# AIR-SHIELDS® TRANSPORT INCUBATOR MODELS TI100-1 AND -1E



# **OPERATOR'S MANUAL**

# **OPERATING PRECAUTIONS.**

### **GENERAL PRECAUTIONS**

- Incubator misuse may result in harm to an infant. Incubators should be used only by
  properly trained personnel as directed by an appropriately qualified physician
  aware of currently known hazards and benefits.
- Direct radiation from sunlight or other infrared source could cause overheating of the infant without activating the High Temperature Alarm. Do not leave the incubator in direct sunlight or near other sources of radiant heat.
- For infant safety DO NOT leave infant unattended when the Access Doors are open.
- Incubator temperature will change from Set Point if any access openings are left open.
- A dirty air filter will affect oxygen concentrations and may result in carbon dioxide buildup.
- The Auto Test Sequence should be performed before each use to be certain that all
  control and alarm indicators are functional. Do not use if the test sequence does not
  perform as specified.
- · Before using the Adjustable Stand, read the operating instructions.
- Compressed gas cylinders, such as oxygen cylinders, can become hazardous
  projectiles if the gas is released rapidly due to damage or other causes. Cylinders
  must be securely fastened to prevent movement or damage from shock or impact to
  the stand or incubator. Tighten clamp screw as required to prevent cylinder
  movement.

## **ELECTRICAL PRECAUTIONS**

- To ensure grounding reliability, connect AC Power Cord only to properly grounded 3-wire hospital grade or hospital use outlet. DO NOT USE EXTENSION CORDS.
- An electric shock hazard exists within the power pack when the electronics cover is removed. Servicing should be performed only by qualified personnel.

#### **EXPLOSION PRECAUTIONS**

- . Do not use in the presence of flammable anesthetics.
- Shut off oxygen cylinders before performing electrical service procedures or before changing the battery.

# - OPERATING PRECAUTIONS (CONT.) -

## **OXYGEN PRECAUTIONS**

- Improper use of supplemental oxygen can cause serious side effects including blindness, brain damage, and death. The risks vary with each infant. The method, concentration, and the duration of oxygen administration should be prescribed by the attending physician.
- If it is necessary to administer oxygen in an emergency, the attending physician should be notified immediately.

**NOTE:** See current edition of "Guidelines for Perinatal Care" of the American Academy of Pediatrics/The American College of Obstetricians and Gynecologists.

- Oxygen flow rates can not be used as an accurate indication of oxygen concentrations in an incubator. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals directed by the attending physician.
- The oxygen concentration inspired by an infant does not predictably determine the
  partial pressure of oxygen (pO<sub>2</sub>) in the blood. When deemed advisable by the
  attending physician, blood pO<sub>2</sub> should be measured by accepted clinical
  techniques.
- The use of oxygen in therapy requires that special care betaken to prevent fire. Any
  materials which burn in air, and some that will not are easily ignited and burn rapidly
  in high concentrations of oxygen. Accordingly, for safety it is necessary that all
  sources of ignition be kept away from the incubator and preferably out of the area in
  which it is being used. "NO SMOKING" signs should be prominently displayed.
- A spontaneous and violent ignition may occur if oil, grease, or greasy substances come in contact with oxygen under pressure. These substances must be kept away from oxygen regulators, cylinder valves, tubing and connections, and all other oxygen equipment.
- On high pressure oxygen cylinders, use only approved reducing or regulating
  valves marked for oxygen service. Do not use these valves for air or gases other than
  oxygen, since they may be hazardous when returned to oxygen service. Such
  equipment must be operated strictly in accordance with manufacturer's directions.

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# TABLE OF DEFINITIONS AND SYMBOLS

# **TECHNICAL DEFINITIONS**

Set Point, Incubator Temperature selected for operation during use.

**Incubator Temperature.** Air temperature at a point 10 cm (4 in.) above and centered over the mattress surface.

**Temperature Equilibrium.** The condition reached when the average Incubator Temperature does not vary more than 0.2° C over a period of one hour.

**Temperature Overshoot.** The amount by which Incubator Temperature exceeds average Incubator Temperature at Temperature Equilibrium when the set point is changed from 30° C to 34° C.

**Temperature Rise Time.** The time required for the Incubator Temperature to rise to 34° C from an ambient of 23° C with a 35° C set point.

**Temperature Uniformity.** The amount by which the average temperature at each of four points 10 cm (4 in.) above the mattress surface differs from the average Incubator Temperature at Temperature Equilibrium. The four points are the centers of four areas formed by lines that divide the width and length of the mattress surface.

**Temperature Variability.** The variability of the Incubator Temperature that will be observed over a one-hour period after Temperature Equilibrium has been reached.

# NOTE, IMPORTANT, CAUTION AND WARNING

**NOTE.** A Note is inserted in text to point out procedures or conditions which may otherwise be misinterpreted or overlooked. A Note may also be used to clarify apparently contradictory or confusing situations.

IMPORTANT. Similar to a Note but used where greater emphasis is required.

CAUTION. A Caution is inserted in text to call attention to a procedure which, if not followed exactly, can lead to damage or destruction of the equipment.

WARNING. A Warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

#### SYMBOLS



Attention; consult accompanying documents.



Type B equipment with an F-type isolated (floating) applied part.

## **SECTION 1**

# **GENERAL INFORMATION**

# 1.1 INTRODUCTION

This manual provides instructions for installation, use, operator maintenance, and troubleshooting of the Air-Shields® Transport Incubator, Model TI100. Air-Shields cannot be responsible for the performance and safety of the Incubator if the user does not operate the unit in accordance with the instructions, fails to follow the maintenance recommendations in Section 5 of this manual, or effects any repairs with unauthorized components. Calibration and repair should be performed only by qualified service personnel. Additional technical information is available from the manufacturer upon request through your local distributor.

This manual should be read, thoroughly understood, and readily accessible to all personnel who will be working with the unit. The manual should be stored with the Incubator when not in use. If there is anything you do not understand, please contact your Air-Shields representative for further information.

# 1.2 DESCRIPTION

The Transport Incubator, Model TI100, is intended for transport of high risk, premature, low birth-weight, or critically ill newborns. It provides a means to control air temperature, oxygen concentrations, and relative humidity. A double walled hood permits full visibility and provides an effective thermal barrier from the environment. Front and head access is provided by arm ports and door panels and the mattress tray slides out of the head end for additional access. Tubing access grommets are provided on both sides of the front access panel and at the head end panel. Also included is an observation lamp.

The incubator is designed to operate from either a sine or square wave AC power source. In addition, the Incubator can operate from an external 12 VDC source or an integral 12 volt battery. The batteries are automatically charged whenever the unit is connected to an AC voltage source and the Main AC POWER switch is set to the ON-1 position. A comprehensive visual and audible fault alarm system with a test function to verify proper alarm operation is included. A CHARGING indicator is also provided.

# 1.3 SPECIFICATIONS

Specifications for the Air-Shields® Transport Incubator Model TI100 are provided in Table 1.1. The use of infant seats, head hoods, or other accessories 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. All specifications are subject to change without notice.

# **TABLE 1.1 SPECIFICATIONS**

# ELECTRICAL

EXTERNAL POWER REQUIREMENTS:		
Model TI100-1:		
AC		
DC		
Model TI100-1E:		
AC		
DC		
Model TI100-1E:		
AC		
DC		
INTERNAL BATTERY SPECIFICATIONS:		
Type Gel Type, Sealed and rechargeable.		
Voltage		
Quantity2		
Charging Time (from full discharge) Two batteries: 20 hours.		
Life Expectancy Minimum 200 full charge/discharge cycles.		
Battery Performance		
CHASSIS LEAKAGE CURRENT		
ALARMS:		
HIGH TEMP Actuates at Incubator Temperature of $39 \pm 1.0^{\circ}$ C.		
SENSOR		
POWER FAILURE Actuates if main AC power fails and no DC back-up power is present.		
HEATER TEMP Actuates if heater temperature exceeds 77° C (nominal).		
LOW DC		

