USER MANUAL - EN

MAQUET
GETINGE GROUP

X'Ten™

SURGICAL WORKPLACES

Subject to technical changes.

The illustrations and technical specifications provided in this manual may, on account of future product developments, differ slightly from the actual product supplied.

31 October 2012 | Ed3A

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QUALITY STANDARDS COMPLIANCE

CERTIFICATION OF MAQUET SAS'S QUALITY SYSTEM

LNE/G-MED certifies that the quality system developed by MAQUET SAS for design, implementation, sales, installation and after-sales service of surgical lights complies with the requirements of the following international standards:

- ISO 9001:2000
- ISO 13485:2004

CE MARKING

Compliance with the requirements of European Directive 93/42/EEC dated 14 June 1993 relating to medical devices was assessed as described in Annex VII of the Directive. X'TEN surgical lights belong to Class I as described in Annex IX of Directive 93/42/EEC.

WARNINGS

WARNING

Changes or modifications not expressly approved by MAQUET SAS could void the user's authority to operate the equipment.

WARNING

Light is a form of energy that can dry out tissue, particularly if light beams from more than one lighthead are superimposed. Users must be vigilant and set appropriate illumination levels for each operation and patient, in particular for long operations.

WARNING

Light is a form of energy that, on account of certain wavelengths emitted, may not be suitable for certain pathologies.

WARNING

The surgical light is a high-intensity light source. Do not look directly into it.

WARNING

Do not use the device in the presence of flammable anaesthetic gases.

WARNING

Do not use in an MRI environment.

WARNING

Check that the sterilisable/disposable handle is compatible with the product.

WARNING

Before reusing the handle after it has been sterilised, always:

- Check for cracks.
- Check that the handle clicks into place correctly in the surgical light.

WARNING

To avoid all risks of asepsis, never touch the control keypad on the fork during a surgical procedure unless it is protected by a single-use cover.

WARNING

To avoid all risk of asepsis, only the medical team may touch the sterilisable handle during procedures.

WARNING

Do not store objects on the wall power supply units.

WARNING

- Solutions containing glutaraldehyde, phenol, iodine, bleach, alcohol or chloride ions must not be used.
- Fumigation methods are unsuitable for disinfecting the unit and must not be used.

WARNING

In the event of a power cut, only lightheads connected to a backup power supply will remain on.

WARNING

The unit is designed to operate with the cover closed. When conducting maintenance, take precautions to avoid touching surfaces marked as hot with the appropriate symbol.

WARNING

The operation and safety of the device may be affected by the removal of certain components during servicing operations. For example:

- When servicing the electrical power supply.
- When servicing the suspension arms and balance system.

Contact the authorised MAQUET after-sales service department for this type of inspection.

AVERTISSEMENT

Contact between patient and non sterile parts of a device is forbidden.

WARNING

To avoid any risk of an electric shock, class I devices must be connected to a power supply system which is earthed.

SYMBOLS USED IN THIS MANUAL

Symbols	Meaning
	**Mandatory** May affect patient or user safety
	**Recommendation** Risk of damage to device or accessories
	**CE label** The device complies with the requirements of European directive 93/42/EEC relating to medical devices.
	**Medical Equipment** Classified with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, IEC 60601-2-41 and CSA C22.2 No. 601-M90.

SYMBOLS USED ON THE PRODUCT

Symbols	Meaning
	**Caution** Follow the instructions for use
	**R**ead the documents supplied with unit carefully
	Manufacturer
~	Alternating current
⎓	Direct current
REF. SN.	Product technical description and serial numbers.
	Comply with the applicable handling precautions for products that are sensitive to electrostatic discharges.
$23.5V_{RMS}$ (V^{RMS}_{AC+DC})	Rectified true RMS voltage on bulb terminals
	Metal housing protection class Class 1B device
	Use black lamp holders only
	Hot surface
	**Medical Equipment** Classified with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, IEC 60601-2-41 and CSA C22.2 No. 601-M90.
	**CE label** The device complies with the requirements of European directive 93/42/EEC relating to medical devices.
	Do not dispose of this device as unsorted municipal waste. Take it to a collection facility for value enhancement, recycling or re-use.

1 INTRODUCTION

1.1 INTENDED USE

- The X'TEN range is designed for use in medical applications to illuminate patients' bodies during operations, diagnosis or treatment.
- The X'TEN range consists of single-arm, dual-arm or triple-arm ceiling-mounted lights with single or double forks. Some models are equipped with LED ambient lighting and are prewired for video.

1.2 SPECIAL FEATURES

- Excellent shadow dilution
- Wide range of movement
- Compatible with laminar flows
- Incredible volume of light
- LEDs for ambient light
- Upgraded multimedia

1.3 INAPPROPRIATE USE

- The unit is intended only for use as mentioned in the user manual and is suitable only for such use. Any other use may result in danger to users and/or damage to the device or its environment.
- For safety reasons, do not alter or adapt the device in any way without MAQUET SAS's approval.

1.4 INTENDED USERS

- The device may be operated only by trained medical staff.
- The device must be cleaned by specialised personnel.

1.5 INTENDED EQUIPMENT

The models named in this document may be equipped with other manufacturers' end appliances (e.g. flat screens). For information on operating them, please refer to each manufacturer's user manuals.

1.6 ENVIRONMENTAL REQUIREMENTS

TRANSPORT AND STORAGE

- Ambient temperature: -10°C to 60°C
- Relative humidity: 20-75%
- Atmospheric pressure: 500 to 1060 hPa

OPERATION

- Ambient temperature: 10°C to 40°C
- Relative humidity: 20-75%
- Atmospheric pressure: 700 to 1060 hPa
- The X'TEN system must be installed and commissioned in accordance with the EMC information provided in chapter 10.
- Portable and mobile RF communication devices may affect the correct operation of this equipment.

1.7 MAINTENANCE

MAQUET SAS's warranty and the safety and integrity of the operation of the product are guaranteed only if:

- All inspection, maintenance and repair operations are performed by a MAQUET engineer or a trained and authorised technical support technician.
- Only original accessories, consumables and spare parts are used.
- Maintenance operations and checks are performed and documented at least once a year as specified by the preventive maintenance programme.

1.8 USER MANUAL

- This user manual is an integral component of the equipment.
- It must be kept near the equipment for future reference.
- It must be read in full before attempting to use the equipment.

1.9 FCC PART 15

(USA only) This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at personal expense.

