HyLED C50 Vet

HyLED C50/C50 Vet

LED Surgical Lights

Operator's Manual

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- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray Animal Medical authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements;
- the product is used in accordance with the instructions for use.

WARNING

- **This equipment must be operated by skilled/trained clinical professionals.**
- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

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Mindray Animal Medical's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the device or the use of parts or accessories not approved by Mindray Animal Medical or repairs by people other than Mindray Animal Medical authorized personnel.

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- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
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- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

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Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures animal and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to perform daily operations of the product, maintain and troubleshoot the product and learn how to use the product.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your equipment.

Conventions

- ***Italic text*** is used in this manual to quote the referenced chapters or sections.
- ***Bold text*** is used to indicate the screen texts.
- → is used to indicate operational procedures.

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Contents

1 Safety

1.1 Safety Information

WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 Warning

WARNING

- **The equipment is to be used for its intended purposes only. Do not use it for other purposes.**
- **The equipment is to be installed by personnel authorized by Mindray Animal Medical only.**
- **The equipment is to be operated by trained personnel only.**
- **Before using the equipment, be sure to read and fully understand this manual.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **To avoid the risk of electric shock, the equipment must only be connected to a mains supply with protective earth.**
- **When installing the surgical light, make sure that it is connected to a switch that can shut off the mains supply. This switch is not included in the surgical light.**

- **Do not use the LED surgical lights in an MRI environment.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.**
- **Use and store the equipment within the specified temperature, humidity, and atmospheric pressure.**
- **Before putting the equipment into operation, the user must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **Do not touch the animal and live parts simultaneously. Otherwise, injury may occur.**
- **Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact Mindray Animal Medical.**
- **Be sure to operate the equipment as instructed in this manual. Warranty does not cover damage caused by non-compliance.**
- **Device service or maintenance should be completed by the authorized personnel only. Warranty does not cover damage caused by unapproved service or maintenance.**
- **Before maintaining or servicing the surgical light, be sure to shut off the mains supply first.**
- **Be sure to only use accessories made by Mindray Animal Medical. Accessories produced by other manufacturers must not be used as they may cause personal injury. If accessories of other manufacturers must be used, their use should be expressly permitted by Mindray Animal Medical.**
- **Before using accessories, be sure to read the operator's manual thoroughly.**
- **Do not open the equipment housings.**
- **No modification of this device is allowed.**
- **Do not use agents containing alcohol where high-frequency equipment is being used. Neglect of this may cause fire hazard.**
- **There may be a risk of infection if the surgical light is under the complicated and changeable medical conditions. Follow the hospital requirements and refer to "Cleaning and Disinfection" chapter to clean/disinfect the surgical light.**

- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the local regulations. If you have any questions concerning disposal of the equipment, please contact Mindray Animal Medical.**
- **For disposal of parts and accessories, unless otherwise specified, follow local regulations regarding disposal of hospital waste.**
- **Dispose of the package material as per the applicable waste control regulations. Keep it out of children's reach.**
- **Make sure the electrical installation of building complies with the requirements of IEC 60364-7-710.**
- **When moving the surgical light, be aware that your view of the area you are moving to may be obscured by the surgical light. Carelessness when moving the unit can result in personal injury and/or device damage.**
- **When moving the lighthead, avoid collisions among the lighthead, arms (both swivel arms and spring arms), and other devices or parts, which may cause personal injury and/or property damage.**
- **Do not place objects on the lightheads or the arms. Otherwise, these objects may fall off and cause personal injury and/or property damage.**
- **Do not direct the light source towards animal eyes. Otherwise, it may cause personal injury.**
- **Long-time exposure to the light source may cause eye fatigue. Be sure to select a proper illuminance level for long-time surgeries.**
- **Be sure to adjust the illuminance level based on the needs of the operation. Note that there is a risk of too much heat in the operating field by overlapping the light fields of several lightheads, in which case the surgical light system may exceed a total irradiance of 1000 W/m^2.**
- **After each sterilization and before each new use of the sterilizable handle, be sure to check if it has any sign of wear, such as cracking and color fading, and install it correctly until it clicks.**
- **The optional camera assembly is applicable only to auxiliary teaching and medical training, and it cannot be used for medical diagnosis.**
- **Before connecting any equipment to the surgical light, make sure the equipment is suitable for use within the patient environment.**
- **If an LED card is defective, be sure to contact the customer service department authorized by Mindray Animal Medical.**
- **The surgical light may be used together with other manufacturers' devices (e.g. displays). Be sure to refer to each manufacturer's instructions for how to use the device.**

1.1.2 Caution

CAUTION

- **Exercise caution when transporting or moving the equipment. Do not damage it during transportation or movement.**
- **Always install or carry the equipment or accessories properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
- **Check the screws for components and parts regularly to prevent them falling off.**
- **Be sure to use spare parts supplied by Mindray Animal Medical only.**
- **The portable or mobile RF communication device can affect operation of medical devices. Make sure that the surgical light is installed in a proper environment. See chapter A.6 for details.**
- **Do not use cleaning solutions containing chloride ions. Otherwise, the device may be damaged.**
- **Use of spare parts other than those supplied by Mindray Animal Medical, especially such electrical parts as cables, batteries, bulbs, may compromise EMC performance of the surgical light.**

1.1.3 Note

NOTE

- **Contents of this manual are based on the full configuration of the surgical light. Some of them may not apply to your operatinglight. Use your light according to the actual configuration. If you have any questions, contact the customer service department authorized by Mindray Animal Medical or your local distributor.**
- **Training materials are available. Be sure to contact Mindray Animal Medical or your local distributor for them.**
- **The software was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.**
- **The equipment software copyright is solely owned by Mindray Animal Medical. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **Batteries are recommended to be replaced regularly. The battery must only be replaced by personnel authorized by Mindray Animal Medical.**

1.2 Equipment Symbols

Some symbols may not appear on your equipment.

Symbol	Description	Symbol	Description
 (Blue)	Refer to instruction manual/booklet		Caution
	Protective earth (ground)		Earth (ground)
	Alternating current		Direct current
	On/Off		Battery indicator
	Input	IP55	Dust-protected; protect against splashing water (except gimbal joint assembly, integrated camera assembly)
	Unlocking		Locking
	Stand-by	SN	Serial number
	Manufacturer		Date of manufacture
	Anti-static		This way up
	Keep dry		Fragile, handle with care

Symbol	Description	Symbol	Description
	Stacking limit by number		Do not roll
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation		Recyclable
EC REP	Authorized representative in the European Community		Separate collection for electrical and electronic equipment
CE	This product is provided with a CE marking in accordance with the regulations stated in Regulation(EU) 2017/ 745 concerning Medical Devices.	EAC	Unified circulation mark indicates that products marked them passed all specified in the technical regulations of the Customs Union of the procedure for the assessment (confirmation) of conformity and complies with the requirements applicable to all the products technical regulations of the Customs Union.
UK CA	UKCA marking		

2 Equipment Introduction

2.1 Intended Use

2.1.1 Intended Purpose

The LED surgical light is intended for operation, treatment and diagnosis within the operating/treatment room.

2.1.2 Intended Users

The device may only be operated by medically trained staff.

2.1.3 Intended Patient Population

The LED surgical light is intended for animals who are in surgical procedures.

2.1.4 Intended Medical Conditions

The device is to be used in healthcare facilities by clinical professionals or under their guidance.
It is not intended for home use.

2.1.5 Contra-indications

None.

2.1.6 Side-effects

According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there are no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed.

See the table below for all the available models and their configurations.

