

LED SURGICAL LIGHT

LED MULTI-COLOR PLUS
E700L, E500L



USER MANUAL

NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD

ADDRESS: NO.666 YAOHU WEST 5TH ROAD, HI-TECH ZONE,
NANCHANG, JIANGXI, CHINA

www.ledoperatinglamp.com / www.micare-med.com

Explanation of the symbols:

The following symbols are part of these operating instructions and/or the product label

	Safety warning symbol Caution: Indicates a situation which, if not avoided, may result in minor or moderate injury. WARNING: Indicates a situation which, if not avoided, could result in death or serious injury. DANGER: Indicates a situation which, if not avoided, will result in death or serious injury.
	Medical Device
	Instruction For Use
	Instruction For Use
	MICARE Order Reference Number (Item Number)
	Serial Number
	Manufacturer and date of manufacture.
	CE Mark
	This product should not be disposed of as normal household waste.

Direct Line:

If you have any questions about how to operate a device or product or use it for clinical applications, please feel free to contact your Product Manager: Phone: +86-0791-88322589

For technical questions and questions about maintenance and training contracts, please contact our MICARE service center:

Email: info@micare.cn, Web: www.ledoperatinglamp.com / www.micare-med.com

Notes for this document:

To better answer your technical questions, our service technicians will ask you for the catalog, reference number (REF), serial number (SN) and manufacturing date of the product. All this information can be found on the Ceiling Enclosure.

Notes for this document:

iPossible danger to the life of patients, users and other persons if these instructions for use are not followed!

This document applies equally to people of all genders. References to different genders are avoided solely for reasons of readability.

Manufacturer:

Thank you for purchasing one of our products.

This product bears the CE mark. This means that it meets the basic safety and performance requirements for medical devices set out in the respective applicable European regulations.

We are the manufacturer of this product:



NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD
NO.666 YAOHU WEST 5TH ROAD, HI-TECH ZONE, NANCHANG, JIANGXI, CHINA
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Intended use

Special purpose

- E700L, E500L surgical lighting equipment is used to illuminate the patient's body during surgery, diagnosis and treatment.
- This surgical lighting equipment is suitable for installation in operating rooms, examination rooms, consultation rooms and outpatient clinics.

WARNING



iRisk of serious injury from electric shock!

To reduce the risk of electric shock, be sure to connect appliances only to power systems that provide a protective ground connection.

WARNING



iRisk of injury due to unauthorized modifications to the product!

Any modification to the product may pose a risk of death due to electric shock caused by malfunction of the product. In addition, this may cause the light to dim or the spring arm to rise sharply in response to the high spring. Therefore, unauthorized modifications are strictly prohibited under any circumstances.

WARNING



iRisk of infection due to contaminated system components!

Before beginning any maintenance work on your lighting system, ensure that all system components have been properly cleaned and disinfected.

NOTICE:

Risk of interference and malfunction:

- As a medical electrical device, the operating light is subject to special precautions regarding electromagnetic compatibility (EMC). The device must be installed and used in accordance with the EMC directives.
- As a medical electrical device, the operating light is subject to special precautions regarding electromagnetic compatibility (EMC).
- Surgical lights should not be placed near or on top of other devices. If proximity to other devices cannot be avoided, be sure to check the functional reliability of the work light before using it in such a facility.
- Do not hang or run cables over or above the work lighting system

Safety Notices / General Information:

MULTI-COLOR LED PLUS Surgical Lights are quality products, designed and manufactured in accordance with recognized technical guidelines. The products leave the factory in completely safe operating conditions. To maintain this status, you, the user, must refrain from or prevent any action that may have a negative impact on the safety performance of the lights.

- Read the safety instructions carefully when carrying out maintenance work!
- Make sure to follow the instructions in this document!

Be sure to follow the instructions in this document!

- Disconnect the flashlight from the power supply!
- Protect the lights and their components from dangerous contacts! Post warning signs where necessary!
- Contact the manufacturer or service technician immediately!

The service works:

- Any service work must be carried out:
 - by qualified persons specifically authorized by NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD to carry out such work.
 - in accordance with the instructions given in this manual.
 - competently and with the utmost precision.
 - in compliance with the relevant technical, safety and accident prevention standards.

Inspection:

- Check all safety-related parts according to the inspection plan.
- The results must be documented in the audit plan.

We recommend periodically checking all functions of the lights, springs/guide arms, roof tube and power supply to ensure they are working properly. Every 24 months you must have an inspection by an authorized person.

Ensuring your serviceability and operational safety!

NOTIFICATION:

Only components or systems approved by NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD as accessories may be connected, installed or secured to the lighting systems.

Personal protection:**Risk of serious injury from electric shock!****WARNING**

- Before starting any maintenance work, ensure that all power lines are switched off and cannot be live while working on the lights.
- The installation in the building must include a disconnect switch (e.g. circuit breaker) that allows for the simultaneous and omnipolar disconnection of all electrical circuits of the lights (mains supply 100-240 V, DC supply 24-36 V) from the power source to which the lights are connected. The switch or circuit breaker used must comply with IEC60601-1 requirements for distances and clearances or must be CE listed.
- To reduce the risk of electric shock, ensure that fixtures are connected only to power systems that provide protective earthing.
- For mobile lights with a removable power plug (mains cable), free access to the plug must be provided at all times to ensure that the lights can be easily disconnected from the power source.
- The DC power supply to the lights must comply with Safety Extra Low Voltage (SELV) requirements according to IEC60601-1.
- Be sure to turn off the building-side circuit breaker before performing any maintenance on the lighting system!
- The power cables must be protected against accidental loosening or breaking at the terminals (strain relief)!

WARNING**iRisk of serious injury due to defective lamps!****Defective work lights can cause damage or even endanger the lives of users or patients!**

- Therefore, never use defective lamps!

WARNING**iDanger of explosion!**

Surgical lights may only be used at a safe distance from openings or surfaces that emit or emit anesthetic gases, oxygen or other flammable or oxidizing gases.

WARNING



!Risk of damage or injury due to high weight!

!Some lighting system components are heavy!

Falling system components can cause personal injury and property damage.

- Never attempt to replace heavy system components that require disassembly alone, always do so with an assistant and, if necessary, support such components with a lifting device.

WARNING



Risk of injury due to high spring force!

!Spring arms with disconnected weights (light heads or light head assemblies) or with the transport guard removed can spring upwards rapidly and with great force and cause serious injuries!

- Before removing the load from the spring arm, always lock the spring arm vertically or secure it first!

WARNING



!Observe national / local safety regulations!

The Medical Devices Act (MPG) and the Accident Prevention Regulations (BGV) are important parts of the legal framework that must be observed in China. Make sure that you comply with the applicable local laws, directives and regulations!

Screw lock:

All screws installed during initial installation or replaced during inspection or conversion must be original replacement screws equipped with thread locking agent.

Replacement screws supplied by NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD are coated with PA (blue polyamide coating) as a thread locking agent.

NOTICE:

!Danger of loosening of threaded connections!

If the screws are installed without thread-locking liquid/paste, they may become loose during the process of using the lamps.

- Observe "Secure screws with thread locker".
- When reinstalling removed screws, thread locker fluid must be used.
- Screws that are susceptible to this risk are marked in this document with the following symbol

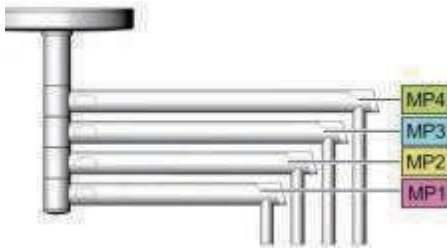
WARNING



!Risk of injury from falling parts!

System parts can fall if the safety screws are not tightened to the correct torque.

Declaration of arms:



- The numbering of the mounting locations starts clockwise from the right with MP1, next to the central potential equalization terminal.
- MP1 contains a consumer power supply on the lower track arm. In one example, this could be a camera on a separate mount.
- If the configuration includes additional weapon systems (example: MP2 with illumination), the power modules for their consumers are assigned the following mounting positions (MP2–MP4).
- The MP3 contains input terminals (100-240V) to supply power to a mains powered device.

The Company constantly strives to improve its products and therefore reserves the right to supply, without prior notice, a product structure with different characteristics than those described in this manual. However, the Company guarantees that these improvements comply with applicable regulations and reserves all rights;

Installation Considerations:

- The ceiling anchor ring is not required for a combined pendant and LED configuration.
 - During assembly, make sure that neither the flange nor the fixing elements come into contact with reinforcing components of the solid ceiling.
 - Depending on the stability of the location, it may be necessary to use a counter plate for fixing to the wall.
 - The forces arising when widely extended articulated arms are tilted make it necessary to drill very carefully with a certified hammer drill, paying close attention to the drilling tolerances.
 - The suspension tube of the lamp or lamp combination must be adjusted vertically to prevent the lamp body
- To do this, the 4 M14 lock nuts on the fixing bolt must be adjusted accordingly.
- For false ceilings, the suspension tubes of all lamps can be mounted directly on the solid ceiling.

The opening required for this purpose can be closed after completion of the work. This can be completed by using the ceiling cover with a diameter of 430 mm (16.93") or a cover plate.

- NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD is only responsible for the safety of the lamp if repairs and alterations are carried out by NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD or a company that guarantees compliance with safety regulations.
- NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD is not responsible for personal injury or property damage if the light is used improperly or incorrectly or used for purposes other than those for which it is intended.
- Carefully read the instructions for installing your lighting system and avoiding damage to the device. Pay attention to the instructions for use when handling the lamp.
- This device has not been designed for use in potentially explosive areas according to the Medical Device Regulation, the light is classified as class I in Canada and USA according to the FDA.
- This device requires connection to a backup system (made on site and provided by the facility) in case of interruption of the supply network for the safety service. The backup system shall restore power within (0.5) seconds.

【Abstract】

You have just purchased a E700, E500 surgical light from NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD. Congratulations on your choice and hope you will be satisfied with its use and performance.

We recommend that you read this manual carefully before using the LED surgical lights, familiarize yourself with their operating method and fully evaluate their effectiveness.

Please keep this manual in a safe place so that you can read it at any time. Thank you for your trust in our company.

[Quality assurance]

The user is responsible for compliance with applicable laws governing the use and maintenance of the equipment.

The company is not responsible for any malfunction, physical damage, injury or lack of quality caused by misuse or poor maintenance due to the user's failure to follow the suggested diagram.

The LED Surgical Light should not be used if the electrical or mechanical safety devices are defective, or if the instructions for use and maintenance are not followed.

