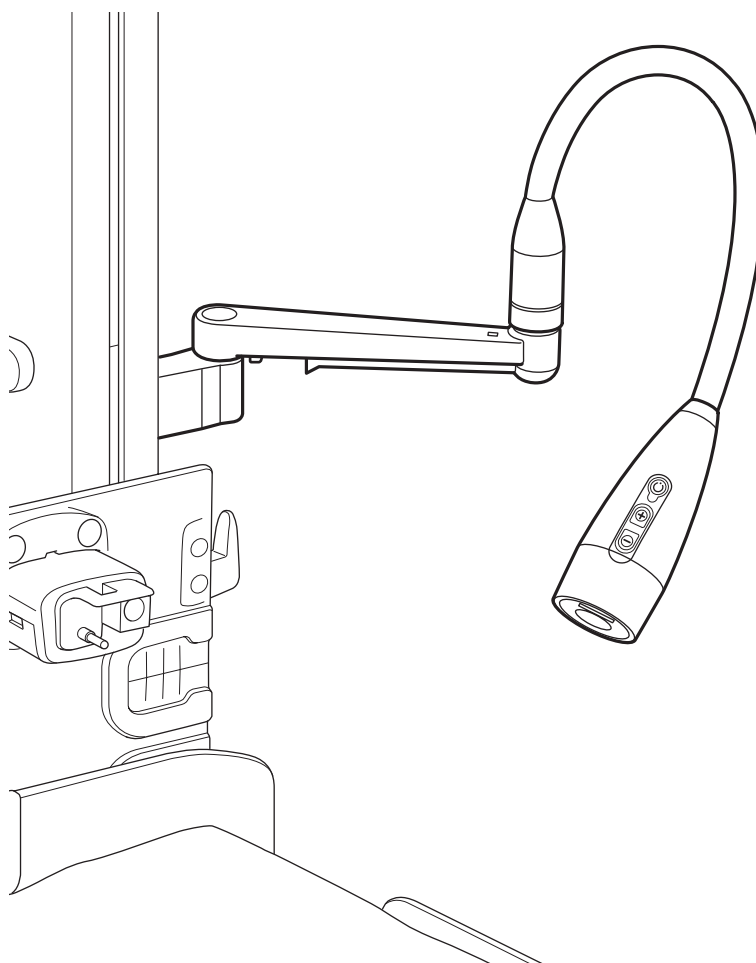


InfaLite

Operation Manual



TO THE OPERATOR AND THE PERSON IN CHARGE OF MAINTENANCE AND CARE OF THE UNIT:

- Read this **Manual** carefully before operating the unit.
 - Keep this **Manual** where it is readily accessible for reference when needed.
 - This Manual contains description of all the functions available. Please skip any section unrelated to your unit.
-



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INTRODUCTION

This Operation Manual deals with the specifications, operation and maintenance of the InfaLite. Atom is by no means responsible for any malfunction arising from a user ignoring the instructions for operation and maintenance described in this Manual as well as any accident attributable to repair by someone other than technical personnel belonging to your local Atom representative.

Read this Manual carefully and familiarize yourself with its contents before operating the unit. Keep this Manual where it is readily accessible for reference when needed. If any technical problem should arise, please contact your local Atom representative.

CAUTION



This product is shipped without being disinfected. Be sure to clean and disinfect the unit before using it for the first time after purchase.



Used products and parts past their expected life span should be disinfected and/or sterilized to prevent infection from them and then disposed of in accordance with applicable waste disposal laws and regulations.



Federal (US and Canada) Law restricts this device to sale by or on the order of a physician.

INTENDED USE

The unit utilizes quality medical white light emitting diodes (white LED) during operation.

SAFETY INFORMATION

Instructions to ensure the safe operation of the unit are found throughout this Manual.

Please read the Manual carefully before operating the unit. Please follow the instructions when operating the unit.

Basic Instructions

1. Follow the instructions for the safe use of the unit.
Follow the operating instructions described in this Manual for the safe use of the unit.
2. Inspect the unit on a periodical basis.
Periodical inspection is needed to use the unit in the optimum condition.
3. Never use the unit if it is found to be defective.
If any damage or malfunction of the unit should be noticed, stop using it immediately and contact your local Atom representative.
4. Follow the EMC information described in this Manual.
Medical electrical equipment needs special precautions regarding EMC. It needs to be installed and put into service according to the EMC information described in this Manual.

2 Definition of Warning Indication

Three levels of warning indication are used throughout this Manual and on the unit. They are defined as follows.



DANGER: A **DANGER** notice indicates **an immediately hazardous situation** which, if not avoided, will result in death or serious injury, serious damage to property such as total loss of use of equipment, or fire.



WARNING: A **WARNING** notice indicates **an indirectly (potentially) hazardous situation** which, if not avoided, will result in death or serious injury, serious damage to property such as total loss of use of equipment, or fire.



CAUTION: A **CAUTION** notice indicates a hazardous situation which, if not avoided, can result in **minor or moderate injury, partial damage to equipment, and loss of data stored in computers.**

3 Definition of Symbols

1. Symbols to indicate danger, warning or caution

Symbol	《Title》 and indication
	《General attention》 Indicates unspecified general danger, warning or caution.

2. Symbols to prohibit action

Symbol	《Title》 and indication
	《General prohibition》 Indicates unspecified general prohibition.
	《Prohibition of disassembly》 Indicates prohibition of disassembly of the unit where it may cause an electric shock or other hazards.
	《Prohibition of use of fire》 Indicates prohibition of use of fire where an external use of fire may cause the unit to ignite under certain conditions.

3. Symbols to give instructions for action

Symbol	《Title》 and indication
	《General instruction》 Indicates unspecified general action on the part of the user.
	《Remove the AC adapter plug from the power outlet》 Instructs the user to remove the AC adapter plug from the power outlet in the case of malfunction or when there is a threat of lightning.

