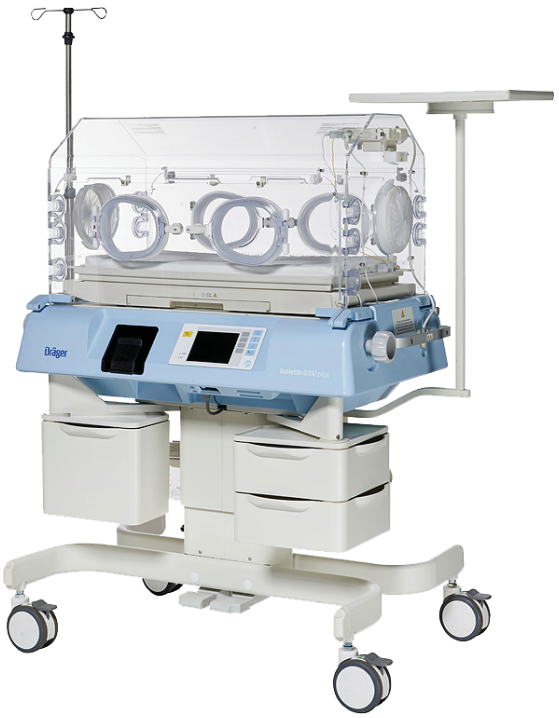
Instructions for use

Isolette 8000 plus



WARNING

To properly use this medical device, read and comply with these instructions for use.

Incubator
Software 5.n

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Contents

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1 Information about these instructions for use

1.1 Typographical conventions

1	Consecutive numbers indicate steps of action, with the numbering restarting with "1" for each new sequence of actions.
●	Bullet points indicate individual actions or different options for action.
–	Dashes indicate the listing of data, options, or objects.
(A)	Letters in parentheses refer to elements in the related illustration.
A	Letters in illustrations denote elements referred to in the text.
►	Preventive measures in a safety message.
>	The greater-than symbol indicates the navigation path in a dialog window.
⇒	Result of a step.
✓	Final result of a sequence of steps.
	Indicates information that makes it easier to use the product.

Bold, italicized text indicates labels on the device and texts that are displayed on the screen.

1.1.1 Use of terms

Dräger uses the term "accessories" not only for accessories in the sense of IEC 60601-1, but also for consumables, removable parts, and attached parts.

1.1.2 Illustrations

Illustrations of products and screen content in this document may differ from the actual products depending on configuration and design.

1.2 Trademarks

1.2.1 Trademarks owned by Drager

Trademark
Infinity®
Isolette®
Kangaroo mode®
MEDIBUS.X®
SoftBed™
Thermomonitoring®
ThermoPad™

Trademark
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The following web page provides a list of the countries in which the trademarks are registered: www.draeger.com/trademarks

1.2.2 Trademarks owned by third-party manufacturers

Trademark	Trademark owner
terralin protect	Schülke & Mayr
Google Earth	Google
Actichlor plus	Ecolab
BruTab 6S	Brulin
Clorox Professional	Clorox
Dispatch Hospital Cleaner Disinfectant Towels with Bleach	
Klorsept 17	Medentech
Descogen Liquid	Antiseptica
Descogen Liquid r.f.u.	
Neodisher	Chemische Fabrik Dr. Weigert GmbH & Co. KG

1.3 Information on safety instructions and precautionary statements

Safety instructions and precautionary statements warn of risks and give instructions for the safe use of the product. Failure to observe them may lead to personal injury or property damage.

1.3.1 Safety instructions

This document contains sections with safety instructions that warn of risks. The type of risk and the consequences of non-compliance are described in each safety instruction.

1.3.2 Precautionary statements

Precautionary statements relate to process steps and warn of risks that may arise when executing the process steps. Precautionary statements precede the process steps.

The following warning signs and signal words indicate precautionary statements and differentiate the possible consequences of noncompliance.

Symbol	Signal word	Consequences of non-compliance
⚠	**WARNING**	May result in death or serious injury.
⚠	**CAUTION**	May result in moderate or minor injury.
	NOTICE	May result in property damage.

1.3.3 Informational statements

An informational statement provides additional information intended to avoid inconvenience during operation.

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2 For your safety and that of your patients

2.1 Information on safety instructions and precautionary statements

The following WARNING and CAUTION statements apply to general operation of the medical device.

WARNING and CAUTION statements specific to subsystems or particular features of the medical device appear in the respective sections of these instructions for use or in the instructions for use of another product being used with this medical device.

2.2 Basic safety instructions

2.2.1 Strictly follow these instructions for use

Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.

- ► Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under Intended use on page 25 and with appropriate patient monitoring (see page 13).
- ► Strictly observe all precautionary statements throughout these instructions for use and all statements on medical product labels.
- ► Instructions for use must be kept accessible to the user.

2.2.2 Restrictions for use

- ► Device for use in healthcare facilities only and exclusively by persons with specific training and experience in its use.

2.2.3 Service

If service is not performed regularly, malfunctions may occur, which can result in personal injury and property damage.

- ► Observe chapter Service.
- ► The medical device must be inspected and serviced regularly by service personnel. Repair and complex maintenance carried out on the medical device must be performed by specialized service personnel.
- ► Dräger recommends that a service contract is obtained with DrägerService and that all repairs are performed by DrägerService. For maintenance, Dräger recommends the use of authentic Dräger repair parts.
- ► Do not service the device while the patient is in the incubator.
- ► Assess system components for signs of loosened fasteners according to specified inspection intervals. See Inspection on page 148. Secure if necessary.

2.2.4 Safety checks

The medical device must be subject to regular safety checks. See chapter Service.

2.2.5 Safety during cleaning and service

2.2.5.1 Risk of infection

Users and service personnel can become infected with pathogens.

► Disinfect and clean the device thoroughly before using it for the first time, and then once a week and every time the patient changes.

2.2.5.2 Risk due to inappropriately reprocessed products

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

► Observe the hygiene regulations and reprocessing regulations of the healthcare facility.

► Observe national hygiene regulations and reprocessing regulations.

► Use validated procedures for reprocessing.

► Reprocess reusable products after every use.

► Observe the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.

2.2.6 Essential performance characteristics

The essential performance consists of:

– Skin temperature regulation
  – The skin temperature setting (target value) is compared to the actual central skin temperature which is regulated, or an alarm is generated.
– Air temperature regulation
  – The incubator air temperature setting (target value) is compared to the actual incubator air temperature which is regulated or an alarm is generated.

The medical device is equipped with basic safety features to reduce the possibility of patient injury while the cause of an alarm is remedied.

2.2.7 Modifications to the product

Modifications to the product may lead to malfunctions and unforeseen risks. This may result in injury to the patient or the user or in property damage.

► Do not modify this product.

► If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

2.2.8 Accidental disconnect

Catheters, breathing hoses, sample lines, lead wires, or cables could become accidentally disconnected.

► To allow for the full range of mattress height adjustment, secure all lead wires, infusion lines, and ventilator hoses to the mattress with sufficient excess length.

► Use caution when opening doors fitted with hose grommets.

Possible trip and fall hazards.

► Always properly secure the power cable.

2.2.9 Training

Training for users is available from the Dräger organization, see www.draeger.com.

Incubator misuse may result in harm to an infant.

► Only properly trained personnel should use the incubator as directed by an appropriately qualified attending physician aware of currently known risks and benefits.

2.2.10 Use of temperature probes

Using incorrect temperature probes can negatively impact device performance.

► For proper operation of the incubator, use only skin temperature probes from Dräger, identified on the list of accessories.

2.2.11 Patient safety

The design of the medical device, the accompanying documentation, and the labeling on the medical device are based on the assumption that the purchase and the use of the medical device are restricted to persons familiar with the most important inherent characteristics of the medical device.

Instructions and precautionary statements are therefore limited to the specifics of the Dräger medical device.

The instructions for use do not contain any information on the following points:

– Risks that are obvious to users
– Consequences of obvious improper use of the medical device
– Potentially negative effects on patients with different underlying diseases

Medical device modification or misuse can be dangerous.

Risk of patient injury.

► Do not make therapeutic decisions based solely on individual measured values and monitoring parameters.
► To make therapeutic decisions, also use visual assessment of patient and medical expertise.

Accidental opening could occur.

► Do not raise the hood at any time while the infant is in the incubator.
► Gain access to the infant through the access panels and hand ports.
► Secure all hand port latches and access panel locking knobs.
► For infant safety, do not leave the infant unattended when the access panels or hand ports are open.
► Do not use the device if access panels are removed or broken.

2.2.12 Patient monitoring

The user of the medical device is responsible for choosing a suitable patient monitoring system that provides appropriate information on medical device performance and patient condition.

Patient safety can be achieved by a wide variety of means ranging from electronic surveillance of medical device performance and patient condition to direct observation of clinical signs.

The responsibility for selecting the best level of patient monitoring lies solely with the user of the medical device.

2.2.13 Safe connection with other electrical equipment

Unapproved electrical connections can lead to patient injury or device failure.

► Electrical connections to equipment not listed in these instructions for use or these assembly instructions must only be made when approved by each respective manufacturer.

2.3 Target groups

2.3.1 Duties of the operating organization

The tasks described in this document specify the requirements that have to be met by each respective target group.

The operating organization of this product must ensure the following:

– The target group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).
– The target group has been trained to perform the task.
– The target group has read and understood the chapters required to perform the task.

2.3.2 Description of target groups

The target groups may only perform the following tasks if they meet the corresponding requirements.

2.3.2.1 User

Task	Requirement
Use of the product in accordance with the intended use	Specialist medical knowledge in neonatology
Use of the product in accordance with the intended use	Specialist medical knowledge in the use of the product

2.3.2.2 Reprocessing personnel

Task	Requirement
Reprocessing	Specialist knowledge in the reprocessing of medical devices

2.3.2.3 Service personnel

Task	Requirement
Installation	Experience in the servicing of medical devices
Basic service work (inspection, maintenance according to the "Maintenance" chapter)	

2.3.2.4 Specialized Service Personnel

Task	Requirement
Basic and complex service work (inspection, maintenance, repair)	Specialist knowledge in electrical engineering and mechanics Experience in the servicing of medical devices Experience in complex service work on this product

Dräger recommends arranging a service contract with DrägerService.

2.4 Safety instructions for accessories

2.4.1 Accessories

The use of incompatible accessories may adversely affect the functional integrity of the product causing a risk of patient injury due to medical device failure. Property damage may also occur as a consequence.

- ► Dräger has tested the compatibility only of accessories listed in the current list of accessories.
- ► Dräger recommends that the medical device is only used together with accessories listed in the current list of accessories.
- ► Use only compatible accessories. The accessories that are compatible with this product are listed in the list of accessories supplied with the product.
- ► Do not use single-use components or accessories if packaging is damaged.

2.4.2 Reusing or reprocessing accessories

Reusing, reprocessing, or sterilizing disposable products can lead to a failure of the medical device and cause injury to the patient.

- ► Do not reuse, reprocess, or sterilize disposable products. Disposable products were designed, tested, and manufactured for one-time use only.

2.4.3 Installing accessories

Installing accessories incorrectly can lead to device failure.

- ► Strictly observe instructions for use and assembly instructions.
- ► Install accessories to the basic device in accordance with the instructions for use of the basic device.

► Make sure that there is a safe connection to the basic device.

Installing accessories incorrectly can lead to compromised hygienic safety.

► Ensure the cover is installed on the mattress before use and before reusing after cleaning.

2.5 Electrical safety

The potential for electrical shock exists when electrical equipment is used. To avoid the risk of personal injury and property damage, the following preventive measures must be taken:

► The maximum total earth leakage current of the system, including all items plugged into the auxiliary mains outlets and any items plugged into external sockets, must not exceed 500 µA.

► Establish policies and procedures to educate your staff on the risks associated with electrical equipment.

► Due to the risk of electrical shock, only properly trained personnel with appropriate service documentation should service the device.

► To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective grounding.

► To prevent damage to the device or accidental power disconnections, do not connect a power cable from the incubator controller directly to an AC wall connection.

► Always provide power to the incubator by using the power cable coming directly from the trolley.

► Do not connect the Isolette 8000 plus to a surge suppressor.

► Do not reset circuit breakers or replace fuses without assessing and correcting what caused the circuit breaker or fuse to activate.

► Power cables must be accessible if it becomes necessary to quickly disconnect from the main power.

► Additional equipment connected to the patient must be electrically safe.

2.5.1 EMC precautions

The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

► All medical accessory equipment in the patient vicinity must comply with the safety requirements of IEC 60601-1 and must have the relevant safety certifications.

► The equipment shall not be used near other devices unless normal operation is verified in the configuration in which it is to be used.

► Use of accessories other than what is listed and approved for use in this product as original or replacement items may result in increased electromagnetic emissions or decreased electromagnetic immunity.

► Devices connecting to the serial port must be compliant with IEC60601-1-2, the EMC requirement for Medical Devices.

► The incubator display may go blank during an episode of static discharge to the sensor module.

► Medical electrical equipment needs special precautions regarding EMC and must be installed and put into service according to the EMC information provided in this manual.
► In addition, portable and mobile RF communications equipment can affect medical electrical equipment.

2.5.2 Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility. Observe the EMC information during installation and initial operation. For further information, see the following section: "EMC Declaration" (page 172).

Portable and mobile high-frequency communication equipment can affect medical electrical equipment.

To avoid the risk due to electromagnetic interference, malfunctions that endanger the patient may occur if no protective measures against electrostatic discharge are employed in the following situations:
► When touching the pins of connectors that carry the ESD warning symbol.
► When establishing connections with these connectors.

To prevent malfunctions, observe the following measures and train the relevant personnel:
► Observe the ESD protective measures. Such measures may include wearing anti-static clothing and shoes, touching a potential equalization pin before and while making the connection, or using electrically insulating and anti-static gloves.
► Observe the requirements for the electromagnetic environment. Observe the following section: "Electromagnetic immunity" (page 172).

Electromagnetic fields may interfere with the device function and consequently endanger the patient. Electromagnetic fields are generated by, e.g.:
– Cellular phones
– High-frequency electrosurgical equipment
– Defibrillators
– Shortwave therapy equipment
► Maintain the separation distances. Observe the following section: "Recommended separation distances to portable and mobile radio frequency communication devices" (page 172).
► Do not use device in MRI environment.

2.5.3 Anti-static castors

Castor wheels do not control all the ESD characteristics of the device on which they are mounted. They do, however, prevent the build-up of charge on the wheels from friction during motion.
► ESD is a product of the environment and only the user/owner can control the ESD in that environment. Control is accomplished by maintaining a conductive floor, equipping employees with ESD clothing and control devices, etc.

2.6 Explosion protection

Use of the device in areas of explosion hazard can lead to patient injury or device failure.

► Do not use the device in areas where combustible or explosive gas mixtures are present. The medical device is not approved for use in areas where combustible or explosive gas mixtures are likely to occur.

2.6.1 Flammable anesthetics

In the presence of oxygen concentrations greater than 25 Vol%, combustible or explosive gas mixtures, there is an increased risk of explosion and fire, which may lead to personal injury and property damage.

► Do not use in the presence of flammable anesthetics.

2.6.2 Combustibles

Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

► Keep matches, and all other sources of ignition, out of the room in which the incubator is located.

2.6.3 Other flammable agents

Small quantities of flammable agents, such as ether and alcohol, left in or around the incubator may result in a risk of fire in oxygen-enriched environments.

► Ensure that the patient compartment is free of such agents.

► Ensure that there is adequate ventilation to avoid accumulating oxygen around the incubator.

2.6.4 Cleaning

A fire and explosion hazard exists when cleaning or performing maintenance procedures in an oxygen-enriched environment.

► Make sure that the oxygen supply is turned off and the oxygen hose to the incubator is disconnected when cleaning and performing maintenance procedures. Switch off or disconnect oxygen supplies during periods of non-use.

► Ensure that oxygen connectors are free from grease and oil.

Misuse of cleaning products can be dangerous.

► Use all cleaning products as recommended by their respective manufacturers.

A shock hazard exists when performing cleaning and maintenance procedures on powered devices.

► Unplug the device from its power source before cleaning or maintenance.

Penetrating liquid may cause the following: damage to the device, electric shock, device malfunctions.

► Ensure that no liquid penetrates the device.

2.6.5 High-pressure oxygen

If their ignition temperature is reached, violent ignition of oil, grease, greasy substances, small particles or dust, dirt, or other particulate contaminants, even small particles of metal, could occur in the presence of high-pressure oxygen.

► Take care when using high-pressure oxygen, such as that found in medical oxygen cylinders.

2.7 Use of oxygen

2.7.1 Oxygen supply

Improper use of supplemental oxygen may be associated with serious side effects including blindness, brain damage, and death. The risks vary with each infant.

► The qualified attending physician should prescribe the method, the concentration, and the duration of oxygen administration.

► If it is necessary to administer oxygen in an emergency, notify the attending physician immediately.

► Disconnect the incubator from the hospital oxygen source when oxygen is not in use.

► Do not place auxiliary equipment that produces sparks in an incubator.

► The administration of oxygen may increase the noise level for the baby within the incubator.

► In patient compartment, use only electrical devices that are approved for use in an oxygen-enriched atmosphere.

► Be aware that oxygen delivered to the patient is not humidified.

2.7.2 Oxygen concentration

The oxygen concentration inspired by an infant does not accurately determine the partial pressure of oxygen (pO_2) in the blood.

► When deemed advisable by the attending physician, measure blood pO_2 by accepted clinical techniques.

► After each change of oxygen flow, allow at least 30 min to achieve new concentrations.

Oxygen levels within the hood environment may be affected when the hand ports or access panels are opened.

► Make sure that all hood hand port gaskets and hose grommets are properly installed. Any open gaps in the hood may reduce the incubator internal oxygen.

2.7.3 Oxygen cylinders

If the gas is released rapidly due to damage or other causes, compressed gas cylinders, such as oxygen cylinders, can become hazardous projectiles.

► Securely fasten the cylinder.

► Consult the facility gas cylinder safety procedures for the correct method to use gas cylinders.

2.7.4 Oxygen sensors

The oxygen sensor is a sealed unit that contains potassium hydroxide electrolyte. Failure to comply with the following precautionary measures could lead to death or serious injury.

- ► If the sensor develops a leak, discard it immediately.
- ► If contact with the skin or clothing occurs, rinse the area with a large quantity of water.
- ► In case of eye contact, flush the eye immediately for at least 15 min, holding the eye open, and call a physician.
- ► Use only Dräger Medical recommended oxygen sensors for proper operation.

2.7.5 Oxygen maintenance

The use of poorly maintained oxygen components increases the risk of fire and could lead to death or serious injury.

- ► Inspect gas/oxygen components at regular preventive maintenance intervals for signs of corrosion or damage.
- ► Routinely inspect oxygen cells for signs of degradation or leakage, and replace if necessary.

2.7.6 Oxygen monitoring

Use of anesthetic agents can interfere with the accuracy of an oxygen analyzer.

- ► Routinely monitor oxygen using an oxygen analyzer.

2.8 Use of humidity

2.8.1 Open gaps in the hood

Any open gaps in the hood reduce the incubator internal relative humidity.

- ► Make sure that all hand port gaskets and hose grommets are properly installed on the hood.

2.8.2 Water spillage

Water spillage may occur.

- ► Fill the reservoir to the maximum filling limit line.
- ► Do not overfill.
- ► When using high levels of humidity, Dräger recommends using the optional condensation management system.

2.9 Temperature stabilization

2.9.1 Open access panels

When the front or rear access panel is open, the temperature display may not accurately reflect the incubator temperature.

- ► Do not leave the access panel open longer than essential.

► Using infant seats or other accessories or optional components within the incubator can alter the airflow pattern. This practice may affect temperature uniformity, temperature stability, the correlation of the incubator temperature reading to center mattress temperature, and infant skin temperature.
► Use only Dräger-approved accessories.

2.9.2 Blocked ventilation slots

If ventilation slots in the incubator are blocked during clinical usage, patient safety and incubator performance may be compromised.
► Keep the ventilation slots clear of obstructions, such as blankets, positioning aids, and cuddly toys.

Failure to comply could cause death or serious injury.
► Do not insert any object into any of the ventilation holes or any other opening on the Isolette 8000 plus.

2.9.3 Air curtain

When the access panels are open, a curtain of warm air flows along the length of the mattress toward the top of the access panel openings. The temperature of this air curtain is higher than the typical incubator air temperature.
► Keep the infant clear of this warm air path.

Interference with the warm air curtain or side vents may cause heat-induced injury and burns.
► If using surgical covers or blankets over the infant, ensure that they do not interfere with the warm air curtain or side vents.

2.9.4 Overheating risk

Overheating the infant due to direct radiation and increased incubator temperature could occur.
► Do not position the incubator in direct sunlight or under other sources of radiant heat.

2.9.5 Kangaroo mode

Temperature of infants outside the incubator can fluctuate.
► When using kangaroo mode, the central temperature of the infant who is outside the controlled climate of the incubator must be monitored constantly.
► Particular attention must be paid to critical care O_2 vital signs, especially a critical O_2 partial pressure.
► Ensure that all cables and hoses are routed correctly and safely.

2.10 Use of phototherapy

2.10.1 Temperature monitoring

Use of phototherapy devices with the incubator may affect hood wall temperature, incubator temperature, and infant skin temperature.

► Monitor incubator temperature during phototherapy.
► Monitor infant skin temperature during phototherapy.
► Position phototherapy device according to manufacturer instructions.

2.10.2 Interference with height adjustment

Phototherapy lights placed over the top of the hood may interfere with upward travel of the height adjustment trolley.

► To prevent this interference, always remove the phototherapy light before positioning the incubator trolley.

2.11 Mechanical safety

2.11.1 Moving the incubator

Correct preparation of the incubator before moving can prevent injuries and damage to the device.

► Always use 2 people when moving the incubator and patient together.

When moving the incubator within the same floor space:

► Check that the patient is secured safely in the device
► Remove or secure all loose system components
► Lower the height adjustment trolley, IV pole, and shelves to their lowest position
► Do not use the IV pole or shelf to move the incubator. Use the handles.
► Close all drawers
► Remove all components from the rails

► Before moving the device, always ensure that the mattress is level, i.e., not in the Trendelenburg or Reverse Trendelenburg position.

2.11.2 Trendelenburg safety

Safe movement of the bed can prevent injuries.

► To place the bed in Trendelenburg or Reverse Trendelenburg, always tilt one end of the bed and keep the opposite end in the lowest position.
► Elevating both ends simultaneously is not recommended.

Avoiding pinch hazards can prevent injuries or death.

► Before placing the bed in Trendelenburg or Reverse Trendelenburg, ensure that patient extremities are not caught between the bed and the hood walls.

2.11.3 Preventing tip over

The device could tip over.

- ► For optimum stability, always lower the incubator to its lowest position before moving the device.
- ► Make sure that items placed on the utility shelf are properly secured.
- ► For optimum incubator stability, always lock all trolley wheels.
- ► Do not leave the device unattended when parking on an incline.
- ► Always close drawers when not in use, particularly when the incubator is being moved.
- ► The drawers and rail system are labeled for acceptable weights. Do not exceed these weight limitations.
- ► Optional components such as trays, baskets, and shelves should not be used to hold an infant.
- ► Do not overload.

If the wheels encounter any obstacle, lateral or angular movement (across the width) can result in inadvertent tip-over.

- ► Always push or pull the incubator forward or backward in a straight line along the length of the trolley (from the ends).

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3 Application

3.1 Intended use

The Isolette 8000 plus incubator provides a controlled environment for both premature and full-term babies up to a maximum of 10 kg (22 lb). It controls temperature, oxygen (optional), and humidity (optional).

3.2 Environment of use

The Isolette 8000 plus incubator can be used in any department of the hospital that provides neonatal and infant care, including all levels of the Neonatal Intensive Care Unit (NICU), Special Baby Care Unit, Step Down Nursery, Newborn Nursery, and Pediatrics.

3.3 Indications/contraindications

The Isolette 8000 plus incubator is indicated for thermoregulation and controlling oxygen (optional), and humidity (optional).

The Isolette 8000 plus incubator is not intended for home use.

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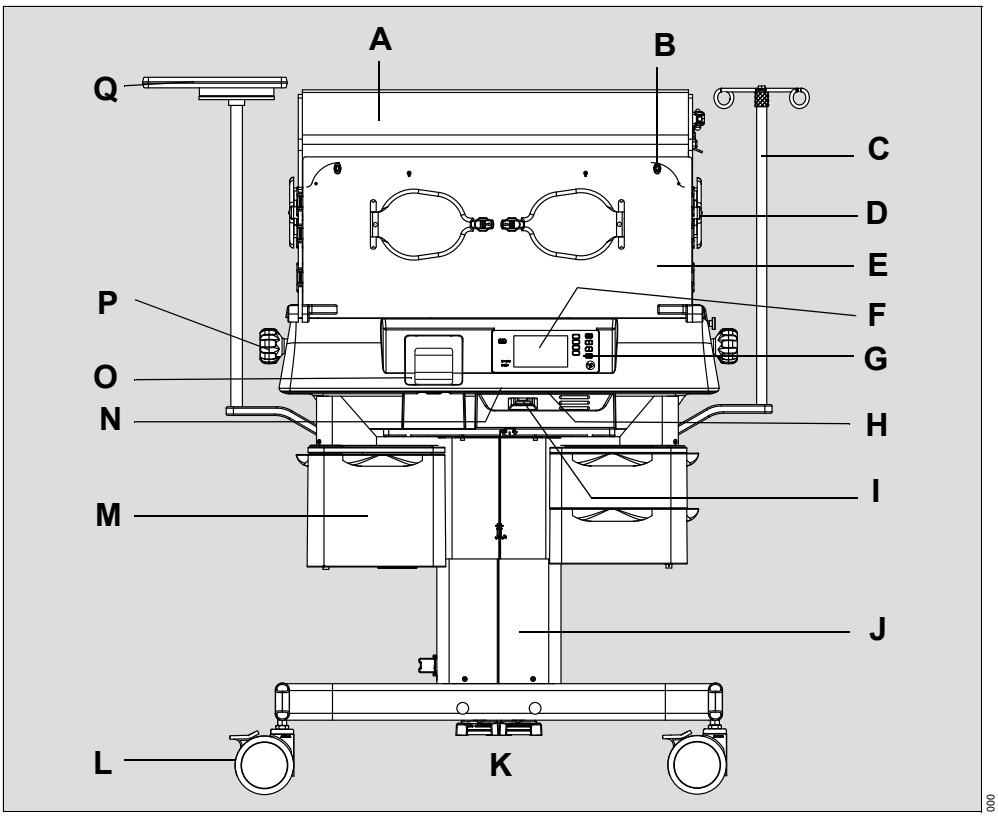
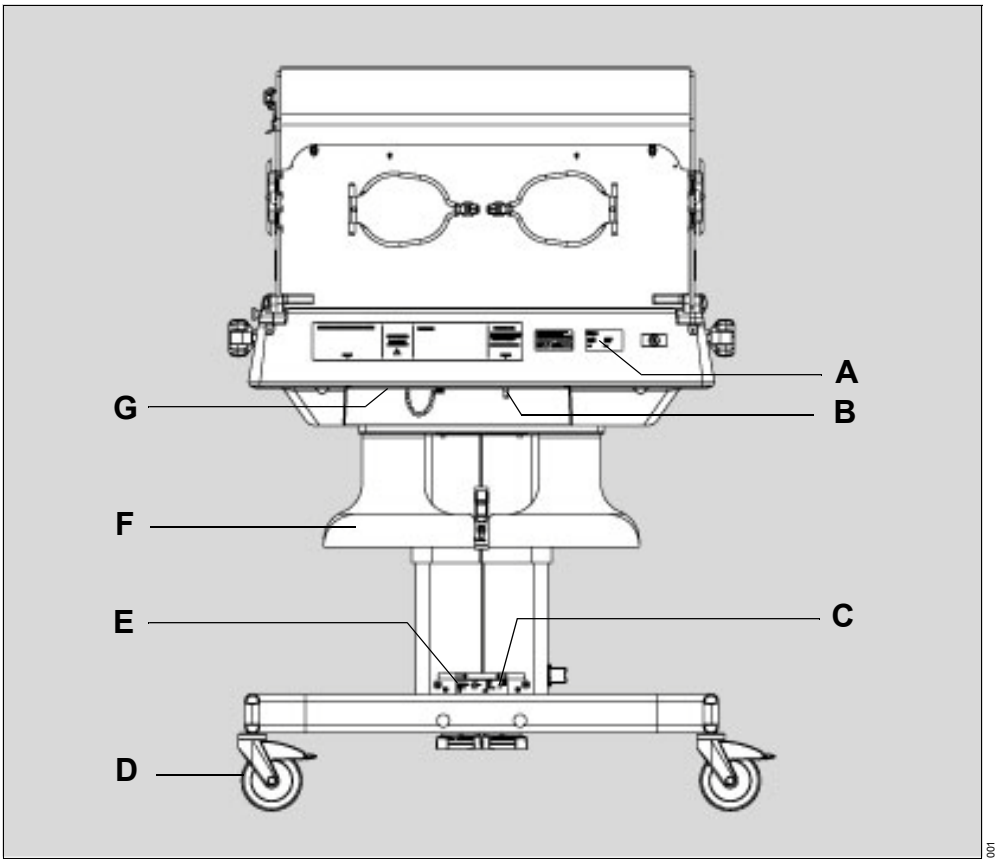
4 Overview

4.1 Front view



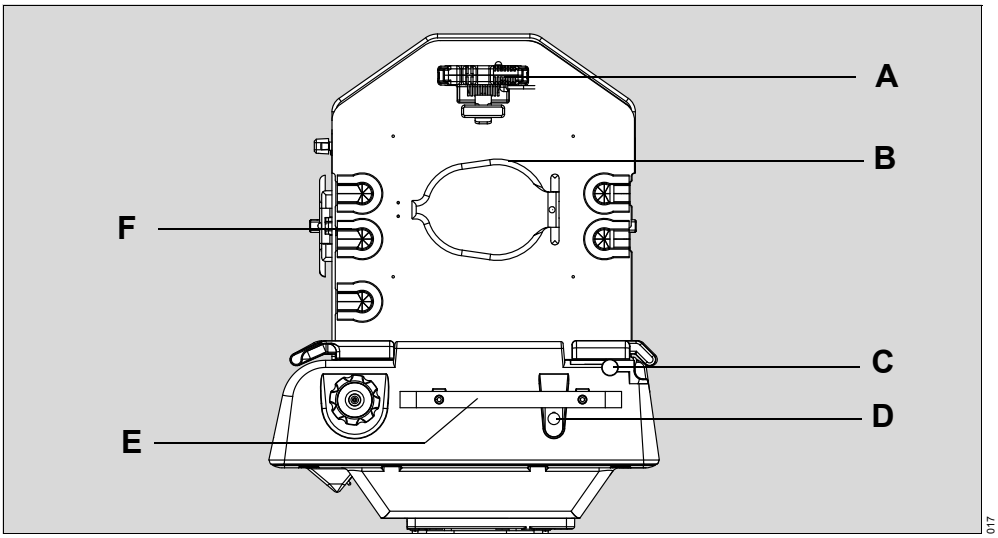
A	Hood	J	Trolley with height adjustment
B	Locking knob	K	Height adjustment controls
C	IV pole (optional)	L	Castor wheels (with brakes)
D	Hand port	M	Drawers (optional)
E	Access panel	N	Incubator power cable receptacle
F	Screen	O	Water reservoir (optional)
G	Front panel of controller	P	Trendelenburg bed-tilt knob
H	Serial port	Q	Monitor shelf (optional)
I	Incubator on/off switch		

4.2 Rear view



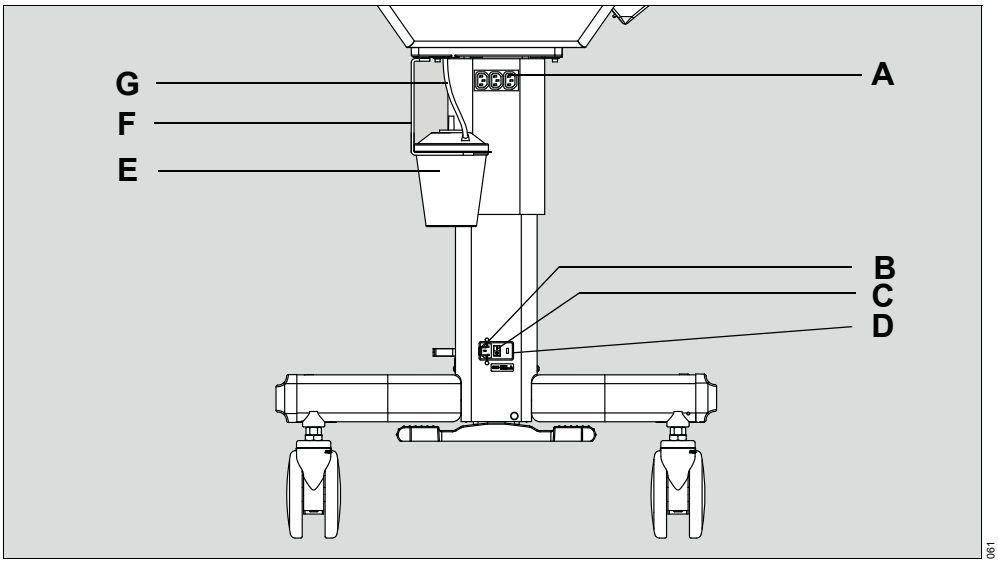
A Incubator rating plate
B Oxygen inlet
C Height adjustment trolley rating plate
D Steering castor wheel
E Cable wrap
F Cylinder mount (optional)
G Air inlet filter

4.3 Right side view



A Sensor module
B Oval hand port (or optional iris port)
C Hood release knob
D Controller/sensor module interface connector
E Accessory rail/handle
F Hose grommets

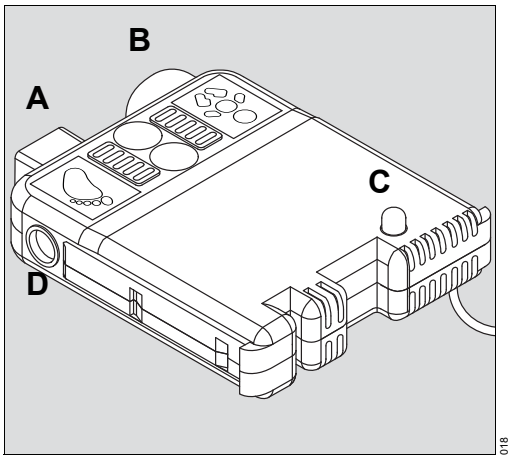
4.4 Left side view



A Auxiliary power sockets
B Power cable receptacle
C Main on/off switch
D Fuse holder
E Collection bottle for condensation management (optional)
F Bracket for condensation management (optional)
G Hose for condensation management (optional)

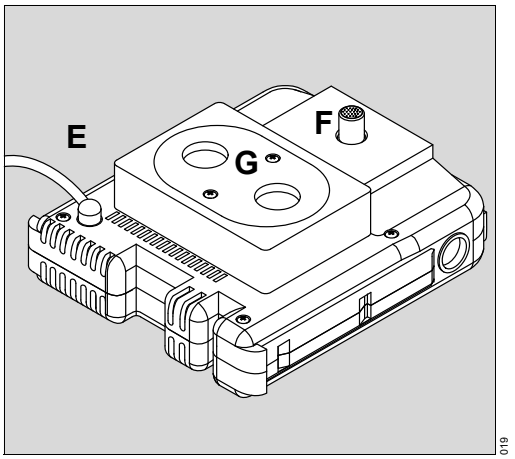
4.5 Sensor Module

4.5.1 Top view



A Peripheral skin probe connector
B Central skin probe connector
C Alarm indicator
D Scale connector

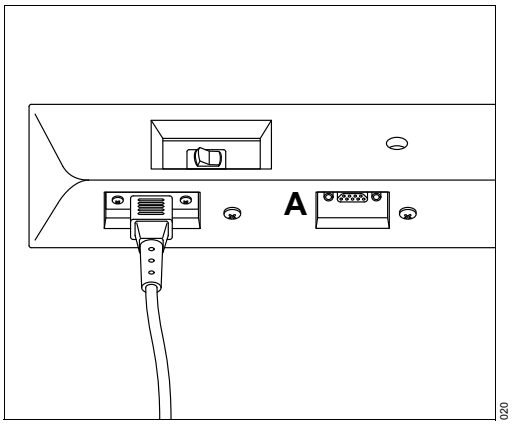
4.5.2 Bottom view



E Controller interface cable
F Air, temperature, and humidity sensor housing
G Oxygen sensor housing

4.6 External devices

The Isolette 8000 plus has a serial port (A) that provides an isolated communication link between the incubator and an external device, such as, a central monitoring system or a patient monitor. The serial port has 2 communication options, serial data, or MEDIBUS.X. The port is located underneath the incubator shell on the front of the device.

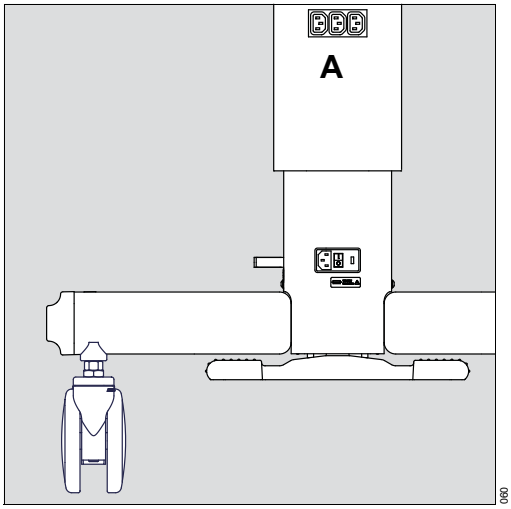


⚠ WARNING
Risk of death or serious injury
Noncompliance may result in death or serious injury.
► Devices connecting to the serial port must be compliant with IEC60601-1-2, the EMC requirement for medical devices, and IEC60601-1.

