

Isolette® Infant Incubator (Models C2000 and C2000e)



WARNING:

For a full understanding of the performance characteristics of this equipment, the user should carefully read this manual before operating.

Operating Instructions

This "Instructions for Use" manual is published for public use and is only meant for your information.
We do not guarantee the accuracy of these instructions with respect to your specific device type or status.
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Notes:

Section 1

Definitions, Intended Use, and Disclaimer

Definitions

This manual contains different typefaces and icons designed to improve readability and increase understanding of its content. Note the following examples:

- Standard text—used for regular information.
- **Boldface text**—emphasizes a word or phrase.
- **NOTE:**—sets apart special information or important instruction clarification.

The **Definitions** subsection contains label symbol definitions and technical definitions. Additional definitions of system symbols and icons are located in Section 5 (see “Controls, Indicators and Connectors” on page 5-1).

Some of the warnings contained in this user manual include number tags or bracketed wording (for example [6.8.2.9] or IHA025]). These are requirements, which are used solely for internal documentation purposes.

Symbol Definitions

- The symbol below highlights a WARNING or CAUTION:

Warning and Caution



- A WARNING identifies situations or actions that may affect patient or user safety. Disregarding a warning could result in patient or user injury.
- A CAUTION points out special procedures or precautions that personnel must follow to avoid equipment damage.

- The symbol below highlights an ELECTRICAL SHOCK HAZARD WARNING:

Electrical Shock Hazard Warning



- The symbol below indicates “Attention: Consult accompanying documents:”

Attention: Consult Accompanying Documents



- The symbol below indicates a “Type BF applied part:”

Type BF Applied Part



- The instrument provides a specified degree of protection against electric shock, particularly the leakage current and reliability of the protective ground connection with a BF-type applied part.
- A BF-type applied part indicates an applied part isolated from all other parts of the instrument to such a degree that the patient leakage current allowable in a single-fault condition is not exceeded.

- The symbol below indicates “AC power:”

AC Power



- The symbol below indicates “Protective earth (ground):”

Protective Earth (Ground)



- The symbol below indicates “Caution: Hot surface:”

Caution: Hot Surface



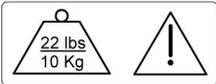
- The symbol below indicates “Weight limit:”

Weight Limit



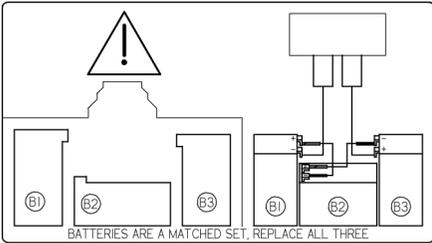
- The symbol below indicates “Consult Accompanying Document on the Battery Weight:”

Battery Weight



- The symbol below indicates “Consult Accompanying Document on Battery Pack Orientation:”

Battery Pack Orientation



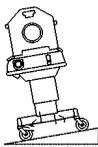
- The symbol below indicates “Power Failure:”

Power Failure



- The symbol below indicates “Lock casters when parked on an incline:”

Lock Casters



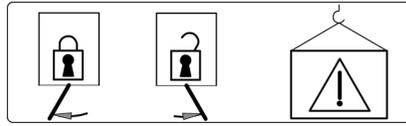
- The symbol below indicates an ELECTROSTATIC DISCHARGE (ESD) sensitive part:

Electrostatic Discharge (ESD) Sensitive Part



- The symbol below indicates “Consult accompanying documents on latch lock/unlock and rail loading:”

Latch Lock/Unlock and Rail Loading



- The symbol below indicates “Electromagnetic interference:”

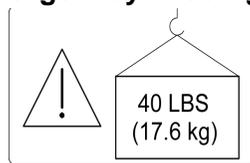
Electromagnetic Interference



Interference can occur in the vicinity of the equipment marked with the **Electromagnetic Interference** symbol.

- The symbol below indicates “Consult accompanying document on the large tray loading:”

large Tray Loading



- The symbol below indicates a “Communication port”

Communication Port



Technical Definitions

- **Incubator temperature**—Air temperature at a point 4" (10 cm) above and centered over the mattress surface.
- **Control temperature**—The temperature controller set point selected by the user.
- **Average incubator temperature**—The average of the maximum and minimum incubator temperatures achieved during temperature equilibrium.
- **Incubator temperature equilibrium**—The condition reached when the average temperature of the incubator does not vary more than 1°C over a period of 1 hour.
- **Temperature uniformity**—The amount by which the average temperatures at each of four points 4" (10 cm) 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 1-hour period after incubator temperature equilibrium has been reached.
- **Temperature rise time**—The time required for the incubator temperature to rise 20°F (11°C), when the air control temperature is at least 22°F (12°C) above the ambient 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 correlation—Temperature indicator versus incubator temperature**—The amount the air temperature indicator at incubator temperature equilibrium differs from the incubator temperature.
- **Temperature correlation—Incubator temperature versus control temperature**—The amount the average incubator temperature in Air mode at incubator temperature equilibrium differs from the control temperature.
- **Temperature correlation—Temperature indicator versus control temperature**—The amount the air temperature indicator in Air mode at incubator temperature equilibrium differs from the control temperature.
- **Measurement points**—Measurements are taken at five points in a plane parallel to and 4" (10 cm) above the mattress surface. One point is 4" (10 cm) 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.

Intended Use

This manual provides an overall functional description and the instructions for use of the Isolette® Infant Incubator, Models C2000 and C2000e.

The Isolette® Infant Incubator, Models C2000 and C2000e should be used only by appropriately trained personnel and under the direction of qualified medical personnel.

Disclaimer

Dräger Medical cannot be responsible for the performance of the incubator if the user does not operate the unit in accordance with the instructions, fails to follow the maintenance recommendations, or makes any repairs with unauthorized components. Only qualified service personnel should calibrate and repair it. Technical information is available through local distributors.

All personnel working with the unit should read, thoroughly understand, and have ready access to this manual. Store the manual with the incubator when not in use. Please contact your local representative for clarity or further information.

Notes:

Section 2

Introduction, Features, and Specifications

Introduction

The **Introduction** subsection provides a system overview and functional description of the Isolette® Infant Incubator, Models C2000 and C2000e.

System Overview

The Isolette® Infant Incubator, Models C2000 and C2000e is a modular controller-based incubator, which enables simultaneous control of temperature, oxygen and humidity parameters affecting the infant. The incubator hood and shell assemblies are mounted on a variable height adjustable (VHA) stand or fixed height (FH) stand.

Humidity System (Optional)

When installed, the built-in humidifier provides humidification of the incubator from 30% to 95% relative humidity (RH) in 1% increments. When the humidity system senses an absence of water an audible and visual **Low Humidity** alarm occurs. The humidifier is a three-part system consisting of a humidity reservoir, manifold assembly and evaporator assembly.

Humidity Reservoir

The humidity reservoir has a 1 liter capacity. The reservoir permits visual inspection of the water level. It is located in a drawer in the front of the incubator shell. When the drawer is closed and the latching handle is engaged, the reservoir is connected to a manifold.

Manifold Assembly

The manifold assembly allows the water to flow into the metering valve and the evaporator assembly.

Evaporator Assembly

The metering valve regulates the flow of water to the evaporator chamber to maintain a constant level of water, ensuring optimum responsiveness of the evaporator heater. The evaporator assembly raises the temperature of the water to the boiling point, causing vaporization. Any waterborne bacteria are killed, preventing transfer into the patient compartment. 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, which sends information to the controller module. The controller module regulates the output of the evaporator.

Oxygen Control System (Optional)

When installed, the oxygen (servo) control system adjusts the flow of oxygen within the incubator hood with a valve and an oxygen sensor module. The sensor module houses two independent oxygen fuel cells.

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.

Weighing System (Accessory)

NOTE:

The description in this section does not apply to the EU (Type NAWI) weighing system. Refer to the *Isolette® Infant Incubator, Type - NAWI, Weighing System Quick Reference Guide*.

When installed, the weighing system is located in a platform under the mattress. The scale contains two load beams, which perform the actual weighing function. The controller processes the load beam information and displays the weight in kilograms or pounds in the Trend/Alarm window.

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

System prompts are displayed in the Trend/Alarm window, during the weighing procedure.

Uninterruptible Power Supply (UPS) (Optional)

When installed, the UPS system provides an on-line uninterruptible back-up power supply to the incubator, which can also be used for intra-facility transport.

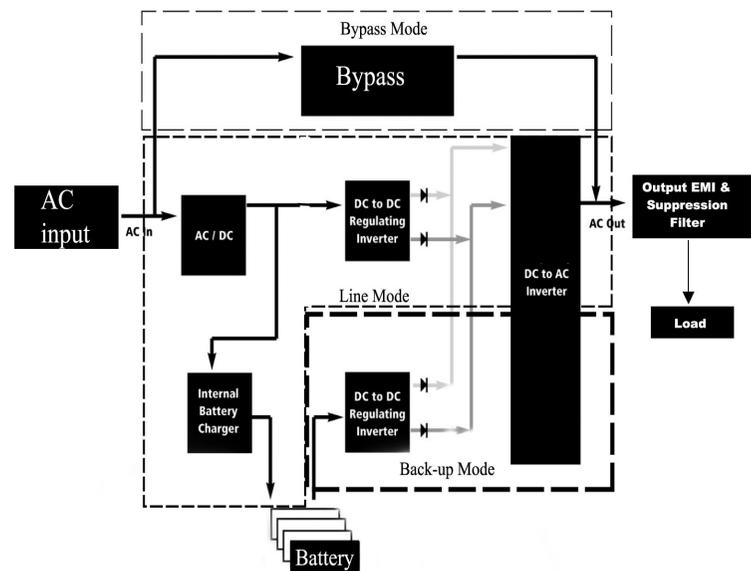
With batteries fully charged, the power available from battery backup is sufficient to maintain a C2000e incubator in operation for 30 min in a 20°C ambient at a set point of 39°C in the Air mode, without oxygen or humidity control, or additional loads drawn from the accessory outlets.

Battery back-up usage occurs during power failure or while transporting an unplugged incubator within the facility.

The UPS system consists of two main components: the electronics control module and battery pack module. The battery pack module consists of 3 sealed gel cell batteries that are charged by the electronics module. The electronics module is responsible for monitoring, distributing and controlling the power delivered to the incubator.

The UPS system operates in three modes: line, back-up and bypass. Refer to the table below:

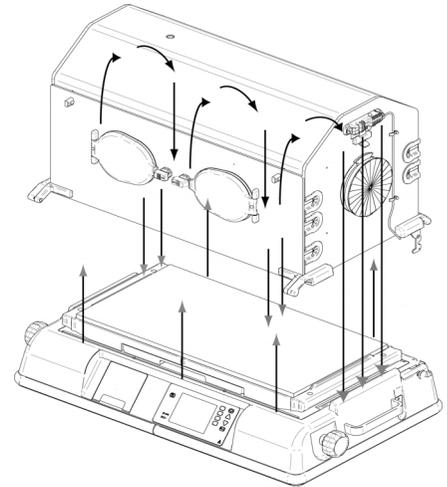
Modes	Operating Conditions
Line	AC input normal; load range acceptable; inverter (DC to AC) operational
Back-up	Loss of AC input; load range acceptable; inverter operational
Bypass	Loss of inverter output; acceptable load; power supplied from AC only



Functional Description

The temperature, humidity, and oxygen concentration is controlled by the forced air circulation system. A controlled amount of room air, approximately 7 lpm, 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 re-circulated 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 then passes between the front and rear inner walls. 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 panel(s) of the hood is/are open, the air continues to flow upward past the opening, creating a warm air curtain. This curtain minimizes the drop in air temperature in the incubator.



Temperature is regulated by using either incubator air or 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. The Air and Skin modes are described below.

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** and **Down Arrow** keys on the front panel. In Temperature Override mode, the temperature can be maintained from 37.0°C (98.6.0°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** and **Down Arrow** keys on the controller front panel 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 “Controls, Indicators and Connectors” on page 5-1). 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.

Features

The **Features** subsection provides a list of the standard and optional features and available accessories for the Isolette® Infant Incubator, Models C2000 and C2000e.

Standard Features

Standard features include:

- Oval access doors with a quiet latch
 - Trendelenberg mattress tilt mechanism (0° to 12°)
 - Pedestal base cover (C2000e, only)
 - Rail system (C2000e, only)
-

Optional Features

Options include:

- Oxygen control system
- Humidity system
- Fixed height stand (without UPS system)
- VHA stand (without UPS system)

C2000e only

- Fixed height stand (with UPS system)
 - VHA stand (with UPS system)
-

Accessories

Accessories include:

- Weighing system
- Ventilation support
- Temperature probes
- Port sleeves and cuffs
- 5 kg weight
- Gas tank mounts and tanks (E and D sizes)

C2000e only

- Rail mounted accessories

C2000 only

- Non-rail mounted accessories

Specifications

The **Specifications** subsection provides specifications for the standard and optional features and available accessories of the Isolette® Infant Incubator, Models C2000 and C2000e. It also includes regulation, standards and code information for the system.

Standard Features

Feature	Dimension
Physical	
<i>C2000</i>	
Depth	67.31 cm (26.5)
Width	102.9 cm (40.5")
<i>C2000e</i>	
Depth	67.31 cm (26.5")
Width	120 cm (47.25") (including rail width)
Incubator Weight	≥ 49 kg (108 lb)
Mattress tray width	79 cm (31")
Mattress tray depth	41 cm (16")
Mattress Trendelenburg/Reverse Trendelenburg tilt	Continuously variable to 12° ± 1°
Electrical	
Convenience outlets (Model C2000, 100V, only)	100V, 50/60 Hz, 300 W maximum
Convenience outlets (120V)	120V, 50/60 Hz, 300 W maximum
Convenience outlets (230V)	230V, 50/60 Hz, 300 W maximum
Chassis current leakage (100V and 120V)	≤ 300 μA
Chassis current leakage (230V)	≤ 500 μA
Environmental	
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)
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)
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
Environment temperature operating range	20°C (68°F) to 30°C (86°F)
Operating temperature— RH sensor	20°C (68°F) to 41°C (106°F)
Operating temperature— oxygen sensor	20°C (68°F) to 41°C (106°F)
Operating humidity range	5% to 99% RH non-condensing

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Feature	Dimension
Noise level within the hood environment	< 47 dBA with 37 dBA or less ambient
Air velocity over the mattress	< 4"/second (10 cm/second); average of five points at 4" (10 cm) above the mattress
Storage temperature	-25°C (-13°F) to 60°C (140°F)
Storage humidity range	0% to 99% relative humidity non-condensing
Carbon Dioxide (CO ₂) Level (per EN60601-2-19, Clause 105)	<0.5%
Operational	
Set point data retention (non-UPS systems)	power failures lasting <10 min
Set point data retention (UPS systems)	power failures lasting <(battery charge depletion time + 10 min)

Options and Accessories

Stands

Feature	Dimension
Physical	
<i>Fixed Height Stand</i>	
Top of hood to floor (incubator with FH stand)	142 cm (56") ± 12.7 mm (½")
Mattress to floor (incubator with FH stand)	100.97 cm (39¾") ± 12.7 mm (½")
Weight (without UPS system and accessories)	49.4 kg (109 lb)
<i>Variable Height Stand</i>	
Top of hood to floor (incubator with VHA stand)	133.35 cm (52½") ± 12.7 mm (½") to 152 cm (60") ± 12.7 mm (½")
Mattress to floor (incubator with VHA stand)	90.17 cm (35½") ± 12.7 mm (½") to 110½" (43½") ± 12.7 mm (½")
Weight (with UPS system and accessories)	≤ 97 kg (214 lb)
<i>UPS</i>	
Battery pack weight	9.5 kg (20.9 lb)
Electrical	
<i>Fixed Height Stand</i>	
Power requirements for 100V/120 FH stand (100V for Model C2000, only)	100 V/120 V, 50/60 Hz, 9.9 A maximum
Power requirements for 230V FH stand	230 V, 50/60 Hz, 9.9 A maximum
<i>Variable-Height Stand</i>	
Power requirements for 100/120V VHA stand (100V for Model C2000 only)	Without UPS: 100 V/120 V, 50/60 Hz, 9.9 A maximum
	With UPS: 120 V, 50/60 Hz, 11 A maximum
Power requirements for 230V VHA stand model	With and without UPS: 230V, 50/60 Hz, 9.9 A maximum
<i>UPS</i>	
Input current breaker rating	15 A for 120 V; 7A for 230 V

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Feature	Dimension
Output circuit breaker rating	10 A for 120 V; 5 A for 230 V
Input frequency	50/60 Hz (auto sensed by the microprocessor) 45-65 Hz (inverter phase-lock frequency range)
Battery type	gel cell
Operational	
UPS charge time	Full capacity after 8 hours
UPS operating time	With batteries fully charged, the power available from battery backup is sufficient to maintain a C2000e incubator in operation for 30 min in a 20°C ambient at a set point of 39°C in the Air mode, without oxygen or humidity control, or additional loads drawn from the accessory outlets.

Humidity System

Feature	Dimension
Humidity System	
Humidity control operating time without refilling	24 hours maximum @ 85% RH and 36°C, in Air mode
Humidity control reservoir capacity	1000 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% @ 68°F (20°C) to 104°F (40°C)	± 6% RH
Maximum humidity levels	>85% (incubator set temp at 39°C, with at least 30% RH at ambient)

Oxygen System

Feature	Dimension
Oxygen Control System	
Oxygen inlet pressure	40 psi to 150 psi
Oxygen inlet flow rate	30 liters/min
Oxygen control range	21% to 65%
Oxygen display resolution	1% increments
Oxygen control accuracy at 100% calibration	± 3%
Oxygen control accuracy at 21% calibration	± 5%

Weighing System

NOTE:

The procedures described in this section do not apply to the EU (Type NAWI) weighing system. Refer to the *Isolette® Infant Incubator, Type -NAWI, Weighing System Quick Reference Guide*.

Feature	Dimension
Weighing System	
Weight display range	0 kg (0 lb) to 7 kg (15 lb)
Weight display resolution	1.0 g or 0.04 oz
Weight display accuracy	0 - 2 kg; 2 g ± ½ digit
	> 2 kg; ±5 g ± ½ digit
Maximum tare weight	4.0 kg (8.82 lb)

Rail Accessory Weight Limitations

Feature	Dimension
Rail System Assembly	Total rail accessory weight not to exceed 36.3 kg (80 lb); 13.1 kg (40 lb) per side rail or 6.8 kg (15 lb) per front and rear rail (with remaining weight distributed along side rails)
Monitor shelf assembly, high/low, C2000e	11 kg (25 lb)
I.V. pole assembly, C2000e	5 kg (11 lb)
Basket 18.0 W x 9.5 D x 4.0 H	4.4 kg (10 lb)
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	
Hinged mayo tray, 13.5 W x 9.75 D	2.2 kg (5 lb)
Hinged mayo tray, 17.0 W x 11.5 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)
Ball action adapter	2.2 kg (5 lb)
Double cam adapter	2.2 kg (5 lb)
Cam adapter, threaded mount	2.2 kg (5 lb)
Utility hook assembly	2.2 kg (5 lb)

Non-Rail Accessory Weight Limitations

Feature	Dimension
Monitor shelf assembly, high, C2000e	11 kg (25 lb)
Monitor shelf assembly, low, C2000e	11 kg (25 lb)
I.V. pole assembly, C2000e	5 kg (11 lb)
Tray assembly, large	17.6 kg (40 lb)
Swivel drawer assembly, large	Tray - 0.91 kg (2 lb) Drawer - 4.5 kg (10 lb)
Swivel drawer assembly, small	Tray - 0.91 kg (2 lb) Drawer - 2.2 kg (5 lb)
Swivel drawer assembly, small, C2000e	Tray - 0.91 kg (2 lb) Drawer - 2.2 kg (5 lb)
Drawer housing assembly, shallow, short	2.2 kg (5 lb)
Drawer housing assembly, shallow, long	2.2 kg (5 lb)
Swivel drawer assembly, large, C2000e	Tray - 0.91 kg (2 lb) Drawer - 4.5 kg (10 lb)
Drawer housing assembly, deep, short	4.5 kg (10 lb)
Drawer housing assembly, deep, long	4.5 kg (10 lb)

Regulations, Standards, and Codes

The Isolette® Infant Incubator, Models C2000 and C2000e complies with the following safety standards and performance standards:

- EN 60601-1—1990, *Medical Electrical Equipment, Part 1: General Requirements for Safety*, including Amendments 1, 2, 12 and 13
- EN 60601-1-2—2002, *Collateral Standard: Electromagnetic Compatibility—Requirements and Tests*
- EN 60601-2-19—1996, *Particular Requirements for the Safety of Baby Incubators*, including Amendment 1

Electromagnetic Compatibility (EMC) Guidance and Manufacturer Declarations

Guidance and Manufacturer's Declaration— Emissions		
The C2000 is intended for use in the electromagnetic environment specified below. The customer or user of the unit should ensure that the unit is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment—Guidance
Radio frequency (RF) emissions—CISPR 11	Group 1	The C2000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The C2000 is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Class A	

Guidance and Manufacturer's Declaration—Immunity

The C2000 is intended for use in the electromagnetic environment specified below. The customer or user of the C2000 should ensure that the unit is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
ESD IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains No I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV Differential ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Drop-out IEC 61000-4-11	> 95% dip for 0.5 cycle 60% dip for 5 cycle 30% dip in for 25 cycles > 95% dip for 5 seconds	> 95% dip for 0.5 cycle 60% dip for 5 cycle 30% dip in for 25 cycles > 95% dip for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the C2000 requires continued operation during power mains interruptions, it is recommended that the C2000 be powered from an uninterruptible power supply or battery.
Power frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration— Immunity

The C2000 is intended for use in the electromagnetic environment specified below. The customer or user of the C2000 should ensure that the unit is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms (outside ISM) 20Vrms (in ISM bands) 150 KHz to 80 MHz	V1=3 Vrms V2=10 Vrms	Portable and mobile communications equipment should be separated from the C2000 by no less than the distances calculated/listed below: $D = 1.167\sqrt{P}$ outside ISM $D = 1.2\sqrt{P}$ in ISM
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	E1=10 V/m	$D = 1.2\sqrt{P}$ 80 MHz to 800 MHz $D = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum power in watts and D is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1, V2, and E).

