



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.SNOA.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

Certificate Number

47946/1

Date:

30 July 2020

Valid Until:

30 July 2023

EAC Code:

17



015





Zhangjiagang Braun Industry Co.,Ltd.

Building C7, No 199, Hongwu Avenue, Tangqiao Town, Zhangjiagang City, Jiangsu Province, China.

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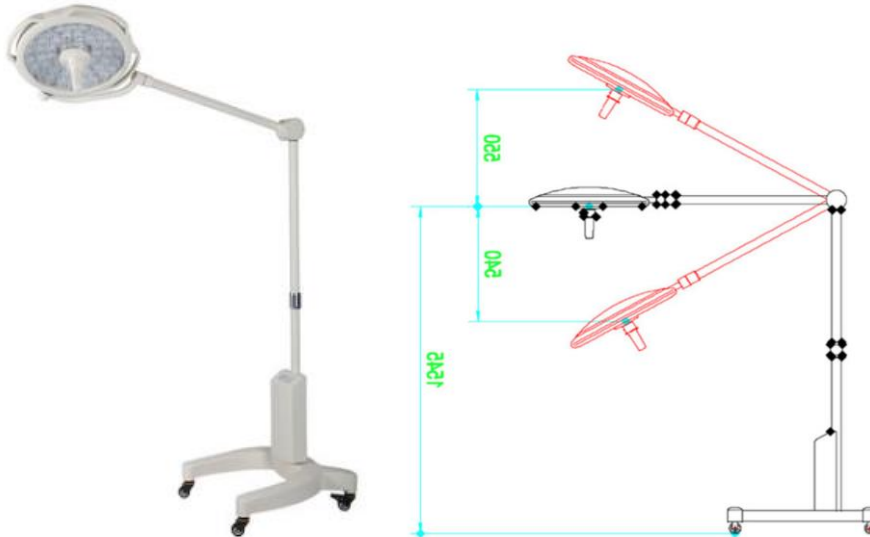
Email: info@bihealth-care.com daniel@bihealth-care.com

Skype: dan.bihealthcare Whatsapp (Wechat, Viber): 86 18626299207

Focus on Medical Supply, Provide Best Medical Solution. We Care What you Need.

Product Name: Mobile Light

Model Number: BIOL600M



BIOL600M Mobile Light:

- Light head with 500mm diameter can be installed on a moveable and flexible stand, which will be ideal for the hospital, outpatient clinic, first-aid, emergency and disaster releasing, and any other complicated conditions.
- The rechargeable built-in battery can sustain normal use at least 2 hours when power failure.
- Mounted on swivel castors with brakes
- Illumination Intensity (lux) 40,000-120,000
- Heat to Light Ratio($mW/m^2 \cdot lux$) <3.6 , color rendering index 98 Ra
- Diameter of Light Spot (mm) 120-300
- Illumination Depth (mm) >1400
- LED OSRAM bulb Quantities(pc) 54
- LED Service Life(h) $>50,000$
- Touch screen control panel on light head for adjustment
- Adjustable color temperature : 3500-5000K
- Light with endoscopy mode
- Sterile grip handle x 3 units
- Packed in strong carton





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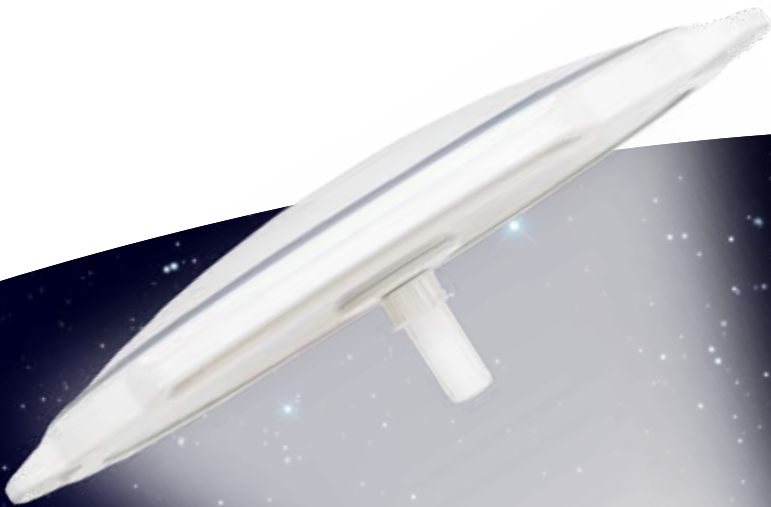
Focus on Medical Supply, Provide Best Medical Solution. We Care What you Need..

