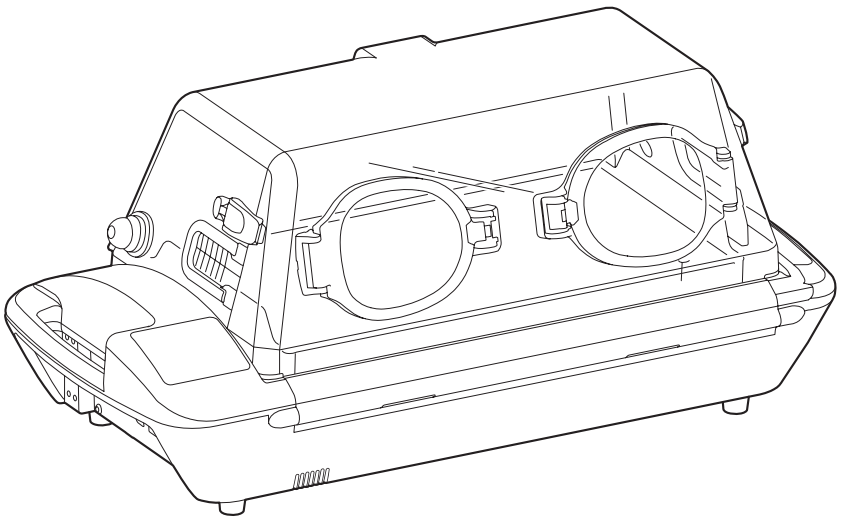
Equipment for neonatal and premature infants: Incubator

ORIGINAL

CE 0123

IncuArch

Operation Manual



Digitally signed by Prodan Sveatoslav
Date: 2024.09.19 17:24:44 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ

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 describes operations of this unit and instructions on how to operate the pulse oximeter and oxygen monitor. You may skip any section(s) describing functions that are not included in your specific unit.

ATOM

EC REP ATOM MEDICAL INTERNATIONAL, INC. EU OFFICE
Via Libia, 54 - 20081 Abbiategrasso (MI) - Italy
Tel: +39 02 99763101 Fax: +39 02 99763110

INTRODUCTION

Thank you for purchasing IncuArch.
This Operation Manual deals with the specifications, operation and maintenance of the IncuArch. 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 or authorized by Atom.
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 problems should arise, please contact your local Atom representative.

⚠ CAUTION

- The unit is shipped without being disinfected. Be sure to clean and disinfect the unit before using it for the first time after purchase.
- The product and its parts that are past their service lives should be disinfected before being disposed of in accordance with the applicable waste management laws.
- This product maintains the ambient temperature around an infant by drawing in the air outside and warming it. It does not have the capability to cool the air drawn from outside. Be sure to set the incubator air temperature at least 3°C higher than the ambient temperature. In particular, if a phototherapy unit, a heated humidifier, or some other heat-generating device is used with the incubator, set the incubator air temperature at least 5°C higher than the ambient temperature. If a lower setting is selected, the incubator may not be controlled correctly.

INTENDED USE

The IncuArch is a closed-care transport incubator for neonatal and premature infants and is intended to transport low birth weight infants and seriously ill neonates.

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.

1 Basic Instructions

1. Follow the instructions for the safe use of the unit.
   Please follow the operating instructions described in this Manual to help ensure safe use of the unit.
2. Inspect the unit on a periodical basis.
   It is necessary to carry out appropriate periodical inspections in order to maintain the unit in 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 given in this Manual.
   Electrical equipment for medical use needs special precautions regarding EMC. It needs to be installed and put into service according to the EMC information provided in this Manual.

2 Definitions 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 immediate 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 indirect (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 injuries, 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.
	**《Caution: Hot surface》** Indicates that the surface can be dangerously hot under certain conditions.

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.
	**《Prohibition of contact》** Indicates that touching a certain part of the unit where it may cause injury is prohibited 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.
	**《Connect a ground wire》** Instructs the user to connect the ground wire without fail where the unit is provided with a ground terminal.
	**《Remove the power plug from the power outlet》** Instructs the user to remove the power plug from the power outlet in the case of malfunction or when there is a threat of lightning.

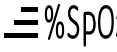
4. Symbols of international standards (IEC)

Symbols	《Title》and indication
	**《Type BF applied part》** Indicates that the device is classified as Type BF in terms of the degree of protection against electric shock.
	**《See Operation Manual》** Follow operation manual.
	**《Attention》** Indicates that the user needs to consult accompanying documents.
	**《Date of manufacture》** Indicates the date when the unit was manufactured in the factory.
	**《Lighting》** Indicates a switch that controls lighting.
	**《Power》** Indicates a switch to turn the power on or off.
	**《Electrostatic discharge》** Indicates a caution regarding electrostatic discharges.
	**《Recycle mark》** Indicates that recycling is recommended.
	**《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.
	**《Manufacturer》** This symbol indicates the name and the address shown adjacent to the symbol is of the manufacturer.
EC REP	**《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.

5. Other symbols

Symbol	《Title》and indication
	**《Setting》** Indicates that a setting is increased.
	**《Setting》** Indicates that a setting is decreased.

Symbol	《Title》and indication
	《**AC Power**》 Indicates that the AC power is being supplied if an adjacent indicator is on. Indicates that the AC power is not being supplied if an adjacent indicator is off.
	《**Alarm**》 Indicates that an audible alarm is silenced.
	《**Alarm**》 Indicates that a system of the unit is in an abnormal condition.
	《**Alarm**》 Indicates that the rotation of the fan is abnormal or the fan has not been attached.
	《**Alarm**》 Indicates an alarm related to temperature.
	《**Alarm**》 Indicates an alarm related to a skin temperature probe.
	《**Battery**》 Indicates the power level of battery 1 and 2.
⎓ 24V12V	《**DC power connecting port**》 Indicates the DC power connecting port of the main body.
	《**Alarm**》 Indicates excessive temperature condition.
	《**Alarm**》 Indicates a low battery level.
	《**Alarm**》 Indicates an alarm related to the SpO_2 patient cable. (For Masimo pulse oximeter)
	《**Alarm**》 Indicates an alarm related to a failure of the SpO_2 patient cable. (For Masimo pulse oximeter)
	《**Alarm**》 Indicates an alarm related to the SpO_2 sensor.
	《**Alarm**》 Indicates an alarm related to a failure of the SpO_2 sensor.
%SpO₂	《**Alarm**》 Indicates an alarm related to a failure of the SpO_2 sensor function.
 (Red marking)	《**Alarm**》 Indicates the inability to detect pulse during measurement. (For Nellcor pulse oximeter)
	《**Alarm**》 Indicates an alarm related to an oxygen sensor.

Symbol	《Title》 and indication
Max	《**Sensitivity setting indicator**》 Indicates that the sensitivity mode is set to “Max”. (For Masimo pulse oximeter)
APOD	《**Sensitivity setting indicator**》 Indicates that the sensitivity mode is set to “APOD”. (For Masimo pulse oximeter)
	《**Pulse search indicator**》 Indicates that a pulse is being detected. (For Masimo pulse oximeter)
	《**Interference indicator**》 Indicates that interference is detected. (For Masimo pulse oximeter)
	《**Fast response mode indicator**》 Indicates that the response mode of the pulse oximeter is set to “Fast.” (For Nellcor pulse oximeter)
	《**Pulse search indicator**》 Indicates that a pulse is being detected. (For Nellcor pulse oximeter)
	《**Interference indicator**》 Indicates that interference is detected. (For Nellcor pulse oximeter)
	《**Rotating parts**》 Indicates there is a risk of injury if you touch rotating fan blades.

4 Precautions on Jamming

⚠ WARNING

Electric surgical knives, portable and mobile wireless communication devices (e.g., cellular phones) that generate high frequency noise may jam various types of electrical equipment for medical use and thus result in malfunction.
Since portable phones and other devices are often used in medical facilities, some measures should be taken to prevent jamming due to such devices.
Portable phones and other devices that generate high frequencies should not be used near the unit when it is operating in order to prevent the unit malfunctioning due to jamming.

The unit should not be used adjacent to or stacked with other equipment. If the unit needs to be adjacent to or stacked with other equipment, the unit should be observed to verify that it operates normally in the configuration it is in.

5 Responsibility for Care of Equipment

⚠ CAUTION

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

6 Prohibition of Modification

⚠ WARNING

Do not disassemble or modify the unit.
Otherwise, a fire, electric shock or injury may result.

7 Periodical Inspection

⚠ CAUTION

Proper periodical inspection is needed to use the unit in the optimum condition.

8 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.

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.

Table of Contents

[1] Safety Instructions

Please follow the operating instructions described in this Manual to help ensure safe use of the unit. The unit should be operated only by those who have received relevant training and instruction regarding its operation. The unit should only be operated according to its intended use.

1-1. ⚠ DANGER

Death or serious injury, damage to equipment or a fire will result if the instructions given below are not followed.

Monitor the infant's skin temperature when operating the unit.

Be sure to keep the admittance panels and snap-open access ports closed while the unit is in use.

Using the unit with the admittance panel or snap-open access port left open may cause the infant to fall out of the baby compartment. Be sure to close the admittance panels and the snap-open access ports when administering phototherapy to an infant.

Do not leave the unit unattended when any of the admittance panels or snap-open access ports are open.

The infant may be in danger of falling.

Stop using the unit immediately and request repairs if you find any abnormalities, such as a misaligned admittance panel or snap-open access port, or a loose press bar.

The admittance panel or snap-open access port may unexpectedly open, causing the infant to fall out of the baby compartment.

When providing phototherapy to an infant in the incubator, watch for any increase in the incubator air temperature.

Since a mature infant emits a lot of heat, the incubator air temperature may rise if you place the infant in the incubator and perform phototherapy. The incubator air temperature may also rise if you use multiple phototherapy units at the same time, or if the room temperature is high. In such a case, proceed with the phototherapy after placing the infant in a cot or an open-type incubator, as directed by the doctor.

Do not overtighten the dispo safety bands.

Doing so may harm the infant.

Any type of ignition source, such as a hand warmer, must be kept away from the incubator.

Hand warmers or other items that may catch fire, or devices that generate sparks may cause an explosion or a fire if used near the unit when oxygen is being supplied.

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

Otherwise, a fire or an explosion may result.

Do not use ether, alcohol or any other flammable substances.
Even a small amount of ether, alcohol or other flammable substances may cause a fire when mixed with the oxygen in the incubator.

Analyze arterial gas levels repeatedly when a high oxygen environment is required.
It has been reported that when setting the concentration of oxygen in the incubator to a high level, it is extremely important and essential to repeatedly measure the oxygen concentrations inside the incubator and analyze arterial blood gas in order to correctly maintain oxygen concentrations. Follow the doctor's instructions for measuring the oxygen concentration because ignoring essential requirements may increase the risk of retinopathy of prematurity and other adverse effects.

1-2. ⚠ WARNING

Death or serious injury, damage to equipment or a fire will result if the instructions given below are not followed.

Be sure to follow the doctor's instructions in setting the incubator air temperature.

The doctor is responsible for making a decision on transporting a premature infant. Watch the infant continuously during transport.
Transporting a premature infant is associated with a risk of intracerebral hemorrhage due to vibration during transport.

Smoking is prohibited in the room where the unit is installed. Do not place any potential ignition sources in the room.

Follow the doctor's instructions when selecting an appropriate method of oxygen administration, an appropriate oxygen concentration, and an appropriate duration of administration.
Incorrect use of supplementary oxygen may cause serious side effects including loss of sight, damage to the brain, and death. The risks of side effects vary with infants. The concentration of oxygen delivered to an incubator must be followed by the doctor's instructions.

Use oxygen for medical use only.

Be sure to bear in mind the following precautions when supplying oxygen.
- A hand warmer, flashlight, oils and fats, or combustible vaporized gases should not be placed in or near the incubator.
- Use pure cotton for the infant's clothing, bed sheets, etc. Do not use any material that is easily charged with static electricity.
- Be sure that the clothing of doctors, nurses and ambulance attendants who handle this unit is made from pure cotton or fire-proof materials.

Observe the following precautions when oxygen supply equipment is in use.
- A spontaneous and violent ignition may occur if oil, grease, or greasy substances come in contact with pressurized oxygen. These substances must be kept away from oxygen regulators, cylinder valves, tubing and connections, and all other oxygen supply equipment.
- On a high-pressure oxygen cylinder, only use tested pressure reducing or regulating valves marked for oxygen service. Do not use these valves for air or gases other than oxygen. It is dangerous to use a valve to supply a gas other than air or oxygen and then to supply oxygen again.

Do not use any devices that generate high frequencies near the unit.
Using electric surgical knives, mobile phones, or other devices that generate high frequencies near the unit may cause malfunctions due to jamming.

Ensure the unit is securely grounded when connecting the unit to a power source.
This can prevent electric shock due to current leakage. In order to complete the ground connection, be sure to connect the power plug to a three-prong, correctly grounded outlet. Do not operate the unit if you have any doubts about its ground connection.

Ensure the peripheral electrical equipment is securely grounded when connecting the unit to a power source.

Avoid damaging the power cord.
A damaged power cord may cause a fire or electric shock. If a power cord is damaged, it should be immediately replaced with a new one.

- Do not allow the power cord to get caught between the unit and wall, shelf or floor.
- Do not place the power cord near a heating apparatus or heat it.
- Do not place any heavy objects on the power cord.
- Always grasp the power plug with your hand to remove the power cord from the power outlet.

Only use the power cord supplied with the unit.
Otherwise, a fire or electric shock may result.

Do not put multiple loads on one power outlet.
The power outlet should be located near the unit in order to prevent accidental contact with a trailing power cord. Use a separate power outlet for each unit.

Avoid connecting the unit to a power source other than a appropriately rated power source.
The electrical rating of this unit is as follows:
Power voltage - AC100-240V; frequency - 50/60Hz; power consumption - 220VA; operating voltage range -AC100-240V±10%. Do not connect the unit to any other power source.

Do not touch the power plug with wet hands.
Touching the power plug with wet hands may cause electric shock.

Charge the battery as instructed.
Failure to do so may cause the battery to leak, generate heat or smoke, rupture, or ignite.

If the battery is not fully charged after the specified charging time period has elapsed, stop charging it.
Failure to do so may cause the battery to leak, generate heat or smoke, rupture, or ignite.

Do not charge the battery in locations such as gas stations where flammable gases (propane gas, gasoline, etc.) or fine particulates are produced.
Otherwise, gases may ignite.
Doing so may cause an explosion or fire.

If a leakage is suspected or you detect a strange odor, keep the battery away from fire.
Failure to do so may cause the battery to leak, generate heat or smoke, rupture, or ignite.

Do not directly touch electrolyte that has leaked from the battery cover.
If any electrolyte comes in contact with your eyes, you may lose your sight. If it comes in contact with your skin or clothing, it may cause irritation. Flush it immediately with plenty of water and consult a physician.

Install the unit on a stable surface.
Installing it on an unstable surface or a slope may cause it to topple, fall, or move, resulting in injury or damage. Therefore, before installing the unit, make sure that the place where the unit is to be installed is stable and strong enough to support the weight of the unit.

Do not subject the oxygen sensor to impact.
If the oxygen sensor is damaged, the electrolyte inside may leak out of the sensor. If contact with the skin or clothing occurs, rinse the area immediately with running water.

Do not touch the heaters during use or shortly after use.
The heaters are very hot during use and shortly after use. Allow the heaters to cool down sufficiently before cleaning and disinfecting them in order to avoid injury.

Do not attempt to disassemble or modify the unit.
A fire, electric shock or injury may result.

The unit should only be serviced by qualified personnel in accordance with the appropriate service manual.

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 result in a defect passing unnoticed and cause a potentially unfavorable outcome.

If the unit fails to operate correctly, stop using it immediately.
Indicate on the incubator that it is out of order and contact your local Atom representative.

Do not reuse the dispo safety bands.
Change the dispo safety bands for every infant. Reusing them could lead to infection.

Do not stare into the lighting lamp or expose your eyes to the light.
Doing so may cause retinal damage.

1-3. ⚠ CAUTION

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

Place the infant in the incubator only after the incubator air temperature has stabilized.
Prior to placing the infant in the incubator, pre-warm the incubator to keep the incubator air temperature stable.

Do not forcefully pull on or twist cords.

When feeding the cords and tubes into the unit, be very careful not to let them wind or tighten around the infant.

Do not press strongly or rub on the LCD screen.
Doing so may result in damage or malfunction.

Do not allow any chemicals to adhere to the display.
If any chemicals do adhere to the display, wipe them off immediately.

Check that the peripheral devices operate correctly.
A device that transmits or receives faint signals may be affected by the electromagnetic waves generated by the unit. If such a device is used in the vicinity of the unit, check the operation of that device for any detrimental effects before using the unit in clinical environments. Stop using the unit immediately if any problems occur.

Unplug the power plug before moving the unit to another location or when the unit is not used for an extended period of time.
Moving the unit to another location with the power plug connected to a power outlet will damage the power cord and may cause a fire or electric shock.

Do not apply impact to the unit or hit it on something.
Doing so may result in damage or malfunction.

Do not install the unit in excessively hot or humid places, excessively dusty environments, or where it will be exposed to steam.
Installing the unit in such a place may cause a fire or electric shock.

Do not install the unit in direct sunlight or near a heating apparatus.

Keep the unit out of reach of small children.

Do not place any heavy objects on the unit.

Do not pour liquids directly onto the unit.
A fire or electric shock may result, or the unit may malfunction. If a large amount of liquid has spilled on the unit, immediately wipe it up and call your local Atom representative to request checking of the internal electronic circuit.

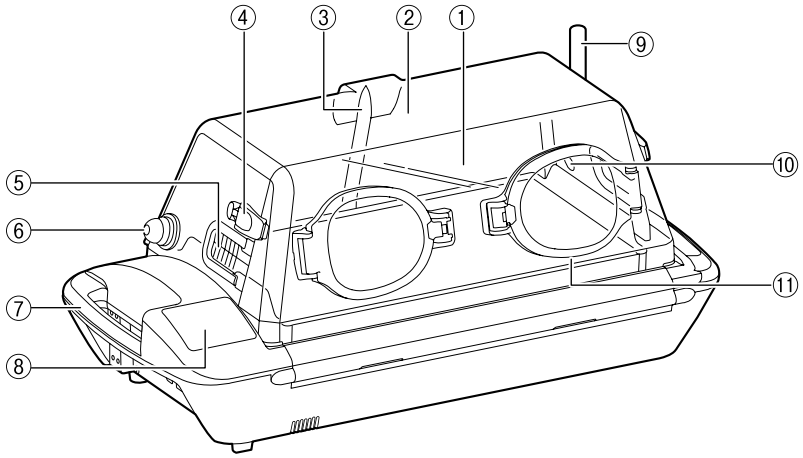
Be sure to clean and disinfect the unit before using it for the first time after purchase.
The unit is shipped without being disinfected.

Remove the power plug from the power outlet before cleaning and disinfecting the unit.
Cleaning and disinfecting the unit with the power plug connected to the power outlet may cause electric shock.

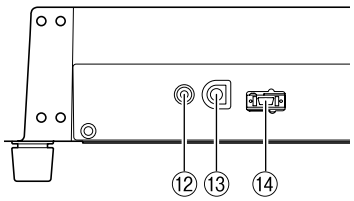
Do not connect any equipment items other than those we specify.

[2] Parts Identification

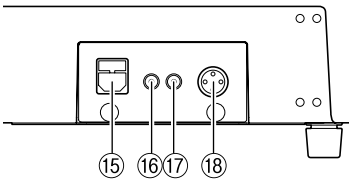
2-1. Main body



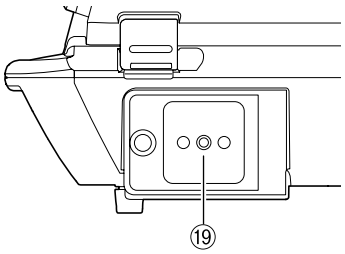
■ Left side



■ Right side



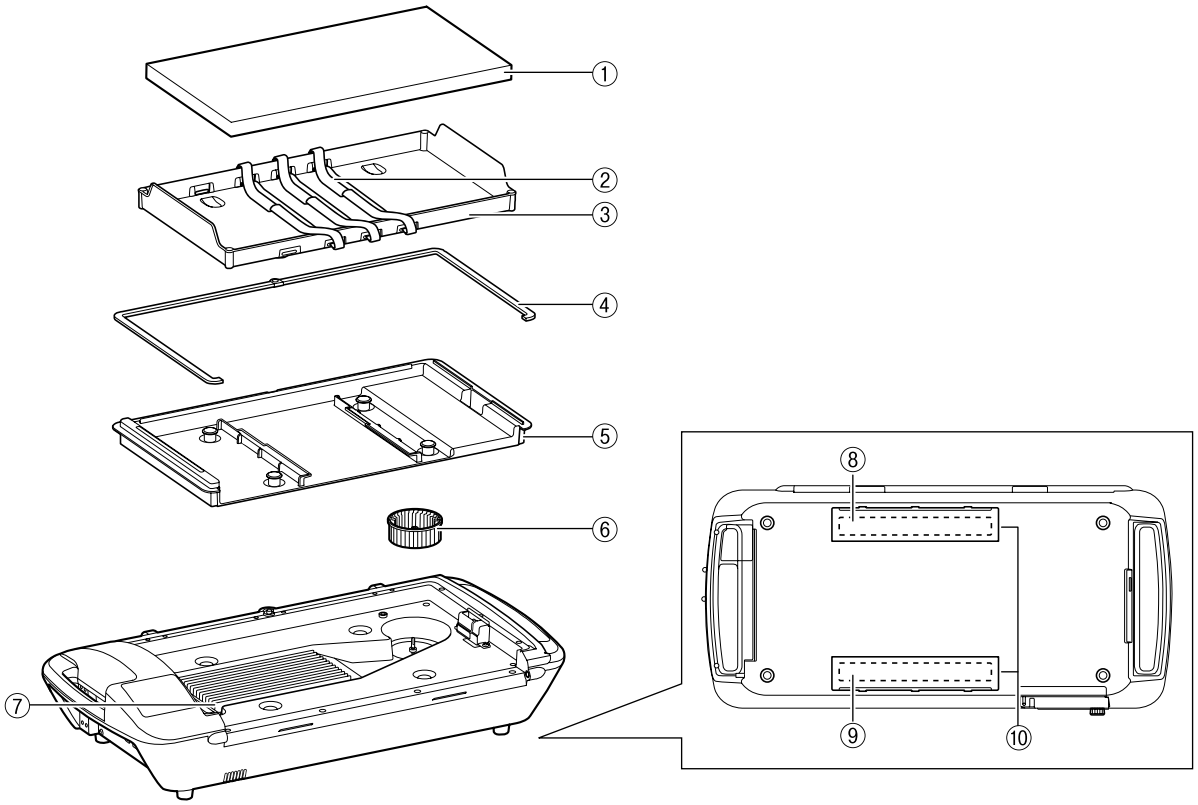
■ Rear of the main body



No.	Name
①	Admittance panel
②	Hood
③	Lighting lamp
④	Admittance panel latch
⑤	Tube introduction slit
⑥	Oxygen sensor module
⑦	Handle
⑧	Operation panel
⑨	Multi-purpose pole (option)
⑩	Oxygen supply port

