



Compliance Report

Applicant: Zhangjiagang Braun Industry Co., Ltd.
Address: Buliding C7, No. 199, Hongwu Avenue, Tangqiao Town, Zhangjiagang City, Suzhou City, Jiangsu Province, China

Product: Electric Hospital Bed, Hydraulic Hospital Bed, Manual Hospital Bed, Electric Stretcher, Hydraulic Stretcher, Manual Stretcher, Electric Birthing Bed, Delivery Table, Electro-Hydraulic Operating Table, Electric Operating Table, Manual Operating Table, Surgical Light, Patient Pendant, Examination Table, Baby Bassinet, Bedside Cabinet, Overbed Table, Patient Chair, Mattress, Medical Cart, Workstation Cart, Cabinet, Stool, Screen, IV. Stand, Stainless Steel Equipment

Type: See annex for details

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **03220**

Initial Issue Date: **25 May 2020**

Reissue Date: **14 Aug 2020**

Berry Bao

Signer

This report is the property of NQA and should be returned to NQA upon request.

The report information can be found on, WWW.SNQA.COM.CN.





Annex to Report (No. 03220)

Zhangjiagang Braun Industry Co., Ltd.

Product Name	Type
Electric Hospital Bed	BIH-E Series
Hydraulic Hospital Bed	BIH-H Series
Manual Hospital Bed	BIH-M Series
Electric Stretcher	BIPT-E Series
Hydraulic Stretcher	BIPT-H Series
Manual Stretcher	BIPT-M/ST Series
Electric Birthing Bed	BIDB Series
Delivery Table	BID Series
Electro-Hydraulic Operating Table	BIOT-EH Series
Electric Operating Table	BIOT-E Series
Manual Operating Table	BIOT-M Series
Surgical Light	BIOL Series
Patient Pendant	BIOP Series
Examination Table	BIDE Series
Baby Bassinet	BIHB Series
Bedside Cabinet	BIHC Series
Overbed Table	BIHT Series
Patient Chair	BIHA Series
Mattress	BIHM Series
Medical Cart	BIE Series
Workstation Cart	BIEW Series
Cabinet	BIOC Series
Stool	BIHF Series
Screen	BIHS Series
IV stand	BIHR Series
Stainless Steel Equipment	BIOS Series

This annex is only valid if attached to the report mentioned above.



This is to certify that the Quality Management System of

Zhangjiagang Braun Industry Co., Ltd.

Unified Social Credit Code : 91320582MA1Y67PN9F

Operation Address : Building C7, No.199, Hongwu Avenue, Tangqiao Town, Zhangjiagang City, Suzhou City, Jiangsu Province, China

Registered Address : No.199, Hongwu Avenue, Tangqiao Town, Zhangjiagang City, Suzhou City, Jiangsu Province, China

applicable to

Manufacturing of Hospital Bed, Rehab Bed, Patient Stretcher, Delivery Bed, Operating Table and Examination Table(Within the Scope of License Qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website : www.snqa.com.cn

Managing Director

Managing Director

Certificate Number

47946/1

Date:

30 July 2020

Valid Until:

30 July 2023

EAC Code:

17



015



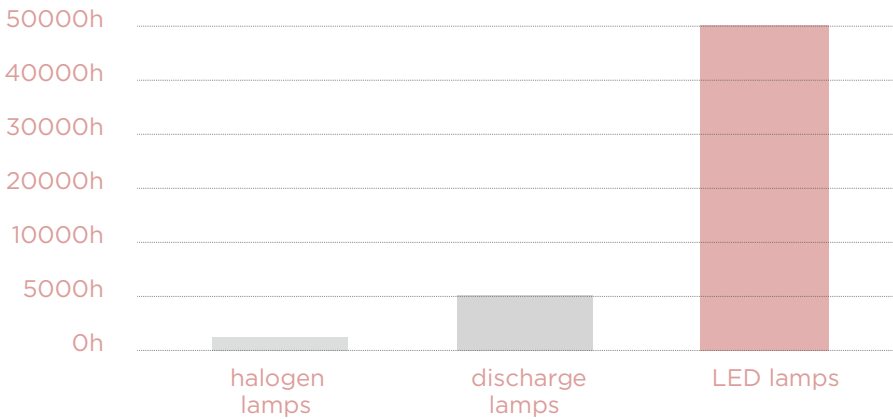
LED Surgical Light

LED Technology

Sources of light in LED technology have several times longer lifetime in comparison to traditional light sources. It directly contributes to the reduction of waste. In addition, it does not contain lead, mercury and other hazardous substances which will facilitate their future disposal.

LED technology also helps to protect our health. Light source in LED technology produces no harmful UV rays.

