

CE Documentation Review



No. 3J190729.SHMTN80

Holder: Shanghai Huifeng Medical Instrument Co., Ltd.

2 Buildings, No. 885, Qiuxing Road, Nicheng Town,
Pudong New Area, Shanghai, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Operating Table, Shadowless Operating Lamp

Model(s): (see the following annex I)

Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 29 July 2019

Expiry date 28 July 2024

Chief Manager
Marco Morina

Deputy Manager
Amanda Payne

Annex I

No. 3J190729.SHMTN80

Name	Model/ Type
Operating Table	HFEOT99C, HFEOT99, HFEOT99D, HFEPB99A, HFEPB99B, HFEPB99C, HFEPB99, HFEOT99S, HFEOT99X, HFOOT99A
Shadowless Operating Lamp	SY02-LED3+5, SY02-LED3, SY02-LED5, SY02-LED5+5, SY02-LED3+5-TV, SY02-LED5+5-TV, SY02-LED3+3, HF-L3+4CLED, HF-L4+4CLED, HF-L3+3CLED, HF-L4CLED, HF-L3CLED, HF-L4WLED, HF-L3WLED, HF-L4SLED, HF-L3SLED, HF-L4ELED, HF-L3ELED, 700/500LED, 700LED, 500LED



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America

CERTIFICATE

No. QS5 061501 0011 Rev. 00

Certificate Holder:

Shanghai Huifeng Medical Instrument Co., Ltd.

Building NO.2, NO.885, Qiuxing Road, Nicheng Town
Pudong New Area
201306 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Air Cushions for Bedsore, Shadowless Operating Lamps, Electric-Heating Boiling Disinfectors and Electric Pneumatic Hemostat; Distribution of Operating Table, Pendant and Bedhead Unit

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

SH1811713

Effective Date:

2019-04-17

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2022-04-16

Page 1 of 1

Date of Issue: 2019-04-26

(Arie Henkin)
Manager, Certification Body MHS

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TÜV®



Certificate

No. Q5 061501 0009 Rev. 01

Holder of Certificate: **Shanghai Huifeng Medical Instrument Co., Ltd.**

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Facility(ies):

Shanghai Huifeng Medical Instrument Co., Ltd.
Building NO.2, NO.885, Qiuxing Road, Nicheng Town, Pudong
New Area, 201306 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

**Design and Development,
Production and Distribution of
Air Cushions for Bedsore,
Shadowless Operating Lamps,
Electric-Heating Boiling Disinfectors,
Electric Pneumatic Hemostat
Distribution of Operating table,
ICU Pendant and Bedhead Unit**

