U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K003335 - 325 pages
COMPANY:	HILL-ROM AIR-SHIELDS (HILLROMAIRSHIE)
PRODUCT:	WARMER, INFANT RADIANT (FMT)
SUMMARY:	Product: RESUSCITAIRE RADIANT WARMER; RESUSCITAIRE BIRTHING ROOM WARMER; RESUSC
DATE REQUESTED:	Apr 13, 2016
DATE PRINTED:	Apr 13, 2016
Note:	Printed

K003335

NOV 1 7 2000

510(k) Summary

September 27, 2000

Applicant:

Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, PA 19040
Reg. No: 2510954

Contact Person:

James G. Carpenter
Ph: (215) 675-5200
Fx: (215) 682-8689

Device trade/proprietary name:

Resuscitaire® Radiant Warmer
Resuscitaire® Birthing Room Warmer
Resuscitaire® Wall Mounted Radiant Warmer

Device common/usual/classification name:

WARMER, INFANT RADIANT

Classification:

General Hospital
21 CFR 880.5130
Infant Radiant Warmer, FMT, Class II

Performance Standards:

None applicable.

Predicate (Current) Device:

K940951 RW Resuscitaire Infant Radiant Warmer

Device Description

The Resuscitaire® Radiant Warmer is designed specifically for labor and delivery room use. The Resuscitaire® Radiant Warmer consists of a Bassinet, Warmer, and controller module, which provides heat control, monitoring of skin temperature and Apgar timing. The Resuscitaire® Radiant Warmer also includes an optional basic resuscitation package, which includes suction and oxygen delivery.

Intended Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.

This is the same intended use as previously cleared for the RW Resuscitaire® Infant Radiant Warmer, K940951 RW Resuscitaire Infant Radiant Warmer.

Description of Modifications:

The modifications that are the subject of this submission are summarized below:

- Addition of a new resuscitation module using the existing module with the following changes.
  - Change the 15mm outlet on the Gas Delivery Module to a tapered, barbed fitting that is consistent with currently accepted caregiver practice in the United States and Canada.
  - Replacement of the user adjustable airway relief valve with an internal fixed relief valve.
  - Appropriate modifications to module overlay and user manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2000

Mr. Larry W. Krasley
Regulatory Affairs Specialist
Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, Pennsylvania 19040

Re: K003335
Trade Name: Resuscitaire Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: October 24, 2000
Received: October 25, 2000

Dear Mr. Krasley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Resuscitaire Radiant Warmer

Indications for Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

✓

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003335

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food and Drug Administration

Memorandum

Date: 11/21/00

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K003335-/A2

To: Division ~~Director~~: HO/DDIC

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

✓ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_____ Additional information requires a new 510(k); please process [This information will be made into a new 510(k)

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: SWF

Date: NOV 28 2000

Draft #2 : 9/8/99
Draft #3: 1/3/00

K003335/A2

Hill-Rom Air-Shields.
A HILLENBRAND INDUSTRY

November 16, 2000

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference: **SPECIAL 510(k):** K9003335 Resuscitaire Radiant Warmer

Dear Madam/Sir:

Attached please find copies of the updates for 510(k) K003335. I have also faxed the updates to Ms Farah Foster (301-480-3002).

Please replace the following:

- Section III Pages 12-63 remove and replace with attached Operator's Manual.

Please feel free to contact me should you have any further questions or concerns.

Sincerely,

Larry W. Krasley

Larry W. Krasley
Regulatory Affairs Specialist
Hill-Rom Air-Shields

RECEIVED
NOV 21 9 56 AM '00
FDA/CDRH/ODE/DMC

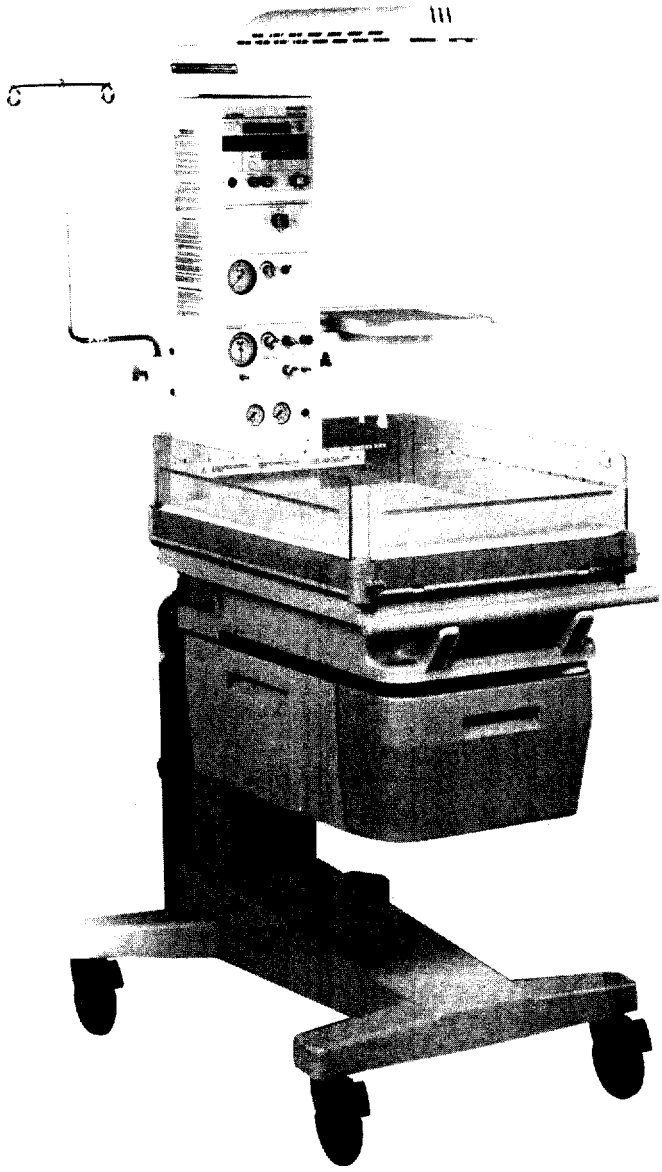
SK7 2

Hill-Rom Air-Shields®

A HILLENBRAND INDUSTRY

RESUSCITAIRE® Radiant Warmer

MODEL RW82-1



OPERATOR'S MANUAL

3

OPERATING PRECAUTIONS

GENERAL PRECAUTIONS

- Federal Law restricts this device to sale by or on order of a physician.
- Infant radiant warmers should be used only by properly trained personnel as directed by an appropriately qualified physician aware of currently known risks and benefits.
- The functional checkout procedure should be performed before the unit is first placed into use and after disassembly for cleaning, servicing or maintenance. Refer to qualified service personnel if the unit does not perform as specified.
- The Bassinet end and side panels cannot be used for pushing or pulling the ***Resuscitaire® Radiant Warmer.***
- Do not leave the infant unattended in the Bassinet of the ***Resuscitaire® Radiant Warmer*** when the side panels or the front panel are folded down.
- To avoid overheating or underheating, skin temperature must be continuously monitored and controlled either manually or automatically. Rectal temperature should never be used to control skin temperature.
- To avoid overheating or underheating when operating in manual mode, observe the infant constantly and monitor the temperature using the temperature probe supplied with the equipment or other electronic thermometer.
- The skin temperature sensing probe must be in direct contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain direct skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment, reddened skin areas, and proper skin temperature.
- The skin temperature sensing probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The skin temperature probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.
- To avoid overheating the skin, the location of the skin temperature probe must be such that the skin around the Sensor is in direct line with the radiation from the warmer. Do not place anything between the radiant warmer and the infant that will interfere with the radiation from the warmer.
- Radiant warming increases insensible water loss. Appropriate measures to maintain proper fluid balance should be considered.
- Phototherapy units located too close to the Bassinet may affect mattress and infant temperature.
- The warmer cannot differentiate between an increase in core temperature and cold skin (fever) and low core temperature (hypothermia). It is recommended that patient core temperature be monitored with a separate calibrated electronic thermometer.
- 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 avoid overheating of the warmer, do not place objects (equipment, blankets, clothing or sterile packs) on top of the warmer.
- Air currents across the Bassinet area can affect patient thermal balance. Avoid placing the Warmer near heating or air conditioning ducts that may blow air across the Bassinet.
- Temperature uniformity (per IEC 601-2-21) across the mattress surface may not be maintained when the Bassinet is tilted in the 5- and 10-degree positions.
- During service intervals, inspect the secondary reflector directly under the warmer heater element for particles. If particles are present, replace the heater element. The life expectancy of the heater element is 1000 hours of operation.

OPERATING PRECAUTIONS (Continued)

GENERAL PRECAUTIONS (Continued)

- Should any of the control knobs on the Resuscitation Module come loose for any reason, do not attempt to refasten them. The calibration of these controls depends on the position of the knob on the shaft. If this occurs, recalibration must be performed by qualified service personnel.
- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Only connect the power cord to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with or provided for the ***Resuscitaire® Radiant Warmer.***
- The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
- Use of the accessory in the PATIENT VICINITY.
- Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.
- When raising or lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA,*** make sure that any attached cables, tubing or hoses are not compromised.
- When lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA*** to its minimum height, ensure thatthe gas tanks, if installed, do not contact the floor.
- Always lower the ***Resuscitaire® Radiant Warmer VHA*** to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.
- To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport. Use the handle when moving the equipment.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

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OPERATING PRECAUTIONS (Continued)

ELECTRICAL PRECAUTIONS

- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Confirm that the **Oxygen Supply** is turned off and that the equipment 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.
- Connect the power cord only to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with the Warmer.

EXPLOSION PRECAUTIONS

- Do not use in the presence of flammable anesthetics.
- Confirm that the oxygen supply is turned off and that the equipment 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.

OXYGEN PRECAUTIONS

- Improper use of supplemental oxygen may be associated with serious side effects including blindness, brain damage, and death. The risks vary with each infant. All clinical practices with regard to 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 the 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_2) in the blood. When deemed advisable by the attending physician, blood PO_2 should be measured by accepted clinical techniques.
- Oxygen flow rates cannot be used as an accurate indication of oxygen concentrations. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals directed by the attending physician.
- Keep matches, lighted cigarettes, and all other sources of ignition out of the room in which the equipment is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.
- Although oxygen compatible materials are used in the oxygen delivery system, special care must be taken when high pressure oxygen such as found in a medical oxygen cylinder is used. Violent ignition of oil, grease, greasy substances, small particles of dust, dirt or other particulate contaminants (even small particles of metal), can occur in the presence of high pressure oxygen if their ignition temperature is reached. An instantaneous increase in temperature can occur due to friction, particle acceleration, or adiabatic compression, if the oxygen cylinder valve is opened too rapidly. **SERIOUS INJURY MAY RESULT!** Always observe the following precautions:

OXYGEN PRECAUTIONS (Continued)

- Oil, grease, greasy substances, dust, dirt and other particulate contaminants must be kept away from oxygen regulators, cylinder valves, tubing and all other oxygen equipment.
- Always open oxygen cylinder shut-off valves **very slowly** and **carefully.**
- On high pressure oxygen cylinders use only pressure regulators or reducing valves approved for oxygen service. Do not use oxygen pressure regulators or reducing valves for air or gases other than oxygen as they may be hazardous. Operate such devices in strict accordance with the manufacturer's recommendations.
- When new or replacement oxygen cylinders are to be installed, they should have their outlet ports cleared by cracking the cylinder valve momentarily before attachment to the equipment.

LOW FLOW MICROBLENDER WARNINGS

- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FiO_2 and flow output from the microblender.
- Always operate the low flow microblender with clean/dry medical grade gases.
- Air inlet water filters are recommended for use with the low flow microblender.
- The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.

7

TABLE OF DEFINITIONS AND SYMBOLS

NOTE, IMPORTANT, PRECAUTION, 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 when greater emphasis is required.*

PRECAUTION: *A Precaution is supplemental information to assist the user in the safe and effective use of the equipment.*

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.

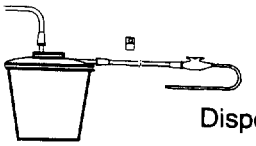
WARNING: A Warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

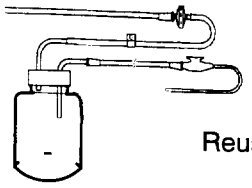
SYMBOLS


Attention: consult accompanying documents.

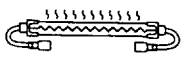

Type B equipment with an F-type isolated (floating) applied part.


Danger! High Voltage!


Disposable Suction Bottle


Reusable Suction Bottle


Patient


Heater Element


Suction Line Filter


Load Symbol


Examination Light


Examination Light Switch


Mode Control Key

Temperature Override Mode Key


Keypad Lock Key


Set Temperature Keys


Power On/Off Switch

Celsius/Fahrenheit Selection Key


Silence/Reset Key


Procedural Silence Indicator


Apgar Timer Keys

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SECTION 1
GENERAL INFORMATION

1.1 INTRODUCTION

This manual provides instructions for installation, use, operator maintenance and troubleshooting of the equipment. Hill-Rom Air-Shields cannot be responsible for the performance of the equipment if the user does not operate the equipment 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. Service manuals are available from Hill-Rom Air-Shields.

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

1.2 DESCRIPTION

The ***Resuscitaire® Radiant Warmer*** is designed specifically for labor and delivery room use. The ***Resuscitaire® Radiant Warmer*** consists of a Bassinet, Warmer, and a Controller module which provides heat control, monitoring of skin temperature and Apgar timing. The ***Resuscitaire® Radiant Warmer with VHA*** provides an adjustable Mattress Height from 89.2 cm (35.4 inches) to 110.2 cm (43.3 inches).

The ***Resuscitaire® Radiant Warmer*** also includes optional basic resuscitation packages which includes suction and oxygen delivery.

1.3 SPECIFICATIONS

Specifications for the ***Resuscitaire® Radiant Warmer*** are provided in Table 1.1. All specifications are subject to change without notice.

TABLE 1.1 SPECIFICATIONS

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer*

120V Models	120V, 60 Hz, 750W
100V Models (Japan)	100V, 50/60 Hz, 750W
230V Models	230V, 50/60 Hz, 750W

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer with VHA*

120V Models	120V, 60 Hz, 1300W
230V Models	230V, 50/60 Hz, 1300W

OVERLOAD PROTECTION

120V Models	Dual 12A Circuit Breakers
100V Models (Japan)	Dual 12A Circuit Breakers
230V Models	Dual 6A Circuit Breakers

Resuscitaire® Radiant Warmer with VHA also has in addition:

120V Models	Dual 6A Circuit Breakers
230V Models	Dual 3A Circuit Breakers

CHASSIS LEAKAGE CURRENT (Single fault condition, loss of ground)

100V and 120V Models	Less than 300 μA
230V Models	Less than 500 μA

EXAMINATION LIGHT ..... >100 Foot Candles (0.11 lumens/cm^2)

ALARMS

High Temperature	Activates if Skin Temperature Probe is attached and the skin temperature sensor reaches 39.0 °C. Resets at 38.5 °C.
Check Patient	Activates in Manual Mode after 10 minutes. Remains on with audible alarm every 30 seconds for 5 minutes; totalling 15 minutes. Then the heater is turned *Off*.
Apgar Timer	Activates at the 1-, 5- and 10-minute Apgar Time intervals.
Power Fail	Activates when there is a loss of power.
Probe	Activates if Skin Temperature Probe fails (open or short).
System Fail	Indicates system failure, refer unit to service immediately.
Baby Temp	Activates if Baby Temperature fluctuates 1°C above or below set point.
Electrical Module Audio Alarms	Tone Frequency: 1.2 KHz maximum three-stage sound level: 15 seconds low, 15 seconds medium, then high.
Blender Module Pneumatic Audio Alarm	Vibrating Reed.

MANUAL HEAT CONTROL ..... Adjustable in 10% increments from zero to full power (100%)

DATA PORT ..... 2400 Bits/second fixed Baud Rate. RS232C Compatible.

MATTRESS TILT ..... 0, 5 and 10 degrees.

DISPLAYS

Skin Temperature Display

Range	18 to 40 °C (64.4 to 104°F)
Accuracy	± 0.2 °C for 31 °C to 37 °C (88 °F to 98.6°F)
Resolution	0.1°C (0.5 °F)

TABLE 1.1 SPECIFICATIONS (Cont.)

DISPLAYS (Cont.)

Apgar Timer Display

Range	0 to 59 minutes, 0 to 59 seconds
Resolution	1 second
Accuracy	0 ± 1 second

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer*

Mattress Height	100 cm (39.4 - inches)
Height	188 cm (74 - inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	100 kg (220 lbs)

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer with VHA*

Mattress Height	89.2 to 110.2 cm (35.4 to 43.3 inches)
Bassinet Tilt (continuously)	±10 degrees from horizontal
Height	180.6 to 200.7 cm (71.1 to 79 inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	127 kg (280 lbs)

ENVIRONMENTAL

Operating Temperature Range	18 °C to 30 °C ambient
Storage Temperature Range	- 30 °C to +70 °C ambient
Relative Humidity Operating Range	5% RH to 95% RH, non-condensing

RESUSCITATION

Wall Supply Pressure	40 to 75 psi (2.8 to 5.2 bar)
Cylinder Pressure	2900 psi max (199.8 bar)
Cylinder Diameter	10-12 cm (4-5 inches) max

Suction Circuit

Adjustable Suction Intensity	0 to 150 mmHg

Patient Gas Supply

Airway Pressure Limit, Operator Adjustable	0 to 50 cm H_2O (4.9 kPa) ± 10%
Fixed Pressure Relief, Factory Set	60 cm H_2O (5.9 kPa) ± 20%

Primary Supply

Primary Pressure Limit	160 cm H_2O (15.7 kPa) ± 20%
Primary Flow Range	0 - 15 lpm

Auxiliary Supply

Auxiliary Pressure Limit	160 cm H_2O (15.7 kPa) ± 10%
Auxiliary Flow Range	0 - 15 lpm

1.4 EQUIPMENT PROVIDED

- *Bassinet* - The Bassinet provides maximum visibility and access to the infant. The Bassinet tilts up in the rear 5 and 10 degrees and provides for X-ray Tray (optional) insertion.
- *Warmer Module* - The Warmer Module houses a heating element and an Examination Light for special procedures.
- *Controller* - The Controller provides Pre-Warm, Manual heat control, automatic skin temperature servo-control and contains an Apgar Timer, Skin Temperature monitor and probe connection.
- *Resuscitation Module (Optional)* - The Resuscitation Module contains a suction circuit, a patient oxygen delivery circuit with airway pressure relief and an auxiliary oxygen delivery circuit. There are two varieties of resuscitation modules, both versions can accept an optional blender.

1.5 FACTORY INSTALLED OPTIONS

- Resuscitation Module
- Resuscitation Module 2001
- Integrated Precision Blender
- Gas Supply Module
  - O_2 Pipeline and Cylinder
  - O_2/Air Pipeline and Cylinder

1.6 FIELD INSTALLED ACCESSORIES (Refer to Section 6 for Part Numbers)

- Instrument Tray (left or right mount)
- X-ray Cassette Tray
- Pass-Through Drawer Organizer Tray
- I.V. Pole
- Monitor Shelf

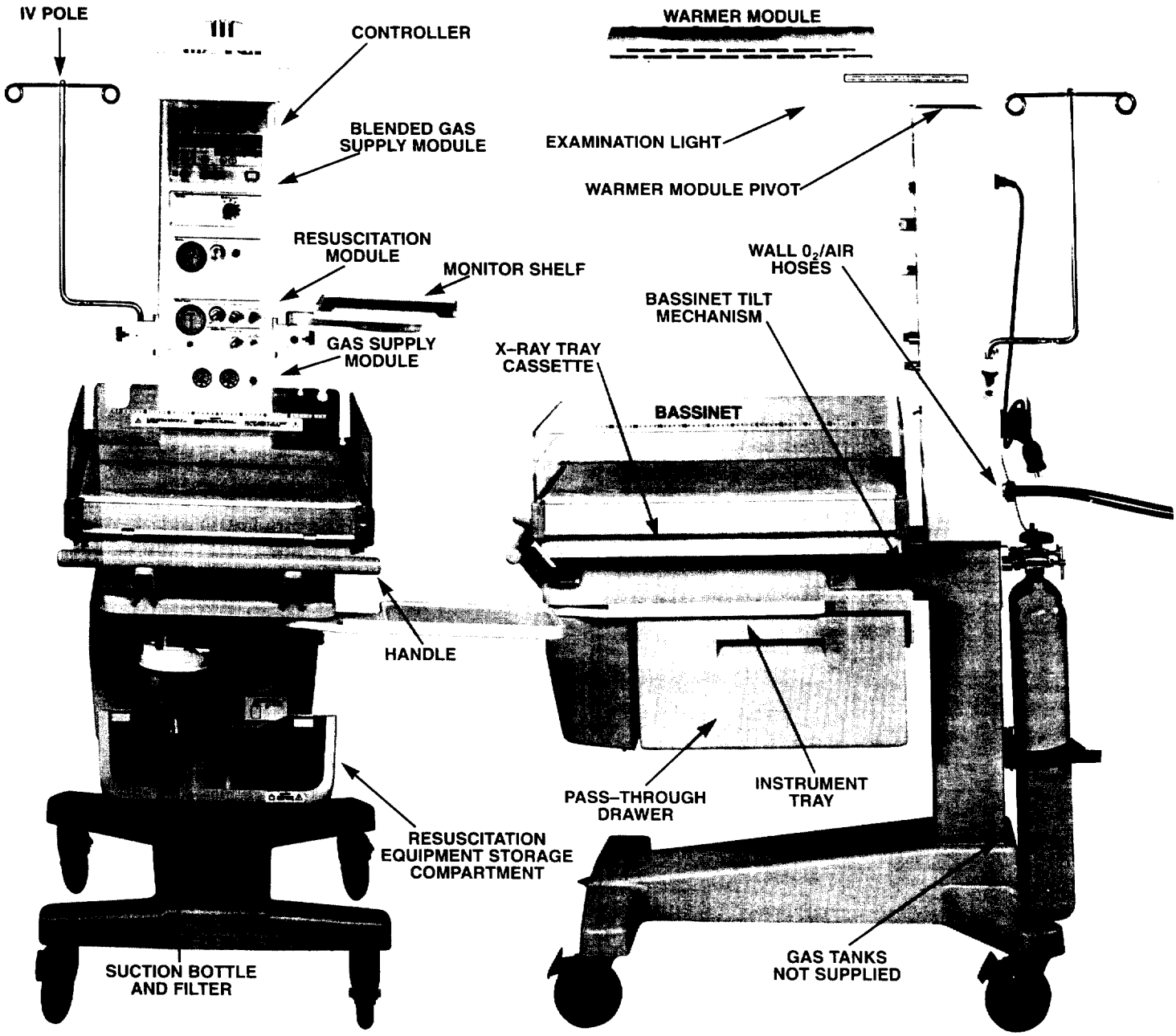


FIGURE 1.1 EQUIPMENT PROVIDED WITH FACTORY INSTALLED OPTIONS AND FIELD INSTALLED ACCESSORIES

SECTION 2
INSTALLATION

2.1 UNPACKING

The ***Resuscitaire® Radiant Warmer*** is shipped in one carton which contains the following assemblies:

- Bassinet/Cart Assembly
- Upper Post Assembly
- Warmer Module Assembly
- Any user installed Accessories that were ordered

When removing the equipment from the carton, use care not to scratch or otherwise damage unprotected surfaces; remove all packing material.

2.2 ASSEMBLY (Refer to Figure 2.1)

NOTE: *The required mounting hardware is stored in a bag located in the pass-through drawer.*

1. **REMOVE THE BACK COVER** (1) from the Upper Column (2).
2. **REMOVE THE CONTROLLER** (3) from the Upper Column (2).
3. **REST THE UPPER COLUMN** (2) on top of the Bassinet/Cart column opening. Fully extend the suction hoses (4) and (11) out of the column.
4. **CONNECT THE SUCTION HOSE** (4) to the Suction Hose (11).
5. **REPOSITION AND MOUNT THE UPPER COLUMN** (2) on the Bassinet/Cart using four 10 - 32 x 3/8 inch screws (5). Exercising care not to kink the hoses, carefully push the connected suction hoses into the column.
6. **INSTALL TWO 10 - 32 X 3/8 INCH SCREWS (6) IN THE UPPER HOLES OF THE UPPER COLUMN** (2). Do not tighten the screws.
7. **RAISE THE WARMER** (7) above the open end of the Upper Column (2) and insert the Power Cable (10) into the open end of the column.
8. **SLOWLY LOWER THE WARMER** (7) onto the Upper Column. Align the slots of the warmer over the screws (6) on the column. Install the screws on the pivot bracket. Tighten the screws on the upper holes of the column using a nine-inch Phillips Head screwdriver.
9. **THREAD THE WARMER POWER CABLE** out through the Controller opening. Connect the Power Cable (10) to connector J4 on the Controller (3).
10. **REMOUNT THE CONTROLLER** on the Upper Column. Remount the Back Cover (1) on the Upper Column.
11. ***Resuscitaire® Radiant Warmer***

    CONNECT THE LINE CORD to the **POWER** Connector on the rear of the Controller (refer to Figure 4.2).

11A. ***Resuscitaire® Radiant Warmer with VHA***

    CONNECT THE LINE CORD to the Power Connector (Refer to Figure 4.2A) on the right side of the Lower Post. Connect the 40-inch Power Cord provided with the VHA between the AC connector on the left side of the Lower Post and the Controller Power Connector.

12. ***Resuscitaire® Radiant Warmer***

    SECURE THE LINE CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

12A. ***Resuscitaire® Radiant Warmer with VHA***

    SECURE THE 40-INCH POWER CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

CAUTION: Securing the Line Cord to the back panel is required to prevent removal of the Controller chassis with the AC power applied.

13. **INSTALL ANY ACCESSORIES** that were ordered using the installation instructions provided with the accessory.
14. **INSTALL THE END AND SIDE PANELS** on the Bassinet (refer to Paragraph 5.6 and Figures 5.1, 5.2, 5.3 and 5.4).

PARTS LIST

Screw, 10 - 32 x 3/8 TR, PH Nylok (Qty 10)	99 041 36
Screw, 8 - 32 x 3/8 TR PH SS	99 031 38
Cable Clamp	17 725 64

FIGURE 2.1 INSTALLATION

SECTION 3
FUNCTIONAL DESCRIPTION

3.1 GENERAL

This section provides a functional description of the equipment.

3.2 FUNCTIONAL DESCRIPTION

3.2.1 WARMER MODULE

The Warmer is controlled by a Controller which provides **Pre-Warm** Mode, **Manual** Mode heater control, or **Baby** Mode (automatic skin temperature control). An Examination Light provides added illumination of the mattress area. A Warmer Head Pivot permits the Warmer to be pivoted 90° to either side for X-ray procedures. In addition, when the Warmer is pivoted, it continues to provide heat.

3.2.2 BASSINET

The Bassinet is designed to provide maximum function and utility to aid in the care of the newborn. The side and front panels may be folded down to permit access to the infant. The mattress may be tilted up from the rear at a 5- or 10-degree angle. Openings are provided on each side of the Bassinet for the insertion of the optional X-ray Cassette Tray.

3.2.3 CONTROLLER

At power-up, the microprocessor within the Controller performs a series of diagnostic tests to confirm the proper operation of the system. During this time, all displays and indicators are lighted and an audible tone is sounded.

When powered up, the system initializes in **Pre-Warm** Mode, the Controller will start the heater at 100% power and maintain that setting for three minutes, reduce to 60% for 12 minutes and then reduce the heater power to 30%.

When operating the Controller in the **Manual** Mode, the operator can adjust the heater power from 0 to full power in 10% increments. After 10 minutes of operation in the Manual Mode, a **Chk Patient** Alarm occurs.

Failure to acknowledge the Check Patient Alarm within the next 5 minutes will cause the heater to be turned off.

When operated in the **Baby** Mode, the Controller utilizes a Skin Temperature Probe, connected between the Controller input and the infant, to automatically adjust the heater output of the Warmer Module to maintain a digitally displayed preset **Set Temperature**.

The Apgar Timer displays the elapsed time and sounds an audible dual tone to alert the operator that 1, 5, and 10 minutes have elapsed since the timer was activated.

The **Keypad Lock** Key, when pressed, renders the Up/Down Arrows and Select Mode Keys inactive or active.

A Procedural Silence Timer prevents **Baby Temp** audible Alarms during routine procedures.

3.2.4 BLENDER MODULE (Optional)

The Blender Module provides blended oxygen from 21% to 100% to the **Patient Outlet** on the Resuscitation Module.

3.2.5 RESUSCITATION MODULE (Optional)

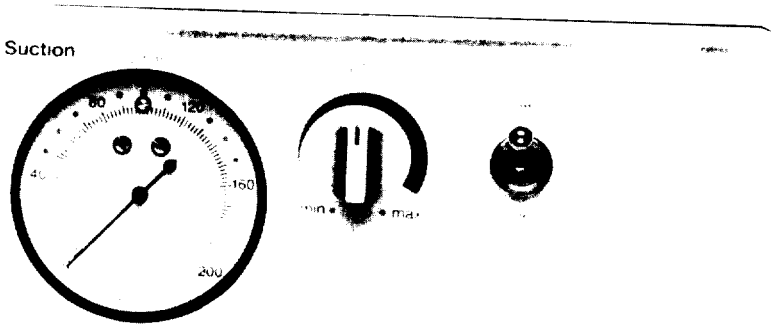
WARNING: Always monitor Airway Pressure and or/provide appropriate relief during infant resuscitation.

The Resuscitation Module contains pneumatic circuitry necessary for infant resuscitation. Controls and displays for the module are located above the rear of the Bassinet.

The Resuscitation Module is provided in two varieties. It consists of the following factory installed components:

- **Suction** - The **Suction** Circuit is driven by a gas powered venturi actuated vacuum generator which provides a negative pressure for suctioning the patient's airway. The suction pressure is indicated on the **Suction** Gauge (Figure 3.1). Suction may be adjusted using the

Suction Control and turned on or off using the **On/Off** Switch. A fixed internal relief valve limits the maximum suction pressure to 150 mmHg.



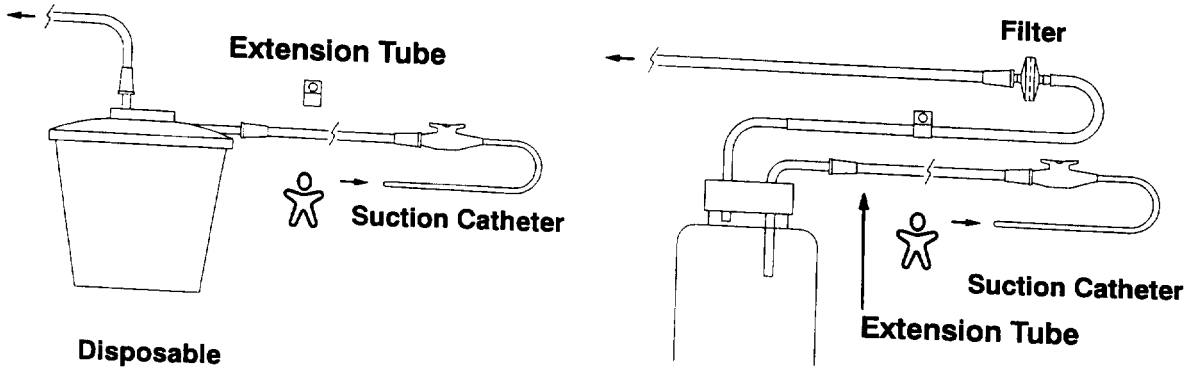


FIGURE 3.1 SUCTION FUNCTIONAL BLOCK DIAGRAM

RESUSCITATION MODULE 2001 WITH PRIAMRY OUTLET AND AUXILIARY FLOW ONLY (FACTORY INSTALLED OPTION)

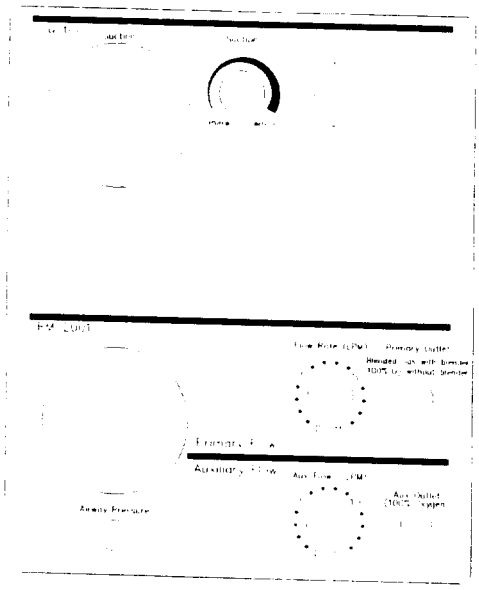


FIGURE 3.2 RESUSCITATION MODULE 2001 WITH PRIMARY OUTLET AND AUXILIARY FLOW ONLY

RESUSCITATION MODULE 2001 PRECAUTIONS

- The Resuscitation Module 2001 (option) is intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- If the blender option was added, confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- Always monitor **Airway Pressure**.
- When using **Primary Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Primary Supply** module.

- A humidifier, if used, must be placed between the **Primary Outlet** connection and the patient. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

- **Primary Outlet** -

The **Primary Gas Supply** circuit may be used to provide continuous gas flow to a breathing circuit. When the **Blender** module is included in the system, the **Primary Outlet** provides 0 to 15 lpm of O_2 selected by the operator. The **Flow Rate (LPM)** control is a calibrated dial type flow adjustment.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 160 ± 10 cm H_2O (15.9 ± 1 kPa)

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet** -

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother , or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The outlet 1/4" hose barb fittings of the gas delivery module will attach to commercially available oxygen supply tubing or self-inflating resuscitation bag. Hill-rom Air shields part number 67 361 72.

RESUSCITATION MODULE (FACTORY INSTALLED OPTION) PATIENT SUPPLY

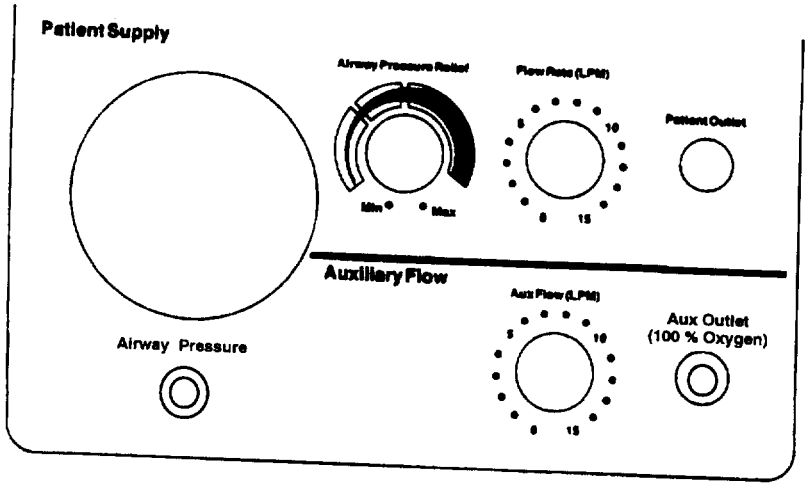


FIGURE 3.3 RESUSCITATION MODULE WITH PATIENT GAS SUPPLY AND AUXILIARY FLOW ONLY - PATIENT SUPPLY

RESUSCITATION PRECAUTIONS

- The Resuscitation Module (options) are intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- Confirm the setting and flow of the Airway Pressure relief valve before patient use.
- Confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- Always monitor **Airway Pressure**.
- When using **Patient Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Patient Supply** module.
- A humidifier, if used, must be placed between the **Patient Outlet** connection and the patient circuit. DO

NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.

- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.

- **Patient Outlet** -

The **Patient Gas Supply** Circuit may be used to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet** -

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother , or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The patient breathing circuit used in conjunction with the Resuscitation Module is illustrated in Figure 3.4. In addition, a patient supply circuit for Manual Bagging (Figure 3.5) may also be used.

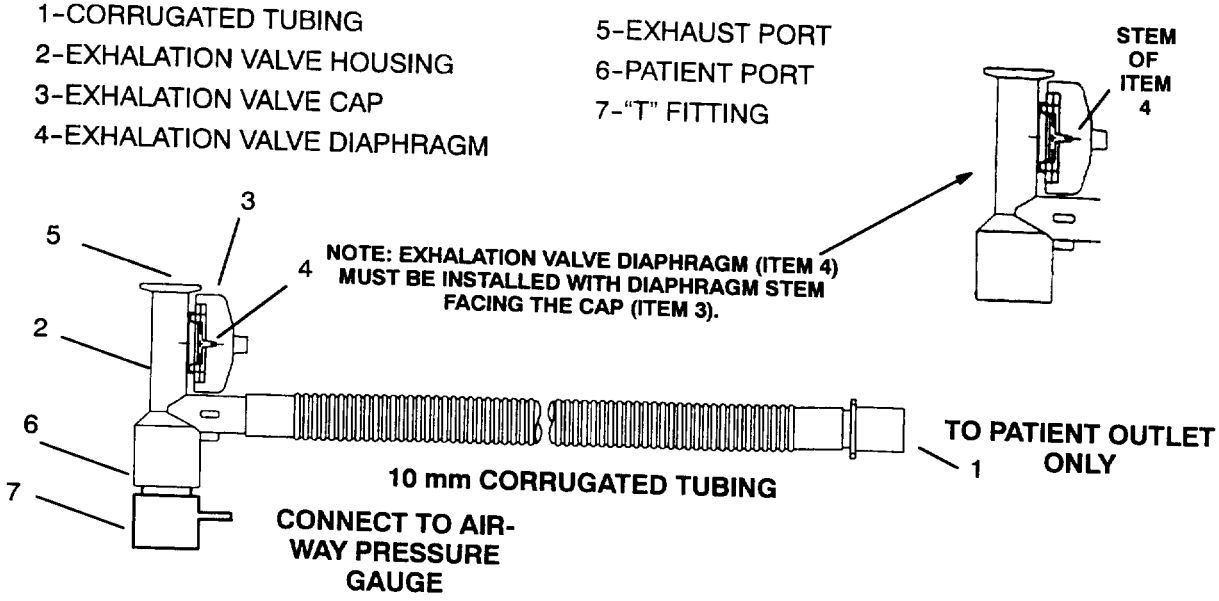


FIGURE 3.4 PATIENT BREATHING CIRCUIT FOR MANUAL VENTILATION

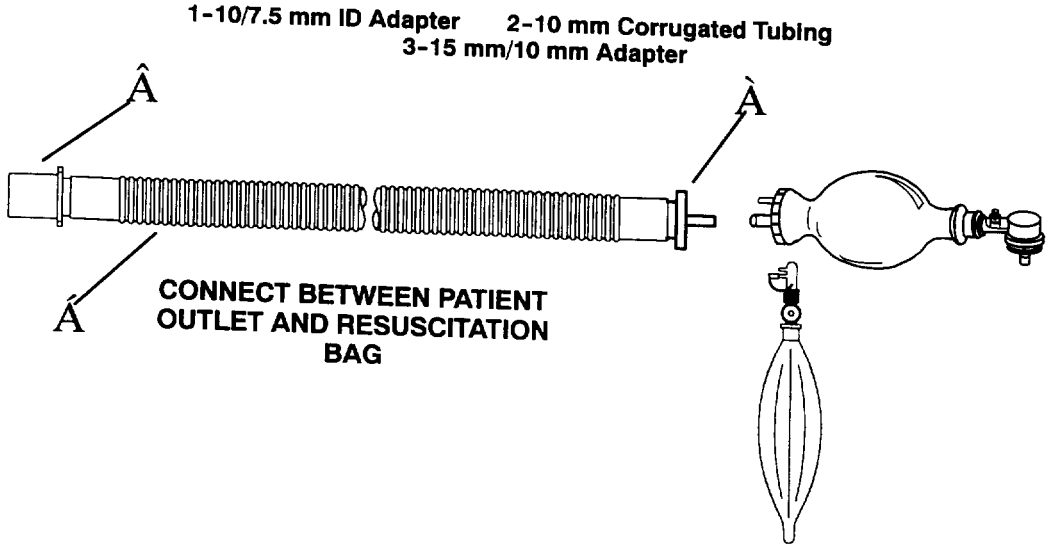


FIGURE 3.5 PATIENT BREATHING CIRCUIT FOR MANUAL BAGGING

3.2.6 GAS SUPPLY MODULE

The **Gas Supply** Module includes an On/Off Switch which controls the pipeline and cylinder gas supply to the Resuscitation Module. An oxygen cylinder Pressure Gauge is provided if the oxygen cylinder option is included. Oxygen and Air Pressure Gauges are provided on units equipped with the Blender Module.

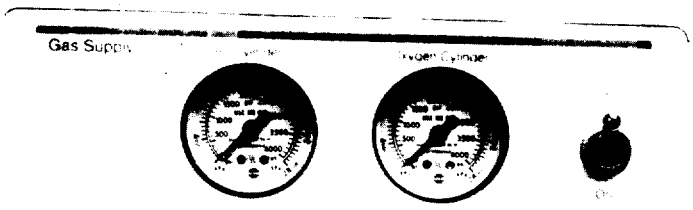


FIGURE 3.6 GAS SUPPLY MODULE

3.2.7 ALARMS

HIGH TEMPERATURE. When the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C, the heater is automatically turned off, the **High Temp** Indicator will flash and the audible alarm will sound continuously. Press the **Silence/Reset** Key to silence the alarm for two minutes. After the alarm condition is corrected (a skin temperature of 38.5 °C or less), the alarm will automatically reset.

CHECK PATIENT. When in the **Manual** Mode the **Chk Patient** Indicator will illuminate and the alarm will sound one time after 10 minutes of operation. Thereafter, the **Chk Patient** Indicator will remain illuminated and the audible alarm will sound every 30 seconds for 5 minutes. If the alarm has not been acknowledged at the end of 5 minutes, the heater will shut down and a continuous ramping audible alarm will sound. The **Silence/Reset** Key then must be pressed to reactivate the heater.

PROBE. If the Skin Temperature Probe fails (short- or open circuited), the **Probe** Indicator will flash and a ramping audible alarm will sound. After the alarm condition is corrected (the Probe is replaced), the alarm will automatically reset.

BABY TEMPERATURE. When the temperature sensed by the Skin Temperature Probe is 1 °C above or 1°C below the selected **Set Temperature** Display setting, the **Baby Temp** Indicator will flash and a ramping audible alarm will sound. In addition, if the temperature is 0.2 °C above the selected **Set Temperature,** the heater will be turned off automatically. Press **Silence/Reset** to silence the alarm for 10 minutes.

POWER FAIL. When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. The alarm may be silenced by turning off the power switch.

IMPORTANT: *Turning off the Power switch will prevent the Controller and Heater from restarting automatically when power is returned to the unit. The settings will be retained in memory until power is restored.*

SYSTEM FAIL. If an internal malfunction is detected, the **System Fail** Indicator will flash and the audible alarm will beep. In addition, an Error Code (eR00 to eR025) will be displayed in the **Baby Temperature** Display. This alarm is not resettable and the unit should be referred to qualified service personnel. A prolonged brown-out (five minutes or more with supply voltage leas than 90% of nominal) will also cause a System Fail alarm.

3.2.8 BLENDER DIFFERENTIAL BYPASS ALARM (Optional)

The blender Module (factory installed option) will alarm and bypass whenever the pressure differential between the O_2 and air supplies exceeds 30 psi ± 2 psi. When this condition occurs, the blender will continue to supply whichever gas is the higher pressure: either 100% Air or 100% Oxygen. This is an audible alarm only. There are no visual indicators.

3.2.9 APGAR TIMER

When the **Apgar Timer** is running, the Apgar Timer Display will show elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar time intervals.

SECTION 4
OPERATION

4.1 CONTROLS, INDICATORS AND CONNECTORS

Controls, Indicators and Connectors for the Controller are presented in Figures 4.1 and 4.2 and Tables 4.1 and 4.2. Controls, Indicators and Connectors for the Resuscitation Module are presented in Figure 4.3 and Table 4.3.

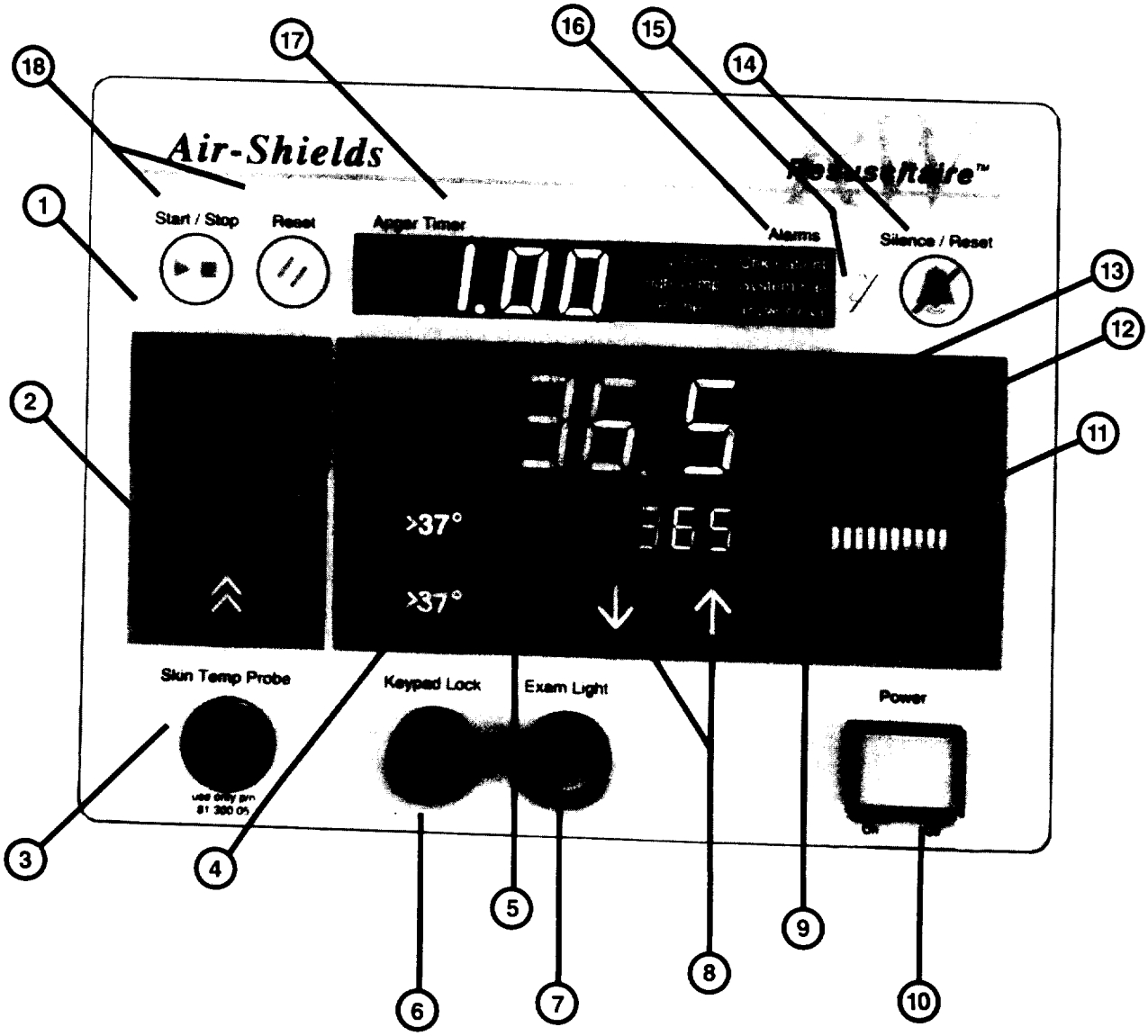


FIGURE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

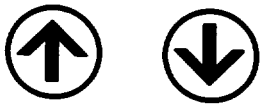
ITEM	NAME	DESCRIPTION
1	**Mode**	
	Pre-Warm Indicator	Indicates that the Controller is operating in the **Pre-Warm Mode**.
	Manual Indicator	Indicates that the Controller is operating in the **Manual Mode**.
	Baby Indicator	Indicates that the Controller is operating in the **Baby Mode**.
2	**Mode** Select Key 	Press to select either **Pre-Warm, Manual** or **Baby Mode** of operation.
3	**Skin Temp Probe** Connector	Accepts Skin Temperature Probe for monitoring infant skin temperature. When connected, the **Baby Temperature** Display indicates the temperature sensed by the probe. When probe is disconnected, the **Baby Temperature** Display is blank. When disconnected in **Baby** Mode, a **Probe** Alarm also occurs.
4	**>37 °C** Key 	Press to place **Set Temperature** Display (refer to Item 9) in Temperature Override Mode, >37 °C (98.6 °F). ***NOTE:*** *This Key is inactive until the **Set Temperature** has been set to 37 °C.*
5	**>37 °C** Indicator	Lights to indicate that the Temperature Override Mode, >37 °C (98.6 °F), has been selected.
6	**Keypad Lock** Key 	Press to disable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys (refer to Items 2, 4 and 8). Press again to enable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys. Key lights to indicate that Keypad is locked.
7	**Exam Light** Key 	Press to turn on or turn off the Examination Light located in the Warmer Module.
8		**Manual Mode** Press the Up Arrow Key to raise heater power from 0% to 100% in 10% increments (refer to Item 11, **Heater Power** Display). Press the Down Arrow Key to lower relative heater power from 100% to 0% in 10% increments (refer to Item 11, **Heater Power** Display).

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

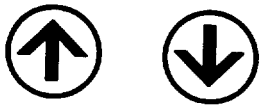
ITEM	NAME	DESCRIPTION
8		**Baby Mode** Press the Up Arrow Key to raise the Set Temperature from 34.0 °C (93 °F) to 37.0 °C (98.6 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to raise the Set Temperature from 37.0 °C (98.6 °F) to 38.0 °C (102.2 °F). Press one time to raise the Set Temperature in 0.1° increments. Press and hold to raise the Set Temperature rapidly. Press the Down Arrow Key to lower the Set Temperature from 37.0 °C (98.6 °F) to 34.0 °C (93 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to lower the Set Temperature from 38.0 °C (102.2 °F) to 34.0 °C (93 °F). Press one time to lower the Set Temperature in 0.1° increments. Press and hold to lower the Set Temperature rapidly. ***NOTE:*** *The Up/Down Arrow Keys may be locked by pressing the Keypad Lock Key (refer to Item 6).*
9	**Set Temperature** Display	In **Baby Mode,** displays the **Set Temperature** as selected by the Up/Down Arrow Keys (refer to Item 8) and in °C or °F as selected by the **°C/°F** Key (refer to Item 12). Display is blank in **Pre-Warm** and **Manual** Modes.
10	**Power** Key 	Press to turn on or turn off the Controller and Warmer Module.
11	**Heater Power** Display	Displays relative heater power in 10% increments from 0% to 100%.
12		Press to alternately select °C or °F for the **Baby Temperature** and **Set Temperature** Displays.
13	**Baby Temperature** Display	Digital display of infant temperature in °C or °F (refer to Item 12), whether in **Manual, Pre-Warm** or **Baby Mode.** The display is blank if the Skin Temperature Probe (refer to Item 3) is disconnected from the Controller.

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
14	**Silence/Reset** Key 	In **Manual Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Resets **Chk Patient** (refer to Item 16), restores heater power and silences Audible Alarm at any time after 10 minutes of warmer operation. Resets **Chk Patient** (refer to Item 16), silences Audible Alarm and restores heater power after15-minutes of continuous operation is complete. In **Baby Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Press to silence **Baby Temp** (refer to Item 16) Alarm for 10 minutes. During non-alarm conditions, press to enter Procedural Silence (refer to Item 15).
15	**Procedural Silence** Indicator 	When illuminated, indicates that the unit is in Procedural Silence. Procedural silence interval is 5 minutes. During Procedural Silence, the **Baby Temp** Alarms are blocked.
16	**Alarms** **Baby Temp**	The **Baby Temp** Indicator will flash with a three-level audible alarm to indicate that the baby's skin temperature is 1 °C above or below the selected Set Temperature (refer to Item 9). Press **Silence/Reset** Key to silence alarm for 10 minutes.
	High Temp	The **High Temp** Indicator will flash, the audible alarm will sound continuously, and the heater will be turned off when the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C. High Temp (39.0 °C) Alarms can only be silenced for two minutes by the Silence/Reset Key. Press the **Silence/Reset** Key to silence the audible alarm for 2 minutes. When the temperature falls to 38.5 °C, the alarm will automatically reset.
	Probe	When in **Baby Mode**, if the Skin Temperature Probe fails (open probe), the **Probe** Indicator will flash and a three-level audible alarm will sound. After the Alarm condition is corrected (the Skin Temperature Probe is replaced), the alarm will automatically reset. Also refer to Table 5.1. When in **Baby Mode**, if the Skin Temperature Probe fails (shorted probe), the **System Fail** Indicator will light and an audible alarm will sound. This Alarm cannot be Silenced. The **Power MUST BE TURNED OFF then ON** to Reset the Alarm condition.

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
16	**Alarms (Cont.)**	
	Chk Patient	When in the **Manual** Mode, if the warmer is in operation for longer than 10 minutes, the **Chk Patient** Indicator will illuminate and the audible alarm will sound one time. Thereafter, the **Chk Patient** Indicator will remain on and the audible alarm will sound every 30 seconds for the next 5 minutes. If at the end of 5 minutes (15 minutes total) the alarm has not been acknowledged by pressing the **Silence/Reset** Key (refer to Item 14), the warmer will be shut down.
	System Fail	When an internal malfunction is detected, the **System Fail** Indicator will illuminate and the audible alarm will sound continuously. In addition, an Error Code (Er00 to Er025) will be displayed in the **Baby Temperature** Display. When a malfunction is detected, the Controller will automatically perform the self-test function (refer to para. 4.2 Step 3) to determine if the fault has corrected itself. If the fault has not corrected itself, the error code will be displayed until corrected. This alarm is not resettable and the unit should be referred to qualified service personnel. ***NOTE:*** *Error code 023 may be corrected by the Operator, refer to Table 5.1.*
	Power Fail	When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. Push the **Power** Key to silence the Alarm.
17	**Apgar Timer**	When the **Apgar Timer** (refer to Item 18) is running, the Apgar Timer displays elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar Time intervals.
18	**Stop/Start** 	Press to start or stop the **Apgar Timer**.
	Reset 	When timer is running, press to reset the timer to zero and restart the Apgar count. When timer is stopped, press to turn timer off. ***NOTE:*** *The Timer can be reset any time.*

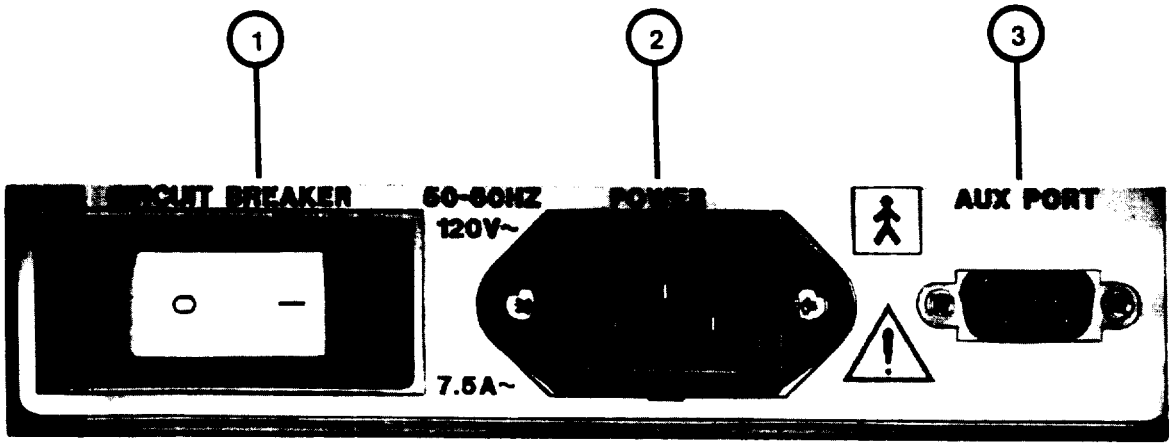


FIGURE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

TABLE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	CIRCUIT BREAKER	Turns Controller on and off when switched by operator or the presence of excessive current drain is detected.
2	POWER	Accepts ac power cord. Accepts 40-inch power cord on VHA units
3	AUX PORT	Data port for connection to printer or host system.

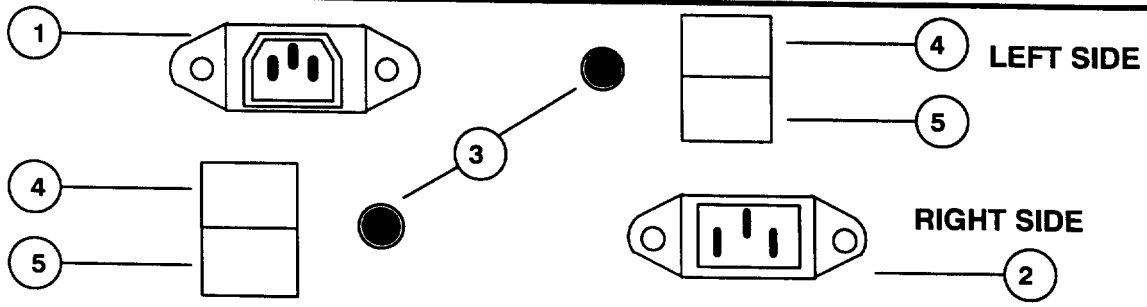


FIGURE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS LOCATED ON BOTH SIDES OF LOWER POST

TABLE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	POWER OUT	Accepts 40-inch ac power cord.
2	POWER IN	Accepts ac power cord.
3	CIRCUIT BREAKER	Turns Actuator off when presence of excessive current drain is detected. Press to reset.
4	UP SWITCH	Press to raise Upper Post
5	DOWN SWITCH	Press to lower Upper Post

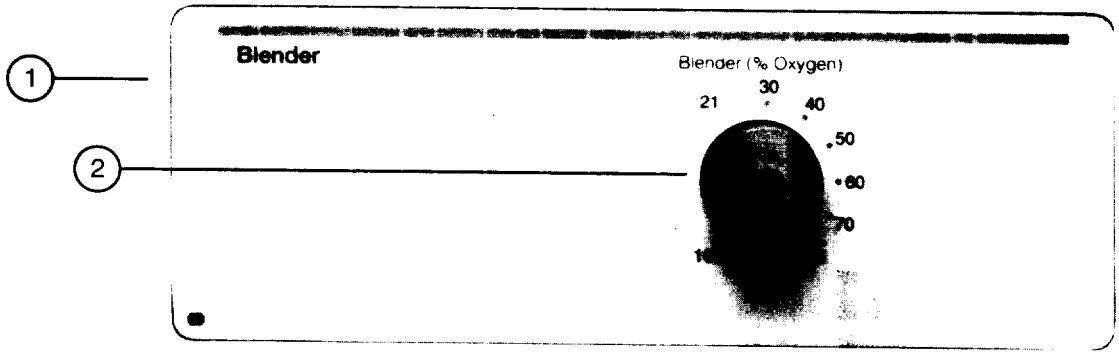


FIGURE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

TABLE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

ITEM	NAME	DESCRIPTION
1	**Blended Gas Supply Module (Optional)**	
2	**Blender % Oxygen** Control	Blends air and oxygen mixture from 21 to 100% O_2.

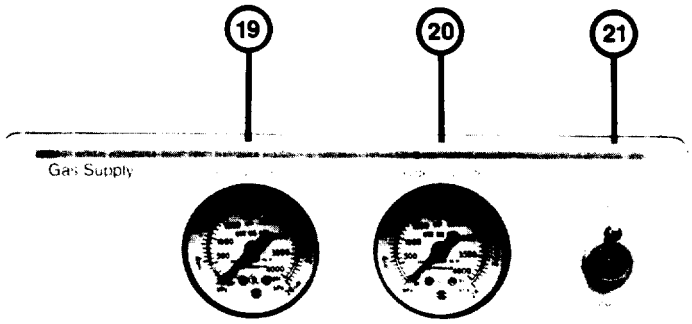


FIGURE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

TABLE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

ITEM	NAME	DESCRIPTION
	Supply Pressure (Optional)	
19	**Air Cylinder** Gauge	**Provides indication of air cylinder supply pressure 0 to 4000 psi (275.8 bar).**
20	**Oxygen Cylinder** Gauge	**Provides indication of oxygen cylinder supply pressure 0 to 4000 psi (275.8 bar).**
21	**Gas Supply On/Off** Switch	Turns gas supply to pneumatic system on and off.

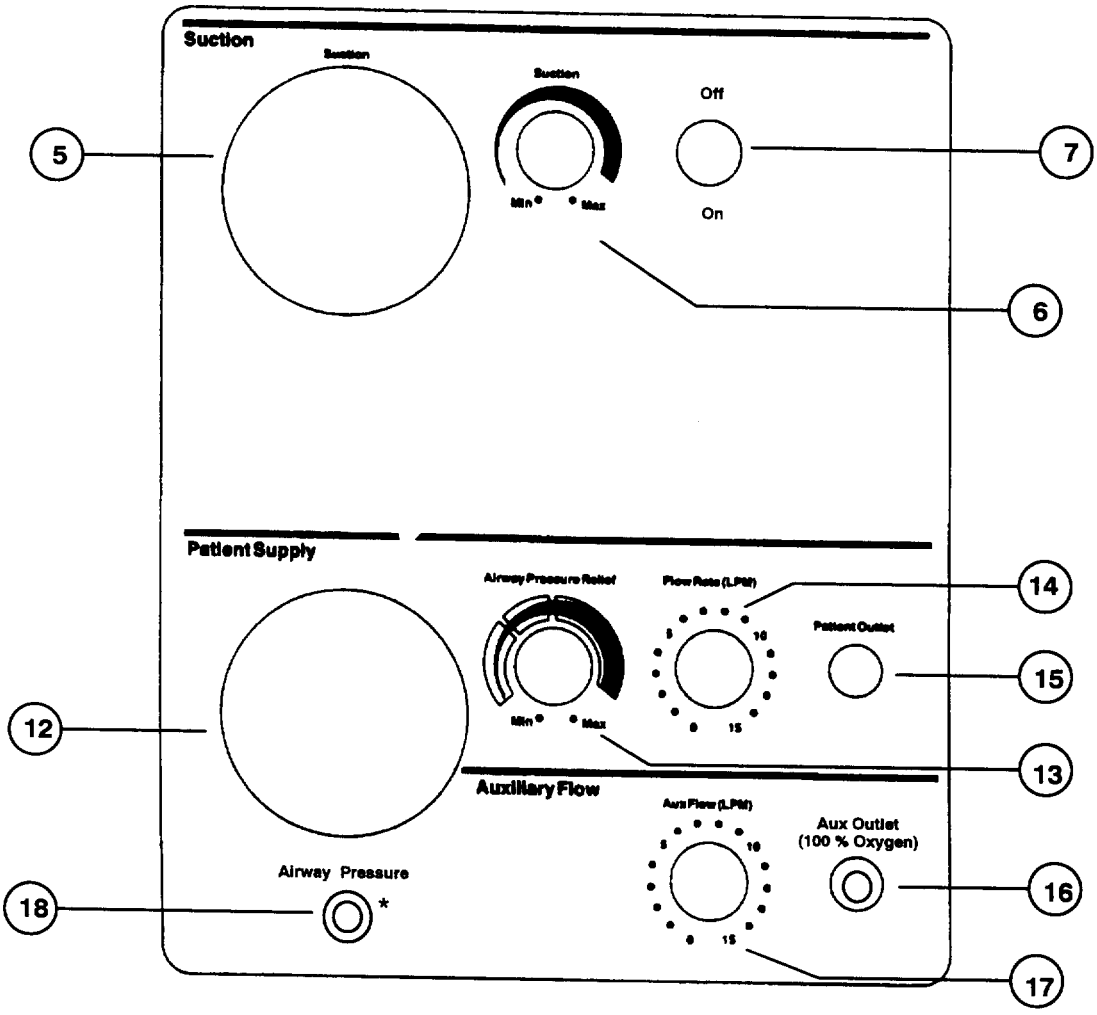


FIGURE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Suction	
5	**Suction** Gauge	Displays suction level from 0 to 200 mmHg of vacuum.
6	**Suction Min Max** Control	Adjusts suction level from 0 to 150 mmHg of vacuum.
7	**On/Off** Switch	Turns **Suction** on and off.
	Patient Supply	
12	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.
13	**Airway Pressure Relief Min Max** Control	Adjusts airway pressure relief setting from 0 to 50 cm H_2O.
14	**Flow Rate (LPM)** Control	Adjusts patient gas flow from 0 to 15 LPM. Delivers blended gas if blender option is incorporated.
15	**Patient Outlet** Connector	**Accepts breathing circuit.**
	Auxiliary Flow	
16	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
17	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
18	**Airway Pressure Port**	Connects Airway Pressure Gauge to Patient Circuit.

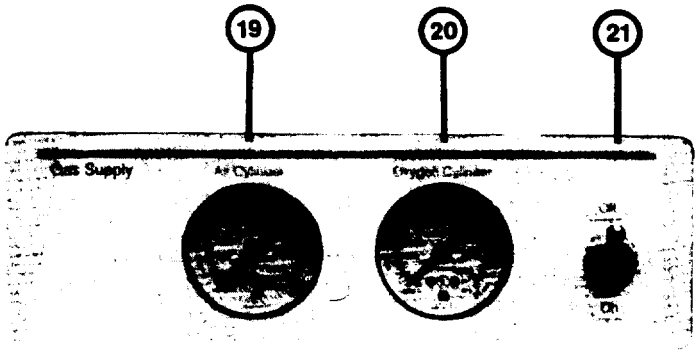


FIGURE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

TABLE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

ITEM	NAME	DESCRIPTION
	Supply Pressure (Optional)	
19	**Air Cylinder** Gauge	**Provides indication of air cylinder supply pressure 0 to 4000 psi (275.8 bar).**
20	**Oxygen Cylinder** Gauge	**Provides indication of oxygen cylinder supply pressure 0 to 4000 psi (275.8 bar).**
21	**Gas Supply On/Off** Switch	Turns gas supply to pneumatic system on and off.

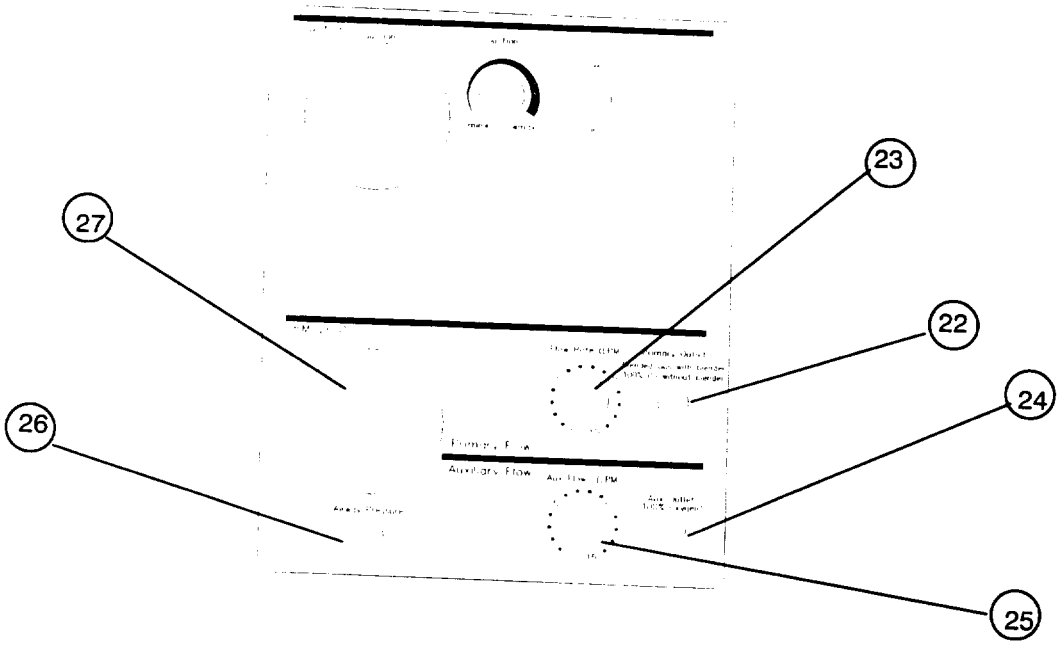


FIGURE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Primary Flow	
22	**Primary Outlet**	Accepts primary gas delivery line. Delivers blended gas if blender option is installed: 100% oxygen if no blender installed.
23	**Flow Rate (LPM)** Control	Adjusts primary gas flow from 0 to 15 LPM
	Auxiliary Flow	
24	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
25	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
26	**Airway Pressure Port**	Connect Airway Pressure Gauge to Patient Circuit.
27	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.

4.2 OPERATIONAL CHECKOUT PROCEDURE - CONTROLLER

WARNING: The Warmer should not be used if the Controller fails to function as described below. Service should be referred to qualified personnel.

CAUTION: **HEAVY EQUIPMENT: To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport. Use the handle when moving the equipment.**

IMPORTANT: *Before attempting to perform this procedure, refer to Paragraph 4.1, Controls, Indicators and Connectors.*

NOTE: *The Operational checkout procedure described below should be performed before the equipment is first put into service, then at least weekly.*

1. **CONNECT THE AC LINE CORD TO THE POWER CONNECTOR** on the Controller Rear Panel.

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

2. **CHECK THE POWER FAILURE ALARM.** Turn off the **CIRCUIT BREAKER** on the Rear Panel. Turn on the **Power** Switch on the Front Panel. The **Power Fail** Indicator should come on and the Audible alarm should sound. Turn off the **Power** Switch and turn on the **CIRCUIT BREAKER.**

NOTE: *The unit must be connected to the ac line for at least eight minutes before the **Power Fail** circuitry becomes active.*

3. **CHECK THE SELF-TEST FUNCTION.** Turn on the **Power** Switch, the Self-Test Function should be initiated and the following should occur:
   - **Apgar Timer, Baby Temperature** and **Set Temperature** Digital Displays show all eights
   - All **Alarms** Indicators light (except **Power Fail**)
   - All **Mode** Indicators light
   - The **> 37 °C** Indicator lights
   - All ten segments of the **Heater Power** Indicator light
   - The Procedural Silence Indicator lights
   - The **Keypad Lock** Switch lights
   - The audible alarm will sound a high pitch tone, a low pitch tone, then a beep-beep-beep

   When the Self-Test Function is complete, the Controller should begin operating in the **Pre-Warm Mode**.

4. **CHECK THE PRE-WARM MODE.** The **Pre-Warm** Indicator should be on and the **Heater Power** Indicator should display 10 segments (100%) for three minutes, reduce to 6 segments (60%) for 12 minutes, then reduce to 3 segments (30%).

5. **CHECK THE MANUAL MODE.** Select **Manual Mode** by pressing the **Mode** Select Key. The **Manual** Indicator should light.
   Press the Up Arrow Key until all the **Heater Power** Display segments are lit. Press the Down Arrow key until all the **Heater Power** Indicators are off. Connect the skin temperature probe to the **Skin Temp Probe** Connector, the **Baby Temperature** Display should come on.

   Set the **Heater Power** Indicator to 100%, all segments are lit. Wait 10 minutes. After 10 minutes have elapsed, the **Chk Patient** Indicator should come on and the audible alarm should sound one time. Wait an additional 5 minutes. During this time, the audible alarm should sound at 30-second intervals. At the end of 5 minutes (15 total), the heater should shut down, the **Heater Power** Indicators should go off and the audible alarm should sound continuously and ramp up in volume. Press the **Silence/Reset** Key, the **Chk Patient** Indicator and audible alarm should go off, the heater power should return and all ten **Heater Power** Indicators should illuminate.

6. **CHECK THE KEYPAD LOCK.** Press the **Keypad Lock** Switch. The **Keypad Lock** Switch should light up. The **Mode** Key and the Up/

Down Arrow Keys Key should be inoperative. Press the Keypad Lock Switch. The **Keypad Lock** Switch Light should go off and the Keypad should be enabled.

7. **CHECK THE BABY MODE.** Select **Baby Mode** by pressing the Mode Select Key. The **Baby** Indicator should light and the **Set Temperature** Display should activate. In addition, the **Baby Temp** Indicator should flash and the audible alarm should sound (if the temperature and set point are more than 1° C apart) Press the **Silence/Reset** Key, the audible alarm should go off, the **Baby Temp** Indicator should become steady on.

8. **CHECK TEMPERATURE OVERRIDE MODE.** Press the Up Arrow Key to raise the **Set Temperature** to 37.0 °C. Press the **>37 °C** Key, the **>37 °C** Indicator should come on. Press the Up Arrow Key to raise the **Set Temperature** to 38.0 °C.

   Press the Down Arrow Key to lower the **Set Temperature** to below 37.0 °C. When the **Set Temperature** falls below 37.0 °C, the **>37 °C** Indicator should go off.

9. **CHECK THE PROBE ALARM.** Disconnect the skin temperature probe from the **Skin Temp Probe** Connector. The **Baby Temperature** Display should go off, the **Probe** Indicator should flash and the audible alarm should sound. Replace the probe.

10. **CHECK THE APGAR TIMER.** Press the **Start /Stop** Key, the **Apgar Timer** Display should come on and begin to count up from zero seconds. Press the **Start/Stop** Key, the **Apgar Timer** count should stop. Press the **Reset** Key, the **Apgar Timer** Display should go off.

11. **CHECK THE EXAMINATION LIGHT.** Press the **Exam Light** Switch. The Examination Light should come on. Press the Exam Light Switch, the Examination Light should go off.

4.3 MECHANICAL CHECKOUT

1. **CHECK THE MATTRESS TILT CONTROL** (Figure 4.4) by pulling up on the lever located at the bottom rear of the Bassinet while supporting the rear lower edge of the Bassinet with the palm. Place the Bassinet in the 5-degree and then the 10-degree tilt position. Return the Bassinet to the level position.

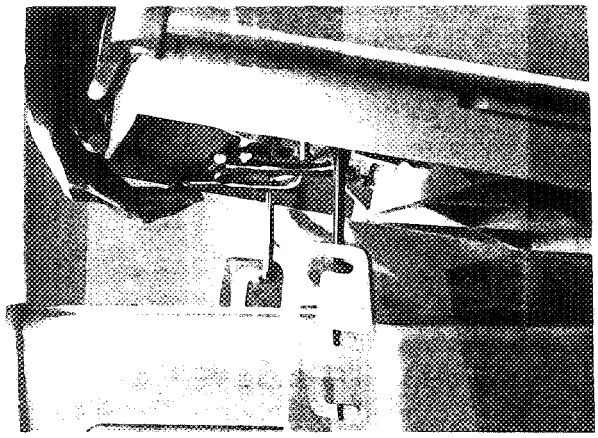


FIGURE 4.4 BASSINET TILT CONTROL

2. **CHECK THE BASSINET SIDE PANELS** (Figure 4.5) by raising each panel and pivoting it to hang straight down. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

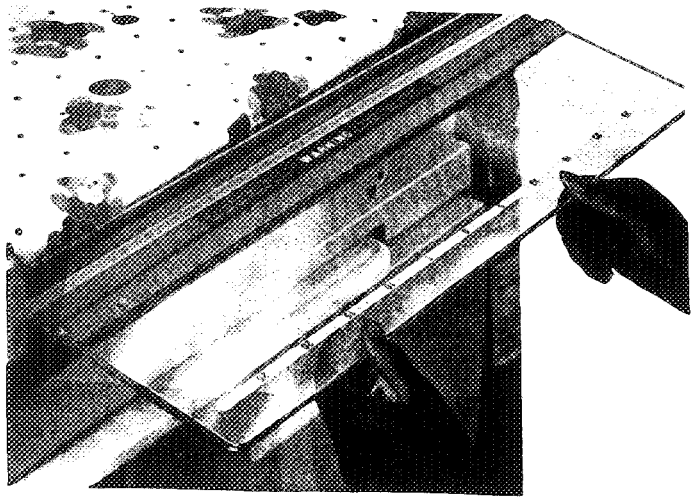


FIGURE 4.5 CHECKING THE BASSINET SIDE PANELS

3. **CHECK THE BASSINET FRONT PANEL** (Figures 4.6 and 4.7) by raising the panel and and sliding it under the mattress. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

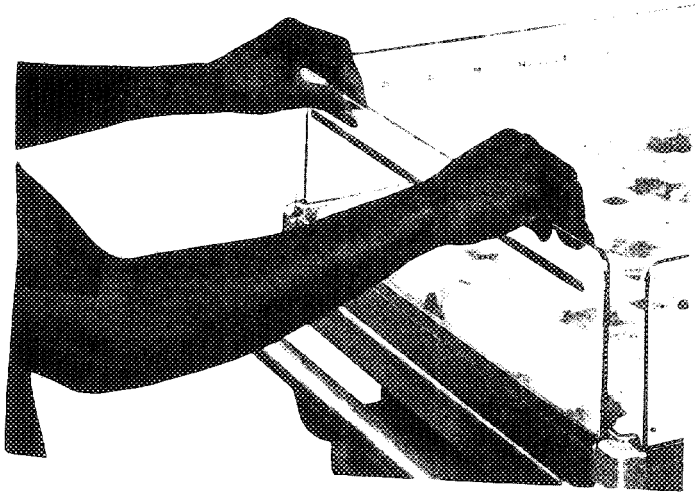


FIGURE 4.6 CHECKING THE BASSINET FRONT PANEL

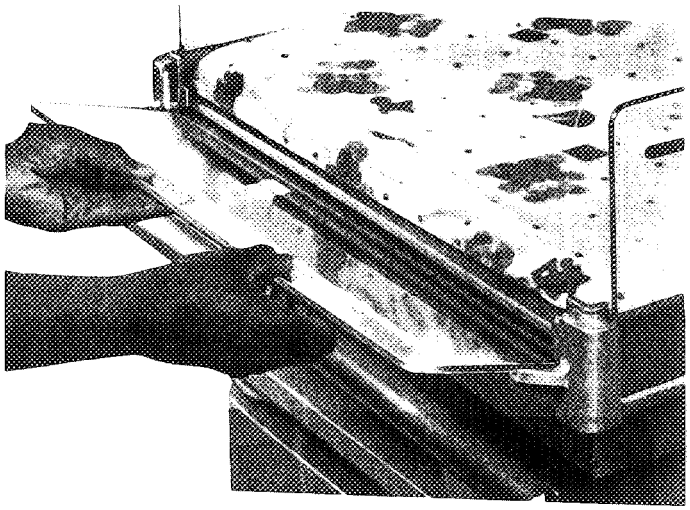


FIGURE 4.7 CHECKING THE BASSINET FRONT PANEL

4. **CHECK THE PASS-THROUGH DRAWER** (Figure 4.8) by sliding the drawer in and out on both sides of the Bassinet. Return to center position.