Lifetime of LED lamps

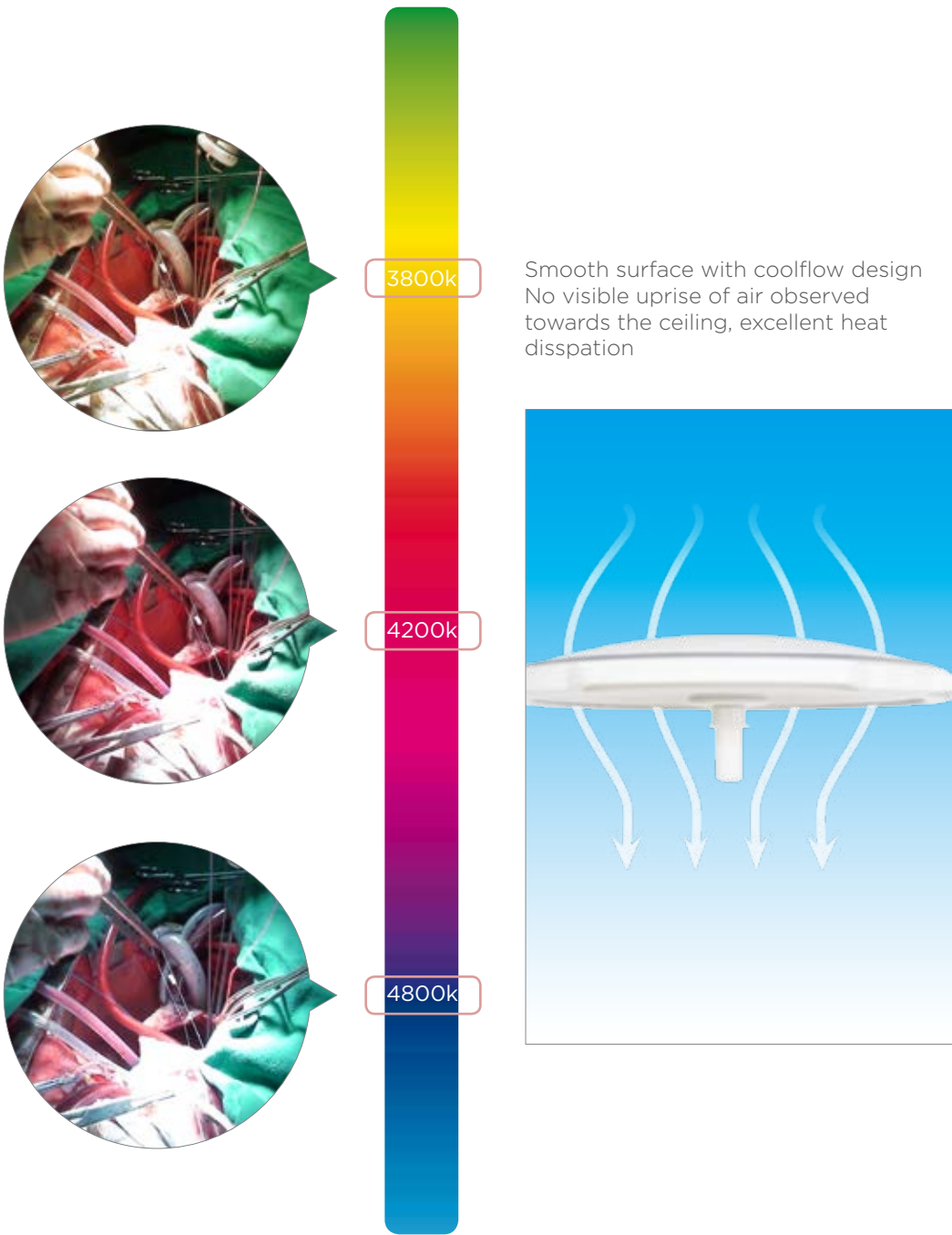


The LEDs used in operating room are characterized by very long lifetime, estimated at more than 50,000 h. In relation to other light sources used in halogen or discharge lamps, it is respectively more than 50 or 10 - times longer times between exchanges of light sources, which minimizes service actions. Additionally, low energy consumption of LED lamps: 2 or 3 times smaller than traditional surgical light, enables to save the environment and reduce the cost of maintaining the operating theater.

LED Surgical Light

Color temperature adjustment

Wide range of color temperature adjustment enables changing the contrast of the observed tissue and reduces fatigue of operating surgeon, which affects the comfort and ergonomics of the medical staff.



LED Light features



Osram LED bulbs

Natural sun-light lighting effect, real eye-sight of the human tissue
10-grade adjustable of illumination, color and ratio of radiation illumination
CAD modularized designed LED bulb set, adjustable depth more than 1,400mm. Glass imported from South Korea.



Endoscopic Mode

Invariable light of endoscopic mode, offering lighting needs for endoscopic surgery.



German Ondal spring arm

German Ondal spring arm ensure the high performance of the whole lighting system, stable and reliable during the surgery



LCD touching screen control panel

10-grade adjustable control panel, adjust by LCD touching screen
Quick and accurate adjust any time



Sterile grasp handle

Highly steriled grasp handle, one time shaping technology ensure highly hygiene degree