No.	Name
⑪	Snap-open access port
⑫	Oxygen sensor connection port
⑬	Skin temperature probe connection port
⑭	Connector for SpO_2 sensor
⑮	AC inlet
⑯	DC power breaker (for 24V)
⑰	DC power breaker (for 12V)
⑱	External DC power inlet
⑲	Filter cover

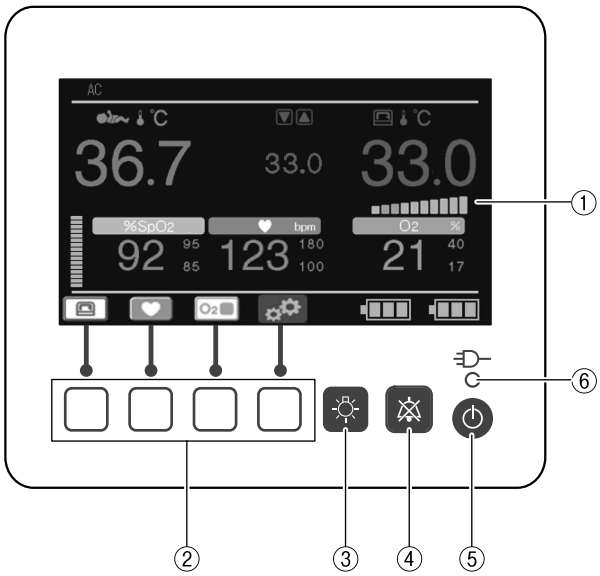
Mattress Platform and Inside of Incubator



No.	Name
①	Mattress
②	Dispo safety band
③	Mattress platform
④	Packing for main body
⑤	Middle board

No.	Name
⑥	Fan (common to both V-707 and V-808)
⑦	Heater
⑧	Battery 1
⑨	Battery 2 (option)
⑩	Battery cover

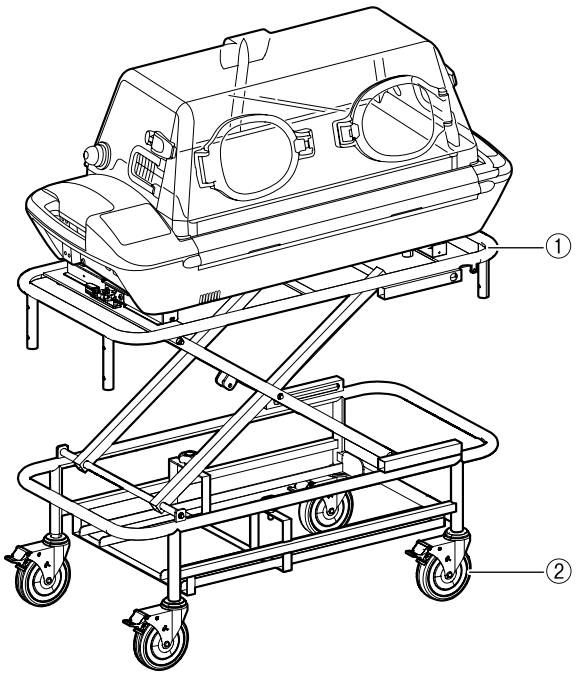
2-2. Operation panel



No.	Name	Description
①	Display area	Displays skin temperature, set temperature, SpO_2, pulse rate, oxygen concentration, etc.
②	Control switches	Used to switch display screens or to specify various settings.
③	Light switch	Used to turn the light ON or OFF or to change brightness.
④	Alarm silence switch	Used to silence alarms.
⑤	Power switch	Used to turn the power ON or OFF.
⑥	AC power indicator	Lights up when the power cord is connected to an AC outlet.

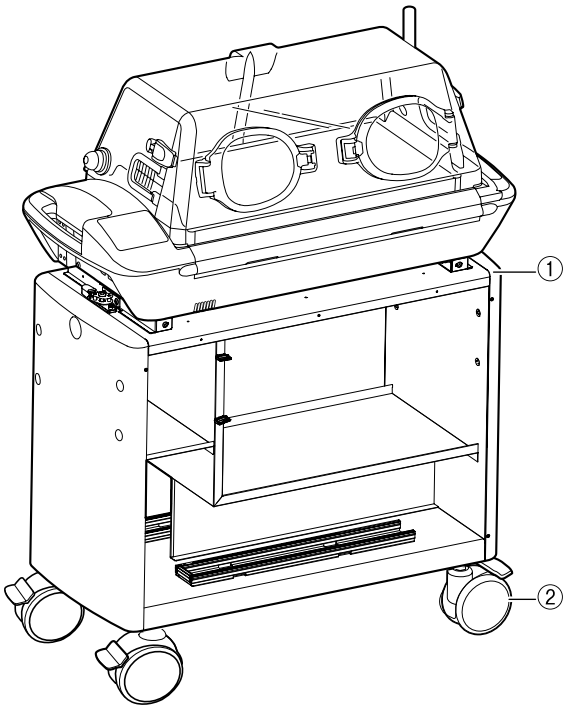
2-3. Stands

■ HL stand (option)



No.	Name
①	HL stand
②	Caster

■ Cabinet stand (option)



No.	Name
①	Cabinet stand
②	Caster

[3] Preparation before Use

3-1. Assembly

⚠ WARNING

Be sure to secure the incubator and a stand using the incubator retainer. Failure to do so may cause the incubator to tip over if a force is applied while the hood is open, or to fall due to shock received during transportation. Never operate the incubator until it has been firmly secured.

⚠ CAUTION

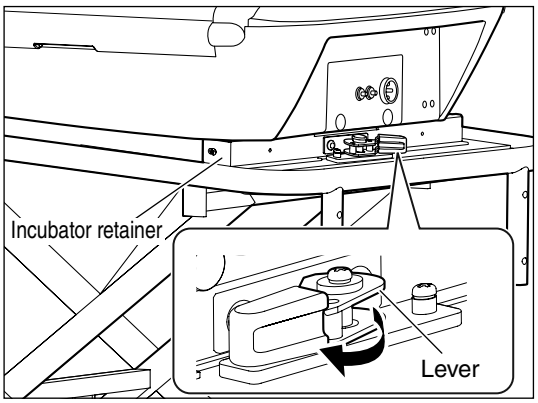
The incubator is heavy and should be assembled and moved by at least two people.

The incubator is packed when shipped. When using the incubator placed on the HL or cabinet stand, follow the procedure below to assemble the stand.

3-1-1. For HL Stand (Option)

(1) Mount the incubator on the high-low stand.

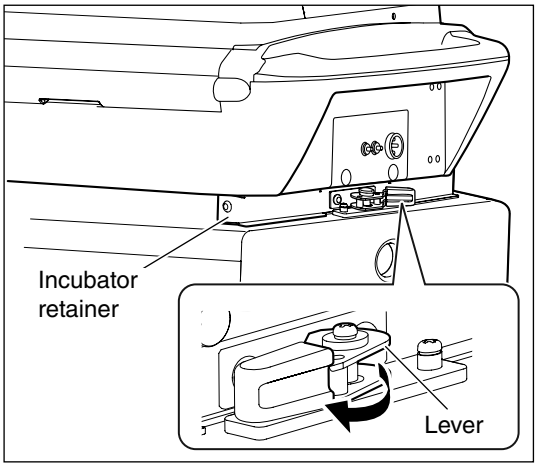
(2) Be sure that the rubber feet of the incubator are placed on the incubator retainer before tightening the lever of the retainer to secure the incubator.



3-1-2. For Cabinet Stand (Option)

(1) Mount the incubator on the cabinet stand.

(2) Be sure that the rubber feet of the incubator are placed on the incubator retainer before tightening the lever of the retainer to secure the incubator.



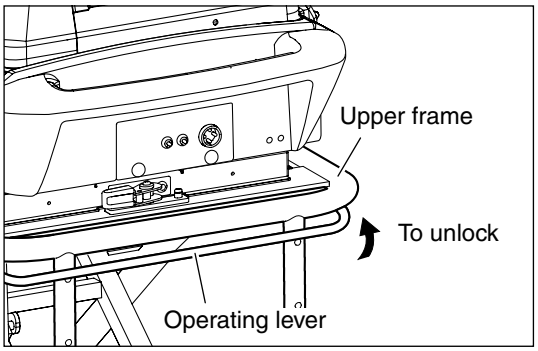
3-2. Adjusting the HL Stand

The HL stand is steplessly adjustable in height in a range from 48 to 80cm (from the bottom of the incubator to the floor). Perform the following procedures to adjust the height of the stand.

(1) Make sure that the stand is secured using the retainer.

(2) Grasp the top frame with both hands and raise the operating lever up to unlock the lever. Raise the stand to the desired height.

(3) To lock the stand, release the operating lever.



⚠CAUTION

- The stand has a damper to assist with raising and lowering. For safety, two persons must raise or lower the stand with an incubator in position.

3-3. Where to Install the Incubator

⚠CAUTION

Avoid installing the incubator in direct sunlight, near a stove or a radiator, in the direct airflow of an air conditioner, or by a cold window in order to prevent it from being directly affected by such external thermal conditions.

Install the incubator on a level surface in a location where it is easy to operate except when being transported. Avoid installing it near a heating apparatus, beside a window, or where fire is used.

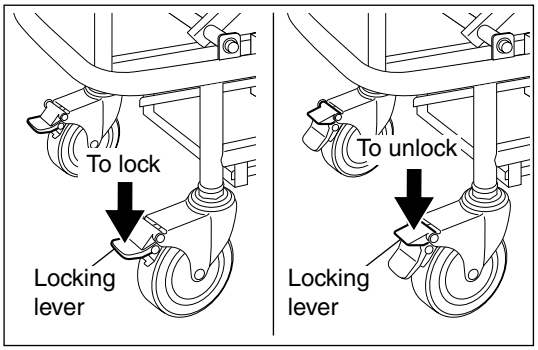
3-4. Locking the Casters

The casters of the HL stand and cabinet stand have locks. When using the incubator placed on the HL or cabinet stand, follow the procedure below to lock the casters:

3-4-1. For HL Stand (Option)

■ To lock the casters
Lower the locking lever on each caster to the locked position.

■ To unlock the casters
Step on the unlocking pedal with the locking lever in the down position to unlock the casters.



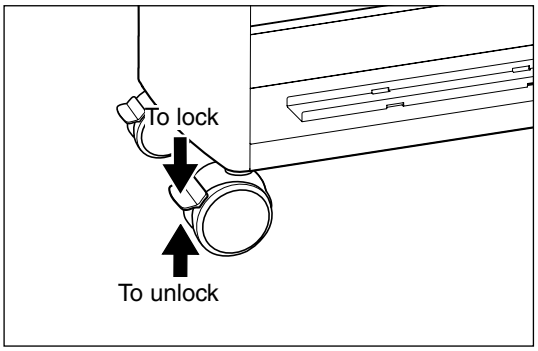
3-4-2. For Cabinet Stand (Option)

■ To lock the casters
Lower the locking lever on the casters to the locked position.

■ To unlock the casters
Raise the locking lever on the casters to the unlocked position.

⚠CAUTION

- Place the stand on a level, stable surface. Step on the four locking levers to lock the casters securely. To move the incubator to another location, be sure to unlock the casters.



3-5. Securing the Unit to an Ambulance

⚠ WARNING

When securing the unit using the HL stand, ensure that incubator is secured to the stand using the retainers.

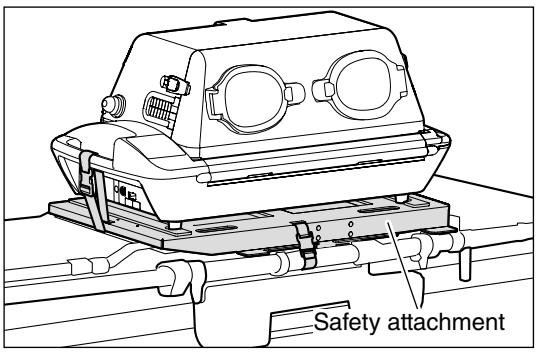
⚠ CAUTION

The unit must be loaded into an ambulance by at least two people. When using the HL stand, lower it to the lowest position before utilizing at least two people to lift the unit.

The method of securing the unit to an ambulance varies from one ambulance to another. Determine it in consultation with relevant organizations (hospitals, fire departments, etc).

■ Attaching the unit to a stretchers

To secure the unit to a stretcher designed for high-standard ambulances, use the safety attachments (option). For information on how to secure the unit to the safety attachment, refer to the Instructions for Use that comes with the safety attachment.



3-6. Inspections Before Start

⚠ DANGER

Always verify that the admittance panel retainers and the press bars of the snap-open access ports function correctly. If an admittance panel or a snap-open access port fails to close firmly, stop using the unit immediately and request repairs.

⚠ WARNING

Be sure to perform the relevant checks before putting the unit into service. Failure to do so may result in failures being overlooked, which may cause a serious accident.

Before using the unit, check it carefully for any faults, contamination, and missing or defective parts to ensure it can be operated safely.

[4] Power requirements

The unit can operate from an AC power source (AC100-240V), built-in batteries or an external DC power source (DC12/24V).

⚠ CAUTION

Whenever the power cord is not connected to a power outlet, or the power supply from an AC power source (AC100-240V) or an external DC power source (DC12/24V) is shut down, the power is automatically supplied from the built-in batteries.

■ Memory function

Preselected settings are retained in memory even if the power supply is interrupted. When the power supply is resumed, the settings that were selected before the power supply interruption will be displayed.

4-1. Power Outlet and Grounding

⚠ WARNING

The following power supply ratings are available. Do not connect the unit to any other power source.

① Voltage - AC100-240V; power consumption - 220VA; frequency - 50/60Hz; operating voltage range - AC100-240V±10%

② Voltage - DC12V; current - 13A; operating voltage range - DC12.4-15.1V

③ Voltage - DC24V; current - 6.5A; operating voltage range - DC24.8-30.3V

The power outlet should be located near the unit in order 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.

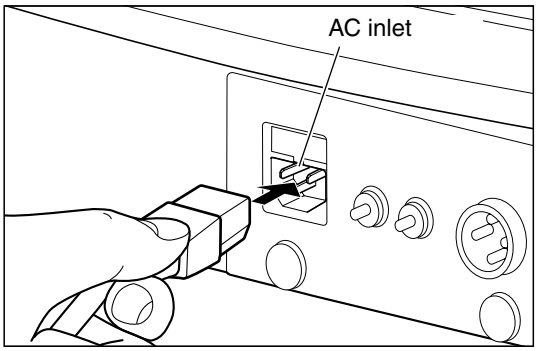
In order to complete the ground connection, only connect the power cord to a correctly grounded 3-prong power outlet.

Do not operate the unit if you have any doubts about its ground connection.

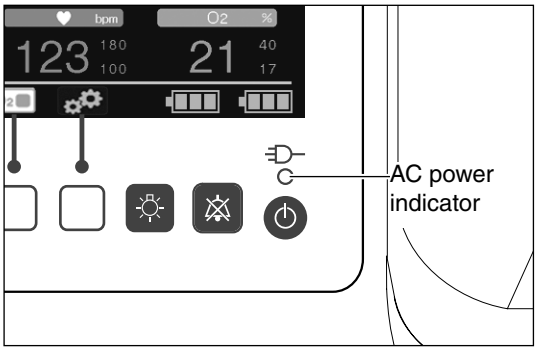
Peripheral electrical equipment must also be grounded securely.

4-2. Using an AC Power Source (AC100-240V)

(1) Connect the power cord to the AC inlet on the right side of the main body. Then connect the power plug on the other end of the power cord to a power outlet.



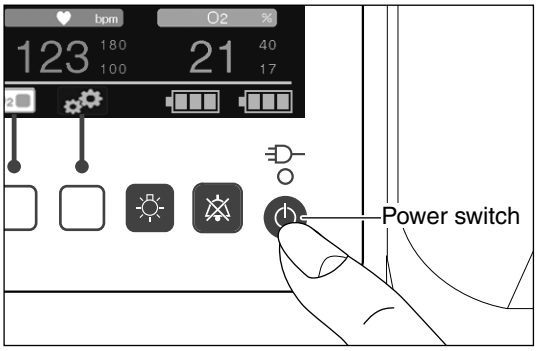
The AC power indicator is lit and the in built batteries will begin to automatically charge. After Battery 1 has been recharged, recharging of Battery 2 (option) starts automatically.



⚠CAUTION

- Recharging of Battery 2 (option) only starts automatically when the power is turned on.

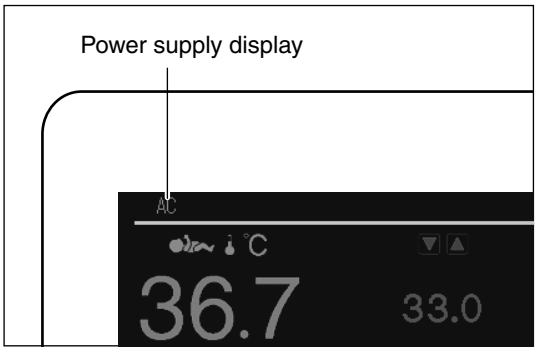
(2) Press the ⏻ switch on the control panel to turn the power on. The unit will begin to operate.



⚠CAUTION

- To turn the power off and then back on again, wait for at least 5 seconds before pressing the ⏻ switch.

(3) "AC" appears in the power supply display area on the display.



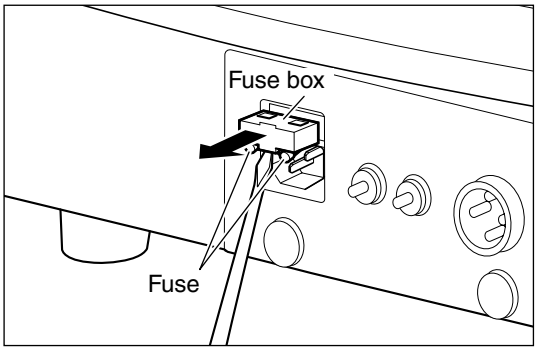
How to Replace the 4A Fuse (for AC Power)

If an overcurrent condition occurs during use, the fuse blows out to interrupt the power supply in order to prevent accidents. Follow the steps below to replace the blown fuse.

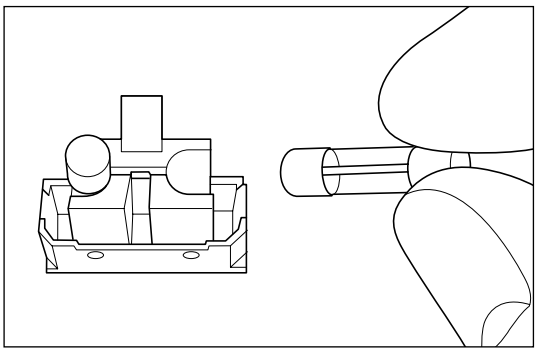
(1) Press the ⏻ switch to turn the power off.

(2) Disconnect the power cord from the AC inlet.

(3) Insert the tip of a flat blade screwdriver into the slot in the top of the fuse box. Push the screwdriver to pull the fuse box out.



(4) Remove the old fuse and replace it with a new one.



(5) Push the fuse box back into place.

(6) Reconnect the power cord to the AC inlet.

⚠CAUTION

- If the replaced fuse blows out again, stop using the incubator and contact your local Atom representative.

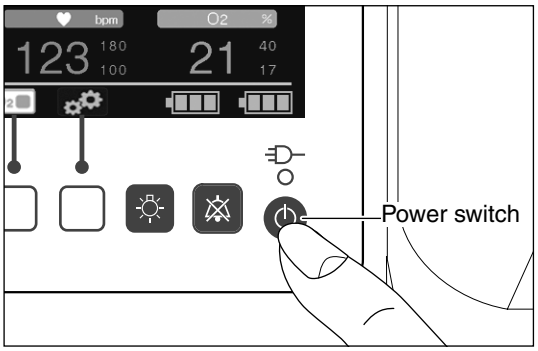
4-3. Using the Built-in Battery Power Supply

⚠ CAUTION

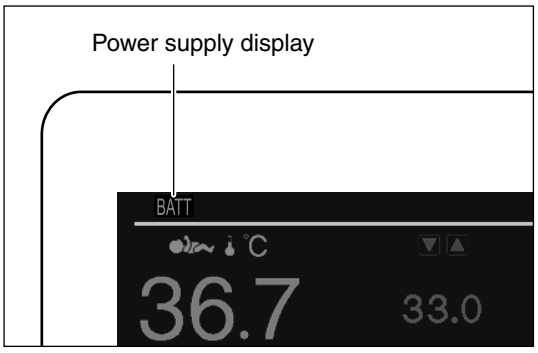
- If the unit is operated from the built-in battery power supply, the built-in batteries will be rapidly degraded. The unit should be operated using the built-in batteries only when an AC source (AC100-240V) or an external DC source (DC12V/24V) is not available. Operate the unit using an AC source whenever possible.
- The IncuArch is a transport infant incubator that can operate on built-in batteries. With fully charged non-degraded batteries, the unit operates for approximately 180 minutes after the incubator temperature has been stabilized under conditions in which the incubator temperature is 36°C and ambient temperature is 15°C.
- Periodically check the built-in batteries for degradation. To check it, fully charge the batteries (for 10 or more hours) and measure the operating hours. If the batteries are not degraded, the unit operates for approximately 180 minutes.
- After the unit has been operating from the built-in batteries,recharge them regardless of the length of time the unit was operated. The built-in batteries do self-discharge when left unused and stored for a long period of time even if they are fully charged. Recharge them on a regular basis (about once every three months).

(1) Make sure that the unit is not connected to either an AC power source or an external DC power source (DC12 or 24V).

(2) Press the ⏻ switch on the control panel to turn the power on. Power is supplied and the unit begins operating.

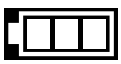


(3) "BATT" appears in the power supply display area on the display.



Checking the Battery Status

The unit has two battery status indicators that show the charging status of batteries 1 and 2. The number of cells decreases with the battery power discharge.

Indicator 1	Indicator 2	Indication	Name	Charging status of battery
 A white frame with 3 lit cells	-	Indicator 1 is lit	Remaining battery level 3 or fully charged	The battery is fully charged. If the unit is connected to an AC power source, the battery is fully charged.
 A white frame with 2 lit cells	-	Indicator 1 is lit	Remaining battery level 2	The battery level is somewhat low.
 A white frame with 1 lit cell	-	Indicator 1 is lit	Remaining battery level 1	The battery level is considerably low.
 A white frame	-	Indicator 1 is lit	Remaining battery level 0	The battery level is very low.
 A red frame with a yellow lit cell	-	Indicator 1 is lit	Low battery	Battery has no remaining charge. A low battery alarm activates. If you keep on using the unit, power is automatically turned off. So, connect it to an AC power source.
 Symbol surrounded by a dotted line	-	Indicator 1 is lit	Battery not connected	Batteries are not loaded. Or battery has no remaining charge.
 A red frame	-	Indicator 1 is lit	Battery failure	Battery has a defect. Turn off the power switch and contact your local Atom representative.
 A white frame with 3 lit cells	 A white frame with a charging symbol	Indicators 1 and 2 illuminate alternately.	Remaining battery level 3 (charging)	The battery is charging. The battery level is somewhat low.
 A white frame with 2 lit cells	 A white frame with a charging symbol	Indicators 1 and 2 illuminate alternately.	Remaining battery level 2 (charging)	The battery is charging. The battery level is considerably low.

