Instructions for Use

# Isolette 8000

**WARNING**
**To properly use this medical device, the user must obtain a full understanding of the performance characteristics of this medical device prior to use by carefully reading these Instructions for Use.**

## Infant Incubator

## Working with these Instructions for Use

The **title of the main chapter** in the header line helps with orientation and navigation.

The **instructions for the user** combine text and illustrations, providing a comprehensive overview of the system. The information is presented as sequential steps of action, allowing the user to learn directly how to use the device.

The **text** provides explanations and instructs the user step-by-step in the practical use of the product, with short, clear instructions in easy-to-follow sequence.

**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 relevant illustration.

The **illustrations** show the relationship between the text and the device. Elements mentioned in the text are highlighted. Unnecessary details are omitted.

Schematic renderings of screen images guide the user and allow to reconfirm actions performed. The actual screen images differ in look or in configuration.

**A** Letters denote elements referred to in the text.

### Typing conventions

Any text shown on the screen and any labeling on the device are printed in bold and italics, for example, ***Cal***, ***Air***, or ***Alarm Silence/Reset***.

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– Isolette®
– SoftBed™

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is a trademark of Metrex Research Corporation.

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is a trademark of Schülke & Mayr.

## Definitions

**WARNING**

**A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.**

**CAUTION**

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

**NOTE**

A NOTE provides additional information intended to avoid inconveniences during operation.

## Abbreviations and Symbols

Please refer to "Abbreviations" on page 30 and "Symbols" on page 31 for explanations.

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# Contents

# For Your Safety and that of Your Patients

## Strictly follow these Instructions for Use

**WARNING**
**Any use of the medical device requires full understanding and strict observation of all portions of these Instructions for Use. The medical device is only to be used for the purpose specified under "Intended Use" on page 18 and in conjunction with appropriate patient monitoring. Strictly observe all WARNING and CAUTION statements throughout these Instructions for Use and all statements on medical device labels.**

## Maintenance

**WARNING**
**The medical device must be inspected and serviced regularly by properly trained service personnel.**
**Repair of the medical device may also only be carried out by properly trained service personnel.**

**Dräger recommends that a service contract be obtained with DrägerService and that all repairs also be carried out by them. Dräger recommends that only authentic Dräger Medical repair parts be used for maintenance. Otherwise the correct functioning of the medical device may be compromised.**
**See chapter "Maintenance".**

## Accessories

**WARNING**
**Only the accessories indicated on the list of accessories on page 147 have been tested and approved to be used with the medical device. Accordingly it is strongly recommended that only these accessories be used in conjunction with the specific medical device. Otherwise the correct functioning of the medical device may be compromised.**

## Training

For training for medical professionals, see www.draeger.com.

## Connected Devices

**WARNING**
**Any connected devices, or combination of devices, not complying with the requirements mentioned in these Instructions for Use may compromise the correct functioning of the medical device. Prior to operating the medical device, consult the respective documentation and Instructions for Use of all connected devices or combination of devices.**

## Not for use in areas of explosion hazard

**WARNING**
**This medical device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely to occur.**

## Safe connection with other electrical equipment

**CAUTION**
Electrical connections to equipment which is not listed in these Instructions for Use should only be made following consultation with the respective manufacturers. Equipment malfunction may result with the risk of patient injury.

## Networking

Device combinations approved by Dräger (see Instructions for Use of the individual devices or units) meet the requirements set forth by the following standards:

– IEC 60601-1 (EN 60601-1)
  Medical Electrical Equipment
  Part 1: General Requirements for Safety

– IEC 60601-1-2 (EN 60601-1-2)
  Medical Electrical Equipment
  Part 1-2: General Requirements for Basic Safety and Essential Performance
  Collateral Standard: Electromagnetic Compatibility; Requirements and Tests

If Dräger devices or units are connected to other Dräger devices or third-party devices and the resulting combination is not approved by Dräger, the correct functioning of the devices may be compromised. The operator is responsible for ensuring that the resulting system meets the requirements set forth by the above standards.

Strictly follow Assembly Instructions and Instructions for Use for each networked device.

## Patient safety

The design of the medical device, the accompanying literature, and the labeling on the medical device take into consideration that the purchase and use of the medical device are restricted to trained professionals, and that certain inherent characteristics of the medical device are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Dräger design.
This publication excludes references to various hazards which are obvious to a medical professional and operator of this medical device, to the consequences of medical device misuse, and to potentially adverse effects in patients with abnormal conditions. Medical device modification or misuse can be dangerous.

## Patient monitoring

The operators of the medical device are responsible for choosing appropriate safety monitoring that supplies adequate information on medical device performance and patient condition.
Patient safety may be achieved through a wide variety of means ranging from electronic surveillance of medical device performance and patient condition, to simple, direct observation of clinical signs.
The responsibility for the selection of the best level of patient monitoring lies solely with the medical device operator.

### Restriction of Distribution

**CAUTION**
Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

**CAUTION**
Device for use in health care facilities only and exclusively by persons with specific training and experience in its use.

## General WARNINGS and CAUTIONS

The following WARNINGS and CAUTIONS apply to general operation of the device. WARNINGS and CAUTIONS specific to subsystems or particular features appear with those topics in later sections of these Instructions for Use or in the Instructions for Use of any product being used with this device.

### Note on EMC/ESD risk for the device function

General information on electromagnetic compatibility (EMC) pursuant to international EMC standard IEC 60601-1-2:

Electromedical devices are subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information on page 143.

Portable and mobile RF communications equipment can affect medical electrical equipment.

**WARNING**

**Connector pins with an electrostatic discharge (ESD) warning sign should not be touched and no connections should be made between these connectors without implementing ESD protective measures. Such precautionary procedures may include antistatic clothing and shoes, the touch of a ground stud before and during connecting the pins or the use of electrically isolating and antistatic gloves. All staff involved in the above shall receive instruction in these ESD precautionary procedures.**

### Sterile Accessories

**CAUTION**
Do not use sterile-packaged accessories if the packaging has been opened, is damaged or there are other signs of non-sterility. Disposable articles may not be reprocessed and resterilized.

Reuse, processing or sterilization can lead to a failure of the medical devices and cause injuries to patient.

## Installing Accessories

**CAUTION**

Installation to the basic device must be in accordance with the Instructions for Use for the basic device. Confirm that connection is secure with the basic device system.

Strictly follow Assembly Instructions and Instructions for Use.

### Electrical Precautions

**WARNING**

**The total electrical current leakage of all items powered through the incubator must be less than 300 µA for 120V AC/100V AC systems and less than 500 µA for 230V AC systems. Noncompliance may result in death or serious injury.**

**WARNING**

**The potential for electrical shock exists with electrical equipment. Establish policies and procedures to educate your staff on the risks associated with electrical equipment. Noncompliance may result in death or serious injury.**

**WARNING**

**Due to the risk of electrical shock hazard, only properly trained personnel with appropriate service documentation should service the unit. Noncompliance may result in death or serious injury.**

**WARNING**

**To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth (protective ground). Noncompliance may result in death or serious injury.**

**CAUTION**

To prevent equipment damage or accidental power disconnections, do not connect a power cable from the incubator controller directly to an AC wall socket. Always provide power to the incubator by using the power cable coming directly from the stand. Noncompliance may result in injury or equipment damage.

### Explosion Precautions

**WARNING**

**Do not use in the presence of flammable anesthetics. Noncompliance may result in death or serious injury.**

**WARNING**

**Keep matches, and all other sources of ignition, out of the room in which the incubator is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen. Noncompliance may result in death or serious injury.**

**WARNING**

**Small quantities of flammable agents, such as ethyls and alcohol, left in the incubator may result in a fire hazard in oxygen enriched environments. Ensure that the incubator is free of such agents and that oxygen levels are at near room ambient levels. Noncompliance may result in death or serious injury.**

**WARNING**

**A fire and explosion hazard exists when performing cleaning or 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 performing cleaning and maintenance procedures. Turn off or disconnect oxygen supplies during periods of non-use. Noncompliance may result in death or serious injury.**

### EMC Precautions

**WARNING**

**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 International Electrotechnical Commission (IEC) 60601-1 and must have the relevant safety certifications. Noncompliance may result in death or serious injury.**

**CAUTION**

Use of accessories other than those listed and approved for use in this product as original or replacement items may result in increased emissions or decreased immunity. Noncompliance may result in injury or equipment damage.

**CAUTION**

The equipment shall not be used adjacent to other devices unless verification of normal operation in the configuration in which it is to be used can be achieved. Noncompliance may result in injury or equipment damage.

**CAUTION**

Devices connecting to the serial port must be compliant with EN 60601-1-2, the EMC requirement for Medical Devices. Noncompliance may result in injury or equipment damage.

**CAUTION**

The incubator display may go blank during an episode of static discharge to the sensor module. This may result in injury or equipment damage.

**CAUTION**

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. Noncompliance may result in injury or equipment damage.

### Oxygen Precautions

**WARNING**

**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. Noncompliance may result in death or serious injury.**

**WARNING**

**If it is necessary to administer oxygen in an emergency, notify the attending physician immediately. Noncompliance may result in death or serious injury.**

**WARNING**

**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. Noncompliance may result in death or serious injury.**

**WARNING**

**After each change of oxygen flow, allow at least 30 minutes to achieve new concentrations. Noncompliance may result in death or serious injury.**

**WARNING**

**Oxygen levels within the incubator hood environment may be affected when the access doors or access panels are opened. Make sure that all hood access door gaskets and tubing grommets are properly installed. Any open gaps in the incubator hood may reduce the incubator internal oxygen. Noncompliance may result in death or serious injury.**

**WARNING**

**Compressed gas cylinders, such as oxygen cylinders, can become hazardous projectiles if the gas is released rapidly due to damage or other causes. Securely fasten the cylinder. Noncompliance may result in death or serious injury.**

**WARNING**

**Disconnect the incubator from the hospital oxygen source when oxygen is not in use. Noncompliance may result in death or serious injury.**

**WARNING**

**Because oxygen use increases the risk of fire, do not place auxiliary equipment that produces sparks in an incubator. Noncompliance may result in death or serious injury.**

**WARNING**

**The oxygen sensor is a sealed unit that contains potassium hydroxide electrolyte. 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 minutes, holding the eye open, and call a physician. Noncompliance may result in death or serious injury.**

**WARNING**

**Use only Dräger Medical recommended oxygen sensors for proper operation. Noncompliance may result in death or serious injury.**

**WARNING**

**Inspect gas/oxygen service components at regular service intervals for signs of corrosion or damage. Noncompliance may result in death or serious injury.**

**WARNING**

**Routinely inspect oxygen cells for signs of degradation or leakage, and replace if necessary. Noncompliance may result in death or serious injury.**

**WARNING**

**Use of anesthetic agents can interfere with oxygen analyzer accuracy. Noncompliance may result in death or serious injury.**

**CAUTION**

The administration of oxygen may increase the noise level for the baby within the incubator. This may result in injury or equipment damage.

### Humidity Precautions

**WARNING**

**Make sure that all access door gaskets and tubing grommets are properly installed on the hood. Any open gaps in the incubator hood reduce the incubator internal relative humidity. Noncompliance may result in death or serious injury.**

**CAUTION**

Fill the reservoir to the Maximum Filling Limit line. Do not overfill. Water spillage may result, and noncompliance may result in injury or equipment damage.

**Safety Tips**

**WARNING**
**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. Noncompliance may result in death or serious injury.**

**WARNING**
**If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment. Noncompliance may result in death or serious injury.**

**WARNING**
**Do not raise the hood at any time while the infant is in the incubator. Gain access to the infant by the access panels and access doors. Noncompliance may result in death or serious injury.**

**WARNING**
**Always use two 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 unit**
- **remove or secure all loose system components**
- **lower the VHA stand, I.V. pole, and shelves to their lowest position**
- **close all drawers**
- **remove all accessories from the rails**

**Noncompliance may result in death or serious injury.**

**WARNING**
**For optimum stability, always lower the incubator to its lowest position before moving the unit. Make sure that items placed on the monitor shelf are properly secured. Noncompliance may result in death or serious injury.**

**WARNING**
**Always push or pull the incubator forward or backward in a straight line along the length of the stand (from the ends). Lateral or angular movement (across the width) can result in inadvertent tip-over if the wheels encounter any obstacle. Noncompliance may result in death or serious injury.**

**WARNING**
**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. Noncompliance may result in death or serious injury.**

**WARNING**
**Positively secure all access panel latches to avoid accidental opening. Noncompliance may result in death or serious injury.**

**WARNING**
**For infant safety, do not leave the infant unattended when the access panels are open. Noncompliance may result in death or serious injury.**

**WARNING**
**The use of infant seats or other accessories within the incubator that can alter the airflow pattern may affect temperature uniformity, temperature variability, the correlation of the incubator temperature reading to center mattress temperature, and infant skin temperature. Noncompliance may result in death or serious injury.**

**WARNING**
**If airflow passages are not kept clear of obstructions, such as blankets and stuffed animals, during clinical usage, patient safety and incubator performance may be compromised. Noncompliance may result in death or serious injury.**

**WARNING**

**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; therefore, keep the infant clear of this warm air path. Noncompliance may result in death or serious injury.**

**WARNING**

**If using surgical covers or blankets over the infant, ensure that they do not interfere with the warm air curtain or side vents. This may cause heat-induced injury and burns. Noncompliance may result in death or serious injury.**

**WARNING**

**To avoid overheating the infant due to direct radiation, do not position the incubator in direct sunlight or under other sources of radiant heat. Noncompliance may result in death or serious injury.**

**WARNING**

**Use of phototherapy units with the incubator may affect hood wall temperature, incubator temperature, and infant skin temperature. This may result in death or serious injury.**

**WARNING**

**Phototherapy lamps placed over the top of the incubator hood may interfere with upward travel of the variable height adjustable stand. To prevent this interference, always remove the phototherapy lamp before positioning the stand. Noncompliance may result in death or serious injury.**

**WARNING**

**For proper operation of the incubator, use only skin temperature probes from Dräger Medical. Noncompliance may result in death or serious injury.**

**WARNING**

**Never place objects taller than the top of the wheel casters beneath the incubator stand. Placement of objects there could interfere with the stability of the variable height adjustable stand. Noncompliance may result in death or serious injury.**

**WARNING**

**To avoid possible tip-over or damage to adjacent carts, I.V. stands, shelves, etc., keep at least a 30 cm (12 in) perimeter area clear around the stand. Noncompliance may result in death or serious injury.**

**WARNING**

**For optimum incubator stability, always lock all stand wheels. Do not leave the unit unattended when parking on an incline. Noncompliance may result in death or serious injury.**

**WARNING**

**To prevent accidental disconnection, secure all patient leads, infusion lines, and ventilator tubing to the mattress with sufficient excess length to allow for the full range of mattress height adjustment. Noncompliance may result in death or serious injury.**

**WARNING**

**Accessories such as trays, baskets, and shelves should never be used to hold an infant and should not be overloaded due to tipover hazard. Noncompliance may result in death or serious injury.**

**WARNING**

**Always close drawers when not in use, particularly when the incubator is being moved. Noncompliance may result in death or serious injury.**

**WARNING**

**The drawers and rail system are labeled for acceptable weights. Do not exceed these weight limitations. Noncompliance may result in death or serious injury.**

**WARNING**

**Do not insert any object into any of the ventilation holes or any other opening on the Isolette 8000. Noncompliance may result in death or serious injury.**

**WARNING**

**To prevent possible trip and fall hazards, always properly secure the power cable. Noncompliance may result in death or serious injury.**

**WARNING**

**Before moving the device, always ensure that the mattress is level, i.e., not in the Trendelenburg or Reverse Trendelenburg position. Noncompliance may result in death or serious injury.**

**WARNING**

**To place the mattress in Trendelenburg or Reverse Trendelenburg, always tilt one end of the mattress and keep the opposite end in the lowest position. Elevating both ends simultaneously is not recommended. Noncompliance may result in death or serious injury.**

**WARNING**

**Before placing the mattress in Trendelenburg or Reverse Trendelenburg, ensure that patient extremities are not caught between the mattress tray and the hood walls. Noncompliance may result in death or serious injury.**

**WARNING**

**Use caution when opening doors fitted with tubing grommets so that patient lines or cables do not become accidentally disconnected. Noncompliance may result in death or serious injury.**

**CAUTION**

Do not connect the Isolette 8000 to a surge suppressor. Noncompliance may result in injury or equipment damage.

# Application

## Intended Use

The Isolette 8000 Infant Incubator should be used only by appropriately trained personnel and under the direction of qualified medical personnel.

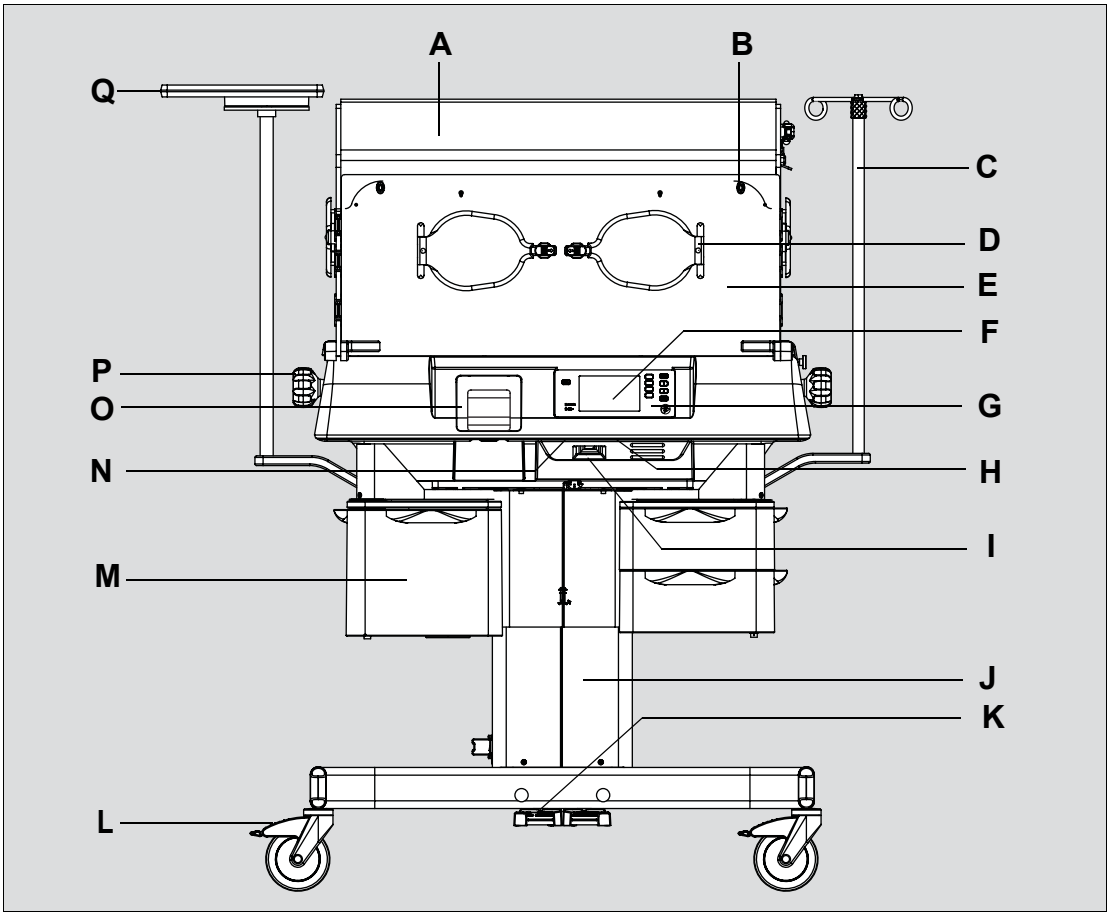
The Isolette 8000 Infant Incubator provides a controlled environment for both premature and full-term babies. It controls temperature, oxygen (optional), and humidity (optional). It can be used in any department of the hospital that provides neonatal and infant care, including all levels of the Neonatal Intensive Care Unit (NICU), Special Baby Care Unit, Step Down Nursery, Newborn Nursery, and Pediatrics.

## Indications/Contraindications

The device is not intended for home use.

# Overview

## Front View




**A** Hood

**B** Pawl latch

**C** I.V. pole (optional)

**D** Oval access door

**E** Access panel

**F** Screen

**G** Front panel of controller

**H** Serial port

**I** Incubator ON/OFF switch

**J** Variable Height Adjustable (VHA) stand

**K** VHA controls

**L** Caster wheel (with brake)

**M** Storage drawers (optional)

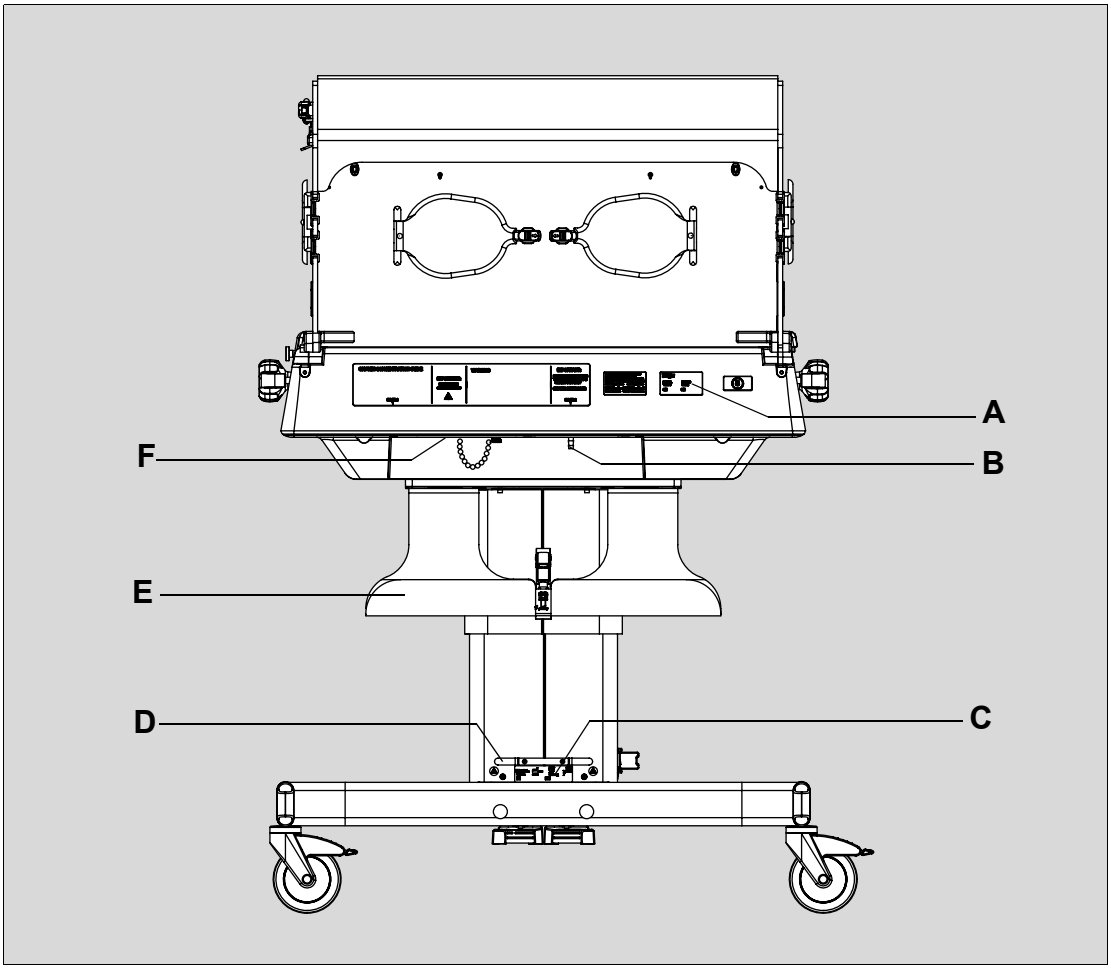
**N** Incubator AC power cable receptacle

**O** Humidity reservoir (optional)

**P** Trendelenburg mattress tilt control

**Q** Monitor shelf (optional)

## Rear View




**A** Incubator type plate

**B** Oxygen inlet

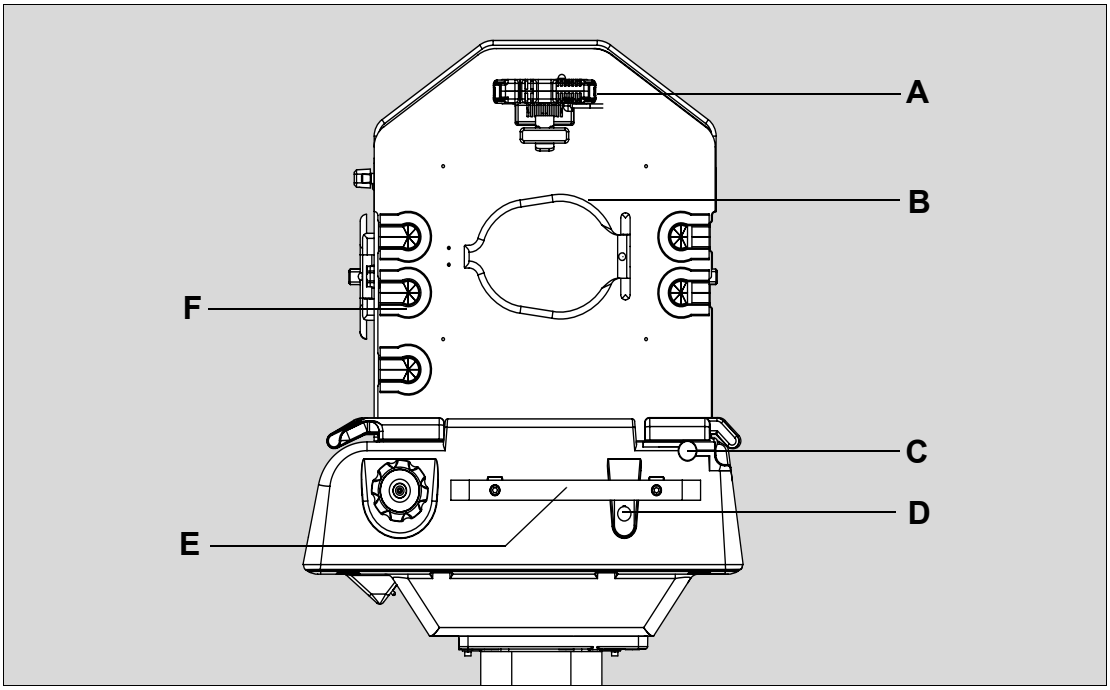
**C** VHA stand type plate

**D** Cable wrap

**E** Cylinder mount (optional)

**F** Air intake microfilter

## Right Side View




**A** Sensor module

**B** Oval access door (or optional iris port)

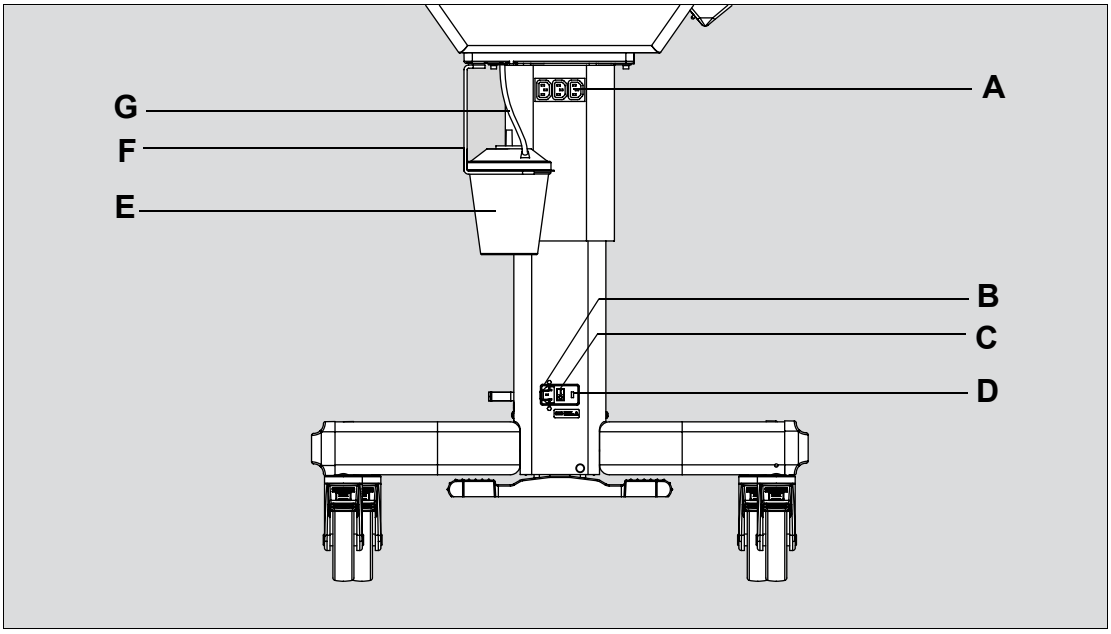
**C** Hood release knob

**D** Controller/sensor module interface connector

**E** Accessory rail/handle

**F** Tubing grommets

## Left Side View




**A** Convenience outlets

**B** AC power cable receptacle

**C** Main ON/OFF switch

**D** Fuse holder

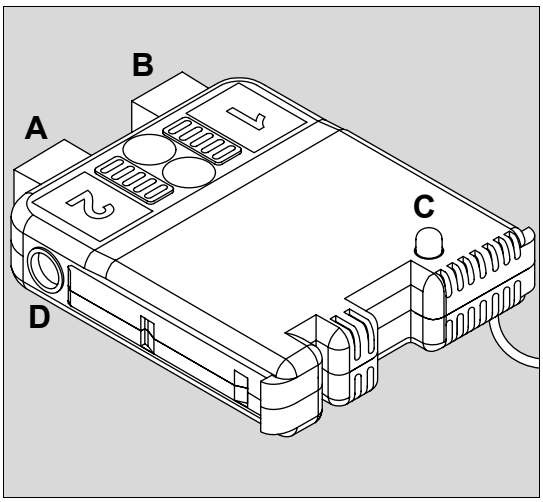
**E** Condensation management collection bottle (optional)

**F** Condensation management bracket (optional)

**G** Condensation management hose (optional)

## Sensor Module

**Top View**



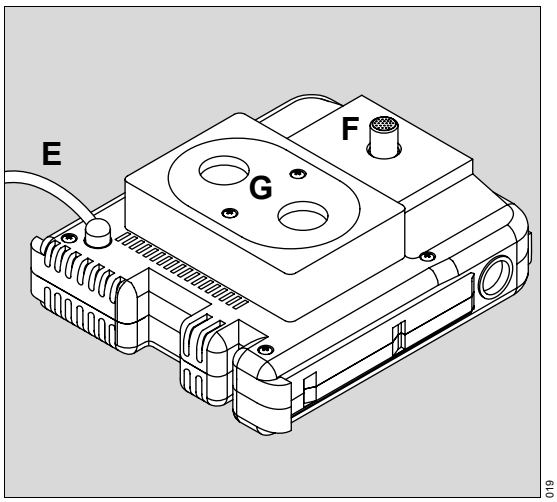

**A** Skin 2 probe connector

**B** Skin 1 probe connector

**C** Alarm indicator

**D** Scale connector

**Bottom View**




**E** Controller interface cable

**F** Air, temperature, and humidity sensor housing

**G** Oxygen sensor housing

## Isolette 8000 Overview

The Isolette 8000 Infant 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 access doors with a quiet latch on the front and rear hood panels, either oval access doors or iris ports on the side hood panels, rails for attaching accessories, and a Trendelenburg mattress tilt mechanism (0° to 12°). The incubator hood and shell assembly is mounted on a variable height adjustable (VHA) stand. Information is displayed on a liquid crystal display (LCD) display.

