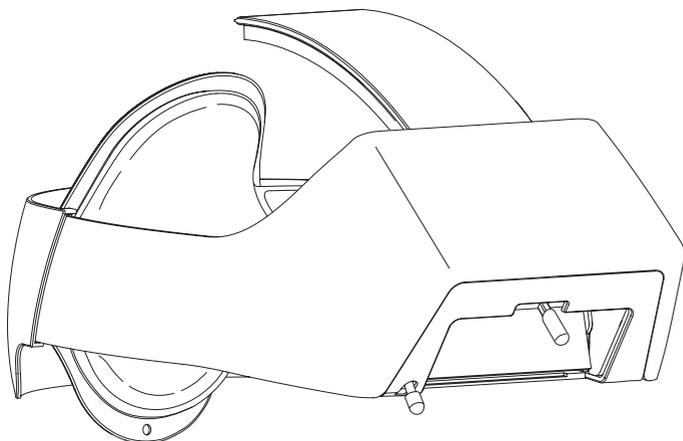




Wearable Surgical Lighting System

OPELA III™



Safety Precautions

Part names

How to use

Storage

Maintenance

Repair & Inspection

Troubleshooting

Specifications

Warranty

Thank you for purchasing the
Wearable Surgical Lighting System O P E L A III®



Please be sure to read this instruction manual before use.
Please also keep this manual close at hand for future reference.



1

Introduction

This product is a wearable surgical lighting system focused on the quality of light, while providing both moveableness (with installed batteries) and a comfortable feel.

[Purpose of Use] To wear on your head and illuminate the field of vision during surgery, examinations, and treatment.

[Target Users] Physicians, Medical staff

[Place of Use] Indoor

[Models]

-H (High Illumination Model)

Achieves 145,000 Lux in pursuit of high illumination.

[Basic Performance] Central Illumination: 6,000 to 145,000 Lux $\pm 10\%$
(For Mode-H, Illumination Distance 400 mm(16inch), Illumination Field Diameter $\phi 75$ mm(3inch))

[Continuous Lighting Hours]

- Dimmer Knob MAX (Dimming Level 100%): Approx. 2.5 Hours
- Dimmer Knob # 7 (Dimming Level 70%): Approx. 3.5 Hours
- Dimmer Knob # 5 (Dimming Level 50%): Approx. 6 Hours

Adjust use in consideration of the surgery time.

If necessary, prepare spare batteries.

The continuous lighting hours are estimates at the time of purchase.

Note that the time of a single use of a battery becomes shorter with each charge.

When the time of a single use is extremely short as compared at the time of purchase, buy a replacement.

2

Safety Precautions

The safety precautions described here are for safe and correct use of the product to prevent injury to yourself and others, or damage to property.

■ Indications

The safety precautions are classified into and clearly specified as “Warning”, “Caution”, and “Notice”. Be sure to follow them during use.

WARNING

Indicates potential death or serious injury if this description is ignored and improperly handled.

CAUTION

Indicates potential mild or moderate injury if this description is ignored and improperly handled.

NOTICE

Indicates expected failure, damage, malfunction, or defects if this description is ignored and improperly handled.

■ Examples of picture indications

The following symbols indicate actions that you should not perform.

	Indicates an action that you should not perform.
	Indicates that you should not disassemble the product.

The following symbol indicates an action that you must perform.

	Indicates that the description must be followed.
---	--

■ General Precautions

 WARNING	
	<p>Do not disassemble, repair, or modify the product. It may cause battery leakage, heat generation, rupture, ignition, or damage and failure of the main unit. If repairs are necessary, contact the distributor.</p>
	<p>Do not perform any actions that may damage the cords. It may cause electric shock or ignition.</p> <ul style="list-style-type: none"> • Do not modify the cords. • Do not place heavy objects on the cords. • Do not forcefully bend, twist, or pull the cords. • Do not place the cords near heating appliances while charging. <p>If the cords get damaged, discontinue use and contact the distributor.</p>

 CAUTION	
	<p>Do not let the product get wet. It may cause electric shock or failure.</p>
	<p>Do not apply strong force or shock, throw the product, or place heavy objects on it. It may cause battery leakage, heat generation, rupture, ignition, damage to the heat sink of the main unit, or cord breakage.</p>
	<p>Do not use the dedicated AC adapter and battery unit with other products. It may cause electric shock, ignition, or failure.</p>
	<p>Do not use products that have loose levers or knobs. It may cause the product to drop or malfunction. Request for repair at the distributor.</p>
	<p>If you drop the product, check that all 3 LED lights illuminate. If only 2 or fewer LEDs illuminate or if they flicker, discontinue use and contact the distributor.</p>
	<p>Do not use damaged or failing products. It may cause the product to drop, heat generation, or electric shock. Request for repair at the distributor.</p>

■ Precautions for Usage, Charging, and Storage Locations

 WARNING	
	<p>Do not use, charge, or store in locations other than the specified environment (refer to 8. Specifications), such as high humidity environments or high temperature environments. It may cause battery leakage, heat generation, rupture, or ignition. It may also reduce the battery capacity and charging efficiency.</p>
	<p>Do not bring the product into MRI environments. It may get pulled into a powerful magnetic field and cause a serious accident.</p>
	<p>Do not use in environments where flammable anesthetics or nitrous oxide is used. The product is not classified as AP or APG. Using it may cause flammable gas to ignite and create a fire.</p>
	<p>Charge or store in locations away from direct sunlight. The temperature will increase due to direct sunlight, and may cause battery leakage, heat generation, rupture, or ignition.</p>

 CAUTION	
	<p>Do not use in locations with much sand or dust. It may cause failure.</p>
	<p>Do not use in locations exposed to pathogens that cannot be disinfected with ethanol. Using a disinfectant other than ethanol for disinfection may cause discoloration, deformation, or failure. It may also cause infection due to improper disinfection.</p>

NOTICE	
	<p>Do not store in locations with corrosive gas or liquid. It may cause failure or damage.</p>

■ Handling the Battery Unit

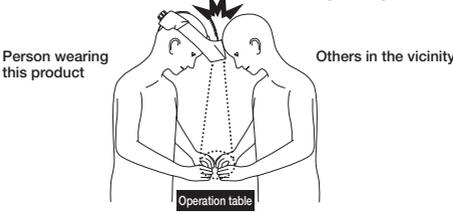
 WARNING	
	Do not drop in fire or heat up. It may cause rupture or ignition.
	Do not leave the battery unit under direct sunlight or in sun-heated cars. It may cause leakage, heat generation, rupture, or ignition.
	If fluid in the battery unit gets into your eyes, immediately flush with water and seek medical attention. It may cause blindness.
	Do not let conductive foreign objects (such as metals or pencil leads) touch the OUTPUT jack. It may short-circuit and cause failure.
	Do not cover the battery unit with air-blocking materials (eg. cloth, plastic bag,) while charging. It may cause leakage, heat generation, rupture, or ignition.