4. Symbols of international standards (IEC)

Symbol	《Title》 and indication
	《stand-by or preparatory state for a part of equipment》 This symbol indicates that the unit is in standby, or a part of the unit is in a preparatory state.
	《Manufacturer》 This symbol indicates the name and the address shown adjacent to the symbol is of the manufacturer.
	《Date of manufacture》 Indicates the date when the unit was manufactured in the factory.
	《Authorised representative in the european community》 This symbol indicates the name and the address shown adjacent to the symbol is of the authorised representative in the European Community.
	《WEEE symbol》 In the EC area, an electrical and electronic product falling in one of the categories specified by “DIRECTIVE 2002/96/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003 on Waste Electrical and Electronic Equipment (WEEE)” should be disposed of in a manner consistent with relevant laws and regulations. This symbol indicates that the above-mentioned requirement applies to this product.
	《Class II device》 This symbol shows that the device is categorized into class II device in terms of protection against electric shock.

5. Other symbols

Symbol	《Title》 and indication
	《Operation》 This symbol is used to indicate that the user has increased the light intensity.
	《Operation》 This symbol is used to indicate that the user has reduced the light intensity.

1 Precautions on Jamming

WARNING



The unit is intended for use in hospitals.

Portable and mobile communication equipment and other devices which generate high frequency should be used at least 30cm away from the unit, including cables specified by the manufacturer. Failure to do so may cause malfunction.

Note: The emission characteristics of this unit make it suitable for use in industrial areas or hospitals (CISPR11 Class A). Take care when using the unit in residential environments (normally CISPR11 Class B), as it may not provide adequate protection from wireless frequency communication services. The user may also need to relocate or realign the unit to alleviate the problem.

2 Responsibility for Care of Equipment

CAUTION



It is the user (a hospital, a doctor's office, a clinic) that is responsible for the operation, maintenance and care of the electric equipment for medical use. The equipment should be used only by medical personnel.

3 Prohibition of Modification

WARNING



Do not disassemble or modify the unit.

Otherwise, a fire, an electric shock or injury may result.

4 Periodical Inspection

CAUTION



Periodical inspection is needed to use the unit in the optimum condition.

5 In Case of Trouble

CAUTION



If any abnormal condition or trouble should occur to the unit, indicate on the unit that it is out of order and contact your local Atom representative or service engineer immediately. See the end of this Operation Manual for whom to contact.



If any abnormal condition or trouble should occur, do not use the unit until it has been repaired completely by a service engineer so as to prevent possible danger.

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[1] Operating Precautions

Please follow the operating instructions described in this Manual for the safe use of the unit. The unit should be operated only by those who have been trained and instructed properly in its operation. The unit should be operated only for its intended use.

1-1. DANGER

Death or serious injury due to a fire or an electric shock will result if the instructions given below are not followed.



Never place a body warmer or any other possible ignition source in or near the unit.

Use of oxygen will increase the risk of explosion or fire. Body warmers or other devices in which fire is used or which will generate a spark may cause an explosion or a fire if used near the unit.



Do not use the unit in the presence of a flammable anesthetic gas.

The unit may cause an explosion or a fire if used in the presence of such a gas.

1-2. WARNING

Death or serious injury due to a fire or an electric shock will result if the instructions given below are not followed.



Take care of the usage environment.

Using the unit in a strong electromagnetic environment may affect the light intensity.



Do not use the unit next to other devices.

Using the unit next to or stacked with other devices may cause malfunction.

When it is unavoidable to do so, it is necessary to check that the unit and the other devices are operating correctly.



Do not use a power cord other than the one supplied with the unit.

Otherwise, a fire or an electric shock may result. A power cord or an AC adapter other than the one supplied with the unit can generate high frequency noise, cause jamming to other electric devices for medical use and thus result in malfunction. In addition, when such a power cord or an AC adapter is used, the unit may become susceptible to high frequency noise generated by other electric devices and thus result in malfunction.



Do not stare into the light source or continuously shine it into someone's eyes.

It may cause damage to the retina of the eye.



If the infant's pupils seem abnormal, shield their eyes from the light source.

It may cause damage to the retina of the eye.



Do not let the light source directly touch the infant.

Keep it at least 30cm away from the infant at all times.

1-3. CAUTION

Injury or damage to surrounding objects may result if the instructions given below are not followed.



Remove the AC adapter plug from the power outlet before moving the unit to another place or when the unit is not going to be used for a long time.

Moving the unit to another place with the AC adapter plug connected to the power outlet will damage the AC adapter cable and may cause a fire or an electric shock.



Do not expose the unit to extraordinarily high temperature or excessive humidity.



Do not let the unit hit anything, fall or drop inadvertently.



Do not forcefully bend the flexing arm.

When adjusting the position of the irradiation head, do not forcefully bend the flexing arm. Doing so may cause a breakdown.