LED Surgical Light Examples of configuration



Standard ceiling mounted

All models compatible



Mobile basis curved arm

All models compatible



Low ceiling height mounted

All models compatible



Mobile basis straight arm

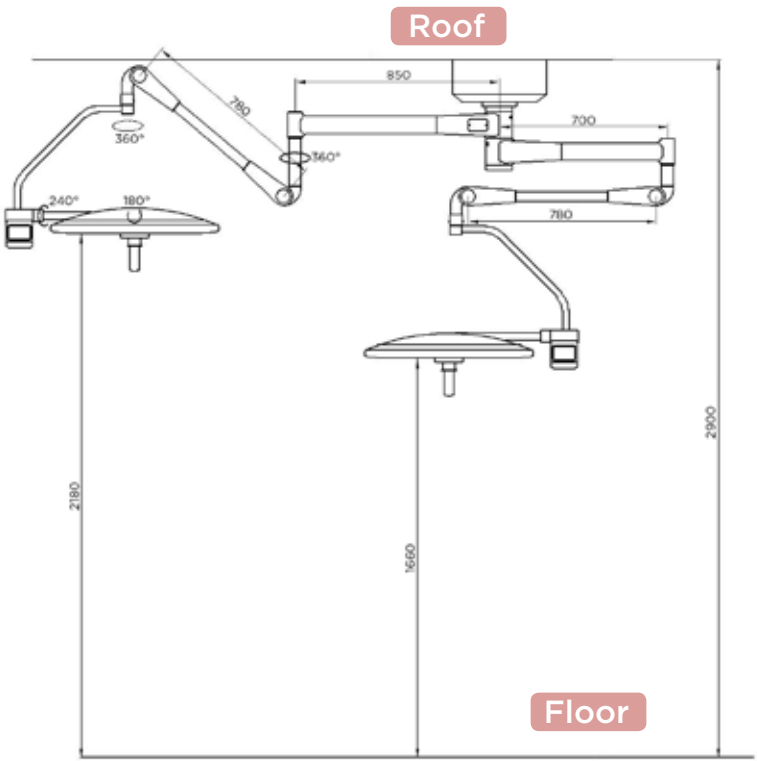
All models compatible



Wall mounted

All models compatible

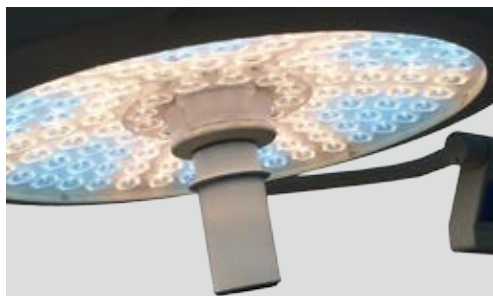
Installation guide





BIOL800M
Mobile basis, curved arm

Single ceiling mounted BIOL800



Technica Specifications	BIOL800
Illumination(lux)	60000-160000
Color Temperature(k)	3500-5000
Color Rendering Index(Ra)	85-98
Ratio of radiation illumination(mW/m^2 -lux)	< 3.6
Max. irradiation (w/m^2)	3.6
Diameter of Light Spot(mm)	120-350
Light field, D10 (mm)	160 +/-10
Light field, D50(mm)	80+/-10
Lighting Depth(mm)	≥ 700
Working distance(mm)	700-1400
Shadowless Rate(%)	98
Power(W)	120
LED bulbs(pcs)	120
Voltage used for LEDs (V)	30
Dome diameter(mm)	700
Weight of lamp body (kg)	65
Electric & frequency(V&Hz)	100-240 & 50/60
LED Working Life(h)	> 50000
No emission of IR and UV	



BIOL600M
Mobile basis, straight arm



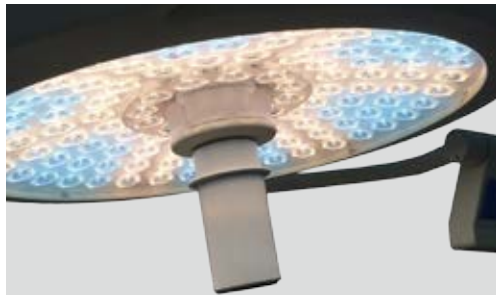
Single ceiling mounted BIOL600



Technica Specifications	BIOL600
Illumination(lux)	40000-120000
Color Temperature(k)	3500-5000
Color Rendering Index(Ra)	85-98
Ratio of radiation illumination(mW/m^2 -lux)	< 3.6
Max. irradiation (w/m^2)	3.6
Diameter of Light Spot(mm)	120-350
Light field, D10 (mm)	90 +/-10
Light field, D50(mm)	45 +/-10
Lighting Depth(mm)	≥ 700
Working distance(mm)	700-1400
Shadowless Rate(%)	88
Power(W)	54
LED bulbs(pcs)	54
Voltage used for LEDs (V)	30
Dome diameter(mm)	500
Weight of lamp body (kg)	55
Electric & frequency(V&Hz)	100-240 & 50/60
LED Working Life(h)	> 50000
No emission of IR and UV	



Dual ceiling mounted
BIOL800/800



Technica Specifications	BIOL800	BIOL800
Ilumination(lux)	60000-160000	60000-160000
Color Temperature(k)	3500-5000	3500-5000
Color Rendering Index(Ra)	85-98	85-98
Ratio of radiation illumination(mW/m ² -lux)	< 3.6	< 3.6
Max. irradiation (w/m2)	3.6	3.6
Diameter of Light Spot(mm)	120-350	120-350
Light field, D10 (mm)	160 +/-10	160 +/-10
Light field, D50(mm)	80+/-10	80+/-10
Lighting Depth(mm)	≥ 700	≥ 700
Working distance(mm)	700-1400	700-1400
Shadowless Rate(%)	98	98
Power(W)	120	120
LED bulbs(pcs)	120	120
Voltage used for LEDs (V)	30	30
Dome diameter(mm)	700	700
Weight of lamp body (kg)	65	65
Electric & frequency(V&Hz)	100-240 & 50/60	100-240 & 50/60
LED Working Life(h)	> 50000	> 50000
No emission of IR and UV		