Recommended Separations Distances for the C2000

The C2000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the C2000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the C2000 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 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

Device Classification

The Isolette® Infant Incubator, Models C2000 and C2000e meets the requirements for the following classifications:

- Class I
- Type BF
- IPX0—Ordinary equipment
- Not AP
- Continuous operation

Section 3

Precautions and Safety Tips

Precautions

This section contains a list of electrical, explosion, EMC, Oxygen and Humidity precautions.

Electrical Precautions

WARNING:

The total electrical current leakage of all items powered through the incubator, including devices on the outlet strip, must be less than 300 μ A for 120V AC/100V AC systems and less than 500 μ A for 230V AC systems. Otherwise, personal injury or equipment damage could occur.

SHOCK HAZARD:

The potential for electrical shock exists with electrical equipment. Establish policies and procedures to educate your staff on the risks associated with electrical equipment.

SHOCK HAZARD:

To ensure grounding reliability, plug the AC power cord only into a properly grounded 3-wire hospital-grade or hospital-use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment. Personal injury or equipment damage could occur.

SHOCK HAZARD:

Due to the risk of electrical shock hazard, only qualified personnel with appropriate service documentation should service the unit.

SHOCK HAZARD:

To prevent equipment damage or accidental power disconnections, do **not** plug an incubator power cord directly to an AC wall socket when the incubator is mounted on a pedestal/stand. Always provide power to the incubator by using the power cord coming directly from the pedestal/stand.

SHOCK HAZARD:

Make sure the building power source is compatible with the electrical specifications shown on the column of the pedestal/stand and on the incubator. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

The total power of all equipment connected to the convenience outlet strip on the pedestal/stand must be within the electrical requirements shown on the rear of the pedestal/stand. Otherwise, personal injury or equipment damage could occur.

 **SHOCK HAZARD:**

Batteries can present a risk of electric shock. The following precautions should be taken when working on batteries: remove watches, rings or other metal objects; use tools with insulated handles.

 **SHOCK HAZARD:**

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. Personal injury or equipment damage could occur.

 **SHOCK HAZARD:**

Unplug the unit from its power source prior to cleaning or maintenance. For units equipped with an uninterruptible power supply (UPS) system, also remove the battery pack prior to cleaning or maintenance. Failure to do so could result in personal injury or equipment damage.

 **SHOCK HAZARD:**

Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

Explosion Precautions

 **WARNING:**

Do not use in the presence of flammable anesthetics. Personal injury or equipment damage could occur.

 **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. Personal injury or equipment damage could occur.

 **WARNING:**

Small quantities of flammable agents, such as ethyls and alcohol, left in the incubator may cause a fire in connection with oxygen. Personal injury or equipment damage could occur.
[6.8.2.4]

 **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. Failure to do so could result in personal injury or equipment damage.

EMC Precautions

⚠ WARNING:

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.

⚠ WARNING:

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.

⚠ WARNING:

Devices connecting to the serial data port must be compliant with EN 60601-1-2, the EMC requirement for Medical Devices. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

The incubator display may go blank during an episode of static discharge to the sensor module. Personal injury or equipment damage could occur.

⚠ WARNING:

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

⚠ WARNING:

Pins of connectors identified with the ESD warning symbol shall not be touched and not be connected unless ESD precautionary procedures are used. 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 procedures.

⚠ 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. Consider the use of the accessory in the patient's vicinity and evidence that the safety certifications of the accessory have been performed in accordance with the appropriate International Electrotechnical Commission (IEC) 606-1 and/or IEC -1-1 harmonized national standard. Personal injury or equipment damage could occur.

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.

⚠ WARNING:

Measure the oxygen concentrations to verify delivery of the prescribed oxygen concentration. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

If it is necessary to administer oxygen in an emergency, notify the attending physician immediately. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

If the patient's arterial oxygen levels cannot be maintained when the oxygen control settings is set to maximum, the attending physician should prescribe alternate means of oxygenation. Failure to do so could result in personal injury or equipment damage.

⚠ 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. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

The oxygen flow rates labeled on the rear panel cannot be used as an accurate indication of oxygen concentrations in an incubator and should only be used as a guide. Measure oxygen concentrations with a calibrated oxygen analyzer at intervals directed by the attending physicians. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

After each change of oxygen flow, allow at least 30 min to achieve new concentrations. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Oxygen levels within the incubator hood environment may be affected when the access doors or access panels are opened. Make sure all hood access door gaskets and tubing ports are properly installed. Any open gaps in the incubator hood may reduce the incubator's internal oxygen. Personal injury could occur.

⚠ 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. Failure to do so could result in personal injury or equipment damage.

This "Instructions for Use" manual is published for public use and is only meant for your information.

We do not guarantee the accuracy of these instructions with respect to your specific device type or status.

Only the "Instructions for Use" manual delivered together with a device is officially published for the use of that specific device.

⚠ WARNING:

Disconnect the incubator from the hospital oxygen source when oxygen is not in use. Failure to do so could result in personal injury or equipment damage.

⚠ 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. Particularly, if the unit is used in an unusually dusty environment, more frequent replacements may be necessary. Failure to do so could result in infant injury or equipment damage.

⚠ WARNING:

As oxygen use increases the danger of fire, do not place auxiliary equipment that produces sparks in an incubator. Personal injury or equipment damage could occur. [6.8.2.3]

⚠ 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 min, holding the eye open, and call a physician. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Use only Dräger Medical recommended fuel cells for proper operation. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Inspect gas/oxygen service components at regular service intervals for signs of corrosion or damage. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Routinely inspect oxygen cells for signs of degradation or leakage, and replace if necessary. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

The administration of oxygen may increase the noise level for the baby within the incubator. Personal injury could occur. [6.8.2.9]

Humidity Precautions

⚠ WARNING:

Higher incubator relative humidity at any given temperature decreases an infant's evaporative heat loss, and may cause an increase in the infant temperature. Routinely monitor the infant's rectal and/or axillary temperature according to the attending physician's orders or Nursery Standing Orders. Failure to do so could result in personal injury.

⚠ 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 rectal and/or axillary temperature according to the attending physician's orders or Nursery Standing Orders. Failure to do so could result in personal injury.

⚠ WARNING:

Make sure all hood access door gaskets and tubing ports are properly installed. Any open gaps in the incubator hood will reduce the incubator's internal relative humidity. Personal injury or equipment damage could occur.

⚠ WARNING:

Fill the reservoir to the Maximum Filling Limit line. **Do not overfill.** Water spillage may result, and personal injury could occur.

Safety Tips

⚠ WARNING:

Federal law restricts this device to sale by or on the order of a physician. Otherwise, personal injury or equipment damage could occur.[CFR Requirement]

⚠ WARNING:

Thoroughly read and understand the manual prior to use of the incubator. Failure to do so could result in personal injury or equipment damage.

⚠ 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. [IHA025] [6.8.2.1]

⚠ 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. Failure to do so could result in personal injury or equipment damage.

⚠ 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 and either remove or secure all loose system components to prevent possible patient injury or equipment damage. If the move involves varying floor heights or a complete floor level change (i.e. thresholds, ramps, elevators), remove all items either not being used or not necessary for the move, lower the VHA, IV poles and shelves to their lowest position, place all drawers in their locked state, and remove all accessories from the front and rear rail position. [IHA033]

⚠ WARNING:

When the front access panel (or optional rear) is open, the temperature display may not accurately reflect the incubator temperature. Do not leave the front access panel (or optional rear) open longer than essential. Personal injury could occur.

⚠ WARNING:

Positively secure all access panel latches to avoid accidental opening. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

For infant safety, **do not** leave the infant unattended when the access panels are open. Personal injury could occur.

⚠ 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. Personal injury could occur.

⚠ 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.

⚠ 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. Failure to do so could result in personal 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. [6.8.2.2]

⚠ WARNING:

Do not place surgical covers or blankets over the infant and warm air curtain or side vents simultaneously. This may cause heat-induced injury and burns.

⚠ WARNING:

Phototherapy units located too close to the incubator may affect hood wall temperature, incubator hood temperature, and infant skin temperature. Personal injury or equipment damage could occur.

⚠ WARNING:

Phototherapy lamps placed over the top of the incubator hood may interfere with upward travel of the vertical height adjustable stand. To prevent this interference, always remove the phototherapy lamp prior to positioning the stand.

⚠ WARNING:

For proper operation of the incubator, use only skin temperature probes from Dräger Medical. Using other probes could result in personal injury or equipment damage.

⚠ WARNING:

Never place the skin temperature probe under the infant or use it rectally. Personal injury could occur. [6.8.2.6]

⚠ WARNING:

When in skin mode, the skin temperature probe must be in direct contact with the skin to provide accurate monitoring of the infant's 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. [6.8.2.6]

⚠ 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.

⚠ WARNING:

Attach the incubator to the stand or the vertical height adjustable 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. Personal injury or equipment damage could occur.

⚠ 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 vertical height adjustable stand. Personal injury or equipment damage could occur.

⚠ WARNING:

To avoid possible tip-over or damage to adjacent carts, IV stands, shelves, etc., keep at least a 12" (30 cm) perimeter area clear around the vertical height adjustable stand.

⚠ WARNING:

For optimum incubator stability, always lock all stand wheels. Do not leave the unit unattended when parking on an incline. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

When operating the variable height adjustable stand, always place one hand on the incubator for support to keep from losing your balance. Failure to do so could result in personal injury or equipment damage.

⚠ 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.

⚠ WARNING:

For optimum stability, always lower the incubator to its lowest position prior to transport. Make sure that items placed on the monitor shelf are properly secured. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Only one monitor shelf should be used per incubator. When using the monitor shelf, always place the monitor in the center of the shelf, ensure that the monitor fits within the border of the shelf, and avoid stacking monitors on the shelf. Personal injury or equipment damage could occur.

⚠ WARNING:

When raising or lowering the incubator, the operator should ensure that both equipment and appendages are clear of the unit's travel path. 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 that there is sufficient clearance between the incubator and stand assembly. Do not raise or lower the unit while installing or removing medical gas tanks from the tank holder assembly. Failure to do so could result in personal injury or equipment damage. [IHA011]

⚠ WARNING:

Accessories such as trays, baskets and shelves should never be overloaded and are not intended to hold an infant. [IHA014]

⚠ WARNING:

Inspect the battery module for possible leakage during service intervals and prior to removal and handling. The battery module is heavy and therefore requires sufficient strength and the proper lift method in order to avoid injury upon removal or installation. Observe local, state and federal regulations with regards to handling, storage and disposal of sealed gel cell batteries. [IHA021,033]

⚠ WARNING:

Always close and latch drawers when not in use and particularly when the incubator is being moved. [IHA28]

⚠ WARNING:

To avoid injury or equipment damage, use only Dräger Medical listed latches and accessories with the 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 will snap into an 8 o'clock position on the latch body, when locked. Total rail load must not exceed 36.3 kg (80 lb). The side rail loads must not exceed 13.61 kg (30 lb). The front and rear rail loads must not exceed 6.8 kg (15 lb). [IHA029]

⚠ WARNING:

The drawers and rail system are labeled for acceptable weights.[IHA010]

⚠ WARNING:

Do not insert any object into any of the ventilation holes or any other opening on the uninterruptible power supply (UPS) system.

⚠ WARNING:

Do not plug the AC input supply power cord of the uninterruptible power supply (UPS) system into any of the output receptacles on the incubator stand. This is a safety hazard and may cause irreparable damage to the UPS system.

⚠ WARNING:

Do not add external batteries to the UPS system. Personal injury or equipment damage could occur.

⚠ WARNING:

Do not connect the Isolette® Infant Incubator, Models C2000 or C2000e to a surge suppressor.

⚠ WARNING:

Incubator stability can be reduced by both the number of accessories attached, the height and loading of accessories, as well as their position on the rail. It is therefore recommended that rail accessories be kept to a minimum, be adjusted to their lowest usable height and with respect to the end rail, mounted as close to the center of the incubator, as possible.

⚠ WARNING:

To prevent transport interference or possible trip and fall hazards, always properly secure the power cord. Failure to do so could result in personal injury or equipment damage.

⚠ 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. Infant injury could occur.

⚠ WARNING:

Follow all product manufacturer's cleaning instructions. Failure to do so could result in personal injury or equipment damage.

⚠ 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. Personal injury or equipment damage could occur.

⚠ 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.

⚠ WARNING:

Only facility-authorized personnel should perform preventive maintenance or troubleshooting on the Isolette® Infant Incubator, Models C2000 and C2000e. Preventive maintenance performed by unauthorized personnel could result in personal injury or equipment damage.

⚠ WARNING:

At the end of the life of the Isolette® Infant Incubator, Models C2000 and C2000e safely dispose of the unit per local requirements. Failure to do so could result in personal injury.

⚠ WARNING:

Failure to adhere to the weight and placement requirements for rail accessories on the rail system can result in personal injury or equipment damage.

⚠ 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. [IHA036]

⚠ WARNING:

Only connect equipment to the serial port that complies with the relevant IEC standard; and use data cables with plastic body connectors.

⚠ WARNING:

The flow rate label on the rear panel is not valid when in oxygen control mode.

⚠ WARNING:

Do not connect oxygen hoses to both the non-servo control input (Inlet 1) and oxygen control (servo) input (Inlet 2) at the same time.

⚠ WARNING:

Prior to transport, always ensure the mattress is level, i.e., not in the Trendelenburg or Reverse Trendelenburg position.

⚠ WARNING:

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

Section 4

Installation and Operational Checkout

Installation

Refer to the *Isolette® Infant Incubator, Models C2000 and C2000e Service Manual* for additional installation, assembly and disassembly procedures.

1. Open the shipping cartons and remove all packing material.
2. Unpackage the hood/shell assembly and stand assembly (see “Unpackaging” on page 4-2).

NOTE:

If the packaging and/or unit is damaged, contact a local service representative.

▲ 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. Personal injury or equipment damage could occur.

3. For C2000e systems only, install the rail assembly (see “Rail Assembly and Accessories Installation” on page 4-3).
4. For C2000e systems equipped with a uninterruptible power supply (UPS) system, install the electronic module and battery pack (see “UPS System Installation” on page 4-8) and then install the mattress restraint straps (see “Mattress Restraint Strap Installation” on page 4-7).
5. Assemble the hood/shell assembly and the stand assembly (see “Hood, Shell, and Stand Assembly” on page 4-6).
6. To install the weighing system, refer to “Weighing System (Scale Assembly)” on page 4-9.
7. To install the humidity system, refer to “Humidity System” on page 4-10.
8. To install the oxygen control system, refer to “Oxygen Control System” on page 4-10.
9. Before the unit is placed in service, perform the operation checkout procedures (see “Operational Checkout” on page 4-12).

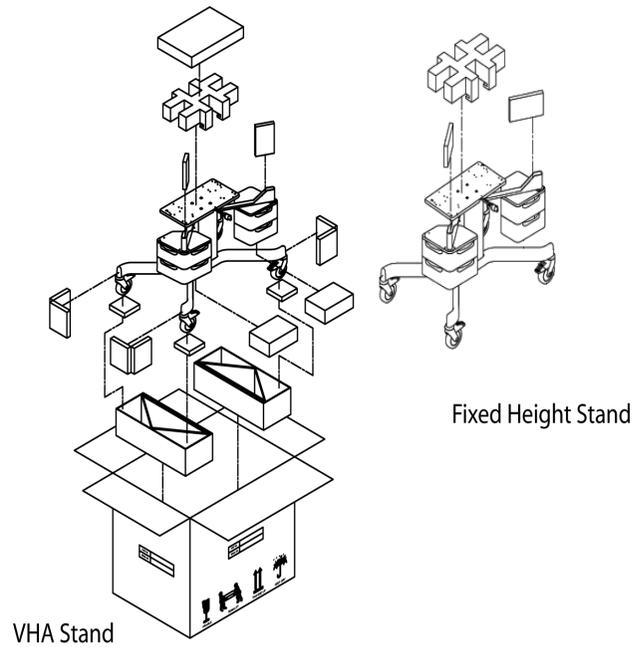
Unpackaging

NOTE:

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

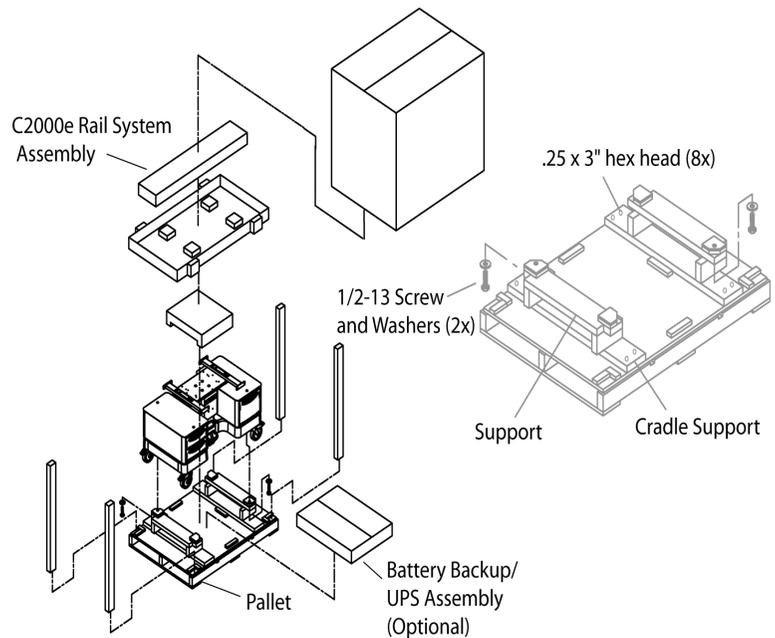
C2000 Stand Assembly

Carefully lift the stand assembly and remove it from the packaging.



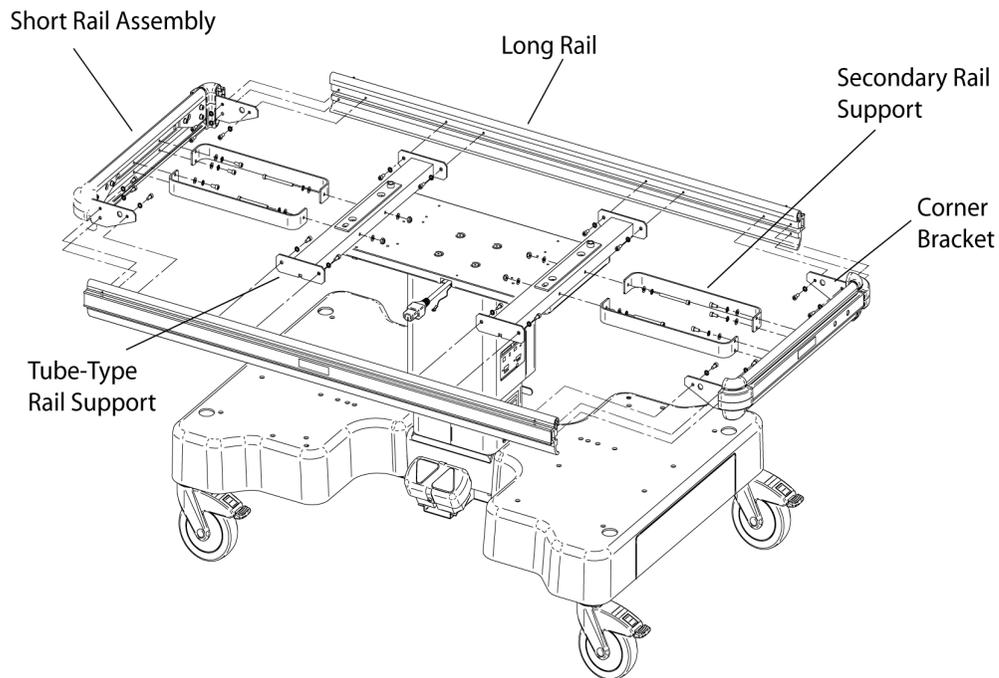
C2000e Stand Assembly

1. Prior to removing the stand assembly from the packing box, remove the two 1/2 -13 mounting screws and washers securing one leg of the stand assembly to the support.
2. At one side of the pallet, remove the 4 lag bolts (.25 x 3") from the cradle support.
3. Lift that end of the stand, remove the cradle support and lower the stand to the pallet.
4. Then repeat steps 2 and 3 for the remaining leg.