Only the Company or a third party designated by the Company may modify or expand the operating light. Such modifications must be made in accordance with the applicable regulations in the country of use and normal business practice.

If there is any problem with the operating light, please contact the distributor or our company. We will do our best to provide you with quality service and assistance.

When you use a surgical light for the first time, the company and its distributor will be happy to assist you and answer any questions you may have. The delivery time is indicated on the invoice.

Under no circumstances may packaging materials manufactured by us be used for any purpose other than transportation. The instructions in this manual fully explain the use of the LED surgical lights.

The company effectively provides a 1-year free warranty for all surgical light spare parts. Otherwise, a free warranty period will be provided from the date of manufacture.

Attention: The manufacturer is responsible for the safety, reliability and performance of the equipment only if:

- (1) Installation and any repairs or modifications must be carried out by qualified personnel.
- (2) The electrical wiring of the workplace must comply with all codes in force at the time of installation.
- (3) The product must avoid exposure to strong magnetic fields or create strong electromagnetic interference in the environment used.

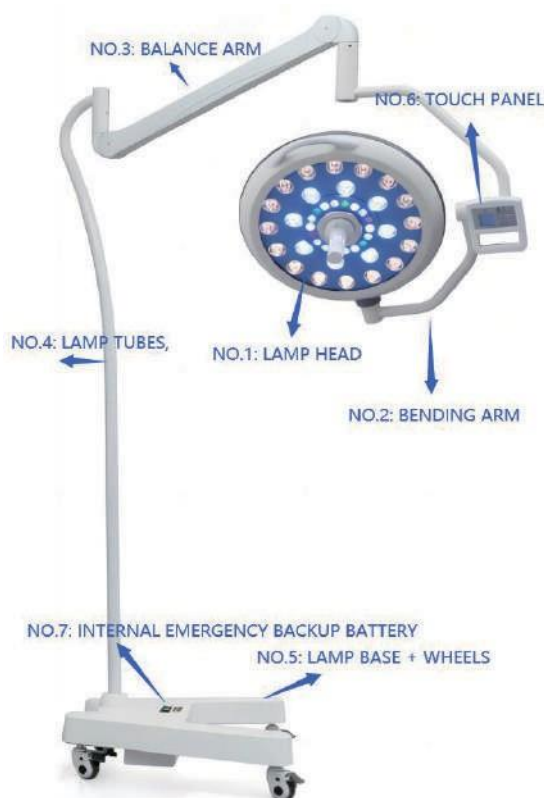
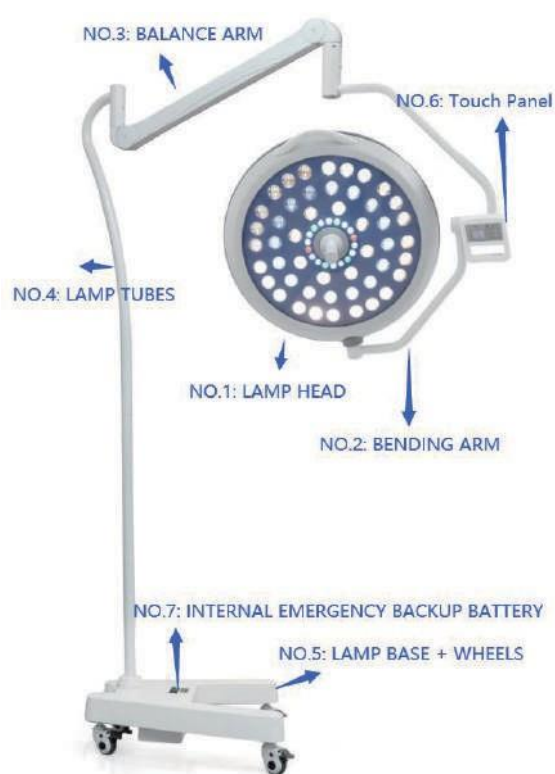
Follow the instructions:

This manual aims to explain the operation, installation, debugging, operation, maintenance and troubleshooting of LED surgical lights.

The following is the meaning of this manual or the label on the outside of the equipment: Note The main content of the statement must be taken seriously.

High-impact resistant polycarbonate dome assembly with Aluminum material in IP54 protection class

[Product appearance structure]: MULTI-COLOR LED PLUS E700L, E500L



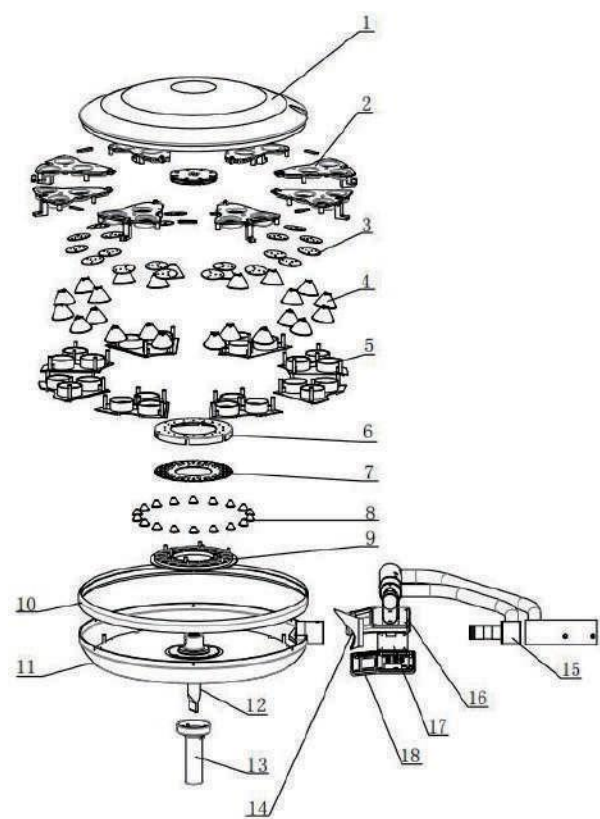
NO.1: LAMP HEAD, NO.2: BENDING ARM, NO.3: BALANCE ARM, NO.4: LAMP TUBES,
NO.5: LAMP BASE + WHEELS, NO.6: TOUCH KEYBOARD / LCD TOUCH SCREEN
NO.7: INTERNAL EMERGENCY BACKUP BATTERY

[Key technical indicators and reference data]

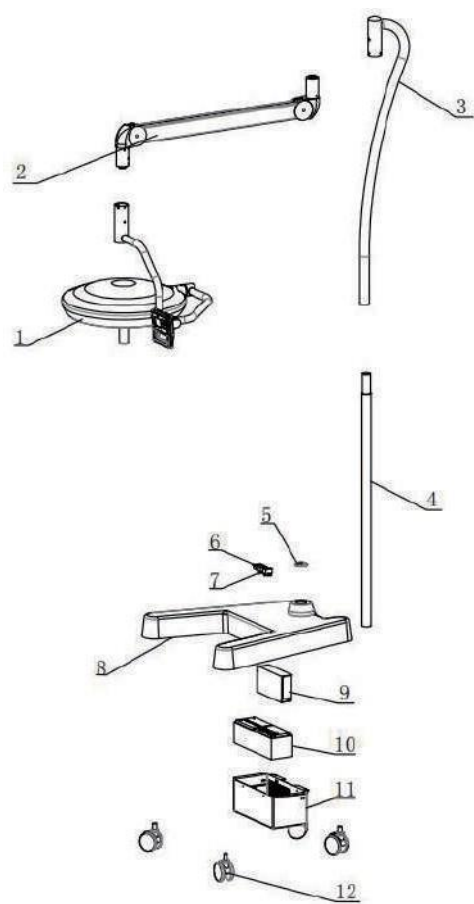
[Product Name] MICARE E700L, E500L MULTI-COLOR LED PLUS SURGICAL LIGHTS

Technical Details	E700L	E500L
Voltage	95V - 245V ~ , 50/60Hz	95V - 245V ~ , 50/60Hz
Illuminance at distance of 1m(LUX)	60,000 - 180.000LUX	40,000 - 160.000LUX
Control Of Light Intensity	0 - 100%Stepless Control	0 - 100%Stepless Control
Lamp Head Diameter	700MM	500MM
Quantity Of LEDS	66 PCS	42 PCS
Color Temperature Adjustable	3,500 - 5,700 K (Stepless Control)	3,500 - 5,700 K (Stepless Control)
Color Rendering Index RA	96	96
Color Rendering Index R9	98	98
Color Rendering Index R13	99	99
Focusable light field size	15-28CM	18-26CM
Total radiant flux density	364W/m2 - 5 0 0 W/ m²	364W/m2 - 5 0 0 W/ m²
Endoscopy Mode Ambients LEDS	Green + Red	Green + Red
Endoscopy Mode LEDS	18pcs	18pcs
LED service life	80,000Hrs	80,000Hrs
Main Material & Protection	Aluminum,IP54	Aluminum,IP54
Depth of illumination L1+L2 at 20%	1600	1500
Depth of illumination L1+L2 60%	850	800
Temperature increase in head area	1° C	
Arm Adjustment & Rotating Angle	UP+45° , Down-50° 1100MM360°	
Surgery Mode Choice In One Button	General Practice, Cardiac surgery, orthopedic surgery, urological surgery, Suficial Surgery, Deep Surgery	
Operating Element	Touch Panel(Standard)	
Dynamic Obstacle Compensation	Optional	
Synchronization Control	Optional	
4.3" LCD Touch Screen	Optional	
10" Wall Mounted Control	Optional	
Remote Wireless Control	Optional	
Back Up Battery (8-10hrs)	Optional	
Medical Uninterruptible Power Supply	Optional	
Internal/External Sony Camera (30X)	Optional	
Medical Monitor With Extra Arm	22" / 27" / 32"	

Product explosion diagram (E700L, E500L):



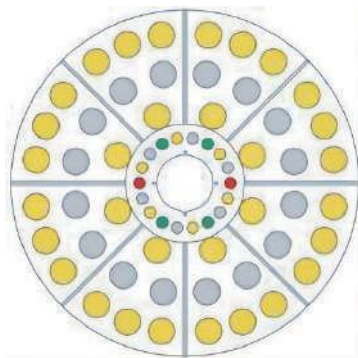
Product details	
No.1	lamp housing cover
No.2	Motherboard fixing plate
No.3	Aluminum plate
No.4	Lens $\phi 48$
No.5	Pressure Plate For Lens
No.6	Small lens mounting plate
No.7	Aluminum substrate for small lenses
No.8	Small lens $\phi 20$
No.9	Small lens mounting plate
No.10	Lamp retainer
No.11	Lamp housing
No.12	Dimming handle
No.13	Sterilization Handles
No.14	Silicone retainer
No.15	Bending tube
No.16	Back Cover For LCD Touch screen
No.17	Main board for LCD touch screen
No.18	Front Cover for LCD Touch screen



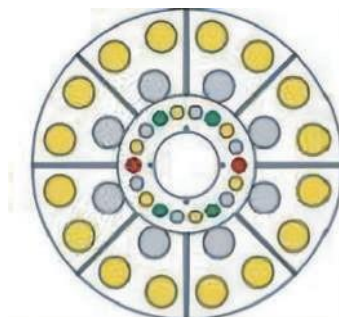
Product details	
No.1	LAMP HEAD 500
No.2	BALANCE ARM
No.3	Bend tube
No.4	Ascent tube
No.5	Sewing stop
No.6	Battery level display
No.7	Switch On / off
No.8	Lamp base
No.9	Power Supply
No.10	Emergency batteries
No.11	Battery box
No.12	Wheels with brakes

Driver fee:

The drive plate is the core of the entire LED work light controller, which is mainly composed of 108051 Dual-core ASIC IC micro controllers and 32-channel PT4115 DC regulator circuit, as well as TTL communication circuit. The 8051 Dual-core ASIC IC is a low-power micro controller manufactured by Macro Crystal Technologies. Its supply voltage is 5.5-3.8 V, which allows for low-power operation. It is suitable for many applications that require high integration and low cost, and can meet various performance requirements. All 175°C 8 hours high temperature baking guarantee high quality production.