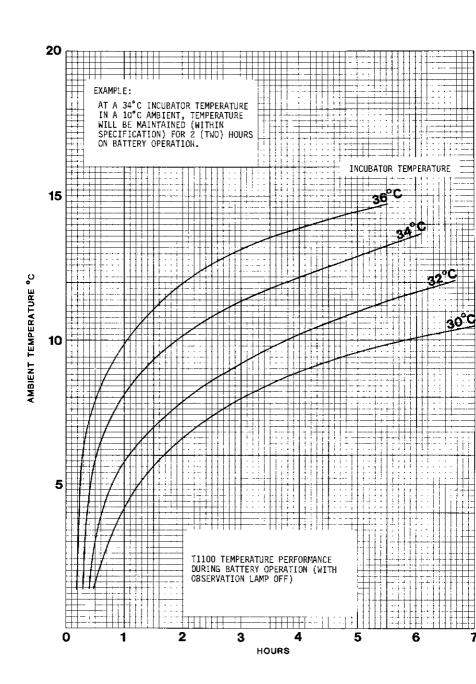


FIGURE 1.1 BATTERY LIFE CURVE

# **TABLE 1.1 SPECIFICATIONS (CONT.)**

# **ELECTRICAL (CONT.)**

TEMPERATURE SET POINT RANGE 22°C ±0.5°C to 38°C		
TEMPERATURE RISE TIME**		
TEMPERATURE VARIABILITY** 0.2°C		
TEMPERATURE OVERSHOOT**		
TEMPERATURE UNIFORMITY** 1°C		
CORRELATION OF DISPLAYED INCUBATOR TEMPERATURE TO ACTUAL INCUBATOR TEMPERATURE** AT TEMPERATURE EQUILIBRIUM**		
CORRELATION OF DISPLAYED INCUBATOR TEMPERATURE** TO SET POINT AT TEMPERATURE EQUILIBRIUM** ± 0.5°C		
OBSERVATION LIGHT OUTPUT		
ENVIRONMENTAL		
RELATIVE HUMIDITY (TYPICAL) 50% - 70% at 6 LPM Flow Rate.		
OXYGEN CONCENTRATION RANGE		
NOISE LEVEL WITHIN HOOD ENVIRONMENT Less than 65 dBA.		
MECHANICAL		
NOMINAL DIMENSIONS (With Stand):		
Length       102 cm (40.25 in.)         Width       56.5 cm (22.25 in.)         Height       118.7 cm (46.75 in.) maximum         88.3 cm (34.75 in.) minimum		

(Including Hood, Stand, and Batteries).

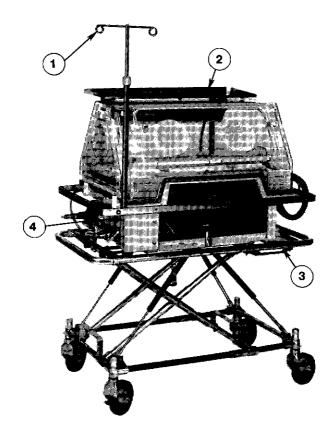
NOMINAL WEIGHT, BATTERY TRAY, WITH BATTERIES .... 22.7 kg (50 lbs)

<sup>\*</sup>At full heater power with observation lamp operating.

<sup>\*\*</sup>Refer to Table of Definitions and Symbols.

# 1.4 ACCESSORIES

Accessories available for use with the Model TI100 are illustrated in Figure 1.2. Par numbers for the accessories are listed in Section 6 of this manual.



- 1. I.V. Pole
- 2. Accessory Shelf
- 3. Adjustable Stand
- 4. Pressure Regulator and Flowmeter
- 5. DC Power Cord Receptacle (not shown)

**FIGURE 1.2 ACCESSORIES** 

# - SECTION 2 - INSTALLATION

# 2.1 UNPACKING

The Hood and Base Assembly and the Adjustable Stand Assembly (Accessory) 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.

CAUTION: DO NOT RELEASE THE FRAME RETAINING LATCHES or raise the Adjustable Stand Assembly until after the Incubator has been installed on the Stand; damage to the Stand may result.

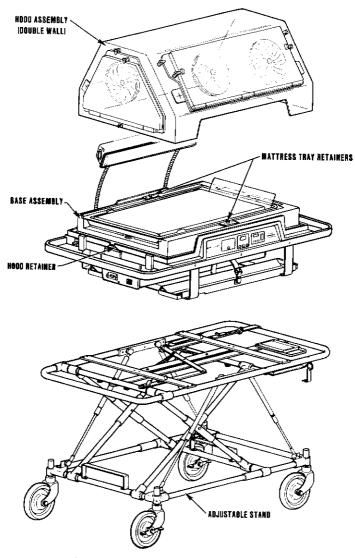


FIGURE 2.1 ASSEMBLY

## 2.2 ASSEMBLY

To install the Transport Incubator on an Air-Shields® Adjustable Stand (accessory) refer to Figure 2.1 and proceed as follows:

CAUTION: DO NOT RELEASE THE FRAME RETAINING LATCHES or raise the Adjustable Stand Assembly until after the Incubator has been installed on the Stand; damage to the Stand may result.

A. INSTALL THE HOOD ON THE BASE ASSEMBLY as shown in Figure 2.1. Make sure that the Hood is secured to the Base with the two rubber retainers.

WARNING: For safety, the Transport Incubator should always be handled by two persons.

**B. POSITION THE HOOD AND BASE ASSEMBLY** on the Stand so that the Battery Tray faces the end of the Stand with the Height Adjustment Latch. Set the Base Assembly down on the alignment pins.

CAUTION: Make sure that the Base Assembly is firmly seated on the alignment pins.

C. RELEASE the two Frame Retaining Latches.

WARNING: For safety, the Transport Incubator should always be handled by two persons.

- D. PULL THE INCUBATOR LOCKING HANDLE to the UNLOCK position and hook the Retaining Latch to the top frame of the Stand.
- E. WITH AN ATTENDANT AT EACH END, firmly grasp the four corners of the top frame of the Stand, with palms of hands upward.

WARNING: Keep fingers clear of rollertracks and other moving parts.

- F. LIFT SLIGHTLY to take the weight off the Height Adjustment Latch, then unlock the Height Adjustment Latch by pulling and holding the Latch Unlocking Handle outward with fingers of left hand.
- G. RAISE THE STAND to the desired position.
- H. RELEASE THE HEIGHT ADJUSTMENT LATCH and continue raising slightly until the Height Adjustment Latch engages with a positive click.

WARNING: The Incubator weight must be fully supported until the Height Adjustment Latch is firmly locked in the desired position. The integral gas springs on the stand assist in supporting this weight.

- RELEASE THE RETAINING LATCH and allow the Locking Handle to return to the lock position. Make sure the Base Assembly is secured by lifting it up at both ends.
- J. TO LOWER THE INCUBATOR, reverse the above procedure:

**IMPORTANT:** When the Stand is in the lowest position, always latch the Frame Retaining latches to the lower bar.

CAUTION: For adequate external DC voltage, DO NOT USE the cigarette lighter for the terminal point. The ambulance wiring leading to the terminal point should be at least 10 gauge and kept as short as possible.

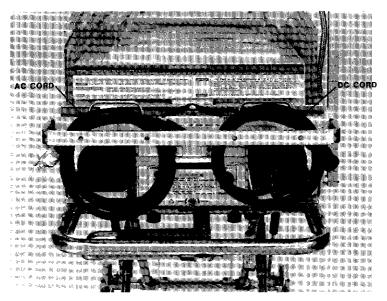


FIGURE 2.2 AC AND DC POWER CORD STORAGE LOCATIONS

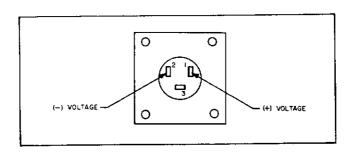


FIGURE 2.3 DC POWER CORD RECEPTACLE ELECTRICAL CONNECTIONS

# 2.4 INSTALLATION OF OXYGEN CYLINDERS

WARNING: Compressed gas cylinders, such as oxygen cylinders, can become hazardous projectiles if the gas is released rapidly due to damage or other causes. Cylinders must be securely fastened to prevent movement of damage from shock or impact to the Stand or Incubator. Tighten clamp screw as required to prevent cylinder movement.

- A. SLIDE THE OXYGEN CYLINDERS, valve end toward the Head end of the incubator, into the compartments provided (Figure 2.4). Tighten the yokes on the cylinders, make sure that the cylinders are firmly clamped (Figure 2.5).
- **B. TO ADJUST THE LATCH TENSION** turn the drawhook (Figure 2.5) clockwise to increase tension or turn the drawhook counterclockwise to decrease tension.
- C. ATTACH AN APPROPRIATE REGULATOR/FLOWMETER (such as Air-Shields Part number 67 090 75) to the cylinder.

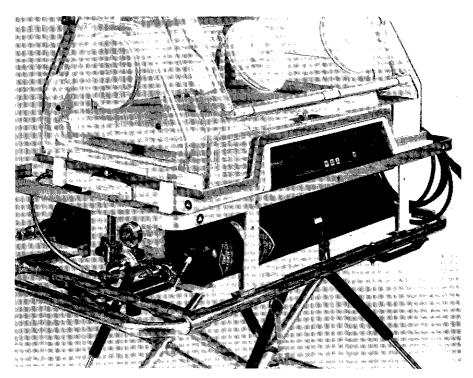


FIGURE 2.4 OXYGEN CYLINDER INSTALLED IN INCUBATOR

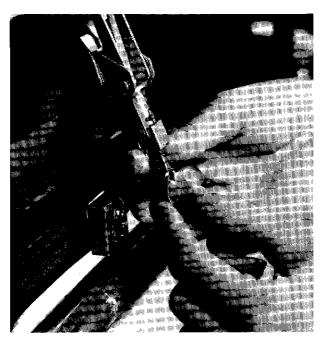


FIGURE 2.5 CYLINDER CLAMP TENSION ADJUSTMENT

# 2.5 GENERAL OPERATION AND FUNCTIONAL CHECKOUT

After installation, perform the General Operation and Functional Checkout Procedure given in paragraph 4.3.1. The Incubator should not be placed in service unless this procedure has been performed. Upon completion of this procedure, the unit should be connected to an AC power source and the AC POWER switch on the Power Chassis set to the ON-1 position so that the batteries can maintain a full charge.

