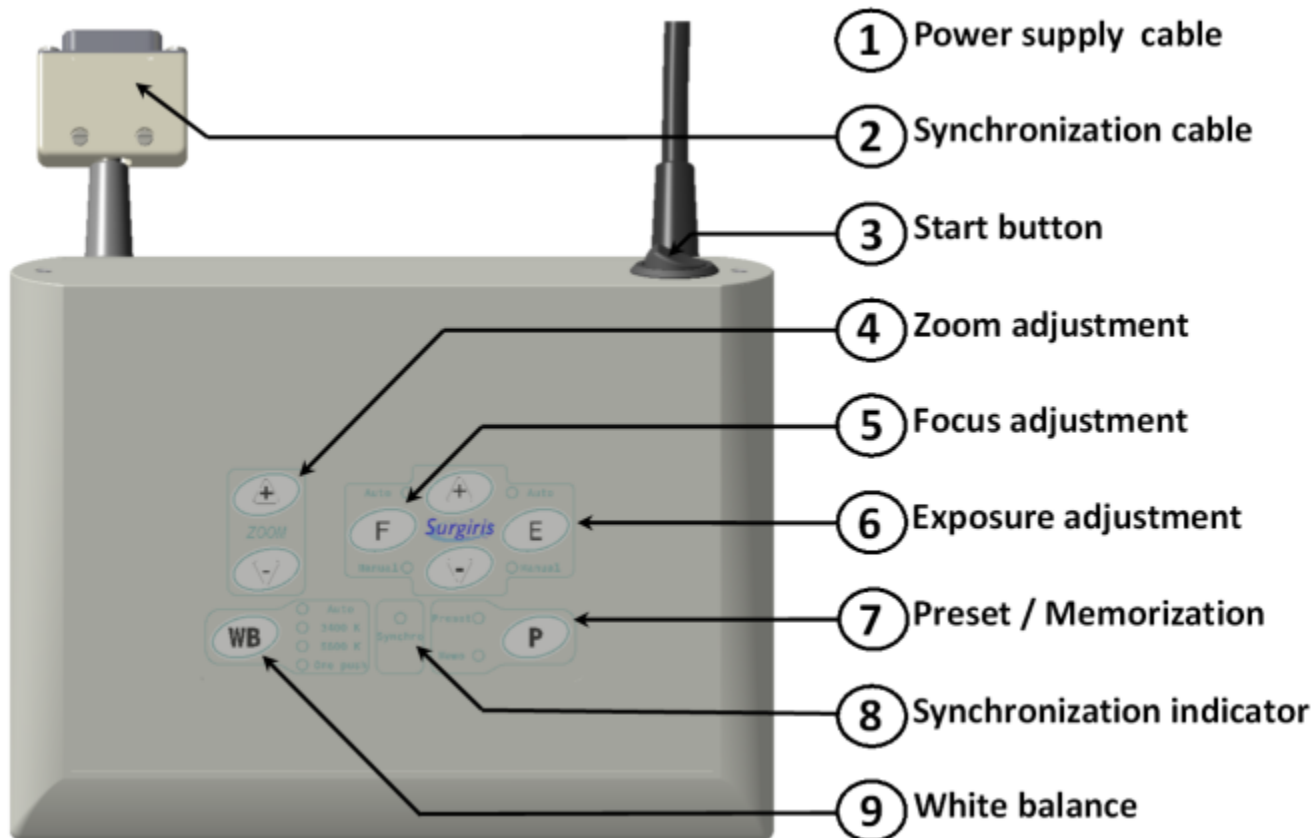
- **Select** the surgical light that you want controlled on the wall report with the identification by color by pressing the  button.
- **Change the settings** as mentioned previously from the wall report until you have desired settings.

This system allows you to adjust and control the settings of your surgical lights without direct intervention on the surgical light avoiding any aseptic compromise.

5.1.5.2. Adjustment of the surgical light setting:

All the settings from the wall report are unchanged in regard with the settings of the control box on each surgical light. (See chapter 5.1.3.)

5.2.HD / HR Camera (option):



5.2.1. Synchronization:



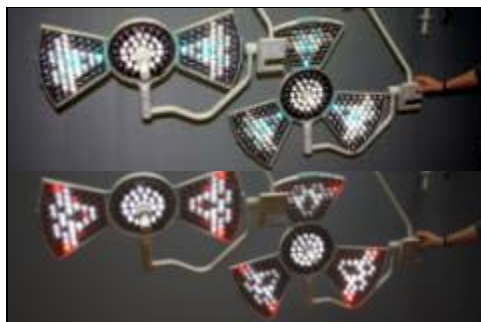
The synchronization light informs the user that all the system (camera remote control and surgical light) is synchronized.

Flashing green light: non-operational synchronization.

Continuous green light: operational synchronization.

5.2.2. Starting:

It is necessary, before every camera start, to synchronize the remote control with the camera.



Check the surgical light **synchronization** by changing the **color temperature** of one light causing the variation of the second one.



Remove the **sterilizable handle** by pushing the stop pin.



Remove the **sterilizable handle socket** by pushing the stop pin, showing the connection for the camera system.



Plug the remote control on the main power supply and press the on/off switch on the "1" position.



Plug the **synchronization cable** of the remote control on the surgical light socket.



Connecting the remote control to the camera socket of the surgical light, the SYNCHRO light flashes and turns on permanently and other lights to indicate that the system is synchronized.



Unplug the remote control and **turn off** it.



Turn the upper part of the camera in the “open padlock” position (to the left) until it is in the locked position.



Align the security button with the open padlock.



Interlock the camera by **firmly holding** the surgical light with one hand and holding the camera with the other one.



Turn the **upper part** of the camera in the “close padlock” sense (to the right) until you hear a click.



Check the **right fixation** of the camera on its socket. The camera start is automatic.




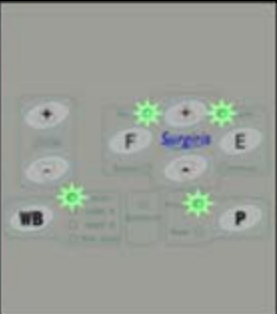
To adjust the image, turn the **bottom part of the camera**



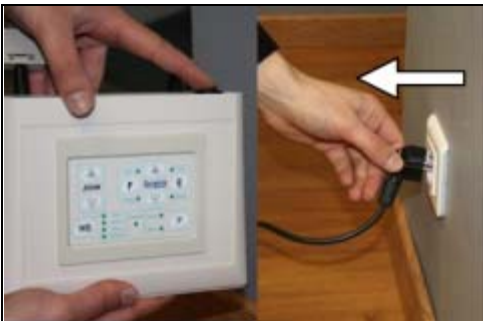


Put the **sterilizable handle** into position until it clicks. Check the proper engagement of the handle.