1.10 MANUFACTURED BY

MAQUET SAS
Parc de Limère
Avenue de la Pomme de Pin
CS 10008 ARDON
45074 ORLÉANS CEDEX 2
FRANCE
Telephone: +33 (0) 2 38 25 88 88
Fax: +33 (0) 2 38 25 88 00
www.maquet.com

2 DESCRIPTION

2.1 EXAMPLE OF DOUBLE CONFIGURATION

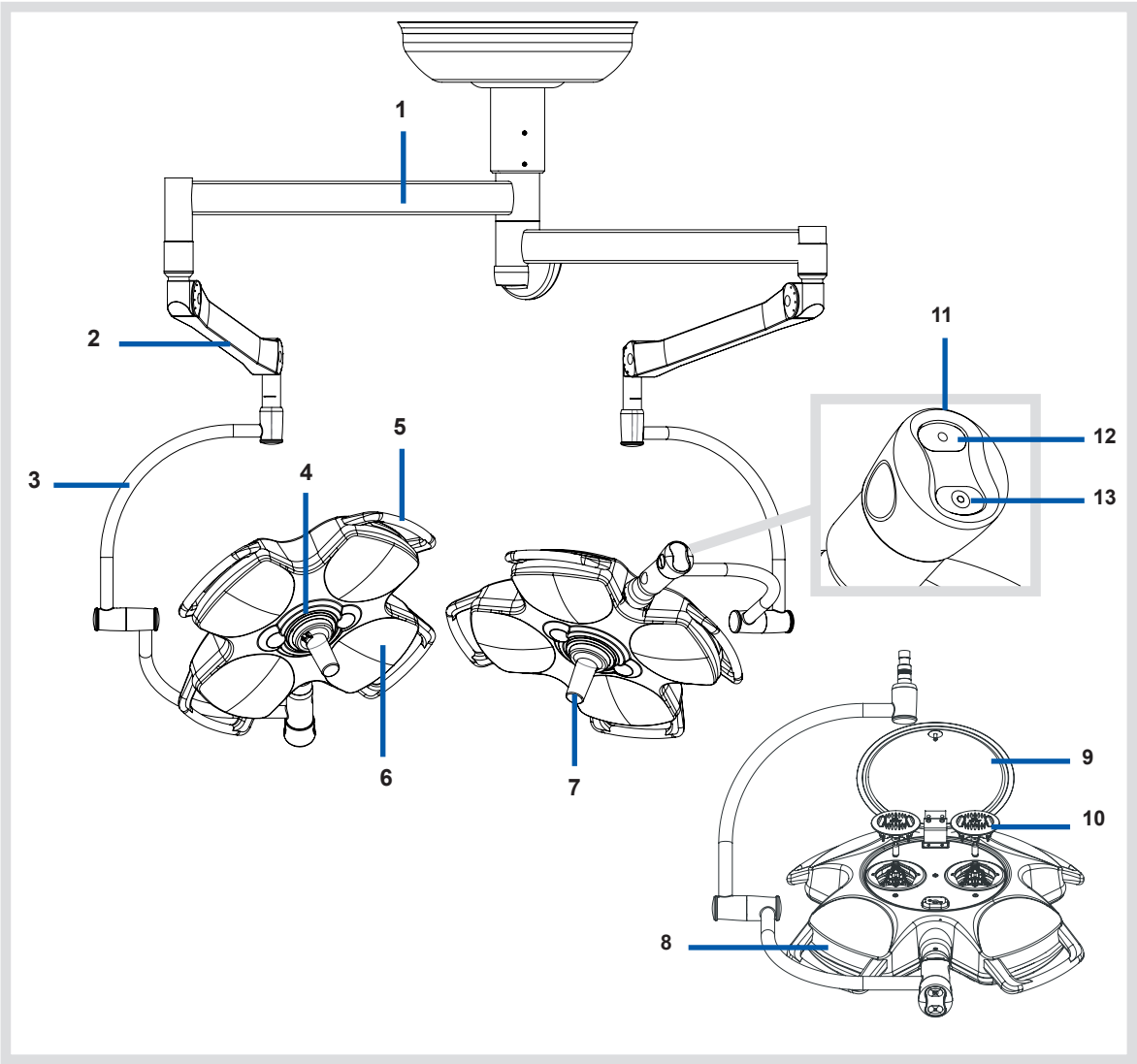


Figure 1

1	Main arm
2	Spring arm
3	Double fork
4	Ambient light: ring of LEDs
5	Side positioning handle
6	Underside
7	Sterilisable handle
8	Shell
9	Cover
10	Lamp holder
11	Keypad
12	Surgical light button
13	Ambient light button

2.2 VERSIONS AVAILABLE

Standard version	Simple surgical light		
LED Version	Surgical light	+ Ambient light	
Video version	Surgical light	+ Ambient light	+ Video prewiring

MAIN LIGHTING

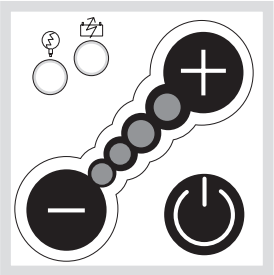
- for performing surgical procedures under the best conditions.

AMBIENT LIGHTING

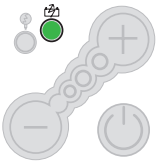
- for easy viewing of and around operating fields.

3 USE

3.1 ENERGIX WPS POWER SUPPLY UNIT

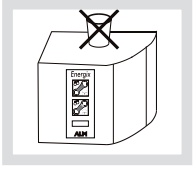


The light is turned on and off via the ENERGIX WPS power supply units.

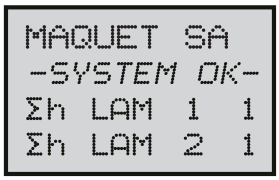
	On/Off button	■ Turns lighthead on and off with a single press. ■ Lighthead lights up gradually to the last intensity value stored in its memory. ■ Factory set to 100% illumination.
	LED off	■ Power supply off
	Green LED	■ Power supply on
	Red LED	■ Backup power supply on (WPS XX1 only)
	Illumination adjustment	■ To change levels, press once or press and hold. ■ 8 illumination levels (2 per LED)
	Flashing yellow LED	■ Bulb failure or ■ Ambient light

WARNING

Do not store objects on the wall power supply units.

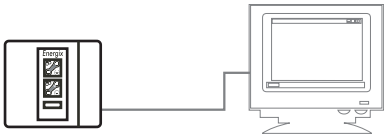


3.2 OPTIONAL LCD



The LCD is used to:
- Check the service life of consumables (bulbs, bulb holder, batteries),
- Perform routine tests (backup tests),
- Troubleshoot malfunctions.

3.3 OPTIONAL CONTROL VIA A REMOTE PC

	■ Light turned on via the ENERGIX unit	■ Link not operational ■ Settings are adjusted via the ENERGIX unit
	■ Light turned on via the PC	■ Operational link ■ Settings are adjusted via the PC ⚠ The link will be cut if adjustments are made via the ENERGIX unit.

3.4 OPTIONAL AMBIENT LIGHT

Use the keypad on the lighthead fork to toggle between lighting modes.

	■ **Press the button once** to switch off the surgical light and turn on the ambient light. ■ To increase the illumination, press the button again (4 illumination levels: 50 lx, 90 lx, 140 lx, 210 lx ± 10%).
	■ Flashing yellow LED = ambient light on.
	■ Press to switch off the ambient light and turn on the surgical light.

Note: Lighting differences may occur in low-intensity ambient lighting mode (LEDinside™).