Accessories include a weighing system, a cylinder mount for D or E size gas cylinders, storage drawers, monitor shelf, and I.V. pole.

## Oxygen System

The Isolette 8000 is equipped with either a servo oxygen control system or a manual oxygen control system.

### Servo Oxygen Control System (Option)

When installed, the servo oxygen control system maintains oxygen concentration within the incubator hood via a valve and an oxygen sensor module. The sensor module houses two independent oxygen fuel cells. Oxygen concentration is displayed on the screen, and oxygen-related alarm conditions are indicated to the operator via audible and visual alarms.

When the sensor module is outside of the hood during Oxygen Control mode, audible and visual alarms are enabled and the flow of oxygen is interrupted.

### Manual Oxygen Control System (Option)

With the manual oxygen control system, oxygen flow is controlled by an external flow meter. Oxygen concentration is not displayed on the Isolette 8000 display screen and no oxygen alarms are generated. To achieve desired oxygen concentration, the use of a calibrated oxygen analyzer is recommended.

## Humidity System (Option)

When installed, the built-in humidifier provides humidification of the incubator from 30% to 95% relative humidity (RH) in 1% increments. If the humidity has not risen to a predetermined threshold within a designated time, an audible and visual ***Low Humidity*** alarm occurs. The humidifier is a three-part system consisting of a humidity reservoir assembly, an evaporator, and a heater/impeller cover with duct cover.

### Humidity Reservoir Assembly

The humidity reservoir assembly consists of a water reservoir in the front, an evaporator chamber in the back, and a cover with a water fill opening. 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 humidity reservoir is empty or not fully inserted in the incubator shell, an audible and visual ***Check Water Supply*** alarm occurs.

### Evaporator

The water enters the evaporator chamber located at the back of the reservoir. The evaporator 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 evaporator 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 evaporator.

### Heater/Impeller Cover with Duct Cover

The humidity reservoir connects to a duct in the heater/impeller cover that directs the flow of humidified air into the heater well.

## Condensation Management System (Option)

Condensation can occur on the inside of the hood under certain environmental conditions. On Isolette 8000 units 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.

## Weighing System (Accessory)

When installed, the weighing system is located on a tray under the mattress. The scale contains two 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.

### Non-OIML/NAWI Scales

The Weight soft key allows for repeated re-weighing of the infant after the weighing routine has been initiated.

### OIML/NAWI Scales

Since the weighing routine is continuous, no re-weigh function is required to update the weight measurements.

## Functional Description

### Air Circulation System

The Isolette 8000 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 intake filter by the motor-driven impeller located in the shell.

The impeller internally recirculates air at a much greater flow than that of the fresh gas inflow. The total inflow of fresh and recirculated air is directed around the heater. The air enters the infant compartment up through the slots at the front and rear of the main deck. It forms two streams, one passing between the inner and outer walls of the front panel, and the other between the inner and outer walls of the rear 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 infant compartment, the air is then recirculated down through a slot in the right end of the main deck, 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.

### Temperature Regulation

Temperature is regulated by using either incubator air or infant skin temperature. The front panel keys enable the user to select the desired Air or Skin mode.

In either mode of operation, the heater output is proportional to the amount of heat required to maintain the desired temperature.

#### Air Mode

In the Air mode, the air temperature can be maintained from 20.0°C (68.0°F) to 37.0°C (98.6°F) as selected by the ***Up Arrow*** and ***Down Arrow*** keys on the front panel. In Temperature Override mode, the temperature can be maintained from 37.0°C (98.6°F) to 39.0°C (102.2°F).

The incubator air temperature is monitored by a probe located in the sensor module and compared with the air set temperature parameter. The information from this 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 sensor within the air temperature probe 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: 1) the air temperature and 2) the ability of the infant to establish and maintain his/her own temperature. A small infant, or one with underdeveloped homeostatic control, may not be able to maintain a stable temperature at the desired level.

**Skin Mode**

In the Skin mode, the ***Up Arrow*** and ***Down Arrow*** keys on the front panel of the controller are used to select the infant temperature from 34.0°C (93.2°F) to 37.0°C (98.6°F). In Temperature Override mode, the temperature can be selected from 37.0°C (98.6°F) to 38.0°C (100.4°F).

A temperature sensing 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.

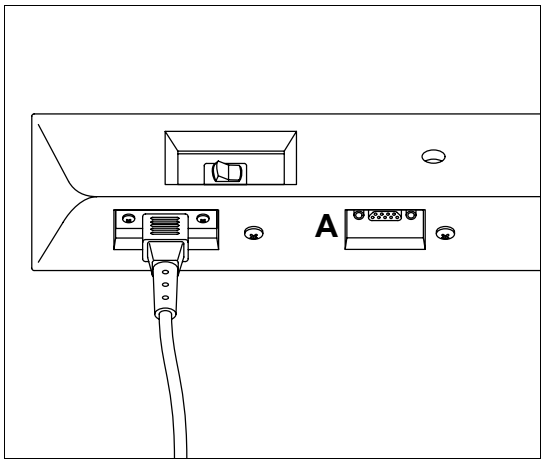
The air temperature is still shown in Skin mode, but for information purposes only. If the Air mode is selected while the skin probe remains connected, the skin temperature parameter continues to display the actual skin temperature. However, it does not control the incubator temperature.

The sensor module is equipped to accept two skin probes. To control the incubator temperature in the skin mode, insert a skin probe into the skin probe 1 connector (see "Sensor Module" on page 24). When a second skin probe is connected to the sensor module while operating in the skin mode, an alarm sounds and the message ***Remove Skin 2 Probe*** is displayed. To connect a second skin probe, select the Air mode first. The controller then displays the respective Skin 1 and Skin 2 temperatures monitored by the skin probes.

If Probe 1 is disconnected from its receptacle while in the Skin mode, the skin temperature parameter goes blank on the display, an alarm sounds, and the heater turns off.

## External Devices

The Isolette 8000 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 bedside patient monitor, such as the Dräger Infinity Delta, Delta XL, and Kappa monitors. It is located underneath the incubator shell on the front of the device.



**WARNING**

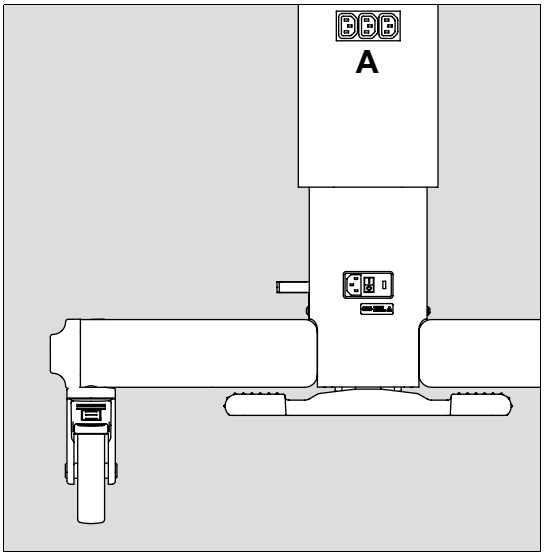
**Only connect equipment to the serial port that complies with the relevant IEC standard; and use data cables with plastic body connectors. Noncompliance may result in death or serious injury.**

**WARNING**

**Devices connecting to the serial port must be compliant with EN 60601-1-2, the EMC requirement for Medical Devices. Noncompliance may result in death or serious injury.**

## Convenience Outlets

Three electrical convenience outlets (**A**) are located on the left side of the VHA stand.




**CAUTION**

The total power of all equipment connected to the convenience outlets on the stand must be within the electrical requirements shown on the stand. Noncompliance may result in injury or equipment damage.

**WARNING**

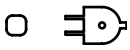
**Connecting some electrical equipment to the convenience outlets could negatively alter the medical device resulting in a reduced level of safety, including device malfunction. Noncompliance may result in death or serious injury.**

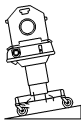
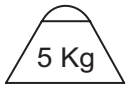
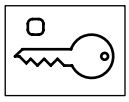
## Abbreviations

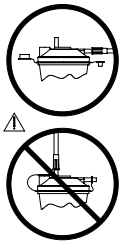
| Abbreviation | Meaning |
|---|---|
| AC | alternating current |
| DIN | Deutsches Institut für Normung |
| EMC | electromagnetic compatibility |
| ESD | electrostatic discharge |
| GMDN | Global Medical Device Nomenclature |
| IEC | International Electrotechnical Commission |
| I.V. | intravenous |
| LCD | liquid crystal display |
| lpm, 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 |
| VHA | variable height adjustable |

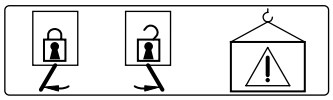
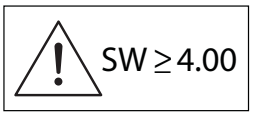
## Symbols

The following symbols appear on labels on the Isolette 8000 incubator, on the display screen, and in these instructions for use.

| Symbol | Meaning |
|---|---|
|  | Warning |
|  | Caution |
|  | Refer to instruction manual or booklet |
|  | Caution: Risk of electric shock. |
|  | Degree of protection against electric shock: Type BF |
|  | AC power |
|  | Protective earth (ground) |
|  | Caution: hot surface |
|  | Weight limit: |
|  | Power failure |

| Symbol | Meaning |
|---|---|
|  | Lock casters when parked on an incline |
|  | Electrostatic discharge (ESD) sensitive part |
|  | Electromagnetic interference |
|  | Communication port |
|  | Access panel open indicator (displayed on screen) |
|  | Prompt to lift the infant from the mattress (displayed on screen during the zeroing routine) |
|  | Prompt to place a 5 kg weight on the mattress (displayed on screen during the calibration routine) |
|  | Indicates the active status of a mode of operation (displayed on the screen in the respective windows) |
|  | Displays the progress of the weight sampling for scale (displayed on the screen, non-OIML scale only) |
|  | Level indicator mounted on the scale (OIML scale only) |
|  | Keypad lock |

| Symbol | Meaning |
|---|---|
|  | Do not reuse |
|  | Maximum water level |
|  | Half-full water level |
|  | Minimum water level |
|  | Batch code |
|  | Do not use tap water |
|  | Rotation control |
|  | Do not overfill |
|  | Do not spill |
|  | Correct/incorrect connection of condensation management system hose on the collection bottle |
|  | Phthalate present |

| Symbol | Meaning |
|---|---|
|  | Weight limit warning (DIN compatible rails) |
|  | Latch lock/unlock and rail loading warning (Fairfield compatible rails) |
|  | Warning: Use only with software version 4.00 or higher. |

## Technical Definitions

| Term | Definition |
|---|---|
| Average incubator temperature | The average of the maximum and minimum incubator temperatures achieved during temperature equilibrium. |
| Control accuracy—Temperature indicator versus control temperature | The amount the air temperature indicator in Air mode at incubator temperature equilibrium differs from the control temperature. |
| Control correlation—Incubator temperature versus control temperature | The amount the average incubator temperature in Air mode at incubator temperature equilibrium differs from the control temperature. |
| Control temperature | The temperature set point selected by the user. |
| Incubator temperature | Air temperature at a point 10 cm (4 inches) above and centered over the mattress surface. |
| Incubator temperature equilibrium | The condition reached when the average temperature of the incubator does not vary more than 1 °C over a period of one hour. |
| Measurement points | Measurements are taken at five points in a plane parallel to and 10 cm (4 inches) above the mattress surface. One point is 10 cm (4 inches) above the center of the mattress, the remaining four points are the centers of the four areas formed by lines that divide both the width and length in two parts. |
| Temperature correlation—Temperature indicator versus incubator temperature | The amount the air temperature indicator at incubator temperature equilibrium differs from the incubator 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 control temperature. |
| Temperature rise time | The time required for the incubator temperature to rise 11 °C (20 °F), when the air control temperature is at least 12 °C (22 °F) above the ambient temperature. |
| Temperature uniformity | The amount by which the average temperatures at the center of the mattress quadrants, 10 cm (4 inches) above the mattress, surface differs from the average incubator temperature at incubator temperature equilibrium. |
| Temperature variability | The variability of the incubator temperature that will be observed over a one hour period after incubator temperature equilibrium has been reached. |

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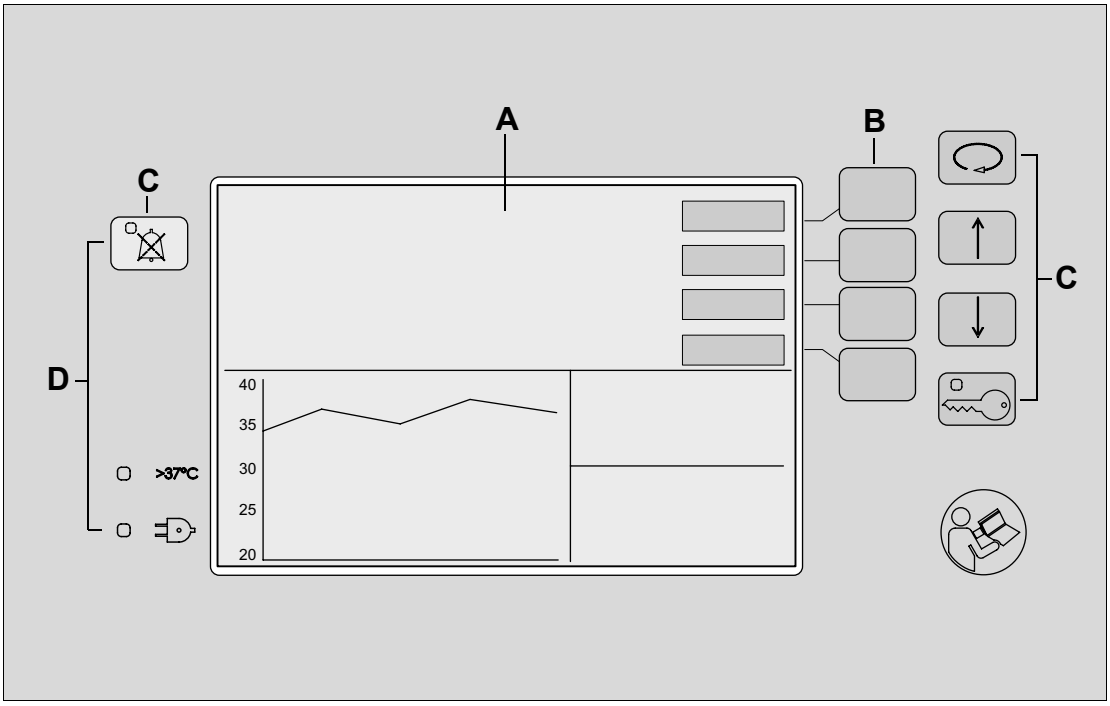
# Operating Concept

## Front Panel of Controller




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

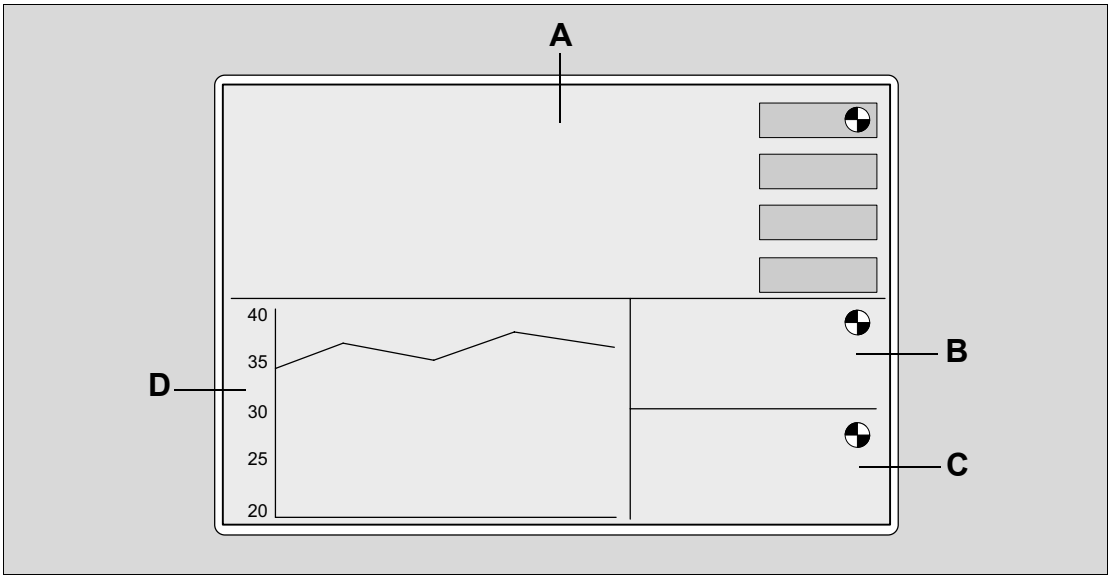
**A** A screen displaying all patient and system information in numeric and graphic form

**B** Keys with variable functions (referred to as “soft keys” in this manual)

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

**D** LED indicators

## Screen




**NOTE**
The actual screen display may differ in appearance or configuration.

The basic Isolette 8000 screen can be toggled between Display 1 and Display 2. The two displays differ in the selection of soft keys available in the Temperature window. Both displays are divided into the following four windows:

**A** **Temperature Window** - The Temperature window displays the actual air and/or skin temperature and the set point temperature of the controlling parameter.

Pressing the available soft key enables the user to access the corresponding displays or perform a designated function.

**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.

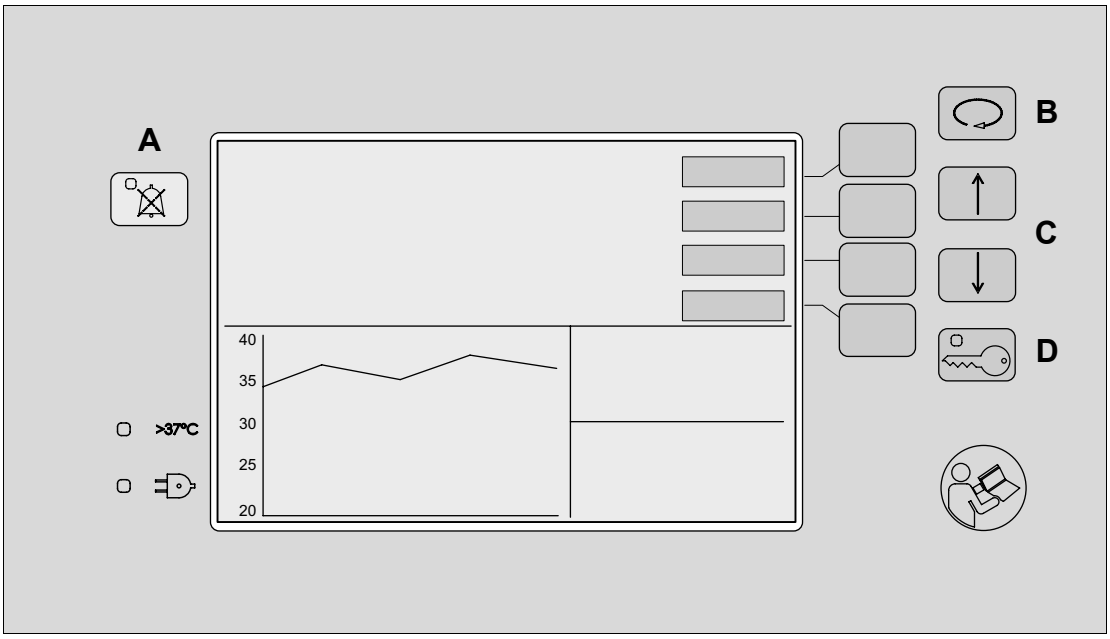
For systems configured without servo oxygen, the message ***Not Installed*** is displayed for a few seconds, and then the Oxygen window remains blank.

**D** **Trend/Alarm Window** - Four standard parameters are presented as trend graphs in the Trend/Alarm window (see "Trend Display" on page 96): air temperature, skin temperature 1, skin temperature 2, and heater power.

Additional trend displays are also available when the unit is equipped with any of the following: Servo Oxygen Control System, Humidity 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 seven days.

## Hard Keys




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

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

If no alarms are present, the ***Alarm Silence/Reset*** key enables a procedural silence. To indicate that a silence period is in progress, the ***Alarm Silence/Reset*** LED illuminates.

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

**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 required to operate and control the system.

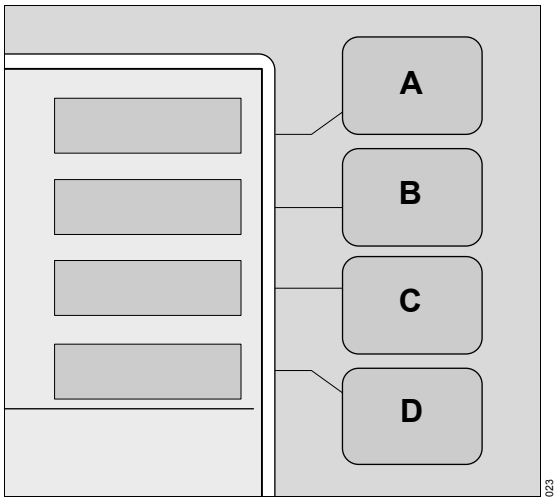
When the keypad is not locked (in Display 1 and Display 2), use the ***Up Arrow*** and ***Down Arrow*** keys to adjust the screen brightness.

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

## Soft Keys

The functions of the four soft keys located next to the screen are indicated by the labels shown on the screen beside each key. The soft keys enable the user to select parameter and menu options at the various displays.

**NOTE**
Use the ***Display Selection*** key to switch between Display 1 and Display 2.




### Display 1 Soft Keys

The following soft keys are available at Display 1:

**A** ***Air*** - selects the Air mode

**B** ***Skin*** - selects the Skin mode

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

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

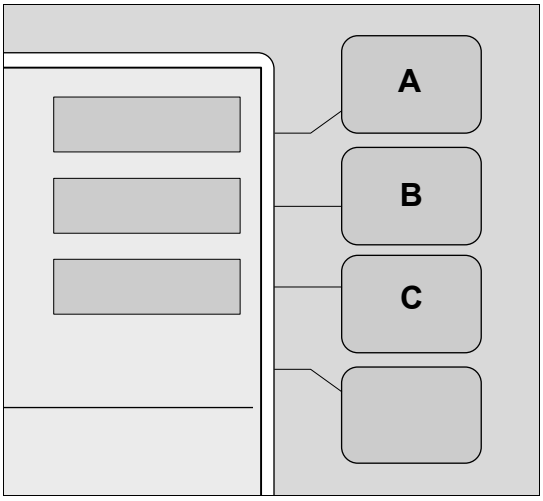
## Display 2 Soft Keys

The following soft keys are available at Display 2:

**A** ***Trend*** - selects the Trend display

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

**C** ***°C/°F*** - enables the user to select the temperature display units in Celsius or Fahrenheit degrees for the air temperature, skin temperature, and set point temperature




## Additional Soft Keys

Additional soft keys become available when certain keys in Display 1 or Display 2 are selected. For complete information, see "Operation" on page 69.

– The ***Home*** soft key enables the user to return to the previous display.

– The ***On*** soft key is available at the Oxygen and Humidity displays. When pressed, this soft key activates the Oxygen or Humidity systems.

– The ***Off*** soft key is available at the Oxygen and Humidity displays. When pressed, this soft key deactivates the Oxygen or Humidity systems.

– The ***Cal*** soft key is available at the Oxygen display and the Weight display (non-OIML scale only). When pressed, this soft key initiates the calibration function for the oxygen sensor or scale.

– The ***Hours*** soft key is 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.

– The ***Clear*** soft key is available at the Trend display. When pressed, it clears all of the trend data stored in the Trend/Alarm window.

– The ***Display*** soft key is available at the Trend display. When pressed, it selects one of following trends to display in the Trend/Alarm window: Air, Skin 1, Skin 2, Oxygen %, Humidity %, Heater Power %, or Weight Gain.

– The ***Store*** soft key is available at the Weight display. When pressed, it stores the infant weight for trending in the Trend/Alarm window.

– ***>37°C*** soft key activates the Temperature Override mode (greater than 37.0°C (98.6°F)).

– ***->0/T<-*** (Zero/Tare) soft key is available at the Weight display. When pressed, it provides zero setting and tare balancing.

## LED Indicators

Several LED indicators are located on the front panel of the Isolette 8000 controller.

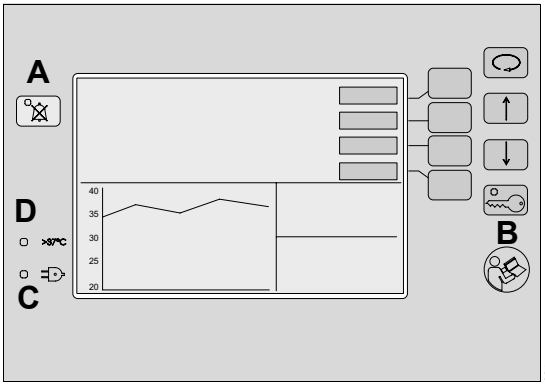
**A** The yellow LED on the ***Alarm Silence/Reset*** key illuminates to indicate that an alarm or an alarm silence period is in progress.

**B** The LED on the ***Keypad Lock*** key illuminates to indicate that the keys are locked (except for the ***Alarm Silence/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.