Rail Assembly and Accessories Installation

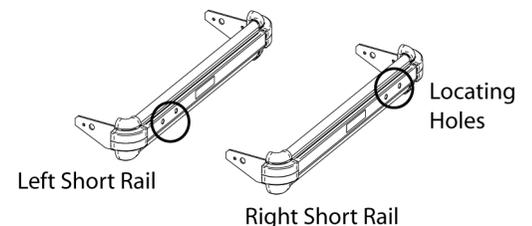
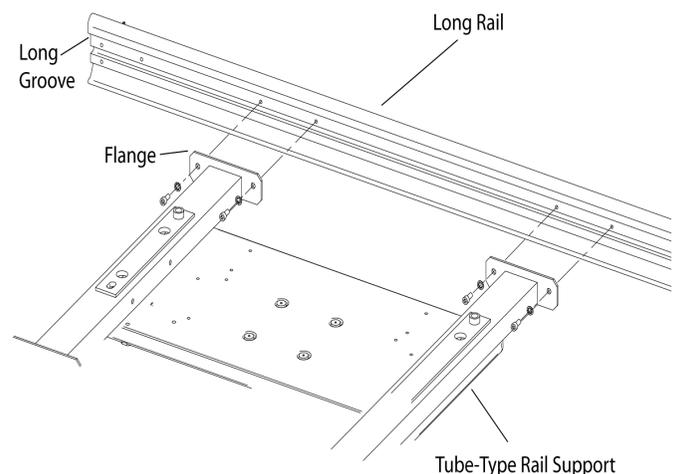
Perform the operation checkout procedure, prior to using the rail system (see “Rail System Operational Checkout” on page 4-19).



Rail Assembly

To install the rail assembly:

1. Mount a long rail on the tube-type rail supports, engaging the long groove of the long rail on the 2 flanges of the tube-type rail support.
2. Align the screw holes on the tube-type rail support with the mounting holes on the long rail.
3. Secure the long rail to the tube-type rail support, using 4 screws (10-32 x 7/16") and 4 internal tooth washers.
4. Then tighten the screws with a 5/32 Allen wrench.
5. Repeat steps 1 through 3 for the remaining long rail.
6. Select one of the short rail assemblies.



NOTE:

The position of the locating holes, on the short rail assembly determine where the short rails are mounted on the rail assembly.

This "Instructions for Use" manual is published for public use and is only meant for your information.
We do not guarantee the accuracy of these instructions with respect to your specific device type or status.
Only the "Instructions for Use" manual delivered together with a device is officially published for the use of that specific device.

7. Align the 3 screw holes on each of the corner brackets with the 3 screw holes on the front and rear long rails.

8. Secure the corner brackets, of the short rail assembly, to the long rails using 6 screws (10-32 x 7/16") and internal tooth washers.

9. Then tighten the screws with a 5/32 Allen wrench.

10. Repeat steps 7 through 9, for the remaining short rail assembly.

11. Secure one end of a secondary rail support, with two mounting holes, to the short rail assembly, using 2 screws (10-32 x 7/16"), flat washers and internal tooth washers.

12. Secure the other end of the secondary rail support to the tube-type rail support.

a. Insert a screw (10-32 x 2.50"), flat washer and internal tooth washer through the secondary rail and tube-type support.

b. At the other end of the screw, add a flat washer and nut.

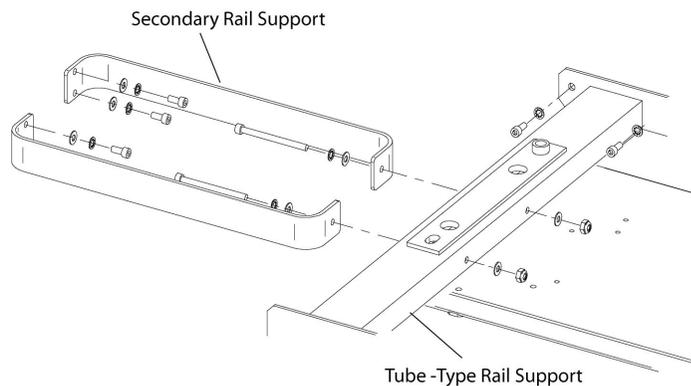
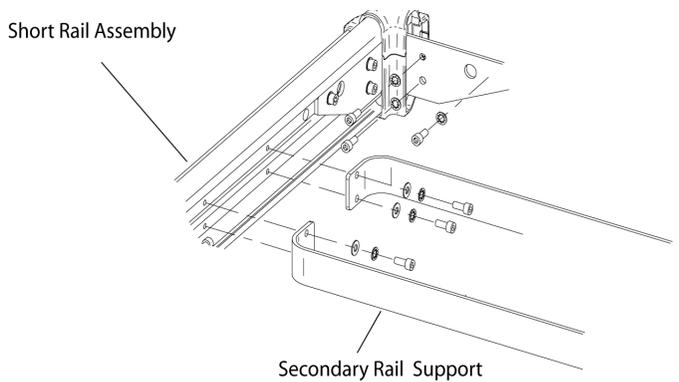
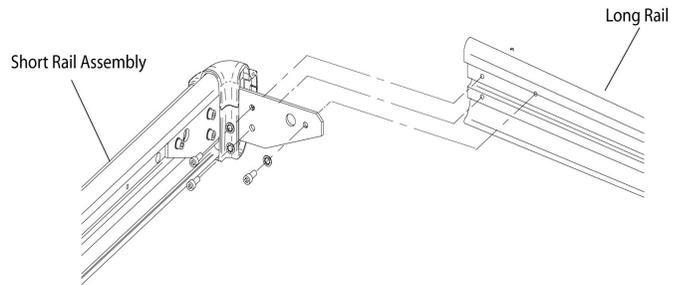
c. Then tighten the screw and nut with a 5/32 Allen wrench or socket wrench.

13. Repeat steps 11 and 12, for the remaining 3 remaining secondary rail supports.

NOTE:

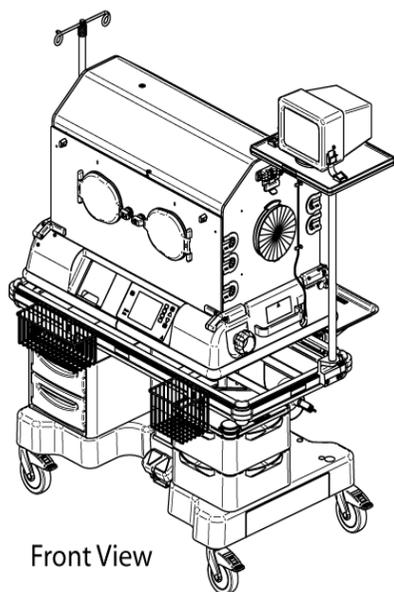
Two secondary rail supports are required on both sides of the incubator stand.

14. Ensure all screws are fully tightened.

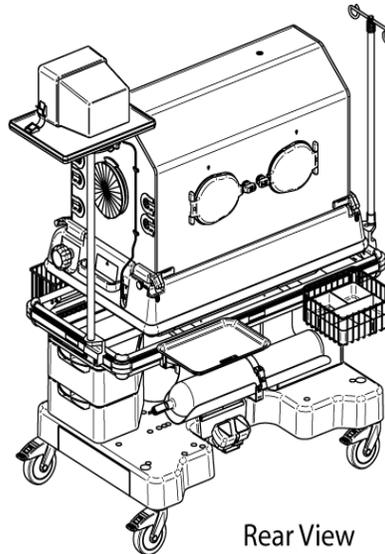


Rail Accessories

To install rail accessories refer to the *Isolette® Infant Incubator Retrofit and Upgrade Installation Instructions*.



Front View



Rear View

NOTE:

The monitor shelf and I.V. pole can be mounted only on the side rails. The monitor shelf can only be secured on the locating holes towards the rear of the unit, on the side rails.

⚠ WARNING:

Incubator stability can be reduced by both the number of accessories attached, the height and loading of accessories, as well as their position on the rail. It is therefore recommended that rail accessories be kept to a minimum, be adjusted to their lowest usable height and with respect to the end rail, mounted as close to the center of the incubator as possible.

⚠ WARNING:

To avoid injury or equipment damage, use only Dräger Medical listed latches and accessories with the 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 will snap into an 8 o'clock position on the latch body, when locked. Total rail load must not exceed 36.3 kg (80 lb). The side rail loads must not exceed 13.61 kg (30 lb). The front and rear rail loads must not exceed 6.8 kg (15 lb). [IHA029]

⚠ WARNING:

Failure to adhere to the weight and placement requirements for rail accessories on the rail system can result in personal injury or equipment damage.

⚠ 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.

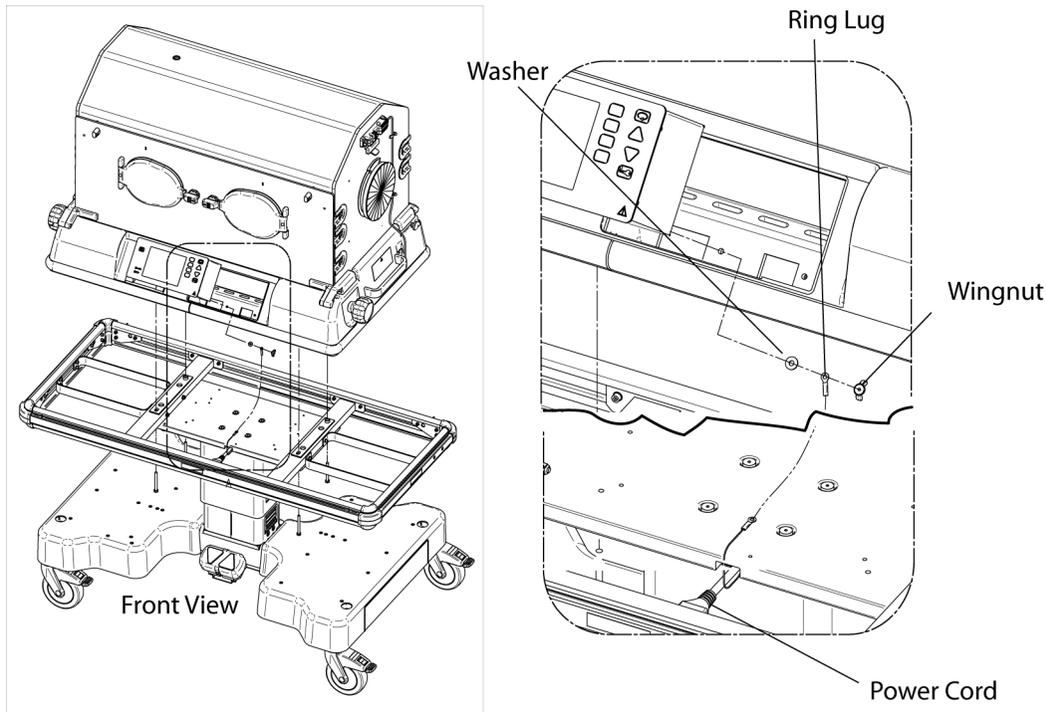
⚠ WARNING:

Only one monitor shelf should be used per incubator. When using the monitor shelf, always place the monitor in the center of the shelf, ensure that the monitor fits within the border of the shelf, and avoid stacking monitors on the shelf. Personal injury or equipment damage could occur.

Hood, Shell, and Stand Assembly

NOTE:

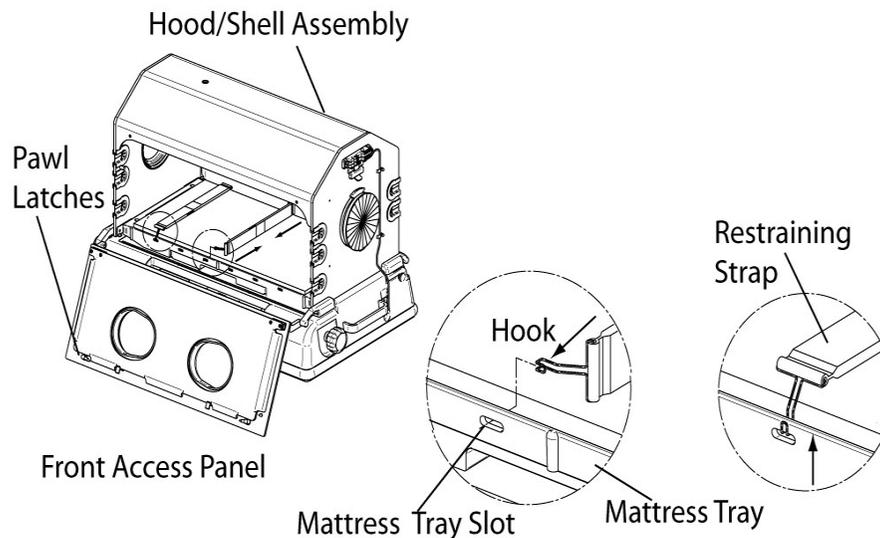
The stand and incubator assemblies are keyed so that the incubator can only mount in one orientation.



To assembly the hood/shell and stand assemblies:

1. Mount the hood/shell assembly on the stand with the provided screws.
2. Plug the stand power cord into the incubator power cord receptacle.
3. Remove the wing nut, next to the power cord connector, on the stand.
4. Place the ring lug between the washer and wingnut, on the stud.
5. Install the wing nut.

Mattress Restraint Strap Installation



1. Rotate the pawl latches and open the front access panel of the incubator.
2. Remove the restraint straps from the packaging.

NOTE:

Each package contains two pairs of interlocking restraints.

3. Place the restraining strap pairs on the mattress.
4. Locate the slots along the side of the mattress tray.
5. Lift one end of the restraining strap, and then turn the hook sideways, facing the inner ridge of the mattress tray.
6. Slide the hook into the required mattress slot.
7. When the hook clears the mattress slot opening, turn the hook, and then pull upward on the restraining strap.
8. Repeat steps 5 through 7 for the remaining restraining strap pair.

9. If necessary, adjust the width of the restraining strap so that it extends the across the mattress.
10. If the incubator is not equipped with a rear (optional) access panel, only perform steps 11 through 13; however, if the incubator is equipped with a rear (optional) access panel, perform steps 13 through 16.
11. Locate the corresponding slots on the other side of the mattress tray.
12. Repeat steps 5 through 8.
13. Close the front access panel, and rotate both sets of pawl latches until they are fully engaged.
14. Rotate the pawl latches and open the rear access panel.
15. Locate the corresponding slots on the other side of the mattress tray, and then repeat steps 5 through 8.
16. Close the rear access panel, and then rotate both pawl latches until they are fully engaged.

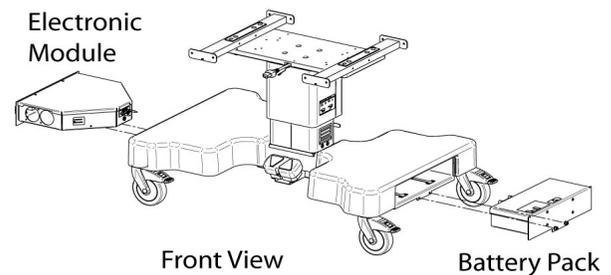
UPS System Installation

⚠ CAUTION:

Prior to installing the UPS battery pack, the power cord must be removed and the UPS module must be turned off to prevent the unit from spontaneously starting.

To install the UPS electronic module and battery pack of the UPS system:

1. Facing the front of the unit, the UPS electronic module will slide in from the left side of the stand, into the support plate with the vented brackets.
2. Use the 2 fastener screws to secure the UPS electronic module in place.
3. Facing the front of the unit, the battery pack will slide in from the right side of the stand, into the support plate.
4. Use the 2 fastener screws to secure the battery pack in place.



Weighing System (Scale Assembly)

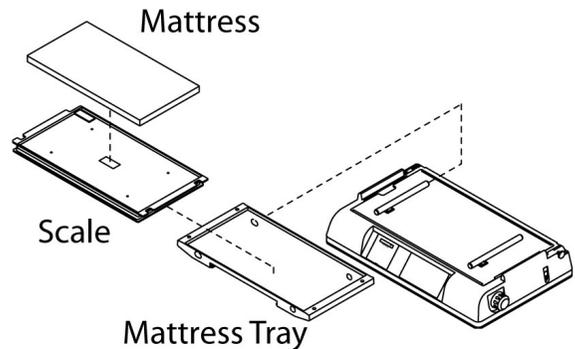
(PN 83 600 50)

NOTE:

The procedures in this section do not apply to the EU (Type NAWI) weighing system. Refer to the *Isolette® Infant Incubator, Type -NAWI, Weighing System Quick Reference Guide*.

To install the weighing system:

1. If required, remove all rail accessories from the front rail of the unit.
2. Rotate the pawl latches and open the front access panel of the incubator.
3. Remove the mattress from the incubator.
4. Ensure that the scale cable is located on the right-hand side of the incubator, towards the sensor module assembly.
5. Place the scale in the incubator, on the mattress tray.
6. Replace the mattress.
7. Connect the scale cable to the weight connector on the sensor module assembly (see “Sensor Module Connectors” on page 5-5).
8. Ensure all sensor leads are properly routed.
 - Make sure there is sufficient cable slack between the edge of the hood and the scale to permit the hood to rise to its fully open position and the mattress tray to be fully withdrawn from the hood.
 - 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.
9. If required, place previously dismantled rail accessories on the front rail of the unit.
10. To ensure proper operation, perform the scale operational checkout (see “Weighing System Operational Checkout” on page 4-20).



⚠ WARNING:

Utilize cable management clips to avoid infant entanglement and possible injury.

Humidity System

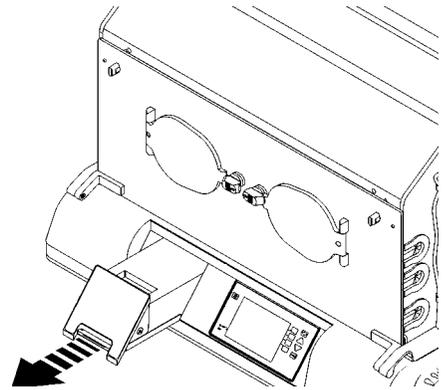
(PNs 83 613 70, 80, 81, 90) AND (PNs 83 615 70, 80, 81 AND 90)

NOTE:

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

To install the humidity reservoir:

1. Mount the reservoir and reservoir lid on the humidity tray.
2. Insert the humidity tray in the shell, and lock the handle.



Oxygen Control System

(PN 83 620 50, 51, 52, 53, 54, 23 AND PN 85 620 50, 51, 52, 53, 54, 23)

NOTE:

The oxygen control system is normally factory installed. To install the oxygen control system in the field, refer to the accompanying installation instructions.

Oxygen Sensor Cells

To install the oxygen sensor cells:

1. Remove the sensor module from the hood by withdrawing it until it stops.
2. Pull out on the clip located on the left side of the module, and remove the module from the hood.
3. Remove the oxygen sensor cover. Retain the hardware.
4. Withdraw the sensor cell connectors from inside the sensor module housing.
5. Screw the sensor cells into the oxygen cell mounting plate provided.
6. Connect the sensor cells to the sensor module.



NOTE:

The wires can plug into either sensor.

7. Install the oxygen cell mounting plate on the sensor module.
8. Replace the sensor module in the hood.
9. Activate the oxygen system (see “Oxygen Mode” on page 5-28).
10. Calibrate the oxygen system (see “Oxygen Sensor Calibration” on page 5-33).

Oxygen Calibration Fixture

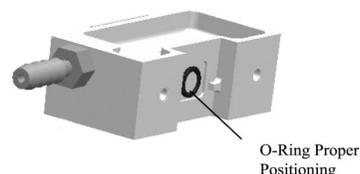
(PN 83 620 55, 83 620 71)

To install the 100% oxygen calibration fixture:

1. Withdraw the sensor module from the hood.
2. Pull out on 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 or rear (optional) 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. If equipped, also remove the sensor module slide lock.
6. Ensure the proper positioning of the O-ring 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.