Dual ceiling mounted
BIOL800/600



Technica Specifications	BIOL800	BIOL600
Ilumination(lux)	60000-160000	40000-120000
Color Temperature(k)	3500-5000	3500-5000
Color Rendering Index(Ra)	85-98	85-98
Ratio of radiation illumination(mW/m ² -lux)	< 3.6	< 3.6
Max. irradiation (w/m2)	3.6	3.6
Diameter of Light Spot(mm)	120-350	120-350
Light field, D10 (mm)	160 +/-10	90+/-10
Light field, D50(mm)	80+/-10	45+/-10
Lighting Depth(mm)	≥ 700	≥ 700
Working distance(mm)	700-1400	700-1400
Shadowless Rate(%)	98	88
Power(W)	120	54
LED bulbs(pcs)	120	54
Voltage used for LEDs (V)	30	30
Dome diameter(mm)	700	220 & 50
Weight of lamp body (kg)	65	55
Electric & frequency(V&Hz)	100-240 & 50/60	100-240 & 50/60
LED Working Life(h)	> 50000	> 50000
No emission of IR and UV		

Camera & Screen
Visual Operating System
BIOL800/600/C/M



Camera	
Model	SR-10A
Resolution	210megapixel 1920(H)X 1080(V)
Communication mode	RS232
Communication protocols	HITACHI
Connector	LVC MOS-36pFPC(YCbCr 4:2:2) compatibility 110/LVDS 30P
Sensor type	1/2.9" CMOS
Scan mode	Progressive Scan
Day And Night System	Color/black and white/automatic
Minimum illumination	color/0.1Lux black and white:0.01Lux
Synchronization mode	inter-sync
Video output	digital signal
SNR	≥50dB(AGC OFF)
Lens	
IRCUT	IRCUT double filter automatic switching
automatic diaphragm	Support
Optical lenses	10X f=5mm ~ 50mm
Field angle	H:47°(W)-5.3°(T) V:35.6°(W)-3.96°(T)
Generic specification	
Dimensions	56(W)* 56(H)* 110(L)mm
Work Temperature/humidity	-10-50℃ -10%RH-60%RH
Storage Temp/humidity	- 20℃ ~ 60℃, 10% RH ~ 80% RH
Power supply	DC 12V±10%
Power consumption	5W MAX
Net weight	270g

Function	
exposure mode	A/M
white balance	Automatic/indoor/outdoor/manual
Focus Mode	A/M
gain control	A/M
Picture Effect	Automatic/color/black and white/negative
electronic amplification	—
backlight compensation	on/off
Image Freeze	—
mirroring function	Support (horizontal mirror + vertical mirror)
image rollovers	Support
Blank Screen	—
Wide Dynamic	D-WDR
DNR	2D-DNR
electronic shutter	1/30s~1/10,000s
Digital Slow Shutter	—
contrast ratio	Adjustable
saturation	Adjustable
Anti-fog function	Support
motion detection	—
Privacy Shelter	—
Marginal	Support

HD Monitor main parameter	
TYPE	SRUI-M2201SD-W
Screen size	21.5"
Backlight Mode	LED
Display Area	475.2mm(W) × 267.3mm(H)
Aspect Ratio	16:9
Max Resolution	1920 × 1080
Display Color	16.7M
Pixel Pitch	0.2475(H)×0.2475(V)
Luminance	300cd/ m ²
Image Contrast	1500:1
Viewing Angle	850/850/750/650
Response Time	8MS
Field Frequency	50Hz、60Hz、70Hz

OSD	
Language	Chinese/English/French/German/ Italian/Spanish/ Portuguese/Dutch/Polish

Input and output	
SDI IN	1
SDI OUT	1
AV IN	22(2 × BNC)
AV OUT	1
S-VEDIO	1
VGA Input	1
HDMI Input	1
YPbPr/YCbCr Input	3(3×BNC)
RS232 Input(Optional)	1
Audio input	1
Audio output	1
Color system	PAL / NTSC / SECAM
Field Frequency	50Hz、60Hz、70Hz

OSD	
Power	DC 12V,50/60Hz
Pmax	35W-55W
Standby Power	5W

BiHealthcare is a leading Chinese manufacturer and provider of medical technology and equipments for operation room, our surgical LED light use most advanced technology to ensure the high performance the surgery and decrease the risk of eye tired during surgery.

“MAKE IT SAFER” is our guiding principle, both on our design principle for our products and related services we offered. Our products design is maximum based on ergonomics which could highly reduce the pain of patients, for caregivers, we fully consider to offer most simple and functional.

BiHealthcare is offering value to our customers and distributors all over the world, better quality products at a competitive cost helped us earn lots of customers and distributors who are willing to stay with us no matter in the past, today and in the future. We are expecting you will be the next one with us to continually create value.



BiHealthcare
MAKE IT SAFER

WARRANTY

- Three years warranty
- 24 hours quick response

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■ As the circumstance of printing, the photos might have minor difference on color, tactile from real products.

■ As the update of design and improvement, parameters and outlook of products might change, thanks for understanding.



MANUAL BOOK

Surgical LED light series

Model:
BIOL800/800, BIOL800/600, BIOL600/600, BIOL800 (M),
BIOL600 (M), BIOL840/830, BIOL840 (M), BIOL830 (M), BIOL210

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Precautions

Dear User,

Thank you for choosing shadowless lamp serial products manufactured by BiHealthcare

For proper operating the equipment, please read the user manual carefully.

In any case of the equipment operating, make sure operator fully understands the contents of this user manual and strictly follows instructions during operating.

Notice: the equipment is not suitable for use in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide.

Liability for Damage (Disclaimer)

Installation and setup of the equipment should be performed by our company or its authorized persons.

Liability of damages caused by non-authorized institute or personnel would be borne by its owner or operator. No warrant grants such damage liability by the company.