- Mobile support, with at least 4 wheels, 2 lockable. - **YES**
- Support height 190-210 cm, - **YES**
- Illuminator mounted on the articulated arm of at least 90-100 cm, • Arm movement range: up / down at least 70 cm, - **YES**
- Rotate the illuminator around the axis of the arm - at least 90 °, - **YES**
- Rotate the illuminator perpendicular to the arm - minimum 140 °, - **YES**
- Lighting in the center $\geq 120,000$ Lux, Color temperature: 4500 ° K \pm 5%, - **YES**
- Lighting field size, focusable: 150-300mm, - **YES**
- Brightness adjustment from 10% to 100%, - **YES**
- type of bulbs- LED, - **YES**
- bulb life > 30000 h, - **YES**
- Internal batteries, battery working time min 1 h. - **YES**
- Accessories: Autoclavable handle.-3pcs - **YES**



 Healthcare

MAKE IT SAFER



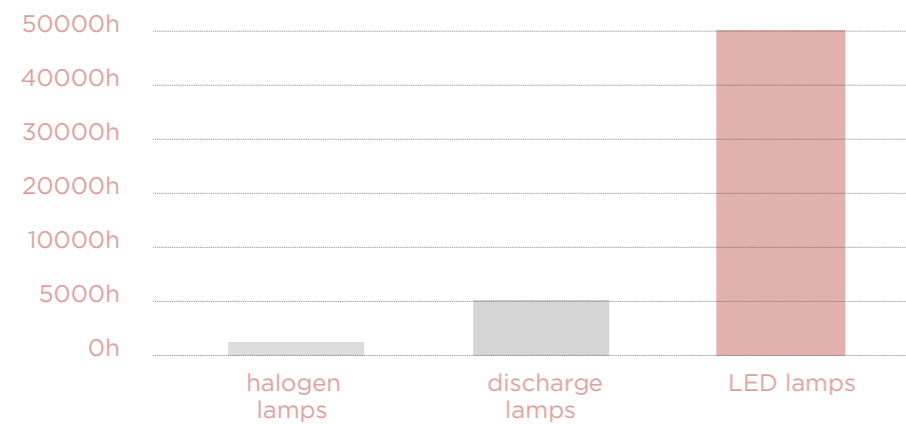
LED Surgical Light

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.

3800k

4200k

4800k

Smooth surface with coolflow design
No visible uprise of air observed towards the ceiling, excellent heat dissipation

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.