When the image appears on the monitor, **turn on the remote control**.

		<p>The SYNCHRO light is flashing: Camera research. (this step can take more than 1 minute)</p> <p>The SYNCHRO light is turn off: Camera in connection with the remote control, the other setting lights turn on.</p>
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5.2.3. Camera dismount:

	<p>Turn off the remote control and unplug it.</p>
	<p>Remove the sterilizable handle.</p>
	<p>Turn the upper part of the camera in the “open padlock” position (to the left) maintaining it firmly.</p>



Unplug the camera by pressing the stop pin.



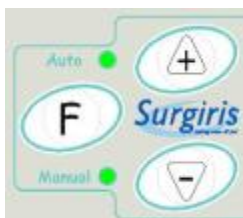
Interlock the sterilizable handle socket.

5.2.4. Zoom adjustment:



- For a **tight framing**, press the **+** button
- For a **large framing**, press the **-** button

5.2.5. Focus adjustment:

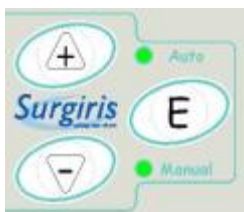


To switch from **Auto** to **Manual** mode, maintain the **F** button until the indicator turns on. Press **one time** briefly the **F** button to pass to **Auto** mode.

Manual mode:

- To **focus**, keep pressing the **F** button and press **+** button.
- To **defocus**, keep pressing the **F** button and press the **-** button.

5.2.6. Exposure adjustment:



To switch from **Auto** to **Manual**, depress the **E** button until the illumination of the “**Manual**” indicator.

Press the E button once briefly to switch to **Auto** mode.

Manual mode:

- To **increase** exposure, simultaneously depress the button **E** and the **+** button.
- To **reduce** exposure, simultaneously depress button **E** and the **-** button.

5.2.7. Preset / Memorization:



Preset: this mode restores the device to the default factory settings.

Memo: This function allows memorizing the set parameters.

To **memorize** the adjustment established, select the **Memo mode** by first briefly pressing the P button, then keeping the **P** button depressed.

5.2.8. White balance:



The white balance allows to calibrate the sensor and to correct color cast depending on ambient lighting.

Different modes exist:

To pass from a mode to another one, press one time on the **button**.



- **Auto:** automatic white balance.
- **3400°K:** adjusting the white balance with a dominant **red** color.
- **5600°K:** adjusting the white balance with a dominant **blue** color.
- **One push:** Press the button to **memorize** the state of the white balance depending on the type of light at the time.

6. CLEANING, DISINFECTION, STERILIZATION:

Turn off the surgical light and wait its cooling before cleaning it.



6.1.Cleaning, disinfection:

- Remove the sterilizable handles.
- **Clean** the system with a damp cloth containing surface detergent that conforms with manufacturer requirements and protocol.
- **Disinfect** the system with a damp cloth containing surface disinfectant ensuring that the correct dosage is maintained. Do not allow any liquid to be introduced into the light or in the support arm system.

The cleaning and disinfecting protocol remains to the responsibility of the health establishment, the user must follow the cleaning and disinfection protocols of his health establishment as well as the requirements and protocol of the manufacturer.

Example of recommended products:

Anios DDSH, Anios TSA, Surfa'safe, Wip'anios and Surfanios



All products containing glutaraldehyde, phenol, iodine, bleach, alcohol or chloride ions are avoided.

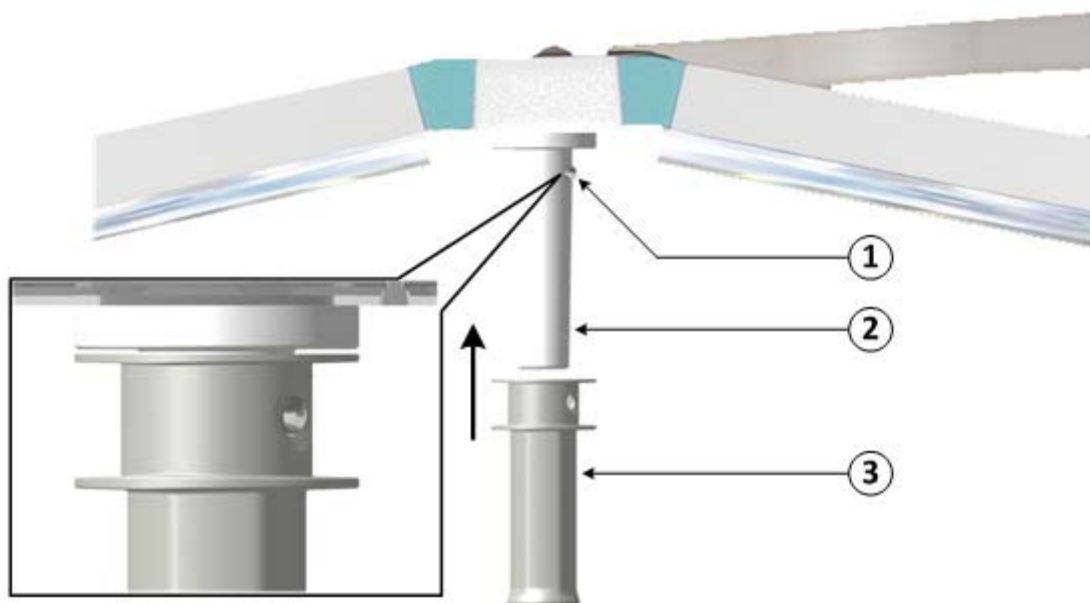


The user must employ and respect these previous products following the requirements and protocols established by the health experts of its establishment.

In case of biocompatibility doubt of a product with the lighting system, contact SURGIRIS.



It is prohibited to clean and disinfect the optical surface with products containing alcohol otherwise damage the optical surface.



- ① Stop pin
- ② Socket of sterilizable handle
- ③ Sterilizable handle

To remove **the handle ③** of its **base ②**, press **the stop pin ①** and lower the handle.

Similarly for the engagement of a new handle, push the handle upwards till the stop pin is engaged in the window handle.