E700 Layout Diagram



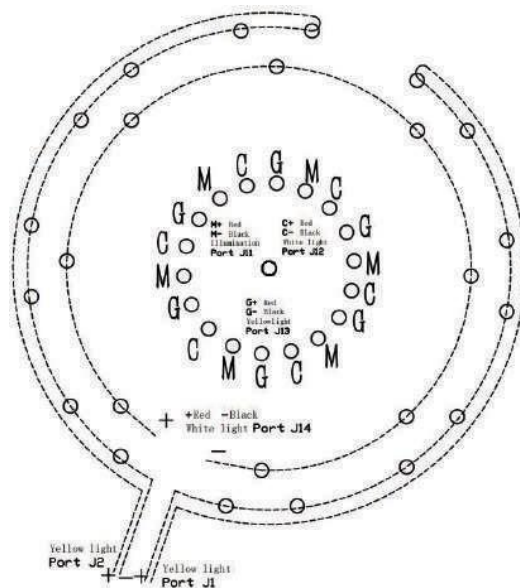
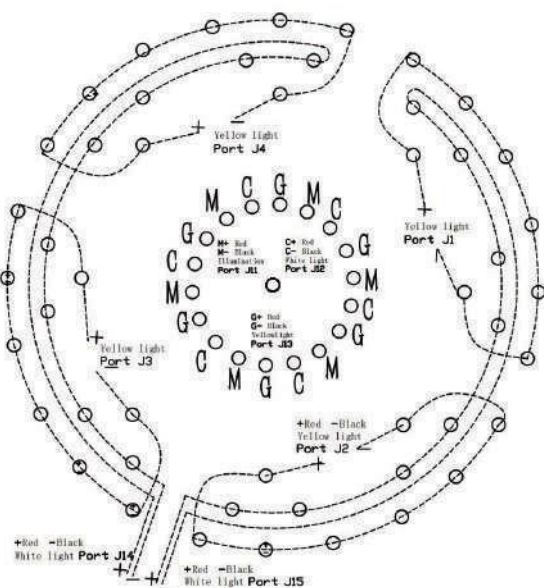
E500 Layout Diagram

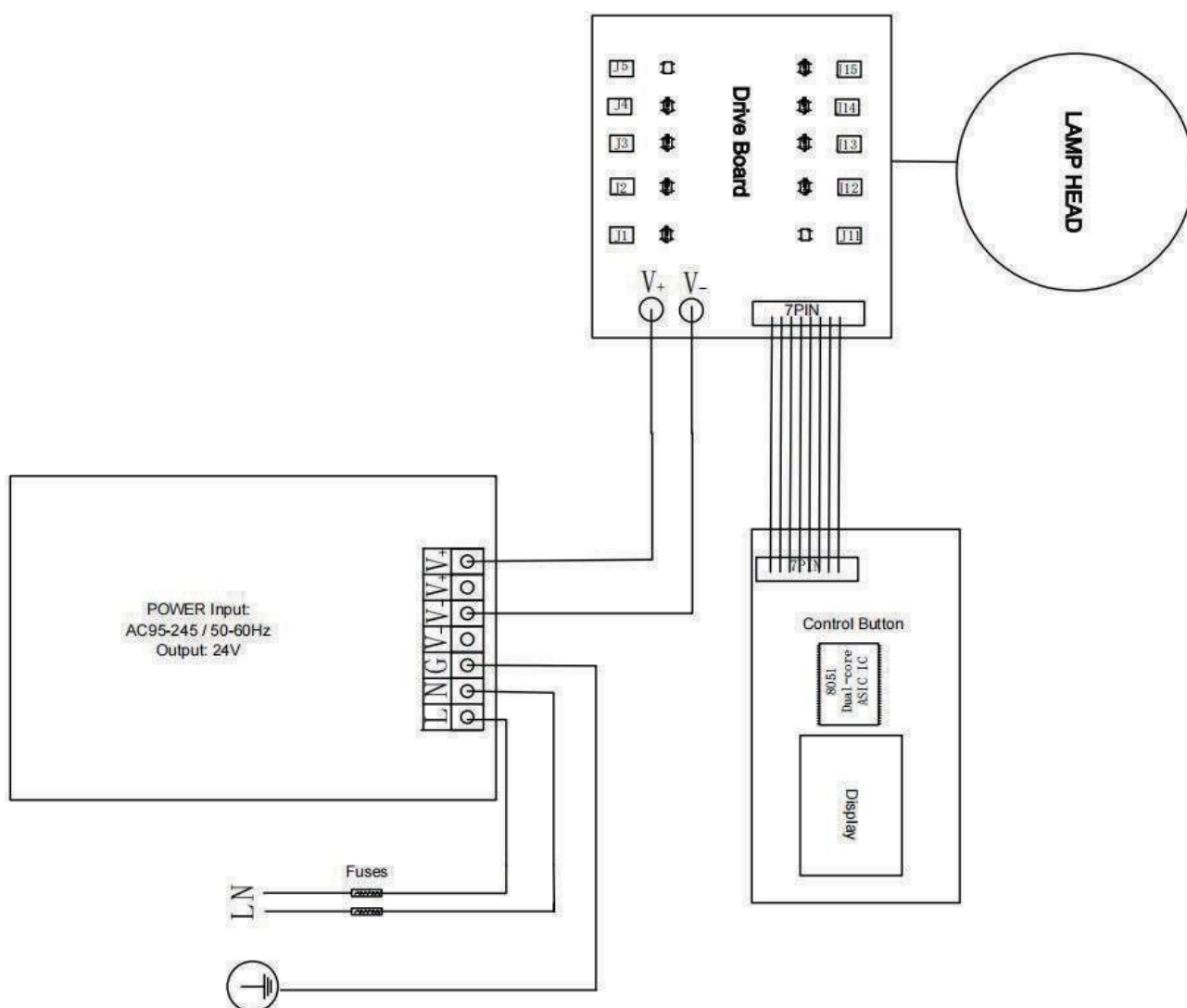
The PT4115 series micro controller is a single clock/machine cycle (1T) micro controller manufactured by STC. This is a new generation 8051 micro controller with high speed, high reliability, low power consumption and ruggedness

Interference protection. It uses eighth generation encryption technology with strong encryption, and the instruction code is fully compatible with traditional 8051, but the speed is 6-12 times faster. Internal built-in high-precision radio-controlled clock, temperature drift $\pm 1\%$, temperature drift at room temperature 5% , a wide range of 5-35 MHz can be set, completely avoiding expensive external crystal vibration. Internal high-reliability reset, 8 levels of optional reset threshold voltage, can completely eliminate the external reset circuit.

The PT4115 is a buck type constant current LED driver that can drive up to 81W white LEDs. The PT4115's input voltage can range from 6V to 30V, and the output current can be adjusted using an external sampling resistor. The output current can reach up to 1A. PT4115 can operate at high operating frequencies, up to 1MHz, which significantly saves peripheral device size and PCB battery. In addition, PT4115 supports two dimming modes: analog dimming mode and PWM mode. PT4115 is mainly used in MR16 lamp sockets, automotive LED lights and other LED lighting. Characteristics of the PT4115 chip: 1. Drive output current up to 1A; 2. High precision DC current; 3. System efficiency up to 98%.

Integration of high voltage MOS with 0.25 ohm resistance; Operating switching frequency up to 1 MHz; Equipped with analog / PWM dimming function. PT4115 chip is used for constant current with small current fluctuations, which can fully meet the requirement of surgical light



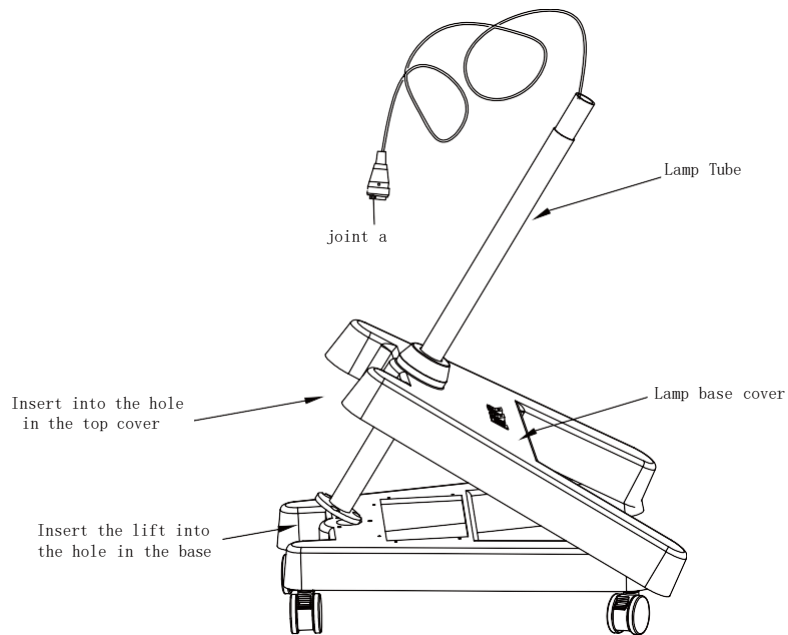


Electrical circuit diagram of LED work light (main and secondary lamps are the same)