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1811713

Valid from: 2019-05-01

Valid until: 2022-04-30

Date, 2019-04-15

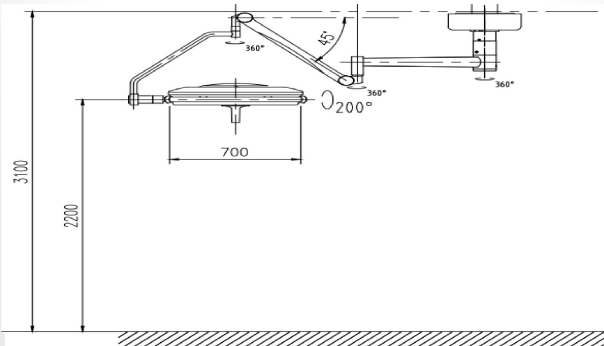
Stefan Preiß

	Surgical lamp for the operating room with ceiling mounting		
	Specification requested by customer		Specifications proposed by the manufacturer
	Parameter Specification		700 LED with HD camera
	The degree of illumination of a surface	120,000-160,000 lux	120,000-160,000 lux
	Lighting field diameter	22 - 30 cm (options: circular or oval)	25 - 30 cm circular
	Working field adjustment	"Adjusting the working field size and lighting while maintaining a given color temperature"	"Adjusting the working field size and lighting while maintaining a given color temperature"
	color temperature	3800 - 4800 K, variable	3800±500K, 4400±500K, 5000±500K
	Adjustable	Yes	Yes
	Color rendering index	95	95
	Depth of illumination	> 80 cm	> 100 cm
	Light sources	High-performance LEDs	High-performance LEDs
	High-performance LED light sources prevent the appearance of colored shadows		YES
	LED lifespan	≥ 25,000 hours	50000 hours
	Sterile operation by sense	Grip	Grip
	Non-sterile via the senso panel	Touch	Touch
	aperture	≥ 1.8 - 2.1	≥ 1.8 - 2.1
	sensors	1/3 type HD CMOS	1/2.8 inch type HD CMOS
	focus	Automatic included	Automatic included
	White balance	Automatic / manual	Automatic / manual
	Brightness level	Automatic / manual	Automatic / manual
	NTSC SD Video Signal (CROP)	NTSC (SQUEEZE); pal	NTSC (SQUEEZE); pal
	Working humidity from	20% to 80%	20% to 80%
	certificates		
	Manufacturer's certificate attesting to the quality of the ISO 13485 product	provide us with	yes, we have.
	EC certificate or EC declaration of conformity based on assessment of conformity with the corresponding annexes for the products offered	provide us with	yes, I will provide EC certificate.
	Confirmatory documents		
	Service manuals in one of the international languages (Russian / English) and user manual with presentation of the translation at the time of delivery in the state language	provide us with	We only have English user manual.
	Manufacturer's catalog / prospectuses / technical documents, on paper or in electronic format, with the indication / marking of the reference number / model of the article assigned to the lot number provided.	provide us with	yes, we have.



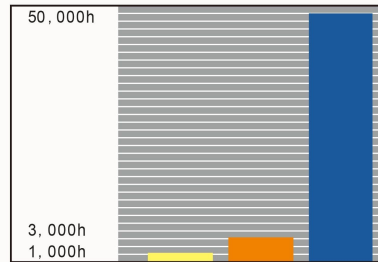
INSTALLATION DIAGRAM

700LED



700LED

Optional color temperature, there are three color temperature section, respectively is 3800 k, 4400 k, 5000 k. color temperature can be adjusted. First, the color temperature adjustable benefits is to reduce the doctor eyes visual fatigue. Second, according to the different color of skin, choose the right color temperature.



Long service life:
Halogen generally is 1000 hours,
the LED is the (Osram) more than 50000 hours.

Main Technical Data

700/500LED Adjust Color Temperature	
Illuminance	≥160,000Lux
Colour temperature	3800±500K 4400±500K 5000±500K
Colour reduction index(Ra)	95
Total irradiance	544W/m ²
Size of light field	250~300mm
Service life of illuminant	50,000h
Power supply voltage	AC110-240V 50/60Hz
Lowest height of installation	2900mm
Total power consumptio	80W
Total LED bulb quantity	108 pcs



700 LED Shadowless Operating Lamp

Operation, Installation and Maintenance Manual (Technical Specifications)

Part I General Features

1. General Specifications and Definitions

1.1 General Specifications

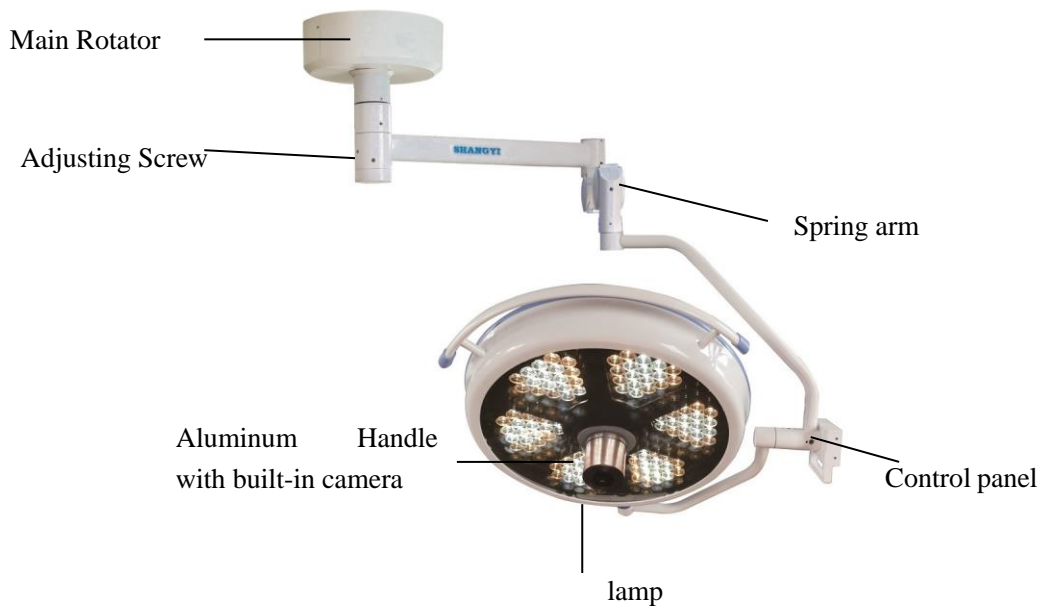
This manual is prepared to describe performance, installation, trial operation, operation, maintenance and troubleshooting of this 700 LED Shadowless Operating Lamp on Ceiling

The wall-mounted type and mobile type products are described separately.