Model	Configuration
HyLED C50 Vet	Single lighthead
HyLED C50/C50 Vet	Double lightheads

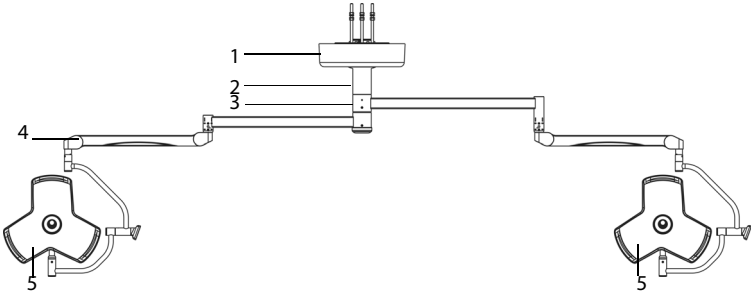
WARNING

- **Contents of this manual are based on the full configuration of the LED surgical light. Some of them may not apply to your LED surgical light. Use your LED surgical light according to the actual configuration. If you have any questions, contact the customer service department authorized by Mindray Animal Medical or your local distributor.**

2.2 Main Components

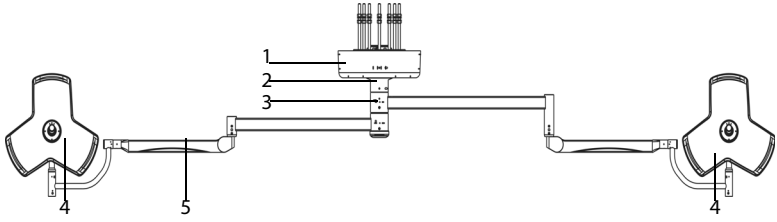
The main components of HyLED C50 Vet series LED surgical lights are shown in the figures below.

■ HyLED C50 Vet



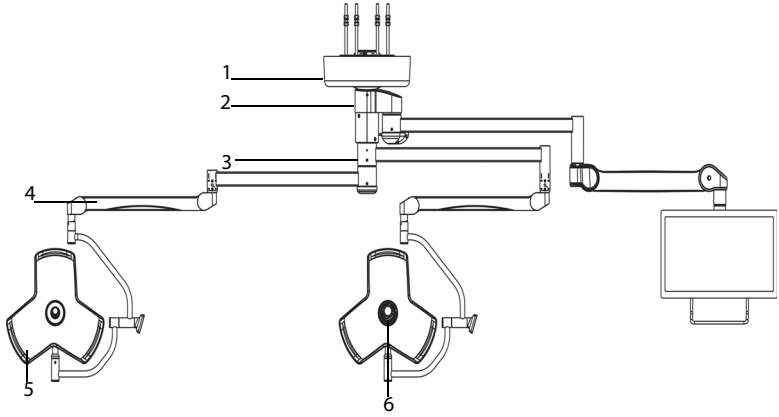
1. Ceiling cover
2. Flange tube
3. Swivel arm assembly
4. Standard spring arm
5. HyLED C50 Vet lighthead

■ LCH spring arm(optional)



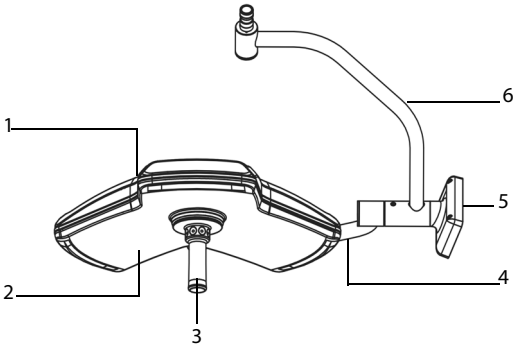
1. Ceiling cover
2. Flange tube
3. Swivel arm assembly
4. Lighthead
5. LCH (Low ceiling height) spring arm (optional)

■ Integrated camera(optional)



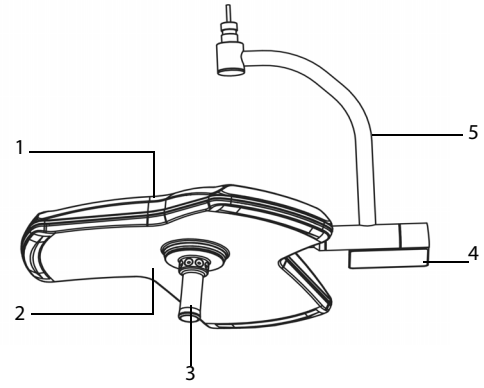
1. Ceiling cover
2. Flange tube
3. Swivel arm assembly
4. Standard spring arm
5. Lighthead
6. Integrated camera (optional)

■ Two gimbal joints



1. Lamp housing hood
2. Glass
3. Sterilizable handle (common)
4. Horizontal gimbal joint
5. Touch screen control
6. Vertical gimbal joint

■ One gimbal joint



1. Lamp housing hood
2. Glass

3. Sterilizable handle (common)
4. Touch screen control
5. Gimbal joint

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3 Daily Operations

3.1 Preparations

Each time before using the LED surgical light,

1. Make sure the sterilizable handle is sterilized. See chapter ***4.4 Sterilization of Sterilizable Handle*** for details.
2. Check and make sure:

- the indoor power supply is normal.
- the indoor temperature and humidity are in compliance with the operating conditions of the light.
- the arms (both swivel arms and spring arms) and the lightheads are not damaged.
- the arms and the lightheads can stay at the desired positions.
- the lightheads function normally.
- the camera and the display function normally.

3.2 Using Lighthead

You can:

1. Use the sterilizable handle/encircling handle to adjust the lighthead position.
2. Use the touch screen control (optional) to operate the lighthead and camera.

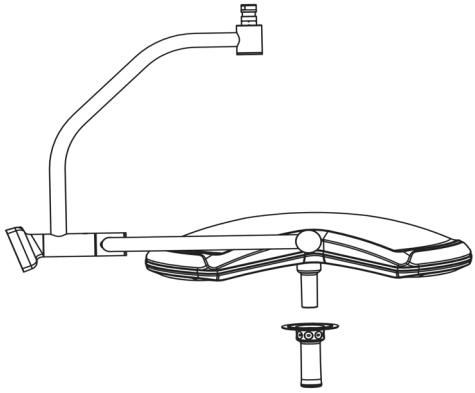
WARNING

- **Do not direct the light source towards animal eyes. Otherwise, it may cause personal injury.**
- **Do not lean on the spring arm. Otherwise, the lighthead may swing and cause personal injury and/or property damage.**
- **Be sure to adjust the illuminance level based on the needs of the operation. Note that there is a risk of too much heat in the operating field by overlapping the light fields of several lightheads, in which case the surgical light system may exceed a total irradiance of 1000 W/m².**

3.2.1 Installing/Removing Sterilizable Handle

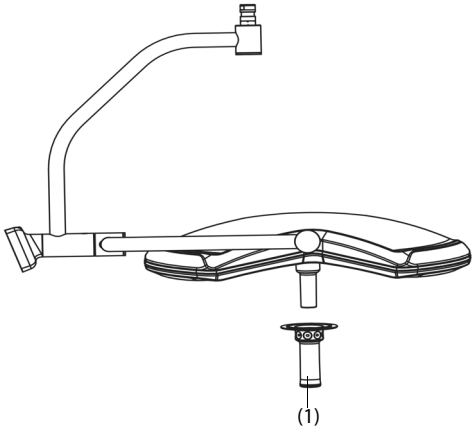
To install the sterilizable handle:

1. Slide the sterilizable handle onto the central handle of the lighthead.
2. Push the sterilizable handle upward until it clicks.
3. Pull the sterilizable handle downward to make sure it is not loose.



To remove the sterilizable handle:

1. Grab the lighthead with one hand.
2. Grab the handle with the other hand. Press the button(1) at the bottom and pull the handle downward.