Liability for Damage/Disclaimer is also applicable for Sales Contracts and Transportation Agreements.

BiHealthcare

Permissible Environmental Conditions	
During Transport and Storage (in Original Packaging Materials)	During Use - For Dry Locations
<i>Ambient Temperature:</i> 14° to 140° F (-10 to 60 °C) • <i>Relative Humidity:</i> 10% to 85% (No Condensation) • <i>Atmospheric Pressure:</i> 14 to 31 inHg (500 to 1060 hPa)	• <i>Ambient Temperature:</i> 60° to 85° F (15 to 30 °C) • <i>Relative Humidity:</i> 30% to 60% (No Condensation) • <i>Atmospheric Pressure:</i> 20.7 to 31.3 inHg (700 to 1060 hPa)

A. Introduction

BiHealthcare BICL Serial LED Luminescence Operating Shadowless Lamps (Abbr. Shadowless Lamps) is newly developed product by the Company. The serial products employ multiple LED light pillars, universal lifting linkage and totally enclosed and streamlining designed lamp cap, complying with requirements both for illumination for surgeries and examinations, and sterilizing and laminar flow cleaning in all kinds of operating rooms.

BIOL Serial products are Class I (protective earth), Type B  equipment (indirect contact human body).

The serial products include pendant Shadowless Lamp, wall-mounted Shadowless Lamp, wall-mounted intervention lamp, Floor-Standing Shadowless lamp and Floor-Standing intervention lamp, and are capable to fulfill all kinds of requirements for operation.

B. Characteristics

1. Shadowless lamps employ multiple LED designed by Computer Assisted Module Design, producing multipoint light pillar illumination, deep illumination of 60 cm of light pillar, and excellent shadowless effectiveness. Illumination intensity of light spots is higher than 60,000 lx, providing color temperature close to natural sunlight with 3,500 k ~ 5,000 k, reflecting actual colors of human tissue, completely fulfill all kinds of requirements for operation.
2. Switch box is controlled by LCD touch screen, which do not move illuminating area because of light adjustments. Handling on switch box knob and central sterilization knob can manipulate and use all functions of the light at one position.
3. Integrated control method with multi-homo-power, multiunit and multipath, ensures single damaged LED in one path will not affect requirements of operation.
4. Universal appending system provides maximal adjusting range, suitable for any form of operating room. Appending arm is made of nova alloy, characterized as light-strong structure, convenient operation and accurate positioning.
5. Totally enclosed and streamlining designed lamp cap, complying with requirements of sterilizing and laminar flow cleaning in all kinds of operating rooms.
6. Multiple choices of pendant Shadowless Lamp, wall-mounted Shadowless Lamp, and Floor-Standing Shadowless lamp are capable to fulfill all kinds of requirements for operation.

C. Main Specifications

Table 1

Specifications	LED Serial Products				
	BIOL800	BIOL600	BIOL800M	BIOL600M	BIOL800/600
Illumination Intensity (lux)	≥ 160,000	≥ 14,0000	≥ 160,000	≥ 14,0000	≥ 160,000, ≥ 14,0000
Color Temperature(k)	3,500 ~ 5,000	3,500 ~ 5,000	3,500 ~ 5,000	3,500 ~ 5,000	3,500 ~ 5,000
Chromogenic Index	85-98	85-96	85-96	85-96	≥90
Diameter of Light Spot (mm)	120-350	120-350	120-350	120-350	150
Illumination Depth (mm)	1400	1400	1400	1400	500

Specifications of Movement Range

Table 2

Movement	Movement Range		
	Pendant Shadowless Lamp	Wall-mounted Shadowless Lamp	Floor-Standing Shadowless Lamp
Horizontal Arm rotates around holder	360°	180°	—
Balance Arm rotates around Horizontal Arm	360°	180°	—
Pendant Arm rotates around Balance Arm	360°	360°	360°
Connecting Arm rotates around Pendant Arm	240°	240°	240°
Balance Arm moves vertically	40°	40°	40°
Lamp body rotates around Connecting Arm	180°	—	—

Other specifications

Table 3

Light head diameter		LED bulb life time
BIOL800, BIOL800M	700mm	50,000 hours
BIOL600, BIOL600M	500mm	
BIOL840, BIOL830	250mm each	

D. Diagram of Product Structure

D Serial Products employ six sets of advanced universal joint system, which main structure consists of Lamp Body, Balance Arm, Horizontal Arm, Holder, Pendant Arm, Connecting Arm and Switch Box. Product structures of specific model are shown as Fig. 1 – 3. Specifications of movement range refer to Table 2. See Fig. 4 for control panel.