Indicator 1	Indicator 2	Indication	Name	Charging status of battery
 A white frame with 1 lit cell	 A white frame with a charging symbol	Indicators 1 and 2 illuminate alternately.	Remaining battery level 1 (charging)	The battery is charging. The battery level is very low.
 A white frame	 A white frame with a charging symbol	Indicators 1 and 2 illuminate alternately.	Remaining battery level 0 (charging)	The battery is charging. Battery has about 25% charge remaining.
 A red frame with a yellow lit cell	 A white frame with a charging symbol	Indicators 1 and 2 illuminate alternately.	Low battery (charging)	The battery is charging. Battery has no remaining charge. A low battery alarm does not occur because the battery is charging.

4-4. Using an External DC Power Source (DC12V/24V)

⚠CAUTION

- Use only an external DC power source which meets the requirements of the international standards IEC60601-1 and IEC60601-1-2 or which is its equivalent in performance and safety.
- Ensure that the DC Power Source to be connected to the unit is capable of supplying a specified voltage and current.
- Be sure to disconnect the power plug from an AC outlet before connecting an external DC power source.

4-4-1. Requirements for External DC Power Source

Only use DC power supplies that satisfy the requirements listed in the table at right. The use of other supplies may disable the unit.
When using a connection cable, verify that it complies with the requirements listed in the table on the right before contacting your local Atom representative.

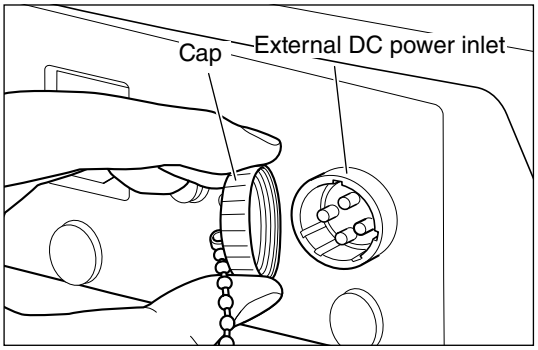
	DC12V	DC24V
DC voltage range	12.4-15.1V	24.8-30.3V
Maximum DC current	13A	6.5A

⚠CAUTION

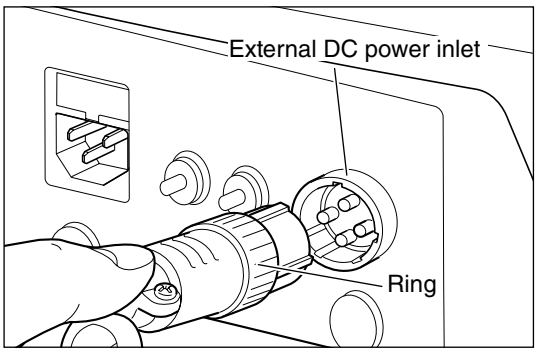
- A cigarette lighter socket in an ambulance does not provide adequate external DC voltage. So, do not use it as a terminal point for connection cable.

4-4-2. Connecting External DC Power Source and Connection Cable

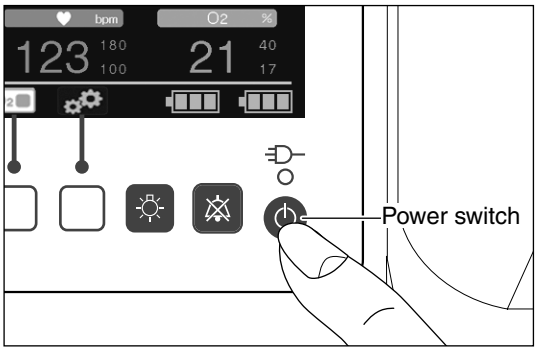
(1) Remove the cap from the external DC power connection port on the right side of the main body.



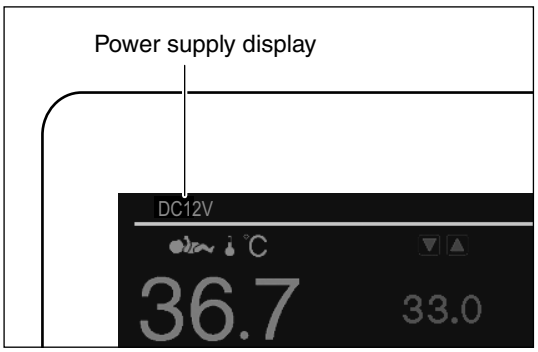
(2) Plug the connection cable into the DC power connection port and turn the ring to firmly secure the cable.



(3) Press the ⏻ switch on the control panel to turn the power on. Power is supplied and the unit begins operating.



(4) "DC12V" or "DC24V" appears in the power supply display area on the display.



(5) To stop operating the unit from an external DC power source, press the ⏻ switch to turn the power off and then remove the cable from the external DC power connection port.

(6) If the external DC power source is not used, put the cap back on the DC power connection port.

⚠CAUTION

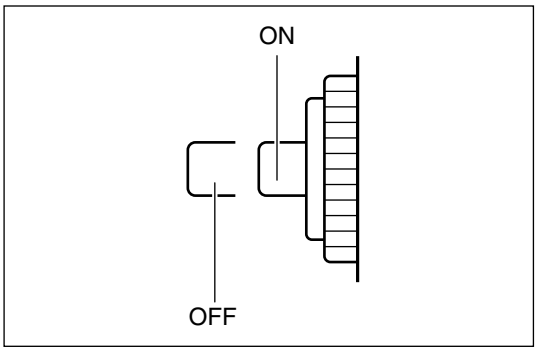
- If an external DC power source is connected, batteries 1 and 2 are not recharged.
- If the unit is connected to both AC and external DC power sources, it operates on AC.

How to Reset a Tripped Breaker (for DC Power)

If an overcurrent condition occurs during use, the breaker is activated (tripped) to interrupt the power supply in order to prevent accidents. Follow the steps below to reset the tripped breaker.

(1) Press the ⏻ switch to turn the power off.

(2) Wait for at least one minute after the breaker has been tripped before pushing the breaker switch to the “ON” position.



(3) Press the ⏻ switch to turn the power on.

⚠CAUTION

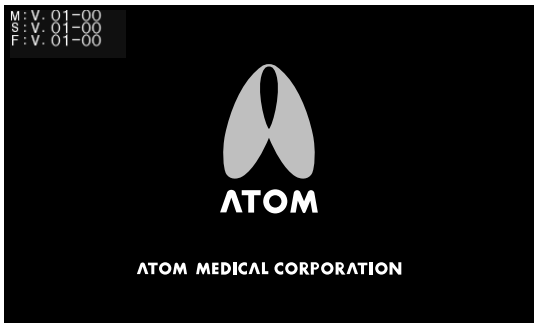
- To avoid failures, wait for at least one minute or so after the breaker has been tripped, and then push the bottom.
- If the reset breaker is tripped again, stop using it and contact your local Atom representative.

[5] Display Screens

5-1. Overview of Display Screens

■ Start screen

The start screen appears when the power switch ⏻ is turned on.
The version number of the IncuArch program appears in the upper left of the screen.



■ Main screen

The view can be changed between the “Enlarged Temperature Display (Standard Display)” that enlarges the display of a temperature reading, and the “Enlarged SpO_2 Display” that enlarges the display of measurements taken by the pulse oximeter. For details on how to change these views, see “9-1-3. Setting the Display Size”.

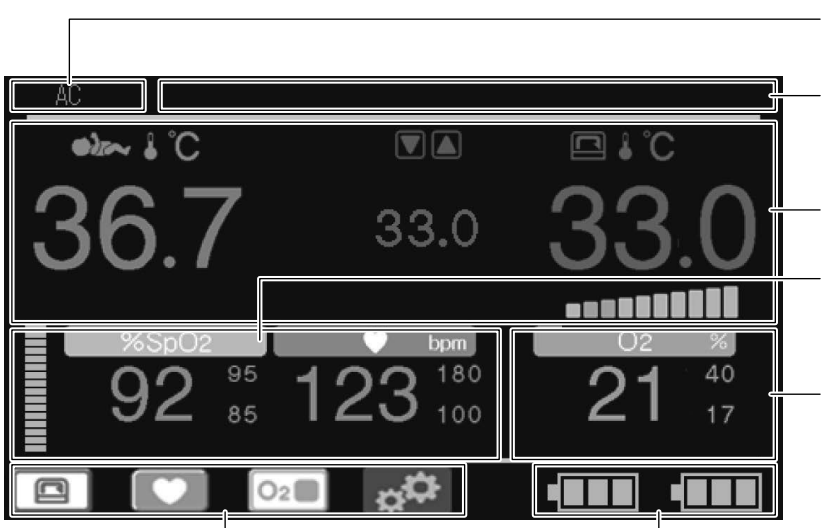
Enlarged Temperature Display (Standard Display)

Enlarged SpO_2 Display

■ Menu screen

When you press the ⚙ control switch on the main screen, the screen switches to the menu screen.
Use this screen to select advanced settings.

5-2. Main screen



Power supply display area (see p.33)

Alarm display area (see p.33)

Temperature area (see p.34)

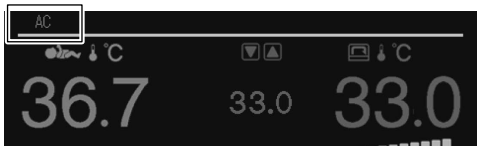
Pulse area (see p.34)

Oxygen area (see p.35)

Battery status display area (see p.36)

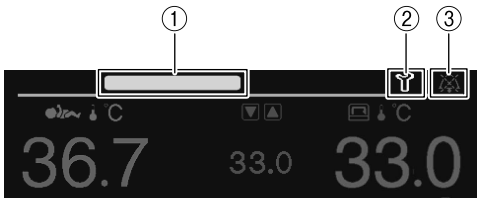
Control switch display area (see p.35)

■ Power supply display area



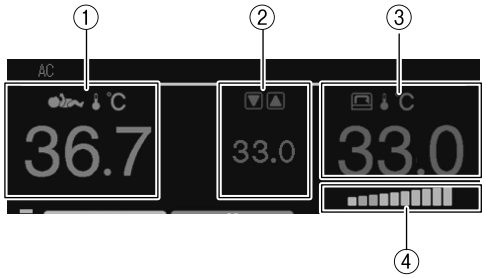
Display	Description
AC	It displays when the unit is connected to an AC power source.
BATT	It displays when the unit operates using power from the built-in batteries.
DC12V	It displays when the unit operates using power from an external DC power source (DC12V).
DC24V	It displays when the unit operates using power from an external DC power source (DC24V).

■ Alarm display area



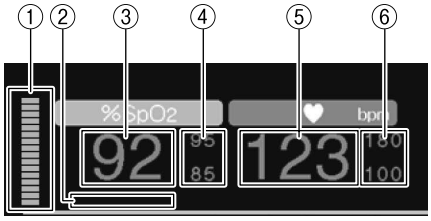
No.	Name	Description
①	Alarm priority indicator	Depending on the alarm priority level, the alarm priority indicator is activated as shown below. High - Flashes red Middle - Flashes yellow Low - Lights up yellow
②	Alarm icon	Appears when an alarm is activated. (For details, see “[12] Alarms”.)
③	Silence icon	Appears when the audible alarm is silenced.

Temperature area



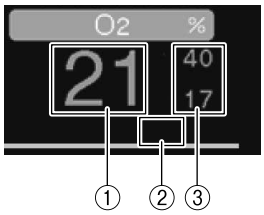
No.	Name	Description
①	Skin temperature display	Displays the skin temperature digitally.
②	Set temperature display	Displays the set temperature in the incubator digitally.
③	Incubator air temperature display	Displays the incubator air temperature digitally.
④	Heater output display	Displays the heat supply in ten levels.

Pulse area



No.	Name	Description
①	Plethysmograph bar	Indicates changes in the arterial blood.
②	Status indicator	Displays the status of pulse oximeter.
③	%SpO_2 display	Displays the hemoglobin oxygen saturation value digitally.
④	SpO_2 alarm limits display	Displays the SpO_2 upper alarm limit setting in the upper row and the SpO_2 lower alarm limit setting in the lower row digitally.
⑤	Pulse rate display	Displays a detected pulse rate digitally.
⑥	Pulse rate alarm limits display	Displays the pulse rate upper alarm limit setting in the upper row and the pulse rate lower alarm limit setting in the lower row digitally.

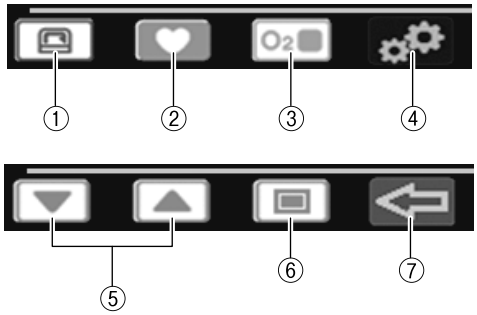
Oxygen area



No.	Name	Description
①	Oxygen concentration display	Displays oxygen concentration in the incubator digitally.
②	Status indicator	Displays the status of oxygen sensor.
③	Oxygen level alarm limits display	Displays the oxygen level upper alarm limit setting in the upper row and the oxygen level lower alarm limit in the lower row digitally.

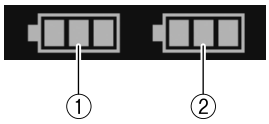
Control switch display area

These indicators identify the functions of control switches. The control switch indicator switches to set the settings.



No.	Name	Description
①	Change set temperature switch indicator	This indicator identifies the switch used to set the incubator air temperature.
②	SpO_2 alarm setting switch indicator	This indicator identifies the switch used to set the SpO_2 upper and lower limits and pulse rate upper and lower limits.
③	Oxygen level alarm setting switch indicator	This indicator identifies the switch used to set the oxygen level upper and lower limits.
④	Menu screen display switch indicator	This indicator identifies the switch used to display the menu screen.
⑤	Up/Down Arrow switch indicators	These switches are used to switch various parameters or to change settings.
⑥	Select Switch indicator	This switch is used to select various parameters or settings.
⑦	Return Switch indicator	This switch is used to return to the previous screen.

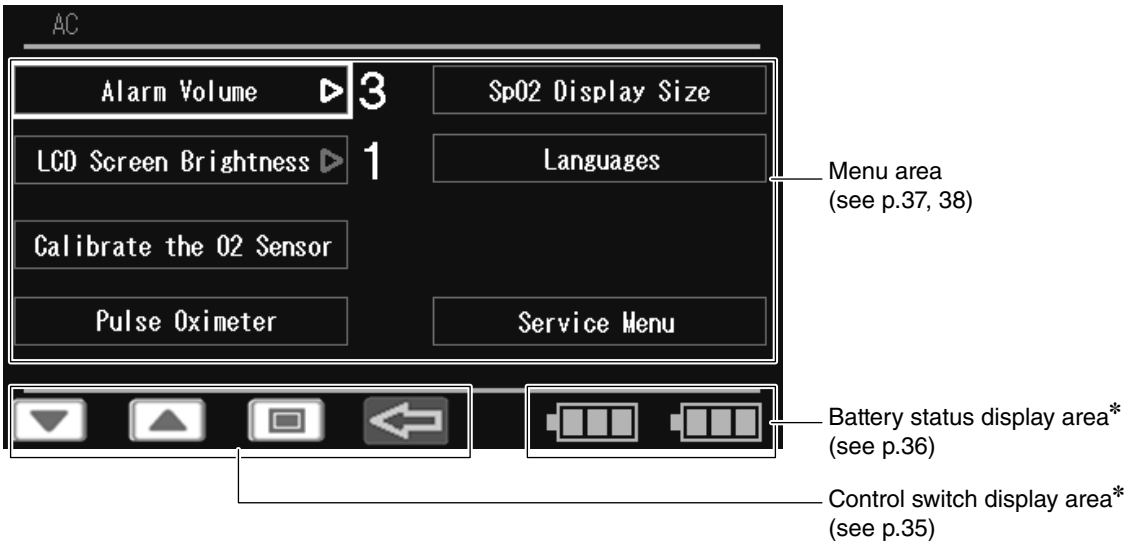
■ Battery status display area



No.	Name	Description
①	Battery status indicator 1	Shows the power level of battery 1.
②	Battery status indicator 2	Shows the power level of battery 2.

✻ For details on the battery status indicators, see “4-3. Using the Built-in Battery Power Supply”.

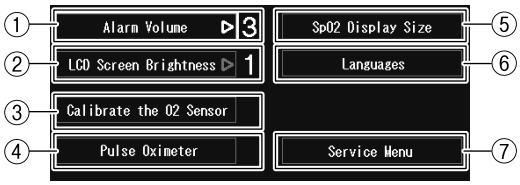
5-3. Menu Screen



* The battery status and control switch display areas are the same as those described in "5-2. Main screen". (Therefore the explanation is omitted.)

■ Menu area 1

This screen appears first when the menu screen is selected.

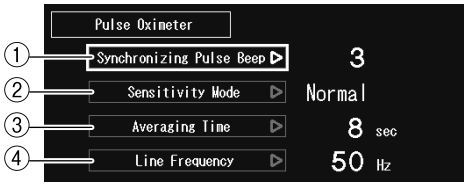


No.	Menu	Description
①	Alarm Volume	Select this to set the alarm volume.
②	LCD Screen Brightness	Select this to adjust the brightness of the display.
③	Calibrate the O_2 Sensor	Select this to proceed to the oxygen sensor calibration procedure.
④	Pulse Oximeter	Select this to change the view to menu area 2 for advanced settings for the pulse oximeter.
⑤	SpO_2 Display Size	Select this to change the screen layout.
⑥	Languages	Select this to change the language.
⑦	Service Menu	Select this to make further detailed settings for the unit. For details of the operation of this menu option, see the Service Manual.

Menu area 2

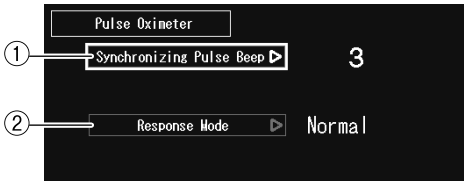
This screen appears when [Pulse Oximeter] is selected in the menu area 1.

● For the unit equipped with the Masimo pulse oximeter



No.	Menu	Description
①	Synchronizing Pulse Beep	Select this to set the synchronizing pulse beep volume.
②	Sensitivity Mode	Select this to set the pulse oximeter sensitivity.
③	Averaging Time	Select this to set the pulse oximeter averaging time.
④	Line Frequency	Select this to change the line frequency of the pulse oximeter.

● For the unit equipped with the Nellcor pulse oximeter



No.	Menu	Description
①	Synchronizing Pulse Beep	Select this to set the synchronizing pulse beep volume.
②	Response Mode	Select this to set the pulse oximeter response time.

[6] Setting the Incubator Temperature and Placing the Infant in the Incubator

6-1. Setting the Incubator Temperature

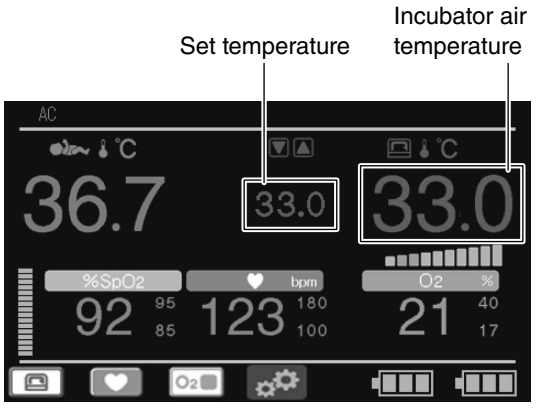
⚠ WARNING

- Be sure to set the incubator temperature according to orders from a doctor.

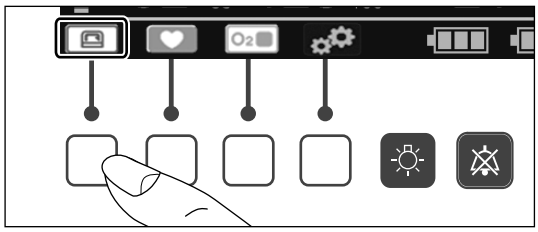
⚠ CAUTION

- Practice and master the operation procedure before placing the infant in the incubator, and conduct temperature tests while the unit is empty to check that it operates normally.
- While the infant is in the incubator, check the heater output, incubator temperature, oxygen concentration, and the like, and constantly monitor the infant for abnormalities.
- Check that the air inlets and outlets are not blocked with obstacles such as a diaper, gauze, etc. If they are blocked, the temperature in the incubator cannot be controlled correctly.

(1) Press the ⏻ switch to turn the power on and check that the incubator temperature and set temperature are displayed.
The incubator temperature is displayed in the range of 20.0-42.0°C in 0.1°C increments. "LOW" is displayed if it is below 20.0°C; "HIGH" is displayed if it is above 42.0°C.
The temperature can be set in the range of 23.0-38.0°C in 0.1°C increments.



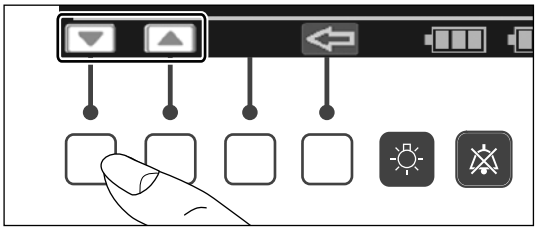
(2) To change the incubator temperature, press the [🛏] switch.
The control switch indication switches and the set temperature is highlighted.



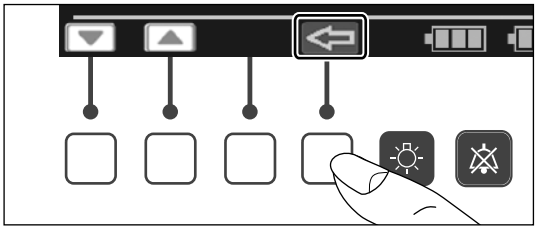
(3) While the set temperature is highlighted, press the ▼ or ▲ switch to set the incubator temperature to the desired level.

⚠WARNING

- Be sure to set the incubator temperature according to orders from a doctor.



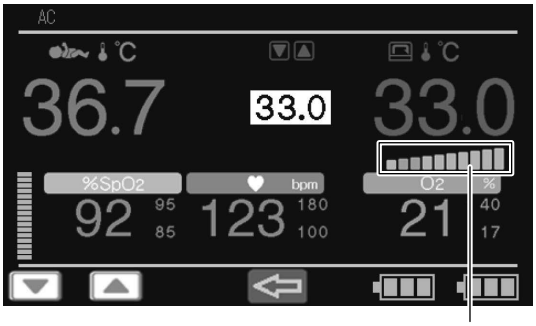
(4) The setup is finished when the ⇦ switch is pressed or a given period of time has elapsed.



(5) Allow about 30-40 minutes for the incubator temperature to stabilize (depending on the ambient temperature).
The incubator temperature is regarded as having stabilized when the incubator temperature reading is identical or close to the set temperature.

■ Heater output indicator

The heater output indicator shows the amount of heat required to maintain the set incubator temperature using the number of lit bars. As the incubator temperature rises close to the set temperature, the amount of heat supplied decreases; and the number of lit bars in the heater output indicator decreases gradually.