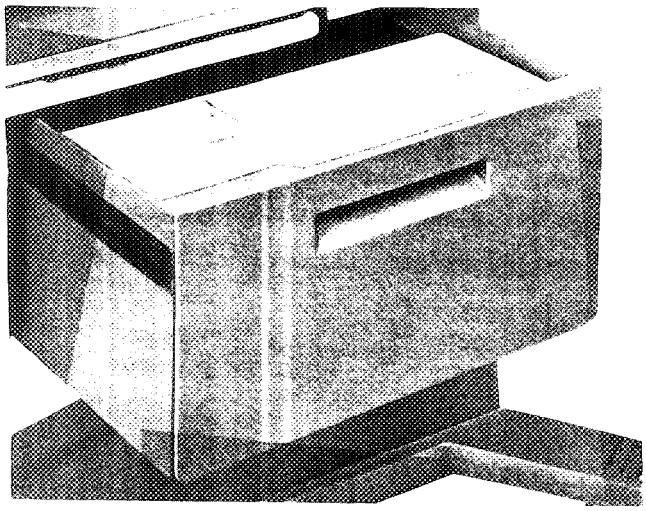


FIGURE 4.8 CHECKING THE PASS-THROUGH DRAWER

5. **CHECK THE WARMER MODULE SWIVEL OPERATION** (Figure 4.9) by rotating the Warmer Module 90 degrees to the left or right of center. Return to center position.

WARNING: When the Warmer Module is swiveled and energized, objects (Monitors etc.) located on the optional Monitor Shelf may overheat or become hot to the touch.

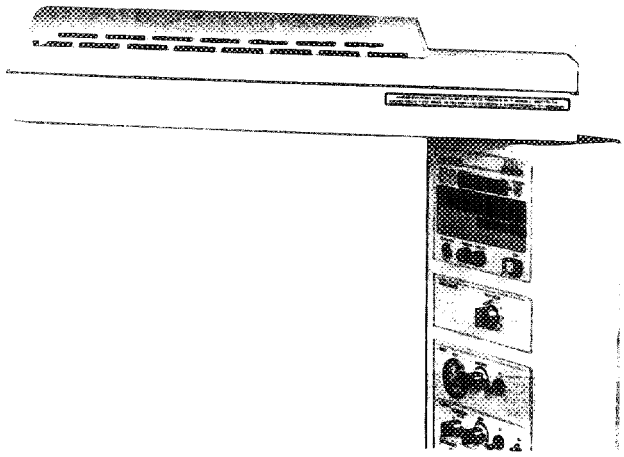


FIGURE 4.9 CHECKING THE WARMER MODULE SWIVEL

6. **CHECK THE OPERATION OF THE X-RAY CASSETTE TRAY (ACCESSORY)** (Figure 4.10) by pulling up the middle of a Side Panel and pulling the X-ray Cassette Tray out from under the Bassinet. Replace the X-ray Cassette Tray by reversing the procedure.

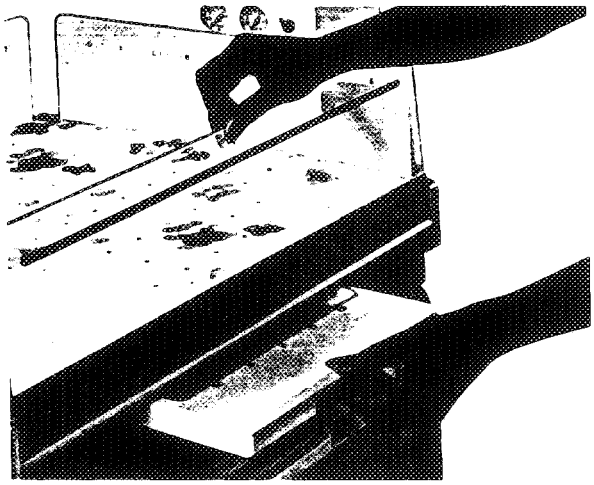


FIGURE 4.10 CHECKING THE X-RAY TRAY

7. **CHECK THE INSTRUMENT TRAY (ACCESSORY)** (Figure 4.11) by swinging it out from under the Bassinet.

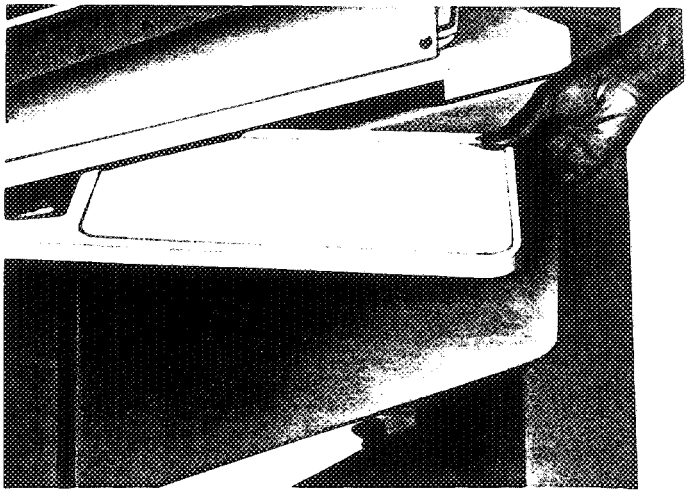


FIGURE 4.11 CHECKING THE INSTRUMENT TRAY

8. **CHECK THE VHA** by pressing the upper portion of the Switch on the right side of the Lower Post until the Upper Post raises to its maximum height. Press and hold the lower portion of the Switch until the Upper Post lowers to its minimum height. Repeat the procedure using the Switch on the left side of the Lower Post. Verify the Upper Post operates smoothly and re-adjust to desired height.

CAUTION: **Always lower the Resuscitaire® Radiant Warmer VHA to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.**

9. **CHECK BASSINET TILT CONTROL Operation as follows (VHA) only)*:**

a. Turn the Bassinet Tilt Control clockwise (Figure 4.11A) until the Bassinet Foot End is fully raised and comes to a stopl.

b. Turn the Bassinet Tilt Control counterclockwise until the Bassinet Head End is fully raised and comes to a stop.

c. Return the Bassinet to the horizontal position.

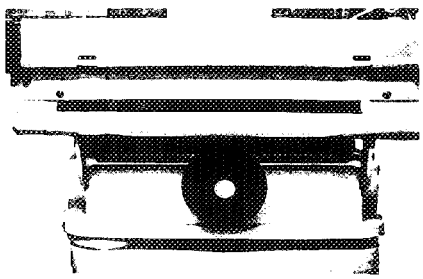


FIGURE 4.11A CHECKING THE BASSINET TILT CONTROL (VHA ONLY)

4.4 RESUSCITATION EQUIPMENT PRE-USE CHECKOUT/SET-UP

SUPPLY PRESSURE

1. Ensure that O_2 (and AIR) pipeline(s) are securely attached to appropriate fittings on the rear of the unit and that the gas supply present is 40 to 75 psi.

If using Reserve Gas Supply from cylinders:

2. Ensure that cylinder(s) are properly secured in the mounting yokes on the rear of the warmer and that the cylinder valve located on the top of the cylinder is open.
3. Examine the appropriate cylinder pressure gauges on the front of the upper column to ensure that sufficient reserve gas supply is present.

*Not available in USA or Canada.

4. Set the **Gas Supply On/Off** Switch to the On position.

BLENDED GAS SUPPLY (Optional)

LOW FLOW MICROBLENDER WARNINGS

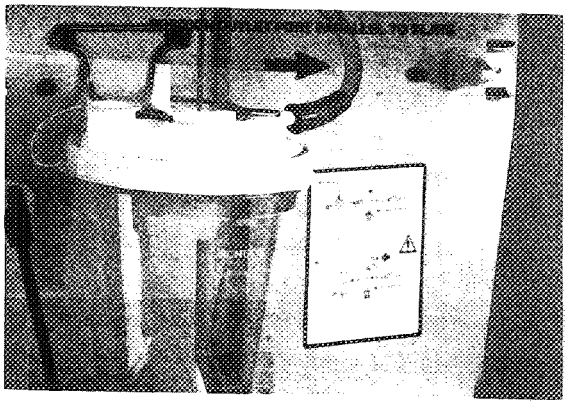
- **If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FIO_2 and flow output from the microblender.**
- **Always operate the low flow microblender with clean/dry medical grade gases.**
- **Air inlet water filters are recommended for use with the low flow microblender.**
- **The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.**

1. If present, set the precision blender to the desired oxygen % concentration using the Blender Control Knob.

RESUSCITATION MODULE (Optional)

SUCTION

NOTE: *To obtain suction, the **Gas Supply On/Off** Switch (Figure 4.3C) must be **ON**.*



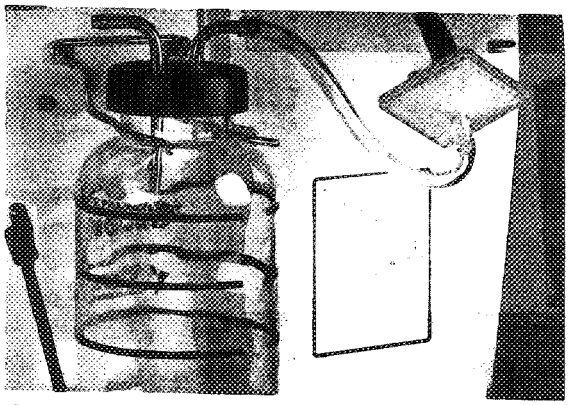


FIGURE 4.12 CHECKING THE SUCTION BOTTLE

NOTE: *The filter and tubing resistance will not affect the desired maximum value that is set in Step 5 below. The pressure value on the Suction Gauge matches the actual pressure value at the end of the catheter.*

5. Block the patient outlet of the suction bottle. Adjust the suction magnitude using the **Suction Min Max** Control while viewing the suction level on the **Suction** Gauge. Adjust the suction magnitude to the desired maximum suction pressure value.
6. Turn off the **Suction On/Off** Switch.

1. Check that a clean suction bottle (reusable or disposable, Figure 4.12) is installed and properly connected in the Resuscitation Equipment Storage Compartment at the front of the warmer.

CAUTION: When installing the disposable Suction Bottle: to prevent the suction tube from being blocked or damaged, position the Outlet Port parallel to the plate (Figure 4.12).

2. Ensure that a bacterial filter is connected in-line with the supply connection to the reusable suction bottle (a filter is built-in on the disposable bottle).

3. Connect the desired extension tubing to the outlet of the suction bottle outlet port (refer to Figure 3.1) and secure the free end of the extension tubing in either tubing retaining slot provided on the front panel of the Bassinet.

4. Turn on the **Suction On/Off** Switch. There may be an initial reading of up to 30 mmHg on the Suction Gauge (refer to Figure 3.1) due to flow resistance of the hydrophobic filter and suction tubing.

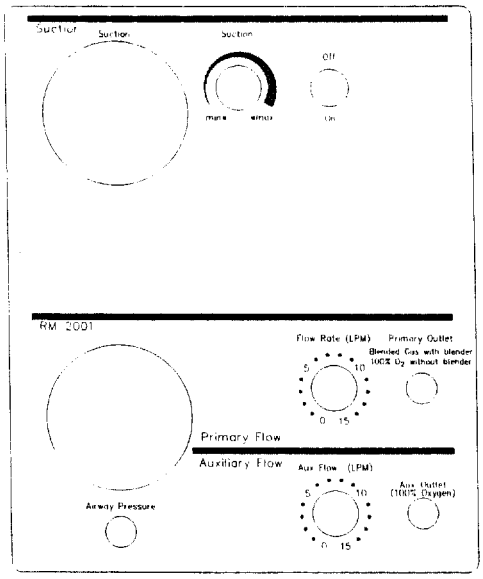


FIGURE 4.13 RESUSCITATION MODULE 2001

RESUSCITATION MODULE 2001 (Optional)

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

PRIMARY FLOW (provides blended gas if optional blender is installed; 100% oxygen if no blender is installed)

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the desired device to be supplied by the **Primary Flow** circuit to the **Primary Outlet** connector.
2. Adjust desired primary flow using the Primary **Flow Rate (LPM)** control and check flow.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

AIRWAY PRESSURE

Airway Pressure fitting may be used to measure airway pressure during mechanical resuscitation.

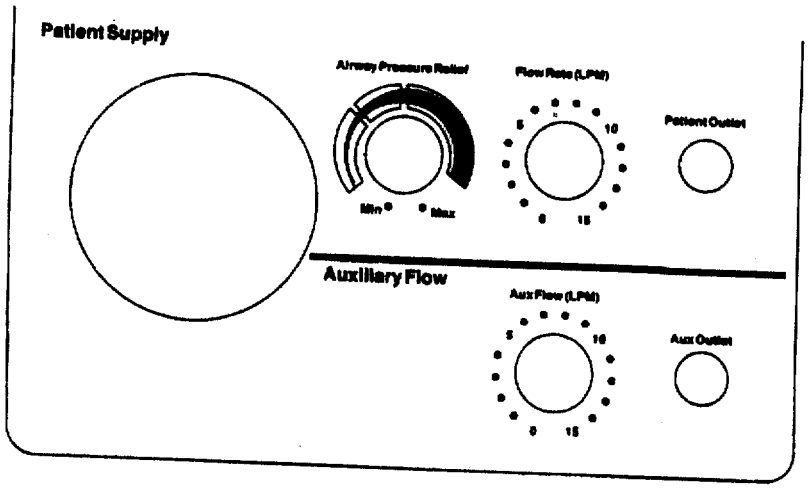


FIGURE 4.14 RESUSCITATION MODULE (PATIENT SUPPLY)

RESUSCITATION MODULE (Optional) Patient Supply

Manual Resuscitation - Use with Patient Breathing Circuit - 10 mm tubing with thumb (finger) hole at patient end.

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the Patient Circuit to the **Patient Outlet** (refer to Figure 4.4).
2. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
3. Set the **Airway Pressure Relief** control to the desired pressure limit according to the color coded bands on the **Airway Pressure** Gauge and **Airway Pressure Relief** Control. Alternately, a "T" Fitting with an airway pressure monitor can be inserted into the **Patient Outlet** Port and connected to the **Airway Pressure** Port to indicate the breathing circuit pressure. Adjust the **Airway Pressure Relief** Control as necessary.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

4.5 CONTROLLER OPERATION

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital-use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

Connect the unit to the ac line. Turn on the **CIRCUIT BREAKER** on the Rear Panel and the **Power** Switch on the Front Panel. Observe the Functional Test.

4.5.1 PRE-WARM MODE

After the Functional Test is complete, the **Pre-Warm Mode** will activate. The **Heater Power** Indicator will be at 100% (all lights on) for three minutes, reduce to 60% (six lights on) for 12 minutes and then be reduced to 30% (three lights on).

NOTE: *Selection of **Manual** or **Baby** and then returning to **Pre-Warm** during the three minutes of 100% or 12 minutes of 60% power will automatically reduce the power to 30%.*

During **Pre-Warm** Mode, the **Chk Patient** Alarm is disabled.

4.5.2 MANUAL MODE

WARNING:

To avoid overheating or underheating, observe the infant constantly and monitor the temperature using the skin temperature probe supplied with the equipment or other electronic thermometer.

Inspect infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Use the Mode key to select **Manual Mode**.
2. Use only for short-term warming with nursing personnel in constant attendance.
3. Do not use warmer in **Manual Mode** if **Manual** Indicator is not on.
4. Set the **Heater Power** Indicator to the desired level. The heater power will be maintained for 10 minutes.
5. After 10 minutes, the **Chk Patient** Alarm will sound one time. Press the **Silence/Reset** Key to initiate another 10-minute warming period.
6. If the **Chk Patient** Alarm is not acknowledged, the heater will be automatically disabled after an additional 5 minutes of operation.
7. Heater power output must be adjusted manually to maintain Baby Temperature within the desired range.
8. Check infant's temperature and condition at least every 15 minutes. When initially setting or when changing heater power output, check Baby Temperature more frequently to be sure it is maintained within the desired range.

CAUTION: A change in heater power output will not result in an immediate change in Baby Temperature. Wait for results. Large changes in heater power output will cause a more rapid change in Baby Temperature.

9. Use Skin Temperature Probe to continuously monitor Baby Temperature whenever possible. Refer to paragraph 4.5.3 to attach the probe to the patient.

IMPORTANT: *In **Manual Mode**, the Skin Temperature Probe monitors only -- it does not control.*

NOTE: *It is not necessary that the Skin Temperature Probe be connected to the Controller for **Manual Mode**.*

4.5.3 BABY MODE

WARNING:

To avoid hazards of overheating or underheating, the infant should not be left unattended. Use only with the Hill-Rom Air-Shields' Skin Temperature Probe supplied with the unit. Inspect the infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Plug Skin Temperature Probe into Controller **Skin Temp Probe** Connector.

2. Use the Mode key to select **Baby Mode**.

3. Attach the Skin Temperature Probe to the infant. The probe should be located on the infant's abdomen, halfway between the xyphoid and the umbilicus (Figure 4.13). The metal side of the probe should be placed in direct contact with the skin (when using the reusable probe).

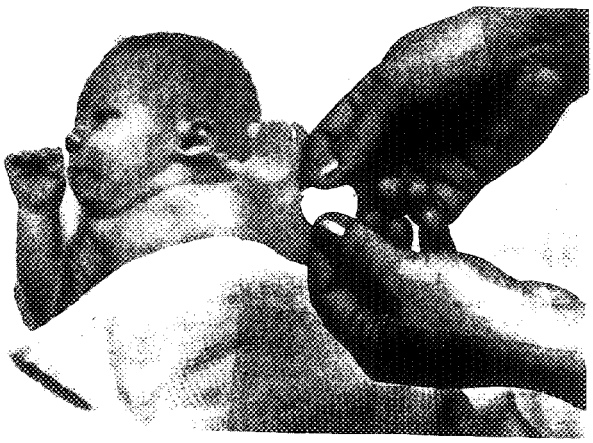


FIGURE 4.13A ATTACHING SKIN PROBE

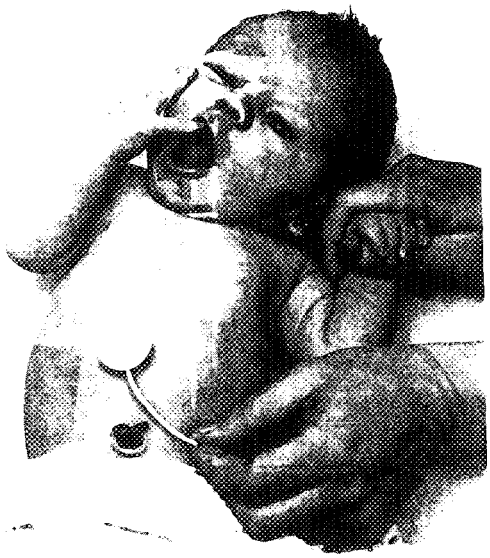


FIGURE 4.13B ATTACHING SKIN PROBE

WARNING:

The location of the Skin Temperature Probe must be such that the skin around the Sensor is in direct line with the heat from the Warmer Module. If the location is shadowed, for example, by the infant's body, overheating and possible burning of the infant's skin can result. Do not use a rectal probe. Use of a rectal probe can result in overheating or underheating of the infant.

The Skin Temperature Probe must be in intimate contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain intimate skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment and feel infant's skin for signs of overheating.

The Skin Temperature Probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The Skin Temperature Probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.

4. When the infant is prone, the Skin Temperature Probe should be located on the infant's back.

5. The skin area around the probe should be thoroughly cleansed and dried before the probe is placed on the skin.

6. To obtain an accurate reading of the infant's skin temperature, place the probe in position and cover with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or tape the probe into position, cover it with a small piece of cotton just large enough to cover the tip of the probe, and then place a second piece of tape over the cotton. If it is desired to reduce tape contact on the infant's skin, the cotton can be applied directly to the probe tip without the first piece of tape. To stabilize the attached probe, a third piece of tape may be placed over the probe wire approximately three to four centimeters from the probe tip.To minimize the effect of direct radiation on the Skin Temperature Probe, in order to obtain a more accurate **Baby Temperature** measurement, cover the Sensor with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or an equivalent insulating cover with a reflective surface facing the Warmer Module.

7. Baby Mode should be used for long-term warming and when attending personnel cannot be in constant attendance.

8. Set the **Set Temperature** Display to the prescribed temperature. A higher Set Temperature setting does not increase rapid warming.

9. Verify that **Baby Temperature** Display reading stabilizes within 0.2 °C of **Set Temperature** Display. Fluctuations in the **Heater Power** Indicators or the **Baby Temperature** Display reading can result from air currents, obstruction of radiation to the infant or the Skin Temperature Probe not being in intimate contact with the skin.

10. **Baby Temp** Alarms can be silenced for 10 minutes by pressing the **Silence/Reset** Key.

11. **Probe, High Temp** and **Baby Temp** (39.0 °C) Alarms are automatically reset after the alarm condition is corrected. The **High Temp** Alarm may be silenced for 2 minutes by pressing the **Silence/Reset** Key.

*NOTE: In the event of a **Probe** Alarm, **Manual Mode** can be used temporarily until a replacement Skin Temperature Probe is available and only if nursing personnel are in constant attendance.*

4.5.4 EXAMINATION LIGHT

The light is turned on and off by the **Exam Light** Switch. Turn the light on only as required for optimum bulb life.

4.6 X-RAY PROCEDURES

1. Swing the Warmer Module (Figure 4.9) to the right or left of center as required to position the X-ray machine.

2. Lift the Left or Right Bassinet Side Panel up, slide the X-ray Tray out (Figure 4.10); place the X-ray Cassette on the tray and return the tray to the Bassinet. Align the cassette as desired with the markings on the X-ray Cassette Tray and relative markings on the inside of the Bassinet panels.

3. When the X-ray is complete, remove the X-ray Cassette Tray and return the X-ray Tray. Place the Warmer Module in its normal operating position.

SECTION 5
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 Hill-Rom service personnel.

WARNING:

If oxygen is in use, make sure that the oxygen supply to the equipment is turned off and that it 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 cleaning and maintenance procedures; make sure that the Power Cord is disconnected from the wall receptacle.

5.2 CLEANING

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and 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

1. Remove both Bassinet Side Panels (Figure 5.1) by pulling them straight up.

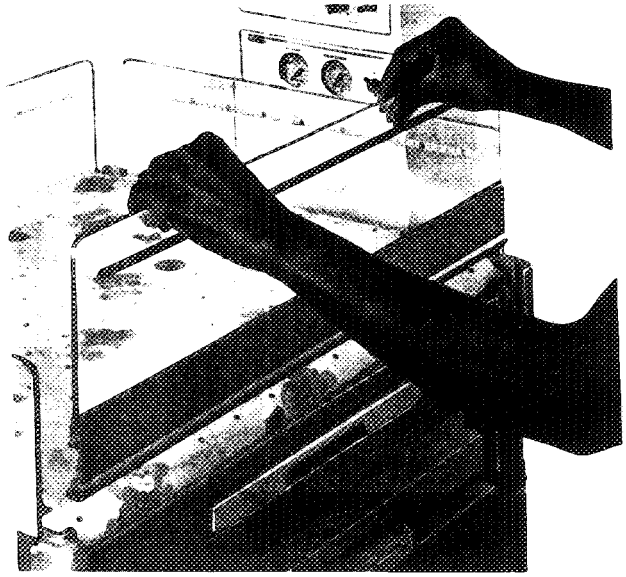


FIGURE 5.1 REMOVING BASSINET SIDE PANELS

2. Remove the Bassinet Back Panel (Figure 5.2) by raising it straight up until the bottom pins are adjacent to the slots in the corner brackets.

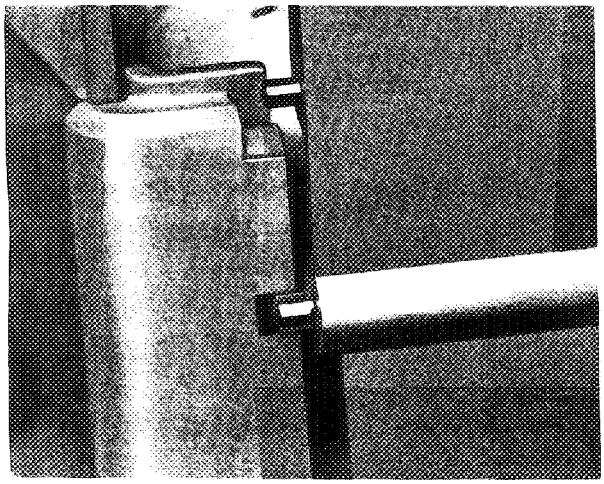


FIGURE 5.2 REMOVING BASSINET BACK PANEL

3. Remove the Bassinet Front Panel (Figure 5.3) by raising it and then swiveling it down. At the corners, press up on the release buttons and pull the panel straight out (Figure 5.4).

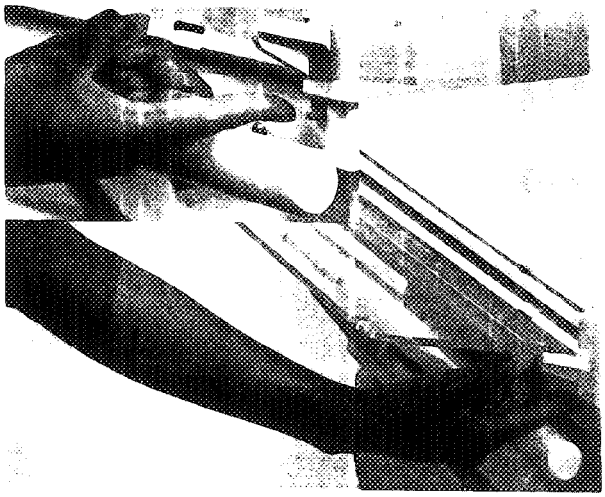


FIGURE 5.3 BASSINET FRONT PANEL RELEASE BUTTONS

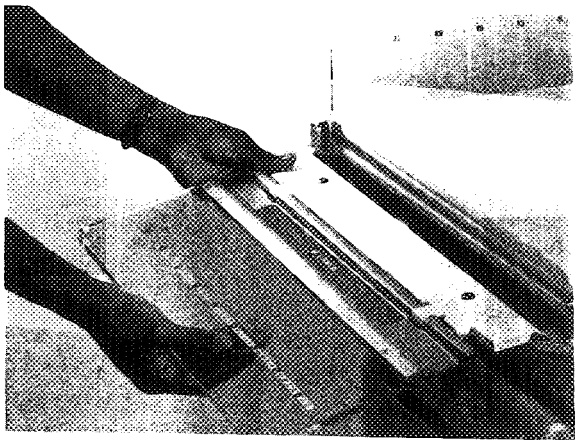


FIGURE 5.4 REMOVING BASSINET FRONT PANEL

4. Remove the Mattress from the Bassinet.

5. Remove the X-ray Tray (Figure 4.10).

6. Remove the Suction Bottle and Filter (Figure 4.12) from the front of the Bassinet.

5.4 CLEANING PROCEDURES

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and disinfected.

5.4.1 CLEANING AGENTS

An intermediate-level detergent/disinfectant registered by the U.S. Environmental Protection Agency should be used, but only when the equipment is not in use and disassembled as described elsewhere in this section. 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 PAINTED SURFACES

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

5.4.3 CLEAR PLASTIC AND ACRYLIC SURFACES

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

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.

Use a detergent/disinfectant to clean all surfaces thoroughly. Make sure to clean all holes, indentations, baffles, etc.; then dry with a clean cloth or paper towel.

5.4.4 METAL SURFACES

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

IMPORTANT: *After cleaning, a complete operational checkout should be performed before returning the unit to service.*

5.4.5 SKIN TEMPERATURE PROBE, REUSABLE

CAUTION: Do not pull on the tip of the skin temperature probe when cleaning or drying; damage to the probe may result.

Use a detergent/ to thoroughly clean all surfaces; then dry with a clean soft cloth or paper towel.

5.5 STERILIZATION (IF DESIRED)

CAUTION: DO NOT STEAM AUTOCLAVE.

Sterilization can be accomplished by the following methods:

A. COLD (LIQUID) STERILIZATION

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

B. GAS STERILIZATION (ETHYLENE OXIDE). Prior to gas sterilization, the entire unit should be thoroughly cleaned as described elsewhere in this section. Remove and discard all used disposable elements. New disposable elements should be installed after sterilization.

Standard gas sterilization procedures are satisfactory as these do not normally exceed 54.4 °C (130 °F).

IMPORTANT: *After sterilization, a complete functional checkout procedure should be performed before returning the unit to service.*

5.6 REASSEMBLY AFTER CLEANING

1. Replace the Mattress on the Bassinet.
2. Replace the X-ray Tray (Figure 4.10).
3. Replace the Bassinet Back Panel by inserting the pins in the Corner Brackets (Figure 5.2).
4. Replace the Bassinet Side Panels by pushing them straight down into their slots (Figure 5.1).
5. Replace the Bassinet Front Panel by sliding it into the front of the Bassinet (Figure 5.4) until the release tabs catch. Raise the Panel into position.
6. Install a new Suction Filter if using a Reusable Bottle (Figures 3.1 and 4.12). Replace the Suction Bottle if using a Disposable Bottle.

5.7 CALIBRATION

The equipment should be completely checked and calibrated at least once a year by qualified service personnel. Refer to the appropriate Service Manual for details.

5.8 TROUBLESHOOTING

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

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TABLE 5.1 TROUBLESHOOTING

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
No Power and **Power Fail** Alarm is not activated	a. Circuit Breaker not set to On.	a. Set Circuit Breaker to On.
Power Fail Alarm activated	a. Circuit Breaker tripped. b. Power Cord unplugged. c. Defective Power Cord.	a. Reset Circuit Breaker (Figure 4.2). b. Connect Power Cord to POWER connector (Figure 4.2) or wall socket. c. Replace Power Cord.
System Fail Alarm activated	a. Internal malfunction.	a. Refer to service.
Probe Alarm Activated	Possible Defective Skin Probe(s)	a. Check to ensure Skin Probe is in good contact with the skin. b. Replace Skin Probe(s). If condition is not corrected, refer to service.
Error Code Er02 through Er022 Er024 and Er025	a. Internal malfunction	a. Refer to service.
Error Code Er023	Ambient Temperature in excess of 32 °C (90 °F).	Verify ambient temperature with an external thermometer.

SECTION 6
PARTS LIST

6.1 GENERAL

This section provides a listing of Operator replacement parts. Parts other than those listed here should be replaced by qualified service personnel. For an illustration of accessories, refer to Figure 1.1 of this manual.

REPLACEMENT PARTS	PART NUMBER
Bassinet Side Panel (Eng)	81 900 00
Bassinet Rear Panel (Eng)	81 900 01
Bassinet Front Panel (Eng)	81 900 02
Power Cord 220/240V Units	17 AZ 204
Skin Temperature Probe (Reusable)	81 300 05
Reusable Suction Bottle Kit (750 ml) (Bottle, Stopper, Tubing and Filter)	81 001 50
Reusable Suction Bottle Only	08 131 00
Filters (Box of 25)	81 001 50
40-Inch Power Cord	17 AZ 211

DISPOSABLES	
Premi-Probe® 3 Skin Temperature Probe (Box of 10)	81 300 08
Premi-Probe® 3 Skin Temperature Probe (10 Boxes of 10)	81 300 09
Breathing Circuit Connector with Pressure Monitor Port (Box of 25)	81 001 29
Critter Covers® Probe Covers (Box of 100)	68 209 46
Critter Covers® Probe Covers (Box of 600)	68 209 45
Care-for-Me Probe Covers, 100 Large (10% discount when you order 5)	68 209 47
Care-for-Me Probe Covers, 100 Standard (10% discount when you order 5)	68 209 48
Neat Clips - 3/8" Diameter (Box of 100)	68 120 53
1.00" Diameter (50/Case)	68 120 54
Disposable Suction Bottle, 800 ml (Box of 100)	81 001 51

OPTIONS	
Instrument Tray - Right Hand	81 101 70R
Instrument Tray - Left Hand	81 101 70L
Pass-Through Drawer Organizer Tray	81 101 11
Air Hose Assembly, Green DISS	78 464 10
Oxygen Hose Assembly, Yellow DISS	78 465 10
Air Hose Assembly, Black NIST	81 501 45
Oxygen Hose Assembly, White NIST	68 507 50
Air Hose Assembly Black DISS	81 501 50
Oxygen Hose Assembly White DISS	68 507 30
Oxygen/Air Sealing Washer	81 502 02
X-ray Cassette Tray	81 100 44
IV Pole	82 001 53
Monitor Shelf	82 001 52

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NOTES

LIMITED 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 Hill-Rom Air-Shields, Inc., 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 Hill-Rom Air-Shields, Inc. cannot be held liable for conditions resultant therefrom if:

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 Hill-Rom Air-Shields, Inc.
4. Sale or service is performed by a non-certified service/dealer agency.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE. HILL-ROM AIR-SHIELDS' OBLIGATION UNDER THESE WARRANTIES SHALL NOT INCLUDE ANY LIABILITY FOR LOSS OF PROFITS, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES OR DELAYS. Some states, provinces, or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion or limitation may not apply. Any improper or negligent use, any alterations or repairs not in accordance with Hill-Rom Air-Shields' manuals or performed by others in such manner as in Hill-Rom Air-Shields' sole judgement affects the product materially and adversely, shall void these warranties. These warranties do not cover failures due to misuse, abuse, neglect, or lack of routine maintenance. No employee or representative of Hill-Rom Air-Shields is authorized to change these warranties in any way or grant any other warranty unless in writing and signed by a Hill-Rom officer. These warranties provide specific legal rights; but, there may be other available rights; which vary from state to state, province to province, or country to country.

*The Accreditation Manual for Hospitals requires each piece of equipment to be tested prior to initial use and at least annually thereafter. To comply with this standard, we recommend that you participate in our Preventive Maintenance 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. Technical Services representatives are located throughout the United States and Canada and are dispatched for required maintenance by calling USA (800) 445-3720 and Canada (800) 267-2337. Customers outside the U.S. and Canada should contact their local factory-authorized Hill-Rom Air-Shields' distributor for service.

Hill-Rom Air-Shields.
A HILLENBRAND INDUSTRY
330 Jacksonville Road, Hatboro, PA 19040

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Hill-Rom Air-Shields®
A HILLENBRAND INDUSTRY

November 15, 2000

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference: **SPECIAL 510(k)**: K9003335 Resuscitaire Radiant Warmer

Dear Madam/Sir:

Attached please find copies of the updates for 510(k) K003335. I have also faxed the updates to Ms Farah Foster (301-480-3002).

Please replace the following:

- Section III, Page 10. Revised drawing (81 400 34) Sheet 1of 2.
- Section III Pages 12-63 remove and replace with attached Operator's Manual.

Please feel free to contact me should you have any further questions or concerns.

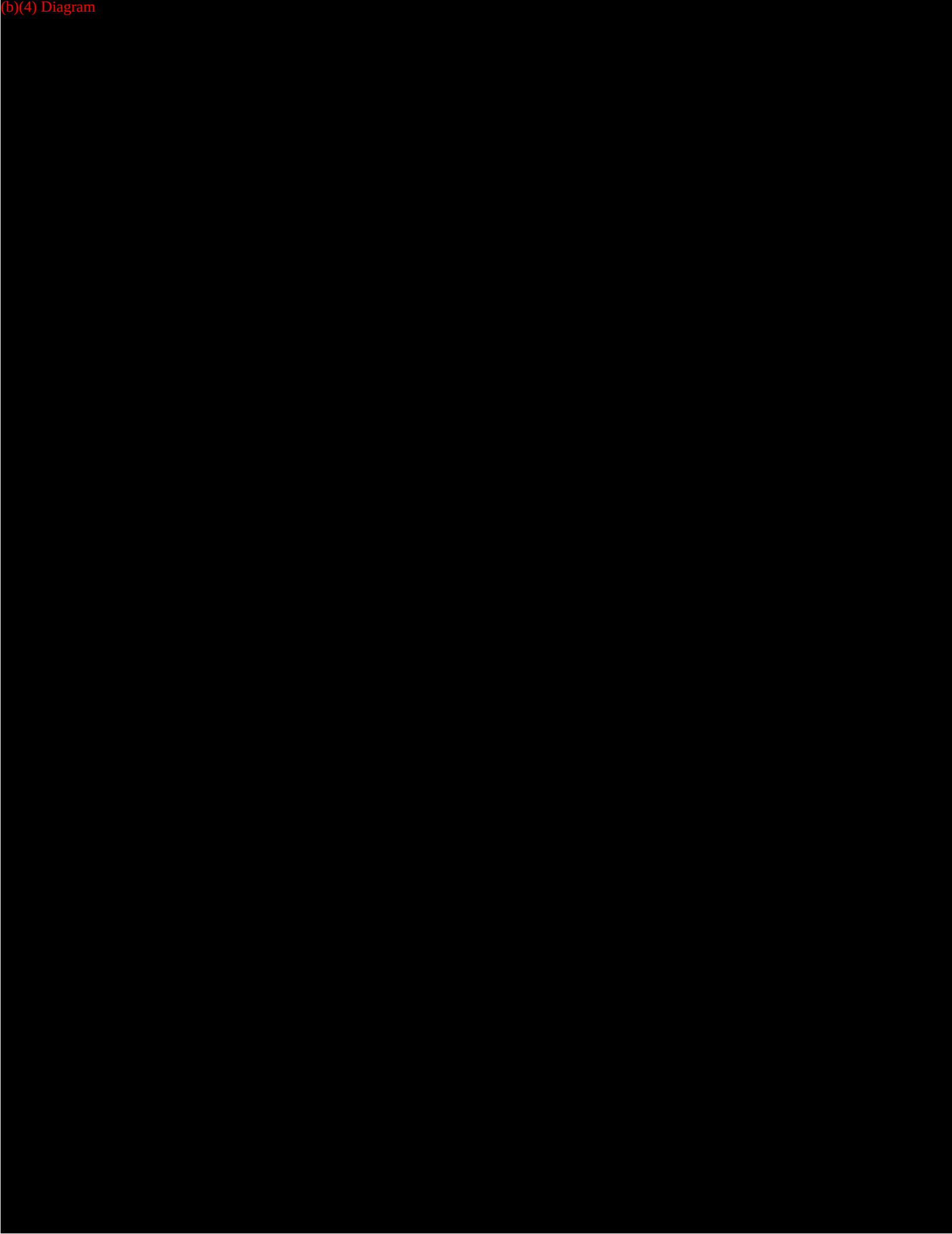
Sincerely,

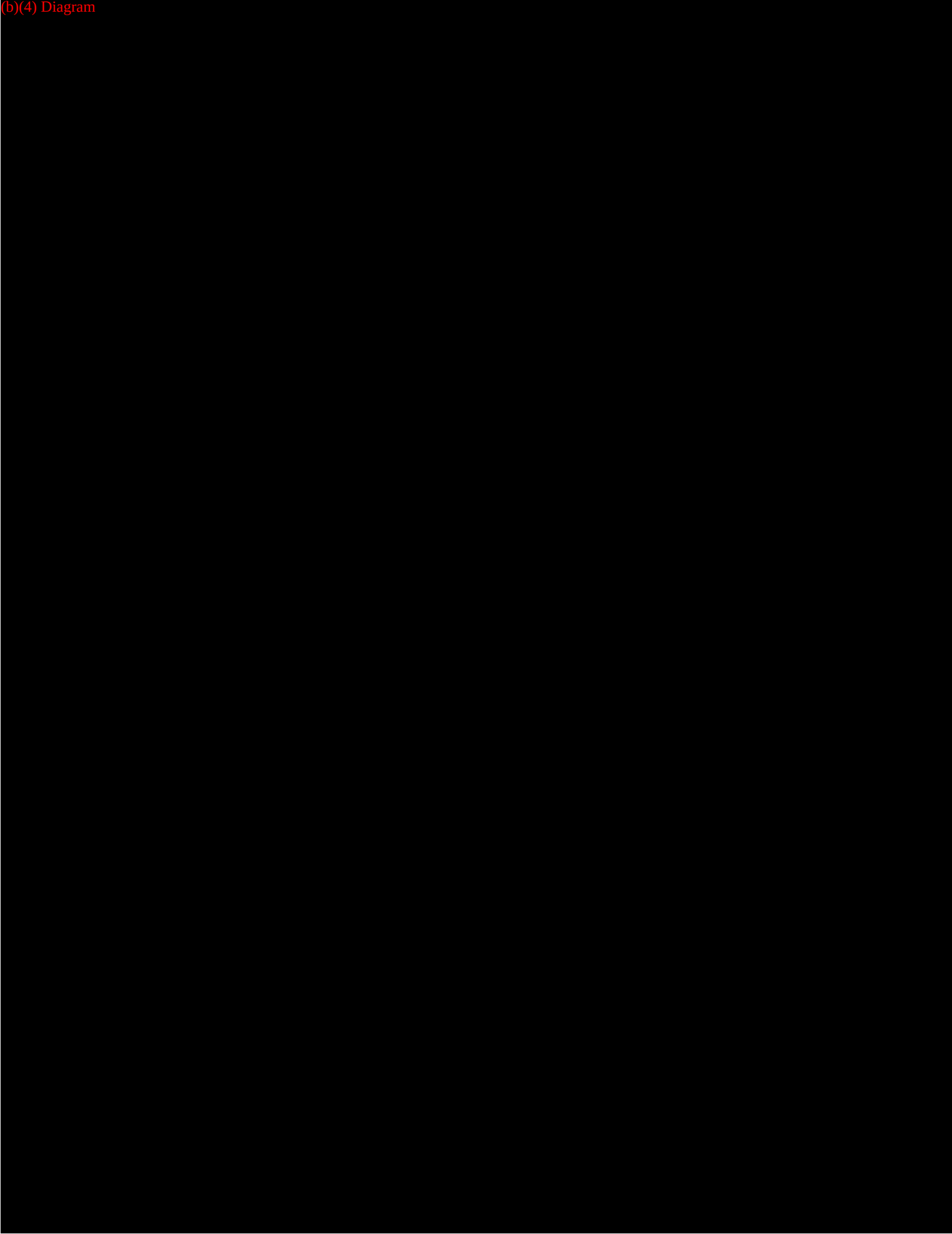
Larry W. Krasley

Larry W. Krasley
Regulatory Affairs Specialist
Hill-Rom Air-Shields

SKL 1

330 JACKSONVILLE ROAD, HATBORO, PA 19040 215-675-5200 Fax: 215-675-1859


(b)(4) Diagram

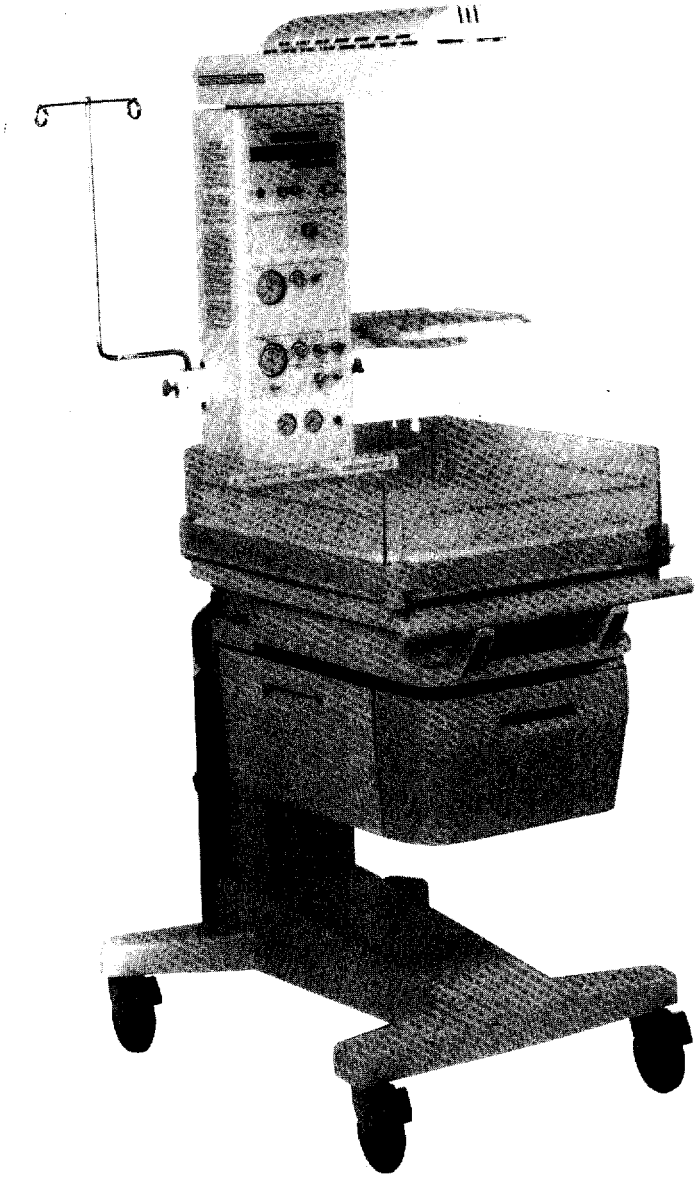

(b)(4) Diagram

Hill-Rom Air-Shields®

A HILLENBRAND INDUSTRY

RESUSCITAIRE® Radiant Warmer

MODEL RW82-1



OPERATOR'S MANUAL

OPERATING PRECAUTIONS

GENERAL PRECAUTIONS

- Federal Law restricts this device to sale by or on order of a physician.
- Infant radiant warmers should be used only by properly trained personnel as directed by an appropriately qualified physician aware of currently known risks and benefits.
- The functional checkout procedure should be performed before the unit is first placed into use and after disassembly for cleaning, servicing or maintenance. Refer to qualified service personnel if the unit does not perform as specified.
- The Bassinet end and side panels cannot be used for pushing or pulling the ***Resuscitaire® Radiant Warmer.***
- Do not leave the infant unattended in the Bassinet of the ***Resuscitaire® Radiant Warmer*** when the side panels or the front panel are folded down.
- To avoid overheating or underheating, skin temperature must be continuously monitored and controlled either manually or automatically. Rectal temperature should never be used to control skin temperature.
- To avoid overheating or underheating when operating in manual mode, observe the infant constantly and monitor the temperature using the temperature probe supplied with the equipment or other electronic thermometer.
- The skin temperature sensing probe must be in direct contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain direct skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment, reddened skin areas, and proper skin temperature.
- The skin temperature sensing probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The skin temperature probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.
- To avoid overheating the skin, the location of the skin temperature probe must be such that the skin around the Sensor is in direct line with the radiation from the warmer. Do not place anything between the radiant warmer and the infant that will interfere with the radiation from the warmer.
- Radiant warming increases insensible water loss. Appropriate measures to maintain proper fluid balance should be considered.
- Phototherapy units located too close to the Bassinet may affect mattress and infant temperature.
- The warmer cannot differentiate between an increase in core temperature and cold skin (fever) and low core temperature (hypothermia). It is recommended that patient core temperature be monitored with a separate calibrated electronic thermometer.
- 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 avoid overheating of the warmer, do not place objects (equipment, blankets, clothing or sterile packs) on top of the warmer.
- Air currents across the Bassinet area can affect patient thermal balance. Avoid placing the Warmer near heating or air conditioning ducts that may blow air across the Bassinet.
- Temperature uniformity (per IEC 601-2-21) across the mattress surface may not be maintained when the Bassinet is tilted in the 5- and 10-degree positions.
- During service intervals, inspect the secondary reflector directly under the warmer heater element for particles. If particles are present, replace the heater element. The life expectancy of the heater element is 1000 hours of operation.

5

OPERATING PRECAUTIONS (Continued)

GENERAL PRECAUTIONS (Continued)

- Should any of the control knobs on the Resuscitation Module come loose for any reason, do not attempt to refasten them. The calibration of these controls depends on the position of the knob on the shaft. If this occurs, recalibration must be performed by qualified service personnel.
- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Only connect the power cord to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with or provided for the ***Resuscitaire® Radiant Warmer***.
- The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
- Use of the accessory in the PATIENT VICINITY.
- Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.
- When raising or lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA,*** make sure that any attached cables, tubing or hoses are not compromised.
- When lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA*** to its minimum height, ensure thatthe gas tanks, if installed, do not contact the floor.
- Always lower the ***Resuscitaire® Radiant Warmer VHA*** to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.
- To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport. Use the handle when moving the equipment.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

OPERATING PRECAUTIONS (Continued)

ELECTRICAL PRECAUTIONS

- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Confirm that the **Oxygen Supply** is turned off and that the equipment 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.
- Connect the power cord only to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with the Warmer.

EXPLOSION PRECAUTIONS

- Do not use in the presence of flammable anesthetics.
- Confirm that the oxygen supply is turned off and that the equipment 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.

OXYGEN PRECAUTIONS

- Improper use of supplemental oxygen may be associated with serious side effects including blindness, brain damage, and death. The risks vary with each infant. All clinical practices with regard to 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 the 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_2) in the blood. When deemed advisable by the attending physician, blood PO_2 should be measured by accepted clinical techniques.
- Oxygen flow rates cannot be used as an accurate indication of oxygen concentrations. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals directed by the attending physician.
- Keep matches, lighted cigarettes, and all other sources of ignition out of the room in which the equipment is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.
- Although oxygen compatible materials are used in the oxygen delivery system, special care must be taken when high pressure oxygen such as found in a medical oxygen cylinder is used. Violent ignition of oil, grease, greasy substances, small particles of dust, dirt or other particulate contaminants (even small particles of metal), can occur in the presence of high pressure oxygen if their ignition temperature is reached. An instantaneous increase in temperature can occur due to friction, particle acceleration, or adiabatic compression, if the oxygen cylinder valve is opened too rapidly. **SERIOUS INJURY MAY RESULT!** Always observe the following precautions:

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OXYGEN PRECAUTIONS (Continued)

- Oil, grease, greasy substances, dust, dirt and other particulate contaminants must be kept away from oxygen regulators, cylinder valves, tubing and all other oxygen equipment.
- Always open oxygen cylinder shut-off valves **very slowly** and **carefully.**
- On high pressure oxygen cylinders use only pressure regulators or reducing valves approved for oxygen service. Do not use oxygen pressure regulators or reducing valves for air or gases other than oxygen as they may be hazardous. Operate such devices in strict accordance with the manufacturer's recommendations.
- When new or replacement oxygen cylinders are to be installed, they should have their outlet ports cleared by cracking the cylinder valve momentarily before attachment to the equipment.

LOW FLOW MICROBLENDER WARNINGS

- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FiO_2 and flow output from the microblender.
- Always operate the low flow microblender with clean/dry medical grade gases.
- Air inlet water filters are recommended for use with the low flow microblender.
- The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.

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TABLE OF DEFINITIONS AND SYMBOLS

NOTE, IMPORTANT, PRECAUTION, 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 when greater emphasis is required.*

PRECAUTION: *A Precaution is supplemental information to assist the user in the safe and effective use of the equipment.*

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.

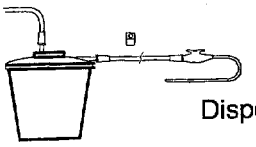
WARNING: A Warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

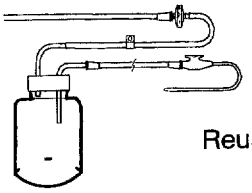
SYMBOLS


Attention: consult accompanying documents.

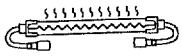

Type B equipment with an F-type isolated (floating) applied part.


Danger! High Voltage!


Disposable Suction Bottle


Reusable Suction Bottle


Patient


Heater Element


Suction Line Filter


Load Symbol


Examination Light


Examination Light Switch


Mode Control Key

Temperature Override Mode Key


Keypad Lock Key


Set Temperature Keys


Power On/Off Switch

Celsius/Fahrenheit Selection Key


Silence/Reset Key


Procedural Silence Indicator


Apgar Timer Keys

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SECTION 1
GENERAL INFORMATION

1.1 INTRODUCTION

This manual provides instructions for installation, use, operator maintenance and troubleshooting of the equipment. Hill-Rom Air-Shields cannot be responsible for the performance of the equipment if the user does not operate the equipment 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. Service manuals are available from Hill-Rom Air-Shields.

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

1.2 DESCRIPTION

The ***Resuscitaire® Radiant Warmer*** is designed specifically for labor and delivery room use. The ***Resuscitaire® Radiant Warmer*** consists of a Bassinet, Warmer, and a Controller module which provides heat control, monitoring of skin temperature and Apgar timing. The ***Resuscitaire® Radiant Warmer with VHA*** provides an adjustable Mattress Height from 89.2 cm (35.4 inches) to 110.2 cm (43.3 inches).

The ***Resuscitaire® Radiant Warmer*** also includes optional basic resuscitation packages which includes suction and oxygen delivery.

1.3 SPECIFICATIONS

Specifications for the ***Resuscitaire® Radiant Warmer*** are provided in Table 1.1. All specifications are subject to change without notice.

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TABLE 1.1 SPECIFICATIONS

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer*	
120V Models	120V, 60 Hz, 750W
100V Models (Japan)	100V, 50/60 Hz, 750W
230V Models	230V, 50/60 Hz, 750W
POWER REQUIREMENTS *Resuscitaire® Radiant Warmer with VHA*	
120V Models	120V, 60 Hz, 1300W
230V Models	230V, 50/60 Hz, 1300W
OVERLOAD PROTECTION	
120V Models	Dual 12A Circuit Breakers
100V Models (Japan)	Dual 12A Circuit Breakers
230V Models	Dual 6A Circuit Breakers
Resuscitaire® Radiant Warmer with VHA also has in addition:	
120V Models	Dual 6A Circuit Breakers
230V Models	Dual 3A Circuit Breakers
CHASSIS LEAKAGE CURRENT (Single fault condition, loss of ground)	
100V and 120V Models	Less than 300 µA
230V Models	Less than 500 µA
EXAMINATION LIGHT	>100 Foot Candles (0.11 lumens/cm^2)
ALARMS	
High Temperature	Activates if Skin Temperature Probe is attached and the skin temperature sensor reaches 39.0 °C. Resets at 38.5 °C.
Check Patient	Activates in Manual Mode after 10 minutes. Remains on with audible alarm every 30 seconds for 5 minutes; totalling 15 minutes. Then the heater is turned *Off*.
Apgar Timer	Activates at the 1-, 5- and 10-minute Apgar Time intervals.
Power Fail	Activates when there is a loss of power.
Probe	Activates if Skin Temperature Probe fails (open or short).
System Fail	Indicates system failure, refer unit to service immediately.
Baby Temp	Activates if Baby Temperature fluctuates 1°C above or below set point.
Electrical Module Audio Alarms	Tone Frequency: 1.2 KHz maximum three-stage sound level: 15 seconds low, 15 seconds medium, then high.
Blender Module Pneumatic Audio Alarm	Vibrating Reed.
MANUAL HEAT CONTROL	Adjustable in 10% increments from zero to full power (100%)
DATA PORT	2400 Bits/second fixed Baud Rate. RS232C Compatible.
MATTRESS TILT	0, 5 and 10 degrees.
DISPLAYS	
Skin Temperature Display	
Range	18 to 40 °C (64.4 to 104°F)
Accuracy	± 0.2 °C for 31 °C to 37 °C (88 °F to 98.6°F)
Resolution	0.1°C (0.5 °F)

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TABLE 1.1 SPECIFICATIONS (Cont.)

DISPLAYS (Cont.)

Apgar Timer Display

Range	0 to 59 minutes, 0 to 59 seconds
Resolution	1 second
Accuracy	0 ± 1 second

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer*

Mattress Height	100 cm (39.4 - inches)
Height	188 cm (74 - inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	100 kg (220 lbs)

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer with VHA*

Mattress Height	89.2 to 110.2 cm (35.4 to 43.3 inches)
Bassinet Tilt (continuously)	±10 degrees from horizontal
Height	180.6 to 200.7 cm (71.1 to 79 inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	127 kg (280 lbs)

ENVIRONMENTAL

Operating Temperature Range	18 °C to 30 °C ambient
Storage Temperature Range	- 30 °C to +70 °C ambient
Relative Humidity Operating Range	5% RH to 95% RH, non-condensing

RESUSCITATION

Wall Supply Pressure	40 to 75 psi (2.8 to 5.2 bar)
Cylinder Pressure	2900 psi max (199.8 bar)
Cylinder Diameter	10-12 cm (4-5 inches) max

Suction Circuit

Adjustable Suction Intensity	0 to 150 mmHg

Patient Gas Supply

Airway Pressure Limit, Operator Adjustable	0 to 50 cm H_2O (4.9 kPa) ± 10%
Fixed Pressure Relief, Factory Set	60 cm H_2O (5.9 kPa) ± 20%

Primary Supply

Primary Pressure Limit	160 cm H_2O (15.7 kPa) ± 20%
Primary Flow Range	0 - 15 lpm

Auxiliary Supply

Auxiliary Pressure Limit	160 cm H_2O (15.7 kPa) ± 10%
Auxiliary Flow Range	0 - 15 lpm

AutoBreath Circuit (Factory Installed Option)

I:E Ratio	Fixed at 1:2 ± 20%
PEEP	0 to 18 ± 4 cm H_2O (1.8 ± 0.4 kPa)
Breath Rate	18 to 60 BPM ± 10% of setting
Airway Pressure Relief, Operator Adjustable	0 to 50 ± 5 cm H_2O (4.9 ± 0.5 kPa)
Fixed Maximum Pressure	60 cm H_2O ± 10%(5.9 kPa ±20%)
Oxygen Consumption	50 LPM max.

1.4 EQUIPMENT PROVIDED

- *Bassinet* - The Bassinet provides maximum visibility and access to the infant. The Bassinet tilts up in the rear 5 and 10 degrees and provides for X-ray Tray (optional) insertion.
- *Warmer Module* - The Warmer Module houses a heating element and an Examination Light for special procedures.
- *Controller* - The Controller provides Pre-Warm, Manual heat control, automatic skin temperature servo-control and contains an Apgar Timer, Skin Temperature monitor and probe connection.
- *Resuscitation Module (Optional)* - The Resuscitation Module contains a suction circuit, a patient oxygen delivery circuit with airway pressure relief and an auxiliary oxygen delivery circuit. There are two varieties of resuscitation modules, both versions can accept an optional blender. AutoBreath is another option but is not available in the USA or Canada.

1.5 FACTORY INSTALLED OPTIONS

- Resuscitation Module
- Resuscitation Module 2001
- Resuscitation Module with AutoBreath
- Integrated Precision Blender
- Gas Supply Module
  - O_2 Pipeline and Cylinder
  - O_2/Air Pipeline and Cylinder

1.6 FIELD INSTALLED ACCESSORIES (Refer to Section 6 for Part Numbers)

- Instrument Tray (left or right mount)
- X-ray Cassette Tray
- Pass-Through Drawer Organizer Tray
- I.V. Pole
- Monitor Shelf

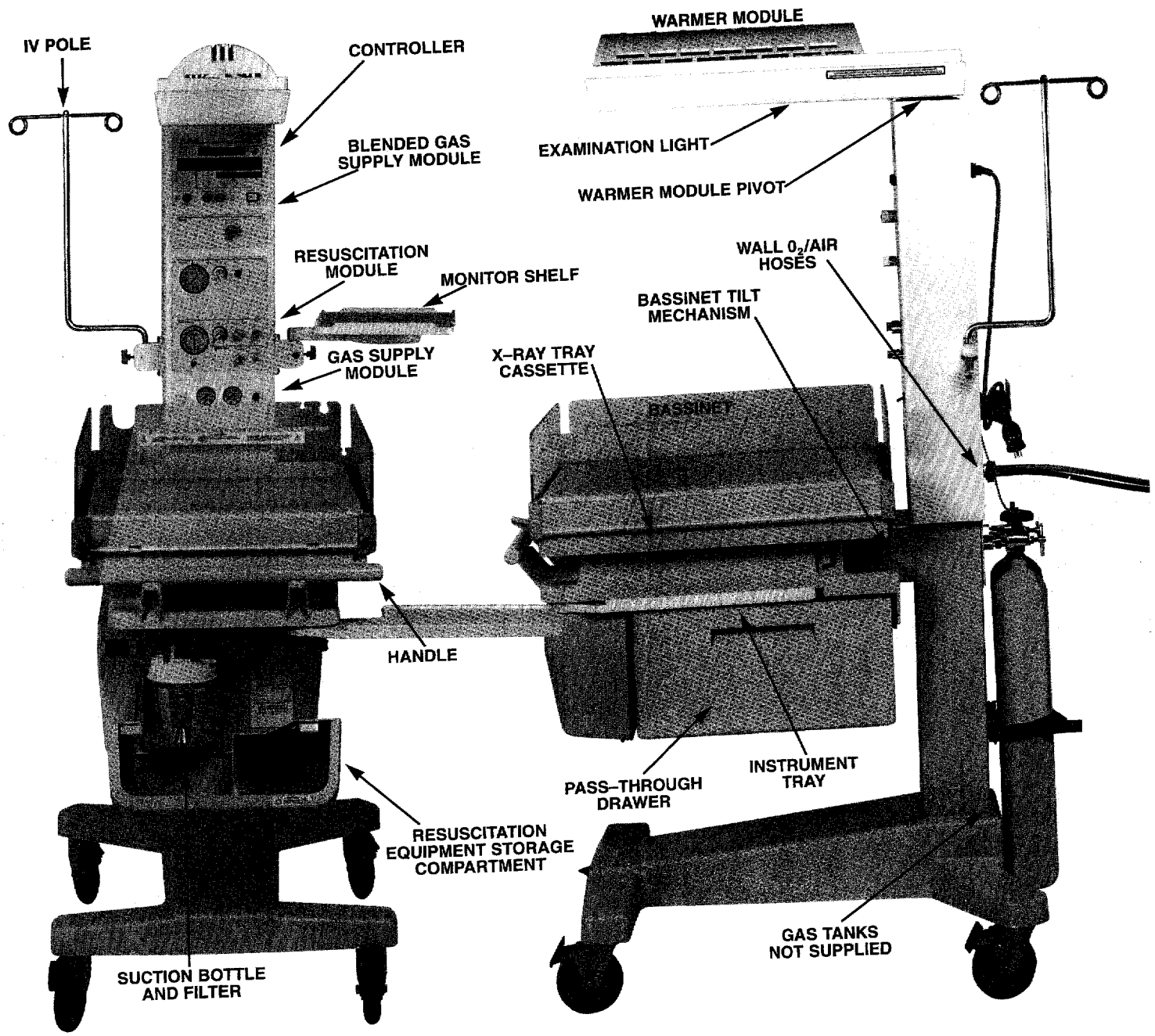

FIGURE 1.1 EQUIPMENT PROVIDED WITH FACTORY INSTALLED OPTIONS AND FIELD INSTALLED ACCESSORIES

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SECTION 2
INSTALLATION

2.1 UNPACKING

The ***Resuscitaire® Radiant Warmer*** is shipped in one carton which contains the following assemblies:

- Bassinet/Cart Assembly
- Upper Post Assembly
- Warmer Module Assembly
- Any user installed Accessories that were ordered

When removing the equipment from the carton, use care not to scratch or otherwise damage unprotected surfaces; remove all packing material.

2.2 ASSEMBLY (Refer to Figure 2.1)

NOTE: *The required mounting hardware is stored in a bag located in the pass-through drawer.*

1. **REMOVE THE BACK COVER** (1) from the Upper Column (2).
2. **REMOVE THE CONTROLLER** (3) from the Upper Column (2).
3. **REST THE UPPER COLUMN** (2) on top of the Bassinet/Cart column opening. Fully extend the suction hoses (4) and (11) out of the column.
4. **CONNECT THE SUCTION HOSE** (4) to the Suction Hose (11).
5. **REPOSITION AND MOUNT THE UPPER COLUMN** (2) on the Bassinet/Cart using four 10 - 32 x 3/8 inch screws (5). Exercising care not to kink the hoses, carefully push the connected suction hoses into the column.
6. **INSTALL TWO 10 - 32 X 3/8 INCH SCREWS (6) IN THE UPPER HOLES OF THE UPPER COLUMN** (2). Do not tighten the screws.
7. **RAISE THE WARMER** (7) above the open end of the Upper Column (2) and insert the Power Cable (10) into the open end of the column.
8. **SLOWLY LOWER THE WARMER** (7) onto the Upper Column. Align the slots of the warmer over the screws (6) on the column. Install the screws on the pivot bracket. Tighten the screws on the upper holes of the column using a nine-inch Phillips Head screwdriver.
9. **THREAD THE WARMER POWER CABLE** out through the Controller opening. Connect the Power Cable (10) to connector J4 on the Controller (3).
10. **REMOUNT THE CONTROLLER** on the Upper Column. Remount the Back Cover (1) on the Upper Column.
11. ***Resuscitaire® Radiant Warmer***

    CONNECT THE LINE CORD to the **POWER** Connector on the rear of the Controller (refer to Figure 4.2).

11A. ***Resuscitaire® Radiant Warmer with VHA***

CONNECT THE LINE CORD to the Power Connector (Refer to Figure 4.2A) on the right side of the Lower Post. Connect the 40-inch Power Cord provided with the VHA between the AC connector on the left side of the Lower Post and the Controller Power Connector.

12. ***Resuscitaire® Radiant Warmer***

SECURE THE LINE CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

12A. ***Resuscitaire® Radiant Warmer with VHA***

SECURE THE 40-INCH POWER CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

CAUTION: Securing the Line Cord to the back panel is required to prevent removal of the Controller chassis with the AC power applied.

13. **INSTALL ANY ACCESSORIES** that were ordered using the installation instructions provided with the accessory.
14. **INSTALL THE END AND SIDE PANELS** on the Bassinet (refer to Paragraph 5.6 and Figures 5.1, 5.2, 5.3 and 5.4).

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PARTS LIST

Screw, 10 - 32 x 3/8 TR, PH Nylok (Qty 10)	99 041 36
Screw, 8 - 32 x 3/8 TR PH SS	99 031 38
Cable Clamp	17 725 64

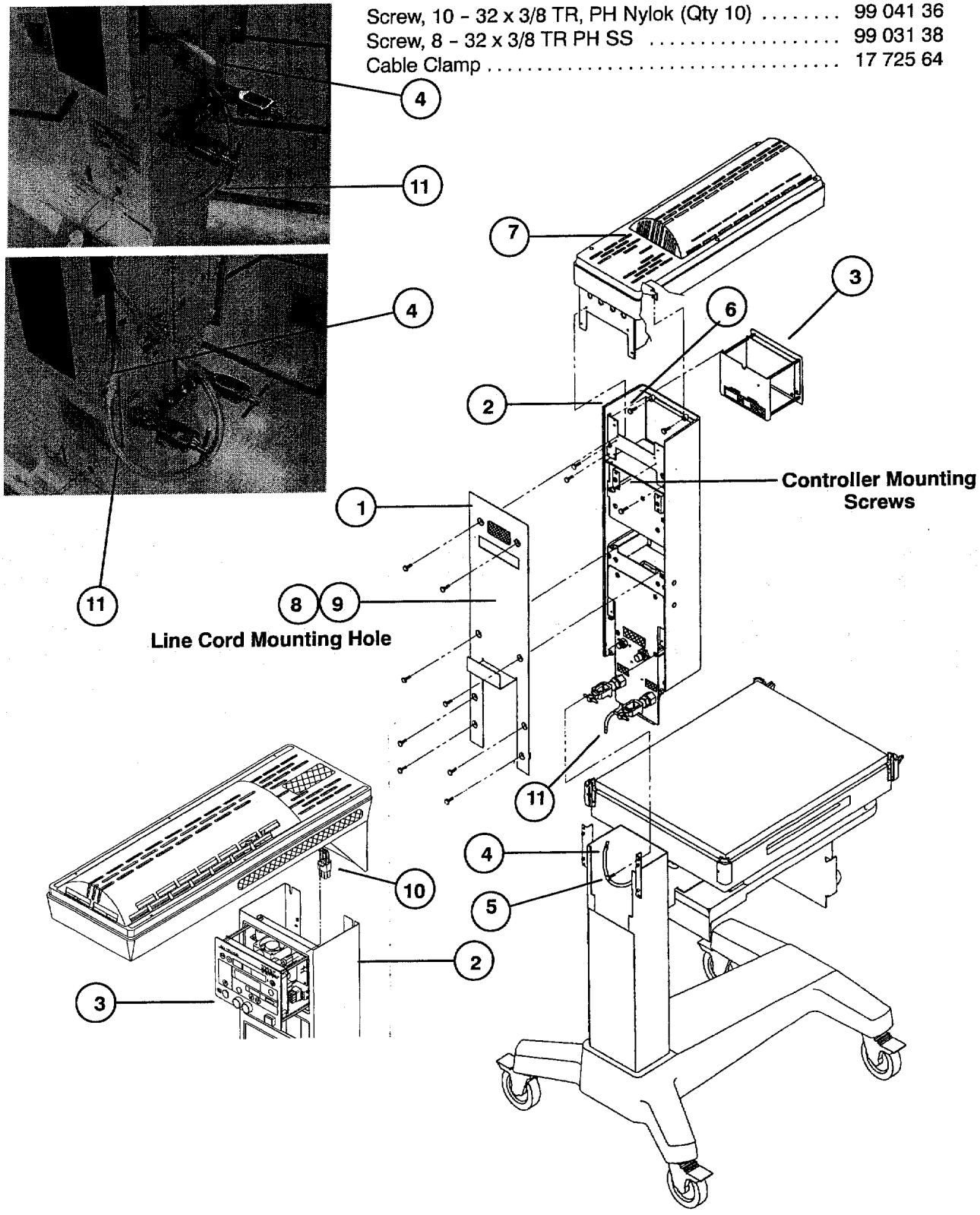

FIGURE 2.1 INSTALLATION

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SECTION 3
FUNCTIONAL DESCRIPTION

3.1 GENERAL

This section provides a functional description of the equipment.

3.2 FUNCTIONAL DESCRIPTION

3.2.1 WARMER MODULE

The Warmer is controlled by a Controller which provides **Pre-Warm** Mode, **Manual** Mode heater control, or **Baby** Mode (automatic skin temperature control). An Examination Light provides added illumination of the mattress area. A Warmer Head Pivot permits the Warmer to be pivoted 90° to either side for X-ray procedures. In addition, when the Warmer is pivoted, it continues to provide heat.

3.2.2 BASSINET

The Bassinet is designed to provide maximum function and utility to aid in the care of the newborn. The side and front panels may be folded down to permit access to the infant. The mattress may be tilted up from the rear at a 5- or 10-degree angle. Openings are provided on each side of the Bassinet for the insertion of the optional X-ray Cassette Tray.

3.2.3 CONTROLLER

At power-up, the microprocessor within the Controller performs a series of diagnostic tests to confirm the proper operation of the system. During this time, all displays and indicators are lighted and an audible tone is sounded.

When powered up, the system initializes in **Pre-Warm** Mode, the Controller will start the heater at 100% power and maintain that setting for three minutes, reduce to 60% for 12 minutes and then reduce the heater power to 30%.

When operating the Controller in the **Manual** Mode, the operator can adjust the heater power from 0 to full power in 10% increments. After 10 minutes of operation in the Manual Mode, a **Chk Patient** Alarm occurs.

Failure to acknowledge the Check Patient Alarm within the next 5 minutes will cause the heater to be turned off.

When operated in the **Baby** Mode, the Controller utilizes a Skin Temperature Probe, connected between the Controller input and the infant, to automatically adjust the heater output of the Warmer Module to maintain a digitally displayed preset **Set Temperature**.

The Apgar Timer displays the elapsed time and sounds an audible dual tone to alert the operator that 1, 5, and 10 minutes have elapsed since the timer was activated.

The **Keypad Lock** Key, when pressed, renders the Up/Down Arrows and Select Mode Keys inactive or active.

A Procedural Silence Timer prevents **Baby Temp** audible Alarms during routine procedures.

3.2.4 BLENDER MODULE (Optional)

The Blender Module provides blended oxygen from 21% to 100% to the **Patient Outlet** on the Resuscitation Module.

3.2.5 RESUSCITATION MODULE (Optional)

WARNING: Always monitor Airway Pressure and or/provide appropriate relief during infant resuscitation.

The Resuscitation Module contains pneumatic circuitry necessary for infant resuscitation. Controls and displays for the module are located above the rear of the Bassinet.

The Resuscitation Module is provided with AutoBreath (International only) or without AutoBreath in two varieties. It consists of the following factory installed components:

- **Suction** - The **Suction** Circuit is driven by a gas powered venturi actuated vacuum generator which provides a negative pressure for suctioning the patient's airway. The suction pressure is indicated on the **Suction** Gauge (Fig-

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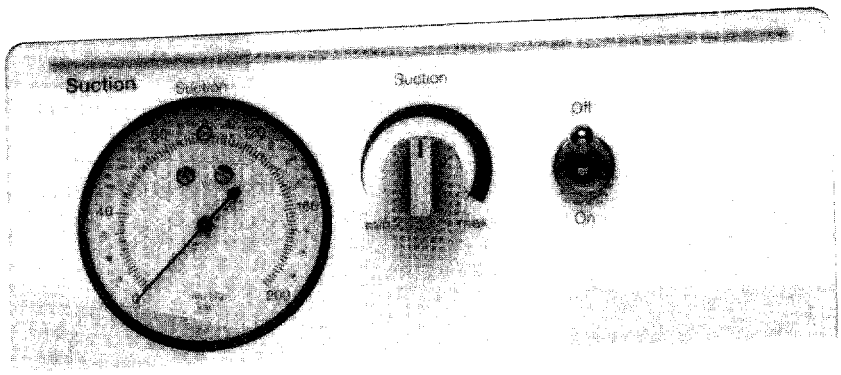
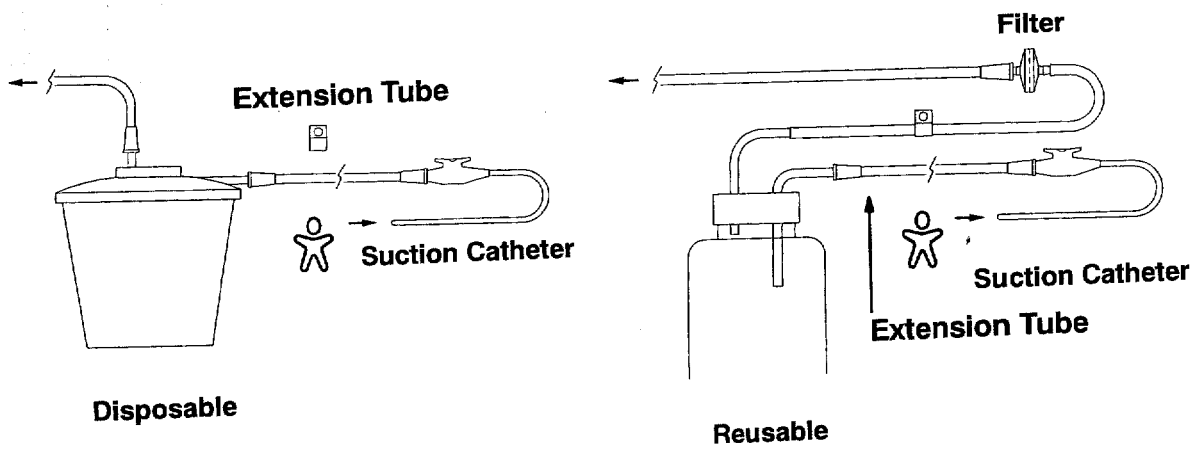
Suction Control and turned on or off using the **On/Off** Switch. A fixed internal relief valve limits the maximum suction pressure to 150 mmHg.