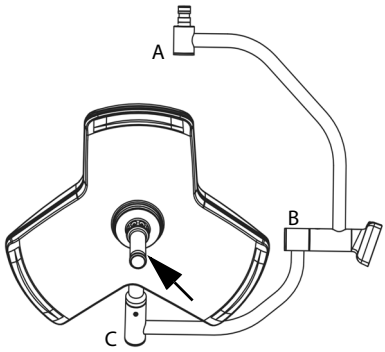


WARNING

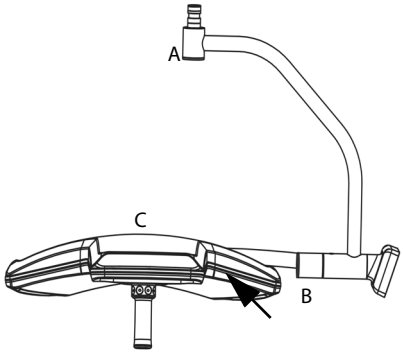
- **Be sure to install the sterilizable handle to the lighthead before use.**
- **Make sure the sterilizable handle is sterilized each time before use.**
- **The sterilizable handle shall be used by sterile personnel only. Do not touch the area outside of the sterilizable handle when using it. Otherwise, it may cause infection.**
- **If the sterilizable handle falls off during the operation, it might infect the operative wound. Make sure the sterilizable handle is properly and reliably installed.**
- **Only Covidien disposable handle is recommended and it needs to be used with Covidien disposable handle adaptor. Other sterile disposable handles may fall off during the operation, infect the operative wound or affect the normal use of the surgical light.**
- **Make sure the sterilizable handle is sterilized each time after use.**

3.2.2 Adjusting Lighthead Position

The sterile person can only use the sterilizable handle to move the lighthead.



The non-sterile person can use the encircling handle to move the lighthead.



The gimbal joint (A/B/C point in the above figure) of the LED surgical light can be rotated at any position when the LED surgical light has an optional function of unlimited lighthead.

WARNING

- **Exercise caution when adjusting the lighthead position. Do not pull the spring arms beyond their limits.**
- **When moving the lighthead, avoid collisions among the lighthead, arms (both swivel arms and spring arms), and other devices or parts, which may cause personal injury and/or property damage.**
- **To avoid the risk of infection, only the sterile personnel may touch the sterilizable handle during the operations.**

NOTE

- **Do not grab the touch screen control when adjusting the lighthead position. Otherwise, misoperation may occur.**

3.2.3 User Interface Symbols

The following tables describe the symbols of the touch screen control.

3.2.3.1 Symbols of Lighting Control Interface

Symbol	Description	Symbol	Description
	Lighthead		Standby
	MIS lighting		Illuminance
	Light field		Color temperature
	Back to the previous interface		

3.2.3.2 Symbols of Camera Control Interface

Symbol	Description	Symbol	Description
	Camera		Standby
	Zoom in		Zoom out
	Access more functions		Back to the previous interface
	Freeze/Unfreeze		White balance

Symbol	Description	Symbol	Description
	Focus		Iris
	Auto mode		

3.2.3.3 Other Symbols

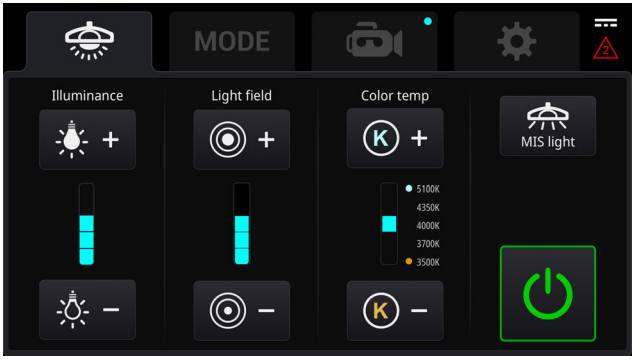
Symbol	Description	Symbol	Description
	Settings		Configuration
	Version information		

3.2.4 Using Touch Screen Control (Optional)

The buttons on the top of the touch screen control can access the functions of the lighthead (), specialized illuminance modes (), camera () and settings (). The functions are described as follows.

NOTE

- **During the power-on process, do not press and hold the touch screen.**
- **Make sure no liquid or particles remain on the touch screen control before use. Otherwise, misoperation may occur.**
- **When the touch screen control is not operated for a long time, the touch screen will be automatically locked. If you need operate it again, click any point of the touch screen before operation.**



3.2.4.1 Turn on/off the Lighthead

- When the surgical light is powered on, press  to turn on the lighthead.
- Press  to turn off the lighthead.
- Once the lighthead is turned on or off, the brightness will change smoothly.

3.2.4.2 Adjusting the Illuminance

- Press  to increase the Illuminance.
- Press  to decrease the Illuminance.
- The illuminance is ten-level adjustable. Check the illuminance level by the illuminance indicator  .

NOTE

- **The lighthead can automatically calculate a coefficient for illuminance compensation according to the service time and change of state, ensuring an effective illuminance in the life circle.**

3.2.4.3 Adjusting the Light Field

- Press  to enlarge the light field.

- Press  to diminish the light field.
- The light field is five-level adjustable. Check the light field size by the light field indicator  .

3.2.4.4 Adjusting the Color Temperature (Optional)

- Press  to increase color temperature.
- Press  to decrease color temperature.
- The color temperature is five-level adjustable: 3500K, 3700K, 4000K, 4350K, 5100K. Check the color temperature value by the color temperature indicator 

.

3.2.4.5 MIS Lighting Mode

Press  to enter/quit the MIS lighting mode. In this mode, the illuminance is no greater than 8000 lx, which is sufficient for Minimally Invasive Surgeries.

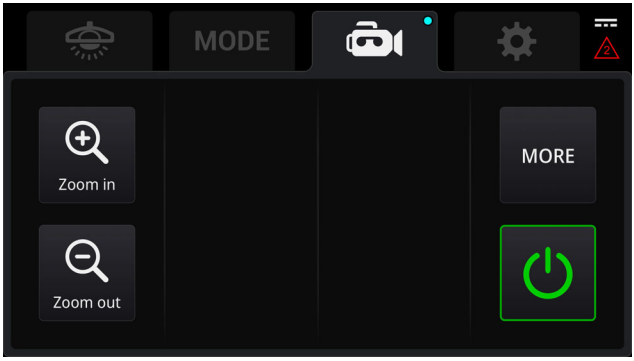
NOTE

- **In the MIS lighting mode, the color temperature, light field, illuminance cannot be adjusted.**

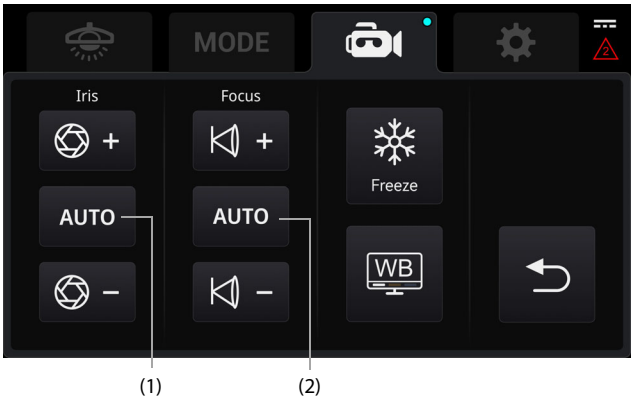
3.2.4.6 Full Illuminance Mode

1. Press  , increase the illuminance to ten level and then release  .
2. Long press  till the top grid of the illuminance indicator () flickers. In this way, you have entered the full illuminance mode.

3.2.4.7 Camera Control



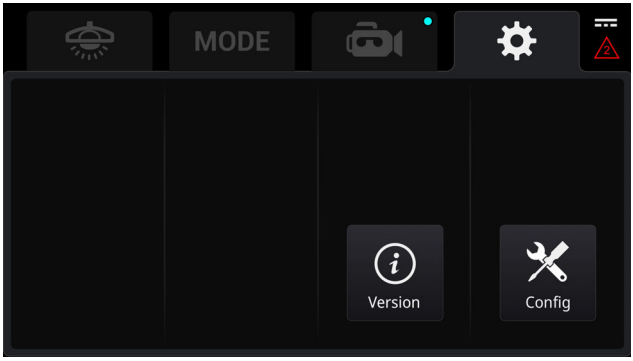
- Turn on/off the camera:
  - Switch the touch screen to the camera control and press  to turn on the camera. At the same time, the green indicator on the right side of the camera icon () will be on. That means the camera is being activated.
  - Press  to turn off the camera. The green indicator on the right side of the camera icon will go off.
- Zoom in or zoom out to magnify or minify the image: press  or  .
- More functions: press  to access more functions.