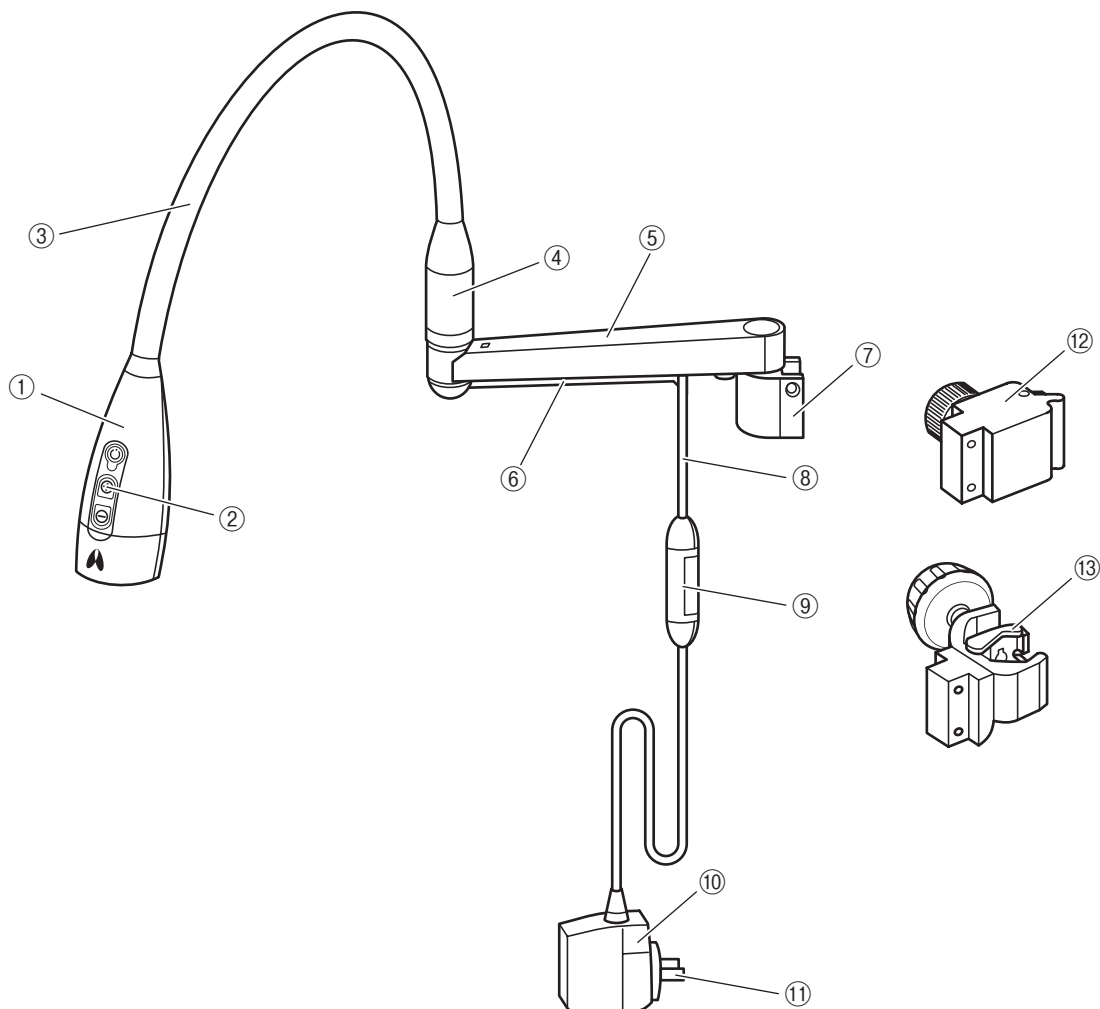


The unit is not water resistant.

If the unit has water or another liquid spilled on it, turn off the stand-by switch, remove the AC adapter plug from the power outlet and then clean the liquid with a dry cloth. If water has condensed on the inside of the lens cover, wait until the water has completely evaporated and then inspect the unit before use.

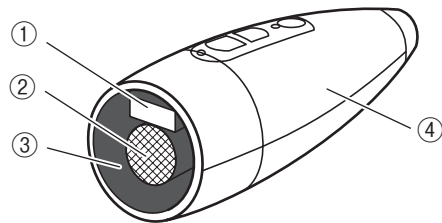
[2] Parts Identification

2-1. Main Unit



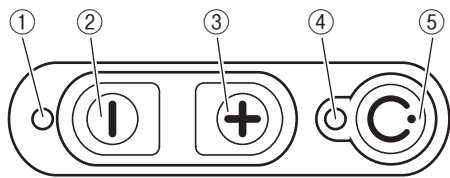
No.	Name
①	Irradiation head
②	Operation panel
③	Flexing arm
④	Arm joint
⑤	Linking arm
⑥	Arm cover
⑦	Mounting section
⑧	Relay cable
⑨	Cable cover
⑩	AC adapter
⑪	AC adapter plug
⑫	F-Rail Attachment (sold separately)
⑬	Pole Mounting Attachment (sold separately)

2-2. Irradiation Head



No.	Name
①	Non-contact sensor
②	White LED (with lens)
③	Lens cover
④	Irradiation head cover

2-3. Operation Panel



No.	Name
①	Operation indicator
②	Light control button “-”
③	Light control button “+”
④	Stand-by indicator
⑤	Stand-by switch

[3] Preparation before Use

3-1. Assembling the Mounting Section



WARNING



Make sure that the F-Rail Attachment/Pole Mounting Attachment is securely attached to the main unit.

Attach the appropriate part to the unit (F-Rail Attachment or Pole Mounting Attachment, sold separately) according to the “Installation Manual” included with this unit.

3-2. Power Outlet



WARNING



The electrical rating of this unit is as follows:

AC120–240V; power consumption 13VA; frequency 50/60Hz; operating voltage range; AC120–240V $\pm$ 10%. Do not connect the unit to any other power source.



The power outlet should be located near the unit to prevent accidental contact with a trailing power cord. Use a separate power outlet for each unit.



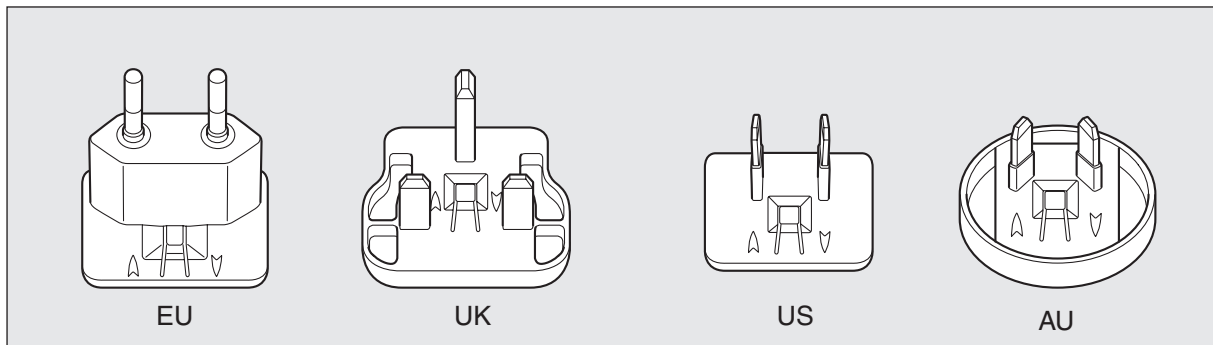
Do not put many loads on one power outlet.



The unit should be serviced only by qualified personnel according to an appropriate service manual. Be sure to use the replacement parts specified by Atom.