# FUNCTIONAL DESCRIPTION

# 3.1 GENERAL

This section provides a functional description of the Air-Shields® Model TI100 Transport Incubator and the Air-Shields® Adjustable Stand (accessory).

## 3.2 FUNCTIONAL DESCRIPTION

# 3.2.1 OVERALL

The control of temperature, humidity, and oxygen concentration is achieved by means of a forced air circulation system. A controlled amount of room air is drawn through the air/oxygen intake filter by means of a motor driven impeller. Supplemental oxygen which is introduced through the Oxygen Inlet Connector on the left side of unit displaces a portion of room air to maintain the total gas intake (including oxygen) at the same level. Since the amount of room air is controlled by the impeller/filter characteristics and the amount of oxygen is controlled by the flowmeter setting, predictable oxygen concentration within the Incubator can be attained.

In addition to drawing fresh, filtered air into the Incubator, the impeller provides an internal recirculation at a much greater flow than that of the fresh gas inflow. The air is directed over the humidity reservoir for humidification. When the access panel of the hood is closed, the air enters the infant compartment up through the slots at the right end of the housing. After circulating within the infant compartment, the air is then recirculated down the left end of the housing, past the temperature sensing probe and back to the impeller.

The Air-Shields® Model TI100 Transport Incubator is designed to operate from one of three power sources which may be connected to the Incubator simultaneously. Power selection is determined in the following priority sequence: external AC, external DC, or internal battery. If a higher priority source is connected to the unit during operation from a lower priority source, the unit will automatically switch to the higher priority power source. Conversely, if a higher priority source is disconnected, the unit will automatically switch to the next lower priority source.

# 3.2.2 TEMPERATURE CONTROL

Incubator Temperature is regulated by means of a temperature sensor, located in the recirculation air path, and a proportional control circuit which determines the heater output required to maintain the desired Incubator Temperature. The relative amount of heat provided is indicated by the number of HEATER POWER lamps (it on the control panel.

The Incubator Temperature can be maintained from 22° C to 38° C as selected by the temperature controls on the control panel. The temperature as sensed by a sensor located within the housing is compared with the set point. The information from this sensor is

supplied to the heater control circuitry which proportions the heater output to maintain the set point. The temperature is displayed on the front panel temperature display. The initial set point is preset to  $35^{\circ}$  C  $\pm$  0.1° C and the Incubator will heat to this temperature unless the setting is changed. The set point can be changed to a prescribed temperature by using the SET TEMP controls on the control panel as described in paragraph 4.2.2. An additional sensor within the housing serves as a backup to limit the Incubator maximum air temperature to  $40.0^{\circ}$  C; at this limit an alarm is activated and the heater is shut off.

# **3.2.3 ALARMS**

Each time the unit is turned on, the unit automatically activates a test sequence to verify that the visual display and the audible alarm are functional.

HIGH TEMPERATURE ALARM. A sensor located below the deck sounds this alarm and Incubator Temperature is limited to less than 40° C. A high temperature alarm is indicated by a flashing light and an intermittent audible tone. This alarm is non self-resetting and cannot be cancelled by the SILENCE/RESET switch until the alarm condition is corrected.

SENSOR ALARM. Circuitry is provided to monitor the high temperature alarm sensor for shorted or open condition. A SENSOR alarm is indicated by a flashing light and an intermittent audible tone. This alarm is non self-resetting and it cannot be cancelled by the SILENCE/RESET switch until the sensor is replaced; however, an open sensor alarm may be silenced by the SILENCE/RESET switch for a nominal 5 minutes. If a HIGH-TEMP alarm occurs simultaneously with a SENSOR alarm a shorted probe is probably the true cause of the alarm, since a shorted probe will appear as a high temperature condition.

HEATER TEMPERATURE ALARM. The HEATER TEMP alarm flashes and an intermittent audible tone sounds to indicate that the heater temperature has exceeded a predetermined temperature. When this condition occurs, the heater and HEATER POWER indicator are turned off.

LOW DC ALARM. The LOW DC alarm flashes and an intermittent alarm sounds to indicate that the Incubator DC power source has fallen below a predetermined value. If operation is continued, the POWER FAILURE alarm indicator will begin to glow when battery voltage drops sufficiently. The audible alarm may be silenced by the SILENCE/RESET switch for a nominal 5 minutes.

POWER FAILURE ALARM. The POWER FAILURE alarm circuit is powered by a separate internal battery. The alarm indicator lights and a continuous tone sounds if AC power is lost and no DC back-up power is present.

# 3.2.4 ADJUSTABLE STAND (ACCESSORY)

The Adjustable Stand is designed to provide a convenient means of moving the Transport Incubator. The stand is adjustable to three height positions, and is designed to lock into the litterbar latch of an ambulance.

# 4.1 GENERAL

This section provides operating procedures for the Air-Shields® TI100 Transport Incubator. These procedures should be read carefully and understood by all personnel who will be operating the unit.

# 4.2 OPERATING CONTROLS, INDICATORS, AND CONNECTORS

The controls, indicators, and connectors used in operating the Incubator are shown in Figure 4.1. Table 4.1 provides and explanation of each item.

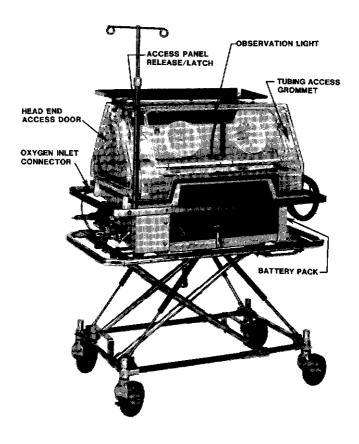


FIGURE 4.1A CONTROLS, INDICATORS, AND CONNECTORS

# TABLE 4.1 CONTROLS, INDICATORS, AND CONNECTORS

ITEM	NAME	FUNCTION
INCUBATOR (FIGURE 4.1A)		
	Access Panel Release/Latch	Rotate to latch or release Access Panel.
	Tubing Access Grommet	Provides routing for tubing, probe, leads, etc. into infant compartment.
	Oxygen Inlet Connector	Provides connection point for external oxygen source.
	Head End Access Door	Opens to provide access to infant through head end of Incubator.
	Observation Light	Provides illumination of mattress surface. The light is turned ON and OFF by a switch at the top center of the light housing.
	Battery Tray	Provides back-up DC power for operating the Incubator.

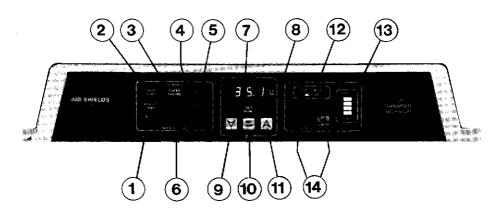


FIGURE 4.1B CONTROLS, INDICATORS, AND CONNECTORS

ITEM	NAME	FUNCTION	
	CONTROLLER (FIGURE 4.1B)		
1	HEATER TEMP Lamp	Flashes to indicate that heater has exceeded a pre- determined temperature; an intermittent tone also sounds and the heater and HEATER POWER indicator are turned off and remain off until manually reset.	
2	HIGH TEMP Lamp	Flashes to indicate high Incubator temperature; an intermittent audible tone also sounds and the heater and HEATER POWER Indicator are turned off and remain off until manually reset.	
3	POWER FAILURE Lamp	Lights continuously if external AC or DC power is lost and no DC back-up (battery) power is present; a continuous tone also sounds. The alarm may be disabled by pressing the CONTROLLER POWER OFF switch.	
4	LOW DC Lamp	Flashes to indicate that the Incubator DC power source has fallen below a predetermined value; an intermittent audible tone also sounds, the audible tone may be silenced temporarily by depressing the SILENCE/RESET switch.	
5	SENSOR Lamp	Flashes to indicate that the high temperature alarm sensor is open or shorted; an intermittent audible tone also sounds, the audible tone may be silenced temporarily by depressing the SILENCE/RESET switch if the condition is an open sensor alarm. If the sensor is shorted, the heater and HEATER POWER indicators are shut off.	
6	SILENCE/RESET Pushbutton Switch	<ul> <li>A. Cancels audible and visual portions of alarms if alarm condition has cleared.</li> <li>B. Silences open SENSOR and LOW DC audible alarm for approximately 5 minutes if alarm condition is still present. Visual alarm continues to flash. If the condition is still present after 5 minutes, the alarm will sound again.</li> <li>C. This switch cannot be used to silence or reset POWER FAILURE alarm.</li> </ul>	
7	°C Temperature Display	Digital display of Incubator Temperature or set point.	

