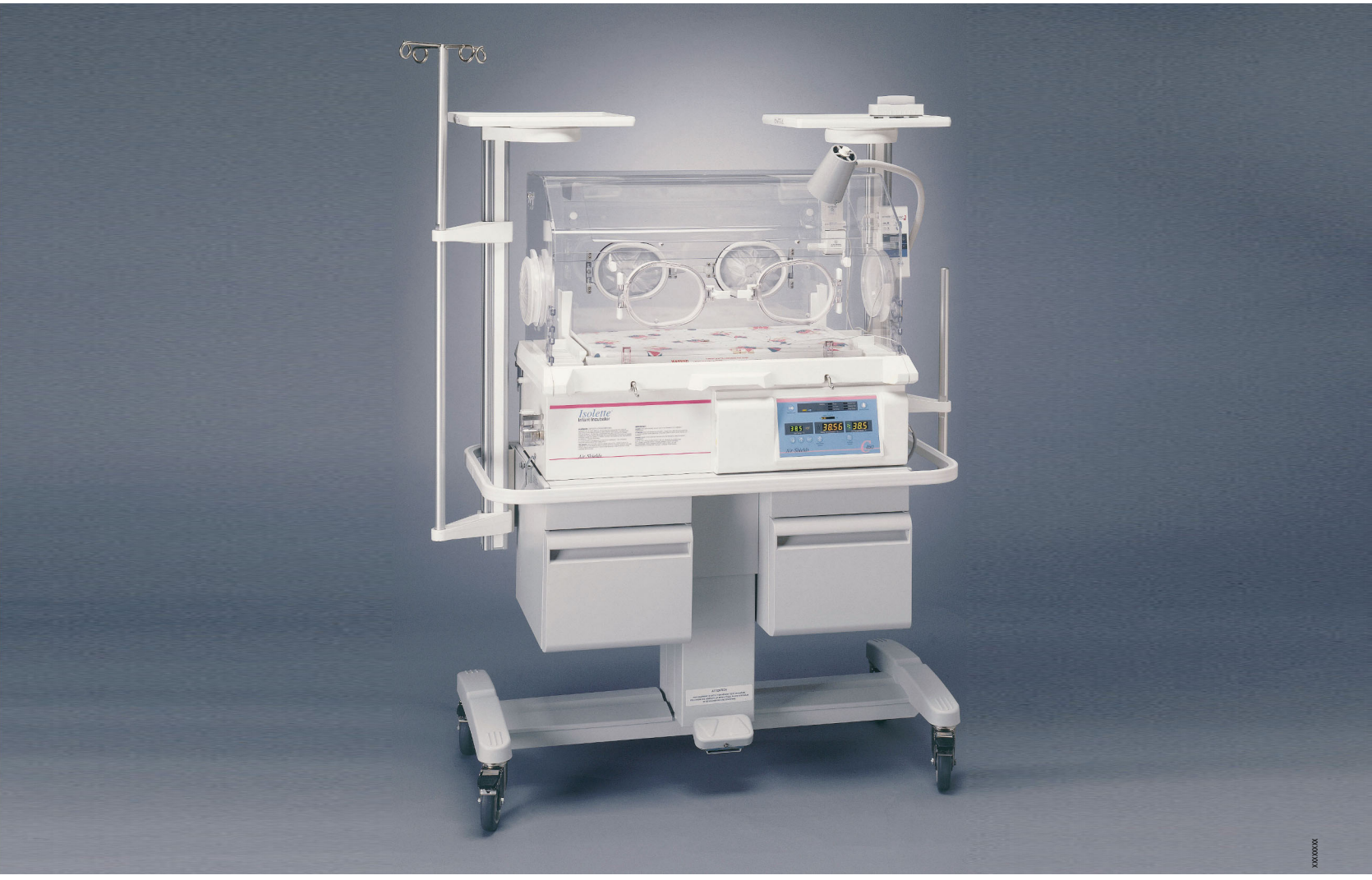
Dräger medical
A Dräger and Siemens Company

Air-Shields® Isolette® Infant Incubators



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

Models C400 QT® and C450 QT®
Operating Instructions

Table of Contents

NOTES:

Section 1
Symbol Definition and Intended Use

Symbol Definition

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 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 a CAUGHT HAZARD WARNING:

Caught Hazard Warning

- The symbol below highlights a CHEMICAL HAZARD WARNING:

Chemical Hazard Warning

- The symbol below highlights an ELECTRICAL SHOCK HAZARD WARNING:

Electrical Shock Hazard Warning

This product contains different icons designed to increase understanding. Note the following examples:

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

Attention: Consult Accompanying Documents

- The symbol below indicates “Type B equipment with an F-type floating applied part:”

Type B Equipment with an F-Type Floating Applied Part

- The symbol below indicates “AC power:”

AC Power

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

Protective Earth (Ground)

- The symbol below indicates “Air Mode Control indicator:”

Air Mode Control Indicator

- The symbol below indicates “Air Mode Control selection key:”

Air Mode Control Selection Key

- The symbol below indicates “Baby Mode Control indicator:”

Baby Mode Control Indicator

- The symbol below indicates “Baby Mode Control selection key:”

Baby Mode Control Selection Key

- The symbol below indicates the Keypad Lock key:

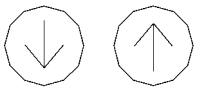
Keypad Lock Key

- The symbol below indicates the Keypad Lock indicator:

Keypad Lock Indicator

- The symbol below indicates the Set Temperature keys:

Set Temperature Keys



- The symbol below indicates the Temperature Override Mode (>37°C) selection key:

Temperature Override Mode (>37°C) Selection Key

- The symbol below indicates the Temperature Override Mode (>37°C) indicator:

Temperature Override Mode (>37°C) Indicator

- The symbol below indicates the Silence/Reset switch:

Silence/Reset

- The symbol below indicates the Power Off/On switch:

Power Off/On

- The symbol below indicates that the cabinet stand doors must remain closed to minimize the risk of tipping during transport:

Cabinet Stand Doors Must Remain Closed

- The symbol below indicates a sensitivity to ELECTROSTATIC DISCHARGE (ESD):

Electrostatic Discharge (ESD)

- The symbol below indicates the surface could be hot.

Caution, Hot Surface

Technical Definitions

- **Control zone**—A plane 10 cm (4") above the mattress with an area defined by the center of four quadrants formed by lines that divide the width and length of the mattress surface.
- **Incubator temperature**—The air temperature at a point 10 cm (4") above and centered over the mattress surface.
- **Average incubator temperature**—The average of the maximum and minimum incubator temperature achieved during steady temperature condition.
- **Steady temperature condition**—The condition reached when the average incubator temperature does not vary more than 0.5°C over a period of 1 hour.
- **Temperature overshoot**—The amount by which the incubator temperature exceeds the average incubator temperature during steady temperature condition, resulting from a change in temperature.
- **Temperature rise time**—The time required for the incubator temperature to rise 11°C (20°F).
- **Temperature uniformity**—The amount by which the average temperature at each of four points 10 cm (4") above the mattress surface differs from the average incubator temperature at steady temperature condition. The four points are the centers of four quadrants formed by lines that divide the width and length of the mattress surface.
- **Temperature variation**—The difference between the incubator temperature and the average incubator temperature during steady temperature condition.

Intended Use

This manual provides instructions for installation, use, operator maintenance, and troubleshooting of the Model C400 (discontinued January 2005) and C450 Isolette® Infant Incubator having QT® features, CE Mark version. 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 of the manual, or makes any repairs with unauthorized components. Only qualified service personnel should perform calibration and repair. Technical information is available through your local distributor.

All personnel who will be working with the unit should read, thoroughly understand, and have ready access to this manual. Store the manual on the shelf in the cabinet stand when not in use. If there is anything you do not understand, please contact your technical support representative for further information.

Section 2
Introduction, Features, and Specifications

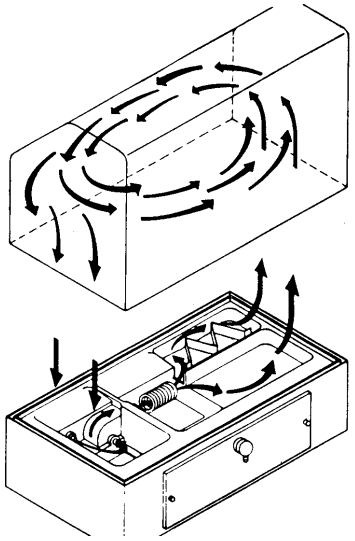
Introduction

The forced air circulation system of the incubator permits stable temperature control, uniform heat distribution, humidification, effective isolation of the infant from airborne contaminants, and control of oxygen concentrations. An access panel, access doors, and iris entry ports provide accessibility to the infant. When the access panel is open, a curtain of warm air flows from beneath the front edge of the mattress toward the top of the access panel opening; this air curtain minimizes the temperature drop within the hood environment. The incubator is designed for use in a nursery environment having a typical ambient operating temperature range of 20°C (68°F) to 30°C (86°F). A guard rail is standard.

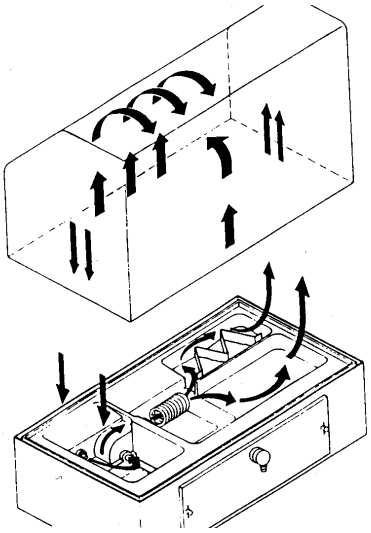
On Model C450 QT® Isolette® Infant Incubator, baby or air temperature control is selected by a front panel control. The Model C400 QT® Isolette® Infant Incubator (discontinued January 2005) is equipped only for air temperature control. Instrumentation includes a digital display for temperature, relative indication of heater output, and a comprehensive visual and audible alarm system, which includes an alarm test feature.

Functional Description

The forced air circulation system controls temperature, humidity, and oxygen concentration. The motor-driven impeller on the controller draws a controlled amount of room air (approximately 35 litres per minute (lpm)) through the air intake filter.



Supplemental oxygen, introduced through the oxygen input valve on the air intake filter cover, displaces a portion of room air to maintain the total gas intake (including oxygen) at 35 lpm. Since the impeller/filter characteristics control the amount of room air, and the flowmeter setting controls the amount of oxygen, predictable oxygen concentrations within the incubator can be attained. When oxygen flow exceeds 8 lpm, a valve within the oxygen inlet housing restricts air intake so that a higher oxygen concentration can be achieved without excessive oxygen flow. At 12 lpm, maximum air intake restriction is achieved.



In addition to drawing fresh, filtered air into the incubator, the impeller internally recirculates at a much greater flow than that of the fresh gas inflow. The total flow of fresh plus recirculated air is directed past the air flow sensor and around the heater with a predetermined portion being directed over the humidity reservoir for humidification. When the access panel of the hood is closed, the air curtain cover is closed, and all the air enters the infant compartment up through the slot at the right end of the main deck. After circulating within the infant compartment, the air is then recirculated down through the slot in the left end of the main deck. There it goes past the temperature sensing probe, which encapsulates the air temperature control thermistor and a high air temperature alarm thermistor, and back to the impeller. When the access panel of the hood is open, the air curtain cover is raised, permitting a portion of the air to flow upward past the opening creating a warm air curtain, which minimizes the drop in air temperature in the incubator.

Features

Isolette® Infant Incubator with Standard Cabinet Stand

Standard Features

Temperature Control

On the Model C450 QT® Isolette® Infant Incubator, temperature is regulated by using either incubator air or the infant's skin temperature as the controlling parameter. A front panel key enables selection of the desired mode. The Model C400 QT® Isolette® Infant Incubator (discontinued January 2005) provides only Air Mode.

In either mode of operation, the heater output is proportional to the amount of heat required to maintain the desired temperature, and the relative amount of heat being provided is indicated by the number of lit **Heater Power %** indicators on the front panel. Changes in the number of lamps illuminated indicate the amount of power required to maintain a given temperature. During Baby Mode, the Model C450 QT® Isolette® Infant Incubator provides an indication of the degree of the infant's dependency upon the temperature of its environment to maintain body temperature.

Air Mode

In Air Mode, the air temperature can be maintained from 20°C (68°F) to 37°C (99°F) as indicated by the **Set Temp °C** display setting. In Temperature Override Mode, the temperature can be maintained from 37°C (99°F) to 38.5°C (101.3°F). A probe located below deck monitors the air temperature, and compares it with the **Set Temp °C** display setting. The information from this probe is supplied to the heater control circuitry, which proportions the heater output to maintain the air temperature at the **Set Temp °C** display setting. Actual air temperature is displayed by the **Air Temperature °C** display. A second sensor within the air temperature probe serves as a backup to limit the incubator temperature to between 39°C (102°F) and 40°C (104°F). At this temperature, an alarm activates, and the heater shuts off.

If desired, an auxiliary air temperature probe can control the air temperature. This probe is suspended above the mattress through the weighing scale hole, and plugged into a special receptacle on the side of the incubator. When plugged in, the primary air temperature control probe is disconnected, but the backup sensor within the primary temperature probe remains connected. Thus, the auxiliary probe controls the air temperature.

In Air Mode, the infant's temperature is a function of the air temperature and the infant's ability to establish and maintain its own temperature. A small infant, or one with underdeveloped homeostatic control, may not be able to maintain a stable temperature at the desired level.

Baby Mode (Model C450 QT® Isolette® Infant Incubator Only)

In Baby Mode, the infant’s skin temperature can be maintained from 34°C (93°F) to 37°C (99°F) as indicated by the **Skin Temp °C** display. In Temperature Override Mode, the temperature can be maintained from 37°C (99°F) to 37.9°C (101.3°F). A temperature sensing probe is attached directly to the infant's skin. The information from the probe is supplied to the heater control circuitry, which proportions the heater output to maintain the baby's temperature at the **Set Temp °C** setting. The actual baby temperature appears on the **Baby Temperature °C** display. The **Set Temp °C** setting does not control air temperature while in Baby Mode, but air temperature is still displayed. The air temperature is still limited to 38.5°C (101.3°F). If Air Mode is selected while the skin probe remains connected, the **Baby Temperature °C** display continues to display actual skin temperature, but it does not control.

If the probe is disconnected from its receptacle during Baby Mode, the **Baby Temperature °C** display goes blank, and a **Probe** alarm activates. The high temperature alarm sensor within the air temperature probe remains in the circuit to limit the air temperature to less than 40°C (104°F).

Alarms

Alarms are provided for power failure, system failure, inadequate air flow, probe failure, high temperature, and variation from the set temperature. Each time the unit is turned on, the unit automatically goes through an alarm check sequence to verify proper alarm function. After the automatic alarm check, the low **Set Temp** alarm is disabled for 60 min or until the temperature reaches the **Set Temp °C** setting, whichever occurs first. Each of these alarms is described below.