- Adjust the iris size: + : Iris up; AUTO (1): Auto iris; − : Iris down
- Adjust the camera focus: + : Focus far; AUTO (2): Auto focus; − : Focus near
- Freeze/unfreeze the image: press .
- White balance (WB): Press WB to select different white-balance modes and obtain the proper color. Three modes are available: Indoor, Outdoor and Auto WB. Press it to toggle among the modes.

3.2.4.8 Configuration

■ Press  to enter the service configuration and factory configuration interfaces. The service configuration is for service engineers only and factory configuration for factory only.



3.3 Using Rotatable Integrated Camera (Optional)

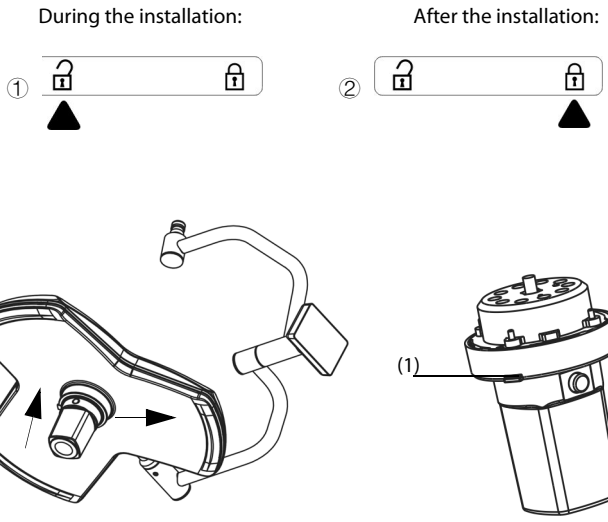
You can:

1. Use the sterilizable handle to adjust the position of the lighthead configured with the rotatable integrated camera.
2. Turn the sterilizable handle to rotate the camera if you find the displayed image is upside-down.
3. Use the touch screen control/video recorder and camera controller to operate the camera.

3.3.1 Installing/Removing Rotatable Integrated Camera

To install the rotatable Integrated camera:

1. As figure ① shows, align the triangle symbol on the camera with the unlock symbol on the lighthead during the installation.
2. Rotate the camera rightwards until it clicks, and the fastener(1) will lock the camera. The triangle symbol will be aligned with the lock symbol as shown in figure ② after the installation.

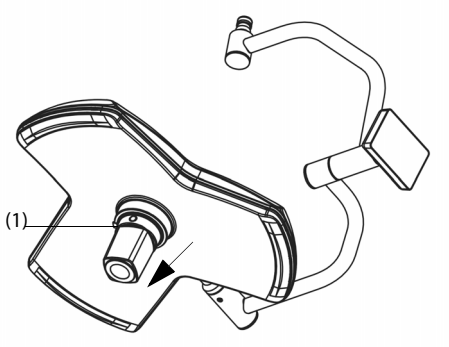


CAUTION

- **During the installation, hold the camera carefully and remember to rotate the camera rightwards. Make sure the triangle symbol is aligned with the lock symbol after the installation. Otherwise, the camera may drop down.**

To remove rotatable integrated camera:

1. Pull the fastener (1) downwards.
2. Slightly rotate the camera leftwards and remove it.



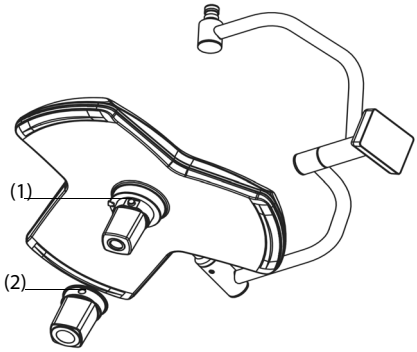
3.3.2 Installing/Removing Sterilizable Handle of Integrated Camera

To install the sterilizable handle:

1. Slide the sterilizable handle(2) onto the camera until it is fully engaged with the button(1).
2. Pull the sterilizable handle downward to make sure it is not loose.

To remove the sterilizable handle:

1. Grab the lighthead with one hand.
2. Grab the handle with the other hand. Press the button (1) as shown in the figure below and pull the handle downward.



3.3.3 Using Touch Screen Control (Optional)

Use the touch screen control to adjust the camera. See ***3.2.4.7 Camera Control*** for details.

3.3.4 Using Video Recorder and Camera Controller (Optional)

You can use the video recorder and camera controller to adjust the camera. Please refer to the operator's manual of the video recorder and camera controller for how to control the camera.

3.4 Using Display Arm (Optional)

CAUTION

- **It is not recommended that a medical display be used due to uncertain interference during the surgery.**
- **Do not let the display automatically scan the signal source at every start. Otherwise, you may need to reset the input source. Refer to the instruction for use of the display for how to disable the auto scanning function.**

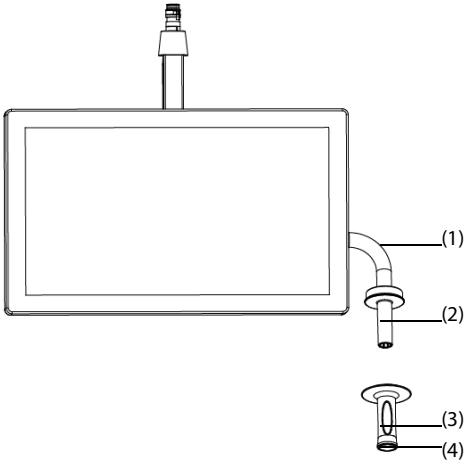
3.4.1 Installing/Removing Sterilizable Handle of Display Arm

To install the sterilizable handle:

1. Slide the sterilizable handle (3) onto the central handle (2).
2. Push the sterilizable handle upward until it clicks.
3. Pull the sterilizable handle downward to make sure it is not loose.

To remove the sterilizable handle:

1. Grab the display arm (1) with one hand.
2. Grab the handle with the other hand. Press the button (4) at the bottom and pull the handle downward.


(1)
(2)
(3)
(4)

4 Cleaning and Disinfection

4.1 Safety Information

The product must be cleaned and disinfected after every use or at least once a week.

WARNING

- **Use only Mindray Animal Medical approved cleaners and disinfectants and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.**
- **Do not mix disinfecting solutions as hazardous gases may result.**
- **Do not use the ultraviolet disinfection method and the alcohol disinfectant at the same time, which may cause personal injury and/or property damage.**
- **We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's infection control officer or epidemiologist.**
- **Agents containing alcohol can form explosive vapor mixtures and ignite where high-frequency equipment is being used. Do not use the cleaners or disinfectants containing alcohol where high-frequency surgical equipment may be used.**
- **Always wear gloves for cleaning and disinfection. Neglect of this may cause infection.**
- **Be sure to disconnect the power supply before cleaning and disinfection.**
- **The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.**

CAUTION

- **Do not clean/disinfect the LED surgical light mechanically.**
- **Never immerse any part of the equipment or accessories in liquids.**
- **Particles of grime may become encapsulated and lead to the product not reaching the desired LED surgical lightgerm-reduction after disinfection. Before disinfection, the product must be cleaned thoroughly of contamination and encapsulated particles of grime and then be dried.**

- **Any contact of cleaners or disinfectants with connectors may cause corrosion.**
- **Do not pour or spray any liquid directly on the equipment or accessories or permit fluid to seep into live parts inside the equipment.**
- **If you spill liquid on the equipment or accessories, disconnect the power supply, dry the equipment and contact your service personnel.**
- **Improper cleaning/disinfection can damage the LED surgical light. Do not spray the cleaning agent/disinfectant directly into the joints or gaps. Do not use high pressure to clean/disinfect components.**
- **Never use abrasive materials (such as steel wool or silver polish), or strong solvent (such as acetone or acetone-based cleaners) for cleaning.**
- **Do not use polish or steel cleaner to clean or disinfect stainless steel surfaces.**
- **Dilute and use the cleaners or disinfectants according to the manufacturer's instructions.**

NOTE

- **Be sure to follow the related national hygiene and disinfection regulations to carry out cleaning and disinfection procedures.**
- **Check the equipment or accessories after cleaning and disinfecting. Stop use if there is any sign of wear or damage.**
- **Clean or disinfect the equipment surface at room temperature. Be sure to follow the disinfectants' instruction if the disinfectants have special temperature requirements for disinfection.**

4.2 Cleaning

4.2.1 Preparation before Cleaning

Switch off the LED surgical light, and wait until it cools down completely.

