Surgical Light User Manual

XR1 Pro mobile, wall mounted, ceiling mounted

CE

Dear customer:

Thank you for choosing the XR1 Pro LED surgical light produced by Shanghai Pax Medical Instrument Co., Ltd

The XR1 Pro LED surgical light is designed specifically for patient examinations and small surgical procedures. The lamp is easy to operate, and can be operated through the preset program of the control panel and sensing buttons, or directly operate the handle and sensing switch; The lamp head is made of high-quality materials and is lightweight; The fixed clip has been certified by the medical field; And it is equipped with an integrated power system that can adapt to various work scenarios.

The surgical light adopts a brand new and exclusively developed optical concept and innovative LED technology, with low illumination, high illumination, low heat generation (no infrared radiation), uniform illumination and other modes, providing you with the best light conditions and high color rendering index areas.

Thank you again for using our XR1 Pro LED surgical light. We wish you a pleasant experience.

Shanghai Pax Medical Instrument Co., Ltd

Registered address of the company: No.3 Building No.438 Fulian Two Road, Baoshan, District, Shanghai, China

Postal Code: 201906

Production address, sales and maintenance department address: No.3 Building No.438 Fulian Two Road, Baoshan District, Shanghai, China 201906

Phone:+86-21-52820699

catalogue

Please place the user manual near the device!

Warning and safety instructions for installation and use

- Before each use, please ensure that the XR1 Pro LED surgical light is in good condition.
- Note that in mobile devices, the XR1 Pro LED surgical light can only be powered by the power supply in the base; Ceiling mounted is only powered by the power supply in the bracket; Wall mounted is powered by an in wall power supply.
- Disconnect power: When using wall mounted and mobile devices, unplug the power plug from the socket to power off the device; In ceiling equipment, a separate switch should be installed for complete power outage during construction to disconnect the equipment from the main power source!
- The XR1 Pro LED surgical light is a small surgical light that is not equipped with a fail safe power supply or electronic storage medium. In case of power interruption or disconnection from the main power supply of the facility, the lights will not operate.
- Only connect the device to the power grid with a grounding wire.
- This device is not suitable for areas with explosion risks.
- If multiple lamps are operated simultaneously, please ensure that the total irradiation intensity does not exceed 1000 W/m2 to avoid overheating in the area.
- Do not approach strong magnetic fields such as MRI systems.
- Do not use in environments with flammable anesthetic gases.
- If you need to adjust the equipment, please refer to the installation manual
- Before assembly, please store the unopened equipment in the required installation room for at least 24 hours to avoid interference from temperature changes.
- The assembly, maintenance, and upkeep of the product can only be completed by professionals - please also refer to the installation manual.
- If the user maintains and modifies the device themselves, or if the maintenance and modification are carried out by a company that complies with safety regulations and only uses original replacement parts, the manufacturer is responsible for the quality of the light fixtures.
- The manufacturer shall not be liable for any personal injury or component damage caused by improper use or operation.
- When installing/removing small surgical light fixtures, the entire system must be completely disconnected from the power supply (including fixed devices)!
- The XR1 Pro LED surgical light can only use the original charger and bracket.
- Medical equipment must comply with EMC related special precautions and must be installed and debugged according to the EMC information contained in the operating and installation instructions.
- Portable and mobile HF communication devices may affect medical electronic devices.
- The bracket, installation system, and components (such as spring arms and brackets) that are compatible with the XR1 Pro LED surgical light must be used; Using accessories such as power supply devices and wires other than those described in the operation and installation instructions may result in increased emissions or affect the light system.
- These devices are specifically designed to support and position the XR1 Pro LED surgical light head, and provide power to the equipment.
- This device is available for continuous operation.
- Except for the lamp body, the equipment shall not be loaded with any additional heavy objects.
- The support arm system needs to be kept away from strong magnetic fields.
- The support arm system is only for connecting XR1 Pro LED surgical light.

The definition of minimum operational quality and basic state:

- Allow the surgical light to flash or turn off briefly (less than one second), as it does not affect any examination, diagnosis, or treatment.
- If there is a short-term power outage, the indicator light will turn off, and if necessary, the operator must manually turn it on again.

Target group

The user manual can be read by medical personnel/operators who require use, cleaning, sterilization, and disinfection.

The installation manual has been revised and certified by the technical/installation personnel of Shanghai Pax Medical Instrument Co., Ltd

This device can only be assembled by hospital technicians or qualified installers recognized by Shanghai Pax Medical Instrument Co., Ltd

The following are the requirements for qualified personnel:

- Having relevant skills, through professional training in the fields of healthcare and medical technology,
- Assess safety related regulations and determine potential hazards based on their work experience and training.
- In countries that conduct qualification audits for professionals in the medical or medical technology field, qualified personnel should be authorized accordingly.