Note: Disposable bottle has built-in filter

FIGURE 3.1 SUCTION FUNCTIONAL BLOCK DIAGRAM

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RESUSCITATION MODULE 2001 WITH PRIAMRY OUTLET AND AUXILIARY FLOW ONLY (FACTORY INSTALLED OPTION)

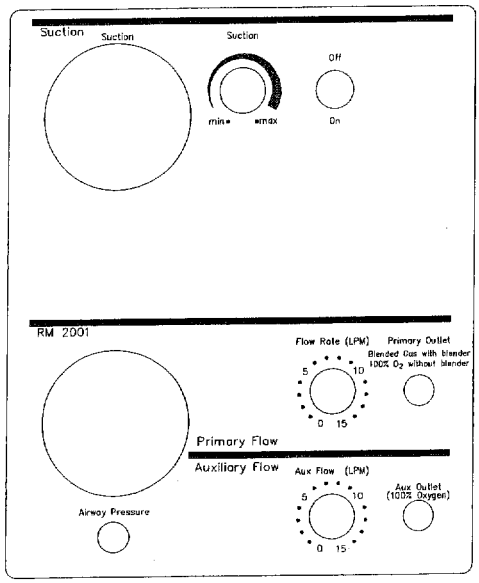

FIGURE 3.2 RESUSCITATION MODULE 2001 WITH PRIMARY OUTLET AND AUXILIARY FLOW ONLY

RESUSCITATION MODULE 2001 PRECAUTIONS

- The Resuscitation Module 2001 (option) is intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- If the blender option was added, confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- Always monitor **Airway Pressure**.
- When using **Primary Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Primary Supply** module.

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- A humidifier, if used, must be placed between the **Primary Outlet** connection and the patient. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

- **Primary Outlet** -

The **Primary Gas Supply** circuit may be used to provide continuous gas flow to a breathing circuit. When the **Blender** module is included in the system, the **Primary Outlet** provides 0 to 15 lpm of O_2 selected by the operator. The **Flow Rate (LPM)** control is a calibrated dial type flow adjustment.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 160 ± 10 cm H_2O (15.9 ± 1 kPa)

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet** -

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother , or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The outlet 1/4" hose barb fittings of the gas delivery module will attach to commercially available oxygen supply tubing or self-inflating resuscitation bag. Hill-rom Air shields part number 67 361 72.

RESUSCITATION MODULE WITHOUT AUTOBREATH (FACTORY INSTALLED OPTION) PATIENT SUPPLY

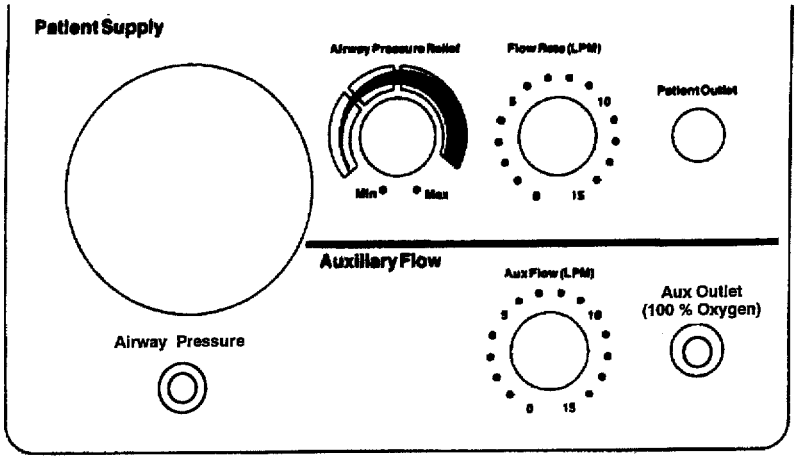

FIGURE 3.3 RESUSCITATION MODULE WITH PATIENT GAS SUPPLY AND AUXILIARY FLOW ONLY - PATIENT SUPPLY

RESUSCITATION PRECAUTIONS

- The Resuscitation Module (options) are intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- Confirm the setting and flow of the Airway Pressure relief valve before patient use.
- Confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- Always monitor **Airway Pressure**.
- When using **Patient Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Patient Supply** module.

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- A humidifier, if used, must be placed between the **Patient Outlet** connection and the patient circuit. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.

- **Patient Outlet -**

The **Patient Gas Supply** Circuit may be used to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet -**

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother , or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The patient breathing circuit used in conjunction with the Resuscitation Module without AutoBreath is illustrated in Figure 3.4. In addition, a patient supply circuit for Manual Bagging (Figure 3.7) may also be used.

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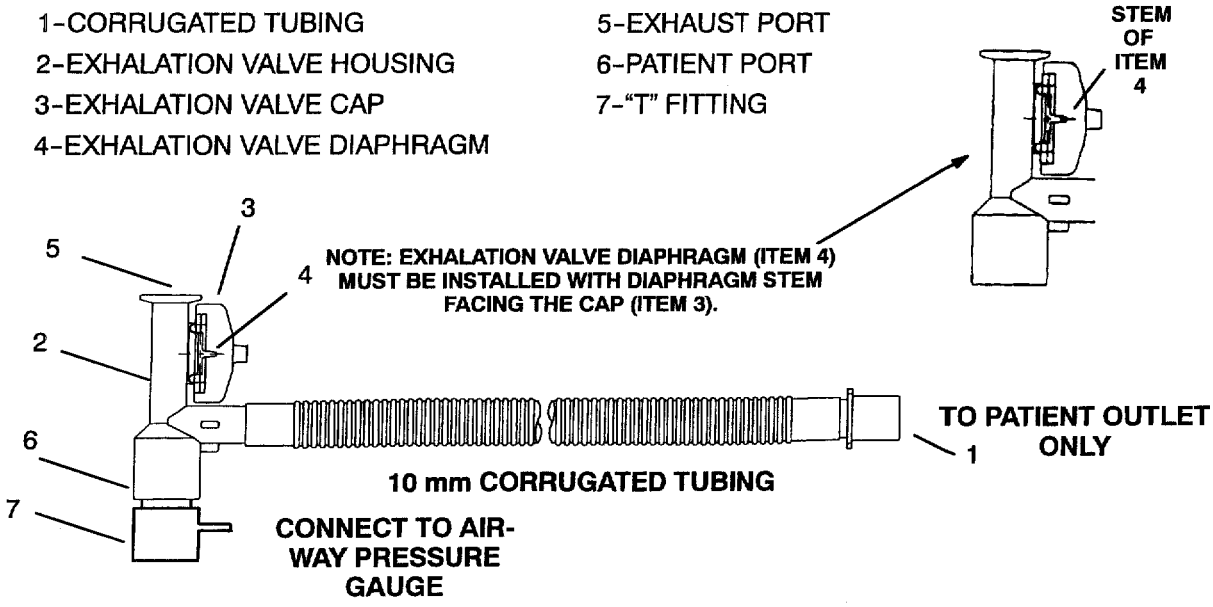

FIGURE 3.4 PATIENT BREATHING CIRCUIT FOR MANUAL VENTILATION

RESUSCITATION MODULE WITH AUTOBREATH (FACTORY INSTALLED OPTION) NOT AVAILABLE IN THE USA OR CANADA

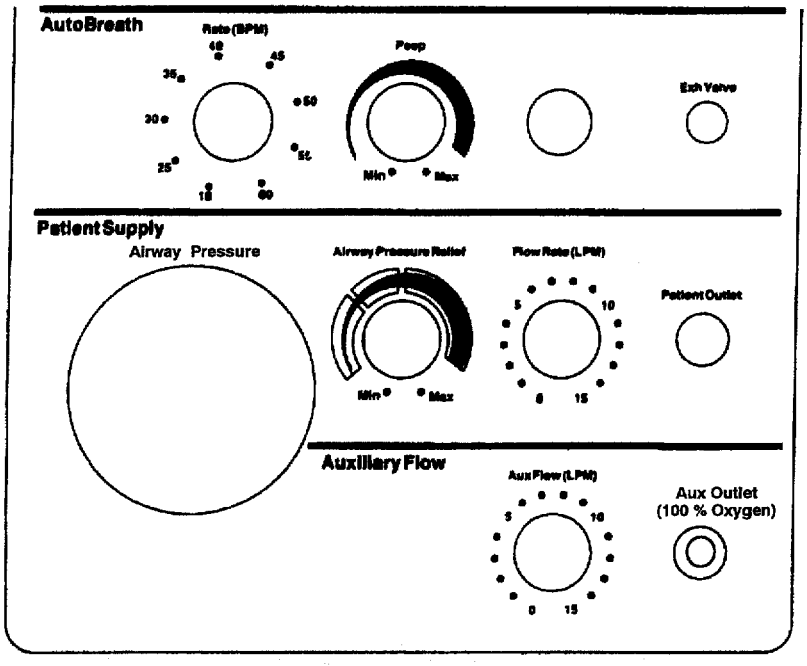

FIGURE 3.5 RESUSCITATION MODULE WITH AUTOBREATH, PATIENT GAS SUPPLY AND AUXILIARY FLOW

AUTOBREATH PRECAUTIONS

- The Resuscitation Autobreath (option) is intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Any humidifier used with the **AutoBreath** must be a "flow-through" type having a low pressure drop. Use of a humidifier with a bubbler tube or pressure jet will render the Safety Relief Valve ineffective. A pressure jet nebulizer or unmodified bubbler humidifier may not be used.
- When setting the **Rate (BPM)** Control for optimum repeatability, always approach the desired setting by turning the knob in a clockwise direction.
- When setting the **PEEP** control, always start with the knob fully counterclockwise to avoid setting PEEP above the maximum pressure limit.
- An airway pressure monitor must be used if the **AutoBreath** is to be used unattended.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.
- A humidifier, when used, must be placed between the **Patient Outlet** connection and the patient circuit. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

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- **AutoBreath**

The **AutoBreath** Circuit is a gas-powered, time-cycled, continuous flow, pressure limited resuscitator. It has a **Rate (BPM)** Control and a fixed I/E ratio of 1:2 nominal. An **On/Off** Switch allows the timing circuit to be turned on and off as needed. A **PEEP** Control adjusts the Positive End Expiratory Pressure in the patient circuit. The resuscitator is utilized in conjunction with the continuous gas flow provided by the **Patient Supply** sub-module.

WARNING: An airway pressure disconnect monitor should be used if the AutoBreath Infant Resuscitator is to be used unattended.

- **Patient Gas Supply**

The **Patient Gas Supply** Circuit may be used with the **AutoBreath** Infant Resuscitator on or off to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet**

The **Aux Outlet** circuit supplies 100% oxygen through the **Aux Flow (LPM)** Control to the **Aux Outlet** Connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother, or a second neonate, i/e., twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 kPa).

- **Patient Breathing Circuits**

The patient breathing circuit used in conjunction with the AutoBreath Infant Resuscitator is illustrated in Figure 3.3. In addition, a patient supply circuit for Manual Bagging (Figure 3.4) may also be used.

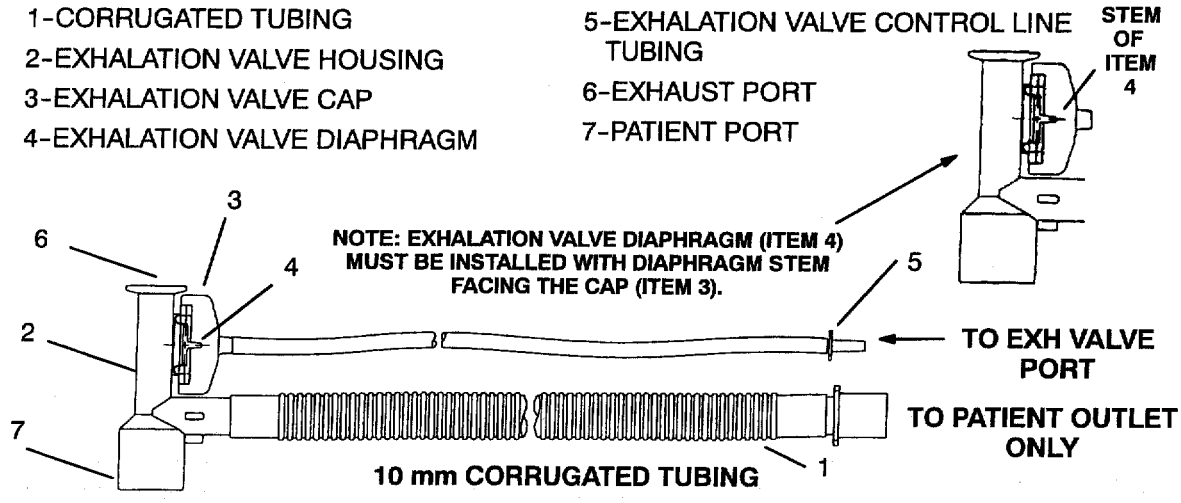

FIGURE 3.6 PATIENT BREATHING CIRCUIT FOR AUTOMATIC VENTILATION

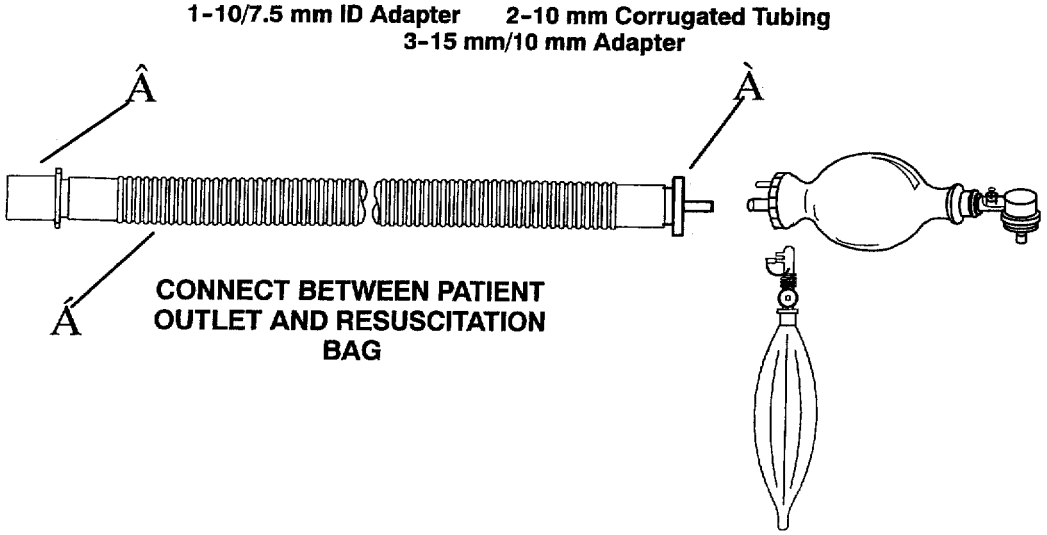

FIGURE 3.7 PATIENT BREATHING CIRCUIT FOR MANUAL BAGGING

3.2.6 GAS SUPPLY MODULE

The **Gas Supply** Module includes an On/Off Switch which controls the pipeline and cylinder gas supply to the Resuscitation Module. An oxygen cylinder Pressure Gauge is provided if the oxygen cylinder option is included. Oxygen and Air Pressure Gauges are provided on units equipped with the Blender Module.

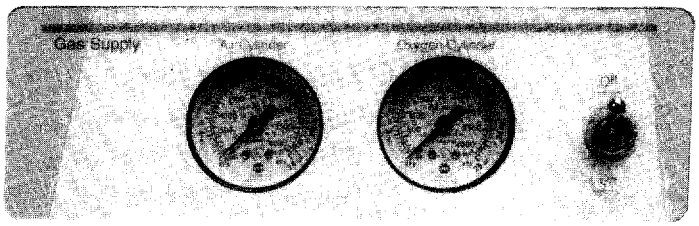

FIGURE 3.8 GAS SUPPLY MODULE

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3.2.7 ALARMS

HIGH TEMPERATURE. When the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C, the heater is automatically turned off, the **High Temp** Indicator will flash and the audible alarm will sound continuously. Press the **Silence/Reset** Key to silence the alarm for two minutes. After the alarm condition is corrected (a skin temperature of 38.5 °C or less), the alarm will automatically reset.

CHECK PATIENT. When in the **Manual** Mode the **Chk Patient** Indicator will illuminate and the alarm will sound one time after 10 minutes of operation. Thereafter, the **Chk Patient** Indicator will remain illuminated and the audible alarm will sound every 30 seconds for 5 minutes. If the alarm has not been acknowledged at the end of 5 minutes, the heater will shut down and a continuous ramping audible alarm will sound. The **Silence/Reset** Key then must be pressed to reactivate the heater.

PROBE. If the Skin Temperature Probe fails (short- or open circuited), the **Probe** Indicator will flash and a ramping audible alarm will sound. After the alarm condition is corrected (the Probe is replaced), the alarm will automatically reset.

BABY TEMPERATURE. When the temperature sensed by the Skin Temperature Probe is 1 °C above or 1°C below the selected **Set Temperature** Display setting, the **Baby Temp** Indicator will flash and a ramping audible alarm will sound. In addition, if the temperature is 0.2 °C above the selected **Set Temperature,** the heater will be turned off automatically. Press **Silence/Reset** to silence the alarm for 10 minutes.

POWER FAIL. When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. The alarm may be silenced by turning off the power switch.

IMPORTANT: *Turning off the Power switch will prevent the Controller and Heater from restarting automatically when power is returned to the unit. The settings will be retained in memory until power is restored.*

SYSTEM FAIL. If an internal malfunction is detected, the **System Fail** Indicator will flash and the audible alarm will beep. In addition, an Error Code (eR00 to eR025) will be displayed in the **Baby Temperature** Display. This alarm is not resettable and the unit should be referred to qualified service personnel. A prolonged brown-out (five minutes or more with supply voltage leas than 90% of nominal) will also cause a System Fail alarm.

3.2.8 BLENDER DIFFERENTIAL BYPASS ALARM (Optional)

The blender Module (factory installed option) will alarm and bypass whenever the pressure differential between the O_2 and air supplies exceeds 30 psi ± 2 psi. When this condition occurs, the blender will continue to supply whichever gas is the higher pressure: either 100% Air or 100% Oxygen. This is an audible alarm only. There are no visual indicators.

3.2.9 APGAR TIMER

When the **Apgar Timer** is running, the Apgar Timer Display will show elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar time intervals.

SECTION 4
OPERATION

4.1 CONTROLS, INDICATORS AND CONNECTORS

Controls, Indicators and Connectors for the Controller are presented in Figures 4.1 and 4.2 and Tables 4.1 and 4.2. Controls, Indicators and Connectors for the Resuscitation Module are presented in Figure 4.3 and Table 4.3.

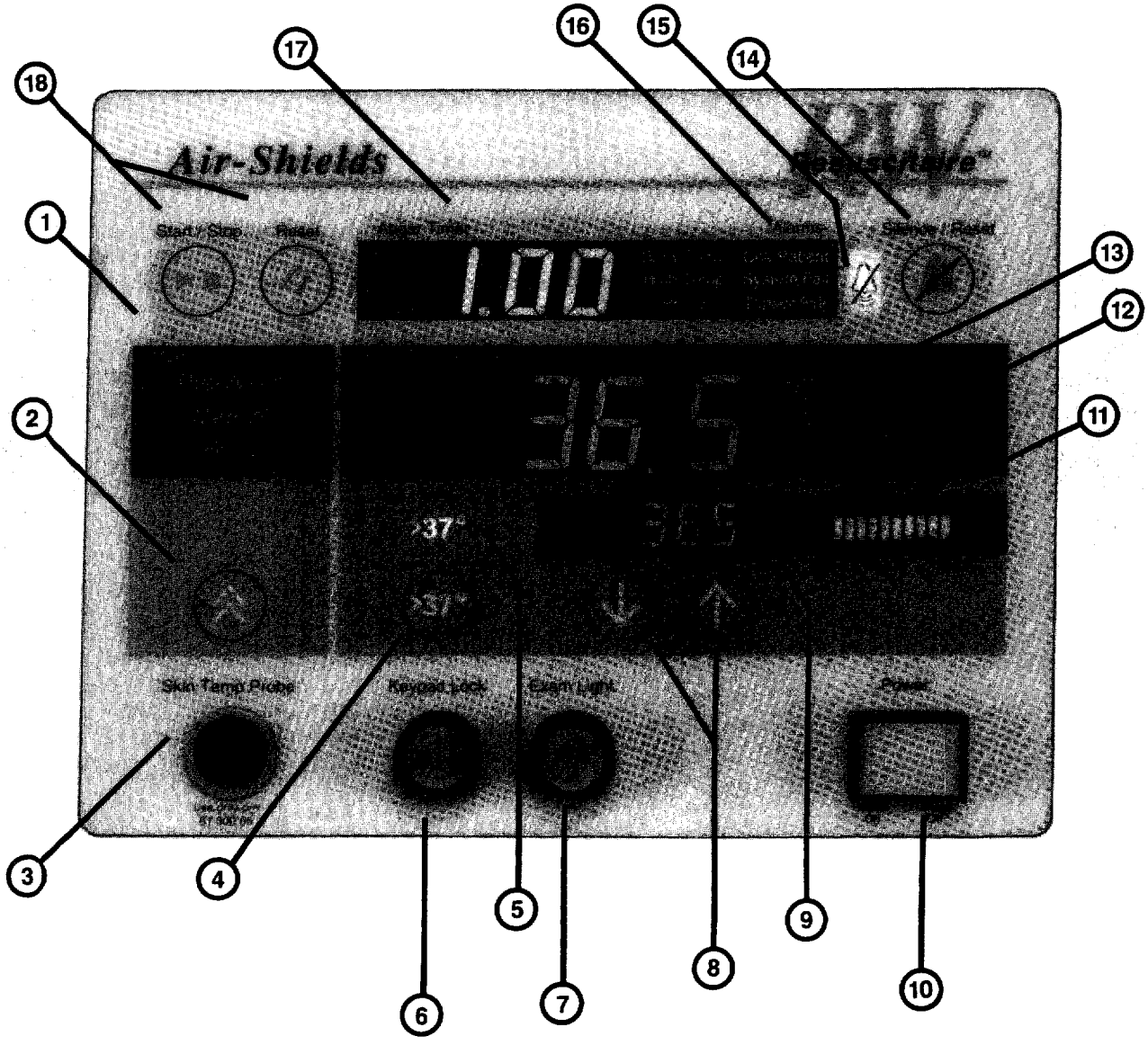

FIGURE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	**Mode**	
	Pre-Warm Indicator	Indicates that the Controller is operating in the **Pre-Warm Mode**.
	Manual Indicator	Indicates that the Controller is operating in the **Manual Mode**.
	Baby Indicator	Indicates that the Controller is operating in the **Baby Mode**.
2	**Mode** Select Key 	Press to select either **Pre-Warm, Manual** or **Baby Mode** of operation.
3	**Skin Temp Probe** Connector	Accepts Skin Temperature Probe for monitoring infant skin temperature. When connected, the **Baby Temperature** Display indicates the temperature sensed by the probe. When probe is disconnected, the **Baby Temperature** Display is blank. When disconnected in **Baby** Mode, a **Probe** Alarm also occurs.
4	**>37 °C** Key 	Press to place **Set Temperature** Display (refer to Item 9) in Temperature Override Mode, >37 °C (98.6 °F). ***NOTE:*** *This Key is inactive until the **Set Temperature** has been set to 37 °C.*
5	**>37 °C** Indicator	Lights to indicate that the Temperature Override Mode, >37 °C (98.6 °F), has been selected.
6	**Keypad Lock** Key 	Press to disable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys (refer to Items 2, 4 and 8). Press again to enable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys. Key lights to indicate that Keypad is locked.
7	**Exam Light** Key 	Press to turn on or turn off the Examination Light located in the Warmer Module.
8		**Manual Mode** Press the Up Arrow Key to raise heater power from 0% to 100% in 10% increments (refer to Item 11, **Heater Power** Display). Press the Down Arrow Key to lower relative heater power from 100% to 0% in 10% increments (refer to Item 11, **Heater Power** Display).

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
8		**Baby Mode** Press the Up Arrow Key to raise the Set Temperature from 34.0 °C (93 °F) to 37.0 °C (98.6 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to raise the Set Temperature from 37.0 °C (98.6 °F) to 38.0 °C (102.2 °F). Press one time to raise the Set Temperature in 0.1° increments. Press and hold to raise the Set Temperature rapidly. Press the Down Arrow Key to lower the Set Temperature from 37.0 °C (98.6 °F) to 34.0 °C (93 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to lower the Set Temperature from 38.0 °C (102.2 °F) to 34.0 °C (93 °F). Press one time to lower the Set Temperature in 0.1° increments. Press and hold to lower the Set Temperature rapidly. ***NOTE:*** *The Up/Down Arrow Keys may be locked by pressing the Keypad Lock Key (refer to Item 6).*
9	**Set Temperature** Display	In **Baby Mode,** displays the **Set Temperature** as selected by the Up/Down Arrow Keys (refer to Item 8) and in °C or °F as selected by the **°C/°F** Key (refer to Item 12). Display is blank in **Pre-Warm** and **Manual** Modes.
10	**Power** Key 	Press to turn on or turn off the Controller and Warmer Module.
11	**Heater Power** Display	Displays relative heater power in 10% increments from 0% to 100%.
12		Press to alternately select °C or °F for the **Baby Temperature** and **Set Temperature** Displays.
13	**Baby Temperature** Display	Digital display of infant temperature in °C or °F (refer to Item 12), whether in **Manual, Pre-Warm** or **Baby Mode.** The display is blank if the Skin Temperature Probe (refer to Item 3) is disconnected from the Controller.

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
14	**Silence/Reset** Key 	In **Manual Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Resets **Chk Patient** (refer to Item 16), restores heater power and silences Audible Alarm at any time after 10 minutes of warmer operation. Resets **Chk Patient** (refer to Item 16), silences Audible Alarm and restores heater power after15-minutes of continuous operation is complete. In **Baby Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Press to silence **Baby Temp** (refer to Item 16) Alarm for 10 minutes. During non-alarm conditions, press to enter Procedural Silence (refer to Item 15).
15	**Procedural Silence** Indicator 	When illuminated, indicates that the unit is in Procedural Silence. Procedural silence interval is 5 minutes. During Procedural Silence, the **Baby Temp** Alarms are blocked.
16	**Alarms** **Baby Temp**	The **Baby Temp** Indicator will flash with a three-level audible alarm to indicate that the baby's skin temperature is 1 °C above or below the selected Set Temperature (refer to Item 9). Press **Silence/Reset** Key to silence alarm for 10 minutes.
	High Temp	The **High Temp** Indicator will flash, the audible alarm will sound continuously, and the heater will be turned off when the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C. High Temp (39.0 °C) Alarms can only be silenced for two minutes by the Silence/Reset Key. Press the **Silence/Reset** Key to silence the audible alarm for 2 minutes. When the temperature falls to 38.5 °C, the alarm will automatically reset.
	Probe	When in **Baby Mode**, if the Skin Temperature Probe fails (open probe), the **Probe** Indicator will flash and a three-level audible alarm will sound. After the Alarm condition is corrected (the Skin Temperature Probe is replaced), the alarm will automatically reset. Also refer to Table 5.1. When in **Baby Mode**, if the Skin Temperature Probe fails (shorted probe), the **System Fail** Indicator will light and an audible alarm will sound. This Alarm cannot be Silenced. The **Power MUST BE TURNED OFF then ON** to Reset the Alarm condition.

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
16	**Alarms (Cont.)**	
	Chk Patient	When in the **Manual** Mode, if the warmer is in operation for longer than 10 minutes, the **Chk Patient** Indicator will illuminate and the audible alarm will sound one time. Thereafter, the **Chk Patient** Indicator will remain on and the audible alarm will sound every 30 seconds for the next 5 minutes. If at the end of 5 minutes (15 minutes total) the alarm has not been acknowledged by pressing the **Silence/Reset** Key (refer to Item 14), the warmer will be shut down.
	System Fail	When an internal malfunction is detected, the **System Fail** Indicator will illuminate and the audible alarm will sound continuously. In addition, an Error Code (Er00 to Er025) will be displayed in the **Baby Temperature** Display. When a malfunction is detected, the Controller will automatically perform the self-test function (refer to para. 4.2 Step 3) to determine if the fault has corrected itself. If the fault has not corrected itself, the error code will be displayed until corrected. This alarm is not resettable and the unit should be referred to qualified service personnel. ***NOTE:*** *Error code 023 may be corrected by the Operator, refer to Table 5.1.*
	Power Fail	When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. Push the **Power** Key to silence the Alarm.
17	**Apgar Timer**	When the **Apgar Timer** (refer to Item 18) is running, the Apgar Timer displays elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar Time intervals.
18	**Stop/Start** 	Press to start or stop the **Apgar Timer.**
	Reset 	When timer is running, press to reset the timer to zero and restart the Apgar count. When timer is stopped, press to turn timer off. ***NOTE:*** *The Timer can be reset any time.*

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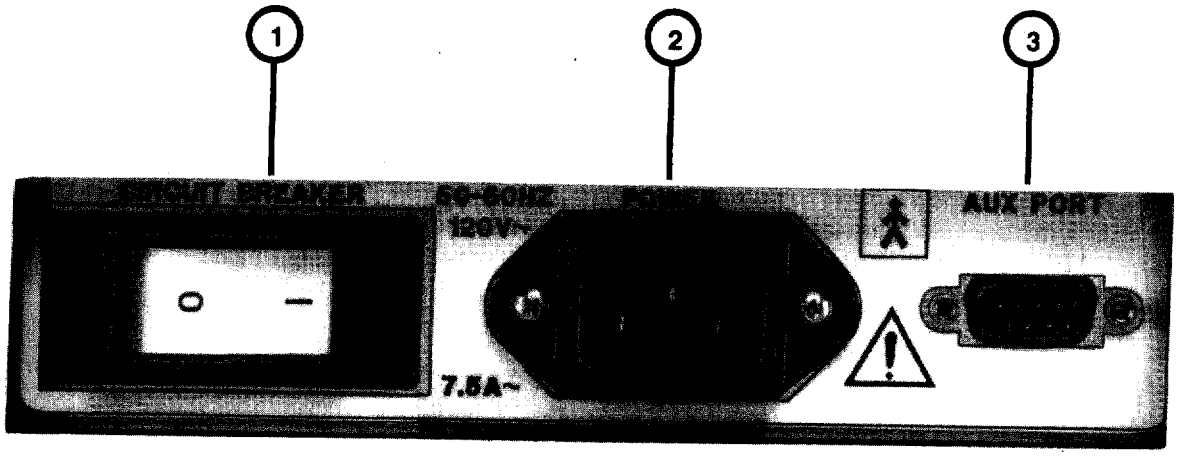


FIGURE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

TABLE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	CIRCUIT BREAKER	Turns Controller on and off when switched by operator or the presence of excessive current drain is detected.
2	POWER	Accepts ac power cord. Accepts 40-inch power cord on VHA units
3	AUX PORT	Data port for connection to printer or host system.

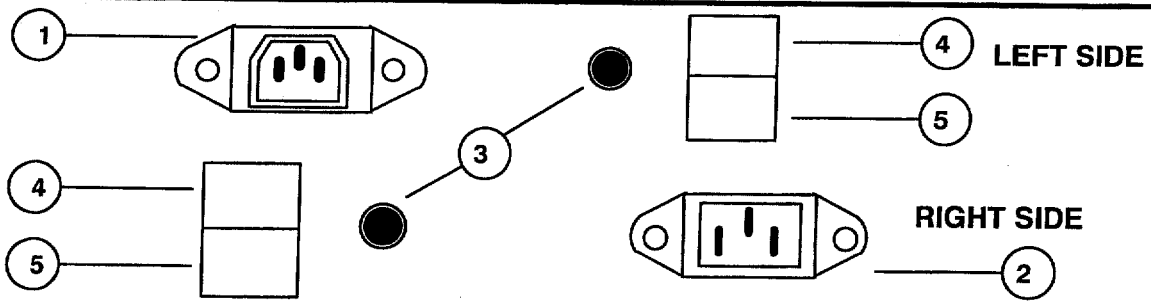


FIGURE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS LOCATED ON BOTH SIDES OF LOWER POST

TABLE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	POWER OUT	Accepts 40-inch ac power cord.
2	POWER IN	Accepts ac power cord.
3	CIRCUIT BREAKER	Turns Actuator off when presence of excessive current drain is detected. Press to reset.
4	UP SWITCH	Press to raise Upper Post
5	DOWN SWITCH	Press to lower Upper Post

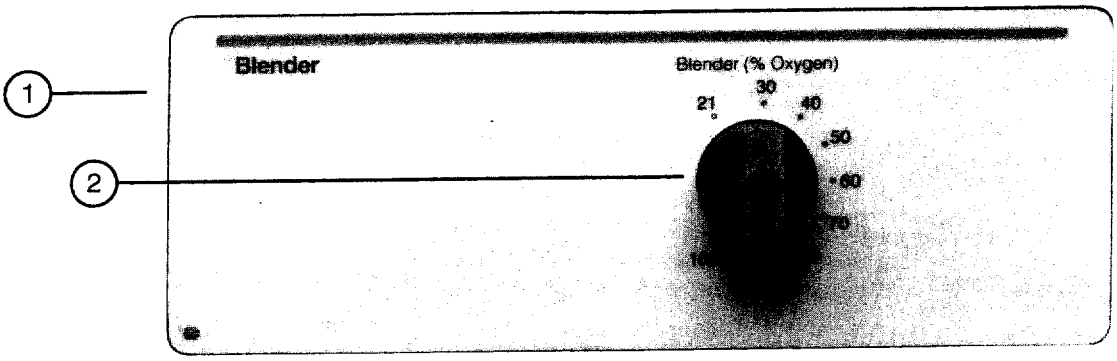
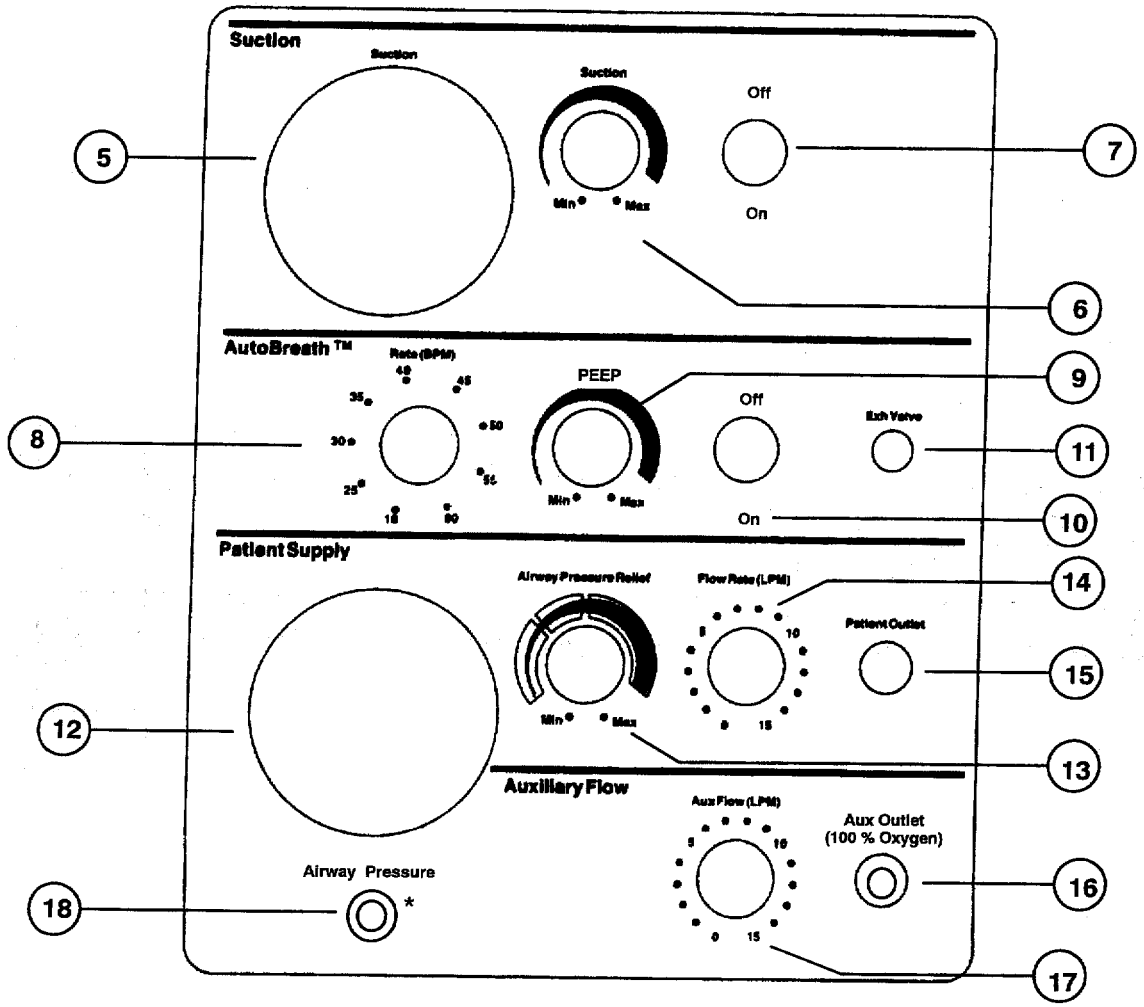


FIGURE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

TABLE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

ITEM	NAME	DESCRIPTION
1	**Blended Gas Supply Module (Optional)**	
2	**Blender % Oxygen** Control	Blends air and oxygen mixture from 21 to 100% O_2.



*Not Mounted On Units equipped with AutoBreath.

FIGURE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Suction	
5	**Suction** Gauge	Displays suction level from 0 to 200 mmHg of vacuum.
6	**Suction Min Max** Control	Adjusts suction level from 0 to 150 mmHg of vacuum.
7	**On/Off** Switch	Turns **Suction** on and off.
	AutoBreath	
8	**Rate (BPM)** Control	Adjusts breath frequency from 18 to 60 breaths per minute.
9	**PEEP min max** Control	Adjusts positive end expiratory pressure from 0 to 18 cm H_2O.
10	**On/Off** Switch	Turns **AutoBreath** Infant Resuscitator on and off (including **PEEP**).
11	**Exh Valve**	Accepts exhaust valve line of patient circuit for expiratory valve control.
	Patient Supply	
12	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.
13	**Airway Pressure Relief Min Max** Control	Adjusts airway pressure relief setting from 0 to 50 cm H_2O.
14	**Flow Rate (LPM)** Control	Adjusts patient gas flow from 0 to 15 LPM. Delivers blended gas if blender option is incorporated.
15	**Patient Outlet** Connector	**Accepts breathing circuit.**
	Auxiliary Flow	
16	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
17	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
18	**Airway Pressure Port**	Connects Airway Pressure Gauge to Patient Circuit. Not Mounted on Units equipped with AutoBreath.

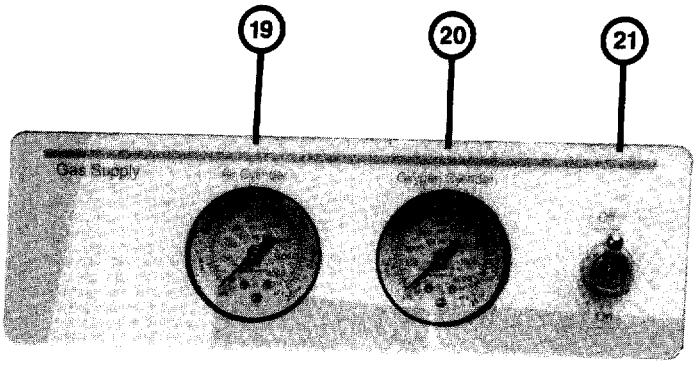


FIGURE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

TABLE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

ITEM	NAME	DESCRIPTION
	Supply Pressure (Optional)	
19	**Air Cylinder** Gauge	Provides indication of air cylinder supply pressure 0 to 4000 psi (275.8 bar).
20	**Oxygen Cylinder** Gauge	Provides indication of oxygen cylinder supply pressure 0 to 4000 psi (275.8 bar).
21	**Gas Supply On/Off** Switch	Turns gas supply to pneumatic system on and off.

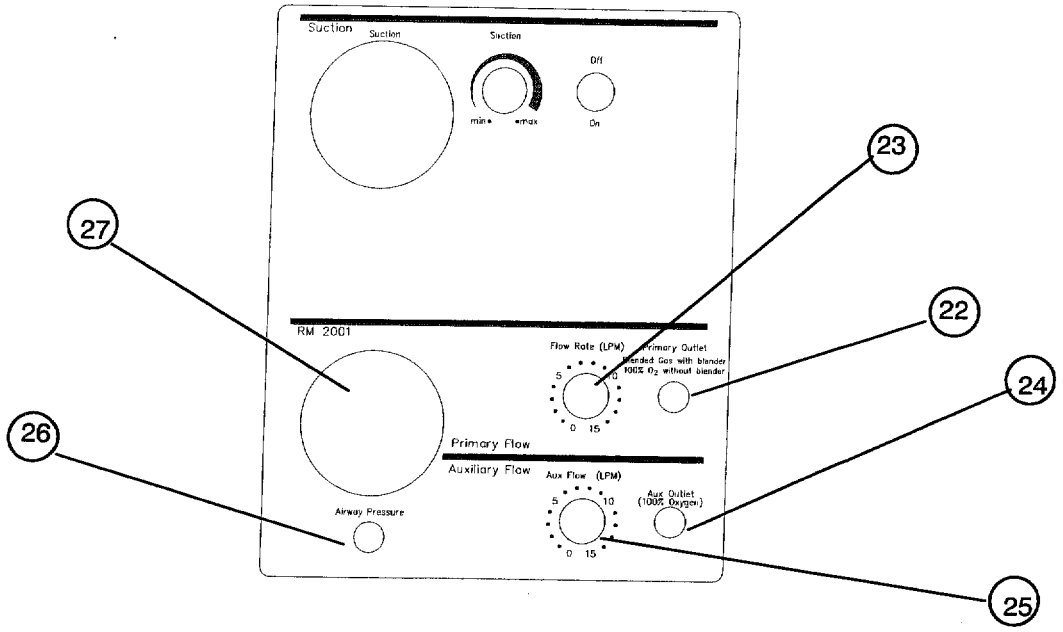


FIGURE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Primary Flow	
22	**Primary Outlet**	Accepts primary gas delivery line. Delivers blended gas if blender option is installed: 100% oxygen if no blender installed.
23	**Flow Rate (LPM)** Control	Adjusts primary gas flow from 0 to 15 LPM
	Auxiliary Flow	
24	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
25	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
26	**Airway Pressure Port**	Connect Airway Pressure Gauge to Patient Circuit. Not mounted on units equipped with AutoBreath
27	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2 O.

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4.2 OPERATIONAL CHECKOUT PROCEDURE - CONTROLLER

WARNING: The Warmer should not be used if the Controller fails to function as described below. Service should be referred to qualified personnel.

CAUTION: HEAVY EQUIPMENT: To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport. Use the handle when moving the equipment.

IMPORTANT: *Before attempting to perform this procedure, refer to Paragraph 4.1, Controls, Indicators and Connectors.*

NOTE: *The Operational checkout procedure described below should be performed before the equipment is first put into service, then at least weekly.*

1. **CONNECT THE AC LINE CORD TO THE POWER CONNECTOR** on the Controller Rear Panel.

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

2. **CHECK THE POWER FAILURE ALARM.** Turn off the **CIRCUIT BREAKER** on the Rear Panel. Turn on the **Power** Switch on the Front Panel. The **Power Fail** Indicator should come on and the Audible alarm should sound. Turn off the **Power** Switch and turn on the **CIRCUIT BREAKER.**

NOTE: *The unit must be connected to the ac line for at least eight minutes before the **Power Fail** circuitry becomes active.*

3. **CHECK THE SELF-TEST FUNCTION.** Turn on the **Power** Switch, the Self-Test Function should be initiated and the following should occur:
   - **Apgar Timer, Baby Temperature** and **Set Temperature** Digital Displays show all eights
   - All **Alarms** Indicators light (except **Power Fail**)
   - All **Mode** Indicators light
   - The **> 37 °C** Indicator lights
   - All ten segments of the **Heater Power** Indicator light
   - The Procedural Silence Indicator lights
   - The **Keypad Lock** Switch lights
   - The audible alarm will sound a high pitch tone, a low pitch tone, then a beep-beep-beep

   When the Self-Test Function is complete, the Controller should begin operating in the **Pre-Warm Mode.**

4. **CHECK THE PRE-WARM MODE.** The **Pre-Warm** Indicator should be on and the **Heater Power** Indicator should display 10 segments (100%) for three minutes, reduce to 6 segments (60%) for 12 minutes, then reduce to 3 segments (30%).

5. **CHECK THE MANUAL MODE.** Select **Manual Mode** by pressing the **Mode** Select Key. The **Manual** Indicator should light.
   Press the Up Arrow Key until all the **Heater Power** Display segments are lit. Press the Down Arrow key until all the **Heater Power** Indicators are off. Connect the skin temperature probe to the **Skin Temp Probe** Connector, the **Baby Temperature** Display should come on.

   Set the **Heater Power** Indicator to 100%, all segments are lit. Wait 10 minutes. After 10 minutes have elapsed, the **Chk Patient** Indicator should come on and the audible alarm should sound one time. Wait an additional 5 minutes. During this time, the audible alarm should sound at 30-second intervals. At the end of 5 minutes (15 total), the heater should shut down, the **Heater Power** Indicators should go off and the audible alarm should sound continuously and ramp up in volume. Press the **Silence/Reset** Key, the **Chk Patient** Indicator and audible alarm should go off, the heater power should return and all ten **Heater Power** Indicators should illuminate.

6. **CHECK THE KEYPAD LOCK.** Press the **Keypad Lock** Switch. The **Keypad Lock** Switch should light up. The **Mode** Key and the Up/

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Down Arrow Keys Key should be inoperative. Press the Keypad Lock Switch. The **Keypad Lock** Switch Light should go off and the Keypad should be enabled.

7. **CHECK THE BABY MODE.** Select **Baby Mode** by pressing the Mode Select Key. The **Baby** Indicator should light and the **Set Temperature** Display should activate. In addition, the **Baby Temp** Indicator should flash and the audible alarm should sound (if the temperature and set point are more than 1° C apart) Press the **Silence/Reset** Key, the audible alarm should go off, the **Baby Temp** Indicator should become steady on.

8. **CHECK TEMPERATURE OVERRIDE MODE.** Press the Up Arrow Key to raise the **Set Temperature** to 37.0 °C. Press the **>37 °C** Key, the **>37 °C** Indicator should come on. Press the Up Arrow Key to raise the **Set Temperature** to 38.0 °C.

   Press the Down Arrow Key to lower the **Set Temperature** to below 37.0 °C. When the **Set Temperature** falls below 37.0 °C, the **>37 °C** Indicator should go off.

9. **CHECK THE PROBE ALARM.** Disconnect the skin temperature probe from the **Skin Temp Probe** Connector. The **Baby Temperature** Display should go off, the **Probe** Indicator should flash and the audible alarm should sound. Replace the probe.

10. **CHECK THE APGAR TIMER.** Press the **Start /Stop** Key, the **Apgar Timer** Display should come on and begin to count up from zero seconds. Press the **Start/Stop** Key, the **Apgar Timer** count should stop. Press the **Reset** Key, the **Apgar Timer** Display should go off.

11. **CHECK THE EXAMINATION LIGHT.** Press the **Exam Light** Switch. The Examination Light should come on. Press the Exam Light Switch, the Examination Light should go off.

4.3 MECHANICAL CHECKOUT

1. **CHECK THE MATTRESS TILT CONTROL** (Figure 4.4) by pulling up on the lever located at the bottom rear of the Bassinet while supporting the rear lower edge of the Bassinet with the palm. Place the Bassinet in the 5-degree and then the 10-degree tilt position. Return the Bassinet to the level position.

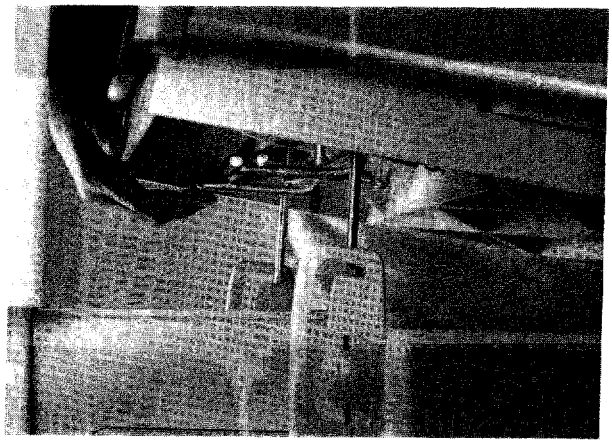

FIGURE 4.4 BASSINET TILT CONTROL

2. **CHECK THE BASSINET SIDE PANELS** (Figure 4.5) by raising each panel and pivoting it to hang straight down. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

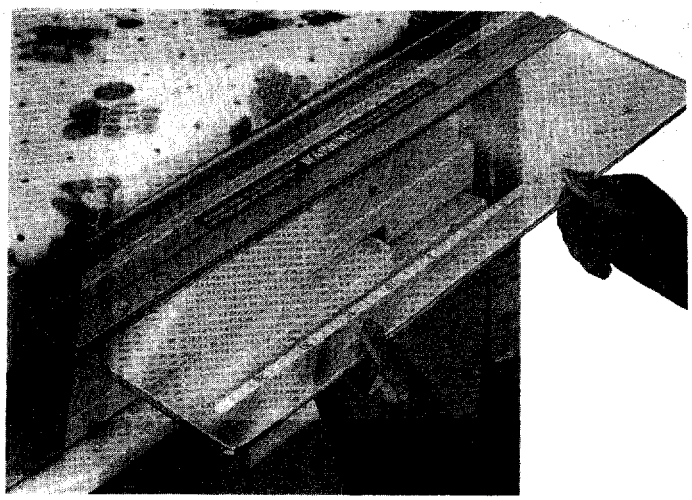

FIGURE 4.5 CHECKING THE BASSINET SIDE PANELS

3. **CHECK THE BASSINET FRONT PANEL** (Figures 4.6 and 4.7) by raising the panel and and sliding it under the mattress. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

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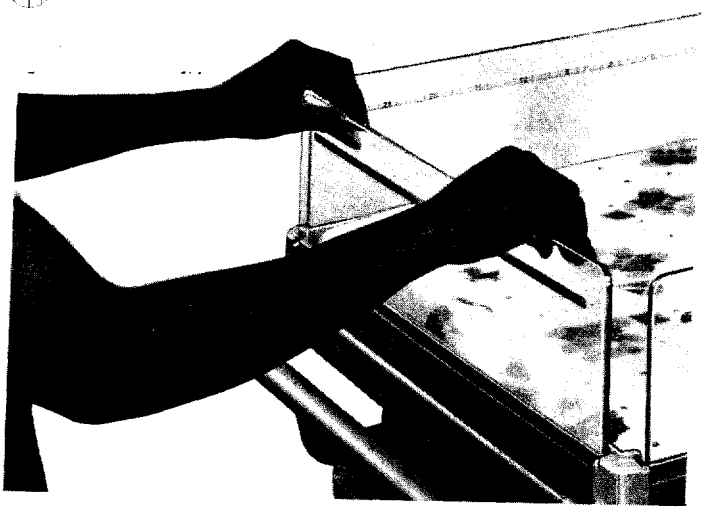


FIGURE 4.6 CHECKING THE BASSINET FRONT PANEL

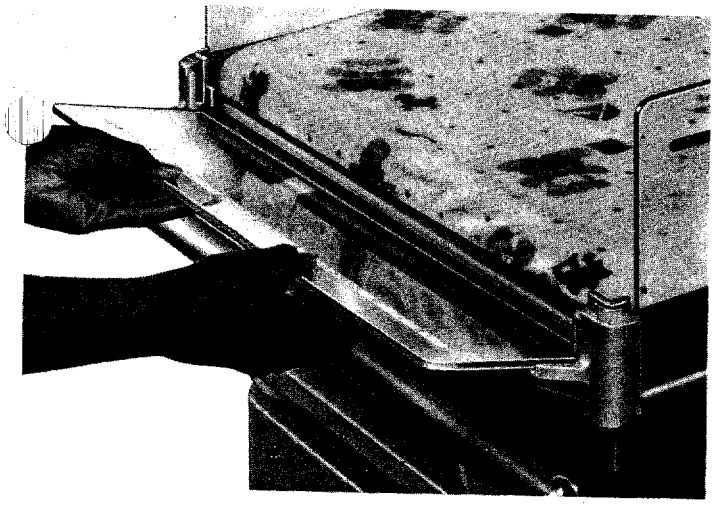


FIGURE 4.7 CHECKING THE BASSINET FRONT PANEL

4. **CHECK THE PASS–THROUGH DRAWER** (Figure 4.8) by sliding the drawer in and out on both sides of the Bassinet. Return to center position.

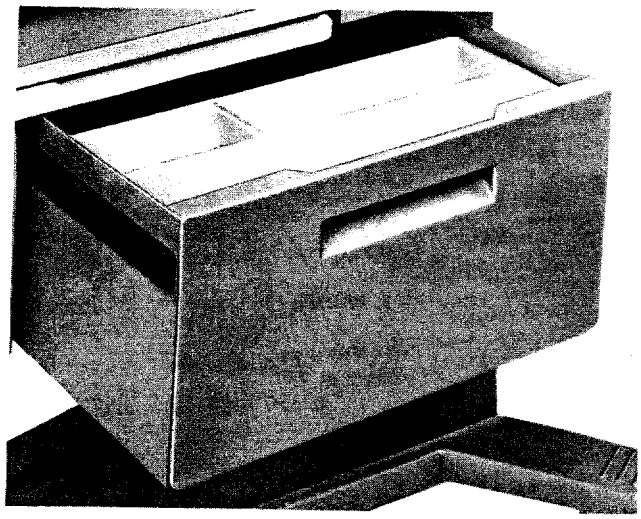


FIGURE 4.8 CHECKING THE PASS–THROUGH DRAWER

5. **CHECK THE WARMER MODULE SWIVEL OPERATION** (Figure 4.9) by rotating the Warmer Module 90 degrees to the left or right of center. Return to center position.

WARNING: When the Warmer Module is swiveled and energized, objects (Monitors etc.) located on the optional Monitor Shelf may overheat or become hot to the touch.

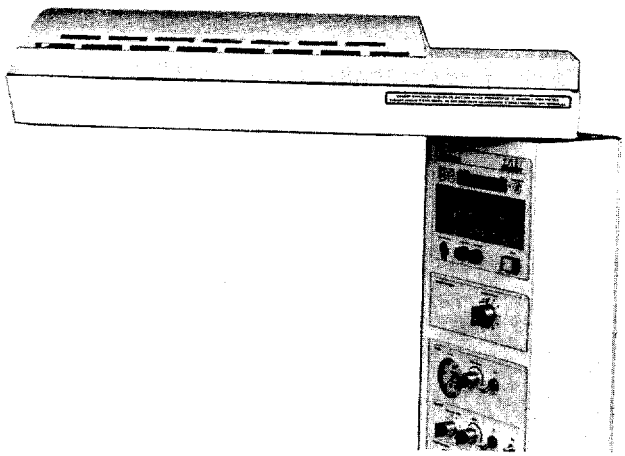


FIGURE 4.9 CHECKING THE WARMER MODULE SWIVEL

6. **CHECK THE OPERATION OF THE X-RAY CASSETTE TRAY (ACCESSORY)** (Figure 4.10) by pulling up the middle of a Side Panel and pulling the X-ray Cassette Tray out from under the Bassinet. Replace the X-ray Cassette Tray by reversing the procedure.

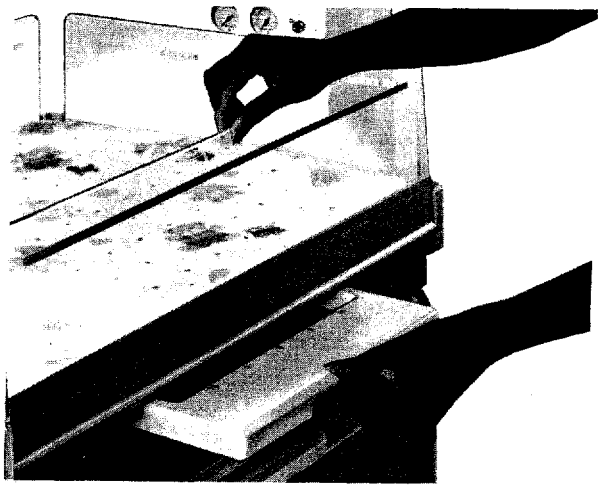


FIGURE 4.10 CHECKING THE X-RAY TRAY

7. **CHECK THE INSTRUMENT TRAY (ACCESSORY)** (Figure 4.11) by swinging it out from under the Bassinet.

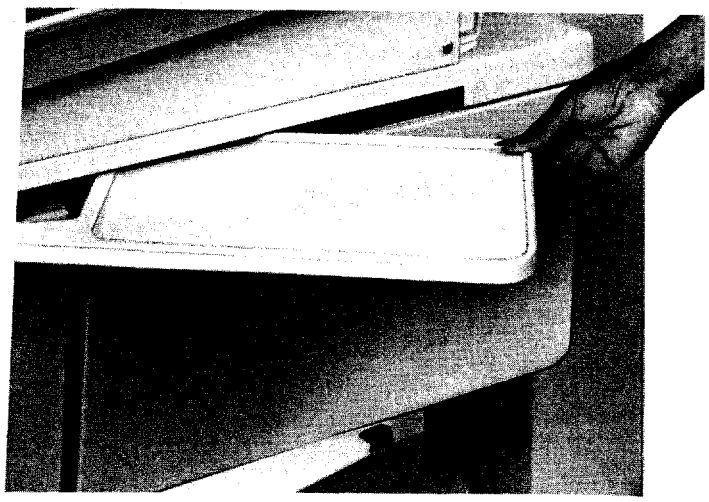


FIGURE 4.11 CHECKING THE INSTRUMENT TRAY

8. **CHECK THE VHA** by pressing the upper portion of the Switch on the right side of the Lower Post until the Upper Post raises to its maximum height. Press and hold the lower portion of the Switch until the Upper Post lowers to its minimum height. Repeat the procedure using the Switch on the left side of the Lower Post. Verify the Upper Post operates smoothly and re-adjust to desired height.

CAUTION: Always lower the Resuscitaire® Radiant Warmer VHA to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.

9. **CHECK BASSINET TILT CONTROL Operation as follows (VHA) only*:**

a. Turn the Bassinet Tilt Control clockwise (Figure 4.11A) until the Bassinet Foot End is fully raised and comes to a stopl.

b. Turn the Bassinet Tilt Control counterclockwise until the Bassinet Head End is fully raised and comes to a stop.

c. Return the Bassinet to the horizontal position.

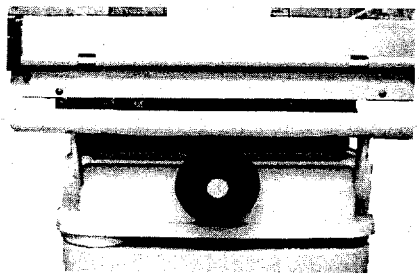


FIGURE 4.11A CHECKING THE BASSINET TILT CONTROL (VHA ONLY)

4.4 RESUSCITATION EQUIPMENT PRE-USE CHECKOUT/SET-UP

SUPPLY PRESSURE

1. Ensure that O_2 (and AIR) pipeline(s) are securely attached to appropriate fittings on the rear of the unit and that the gas supply present is 40 to 75 psi.

If using Reserve Gas Supply from cylinders:

2. Ensure that cylinder(s) are properly secured in the mounting yokes on the rear of the warmer and that the cylinder valve located on the top of the cylinder is open.
3. Examine the appropriate cylinder pressure gauges on the front of the upper column to ensure that sufficient reserve gas supply is present.

*Not available in USA or Canada.

4. Set the **Gas Supply On/Off** Switch to the **On** position.

BLENDED GAS SUPPLY (Optional)

LOW FLOW MICROBLENDER WARNINGS

- **If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FIO_2 and flow output from the microblender.**
- **Always operate the low flow microblender with clean/dry medical grade gases.**
- **Air inlet water filters are recommended for use with the low flow microblender.**
- **The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.**

1. If present, set the precision blender to the desired oxygen % concentration using the Blender Control Knob.

RESUSCITATION MODULE (Optional)

SUCTION

NOTE: *To obtain suction, the **Gas Supply On/Off** Switch (Figure 4.3C) must be **ON.***

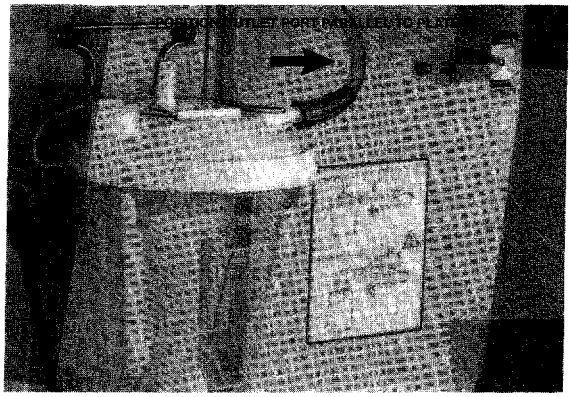
1. Check that a clean suction bottle (reusable or disposable, Figure 4.12) is installed and properly connected in the Resuscitation Equipment Storage Compartment at the front of the warmer.

CAUTION: When installing the disposable Suction Bottle: to prevent the suction tube from being blocked or damaged, position the Outlet Port parallel to the plate (Figure 4.12).

2. Ensure that a bacterial filter is connected in-line with the supply connection to the reusable suction bottle (a filter is built-in on the disposable bottle).

3. Connect the desired extension tubing to the outlet of the suction bottle outlet port (refer to Figure 3.1) and secure the free end of the extension tubing in either tubing retaining slot provided on the front panel of the Bassinet.

4. Turn on the **Suction On/Off** Switch. There may be an initial reading of up to 30 mmHg on the Suction Gauge (refer to Figure 3.1) due to flow resistance of the hydrophobic filter and suction tubing.



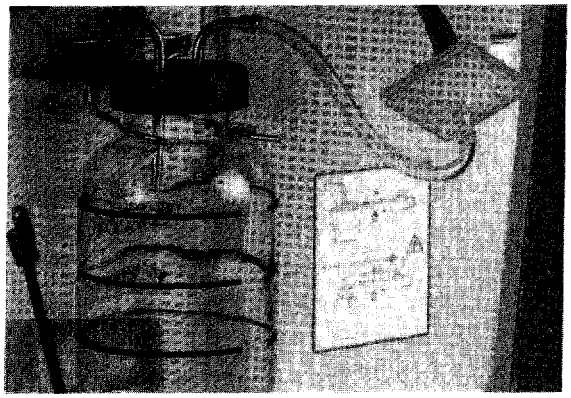


FIGURE 4.12 CHECKING THE SUCTION BOTTLE

NOTE: *The filter and tubing resistance will not affect the desired maximum value that is set in Step 5 below. The pressure value on the Suction Gauge matches the actual pressure value at the end of the catheter.*

5. Block the patient outlet of the suction bottle. Adjust the suction magnitude using the **Suction Min Max** Control while viewing the suction level on the **Suction** Gauge. Adjust the suction magnitude to the desired maximum suction pressure value.
6. Turn off the **Suction On/Off** Switch.

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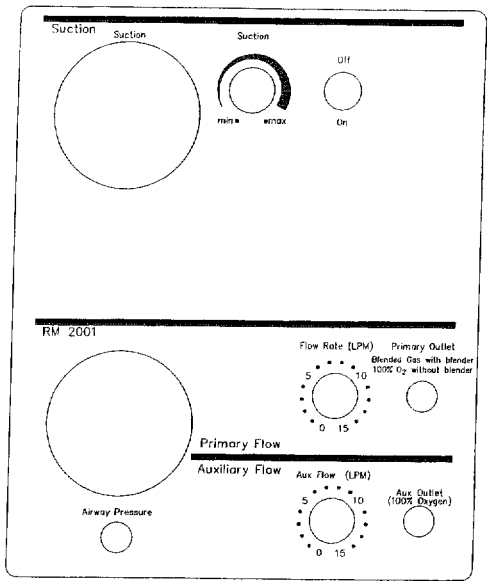

FIGURE 4.13 RESUSCITATION MODULE 2001

RESUSCITATION MODULE 2001 (Optional)

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

PRIMARY FLOW (provides blended gas if optional blender is installed; 100% oxygen if no blender is installed)

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the desired device to be supplied by the **Primary Flow** circuit to the **Primary Outlet** connector.
2. Adjust desired primary flow using the Primary **Flow Rate (LPM)** control and check flow.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

AIRWAY PRESSURE

Airway Pressure fitting may be used to measure airway pressure during mechanical resuscitation.

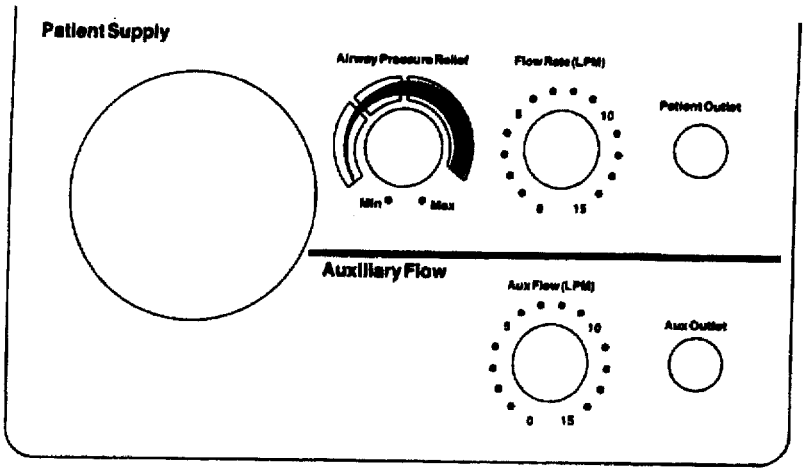

FIGURE 4.14 RESUSCITATION MODULE (PATIENT SUPPLY)

RESUSCITATION MODULE WITHOUT AUTO-BREATH (Optional) Patient Supply

Manual Resuscitation - Use with Patient Breathing Circuit - 10 mm tubing with thumb (finger) hole at patient end.

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the Patient Circuit to the **Patient Outlet** (refer to Figure 3.3).
2. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
3. Set the **Airway Pressure Relief** control to the desired pressure limit according to the color coded bands on the **Airway Pressure** Gauge and **Airway Pressure Relief** Control. Alternately, a "T" Fitting with an airway pressure monitor can be inserted into the **Patient Outlet** Port and connected to the **Airway Pressure** Port to indicate the breathing circuit pressure. Adjust the **Airway Pressure Relief** Control as necessary.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

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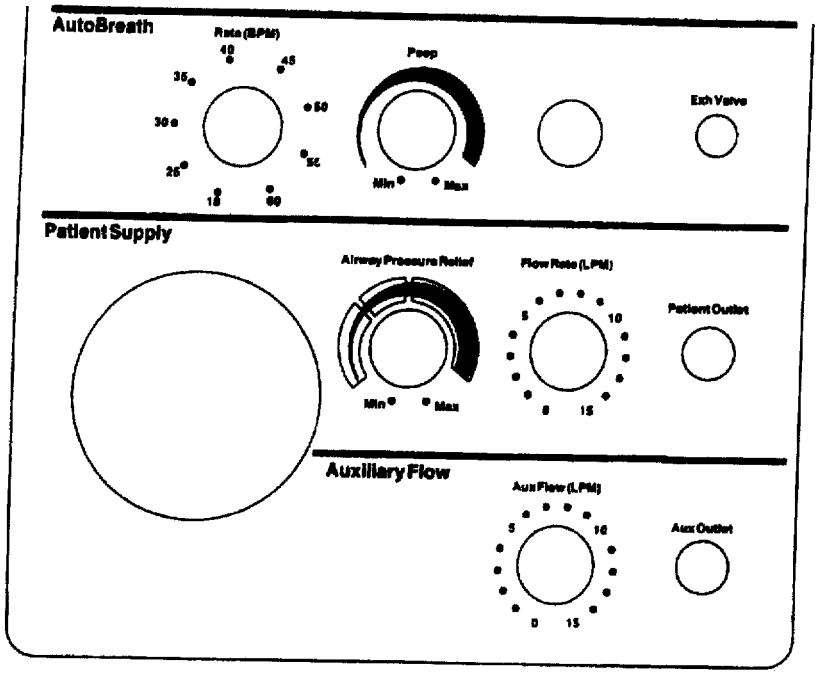

FIGURE 4.15 RESUSCITATION MODULE WITH AUTOBREATH

RESUSCITATION MODULE WITH AUTOBREATH (Optional) Not Avaialbe in USA or Canada

Automatic Resuscitation (Resuscitation Module with **AutoBreath** Infant Resuscitator Only) - Use with Automatic Patient Circuit -15 mm tubing with exhalation valve and exhalation valve control line tubing.

WARNING:
Excessive air pressure can cause damage to patient's lungs.
For prolonged ventilation, use of a heat and moisture exchanger is recommended.
For unattended auto ventilation use patient airway monitor.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Turn the **AutoBreath** Infant Resuscitator circuit off using the **On/Off** Control.
2. Connect the Patient Circuit for Automatic Breathing to the **Patient Outlet** Connector and the exhalation valve control line tubing to the **Exh Valve** Connector (refer to Figure 3.2).
3. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
4. Check the fixed internal **Airway Pressure Relief** Control by setting the desired Airway Pressure Limit and blocking the exhalation valve port exhaust and the patient port of the Exhalation Valve.
5. Observe the **Airway Pressure** Gauge to check pressure limit.
6. Turn on the **AutoBreath** Infant Resuscitator circuit.
7. Adjust the **Rate (BPM)** Control to 18 breaths per minute.
8. Set the **PEEP** threshold by blocking the patient port of the Patient Breathing circuit. Do not block the exhalation valve exhaust port. Observe the Positive End Expiratory Pressure indicated on the **Airway Pressure** Gauge and adjust the desired PEEP using the **PEEP** Control.
9. Check the I:E ratio by measuring the Inspiratory and Expiratory Phase Times and dividing the Expiratory Phase Time by the Inspiratory Phase Time. The result should be approximately 2.0.
10. Check the desired Breath Rate by counting the number of breath cycles per minute.

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4.5 CONTROLLER OPERATION

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital-use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

Connect the unit to the ac line. Turn on the **CIRCUIT BREAKER** on the Rear Panel and the **Power** Switch on the Front Panel. Observe the Functional Test.

4.5.1 PRE-WARM MODE

After the Functional Test is complete, the **Pre-Warm Mode** will activate. The **Heater Power** Indicator will be at 100% (all lights on) for three minutes, reduce to 60% (six lights on) for 12 minutes and then be reduced to 30% (three lights on).

NOTE: *Selection of **Manual** or **Baby** and then returning to **Pre-Warm** during the three minutes of 100% or 12 minutes of 60% power will automatically reduce the power to 30%.*

During **Pre-Warm** Mode, the **Chk Patient** Alarm is disabled.

4.5.2 MANUAL MODE

WARNING:

To avoid overheating or underheating, observe the infant constantly and monitor the temperature using the skin temperature probe supplied with the equipment or other electronic thermometer.

Inspect infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Use the Mode key to select **Manual Mode**.
2. Use only for short-term warming with nursing personnel in constant attendance.
3. Do not use warmer in **Manual Mode** if **Manual** Indicator is not on.
4. Set the **Heater Power** Indicator to the desired level. The heater power will be maintained for 10 minutes.
5. After 10 minutes, the **Chk Patient** Alarm will sound one time. Press the **Silence/Reset** Key to initiate another 10-minute warming period.
6. If the **Chk Patient** Alarm is not acknowledged, the heater will be automatically disabled after an additional 5 minutes of operation.
7. Heater power output must be adjusted manually to maintain Baby Temperature within the desired range.
8. Check infant's temperature and condition at least every 15 minutes. When initially setting or when changing heater power output, check Baby Temperature more frequently to be sure it is maintained within the desired range.

CAUTION: A change in heater power output will not result in an immediate change in Baby Temperature. Wait for results. Large changes in heater power output will cause a more rapid change in Baby Temperature.

9. Use Skin Temperature Probe to continuously monitor Baby Temperature whenever possible. Refer to paragraph 4.5.3 to attach the probe to the patient.

IMPORTANT: *In **Manual Mode**, the Skin Temperature Probe monitors only -- it does not control.*

NOTE: *It is not necessary that the Skin Temperature Probe be connected to the Controller for **Manual Mode**.*

4.5.3 BABY MODE

WARNING:

To avoid hazards of overheating or underheating, the infant should not be left unattended. Use only with the Hill-Rom Air-Shields' Skin Temperature Probe supplied with the unit. Inspect the infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Plug Skin Temperature Probe into Controller **Skin Temp Probe** Connector.
2. Use the Mode key to select **Baby Mode**.
3. Attach the Skin Temperature Probe to the infant. The probe should be located on the infant's abdomen, halfway between the xyphoid and the umbilicus (Figure 4.13). The metal side of the probe should be placed in direct contact with the skin (when using the reusable probe).

FIGURE 4.13A ATTACHING SKIN PROBE

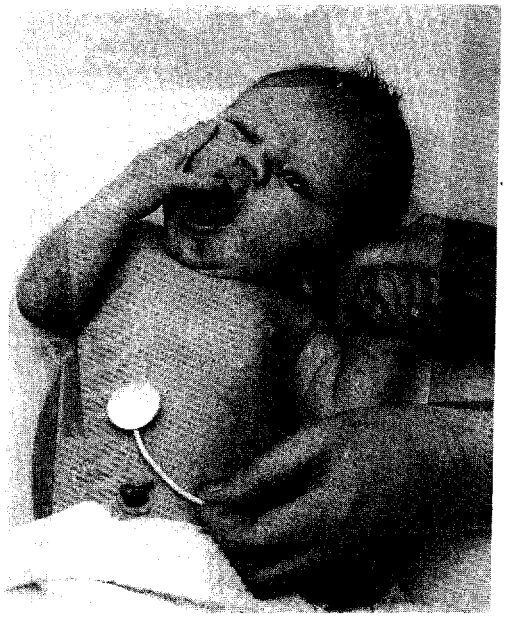

FIGURE 4.13B ATTACHING SKIN PROBE

WARNING:

The location of the Skin Temperature Probe must be such that the skin around the Sensor is in direct line with the heat from the Warmer Module. If the location is shadowed, for example, by the infant's body, overheating and possible burning of the infant's skin can result. Do not use a rectal probe. Use of a rectal probe can result in overheating or underheating of the infant.

The Skin Temperature Probe must be in intimate contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain intimate skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment and feel infant's skin for signs of overheating.

The Skin Temperature Probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The Skin Temperature Probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.

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4. When the infant is prone, the Skin Temperature Probe should be located on the infant's back.

5. The skin area around the probe should be thoroughly cleansed and dried before the probe is placed on the skin.

6. To obtain an accurate reading of the infant's skin temperature, place the probe in position and cover with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or tape the probe into position, cover it with a small piece of cotton just large enough to cover the tip of the probe, and then place a second piece of tape over the cotton. If it is desired to reduce tape contact on the infant's skin, the cotton can be applied directly to the probe tip without the first piece of tape. To stabilize the attached probe, a third piece of tape may be placed over the probe wire approximately three to four centimeters from the probe tip.To minimize the effect of direct radiation on the Skin Temperature Probe, in order to obtain a more accurate **Baby Temperature** measurement, cover the Sensor with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or an equivalent insulating cover with a reflective surface facing the Warmer Module.

7. Baby Mode should be used for long-term warming and when attending personnel cannot be in constant attendance.

8. Set the **Set Temperature** Display to the prescribed temperature. A higher Set Temperature setting does not increase rapid warming.

9. Verify that **Baby Temperature** Display reading stabilizes within 0.2 °C of **Set Temperature** Display. Fluctuations in the **Heater Power** Indicators or the **Baby Temperature** Display reading can result from air currents, obstruction of radiation to the infant or the Skin Temperature Probe not being in intimate contact with the skin.

10. **Baby Temp** Alarms can be silenced for 10 minutes by pressing the **Silence/Reset** Key.

11. **Probe, High Temp** and **Baby Temp** (39.0 °C) Alarms are automatically reset after the alarm condition is corrected. The **High Temp** Alarm may be silenced for 2 minutes by pressing the **Silence/Reset** Key.

NOTE: *In the event of a **Probe** Alarm, **Manual Mode** can be used temporarily until a replacement Skin Temperature Probe is available and only if nursing personnel are in constant attendance.*

4.5.4 EXAMINATION LIGHT

The light is turned on and off by the **Exam Light** Switch. Turn the light on only as required for optimum bulb life.

4.6 X-RAY PROCEDURES

1. Swing the Warmer Module (Figure 4.9) to the right or left of center as required to position the X-ray machine.

2. Lift the Left or Right Bassinet Side Panel up, slide the X-ray Tray out (Figure 4.10); place the X-ray Cassette on the tray and return the tray to the Bassinet. Align the cassette as desired with the markings on the X-ray Cassette Tray and relative markings on the inside of the Bassinet panels.

3. When the X-ray is complete, remove the X-ray Cassette Tray and return the X-ray Tray. Place the Warmer Module in its normal operating position.

SECTION 5
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 Hill-Rom service personnel.

WARNING:

If oxygen is in use, make sure that the oxygen supply to the equipment is turned off and that it 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 cleaning and maintenance procedures; make sure that the Power Cord is disconnected from the wall receptacle.