3.5 OPTIONAL BACKUP POWER SUPPLY

WARNING

In the event of a power cut, only lightheads connected to a backup power supply will remain on.

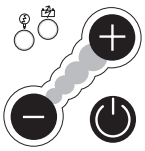
- The power supplies may be optionally equipped for use with your operating room's 24 V backup power supply.
- If the mains supply is restored after being cut, the light turns on in surgical light mode.

	Red LED	Backup power supply on (WPS XX1 only)

BATTERY BACKUP TEST (DAILY CHECK)

	■ Turn on the lighthead. ■ Press and hold the On/Off button for 3 seconds.
	■ The backup batteries take over. ■ The LED turns from green to red. ■ The lighthead automatically switches back to the mains supply 3 seconds later.

BATTERY CAPACITY TEST (MONTHLY CHECK)

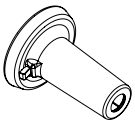
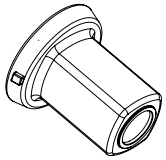
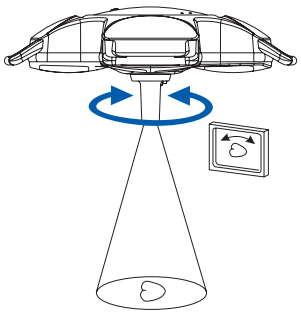
	■ Press and hold the «+», «-» buttons and the On/Off button for 2 seconds.
	■ The backup batteries take over. ■ Allow the batteries to discharge (one hour per lighthead).
BATTERY GOOD	■ Battery charge sufficient.
BATTERY BAD	■ Replace the batteries.
	■ Press the On/Off button to interrupt the test or to switch back to the mains supply.

3.6 OPTIONAL VIDEO CAMERA

The lighthead prewired for video can be used with:
- a PRV-ZOOM camera or
- a PRV-CFF camera (versions 4 and higher).

For information on the camera's features, refer to the Prismavision camera user manual.

USE

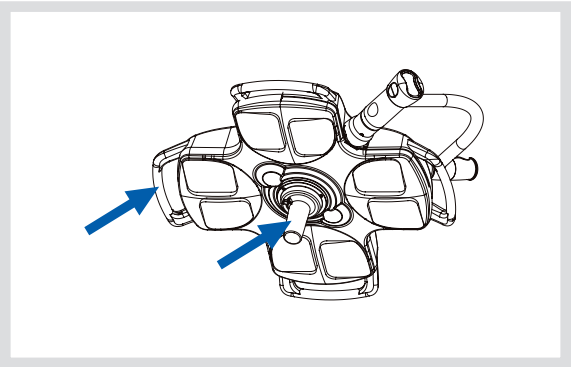
	■ The camera turns on when the lighthead is switched on.
 *PRV-CFF camera*	■ A sterilisable handle with viewing window is required to use the camera.
 *PRV-ZOOM camera*	
	■ The image on the screen rotates when the handle is turned. This allows the operator/observer to adjust the image so that it is positioned correctly.

Note: the light volume can no longer be adjusted if a camera is fitted on the lighthead. It is therefore recommended to adjust the volume before fitting a camera.

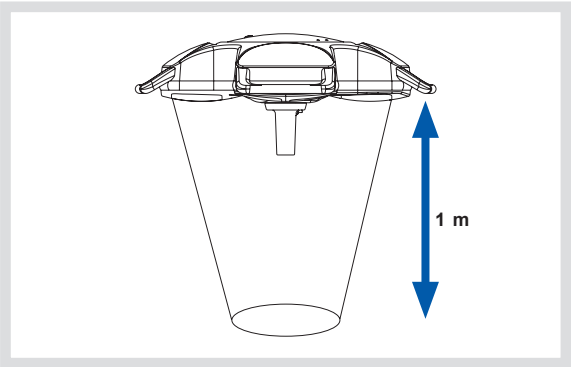
4 POSITIONING

4.1 MOVING THE LIGHTHEAD

- The light should be positioned prior to any procedures to avoid having to move it more than necessary later on. Correctly positioning the light for each operation will limit the chances of it coming into contact with other objects (IV pole, pendant, etc.).

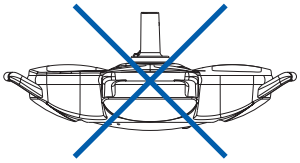


- Use the removable handle at the centre or the handle on the side to position the lighthead.



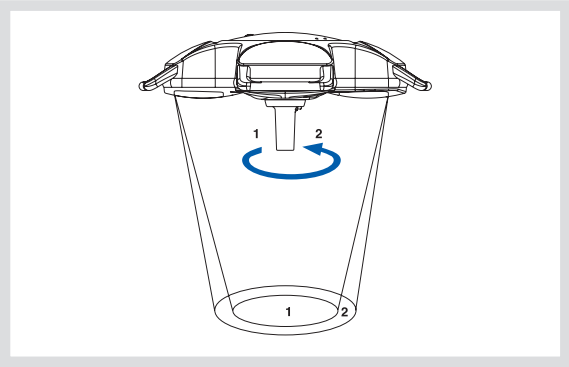
- Recommended distance between the underside and the operating field: 1 m.

RECOMMENDATION



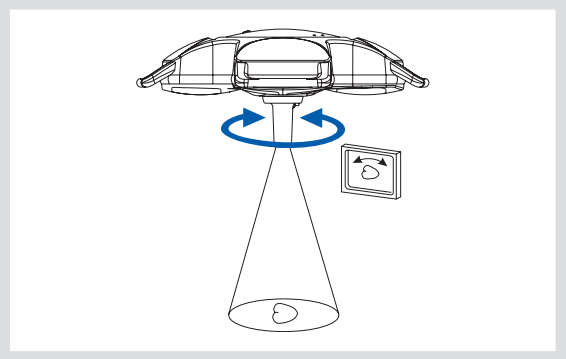
Do not direct the lighthead towards the ceiling while the light is on. Doing so could damage certain internal parts.

LIGHTHEAD WITHOUT CAMERA



- Turn the handle to adjust the light volume to the needs of the procedure. The range of the adjustment is limited by stops.

LIGHTHEAD WITH CAMERA



- The image on the screen rotates when the handle is turned. This allows the operator/ observer to adjust the image so that it is positioned correctly.