2. Technical Data


Electrical Specification	
Description	700 LED
Supply Voltage	AC 220V \pm 10%
Supply Frequency	50Hz \pm 1Hz
Power Input	80VA
Bulb Power	3.2V1W
Main Fuse	F2AL 250V (quick-acting fuse)
Performance Specification	
Description	700 LED
Rated Illumination	100000-160000lx
Color Temperature	3800 \pm 200K/4400 \pm 200K/5000 \pm 200K
Mechanical Specification	
Description	700 LED
Cross Arm turns around fixed seat	360°
Lamp body turns around riser	360°

2.1 Structural Configuration:



3. Conformity Specification

3.1 Device Type

Electric Shock Proofing Type	I
Electric Shock Proofing Grade	 Type B device
Operating Mode	Continuous Operation
Protection Level	Ordinary device, not liquid intrusion proofing
Place for Use	Not applicable to inflammable or detonable environment

3.2 Product Standards

The enterprise product registration standard should be applied.

3.3 Compulsory Standards

Fully apply the national standard, *GB9706.1 Medical Electrical Equipment, Part I-General Requirements for Safety* (equivalent to IEC 601-1, *Medical Electrical Equipment, Part I-General Requirements for Safety*)

3.4 Legal Statement

Our product and the related instructions, advertising articles and samples were audited and approved by the authorities, and then be protected by the law concerned.

4. Transportation and Storage

This apparatus shall be transported and stored in the following environments:

- 1) Ambient temperature: -40°C~+55°C
- 2) Relative Humidity: ≤93%
- 3) Atmospheric Pressure: 500hPa~1060hPa

5. Environment Safety

5.1 Disposal of Packaging Material

Any used packing and packaging materials shall be disposed in categories.

Discard of Apparatus

This apparatus shall not be used when its service life is expired. Components and parts removed from this apparatus shall be disposed according to material type.

Warning: Switch off and disconnect power supply before dismantling this apparatus.

II Preinstallation of Shadowless Operating Lamp

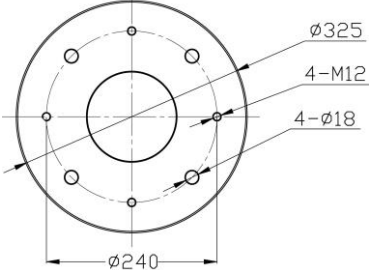
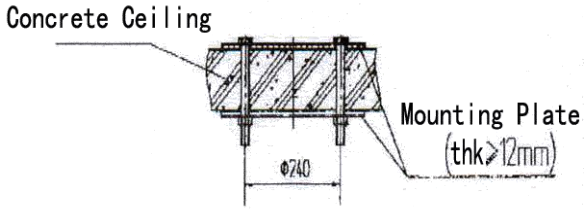
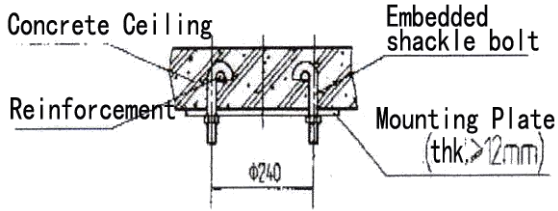
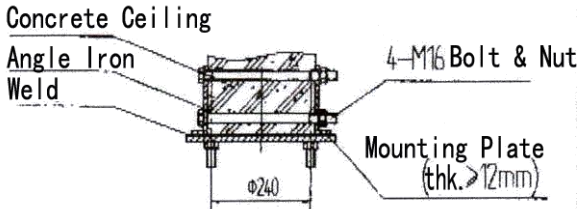
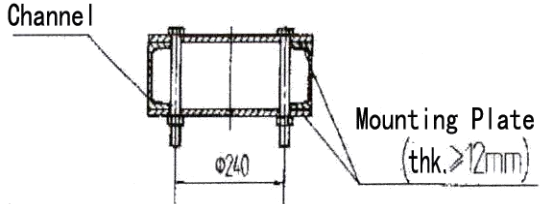
1. Requirements on Mounting Base

Shadowless operating lamp is the special-purpose device suspended on ceiling of operating room, it is very important to ensure the safety of mounting base. For this apparatus, the mounting base should be capable of bearing static load 500Kg and have sufficient rigidity.