In addition, there is a yellow LED located on the sensor module that indicates certain oxygen or humidity alarms (see "Sensor Module" on page 24).



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# Assembly

## Unpackaging

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

Open the shipping cartons and remove all packing material. Carefully lift and remove the hood/shell assembly and the stand assembly from the packaging.

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

## Proper Assembly

**WARNING**
**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 unit may be compromised or degraded. Noncompliance may result in death or serious injury.**

After the device is assembled and before it is placed into service, perform the operational checkout procedure on page 57.

## Attaching the Hood/Shell Assembly to the VHA Stand

**WARNING**
**Attach the incubator to the stand using the bolts provided. Failure to do so could result in the incubator separating from the stand if sufficiently tilted, particularly with the hood open. Noncompliance may result in death or serious injury.**

**NOTE**
The stand and hood/shell assemblies are keyed so that the incubator can only be mounted in one orientation.

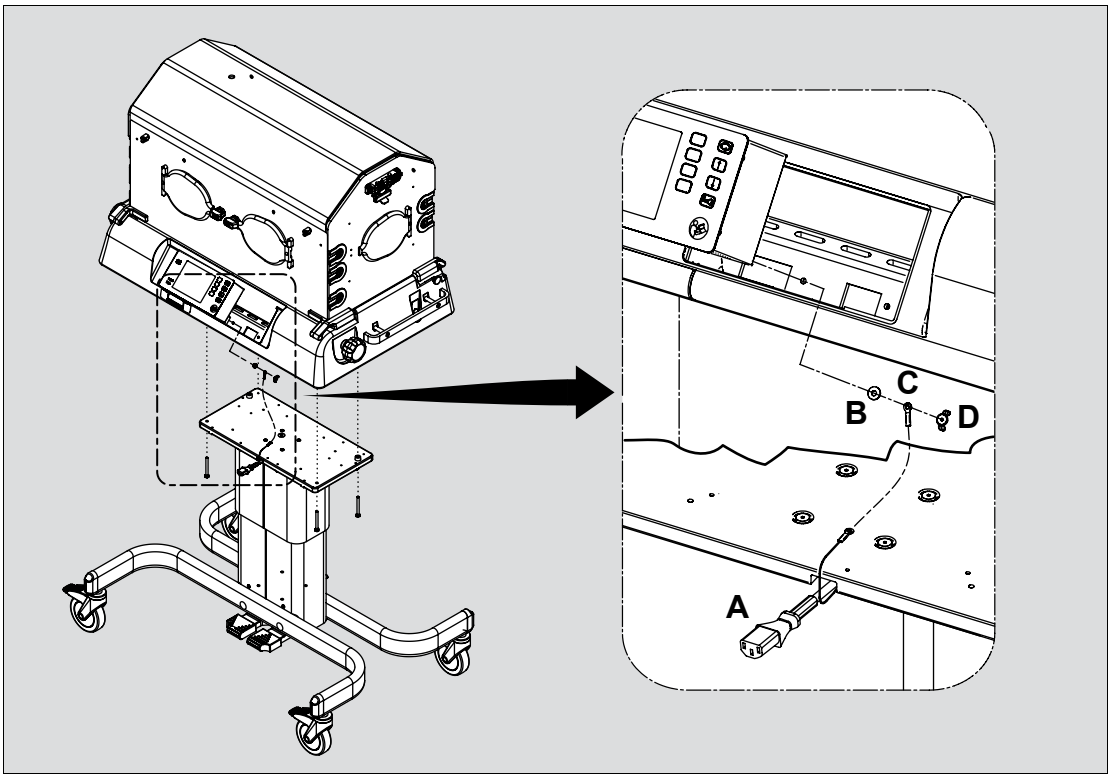
**1** Mount the hood/shell assembly on the VHA stand with the provided bolts.

**2** Plug the stand power cable (**A**) into the incubator power cable receptacle.

**3** Remove the wing nut from the stud located next to the power cable receptacle on the underside of the incubator.

**4** Place the washer (**B**) and the ring lug (**C**) on the stud. The ring lug is on the end of the ground wire protruding from the stand.

**5** Install and tighten the wing nut (**D**).



## Attaching Accessories

To install the I.V. pole, monitor shelf, and rail accessories, refer to their Installation Instructions.

**WARNING**

**Strictly adhere to the weight and placement requirements for accessories. Noncompliance may result in death or serious injury.**

**WARNING**

**Incubator stability can be reduced by the number of accessories attached, the height and loading of accessories, and the position of the accessories on the rail. It is therefore recommended that rail accessories are kept to a minimum, are adjusted to their lowest usable height, and are mounted as close to the center of the incubator as possible. Noncompliance may result in death or serious injury.**

**WARNING**

**This product has been validated with the accessories and options listed in this manual and found to comply with all relevant safety and performance requirements applicable to the device. It is therefore 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. Noncompliance may result in death or serious injury.**

**WARNING**

**The monitor shelf and I.V. pole assembly are labeled for acceptable weights. Do not exceed these weight limitations. Noncompliance may result in death or serious injury.**

**WARNING**

**Only one monitor shelf should be used per incubator. When using the monitor shelf, always place the object in the center of the shelf, ensure that the object fits within the border of the shelf, and avoid stacking objects on the shelf. Noncompliance may result in death or serious injury.**

**WARNING**

**Total load for the monitor shelf must not exceed 11.4 kg (25 lb). Total load for the I.V. pole must not exceed 5 kg (11 lb). Noncompliance may result in death or serious injury.**

**WARNING**

**To avoid injury or equipment damage, use only Dräger Medical listed latches 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, as well as periodically check both the operation and retention of the latch to securely hold 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 not to exceed 13.6 kg (30 lb); 6.8 kg (15 lb) per side. Noncompliance may result in death or serious injury.**

**NOTE**

The I.V. pole and monitor shelf can only be mounted on the side of the hood/shell assembly.

**NOTE**

For weight limitations for all accessories for the Isolette 8000, see "Technical Data" on page 137.

# Installing the Weighing System (Accessory)

## Non-OIML/NAWI Scale Assembly

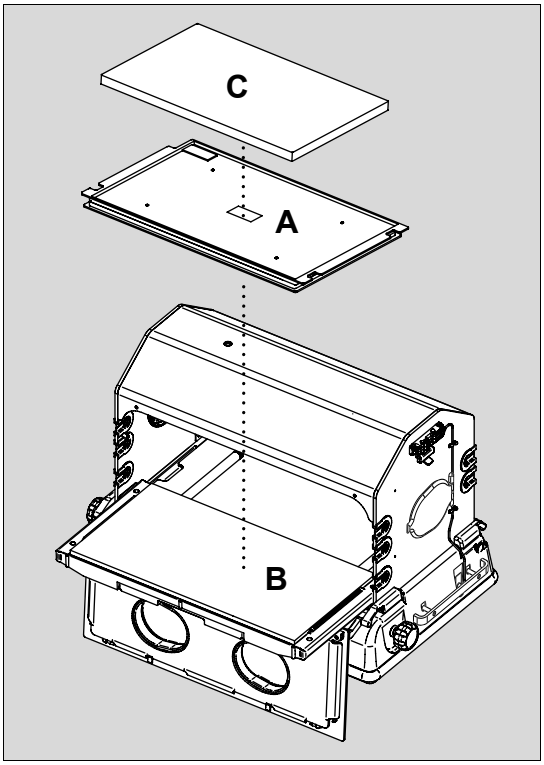
**1** Rotate the pawl latches, and open the front access panel of the incubator.

**2** Remove the mattress from the incubator.

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

**4** Place the scale (**A**) in the incubator on the mattress tray (**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 24).

**7** Ensure that all sensor leads are properly routed.

- Make sure that there is sufficient cable slack between the edge of the hood and the scale to allow the mattress tray to be fully withdrawn from the hood and to allow the sensor module to be withdrawn from the hood for $O_2$ calibration.
- To allow for correct weight measurements, make sure 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 on the inside of the incubator wall.
- Loop the cable at the lower clip.

**8** To ensure proper operation, perform the scale operational checkout (see "Weighing System Operational Checkout (Accessory)" on page 67).

**WARNING**

**Use cable management clips to avoid infant entanglement and possible injury. Noncompliance may result in death or serious injury.**

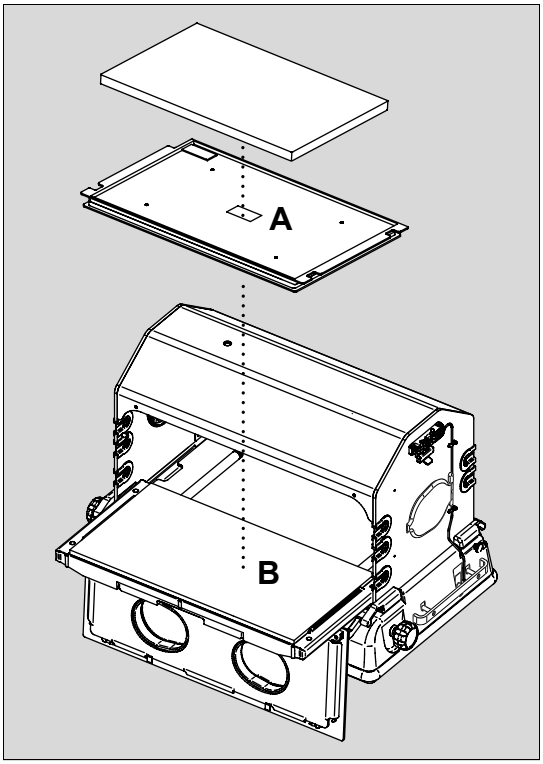
## OIML/NAWI Scale Assembly

**1** Rotate the pawl latches, 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 located on the right-hand side of the incubator towards the sensor module assembly.

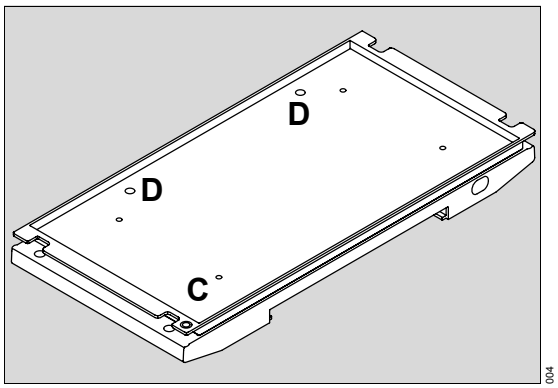
**4** Place the scale (**A**) in the incubator on the mattress tray (**B**).




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

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

**7** If necessary, remove the two level-adjuster plugs, and then fine-tune the two 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 mattress tilt mechanism 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 24).

**WARNING**

**Use cable management clips to avoid infant entanglement and possible injury. Noncompliance may result in death or serious injury.**

**10** Ensure that all sensor leads are properly routed.

- Make sure that there is sufficient cable slack between the edge of the hood and the scale to allow the mattress tray to be fully withdrawn from the hood and to allow the sensor module to be withdrawn from the hood for O2 calibration.
- To allow for correct weight measurements, make sure 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 on the inside of the incubator wall.
- Loop the cable at the lower clip.

**11** To ensure proper operation, perform the scale operational checkout (see "Weighing System Operational Checkout (Accessory)" on page 67).

## Installing the Humidity System (Option)

**WARNING**

**The humidity system with the heater/impeller cover with duct cover must be used with software version 4.00 or higher. Noncompliance with this warning may result in death or serious injury.**

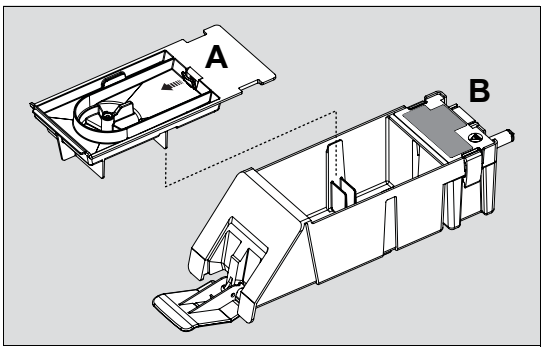
**NOTE**

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

On factory installed systems, install the humidity reservoir assembly:

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

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

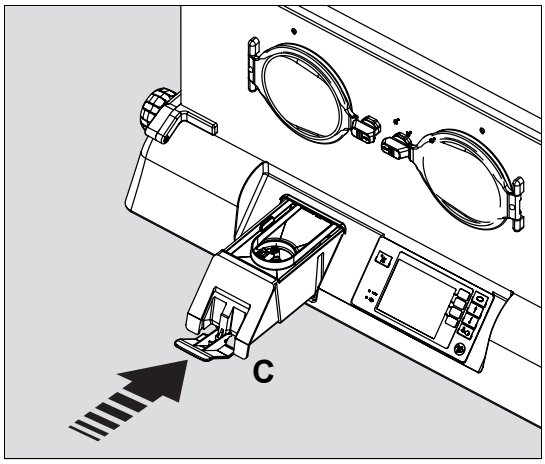



**3** Reinstall the lid on the reservoir and push back the latch on top of the lid to secure it.

**CAUTION**

Do not use the reservoir without the lid installed and the cover on the fill opening closed. Noncompliance may result in injury or equipment damage.

**4** Insert the humidity 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.



## Installing the Condensation System Collection Bottle

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

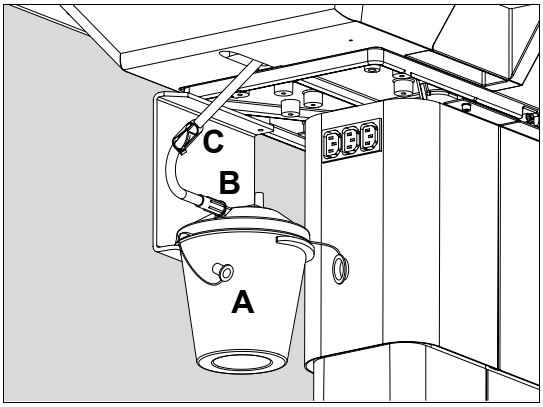
**2** Remove the caps from the ports on the collection bottle.

**NOTE**

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 protruding from the underside of the incubator to the patient port (**B**) on the side of the collection bottle.

**4** Ensure that the hose is unclamped (**C**).




**CAUTION**

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. Noncompliance may result in injury or equipment damage.

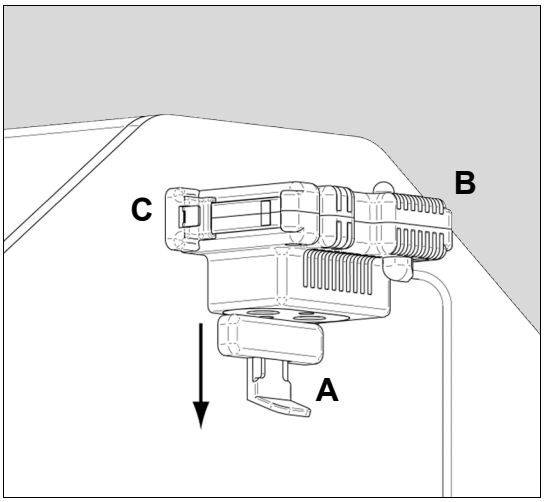
## Installing the Servo Oxygen Control System (Option)

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

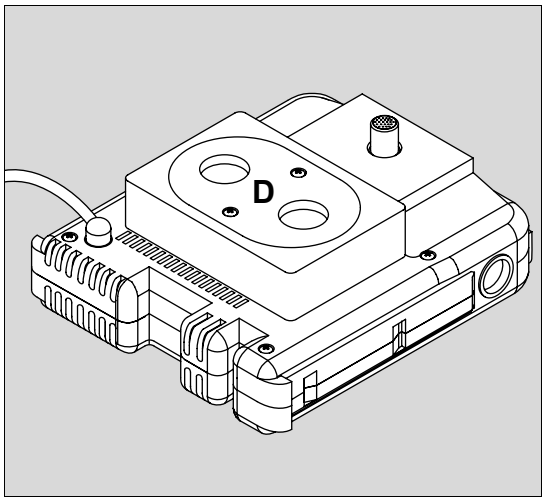
### Installing the Oxygen Sensor Cells in the Sensor Module

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

**2** Pull out on the clip (**C**) located on the left side of the module, and remove the module from the hood.

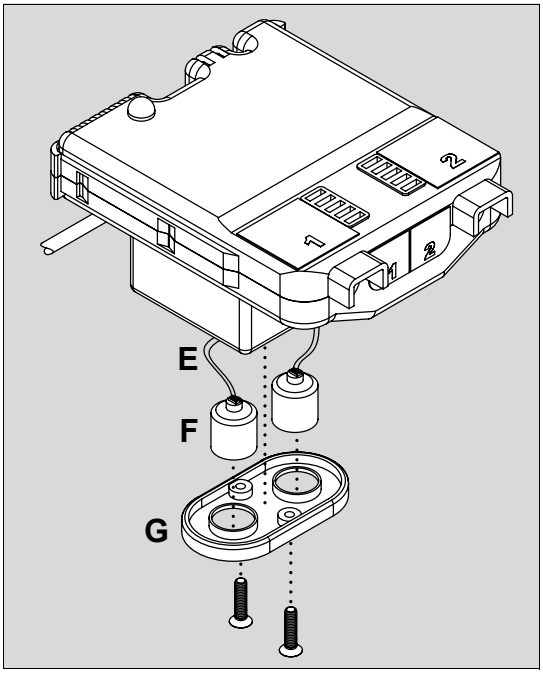



**3** Remove the oxygen sensor cover (**D**). Retain the hardware.



**4** Withdraw the sensor cell connectors (**E**) from inside the sensor module housing.

**5** Screw the sensor cells (**F**) into the oxygen cell mounting plate (**G**) provided with the cells.




**6** Connect the sensor cells to the sensor module.

**NOTE**
Either cable connection can plug into either sensor.

**7** Install the oxygen cell mounting plate on the sensor module using existing hardware.

**8** Replace the sensor module in the hood.

**9** Activate the oxygen system (see "Setting the Servo Control Oxygen (Option)" on page 78).

**10** Calibrate the oxygen system (see "Oxygen Sensor Calibration (Option)" on page 86).

## Installing the 100% Oxygen Calibration Fixture (Optional)

**NOTE**
Do not install when the incubator is configured for 21% oxygen calibration (see "System Configuration Menu" on page 98).

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 located on the left side of the module, and remove the module from the hood.

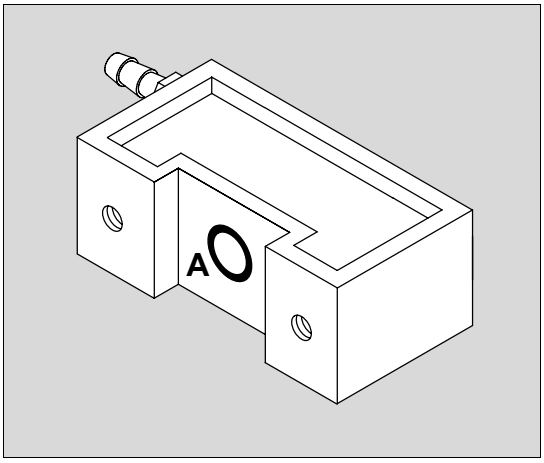
3 Rotate the pawl latches, and open the front access panel of the incubator.

4 Remove and retain the two 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 provided 100% calibration fixture.

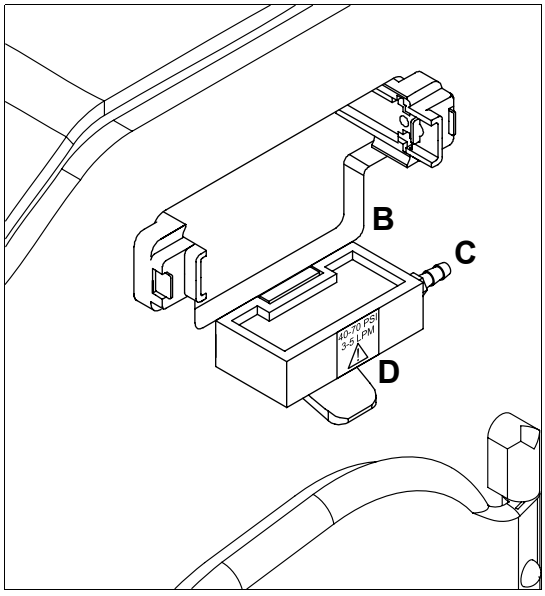
**NOTE**
The 100% calibration fixture is packaged with a small O-ring, which is coated with a lubricant. The O-ring could possibly become loose during shipping.




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 two screws to secure the sensor module slide lock and the 100% calibration fixture.

**NOTE**
Make sure that the brass connector (**C**) is facing the rear of the incubator and the wording on the label (**D**) is properly displayed.



**9** Close the front access panel, and rotate the pawl latches until they are fully engaged.

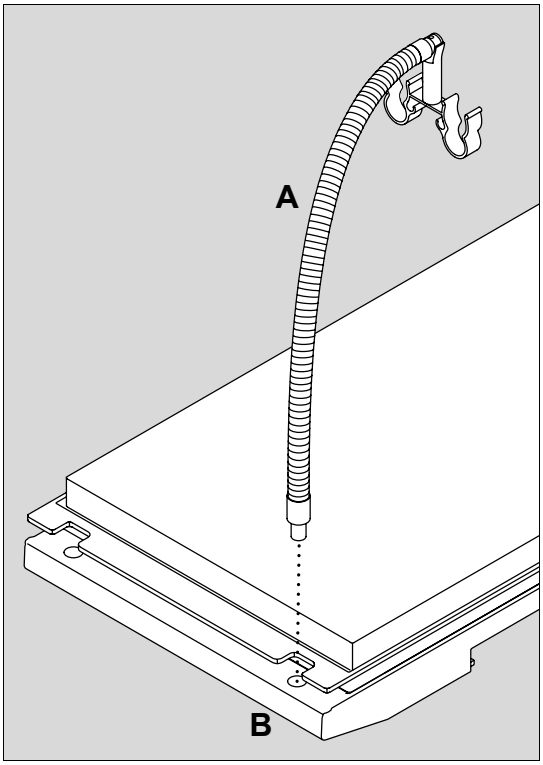
**10** Install the sensor module assembly in the hood assembly.

**NOTE**
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 98).

## Installing the Ventilator Tubing Support (Accessory)

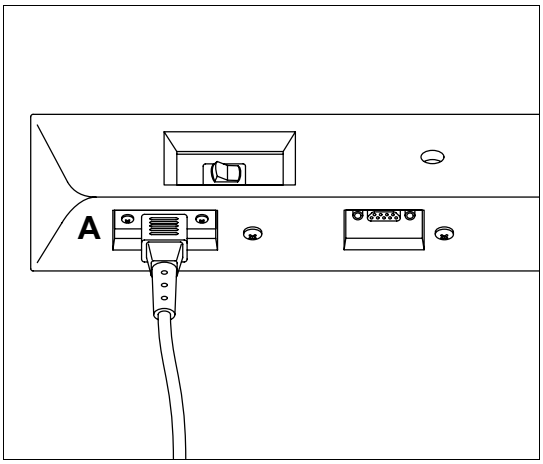
Insert the ventilator tubing support (**A**) into one of the four support holes (**B**) located on the corners of the mattress tray. Ensure that the slot in the bottom of the support tube aligns with the cross pin in the support hole. When installed, the support can be adjusted vertically and horizontally for convenient positioning of ventilator tubing.



# Getting Started

## System Start-Up

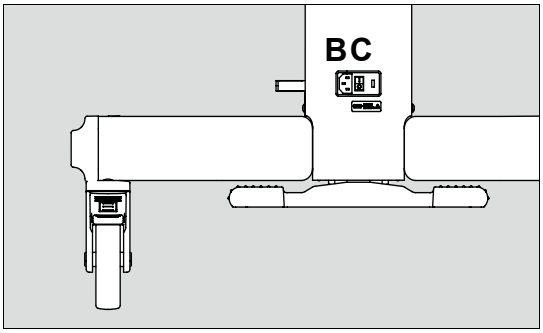
**1** Verify that the power cable from the stand is firmly attached to the receptacle (**A**) under the incubator shell assembly.



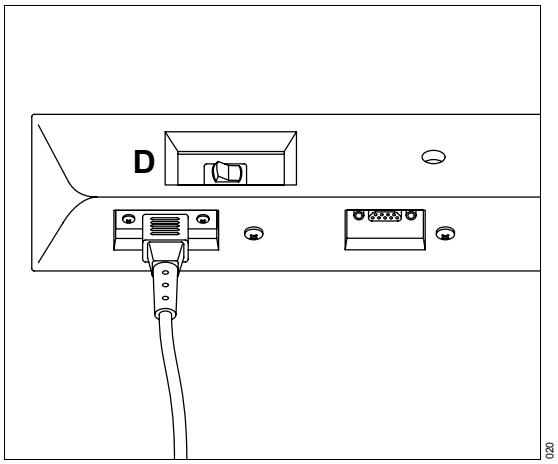

**2** Plug the stand power cable into an appropriate AC power source.

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

**4** Turn on the ***Main Power*** switch (**C**) located on the stand.




**5** Locate the ***On/Off*** switch (**D**) under the incubator shell assembly, and then turn on the incubator.




During the self-test, all indicator lamps illuminate, and the acoustic alarm pulses. After the system start-up tests, the incubator boots up in the Air mode at Display 1.

**NOTE**

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

**6** Perform the operational checkout procedure provided on page 57.

**7** Following the successful completion of the operational checkout procedure, select the desired system options, parameters, and operating modes using the control panel of the controller (see "System Configuration Menu" on page 98).

## Operational Checkout Procedure

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

**WARNING**

**Do not use the incubator if it fails to function as described in the operational checkout procedure. Refer service to qualified personnel. Noncompliance may result in death or serious injury.**

**NOTE**

For units equipped with accessories, remove any accessories that interfere with the checkout procedure, and replace when completed.

### Controller Operational Checkout

**WARNING**

**To ensure grounding reliability, plug the AC power cable only into a properly grounded (properly earthed) 3-wire hospital-grade or hospital-use outlet. Do not use extension cables. If any doubt exists as to the grounding connection, do not operate the equipment. Noncompliance may result in death or serious injury.**

**CAUTION**

Make sure that the building power source is compatible with the electrical specifications shown on the VHA stand or on the incubator. Noncompliance may result in injury or equipment damage.

**1** Perform the initial power up procedures (see "System Start-Up" on page 56).

**2** Check the ***Power Failure*** alarm:

- Unplug the power cable from the controller on the front of the incubator.
- Verify that the ***Power Failure*** alarm sounds, and the ***Power Failure*** indicator on the front panel of the controller illuminates.
- Then reconnect the power cable to the controller, and verify that after the self-test, Display 1 is shown on the screen.

**3** Check the ***Low Air Temperature*** alarm.

- Rotate the pawl latches and open the front or rear access panel of the incubator.
- Verify that within approximately 5 minutes the ***Low Air Temperature*** alarm message is displayed in the Trend/Alarm window and the audible alarm sounds.

**NOTE**

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

- Close the front or rear access panel, and rotate the pawl latches until they are fully engaged.

**4** Check the Skin Mode of operation.

- Insert a skin probe into the skin probe 1 connector of the sensor module.
- Place the skin probe 10 cm (4 in) above the center of the mattress.
- Set the skin set temperature to 35°C (95°F).
- When the temperature stabilizes, rotate the pawl latches, and open the front or rear access panel.
- Verify that within approximately 5 minutes the ***Low Skin Temperature*** alarm message is displayed in the Trend/Alarm window and the audible alarm sounds.

**NOTE**

The alarm will 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 set point. At high ambient temperatures, fanning the air within the hood can be performed to induce the alarm.

- Close the front or rear access panel, and rotate both latches until fully engaged.
- Press the ***Alarm Silence/Reset*** key to silence the alarm.

**5** Check the ***Remove Skin 2 Probe*** alarm.

- While operating in the Skin mode, with a skin probe connected in the skin probe 1 connector, insert a second skin probe into the skin probe 2 connector of the sensor module.
- Verify that when a second probe is connected to the sensor module, the ***Remove Skin 2 Probe*** alarm message is displayed in the Trend/Alarm window and an audible alarm sounds.
- Remove the second skin probe from the skin probe 2 connector.

**6** Check the ***Skin Probe Disconnect*** alarm.

- In the Skin mode, disconnect the skin probe from the skin probe 1 connector of the sensor module.
- Verify that the skin display goes blank, the ***Skin Probe Disconnect*** alarm message is displayed in the Trend/Alarm window, and the audible alarm sounds.
- Press the ***Alarm Silence/Reset*** key. The audible alarm silences for 5 minutes.
- Reconnect the skin probe in the skin probe 1 connector.
- Verify that the incubator returns to normal operation.