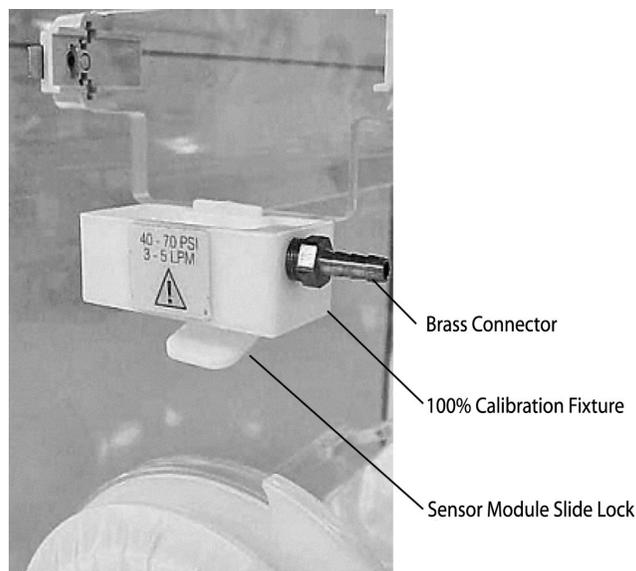


7. Mount the sensor module slide lock and 100% calibration fixture directly under the sensor module opening on the hood assembly.
8. Install the two screws to secure the sensor module slide lock and the 100% calibration fixture.

NOTE:

Make sure that the brass connector is facing the rear of the incubator and the wording on the label 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 will move up and down smoothly.

11. Select the 100% calibration level (see “System Configuration” on page 5-22).

Operational Checkout

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

NOTE:

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

WARNING:

Do not use the incubator if it fails to function as described below. Refer service to qualified personnel.

Controller Operational Checkout

SHOCK HAZARD:

Make sure the building power source is compatible with the electrical specifications shown on the column of the pedestal/stand or on the incubator. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:

To ensure grounding reliability, plug the AC power cord only into a properly grounded 3-wire hospital-grade or hospital-use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment. Personal injury or equipment damage could occur.

1. Before attempting to perform this procedure, refer to “Controls, Indicators and Connectors” on page 5-1.
2. Perform the initial power up procedures (see “System Start-Up and Shut-Down” on page 5-20).
3. Check the **Power Failure** alarm:
 - a. Unplug the power cord from the controller module.
 - b. Verify that the **Power Failure** alarm sounds, and the **Power Fail** indicator on the controller lights.
 - c. Then re-connect the power cord to the controller module and verify that after the self-test, Display 1 is shown on the controller module display screen.
4. Check the **Low Air Temperature** alarm.
 - a. Rotate the pawl latches and open the front or rear (optional) access panel of the incubator.
 - b. Verify that within approximately 5 min 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 below set point. At high ambient temperatures, fanning the air within the hood can be performed to induce the alarm.

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

5. Check the Skin mode of operation.
 - a. Insert a skin probe into the skin probe 1 connector of the sensor module.
 - b. Place the skin probe 10 cm (4") above the center mattress.
 - c. Set the skin set temperature to 35°C (95°F).
 - d. When the temperature stabilizes, rotate the pawl latches and open the front or rear (optional) access panel.
 - e. Verify that within approximately 5 min, the **Low Skin Temperature** alarm message is displayed in the Trend/Alarm window and the audible alarm sounds.
 - f. Close the front or rear access panel, and rotate both latches until fully engaged.

NOTE:

The alarm will not occur until the temperature falls 0.5°C or 1.0°C (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.

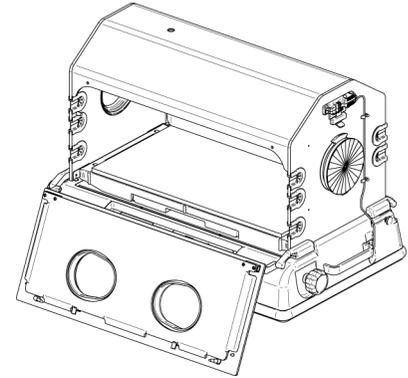
6. Check the **Remove Skin 2 Probe** alarm.
 - a. While operating in the Skin mode, with a skin probe connected in the skin probe 1 connector, insert a second skin probe into skin probe 2 connector of the sensor module.
 - b. Verify that when a second probe is connected to the sensor module, the **Remove Skin 2 Probe** alarm message is displayed in the Trend/Alarm window and an audible alarm sounds.
 - c. Remove the second skin probe from the skin probe 2 connector.
7. Check the **Skin Probe Disconnect** alarm.
 - a. In the Skin mode, disconnect the skin probe from the skin probe 1 connector of the sensor module.
 - b. Verify that the skin display blanks, the **Skin Probe Disconnect** alarm message is displayed in the Trend/Alarm window and the audible alarm sounds.
 - c. Press the **Alarm Silence/Reset** key. The audible alarm silences for 5 min.
 - d. Reconnect the skin probe in the skin probe 1 connector.
 - e. Verify that the incubator returns to normal operation.
8. Check the maximum air temperature.
 - a. Connect a skin probe to the sensor module and select Skin mode.
 - b. In the Temperature Override mode, select a temperature >37°C (see "Skin Mode" on page 5-24).
 - c. Place the skin probe outside the incubator.
 - d. Allow the incubator to heat.
 - e. If the **High Temperature Cut Out** alarm sounds, press the **Alarm Silence/Reset** key.
 - f. Verify that the incubator does not heat above 39.9°C (103.82°F), as indicated on the display screen.

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

Hood/Shell Operational Checkout

To check the hood/shell operation:

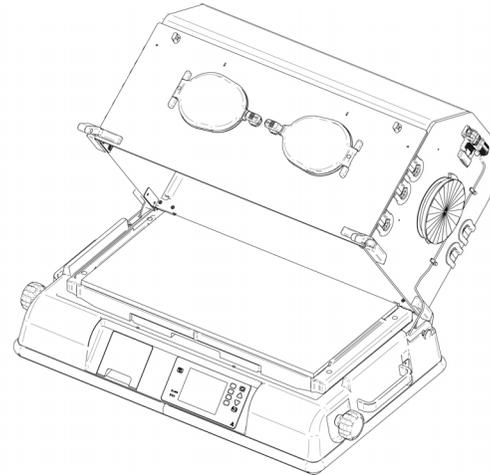
1. Check the access panel(s):
 - a. Rotate the pawl latches, and open the front and rear (optional) access panels.
 - b. At the controller, check that the door open symbol turns on.
 - c. Pivot the access panels to the full open position (hanging straight down).
 - d. Close the access panels, and rotate both sets of latches until fully engaged.
 - e. At the controller, check that the door open symbol turns off.



NOTE:

Both latches must fully engage to avoid accidental opening of the panels.

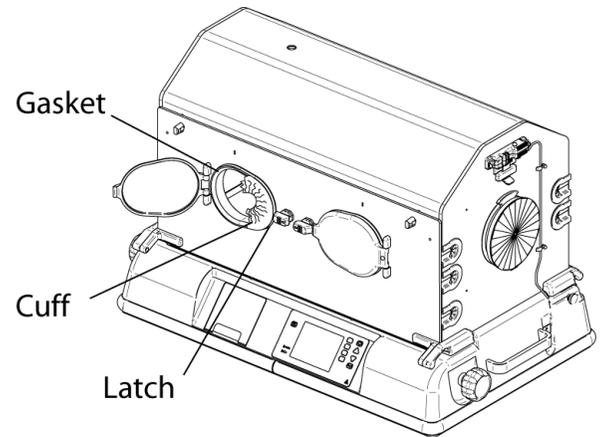
2. Check the hood operation
 - a. Rotate the pawl latches and open the front or rear (optional) access panel.
 - b. If equipped with a weighing scale, disconnect the weighing scale cable from the sensor module.
 - c. Close the access panel, and rotate both latches until they are fully engaged.
 - d. Slowly tilt the hood back until the hood locks in place.
 - e. To release the hood, pull on and hold the knob located on the right rear hinge while closing the hood.
 - f. If equipped with a weighing scale, perform steps g through i.
 - g. Rotate the pawl latches and open the front or rear (optional) access panel.
 - h. Reconnect the weighing scale cable to the sensor module.
 - i. Close the access panel and rotate both latches until they are fully engaged.



3. Rotate the outer ring of the iris entry ports. The iris opens and closes as rotation is continued through 360°.



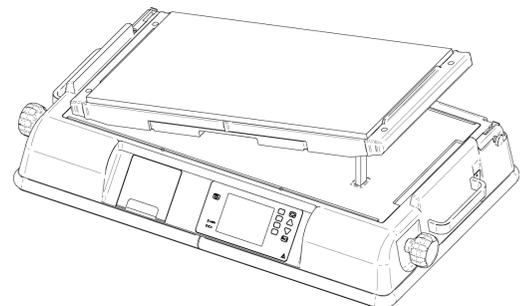
4. Check the access door latches and gaskets.
 - a. Press the door release of each access door and verify that the access door swings open.
 - b. Close the doors, and check for proper latching and quietness.
 - c. Check that the access door gaskets are properly installed in the port opening behind the access door.
 - d. If installed, check that the cuff is properly placed on the access door gasket.



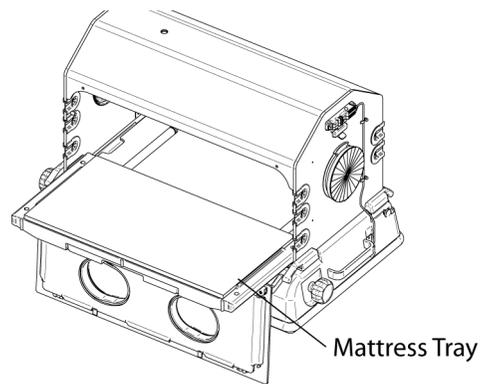
NOTE:

When installed correctly, there is a small opening in the center of the cuff.

5. Check that the inner walls are properly latched.
 - a. Open the front and rear (optional) access panels, and check that the front and rear inner walls are properly latched and the door open symbol turns on.
 - b. Close the front and rear access panels and check that the door open symbol, on the controller display, turn off.
6. Check the mattress elevators:
 - a. Rotate the right mattress tilt mechanism knob 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.
 - c. Repeat steps a and b for the left mattress tilt mechanism knob.
7. Check the mattress tray operation:



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



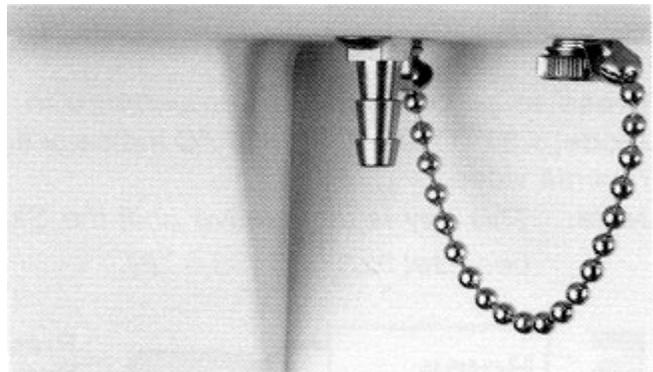
⚠ WARNING:

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. Failure to do so could result in personal injury or equipment damage.

8. Check the air intake microfilter, which is located under the rear shell of the incubator:
 - a. Loosen the two thumbscrews of the air intake filter cover, and remove the cover.
 - b. Inspect the microfilter. If visibly dirty, refer to “Air Intake Microfilter Maintenance” on page 6-10.
 - c. Install the air intake filter cover.

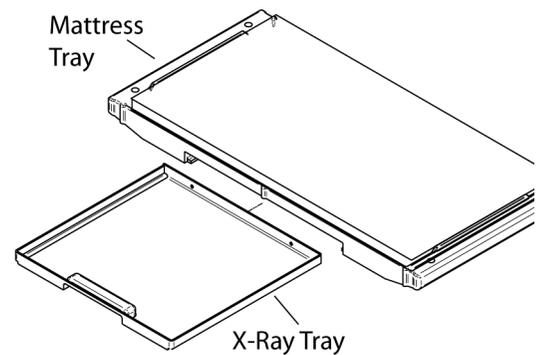


9. Check the air/oxygen system, located under the rear shell of the incubator:
 - a. Introduce a carefully measured 9 lpm of oxygen into the oxygen input connector.
 - b. Using a calibrated oxygen analyzer, monitor the level within the hood.
 - c. Verify that the level reaches the predicted level as indicated on the rear panel of the incubator (9 lpm equals 50% to 70%).



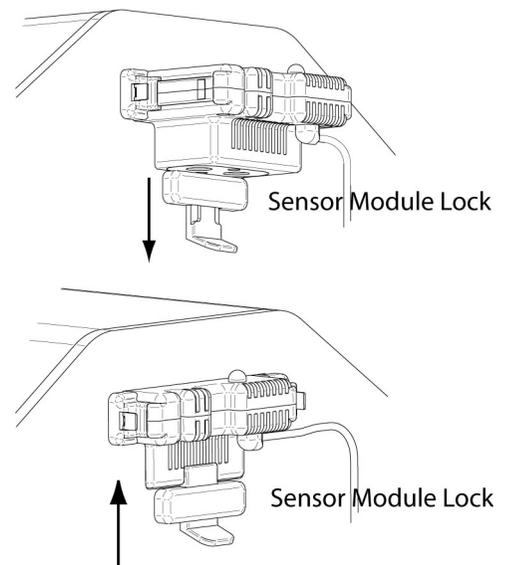
10. Check the x-ray tray:

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



11. Check the sensor module lock.

- a. Pull the sensor module lock down, and check that the sensor module slides in and out of the hood.
- b. Push the sensor module lock up.
- c. When the sensor module lock is in the up position, check that the sensor module is locked securely in place.



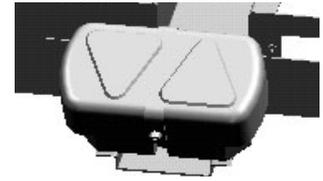
VHA Stand Operational Checkout

(OPTIONAL FEATURE)

⚠ WARNING:

When raising or lowering the incubator, the operator should ensure that both equipment and appendages are clear of the unit's travel path. 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 that there is sufficient clearance between the incubator and stand assembly. Do not raise or lower the unit while installing or removing medical gas tanks from the tank holder assembly. Failure to do so could result in personal injury or equipment damage. [IHA011]

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.



To check the VHA stand:

1. Make sure the system is fully powered (see “System Start-Up and Shut-Down” on page 5-20).
2. Press and hold the foot pedal control of the VHA stand, at the front of the unit, to raise or lower the stand to the maximum and minimum height.
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.

UPS System Operational Checkout

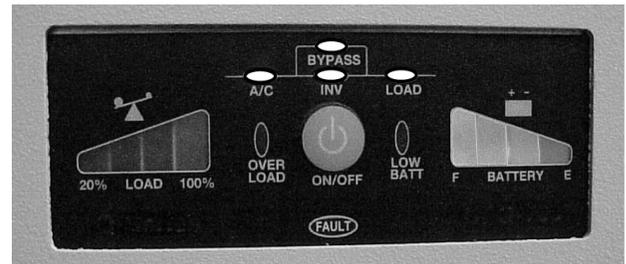
(OPTIONAL FEATURE)

⚠ WARNING:

Do not plug the AC input supply power cord of the uninterruptible power supply (UPS) system into any of the output receptacles on the incubator stand. This is a safety hazard and may cause irreparable damage to the UPS system.

1. Ensure the AC power cord is plugged into the AC inlet of the UPS electronic module and a properly grounded 3-wire hospital-grade or hospital-use outlet.
2. If the unit is switched off, at the UPS electronic module, press the **On/Off/Test** switch hold for 1 second or until the system beeps.
3. Press the **Power Switch** on the incubator.
4. Verify when initially turned on all LED indicators are turned on, the audible alarm pulses, and after a few seconds the **Bypass** LED turns off.
5. If the unit fails the self-test, remove it from service.

If the unit fails the self-test the **Fault** LED turns on. If AC power is still available, the **Bypass** LED is also illuminated.



Check On/Off/Test Switch and Low Battery Alarm

6. At the UPS electronic module, press and hold the **On/Off/Test** switch for 1 second or until the system beeps.
7. Verify that the system toggles on/off.
8. Quickly press the **On/Off/Test** switch (<1 second) in the line mode, and then verify:
 - Unit switches to battery operation for 10 seconds
 - **AC** LED turns off for 10 sec and then back on again

Test Battery Back-up Function

9. Unplug the AC power cord, at the electronics module, from the AC power source.
10. Verify the battery back-up audio beeps twice every 8 seconds.
11. Verify the **AC** LED turns off.
12. Quickly press the **On/Off/Test** switch (<1 second) to silence the audio.
13. Re-plug the AC power cord into an appropriate power source and verify the following indicator status:
 - **AC** LED turns on
 - **Inv.** LED and **Load** LED remain on
 - **Bypass** LED turns off

Rail System Operational Checkout

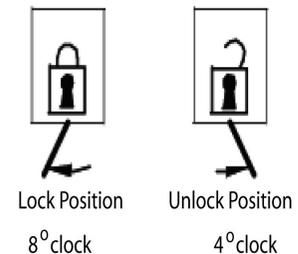
(STANDARD FEATURE ON C2000e, ONLY)

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

Verify that all latches are properly secured to the rail when in the locked position.

NOTE:

The mounting adapter locks when the toggle handle is switched to the left position (8 o'clock) and unlocks when the toggle handle is switched to the right position.



Oxygen Control Module Operational Checkout

(OPTIONAL FEATURE)

Perform the 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 “Oxygen Mode” on page 5-28).
4. Set the oxygen set point to 45% (see “Oxygen Control Set Point” on page 5-29).
5. Verify the oxygen analyzer reads 45% ± 5% within 5 min.

NOTE:

If the oxygen analyzer and the oxygen display do not read 45% ± 5% within 5 min, contact a local service representative.

Humidity System Operational Checkout

(OPTIONAL FEATURE)

To install the humidity reservoir:

1. Make sure the reservoir is full.
2. Place the probe of a calibrated hygrometer inside the hood at the center of the mattress.
3. Pre-warm the incubator to 35.0°C (95.0°F).
4. Activate the Humidity system (see “Humidity Mode” on page 5-29).
5. Set the humidity set point to 50% (see “Humidity Control Set Point” on page 5-30).
6. Verify within 30 min 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.

1. Ensure that the mattress is level, and not in the Trendelenburg or Reverse Trendelenburg position.
2. Activate the Weighing system (see “Scale Measurements” on page 5-27)
3. Verify that the Weight display is shown.
4. Remove any objects from the mattress before pressing the **Zero** softkey.
5. Press the **Zero** softkey 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. Reweigh the object (see “Re-weigh” on page 5-28)
10. Verify that the display again shows the value of the weight on the mattress.

Section 5

Instructions for Use

Controls, Indicators and Connectors

The **Controls, Indicators and Connectors** subsection lists and describes the controls, indicators and connectors on the system.

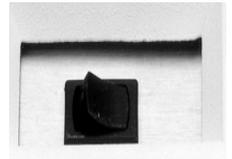
Incubator

Below are the incubator controls, indicators and connectors:

Incubator Controls

Power switch:

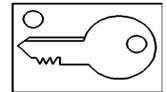
The **Main Power** (On/Off) switch is used to provide power for the main incubator functions. It is located in the front of the unit under the shell assembly.



Hardkeys

Keypad Lock key:

The **Keypad Lock** key disables all the controls on the user interface, except for the **Alarm Silence/Reset** key. After 15 s, the **Keypad Lock** LED lights to indicate that the keys are locked.



Alarm Silence/Reset key:

The **Alarm Silence/Reset** key silences the alarm conditions for 4, 5, 10 or 15 min.

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 lights.



Up/Down Arrow keys:

The **Up Arrow** and **Down Arrow** keys enable the user to select settings in the various displays and the System Configuration menu.

At the Set Up 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.



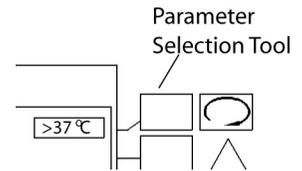
Display Selection key:

The **Display Selection** key enables the user to select between displays, which are not accessible via softkeys.



Parameter Selection keys:

The **Parameter Selection** keys enable the user to select parameter and menu options at the various displays.



Softkeys

Air softkey:

The **Air** softkey selects the Air mode, at Display 1.

Skin softkey:

The **Skin** softkey selects the Skin mode, at Display 1.

Humidity softkey:

The **Humidity** softkey selects the Humidity display, at Display 1.

Oxygen softkey:

The **Oxygen** softkey selects the Oxygen display, at Display 1.

Trend softkey:

The **Trend** softkey selects the Trend display, at Display 2.