ITEM	NAME	FUNCTION
CONTROLLER (FIGURE 4.1B)		
8	SET POINT Lamp	Lights to indicate that SET TEMP mode has been selected.
9	SET POINT Lower Pushbutton Switch	When in SET TEMP mode depressing and holding the (♥) switch lowers the set point.
10	SET TEMP Pushbutton Switch	When depressed the SET POINT indicator lights, a short "beep" is heard, and the set point raise ( △ ) and lower ( ▽ ) switches are activated for approximately 15 seconds; the digital display indicates set point.
11	SET POINT Raise Pushbutton Switch	When in SET TEMP mode depressing and holding the (
12	AC DC POWER MODE Lamps	A. AC indicator lights to show incubator is powered by AC line voltage.     B. DC indicator lights to show incubator is being powered by external DC source or internal batteries.
13	HEATER POWER Lamps	Four lamps that provide a relative indication of heater power output.
14	CONTROLLER POWER Pushbutton Switches:	
	ON	A. When primary power is applied by the AC POWER switch on the Power Chassis, depressing this switch provides low voltage power to the front panel Incubator control circuitry.     B. Master ON switch when operating from a DC source.
	OFF	<ul> <li>A. When primary power is applied by the AC POWER switch on the Power Chassis, depressing this switch removes low voltage power from the Incubator control circuitry.</li> <li>B. Deactivates POWER FAILURE Alarm.</li> <li>C. Master OFF switch when operating from a DC source.</li> </ul>

ITEM	NAME	FUNCTION	
POWER CHASSIS (FIGURE 4.1C)			
15	AC POWER Switch	Controls application of main power to Incubator.	
16	Primary Power Connector	Accepts AC power cord.	
17	Circuit Breaker(s)	Provide overload protection for the Incubator. One or two 3.0 Amp circuit breaker(s) depending on operating voltage configuration.	

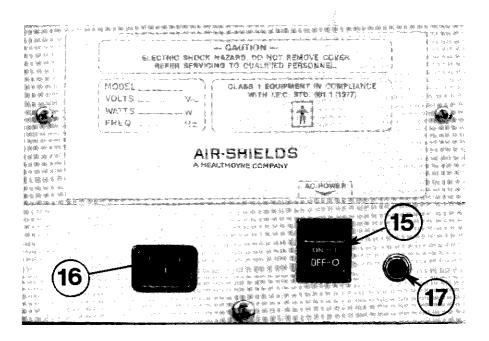


FIGURE 4.1C CONTROLS, INDICATORS, AND CONNECTORS

ITEM	NAME	FUNCTION	
	BATTERY PACK (FIGURE 4.1D)		
18	CHARGING Lamp	Indicates that internal batteries are being charged. Lamp will become dimmer as battery charge increases and will go off or flicker when batteries are fully charged. The Incubator must be connected to an AC source with the AC POWER switch on the Power Chassis set to the ON-1 position for battery charging to occur.	
19	POLARITY FAULT Lamp	Indicates reverse polarity condition of external DC supply or internal batteries.	
20	EXTERNAL DC Connector	Accepts external DC power cord.	
21	CIRCUIT BREAKERS	EXT. DC-Single 10 Amp. DC Circuit Breaker.	
		BATTERY-Single 10 Amp DC Circuit Breaker.	

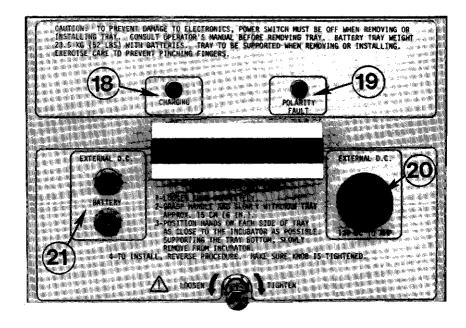


FIGURE 4.1D CONTROLS, INDICATORS, AND CONNECTORS

# 4.3 OPERATION

The operating procedure is divided into two main sections: General Operation and Functional Checkout Procedure (4.3.1), and Operation During Use (4.3.2). Section 4.3.1 should be performed each time the Incubator is placed in service to verify proper operation of all functions. Section 4.3.2 should be used for routine operation.

#### IMPORTANT:

- The use of infant seats, head hoods or other accessories not specifically designed for
  use with this Incubator can alter the air flow pattern and may affect temperature
  uniformity, temperature variability, the correlation of the Incubator Temperature
  displayed to center mattress temperature and infant skin temperature.
- Make sure that the Air Flow Slots at the ends of the Incubator are not obstructed by blankets, diapers, etc., this can also alter the air flow pattern.

WARNING: The Incubator should not be used if it falls to function properly. Service should be referred to qualified personnel.

# 4.3.1 GENERAL OPERATION AND FUNCTIONAL CHECKOUT PROCEDURE

The functional checkout should be performed before the Incubator is first placed into use and after disassembly for cleaning or maintenance. To operate the Incubator, refer to the controls and indicators illustrations (Figure 4.1) and proceed as follows:

#### **ELECTRICAL CHECKOUT**

NOTE: The Electrical Checkout procedure may be performed with the Incubator connected to an AC power source, an external DC power source, or internal batteries. In the following procedure the Incubator is connected to an AC power source.

CAUTION: Make sure that the building power source is compatible with the electrical specifications shown on the unit. For proper grounding reliability, connect the power cord only to a properly marked hospital grade receptacle. DO NOT USE EXTENSION CORDS. If any doubt exists as to the grounding connection, do not operate the equipment.

- A. CONNECT THE AC POWER CORD. Insert one end of the power cord into the receptacle on the Power Chassis and the other into a wall receptacle.
- B. SET THE MAIN AC POWER SWITCH on the Power Chassis to the ON-1 position; the AC POWER MODE indicator on the Controller should light. The CHARGING indicator on the Battery Tray will light if the internal batteries require charging; the indicator will be off if the batteries are fully charged. Depress the CONTROLLER ON switch on the Controller, the unit should perform an approximate 7-second auto test as follows:

#### IMPORTANT:

- This test should be performed immediately before leaving the base hospital and immediately before placing an infant in the Incubator by turning the Incubator off and then on again using the CONTROLLER ON and OFF switches.
- The auto test checks the lamps and display by simulating functional failures of the respective alarm sensors. Do not use the Incubator if all indicators are not displayed and the audible alarm does not sound briefly at the end of the test cycle.
  - 1. The °C digital display should display all eights (88.8).
  - 2. All HEATER POWER indicators should light.
  - The POWER FAILURE Alarm and AC DC POWER MODE indicators should light steady.

**NOTE:** The AC POWER MODE indicator will not light if the unit is tested while operating from DC power.

- 4. The HIGH TEMP, SENSOR, HEATER TEMP, and LOW DC Alarm indicators should flash.
- At the end of the auto test sequence, a short beep should be heard. The AC POWER MODE indicator should remain on and one or more of the HEATER POWER indicators may remain on depending on Incubator temperature.
- The SET POINT indicator should light and the °C digital display should indicate 35° C±0.1° C for approximately 15 seconds. This is the automatically set initial set point. The unit will heat to this temperature unless the set point is changed.

# C. CHECK SET POINT ADJUST as follows:

- Depress the SET TEMP switch, a short "beep" should be heard and the SET POINT indicator should light indicating that the "C temperature display is indicating the set point.
- 2. Depress and hold the raise ( ) switch until the °C display indicates maximum (38°C).
- 3. Repeat Step 1.
- Depress and hold the lower ( ⋈ ) switch until the °C display indicates 34°C.
- D. CHECK TEMPERATURE CONTROL. With all access openings closed, allow the Incubator to warm up to the set point temperature setting (34°C); it should take less than 30 minutes, nominal. When the temperature display has stabilized, the number of HEATER POWER indicator lamps illuminated will typically be reduced to no more than two. Check that the digital display remains within 0.5°C of set point for 15 minutes after Temperature Equilibrium has been reached.

- E. CHECK OPERATION OF OBSERVATION LIGHT. The Observation Light is turned on and off by the ON-OFF switch located in the center of the light housing. The light is mounted on flexible tubes and may be positioned as required. The light should be turned off between uses to extend battery life. The light will not operate if the Battery Tray is not inserted.
- F. CHECK THAT THE INCUBATOR SWITCHES FROM AC TO DC OPERATION by disconnecting the AC power cord. The unit should continue to operate, and maintain set point, and the DC POWER MODE indicator should light.



WARNING: When disconnecting the Battery Tray to test the POWER FAILURE alarm, avoid contact with internal components of the battery charger. The components may be hot enough to cause burns.

G. CHECK POWER FAILURE ALARM by disconnecting external AC and DC power from the Incubator; slide the Battery Tray out approximately two inches to disconnect the internal batteries. The POWER FAILURE lamp on the Controller should light and a steady audible alarm should sound. The alarm should terminate when power is restored or the CONTROLLER OFF switch is depressed.