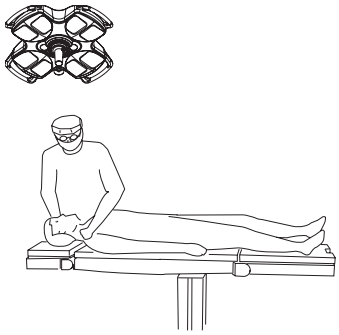
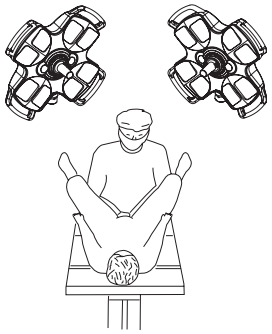
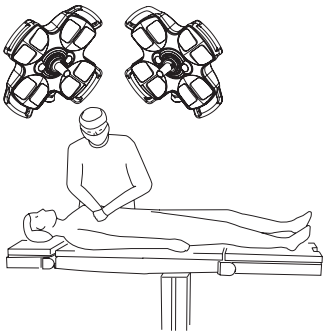
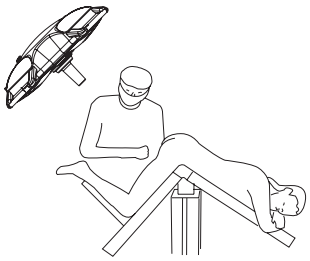
WARNING

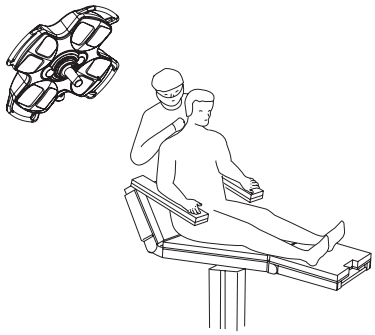
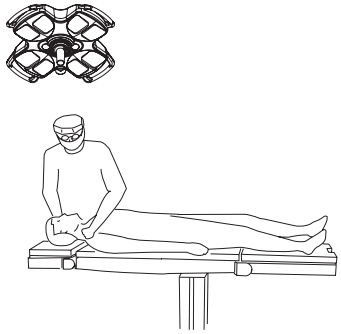
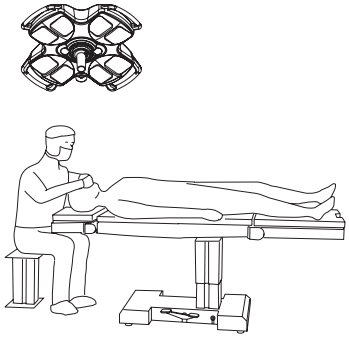
To avoid all risk of asepsis, only the medical team may touch the sterilisable handle during procedures.

RECOMMENDATION

- Do not use the light suspension system to carry or raise objects.
- Do not hang from the light.

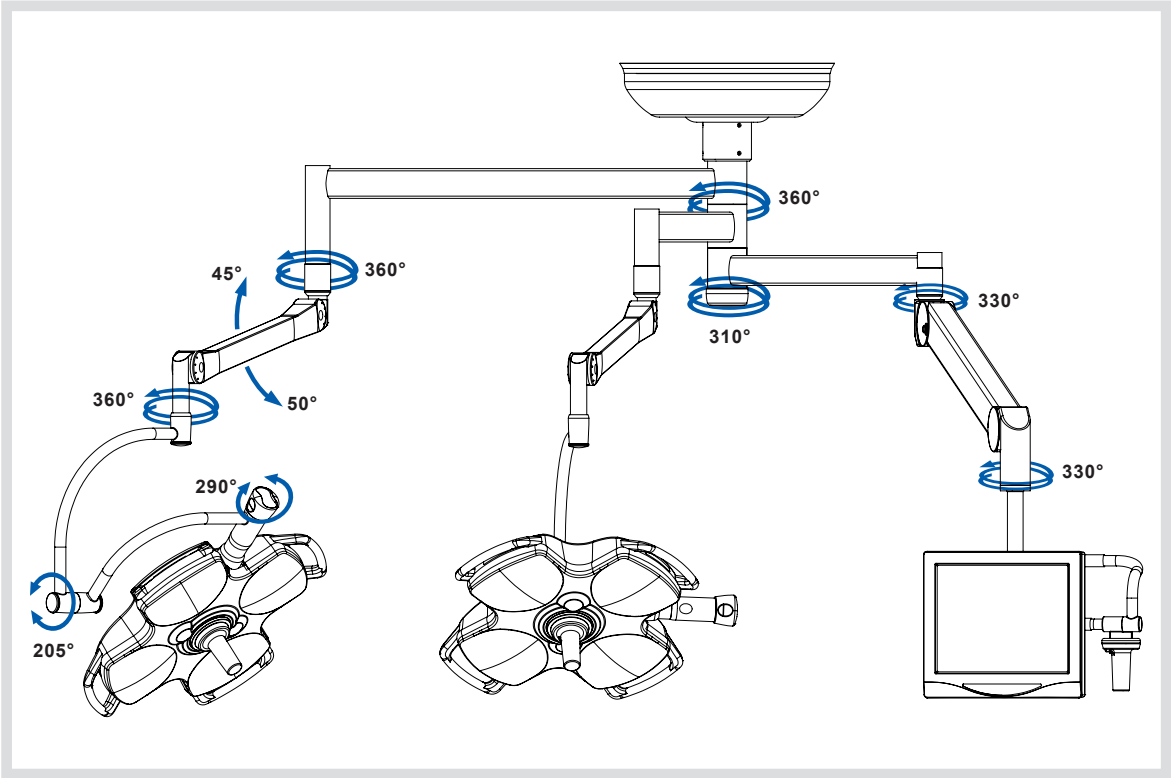
4.2 PRE-POSITIONING EXAMPLES BY SPECIALITY

Pre-positioning examples	Surgical specialities
 *Figure 1*	General surgery
 *Figure 2*	Urology, organ transplants, gynaecology, delivery
 *Figure 3*	General surgery, abdominal surgery, digestive surgery, thoracic surgery
 *Figure 4*	Proctology

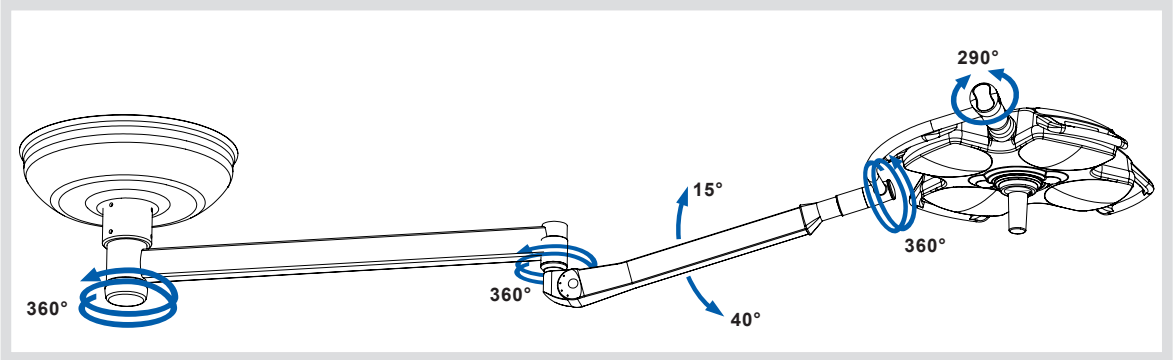
Pre-positioning examples	Surgical specialities
 *Figure 5*	Neurosurgery
 *Figure 6*	Plastic and reconstructive surgery, face transplants, oral and maxillofacial surgery
 *Figure 7*	Otolaryngology, ophthalmology, dermatology

Note: The positions illustrated are given for guidance only. Each operator will choose the correct position of the light for his/her work habits.