Weight softkey:

The **Weight** softkey selects the Weight display, at Display 2, and activates the weighing function.

°C/°F softkey:

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

Home softkey:

The **Home** softkey enables the user to return to the previous display.

On softkey:

The **On** softkey is available at the Oxygen and Humidity displays. When pressed this softkey activates the Oxygen or Humidity systems.

Off softkey:

The **Off** softkey is available at the Oxygen and Humidity displays. When pressed this softkey deactivates the Oxygen or Humidity systems.

Cal softkey:

The **Cal** softkey is available at the Oxygen display and the Weight display. When pressed, this softkey initiates the calibration function for the oxygen sensors or scale.

Hours softkey:

The **Hours** softkey 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.

Clear softkey:

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

Display softkey:

The **Display** softkey 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.

Store softkey:

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

>37°C softkey:

The >37°C softkey activates the Temperature Override mode (greater than 37.0°C (98.6°F)).

->0/T<- (Zero/Tare) or **Zero** softkey:

The ->0/T<- softkey is available at the Weight display. When pressed it provides zero setting and tare balancing.

Incubator Indicators

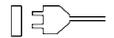
°C/°F indicator

The °C/°F indicator displays Celsius or Fahrenheit degrees for the air temperature, skin temperature and set point parameters.

Temperature °C

Power Failure indicator

The **Power failure** indicator lights when an interruption in power occurs.



>37°C indicator

The >37°C indicator lights when the set temperature is set to 37°C (98.6°F) or higher.



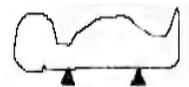
Door Open indicator

The **Door Open** indicator lights when the front and/or rear (optional) access panel(s) open(s).



Lift Baby indicator

The **Lift Baby** indicator is displayed during the zeroing routine. It prompts the user to lift the infant from the mattress.



5 kg symbol

The **5 kg** symbol is displayed during the calibration routine. It prompts the user to place a 5 kg weight on the mattress.



Rotating Wheel symbol

The **Rotating Wheel** symbol indicates the active status of a mode of operation. This symbol is displayed on the front panel in the respective window of the controlling parameter.



Weigh Sample bar (non EU scales)

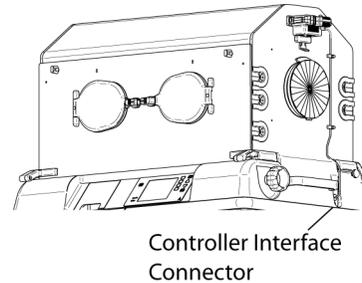
The Weigh Sample bar is used to display the progress of the weight sampling for the scale.



Incubator Connectors

Controller Interface Connector

The controller interface connector provides communication between the controller and sensor module.



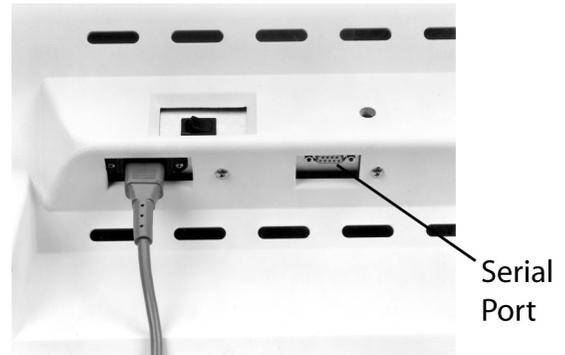
Serial Port

⚠ WARNING:

Devices connecting to the serial port must be compliant with EN 60601-1-2, the EMC requirement for Medical Devices. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Only connect equipment to the serial port that complies with the relevant IEC standard; and use data cables with plastic body connectors.



The serial port is located underneath the incubator shell, on the back of the controller and provides an isolated serial communication link. This port is used to connect the incubator to a bedside patient monitor or a central monitoring system. It enables viewing of the following system parameters using the VueLink™¹ system:

- Air and skin set point temperatures
- Current air and skin temperatures
- Alarm messages
- Oxygen set point
- Oxygen level
- Humidity set point
- Humidity level
- Infant weight

1. VueLink™ is a trademark of Philips Medical Systems.

This "Instructions for Use" manual is published for public use and is only meant for your information.

We do not guarantee the accuracy of these instructions with respect to your specific device type or status.

Only the "Instructions for Use" manual delivered together with a device is officially published for the use of that specific device.

Sensor Module

Below are the sensor module controls, indicators and connectors:

Sensor Module Controls

There are no controls on the sensor module.

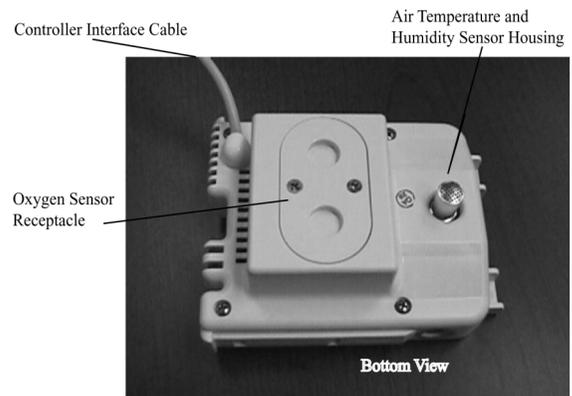
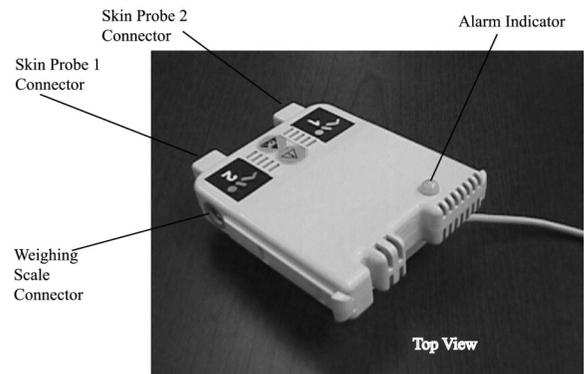
Sensor Module Indicators

The sensor module has one alarm indicator.

Sensor Module Connectors

The following connectors are found on the sensor module:

- Skin probe 1 connector
- Skin probe 2 connector
- Oxygen sensor receptacle
- Scale connector



Stand

Below are the fixed height and VHA stand controls, indicators and connectors:

Stand Controls

Main Circuit Breaker

The main circuit breaker is located on the stand assembly for all units not equipped with a uninterruptible power supply (UPS) system. For units equipped with UPS systems refer to “UPS Electronic Module” on page 5-7.



Main Circuit Breaker Locations

Incubator Model	Stand Configurations	Main Circuit Breaker Locations
Models C2000 and C2000e	Fixed Height stands without UPS systems	On the stand column below the AC receptacles (convenience outlet strip)
Model C2000e only	Fixed height stands with UPS systems	On the UPS electronic control module
Model C2000e only	Variable height adjustable (VHA) stands without UPS systems	At the rear, below the stand column
Model C2000 only	VHA stands without UPS systems	At the right side of the unit, between the stand legs
Model C2000e only	VHA stands with UPS systems	On the UPS electronic control module

Foot Pedal Controls

On all variable height adjustable (VHA) stands, foot pedal controls are provided. These controls are located on the front and rear bottom of the VHA stand and enable the user to adjust the height of the hood and shell assemblies.



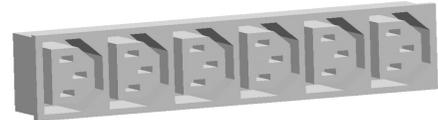
Stand Indicators

There are no indicators on the various stand configurations.

Stand Connectors

Convenience Outlet

An integral convenience outlet strip is located on the rear panel of all stand configurations.



AC Input Connector

The AC power cord plugs into the AC input connector and provides power to the unit from a properly grounded 3-wire hospital-grade or hospital-use outlet.

AC Input Connector Locations

Incubator Model	Stand Configurations	AC Power Cord Locations
Models C2000 and C2000e	Fixed Height stands without UPS systems	On the stand column below the AC receptacles (convenience outlet strip)
Model C2000e only	Fixed height stands with UPS systems	On the UPS electronic control module
Model C2000e only	Variable height adjustable (VHA) stands without UPS systems	At the rear, below the stand column
Model C2000 only	VHA stands without UPS systems	At the right side of the unit, between the stand legs
Model C2000e only	VHA stands with UPS systems	On the UPS electronic control module

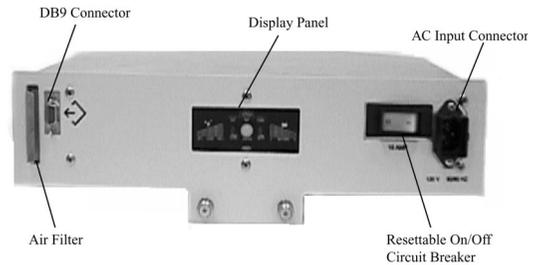
UPS Electronic Module

The UPS electronic module is mounted in the pedestal cover of units equipped with UPS systems.

UPS Electronic Module Controls

The exposed panel of the UPS electronic module contains the following controls:

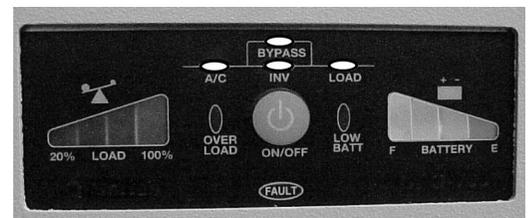
- **Resettable** circuit breaker
- Inverter **On/Off/Test** switch (located on the UPS electronic module display panel)



UPS Electronic Module Indicators

The front panel of the UPS electronic module contains the following indicators:

- **Load Level (LED) Bar**- when illuminated, the 4 LED bars indicate the relative load level range: 20%-40%, 40%-60%, 60%-80%, 80%-100%.
- **Overload LED** - the red LED indicates an overload condition.
- **System Fault LED** - the red LED indicates one or more of the following fault conditions: the system may need service; the connected load is too large; or there is a short circuit.
- **Low Battery LED** - the red LED indicates that the batteries are low and the battery back-up mode of the UPS system will soon shut down.
- **Battery Level (LED) Bar** - when illuminated, the 4 LED bars indicates the relative battery condition and back-up time available, on a scale from Full to Empty.
- **Line (Load) Status LED** - the blue LED indicates that AC power is available.
- **Inverter Status LED** - the blue LED indicates that the UPS system is on-line. This LED should always be illuminated while the UPS system is in normal operating mode or in a battery back-up mode. If the **Inverter Status LED** is not lit, the inverter has shutdown and should be in automatic bypass mode due to a system failure. A blinking **Inverter Status LED** means that the system is in Sleep mode.
- **Bypass Mode LED** - the amber LED indicates that output power is supplied via the bypass line (filtering only).
- **Load Status LED** - the blue LED indicates that power is being delivered to the load.



Uninterruptible Power Supply (UPS) Indicator Status

Mode	System Condition	Fault	Bypass	Inv.	AC LED	Beep
Bypass	Normal Line	—	On	On	On	—
Line	Normal Line	—	—	On	On	—
Line or Backup	Overload	—	—	On	On (Line)	Continuous
Backup	Normal Battery	—	—	On	—	Twice/8 s
Backup	Low Battery	—	—	On	—	Twice/s
Backup	System Fault	On	—	—	—	Continuous
Line	System Fault	On	On	—	On	Continuous
Line	System Fault, Line Abnormal	On	—	—	—	Continuous

UPS Electronic Module Connectors

The front panel of the UPS electronic module contains the following connectors:

- AC input
- DB9 connector

NOTE:

The DB9 connector is an electronic port for factory use only.

Displays

The controller displays supports the following windows: Temperature, Trend/Alarm window, Humidity window and Oxygen window. If the oxygen, humidity and scale options/accessories are installed, the associated data are displayed when the control is enabled.

The UPS electronic module is also equipped with a front display panel (see “UPS Electronic Module” on page 5-7.)

Temperature Window

The Temperature window also displays the actual air and/or skin temperature and the set point temperature of the controlling parameter.

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

Trend/Alarm Window

Four standard parameters are presented as trend graphs in the Trend/Alarm window (see “Displays” on page 5-9): 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: Oxygen (Servo) 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.

Humidity Window

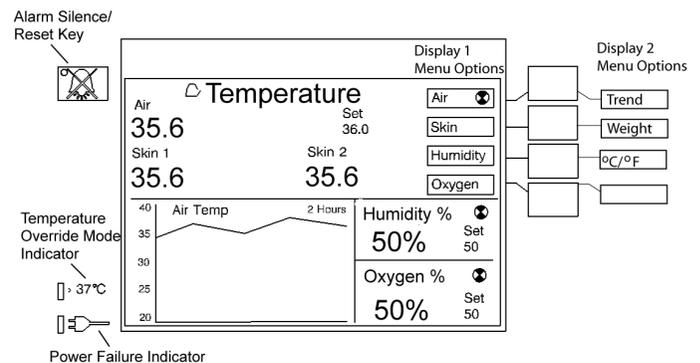
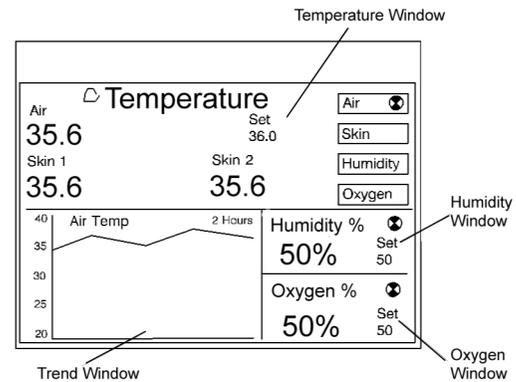
When the Humidity mode is activated, the actual and set point humidity values are displayed. A rotating wheel is displayed in the upper right-hand corner of the Humidity window.

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

Oxygen Window

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



System Displays

The controller has two system displays, Display 1 and Display 2, from which the following displays can be accessed:

- Temperature
- Trend
- Weight
- Oxygen
- Humidity

Temperature Displays

Access to the temperature displays is made available at Display 1. The temperature displays enable the user to:

- Select the air/skin control set point temperature
- Activate the Temperature Override mode

Trend Display

Access to the trend display is made available at Display 2. The trend display enables the user to select one of the following parameters for trending:

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

Weight Displays

Access to the scale displays is made available at Display 2. The scale displays enable the user to:

- Store weight measurements for trending
- Perform the zero/tare function
- Calibrate the scale (PN 83 600 50 only)
- Select the weight measurement display units

Oxygen Display

Access to the oxygen display is made available at Display 1. The Oxygen display enables the user to:

- Activate the oxygen system
- Select the oxygen control set point
- Calibrate the oxygen sensor

Humidity Display

Access to the humidity display is made available at Display 1. The humidity display enables the user to:

- Activate the humidity system
- Select the humidity control set point

Factory Default Settings

For non-UPS systems, in the event of a power failure lasting 10 min or less, the set points and operating mode are retained. For UPS systems, in the event of a power failure, the incubator operating time is determined by the amount of battery charge remaining when the event occurs. When the charge is depleted, and the system enters the Power Failure mode and the set points and operating mode are retained for 10 min.

For both UPS and non-UPS systems, when the incubator power is turned off, the temperature set point reverts to the factory setting of 35°C (95°F).

Factory default settings are listed in the table below:

Factory Default Settings

System Parameters	Defaults
Temperature control mode	Air mode
Skin set temperature	36.5°C (97.7°F)
Humidity set value	50% RH
Oxygen control mode	Off
Oxygen control set value	21%
Temperature units	°C
Weight units	kg
Trend	Air, 2 hours
Language	English
Altitude	0 ft (0 m)
Vuelink™ ^a	No
Air set temperature	35 °C (95°F)

a. Vuelink™ is a trademark of Philips Medical Systems.

Alarms

An alarm is signaled whenever a condition, which could be potentially hazardous, is detected.

System Alarms

System alarm conditions are always signaled with a visual and audible indication and an appropriate message in the Trend/Alarm window.

In the event that two or more system alarms occur simultaneously, or one after the other, the messages that describe the alarms are presented in sequence. A total of five messages can be presented in the Trend/Alarm window.

The **Alarm Silence/Reset** key is used to silence the audio alarm for a fixed amount of time and/or initiate a silence period before an alarm is actually activated.

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

- Reset one or multiple latched 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 previous latched alarm and silence a current alarm condition.

Alarm Message	Alarm Silence	Procedural Silence	Description
System Alarms			
Power Failure	N/A	N/A	This alarm is activated to signal complete failure of the electrical power or inadvertent disconnection from the power source.
Motor Failed	N/A	N/A	This alarm is activated when the fan motor speed falls outside specified tolerances for a period of > 40 s.
Controller Failure 1	N/A	N/A	This alarm is activated if a failure is detected in the EPROM circuitry.
Controller Failure 2	N/A	N/A	Not used.
Controller Failure 3	N/A	N/A	This alarm occurs if a failure is detected in the ambient air probe.
Controller Failure 4	N/A	N/A	This alarm occurs if a failure is detected in the cooling fan.
Controller Failure 5	N/A	N/A	This alarm occurs if a failure is detected with the display test.
Controller Failure 6	N/A	N/A	This alarm occurs if a failure is detected with the serial port loop-back test.
Controller Failure 7	N/A	N/A	This alarm occurs when a failure is detected with the power supply voltage
Controller Failure 8	N/A	N/A	This alarm occurs when a failure is detected with RAM test.

Alarm Message	Alarm Silence	Procedural Silence	Description
Controller Failure 9	N/A	N/A	This alarm occurs when a failure is detected with real time clock.
Controller Failure 10	N/A	N/A	This alarm occurs when a failure is detected with the watchdog timer test.
Controller Failure 11	N/A	N/A	This alarm occurs when a failure is detected with the relay test.
Controller Failure 12	N/A	N/A	Not used.
Controller Failure 13	N/A	N/A	This alarm occurs when a failure is detected with the heater circuit after the relays are off for 1 min. This can also occur if the current is above the maximum limits, during power up.
Controller Failure 14	N/A	N/A	This alarm occurs when the heater current is low.
Controller Failure 15	N/A	N/A	This alarm occurs on start-up when it is detected that a single parameter from non-volatile memory has been modified.
Controller Failure 16	N/A	N/A	This alarm occurs when on start-up it is detected that values of multiple parameters from non-volatile memory have been modified.
Controller Failure 17	N/A	N/A	This alarm occurs when a periodic check of all parameters stored in non-volatile memory determines that parameters have been modified without operator action.
Heater Failed 1	5 min	N/A	This alarm occurs when the incubator heater thermocouple voltage exceeds ± 40 mV.
Heater Failed 2	N/A	N/A	This alarm occurs when the heater thermocouple wires are open or shorted.
Humidity Heater Fail	15 min	N/A	This alarm occurs when the optional humidity system is installed and the humidity heater circuit draws too much current.
Sensor Disconnect	N/A	N/A	This alarm occurs when communication with the sensor module fails.
Sensor Out of Position	5 min	N/A	This alarm occurs when the sensor module is not in the hood or calibration position.
Stuck Key	N/A	N/A	This alarm occurs when a stuck key is detected.
Skin Mode Disabled	N/A	N/A	This alarm occurs when the controller is configured for Air only operation and the Skin mode is selected.
Sensor Module Failure 1	N/A	N/A	This alarm occurs when the sensor module PCB is disconnected.
Sensor Module Failure 2	N/A	N/A	This alarm occurs when the controller detects a relative humidity (RH) sensor temperature failure and humidity is installed.

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Alarm Message	Alarm Silence	Procedural Silence	Description
Sensor Module Failure 3	N/A	N/A	This alarm occurs when the controller detects a sensor module fan is not rotating.
Sensor Module Failure 4	N/A	N/A	This alarm occurs when the controller detects a sensor module analog-to-digital failure.
Sensor Module Failure 5	N/A	N/A	This alarm occurs when the controller detects an oxygen multiplexer calibration failure.
Sensor Module Failure 6	N/A	N/A	This alarm occurs when the controller detects a temperature multiplexer calibration failure.
Sensor Module Failure 7	N/A	N/A	This alarm occurs when the controller detects a sensor module RAM test failure.
Sensor Module Failure 8	N/A	N/A	This alarm occurs when the controller detects that the sensor module watchdog reset.
Temperature Specific Alarms			
High Temp CutOut	5 min	N/A	Under air control, this alarm is activated if the displayed incubator temperature reaches $37.7^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ for set temperatures $<37^{\circ}\text{C}$, or $39.7^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ for set temperatures $>37^{\circ}\text{C}$. Under skin control, this alarm is activated if the incubator temperature reaches $39.7^{\circ}\text{C} \pm 0.1^{\circ}\text{C}$ for any set temperature.
Skin 1 Probe Fail	N/A	N/A	This alarm is activated when the controlling skin temperature probe (only in the Skin mode) is mechanically connected but electrically open or short-circuited. The associated monitoring display reads “----.”
Skin Probe Disconnect	5 min	N/A	This alarm is activated when the Skin1 temperature probe (only in the Skin mode) is removed from the sensor module. The associated monitoring display is blanked.
Remove Skin2 Probe	N/A	N/A	This alarm occurs when two skin probes are installed and the Skin mode is selected.
Low Air Flow	15 min	15 min	This alarm occurs when an air circulation failure is detected.
High Air Temperature	15 min	N/A	This alarm occurs when the indicated displayed temperature differs from the set temperature by $>1.5^{\circ}\text{C}$.
Low Air Temperature	15 min	15 min	This alarm occurs when the indicated displayed temperature differs from the set temperature by $<2.5^{\circ}\text{C}$.
High Skin Temperature	15 min	N/A	This alarm occurs when the indicated displayed temperature differs from the set temperature by $>1.0^{\circ}\text{C}$ or 0.5°C (user selectable).