 CAUTION	
	If fluid in the battery unit gets on your skin or clothes, immediately flush with water. It may cause burns.

NOTICE	
	Do not charge when there is lightning or thunder. It may cause electric shock, fire, or malfunction.
	If there is thunder while charging, do not touch the adapter or battery. It may cause electric shock.

■ Usage Precautions

⚠ WARNING	
	Do not use at illumination level higher and at distance closer than necessary. Heat generated by light energy may cause thermal injury (particularly with prolonged illumination of a fixed location by multiple light sources, etc.)
	Observe tissue during use of this product. Heat generated by light energy may cause thermal injury. If thermal injury occurs immediately discontinue use and take appropriate measures.
	Do not use for ophthalmic procedures. It may cause damage to the eyes.
	Do not use for photosensitive patients or patients who have received photosensitizing agents. It may cause burns.
	Do not use for neonatal transillumination. It may cause burns.

⚠ CAUTION	
	Avoid direct exposure to the eyes of those in the vicinity. It may cause damage to the eyes.
	Do not look into the light source unit during use. It may cause damage to the eyes.
	Do not cover the light source unit or heat sink with cloth or paper. The heat will build up and may cause heat generation, ignition, or failure.
	<p>Be careful so that your head does not touch others in the vicinity while wearing the product. It may cause injury, or the product may drop, malfunction, or get damaged.</p> <p><Image figure></p> <div style="text-align: center;"> <p>Heads may bump</p>  </div>
	Do not use the product without wearing it on your head or use while it is secured on a stand. It may cause an accident such as a fall.
	Place the main unit on the calibration kit instead of directly on a platform or desk. Otherwise, the illumination position adjustment lever will touch the platform or desk, and may cause it to bend or cause the protective cap to come off easily. Broken parts can fall into the operating field and cause contamination.
	Do not use accessories other than those included with the product. It may cause battery heat generation, rupture, ignition, electric shock, or failure.
	If it has not been used for a long time, check that fluid is not leaking from the battery unit before use. Touching the fluid may cause burns. Discontinue use, put it in a plastic bag, and contact the distributor.

■ Maintenance Precautions

 CAUTION	
	<p>Do not wash it by exposing it to or submerging it in water. It may cause electric shock or failure.</p>

NOTICE	
	<p>When cleaning, use ethanol for disinfection. Using detergent or disinfectants other than ethanol for disinfection may cause damage, discoloration, or failure.</p>
	<p>Do not sterilize. It may cause failure or damage.</p>

■ Transport and Storage Precautions

NOTICE	
	<p>Always use the storage bag/hard case when storing or carrying. (Refer to 5-7. Storage) Leaving the product out or carrying it without putting it in the storage bag/hard case may cause failure or damage. Also, if the heat sink is bent or warped, you may be unable to wear the product, or the light source unit may get hot and malfunction.</p>
	<p>When the product is moved from a warm place to a cold place (and vice versa), allow it to settle down for a while before taking out of the package. Taking it out immediately will cause condensation to occur due to sudden change in temperature, leading to potential failure.</p>
	<p>Do not store with the connection cord still connected to the battery unit. It may cause failure.</p>
	<p>Do not carry by the heat sink. It may cause failure or damage.</p>
	<p>Do not drop the storage bag/hard case. It may cause failure, damage or injury.</p>

■ Symbols on Labels

Symbol	Description
	Consult instructions for use or consult electronic instructions for use
	Caution
	Refer to instruction manual/booklet
Rx Only	Caution: Federal law restricts this product to sale by or on the order of a physician
	Direct current
	Alternating current
	Serial number
	Date of manufacture

Symbol	Description
	Polarity of d.c. power connector
	Manufacturer
	Class II equipment
	For indoor use only
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

■ Labels Attached to the Product

Main unit

Wearable Surgical Lighting System OPELAIM
Model – H (High illumination)

TAIYO CORPORATION
3 0-9, Shiba 5 Chome,
Minato-ku, TOKYO, JAPAN

9 V $\overline{\text{---}}$ 7.2 W MADE IN JAPAN



Rx Only Class 2

XXXXXX
 XXXX-XX-XX



(01)XXXXXXXXXXXXXXXXX
(11)XXXXXX(21)XXXXXX

CLASSIFIED
MET E300019
us

ANSI/AAMI ES60601-1
CSA-C22.2 No.60601-1

Wearable Surgical
Lighting System
OPELAIM Model - H
TAIYO CORPORATION

Battery unit

Battery Unit (for Wearable Surgical Lighting System OPELAIM only)

9 V $\overline{\text{---}}$ 0.8 A 4 5 0 0 mAh

AC Adapter : MPU3 2B - 1 0 5

(SINPRO ELECTRONICS CO., LTD)

TAIYO CORPORATION
3 0-9, Shiba 5 Chome,
Minato-ku, TOKYO, JAPAN

WARNING AVERTISSEMENT

DO NOT DROP IN FIRE OR HEAT UP.
MAY CAUSE RUPTURE OR IGNITION.
NE PAS TOMBER AU FEU OU
CHAUFFER.
PEUT CAUSER UNE RUPTURE OU
UNE INFLAMMATION.

CAUTION ATTENTION

DO NOT TOUCH WITH WET HANDS.
MAY CAUSE ELECTRIC SHOCK
OR FAIRURE.
NE PAS TOUCHER AVEC DES
MAINS HUMIDES.
PEUT CAUSER UN CHOC ÉLECTRIQUE
OU UNE FAIRURE.



(01)XXXXXXXXXXXXXXXXX
(11)XXXXXX(21)XXXXXX-X

XXXXXX-X
 XXXX-XX-XX



MADE IN JAPAN

Dedicated AC adapter

SINPRO

SWITCHING POWER SUPPLY
MODEL NO.:MPU32B-105
INPUT:100-240V \sim 47-63Hz
0.6-0.4A

OUTPUT:12V $\overline{\text{---}}$ 2.5A max.



CE **UL** **US**
E 230351

Efficiency Level ∇

Indoor use only

株式会社 アスター電機

CAUTION DO NOT OPEN

RISK OF ELECTRIC SHOCK

ATTENTION RISQUE DE CHOC ÉLECTRIQUE

NE PAS OUVRI

MADE IN TAIWAN

This product includes the following items.