# H. CHECK HIGH TEMPERATURE ALARM as follows:

- Depress the SET TEMP, switch, the SET POINT indicator should light and a short "beep" should be heard indicating that the temperature display is indicating set point.
- Within 15 seconds after performing step 1, simultaneously depress and hold both the raise ( <a> | □</a> ) and lower ( <a> | □</a> ) switches and observe the temperature display.
- When the temperature display indicates 40.0°C, release the raise and lower switches.
- 4. Allow the Incubator to heat up.
- The displayed Incubator temperature should be 39°C ± 1°C when the High Temperature alarm activates. The HIGH TEMP indicator should flash, an intermittent audible tone should sound, and the heater and HEATER POWER indicators should turn off.

**NOTE:** The actual Incubator Temperature may not necessarily correlate to display temperature, within 1.0° C during this test.

Turn the Incubator off by depressing the CONTROLLER OFF switch and then setting the AC POWER switch to the OFF-O position unless battery charging is required.

**IMPORTANT:** The CONTROLLER OFF switch only removes power from the control electronics. To remove main AC power from the Incubator the AC POWER switch on the power chassis must be set to the OFF-O position.

## I. THE ELECTRICAL CHECKOUT IS COMPLETE.

## MECHANICAL CHECKOUT

A. CHECK FRONT AND HEAD END ACCESS PANELS. Rotate access panel latches (Figure 4.2) and open the access panel. Pivot the access panel to the full open position (hanging straight down).

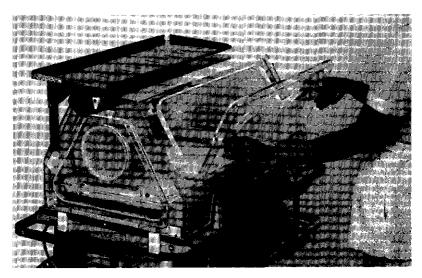


FIGURE 4.2 ACCESS PANEL OPERATION

B. CHECK SHELL LATCHES AND RUBBER HOOD RETAINERS. Check the shell latches and rubber hood retainers (Figure 4.3). All four latches should be properly secured and both rubber hood retainers should be free from cracks and intact.

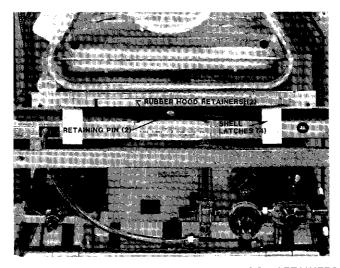


FIGURE 4.3 SHELL LATCHES AND RUBBER HOOD RETAINERS

- C. CHECK FRONT AND HEAD END ACCESS PANEL LATCHES by closing the access panels and rotating the latches until fully engaged. The latches must be fully engaged to avoid accidental opening of the access panels.
- D. CHECK MATTRESS TRAY. Open the Head End Access Door. Slide the tray out of the Incubator until it reaches its mechanical stop (Figure 4.4). Check that the tray is stable when force is applied to the extended portion. Return the mattress tray to the Incubator. Check that the restraining straps are in good working order. Close the access door.

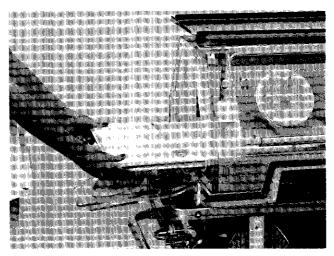


FIGURE 4.4 MATTRESS TRAY OPERATION

E. CHECK THE CONDITION OF THE AIR FILTER by first loosening the two thumbscrews on the air filter cover (Figure 4.5) and then remove the cover. Remove the filter, if the filter is visibly dirty it should be replaced.

WARNING: A dirty air intake filter may affect the oxygen concentrations and/or cause carbon dioxide buildup. The filter must be checked on a routine basis and changed at least every three months.



FIGURE 4.5 AIR FILTER COVER

F. CHECK AIR/OXYGEN SYSTEM. Connect the output of a flowmeter to the OXYGEN INLET connector on the left side of the Incubator using 3/16 - inch ID surgical tubing. Introduce 6 LPM of oxygen, then monitor levels within the hood to verify that they reach the predicted level as indicated on the Oxygen Concentration Guide located on the front lower left side of the hood.

# G. MECHANICAL CHECKOUT IS COMPLETE.

**IMPORTANT:** Upon satisfactory completion of the General Operation and Functional Checkout Procedure, the Transport Incubator should be connected to an AC power source with the Main AC POWER switch on the Power Chassis set to the ON-1 position to maintain the batteries at full charge.

# 4.3.2 OPERATION DURING USE

#### IMPORTANT:

- The Incubator should not be placed in service unless the General Operation and Functional Checkout Procedure (paragraph 4.3.1) has been performed. Do not use the Incubator if the auto test sequence does not perform as specified.
- The Incubator should be prewarmed to the temperature prescribed by the attending
  physician or according to the Nursery Standing Orders. To obtain maximum use of
  the batteries during transport, the Incubator should be prewarmed while connected to
  an external AC power source before switching to battery operation. Batteries should
  be charged fully before using the Incubator for transport.
- The Incubator should be run with no water in the humidity reservoir during prewarming unless humidification is prescribed.

# **WARNING:**

- Incubator misuse may result in harm to an infant. Incubators should be used only
  by properly trained personnel as directed by an appropriately qualified attending
  physician aware of currently known hazards and benefits.
- To prevent harm to the infant, the hood should not be removed while leads or tubing are connected to the infant. There should be no need to raise the hood at any time while the infant is cared for in the Incubator. All necessary access to the infant can be achieved by means of the access panels.
- The Incubator is equipped with a High Temperature Alarm, but it is activated only
  by the air temperature. Direct radiation of the infant from sunlight or other sources
  of radiant heat could cause overheating of the infant without triggering the alarm.
  Do not position the Incubator in direct sunlight or under other sources of radiant
  heat.
- Phototherapy units located too close to the Incubator may affect hood wall temperature, Incubator Temperature and infant skin temperature.

CAUTION: Make sure that the building power source is compatible with the electrical specifications shown on the unit. For proper grounding reliability, connect the power cord only to a properly marked hospital grade receptacle. DO NOT USE EXTENSION CORDS. If any doubt exists as to the grounding connection, do not operate the equipment.

- A. CONNECT THE AC POWER CORD. Insert one end of the power cord into the receptacle on the Power Chassis and the other into a wall receptacle.
- B. SET THE MAIN AC POWER SWITCH on the Power Chassis to the ON-1 position; the AC POWER MODE indicator on the Controller should light. The CHARGING indicator on the Battery Tray should also light if the internal batteries require charging. If the batteries are fully charged, the CHARGING indicator will be off. Depress the CONTROLLER ON switch on the Controller, the unit should perform an approximate 7 second auto test as follows:

# IMPORTANT:

- This test should be performed immediately before leaving the base hospital and immediately before placing an infant in the Incubator by turning the Incubator off and then on again using the CONTROLLER ON and OFF switches.
- The auto test checks the lamps and display by simulating functional failures of the respective alarm sensors. Do not use the Incubator if all indicators are not displayed and the audible alarm does not sound briefly at the end of the test cycle.
- 1. The °C digital display should display all eights (88.8).
- 2. All HEATER POWER indicators should light.
- The POWER FAILURE Alarm and AC DC POWER MODE indicators should light steady.

**NOTE:** The AC POWER MODE indicator will not light if the unit is tested while operating from DC power.

- The HIGH TEMP, SENSOR, HEATER TEMP, and LOW DC Alarm indicators should flash.
- At the end of the auto test sequence, a short beep should be heard. The AC POWER MODE indicator should remain on and one or more of the HEATER POWER indicators may remain on depending on Incubator temperature.
- The SET POINT indicator should light and the °C digital display should indicate 35°C ± 0.1°C for approximately 15 seconds. This is the automatically set initial set point. The unit will heat to this temperature unless the set point is changed.
- C. SET TEMPERATURE. The unit automatically sets to 35° C when power is first applied. The temperature settings should be prescribed by the attending physician and set as follows:
  - 1. To change the SET POINT, depress the SET TEMP, switch, the SET POINT indicator should light and a short "beep" should be heard indicating that the temperature display is indicating the set point. Observe the temperature display and depress the raise switch ( ☒ ) or the lower switch ( ☒ ) until the prescribed SET POINT is reached.
  - 2. When the SET POINT lamp goes off, the temperature display will indicate Incubator Temperature.

- 3. After initial warm-up, verify that the digital display reads within 0.5° C of Set Point.
- 4. If an alarm occurs during operation, the appropriate alarm indicator(s) will flash and the audible alarm will sound. During HIGH TEMP and HEATER TEMP alarm, power is removed from the heater and the HEATER POWER indicator will turn off. The alarm indications (except for POWER FAILURE) may be cancelled by depressing the SILENCE/RESET switch if the alarm condition has cleared. The LOW DC audible alarm may be silenced temporarily if the alarm condition has not cleared by depressing the SILENCE/RESET switch. This also applies for a SENSOR alarm if the cause of the alarm is not a shorted sensor; a shorted sensor alarm may not be silenced since the HI TEMP alarm occurs simultaneously for this condition.
- D. PLACE INFANT IN INCUBATOR through opened access panel (Figure 4.2). Close Access Panel. The Access Panel Latches must be positively secured to avoid accidental opening.