6-2. Placing the Infant in the Incubator

⚠ DANGER

- NEVER open an admittance panel or an access port in order to lower the incubator temperature. This can be dangerous because the heater output will increase automatically to maintain the incubator temperature.
- To help ensure infant safety, never leave the incubator unattended when an admittance panel or an access port is open.

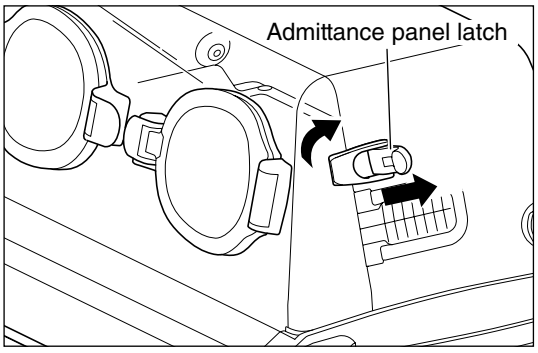
⚠ WARNING

- Place the infant in the incubator only after the incubator temperature has stabilized.

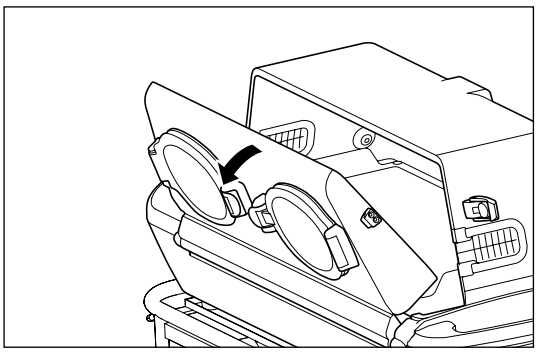
⚠ CAUTION

- Opening an admittance panel or an access port, using an infant sheet or using an oxygen head box in the incubator will alter the air circulation pattern inside the incubator. This may affect temperature uniformity, temperature variability, detection and control of the incubator temperature, as well as the infant's skin temperature.
- Avoid opening the entire hood to place the infant inside the incubator. This may cause the incubator temperature to fluctuate significantly.
- Never open the entire hood when the infant is inside the incubator. Cords and tubes may disable the infant. All procedures must be performed through the front admittance panel or access ports.

(1) Flip up the latch lever on both sides of the admittance panel and remove the hook securing the panel.



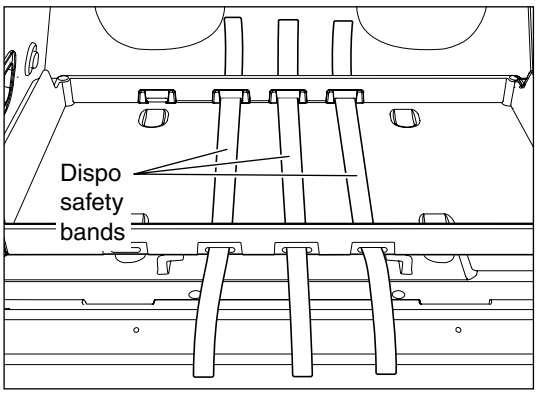
(2) Slowly tilt the admittance panel toward you to open it.



⚠DANGER

- The pivot shaft between the admittance panel and the hood has a shock absorber to absorb impact when the panel is opened. Note that if you remove your hand from the panel before the panel is closed, the shock absorber may not work.

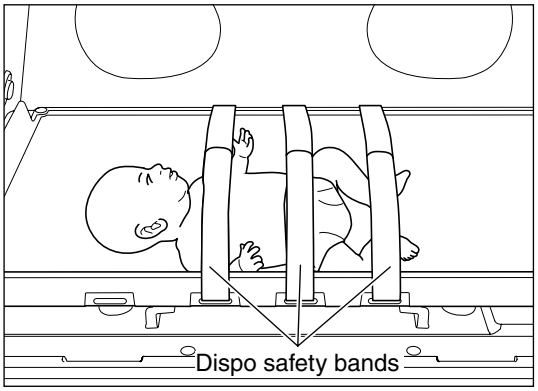
(3) Attach the dispo safety bands to the mattress platform.
Remove the mattress from the mattress platform. Attach three dispo safety bands by inserting them through the slits in the sides of the mattress platform with the hook and loop fastener side facing down.
After attaching the thee dispo safety bands, put the mattress back onto the mattress platform.



⚠WARNING

- To prevent cross infection, replace the dispo safety bands with new ones for every infant.

(4) Place the infant at the center of the mattress with his or her head to the left and legs to the right. Secure the infant using the dispo safety bands attached to the mattress platform.

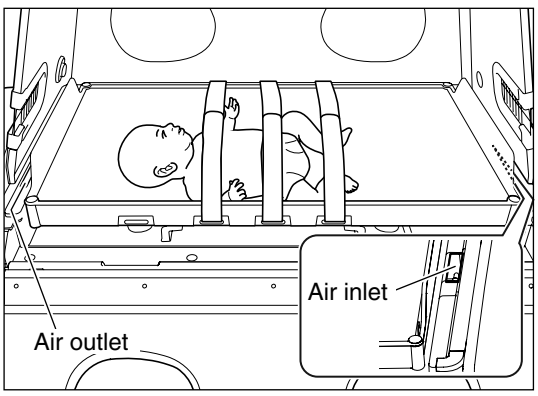


⚠DANGER

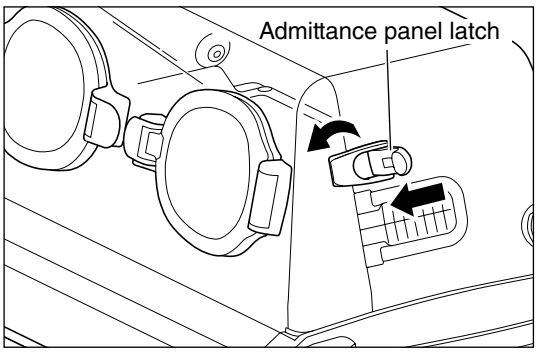
- Do not overtighten the dispo safety bands. Doing so may harm the infant.

⚠CAUTION

- Check that the air inlets and outlets are not blocked with obstacles such as a diaper, gauze, etc. If they are blocked, temperature in the incubator cannot be controlled correctly, which may affect the infant's skin temperature or damage the main body.



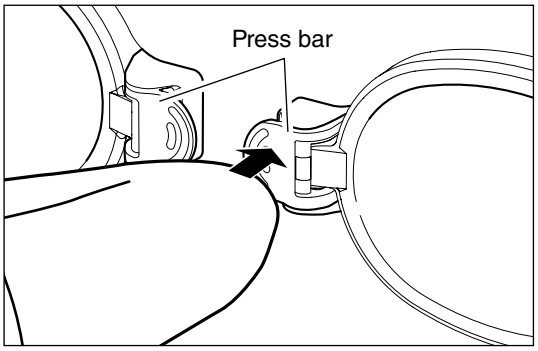
(5) After placing the infant into the incubator, close the admittance panel. Put the latch hooks on both sides of the admittance panel and flip down the lever to lock.



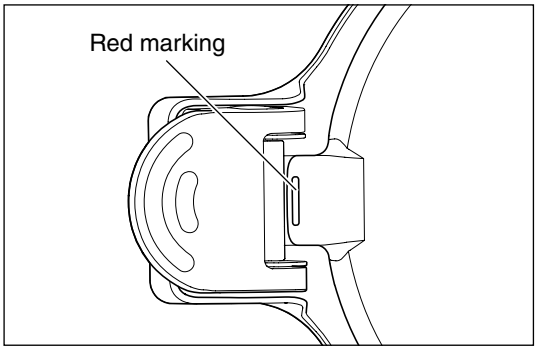
⚠DANGER

- After the infant is placed in the incubator, check again that the admittance panels are closed securely.

(6) A gentle touch of the elbow on the press bar will open a snap-open access port door via a spring action. To close the doors, push them until they latch.



(7) Make sure that the red marking on the snap-open access port is not visible after it is closed. If the red marking is visible, close the access port completely again.



⚠DANGER

- Always check that the admittance panel retainers and the press bars of the snap-open access ports function correctly. If an admittance panel or a snap-open access port fails to close firmly, stop using the unit immediately and request repairs.
- Be sure to slowly open and close the access ports. Avoid opening and closing them forcefully.

■ Dispo safety bands

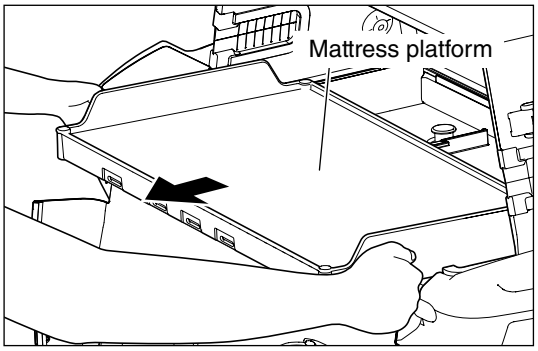
An dispo safety band can be used to secure an infant's head.
Four optional dispo safety bands can be attached to the mattress platform.

6-3. Drawing out the Mattress Platform

⚠ WARNING

- Before drawing out the mattress platform, check that the mattress platform stopper has engaged the rail. If it has not engaged, the mattress platform will come off, posing a risk of injury.
- When drawing out the mattress platform with the infant on it, be careful not to get the patient circuit pulled out or pulled by force.

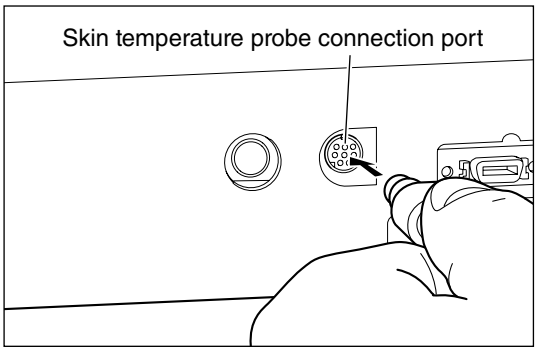
Open the admittance panel and draw out the mattress platform toward you. When the mattress platform is drawn out to a certain point, the stopper will function.



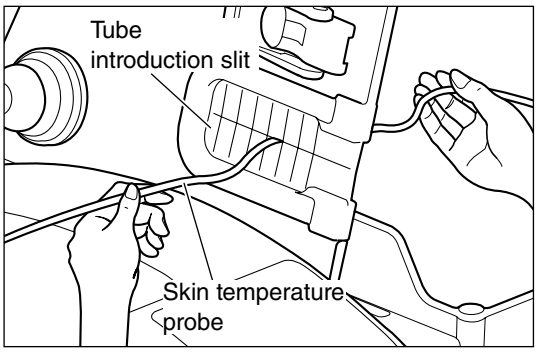
6-4. Skin Temperature Monitoring

To monitor the skin temperature of the infant placed in the incubator, attach a skin temperature probe to the infant.

(1) Insert the cable plug of the skin temperature probe firmly into the skin temperature probe connection port on the left side of the main body.

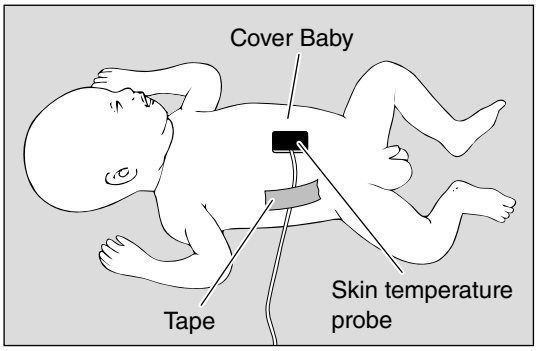


(2) Run the skin temperature probe cable into the incubator through the tube introduction slit in the side of the hood.



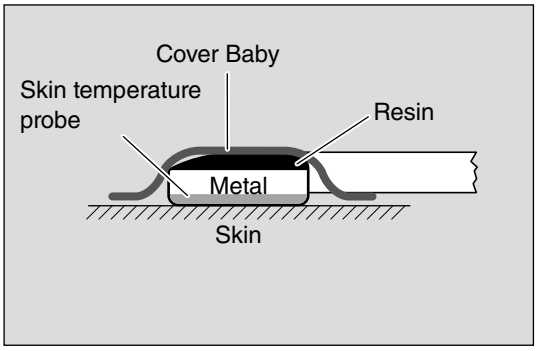
(3) Before attaching the skin temperature probe to the infant, clean the site of attachment using alcohol or lukewarm water to get rid of any fetal fat or dirt.

(4) Attach the heat-sensing portion of the temperature probe to a site between the navel and the xiphoid process on the infant's abdominal median line using the "Cover Baby". The heat-sensing surface should touch the skin. Affix a piece of tape a slight distance from the tip of the probe and fix the probe securely to the skin.



⚠WARNING

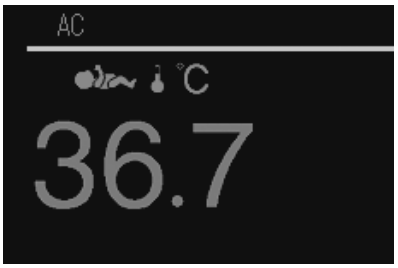
- Do not place the skin temperature probe under the infant. Do not use it as a rectal probe.



⚠CAUTION

- If the heat-sensing portion of the skin temperature probe is not correctly attached to the infant, or if it accidentally comes off the infant, the skin temperature will not be able to be detected accurately.
- Follow the doctor's instructions as to the site of attachment of the skin temperature probe when the infant is in a prone position.

(5) The temperature detected by the skin temperature probe will be displayed on the skin temperature display.



(6) Allow 4-5 minutes after attaching the skin temperature probe to the infant for the skin temperature reading to stabilize before starting skin temperature monitoring.
The skin temperature is displayed in the range of 30.0-42.0°C in 0.1°C increments. "LOW" will be displayed if it is below 30.0°C; "HIGH" will be displayed if it is above 42.0°C.

⚠CAUTION

- During skin temperature monitoring, make sure that the infant does not become tangled in the probe cable.

[7] Oxygen Supply

⚠ DANGER

The risk of fire hazards increases while oxygen is being supplied. Do not use body warmers or other devices that may produce sparks around the unit.

It has been reported that when setting the concentration of oxygen in the incubator to a high level, it is extremely important and essential to repeatedly measure the oxygen concentrations inside the incubator and analyze arterial blood gas in order to correctly maintain oxygen concentrations. Follow the doctor's instructions for measuring the oxygen concentration because ignoring essential requirements may increase the risk of retinopathy of prematurity and other adverse effects.

⚠ WARNING

Incorrect use of supplementary oxygen may cause serious side effects including loss of sight, damage to the brain, and death. The risks of side effects vary with infants. The concentration of oxygen delivered to an incubator must be in accordance with the doctor's instructions.

While oxygen is being supplied, continuously measure the oxygen concentrations inside the incubator using an oxygen monitor. Pay particular attention to changes in oxygen concentration. If the oxygen concentration in the incubator deviates from a desired level, make necessary adjustments by increasing or reducing the oxygen flow rate.

Be sure to use oxygen for medical use.

A spontaneous and violent ignition may occur if oil, grease, or greasy substances come in contact with pressurized oxygen. These substances must be kept away from oxygen regulators, cylinder valves, tubing and connections, and all other oxygen supply equipment.

On a high-pressure oxygen cylinder, only use tested pressure reducing or regulating valves marked for oxygen service.

The oxygen flowmeter cannot be expected to provide an accurate indication of the oxygen concentrations inside the incubator. Check the oxygen concentration using a calibrated oxygen monitor by following the doctor's instructions.

The oxygen concentration in the incubator varies with the operating conditions of the incubator, the accuracy of the oxygen flowmeter, etc. To accurately maintain the oxygen concentration inside the incubator at a desired level, measure it repeatedly using an accurate oxygen monitor.

If performing the cleaning and maintenance procedures in an oxygen-enriched environment, there is a risk that a fire or explosion may occur. Turn off the oxygen supply and disconnect the oxygen supply hose from the incubator before cleaning the incubator. When the incubator is not in use, turn off the oxygen supply and remove the oxygen supply hose from the incubator.

⚠CAUTION

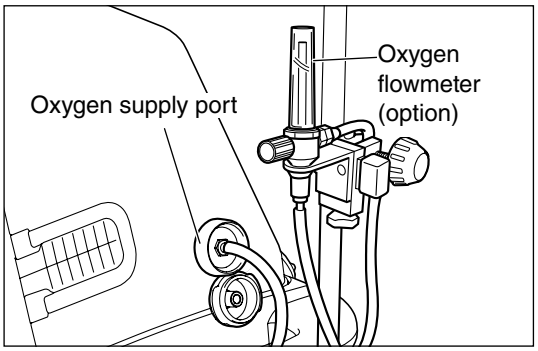
- The oxygen concentration in the incubator may be affected when the snap-open access ports or admittance panels are opened. Any open gaps in the incubator hood may reduce the incubator's internal oxygen level. Make sure that all access port packing and tube introduction slit packing is correctly installed.
- A contaminated filter will affect the oxygen concentration. Check the filter. If it is contaminated, replace it.
- When you use the oxygen flowmeter to supply oxygen, the supply flow rate must not exceed 10L/min.
  If it exceeds 10L/min, the oxygen supply hose may come off.
- Supplementing oxygen may increase the noise level for the infant in the incubator.

7-1. Supplying Oxygen

(1) Connect an oxygen supply source and the oxygen flowmeter (option) and fit the oxygen supply hose into the oxygen flowmeter hose fitting.

(2) Remove the cap from the oxygen supply port and connect the oxygen tubing to the oxygen supply port.

(3) Turn the knob on the oxygen flowmeter and adjust the flow rate to a desired level.
The oxygen concentration in the incubator will stabilize in approximately 30 minutes (at a flow rate of 10L/min). Increase the supply flow rate if the detected oxygen concentration in the incubator is lower than the desired level; reduce the supply flow rate if the detected oxygen concentration in the incubator is higher than the desired level.



⚠CAUTION

- Continuously measure the oxygen concentrations in the incubator using an oxygen monitor until the oxygen concentration inside the incubator has stabilized. Pay particular attention to changes in oxygen concentration.
- Be sure to use the oxygen flowmeter (option) to supply oxygen.

■ Connecting an Oxygen Cylinder

To connect an oxygen cylinder to the unit, use the optional pressure reducing regulator.

7-2. Using the Oxygen Monitor

⚠ WARNING

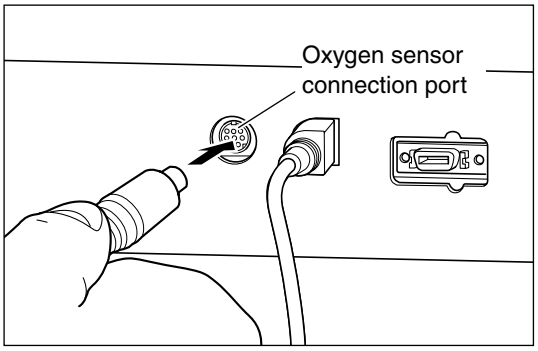
- Before using the incubator, check the oxygen sensor for any sign of degradation or leakage, and replace it immediately if any cracks are found on the surfaces.
- The oxygen sensor is a sealed unit that contains potassium hydroxide electrolyte. The electrolyte may leak out if the sensor is damaged when dropped, etc. If contact with the skin or clothing occurs, wash the area using large amounts of water. In case of eye contact, flush eyes immediately using large amounts of water and consult a doctor.
- Calibrate the oxygen monitor before each use.

⚠ CAUTION

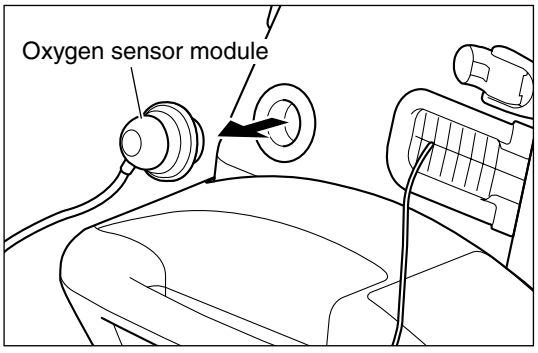
- Be sure to perform the 21% calibration (calibration of the oxygen sensor to room air) when oxygen is not in use before using the unit for a new patient (before disinfection). If the 21% calibration is performed while oxygen is being supplied to the incubator or after it is supplied to it, oxygen inside the hood will leak and may affect the calibration.

7-2-1. Calibrating the Oxygen Monitor

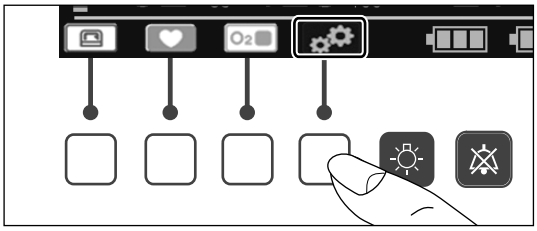
(1) Insert the oxygen sensor module plug into the oxygen sensor connection port on the left side of the main body.



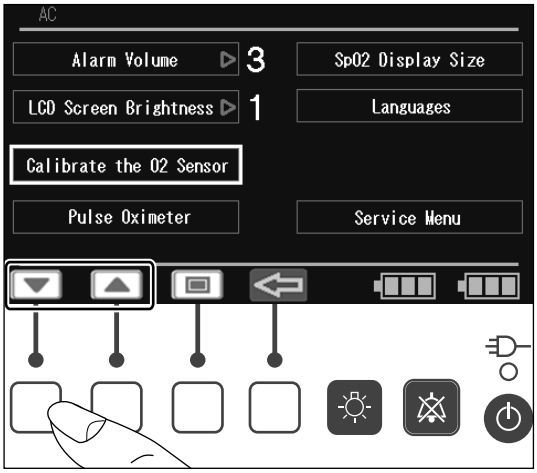
(2) Remove the oxygen sensor module from the oxygen sensor inlet.

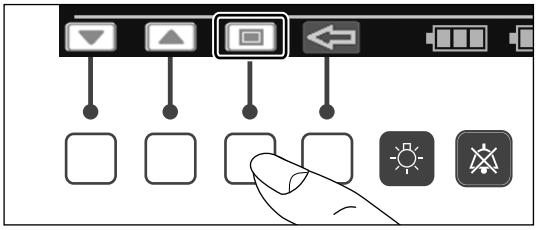


(3) Press the switch to display the menu screen.

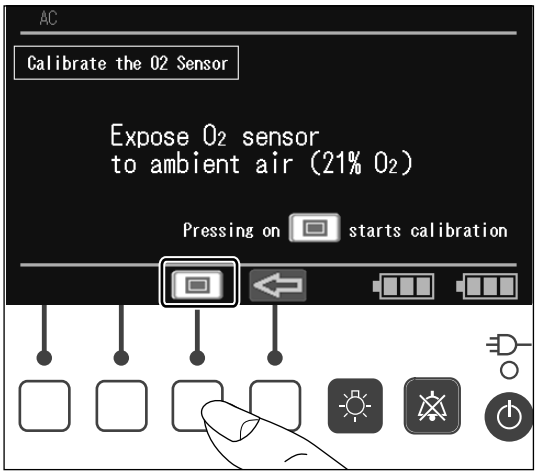


(4) Press the ▼ or ▲ switch, place the cursor on the [Calibrate the O_2 Sensor] menu, and then press the ▣ switch.