Alarm Message	Alarm Silence	Procedural Silence	Description
Low Skin Temperature	N/A	N/A	This alarm occurs when the indicated displayed temperature differs from the set temperature by $<1.0^{\circ}\text{C}$ or 0.5°C (user selectable).
Air Probe Failed	N/A	N/A	This alarm occurs when one of the three thermistors in the sensor module differ from the other two by 0.8°C or all three thermistors have a measurement error exceeding acceptable limits.
Connect Skin 1 Probe	N/A	N/A	This alarm occurs if the Skin mode is selected and there is no probe in the Skin1 probe connector.
High Skin1 Temperature	15 min	N/A	This alarm occurs when the Air mode is enabled and the infant skin temperature (from the Skin1 probe) is $>38.0^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$ when the Override mode is not active, or $>39.0^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$ when the $>37^{\circ}\text{C}$ mode of operation is active.
High Skin 2 Temperature	15 min	N/A	This alarm occurs when the Air mode is enabled and the infant skin temperature (from the Skin2 probe) is $>38.0^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$ when the Override mode is not active, or $>39.0^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$, when the $>37^{\circ}\text{C}$ mode of operation is active.
Remove Skin2 Probe			This alarm occurs in the Skin mode when a skin probe is inserted into the Skin2 probe connector.
Skin1 Probe Fail Alarm	5 min	N/A	This alarm occurs in the Skin mode if the Skin1 probe is electrically open or shorted.
Air Flow Probe Failed	N/A	N/A	This alarm occurs if the air flow probe connection is open or short circuited.
Humidity Specific Alarm			
Low Humidity	15 min	N/A	This alarm occurs when the humidity has not risen to a predetermined threshold within a designated amount of time. The most likely cause for this alarm is a low water level. This alarm is only available when the humidity control is activated.
Oxygen Specific Alarms			
High Oxygen%	4 min	N/A	This alarm occurs when the displayed oxygen value is $>3\%$ above the oxygen set point.
Low Oxygen%	4 min	4 min	This alarm occurs when the displayed oxygen value is $>3\%$ below the oxygen set point.
Oxygen Cell Difference	4 min	N/A	This alarm occurs when the oxygen cell readings differ by more than 3%. As a result, the oxygen flow into the system is interrupted.

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Alarm Message	Alarm Silence	Procedural Silence	Description
Oxygen Solenoid Fail	N/A	N/A	This alarm occurs when the oxygen solenoid voltage is not within limits.
Slide In Sensor	N/A	N/A	This alarm occurs after calibration is completed but the sensor module was not returned to the hood position.

UPS Alarms

UPS alarms conditions are signaled with an audible indication, generated by the UPS system.

The **Alarm Silence/Reset** key cannot be used to silence or reset UPS generated audible alarms.

Alarm Message	Alarm Silence	Procedural Silence	Description
AC Supply Failure Alarm	N/A	N/A	An audible alarm is produced when the AC supplied power fails. The system produces two short beeps every 8 s.
Low Battery Alarm	N/A	N/A	An alarm is produced when the battery voltage is low. The system produces two short beeps every second.
System Fault Alarm	N/A	N/A	An alarm is produced if the system detects a fault, overload or short circuit on the output. The system produces a continuous audible alarm.

System Prompts

Below is a description of messages appearing on the controller display screen, which do not generate audible or visual alarms:

System Prompt Messages

Alarm Messages	Description
Alarm Reset	This message is displayed when a previously latched alarm condition has been cleared with the Alarm Silence/Reset key.
Check Settings	This message is displayed when a failure is detected with the controller non-volatile memory test.
Keypad Locked - Press 	This message is displayed when the user presses a key and the Keypad Lock key is illuminated and active.
Not Installed (Humidity)	This message is displayed when humidity control is attempted, but the humidity system is not active and/or installed.
Not Installed (Oxygen)	This message is displayed when oxygen control is attempted, but the servo-controlled oxygen system is not active and/or installed.
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.
Procedure Silence	This message is displayed when no alarm conditions are present and the Alarm Silence/Reset key is pressed.

Alarm Messages	Description
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.
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.
Scale Disconnect	This message is displayed when a weighing function is initiated, but the controller determines that the scale is disconnected.
Too Much Weight	This message is displayed when the controller determines that the weight placed on the scale is >7 Kg.
Calibration Failed	This message is displayed when the scale fails the 5 Kg calibration.
Clear Mattress	This message is displayed when a scale calibration is attempted, and there is >1 Kg on the mattress.
Wait...	This message is displayed during the zeroing and calibration routine.
Zeroing Failed	This message is displayed when an additional weight in the mattress exceeds 4000±500 g when zeroing during infant weight.
Scale Failure 1	This message is displayed when the scale analog-to-digital converter fails.
Scale Failure 2	This message is displayed when the scale communication with the host fails.
Scale Failure 3	This message is displayed when the scale load cells fail.
100% Cal	This message is displayed when the oxygen system is performing 100% calibration.
21% Cal	This message is displayed when the oxygen system is performing 21% calibration.
Cal Fail	This message is displayed when the oxygen calibration fails.
Cal Pass	This alarm occurs when the oxygen calibration passes.
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.
Oxygen Cal Required	This message is displayed when re-calibration is required to use the oxygen control. This occurs after seven days of continuous oxygen control.
Slide Out Sensor	This message is displayed when the Cal softkey is pressed, but the sensor module is not pulled out into the calibration position.

Infant Placement

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

⚠ WARNING:

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

1. Pre-warm the incubator.
2. If rail accessories are mounted on the front rail, remove them.
3. Rotate the pawl latches and open the front access panel.
4. Pull the mattress tray out to the stop.
5. Place the infant on the mattress.
6. Return the mattress tray to normal-use position.
7. Close the access panel and ensure the pawl latches are fully engaged.
8. Re-install any rail accessories previously removed.

Operating Instructions

The **Operating Instructions** subsection describes the procedures required to operate the incubator, stand, options and accessories.

System Start-Up and Shut-Down

Below are the initial start-up procedures for UPS and non-UPS systems:

System Start-up

Initial Start-up for systems without UPS

To power up the system:

1. Plug the stand power cord into an appropriate AC power source.

If the unit is equipped with a detachable power cord, ensure the AC power cord is attached to the AC inlet of the stand.

2. Verify the power cord, from the stand, is firmly attached to the connector under the incubator shell assembly.
3. Turn on the **Main Power** circuit breaker on the stand.
4. Locate the **On/Off** switch under the incubator shell assembly, and then turn on the incubator.

During the self-test, all indicator lamps light, and the audible 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 **13**, or **Check Settings**.

5. At the incubator controller, select the desired system options, parameters and operating modes (see “System Configuration” on page 5-22).

Initial Start-up for systems with UPS

To power up the system:

⚠ WARNING:

Do not plug the AC input supply power cord of the uninterruptible power supply (UPS) system into any of the output receptacles on the incubator stand. This is a safety hazard and may cause irreparable damage to the UPS system.

1. Plug the power cord of UPS electronic module into an appropriate AC power source.
2. Verify the **Resettable** circuit breaker, on the UPS electronic control module, is in the On (1) position.
3. Then press and hold in the **On/Off/Test** switch until AC power is activated.
4. Verify the power cord, from the stand, is firmly attached to the connector under the incubator shell assembly.
5. Locate the **On/Off** switch under the incubator shell assembly, and then turn on the incubator.

During the self-test, all indicator lamps light, and the audible 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 appears in the Trend/Alarm window, refer the unit to service: **Controller Failure 1** through **13**, or **Check Settings**.

6. Select the desired system options, parameters and operating modes at the incubator controller (see “System Configuration” on page 5-22).
7. Make sure the unit is charged fully charged before the unit is ready for transport.

Recovery from Power Failure (non-UPS systems)

A flashing alarm indicator is displayed with a continuous audible alarm to indicate that primary power to the incubator controller failed.

When the primary power is restored, the unit reboots.

NOTE:

For power failures lasting 10 min or less, the set points selected in the Air mode or Skin mode and operating modes are retained.

Recovery from Power Failure (UPS systems)** CAUTION:**

When operating in the battery back-up mode, all accessories should be powered off to maximize battery-power usage time.

In the event of power failure, the main incubator functions continue without interruption, using battery back-up power. The variable height adjustable (VHA) stand is inoperable during power outages.

With batteries fully charged, the power available from battery backup is sufficient to maintain a C2000e Isolette® incubator in operation for 30 min in a 20°C ambient at a set point of 39°C in the Air mode, without oxygen or humidity control, or additional loads drawn from the accessory outlets. If the power outage extends beyond the duration of the battery back-up mode, the Power Failure Alarm is activated. A flashing alarm indicator is displayed with a continuous audible alarm to indicate that primary power to the incubator controller failed.

When the primary power is restored, the unit reboots. The system should be allowed to charge the battery for a maximum of 8 hours to ensure the battery pack is fully charged, prior to transport or attempting a transport.

NOTE:

For power failures lasting 10 min or less beyond the duration of the battery back-up mode, the set point selected in the Air mode or Skin mode and operating modes are retained.

System Shut Down

To properly shut down the unit:

1. Remove power from any device plugged into the convenience outlet strip.
2. Disconnect the incubator from the hospital oxygen source.
3. Turn off the **Power Switch**, on the incubator shell, to power down the incubator.
4. Turn off the main power source.

If the unit is equipped with a UPS system, press the **On/Off/Test** switch, on the Electronics Module.

If the unit is not equipped with a UPS system, turn off the **Main Power** circuit breaker, on the stand.

System Configuration

The System Configuration menu enables the user to access the system-configurable parameters. Refer to the table below:

System Configuration Menu

Display Selection Key Selections	Up/Down Arrow Key Selections	Default Setting
Humidity option	Yes/No	No
Oxygen option	Yes/No	No
Oxygen calibration level	100%/21%	21%
Skin temperature alarm limit	1.0°C/.05°C	1.0°C
Skin mode	Yes/No	Yes
Language	ENG, FRN, GER, SPN, ITAL, JAP, DUT, DAN, NOR, POL, POR, SWE, FIN, FLE, GREEK, CZECK, SLOVAK	English
Weight unit	lb/kg	kg
Air set temperature	30.0°C to 37.0°C (increments of .1°C)	35.0°C
Altitude	0 ft - 12,000 ft (3657 m) (increments of 2000 ft)	0 ft
VueLink™ ^a	Yes/No	No

a. VueLink™ is a trademark of Philips Medical Systems.

To select desired settings, at the System Configuration menu:

1. If the incubator is already turned on, perform steps 2 and 3 to enter the configuration mode; otherwise continue at step 5.
2. If the keypad is locked, press the **Keypad Lock** key to unlock the keypad.
3. Press the following key sequence:
 - **Trend** key
 - **Up Arrow** key
 - **Keypad Lock** key
 - **Down Arrow** key
 - **Display Selection** key
4. Continue at step 7.
5. Press and hold the **Alarm Silence/Reset** key.
6. Turn the incubator on and continue to hold the **Alarm Silence/Reset** key while the unit powers up.
7. Select the menu options, using the **Display Selection** key.

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8. Select the required setting(s) using the **Up Arrow** and **Down Arrow** keys.
9. Press the **Alarm Silence/Reset** key, to exit the Set Configuration menu.

Variable Height Adjustment

▲ WARNING:

When raising or lowering the incubator, the operator should ensure that both equipment and appendages are clear of the unit's travel path. 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 that there is sufficient clearance between the incubator and stand assembly. Do not raise or lower the unit while installing or removing medical gas tanks from the tank holder assembly. Failure to do so could result in personal injury or equipment damage. [IHA011]

If the unit has the optional vertical height adjustable stand, it includes 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 on the front/rear foot pedal of the VHA stand.

Temperature Settings

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.

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

- Before attempting to operate the incubator, become familiar with the operating precautions. In addition, refer to "Controls, Indicators and Connectors" on page 5-1.
- If the incubator is turned off, or has been out of service for cleaning or maintenance, refer to the *Isolette® Infant Incubator, Models C2000 and C2000e Service Manual*, and perform the function checks. If the incubator is already in service, and the function checks have not been performed, become familiar with the various aspects of the hood/shell operation.
- Keep the infant clear of the slots where the warm air enters the patient compartment.
- Routinely monitor the infant rectal and/or auxiliary temperature according to the attending physician orders or Nursery Standing Orders.

Air Mode

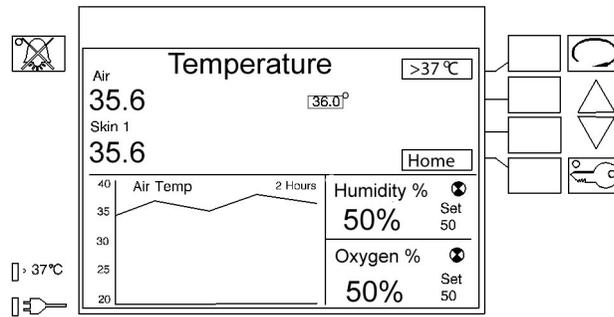
To select the air temperature control set point:

1. At Display 1, press the **Air** softkey to select the Air mode.

NOTE:

If no keys are pressed within 15 s of selecting this display, it automatically reverts to Display 1.

2. Set the air temperature to the prescribed setting.
 - a. Press the **Up Arrow** key 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, press the **Up Arrow** key to raise the set temperature from 37.0°C (98.6°F) to 39.0°C (102.2°F).
 - b. Press the **Down Arrow** key to lower the set temperature from 39.0°C (98.6°F) to 20°C (68°F) in 0.1° decrements.



NOTE:

The **>37°C** softkey activates the Temperature Override mode (greater than 37.0°C (98.6°F)). The **>37°C** indicator lights, and **>37°C** displays in reverse video.

NOTE:

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

3. To confirm the **Air Set Temperature** setting and return to Display 1, press the **Home** softkey.

NOTE:

Once stabilized, the incubator temperature stays within 0.5°C of the set temperature.

4. To lock the keypad, press the **Keylock** key.

Skin Mode

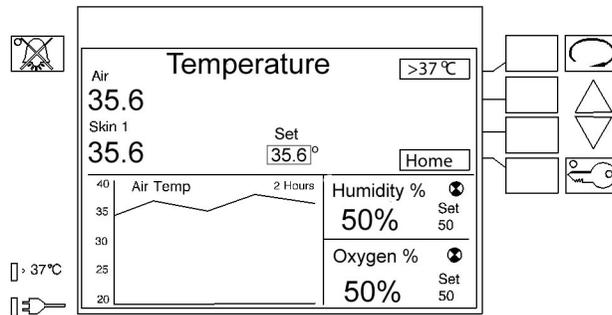
1. At Display 1, press the **Skin** softkey to select the Skin mode.

NOTE:

If no keys are pressed within 15 s of selecting this display, it automatically reverts to Display 1.

2. Attach the skin probe to the infant (see “Skin Probe Attachment” on page 5-25).
3. Set the temperature to the prescribed setting:

- a. Press the **Up Arrow** key to raise the set temperature from 34.0°C (93.2°F) to 37.0°C (98.6°F) in 0.1° increments. In Temperature Override mode, press the **>37°C** key, and press the **Up Arrow** key to raise the set temperature from 37.0°C (98.6°F) to 38.0°C (100.4°F).
- b. Press the **Down Arrow** key to lower the set temperature from 38.0°C (98.6°F) to 34.0°C (93.2°F) in 0.1° decrements.



NOTE:

The **>37°C** softkey activates the Temperature Override mode (greater than 37.0°C (98.6°F)). The **>37°C** indicator lights, and **>37°C** displays in reverse video.

NOTE:

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

4. To confirm the **Skin Set Temperature** setting and return to Display 1, press the **Home** softkey.

NOTE:

Once stabilized, the incubator temperature stays within 0.5°C of the set temperature.

5. To lock the keypad, press the **Keylock** key.

Skin Probe Attachment

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

⚠ WARNING:

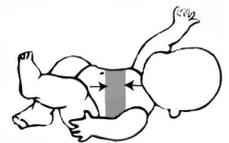
Never place the skin temperature probe under the infant or use it rectally. Personal injury could occur.

⚠ 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.

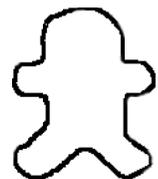
3. Place the probe on the infant:

- a. When the infant is on his/her back or side, place the probe on the abdomen, halfway between the xyphoid and the umbilicus.
- b. 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.

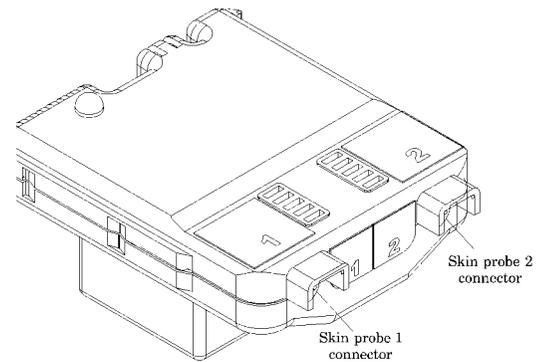
- a. Remove the backing from the Care-For-Me™ cover and attach the probe.
- b. To stabilize the attached probe, place another Care-For-Me™ cover over the probe wire approximately 3 cm (1") to 4 cm (2") from the probe tip.



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 min 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 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.

Data Trends

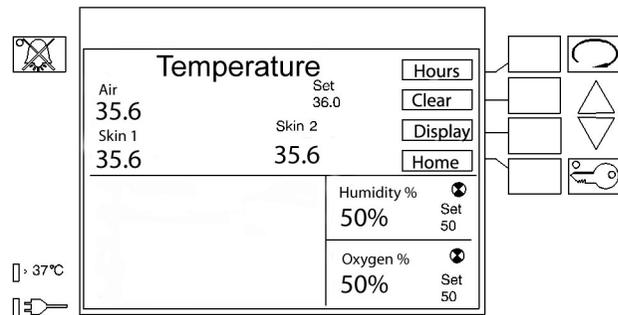
To select a trend display for viewing, perform the following steps:

1. If necessary, unlock the keypad.
2. Access the Trend display.
 - a. At Display 1, press the **Display Selection** key, and select Display 2.
 - b. At Display 2, press the **Trend** softkey to select the Trend display and view the menu options.
3. To clear all previous Trend displays, press and hold the **Clear** softkey.
4. Press the **Hours** softkey to select the trend period: 2, 4, 8, 12, or 24 hours.

NOTE:

The **Hours** softkey is not required for trends of the infant weight. Refer to “Scale Measurements” on page 5-27.

5. To select one of the following Trend displays, press the **Display Selection** key 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** softkey.
7. To lock the keypad, press the **Keylock** key.



Scale Measurements

NOTE:

The procedures described in this section do not apply to the EU (Type NAWI) weighing system. Refer to the *Isolette® Infant Incubator, Type -NAWI, Weighing System Quick Reference Guide*.

Methods and Techniques to Obtain Accurate Infant Weight are described below:

- 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 IV 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, IV tubes, sensor leads.

Initial Weigh

⚠ WARNING:

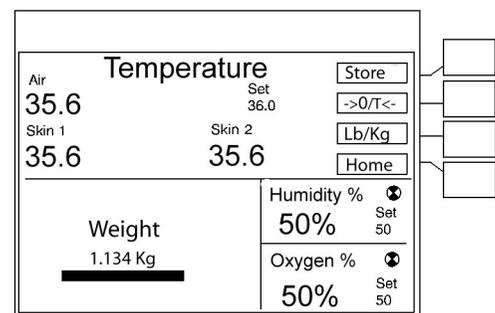
For infant safety, do **not** leave the infant unattended when the access panel is open. Personal injury could occur.

NOTE:

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

To perform the initial weighing function:

1. If necessary, unlock the keypad.
2. At Display 1, press the **Display Selection** key, and select Display 2.
3. At Display 2, press the **Weight** softkey.
4. Press the **->0/T<-** or **Zero** softkey. The **Lift Baby** indicator is displayed.
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.
8. To enter the infant weight in the Trend/Alarm window, press the **Store** key.