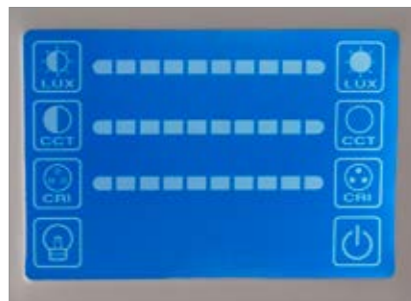
Endoscopic Mode

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

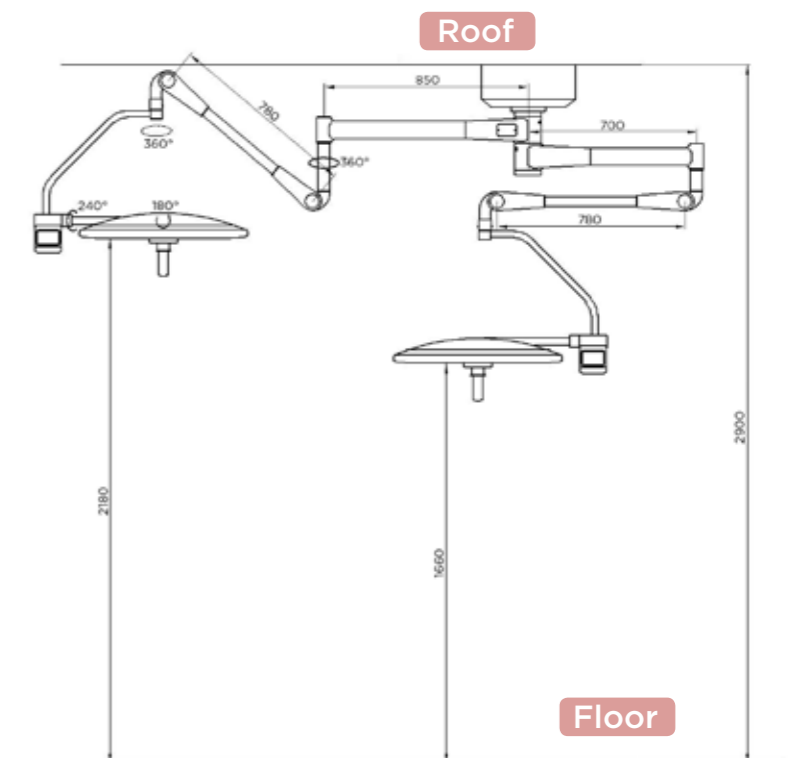
All models compatible



Wall mounted

All models compatible

Installation guide



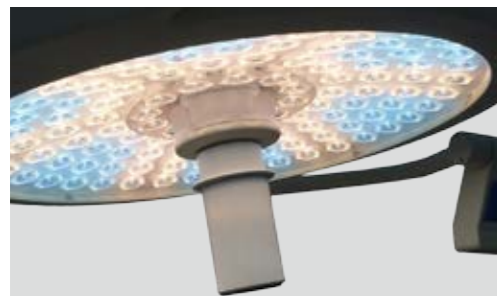


BIOL800M
Mobile basis, curved arm



BIOL600M
Mobile basis, straight 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	

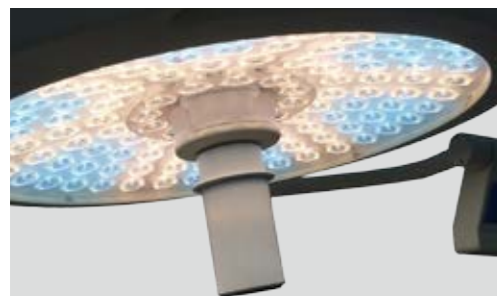
Single ceiling mounted BIOL600



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
Illumination(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/m ²)	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
Illumination(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/m ²)	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		



Single ceiling mounted
BIOL840



Technica Specifications	BIOL840
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/m2)	3.6
Diameter of Light Spot(mm)	120-350
Light field, D10 (mm)	150+/-10
Light field, D50(mm)	75+/-10
Lighting Depth(mm)	≥ 700
Working distance(mm)	700-1400
Shadowless Rate(%)	95
Power(W)	80
LED bulbs(pcs)	80
Voltage used for LEDs (V)	30
Dome diameter(mm/each)	250
Weight of lamp body (kg)	70
Electric & frequency(V&Hz)	100-240 & 50/60
LED Working Life(h)	> 50000
No emission of IR and UV	



Single ceiling mounted
BIOL830



Technica Specifications	BIOL830
Illumination(lux)	60000-140000
Color Temperature(k)	3500-5000
Color Rendering Index(Ra)	85-98
Ratio of radiation illumination(mW/m ² -lux)	< 3.6
Max. irradiation (w/m2)	3.6
Diameter of Light Spot(mm)	120-350
Light field, D10 (mm)	140+/-10
Light field, D50(mm)	70+/-10
Lighting Depth(mm)	≥ 700
Working distance(mm)	700-1400
Shadowless Rate(%)	88
Power(W)	60
LED bulbs(pcs)	60
Voltage used for LEDs (V)	30
Dome diameter(mm/each)	250
Weight of lamp body (kg)	60
Electric & frequency(V&Hz)	100-240 & 50/60
LED Working Life(h)	> 50000
No emission of IR and UV	