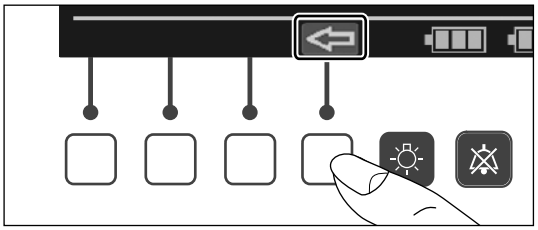




(5) The “Calibrate the O_2 sensor” message appears. To start the calibration, press the ▣ switch.



(6) When the calibration is successfully completed, “Calibration Completed” will be displayed.
To return to the menu screen, press the ⇦ switch once. To return to the main screen, press the switch again.



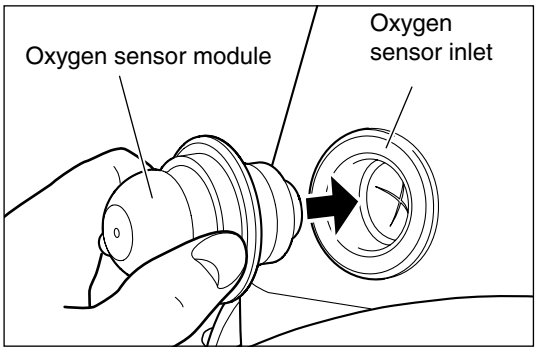
⚠CAUTION

- If the display shows “Calibration Error”, the oxygen sensor may be faulty. Replace it with a new one.

(7) Insert the oxygen sensor module into the oxygen sensor inlet.

⚠CAUTION

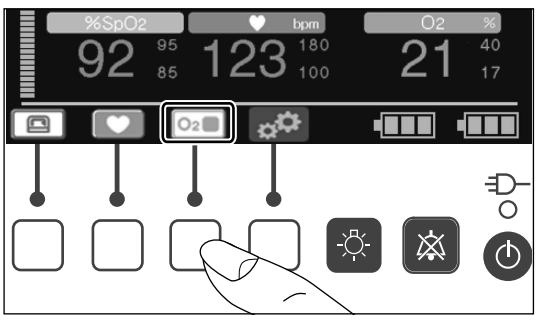
- Be sure to calibrate the oxygen sensor before use.
- To calibrate the oxygen sensor, it must be placed in ambient air (21% oxygen).
- Be sure to calibrate the oxygen sensor with the sensor in the oxygen sensor module facing downward.



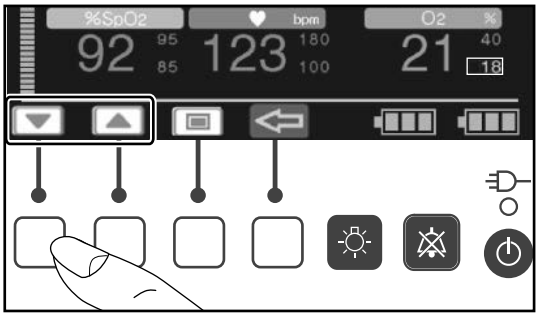
7-2-2. Setting the Upper and Lower Alarm Limits for Oxygen Level

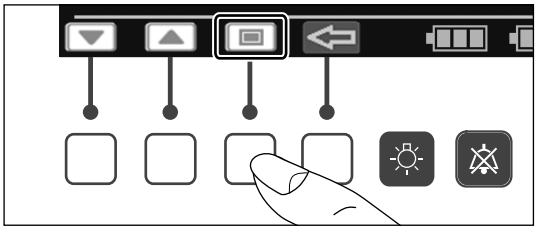
The unit allows you to set the upper and lower alarm limits for oxygen level. Audible and visual alarms will be activated if any of the alarm limits are violated (see “[12] Alarms”).

(1) When you press the O2 switch, the cursor control screen appears.

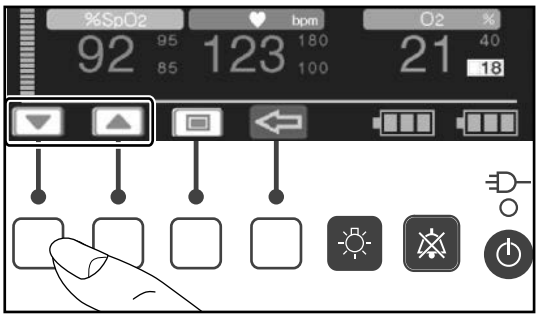


(2) Press the ▼ or ▲ switch to place the cursor on the alarm limit you want to change. Press the ▣ switch to highlight the selected alarm limit.

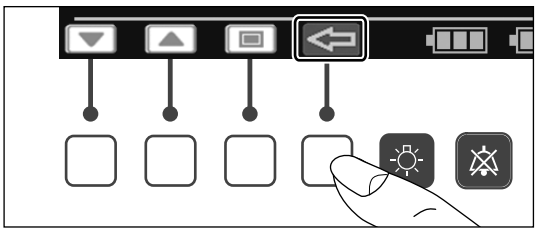




(3) While the alarm limit is highlighted, press the ▼ or ▲ switch to change it to your desired value. The upper alarm limit can be set in the range of 22-99% in 1% increments. The lower alarm limit can be set in the range of 19-96% in 1% increments.



(4) The setup is finished when the ⇦ switch is pressed or a given period of time has elapsed.



[8] Pulse Oximeter

8-1. Attaching the SpO_2 Sensor

The procedure for attaching the sensor to the infant varies with the SpO_2 sensor to be used. For information on how to attach sensors to the infant, follow the instructions in the Operation Manual provided with the respective sensor.

⚠ WARNING

- Wrap the adhesive tape for securing the sensor, but not too tightly. Wrapping it too tightly will hinder the circulation of the blood and may result in no measurements.
- The sensor is for single patient use only.
- The sensors are shipped without being disinfected. (For Masimo pulse oximeter)
- Failure to correctly attach the sensor to the infant may result in inaccurate measurements.
- Leaving the sensor attached to the infant for a long time may result in inaccurate measurements. Moreover, it may cause necrosis due to compression, and skin irritation due to application of adhesive tape. Change the sensor site at least every eight hours.
- Constantly check the circulation distal to the sensor site.
- Make sure that the emitter and the detector face each other across the tissue.
- Do not use a damaged sensor.
- Do not immerse the sensor in any liquid.
- Elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) or the presence of intravascular dyes may result in inaccurate measurements.
- Do not use the sensor during MRI scanning.
- Do not attach the sensor to the hand or foot to which a blood pressure cuff or an arterial catheter is attached.
- Premature infants tend to develop retinopathy of prematurity in a high oxygen environment. Therefore, be especially cautious in setting the SpO_2 upper alarm limit.
- Do not expose the sensor to xenon light, phototherapy light, fluorescent light, infrared light or direct sunlight. Otherwise, the performance of the sensor may be affected.
- The plethysmograph bar on the display is not proportional to the size of the detected pulse. (For Masimo pulse oximeter)

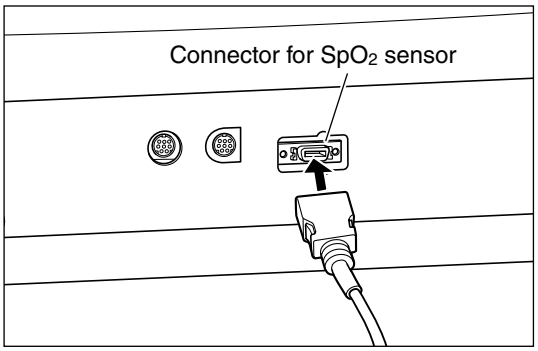
⚠ CAUTION

- Only use sensors and patient cables specified by Atom to connect to the pulse oximeter in this unit. Do not use any other sensors or patient cables.
- The above sensors and patient cables are not waterproof.

8-2. Connecting the Patient Cable

(1) Connect the patient cable to the SpO_2 sensor.

(2) Guide the patient cable out of the incubator through the tube introduction slit and plug the cable into the connector for SpO_2 on the left side of the main body.
After a short time, a detected SpO_2 value and pulse rate appear in the pulse area.

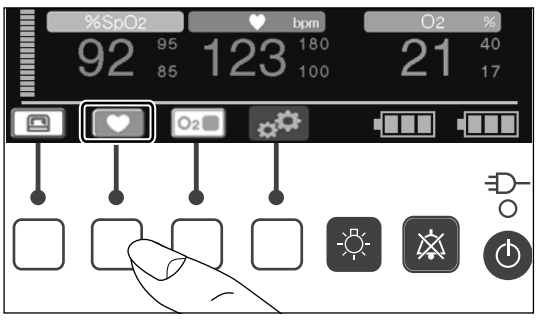


8-3. Setting Alarm Limits

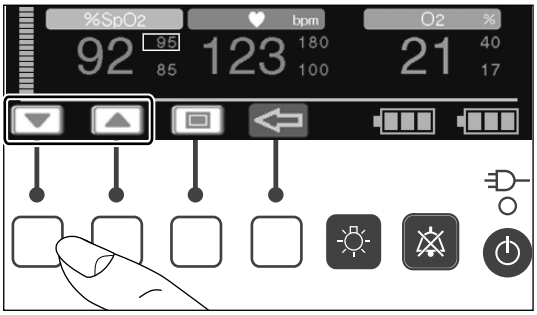
You can set upper/lower alarm limits respectively for the SpO_2 value and the pulse rate monitored with the pulse oximeter. Audible and visual alarms will be activated if any of the alarm limits are violated (see "[12] Alarms").

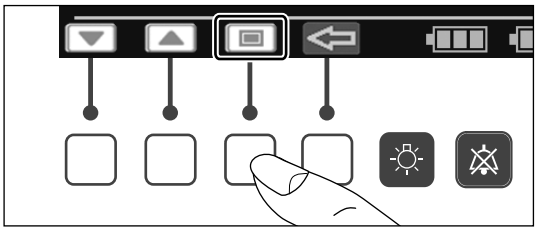
8-3-1. Setting SpO_2 Upper/Lower Alarm Limits

(1) When you press the ♥ switch, the cursor control screen appears.

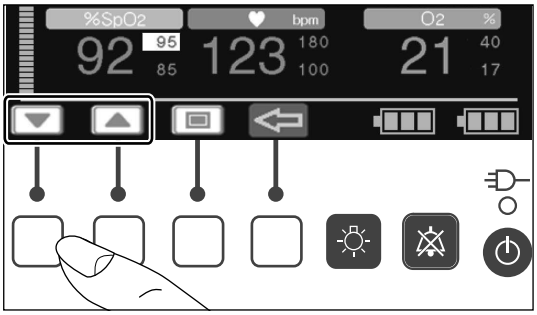


(2) Press the [▼] or [▲] switch to place the cursor on the alarm limit you want to change. Press the [▣] switch to highlight the selected alarm limit.





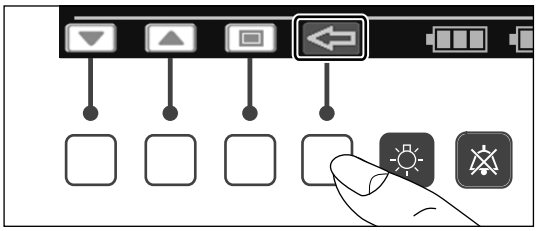
(3) While the alarm limit is highlighted, press the [▼] or [▲] switch to change it to your desired value.
The upper alarm limit can be set in the range of 50-99% in 1% increments. The lower alarm limit can be set in the range of 45-95% in 1% increments.
To set the upper alarm to OFF, press the [▲] switch when 99% is displayed. To set the lower alarm to OFF, press the [▼] switch when 45% is displayed. The setting will be displayed as "— — —".



⚠WARNING

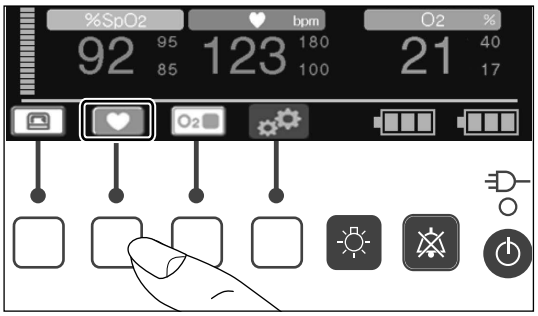
- High oxygen concentrations may predispose a premature infant to retinopathy. Therefore, the upper alarm limit for SpO_2 must be carefully selected.

(4) The setup is finished when the [⇦] switch is pressed or a given period of time has elapsed.

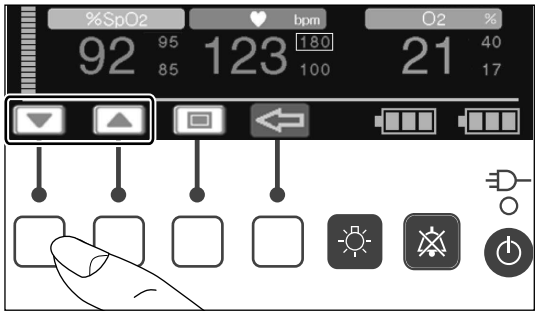


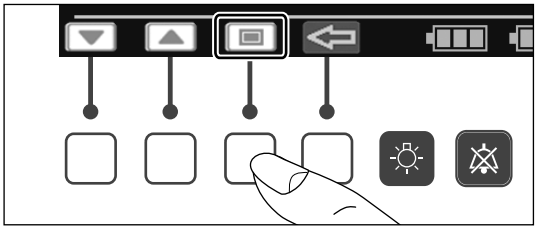
8-3-2. Setting Pulse Rate Upper/Lower Alarm Limits

(1) When you press the ♥ switch, the cursor control screen appears.

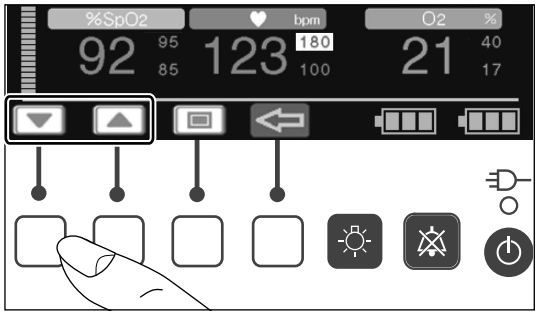


(2) Press the ▼ or ▲ switch to place the cursor on the alarm limit you want to change. Press the ▣ switch to highlight the selected alarm limit.

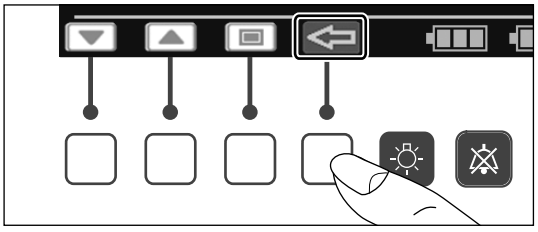




(3) While the alarm limit is highlighted, press the ▼ or ▲ switch to change it to your desired value.
The upper alarm limit can be set in the range of 80-235bpm in 5bpm increments. The lower alarm limit can be set in the range of 35-180bpm in 5bpm increments.
To set the upper alarm to OFF, press the ▲ switch when 235bpm is displayed. To set the lower alarm to OFF, press the ▼ switch when 35bpm is displayed. The setting will be displayed as "— — —".



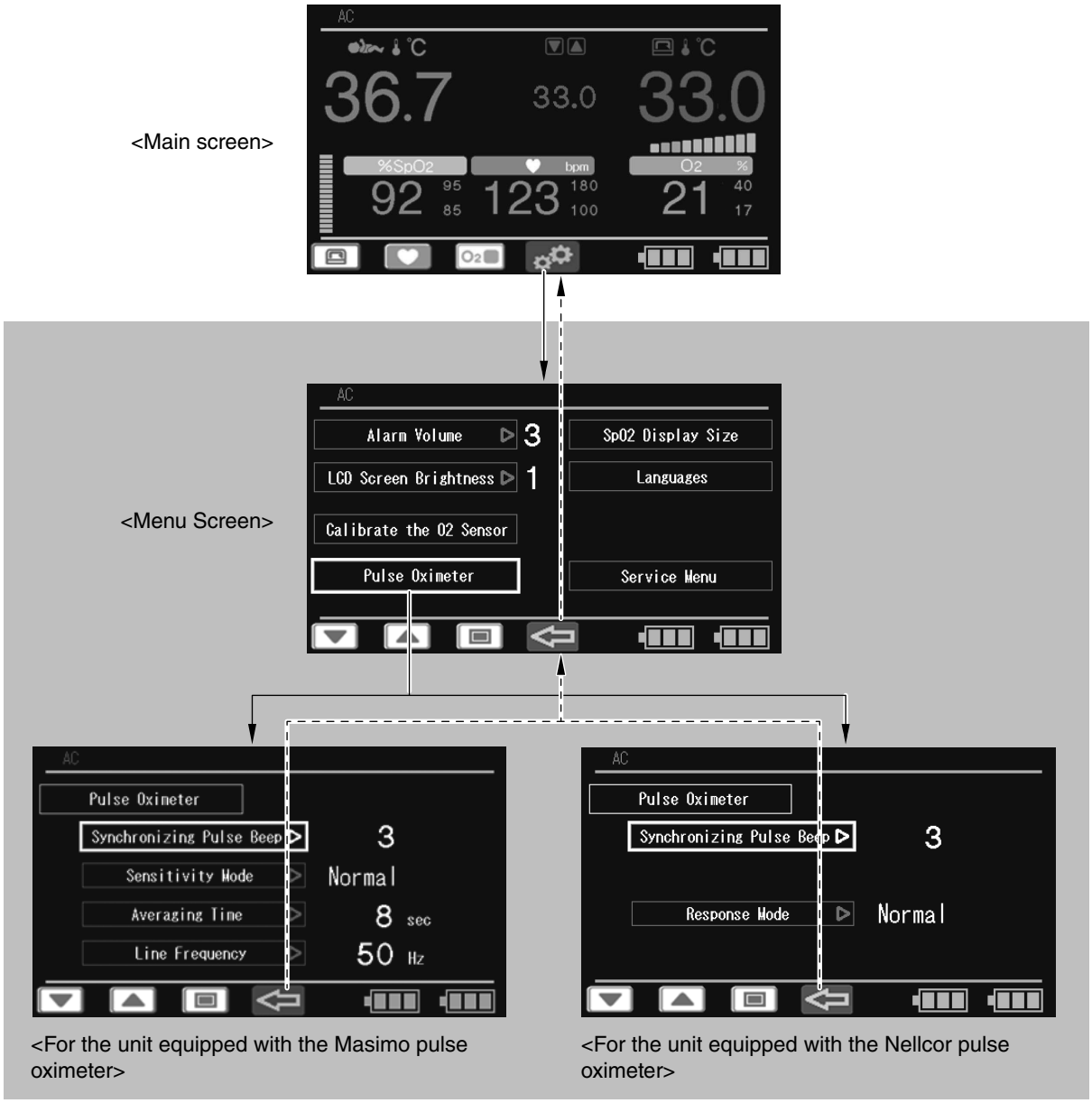
(4) The setup is finished when the ⇦ switch is pressed or a given period of time has elapsed.



[9] Other Operation Procedures

9-1. Working with the Menu Screen

When you press the switch on the main screen, the menu screen appears.
The menu screen transitions as shown below.

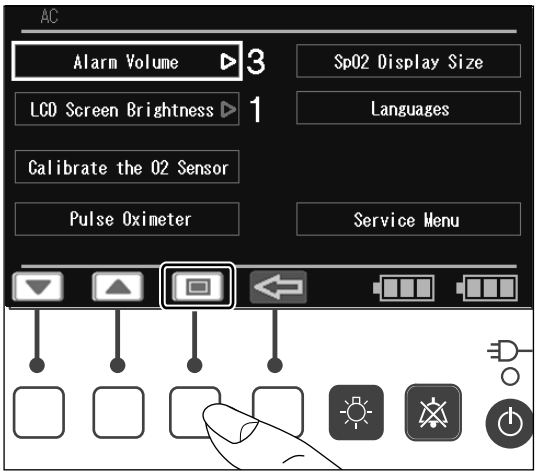


<For the unit equipped with the Masimo pulse oximeter>

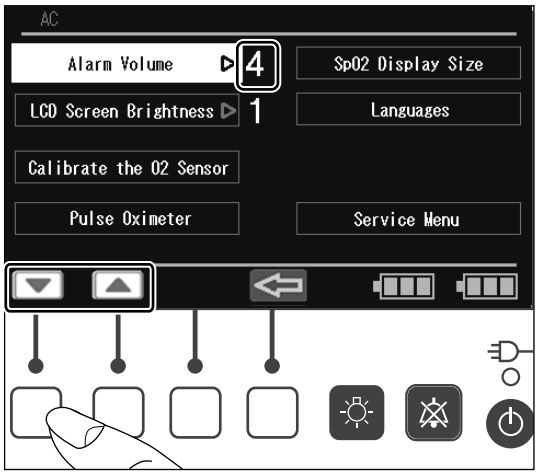
<For the unit equipped with the Nellcor pulse oximeter>

9-1-1. Setting the Alarm Volume

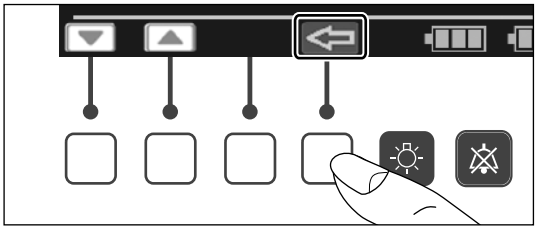
(1) Press the ▼ or ▲ switch to place the cursor on the [Alarm Volume] menu, and then press the ▣ switch. The menu is then highlighted.



(2) While the menu is highlighted, press the ▼ or ▲ switch to set the alarm volume level in the range of 1-7. The larger the number, the louder the sound. (An alarm sound cannot be muted.)
The minimum alarm volume is 55-65dBA, and the maximum alarm volume is 75-80dBA.

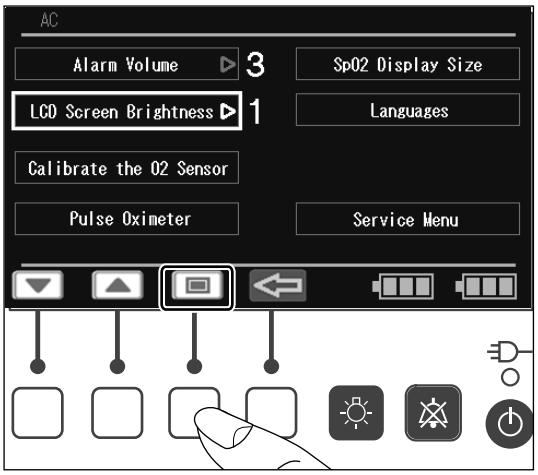


(3) The screen returns to the cursor control screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the main screen.