The operating room where this apparatus will be mounted shall have typical ceiling height 2.9m.

Note: User should be responsible for construction and safety of the mounting base.

2. Precast Method (for information only)

Description of Requirements	Sketch
<p>2.1 Dimension of Precast Mounting plate</p> <p>Fabricate four $\Phi 14$ holes on mounting plate. These holes shall be equally distributed around the center of a circle in diameter $\Phi 240$.</p> <p>Mounting plate: thickness $\geq 12\text{mm}$, steel grade 45, outside diameter $\geq \Phi 360\text{mm}$ (or $\geq \square 360\text{mm}$ if it is fabricated as a square plate)</p>	 <p>$\Phi 325$ 4-M12 4-$\Phi 18$ $\Phi 240$</p>
<p>2.2 Mount through on-ceiling mounting plate couple</p> <p>Place and secure two mounting plates on both top and bottom surface of ceiling with M12 bolts, nuts, spring washers and flat washers.</p> <p>The threaded part of each M12 bolt shall be 60mm higher than the surface of mounting plate.</p>	 <p>Concrete Ceiling Mounting Plate (thk. $> 12\text{mm}$) $\Phi 240$</p>
<p>2.3 Mount through embedded part in ceiling</p> <p>Embed four M12 shackle bolts into ceiling during construction and weld them to reinforcement.</p> <p>These bolts shall be located as per figure 1.</p> <p>The threaded part of each M12 bolt shall be 60 higher than the surface of mounting plate.</p>	 <p>Concrete Ceiling Reinforcement Embedded shackle bolt Mounting Plate (thk. $> 12\text{mm}$) $\Phi 240$</p>
<p>2.4 Mount through beam attachments</p> <p>Securely weld mounting plate on angle iron, drill holes in beam, and attach plate on beam with M16 bolts.</p> <p>Weld 4 M12\times60 bolts on mounting plate as per dimensions shown in Table 2.1.</p>	 <p>Concrete Ceiling Angle Iron Weld 4-M16 Bolt & Nut Mounting Plate (thk. $> 12\text{mm}$) $\Phi 240$</p>
<p>2.5 Mount through channel</p> <p>Install 2 channels on wall and secure mounting plate with M12 bolts. The threaded part of each bolt shall be 60mm higher than the surface of mounting plate.</p> <p>Note: The channels shall be arranged in such a way that during operation the shadowless operating lamp will not sway.</p>	 <p>Channel Mounting Plate (thk. $> 12\text{mm}$) $\Phi 240$</p>

Description of Requirements	
2.6 Versatility of Mounting Base	<p>Our base plate has the same installation dimension with those manufactured by other companies in China. There is no need to change base plate in case product will be changed. For the sake of safety, user is required to inspect the strength and other conditions of base plate before mounting on apparatus.</p> <p>We can also provide custom-tailored adapter plate when the existing base plate can not meet your requirements on dimensions.</p>
2.7 Solutions for Operating Room with Ultrahigh Ceiling Height	<p>If ceiling height of operating room exceeds 2.9m, an extending frame must be attached to the mounting plate. We provide custom-tailored extending frame.</p>
2.8 Wiring Requirements	<p>The power supply for shadowless operating lamp is rated at 220V±10%, 50Hz±1Hz.</p> <p>On the wall of operating room, the user should install main switch (10A) and quick-acting fuse (5A) in such a manner that the switch can cut off phase lines and zero line simultaneously.</p> <p>The wiring should be made from main switch to base plate with power cord rated at safe current 15A.</p> <p>Warning: Power supply must be reliably earthed by additional separate protection earthing line, which should be connected to protection earthing terminal of shadowless operating lamp.</p>

III Installation of Shadowless Operating Lamp

1. Unpacking

At the unpacking time, user should, in accordance with the order sheet, inspect the packing box. If loss of pack is found, contact the carrier as soon as possible.

Unpack the rotator, balancer and lamp holder box, remove polystyrene packaging material and take out of every components of operating lamp for inspection against the enclosed packing list. If loss of component is found, contact us as soon as possible.