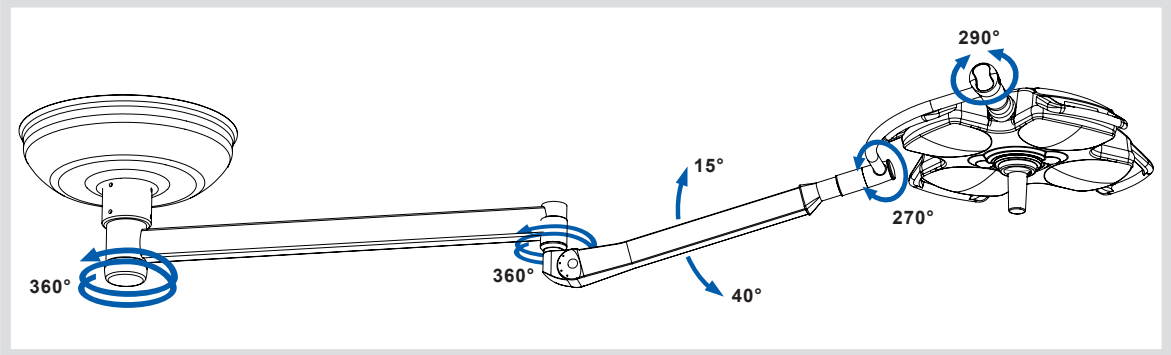
4.3 DEGREES OF ROTATION



Double fork version



Single fork version



Single fork video version

4.4 FITTING THE STERILISABLE HANDLE

WARNING

Check that the sterilisable/disposable handle is compatible with the product.

Before reusing the handle after it has been sterilised, always:
- Check for cracks.
- Check that the handle clicks into place correctly in the surgical light.

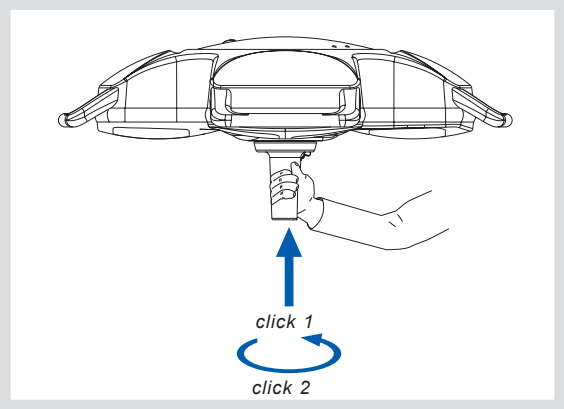


Figure 1

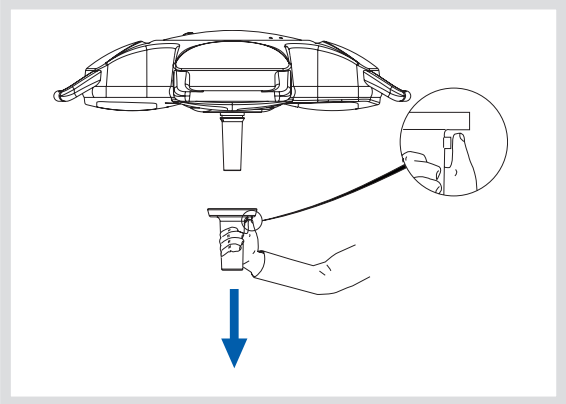


Figure 2

Fitting the sterilisable handle
- Insert the handle into the mount until it clicks into place.
- Turn the handle until it locks into place with a second click.

Removing the sterilisable handle
- Press down on the push button while removing the handle.

4.5 FITTING THE SINGLE-USE STERILE HANDLE (DEVON OR DEROYAL)

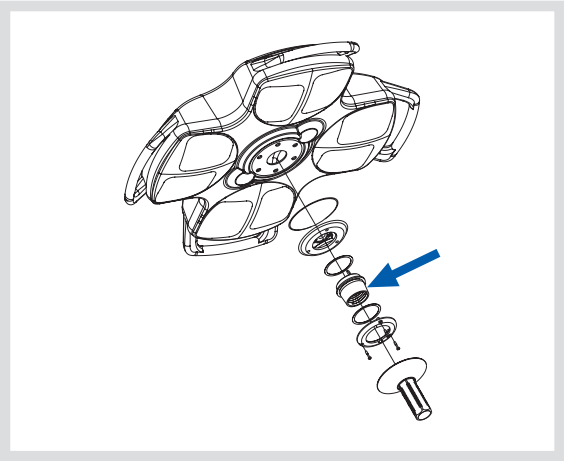


Figure 3

- If you want to use Devon® and Deroyal® brand single-use sterile handles, you must first remove the handle mount and replace it with a special adapter (see table on page 29).

5 CLEANING / DISINFECTION / STERILISATION

Users must contact their hospital's sanitary specialists. The recommended products and procedures must be applied. Should there be any doubt concerning the compatibility of active agents to be used, contact the local MAQUET customer service department.

5.1 CLEANING AND DISINFECTING THE SURGICAL LIGHT

RECOMMENDATION

Check that the power is switched off and the light has cooled down before starting cleaning.

GENERAL INSTRUCTIONS CONCERNING CLEANING, DISINFECTION AND SAFETY

- Remove the sterilisable handles.
- Wipe the equipment with a cloth moistened with a surface cleaner. Follow the manufacturer's dilution, application time, and temperature recommendations.
- Rinse the unit with a cloth and clean water. Wipe dry.
- Wipe evenly with a cloth moistened with disinfectant. Follow the manufacturer's recommendations.
- Use a cloth to rinse with clean water in order to remove residues (in particular products containing aldehydes, quaternary ammonium or surfactants).
- Wipe with a dry cloth.
- Make sure no liquid residue is left on the device after cleaning.

RECOMMENDED PRODUCTS

Getinge USA product: TEC-QUAT 256.
Anios products: Surfa'Safe; 0.5% Hexanios G + R; Aniosyme P.L.A.; Salvanios pH 10; Anios DDSH.
Schülke & Mayr products: Antifect Plus.

PROHIBITED PRODUCTS

WARNING

- Solutions containing glutaraldehyde, phenol, iodine, bleach, alcohol or chloride ions must not be used.
- Fumigation methods are unsuitable for disinfecting the unit and must not be used.

5.2 CLEANING AND STERILISING THE HANDLES

BEFORE CLEANING

- Use a soft cloth immediately after use to wipe away soiling from the handle surface.
- Store handles in a place that keeps them moist to make further cleaning easier.
- Take care to store them in such a way that the inside does not get soiled.

CLEANING

- Immerse the handles in a detergent solution.[1]
- Soak for 15 minutes to allow the solution to act, then clean by hand with a soft brush and a lint-free cloth.
- During cleaning, check regularly that the handles are fully clean and that no soiling remains on the inside or outside.
- If any soiling remains, repeat cleaning or use an ultrasonic cleaning process.
- Rinsing: Rinse thoroughly in clean water to completely eliminate the detergent solution.
- Drying: Wipe with a clean lint-free cloth.