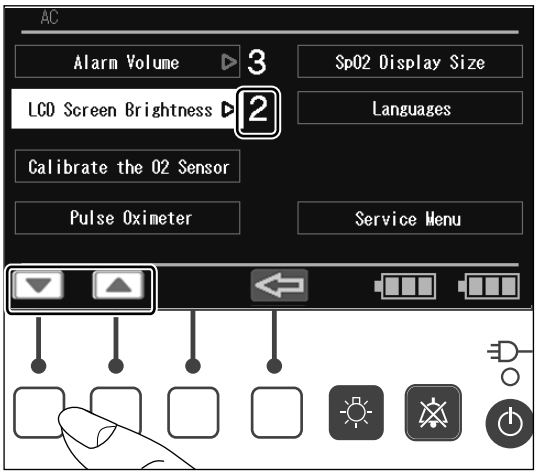


9-1-2. Setting the LCD Screen Brightness

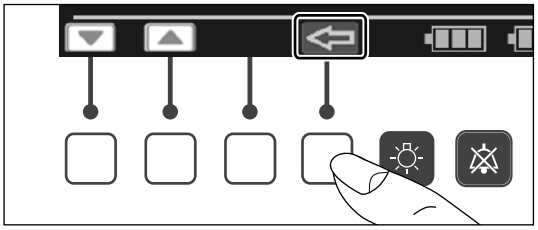
(1) Press the ▼ or ▲ switch to place the cursor on the [LCD Screen Brightness] menu, and then press the ▣ switch. The menu is then highlighted.



(2) While the menu is highlighted, press the ▼ or ▲ switch to set the LCD screen brightness in the range of 1-4. The larger the number, the brighter the screen.

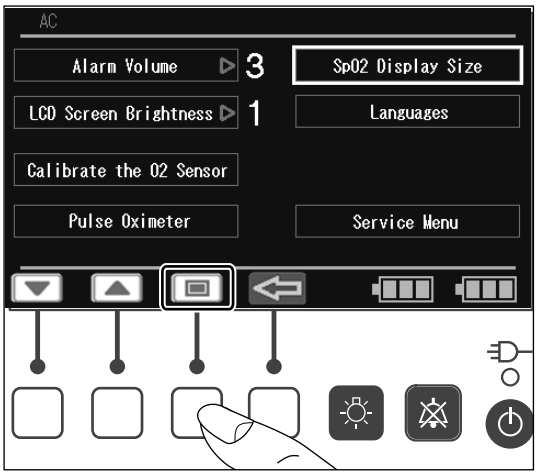


(3) The screen returns to the cursor control screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the main screen.

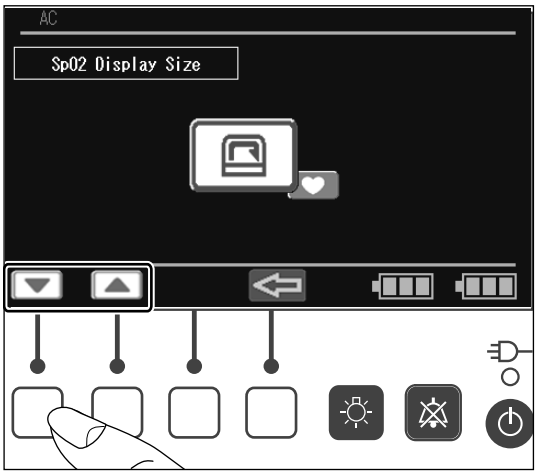


9-1-3. Setting the Display Size

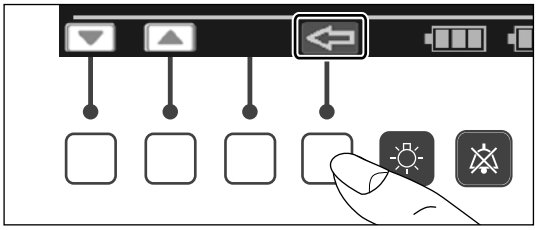
(1) Press the ▼ or ▲ switch to place the cursor on the [SpO_2 Display Size] menu, and then press the ▣ switch. The SpO_2 Display Size screen appears.



(2) Press the ▼ or ▲ switch and select the Enlarged Temperature display (🌡) or Enlarged SpO_2 display (♥).

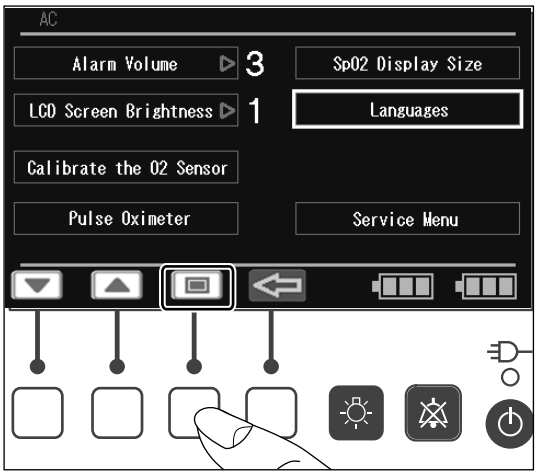


(3) The screen returns to the menu screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the main screen.

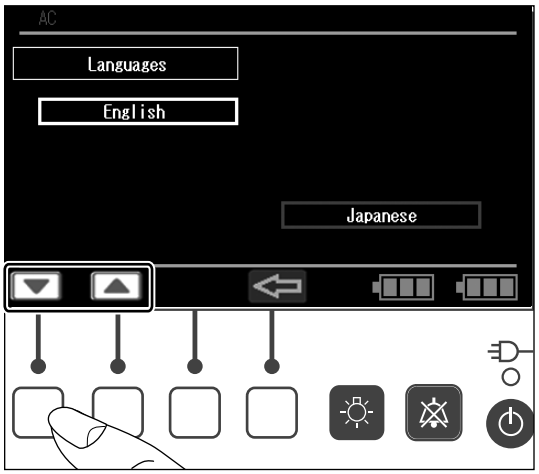


9-1-4. Setting the Language

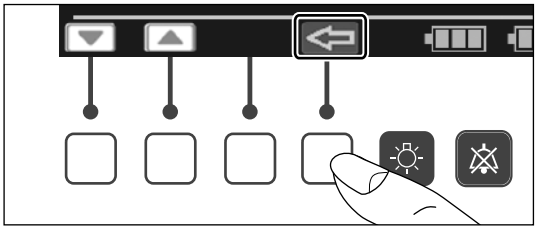
(1) Press the ▼ or ▲ switch to place the cursor on the [Languages] menu, and then press the ▣ switch. The Languages screen appears.



(2) Press the ▼ or ▲ switch to select the language you require.



(3) The screen returns to the menu screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the main screen.

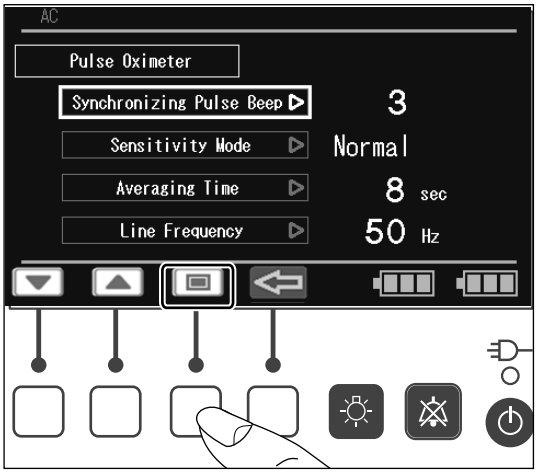


9-1-5. Setting the Synchronizing Pulse Beep Volume

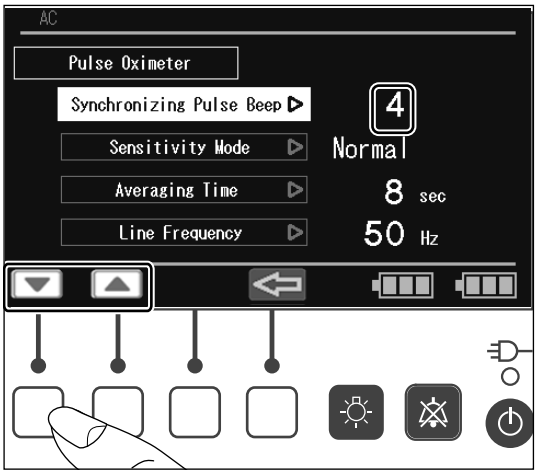
Masimo pulse oximeter and Nellcor pulse oximeter

(1) Press the ▼ or ▲ switch on the pulse oximeter setting screen to place the cursor on the [Synchronizing Pulse Beep] menu, and then press the ▣ switch. The menu is then highlighted.

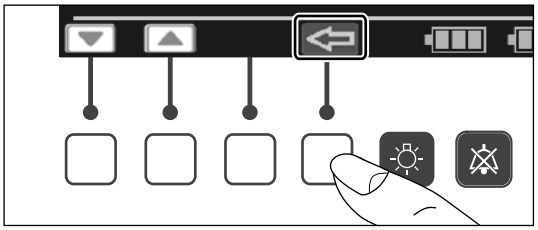
✻ The screen is for a Masimo pulse oximeter.



(2) While the menu is highlighted, press the ▼ or ▲ switch to set the synchronizing pulse beep volume level in the range of 0 (OFF)-7. The larger the number, the louder the sound.



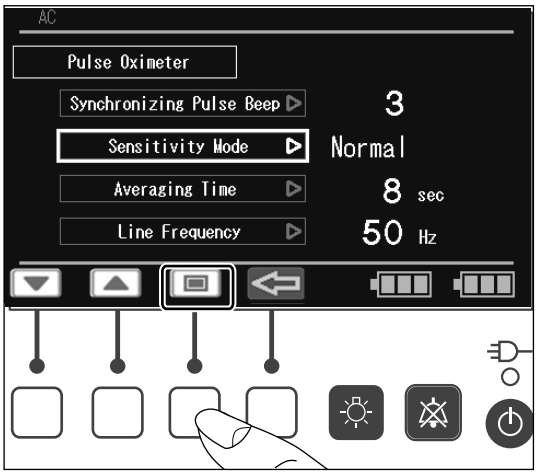
(3) The screen returns to the cursor control screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the menu screen.



OPERATION

9-1-6. Setting the Sensitivity Mode Masimo pulse oximeter

(1) Press the ▼ or ▲ switch to place the cursor on the [Sensitivity Mode] menu, and then press the ▣ switch. The menu is then highlighted.



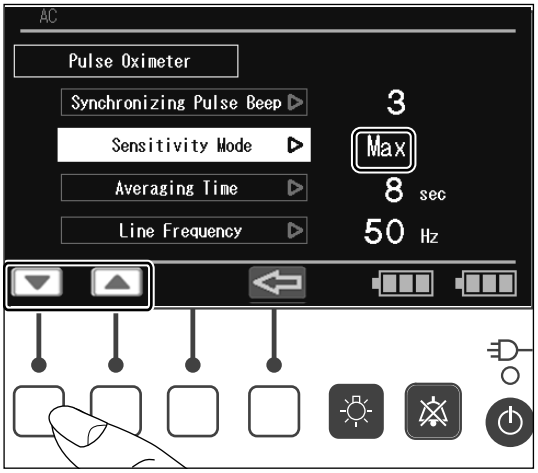
(2) While the menu is highlighted, press the ▼ or ▲ switch to select the desired sensitivity mode.

[Normal] is appropriate for monitoring average infants.

[APOD] is appropriate for monitoring infants who are active and where there is a risk of the sensor becoming detached.

Selecting [APOD] enhances sensor-off detection performance.

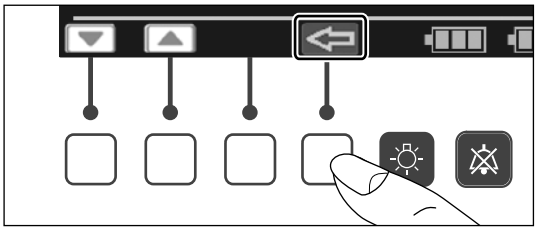
[Max] is appropriate for characteristic improvement against low perfusion. Selecting [Max] will result in reduced sensor-off detection performance accuracy.



⚠CAUTION

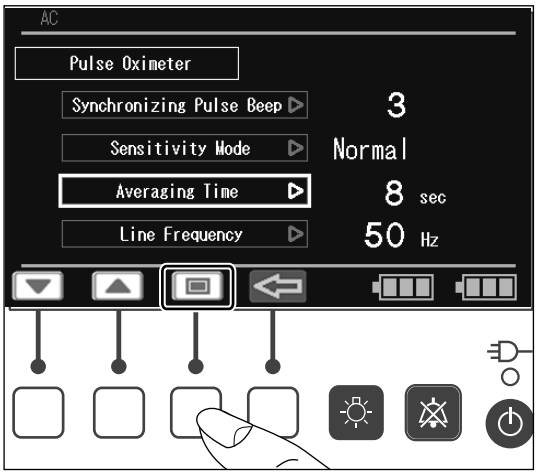
- When the sensitivity mode is set to “Max”, the pulse oximeter becomes susceptible to outside light and the accuracy of SpO_2 measurements and accuracy of sensor-off detection may be reduced. Whenever the sensitivity mode is set to “Max”, the patient must be accompanied by a physician or medical staff.
- The Max sensitivity setting will not be stored in the unit.
  After a power off and on cycle, the sensitivity will change from the “Max” to “Normal”.

(3) The screen returns to the cursor control screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the menu screen.

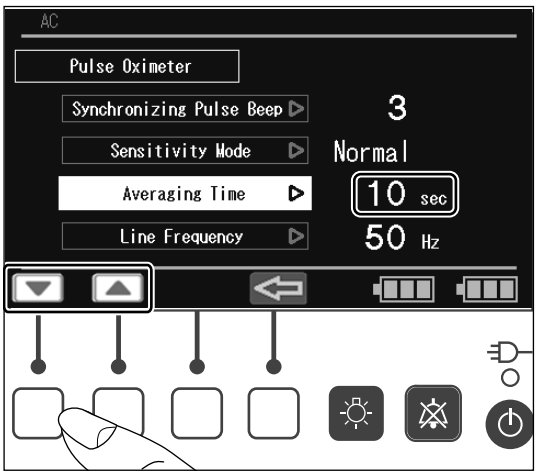


9-1-7. Setting the Averaging Time Masimo pulse oximeter

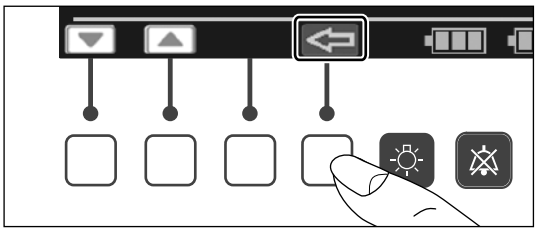
(1) Press the ▼ or ▲ switch to place the cursor on the [Averaging Time] menu, and then press the ▣ switch. The menu is then highlighted.



(2) While the menu is highlighted, press the ▼ or ▲ switch until the desired averaging time (2, 4, 8, 10, 12, 14 or 16 sec) is obtained.

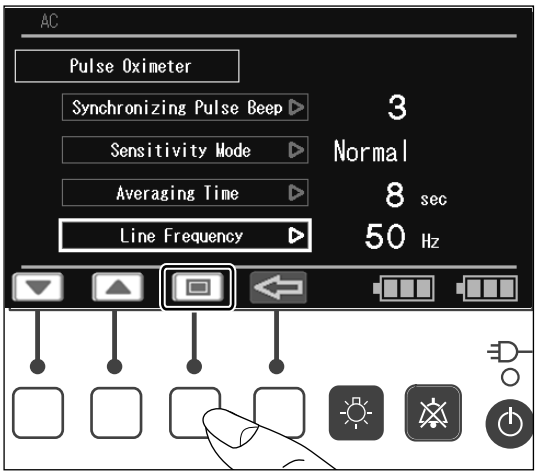


(3) The screen returns to the cursor control screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the menu screen.

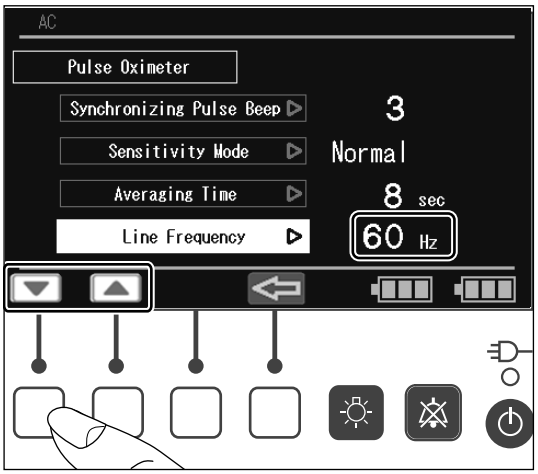


9-1-8. Setting the Pulse Oximeter Power Frequency Masimo pulse oximeter

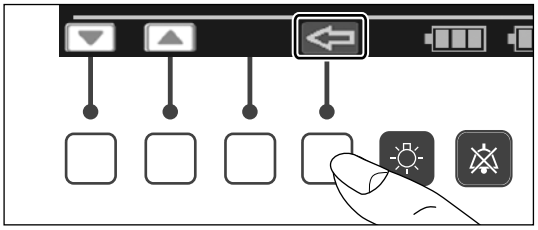
(1) Press the ▼ or ▲ switch to place the cursor on the [Line Frequency] menu, and then press the ▣ switch. The menu is then highlighted.



(2) While the menu is highlighted, press the ▼ or ▲ switch to select either [50Hz] or [60Hz] for the power frequency.



(3) The screen returns to the cursor control screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the menu screen.

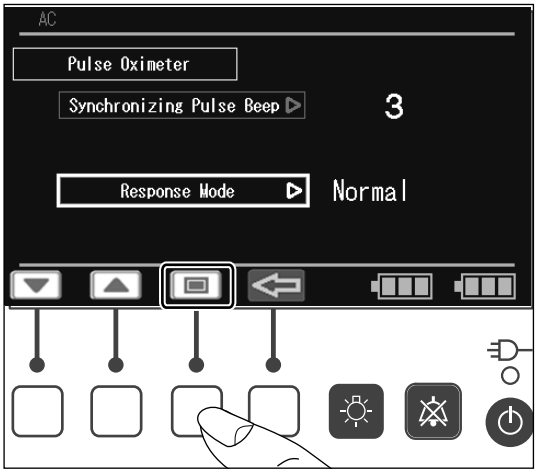


⚠CAUTION

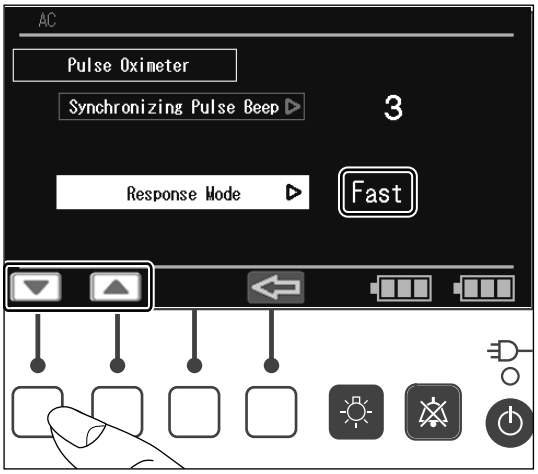
- SpO_2 measurement accuracy may degrade if the power frequency is not correctly set.

9-1-9. Setting the Response Mode (Nellcor pulse oximeter)

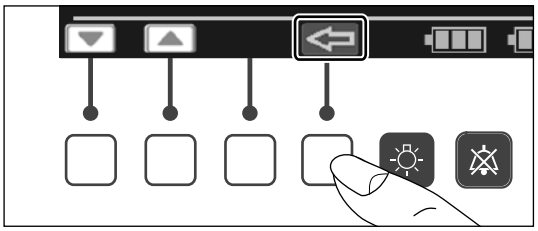
(1) Press the ▼ or ▲ switch to place the cursor on the [Response Mode] menu, and then press the ▣ switch. The menu is then highlighted.



(2) While the menu is highlighted, press the ▼ or ▲ switch to select either [Normal] (5-7 sec) or [Fast] (2-4 sec) as the response mode.



(3) The screen returns to the cursor control screen when the ⇦ switch is pressed.
Press the ⇦ switch again to return to the menu screen.

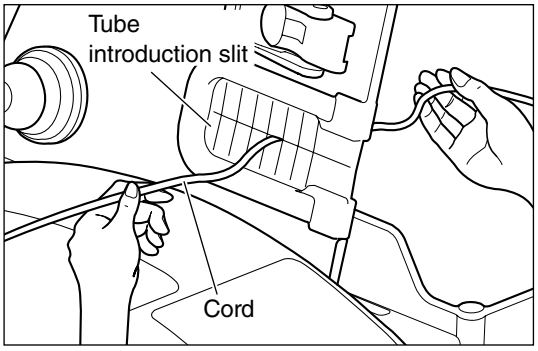


9-2. Feeding Cords and Tubes into or out of the Incubator

⚠ CAUTION

- Always guide the cords and tubes into the incubator in such a way that they will not become wrapped around the infant.
- Always watch the infant in order to prevent cords or tubes from being wrapped around the infant.

Guide the cords and tubes into the incubator through the tube introduction slit on either side of the hood. The cords and tubes can be let into or out of the incubator from the side of the tube introduction slit.

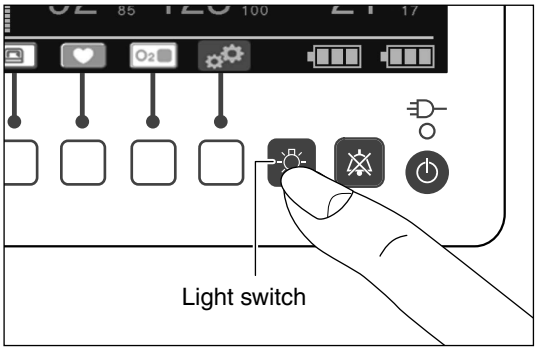


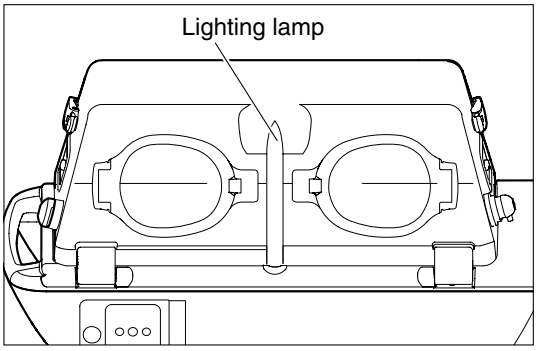
9-3. Lighting lamp

⚠ WARNING

- Do not stare into the light or expose your eyes to the light. Doing so may cause retinal damage.

Every time the switch is pressed, the lamp state changes cyclically as follows: Off, On (bright), On (dark), and Off.



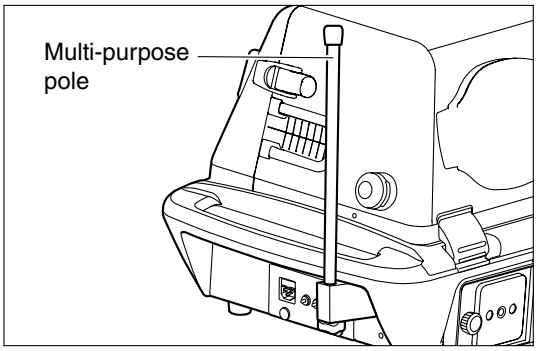


9-4. Multi-purpose pole (option)

WARNING

The maximum acceptable weight of the multi-purpose pole accessories is 4kg.

The multi-purpose pole can be mounted on both sides of the main body. For information on how to mount the multi-purpose poles, see the instruction manual that was delivered with them.