1. Pendant shadowless lamp:

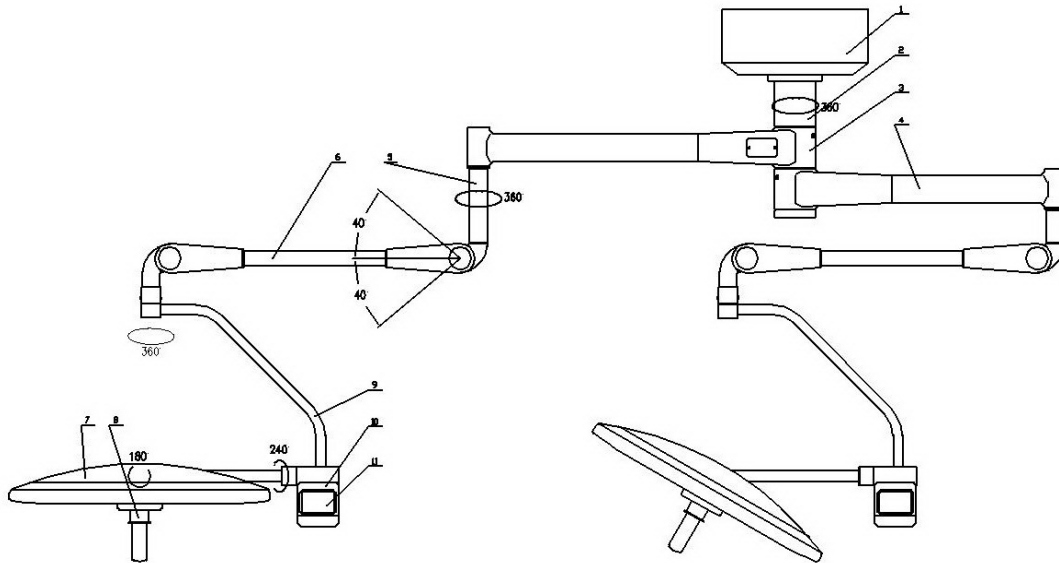


Fig. 1 Diagram for Pendant Shadowless Lamp

1. cover plate assembly 2. Fixed tray 3. Main horizontal arm 4. Auxiliary horizontal arm 5. Connecting rod to balance arm 6. Balance arm assembly 7. Lamp cap assembly 8. Sterilization knob 9. Pendant rod of lamp cap 10. Switch box 11. LCD screen

2. Wall-mounted Shadowless Lamp

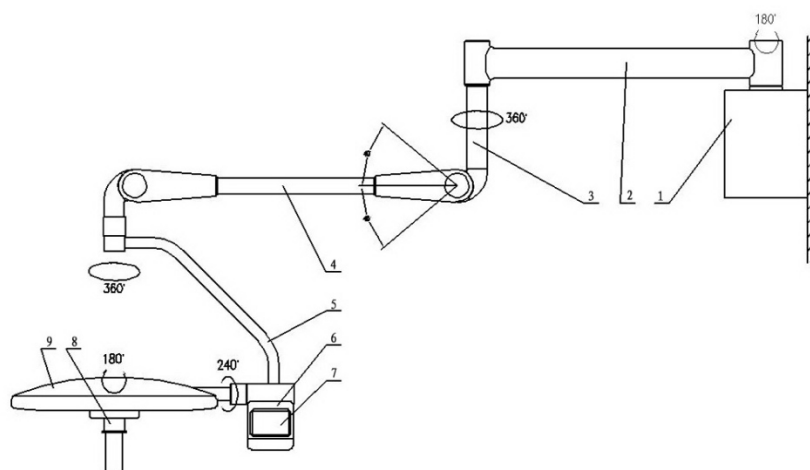


Fig. 2 Diagram for Wall-mounted Shadowless Lamp

1. cover plate assembly 2. Horizontal arm 3. Connecting rod to balance arm 4. Balance arm assembly 5. Pendant rod of lamp cap 6. Switch box 7. LCD screen 8. Sterilization knob 9. Lamp cap assembly