Air Flow

A sensor located below deck in the normal air path of the fan controls this alarm. If air flow stops due to a fan failure, the temperature of the self-heated sensor rises, causing the **Air Flow** alarm indicator on the front panel to light and produce a pulsating tone. A short-circuited, air flow sensor failure also actuates the alarm within 10 s of the failure. This alarm is not self-resetting and cannot be silenced or canceled by the **Silence/Reset** key until the alarm condition is corrected.

High Temperature

A second sensor within the air temperature probe sounds this alarm if the incubator temperature reaches 39.5°C ± 0.5°C (103.1°F ± 0.9°F). A solid light and a pulsing tone indicate a **High Temperature** alarm. This alarm is not self-resetting and cannot be canceled by the **Silence/Reset** key until the alarm condition is corrected.

Power Failure

If primary power to the incubator is interrupted for any reason, including a disconnected power cord, an audible alarm is activated, and the **Power Fail** indicator lights. To silence this alarm for two min, press the **Silence/Reset** key. To deactivate this alarm, restore the primary power or set the incubator **Power** switch to off.

System Fail

If an internal malfunction is detected, the **System Fail** indicator flashes and the alarm sounds. This alarm is not resettable. Refer the unit to qualified service personnel.

Probe

Circuitry is provided to monitor the air, skin, and high temperature sensors for short circuits, open circuits, or disconnected conditions and the air flow sensor for an open condition.

The **Probe** alarm actuates within 10 s if the air flow sensor has an open circuit and the temperature sensed below the mattress deck is greater than approximately 30°C (86°F). However, if the temperature sensed below the mattress deck is less than that, the alarm does not activate. During warm-up, it can take anywhere from 15 to 30 min before the alarm actuates, depending on the temperature setpoint and the ambient room temperature. If the high set temperature is below 29°C (84°F), the **Probe** alarm indicating an open-circuited air flow sensor is not activated.

If a probe shorts (except for the air flow probe or **High Temperature** alarm probe), it also appears as a set temperature violation, and the **Set Temp** alarm indicator lights. This alarm is not self-resetting and cannot be canceled by the **Silence/Reset** key until the alarm condition is corrected. If a **Probe** alarm occurs simultaneously with a **Set Temp** alarm, a shorted probe is probably the true cause of the alarm since a shorted probe appears as a high temperature condition.

On the Model C450 QT® Isolette® Infant Incubator, a **Probe** indicator light flashes and an alarm sounds within 10 s to indicate a damaged air temperature, baby temperature, auxiliary air sensor, or an open-circuited air flow sensor. The **Probe** alarm also activates if the skin temperature probe is disconnected while in Baby Mode.

The Model C400 QT® Isolette® Infant Incubator (discontinued January 2005) is equipped only for air control. Therefore, no Baby Mode **Probe** alarm is provided. The **Probe** alarm activates to indicate a damaged air temperature, or auxiliary sensor, or an open-circuited air flow sensor.

Set Temperature

The **Set Temperature** alarm actuates if the baby or air temperature fluctuates from the set temperature as follows:

- Baby temperature—+1.0°C ± 0.3°C, -1.0°C ± 0.3°C
- Air temperature—+1.5°C ± 0.5°C, -3.0°C ± 0.5°C (-2.5°C ± 0.5°C for IEC units)

A temperature below the set temperature is indicated by a flashing light, a tone, and the set temperature setting alternating with LO in the **Set Temp °C** display. A temperature above the set temperature is indicated by a flashing light, a tone, and the set temperature setting alternating with HI in the **Set Temp °C** display. If a **Set Temp** alarm occurs simultaneously with a **Probe** alarm, a shorted probe is probably the true cause of the alarm, since a shorted probe appears as a high temperature condition.

The **Set Temperature** alarm is self-resetting (that is, if the alarm condition is corrected, the alarm automatically silences, and the light turns off).

To silence the **Set Temperature** alarm, press the **Silence/Reset** key. The other audible and visual alarms are not affected by the use of the 15-min alarm silence. When silenced, the alarm indicator remains on until the alarm condition is corrected. If the alarm condition is not corrected within 15 min, the audible alarm reactivates.

If you change the air or baby set temperature (either high or low) after the incubator is in operation, the **Set Temperature** HI and LO alarms automatically silence for a specific amount of time after the change. The time the alarm remains silent is 5 min per degree (plus or minus) change from the current set temperature. If the incubator fails to reach the new set temperature after the specified time, the alarm sounds. For example, if you change the set temperature ±1.5°, the alarm silence period is 7.5 min.

Continuously Variable Mattress Tilt Mechanism

The Isolette® Infant Incubator is equipped with a 0° to ± 9° continuously variable mattress tilt mechanism, which permits placing the infant in the Trendelenburg or Reverse Trendelenburg position.

Quiet Latch Access Doors

The Isolette® Infant Incubator is equipped with quiet-latching access doors. The latch mechanism of these doors is designed so that the doors may be opened with an elbow one at a time or simultaneously.

Optional Features

Optional features available for use with the Isolette® Infant Incubator include:

- Filter Cover with O_2 Limiter
- Filter Cover with Dew-ette® 2 Incubator Humidifier

Accessories

Accessories available for use with the Isolette® Infant Incubator include:

- Cabinet Stand (standard)
- Guard Rail
- Micro-Lite® Phototherapy System
- Dew-ette® 2 Incubator Humidifier
- Remote Alarm Module
- Warm Weigh® Infant Scale, Model I20
- Monitor Shelf Package
- Utility Pole Assembly
- I.V. Tree Assembly
- Oxygen Flowmeter Kit
- Rail System

Specifications

Specifications for the Isolette® Infant Incubator are provided. All specifications are subject to change without notice. Opening access doors or panels, or using infant seats, head hoods, or other equipment or supplies within the incubator, which can alter the air flow pattern, may affect temperature uniformity, temperature variability, the correlation of the incubator temperature reading to center mattress temperature, and infant skin temperature.

Standard Features

Feature	Dimension
Power requirements	120V ± 10%, 50/60 Hz, 500 W maximum
	230V ± 10%, 50/60 Hz, 500 W maximum
	100V ± 10%, 50/60 Hz, 500 W maximum
Chassis leakage current	less than 500 uA (220V to 240V units)
	less than 100 uA (120V units)
Air Mode temperature control range	20°C (68°F) to 37°C (99°F) (37°C (99°F) to 38.5°C (101.3°F) in Temperature Override Mode)
Baby Mode temperature control range (Model C450 QT® Isolette® Infant Incubator only)	34°C (93°F) to 37°C (99°F) (37°C (99°F) to 37.9°C (100.2°F) in Temperature Override Mode)
Temperature rise time	< 50 min
Temperature variation	1.5°C
Temperature overshoot	0.5°C maximum
Temperature uniformity	1.0°C
	0.8°C (IEC/CE units)
Correlation of indicated air temperature to actual incubator temperature (after steady temperature condition is reached)	± 1.0°C
	± 0.8°C (IEC/CE units)
Correlation of indicated air temperature to set temperature (Air Mode)	± 0.5°C
Correlation of indicated air temperature to set temperature (Baby Mode) (Model C450 QT® Isolette® Infant Incubator only)	± 0.3°C
Oxygen concentration range	21% to 65% or greater
Humidity (with no supplemental oxygen, set temperature > 32°C, and ambient temperature at 20°C to 30°C)	Typically between 50% and 60% with water in the humidity reservoir
Height from floor (mounted on cabinet stand)	137 cm (53.75")
	140 cm (55") (IEC/CE units)
Depth (mounted on cabinet stand)	53 cm (21") without guard rail, 56 cm (22") with guard rail
Width (mounted on cabinet stand)	94 cm (37") without guard rail, 115 cm (45") with guard rail
Weight with guard rail and no accessories (mounted on cabinet stand)	76 kg (168 lb)
Mattress dimensions	63 cm (24.8") x 34.8 cm (13.7")
Mattress tilt Trendelenburg/Reverse Trendelenburg	0° to 9° ± 1°, continuously variable

Feature	Dimension
Ambient operating temperature range	20°C (68°F) to 30°C (86°F)
Non-condensing operating humidity range	5% to 95% relative humidity
Ambient storage temperature range	-30°C (-22°F) to 70°C (158°F)
Non-condensing storage humidity range	0% to 99% relative humidity
Noise level within the hood environment	60 dBA or less, 10 cm (4") above center mattress in surroundings of 39 dBA or less
	80 dBA or less with an alarm sounding
Air velocity over mattress	Does not exceed 25 cm/s (11"/s) within the Control Zone
Carbon dioxide (CO_2) within the hood	< 0.5% when a 4% mixture of CO_2 in the air is delivered at 740 ml/min at a point 10 cm (4") above the center of the mattress
Warm-up time, as specified by sub-clause 50.108 of EN 60601-2-19	35 minutes

Optional Features (VHA discontinued Jan. 2005)

Feature	Dimension
Variable height adjustable (VHA) stand power requirements (including incubator)	230V ± 10%, 50/60 Hz, 600 W, nominal
VHA stand chassis current leakage	Less than 500 uA
VHA stand height range	60.3 cm (23.7") to 81.9 cm (32.2")
VHA stand depth	53.3 cm (20.9")
VHA stand width	95.2 cm (37.4")
VHA stand weight (without incubator mounted)	95.2 kg (209.9 lb)
VHA stand weight (with incubator mounted)	140.6 kg (309.9 lb)
VHA stand height range (with incubator mattress)	87.6 cm (34.5") to 109 cm (43")

Alarms

Feature	Specification
High temp	Activates if the incubator temperature exceeds 39.5°C ± 0.5°C. Activates if the incubator temperature exceeds 37.5°C ± 0.5°C for set temps <37°C or at 39.5°C ± 0.5°C for set temps >37°C (for IEC units).
Air Flow	Activates when a fan fails or an Air Flow probe short-circuits.
Set Temp	Activates if Baby* or Air Temperature fluctuate from set temperature as follows: Baby Temperature—+1.0°C ± 0.3°C, -1.0°C ± 0.3°C Air temperature—+1.5°C ± 0.5°C, -3.0°C ± 0.5°C (-2.5°C ± 0.5°C for IEC units)
Power fail	Activates when there is a loss of power or disconnection from the power source.
Probe	Activates if the any of the air temperature probes are open or short-circuited, if the Baby* Temperature Probe is open-circuited or disconnected while in Baby* Mode, or if the Air Flow probe is open-circuited when the temperature sensed below deck is greater than 30°C to 31°C.
System fail	Indicates a system failure. Refer the unit to service immediately.
Silence/Reset	
Silence	Silences the Set Temp audible alarm for 15 mins; alarm silence is automatically overridden if a subsequent alarm occurs within the period of silence.
Reset	Cancels High Temp, Air Flow, and Probe alarms if alarm condition no longer exists.

* Model C450 QT® only

Regulations, Standards, and Codes

The Isolette® Infant Incubator complies with the following safety standards and performance standards:

- EN 60601-1—*1998, Medical Electrical Equipment, Part 1: General Requirements for Safety,* including Amendments 1 and 2
- EN 60601-1-2—*2001, Collateral Standard: Electromagnetic Compatibility—Requirements and Tests*
- EN 60601-2-19—*1990, Particular Requirements for the Safety of Baby Incubators,* including Amendment 1
- UL 60601-1—*2003, Medical Electrical Equipment, Part 1: General Requirements for Safety*
- Directive 2002/96/EC of the *European Parliament and of the Council of 2003-01-27 on Waste Electrical and Electronic Equipment (WEEE) Annex IV, prEN 50419*

Device Classification (EN60601 Medical Electrical Equipment Part I: General Requirements for Safety)

The C400 QT® (discontinued January 2005) or C450 QT® Isolette® Infant Incubator meets the requirements for the following classifications:

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

Electromagnetic Compatibility (EMC) Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator 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 C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator 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 C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions—IEC 61000-3-2	Pass	
Voltage fluctuations/ flicker emissions—IEC 61000-3-4	Pass	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator 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.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment—Guidance**
Electrostatic discharge (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 material, the relative humidity should be at least 30%.
Electrical fast transient/burst—IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± N/A for input/output lines	Mains power quality should be that of a typical commercial or hospital environment. There are no I/O cables for this product.
Surge—IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines—IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	< 5% U_T (> 95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the unit requires continued operation during power mains interruptions, it is recommended that the unit be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field—IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to the application of the test level.			

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator 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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance Recommended Separation Distance
Conducted RF—IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands	3 Vrms 10 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$
Radiated RF—IEC 61000-4-3)	10 V/m 80 MHz to 2.5 GHz	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 output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE:
At 80 MHz and 800 MHz, the higher frequency range applies.

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

a. The industrial, scientific, and medical (ISM) bands between 150 kHz and 80 MHz are 6765 MHz to 6795 MHz; 13553 MHz to 13567 MHz; 26957 MHz to 27283 MHz; and 4066 MHz to 4070 MHz.

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

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

d. Over the frequency range 150 kHz to 80 MHz, field strengths should be < 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator

The C400 QT® and C450 QT® Air-Shields ® Isolette® Infant Incubator is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the unit can help prevent electromagnetic interference (EMI) by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the unit as recommended, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of the Transmitter (W)	Separation Distance According to the Frequency of the Transmitter (m)			
	150 kHz to 80 MHz Outside ISM Bands $d = 1.2\sqrt{P}$	150kHz to 80 MHz in ISM Bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01 W	0.12 m	0.12 m	0.12 m	0.23 m
0.1 W	0.38 m	0.38 m	0.38 m	0.73 m
1 W	1.2 m	1.2 m	1.2 m	2.3 m
10 W	3.8 m	3.8 m	3.8 m	7.3 m
100 W	12 m	12 m	12 m	23 m

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

NOTE:
At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE:
The industrial, scientific, and medical (ISM) bands between 150 kHz and 80 MHz are 6765 MHz to 6795 MHz; 13553 MHz to 13567 MHz; 26957 MHz to 27283 MHz; and 4066 MHz to 4070 MHz.

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

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

Section 3
Precautions and Safety Tips

Precautions

Electrical Precautions

SHOCK HAZARD:
To ensure grounding reliability, plug the AC power cord only into a properly grounded three-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:
An electric shock hazard exists within the controller when the cover is removed. Only qualified personnel should service it.

SHOCK HAZARD:
To prevent equipment damage or accidental power disconnections, **do not** plug an incubator power cord directly into an AC wall socket when the incubator is mounted on a variable height adjustable stand. Always provide power to the incubator by using the power cord coming directly from the variable height adjustable stand. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:
Make sure the building power source is compatible with the electrical specifications shown on the rear center column of the variable height adjustable stand or on the incubator. Failure to do so could result in personal injury or equipment damage.