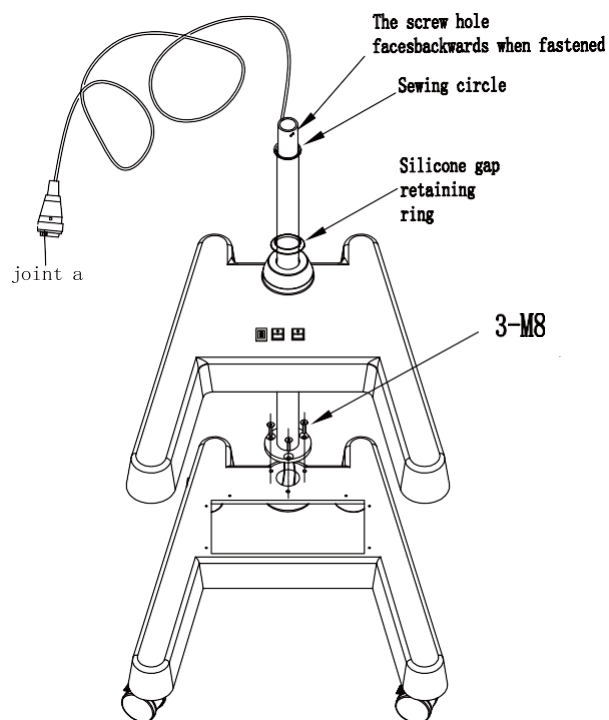
1. Installation and use

The surgical light is suspended from the ceiling of the operating room, with a standard installation height of 3m. Four M12 bolts should be embedded into the reinforced concrete ceiling (note: the diameter is Ø 240mm, divided into four parts at 360° in circumference), leaving the ceiling more than 150mm exposed to facilitate the installation of fixed plates and rotating base.

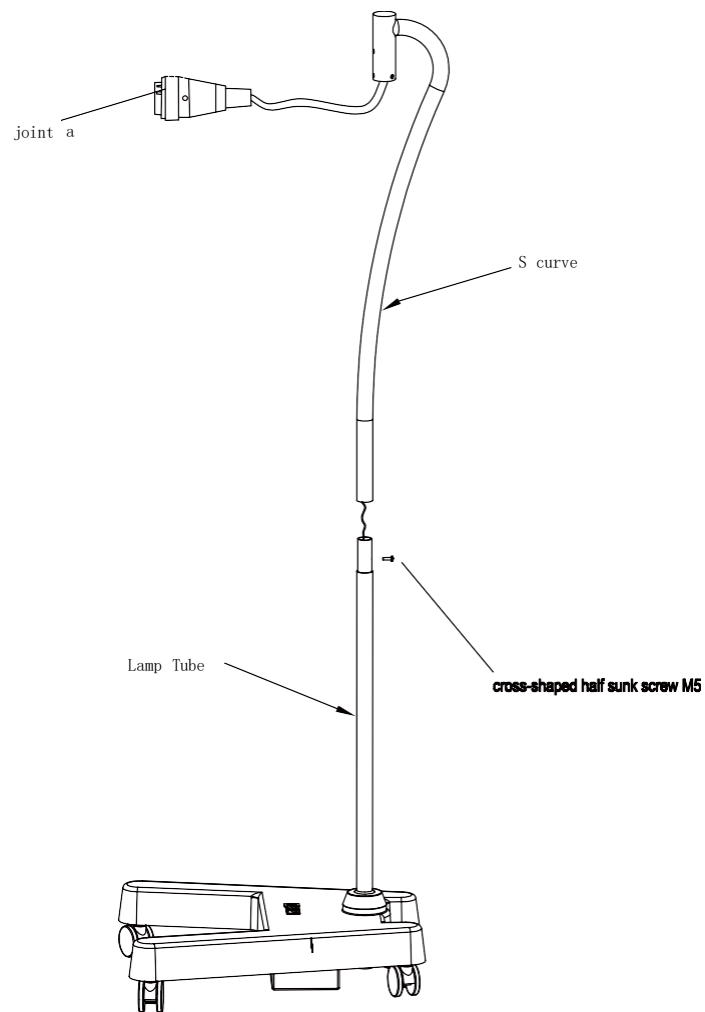
 Important reminder: The installation base of the surgical lamp must be firm and reliable, and must bear a load greater than 500 kilograms.



Fix the elevator chassis to the screw holes on the base with M8 screws (note that the screw holes on the top of the elevator face backwards), and then install the silicone gap retaining ring and the plastic gap retaining ring in turn..

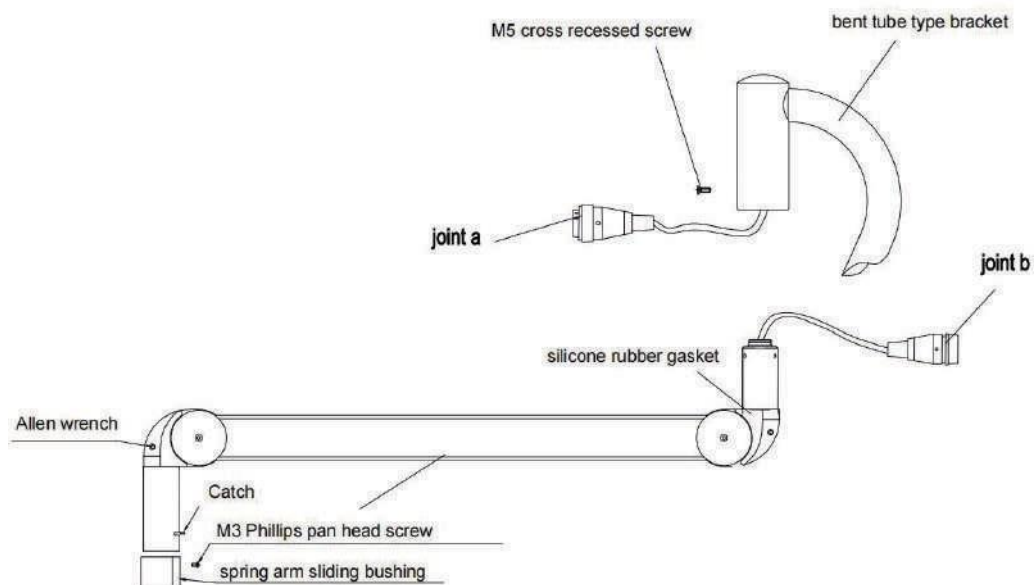


Connect the S tube to the vertical tube. Put the cable into the S tube, install the S tube into the inner hole and tighten it with M5 screws.



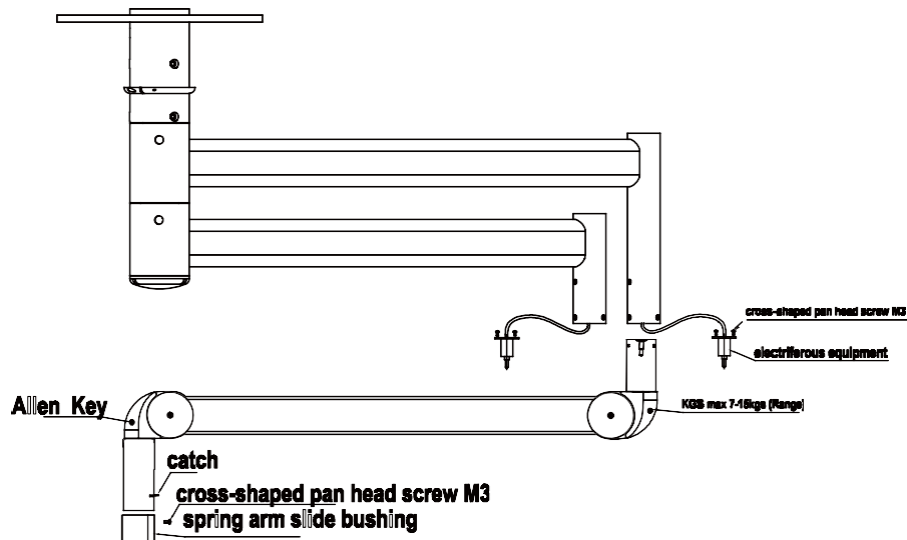
Connect the balance arm to the end of the S tube

Connect the joint ports a and b of the balance arm, then install the balance arm joint into the hole of the S tube and secure it with an M5 ground clamp.



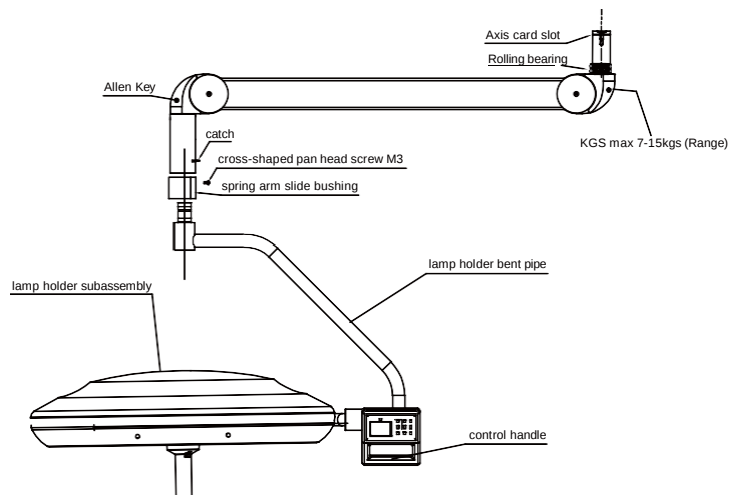
Installing the balance arm:

Align and tighten the aviation joint female head below the rotating arm with the aviation joint male head above the balance arm, then insert the upper end of the balance arm into the corresponding hole of the rotating arm and tighten it with cross groove half countersunk head screws M5



Take care:

Confirm that the type of balance arm to be installed is correct. Align the balance arm at one end of the spring clamp with the rotating arm, insert the aviation joint (male) on the balance arm into the aviation joint (female) on the rotating arm, and tighten the tightening nut. Install the balance arm into the rotating arm and tighten the M5 screw. (Pay attention to the direction of the balance arm) Pull out the balance arm aviation joint (male head) and insert it into the lamp head balance bend aviation joint (female head), tighten the nut, then install the balance arm into the corresponding connection hole of the lamp head bend, and tighten it with M5 screws. After installing the lamp head, remove the spring clip used for positioning on the balance arm, and then close the balance arm cover



Adjusting the spring force on the spring arms:

The spring arm has a spring to counteract the weight of the light head if the spring arm is depressed. If the light head does not stay in position, the spring force must be adjusted. Spring force so that the spring arm with light head stays where it is positioned.