Check the correct engagement of the handle by rotating the handle and by changing the height of the surgical light.



The use of the sterile handle is strictly reserved for nursing staff that completed the disinfection requirements. Any staff member who has not satisfied these requirements would compromise the aseptic conditions of the handle. This staff member must use the position handles located on each side of the module.

The sterilizable handles are made from an alloy of polymers resistant to heat and shocks.

Clean the handles before sterilization with non-chlorinated products. Rinse to remove all traces of product before the sterilization.

6.2.Sterilization:

The handles are autoclavable. The recommended settings are:

France	134°C	during 18 min
USA	132-135°C	during 10 min, 16 min of drying
Other countries	Comply with regulatory requirements of countries.	

During the autoclave loading, make sure that the open part of the handle is pointing down. The handles should not touch other items or accessories during the sterilization process.



Sterilization by hot air is prohibited.



NOTE:

The sterilizable handles are subject to natural wear.

Following the parameters of sterilization for France and the USA, sterilizable handles are guaranteed for a minimum of 350 uses.

Damaged should be not be used.

The user must comply with the requirements of the national commission responsible for sanitation and disinfection.

The cleaning and disinfecting protocol remains to the responsibility of the health establishment, the user must follow the cleaning and disinfection protocols of his health establishment as well as the requirements and protocol of the manufacturer.

7. CONTROLS AND SETTINGS:



Disconnect general power before dismounting the surgical light.

7.1.Controls:

Visual control:

- Check the condition of **the optical surface**. (before each intervention)

If it is damaged or broken, debris may fall. In this case, turn off the lights and do not use it again until it is repaired.

- **Check the operation of the surgical light.**(each morning, before the beginning of the surgical program)

Turn on the surgical light and check its good operation during the adjustment of settings. Also check the surgical lights synchronization in the same room.

Check the operation of all the LEDS.

- **Check the wear condition of sterilizable handles.**(before each intervention)

They cannot be used in case of advanced wear. (They are guaranteed for at least 350 cycles)

Mechanical control:

- **Check the arm brakes.**(every year)

The lights must be able to hold the position. In case of problem, see “arm settings” chapter.

- **Check the proper engagement of the handle.** (before each intervention)

Check the proper engagement of the handle on its socket by rotating the handle and altering the height of the light.

- **Check the operation of the control keyboard.**(before each intervention)

- **Check the proper attachment of the camera.**(before each intervention)

- **Check the proper balancing of the spring arm.** (every year)

- **Check the presence of the screw on the security ring** (every year) holding the key at the spring arm / yoke articulation (photo 1).

1



Never look directly inside the light on and avoid inserting any object reflecting the light beam: risk of glare from the high light output.



All intervention on the surgical light system is reserved for the SURGIRIS technicians or to persons competent, trained and authorized by SURGIRIS.

7.2. Arm setting of a ceiling light:

You can adjust the arms in 2 different points:

- **The balancing of the spring arm** under the extension arm / spring arm articulation, to allow the high stability of the surgical light
- **The travel in maximum height** of the lighting system on the side of the spring arm / yoke articulation, to avoid any collision with the ceiling.

7.2.1. Balancing of the spring arm:

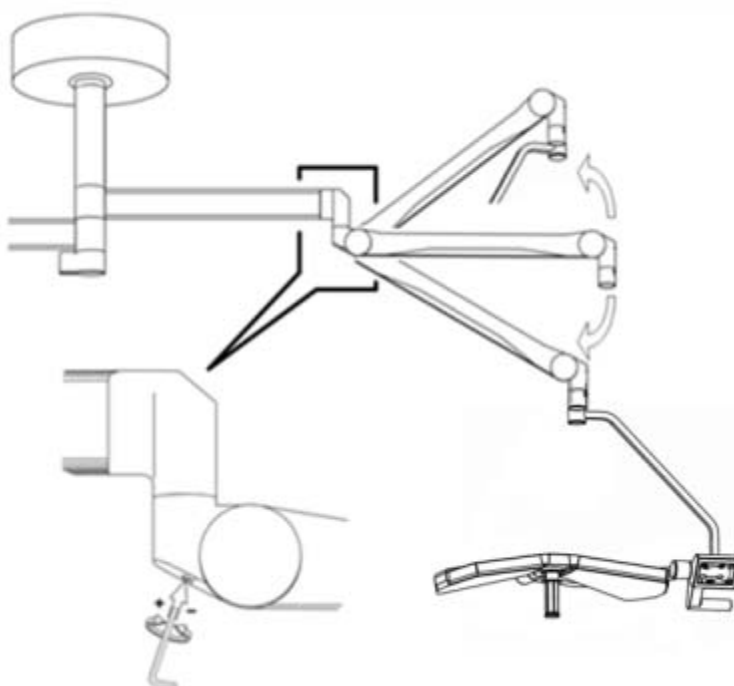


Respect the warnings. Spring system can cause injury and damage.



The settings must be realized only on **systems with surgical lights installed.**

You can adjust the balancing which will hold the light in the desired position.



If the arm goes down, the spring is too weak and you must increase its force.

- **Ease the spring arm** positioning it horizontally
- **Insert a male 6 sections key** into the slot located under the extension arm / spring arm articulation.
- Turn the key in a **clockwise direction**.
- **Check** that the arm maintains the position by gradually reducing the force exerted on it.

If the arm goes up, the spring is too strong and you must decrease its force.

- **Ease the spring arm** positioning it horizontally
- **Introduce a male 6 sections key** into the slot located under the extension arm / spring arm articulation.
- Turn the key in an **anti-clockwise direction**.
- **Check** that the arm keeps the position by reducing gradually the force exerted on it.