Explosion Precautions

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

WARNING:
Make sure that the oxygen supply to the incubator is turned off and that the incubator is disconnected from the oxygen supply when performing cleaning and maintenance procedures; a fire and explosion hazard exists when performing cleaning and maintenance procedures in an oxygen-enriched environment.

WARNING:
Keep matches, lighted cigarettes, 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]

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 method, the concentration, and the duration of oxygen administration should be prescribed by the attending physician.

⚠ WARNING:

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

⚠ WARNING:

The oxygen concentration inspired by an infant does not predictably 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.

⚠ WARNING:

Do not use oxygen flow rates as an accurate indication of oxygen concentrations in an incubator. Measure oxygen concentrations with a calibrated oxygen analyzer at intervals directed by the attending physician. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

A dirty air intake filter may increase oxygen concentrations and cause carbon dioxide build-up. Personal injury or equipment damage could occur.

⚠ WARNING:

Oxygen administration may increase the noise level within the infant compartment. Personal injury could occur.

⚠ 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:

An oxygen analyzer must be used any time oxygen is delivered to an infant. [6.8.2.9]

Electromagnetic Compatibility Precautions

General information on electromagnetic compatibility (EMC) according to the international EMC standard IEC 60601-1-2: 2001

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.

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

NOTE:
Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the technical documentation available from Dräger Service upon request.

⚠ 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:
Do not use equipment adjacent to other devices unless verification of normal operation in the configuration in which it is to be used can be achieved. Infant injury, personal injury, or equipment damage could occur.

Safety Tips

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.

WARNING:
Only properly trained personnel should use the incubator as directed by an appropriately qualified attending physician aware of currently known hazards and benefits. Incubator misuse may result in harm to an infant.

WARNING:
Do not use the incubator if it fails to function properly. Refer service to qualified personnel. Failure to do so could result in personal injury or equipment damage.

WARNING:
If the access panel is left open, the mattress temperature may rise above preset level. Therefore, do not leave the access panel open longer than essential. When the access panel is open, do not rely on the temperature indicator. Personal injury or equipment damage could occur.

WARNING:
For infant safety, **do not** leave the infant unattended when the access panel is open.

WARNING:
When the access panel is open, a curtain of warm air flows from beneath the front edge of the mattress toward the top of the access panel opening. 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:
Attach the incubator to the stand, cabinet, or variable height adjustable stand using the clamps 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:
To avoid overheating the infant due to direct radiation, do not position the incubator in direct sunlight or under other sources of radiant heat. The high air temperature alarm might not be activated under these conditions.

WARNING:
To avoid overheating or underheating, continuously monitor and control the skin temperature either in Baby or Air Mode. Never use rectal temperature to control skin temperature. Personal injury could occur.

⚠ WARNING:

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

⚠ WARNING:

When an x-ray is taken through the hood, the hole in the top of the hood used with the optional sling weighing scale could show up on the x-ray as a radiolucent shadow and could result in incorrect diagnosis. Personal injury could occur.

⚠ WARNING:

To prevent harm to the infant, do not raise the hood while leads or tubing are connected to the infant or if the mattress is tilted. There should be no need to raise the hood at any time while the infant is cared for in the incubator. Gain access to the infant by the access panel and access doors.

⚠ WARNING:

The use of infant seats, head hoods, or other accessories within the incubator that can alter the air flow 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:

Do not lubricate the mattress tilt mechanism with oil or other potentially flammable material. Flammability is enhanced in an oxygen-enriched environment. Personal injury or equipment damage could occur.

⚠ WARNING:

Be sure that all the thumbscrews that secure the mattress tilt mechanism to the deck are fully tightened to ensure mattress tray stability. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

To minimize the risk of tipping during transport, keep the standard cabinet stand doors closed during transport.

⚠ WARNING:

If the incubator is equipped with a rail system, to avoid tip-over or mechanical damage, the maximum weight allowed for equipment placed on the rail system shelf is 22.7 kg (50.0 lb). The total permissible weight load for both rails combined is 45 kg (99 lb).

⚠ WARNING:

Phototherapy lamps placed over the top of the incubator hood may interfere with upward travel of the VHA stand. To prevent this interference, always remove the phototherapy lamp prior to repositioning the elevator. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Never place objects taller than the top of the wheel casters beneath the incubator stand. Placement of these objects here could interfere with stability or operation of the VHA 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 30 cm (12") perimeter area around the variable height adjustable stand. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

For optimum incubator stability, always lock at least two of four variable height adjustable stand wheels during use. 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. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

When moving the incubator, two persons of sufficient strength are required for adequate control. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

If the auxiliary air probe contacts the infant's skin when the mattress is in the Trendelenburg/ Reverse Trendelenburg position, erratic air temperature control can result. Always ensure this probe tip does not contact the infant. Personal injury could occur.

⚠ WARNING:

When an IV pole is present, use caution when raising the VHA stand. Personal injury or equipment damage could occur.

⚠ WARNING:

Follow all hospital procedures for disinfection and potential biohazard exposure avoidance. Failure to do so could result in personal injury.

⚠ WARNING:

The accessory equipment connected to the analog and digital interfaces must be certified according to the respective International Electrotechnical Commission (IEC) standards, such as IEC 950 for data processing equipment and IEC 601-1 for medical equipment. Furthermore, all configurations shall comply with the systems standard IEC 601-1-1. Any person who connects additional equipment to the signal input or the signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the system standard IEC 601-1-1. If in doubt, consult the technical service department or your local representative. Failure to do so could result in infant injury, personal injury, or equipment damage.

⚠ WARNING:

Do not use equipment adjacent to other devices unless verification of normal operation in the configuration in which it is to be used can be achieved. Infant injury, personal injury, or equipment damage could occur.

⚠ CAUTION:

Use only sterile distilled water. Use of tap water could result in equipment damage.

⚠ CAUTION:

Never refill a partially filled humidity reservoir. Always drain the humidity reservoir completely before refilling. Failure to do so could result in equipment damage.

Swivel Monitor Shelves

⚠ WARNING:

For optimum stability, always lower the incubator to its lowest position prior to transport. Make sure the swivel monitor shelves are empty. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Always tighten the knob for securing the position of the shelf when in use, or after repositioning. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Always place the monitor in the center of the shelf. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Ensure that the monitor fits within the raised border of the shelf. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:

Never stack another monitor atop the monitor on the shelf. Personal injury or equipment damage could occur.

Warning Labels

Section 4
Installation and Assembly

Installation

Unpacking

Typically, the cabinet stand or optional VHA stand (discontinued in January 2005), the hood/base assembly, the filter and filter cover assembly, and the guard rail are shipped in separate cartons. When removing the equipment from the cartons, take care not to scratch or otherwise damage unprotected surfaces. Remove all packing materials from the shelf assembly.

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

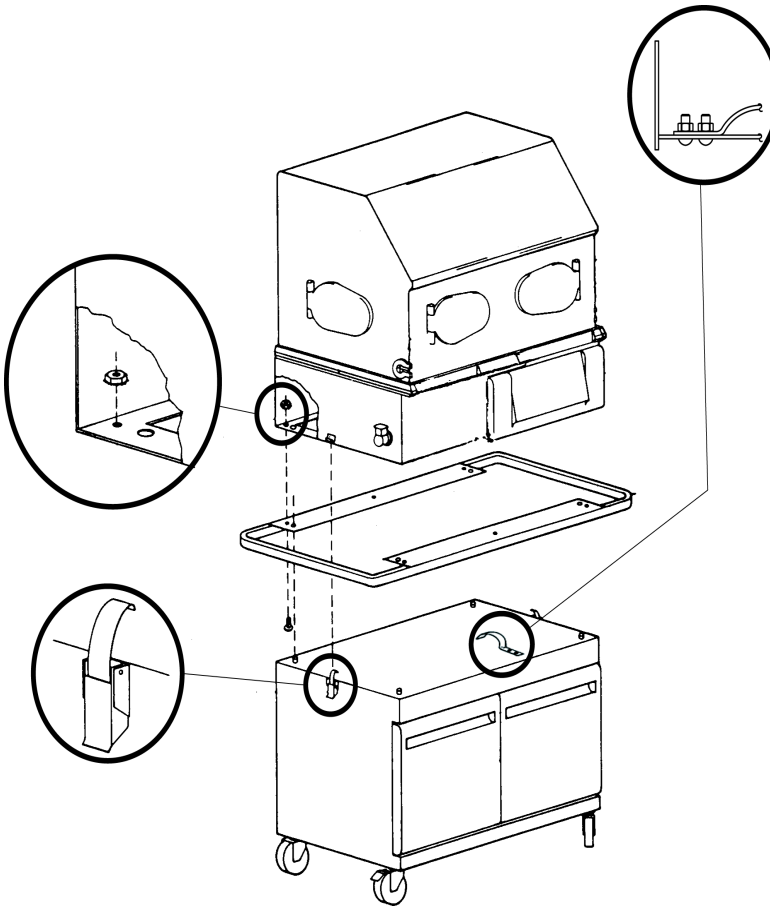
Assembly

Incubators Equipped with the Standard Cabinet Stand

⚠ WARNING:

Two people are required to assemble the hood/base assembly and the cabinet stand. Failure to do so could result in personal injury or equipment damage.

1. Remove the controller from the incubator.
2. Attach the guard rail to the underside of the base assembly using the six #10-32 x ½" screws (P/N 99 042 01) and keps nuts (P/N 99 107 36) supplied.
3. Install the grounding spring inside the controller opening using the six #6-32 x 3/8" screws and hex nuts supplied.
4. Return the controller to the incubator.
5. Place the guard rail and base assembly on the cabinet stand.



⚠ WARNING:

Attach the incubator to the cabinet stand using the clamps 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.

6. Secure the hood/base assembly to the cabinet stand using the clamp on each side of the cabinet stand.
7. Adjust the threaded clamp on the stand for positive latching. The locking bar should be approximately horizontal when the clamp is engaged in the retainer.
8. Lock the clamp by rotating the locking bar to the vertical position.

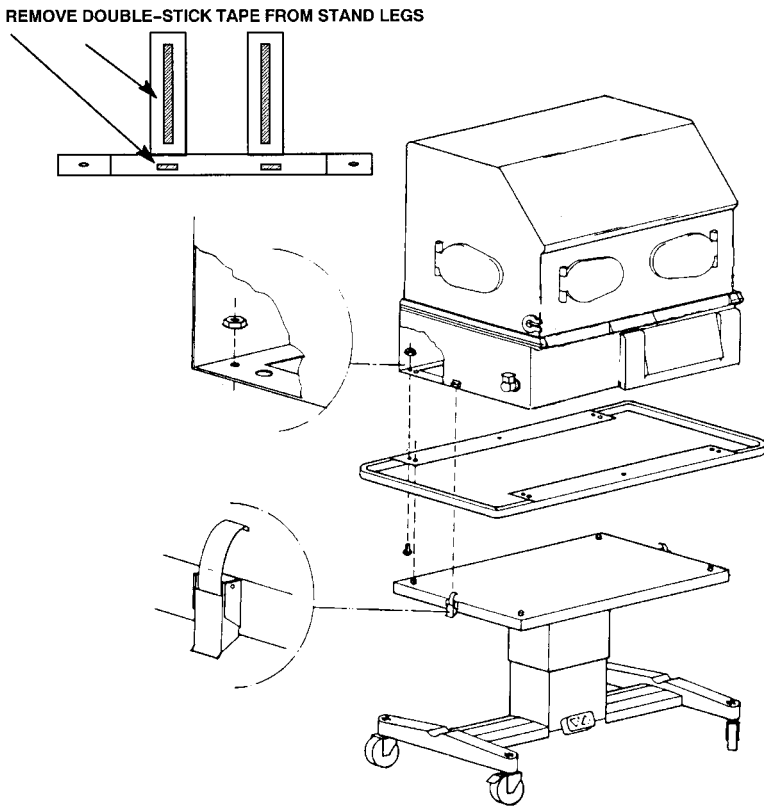
NOTE:

This incubator has been shipped without a filter and filter cover assembly. The filter cover assembly has been shipped in a separate carton. **Do not** place the incubator into use until properly installed.

9. Install the air filter and filter cover on the rear of the unit. If the unit is to be equipped with a Dew-ette® 2 Incubator Humidifier, Model DH90-2, refer to the *Dew-ette® 2 Incubator Humidifier User Manual*, and install the special air filter.
10. Connect the power cord to the incubator.

Incubators Equipped with a Variable Height Adjustable (VHA) Stand (discontinued Jan. 2005)

NOTE:
Before proceeding with incubator assembly, remove the backing from the double-stick tape on the legs of the VHA stand. Place the base covers over the legs, and press down firmly on all corners.



⚠ WARNING:
To prevent injury or damage to the incubator/stand, two persons of sufficient strength are required to adequately control the incubator when transporting it.

⚠ WARNING:
For optimum stability, always lower the incubator to its lowest position prior to transport. Failure to do so could result in personal injury or equipment damage.

1. Remove the controller from the incubator.
2. Attach the guard rail to the underside of the base assembly using the six bolts and keps nuts supplied.
3. Place the guard rail and base assembly on the variable height adjustable (VHA) stand.

⚠ WARNING:
Securely attach the incubator to the variable height adjustable stand using the clamps 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.

4. Secure the base assembly to the VHA stand using the clamp on each side of the VHA stand.

⚠ WARNING:
The VHA stand is intended for use with incubators that use the Model C400 QT® or C450 QT® Isolette® Infant Incubator base assembly. **Do not use** the VHA stand with other incubators. Incubator instability or tip-over could result.

5. Check to be certain that the incubator is firmly secured to the stand at both ends. Do not place in service if not firmly secured.

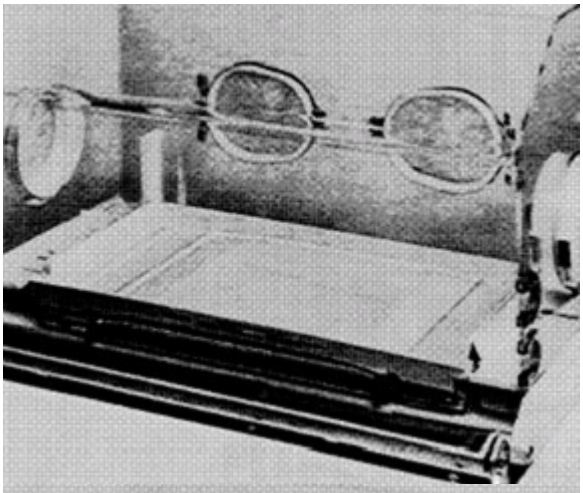
NOTE:
This incubator has been shipped without a filter and filter cover assembly. The filter cover assembly has been shipped in a separate carton. **Do not** place the incubator into use until properly installed.

6. Install the air filter and filter cover on the rear of the unit. If the unit is to be equipped with a Dew-ette® 2 Incubator Humidifier, Model DH90-2, refer to the *Dew-ette® 2 Incubator Humidifier User Manual*, and install the air intake valve assembly, special air filter, and humidifier filter cover.
7. Plug the VHA power cord into an appropriate power source.
8. Plug the interconnecting power cord on the VHA stand into the incubator power cord receptacle.