■ Standard Package / Protected Special Package

Description	Part number	Quantity
Main Unit (Model - H)	HTH	1
Cord Tie Band	CBX	1
Cord Clip (Small)	CCS	2
Cord Clip (Large)	CCL	2
COOLMAX® Comfort Inner Pads	IPX	Front : 1, Back : 1
Battery Unit	BAN	2
Dedicated AC Adapter	ACX	1
Attached Belt (M-L, LL or 3L)	BLM / BLL / BL3	1
Storage Bag / Hard Case (with calibration kit)	BGX / HCX	1
Instruction Manual (This document)	OP_P_02US(03)	1 copy

■ Accessories (sold separately)

Description	Part number	Order Unit
Cord Clip (Small)	CCS	9
Cord Clip (Large)	CCL	4
Battery Unit	BAN	Depending on the country
Dedicated AC Adapter	ACX	1
COOLMAX® Comfort Inner Pads	IPX	5 sets (Front : 5, Back : 5)
Attached Belt (M-L)	BLM	1
Attached Belt (LL)	BLL	1
Attached Belt (3L)	BL3	1
Storage Bag (without calibration kit)	BGX	1
Hard Case (without calibration kit)	HCX	1
Calibration Kit	CKX	1



This product uses "COOLMAX®" as interior fabric which allows sweat to evaporate for lasting comfort.

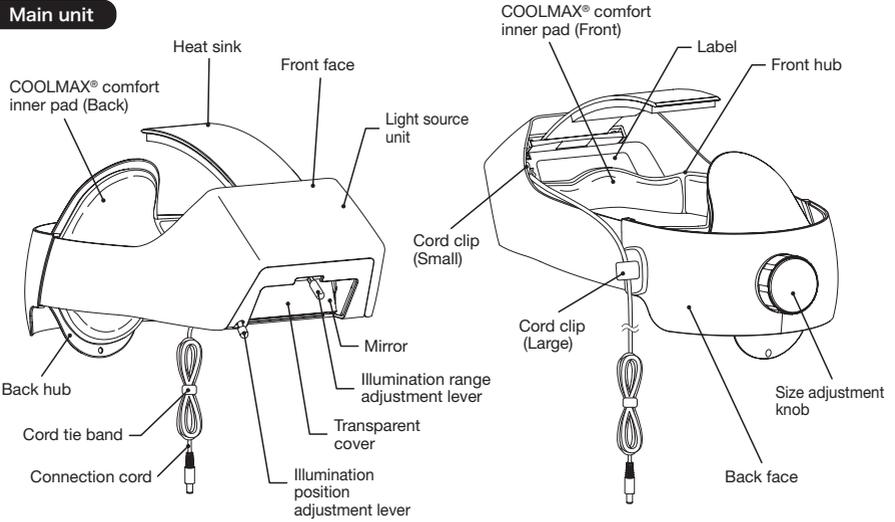
- COOLMAX® exhibits superior moisture control by allowing perspiration to escape, while letting air enter, keeping the fabric cool and dry, effectively lowering surface temperature.
- COOLMAX® is soft, lightweight with natural texture and excellent air permeability.

※ COOLMAX® is a registered trademark of INVISTA.

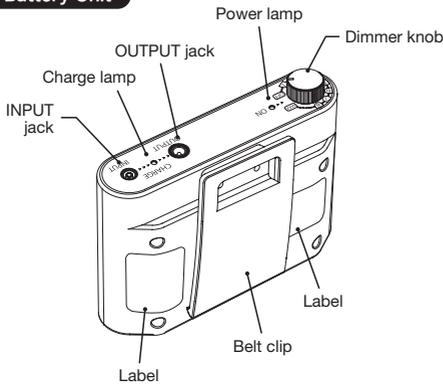
4

Part names

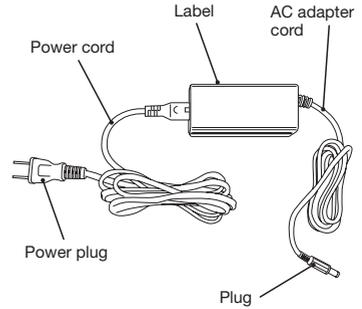
Main unit



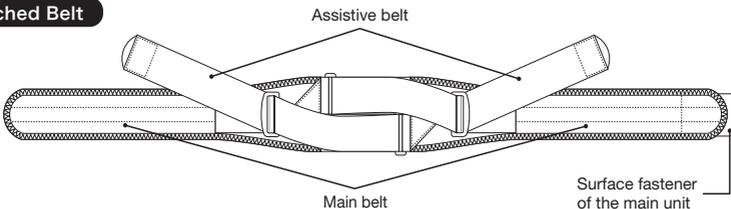
Battery Unit



Dedicated AC adapter



Attached Belt



5

How to use

Charging

Check 1

Wearing

Check 2

Lighting

After Use

■ Battery Unit: Safety Precautions

 WARNING	
	Charge in locations away from direct sunlight. The temperature will increase due to direct sunlight, and may cause leakage, heat generation, or ignition.
	Charge in locations according to the Environmental Specifications (Refer to 8. Specifications). Charging in locations with high temperature and high humidity may cause electric shock, leakage, heat generation, or ignition.
	Do not plug and unplug the power plug with wet hands. It may cause electric shock.
	When unplugging the power plug, be sure to hold the power plug, not the power cord. It may damage the power cord or cause electric shock or ignition.
	If fluid in the battery unit gets into your eyes, immediately flush with water and seek medical attention. It may cause blindness.

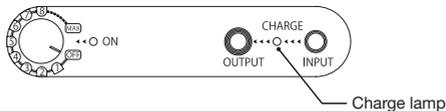
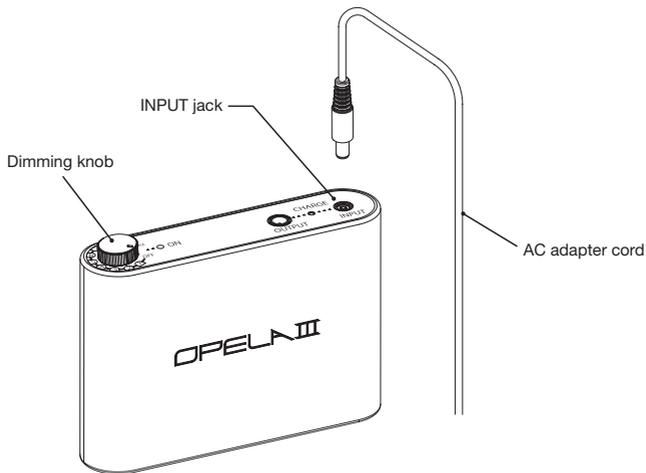
 CAUTION	
	Use the dedicated AC adapter when charging. Using products other than the dedicated AC adapter may cause electric shock, heat generation, leakage, or rupture.
	When charging is complete, immediately disconnect the dedicated AC adapter from the battery unit. Continuing to charge may cause leakage, rupture, ignition, or shorter battery life due to overcharging.
	Do not use the main unit while charging. You may trip on the cord and fall, or the product may drop.
	When charging, connect the power plug to an outlet that is easy to reach. Being unable to unplug the power plug immediately during an emergency may cause an accident.
	If fluid in the battery unit gets on your skin or clothes, immediately flush with water. It may cause burns.