4.2.2 Cleaning Procedure

1. Use a piece of lint-free clean cloth to wipe off the dust gently and thoroughly.
2. Use a piece of lint-free cloth moistened with cleaner (clean water or soap solution) to wipe the surface.
3. Use a piece of disposable lint-free cloth moistened with water to clean the surface.
4. Use a piece of dry lint-free cloth to wipe the surface dry.

CAUTION

- **When cleaning the lighthead glass, be sure to wipe from the inside to the outside along the radius, as the figure above shows. Do not wipe back and forth or in circles. Otherwise, the glass surface may be damaged.**

NOTE

- **Use proper amount of the cleaning agent to clean the LED surgical light, and remove any excessive agent by the dry cloth.**
- **Be sure to disinfect the equipment after cleaning.**

4.3 Disinfection

4.3.1 Recommended Disinfectants

Disinfect the equipment as required in your hospital's servicing schedule. Cleaning the equipment before disinfection is recommended. Always dilute and use disinfectants according to the manufacturer's instructions. The following table lists approved disinfectants:

Product name	Product type	Manufacturer
Alpet® D2 Surface Sanitizing Wipes	Wipes	BEST SANITIZERS INC™.
CIDEX® OPA	Liquid	Gilag GmbH International Advanced Sterilization products
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Wipes	Clorox professional products company
Clorox Healthcare® Bleach Germicidal Wipes	Wipes	Clorox professional products company
Metrex CaviCide1™	Liquid, spray	METERX® RESEARCH
Metrex CaviWipes™	Wipes	METERX® RESEARCH
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Bleach Germicidal Disposable Wipe	Wipes	PDI Inc.

Product name	Product type	Manufacturer
PDI Sani-Cloth® HB Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Plus Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Super Sani-Cloth® Germicidal Disposable Wipe	Wipes	PDI Inc.
Virex® II 256 (1:256)	Liquid	Diversey Inc
JIAN ZHI SU Disinfectant Tablets	Tablet	Beijing ChangJiangMai Medical Science Technology Co. Ltd
JIAN ZHI SU Surface Disinfectant Spray	Liquid, spray	Beijing ChangJiangMai Medical Science Technology Co. Ltd
JIAN ZHI SU Disinfectant, Double-chain Quaternary Ammonium	Liquid	Beijing ChangJiangMai Medical Science Technology Co. Ltd
DIAN'ERKANG Surface Wipes	Wipes	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
DIAN'ERKANG Surface Disinfectant	Liquid	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
DIAN'ERKANG Disinfectant Spray	Liquid, spray	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
Clinell® Universal Wipes	Wipes	GAMA Healthcare Ltd
Clinell ® Sporicidal Wipes	Wipes	GAMA Healthcare Ltd
Surfa 'safe	Liquid, spray	ANIOS LABORATORIES
Aniosurf ND premium, 0.25%	Liquid	ANIOS LABORATORIES
Glutaraldehyde, 2%	Liquid	/
Ethanol, 75%	Liquid	/
Isopropanol, 70%	Liquid	/
Hydrogen peroxide, 3%	Liquid	/
Rely+On™ Virkon® High Level surface Disinfectant	Powder	Antec International Ltd
84 disinfectant (2000mg/L available chlorine)	Liquid	/

Product name	Product type	Manufacturer
Trichloroisocyanuric acid (2000mg/L available chlorine)	Liquid	/
Peroxyacetic acid, 1%	Liquid	/
Domiphen, 2000mg/L	Liquid	/

4.3.2 Disinfection

1. Use a piece of lint-free cloth moistened with disinfectant to wipe the surface.
2. Use a piece of disposable lint-free cloth moistened with water to clean the surface.
3. Use a piece of dry lint-free cloth to wipe the surface dry.

CAUTION

- **When disinfecting the lighthead glass, be sure to wipe from the inside to the outside along the radius. Do not wipe back and forth or in circles. Otherwise, the glass surface may be damaged.**
- **Do not disinfect the equipment by fumigation methods. Otherwise, the equipment may be damaged.**

4.4 Sterilization of Sterilizable Handle

Only cleaned and disinfected handles can be sterilized. Before sterilization, make sure the handle is placed in a sterilization pack that complies with ISO 11607. The whole sterilization procedure shall comply with BS EN ISO 17665, with maximum sterilization temperature not over 134°C and holding time not over 7 minutes.

WARNING

- **The sterilizable handle should be installed only right before use.**

CAUTION

- **Do not apply any load to the handle during sterilization. Otherwise, the handle may deform permanently.**
- **The sterilizable handle may wear out after a certain period of service. Be sure to replace the handle if you see any sign of wear, such as cracking, color fading, etc.**

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5 Maintenance

Regular maintenance is essential to ensure that the equipment functions properly. This chapter contains information on equipment maintenance method and frequency.

5.1 Maintenance Safety Information

WARNING

- **To avoid electric shock, stop using the equipment if you find the housing has signs of damage. Contact the service personnel for help in that case.**
- **Failure on the part of the responsible individual hospital or institution using this equipment to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards.**
- **If you have any questions during the inspection, contact the customer service department authorized by Mindray Animal Medical.**
- **The device maintenance that requires disassembling shall be performed by the professional service personnel authorized by Mindray Animal Medical. Otherwise, device failure or personal safety accidents may occur.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**
- **Before maintaining or servicing the surgical light, be sure to shut off the mains supply first.**

CAUTION

- **The equipment and accessories shall not be tested or maintained while in use with a patient.**
- **Disassembly of certain components can affect operation and safety (e.g. when servicing the electrical power supply, when servicing the swivel arm assembly and the spring arms).**

NOTE

- **This equipment contains no user serviceable parts. Refer servicing to qualified service personnel.**
- **The service life of the surgical light is 10 years. At the end of its service life, the device, as well as its accessories, must be disposed of in compliance with local governmental or hospital regulations.**

5.2 Maintenance Schedule

Follow the maintenance schedule or local regulations to perform maintenance. Be sure to clean and disinfect the equipment before test or maintenance. The following table lists the maintenance and testing schedule:

Test/Maintenance Item(user)	Recommended Frequency	Method
The lightheads and the arms (both swivel arms and spring arms) are not damaged.	Every day, before first use.	Visual inspection.
The sterilizable handle is not damaged.		Visual inspection.
The arms do not drift and the lightheads can stay at the desired positions.		See ***5.3 Adjusting Arm Systems*** for details.
The lighthead functions normally.		Turn on the lighthead and operate it as described in ***3 Daily Operations***.
Load capacity of the spring arm is proper.		See ***5.3.4.1 Adjusting Counterweight*** for details.
Height stop of the spring arm is proper.		See ***5.3.4.2 Adjusting Height Stop*** for details.
The touch screen functions normally.		See ***3.2.4 Using Touch Screen Control (Optional)*** for details.

Test/Maintenance Item (must be performed by authorized personnel)	Recommended Frequency	Method
Joint stability check.	On- demand service (yearly check is recommended.)	See ***5.3 Adjusting Arm Systems*** for details.
Load capacity of the spring arm is proper.		See ***5.3.4.1 Adjusting Counterweight*** for details.
Height stop of the spring arm is proper.		See ***5.3.4.2 Adjusting Height Stop*** for details.
The device does not shake.		Rotate the device to check whether it shakes.
The illuminance is stable.		Visual inspection.
All the covers and caps are fixed in place.		Visual inspection.
All the screws are tightened.		Check whether screw heads fit closely to the parts through visual inspection and whether screws are tightened using a tool.