1. Insert a size 5 hex head wrench into the hole.

provided (1).

- Move the spring arm to its highest position to relieve pressure on it.

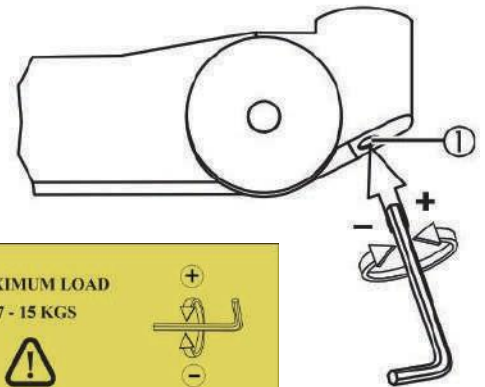
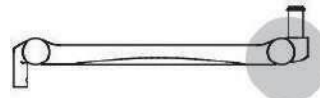
If the spring arm drops, the spring force is too low:

- Turn the size 5 hex head screw towards the + (counterclockwise).

If the spring arm rises, the spring force is too high:

- Turn the size 5 hex head screw towards the - (clockwise).

3. Perform functional test.



Adjusting the height stop on the spring arms:

When the unit leaves the factory, the spring arm's swing range in the horizontal plane is The swing range is set by default upward to approximately 45 degrees.

1. Insert a size 5 hex head wrench into the hole. provided (1).

- Pull down on the spring arm to take up the pressure. of the adjustment screw.

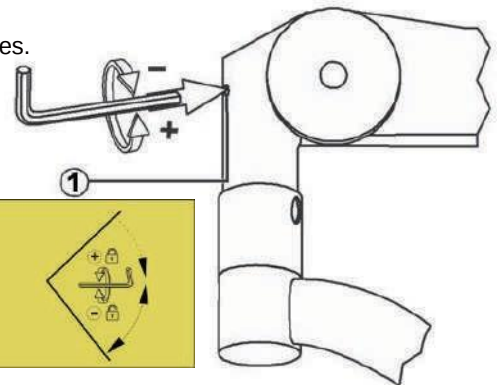
To reduce the upward swing range:

- Turn the size 5 hex head screw to the - (clockwise).

To increase the upward swing range:

- Turn the adjustment screw to + (counter-clockwise).

2. Perform functional test.

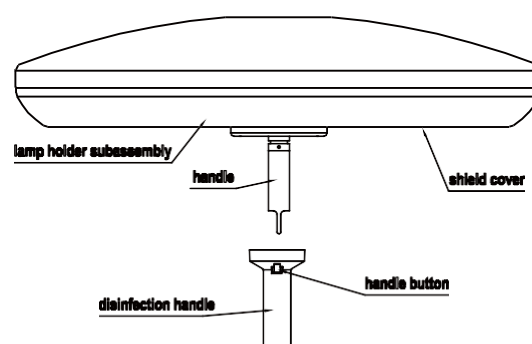


Warning :

If you want to disassemble the lamp head, please make sure to install the limit spring clip first to prevent accidents.

Take care:

During the installation process, avoid forcefully pulling on the circuit to avoid damage



Technical drawing of the lighting fixture showing dimensions and articulation. The drawing includes the following dimensions and features:

- Overall height: 2600 [102.36"]
- Height to the top of the fixture: 2300 [90.55"]
- Height to the bottom of the fixture: 2050 [80.70"]
- Height to the top of the fixture (excluding the base): 1500 [59.04"]
- Height to the bottom of the fixture (excluding the base): 600 [23.62"]
- Height to the bottom of the fixture (excluding the base): 550 [21.65"]
- Height to the bottom of the fixture (excluding the base): 270 [10.63"]
- Articulation angles: 50°, 360°, 330°, 270°

Make sure that the balance arm can rotate 360° around the axis of the rotating body and that the balance arm itself can swing up and down 40°. Make sure that the balance curve of the lamp head can rotate 360° around the lower axis of the balance arm

Make sure that the balance curve of the lamp head can rotate 360° around the lower axis of the balance arm.

Make sure that the curve of the lamp head can rotate 180° around the balance curve of the lamp head.

Make sure that the lamp head can rotate 180° around the curve of the lamp head.

Pull the control handle to move the lamp head up and down and rotate around the balance arm, and push the sterile handle to rotate the lamp head back and forth or left and right to ensure that the lamp head can remain stable in the desired position.

Turn on the power switch of the shadowless surgical lamp network to ensure that the lamp holder can be used normally. At this point, the control panel screen lights up and is in standby mode.

The on/off button has not been pressed for 30 seconds and the screen enters the screen saver mode.

Operating environment conditions

Transportation and storage:

Ambient temperature: -15° C ~ 60° C

Relative humidity: 10% ~ 85%

Atmospheric pressure: 500 - 1060 hPa

Working:

Ambient temperature: 10° C ~ 35° C

Relative humidity: 30% ~ 75%

Atmospheric pressure: 700 - 1060 hPa

Altitude ≤ 2000M.

Network power overvoltage category is Class II, and secondary circuit overvoltage category is Class I.

Pollution degree is 2.

This product should be installed and used in accordance with the electromagnetic compatibility (EMC) information given in this document.

Portable mobile radio frequency communication equipment may affect the normal operation of this equipment.

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COMPLIANCE WITH QUALITY STANDARDS:

QUALITY SYSTEM CERTIFICATION OF "NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD" certifies that the quality system developed by "NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD" for the design, implementation, sales, installation and after-sales service of surgical lights meets the requirements of the following international standards:

ISO13485:2016 / ISO9001:2015 / FDA Certify

EN60601-1-2:2015+A1:2020 / EN60601- 1:2006+A1:2013+AC:2014+A12:2014+A2:2020

EN 60601-2-41:2009 + A11:2011+A1:2015 / EN ISO20417:2021, EN ISO15223-1:2021, EN ISO14971:2019

Annex II + III of Regulation (EU) 2017/745 Compliance with the requirement of the European Directive

IEC 60601-1:2005 + A1:2012 + A2:2020& EN 60601-1:2006 + A1:2013 + A2:2021

IEC 60601-1 Clause 14 PEMS + Software Evaluation

IEC 60601-2-41:2021 EN IEC 60601-2-41:2021+CSA C22.2 NO. 60601-2-41:23

IEC 62471:2006 EN 62471:2008 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 62366-1:2015 + A1:2020

EN 60601-1-6:2010 + A1:2015 + A2:2021 EN 62366-1:2015 + A1:2020+CAN/CSA C22.2 No. 60601-1-6

LED SURGICAL LIGHT

(PORTABLE FLOOR TYPE)



Model E700L

UDI-DI: 06975899060043

SN #08192301

 2023-08



Caution



**Follow
instruction
for use**



**BF
Applied
part**



110 / 220 V

50/60 Hz

MD



Manufacturer by:

NANCHANG MICARE MEDICAL
EQUIPMENT CO.,LTD
NO.666 YAOHU WEST 5TH ROAD, HI-
TECH ZONE, NANCHANG, CHINA

EC REP

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Email: ec.rep@sungogroup.com

CLEANING / DISINFECTION / STERILIZATION:

Users should contact the healthcare specialists at their hospital. Recommended products and procedures should be applied. If there is any doubt about the compatibility of the active agents to be used, please contact "NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD".

CLEANING AND DISINFECTION OF SURGICAL LAMPS

Make sure the power is off and the lamp has cooled before beginning cleaning.

Make sure the power is off and the lamp has cooled before beginning cleaning.

- 1) Remove the sterilization handles.
- 2) Wipe the equipment with a cloth moistened with a surface cleaner. Follow the manufacturer's recommendations for dilution, application time and temperature.
- 3) Use a cloth to rinse the unit with clean water and dry.
- 4) Wipe evenly with a cloth moistened with disinfectant. Follow the manufacturer's recommendations.
- 5) Remove residue (particularly products containing aldehydes, quaternary ammonium or surfactants) by wiping with a cloth moistened with clean water.
- 6) Wipe with a dry cloth.

Make sure that no liquid residue remains on the device after cleaning.

The lens system (front glass) is made of high quality clear acrylic:

Please pay attention to the following when cleaning:

Never wipe the lens system with a dry cloth (always wipe with a wet/damp cloth).

- 1) Do not use alcohol disinfectants.
- 2) In addition, the following disinfectants can be used to clean the lens.
- 3) Accelerated hydrogen peroxide 0.5%
- 4) Hospital Cleaner disinfectant wipes with bleach
- 5) Disinfectant wipes with bleach
- 6) Wipe the lens system after cleaning with an antistatic, non-fluffy cloth.

WARNING:

- 1) Solutions containing glutaraldehyde, phenol, iodine, bleach, alcohol or chloride ions should not be used.
- 2) Fumigation methods are not suitable for disinfecting the unit and should not be used.

Handle cleaning and sterilization.:

BEFORE CLEANING:

- 1) Use a soft cloth immediately after use to wipe off any dirt on the surface of the handle.
- 2) Store the handles in a place that keeps them moist for easy cleaning later.
- 3) Be careful to store them so that the inside does not get dirty.

CLEANING:

- 1) Soak the handles in a detergent solution.
- 2) Soak for 15 minutes to allow the solution to work, then clean by hand with a soft brush and lint-free cloth.
- 3) During cleaning, periodically check that the handles are completely clean and that no dirt remains on the inside or outside.
- 4) If dirt still remains, repeat cleaning or use an ultrasonic cleaning process.
- 5) Rinse: Rinse thoroughly with clean water to completely remove the detergent solution.

Dry: Wipe with a clean, lint-free cloth.

DISINFECTION:

Handles can be machine sanitized (NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD) and rinsed at a maximum temperature of 93° .

Typical recommended cycles:

Scenery	Temperature	Time
Pre-cleaning	18-35°C	60 Seconds
Cleaning	46-50°C	5 Minutes
Neutralizer	41-43°C	30 Seconds
Cleaning 2	24-28°C	30 Seconds
Rinse	92-93°C	10 Minutes
Dry	No Applicable	20 Minutes

STERILIZATION:

After cleaning, the handles should be steam sterilized as follows:

Countries	Sterilization cycle	Temperature (°C)	Time (Min.)	Drying (Min.)
USA & Canada	Pre-vacuum	132-135	10	16
France	ATNC (prion)	134	18	
Other Countries	Pre-vacuum	Comply with national regulations		

To ensure the sterilization effect, be careful not to leave any stains inside the handle.