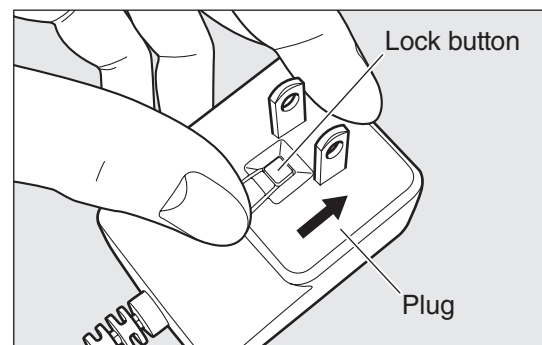
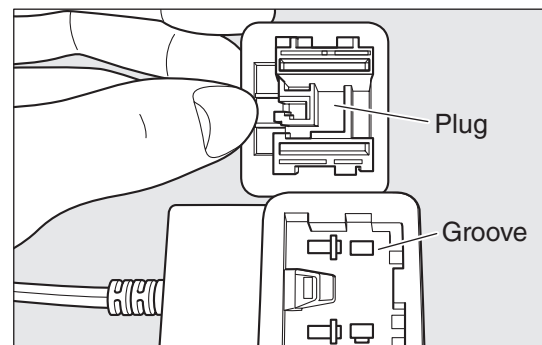
(1) How to attach and remove a plug to and from the power adapter

You can attach a plug appropriate for use in your region to the power adapter supplied with the unit.



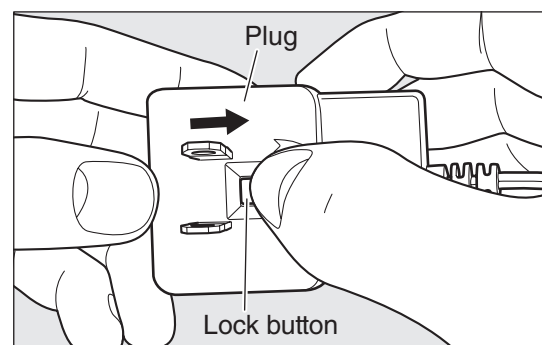
- Attaching a plug to the power adapter

Align the plug with the groove of the power adapter. Slide the plug in the direction of the arrow until the lock button clicks.



- Removing a plug from the power adapter

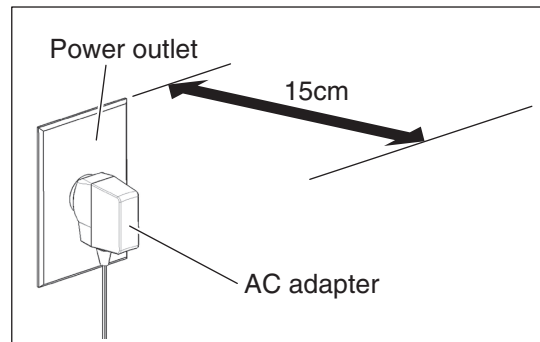
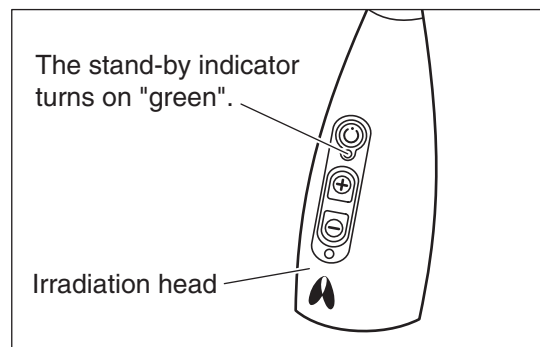
Slide the plug in the direction of the arrow while pressing the lock button, and then remove the plug.



- (2) Insert the AC adapter into the power outlet. The stand-by indicator on the irradiation head will turn green.

! CAUTION

- Keep an area of over 15cm around the power outlet clear so that the AC adapter can be quickly removed.
-



3-3. Unit Installation

WARNING



Be sure to attach the unit securely to the incubator/infant warmer.

- (1) When attaching the F-Rail Pole to the incubator or infant warmer, refer to the unit placement dimensions in the diagram to secure the F-Rail Attachment.

• **Attachable Products**

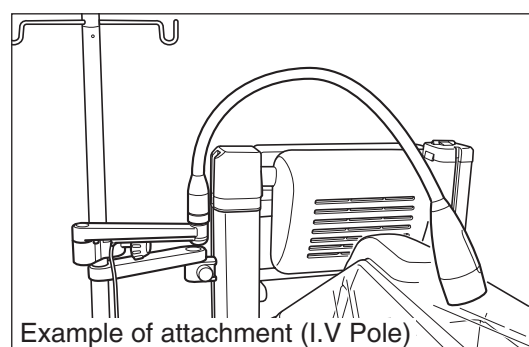
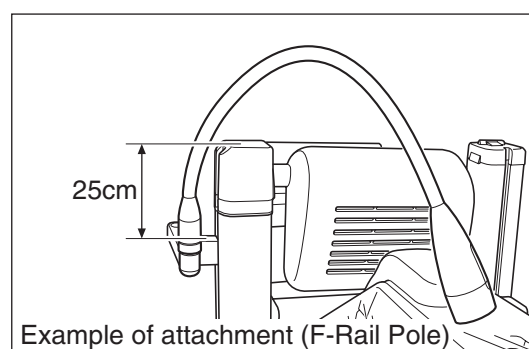
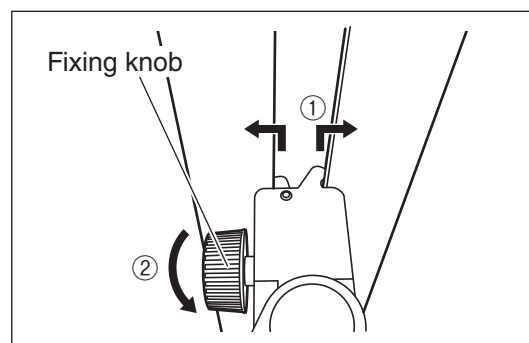
Dual Incu *i*, Incu *i*

Atom Infant Incubator V-2200, Atom Infant Incubator V-2100G, Rabee Incu *i* (Only applicable when the F-Rail Pole is attached.)

Infra Warmer *i*, Infra Warmer V-505

* For other products, contact your local Atom representative.