5.3 Adjusting Arm Systems

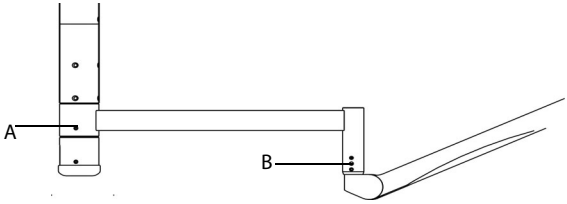
WARNING

- **Before maintaining or servicing the surgical light, be sure to shut off the mains supply first.**

5.3.1 Swivel Arm Assembly and Spring Arm (Standard and LCH)

If the surgical light cannot stay at the desired position, you can adjust the braking screws at joint A and/or B as needed.

- If the swivel arm moves too easily, adjust the two braking screws at joint A with a 5mm Allen key.
- If the spring arm moves too easily, adjust the two braking screws at joint B with a 5mm Allen key.



CAUTION

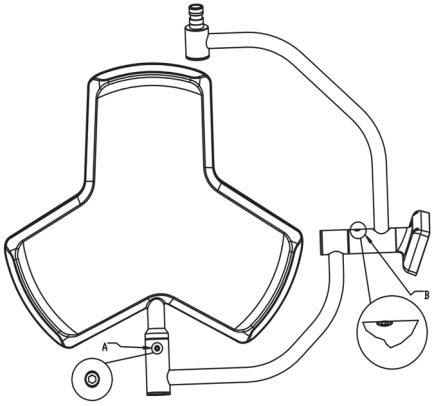
- **It is recommended that the braking screw at point A be tighter than point B.**
- **The swivel range of the swivel arm and spring arm can be restricted by internal limit stops.**

5.3.2 Adjusting Braking Force of Gimbal Joint and Lighthead

If the gimbal joint cannot keep the lighthead staying at the desired position, you can adjust the braking force of joints A and/or B.

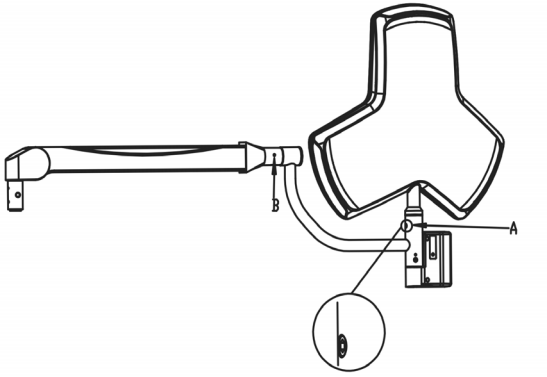
1. For a lighthead with two gimbal joints

   ◆ Use a 5mm Allen key to adjust the braking screw until the desired braking force is obtained.



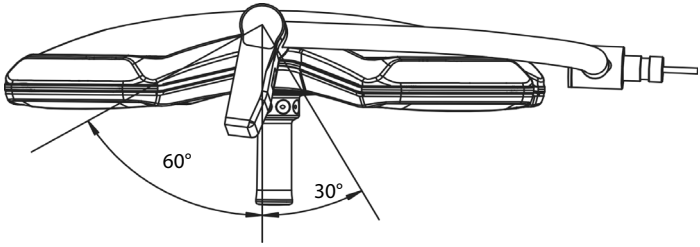
2. For a lighthead with a single gimbal joint

   - Use a 5mm Allen key to adjust the braking screw at joint A and/or a 5mm flat-bladed screwdriver at joint B until the desired braking force is obtained.

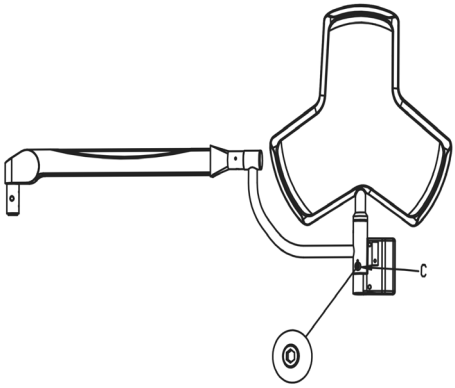


5.3.3 Adjusting Braking Force of Rotatable Control Unit (Optional)

For a lighthead with a single gimbal joint, the rotation angle of the rotatable control unit (touch screen control) is shown below.



If a rotatable control unit cannot stay at the desired position, adjust the braking screw(at C point) with a 5mm Allen key until the desired braking force is obtained.



5.3.4 Adjusting Spring Arm

CAUTION

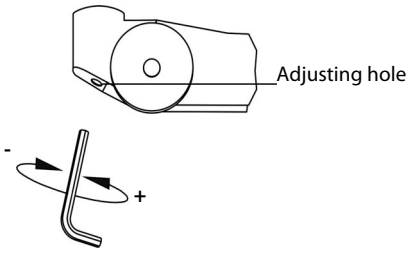
- **When adjusting the spring arm, raise it to a position approx. 10° above the horizontal to release the adjustment screw. If necessary, set the upper stop to a higher position. See section "Adjusting Height Stop" for details.**

5.3.4.1 Adjusting Counterweight

If the lighthead cannot be positioned at the desired height, you can adjust the load capacity of the spring arm.

Standard Spring Arm and LCH Spring Arm:

1. Insert a 5mm Allen key into the adjusting hole as far as possible.
2. Adjust the hexagon socket screw:
   - If the lighthead tends to move upward, turn the Allen key clockwise (in the "-" direction).
   - If the lighthead tends to move downward, turn the Allen key counterclockwise (in the "+" direction).



5.3.4.2 Adjusting Height Stop

CAUTION

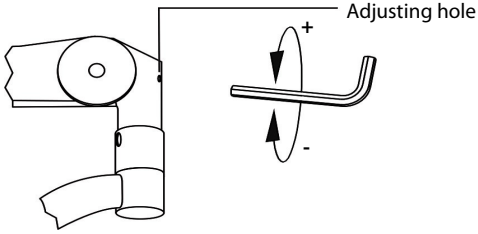
- **When adjusting the height stop, pay attention to the distance between the floor and the ceiling. Make sure the lighthead does not collide with anything.**

Vertical movement of the lighthead is limited by a fixed lower stop and an adjustable upper stop.

Standard Spring Arm:

The adjustable upper stop can be adjusted with a 5mm Allen key.

- Turn the Allen key clockwise (in the "-" direction) to reduce the stop.
- Turn the Allen key counterclockwise (in the "+" direction) to raise the stop.

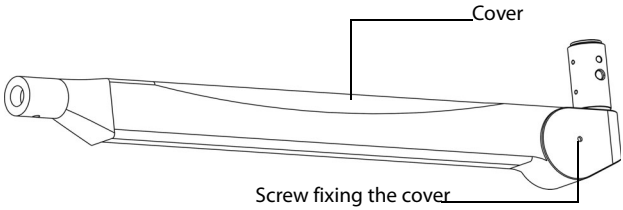


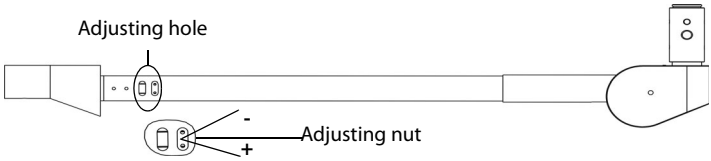
LCH Spring Arm:

1. Level the LCH spring arm.
2. Remove the screw fixing the cover and then remove the cover.
3. Insert a pin into the adjusting hole to turn the adjusting nut.

- Turn the adjusting nut upwards (in the "-" direction) to reduce the stop.
- Turn the adjusting nut downwards (in the "+" direction) to raise the stop.