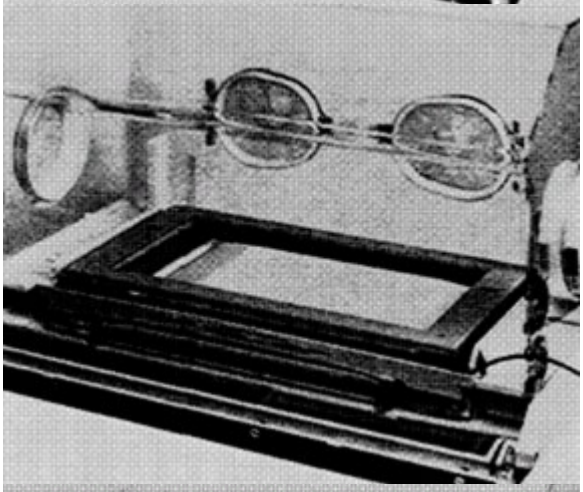
Warm Weigh® Infant Scale, Model I20 (Accessory)

For more information, refer to the I20/W30 User Manual.

1. Open the front access panel of the incubator.
2. Remove the mattress from the incubator.

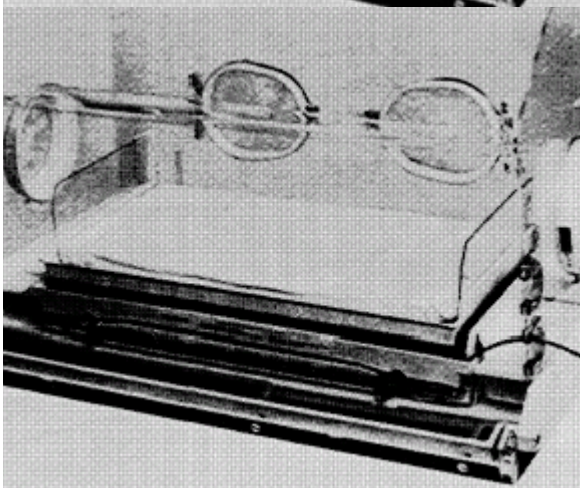


3. Install the weighing platform in the incubator mattress tray, and ensure it is level.



4. Place the mattress tray and the mattress provided with the scale on the weighing platform.

NOTE:
Use the mattress supplied with the scale. Using the C400/C450 mattress may cause inaccurate readings due to interference with the surrounding walls.



5. Insert the cable into the hood access port.

NOTE:
The load cell must be unlocked before operating the scale. Refer to the instructions provided with the scale to unlock the load cell.

General Operation and Functional Checkout Procedure

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

NOTE:
Two persons are required to perform this check—one to lift, and one to check the casters. The lifting weight minimum is approximately 150 kg (331 lb). Use a block to support the raised end in the event a caster falls out.

⚠ WARNING:
A loose caster may fall out during use if the incubator is lifted over cables, door sills, or elevator thresholds. This could result in the incubator tipping over when lowered to floor. Do not use the incubator until the loose casters are replaced. Personal injury or equipment damage could occur.

1. With a standard cabinet stand only, check for loose casters:
   a. Lift each end of the incubator approximately 5 cm (2").
   b. Pull down on each caster.
2. Before plugging the incubator into an appropriate power source, press the **Power** switch. The **Power Failure** alarm sounds, and the **Power Fail** indicator lights. This tests the operation of the **Power Failure** alarm circuit, and ensures that the rechargeable battery that powers the circuit is in good condition.
3. Press the **Power** switch a second time to silence the alarm.
4. When the incubator is mounted on a standard cabinet stand, plug the AC power cord directly into the incubator.

⚠ CAUTION:
Connect the incubator power cord to the variable height adjustable stand receptacle to prevent accidental disconnection or damage when the incubator is raised or lowered.

5. When the incubator is mounted on an optional variable height adjustable (VHA) stand, plug the AC power cord into the VHA stand's AC power outlet.

SHOCK HAZARD:
Make sure that the building power source is compatible with the electrical specifications shown on the right side of the incubator and variable height adjustable stand. For proper grounding reliability, plug the power cord only into a properly marked, three-wire, hospital-grade or hospital-use receptacle. Do not use extension cords. Personal injury or equipment damage could occur.

6. Check the building power source against the specifications on the right side of the incubator.

⚠ WARNING:
To minimize the risk of tipping over during transport when the incubator is mounted on a standard cabinet stand, keep the cabinet stand doors closed during transport. Failure to do so could result in personal injury or equipment damage.

7. When transporting the incubator, make sure the cabinet stand doors are closed.

⚠ WARNING:

To prevent injury or damage to the incubator mounted on a variable height adjustable stand when transporting, two persons of sufficient strength are required to adequately control the incubator.

8. When transporting the incubator mounted on a VHA stand, use two persons of sufficient strength to adequately control the 140 kg (310 lb) incubator and stand.
9. When the incubator is mounted on a VHA stand, check the VHA stand:
    a. Turn on the main **Power** switch.
    b. Use your foot to press the right portion of the VHA stand Up and Down switch to raise the stand to the maximum height.
    c. Press and hold the left portion of the VHA stand Up and Down switch to lower the stand to the minimum height.
    d. Verify that the stand operates smoothly, and adjust it to the desired height.

⚠ WARNING:

To keep the incubator from losing its balance, always place one hand on it for support when adjusting the height. Failure to do so could result in personal injury or equipment damage.

10. Press the **Power** switch. The switch lights.

NOTE:
Newer switches do not light.

⚠ CAUTION:

Perform the self-test on a daily basis. Failure to do so could result in equipment damage.

11. Perform the self-test after maintenance or cleaning.

NOTE:
When initially turned on, the controller performs a 5 s self-test: all alarm indicators light, all mode indicators light, all **Heater Power %** indicators light, the alarm pulses, and each digital display shows 8.

12. If any function does not occur or the digital display is missing a segment, refer the unit to service.
13. Set the **Set Temperature °C** display to 33.0°C (91.4°F). All five **Heater Power %** indicators light, indicating full heater output.
14. Allow the unit to operate while continuing the operational checkout.

15. Check the hood hinge and latch operation for proper positioning.
    a. Using the hood lift handle, slowly tilt the hood back until the hood latch engages.
    b. Close the hood by releasing the hood latch.

16. Check the access panel detent.
    a. Rotate both latch releases inwardly, and open the access panel. The air curtain cover rises slightly as the access panel opens, and the detents create a noticeable "drag" during initial movement of the panel (non-IEC units only).
    b. Pivot the access panel to the full open position, that is, hanging straight down.

17. Check the iris entry ports. Rotate the outer ring of each iris port. The iris opens and closes as rotation is continued through 360°.
18. Check the access panel latches:
    a. Close the access panel.
    b. Rotate both latches until fully engaged. Both latches must fully engage to avoid accidental opening of the access panel.

19. Check the access door latch.

    a. Press the door release of each access door. Each access door swings open.

    b. Close the access doors.

    c. Check for proper latching and quietness.

20. Ensure that all the thumbscrews that secure the mattress tilt mechanism to the deck are fully tightened to ensure mattress tray stability.

NOTE:
The mattress elevators are provided to permit the infant to be positioned in the Trendelenburg or Reverse Trendelenburg position.

21. Do not elevate both ends of the mattress at the same time except possibly during magnification x-ray procedures.

22. Never leave the infant unattended while both elevators are raised.

23. Check the mattress elevators.

⚠ WARNING:
Do not lift the main deck or touch the heater when checking the mattress elevators. The heater can be sufficiently hot to cause burns.

    a. Rotate the right mattress tilt mechanism handle clockwise until it stops. The right end of the mattress is at a 9° angle.

⚠ WARNING:
Do not attempt to raise the hood when the mattress is raised. Personal injury or equipment damage could occur.

    b. Rotate the handle counterclockwise until it stops. The mattress is level.

    c. Repeat the procedure using the left mattress handle.

24. Check the mattress tray:

    a. Slide the mattress tray out to the fully extended position.

    b. Lean on the mattress tray.

    c. Make sure it is properly supported to provide a firm platform for the infant.

⚠ WARNING:

A dirty air intake microfilter may affect oxygen concentrations and/or cause carbon dioxide build-up. Check the filter on a routine basis, and change it at least every three months.

25. Check the air intake microfilter.

    a. Loosen the two thumbscrews of the air intake filter cover.
    b. Remove the air intake filter cover.
    c. Inspect the microfilter.
    d. If the microfilter is visibly dirty, replace it.

26. Check the air/oxygen system:
    a. Introduce a carefully measured 8 lpm of oxygen into the optional oxygen input valve.
    b. Monitor levels within the hood to verify that they reach the predicted level as indicated on the filter cover assembly.
27. Check Air Mode:
    a. With all access openings closed, allow the incubator to warm up to the **Set Temp °C** display setting of 33.0°C (91.4°F). It should take less than 1 hour.
    b. While the unit is warming up, suspend the auxiliary probe through the hole in the top of the incubator hood, and position the patient probe on the center of the mattress surface. Do not connect the probe plugs to the receptacles.
    c. When the **Air Temperature °C** display has stabilized, the number of **Heater Power %** indicators illuminated typically reduce to no more than two.
    d. Check that the **Air Temperature °C** display remains within 0.5°C (0.9°F) of the **Set Temp °C** display for 15 min after stabilization.
28. Check the auxiliary probe:
    a. Insert the auxiliary probe connector into the **Auxiliary Air Probe** receptacle.
    b. When the **Air Temperature °C** display has stabilized, the number of **Heater Power %** indicators illuminated typically reduce to no more than two.
    c. Check that the **Air Temperature °C** display remains within 0.5°C (0.9°F) of the **Set Temp °C** display for 15 min after stabilization.
29. On the Model C450 QT® Isolette® Infant Incubator, check Baby Mode:
    a. Connect the patient probe plug to the **Patient Probe** receptacle, and select Baby Mode.
    b. Set the **Set Temp °C** display to 36.0°C (96.8°F).
    c. Locate the sensor to control air temperature above the center of the mattress.
    d. If the **Set Temperature** alarm actuates, press the **Silence/Reset** key.

30. On the Model C450 QT® Isolette® Infant Incubator, check the **Baby Set Temperature** alarm:
    a. Allow the incubator temperature to stabilize at 36.0°C (96.8°F).
    b. Remove the patient probe from the incubator. In approximately 15 s, the **Set Temperature** LO alarm activates.
31. On the Model C450 QT® Isolette® Infant Incubator, check the **Patient Probe** alarm:
    a. Disconnect the patient probe from the receptacle. The audible and visual alarms activates, the **Baby Temperature °C** display blanks, and the **Heater Power %** indicators all go off.
    b. Connect the patient probe, and press the **Silence/Reset** key. The incubator returns to normal operation.
32. Check the **air flow** alarm:
    a. Set the **Power** switch to off.
    b. Remove the controller from the incubator.
    c. Remove the fan impeller from the fan motor shaft.
    d. Install the controller in the incubator.
    e. Set the **Power** switch to ON, and wait for the end of the Auto-Test cycle that takes 5 s.
    f. Within 5 min, the air flow indicator flashes, a pulsating alarm sounds, and all the **Heater Power %** indicators go out.
    g. Install the fan impeller, and restore the incubator to normal operating condition before proceeding.
33. Check the **High Temperature** alarm:
    a. Select Air Mode, and set the **Set Temp °C** display to 36.0°C (96.8°F).
    b. Position the probe end of the auxiliary probe outside the incubator.
    c. Press the **Keypad Lock** key.
    d. With the keypad locked, simultaneously hold the **>37°C** key and the Up arrow key for 3 s.

NOTE:
The **Baby Temperature °C** display shows [.], and the **Air Temperature °C** display shows the current incubator temperature, and begins to rise.

    e. If the **Set Temperature** alarm actuates, press the **Silence/Reset** key.

NOTE:
When incubator temperature reaches 37.5°C (99.5°F) ± 0.5°C, the **High Temperature** indicator comes on and the alarm sounds.

    f. Press the **Keypad Lock** key to exit the High Temperature test mode.
    g. Return the auxiliary probe to inside the incubator.
    h. When the incubator temperature falls below 37.0°C (98.6°F), press the **Silence/Reset** key to cancel the **High Temperature** alarm.
34. Check the oxygen input valve filter:
    a. Check the oxygen input valve filter cartridge once every four months.
    b. Replace it if the ends are gray or black.

c. Refer servicing to qualified service personnel.

35. Disconnect and store the auxiliary and patient probes.
36. If the incubator is to be used, place it in Air Mode, and leave the incubator running until ready for use.
37. If the incubator is not going to be used, shut it off.

NOTES:

Section 5
Instructions for Use

Instructions for Use

⚠ WARNING:
Phototherapy units located too close to the incubator may affect the hood wall temperature, incubator temperature, and infant skin temperature. Personal injury could occur.

1. Do not place phototherapy units too close to the incubator.

⚠ WARNING:
If the incubator is on a variable height adjustable stand, phototherapy lamps placed over the top of the incubator hood can interfere with the elevator positioning and monitor shelf placement. To prevent this interference, always remove the phototherapy lamp prior to positioning the elevator. Failure to do so could result in personal injury or equipment damage.

2. Remove the phototherapy lamp before positioning the elevator.

⚠ WARNING:
For optimum stability, always lower the incubator to its lowest position prior to transport, and remove the monitors from the swivel shelves. Failure to do so could result in personal injury or equipment damage.

3. Before moving the incubator, lower it to its lowest position, and remove monitors from the swivel shelves.

⚠ WARNING:
If leads or tubing are connected to the infant, raising the hood or tilting the mattress tray could result in harm to the infant. There should be no need to raise the hood at any time while the infant is cared for in the incubator. Gain access to the infant by means of the access panel, access doors, and iris entry ports.

4. Do not raise the hood to gain access to the infant. Open the access panel, access doors, or iris entry ports.
5. Do not place the incubator in service unless the general operation and function checkout procedure has been performed (see “General Operation and Functional Checkout Procedure” on page 4-5).
6. Ventilate and pre-warm the incubator in Air Mode to the temperature prescribed by the attending physician or according to the nursery standing orders. During pre-warming, run the incubator with no water in the humidity reservoir.

NOTE:
The air curtain, which functions when the access panel is open, can be disturbed by drafts, fans, air conditioning, etc.

7. Take necessary measures to keep the incubator away from drafts, fans, or air conditioning.

⚠ WARNING:
To prevent infant fall when the access door is open, do not raise the hood when the mattress is elevated or force the mattress tray when pulling it out. The tray can be dislodged from the support rails on the incubator hood baffles.

8. Pull the mattress tray out to the stop. Do not raise the hood when the mattress is elevated or force the mattress tray when pulling it out.

⚠ WARNING:
When the access panel is opened, a curtain of warm air flows from beneath the front edge of the mattress toward the top of the access panel opening. The temperature of this air curtain is higher than the typical incubator air temperature. Therefore, keep the infant clear of this warm air path. Personal injury could occur.