- ① Support the unit with your hand, and insert the tip of the F-Rail Attachment into the F-Rail groove in the products mentioned above.
 - ② Tighten the fixing knob.
 - ③ Make sure that the placement of the mounting section does not interfere with the operation of the incubator or the treatment of the infant.
 - ④ Make sure that the F-Rail Attachment is secured correctly to the F-Rail of the incubator etc. to prevent the unit from falling off while in use.
- (2) When attaching the I.V Pole, refer to the diagram to secure the Pole Mounting Attachment.
- ① Support the unit with your hand, and loosen the Pole Mounting Attachment knob while inserting the I.V Pole.
 - ② Tighten the knob.
 - ③ Make sure that the placement of the mounting section does not interfere with the operation of the incubator or the treatment of the infant.
 - ④ Make sure that the I.V Pole is secured correctly to the Pole Mounting Attachment to prevent the unit from falling off while in use.



3-4. Daily Inspection

Before using the unit, follow “6-2. Inspection before Use” to check the unit carefully for any faults, contamination, missing parts or defective parts to make sure that it can be operated safely.



WARNING



Be sure to inspect the unit at the start of each day. Operating the unit without inspecting it at the start of each day may let a defect pass unnoticed and cause a potentially unfavorable outcome.

[4] How to Operate the Unit

WARNING

-  Do not stare into the light source or continuously shine it into someone's eyes. It may cause damage to the retina of the eye.
-  If the infant's pupils seem abnormal, shield their eyes from the light source. It may cause damage to the retina of the eye.
-  Do not let the light source directly touch the infant. Keep it at least 30cm away from the infant at all times.
-  Do not let the irradiation head close to the heater unit in the canopy of the Infa Warmer i or Infa Warmer V-505.
Be sure to place the irradiation head away from the heater unit. Otherwise, the irradiation unit will overheat and cause the unit to break down.
-  Do not operate the unit covered with a cloth. Otherwise, the irradiation unit will overheat and cause the unit to break down.
-  Make sure that the Dual Incu i canopy does not hit anything when raising and lowering it. Before moving the canopy of the Dual Incu i upward, be sure to move the InfaLite away so that it does not interfere with the canopy. Also make sure that the InfaLite does not interfere with the canopy when moving it downward.

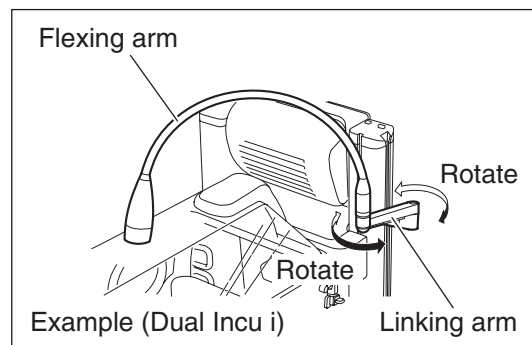
4-1. Operating the Irradiation Head

CAUTION

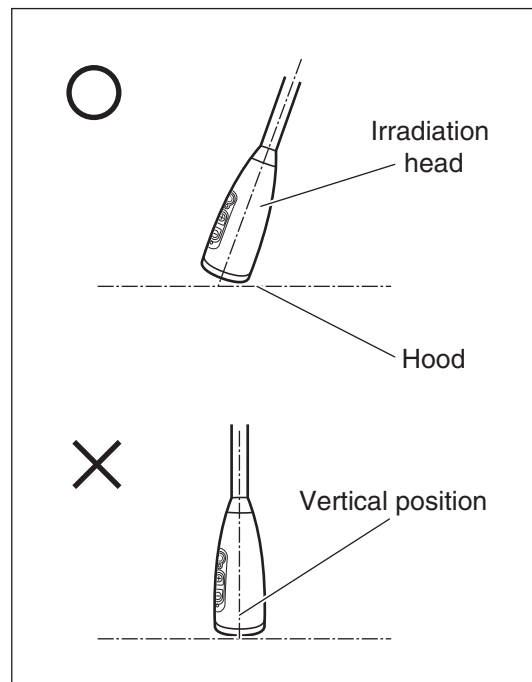
-  If you are using an incubator with this unit, make sure that the irradiation head of this unit and hood of the incubator do not become perpendicular. Otherwise, the non-contact sensor may become unresponsive.
-  Do not forcefully bend the flexing arm.
When adjusting the position of the irradiation head, do not forcefully bend the flexing arm. Doing so may cause a breakdown.
-  Keep the irradiation head at least 30cm away from the infant at all times. This is so that the irradiation and head of the infant do not make contact.

- (1) Move the linking arm or flexing arm so that the infant is exposed to, but at least 30cm away from the irradiation head.

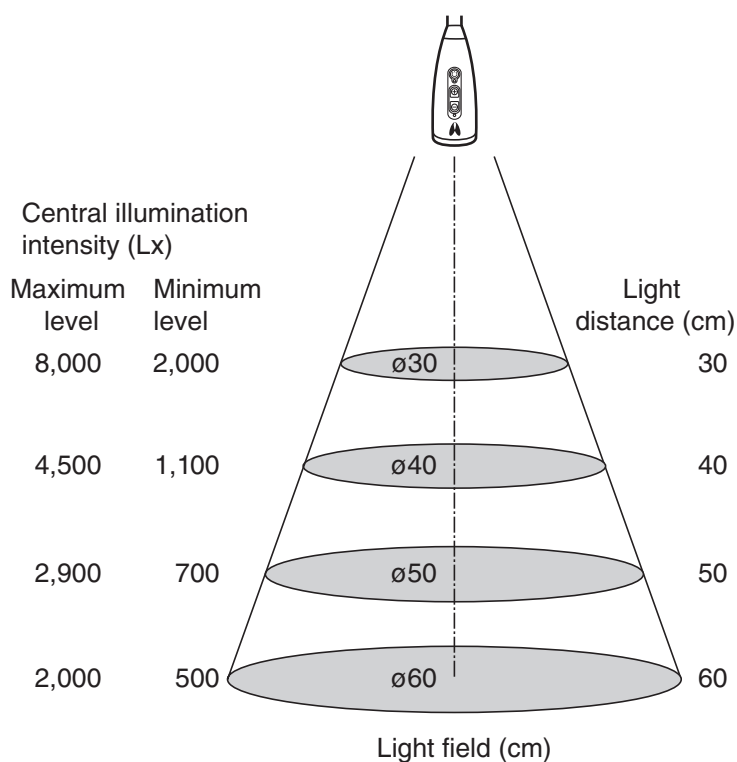
*The flexing arm may not be secure while in a horizontal position and may drop downward.