NOTICE	
	Be sure to charge if it is being used for the first time or if it has not been used for a long time (3 months or longer). Charging may stop before it is fully charged when it is being charged for the first time in a long time (3 months or longer). In such cases, repeatedly charge and discharge several times before use.

5-1 Charging the Battery Unit

1. Turn the dimming knob clockwise to switch it on. If the charge lamp is illuminated orange, the battery needs to be charged.
2. Turn the dimming knob counter-clockwise to turn it off, and connect the dedicated AC adapter and battery unit (INPUT jack).
3. The charge lamp will turn orange when you insert the power plug into an outlet, and then the charging will start.
4. Immediately disconnect the dedicated AC adapter from the outlet and battery unit once charging is complete.

*When the charge lamp illuminates in orange (insufficient charge) during use, replace the battery unit.



Charge lamp	Status
Orange	Charging
Orange	Insufficiently charged
Off	Charged

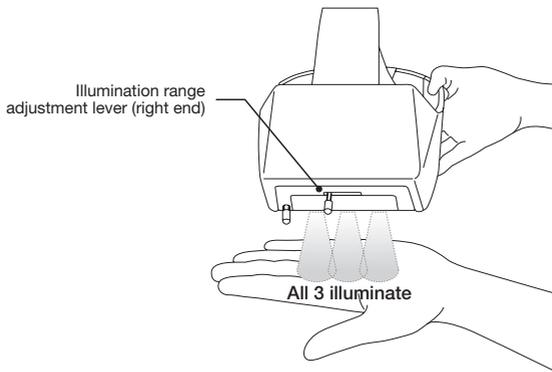
5-2 Check 1

Check that all 3 LED lights illuminate.

Product safety may be affected if only 2 or fewer LEDs illuminate or if they flicker. Discontinue use and contact the distributor.

<How to check>

Move the Illumination Field Diameter adjustment lever all the way to the right, turn the dimming knob of the battery unit clockwise to turn it on, and place the palm of your hand near the light source to check for 3 light sources.

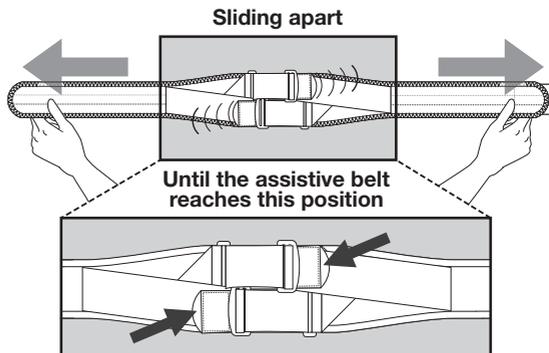
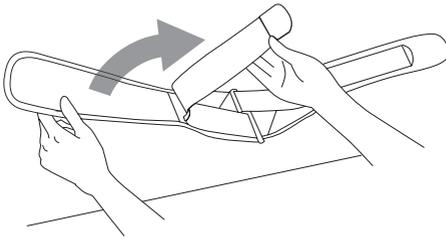


5-3 Wearing (Attached belt, battery unit)

⚠ CAUTION

	<p>Do not use with other belts. Do not use with other belts. This may cause the attached belt to loosen and the battery unit to fall. (Be sure to use the attached belt of this product.)</p>
	<p>Wear the attached belt for a couple of hours before use. Wear it for a couple of hours at first to check that there is no discomfort or itchiness. You can use it all day once it fits comfortably.</p>
	<p>Wrap the attached belt around your pelvis so that it does not loosen. The battery unit may fall if the attached belt loosens or moves around. Make sure to put on the attached belt by following the steps in the correct order.</p>

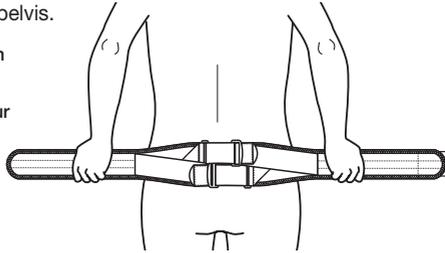
1. Remove the assistive belt and pull the main belt sideways from both directions.



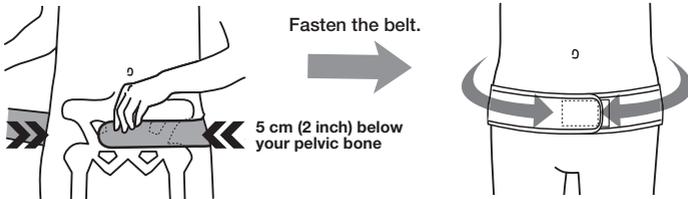
- 2.** Place the attached belt on your pelvis.

*Wear the attached belt underneath your surgery gown.

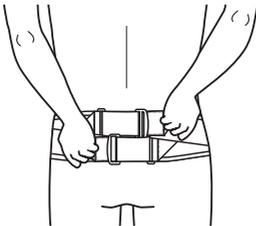
*Wear the attached belt around your pelvis, not your waist.



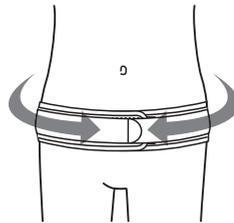
- 3.** Wrap the attached belt around your pelvis.



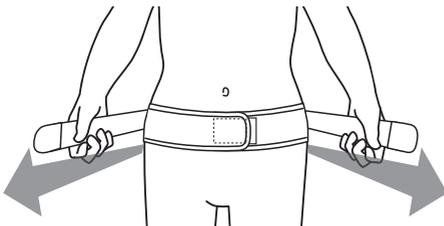
- 4.** Hold the assistive belt at the back.