9. Place the infant in the incubator through the opened access panel, clear of the warm air path caused when the access panel is open.

⚠ WARNING:
For infant safety, do not leave the infant unattended while the access panel is open. Personal injury could occur.

10. Do not leave the infant unattended while the access panel is open.

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

⚠ WARNING:
The use of infant seats, head hoods, or other equipment or supplies within the incubator which can alter the air flow pattern may affect temperature uniformity, temperature variability, the correlation of the incubator temperature reading to the center mattress temperature, and infant skin temperature.

⚠ WARNING:
The incubator temperature may fall below the **Set Temp °C** setting if the access panel is left open. Do not leave it open longer than essential. When the access panel is open, the **Air Temperature °C** display does not accurately reflect the incubator temperature. Personal injury could occur.

11. Return the mattress tray to normal use position, and close the access panel.
12. Positively secure both access panel latches.

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

13. Routinely monitor the infant's rectal and/or auxiliary temperature according to the attending physician's orders or the nursery standing orders.
14. Select the temperature control mode (Air or Baby). For instructions on using Air Mode, go to “Air Mode” on page 5-3. For instructions on using Baby Mode, go to “Baby Mode” on page 5-4.

Air Mode

To Select:

Use the Up and Down arrows to set the **Set Temp °C** display to the prescribed temperature.

The **Set Temperature** LO alarm is silenced for up to 60 minutes after the incubator is turned on, or until the selected set temperature is reached.

Once stabilized, the incubator temperature is maintained within 0.5°C (0.9°F) of the **Set Temp °C**.

If you change the set temperature (either high or low) after the incubator is in operation, the **Set Temperature** LO and HI alarms automatically silence for a specific amount of time after the change. The time the alarm remains silent is 5 min per degree (plus or minus) from the current incubator temperature. For example, a ±1.5° change from set temperature generates an alarm silence period of 7.5 min.

If the incubator fails to reach the new set temperature after the specified time, the alarm sounds.

The number of **Heater Power %** lights illuminated provides an indication of the amount of heater output required to maintain the incubator air temperature.

The **Air Temperature °C** display indicates the incubator temperature.

On the Model C450 QT® Isolette® Infant Incubator, if the patient probe is connected to the patient probe receptacle, the **Baby Temperature °C** display indicates, but does not control, the baby temperature. Otherwise, this display is blank.

Auxiliary Air Probe

NOTE:
The **High Temperature** alarm and the **Air Temperature °C** display still use the probe below the deck.

If desired, use the auxiliary air probe in Air Mode to control the incubator temperature rather than the probe below the main deck.

1. Insert the probe end through the hole on the top of the hood.

⚠ WARNING:
For proper temperature control, the auxiliary air probe must be directly beneath the hole in the hood. Do not operate the incubator with the auxiliary air probe outside the incubator or other than as recommended. Overheating will occur, and personal injury could result.

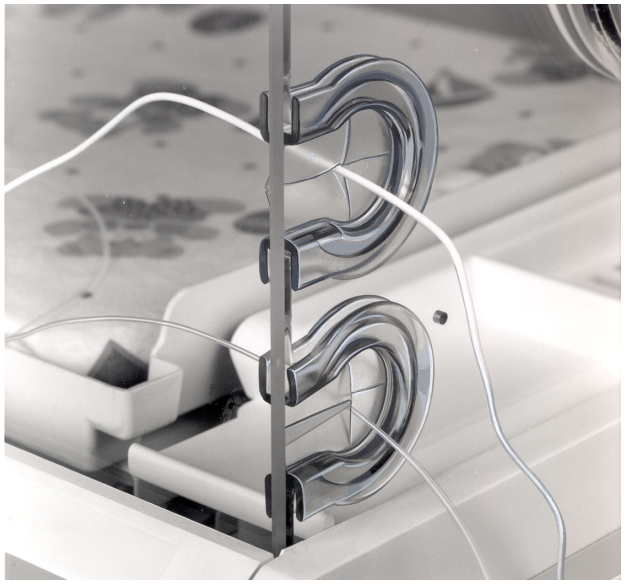
2. Make sure the probe hangs freely inside the incubator.

⚠ WARNING:
If the auxiliary air probe contacts the infant's skin when the mattress is in the Trendelenburg/Reverse Trendelenburg position, erratic air temperature control can result. Always ensure that the probe tip does not contact the infant. Doing so could result in personal injury or equipment damage.

3. To use the probe, insert its plug into the auxiliary air probe receptacle.

Baby Mode

1. Connect the plug of the skin temperature probe to the patient probe receptacle.
2. Insert the probe into the hood compartment through the right tubing access grommet.



The **Set Temperature** LO alarm is silenced for up to 60 min after the incubator is turned on, or until the selected set temperature is reached.

If you change the set temperature (either high or low) after the incubator is in operation, the **Set Temperature** LO and HI alarms automatically silence for a specific amount of time after the change. The time the alarm remains silent is 5 min per degree (plus or minus) from the current incubator temperature. For example, a ±1.5° change from set temperature generates an alarm silence period of 7½ min.

If the incubator fails to reach the new set temperature after the specified time, the alarm sounds.

3. Thoroughly clean and dry the skin area where the probe is to be placed before placing the probe on the skin:
    a. When the infant is on its 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 infant's back.
    c. Never place the probe under the infant, or use it rectally.

4. Attach the probe to the infant using a Critter Covers® Probe Cover.
5. To stabilize the attached probe, place a Critter Covers® Probe Cover over the probe wire approximately 3 cm (1") to 4 cm (2") from the probe tip.
6. Use the Up and Down arrows to set the **Set Temp °C** display to the desired temperature.

Once stabilized, the infant probe temperature is automatically controlled within 0.3°C of the **Set Temp °C** display as indicated by the **Baby Temperature °C** display.

The number of **Heater Power %** lights illuminated provides an indication of the amount of heater output required to maintain the baby temperature.

The **Baby Temperature °C** display indicates the skin probe temperature.

The **Air Temperature °C** display indicates the actual incubator air temperature necessary to maintain the baby temperature.

Oxygen Therapy

⚠ WARNING:
Improper use of supplemental oxygen can cause serious side effects including blindness, brain damage, and death. The risks vary with each infant. The attending physician should prescribe the method, the concentration, and the duration of oxygen administration.

⚠ WARNING:
Administration of oxygen may increase the noise level for the patient within the incubator. Infant injury could occur.

⚠ 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.

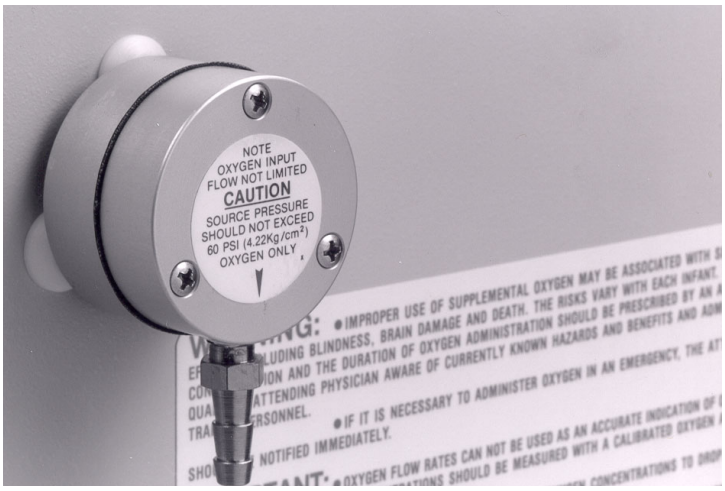
1. Properly administer oxygen from a wall source or the oxygen cylinder on the standard incubator cabinet stand. If it is necessary to administer oxygen in an emergency, notify the attending physician immediately.

⚠ WARNING:
The oxygen concentration inspired by an infant does not predictably 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.

2. When deemed advisable by the attending physician, measure the blood pO_2 by accepted clinical techniques. Refer to the current edition of *Guidelines for Perinatal Care of the American Academy of Pediatrics/The American College of Obstetricians and Gynecologists*.

⚠ WARNING:
The use of external humidification will alter predicted incubator oxygen concentrations. Personal injury could occur.

3. Do not use external humidification.
4. Connect the output of the oxygen flowmeter to the nipple of the optional oxygen input valve by using 3/16" inner diameter surgical tubing.



NOTE:
An oxygen concentration guide is provided on the air input filter cover on the back of the incubator.

⚠ WARNING:
When administering oxygen therapy by means other than the rear panel oxygen input valve, the oxygen concentrations guide values identified are not valid. Independently measure the oxygen concentrations to verify delivery of the prescribed oxygen concentration. Failure to do so could result in personal injury or equipment damage.

5. When administering oxygen therapy by means other than the rear panel oxygen input valve, the oxygen concentrations guide values identified are not valid. To verify delivery of the prescribed oxygen concentration, independently measure the oxygen concentrations.

NOTE:
The values shown in the table on page 5-6 are intended as guidelines only.

Oxygen Concentration Guide for Optional Oxygen Input Valve at 50 Hz to 60 Hz Operation

Oxygen Input	Normal Range of Oxygen
4 lpm	25% to 30%
6 lpm	29% to 35%
8 lpm	33% to 41%
10 lpm	37% to 52%
12 lpm	45% to 75%
14 lpm	65% to 95%

6. Adjust the flow as required to achieve the prescribed concentrations. See the warning label and important operating instructions.
7. Allow 30 min for final concentrations after each change of the oxygen flow setting.

Humidity Reservoir

The ambient relative humidity of the operating environment influences the level of relative humidity attained within the incubator.

When the temperature inside the incubator is significantly higher than the temperature in the nursery, condensation may form on the inside of the hood. When there is relatively little temperature difference between the incubator and the nursery, condensation does not form. This does not mean the incubator air is not adequately humidified, but rather that the difference in temperature is not great enough to produce condensation.

1. To minimize contamination in the humidity reservoir, completely drain and refill it daily.

⚠ CAUTION:

Use only sterile distilled water. Use of tap water could result in equipment damage.

2. Use only sterile distilled water.

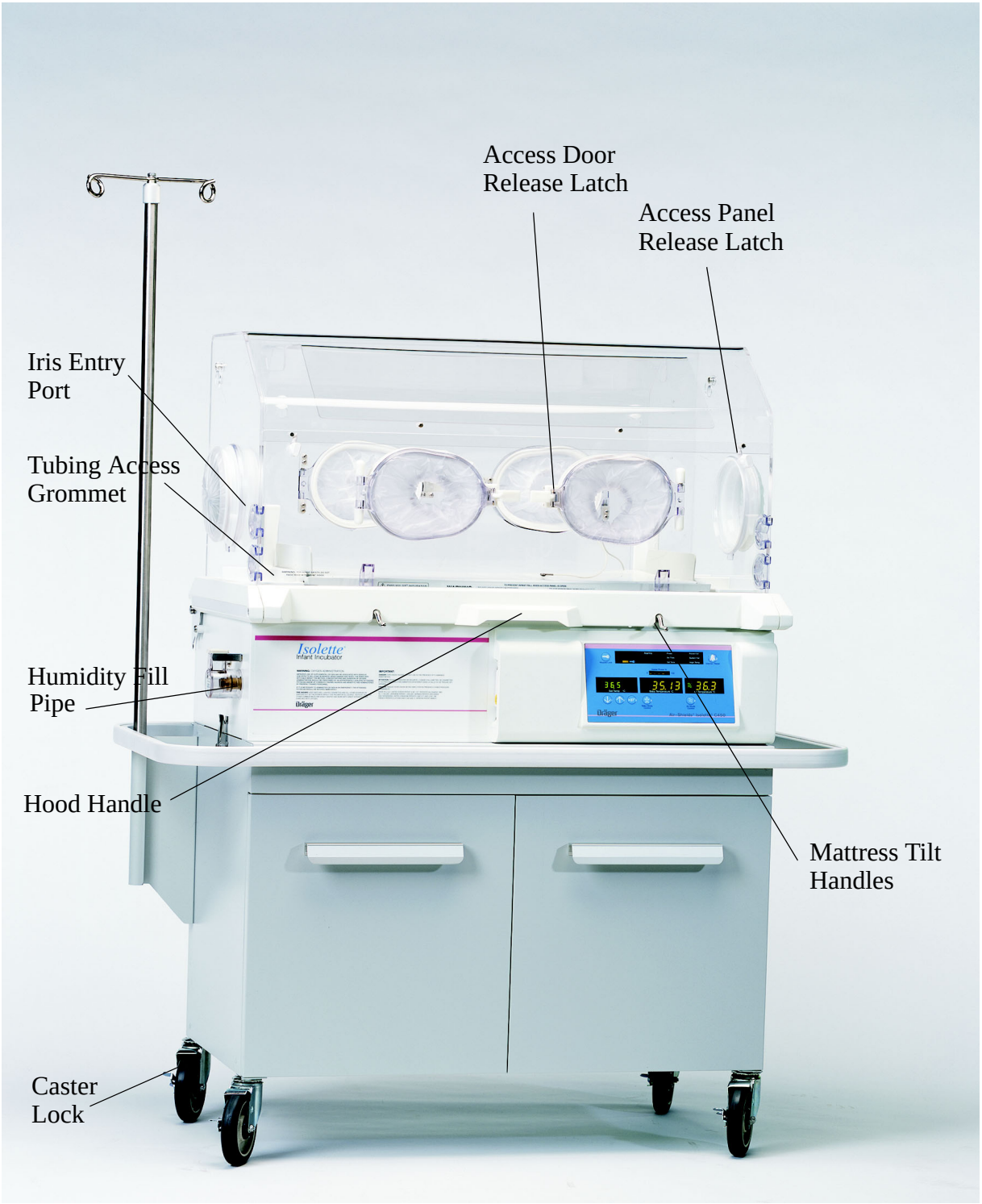
⚠ CAUTION:

Never refill a partially filled humidity reservoir. Always drain the humidity reservoir completely before refilling. Failure to do so could result in equipment damage.

3. Never refill a partially filled humidity reservoir. Always drain it completely before refilling.

NOTE:
A single filling is enough for at least one full day of operation. Relative humidity inside the incubator is typically at 50% to 60% under these conditions.