3. Floor-Standing Shadowless Lamp

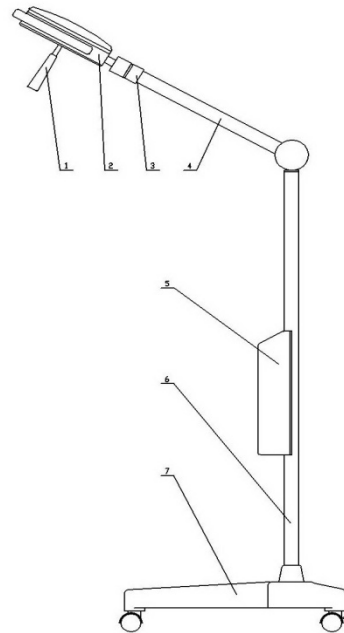


Fig. 3 Diagram for Floor-Standing Shadowless Lamp

1. Handle 2. Lamp cap assembly 3. Sheath 4. Balance arm assembly 5. Switch box 6. Upright rod 7. base

4. LCD Display

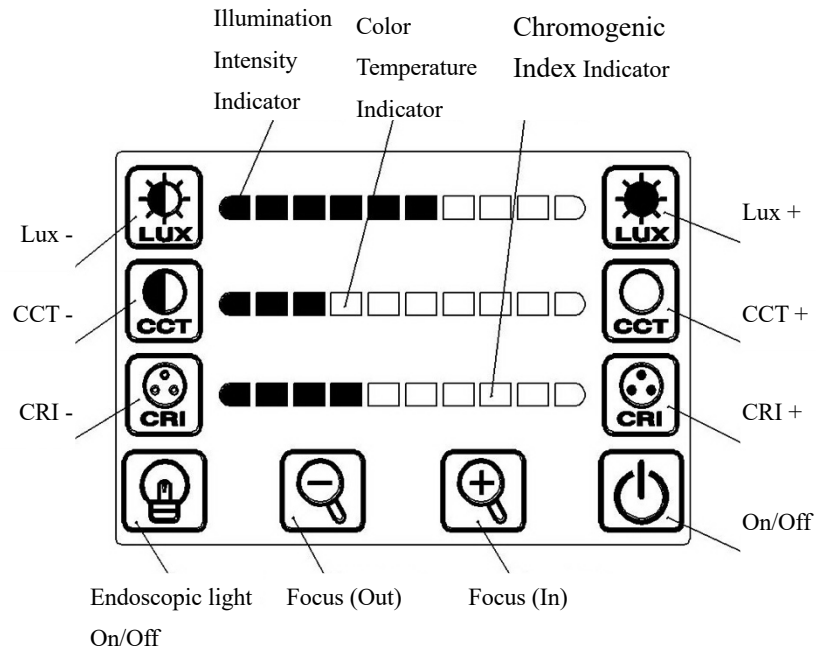


Fig. 4 LCD Display

5. LCD Display

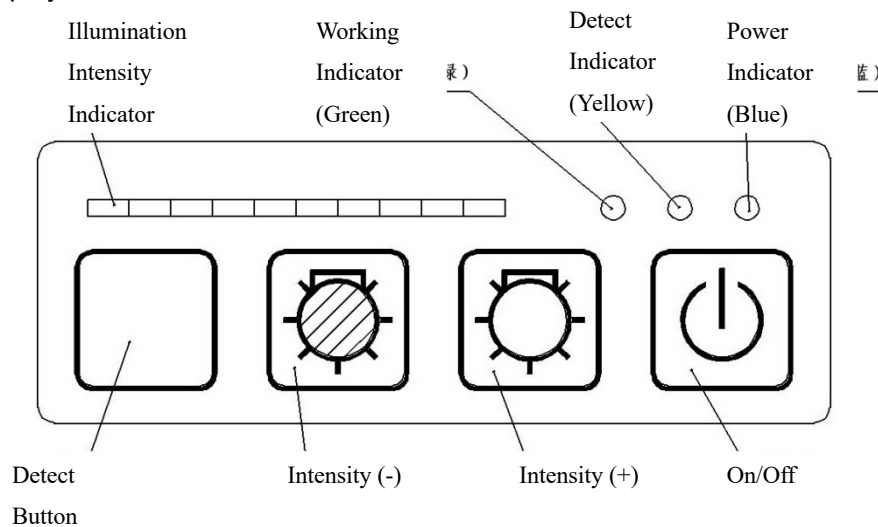


Fig. 5 LCD Display on Floor-Standing Lamp

E. Instruction for Use

Special Note: unless otherwise specified, each model of Shadowless Lamp is operated per this instruction.

1. Adjust position of shadowless lamp
 - a) Pendant and wall-mounted shadowless lamp: hold switch box knob in one hand and sterilization knob in another. Adjust lamp cap to expected position. Release knobs. Pendant arm will be positioned by damping.
 - b) Floor-standing shadowless lamp: move lamp body to working position. Keep position by using brake pedal on rear wheel. Handle knob to move lamp cap to expected position for operating (examining) illumination. Release knob. Lamp cap will be positioned by damping.
2. Power on shadowless lamp
 - a) Pendant and wall-mounted shadowless lamp: turn on power switch on shadowless lamp (mains plug is detachable, with control switch and fuse). LCD display is lighten, showing each icons of function button (Refer to Fig. 4).
 - b) Floor-standing: pull mains plug out and connect to mains supply. Blue indicator on pillar switch panel will turn on.
3. Turn on shadowless lamp
 - a) Turn on: touch switch button. Shadowless lamp will turn on;
 - b) Illumination adjustment: touch illumination (+) on the display to increase illumination indicator and lamp illumination; touch illumination (-) on the display to decrease illumination indicator and lamp illumination;
 - c) Color temperature adjustment: touch color temperature (+) to increase color temperature indicator of display and color temperature; touch color temperature (+) to

- decrease color temperature indicator of display and color temperature;
- d) Chromogenic Index adjustment: touch chromogenic index button (+) to increase chromogenic index indicator and chromogenic index; touch chromogenic index button (-) to decrease chromogenic index indicator and chromogenic index;
- 4. Light spot adjustment
Holding central sterilization handle, rotate the handle according to working requirements to adjust light spot to proper size. Release the handle.
- 5. Focus adjustment of integrated camera (for lamp with integrated camera):
Touch focus button (In) to zoom in images, or touch focus button (Out) to zoom out images.
- 6. Turn floor-standing shadowless lamp
 - a) Turn on: press switch on switch box to turn on shadowless lamp.
 - b) Illumination adjustment: press illumination (+) on switch box to increase illumination; press illumination (-) on switch box to decrease illumination
- 7. Turn off shadowless lamp
 - a) Pendant or wall-mounted lamp: when operation complete, touch On/Off button to turn off shadowless lamp. Turn off mains switch also to shut down power supply.
 - b) Floor-standing: when operation complete, press On/Off key to turn off shadowless lamp. Turn off mains switch also to shut down power supply.
- 8. Endoscopic light (with endoscopic light lamp)
Touch endoscopic light On/Off key to turn on endoscopic light. Touch again to turn off endoscopic light.

F. Clean and Sterilization

**Precautions: always cut off power supply before sterilizing and maintaining the lamp!
Keep shadowless lamp in complete power off status.**

Special Note: unless otherwise specified, clean and sterilize each model of shadowless according to this instruction.