5.2 CLEANING

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and 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

1. Remove both Bassinet Side Panels (Figure 5.1) by pulling them straight up.

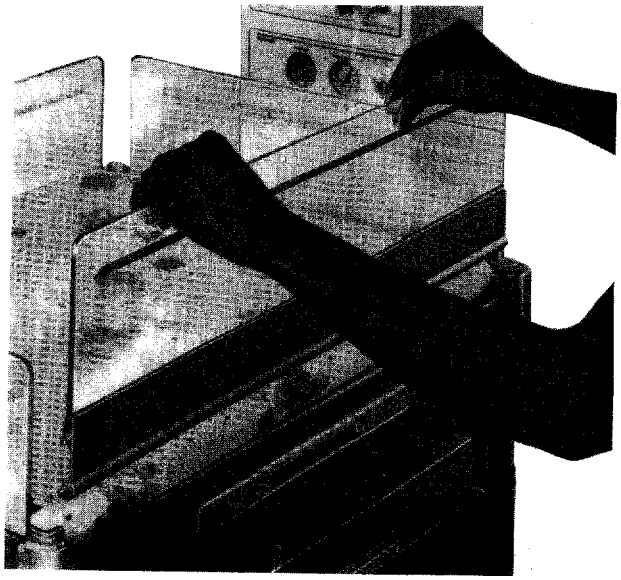

FIGURE 5.1 REMOVING BASSINET SIDE PANELS

2. Remove the Bassinet Back Panel (Figure 5.2) by raising it straight up until the bottom pins are adjacent to the slots in the corner brackets.

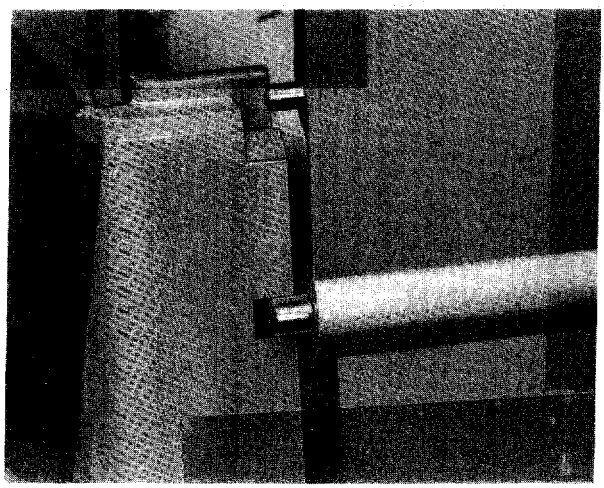

FIGURE 5.2 REMOVING BASSINET BACK PANEL

3. Remove the Bassinet Front Panel (Figure 5.3) by raising it and then swiveling it down. At the corners, press up on the release buttons and pull the panel straight out (Figure 5.4).

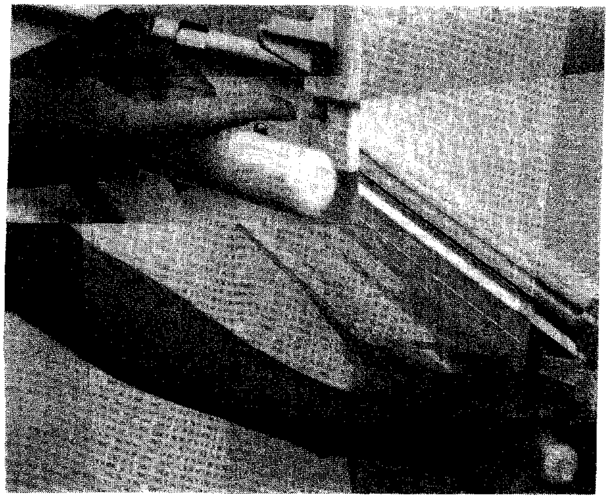

FIGURE 5.3 BASSINET FRONT PANEL RELEASE BUTTONS

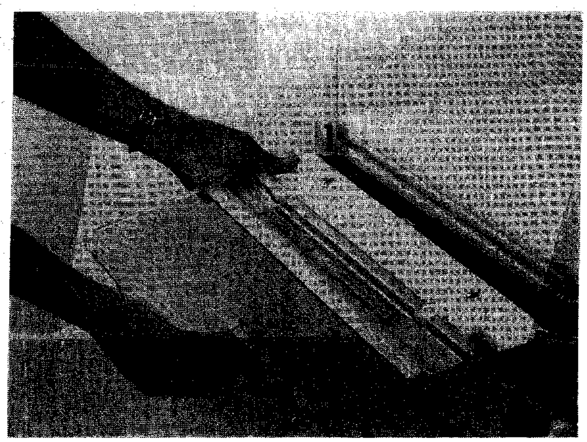

FIGURE 5.4 REMOVING BASSINET FRONT PANEL

4. Remove the Mattress from the Bassinet.

5. Remove the X-ray Tray (Figure 4.10).

6. Remove the Suction Bottle and Filter (Figure 4.12) from the front of the Bassinet.

5.4 CLEANING PROCEDURES

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and disinfected.

5.4.1 CLEANING AGENTS

An intermediate-level detergent/disinfectant registered by the U.S. Environmental Protection Agency should be used, but only when the equipment is not in use and disassembled as described elsewhere in this section. 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 PAINTED SURFACES

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

5.4.3 CLEAR PLASTIC AND ACRYLIC SURFACES

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

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.

Use a detergent/disinfectant to clean all surfaces thoroughly. Make sure to clean all holes, indentations, baffles, etc.; then dry with a clean cloth or paper towel.

5.4.4 METAL SURFACES

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

IMPORTANT: *After cleaning, a complete operational checkout should be performed before returning the unit to service.*

5.4.5 SKIN TEMPERATURE PROBE, REUSABLE

CAUTION: Do not pull on the tip of the skin temperature probe when cleaning or drying; damage to the probe may result.

Use a detergent/ to thoroughly clean all surfaces; then dry with a clean soft cloth or paper towel.

5.5 STERILIZATION (IF DESIRED)

CAUTION: DO NOT STEAM AUTOCLAVE.

Sterilization can be accomplished by the following methods:

A. COLD (LIQUID) STERILIZATION

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

B. GAS STERILIZATION (ETHYLENE OXIDE). Prior to gas sterilization, the entire unit should be thoroughly cleaned as described elsewhere in this section. Remove and discard all used disposable elements. New disposable elements should be installed after sterilization.

Standard gas sterilization procedures are satisfactory as these do not normally exceed 54.4 °C (130 °F).

IMPORTANT: *After sterilization, a complete functional checkout procedure should be performed before returning the unit to service.*

5.6 REASSEMBLY AFTER CLEANING

1. Replace the Mattress on the Bassinet.
2. Replace the X-ray Tray (Figure 4.10).
3. Replace the Bassinet Back Panel by inserting the pins in the Corner Brackets (Figure 5.2).
4. Replace the Bassinet Side Panels by pushing them straight down into their slots (Figure 5.1).
5. Replace the Bassinet Front Panel by sliding it into the front of the Bassinet (Figure 5.4) until the release tabs catch. Raise the Panel into position.
6. Install a new Suction Filter if using a Reusable Bottle (Figures 3.1 and 4.12). Replace the Suction Bottle if using a Disposable Bottle.

5.7 CALIBRATION

The equipment should be completely checked and calibrated at least once a year by qualified service personnel. Refer to the appropriate Service Manual for details.

5.8 TROUBLESHOOTING

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

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TABLE 5.1 TROUBLESHOOTING

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
No Power and **Power Fail** Alarm is not activated	a. Circuit Breaker not set to On.	a. Set Circuit Breaker to On.
Power Fail Alarm activated	a. Circuit Breaker tripped. b. Power Cord unplugged. c. Defective Power Cord.	a. Reset Circuit Breaker (Figure 4.2). b. Connect Power Cord to POWER connector (Figure 4.2) or wall socket. c. Replace Power Cord.
System Fail Alarm activated	a. Internal malfunction.	a. Refer to service.
Probe Alarm Activated	Possible Defective Skin Probe(s)	a. Check to ensure Skin Probe is in good contact with the skin. b. Replace Skin Probe(s). If condition is not corrected, refer to service.
Error Code Er02 through Er022 Er024 and Er025	a. Internal malfunction	a. Refer to service.
Error Code Er023	Ambient Temperature in excess of 32 °C (90 °F).	Verify ambient temperature with an external thermometer.

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SECTION 6
PARTS LIST

6.1 GENERAL

This section provides a listing of Operator replacement parts. Parts other than those listed here should be replaced by qualified service personnel. For an illustration of accessories, refer to Figure 1.1 of this manual.

REPLACEMENT PARTS	PART NUMBER
Bassinet Side Panel (Eng)	81 900 00
Bassinet Rear Panel (Eng)	81 900 01
Bassinet Front Panel (Eng)	81 900 02
Power Cord 220/240V Units	17 AZ 204
Skin Temperature Probe (Reusable)	81 300 05
Reusable Suction Bottle Kit (750 ml) (Bottle, Stopper, Tubing and Filter)	81 001 50
Reusable Suction Bottle Only	08 131 00
Filters (Box of 25)	81 001 50
40-Inch Power Cord	17 AZ 211

DISPOSABLES	
Premi-Probe® 3 Skin Temperature Probe (Box of 10)	81 300 08
Premi-Probe® 3 Skin Temperature Probe (10 Boxes of 10)	81 300 09
Autobreath Disposable Breathing Circuit and Exhalation Valve (Box of 25)	81 000 06
Autobreath Disposable Gas Supply Circuit (Box of 25)	81 001 27
Breathing Circuit Connector with Pressure Monitor Port (Box of 25)	81 001 29
Critter Covers® Probe Covers (Box of 100)	68 209 46
Critter Covers® Probe Covers (Box of 600)	68 209 45
Care-for-Me Probe Covers, 100 Large (10% discount when you order 5)	68 209 47
Care-for-Me Probe Covers, 100 Standard (10% discount when you order 5)	68 209 48
Neat Clips - 3/8" Diameter (Box of 100)	68 120 53
1.00" Diameter (50/Case)	68 120 54
Disposable Suction Bottle, 800 ml (Box of 100)	81 001 51

OPTIONS	
Instrument Tray - Right Hand	81 101 70R
Instrument Tray - Left Hand	81 101 70L
Pass-Through Drawer Organizer Tray	81 101 11
Air Hose Assembly, Green DISS	78 464 10
Oxygen Hose Assembly, Yellow DISS	78 465 10
Air Hose Assembly, Black NIST	81 501 45
Oxygen Hose Assembly, White NIST	68 507 50
Air Hose Assembly Black DISS	81 501 50
Oxygen Hose Assembly White DISS	68 507 30
Oxygen/Air Sealing Washer	81 502 02
X-ray Cassette Tray	81 100 44
IV Pole	82 001 53
Monitor Shelf	82 001 52

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LIMITED 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 Hill-Rom Air-Shields, Inc., 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 Hill-Rom Air-Shields, Inc. cannot be held liable for conditions resultant therefrom if:

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 Hill-Rom Air-Shields, Inc.
4. Sale or service is performed by a non-certified service/dealer agency.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE. HILL-ROM AIR-SHIELDS' OBLIGATION UNDER THESE WARRANTIES SHALL NOT INCLUDE ANY LIABILITY FOR LOSS OF PROFITS, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES OR DELAYS. Some states, provinces, or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion or limitation may not apply. Any improper or negligent use, any alterations or repairs not in accordance with Hill-Rom Air-Shields' manuals or performed by others in such manner as in Hill-Rom Air-Shields' sole judgement affects the product materially and adversely, shall void these warranties. These warranties do not cover failures due to misuse, abuse, neglect, or lack of routine maintenance. No employee or representative of Hill-Rom Air-Shields is authorized to change these warranties in any way or grant any other warranty unless in writing and signed by a Hill-Rom officer. These warranties provide specific legal rights; but, there may be other available rights; which vary from state to state, province to province, or country to country.

*The Accreditation Manual for Hospitals requires each piece of equipment to be tested prior to initial use and at least annually thereafter. To comply with this standard, we recommend that you participate in our Preventive Maintenance 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. Technical Services representatives are located throughout the United States and Canada and are dispatched for required maintenance by calling USA (800) 445-3720 and Canada (800) 267-2337. Customers outside the U.S. and Canada should contact their local factory-authorized Hill-Rom Air-Shields' distributor for service.

Hill-Rom Air-Shields®
A HILLENBRAND INDUSTRY
330 Jacksonville Road, Hatboro, PA 19040

CAT NO. 82 990 15-9
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A 1 2 3 4 5 6 7 8 9

Printed in USA 11/00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2000

Mr. Larry W. Krasley
Regulatory Affairs Specialist
Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, Pennsylvania 19040

Re: K003335
Trade Name: Resuscitaire Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: October 24, 2000
Received: October 25, 2000

Dear Mr. Krasley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

Indications for Use

510(k) Number:

Device Name: Resuscitaire Radiant Warmer

Indications for Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

✓

(Optional Format 1/2/96)

Patricia Cascante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003335

3

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food and Drug Administration

Memorandum

From: 11/17/00 Reviewer(s) - Name(s) Sarah Foster

Subject: 510(k) Number K003335

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☑ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☑ Enclosed
(required for originals received 3-14-95 and after)

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☑ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 80 FMT / Class II

Additional Product Code(s) with panel (optional):

Review: Patricia Cicenia (Branch Chief) — DGNDB (Branch Code) — 11/17/00 (Date)

Final Review: for Alan Colandreo (Division Director) — 11/17/00 (Date)

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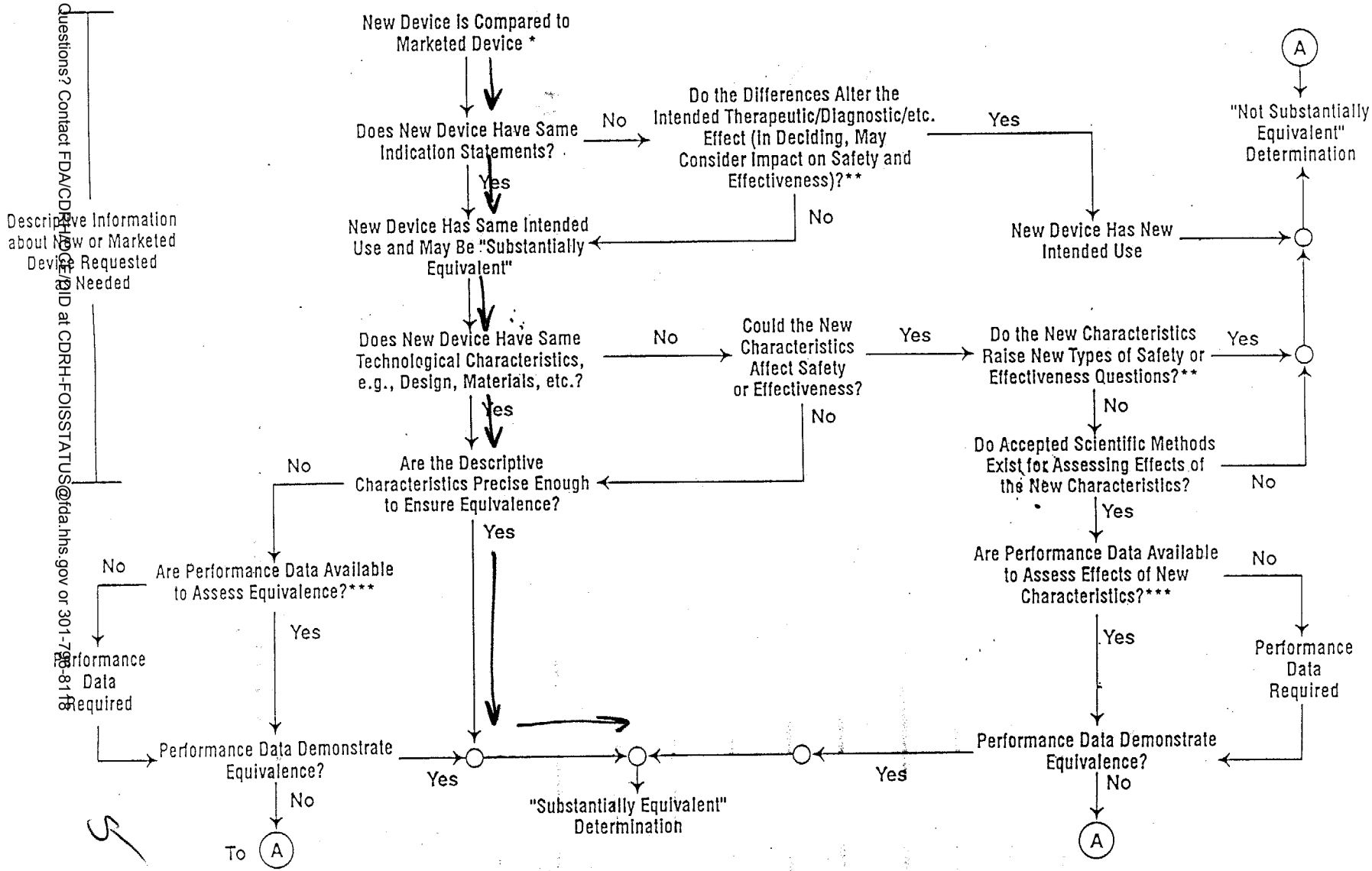
Revised:8/17//99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Test Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K003335

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for: *modifications to the optional resuscitation module which include changing the 15 mm outlet to a tapered fitting better suited for clinical environments in the United States and Canada, and for the replacement of the user adjustable airway relief valve with an internal fixed relief valve of 160cm H_2O.*
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and *gas outlet type, airway relief, operating principal, materials, and function.*
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Sarah Foster
(Reviewer's Signature)

11/17/00
(Date)

Comments:
Because the modifications to this Resuscitaire® Infant Radiant Warmer were made to the resuscitation module, the decisions during this review were made after consulting Dr. Mike Bazaral of the Anesthesiology Branch of ODE.

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11/17/00

Memo

To: The File

From: Sarah Foster, Reviewer

Date: 11/17/00

Re: Document Number K003335

Memo Regarding Conference Call on 11/08/00

This memo confirms the conference call held on 11/08/00 with Larry Krasley and members of the marketing and engineering groups of Hill-Rom Air-Shields , and Dr. Mike Bazaral of the Anesthesiology Branch with myself, Sarah Foster of DDIGD. This conference call was regarding modifications made to the resuscitation module of the Hill-Rom Air-Shields Resuscitaire® Infant Warmer. After discussing the modifications with Dr. Bazaral, we felt that these changes were not properly reflected in the device operating manual. Specifically, the change from a user adjustable airway relief valve to a fixed internal airway relief valve of 160cm H_2O. Both instructions reflecting the new modifications as well as instructions now obsolete were included together in the proposed operator's manual.

Hill-Rom Air-Shields informed us that information for both the modified and original device are included together because the unmodified device is still in use. Dr. Bazaral and I felt that this would create much confusion for the user, and suggested that Hill-Rom Air-Shields create and submit an insert or separate supplement to the operator's manual that would be specific to the modified device.

A modified operator's manual was faxed to DDIGD on 11/14/00 and 11/15/00 in response to the requests made in the 11/08/00 conference call. The modified operator's manual did include a new section listing precautions specific to the modified device as requested. However, the modifications were still not adequate as there remained several references to the "AutoBreath" resuscitation module, which is not available in the United States. Dr. Bazaral had asked the company to remove all references to the "AutoBreath" module in the 11/08/00 call.

Sarah Foster

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Hill-Rom Air-Shields™

A HILLENBRAND INDUSTRY

330 Jacksonville Road
Hatboro, PA U.S.A. 19040-2211
Voice: (215) 682-8688 Fax (215) 682-8689

Facsimile Transmission Sheet

To:	**Farah Foster**	**Date:**	November 14, 2000
Company:	**FDA**	**Pages:**	56
From:	Larry W. Krasley	**FAX No.**	301-480-3002
Copies:			

Dear Ms. Foster,

Attached please find copies of the updates for 510(k) K003335. I have also sent the updates to the Document Mail Center.

- Section III, Page 10. Revised drawing (81 400 34) Sheet 1of 2.
- Section III Pages 12-63 remove and replace with attached Operator's Manual.

Please feel free to contact me should you have any further questions or concerns.

Regards,

Larry

Larry W. Krasley
Regulatory Affairs Specialist

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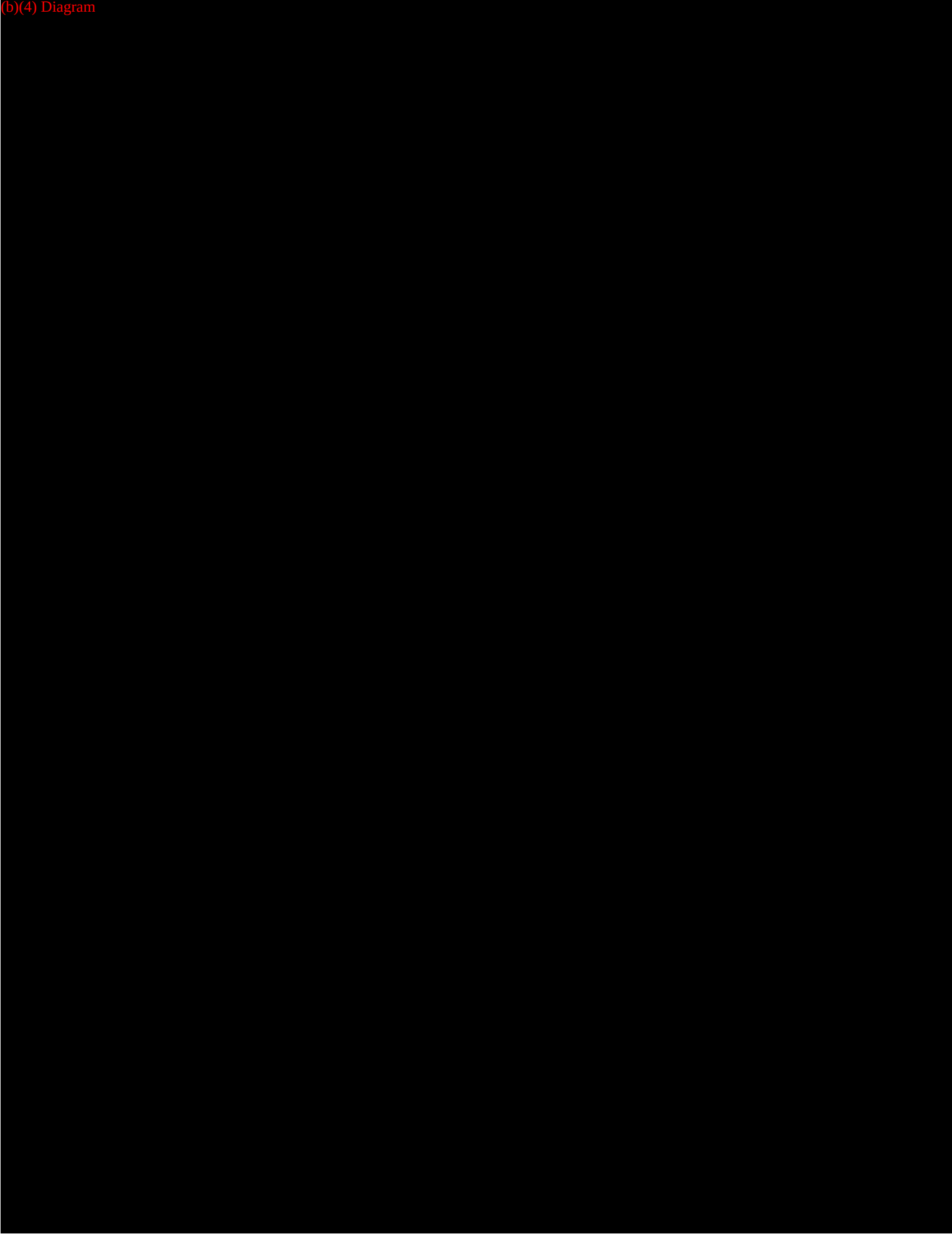
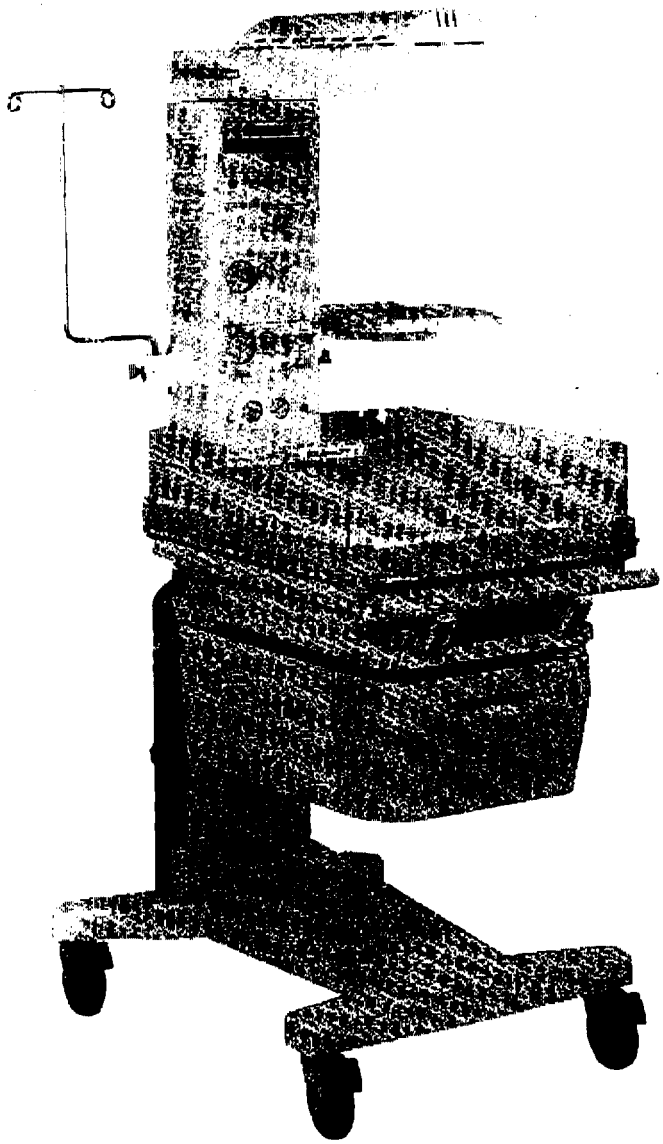

(b)(4) Diagram

Hill-Rom Air-Shields®

A HILLENBRAND INDUSTRY

RESUSCITAIRE® Radiant Warmer

MODEL RW82-1



OPERATOR'S MANUAL

10

OPERATING PRECAUTIONS

GENERAL PRECAUTIONS

- Federal Law restricts this device to sale by or on order of a physician.
- Infant radiant warmers should be used only by properly trained personnel as directed by an appropriately qualified physician aware of currently known risks and benefits.
- The functional checkout procedure should be performed before the unit is first placed into use and after disassembly for cleaning, servicing or maintenance. Refer to qualified service personnel if the unit does not perform as specified.
- The Bassinet end and side panels cannot be used for pushing or pulling the ***Resuscitaire® Radiant Warmer.***
- Do not leave the infant unattended in the Bassinet of the ***Resuscitaire® Radiant Warmer*** when the side panels or the front panel are folded down.
- To avoid overheating or underheating, skin temperature must be continuously monitored and controlled either manually or automatically. Rectal temperature should never be used to control skin temperature.
- To avoid overheating or underheating when operating in manual mode, observe the infant constantly and monitor the temperature using the temperature probe supplied with the equipment or other electronic thermometer.
- The skin temperature sensing probe must be in direct contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain direct skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment, reddened skin areas, and proper skin temperature.
- The skin temperature sensing probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The skin temperature probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.
- To avoid overheating the skin, the location of the skin temperature probe must be such that the skin around the Sensor is in direct line with the radiation from the warmer. Do not place anything between the radiant warmer and the infant that will interfere with the radiation from the warmer.
- Radiant warming increases insensible water loss. Appropriate measures to maintain proper fluid balance should be considered.
- Phototherapy units located too close to the Bassinet may affect mattress and infant temperature.
- The warmer cannot differentiate between an increase in core temperature and cold skin (fever) and low core temperature (hypothermia). It is recommended that patient core temperature be monitored with a separate calibrated electronic thermometer.
- 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 avoid overheating of the warmer, do not place objects (equipment, blankets, clothing or sterile packs) on top of the warmer.
- Air currents across the Bassinet area can affect patient thermal balance. Avoid placing the Warmer near heating or air conditioning ducts that may blow air across the Bassinet.
- Temperature uniformity (per IEC 601-2-21) across the mattress surface may not be maintained when the Bassinet is tilted in the 5- and 10-degree positions.
- During service intervals, inspect the secondary reflector directly under the warmer heater element for particles. If particles are present, replace the heater element. The life expectancy of the heater element is 1000 hours of operation.

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OPERATING PRECAUTIONS (Continued)

GENERAL PRECAUTIONS (Continued)

- Should any of the control knobs on the Resuscitation Module come loose for any reason, do not attempt to refasten them. The calibration of these controls depends on the position of the knob on the shaft. If this occurs, recalibration must be performed by qualified service personnel.
- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Only connect the power cord to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with or provided for the ***Resuscitaire® Radiant Warmer.***
- The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
  - Use of the accessory in the PATIENT VICINITY.
  - Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.
- When raising or lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA,*** make sure that any attached cables, tubing or hoses are not compromised.
- When lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA*** to its minimum height, ensure thatthe gas tanks, if installed, do not contact the floor.
- Always lower the ***Resuscitaire® Radiant Warmer VHA*** to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.
- To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport. Use the handle when moving the equipment.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

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OPERATING PRECAUTIONS (Continued)

ELECTRICAL PRECAUTIONS

- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Confirm that the **Oxygen Supply** is turned off and that the equipment 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.
- Connect the power cord only to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with the Warmer.

EXPLOSION PRECAUTIONS

- Do not use in the presence of flammable anesthetics.
- Confirm that the oxygen supply is turned off and that the equipment 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.

OXYGEN PRECAUTIONS

- Improper use of supplemental oxygen may be associated with serious side effects including blindness, brain damage, and death. The risks vary with each infant. All clinical practices with regard to 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 the 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_2) in the blood. When deemed advisable by the attending physician, blood PO_2 should be measured by accepted clinical techniques.
- Oxygen flow rates cannot be used as an accurate indication of oxygen concentrations. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals directed by the attending physician.
- Keep matches, lighted cigarettes, and all other sources of ignition out of the room in which the equipment is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.
- Although oxygen compatible materials are used in the oxygen delivery system, special care must be taken when high pressure oxygen such as found in a medical oxygen cylinder is used. Violent ignition of oil, grease, greasy substances, small particles of dust, dirt or other particulate contaminants (even small particles of metal), can occur in the presence of high pressure oxygen if their ignition temperature is reached. An instantaneous increase in temperature can occur due to friction, particle acceleration, or adiabatic compression, if the oxygen cylinder valve is opened too rapidly. **SERIOUS INJURY MAY RESULT!** Always observe the following precautions:

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OXYGEN PRECAUTIONS (Continued)

- Oil, grease, greasy substances, dust, dirt and other particulate contaminants must be kept away from oxygen regulators, cylinder valves, tubing and all other oxygen equipment.
- Always open oxygen cylinder shut-off valves **very slowly** and **carefully.**
- On high pressure oxygen cylinders use only pressure regulators or reducing valves approved for oxygen service. Do not use oxygen pressure regulators or reducing valves for air or gases other than oxygen as they may be hazardous. Operate such devices in strict accordance with the manufacturer's recommendations.
- When new or replacement oxygen cylinders are to be installed, they should have their outlet ports cleared by cracking the cylinder valve momentarily before attachment to the equipment.

LOW FLOW MICROBLENDER WARNINGS

- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FiO_2 and flow output from the microblender.
- Always operate the low flow microblender with clean/dry medical grade gases.
- Air inlet water filters are recommended for use with the low flow microblender.
- The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.

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TABLE OF DEFINITIONS AND SYMBOLS

NOTE, IMPORTANT, PRECAUTION, 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 when greater emphasis is required.*

PRECAUTION: *A Precaution is supplemental information to assist the user in the safe and effective use of the equipment.*

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.

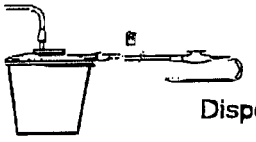
WARNING: A Warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

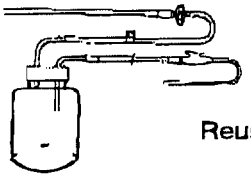
SYMBOLS


Attention: consult accompanying documents.

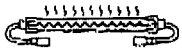

Type B equipment with an F-type isolated (floating) applied part.


Danger! High Voltage!


Disposable Suction Bottle

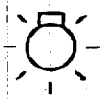

Reusable Suction Bottle


Patient


Heater Element


Suction Line Filter


Load Symbol


Examination Light


Examination Light Switch


Mode Control Key

Temperature Override Mode Key


Keypad Lock Key


Set Temperature Keys


Power On/Off Switch

Celsius/Fahrenheit Selection Key


Silence/Reset Key


Procedural Silence Indicator


Apgar Timer Keys

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SECTION 1
GENERAL INFORMATION

1.1 INTRODUCTION

This manual provides instructions for installation, use, operator maintenance and troubleshooting of the equipment. Hill-Rom Air-Shields cannot be responsible for the performance of the equipment if the user does not operate the equipment 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. Service manuals are available from Hill-Rom Air-Shields.

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

1.2 DESCRIPTION

The ***Resuscitaire® Radiant Warmer*** is designed specifically for labor and delivery room use. The ***Resuscitaire® Radiant Warmer*** consists of a Bassinet, Warmer, and a Controller module which provides heat control, monitoring of skin temperature and Apgar timing. The ***Resuscitaire® Radiant Warmer with VHA*** provides an adjustable Mattress Height from 89.2 cm (35.4 inches) to 110.2 cm (43.3 inches).

The ***Resuscitaire® Radiant Warmer*** also includes optional basic resuscitation packages which includes suction and oxygen delivery.

1.3 SPECIFICATIONS

Specifications for the ***Resuscitaire® Radiant Warmer*** are provided in Table 1.1. All specifications are subject to change without notice.

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RESUSCITAIRE® Radiant Warmer

TABLE 1.1 SPECIFICATIONS

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer*

120V Models	120V, 60 Hz, 750W
100V Models (Japan)	100V, 50/60 Hz, 750W
230V Models	230V, 50/60 Hz, 750W

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer with VHA*

120V Models	120V, 60 Hz, 1300W
230V Models	230V, 50/60 Hz, 1300W

OVERLOAD PROTECTION

120V Models	Dual 12A Circuit Breakers
100V Models (Japan)	Dual 12A Circuit Breakers
230V Models	Dual 6A Circuit Breakers

Resuscitaire® Radiant Warmer with VHA also has in addition:

120V Models	Dual 6A Circuit Breakers
230V Models	Dual 3A Circuit Breakers

CHASSIS LEAKAGE CURRENT (Single fault condition, loss of ground)

100V and 120V Models	Less than 300 µA
230V Models	Less than 500 µA

EXAMINATION LIGHT ..... >100 Foot Candles (0.11 lumens/cm^2)

ALARMS

High Temperature	Activates if Skin Temperature Probe is attached and the skin temperature sensor reaches 39.0 °C. Resets at 38.5 °C.
Check Patient	Activates in Manual Mode after 10 minutes. Remains on with audible alarm every 30 seconds for 5 minutes; totalling 15 minutes. Then the heater is turned *Off*.
Apgar Timer	Activates at the 1-, 5- and 10-minute Apgar Time intervals.
Power Fail	Activates when there is a loss of power.
Probe	Activates if Skin Temperature Probe fails (open or short).
System Fail	Indicates system failure, refer unit to service immediately.
Baby Temp	Activates if Baby Temperature fluctuates 1°C above or below set point.
Electrical Module Audio Alarms	Tone Frequency: 1.2 KHz maximum three-stage sound level: 15 seconds low, 15 seconds medium, then high.
Blender Module Pneumatic Audio Alarm	Vibrating Reed.

MANUAL HEAT CONTROL ..... Adjustable in 10% increments from zero to full power (100%)

DATA PORT ..... 2400 Bits/second fixed Baud Rate. RS232C Compatible.

MATTRESS TILT ..... 0, 5 and 10 degrees.

DISPLAYS

Skin Temperature Display

Range	18 to 40 °C (64.4 to 104°F)
Accuracy	± 0.2 °C for 31 °C to 37 °C (88 °F to 98.6°F)
Resolution	0.1°C (0.5 °F)

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****

*** ACTIVITY REPORT ***

****

(b)(4)

[redacted]

TABLE 1.1 SPECIFICATIONS (Cont.)

DISPLAYS (Cont.)

Apgar Timer Display

Range	0 to 59 minutes, 0 to 59 seconds
Resolution	1 second
Accuracy	0 ± 1 second

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer*

Mattress Height	100 cm (39.4 - inches)
Height	188 cm (74 - inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	100 kg (220 lbs)

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer with VHA*

Mattress Height	89.2 to 110.2 cm (35.4 to 43.3 inches)
Bassinet Tilt (continuously)	±10 degrees from horizontal
Height	180.6 to 200.7 cm (71.1 to 79 inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	127 kg (280 lbs)

ENVIRONMENTAL

Operating Temperature Range	18 °C to 30 °C ambient
Storage Temperature Range	- 30 °C to +70 °C ambient
Relative Humidity Operating Range	5% RH to 95% RH, non-condensing

RESUSCITATION

Wall Supply Pressure	40 to 75 psi (2.8 to 5.2 bar)
Cylinder Pressure	2900 psi max (199.8 bar)
Cylinder Diameter	10-12 cm (4-5 inches) max

Suction Circuit

Adjustable Suction Intensity	0 to 150 mmHg

Patient Gas Supply

Airway Pressure Limit, Operator Adjustable	0 to 50 cm H_2O (4.9 kPa) ± 10%
Fixed Pressure Relief, Factory Set	60 cm H_2O (5.9 kPa) ± 20%

Primary Supply

Primary Pressure Limit	160 cm H_2O (15.7 kPa) ± 20%
Primary Flow Range	0 - 15 lpm

Auxiliary Supply

Auxiliary Pressure Limit	160 cm H_2O (15.7 kPa) ± 10%
Auxiliary Flow Range	0 - 15 lpm

AutoBreath Circuit (Factory Installed Option)

I:E Ratio	Fixed at 1:2 ± 20%
PEEP	0 to 18 ± 4 cm H_2O (1.8 ± 0.4 kPa)
Breath Rate	18 to 60 BPM ± 10% of setting
Airway Pressure Relief, Operator Adjustable	0 to 50 ± 5 cm H_2O (4.9 ± 0.5 kPa)
Fixed Maximum Pressure	60 cm H_2O ± 10%(5.9 kPa ±20%)
Oxygen Consumption	50 LPM max.

1.4 EQUIPMENT PROVIDED

- *Bassinet* - The Bassinet provides maximum visibility and access to the infant. The Bassinet tilts up in the rear 5 and 10 degrees and provides for X-ray Tray (optional) insertion.
- *Warmer Module* - The Warmer Module houses a heating element and an Examination Light for special procedures.
- *Controller* - The Controller provides Pre-Warm, Manual heat control, automatic skin temperature servo-control and contains an Apgar Timer, Skin Temperature monitor and probe connection.
- *Resuscitation Module (Optional)* - The Resuscitation Module contains a suction circuit, a patient oxygen delivery circuit with airway pressure relief and an auxiliary oxygen delivery circuit. There are two varieties of resuscitation modules, both versions can accept an optional blender. AutoBreath is another option but is not available in the USA or Canada.

1.5 FACTORY INSTALLED OPTIONS

- Resuscitation Module
- Resuscitation Module 2001
- Resuscitation Module with AutoBreath
- Integrated Precision Blender
- Gas Supply Module
  - O_2 Pipeline and Cylinder
  - O_2/Air Pipeline and Cylinder

1.6 FIELD INSTALLED ACCESSORIES (Refer to Section 6 for Part Numbers)

- Instrument Tray (left or right mount)
- X-ray Cassette Tray
- Pass-Through Drawer Organizer Tray
- I.V. Pole
- Monitor Shelf

RESUSCITAIRE® Radiant Warmer

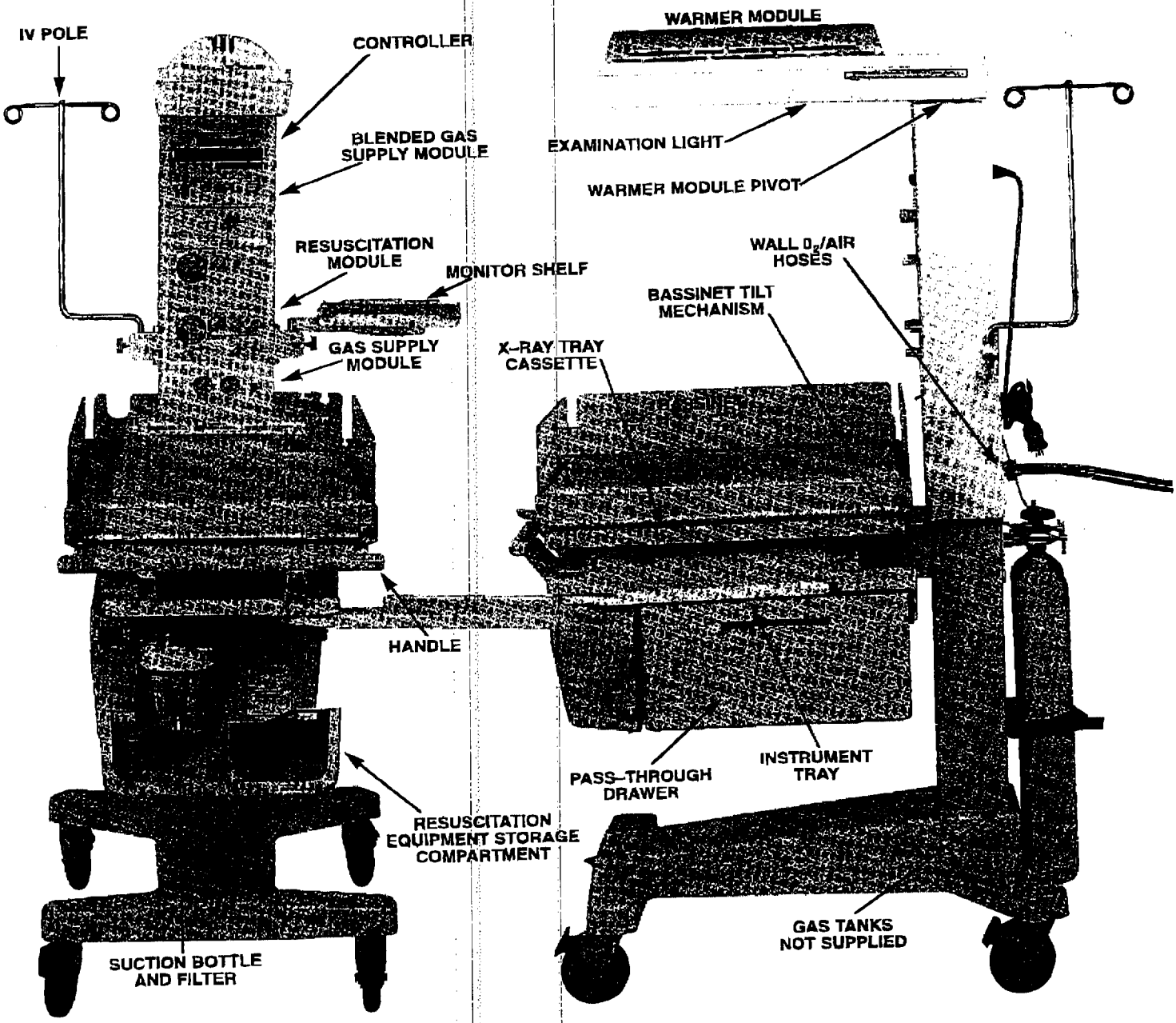

FIGURE 1.1 EQUIPMENT PROVIDED WITH FACTORY INSTALLED OPTIONS AND FIELD INSTALLED ACCESSORIES

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SECTION 2
INSTALLATION

2.1 UNPACKING

The ***Resuscitaire® Radiant Warmer*** is shipped in one carton which contains the following assemblies:

- Bassinet/Cart Assembly
- Upper Post Assembly
- Warmer Module Assembly
- Any user installed Accessories that were ordered

When removing the equipment from the carton, use care not to scratch or otherwise damage unprotected surfaces; remove all packing material.

2.2 ASSEMBLY (Refer to Figure 2.1)

NOTE: *The required mounting hardware is stored in a bag located in the pass-through drawer.*

1. **REMOVE THE BACK COVER** (1) from the Upper Column (2).
2. **REMOVE THE CONTROLLER** (3) from the Upper Column (2).
3. **REST THE UPPER COLUMN** (2) on top of the Bassinet/Cart column opening. Fully extend the suction hoses (4) and (11) out of the column.
4. **CONNECT THE SUCTION HOSE** (4) to the Suction Hose (11).
5. **REPOSITION AND MOUNT THE UPPER COLUMN** (2) on the Bassinet/Cart using four 10 – 32 x 3/8 inch screws (5). Exercising care not to kink the hoses, carefully push the connected suction hoses into the column.
6. **INSTALL TWO 10 - 32 X 3/8 INCH SCREWS (6) IN THE UPPER HOLES OF THE UPPER COLUMN** (2). Do not tighten the screws.
7. **RAISE THE WARMER** (7) above the open end of the Upper Column (2) and insert the Power Cable (10) into the open end of the column.
8. **SLOWLY LOWER THE WARMER** (7) onto the Upper Column. Align the slots of the warmer over the screws (6) on the column. Install the screws on the pivot bracket. Tighten the screws on the upper holes of the column using a nine-inch Phillips Head screwdriver.
9. **THREAD THE WARMER POWER CABLE** out through the Controller opening. Connect the Power Cable (10) to connector J4 on the Controller (3).
10. **REMOUNT THE CONTROLLER** on the Upper Column. Remount the Back Cover (1) on the Upper Column.
11. ***Resuscitaire® Radiant Warmer***

    CONNECT THE LINE CORD to the **POWER** Connector on the rear of the Controller (refer to Figure 4.2).

11A. ***Resuscitaire® Radiant Warmer with VHA***

    CONNECT THE LINE CORD to the Power Connector (Refer to Figure 4.2A) on the right side of the Lower Post. Connect the 40-inch Power Cord provided with the VHA between the AC connector on the left side of the Lower Post and the Controller Power Connector.

12. ***Resuscitaire® Radiant Warmer***

    SECURE THE LINE CORD to the Back Cover (1) using the Cable Clamp (8) and 8 – 32 x 3/8 screw (9).

12A. ***Resuscitaire® Radiant Warmer with VHA***

    SECURE THE 40-INCH POWER CORD to the Back Cover (1) using the Cable Clamp (8) and 8 – 32 x 3/8 screw (9).

CAUTION: Securing the Line Cord to the back panel is required to prevent removal of the Controller chassis with the AC power applied.

13. **INSTALL ANY ACCESSORIES** that were ordered using the installation instructions provided with the accessory.
14. **INSTALL THE END AND SIDE PANELS** on the Bassinet (refer to Paragraph 5.6 and Figures 5.1, 5.2, 5.3 and 5.4).

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RESUSCITAIRE® Radiant Warmer

PARTS LIST

Screw, 10 - 32 x 3/8 TR, PH Nylok (Qty 10)	99 041 36
Screw, 8 - 32 x 3/8 TR PH SS	99 031 38
Cable Clamp	17 725 64

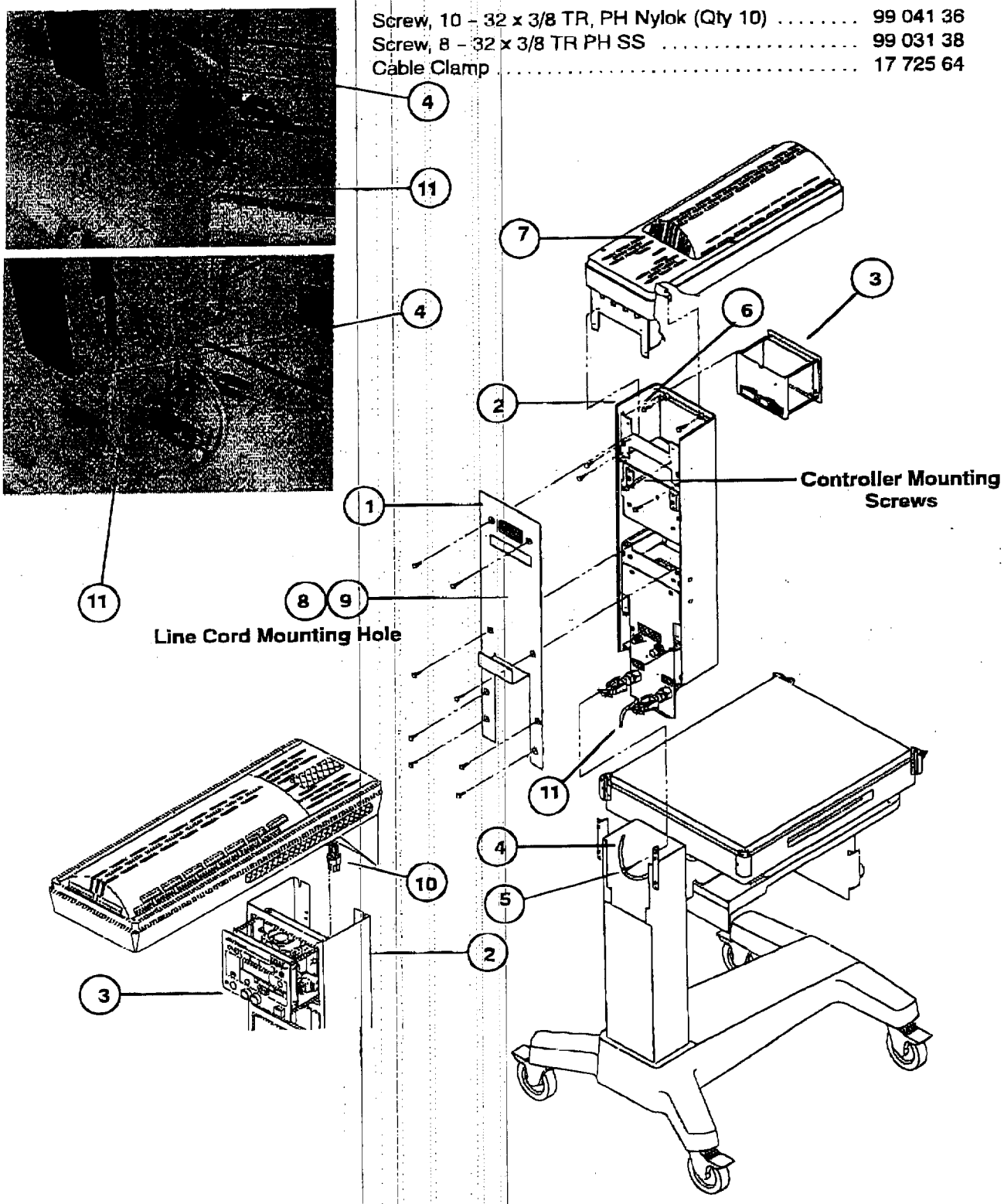

FIGURE 2.1 INSTALLATION

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SECTION 3
FUNCTIONAL DESCRIPTION

3.1 GENERAL

This section provides a functional description of the equipment.

3.2 FUNCTIONAL DESCRIPTION

3.2.1 WARMER MODULE

The Warmer is controlled by a Controller which provides **Pre-Warm** Mode, **Manual** Mode heater control, or **Baby** Mode (automatic skin temperature control). An Examination Light provides added illumination of the mattress area. A Warmer Head Pivot permits the Warmer to be pivoted 90° to either side for X-ray procedures. In addition, when the Warmer is pivoted, it continues to provide heat.

3.2.2 BASSINET

The Bassinet is designed to provide maximum function and utility to aid in the care of the newborn. The side and front panels may be folded down to permit access to the infant. The mattress may be tilted up from the rear at a 5- or 10-degree angle. Openings are provided on each side of the Bassinet for the insertion of the optional X-ray Cassette Tray.

3.2.3 CONTROLLER

At power-up, the microprocessor within the Controller performs a series of diagnostic tests to confirm the proper operation of the system. During this time, all displays and indicators are lighted and an audible tone is sounded.

When powered up, the system initializes in **Pre-Warm** Mode, the Controller will start the heater at 100% power and maintain that setting for three minutes, reduce to 60% for 12 minutes and then reduce the heater power to 30%.

When operating the Controller in the **Manual** Mode, the operator can adjust the heater power from 0 to full power in 10% increments. After 10 minutes of operation in the Manual Mode, a **Chk Patient** Alarm occurs.

Failure to acknowledge the Check Patient Alarm within the next 5 minutes will cause the heater to be turned off.

When operated in the **Baby** Mode, the Controller utilizes a Skin Temperature Probe, connected between the Controller input and the infant, to automatically adjust the heater output of the Warmer Module to maintain a digitally displayed preset **Set Temperature.**

The Apgar Timer displays the elapsed time and sounds an audible dual tone to alert the operator that 1, 5, and 10 minutes have elapsed since the timer was activated.

The **Keypad Lock** Key, when pressed, renders the Up/Down Arrows and Select Mode Keys inactive or active.

A Procedural Silence Timer prevents **Baby Temp** audible Alarms during routine procedures.

3.2.4 BLENDER MODULE (Optional)

The Blender Module provides blended oxygen from 21% to 100% to the **Patient Outlet** on the Resuscitation Module.

3.2.5 RESUSCITATION MODULE (Optional)

WARNING: Always monitor Airway Pressure and or/provide appropriate relief during infant resuscitation.

The Resuscitation Module contains pneumatic circuitry necessary for infant resuscitation. Controls and displays for the module are located above the rear of the Bassinet.

The Resuscitation Module is provided with Auto-Breath (International only) or without AutoBreath in two varieties. It consists of the following factory installed components:

- **Suction** – The **Suction** Circuit is driven by a gas powered venturi actuated vacuum generator which provides a negative pressure for suctioning the patient's airway. The suction pressure is indicated on the **Suction** Gauge (Fig-

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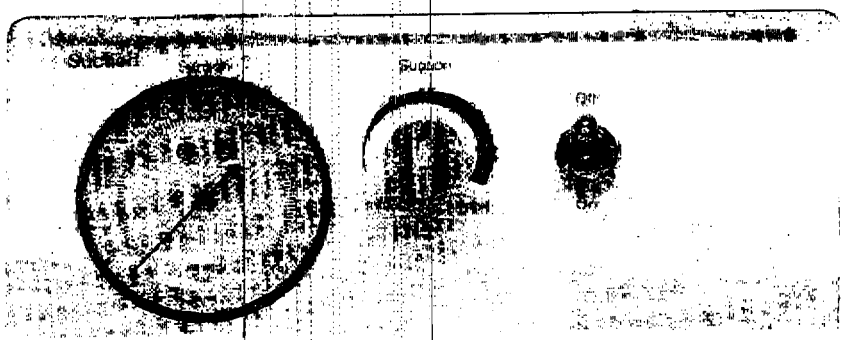
Suction Control and turned on or off using the **On/Off** Switch. A fixed internal relief valve limits the maximum suction pressure to 150 mmHg.



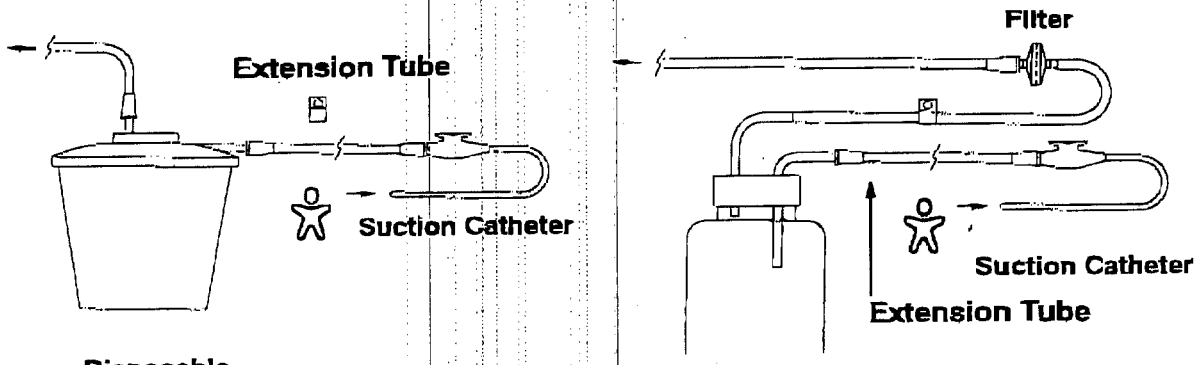


FIGURE 3.1 SUCTION FUNCTIONAL BLOCK DIAGRAM

RESUSCITATION MODULE 2001 WITH PRIAMRY OUTLET AND AUXILIARY FLOW ONLY (FACTORY INSTALLED OPTION)

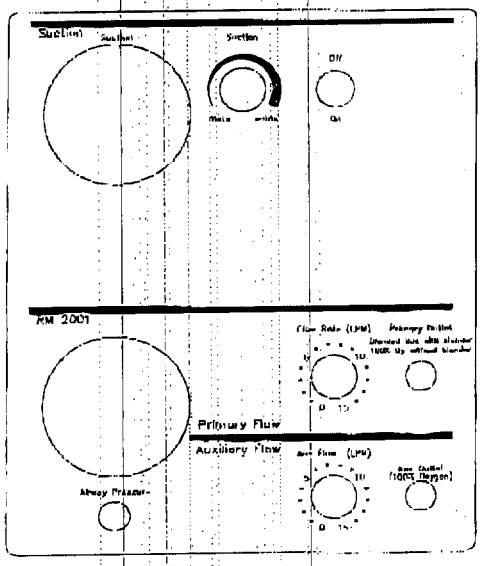


FIGURE 3.2 RESUSCITATION MODULE 2001 WITH PRIMARY OUTLET AND AUXILIARY FLOW ONLY

RESUSCITATION MODULE 2001 PRECAUTIONS

- The Resuscitation Module 2001 (option) is intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- If the blender option was added, confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- Always monitor **Airway Pressure**.
- When using **Primary Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Primary Supply** module.

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- A humidifier, if used, must be placed between the **Primary Outlet** connection and the patient. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

- **Primary Outlet** –

The **Primary Gas Supply** circuit may be used to provide continuous gas flow to a breathing circuit. When the **Blender** module is included in the system, the **Primary Outlet** provides 0 to 15 lpm of O_2 selected by the operator. The **Flow Rate (LPM)** control is a calibrated dial type flow adjustment.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 160 ± 10 cm H_2O (15.9 ± 1 kPa)

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet** –

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother , or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The outlet 1/4" hose barb fittings of the gas delivery module will attach to commercially available oxygen supply tubing or self-inflating resuscitation bag. Hill-rom Air shields part number 67 361 72.

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RESUSCITATION MODULE WITHOUT AUTOBREATH (FACTORY INSTALLED OPTION) PATIENT SUPPLY

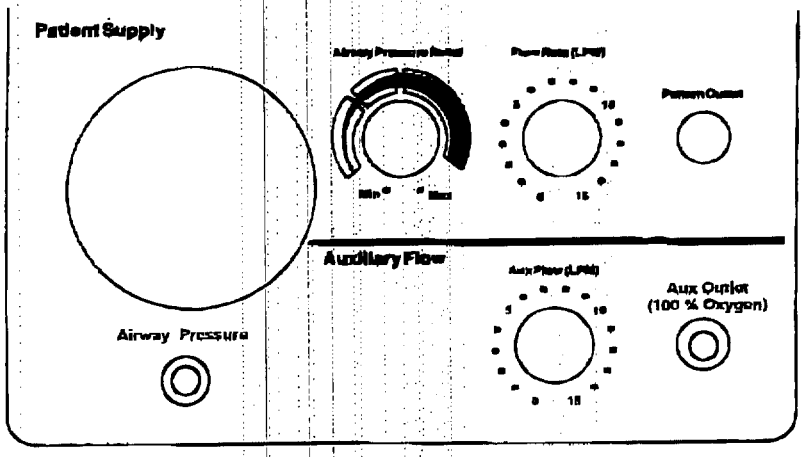

FIGURE 3.3 RESUSCITATION MODULE WITH PATIENT GAS SUPPLY AND AUXILIARY FLOW ONLY - PATIENT SUPPLY

RESUSCITATION PRECAUTIONS

- The Resuscitation Module (options) are intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- Confirm the setting and flow of the Airway Pressure relief valve before patient use.
- Confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- Always monitor **Airway Pressure**.
- When using **Patient Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Patient Supply** module.

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- A humidifier, if used, must be placed between the **Patient Outlet** connection and the patient circuit. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.

- **Patient Outlet** –

The **Patient Gas Supply** Circuit may be used to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet** –

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother, or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The patient breathing circuit used in conjunction with the Resuscitation Module without AutoBreath is illustrated in Figure 3.4. In addition, a patient supply circuit for Manual Bagging (Figure 3.7) may also be used.

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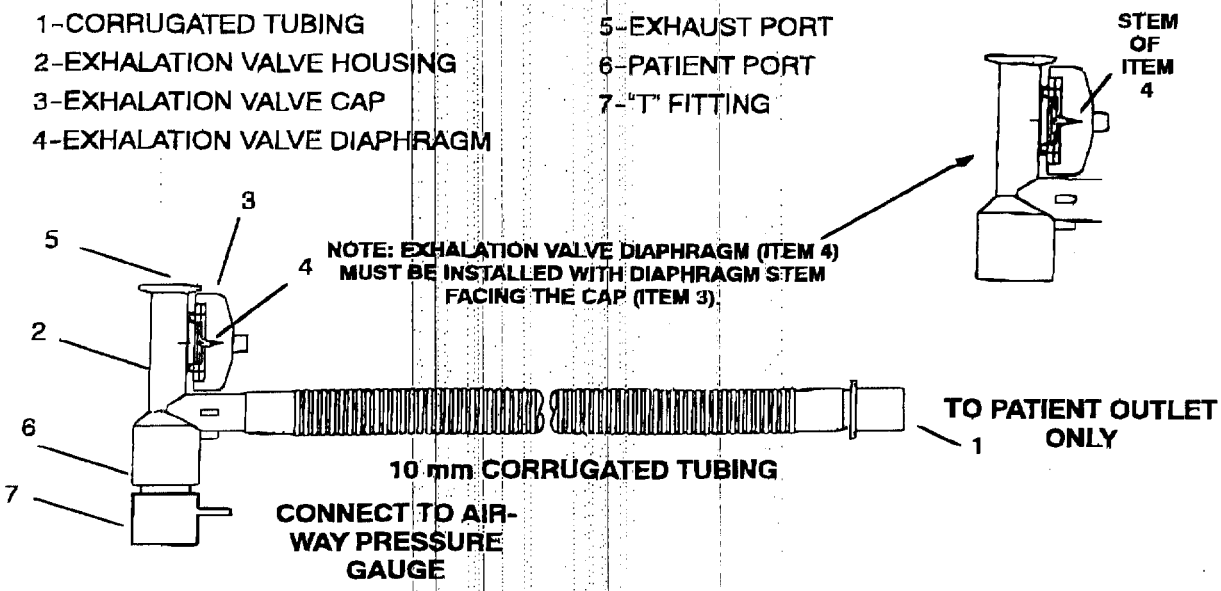

FIGURE 3.4 PATIENT BREATHING CIRCUIT FOR MANUAL VENTILATION

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RESUSCITATION MODULE WITH AUTOBREATH (FACTORY INSTALLED OPTION) NOT AVAILABLE IN THE USA OR CANADA

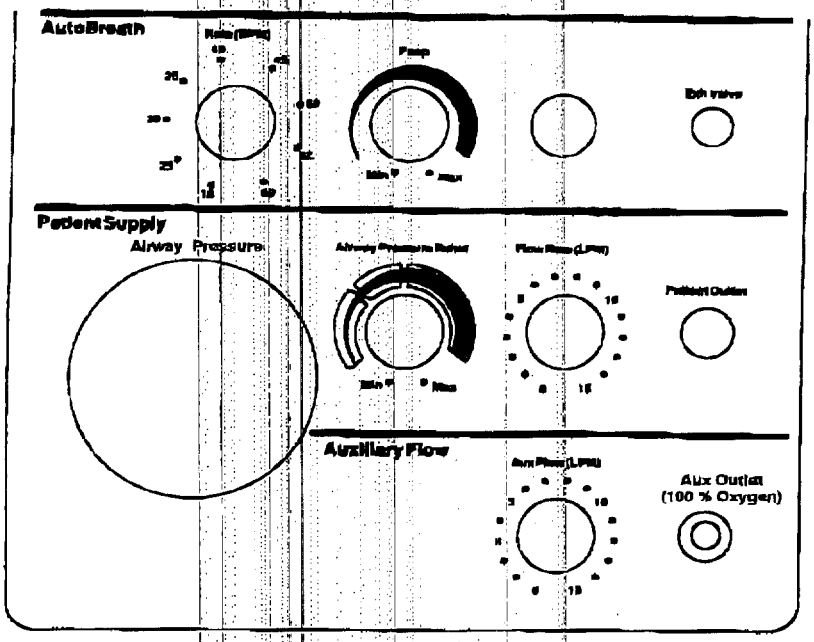

FIGURE 3.5 RESUSCITATION MODULE WITH AUTOBREATH, PATIENT GAS SUPPLY AND AUXILIARY FLOW

AUTOBREATH PRECAUTIONS

- The Resuscitation Autobreath (option) is intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Any humidifier used with the **AutoBreath** must be a "flow-through" type having a low pressure drop. Use of a humidifier with a bubbler tube or pressure jet will render the Safety Relief Valve ineffective. A pressure jet nebulizer or unmodified bubbler humidifier may not be used.
- When setting the **Rate (BPM)** Control for optimum repeatability, always approach the desired setting by turning the knob in a clockwise direction.
- When setting the **PEEP** control, always start with the knob fully counterclockwise to avoid setting PEEP above the maximum pressure limit.
- An airway pressure monitor must be used if the **AutoBreath** is to be used unattended.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.
- A humidifier, when used, must be placed between the **Patient Outlet** connection and the patient circuit. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

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- **AutoBreath**

The **AutoBreath** Circuit is a gas-powered, time-cycled, continuous flow, pressure limited resuscitator. It has a **Rate (BPM)** Control and a fixed I/E ratio of 1:2 nominal. An **On/Off** Switch allows the timing circuit to be turned on and off as needed. A **PEEP** Control adjusts the Positive End Expiratory Pressure in the patient circuit. The resuscitator is utilized in conjunction with the continuous gas flow provided by the **Patient Supply** sub-module.

WARNING: An airway pressure disconnect monitor should be used if the AutoBreath Infant Resuscitator is to be used unattended.

- **Patient Gas Supply**

The **Patient Gas Supply** Circuit may be used with the **AutoBreath** Infant Resuscitator on or off to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet**

The **Aux Outlet** circuit supplies 100% oxygen through the **Aux Flow (LPM)** Control to the **Aux Outlet** Connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother, or a second neonate, i/e., twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 kPa).

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- **Patient Breathing Circuits**

The patient breathing circuit used in conjunction with the AutoBreath Infant Resuscitator is illustrated in Figure 3.3. In addition, a patient supply circuit for Manual Bagging (Figure 3.4) may also be used.

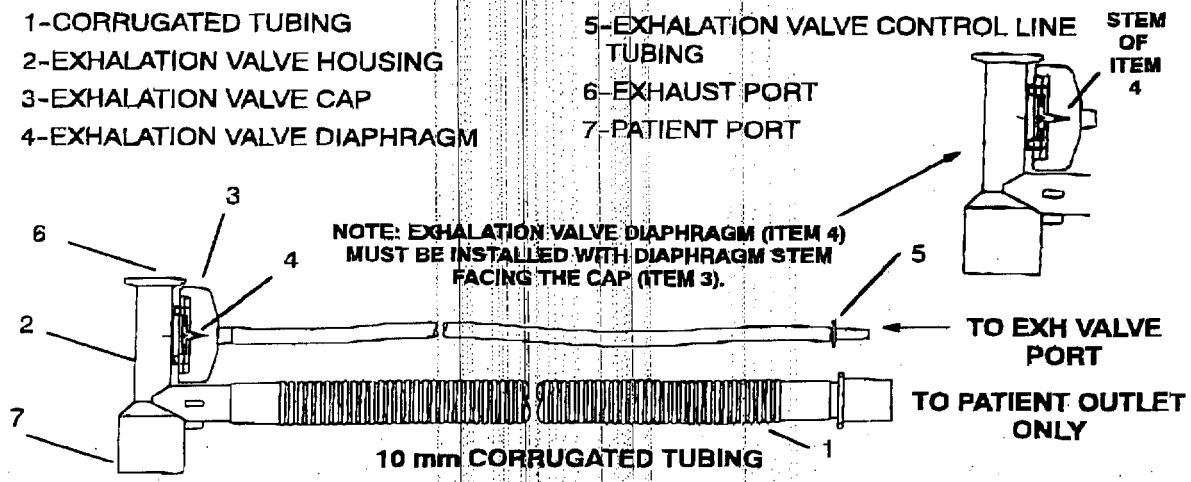

FIGURE 3.6 PATIENT BREATHING CIRCUIT FOR AUTOMATIC VENTILATION

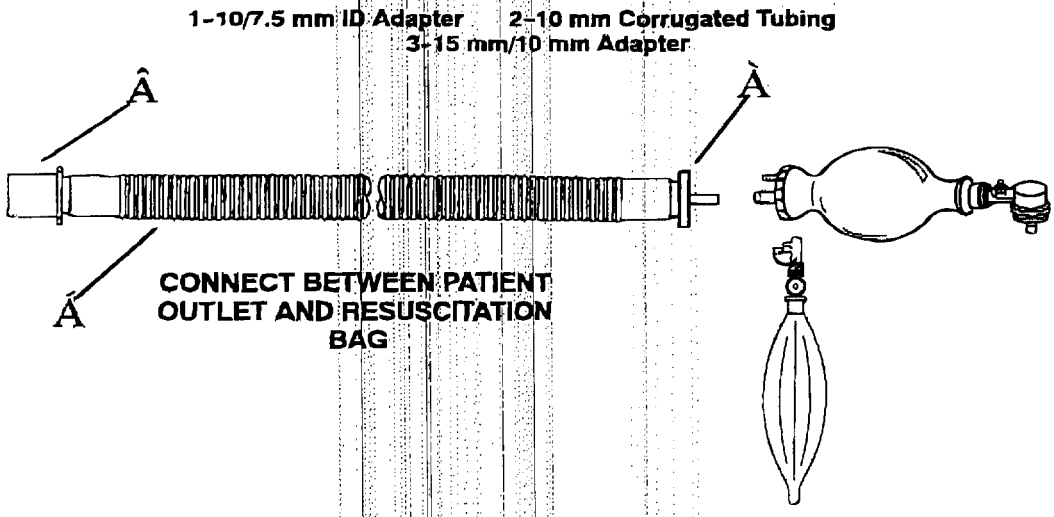

FIGURE 3.7 PATIENT BREATHING CIRCUIT FOR MANUAL BAGGING

3.2.6 GAS SUPPLY MODULE

The **Gas Supply** Module includes an On/Off Switch which controls the pipeline and cylinder gas supply to the Resuscitation Module. An oxygen cylinder Pressure Gauge is provided if the oxygen cylinder option is included. Oxygen and Air Pressure Gauges are provided on units equipped with the Blender Module.

FIGURE 3.8 GAS SUPPLY MODULE

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3.2.7 ALARMS

HIGH TEMPERATURE. When the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C, the heater is automatically turned off, the **High Temp** Indicator will flash and the audible alarm will sound continuously. Press the **Silence/Reset** Key to silence the alarm for two minutes. After the alarm condition is corrected (a skin temperature of 38.5 °C or less), the alarm will automatically reset.

CHECK PATIENT. When in the **Manual** Mode the **Chk Patient** Indicator will illuminate and the alarm will sound one time after 10 minutes of operation. Thereafter, the **Chk Patient** Indicator will remain illuminated and the audible alarm will sound every 30 seconds for 5 minutes. If the alarm has not been acknowledged at the end of 5 minutes, the heater will shut down and a continuous ramping audible alarm will sound. The **Silence/Reset** Key then must be pressed to reactivate the heater.

PROBE. If the Skin Temperature Probe fails (short- or open circuited), the **Probe** Indicator will flash and a ramping audible alarm will sound. After the alarm condition is corrected (the Probe is replaced), the alarm will automatically reset.

BABY TEMPERATURE. When the temperature sensed by the Skin Temperature Probe is 1 °C above or 1°C below the selected **Set Temperature** Display setting, the **Baby Temp** Indicator will flash and a ramping audible alarm will sound. In addition, if the temperature is 0.2 °C above the selected **Set Temperature,** the heater will be turned off automatically. Press **Silence/Reset** to silence the alarm for 10 minutes.

POWER FAIL. When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. The alarm may be silenced by turning off the power switch.

IMPORTANT: *Turning off the Power switch will prevent the Controller and Heater from restarting automatically when power is returned to the unit. The settings will be retained in memory until power is restored.*

SYSTEM FAIL. If an internal malfunction is detected, the **System Fail** Indicator will flash and the audible alarm will beep. In addition, an Error Code (eR00 to eR025) will be displayed in the **Baby Temperature** Display. This alarm is not resettable and the unit should be referred to qualified service personnel. A prolonged brown-out (five minutes or more with supply voltage leas than 90% of nominal) will also cause a System Fail alarm.

3.2.8 BLENDER DIFFERENTIAL BYPASS ALARM (Optional)

The blender Module (factory installed option) will alarm and bypass whenever the pressure differential between the O_2 and air supplies exceeds 30 psi ± 2 psi. When this condition occurs, the blender will continue to supply whichever gas is the higher pressure: either 100% Air or 100% Oxygen. This is an audible alarm only. There are no visual indicators.

3.2.9 APGAR TIMER

When the **Apgar Timer** is running, the Apgar Timer Display will show elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar time intervals.

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SECTION 4
OPERATION

4.1 CONTROLS, INDICATORS AND CONNECTORS

Controls, Indicators and Connectors for the Controller are presented in Figures 4.1 and 4.2 and Tables 4.1 and 4.2. Controls, Indicators and Connectors for the Resuscitation Module are presented in Figure 4.3 and Table 4.3.

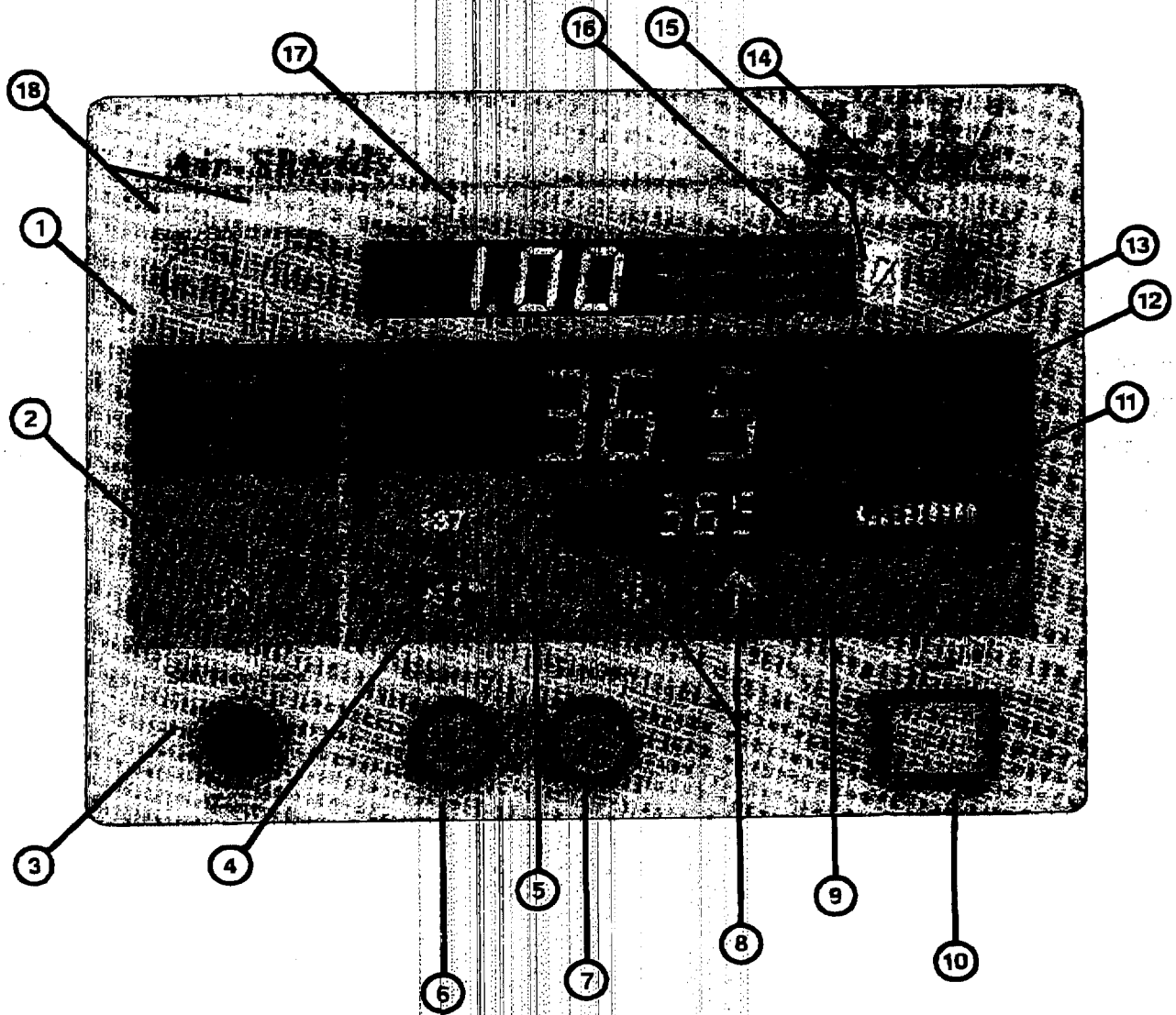

FIGURE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

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RESUSCITAIRE® Radiant Warmer

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

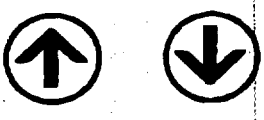
ITEM	NAME	DESCRIPTION
1	**Mode**	
	Pre-Warm Indicator	Indicates that the Controller is operating in the **Pre-Warm Mode.**
	Manual Indicator	Indicates that the Controller is operating in the **Manual Mode.**
	Baby Indicator	Indicates that the Controller is operating in the **Baby Mode.**
2	**Mode** Select Key 	Press to select either **Pre-Warm, Manual** or **Baby Mode** of operation.
3	**Skin Temp Probe** Connector	Accepts Skin Temperature Probe for monitoring infant skin temperature. When connected, the **Baby Temperature** Display indicates the temperature sensed by the probe. When probe is disconnected, the **Baby Temperature** Display is blank. When disconnected in **Baby** Mode, a **Probe** Alarm also occurs.
4	**>37 °C** Key 	Press to place **Set Temperature** Display (refer to Item 9) in Temperature Override Mode, >37 °C (98,6 °F). ***NOTE:*** *This Key is inactive until the* ***Set Temperature*** *has been set to 37 °C.*
5	**>37 °C** Indicator	Lights to indicate that the Temperature Override Mode, >37 °C (98.6 °F), has been selected.
6	**Keypad Lock** Key 	Press to disable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys (refer to Items 2, 4 and 8). Press again to enable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys. Key lights to indicate that Keypad is locked.
7	**Exam Light** Key 	Press to turn on or turn off the Examination Light located in the Warmer Module.
8		**Manual Mode** Press the Up Arrow Key to raise heater power from 0% to 100% in 10% increments (refer to Item 11, **Heater Power** Display). Press the Down Arrow Key to lower relative heater power from 100% to 0% in 10% increments (refer to Item 11, **Heater Power** Display).