7.2.2. Travel in maximum height:

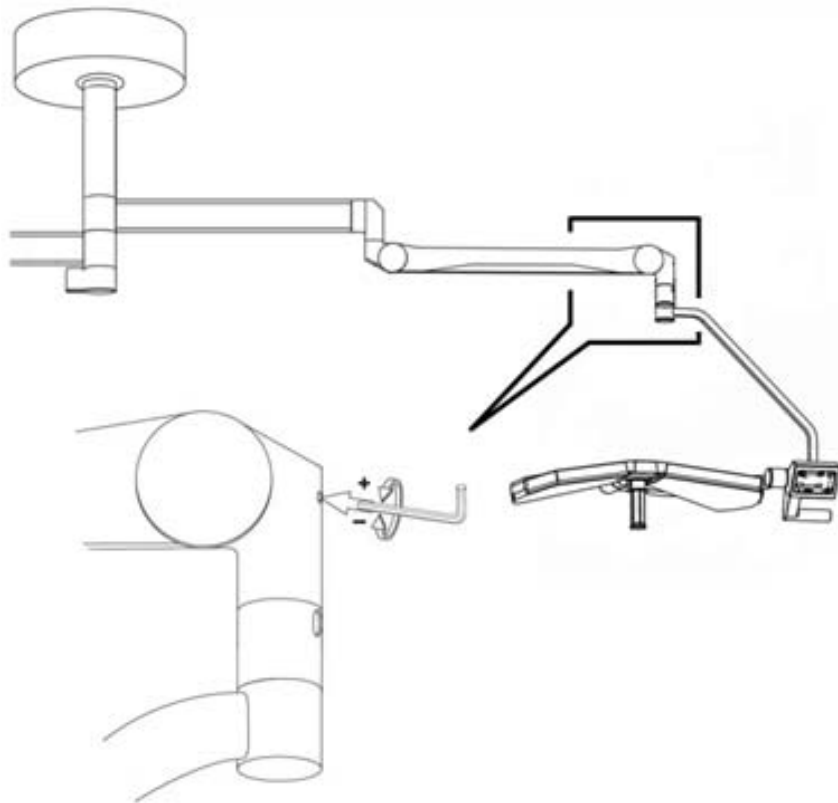


Respect the warnings. Spring system can cause injury and damage.



The settings must be adjusted only on **systems with surgical lights installed**.

You can set the travel of the light system which will limit the height of the system.



To **decrease** the height,

- **Ease the spring arm** by applying a force down with a hand and hold the horizontal position.
- **Introduce a male 6 sections key** into the slot located on the site of the spring arm / yoke articulation
- Turn the key in a **clockwise direction**.
- **Check the arm height** by reducing gradually the force exerted on it.

To **increase** the height,

- **Ease the spring arm** by applying a force down with a hand and hold the horizontal position.
- **Introduce a male 6 sections key** into the slot located on the site of the spring arm / yoke articulation
- Turn the key in an **anti-clockwise direction**.
- **Check the arm height** by reducing gradually the force exerted on it.



Improper height setting of the stop arm can cause collisions between the arm and damage the lighting system.



Any intervention on the suspension system can cause a risk of falling.



Ensure that no object suspended in space of the operating light system can collide with it. (ex: fire detector)

7.3.Front arm setting:



If you have an arm with a front fixation, you can also adjust the brake force and the stop height.

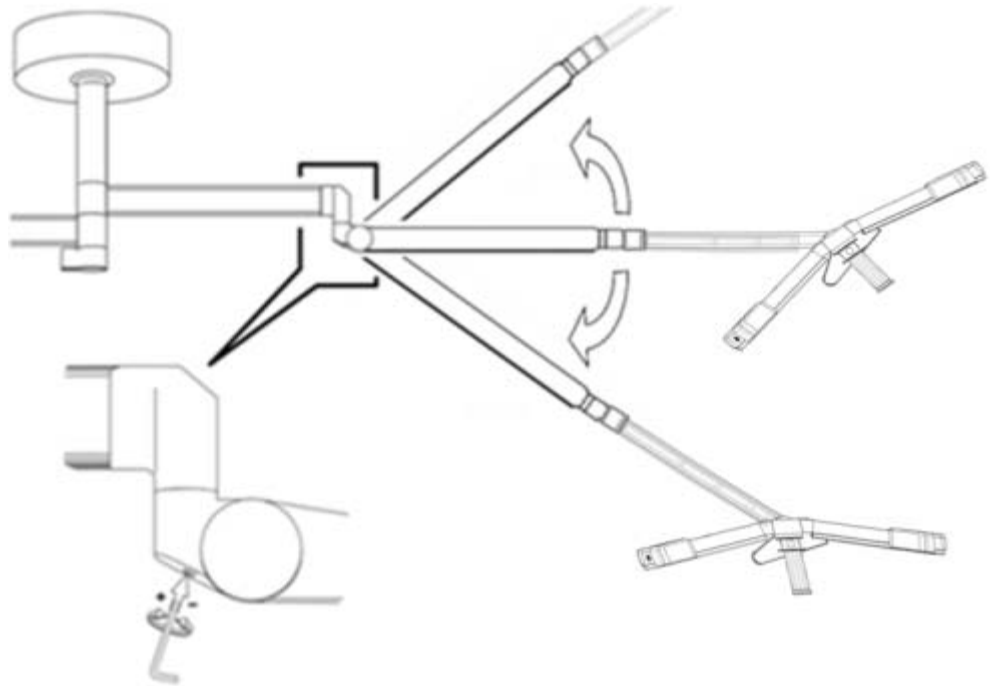
7.3.1. Balancing of the spring arm:



Respect the warnings. Spring system can cause injury and damage.



The settings must be adjusted only on **systems with surgical lights installed.**



If the arm goes down, the spring is too weak and you must increase its force.

- **Ease the spring arm** positioning it horizontally
- **Introduce a male 6 sections key** into the slot located under the extension arm / spring arm articulation.
- Turn the key in a **clockwise direction**.
- **Check** that the arm keeps the position by reducing gradually the force exerted on it.

If the arm goes up, the spring is too strong and you must decrease its force.

- **Ease the spring arm** positioning it horizontally
- **Introduce a male 6 sections key** into the slot located under the extension arm / spring arm articulation.
- Turn the key in an **anti-clockwise direction**.
- **Check** that the arm keeps the position by reducing gradually the force exerted on it.