DISINFECTION

Handles may be disinfected by machine (e.g. Getinge) and rinsed at a maximum temperature of 93°C.
Typical recommended cycles:

Step	Temperature	Time
Pre-wash	18-35°C	60 sec
Wash	46-50°C	5 min
Neutralisation	41-43°C	30 sec
Wash 2	24 - 28°C	30 sec
Rinse	92-93°C	10 min
Dry		20 min

1 A non-enzyme-based detergent is recommended. Enzymatic detergents may damage the handles. Never soak the handles in these detergents for prolonged periods. Rinse thoroughly.

STERILISATION

After cleaning, the handles must be steam sterilised as set out below:

Countries	Sterilisation cycle	Temperature [°C]	Time [min]	Drying [min]
USA & Canada	Prevacuum[1]	132 - 135	10	16
France	ATNC (Prion) (Prevacuum)	134	18	
Other countries	Prevacuum[1]	Comply with national regulations		

- Check that each handle is clean before continuing the process.
- Wrap the handles with sterilisation wrapper material (double wrapper or equivalent). They may also be placed in paper or plastic sterilisation bags[2], for easier identification and reuse.
- Place the handles on steriliser trays with the opening downwards.[3]
- Package with biological and/or chemical indicators for monitoring the sterilisation process, in accordance with applicable regulations.
- Run the sterilisation cycle according to the steriliser manufacturer's instructions.

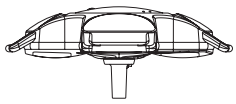
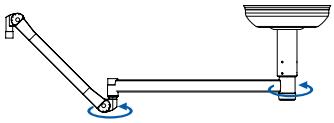
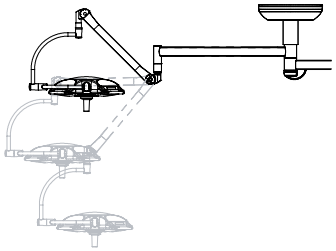
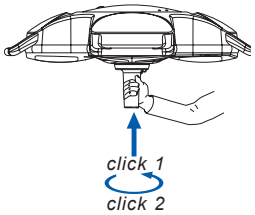
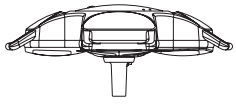
RECOMMENDATION

- To ensure correct sterilisation do not allow any soiling to penetrate inside the handle.
- Handles are guaranteed for no more than 50 sterilisation cycles when the above sterilisation parameters are used.
- Dispose of sterilisable handles in the same way as other hazardous products in a hospital environment.

1 This handle is made of a porous material.
2 Possible sterilisation bag suppliers :
Medical Action Industries
SBW Medical
Baxter International
3 For air removal and faster drying.

6 MAINTENANCE

6.1 FIRST LEVEL MAINTENANCE

Daily checks (user) Solutions are listed in Section 11	
	■ Check the lightheads for chipped paint, impact marks and any other damage.
	■ Check the stability/drift of the main arms and the spring arms.
	■ Check that the spring arm remains in position. ■ Three checkpoints: bottom, middle, top.
	■ Check whether the sterilisable handle clicks and locks in place correctly; replace it if not.
	■ Check whether the system switches correctly between the surgical light and the ambient light.
	■ Check that the bulbs operate correctly.
Monthly checks (X'TEN power supply units with battery backup only)	
	■ Check the lightheads for chipped paint, impact marks and any other damage.
	■ Check whether the backup power supply turns on and the light operates correctly if a power cut were to occur (red LED). ■ Check the capacity of the batteries (see page 14).

6.2 ANNUAL MAINTENANCE

To preserve your surgical light's original performance and reliability and ensure its safety, annual maintenance and inspections should be performed by:

- a MAQUET technician or
- an authorised MAQUET distributor, or
- a hospital technician trained in servicing MAQUET SAS surgical lights.

Note: To find the training solution that best matches your needs, please contact your nearest MAQUET office.

RECOMMENDATION

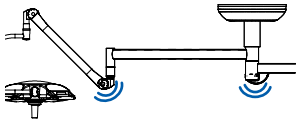
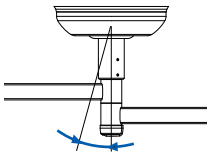
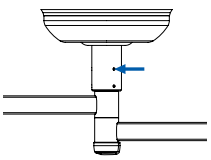
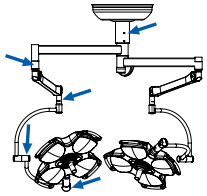
- We strongly recommend taking out a MAQUET maintenance contract for all maintenance work on the light.

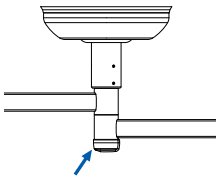
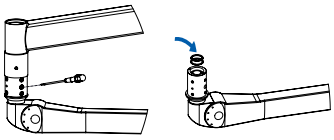
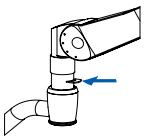
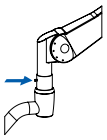
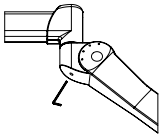
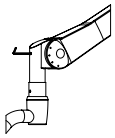
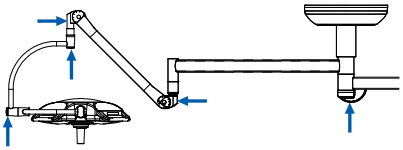
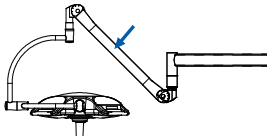
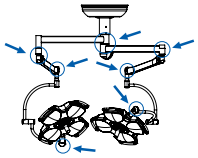
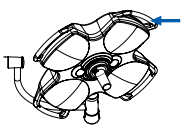
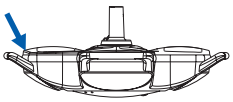
WARNING

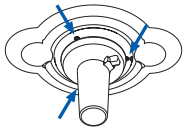
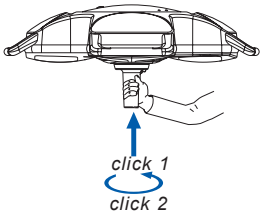
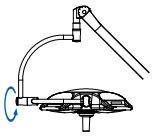
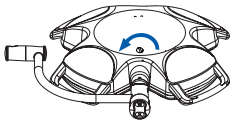
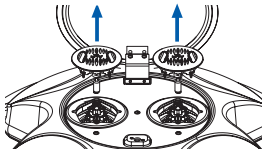
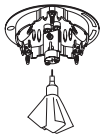
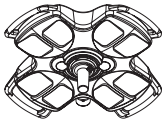
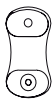
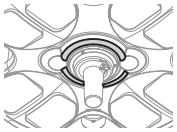
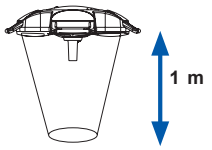
The operation and safety of the device may be affected by the removal of certain components during servicing operations. For example:

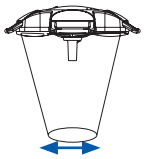
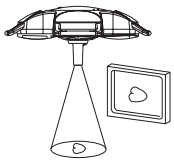
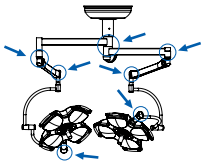
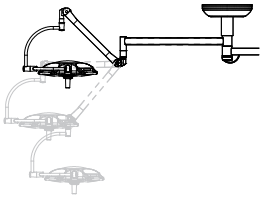
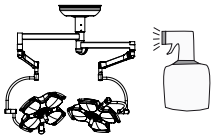
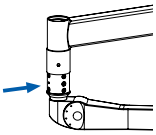
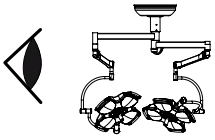
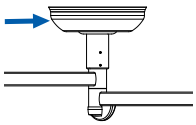
- When servicing the electrical power supply.
- When servicing the suspension arm and balance system.
- Servicing the optical system of cupolas equipped with filters designed to eliminate radiation not visible to the patient. Surgical lights must never be used without these filters.