**7** Check the Maximum Air Temperature.

- Connect a skin probe to the sensor module, and select Skin Mode.
- In the Temperature Override mode, select a temperature >37°C (see "Skin Mode" on page 72).
- Place the skin probe outside the incubator.
- Allow the incubator to heat.
- If the ***High Temp CutOut*** alarm sounds, press the ***Alarm Silence/Reset*** key.
- Verify that the incubator does not heat above 39.9°C (103.82°F) as indicated on the display screen.

**8** Check the ***Connect Skin 1 Probe*** alarm.

- While operating in the Air mode, disconnect the skin probe 1, and then select the Skin mode.
- Verify that the ***Connect Skin 1 Probe*** alarm sounds.

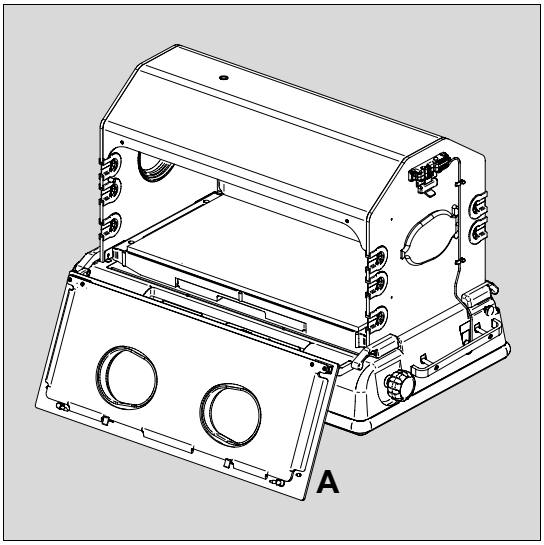
**9** Check the screen intensity feature at the system displays (see "Hard Keys" on page 38).

- Use the ***Up Arrow*** key to increase the screen intensity three levels.
- Use the ***Down Arrow*** key to decrease the screen intensity three levels.

## Hood/Shell Operational Checkout

**1** Check the access panels:

- Rotate the pawl latches, and open the front access panel.
- At the controller screen, check that the access panel open symbol ( ) turns on.
- Pivot the access panel to the full open position (hanging straight down) (**A**).




- Close the access panel, and rotate both latches until fully engaged.
- At the controller screen, check that the access panel open symbol turns off.
- Repeat steps for the rear access panel.

**CAUTION**
Both latches must fully engage to avoid accidental opening of the panels. Noncompliance may result in injury or equipment damage.

**2** Check the hood operation:

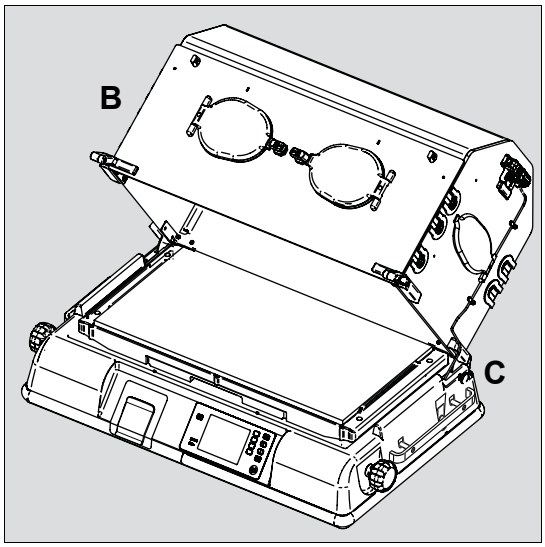
- If equipped with a weighing scale, first disconnect the weighing scale cable as follows:

– rotate the pawl latches 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.

- Slowly tilt the hood back until the hood locks in place (**B**).
- To release the hood, pull on and hold the knob (**C**) located on the right rear hinge while closing the hood.



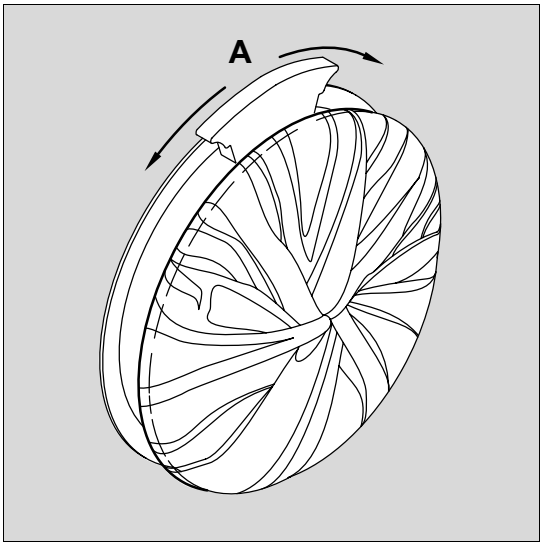
- If equipped with a weighing scale, reconnect the weighing scale cable as follows

– Rotate the pawl latches and open the front or rear access panel.

– Reconnect the weighing scale cable to the sensor module.

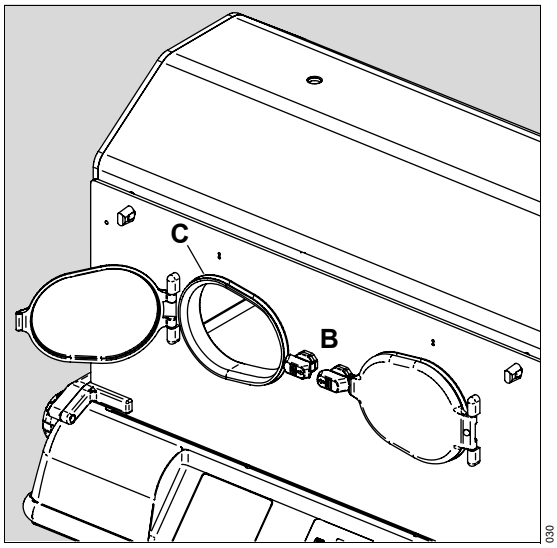
– Close the access panel, and rotate both latches until they are fully engaged.

**3** If equipped with the optional iris ports on the side 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 access door latches and gaskets.

- Press the door release (**B**) of each access door and verify that the access door swings open.
- Close the doors, and check for proper latching and quietness.
- Check that the access door gaskets (**C**) are properly installed in the access door openings.

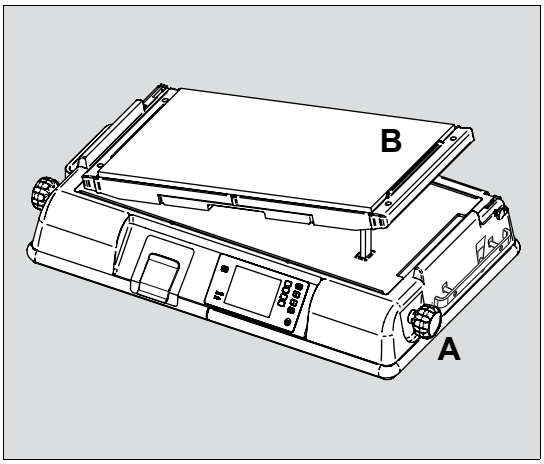


**5** Check that the inner walls are properly latched:

- Open the front access panel, and check that the front inner wall is properly latched and that the access panel open symbol on the controller screen ( ) turns on.
- Close the front access panel and check that the access panel open symbol on the controller screen turns off.
- Repeat steps for the rear access panel and rear inner wall.

**6** Check the mattress elevators:

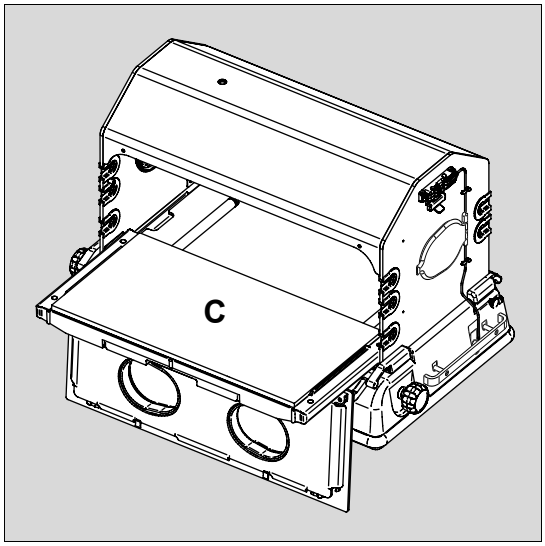
- Rotate the right mattress tilt mechanism knob (**A**) counterclockwise until it stops. Check that the mattress is in the full “up” position (**B**).
- Rotate the knob clockwise until it stops. Check that the mattress is level.




- Rotate the left mattress tilt mechanism knob clockwise until it stops. Check that the mattress is in the full “up” position.
- Rotate the knob counterclockwise until it stops. Check that the mattress is level.

**7** Check the mattress tray operation:

- Rotate the pawl latches, and open the front access panel.
- Pivot the front access panel to the full open position (hanging straight down).
- Slide out the mattress tray to the fully extended position (**C**).
- Carefully lean on the mattress tray to ensure it is properly supported and provides a firm infant platform.
- Return the mattress tray.
- Close the front access panel, and rotate both pawl latches until they are fully engaged.

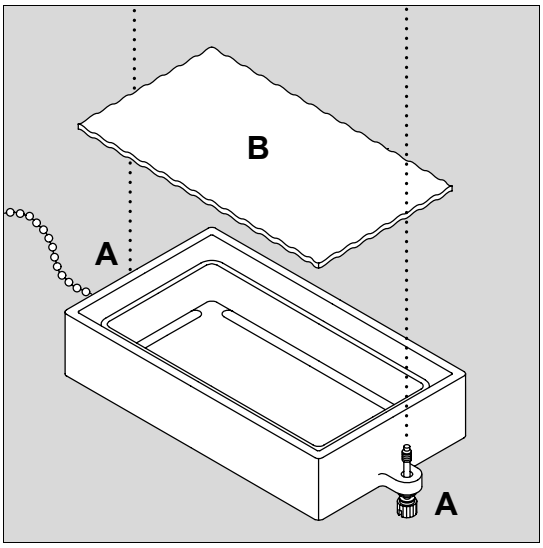


**WARNING**

**A dirty air intake microfilter may affect oxygen concentrations, and/or cause carbon dioxide build-up. Check the filter routinely, and change at least every three months. Noncompliance may result in death or serious injury.**

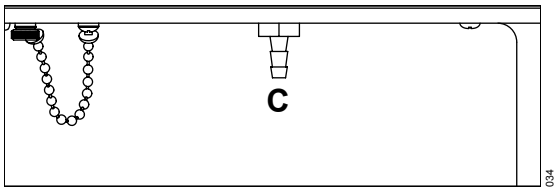
**8** Check the air intake microfilter, which is located under the rear shell of the incubator:

- Loosen the two thumbscrews (**A**) of the air intake microfilter cover, and remove the cover.
- Inspect the microfilter (**B**). If visibly dirty, see "Air Intake Microfilter Maintenance" on page 131.
- Install the air intake microfilter cover.



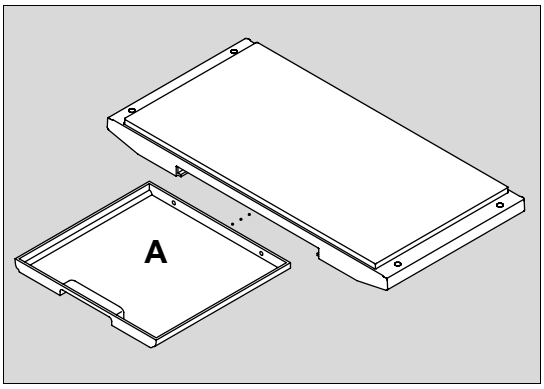

**9** For systems without servo oxygen control, check the manual air/oxygen system located under the rear shell of the incubator:

- Introduce a carefully measured 9 L/min of oxygen into the oxygen input connector (**C**) labeled ***O2 INLET***.
- Using a calibrated oxygen analyzer, monitor the level within the hood.
- Verify that the level reaches the predicted level as indicated on the rear panel of the incubator (9 L/min equals 45% to 75%).



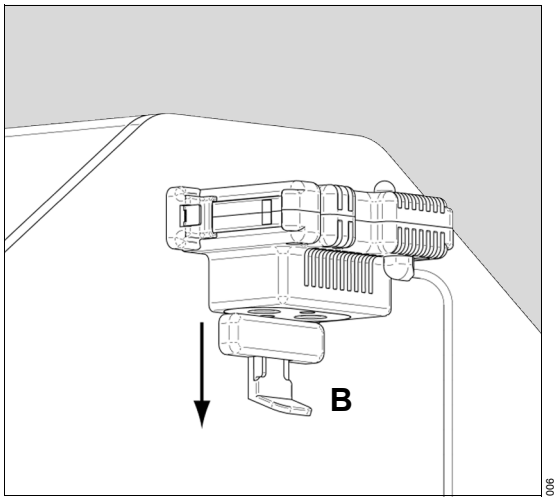
**10** Check the x-ray tray:

- Rotate the pawl latches, and open the front access panel.
- Pivot the front access panel to the full open position (hanging straight down).
- Slide out the x-ray tray (**A**).
- Check the tray for any defects.
- Ensure the tray slides smoothly in and out of the opening.
- Return the x-ray tray.
- Close the front access panel, and rotate both latches until they are fully engaged.

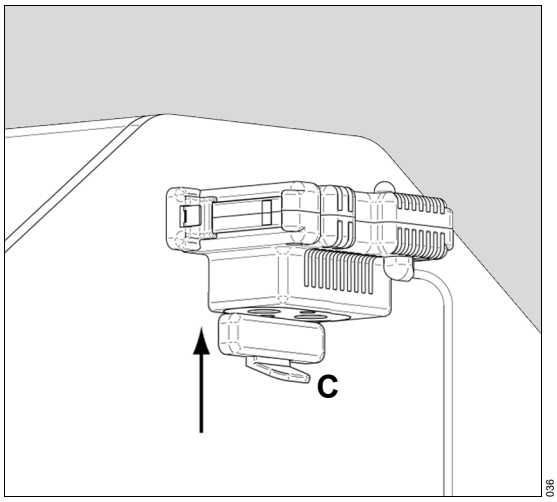



**11** Check the sensor module lock.

- Pull down the sensor module lock (**B**), and check that the sensor module slides in and out of the hood.



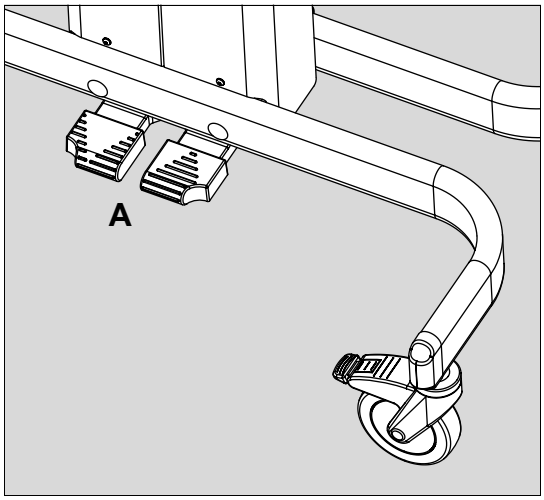

- Push up the sensor module lock (**C**).
- When the sensor module lock is in the up position, check that the sensor module is locked securely in place.



## VHA Stand Operational Checkout

**WARNING**

**When raising or lowering the incubator, the operator should ensure that the travel path of the device is clear of any obstructions, including people's limbs. Patient and incubator connections must also be checked before adjusting the incubator height. Never place any objects on top of the drawer assembly and always check before lowering the VHA to ensure there is sufficient clearance between the incubator and stand assembly. Do not raise or lower the unit while installing or removing medical gas cylinders from the cylinder mount. Noncompliance may result in death or serious injury.**




Perform this operational checkout procedure along with the operational checkout 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 56).

**2** To raise or lower the stand to the maximum and minimum height, press and hold the foot pedal control of the VHA stand (**A**) at the front of the unit.

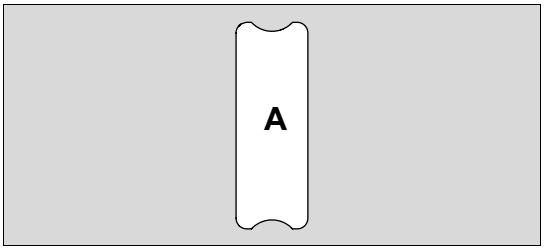
**3** Verify that the stand operates smoothly and adjusts to the desired height.

**4** Repeat steps 2 and 3 for the foot pedal control at the rear of the unit.

## Rail System Operational Checkout

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

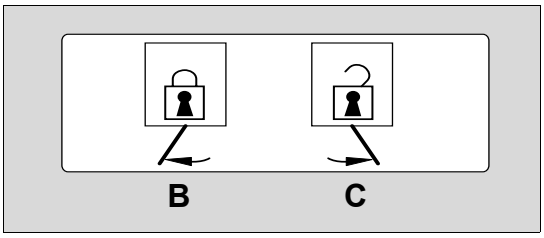
**For the Fairfield compatible rail (A) (cross section shown):**



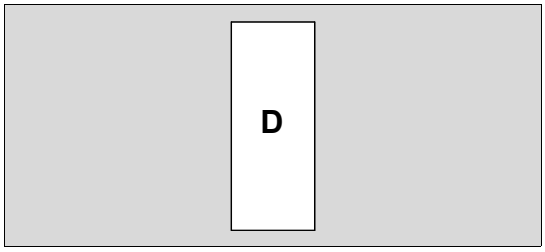

Verify that all cam adapter latches are properly secured to the Fairfield compatible rail when in the locked position.

**NOTE**

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




**For the 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.

## Servo Oxygen Control Module Operational Checkout (Option)

Perform the servo oxygen system operational checkout 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 mattress.
2. If necessary, unlock the keypad.
3. Activate the Oxygen system (see "Turning the Oxygen Mode ON/OFF" on page 78).
4. Set the oxygen set point to 45% (see "Setting the Oxygen Control Set Point" on page 79).
5. Verify that the oxygen analyzer reads 45% ± 5% within 5 minutes.

**NOTE**

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 units calibrated to 21% oxygen. Units calibrated to 100% oxygen are accurate to ± 3%.

## Humidity System Operational Checkout (Option)

**NOTE**

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

Perform the Humidity System Operational Checkout procedure before the system is first placed into service and after disassembly for cleaning or maintenance.

1. Make sure that the reservoir is full.
2. Make sure that the condensation management system is installed properly.
3. Place the probe of a calibrated hygrometer inside the hood 10 cm (4 inches) above the center of the mattress.
4. Pre-warm the incubator to 35.0°C (95.0°F).
5. Activate the Humidity system (see "Turning the Humidity Mode ON/OFF" on page 76).
6. Set the humidity set point to 50% (see "Setting the Humidity Control Set Point" on page 77).
7. Verify within 30 minutes that the hygrometer and the humidity display reads 50% ± 6% relative humidity (RH).

## Weighing System Operational Checkout (Accessory)

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

**WARNING**

**Do not use the scale if it fails to function as described in the operational checkout procedure. Refer service to qualified personnel. Noncompliance may result in death or serious injury.**

### Non-OIML/NAWI Scale

1. Ensure that the mattress is level and not in the Trendelenburg or Reverse Trendelenburg position.
2. Activate the Weighing system (see "Scale Measurements (Accessory)" on page 82).
3. Verify that the Weight display is shown.
4. Remove any objects from the mattress before pressing the ***->0/T<-*** soft key (see "Soft Keys" on page 39).
5. Press the ***->0/T<-*** soft key twice.
6. Verify that the Weight display reads zero and the Weight Sample bar searches.
7. Place a weight of known value, but less than 7 kg (15 lb), on the mattress.
8. Verify that when the Weight Sample bar stops searching, or the bar is filled, a beep sounds and the weight is locked and displayed in the Trend/Alarm window.
9. Re-weigh the object (see "Re-Weigh" on page 83).
10. Verify that the display again shows the value of the weight on the mattress.

### OIML/NAWI Scale

**NOTE**

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.

**NOTE**

If the OIML/NAWI scale is moved to a different geographical location, the scale must be recalibrated, the Isolette 8000 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 properly trained service personnel.

1. Ensure that the mattress is level and not in the Trendelenburg or Reverse Trendelenburg position.
2. Verify that the bubble on the scale level indicator is within the circle (see "Symbols" on page 31).
3. Select Display 2, and press the ***Weight*** soft key. The weight screen is displayed.
4. If necessary, remove any objects from the mattress before pressing the ***->0/T<-*** soft key (see "Soft Keys" on page 39).
5. Press the ***>0/T<-*** soft key twice.
6. Verify that the weight display reads zero and is in reverse video.
7. Place a weight of known value, but less than 7 kg (15 lb), on the mattress and verify that the correct weight is displayed.
8. Remove the weight from the mattress, and press the ***Home*** soft key.

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# Operation

The actual screen display may differ in appearance or configuration.

## Setting the Temperature

Set the incubator temperature in either Air Mode or Skin Mode.

**WARNING**

**The attending physician should prescribe the temperature control mode and temperature settings. Noncompliance may result in death or serious injury.**

**WARNING**

**Routinely monitor the infant temperature according to the attending physician orders or Nursery Standing Orders. Noncompliance may result in death or serious injury.**

**WARNING**

**Keep the infant clear of the slots where the warm air enters the patient compartment. Noncompliance may result in death or serious injury.**

**NOTE**

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.

**NOTE**

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.

### Air Mode

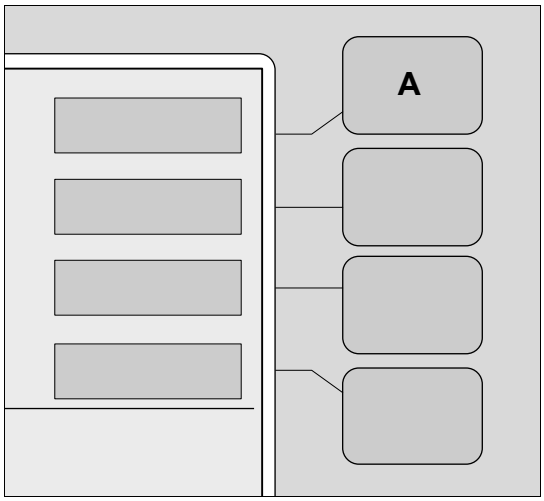
To select the air temperature control set point:

**NOTE**

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 ***Air*** soft key (**A**) to select the Air mode.



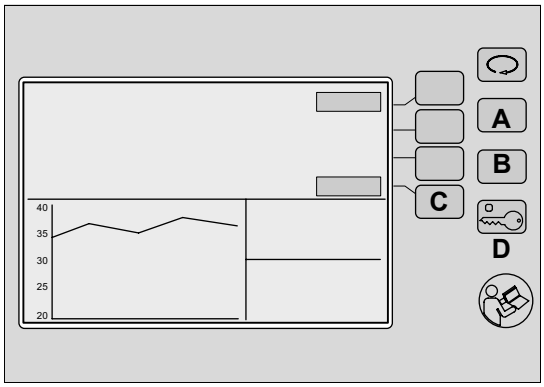
The screen changes to the temperature display with new soft key labels and a border around the current temperature set point.

**3** Set the air temperature to the prescribed setting.

- Press the ***Up Arrow*** key (**A**) to raise the set temperature from 20°C (68°F) to 37.0°C (98.6°F) in 0.1° increments. In Temperature Override mode, the temperature can be set from 37.0°C (98.6°F) to 39.0°C (102.2°F) in 0.1° decrements.
- Press the ***Down Arrow*** key (**B**) to lower the set temperature from 39.0°C (98.6°F) to 20°C (68°F) in 0.1° decrements.

**4** To confirm the Air Set Temperature setting and return to Display 1, press the ***Home*** soft key (**C**).

**5** To lock the keypad, press the ***Keypad Lock*** (**D**) key.




**Activating Temperature Override Mode**

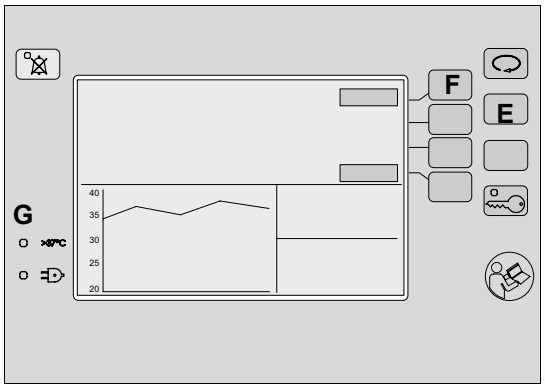
**1** Press the ***Up Arrow*** key (**E**) to raise the set temperature to 37.0°C (98.6°F).

**2** Press the ***>37°C*** soft key (**F**) to activate the Temperature Override mode; the ***>37°C*** LED indicator (**G**) illuminates and the ***>37°C*** soft key label is displayed in reverse video.

**NOTE**

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

**3** Press the ***Up Arrow*** key (**E**) to raise the set temperature from 37.0°C (98.6°F) to 39.0°C (102.2°F) in 0.1° increments.



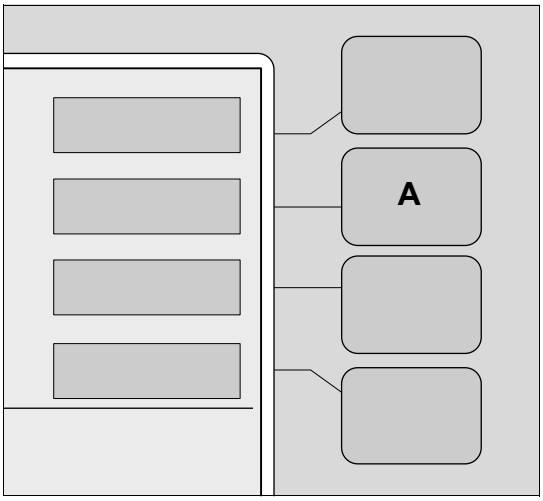
## Skin Mode

To select the skin temperature control set point:

**NOTE**
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 ***Skin*** soft key (**A**) to select the Skin mode.




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

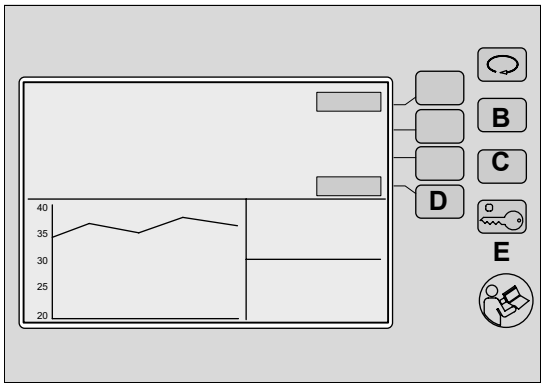
**3** Attach the skin probe to the infant (see "Skin Probe Attachment" on page 73).

**4** Set the skin temperature to the prescribed setting.

- Press the ***Up Arrow*** key (**B**) to raise the set temperature from 34°C (93.2°F) to 37.0°C (98.6°F) in 0.1° increments. 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.
- Press the ***Down Arrow*** key (**C**) to lower the set temperature from 38.0°C (100.4°F) to 34.0°C (93.2°F) in 0.1° decrements.

**5** To confirm the Skin Set Temperature setting and return to Display 1, press the ***Home*** soft key (**D**).

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



**Activating Temperature Override Mode**

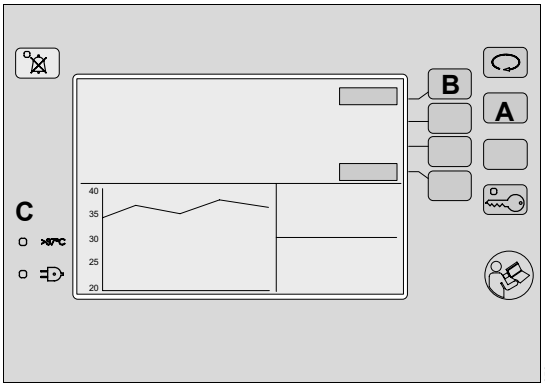
1 Press the ***Up Arrow*** key (**A**) to raise the set temperature to 37.0°C (98.6°F).