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

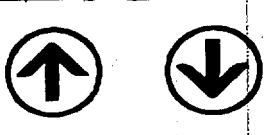
ITEM	NAME	DESCRIPTION
8		**Baby Mode** Press the Up Arrow Key to raise the Set Temperature from 34.0 °C (93 °F) to 37.0 °C (98.6 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to raise the Set Temperature from 37.0 °C (98.6 °F) to 38.0 °C (102.2 °F). Press one time to raise the Set Temperature in 0.1° increments. Press and hold to raise the Set Temperature rapidly. Press the Down Arrow Key to lower the Set Temperature from 37.0 °C (98.6 °F) to 34.0 °C (93 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to lower the Set Temperature from 38.0 °C (102.2 °F) to 34.0 °C (93 °F). Press one time to lower the Set Temperature in 0.1° increments. Press and hold to lower the Set Temperature rapidly. ***NOTE:*** *The Up/Down Arrow Keys may be locked by pressing the Keypad Lock Key (refer to Item 6).*
9	**Set Temperature** Display	In **Baby Mode**, displays the **Set Temperature** as selected by the Up/Down Arrow Keys (refer to Item 8) and in °C or °F as selected by the **°C/°F** Key (refer to Item 12). Display is blank in **Pre-Warm** and **Manual** Modes.
10	**Power Key** 	Press to turn on or turn off the Controller and Warmer Module.
11	**Heater Power** Display	Displays relative heater power in 10% increments from 0% to 100%.
12		Press to alternately select °C or °F for the **Baby Temperature** and **Set Temperature** Displays.
13	**Baby Temperature** Display	Digital display of infant temperature in °C or °F (refer to Item 12), whether in **Manual, Pre-Warm** or **Baby Mode.** The display is blank if the Skin Temperature Probe (refer to Item 3) is disconnected from the Controller.

TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
14	**Silence/Reset** Key 	In **Manual Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Resets **Chk Patient** (refer to Item 16), restores heater power and silences Audible Alarm at any time after 10 minutes of warmer operation. Resets **Chk Patient** (refer to Item 16), silences Audible Alarm and restores heater power after15-minutes of continuous operation is complete. In **Baby Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes Press to silence **Baby Temp** (refer to Item 16) Alarm for 10 minutes. During non-alarm conditions, press to enter Procedural Silence (refer to Item 15).
15	**Procedural Silence** Indicator 	When illuminated, indicates that the unit is in Procedural Silence. Procedural silence interval is 5 minutes. During Procedural Silence, the **Baby Temp** Alarms are blocked.
16	**Alarms** **Baby Temp**	The **Baby Temp** Indicator will flash with a three-level audible alarm to indicate that the baby's skin temperature is 1 °C above or below the selected Set Temperature (refer to Item 9). Press **Silence/Reset** Key to silence alarm for 10 minutes.
	High Temp	The **High Temp** Indicator will flash, the audible alarm will sound continuously, and the heater will be turned off when the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C. High Temp (39.0 °C) Alarms can only be silenced for two minutes by the Silence/Reset Key. Press the **Silence/Reset** Key to silence the audible alarm for 2 minutes. When the temperature falls to 38.5 °C, the alarm will automatically reset.
	Probe	When in **Baby Mode**, if the Skin Temperature Probe fails (open probe), the **Probe** Indicator will flash and a three-level audible alarm will sound. After the Alarm condition is corrected (the Skin Temperature Probe is replaced), the alarm will automatically reset. Also refer to Table 5.1. When in **Baby Mode**, if the Skin Temperature Probe fails (shorted probe), the **System Fail** Indicator will light and an audible alarm will sound. This Alarm cannot be Silenced. The **Power MUST BE TURNED OFF then ON** to Reset the Alarm condition.

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
16	**Alarms (Cont.)**	
	Chk Patient	When in the **Manual** Mode, if the warmer is in operation for longer than 10 minutes, the **Chk Patient** Indicator will illuminate and the audible alarm will sound one time. Thereafter, the **Chk Patient** Indicator will remain on and the audible alarm will sound every 30 seconds for the next 5 minutes. If at the end of 5 minutes (15 minutes total) the alarm has not been acknowledged by pressing the **Silence/Reset** Key (refer to Item 14), the warmer will be shut down.
	System Fail	When an internal malfunction is detected, the **System Fail** Indicator will illuminate and the audible alarm will sound continuously. In addition, an Error Code (Er00 to Er025) will be displayed in the **Baby Temperature** Display. When a malfunction is detected, the Controller will automatically perform the self-test function (refer to para. 4.2 Step 3) to determine if the fault has corrected itself. If the fault has not corrected itself, the error code will be displayed until corrected. This alarm is not resettable and the unit should be referred to qualified service personnel. ***NOTE:*** *Error code 023 may be corrected by the Operator, refer to Table 5.1.*
	Power Fail	When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. Push the **Power** Key to silence the Alarm.
17	**Apgar Timer**	When the **Apgar Timer** (refer to Item 18) is running, the Apgar Timer displays elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar Time intervals.
18	**Stop/Start** 	Press to start or stop the **Apgar Timer**.
	Reset 	When timer is running, press to reset the timer to zero and restart the Apgar count. When timer is stopped, press to turn timer off. ***NOTE:*** *The Timer can be reset any time.*

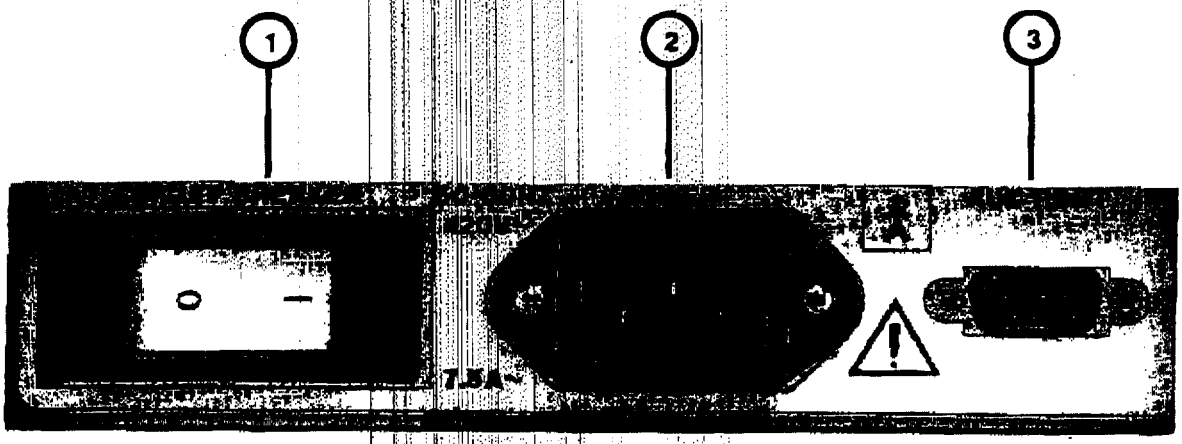

FIGURE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

TABLE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	CIRCUIT BREAKER	Turns Controller on and off when switched by operator or the presence of excessive current drain is detected.
2	POWER	Accepts ac power cord. Accepts 40-inch power cord on VHA units
3	AUX PORT	Data port for connection to printer or host system.

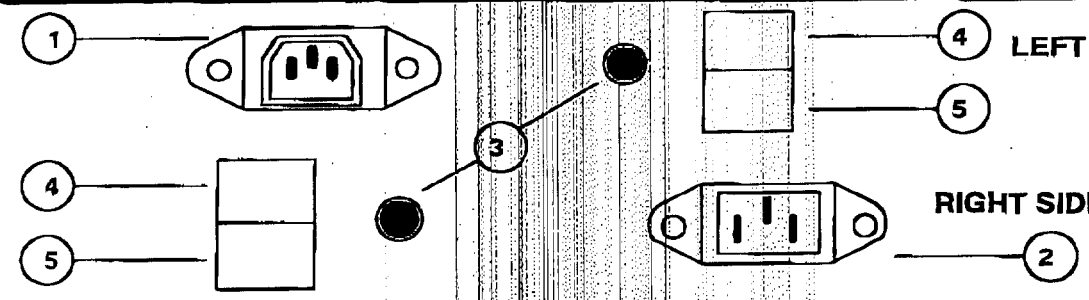

FIGURE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS LOCATED ON BOTH SIDES OF LOWER POST

TABLE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	POWER OUT	Accepts 40-inch ac power cord.
2	POWER IN	Accepts ac power cord.
3	CIRCUIT BREAKER	Turns Actuator off when presence of excessive current drain is detected. Press to reset.
4	UP SWITCH	Press to raise Upper Post
5	DOWN SWITCH	Press to lower Upper Post

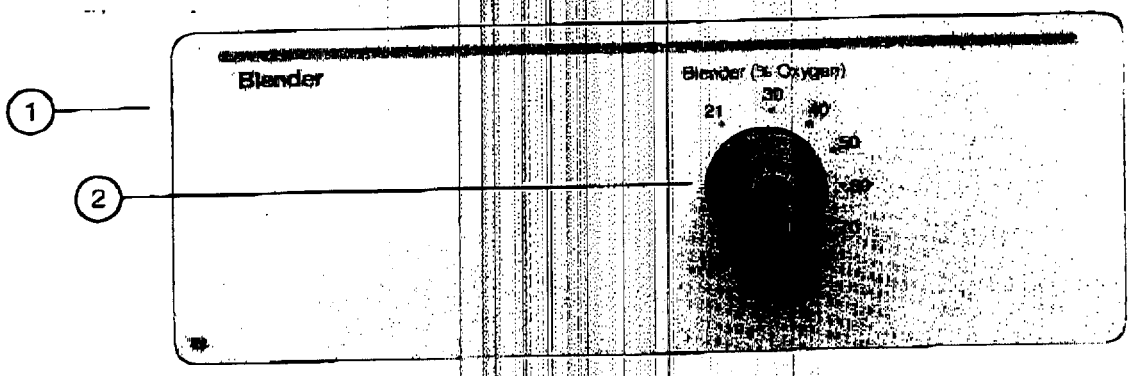

FIGURE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

TABLE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

ITEM	NAME	DESCRIPTION
1	Blended Gas Supply Module (Optional)	
2	Blender % Oxygen Control	Blends air and oxygen mixture from 21 to 100% O_2.

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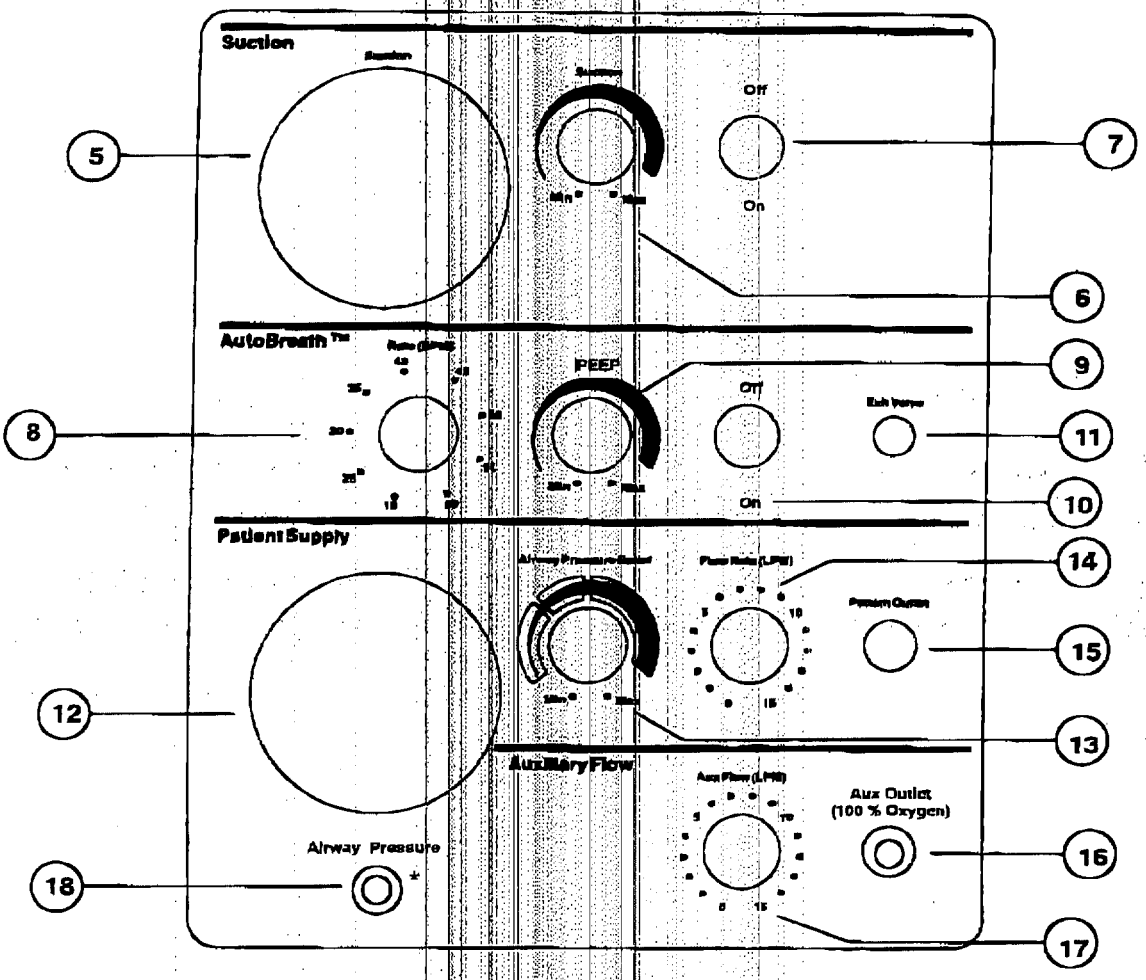

*Not Mounted On Units equipped with AutoBreath.

FIGURE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Suction	
5	**Suction** Gauge	Displays suction level from 0 to 200 mmHg of vacuum.
6	**Suction Min Max** Control	Adjusts suction level from 0 to 150 mmHg of vacuum.
7	**On/Off** Switch	Turns **Suction** on and off.
	AutoBreath	
8	**Rate (BPM)** Control	Adjusts breath frequency from 18 to 60 breaths per minute.
9	**PEEP min max** Control	Adjusts positive end expiratory pressure from 0 to 18 cm H_2O.
10	**On/Off** Switch	Turns **AutoBreath** Infant Resuscitator on and off (including **PEEP**).
11	**Exh Valve**	Accepts exhaust valve line of patient circuit for expiratory valve control.
	Patient Supply	
12	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.
13	**Airway Pressure Relief Min Max** Control	Adjusts airway pressure relief setting from 0 to 50 cm H_2O.
14	**Flow Rate (LPM)** Control	Adjusts patient gas flow from 0 to 15 LPM. Delivers blended gas if blender option is incorporated.
15	**Patient Outlet** Connector	**Accepts breathing circuit.**
	Auxiliary Flow	
16	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
17	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
18	**Airway Pressure Port**	Connects Airway Pressure Gauge to Patient Circuit, Not Mounted on Units equipped with AutoBreath.

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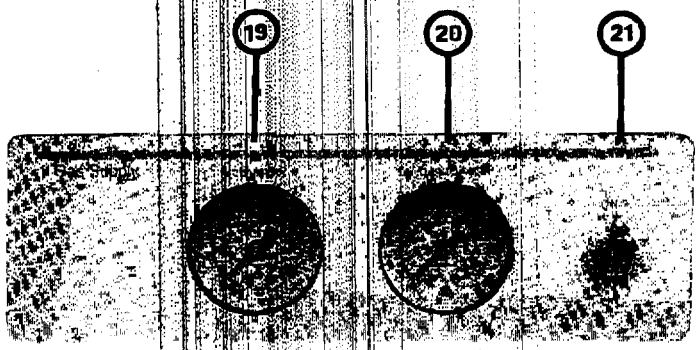

FIGURE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

TABLE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

ITEM	NAME	DESCRIPTION
	Supply Pressure (Optional)	
19	**Air Cylinder** Gauge	Provides indication of air cylinder supply pressure 0 to 4000 psi (275.8 bar).
20	**Oxygen Cylinder** Gauge	Provides indication of oxygen cylinder supply pressure 0 to 4000 psi (275.8 bar).
21	**Gas Supply On/Off** Switch	Turns gas supply to pneumatic system on and off.

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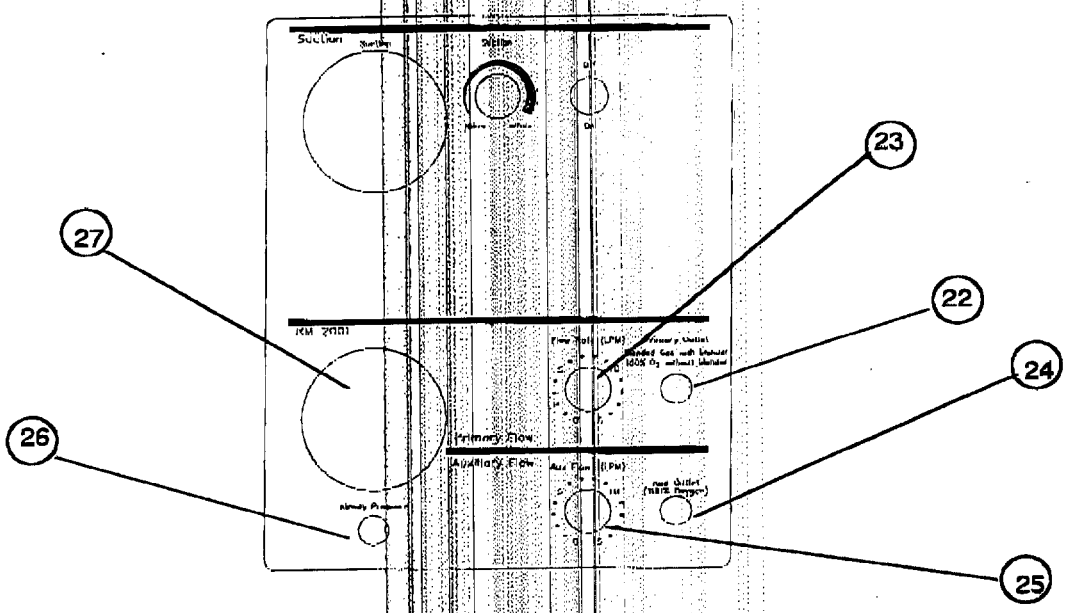

FIGURE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Primary Flow	
22	**Primary Outlet**	Accepts primary gas delivery line. Delivers blended gas if blender option is installed: 100% oxygen if no blender installed.
23	**Flow Rate (LPM)** Control	Adjusts primary gas flow from 0 to 15 LPM
	Auxiliary Flow	
24	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
25	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
26	**Airway Pressure Port**	Connect Airway Pressure Gauge to Patient Circuit. Not mounted on units equipped with AutoBreath
27	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.

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RESUSCITAIRE® Radiant Warmer

4.2 OPERATIONAL CHECKOUT PROCEDURE - CONTROLLER

WARNING: The Warmer should not be used if the Controller fails to function as described below. Service should be referred to qualified personnel.

CAUTION: HEAVY EQUIPMENT: To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport. Use the handle when moving the equipment.

IMPORTANT: *Before attempting to perform this procedure, refer to Paragraph 4.1, Controls, Indicators and Connectors.*

NOTE: *The Operational checkout procedure described below should be performed before the equipment is first put into service, then at least weekly.*

1. **CONNECT THE AC LINE CORD TO THE POWER CONNECTOR** on the Controller Rear Panel.

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

2. **CHECK THE POWER FAILURE ALARM.** Turn off the **CIRCUIT BREAKER** on the Rear Panel. Turn on the **Power** Switch on the Front Panel. The **Power Fail** Indicator should come on and the Audible alarm should sound. Turn off the **Power** Switch and turn on the **CIRCUIT BREAKER.**

NOTE: *The unit must be connected to the ac line for at least eight minutes before the* ***Power Fail*** *circuitry becomes active.*

3. **CHECK THE SELF-TEST FUNCTION.** Turn on the **Power** Switch, the Self-Test Function should be initiated and the following should occur:
   - **Apgar Timer, Baby Temperature** and **Set Temperature** Digital Displays show all eights
   - All **Alarms** Indicators light (except **Power Fail**)
   - All **Mode** Indicators light
   - The **> 37 °C** Indicator lights
   - All ten segments of the **Heater Power** Indicator light
   - The Procedural Silence Indicator lights
   - The **Keypad Lock** Switch lights
   - The audible alarm will sound a high pitch tone, a low pitch tone, then a beep-beep-beep

When the Self-Test Function is complete, the Controller should begin operating in the **Pre-Warm Mode.**

4. **CHECK THE PRE-WARM MODE.** The **Pre-Warm** Indicator should be on and the **Heater Power** Indicator should display 10 segments (100%) for three minutes, reduce to 6 segments (60%) for 12 minutes, then reduce to 3 segments (30%).

5. **CHECK THE MANUAL MODE.** Select **Manual Mode** by pressing the **Mode** Select Key. The **Manual** Indicator should light.
   Press the Up Arrow Key until all the **Heater Power** Display segments are lit. Press the Down Arrow key until all the **Heater Power** Indicators are off. Connect the skin temperature probe to the **Skin Temp Probe** Connector, the **Baby Temperature** Display should come on.

   Set the **Heater Power** Indicator to 100%, all segments are lit. Wait 10 minutes. After 10 minutes have elapsed, the **Chk Patient** Indicator should come on and the audible alarm should sound one time. Wait an additional 5 minutes. During this time, the audible alarm should sound at 30-second intervals. At the end of 5 minutes (15 total), the heater should shut down, the **Heater Power** Indicators should go off and the audible alarm should sound continuously and ramp up in volume. Press the **Silence/Reset** Key, the **Chk Patient** Indicator and audible alarm should go off, the heater power should return and all ten **Heater Power** Indicators should illuminate.

6. **CHECK THE KEYPAD LOCK.** Press the **Keypad Lock** Switch. The **Keypad Lock** Switch should light up. The **Mode** Key and the Up/

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Down Arrow Keys Key should be inoperative. Press the Keypad Lock Switch. The **Keypad Lock** Switch Light should go off and the Keypad should be enabled.

7. **CHECK THE BABY MODE.** Select **Baby Mode** by pressing the Mode Select Key. The **Baby** Indicator should light and the **Set Temperature** Display should activate. In addition, the **Baby Temp** Indicator should flash and the audible alarm should sound (if the temperature and set point are more than 1° C apart) Press the **Silence/Reset** Key, the audible alarm should go off, the **Baby Temp** Indicator should become steady on.

8. **CHECK TEMPERATURE OVERRIDE MODE.** Press the Up Arrow Key to raise the **Set Temperature** to 37.0 °C. Press the **>37 °C** Key, the **>37 °C** Indicator should come on. Press the Up Arrow Key to raise the **Set Temperature** to 38.0 °C.

   Press the Down Arrow Key to lower the **Set Temperature** to below 37.0 °C. When the **Set Temperature** falls below 37.0 °C, the **>37 °C** Indicator should go off.

9. **CHECK THE PROBE ALARM.** Disconnect the skin temperature probe from the **Skin Temp Probe** Connector. The **Baby Temperature** Display should go off, the **Probe** Indicator should flash and the audible alarm should sound. Replace the probe.

10. **CHECK THE APGAR TIMER.** Press the **Start /Stop** Key, the **Apgar Timer** Display should come on and begin to count up from zero seconds. Press the **Start/Stop** Key, the **Apgar Timer** count should stop. Press the **Reset** Key, the **Apgar Timer** Display should go off.

11. **CHECK THE EXAMINATION LIGHT.** Press the **Exam Light** Switch. The Examination Light should come on. Press the Exam Light Switch, the Examination Light should go off.

4.3 MECHANICAL CHECKOUT

1. **CHECK THE MATTRESS TILT CONTROL** (Figure 4.4) by pulling up on the lever located at the bottom rear of the Bassinet while supporting the rear lower edge of the Bassinet with the palm. Place the Bassinet in the 5-degree and then the 10-degree tilt position. Return the Bassinet to the level position.

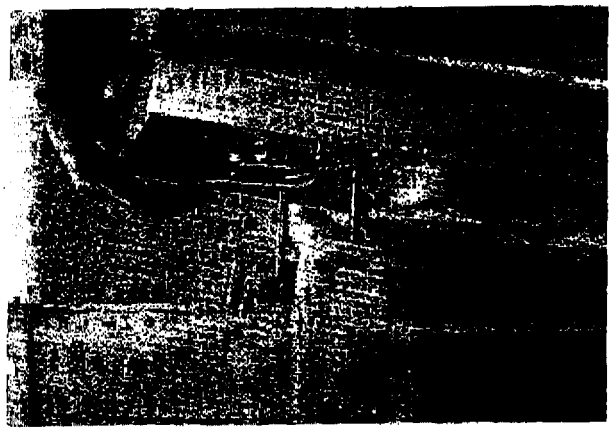

FIGURE 4.4 BASSINET TILT CONTROL

2. **CHECK THE BASSINET SIDE PANELS** (Figure 4.5) by raising each panel and pivoting it to hang straight down. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

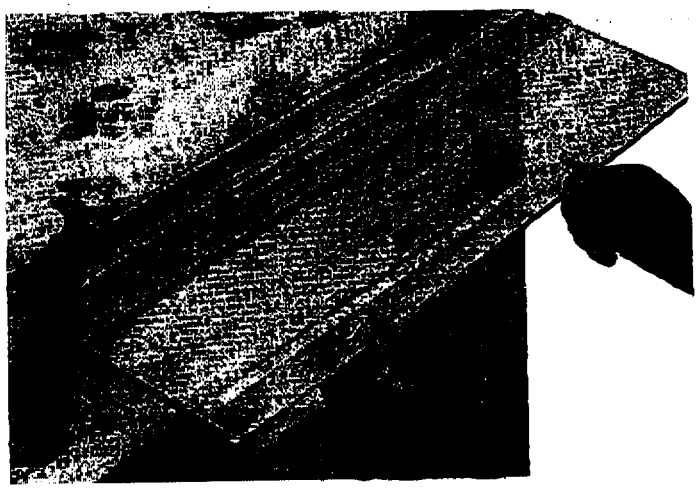

FIGURE 4.5 CHECKING THE BASSINET SIDE PANELS

3. **CHECK THE BASSINET FRONT PANEL** (Figures 4.6 and 4.7) by raising the panel and and sliding it under the mattress. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

RESUSCITAIRE® Radiant Warmer

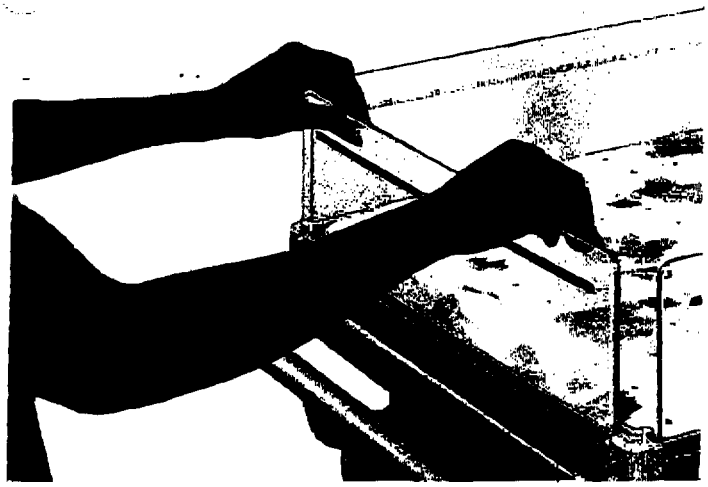

FIGURE 4.6 CHECKING THE BASSINET FRONT PANEL

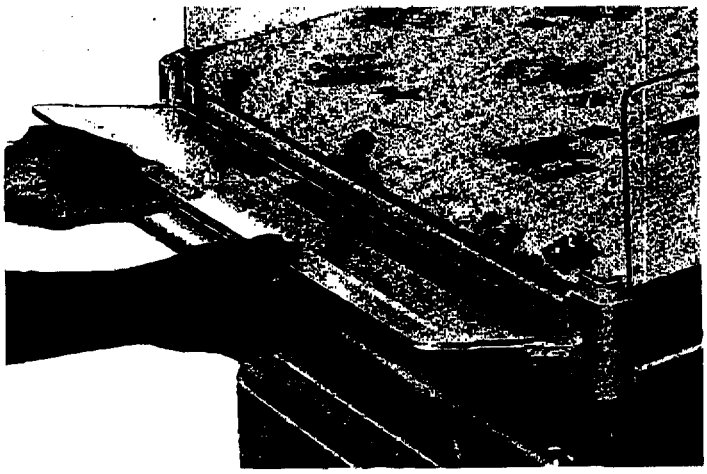

FIGURE 4.7 CHECKING THE BASSINET FRONT PANEL

4. **CHECK THE PASS–THROUGH DRAWER** (Figure 4.8) by sliding the drawer in and out on both sides of the Bassinet. Return to center position.

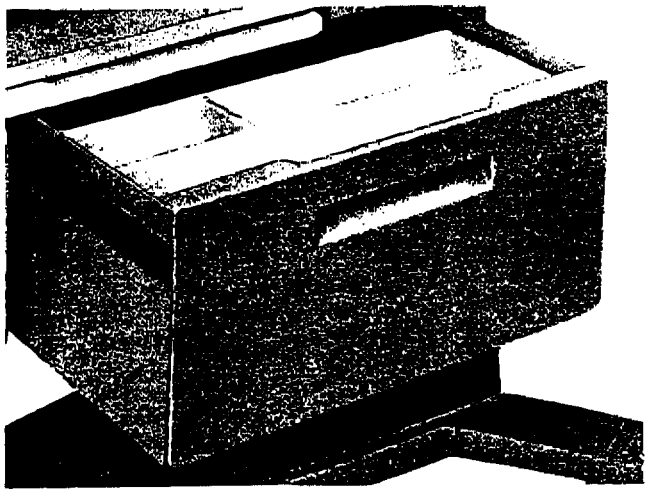

FIGURE 4.8 CHECKING THE PASS–THROUGH DRAWER

5. **CHECK THE WARMER MODULE SWIVEL OPERATION** (Figure 4.9) by rotating the Warmer Module 90 degrees to the left or right of center. Return to center position.

WARNING: When the Warmer Module is swiveled and energized, objects (Monitors etc.) located on the optional Monitor Shelf may overheat or become hot to the touch.

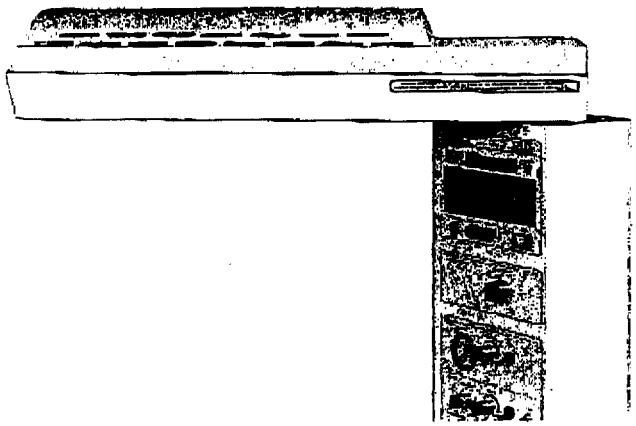

FIGURE 4.9 CHECKING THE WARMER MODULE SWIVEL

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6. **CHECK THE OPERATION OF THE X-RAY CASSETTE TRAY (ACCESSORY)** (Figure 4.10) by pulling up the middle of a Side Panel and pulling the X-ray Cassette Tray out from under the Bassinet. Replace the X-ray Cassette Tray by reversing the procedure.

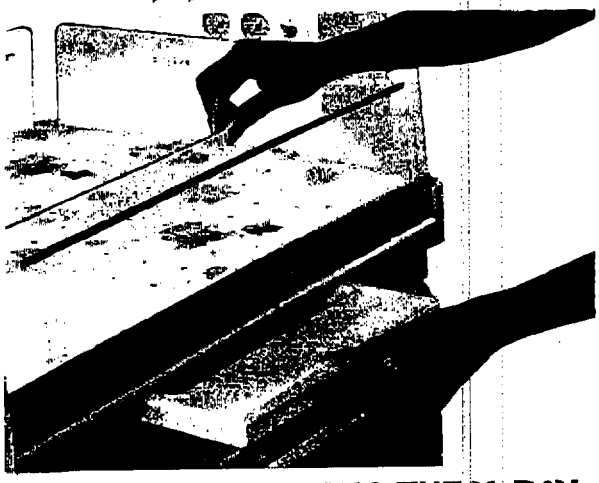

FIGURE 4.10 CHECKING THE X-RAY TRAY

7. **CHECK THE INSTRUMENT TRAY (ACCESSORY)** (Figure 4.11) by swinging it out from under the Bassinet.

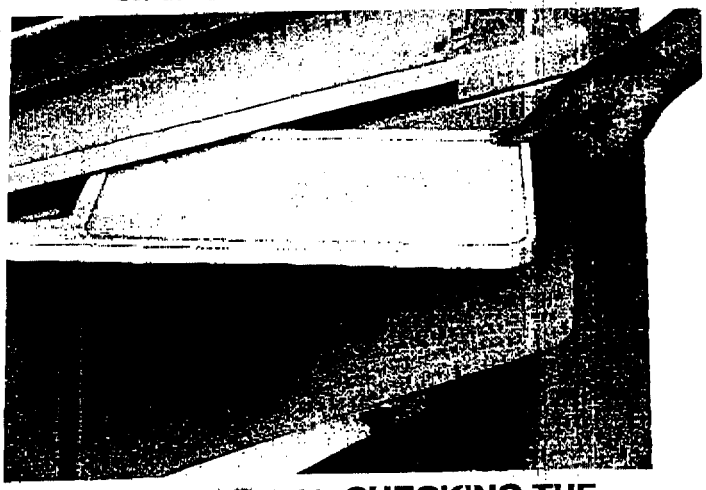

FIGURE 4.11 CHECKING THE INSTRUMENT TRAY

8. **CHECK THE VHA** by pressing the upper portion of the Switch on the right side of the Lower Post until the Upper Post raises to its maximum height. Press and hold the lower portion of the Switch until the Upper Post lowers to its minimum height. Repeat the procedure using the Switch on the left side of the Lower Post. Verify the Upper Post operates smoothly and re-adjust to desired height.

CAUTION: Always lower the Resuscitaire® Radiant Warmer VHA to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.

9. **CHECK BASSINET TILT CONTROL Operation as follows (VHA) only*:**

a. Turn the Bassinet Tilt Control clockwise (Figure 4.11A) until the Bassinet Foot End is fully raised and comes to a stop!.

b. Turn the Bassinet Tilt Control counterclockwise until the Bassinet Head End is fully raised and comes to a stop.

c. Return the Bassinet to the horizontal position.

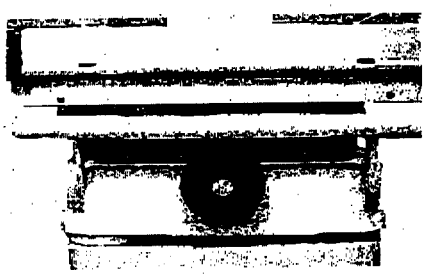

FIGURE 4.11A CHECKING THE BASSINET TILT CONTROL (VHA ONLY)

4.4 RESUSCITATION EQUIPMENT PRE-USE CHECKOUT/SET-UP

SUPPLY PRESSURE

1. Ensure that O_2 (and AIR) pipeline(s) are securely attached to appropriate fittings on the rear of the unit and that the gas supply present is 40 to 75 psi.

If using Reserve Gas Supply from cylinders:

2. Ensure that cylinder(s) are properly secured in the mounting yokes on the rear of the warmer and that the cylinder valve located on the top of the cylinder is open.

3. Examine the appropriate cylinder pressure gauges on the front of the upper column to ensure that sufficient reserve gas supply is present.

*Not available in USA or Canada.

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4. Set the **Gas Supply On/Off** Switch to the **On** position.

BLENDED GAS SUPPLY (Optional)

LOW FLOW MICROBLENDER WARNINGS

- **If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FIO_2 and flow output from the microblender.**
- **Always operate the low flow microblender with clean/dry medical grade gases.**
- **Air inlet water filters are recommended for use with the low flow microblender.**
- **The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.**

1. If present, set the precision blender to the desired oxygen % concentration using the Blender Control Knob.

RESUSCITATION MODULE (Optional)

SUCTION

NOTE:** To obtain suction, the **Gas Supply On/Off** Switch (Figure 4.3C) must be **ON.

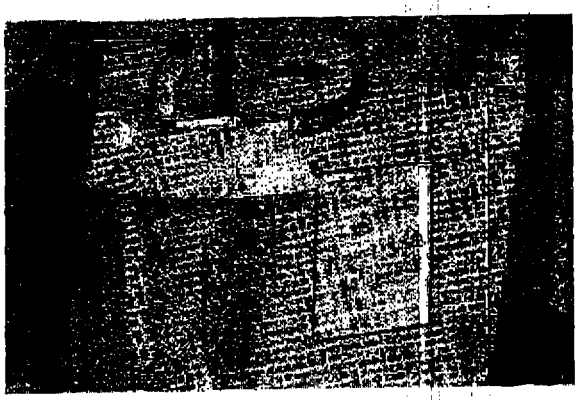

FIGURE 4.12 CHECKING THE SUCTION BOTTLE

***NOTE:** The filter and tubing resistance will not affect the desired maximum value that is set in Step 5 below. The pressure value on the Suction Gauge matches the actual pressure value at the end of the catheter.*

5. Block the patient outlet of the suction bottle. Adjust the suction magnitude using the **Suction Min Max** Control while viewing the suction level on the **Suction** Gauge. Adjust the suction magnitude to the desired maximum suction pressure value.
6. Turn off the **Suction On/Off** Switch.

1. Check that a clean suction bottle (reusable or disposable, Figure 4.12) is installed and properly connected in the Resuscitation Equipment Storage Compartment at the front of the warmer.

CAUTION: When installing the disposable Suction Bottle: to prevent the suction tube from being blocked or damaged, position the Outlet Port parallel to the plate (Figure 4.12).

2. Ensure that a bacterial filter is connected in-line with the supply connection to the reusable suction bottle (a filter is built-in on the disposable bottle).

3. Connect the desired extension tubing to the outlet of the suction bottle outlet port (refer to Figure 3.1) and secure the free end of the extension tubing in either tubing retaining slot provided on the front panel of the Bassinet.

4. Turn on the **Suction On/Off** Switch. There may be an initial reading of up to 30 mmHg on the Suction Gauge (refer to Figure 3.1) due to flow resistance of the hydrophobic filter and suction tubing.

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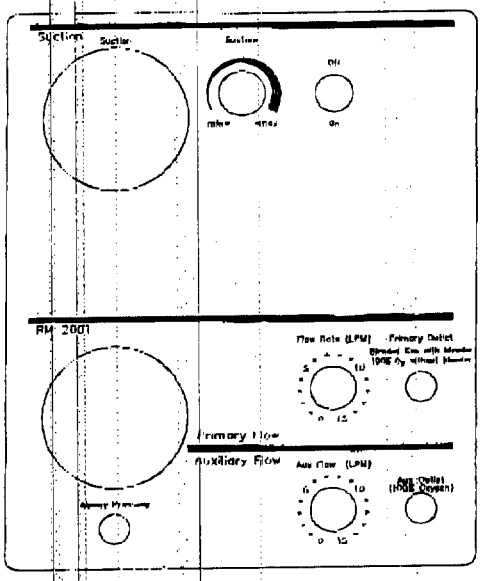

FIGURE 4.13 RESUSCITATION MODULE 2001

RESUSCITATION MODULE 2001 (Optional)

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

PRIMARY FLOW (provides blended gas if optional blender is installed; 100% oxygen if no blender is installed)

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the desired device to be supplied by the **Primary Flow** circuit to the **Primary Outlet** connector.
2. Adjust desired primary flow using the Primary **Flow Rate (LPM)** control and check flow.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

AIRWAY PRESSURE

Airway Pressure fitting may be used to measure airway pressure during mechanical resuscitation.

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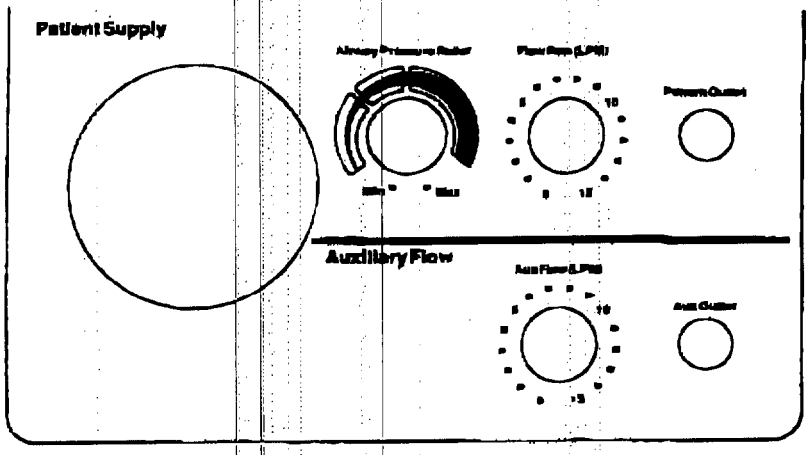

FIGURE 4.14 RESUSCITATION MODULE (PATIENT SUPPLY)

RESUSCITATION MODULE WITHOUT AUTO-BREATH (Optional) Patient Supply

Manual Resuscitation - Use with Patient Breathing Circuit - 10 mm tubing with thumb (finger) hole at patient end.

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the Patient Circuit to the **Patient Outlet** (refer to Figure 3.3).
2. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
3. Set the **Airway Pressure Relief** control to the desired pressure limit according to the color coded bands on the **Airway Pressure** Gauge and **Airway Pressure Relief** Control. Alternately, a "T" Fitting with an airway pressure monitor can be inserted into the **Patient Outlet** Port and connected to the **Airway Pressure** Port to indicate the breathing circuit pressure. Adjust the **Airway Pressure Relief** Control as necessary.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

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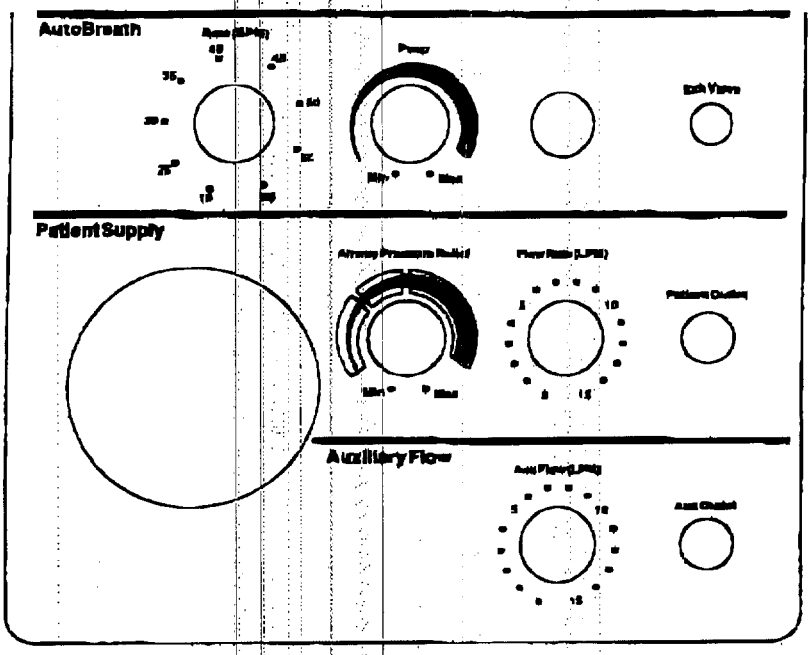

FIGURE 4.15 RESUSCITATION MODULE WITH AUTOBREATH

RESUSCITATION MODULE WITH AUTO-BREATH (Optional) Not Availalbe in USA or Canada

Automatic Resuscitation (Resuscitation Module with **AutoBreath** Infant Resuscitator Only) – Use with Automatic Patient Circuit –15 mm tubing with exhalation valve and exhalation valve control line tubing.

WARNING:
Excessive air pressure can cause damage to patient's lungs.
For prolonged ventilation, use of a heat and moisture exchanger is recommended.
For unattended auto ventilation use patient airway monitor.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Turn the **AutoBreath** Infant Resuscitator circuit off using the **On/Off** Control.
2. Connect the Patient Circuit for Automatic Breathing to the **Patient Outlet** Connector and the exhalation valve control line tubing to the **Exh Valve** Connector (refer to Figure 3.2).
3. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
4. Check the fixed internal **Airway Pressure Relief** Control by setting the desired Airway Pressure Limit and blocking the exhalation valve port exhaust and the patient port of the Exhalation Valve.
5. Observe the **Airway Pressure** Gauge to check pressure limit.
6. Turn on the **AutoBreath** Infant Resuscitator circuit.
7. Adjust the **Rate (BPM)** Control to 18 breaths per minute.
8. Set the **PEEP** threshold by blocking the patient port of the Patient Breathing circuit. Do not block the exhalation valve exhaust port. Observe the Positive End Expiratory Pressure indicated on the **Airway Pressure** Gauge and adjust the desired PEEP using the **PEEP** Control.
9. Check the I:E ratio by measuring the Inspiratory and Expiratory Phase Times and dividing the Expiratory Phase Time by the Inspiratory Phase Time. The result should be approximately 2.0.
10. Check the desired Breath Rate by counting the number of breath cycles per minute.

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4.5 CONTROLLER OPERATION

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital-use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

Connect the unit to the ac line. Turn on the **CIRCUIT BREAKER** on the Rear Panel and the **Power** Switch on the Front Panel. Observe the Functional Test.

4.5.1 PRE-WARM MODE

After the Functional Test is complete, the **Pre-Warm Mode** will activate. The **Heater Power** Indicator will be at 100% (all lights on) for three minutes, reduce to 60% (six lights on) for 12 minutes and then be reduced to 30% (three lights on).

*NOTE: Selection of **Manual** or **Baby** and then returning to **Pre-Warm** during the three minutes of 100% or 12 minutes of 60% power will automatically reduce the power to 30%.*

During **Pre-Warm** Mode, the **Chk Patient** Alarm is disabled.

4.5.2 MANUAL MODE

WARNING:

To avoid overheating or underheating, observe the infant constantly and monitor the temperature using the skin temperature probe supplied with the equipment or other electronic thermometer.

Inspect infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Use the Mode key to select **Manual Mode**.
2. Use only for short-term warming with nursing personnel in constant attendance.
3. Do not use warmer in **Manual Mode** if **Manual** Indicator is not on.
4. Set the **Heater Power** Indicator to the desired level. The heater power will be maintained for 10 minutes.
5. After 10 minutes, the **Chk Patient** Alarm will sound one time. Press the **Silence/Reset** Key to initiate another 10-minute warming period.
6. If the **Chk Patient** Alarm is not acknowledged, the heater will be automatically disabled after an additional 5 minutes of operation.
7. Heater power output must be adjusted manually to maintain Baby Temperature within the desired range.
8. Check infant's temperature and condition at least every 15 minutes. When initially setting or when changing heater power output, check Baby Temperature more frequently to be sure it is maintained within the desired range.

CAUTION: A change in heater power output will not result in an immediate change in Baby Temperature. Wait for results. Large changes in heater power output will cause a more rapid change in Baby Temperature.

9. Use Skin Temperature Probe to continuously monitor Baby Temperature whenever possible. Refer to paragraph 4.5.3 to attach the probe to the patient.

***IMPORTANT:** In **Manual Mode**, the Skin Temperature Probe monitors only -- it does not control.*

***NOTE:** It is not necessary that the Skin Temperature Probe be connected to the Controller for **Manual Mode**.*

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RESUSCITAIRE® Radiant Warmer

4.5.3 BABY MODE

WARNING:

To avoid hazards of overheating or underheating, the infant should not be left unattended. Use only with the Hill-Rom Air-Shields' Skin Temperature Probe supplied with the unit. Inspect the infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Plug Skin Temperature Probe into Controller **Skin Temp Probe** Connector.
2. Use the Mode key to select **Baby Mode**.
3. Attach the Skin Temperature Probe to the infant. The probe should be located on the infant's abdomen, halfway between the xyphoid and the umbilicus (Figure 4.13). The metal side of the probe should be placed in direct contact with the skin (when using the reusable probe).

FIGURE 4.13A ATTACHING SKIN PROBE

FIGURE 4.13B ATTACHING SKIN PROBE

WARNING:

The location of the Skin Temperature Probe must be such that the skin around the Sensor is in direct line with the heat from the Warmer Module. If the location is shadowed, for example, by the infant's body, overheating and possible burning of the infant's skin can result. Do not use a rectal probe. Use of a rectal probe can result in overheating or underheating of the infant.

The Skin Temperature Probe must be in intimate contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain intimate skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment and feel infant's skin for signs of overheating.

The Skin Temperature Probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The Skin Temperature Probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.

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4. When the infant is prone, the Skin Temperature Probe should be located on the infant's back.

5. The skin area around the probe should be thoroughly cleansed and dried before the probe is placed on the skin.

6. To obtain an accurate reading of the infant's skin temperature, place the probe in position and cover with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or tape the probe into position, cover it with a small piece of cotton just large enough to cover the tip of the probe, and then place a second piece of tape over the cotton. If it is desired to reduce tape contact on the infant's skin, the cotton can be applied directly to the probe tip without the first piece of tape. To stabilize the attached probe, a third piece of tape may be placed over the probe wire approximately three to four centimeters from the probe tip. To minimize the effect of direct radiation on the Skin Temperature Probe, in order to obtain a more accurate **Baby Temperature** measurement, cover the Sensor with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or an equivalent insulating cover with a reflective surface facing the Warmer Module.

7. Baby Mode should be used for long-term warming and when attending personnel cannot be in constant attendance.

8. Set the **Set Temperature** Display to the prescribed temperature. A higher Set Temperature setting does not increase rapid warming.

9. Verify that **Baby Temperature** Display reading stabilizes within 0.2 °C of **Set Temperature** Display. Fluctuations in the **Heater Power** Indicators or the **Baby Temperature** Display reading can result from air currents, obstruction of radiation to the infant or the Skin Temperature Probe not being in intimate contact with the skin.

10. **Baby Temp** Alarms can be silenced for 10 minutes by pressing the **Silence/Reset** Key.

11. **Probe, High Temp** and **Baby Temp** (39.0 °C) Alarms are automatically reset after the alarm condition is corrected. The **High Temp** Alarm may be silenced for 2 minutes by pressing the **Silence/Reset** Key.

NOTE: *In the event of a **Probe Alarm**, **Manual Mode** can be used temporarily until a replacement Skin Temperature Probe is available and only if nursing personnel are in constant attendance.*

4.5.4 EXAMINATION LIGHT

The light is turned on and off by the **Exam Light** Switch. Turn the light on only as required for optimum bulb life.

4.6 X-RAY PROCEDURES

1. Swing the Warmer Module (Figure 4.9) to the right or left of center as required to position the X-ray machine.

2. Lift the Left or Right Bassinet Side Panel up, slide the X-ray Tray out (Figure 4.10); place the X-ray Cassette on the tray and return the tray to the Bassinet. Align the cassette as desired with the markings on the X-ray Cassette Tray and relative markings on the inside of the Bassinet panels.

3. When the X-ray is complete, remove the X-ray Cassette Tray and return the X-ray Tray. Place the Warmer Module in its normal operating position.

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SECTION 5
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 Hill-Rom service personnel.

WARNING:

If oxygen is in use, make sure that the oxygen supply to the equipment is turned off and that it 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 cleaning and maintenance procedures; make sure that the Power Cord is disconnected from the wall receptacle.

5.2 CLEANING

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and 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

1. Remove both Bassinet Side Panels (Figure 5.1) by pulling them straight up.

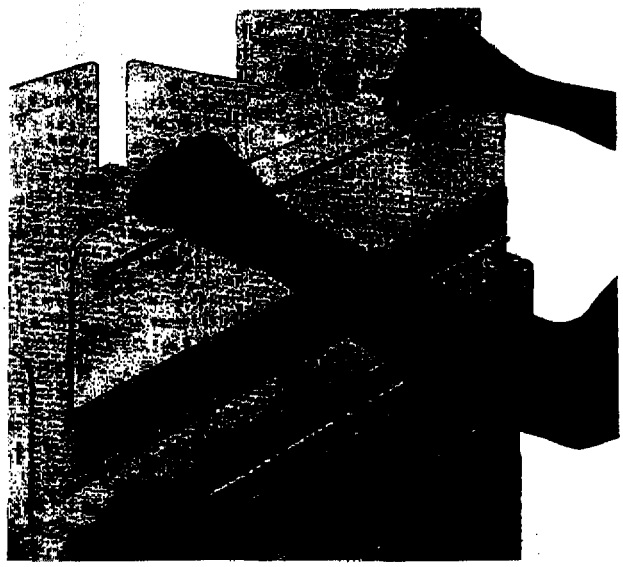

FIGURE 5.1 REMOVING BASSINET SIDE PANELS

2. Remove the Bassinet Back Panel (Figure 5.2) by raising it straight up until the bottom pins are adjacent to the slots in the corner brackets.

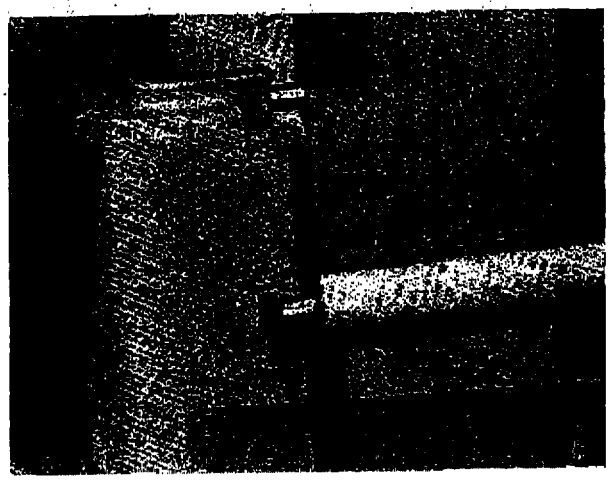

FIGURE 5.2 REMOVING BASSINET BACK PANEL

3. Remove the Bassinet Front Panel (Figure 5.3) by raising it and then swiveling it down. At the corners, press up on the release buttons and pull the panel straight out (Figure 5.4).

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FIGURE 5.3 BASSINET FRONT PANEL RELEASE BUTTONS

FIGURE 5.4 REMOVING BASSINET FRONT PANEL

4. Remove the Mattress from the Bassinet.
5. Remove the X-ray Tray (Figure 4.10).
6. Remove the Suction Bottle and Filter (Figure 4.12) from the front of the Bassinet.

5.4 CLEANING PROCEDURES

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and disinfected.

5.4.1 CLEANING AGENTS

An intermediate-level detergent/disinfectant registered by the U.S. Environmental Protection Agency should be used, but only when the equipment is not in use and disassembled as described elsewhere in this section. 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 PAINTED SURFACES

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

5.4.3 CLEAR PLASTIC AND ACRYLIC SURFACES

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

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.

Use a detergent/disinfectant to clean all surfaces thoroughly. Make sure to clean all holes, indentations, baffles, etc.; then dry with a clean cloth or paper towel.

5.4.4 METAL SURFACES

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

IMPORTANT: *After cleaning, a complete operational checkout should be performed before returning the unit to service.*

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5.4.5 SKIN TEMPERATURE PROBE, REUSABLE

CAUTION: Do not pull on the tip of the skin temperature probe when cleaning or drying; damage to the probe may result.

Use a detergent/ to thoroughly clean all surfaces; then dry with a clean soft cloth or paper towel.

5.5 STERILIZATION (IF DESIRED)

CAUTION: DO NOT STEAM AUTOCLAVE.

Sterilization can be accomplished by the following methods:

A. COLD (LIQUID) STERILIZATION

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

B. GAS STERILIZATION (ETHYLENE OXIDE).

Prior to gas sterilization, the entire unit should be thoroughly cleaned as described elsewhere in this section. Remove and discard all used disposable elements. New disposable elements should be installed after sterilization.

Standard gas sterilization procedures are satisfactory as these do not normally exceed 54.4 °C (130 °F).

IMPORTANT: *After sterilization, a complete functional checkout procedure should be performed before returning the unit to service.*

5.6 REASSEMBLY AFTER CLEANING

1. Replace the Mattress on the Bassinet.
2. Replace the X-ray Tray (Figure 4.10).
3. Replace the Bassinet Back Panel by inserting the pins in the Corner Brackets (Figure 5.2).
4. Replace the Bassinet Side Panels by pushing them straight down into their slots (Figure 5.1).
5. Replace the Bassinet Front Panel by sliding it into the front of the Bassinet (Figure 5.4) until the release tabs catch. Raise the Panel into position.
6. Install a new Suction Filter if using a Reusable Bottle (Figures 3.1 and 4.12). Replace the Suction Bottle if using a Disposable Bottle.

5.7 CALIBRATION

The equipment should be completely checked and calibrated at least once a year by qualified service personnel. Refer to the appropriate Service Manual for details.

5.8 TROUBLESHOOTING

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

TABLE 5.1 TROUBLESHOOTING

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
No Power and **Power Fail** Alarm is not activated	a. Circuit Breaker not set to On.	a. Set Circuit Breaker to On.
Power Fail Alarm activated	a. Circuit Breaker tripped.	a. Reset Circuit Breaker (Figure 4.2).
	b. Power Cord unplugged.	b. Connect Power Cord to POWER connector (Figure 4.2) or wall socket.
	c. Defective Power Cord.	c. Replace Power Cord.
System Fail Alarm activated	a. Internal malfunction.	a. Refer to service.
Probe Alarm Activated	Possible Defective Skin Probe(s)	a. Check to ensure Skin Probe is in good contact with the skin.
		b. Replace Skin Probe(s). If condition is not corrected, refer to service.
Error Code Er02 through Er022 Er024 and Er025	a. Internal malfunction	a. Refer to service.
Error Code Er023	Ambient Temperature in excess of 32 °C (90 °F).	Verify ambient temperature with an external thermometer.

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SECTION 6
PARTS LIST

6.1 GENERAL

This section provides a listing of Operator replacement parts. Parts other than those listed here should be replaced by qualified service personnel. For an illustration of accessories, refer to Figure 1.1 of this manual.

	PART NUMBER
REPLACEMENT PARTS	
Bassinet Side Panel (Eng)	81 900 00
Bassinet Rear Panel (Eng)	81 900 01
Bassinet Front Panel (Eng)	81 900 02
Power Cord 220/240V Units	17 AZ 204
Skin Temperature Probe (Reusable)	81 300 05
Reusable Suction Bottle Kit (750 ml) (Bottle, Stopper, Tubing and Filter)	81 001 50
Reusable Suction Bottle Only	08 131 00
Filters (Box of 25)	81 001 50
40-Inch Power Cord	17 AZ 211
DISPOSABLES	
Premi-Probe® 3 Skin Temperature Probe (Box of 10)	81 300 08
Premi-Probe® 3 Skin Temperature Probe (10 Boxes of 10)	81 300 09
Autobreath Disposable Breathing Circuit and Exhalation Valve (Box of 25)	81 000 06
Autobreath Disposable Gas Supply Circuit (Box of 25)	81 001 27
Breathing Circuit Connector with Pressure Monitor Port (Box of 25)	81 001 29
Critter Covers® Probe Covers (Box of 100)	68 209 46
Critter Covers® Probe Covers (Box of 600)	68 209 45
Care-for-Me Probe Covers, 100 Large (10% discount when you order 5)	68 209 47
Care-for-Me Probe Covers, 100 Standard (10% discount when you order 5)	68 209 48
Neat Clips - 3/8" Diameter (Box of 100)	68 120 53
1.00" Diameter (50/Case)	68 120 54
Disposable Suction Bottle, 800 ml (Box of 100)	81 001 51
OPTIONS	
Instrument Tray - Right Hand	81 101 70R
Instrument Tray - Left Hand	81 101 70L
Pass-Through Drawer Organizer Tray	81 101 11
Air Hose Assembly, Green DISS	78 464 10
Oxygen Hose Assembly, Yellow DISS	78 465 10
Air Hose Assembly, Black NIST	81 501 45
Oxygen Hose Assembly, White NIST	68 507 50
Air Hose Assembly Black DISS	81 501 50
Oxygen Hose Assembly White DISS	68 507 30
Oxygen/Air Sealing Washer	81 502 02
X-ray Cassette Tray	81 100 44
IV Pole	82 001 53
Monitor Shelf	82 001 52

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LIMITED 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 Hill-Rom Air-Shields, Inc., 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 Hill-Rom Air-Shields, Inc. cannot be held liable for conditions resultant therefrom if:

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 Hill-Rom Air-Shields, Inc.
4. Sale or service is performed by a non-certified service/dealer agency.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE. HILL-ROM AIR-SHIELDS' OBLIGATION UNDER THESE WARRANTIES SHALL NOT INCLUDE ANY LIABILITY FOR LOSS OF PROFITS, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES OR DELAYS. Some states, provinces, or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion or limitation may not apply. Any improper or negligent use, any alterations or repairs not in accordance with Hill-Rom Air-Shields' manuals or performed by others in such manner as in Hill-Rom Air-Shields' sole judgement affects the product materially and adversely, shall void these warranties. These warranties do not cover failures due to misuse, abuse, neglect, or lack of routine maintenance. No employee or representative of Hill-Rom Air-Shields is authorized to change these warranties in any way or grant any other warranty unless in writing and signed by a Hill-Rom officer. These warranties provide specific legal rights; but, there may be other available rights; which vary from state to state, province to province, or country to country.

*The Accreditation Manual for Hospitals requires each piece of equipment to be tested prior to initial use and at least annually thereafter. To comply with this standard, we recommend that you participate in our Preventive Maintenance 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. Technical Services representatives are located throughout the United States and Canada and are dispatched for required maintenance by calling USA (800) 445-3720 and Canada (800) 267-2337. Customers outside the U.S. and Canada should contact their local factory-authorized Hill-Rom Air-Shields' distributor for service.

Hill-Rom Air-Shields.
A HILLENBRAND INDUSTRY
330 Jacksonville Road, Hatboro, PA 19040

CAT NO. 82 990 15-9
E 1 2 3 4 5 6 7 8 9
A 1 2 3 4 5 6 7 8 9

Printed in USA 11/00

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Memo

To: The File

From: Sarah Foster, Reviewer

Date: 11/17/00

Re: Document Number K003335

Memo Regarding Telephone Conversation on 11/16/00

This memo confirms the phone conversation held on 11/16/00 with Larry Krasley of Hill-Rom Air-Shields and myself, Sarah Foster of DDIGD. This call was regarding modifications made to the operator's manual for the Hill-Rom Air-Shields Resusitaire® Infant Warmer upon request from a previous conference call on 11/08/00. The modified operator's manual still contained references to the "AutoBreath" resuscitation module, which is not available in the United States. After speaking with Dr. Bazaral of the Anesthesiology Branch, I called Mr. Krasley and requested that he remove all pages mentioning the "AutoBreath" option. Those pages in particular were: 14-17, 27-28, 30, 38.

The appropriately modified operator's manual was faxed to DDIGD on 11/16/00. A hard copy will follow.

Sarah Foster 11/17/00

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Hill-Rom Air-Shields™

A HILLENBRAND INDUSTRY

330 Jacksonville Road
Hatboro, PA U.S.A. 19040-2211
Voice: (215) 682-8688 Fax (215) 682-8689

Facsimile Transmission Sheet

To: Farah Foster **Date:** November 16, 2000

Company: FDA **Pages:** 50 + cover

From: Larry W. Krasley **FAX No.** 301-480-3002

Copies:

Dear Ms. Foster,

Attached please find copies of the updates for 510(k) K003335. I have also sent the updates to the Document Mail Center.

- Section III Pages 12-63 remove and replace with attached Operator's Manual.

I will also forward a copy to the Document Mail Center.

Please feel free to contact me should you have any further questions or concerns.

Regards,

Larry

Larry W. Krasley
Regulatory Affairs Specialist

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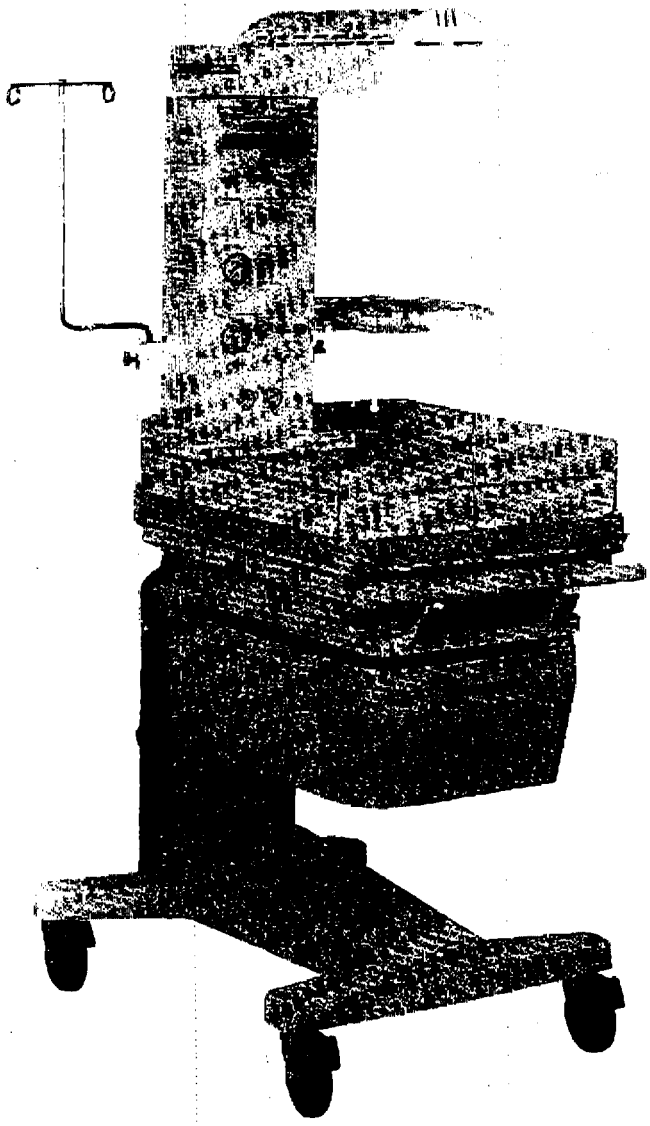
Hill-Rom Air-Shields®

A HILLENBRAND INDUSTRY

RESUSCITAIRE® Radiant Warmer

MODEL RW82-1



OPERATOR'S MANUAL

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OPERATING PRECAUTIONS

GENERAL PRECAUTIONS

- Federal Law restricts this device to sale by or on order of a physician.
- Infant radiant warmers should be used only by properly trained personnel as directed by an appropriately qualified physician aware of currently known risks and benefits.
- The functional checkout procedure should be performed before the unit is first placed into use and after disassembly for cleaning, servicing or maintenance. Refer to qualified service personnel if the unit does not perform as specified.
- The Bassinet end and side panels cannot be used for pushing or pulling the ***Resuscitaire® Radiant Warmer***.
- Do not leave the infant unattended in the Bassinet of the ***Resuscitaire® Radiant Warmer*** when the side panels or the front panel are folded down.
- To avoid overheating or underheating, skin temperature must be continuously monitored and controlled either manually or automatically. Rectal temperature should never be used to control skin temperature.
- To avoid overheating or underheating when operating in manual mode, observe the infant constantly and monitor the temperature using the temperature probe supplied with the equipment or other electronic thermometer.
- The skin temperature sensing probe must be in direct contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain direct skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment, reddened skin areas, and proper skin temperature.
- The skin temperature sensing probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The skin temperature probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.
- To avoid overheating the skin, the location of the skin temperature probe must be such that the skin around the Sensor is in direct line with the radiation from the warmer. Do not place anything between the radiant warmer and the infant that will interfere with the radiation from the warmer.
- Radiant warming increases insensible water loss. Appropriate measures to maintain proper fluid balance should be considered.
- Phototherapy units located too close to the Bassinet may affect mattress and infant temperature.
- The warmer cannot differentiate between an increase in core temperature and cold skin (fever) and low core temperature (hypothermia). It is recommended that patient core temperature be monitored with a separate calibrated electronic thermometer.
- 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 avoid overheating of the warmer, do not place objects (equipment, blankets, clothing or sterile packs) on top of the warmer.
- Air currents across the Bassinet area can affect patient thermal balance. Avoid placing the Warmer near heating or air conditioning ducts that may blow air across the Bassinet.
- Temperature uniformity (per IEC 601-2-21) across the mattress surface may not be maintained when the Bassinet is tilted in the 5- and 10-degree positions.
- During service intervals, inspect the secondary reflector directly under the warmer heater element for particles. If particles are present, replace the heater element. The life expectancy of the heater element is 1000 hours of operation.

OPERATING PRECAUTIONS (Continued)

GENERAL PRECAUTIONS (Continued)

- Should any of the control knobs on the Resuscitation Module come loose for any reason, do not attempt to refasten them. The calibration of these controls depends on the position of the knob on the shaft. If this occurs, recalibration must be performed by qualified service personnel.
- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Only connect the power cord to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with or provided for the ***Resuscitaire® Radiant Warmer.***
- The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
  - Use of the accessory in the PATIENT VICINITY.
  - Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.
- When raising or lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA,*** make sure that any attached cables, tubing or hoses are not compromised.
- When lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA*** to its minimum height, ensure thatthe gas tanks, if installed, do not contact the floor.
- Always lower the ***Resuscitaire® Radiant Warmer VHA*** to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.
- To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport. Use the handle when moving the equipment.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

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OPERATING PRECAUTIONS (Continued)

ELECTRICAL PRECAUTIONS

- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Confirm that the **Oxygen Supply** is turned off and that the equipment 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.
- Connect the power cord only to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with the Warmer.

EXPLOSION PRECAUTIONS

- Do not use in the presence of flammable anesthetics.
- Confirm that the oxygen supply is turned off and that the equipment 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.

OXYGEN PRECAUTIONS

- Improper use of supplemental oxygen may be associated with serious side effects including blindness, brain damage, and death. The risks vary with each infant. All clinical practices with regard to 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 the 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_2) in the blood. When deemed advisable by the attending physician, blood PO_2 should be measured by accepted clinical techniques.
- Oxygen flow rates cannot be used as an accurate indication of oxygen concentrations. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals directed by the attending physician.
- Keep matches, lighted cigarettes, and all other sources of ignition out of the room in which the equipment is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.
- Although oxygen compatible materials are used in the oxygen delivery system, special care must be taken when high pressure oxygen such as found in a medical oxygen cylinder is used. Violent ignition of oil, grease, greasy substances, small particles of dust, dirt or other particulate contaminants (even small particles of metal), can occur in the presence of high pressure oxygen if their ignition temperature is reached. An instantaneous increase in temperature can occur due to friction, particle acceleration, or adiabatic compression, if the oxygen cylinder valve is opened too rapidly. **SERIOUS INJURY MAY RESULT!** Always observe the following precautions:

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OXYGEN PRECAUTIONS (Continued)

- Oil, grease, greasy substances, dust, dirt and other particulate contaminants must be kept away from oxygen regulators, cylinder valves, tubing and all other oxygen equipment.
- Always open oxygen cylinder shut-off valves **very slowly** and **carefully.**
- On high pressure oxygen cylinders use only pressure regulators or reducing valves approved for oxygen service. Do not use oxygen pressure regulators or reducing valves for air or gases other than oxygen as they may be hazardous. Operate such devices in strict accordance with the manufacturer's recommendations.
- When new or replacement oxygen cylinders are to be installed, they should have their outlet ports cleared by cracking the cylinder valve momentarily before attachment to the equipment.

LOW FLOW MICROBLENDER WARNINGS

- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FiO_2 and flow output from the microblender.
- Always operate the low flow microblender with clean/dry medical grade gases.
- Air inlet water filters are recommended for use with the low flow microblender.
- The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.

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TABLE OF DEFINITIONS AND SYMBOLS

NOTE, IMPORTANT, PRECAUTION, 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 when greater emphasis is required.*

PRECAUTION: *A Precaution is supplemental information to assist the user in the safe and effective use of the equipment.*

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.

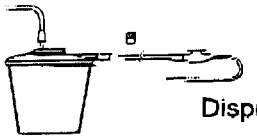
WARNING: A Warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

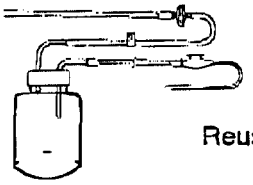
SYMBOLS


Attention: consult accompanying documents.

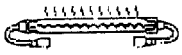

Type B equipment with an F-type isolated (floating) applied part.


Danger! High Voltage!


Disposable Suction Bottle


Reusable Suction Bottle


Patient


Heater Element


Suction Line Filter


Load Symbol


Examination Light


Examination Light Switch


Mode Control Key

Temperature Override Mode Key


Keypad Lock Key


Set Temperature Keys


Power On/Off Switch

Celsius/Fahrenheit Selection Key


Silence/Reset Key


Procedural Silence Indicator


Apgar Timer Keys

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SECTION 1
GENERAL INFORMATION

1.1 INTRODUCTION

This manual provides instructions for installation, use, operator maintenance and troubleshooting of the equipment. Hill-Rom Air-Shields cannot be responsible for the performance of the equipment if the user does not operate the equipment 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. Service manuals are available from Hill-Rom Air-Shields.

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

1.2 DESCRIPTION

The ***Resuscitaire® Radiant Warmer*** is designed specifically for labor and delivery room use. The ***Resuscitaire® Radiant Warmer*** consists of a Bassinet, Warmer, and a Controller module which provides heat control, monitoring of skin temperature and Apgar timing. The ***Resuscitaire® Radiant Warmer with VHA*** provides an adjustable Mattress Height from 89.2 cm (35.4 inches) to 110.2 cm (43.3 inches).

The ***Resuscitaire® Radiant Warmer*** also includes optional basic resuscitation packages which includes suction and oxygen delivery.

1.3 SPECIFICATIONS

Specifications for the ***Resuscitaire® Radiant Warmer*** are provided in Table 1.1. All specifications are subject to change without notice.