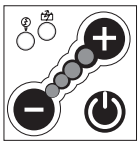
Contact the authorised MAQUET after-sales service department for this type of inspection.

Annual checks The instructions in bold are safety items	
	■ **Check that the suspension is firmly attached by shaking the configuration.**
	■ Check that the suspension tube is vertical.
	■ **Check that the six attachment screws are tightly fastened to the suspension tube.**
	■ Check that all visible screws are tightly fastened.

	■ Check that the slotted nut is tightly fastened for suspensions with stop.
	■ Check the assembly of the spring arm and the positioning of the circlips.
	■ **Check that the snap ring is present and in the right position (between the spring arm and the fork, and between the fork and the lighthead).**
	■ **Check the wear of the retaining ring (remove and lubricate).** ☞ **RECOMMENDATION** Replace the spring arm every 6 years.
	■ Check that the spring arm is balanced.
	■ Adjust the top stop on the spring arm.
	■ **Check for any loose covers and caps.**
	■ **Check for any loose side plastic covers.** ■ Check the general appearance of side plastic covers.
	■ Check the front pivot on the DF Acrobat 2000 spring arm (in case manufacturing date is between 2004 and 2006). Replace the spring arm at the slightest sign of visible cracking.
	■ Check the overall condition of the side handles ■ **Check that the side handles are not loose.**
	■ Check the condition of the lighthead seals.

	■ **Check that the sterilisable handle bracket is not loose.**
	■ Check the locking mechanism for the sterilisable handle.
	■ Check that the stop on the fork works properly.
	■ Check the cover closing mechanism.
	■ Replace the two lamp brackets.
	■ Replace the bulbs.
	■ Check that the underside is in good condition.
	■ Check the focus and adjust the tilt of the mirrors if necessary.
	■ Check that the LED / surgical light switchover works correctly.
	■ Check that the LED ring works correctly: four intensity levels.
	■ Check standard illumination at 1 metre: Serial no. < 20,000: 110,000 lux ± 15 % Serial no. > 20,000: 130,000 lux minimum

	■ Check maximum illumination of the ring of LEDs: Serial no. < 20,000: 150 lux ± 10 % Serial no. > 20,000: 210 lux ± 10 %
	■ Check the light patch diameter: Serial no. < 20,000: 25 cm ≤ diameter ≤ 30 cm Serial no. > 20,000: 24 cm ≤ diameter ≤ 30 cm
	■ Check that the camera operates correctly (CFF or VZ): stable and clean image.
	■ Check that all the standards labels are in place: exclamation mark, hot, bulb holder.
	■ Ensure there are no points of friction when the arm and the lighthead rotate.
	■ Check the movement of the equipment and how stable the lighthead is in each position. ■ Adjust the brakes if necessary.
	■ Clean the entire configuration with ECL NET or soap water. ■ Do not use alcohol to clean the underside.
	■ Check that there is no corrosion, in particular on the main arm, beneath the safety clamp.
	■ Check that there is no chipped paint.
	■ Check for any loose ceiling covers

	■ **Turn the lighthead on and simulate a power supply failure.** ■ **Check that the switch to batteries (see next page) and to the establishment's emergency system is working.** ■ **Illumination should remain at > 40,000 lux for at least 1 hour.**
	■ Check the condition of the control keypad. ■ Check the eight illumination levels

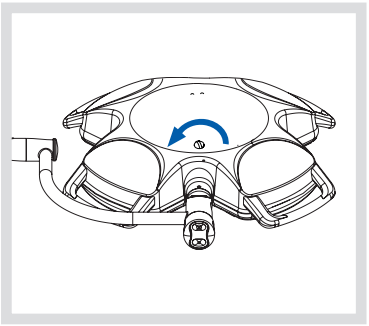
7 REPLACING THE BULBS

WARNING

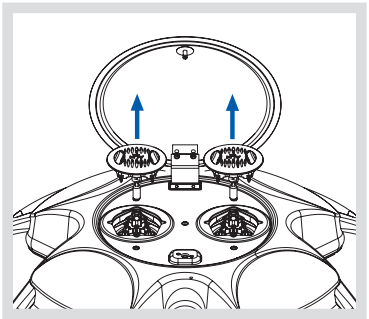
- Do not change the bulbs while the system is in use.
- Do not use the unit with the cover open. When performing maintenance, beware of hot surfaces which are indicated by the following icon:

RECOMMENDATION

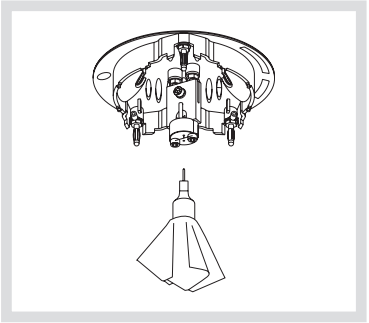
- Replace bulbs every 600 to 800 hours.
- Switch off the power supply and leave the lighthead to cool for 5 minutes.
- Only use MAQUET bulbs.
- Handle the bulbs with care. Use a clean dry cloth when removing/replacing them.
- Never touch bulbs with bare hands. Oils from the skin can reduce the service life of the bulbs and even cause them to break.



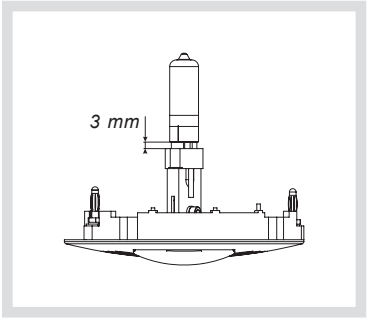
- Turn the knob and open the top cover.



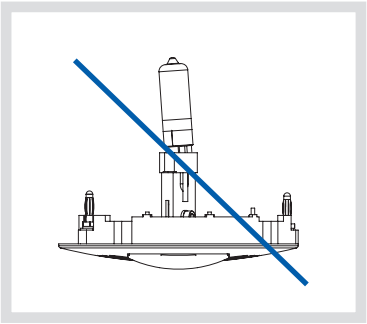
- Remove the bulb holder.