According to the above sterilization parameters, the PSX sterilizable handle will no longer guarantee sterility after 50 Times.

It should be disposed of in the same way as other hospital risk products.

- 1) Check that each handle is clean before continuing with the process.
- 2) Wrap the handles with sterilization wrapping material (double wrap or equivalent). The handles
- 3) can also be placed in paper or plastic sterilization bags 2, to facilitate their identification and reuse.
- 4) Place the handles on sterilization trays with the opening facing down.3
- 5) Pack with biological and/or chemical indicators to monitor the sterilization process, in accordance with current regulations.
- 6) Run the sterilization cycle according to the instructions of the sterilization product manufacturer

Safety and maintenance instructions

Safety tips



Only authorized facility service personnel should troubleshoot the unit. Troubleshooting by unauthorized personnel may result in personal injury or property damage.



Only authorized facility service personnel should troubleshoot the unit. Troubleshooting by unauthorized personnel may result in personal injury and/or property damage..



After completing a repair to the unit, make sure it is in proper working condition. Failure to do so could result in personal injury or property damage.



Do not touch the LEDs or lenses directly. Body oils can significantly reduce the optical performance of these parts and may cause damage to the equipment.



Follow the product manufacturer's instructions. Failure to do so may result in personal injury and/or property damage.



If the unit fails any of the preventive maintenance functional checks, have it repaired before using it on any patient. Failure to do so may result in personal injury or property damage.



Do not use harsh cleaners, solvents or detergents. Doing so may damage the equipment.



Do not use silicone-based lubricants. Damage to the equipment may occur.



Turn off the appliance or unplug the power cord before beginning any repairs. Failure to do so could result in personal injury or property damage.



Do not pinch any wires during installation or any repairs. Pinched wires can cause a risk of electric shock, which may result in personal injury or property damage.



Do not pinch any wires during installation or any repairs. Pinched wires can cause a risk of electric shock, which may result in personal injury or property damage.



Do not place objects or liquids on the lamp head. Spilled liquids will damage the lamp head and arms, resulting in a risk of electric shock.

Light intensity control

Description::

The surgical light control terminal is equipped with a 4.3-inch resistance touch screen with a resolution of up to 480 x 272. The man-machine interface can realize the control functions of LED lamp and HD camera. The operation is simple and convenient, and the performance is stable and reliable.

Product characteristics:

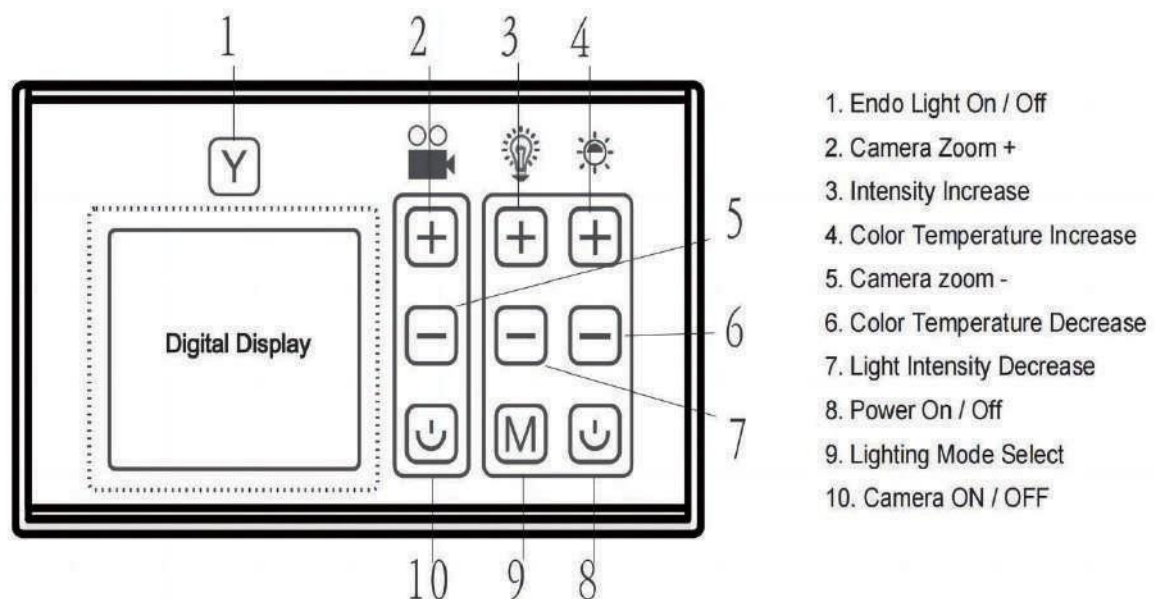
Closed head with smooth external surface, no edges, no screws, no gaps, for easy cleaning and disinfection. Smooth surface design for hygiene with electronic control panel for switching on, off, increasing and decreasing adjustable light intensity. Control keyboard on the dome for parameter adjustment.

- 1) Switching the dome on and off.
- 2) Increasing and decreasing the light intensity in a range of 0 to 100 percent.
- 3) Adjusting the diameter of the illuminated field.

Classified degree of protection against ingress of water: IPX2

HD camera and LED surgical light can be controlled by a simple touch.

Intelligent compensation technology: When the operator shades a part of the Surgical lamp, the brightness of other areas is automatically enhanced to ensure the brightness of the operating field. This function needs to be equipped with our company's supporting constant current source board. Automatic control, mutual control and equal control can be realized between the child and mother lamps, and the brightness, color temperature and light spot adjustment can be realized according to different operation requirements. The infrared remote control can adjust the brightness of the surgical lamp, color temperature, camera. PWM step less dimming The illumination of the surgical lamp is digitally adjusted to achieve smooth dimming without poles.



VERSION FOR TOUCH PANEL (STANDARD)

One-key Cavity Endo lighting.

The control panel supports four illumination modes: endoscope, deep cavity, superficial and normal, to meet different surgical illumination requirements. It also supports one-key cavity quick switching adjustment for endoscopy mode. Perfectly compatible with laminar flow, generating turbulence less than 20% according to DIN1946-4 regulations.



VERSION FOR LCD TOUCH SCREEN / WALL MOUNTED CONTROL (OPTIONAL)

LED Surgical lamp switch:

Click the button to turn on or off the Surgical lamp, and the control board remembers the Surgical lamp switch status. The next power-on will maintain the switch status before the last power off.



After the control terminal of the LED surgical light is turned on, the lamp control interface will be entered by default, which can adjust the switch, light intensity, color temperature, spot size field diameter
Endoscopy position of main lamp cavity, red and green balance switch and synchronous control switch of main lamp and auxiliary lamp

The keys	Instructions
 	When the lighting mode is normal, you can adjust the brightness from 10% to 100%. This button is not available when the lighting mode is deep cavity or shallow surface. When the lighting mode is mirror mode, click this button to switch to normal mode.

The key state	Details
	Turn on the surgical light, 2 lamp heads synchronize control in all functions. All the tap ICONS are green and adjustable



LED surgical lamp closed, do not operate the lights, synchronous control switch and equipment adjustment. All faucet ICONS are gray and cannot be tuned

Take care:

Surgery completed: Turn off the surgical lamp, then turn off the power, and move the surgical lamp to a fixed position. Touch screen is a resistive screen. Please do not spray alcohol or disinfectant directly on the screen to prevent liquid ingress and multi-function.

Warning:

After the surgery, the lamp head should be pushed up to avoid injury to the head of personnel passing through the surgical lamp head.

Warning:

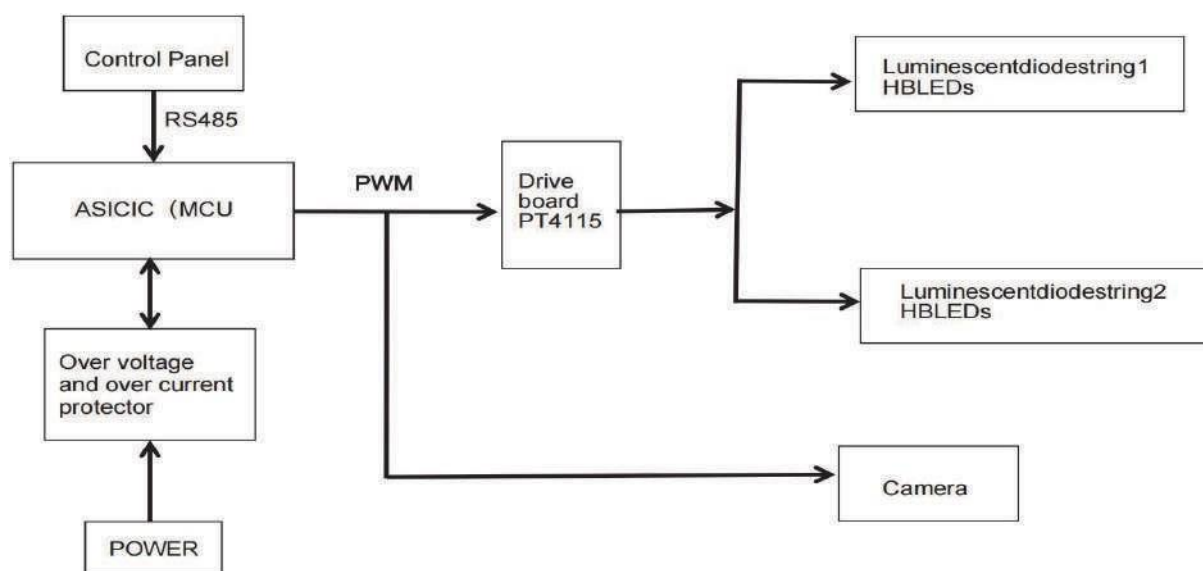
When adjusting the lamp head, the control handle or sterile handle on the control box can be manually pushed and pulled to avoid collision and interference between the lamp head or lamp arm (rotating arm, balance arm) and other structural components during the adjustment process.

Important:

During the surgery, in order to avoid cross infection and facilitate disinfection in the later stage, the angle of the lamp head should be adjusted as much as possible through a sterile handle.

Take care:

Press the buttons on the control panel with excessive force to prevent damage and loss of control



Adjusting the camera zoom:

The keys	Instructions
	The button for 1X to 30X adjustable camera zoom changes widely, it should be optional with the camera function

Color temperature adjustment:

The keys	Instructions
	The lighting mode is normal and shallow, which can adjust the color. Temperature 3,500 -5,700 K. The parameters of the faucet in the two modes. It can be remembered separately. When the lighting mode is mirror mode, click this button to switch to normal mode. This button is not available when the lighting mode is deep cavity.