⚠ WARNING
Risk of electric shock
The potential for electrical shock exists with electrical equipment.
► Connect external devices to the interfaces only while the incubator is properly grounded. Grounding can be achieved by its power cable and a grounded wall terminal unit, or by the grounding pin on the rear of the control unit.

4.7 Auxiliary power sockets

Three auxiliary power sockets (A) are on the left side of the height adjustment trolley.



⚠ WARNING
Risk of death or serious injury
Connecting certain electrical equipment to the auxiliary power sockets could negatively alter the medical device resulting in a reduced level of safety, including device malfunction.

► When plugging in items other than items supplied with the system, ensure that the total current does not exceed acceptable limits identified in the technical data.

⚠ WARNING
Risk of reduced level of safety
Connecting other devices to auxiliary power sockets on the Isolette 8000 plus may lead to a reduced level of safety.

► Comply with the requirements of IEC 60601-1 when connecting other devices to auxiliary power sockets on the Isolette 8000 plus.

► Do not use auxiliary power sockets that are separate from the Isolette 8000 plus

⚠ CAUTION
Risk of damage to the device
The total power of all equipment connected to the auxiliary power sockets on the trolley must be within the electrical requirements shown on the trolley.

► Do not exceed the power limit shown on the trolley.

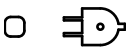
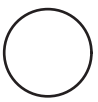
► The maximum total earth leakage current of the system, including all items plugged into the auxiliary mains outlets must not exceed 500 µA.

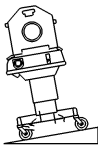
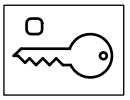
4.8 Abbreviations

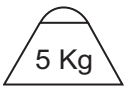
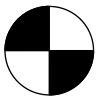
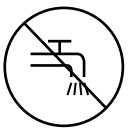
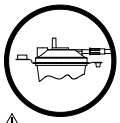
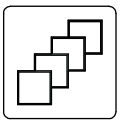
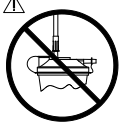
Abbreviations	Meaning
AC	Alternating current
AP	Applied part
DIN	Deutsches Institut für Normung
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
GMDN	Global Medical Device Nomenclature
IEC	International Electrotechnical Commission
IV	Intravenous
LCD	Liquid crystal display
L/min	Liters per minute
MIB	Medical Information Bus
NAWI	Non-Automatic Weighing Instrument
OIML	Organisation Internationale de Métrologie Légale (International Organization of Legal Metrology)
RH	Relative humidity
UMDNS	Universal Medical Device Nomenclature System

4.9 Symbols

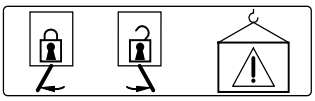
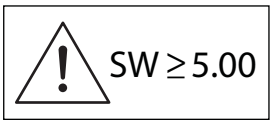
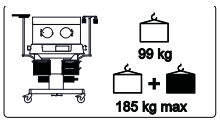
The following symbols appear on labels on the Isolette 8000 plus incubator, on the screen, and in these instructions for use. These standards apply as noted in the table.

Symbol	Meaning	Symbol	Meaning
	Warning		***Power Failure*** alarm
	Caution		Power On
	Refer to instructions for use		Power Off

Symbol	Meaning	Symbol	Meaning
	Caution: Risk of electric shock.		Protective earth (ground)
	Type BF applied part		Earth (ground) / Functional earth
	Not AP rated		Fuse box location
	AC power		Caution: Hot surface
	Weight limit		Indicates relative time remaining in alarm silence period (displayed on the screen)
	Lock castor wheels when parked on an incline		Displays the progress of the weight sampling for scale (displayed on the screen, standard scale only)
	Steering castor wheel		Level indicator mounted on the scale (OIML scale only)
	Castor wheel locked		Keypad lock
	Castor wheel unlocked		Alarm ***Audio Paused/Reset*** key
	Electrostatic discharge (ESD) sensitive part		Do not reuse
	Electromagnetic interference		Maximum level indicator
	Communication port		Half-full level indicator

Symbol	Meaning	Symbol	Meaning
	Access panel open indicator (displayed on screen)		Minimum level indicator
	***Lift Baby*** prompt to lift the infant from the bed (displayed on screen during the zeroing routine)		Lot number
	Revision index		Scale conformity mark
	Serial number		Part number
	Prompt to place a 5-kg weight on the bed (displayed on screen during the calibration routine)		Manufacturer ISO 15223-1 (5.1.3)
	Indicates the active status of a mode of operation (displayed on the screen in the respective windows)		Do not use tap water
	Rotation control		Central skin temperature probe connector
	Do not overfill		Peripheral skin temperature probe connector
	Do not spill		Storage temperature limits
	Correct connection of condensation management hose on the collection bottle		Quantity
	Incorrect connection of condensation management hose on the collection bottle		
	Phthalate present		Use by

Symbol	Meaning	Symbol	Meaning
	Weight limit warning (DIN compatible rails)		Do Not Discard
	EC Rep		Date of manufacture

Symbol	Meaning
	Latch lock/unlock and rail loading warning (Fairfield compatible rails)
	Warning: Use only with software version 5.00 or higher.
	Total mass including safe working load

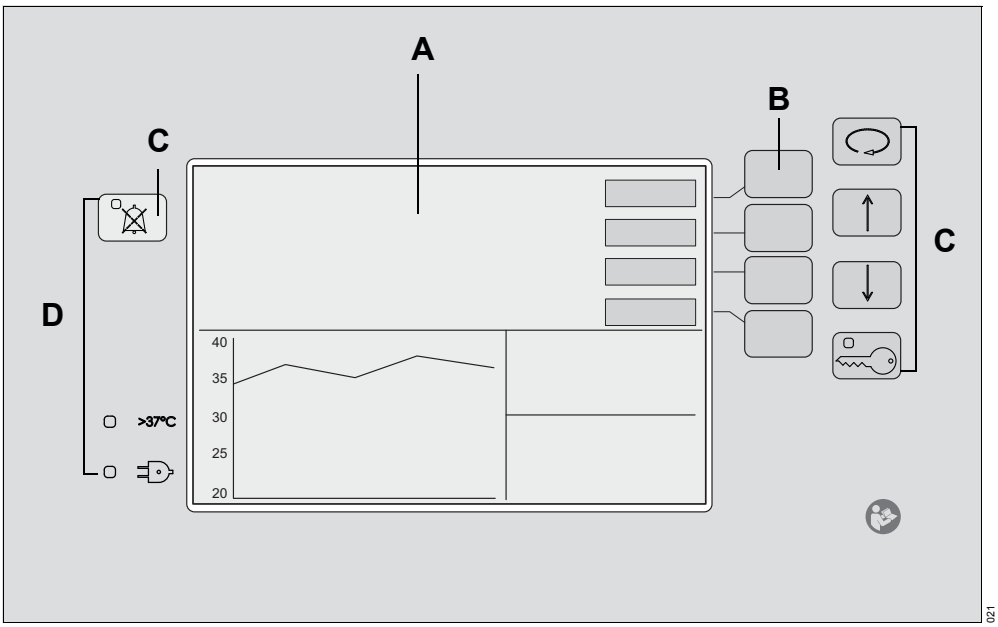
4.10 Technical definitions

Term	Definition
Accuracy of incubator temperature indication	The displayed average incubator temperature versus the actual average temperature in the patient compartment.
Average incubator temperature	The average of the incubator temperature readings, taken at regular intervals, achieved during temperature equilibrium.
Incubator temperature	Temperature of the air at a point 10 cm (4 inches) above the center of the mattress surface in the compartment.
Incubator temperature equilibrium	The condition reached when the incubator temperature does not vary more than 1 °C over a period of one hour (also known as steady temperature condition).
Incubator warm-up time	The time required for the incubator temperature to rise 11 °C (20 °F), when the air set point is at least 12 °C (22 °F) above the ambient temperature.
Set point	The temperature selected by the user at the temperature control (also known as control temperature).
Temperature overshoot	The amount by which the incubator temperature exceeds the average incubator temperature at incubator temperature equilibrium as a result of an increase in set point.
Temperature uniformity	The amount by which the average temperatures at the center of the mattress quadrants, 10 cm (4 in) above the mattress surface, differ from the average incubator temperature at incubator temperature equilibrium.

Term	Definition
Temperature variation (stability)	The variation of the incubator temperature that will be observed over a one hour period after steady temperature condition has been reached.

5 Operating concept

5.1 Front panel of controller



The front panel of the Isolette 8000 plus controller is on the front of the incubator shell assembly. It consists of the following elements:

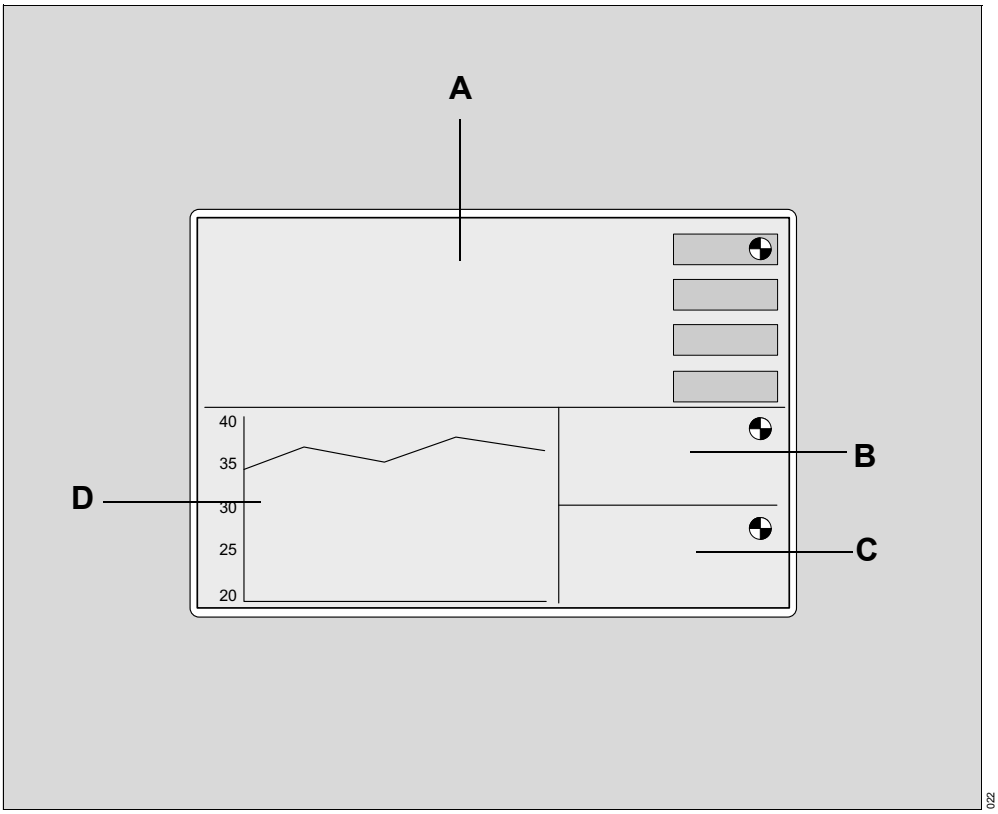
A A screen displaying all patient and system information in numeric and graphic form

B Variable-function keys (referred to as “buttons” in this manual)

C Fixed-function keys (referred to as “keys” in this manual)

D LED indicators

5.2 Screen



The actual screen display may differ in appearance or configuration.

The basic Isolette 8000 plus screen can be toggled between display 1 and display 2. The displays differ in the selection of buttons available in the Temperature window. Both displays are divided into the following 4 windows:

A **Temperature window** - The temperature window displays the actual air and/or skin temperature and the set point of the controlling parameter. It can also display the difference between the central and peripheral skin temperatures if that feature is switched on in the system configuration menu.

B **Humidity window (optional)** - When the humidity mode is activated, the actual and set point humidity values are displayed. A rotating wheel is displayed in the upper right-hand corner of the humidity window.

For systems not configured with humidity, the message ***Not Installed*** is displayed for a few seconds, and then the humidity window remains blank.

C **Oxygen window (optional)** - When the oxygen mode is activated, the actual and set point oxygen values are displayed. A rotating wheel is displayed in the upper right-hand corner of the oxygen window.

For systems configured without servo oxygen, the message ***Not Installed*** is displayed for a few seconds, and then the oxygen window remains blank.

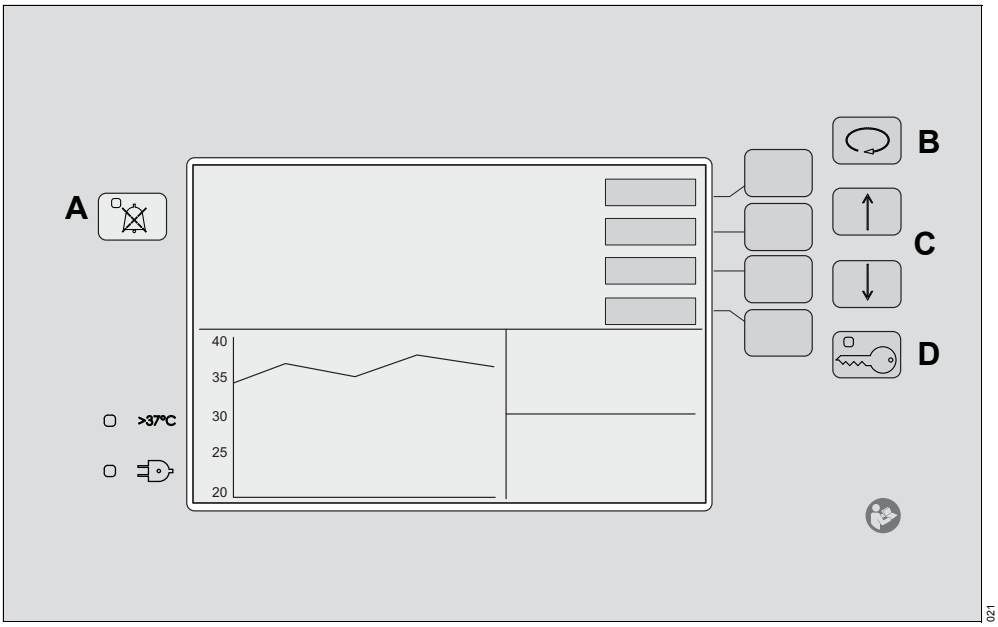
D **Trend/Alarm window** - 3 standard parameters are presented as trend histories in the Trend/Alarm window (see Trending on page 92): Air temperature, skin temperature (central and peripheral), and heater power. Also, the skin temperature trend shows the temperature difference between central and peripheral skin temperatures).

More trend displays are also available when the device is equipped with any of the following: Servo oxygen control system, humidification system, and weighing system.

The trend time is user-selectable in intervals of 2, 4, 8, 12, and 24 hours. These intervals are applicable to all parameters except weight, which provides a trend of 7 days.

5.3 Keys

Fixed-function keys are on both sides of the screen and provide access to specific functions.



A ***Audio Paused/Reset*** key silences the alarm conditions for 4, 5, or 15 minutes.

If no alarms are present, the ***Audio Paused/Reset*** key enables a alarm silence.

B The ***Display Selection*** key enables the user to switch between displays that are not accessible via the currently displayed buttons.

C The ***Up Arrow*** and ***Down Arrow*** keys enable the user to select settings in the various displays and the system configuration menu.

At the system configuration menu, the ***Up Arrow*** and ***Down Arrow*** keys enable the user to select various parameters, modes, and settings. These settings are required to operate and control the system.

When the keypad is not locked (in display 1 and display 2), use the ***Up Arrow*** and ***Down Arrow*** keys to adjust the screen brightness.

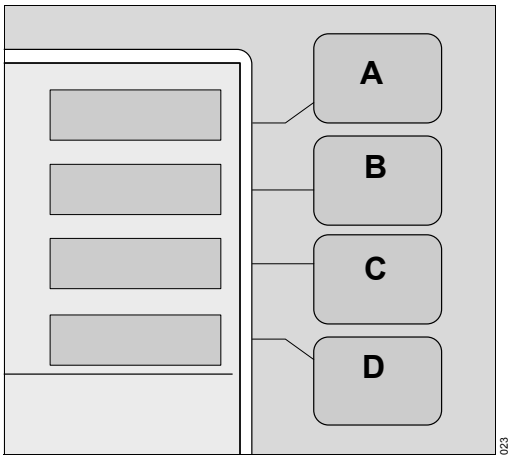
D The ***Keypad Locked*** key disables all the controls on the front panel of the controller, except for the ***Audio Paused/Reset*** key. After 15 seconds of inactivity, the keypad locks, and the ***Keypad Locked*** LED illuminates to indicate that the keys are locked.

5.4 Buttons

The functions of the 4 buttons located next to the screen are indicated by the labels shown on the screen beside each key. The buttons enable the user to select parameter and menu items at the various displays.

Use the display selection key to switch between display 1 and display 2.

5.4.1 Display 1 buttons



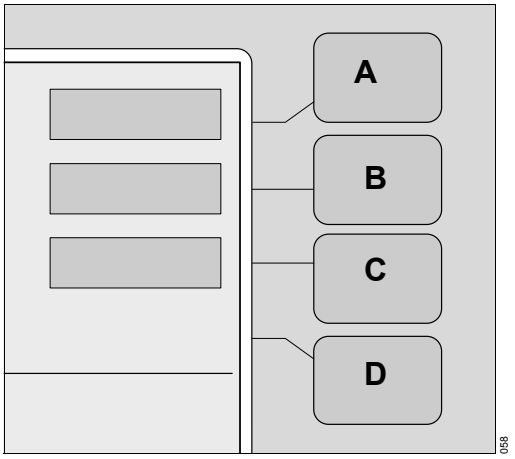
A ***Air*** –selects the air temperature mode

B ***Skin***–selects the skin temperature mode

C ***Humidity*** (optional)–selects the humidity display

D ***Oxygen*** (optional)–selects the oxygen display

5.4.2 Display 2 buttons



A ***Trend***–selects the Trend display

B ***Weight***–selects the Weight display and activates the weighing function

C ***Kangaroo***–selects the kangaroo display and activates kangaroo mode

D ***Setup***–selects the Setup display and allows review and modification of alarm limits, temperature limits, and skin temperature differences

5.4.3 More buttons

Home	Enables the user to return to the previous display
On	Available at the oxygen displays. When pressed, this button activates the oxygen systems
Off	Available at the oxygen and humidity displays. When pressed, this button deactivates the oxygen or Humidification systems
Cal	Available at the oxygen display and the Weight display (standard scale only). When pressed, this button initiates the calibration function for the oxygen sensor or scale.
Hours	Available at the Trend display. When pressed, it enables the user to select either 2, 4, 8, 12, or 24-hour trends for display in the Trend/Alarm window.
Clear	Available at the Trend display. When pressed, it clears all the trend data stored in the Trend/Alarm window.
Display	Available at the Trend display. When pressed, it selects one of following trends to display in the Trend/Alarm window: Air, skin, oxygen %, humidity %, heater power %, or weight gain.
Store	Available at the Weight display. When pressed, it stores the infant weight for trending in the Trend/Alarm window.
>37°C	Activates the temperature override mode (greater than 37.0 °C (98.6 °F)).
->0/T<-	Available at the Weight display. When pressed, it provides zero setting and tare balancing.

Auto Available at the humidity display. When pressed, it turns on the Auto humidity function.

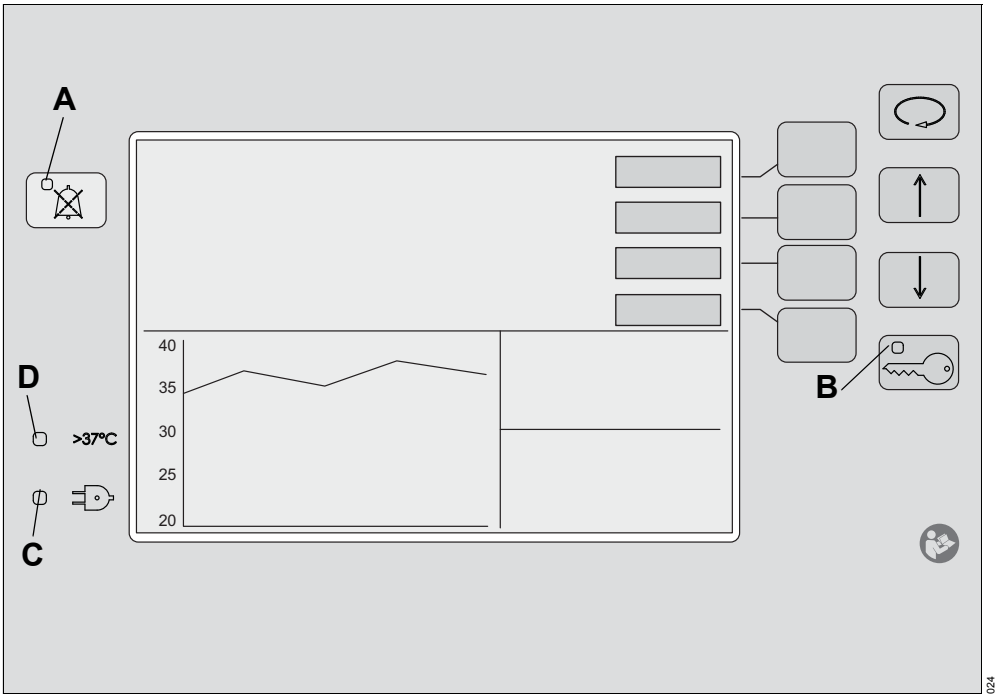
Manual Available at the humidity display. When pressed, it turns on the Manual humidity function.

°C/°F Available at the Setup display. When pressed, it enables the user to select the temperature display units in Celsius or Fahrenheit degrees for the air temperature, skin temperature, and set point temperature.

Temp/O2 Available at the Setup display. When pressed, it enables the user to display alarm limits for temperature and oxygen.

Kangaroo Available at the Setup display. When pressed, it enables the user to display and adjust the alarm limits for kangaroo mode.

5.5 LED indicators



A The LED on the ***Audio Paused/Reset*** key illuminates to indicate that an alarm is in progress.

B The LED on the ***Keypad Locked*** key illuminates to indicate that the keys are locked (except for the ***Audio Paused/Reset*** key).

C The yellow ***Power Failure*** (⏻) indicator illuminates when an interruption in power occurs.

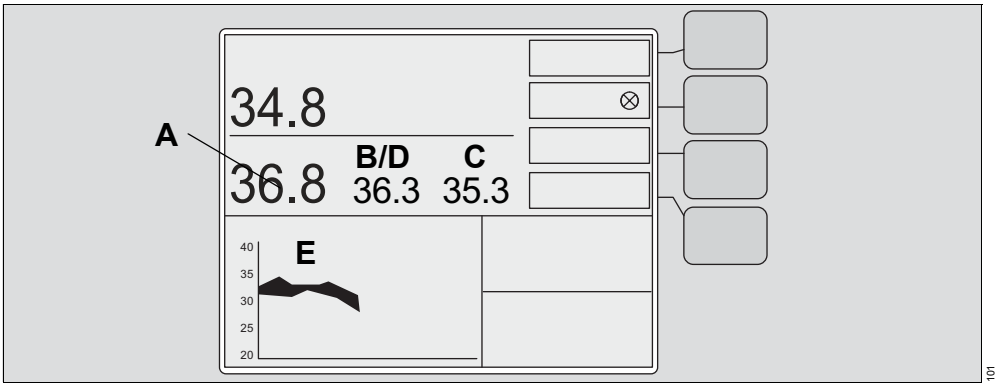
D The ***>37°C*** LED indicator illuminates when the set temperature is set to 37 °C (98.6 °F) or higher.

There is also a yellow LED on the sensor module that illuminates to indicate that an alarm is in progress (see Sensor Module on page 31).

5.6 Thermomonitoring

Thermomonitoring is the continuous measurement and display of the central and peripheral skin temperatures, even when skin temperature mode is not active.

5.6.1 Main screen showing thermomonitoring information



A	***Central***	Shows the central skin temperature
B	***Peripheral***	Shows the peripheral skin temperature
C	***Set***	Shows the temperature set point
D	***Difference***	Can be configured to show a value for the difference between the central and peripheral skin temperatures (appears in place of ***Peripheral*** when ***Difference*** is selected).
E	***Skin temp***	Shows the central and peripheral skin temperature histories and the difference between them shaded in between their data lines. Trends are shown in graph format.

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6 Assembly and preparation

6.1 Unpacking

⚠ WARNING
Risk of death or serious injury or damage to the device
The device could tip over.
► Use 2 persons of sufficient strength to lift or move the incubator when unpacking.

When removing the equipment from the carton, take care not to scratch or otherwise damage unprotected surfaces.

Open the shipping carton and remove all packing material. Carefully lift and remove the incubator from the packaging.

If the packaging or the device is damaged, contact an authorized DrägerService representative.

6.2 Proper assembly

⚠ WARNING
Risk of death or serious injury
If the incubator is assembled incorrectly, or parts/assemblies are not reinstalled after cleaning or maintenance, the essential performance and/or basic safety of the device may be compromised. Noncompliance may result in death or serious injury.
► Assembly and functional check must be performed by service personnel.

After the device is assembled and before it is placed into service, perform the Functional check procedure on page 63.

The hood/shell assembly and the adjustable trolley are shipped assembled in one carton.

6.3 Attaching accessories or optional components

To install the IV pole, utility shelf, and rail components, refer to their assembly instructions.

⚠ WARNING
Risk of death or serious injury
The device could tip over.
► Strictly adhere to the weight and placement requirements for accessories and optional components.

⚠ WARNING
Risk of death or serious injury
Incubator stability can be reduced by the number of components or accessories attached, the height, and loading of components or accessories, and the position of the components or accessories on the rail.
► Keep rail components to a minimum, adjust them to their lowest usable height, and mount them as close to the center of the incubator as possible.

⚠ WARNING
Risk of death or serious injury
This product has been validated with the accessories and options listed in this manual. They comply with all relevant safety and performance requirements applicable to the device.
► It is the responsibility of that person or organization who makes an unauthorized modification, or incorporates an unapproved attachment to the device, to ensure that the system still complies with those requirements.

⚠ WARNING
Risk of death or serious injury
The utility shelf and IV pole assembly are labeled for acceptable weights.
► Do not exceed these weight limitations.

⚠ WARNING
Risk of death or serious injury
A tip-over hazard exists.
► Only one utility shelf should be used per incubator.
► When using the utility shelf, always place the object in the center of the shelf.
► Ensure that the object fits within the border of the shelf.
► Avoid stacking objects on the shelf.

⚠ WARNING
Risk of death or serious injury
A tip-over hazard exists.
► Total load for the utility shelf must not exceed 11.4 kg (25 lb).
► Total load for the IV pole must not exceed 5 kg (11 lb).
► Total load for the rail system must not exceed 13.6 kg (30 lb); 6.8 kg (15 lb) per side.
► Total load for the holder for litter bags must not exceed 0.7 kg (1.5 lb).
► Total load for the basket must not exceed 0.3 kg (0.7 lb).
► Total load for the tray must not exceed 1.2 kg (2.6 lb).
► Total load for the swivel drawer large must not exceed 4.5 kg (10 lb).
► Total load for the swivel drawer small must not exceed 2.2 kg (5 lb).

⚠ WARNING

Risk of death or serious injury

Latches can come loose leading to disconnecting of devices from the rail.

- ► To avoid injury or damage to the device, use only Dräger-approved latches, components, and accessories with the Fairfield-compatible rail system.
- ► It is also important to secure the latch properly to the rail as identified in the manual.
- ► Periodically check the operation of the latch to hold securely the accessory being used. When the latch is properly locked, both visual and physical feedback are provided. The toggle handle snaps into an 8 o'clock position on the latch body, when locked.
- ► Total rail system weight should not exceed 13.6 kg (30 lb); 6.8 kg (15 lb) per side.

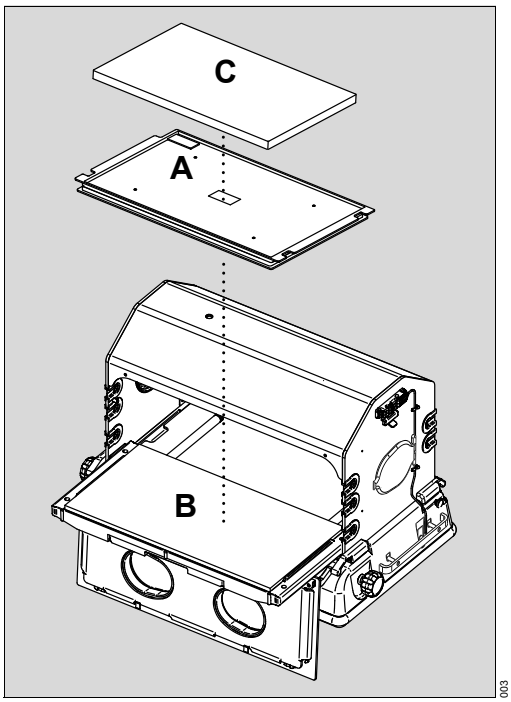
For weight limitations for accessories and components for the Isolette 8000 plus, see Technical Data on page 167.

6.4 Installing the weighing system (option)

6.4.1 Standard scale assembly

1. Rotate the locking knobs, and open the front access panel of the incubator.
2. Remove the mattress from the incubator.
3. Orient the scale so that the scale cable is on the right-hand side of the incubator towards the sensor module assembly.
4. Place the scale (A) in the incubator on the bed (B).

5 Replace the mattress (C).



6 Connect the scale cable to the weight connector on the sensor module assembly (see Sensor Module on page 31).

⚠ WARNING
Risk of death or serious injury
Infant could become entangled with cables and be injured.
► Use cable management clips.

7 Ensure that all sensor leads are properly routed.
- To allow the bed to be fully withdrawn from the hood, and to allow the sensor module to be withdrawn from the hood for O_2 calibration, ensure that there is sufficient cable slack between the edge of the hood and the scale.
- To allow for correct weight measurements, make sure that there is no interference or rubbing of the cable with the scale top.
- Secure the scale cable to the incubator end wall using the cable clips provided inside the incubator wall.
- Loop the cable at the lower clip.

8 To ensure proper operation, perform the scale check (see Weighing system (option) functional check on page 75).

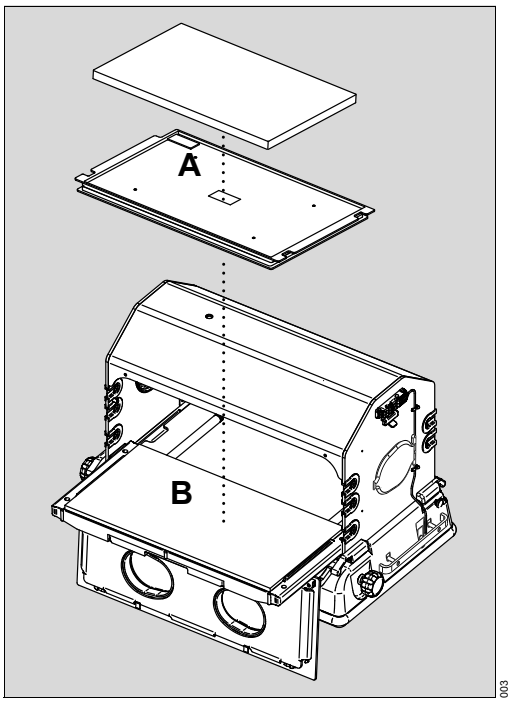
6.4.2 OIML/NAWI scale assembly (not available in all markets)

1 Rotate the locking knobs, and open the front access panel of the incubator.

2 Remove the mattress from the incubator.

3 Orient the scale so that the scale cable is on the right-hand side of the incubator towards the sensor module assembly.

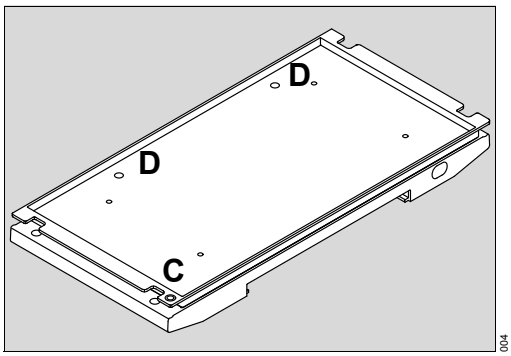
4 Place the scale (A) in the incubator on the bed (B).



5 Ensure that the bed is level and not in the Trendelenburg or Reverse Trendelenburg position.

6 Determine if leveling is required by checking the level indicator (C).

7 If necessary, remove the 2 level-adjuster plugs. Then fine-tune the 2 level adjusters (D) on the scale until the bubble on the level indicator is within the circle. For right or left level adjustments, use the right-hand or left-hand bed-tilt knob. Reinstall plugs.



8 Replace the mattress.

9 Connect the scale cable to the weight connector on the sensor module assembly (see Sensor Module on page 31).

⚠ WARNING
Risk of death or serious injury
Infant could become entangled with cables and be injured.
► Use cable management clips.

10 Ensure that all sensor cables are properly routed.

- To allow the bed to be fully withdrawn from the hood, and to allow the sensor module to be withdrawn from the hood for O_2 calibration, ensure that there is sufficient cable slack between the edge of the hood and the scale.
- To allow for correct weight measurements, make sure that there is no interference or rubbing of the cable with the scale top.
- Secure the scale cable to the incubator end wall using the cable clips provided inside the incubator wall.
- Loop the cable at the lower clip.

11 To ensure proper operation, perform the scale functional check (see Weighing system (option) functional check on page 75).

6.5 Installing the humidification system (option)

⚠ WARNING
Risk of death or serious injury
Using older software versions can lead to incorrect operation of the humidification system which may cause patient injury.

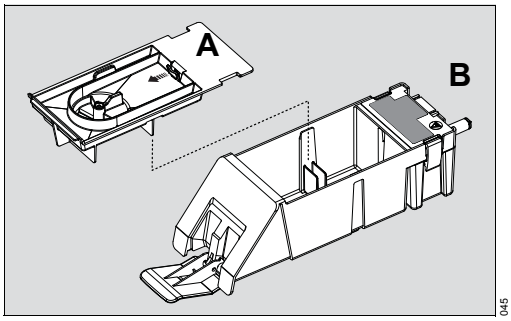
► The humidification system with the heater/impeller cover with duct cover must be used with software version 5.n or higher.

The humidification system is normally factory installed. To install the humidification system in the field, refer to the assembly instructions provided with the system.

On factory installed systems, install the water reservoir assembly:

1 Pull the latch on top of the water reservoir lid forward (A), and remove the lid.

2 Ensure that the evaporator is installed in the evaporator chamber (B) at the rear of the reservoir.



3 Secure the lid by reinstalling it on the reservoir and pushing back the latch on top of the lid.

⚠ CAUTION

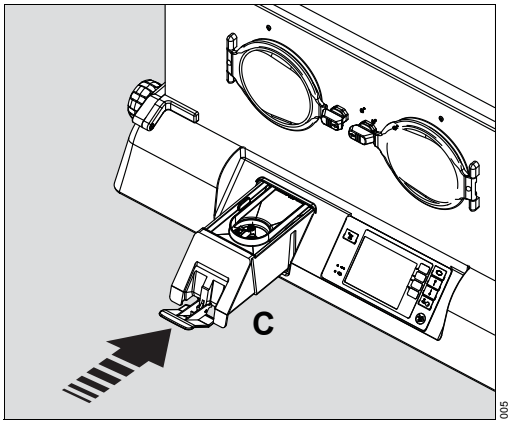
Risk of injury or damage to the device

Using an incomplete water reservoir can prevent the system from operating correctly.

► Ensure that the reservoir lid is installed.

► Ensure that the cover on the filling inlet is closed.

4 Insert the water reservoir assembly (C) in the shell with the latch open. Then slide it in fully and lock it in place by pushing in the latch.



6.5.1 Installing the collection bottle for the condensation management system

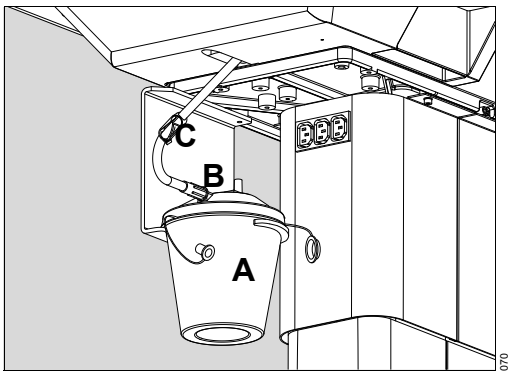
1 Slide the new collection bottle (A) onto the bracket located underneath the left side of the incubator.

2 Remove the caps from the ports on the collection bottle.

The large port on top of the collection bottle must remain uncapped during operation to ensure that water drains properly into the bottle.

3 Connect the condensation management hose that protrudes from the underside of the incubator to the patient port (B) on the side of the collection bottle.

4 Secure the hose clamp (C).



⚠ CAUTION
Risk of injury or damage to the device
Excess fluid in the collection bottle can lead to spillage and a safety hazard.
► To avoid overflow, check the water level in the collection bottle every 8 hours.
► When the water level reaches the maximum mark on the bottle, replace the bottle.