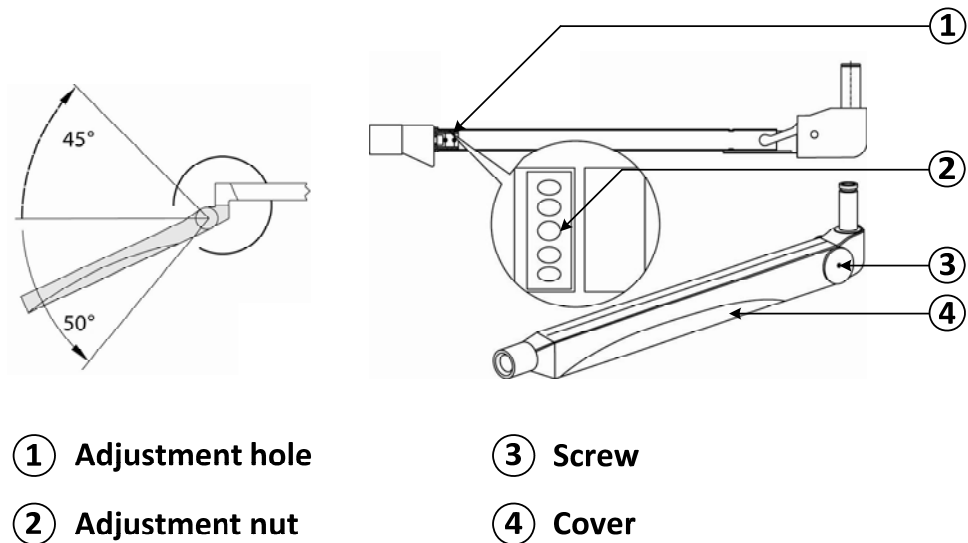
7.3.2. Travel in maximum height:



Respect the warnings. Spring system can cause injury and damage.



The settings must be adjusted only on **systems with surgical lights installed.**



① Adjustment hole

② Adjustment nut

③ Screw

④ Cover

- Remove the **screws ③** and the **cover ④**.
- **Ease** the spring arm by applying a force down with a hand until you see the **adjustment nut ②** in the **opening ①** on the side.
- To **increase** the height, place a metal rod in the **adjustment openings ①** and turn the **nut ②** down.
- To **decrease** the height, place a metal rod in the **adjustment openings ①** and turn the **nut ②** up.
- **Check** the arm height by reducing gradually the force exerted on it.



Improper height setting of the stop arm can cause collisions between the arm and damage the lighting system.





Any intervention on the suspension system can cause a risk of falling.



Ensure that no object suspended in space of the operating light system can collide with it. (ex: fire detector)


7.4.Consumable:

Photo	Description	Référence
	Sterilizable handle	POIG 0003
	Sterilizable handle for camera	POIG 0005

8. STORAGE, USING CONDITIONS AND RECYCLING:

8.1.Storage:

For a transport or a storage exceeding 15 days, you must respect this conditions.


	Temperature	-10°C to +50°C
	Humidity	10% to 75%
	Pressure	500 hPa to 1060 hPa
	Altitude	De 0 à 5574 m (Standard value at 500 hPa)

The device must be stored in a closed place and covered. Avoid frequent changes of storage places.

To avoid any condensation problems, leave the lighting system in the installation room in its closed packaging for a minimum of 2hours before removing it from the packaging.

8.2.Using condition:

Normal using conditions are:

	Temperature	+5°C to +40°C
	Humidity	30% to 75%
	Pressure	700 hPa to 1060 hPa
	Altitude	De 0 to 3013 m (Standard value at 700 hPa)

8.3.Recycling:



The X3®, X2® and X1® surgical lights must be discarded by appropriate and regular channels and according to the standards in effect in the country at the time of the disposal.

9. TECHNICAL DATA:

9.1.Surgical light

OPTICAL CHARACTERISTICS	X1	X2 ^{FIX}	X2 ^{COLOR}	X3 ^{FIX}	X3 ^{COLOR}
Light source	LED	LED		LED	
Central lighting at 1m (+/- 10%)	100.000 Lux	150.000 Lux	160.000 Lux	160.000 Lux	160.000 Lux
Color temperature in °K	4500K	4500K	3500 to 5000K	4500K	3500 to 5000K
Color rendering index	>95	>95		>95	
Lighting field diameter (d10)	15 to 20 cm	15 to 30 cm		15 to 32 cm	
Depth of constant field L1+L2	80 cm	110 cm		130 cm	
Light intensity variation	5 to 100 %	5 to 100 %		5 to 100 %	
Temperature elevation level at the surgeon head	<1 °C	<1 °C		<1 °C	

According to IEC-60601-2-41

ELECTRICAL CHARACTERISTICS					
Light source	LED	LED		LED	
LEDs lifetime	>40 000 h	>40 000 h		>40 000 h	
Electrical power at maximum lighting	42 W	90 W	120 W	110 W	160 W
Electrical supply	100 to 240 V	100 to 240 V		100 to 240 V	
Frequency	50 / 60 Hz	50 / 60 Hz		50 / 60 Hz	
Product classification	Class I	Class I		Class I	
Type	B	B		B	

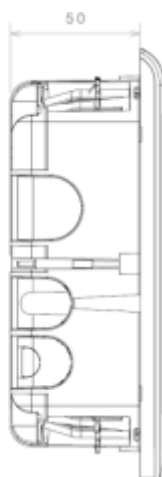
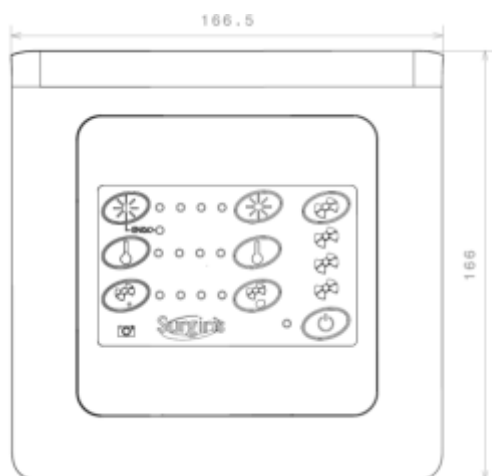
PHYSICAL CHARACTERISTICS					
Light surface emitting	660 cm ²	1400 cm ²		2100 cm ²	
Weight of the surgical light	5 kg	11 kg		15 kg	
Diameter of the surgical light	30 cm	64 cm		70 cm	
Rotation	360 °	360 °		360 °	
Vertical travel	120 cm	120 cm		120 cm	

QUALITATIVE CHARACTERISTICS					
Compliance	CE		CE		CE
	60601-1		60601-1		60601-1
	60601-2		60601-2		60601-2
	60601-2-41		60601-2-41		60601-2-41