NOTE:

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

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

Re-weigh

1. To re-weigh the infant without removing or adding anything to the mattress, press the **Weight** softkey 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 5-27, to ensure accurate measurement of the infant weight.

Oxygen Control

⚠ WARNING:

If the patient’s arterial oxygen levels cannot be maintained when the oxygen control settings is set to maximum, the attending physician should prescribe alternate means of oxygenation. Failure to do so could result in personal injury or equipment damage.

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 $\pm 3\%$ from the current set point. If the oxygen concentration rises above or falls below the $\pm 3\%$ limit, an audible and visual alarm occur, and the message Low Oxygen% or High Oxygen% is displayed in the Trend/Alarm window.

NOTE:

When using the servo-controlled oxygen system during oxygen administration, the oxygen concentration guide is not valid.

Oxygen Mode

The activate the Oxygen Control mode:

1. Ensure the oxygen supply provides an inlet pressure and inlet flow rate in compliance with the specifications (see “Oxygen System” on page 2-8).
2. Connect the oxygen hose (at Inlet 2) to the oxygen supply.
3. At Display 1, press the **Oxygen** softkey.

NOTE:

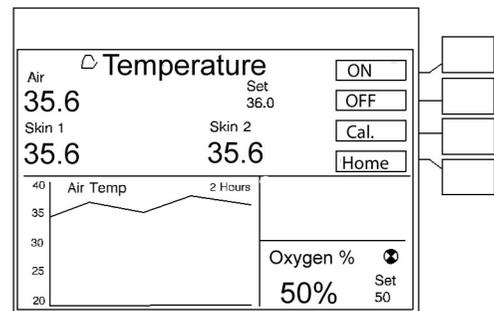
If no keys are pressed within 15 s of selecting the **Oxygen** softkey, the display automatically reverts to Display 1.

4. Press the **ON** softkey to activate the Oxygen mode.

NOTE:

When the Oxygen mode is activated the rotating wheel is displayed in the Oxygen window.

5. If the message **Cal Required** is displayed, calibrate the oxygen control system (see “Oxygen Sensor Calibration” on page 5-33).
6. To deactivate the Oxygen mode, press the **OFF** softkey.



Oxygen Control Set Point

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

1. Activate the Oxygen mode (see “Oxygen Control” on page 5-28).
2. Adjust the oxygen set point:
 - a. Press the **Up Arrow** key to raise the set point from 21% to 65%.
 - b. Press the **Down Arrow** to lower the set point from 65% to 21%.
3. Press the **Home** softkey to acknowledge the Oxygen Control setting, and return to Display 1.
4. Press the **Keylock** key to lock the keypad.

Humidity Settings

⚠ 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 rectal and/or axillary temperature according to the attending physician’s orders or Nursery Standing Orders. Failure to do so could result in personal injury.

NOTE:

At humidity levels greater than 60 RH%, 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.

If the humidity system is not in use, remove water from the humidity reservoir.

Humidity Mode

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

⚠ CAUTION:

To prolong the useful life of the humidity module, use only distilled water. **Sterile water is not an acceptable substitute for distilled water.** Equipment damage could occur.

2. Fill the humidity reservoir with distilled water.
3. At Display 1, press the **Humidity** softkey.
4. Press the **ON** softkey to activate the Humidity mode.

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

5. To deactivate the Humidity mode, press the **OFF** softkey.

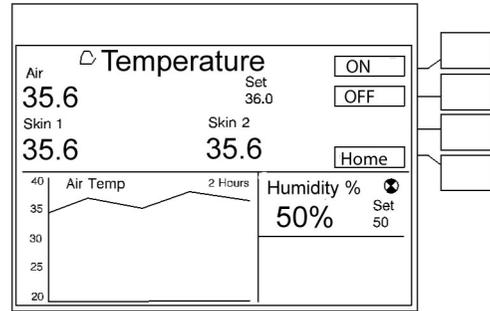
Humidity Control Set Point

1. Activate the humidity system (see “Humidity Mode” on page 5-29).

NOTE:

If no keys are pressed within 15 s of selecting the **Humidity** display, the display automatically reverts to Display 1.

2. Adjust the humidity set point.
 - a. Press and hold the **Up Arrow** key to raise the humidity set point from a range of 30% to 95%, in 1% increments.
 - b. Press and hold the **Down Arrow** key to lower the humidity set point from a range of 95% to 30%, in 1% decrements.
3. Press the **Home** softkey to acknowledge the Humidity control setting, and return to Display 1.
4. Press the **Keylock** key to lock the keypad.



VueLink™¹ Monitoring

VueLink™ software enables the user to view patient parameters from the Isolette® Infant Incubator, Models C2000 and C2000e 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 “Incubator Connectors” on page 5-4).
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.

NOTE:

Values from the bedside patient monitor can be archived using a central monitoring system. For details on this function, contact a local Philips Medical representative.

1. VueLink™ is a trademark of Philips Medical Systems.

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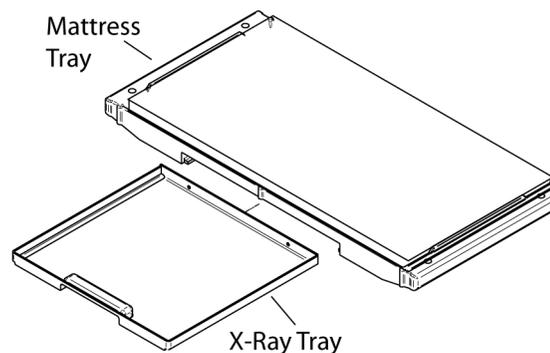
X-Ray Tray Usage

⚠ WARNING:

For infant safety, do **not** leave the infant unattended when the access panel is open. Personal injury could occur.

To use the x-ray tray, perform the following steps:

1. For units equipped with the rail system, 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 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 the pawl latches are fully engaged.
8. When the x-ray is completed, repeat steps 1 and 2 above.
9. Remove the x-ray cassette from the tray, and return the tray.
10. Close the access panel and ensure the pawl latches are fully engaged.



Non-Servo Control Oxygen Usage

⚠ WARNING:

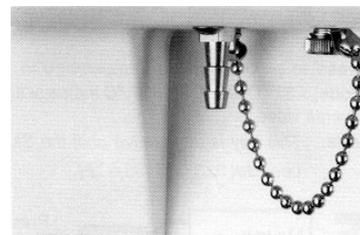
The oxygen flow rates labeled on the incubator and percentages displayed on the oxygen display cannot be used as an accurate indication of oxygen concentrations in an incubator and should only be used as a guide. Measure oxygen concentrations with a calibrated oxygen analyzer at intervals directed by the attending physicians. Failure to do so could result in personal injury or equipment damage.

To use non-servo control oxygen, perform the following steps:

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 pedestal/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 Inlet 1, using the 3/16" inner diameter surgical tubing.
4. Allow oxygen concentrations to stabilize.

NOTE:

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



Oxygen Concentration Guide

Oxygen Supply	Approximate Oxygen%
3 lpm	30% - 45%
6 lpm	46% - 60%
9 lpm	50% - 70%
12 lpm	55% - 75%
15 lpm	60% - 80%

Calibration

Scale Calibration

NOTE:

The procedures described in this section do not apply to the EU (Type NAWI) weighing system. Refer to the *Isolette® Infant Incubator, Type -NAWI, Weighing System Quick Reference Guide*.

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 should 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** softkey.
3. If necessary, remove any objects from the mattress.
4. At the Weight display, press the **->0/T<-** or **Zero** softkey two times, and then press the Display Selection key.
5. At the Scale Calibration display, press the **Cal** softkey.

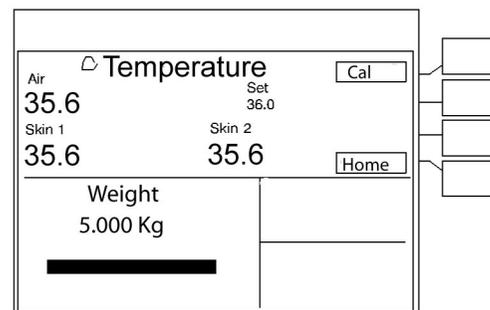
The **Wait...** message is displayed, and then replaced with the **5 kg** symbol.

6. Within 12 s 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 s 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.
8. Remove the weight, and then press the **Home** softkey to return to Display 2.



Oxygen Sensor Calibration

NOTE:

Only single point calibration is required.

NOTE:

If the message **Cal Required** is displayed, calibrate the oxygen control system. At a minimum, daily calibrations are recommended.

NOTE:

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

Oxygen Sensor Calibration to Room Air (21%)

⚠ WARNING:

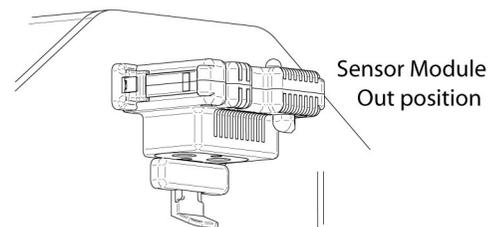
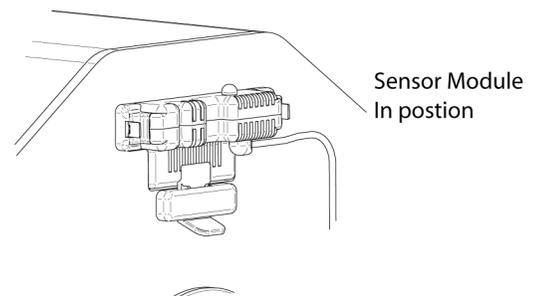
To perform the 21% oxygen calibration procedure, ensure that the incubator is equipped with the standard sensor module slide-lock. If the 100% oxygen calibration fixture is used during the 21% calibration procedure, the calibration will be inaccurate. Infant injury could occur.

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” on page 5-22).
2. If required, configure the oxygen calibration level setting for 21%.
3. Ensure that the incubator is equipped with the standard sensor module slide-lock, **not** the 100% oxygen calibration fixture.
4. At Display 1, press the **Oxygen** softkey.
5. Press the **ON** softkey, and then the **Cal** softkey. The message **Slide Out Sensor** is displayed.
6. Within 5 s, withdraw the sensor module from the incubator hood to prevent a **Cal Fail** message.

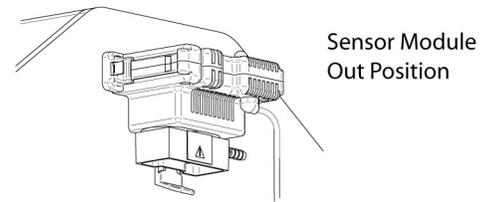
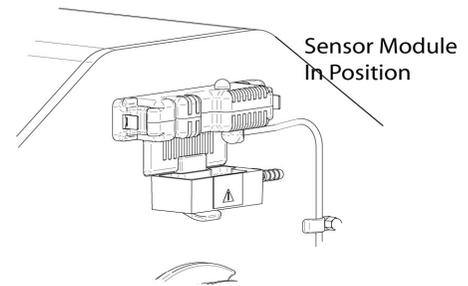
When calibration is complete, the message **Cal Pass** is displayed in the Oxygen window.

7. Slide the sensor module inside the hood, and then press the **ON** softkey.
8. Use the **Up** and **Down Arrow** keys to set the oxygen percentage.
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 “Oxygen Calibration Fixture” on page 4-11).
2. Verify the oxygen calibration level setting (21% or 100%) at the System Configuration Menu (see “System Configuration” on page 5-22).
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 lpm to 5 lpm and to the barb fitting on the calibration fixture.
5. Turn on the oxygen.
6. At Display 1, press the **Oxygen** softkey.
7. Press the **ON** softkey, and then the **Cal** softkey.
8. Within 5 s, withdraw the sensor module from the incubator hood to prevent a **Cal Fail** message.



NOTE:

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** softkey.
12. Use the **Up** and **Down Arrow** keys to set the oxygen percentage.
13. If the message **Cal Fail** is displayed, repeat the procedure.
14. If the calibration procedure is unsuccessful a second time, refer the unit to qualified service personnel.

Patient Transport

With batteries fully charged, the power available from battery backup is sufficient to maintain an Isolette® Infant Incubator, Model C2000e in operation for 30 min in a 20°C ambient at a set point of 39°C in the Air mode, without oxygen or humidity control, or additional loads drawn from the accessory outlets.

To transport the patient:

SHOCK HAZARD:

To ensure grounding reliability, plug the AC power cord only into a properly grounded 3-wire hospital-grade or hospital-use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment. Personal injury or equipment damage could occur.

1. At the display panel on the UPS electronic module, verify the battery level.
2. If the battery is not fully charged, plug the unit into an acceptable AC power source and ensure that the **Resettable** circuit breaker is in the On (1) position.

NOTE:

Allow a maximum of 8 hours to fully charge the battery pack. Do not attempt to transport the patient until the battery is fully charged.

CAUTION:

When operating in the battery back-up mode, all accessories plugged into the stand receptacles should be powered off to maximize battery-power usage time.

3. Turn off all accessories plugged into the stand receptacles and remove accessories and items not in use or necessary for the patient care during transport.
4. Secure all accessories deemed necessary for the patient care during transport.

WARNING:

For optimum stability, always lower the incubator to its lowest position prior to transport. Make sure that items placed on the monitor shelf are properly secured. Failure to do so could result in personal injury or equipment damage.

WARNING:

When raising or lowering the incubator, the operator should ensure that both equipment and appendages are clear of the unit's travel path. 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 that there is sufficient clearance between the incubator and stand assembly. Do not raise or lower the unit while installing or removing medical gas tanks from the tank holder assembly. Failure to do so could result in personal injury or equipment damage. [IHA011]

5. If equipped with VHA, adjust the stand to its lowest position prior to transporting the patient.

⚠ WARNING:

Prior to transport, always ensure the mattress is level, i.e., not in the Trendelenburg or Reverse Trendelenburg position.

6. Ensure the mattress is in the flat position.
7. Secure the infant using the restraining straps with the slotted mattress tray.

NOTE:

The straps should be placed over the infant and the ends firmly pressed together. Care should be taken not to overtighten the straps.

8. If a monitor is on top of the monitor shelf, make sure the monitor straps are properly installed and secured.
9. Unplug the power cord from the AC source.

The unit automatically switches to the battery back-up mode.

⚠ WARNING:

To prevent transport interference or possible trip and fall hazards, always properly secure the power cord. Failure to do so could result in personal injury or equipment damage.

10. Coil up the power cord and secure it.

⚠ 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 and either remove or secure all loose system components to prevent possible patient injury or equipment damage. If the move involves varying floor heights or a complete floor level change (i.e. thresholds, ramps, elevators), remove all items either not being used or not necessary for the move, lower the VHA, IV poles and shelves to their lowest position, place all drawers in their locked state, and remove all accessories from the front and rear rail position. [IHA033]

⚠ 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. Personal injury or equipment damage could occur.

⚠ WARNING:

Always close and latch drawers when not in use and particularly when the incubator is being moved.

11. Safely transport the patient within the facility.

⚠ WARNING:

Do not plug the AC input supply power cord of the uninterruptible power supply (UPS) system into any of the output receptacles on the incubator stand. This is a safety hazard and may cause irreparable damage to the UPS system.

12. When the transport is completed, plug the unit into an appropriate AC source to fully charge the battery.

NOTE:

Allow a maximum of 8 hours to fully charge the battery pack. Do not attempt to transport the patient until the battery is fully charged.

Notes:

Section 6

Cleaning, Maintenance, and Replacement Parts

Cleaning

⚠ WARNING:

Follow the product manufacturer's cleaning instructions. Failure to do so could result in personal injury or equipment damage.

⚠ 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. Personal injury or equipment damage could occur.

⚡ SHOCK HAZARD:

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. Personal injury or equipment damage could occur.

⚡ SHOCK HAZARD:

Unplug the unit from its power source prior to cleaning or maintenance. For units equipped with an uninterruptible power supply (UPS) system, also remove the battery pack prior to cleaning or maintenance. Failure to do so could result in personal injury or equipment damage.

⚡ SHOCK HAZARD:

Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

⚠ CAUTION:

Do not use harsh cleansers/detergents such as scouring pads or heavy duty grease removers or solvents, such as acetone. Equipment damage could occur.

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.

Steam Cleaning

Do not use any steam cleaning device on the unit. Excessive moisture can cause damage.

Stain Cleaning

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.

Disinfecting

- Use an intermediate level, tuberculocidal cleanser/disinfectant or equivalent only after the unit is empty and disassembled (see “Disassembly for Cleaning” on page 6-2).

NOTE:

For US markets only, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA), such as Kleenaseptic®¹ Germicidal Surface Cleanser or a 2% gluteraldehyde solution.

- Dilute the disinfectant as specified on the manufacturer label.
 - Thoroughly 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, refer to disassembly procedures described in the *Isolette® Infant Incubator, Models C2000 and C2000e Service Manual*.

⚠ CAUTION:

Prior to disassembling the hood and shell assemblies, remove accessories mounted to the rail or transition plate. Equipment damage could occur.

1. Unplug the unit from its power source.

1. Kleenaseptic® is a registered trademark of Metrex Research Corporation.

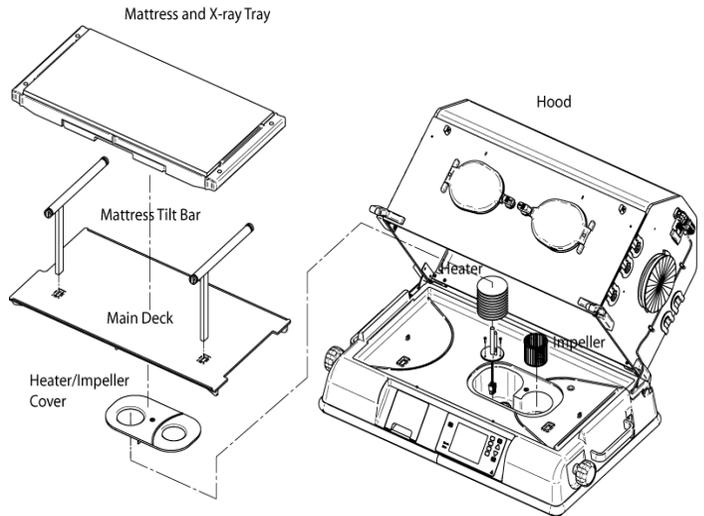
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Mattress Tray, X-Ray Tray, Main Deck, Scale (optional)

2. Disconnect the cables from the sensor module.
3. Slowly raise the hood.
4. Remove the mattress.
5. If the incubator is equipped with a weighing scale, perform steps 6 through 8; otherwise continue at step 8.
6. Disconnect the scale cable from the sensor module.
7. Remove the cable from the clamps that hold it to the incubator.
8. Lift the scale from the mattress tray
9. Remove the mattress tray and x-ray tray.
10. Remove the mattress tilt bars.
11. Remove the main deck.



Heater and Impeller

12. Remove the heater/impeller cover.

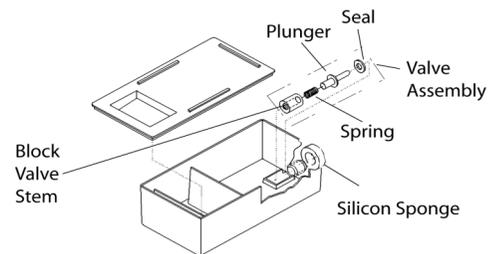
⚠ WARNING:

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.

13. When the unit has cooled, remove the heater and impeller:
 - a. Remove the heater.
 - b. Pull the impeller off the motor shaft.

Humidity Tray and Reservoir

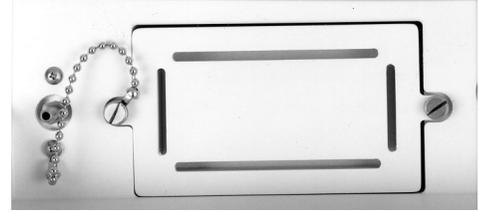
14. Pull down on the handle and slide the humidity tray out from the front of the incubator.
15. Remove the reservoir from the tray.
16. If the seal at the rear of the reservoir assembly contains a silicon sponge, perform steps 17 and 18; otherwise continue at step 19.
17. Compress the ends and lift up on the rear end to remove the reservoir valve.
18. Dismantle the reservoir valve assembly, and then place them in the reservoir.



Access Door Gaskets, Tubing, Iris Entry Port Sleeves, Cuffs

19. Remove the disposable access door cuff from each access door by pulling it from the outside.

20. Pull the access door gaskets from each side of the hood to remove them.
21. Pull the tubing access grommets from each side of the hood.
22. Remove the disposable iris entry port sleeves from the retainer rings.
23. Wipe the retainer rings clean.
24. Discard all disposable sleeves and cuffs.