6.6 Installing the servo oxygen control system (option)

The oxygen control system is normally factory installed. To install the oxygen control system in the field, refer to the assembly instructions provided with the system.

6.6.1 Installing the oxygen sensor cells in the sensor module

The incubator uses 2 independent oxygen sensors to provide redundancy and cross-checking. For this reason, the oxygen sensor cells must be installed at the same time, and are therefore provided as a pair.

1 Open the 2 bags containing the new oxygen sensors, and expose the sensors to air. Note the time.

The individual oxygen sensor cells are packaged in airtight bags. After packaging, the sensor slowly consumes all the oxygen in the bag, and then enters a “sleep” state. When the bag is opened, the sensor must “wake up” before its operation can stabilize. Therefore, the sensor should be exposed to room temperature air for at least 30 min before attempting calibration. If possible, open the bags 24 hours before installation.

If the oxygen sensor has been exposed to extreme temperatures (e.g., >50 °C (122 °F) or <0 °C (32 °F)), it might require up to 24 hours to return to normal operation.

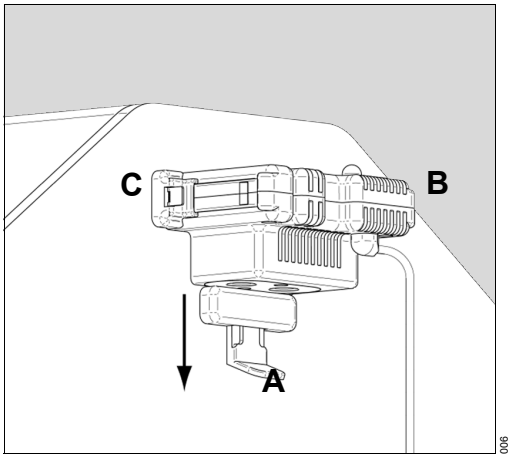
2 Switch off the incubator on/off switch.

3 Unplug the sensor module cable from the shell.

4 If present, unplug the scale cable and any skin temperature probe cables from the sensor module.

5 Pull down the lock (A) on the sensor module (B) and slide the module out from the hood until it stops.

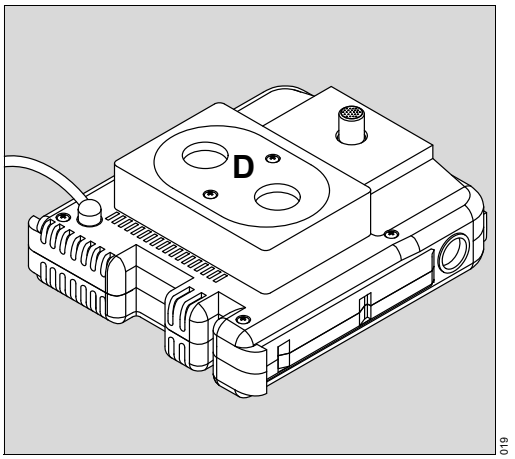
6 Pull out the clip (C) on the left side of the sensor module and remove the module from the hood completely.



7 Install the oxygen sensors on the underside of the sensor module:

1 Remove O2 sensor cover from the sensor module.

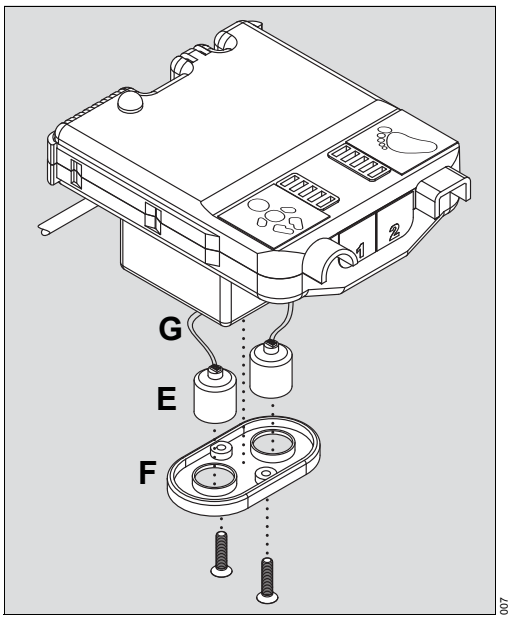
2 Remove and retain the 2 screws securing the oxygen sensor cover (D).



8 Screw each new sensor (E) into the sensor plate (F), and connect the cables (G). Either cable may be attached to either sensor.

9 Reinstall the plate with sensors into the sensor module, and reinstall the screws.

10 Reinstall the sensor module in the hood, and position it in the normal (innermost) position.



11 Reconnect the cables that were previously removed.

⇒ Sensor module cable is connected to the shell.

⇒ Scale cable and temperature probes cables are connected to the sensor module.

12 Switch on the incubator at the controller on/off switch, while pressing the ***Audio Paused/Reset*** key.

⇒ System configuration mode appears.

13 Confirm that the Altitude field contains the correct height above sea level of the site, to the nearest 1000 feet (300 meters). Consult a map or Google Earth if the height above sea level is not known. Correct if necessary.

14 Note the oxygen calibration level.

⇒ Oxygen calibration level is either 21% or 100%.

15 If the oxygen calibration level is 100%, the 100% calibration fixture (with hose barb) must be installed below the sensor module. If the oxygen Calibration Level is 21%, the slide lock fixture (without hose barb) must be installed below the sensor module.

16 Switch off the incubator at the controller on/off switch, wait 1 minute, and turn the incubator back on in normal mode.

17 When 30 minutes have elapsed since step 1 (exposing the oxygen sensors to air), begin oxygen calibration (see Oxygen sensor calibration (option) on page 160). Note carefully the use of room air (21% oxygen) or pure oxygen, as dictated by the presence or absence of the 100% oxygen calibration fixture on the hood.

6.7 Installing the 100% oxygen calibration fixture (optional)

Do not install when the incubator is configured for 21% oxygen calibration (see System configuration menu on page 113).

1 Pull down the lock on the sensor module, and slide the module out from the hood until it stops.

2 Pull out the clip on the left side of the module, and remove the module from the hood.

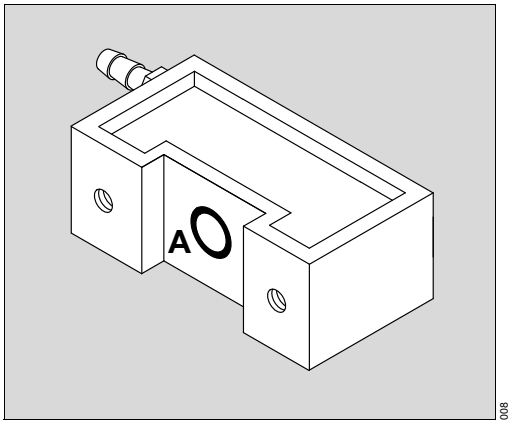
3 Rotate the locking knobs, and open the front access panel of the incubator.

4 Remove and retain the 2 mounting screws securing the cover plate slide fixture.

5 Remove the cover plate slide fixture. Also remove the sensor module slide lock.

6 Ensure the proper positioning of the O-ring (A) on the 100% calibration fixture.

The 100% calibration fixture is packaged with a small O-ring, which is coated with a lubricant. The O-ring could possibly become loose during shipping.

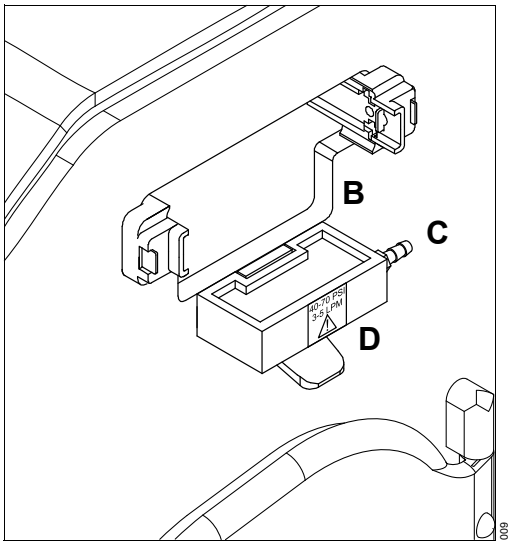


7 Mount the sensor module slide lock and 100% calibration fixture directly under the sensor module opening on the hood assembly (B).

8 Install the 2 screws to secure the sensor module slide lock and the 100% calibration fixture.

⇒ The brass connector (C) is facing the rear of the incubator.

⇒ The wording on the label (D) is displayed according to the illustration.



9 Close the front access panel, and rotate the locking knobs until they are fully engaged.

10 Install the sensor module assembly in the hood assembly.

When the slide lock and 100% calibration fixture are properly installed, the slide lock moves up and down smoothly.

11 Select the 100% calibration level (see System configuration menu on page 113).

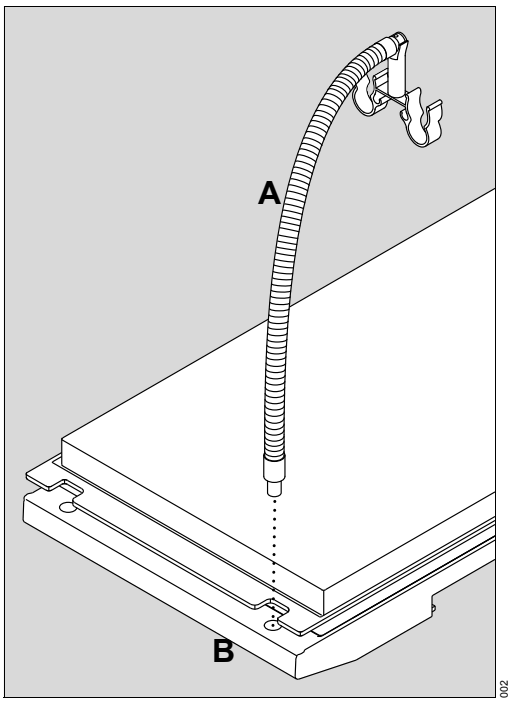
✓ Oxygen calibration fixture is set to 100% and the installation is complete.

6.8 Installing the breathing hose holder (accessory)

1 Insert the breathing hose holder (A) into one of the 4 support holes (B) on the corners of the bed.

2 Ensure that the slot in the bottom of the holder aligns with the cross pin in the support hole.

✓ When installed, the holder can be adjusted vertically and horizontally for convenient positioning of breathing hoses.



When adjusting the breathing hose holder, make sure that it does not interfere with the scale (if installed) to allow for correct weight measurements.

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7 Getting started

7.1 System start-up

⚠ WARNING
Risk due to incorrect mains voltage or missing protective grounding
If the device is connected to a power socket with incorrect mains voltage or a power socket without a protective grounding, an electric shock may occur.
► Connect the device only to power sockets with correct mains voltage and a protective grounding.

⚠ WARNING
Risk of reduced level of safety
Connecting other devices to auxiliary power sockets on the I8000 plus may lead to a reduced level of safety.
► Comply with the requirements of IEC 60601-1 when connecting other devices to auxiliary power sockets on the Isolette 8000 plus.
► Do not use auxiliary power sockets that are separate from the Isolette 8000 plus

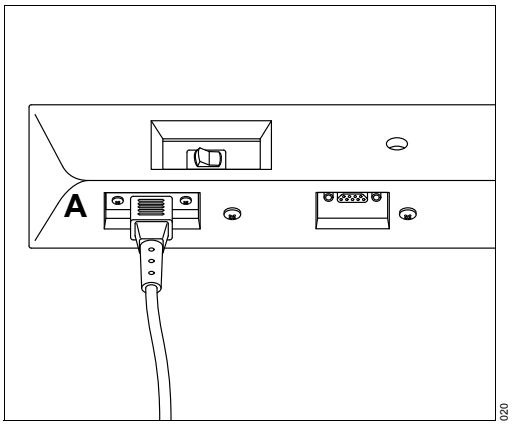
⚠ WARNING
Risk of patient injury or device failure
If the device loses its power source, the patient could be injured or the device damaged.
► The incubator must be connected to an appropriate power source when loss of power source would result in an unacceptable risk.

Prerequisites:
– The device has been reprocessed and assembled ready for operation.

Procedure:

Always perform the following test steps before operating the device.

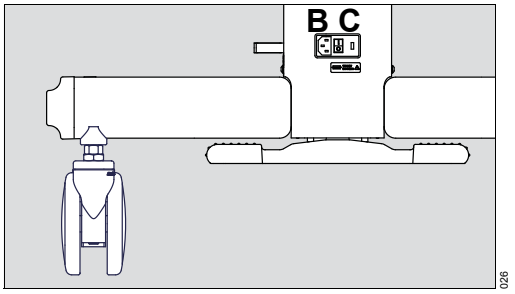
1 Verify that the power cable from the trolley is firmly attached to the receptacle (A) under the incubator shell assembly.



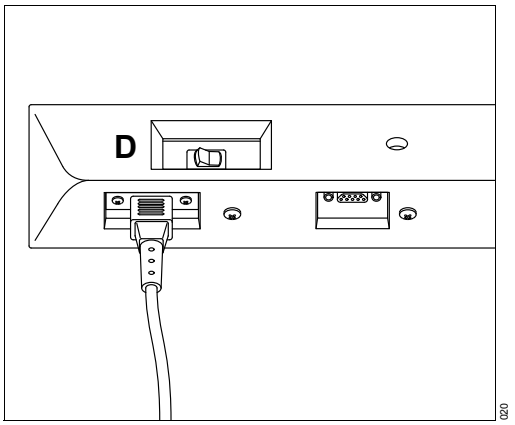
2 Plug the trolley power cable into an appropriate AC power source.

3 Ensure that the power cable is attached to the AC receptacle (B) of the trolley. Secure the power cable by rotating the retaining clip over the power cable.

4 Switch on the main on/off switch (C) on the trolley.



5 Locate the on/off switch (D) under the incubator shell assembly, and switch on the incubator.



⇒ During the self-test, all indicator lights illuminate, and the acoustic alarm signal pulses.

⇒ After the self-test, the incubator boots up in the air temperature mode at display 1.

If the device fails the self-test, the alarm sounds, and one or more of the following messages are displayed in the Trend/Alarm window, contact service personnel: ***Controller Failure 1*** through ***17***, or ***Check Settings***.

6 Perform the functional check procedure provided on page 63.

7 Following the successful completion of the functional check procedure, select the desired system options, parameters, and operation modes using the control panel of the controller (see System configuration menu on page 113).

✓ Incubator and options are set to the desired mode and configuration.

7.2 Functional check procedure

Perform the functional check procedure before the incubator is first placed into service and after any disassembly for cleaning or maintenance.

⚠ WARNING
Risk of death or serious injury
A malfunctioning incubator may not provide therapy as set.
► Do not use the incubator if it fails to function as described in the functional check procedure.
► Refer service to qualified personnel.

⚠ CAUTION
Risk due to faulty products
Signs of wear, e.g., cracks, deformation, or peeling, may occur with reprocessed products.
► Check the products for signs of wear, pronounced hardening, and residual soiling, and replace them if necessary.

For devices equipped with accessories and optional components, remove any items that interfere with the functional check procedure, and replace when completed.

7.2.1 Controller functional check

⚠ WARNING
Risk of fire
Missing or inadequate grounding can cause death or serious injury.
► To ensure grounding reliability, plug the power cable only into a properly grounded 3-wire hospital-grade or hospital-use outlet.
► Do not use extension cables or extra outlets with multiple sockets.
► If any doubt exists as to the grounding connection, do not operate the equipment.

⚠ CAUTION
Risk of injury or damage to the device
The device may not operate correctly with incompatible power.
► Make sure that the building power source is compatible with the electrical specifications shown on the height adjustment trolley or on the incubator.

1 Perform the initial power-up procedures (see System start-up on page 61).
⇒ The incubator is powered on for at least 1 minute.
2 Check the ***Power Failure*** alarm:

The incubator must be powered on for at least 1 minute before this test is performed.

1 Unplug the power cable from the controller on the front of the incubator.
   ⇒ The ***Power Failure*** alarm sounds.
   ⇒ The ***Power Failure*** indicator on the front panel of the controller illuminates.
2 Reconnect the power cable to the controller.
   ⇒ The incubator self-test runs.
   ⇒ Display 1 appears on the screen.

3 Check the ***Low Air Temperature*** alarm.
1 Rotate the locking knobs and open the front or rear access panel of the incubator.
   ⇒ Within approximately 5 minutes, the ***Low Air Temperature*** alarm message is displayed in the Trend/Alarm window.
   ⇒ The acoustic alarm signal sounds.

The alarm does not occur until the temperature falls 2.5 °C (4.5 °F) below the set point. At high ambient temperatures, fanning the air within the hood can be performed to induce the alarm.

2 Close the front or rear access panel, and rotate the locking knobs until they are fully engaged.

4 Check the ***Low Skin Temperature*** alarm.
1 Set the air temperature to 35 °C (95 °F), and allow the temperature to stabilize for 1 hour.
2 Insert a skin probe into the central skin probe connector of the sensor module.
3 Place the skin probe 10 cm (4 in) above the center of the bed.
4 Set the skin set temperature to 35 °C (95 °F).
5 Rotate the locking knobs, and open the front or rear access panel.
   ⇒ Within approximately 5 minutes, the ***Low Skin Temperature*** alarm message is displayed in the Trend/Alarm window.
   ⇒ The acoustic alarm signal sounds.

The alarm does not occur until the temperature falls 0.5 °C (0.9 °F) or 1.0 °C (1.8 °F) (depending on the skin temperature alarm limit setting) below the set point. At high ambient temperatures, fanning the air within the hood can be performed to induce the alarm.

6 Close the front or rear access panel, and rotate both latches until fully engaged.
7 Press the ***Audio Paused/Reset*** key.
   ⇒ The alarm is silenced.

5 Check the ***Central Probe Missing*** alarm.

1 In the skin temperature mode, disconnect the skin probe from the central skin probe connector of the sensor module.
   ⇒ The skin display goes blank.
   ⇒ The ***Central Probe Missing*** alarm message is displayed in the Trend/Alarm window.
   ⇒ The acoustic alarm signal sounds.
2 Press the ***Audio Paused/Reset*** key.
   ⇒ The acoustic alarm signal silences for 5 minutes.
3 Reconnect the skin probe in the central skin probe connector.
   ⇒ The incubator returns to normal operation.

6 Check the maximum air temperature.
1 Connect a central skin probe to the sensor module, and select skin temperature mode.
2 In the temperature override mode, select a temperature >37 °C (see Skin temperature mode on page 79).
3 Place the skin probe outside the incubator.
4 Allow the incubator to heat.
5 If the ***High Temp CutOut*** alarm sounds, press the ***Audio Paused/Reset*** key.
6 Verify that the incubator does not heat above 39.9 °C (103.82 °F) as indicated on the screen.

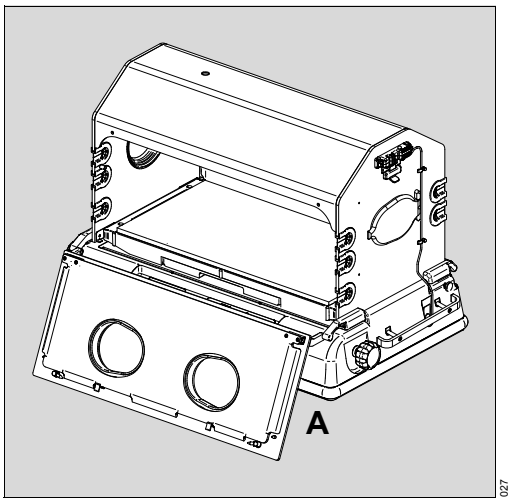
7 Check the ***Connect Central Skin Probe*** alarm.
1 While operating in the air temperature mode, disconnect the central skin probe.
2 Select the skin temperature mode.
   ⇒ The ***Connect Central Skin Probe*** alarm sounds.

8 Check the screen intensity feature at the system displays (see Keys on page 41).
- Use the ***Up Arrow*** key to increase the screen intensity 3 levels.
- Use the ***Down Arrow*** key to decrease the screen intensity 3 levels.

7.2.2 Hood/shell functional check

1 Check the access panels:
1 Rotate the locking knobs, and open the front access panel.
   ⇒ At the controller screen, the access panel open symbol () appears.

2 Pivot the access panel to the full open position (hanging straight down) (A).



3 Close the access panel, and rotate both latches until fully engaged.
⇒ At the controller screen, the access panel open symbol turns off.

4 Repeat steps 1 through 5 for the rear access panel.

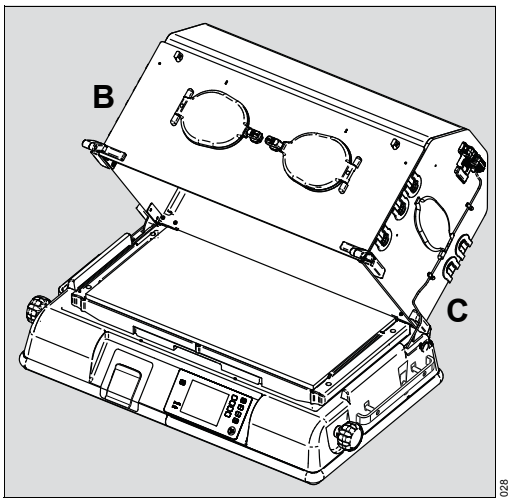
⚠ CAUTION
Risk of injury
Both locking knobs must be fully engaged to avoid accidental opening of the panels.
► Ensure that locking knobs are secure.

2 Check the hood operation:

1 If equipped with a weighing scale, first disconnect the weighing scale cable as follows:
– Rotate the locking knobs and open the front or rear access panel.
– Disconnect the weighing scale cable from the sensor module.
– Close the access panel, and rotate both latches until they are fully engaged.

2 Slowly tilt the hood back until the hood locks in place (B).

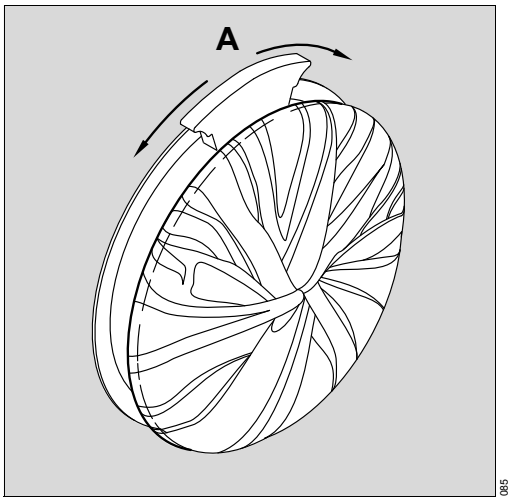
3 To release the hood, pull on and hold the knob (C) on the right rear hinge while closing the hood.



4 If equipped with a weighing scale, reconnect the weighing scale cable as follows
   – Rotate the locking knobs and open the front or rear access panel.
   – Reconnect the weighing scale cable to the sensor module.
   – Close the access panel, and rotate both latches until they are fully engaged.

3 If equipped with the optional iris ports on the side access panels, rotate the outer ring (A) of the iris ports.

   ⇒ The iris port opens and closes as rotation is continued through 360 °.



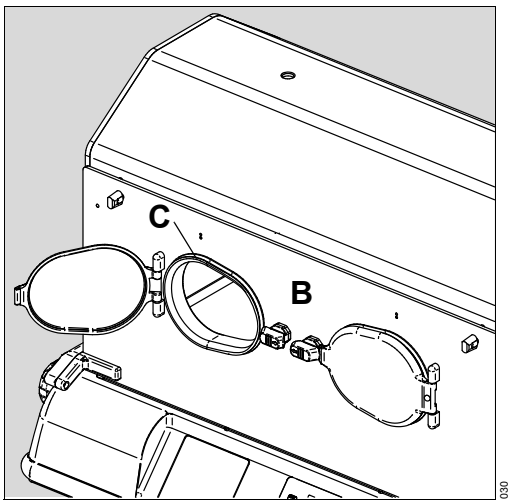
4 Check the hand port latches and gaskets.

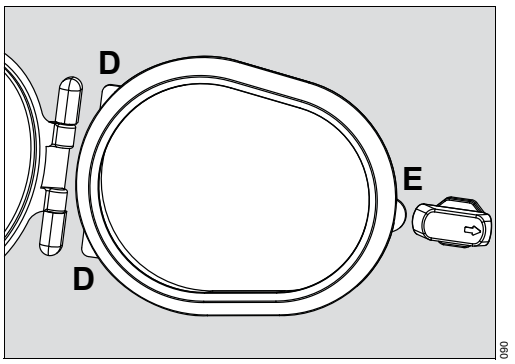
   1 Press the latch (B) on each hand port.

      ⇒ The door swings open.

2 Check that the gaskets (C) are properly installed in the openings.

⇒ The 2 tabs on each gasket are on the hinge side of the door opening (D), and the single tab is on the latch side of the door opening (E).





3 Close the doors, and check for proper latching and quietness.

5 Check that the inner double walls are properly latched:

1 Open the front access panel.

⇒ The access panel open symbol ( ) appears on the controller screen.

2 Check that the front inner double wall is properly latched.

3 Close the front access panel.

⇒ The access panel open symbol on the controller screen turns off.

4 Repeat steps 1 through 3 for the rear access panel and rear inner double wall.

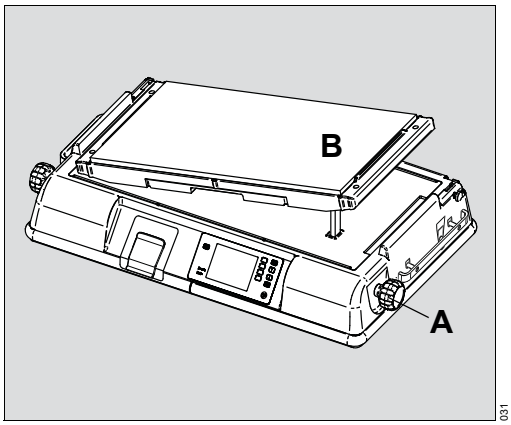
6 Check the bed elevators:

1 Rotate the right bed-tilt knob (A) counterclockwise until it stops.

⇒ The bed is in the full “up” position (B).

2 Rotate the knob clockwise until it stops.

⇒ The bed is level.



3 Rotate the left bed-tilt knob clockwise until it stops.

⇒ The bed is in the full “up” position.

4 Rotate the knob counterclockwise until it stops.

⇒ The bed is level.

7 Check the bed operation:

1 Rotate the locking knobs, and open the front access panel.

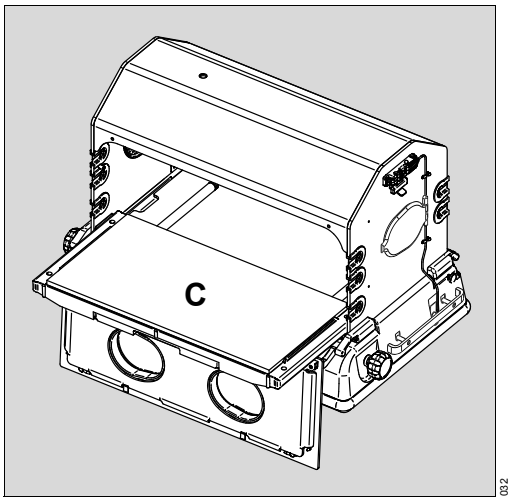
2 Pivot the front access panel to the full open position (hanging straight down).

3 Slide out the bed to the fully extended position (C).

4 Carefully lean on the bed to ensure that it is properly supported and provides a firm infant platform.

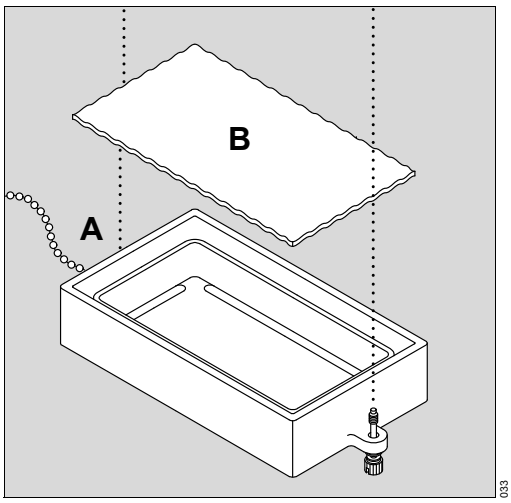
5 Return the bed.

6 Close the front access panel, and rotate both locking knobs until they are fully engaged.



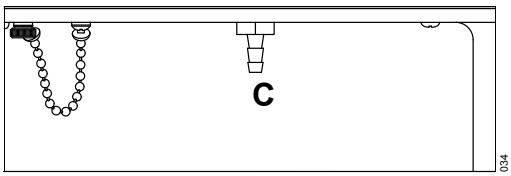
⚠ WARNING
Risk of death or serious injury
A dirty air inlet filter may affect oxygen concentrations, and/or cause carbon dioxide build-up.
► Check the filter routinely, and change at least every 3 months.
► Use only the filter specified.

8 Check the air inlet filter, which is located under the rear shell of the incubator:
1 Loosen the 2 thumbscrews (A) of the air inlet filter cover, and remove the cover.
2 Inspect the filter (B). If it is visibly dirty, see Air inlet filter maintenance on page 151.
⇒ The filter is oriented so that the side with the text "THIS SIDE OUT" faces inside the air inlet filter cover.



3 Install the air inlet filter cover.

9 For systems without servo oxygen control, check the manual air/oxygen system located under the rear shell of the incubator:
1 Introduce a carefully measured 9 L/min of oxygen into the oxygen input connector (C) labeled ***O2 INLET***.
2 Using a calibrated oxygen analyzer, check the oxygen level within the hood.
⇒ The level reaches the predicted level as indicated on the rear panel of the incubator (9 L/min should result in 45% to 75% oxygen concentration).



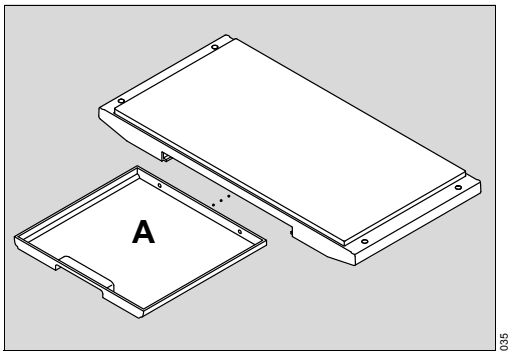
10 Check the X-ray tray:
1 Rotate the locking knobs, and open the front access panel.
2 Pivot the front access panel to the full open position (hanging straight down).
3 Slide out the X-ray tray (A).

4 Check the tray for any defects.

5 Ensure the tray slides smoothly in and out of the opening.

6 Return the X-ray tray.

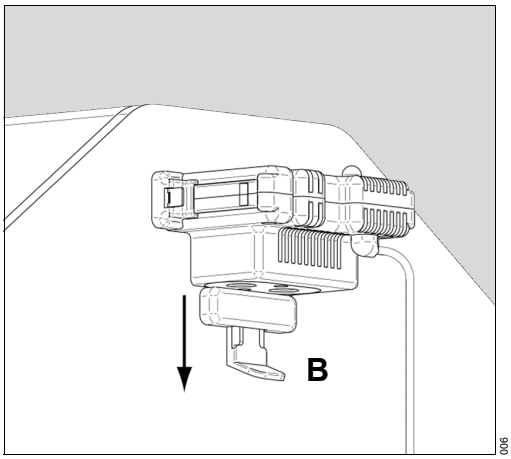
7 Close the front access panel, and rotate both latches until they are fully engaged.



11 Check the sensor module lock.

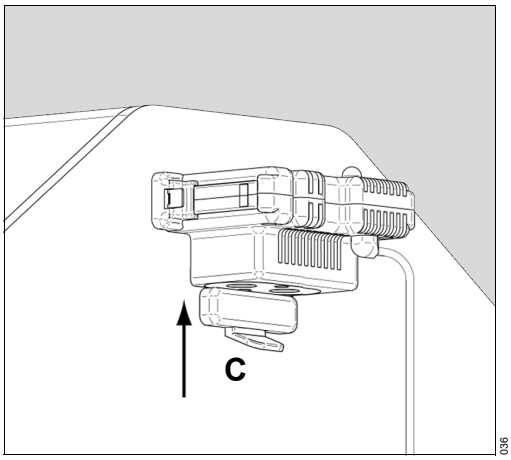
1 Pull down the sensor module lock (B).

⇒ The sensor module slides in and out of the hood.



2 Push up the sensor module lock (C).

⇒ The sensor module is locked securely in place.



7.2.3 Height adjustment trolley functional check

⚠ WARNING

Risk of death or serious injury

Raising or lowering the incubator with obstructions can cause death or serious injury to the patient and user.

When raising or lowering the incubator:

- ► Ensure that the travel path of the device is clear of any obstructions, including limbs.
- ► Check patient and incubator connections.
- ► Before lowering the device, check to ensure that there is sufficient clearance between the incubator and trolley assembly, especially under the drawers.
- ► Do not place any items on the trolley legs.
- ► Do not raise or lower the device while installing or removing medical gas cylinders from the cylinder holder.

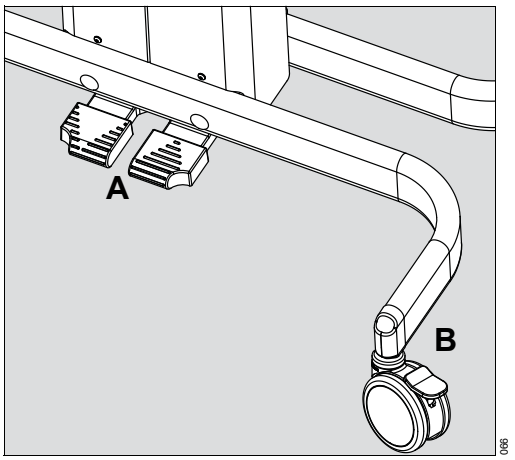
Perform this functional check procedure, along with the functional check procedure for the controller, before placing the incubator into service and after any disassembly or maintenance.

1 Make sure that the system is fully powered (see System start-up on page 61).

2 To raise or lower the trolley to the maximum and minimum height, press and hold the foot pedal of the height adjustment trolley (A) at the front of the device.

3 Verify that the trolley operates smoothly and adjusts to the desired height.

4 Repeat steps 2 and 3 for the foot pedal at the rear of the device.



7.2.4 Castor wheel lock functional check

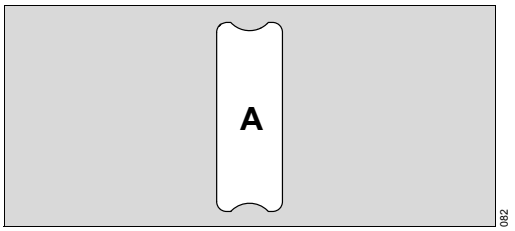
1 Press the castor wheel locks (B) and ensure that they keep the device from moving.

2 Release the locks and ensure that the device can move freely.

7.2.5 Rail system functional check

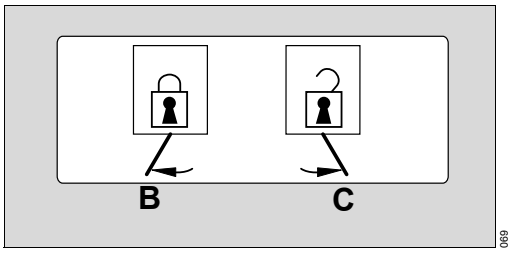
Proper latching of rail components to the rail is both visually and physically evident to the user.

7.2.5.1 Fairfield-compatible rail (A) (cross section shown):

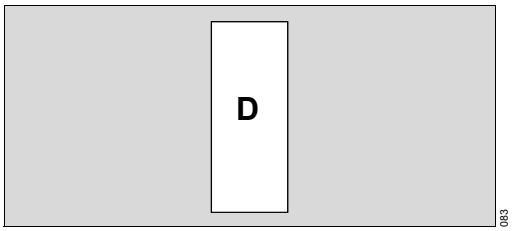


Verify that all cam adapter latches are properly secured to the Fairfield-compatible rail when in the locked position.

The mounting adapters lock when the toggle handle is switched to the left position (8 o'clock) (B). They unlock when the toggle handle is switched to the right position (4 o'clock) (C).



7.2.5.2 Deutsches Institut für Normung (DIN)-compatible rail (D) (cross section shown):



Verify that all DIN-compatible accessories are properly secured to the DIN-compatible rail when in the locked position.

7.2.6 Servo oxygen system (option) functional check

Perform the servo oxygen system functional check before the system is first placed into service and after any disassembly for cleaning or maintenance.

1 Place a calibrated oxygen analyzer inside the hood at the center of the bed.

2 If necessary, unlock the keypad.

3 Activate the oxygen system (see Turning the oxygen mode on or off on page 90).

4 Set the oxygen set point to 45% (see Setting the oxygen set point on page 91).

✓ The oxygen analyzer reads 45% ± 5% within 5 minutes.

If the oxygen analyzer and the oxygen display do not read 45% ± 5% within 5 minutes, contact a local service representative.
The ± 5% accuracy applies to devices calibrated to 21% oxygen. Devices calibrated to 100% oxygen are accurate to ± 3%.

7.2.7 Humidification system (option) functional check

Ambient relative humidity must be <40% to perform this check.

Perform the humidification system functional check procedure before the system is first placed into service and after disassembly for cleaning or maintenance.

1 Ensure that the reservoir is full.

2 Ensure that the condensation management system (if installed) is installed properly.

3 Place the probe of a calibrated hygrometer inside the hood 10 cm (4 inches) above the center of the bed.

4 Pre-warm the incubator to 35.0 °C (95.0 °F).

5 Activate the humidification system manual mode (see "Selecting the humidity mode" on page 87).

6 Set the humidity set point to 50% (see Setting the humidity set point in manual mode on page 89).

✓ Within 30 minutes, the hygrometer and the humidity display both read 50% ± 6% relative humidity (RH).