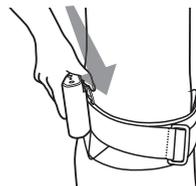
- 6.** Fasten the assistive belt.



- 5.** Pull the assistive belt.



- 7.** Insert the belt clip of the battery unit deeply and tightly on the backside of the main belt.



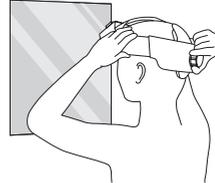
5-4 Wearing (Main unit)

⚠ CAUTION

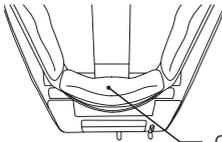


Put the product on yourself in front of a mirror before washing your hands.

It may fall off if others put the product on for you as it tends to become loose or tilt. Be sure to put it on yourself in front of a mirror before washing your hands, to ensure it is worn in the correct position.



1. Replacing the COOLMAX® comfort inner pads
Replace the COOLMAX® comfort inner pads with a new one if sweat or stains bother you.

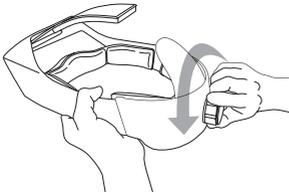


COOLMAX® comfort inner pads

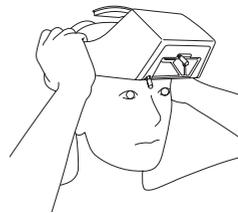
4. Place your forehead against the front hub.



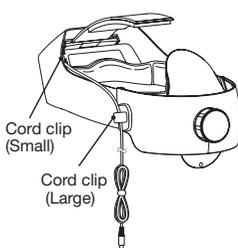
2. Turn the size adjustment knob counter-clockwise to make the size bigger.



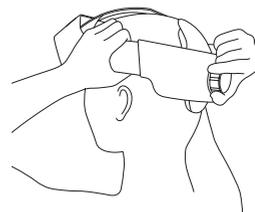
5. Lift your head with the front hub kept attached to your forehead.



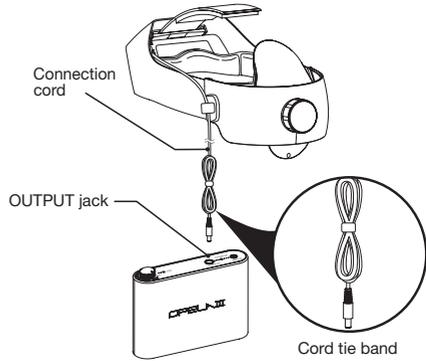
3. Set the connection cord along the cord clip, and hold the main unit with both hands.



6. Turn the size adjustment knob to lock the main unit into position.



7. Tie the connection cord of the main unit with a tie band, and connect the main unit to the battery unit (OUTPUT jack) with the connection cord.
8. Put on your surgery gown. Flip your gown when controlling the battery unit.



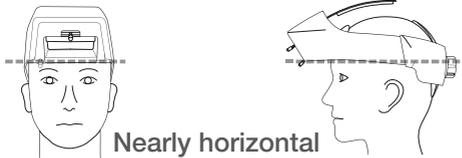
5-5 Check 2

Check that it is worn in the correct position with no loose points.

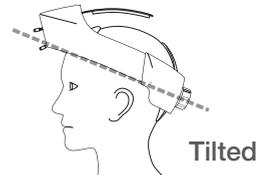
Wear the product in the correct position as shown below so that it does not move. A loose fit may result in the device falling.

If the device cannot be worn in the correct position, discontinue use and contact the location of purchase, as it may have a distortion or defect.

Correct



Incorrect



Wear it deeply, up to slightly above your eyebrows.

*Tie your hair below the main unit.

If the heat sink touches your head, calibrate the height of the heat sink with the calibration kit. (Refer to 5-8. Maintenance [Calibrating the heat sink height])

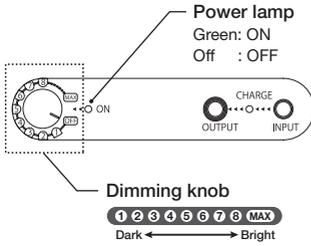
NOTICE



Do not adjust the position of the heat sink with your hands.
It may damage the heat sink. Make sure to use the calibration kit.

5-6 How to Adjust Lighting

1. Turn the dimming knob clockwise to turn it on and adjust the brightness.



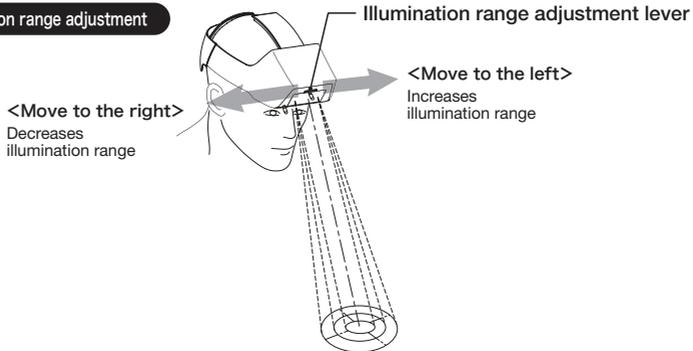
[Continuous Lighting Hours]

- Dimmer Knob MAX (Dimming Level 100%): Approx. 2.5 Hours
- Dimmer Knob # 7 (Dimming Level 70%): Approx. 3.5 Hours
- Dimmer Knob # 5 (Dimming Level 50%): Approx. 6 Hours

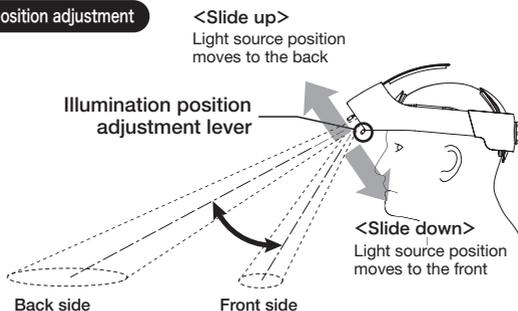
*Adjust use in consideration of the required surgery time.
If necessary, prepare spare batteries.

2. Adjust the light source position and range according to the operative field you want to illuminate.

Illumination range adjustment

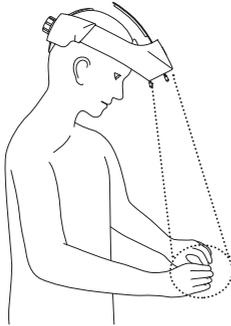


Illumination position adjustment



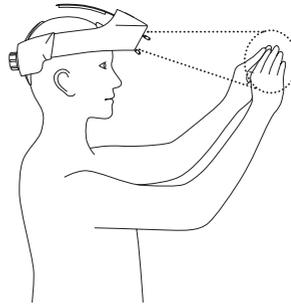
The optimal illumination position depends on the operation.