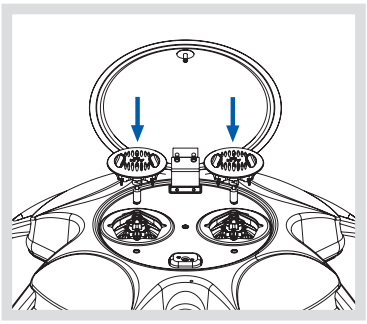
- Remove the bulb.



- Insert the new bulb fully in the bulb holder.

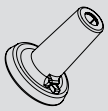
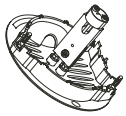


- Check that the bulb is correctly seated.



- Insert the bulb holder in the lighthead.
- Close the cover and lock it.

8 ACCESSORIES

Accessories		Code	Part number
	Set of 5 sterilisable handles	3 672 03 976	PSX 003
	Pack of 5 sterilisable handles for lightheads equipped with a CFF camera (with viewing window)	3 672 03 975	PSX 004
	Pack of 5 sterilisable handles for lightheads equipped with a ZOOM camera (with viewing window)	3 672 03 974	PSX 005
	100 W - 24 V halogen bulb	186 762	AX 186762
	Lamp holder	3 678 19 998	SL X10 001
	Adapter for Devon® and Deroyal® disposable sterile handles	5 675 01 253	DAX 001

9 GENERAL CHARACTERISTICS

(IN ACCORDANCE WITH STANDARD IEC 60601-2-41 AND IEC 60601-1)

Specifications		Unit	X'TEN
Main light			
Nominal illumination (Ec)		lx	130,000 ± 15%
Diameter d10		cm (inches)	26 (10.2") ± 10%
Diameter d50		cm (inches)	15 (5.9") ± 10%
Illumination depth 20%		cm (inches)	100 (39.4")
Illumination depth 60%		cm (inches)	50 (19.7") ±10
Colour temperature (Ra)		K	3,500 ± 10%
R9 specific index		N/A	60 ±5
Colour rendering index		N/A	95
Shadow dilution	With one mask	%	74
	With two masks	%	47
	At base of tube	%	100
	With one mask, at base of tube	%	74
	With two masks, at base of tube	%	47
Radiant energy		$mW.m^{-2}.lx^{-1}$	≤ 4.4
Electrical classification		N/A	Protection class I
Ambient light			
Illumination		lux	< 500
Other characteristics			
Degree of protection against harmful ingress of water		N/A	Ordinary
Methods of sterilization or disinfection		N/A	See chapter 5
Mode of operation		N/A	Continuous operation

Note:

- The toleranced values are guaranteed on the date of purchase of the product.
- The untoleranced values have been measured by an authorised body on a production sample.

10 EMC DECLARATION

(IN ACCORDANCE WITH STANDARD EN 60601-1-2: 2001)

Table 201 - Guidance and manufacturer's declaration — electromagnetic emissions

The X'TEN system is intended for use in the electromagnetic environment specified below. The customer or the user of the X'TEN system should ensure that it is used in such an environment.

Immunity test	Conformity	Electromagnetic environment – guidance
Radio-frequency emissions CISPR 11	Group 1	The X'TEN system uses radio-frequency energy for its internal functions only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio-frequency emissions CISPR 11	Class A	The X'TEN system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic current emissions }IEC 61000-3-2	N/A	
Voltage fluctuations and flicker IEC 61000-3-3	N/A	

Table 202 - Guidance and manufacturer's declaration — electromagnetic immunity

The X'TEN system is intended for use in the electromagnetic environment specified below. The customer or the user of the X'TEN system should ensure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (DES) 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 for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (95% dip in U_T) for 5 cycles	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (95% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the X'TEN system requires continued operation during power mains interruptions, it is recommended that the X'TEN system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: V_T is the AC mains voltage prior to application of the test level.

Table 204 - Guidance and manufacturer's declaration — electromagnetic immunity

The X'TEN system is intended for use in the electromagnetic environment specified below. The customer or the user of the X'TEN system should ensure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the X'TEN system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = [\,{}^{3,5}/_{V1}\,]\sqrt{P} = 1{,}17\ \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [\,{}^{3,5}/_{E1}\,]\sqrt{P}$ 80 MHz - 800 MHz = $1{,}17\ \sqrt{P}$ $d = [\,{}^{7}/_{E1}\,]\sqrt{P}$ 800 MHz - 2,5 GHz = $2{,}34\ \sqrt{P}$ 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). 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: 

NOTE 1: At 80 MHz and 800 MHz, 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.

[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 X'TEN system is used exceeds the applicable RF compliance level above, the X'TEN system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the X'TEN system.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Table 206 - Recommended separation distances between portable and mobile RF communications equipment and the X'TEN system

The X'TEN system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X'TEN system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X'TEN system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\ 1.17\ ]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\ 1.17\ ]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\ 2.34\ ]\sqrt{P}$
0 01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.70	11.70	23.40

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 TROUBLESHOOTING

Problem	Likely cause	Corrective action
■ The lighthead does not turn on	■ Faulty or missing bulb	■ Cut off the power supply and replace the bulb(s)
	■ Power cut	■ Check if other devices on the same supply network are operating
	■ Other reason	■ Call MAQUET technical department
■ None of the lightheads light up	■ Each lighthead has its own control	■ Check the LED on the keypad on each lighthead (green LED)
■ The lighthead does not turn on; only ambient light operates	■ Faulty or missing bulb	■ Switch off power supply and replace bulb(s)
	■ Other reason	■ Call MAQUET technical department
■ Ambient light does not turn on	■ The button is defective	■ Call MAQUET technical department
■ Bulb service life too short	■ Improper bulb or overvoltage condition	■ Make sure that you are using the required MAQUET bulbs exclusively
		■ Check voltage at the bulb pins: $23.5V_{EFF}$ (V^{RMS}_{AC+DC})
■ The sterilisable handle does not click into place correctly	■ Sterilisation parameters (temperature, time) exceeded	■ Check whether the locking mechanism operates correctly (audible click) and check the entire handle
	■ Its maximum service life has expired or the handle is twisted or bent.	■ Replace the handle
■ The lighthead drifts	■ Suspension tube not vertical	■ Check tube verticality and ceiling structure
	■ Ceiling structure unstable	■ Call MAQUET technical department
	■ Brake incorrectly adjusted	■ Adjust the brake
■ Lighthead too flexible or too rigid to manoeuvre	■ Brake incorrectly adjusted	■ Adjust the brake screw
	■ Insufficient lubrication	■ Call MAQUET technical department

MAQUET
GETINGE GROUP

MAQUET SAS
Parc de Limère
Avenue de la Pomme de Pin
CS 10008 ARDON
45074 ORLÉANS CEDEX 2, France
Phone number: +33 (0) 2 38 25 88 88
Fax: +33 (0) 2 38 25 88 00

To find your closest representative:
Please go to
www.maquet.com

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