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RESUSCITAIRE® Radiant Warmer

TABLE 1.1 SPECIFICATIONS

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer*

120V Models	120V, 60 Hz, 750W
100V Models (Japan)	100V, 50/60 Hz, 750W
230V Models	230V, 50/60 Hz, 750W

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer with VHA*

120V Models	120V, 60 Hz, 1300W
230V Models	230V, 50/60 Hz, 1300W

OVERLOAD PROTECTION

120V Models	Dual 12A Circuit Breakers
100V Models (Japan)	Dual 12A Circuit Breakers
230V Models	Dual 6A Circuit Breakers

Resuscitaire® Radiant Warmer with VHA also has in addition:

120V Models	Dual 6A Circuit Breakers
230V Models	Dual 3A Circuit Breakers

CHASSIS LEAKAGE CURRENT (Single fault condition, loss of ground)

100V and 120V Models	Less than 300 μA
230V Models	Less than 500 μA

EXAMINATION LIGHT >100 Foot Candles (0.11 lumens/cm^2)

ALARMS

High Temperature	Activates if Skin Temperature Probe is attached and the skin temperature sensor reaches 39.0 °C. Resets at 38.5 °C.
Check Patient	Activates in Manual Mode after 10 minutes. Remains on with audible alarm every 30 seconds for 5 minutes; totalling 15 minutes. Then the heater is turned *Off*.
Apgar Timer	Activates at the 1-, 5- and 10-minute Apgar Time intervals.
Power Fail	Activates when there is a loss of power.
Probe	Activates if Skin Temperature Probe fails (open or short).
System Fail	Indicates system failure, refer unit to service immediately.
Baby Temp	Activates if Baby Temperature fluctuates 1°C above or below set point.
Electrical Module Audio Alarms	Tone Frequency: 1.2 KHz maximum three-stage sound level: 15 seconds low, 15 seconds medium, then high.
Blender Module Pneumatic Audio Alarm	Vibrating Reed.

MANUAL HEAT CONTROL Adjustable in 10% increments from zero to full power (100%)

DATA PORT 2400 Bits/second fixed Baud Rate. RS232C Compatible.

MATTRESS TILT 0, 5 and 10 degrees.

DISPLAYS

Skin Temperature Display

Range	18 to 40 °C (64.4 to 104°F)
Accuracy	± 0.2 °C for 31 °C to 37 °C (88 °F to 98.6°F)
Resolution	0.1°C (0.5 °F)

RESUSCITAIRE® Radiant Warmer

TABLE 1.1 SPECIFICATIONS (Cont.)

DISPLAYS (Cont.)

Apgar Timer Display

Range	0 to 59 minutes, 0 to 59 seconds
Resolution	1 second
Accuracy	0 ± 1 second

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer*

Mattress Height	100 cm (39.4 - inches)
Height	188 cm (74 - inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	100 kg (220 lbs)

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer with VHA*

Mattress Height	89.2 to 110.2 cm (35.4 to 43.3 inches)
Bassinet Tilt (continuously)	±10 degrees from horizontal
Height	180.6 to 200.7 cm (71.1 to 79 inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	127 kg (280 lbs)

ENVIRONMENTAL

Operating Temperature Range	18 °C to 30 °C ambient
Storage Temperature Range	- 30 °C to +70 °C ambient
Relative Humidity Operating Range	5% RH to 95% RH, non-condensing

RESUSCITATION

Wall Supply Pressure	40 to 75 psi (2.8 to 5.2 bar)
Cylinder Pressure	2900 psi max (199.8 bar)
Cylinder Diameter	10-12 cm (4-5 inches) max

Suction Circuit

Adjustable Suction Intensity	0 to 150 mmHg

Patient Gas Supply

Airway Pressure Limit, Operator Adjustable	0 to 50 cm H_2O (4.9 kPa) ± 10%
Fixed Pressure Relief, Factory Set	60 cm H_2O (5.9 kPa) ± 20%

Primary Supply

Primary Pressure Limit	160 cm H_2O (15.7 kPa) ± 20%
Primary Flow Range	0 - 15 lpm

Auxiliary Supply

Auxiliary Pressure Limit	160 cm H_2O (15.7 kPa) ± 10%
Auxiliary Flow Range	0 - 15 lpm

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1.4 EQUIPMENT PROVIDED

- *Bassinet* - The Bassinet provides maximum visibility and access to the infant. The Bassinet tilts up in the rear 5 and 10 degrees and provides for X-ray Tray (optional) insertion.
- *Warmer Module* - The Warmer Module houses a heating element and an Examination Light for special procedures.
- *Controller* - The Controller provides Pre-Warm, Manual heat control, automatic skin temperature servo-control and contains an Apgar Timer, Skin Temperature monitor and probe connection.
- *Resuscitation Module (Optional)* - The Resuscitation Module contains a suction circuit, a patient oxygen delivery circuit with airway pressure relief and an auxiliary oxygen delivery circuit. There are two varieties of resuscitation modules, both versions can accept an optional blender.

1.5 FACTORY INSTALLED OPTIONS

- Resuscitation Module
- Resuscitation Module 2001
- Integrated Precision Blender
- Gas Supply Module
  - O_2 Pipeline and Cylinder
  - O_2/Air Pipeline and Cylinder

1.6 FIELD INSTALLED ACCESSORIES (Refer to Section 6 for Part Numbers)

- Instrument Tray (left or right mount)
- X-ray Cassette Tray
- Pass-Through Drawer Organizer Tray
- I.V. Pole
- Monitor Shelf

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RESUSCITAIRE® Radiant Warmer

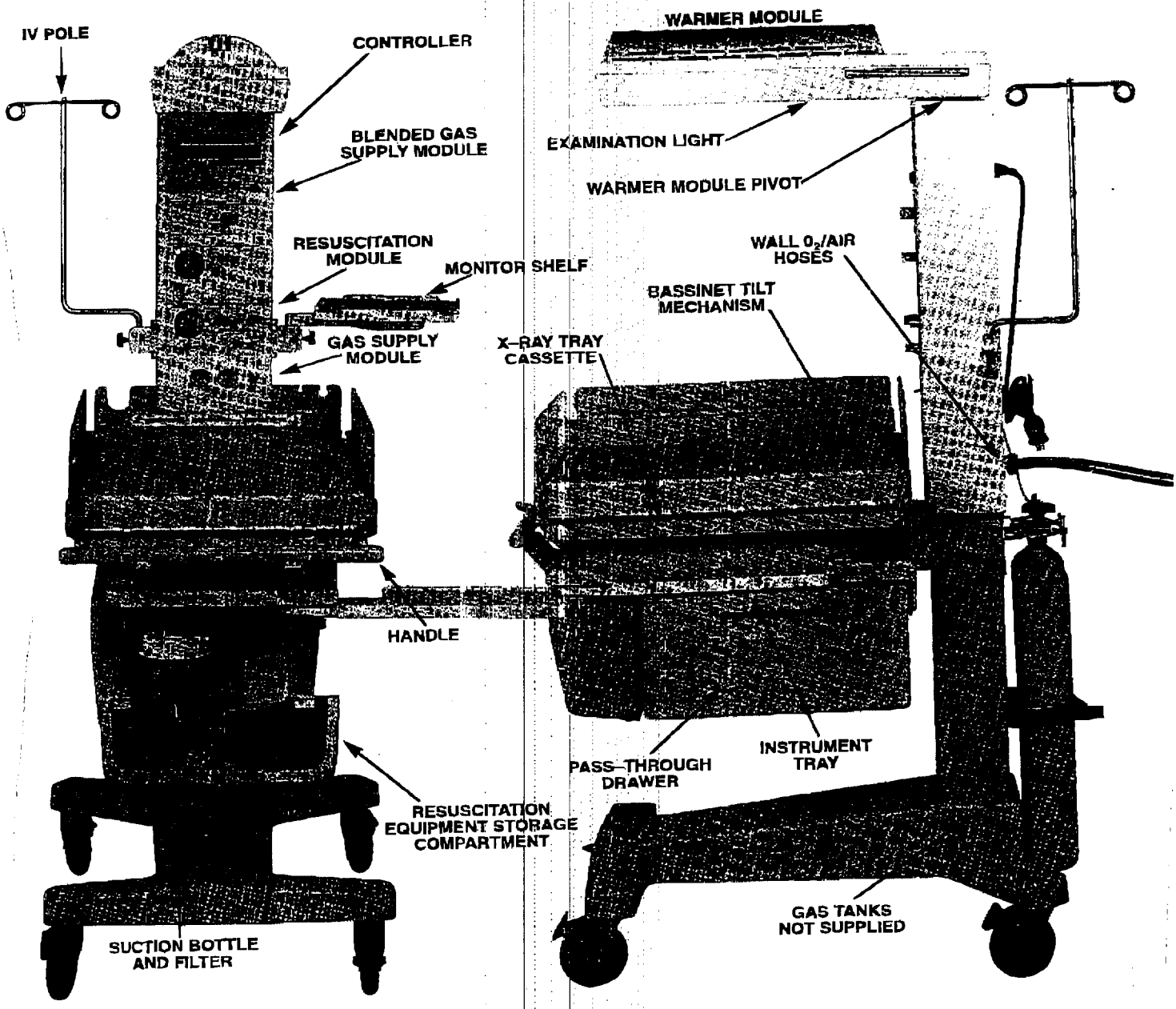

FIGURE 1.1 EQUIPMENT PROVIDED WITH FACTORY INSTALLED OPTIONS AND FIELD INSTALLED ACCESSORIES

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SECTION 2
INSTALLATION

2.1 UNPACKING

The ***Resuscitaire® Radiant Warmer*** is shipped in one carton which contains the following assemblies:

- Bassinet/Cart Assembly
- Upper Post Assembly
- Warmer Module Assembly
- Any user installed Accessories that were ordered

When removing the equipment from the carton, use care not to scratch or otherwise damage unprotected surfaces; remove all packing material.

2.2 ASSEMBLY (Refer to Figure 2.1)

NOTE: *The required mounting hardware is stored in a bag located in the pass-through drawer.*

1. **REMOVE THE BACK COVER** (1) from the Upper Column (2).
2. **REMOVE THE CONTROLLER** (3) from the Upper Column (2).
3. **REST THE UPPER COLUMN** (2) on top of the Bassinet/Cart column opening. Fully extend the suction hoses (4) and (11) out of the column.
4. **CONNECT THE SUCTION HOSE** (4) to the Suction Hose (11).
5. **REPOSITION AND MOUNT THE UPPER COLUMN** (2) on the Bassinet/Cart using four 10 - 32 x 3/8 inch screws (5). Exercising care not to kink the hoses, carefully push the connected suction hoses into the column.
6. **INSTALL TWO 10 - 32 X 3/8 INCH SCREWS (6) IN THE UPPER HOLES OF THE UPPER COLUMN** (2). Do not tighten the screws.
7. **RAISE THE WARMER** (7) above the open end of the Upper Column (2) and insert the Power Cable (10) into the open end of the column.
8. **SLOWLY LOWER THE WARMER** (7) onto the Upper Column. Align the slots of the warmer over the screws (6) on the column. Install the screws on the pivot bracket. Tighten the screws on the upper holes of the column using a nine-inch Phillips Head screwdriver.
9. **THREAD THE WARMER POWER CABLE** out through the Controller opening. Connect the Power Cable (10) to connector J4 on the Controller (3).
10. **REMOUNT THE CONTROLLER** on the Upper Column. Remount the Back Cover (1) on the Upper Column.
11. ***Resuscitaire® Radiant Warmer***

    CONNECT THE LINE CORD to the **POWER** Connector on the rear of the Controller (refer to Figure 4.2).

11A. ***Resuscitaire® Radiant Warmer with VHA***

    CONNECT THE LINE CORD to the Power Connector (Refer to Figure 4.2A) on the right side of the Lower Post. Connect the 40-inch Power Cord provided with the VHA between the AC connector on the left side of the Lower Post and the Controller Power Connector.

12. ***Resuscitaire® Radiant Warmer***

    SECURE THE LINE CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

12A. ***Resuscitaire® Radiant Warmer with VHA***

    SECURE THE 40-INCH POWER CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

CAUTION: Securing the Line Cord to the back panel is required to prevent removal of the Controller chassis with the AC power applied.

13. **INSTALL ANY ACCESSORIES** that were ordered using the installation instructions provided with the accessory.
14. **INSTALL THE END AND SIDE PANELS** on the Bassinet (refer to Paragraph 5.6 and Figures 5.1, 5.2, 5.3 and 5.4).

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RESUSCITAIRE® Radiant Warmer

PARTS LIST

Screw, 10 – 32 x 3/8 TR, PH Nylok (Qty 10)	99 041 36
Screw, 8 – 32 x 3/8 TR PH SS	99 031 38
Cable Clamp	17 725 64

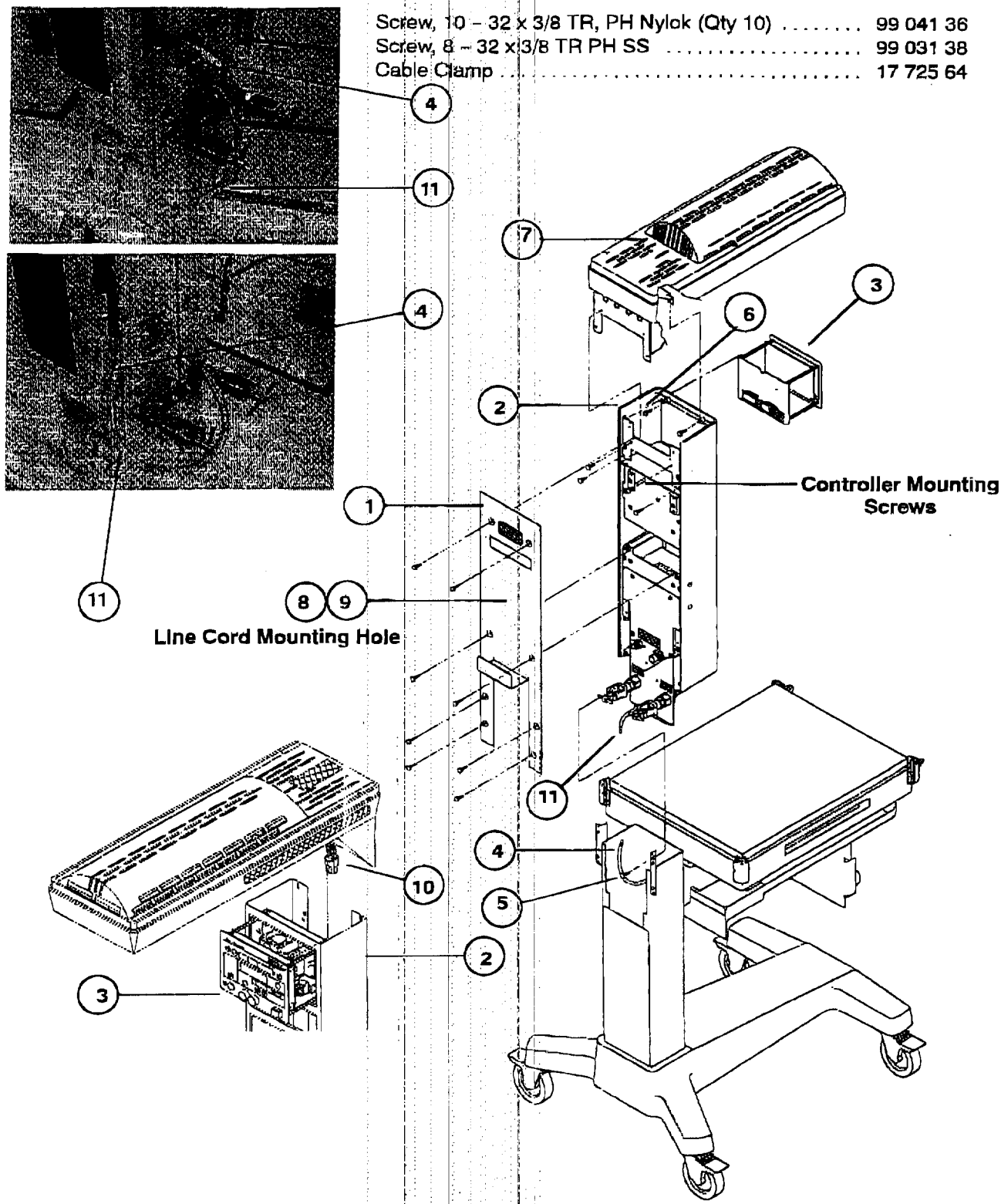

FIGURE 2.1 INSTALLATION

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SECTION 3
FUNCTIONAL DESCRIPTION

3.1 GENERAL

This section provides a functional description of the equipment.

3.2 FUNCTIONAL DESCRIPTION

3.2.1 WARMER MODULE

The Warmer is controlled by a Controller which provides **Pre-Warm** Mode, **Manual** Mode heater control, or **Baby** Mode (automatic skin temperature control). An Examination Light provides added illumination of the mattress area. A Warmer Head Pivot permits the Warmer to be pivoted 90° to either side for X-ray procedures. In addition, when the Warmer is pivoted, it continues to provide heat.

3.2.2 BASSINET

The Bassinet is designed to provide maximum function and utility to aid in the care of the newborn. The side and front panels may be folded down to permit access to the infant. The mattress may be tilted up from the rear at a 5- or 10-degree angle. Openings are provided on each side of the Bassinet for the insertion of the optional X-ray Cassette Tray.

3.2.3 CONTROLLER

At power-up, the microprocessor within the Controller performs a series of diagnostic tests to confirm the proper operation of the system. During this time, all displays and indicators are lighted and an audible tone is sounded.

When powered up, the system initializes in **Pre-Warm** Mode, the Controller will start the heater at 100% power and maintain that setting for three minutes, reduce to 60% for 12 minutes and then reduce the heater power to 30%.

When operating the Controller in the **Manual** Mode, the operator can adjust the heater power from 0 to full power in 10% increments. After 10 minutes of operation in the Manual Mode, a **Chk Patient** Alarm occurs.

Failure to acknowledge the Check Patient Alarm within the next 5 minutes will cause the heater to be turned off.

When operated in the **Baby** Mode, the Controller utilizes a Skin Temperature Probe, connected between the Controller input and the infant, to automatically adjust the heater output of the Warmer Module to maintain a digitally displayed preset **Set Temperature.**

The Apgar Timer displays the elapsed time and sounds an audible dual tone to alert the operator that 1, 5, and 10 minutes have elapsed since the timer was activated.

The **Keypad Lock** Key, when pressed, renders the Up/Down Arrows and Select Mode Keys inactive or active.

A Procedural Silence Timer prevents **Baby Temp** audible Alarms during routine procedures.

3.2.4 BLENDER MODULE (Optional)

The Blender Module provides blended oxygen from 21% to 100% to the **Patient Outlet** on the Resuscitation Module.

3.2.5 RESUSCITATION MODULE (Optional)

WARNING: Always monitor Airway Pressure and or/provide appropriate relief during infant resuscitation.

The Resuscitation Module contains pneumatic circuitry necessary for infant resuscitation. Controls and displays for the module are located above the rear of the Bassinet.

The Resuscitation Module is provided in two varieties. It consists of the following factory installed components:

- **Suction** - The **Suction** Circuit is driven by a gas powered venturi actuated vacuum generator which provides a negative pressure for suctioning the patient's airway. The suction pressure is indicated on the **Suction** Gauge (Figure 3.1). Suction may be adjusted using the

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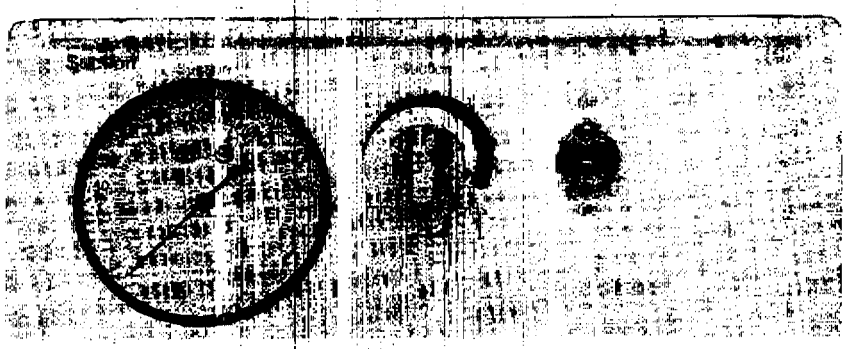
Suction Control and turned on or off using the **On/Off** Switch. A fixed internal relief valve limits the maximum suction pressure to 150 mmHg.



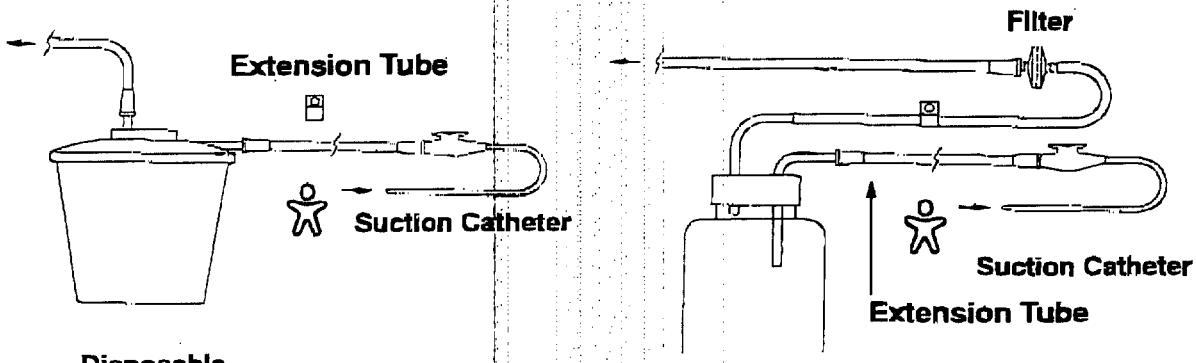


FIGURE 3.1 SUCTION FUNCTIONAL BLOCK DIAGRAM

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RESUSCITATION MODULE 2001 WITH PRIAMRY OUTLET AND AUXILIARY FLOW ONLY (FACTORY INSTALLED OPTION)

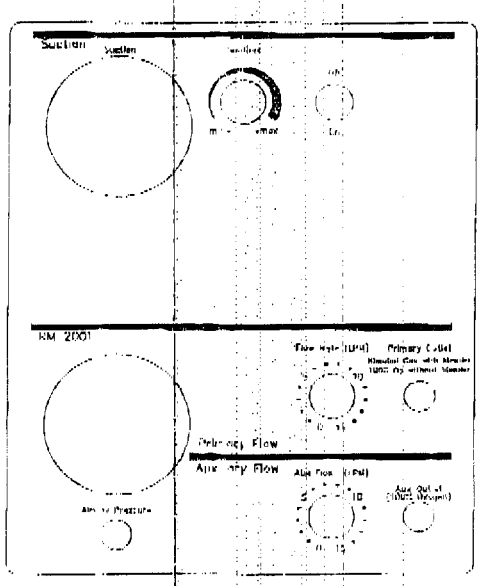

FIGURE 3.2 RESUSCITATION MODULE 2001 WITH PRIMARY OUTLET AND AUXILIARY FLOW ONLY

RESUSCITATION MODULE 2001 PRECAUTIONS

- The Resuscitation Module 2001 (option) is intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- If the blender option was added, confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- Always monitor **Airway Pressure**.
- When using **Primary Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Primary Supply** module.

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RESUSCITAIRE® Radiant Warmer

- A humidifier, if used, must be placed between the **Primary Outlet** connection and the patient. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

- **Primary Outlet** –

The **Primary Gas Supply** circuit may be used to provide continuous gas flow to a breathing circuit. When the **Blender** module is included in the system, the **Primary Outlet** provides 0 to 15 lpm of O_2 selected by the operator. The **Flow Rate (LPM)** control is a calibrated dial type flow adjustment.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 160 ± 10 cm H_2O (15.9 ± 1 kPa)

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet** –

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother , or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The outlet 1/4" hose barb fittings of the gas delivery module will attach to commercially available oxygen supply tubing or self-inflating resuscitation bag. Hill-rom Air shields part number 67 361 72.

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RESUSCITATION MODULE (FACTORY INSTALLED OPTION) PATIENT SUPPLY

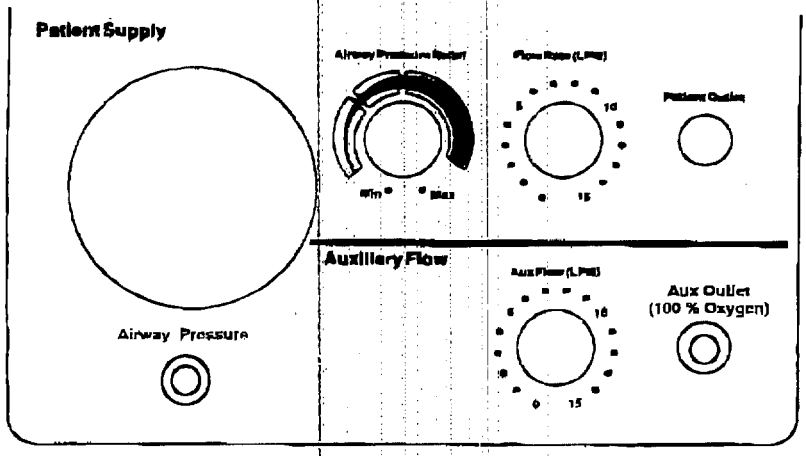

FIGURE 3.3 RESUSCITATION MODULE WITH PATIENT GAS SUPPLY AND AUXILIARY FLOW ONLY – PATIENT SUPPLY

RESUSCITATION PRECAUTIONS

- The Resuscitation Module (options) are intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- Confirm the setting and flow of the Airway Pressure relief valve before patient use.
- Confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- The **Aux (Auxiliary) Outlet** does not provide adjustable pressure limiting.
- **Auxiliary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- Always monitor **Airway Pressure**.
- When using **Patient Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Patient Supply** module.
- A humidifier, if used, must be placed between the **Patient Outlet** connection and the patient circuit. DO

NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.

- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.

- **Patient Outlet -**

The **Patient Gas Supply** Circuit may be used to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet -**

The **Aux Outlet** circuit supplies 100% oxygen through the **AUX Flow (LPM)** Control to the **AUX Outlet** connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother , or a second neonate, i.e. twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The patient breathing circuit used in conjunction with the Resuscitation Module is illustrated in Figure 3.4. In addition, a patient supply circuit for Manual Bagging (Figure 3.5) may also be used.

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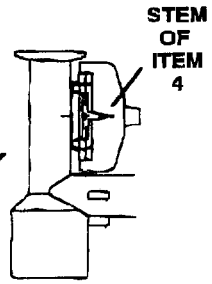
1-CORRUGATED TUBING
2-EXHALATION VALVE HOUSING
3-EXHALATION VALVE CAP
4-EXHALATION VALVE DIAPHRAGM
5-EXHAUST PORT
6-PATIENT PORT
7-"T" FITTING



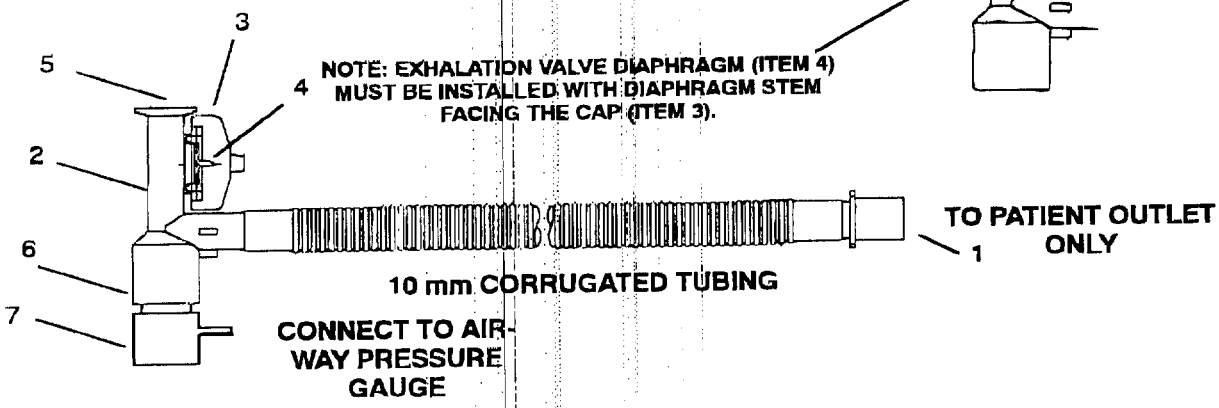


FIGURE 3.4 PATIENT BREATHING CIRCUIT FOR MANUAL VENTILATION

1-10/7.5 mm ID Adapter 2-10 mm Corrugated Tubing
3-15 mm/10 mm Adapter

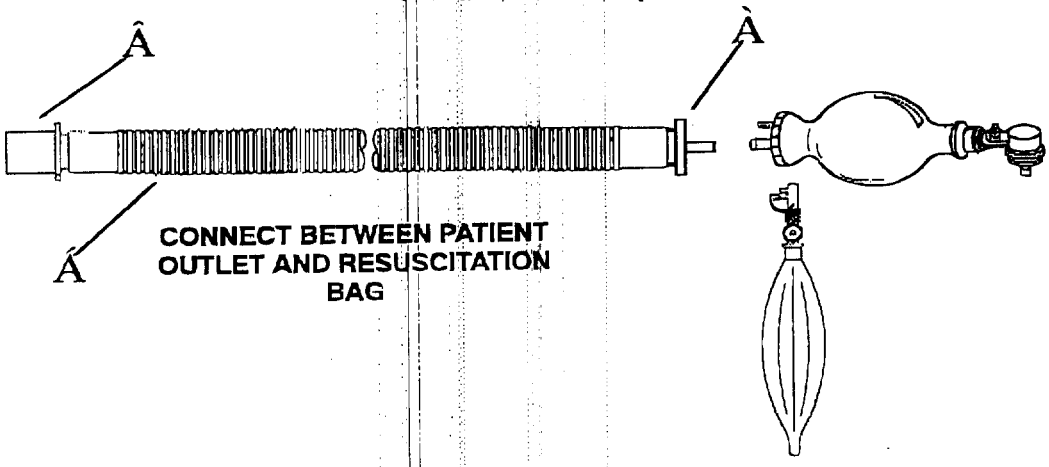


FIGURE 3.5 PATIENT BREATHING CIRCUIT FOR MANUAL BAGGING

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3.2.6 GAS SUPPLY MODULE

The **Gas Supply** Module includes an On/Off Switch which controls the pipeline and cylinder gas supply to the Resuscitation Module. An oxygen cylinder Pressure Gauge is provided if the oxygen cylinder option is included. Oxygen and Air Pressure Gauges are provided on units equipped with the Blender Module.

FIGURE 3.6 GAS SUPPLY MODULE

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3.2.7 ALARMS

HIGH TEMPERATURE. When the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C, the heater is automatically turned off, the **High Temp** Indicator will flash and the audible alarm will sound continuously. Press the **Silence/Reset** Key to silence the alarm for two minutes. After the alarm condition is corrected (a skin temperature of 38.5 °C or less), the alarm will automatically reset.

CHECK PATIENT. When in the **Manual** Mode the **Chk Patient** Indicator will illuminate and the alarm will sound one time after 10 minutes of operation. Thereafter, the **Chk Patient** Indicator will remain illuminated and the audible alarm will sound every 30 seconds for 5 minutes. If the alarm has not been acknowledged at the end of 5 minutes, the heater will shut down and a continuous ramping audible alarm will sound. The **Silence/Reset** Key then must be pressed to reactivate the heater.

PROBE. If the Skin Temperature Probe fails (short- or open circuited), the **Probe** Indicator will flash and a ramping audible alarm will sound. After the alarm condition is corrected (the Probe is replaced), the alarm will automatically reset.

BABY TEMPERATURE. When the temperature sensed by the Skin Temperature Probe is 1 °C above or 1°C below the selected **Set Temperature** Display setting, the **Baby Temp** Indicator will flash and a ramping audible alarm will sound. In addition, if the temperature is 0.2 °C above the selected **Set Temperature,** the heater will be turned off automatically. Press **Silence/Reset** to silence the alarm for 10 minutes.

POWER FAIL. When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. The alarm may be silenced by turning off the power switch.

IMPORTANT: *Turning off the Power switch will prevent the Controller and Heater from restarting automatically when power is returned to the unit. The settings will be retained in memory until power is restored.*

SYSTEM FAIL. If an internal malfunction is detected, the **System Fail** Indicator will flash and the audible alarm will beep. In addition, an Error Code (eR00 to eR025) will be displayed in the **Baby Temperature** Display. This alarm is not resettable and the unit should be referred to qualified service personnel. A prolonged brown-out (five minutes or more with supply voltage leas than 90% of nominal) will also cause a System Fail alarm.

3.2.8 BLENDER DIFFERENTIAL BYPASS ALARM (Optional)

The blender Module (factory installed option) will alarm and bypass whenever the pressure differential between the O_2 and air supplies exceeds 30 psi ± 2 psi. When this condition occurs, the blender will continue to supply whichever gas is the higher pressure: either 100% Air or 100% Oxygen. This is an audible alarm only. There are no visual indicators.

3.2.9 APGAR TIMER

When the **Apgar Timer** is running, the Apgar Timer Display will show elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar time intervals.

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SECTION 4
OPERATION

4.1 CONTROLS, INDICATORS AND CONNECTORS

Controls, Indicators and Connectors for the Controller are presented in Figures 4.1 and 4.2 and Tables 4.1 and 4.2. Controls, Indicators and Connectors for the Resuscitation Module are presented in Figure 4.3 and Table 4.3.

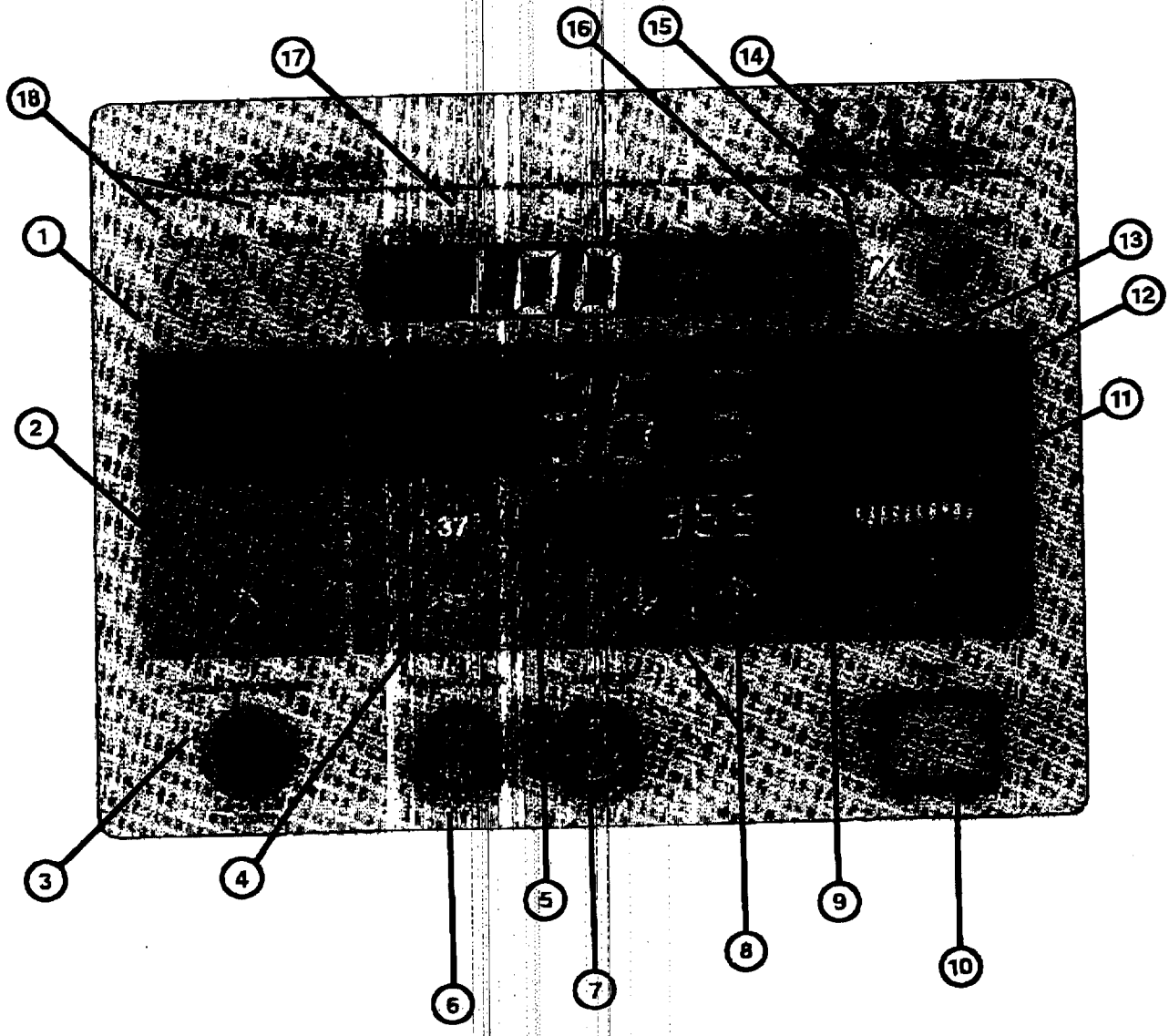

FIGURE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	**Mode**	
	Pre-Warm Indicator	Indicates that the Controller is operating in the **Pre-Warm Mode.**
	Manual Indicator	Indicates that the Controller is operating in the **Manual Mode.**
	Baby Indicator	Indicates that the Controller is operating in the **Baby Mode.**
2	**Mode** Select Key 	Press to select either **Pre-Warm, Manual** or **Baby Mode** of operation.
3	**Skin Temp Probe** Connector	Accepts Skin Temperature Probe for monitoring infant skin temperature. When connected, the **Baby Temperature** Display indicates the temperature sensed by the probe. When probe is disconnected, the **Baby Temperature** Display is blank. When disconnected in **Baby** Mode, a **Probe** Alarm also occurs.
4	**>37 °C** Key 	Press to place **Set Temperature** Display (refer to Item 9) in Temperature Override Mode, >37 °C (98.6 °F). *NOTE: This Key is inactive until the **Set Temperature** has been set to 37 °C.*
5	**>37 °C** Indicator	Lights to indicate that the Temperature Override Mode, >37 °C (98.6 °F), has been selected.
6	**Keypad Lock** Key 	Press to disable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys (refer to Items 2, 4 and 8). Press again to enable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys. Key lights to indicate that Keypad is locked.
7	**Exam Light** Key 	Press to turn on or turn off the Examination Light located in the Warmer Module.
8		**Manual Mode** Press the Up Arrow Key to raise heater power from 0% to 100% in 10% increments (refer to Item 11, **Heater Power** Display). Press the Down Arrow Key to lower relative heater power from 100% to 0% in 10% increments (refer to Item 11, **Heater Power** Display).

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
8		**Baby Mode** Press the Up Arrow Key to raise the Set Temperature from 34.0 °C (93 °F) to 37.0 °C (98.6 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to raise the Set Temperature from 37.0 °C (98.6 °F) to 38.0 °C (102.2 °F). Press one time to raise the Set Temperature in 0.1° increments. Press and hold to raise the Set Temperature rapidly. Press the Down Arrow Key to lower the Set Temperature from 37.0 °C (98.6 °F) to 34.0 °C (93 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to lower the Set Temperature from 38.0 °C (102.2 °F) to 34.0 °C (93 °F). Press one time to lower the Set Temperature in 0.1° increments. Press and hold to lower the Set Temperature rapidly. ***NOTE:*** *The Up/Down Arrow Keys may be locked by pressing the Keypad Lock Key (refer to Item 6).*
9	**Set Temperature** Display	In **Baby Mode**, displays the **Set Temperature** as selected by the Up/Down Arrow Keys (refer to Item 8) and in °C or °F as selected by the **°C/°F** Key (refer to Item 12). Display is blank in **Pre-Warm** and **Manual** Modes.
10	**Power** Key 	Press to turn on or turn off the Controller and Warmer Module.
11	**Heater Power** Display	Displays relative heater power in 10% increments from 0% to 100%.
12		Press to alternately select °C or °F for the **Baby Temperature** and **Set Temperature** Displays.
13	**Baby Temperature** Display	Digital display of infant temperature in °C or °F (refer to Item 12), whether in **Manual, Pre-Warm** or **Baby Mode**. The display is blank if the Skin Temperature Probe (refer to Item 8) is disconnected from the Controller.

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
14	**Silence/Reset** Key 	In **Manual Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Resets **Chk Patient** (refer to Item 16), restores heater power and silences Audible Alarm at any time after 10 minutes of warmer operation. Resets **Chk Patient** (refer to Item 16), silences Audible Alarm and restores heater power after15-minutes of continuous operation is complete. In **Baby Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Press to silence **Baby Temp** (refer to Item 16) Alarm for 10 minutes. During non-alarm conditions, press to enter Procedural Silence (refer to Item 15).
15	**Procedural Silence** Indicator 	When illuminated, indicates that the unit is in Procedural Silence. Procedural silence interval is 5 minutes. During Procedural Silence, the **Baby Temp** Alarms are blocked.
16	**Alarms** **Baby Temp**	The **Baby Temp** Indicator will flash with a three-level audible alarm to indicate that the baby's skin temperature is 1 °C above or below the selected Set Temperature (refer to Item 9). Press **Silence/Reset** Key to silence alarm for 10 minutes.
	High Temp	The **High Temp** Indicator will flash, the audible alarm will sound continuously, and the heater will be turned off when the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C. High Temp (39.0 °C) Alarms can only be silenced for two minutes by the Silence/Reset Key. Press the **Silence/Reset** Key to silence the audible alarm for 2 minutes. When the temperature falls to 38.5 °C, the alarm will automatically reset.
	Probe	When in **Baby Mode**, if the Skin Temperature Probe fails (open probe), the **Probe** Indicator will flash and a three-level audible alarm will sound. After the Alarm condition is corrected (the Skin Temperature Probe is replaced), the alarm will automatically reset. Also refer to Table 5.1. When in **Baby Mode**, if the Skin Temperature Probe fails (shorted probe), the **System Fail** Indicator will light and an audible alarm will sound. This Alarm cannot be Silenced. The **Power MUST BE TURNED OFF then ON** to Reset the Alarm condition.

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
16	**Alarms (Cont.)**	
	Chk Patient	When in the **Manual** Mode, if the warmer is in operation for longer than 10 minutes, the **Chk Patient** Indicator will illuminate and the audible alarm will sound one time. Thereafter, the **Chk Patient** Indicator will remain on and the audible alarm will sound every 30 seconds for the next 5 minutes. If at the end of 5 minutes (15 minutes total) the alarm has not been acknowledged by pressing the **Silence/Reset** Key (refer to Item 14), the warmer will be shut down.
	System Fail	When an internal malfunction is detected, the **System Fail** Indicator will illuminate and the audible alarm will sound continuously. In addition, an Error Code (Er00 to Er025) will be displayed in the **Baby Temperature** Display. When a malfunction is detected, the Controller will automatically perform the self-test function (refer to para. 4.2 Step 3) to determine if the fault has corrected itself. If the fault has not corrected itself, the error code will be displayed until corrected. This alarm is not resettable and the unit should be referred to qualified service personnel. ***NOTE:*** *Error code 023 may be corrected by the Operator, refer to Table 5.1.*
	Power Fail	When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. Push the **Power** Key to silence the Alarm.
17	**Apgar Timer**	When the **Apgar Timer** (refer to Item 18) is running, the Apgar Timer displays elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar Time intervals.
18	**Stop/Start** 	Press to start or stop the **Apgar Timer.**
	Reset 	When timer is running, press to reset the timer to zero and restart the Apgar count. When timer is stopped, press to turn timer off. ***NOTE:*** *The Timer can be reset any time.*

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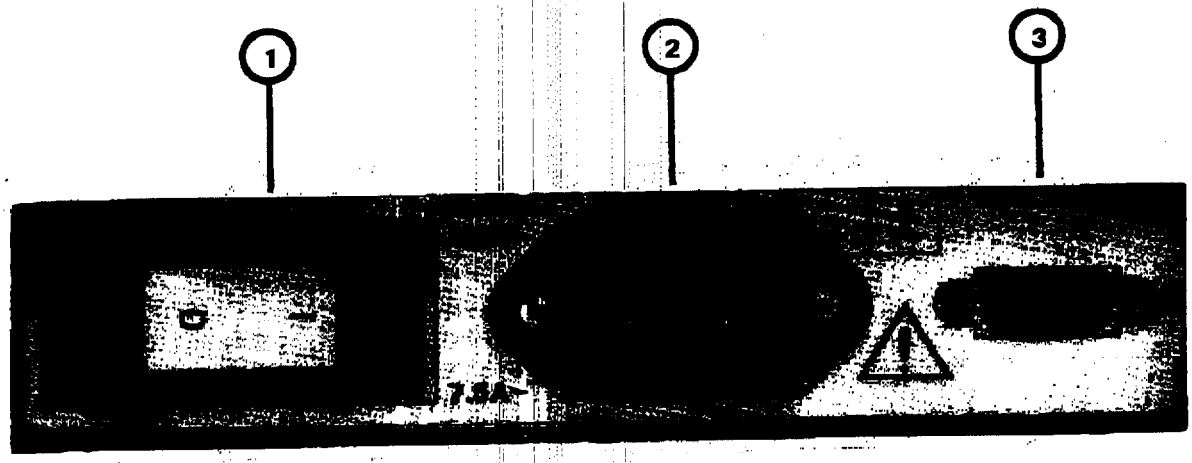

FIGURE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

TABLE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	CIRCUIT BREAKER	Turns Controller on and off when switched by operator or the presence of excessive current drain is detected.
2	POWER	Accepts ac power cord. Accepts 40-inch power cord on VHA units
3	AUX PORT	Data port for connection to printer or host system.

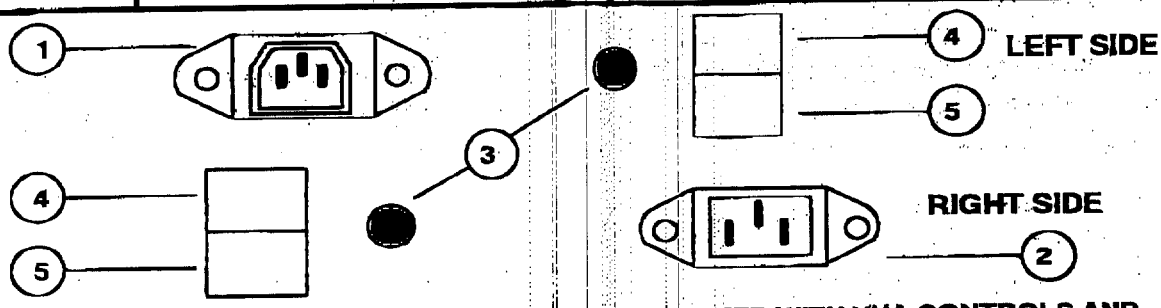

FIGURE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS LOCATED ON BOTH SIDES OF LOWER POST

TABLE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	POWER OUT	Accepts 40-inch ac power cord.
2	POWER IN	Accepts ac power cord.
3	CIRCUIT BREAKER	Turns Actuator off when presence of excessive current drain is detected. Press to reset.
4	UP SWITCH	Press to raise Upper Post
5	DOWN SWITCH	Press to lower Upper Post

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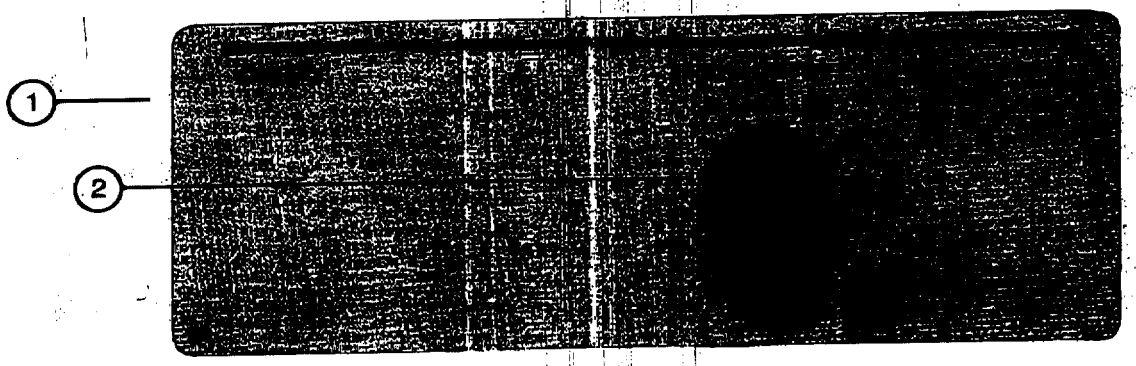

FIGURE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

TABLE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

ITEM	NAME	DESCRIPTION
1	Blended Gas Supply Module (Optional)	
2	Blender % Oxygen Control	Blends air and oxygen mixture from 21 to 100% O_2.

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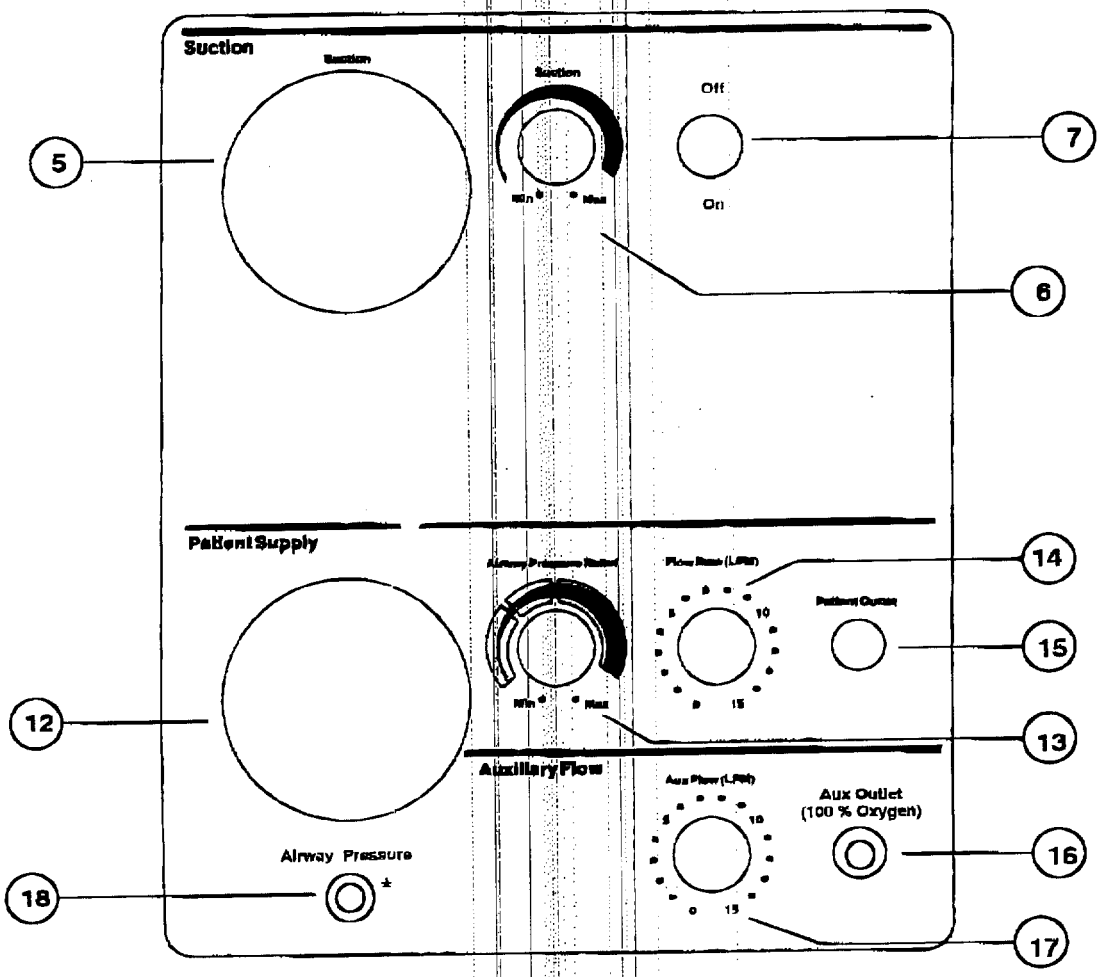

FIGURE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

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TABLE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Suction	
5	**Suction** Gauge	Displays suction level from 0 to 200 mmHg of vacuum.
6	**Suction Min Max** Control	Adjusts suction level from 0 to 150 mmHg of vacuum.
7	**On/Off** Switch	Turns **Suction** on and off.
	Patient Supply	
12	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.
13	**Airway Pressure Relief Min Max** Control	Adjusts airway pressure relief setting from 0 to 50 cm H_2O.
14	**Flow Rate (LPM)** Control	Adjusts patient gas flow from 0 to 15 LPM. Delivers blended gas if blender option is incorporated.
15	**Patient Outlet** Connector	**Accepts breathing circuit.**
	Auxiliary Flow	
16	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
17	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
18	**Airway Pressure Port**	Connects Airway Pressure Gauge to Patient Circuit.

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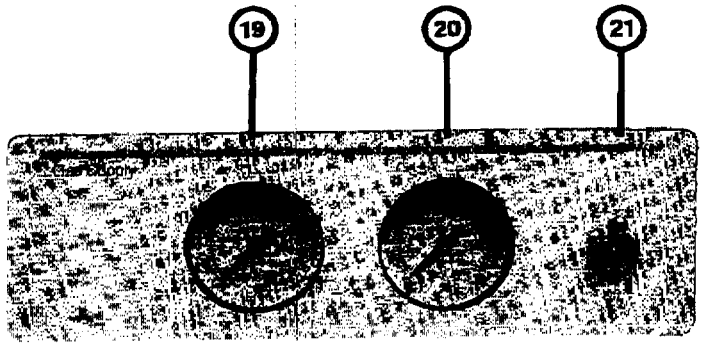

FIGURE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

TABLE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

ITEM	NAME	DESCRIPTION
	Supply Pressure (Optional)	
19	**Air Cylinder** Gauge	**Provides indication of air cylinder supply pressure 0 to 4000 psi (275.8 bar).**
20	**Oxygen Cylinder** Gauge	**Provides indication of oxygen cylinder supply pressure 0 to 4000 psi (275.8 bar).**
21	**Gas Supply On/Off** Switch	Turns gas supply to pneumatic system on and off.

RESUSCITAIRE® Radiant Warmer

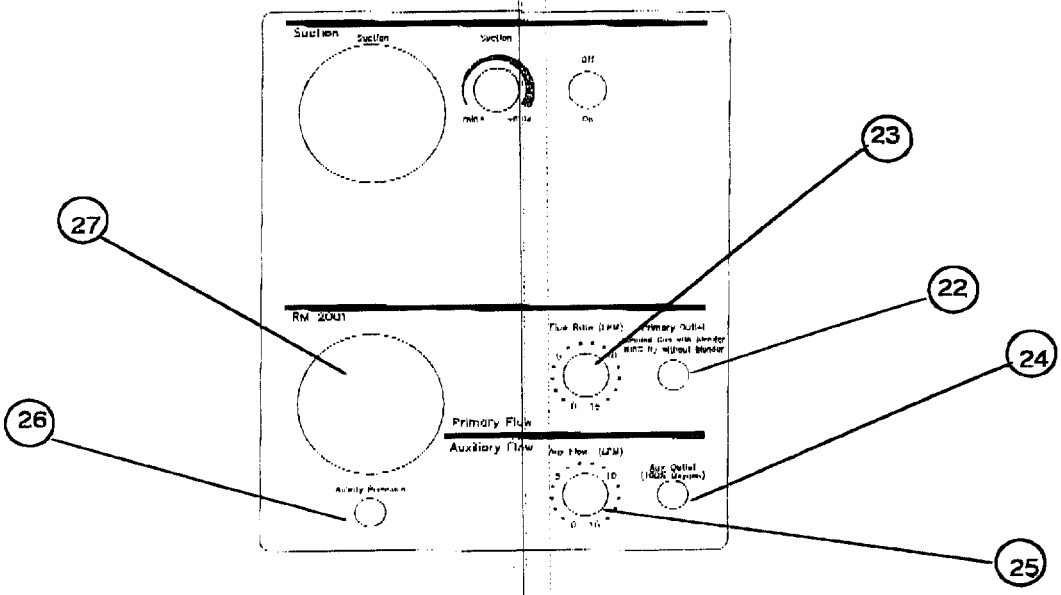

FIGURE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3D RESUSCITATION MODULE 2001 CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Primary Flow	
22	**Primary Outlet**	Accepts primary gas delivery line. Delivers blended gas if blender option is installed: 100% oxygen if no blender installed.
23	**Flow Rate (LPM)** Control	Adjusts primary gas flow from 0 to 15 LPM
	Auxiliary Flow	
24	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
25	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
26	**Airway Pressure Port**	Connect Airway Pressure Gauge to Patient Circuit.
27	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.

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Down Arrow Keys Key should be inoperative. Press the Keypad Lock Switch. The **Keypad Lock** Switch Light should go off and the Keypad should be enabled.

7. **CHECK THE BABY MODE.** Select **Baby Mode** by pressing the Mode Select Key. The **Baby** Indicator should light and the **Set Temperature** Display should activate. In addition, the **Baby Temp** Indicator should flash and the audible alarm should sound (if the temperature and set point are more than 1° C apart) Press the **Silence/Reset** Key, the audible alarm should go off, the **Baby Temp** Indicator should become steady on.

8. **CHECK TEMPERATURE OVERRIDE MODE.** Press the Up Arrow Key to raise the **Set Temperature** to 37.0 °C. Press the **>37 °C** Key, the **>37 °C** Indicator should come on. Press the Up Arrow Key to raise the **Set Temperature** to 38.0 °C.

   Press the Down Arrow Key to lower the **Set Temperature** to below 37.0 °C. When the **Set Temperature** falls below 37.0 °C, the **>37 °C** Indicator should go off.

9. **CHECK THE PROBE ALARM.** Disconnect the skin temperature probe from the **Skin Temp Probe** Connector. The **Baby Temperature** Display should go off, the **Probe** Indicator should flash and the audible alarm should sound. Replace the probe.

10. **CHECK THE APGAR TIMER.** Press the **Start /Stop** Key, the **Apgar Timer** Display should come on and begin to count up from zero seconds. Press the **Start/Stop** Key, the **Apgar Timer** count should stop. Press the **Reset** Key, the **Apgar Timer** Display should go off.

11. **CHECK THE EXAMINATION LIGHT.** Press the **Exam Light** Switch. The Examination Light should come on. Press the Exam Light Switch, the Examination Light should go off.

4.3 MECHANICAL CHECKOUT

1. **CHECK THE MATTRESS TILT CONTROL** (Figure 4.4) by pulling up on the lever located at the bottom rear of the Bassinet while supporting the rear lower edge of the Bassinet with the palm. Place the Bassinet in the 5-degree and then the 10-degree tilt position. Return the Bassinet to the level position.

FIGURE 4.4 BASSINET TILT CONTROL

2. **CHECK THE BASSINET SIDE PANELS** (Figure 4.5) by raising each panel and pivoting it to hang straight down. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

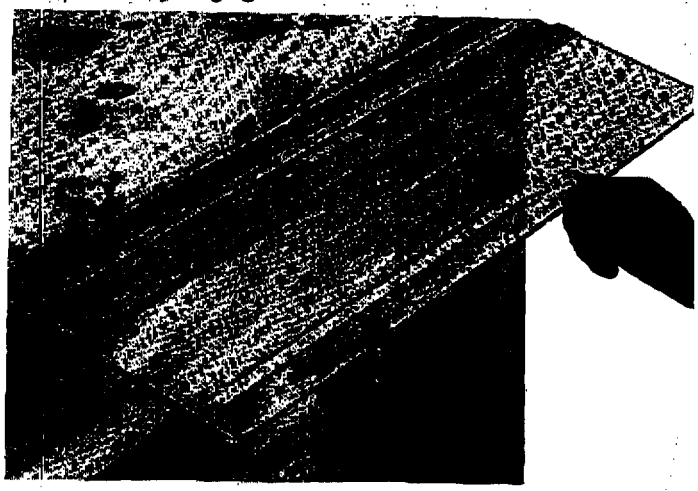

FIGURE 4.5 CHECKING THE BASSINET SIDE PANELS

3. **CHECK THE BASSINET FRONT PANEL** (Figures 4.6 and 4.7) by raising the panel and and sliding it under the mattress. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

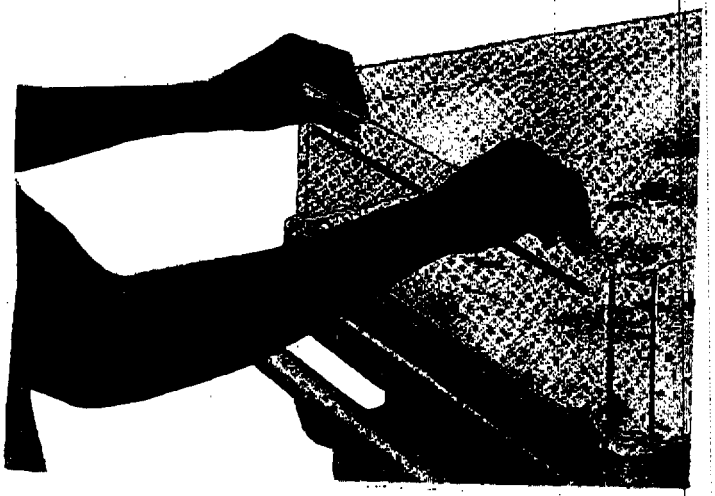

FIGURE 4.6 CHECKING THE BASSINET FRONT PANEL

FIGURE 4.7 CHECKING THE BASSINET FRONT PANEL

4. **CHECK THE PASS-THROUGH DRAWER** (Figure 4.8) by sliding the drawer in and out on both sides of the Bassinet. Return to center position.

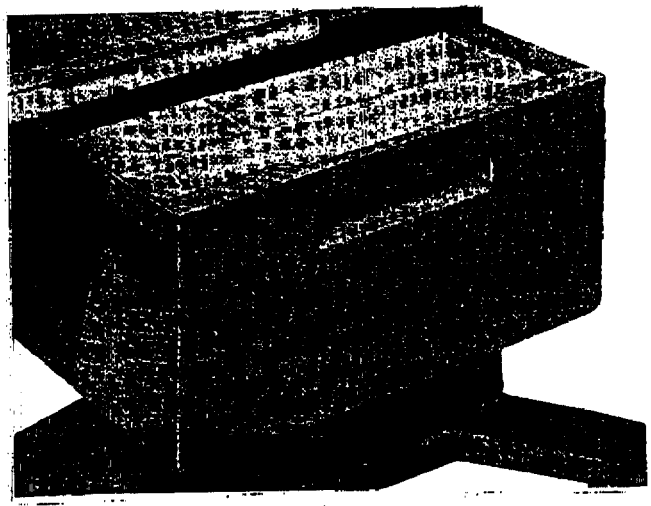

FIGURE 4.8 CHECKING THE PASS-THROUGH DRAWER

5. **CHECK THE WARMER MODULE SWIVEL OPERATION** (Figure 4.9) by rotating the Warmer Module 90 degrees to the left or right of center. Return to center position.

WARNING: When the Warmer Module is swiveled and energized, objects (Monitors etc.) located on the optional Monitor Shelf may overheat or become hot to the touch.

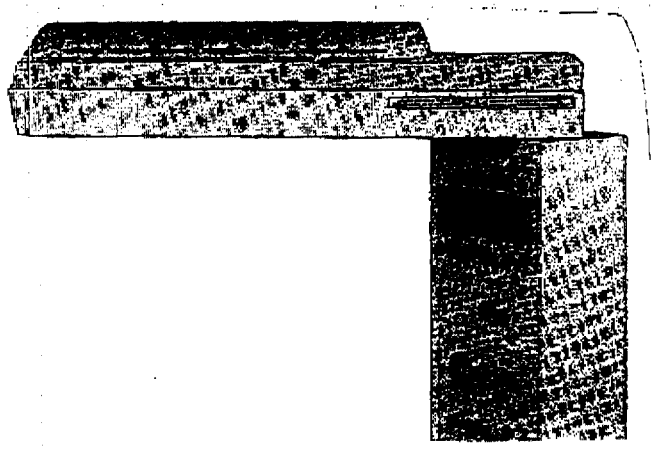

FIGURE 4.9 CHECKING THE WARMER MODULE SWIVEL

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6. **CHECK THE OPERATION OF THE X-RAY CASSETTE TRAY (ACCESSORY)** (Figure 4.10) by pulling up the middle of a Side Panel and pulling the X-ray Cassette Tray out from under the Bassinet. Replace the X-ray Cassette Tray by reversing the procedure.

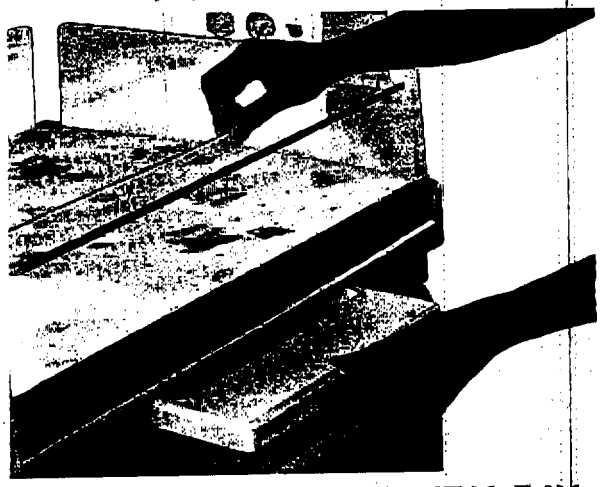

FIGURE 4.10 CHECKING THE X-RAY TRAY

7. **CHECK THE INSTRUMENT TRAY (ACCESSORY)** (Figure 4.11) by swinging it out from under the Bassinet.

FIGURE 4.11 CHECKING THE INSTRUMENT TRAY

8. **CHECK THE VHA** by pressing the upper portion of the Switch on the right side of the Lower Post until the Upper Post raises to its maximum height. Press and hold the lower portion of the Switch until the Upper Post lowers to its minimum height. Repeat the procedure using the Switch on the left side of the Lower Post. Verify the Upper Post operates smoothly and re-adjust to desired height.

CAUTION: Always lower the Resuscitaire® Radiant Warmer VHA to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.

9. **CHECK BASSINET TILT CONTROL Operation as follows (VHA) only)*:**

a. Turn the Bassinet Tilt Control clockwise (Figure 4.11A) until the Bassinet Foot End is fully raised and comes to a stop.

b. Turn the Bassinet Tilt Control counterclockwise until the Bassinet Head End is fully raised and comes to a stop.

c. Return the Bassinet to the horizontal position.

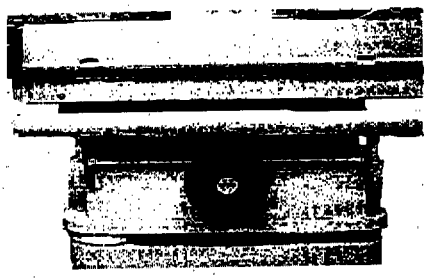

FIGURE 4.11A CHECKING THE BASSINET TILT CONTROL (VHA ONLY)

4.4 RESUSCITATION EQUIPMENT PRE-USE CHECKOUT/SET-UP

SUPPLY PRESSURE

1. Ensure that O_2 (and AIR) pipeline(s) are securely attached to appropriate fittings on the rear of the unit and that the gas supply present is 40 to 75 psi.

If using Reserve Gas Supply from cylinders:

2. Ensure that cylinder(s) are properly secured in the mounting yokes on the rear of the warmer and that the cylinder valve located on the top of the cylinder is open.

3. Examine the appropriate cylinder pressure gauges on the front of the upper column to ensure that sufficient reserve gas supply is present.

*Not available in USA or Canada.

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4. Set the **Gas Supply On/Off** Switch to the **On** position.

BLENDED GAS SUPPLY (Optional)

LOW FLOW MICROBLENDER WARNINGS

- **If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FIO_2 and flow output from the microblender.**
- **Always operate the low flow microblender with clean/dry medical grade gases.**
- **Air inlet water filters are recommended for use with the low flow microblender.**
- **The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.**

1. If present, set the precision blender to the desired oxygen % concentration using the Blender Control Knob.

RESUSCITATION MODULE (Optional)

SUCTION

NOTE: *To obtain suction, the **Gas Supply On/Off** Switch (Figure 4.3C) must be **ON**.*

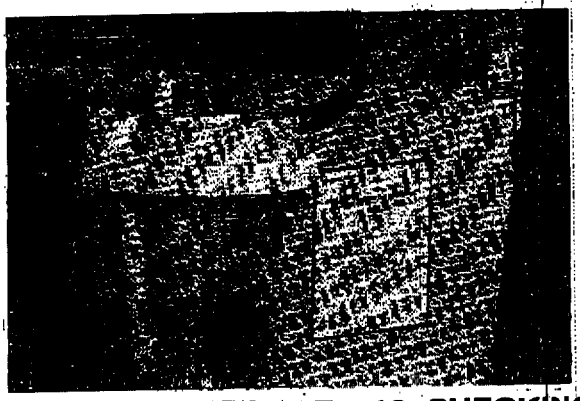

FIGURE 4.12 CHECKING THE SUCTION BOTTLE

NOTE: *The filter and tubing resistance will not affect the desired maximum value that is set in Step 5 below. The pressure value on the Suction Gauge matches the actual pressure value at the end of the catheter.*

5. Block the patient outlet of the suction bottle. Adjust the suction magnitude using the **Suction Min Max** Control while viewing the suction level on the **Suction** Gauge. Adjust the suction magnitude to the desired maximum suction pressure value.
6. Turn off the **Suction On/Off** Switch.

1. Check that a clean suction bottle (reusable or disposable, Figure 4.12) is installed and properly connected in the Resuscitation Equipment Storage Compartment at the front of the warmer.

CAUTION: When installing the disposable Suction Bottle: to prevent the suction tube from being blocked or damaged, position the Outlet Port parallel to the plate (Figure 4.12).

2. Ensure that a bacterial filter is connected in-line with the supply connection to the reusable suction bottle (a filter is built-in on the disposable bottle).

3. Connect the desired extension tubing to the outlet of the suction bottle outlet port (refer to Figure 3.1) and secure the free end of the extension tubing in either tubing retaining slot provided on the front panel of the Bassinet.

4. Turn on the **Suction On/Off** Switch. There may be an initial reading of up to 30 mmHg on the Suction Gauge (refer to Figure 3.1) due to flow resistance of the hydrophobic filter and suction tubing.

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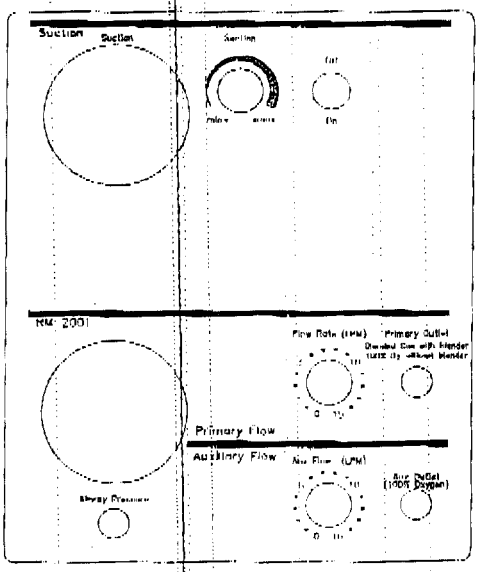

FIGURE 4.13 RESUSCITATION MODULE 2001

RESUSCITATION MODULE 2001 (Optional)

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

PRIMARY FLOW (provides blended gas if optional blender is installed; 100% oxygen if no blender is installed)

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the desired device to be supplied by the **Primary Flow** circuit to the **Primary Outlet** connector.
2. Adjust desired primary flow using the Primary **Flow Rate (LPM)** control and check flow.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

AIRWAY PRESSURE

Airway Pressure fitting may be used to measure airway pressure during mechanical resuscitation.

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RESUSCITAIRE® Radiant Warmer

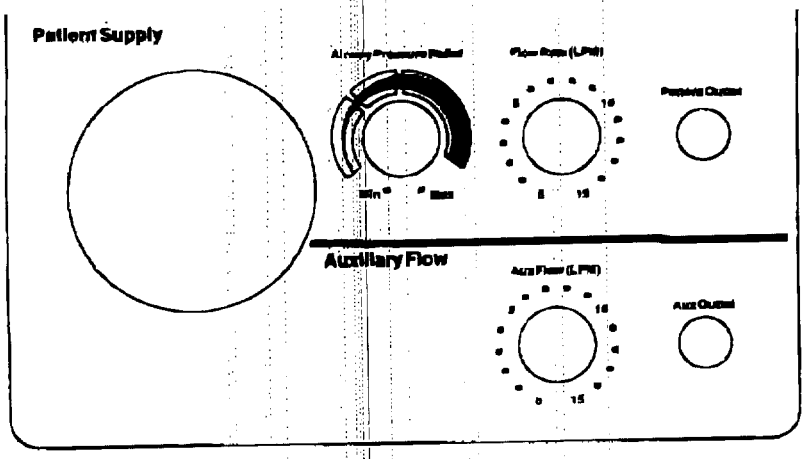

FIGURE 4.14 RESUSCITATION MODULE (PATIENT SUPPLY)

RESUSCITATION MODULE (Optional) Patient Supply

Manual Resuscitation - Use with Patient Breathing Circuit - 10 mm tubing with thumb (finger) hole at patient end.

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the Patient Circuit to the **Patient Outlet** (refer to Figure 4.4).
2. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
3. Set the **Airway Pressure Relief** control to the desired pressure limit according to the color coded bands on the **Airway Pressure** Gauge and **Airway Pressure Relief** Control. Alternately, a "T" Fitting with an airway pressure monitor can be inserted into the **Patient Outlet** Port and connected to the **Airway Pressure** Port to indicate the breathing circuit pressure. Adjust the **Airway Pressure Relief** Control as necessary.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

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4.5 CONTROLLER OPERATION

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital-use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

Connect the unit to the ac line. Turn on the **CIRCUIT BREAKER** on the Rear Panel and the **Power** Switch on the Front Panel. Observe the Functional Test.

4.5.1 PRE-WARM MODE

After the Functional Test is complete, the **Pre-Warm Mode** will activate. The **Heater Power** Indicator will be at 100% (all lights on) for three minutes, reduce to 60% (six lights on) for 12 minutes and then be reduced to 30% (three lights on).

NOTE: *Selection of **Manual** or **Baby** and then returning to **Pre-Warm** during the three minutes of 100% or 12 minutes of 60% power will automatically reduce the power to 30%.*

During **Pre-Warm** Mode, the **Chk Patient** Alarm is disabled.

4.5.2 MANUAL MODE

WARNING:

To avoid overheating or underheating, observe the infant constantly and monitor the temperature using the skin temperature probe supplied with the equipment or other electronic thermometer.

Inspect infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Use the Mode key to select **Manual Mode**.
2. Use only for short-term warming with nursing personnel in constant attendance.
3. Do not use warmer in **Manual Mode** if **Manual** Indicator is not on.
4. Set the **Heater Power** Indicator to the desired level. The heater power will be maintained for 10 minutes.
5. After 10 minutes, the **Chk Patient** Alarm will sound one time. Press the **Silence/Reset** Key to initiate another 10-minute warming period.
6. If the **Chk Patient** Alarm is not acknowledged, the heater will be automatically disabled after an additional 5 minutes of operation.
7. Heater power output must be adjusted manually to maintain Baby Temperature within the desired range.
8. Check infant's temperature and condition at least every 15 minutes. When initially setting or when changing heater power output, check Baby Temperature more frequently to be sure it is maintained within the desired range.

CAUTION: A change in heater power output will not result in an immediate change in Baby Temperature. Wait for results. Large changes in heater power output will cause a more rapid change in Baby Temperature.

9. Use Skin Temperature Probe to continuously monitor Baby Temperature whenever possible. Refer to paragraph 4.5.3 to attach the probe to the patient.

IMPORTANT: *In **Manual Mode**, the Skin Temperature Probe monitors only -- it does not control.*

NOTE: *It is not necessary that the Skin Temperature Probe be connected to the Controller for **Manual Mode**.*

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4.5.3 BABY MODE

WARNING:

To avoid hazards of overheating or underheating, the infant should not be left unattended. Use only with the Hill-Rom Air-Shields' Skin Temperature Probe supplied with the unit. Inspect the infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Plug Skin Temperature Probe into Controller **Skin Temp Probe** Connector.
2. Use the Mode key to select **Baby Mode.**
3. Attach the Skin Temperature Probe to the infant. The probe should be located on the infant's abdomen, halfway between the xyphoid and the umbilicus (Figure 4.13). The metal side of the probe should be placed in direct contact with the skin (when using the reusable probe).

FIGURE 4.13A ATTACHING SKIN PROBE

FIGURE 4.13B ATTACHING SKIN PROBE

WARNING:

The location of the Skin Temperature Probe must be such that the skin around the Sensor is in direct line with the heat from the Warmer Module. If the location is shadowed, for example, by the infant's body, overheating and possible burning of the infant's skin can result. Do not use a rectal probe. Use of a rectal probe can result in overheating or underheating of the infant.

The Skin Temperature Probe must be in intimate contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain intimate skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment and feel infant's skin for signs of overheating.

The Skin Temperature Probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The Skin Temperature Probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.