[10] Cleaning and Disinfection

⚠ WARNING

- The heaters remain very hot after use. Allow the heaters to cool down sufficiently before cleaning and disinfecting them in order to avoid burns.
- A fire and explosion hazard exists when performing cleaning in an oxygen-enriched environment. Turn off the oxygen supply and disconnect the oxygen supply hose from the incubator before cleaning the incubator.

⚠ CAUTION

- The unit is shipped without being disinfected. Be sure to clean and disinfect the unit before using it for the first time after purchase.
- To prevent infections, disinfect the unit at regular intervals. The intervals to disinfect and disinfection methods vary depending on the usage frequency and the environment in which the unit is used. Medical institutions that use the unit should determine appropriate disinfection intervals and methods.
- 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 disinfectants, such as Osvan, Hyamine, and Hibitane. NEVER use undiluted solution.
- Do not use any abrasive cloth, cleaner, alcohol, acetone or other types of solvent for cleaning or disinfecting.
- Turn the power switch off and unplug the power plug before cleaning and disinfecting the unit.
- Clean and disinfect the unit whenever it is used for a different infant.
- Clean and disinfect the unit whenever you notice any dirt or contamination which may introduce an infection.
- After cleaning and disinfecting, reassemble the removed parts correctly and check that the unit operates normally.
- After cleaning and disinfecting, remove the disinfectant solution thoroughly from the incubator before using it.

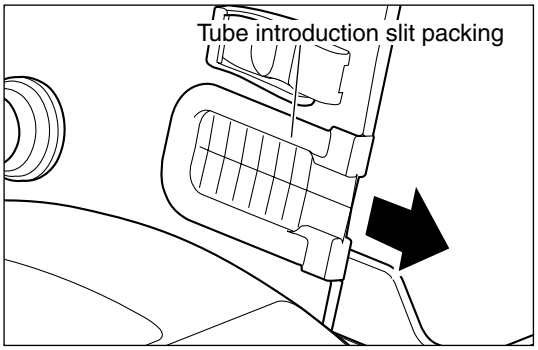
Provide a soft clean cloth and a disinfectant solution suitable for cleaning and disinfection.

* Recommended disinfectant solutions include:

- Benzalkonium chloride aqueous solution (e.g. Osvan)
- Benzethonium chloride aqueous solution (e.g. Hyamine)
- Chlorhexidine aqueous solution (e.g. Hibitane)

10-1. Hood Assembly

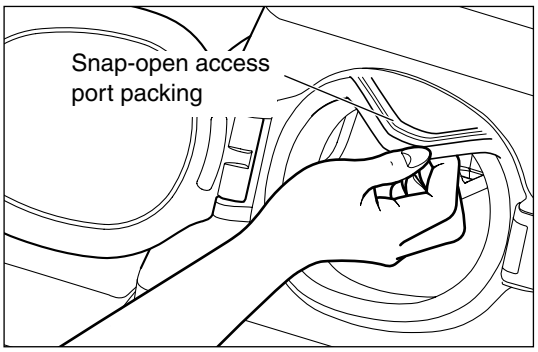
(1) Open the admittance panels and remove all of the tube introduction slit packing.



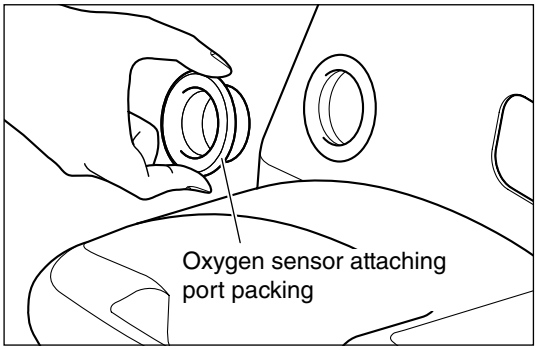
⚠CAUTION

- When putting the hood assembly back into place, ensure that it is seated all the way in the packing on the hood.

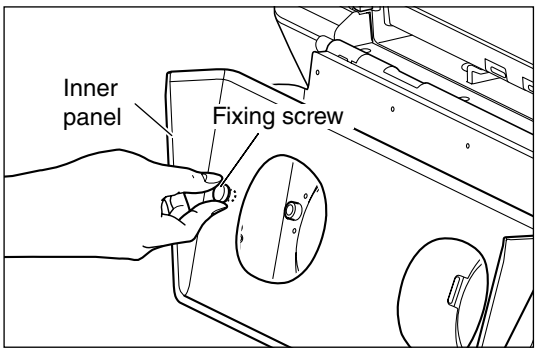
(2) Remove all packings from the snap-open access ports.

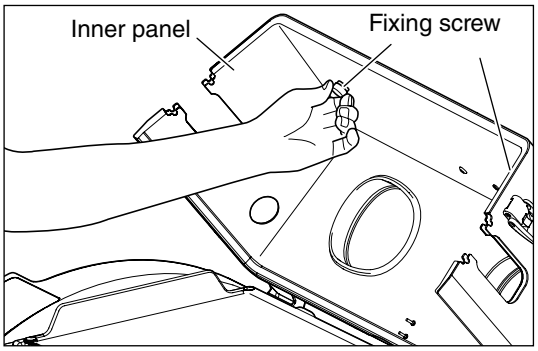


(3) Remove the oxygen sensor attaching port packing.

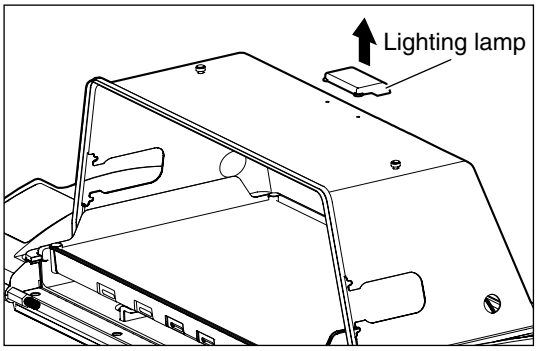


(4) Loosen the fixing screws and remove the admittance panel and hood inner panel.





(5) Remove the lighting lamp from the inner panel.

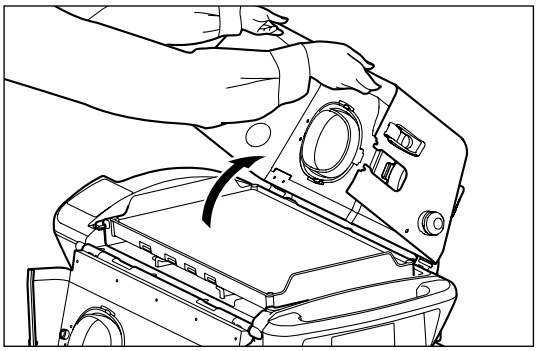


(6) Disinfect the removed parts.

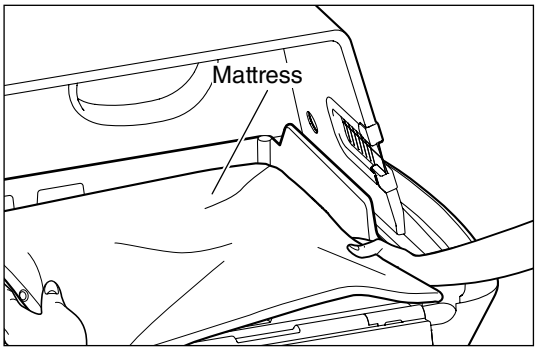
Parts that are to be cleaned by immersing them in a disinfectant solution	Tube introduction slit packing Snap-open access port packing Oxygen sensor attaching port packing
Parts that are to be cleaned using a soft cloth that has been soaked in a disinfectant solution and wrung out	Inner and outer faces of hood Admittance panel Inner panel Lighting lamp

10-2. Mattress Platform and Inside of Incubator

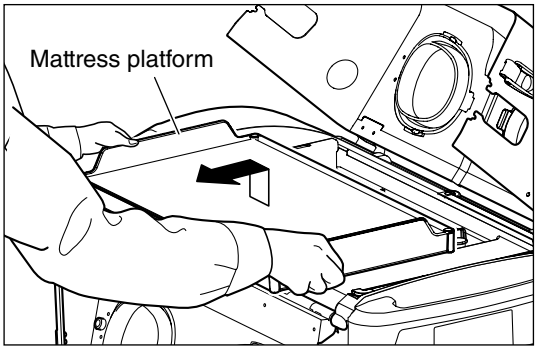
(1) Open the hood.



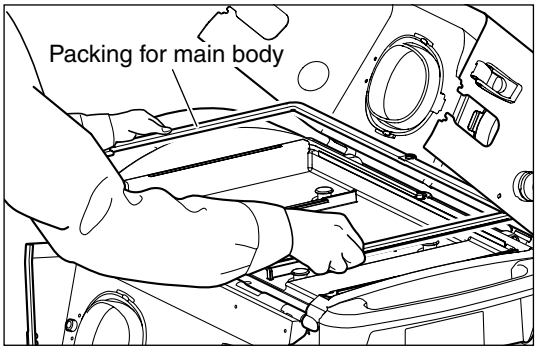
(2) Remove the mattress.
Since the mattress consists of a special sponge fully sealed with a plastic cover, the sponge inside cannot become contaminated unless the cover gets damaged.



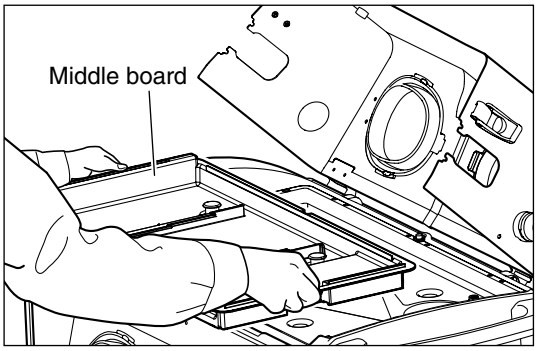
(3) Hold the mattress platform at both ends and then remove it by lifting it up slightly.



(4) Remove the main body packing from the middle board.



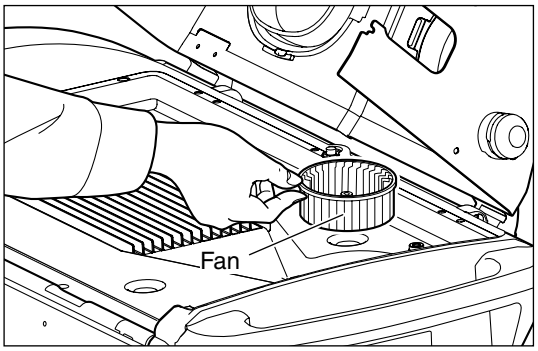
(5) Hold both ends of the middle board, raise it and then remove.



⚠WARNING

- The heater and its surrounding surfaces may be hot enough to cause burns. Avoid touching them until they have cooled down.

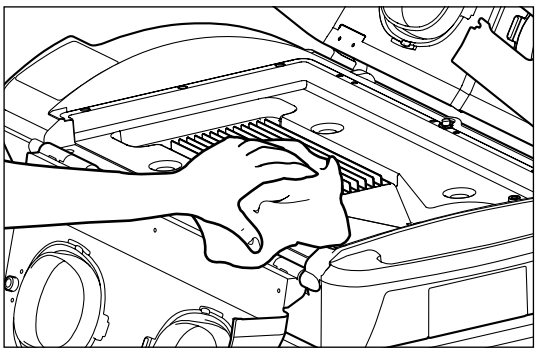
(6) Remove the fan by pulling it up.



⚠CAUTION

- When placing the cleaned fan back into place, be sure to push the fan onto the shaft as far as it will go. An incorrectly installed fan may cause abnormal noise or malfunction.

(7) When all parts have been removed by following the procedures above, the conditioning chamber comes into view.
Clean the inside of the conditioning chamber using a soft cloth that has been soaked in a disinfectant solution and wrung out.



(8) Disinfect the removed parts.

Parts that are to be cleaned by immersing them in a disinfectant solution	Fan
Parts that are to be cleaned using a soft cloth that has been soaked in a disinfectant solution and wrung out	Mattress Mattress platform Packing for main body Middle board

(9) After cleaning and disinfecting, allow each part to dry sufficiently and reassemble all parts removed in reverse order.

10-3. Others

■ Skin temperature probe

Wipe a used skin temperature probe lightly using a soft dry cloth. Wipe and disinfect the heat-sensing portion using a soft cloth dampened with a disinfectant solution.

Be sure to keep the skin temperature probe in its case.

⚠CAUTION

- Never clean the skin temperature probe using alcohol, as doing so will cause the material to harden.

■ Patient cables

Clean the Red patient cables by wiping with a 70% isopropyl alcohol pad and allowing to dry thoroughly.

[11] Maintenance and 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 and its accessories before maintenance inspections, repairs, or disposal

- **Inspection before use**
  Check the basic functional operation of each part of the unit every time before, during, and after use.
- **Periodical inspection**
  Inspections should be carried out approximately once a year. Contact your local Atom representative for periodical inspection.
- **Periodical Replacement Parts**
  Some parts need to be replaced periodically depending on their period of use.

11-1. Inspection Checklist

⚠ WARNING

- Keep this Manual in a location that is readily accessible should any problems occur on the unit.
- If any problems are detected during any inspection, indicate on the unit that it is out of order, arrange repairs without fail, and do not use the unit until it has been repaired. Contact your local Atom representative for further information on repairs.
- The inspection checklist before use is used to carry out an operation check before using the unit. In order to maintain the cleanliness of the interior of the incubator, it does not contain any items involving checking of temperature, or oxygen concentration control functions. If any problems are detected in relation to any of the control functions during use, indicate on the unit that it is out of order and do not use the unit until it has been repaired.

11-1-1. Inspection Checklist - Before Use

Device Name	IncuArch	Date of Inspection	
Serial No.		Inspector	

When the power is turned on, check the following items.

No.	Inspection	Item to check	Yes/No
1	Main body	(1) Are there any appearance-related abnormalities?	
		(2) Are the main body and stand securely locked?	
		(3) When the admittance panels and snap-open access ports are fully closed, do they stay locked in place when they are pushed from the inside?	
		(4) Is each part of the unit correctly assembled?	
2	Operation Checking for operation when the power is turned on	(1) Is the power cord securely connected and has the AC power indicator lit up? * When there is remaining battery charge, the AC power indicator is activated even if the power cord is not connected. Check that the power cord is securely connected.	
		(2) Is the measured value displayed when you connect and attach the skin temperature probe?	
		(3) Is the measured value displayed when you connect and attach the SpO_2 sensor?	
		(4) Is the measured value displayed after you connect the oxygen sensor module and perform calibration?	
		(5) Does the lighting lamp light up?	

11-1-2. Inspection Checklist - During Use

Device Name	IncuArch	Date of Inspection	
Serial No.		Inspector	

During the incubator warm operation mode, periodically check the following items.

No.	Inspection	Item to check		Yes/No
1	Main body	(1) Are the main body and hood free of damage and not deformed in any way?		
		(2) Is the power cord securely connected?		
		(3) Are the main body and stand securely locked?		
		(4) Are the admittance panels and snap-open access ports securely locked?		
		(5) Are the air inlets and outlets free of obstacles that may block air circulation? * Check that no objects are placed in any spaces other than the mattress in the incubator.		
2	Operation	(1) Is the incubator air temperature controlled as specified? * Be sure to set the incubator air temperature at least +3°C higher than the ambient temperature. If a phototherapy unit or a heated humidifier is used in combination with the incubator, set the incubator air temperature at least +5°C higher than the ambient temperature.		
		(2) Battery test	Does the power supply switch to battery mode when the power plug is disconnected from the power outlet?	
			Does the battery status indicator show a white frame with three lit cells after the battery has been charged?	

11-1-3. Inspection Checklist - After Use

Device Name	IncuArch	Date of Inspection	
Serial No.		Inspector	

Before storage, check the following items.

No.	Inspection	Item to check		Yes/No
1	Main body	(1) Are the main body and hood free of damage and not deformed in any way?		
		(2) Are the packings free of deterioration and attached securely? [Tube introduction slit packings, snap-open access port packings, oxygen sensor attaching port packings, and packing for main body]		
		(3) Do the admittance panel latches function correctly? When the admittance panels are fully closed, do they stay locked in place when they are pushed from the inside?		
		(4) Are the press levers of the snap-open access ports secured tightly and able to work correctly to open and close the snap-open access ports? When the snap-open access ports are fully closed, do they stay locked in place when they are pushed from the inside?		
2	Operation	(1) Does the power switch turn the power on and off reliably?		
		(2) Battery test	Does the power supply switch to battery mode when the power plug is disconnected from the power outlet?	
			Does the battery status indicator show a white frame with three lit cells after the battery has been charged?	
3	Overall judgment	Are any abnormalities discovered after performing the above inspections?		

11-2. Periodic Replacement of Parts

Periodic replacement parts are those which gradually deteriorate and wear down with use. They need to be replaced periodically in order to maintain the accuracy and performance of the unit at an appropriate level. Timing of replacement varies with the frequency and conditions of use.
Consult your local Atom representative for replacement services.

Part name	Period of use	Reason for replacement
Filter	3 months	Air circulation control failure due to a build-up of dust or clogging
Snap-open access port packing	1-2 years	Decreased air tightness due to damage or deformation
Tube introduction slit packing	1-2 years	Decreased air tightness due to damage or deformation
Packing for main body	1-2 years	Decreased air tightness due to damage or deformation
Mattress	1-2 years	Decreased elasticity due to damage or deformation
Fan motor	3 years	Decreased air circulation
Fan	3 years	Decreased air circulation
Middle board	3 years	Temperature control failure due to damage or deformation
Oxygen sensor	Variable depending on operating conditions*	Calibration failure due to sensor life
Batteries	Variable depending on operating conditions	Operation failure due to used up battery power supply

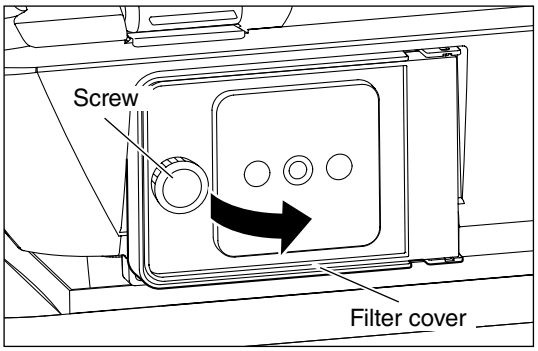
* The oxygen sensor is a consumable and its life is affected greatly by the ambient conditions under which it is used (i.e. ambient temperature, oxygen concentration). It is recommended that an oxygen sensor be replaced when one or more years have passed since it was taken out of its package.

11-3. Replacing the Filter

⚠ CAUTION

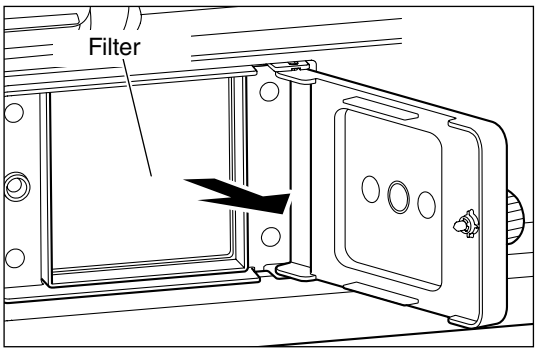
Replace the filter with a new one every three months as a general rule. The degree of filter contamination varies with the level of air pollution or frequency of use. Check the filter for contamination through the window of the filter cover. If the filter is discolored, replace it with a new one even if it has not been used for three months.

(1) Loosen the screw of the filter cover and open the cover.



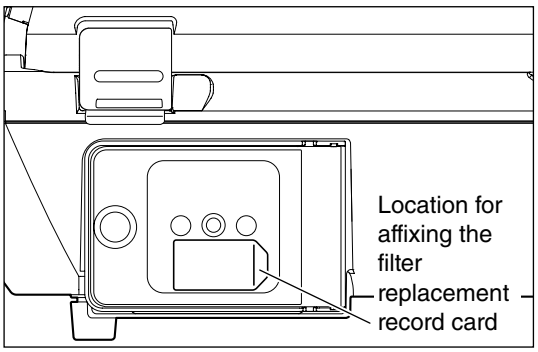
(2) Remove the contaminated filter slowly, taking care not let dust spread, and dispose of it.

(3) Clean the filter holder and the filter cover using a soft cloth that has been soaked in a disinfectant solution and wrung out.



(4) Attach a new filter to the filter holder. Write the date of replacement on a new filter card and stick it in place as shown in the figure on the right for future reference.

(5) Close the filter cover and tighten the screw.



⚠ WARNING

- Do not attempt to reuse a contaminated filter by washing it or attaching it inside out.
- Open the filter cover only when replacing the old filter with a new one.

11-4. Replacing the Oxygen Sensor

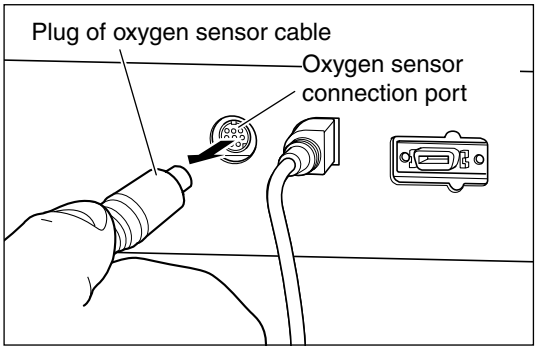
⚠ WARNING

- As part of a daily inspection routine, check the oxygen sensor for any signs of deterioration or leaking liquid. If any cracks are found on the external surface, replace it immediately with a new one.
- The oxygen sensor is a sealed device containing a potassium hydroxide electrolyte. The electrolyte may leak out if the sensor should be damaged when dropped, etc. If the electrolyte should touch your skin or clothes, wash it away with copious amounts of water. If it should get in your eye, wash your eye immediately with copious amounts of water and consult the doctor.
- Dispose of a used oxygen sensor in accordance with the appropriate disposal procedure.

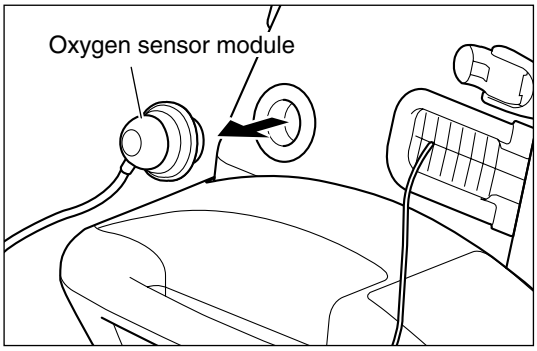
⚠ CAUTION

- There are small holes in the bag containing the oxygen sensor. They are intended to prevent a voltage defect which can occur during initial use if the oxygen sensor is contained in airtight packaging. Thus there is no effect on the replacement period which Atom recommends for the oxygen sensor.
- If “Calibration Error” is displayed during 21% calibration, the oxygen sensor may be faulty. Replace it with a new one.
- Wait at least one hour after attaching the oxygen sensor to the incubator before using it. The electrolytes contained in the oxygen sensor are not equalized immediately after installation, so sensor output is therefore unstable and an oxygen sensor alarm may occur.
- Avoid direct sunlight and high temperature when storing the oxygen sensor.
- The life span of the oxygen sensor varies depending on the ambient conditions under which it is used. It is recommended that an oxygen sensor be replaced when more than one year has passed since it was first used.
- Avoid imposing shocks on the oxygen sensors when replacing them.