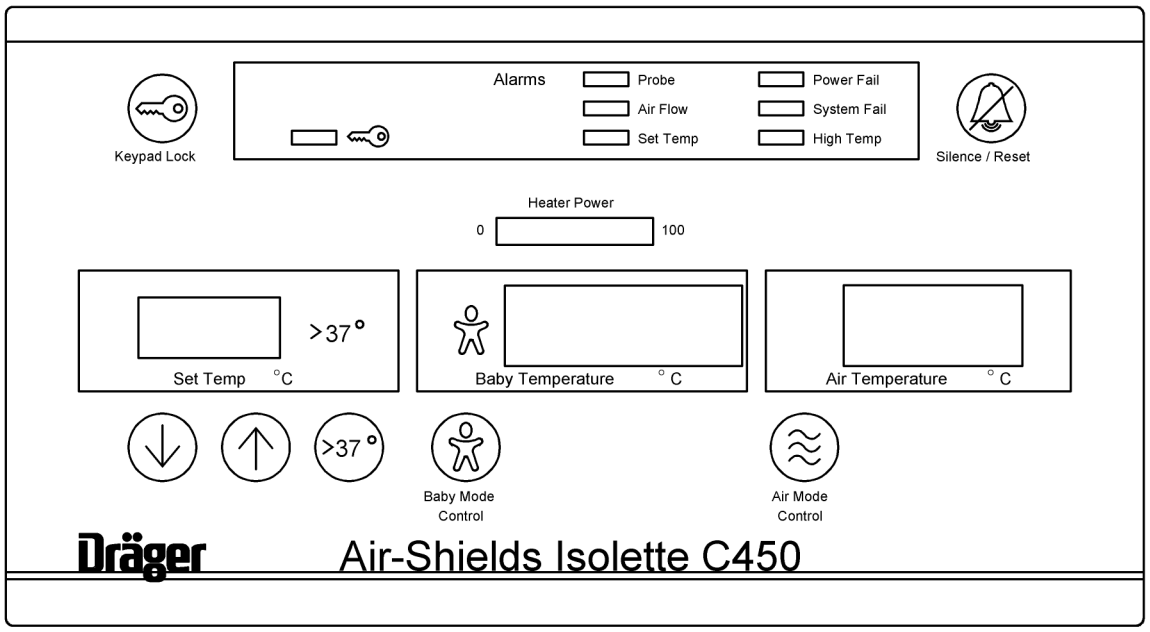
4. If the attending physician prescribes additional humidification, fill the humidity reservoir with 2200 cc of sterile distilled water.

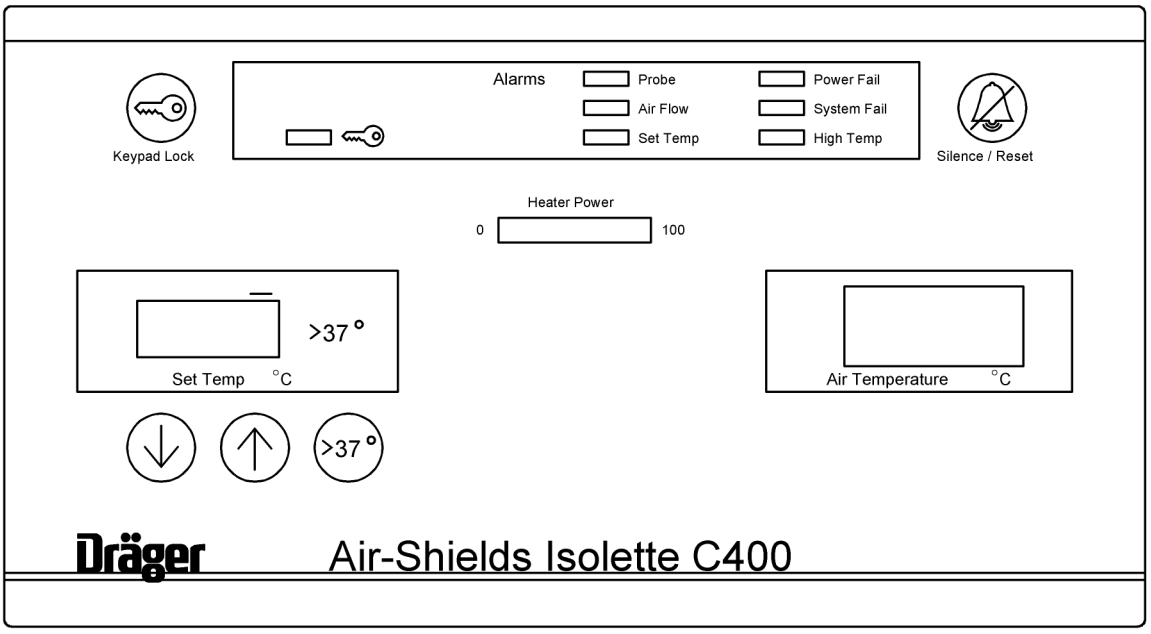

Access Door
Release Latch
Access Panel
Release Latch
Iris Entry
Port
Tubing Access
Grommet
Humidity Fill
Pipe
Hood Handle
Mattress Tilt
Handles
Caster
Lock

Incubator Handles, Latches, and Openings

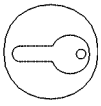
Name	Description
Hood lift handle	Use the hood lift handle to lift the hood assembly for cleaning or maintenance.
Hood hinge latch	Located on the right rear corner of the incubator, the hood hinge latch is used to latch the hood assembly in the open position. Press to fasten.
Mattress tilt handles	Use the mattress tilt handles to position the mattress in Trendelenburg or Reverse Trendelenburg position. The angle of the mattress is variable from 0° ± 9°. Rotate clockwise to raise the mattress, and counter-clockwise to lower the mattress.
Iris entry port	The iris entry port provides access to the infant compartment.
Access door release latch	The access door release/latch releases and latches the access door.
Access panel release latch	Rotate the access panel release/latch to latch or release the access panel.
Humidity fill pipe	The humidity fill pipe provides the means to fill the humidity reservoir.
Tubing access grommet	The tubing access grommet provides the routing for tubing, probe leads, etc. into the infant compartment.
Caster lock	Located on the diagonal corners of the cabinet stand, the caster lock restricts the incubator movement.
Oxygen input connection	Located on the rear of the incubator, the oxygen input connection provides the connection point for output of the oxygen flow meter.

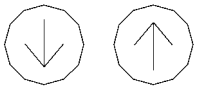
Controller Front Panel Operating Controls, Indicators, and Connectors



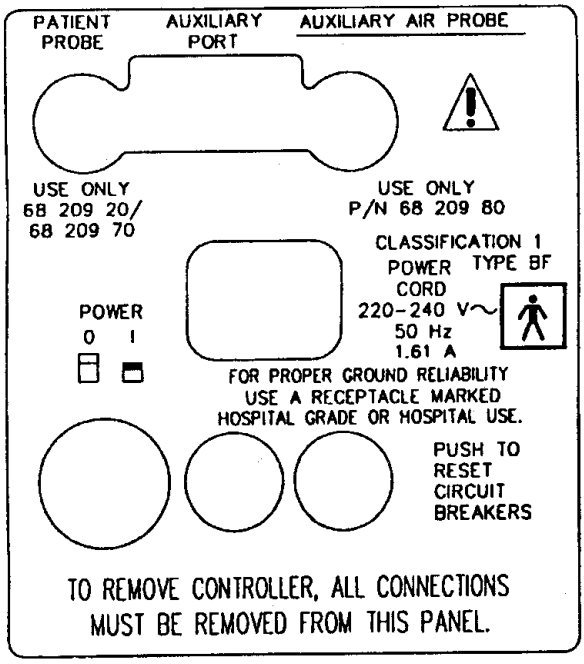


Controller Front Panel Controls and Indicators

Name	Description
Baby Mode control (Model C450 QT® Isolette® Infant Incubator only) 	Press the **Baby Mode** control to enable Baby Mode.
Baby Mode control indicator (Model C450 QT® Isolette® Infant Incubator only)	Lights to indicate that the unit is operating in Baby Mode.
Baby Temperature °C digital display (Model C450 QT® Isolette® Infant Incubator only)	Displays the baby temperature in Celsius degrees. When the baby probe is disconnected from the unit during Baby Mode, the display goes blank and the alarm sounds. When the baby probe is disconnected from the unit in Air Mode, the display goes blank, but no alarm sounds.
Air Mode control 	Press to enable Air Mode.
Air Mode control indicator	Lights to indicate that the unit is operating in Air Mode.
Air Temperature °C digital display	Displays the incubator air temperature in Celsius degrees. If the air temperature probe fails, the display goes blank.
Silence/Reset switch 	Turns off the audible portion of the **Set Temperature** alarm for nominally 15 min. If another alarm occurs within the period of silence, alarm silence is automatically overridden. Turns off the **Power Fail** alarm for two min. Reset functions as the alarm reset for the **air flow**, **High Temperature**, and **Probe** alarms, but only after the alarm condition is corrected.
Heater Power % indicator	Provides an indication of relative heater output from 0% to 100%.
Keypad Lock control 	Press to disable the **Baby Mode** control, **Air Mode** control, Up and Down arrows, and **>37°C** keys. Press it again to enable the **Baby Mode** control, **Air Mode** control, Up and Down arrows, and **>37°C** keys. The key indicator lights to indicate that the keypad is locked. An unlocked keypad automatically locks after approximately 15 s of no keypad activity.
Keypad Lock indicator	Lights to indicate that the keypad is locked. An unlocked keypad automatically locks after approximately 15 s of no keypad activity.

Name	Description
Up and Down arrow 	In Air Mode, press the Up arrow to raise the **Set Temp °C** temperature setting from 20°C (68°F) to 37°C (99°F). In Temperature Override Mode, press the Down arrow to raise the **Set Temp °C** temperature setting from 20°C (68°F) to 38.5°C (101.3°F). Press the Down arrow to lower the **Set Temp °C** temperature setting from 37°C (99°F) to 20°C (68°F). In Temperature Override Mode, press the Down arrow to lower the **Set Temp °C** temperature setting from 38.5°C (101.3°F) to 20°C (68°F). In Baby Mode (Model C450 QT® Isolette® Infant Incubator only), press the Up arrow to raise the **Set Temp °C** temperature setting from 34°C (93°F) to 37°C (99°F). In Temperature Override Mode, press the Up arrow to raise the **Set Temp °C** temperature setting from 34°C (93°F) to 37.9°C (100.2°F). Press the Down arrow to lower the **Set Temp °C** temperature setting from 37°C (99°F) to 34°C (93°F). In Temperature Override Mode, press the Down arrow lower the **Set Temp °C** temperature setting from 37.9°C (100.2°F) to 34°C (93°F). To raise the **Set Temp °C** temperature setting in 0.1° increments, press the Up arrow once. To raise the **Set Temp °C** temperature setting rapidly, press and hold the Up arrow. To lower the **Set Temp °C** temperature setting in 0.1° increments, press the Down arrow once. To lower the **Set Temp °C** temperature setting rapidly, press and hold the Down arrow.
Set Temp °C digital display	Displays the baby or air set temperature setting in °C as selected by the Up and Down arrow keys. During a **Set Temperature** alarm, it flashes and alternates with LO or HI to indicate that the air or baby temperature is above or below the setpoint.
>37° control 	Press to place Baby Mode or Air Mode in Temperature Override Mode. This key is inactive until the **Set Temp °C** temperature setting has been set to 37°C (99°F).
>37°C indicator	Lights to indicate that Temperature Override Mode is selected.

Side Panel Controls, Indicators, and Connectors

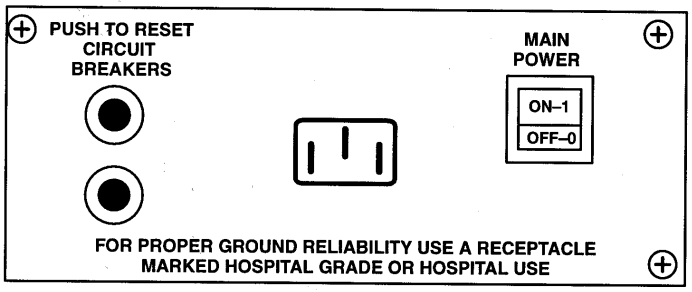


Controller Side Panel Controls and Connectors

Name	Description
Power switch	Press to turn on or turn off the controller.
Circuit breakers	Provide overload protection. To reset the unit, press the circuit breakers.
Auxiliary port connector	Accepts the connector from the remote alarm module accessory.
Patient probe connector	Accepts the skin temperature probe for monitoring and controlling the infant's skin temperature. When the patient probe is connected, the **Baby Temperature °C** display indicates the temperature sensed by the probe. When the patient probe is disconnected, the **Baby Temperature °C** display is blank.
Auxiliary air probe connector	Accepts the auxiliary air temperature probe and disconnects the internal air temperature probe to permit the air temperature control by the auxiliary probe.
Power cord connector	Accepts the AC power cord.

Optional Features (discontinued Jan. 2005)

Variable Height Adjustable (VHA) Stand Controls, Indicators, and Connectors



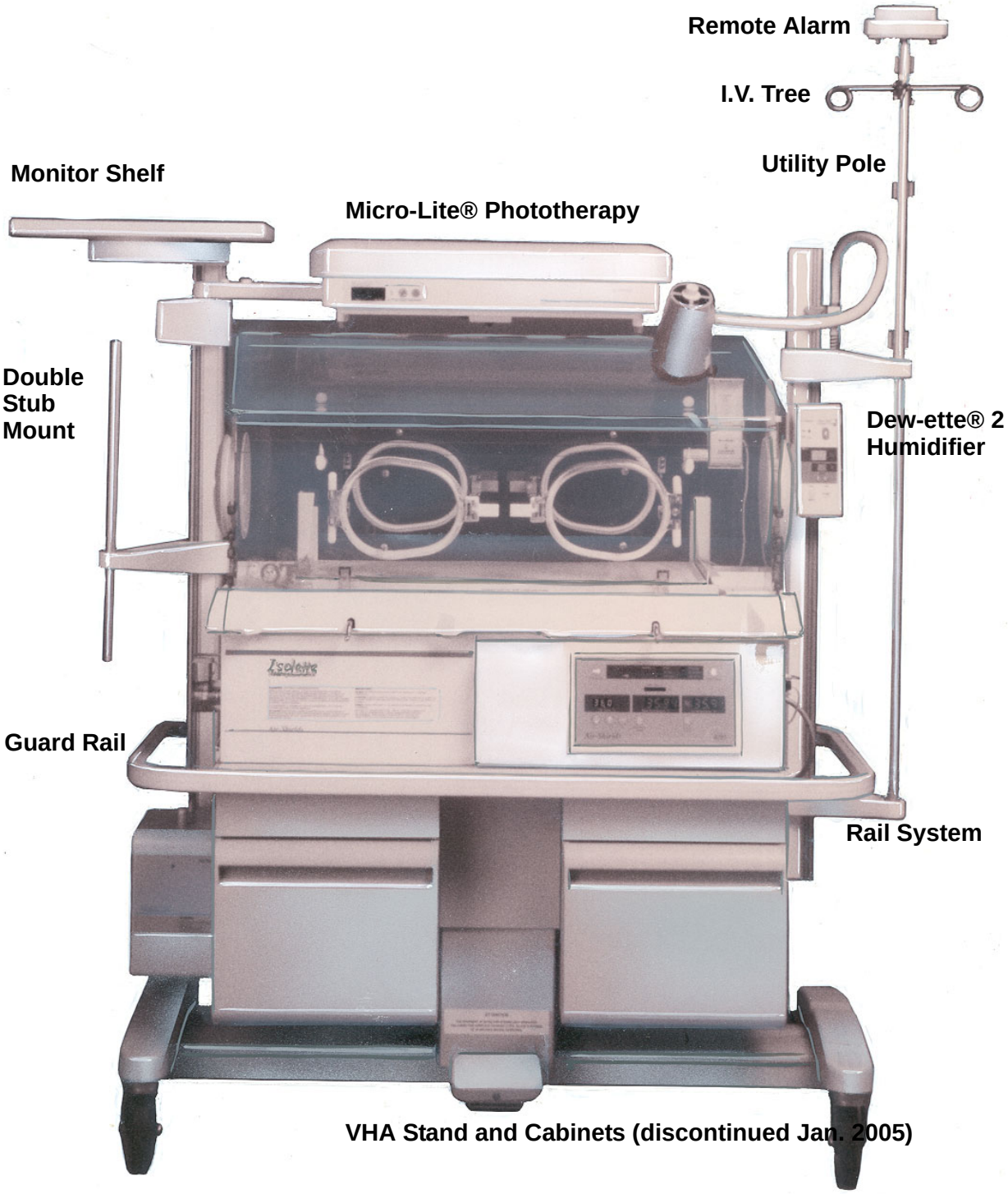
Name	Description
VHA stand	Enables the incubator height from the floor level to be varied
Up and Down switch	**⚠ WARNING:** When an IV pole is present, use caution when raising the VHA stand. Personal injury or equipment damage could occur. Press to move the VHA stand up or down. Use caution when an IV pole is present.
Circuit breakers	Provide the VHA stand with overload protection. To reset, press the circuit breakers.
AC receptacle	The AC receptacle accepts the AC power cord.
Main power switch	Supplies the main power to the VHA stand and incubator.