- (2) If operating the irradiation head with an incubator, make sure that the hood of the incubator and irradiation head of this unit are slightly angled so that they do not become perpendicular. If they are perpendicular, the non-contact sensor may become unresponsive.



Estimated Illumination Intensity at the Center of the Light Field



*The standard light intensity is set to be the central light intensity at a distance of 60cm.

4-2. Lighting and Light Control

CAUTION

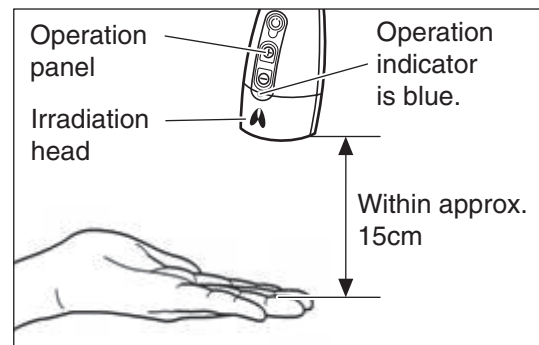


The non-contact sensor may not respond to black objects. Make sure to use the palm of your hand to activate it.

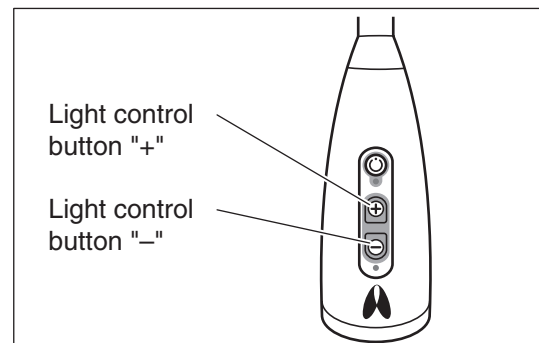


If the front of the lens cover is dirty, wipe the dirt away. If the lens cover is used while dirty, the light intensity may drop and the response of the non-contact sensor may become poor.

- (1) Press the stand-by switch of the operation panel.
- (2) Confirm that the color of the operation light is “blue”, then hold the palm of your hand in front of the irradiation head to turn it on.
 - * The non-contact sensor responds when an object is within 15cm of the irradiation head.



- (3) When adjusting the light, press the light control button “+” or “-” to adjust the light to the desired level.
 - * The light is set to its highest intensity as a factory default.
 - If you are not using the non-contact sensor, contact your local Atom representative.



4-3. Turning Off and Storing the Light

- (1) Hold the palm of your hand against the front of the irradiation head to turn it off.
- (2) Press the stand-by switch of the operation panel.
- (3) Remove the AC adapter plug from the power outlet.
- (4) Move the linking arm or flexing arm so that it does not interfere with the operation of the incubator/ infant warmer or the operator.

[5] Cleaning and Disinfection

CAUTION

-  This product is shipped without being disinfected. Be sure to clean and disinfect the unit before using it for the first time after purchase.
-  See the accompanying document of the disinfectant you are going to use for appropriate concentration, contact time and handling. Follow the directions for use and dosage and precautions given in the document.
-  Be sure to dilute disinfectant agents with water for cleaning and disinfection. Never use the agents undiluted.
-  Do not use any abrasive cloth, cleaner, thinner or other solvent, alcohol, acetone or other solution for cleaning and disinfection.
-  Be sure to turn off the stand-by switch and remove the AC adapter from the power outlet before cleaning and disinfecting the unit.
-  If any part of the unit is dirty, clean it before disinfecting the unit.
-  Disinfect the unit periodically in order to prevent contamination. If contamination is suspected while the unit is in operation, stop using it immediately and disinfect it.
-  The timing and method of disinfection varies with the frequency and conditions of use. The medical institution should determine the timing and method appropriate for the institution.
-  Do not autoclave (sterilize with high pressure steam) or sterilize the unit with EOG. Do not boil the unit for disinfection.
-  Dirt on the lens cover may cause a lowered light intensity or a loss in non-contact sensor responsiveness. Use a soft, clean cloth and disinfectant to clean the lens cover, and then wipe the lens cover with a soft, dry cloth.

- (1) Obtain a soft clean cloth and a disinfectant solution for cleaning and disinfection.
 - * Recommended disinfectant solutions include the following. Never use these solutions undiluted.
 - Benzalkonium chloride aqueous solution
 - Benzethonium chloride aqueous solution
 - Chlorhexidine aqueous solution
 - Amphoteric surfactant aqueous solution
- (2) After cleaning the unit and its parts with a soft cloth dampened with a disinfectant solution, wipe them again with a soft, dry cloth.

[6] Maintenance Inspection

In order to use the unit safely for a longer period, perform the maintenance inspections described below.

⚠ CAUTION

- ❗ Medical institutions are responsible for performing the maintenance inspections. They are allowed to entrust the maintenance inspections of the unit to an appropriate external contractor.
- ❗ Clean and disinfect the unit before maintenance inspections, repairs, or disposal.

- **Inspection before use**

Check the basic functional operation of each part of the unit every time you are going to use the unit.

- **Monthly inspection**

Check the operation of each function of the unit every month.

- **Semiannually inspection**

Check the operation of each function of the unit every six months.

- **Periodical inspection**

Contact your local Atom representative annually for periodical inspection.

- **Parts requiring periodical replacement**

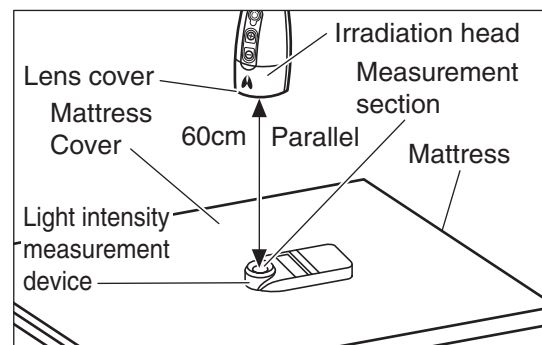
Some parts need to be replaced periodically depending on their period of use.