2 Press the ***>37°C*** soft key (**B**) to activate the Temperature Override mode; the ***>37°C*** LED indicator illuminates (**C**) and the ***>37°C*** soft key label is displayed in reverse video.

**NOTE**

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

3 Press the ***Up Arrow*** key (**A**) to raise the set temperature from 37.0°C (98.6°F) to 38.0°C (100.4°F) in 0.1° increments.




## Skin Probe Attachment

**CAUTION**

Do not clean and reuse single-use components. Noncompliance may result in injury or equipment damage.

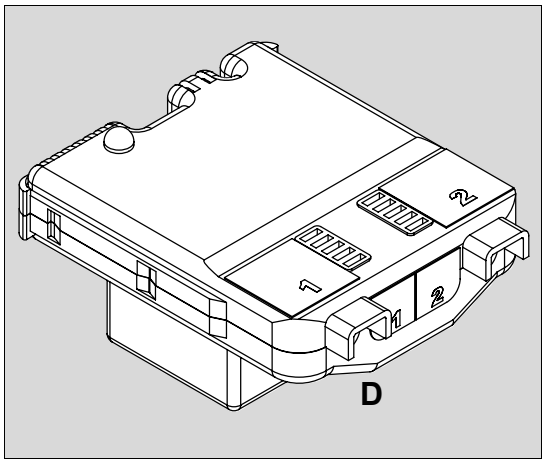
**NOTE**

The sensor module is equipped to accept two skin probes.

**Single Temperature Monitoring**

1 While operating in the Skin mode, insert a skin probe into the Skin Probe #1 connector (**D**).

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




**WARNING**

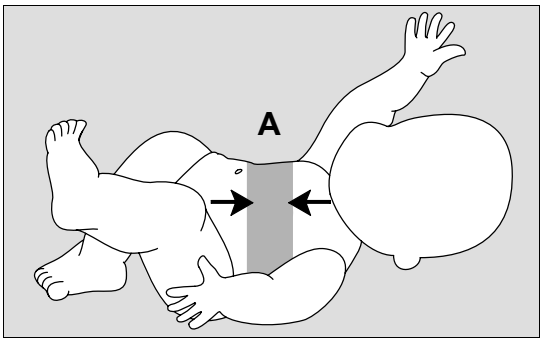
**Never place the skin temperature probe under the infant or use it rectally. Noncompliance may result in death or serious injury.**

**WARNING**

**When in skin mode, the skin temperature probe must be in direct contact with the skin to provide accurate monitoring of the infant skin temperature. When in skin mode, failure to maintain direct skin contact can result in overheating. Routinely check the infant's condition for correct sensor attachment, and feel the infant's skin for signs of overheating. Noncompliance may result in death or serious injury.**

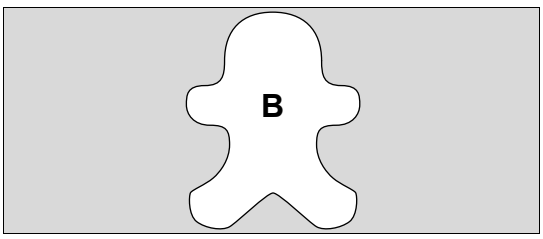
**3** Place the probe on the infant.

- When the infant is on his/her back or side, place the probe on the abdomen (**A**), halfway between the xyphoid and the umbilicus.
- When the infant is prone, place the probe on the back of the infant.




**4** Attach the probe to the infant using a Care-For-Me™ cover (**B**).

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




**5** Set Skin Temperature to the prescribed temperature. Once stabilized, the infant probe temperature is automatically controlled to within 0.5°C of the set temperature.

**6** 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.

**Dual Temperature Monitoring**

The dual skin temperature monitoring feature can be used **only** in the Air mode. When skin probes are inserted into the Skin Probe #1 and Skin Probe #2 connectors, the controller screen displays the respective Skin 1 and Skin 2 temperatures.

**NOTE**

When a second skin probe is connected to the sensor module while operating in Skin mode, an alarm sounds and the ***Remove Skin 2 Probe*** alarm is activated.

## Setting the Humidity (Option)

**WARNING**

**Higher relative humidity will, at any given time, decrease an infant's evaporative water loss, and may cause an increase in infant temperature. This effect is greatest in very low birth-weight, premature infants. The attending physician should prescribe Temperature Control mode, temperature setting, and humidity output level setting. Routinely monitor the infant's temperature according to the attending physician's orders or Nursery Standing Orders. Noncompliance may result in death or serious injury.**

**WARNING**

**The evaporator can be sufficiently hot to cause burns. Avoid removing or touching the evaporator until the humidity reservoir has been disconnected from the incubator for at least 45 minutes. Noncompliance may result in death or serious injury.**

**CAUTION**

If humidity has been in use but is no longer required, empty and dry the reservoir to avoid possible bacterial contamination, and then reinstall the reservoir assembly in the incubator shell. Noncompliance may result in injury or equipment damage.

**NOTE**

Under certain environmental conditions, condensation may form on the inside walls of the hood. This can be minimized or eliminated if desired by changing the set RH % to a lower humidity setting.

**NOTE**

Check the water level in the humidity reservoir twice a day.

### Filling the Humidity Reservoir

**CAUTION**

Use distilled water only (<10 ppm total dissolved solids). Sterile water is not an acceptable substitute for distilled water. Noncompliance may result in injury or equipment damage.

**CAUTION**

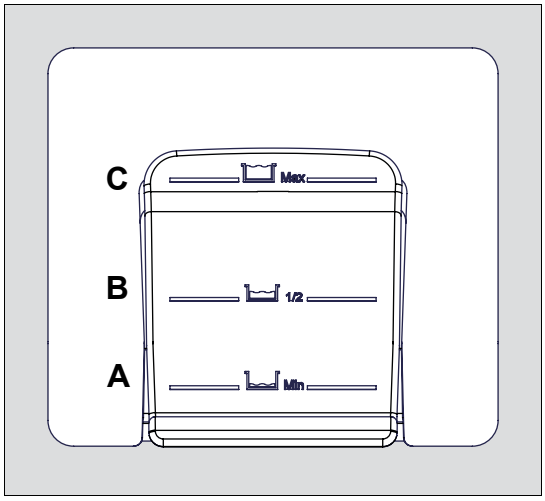
If any fluids spill or leak around the device, wipe the area dry to prevent slipping hazard. Noncompliance may result in injury or equipment damage

**NOTE**

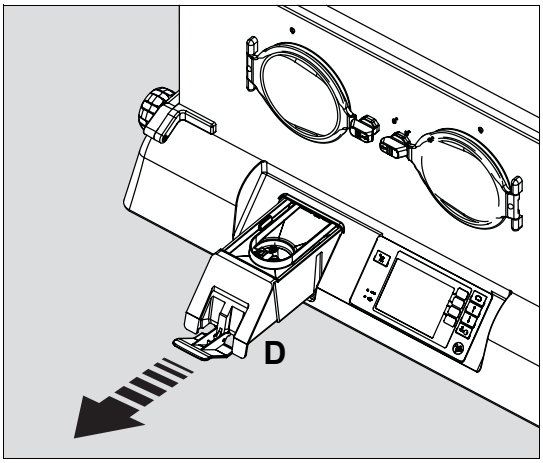
Mineral deposits may form on the evaporator, depending on the quality of the distilled water.

**NOTE**

The water level is visible through the front of the humidity 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.

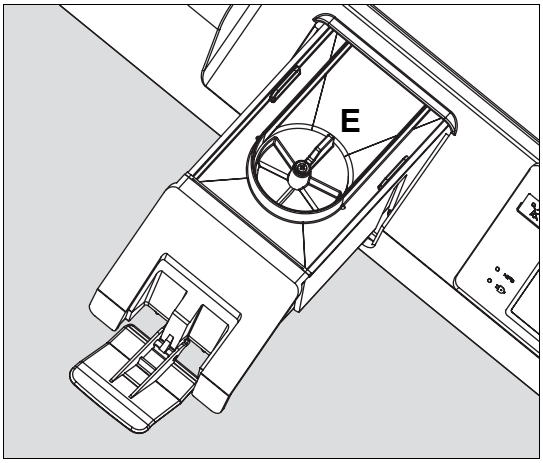


**1** Pull the latch forward and slide the reservoir assembly (**D**) halfway out from the front of the incubator shell.




**2** Open the cover (**E**) on the fill opening by rotating it.

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




- Close the cover on the fill opening, slide the reservoir assembly fully into the shell, and lock it in place by pushing in the latch.

**CAUTION**

Do not use the reservoir without the lid installed and the cover on the fill opening closed. Noncompliance may result in injury or equipment damage.

## Turning the Humidity Mode ON/OFF

**1** Prewarm the incubator in Air mode to the temperature prescribed by the attending physician or according to Nursery Standing Orders.

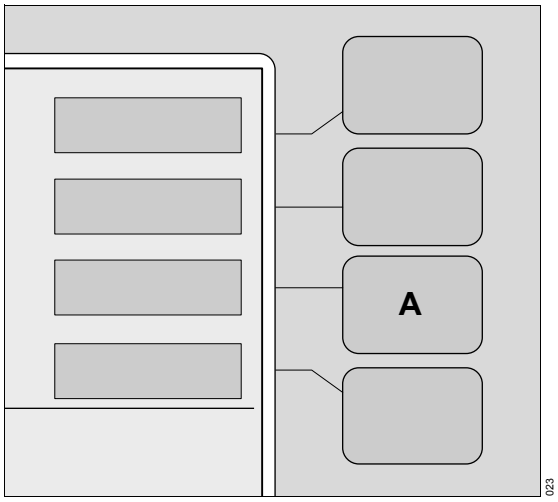
**2** Ensure that the humidity reservoir is filled with distilled water.

**3** If necessary, unlock the keypad.

**4** At Display 1, press the ***Humidity*** soft key (**A**).

**NOTE**

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

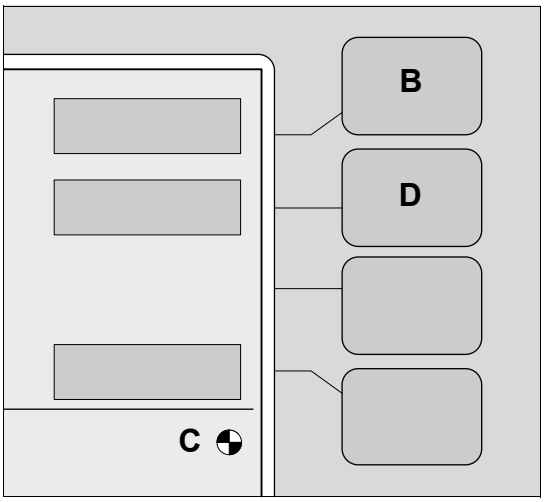



The screen changes to the humidity display with new soft key labels.

**5** Press the ***ON*** soft key (**B**) to activate the Humidity mode.

The rotating wheel (**C**) indicates the Humidity mode is active. The actual RH% achievable inside the system is dependent on the incubator set temperature and room conditions.

- To deactivate the Humidity mode, press the ***OFF*** soft key (**D**).




## Setting the Humidity Control Set Point

To set the humidity set point:

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

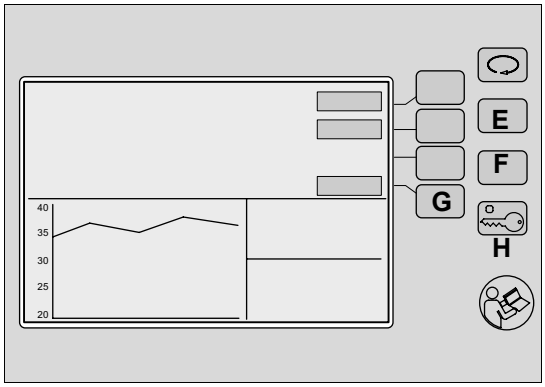
**1** Activate the humidity system (see "Turning the Humidity Mode ON/OFF" on page 76).

**2** Adjust the humidity set point.

- Press and hold the ***Up Arrow*** key (**E**) to raise the humidity set point from a range of 30% to 95% in 1% increments.
- Press and hold the ***Down Arrow*** (**F**) key to lower the humidity set point from a range of 95% to 30% in 1% decrements.

**3** Press the ***Home*** soft key (**G**) to acknowledge the Humidity control setting, and return to Display 1.

**4** Press the ***Keypad Lock*** key (**H**) to lock the keypad.



## Setting the Servo Control Oxygen (Option)

**WARNING**

**If the patient's arterial oxygen levels cannot be maintained when the oxygen control setting is set to maximum, the attending physician should prescribe alternate means of oxygenation. Noncompliance may result in death or serious injury.**

In Oxygen Control mode, the oxygen sensors and control valve module control the concentration level of oxygen (from 21% to 65%). The alarm limit default is ± 3% from the current set point. If the oxygen concentration rises above or falls below the ± 3% limit, an audible and visual alarm occurs, and the message ***Low Oxygen%*** or ***High Oxygen%*** is displayed in the Trend/Alarm window.

**WARNING**

**When using the servo control oxygen system during oxygen administration, do not use the oxygen concentration guide provided on the label on the back of the device. The guide is valid only for manual control oxygen usage. Noncompliance with this warning may result in death or serious injury.**

### Turning the Oxygen Mode ON/OFF

1 Ensure that the oxygen supply provides an inlet pressure and inlet flow rate in compliance with the specifications (see " Oxygen Control System" on page 140).

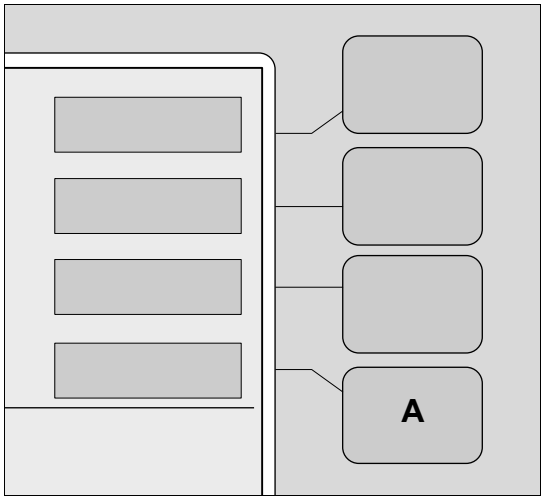
2 Connect the oxygen hose from the oxygen inlet located under the rear shell of the incubator to the oxygen supply.

3 If necessary, unlock the keypad.

4 At Display 1, press the ***Oxygen*** soft key (**A**).

**NOTE**

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



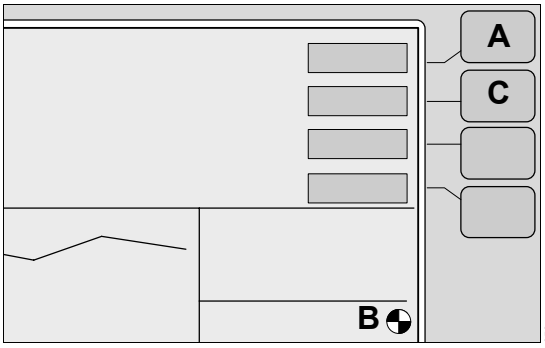

The screen changes to the Oxygen display with new soft key labels.

5 Press the ***ON*** soft key (**A**) to activate the Oxygen mode.

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

6 If the message ***Cal Required*** is displayed, calibrate the oxygen control system (see "Oxygen Sensor Calibration (Option)" on page 86).

7 To deactivate the Oxygen mode, press the ***OFF*** soft key (**C**).




## Setting the Oxygen Control Set Point

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

1 Activate the Oxygen mode (see "Turning the Oxygen Mode ON/OFF" on page 78).

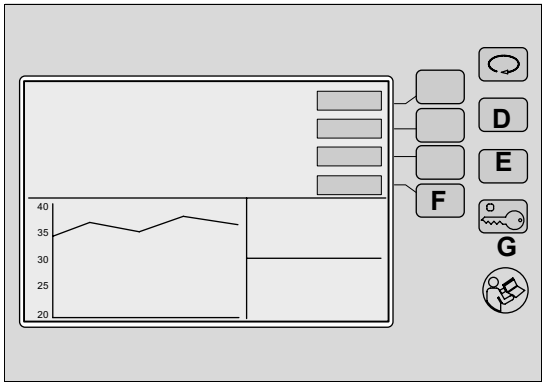
**NOTE**
If no keys are pressed within 15 seconds of making any selection, the screen automatically reverts to the previous display.

2 Adjust the oxygen set point:

- Press the ***Up Arrow*** key (**D**) to raise the set point from a range of 21% to 65%.
- Press the ***Down Arrow*** key (**E**) to lower the set point from a range of 65% to 21%.

3 Press the ***Home*** soft key (**F**) to acknowledge the Oxygen Control setting, and return to Display 1.

4 Press the ***Keypad Lock*** key (**G**) to lock the keypad.



## Manual Control Oxygen Usage (Option)

**WARNING**

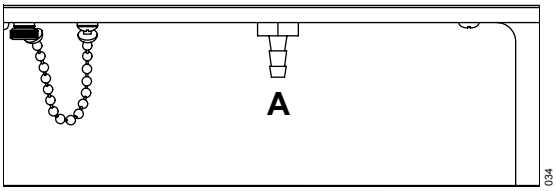
**The oxygen flow rates shown here and on the label on the back of the incubator cannot be used as an accurate indication of oxygen concentrations in the incubator and should only be used as a guide. Measure oxygen concentrations with a calibrated oxygen analyzer at intervals directed by the attending physicians. Noncompliance may result in death or serious injury.**

**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 stand. 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 oxygen flow meter to the barbed fitting labeled ***O2 INLET*** (**A**) using 3/16 inch inner diameter surgical tubing.

**4** Allow oxygen concentrations to stabilize.




**NOTE**

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

| Oxygen Supply | Approximate Oxygen % |
|---|---|
| 3 lpm | 30% – 45% |
| 6 lpm | 40% – 60% |
| 9 lpm | 45% – 75% |
| 12 lpm | 50% – 85% |
| 15 lpm | 60% – 90% |

## Variable Height Adjustment

**WARNING**

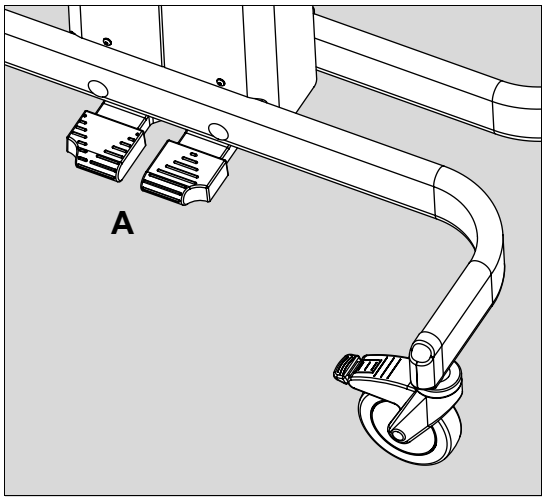
**When raising or lowering the incubator, the operator should ensure that the travel path of the device is clear of any obstructions, including people's limbs. Patient and incubator connections must also be checked before adjusting the incubator height. Never place any objects on top of the drawer assembly and always check before lowering the stand to ensure there is sufficient clearance between the incubator and stand assembly. Do not raise or lower the unit while installing or removing medical gas cylinders from the cylinder mount. Noncompliance may result in death or serious injury.**

**WARNING**

**When operating the VHA stand, always place one hand on the incubator for support to keep from losing your balance. Noncompliance may result in death or serious injury.**

The Isolette 8000 has two sets of foot pedals, one on the front and one on the rear of the unit.

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




## Infant Placement

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

**WARNING**

**Before placing the infant in the incubator, prewarm the incubator to the temperature prescribed by the attending physician, or according to nursing protocol. Noncompliance may result in death or serious injury.**

**1** Pre-warm the incubator.

**2** Rotate the pawl latches, and open the front access panel.

**3** Place the infant in the center of the mattress.

**4** Close the access panel, and ensure that the pawl latches are fully engaged.

# Scale Measurements (Accessory)

## Techniques for Accurate Scale Measurements

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

**NOTE**

Support the ventilator tubing and I.V. tubes to ensure they do not touch the mattress.

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

**WARNING**

**For infant safety, do not leave the infant unattended when the access panel is open. Noncompliance may result in death or serious injury.**

**NOTE**

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

## Non-OIML/NAWI Scale Measurements

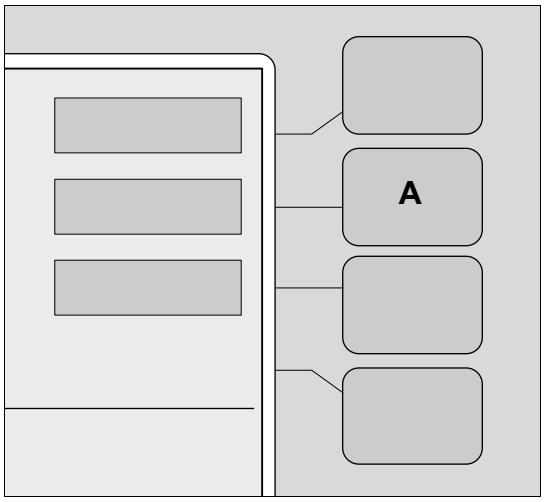
### Initial Weigh

To perform the initial weighing function:

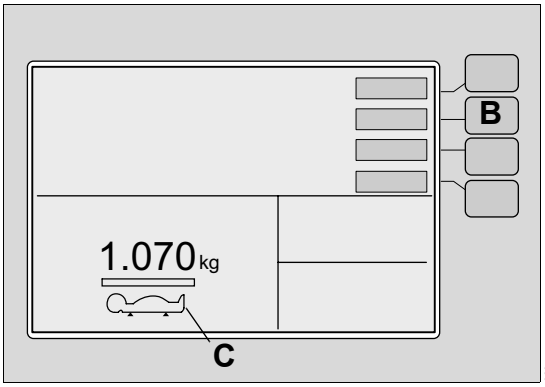
**1** If necessary, unlock the keypad.

**2** At Display 1, press the ***Display Selection*** to view Display 2.

**3** At Display 2, press the ***Weight*** soft key (**A**).



**4** Press the ***->0/T<-*** soft key (**B**). The ***Lift Baby*** indicator is displayed (**C**).




**5** Lift the infant off the mattress.

**6** When the ***Lift Baby*** indicator is removed, place the infant on the mattress.

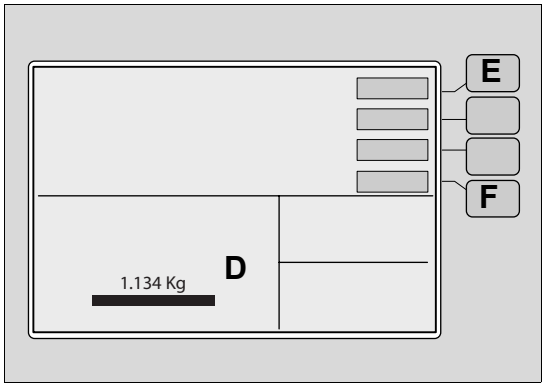
**7** The Weight Sample bar fills, and the weight of the infant is displayed in the Trend/Alarm window (**D**).

**8** To enter the infant weight in the Trend/Alarm window, press the ***Store*** soft key (**E**).

**NOTE**

The trend of the infant weight is tracked over a period of seven 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 six days represent the difference between the last stored weight, within a 24-hour period, and the baseline weight measurement.

**9** To return to Display 2, press the ***Home*** soft key (**F**).




**Re-Weigh**

**1** To re-weigh the infant without removing or adding anything to the mattress, press the ***Weight*** soft key on Display 2.

**2** If any objects are added or removed from the mattress, or a power failure occurs, refer to "Initial Weigh" on page 82 to ensure accurate measurement of the infant weight.

### OIML/NAWI Scale Measurements

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 to view Display 2.

**3** At Display 2, press the ***Weight*** soft key.

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

**NOTE**
The ***Lift Baby*** indicator 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 mattress.

**6** When the ***Lift Baby*** indicator is removed, place the infant on the mattress.

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

**8** To return to Display 2, press the ***Home*** soft key.

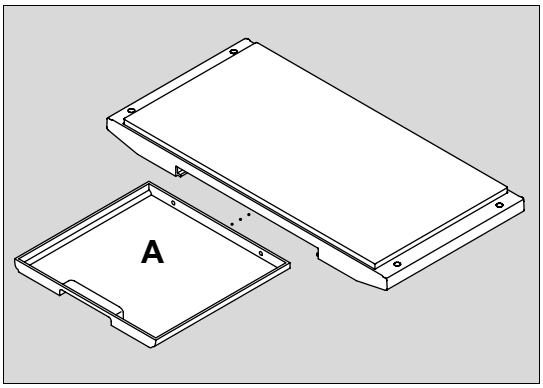
## X-Ray Tray Usage

**WARNING**
**For infant safety, do not leave the infant unattended when the access panel is open. Noncompliance may result in death or serious injury.**

**1** Remove any accessories that may interfere with front access panel movement.

**2** Rotate the pawl latches, and open the front access panel.

**3** Slide out the x-ray tray (**A**) from under the mattress.




**4** Place the x-ray cassette in the center of the x-ray tray.

**5** Push the x-ray tray back in under the mattress.

**6** Place the infant at the center of the mattress.

**7** Close the access panel, and ensure that the pawl latches are fully engaged.

**8** When the x-ray is completed, repeat steps 1 and 2.

**9** Remove the x-ray cassette from the tray, and return the tray.

**10** Close the access panel, and ensure that the pawl latches are fully engaged.

**11** Replace any accessories that were previously removed.

**WARNING**
**When an x-ray is taken through the hood, the hood could show up on the x-ray as a radiolucent shadow and could result in incorrect diagnosis. Noncompliance may result in death or serious injury.**

## Dräger Infinity Delta, Delta XL, and Kappa Monitoring

To view patient parameters from the Isolette 8000 infant incubator on a Dräger Infinity Delta, Delta XL, or Kappa monitor, perform the following procedures.

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

1 Turn off the incubator ***Power Switch***.

2 Connect the DB-9 male end of the Medical Information Bus (MIB) cable (part number MS18805) to the bottom of the incubator shell assembly (see "External Devices" on page 28).

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

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

5 Connect the other end of the MIB patch cable to the Infinity Docking Station (IDS) (for the Delta and Delta XL monitors), or to the Kappa monitor.

6 Turn on the incubator ***Power Switch***.

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

**NOTE**
For the parts needed to connect the Isolette 8000 infant incubator to the Dräger Infinity Delta, Delta XL, and Kappa monitors, see "Accessories" on page 148.

## VueLink™ Monitoring

VueLink software enables the user to view patient parameters from the Isolette 8000 infant incubator on a bedside patient monitor or a central monitoring system.

To view patient parameters using the VueLink software, perform the following procedures:

1 Turn off the incubator ***Power Switch***.

2 Connect the DB-9 male end of the VueLink cable to the bottom of the incubator shell assembly (see "External Devices" on page 28).

3 Connect the DB-25 female end of the VueLink cable to the bedside patient monitor or central monitoring system.

4 While pressing the ***Alarm Silence/Reset*** key, turn on the incubator ***Power Switch*** to enter the System Set Up menu.

5 Using the ***Display Selection*** key, scroll down to the VueLink software option.

6 Press the ***Up Arrow*** key to select ***Yes***.

7 Press the ***Alarm Silence/Reset*** key to exit the set-up menu.

8 On the bedside patient monitor, press the ***Module Setup*** key. The ***Module Setup*** window is displayed on the VueLink software screen.

9 Press the gray key beneath the ***HRAS C2000*** caption. Values for the incubator are displayed on the VueLink software screen of the bedside patient monitor. Alarm messages resulting from alarm conditions are displayed automatically.

**NOTE**
VueLink software does not have touch-screen capability.

## Oxygen Sensor Calibration (Option)

**WARNING**

**If the message *Cal Required* is displayed, calibrate the servo oxygen control system. Calibration of the oxygen sensor must be done at a minimum of 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. Noncompliance may result in death or serious injury.**

**NOTE**

Only single point calibration is required.

**NOTE**

If the sensor module cable is disconnected from the shell connector during operation, the message ***Cal Required*** is displayed to indicate that the servo oxygen control system must be calibrated.

### Oxygen Sensor Calibration to Room Air (21%)

**WARNING**

**To perform the 21% oxygen calibration procedure, ensure that the incubator is equipped with the standard sensor module slide-lock. If the 100% oxygen calibration fixture is used during the 21% calibration procedure, the calibration will be inaccurate. Noncompliance may result in death or serious injury.**

To calibrate the oxygen sensor to room air (21%):

1 Verify the oxygen calibration level setting (21% or 100%) at the System Configuration Menu (see "System Configuration Menu" on page 98).