9.2. Camera technical data (option):

	Haute résolution / High resolution	Haute définition / High definition
Capteur <i>Image sensor</i>	CCD 3/4	CMOS 1/3"
Nombre de pixels <i>Effective number of pixels</i>	440 000 pixels	2 000 000 pixels
Format <i>Aspect ratio</i>	4:3	16:9
Standard vidéo <i>Signal system</i>	PAL	1080i
Résolution <i>Resolution</i>	530 TV Lignes	N/A
Objectif <i>Lens</i>	36x (zoom optique) et 12x (zoom numérique) 36x (optical zoom) and 12x (digital zoom)	10x (zoom optique) et 12x (zoom numérique) 10x (optical zoom) and 12x (digital zoom)
Focale <i>Focal</i>	f=3,4 mm à 122,4 mm f=3,4 mm to 122,4 mm	f=5,1 mm to 51,0 mm f=5,1 mm à 51,0 mm
Ouverture <i>Opening</i>	F 1,6 à F 4,5 F 1,6 to F 4,5	F 1,8 à F 2,1 F 1,8 to F 2,1
Focalisation automatique <i>Automatic focal</i>	Auto/Manuel Auto/Manual	Intégré Integrated
Sensibilité <i>Sensibility</i>	1,4 lux (F 1,6 50IRE)	1 lux (F 1,8 50IRE)
Balance des blancs <i>White balance</i>	Auto/Manuel Auto/Manual	Auto/Manuel Auto/Manual
Distance mini. de mise au point <i>Minimum object distance</i>	320 (grand angle) à 1500mm (télé) 320 (wide) to 1500mm (tele)	10 (grand angle) à 800 mm (télé) 10 (wide) to 800 mm (tele)
Signal/Bruit <i>Signal/Noise ratio</i>	>50 dB	>50 dB
Sortie <i>Output connection</i>	2 BNC Composite 1 S-VHS 1 SDI - sortie numérique	1 Y/Pb/Pr 1 DVI 1 SDI - sortie numérique
Boîtier de contrôle <i>Control box</i>	Mobile en WCT (sans fil) Mobil with wireless WCT	Mobile en WCT (sans fil) Mobil with wireless WCT

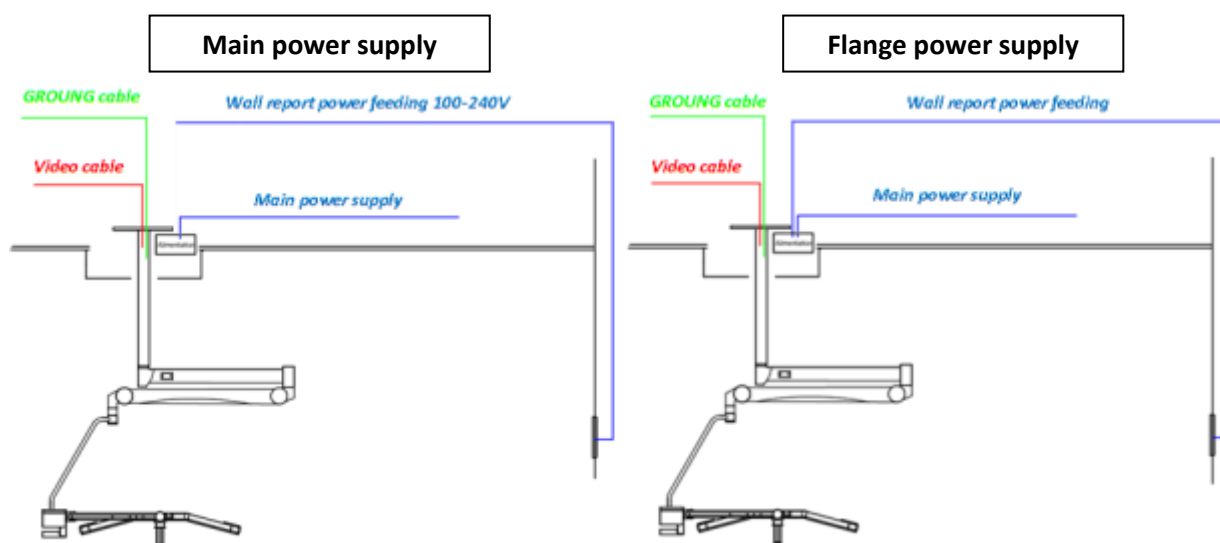
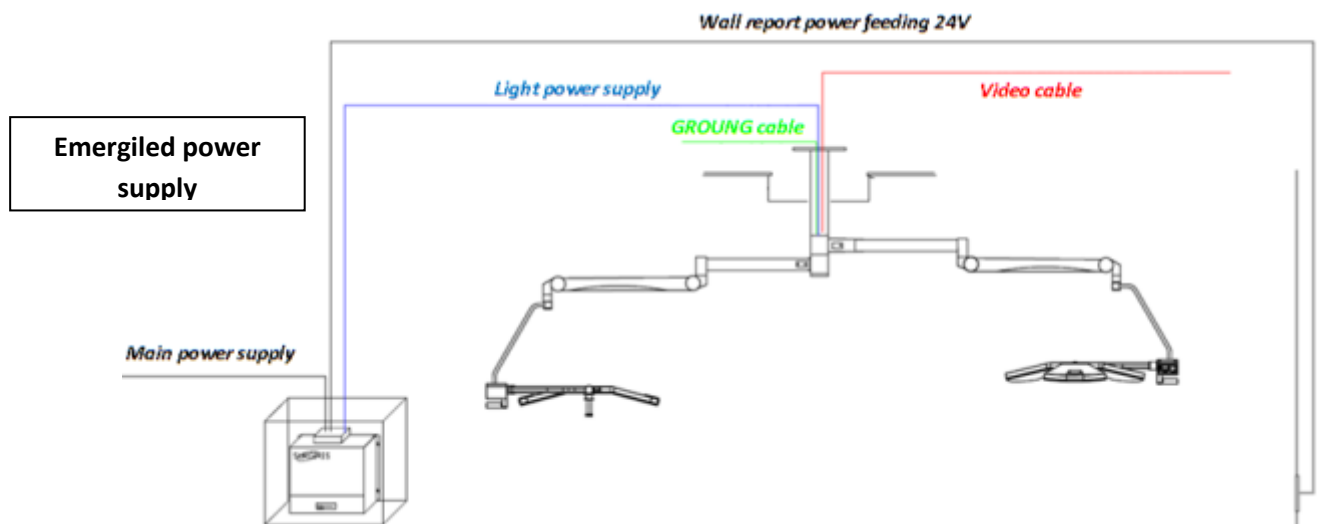
9.3.Wall report (option):



Power supply 100-240V AC, 50/60Hz (by the general power supply).

Or

Power supply 27,3V DC, 45 mA (by the Emergiled or the power supply flange).