#### WARNING:

- Do not leave the access panels open longer than essential. The air temperature indicator does not accurately reflect Incubator Temperature when the access panels are open. Under these conditions the Incubator Temperature may be significantly lower than the displayed temperature.
- For infant safety, do not leave the infant unattended while the access panel(s) are open.

**IMPORTANT:** Infant's rectal and/or axillary temperature should be routinely monitored and noted according to the attending physician's orders or Nursery Standing Orders.

- E. INFANT ACCESS THROUGH DOOR CUFFS. Infant access through the door cuffs is accomplished by unlatching and opening the outer access panels (Figure 4.1A) at the front and/or head end. To minimize heat loss, the front and head access panels should be closed immediately after the task has been performed.
- F. TUBING ACCESS GROMMETS. The tubing access grommets (Figure 4.1A) provide convenient access for tubing and monitor leads.
- G. TO OPERATE THE ADJUSTABLE STAND (ACCESSORY) proceed as follows:

CAUTION: For safety, when raising or lowering the Stand with an Incubator in position, the full weight of the Incubator must be supported by two persons. The Height Adjustment Latch must not be unlocked unless the weight is fully supported.

1. Before raising the Stand, release the two frame Retaining Latches (Figure 4.6).

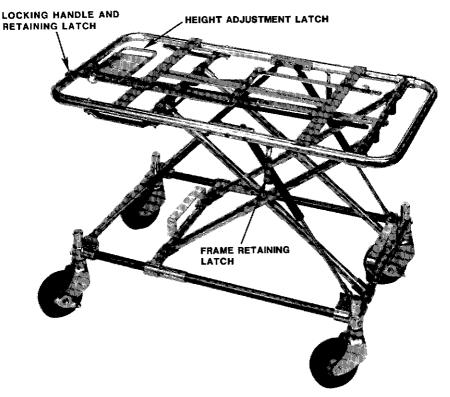


FIGURE 4.6 ADJUSTABLE STAND

2. With an attendant at each end, firmly grasp the four corners of the top frame of the Stand, with palms of hands upward.

WARNING: Keep fingers clear of rollertracks and other moving parts.

- 3. Lift slightly to take the weight off the Height Adjustment Latch (Figure 4.6), then unlock the Height Adjustment Latch by pulling and holding the Latch Unlocking Handle outward with fingers of left hand.
- 4. Raise or lower the Stand to the desired position.
- Release the Height Adjustment Latch and continue raising or lowering slightly until the Height Adjustment Latch engages with a positive click.

WARNING: The Incubator weight must be fully supported until the Height Adjustment Latch is firmly locked in the desired position. The integral gas springs on the stand assist in supporting this weight.

When the stand is in the lowest position always latch the Frame Retaining Latches to the lower bar.

WARNING: Whenever transporting, the Stand must be latched with frame retaining latches in the lower position and locked to the Litterbar Latch of the ambulance. If necessary to transport in the intermediate or high positions, additional latching must be made to secure the top bar of the stand to the side of the ambulance.

H. TO OPERATE THE OBSERVATION LIGHT, set the switch on the light assembly to the ON position. The light assembly is mounted on flexible tubes and may be positioned as required. The light should be turned OFF between uses to extend battery life. The light will not operate if the battery tray is not installed.

#### IMPORTANT:

- To obtain maximum use of the batteries during transport, it is recommended that
  the unit be operated from an external power source to bring the Incubator
  Temperature to the desired level before switching to battery operation.
- The internal battery supply is intended for use only as a back-up power source. The
  Incubator should be operated from an external power source whenever possible.
   All vehicles used for transporting the Incubator should be equipped with a suitable
   AC or DC power source.
- TO OPERATE THE INCUBATOR FROM THE BATTERY SUPPLY, disconnect all external power, the Incubator will automatically switch to battery power. With fully charged batteries the Incubator should operate for at least 2 hours before the LOW DC alarm activates. When this occurs, the unit should be switched to an alternate power source as soon as possible.

After the LOW DC alarm is activated, the unit will continue to operate for approximately 15 minutes with the heater on continuously though at reduced wattage due to the dropping battery voltage.

**IMPORTANT:** Operation after the LOW DC alarm is activated **should be kept to an absolute minimum** except in an emergency. Continued use after the LOW DC alarm is activated will adversely affect battery performance and result in more frequent battery replacement.

 OXYGEN. Oxygen can be administered from a regulated wall source or oxygen cylinder.

#### 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.
- If it is necessary to administer oxygen in an emergency, the attending physician should be notified immediately.

Note: See current edition of "Guidelines for Perinatal Care" of the American Academy of Pediatrics/The American College of Obstetricians and Gynecologists.

- The oxygen concentration inspired by an infant does not predictably determine the partial pressure of oxygen (pO<sub>2</sub>) in the blood. When deemed advisable by the attending physician, blood pO<sub>2</sub> should be measured by accepted clinical techniques.
- Oxygen flow rates cannot be used as an accurate indication of oxygen concentrations in an Incubator. Oxygen concentrations should be measured with a calibrated analyzer at intervals directed by the attending physician.
- A dirty air intake filter may affect oxygen concentrations or cause carbon dioxide buildup.
- 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.

Connect the output of the oxygen flowmeter to the nipple of the OXYGEN INLET connector (Figure 4.7) using 3/16 - inch ID surgical tubing. An oxygen concentration

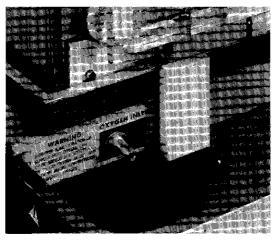
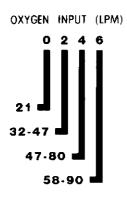


FIGURE 4.7 OXYGEN INLET CONNECTOR

guide is provided in Figure 4.8. This guide also appears on the lower left front on the hood.



# **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 AN APPROPRIATELY QUALIFIED ATTENDING PHYSICIAN AWARE OF CURRENTLY KNOWN HAZARDS AND BENEFITS AND ADMINISTERED BY PROPERLY TRAINED PERSONNEL.
- IF IT IS NECESSARY TO ADMINISTER DXYGEN IN AN EMERGENCY, THE ATTEN-DING PHYSICIAN SHOULD BE NOTIFIED IMMEDIATELY.

# IMPORTANT:

- OXYGEN FLOW RATES CANNOT BE USED AS AN ACCURATE INDICATION OF OXYGEN CONCENTRATIONS IN AN INCUBATOR. OXYGEN CONCENTRATIONS SHOULD BE MEASURED WITH A CALIBRATED DXYGEN ANALYZER AT INTER-YALS DIRECTED BY THE ATTENDING PHYSICIAN.
- OPENING ACCESS PORTS WILL CAUSE OXYGEN CONCENTRATIONS TO DROP.
   ALLOW TIME FOR CONCENTRATION TO RESTABILIZE BEFORE MEASUREMENT.
- ◆ THE OXYGEN CONCENTRATION INSPIRED BY AN INFANT DOES NOT PREDICTABLY DETERMINE THE PARTIAL PRESSURE OF OXYGEN (p02) IN THE BLOOD. WHEN DEEMED ADVISABLE BY THE ATTENDING PHYSICIAN, THE BLOOD p02 SHOULD BE MEASURED BY ACCEPTED CLINICAL TECHNIQUES.

HOOD OXYGEN %

ALLOW 40 MINUTES FOR HOOD OXYGEN TO STABILIZE INTERMEDIATE CONCENTRATIONS MAY BE ACHIEVED BY APPROPRIATE FLOW

# FIGURE 4.8 OXYGEN CONCENTRATION GUIDE

K. HUMIDIFICATION. If additional humidification is prescribed by the attending physician proceed as follows:

#### NOTE:

- The level of relative humidity attained within the Incubator will be influenced by the ambient relative humidity of the operating environment.
- 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 will 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.
- Unlatch the Head End and Front Access Panels and open the panels until they hang down on the Guard Rail.
- Slide the Mattress Tray out the Head End Access opening until it reaches its mechanical stop.
- Soak the sponge (Figure 4.9) with 473 ml (16 oz.) of sterile distilled water. One soaking will provide humidity for a minimum of 12 hours.
- Return the Mattress Tray to the Incubator and close the Head End and Front Access Panels.

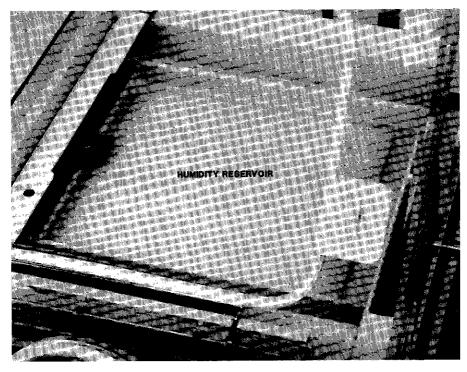


FIGURE 4.9 HUMIDITY RESERVOIR LOCATION

#### **CLEANING AND MAINTENANCE**

#### 5.1 GENERAL

This section provides cleaning and maintenance instructions. Where necessary, disassembly instructions are provided. Maintenance other than that provided in this section should be performed only by qualified service personnel.