Hello, installation personnel,

Please read the installation instructions carefully and follow the safety instructions and requirements.

If there are any special issues that are not detailed in these installation instructions, please contact the supplier to ensure safety.

Installation personnel need to obtain electrical national certification to install this product. No modifications are allowed to this product!

If you need product warranty, please contact your local dealer or directly contact the supplier.

1. Instructions for use

1.1 Lamp head

Expected use: Used in operating rooms and treatment rooms to provide light for patients' surgical or examination areas.

Product description: Usually composed of a light source, lamp holder, etc. Used for surgical auxiliary light, it can also be used separately for small surgeries. It does not have a shadowless effect. It can be classified as ceiling mounted, wall mounted, or mobile.

The XR1 Pro LED surgical light is used for patient examinations and small surgical procedures. The central illumination is 100000 lx at 1 meter.

In the surgical light system, equipotential connection interfaces and other devices can be used to connect equipotential connection cables to the corresponding equipotential connection busbars.

As a small surgical light fixture, the XR1 Pro LED surgical light fixture is not equipped with a fail safe power supply or electronic storage medium. If the room power is interrupted or disconnected, the function of the light will be interrupted.

Use the side control panel or induction switch of the lamp head and the handle to operate the small surgical light.

1.2 Fixed fixture system and accessories

Secure the lamp head using a fixture system and joint interface, and supply power using a power pack.

The main power supply must be grounded for protection!

Do not modify or deform the product in any way!

The XR1 Pro lamp head is designed to be compact and can be positioned in the appropriate position through a bracket. Please refer to the installation manual provided with the product.

Figure 3

Figure 4

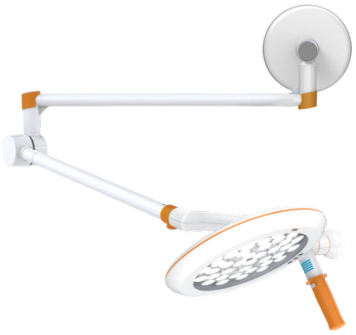

Figure 5

2 Operations

2.1 Pre-use inspection

Check if there are any visible deformations in the system. If such a situation is found, please contact the local dealer immediately, and the dealer will immediately forward the information to the manufacturer.

- Ensure that the system has the necessary hygiene status.

- Before each startup, check if the entire device is functioning properly. The equipment should be moved within its available range and its main functions, including the control panel, should be checked.
- If the connection of the light fixture is difficult to rotate or cannot be fixed, please adjust the holding force according to the installation instructions to support and fix the equipment.
- Check for cracks on the handle!

If you have any questions about electrical safety or static/dynamic stability, do not operate the light fixtures.

2.2 Lamp head operation instructions

Short press once: The lamp head is turned on (displaying a constant blue light).

Short press again: turn off the lamp head (display blue breathing light).

Adjust brightness (ten level brightness)

Short press once: Decrease the brightness by one level.

Adjust brightness (ten level brightness)

Short press to increase the brightness by one level.

Adjust color temperature.

Short press to switch color temperature, with a total of 5 color temperature cycles.

Adjust the light spot.

Short press to switch the light spot, there are 2 levels of light spot cycling.

Dimming function of handle

Spot function

Color temperature function

Brightness function

The currently activated function mode will be highlighted in "blue", while the remaining modes will be displayed in white.

Adjust the current function level (spot size/color temperature/brightness):

Rotate the 'orange handle' to adjust the current activated function (spot, color temperature, or brightness) level.

Left turn:

Spot mode: Spot becomes "smaller"

Color temperature mode: Color temperature "decreases" (slightly warm)

Brightness mode: Brightness"decreases"

Right rotation:

Spot mode: Spot becomes "larger"

Color temperature mode: Color temperature "increases" (cooler)

Brightness mode: Brightness "increases"

Level indication: The current level status of the function is displayed through a blue indicator light bar (spot 2 levels, color temperature 5 levels cycle, brightness 10 levels).

Short press the white function switch button at the bottom of handle to cycle between the three function modes of "spot", "color temperature", and "brightness".

Sensing function

Induction control function (operated through the "black elliptical area induction window")

Sensing area: The black elliptical area in front of the lamp head (effective distance of about 0-5cm).

Operation method:

1. Switch control: Within the induction zone , waving once can control the lamp head on/off (the same effect as short pressing the switch button).

2. Automatic brightness adjustment: within induction zone, hold your hand in front of the sensing window. The brightness will automatically cycle from the lowest level to the highest level.

After moving your hand away, the brightness will be locked in the current level.