7.2.8 Weighing system (option) functional check

The weighing system functional check should be performed before the system is first placed into service and after any disassembly for cleaning or maintenance.

⚠ CAUTION
Risk of patient injury
Incorrect weight measurements could interfere with therapies.
► Do not use the scale if it fails to function as described in the functional check procedure.
► Refer service to qualified personnel.

7.2.8.1 Standard scale

1 Ensure that the bed is level and not in the Trendelenburg or Reverse Trendelenburg position.
2 Activate the Weighing system (see Standard scale measurements on page 94).
⇒ The Weight display appears.
3 Remove any objects from the bed.
4 Press the ***->0/T<-*** button twice (see Buttons on page 42).
5 Verify that the Weight display reads zero.
⇒ The weight sampling bar searches for weight samples and shows the weight sampling progress.
6 Place a weight of known value, but less than 7 kg (15 lb), on the bed.
7 Verify that when the weight sampling bar stops searching, a beep sounds.
⇒ The weight sampling bar is filled, and the weight is then locked and displayed in the Trend/Alarm window.
8 Reweigh the object (see Reweigh on page 96).
9 Verify that the display again shows the value of the weight on the bed.
⇒ The correct weight is shown.

7.2.8.2 OIML/NAWI scale (if installed)

Verify that the latitude and altitude recorded on the OIML/NAWI scale calibration label on the back of the incubator are correct for the geographical location of use. Verify that the serial number of the scale in the incubator matches the serial number on the scale calibration label on the back of the incubator.

If the OIML/NAWI scale is moved to a different geographical location, the scale must be recalibrated. Also, the Isolette 8000 plus controller must be reconfigured, and the scale calibration label on the back of the incubator must be updated with new latitude and altitude values. OIML/NAWI scales can only be calibrated by service personnel.

1 Ensure that the bed is level and not in the Trendelenburg or Reverse Trendelenburg position.

   ⇒ The bubble on the scale level indicator is within the circle (see Symbols on page 34).

2 Select display 2, and press the ***Weight*** button.

   ⇒ The weight screen is displayed.

3 If necessary, remove any objects from the bed.

4 Press the ***->0/T<-*** button twice (see Buttons on page 42).

   ⇒ The weight display reads zero and the background color changes.

5 Place a weight of known value, but less than 7 kg (15 lb), on the bed and verify that the correct weight is displayed.

6 Remove the weight from the bed, and press the ***Home*** button.

7.2.9 Utility shelf (optional component) functional check

1 Ensure that the utility shelf and support arm are secure.

2 Ensure that the utility shelf rotates with the desired resistance.

8 Operation

Illustrations of products and screen content in this document may differ from the actual products depending on configuration and design.

Prerequisites:

– The device has been reprocessed and assembled ready for operation.

8.1 Setting the temperature

Set the temperature in either air temperature mode or skin temperature mode.

⚠ WARNING
Risk of death or serious injury
Temperatures that are too high or too low can injure the patient.

► The attending physician should prescribe the temperature control mode and temperature settings.

► Routinely monitor the infant temperature according to the attending physician orders or Nursery Standing Orders.

► Keep the infant clear of the slots where the warm air enters the patient compartment.

NOTICE
Risk of damage to the device
The air curtain that functions when the access panels are open can be disturbed by drafts, fans, air-conditioning, etc.

► Take necessary measures to keep the incubator away from these drafts.

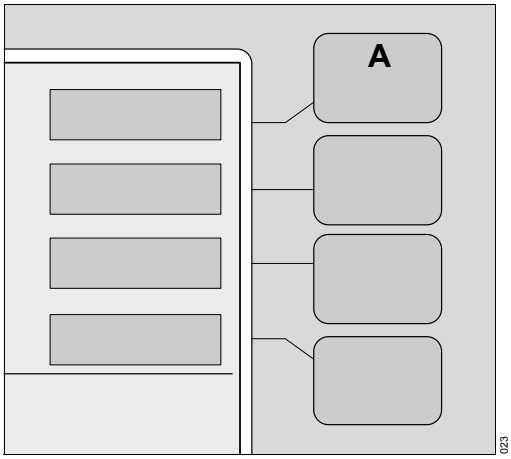
The temperature of the warm air entering the patient compartment at the front and rear of the incubator is higher than the typical incubator air temperature.

8.1.1 Air temperature mode

To select the air temperature control set point:

1 If necessary, unlock the keypad.

2 At display 1, press the ***Air*** button (A) to select the air temperature mode.



If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

⇒ The screen changes to the temperature display with new button labels and a border around the current temperature set point.

3 Set the air temperature to the prescribed setting.

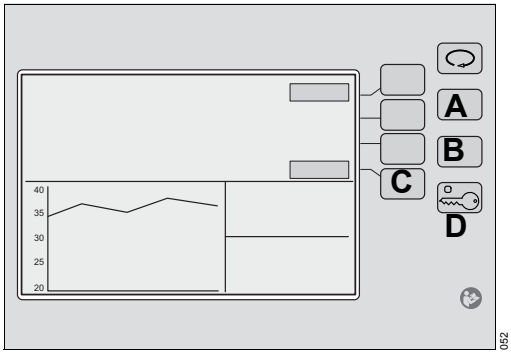
- To raise the set temperature in 0.1° increments, press the ***Up Arrow*** key (A).
- To lower the set temperature in 0.1° decrements, press the ***Down Arrow*** key (B).

4 Press the ***Home*** button (C) and confirm the air set temperature setting.

⇒ Device returns to display 1.

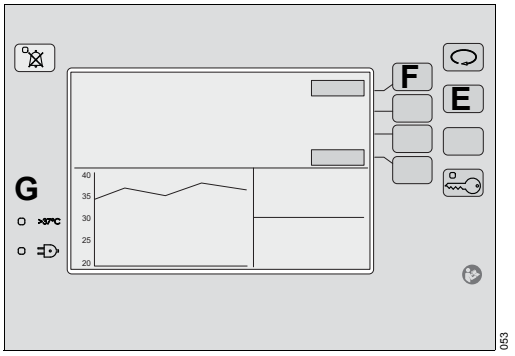
5 Press the ***Keypad Lock*** (D) key.

✓ Keypad is locked.



8.1.1.1 Activating temperature override mode when setting the temperature

1 Press the ***Up Arrow*** key (E) and raise the set temperature to 37.0 °C (98.6 °F).



2 To activate the temperature override mode, press the ***>37°C*** button (F).

⇒ The ***>37°C*** LED indicator (G) illuminates and the color of the ***>37°C*** button label changes.

The ***>37°C*** button is inoperative until the air set temperature is set to 37.0 °C (98.6 °F).

3 To raise the set temperature beyond 37.0 °C (98.6 °F) up to 39.0 °C (102.2 °F), press the ***Up Arrow*** key (E).

⇒ Pressing this key raises the temperature in 0.1° increments.

8.1.2 Skin temperature mode

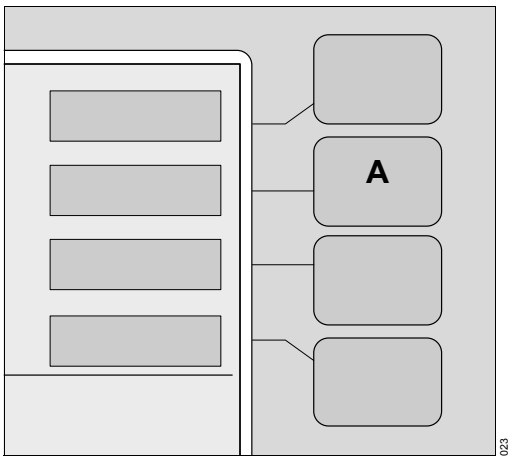
The incubator must be pre-warmed for at least 1 hour in air temperature mode before switching to skin temperature mode.

To select the set point in skin temperature mode:

1 If necessary, unlock the keypad.

If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

2 At display 1, press the ***Skin*** button (A) to select the skin temperature mode.

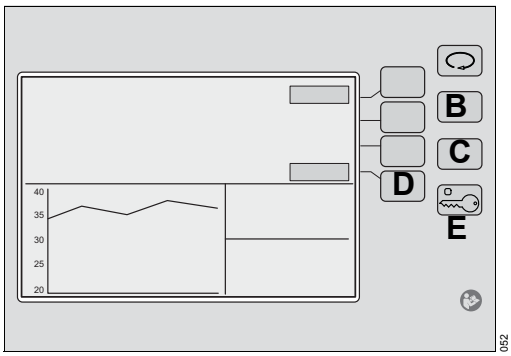


⇒ The screen changes to the temperature display with new button labels and a border around the current temperature set point.

3 Attach the central skin probe to the infant (see Connecting skin probes on page 81).

4 Set the skin temperature to the prescribed setting.

- To raise the set temperature from 34 °C (93.2 °F) to 37.0 °C (98.6 °F) in 0.1° increments, press the ***Up Arrow*** key (B). In temperature override mode, the temperature can be set from 37.0 °C (98.6 °F) to 38.0 °C (100.4 °F) in 0.1° increments.
- To lower the set temperature from 38.0 °C (100.4 °F) to 34.0 °C (93.2 °F) in 0.1° decrements, press the ***Down Arrow*** key (C).



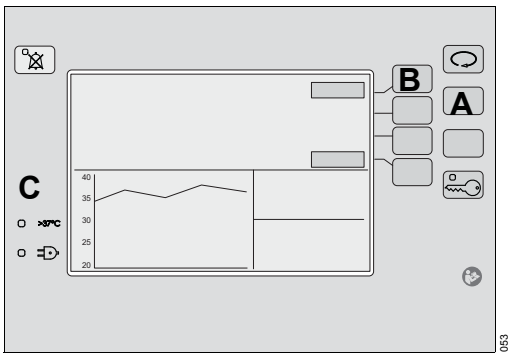
5 To confirm the skin set temperature setting, press the ***Home*** button (D).

⇒ Device returns to display 1.

6 To lock the keypad, press the ***Keypad Lock*** key (E).

8.1.2.1 Activating temperature override mode

1 To raise the set temperature to 37.0 °C (98.6 °F), Press the ***Up Arrow*** key (A).



2 To activate the temperature override mode, press the ***>37°C*** button (B).

⇒ The ***>37°C*** LED indicator illuminates (C) and the color of the ***>37°C*** button label changes.

The ***>37°C*** button is inoperative until the air set temperature is set to 37.0 °C (98.6 °F).

3 To raise the set temperature from 37.0 °C (98.6 °F) to 38.0 °C (100.4 °F), press the ***Up Arrow*** key (A).

✓ The set temperature increases in 0.1° increments.

8.1.3 Monitoring single or dual temperatures

The sensor module is equipped to accept 2 skin probes. When skin probes are inserted into the central skin probe connector and peripheral skin probe connector, the controller screen displays the respective central skin and peripheral skin temperatures.

In skin temperature mode, only the central skin probe (yellow) is used to control the temperature. The peripheral skin probe (white) provides more skin temperature monitoring for informational purposes only.

8.1.4 Connecting skin probes

⚠ CAUTION
Risk of injury or damage to the device
Noncompliance may result in injury or damage to the device.

► Do not clean and reuse single-use components.

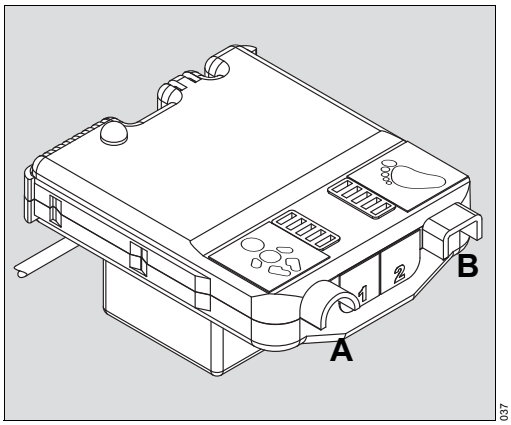
► Do not use single-use components or accessories if packaging is damaged.

Dräger recommends that the central skin temperature and peripheral skin temperature are measured and monitored. If 2 skin temperature probes are used, changes in skin temperature can be detected more quickly using the thermomonitoring function. Dräger recommends the use of original Dräger skin temperature probes.

The following table shows the differences between the skin temperature probes:

Symbols on the device	Probe color	Temperature measurement	Attachment position
	Yellow	Central skin temperature	In the liver or kidney region
	White	Peripheral skin temperature	Foot or hand

1 While operating in the skin temperature mode, insert a yellow skin probe into the central skin probe connector (A).



2 If monitoring 2 temperatures, insert a white skin probe into the peripheral skin probe connector (B).

8.1.5 Attaching the skin probe to the patient

⚠ WARNING
Risk of death, serious injury, hypothermia, or hyperthermia
The skin temperature probe must be in direct contact with the skin to provide accurate monitoring of the infant skin temperature. Failure to maintain direct skin contact can result in overheating.

- ► Routinely check patient for correct probe attachment, and feel the skin for signs of overheating.
- ► Do not place the skin temperature probe under the infant or use it rectally.
- ► Place the yellow skin temperature probe on the liver or kidney region only.
- ► Place the white skin temperature probe on the foot or hand only.
- ► To prevent false temperature indications, the skin temperature probe must be placed at least 3.8 cm (1.5 in) from any transcutaneous monitor probe.
- ► Do not place skin temperature probes on areas previously used by transcutaneous monitor probes.

⚠ WARNING
Risk of hypothermia or hyperthermia
If the skin temperature probes are wet, the patient can become too hot or too cold.

- ► Use dry skin temperature probes only.

⚠ WARNING
Risk of hypothermia or hyperthermia
Incorrect interpretation of the skin temperature values can result in the patient becoming too hot or too cold.

- ► Ensure that skin temperature values are interpreted correctly.

⚠ WARNING
Risk of hypothermia or hyperthermia
The incubator cannot differentiate between an increase in the core temperature and cold skin (fever) and low core temperature (hypothermia).

- ► Monitor the patient core temperature with a separate calibrated thermometer. Failure to do so could result in patient injury.

The skin temperature sensor is not a clinical thermometer.

- ► Check the patient core temperature regularly using an independent thermometer.

⚠ WARNING

Risk to patient due to incorrect use of the skin temperature probe

If the rectal temperature is measured with the skin temperature probes, the device displays incorrect values or regulates the temperature based on incorrect values.

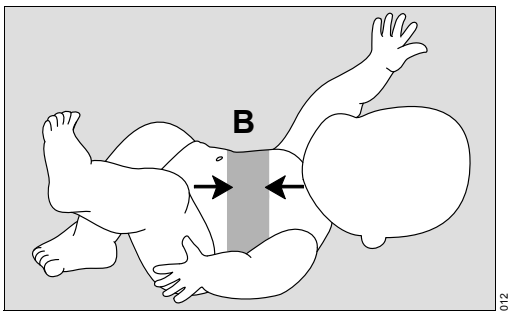
► Only use the yellow skin temperature probe for measuring the central skin temperature.

► Only use the white skin temperature probe for measuring the peripheral skin temperature.

1 Before the probe is placed on the skin, thoroughly clean and dry the skin area where the probe is to be placed.

2 Place the yellow skin temperature probe on the infant.

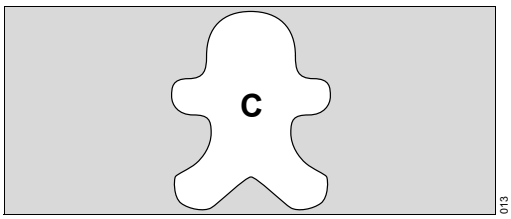
- When the infant is on their back or side, place the yellow probe on the abdomen (B), halfway between the xyphoid and the umbilicus.



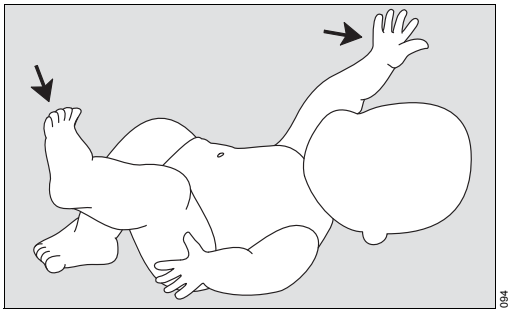
- When the infant is prone, place the yellow probe on the back of the infant.

3 Attach the probe to the infant using a Care-For-Me cover (C) or ThermoPad cover.

- Remove the backing from the Care-For-Me cover or ThermoPad cover, and attach the probe.
- To stabilize the attached probe, place another Care-For-Me cover or ThermoPad cover over the probe wire approximately 3 cm (1 in) to 4 cm (1.5 in) from the tip of the probe.



4 If planning to use peripheral skin temperature probe, place the white probe on the infant at either hand or foot.



5 Check the condition of the infant at least every 15 minutes for correct sensor attachment, and feel the skin of the infant for signs of overheating.

8.2 Setting the humidity (option)

⚠ WARNING
Risk of death or serious injury
Higher relative humidity will, at any given time, decrease evaporative water loss and may cause an increase in infant temperature. This effect is greatest in premature babies of very low birth-weight.

► The attending physician should prescribe the temperature control mode, temperature setting, and humidity setting.

► Routinely monitor the patient temperature according to the attending physician orders or Nursery Standing Orders.

⚠ WARNING
Risk of death or serious injury
The evaporator can be sufficiently hot to cause burns.

► Avoid removing or touching the evaporator until the water reservoir has been disconnected from the incubator for at least 45 minutes.

⚠ CAUTION
Risk of injury or damage to the device
Failure to comply can cause injury to the patient or damage to the device.

► If humidity has been in use but is no longer required, empty and dry the reservoir to avoid bacterial contamination. Then reinstall the reservoir assembly in the incubator shell.

► Liquid in the collection bottle can contain patient fluids. Collection bottles and fluids should be handled according to hospital guidelines.

ℹ Under certain environmental conditions, condensate may appear on the inner double walls of the hood. Condensate formation can be minimized or eliminated by lowering the relative humidity setting.

ℹ Check the water level in the water reservoir twice per day.

When using high levels of humidity, Dräger recommends using the optional condensation management system.

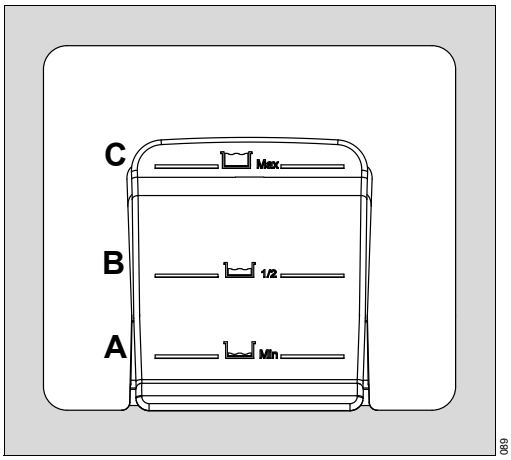
8.2.1 Filling the water reservoir

⚠ CAUTION
Risk of injury or damage to the device
Sterile water is not an acceptable substitute for distilled water.
► Use distilled water only (<10 ppm total dissolved solids).

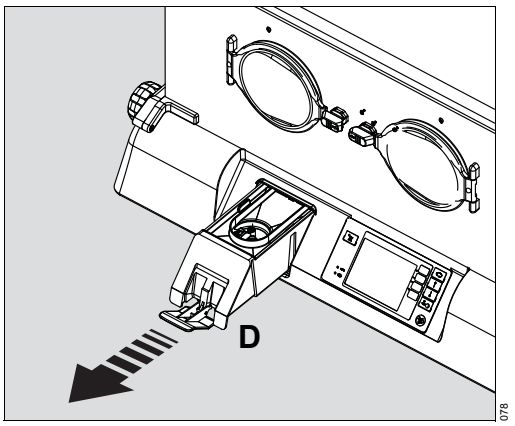
⚠ CAUTION
Risk of injury or damage to the device
Spilled liquids could cause a slip hazard.
► If any liquids spill or leak around the device, dry the area.

Mineral deposits may form on the evaporator, depending on the quality of the distilled water.

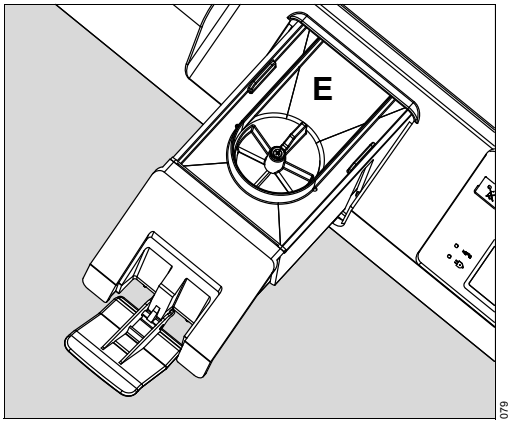
The water level is visible through the front of the water reservoir. In addition, the minimum (A), half-full (B), and maximum (C) water marks on the reservoir latch can be used to assess the water level.



1 Pull the latch forward and slide the reservoir assembly (D) halfway out from the front of the incubator shell.



2 Open the cover (E) on the filling inlet by rotating it.



3 Pour distilled water into the reservoir until the water level is just below the bottom of the filling inlet. Do not overfill. The water level should not exceed the maximum mark on the front latch of the reservoir.

4 Close the cover on the filling inlet.

5 Slide the reservoir assembly fully into the shell.

6 Lock it in place by pushing in the latch.

⚠ CAUTION

Risk of injury or damage to the device

Using an incomplete water reservoir can prevent the system from operating correctly.

► Ensure that the reservoir lid is installed.

► Ensure that the cover on the filling inlet is closed.

8.2.2 Selecting the humidity mode

1 Pre-warm the incubator in air temperature mode to the temperature prescribed by the attending physician or according to Nursery Standing Orders.

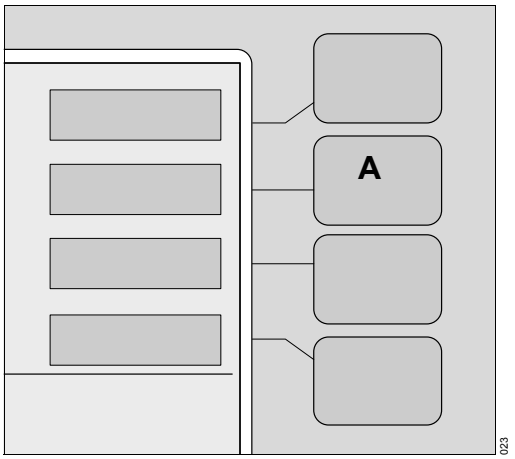
⇒ Incubator is warmed.

2 Ensure that the water reservoir is filled with distilled water.

⇒ Water reservoir is filled.

3 If necessary, unlock the keypad.

4 At display 1, press the ***Humidity*** button (A).



⇒ The screen changes to the humidity display with new button labels.

If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

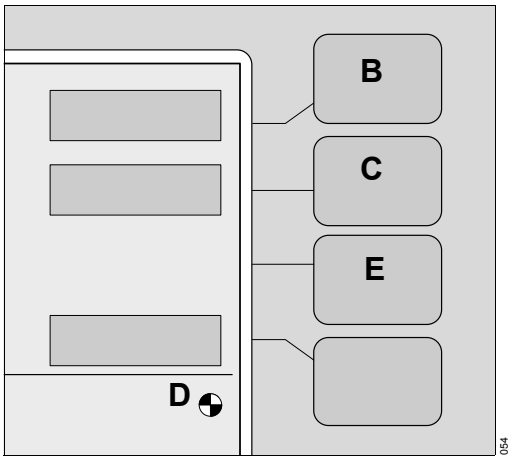
5 To activate the desired humidity mode, press the ***Auto*** (B) or ***Manual*** (C) button.

⇒ When Auto humidity is activated, the humidity set point is automatically pre-selected and the system returns to the display 1.

⇒ When Manual humidity is activated, the system remains in the humidity screen and allows the user to enter the humidity set point.

⇒ The rotating wheel (D) indicates that a humidity mode is active. The actual RH% achievable inside the system depends on the incubator temperature set point and room conditions.

6 Press the ***Off*** button (E).



✓ Humidity mode is deactivated.

8.2.3 Setting the humidity set point in manual mode

ℹ If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

To set the humidity set point:

1 Activate the humidification system in manual mode (see Selecting the humidity mode on page 87).

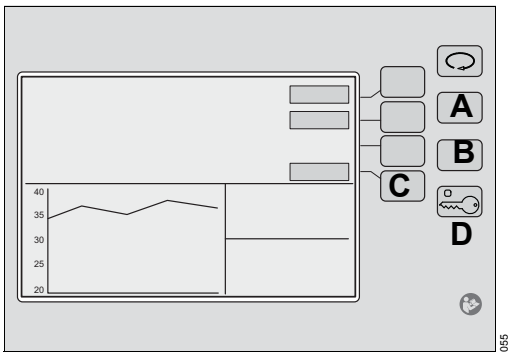
2 Adjust the humidity set point.

- To raise the humidity set point within a range of 30% to 95% in 1% increments, press and hold the Up Arrow key (A).
- To lower the humidity set point within a range of 95% to 30% in 1% decrements, press and hold the Down Arrow key (B).

3 To confirm the humidity setting, press the Home button (C).

⇒ Device returns to display 1.

4 Press the Keypad Lock key (D).



✓ Keypad is locked.

8.3 Setting the servo control oxygen (option)

In oxygen control mode, the oxygen sensors and control valve module control the oxygen concentration (from 21% to 65%). The alarm limit default is ± 3% from the set point. If the oxygen concentration rises above or falls below the ± 3% limit, acoustic and optical alarm signals are issued. Also, the message ***Low Oxygen %*** or ***High Oxygen %*** is displayed in the Trend/Alarm window.

⚠ WARNING
Risk of death or serious injury
The oxygen concentration guide is valid only for manual control oxygen usage.

► When using the servo control oxygen system during oxygen administration, do not use the oxygen concentration guide on the rear of the device.

ℹ If arterial oxygen levels cannot be maintained when the oxygen control setting is set to maximum, the attending physician should prescribe alternate means of oxygenation.

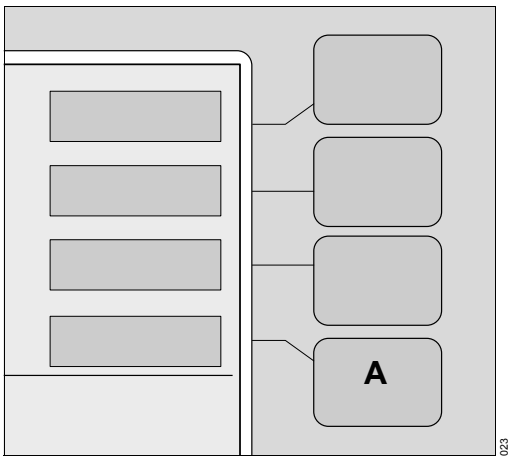
8.3.1 Turning the oxygen mode on or off

1 Ensure that the oxygen supply provides an inlet pressure and inlet flow rate in compliance with the specifications (see Oxygen control system (option) on page 170).

2 Connect the oxygen hose from the oxygen inlet located under the rear shell of the incubator to the oxygen supply.

3 If necessary, unlock the keypad.

4 At display 1, press the ***Oxygen*** button (A).



If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

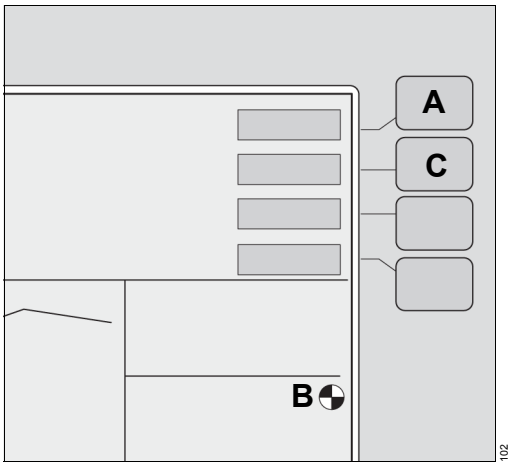
⇒ The screen changes to the oxygen display with new button labels.

5 To activate the oxygen mode, press the ***On*** button (A).

⇒ The rotating wheel (B) indicates that the oxygen mode is active.

6 If the message ***Cal Required*** is displayed, calibrate the oxygen control system (see Shutting down the Isolette 8000 plus properly on page 108).

7 Press the ***Off*** button (C).



✓ Oxygen mode is deactivated.

8.3.2 Setting the oxygen set point

To set the oxygen set point in accordance with the attending physician recommendations:

1 Activate the oxygen mode (see Turning the oxygen mode on or off on page 90).

If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

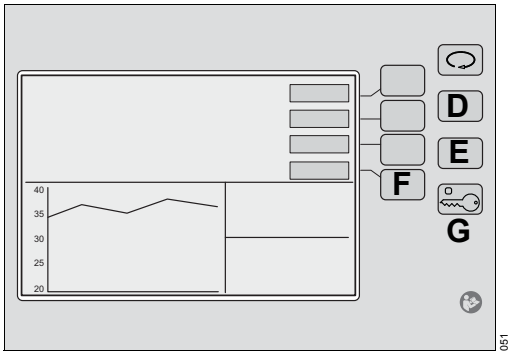
2 Adjust the oxygen set point:

- To raise the set point within a range of 21% to 65%, press the ***Up Arrow*** key (D).
- To lower the set point within a range of 65% to 21%, press the ***Down Arrow*** key (E).

3 To acknowledge the oxygen control setting, press the ***Home*** button (F).

⇒ Device returns to display 1.

4 Press the ***Keypad Lock*** key (G).



✓ Keypad is locked.

8.4 Using manual control of oxygen (option)

⚠ WARNING
Risk of death or serious injury
The oxygen flow rates shown here and on the label on the back of the incubator cannot be used as an accurate indication of oxygen concentrations in the incubator. These rates should only be used as a guide.

► Measure oxygen concentrations with a calibrated oxygen analyzer at intervals directed by the attending physicians.

⚠ WARNING
Risk of death or serious injury
If their ignition temperature is reached, violent ignition of oil, grease, greasy substances, small particles or dust, dirt, or other particulate contaminants, even small particles of metal, could occur in the presence of high-pressure oxygen.

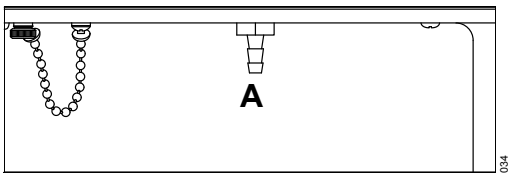
► Take care when using high-pressure oxygen, such as that found in medical oxygen cylinders.

1 Make sure all fittings and connections for the supply oxygen are clean.

2 Administer oxygen from a wall source or the accessory oxygen cylinder on the incubator trolley. Refer to the current edition of *Guidelines for Perinatal Care of the American Academy of Pediatrics* (The American College of Obstetricians and Gynecologists).

3 Connect the output of the O_2 flowmeter to the barbed fitting labeled ***O2 INLET*** (A) using 3/16-inch inner diameter surgical hose.

4 Allow oxygen concentrations to stabilize.



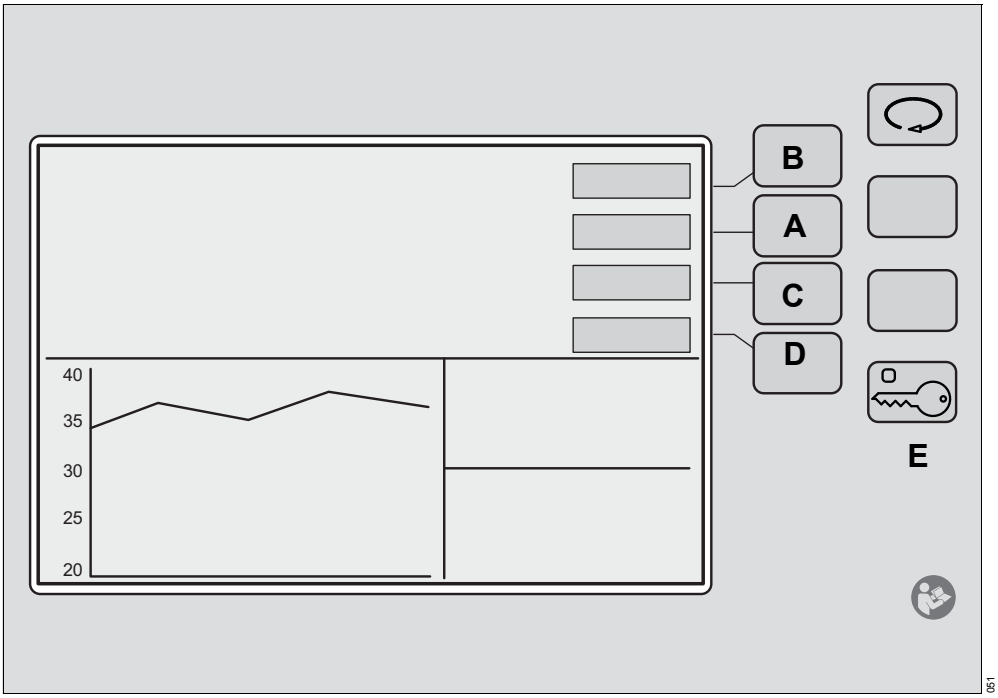
An oxygen concentration guide is provided. This guide is also displayed on a label on the back of the incubator.

Oxygen supply	Approximate oxygen %
3 L/min	30% to 50%
6 L/min	40% to 65%
9 L/min	45% to 75%
12 L/min	50% to 90%
15 L/min	60% to 100%

8.5 Trending

The actual screen display may differ in appearance or configuration.

8.5.1 Displaying trends



If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

1 If necessary, unlock the keypad.

2 At display 1, press the ***Display Selection*** key.

⇒ Display 2 appears.

3 At display 2, press the ***Trend*** button to select the Trend display.

⇒ Trend menu items appear.

4 Press and hold the ***Clear*** button (A).

⇒ All Trend displays are cleared.

5 To select the trend period: 2, 4, 8, 12, or 24 hours, press the ***Hours*** button (B).

The ***Hours*** button is not applicable for trends of the infant weight. The trend interval for infant weight is 7 days.

6 To select one of the following Trend displays, press the ***Display*** button (C) repeatedly until the desired setting is shown:

- ***Air temp***
- ***Skin temp***
- ***Heater power %***
- ***Oxygen*** (optional)
- ***Humidity*** (optional)
- ***Weight*** (optional)

7 To confirm the Trend display selection, press the ***Home*** button (D).
⇒ Device returns to display 2.
8 Press the ***Keypad Lock*** key (E).
✓ Keypad is locked.

8.6 Weighing– scale measurements (option)

8.6.1 Techniques for accurate scale measurements

- Always weigh the infant in the center of the bed with the bed in its flat position.
- Do not allow stuffed toys or other objects on the bed to lean against the incubator walls or access panels. Inaccurate readings can occur.
- Do not allow the mattress cover to touch the hood.
- Secure the ventilator hose to the incubator walls in a manner that permits water in the hose to drain away from the infant.

To ensure that they do not touch the bed, support the ventilator hose and I.V. tubes.

- Place the following items so that they return to the same relative position when the infant has been lifted off and returned to the bed: Breathing hoses, I.V. tubes, and sensor leads.

⚠ WARNING
Risk of death or serious injury
Failure to comply could impact infant safety.
► Do not leave the infant unattended when the access panel is open.
► Double-check therapeutic decisions that are based on the patient weight by performing a reference measurement using an external scale.

⚠ WARNING
Risk of measuring error due to incorrect taring weight
If a tare weight is not determined before weighing, measuring errors may occur.
► Tare the scale before each weighing process.

The bed should be level, i.e., not in the Trendelenburg or Reverse Trendelenburg position.

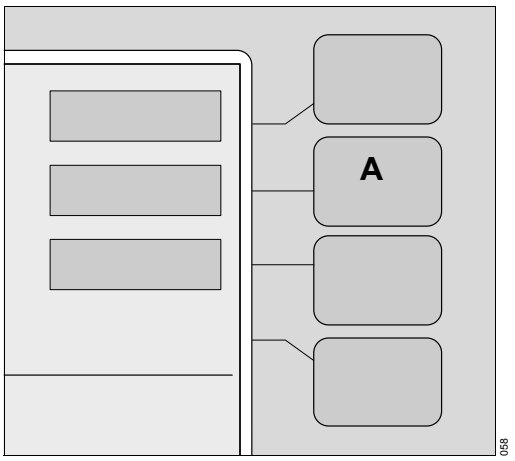
8.6.2 Standard scale measurements

8.6.2.1 Initial weigh

To perform the initial weighing function:

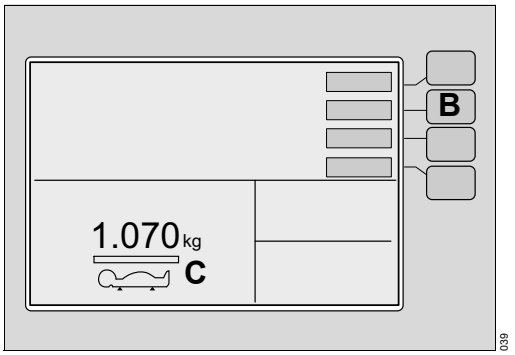
1 If necessary, unlock the keypad.
2 At display 1, press the ***Display Selection.***
⇒ Display 2 appears.

3 At display 2, press the ***Weight*** button (A).



4 Press the ***->0/T<-*** button (B).

⇒ The ***Lift Baby*** prompt symbol is displayed (C).