#### 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/or maintenance procedures in an oxygen enriched environment.
- An electrical shock hazard exists when performing service procedures, unplug power cord (AC or DC) from power source. Loosen the Battery Compartment Fastening Knob and slide the compartment out approximately 5 cm (2 inches); this disconnects the batteries and charger from the Incubator.



WARNING: Components in the battery charger may be hot enough to cause burns. Avoid contact with charger components until the unit has cooled for at least 20 minutes.

#### 5.2 CLEANING

When an infant is discharged, or at least once a week, the Incubator should be thoroughly disinfected. Cleaning can most effectively be accomplished by disassembling, then grouping the parts and/or assemblies in categories according to the method of cleaning required.

## 5.3 DISASSEMBLY FOR CLEANING

#### 5.3.1 ACCESS PANEL CUEES

- A. UNLATCH THE FRONT AND HEAD-END ACCESS PANELS and open the panels until they hang down on the guard rail.
- B. REMOVE THE ACCESS PANEL CUFFS and retaining rings (Figure 5.1).



FIGURE 5.1 ACCESS PANEL CUFF REMOVAL

#### **5.3.2 TUBING ACCESS GROMMETS**

A. GRASP THE CENTER OF EACH TUBING ACCESS GROMMET and remove from access port.

#### 5.3.3 **HOOD**

- A. CLOSE AND LATCH the access panels.
- B. RELEASE THE RUBBER HOOD RETAINERS located at the head and foot ends of the Incubator.
- C. CAREFULLY LIFT THE HOOD straight up and set aside.

#### 5.3.4 MATTRESS TRAY

- A. SLIDE THE TRAY TO THE LEFT until it reaches its mechanical stop.
- B. REMOVE THE MATTRESS from the tray.
- C. DEPRESS THE MATTRESS TRAY STOP (Figure 5.2) and slide the tray off the upper shell.

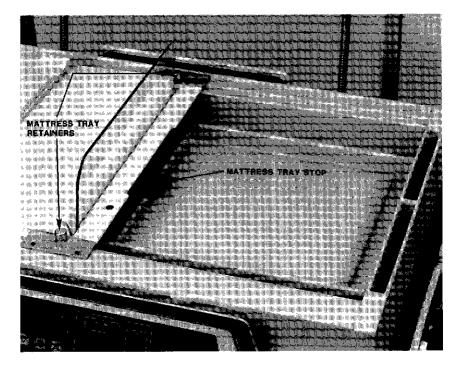


FIGURE 5.2 MATTRESS TRAY STOP AND RETAINERS

#### 5.3.5 UPPER SHELL

- A. REMOVE THE HUMIDITY PAD.
- B. RELEASE AND PULL BACK THE FOUR SHELL LATCHES at the head and foot end of the Incubator (Figure 5.3).
- C. LIFT THE UPPER SHELL straight up.



WARNING: The heater fins may be hot enough to cause burns; avoid touching the heater fins until the unit has cooled for at least 20 minutes.

#### **5.4 CLEANING PROCEDURES**

#### **5.4.1 CLEANING AGENTS**

An iodophor or quaternary disinfectant-detergent registered by the U.S. Environmental Protection Agency should be used, but only after the Incubator is empty and disassembled as described elsewhere in this section. A cleanser such as Air-Shields® Kleenaseptic® Germicidal Surface Cleanser may be used. When using any cleaning agent follow the manufacturer's directions for use. Before cleaning, remove all solid wastes and contaminants from the disassembled parts.

#### **5.4.2 CLEANING LOWER SHELL**

The lower shell should be cleaned every 3 to 4 months during routine service, maintenance, or when contamination is known or suspected.



WARNING: The heater fins may be hot enough to cause burns; avoid touching the heater fins until the unit has cooled for at least 20 minutes.

To gain access to the Incubator Lower Shell the unit should be disassembled as described in paragraph 5.3.

**A. REMOVE ANY LINT** from the heater fins, fan motor impeller, and air temperature probe (Figure 5.3).

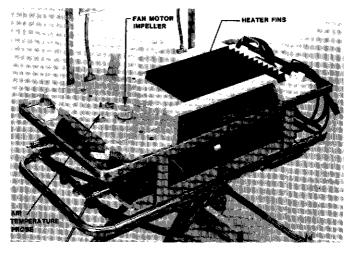


FIGURE 5.3 LOWER SHELL

B. WIPE THE HEATER FINS, air temperature probe, fan motor impeller, and adjacent surfaces with detergent germicidal solution, wipe with a clean paper towel moistened with hot water and wipe dry.

WARNING: After cleaning, be sure to replace impeller on the motor shaft. Fallure to do so will cause the heater to overheat, disabling the heater. If impeller is installed improperly, oxygen and temperature will be adversely affected. Make sure impeller turns freely after installation.

C. SPRAY EXPOSED SURFACES with Vapaseptic® Air Sanitizer.

## 5.4.3 CLEANING HUMIDITY CHAMBER AND UPPER SHELL

Use a disinfectant-detergent to thoroughly clean all surfaces, then dry with a clean cloth or paper towel. Inspect black rubber gasket on under side of upper shell for obvious physical damage.

## 5.4.4 CLEANING MATTRESS TRAY AND DECK.

Use a disinfectant-detergent to clean all surfaces thoroughly, then dry with a clean cloth or paper towel.

## 5.4.5 CLEANING HOOD AND ADJUSTABLE STAND (ACCESSORY)

#### **CAUTION:**

- Alcohol can cause crazing of the clear Plexiglas® hood. Do not use alcohol, acetone, or any organic solvents for cleaning.
- 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 Plexiglas® hood.

Use a disinfectant-detergent to clean all surfaces of the hood thoroughly, including the inner wall and access panels. Make sure to clean all holes, indentations, baffles, etc., then dry with a clean cloth or paper towel. Clean all surfaces of the stand.

## 5.4.6 CLEANING TUBING ACCESS PORT GROMMETS

Thoroughly clean the three tubing access port grommets using a disinfectant-detergent. Rinse with warm water and dry with a clean cloth or paper towel.

#### **5.4.7 AIR-INTAKE FILTER**

WARNING: A dirty filter may affect oxygen concentration and/or cause carbon dioxide buildup. Be sure the filter is checked on a routine basis commensurate with local conditions.

Do not attempt to clean or reverse the filter. If visibly dirty, or older than 3 months, it should be replaced. Before installing a new filter, clean the filter chamber and filter cover with a disinfectant-detergent. Replace only with the correct filter.

#### 5.5 REASSEMBLY AFTER CLEANING

Perform the reassembly of the Incubator in the following sequence. During the reassembly spray all surfaces with air sanitizer.

CAUTION: Exercise care when lowering the upper shell onto the lower shell to avoid damage to the air temperature probe.

- A. ALIGN THE AIR TEMPERATURE PROBE with the hole on the upper shell. Secure the latches at the head and foot ends of the unit (Figure 5.3). Make sure impeller is approximately 1.6 mm (1/16") from cover and rotates freely.
- B. PLACE THE HUMIDITY PAD in the humidity reservoir.
- C. PLACE THE MATTRESS TRAY on the left end of the upper shell, then slide the Tray to the right, under the mattress tray retainers, (Figure 5.2), until it passes the mattress tray stop and stops at the right end of the upper shell.
- D. PLACE THE MATTRESS (in mattress cover) in the mattress tray.
- E. INSTALL HOOD on upper molding.
- F. SECURE THE RUBBER HOOD RETAINERS at the head and foot ends to the pins on the hood; open the front and head-end access panels of the hood.
- G. INSTALL AN ACCESS PORT GASKET behind each access port as shown in Figure 5.4.

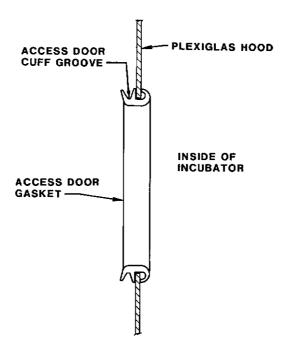


FIGURE 5.4 INSTALLATION OF ACCESS PORT GASKET

H. INSTALL A NEW ACCESS PORT CUFF onto each access port gasket by stretching the larger diameter elastic band into the groove in the gasket as shown in Figure 5.5. When installed correctly, the cuff has a small opening at its center.