6-1. Measuring the Light Intensity

Check that the light intensity is operating at its specified level every six months.

Use a calibrated commercial light intensity measurement device to measure the light intensity.

- (1) Attach the mattress cover to the mattress, then place the light intensity measurement device on the mattress cover. Make sure that the lens cover of the irradiation head and the light intensity measurement device are parallel, and that the distance between them is 60cm. Next, align the center of the irradiation head with the center of the light intensity measurement device.



⚠ CAUTION

- Use a clean mattress cover so that correct measurements can be obtained.

- (2) Turn on the unit's light, then press “+” on the light control button to set it to its highest intensity. Wait at least ten minutes, and then confirm that the light intensity has reached the value specified for the maximum intensity.

Next, press “-” on the light control button to set it to the lowest intensity. Confirm that the light intensity dims to the value specified for the lowest intensity.

CAUTION

- Allow at least 10 minutes for the irradiance of the LED light source to stabilize.
- The specified value is a minimum light intensity of 500Lx or lower and a maximum of 2,000Lx or higher.

6-2. Inspection before Use

Check the following points every time you are going to use the unit.

CAUTION



If you should notice any strange smell, strange noise, overheating, strange vibration, missing parts or defective function in the inspection, stop using the unit immediately and contact your local Atom representative.

Item to check	Description
Appearance	The main unit should be free of damage. (Otherwise, the infant and/or the user may get injured due to breakage, etc.)
AC adapter	The AC adapter plug should be neither deformed or broken. The AC adapter cable should be neither damaged or dirty. (Otherwise, the unit may not receive power.)
Cable cover	The F-Rail Attachment/Pole Mounting Attachment should not be broken. (Otherwise, the unit may not receive power.)
Stand-by switch	Pressing the stand-by switch and activating the non-contact sensor should cause its light to turn on.
Non-contact sensor	Pressing the stand-by switch and activating the non-contact sensor should cause the light to turn on or off.
Light control button “-”/“+”	After turning on the power, turning on the light with the non-contact sensor, and pressing “-” or “+” on the light control button should cause the light intensity to change.
Lens cover	The lens cover should not have any cracks, dirt, fog, or damage. (Otherwise, the light intensity may drop and the response of the non-contact sensor may become poor.)
Flexing arm	The F-Rail Attachment/Pole Mounting Attachment should not be broken, and the irradiation head should be held securely in place. * It may not be secure while in a horizontal position and may drop downward, but this is not a defect.
Linking arm	The F-Rail Attachment/Pole Mounting Attachment should not be broken, and the movable parts should be able to rotate.
F-Rail Attachment/Pole Mounting Attachment (Sold separately)	The F-Rail Attachment/Pole Mounting Attachment should not be broken, and should be securely fixed to the incubator, etc.
Operation Manual	The operation manual should be kept where it is readily accessible. (Otherwise, the unit may be operated incorrectly due to lack of accessible information.)

6-3. Monthly Inspection

Check the following points every month.

Item to check	Procedure	Description
F-Rail Attachment/ Pole Mounting Attachment (Sold separately)	Shake the main unit.	Shake the unit to check that the F-Rail Attachment/Pole Mounting Attachment is not loose.
	Loosen the fixing knob.	Remove the main unit from the peripheral devices.
All parts	Visually check each part.	They should not be deteriorated (cracked, bent, damaged, etc.)
White LED (with lens)	Visually check the LED.	The white LED should emit light.
Flexing arm	Move the main unit.	The irradiation head should hold in place. *It may not be secure while in a horizontal position and may drop downward, but this is not a defect.
Linking arm	Move the main unit.	Each movable part should rotate without becoming loose.
AC adapter	Insert the AC adapter plug into the power outlet.	The stand-by indicator on the irradiation head should turn “green”.

6-4. Semiannually Inspection

Check the following points every six months.

Item to check	Procedure	Description
White LED (with lens)	Measure the light intensity with a light intensity measurement device.	The light intensity of the white LED should reach the specified value (see “6-1. Measuring the Light Intensity”).

6-5. Periodical Replacement Parts

Periodical replacement parts are those which gradually deteriorate and wear down with use. They need periodical replacement to keep the accuracy and performance of the unit at a proper level. Timing of replacement varies with the frequency and conditions of use. Consult your local Atom representative for replacement.

Part name	Period of use	Reason for replacement
AC adapter plug	2~3 years	Damage or deformation of the plug may cause malfunctions during operation.
AC adapter*	2~3 years	Damage or dirt on the cord may cause malfunctions during operation.
Flexing arm*	2~3 years	Deterioration or damage of the flexing arm may cause it to be unable to hold in a position.
White LED (with lens)*	When the operation time of the unit has exceeded 10,000 hours. Light intensity does not reach the specified value (see “6-1. Measuring the Light Intensity”).	A lowered light intensity may interfere with treatment.
Lens cover*	2~3 years	A lowered light intensity or a loss in non-contact sensor responsiveness may interfere with treatment.

*If a replacement is necessary, contact your local Atom representative.

6-6. Inspection Checklist

WARNING



If any trouble is detected in any inspection, indicate on the unit that it is out of order and seek repair without fail.



Contact your local Atom representative for further information on repairs.