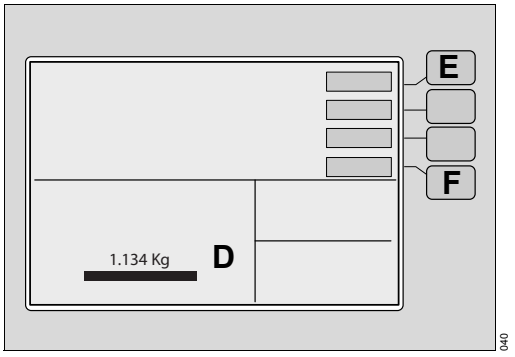


5 Lift the infant off the bed.

⇒ The ***Lift Baby*** prompt symbol disappears.

6 Place the infant on the bed.

⇒ The Weight Sample bar fills, and the weight of the infant is displayed in the Trend/Alarm window (D).



7 To enter the infant weight in the Trend/Alarm window, press the ***Store*** button (**E**).

The trend of the infant weight is tracked over a period of 7 days or seven 24-hour periods. The first stored weight is used as the baseline weight measurement and initiates the count for the first 24-hour period. The first trend data represents the difference between the baseline weight measurement and the last weight stored during that 24-hour period. Subsequent trend data for the remaining 6 days represent the difference between the last stored weight, within a 24-hour period, and the baseline weight measurement.

8 Press the ***Home*** button (F).

✓ Device returns to display 2.

8.6.2.2 Reweigh

1 To reweigh the infant without removing or adding anything to the bed, press the ***Weight*** button on display 2.

✓ Updated infant weight appears on the display.

2 If objects are added or removed from the bed, or a power failure occurs, refer to Initial weigh on page 94 to ensure accurate measurement of the infant weight.

8.6.3 OIML/NAWI scale measurements (not available in all markets)

The OIML/NAWI scale continuously displays the active weight of the infant in the Trend/Alarm window.

To initiate the weighing function:

1 If necessary, unlock the keypad.

2 At display 1, press the ***Display Selection*** key.

⇒ Display 2 appears.

3 Press the ***Weight*** button.

4 At the Weight screen, press the ***->0/T<-*** button.

⇒ The ***Lift Baby*** prompt symbol and Weight Sample bar are displayed.

The Weight Sample bar is used only to indicate the progress of the zeroing feature.

5 Lift the infant off the bed.

⇒ The ***Lift Baby*** prompt disappears.

6 Place the infant on the bed.

7 To enter the infant weight for trending, press the ***Store*** key.

The trend of the infant weight is tracked over a period of 7 days or seven 24-hour periods. The first stored weight is used as the baseline weight measurement and initiates the count for the first 24-hour period. The first trend data represents the difference between the baseline weight measurement and the last weight stored during that 24-hour period. Subsequent trend data for the remaining 6 days represent the difference between the last stored weight, within a 24-hour period, and the baseline weight measurement.

8 Press the ***Home*** button.

✓ Device returns to display 2.

8.7 Using kangaroo mode

⚠ WARNING
Risk of death or serious injury
Temperature of infants outside the incubator can fluctuate.

► When using kangaroo mode, the central temperature of the infant, who is outside the controlled climate of the incubator, must be monitored constantly.

► Particular attention must be paid to critical care O_2 vital signs, especially a critical O_2 partial pressure.

► Ensure that all cables and hoses are routed correctly and safely.

8.7.1 Overview of kangaroo mode

In kangaroo mode, the patient is warmed by the parent's body heat instead of the device. Place the patient on the mother's or the father's naked breast. To prevent heat loss, also cover the patient with a blanket.

8.7.2 Incubator operation

Once kangaroo mode is activated, the incubator operates in air temperature mode and the incubator air temperature set point is controlled using the air temperature sensor. When switching from air temperature mode to kangaroo mode, all settings remain unchanged and active. When switching from skin temperature mode to kangaroo mode, the current incubator temperature is used as the air temperature set point (limited to 37 °C). All other settings remain unchanged and active.

Settings adopted from the previously set mode:

– Air temperature
– Humidity
– Oxygen (Optional)

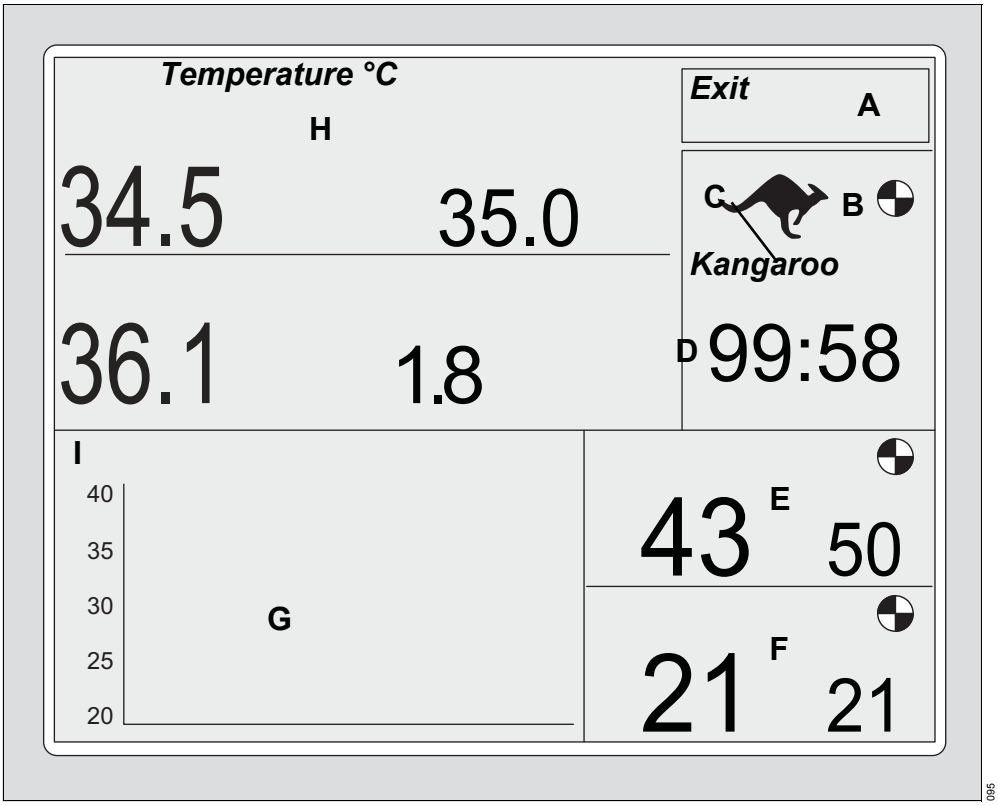
Depending on the patient, kangarooing may last for several minutes or hours. When the patient is returned to the incubator and kangaroo mode has ended, the incubator resumes the warming therapy mode and settings that were active before kangaroo mode.

After switching to kangaroo mode, the following alarms are inhibited for 4 minutes:

– ***Low Air Temperature***
– ***Low Humidity***
– ***Low Oxygen %***
– ***Central Skin Temp Low***
– ***Peripheral Skin Temp Low***
– ***Skin Temp Diff High***
– ***Skin Temp Diff Low***

If an alarm is active when switching to kangaroo mode, the alarm is canceled and inhibited.

8.7.2.1 Screen showing kangaroo mode selected and active

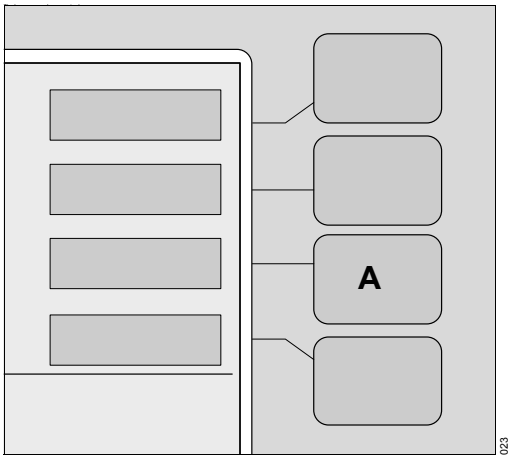


No.	Designation	Description
A	***Exit***	Ends kangaroo mode
B	Activity indicator	Rotating wheel indicates that kangaroo mode is active
C	***Kangaroo*** indicator	Indicates kangaroo mode selected
D	Timer	Shows elapsed time (hours and minutes) in kangaroo mode
E	***Humidity*** parameter field	Shows humidity status
F	***Oxygen*** parameter field	Shows oxygen status
G	Trend parameter field	Shows trends
H	***Temperature*** parameter field	Shows temperature status
I	Alarm display	Shows alarm messages, if applicable, replaces the Trend display

8.7.3 Starting kangaroo mode:

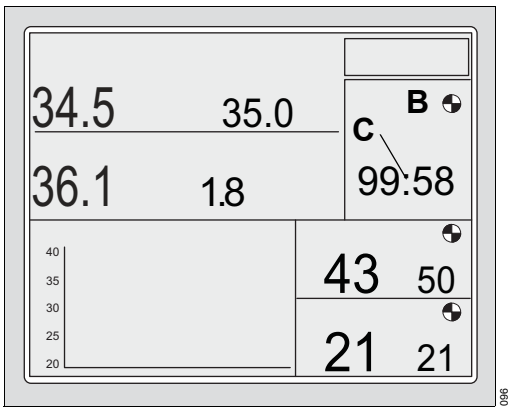
1 If necessary, unlock the keypad.

2 At display 2, press the ***Kangaroo*** button (A) to select the kangaroo mode.



⇒ The kangaroo screen shows the rotating wheel (B).

⇒ The duration of kangaroo mode is continuously shown on the elapsed time meter (C).



3 Open the hood or access panel and remove the patient from the incubator.

4 Place the patient on the parent's naked chest.

5 To prevent heat loss, cover the patient with a blanket.

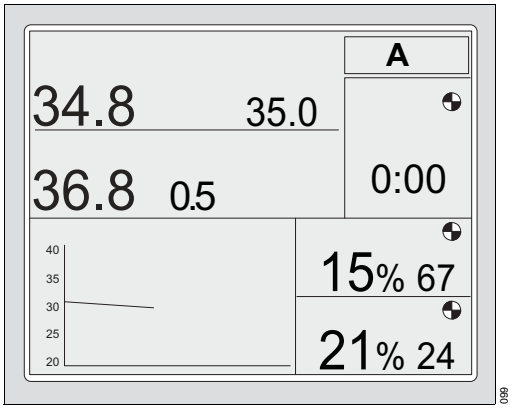
6 If skin temperature probes are used, ensure that they are connected correctly to both the device and to the patient.

In kangaroo mode, the yellow probe monitors the central skin temperature. However, the central skin temperature value does not affect the temperature in the patient compartment.

7 Close the hood or access panel. **Ensure that the hoses and cables do not get caught or kinked.**

8.7.4 Ending kangaroo mode:

1 Touch the ***Exit*** key (A) on the kangaroo screen.



⇒ The incubator exits kangaroo mode and returns to the main screen.

✓ The incubator continues warming therapy with the settings that were active before kangaroo mode.

2 Open the access panel and place the patient inside the incubator.

3 If skin probes are used, ensure that they are correctly connected to the device and attached to the patient.

4 Close the device, and confirm that locking knobs are secure.

5 Depending on the operation mode, check the following settings and adjust as necessary:

– Skin temperature

– Air temperature

– Oxygen (optional)

– Humidity

8.8 Setting up alarm limits and display units

The Setup screen allows the user to review and change display settings for some features:

– Temperature display units in Celsius or Fahrenheit degrees

– Alarm limits for temperature and oxygen

– Alarm limits for kangaroo mode

The following table shows alarm limit ranges and defaults:

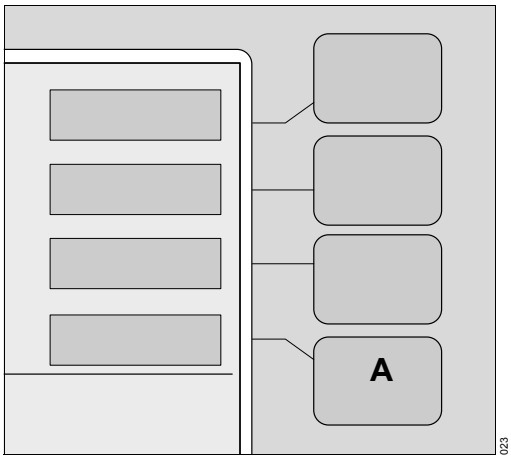
Ranges	
Air temperature upwards deviation limit range	+1.5 °C (+2.7 °F) to +2.5 °C (4.5 °F)
Air temperature downwards deviation limit range	- 1.5 °C (- 2.7 °F) to - 2.5 °C (- 4.5 °F)
Skin temperature deviation limit range	0.3 °C (0.5 °F) to 1.0 °C (1.8 °F)
Oxygen deviation limit range	3% to 5%

Defaults	
Air temperature upwards deviation limit default	+1.5 °C (+2.7 °F)
Air temperature downwards deviation limit default	- 2.5 °C (-4.5°F)
Skin temperature deviation limit default	1.0 °C (1.8 °F)
Oxygen deviation limit default	3%

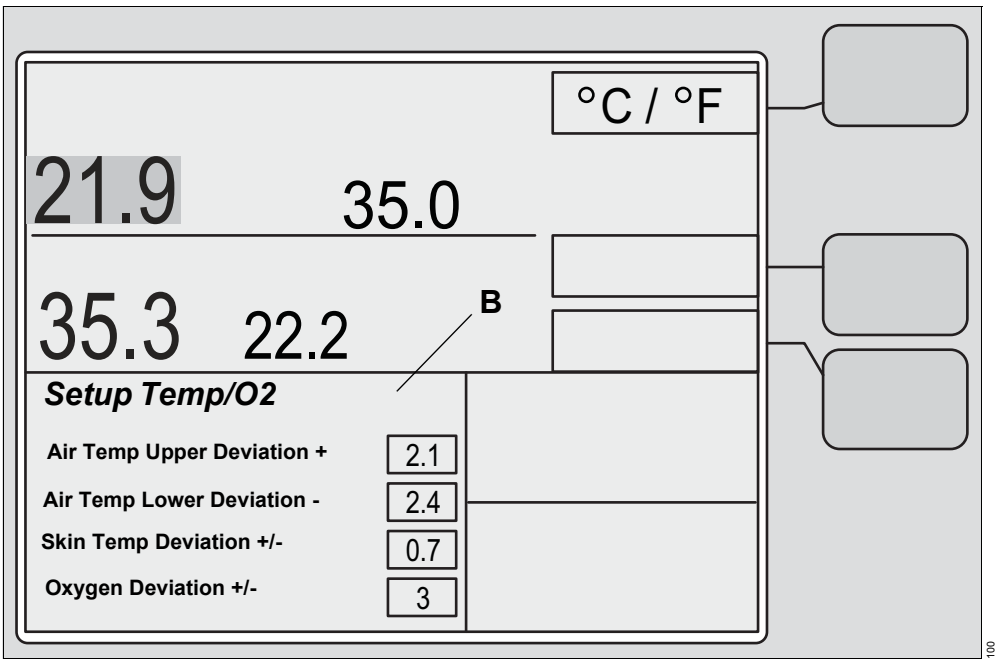
8.8.1 Entering the setup menu

1 If necessary, unlock the keypad.

2 At display 2, press the ***Setup*** button (A).



⇒ The ***Temp/O2 setup*** screen appears.



Setup automatically goes to Temp/O2 setup screen.

3 Set or change the Temp/O2 settings (B) or refer to Setting up alarm limits in kangaroo mode on page 102.

⇒ Temperature and oxygen settings are as desired.

4 Set or change the desired display settings.

⇒ Display is set as desired.

5 To exit the Setup screen, press ***Home*** (C).

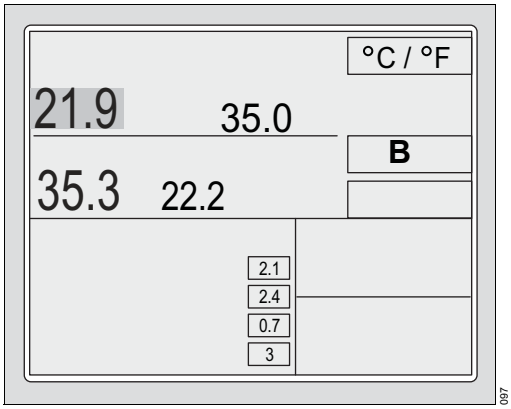
✓ Device exits Setup screen and returns to display 2.

8.8.2 Setting up alarm limits in kangaroo mode

The following table shows alarm limit ranges and defaults:

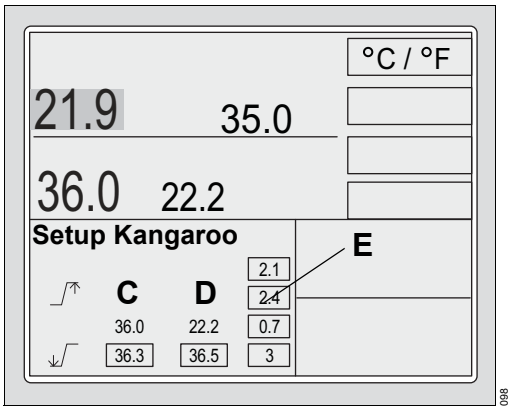
Ranges	
Kangaroo mode central skin temperature lower limit range	Off, 33.0 °C (91.4 °F) to 36.5 °C (97.7 °F)
Kangaroo mode peripheral skin temperature lower limit range	Off, 33.0 °C (91.4 °F) to 36.5 °C (97.7 °F)
Kangaroo mode skin temperature difference upper limit range	2.0 °C (3.6 °F) to 5.0 °C (9.0 °F), Off
Kangaroo mode skin temperature difference lower limit range	Off, -2.0°C (-3.6°F) to 2.0 °C (3.6 °F)
Defaults	
Kangaroo mode central skin temperature lower limit default	35.0 °C (95.0 °F)
Kangaroo mode peripheral skin temperature lower limit default	35.0 °C (95.0 °F)
Kangaroo mode skin temperature difference upper limit default	5.0 °C(9.0 °F)
Kangaroo mode skin temperature difference lower limit default	Off

1 Press the ***Kangaroo*** key (B).



⇒ The ***Setup Kangaroo*** screen appears.

⇒ The kangaroo mode alarm limits appear.



2 Set and confirm the lower alarm limit for the central skin temperature (C).

3 Set and confirm the lower alarm limit for the peripheral skin temperature (D).

4 Set the alarm limits for the difference (E) between the central and peripheral skin temperatures.

✓ Alarm limits are set as desired.

To disable kangaroo mode alarm limits, set them to Off.

If the skin temperature from the yellow central skin temperature probe falls below the alarm limit:

– The screen shows an alarm message ***Central Skin Temp Low***.

– An acoustic alarm signal begins.

If the skin temperature from the white peripheral skin temperature probe falls below the alarm limit:

– The screen shows an alarm message ***Peripheral Skin Temp Low***.

– An acoustic alarm signal begins.

If the difference between the measured central skin temperature and the measured peripheral skin temperature exceeds the temperature difference upper limit:

– The screen shows an alarm message ***Skin Temp Diff High***.

– An acoustic alarm signal begins.

If the difference between the measured central skin temperature and the measured peripheral skin temperature is less than the temperature difference lower limit:

– The screen shows an alarm message ***Skin Temp Diff Low***.

– An acoustic alarm signal begins.

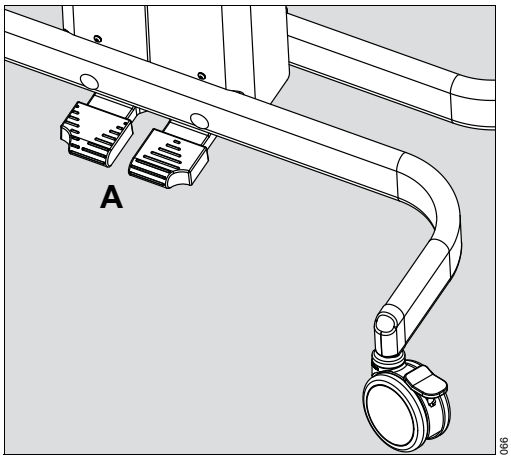
8.9 Adjusting height

⚠ WARNING
Risk of death or serious injury
Raising or lowering the incubator with obstructions can cause death or serious injury to the patient and user.
When raising or lowering the incubator:

- ► Ensure that the travel path of the device is clear of any obstructions, including limbs.
- ► Check patient and incubator connections.
- ► Before lowering the device, check to ensure that there is sufficient clearance between the incubator and trolley assembly, especially under the drawers.
- ► Do not place any items on the trolley legs.
- ► Do not raise or lower the device while installing or removing medical gas cylinders from the cylinder holder.
- ► When operating the height adjustment trolley, always place one hand on the incubator for support to keep from losing your balance.

The Isolette 8000 plus has 2 sets of foot pedals, one on the front of the device and one on the rear of the device.

- To adjust the height of the incubator, press the up/down arrow (A) on the front/rear pedal of the height adjustment trolley.



✓ The incubator rises or lowers as desired.

8.10 Placing the Infant

⚠ WARNING
Risk of death or serious injury
Failure to pre-warm the incubator could lead to inaccurate temperature readings.

- ► Before placing the infant in the incubator, pre-warm the incubator to the temperature prescribed by the attending physician, or according to nursing protocol.

To place an infant in the incubator, perform the following:

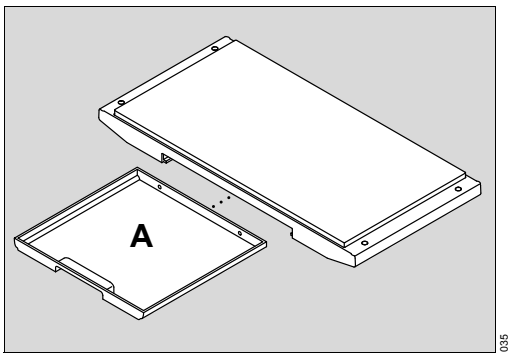
1 Pre-warm the incubator.
2 Rotate the locking knobs, and open the front access panel.
3 Place the infant in the center of the bed.
4 Close the access panel, and ensure that the locking knobs are fully engaged.

8.11 Using the X-ray tray

⚠ WARNING
Risk of death or serious injury
Unattended infants could roll out of the incubator.
► Do not leave the infant unattended when the access panel is open.

⚠ WARNING
Risk of death or serious injury
When an X-ray is taken through the hood, the hood could show up on the X-ray as a translucent shadow and could result in incorrect diagnosis.
► Be aware of this possibility when taking X-rays through the hood.

1 Remove any accessories that may interfere with movement of the front access panel.
2 Rotate the locking knobs, and open the front access panel.
3 Slide out the X-ray tray (A) from under the bed.



4 Place the X-ray cassette in the center of the X-ray tray.
5 Use the numbered scales on the X-ray tray and on the hood to position the patient and the X-ray cassette.
6 Push the X-ray tray back in under the bed.
7 Place the infant at the center of the bed.
8 Close the access panel, and ensure that the locking knobs are fully engaged.
9 When the X-ray is completed, repeat steps 1 and 2.
10 Remove the X-ray cassette from the tray, and return the tray.
11 Close the access panel, and ensure that the locking knobs are fully engaged.
12 Replace any accessories that were previously removed.

8.12 Using the communication interface

The RS-232 port enables the user to export incubator data (actual values, set points, alarms) to a patient monitor or a central monitoring system.

The Isolette 8000 plus supports serial data output and Dräger MEDIBUS.X communication protocol.

MEDIBUS.X is a software protocol for data exported between Isolette 8000 plus and an external device by an RS-232 interface. (Examples are hemodynamic monitors, data management systems, or computers).

Before transferring data, strictly follow the information in these documents:

– MEDIBUS.X, Rules and Standards for Implementation (9052607)
– MEDIBUS.X, Profile Definition for Data Communication V1.n (9052608)
– Serial Data Output Protocol Description for Isolette family (MU22509)

8.12.1 Configuring the communication protocol

To select the desired communication protocol, perform the following procedure:

1 Switch off the incubator ***on/off switch***.
2 While pressing the ***Audio Paused/Reset*** key, switch on the incubator ***on/off switch*** to enter the system set-up menu.
3 Using the ***Display Selection*** key, scroll down to the ***External interface*** option.
4 Select ***Serial Data*** or ***MEDIBUS.X***.
5 To exit the set-up menu, press the ***Audio Paused/Reset*** key.
✓ Data exports automatically.

⚠ WARNING
Risk of patient injury
All data exported over the MEDIBUS.X interface are for information only. Data accessible through this interface are not suitable for a decentralized alarm system in accordance with IEC 60601-1-8 (regarding remote monitoring).
► Data must not be used as the sole basis for diagnostic or therapeutic decisions.

⚠ WARNING
Risk of electrical shock
Connecting devices to the MEDIBUS.X interface can lead to an increased leakage current. If the protective grounding of one of these devices fails, the leakage current may rise above permissible values.
► Only connect with the approval of the respective device manufacturer.
► Service personnel must check the leakage current.
► If permissible values are exceeded, disconnect the devices from the MEDIBUS.X interface.

8.12.2 Using external monitors (Dräger Infinity Delta and Delta XL)

To view incubator status data on an external monitor, perform the following procedures.

Infinity Delta or Delta XL monitors require a minimum software version of VF7.1. The MIB2 protocol converter requires a minimum software version of VF7.

1 Switch off the incubator ***on/off switch***.

2 Connect the DB-9 male end of the Medical Information Bus (MIB) network cable (part number MS18805) to the RS-232 port on the bottom of the incubator shell assembly (see External devices on page 32).

3 Connect the DB-25 male end of the MIB network cable to the MIB2 protocol converter.

4 Connect one end of the appropriate length MIB network cable to the MIB2 protocol converter.

5 Connect the other end of the MIB patch cable to the Infinity Docking Station (IDS).

6 Switch on the incubator ***on/off switch***.

7 Configure the external interface to serial data output protocol (see To select desired settings in the system configuration menu: on page 114).

8 See the instructions for use for the specific patient monitor for further setup and operation information.

For the parts required to connect the Isolette 8000 plus infant incubator to the Dräger Infinity Delta or Delta XL monitors, see Optional components on page 182.

8.13 Shutting down the Isolette 8000 plus properly

1. Remove power from any devices plugged into the auxiliary power sockets.
2. Shut off the oxygen source.
3. Disconnect the incubator from the oxygen source.
4. Switch off the ***on/off switch*** on the incubator shell to power down the incubator.
5. Switch off the main On/Off switch on the stand.

9 Alarms

⚠ WARNING
Risk of not hearing alarm signals can cause patient injury
If the alarm volume is too low, alarm signals may not be heard.
► The user must remain within earshot of the alarm signals.

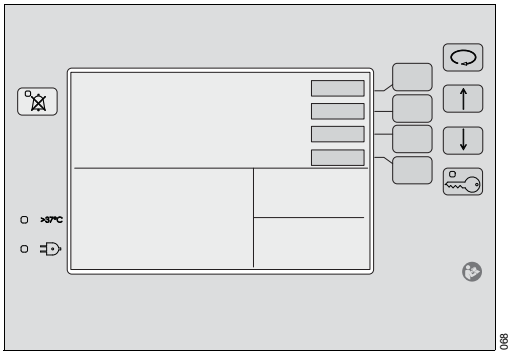
⚠ WARNING
Risk of death or serious injury
A potential hazard exists if different alarm settings are used for different incubators in any single area of the hospital.
► Monitor the alarm setup for each incubator and patient.

The acoustic and optical alarms are observable from the user operating position of at least 1 meter from the front panel of the controller.

9.1 Display of alarms

Alarms are signaled optically and acoustically according to their alarm priority. An alarm is reported whenever a condition that could be hazardous is detected.

- An appropriate message appears in the Trend/Alarm window (**A**)
- An LED indicator illuminates (on the ***Audio Paused/Reset*** key (**B**) or on the sensor module)
- An acoustic alarm signal sounds



Alarm behavior is summarized in the following table:

Color	Signal	Acoustic alarm signal	Priority	Required action
Yellow	Blinking	Repeating single tone (for the ***Power Failure*** alarm only)	Medium	Prompt action required to avert risk.
Yellow	Intermittent	Repeating 3 tones	Medium	Prompt action required to avert risk.
Yellow	Continuous	Repeating 2 tones Note: Three stage alarm volume level: 15s low, 15s medium, and then high.	Low	Delayed action required to avert risk.

If two or more system alarms occur simultaneously, or one after the other, the alarm messages of the highest priority (for example, Controller Failure alarms) are presented first. They are then followed by all other messages in sequence. A total of 6 messages can be presented in the Trend/Alarm window.

The Isolette 8000 plus automatically delays certain alarms for a brief period to verify that the alarm condition is valid. Similarly, some alarms are inhibited during calibration or setup procedures to minimize nuisance alarms. For the specific alarms that are delayed or inhibited, see Alarm – Cause – Remedy on page 115).

A message without an audible or visual LED indication may also be displayed to tell the user of conditions that are not hazardous but require attention or correction.

For a complete list of Isolette 8000 plus alarm messages, see Alarm – Cause – Remedy on page 115.

9.2 Alarm priorities

Isolette 8000 plus alarms are organized into one of 2 categories based on the urgency of the alarm:

Color	Priority of the alarm message			Action required
Yellow	Caution	Medium-priority alarm	!!	Prompt action required to avert risk.
				For alarm conditions that do not cause patient injury or death until at least several minutes have passed
Yellow	Note	Low-priority alarm	!	Delayed action required to avert risk.
				For alarm conditions that cause patient injury only after many minutes or hours have passed

9.3 Disabling the acoustic alarm signal

The ***Audio Paused/Reset*** key (B) is used to silence the acoustic alarm signal for a fixed amount of time. It can also initiate a silence period before an alarm is activated (procedural silence).

Alarms can be silenced for 4, 5, or 15 minutes, depending on the alarm, and some alarms cannot be silenced at all (see Alarm – Cause – Remedy on page 115).

The ***Audio Paused/Reset*** key can perform the following functions:

– If there are no current alarms present, reset one or multiple latched (not currently active) alarms.

– Silence one or more alarms if no previously latched alarms are present.

The ***Audio Paused/Reset*** key cannot simultaneously reset a previously latched alarm and silence a current alarm condition.

9.3.1 To initiate a procedural silence:

- When alarms are inactive, press the ***Audio Paused/Reset*** key for a temporary procedural silence. The message ***Procedural Silence*** appears in the Trend/Alarm window.

If there is a new alarm during the silence period, the device reacts as follows:

– There is no acoustic alarm signal unless there is a high temperature, probe failure, or air flow alarm.

– The alarm message and the measured value are displayed.

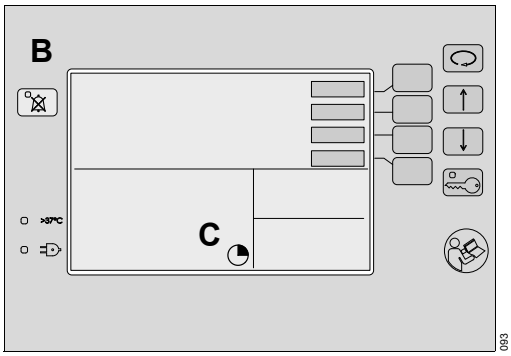
– The LED on the ***Audio Paused/Reset*** key (B) illuminates for the new alarm.

9.3.2 To disable acoustic alarm signals:

- When alarms are active, press the ***Audio Paused/Reset*** key. A symbol (C) is displayed on the screen to indicate the time remaining in the silence period.

If there is a new alarm during the silence period, the device reacts as follows:

- Acoustic alarm signal sounds.
- The new alarm message is displayed.
- The LED on the ***Audio Paused/Reset*** key (B) illuminates (depends on priority of the alarm).



10 Configuration

The actual screen display may differ in appearance or configuration.

10.1 System configuration menu

The system configuration menu enables the user to view and change configurable system parameters.

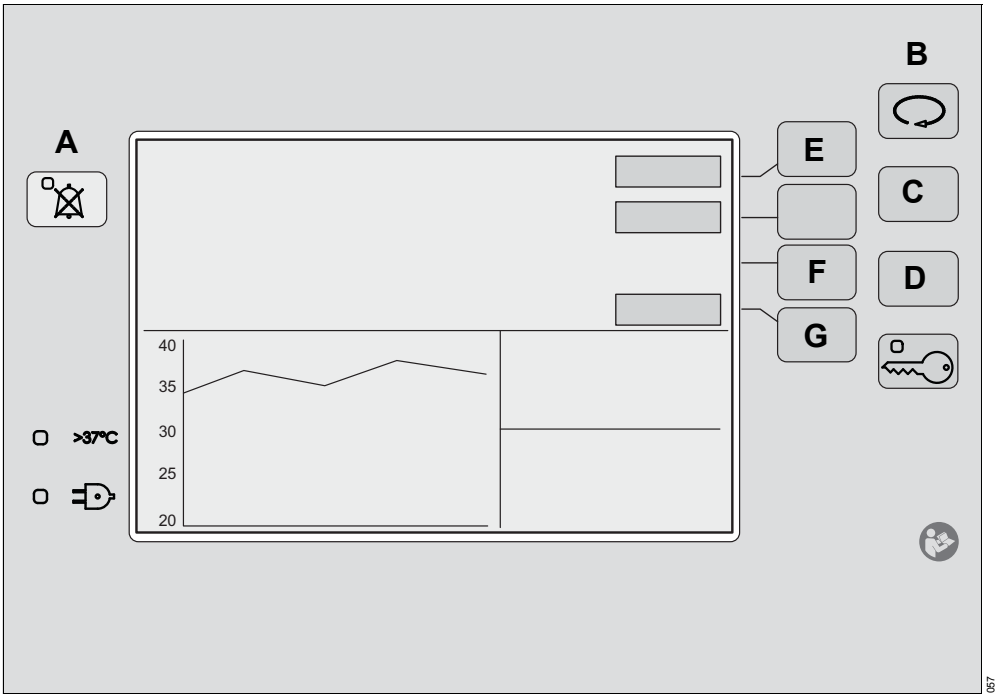
10.1.1 Default settings

With power failures lasting 10 minutes or less, the set points and operation mode are retained. With power failures lasting more than 10 minutes, the set points and operation mode revert to factory default settings or to the settings selected in the system configuration menu.

System configuration menu items	Setting options	Default settings
Humidity Option	***Yes/No***	***No***
Oxygen Option	***Yes/No***	***No***
Oxygen Cal Level	100%/21%	21%
Skin Control Mode	***Yes/No***	***Yes***
Skin Temperature Difference	***Yes/No***	***No***
Language	***English, French, German, Spanish, Italian, Japanese, Dutch, Danish, Norwegian, Polish, Portuguese, Swedish, Finnish, Greek, Czech, Slovak, Russian, Bulgarian, Chinese, Hungarian, Turkish, Lithuanian, Serbian, Croatian, Slovenian, Romanian***	***English***
Weight Units	***lb/kg***[1)]	***kg***
Air Set Temp	20.0 °C to 37.0 °C (increments of 0.1 °C)	35.0 °C
Altitude[2)]	0 ft to 12,000 ft (0 to 3657 m) (increments of 2000 ft)	***0 ft (0 m)***
External interface	***Serial Data/MEDIBUS.X***	***Serial Data***
Display Color	***Yellow/black / White/blue***	***White/blue***

1) For OIML devices, only kg units shall be displayed.
2) Used for 21% oxygen calibration offset

10.1.2 To select desired settings in the system configuration menu:



1 Switch off the incubator using the ***on/off switch*** located under the incubator shell assembly.

2 Press and hold the ***Audio Paused/Reset*** key (A).

3 Switch on the incubator and continue to hold the ***Audio Paused/Reset*** key while the device powers up.

   ⇒ The system configuration menu appears.

4 Select the menu items using the ***Display Selection*** key (B).

5 Select the desired settings using the ***Up Arrow*** (C) and ***Down Arrow*** (D) keys.

   - To set all configuration options to factory default settings, press the ***Hard Default*** button (E).
   - To display a system information screen, press the ***Diag Info*** button (F).
   - To access more configuration menu items, press the ***Page 2*** button (G).
   - Press the ***Audio Paused/Reset*** key (A).

✓ System exits the system configuration menu.

11 Troubleshooting

11.1 Alarm – Cause – Remedy

The Isolette 8000 plus displays alarm messages in the Trend/Alarm window. If two or more system alarms occur simultaneously, or one after the other, the alarm messages of the highest priority (i.e., Controller Failure alarms) are presented first. They are followed by all other messages in sequence. A total of 6 messages can be presented in the Trend/Alarm window.

In addition to a displayed message, alarm conditions are also indicated by an acoustic alarm signal and a lighted LED.

In the following table, the alarm messages are listed in alphabetical order. If an alarm occurs, the table helps to identify causes and remedies. The different causes and remedies should be worked through in the order listed until the alarm has been resolved.

To help service personnel, all failures and error codes should be recorded.

11.1.1 System alarms

Alarm priority	Alarm	Cause	Remedy
Medium	***Check Settings***	A failure is detected with the controller non-volatile memory test.	Check all settings to make sure that they are configured correctly.
Medium	***Controller Failure 1-14*** (For Controller Failure alarms 3, 4, and 7, alarm is delayed for 1 minute after the alarm condition occurs)	An internal malfunction occurred.	Switch off the incubator and then turn it on again. If the failure continues, switch off the incubator and remove it from service.
Medium	***Controller Failure 15-17***	This is the first time the device was installed or new software was loaded onto the controller.	Press the ***Audio Paused/Reset*** key.
		Controller memory failure was detected.	Reset settings to factory defaults by pressing the ***Hard Default*** button in the system configuration menu. Check the desired settings. If the failure continues, switch off the incubator and remove it from service.
Medium	***Heater Failed 1*** (Alarm can be silenced for 5 minutes)	The heater thermocouple voltage exceeds 40 mV.	Switch off the incubator, and remove it from service.