Air Intake Microfilter

25. Loosen the two thumbscrews to remove the air intake microfilter cover.

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 Access Ports

1. Place the access door gaskets and tubing access ports 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, and Stand

▲ CAUTION:

When cleaning the interior of the incubator shell, prevent liquids from entering the motor shaft opening. Equipment damage could occur.

▲ CAUTION:

When cleaning the surface of the air circulation well, take care to prevent liquids from entering the motor shaft opening. Failure to do so could result in equipment damage.

Use an intermediate level, tuberculocidal cleanser/disinfectant or equivalent to clean all surfaces thoroughly; then dry with a clean cloth or paper towel.

NOTE:

For US markets only, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA), such as Kleenaseptic®¹ Germicidal Surface Cleanser or a 2% gluteraldehyde solution.

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

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Sensor Module, Hood, and Inner Walls

⚠ CAUTION:

Alcohol can cause crazing (small stress cracks) of the clear acrylic. Do not use alcohol for cleaning. Equipment damage could occur.

⚠ CAUTION:

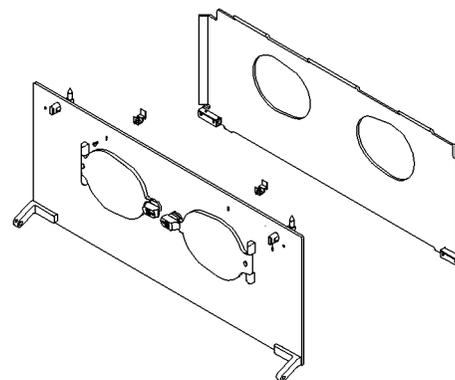
Do not expose the clear acrylic to direct radiation from germicidal lamps. Ultraviolet radiation from these sources can cause cracking and/or crazing of the acrylic surface.

1. Press on the catches located at the top of the inner wall to release the inner wall.

NOTE:

The inner walls are hinged on the access panels or rear wall of the incubator.

2. Use an intermediate level, tuberculocidal cleanser/disinfectant 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 only, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA), such as Kleenaseptic®¹ Germicidal Surface Cleanser or a 2% glutaraldehyde solution.

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

Heater Radiator and Fan Impeller

⚡ SHOCK HAZARD:

Unplug the unit from its power source prior to cleaning or maintenance. For units equipped with an uninterruptible power supply (UPS) system, also remove the battery pack prior to cleaning or maintenance. Failure to do so could result in personal injury or equipment damage.

⚠ 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. Personal injury or equipment damage could occur.

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

Humidity Reservoir

Wipe the heater assembly and the humidity reservoir cap clean using an intermediate level, tuberculocidal cleanser/disinfectant or equivalent.

NOTE:

For US markets only, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA), such as Kleenaseptic®¹ Germicidal Surface Cleanser or a 2% glutaraldehyde solution.

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

NOTE:

The evaporator raises the temperature of the water to the boiling point. Any waterborne bacteria are killed, thus preventing transfer into the patient compartment. Therefore, there is no need to remove the metering valve and the evaporator assembly for cleaning or sterilization.

Air Intake Microfilter

⚠ 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. Particularly, if the unit is used in an unusually dusty environment, more frequent replacements may be necessary. Failure to do so could result in infant injury or equipment damage.

⚠ CAUTION:

Do **not** attempt to clean the air intake microfilter. Equipment damage could occur.

Do not clean the air intake microfilter (see “Air Intake Microfilter Maintenance” on page 6-10).

Before installing a new air intake microfilter, clean the microfilter chamber and its cover with an intermediate level, tuberculocidal cleanser/disinfectant or equivalent.

NOTE:

For US markets only, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA), such as Kleenaseptic®¹ Germicidal Surface Cleanser or a 2% gluteraldehyde solution.

Base Covers, Rail and Accessories, Drawers, Tank Mounts, Monitor Shelf, and I.V. Pole

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, Heater/Impeller Cover, Scale (Optional), and Mattress Tilt Bars

1. Using an intermediate level, tuberculocidal cleanser/disinfectant or equivalent, thoroughly clean all surfaces of the following:
 - Mattress
 - Mattress tray
 - X-ray tray
 - Main deck
 - Heater/impeller cover
 - Scale (optional)
 - Mattress tilt bars

NOTE:

For US markets only, use an intermediate level, tuberculocidal cleaners/disinfectant registered by the Environmental Protection Agency (EPA), such as Kleenaseptic®¹ Germicidal Surface Cleanser or a 2% gluteraldehyde solution.

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

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Uninterruptible Power Supply (UPS) Air Filter

NOTE:

The filter can be inspected and cleaned during operation. However it is recommended that this procedure be performed without a patient in the system.

1. Grasp the handle and firmly pull the filter cartridge until it is removed from the UPS electronic module.
2. Clean the filter by vacuuming any dust accumulated on the filter media.

NOTE:

Always clean per recommended methods without the use of any liquids. Never substitute reversal of the filter cartridge for cleaning.

3. Always replace the filter cartridge after removal for cleaning.



Reassembly After Cleaning

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. Install the heater radiator and fan impeller.
3. Install the heater/impeller cover.

⚠ CAUTION:

Make sure 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.

4. Install the main deck.
5. Install the mattress tilt bars on the main deck.
6. Install the mattress tray, x-ray tray, and scale (optional).
7. 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.
8. Install the mattress.
9. Install the new disposable or reusable iris entry port sleeves.
 - a. Install the smaller diameter elastic band of a new sleeve over the inner ring of the port housing.



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



- c. Rotate the outer ring to close. If properly installed, the sleeve opens again when rotation is reversed.

10. Install the tubing access grommets into the front and rear edges of each side of the hood.

NOTE:

Replace tubing access ports, if distorted or torn.

11. Install an access door gasket on each access door.
12. Stretch the larger diameter elastic band of the new disposable or reusable access door cuff on each required access door gasket.

NOTE:

Ensure the cuff has a small opening at its center.

13. Ensure that the access door latches with slight pressure, and opens when the latch lever is pressed.

14. If the air intake microfilter is damaged, visibly dirty or older than 3 months, replace it.

15. Install the air intake microfilter cover, and tighten the two thumbscrews.

16. If the seal at the rear of the reservoir assembly contains a silicon sponge, reassemble the reservoir valve assembly components, and then re-install it.

NOTE:

Ensure the spring is in place.

17. Replace the lid on the humidity reservoir, and place the humidity reservoir in the humidity tray.

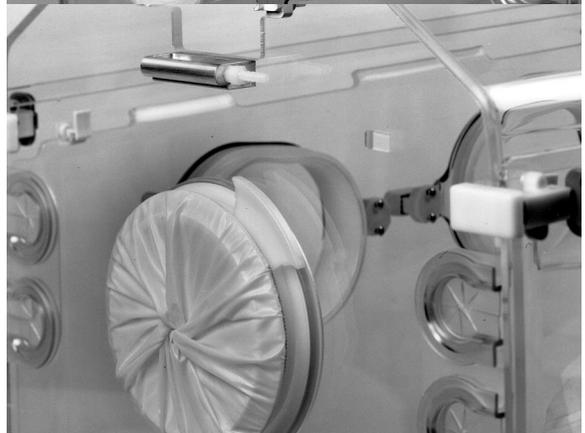
NOTE:

The unit is shipped with two reservoirs.

18. Return the tray and reservoir to the shell.

19. If required, reattach any assemblies previously removed from the transition plate or rail assembly.

20. Perform a complete functional checkout before returning the unit to service. Refer to “Operational Checkout” on page 4-12.



Maintenance

⚠ WARNING:

Only facility-authorized personnel should perform preventive maintenance or troubleshooting on the Isolette® Infant Incubator, Models C2000 and C2000e. Preventive maintenance performed by unauthorized personnel could result in personal injury or equipment damage.

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

⚠ WARNING:

At the end of the life of the Isolette® Infant Incubator, Models C2000 and C2000e safely dispose of the unit per local requirements. Failure to do so could result in personal injury.

Qualified service personnel should completely check and calibrate the equipment at least annually. However, Dräger Medical recommends quarterly. For details, refer to the *Isolette® Infant Incubator, Models C2000 and C2000e Service Manual*.

UPS Battery Pack Maintenance

⚠ WARNING:

Inspect the battery module for possible leakage during service intervals and prior to removal and handling. The battery module is heavy and therefore requires sufficient strength and the proper lift method in order to avoid injury upon removal or installation. Observe local, state and federal regulations with regards to handling, storage and disposal of sealed gel cell batteries.

⚠ WARNING:

Do not add external batteries to the UPS system. Personal injury or equipment damage could occur.

To ensure the useful life of the battery pack module, cycle the UPS system every 3 months or as appropriate.

To cycle the battery pack module:

1. With the unit operational and no patient in it or anticipated, disconnect the AC supply and allow the system to operate from the batteries until the low battery alarm occurs.
2. Restore the AC supply and allow the system to operate a maximum of 8 hours to ensure the battery pack is fully recharged. Failure to do this can invalidate the battery warranty.

If it is anticipated that the battery pack is not to be in use for any extended period of time, the system should be left plugged in 24 hours before storage. This step ensures that the batteries are fully charged before storage. In addition, the system should also be removed from storage every 3 months and recharged for 24 hours prior to placing the system back in storage.

If a loss of battery operation run time is noticed, the batteries in the battery pack could possibly require replacement. Refer to the *Isolette® Infant Incubator, Models C2000 and C2000e Service Manual* for replacement procedures.

UPS Electronics Module Maintenance

The module houses a dust filter cartridge that can be easily cleaned. The filter should be inspected during each operational checkout and cleaned as required. In addition, every three months or as appropriate the filter and electronics module air inlet holes should be cleaned (see “Uninterruptible Power Supply (UPS) Air Filter” on page 6-7).

Air Intake Microfilter Maintenance

Check the air intake microfilter during each preventive maintenance cycle. If the air intake microfilter is one of the following, replace it:

- Damaged
- Visibly dirty
- Older than 3 months

Replacement Parts

This section provides a listing of replacement parts, accessories, and single-use items. Parts not listed here should be replaced by qualified service personnel only.

NOTE:

Refer to the Isolette® Infant Incubator Upgrade and Retrofit Kit Installation Instructions to upgrade C2000 and C2000e incubators.

NOTE:

For C2000e incubator replacement drawers, contact technical support at 800-437-2437.

Replacement Parts List .

Part Number	Description
Miscellaneous	
67 020 72	Restraint strap kit
79 251 74	Kleenaseptic®b*, trigger-spray, 12 @ 24 oz.
81 502 02	Washer, sealing, oxygen/air
83 001 00	Mattress, foam
83 001 05	Ventilator tube support, Isolette®
83 101 30	Filter, replacement, pack of four, Isolette®
83 442 00	Monitor shelf assembly, high, Isolette® (Model C2000 only)
83 442 14	Monitor shelf assembly, low, Isolette® (Model C2000 only)
83 444 00	IV pole assembly, Isolette® (Model C2000 only)
83 930 30	Adapter, DSub, 9 pin male to 25 pin female
85 001 04	Straps, monitor shelf, set of 2
Probes	
68 209 47	Cover, probe, Care-For-Me™, large, 100
68 209 48	Cover, probe, Care-For-Me™, standard, 100
83 102 21	Probe 4, skin temperature, disposable, box/10, CE, Isolette®
83 102 41	Probe 5, skin temperature, reusable
83 104 15	Probe 5, large skin temperature, box of 10
Cuffs	
68 120 71	Iris port cuffs, disposable, soft, 100
83 300 11	Access door cuff, disposable, replacement, carton/100
83 300 40	Cuff, access door, reusable, carton/10, Isolette®
Scale Assembly	
83 600 50	Scale assembly, Isolette®

Part Number	Description
Oxygen	
83 620 23	Oxygen assembly, National Institute of Standards and Technology (NIST) fitting
83 620 30	Cell, oxygen
83 620 50	Oxygen assembly, green diameter index safety system (DISS)
83 620 51	Oxygen assembly, green (hose)
83 620 52	Oxygen assembly, white (hose)
83 620 53	Oxygen assembly, blue (hose)
83 620 54	Oxygen assembly, white DISS
85 620 23	Oxygen assembly, NIST fitting, C2000e
85 620 50	Oxygen assembly, green (hose) DISS, C2000e
85 620 51	Oxygen assembly, green (hose), C2000e
85 620 52	Oxygen assembly, white (hose), C2000e
85 620 53	Oxygen assembly, blue (hose), C2000e
85 620 54	Oxygen assembly, white (hose) DISS, C2000e
Humidity	
83 615 70	Humidity system assembly, 120V, C2000, Colder Products Company fitting
83 615 80	Humidity system assembly, 230V, English/Spanish/French/German/Italian
83 615 81	Humidity system, 230V, Swedish-Greek, C2000, Colder Products Company fitting
83 615 90	Humidity system assembly, 100V, C2000, Colder Products Company fitting
85 615 70	Humidity system assembly, 120V, C2000e, Colder Products Company fitting
85 615 80	Humidity assembly, 240V, English/ Spanish/ French/ German/ Italian, C2000e
85 615 81	Humidity system assembly, 230V, Swedish-Greek, C2000e, Colder Products Company fitting
83 615 90	Humidity system assembly, 100V, C2000, Colder Products Company fitting
Drawers and Tank Holder	
83 440 00	Swivel drawer assembly, large (C2000, only)
83 441 00	Swivel drawer assembly, small (C2000, only)
83 443 00	Oxygen tank bracket assembly, Isolette®
85 441 17	Tray assembly, large (Model C2000e only)
85 441 46	Swivel drawer assembly, small, C2000e (Model C2000e only)

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Part Number	Description
85 441 52	Drawer housing assembly, shallow, short (Model C2000e only)
85 441 53	Drawer housing assembly, shallow, long (Model C2000e only)
85 441 56	Swivel drawer assembly, large, C2000e (Model C2000e only)
85 441 60	Drawer housing assembly, deep, short (Model C2000e only)
85 441 61	Drawer housing assembly, deep, long (Model C2000e only)
Rail and Accessories (Model C2000e only)	
85 442 00	Monitor shelf assembly, high, C2000e
85 442 14	Monitor shelf assembly, low, C2000e
85 444 00	I.V. pole assembly, C2000e
85 460 02	I.V. resuscitator bag holder assembly
85 460 03	Basket, 18.0 W x 9.5 D x 4.0 H, assembly
85 460 04	Basket, 6.5 W x 4.0 D x 5.0 H, assembly
85 460 05	Basket, 11.0 W x 4.0 D x 4.0 H, assembly
85 460 06	Basket, pivoting, assembly
85 460 07	Chart holder, assembly
85 460 08	Hinged tray, 13.5 W x 9.75 D, assembly
85 460 09	Hinged tray, 17.0 W x 11.5 D, assembly
85 460 10	Cable organizer, assembly
85 460 11	Horizontal cord wrap, assembly
85 460 12	Standard cam adapter, assembly
85 460 13	Ball action adapter, assembly
85 460 14	Double cam adapter, assembly
85 460 15	Cam adapter, threaded, assembly
85 460 19	Utility hook assembly
UPS	
83 410 08	Filter, uninterruptible power supply (UPS), C2000e
85 410 50T	Battery, 3 pack, rechargeable, 12V, 7A

a. Kleenaseptic® is a registered trademark of Metrex Research Corporation.

NOTES:

Section 7

Troubleshooting

General

▲ WARNING:

Only facility-authorized personnel should perform preventive maintenance or troubleshooting on the Isolette® Infant Incubator, Models C2000 and C2000e. Preventive maintenance performed by unauthorized personnel could result in personal injury or equipment damage.

If the fault cannot be located, refer the unit to qualified service personnel.

Symptom, Cause, and Remedy

For troubleshooting of the incubator, refer to the table below:

Troubleshooting

Symptom	Possible Cause	Remedy
There is no system power, and the Power Fail alarm does not activate.	The incubator Main Power switch is Off.	At the stand, turn on the Main Power switch.
The Power Fail alarm activates.	For non-UPS systems, only: The power cord is unplugged.	Make sure that the power cord is plugged into the AC power source. If the power cord is detachable, also make sure it is firmly attached to the stand receptacle.
	For non-UPS systems, only: The power cord to the incubator is unplugged.	Re-attach the power cord to the incubator receptacle.
	For UPS systems, only: The batteries are not charged.	After a power failure or prior to initial usage, keep power applied continuously to the UPS system for a maximum of 8 hours. NOTE: Ensure the Resettable circuit breaker is in the On (1) position.
The Low Air /Skin Temperature alarm activates.	An access door or iris entry port is open.	Close all access doors and iris entry ports.
	The skin probe is not properly secured to skin (in Skin mode only).	Check the skin probe connection.
Low oxygen concentrations exist	An access door or iris entry port is open.	Close all access doors and iris entry ports.

Symptom	Possible Cause	Remedy
	An iris entry port sleeve is open or improperly installed.	Check the installation of the iris entry port.
	A tubing access port is not properly installed.	Check the installation of the tubing access port.
	The air intake microfilter cover is not properly secured.	Check and secure the air intake microfilter cover.
	The air intake microfilter is not installed.	Check the air intake microfilter, and install if necessary.
	The internal tubing is not connected.	Turn the incubator off, and remove it from service.
High oxygen concentrations exist	The air intake microfilter is dirty.	Replace the air intake microfilter.
	There is a lack of air circulation within the incubator.	Verify that the impeller is installed. If installed, turn off the incubator and remove if from service.
The variable height adjustable stand will not move up or down.	For non-UPS systems, only: At the stand, the Main Power switch is not on.	Turn on the Main Power switch.
	For UPS systems, only: At the UPS electronic module, the power cord is unplugged.	Plug the power cord into an appropriate power source.
	For UPS systems, only: The AC supply power rating is incorrect or the power cord is unplugged.	At the UPS electronic module, plug the power cord into an appropriate AC power source.
The Motor Failed alarm is activated.	The fan motor malfunctioned.	Turn the incubator off, and remove it from service.
A heater failure alarm is activated.	The fan motor malfunctioned or the heater failed.	Turn the incubator off, and remove it from service.
A controller failure alarm is activated.	An internal malfunction occurred.	Turn the incubator off, and remove it from service.
	This is the first time the unit was installed or new software was loaded onto the controller.	Press the Alarm Silence/Reset key. If the failure continues turn the incubator off and remove it from service
The Key Stuck alarm is activated.	A controller key malfunction occurred.	Turn the incubator off, and remove it from service.
The Air Probe Failure alarm is activated.	The air probe malfunctioned.	Turn the incubator off, and remove it from service.
The Low Air Flow alarm is activated.	There is a lack of air circulation within the incubator.	Verify that the impeller is installed. If installed, turn off the incubator and remove if from service.

Symptom	Possible Cause	Remedy
A sensor module alarm is activated.	A sensor module malfunction occurred.	If the alarm persists, turn the incubator off and remove it from service
The Sensor Out of Position alarm is activated.	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 the incubator off and remove it from service.
The Sensor Disconnected alarm is activated.	The sensor module possibly experienced a communications failure.	If the sensor module is not connected, connect it. If the message persists: <ol style="list-style-type: none"> 1. Replace the sensor module. 2. If the alarm still continues, turn the incubator off, and reposition the sensor. 3. If the alarm persists, remove it from service
The Remove Skin 2 Probe alarm is activated.	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.
The Oxygen Cell Different alarm is activated.	The oxygen cell readings, between the two oxygen cells differ by >3%.	Perform the oxygen calibration (see "Oxygen Sensor Calibration" on page 5-33).
The Oxygen Solenoid Failed alarm is activated.	The oxygen solenoid failed.	Turn the incubator off, and remove it from service.
The Low Humidity alarm is activated.	The humidity reservoir is empty.	Refill the reservoir. If the alarm persists, turn the incubator off and remove it from service.
The Humidity Heater Failed alarm is activated.	The humidity system malfunctioned.	Turn the incubator off, and remove it from service.
The Too Much Weight alarm is activated.	Weight in excess of 7 Kg (15 lb) is on the mattress.	Remove the excess weight.
	When zeroing the scale, weight in excess of 3500g is on the mattress.	Remove the excess weight.
The Scale Disconnected alarm is activated.	The cable between the scale and the sensor module is disconnected.	Re-connect the cable between the scale and sensor module.
	The cable between the scale and the sensor module is broken.	Turn the incubator off, and remove it from service.
A scale failure alarm is activated.	A scale malfunction occurred.	Turn the incubator off, and remove it from service.

Symptom	Possible Cause	Remedy
The Cal Fail message is displayed.	The servo-controlled oxygen system failed to calibrate.	Repeat the calibration procedure. If the calibration procedure fails the second time, refer the unit to qualified service personnel.
The Not Installed message is displayed.	The servo-controlled oxygen and/or humidity system(s) is/are not installed.	Install the oxygen and/or humidity system(s).
	The servo-controlled oxygen and/or humidity system(s) is/are not activated.	Set up the oxygen and/or humidity system at the System Configuration Menu (see “System Configuration” on page 5-22).

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