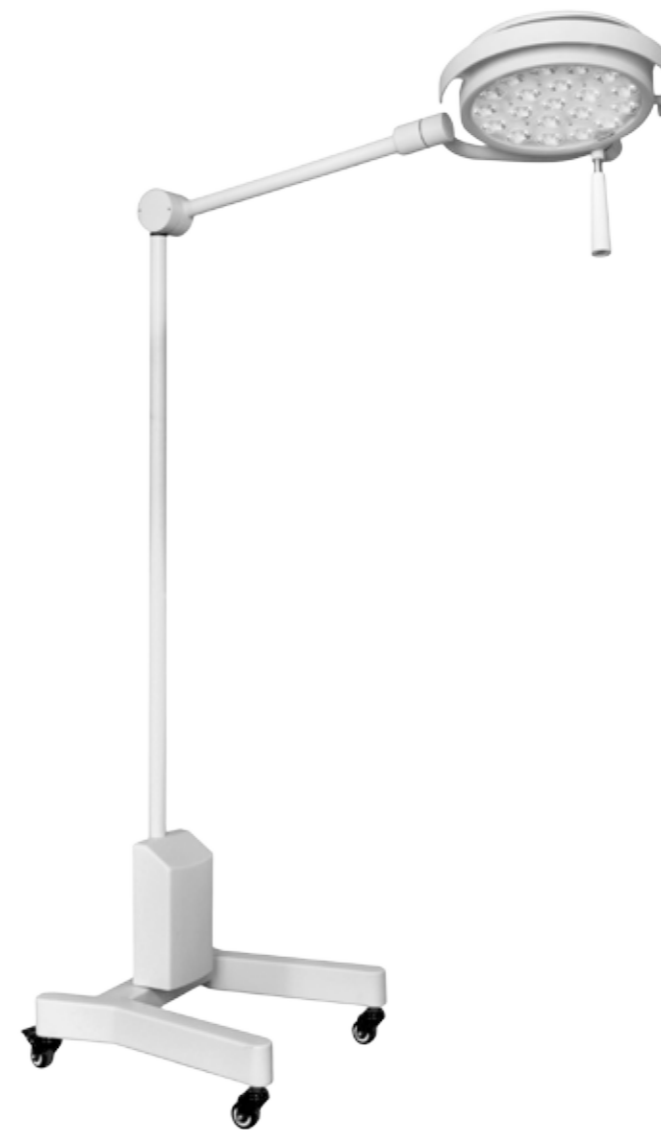


Dual ceiling mounted
BIOL840/830



Technica Specifications	BIOL840	BIOL830
Illumination(lux)	60000-160000	60000-140000
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/m ²)	3.6	3.6
Diameter of Light Spot(mm)	120-350	120-350
Light field, D10 (mm)	150+/-10	140 +/-10
Light field, D50(mm)	75+/-10	70+/-10
Lighting Depth(mm)	≥ 700	≥ 700
Working distance(mm)	700-1400	700-1400
Shadowless Rate(%)	95	88
Power(W)	80	60
LED bulbs(pcs)	80	60
Voltage used for LEDs (V)	30	30
Dome diameter(mm/each)	250	250
Weight of lamp body (kg)	70	60
Electric & frequency(V&Hz)	100-240 & 50/60	100-240 & 50/60
LED Working Life(h)	> 50000	> 50000

No emission of IR and UV



Single mobile basis
BIOL210



BIOL210W
Wall mounted



Control panel

Technica Specifications	BIOL210
Illumination(lux)	40000-60000
Color Temperature(k)	3500-5000
Color Rendering Index(Ra)	≥ 90
Ratio of radiation illumination(mW/m ² -lux)	< 3.6
Max. irradiation (w/m ²)	3.6
Diameter of Light Spot(mm)	150
Light field, D10 (mm)	60+/-10
Light field, D50(mm)	30+/-10
Lighting Depth(mm)	≥ 500
Working distance(mm)	700-1400
Shadowless Rate(%)	—
Power(W)	20
LED bulbs(pcs)	20
Voltage used for LEDs (V)	30
Dome diameter(mm/each)	260
Weight of lamp body (kg)	45
Electric & frequency(V&Hz)	100-240 & 50/60
LED Working Life(h)	> 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	LVCMS-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	
IRCU T	IRCU T 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.



WARRANTY

- Three years warranty
- 24 hours quick response

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Economic Development Zone, Jiangsu, China.

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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.