Alarm priority	Alarm	Cause	Remedy
Medium	***Heater Failed 2*** (Alarm is delayed for 1 minute after the alarm condition occurs)	The heater thermocouple wires are open or shorted.	Switch off the incubator, and remove it from service.
Medium	***Humidity Heater Fail*** (Alarm can be silenced for 15 minutes)	The optional humidification system is installed and the humidifier heater circuit draws too much current.	Switch off the incubator and remove it from service.
Medium	***Motor Failed*** (Alarm is delayed for 40 seconds after the alarm condition occurs)	The fan impeller motor malfunctioned.	Switch off the incubator and remove it from service.
Medium	***Power Failure*** (Alarm activates an acoustic alarm signal and the LED on the front panel illuminates; **no message appears on the screen**)	The main power cable is unplugged.	Make sure that the power cable is plugged into the AC power source. Ensure that the power cable is firmly attached to the height adjustment trolley receptacle.
		The power cable to the incubator on the front of the device is unplugged.	Attach the power cable to the incubator receptacle.
		Over-current protection fuses in the height adjustment trolley have blown.	Switch off the incubator and replace the fuses (see Fuse replacement on page 151).
Medium	***Sensor Disconnect***	The sensor module possibly experienced a communications failure.	If the sensor module is not connected, connect it. If the message persists: Switch off the incubator and then turn it on again. If the alarm still continues, replace the sensor module. If the alarm persists, remove it from service.
Medium	***Sensor Module Failure 1-8***	A sensor module malfunction occurred.	Switch off the incubator and replace the sensor module. If the failure persists, switch off the incubator and remove it from service.
Medium	***Sensor Out of Position*** (Alarm can be silenced for 5 minutes)	The sensor module is not in the correct position for calibration or operation.	Verify proper positioning of the sensor module. If the alarm persists, switch off the incubator and remove it from service.

Alarm priority	Alarm	Cause	Remedy
Low	***Skin Mode Disabled***	The controller is configured for air temperature operation but the skin temperature mode is selected.	If skin temperature mode is desired, select skin temperature mode in the system configuration menu (see System configuration menu on page 113).
Medium	***Stuck Key***	There is a malfunction of the keys on the front panel of the controller.	Switch off the incubator and remove it from service.
Low	***MEDIBUS Comm. Error***	Communication has failed after a successful communication.	Check the cable and the connection.
			To acknowledge the alarm, press the ***Audio paused/Reset*** key.
			Contact DrägerService.

11.1.2 Temperature-specific alarms

Alarm priority	Alarm	Cause	Remedy
Medium	***Air Flow Probe Failed***	The air flow probe connection is open or short circuited.	Switch off the incubator and remove it from service.
Medium	***Air Probe Failed*** (Alarm is delayed for 50 seconds after the alarm condition occurs)	One or more of the temperature sensors in the sensor module have a measurement error exceeding acceptable limits.	Switch off the incubator and replace the sensor module. If the failure continues, switch off the incubator and remove it from service.
Low	***Connect Central Skin Probe***	Skin temperature mode is selected and there is no probe in the central skin probe connector.	Connect a probe to central skin probe connector, and select skin temperature mode.
Medium	***High Air Temperature*** (Alarm can be silenced for 15 minutes) (Alarm is inhibited after a set point change (for a maximum of 30 minutes))	In air temperature mode and kangaroo mode, the displayed temperature differs from the temperature set point by more than the upwards deviation limit.	Check the set point and configuration.
		Hood access panels, hand ports, or gaskets may be loose.	Check hood access panels, hand ports, and gaskets for proper fit.
Medium	***High Skin Temperature*** (Alarm can be silenced for 15 minutes) (Alarm is inhibited after a set point change (for a maximum of 30 minutes))	In skin temperature mode, the displayed temperature exceeds the temperature set point by more than the skin temperature deviation limit.	Verify that the sensor is correctly attached to the patient.
			Check hood access panels, hand ports, and gaskets for proper fit.
			Switch off external heat sources.
Medium	***Central Skin Temp High*** (Alarm can be silenced for 15 minutes)	In air temperature mode or kangaroo mode, the infant skin temperature (from the central skin probe) is > 38.0 °C when the temperature override mode is not active, or > 39.0 °C when the > 37 °C mode of operation is active.	Verify that the sensor is correctly attached to the patient.
			Switch off external heat sources.

Alarm priority	Alarm	Cause	Remedy
Medium	***Peripheral Skin Temp High*** (Alarm can be silenced for 15 minutes)	Occurs when air temperature mode or kangaroo mode is enabled and the infant skin temperature (from the peripheral skin probe) is > 38.0 °C when the temperature override mode is not active, or > 39.0 °C when the > 37 °C mode of operation is active.	Verify that the sensor is correctly attached to the patient. Switch off external heat sources.
Medium	***High Temp CutOut*** (Alarm can be silenced for 5 minutes)	In air temperature mode and kangaroo mode, this alarm is activated if the incubator temperature reaches 37.8 °C for temperature set points < 37 °C, or 39.8 °C for temperature set points > 37 °C. In skin temperature mode, this alarm is activated if the incubator temperature reaches 39.8 °C for any temperature set point.	Switch off the incubator and remove it from service.
Medium	***Low Air Flow*** (Alarm can be silenced for 15 minutes and can also be set to a 15-minute procedural silence) (Alarm is delayed for 30 seconds after the alarm condition occurs)	Lack of air circulation within the incubator.	Verify that the impeller is installed. If installed, switch off the incubator and remove it from service.
Medium	***Low Air Temperature*** (Alarm can be silenced for 15 minutes and can also be set to a 15-minute procedural silence) (Alarm is inhibited for 1 hour after start-up; and after a set point change (for a maximum of 30 minutes))	In air temperature mode and kangaroo mode, the displayed temperature is below the temperature set point by more than the downwards deviation limit.	Check the set point and configuration.
		A hand port or iris port is open.	Close all hand ports and iris ports.
Medium	***Low Skin Temperature*** (Alarm can be silenced for 15 minutes and can also be set to a 15-minute procedural silence) (Alarm is inhibited after a set point change (for a maximum of 30 minutes))	In skin temperature mode, the displayed temperature is below the temperature set point by more than the skin temperature deviation limit.	Check the set point and configuration.
		The skin probe is not properly secured to skin (in skin temperature mode only).	Verify that the probe is correctly attached to the patient.

Alarm priority	Alarm	Cause	Remedy
Medium	***Central Probe Missing*** (In skin temperature mode, alarm can be silenced for 5 minutes) (In air temperature mode or kangaroo mode, the alarm can be reset)	The central skin temperature probe (only in the skin temperature mode) is removed from the sensor module. The associated monitoring display goes blank and the heater shuts off.	Reconnect skin probe to the sensor module. Press ***Audio Paused/Reset*** key to reset alarm (air temperature mode or kangaroo mode only).
Medium	***Central Probe Failed*** (Alarm is delayed for 50 seconds after the alarm condition occurs) (Alarm can be silenced for 5 minutes)	The central skin temperature probe (only in the skin temperature mode) is mechanically connected but electrically open or short-circuited. The associated monitoring display shows "**--.-**".	Replace central skin temperature probe.
Medium	***Peripheral Probe Missing*** Note: If a peripheral skin temperature probe was never connected, the alarm is inhibited. (In air temperature mode or kangaroo mode, the alarm can be reset)	The peripheral skin temperature probe (only in the skin temperature mode) is removed from the sensor module. The associated monitoring display goes blank.	Reconnect skin probe to the sensor module. Press ***Audio Paused/Reset*** key to reset alarm (air temperature mode or kangaroo mode only).
Medium	***Check Central Probe***	This message is displayed in the air temperature mode or kangaroo mode if: The central skin temperature probe is electrically open or shorted.	Replace the central skin temperature probe.
		The measurements from the 2 thermistors in the central skin temperature probe deviate by more than 0.8 °C.	Replace the central skin temperature probe.
		This message is displayed in air temperature mode, kangaroo mode, or skin temperature mode, if: The temperature measured by the central skin temperature probe is ≤ 16.9 °C.	Replace the central skin temperature probe.

Alarm priority	Alarm	Cause	Remedy
Medium	***Check Peripheral Probe***	This message is displayed in all modes if: The peripheral skin probe is electrically open or shorted	Replace the peripheral skin temperature probe.
		The measurements from the 2 thermistors in the peripheral skin temperature probe deviate by more than 0.8 °C	Replace the peripheral skin temperature probe.
		The temperature measured by the peripheral skin temperature probe is ≤ 16.9 °C	Replace the peripheral skin temperature probe.

11.1.3 Kangaroo-specific alarms

Alarm priority	Alarm	Cause	Remedy
Medium	***Central Skin Temp Low*** (Alarm can be silenced for 15 minutes)	Occurs when kangaroo mode is enabled and is generated when the measured central skin temperature drops below the lower limit for central skin temperature in kangaroo mode.	Check the settings.
			Check patient's condition.
		The skin probes are not properly secured to skin.	Verify that the probes are correctly attached to the patient.
Medium	***Peripheral Skin Temp Low*** (Alarm can be silenced for 15 minutes)	Occurs when the kangaroo mode is enabled and the measured peripheral skin temperature drops below the lower limit for peripheral skin temperature in kangaroo mode.	Check the settings.
			Check patient's condition.
		The skin probes are not properly secured to skin.	Verify that the probes are correctly attached to the patient.
Medium	***Skin Temp Diff High*** (Alarm can be silenced for 15 minutes)	Occurs when kangaroo mode is enabled and the difference between the measured central skin temperature and the measured peripheral skin temperature exceeds the temperature difference upper limit.	Check the settings.
			Check patient's condition.
		The skin probes are not properly secured to skin.	Verify that the probes are correctly attached to the patient.

Alarm priority	Alarm	Cause	Remedy
Medium	***Skin Temp Diff Low***	Occurs when kangaroo mode is enabled and the difference between the measured central skin temperature and the measured peripheral skin temperature falls below the temperature difference lower limit.	Check the settings. Check patient's condition.
		The skin probes are not properly secured to skin.	Verify that the probes are correctly attached to the patient.

11.1.4 Humidity-specific alarms

Alarm priority	Alarm	Cause	Remedy
Low	***Check Water Supply*** (Alarm can be silenced for 30 minutes and can also be set to a 30-minute procedural silence) (This alarm is only available when the humidity control is activated.)	Low water level in the water reservoir.	Refill the water reservoir. If the alarm persists for more than 5 minutes, continue to next cause/remedy.
		The water reservoir assembly is not fully inserted in the incubator shell.	Insert the water reservoir assembly fully in the incubator shell.
		The water reservoir assembly is not assembled correctly (for example, the humidifier is not present).	Ensure that the humidifier and all other components of the water reservoir assembly are assembled correctly.
		There is a blockage of the channel between the water compartment and the humidifier chamber.	Check that the humidifier is installed correctly and that there is no blockage of the channel.
		There is a blockage of the holes at the bottom of the humidifier.	Check that there is no blockage of the holes at the bottom of the humidifier.
		Humidifier malfunction.	Replace the humidifier. If the failure continues, switch off the incubator and remove it from service.

Alarm priority	Alarm	Cause	Remedy
Low	***Low Humidity*** (Alarm can be silenced for 15 minutes) (Alarm is inhibited for 30 minutes after start-up; and for 15 minutes after a set point change) (this alarm is only available when the humidity control is activated.)	The displayed humidity value is >10% below the humidity set point for more than 15 minutes:	
		The water reservoir assembly is not fully inserted in the incubator shell.	Insert the water reservoir assembly fully in the incubator shell.
		Low water level in the water reservoir	Refill the water reservoir.
		A hand port or iris port is open.	Close all hand ports and iris ports.
		An iris port sleeve is open or improperly installed.	Check the installation of the iris port sleeve.
		A hose grommet is not properly installed.	Check the installation of the hose grommet.
		Gaps in hand port gaskets	Check gaskets for proper fit. If the alarm persists, switch off the incubator and remove it from service.

11.1.5 Oxygen-specific alarms

Alarm priority	Alarm	Cause	Remedy
Medium	***High Oxygen %*** (Alarm can be silenced for 4 minutes) (Alarm is inhibited during oxygen cell calibration; and after lowering set point (for a maximum of 30 minutes)) (this alarm is only available when servo oxygen control is activated)	The displayed oxygen value is above the oxygen set point by more than the oxygen deviation limit.	
		The air inlet filter is dirty.	Replace the air inlet filter.
		There is a lack of air circulation within the incubator.	Ensure that air ducts are not covered or obstructed.
		There is a malfunction in the oxygen control system.	Switch off the incubator, and remove it from service.
Medium	***Low Oxygen %*** (Alarm can be silenced for 4 minutes and can also be set to a 4-minute procedural silence) (this alarm is only available when servo oxygen control is activated.)	The displayed oxygen value is below the oxygen set point by more than the oxygen deviation limit.	
		A hand port or iris port is open.	Close all hand ports and iris ports.

Alarm priority	Alarm	Cause	Remedy
		An iris port sleeve is open or improperly installed.	Check the installation of the iris port sleeve.
		A hose grommet is not properly installed.	Check the installation of the hose grommet.
		The air inlet filter cover is not properly secured.	Check and secure the air inlet filter cover.
		The air inlet filter is not installed.	Check the air inlet filter, and install if necessary.
		The internal hose is not connected.	Switch off the incubator and remove it from service.
		There is a malfunction in the oxygen control system.	Switch off the incubator, and remove it from service.
Medium	***Oxygen Cell Different*** (Alarm is delayed for 50 seconds after the alarm condition occurs) (Alarm can be silenced for 4 minutes)	The measurements from the 2 oxygen cells differ by more than 3%. As a result, the oxygen flow into the system is interrupted.	Calibrate oxygen (see Oxygen sensor calibration (option) on page 160).
Medium	***Oxygen Solenoid Fail*** (Alarm is delayed for 1 minute after the alarm condition occurs)	The oxygen solenoid voltage is not within limits.	Switch off the incubator and remove it from service.
Low	***Slide In Sensor***	Calibration is completed but the oxygen sensor module was not returned to the hood position.	Slide the oxygen sensor module into the hood.

11.2 Problems/alarm conditions without alarm messages

11.2.1 Power failure alarm

Problem/ alarm condition	Cause	Remedy
There is no system power, and the ***Power Failure*** alarm does not activate.	The main on/off switch is OFF.	Switch on the main on/off switch on the trolley.
There is system power, but there is no screen display and the ***Power Failure*** alarm does not activate.	The incubator on/off switch is OFF.	Switch on the incubator on/off switch on the controller on the front of the device.
Power Failure alarm activates (acoustic alarm signal sounds and LED on front panel of controller illuminates).	The main power cable is unplugged.	Make sure that the power cable is plugged into the AC power source. Also make sure that it is firmly attached to the height adjustment trolley receptacle.
	The power cable to the incubator on the front of the device is unplugged.	Attach the power cable to the incubator receptacle.

Problem/ alarm condition	Cause	Remedy
	Over-current protection fuses in the height adjustment trolley have blown.	Switch off the incubator and replace the fuses (see Fuse replacement on page 151).

11.2.2 No data is displayed

Problem/ alarm condition	Cause	Remedy
No data is displayed on screen at system start-up (only static/noise).	Internal controller failure.	Switch off the incubator and remove it from service.

11.2.3 Adjustment of device height not possible

Problem/ alarm condition	Cause	Remedy
The height adjustment trolley does not move up or down.	The main on/off switch is OFF.	Switch on the main on/off switch on the trolley.
	Over-current protection fuses in the height adjustment trolley have blown.	Switch off the incubator and replace the fuses (see Fuse replacement on page 151).
	The height adjustment trolley was operated for more than 3 minutes continuously which could result in the height adjustment trolley motor overheating.	Wait 10 minutes and try to operate the trolley again.

11.2.4 Water is leaking

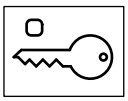
Problem/ alarm condition	Cause	Remedy
Water is leaking onto the floor	Condensation management system is not installed.	Install condensation management system (see Condensation management system replacement (if installed) on page 152).
	Condensation management hose is incorrectly installed:	
	Drain plug on hose is not properly installed.	Ensure that the drain plug is fully inserted into the drain opening so that it is flush with the heater well floor.
	Hose is connected to the wrong port on the collection bottle.	Ensure that the hose is connected to the patient port on the side of the collection bottle.

11.3 System prompt messages

The following messages notify the user of conditions that are not hazardous but require attention or correction.

They do not generate any audible or LED alarms.

11.3.1 General messages

System prompt message	Cause	Remedy
Alarm Reset	A previously latched alarm condition has been cleared with the ***Audio Paused/Reset*** key.	Information only, no action required.
Keypad Locked - Press © 	The user presses a key while the ***Keypad Lock*** key is illuminated and active.	Unlock the keypad by pressing the ***Keypad Lock*** key.
Performing Power-Up Tests	This message is displayed after power is supplied from the main on/off switch and the system is performing the self-test.	Information only, no action required.
Procedural Silence	This message is displayed when no alarm conditions are present and the ***Audio Paused/Reset*** key is pressed.	Information only, no action required.

11.3.2 Calibration messages

System prompt message	Cause	Remedy
100% Cal	The oxygen system is performing 100% calibration.	Information only, no action required.
21% Cal	The oxygen system is performing 21% calibration.	Information only, no action required.
Cal Fail	The servo control oxygen system failed to calibrate.	Repeat the calibration procedure. If the calibration procedure fails again, refer the device to service personnel.
Cal Pass	The oxygen calibration was successful.	Information only, no action required.
Cal Required	This message is displayed when oxygen control is selected after a power-up or after the sensor module connector is disconnected from the incubator.	Calibrate the oxygen sensor.
Calibration Failed	The scale fails the 5-kg calibration.	Retry calibration. If it fails again, remove the scale from service.
Slide Out Sensor	This message is displayed when the ***Cal*** button is pressed during oxygen calibration, but the sensor module is not pulled out into the calibration position.	Slide the sensor module out to the calibration position.

11.3.3 Oxygen messages

System prompt message	Cause	Remedy
Not Installed	Oxygen control is attempted, but the servo control oxygen system is not installed.	Install the servo control oxygen system.
	Oxygen control is attempted, but the servo control oxygen system is not activated.	Set up the servo control oxygen system in the system configuration menu (see System configuration menu on page 113).
Oxygen Cal Required	This message is displayed when re-calibration is required to use the servo oxygen control. It occurs after 7 days of continuous oxygen control.	Calibrate the oxygen sensor.
Slide Out Sensor	This message is displayed when the ***Cal*** button is pressed during oxygen calibration, but the sensor module is not pulled out into the calibration position.	Slide the sensor module out to the calibration position.

11.3.4 Humidity messages

System prompt message	Cause	Remedy
Not Installed	Humidity control is attempted, but the humidification system is not installed.	Install the humidification system.
	Humidity control is attempted, but the humidification system is not activated.	Set up the humidification system in the system configuration menu (see System configuration menu on page 113).

11.3.5 Scale messages

System prompt message	Cause	Remedy
Clear Mattress	A scale calibration is attempted, and there is >1 Kg on the bed mattress.	Remove all items from the bed mattress.
Scale Disconnect	A weighing function is initiated, but the cable between the scale and the sensor module is disconnected.	Reconnect the cable between the scale and the sensor module.
	A weighing function is initiated, but the cable between the scale and the sensor module is broken.	Remove the scale from service.
Too Much Weight	The controller determines that the weight placed on the scale is more than the scale measurement range.	Remove excess weight.

System prompt message	Cause	Remedy
Wait...	This message is displayed during the zeroing and calibration routine.	Information only, no action required.
Weight Below Zero	This message is displayed when there is too little weight on the bed during calibration (for example, no mattress)	Replace mattress and recalibrate.
Zeroing Failed	This message is displayed when an extra weight on the bed exceeds 4000 g when zeroing during infant weight.	Remove extra weight and retry zeroing. If it fails again, remove scale from service.

12 Reprocessing

12.1 Disassembly

12.1.1 Observe before disassembly

NOTICE
Risk of damage to the device
For routine cleaning, there is no need to separate the hood and shell assemblies from the trolley.
► If separation is necessary, contact DrägerService.

⚠ CAUTION
Risk of injury or damage to the device
Accessories and optional components could fall off the device.
► Before disassembling the hood and shell assemblies, remove accessories and optional components mounted to device.

The most effective way to clean the device is to first disassemble the device. Then group the parts and assemblies in categories according to the method of cleaning required.

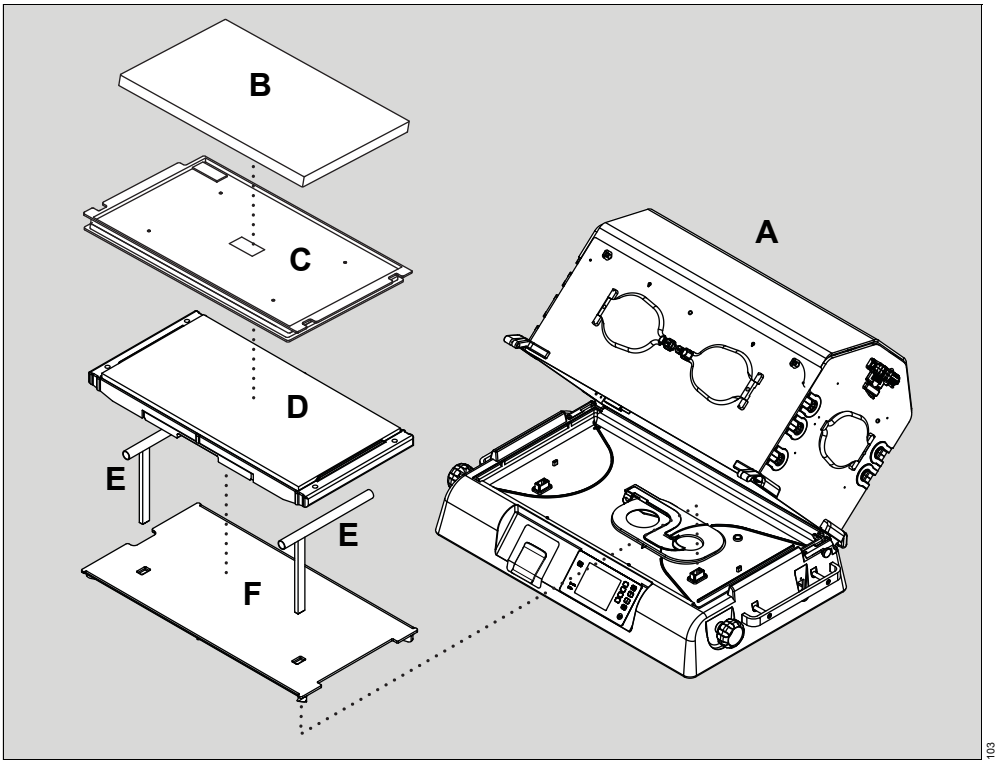
1 Switch off the device and all devices connected to it.

2 Disconnect the mains plugs.

12.1.2 Removing the bed and related components, and optional scale

1 Disconnect the cables from the sensor module.

2 Slowly raise the hood (A).



3 Remove the mattress (B).

4 If the incubator is equipped with a weighing scale, perform steps 5 through 7; otherwise go to step 8.

5 Disconnect the scale cable from the sensor module.

6 Remove the cable from the clamps that hold it to the incubator.

7 Lift the scale (C) from the bed.

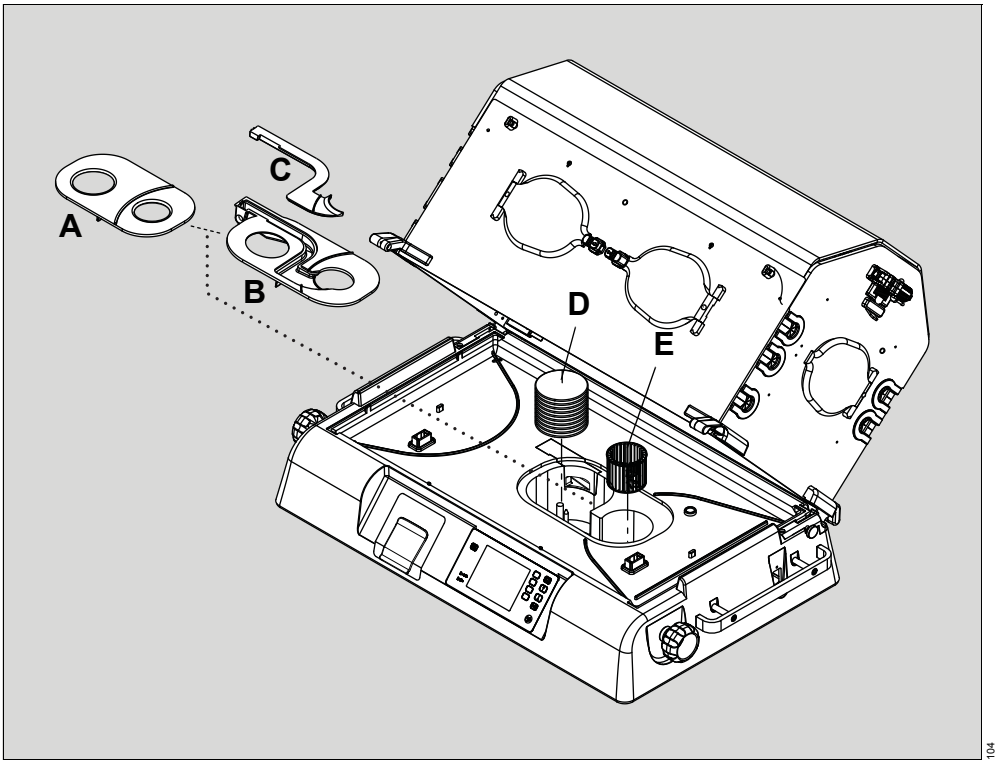
8 Remove the bed (D) and X-ray tray (inside bed).

9 Remove the T-bars (E).

10 Remove the upper cover (F).

12.1.3 Removing the heater radiator and impeller

1 On devices without the humidification system option, remove the heater/impeller cover (A).



2 On devices with the optional humidification system, pull the water reservoir partially out, and remove the heater/impeller cover (B) and the duct cover (C).

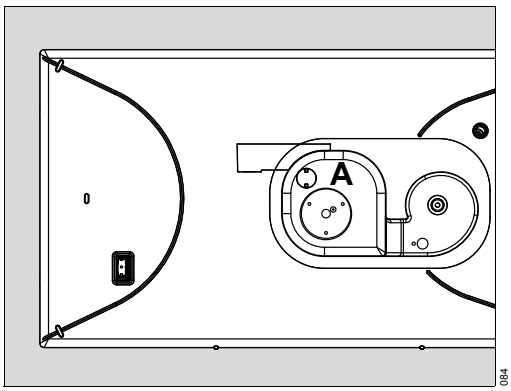
⚠ WARNING
Risk of death or serious injury
The heater can be sufficiently hot to cause burns.
► Avoid removing or touching the heater until the device has been switched off for at least 45 minutes.

3 When the device has cooled, remove the heater radiator (D).

4 Pull the impeller (E) off the motor shaft.

12.1.4 Removing the drain plug with O-ring (if installed)

On devices without the condensation management system, remove the drain plug with O-ring (A) at the bottom of the heater well. Set aside.



12.1.5 Removing the condensation management system (if installed)

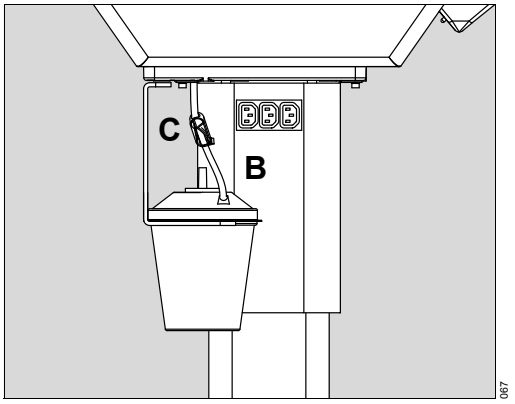
⚠ CAUTION
Risk of injury or damage to the device
Reuse of single-use components can cause patient injury or damage the device.
► Do not reprocess and reuse single-use components.
► Do not use single-use components or accessories if packaging is damaged.

⚠ CAUTION
Risk of injury or damage to the device
Fluid spills or leaks could cause a slip hazard.
► If any fluids spill or leak around the device, wipe the area dry.

⚠ CAUTION
Risk of injury or damage to the device
Liquid in the collection bottle can contain patient fluids.
► Collection bottles and fluids should be handled according to hospital guidelines.

When using high levels of humidity, Dräger recommends using the optional condensation management system.

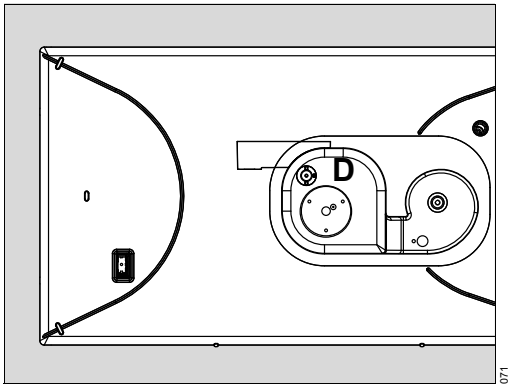
1 Disconnect the condensation management hose (B) from the collection bottle located underneath the left side of the incubator.



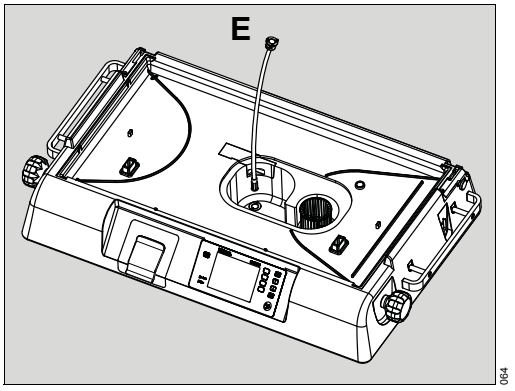
2 Remove the clamp (C) from the condensation management hose and discard.

3 Remove the condensation management hose:

A Turn the plug (D) at the bottom of the heater well 90 degrees counterclockwise.



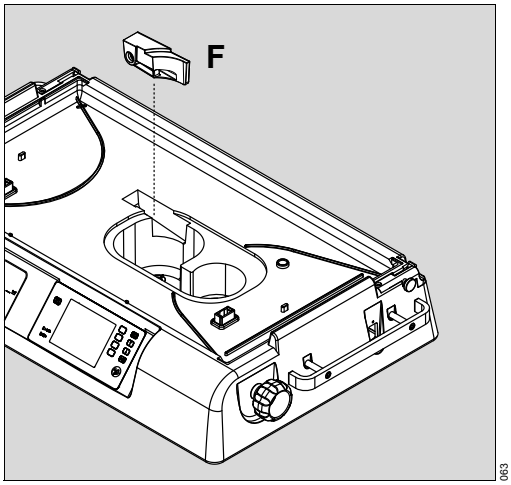
B Pull the hose/plug assembly out completely (E).



4 Discard the collection bottle and hose/plug assembly.

12.1.6 Removing the manifold (if installed)

On devices without the humidification system option, remove the manifold (F) from the shell by pulling up on it. Set aside.

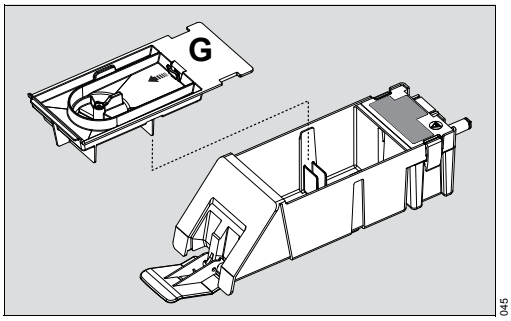


12.1.7 Removing the water reservoir assembly (if installed)

1 Pull the latch forward and slide the reservoir assembly out from the front of the incubator shell.

⚠ WARNING
Risk of death or serious injury
The humidifier and the water in the humidifier chamber can be sufficiently hot to cause burns.
► Avoid removing or touching the humidifier until the water reservoir has been disconnected from the incubator for at least 45 minutes.
► Use caution when emptying or handling the reservoir.

2 Pull the latch on top of the water reservoir lid forward (G), and remove the lid.



3 Empty any water remaining in the reservoir.

NOTICE
Risk of damage to the device
Sharp tools can cause injury or damage the device.
► Do not use sharp tools to remove the humidifier.

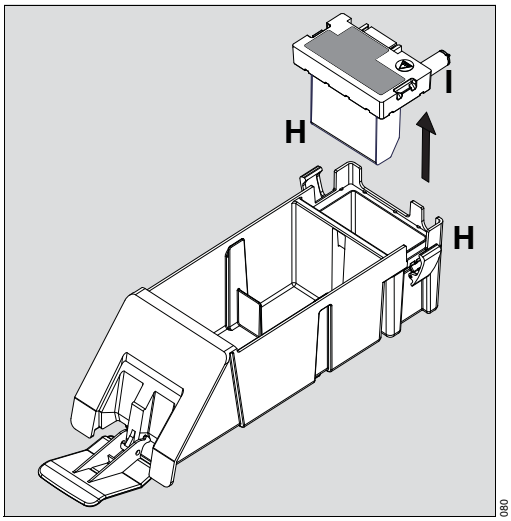
⚠ CAUTION

Risk of injury or damage to the device

Liquid in the collection bottle can contain patient fluids.

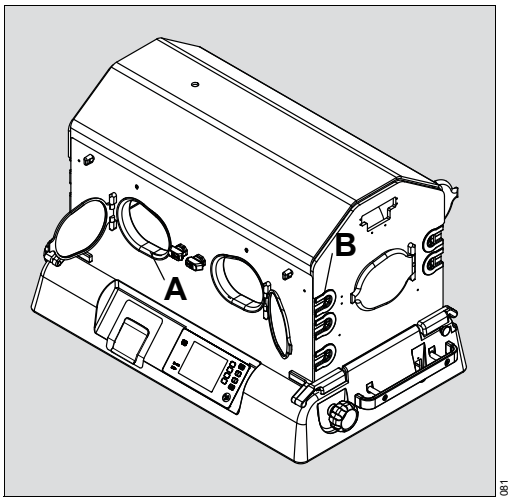
► Collection bottles and fluids should be handled according to hospital guidelines.

4 Lift the latches on the side of the water reservoir (H) and remove the humidifier (I) from the humidifier chamber.



12.1.8 Removing the hand port gaskets, hose grommets, and iris port sleeves (if installed)

1 Pull the hand port gaskets (A) from all sides of the hood to remove them.



2 Pull the hose grommets (B) from each side of the hood to remove them.

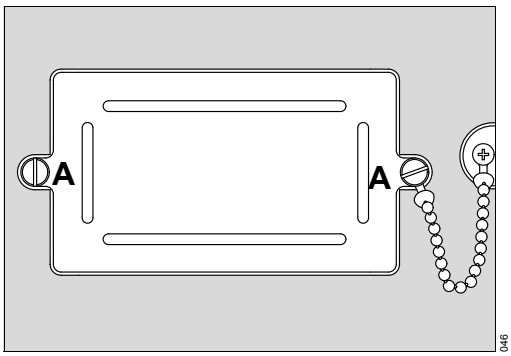
3 If equipped with the optional iris ports on the side access panels, remove the disposable iris port sleeves from the retainer rings.

4 Wipe the retainer rings clean.

5 Discard disposable sleeves.

12.1.9 Removing the air inlet filter

To remove the air inlet filter cover located under the shell assembly on the rear of the device, loosen the 2 thumbscrews (A).



12.2 Information on reprocessing

Instructions for reprocessing are based on internationally accepted guidelines, e.g., standard ISO 17664.

12.2.1 Safety information

⚠ WARNING
Risk of death or serious injury
A fire and explosion hazard exists when performing cleaning and maintenance procedures in an oxygen-enriched environment.

► When performing cleaning and maintenance procedures, confirm that the oxygen supply is turned off and that the equipment is disconnected from the oxygen supply.

NOTICE
Risk of equipment damage
Some chemical cleaning agents may be conductive and leave a residue that may permit a build-up of conductive dust or dirt.

► Do not allow cleaning agents to contact electrical components, and do not spray cleaning solutions onto any of these surfaces.

► Use a cloth dampened with disinfectant. Do not spray cleaning solution directly onto the surface of the device.

NOTICE
Risk of damage to the device
Harsh cleaning methods can damage equipment.

► Do not use harsh cleansers/detergents such as scouring pads or heavy-duty grease removers or solvents, such as acetone.

12.3 Classifications for reprocessing

12.3.1 Classification of medical devices

Medical devices and their components are classified according to the way they are used and the resulting risk.