Adjust the light source position according to the operative field you want to illuminate.



**【Case of illuminating
in vertical direction】**

Major abdominal surgeries
(heart, lung, kidney, liver, etc.)



**【Case of illuminating
in the horizontal direction】**

Surgeries in which the operative field is
near the level of the eye of the operator
(anus, vaginal opening, etc.)

- The illumination position will no longer be aligned if your posture or operative field changes during surgery. Change the angle of your head according to the operative field or re-adjust the illumination position.

3. Turn the dimming knob counter-clockwise after use to turn it off, then remove the connection cord of the main unit from the battery unit.

5-7 Storage

CAUTION

	<p>Store in locations according to the Environmental Specifications (refer to 8. Specifications). Storing in locations with high temperature and high humidity may cause electric shock, leakage, heat generation, or ignition. Storing in locations with high temperature and high humidity may cause electric shock, battery leakage, heat generation, or ignition. It may also reduce the battery capacity and charging efficiency.</p>
	<p>Store in locations away from direct sunlight. The temperature will increase due to direct sunlight, and may cause leakage, heat generation, or ignition.</p>
	<p>Do not store in locations with corrosive gas or liquid. It may cause battery leakage, heat generation, rupture, ignition, or failure.</p>

NOTICE

	<p>Always use the storage bag/hard case when storing or carrying. Leaving the product out or carrying it without putting it in the storage bag/hard case may cause failure or damage. Also, if the heat sink is bent or warped, you may be unable to wear the product, or the light source unit may get hot and malfunction.</p>
	<p>Check that the light source unit has cooled down to normal temperature before placing it into the storage bag/hard case. Putting the light source unit in the bag while it is warm, it may cause a malfunction.</p>
	<p>Do not store with the connection cord still connected to the battery unit. It may cause failure.</p>
	<p>Do not drop the storage bag/hard case. It may cause failure, damage or injury.</p>
	<p>Do not wet the storage bag/hard case. It may cause failure, damage or injury.</p>

[Storage Bag]

1. Check that the calibration kit is firmly pushed to the bottom of the storage bag.



2. Place the main unit on the calibration kit, and firmly close the lid of the storage bag.

*Match the orientation of the main unit with that in the illustration affixed to the calibration kit.

3. Place the battery unit in the front pocket of the storage bag, and firmly close the lid of the pocket.

*Do not place the battery unit on the main unit. The heat sink may get damaged and cause malfunction.

*Wrap the battery unit with buffer material.

*Store the dedicated AC adapter in the side pocket of the storage bag.

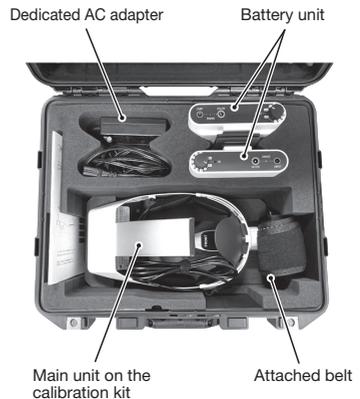
[Hard Case]

1. Push the square buttons and pull the latches, then open the lid of the hard case.
2. Check that the calibration kit is firmly pushed to the bottom of the hard case.



3. Place the main unit on the calibration kit and other components to the correct location and orientation as shown in the picture.

4. Close the lid and push the latches firmly.



*Match the orientation of the main unit with that in the illustration affixed to the calibration kit.

*Do not place the dedicated AC adapter on the main unit.

5-8 Maintenance

⚠ CAUTION



Do not wash it by exposing it to or submerging it in water.
It may cause electric shock or failure.

NOTICE



When cleaning, disconnect the connection cord.
It may cause failure.



When cleaning, use ethanol for disinfection.
Using detergent or disinfectants other than ethanol for disinfection may cause damage, discoloration, or failure.



Do not sterilize.
It may cause failure or damage.

[Cleaning]

Main Body · Battery Unit

- Wipe the transparent cover of the light source unit with a soft cloth after every use. When the inner side of the light source unit transparent cover is dirty, contact the distributor.
- Check that the main unit and battery unit have cooled down to normal temperature, and wipe them with a soft cloth moisturized with a small amount of ethanol for disinfection as necessary.

Attached Belt

- If dirt on the attached belt or its smell bothers you, clean it while referring to the following.
 - ◆ Wash by hand instead of using a washing machine.
 - ◆ Do not use bleach.
 - ◆ Do not tumble dry.
 - ◆ Avoid direct sunlight and hang dry in the shade.
 - ◆ Do not iron.
 - ◆ Do not dry clean.
 - ◆ You can use very gentle wet cleaning.
 - ◆ Use neutral detergents.
 - ◆ Do not use fabric softeners.



COOLMAX® Comfort Inner Pads

- Remove and wash inner pads when they get dirty as needed.
 - ◆ Add shampoo or pH neutral detergent in cold or lukewarm water (less than 35°C) and gently hand wash then rinse thoroughly.
 - ◆ After washing, gently wipe water off with a dry cloth and let it dry naturally in a well-ventilated place, away from direct sunlight.

Storage Bag · Hard Case

- When the storage bag is dirty, gently wipe it with a cloth slightly damp with a neutral detergent.
- When the hard case is dirty, wipe it with mild soap and water and a soft sponge. Do not use any type of brush that will scratch the surface.

[Replacing Consumable Parts]

Replace consumable parts at appropriate times.

Please see **3. Composition** for the list of consumable parts available for purchase.

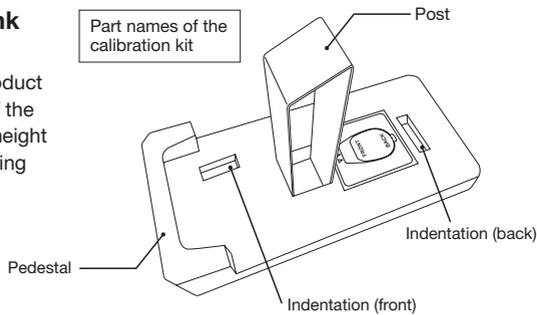
Consumable parts	Approximate time of replacement
Battery Unit	As a guideline, recommended replacement period is 2 years.
COOLMAX® Comfort Inner Pads	When deterioration or stains become noticeable.
Cord Clip	When it is damaged or peeled off. *To replace, refer to "Proper attachment of the cord clip".