9.4. Emergiled emergency power supply (option):



Any parts can be removed or modified. It is important to respect the part characteristics communicated by Surgiris.



No replacement parts outside of parts proposed by Surgiris can be made.

SPECIFICATIONS	EMERGELED MONO 1h	EMERGELED MONO 2h	EMERGELED DUO 1h	EMERGELED MONO 2h
Power	100-240V AC 50/60Hz	100-240V AC 50/60Hz	100-240V AC 50/60Hz	100-240V AC 50/60Hz
Output voltage	27,3V DC	27,3V DC	27,3V DC	27,3V DC
Using temperature	0°C to +40°C	0°C to +40°C	0°C to +40°C	0°C to +40°C
Storage temperature	-10°C to +60 °C	-10°C to +60 °C	-10°C to +60 °C	-10°C to +60 °C
Maximum weight	30 kg	33 kg	36 kg	39 kg
Reservation (in mm)	H : 900, L : 700, P : 250	H : 900, L : 700, P : 250	H : 900, L : 700, P : 250	H : 900, L : 700, P : 250

Battery: 12V, 7,5A

L x l x h (in mm) : 151 x 65 x 97,5

2,65 kg

Reference: SAV-LED-0009 (lot of 2)

Replacement suggested every 5 years

Reference: SAV-LED-0055

Cylindrical type gG HPC 500V 20A,
10x38mm (Emergiled 2h)

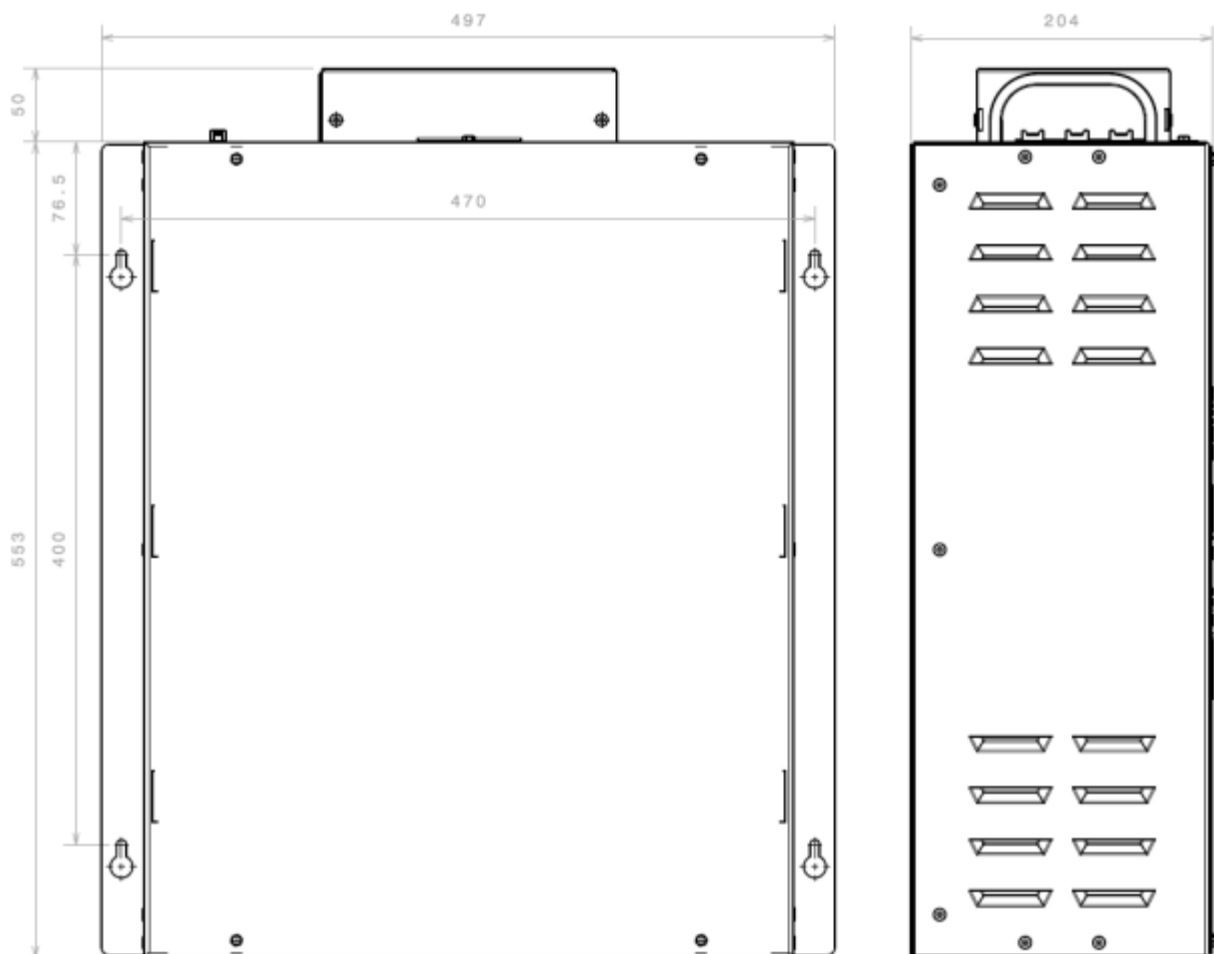
Reference: SAV-LED-0056

Fuse: Cylindrical type gG HPC 500V 16A, 10x38mm
(Emergiled 1h)

The voltage presence 100-240V is indicated by the red light on the front face of the Emergiled. The LED turned on indicates that the lights assigned to the emergency block are fed and protected in case of general power failure.

In case of a general power failure, the Emergiled auto switches the power light on the battery.

Circuit breaker type upstream of the Emergiled	10 A, Magnetothermic
Section of power cable 100-240V	3G 2,5 mm ²
Section of power cables light 27.3 V (<15m)	5G 6 mm ²
Section of power cables light 27.3 V (_ 15m to 30m)	5G 10 mm ²
Section of wall power cables carry 27.3 V	5G 1,5 mm ²
Heat dissipation	120 W/h
Local technical ventilation	Naturally ventilated



Two tests per year must be performed to ensure the safety operation of the emergency block:

- Check battery switching. Cut power of emergency block via its circuit breaker and verify that the light assigned to the block emergency lights correctly.
- Check the battery life. Cut power of emergency block via its circuit breaker and measure the time of illumination provided by the batteries.