2 If required, configure the oxygen calibration level setting for 21%.

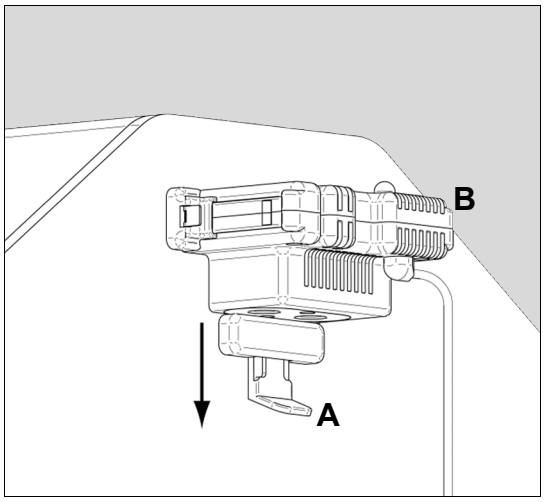
3 Verify that the proper oxygen calibration altitude is selected in the System Configuration menu (see "System Configuration Menu" on page 98).

4 Ensure that the incubator is equipped with the standard sensor module slide-lock, **not** the 100% oxygen calibration fixture.

5 At Display 1, press the ***Oxygen*** soft key.

6 Press the ***ON*** soft key, and then the ***Cal*** soft key. The message ***Slide Out Sensor*** is displayed.

7 Within 5 seconds, withdraw the sensor module from the incubator 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.

8 Slide the sensor module inside the hood, and then press the ***ON*** soft key.

9 If the message ***Cal Fail*** is displayed, repeat the procedure.

**10** If the calibration procedure is unsuccessful a second time, refer the unit to qualified service personnel.

## Oxygen Sensor Calibration to 100% Oxygen

**1** To perform the 100% oxygen calibration procedure, install the 100% oxygen calibration fixture on the hood (see "Installing the 100% Oxygen Calibration Fixture (Optional)" on page 53).

**2** Verify the oxygen calibration level setting (21% or 100%) at the System Configuration Menu (see "System Configuration Menu" on page 98).

**3** If required, configure the oxygen calibration level setting for 100%.

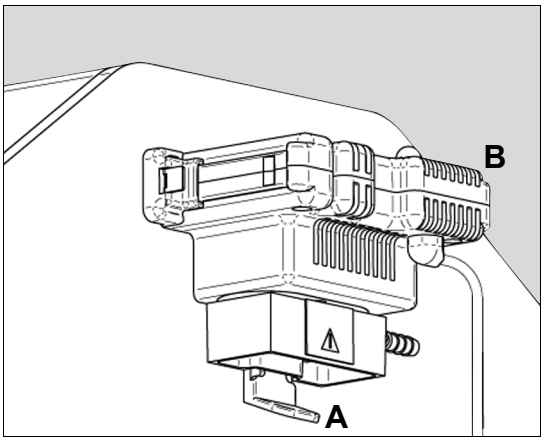
**4** Connect an oxygen hose to a 100% medical-grade oxygen source at 3 L/min to 5 L/min and to the barb fitting on the calibration fixture.

**5** Turn on the oxygen.

**6** At Display 1, press the ***Oxygen*** soft key.

**7** Press the ***ON*** soft key, and then the ***Cal*** soft key.

**8** Within 5 seconds, withdraw the sensor module from the incubator 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*** soft key.

**12** If the message ***Cal Fail*** is displayed, repeat the procedure.

**13** If the calibration procedure is unsuccessful a second time, refer the unit to qualified service personnel.

## Scale Calibration (Accessory)

### Non-OIML/NAWI Scale Calibration

Dräger Medical recommends calibrating the scale using a calibrated 5-kg weight upon installation and every six months thereafter.

**NOTE**
When calibrating the scale, the mattress must be level and not in the Trendelenburg or Reverse Trendelenburg position.

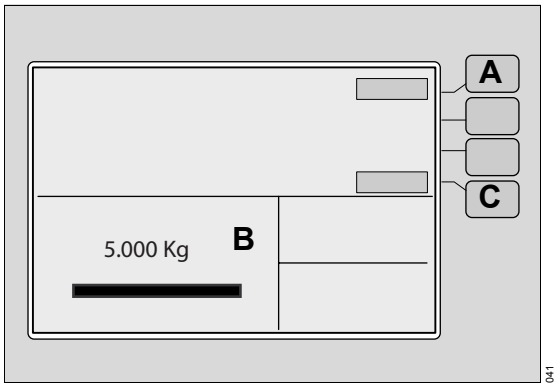
To calibrate the scale:

1. At Display 1, press the ***Display Selection*** key.
2. At Display 2, press the ***Weight*** soft key.
3. If necessary, remove any objects from the mattress.
4. At the Weight display, press the ***->0/T<-*** soft key two times, and then press the ***Display Selection*** key.
5. At the Scale Calibration display, press the ***Cal*** soft key (**A**).

   The ***Wait...*** message is displayed, and then replaced with the ***5-kg symbol***.
6. Within 12 seconds of the ***5-kg symbol*** being displayed, place a calibrated 5-kg weight on the center of the mattress.

**NOTE**
If the 5-kg weight is not placed on the center of the mattress within 12 seconds after the ***5-kg symbol*** is displayed, the ***Cal Failed*** message is displayed.

7. Wait for the Weight Sample bar to fill and a weight reading of ***5.000 kg*** to be displayed (**B**).
8. Remove the weight, and then press the ***Home*** soft key (**C**) to return to Display 2.




### OIML/NAWI Scale Calibration

**NOTE**
OIML/NAWI scales can only be calibrated by properly trained service personnel. Contact DrägerService for further information.

## System Shut-Down

To properly shut down the Isolette 8000:

**1** Remove power from any devices plugged into the convenience outlets.

**2** Shut off the hospital and/or cylinder oxygen source.

**3** Disconnect the incubator from the hospital oxygen source.

**4** Turn off the ***Power Switch*** on the incubator shell to power down the incubator.

**5** Turn off the ***Main Power*** switch on the side of the VHA stand.

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# Alarms

The actual screen display may differ in appearance or configuration.

## Alarm Priority

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

| | |
|---|---|
| **Caution** | medium priority alarm, requiring prompt action |
| **Advisory** | low priority alarm/message that must be noted and action taken if necessary |

## Alarm Indication

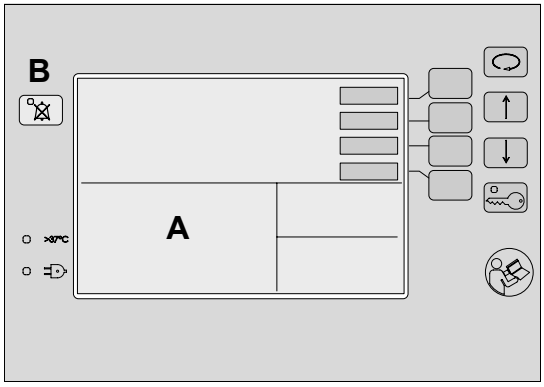
An alarm is signaled whenever a condition that could be potentially hazardous is detected. System alarm conditions are indicated according to their alarm priority:

**Caution**

- an appropriate message appears in the Trend/Alarm window (**A**)
- an intermittent LED indicator illuminates (on the Alarm Silence/Reset key (**B**) or on the sensor module)
- a repeating, 3-tone acoustic alarm signal sounds

**Advisory**

- an appropriate message appears in the Trend/Alarm window (**A**)
- an LED indicator illuminates continuously (on the Alarm Silence/Reset key (**B**) or on the sensor module)
- a repeating, 2-tone acoustic alarm signal sounds




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, followed by all other messages in sequence. A total of six messages can be presented in the Trend/Alarm window.

The Isolette 8000 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 Messages" on page 102).

**NOTE**
A message without an audible or visual LED indication may also be posted on the display to alert the user of conditions that are not hazardous but require attention or correction.

For a complete list of Isolette 8000 alarm messages, see "Alarm Messages" on page 102.

## Silencing Alarms

The ***Alarm Silence/Reset*** key is used to silence the audio alarm for a fixed amount of time and/or to 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 Messages" on page 102). To indicate that a silence period is in progress, the LED on the ***Alarm Silence/Reset*** key (**B**) illuminates.

The ***Alarm Silence/Reset*** key can perform the following functions:

- Reset one or multiple latched (not currently active) alarms if there are no current alarms present.
- Silence one or more alarms if no previously latched alarms are present.

**NOTE**
The ***Alarm Silence/Reset*** key cannot simultaneously reset a previously latched alarm and silence a current alarm condition.

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# Trends

The actual screen display may differ in appearance or configuration.

## Trend Display

To select a trend display for viewing, perform the following steps:

**NOTE**
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** Access the Trend display:

- At Display 1, press the ***Display Selection*** key to access Display 2.
- At Display 2, press the ***Trend*** soft key to select the Trend display and view the menu options.

**3** To clear all previous Trend displays, press and hold the ***Clear*** soft key (**A**).

**4** Press the ***Hours*** soft key (**B**) to select the trend period: 2, 4, 8, 12, or 24 hours.

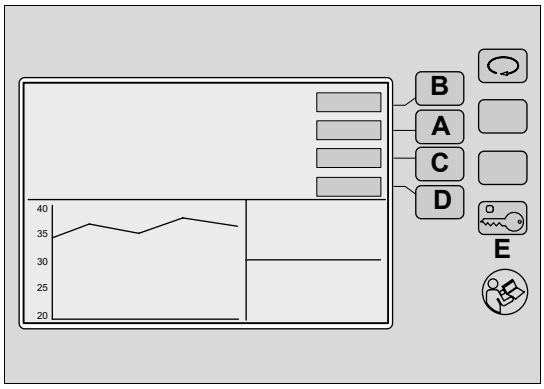
**NOTE**
The ***Hours*** soft key is not applicable for trends of the infant weight. The trend interval for infant weight is seven days.

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

- Air temperature
- Skin temperature 1
- Skin temperature 2
- Heater power %
- Oxygen (optional)
- Humidity (optional)
- Weight (optional)

**6** To confirm the Trend display selection and return to Display 2, press the ***Home*** soft key (**D**).

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



# Configuration

The actual screen display may differ in appearance or configuration.

## System Configuration Menu

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

### Default Settings

In the event of a power failure lasting 10 minutes or less, the set points and operating mode are retained. With power failures lasting more than 10 minutes, the set points and operating mode revert to factory default settings or to the settings selected in the configuration menu.

| System Configuration Menu Options | Setting Options | Default Settings |
|---|---|---|
| Humidity Option | Yes/No | No |
| Oxygen Option | Yes/No | No |
| Oxygen Cal Level | 100%/21% | 21% |
| Skin Temp Alarm Limit | 1.0°C/5.0°C | 1.0°C |
| Skin Control Mode | Yes/No | Yes |
| Language | English, French, German, Spanish, Italian, Japanese, Dutch, Danish, Norwegian, Polish, Portuguese, Swedish, Finnish, Greek, Czech, Slovak, Russian, Chinese, Hungarian, Turkish | English |
| Weight Units | lb/kg | kg |
| Air Set Temp | 30.0°C to 37.0°C (increments of 0.1°C) | 35.0°C |
| Altitude[1)] | 0 ft - 12,000 ft (0 - 3657 m) (increments of 2000 ft) | 0 ft |
| VueLink™ | Yes/No | No |
| Display Color | White on blue/Yellow on black | White on blue |

1) used for 21% oxygen calibration offset

To select desired settings in the System Configuration menu:

**1** To display the Configuration menu, first turn off the incubator using the ***On/Off*** switch located under the incubator shell assembly.

**2** Press and hold the ***Alarm Silence/Reset*** key (**A**).

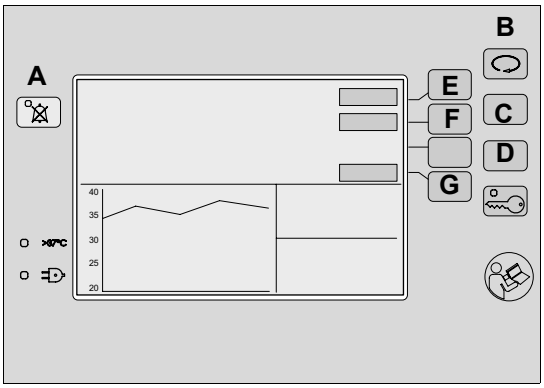
**3** Turn on the incubator and continue to hold the ***Alarm Silence/Reset*** key while the unit powers up.

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

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

- Press the ***Hard Default*** soft key (**E**) to set all configuration options to factory default settings
- Press the ***Diag Info*** soft key (**F**) to display a system information screen
- Press the ***Page 2*** soft key (**G**) to access additional configuration menu options

**6** Press the ***Alarm Silence/Reset*** key (**A**) to exit the System Configuration menu.



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# Problem Solving

## Alarm Messages

The Isolette 8000 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, followed by all other messages in sequence. A total of six messages can be presented in the Trend/Alarm window.

In addition to a displayed message, alarm conditions are also indicated by an audible tone 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.

**NOTE**

To help service personnel, it is recommended that all failures and error codes are recorded.

| Alarm priority | Alarm | Cause | Remedy |
|---|---|---|---|
| Caution | ***Air Flow Probe Failed*** | The air flow probe connection is open or short circuited. | Turn off the incubator and remove it from service. |
| Caution | ***Air Probe Failed***<br>(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. | Turn off the incubator and replace the sensor module.<br>If the failure continues, turn off the incubator and remove it from service. |
| Advisory | ***Check Water Supply***<br>(alarm can be silenced for 30 minutes and can also be set to a 30 minute procedural silence)<br>(this alarm is only available when the humidity control is activated.) | Low water level in the humidity reservoir | Refill the humidity reservoir. If the alarm persists for more than 5 minutes, continue to next cause/remedy. |
| | | The humidity reservoir assembly is not fully inserted in the incubator shell. | Insert the humidity reservoir assembly fully in the incubator shell. |
| | | The humidity reservoir assembly is not assembled correctly (for example, the evaporator is not present). | Ensure that the evaporator and all other components of the humidity reservoir assembly are assembled correctly. |
| | | There is a blockage of the channel between the water compartment and the evaporator chamber. | Check that the evaporator is installed correctly and that there is no blockage of the channel. |

| Alarm priority | Alarm | Cause | Remedy |
|---|---|---|---|
| | | Evaporator malfunction. | Replace the evaporator.<br>If the failure continues, turn off the incubator and remove it from service. |
| Advisory | ***Connect Skin1 Probe*** | Skin mode is selected and there is no probe in the Skin1 probe connector. | Connect a probe to Skin1, and select Skin mode. |
| Caution | ***Controller Failure 1-14***<br>(for Controller Failure alarms 3, 4, and 7, alarm is delayed for 1 minute after the alarm condition occurs) | An internal malfunction occurred. | Turn off the incubator and then turn it on again. If the failure continues, turn off the incubator and remove it from service. |
| Caution | ***Controller Failure 15-17*** | This is the first time the unit was installed or new software was loaded onto the controller. | Press the ***Alarm/Silence Reset*** key. |
| | | Controller memory failure was detected. | Reset settings to factory defaults by pressing the ***Hard Default*** soft key in the System Configuration menu. Check the desired settings.<br>If the failure continues, turn off the incubator and remove it from service. |
| Caution | ***Heater Failed 1***<br>(alarm can be silenced for 5 minutes) | The incubator heater thermocouple voltage exceeds 40 mV. | Turn off the incubator, and remove it from service. |
| Caution | ***Heater Failed 2***<br>(alarm is delayed for 1 minute after the alarm condition occurs) | The heater thermocouple wires are open or shorted. | Turn off the incubator, and remove it from service. |
| Caution | ***High Air Temperature***<br>(alarm can be silenced for 15 minutes)<br>(alarm is inhibited after a set point change (for a maximum of 30 minutes)) | The indicated displayed temperature differs from the set temperature by >1.5°C. | Check hood access panels, access doors, and gaskets for proper fit.<br>Check the set value and configuration. |

| Alarm priority | Alarm | Cause | Remedy |
|---|---|---|---|
| Caution | ***High Oxygen %***<br>(alarm can be silenced for 4 minutes)<br>(alarm is inhibited during oxygen cell calibration; and after lowering set point (for a maximum of 30 minutes))<br>(this alarm is only available when servo oxygen control is activated) | The displayed oxygen value is > 3% above the oxygen set point: | |
| | | The air intake microfilter is dirty. | Replace the air intake microfilter. |
| | | 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. | Turn off the incubator, and remove it from service. |
| Caution | ***High Skin Temperature***<br>(alarm can be silenced for 15 minutes)<br>(alarm is inhibited after a set point change (for a maximum of 30 minutes)) | The indicated displayed temperature differs from the set temperature by > 1.0°C or 0.5°C (user selectable). | Verify that the sensor is correctly attached to the patient.<br>Check hood access panels, access doors, and gaskets for proper fit.<br>Switch off external heat sources. |
| Caution | ***High Skin1 Temperature***<br>(alarm can be silenced for 15 minutes) | Occurs when the Air mode is enabled and the infant skin temperature (from the Skin1 probe) is > 38.0°C ± 0.2°C when the Override mode is not active, or > 39.0°C ± 0.2°C when the > 37°C mode of operation is active. | Verify that the sensor is correctly attached to the patient.<br>Switch off external heat sources. |
| Caution | ***High Skin2 Temperature***<br>(alarm can be silenced for 15 minutes) | Occurs when the Air mode is enabled and the infant skin temperature (from the Skin2 probe) is > 38.0°C ± 0.2°C when the Override mode is not active, or > 39.0°C ± 0.2°C when the > 37°C mode of operation is active. | Verify that the sensor is correctly attached to the patient.<br>Switch off external heat sources. |

| Alarm priority | Alarm | Cause | Remedy |
|---|---|---|---|
| Caution | ***High Temp CutOut***<br>(alarm can be silenced for 5 minutes) | Under air control, this alarm is activated if the displayed incubator temperature reaches 37.7°C ± 0.1 °C for set temperatures < 37°C, or 39.7°C ± 0.1°C for set temperatures > 37°C.<br>Under skin control, this alarm is activated if the incubator temperature reaches 39.7°C ± 0.1°C for any set temperature. | Turn off the incubator and remove it from service. |
| Caution | ***Humidity Heater Fail***<br>(alarm can be silenced for 15 minutes) | The optional humidity system is installed and the humidity heater circuit draws too much current. | Turn off the incubator and remove it from service. |
| Caution | ***Low Air Flow***<br>(alarm can be silenced for 15 minutes and can also be set to a 15 minute procedural silence)<br>(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, turn off the incubator and remove it from service. |
| Caution | ***Low Air Temperature***<br>(alarm can be silenced for 15 minutes and can also be set to a 15 minute procedural silence)<br>(alarm is inhibited for 1 hour after machine start-up; and after a set point change (for a maximum of 30 minutes)) | The indicated displayed temperature is >2.5°C below the set temperature; an access door or iris port is open. | Close all access doors and iris ports. |

| Alarm priority | Alarm | Cause | Remedy |
|---|---|---|---|
| Advisory | ***Low Humidity***<br>(alarm can be silenced for 15 minutes)<br>(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 humidity reservoir assembly is not fully inserted in the incubator shell. | Insert the humidity reservoir assembly fully in the incubator shell. |
| | | Low water level in the humidity reservoir | Refill the humidity reservoir. If the alarm persists, turn off the incubator and remove it from service. |
| | | An access door or iris port is open. | Close all access doors and iris ports. |
| | | An iris port sleeve is open or improperly installed. | Check the installation of the iris port sleeve. |
| | | A tubing grommet is not properly installed. | Check the installation of the tubing grommet. |
| | | Gaps in access door gaskets | Check gaskets for proper fit. If the alarm persists, turn off the incubator and remove it from service. |
| Caution | ***Low Oxygen %***<br>(alarm can be silenced for 4 minutes and can also be set to a 4 minute procedural silence)<br>(this alarm is only available when servo oxygen control is activated.) | The displayed oxygen value is > 3% below the oxygen set point: | |
| | | An access door or iris port is open. | Close all access doors and iris ports. |
| | | An iris port sleeve is open or improperly installed. | Check the installation of the iris port sleeve. |
| | | A tubing grommet is not properly installed. | Check the installation of the tubing grommet. |
| | | The air intake microfilter cover is not properly secured. | Check and secure the air intake microfilter cover. |

| Alarm priority | Alarm | Cause | Remedy |
|---|---|---|---|
| | | The air intake microfilter is not installed. | Check the air intake microfilter, and install if necessary. |
| | | The internal tubing is not connected. | Turn off the incubator and remove it from service. |
| Caution | ***Low Skin Temperature***<br>(alarm is inhibited after a set point change (for a maximum of 30 minutes))<br>(alarm can be silenced for 15 minutes and can also be set to a 15 minute procedural silence) | The indicated displayed temperature is >1.0°C or >0.5°C (user selectable) below the set temperature; the skin probe is not properly secured to skin (in Skin mode only). | Verify that the sensor is correctly attached to the patient. |
| Caution | ***Motor Failed***<br>(alarm is delayed for 40 seconds after the alarm condition occurs) | The fan impeller motor malfunctioned. | Turn off the incubator and remove it from service. |
| Caution | ***Oxygen Cell Different***<br>(alarm is delayed for 50 seconds after the alarm condition occurs)<br>(alarm can be silenced for 4 minutes) | The readings of the two oxygen cells differ by more than 3%. As a result, the oxygen flow into the system is interrupted. | Perform an oxygen calibration (see "Oxygen Sensor Calibration (Option)" on page 86). |
| Caution | ***Oxygen Solenoid Fail***<br>(alarm is delayed for 1 minute after the alarm condition occurs) | The oxygen solenoid voltage is not within limits. | Turn off the incubator and remove it from service. |
| Advisory | ***Remove Skin2 Probe*** | While in the Skin mode, a second probe is connected to the sensor module. | Remove the second probe or place the unit in the Air mode. |
| | | While in the Air mode with two probes connected, the user attempts to enter the Skin mode. | Remove the second probe, and press the ***Alarm Silence/Reset*** key. |
| Caution | ***Sensor Disconnect*** | The sensor module possibly experienced a communications failure. | If the sensor module is not connected, connect it. If the message persists:<br>● Turn off the incubator and then turn it on again.<br>● If the alarm still continues, replace the sensor module.<br>● If the alarm persists, remove it from service. |

| Alarm priority | Alarm | Cause | Remedy |
|---|---|---|---|
| Caution | ***Sensor Module Failure 1-8*** | A sensor module malfunction occurred. | Turn off the incubator and replace the sensor module.<br>If the failure persists, turn off the incubator and remove it from service. |
| Caution | ***Sensor Out of Position***<br>(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, turn off the incubator and remove it from service. |
| Caution | ***Skin1 Probe Fail***<br>(alarm is delayed for 50 seconds after the alarm condition occurs)<br>(alarm can be silenced for 5 minutes) | The controlling skin temperature probe (only in the Skin mode) is mechanically connected but electrically open or short-circuited. The associated monitoring display shows "----". | Replace skin probe. |
| Advisory | ***Skin Mode Disabled*** | The controller is configured for Air only operation and the Skin mode is selected. | If skin mode is desired, select Skin mode in the System Configuration menu (see "System Configuration Menu" on page 98). |
| Caution | ***Skin Probe Disconnect***<br>(alarm can be silenced for 5 minutes) | The Skin1 temperature probe (only in the Skin mode) is removed from the sensor module. The associated monitoring display goes blank. | Reconnect skin probe to the sensor module. |
| Advisory | ***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. |
| Caution | ***Stuck Key*** | There is a malfunction of the hard keys on the front panel of the controller. | Turn off the incubator and remove it from service. |

## Alarm Conditions without Alarm Messages

The following table contains causes and remedies for alarm conditions that are not indicated by an alarm message.

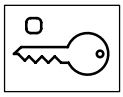
| Alarm Condition | Probable Cause | Remedy |
|---|---|---|
| There is no system power, and the ***Power Failure*** alarm does not activate. | The main power switch is OFF. | Turn on the main power switch on the stand. |
| There is system power, but there is no screen display and the ***Power Failure*** alarm does not activate. | The incubator power switch is OFF. | Turn on the incubator power switch located on the controller on the front of the machine. |
| ***Power Failure*** alarm activates (audible alarm 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. If the power cable is detachable, also make sure that it is firmly attached to the VHA stand receptacle. |
| | The power cable to the incubator on the front of the machine is unplugged. | Attach the power cable to the incubator receptacle. |
| | Over-current protection fuses in the VHA stand have blown. | Turn off the incubator and replace the fuses (see "Fuse Replacement" on page 131). |
| No data is displayed on screen at system start-up (only static/noise). | Internal controller failure. | Turn off the incubator and remove it from service. |
| The VHA stand does not move up or down. | The main power switch is OFF. | Turn on the main power switch on the stand. |
| | Over-current protection fuses in the VHA stand have blown. | Turn off the incubator and replace the fuses (see "Fuse Replacement" on page 131). |
| | The VHA stand was operated for more than 3 minutes continuously which could result in the VHA stand motor overheating. | Wait 10 minutes and try to operate the stand again. |

| Alarm Condition | Probable 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 132). |
| | 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. |

## System Prompt Messages

The following messages alert the user of conditions that are not hazardous but require attention or correction. They do not generate any audible or LED alarms.

| System Prompt Message | Probable 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. |
| ***Alarm Reset*** | A previously latched alarm condition has been cleared with the ***Alarm Silence/Reset*** key. | 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 unit to qualified service personnel. |
| ***Cal Pass*** | The oxygen calibration passes. | 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. |
| ***Cal Failed*** | The scale fails the 5 kg calibration. | Retry calibration. If it fails again, remove the scale from service. |
| ***Check Settings*** | A failure is detected with the controller non-volatile memory test. | Check all settings to make sure they are configured correctly. |

| System Prompt Message | Probable Cause | Remedy |
|---|---|---|
| ***Check Skin1 Probe*** | This message is displayed in the Air mode if the Skin1 probe is electrically open or shorted; or if in the air mode the two Skin1 probe thermistors deviate by more than 0.8 °C; or if in either Air or Skin mode, the Skin1 probe is < 16.9 °C. | Replace the skin probe. |
| ***Check Skin2 Probe*** | This message is displayed in the Air mode if the Skin2 probe is electrically open or shorted; or if in the Air mode the two Skin2 probe thermistors deviate by more than 0.8 °C; or if in either Air or Skin mode, the Skin2 probe is < 16.9 °C. | Replace the skin probe. |
| ***Clear Mattress*** | A scale calibration is attempted, and there is >1 Kg on the mattress. | Remove all items from the mattress. |
| ***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. |
| ***Not Installed (Humidity)*** | Humidity control is attempted, but the humidity system is not installed. | Install the humidity system. |
| | Humidity control is attempted, but the humidity system is not activated. | Set up the humidity system in the System Configuration menu (see "System Configuration Menu" on page 98). |
| ***Not Installed (Oxygen)*** | 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 98). |
| ***Oxygen Cal Required*** | This message is displayed when recalibration is required to use the servo oxygen control. This occurs after seven days of continuous oxygen control. | Calibrate the oxygen sensor. |
| ***Performing Power-Up Tests*** | This message is displayed after power is supplied from the ***Main Power*** switch and the system is performing the self-test. | Information only, no action required. |

| System Prompt Message | Probable Cause | Remedy |
|---|---|---|
| ***Procedural Silence*** | This message is displayed when no alarm conditions are present and the ***Alarm Silence/Reset*** key is pressed. | Information only, no action required. |
| ***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. | Turn off the scale and remove it from service. |
| ***Slide Out Sensor*** | This message is displayed when the ***Cal*** soft key is pressed, but the sensor module is not pulled out into the calibration position. | Slide the sensor module out to the calibration position. |
| ***Too Much Weight*** | The controller determines that the weight placed on the scale is in excess of the scale measurement range. | Remove excess weight. |
| ***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 mattress tray during calibration (for example, no mattress) | Replace mattress and recalibrate. |
| ***Zeroing Failed*** | This message is displayed when an additional weight on the mattress exceeds 4000 ± 500 g when zeroing during infant weight. | Remove additional weight and retry zeroing. If it fails again, remove scale from service. |

# Cleaning, Disinfection, and Sterilization

## Overview

This section of the manual provides instructions for the disassembly and cleaning of the Isolette 8000 incubator.