4. Install the cover and secure it by the fixing screw.





NOTE

- **The pin is delivered together with the LCH spring arm.**

5.4 Disposal

Dispose of the equipment when its service life is reached.

WARNING

- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the local regulations. If you have any questions concerning disposal of the equipment, please contact Mindray Animal Medical.**
- **For disposal of parts and accessories, unless otherwise specified, follow local regulations regarding disposal of hospital waste.**
- **Dispose of the package material as per the applicable waste control regulations. Keep it out of children's reach.**

6 Troubleshooting

6.1 Common Error

WARNING

- **The chapter is meant to help you solve common errors only. In case you encounter problems not included in this chapter or following the introduced methods cannot solve the problem, contact the customer service department authorized by Mindray Animal Medical or your local distributor for help. Unauthorized device servicing is not allowed.**
- **Device servicing is to be performed by personnel authorized by Mindray Animal Medical only. Unauthorized device servicing may cause personal injury and/or property damage.**
- **Be sure to disconnect the equipment from AC power when device servicing.**
- **Device servicing and installation should be strictly based on technical data supplied by Mindray Animal Medical. If you are in need of more technical data, contact the customer service department authorized by Mindray Animal Medical or your local distributor.**

Error	Cause	Solution
The lighthead cannot be turned on.	The fuse is broken.	Contact the customer service department authorized by Mindray Animal Medical.
	The power supply is cut off.	Check the power supply.
	Some electronic parts are broken.	Contact the customer service department authorized by Mindray Animal Medical.
The light flickers.	Improper installation.	Contact the customer service department authorized by Mindray Animal Medical.

Error	Cause	Solution
A group of LEDs or one LED does not light up.	The LED is defective.	Contact the customer service department authorized by Mindray Animal Medical.
	The LED wires are defective or disconnected.	
	Some electronic parts are broken.	
The size of the light field cannot be adjusted.	The focusing mechanism is broken.	Contact the customer service department authorized by Mindray Animal Medical.
The illuminance cannot be adjusted.	Some electronic parts are broken.	Contact the customer service department authorized by Mindray Animal Medical.
The surgical light cannot switch to the MIS lighting mode/M-Field lighting mode.	The MIS lighting mode/ M-Field lighting mode is not configured.	Contact the customer service department authorized by Mindray Animal Medical.
	Some electronic parts are broken.	
The illuminance is too low.	The illuminance setting is too low.	Increase the illuminance. See ***3.2.5.2 Adjusting the Illuminance*** and ***3.2.4.2 Adjusting the Illuminance*** for details.
The lighthead collides with other objects.	The height stop of the spring arm is incorrect.	Adjust the height stop. See ***5.3.4.2 Adjusting Height Stop*** for details.
The spring arm moves too easily.	Braking screws are loose.	Adjust the braking screws. See ***5.3.1 Swivel Arm Assembly and Spring Arm (Standard and LCH)*** for details.
The lighthead moves too easily.	Braking screws are loose.	Adjust the braking screws. See ***5.3.4 Adjusting Spring Arm*** for details.
The glass surface has scratch or cracking.	Incorrect cleaning/ disinfection agents are used or the glass is cleaned before it has completely cooled down.	See ***4.2 Cleaning*** and ***4.3 Disinfection*** for detailed cleaning/disinfection methods.
Service life of the sterilizable handle is shorter.	Incorrect sterilization method is adopted.	Check the sterilization. See ***4.4 Sterilization of Sterilizable Handle*** for details.

Error	Cause	Solution
The sterilizable handle is worn or cracked.	Its service life has expired.	Replace the sterilizable handle. See ***3.2.1 Installing/Removing Sterilizable Handle*** for details.
The sterilizable handle does not engage into the central handle correctly.	Sterilization parameters (temperature, time) exceeded.	See ***4.4 Sterilization of Sterilizable Handle*** for how to sterilize the handle. Make sure the handle clicks into place.
	Its service life has expired.	Replace the sterilizable handle. See ***3.2.1 Installing/Removing Sterilizable Handle*** for details.
The AC indicator is orange and flashing.	Communication error of the surgical light system.	Contact the customer service department authorized by Mindray Animal Medical.
The AC indicator is red and flashing and illuminance indicators are flashing.		
The DC indicator is red and flashing.		
The AC indicator is red and flashing.	Voltage to the lighthead is too low.	Contact the customer service department authorized by Mindray Animal Medical.
Error indicator  or  or  appears.	Communication error of the surgical light system.	Contact the customer service department authorized by Mindray Animal Medical.
Error indicator  appears.	Voltage to the lighthead is too low.	Contact the customer service department authorized by Mindray Animal Medical.
The camera cannot output the image.	Display jacks are not connected correctly.	Reconnect the jacks. Please refer to the instructions for use of the display.
	Improper setting of the display.	Check the setting of the display. Please refer to the instructions for use of the display.
	Video connectors or cables are broken.	Contact the customer service department authorized by Mindray Animal Medical.

Error	Cause	Solution
The display cannot select the exact signal source.	The display automatically scans the signal source at every start.	Refer to the instruction for use of the display for how to disable the auto scanning function.
The output image is not clear.	The focus of the camera does not match the image.	Switch to the auto focus mode.

A Product Specifications

A.1 Safety Specifications

A.1.1 Product Classification

According to the protection against electrical shock	Class I, internal electrical power source (optional). No applied part.
According to the protection against harmful ingress of water or particulate matter	IPX0. Lighthead: IP55
According to the method(s) of sterilization	By methods validated and described by the manufacturer.
According to the suitability for use in an oxygen rich environment	Not suitable for use in the presence of an oxygen rich environment.
According to the mode of operation	Continuous operation.

WARNING

- **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the surgical light shall be operated from its internal electrical power source.**

A.1.2 Environmental Specifications

Item	Temperature (°C)	Humidity (non-condensing)	Atmospheric pressure (kPa)
Operating condition	5-40	15%-95%	70-106
Storage condition	–40-60	10%-95%	50-106

CAUTION

- **The above-mentioned operating and storage conditions do not apply to the cameras and displays. See the accompanying documents of the camera and display for their operating and storage conditions.**
- **During transportation, ensure that the surgical light is well protected from rain, snow or mechanical collision.**
- **The surgical light should be stored in a room that is dry, draughty and without caustic gas.**

A.2 Power Supply Specifications

A.2.1 Power Supply

AC power	100-240V~, ±10%; 50/60Hz, ±1Hz

A.2.2 Input Power

Model	Configuration	Input power
HyLED C50 Vet	Single lighthead	100-240V 1.5-0.7A
HyLED C50/C50 Vet	Double lightheads	100-240V 3.0-1.3A

A.2.3 Lighthead Power

Model	Power
HyLED C50 Vet	55w

A.2.4 Power Consumption of All Light Sources (at the Minimum light Field and Highest Illuminance Level)

Model	Power
HyLED C50 Vet	30W

A.2.5 Fuse

Item	Common power module
Terminal block	250V T 5AH
Power board	250V T 3.15AH

A.2.6 DC 24V Power Supply (Optional)

NOTE

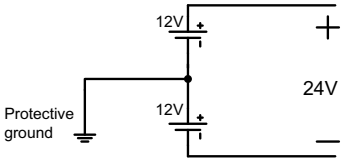
- **It is recommended that Mindray Animal Medical's battery module be used as the DC 24V power supply.**

If the DC 24V power supply is provided from the customer site, it should meet the following requirements.

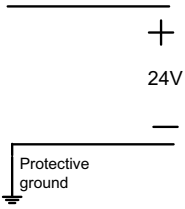
1. The external DC 24V power supply should be isolated from the alternating current mains supply. To meet the requirements of the isolation, the two methods below can be chosen as a reference.
   - If the DC 24V power supply is from a power module, the power module should comply with the IEC 60601-1 requirements.
   - If the DC 24V power supply is from a battery pack or UPS (uninterruptible power supply), the battery pack or UPS should comply with the relevant IEC and ISO standards.
2. Fluctuation range of the voltage at the input port of the Mindray Animal Medical's backup power module: 22V-36V DC
3. DC power output: no less than 250W for single lighthead or 20% greater than that of declared lighthead power listed in ***A.2.1 Power Supply***.