Packaging Box

Model	Name of Packing Box	Qty.
700 LED	Main Rotator, Spring arm	1pc
	Lamp	1pc

2. Installation

Warning: Recheck the condition of base plate to make sure it is safe for apparatus.

Carefully inspect the electrical connection to ensure its safety.

Install apparatus in strictly accordance with the following requirements and procedures.

Installation Specification	
3.1 Installation of Base plate	<p>Screw on four M12 nuts on base plate; locate the mounting plate in such manner that four threaded rods on base plate penetrate through four holes on mounting plate; set flat washer, spring washer in place and screw on nuts; adjust the lower nuts to make mounting plate horizontal; tight the upper four nuts.</p>
3.2 Installation of Rotator	<p>Screw on four M12 nuts on mounting place; locate the rotator in such manner that four threaded rods on</p>

base plate penetrate through four holes on bottom panel of rotator; screw on flat washer, spring washer and screw on nuts; adjust the lower nuts to make bottom panel of rotator horizontal; tight nuts.	
3.3	<p>Installation of Balancer</p> <p>Securely connect the wire of bend and the wire of balancer through terminals.</p> <p>Note: Wiring shall be made against the color marks and be made firmly.</p>
3.4	<p>Installation of Lamp Holder</p> <p>Attach lamp holders to the terminals of balancer in accordance with color marks .</p> <p>Note: Wiring shall be made against the color marks and be made firmly.</p>
3.5	<p>Installation of Top cap</p> <p>Reliably connect electric panel of rotator to the main line in accordance with the wiring diagram. Connect protection earthing line.</p> <p>Unscrew screws on retainer ring of top cap, place the top cap on rotator; and secure the top cap with 6 tapping screws.</p> <p>Close the retainer ring of top cap, place its ferrule into the cap hole and then push up the top cap to make it be flush with the bottom panel of rotator or with the ceiling. At last, tighten up screws for securing retainer ring of top cap.</p>

4. Electric Connection
See attached sheet for detail.

IV Trial Operation of Shadowless Operating Lamp

1. Adjust damping screws on balancer to change the pushing force and pulling force necessary for up-and-down movement of lamp body.
2. Change the tightness of adjusting screws to control the damping force in turning lamp body around lamp frame.
3. Change the tightness of locking knob to control the damping force in turning lamp body around cross arm.

V Operation Instruction

1. Position adjustment of lamp cap

As installed, power on the lamp cap, so that it will be lit up with time-delay. Pull the handle to make the lamp cap move from upside to downside, and vice versa as well as conduct the axial rotation. Push the sterilized handle, so the lamp cap could be inverted backwards & forwards (range is up to 200°) and the right & left (range is up to 200°). Finally, the lamp cap is adjusted as you desired.

2. Rotate the sterilized handle, so as to adjust the light spot as required.

3. Switch & intensity control

Lamp cap switch is controlled by the switching push button. As switched on, the lamp cap would be lit up with time-delay. As required by the operation, the intensity of light can be adjusted via luminance enhancement button or luminance weakening button. Here, the intensity of light will be displayed on the brightness record.

Push down the power switch button, the two-color power light turns into green, brightness indicator light will be displayed on the last brightness record left by the operation shadow less lamp. Also, the light

spot brightness thereof is adjusted to the related level. The control system is provided with the soft startups program, which can be used for the protection and extension of the bulb's life. Therefore, as starting up, it is normal when the intensity of light spot is changed from darkness to brightness with a couple of seconds.

Push the light changes button to adjust the intensity of the light spot, so as to comply with the doctor from the point of vision.

Note: As starting up, the blinking alarm light shows that the bulb has been damaged. So, please change the bulb immediately. For the replacement, please see the “item I, change the bulb in troubleshooting and maintenance” in this operation manual.

4. As the main bulb is damaged, the lamp cap will make autonomous switchover and light up the auxiliary light bulb. Meanwhile, the alarm indication light for the main bulb shines to give the alarm. As the operation is completed, change the bulb immediately.

5. Change the position of the lamp

The position of operation shadow less lamp shall be subject to that of the operation. Prior to operation, pull the handle under the control panel of the operation shadow less lamp; so that the spinning body rotates around the center pin or balancer rotates around the winding pipes of the spinning body. Otherwise, move the balancer to-and-fro or make the lamp body rotate around the balancer, so that the desired position could be reached.

Warning: the process as per stated above shall only be carried out via the handle under the control panel. Never pull the sterilized handle, or the lamp panel may be damaged.