**WARNING**

**Always clean and disinfect the device before placing it into service. Noncompliance may result in death or serious injury.**

**WARNING**

**Use all cleaning products as recommended by the manufacturer. Noncompliance may result in death or serious injury.**

**WARNING**

**When performing cleaning and maintenance procedures, confirm that the oxygen supply is turned off and that the equipment is disconnected from the oxygen supply. A fire and explosion hazard exists when performing cleaning and maintenance procedures in an oxygen-enriched environment. Noncompliance may result in death or serious injury.**

**WARNING**

**Unplug the unit from its power source before cleaning or maintenance. Noncompliance may result in death or serious injury.**

**WARNING**

**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. Noncompliance may result in death or serious injury.**

**CAUTION**

Do not expose the unit to excessive moisture that would allow for liquid pooling. Noncompliance may result in injury or equipment damage.

**CAUTION**

Do not use harsh cleansers/detergents such as scouring pads or heavy-duty grease removers or solvents, such as acetone. Noncompliance may result in injury or equipment damage.

## General Cleaning

Dräger Medical recommends cleaning the unit with detergent and warm water. Do not use excessive liquid or harsh cleansers. The most effective way to clean the unit is to first disassemble the unit, and then group the parts and assemblies in categories according to the method of cleaning required. Do not use alcohol-based products to clean acrylic; alcohol clouds the surface.

At a minimum, thoroughly clean and disinfect the incubator upon discharge of an infant. However, depending on individual facility policy, perform this as often as daily, if desired.

To remove difficult spots or stains, Dräger Medical recommends the use of standard household cleansers and a soft bristle brush. To loosen heavy, dried-on soil, saturation of the spot could be required.

**CAUTION**

Do not autoclave the device, with the exception of components specifically identified in this chapter. Noncompliance may result in injury or equipment damage.

## Disinfecting

- Use an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent only after the unit is empty and disassembled (see "Disassembly for Cleaning" on page 115).

**NOTE**
For US markets, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA).

- To prevent damage to the incubator, avoid disinfectants containing aromatic alcohols (e.g., phenoxyethanol, benzyl alcohol) and/or disinfectants based on quaternary ammonium compounds (e.g., benzalkonium chloride) coupled with a high pH such as terralin®protect.
- Dilute the disinfectant as specified on the manufacturer label.
- Thoroughly rinse and dry the unit before putting it back into use.
- After removing all solid wastes and contaminants from the disassembled parts, refer to the respective cleaning procedures for the individual parts.

## Disassembly for Cleaning

For routine cleaning, there is no need to separate the hood and shell assemblies from the stand. If separation is necessary, contact DrägerService.

**CAUTION**
Before disassembling the hood and shell assemblies, remove accessories mounted to device. Noncompliance may result in injury or equipment damage.

- Unplug the unit from its power source.

## Mattress Tray, X-Ray Tray, Main Deck, and Optional Scale

**1** Disconnect the cables from the sensor module.

**2** Slowly raise the hood.

**3** Remove the mattress.

**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 from the mattress tray.

**8** Remove the mattress tray and x-ray tray (**A**).

**9** Remove the mattress tilt bars (**B**).

**10** Remove the main deck (**C**).

## Heater Radiator and Impeller

**1** On machines without the humidity system option, remove the heater/impeller cover (**D**).

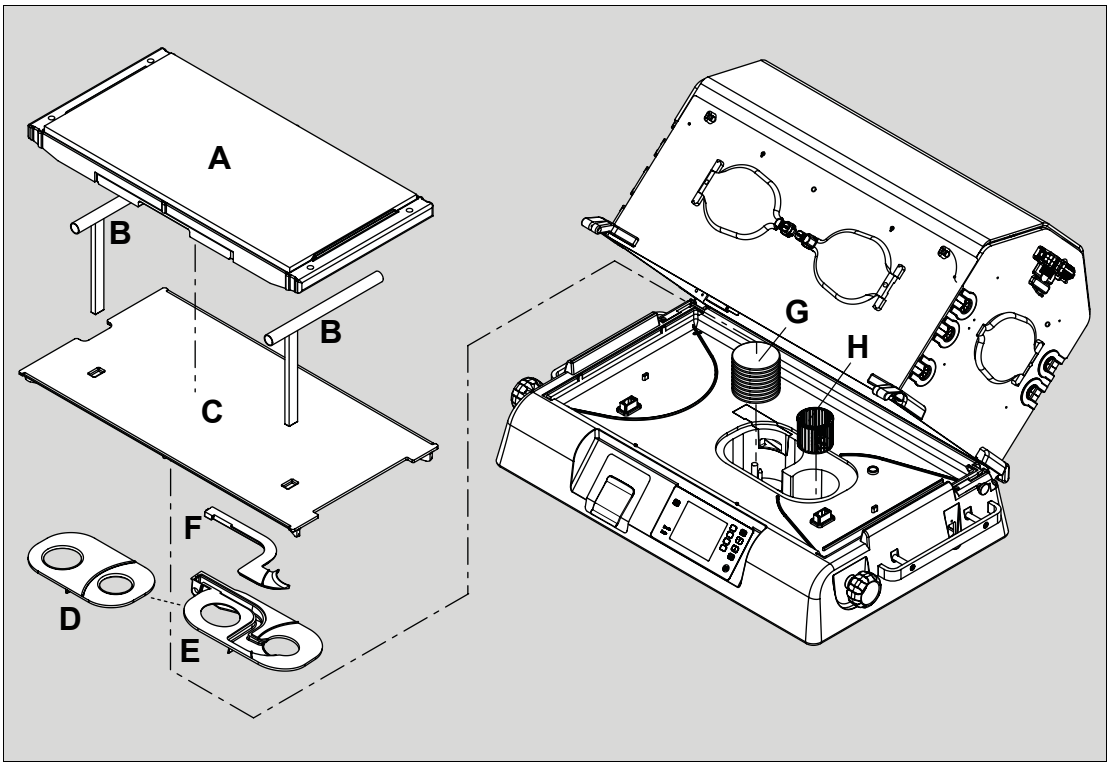
**2** On machines with the humidity system option, remove the heater/impeller cover (**E**) and the duct cover (**F**).

**WARNING**

**The heater can be sufficiently hot to cause burns. Avoid removing or touching the heater until the unit has been switched off for at least 45 minutes. Noncompliance may result in death or serious injury.**

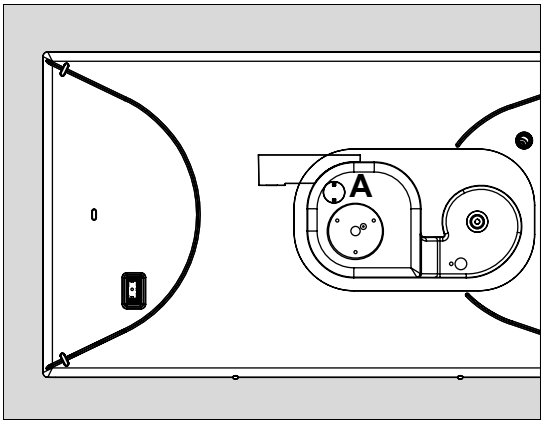
**3** When the unit has cooled, remove the heater radiator (**G**).

**4** Pull the impeller (**H**) off the motor shaft.



## Drain Plug with O-ring (if installed)

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




## Condensation Management System (if installed)

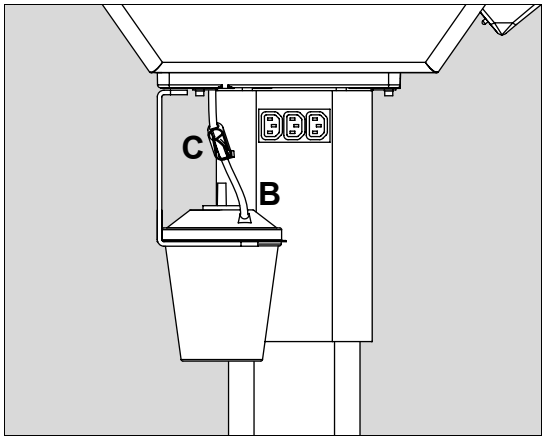
**CAUTION**
Do not clean and reuse single-use components. Noncompliance may result in injury or equipment damage.

**CAUTION**
Liquid in the collection bottle can contain patient fluids and should be handled according to hospital guidelines. Noncompliance may result in injury or equipment damage.

**CAUTION**
If any fluids spill or leak around the device, wipe the area dry to prevent slipping hazard. Noncompliance may result in injury or equipment damage.

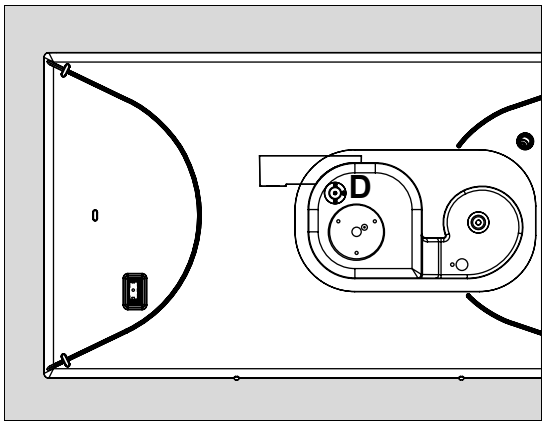
1 Disconnect the condensation hose (**B**) from the collection bottle located underneath the left side of the incubator.

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

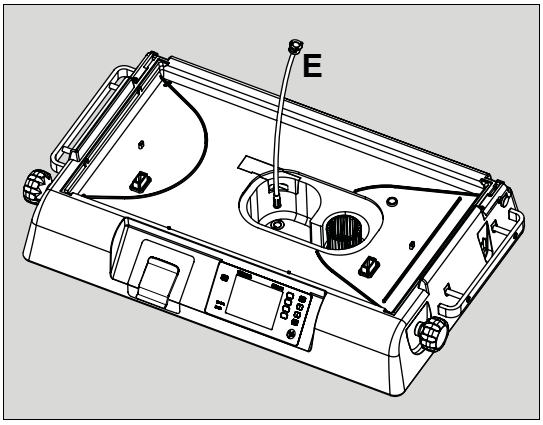



3 Remove the condensation hose:

- Turn the plug (**D**) at the bottom of the heater well a quarter turn counterclockwise.



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

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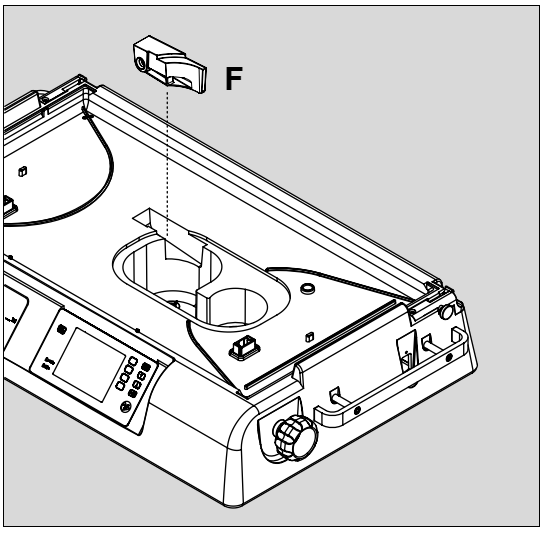
**4** Discard the collection bottle and hose/plug assembly.

## Manifold (if installed)

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

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## Humidity Reservoir Assembly (if installed)

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

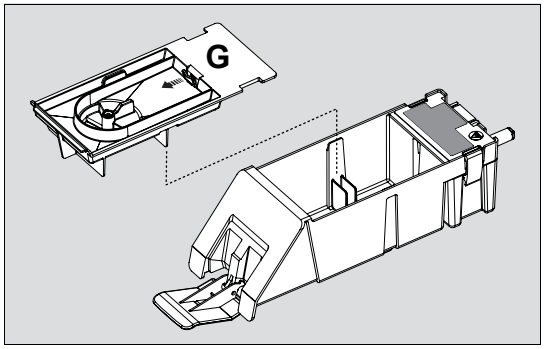
**WARNING**

**The water in the evaporator chamber can be sufficiently hot to cause burns. Use caution when emptying or handling the reservoir. Noncompliance may result in death or serious injury.**

**WARNING**

**The evaporator can be sufficiently hot to cause burns. Avoid removing or touching the evaporator until the humidity reservoir has been disconnected from the incubator for at least 45 minutes. Noncompliance may result in death or serious injury.**

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

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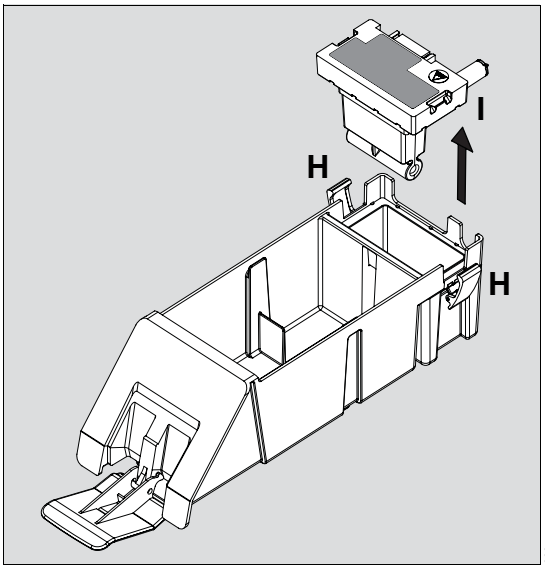
**3** Empty any water remaining in the reservoir.

**CAUTION**

Do not use sharp tools to remove the evaporator. Noncompliance may result in injury or equipment damage.

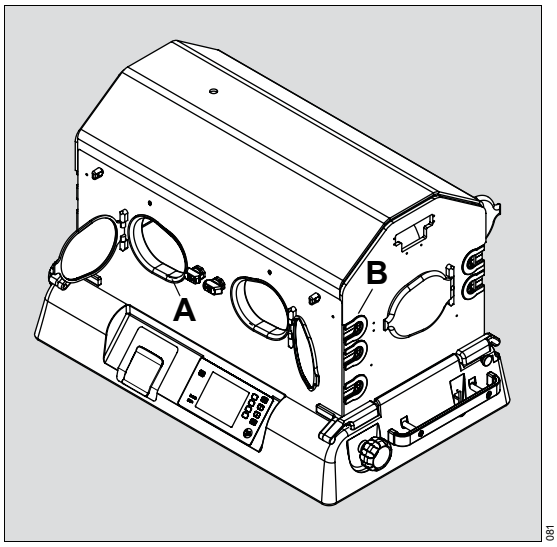
**4** Lift up on the latches on the side of the humidity reservoir (**H**) and remove the evaporator (**I**) from the evaporator chamber.




## Access Door Gaskets, Tubing Grommets, and Iris Port Sleeves (if installed)

**1** Pull the access door gaskets (**A**) from all sides of the hood to remove them.

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



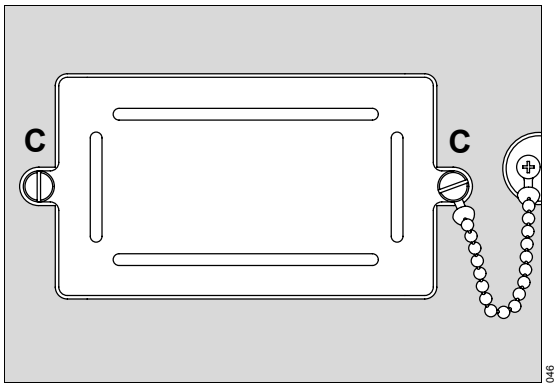

**3** If equipped with the optional iris ports on the side panels, remove the disposable iris port sleeves from the retainer rings.

**4** Wipe the retainer rings clean.

**5** Discard disposable sleeves.

## Air Intake Microfilter

Loosen the two thumbscrews (**C)** to remove the air intake microfilter cover located under the shell assembly on the back of the device.



## Cleaning Procedures

### Reusable Skin Temperature Probe

Using a facility-approved cleanser/detergent, thoroughly clean all surfaces, and dry them with a clean cloth or paper towel.

### Access Door Gaskets and Tubing Grommets

1 Place the access door gaskets and tubing grommets into a suitable container filled with a cleanser/disinfectant.

2 Allow them to soak as recommended by the manufacturer of the cleaning solution.

3 Remove them, and dry them thoroughly with a clean cloth or paper towel.

### Controller, Shell, Stand, and Condensation Management System Bracket (if installed)

**CAUTION**
When cleaning the interior of the incubator shell, prevent liquids from entering the motor shaft opening. Noncompliance may result in injury or equipment damage.

**CAUTION**
When cleaning the surface of the air circulation well, prevent liquids from entering the motor shaft opening. Noncompliance may result in injury or equipment damage.

Use an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent to clean all surfaces thoroughly. Then dry with a clean cloth or paper towel.

**NOTE**
For US markets, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA).

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 machines without the humidity system option).

**CAUTION**
On machines with the condensation management system option, the hose/plug assembly is disposable and should not be cleaned and reused. Noncompliance may result in injury or equipment damage.

In addition, check for fluids that may have dripped onto the bottom surface of the humidity reservoir opening. If fluids are present, use a clean paper towel dampened with a cleaner/disinfectant to wipe the surfaces dry.

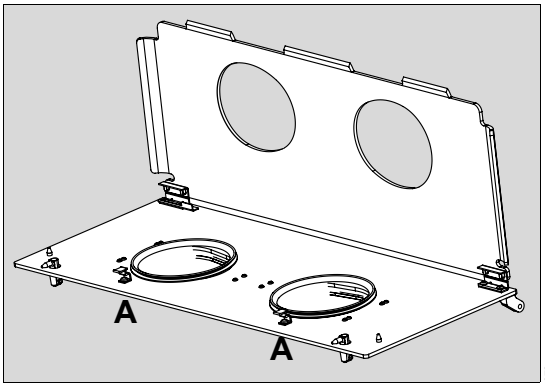
### Sensor Module, Hood, and Inner Walls

**CAUTION**
Alcohol can cause crazing (small stress cracks) of the clear acrylic. Do not use alcohol for cleaning. Noncompliance may result in injury or equipment damage.

**CAUTION**
Do not expose the clear acrylic to direct radiation from germicidal lamps. Ultraviolet radiation from these sources can cause cracking and/or crazing of the acrylic surface. Noncompliance may result in injury or equipment damage.

**1** Press the catches (**A**) located at the top of the inner wall to release the inner wall.

**NOTE**
The inner walls are hinged on the access panels of the incubator.




**2** Use an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent to clean all surfaces of the hood thoroughly, including the sensor module, inner walls, access doors, and access panels.

**NOTE**
For US markets, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA).

**3** Be sure to clean all holes and indentations; then dry with a clean cloth or paper towel.

## Heater Radiator and Fan Impeller

**WARNING**
**Failure to clean the heater radiator and fan impeller could result in sufficient lint build-up to reduce airflow, which could affect the temperature control and cause high oxygen concentrations. Noncompliance may result in death or serious injury.**

**CAUTION**
Do not autoclave parts when disassembling for cleaning. Noncompliance may result in injury or equipment damage.

**1** Remove any lint build-up on the heater radiator and fan impeller.

**2** Wipe the heater assembly using an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent.

Do **not** immerse the heater assembly in liquid.

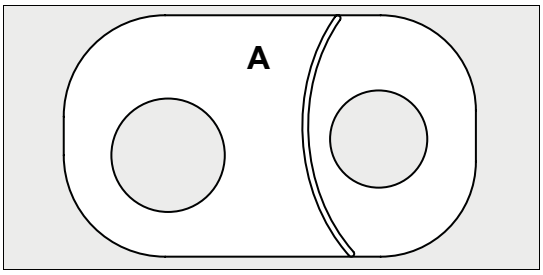
**NOTE**
For US markets, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA).

## Manifold (if installed)

On machines without the humidity system, wipe the manifold clean using an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent. The manifold can be steam autoclaved at 121°C (250°F) for 20 minutes or 134°C (273°F) for 5 minutes.

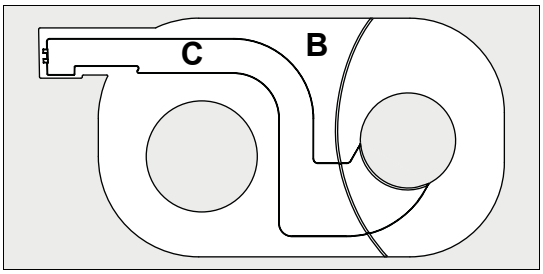
## Heater/Impeller Cover and Duct Cover (if installed)

- On machines without the humidity system option, use an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent to clean the heater/impeller cover (**A**) thoroughly. Then dry with a clean cloth or paper towel.




**NOTE**
For US markets, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA).

- On machines with the humidity system option, wipe the heater/impeller cover (**B**) and duct cover (**C**) clean using an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent. The heater/impeller cover and duct cover can be steam autoclaved at 121°C (250°F) for 20 minutes or 134°C (273°F) for 5 minutes.




## Humidity Reservoir Assembly (if installed)

Wipe the humidity reservoir assembly clean using an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent. The humidity reservoir assembly can be steam autoclaved at 121°C (250°F) for 20 minutes or 134°C (273°F) for 5 minutes.

**CAUTION**
The humidity system should be cleaned at least every 7 days. Noncompliance may result in injury or equipment damage.

## Evaporator

**CAUTION**
Do not autoclave the evaporator. Noncompliance may result in injury or equipment damage.

Wipe the evaporator clean using an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent.

**NOTE**
Mineral deposits may form on the evaporator, depending on the quality of the distilled water. In case of mineral buildup, wipe the evaporator with vinegar.

**CAUTION**
The humidity system should be cleaned at least every 7 days. Noncompliance may result in injury or equipment damage.

## Air Intake Microfilter Chamber and Cover

**WARNING**

**A dirty air intake microfilter could affect performance or cause carbon dioxide (CO2) build-up. Ensure that the filter is checked on a routine basis commensurate with local conditions and replaced as recommended in "Maintenance Intervals" on page 128. Particularly, if the unit is used in an unusually dusty environment, more frequent replacements may be necessary. Noncompliance may result in death or serious injury.**

**CAUTION**

Do not attempt to clean the air intake microfilter. Noncompliance may result in injury or equipment damage.

Do not clean the air intake microfilter (see "Air Intake Microfilter Maintenance" on page 131).

Before installing a new air intake microfilter, clean the microfilter chamber and its cover with an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent.

**NOTE**

For US markets, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA).

## Rail and Accessories, Drawers, Cylinder Mounts, Monitor Shelf, and I.V. Pole (Optional Features)

Clean these items with mild detergent and warm water. Do not use excessive liquid or harsh cleansers.

## Mattress, Mattress Tray, X-Ray Tray, Main Deck, Scale (Optional), and Mattress Tilt Bars

1 Using an intermediate level, tuberculocidal cleanser/disinfectant, such as CaviCide Surface Disinfectant/Decontaminant Cleaner, or equivalent, thoroughly clean all surfaces of the following:

- Mattress
- Mattress tray
- X-ray tray
- Main deck
- Scale (optional)
- Mattress tilt bars

**NOTE**

For US markets, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA).

**NOTE**

For cleaning instructions for the SoftBed mattress, see the SoftBed instructions for use.

2 Dry all surfaces with a clean cloth or paper towel.

## Reassembly After Cleaning

**CAUTION**
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 unit may be compromised or degraded. Noncompliance may result in injury or equipment damage.

**NOTE**
Harsh cleaning agents may attack some of the plastics used in the patient compartment.

1 Inspect all cleaned components for any breakage or cracks before reassembling into the incubator.

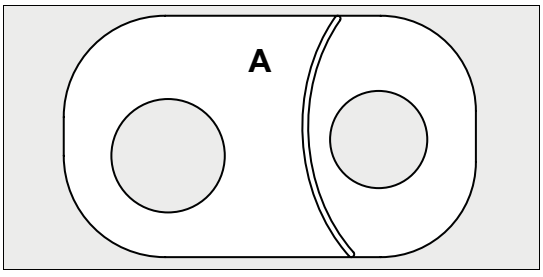
2 On machines without the humidity system option, reinstall the manifold.

3 On machines without the condensation management system, reinstall the drain plug in the bottom of the heater well.

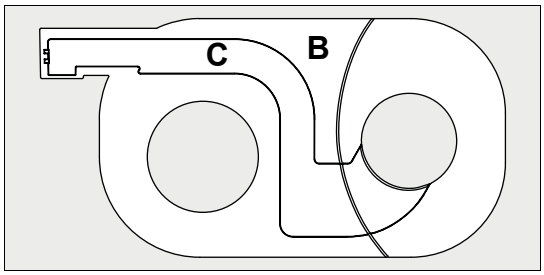
4 On machines with the condensation management system, install a new collection bottle, condensation hose/plug assembly, and clamp (see "Condensation Management System Replacement (if installed)" on page 132).

5 Install the heater radiator and fan impeller.

6 On machines without the humidity system option, install the heater/impeller cover (**A**).




7 On machines with the humidity system option, install the heater/impeller cover (**B**) and the duct cover (**C**).




**WARNING**
**The humidity system with the heater/impeller cover with duct cover must be used with software version 4.00 or higher. Noncompliance with this warning may result in death or serious injury.**

**CAUTION**
Make sure that the hood is raised before attempting to install the main deck. The hood contains four tabs (one at each corner) which keep the deck securely in place. Installing the main deck when the hood is down may result in damage to the main deck and/or jamming of the hood in place. Noncompliance may result in injury or equipment damage.

8 Install the main deck.

9 Install the mattress tilt bars on the main deck.

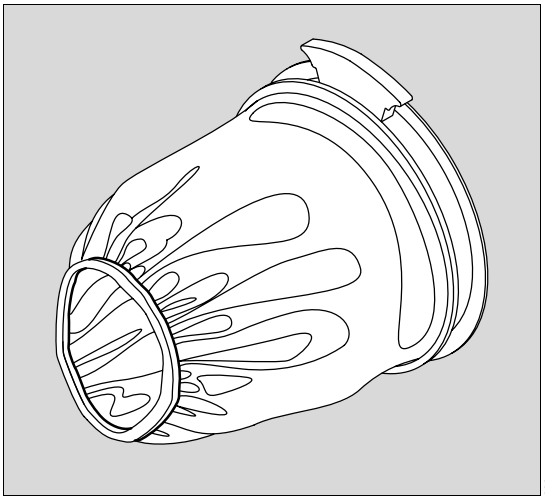
10 Install the mattress tray, x-ray tray, and scale (if installed).

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.

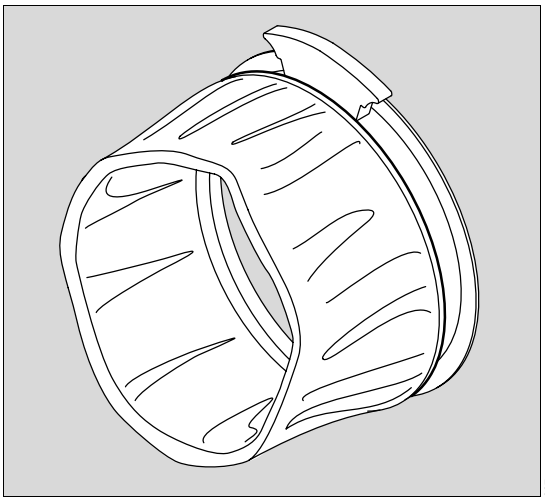
12 Install the mattress.

**13** If equipped with the optional iris ports on the side panels, install the new disposable or reusable iris port sleeves:

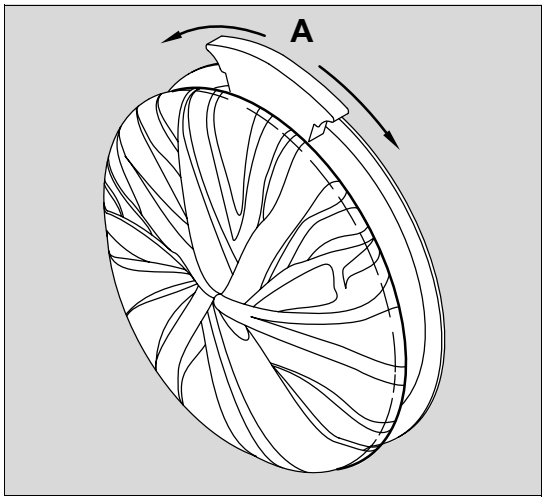
- Install the smaller diameter elastic band of a new sleeve over the inner ring of the port housing.