10. INTERFERANCES ELECTROMAGNETIQUES :

The X1-X2-X3 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled as specified in the following pages. The customer or the user of the X1-X2-X3 should assure that it is used in such an environment and can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X1-X2-X3 as recommended below, according to the maximum output power of the communications equipment.

Table 201 –electromagnetic emissions –

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The X1-X2-X3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The X1-X2-X3 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonic emissions	Not applicable	
IEC 61000-3-3 Voltage fluctuations/ flicker emissions	Not applicable	

Table 202 - electromagnetic immunity

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	≥6 kV contact ≥8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	≥2 kV Non applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	≥1 kV ≥2 kV	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	0V / 10 ms 48V / 100ms 84 V/ 500ms 0V/ 5000ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X1-X2-X3 requires continued operation during power mains interruptions, it is recommended that the X1-X2-X3 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

Table 204 –electromagnetic immunity


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz outside ISM bands^a</p> <p>10 V/m 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the X1-X2-X3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a)Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the X1-X2-X3 is used exceeds the applicable RF compliance level above, the X1-X2-X3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the X1-X2-X3.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the X1-X2-X3

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{F_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.04	0.06	0.12
0.1	0.11	0.18	0.37
1	0.35	0.58	1.17
10	1.11	1.84	3.69
100	3.50	5.83	11.67

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11. FAILURES CHART:

Problem	Probable cause(s)	Action(s) to conduct	Chapter
The light does not turn on	Electric network problem	Check the electrical supply and the fuses	6.3.1.
	Control problem	Call the SURGIRIS technical service	6.3.1.
The light does not turn off	Control problem	Call the SURGIRIS technical service	6.3.1.
The "ENDO" mode does not turn on	Utilization problem	See "Light setting" chapter	6.3.3.
	Control problem	Call the SURGIRIS technical service	6.3.3.
The wall report does not work	Identification problem of the light	See "Light setting" chapter	6.3.7.
	Communication problem of the wall report with the lights	Call the SURGIRIS technical service	6.3.7.
Some LEDs do not light on	Normal working of the light	Some LEDs do not work depending on the light settings	6.3.2.
		Vary the settings to check their good working	6.3.2.
	Working problem of the LEDs	If the number of damaged LEDs is low, you can use the device normally thanks to compensation system with the other LEDs	6.3.2.
		If the number of damaged LEDs is important, call the SURGIRIS technical service	6.3.2.
The light system does not hold the position	Arm overloaded	Left in suspension, only the devices installed by SURGIRIS	8.1
	Setting problem of the arm brakes	Set the brake like in the "Brake setting" chapter	8.2.1. / 8.3.1.
	Fixing problem of the arms to the roof or roof problem	Call the SURGIRIS technical service	8.2.1. / 8.3.1.
The sterile handle does not break away from its base	Utilization problem	See "Cleaning, Disinfection and Maintenance" chapter	7.1.
	Mechanism problem	Check the mechanism of it	7.1.
		Change the handle	7.1.
The sterile handle does not fit on its base	Utilization problem	See "Cleaning, Disinfection and Maintenance" chapter	7.1.
	Mechanism problem	Check the mechanism of it	7.1.
		Change the handle	7.1.
	Problem of the sterilization temperature and/or wear	See "Cleaning and disinfection" chapter to know the sterilization temperatures recommended	7.1. / 7.2.

11. FAILURE CHART

GB

		See "Cleaning, Disinfection and Maintenance" chapter to know the sterilization temperature recommended	7.1.
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12. COMPLIANCE CERTIFICATE:

**COMPLIANCE DECLARATION**

(Annexe VII de la Directive 93/42/CEE)

I undersign , Denis Papin, Industrial Manager, whose headquarter is located at SURGIRIS, 80 rue de la Gare 59170 Croix, FRANCE declares on my own responsibility that :

**Surgical and diagnostic LED Light series: KALEA20,
KALEA30, KALEA40, X2, X1, DIASYS and their
accessories**

are in conformity and comply to the essential requirement of European Medical Device Directive 93/42/CEE, Appendix VII, as well as technical and safety standards required in this matter:

These Devices are a Class I medical, device as defined by the European Medical Device Directive 93/42/CEE, Appendix IX

I undertake to apply all evolutions of the essential requirements and standards applicable on these devices.

Done at: Croix: le 05/01/2011

S.A.S. SURGIRIS
80, rue de la Gare
59170 CROIX
Tél. 03 20 16 07 93
Fax 03 20 95 40 19
SIRET 437 760 812 00036
TVA / VAT : FR 30 437 760 812

13. WARRANTY:

SURGIRIS guarantees the equipment against component or manufacture faults for 18 months from the date of receipt and no later than 24 months after delivery to contract terms.

The warranty covers only new supplies that are manufactured by SURGIRIS. It is limited to replacement parts recognized to be defective. The cost of labor, accommodation, travel and insurance of the personnel performing the parts replacement are all charged to the customer.

All parts replaced will become the property of SURGIRIS and must be returned to it within one month after its replacement, otherwise SURGIRIS reserves the right to charge the value of the replaced part to the customer.

The interventions done under warranty do not extend the original warranty period.

This warranty does not apply to normal wear parts and consumables.

To profit by the warranty, the buyer must notify by letter or telex confirmed by letter, of any defects within 3 days at the latest after its establishment.

The buyer must submit to SURGIRIS all evidence demonstrating that the failure lies with SURGIRIS and give all easiness to SURGIRIS to proceed to their establishments.

SURGIRIS advises the purchase of spare parts that may have to be fitted to the unit.

SURGIRIS can use existing spare parts from the purchaser subject to replace it.

The warranty ceases if the supplies have been modified or repaired made by the buyers or any third party without the prior written consent of SURGIRIS.

This warranty excludes any compensation payment. The engagements of that warranty are personal to the buyer and cease as soon as it sells.

The warranty does not cover:

- The incidents relating to fortuitous or force majeure events described in article XI,
- The repairs or replacements required by normal wear of the equipment,
- The damages or accidents proceeding from the purchaser fact such as negligence, lack of supervision, error

Note:

The repairs or settings must be made by SURGIRIS or his authorized representative. In case of one of the SURGIRIS representative is in charge of repairs, the user must obtain a detailed report of the agent explaining the repairs effected. This report must include the technical data concerning the repairs and be signed by the certified company and the user. When the repairs are not made by SURGIRIS, the modified parts must be reported on behalf of the repair company.