1. Central sterilization handle
The handle should be sterilized before each operation.
Routine sterilization method: press handle position button to release the handle. Immerse in formalin for 20 minutes.
Furthermore, sterilizations using ultraviolet radiation or high temperature less than 120 °C (without pressure) are optional.
2. Lamp cap assembly
Lamp cap assembly can be sterilized before each operation (sterilize after turn off lamp for 10 minutes). The assembly can be sterilized by wiping the surface using a soft cloth dipped with formalin or other disinfectant. Till achieve sterilization requirements.
3. Switch box and control panel.
Should be sterilized before each operation. Wiping the surface using a soft cloth dipped with formalin or medicinal alcohol.
Note: do not use too wet cloth wiping lamp to avoid electrical malfunction!

4. Lamp assembly and other

Lamp assembly and other mechanism need to be sterilized regularly. Wiping the surface using a soft cloth dipped with formalin or other disinfectant. Do not use too wet cloth wiping lamp.

- Cleansing for permanent seat for pendant shadowless lamp is a climbing job. Be careful!
- When cleansing seat of floor-standing or intervention lamp, do not let liquid enter cover of stabilized voltage supply to avoid equipment damage.

G. Precautions

- 1) If service interruption occurs when shadowless lamp works. Press On/Off button to restart shadowless lamp when power supply connected.
- 2) Before operating, check proper work for main bulb and auxiliary bulb. If damaged, change bulb immediately. Ensure main and auxiliary bulbs work properly in operation.
* Check bulbs by press *Switch Main and Auxiliary Bulb* on the operation panel.
- 3) After operation, power off lamp in specified order.
- 4) Shadowless lamp should be serviced by professional service person. Do not disassembly without authorization.
- 5) Sterilize central sterilization handle per instructions.
- 6) The equipment is not suitable for use in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide.
- 7) The equipment need to be maintained twice annually. Please keep records and feedback the Company if problem occurs. Warrant will be invalid for non-maintained reason caused malfunction.

H. Transportation and Storage

1. The equipment should be packaged into box for storage. Moisture-proof and rainproof measures are required. Shadowless lamp should be firmly positioned in box, with soft materials between contact surfaces.
2. Avoid rain, moisture, inversion, stress and roll in transportation.
3. Store the equipment in environment that temperature is between -10 °C ~ 40 °C and relative humidity is not more than 80%, without presence of corrosion air, well ventilation and avoid sunlight.
4. The equipment is High-altitude hanged heavy products, can be used safely for 10 years.

I. Troubleshooting

Special Notice: unless otherwise specified, deal with malfunction per these instructions.

Malfunctions	Identification	Solution	Note
No display on LED touch screen	LED power is on. Power supply works well.	Turn on main switch of shadowless lamp. Change power supply.	

LED lamp does not light, but display on touch screen	Shadowless lamp is not turned on	Touch right bottom to turn on shadowless lamp	Cut off power supply before maintaining! Waiting for bulb cooling down before change bulbs to avoid burned.
A few LED bulb do not light up	Led bulbs damaged	Need to change LED bulbs. Contact the Company.	Do not maintain with power on.
Touch screen failure	Touchable screen damaged	Contact the Company.	Do not repair, contact the Company

Note: if problems remain or other malfunctions not mentioned occur, please contact the Company or local service center. Do not repair.

J. After-sales service

1. If any quality issues occur within one year from the date of installation, the equipment would be repaired or replaced for free (except for bulb and central sterilization handle).
2. If necessary, the Company will provide other available document



Manufacture by:

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No.24, Zhenxing Road, Zhangjiagang Economic
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EC	REP
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EC Representative:

Kingsmead service station
Canterbury Sub Station, Broad Oak Road
Canterbury, Kent, CT27PX
Tel:00442032399738 Fax: 00442032399728
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K. EMC Guidelines

Electromagnetic compatibility (EMC)

The BIOL series shadowless operation light is intended for use in the electromagnetic environment specified below. The customer or the user of the BIOL series shadowless operation light should assure that it is used in such an environment.

Electromagnetic emission

Emission Test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The BIOL series shadowless operation light user RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BIOL series shadowless operation light is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 15	Complies	The BIOL series shadowless operation light is not suitable for interconnection with other equipment.

Electromagnetic immunity

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for	±2kV for power supply lines ±1kV for	Mains power quality should be that of a typical commercial or hospital environment.

	input/output lines	input/output lines	
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5%Ur (>95% dip in U_T) for 0.5 cycle <40%Ur (>60% dip in U_T) for 5 cycle <70%Ur (>30% dip in U_T) for 25 cycle <5%Ur (>95% dip in U_T) for 5 sec	<5%Ur (>95% dip in U_T) for 0.5 cycle <40%Ur (>60% dip in U_T) for 5 cycle <70%Ur (>30% dip in U_T) for 25 cycle <5%Ur (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BIOL series shadowless operation light requires continued operation during power mains interruptions, it is recommended that the BIOL series shadowless operation light be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level			

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC61000-4-6	3V rms 150kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BIOL series shadowless operation light, including cables, than the recommended
Radiated RF	3 V/m	3 V/m	

IEC61000-4-3	80MHz to 2.5 GHz		separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 2.5 \text{ GHz}$ 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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NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateurs 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 BIOL series shadowless operation light is used exceeds the applicable RF compliance level above, the BIOL series shadowless operation light should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BIOL series shadowless operation light.

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

Recommended separation distance

The BIOL series shadowless operation light is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BIOL series shadowless operation light can help prevent electromagnetic interference by maintaining a minimum distance shadowless operation light as recommended below, according to be maximum output power of the communications equipment.

Rated maximum output power of transmitter (w)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	150 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333
For transmitter rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			