Control box function

3. Cleaning/Disinfection/Sterilization of Handle and Clamp

The cleaning work of medical technology facilities is determined by specific hygiene plans and procedures of the institution, and coordinated with the internal environment and the usual required hygiene conditions, especially for the cleaning of medical technology facilities in surgical environments. The cleaning, disinfection procedures, and disinfectants mentioned in this chapter are developed and authorized by professional associations and comply with market standards.

If your workplace requirements are different, please contact our customer service department or your health expert.

Only by cleaning, disinfecting, and sterilizing equipment or products according to specified procedures can the successful sterilization of various components (such as Sterilizable handles) be ensured, provided that the confirmed parameters for each cycle are strictly followed and comply with other hygiene regulations of hospitals and other units.

3.1 Sterilizable Handle

The XR1 Pro LED surgical light is equipped with a Sterilizable handle. This detachable handle can be steam sterilized at temperatures up to 134 ° C.

Before the first use and before each subsequent use, the Sterilizable handle and clip must be disinfected.

The handle and clip need to be removed before disinfection:

To remove the handle and clip, press the two release buttons on the side and then pull down the handle.

To reinstall, slide the handle upward until the buttons on both sides click into place.

During surgery, the handle often becomes unsterile. Therefore keep several handles and clips handy for replacement. (side release buttons)

3.2 Basic knowledge of cleaning/disinfection

As part of the equipment used in a medical environment, effective cleaning/disinfection is a necessary and prerequisite condition for the proper use of handles and clips.

Pollution/infection risks in the work area.

Poor or missing execution of cleaning, disinfection, and sterilization procedures may result in contamination of the workspace/users/patients/third parties (please strictly follow hygiene guidelines and manufacturer's instructions!).

3.3 Disinfection

The handle and clip must be disinfected and cleaned immediately after use. Mechanical cleaning/disinfection procedures (sterilizers) should be used.

Table 1: Disinfection Measures

Pre cleaning:	3 min. pre-rinsing
Cleaning:	5 min. at 48 °C, then rinse 2 min. cold and rinse with purified water
Disinfect	5 min. at 93 °C
Drying:	5 min. at 95 °C
Cleaning agent:	Mediclean forte, produced by Dr. Weigert

3.4 Sterilization

The sterilization of sterilizable handles and clips can be verified through the following mechanical procedures and parameters:

Table 2: Sterilization Measures

Sterilization Procedure: Fractionation Pre Vacuum Method
Temperature: 134 ° C
Stay time: 18 minutes

Only steam sterilization! Not suitable for gamma rays, ethylene dioxide, and other procedures not associated with steam sterilization.

If another sterilization procedure than the described methods is used, the suitability and basic effectiveness of the procedure must be demonstrated as part of a validation.

3.5 Inspection/Service Life

Before reuse, it is necessary to check whether the handle and clip are damaged and replace them promptly. The handles may be cleaned/disinfected, sterilized and re-used a maximum of 500 times.

After the expiration of the usage period, the operator is responsible for ordering new sterilizable handles and clips.

4 Cleaning/Disinfection of holding Fixture System

4.1 General Safety Instructions

WARNING – ELECTRIC SHOCK

The devices can conduct power and is to be treated with caution during cleaning and disinfection.

• If there is a mains cord, please disconnect it.

• Do not use spray cleaning and/or spray disinfection. Do not spray or allow any liquid to penetrate in sockets or device opening

4.2 Cleaning

Cleaning objects: bracket, support arm, and lamp head surface.
Cleaning agent: commercially available neutral soap solution or mild detergent.
Cleaning method:
• Use a mild soap solution commercially available washing-up liquid as a cleaning agent.
• Wipe surfaces of the light heads with a lightly dampened cloth, if necessary, use some mild soap solu-tion (washing-up liquid).
• Finally dry the exterior by wiping with a soft, clean cloth (use an ASC™ antistatic cloth, if necessary)
Warning - Risk of infection and contamination:
The components and joints of the support arm system are made of plastic material.
Do not use strong acids, strong alkalis, solvents, or cleaning agents with an alcohol content exceeding 60%, as these substances can cause plastic to become brittle and crack. Damaged components may fall into the surgical area.
When cleaning, avoid excessive use of liquids to prevent the solution from seeping into the support system or joints, which may contaminate the surgical area (such as open wounds).

4.3 Disinfection

Disinfection target: Support arm system and XR1 Pro LED surgical light outer surface.

Standard disinfection method:

Use validated broad-spectrum disinfectant wipes for surface wiping.

Operators must comply with the hygiene guidelines and safety operating procedures of their institution.

Disinfection frequency:

Daily disinfection: Surfaces are to be disinfected every working day!

Immediate disinfection after contamination: If the surface is contaminated with potential infectious substances (such as blood, body fluids, secretions, excreta), the area must be thoroughly disinfected immediately.