[Manufacturer maintenance & inspection]

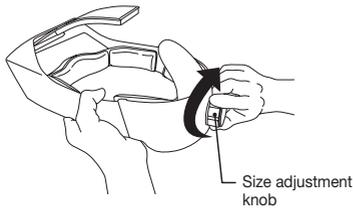
Have the manufacturer perform maintenance and inspection every 2 years (with fee).

[Calibrating the heat sink height]

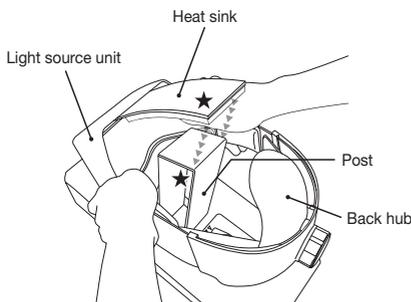
When you cannot wear the product properly because the height of the heat sink is low, calibrate the height of the heat sink with the following procedure.



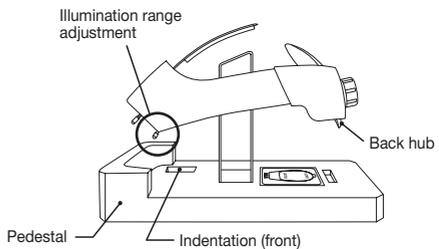
1. Take out the calibration kit from the storage bag/hard case, and place it on a desk.
2. Rotate the size adjustment knob on the main unit clockwise and set the size to "smallest".



3. Hold the sides of the light source unit with both hands, and place the main unit on the calibration kit.

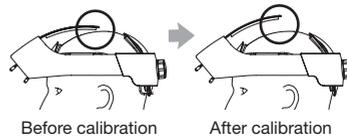


4. Set the illumination position adjustment lever into the indentation (front) of the pedestal.



5. Refer to the figure in step 3 and align the edges of the heat sink and post (★ mark).
6. Slowly press the main unit straight down until the back hub goes into the indentation (back).

The height of the heat sink is calibrated.



*It is normal for the back hub to rise from the pedestal when you let go.

7. Remove the main unit from the calibration kit.
8. Firmly push the calibration kit to the bottom of the storage bag/hard case and return it to the original position.

5-9 Disposal

Please contact the distributor when disposing.

6

Repair & Inspection

The warranty period of this product is 1 year from the time of purchase. Repair and inspection costs will be paid by the customer after the warranty period or if the services are beyond the scope of warranty coverage.

If the product does not function correctly, fill in the required fields in the form below and immediately contact the distributor. You will need to ship the product to the manufacturer for repair and/or inspection.

Name of product	Wearable Surgical Lighting System OPELAIII	
Model		
Serial number <input type="text" value="SN"/>	Main unit	
	Battery unit	
Date of purchase	YY	MM DD
Distributor		
Customer information	Name of institute, affiliation	
	Your name	
	Phone number	
	E-mail address	
Description of problem		

Symptom	Cause	How to handle
Main unit does not illuminate	Dimming knob is turned off	• Turn the dimming knob clockwise.
	Dimming knob is positioned at #1	• Turn the dimming knob clockwise to adjust the brightness.
	Battery unit is insufficiently charged	• Charge the battery unit.
Illuminated period is shorter than 2 hours even when fully charged	Bad connection cord contact	• Repeatedly plug and unplug the plug from the OUTPUT jack several times. • Remove dust from the plug and jack.
	Battery unit is deteriorated	• Repeat charging and discharging several times.
	Battery unit life has been reached	• Replace with a new battery unit.
Charge lamp does not illuminate even if the dedicated AC adapter is connected	Bad power plug connection	• Remove dust from the power plug and repeat plugging and unplugging from the outlet. • Try changing the outlet.
	Bad jack connection	• Remove dust from the INPUT jack and dedicated AC adapter plug.
	Dedicated AC adapter failure	• Contact the distributor.
Power lamp does not illuminate	Dimming knob is turned off	• Turn the dimming knob clockwise.
	Battery unit is insufficiently charged	• Charge the battery unit.
Charge lamp illuminates during use	Battery unit life has been reached	• Replace with a new battery unit.
Charge lamp illuminates during use	Battery unit is insufficiently charged	• Charge the battery unit.
The main unit lamp keeps turning on and off	Main unit illuminates for a few minutes even when it has run out of power when the dimming knob is turned clockwise	• This is not abnormal. • Please charge the battery unit.
Battery unit and dedicated AC adapter turns hot during charging	This is caused by the energy exchange heat during charging	• It is not abnormal if the temperature is around 55°C(131°F).
Lighting does not completely turn off even when the dimming knob is turned to #1	Lighting does not completely turn off even when the dimming knob is turned to #1	• This is not abnormal.

■ Instrument Classification

Electrical Shock Protection Classification	Internally Powered Equipment
Protection Against Harmful Intrusion of Water or Particulates	Unintentional
Sterilization	Unintentional
Use in High Oxygen Concentration Environments	Unintentional
Operation Mode	Continuous Operation

■ Main Body

Brand Name	Wearable Surgical Lighting System OPELAIII
Model	-H (High Illumination Model)
Central Illumination (Illumination range at $\phi 75$ mm (3inch))	145,000 Lux $\pm 10\%$ (Illumination distance: 400 mm(16inch))
Color Temperature	4,500K $\pm 10\%$
Illumination Adjustment	Yes (5 to 100%)
Illumination range	Variable ($\phi 75$ - 125 mm, $\phi 3$ - 5 inch) (Illumination distance: 400 mm(16inch))
LED Used	Power LED x 3
LED Life	50,000 Hours and Over
Rated Power Consumption	Approx. 7.2 W
Rated Voltage	9V \pm
Weight	Approx. 390 g $\pm 10\%$ (Excluding Cable)
Outer Dimensions	Approx. W160 x H170 x D300 to 350 mm $\pm 10\%$ (W6.3 x H6.7 x D11.8~13.8 inch $\pm 10\%$) (Depth can be changed by size adjustment)
Standard Head Circumference	53 to 66 cm (21 to 26 inch)
Photobiological safety	Retinal blue light hazard (LB) : Risk Group 1 / Others : Exempt
FDA Listing No. (Product Code)	D338313 (HPP, Class1), D360523 (FQP, Class2), D360534 (FSQ, Class2)
MET Classified No.	E300019
Notification No. in Japan	13B3X10231000001