086

- Fold back, and slip the larger elastic band over the outer ring of the port housing.


087

- Rotate the outer ring (**A**) to close. If properly installed, the sleeve opens again when rotation is reversed.



088

**14** Install the tubing grommets into the front and rear edges of each side of the hood.

**NOTE**
Replace tubing grommets if distorted or torn.

**15** Install an access door gasket on each access door opening.

**16** Ensure that the access doors latch with slight pressure, and open when the latch lever is pressed.

**17** If the air intake microfilter is damaged, visibly dirty, or older than three months, replace it.

**18** Install the air intake microfilter cover, and tighten the two thumbscrews (see page 131).

**19** On machines with the humidity system option:

- Reinstall the evaporator in the humidity reservoir assembly. Insert it fully into the evaporator chamber and secure it by closing the two latches.
- Reinstall the lid on the humidity reservoir and push back the latch on top of the lid to secure it.
- Insert the humidity 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 required, reattach any accessories previously removed from the device.

**21** Perform a complete functional checkout before returning the device to service. Refer to "Operational Checkout Procedure" on page 57.

# Maintenance

## Overview

**WARNING**

**If the incubator is turned off, or has been out of service for cleaning or maintenance, refer to the "Operational Checkout Procedure" on page 57 and perform the function checks. Noncompliance may result in death or serious injury.**

**CAUTION**

Clean and disinfect device or device parts before each maintenance step and also when returning for repair. Noncompliance may result in injury or equipment damage.

**NOTE**

Properly trained personnel should routinely inspect the patient compartments for signs of breakage and should replace assemblies before placing the incubator into service.

## Maintenance Intervals

Qualified service personnel should completely check and calibrate the equipment at least annually. See the Maintenance Interval table for specific recommended maintenance intervals.

| Maintenance Intervals | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **When Necessary** | **Daily** | **Weekly** | **Every Three Months** | **Every Six Months** | **Once a Year** | **Every Two Years** | **Every Three Years** | **Every Six Years** | **Personnel Responsible** |
| **Replaceable Parts:** | | | | | | | | | | |
| Air intake microfilter | X | | | X | | | | | | Medical and technical personnel |
| Mattress | X | | | | | | | | | Medical and technical personnel |
| Grommets, gaskets | X[1)] | | | | | | | | | Medical and technical personnel |
| Cuffs and iris port sleeves | X[1)2)] | | X[1)2)] | | | | | | | Medical and technical personnel |
| Skin temperature probe | | | X[3)] | | | | | | | Medical and technical personnel |
| Probe covers | | | X[3)] | | | | | | | Medical and technical personnel |
| $O_2$ sensors | X[2)] | | | | | X[2)] | | | | Technical personnel |
| Latch, heat shield | | | | | | | X | | | Technical personnel |
| $O_2$ solenoid valve | | | | | | | X[2)] | | | Qualified service personnel |
| Fan motor including vibration isolators | | | | | | | | X | | Qualified service personnel |
| Fan in sensor module | | | | | | | | X | | Qualified service personnel |
| Fan in controller | | | | | | | | X | | Qualified service personnel |
| $O_2$ membrane and filter disc | | | | | | | | X | | Qualified service personnel |
| $O_2$ pressure reducer | | | | | | | | | X[2)] | Qualified service personnel |
| Humidity reservoir assembly | | | | | | | X[2)] | | | Medical and technical personnel |
| Evaporator | | | | | | | | X[2)] | | Medical and technical personnel |

| Maintenance Intervals | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **When Necessary** | **Daily** | **Weekly** | **Every Three Months** | **Every Six Months** | **Once a Year** | **Every Two Years** | **Every Three Years** | **Every Six Years** | **Personnel Responsible** |
| Manifold<br>(without humidity system option) | | | | | | | X | | | Medical and technical personnel |
| Heater/impeller cover with duct cover<br>(with humidity system option only) | | | | | | | X | | | Medical and technical personnel |
| Collection bottle, condensation management system | | | X[2)3)] | | | | | | | Medical and technical personnel |
| Hose/plug assembly, condensation management system | | | X[2)3)] | | | | | | | Medical and technical personnel |
| Drain plug with O-ring | | | | | | X[2)] | | | | Medical and technical personnel |
| **Maintenance:** | | | | | | | | | | |
| Device servicing and maintenance | | | | | | X | | | | Qualified service personnel |
| **Calibration:** | | | | | | | | | | |
| $O_2$ Sensors | | | X[2)4)] | | | | | | | Medical and technical personnel |
| Non-OIML/NAWI Scales | X[2)] | | | | X[2)] | | | | | Medical and technical personnel |
| OIML/NAWI Scales | X[2)5)] | | | | | X[2)5)] | | | | Qualified service personnel |

1) Replace if the material becomes brittle or sticky or if strips of material have become detached.
2) If installed.
3) And additionally 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 at the installation site.

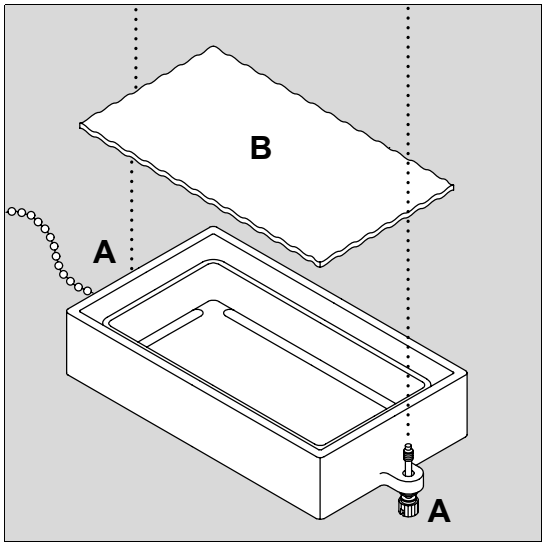
## Air Intake Microfilter Maintenance

Check the air intake microfilter during each preventive maintenance cycle. Replace the air intake microfilter if it is damaged, visibly dirty, or older than three months.

**1** Loosen the two thumbscrews (**A**) to remove the air intake microfilter cover.

**2** Remove the old microfilter and install a new one (**B**). Orient the microfilter so that the side with the text “THIS SIDE OUT” faces the inside of the microfilter cover.

**3** Install the air intake microfilter cover, and tighten the air intake microfilter cover.



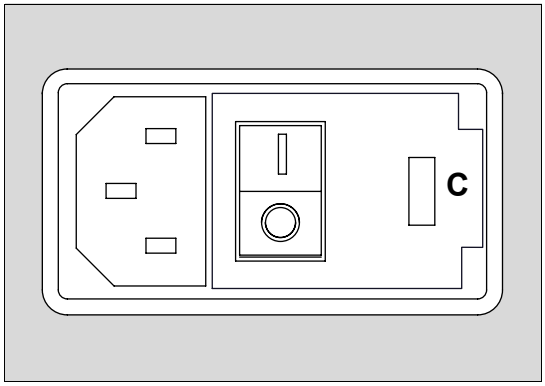

## Fuse Replacement

**1** Disconnect the Isolette 8000 from electrical power.

**2** Using a small screwdriver or similar tool, pry open the fuse holder cover (**C**) on the power switch module located on the VHA stand.

**3** Remove the fuse holder and replace the fuse (or fuses).

**4** Reinstall the fuse holder and reinstall the cover onto the power switch module.



## Condensation Management System Replacement (if installed)

**CAUTION**
Do not clean and reuse single-use components. Noncompliance may result in injury or equipment damage.

**CAUTION**
Liquid in the collection bottle can contain patient fluids and should be handled according to hospital guidelines. Noncompliance may result in injury or equipment damage.

**CAUTION**
If any fluids spill or leak around the device, wipe the area dry to prevent slipping hazard. Noncompliance may result in injury or equipment damage.

**CAUTION**
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. Noncompliance may result in injury or equipment damage.

The condensation management system must be replaced weekly and, additionally, 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 mattress tray.

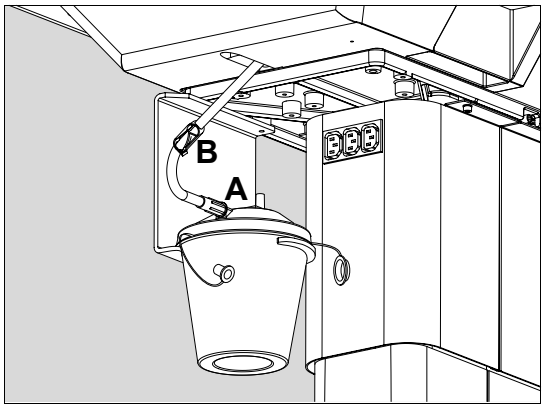
**7** Remove the mattress tray and x-ray tray.

**8** Remove the mattress tilt bars.

**9** Remove the main deck.

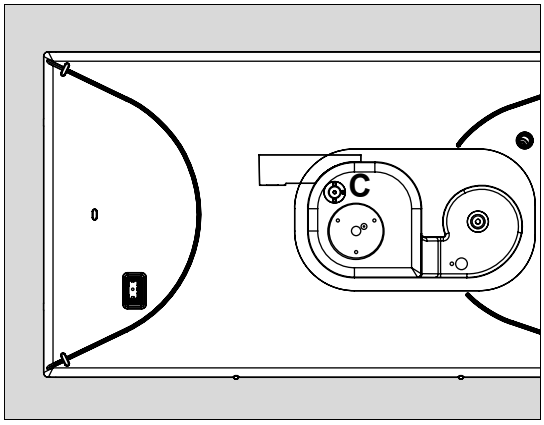
**10** Disconnect the condensation hose (**A**) from the collection bottle located underneath the left side of the incubator.

**11** Remove the clamp (**B**) from the condensation hose.

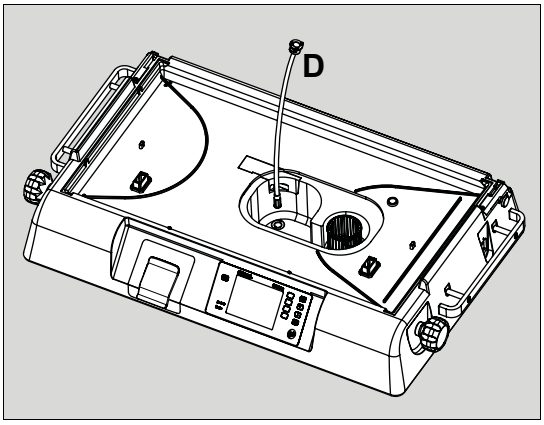



**12** Remove the condensation hose:

- Turn the plug (**C**) at the bottom of the heater well a quarter turn counterclockwise.



- 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 a quarter turn clockwise.

**17** Slide the new collection bottle onto the bracket located underneath the left side of the incubator (**E**).

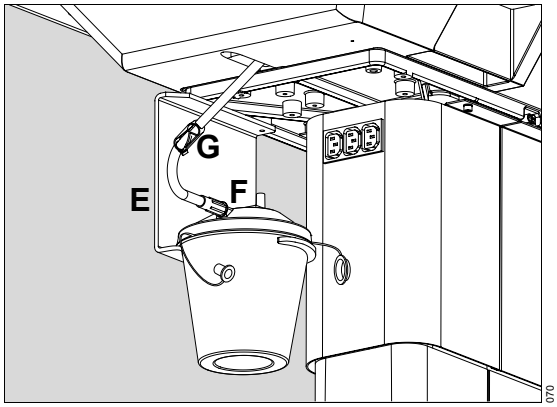
**18** Remove the caps from the ports on the collection bottle.

**NOTE**

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

**19** Connect the condensation management hose to the patient port (**F**) on the side of the collection bottle.

**20** Attach the clamp to the hose (**G**).




**21** Install the heater/impeller cover.

**22** Install the main deck.

**23** Install the mattress tilt bars on the main deck.

**24** Install the mattress tray, x-ray tray, and scale (optional).

**25** Install the mattress.

**26** Close the hood.

## Collection Bottle Replacement (if installed)

**CAUTION**

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. Noncompliance may result in injury or equipment damage.

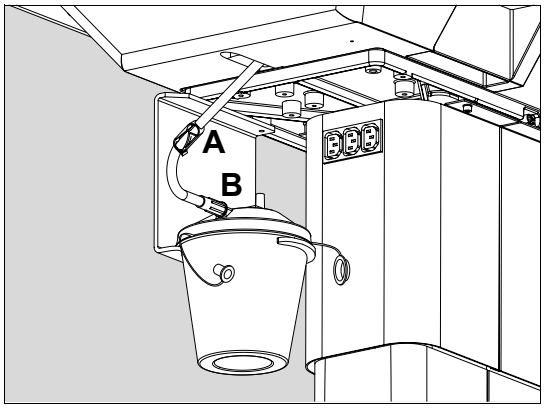
To replace the bottle if it becomes full during operation:

1. Clamp the condensation management hose using the attached clamp (**A**).
2. Disconnect the hose from the collection bottle.
3. Discard the bottle.
4. Slide the new collection bottle onto the bracket located underneath the left side of the incubator.
5. Remove the caps from the ports on the collection bottle.

**NOTE**

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 (**B**) on the side of the collection bottle.
7. Unclamp the hose.



# Disposal

## Safety Information

**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, it may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger Medical has authorized a company to collect and dispose of this device. To initiate take-back or for further information, visit us on the Internet at www.draeger-medical.com and navigate to the DrägerService area where you will find a link to "WEEE". If you have no access to our website, contact your local Dräger Medical Organization.

## Disposal of the medical device

When disposing of the medical device:

- Consult the relevant waste disposal company for appropriate disposal.
- Observe the applicable local regulations.

# Technical Data

## Isolette 8000 System

| | |
|---|---|
| **Device Classification** | |
| Protection class | Class I, Type BF, continuous operation, not AP |
| Ingress of liquids | IPX0 |
| Classification in accordance with EU Directive 93/42/EEC | IIb |
| UMDNS code/GMDN code | 12-113/36025 |
| **Physical Attributes** | |
| Height | 132.6 cm to 152.7 cm (52.2 in to 60.1 in) |
| Width | 104 cm (41 in) |
| Depth | 75 cm (29.5 in) |
| Weight (without options/accessories) | 93 kg (205 lb) ± 3% |
| SoftBed mattress size | 40 x 76 x 2.3 cm (15.7 x 29.9 x 0.9 in) |
| Mattress Trendelenburg/reverse Trendelenburg tilt | Continuously variable to 12° ± 1° |
| **Environmental Requirements** | |
| **Operating** | |
| Temperature | 20°C (68°F) to 30°C (86°F) |
| Humidity | 5% to 95% relative humidity, non-condensing |
| **Storage** | |
| Temperature | -25°C (-13°F) to 60°C (140°F) |
| Humidity | 5% to 95% relative humidity, non-condensing |
| **Electrical Requirements** | |
| Power requirements for 100V/120V units | 100 V/120 V, 50/60 Hz, 9.9 A maximum |
| Power requirements for 230V units | 230 V, 50/60 Hz, 9.9 A maximum |
| Convenience outlets (120V) | 120 V, 50/60 Hz, 300 W maximum |
| Convenience outlets (230V) | 230 V, 50/60 Hz, 300 W maximum |
| Chassis current leakage (100V and 120V) | ≤ 300 µA |
| Chassis current leakage (230V) | ≤ 500 µA |
| **Performance** | |
| Air mode control temperature range | 20.0°C (68.0°F) to 37.0°C (98.6°F) |
| Air mode control override temperature range | 37.0°C (98.6°F) to 39.0°C (102.2°F) |
| Air mode control temperature display range | 15.0°C (59°F) to 45.0°C (113°F) |
| Skin mode control temperature range | 34.0°C (93.2°F) to 37.0°C (98.6°F) |
| Skin mode control override temperature range | 37.0°C (98.6°F) to 38.0°C (100.4°F) |
| Skin mode control temperature display range | 15.0°C (59°F) to 45.0°C (113°F) |

| | |
|---|---|
| Temperature rise time at 22°C (72°F) ambient | < 35 min |
| Temperature variability | < 0.5°C |
| Temperature overshoot | < 0.5°C maximum |
| Temperature uniformity with a level mattress | < 0.8°C |
| Correlation of the indicated air temperature to the actual incubator temperature (after the incubator temperature equilibrium is reached) | ≤ 0.8°C |
| Noise level within the hood environment | ≤ 47 dBa (without Servo Oxygen Control) |
| Air velocity over the mattress | < 10 cm/second (4 in/second); average of five points at 10 cm (4 in) above the mattress |
| Carbon Dioxide (CO2) level (per EN60601-2-19, Clause 105) | < 0.5% |
| **Operational** | |
| Set point data retention | power failures lasting <10 min |
| Alarm sound level (per IEC 60601-1-8) | >65 dBa |
| **Standards Compliance** | |
| Standards | – IEC 60601-1 (EN 60601-1) Medical Electrical Equipment Part 1: General Requirements for Safety<br>– IEC 60601-1-2 (EN 60601-1-2) Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility; Requirements and Tests<br>– IEC 60601-2-19 (EN 60601-2-19) Particular Requirements for Safety - Specification for Baby Incubators<br>– EN 45501 Metrological Aspects of Non-Automatic Weighing Instruments |

## Humidity System (Option)

| | |
|---|---|
| Humidity control operating time after refilling | >24 hours @ 85% RH and 35°C, in Air 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 control accuracy between 10% and 90% @ 20°C (68°F) to 40°C (104°F) | ± 6% RH |
| Humidity display range | 10% to 100% |
| Maximum humidity levels | >85% (incubator set temp at 39°C, with at least 30% RH at ambient) |

## Oxygen Control System

### 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 |

### 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 |

## Non-OIML/NAWI Weighing System (Accessory)

| | |
|---|---|
| Weight display range | 0 kg (0 lb) to 7 kg (15.4 lb) |
| Weight display resolution | 1.0 g or 1 oz |
| Weight display accuracy | 0 - 2 kg: ±2 g |
| | > 2 kg: ±5 g |
| Maximum tare weight | 4.0 kg (8.82 lb) ±0.5 kg |

## OIML/NAWI Weighing System (Accessory)

| | |
|---|---|
| Weight display range | 0 kg (0 lb) to 7 kg (15.4 lb) |
| Weight display resolution | 10 g or 1 oz |
| Weight display accuracy | 10 g (.022 lb) |
| Maximum tare weight | 4.0 kg (8.82 lb) ±0.5 kg |
| Verification scale interval | 10 g (.022 lb) |
| Scale level sensitivity | 90 min (1 min=1/60 degree) |
| Weight display update rate | 1 second |

## Rail Accessory Weight Limitations

| | |
|---|---|
| Rail system | total rail system weight not to exceed 13.6 kg (30 lb); 6.8 kg (15 lb) per side |
| Basket 6.5 W x 4.0 D x 5.0 H | 2.2 kg (5 lb) |
| Basket 11.0 W x 4.0 D x 4.0 H | 2.2 kg (5 lb) |
| Basket - pivoting | 2.2 kg (5 lb) |
| Chart holder | 2.2 kg (5 lb) |
| Hinged Mayo tray 13.5 W x 9.75 D | 2.2 kg (5 lb) |
| Cable organizer | 2.2 kg (5 lb) |
| Horizontal cord wrap | 2.2 kg (5 lb) |
| Standard cam adapter | 2.2 kg (5 lb) |
| Cam adapter, threaded mount | 2.2 kg (5 lb) |
| Utility hook assembly | 2.2 kg (5 lb) |
| Reading lamp | 1.3 kg (2.9 lb) |
| NCL examination lamp | 1.7 kg (3.8 lb) |
| Holder for litter bags, including 100 litter bags | 0.7 kg (1.5 lb) |
| Basket 150, for disposable gloves | 0.3 kg (0.7 lb) |
| Tray 3020 | 1.2 kg (2.6 lb) |

## Non-Rail Accessory Weight Limitations

| | |
|---|---|
| Monitor shelf assembly, high | 11.4 kg (25 lb) |
| I.V. pole assembly | 5 kg (11 lb) |
| Swivel drawer assembly, large | Tray - 0.91 kg (2 lb)<br>Drawer - 4.5 kg (10 lb) |
| Swivel drawer assembly, small | Tray - 0.91 kg (2 lb)<br>Drawer - 2.2 kg (5 lb) |

# Electromagnetic Compatibility (EMC) Guidance and Manufacturer Declarations

## General Information

The EMC conformity of the Isolette 8000 includes the use of external cables and accessories (see List of Accessories on page 148). Use of equipment other than that listed on page 148 may compromise the EMC characteristics of the device. The Isolette 8000 should be observed to verify normal operation in the configuration in which it will be used. Observe the Instructions for Use of the other devices.

## Electromagnetic Emissions

The medical device is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

| **Emissions** | **Compliance according to** | **Electromagnetic environment** |
|---|---|---|
| Radio frequency (RF) emissions (CISPR 11) | Group 1 | The medical device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| | Class A | The medical device is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions (IEC 61000-3-2) | Class A | |
| Voltage fluctuations/flicker emissions (IEC 61000-3-3) | Complies | |

## Electromagnetic Immunity

The medical device is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment** |
|---|---|---|---|
| ESD<br>IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | The floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| EFT<br>IEC 61000-4-4 | ± 2 kV Mains<br>± 1 kV I/Os | ± 2 kV Mains<br>No I/Os | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ± 1 kV Differential<br>± 2 kV Common | ± 1 kV Differential<br>± 2 kV Common | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency<br>50/60 Hz<br>Magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Voltage Dips/Dropout<br>IEC 61000-4-11 | > 95% dip for 0.5 cycle<br>60% dip for 5 cycle<br>30% dip in for 25 cycles<br>> 95% dip for 5 seconds | > 95% dip for 0.5 cycle<br>60% dip for 5 cycle<br>30% dip in for 25 cycles<br>> 95% dip for 5 seconds | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Isolette 8000 requires continued operation during power mains interruptions, it is recommended that the Isolette 8000 be powered from an uninterruptible power supply or battery. |

| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment** |
|---|---|---|---|
| Radiated RF<br>IEC 61000-4-3 | 10 V/m<br>26 MHz to 2.5 GHz | E1=10 V/m | $D = 1.2\sqrt{P}$<br>26 MHz to 800 MHz<br>$D = 2.3\sqrt{P}$<br>800 MHz to 2.5 GHz<br>where *P* is the maximum power in watts and *D* is the recommended separation distance in meters.<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1, V2, and E). |
| Conducted RF IEC 61000-4-6 | 3 Vrms (outside ISM)<br>20Vrms (in ISM bands)<br>150 KHz to 80 MHz | V1=3 Vrms<br>V2=10 Vrms | Portable and mobile communications equipment should be separated from the Isolette 8000 by no less than the distances calculated/listed below:<br>$D = 1.167\sqrt{P}$<br>outside ISM<br>$D = 1.2\sqrt{P}$ in ISM |

## Recommended Separation Distances

The Isolette 8000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Isolette 8000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Isolette 8000 as recommended, according to the maximum output power of the communications equipment.

| **Maximum Output Power (Watts)** | **Separation (m) 150 kHz to 80 MHz Non-ISM** $D = 1.167\sqrt{P}$ | **Separation (m) 150 kHz to 80 MHz ISM** $D = 1.2\sqrt{P}$ | **Separation (m) 80 MHz to 800 MHz** $D = 1.2\sqrt{P}$ | **Separation (m) 800 MHz to 2.5 GHz** $D = 2.3\sqrt{P}$ |
|---|---|---|---|---|
| 0.01 | 0.1167 m | 0.12 m | 0.12 m | 0.23 m |
| 0.1 | 0.369 m | 0.38 m | 0.38 m | 0.73 m |
| 1 | 1.167 m | 1.2 m | 1.2 m | 2.3 m |
| 10 | 3.69 m | 3.8 m | 3.8 m | 7.3 m |
| 100 | 11.67 m | 12 m | 12 m | 23 m |

# List of Accessories

## Accessories

The following table lists replacement parts, accessories, and single-use items. Parts marked with an asterisk (*) should be installed by qualified service personnel.

| Description | Part Number |
|---|---|
| Isolette 8000 Infant Incubator | MU20600 |
| **Probes** | |
| Probe 4, skin temperature, disposable, box of 10, CE | MU12525 |
| Probe 5, skin temperature, reusable | MU12533 |
| Probe 5, large skin temperature, box of 10, YSI | MU12551 |
| Cover, probe, Care-For-Me™, large, 100 | MU06943 |
| Cover, probe, Care-For-Me, standard, 100 | MU06944 |
| Critter covers, probe, 600 | MU06941 |
| Critter covers, probe, 100 | MU06942 |
| Adapter cable, skin probe | MU12520 |
| **Oxygen** | |
| Oxygen assembly, DISS fitting, male | MU16945* |
| Oxygen assembly, DISS fitting, female | MU16946* |
| Oxygen assembly, NIST fitting, male | MU16947* |
| Cell, oxygen | MU13223* |
| **Humidity** | |
| Humidity system option, I-8000, 120V | MU21850* |
| Humidity system option, I-8000, 230V | MU21851* |
| Humidity system option, I-8000, 100V | MU21852* |
| Humidity reservoir assembly, I-8000 | MU21571 |
| Evaporator assembly, 120V | MU21858 |
| Evaporator assembly, 100V | MU21860 |
| Evaporator assembly, 230V | MU21859 |
| Heater/impeller cover with duct | MU21854 |
| Condensation management system option | MU21857 |
| Suction bottle, disposable, box of 20, 800 cc | MU10918 |
| Hose/plug assembly, condensation management, 20 | MU21120 |
| Drain plug with O-ring | MU21156 |

| Description | Part Number |
|---|---|
| **Scale Assembly** | |
| Scale assembly, Isolette, non-OIML/NAWI | MU13060 |
| Scale assembly, OIML, Isolette for OIML/NAWI | MU13089* |
| **Drawers** | |
| Swivel drawer assembly, large | MU17879* |
| Swivel drawer assembly, small | MU17880* |
| **Integris/Fairfield Compatible Rail Accessories** | |
| I.V. resuscitator bag holder assembly | MU14802 |
| Basket, 6.5" W x 4.0" D x 5.0" H, assembly | MU14806 |
| Basket, 11.0" W x 4.0" D x 4.0" H, assembly | MU14808 |
| Basket, pivoting, assembly | MU14810 |
| Chart holder assembly | MU14812 |
| Hinged Mayo tray, 13.5" W x 9.75" D | MU14814 |
| Cable organizer assembly | MU14818 |
| Horizontal cord wrap assembly | MU14820 |
| Standard cam adapter | MU14822 |
| Cam adapter, threaded, assembly | MU14828 |
| Utility hook assembly | MU14833 |
| **DIN Compatible Rail Accessories** | |
| Reading lamp | 2M86199 |
| NCL examination lamp | 2M85657 |
| Holder for litter bags, including 100 litter bags | M24695 |
| Basket 150, for disposable gloves | M26146 |
| Tray 3020 | M24678 |
| **External Monitoring (for Delta, Delta XL, and Kappa monitors)** | |
| MIB2 protocol converter | 7256931 |
| MIB cable, 2 m | MS18805 |
| MIB patch cable, 1.2 m | 4726373 |
| MIB patch cable, 2.4 m | 4726381 |
| MIB patch cable, 4.9 m | 4726399 |

| Description | Part Number |
|---|---|
| **Miscellaneous** | |
| I.V. pole assembly | MU12955* |
| Monitor shelf assembly, high | MU12937* |
| Straps, monitor shelf (2) | MU14688 |
| Oxygen tank bracket assembly, Isolette | MU12952* |
| Ventilator tubing support kit | MU18660 |
| SoftBed mattress | MP01401 |
| Scale weight, 5 kg | MU01732 |
| Air filter, replacement, 4 | MU12504 |
| Neat Clips, 9.6 mm (0.38 in) diameter, 10 | MU06558 |
| Neat Clips, 2.5 cm (1 in) diameter, 10 | MU06560 |
| Grommet | MU12609 |
| Iris port sleeve, disposable, 100 | MU03876 |
| Fuse, 5 mm x 20 mm, 10 amp, slow blow | MU19319* |
| Drain plug with O-ring | MU21156 |
| Kit, HFV access door with grommets | MU18916 |

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These Instructions for Use only apply to
**Isolette 8000 Infant Incubator**
with the Serial No.:
If no Serial No. has been filled in by Dräger, these Instructions for Use are provided for general information only and are not intended for use with any specific device or unit.
This document is provided for customer information only, and will not be updated or exchanged without customer request.

CE 0123
Directive 93/42/EEC
concerning Medical Devices


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