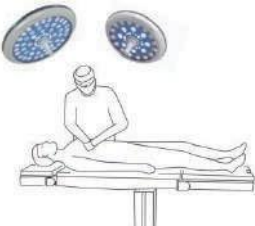
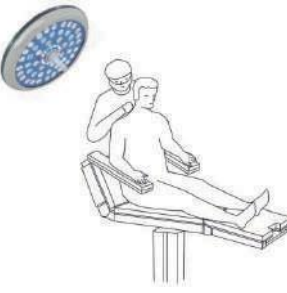
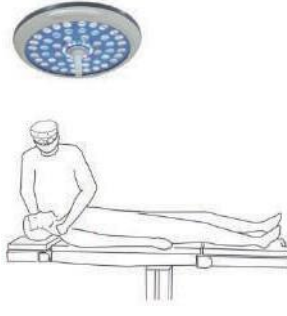
Endoscopic Mode Setting:

The keys	Instructions
	When the lighting mode is normal, surface mode and deep cavity mode, it can be switched to cavity endoscopy mode with one click. At this time, the brightness, light spot and color temperature ICONS are gray and cannot be adjusted, as shown in the photo. When the lighting mode is cavity mirror mode, click this button to adjust the cavity endoscopy mode positions.
	When the lighting mode is normal, surface mode and deep cavity mode, it can be switched to cavity endoscopy mode with one click. At this time, the brightness, light spot and color temperature ICONS are gray and cannot be adjusted, as shown in the photo. When the lighting mode is cavity mirror mode, click this button to adjust the cavity endoscopy mode positions.

Light Setting For Different Surgery:

Application	Urology/ Gynecology	General Practive	Orthopedics	Superficial surgery	Deep surface surgery	Heart surgery
Illumination	70%	0-100%	50%	50%	90%	100%
TK (Color Temperature)	4,600K	3,500K - 5,700K	5,100K	5,300K	4,300K	3,900K
Symbol						

Position Prepare for different surgeries:

Example of a surgical station	Surgery
	Urological surgery, Transplant surgery, Gynecological surgery, Obstetric surgery.
	General surgery, abdominal surgery, Gastroenterological surgery, thoracic surgery.
	Anorectal surgery
	Neurosurgery
	Plastic and reconstructive surgery, Frontal facial skin graft surgery Dental surgery
	Otorhinolaryngologic surgery, eye surgery Dermatologic surgery.

Interface switch tab:

In the control interface of lamp holder 1, you can switch to the control interface of lamp holder 2, camera Control interface and setting interface through the interface switching tab

Wall Mounted control /Remote Control interface -- Optional:



Optional LED surgical lights with 10 inch remote control (LCD touch screen), wall-mounted installation supported, function supported for light intensity control, color temperature control, camera zoom control, lighting mode (general practice, surface, deep surgery and endoscopy), with green and red LED balance control separately

Uninterruptible Power Supply (UPS) -- Optional:

- 1) Medical grade, built-in or inter-built with 1.5-2hours or more backup time.
- 2) 100% battery recharge time, maximum 4-6HRS
- 3) Over current protection device/battery power display/low battery alarm
Setting / LCD display
- 4) Output 2 5-R15 interfaces, American / UK/ European standard 2M grounded power cord, output 2 USB interfaces, 2 RS232 communication port
- 5) The host shell is made of fireproof material.



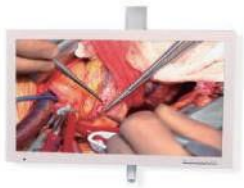
Emergency battery backup -- Optional:

- 1) Over voltage detection
- 2) Low voltage detection
- 3) Discharge over current detection
- 4) Short circuit detection
- 5) Digital battery power display
- 6) Life cycle: 800 cycles (charge/discharge)
- 7) Battery working time: 8-10 hours supply for surgical lights
- 8) Battery charging time: 4.5 hours to 100% power



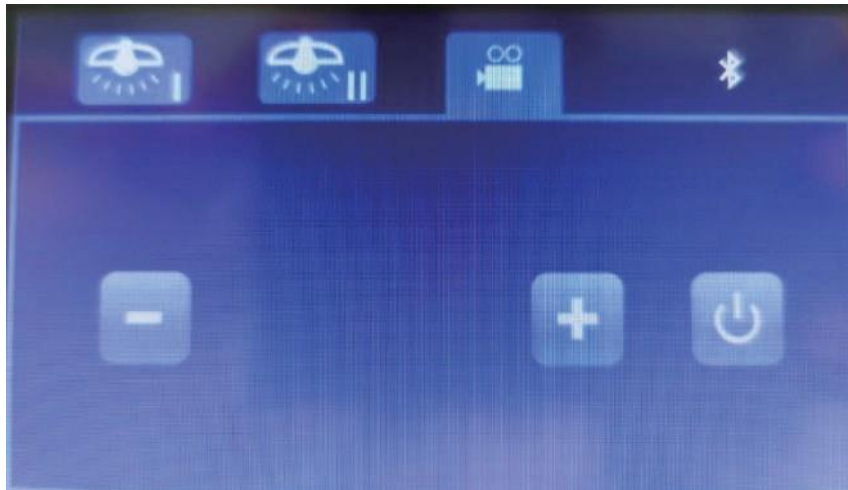
Sony 30X Internal Camera + 22inch / 27Inches Monitor
optional (HD or 4K resolution): 1920*1080P or 3840*2160P -- Optional :



medical monitor	Medical grade display, standard up to 22" for images and video data. 22"/ 27" / 32" For option	
Sony 30x CMOS 1/3" Camera (1920*1080P HD / 3840*2160P 4K)	Integrated SD or HD camera Polaris: Provides a direct view of the operating field with optimal exposure. Replaces the central handle and includes a picture rotation as well as an adjustment for the illumination radius.	
Remote camera control	Intuitive control panel, Wall panel Handles on the lamp head Remote control independent of the light source.	

Product Waste Treatment Requirements:
 About the waste treatment of products, customers should refer to the current environmental standards and local laws with regulations

Camera control page:



The control terminal of the LED surgical lamp can enter the camera control interface through the interface switching TAB, which can adjust the camera focus, zoom, resolution, freeze/thaw of the camera. image, white balance and image inversion parameters

The keys	Instructions
	Press the button and the camera keeps zooming in Lift the button and the camera doubles to stop
	Press the button and the camera keeps doubling and shrinking Lift the button and the camera doubles to stop

Troubleshooting:

If you encounter problems using the MULTI-COLOR LED PLUS surgical lights, please review the following chart. Find the fault and complete the recommended solution. If the fault is not found or the solution does not correct the problem, Contact with “NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD”

Fall	Recommended Solution
The red emergency light indicator is "On"	• Turn off the emergency switch to cancel Emergency By-Pass mode • If one or two LED modules stop working, the fuse may be blown and will need to be replaced by a qualified technician.
One button Mylar main controller has stopped working	• Mylar driver may need to be replaced.
One button on wall Mylar controller has stopped working	• The Mylar wall controller may need to be replaced.
The lamp is drifting	Tighten the exposed screws on the yokes or center shaft using a 3/8" flat head screwdriver.
The glass is dirty	• Follow the procedure "Operation: Cleaning the MICARE Surgical Light"
An LED does not work	• The capsule must be replaced by a qualified technician.

Environmental conditions:

Operation:

	MIN	MAX
Temperature	+10°C	+35°C
Relative atmospheric humidity	30%	75%
Air pressure	700 hPa	1060 hPa

Transportation / Storage:

	MIN	MAX
Temperature	-10°C	+60°C
Relative atmospheric humidity	10%	85%
Air pressure	500 hPa	1060 hPa

References on the package:



- 1)Temperature range for transportation and storage
- 2)Atmospheric humidity for transport and storage
- 3)Air pressure for transportation and storage

Electromagnetic compliance data for the MULTI-COLOR LED PLUS series:

Guidance and manufacturer's declaration: electromagnetic immunity

The equipment or system is intended for use in the electromagnetic environment specified below. The client or The user of the equipment or system must ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment - Orientation
Electromagnetic environment - Orientation	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The floors must be made of wood, concrete or tiles ceramic. If the floors are covered with synthetic material, The relative humidity should be at least 30%.
Fast electrical transients/bursts IEC 61000-4-4	±2 kV for power lines energy supply ±1 kV for power lines entrance exit	±1 kV for power lines ±0.250 kV for input/output lines	The quality of the electrical network should be that of a commercial environment or typical hospitable.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to ground	±1 kV line(s) to line(s) ±2 kV line(s) to ground	The quality of the electrical network must be that of a commercial environment or typical hospitable.
Voltage dips, short interruptions and voltage variations on the input lines of the power supply IEC 61000-4-11	<5% UT (>95% drop in UT) for 0.5 cycles 40% UT (60% drop in UT) for 5 cycles 70%UT (30% drop in UT) for 25 cycles <5% UT (>95% drop in UT) for 5 s	<5% UT (>95% drop in UT) for 0.5 cycles 40% UT (60% drop in UT) for 5 cycles 70%UT (30% drop in UT) for 25 cycles <5% UT (>95% drop in UT) for 5 s	The quality of the electrical network must be that of a commercial or hospital environment typical. If the user of the equipment or system requires continuous operation during power grid outages, recommends that the equipment or system is powered by a power supply uninterrupted or a battery.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	3 amps per minute	Does not apply	Electric Frequency Magnetic Fields should be at levels characteristic of a commercial environment or typical hospitable.

Electromagnetic Compliance Data for MULTI-COLOR LED PLUS Series:

Guidance and manufacturer's declaration: electromagnetic immunity

The ME EQUIPMENT or ME SYSTEM is intended for use in the electromagnetic environment specified below. The customer or user of the ME EQUIPMENT or ME SYSTEM must ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ME EQUIPMENT or ME SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$

			800 MHz to 2,5 GHz 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: 
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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, land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts cannot be predicted accurately. To evaluate the electromagnetic environment of fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the ME EQUIPMENT or ME SYSTEM is used exceeds the applicable RF compliance level above, the ME EQUIPMENT or ME SYSTEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ME EQUIPMENT or ME SYSTEM.