4. When the infant is prone, the Skin Temperature Probe should be located on the infant's back.

5. The skin area around the probe should be thoroughly cleansed and dried before the probe is placed on the skin.

6. To obtain an accurate reading of the infant's skin temperature, place the probe in position and cover with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or tape the probe into position, cover it with a small piece of cotton just large enough to cover the tip of the probe, and then place a second piece of tape over the cotton. If it is desired to reduce tape contact on the infant's skin, the cotton can be applied directly to the probe tip without the first piece of tape. To stabilize the attached probe, a third piece of tape may be placed over the probe wire approximately three to four centimeters from the probe tip. To minimize the effect of direct radiation on the Skin Temperature Probe, in order to obtain a more accurate **Baby Temperature** measurement, cover the Sensor with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or an equivalent insulating cover with a reflective surface facing the Warmer Module.

7. Baby Mode should be used for long-term warming and when attending personnel cannot be in constant attendance.

8. Set the **Set Temperature** Display to the prescribed temperature. A higher Set Temperature setting does not increase rapid warming.

9. Verify that **Baby Temperature** Display reading stabilizes within 0.2 °C of **Set Temperature** Display. Fluctuations in the **Heater Power** Indicators or the **Baby Temperature** Display reading can result from air currents, obstruction of radiation to the infant or the Skin Temperature Probe not being in intimate contact with the skin.

10. **Baby Temp** Alarms can be silenced for 10 minutes by pressing the **Silence/Reset** Key.

11. **Probe, High Temp** and **Baby Temp** (39.0 °C) Alarms are automatically reset after the alarm condition is corrected. The **High Temp** Alarm may be silenced for 2 minutes by pressing the **Silence/Reset** Key.

NOTE: *In the event of a **Probe** Alarm, **Manual Mode** can be used temporarily until a replacement Skin Temperature Probe is available and only if nursing personnel are in constant attendance.*

4.5.4 EXAMINATION LIGHT

The light is turned on and off by the **Exam Light** Switch. Turn the light on only as required for optimum bulb life.

4.6 X-RAY PROCEDURES

1. Swing the Warmer Module (Figure 4.9) to the right or left of center as required to position the X-ray machine.

2. Lift the Left or Right Bassinet Side Panel up, slide the X-ray Tray out (Figure 4.10); place the X-ray Cassette on the tray and return the tray to the Bassinet. Align the cassette as desired with the markings on the X-ray Cassette Tray and relative markings on the inside of the Bassinet panels.

3. When the X-ray is complete, remove the X-ray Cassette Tray and return the X-ray Tray. Place the Warmer Module in its normal operating position.

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SECTION 5
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 Hill-Rom service personnel.

WARNING:

If oxygen is in use, make sure that the oxygen supply to the equipment is turned off and that it 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 cleaning and maintenance procedures; make sure that the Power Cord is disconnected from the wall receptacle.

5.2 CLEANING

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and 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

1. Remove both Bassinet Side Panels (Figure 5.1) by pulling them straight up.

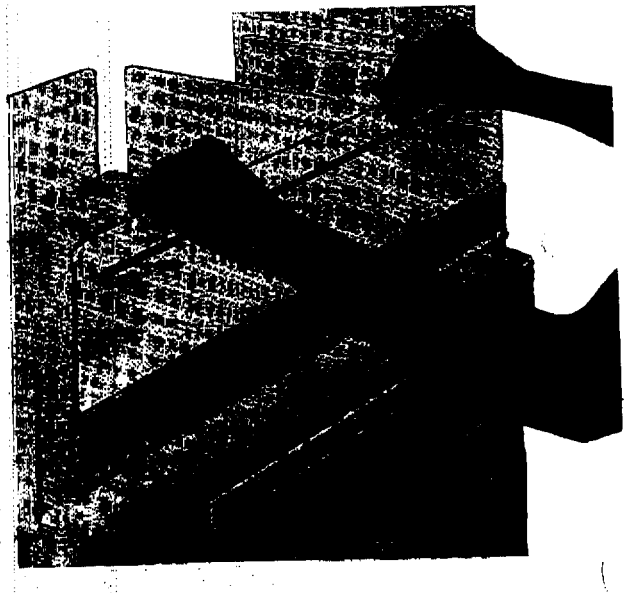

FIGURE 5.1 REMOVING BASSINET SIDE PANELS

2. Remove the Bassinet Back Panel (Figure 5.2) by raising it straight up until the bottom pins are adjacent to the slots in the corner brackets.

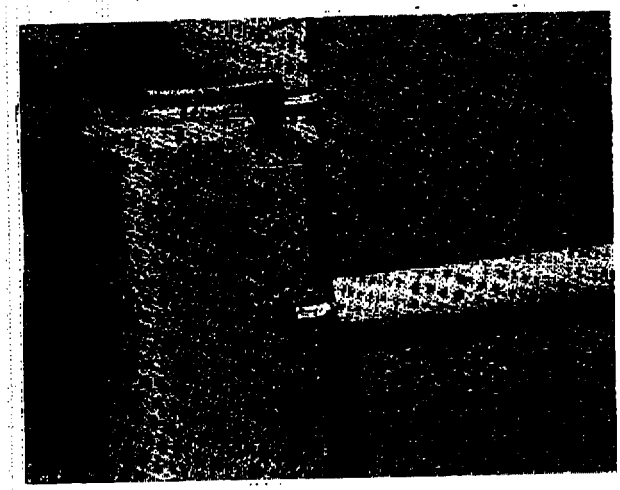

FIGURE 5.2 REMOVING BASSINET BACK PANEL

3. Remove the Bassinet Front Panel (Figure 5.3) by raising it and then swiveling it down. At the corners, press up on the release buttons and pull the panel straight out (Figure 5.4).

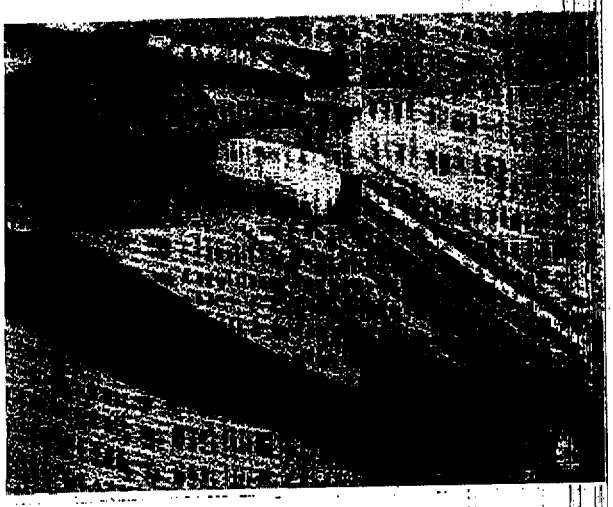

FIGURE 5.3 BASSINET FRONT PANEL RELEASE BUTTONS

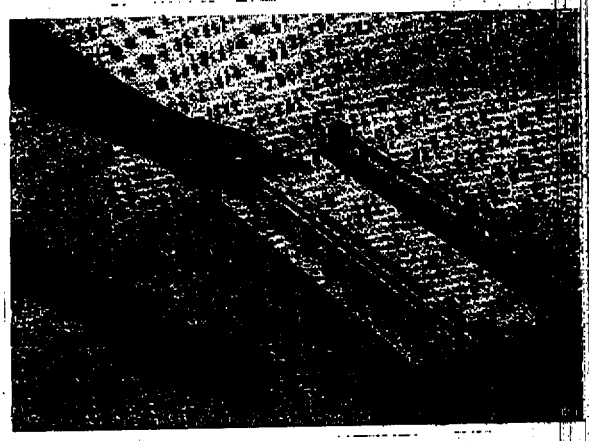

FIGURE 5.4 REMOVING BASSINET FRONT PANEL

4. Remove the Mattress from the Bassinet.
5. Remove the X-ray Tray (Figure 4.10).
6. Remove the Suction Bottle and Filter (Figure 4.12) from the front of the Bassinet.

5.4 CLEANING PROCEDURES

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and disinfected.

5.4.1 CLEANING AGENTS

An intermediate-level detergent/disinfectant registered by the U.S. Environmental Protection Agency should be used, but only when the equipment is not in use and disassembled as described elsewhere in this section. 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 PAINTED SURFACES

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

5.4.3 CLEAR PLASTIC AND ACRYLIC SURFACES

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

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.

Use a detergent/disinfectant to clean all surfaces thoroughly. Make sure to clean all holes, indentations, baffles, etc.; then dry with a clean cloth or paper towel.

5.4.4 METAL SURFACES

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

IMPORTANT: *After cleaning, a complete operational checkout should be performed before returning the unit to service.*

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5.4.5 SKIN TEMPERATURE PROBE, REUSABLE

CAUTION: Do not pull on the tip of the skin temperature probe when cleaning or drying; damage to the probe may result.

Use a detergent/ to thoroughly clean all surfaces; then dry with a clean soft cloth or paper towel.

5.5 STERILIZATION (IF DESIRED)

CAUTION: DO NOT STEAM AUTOCLAVE.

Sterilization can be accomplished by the following methods:

A. COLD (LIQUID) STERILIZATION

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

B. GAS STERILIZATION (ETHYLENE OXIDE).

Prior to gas sterilization, the entire unit should be thoroughly cleaned as described elsewhere in this section. Remove and discard all used disposable elements. New disposable elements should be installed after sterilization.

Standard gas sterilization procedures are satisfactory as these do not normally exceed 54.4 °C (130 °F).

IMPORTANT: *After sterilization, a complete functional checkout procedure should be performed before returning the unit to service.*

5.6 REASSEMBLY AFTER CLEANING

1. Replace the Mattress on the Bassinet.
2. Replace the X-ray Tray (Figure 4.10).
3. Replace the Bassinet Back Panel by inserting the pins in the Corner Brackets (Figure 5.2).
4. Replace the Bassinet Side Panels by pushing them straight down into their slots (Figure 5.1).
5. Replace the Bassinet Front Panel by sliding it into the front of the Bassinet (Figure 5.4) until the release tabs catch. Raise the Panel into position.
6. Install a new Suction Filter if using a Reusable Bottle (Figures 3.1 and 4.12). Replace the Suction Bottle if using a Disposable Bottle.

5.7 CALIBRATION

The equipment should be completely checked and calibrated at least once a year by qualified service personnel. Refer to the appropriate Service Manual for details.

5.8 TROUBLESHOOTING

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

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TABLE 5.1 TROUBLESHOOTING

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
No Power and **Power Fail** Alarm is not activated	a. Circuit Breaker not set to On.	a. Set Circuit Breaker to On.
Power Fail Alarm activated	a. Circuit Breaker tripped. b. Power Cord unplugged. c. Defective Power Cord.	a. Reset Circuit Breaker (Figure 4.2). b. Connect Power Cord to POWER connector (Figure 4.2) or wall socket. c. Replace Power Cord.
System Fail Alarm activated	a. Internal malfunction.	a. Refer to service.
Probe Alarm Activated	Possible Defective Skin Probe(s)	a. Check to ensure Skin Probe is in good contact with the skin. b. Replace Skin Probe(s). If condition is not corrected, refer to service.
Error Code Er02 through Er022 Er024 and Er025	a. Internal malfunction	a. Refer to service.
Error Code Er023	Ambient Temperature in excess of 32 °C (90 °F).	Verify ambient temperature with an external thermometer.

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SECTION 6
PARTS LIST

6.1 GENERAL

This section provides a listing of Operator replacement parts. Parts other than those listed here should be replaced by qualified service personnel. For an illustration of accessories, refer to Figure 1.1 of this manual.

REPLACEMENT PARTS	PART NUMBER
Bassinet Side Panel (Eng)	81 900 00
Bassinet Rear Panel (Eng)	81 900 01
Bassinet Front Panel (Eng)	81 900 02
Power Cord 220/240V Units	17 AZ 204
Skin Temperature Probe (Reusable)	81 300 05
Reusable Suction Bottle Kit (750 ml) (Bottle, Stopper, Tubing and Filter)	81 001 50
Reusable Suction Bottle Only	08 131 00
Filters (Box of 25)	81 001 50
40-Inch Power Cord	17 AZ 211

DISPOSABLES	
Premi-Probe® 3 Skin Temperature Probe (Box of 10)	81 300 08
Premi-Probe® 3 Skin Temperature Probe (10 Boxes of 10)	81 300 09
Breathing Circuit Connector with Pressure Monitor Port (Box of 25)	81 001 29
Critter Covers® Probe Covers (Box of 100)	68 209 46
Critter Covers® Probe Covers (Box of 600)	68 209 45
Care-for-Me Probe Covers, 100 Large (10% discount when you order 5)	68 209 47
Care-for-Me Probe Covers, 100 Standard (10% discount when you order 5)	68 209 48
Neat Clips - 3/8" Diameter (Box of 100)	68 120 53
1.00" Diameter (50/Case)	68 120 54
Disposable Suction Bottle, 800 ml (Box of 100)	81 001 51

OPTIONS	
Instrument Tray - Right Hand	81 101 70R
Instrument Tray - Left Hand	81 101 70L
Pass-Through Drawer Organizer Tray	81 101 11
Air Hose Assembly, Green DISS	78 464 10
Oxygen Hose Assembly, Yellow DISS	78 465 10
Air Hose Assembly, Black NIST	81 501 45
Oxygen Hose Assembly, White NIST	68 507 50
Air Hose Assembly Black DISS	81 501 50
Oxygen Hose Assembly White DISS	68 507 30
Oxygen/Air Sealing Washer	81 502 02
X-ray Cassette Tray	81 100 44
IV Pole	82 001 53
Monitor Shelf	82 001 52

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NOTES

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LIMITED 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 Hill-Rom Air-Shields, Inc., 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 Hill-Rom Air-Shields, Inc. cannot be held liable for conditions resultant therefrom if:

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 Hill-Rom Air-Shields, Inc.
4. Sale or service is performed by a non-certified service/dealer agency.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE. HILL-ROM AIR-SHIELDS' OBLIGATION UNDER THESE WARRANTIES SHALL NOT INCLUDE ANY LIABILITY FOR LOSS OF PROFITS, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES OR DELAYS. Some states, provinces, or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion or limitation may not apply. Any improper or negligent use, any alterations or repairs not in accordance with Hill-Rom Air-Shields' manuals or performed by others in such manner as in Hill-Rom Air-Shields' sole judgement affects the product materially and adversely, shall void these warranties. These warranties do not cover failures due to misuse, abuse, neglect, or lack of routine maintenance. No employee or representative of Hill-Rom Air-Shields is authorized to change these warranties in any way or grant any other warranty unless in writing and signed by a Hill-Rom officer. These warranties provide specific legal rights; but, there may be other available rights; which vary from state to state, province to province, or country to country.

*The Accreditation Manual for Hospitals requires each piece of equipment to be tested prior to initial use and at least annually thereafter. To comply with this standard, we recommend that you participate in our Preventive Maintenance 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. Technical Services representatives are located throughout the United States and Canada and are dispatched for required maintenance by calling USA (800) 445-3720 and Canada (800) 267-2337. Customers outside the U.S. and Canada should contact their local factory-authorized Hill-Rom Air-Shields' distributor for service.

Hill-Rom Air-Shields
A HILLENBRAND INDUSTRY
330 Jacksonville Road, Hatboro, PA 19040

CAT NO. 82 990 15-9
E 1 2 3 4 5 6 7 8 9
A 1 2 3 4 5 6 7 8 9

Printed in USA 11/00

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name:	**K**
Submitter (Company):	

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED YES	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)							
a) trade name, classification name, establishment registration number, device class							
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA						
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer							
f) Truthful and Accurate Statement							
g) Indications for Use enclosure							
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*							
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:							
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) ***STATEMENT - INTENDED USE AND INDICATIONS FOR***			* If no - STOP not a special	

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	USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*			
c)	***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****		* If no - STOP not a special	
d)	Design Control Activities Summary			
	i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis			
	ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied			
	iii) A declaration of conformity with design controls. The declaration of conformity should include:			
	1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met			
	2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4.	**ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE**						
a)	For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type						
b)	If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.						
c)	For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:						
	i) An identification of the applicable recognized consensus standards that were met						
	ii) A specification, for each consensus standard, that all requirements were met, except for						119

inapplicable requirements or deviations noted below				
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed				
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device				
v) A specification of any deviations from each applicable standard that were applied				
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference				
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations				
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards				

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**

Reviewer: Sarah Foster

Date: ____

Concurrence by Review Branch: ____

1/20

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	YES	NO	
1. Is Product A Device			If **NO** = Stop
2. Is Device Subject To 510(k)?			If **NO** = Stop
3. Same Indication Statement?			If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 25, 2000

HILL-ROM AIR-SHIELDS
330 JACKSONVILLE RD.
HATBORO, PA 19040
ATTN: LARRY W. KRASLEY

510(k) Number: K003335
Received: 25-OCT-2000
Product: RESUSCITAIRE RADIANT WARMER; RESUSCITAIRE BIRTHING ROOM WARMER; RESUSCITAIR

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

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K 003335

Hill-Rom Air-Shields.
A HILLENBRAND INDUSTRY

October 24, 2000

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference: **SPECIAL 510(k)**: K940951 RW Resuscitaire Infant Radiant Warmer

Dear Madam/Sir:

Hill-Rom Air-Shields hereby submits this **SPECIAL 510(k)**, Device Modification, to notify the Agency of a modification for our Resuscitaire® Radiant Warmer.

This modification will encompass the offering of an optional resuscitation module. This optional module will use the existing resuscitation module with the following changes:

- Changing the 15mm outlet to a tapered, barbed fitting that is consistent with currently accepted caregiver practice in the United States and Canada.
- Replacement of the user adjustable airway relief valve with an internal fixed relief valve.
- Appropriate modifications to module overlay and user manual.

These changes are being made to accommodate user requests. We believe these modifications are eligible for the Special 510(k) process since they have the same fundamental scientific technology and intended use as the predicate device.

Hill-Rom Air-Shields considers the information contained in this submission to be confidential commercial and or trade secret information and requests that FDA not disclose such information except as required or allowed by applicable statutes and regulations. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q)

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at 215-682-8681 or 812-934-1671.

Sincerely,

Larry W. Krasley

Larry W. Krasley
Regulatory Affairs Specialist
Hill-Rom Air-Shields

HO II

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SK

330 JACKSONVILLE ROAD, HATBORO, PA 19040 215-675-5200 Fax: 215-675-1859

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Hill-Rom Air-Shields TI500 Globetrotter Transport System "Special" 510(k)

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	13	Addendum Cat3 67 990 65 -5A1
	14-73	Operators Manual 67 990 65
4	*74*	Device Descriptions and Comparison
5	*75*	Substantial Equivalence
6	*76*	Summary of Design Control Activities
		▪ Hill-Rom Air-Shields Verification Testing
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	80-83	✓ Self Inflating Bag
7	*84*	Declaration of Conformity with Design Controls
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9	*87*	Truthful and Accuracy Certification
10	*88*	Indications for Use Statement

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: **October 24, 2000**	FDA Document Number:

Section A — Type of Submission

☒ 510(k) (Special)	☐ IDE	☐ PMA	☐ PMA Supplement - Regular
☐ 510(k) Add'l information	☐ IDE Amendment	☐ PMA Amendment	☐ PMA Supplement - Special
	☐ IDE Supplement	☐ PMA Report	☐ PMA Supplement - 30 day
	☐ IDE Report		☐ PMA supplement - Panel Track

Section B1 — Reason for Submission - 510(k)s Only

☐ New device ☐ Additional or expanded indications ☒ Change in technology design, materials, or manufacturing process

☐ Other reason (specify):

Section B2 - Not applicable

Section B3 - Not applicable

Section C — Product Classification

Product code: **FMT**	C.F.R. Section: **880.5130**	Device Class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel: **General Hospital and Personal Use**		

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 **FMT**	2	3	4

Summary of, or statement concerning, safety and effectiveness data
☒ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 **K940951**	1 **RW Resuscitaire Infant Radiant Warmer**	1 **Hill-Rom Air-Shields**
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

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	FDA Document Number:

Section E **Product Information - Applicable to All Applications**

Common or usual name or classification name:

WARMER, INFANT RADIANT

Trade or proprietary or model name	Model Number
1 **Resuscitaire Radiant Warmer**	1 **RW82-1**
2 **Resuscitaire Birthing Room Warmer**	2 **WBR82-1**
3 **Resuscitaire Wall Mounted Radiant Warmer**	3 **WMRW82-1**
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1 **K940951**	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):

The Resuscitaire® Radiant Warmer is designed specifically for labor and delivery room use. The Resuscitaire® Radiant Warmer consists of a Bassinet, Warmer, and controller module, which provides heat control, monitoring of skin temperature and Apgar timing. The Resuscitaire® Radiant Warmer also includes an optional basic resuscitation package, which includes suction and oxygen delivery.

Section F **Manufacturing / Packaging / Sterilization Sites**

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: **2510954**	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler

Company / Institution name: **Hill-Rom Air-Shields**

Division name (if applicable): **Not applicable**	Phone number (include area code): **(215) 675-5200**
Street Address: **330 Jacksonville Road**	FAX number (include area code): **(215) 682-8689**

City:	State / Province:	Country:	ZIP / Postal Code:
Hatboro	**Pennsylvania**	**United States**	**19040**

Contact name: **Larry W. Krasley**

Contact title: **Regulatory Affairs Specialis**

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		FDA Document Number:	
Section G	**Applicant or Sponsor**		
Company / Institution name: **Hill-Rom Air-Shields**			FDA establishment registration number: **2510954**
Division name (if applicable): **Not applicable**			Phone number (include area code): **(215) 675-5200**
Street Address: **330 Jacksonville Road**			FAX number (include area code): **(215) 682-8689**
City: **Hatboro**	State / Province: **Pennsylvania**	Country: **United States**	ZIP / Postal Code: **19040**
Signature:			
Name: **Larry W. Krasley**			
Title: **Regulatory Affairs Specialist**			
Section H - Not Applicable			

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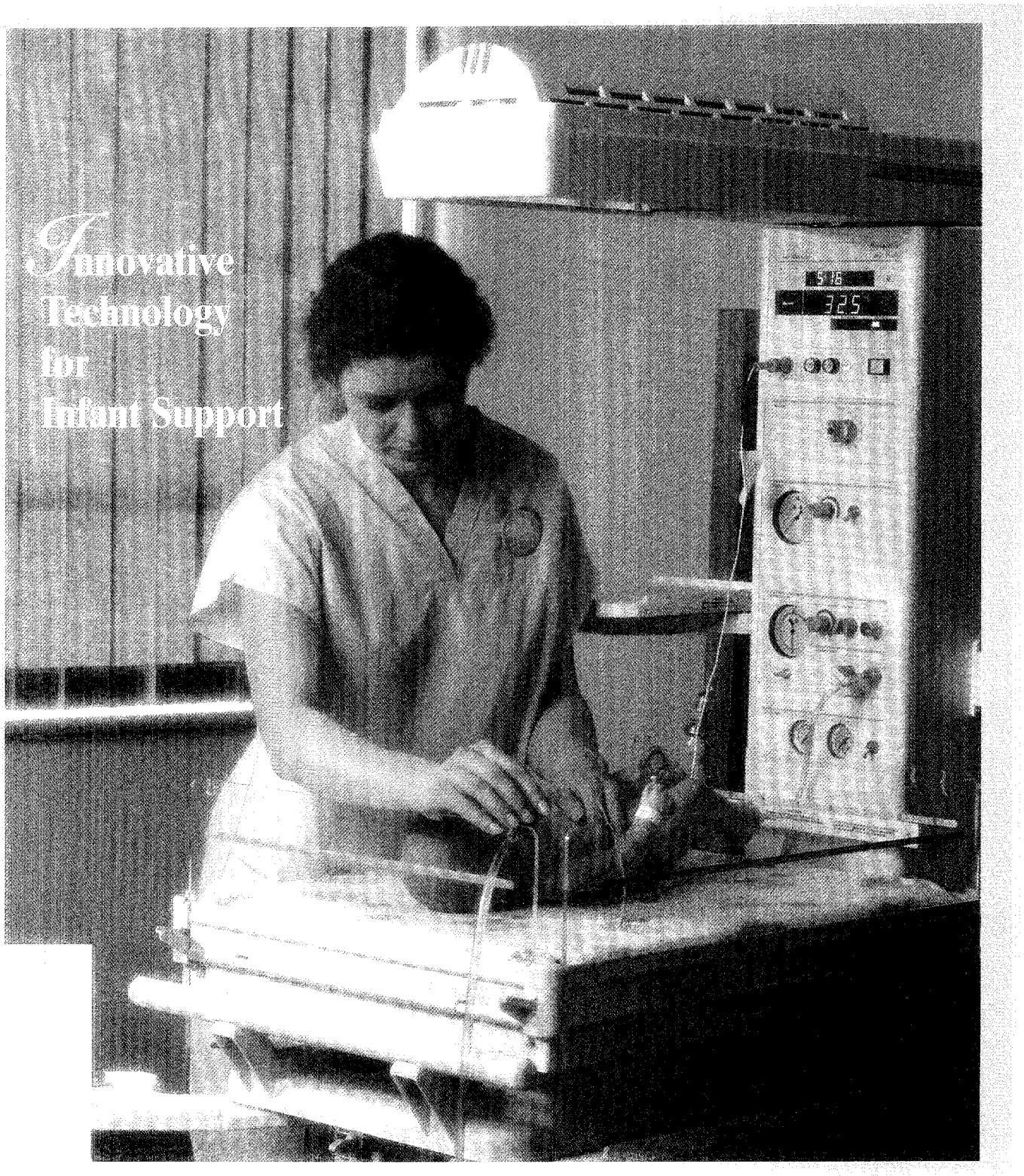
RESUSCITAIRE® RADIANT WARMER



Hill-Rom Air-Shields®
A HILLENBRAND INDUSTRY

We Deliver The Future℠

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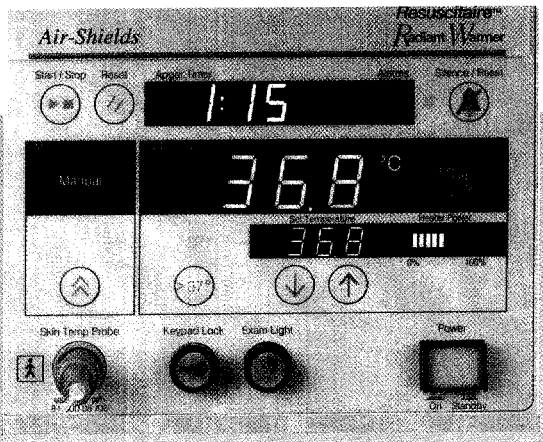
RESUSCITAIRE® RADIANT WARMER



The Pneumatic Module Option...

The primary patient supply provides two gas flow sources for the neonate, and organizes all displays and controls in a logical, easy to access manner.

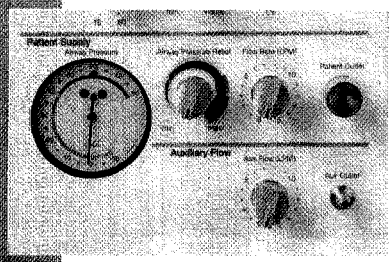
The primary flow source provides blended gas for units equipped with a blender. An auxiliary flow source provides supplementary 100% oxygen, which can be used for a manual bag resuscitator or for a second source of oxygen. An internal preset relief valve limits the auxiliary supply pressure. Each Resuscitaire with pneumatic module features a convenient gas supply on/off switch and easy to see front facing cylinder pressure gauges. Each module also includes tank mounts and venturi suction capability, with adjustable suction and front facing gauges.

Autobreath* When equipped with the Autobreath Resuscitator, the clinician may switch from manual ventilation to automatic ventilation with the simple flip of a switch.

An airway pressure gauge with adjustable airway pressure relief is utilized by our patient circuit. Breathing rates can be set for up to 60 BPM, and includes PEEP control.

*Autobreath not available in the United States.

Autobreath feature replaces manual resuscitation when required



Color-coded airway pressure settings provide quick reference for commonly used settings

The Control System

Each Resuscitaire® Radiant Warmer is equipped for 3 modes of operation: Automatic Pre-Warm, Manual and Baby (Servo) modes. Three function control modes provide the clinician with more flexibility to optimize the thermal environment.

Mode 1: Automatic Pre-Warm

Quickly warms the mattress at 100% heater power. The unit automatically cycles to 60% and thereafter 30% heater power in maintenance mode, ready for immediate use - with NO ALARMS!

Mode 2: Manual Mode

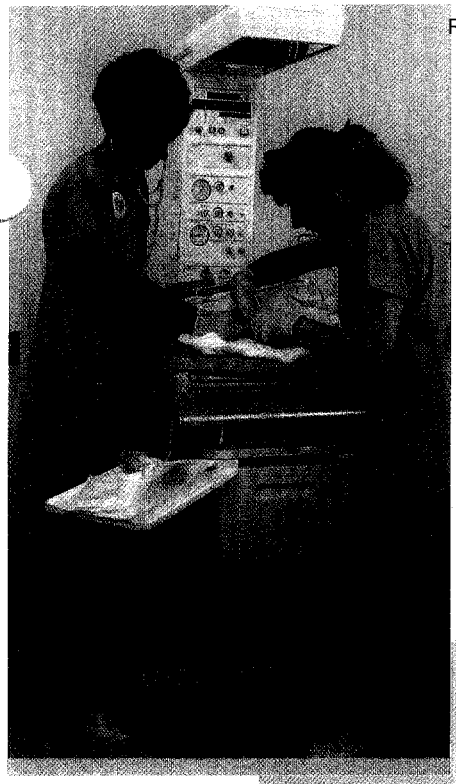
Provides manual heater settings of 0-100%

Mode 3: Servo (Baby) Mode

Heater settings are based on desired infant skin temperature.

Operating Advantages:

- The Resuscitaire Radiant Warmer features an independent ambient temperature probe which maximizes heating efficiency, while limiting the temperature of surfaces that could contact the infant.
- Large, bright temperature displays allow for easy, convenient visualization of Patient Temperature and Set Point. Displays can be converted from °C to °F by the push of a button.
- A digital Apgar timer signals at 1, 5 and 10 minutes, and can be used as a procedure timer.
- Audible Alarms initiate at lower volumes and increase only if unattended.
- A keypad lock prevents inadvertent setting changes.
- A full complement of alarms are provided for safety and convenience.



Advanced Resuscitation for the Most Challenging Situations

The Resuscitaire® Radiant Warmer is designed to meet a wide range of needs in the labor and delivery area, from non-problematic deliveries to emergency resuscitation situations.

Superior Thermo-regulation capabilities...

Our advanced microprocessor-based controller is loaded with a full spectrum of unique features developed to support the needs of your most special patients.

Resuscitaire® Radiant Warmer

- Lightweight
- Integrates resuscitation options
- Advanced microprocessor control system
- Three position bassinet tilt
- Front handle for easy maneuvering
- Front compartment for suction access, tubing, and accessory storage

Integrated Resuscitation Options, Including:

Module with two gas supplies flow controls

- Front facing gas bottle contents gauges
- Front gas on/off control

Optional blender

Optional Autobreath Resuscitator*

*Autobreath not available in the United States

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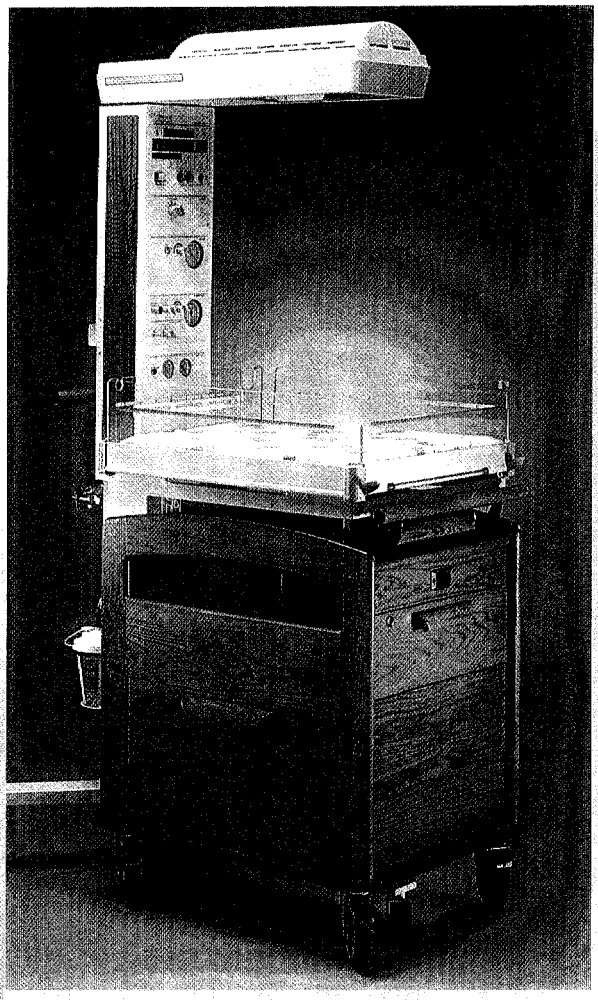
RESUSCITAIRE® BIRTHING ROOM WARMER*



Resuscitaire Birthing Room Warmer and Carts (ordered separately) are available in three popular stains:

- *Standard Oak*
- *Natural Oak*
- *Traditional Cherry*

Incorporating all of the advanced features of our Resuscitaire Control System, and available with the same integrated pneumatic module options, the Resuscitaire Birthing Room Warmer is capable of the most advanced patient support.

The Resuscitaire Birthing Room Warmer utilizes a detachable, high quality wooden cart designed to complement any birthing room or LDRP environment.

- This versatile cart may be used with the radiant warmer as a resuscitation bed, or separately as a mobile bassinet.
- Each cart integrates a front handle for ease of portability, and a pull-out shelf for patient chart notations.
- A locking front drawer can be used for medications.
- A side through access drawer organizes a wide variety of supplies, convenient to either side of the bed.
- Front latch detaches the warmer from the cart.

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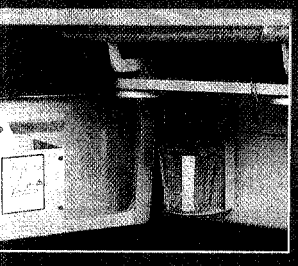
- Fast response accurate quartz heating element
- Parabolic reflector distributes energy evenly across the mattress
- Warmer module pivots 180 degrees while continually supplying heat
- All controls are located within easy reach for quick access, and provides a clear, bright display
- Front handle [illegible]asy [illegible]euvering



Front-Access

Integrated compartment for suction, tubing, and accessories

Superior Storage and Accessory Capabilities...

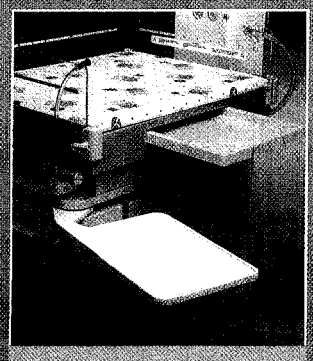
- Roomy slide-through storage drawer
- Optional organizer tray

Front panel folds completely under the mattress for maximum front access

Optional x-ray cassette below mattress is accessible from either side

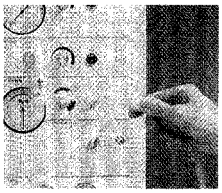
Front and rear organizer panels keep tubing organized and readily available

Optional instrument trays available for either side of the bed



TECHNICAL SPECIFICATIONS

Resuscitaire® Radiant Warmer complies with the following standards
IEC 601-1 1988
IEC 601-2-21 1994
UL 2601 1994
CSA C22.2 No. 601.1-1994
MDD Counsel Directive 93/42 EEC



Breathing Circuits

The Breathing circuit and exhalation valve were designed exclusively for use with the Autobreath Infant Resuscitaire. The reusable circuit requires a diaphragm replacement kit.*

*Autobreath not available in the United States

*** Vertical Height Adjustable Model**

Height.....180-201 cm....(71-79 in)
Mattress Height....90-109 cm....(35-43 in)
Weight.....100-127 kg.....(200-280 lbs)

*UK variants add 5 cm (2 in)

Physical Characteristics

Resuscitaire® Radiant Warmer
Width.....74.9 cm.....(29.5 in)
Depth.....114.9 cm.....(45 in)
Height.....190.5 cm.....(75 in)
Weight.....91-118 Kg.....(200-260lbs)

Mattress
Height from floor....100.0 cm.....(39.4in)
Thickness.....2.54 cm.....(1.0in)
Width.....53.3 cm.....(21.0in)
Length.....66.0 cm.....(26.0in)
Max. Capacity.....4.54 kg.....(15 lb)

Maximum Power Requirements
Model
100V.....100V, 50-60Hz, 750W
120V.....120V, 50-60Hz, 750W
220/240V.....220-240V, 50-60 Hz, 750W

Examination Light
Illumination.....>0.11 lumens/cm^2 (100ft. Candles)
Quartz Bulb Type.....50W (1,076 lux)

Controller
Heating Alarms
Check Patient.....15 minutes in Manual Mode
Baby Temp.....+/-1˚C from Set Point
High Temp.....Skin Temp 39.0˚C +/-0.2˚C
Probe.....Short or open circuit/No probe
System Fail.....Indicates System Fail
Power Fail.....AC Power Interruption

Alarm Silence/Reset Intervals
Check Patient.....Resets clock for 15 minutes (manual mode)
Baby Temp.....10 minutes
High Temp.....2 minutes
Procedural Silence.....PreSilences Baby Temp alarm for 5 minutes

Set Temperature/Heater Output
Set Temp Range.....34-38˚C (>37.0˚C override)
Heater Output.....0-100%, 10% increments
Skin Temp Display.....18-43˚C
Accuracy.....+/-0.2˚C (31˚C to 37˚C)

Resuscitation Module
Wall Supply Pressure.....40-75psi (275-517 kPa)
Cylinder Pressure.....2,900 psi max (19,994 kPa)

Patient Gas Supply
Flow Control Range.....0-15 LPM
Airway Pressure Limit-
Adjustable.....0-50 cm H_2O (0-4.9 kPa)
Internal Preset Limit.....60 cm H_2O (5.9 kPa)

Auxiliary Flow Circuit
Auxiliary Flow Range....0-15 LPM
Auxiliary Pressure Relief
Fixed Internal.....160cm H_2O (15.7 kPa)

Suction Circuit
Intensity.....0-150 mmHg(0-20 kPa)
Disposable Collection Container.....50 or 800 ml
Reusable Collection Container.....750 ml

AutoBreath* Infant Resuscitator (optional)
Adjustable Breath Rate Range.....18-60 BPM
+/-10% of setting
I:E Ratio.....Fixed at 1:2 Nominal
Adjustable Positive End Expiratory
Pressure (PEEP).....0-18 cm H_2O (0-1.77 kPa)
Gas Bleed.....5 LPM Max

Precision Blender
(optional).....21-100% O_2 +/-3% O_2

Alerts
Manual Mode.....System alerts every 30 seconds> 10 minutes, for 15 minutes total
Apgar Timer.....Alerts at 1, 5 and 10 minutes
Timer.....Visual timer up to 1 hour

Instrument Tray (Resuscitaire only)
Length.....33.0 cm.....(13.0 in)
Width.....22.8 cm.....(9.0 in)
Capacity.....2.2 kg.....(5 lb.)

X-Ray Cassette Tray
Pocket Width.....36.8 cm.....(14.5 in)
Pocket Length.....27.9 cm.....(11.0 in)
Thickness.....1.9 cm.....(0.75 in)

IV Pole
Maximum load.....2.2 kg.....(5 lb)

Monitor Shelf
Length.....31.75 cm.....(12.0 in)
Width.....40.64 cm.....(14.0 in)
Maximum load.....4.5 kg.....(10 lb)

Birthing Room Warmer
Overall Unit
Length.....44.5 in
Width.....27.5 in
Weight.....300 lbs

Cart
Mattress Height.....39 in
Length.....30.5 in
Width.....23.7 in
Weight.....150 lbs

BRW Accessories
Front Drawer Organizer Tray

Hill-Rom Air-Shields®
A HILLENBRAND INDUSTRY

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Toll-Free 800.523.5756
Fax 215.675.1859

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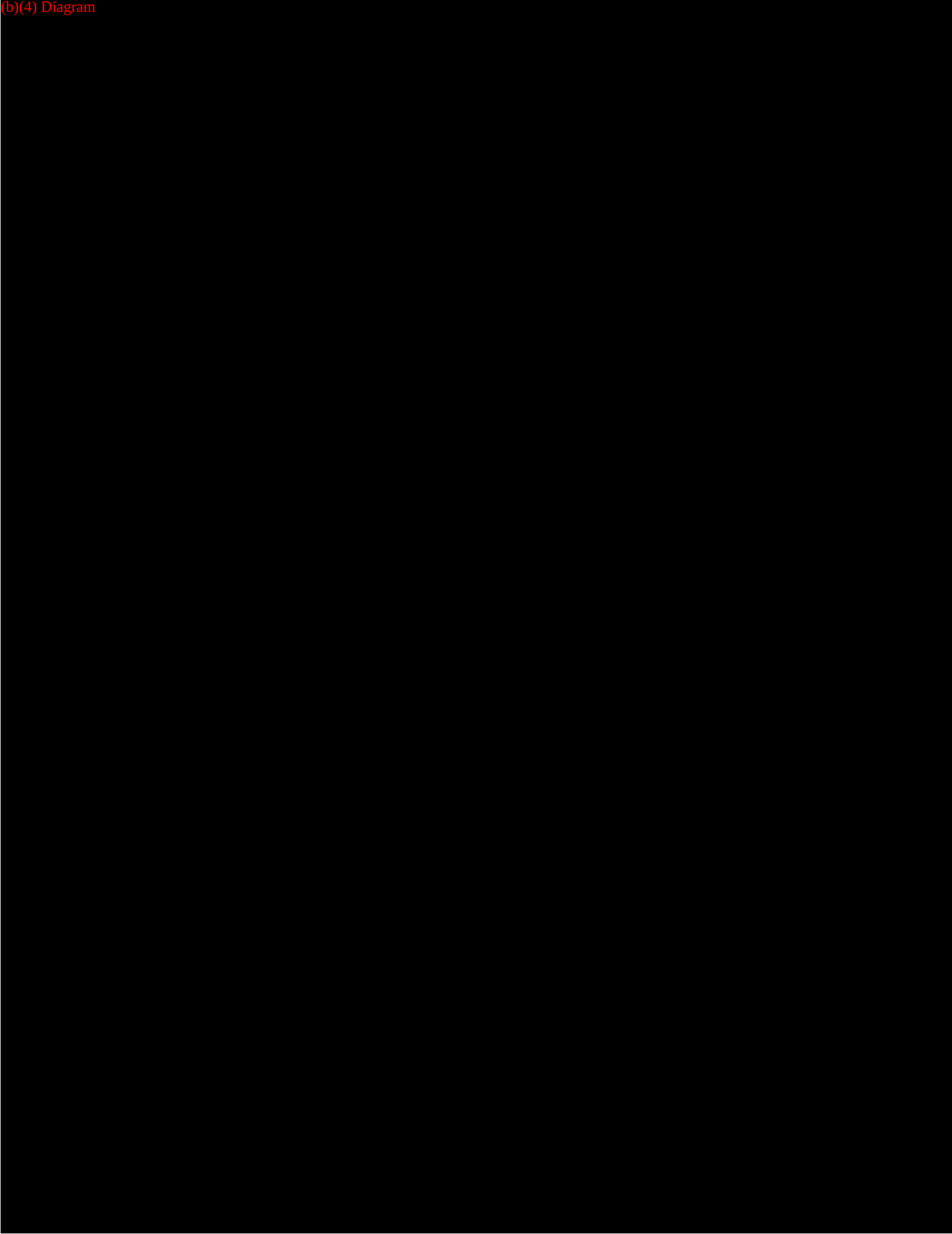
ISO 9001
KEMA CERT 10003.01
Accredited by the Dutch Council for Accreditation (RvA)
Accredited by the Registrar Accreditation Board (RAB)
Scope: The design, production, distribution and servicing of Neonatal Care Products and accessories.

82LIT01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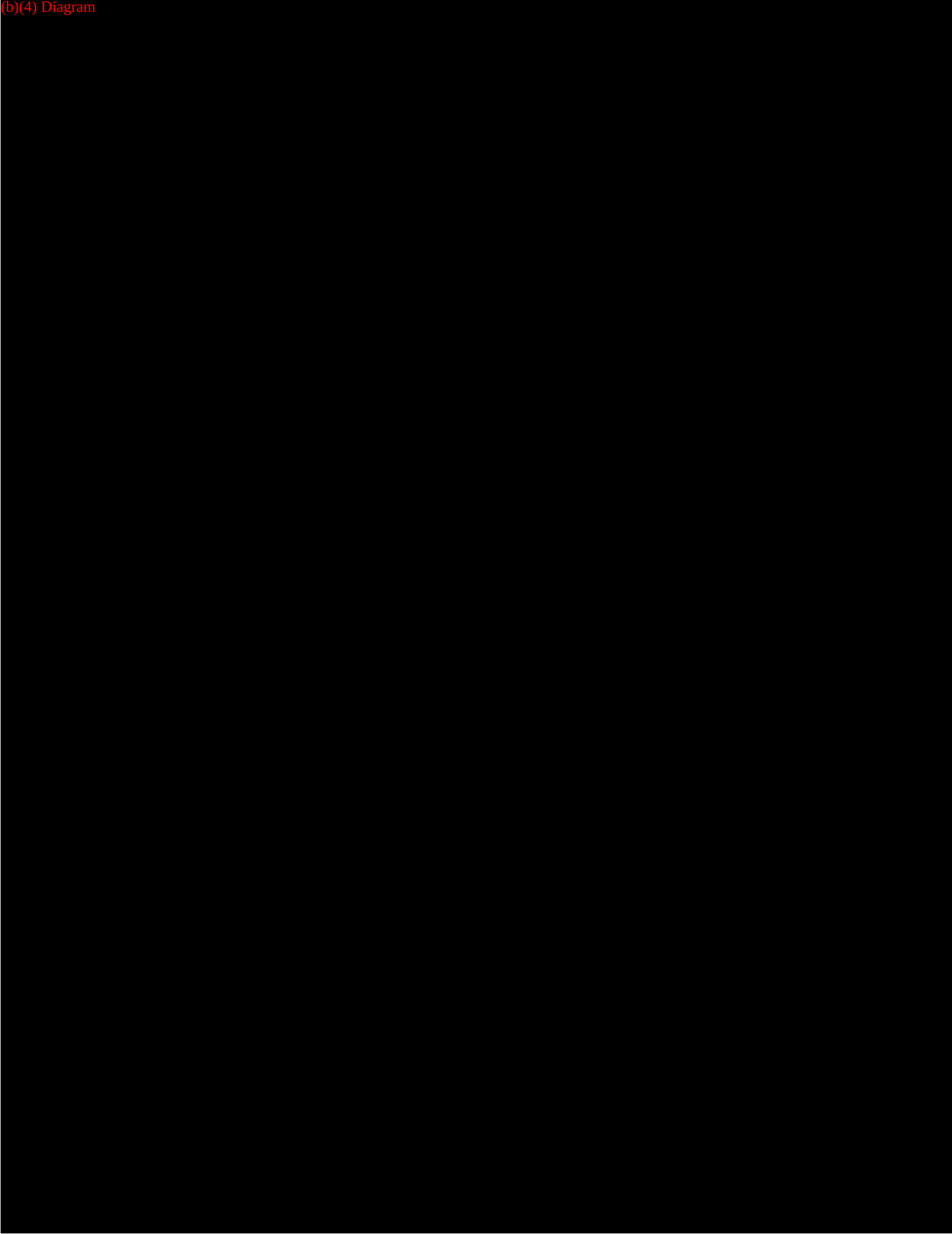
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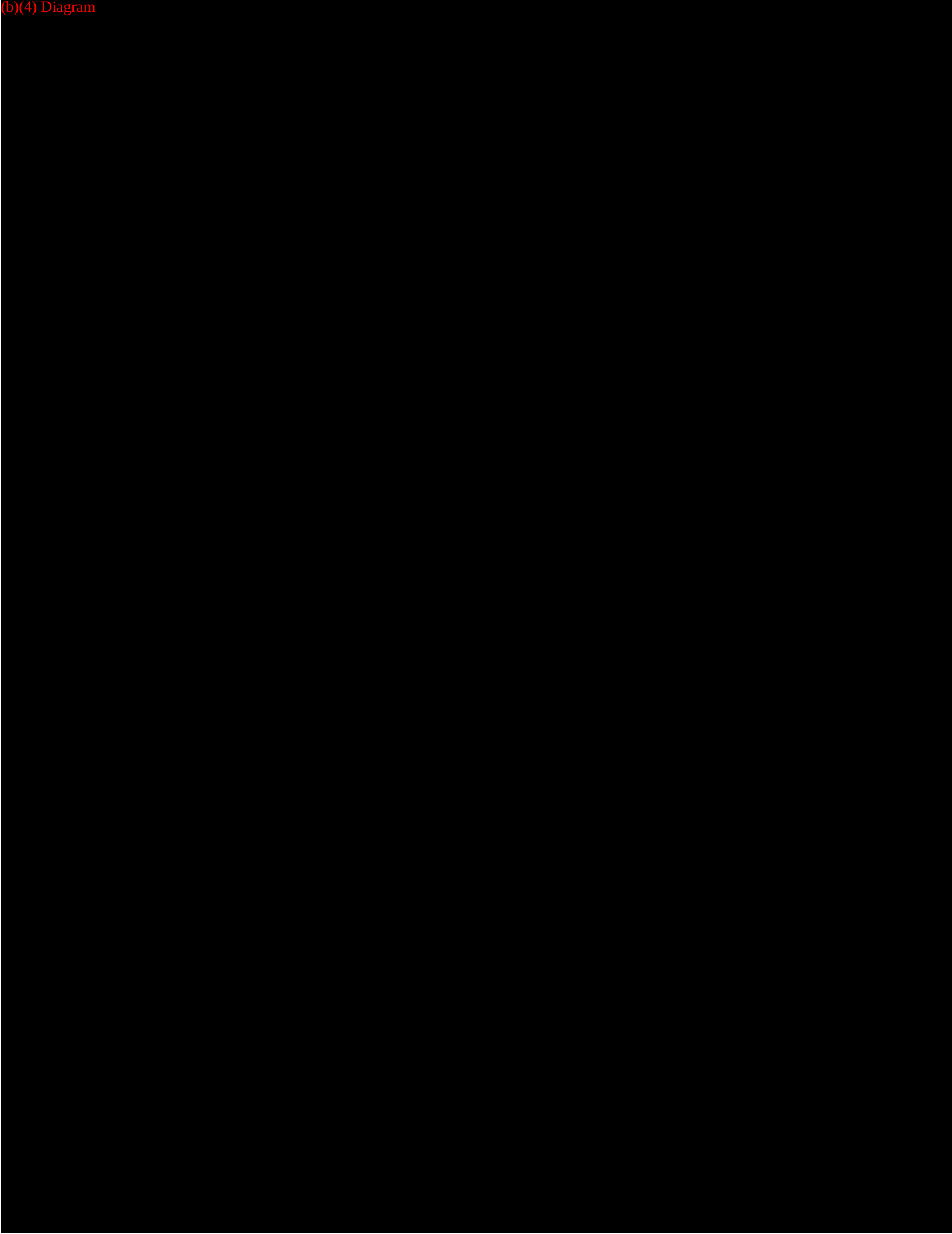
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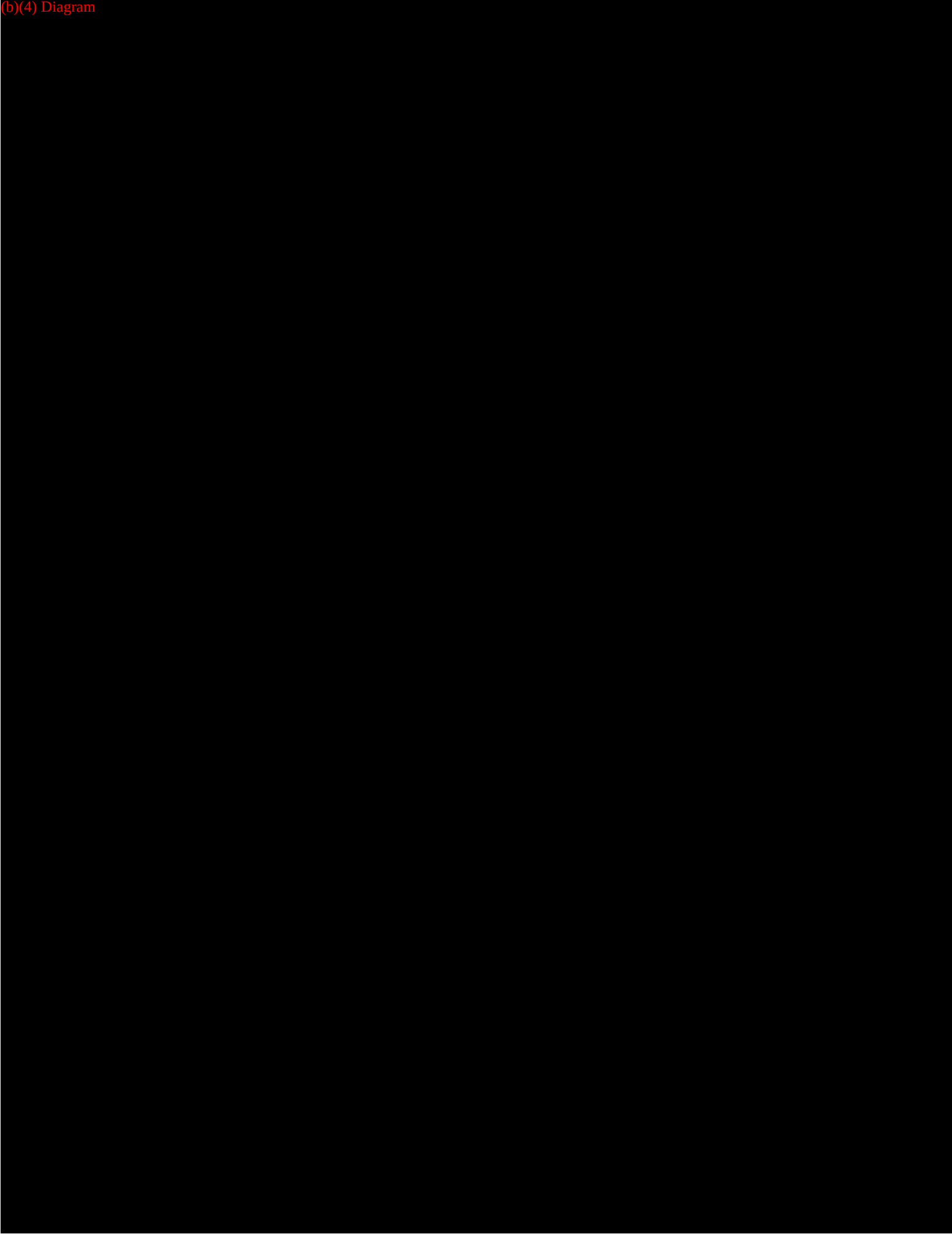
(b)(4) Diagram

Hill-Rom Air-Shields.

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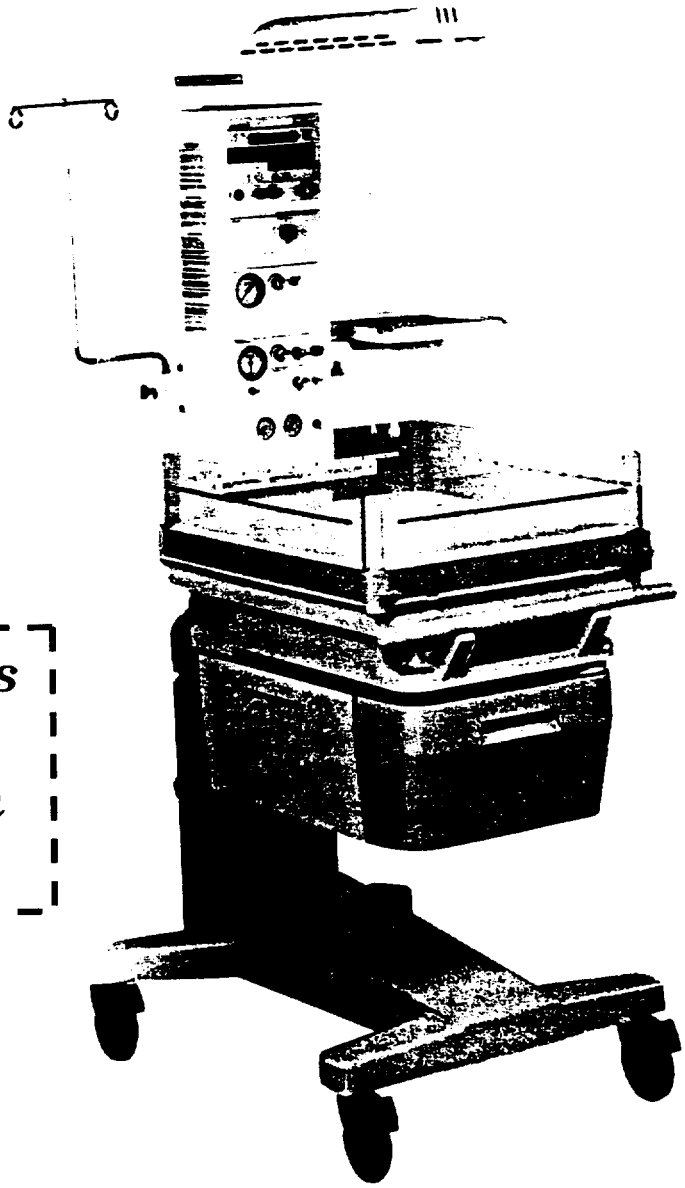
RESUSCITAIRE® Radiant Warmer

MODEL RW82-1



New Pages 14 & 27 have been added

OPERATOR'S MANUAL

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OPERATING PRECAUTIONS

GENERAL PRECAUTIONS

- Federal Law restricts this device to sale by or on order of a physician.
- Infant radiant warmers should be used only by properly trained personnel as directed by an appropriately qualified physician aware of currently known risks and benefits.
- The functional checkout procedure should be performed before the unit is first placed into use and after disassembly for cleaning, servicing or maintenance. Refer to qualified service personnel if the unit does not perform as specified.
- The Bassinet end and side panels cannot be used for pushing or pulling the ***Resuscitaire® Radiant Warmer***.
- Do not leave the infant unattended in the Bassinet of the ***Resuscitaire® Radiant Warmer*** when the side panels or the front panel are folded down.
- To avoid overheating or underheating, skin temperature must be continuously monitored and controlled either manually or automatically. Rectal temperature should never be used to control skin temperature.
- To avoid overheating or underheating when operating in manual mode, observe the infant constantly and monitor the temperature using the temperature probe supplied with the equipment or other electronic thermometer.
- The skin temperature sensing probe must be in direct contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain direct skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment, reddened skin areas, and proper skin temperature.
- The skin temperature sensing probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The skin temperature probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.
- To avoid overheating the skin, the location of the skin temperature probe must be such that the skin around the Sensor is in direct line with the radiation from the warmer. Do not place anything between the radiant warmer and the infant that will interfere with the radiation from the warmer.
- Radiant warming increases insensible water loss. Appropriate measures to maintain proper fluid balance should be considered.
- Phototherapy units located too close to the Bassinet may affect mattress and infant temperature.
- The warmer cannot differentiate between an increase in core temperature and cold skin (fever) and low core temperature (hypothermia). It is recommended that patient core temperature be monitored with a separate calibrated electronic thermometer.
- 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 avoid overheating of the warmer, do not place objects (equipment, blankets, clothing or sterile packs) on top of the warmer.
- Air currents across the Bassinet area can affect patient thermal balance. Avoid placing the Warmer near heating or air conditioning ducts that may blow air across the Bassinet.
- Temperature uniformity (per IEC 601-2-21) across the mattress surface may not be maintained when the Bassinet is tilted in the 5- and 10-degree positions.
- During service intervals, inspect the secondary reflector directly under the warmer heater element for particles. If particles are present, replace the heater element. The life expectancy of the heater element is 1000 hours of operation.

OPERATING PRECAUTIONS (Continued)

GENERAL PRECAUTIONS (Continued)

- Should any of the control knobs on the Resuscitation Module come loose for any reason, do not attempt to refasten them. The calibration of these controls depends on the position of the knob on the shaft. If this occurs, recalibration must be performed by qualified service personnel.
- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Only connect the power cord to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with or provided for the ***Resuscitaire® Radiant Warmer.***
- The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
- Use of the accessory in the PATIENT VICINITY.
- Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 601-1 and/or IEC 601-1-1 harmonized national standard.
- When raising or lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA,*** make sure that any attached cables, tubing or hoses are not compromised.
- When lowering the Upper Post of the ***Resuscitaire® Radiant Warmer with VHA*** to its minimum height, ensure thatthe gas tanks, if installed, do not contact the floor.
- Always lower the ***Resuscitaire® Radiant Warmer VHA*** to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.

AUTOBREATH PRECAUTIONS

- The Resusctation Autobreath (option) is intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Any humidifier used with the **AutoBreath** must be a "flow-through" type having a low pressure drop. Use of a humidifier with a bubbler tube or pressure jet will render the Safety Relief Valve ineffective. A pressure jet nebulizer or unmodified bubbler humidifier may not be used.
- When setting the **Rate (BPM)** Control for optimum repeatability, always approach the desired setting by turning the knob in a clockwise direction.
- When setting the **PEEP** control, always start with the knob fully counterclockwise to avoid setting PEEP above the maximum pressure limit.
- An airway pressure monitor must be used if the **AutoBreath** is to be used unattended.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.
- A humidifier, when used, must be placed between the **Patient Outlet** connection and the patient circuit. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.

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OPERATING PRECAUTIONS (Continued)

RESUSCITATION PRECAUTIONS

- The Resuscitation Module (options) are intended for use by qualified clinical personnel only. These instructions should be read before using the equipment.
- Always operate the Resuscitation Module with clean/dry medical grade gases.
- If the the **Airway Pressure Relief** valve setting is on the module, confirm the setting and flow before patient use.
- Confirm that the oxygen/air blender control of the **Blended Gas Supply** Module is correctly set prior to use.
- Confirm that the patient circuit contains all the parts needed prior to use.
- Ensure that the patient breathing circuit connections are secure and free of obstructions.
- The **Primary and Aux Outlets** circuits do not provide adjustable pressure limiting.
- **Auxiliary Outlet** and **Primary Outlet** Gas Supply Pressure is internally limited to 160 cm H_2O. Always use a patient resuscitation circuit that includes appropriate pressure relief.
- Always monitor **Airway Pressure**.
- When using **Primary Outlet** utilize infant resuscitation bags with built-in pressure relief during infant resuscitation.
- Gas supplies (O_2 and Air) should always be clean and dry. Water trapfilters should be used in the supply lines if necessary.
- All hoses should be securely fastened to fittings. Hand-tighten to avoid damage to fittings.
- Wall/Pipeline gas supplies should be maintained at 40 to 75 psi.
- Flow restrictions (e.g., flowmeter, valve, etc.) must not be placed in the supply line.
- If a compressor is used as the air source, steps should be taken to filter and dehumidify the room air before introducing it into the **Gas Supply** or **Patient Supply** module.
- A humidifier, if used, must be placed between the **Patient Outlet** connection and the patient circuit. DO NOT PLACE A HUMIDIFIER IN THE SUPPLY LINE. The humidifier should have low compliance and water maintained at a high level to minimize compliance.
- Gas going to the patient should not be super-saturated as evidenced by excessive condensation in the tubing. Condensation droplets on the inner walls of the tubing are normal.
- Periodic blood gas measurements should be made to ensure proper levels of ventilation.
- A one-way valve is installed at the **Patient Outlet** connection. This valve opens when pressure in the hose delivering gas to the patient falls below -4 cm H_2O. Its purpose is to allow patient inspiration in the unlikely event of failure of the gas supply.

ELECTRICAL PRECAUTIONS

- An electrical shock hazard exists within the Warmer Module and Controller. Any substitution of components within the Controller or Warmer Module may impair the intrinsic safety of the unit. Service should be performed by qualified personnel.
- Confirm that the **Oxygen Supply** is turned off and that the equipment 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.

- Connect the power cord only to a properly grounded receptacle that is approved for hospital use and of the correct voltage. **DO NOT USE EXTENSION CORDS.**
- Use only with power cords supplied with the Warmer.

EXPLOSION PRECAUTIONS

- Do not use in the presence of flammable anesthetics.
- Confirm that the oxygen supply is turned off and that the equipment 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.

OXYGEN PRECAUTIONS

- Improper use of supplemental oxygen may be associated with serious side effects including blindness, brain damage, and death. The risks vary with each infant. All clinical practices with regard to 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 the 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_2) in the blood. When deemed advisable by the attending physician, blood PO_2 should be measured by accepted clinical techniques.
- Oxygen flow rates cannot be used as an accurate indication of oxygen concentrations. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals directed by the attending physician.
- Keep matches, lighted cigarettes, and all other sources of ignition out of the room in which the equipment is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.
- Although oxygen compatible materials are used in the oxygen delivery system, special care must be taken when high pressure oxygen such as found in a medical oxygen cylinder is used. Violent ignition of oil, grease, greasy substances, small particles of dust, dirt or other particulate contaminants (even small particles of metal), can occur in the presence of high pressure oxygen if their ignition temperature is reached. An instantaneous increase in temperature can occur due to friction, particle acceleration, or adiabatic compression, if the oxygen cylinder valve is opened too rapidly. **SERIOUS INJURY MAY RESULT!** Always observe the following precautions:

OXYGEN PRECAUTIONS (Continued)

- Oil, grease, greasy substances, dust, dirt and other particulate contaminants must be kept away from oxygen regulators, cylinder valves, tubing and all other oxygen equipment.
- Always open oxygen cylinder shut-off valves **very slowly** and **carefully.**
- On high pressure oxygen cylinders use only pressure regulators or reducing valves approved for oxygen service. Do not use oxygen pressure regulators or reducing valves for air or gases other than oxygen as they may be hazardous. Operate such devices in strict accordance with the manufacturer's recommendations.
- When new or replacement oxygen cylinders are to be installed, they should have their outlet ports cleared by cracking the cylinder valve momentarily before attachment to the equipment.

LOW FLOW MICROBLENDER WARNINGS

- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FiO_2 and flow output from the microblender.
- Always operate the low flow microblender with clean/dry medical grade gases.
- Air inlet water filters are recommended for use with the low flow microblender.
- The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.

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TABLE OF DEFINITIONS AND SYMBOLS

NOTE, IMPORTANT, PRECAUTION, 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 when greater emphasis is required.*

PRECAUTION: *A Precaution is supplemental information to assist the user in the safe and effective use of the equipment.*

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.

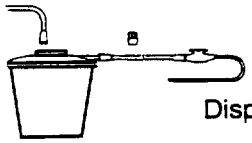
WARNING: A Warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

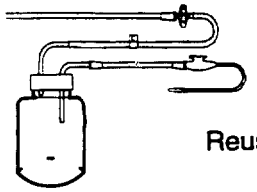
SYMBOLS


Attention: consult accompanying documents.


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


Danger! High Voltage!


Disposable Suction Bottle


Reusable Suction Bottle


Patient


Heater Element


Suction Line Filter


Load Symbol


Examination Light


Examination Light Switch


Mode Control Key

Temperature Override Mode Key


Keypad Lock Key


Set Temperature Keys


Power On/Off Switch

Celsius/Fahrenheit Selection Key


Silence/Reset Key


Procedural Silence Indicator


Apgar Timer Keys

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SECTION 1
GENERAL INFORMATION

1.1 INTRODUCTION

This manual provides instructions for installation, use, operator maintenance and troubleshooting of the equipment. Hill-Rom Air-Shields cannot be responsible for the performance of the equipment if the user does not operate the equipment 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. Service manuals are available from Hill-Rom Air-Shields.

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

1.2 DESCRIPTION

The ***Resuscitaire® Radiant Warmer*** is designed specifically for labor and delivery room use. The ***Resuscitaire® Radiant Warmer*** consists of a Bassinet, Warmer, and a Controller module which provides heat control, monitoring of skin temperature and Apgar timing. The ***Resuscitaire® Radiant Warmer with VHA*** provides an adjustable Mattress Height from 89.2 cm (35.4 inches) to 110.2 cm (43.3 inches).

The ***Resuscitaire® Radiant Warmer*** also includes an optional basic resuscitation package which includes suction and oxygen delivery.

1.3 SPECIFICATIONS

Specifications for the ***Resuscitaire® Radiant Warmer*** are provided in Table 1.1. All specifications are subject to change without notice.

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TABLE 1.1 SPECIFICATIONS

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer*

120V Models	120V, 60 Hz, 750W
100V Models (Japan)	100V, 50/60 Hz, 750W
230V Models	230V, 50/60 Hz, 750W

POWER REQUIREMENTS *Resuscitaire® Radiant Warmer with VHA*

120V Models	120V, 60 Hz, 1300W
230V Models	230V, 50/60 Hz, 1300W

OVERLOAD PROTECTION

120V Models	Dual 12A Circuit Breakers
100V Models (Japan)	Dual 12A Circuit Breakers
230V Models	Dual 6A Circuit Breakers

Resuscitaire® Radiant Warmer with VHA also has in addition:

120V Models	Dual 6A Circuit Breakers
230V Models	Dual 3A Circuit Breakers

CHASSIS LEAKAGE CURRENT (Single fault condition, loss of ground)

100V and 120V Models	Less than 300 µA
230V Models	Less than 500 µA

EXAMINATION LIGHT ..... >100 Foot Candles (0.11 lumens/cm^2)

ALARMS

High Temperature	Activates if Skin Temperature Probe is attached and the skin temperature sensor reaches 39.0 °C. Resets at 38.5 °C.
Check Patient	Activates in Manual Mode after 10 minutes. Remains on with audible alarm every 30 seconds for 5 minutes; totalling 15 minutes. Then the heater is turned *Off*.
Apgar Timer	Activates at the 1-, 5- and 10-minute Apgar Time intervals.
Power Fail	Activates when there is a loss of power.
Probe	Activates if Skin Temperature Probe fails (open or short).
System Fail	Indicates system failure, refer unit to service immediately.
Baby Temp	Activates if Baby Temperature fluctuates 1°C above or below set point.
Electrical Module Audio Alarms	Tone Frequency: 1.2 KHz maximum three-stage sound level: 15 seconds low, 15 seconds medium, then high.
Blender Module Pneumatic Audio Alarm	Vibrating Reed.

MANUAL HEAT CONTROL ..... Adjustable in 10% increments from zero to full power (100%)

DATA PORT ..... 2400 Bits/second fixed Baud Rate. RS232C Compatible.

MATTRESS TILT ..... 0, 5 and 10 degrees.

DISPLAYS

Skin Temperature Display

Range	18 to 40 °C (64.4 to 104°F)
Accuracy	± 0.2 °C for 31 °C to 37 °C (88 °F to 98.6°F)
Resolution	0.1°C (0.5 °F)

TABLE 1.1 SPECIFICATIONS (Cont.)

DISPLAYS (Cont.)

Apgar Timer Display

Range	0 to 59 minutes, 0 to 59 seconds
Resolution	1 second
Accuracy	0 ± 1 second

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer*

Mattress Height	100 cm (39.4 - inches)
Height	188 cm (74 - inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	100 kg (220 lbs)

DIMENSIONS AND WEIGHT *Resuscitaire® Radiant Warmer with VHA*

Mattress Height	89.2 to 110.2 cm (35.4 to 43.3 inches)
Bassinet Tilt (continuously)	±10 degrees from horizontal
Height	180.6 to 200.7 cm (71.1 to 79 inches)
Width (Side to Side)	72.4 cm (28.5 - inches)
Depth (Front to Back)	111.8 cm (44 - inches)
Weight	127 kg (280 lbs)

ENVIRONMENTAL

Operating Temperature Range	18 °C to 30 °C ambient
Storage Temperature Range	- 30 °C to +70 °C ambient
Relative Humidity Operating Range	5% RH to 95% RH, non-condensing

RESUSCITATION

Wall Supply Pressure	40 to 75 psi (2.8 to 5.2 bar)
Cylinder Pressure	2900 psi max (199.8 bar)
Cylinder Diameter	10-12 cm (4-5 inches) max

Suction Circuit

Adjustable Suction Intensity	0 to 150 mmHg

Patient Gas Supply

Airway Pressure Limit, Operator Adjustable	0 to 50 cm H_2O (4.9 kPa) ± 10%
Fixed Pressure Relief, Factory Set	60 cm H_2O (5.9 kPa) ± 20%

Primary Supply

Primary Pressure Limit	160 cm H_2O (15.7 kPa) ± 20%
Primary Flow Range	0 - 15 lpm

Auxiliary Supply

Auxiliary Pressure Limit	160 cm H_2O (15.7 kPa) ± 10%
Auxiliary Flow Range	0 - 15 lpm

AutoBreath Circuit (Factory Installed Option)

I:E Ratio	Fixed at 1:2 ± 20%
PEEP	0 to 18 ± 4 cm H_2O (1.8 ± 0.4 kPa)
Breath Rate	18 to 60 BPM ± 10% of setting
Airway Pressure Relief, Operator Adjustable	0 to 50 ± 5 cm H_2O (4.9 ± 0.5 kPa)
Fixed Maximum Pressure	60 cm H_2O ± 10%(5.9 kPa ±20%)
Oxygen Consumption	50 LPM max.

1.4 EQUIPMENT PROVIDED

- *Bassinet* - The Bassinet provides maximum visibility and access to the infant. The Bassinet tilts up in the rear 5 and 10 degrees and provides for X-ray Tray (optional) insertion.
- *Warmer Module* - The Warmer Module houses a heating element and an Examination Light for special procedures.
- *Controller* - The Controller provides Pre-Warm, Manual heat control, automatic skin temperature servo-control and contains an Apgar Timer, Skin Temperature monitor and probe connection.
- *Resuscitation Module (Optional)* - The Resuscitation Module contains a suction circuit, a patient oxygen delivery circuit with airway pressure relief and an auxiliary oxygen delivery circuit.

1.5 FACTORY INSTALLED OPTIONS

- Resuscitation Module
- Resuscitation Module with AutoBreath
- Integrated Precision Blender
- Gas Supply Module
  - O_2 Pipeline and Cylinder
  - O_2/Air Pipeline and Cylinder

1.6 FIELD INSTALLED ACCESSORIES (Refer to Section 6 for Part Numbers)

- Instrument Tray (left or right mount)
- X-ray Cassette Tray
- Pass-Through Drawer Organizer Tray
- I.V. Pole
- Monitor Shelf

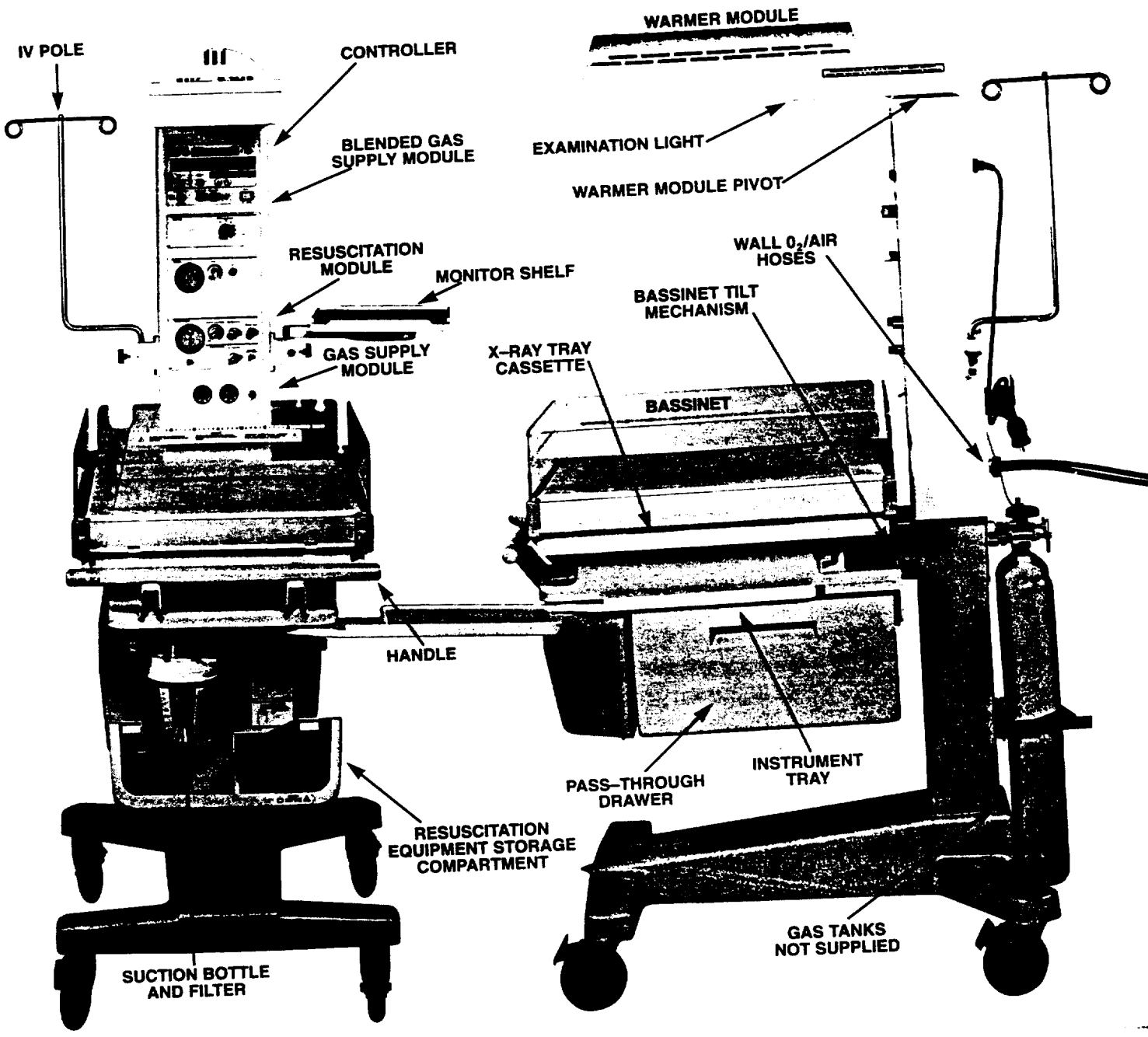

FIGURE 1.1 EQUIPMENT PROVIDED WITH FACTORY INSTALLED OPTIONS AND FIELD INSTALLED ACCESSORIES

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SECTION 2
INSTALLATION

2.1 UNPACKING

The ***Resuscitaire® Radiant Warmer*** is shipped in one carton which contains the following assemblies:

- Bassinet/Cart Assembly
- Upper Post Assembly
- Warmer Module Assembly
- Any user installed Accessories that were ordered

When removing the equipment from the carton, use care not to scratch or otherwise damage unprotected surfaces; remove all packing material.