Key requirements:

Strictly follow the instructions of the disinfectant manufacturer, including the correct concentration and minimum contact time.

Do not spray disinfectant! Only for wiping and disinfection.

Consult your institution's health/infection control department to determine the specific types of disinfectants and disinfection procedures that meet your current internal hygiene requirements and plans.

All disinfection operations must be strictly carried out in accordance with the hygiene plan formulated internally by the institution.

Warning - Health Hazards:

Disinfectants may contain harmful chemicals.

Avoid direct contact between the skin and eyes with disinfectants.

Avoid inhaling disinfectant vapors/aerosols as they may cause irritation or damage to the respiratory tract.

Proper personal protective equipment (such as gloves, goggles) must be worn during operation and carried out in a well ventilated area.

5 EQUIPOTENTIAL BONDING CONDUCTOR

(Optional accessories, not included in the standard supply scope)

Function Description

This wire is used to directly connect the equipotential connection interface of the mobile surgical light fixture (located on the outer shell of the mobile bracket) to the potential equalization bus in the medical field, eliminating potential differences between devices and ensuring equipotential status.

Risk source:

Mobile devices may be used in parallel with other electrical equipment in surgical environments, and if there is a potential difference, it can form parasitic voltage sources.

Potential hazards:

1. Human safety: Parasitic currents may flow through patients or medical staff, posing a risk of electric shock;

2. Equipment safety: Current interference may cause active medical equipment (such as monitors, electric knives) to malfunction.

Installation specifications

In Class 2 medical facilities that comply with DIN VDE 0100 Part 410 standard:

1. All external conductive components (such as equipment casings and metal brackets) must be interconnected through protective grounding wires;

2. The interconnection system must be connected to the potential equalization bus of the site;

3. The connection operation of this wire needs to be carried out by a professional electrician to ensure grounding continuity.

Equipotential connection interface on mobile bracket

The equipotential connection interface on the mobile bracket is equipped with equipotential green yellow connection cables

Equipotential bonding cables for mobile brackets and wall mounted installations.

6 Maintenance

Medical devices should be regularly maintained and inspected to ensure compliance with safety requirements.

To ensure compliance with safety requirements, medical device manufacturers are responsible for determining measures for regular inspections, and operators are responsible for implementing these measures.

When performing all maintenance and inspection work, please switch the light to standby mode, unplug and disconnect the light from the power supply. Fix the light fixtures to avoid reconnection.

There is a risk of damage

The support arm is equipped with a spring device, which may break when disassembling the lamp head.

When carrying out maintenance work, please follow the manufacturer's installation/removal instructions (please refer to the installation instructions provided with the fixture system).

When performing any maintenance measures, please follow the manufacturer's instructions for use. (See attachment "Inspection").

6.1 Fixture System

The operator should investigate all fixed systems:

Electric shock hazard:

Before conducting any inspections, please disconnect the device from the power supply.

Regular inspection: When conducting regular inspections, DIN EN 62353 should be followed. (See the attached "Inspection Plan Table").

Every six months:

- Is the support system deformed
- Are there any cracks in the plastic parts
- Is the paint damaged

Every year:

- Expansion inspection of support systems, such as checking the holding force and fixation of spring arms
- If necessary, tighten the screws at the bottom of the bracket and tighten them again.
- Extension function check, such as free movement of connectors
- Refer to the "Lubrication Locking Part" section in the instructions to check and lubricate the locking part (e.g. using Microgleit GP 360). -
- Electrical safety inspection.

If any malfunctions or damages occur, please contact your supplier.

Your supplier has received training on the scope and content of maintenance work.

6.2 Lamp Head

The following inspections/maintenance must be carried out annually:

- Check for cracks and deformations in plastic components and seals.
- Electrical safety inspection
- Extension operation check
- Paint damage inspection

7 Disposal of waste

Please contact the waste disposal department to properly dispose of the system. You can obtain the address of the waste disposal department from local environmental officials or municipal authorities.

Do not disassemble the spring arm or hinge joint. The spring arm and joint section contain pre tensioned springs, which can suddenly release tension when disassembled improperly.

Please do not use the daily household waste disposal process to dispose of this product.

Please carry out disinfection or sterilization procedures before disposal to avoid environmental pollution.

8 Data

10.1 XR1 Pro photometric data

XR1 Pro	
Central illumination at a distance of 1 meter [lx]	100,000 – 10%
Light field diameter d10 [mm]	220
Light distribution d50/d10	≥ 0.72
Color rendering index Ra	≥ 95±5%
Fixed color temperature [K]*	4,300 ±250
Adjustable color temperature (5 levels) [K]*	3500-5100 ±250
Service life	≥60,000h

Technical data may have some fluctuations. Due to technical reasons of the product, the actual value may slightly differ from the above values.