B. In the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic Compliance Data for MULTI-COLOR LED PLUS Series

Recommended separation distances between portable and mobile RF communications equipment and the equipment or system

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

Rated maximum output power of Transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d=1.2\sqrt{P}$	$d=1.2\sqrt{P}$	$d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

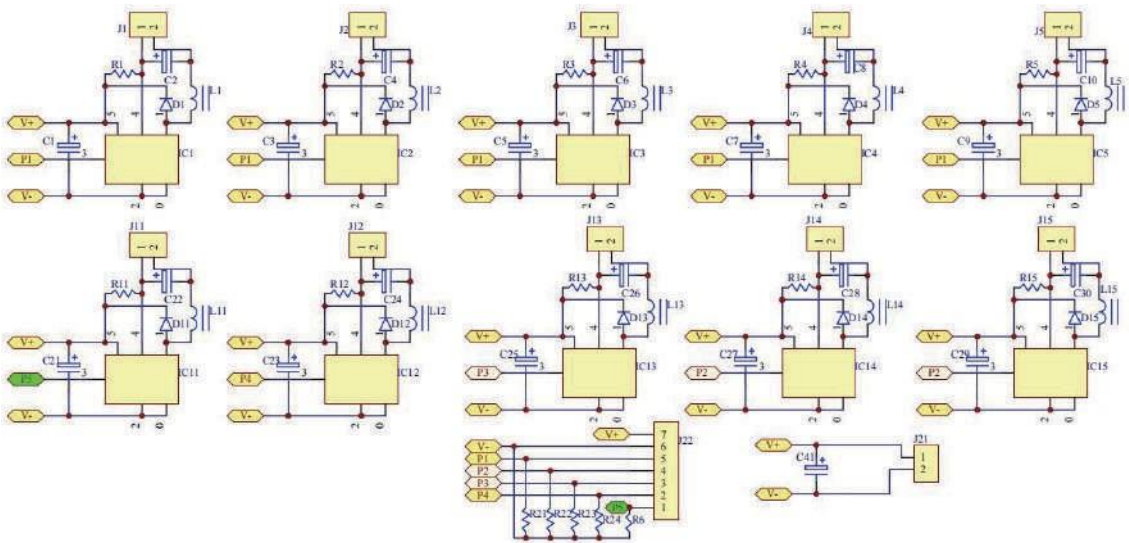
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

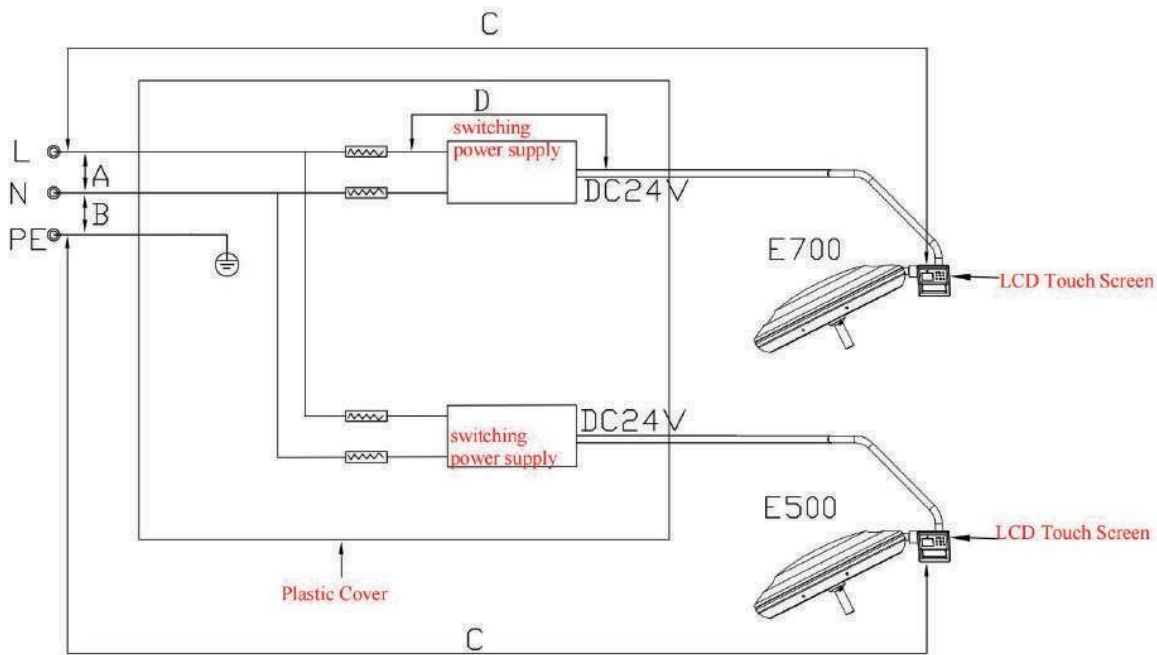
Elimination:

- 1. The surgical light does not contain any hazardous materials.
- 2. Surgical light components should be disposed of properly at the end of their useful life.
- 3. Make sure materials are separated carefully.
- 4. Electrical conductive plates should be sent to an appropriate recycling facility.
- 5. The rest of the components must be disposed of using the methods applicable to the materials they contain.

Safe use period.:



ISOLATED DIAGRAM OF LED SURGICAL LAMP:



Dielectric strength				
Area	Position	Insulation type	Reference Voltage	Test voltage (V)
A	Between L and N	1MOOP	AC220	AC1500
B	Between mains power and grounded housing	1MOOP	AC220	AC1500
C	Between mains power and ungrounded housing	2MOOP	AC220	AC3000
D	Between the primary and secondary of the switching power supply	2MOOP	AC220	AC3000
Note: 1MOOP: Basic insulation; 2MOOP: Double insulation				

Warranty Policy - Surgical Lamps:

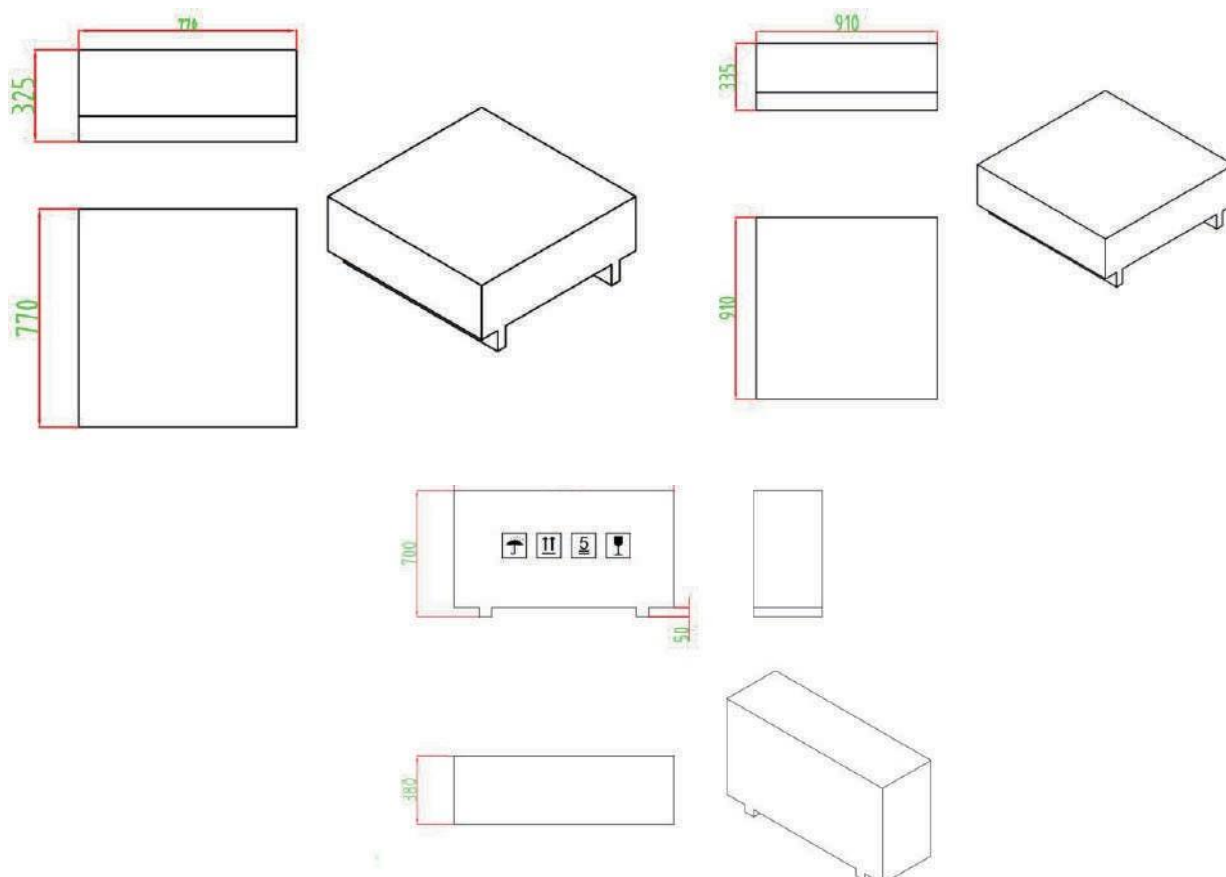
NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD. will guarantee its manufactured equipment for up to One (1) years from the date of installation. NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD warranty will not cover any disposable, sterilizable or single-use products.

E700, E500 series surgical light heads are warranted against defects for One (1) year from the date of installation.

This warranty is valid only when the equipment has been installed correctly as described in the specifications of NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD The validity of this warranty also depends on the proper use and timely maintenance of our equipment in accordance with the recommendations of NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD. does not cover damage resulting from failure to ship, accident, misuse, abuse, neglect, mishandling, alteration, misapplication, or damage that can be attributed to acts of God.

NANCHANG MICARE MEDICAL EQUIPMENT CO.,LTD shall not be liable for incidental or consequential damages resulting from the use or misuse of the equipment.

Drawing of plywood boxes:



Packing List (Portable Mobile Type)
Model Number: E700L, E500L

Series Number	Name	Quantity
1	Lamp Base+ 4Wheels + Brakes	1 Set
2	Suspension Tube	1 set
3	Balance Arm	1 pc
4	Lamp Pipe	1 set
5	Self-tapping screws ST3X8	6 pcs
6	Expansion screw M12	4 pcs
7	Sterilization Handles	3 pcs
8	Dimming torch	1 pc
9	User Manual	1 Pc
10	Fuses	1 Pc
11	Phillips screwdriver	1 Pc
12	M3 hexagon wrench	1 Pc
13	Round head screw M5X8	2 Pcs
14	Gap retaining ring	1 pc
15	Silicone Seam Ring	1 pc