Unit name	InfaLite	Date of inspection	
Serial No.		Inspector	

Item to check	Results
Inspection before use (every time)	
Is the main unit free of damage?	YES / NO
Is the AC adapter free of damage or deformation? Is the cable of AC adapter free of damage or deformation?	YES / NO
Is the cable cover free of damage?	YES / NO
Does pressing the stand-by switch and activating the non-contact sensor cause its light to turn on?	YES / NO
Does pressing the stand-by switch and holding the palm of your hand within 15cm of the non-contact sensor cause the sensor to respond and the light to turn on?	YES / NO
Does turning on the power, turning on the light with the non-contact sensor, then pressing “-” or “+” on the light control button cause the light intensity to change?	YES / NO
Is the lens cover free of any cracks, dirt, or damage?	YES / NO
Is the flexing arm free of damage? Is the irradiation head held in place?	YES / NO
Is the linking arm free of damage? Do the movable parts rotate?	YES / NO
Is the F-Rail Attachment/Pole Mounting Attachment (sold separately) securely attached to the incubator, etc.?	YES / NO
Is the Operation Manual kept where it is readily accessible?	YES / NO
Monthly inspection	
Is the F-Rail Attachment/Pole Mounting Attachment (sold separately) securely attached to the incubator, etc.? Can the F-Rail Attachment/Pole Mounting Attachment be detached from the incubator, etc. by loosening the fixing knob?	YES / NO
Are the parts of the unit deteriorated or damaged (cracked, bent, damaged, etc.)?	YES / NO
Does the white LED emit light?	YES / NO
Does the flexing arm hold the irradiation head in place?	YES / NO
Does each movable part of the linking arm rotate without becoming loose?	YES / NO
Does the stand-by indicator on the irradiation head turn “green” when the AC adapter plug is inserted into the power outlet?	YES / NO
Semiannually inspection	
Does the light intensity of the white LED reach the specified value (see “6-1. Measuring the Light Intensity”)?	YES / NO

6-7. Disposal

The medical institution concerned is responsible for proper disposal of the unit, old parts past their expected life span and disposables in accordance with applicable waste disposal laws and regulations.

[7] Troubleshooting

WARNING



If the unit seems to be defective, indicate on the unit that it is out of order, stop using it immediately, and contact your local Atom representative.

CAUTION



Check the following points before requesting repair service.

Trouble	Action to take
The power does not turn on.	Is the AC adapter plug inserted into the power outlet?
Pressing the light control button does not cause the light to become brighter. Also, it also does not become dimmer.	Are you confusing “-” and “+” on the light control button?
The light does not turn on.	Did you move your hands near the non-contact sensor?
	Is the palm of your hand outside of the detection zone for the non-contact sensor (approx. 15cm)?
	Is the lens cover dirty?
	If you are using an incubator, are the main unit's irradiation head and hood perpendicular?
	*See “4-1. Operating the Irradiation Head”.
	Is the non-contact sensor responding to something black?
The main unit is loose during operation.	Is the operation indicator “blue”?
	*If the operation indicator does not turn on or turns on in a color other than blue, the non-contact sensor has stopped working or is broken. Contact your local Atom representative.
	Is the fitting knob of the F-Rail Attachment/Pole Mounting Attachment (sold separately) loose?

[8] Technical Information

8-1. Technical Data

Power requirements	Rating: AC120–240V; power consumption 13VA; frequency 50/60Hz Operating voltage range: AC120–240V±10%
Classification	Type of protection: Class II equipment Degree of protection: no applied part Not for use in an air and flammable anesthetic gas mixture or an oxygen/nitrous oxide and flammable anesthetic gas mixture Mode of operation: Continuous operation
Light source:	white LED Color temperature: 4,000~4,800K (changes in the ambient temperature may cause slight variations)
Light intensity	Below 500 to above 2,000Lx * when adjusting the light (if the distance from the irradiation head and the light intensity measurement device is 60cm)
Light field	Approximately φ60cm (if the distance from the irradiation head and the light intensity measurement device is 60cm)
Light field life	10,000 hours (lumen maintenance factor 70%)
Non-contact sensor	Responds to objects within approximately 15cm
Dimensions	φ5.5(W) x 25(D) x 87(H) cm * With the flexing arm extended * Not including the F-Rail Attachment/Pole Mounting Attachment (sold separately)
Weight	1.6kg * Not including the F-Rail Attachment/Pole Mounting Attachment (sold separately)
Operating conditions	Ambient temperature: 10~30°C Relative humidity: 30~85% (with no condensation) Pressure: 70~106 kPa(525~795mmHg)
Storage conditions	Ambient temperature: 0~50°C Relative humidity: 30~75% (with no condensation) Pressure: 70~106 kPa(525 - 795mmHg)
Transport conditions	Ambient temperature: 0~50°C Relative humidity: 30~75% (with no condensation) Pressure: 70~106 kPa(525~795mmHg)
Products sold separately	F-Rail Attachment Order No. : 60217 Pole Mounting Attachment Order No. : 60218

*The unit meets the EMC (electromagnetic compatibility) requirements of IEC 60601-1-2.

8-2. EMC Level and Classification

■ Emission test level

The unit is intended for use in the electromagnetic environment specified below.

The customer or the user of the unit should assure that it is used in such an environment.

Emissions test	Compliance
Conducted and radiated RF emissions CISPR11	Group 1
Conducted and radiated RF emissions CISPR11	Class A

■ Immunity test level

The unit is intended for use in the electromagnetic environment specified below.

The customer or the user of the unit should assure that it is used in such an environment.

Immunity test	Compliance level
Electrostatic discharge IEC61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients/bursts IEC61000-4-4	±2kV(power port, ground port)
Surges IEC61000-4-5	±0.5kV, ±1kV (Line-to-line)
Voltage dips, Voltage interruptions IEC61000-4-11	0%Ut: 0.5cycle (0,45,90,135,180,225,270,315°) 0%Ut: 1cycle (single phase: 0°) 70%Ut: 25/30cycle (single phase: 0°) 0%Ut: 250/300cycle
Rated power frequency magnetic fields (50/60Hz) IEC61000-4-8	30A/m
Conducted disturbances induced by RF fields IEC61000-4-6	3Vrms 0.15MHz — 80MHz 6Vrms in ISM bands between 0.15MHz — 80MHz 80%AM at 1kHz
Radiated RF EM fields IEC61000-4-3	3V/m 80MHz~2.7GHz 80%AM at 1kHz Refer to another table for the proximity fields from RF wireless communications equipment

■ Details of test level of proximity fields from RF wireless communications equipment

Test frequency [MHz]	Maximum power [W]	Distance [m]	Immunity test level [V/m]
385	1.8	0.3	27
450	2	0.3	28
710	0.2	0.3	9
745			
780			
810	2	0.3	28
870			
930			
1720	2	0.3	28
1845			
1970			
2450	2	0.3	28
5240	0.2	0.3	9
5500			
5785			

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- The contents of this Manual are subject to change without notice due to technical improvement.
- All possible measures have been taken to ensure the accuracy of the contents of this Manual. However, if any errors should be noticed, Atom would greatly appreciate being informed of them.



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