The VHA stand (discontinued Jan. 2005) provides the Isolette® Infant Incubator with the capability of varying the incubator height over a range of 21.59 cm (8½"). An electric motor powers the VHA stand, and a momentary up/down foot switch controls the electric motor. The VHA stand has its own power cord, and provides power to the incubator, that is mounted on it. In addition, if the VHA stand circuit breakers open, power is still provided to the incubator, which is protected by its own circuit breakers.

Accessories

Accessories available for use with the incubators are illustrated. For part numbers, refer to “Replacement Parts” on page 6-12.

Accessories



Cabinets and Drawers

The incubators are equipped with a standard cabinet stand or a VHA stand (discontinued Jan. 2005). The cabinet is available with a metal door. The VHA stand may be equipped with one or two cabinet or drawer modules, or one of each. These modules may also be equipped with fold-down side shelves.

Swivel Shelves

The cabinet stand or VHA stand may be equipped with up to four, post-mounted, swivel shelves. The swivel shelves operate the same way on both stands:

To Position the Swivel Shelves:

1. Loosen the knob.
2. Position the shelf to the desired position.

⚠ WARNING:
Always tighten the knob for securing the position of the shelf when in use, or after repositioning. Failure to do so could result in personal injury or equipment damage.

3. Tighten the knob.

⚠ WARNING:
Always place the monitor in the center of the shelf. Failure to do so could result in personal injury or equipment damage.

⚠ WARNING:
Ensure that the monitor fits within the raised border of the shelf. Failure to do so could result in personal injury or equipment damage.

4. Place the monitor in the center of the shelf, and ensure that the monitor fits within the raised border of the shelf.

⚠ WARNING:
Never stack another monitor atop the monitor on the shelf. Personal injury or equipment damage could occur.

5. Never stack another monitor atop the monitor on the shelf.

NOTES:

Section 6
Cleaning, Maintenance, Replacement Parts and Storage and Handling

Cleaning

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

⚠ WARNING:
Follow all hospital procedures for disinfection and potential biohazard exposure. Failure to do so could result in personal injury.

SHOCK HAZARD:
Unplug the unit from its power source. Failure to do so could result in personal injury or equipment damage.

SHOCK HAZARD:
Do not expose the unit to excessive moisture. Personal injury or equipment damage could occur.

⚠ CAUTION:
Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.

General Cleaning

We recommend that you clean the unit with detergent and warm water. Do not use excessive liquid or harsh cleansers.

At a minimum, thoroughly clean and disinfect the incubator upon discharge of an infant. However, depending on individual facility policy, perform cleaning procedures as often as daily, if desired. Cleaning can most effectively be accomplished by disassembling and then grouping the parts and/or assemblies in categories according to the method of cleaning required.

Cleaning Agents

When the equipment is not in use and it is disassembled, use an intermediate-level (tuberculocidal) detergent/disinfectant registered by the US Environmental Protection Agency. Disinfect only when the equipment is not in use and disassembled (see "Disassembly for Cleaning" on page 6-2). When using any cleaning agent, follow the manufacturer's directions for use. Cleaning agents safe for use with this equipment include Kleenaseptic® b cleaner or 2% glutaraldehyde solutions. Dilute the disinfectant as

specified on the manufacturer's label. Before cleaning, remove all solid wastes and contaminants from the disassembled parts.

Steam Cleaning

Do not use any steam cleaning device on the unit. Excessive moisture can damage mechanisms in this unit.

Cleaning Difficult to Access Areas

To remove difficult spots or stains, we recommend that you use standard household cleansers and a soft bristle brush. To loosen heavy, dried-on soil, you may first need to saturate the spot.

Cleaning Painted Surfaces

Use an EPA-registered disinfectant-detergent, such as glutaraldehyde-based cold sterilants and quarternary ammonium compound disinfectants to clean all surfaces thoroughly. Make sure to clean all holes and indentations, and then dry with a clean cloth or paper towel.

Cleaning Clear Plastic and Acrylic Surfaces

⚠ CAUTION:

Do not use alcohol, acetone, or any organic solvents for cleaning. Alcohol can cause crazing of plastic and acrylic.

⚠ CAUTION:

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

1. Use an EPA-registered disinfectant-detergent, such as glutaraldehyde-based cold sterilants and quarternary ammonium compound disinfectants to clean all surfaces thoroughly. Make sure to clean all holes and indentations.
2. Dry with a clean cloth or paper towel.

Disinfecting

When there is visible soilage and also between patient use, we recommend that you disinfect the unit using an EPA registered, tuberculocidal, disinfectant. Cleaning agents safe for use with this equipment include Kleenaseptic® b cleaner or 2% glutaraldehyde solutions.

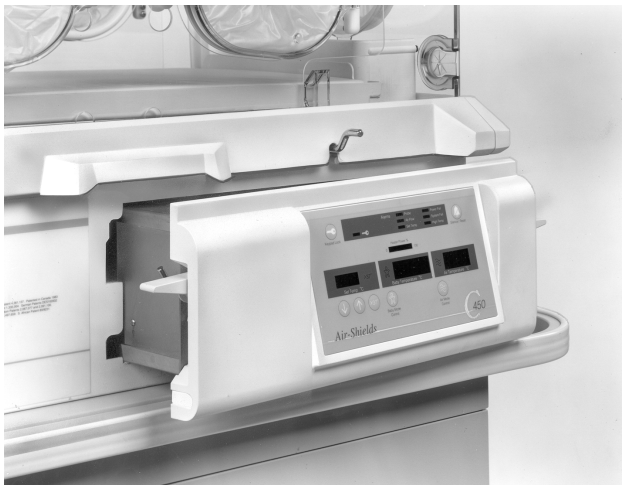
Dilute and use the disinfectant as specified on the manufacturer's label.

Disassembly for Cleaning

NOTE:
For routine cleaning, there is no need to separate the hood/base assembly from the cabinet stand. If separation is necessary, refer to “Installation” on page 4-1.

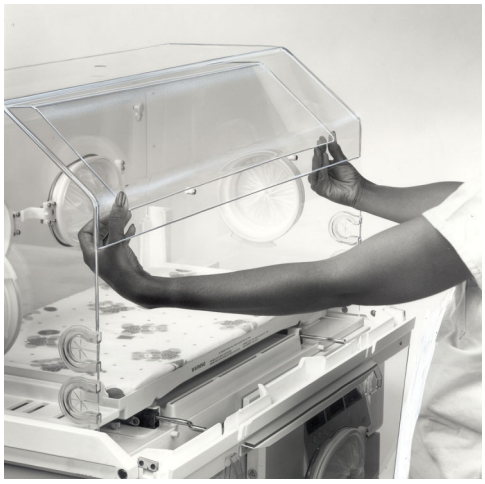
⚠ WARNING:

The controller heater can be sufficiently hot to cause burns. Avoid removing the controller or touching the heater until the unit has been switched off for at least 45 min. Personal injury could occur.



1. After the incubator has been off for 45 min, remove the controller:
   a. Disconnect the power cord and probes from the side of the incubator.
   b. Release the latch on each side of the controller.
   c. Withdraw the unit from the incubator.
2. Remove the mattress tilt mechanism by loosening the thumbscrews that secure it to the main deck.

3. Remove the hood inner walls:
   a. Release the front of the inner wall by pushing it back slightly to release the wall from the two stand-offs located on the front of the hood.

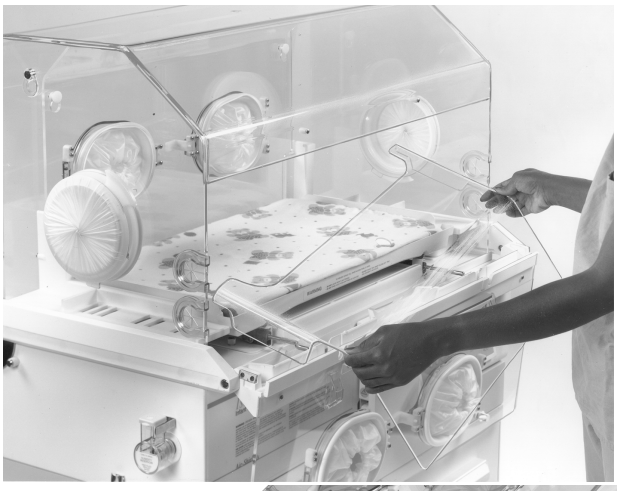


b. Remove the upper inner wall by lowering it.

c. Remove the rear inner wall by first sliding out the mattress tray several inches.

d. Raise the inner wall up to clear the key hole slots.

e. Remove the wall from the incubator.

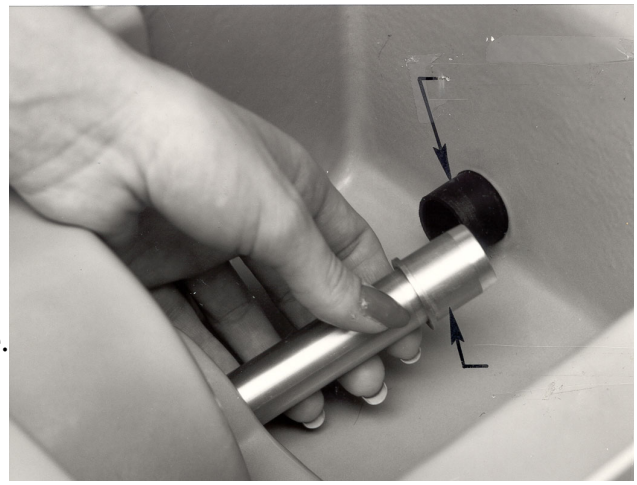


4. Remove the mattress tray:
   a. Close the access panel.
   b. Latch the hood assembly in the open position.
   c. Lift out the mattress tray.
   d. Remove and discard the disposable mattress cover.
   e. Raise and then lock the hood in place.

5. Remove the main deck.

6. Remove the deck plate.

7. Remove the air intake tube:
   a. Grasp the air intake tube.
   b. Twist and pull it toward the front of the incubator until the end of the tube clears the gasket.
   c. Remove the tube from the base assembly.



8. Remove the disposable access door cuff from each access door gasket by pulling it off from the outside.
9. Discard the disposable access door cuffs.
10. Remove the access door gaskets by pulling them free.
11. Remove the tubing access grommets from each side of the hood by pulling them free.
12. Remove the disposable iris entry port sleeves by pulling each one off the retainer rings.
13. Discard the disposable iris entry port sleeves.
14. Remove the air intake microfilter cover by loosening the two thumbscrews.

Cleaning

Use an intermediate-level (tuberculocidal) detergent/disinfectant registered by the U.S. Environmental Protection Agency (EPA), such as Kleenaseptic®[1]-B™[2] Germicidal Cleanser. When using any cleaning agent, follow the manufacturer's directions for use. After removing all solid wastes and contaminants from the disassembled parts, clean them as follows:

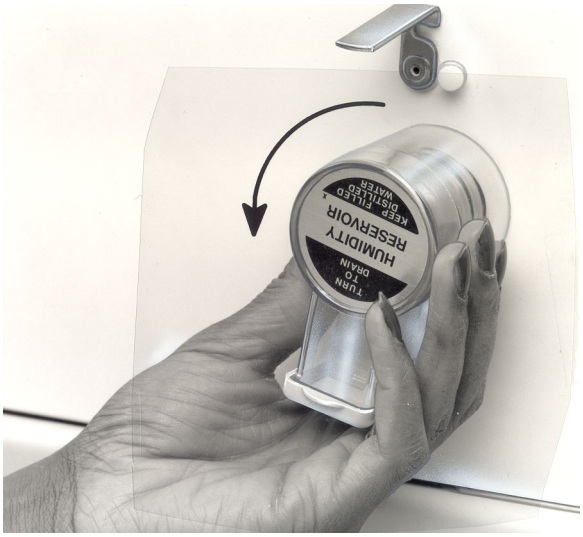
Cleaning the Skin Probe (Model C450 QT® Isolette® Infant Incubator Only)

1. Use the disinfectant-detergent to thoroughly clean all surfaces.
2. Dry with a clean cloth or paper towel.

1. Kleenaseptic® is a registered trademark of Metrex Research Corporation.
2. Kleenaseptic®-B™ is a trademark of Metrex Research Corporation.

Cleaning the Humidity Chamber and Fill Pipe, Air Intake Tube, Access Door Gaskets, and Tubing Access Gaskets

1. Fill the humidity chamber with the disinfectant-detergent.
2. Remove the W-shaped baffle from the chamber, and dry it with a clean cloth or paper towel.
3. Place the air intake tube, access door gaskets, and tubing access grommets into the solution.
4. If necessary, use a larger container than the humidity chamber. If the chamber is not used, clean it and the fill pipe separately.
5. Allow the parts to soak as recommended by the manufacturer.
6. Remove them, and dry completely with a clean cloth or paper towel. If the humidity chamber was filled with the disinfectant solution, perform the following:
   a. Drain the humidity chamber.
   b. Scrub it thoroughly, including all indentations.
   c. Dry the humidity chamber and fill pipe (inside and out) with a clean cloth or paper towel.
7. If it is necessary to remove the fill pipe for cleaning, perform the following:
   a. Rotate the fill pipe assembly about ¼ turn to the left.
   b. Loosen the thumbscrew that secures the fill pipe bracket, and rotate the bracket ¼-turn to the left.
   c. Unscrew the fill pipe assembly by rotating counterclockwise.
   d. Clean the fill pipe assembly and the sleeve that becomes a loose part when the fill pipe assembly is unscrewed.