Classification	Explanation
Non-critical	Components that come only into contact with skin that is intact

12.4 Reprocessing list

Components	Surface disinfection with cleaning	Machine cleaning with thermal disinfection	Special reprocessing measures
Hand port gaskets	Yes	No	No
Hose grommets	Yes	No	No
Controller	Yes	No	No
Shell	Yes	No	No
Trolley	Yes	No	No
Condensation management bracket (if installed)	Yes	No	No
Sensor module	Yes	No	No
Hood	Yes	No	No
Inner double walls	Yes	No	No
Heater radiator	Yes	No	No
Fan impeller	Yes	No	No
Manifold	No	Yes	No
Heater/impeller cover	No	Yes	No
Duct cover	No	Yes	No
Water reservoir assembly	No	Yes	No
Humidifier	Yes	No	No
Air inlet filter chamber	Yes	No	No
Air inlet filter cover	Yes	No	No
Rail and accessories	Yes	No	No
Drawers	Yes	No	No
Cylinder holder	Yes	No	No
Utility shelf	Yes	No	No
IV pole	Yes	No	No
Mattress	Yes	No	No

Components	Surface disinfection with cleaning	Machine cleaning with thermal disinfection	Special reprocessing measures
Bed	Yes	No	No
X-ray tray	Yes	No	No
Upper cover	Yes	No	No
Scale	Yes	No	No
T-bars	Yes	No	No

12.5 Reprocessing procedures

12.5.1 Validated reprocessing procedures

At the time of product-specific validation, the following reprocessing procedures showed good material compatibility and effectiveness:

Procedure	Agent	Manufacturer	Concentration	Contact time	Temperature
Surface disinfection with cleaning	Dismozon plus	BODE Chemie	2.34 %	5 min	–
Machine cleaning (thermal) (Miele Professional G 7835 CD)	neodisher MediClean forte	Chemische Fabrik Dr. Weigert GmbH & Co. KG	–	–	–
Machine disinfection (thermal) (Miele Professional G 7835 CD)	–	–	–	5 min	90 °C (194 °F)

The effectiveness of the listed reprocessing procedures has been validated by independent laboratories that are certified to the standard ISO 17025.

12.5.2 Disinfectants

Use disinfectants that are nationally approved and are suitable for the particular reprocessing procedure.

12.5.2.1 Surface disinfectants

At the time of the test, the surface disinfectants listed in the following table showed good material compatibility. They can be used in addition to the surface disinfectants listed in the section "Validated reprocessing procedures."

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:

– Bactericidal

– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Observe the specifications of the surface disinfectant manufacturers.

Other surface disinfectants are used at one's own risk.

Class of active ingredient	Surface disinfectant	Manufacturer
Chlorine-releasing agents	Actichlor plus	Ecolab
	BruTab 6S	Brulin
	Clorox Professional Disinfecting Bleach Cleaner	Clorox
	Dispatch Hospital Cleaner Disinfectant Towels with Bleach	
	Klorsept 17	Medentech
Oxygen-releasing agents	Descogen Liquid	Antiseptica
	Descogen Liquid r.f.u.	
	Dismozon plus	BODE Chemie
	Dismozon pur	
	Oxycide	Ecolab USA
	Perform	Schülke & Mayr
	Virkon	DuPont
Quaternary ammonium compounds	Mikrozid sensitive liquid[1)]	Schülke & Mayr
	Mikrozid alcohol free liquid[1)]	
	Mikrozid sensitive wipes[1)]	
	Mikrozid alcohol free wipes[1)]	
	acryl-des[1)]	
Aldehydes	Buraton 10 F	

1) Virucidal against enveloped viruses

Oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the device is not functioning correctly.

For disinfectant recommendations for the SoftBed mattress, consult their manufacturer instructions for use.

12.5.3 Surface disinfection with cleaning

Refer to Disinfectants on page 138.

Strictly observe the manufacturer's instructions for using disinfectants. The composition of disinfectants may change.

Procedure:

1 Remove soiling immediately. Use a cloth dampened with disinfectant to remove soiling. **Do not spray cleaning solution directly onto the surface of the device.**

2 Perform surface disinfection.Thoroughly wipe the device 3 times. Observe the recommended contact time specified by the disinfectant manufacturer.

3 After the product has been exposed to the disinfectant for the specified contact time, remove residual disinfectant.

4 Wipe with a cloth dampened with water (preferably drinking-water quality). Allow the product to dry.

5 Check the product for visible soiling. Repeat steps 1 to 5 if necessary.

6 Check the product for visible damage and replace if necessary.

12.5.4 Machine cleaning with thermal disinfection

Use a washer-disinfector that meets the requirements of the standard ISO 15883.

1 Securely position the product in the basket horizontally, in an open basket, or directly on the tray. Ensure the following:
   – All surfaces and interior spaces can be flushed completely.
   – The water can drain off freely.

2 Use a suitable cleaning agent (refer to Validated reprocessing procedures on page 138).

3 Select a suitable cycle (refer to Validated reprocessing procedures on page 138).

4 Use demineralized/deionized/distilled water for the final rinsing.

5 After the cycle has ended, check the product for visible soiling. If necessary, repeat the cycle.

6 Check the product for visible damage and replace if necessary.

7 Allow the product to dry completely.

12.5.5 Additional reprocessing measures

Do not spray cleaning solution directly onto the surface of the device.

12.5.5.1 Reprocessing the shell, trolley, cabinet stand, and condensation management bracket (if installed):

1 Wipe any fluids that may have accumulated in the heater well. Take special care to clean and disinfect the heater well, the drain plug opening, and the drain plug (on devices without the humidification system option).

⚠ CAUTION
Risk of injury or damage to the device
On devices with the condensation management system option, the hose/plug assembly is disposable.
► Do not clean and reuse the hose/plug assembly.

2 Check for fluids that may have dripped onto the bottom surface of the water reservoir opening. If fluids are present, use a clean paper towel dampened with a cleaner/disinfectant to wipe the surfaces dry.

3 Follow surface disinfection recommendations to wipe with a cloth dampened with disinfectant. **Do not spray cleaning solution directly onto the surface of the device**.

12.5.5.2 Reprocessing the controller and the sensor module

1 When reprocessing the underside of the controller near the on/off switch, follow surface disinfection recommendations to wipe with a cloth dampened with disinfectant. **Do not spray cleaning solution directly onto the surface of the device.**

2 Use a low-level or intermediate-level disinfectant to clean all surfaces thoroughly, including the controller and sensor module. Refer to Disinfectants on page 138.

3 Be sure to clean all holes and indentations; then dry with a clean cloth or paper towel.

12.5.5.3 Reprocessing the hood, and inner double walls

NOTICE

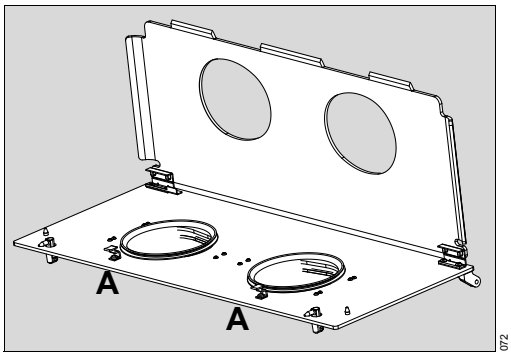
Risk of damage to the device

Alcohol and Ultraviolet radiation can cause cracking and/or crazing (small stress cracks) of the clear acrylic.

► Do not use alcohol for cleaning.

► Do not expose the clear acrylic to direct radiation from germicidal lights.

1 To release the inner double wall, press the catches (A) at the top of the inner double wall.



The inner double walls are hinged on the access panels of the incubator.

2 Use a low-level or intermediate-level disinfectant to clean all surfaces of the hood thoroughly, including the inner double walls, hand ports, and access panels. **Do not spray cleaning solution directly onto the surface of the device**. Refer to Disinfectants on page 138.

3 Be sure to clean all holes and indentations; then dry with a clean cloth or paper towel.

12.5.5.4 Reprocessing the heater radiator and fan impeller

⚠ WARNING
Risk of death or serious injury
Failure to clean the heater radiator and fan impeller could result in sufficient lint build-up to reduce airflow. Reduced airflow could affect the temperature control and cause high oxygen concentrations.
► Clean heater radiator and fan impeller.

⚠ CAUTION
Risk of injury or damage to the device
Autoclaving can damage equipment or impact functional integrity.
► Do not steam sterilize parts when disassembling for cleaning.
► Do not immerse the heater assembly in liquid.

⚠ CAUTION
Risk of injury or damage to the device
Damage can occur to the motor if liquid penetrates the area.
► When cleaning the incubator shell, prevent liquids from entering the motor shaft opening.
► When cleaning the surface of the air circulation well, prevent liquids from entering the motor shaft opening.

1 Remove any lint build-up on the heater radiator and fan impeller.
2 Wipe the heater assembly using a low-level or intermediate-level disinfectant, Refer to Disinfectants on page 138.
Do **not** immerse the heater assembly in liquid.

12.5.5.5 Reprocessing the air inlet filter chamber and cover

⚠ WARNING
Risk of death or serious injury
A dirty air inlet filter could affect performance or cause carbon dioxide (CO_2) build-up.
► Ensure that the filter is checked on a routine basis commensurate with local conditions and replaced as recommended in Maintenance on page 149. Particularly, if the device is used in an unusually dusty environment, more frequent replacements may be necessary.

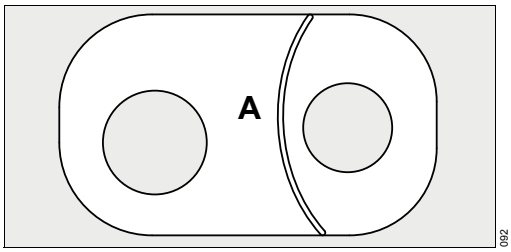
Do not clean the air inlet filter (see Maintenance instructions on page 150).
1 Clean the filter chamber and its cover. Refer to Disinfectants on page 138.
2 Install a new air inlet filter.

12.6 After reprocessing

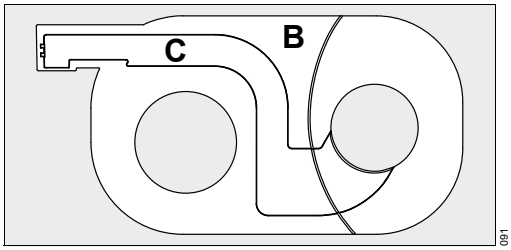
12.6.1 Assembling the components

⚠ CAUTION
Risk of injury or damage to the device
If the incubator is assembled incorrectly, or parts/assemblies are not reinstalled after cleaning or maintenance, the essential performance and/or basic safety of the device may be compromised.
► Assemble the device according to the instructions for use.

1 Inspect all reprocessed components for any breakage or cracks before reassembling into the incubator.
2 On devices without the humidification system option, reinstall the manifold.
3 On devices without the condensation management system, reinstall the drain plug in the bottom of the heater well.
4 On devices with the condensation management system, install a new collection bottle, hose/plug assembly, and clamp (see Condensation management system replacement (if installed) on page 152).
5 Install the heater radiator and fan impeller.
6 On devices without the humidification system option, install the heater/impeller cover (A).



7 On devices with the humidification system option, install the heater/impeller cover (B) and the duct cover (C).



⚠ WARNING
Risk of death or serious injury
Using older software versions can lead to incorrect operation of the humidification system leading to injury.
► The humidification system with the heater/impeller cover with duct cover must be used with software version 5.n or higher.

NOTICE

Risk of damage to the device

The hood contains 4 tabs (one at each corner) which keep the deck securely in place. Installing the upper cover when the hood is down may result in damage to the upper cover and/or jamming of the hood in place.

► Make sure that the hood is raised before attempting to install the upper cover.

8 Install the upper cover.

9 Install the T-bars on the upper cover.

10 Install the bed, X-ray tray, and scale (if installed).

11 Visually and physically examine the mattress for any holes or cuts that enable the entry of fluids onto the inner foam. If the mattress is damaged, replace it.

⚠ CAUTION

Risk of injury and inability to maintain hygienic safety

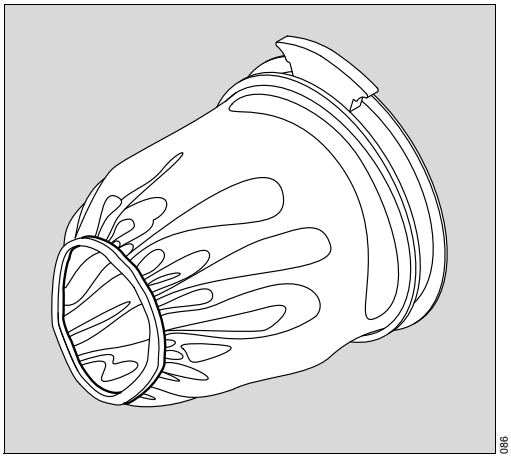
If the incubator parts/assemblies are not reinstalled after cleaning or maintenance, the hygienic safety of the device may be compromised.

► Ensure the cover is installed on the mattress before reuse.

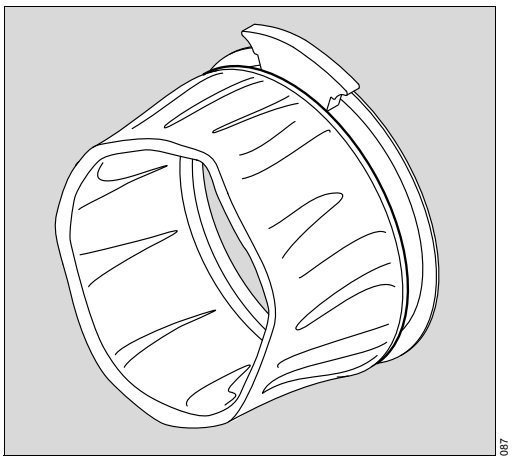
12 Install the mattress.

13 If equipped with the optional iris ports on the side access panels, install the new disposable or reusable iris port sleeves:

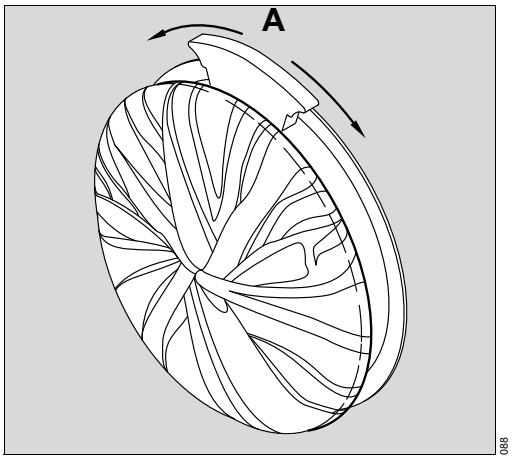
A Install the smaller diameter elastic band of a new sleeve over the inner ring of the port housing.



B Fold back, and slip the larger elastic band over the outer ring of the port housing.



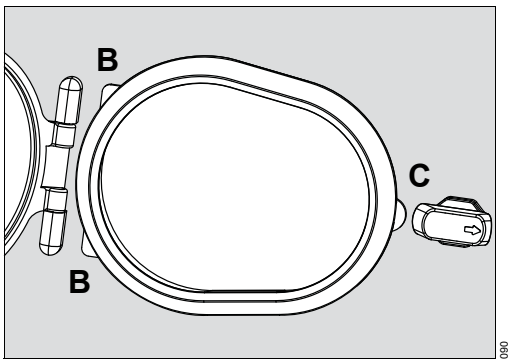
C To close, rotate the outer ring (A). If properly installed, the sleeve opens again when rotation is reversed.



14 Install the hose grommets into the front and rear edges of each side of the hood.

Replace hose grommets if distorted or torn.

15 Install a hand port gasket on each hand port. Orient each gasket so that the 2 tabs on the gasket are on the hinge side of the door opening (B) and the single tab is on the latch side of the door opening (C).



16 Ensure that the hand port latch with slight pressure, and open when the latch lever is pressed.

17 If the air inlet filter is damaged, visibly dirty, or older than 3 months, replace it (see Air inlet filter maintenance on page 151).

18 Install the air inlet filter cover, and tighten the 2 thumbscrews (see page 151).

19 On devices with the humidification system option:

A Reinstall the humidifier in the water reservoir assembly. Insert it fully into the humidifier chamber and secure it by closing the 2 latches.

B Reinstall the lid on the water reservoir and push back the latch on top of the lid to secure it.

C Insert the water reservoir assembly in the shell with the latch open. Then slide it in fully and lock it in place by pushing in the latch.

20 If necessary, reattach any accessories previously removed from the device.

12.7 Preparations before reuse

1 Assemble and prepare the device so that it is ready for use, see chapter Assembly and preparation

2 Check the operational readiness, see chapter Getting started.

13 Service

13.1 Safety information

⚠ WARNING
Risk due to inappropriately reprocessed products
The product may be contaminated with infectious agents.
► Before service is performed and before the product is sent back for repair, reprocess the product in accordance with the chapter Reprocessing.

⚠ WARNING
Risk if service is not performed regularly
Wear and material fatigue of the components may lead to device failure and malfunctions.
► Perform service at the specified intervals.

⚠ WARNING
Risk if service is not performed properly
Personal injury and property damage may occur if service is not performed properly.
► Service must be performed by those target groups that are assigned to the particular measure.

⚠ WARNING
Risk if maintenance is not performed properly
If the device is connected to the power supply or the gas supply during maintenance, there is a risk of personal injury and property damage.
► Before performing maintenance, disconnect all electrical connections from the power supply and all gas connections from the gas supply.

⚠ WARNING
Risk when the housing is being opened
Under the housing, there are live electrical components, which may cause an electric shock.
► The housing may only be opened by those target groups that are assigned to that particular measure.

13.2 Overview

This chapter describes the maintenance measures required to maintain the functional integrity of the medical device. Maintenance measures must be performed by the personnel responsible.

13.3 Definition of service terminology

Concept	Definition
Service	All measures (inspection, maintenance, repair) intended to maintain or restore the functional integrity of a product
Inspection	Measures intended to determine and assess the current state of a product
Maintenance	Regular specified measures intended to maintain the functional integrity of a product
Repair	Measures intended to restore the functional integrity of a product after a failure

Properly trained personnel should routinely inspect the patient compartments for signs of breakage and should replace assemblies before placing the incubator into service.

13.4 Inspection

Measure	Interval	Target group
Inspection and safety check[1)]	Every 1 year	Service personnel
Verification of the scale	According to regulatory requirements for scales which must be verified	Officially authorized specialist personnel

1) Designation applies to the Federal Republic of Germany; corresponds to the "Recurring safety inspection" in the Federal Republic of Austria.

13.4.1 Safety checks

Safety checks are not a substitute for maintenance, which includes the preventive replacement of wearing parts as specified by the manufacturer.

13.4.1.1 Performing the safety checks

1 Check that the respective instructions for use are present.

2 Perform a functional test of the following functions according to the instructions for use:

- Holding force of all hand ports
- Incubator operational procedure
- High temperature alarms

3 Inspect the following features:

- Hand ports
- Hood
- Unauthorized probes or modifications to equipment
- Incubator connection to height adjustment trolley
- Movement of height adjustment trolley

- Castors and movement of the device

4 Check that the product is in good condition:
   - All labels are complete and legible
   - There is no visible damage
   - Fuses that are accessible from the outside are in compliance with the specified values.
   - All gaskets and grommets in the patient compartment are in good condition
5 Observe the instructions for use, and check that all components and accessories required to use the product are present.
6 Check the electrical safety in accordance with the IEC 62353 standard.
7 Check the safety equipment:
   - Functional integrity of all acoustic alarm signals and visual symbols
8 Check temperature correlation – Temperature indicator versus incubator temperature:
   - Set temperature 35 °C
   - Correlation ± 0.8 °C (± 1.44 °F)
   - Use a thermometer with an accuracy of at least ± 0.05 °C.
   - Do not use a mercury-in-glass thermometer.

13.5 Maintenance

There is a power entry module that has fuses on both of the mains lines. It also has a double pole single throw (DPST) switch, which isolates the device from the mains when it is switched to the "OFF" position.

The following table shows the preventive maintenance intervals. This table is not related to warranty periods and no warranty is implied by the intervals listed.

Component	Interval	Measure	Target group
Air inlet filter	Every 3 months or when necessary	Exchange	Users
Mattress	When necessary	Exchange	Users
Grommets, gaskets	When necessary[1)]	Exchange	Users
Cuffs and iris port sleeves[2)]	Weekly or when necessary[1)]	Exchange	Users
Skin temperature probes	Weekly[3)]	Exchange	Users
Probe covers	Weekly[3)]	Exchange	Users
O_2 sensors[2)]	Yearly or when necessary	Exchange	Service personnel
Latch, heat shield	Every 2 years	Exchange	Service personnel
O_2 solenoid valve[2)]	Every 2 years	Exchange	Service personnel
Fan motor service kit	Every 3 years	Exchange	Service personnel
Fan in sensor module	Every 3 years	Exchange	Service personnel
O_2 pressure reducer[2)]	Every 6 years	Exchange	Service personnel

Component	Interval	Measure	Target group
Water reservoir assembly[2)]	Every 2 years	Exchange	Users
Humidifier[2)]	Every 3 years	Exchange	Users
Manifold[2)]	Every 2 years	Exchange	Users
Heater/impeller cover with duct cover[2)]	Every 2 years	Exchange	Users
Tilt bar O-rings	Every 6 years	Exchange	Service personnel
Collection bottle, condensation management system[2)]	Weekly[3)]	Exchange	Users
Hose/plug assembly, condensation management system[2)]	Weekly[3)]	Exchange	Users
Drain plug with O-ring[2)]	Yearly	Exchange	Users
Maintenance:			
Device servicing and maintenance	Yearly	Check and maintain	Service personnel
Calibration:			
O_2 Sensors[2)]	Weekly[4)]	Calibrate	Users
Standard scales[2)]	Every 1 year and when necessary	Calibrate and check accuracy	Users
OIML/NAWI scales[2)]	Every 1 year and when necessary[5)]	Check accuracy[6)]	Users
Adjustment:			
Standard scales	As required	Adjust	Users
OIML/NAWI scales	As required	Adjust[6)]	Specialized service personnel

1) Replace if the material becomes brittle or sticky or if strips of material have become detached.
2) If installed.
3) And also with each new patient.
4) Calibration may need to be done more frequently if barometric pressure changes occur and/or highest level of system accuracy is required by the clinician for patient treatment.
5) Measuring accuracy depends on local gravity, as determined by altitude and latitude. The specified accuracy is only applicable if the scales have been calibrated to the installation site.
6) Verification of the OIML/NAWI scale may also be required by, and performed by, local metro-logical authorities.

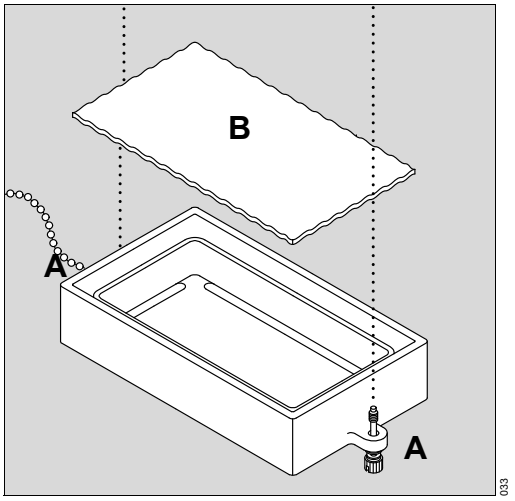
13.5.1 Maintenance instructions

Clean and disinfect device or components before each maintenance step, also before returning for repair.

13.5.1.1 Air inlet filter maintenance

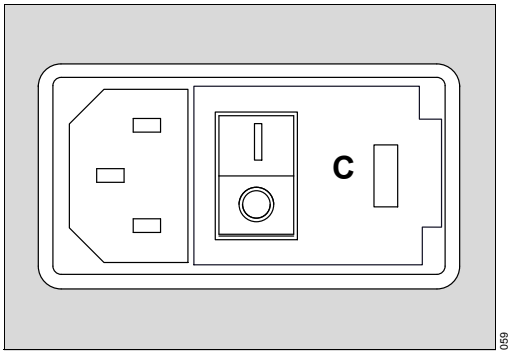
Check the air inlet filter during each preventive maintenance cycle. Replace the filter if it is damaged, visibly dirty, or older than 3 months.

1. To remove the air inlet filter cover, loosen the 2 thumbscrews (A).
2. Remove the old air inlet filter and install a new one (B). Orient the filter so that the side with the text “THIS SIDE OUT” faces the inside of the air inlet filter cover.
3. Install the air inlet filter cover, and tighten the 2 thumbscrews.



13.5.1.2 Fuse replacement

1. Disconnect the Isolette 8000 plus from electrical power.
2. Using a small screwdriver or similar tool, pry open the fuse holder cover (C) on the on/off switch module on the height adjustment trolley.
3. Remove the fuse holder and replace the fuse (or fuses) (T10AL250V).
4. Reinstall the fuse holder and reinstall the cover onto the on/off switch module.



13.5.1.3 Condensation management system replacement (if installed)

⚠ CAUTION
Risk of injury or damage to the device
Noncompliance may result in injury or damage to the device.
- ► Do not reprocess and reuse single-use components.
- ► Do not use single-use components or accessories if packaging is damaged.
- ► If any fluids spill or leak around the device, wipe the area dry to prevent slipping hazard.
- ► Check the water level in the collection bottle every 8 hours to avoid overflow. When the water level reaches the maximum mark on the bottle, replace the bottle.

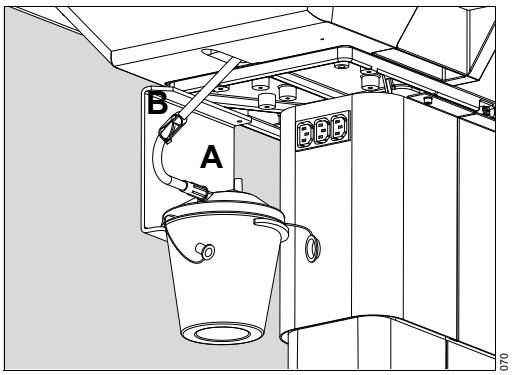
⚠ CAUTION
Risk of injury or damage to the device
Liquid in the collection bottle can contain patient fluids.
- ► Collection bottles and fluids should be handled according to hospital guidelines.

When using high levels of humidity, Dräger recommends using the condensation management system.

The condensation management system must be replaced weekly and, also, with each new patient.

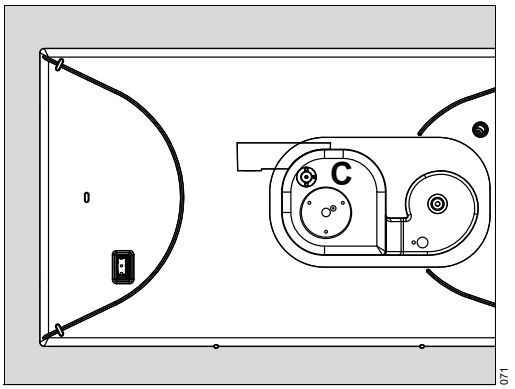
1. Slowly raise the hood.
2. Remove the mattress.
3. If the incubator is equipped with a weighing scale, perform steps 4 through 6; otherwise go to step 7.
4. Disconnect the scale cable from the sensor module.
5. Remove the cable from the clamps that hold it to the incubator.
6. Lift the scale from the bed.
7. Remove the bed and X-ray tray.
8. Remove the T-bars.
9. Remove the upper cover.
10. Disconnect the condensation management hose (A) from the collection bottle located underneath the left side of the incubator.

11 Remove the clamp (B) from the condensation management hose.

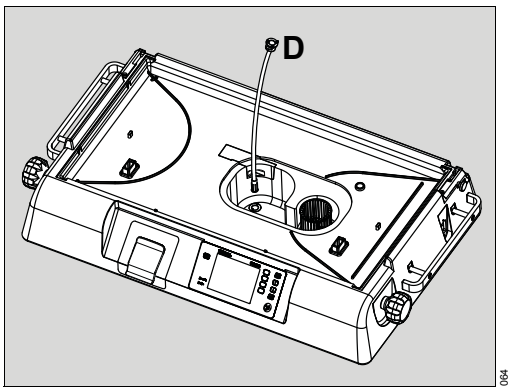


12 Remove the condensation management hose:

A Turn the plug (C) at the bottom of the heater well 90 degrees counterclockwise.



B Pull the hose/plug assembly out completely (D).



13 Discard the collection bottle, hose/plug assembly, and clamp.

14 Remove the clamp from the new condensation management hose and set aside.

15 Insert the new hose/plug assembly fully into the drain opening at the bottom of the heater well.

16 Push the hose plug down until it is flush with the heater well floor. Turn the plug 90 degrees clockwise.

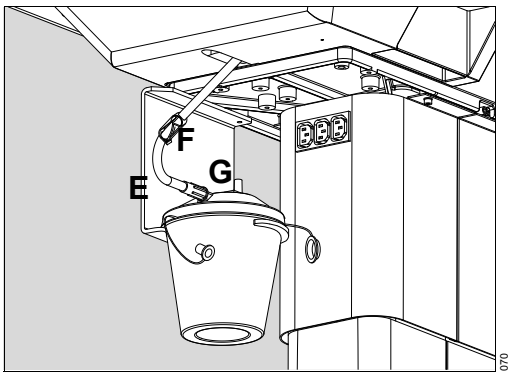
17 Slide the new collection bottle onto the bracket (E) located underneath the left side of the incubator.

18 Remove the caps from the ports on the collection bottle.

The large port on top of the collection bottle must remain uncapped during operation to ensure that water drains properly into the bottle.

19 Attach the clamp to the hose (F).

20 Connect the condensation management hose to the patient port (G) on the side of the collection bottle.



21 Install the heater/impeller cover.

22 Install the upper cover.

23 Install the T-bars on the upper cover.

24 Install the bed, X-ray tray, and scale (optional).

25 Install the mattress.

26 Close the hood.

13.5.1.4 Collection bottle replacement (if installed)

⚠ CAUTION

Risk of injury or damage to the device

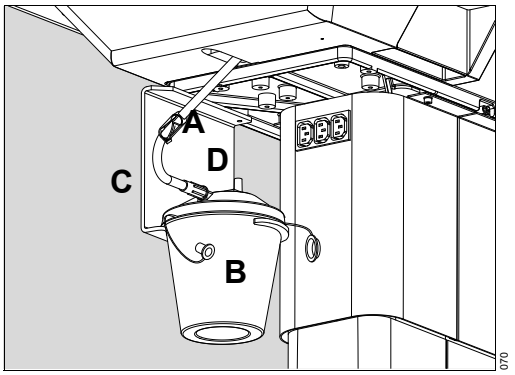
Excess fluid in the collection bottle can lead to spillage and a safety hazard

► To avoid overflow, check the water level in the collection bottle every 8 hours.

► When the water level reaches the maximum mark on the bottle, replace the bottle.

To replace the bottle if it becomes full during operation:

1 Clamp the condensation management hose using the attached clamp (A).



2 Disconnect the hose from the collection bottle (B).

3 Discard the bottle.

4 Slide the new collection bottle onto the bracket (C) located underneath the left side of the incubator.

5 Remove the caps from the ports on the collection bottle.

The large port on top of the collection bottle must remain uncapped during operation to ensure that water drains properly into the bottle.

6 Connect the condensation management hose to the patient port (D) on the side of the collection bottle.

7 Unclamp the hose.

13.5.1.5 O_2 solenoid replacement

1 Remove oxygen servo assembly.

2 Remove O_2 solenoid.

3 Replace O_2 solenoid.

4 Install the oxygen servo assembly.

5 Perform the Functional check procedure on page 63.

13.5.1.6 O_2 pressure reducer replacement

1 Remove oxygen servo assembly.

2 Remove O_2 pressure reducer.

3 Replace O_2 pressure reducer.

4 Set to 40 psi.

5 Install the oxygen servo assembly.

6 Perform the Functional check procedure on page 63.

13.5.1.7 Fresh air valve replacement

1. Perform disassembly instructions (see Disassembly on page 135).
2. Disconnect all external cables from the controller, and remove and retain 2 wing nuts.
3. Partially remove the controller from the shell, disconnect all internal cables, and then fully remove the controller.
4. Open the shell assembly partially, and disconnect the corrugated hose.
5. Remove the upper shell.
6. Remove fresh air valve.
7. Install new fresh air valve.
8. Reassemble by reversing the order of disassembly.
9. Perform the Functional check procedure on page 63.

13.5.1.8 Heat shield latches replacement

Two heat shield latches are on each access panel and on the rear hood wall of single-access devices.

1. Remove heat shield latch.
2. Replace heat shield latch.

13.5.1.9 O-ring replacement

1. Perform the disassembly instructions (see Disassembly on page 135).
2. Disconnect all external cables from the controller, and remove and retain 2 wing nuts.
3. Partially remove the controller from the shell, disconnect all internal cables, and then fully remove the controller.
4. Open the shell assembly partially, and disconnect the corrugated hose.
5. Remove the upper shell.
6. Remove both tilt bar mechanisms.
7. Remove and discard the existing tilt bar O-rings.
8. Install a new tilt bar O-ring onto each tilt bar mechanism.
9. Reassemble by reversing the order of disassembly.
10. Perform the functional check procedure (see page 63).

13.5.1.10 Fan motor replacement (main) including vibration isolators

1. Perform the disassembly instructions (see Disassembly on page 135).
2. Disconnect all external cables from the controller, and remove and retain 2 wing nuts.
3. Partially remove the controller from the shell, disconnect all internal cables, and then fully remove the controller.
4. Open the shell assembly partially, and disconnect the corrugated hose.
5. Remove the upper shell.

6 Remove and retain the screws holding the motor and vibration isolators to the upper shell.
7 Disconnect the motor, and discard it, including the vibration isolators.
8 Install the new vibration isolators on the new motor.
9 Install the new assembly, reusing the screws.
10 Reassemble by reversing the order of disassembly.
11 Perform the functional check procedure (see page 63).

13.5.1.11 Fan replacement (controller)

1 Disconnect all external cables from the controller, and remove and retain 2 wing nuts.
2 Partially remove the controller from the shell, disconnect all internal cables, and then fully remove the controller.
3 Open the controller.
4 Remove the LCD/front panel/CPU PCB subassembly.
5 Disconnect and discard the fan.
6 Install and connect the new fan.
7 Reassemble by reversing the order of disassembly.
8 Perform the functional check procedure (see page 63).

13.5.1.12 Fan replacement (sensor module)

1 Disconnect the sensor module, and remove it from the hood.
2 Carefully cut along the seam any labels that cross the sensor module seam.
3 Open the sensor module.
4 Partially remove the main PCB, and disconnect the ribbon cable.
5 Remove the connector PCB (including fan).
6 Remove and retain the humidity PCB (if present) from the connector PCB.
7 Discard the connector PCB (including fan).
8 Install the humidity PCB (if present) into the new connector PCB (including the fan).
9 Install the new connector PCB (including the fan) into the sensor module.
10 Reassemble by reversing the order of disassembly.
11 Perform the functional check procedure (see page 63).

13.5.1.13 Oxygen sensor cell replacement

⚠ WARNING
Risk of death or serious injury
Use of incorrect oxygen sensor cells can result in inaccurate readings that could cause patient injury.
► Use only the oxygen sensor cell kit specified in the Accessories on page 181.

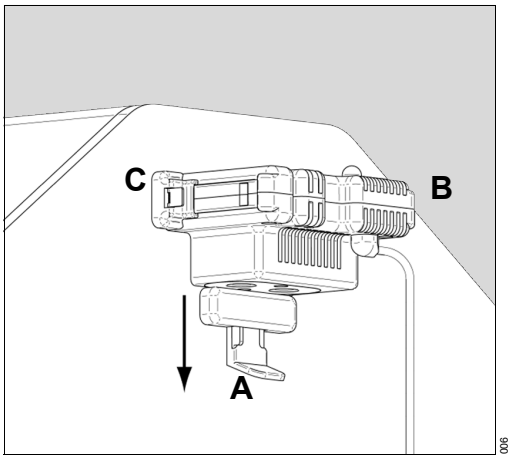
The incubator uses 2 independent oxygen sensors to provide redundancy and cross-checking. For this reason, the oxygen sensor cells must be replaced at the same time, and are therefore provided as a pair.

1 Open the 2 bags containing the new oxygen sensors, and expose the sensors to air. Note the time.

The individual oxygen sensor cells are packaged in airtight bags. After packaging, the sensor slowly consumes all the oxygen in the bag, and then enters a “sleep” state. When the bag is opened, the sensor must “wake up” before its operation can stabilize. Therefore, the sensor should be exposed to room temperature air for at least 30 min before attempting calibration. If possible, open the bags 24 hours before installation.

If the oxygen sensor has been exposed to extreme temperatures (e.g., >50 °C (122 °F) or <0 °C (32 °F)), it might require up to 24 hours to return to normal operation.

2 Switch off the incubator on/off switch.
3 Unplug the sensor module cable from the shell.
4 If present, unplug the scale cable and any skin temperature probe cables from the sensor module.
5 Pull down the lock (A) on the sensor module (B) and slide the module out from the hood until it stops.
6 Pull out the clip (C) on the left side of the sensor module and remove the module from the hood completely.