**NOTE:** If the Incubator is to be gas sterilized, wait until after sterilization to install new cuffs.

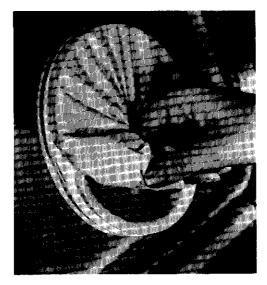


FIGURE 5.5 ACCESS PORT CUFF REPLACEMENT

- INSTALL THE TUBING ACCESS PORT GROMMETS by inserting the grommets into the slots in the outer hood (Figure 4.1A).
- J. CLOSE AND LATCH the front and head-end access panels.
- K. INSTALL A NEW AIR-INTAKE FILTER if necessary. Replace the air intake filter cover and tighten the two thumbscrews. If a new filter is installed, indicate the date on the place provided on the cover. Replace only with the correct filter.

**IMPORTANT:** A complete functional checkout (paragraph 4.3.1) should be performed before returning the unit to service.

#### 5.6 STERILIZATION

CAUTION: Do not steam autoclave. Gas sterilization temperature should not exceed 54.4°C (130°F).

Sterilization can be accomplished with the following agents:

#### **Cold Sterilization**

CAUTION: Do not expose the hood assembly to direct radiation from germicidal lamps. Ultraviolet radiation from these sources can cause cracking of gasket surfaces, fading of paint, and ultimately, crazing of the clear plastic hood.

#### Gas Sterilization (Ethylene Oxide)

Prior to gas sterilization, the entire Incubator should be thoroughly cleaned as described elsewhere in this section. Unlatch and open hood access panels. Remove and discard all used disposable elements such as access panel cuffs and mattress covers. New disposable elements should be installed after sterilization. The air-intake filter may be left in place.

NOTE: Gas sterilization does not eliminate the need for routine replacement of the air intake filter.

Standard gas sterilization procedures as programmed by automatic equipment such as made by American Sterilizers and Wilmot Castle are satisfactory as these do not normally exceed 54.4° C (130° F).

Upon completion of sterilization, an aeration period of 16 to 24 hours should be allowed. The Incubator should be operated in a dry condition for the entire period of aeration at a temperature of 32° C to 35° C (90° F to 95° F). After aeration, if the unit is not to be used immediately, a disposable dust cover should be placed on the Incubator.

**IMPORTANT:** A complete functional checkout procedure should be performed before returning the unit to service.

#### 5.7 BATTERY MAINTENANCE

Check the condition of the batteries before first use of the Incubator and at three month intervals thereafter as follows:

**IMPORTANT:** If the Incubator has not been connected to an AC power source for 20 hours prior to this test, the batteries should be recharged by connecting the Incubator to an AC power source for 20 hours with the AC POWER switch in the ON-1 position; when the recharge period is complete, disconnect the AC power cord.

- A. Open all access doors.
- B. Turn the Observation Light on.
- C. Depress the SET TEMP switch, the SET POINT indicator should light and a short "beep" should be heard indicating that the °C Temperature Display is indicating the set point.
- D. Observe the Temperature Display and depress the raise switch ( (A) ) to raise the set point to maximum (38° C).
- E. With fully charged batteries, the Incubator should operate for at least 2 hours before the LOW DC alarm activates.
- F. If the LOW DC alarm activates in less than 2 hours, replace the batteries.
- G. Immediately, upon successful completion of the test, recharge the batteries for 20 hours as described above.

## 5.8 BATTERY AND BATTERY TRAY REMOVAL/REPLACEMENT

If battery replacement is required, refer to qualified service personnel.

#### 5.9 CALIBRATION AND PREVENTIVE MAINTENANCE

The Incubator should be calibrated at least once every four months by Air-Shields qualified personnel.

#### 5.10 TROUBLESHOOTING

Troubleshooting for the operator of the TI100 Transport Incubator is presented in Table 5.1. If the fault cannot be localized from the chart, the unit should be removed from use and servicing should be referred to factory trained or otherwise qualified service personnel.

**TABLE 5.1 TROUBLESHOOTING** 

SYMPTOM	POSSIBLE CAUSE	REMEDY
AC POWER MODE Indicator not lit when Main AC POWER	a. AC Power cord not connect to wall outlet and/or the Incubator.	a. Check external power connections.
switch is set to ON-1 position.	b. AC circuit breaker(s) open.	b. Reset circuit breaker(s).
DC POWER MODE Indicator not lit when DC	a. Control Panel not energized.	a. Press CONTROLLER POWER ON Switch.
power operation is selected.	b. EXTERNAL DC or BATTERY circuit breakers tripped.	b. Reset circuit breakers.
LOW DC alarm activated.	a. Low DC at wall source     (external DC     operation).	a. Check DC wall power source.
	b. Battery voltage low (battery operation).	b. Check condition of batteries (para. 5.7).
POWER FAILURE alarm activated.	External AC or DC power failure and no DC backup (battery pack) is present.	Check power connection to wall source and Incubator.
HEATER TEMP alarm activated.	a. Circulating fan impeller dirty.	a. Clean fan Impeller (para. 5.4.2).
	b. Circulating fan impeller missing or stalled.	b. Check that fan impeller has been properly installed.

**TABLE 5.1 TROUBLESHOOTING (CONT.)** 

SYMPTOM	POSSIBLE CAUSE	REMEDY	
Incubator will not operate on battery.	a. Batteries discharged.	a. Check condition of batteries (paragraph 5.7)	
battery.	b. Battery circuit over- loaded.	b. Reset BATTERY circuit breaker.	
	c. Battery Tray not properly seated.	c. Check Battery Tray installation.	
Low oxygen concentration.	a. Access panel(s) open.	a. Close and latch access panel(s).	
	b. Tubing access grommets or door cuffs not properly installed.	b. Check installation (para. 5.5).	
	c. Hood not seated properly.	Push hood down against gasket     on upper shell and check that the     hood retainers are attached.	
High oxygen concentrations.	a. Dirty or incorrect air filter.	a. Replace filter (para. 5.4.7).	
	b. Dirty fan impeller.	b. Check fan impeller (para. 5.4).	
Examination Light does not operate.	a. Battery Tray not installed.	a. Install Battery Tray.	
	b. Battery Tray not firmly seated.	b. Check Battery Tray installation.	
Control Panel Erratic.	Circulating fan jammed.	Check fan impeller for proper rotation.	

#### — SECTION 6 ———

#### **PARTS LIST**

#### **6.1 GENERAL**

Table 6.1 provides a replacement parts and accessory parts list for the Air-Shields® TI100 Transport Incubator.

Parts or components other than shown here should be replaced only by qualified service personnel.

## **TABLE 6.1 REPLACEMENT PARTS AND ACCESSORIES**

#### **REPLACEMENT PARTS:**

Tubing Access Grommet	67 0	000	38
Mattress, Disposable (Case of 10)			
Mattress Cover			
Door Cuffs, Disposable (Case of 100)			
Cuff Gasket			
Air Filter (Pack of 6)	67 0	170	75
Humidity Sponge (Case of 25)	67 9	103	75
Restraint Straps (Case of 10)	67 9	103	95
Bulb, Observation Light	17 8	06	92
Inner Hood			
Outer Hood (with door gaskets)			
English Labeling			
Spanish Labeling			
French Labeling	67 9	04	92
German Labeling	67 9	04	93
Battery	67 0	<i>)</i> 60	10
ACCESSORIES:			
I.V. Pole	67 C	101	75
Adjustable Stand Assambly	67.0	าดก	71
Adjustable Stand Assembly		42	7 N
Accessory Shelf			
DC Power Cord Receptacle			
Pressure Regulator and Flowmeter	0/ 0	JJU	10

# WARRANTY

The product being described in this manual is warranted against defects in materials or workmanship for one year from the date of shipment from Air-Shields, Hatboro, with the following exceptions:

All consumable and disposable products are guaranteed to be free from defects upon shipment only.

Calibrations are considered normal maintenance and are not included in the 1 year warranty.\*

During the warranty period any defective parts other than those listed above will be replaced at no charge to the customer. There will be no labor charge for replacing the parts within the continental U.S.

This warranty is rendered void and Air-Shields cannot be held liable for conditions resultant therefrom it:

- 1. Damage to the unit is incurred as a result of mishandling.
- 2. The customer fails to maintain the unit in a proper manner.
- 3. The customer uses any parts, accessories, or fittings not specified or sold by Air-Shields.
- 4. Sale or service is performed by a non-certified service/dealer agency.

This warranty is in lieu of all other warranties, expressed or implied, and Air-Shields shall in no event be liable for incidental or consequential damages including loss of use, property damage, or personal injury resulting from breach of warranty.

\*The Accreditation Manual for Hospitals, Standard II of the Function Safety and Sanitation section, requires that the testing interval for this equipment not exceed six months. To comply with this standard, we recommend that you participate in our Accreditation Testing Compliance Program during the warranty period. This service can be performed by certified technicians through our Product Service Group and authorized dealers.

## SERVICE

For optimal performance, product service should be performed only by qualified service personnel. Product Service Group instrumentation specialists are located throughout the United States and are dispatched for required maintenance by calling 800-523-2404. Customers outside the U.S. should contact their local factory-authorized Air-Shields distributor for service.