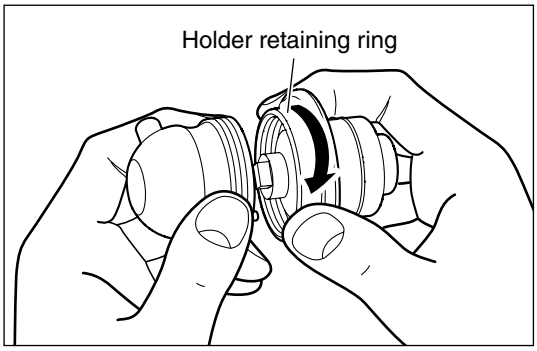
(1) Remove the plug of the oxygen sensor module cable from the oxygen sensor connection port on the left side of the main body.



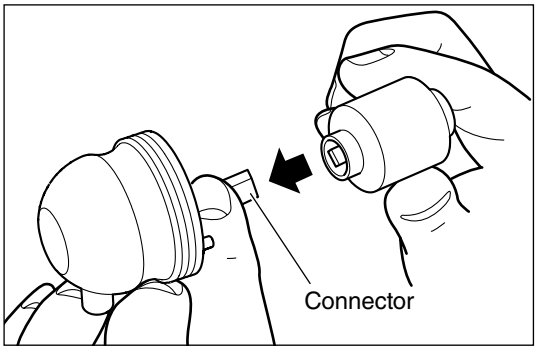
(2) Pull out the oxygen sensor module from the hood.



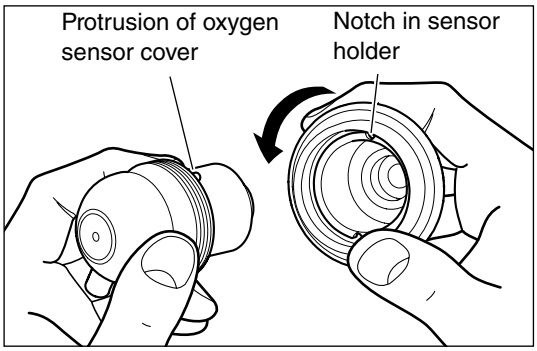
(3) Remove the sensor holder by turning the holder retaining ring in the direction of the arrow shown in the illustration on the right. Then, remove the oxygen sensor.



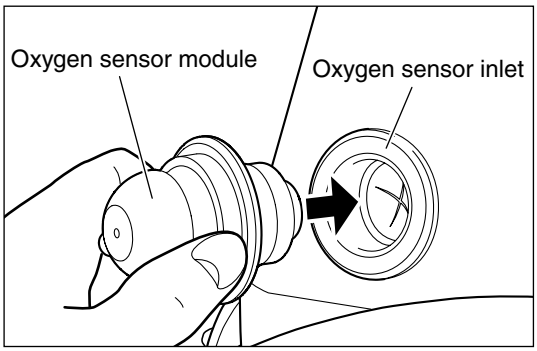
(4) Fit the new oxygen sensor to the connector of the oxygen sensor cover.



(5) Align the protrusion of the oxygen sensor cover with the notch in the sensor holder. Then, turn the holder retaining ring in the direction of the arrow shown in the illustration on the right to fit the sensor to the holder.



(6) Put the oxygen sensor module into the oxygen sensor inlet on the hood and connect the cable connector to the oxygen sensor connection port on the left side of the main body.



11-5. Replacing the Batteries

When batteries are to be replaced, contact your local Atom representative.

11-6. Disposal

The medical institution concerned is responsible for appropriate disposal of the main body, old parts past their expected life span and disposables in accordance with applicable waste management laws and regulations.
Rechargeable lithium-ion batteries and oxygen sensors are used in this unit. Dispose of the batteries and oxygen sensors in accordance with local regulations.

[12] Alarms

⚠ WARNING

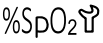
The unit provides the following alarm features. If an alarm condition should occur, check for a possible cause of the alarm and take the correct measures. If the alarm is caused most likely by a failure, the unit needs to be repaired. Indicate on the incubator that it is out of order and contact your local Atom representative.

⚠ CAUTION

After the power has been turned on or a setting value has been changed, the set temperature alarm does not function for 50 minutes. However, when the incubator temperature becomes ±3°C of the set value within 50 minutes, the set temperature alarm activates at that time.

Category	Alarm name	Condition causing the alarm	Icon displayed	When an alarm is activated:	Cancellation of alarm	Priority level*1	Alarm is silenced
Temperature & Heat	Excessive temperature alarm	This alarm activates before the incubator air temperature exceeds 39°C.		The incubator heater is deactivated.	The heater is automatically reactivated when the temperature is reduced to the normal level, however, the audible alarm stays on. The alarm is canceled by pressing the silence switch.	Middle	10 min.
	Set temperature alarm	This alarm activates if the incubator air temperature differs from the set temperature by ±3°C or more.*2		Even if the temperature exceeds -3°C or more, control is maintained. If the temperature exceeds +3°C or more, the heater is turned off.	The alarm is automatically canceled when the temperature difference is less than 3°C.	Low	15 min.
	Skin temperature probe alarm	This alarm activates if the skin temperature probe is electrically open or short-circuited.		Skin temperature display "- - -"	The alarm is automatically canceled when the probe is replaced with a good one.	Low	15 min.

Category		Alarm name	Condition causing the alarm	Icon displayed	When an alarm is activated:	Cancellation of alarm	Priority level*1	Alarm is silenced
Main body		Fan alarm	This alarm activates if the fan speed is faulty.		The incubator heater is deactivated. Fan OFF.	Turn the power off, correctly attach the middle board, fan cover, and fan, and then turn the power on again.	Middle	2 min.
		System failure alarm	This alarm activates if the incubator air temperature sensor is disconnected or short-circuited, or if the heater is disconnected.		The incubator heater is deactivated.	The alarm cannot be canceled. Turn the power off and contact your local Atom representative.	Middle	10 min.
		Low battery alarm	This alarm is activated when the battery voltage is low.		The unit continues to operate until it is shut down.	The alarm is automatically canceled when the unit is connected to a commercial power source.	Low	15 min.
Pulse oximeter	Common to both Masimo and Nellcor	SpO_2 upper alarm limit	This alarm activates if SpO_2 exceeds the upper alarm limit.	The upper alarm limit value blinks.	Measurement is continued.	The alarm will be reset automatically when SpO_2 falls below the upper-limit alarm set value.	Middle	2 min.
		SpO_2 lower alarm limit	This alarm activates if SpO_2 falls below the lower alarm limit.	The lower alarm limit value blinks.	Measurement is continued.	The alarm will be reset automatically when SpO_2 exceeds the lower-limit alarm set value.	Middle	2 min.
		Pulse rate upper alarm limit	This alarm activates if the pulse rate upper alarm limit has been exceeded.	The upper alarm limit value blinks.	Measurement is continued.	The alarm will be reset automatically when the pulse rate falls below the upper-limit alarm set value.	Middle	2 min.
		Pulse rate lower limit alarm	This alarm activates if the pulse rate lower alarm limit has been exceeded.	The lower alarm limit value blinks.	Measurement is continued.	The alarm will be reset automatically when the pulse rate exceeds the lower-limit alarm set value.	Middle	2 min.
	Masimo	SpO_2 sensor alarm	This alarm activates if the sensor is disconnected from the cable or patient during measurement.		%SpO_2 and pulse rate display "---" are displayed	The alarm is automatically canceled when the silence switch is pressed, or when the sensor is correctly connected to the unit and is attached to the patient.	High	Activated for 2 minutes after the sensor is disconnected from the unit, function is deactivated, or the sensor is disconnected from the patient.
		SpO_2 abnormal sensor alarm	This alarm activates if the sensor fails to function correctly or an incompatible sensor is connected.		%SpO_2 and pulse rate display "---" are displayed	The alarm is automatically canceled when the sensor is replaced with a good one.	High	2 min.
		SpO_2 cable alarm	This alarm activates if the patient cable is disconnected from the unit during measurement.		%SpO_2 and pulse rate display "---" are displayed	The alarm is automatically canceled when the silence switch is pressed or the patient cable is correctly connected to the unit.	High	Function is deactivated

Category		Alarm name	Condition causing the alarm	Icon displayed	When an alarm is activated:	Cancellation of alarm	Priority level*1	Alarm is silenced
Pulse oximeter	Masimo	SpO_2 abnormal cable alarm	This alarm activates if the patient cable becomes defective during measurement or an incompatible cable is connected.		%SpO_2 and pulse rate display "---" are displayed	The alarm is automatically canceled when the patient cable is replaced with a good one.	High	2 min.
		Internal error alarm	This alarm activates if the SpO_2 board experiences a fault or an internal communication failure occurs.		%SpO_2 and pulse rate display "---" are displayed	If the power is turned off and back on again and the alarm continues, contact your local Atom representative.	Low	Alarm priority indicator is displayed and the audible alarm is turned off.
	Nellcor	Loss of pulse alarm	This alarm activates if pulse is not detected during measurement.	 (Red marking)	%SpO_2 and pulse rate display "—" are displayed	The alarm is automatically canceled when a pulse is detected.	High	2 min.
		SpO_2 sensor alarm	This alarm activates if the sensor is disconnected from the patient or the unit during measurement.		%SpO_2 and pulse rate display "—" are displayed	The alarm is automatically canceled when the silence switch is pressed or the sensor is correctly connected to the unit and is attached to the patient.	High	Activated for 2 minutes after the sensor is disconnected from the unit, function is deactivated, or the sensor is disconnected from the patient.
		SpO_2 abnormal sensor alarm	This alarm activates if the sensor fails to function correctly during measurement.		%SpO_2 and pulse rate display "—" are displayed	The alarm is automatically canceled when the sensor is replaced with a good one.	High	2 min.
		Internal error alarm	This alarm activates if the SpO_2 board experiences a fault or an internal communication failure occurs.		%SpO_2 and pulse rate display "—" are displayed	If the power is turned off and back on again and the alarm continues, contact your local Atom representative.	Low	Alarm priority indicator is displayed and the audible alarm is turned off.
Oxygen		Oxygen level upper alarm limit	This alarm activates if oxygen level exceeds the upper alarm limit.	The upper alarm limit value blinks.	Measurement is continued.	The alarm will be reset automatically when the oxygen concentration value falls below the upper-limit alarm set value.	Middle	2 min.
		Oxygen level lower alarm limit	This alarm activates if oxygen level falls below the lower alarm limit.	The lower alarm limit value blinks.	Measurement is continued.	The alarm will be reset automatically when the oxygen concentration value exceeds the lower-limit alarm set value.	Middle	2 min.
		Oxygen sensor alarm	This alarm activates if the oxygen sensor is disconnected from the unit or is electrically open or short-circuited.		"—" will be displayed.	The alarm is automatically canceled when the oxygen sensor is connected to the unit.	Middle	2 min.

*1 Depending on the alarm priority level, the alarm priority indicator is activated as shown below.
High - Flashes red, Middle - Flashes yellow, Low - Lights up yellow

[13] Troubleshooting

⚠ WARNING

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

⚠ CAUTION

Check the following points before requesting repair services.

Trouble	Action to take
Battery cannot be charged.	● Check that the power cord is connected to the AC inlet and a power outlet. ● Is the fuse in the AC inlet blown? ● Has the power supply circuit breaker in your hospital tripped? (Check the electrical continuity by connecting another electric device to the power outlet used for the incubator).
The unit does not operate when using an external DC power source.	● Is the unit connected to an AC power source? If the unit is connected to both AC and DC power sources, it operates on AC. ● Has the source voltage decreased? ● Is the DC power breaker tripped?
Incubator temperature does not rise.	● Is the incubator air temperature set too low? ● Has the source voltage decreased? (Do not share the AC outlet used for the incubator.) ● Is the incubator installed in a place exposed to strong wind or in a low ambient temperature environment? ● Is the fan correctly installed? Is the fan free of damage or deformation? ● Are the admittance panel and access ports are firmly closed? ● Are the snap-open access ports closed? ● Are all packings correctly attached? ● Check that the air outlets in the incubator are not blocked by objects such as a diapers, gauze, etc.
The incubator air temperature rises too high.	● Check that the incubator air temperature is not set too high. ● Check that the incubator is not exposed to direct sunlight or affected by a nearby heating apparatus. ● Check that the air inlet in the incubator is not blocked by obstacles such as a diaper, gauze, etc.

Trouble	Action to take
The oxygen concentration does not rise.	● Is the flow rate setting on the oxygen flowmeter correct? ● If the oxygen cylinder empty? ● Are the admittance panel and access ports are firmly closed? ● Is the packing firmly attached? ● Is the filter firmly attached?

[14] Technical Data

Electrical ratings	AC power source	Rating: Voltage - AC100-240V; power consumption - 220VA; frequency - 50/60Hz Operating voltage range: AC100-240V±10%
	External DC power source	DC12V, 13A DC24V, 6.5A Operating voltage range DC12V: DC12.4V-DC15.1V DC24V: DC24.8V-DC30.3V
	Built-in batteries	Battery 1 DC24V/10Ah (lithium-ion battery) Battery 2 DC24V/10Ah (lithium-ion battery) (option)
	Hours of continuous operation	At least 3 hours (When operated by the battery after the incubator temperature has stabilized while a new battery is fully charged, the incubator temperature is set to 36°C, and the ambient temperature is 15°C.)
Equipment classification	Type of protection: Class I, Internally powered Degree of protection: Type BF - Applied part Liquid ingress: IPX0 Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide and flammable anesthetic gas mixture. Mode of operation: Continuously operating device	
Dimensions	Main body: 97.5 (W) × 47.5 (D) × 43.5 (H) cm Mattress: 62 (W) × 33 (D) × 3 (H) cm	
Weight	Main body: Approx. 25kg	
Maximum load capacity	Multi-purpose pole: Approx. 4kg	
Operating conditions	Ambient temperature: 10-30°C Relative humidity: 30-75% Atmospheric pressure: 70-106kPa Air velocity: 0.3-1.0m/s	
Storage conditions	Ambient temperature: 0-50°C Relative humidity: 30-75% Atmospheric pressure: 70-106kPa	
Transporting conditions	When transporting a patient using a HL stand, the stand must be lowered to the lowest position.	

Accessories	Dust cover.....1
	Dispo safety band.....3
	Pneumoclean (Electrostatic air filter).....1
	Skin temperature probe.....1
	Operation Manual.....1
	Access port covers (for iris ports).....4

Temperature

Incubator air temperature control mode	Time proportional control mode
Incubator temperature setting range	23.0-38.0°C (in 0.1°C increments)
Incubator air temperature display range	20.0-42.0°C (accuracy: ±1.0°C)
Skin temperature display range	30.0-42.0°C (accuracy: ±0.3°C)
Heater output	0-100 (indicated in 10 levels)
Warm-up time	Approx. 40 min at ambient temperature of 25°C
Alarms	Excessive temperature, Set temperature, Fan, Skin temperature probe, System

Oxygen concentration

Type of oxygen sensor	Galvanic cell type
Oxygen concentration display range	15-105% Accuracy: 15-25%: ±2%O_2 25-100%: ±3%O_2
Setting range of oxygen level alarms	Upper limit: 22-99%O_2 (in 1% increments) Lower limit: 19-96%O_2 (in 1% increments)
Response time for oxygen concentration display	30 sec (90% response)
Stability of oxygen concentration measurements and calibration intervals	24 hours
Calibration	21%
Useful life of oxygen sensor	Approx. 24 months (at an ambient temperature of 25°C and with 21% oxygen)
Alarms	Oxygen sensor and upper/lower alarm limits

Oxygen supply

Maximum oxygen concentration	≥ 60% (at O_2 flow rate of 10L/min)
Time to maximum blood concentration	≤ 30 min (from 21-55% at O_2 flow rate of 10L/min)

Environment

CO_2 concentration in the hood	≤0.5% when a 4% mixture of CO_2 in the air is delivered at 750mL/min at a point 10cm above the center of mattress

Pulse oximeter[*1, 5, 6, 7] (Masimo pulse oximeter)

The following specifications apply to the IncuArch used with the sensors and patient cables we specify.
For information on the sensor and the patient cable specified by Atom, contact your local Atom representative.

SpO_2

Display range: 1-100%
Measurement accuracy: During no motion[*2] ±3 digits (70-100%)
During motion[*3] ±3 digits (70-100%)
During low perfusion[*4] ±3 digits (70-100%)
Update cycle: 1 second
Alarm setting range: Upper limit OFF, 50-99% (in 1% increments)[*8]
Lower limit OFF, 45-95% (in 1% increments)[*8]

Pulse rate

Display range: 25-240bpm
Measurement accuracy: During no motion[*2] ±3 digits (25-240bpm)
During motion[*3] ±5 digits (25-240bpm)
During low perfusion[*4] ±3 digits (25-240bpm)
Update cycle: 1 second
Alarm setting range: Upper limit OFF, 80-235bpm (in 5bpm increments)[*8]
Lower limit OFF, 35-180bpm (in 5bpm increments)[*8]

Sensor characteristic

Wavelength: 660nm (red light), 905nm (infrared light)
Brightness: ≤15mW
Non-sterile, latex-free

Mode setting

Averaging time: 2, 4, 8, 10, 12, 14, 16 sec (selectable)[*8]
(Factory default: 8 sec)
Sensitivity setting: APOD, Normal (normal sensitivity), Max (high sensitivity)[*8] [*9]
(Factory default: Normal)

*1 This device is calibrated to functional oxygen saturation.

*2 The pulse oximeters have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

✻3 The pulse oximeters have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2-4Hz at an amplitude of 1-2cm and a non-repetitive motion between 1-5Hz at an amplitude of 2-3cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

✻4 In a laboratory test, in the range of 70-100% SpO_2, accuracy in low perfusion conditions were checked against the Biotec Index2 Simulator and the Masimo Simulator, both of whose signal strength is 0.02% or more and permeability 5% or more. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

✻5 The materials accessible to the patient and the user comply with ISO 10993-1.

✻6 All the sensors and patient cables that can be used with this device have been tested and verified by using the Masimo/MX series pulse oximeter technology.

✻7 Since the measurements taken by the pulse oximetry equipment are statistically distributed, only about two-thirds of them fall in the accuracy range (ARMS) of values obtained with a CO-oximeter.

✻8 Even if the power supply is interrupted due to power failure, disconnection of the power plug or some other cause, the preselected settings will be retained in the memory. When the power supply is resumed, the unit will start operation with the last selected settings.

✻9 The Max sensitivity setting will not be stored in the unit. After a power off and on cycle, the sensitivity will change from the "Max" to "Normal" (see "9-1-6. Setting the Sensitivity Mode").

■ Pulse oximeter*1, 4, 5 (Nellcor pulse oximeter)

The following specifications apply to the IncuArch used with the sensors and patient cables we specify.
For information on the sensor and the patient cable specified by Atom, contact your local Atom representative.

SpO_2	Display range: 1-100% Measurement accuracy: During no motion*2 ±3 digits (70-100%) During low perfusion*3 ±3 digits (70-100%) Update cycle: 2 second Alarm setting range: Upper limit OFF, 50-99% (in 1% increments)*6 Lower limit OFF, 45-95% (in 1% increments)*6
Pulse rate	Display range: 25-240 bpm Measurement accuracy: During no motion*2 ±3 digits (25-240bpm) During low perfusion*3 ±3 digits (25-240bpm) Update cycle: 2 second Alarm setting range: Upper limit OFF, 80-235bpm (in 5bpm increments)*6 Lower limit OFF, 35-180bpm (in 5bpm increments)*6
Sensor characteristic	Wavelength: 660nm (red light), 900nm (infrared light) Brightness: <15mW EOG sterilization, latex-free
Mode setting	Response mode: Normal, Fast*6 (Factory default: Normal)

✻1 This device is calibrated to functional oxygen saturation.

✻2 SpO_2 measurement accuracies were validated with healthy recruited volunteers from the local population. Subjects comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Accuracy specifications are based on controlled hypoxia studies with healthy non-smoking adult volunteers over the specified SpO_2 range(s). Pulse oximeter SpO_2 readings were compared with SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1SD. Pulse oximeter equipment measurements are statistically distributed; about two-thirds of pulse oximeter measurements are expected to fall in this accuracy (Arms) range. Because scatter and bias of pulse oximeter SpO_2 and blood SaO_2 comparison commonly increase as the saturation decreases, and accuracy specifications are calculated from data spanning the stated range, different accuracy values may result when describing partially overlapping ranges.

✻3 Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03-1.5%) were validated using signals supplied by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared with the known true saturation and pulse rate of the input signals.

✻4 The materials accessible to the patient and the user comply with ISO 10993-1.

✻5 All the sensors and patient cables that can be used with this device have been tested and verified by using the Nellcor/NELL-1 module pulse oximeter technology.

✻6 Even if the power supply is interrupted due to power failure, disconnection of the power plug or some other cause, the preselected settings will be retained in the memory. When the power supply is resumed, the unit will start operation with the last selected settings.

[15] Device Characteristics - EMC Level and Classification

Guidance and manufacturer's declaration – electromagnetic emissions		
The IncuArch is intended for use in the electromagnetic environment specified below. The customer or the user of the IncuArch should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The IncuArch uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The IncuArch is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions* IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions* IEC 61000-3-3	Complies	
✻ There are no prescribed demands for tests in 100V areas.		

Guidance and manufacturer's declaration – electromagnetic immunity			
The IncuArch is intended for use in the electromagnetic environment specified below. The customer or the user of the IncuArch should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IncuArch requires continued operation during power mains interruptions, it is recommended that the IncuArch be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The IncuArch is intended for use in the electromagnetic environment specified below. The customer or the user of the IncuArch should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz outside ISM bands*[a]	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the IncuArch, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
	10Vrms 150kHz to 80MHz in ISM bands*[a]	10Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz The equipment continues to perform its intended function. 10V/m 80MHz to 2.5GHz The equipment continues to perform its intended function or stops without causing any harm.	10V/m*[c]	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).*[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,*[d] should be less than the compliance level in each frequency range.*[e] Interference may occur in the vicinity of equipment marked with the following symbol.: 
Note 1: At 80MHz and 800MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

✻a The ISM (industrial, scientific, and medical) bands between 150kHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

✻b The ISM compliance level in the ISM frequency band between 150kHz and 80MHz and in the frequency range 80MHz to 2.5GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

✻c Halted with an alarm sounding without any harm being caused.

✻d Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IncuArch is used exceeds the applicable RF compliance level above, the IncuArch should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IncuArch.

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

Recommended separation distances between portable and mobile RF communications equipment and the IncuArch

The IncuArch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IncuArch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IncuArch as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150kHz to 80MHz outside ISM bands $d = 1.2\sqrt{P}$	150kHz to 80MHz in ISM bands $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific, and medical) bands between 150kHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for the transmitters in the ISM frequency band between 150kHz and 80MHz and in the frequency range 80MHz to 2.5GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

ATOM MEDICAL CORPORATION
18-15, Hongo 3-chome, Bunkyo-ku, Tokyo, Japan
Tel: +81 3 38152311 Fax: +81 3 38123144

201703