■ Battery Unit

Built-In Rechargeable Battery	Nickel Hydride Secondary Battery
Continuous Lighting Hours (Reference Value at Full Charge)	Dimmer Knob MAX (Dimming Level 100%) : Approx. 2.5 Hours
	Dimmer Knob # 7 (Dimming Level 70%) : Approx. 3.5 Hours
	Dimmer Knob # 5 (Dimming Level 50%) : Approx. 6 Hours
Rated Input	12V \pm 2.5A
Rated Output	9V \pm 0.8A
Electric Capacity	4,500 mAh
Weight	Approx. 480 g $\pm 10\%$ (Excluding Dedicated AC Adapter)
Outer Dimensions	Approx. W140 x H100 x D50 mm $\pm 10\%$ (W5.5 x H3.9 x D2 inch $\pm 10\%$)

■ Dedicated AC Adapter

Manufacturer	SINPRO ELECTRONICS CO., LTD.
Model Number	MPU32B-105
Rated Input	100 - 240V \sim 47 - 63 Hz 0.6 - 0.4A
Rated Output	12V \pm 2.5A max

■ Storage Bag

Manufacturer	HAKUBA Photo Industry Co., Ltd.
Model Number	SP-BS-SBLBK

■ Hard Case

Manufacturer	PELICAN USA (Case) / Emic.Ltd (Cushion)
Model Number	1507 Air

■ Attached Belt

Manufacturer	Mizuno Corporation
Model Number	C3JKB501
Weight	103g (M-L), 111g (LL), 136g (3L)
Material	Nylon (90%), Polyester (10%)
Pelvis Diameter	75 - 95 cm (30 to 37 inch) (M-L), 95-115 cm (37 to 45 inch) (LL), 115-135 cm (45 to 53 inch) (3L)
Country of Origin	Japan

■ Environmental Specifications

When Charged	15 to 25°C (59 to 77°F), 20 to 85% RH (Non-Condensing)
When Used	15 to 32°C (59 to 89.6°F), 20 to 85% RH (Non-Condensing)
In Storage	-40 to 60°C (-40 to 140°F) (within 4 hours), -20 to 40°C (-4 to 104°F) (over 4 hours), 20 to 85% RH (Non-Condensing)
Atmospheric Pressure Allowance	700 to 1,060 hPa

*Specifications change depending on the usage conditions and are subject to change without notice.

*Using, charging, or storing the product at a temperature or humidity outside of environmental specifications will reduce the battery capacity and charging efficiency and cause the lighting time to become shorter.

*Photobiological safety (IEC62471)

This product is classified as Risk Group 1 (Retinal blue light hazard).

The philosophical basis for Risk Group 1 (Low-Risk) is that the lamp does not pose a hazard due to normal behavioral limitations on exposure.

[Electromagnetic compatibility]

<Precautions>

Portable and mobile wireless communication devices may affect the product. Keep them away at a distance of at least 30 cm.

⚠ WARNING	
	<p>Do not use accessories other than those specified by us. Using accessories other than those specified by us may result the product to increase electromagnetic emissions or reduce electromagnetic immunity.</p>
	<p>Do not use the product near other devices. If use near other devices is necessary, check that the product and other devices operate correctly.</p>

<Conformity information>

- This product satisfies the requirements of CISPR11:2009 + A1:2010 Group 1, Class B.
- This product has been tested for immunity against level 4 electrostatic discharge (contact discharge: 8 kV, air discharge:15 kV) defined in IEC 61000-4-2:2008.
- This product meets the requirements of immunity to conducted disturbances, induced by radio-frequency fields in the range of 3V (6V), 150 kHz to 80 MHz as defined in IEC 61000-4-6:2013.
- This product satisfies the requirements of immunity against radiated radio-frequency interference in the 10 V/m, 80 MHz - 2.7 GHz frequency range defined in IEC 61000-4-3:2006 + A1:2007 + A2:2010.
- This product meets the requirements of immunity to radiated, radio-frequency, electromagnetic fields from communication equipment as defined in IEC 61000-4-3:2006 + A1:2007 + A2:2010.
- This product meets the requirements of immunity to power frequency magnetic fields at 30 A/m, 50/60 Hz as defined in IEC 61000-4-8:2009.
- This product meets the requirements of immunity to electrical fast transients/bursts at 2 kV, 100 kHz as defined in IEC 61000-4-4:2012.
- The dedicated AC adapter complies with IEC 60601-1-2:2014.
- This product complies with part 18 of the FCC Rules.

■ Warranty Coverage

- We will repair or replace the product free of charge if it fails within 1 year from the date of purchase provided it has been used correctly following the instruction manual and precaution notes of attached labels, etc.

■ Disclaimer

- It will not be covered by warranty if the failure or defect falls under any of the following items.
 - a) Defect or damage caused by incorrect use and/or inappropriate repair and modifications.
 - b) Defect or damage caused by dropping after purchase.
 - c) Defect or damage caused by fire, earthquake, flood, lightning, other natural disasters, pollution or abnormal voltage from the power source, power supply that is outside the specifications (voltage, frequency), etc.
 - d) Warranty letter is not provided.
 - e) Warranty letter does not indicate date of purchase, name of customer, or name of product, or they have been re-written.
 - f) Consumable parts. (battery unit, COOLMAX® comfort inner pads, cord clip, etc.)
 - g) Cause of defect is attributable to anything other than this product.
 - h) Any other defect and/or damage caused by usage not specified in this instruction manual.
 - i) Only the main unit and AC adapter are in scope.
- We assume no responsibility or liability for incidental damages (loss of business profits or interruption of business) arising from the use of or inability to use the product.
- This Limited Warranty gives you specific legal rights and you may also have other rights which vary from state to state.

Limited Warranty Letter

Thank you for purchasing our product. This product has been subjected to extensive inspection to maintain high quality. However, in case of failure during normal use, we will repair or replace the product free of charge for 1 year from the date of purchase according to our warranty policy.

■ This warranty is valid only in countries authorized for sale by the manufacturer.

■ Be sure for a distributor to fill in the information below.

Name of product Wearable Surgical Lighting System OPELAIII

 Your name

 Address

 E-mail address

 TEL ()

Distributor

 Address

 TEL ()

 Date of purchase YY MM DD

Manufacturer : TAIYO CORPORATION

Fuji Bldg. 9F, 5-30-9 Shiba, Minato-ku, Tokyo, 108-0014

memo

memo

Manufacturer: TAIYO CORPORATION

Fuji Bldg. 5-30-9 Shiba, Minato-ku, Tokyo, 108-0014

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