As the lamp is moved to the proper position, you could pull the sterilized handle to achieve the rotation movement between the lamp body connectors or the lamp body can rotate around the connectors.

6. As the operation is completed, you must switch off the power source over the network, otherwise, the transformer will be damaged due to be in a hot condition for a long period of time.

VI Maintenance of Shadowless Operating Lamp

1. Cleaning

After a period of operation the shadowless operating lamp must be cleaned due to the casing and faceplate of shadowless operating lamp may be contaminated by dusts, blood or body fluid.

1.1 Casing Cleaning

With liquid paraffin and soft cloth, not only the casing of lamp can be cleaned, but also its coating may be protected. Repeatedly scrub seriously-contaminated parts.

Caution: Acid, alkali solution or grinding agents shall not be used in scrubbing.

1.2 Faceplate Cleaning

Faceplate of this lamp is made of polymers, serious contamination or friction marks may considerably effect the illumination, so only neutral cleaning agents and clean soft cloth may be used in cleaning.

Caution: Acid, alkali solution or grinding agents shall not be used in scrubbing.

2. Sterilization of Hand Grip

Hand grip is made of high-temperature resistant material and it may be immersed into boiled water or be applied with alcohol for sterilization.

Caution: formalin and other solvent solution shall not be used in scrubbing.

3. Routine Inspection

3.1 Connection Inspection

As a permanently suspended device, shadowless operating lamp should be always kept in safe operating conditions by inspect connection between bottom panel of rotator for tightness of bolts and screws.

Please operate in accordance with the requirements of Chapter III, Installation of Shadowless Operating Lamp.

3.2 Electric Inspection

Inspect electric connections of supply line on the power panel in top cap. Any loose connections found on terminal block shall be tightened and any oxidized terminals should be replaced. Check the protection earthing for reliability with magneto-ohmmeter.

Note: The above-described inspections should be made at least once a year.

Warning: Switch off lamp and disconnect main line prior to electric inspection.

We may off routine inspection on your apparatus on the basis of service agreement signed between both parties.

VII Troubleshooting of Shadowless Operating Lamp

1. Troubleshooting

Troubleshooting conducted by the user

Malfunction	Cause	Troubleshooting
Power light on the Control panel is off	Power off	Switch on the power source on the wall surface
	Wire on the Power panel is disconnected	Reconnect the wire on the power panel
Malfunction	Cause	Troubleshooting
Power light on the Control panel is off	Fuse is burnt out	Replace the fuse
Illuminant of operation shadowless lamp blinks	Power voltage over the network is too low	Regulated power supply shall be installed
Bulb indicator light on the Control panel blinks	The bulb is burn out	Replace the bulb

Over high or small equilibrant	Elasticity of the balancer is too high or too small	Adjust the elasticity of the balancer
Spinning body is unable to be positioned	Bed of the Spinning body is imbalanced	Adjust the bed nut
	Damper is loosened	screw the damper tightly
Lamp body is unable to be positioned	Screw inside the rubber band of the lamp body is loosened	Whirl the screw tightly

Warning: Disconnect main line prior to troubleshooting.

2. Change Fuse

Open the top cap of rotator to replace fuse. Please operate in accordance with the requirements of Chapter III, Installation of Shadowless Operating Lamp and the attached sheet.

700 LED: 3.2V/1W.

Note: Fuses are available in our company.

Warning: Disconnect main line prior to before replacing fuse

3. Replacement of Lamp Bulb

4. Lamp bulbs: 3.2V/1W

Note: Lamp bulbs are available in our company.

Warning: Disconnect main line prior to before replacing lamp bulb.

IX Packing List

700 LED	
Description	Qty
Main Rotator	1
Spring arm	1
Lamp Body	1
Hand Grip	2
User Manual	1
HD camera	1
Fuse	2

X Attached Sheet

1. Wiring Legends

Legends for Wiring Diagram

Wiring for transformer and DC outputs has been completed in factory, so at the installation site only the

wiring from main line to AC inputs needs to be made.

Note: Wiring shall be made against the color marks.

2. Legends for Replacement of Fuse

Withdraw the burned fuse from circuit board and replace with new fuse in accordance with the requirements on fuse ratings described in Chapter VII, Troubleshooting of Shadowless Operating Lamp.

Warning: Disconnect the main line prior to replacement of fuse.

Warning: Disconnect main line prior to before replacing fuse

3. Wiring Diagram