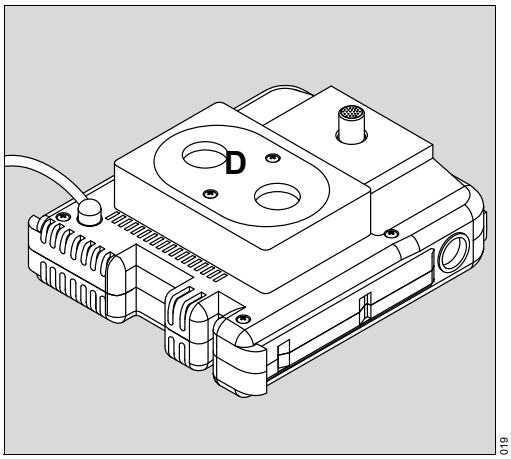


7 Install the oxygen sensors on the underside of the sensor module:

1 Remove O_2 sensor cover from the sensor module.

2 Remove and retain the 2 screws securing the oxygen sensor mounting plate (D).

3 Withdraw the plate, including oxygen sensors and attached connector cables.



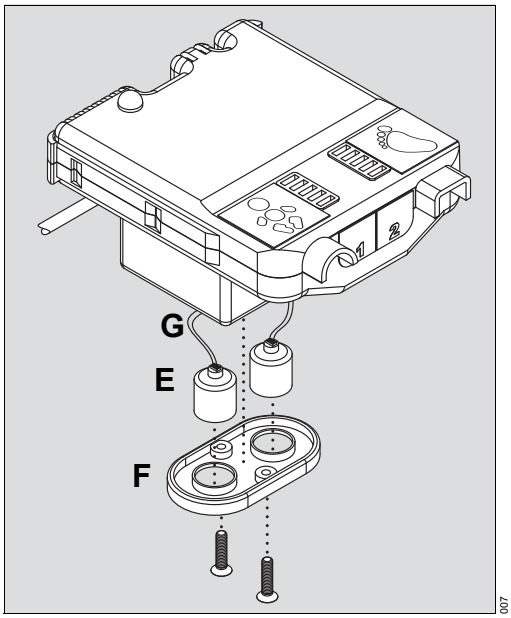
8 Unplug the connector cables from both sensors. It is not necessary to note which is which.

9 Unscrew both sensors from the plate, and discard in accordance with local regulations.

10 Screw each new sensor (E) into the sensor plate (F), and connect the cables (G). Either cable may be attached to either sensor.

11 Reinstall the plate with sensors into the sensor module, and reinstall the screws.

12 Reinstall the sensor module in the hood, and position it in the normal (innermost) position.



13 Reconnect the cables that were previously removed.

⇒ Sensor module cable is connected to the shell.

⇒ Scale cable and temperature probes cables are connected to the sensor module.

14 Switch on the incubator at the controller on/off switch, while pressing the ***Audio Paused/Reset*** key.

⇒ System configuration mode appears.

15 Confirm that the Altitude field contains the correct height above sea level of the site, to the nearest 1000 feet (300 meters). Consult a map or Google Earth if the height above sea level is not known. Correct if necessary.

16 Note the oxygen calibration level.

⇒ Oxygen calibration level is either 21% or 100%.

17 If the oxygen calibration level is 100%, the 100% calibration fixture (with hose barb) must be installed below the sensor module. If the oxygen Calibration Level is 21%, the slide lock fixture (without hose barb) must be installed below the sensor module.

18 Switch off the incubator at the controller on/off switch, wait 1 minute, and turn the incubator back on in normal mode.

19 When 30 minutes have elapsed since step 1 (exposing the oxygen sensors to air), begin oxygen calibration (see Oxygen sensor calibration (option) on page 160). Note carefully the use of room air (21% oxygen) or pure oxygen, as dictated by the presence or absence of the 100% oxygen calibration fixture on the hood.

20 Perform the functional check procedure (see page 63).

13.6 Repair

Dräger recommends that all repairs are performed by DrägerService and that only authentic Dräger repair parts are used.

13.7 Calibration and adjustment

13.7.1 Oxygen sensor calibration (option)

⚠ WARNING

Risk of death or serious injury

Calibration of the oxygen sensor must be done at least every 7 days. Calibration may need to be done more frequently if barometric pressure changes occur and/or highest level of system accuracy is required by the clinician for patient treatment.

► If the message ***Cal Required*** is displayed, calibrate the servo oxygen control system.

If the sensor module cable is disconnected from the shell connector during operation, the message ***Cal Required*** is displayed. This message indicates that the servo oxygen control system must be calibrated.

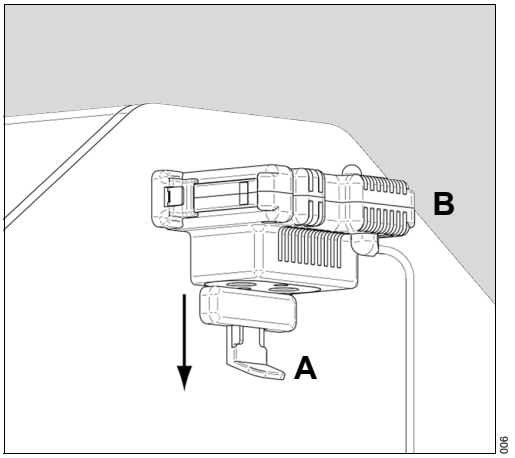
Calibration of the oxygen system is dependent on the altitude.

13.7.1.1 Oxygen sensor calibration to room air (21%)

⚠ WARNING
Risk of death or serious injury
If the 100% oxygen calibration fixture is used during the 21% calibration procedure, the calibration will be inaccurate.
► To perform the 21% oxygen calibration procedure, ensure that the incubator is equipped with the standard sensor module slide-lock.

To calibrate the oxygen sensor to room air (21%):

1 Verify the oxygen calibration level setting (21% or 100%) at the system configuration menu (Refer to System configuration menu on page 113).
2 If necessary, configure the oxygen calibration level setting for 21%.
⇒ The proper oxygen calibration altitude is selected in the system configuration menu (Refer to System configuration menu on page 113).
3 Ensure that the incubator is equipped with the standard sensor module slide-lock, **not** the 100% oxygen calibration fixture.
4 At display 1, press the ***Oxygen*** button.
5 Press the ***On*** button, and then the ***Cal*** button.
⇒ The message ***Slide Out Sensor*** appears.
6 Within 5 seconds, withdraw the sensor module from the hood to prevent a ***Cal Fail*** message. To withdraw the module, pull down the lock (A) and slide out the module (B) from the hood until it stops.

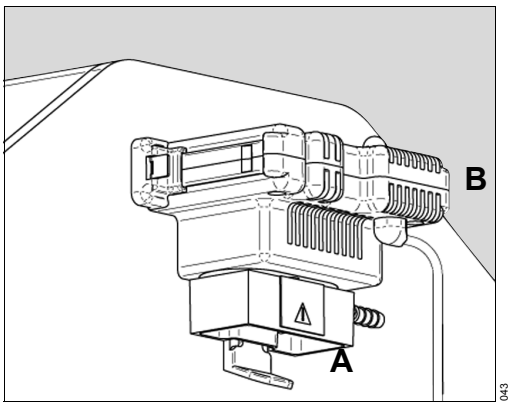


⇒ When calibration is complete, the message ***Cal Pass*** is displayed in the oxygen window.
7 Slide the sensor module inside the hood, and then press the ***On*** button.
8 If the message ***Cal Fail*** is displayed, refer to In case of calibration failure on page 162.
9 If the calibration procedure is unsuccessful a second time, refer the device to service personnel.

13.7.1.2 Oxygen sensor calibration to 100% oxygen

To perform the 100% oxygen calibration procedure:

1. Install the 100% oxygen calibration fixture on the hood (see Installing the 100% oxygen calibration fixture (optional) on page 57).
2. Verify the oxygen calibration level setting (21% or 100%) at the system configuration menu (Refer to System configuration menu on page 113).
3. If necessary, configure the oxygen calibration level setting for 100%.
4. Connect an oxygen hose to a 100% medical-grade oxygen source at 3 L/min to 5 L/min and to the barb fitting on the calibration fixture.
5. Turn on the oxygen.
6. At display 1, press the ***Oxygen*** button.
7. Press the ***On*** button, and then the ***Cal*** button.
8. Within 5 seconds, withdraw the sensor module from the hood to prevent a ***Cal Fail*** message. To withdraw the module, pull down the lock (A) and slide out the module (B) from the hood until it stops.



   ⇒ When calibration is complete, the message ***Cal Pass*** is displayed in the oxygen window.

9. Remove the oxygen source.
10. Slide the sensor module inside the hood.
11. Press the ***On*** button.
12. If the message ***Cal Fail*** is displayed, refer to In case of calibration failure on page 162.
13. If the calibration procedure is unsuccessful a second time, refer the device to service personnel.

13.7.1.3 In case of calibration failure

These measures are independent troubleshooting measures that do not need to be performed in sequence.

- If using 100% oxygen, confirm the flow and oxygen content of the supplied gas. If in doubt, remove the 100% calibration fixture, reprogram the controller to calibrate at 21%, and retry the calibration with room air. Notify the healthcare facility if the 21% passes and the 100% fails. The setting in the controller, the use of the 100% fixture vs. the normal sensor lock, and the use of pure oxygen vs. room air must all agree.
- If using room air, confirm the air concentration using a calibrated independent oxygen meter. Hospital air is often enriched with oxygen.
- Reenter the system configuration mode, then enter the diag info mode, then enter the system test mode. Observe that ***O2*** Monitor Cell (yellow wire) and ***O2*** Control Cell (orange wire) both show ***INSTALLED*** (INSTALLED). If not, inspect the connection of the oxygen sensors.
- Wait 10 minutes and repeat the calibration procedure.

13.7.2 Scale adjustment (accessory)

13.7.2.1 Standard scale adjustment

Dräger recommends adjusting the scale using a calibrated 5-kg weight upon installation and as needed thereafter.

When calibrating the scale, the bed must be level and not in the Trendelenburg or Reverse Trendelenburg position

To adjust the scale:

1 At display 1, press the ***Display Selection*** key.

⇒ Display 2 appears.

2 Press the ***Weight*** button.

⇒ The Weight display appears.

3 If necessary, remove any objects from the bed.

4 Press the ***->0/T<-*** button 2 times

5 Press the ***Display Selection*** key.

⇒ The Scale Calibration display appears.

6 Press the ***Cal*** button (A).

⇒ The ***Wait...*** message is displayed, and then replaced with the ***5-kg symbol***.

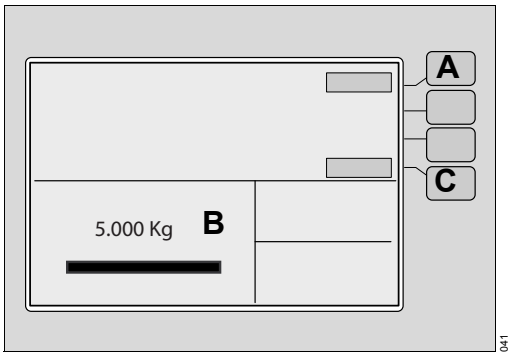
7 Within 40 seconds of the ***5-kg symbol*** being displayed, place a calibrated 5-kg weight on the center of the bed.

If the 5-kg weight is not placed on the center of the bed within 40 seconds after the **5-kg symbol** is displayed, the ***Calibration Failed*** message is displayed.

8 Wait for the Weight Sample bar to fill and a weight reading of ***5.000 kg*** to be displayed (B).

9 Remove the weight, and then press the ***Home*** button (C).

✓ Display 2 appears.



13.7.2.2 OIML/NAWI scale adjustment (if installed)

OIML/NAWI scales can only be adjusted by service personnel. Contact DrägerService for further information.

OIML/NAWI scales can only be verified by representatives of the local authority.

14 Disposal

At the end of its useful life, dispose of the product in accordance with the applicable legal provisions.

14.1 For countries subject to the EU Directive 2002/96/EC

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, this device may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device. To initiate collection or for further information, visit Dräger on the Internet at www.draeger.com. Use the Search function with the keyword "WEEE" to find the relevant information. If access to Dräger's website is not possible, contact the local Dräger organization.

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15 Technical Data

15.1 Specifications

15.1.1 Device classification

Protection class	Class I, Type BF, continuous operation, not AP
Ingress of liquids and particulate matter (IEC 60601-1)	IPX0
Classification in accordance with EU Directive 93/42/EEC	IIb
UMDNS code/GMDN code	12-113/36025

15.1.2 Physical attributes

Height	133.3 cm to 153.7 cm (52.5 in to 60.5 in)
Width	<104 cm (41 in)
Depth	<76.2 cm (30 in)
Weight (without options/accessories)	≤98.5 kg (217.1 lb)
SoftBed mattress size	≥38 cm x 74 cm x 3 cm (15 in x 29.1 in x 1.2 in)
Bed Trendelenburg/reverse Trendelenburg tilt	Continuously variable to 12° ± 1°
Infant weight	10 kg (22 lb) maximum
Expected service life	7 years

15.1.3 Environmental requirements

Operating conditions	
Temperature	20 °C (68 °F) to 30 °C (86 °F)
Humidity	5% to 95% relative humidity, non-condensing
Operating altitude	Up to 3000 m (9800 ft) (per IEC60601-1)
Ambient air pressure	110 kPa to 70 kPa
Storage conditions	
Temperature	-20°C (-4°F) to 60 °C (140 °F)
Humidity	5% to 95% relative humidity, non-condensing
Ambient air pressure	110 kPa to 50 kPa

15.1.4 Electrical requirements

Power requirements for 100/120 V~ devices	100/120 V~, 50/60 Hz, 1900 W maximum, 9.9 A maximum
Power requirements for 220/230 V~ devices	220/230 V~, 50/60 Hz, 1900 W maximum, 9.9 A maximum
Auxiliary power sockets (100 V~) (VHA only)	100 V~, 50/60 Hz, 100 W maximum
Auxiliary power sockets (120 V~) (VHA only)	120 V~, 50/60 Hz, 300 W maximum
Auxiliary power sockets (220/230 V~) (VHA only)	220/230 V~, 50/60 Hz, 300 W maximum
Earth leakage current	≤ 500 µA

15.1.5 General performance

Air temperature mode set point range	20.0 °C (68.0 °F) to 39.0 °C (102.2 °F)
Air temperature mode set point override temperature range	37.0 °C (98.6 °F) to 39.0 °C (102.2 °F)
Air temperature display range	15.0 °C (59 °F) to 45.0 °C (113 °F) ± 0.3 °C
Air temperature warm-up time at 22 °C (72 °F) ambient	< 35 min
Air temperature variation	< 0.5 °C (<0.9 °F)
Air temperature overshoot	< 0.5 °C (<0.9 °F)
Air temperature uniformity with a level mattress	< 0.8 °C (<1.4 °F)
Accuracy of incubator temperature indication	≤ 0.8 °C
Skin temperature mode set point range	34.0 °C (93.2 °F) to 37.0 °C (98.6 °F)
Skin temperature mode set point override temperature range	37.0 °C (98.6 °F) to 38.0 °C (100.4 °F)
Skin temperature display range	15.0 °C (59 °F) to 45.0 °C (113 °F) ± 0.3 °C, except ± 0.2 °C @ 32 °C to 42 °C
Misc specifications	
Noise level within the hood environment	≤ 47 dB(A) (without servo oxygen control)
Air velocity over the mattress	< 10 cm/second (4 in/second); average of 5 points at 10 cm (4 in) above the mattress
Carbon Dioxide (CO_2) level	< 0.5%
Set point data retention	Power failures lasting <10 min
Alarm sound level	>65 dBa

15.1.6 External communication

COM port (output only)	Only connect devices that fulfill the requirements of the standard IEC 60950-1 on unearthed SELV circuits or the requirements of the standard IEC 60601-1 on accessible secondary circuits with max. 60 V DC nominal voltage.
Type	9-pin Sub-D (female), electrically isolated Protocol
Configurations	Serial Data Output (default) or MEDIBUS.X
Serial data output	
Baud rate	2400
Parity	None
Data bits	8
Stop bits	1
Dräger MEDIBUS.X, version 6	By the RS-232 port only
Baud rate	9600
Parity	Even
Data bits	8
Stop bits	1

For a detailed description of the interface protocol, please see the manual Dräger RS 232 MEDIBUS Protocol Definition 90 28 258 and MEDIBUS for Dräger Paediatric Devices 90 29 205.

Pin assignment

Pin 2	RXD
Pin 3	TXD
Pin 5	GND

15.1.7 Humidification system (option)

Humidity control duration of operation after refilling	>24 hours @ 85% RH and 37 °C, in air temperature mode
Humidity control reservoir capacity	1500 mL
Humidity control range	30% to 95% in 1% increments (at high ambient humidity levels, low-level humidity settings may not be attainable)
Humidity display accuracy between 10% and 80% @ 20 °C (68 °F) to 40 °C (104 °F)	± 6% RH
Humidity display range	10% to 100%
Humidity display resolution	1%
Maximum humidity levels	>85% (incubator set temp at 39 °C, with at least 30% RH at ambient)

15.1.8 Oxygen control system (option)

15.1.8.1 Servo oxygen control system (option)

Oxygen inlet pressure	40 psi to 150 psi (2.8 kg/cm^2 to 10.5 kg/cm^2)
Oxygen inlet flow rate	30 L/min
Oxygen control range	21% to 65%
Oxygen display resolution	1%
Oxygen display accuracy (100% calibration)	± 3%
Oxygen display accuracy (21% calibration)	± 5%
Oxygen display range	18% to 100%
Oxygen control accuracy	± 2% of full scale

15.1.8.2 Manual oxygen control system (option)

Oxygen inlet pressure	40 psi to 150 psi (2.8 kg/cm^2 to 10.5 kg/cm^2)
Oxygen inlet flow rate	30 L/min

15.1.9 Weighing system

15.1.9.1 Standard weighing system (option)

Weight display range	0 kg (0 lb) to 7 kg (15.4 lb)
Weight display resolution	1 g or 1 oz
Weight display accuracy	0 to 2 kg: ±2 g (0 to 4.4 lb: ±0.07 oz)
	> 2 kg: ±5 g (>4.4 lb: ±0.18 oz)
Tare weight	≤ 4.0 kg (8.82 lb)

15.1.9.2 OIML/NAWI weighing system (option) (not available in all markets)

Category	Value
Weight display range	0 kg to 7 kg
Weight display resolution	10 g
Weight display accuracy	10 g
Maximum tare weight	≤ 4.0 kg
Verification scale interval	10 g
Scale level sensitivity	90 arc minute (1.5 degrees)
Weight display update rate	1 second

15.1.10 Accessory/optional component weight limitations

15.1.10.1 Rail component weight limitations

Rail system	Total rail system weight not to exceed 13.6 kg (30 lb); 6.8 kg (15 lb) per side
Holder for litter bags, including 100 litter bags	0.7 kg (1.5 lb)
Basket, for disposable gloves	0.3 kg (0.7 lb)
Tray 3020	1.2 kg (2.6 lb)

15.1.10.2 Non-rail component weight limitations

Utility shelf assembly, high	11.4 kg (25 lb)
IV pole assembly	5 kg (11 lb)
Swivel drawer assembly, large	Tray - 0.91 kg (2 lb) Drawer - 4.5 kg (10 lb)
Swivel drawer assembly, small	Tray - 0.91 kg (2 lb) Drawer - 2.2 kg (5 lb)

15.2 Device combinations

This device can be operated in combination with other Dräger devices or with devices from other manufacturers. Observe the accompanying documents of the individual devices.

If a device combination is not approved by Dräger, the safety and the correct functioning of the individual devices can be compromised. The operating organization must ensure that the device combination complies with the applicable editions of the relevant standards for medical devices.

⚠ WARNING
Risk of death or serious injury
All data that are transmitted via medical devices are for information only and should not be used as the sole basis for clinical decisions.

⚠ WARNING
Risk of electric shock.
Any connected devices or device combinations not complying with the requirements mentioned in these instructions for use can compromise the functional integrity of the medical device and lead to an electric shock.

► Before operating the medical device, strictly comply with the instructions for use of all connected devices or device combinations.

15.3 EMC Declaration

15.3.1 General information

This device was tested for electromagnetic compatibility using accessories from the list of accessories. Other accessories may only be used if they do not compromise the electromagnetic compatibility. The use of non-compliant accessories may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

This device may be used in the direct vicinity of other devices only if Dräger has approved this device arrangement. If no approval has been given by Dräger, it must be ensured that this device functions correctly in the desired arrangement before use. The instructions for use for the other devices must be followed.

15.3.1.1 Electromagnetic environment

This device may only be used in environments specified in section "Environment of use" on page 2.

Emissions	Compliance
Radiated emissions	Class A, group 1 (30 MHz to 1 GHz)
Conducted emissions	Class A, group 1 (150 kHz to 30 MHz)
Radiated emissions	Class A, group 2 (30 MHz to 1 GHz)
Conducted emissions	Class A, group 2 (150 kHz to 30 MHz)
Radiated emissions	Class B, group 1 (30 MHz to 1 GHz)
Conducted emissions	Class B, group 1 (150 kHz to 30 MHz)
Radiated emissions	Class B, group 2 (30 MHz to 1 GHz)
Conducted emissions	Class B, group 2 (150 kHz to 30 MHz)

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

15.3.2 Electromagnetic Immunity

Immunity against	Test level and required electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±8 kV
	Air discharge: ±15 kV
Fast transient electrical disturbances (bursts) (IEC 61000-4-4)	Power cable: ±2 kV
	Longer signal input lines/output lines: ±1 kV
Impulse voltages (surges) (IEC 61000-4-5)	Voltage, external conductor – external conductor: ±1 kV
	Voltage, external conductor – protective ground conductor: ±2 kV
Magnetic fields at mains frequency (IEC 61000-4-8)	50 Hz: 30 A/m
Voltage dips and short interruptions in the supply voltage (IEC 61000-4-11)	Voltage dips of 30 % to 100 %, 8.3 ms to 5 s, different phase angles
Radiated high-frequency disturbances (IEC 61000-4-3)	80 MHz to 2.7 GHz: 3 V/m
Conducted high-frequency disturbances (IEC 61000-4-6)	150 kHz to 80 MHz: 3 V, ISM bands: 6 V
Electromagnetic fields in the vicinity of wireless communication devices	Various frequencies from 385 MHz to 5785 MHz: 9 V/m to 28 V/m

15.3.3 Recommended separation distances from wireless communication devices

To ensure that the functional integrity of this device is maintained, there must be a separation distance of at least 1.0 m (3.3 ft) between this device and wireless communication devices.

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16 Principles of operation

16.1 Introduction

The Isolette 8000 plus incubator is a modular controller-based incubator that enables simultaneous control of temperature, oxygen (optional), and humidity (optional) parameters affecting the infant. Standard features include oval hand ports with a quiet hand port latch on the front and rear access panels, either oval hand ports or iris ports on the side hood panels, rails for attaching accessories, and a Trendelenburg bed-tilt mechanism (0° to 12°). The hood and shell assembly is mounted on a variable height adjustable (height adjustment) trolley with anti-static castor wheels. Information is displayed on a liquid crystal display.

Optional components and accessories include a weighing system, a cylinder holder for D or E size gas cylinders, drawers, utility shelf, and IV pole.

16.2 Functional description

16.2.1 Air circulation system

The Isolette 8000 plus incubator uses a forced air circulation system to warm the infant. A controlled amount of room air, approximately 7 liters per minute (L/min), is drawn through the air inlet filter by the motor-driven impeller located in the shell.

The impeller internally recirculates air at a much greater flow than a fresh gas inflow. The total inflow of fresh and recirculated air is directed around the heater. The air enters the patient compartment through the slots at the front and rear of the upper cover. It forms 2 streams, one passing between the inner and outer walls of the front access panel, and the other between the inner and outer walls of the rear access panel. The air circulates past the sensor module containing the temperature sensing probe, which encapsulates the air temperature control thermistor and a high air temperature alarm thermistor. After circulating within the patient compartment, the air is then recirculated down through a slot in the right end of the upper cover, and back to the impeller. When the front and/or rear access panels of the hood are open, the air continues to flow upward past the opening, creating a warm air curtain. This curtain minimizes the drop in air temperature within the incubator.

16.2.2 Temperature regulation

Temperature is regulated by using either incubator air temperature or infant skin temperature. The front panel keys enable the user to select the desired mode.

In any mode of operation, the heater output is proportional to the amount of heat required to maintain the desired temperature.

16.2.2.1 Air temperature mode

In air temperature mode, the air temperature can be maintained at 20.0 °C (68.0 °F) to 37.0 °C (98.6 °F). Temperatures are selected by the ***Up Arrow*** and ***Down Arrow*** keys on the front panel of the controller. In temperature override mode, the temperature can be maintained at 37.0 °C (98.6 °F) to 39.0 °C (102.2 °F).

The incubator air temperature is monitored by a temperature sensor located in the sensor module and compared with the air set temperature. The information from this temperature probe is supplied to the heater control circuitry, which regulates the heater output to maintain the air temperature setting. The actual air temperature is shown in the Temperature window. A second thermistor within the air temperature sensor serves as a backup to limit the maximum incubator temperature. If the high temperature limit is reached, the heater shuts off.

The infant temperature is a function of the air temperature and the ability of the infant to establish and maintain its temperature. A small infant, or one with underdeveloped homeostatic control, may not be able to maintain a stable temperature at the desired level.

16.2.2.2 Skin temperature mode

In skin temperature mode, the ***Up Arrow*** and ***Down Arrow*** keys on the front panel of the controller are used to set the skin temperature at 34.0 °C (93.2 °F) to 37.0 °C (98.6 °F). In temperature override mode, the temperature can be selected at 37.0 °C (98.6 °F) to 38.0 °C (100.4 °F).

A skin temperature probe is attached directly to the skin of the infant. The information from the probe is supplied to the heater control circuitry, which proportions the heater output to maintain the skin set temperature.

The air temperature is still shown in skin temperature mode, but for information purposes only. If the air temperature mode is selected while the skin temperature probe remains connected, the skin temperature parameter continues to display the actual skin temperature. However, it does not control the incubator temperature.

The sensor module is equipped to accept 2 skin temperature probes. To control the incubator temperature in the skin temperature mode, insert a skin probe into the central skin probe connector (see Sensor Module on page 31). When an additional peripheral skin temperature probe is connected, the controller displays the respective central skin temperature and peripheral skin temperature monitored by the skin temperature probes.

If the central skin temperature probe is disconnected from its receptacle while in the skin temperature mode, the skin temperature parameter is invalidated and shows dashes on the display, an acoustic alarm activates, and the heater turns off.

16.2.2.3 Kangaroo mode

Kangaroo mode simplifies the operation of the incubator when the infant is removed from the incubator to have direct skin contact with a parent. In this mode, the patient is warmed by the parent’s body heat instead of the incubator. This mode provides the user with extended monitoring functions to detect infant hyperthermia or hypothermia, even when the infant is outside the patient compartment.

Since the infant is no longer inside the incubator during "kangarooing", the infant skin temperature should no longer be used for controlling the air temperature inside the incubator. Instead, the incubator should be set up so that when "kangarooing" is concluded and the infant is returned to the incubator, the incubator is heated to the same temperature, and climate as when the infant was taken out of the incubator.

Therefore, if the incubator was previously operated in skin temperature mode, it is switched to air temperature mode during kangaroo mode. The current incubator temperature is automatically used as the air temperature setting, but is limited to 37 °C. All other settings (humidity, oxygen) remain unchanged and active.

If the incubator was previously operated in air temperature mode, the settings remain unchanged.

Since, after switching to kangaroo mode, the door is opened and the infant removed from the incubator, alarms triggered by opening the doors are no longer meaningful. All alarms that would normally be activated by opening the access panels are automatically delayed for the next 4 minutes:

– ***Low Air Temperature***
– ***Low Humidity***
– ***Low Oxygen %***

If any of these alarms are active when the incubator is switched to kangaroo mode, the alarm is inhibited for 4 minutes.

Activation of special kangaroo mode alarms

During kangaroo mode, the skin (and central) temperature of the infant can rise or fall. The infant central or skin temperature must be monitored during kangaroo mode. To monitor temperatures with as few nuisance alarms as possible, the incubator activates additional alarms during operation in kangaroo mode:

– ***Central Skin Temp Low***
– ***Peripheral Skin Temp Low***
– ***Skin Temp Diff High***
– ***Skin Temp Diff Low***

However, immediately after switching to kangaroo mode, the kangaroo mode alarms are delayed for 4 minutes. This delay allows the infant time to adapt to the new environment.

16.2.2.4 Thermomonitoring

The term Thermomonitoring refers to the continuous measurement and display of a central skin temperature and a peripheral skin temperature. Instead of the body core temperature, a central skin temperature can be used, because it is measured for the incubator skin temperature control.

The continuous display of the difference between these 2 temperatures permits early detection of cold stress. However, heat stress, thermoregulation problems, and, e.g., infections can also be more rapidly detected by displaying the 2 temperature values and evaluating their difference.

The Isolette 8000 plus trend display shows the trend histories of a maximum of 2 skin temperatures. The difference between central skin temperature and peripheral skin temperature, which is essential for Thermomonitoring, can be displayed continuously.

Also, trend analysis shows values from the past when explaining the development of disease symptoms or the development of hypothermal stress. Values going back a maximum of 24 hours can be accessed. The trend time scale is user-selectable in intervals of 2, 4, 8, 12, and 24 hours.

16.3 Oxygen system

The Isolette 8000 plus is equipped with either a servo oxygen control system or a manual oxygen control system.

16.3.1 Servo oxygen control system (option)

When installed, the servo oxygen control system maintains oxygen concentration within the hood via a valve and an oxygen sensor module. The sensor module houses 2 independent oxygen fuel cells. Oxygen concentration is displayed on the screen, and oxygen-related alarm conditions are indicated to the user via acoustic and optical alarms.

When the sensor module is outside of the hood during oxygen control mode, acoustic and optical alarms are enabled and the flow of oxygen is interrupted.

16.3.2 Manual oxygen control system (option)

With the manual oxygen control system, oxygen flow is controlled by an external flowmeter. Oxygen concentration is not displayed on the Isolette 8000 plus screen and no oxygen alarms are generated. To achieve desired oxygen concentration, use a calibrated oxygen analyzer.

16.4 Humidification system (option)

When installed, the built-in humidifier provides humidification of the incubator air by evaporating boiling water from the water reservoir. With closed-loop humidity control, only the desired relative humidity set point is entered. The system then automatically controls the humidifier output of the humidifier to maintain the preset relative humidity in the patient compartment.

Isolette 8000 plus allows 2 modes to control humidity during incubator operation:

- Automatic humidity set point selection (Auto humidity)
- Manual adjustment of humidity set points

If the humidity has not risen to a predetermined threshold within a designated time, an audible and visual ***Low Humidity*** alarm occurs.

16.4.1 Humidity control

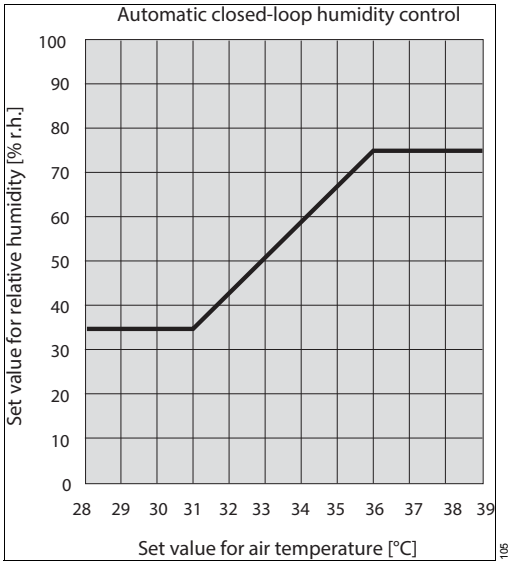
The actual humidity level is measured by a humidity sensor in the patient compartment. If the set point is higher than the actual measured relative humidity (air too dry), the humidifier receives a signal to allow more water vapor into the patient compartment. Relative humidity inside rises.

If the set point is lower than the actual measured relative humidity (air too humid), the humidifier receives a signal to allow less water vapor into the patient compartment. Relative humidity inside falls.

16.4.1.1 Auto humidity

In auto mode, the set point for the relative humidity is calculated and set automatically by the system as a function of air temperature. This function is based on the observation that small and relatively immature infants require both a higher air temperature and higher relative humidity than larger infants.

Example: The lower the air temperature setting, the lower the set point for relative humidity. If the air temperature is increased, the relative humidity is increased correspondingly.



16.4.1.2 Manual humidity

The user sets the relative humidity level manually according to the patient's needs. A value between 30 % and 95 % relative humidity (RH) can be set in 1% increments.

16.4.2 Humidifier

The humidifier is a three-part system consisting of a water reservoir assembly, a humidifier, and a heater/impeller cover with duct cover.

16.4.2.1 Water reservoir assembly

The water reservoir assembly consists of a water reservoir in the front, a humidifier chamber in the back, and a cover with a water filling inlet. The reservoir has a 1.5-liter capacity and permits visual inspection of the water level. It slides in like a drawer in the front of the incubator shell. When the reservoir assembly is fully inserted into the shell and the latch is engaged, the reservoir connects to a duct that directs the flow of humidified air into the heater well. If the water reservoir is empty or not fully inserted in the incubator shell, an acoustic and optical ***Check Water Supply*** alarm occurs.

16.4.2.2 Humidifier

The water enters the humidifier chamber at the back of the reservoir. The humidifier raises the temperature of the water to the boiling point, causing vaporization. No waterborne bacteria are introduced into the patient compartment by the vaporization process.

The rate of vaporization is determined by the level of power transmitted to the humidifier heater. The sensor module, located within the hood environment, houses the humidity sensor that sends information to the controller. The controller regulates the output of the humidifier.

16.4.2.3 Heater/impeller cover with duct cover

The water reservoir connects to a duct in the heater/impeller cover that directs the flow of humidified air into the heater well.

16.5 Condensation management system (option)

Condensate formation can occur on the inside of the hood under certain environmental conditions. On Isolette 8000 plus incubators that are equipped with the condensation management system, excess water is routed to the heater well where it drains via the hose into the collection bottle. The condensation management system consists of a bottle and hose/plug assembly mounted on a bracket underneath the incubator.

16.6 Weighing system (option)

When installed, the weighing system is on a tray under the bed. The scale contains 4 load beams that perform the weighing function. The controller processes the load beam information and displays the weight in kilograms or pounds in the Trend/Alarm window.

System prompts are displayed in the Trend/Alarm window during the weighing procedure.

16.6.1 Standard scales

The ***Weight*** button allows for repeated reweighing of the infant after the weighing routine has been initiated.

16.6.2 OIML/NAWI scales (not available in all markets)

Since the weighing routine is continuous, no reweigh function is required to update the weight measurements.

17 Accessories

Some articles are not available worldwide because they are not approved in all countries of the world.
Technical documentation is available on request.

Parts marked with an asterisk (*) should be installed by service personnel.

Description	Part number
Isolette 8000 plus incubator	MU20602
Reusable	
IV pole assembly	MU12955*
SoftBed mattress	MP01401
Disposable	
Probe, yellow, central skin temperature, disposable, 10	MU26041
Probe, white, peripheral skin temperature, disposable, 10	MU26042
Cover, probe, Care-For-Me, large, 100	MU06943
Cover, probe, Care-For-Me, standard, 100	MU06944
Oxygen Sensor kit	MU24903*

18 Consumables

Description	Part number
Humidity	
Collection bottle, disposable, box of 20, 800 cc	MU10918
Hose/plug assembly, condensation management, 20	MU21120
Miscellaneous	
Air inlet filter, replacement, 4	MU12504
Iris port sleeve, disposable, 100	MU03876

19 Optional components

Parts marked with an asterisk (*) should be installed by service personnel.

Drawers	
Swivel drawer assembly, large	MU17879*
Swivel drawer assembly, small	MU17880*
DIN Compatible Rail components	
Holder for litter bags, including 100 litter bags	M24695
Basket, for disposable gloves	M26146
Tray 3020	M24678
External Monitoring	
MIB2 protocol converter	7256931
MIB cable, 2 m	MS18805
MIB network cable, 1.2 m	4726373
MIB network cable, 2.4 m	4726381
MIB network cable, 4.9 m	4726399
Miscellaneous	
Utility shelf assembly, high	MU12937*
Straps, utility shelf (2)	MU14688
Breathing hose holder kit	MU18660
Grommet	MU12609
Kit, HFV door with grommets	MU18916
Positioning aid Hug it, reusable, size S, for patients up to 800 g	MP01415
Positioning aid Hug it, reusable, size M, for patients up to 1500 g	MP01416
Positioning aid Hug it, reusable, size L, for patients up to 2000 g	MP01412
Positioning aid Hug it, reusable, size XL, for patients up to 3000 g	MP01413
Positioning aid Nesting, reusable, for patients up to 1200 g	MP01417
Positioning aid Set, reusable, 4 small pillows, for patients up to 1000 g	MP01418
Incubator cover, reusable	MP01424
Towel doll Cally, reusable, light blue, or pink	2M30462
Starter package for Isolette, reusable cover and positioning aids	MP01427
VarioLux EU	MP00601
VarioLux US	MP00602
VarioLux GB	MP00603
VarioLux CHN	MP00604
VarioLux BR	MP00605
VarioLux AUS	MP00606
VarioLux ZA	MP00607
VarioLux JPN	MP00608

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These Instructions for use only apply to

Isolette 8000 plus SW 5.n

with the Serial No.:

Without Serial No. filled in by Dräger, these Instructions for use are provided for general information only and do not apply to a specific medical device.

These Instructions for use are provided for customer information only and are only updated or exchanged upon customer request.

CE 0123
Directive 93/42/EEC concerning medical devices

Manufacturer

Draeger Medical Systems, Inc.
3135 Quarry Road
Telford, PA 18969
USA
(215) 721-5400
(800) 4DRAGER
(800 437-2437)
FAX (215) 723-5935
http://www.draeger.com

Distributed in the US by:

Draeger, Inc.
3135 Quarry Road
Telford, PA 18969
U.S.A.
(215) 721-5400
(800) 4DRAGER
(800 437-2437)
FAX (215) 723-5935
http://www.draeger.com

In Europe, Middle East, Africa, Latin America, Asia Pacific distributed by

EC REP **Drägerwerk AG & Co. KGaA**
Moislinger Allee 53 – 55
D-23542 Lübeck
Germany
+49 451 8 82-0
FAX +49 451 8 82-20 80
http://www.draeger.com

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