Cleaning the Controller

1. Wipe the front panel, top, bottom, and two sides of the controller chassis with a clean cloth dampened with the detergent/disinfectant.
2. For cleaning parts on the rear surface that are within the controlled environment, perform the following:

⚠ WARNING:
Failure to clean could result in sufficient lint build-up to reduce air flow, which will affect temperature control, and cause high oxygen concentrations. Personal injury or equipment damage could occur.

   a. Remove any lint build-up from the fan impeller, heater, and air temperature probe.
   b. Clean these surfaces with the detergent/disinfectant.
   c. Dry with a clean cloth or paper towel.
3. When using the disinfecting tank, perform the following:
   a. Fill the disinfecting tank with the detergent/disinfectant.
   b. Immerse the rear surface of the controller.

c. Allow it to soak as recommended by the manufacturer.

d. Dry with a clean cloth or paper towel.

Cleaning the Mattress Tray and Deck Plate

1. Use the detergent/disinfectant to clean all surfaces thoroughly.
2. Dry with a clean cloth or a paper towel.

Cleaning the Mattress Tilt Control

1. Use the detergent/disinfectant to clean all surfaces thoroughly.
2. Dry with a clean cloth or a paper towel.

⚠ WARNING:

Do not lubricate the mattress tilt mechanism with oil or other potentially flammable material in an oxygen-enriched environment. Personal injury or equipment damage could occur.

3. Do not lubricate the mattress tilt mechanism with oil or other potentially flammable material.

Cleaning the Hood and Cabinet Stand

1. Use the detergent/disinfectant to clean all surfaces of the hood thoroughly, including the inner wall and access door heat shield.

⚠ CAUTION:

Alcohol can cause crazing of the clear acrylic hood. Do not use alcohol for cleaning.

⚠ CAUTION:

Do not expose the hood assembly to direct radiation from germicidal lamps. Ultraviolet radiation from these sources can cause cracking of gaskets, fading of paint, and crazing of the clear acrylic hood.

2. Do not use alcohol or germicidal lamps to clean the hood.
3. Clean all holes, indentations, baffles, etc.
4. Dry with a clean cloth or paper towel.

Cleaning the Air Intake Microfilter Chamber

1. Do not attempt to clean or reverse the microfilter.

⚠ WARNING:

A dirty intake filter may affect oxygen concentration, and/or cause carbon dioxide build-up. Check the filter on a routine basis commensurate with local conditions.

2. If the air intake microfilter is visibly dirty, or older than 3 months, replace it.
3. Before installing a new filter, clean the microfilter chamber and its cover with the detergent/disinfectant.

Assembly After Cleaning

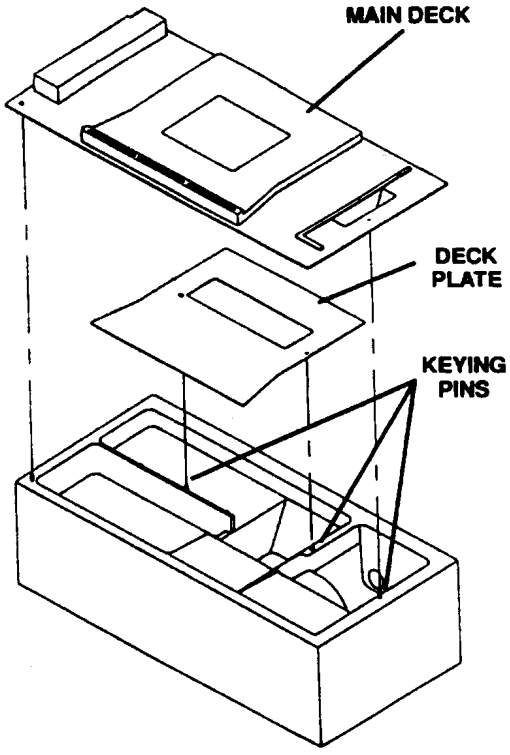
Specific assemblies (inner walls, main deck, mattress tilt mechanisms, oval gaskets) are not interchangeable between the Models C100/C200, C500/550, and the C400 QT® and C450 QT® Isolette® Infant Incubator.

1. Verify proper identification of components prior to assembly.
2. Install the air intake tube into the base assembly.
3. Insert the humidity chamber baffle into the humidity chamber.

⚠ WARNING:
For proper operation, install the deck plate. Failure to do so could result in personal injury or equipment damage.

4. Install the deck plate. Make sure the deck plate is properly aligned on its keying pins.
5. Install the mattress tilt mechanisms on the main deck.

NOTE:
There is a right-hand and left-hand tilt mechanism.

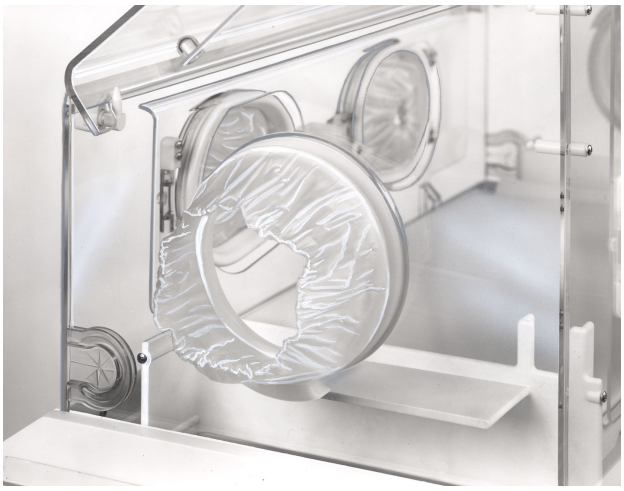


⚠ WARNING:
Be sure the two thumb screws that hold the tilt mechanisms to the deck are tightened securely. Failure to do so could result in personal injury or equipment damage.

6. Securely tighten the two thumbscrews that hold the tilt mechanisms to the deck.
7. Install the mattress tray:
   a. Position the mattress tray a few inches above the mattress rails.
   b. Lower it straight down.
8. Install a new disposable mattress cover over the mattress.
9. Place the mattress onto the tray.

10. Install the disposable iris entry port sleeves.
11. Install the smaller diameter elastic band of a new sleeve over the inner ring of the port housing.

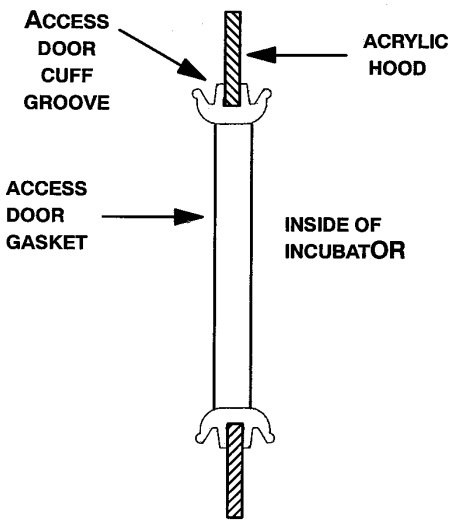
12. Fold the sleeve back, and slip the elastic band over the outer ring of the port housing.



    a. Rotate the outer ring to close.
    b. Rotate the outer ring to open it. If properly installed, the sleeve opens again.

13. Install a tubing access grommet into the front edge of each side of the hood. If a tubing access grommet is distorted or torn, replace it.

14. Install an access door gasket behind each access door.
15. Install a new access door cuff onto each access door gasket:
    a. Stretch the larger diameter elastic band into the groove in the gasket.



NOTE:
When installed correctly, the cuff has a small opening at its center, the access door latches with slight pressure and opens when the latch lever is pressed.

16. Install the hood inner wall.
17. Install a new air intake microfilter, if necessary.
    a. Install the air intake microfilter cover.
    b. Tighten the two thumbscrews.
    c. If a new filter is installed, write the date on the place provided on the cover.
18. Check that incubator is securely clamped to the stand. The locking bar should be approximately horizontal when the locking bar is released and the clamp is engaged in the retainer on the incubator.
19. Perform a complete functional checkout procedure before returning the unit to service (see “General Operation and Functional Checkout Procedure” on page 4-5).

Maintenance

⚠ WARNING:

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

Facility-authorized personnel should perform calibration procedures at 12-month intervals. Refer to *Model C400 QT® and C450 QT® Isolette® Infant Incubator Service Manual* (man203) (MU00925).

NOTE:
For disposal of consumable materials, see “Disposal” on page 6-13.

Power Failure Alarm Battery Maintenance

Check the condition of the power failure alarm battery before first use of the incubator and after the incubator has been out of operation for an extended period of time.

1. Operate the unit for a period of 10 to 24 hours.
2. Trigger a power failure alarm by disconnecting the AC power cord from the wall. The power failure alarm activates and continues to alarm for at least 10 minutes.
3. Plug the unit into the AC line, and charge the battery.

Replacement Parts

This section lists parts that you can replace. Parts not listed here should be replaced by qualified service personnel.

Replacement Parts

Part Number	MU Number	Description
68 209 81	MU06956	Probe, auxiliary air temperature, C4**/C5**
68 209 70	MU06951	Probe-1, temperature, skin, reusable
68 526 40	MU08323	Heat shield, rear, International Electrotechnical Commission (IEC), high, C450 having QT® features
68 232 22-R	MU07186	Heat shield, top, extra large
26 945 70	MU03891	Replacement filters (carton of 4)
68 120 45	MU06553	Grommet, special, hood access
68 120 03	MU06538	Gasket, access door
26 920 70	MU03876	Iris port sleeve, carton/100
68 120 70	MU06570	Access port cuffs, oval, replacement, carton/100
68 142 71	MU06785	Mattress assembly, C100/200/286/386/4**
68 911 0X	MU08672	Replacement mattress tray, C450
68 911 06	MU08677	Replacement slotted mattress tray, French, C450
68 120 43	MU06552	Card, humidity indicator, 20 packages of five
68 120 53	MU06562	Neat-Clips, carton/100, 0.38" diameter
68 120 54	MU06563	Neat-Clips, carton/50, 1.00" diameter
68 416 80	MU07906	Cabinet assembly with door, VHA, C500
68 416 81	MU07907	Cabinet assembly, drawer, VHA

Single-Use Items

Part Number	MU Number	Description
68 209 46	MU06942	Critter Covers® Probe Covers, box of 100
68 209 45	MU06941	Critter Covers® Probe Covers, carton of 600
68 209 47	MU06943	Cover, probe, care for me, large, 100
68 209 48	MU06944	Cover, probe, care for me, standard, 100
68 209 49	MU06945	Cover, probe, care for me, large, 500
68 209 50	MU06946	Cover, probe, care for me, standard, 500
68 209 52	MU06948	Cover, probe, care for me, standard, 25
68 209 20	MU06933	Probe 1, skin temperature, disposable, box/10
68 209 30	MU06935	Probe 1, skin temperature, disposable, carton/100
26 920 72	MU03878	Disposable storage covers, carton/50

Options

Part Number	MU Number	Description
68 410 70CC	MU07783	Guard rail assembly, C400/450
68 452 70	MU08068	IV pole assembly (standard cabinet stand model only)
26 840 70	MU03855	Oxygen tank support
68 414 7X	MU07825	Remote alarm (IV pole model only) assembly
68 400 70CC	MU16570	Cabinet stand assembly, C400/450
68 125 6X	MU06639	Mounting plate assembly, with oxygen

Rail System

Part Number	MU Number	Description
68 407 93	MU07737	Rail system (standard cabinet stand model only)
68 408 00	MU07738	Monitor shelf assembly, 12½” x 16"
68 408 20	MU07746	Utility pole assembly
68 408 30	MU07752	IV tree assembly
68 408 40	MU07756	Stub mount assembly, double

Storage and Handling

Storage

Store the incubator under the following conditions:

- Temperature range: -30°C (-22°F) to 70°C (158°F) ambient
- Humidity range: 0% to 99% relative humidity, non-condensing

Operation

Operate the incubator under the following conditions:

- Temperature range: 20°C (68°F) to 30°C (86°F) ambient
- Humidity range: 5% to 95% relative humidity, non-condensing

Disposal

This device is subject to EU Directive 2002/96/EC (WEEE). It is not registered for use in private households, and may not be disposed of at municipal collection points for waste electrical and electronic equipment.

Dräger Medical has authorized a firm to dispose of this device in the proper manner: for more detailed information, please contact your local Dräger Medical organization. (Alternatively: further information can be obtained from our national Dräger Medical organization.)

Notes:

Section 7
Troubleshooting

Troubleshooting

⚠ WARNING:

Only facility-authorized personnel should troubleshoot the Isolette® Infant Incubator. Troubleshooting by unauthorized personnel could result in personal injury or equipment damage.

If the fault cannot be localized, remove the unit from use, and refer servicing to factory-trained or otherwise qualified personnel.

Troubleshooting

Symptom	Possible Cause	Remedy
No power, and the **Power Fail** alarm is not activated	The **Power** switch is not on.	Press the **Power** switch.
The **Power Fail** alarm is activated.	The circuit breakers are tripped.	Reset the circuit breakers.
	The power cord is unplugged.	Make sure that the power cord is fully plugged into the wall, stand, and incubator receptacles.
The **High Temperature** and/or **High Set Temperature** alarms are activated.	The main deck or hood seat gasket are not properly installed.	Check the installation of the main deck or the hood seat gasket.
The **Set Temperature** LO alarm is activated.	The access doors or iris entry ports are left open.	Close all access doors and iris entry ports.
	The skin probe is not properly secured to the skin (when in skin mode operation only)	Check the skin probe connection.
The **Air Flow** alarm is activated.	The fan has failed.	Replace the fan motor.
The variable height adjustable (VHA) stand will not move up or down	The power switch is not ON.	Turn on the main power switch.
	The power cord is unplugged.	Make sure that the power cord is fully plugged into the wall and the VHA receptacles.
	The circuit breakers are tripped.	Reset the circuit breakers.

Symptom	Possible Cause	Remedy
Low oxygen concentrations are determined.	The access doors or iris entry ports are left open.	Close all access doors and iris entry ports.
	The iris entry port sleeves are opened or improperly installed.	Check the installation of the iris entry port sleeves.
	The tubing access grommets are not properly installed.	Check the installation of the tubing access grommets.
	The main deck is not properly installed.	Check the installation of the main deck.
	The filter cover or the controller are not properly secured.	Check and secure the filter cover and the controller.
	The filter is not installed.	If necessary, check and install the filter.
High oxygen concentrations are determined.	The air intake microfilter is dirty.	Replace the air intake filter.
	The air intake tube is not installed.	Install the air intake filter.
	The fan impeller is dirty.	Clean the fan impeller.

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Part number	Revisions	Date
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