4. Ground connections:

- Unacceptable ground connections:

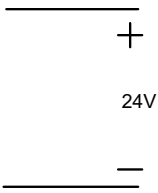


Two 12V power supplies in series, with the middle electrode to the protective ground

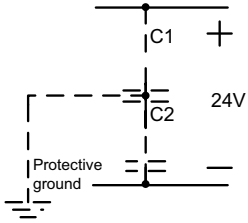


Negative electrode to the protective ground

- Acceptable ground connections:



Floating ground output



Output with one or two capacitors (typically selected in pF or nF) connected to the protective ground (mainly for EMC consideration)

CAUTION

- **Each lighthead should be connected to a separate power supply, which means each DC 24V power supply can only be connected to single backup power module.**
- **The DC power supply should be protected against the over-voltage, over-current, short-circuit and surge.**

A.3 Optical Performance

Model	HyLED C50 Vet
Max. illuminance (Ec) (1m)	About 160,000 lx
Color temperature	Without adjustable color temperature: about 4350k under max. illuminance With adjustable color temperature: about 3500K-5100K
General color rendering index (Ra)	About 99
Specific color rendering index (R9)	About 97
Irradiance (Ee) (Max. illuminance)	About 530 W/m^2
Irradiance (Ee) (Level-6 illuminance)	$\leqslant$ 360 W/m^2
Ee/Ec (average)	About 3.5 $mW/(m^2 \cdot lx)$
Light field diameter (d10)	About 140mm
Min. light field diameter (d10)	About 140mm
Max. light field diameter (d10)	About 270mm
d50/ d10	About 60%
Depth of illumination (20%)	About 1200mm
Depth of illumination (60%)	About 600mm
Depth of illumination (20%) (under large light field)	About 1300mm
Depth of illumination (60%) (under large light field)	About 700mm
Shadow dilution: cavity	About 100%
Shadow dilution: single mask	About 60%
Shadow dilution: single mask and one lateral mask	About 71%
Shadow dilution: double masks	About 56%

Model	HyLED C50 Vet
Shadow dilution: single mask and cavity	About 55%
Shadow dilution: one lateral mask and cavity	About 66%
Shadow dilution: double masks and cavity	About 51%

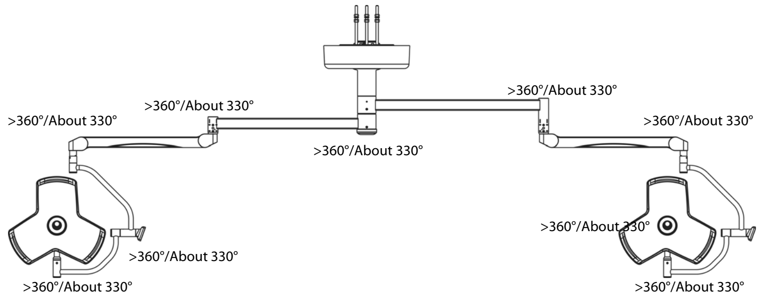
NOTE

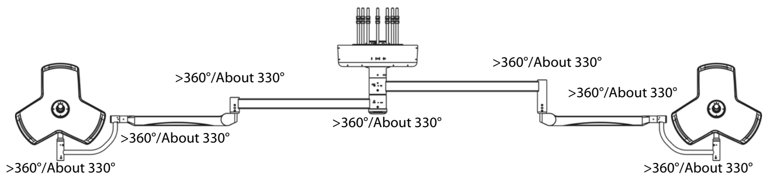
- **The optical performance is subject to fluctuations. Due to manufacturing reasons, the real value may slightly differ from the data mentioned above.**
- **When the adjustable color temperatureis not configured, the max. illuminance (Ec) (1m) is measured under the color temperature of about 4350K. When the adjustable color temperature is configured, the max. illuminance (Ec) (1m) is measured under the color temperature of about 4000K.**
- **Under the specific color temperature (3500K, 3700K, 4000K, 4350K, 5100K), the general color rendering index (Ra) is about 99 and the specific color rendering index (R9) is about 97.**
- **Note that the original IEC 60601-2-41 defined Depth of Illumination as the working range around 1,000mm below the emitting surface of the surgical light, in which the illuminance reaches at least 20% of the central illuminance. However, the latest version has changed the standard to 60%.**

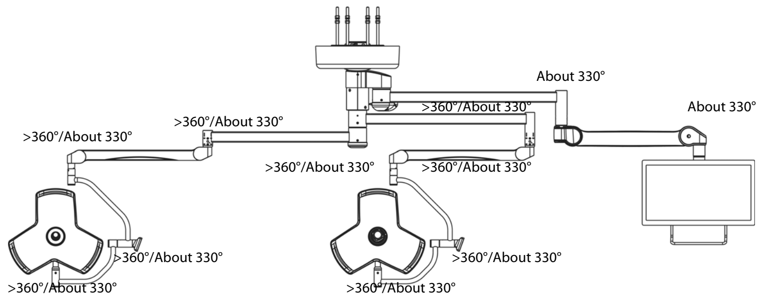
A.4 Camera Specifications

Item	Camera (Full HD)
Picture elements	2000K pixels
Resolution	1080p (1920×1080)
Digital zoom	12×(120× with optical zoom)
Video output	SDI
Camera position	Integrated camera

A.5 Degree of Rotation/Reach







B Accessories and Parts List

NO.	Description
1.	Ceiling fixture
2.	Video recorder and camera controller
3.	Separate flange tube

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C Electronic Interface

You may see the following electronic interface on the surgical light.

Electronic Interface	Specification
SDI	Used for transmitting camera images to the display 3G-SDI, serial digital interface Complies with the SMPTE 424M standard

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D EMC

The device meets the requirements of IEC 60601-1-2.

WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**
- **Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HyLED C50Vet series surgical lights, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.**
- **The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.**
- **This device is intended for use in professional healthcare facility environment only. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
Conducted and radiated RF EMISSIONS CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic device.
Conducted and radiated RF EMISSIONS CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable	

NOTE

- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may affect this device even though they meet the requirements of CISPR.**
- **The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.**
- **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the device and contact the service personnel.**

If the device is operated within the electromagnetic environment listed in Table Guidance and Declaration —Electromagnetic Immunity, the system will remain safe and provide the following essential performance:

■ provide steady illuminance and irradiance as the essential performance.

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV 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 (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/ output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	
Voltage dips and voltage interruptions IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/ 30 cycles 0 % U_T for 250/300 cycle	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/ 30 cycles 0 % U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and Declaration - Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 Test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td rowspan="2">Conducted disturbances induced by RF fields IEC61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td rowspan="5">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
$d = \left[\frac{3.5}{V}\right]\sqrt{P}$ 150kHz to 80 MHz
$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz
$d = \left[\frac{7}{E}\right]\sqrt{P}$ 800 MHz to 2.7 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 meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [b], should be less than the compliance level in each frequency range [c]. Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td>6 Vrms
in ISM bands[a] between 0,15 MHz and 80 MHz</td><td>6 Vrms</td></tr>
<tr><td>Radiated RF EM fields IEC61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>3V/m</td></tr>
<tr><td rowspan="3">Proximity fields from RF wireless communications equipment IEC61000-4-3</td><td>27 V/m
380–390 MHz</td><td>27 V/m</td></tr>
<tr><td>28 V/m
430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz</td><td>28 V/m</td></tr>
<tr><td>9 V/m
704–787 MHz, 5100–5800 MHz</td><td>9 V/m</td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[c] Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment

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

Rated Maximum Output power of Transmitter Watts (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E}\right]\sqrt{P}$
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 at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined 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 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.

Cable:

No.	Description	Length (m)	Shielded or not
1	AC power cord	⩽5	Not shielded

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