2.2 ASSEMBLY (Refer to Figure 2.1)

NOTE: *The required mounting hardware is stored in a bag located in the pass-through drawer.*

1. **REMOVE THE BACK COVER** (1) from the Upper Column (2).
2. **REMOVE THE CONTROLLER** (3) from the Upper Column (2).
3. **REST THE UPPER COLUMN** (2) on top of the Bassinet/Cart column opening. Fully extend the suction hoses (4) and (11) out of the column.
4. **CONNECT THE SUCTION HOSE** (4) to the Suction Hose (11).
5. **REPOSITION AND MOUNT THE UPPER COLUMN** (2) on the Bassinet/Cart using four 10 - 32 x 3/8 inch screws (5). Exercising care not to kink the hoses, carefully push the connected suction hoses into the column.
6. **INSTALL TWO 10 - 32 X 3/8 INCH SCREWS (6) IN THE UPPER HOLES OF THE UPPER COLUMN** (2). Do not tighten the screws.
7. **RAISE THE WARMER** (7) above the open end of the Upper Column (2) and insert the Power Cable (10) into the open end of the column.
8. **SLOWLY LOWER THE WARMER** (7) onto the Upper Column. Align the slots of the warmer over the screws (6) on the column. Install the screws on the pivot bracket. Tighten the screws on the upper holes of the column using a nine-inch Phillips Head screwdriver.
9. **THREAD THE WARMER POWER CABLE** out through the Controller opening. Connect the Power Cable (10) to connector J4 on the Controller (3).
10. **REMOUNT THE CONTROLLER** on the Upper Column. Remount the Back Cover (1) on the Upper Column.
11. ***Resuscitaire® Radiant Warmer***

    CONNECT THE LINE CORD to the **POWER** Connector on the rear of the Controller (refer to Figure 4.2).

11A. ***Resuscitaire® Radiant Warmer with VHA***

    CONNECT THE LINE CORD to the Power Connector (Refer to Figure 4.2A) on the right side of the Lower Post. Connect the 40-inch Power Cord provided with the VHA between the AC connector on the left side of the Lower Post and the Controller Power Connector.

12. ***Resuscitaire® Radiant Warmer***

    SECURE THE LINE CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

12A. ***Resuscitaire® Radiant Warmer with VHA***

    SECURE THE 40-INCH POWER CORD to the Back Cover (1) using the Cable Clamp (8) and 8 - 32 x 3/8 screw (9).

CAUTION: Securing the Line Cord to the back panel is required to prevent removal of the Controller chassis with the AC power applied.

13. **INSTALL ANY ACCESSORIES** that were ordered using the installation instructions provided with the accessory.
14. **INSTALL THE END AND SIDE PANELS** on the Bassinet (refer to Paragraph 5.6 and Figures 5.1, 5.2, 5.3 and 5.4).

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PARTS LIST

Screw, 10 - 32 x 3/8 TR, PH Nylok (Qty 10)	99 041 36
Screw, 8 - 32 x 3/8 TR PH SS	99 031 38
Cable Clamp	17 725 64

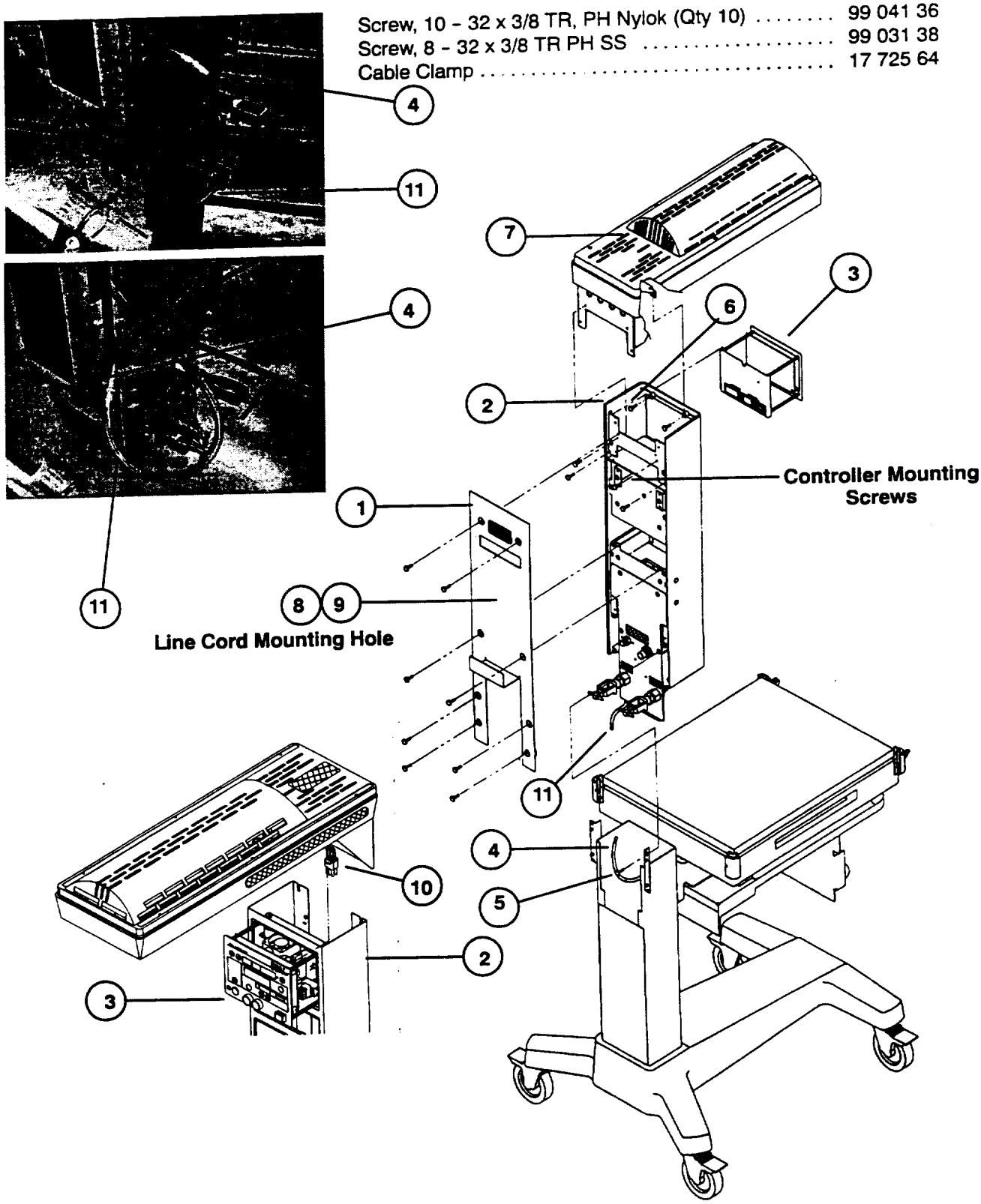

FIGURE 2.1 INSTALLATION

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SECTION 3
FUNCTIONAL DESCRIPTION

3.1 GENERAL

This section provides a functional description of the equipment.

3.2 FUNCTIONAL DESCRIPTION

3.2.1 WARMER MODULE

The Warmer is controlled by a Controller which provides **Pre-Warm** Mode, **Manual** Mode heater control, or **Baby** Mode (automatic skin temperature control). An Examination Light provides added illumination of the mattress area. A Warmer Head Pivot permits the Warmer to be pivoted 90° to either side for X-ray procedures. In addition, when the Warmer is pivoted, it continues to provide heat.

3.2.2 BASSINET

The Bassinet is designed to provide maximum function and utility to aid in the care of the newborn. The side and front panels may be folded down to permit access to the infant. The mattress may be tilted up from the rear at a 5- or 10-degree angle. Openings are provided on each side of the Bassinet for the insertion of the optional X-ray Cassette Tray.

3.2.3 CONTROLLER

At power-up, the microprocessor within the Controller performs a series of diagnostic tests to confirm the proper operation of the system. During this time, all displays and indicators are lighted and an audible tone is sounded.

When powered up, the system initializes in **Pre-Warm** Mode, the Controller will start the heater at 100% power and maintain that setting for three minutes, reduce to 60% for 12 minutes and then reduce the heater power to 30%.

When operating the Controller in the **Manual** Mode, the operator can adjust the heater power from 0 to full power in 10% increments. After 10 minutes of operation in the Manual Mode, a **Chk Patient** Alarm occurs.

Failure to acknowledge the Check Patient Alarm within the next 5 minutes will cause the heater to be turned off.

When operated in the **Baby** Mode, the Controller utilizes a Skin Temperature Probe, connected between the Controller input and the infant, to automatically adjust the heater output of the Warmer Module to maintain a digitally displayed preset **Set Temperature**.

The Apgar Timer displays the elapsed time and sounds an audible dual tone to alert the operator that 1, 5, and 10 minutes have elapsed since the timer was activated.

The **Keypad Lock** Key, when pressed, renders the Up/Down Arrows and Select Mode Keys inactive or active.

A Procedural Silence Timer prevents **Baby Temp** audible Alarms during routine procedures.

3.2.4 BLENDER MODULE (Optional)

The Blender Module provides blended oxygen from 21% to 100% to the **Patient Outlet** on the Resuscitation Module.

3.2.5 RESUSCITATION MODULE (Optional)

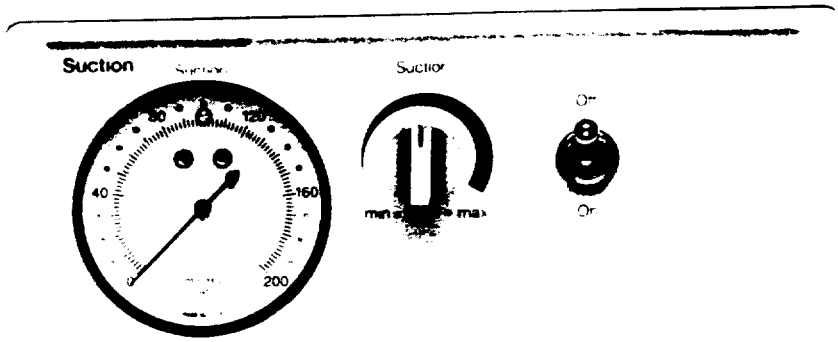
WARNING: Always monitor Airway Pressure and or/provide appropriate relief during infant resuscitation.

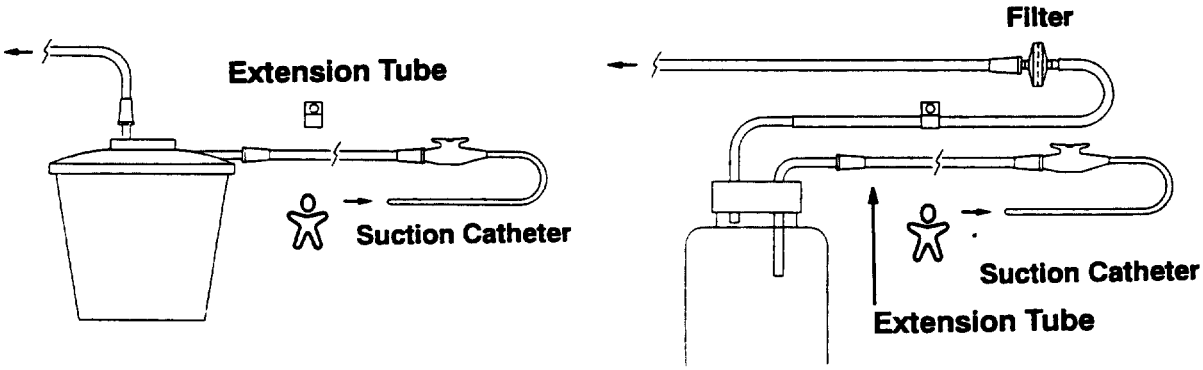
The Resuscitation Module contains pneumatic circuitry necessary for infant resuscitation. Controls and displays for the module are located above the rear of the Bassinet.

The Resuscitation Module is provided with AutoBreath or without AutoBreath and consists of the following factory installed components:

- **Suction** - The **Suction** Circuit is driven by a gas powered venturi actuated vacuum generator which provides a negative pressure for suctioning the patient's airway. The suction pressure is indicated on the **Suction** Gauge (Figure 3.1). Suction may be adjusted using the

Suction Control and turned on or off using the **On/Off** Switch. A fixed internal relief valve limits the maximum suction pressure to 150 mmHg.





Note: Disposable bottle has built-in filter

FIGURE 3.1 SUCTION FUNCTIONAL BLOCK DIAGRAM

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RESUSCITATION MODULE WITH AUTO-BREATH (FACTORY INSTALLED OPTION)

- **AutoBreath**

The **AutoBreath** Circuit is a gas-powered, time-cycled, continuous flow, pressure limited resuscitator. It has a **Rate (BPM)** Control and a fixed I/E ratio of 1:2 nominal. An **On/Off** Switch allows the timing circuit to be turned on and off as needed. A **PEEP** Control adjusts the Positive End Expiratory Pressure in the patient circuit. The resuscitator is utilized in conjunction with the continuous gas flow provided by the **Patient Supply** sub-module.

WARNING: An airway pressure disconnect monitor should be used if the AutoBreath Infant Resuscitator is to be used unattended.

- **Patient Gas Supply**

The **Patient Gas Supply** Circuit may be used with the **AutoBreath** Infant Resuscitator on or off to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet**

The **Aux Outlet** circuit supplies 100% oxygen through the **Aux Flow (LPM)** Control to the **Aux Outlet** Connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother, or a second neonate, i/e., twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 kPa).

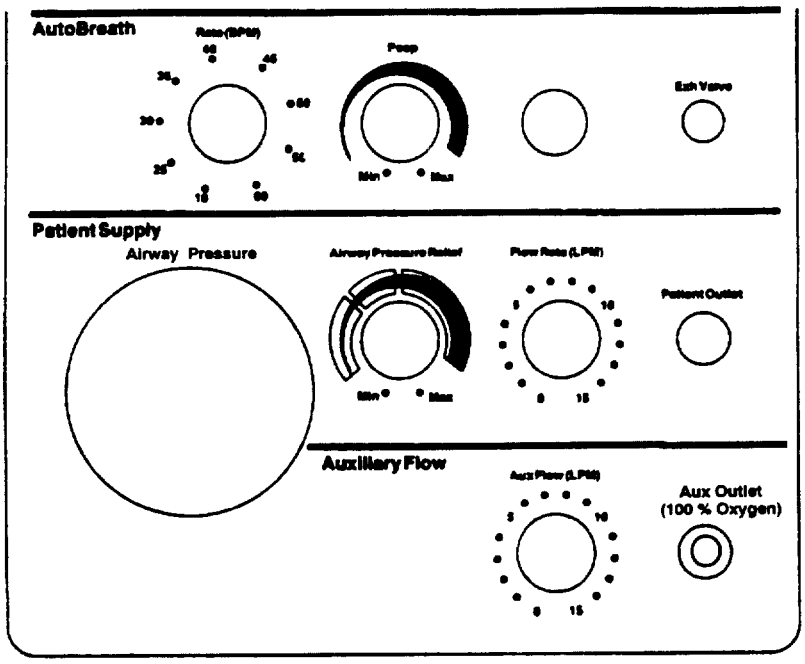

FIGURE 3.2 RESUSCITATION MODULE WITH AUTOBREATH, PATIENT GAS SUPPLY AND AUXILIARY FLOW

- **Patient Breathing Circuits**

The patient breathing circuit used in conjunction with the AutoBreath Infant Resuscitator is illustrated in Figure 3.3. In addition, a patient supply circuit for Manual Bagging (Figure 3.4) may also be used.

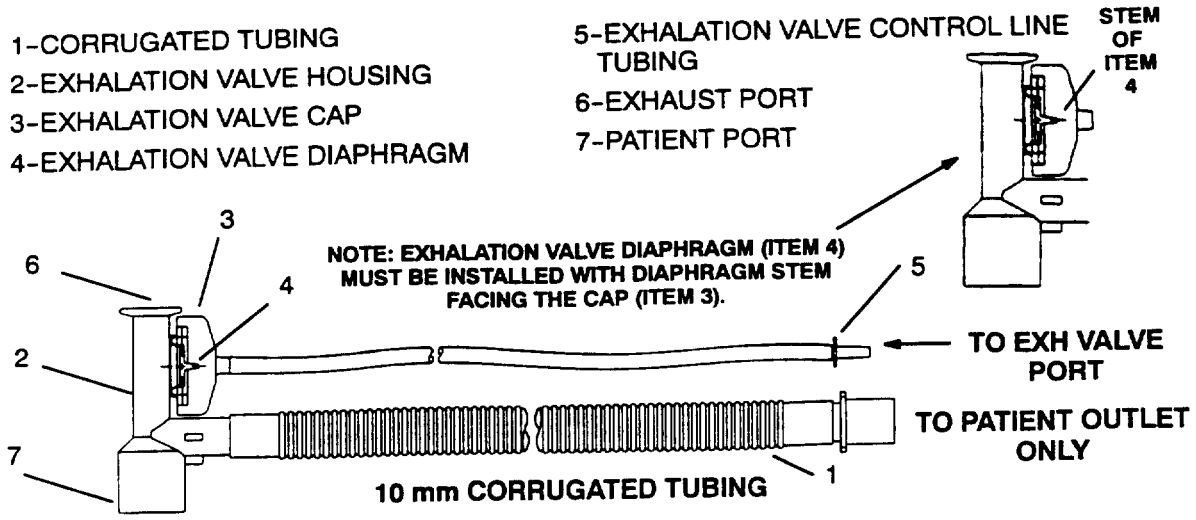

FIGURE 3.3 PATIENT BREATHING CIRCUIT FOR AUTOMATIC VENTILATION

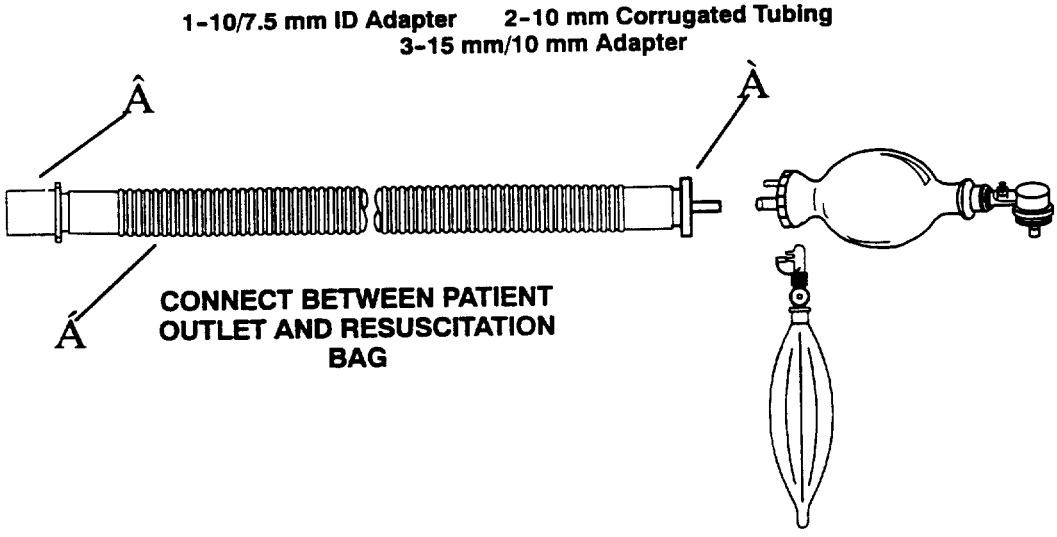

FIGURE 3.4 PATIENT BREATHING CIRCUIT FOR MANUAL BAGGING

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RESUSCITATION MODULE WITHOUT AUTOBREATH (FACTORY INSTALLED OPTION)

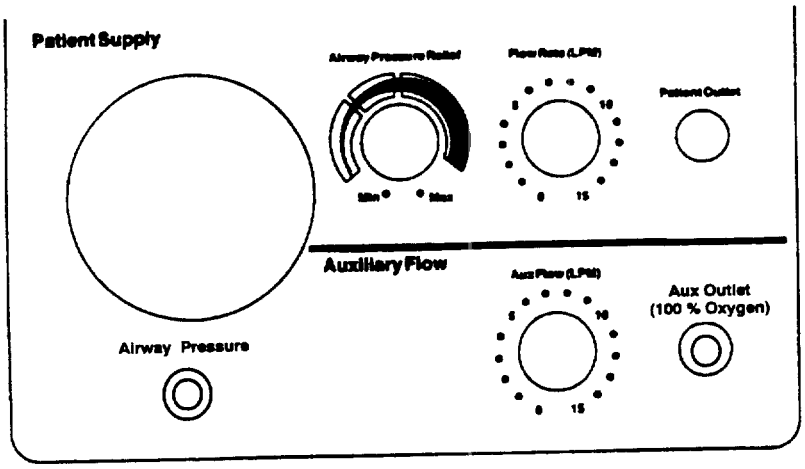

FIGURE 3.5 RESUSCITATION MODULE WITH PATIENT GAS SUPPLY AND AUXILIARY FLOW ONLY

- **Patient Outlet -**

The **Patient Gas Supply** Circuit may be used to provide continuous gas flow to the patient. Controls are provided for **Airway Pressure Relief** (maximum pressure) and **Flow Rate (LPM)** (circuit flow delivering 100% oxygen or blended gas). The adjustable **Airway Pressure Relief** Control is always operative.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 60 ± 10 cm H_2O (5.9 ± 1 kPa) and also allows the patient to inspire room air in the event of gas supply failure.

WARNING: Breathing room air through the 2-way relief valve requires extra effort. This condition, if it occurs, should be rectified as soon as possible.

- **Aux Outlet**

The **Aux Outlet** circuit supplies 100% oxygen through the **Aux Flow (LPM)** Control to the **Aux Outlet** Connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother, or a second neonate, i.e., twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The Airway Pressure Gauge monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The patient breathing circuit used in conjunction with the Resuscitation Module without AutoBreath is illustrated in Figure 3.6. In addition, a patient supply circuit for Manual Bagging (Figure 3.4) may also be used.

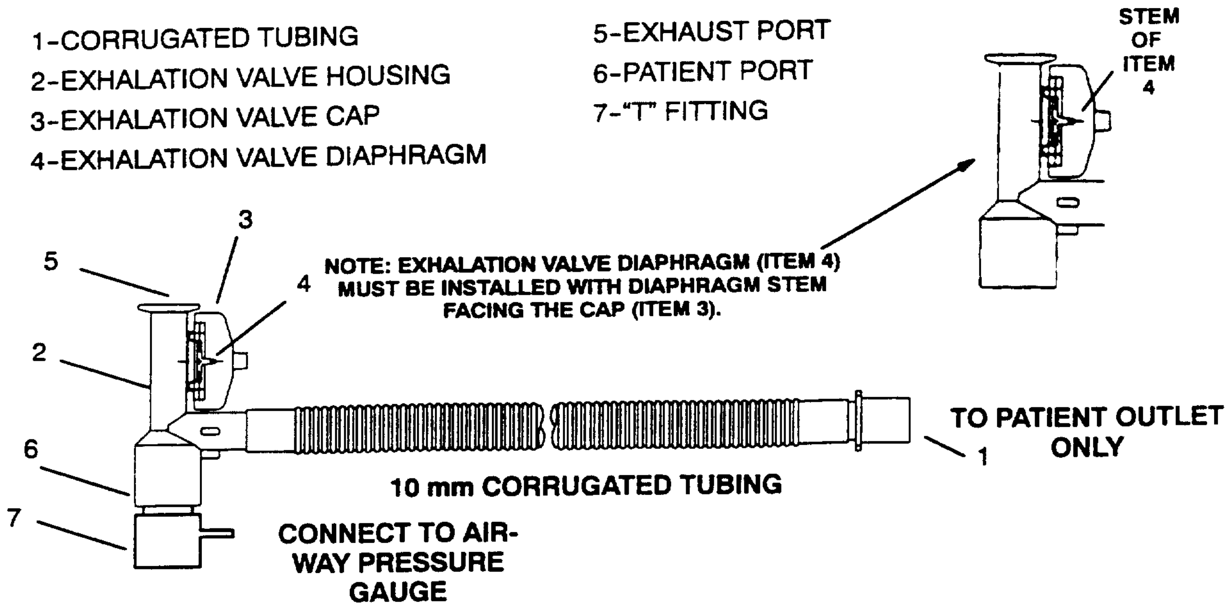

FIGURE 3.6 PATIENT BREATHING CIRCUIT FOR MANUAL VENTILATION

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GAS DELIVERY MODULE (FACTORY INSTALLED OPTION)

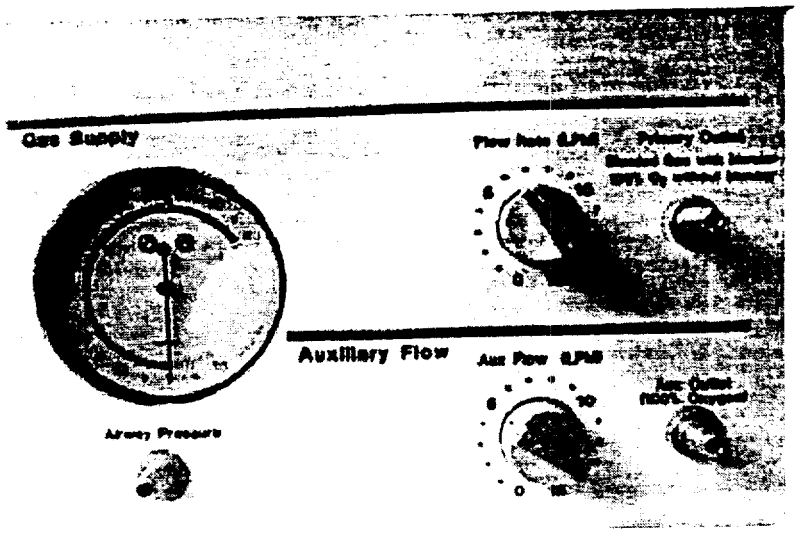

FIGURE 3.7 GAS DELIVERY MODULE WITH PRIMARY GAS SUPPLY AND AUXILIARY FLOW ONLY

- **Primary Outlet -**

The **Primary Gas Supply** circuit may be used to provide continuous gas flow to a breathing circuit. When the **Blender** module is included in the system, the **Primary Outlet** provides 0 to 15 lpm of O2/air mixture selected by the operator. When no **Blender** module is included in the system, the **Primary Outlet** provides 0 to 15 lpm of O_2 selected by the operator. The **Flow Rate (LPM)** control is a calibrated dial type flow adjustment.

A fixed internal safety relief valve is also provided and is also always operable. This valve provides redundant maximum pressure relief at 160 ± 10 cm H_2O (15.9 ± 1 kPa).

WARNING: Always use a breathing circuit or mask equipped with a pressure limiting device.

- **Aux Outlet**

The **Aux Outlet** circuit supplies 100% oxygen through the **Aux Flow (LPM)** Control to the **Aux Outlet** Connector. It is intended for oxygen enrichment of a manual bag resuscitator, for supplemental delivery to the patient, the mother, or a second neonate, i.e., twins. The **Aux Flow LPM** Control adjusts the flow rate from 0 to 15 lpm. An internal pre-set relief valve limits the **AUX Outlet** pressure to 160 cm H_2O (16 ± 1 kPa).

- **Airway Pressure**

The **Airway Pressure Gauge** monitors airway pressure when connected to patient circuits via external connection.

- **Patient Breathing and Supply Circuits**

The outlet barbed fittings of the gas delivery module will attach to commercially available oxygen supply tubing or self-inflating resuscitation bag, Hill-Rom Air Shields part number 67 361 72.

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3.2.6 GAS SUPPLY MODULE

The **Gas Supply** Module includes an On/Off Switch which controls the pipeline and cylinder gas supply to the Resuscitation Module. An oxygen cylinder Pressure Gauge is provided if the oxygen cylinder option is included. Oxygen and Air Pressure Gauges are provided on units equipped with the Blender Module.

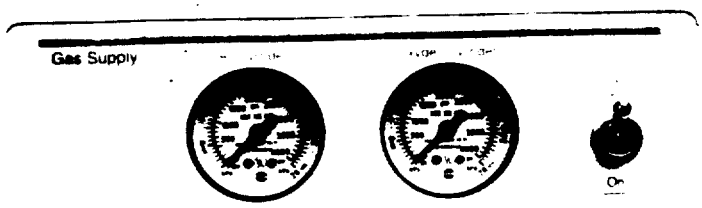

FIGURE 3.8 GAS SUPPLY MODULE

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3.2.7 ALARMS

HIGH TEMPERATURE. When the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C, the heater is automatically turned off, the **High Temp** Indicator will flash and the audible alarm will sound continuously. Press the **Silence/Reset** Key to silence the alarm for two minutes. After the alarm condition is corrected (a skin temperature of 38.5 °C or less), the alarm will automatically reset.

CHECK PATIENT. When in the **Manual** Mode the **Chk Patient** Indicator will illuminate and the alarm will sound one time after 10 minutes of operation. Thereafter, the **Chk Patient** Indicator will remain illuminated and the audible alarm will sound every 30 seconds for 5 minutes. If the alarm has not been acknowledged at the end of 5 minutes, the heater will shut down and a continuous ramping audible alarm will sound. The **Silence/Reset** Key then must be pressed to reactivate the heater.

PROBE. If the Skin Temperature Probe fails (short- or open circuited), the **Probe** Indicator will flash and a ramping audible alarm will sound. After the alarm condition is corrected (the Probe is replaced), the alarm will automatically reset.

BABY TEMPERATURE. When the temperature sensed by the Skin Temperature Probe is 1 °C above or 1°C below the selected **Set Temperature** Display setting, the **Baby Temp** Indicator will flash and a ramping audible alarm will sound. In addition, if the temperature is 0.2 °C above the selected **Set Temperature,** the heater will be turned off automatically. Press **Silence/Reset** to silence the alarm for 10 minutes.

POWER FAIL. When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. The alarm may be silenced by turning off the power switch.

IMPORTANT: *Turning off the Power switch will prevent the Controller and Heater from restarting automatically when power is returned to the unit. The settings will be retained in memory until power is restored.*

SYSTEM FAIL. If an internal malfunction is detected, the **System Fail** Indicator will flash and the audible alarm will beep. In addition, an Error Code (eR00 to eR025) will be displayed in the **Baby Temperature** Display. This alarm is not resettable and the unit should be referred to qualified service personnel. A prolonged brown-out (five minutes or more with supply voltage leas than 90% of nominal) will also cause a System Fail alarm.

3.2.8 BLENDER DIFFERENTIAL BYPASS ALARM (Optional)

The blender Module (factory installed option) will alarm and bypass whenever the pressure differentail between the O_2 and air supplies exceeds 30 psi ± 2 psi. When this condition occurs, the blender will continue to supply whichever gas is the higher pressure: either 100% Air or 100% Oxygen. This is an audilble alarm only. There are no visual indicators.

3.2.9 APGAR TIMER

When the **Apgar Timer** is running, the Apgar Timer Display will show elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar time intervals.

SECTION 4
OPERATION

4.1 CONTROLS, INDICATORS AND CONNECTORS

Controls, Indicators and Connectors for the Controller are presented in Figures 4.1 and 4.2 and Tables 4.1 and 4.2. Controls, Indicators and Connectors for the Resuscitation Module are presented in Figure 4.3 and Table 4.3.

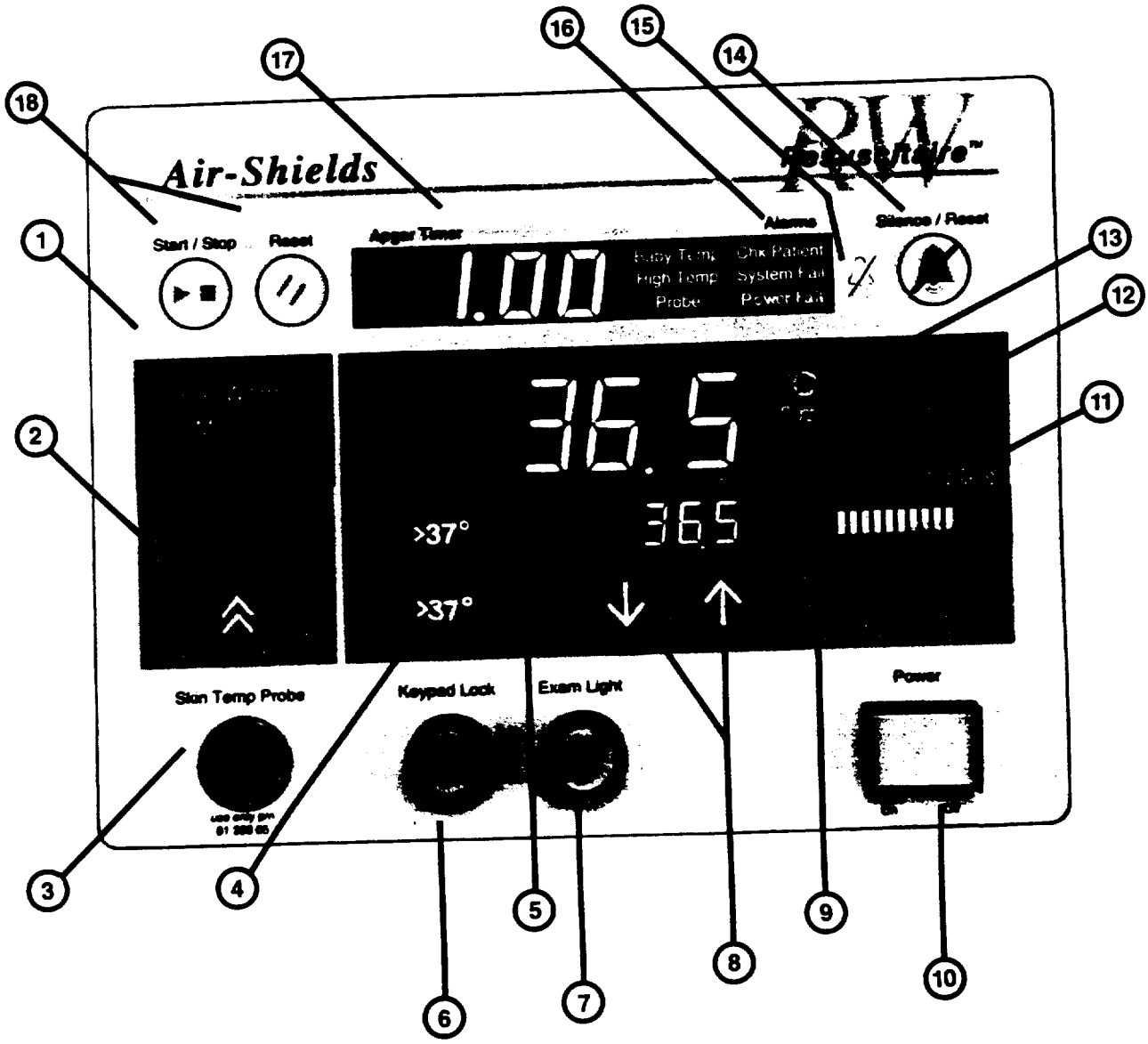

FIGURE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	**Mode**	
	Pre-Warm Indicator	Indicates that the Controller is operating in the **Pre-Warm Mode**.
	Manual Indicator	Indicates that the Controller is operating in the **Manual Mode**.
	Baby Indicator	Indicates that the Controller is operating in the **Baby Mode**.
2	**Mode** Select Key 	Press to select either **Pre-Warm, Manual** or **Baby Mode** of operation.
3	**Skin Temp Probe** Connector	Accepts Skin Temperature Probe for monitoring infant skin temperature. When connected, the **Baby Temperature** Display indicates the temperature sensed by the probe. When probe is disconnected, the **Baby Temperature** Display is blank. When disconnected in **Baby** Mode, a **Probe** Alarm also occurs.
4	**>37 °C** Key 	Press to place **Set Temperature** Display (refer to Item 9) in Temperature Override Mode, >37 °C (98.6 °F). ***NOTE:*** *This Key is inactive until the **Set Temperature** has been set to 37 °C.*
5	**>37 °C** Indicator	Lights to indicate that the Temperature Override Mode, >37 °C (98.6 °F), has been selected.
6	**Keypad Lock** Key 	Press to disable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys (refer to Items 2, 4 and 8). Press again to enable the **>37 °C**, Up/Down Arrow and **Mode** Select Keys. Key lights to indicate that Keypad is locked.
7	**Exam Light** Key 	Press to turn on or turn off the Examination Light located in the Warmer Module.
8	 	**Manual Mode** Press the Up Arrow Key to raise heater power from 0% to 100% in 10% increments (refer to Item 11, **Heater Power** Display). Press the Down Arrow Key to lower relative heater power from 100% to 0% in 10% increments (refer to Item 11, **Heater Power** Display).

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
8		**Baby Mode** Press the Up Arrow Key to raise the Set Temperature from 34.0 °C (93 °F) to 37.0 °C (98.6 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to raise the Set Temperature from 37.0 °C (98.6 °F) to 38.0 °C (102.2 °F). Press one time to raise the Set Temperature in 0.1° increments. Press and hold to raise the Set Temperature rapidly. Press the Down Arrow Key to lower the Set Temperature from 37.0 °C (98.6 °F) to 34.0 °C (93 °F). In the Temperature Override Mode (refer to Items 4 and 5), press to lower the Set Temperature from 38.0 °C (102.2 °F) to 34.0 °C (93 °F). Press one time to lower the Set Temperature in 0.1° increments. Press and hold to lower the Set Temperature rapidly. ***NOTE:*** *The Up/Down Arrow Keys may be locked by pressing the Keypad Lock Key (refer to Item 6).*
9	**Set Temperature** Display	In **Baby Mode,** displays the **Set Temperature** as selected by the Up/Down Arrow Keys (refer to Item 8) and in °C or °F as selected by the **°C/°F** Key (refer to Item 12). Display is blank in **Pre-Warm** and **Manual** Modes.
10	**Power** Key 	Press to turn on or turn off the Controller and Warmer Module.
11	**Heater Power** Display	Displays relative heater power in 10% increments from 0% to 100%.
12		Press to alternately select °C or °F for the **Baby Temperature** and **Set Temperature** Displays.
13	**Baby Temperature** Display	Digital display of infant temperature in °C or °F (refer to Item 12), whether in **Manual, Pre-Warm** or **Baby Mode.** The display is blank if the Skin Temperature Probe (refer to Item 3) is disconnected from the Controller.

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS, INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
14	**Silence/Reset** Key 	In **Manual Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Resets **Chk Patient** (refer to Item 16), restores heater power and silences Audible Alarm at any time after 10 minutes of warmer operation. Resets **Chk Patient** (refer to Item 16), silences Audible Alarm and restores heater power after15-minutes of continuous operation is complete. In **Baby Mode** Press to silence the **High Temp** Alarm (refer to Item 16) for 2 minutes. Press to silence **Baby Temp** (refer to Item 16) Alarm for 10 minutes. During non-alarm conditions, press to enter Procedural Silence (refer to Item 15).
15	**Procedural Silence** Indicator 	When illuminated, indicates that the unit is in Procedural Silence. Procedural silence interval is 5 minutes. During Procedural Silence, the **Baby Temp** Alarms are blocked.
16	**Alarms** **Baby Temp**	The **Baby Temp** Indicator will flash with a three-level audible alarm to indicate that the baby's skin temperature is 1 °C above or below the selected Set Temperature (refer to Item 9). Press **Silence/Reset** Key to silence alarm for 10 minutes.
	High Temp	The **High Temp** Indicator will flash, the audible alarm will sound continuously, and the heater will be turned off when the Skin Temperature Probe is attached to the infant and the skin temperature exceeds 39.0 °C. High Temp (39.0 °C) Alarms can only be silenced for two minutes by the Silence/Reset Key. Press the **Silence/Reset** Key to silence the audible alarm for 2 minutes. When the temperature falls to 38.5 °C, the alarm will automatically reset.
	Probe	When in **Baby Mode**, if the Skin Temperature Probe fails (open probe), the **Probe** Indicator will flash and a three-level audible alarm will sound. After the Alarm condition is corrected (the Skin Temperature Probe is replaced), the alarm will automatically reset. Also refer to Table 5.1. When in **Baby Mode**, if the Skin Temperature Probe fails (shorted probe), the **System Fail** Indicator will light and an audible alarm will sound. This Alarm cannot be Silenced. The **Power MUST BE TURNED OFF then ON** to Reset the Alarm condition.

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TABLE 4.1 CONTROLLER FRONT PANEL: CONTROLS INDICATORS AND CONNECTORS (cont.)

ITEM	NAME	DESCRIPTION
16	**Alarms (Cont.)** **Chk Patient**	When in the **Manual** Mode, if the warmer is in operation for longer than 10 minutes, the **Chk Patient** Indicator will illuminate and the audible alarm will sound one time. Thereafter, the **Chk Patient** Indicator will remain on and the audible alarm will sound every 30 seconds for the next 5 minutes. If at the end of 5 minutes (15 minutes total) the alarm has not been acknowledged by pressing the **Silence/Reset** Key (refer to Item 14), the warmer will be shut down.
	System Fail	When an internal malfunction is detected, the **System Fail** Indicator will illuminate and the audible alarm will sound continuously. In addition, an Error Code (Er00 to Er025) will be displayed in the **Baby Temperature** Display. When a malfunction is detected, the Controller will automatically perform the self-test function (refer to para. 4.2 Step 3) to determine if the fault has corrected itself. If the fault has not corrected itself, the error code will be displayed until corrected. This alarm is not resettable and the unit should be referred to qualified service personnel. ***NOTE:*** *Error code 023 may be corrected by the Operator, refer to Table 5.1.*
	Power Fail	When power to the unit is interrupted while the Controller is on, the **Power Fail** Indicator will flash and the audible alarm will beep. When power is restored to the unit, the alarm will automatically reset. Push the **Power** Key to silence the Alarm.
17	**Apgar Timer**	When the **Apgar Timer** (refer to Item 18) is running, the Apgar Timer displays elapsed minutes and seconds and the audible alarm will sound at the 1-, 5- and 10-minute Apgar Time intervals.
18	**Stop/Start** 	Press to start or stop the **Apgar Timer.**
	Reset 	When timer is running, press to reset the timer to zero and restart the Apgar count. When timer is stopped, press to turn timer off. ***NOTE:*** *The Timer can be reset any time.*

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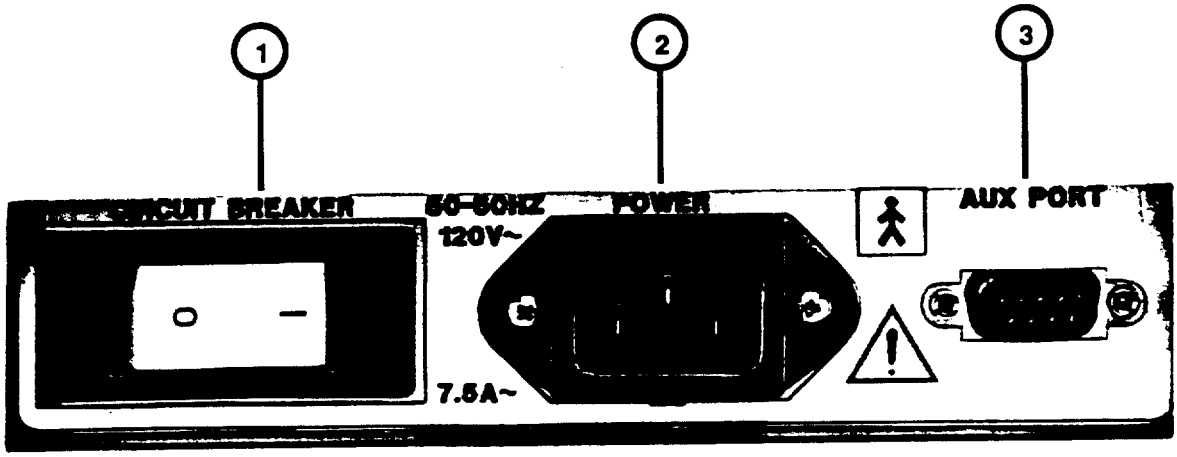

FIGURE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

TABLE 4.2 CONTROLLER REAR PANEL: CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	CIRCUIT BREAKER	Turns Controller on and off when switched by operator or the presence of excessive current drain is detected.
2	POWER	Accepts ac power cord. Accepts 40-inch power cord on VHA units
3	AUX PORT	Data port for connection to printer or host system.

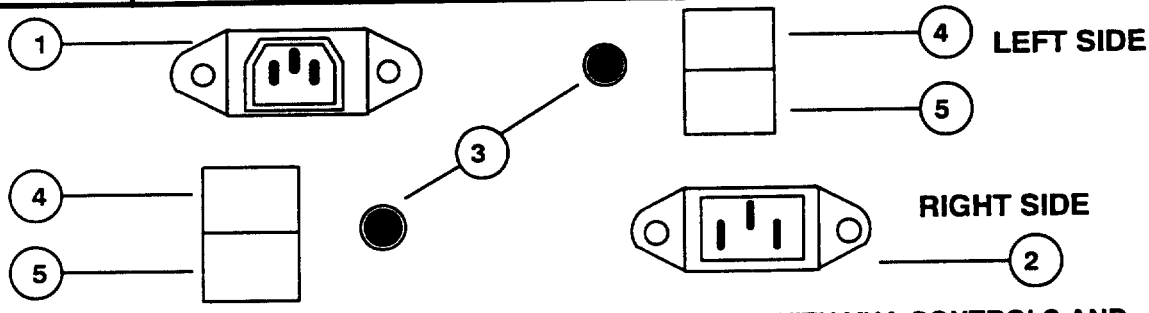

FIGURE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS LOCATED ON BOTH SIDES OF LOWER POST

TABLE 4.2A RESUSCITAIRE® RADIANT WARMER WITH VHA CONTROLS AND CONNECTORS

ITEM	NAME	DESCRIPTION
1	POWER OUT	Accepts 40-inch ac power cord.
2	POWER IN	Accepts ac power cord.
3	CIRCUIT BREAKER	Turns Actuator off when presence of excessive current drain is detected. Press to reset.
4	UP SWITCH	Press to raise Upper Post
5	DOWN SWITCH	Press to lower Upper Post

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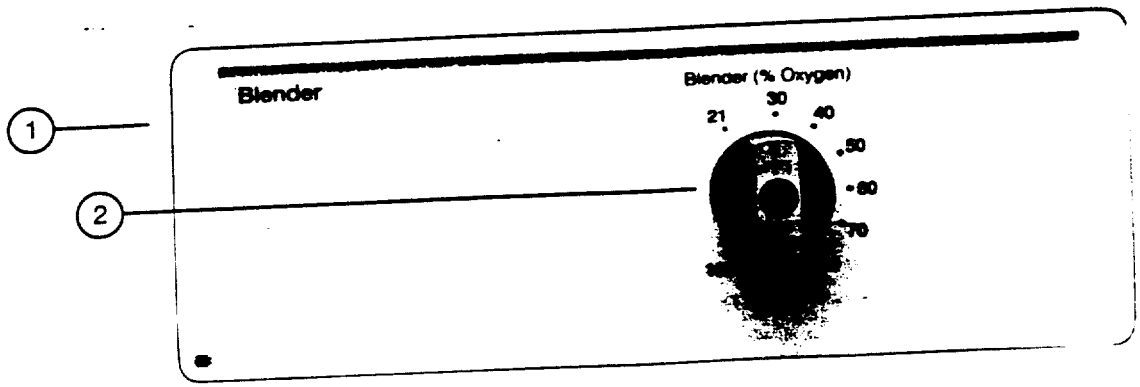

FIGURE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

TABLE 4.3A BLENDED GAS SUPPLY MODULE CONTROL

ITEM	NAME	DESCRIPTION
1	**Blended Gas Supply Module (Optional)**	Blends air and oxygen mixture from 21 to 100% O_2.
2	**Blender % Oxygen** Control	

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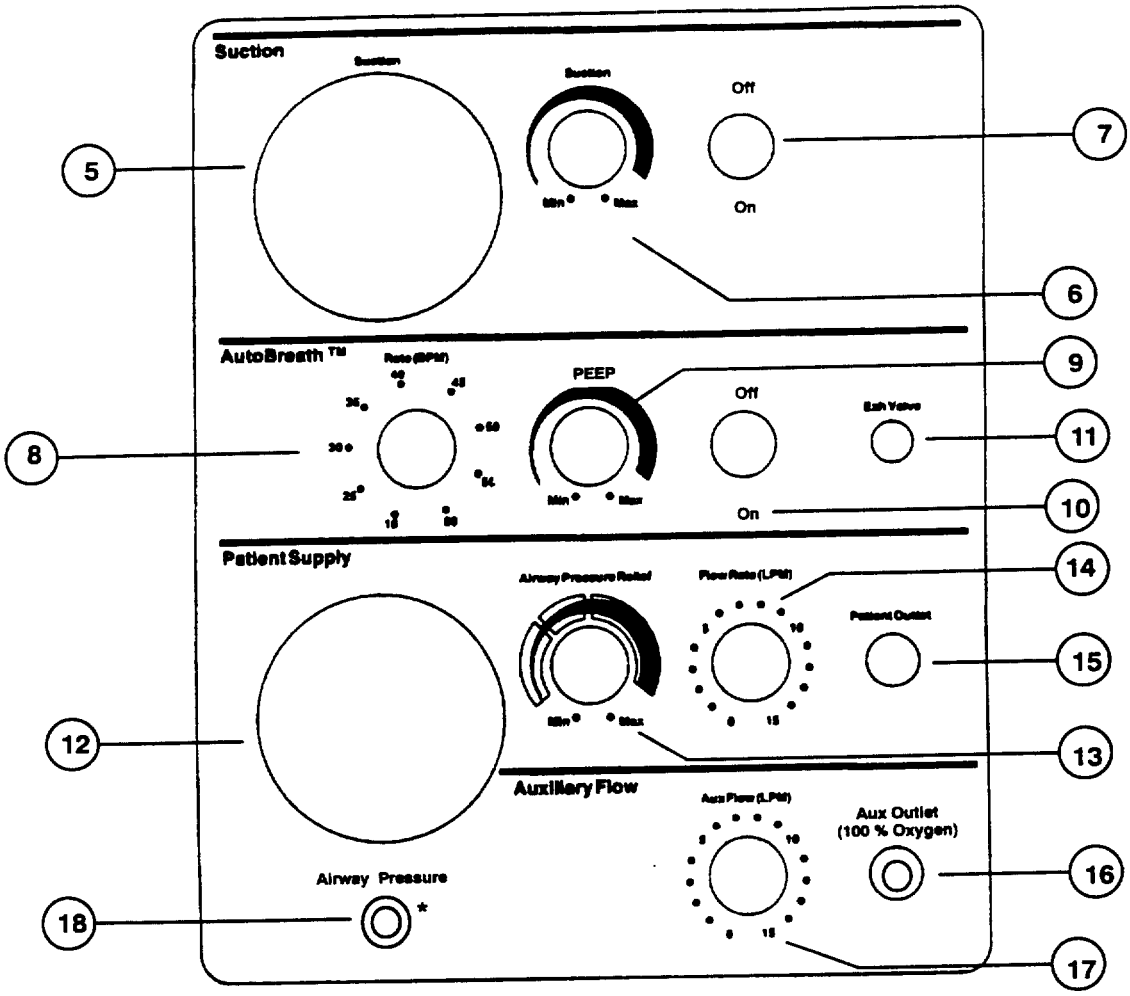

*Not Mounted On Units equipped with AutoBreath.

FIGURE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

TABLE 4.3B RESUSCITATION MODULE: CONTROLS, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	Suction	
5	**Suction** Gauge	Displays suction level from 0 to 200 mmHg of vacuum.
6	**Suction Min Max** Control	Adjusts suction level from 0 to 150 mmHg of vacuum.
7	**On/Off** Switch	Turns **Suction** on and off.
	AutoBreath	
8	**Rate (BPM)** Control	Adjusts breath frequency from 18 to 60 breaths per minute.
9	**PEEP min max** Control	Adjusts positive end expiratory pressure from 0 to 18 cm H_2O.
10	**On/Off** Switch	Turns **AutoBreath** Infant Resuscitator on and off (including **PEEP**).
11	**Exh Valve**	Accepts exhaust valve line of patient circuit for expiratory valve control.
	Patient Supply	
12	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.
13	**Airway Pressure Relief Min Max** Control	Adjusts airway pressure relief setting from 0 to 50 cm H_2O.
14	**Flow Rate (LPM)** Control	Adjusts patient gas flow from 0 to 15 LPM. Delivers blended gas if blender option is incorporated.
15	**Patient Outlet** Connector	**Accepts breathing circuit.**
	Auxiliary Flow	
16	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
17	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
18	**Airway Pressure Port**	Connects Airway Pressure Gauge to Patient Circuit. Not Mounted on Units equipped with AutoBreath.

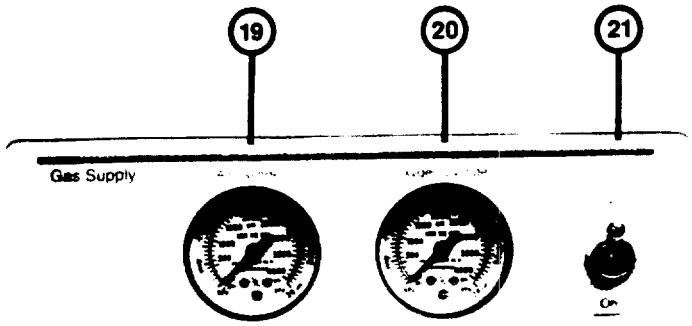

FIGURE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

TABLE 4.3C GAS SUPPLY MODULE: CONTROLS AND INDICATORS

ITEM	NAME	DESCRIPTION
	Supply Pressure (Optional)	
19	**Air Cylinder** Gauge	Provides indication of air cylinder supply pressure 0 to 4000 psi (275.8 bar).
20	**Oxygen Cylinder** Gauge	Provides indication of oxygen cylinder supply pressure 0 to 4000 psi (275.8 bar).
21	**Gas Supply On/Off** Switch	Turns gas supply to pneumatic system on and off.

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FIGURE 4.3D GAS DELIVERY MODULE CONTROL, INDICATORS AND CONNECTORS

TABLE 4.3D GAS DELIVERY MODULE CONTROL, INDICATORS AND CONNECTORS

ITEM	NAME	DESCRIPTION
	<u>Primary Flow</u>	
22	**Primary Outlet**	Accepts primary gas delivery line. Delivers blended gas if blender option option is installed: 100% oxygen if no blender installed
23	**Flow Rate (LPM)** Control	Adjusts primary gas flow from 0 to 15 LPM.
	<u>Auxilliary Flow</u>	
24	**Aux Outlet 100% Oxygen** Connector	Accepts auxiliary gas delivery line.
25	**Aux Flow (LPM)** Control	Adjusts auxiliary patient gas flow from 0 to 15 LPM.
26	**Airway Pressure Port**	Connects Airway Pressure Gauge to Patient Circuit. Not Mounted on Units equipped with Auto-Breath.
27	**Airway Pressure** Gauge	Displays airway pressure from -10 to + 80 cm H_2O.

4.2 OPERATIONAL CHECKOUT PROCEDURE - CONTROLLER

WARNING: The Warmer should not be used if the Controller fails to function as described below. Service should be referred to qualified personnel.

CAUTION: **HEAVY EQUIPMENT: To prevent injury or damage to the Warmer, two persons of sufficient strength are recommended to adequately control the Warmer during transport.**

IMPORTANT: Before attempting to perform this procedure, refer to Paragraph 4.1, Controls, Indicators and Connectors.

NOTE: The Operational checkout procedure described below should be performed before the equipment is first put into service, then at least weekly.

1. **CONNECT THE AC LINE CORD TO THE POWER CONNECTOR** on the Controller Rear Panel.

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

2. **CHECK THE POWER FAILURE ALARM.** Turn off the **CIRCUIT BREAKER** on the Rear Panel. Turn on the **Power** Switch on the Front Panel. The **Power Fail** Indicator should come on and the Audible alarm should sound. Turn off the **Power** Switch and turn on the **CIRCUIT BREAKER.**

*NOTE: The unit must be connected to the ac line for at least eight minutes before the **Power Fail** circuitry becomes active.*

3. **CHECK THE SELF-TEST FUNCTION.** Turn on the **Power** Switch, the Self-Test Function should be initiated and the following should occur:
   - **Apgar Timer, Baby Temperature** and **Set Temperature** Digital Displays show all eights
   - All **Alarms** Indicators light (except **Power Fail**)
   - All **Mode** Indicators light
   - The **> 37 °C** Indicator lights
   - All ten segments of the **Heater Power** Indicator light
   - The Procedural Silence Indicator lights
   - The **Keypad Lock** Switch lights
   - The audible alarm will sound a high pitch tone, a low pitch tone, then a beep-beep-beep

   When the Self-Test Function is complete, the Controller should begin operating in the **Pre-Warm Mode**.

4. **CHECK THE PRE-WARM MODE.** The **Pre-Warm** Indicator should be on and the **Heater Power** Indicator should display 10 segments (100%) for three minutes, reduce to 6 segments (60%) for 12 minutes, then reduce to 3 segments (30%).

5. **CHECK THE MANUAL MODE.** Select **Manual Mode** by pressing the **Mode** Select Key. The **Manual** Indicator should light.

   Press the Up Arrow Key until all the **Heater Power** Display segments are lit. Press the Down Arrow key until all the **Heater Power** Indicators are off. Connect the skin temperature probe to the **Skin Temp Probe** Connector, the **Baby Temperature** Display should come on.

   Set the **Heater Power** Indicator to 100%, all segments are lit. Wait 10 minutes. After 10 minutes have elapsed, the **Chk Patient** Indicator should come on and the audible alarm should sound one time. Wait an additional 5 minutes. During this time, the audible alarm should sound at 30-second intervals. At the end of 5 minutes (15 total), the heater should shut down, the **Heater Power** Indicators should go off and the audible alarm should sound continuously and ramp up in volume. Press the **Silence/Reset** Key, the **Chk Patient** Indicator and audible alarm should go off, the heater power should return and all ten **Heater Power** Indicators should illuminate.

6. **CHECK THE KEYPAD LOCK.** Press the **Keypad Lock** Switch. The **Keypad Lock** Switch should light up. The **Mode** Key and the Up/

Down Arrow Keys Key should be inoperative. Press the Keypad Lock Switch. The **Keypad Lock** Switch Light should go off and the Keypad should be enabled.

7. **CHECK THE BABY MODE.** Select **Baby Mode** by pressing the Mode Select Key. The **Baby** Indicator should light and the **Set Temperature** Display should activate. In addition, the **Baby Temp** Indicator should flash and the audible alarm should sound (if the temperature and set point are more than 1° C apart) Press the **Silence/Reset** Key, the audible alarm should go off, the **Baby Temp** Indicator should become steady on.

8. **CHECK TEMPERATURE OVERRIDE MODE.** Press the Up Arrow Key to raise the **Set Temperature** to 37.0 °C. Press the **>37 °C** Key, the **>37 °C** Indicator should come on. Press the Up Arrow Key to raise the **Set Temperature** to 38.0 °C.

   Press the Down Arrow Key to lower the **Set Temperature** to below 37.0 °C. When the **Set Temperature** falls below 37.0 °C, the **>37 °C** Indicator should go off.

9. **CHECK THE PROBE ALARM.** Disconnect the skin temperature probe from the **Skin Temp Probe** Connector. The **Baby Temperature** Display should go off, the **Probe** Indicator should flash and the audible alarm should sound. Replace the probe.

10. **CHECK THE APGAR TIMER.** Press the **Start /Stop** Key, the **Apgar Timer** Display should come on and begin to count up from zero seconds. Press the **Start/Stop** Key, the **Apgar Timer** count should stop. Press the **Reset** Key, the **Apgar Timer** Display should go off.

11. **CHECK THE EXAMINATION LIGHT.** Press the **Exam Light** Switch. The Examination Light should come on. Press the Exam Light Switch, the Examination Light should go off.

4.3 MECHANICAL CHECKOUT

1. **CHECK THE MATTRESS TILT CONTROL** (Figure 4.4) by pulling up on the lever located at the bottom rear of the Bassinet while supporting the rear lower edge of the Bassinet with the palm. Place the Bassinet in the 5-degree and then the 10-degree tilt position. Return the Bassinet to the level position.

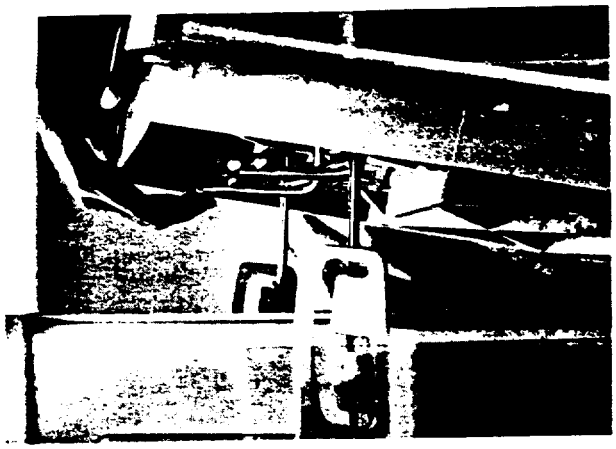

FIGURE 4.4 BASSINET TILT CONTROL

2. **CHECK THE BASSINET SIDE PANELS** (Figure 4.5) by raising each panel and pivoting it to hang straight down. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

FIGURE 4.5 CHECKING THE BASSINET SIDE PANELS

3. **CHECK THE BASSINET FRONT PANEL** (Figures 4.6 and 4.7) by raising the panel and and sliding it under the mattress. Return the panel by reversing the procedure. Check that the panel is positively engaged to confine the infant.

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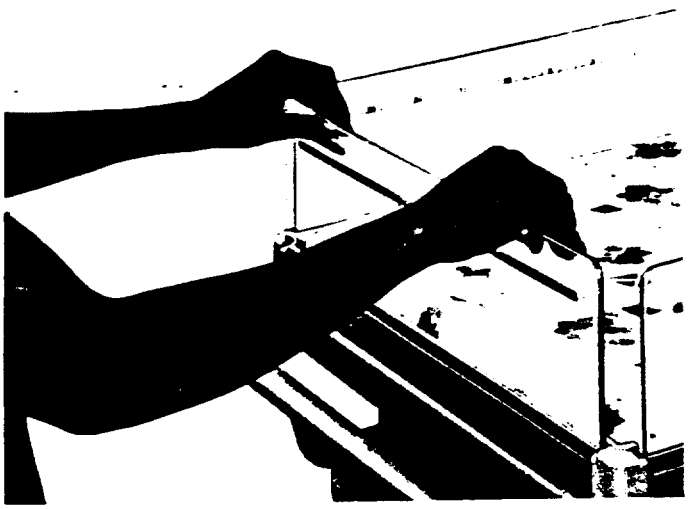

FIGURE 4.6 CHECKING THE BASSINET FRONT PANEL

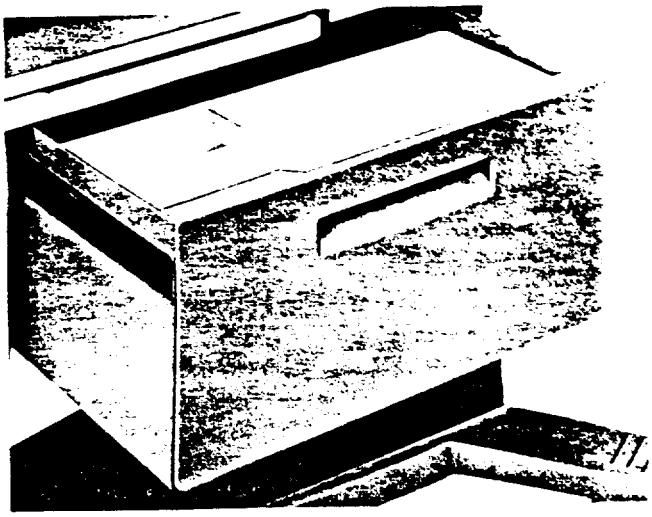

FIGURE 4.8 CHECKING THE PASS–THROUGH DRAWER

5. **CHECK THE WARMER MODULE SWIVEL OPERATION** (Figure 4.9) by rotating the Warmer Module 90 degrees to the left or right of center. Return to center position.

WARMING: When the Warmer Module is swiveled and energized, objects (Monitors etc.) located on the optional Monitor Shelf may overheat or become hot to the touch.

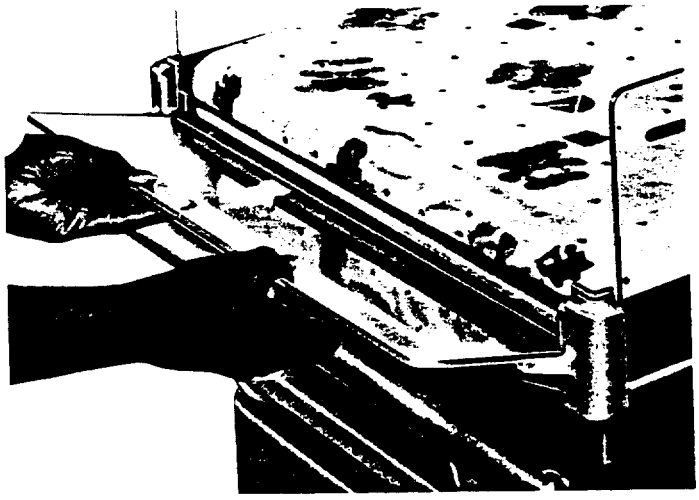

FIGURE 4.7 CHECKING THE BASSINET FRONT PANEL

4. **CHECK THE PASS–THROUGH DRAWER** (Figure 4.8) by sliding the drawer in and out on both sides of the Bassinet. Return to center position.

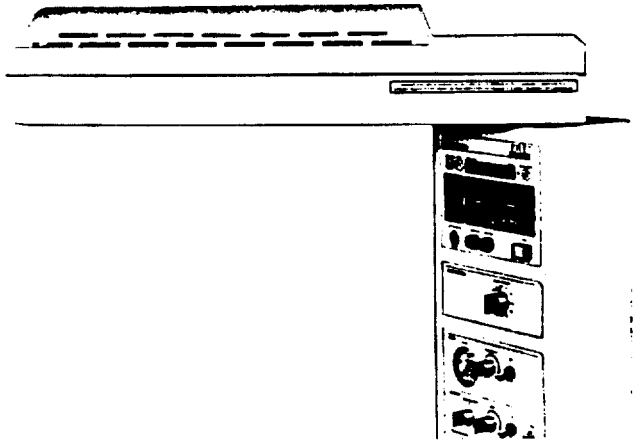

FIGURE 4.9 CHECKING THE WARMER MODULE SWIVEL

6. **CHECK THE OPERATION OF THE X-RAY CASSETTE TRAY (ACCESSORY)** (Figure 4.10) by pulling up the middle of a Side Panel and pulling the X-ray Cassette Tray out from under the Bassinet. Replace the X-ray Cassette Tray by reversing the procedure.

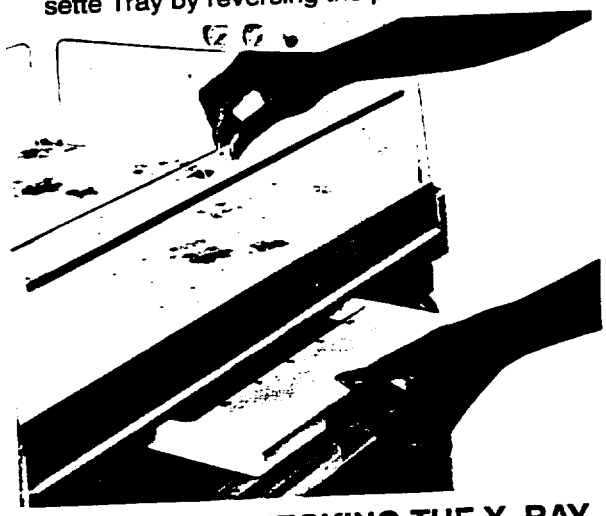

FIGURE 4.10 CHECKING THE X-RAY TRAY

7. **CHECK THE INSTRUMENT TRAY (ACCESSORY)** (Figure 4.11) by swinging it out from under the Bassinet.

FIGURE 4.11 CHECKING THE INSTRUMENT TRAY

8. **CHECK THE VHA** by pressing the upper portion of the Switch on the right side of the Lower Post until the Upper Post raises to its maximum height. Press and hold the lower portion of the Switch until the Upper Post lowers to its minimum height. Repeat the procedure using the Switch on the left side of the Lower Post. Verify the Upper Post operates smoothly and re-adjust to desired height.

CAUTION: Always lower the Resuscitaire® Radiant Warmer VHA to its lowest position prior to transport for optimum stability. If installed, make sure that items placed on the shelves are properly secured.

9. **CHECK BASSINET TILT CONTROL Operation as follows (VHA only):**

a. Turn the Bassinet Tilt Control clockwise (Figure 4.11A) until the Bassinet Foot End is fully raised and comes to a stopl.

b. Turn the Bassinet Tilt Control counterclockwise until the Bassinet Head End is fully raised and comes to a stop.

c. Return the Bassinet to the horizontal position.

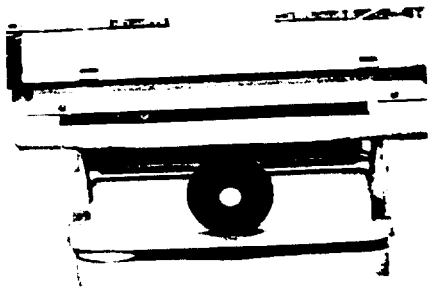

FIGURE 4.11A CHECKING THE BASSINET TILT CONTROL (VHA ONLY)

4.4 RESUSCITATION EQUIPMENT PRE-USE CHECKOUT/SET-UP

SUPPLY PRESSURE

1. Ensure that O_2 (and AIR) pipeline(s) are securely attached to appropriate fittings on the rear of the unit and that the gas supply present is 40 to 75 psi.

If using Reserve Gas Supply from cylinders:

2. Ensure that cylinder(s) are properly secured in the mounting yokes on the rear of the warmer and that the cylinder valve located on the top of the cylinder is open.
3. Examine the appropriate cylinder pressure gauges on the front of the upper column to ensure that sufficient reserve gas supply is present.

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4. Set the **Gas Supply On/Off** Switch to the **On** position.

BLENDED GAS SUPPLY (Optional)

LOW FLOW MICROBLENDER WARNINGS

- **If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 30 psi, the microblender alarm will sound. This condition significantly alters the FIO_2 and flow output from the microblender.**
- **Always operate the low flow microblender with clean/dry medical grade gases.**
- **Air inlet water filters are recommended for use with the low flow microblender.**
- **The concentration of oxygen provided and the partial pressure of oxygen within the patient's blood (PaO_2) should be monitored.**

1. If present, set the precision blender to the desired oxygen % concentration using the Blender Control Knob.

RESUSCITATION MODULE (Optional)

SUCTION

NOTE: *To obtain suction, the* ***Gas Supply On/Off*** *Switch (Figure 4.3C) must be* ***ON.***

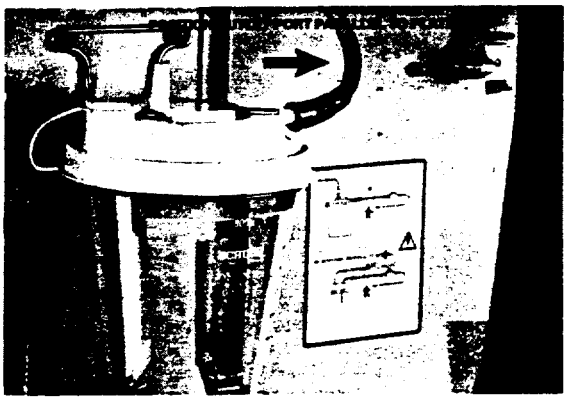
1. Check that a clean suction bottle (reusable or disposable, Figure 4.12) is installed and properly connected in the Resuscitation Equipment Storage Compartment at the front of the warmer.

CAUTION: When installing the disposable Suction Bottle: to prevent the suction tube from being blocked or damaged, position the Outlet Port parallel to the plate (Figure 4.12).

2. Ensure that a bacterial filter is connected in-line with the supply connection to the reusable suction bottle (a filter is built-in on the disposable bottle).

3. Connect the desired extension tubing to the outlet of the suction bottle outlet port (refer to Figure 3.1) and secure the free end of the extension tubing in either tubing retaining slot provided on the front panel of the Bassinet.

4. Turn on the **Suction On/Off** Switch. There may be an initial reading of up to 30 mmHg on the Suction Gauge (refer to Figure 3.1) due to flow resistance of the hydrophobic filter and suction tubing.



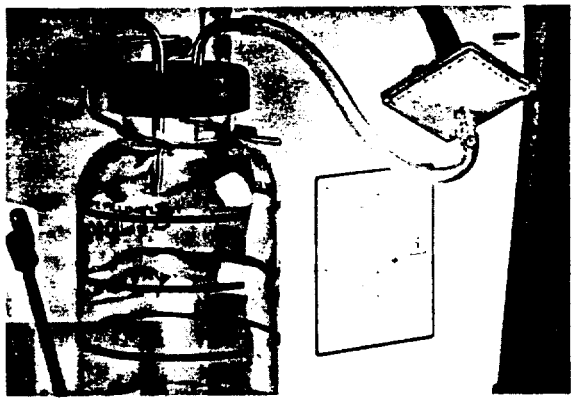


FIGURE 4.12 CHECKING THE SUCTION BOTTLE

NOTE: *The filter and tubing resistance will not affect the desired maximum value that is set in Step 5 below. The pressure value on the Suction Gauge matches the actual pressure value at the end of the catheter.*

5. Block the patient outlet of the suction bottle. Adjust the suction magnitude using the **Suction Min Max** Control while viewing the suction level on the **Suction** Gauge. Adjust the suction magnitude to the desired maximum suction pressure value.
6. Turn off the **Suction On/Off** Switch.

RESUSCITATION MODULE WITHOUT AUTO-BREATH (Optional)

Manual Resuscitation - Use with Patient Breathing Circuit - 10 mm tubing with thumb (finger) hole at patient end.

WARNING: Excessive airway pressure can cause damage to patient's lungs. Always monitor airway pressure and/or provide appropriate pressure relief during resuscitation.

WARNING: For prolonged ventilation, use of a heat and moisture exchanger is recommended.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Connect the Patient Circuit to the **Patient Outlet** (refer to Figure 3.3).
2. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
3. Set the **Airway Pressure Relief** control to the desired pressure limit according to the color coded bands on the **Airway Pressure** Gauge and **Airway Pressure Relief** Control. Alternately, a "T" Fitting with an airway pressure monitor can be inserted into the **Patient Outlet** Port and connected to the **Airway Pressure** Port to indicate the breathing circuit pressure. Adjust the **Airway Pressure Relief** Control as necessary.

RESUSCITATION MODULE WITH AUTO-BREATH (Optional)

Automatic Resuscitation (Resuscitation Module with **AutoBreath** Infant Resuscitator Only) - Use with Automatic Patient Circuit -15 mm tubing with exhalation valve and exhalation valve control line tubing.

WARNING:
Excessive air pressure can cause damage to patient's lungs.
For prolonged ventilation, use of a heat and moisture exchanger is recommended.
For unattended auto ventilation use patient airway monitor.

There are potential hazards associated with the delivery of supplemental oxygen. If it is necessary to administer oxygen, the attending physician should be notified immediately.

1. Turn the **AutoBreath** Infant Resuscitator circuit off using the **On/Off** Control.
2. Connect the Patient Circuit for Automatic Breathing to the **Patient Outlet** Connector and the exhalation valve control line tubing to the **Exh Valve** Connector (refer to Figure 3.2).
3. Adjust the flow rate to the desired fresh gas flow rate using the **Patient Supply Flow Rate (LPM)** Control.
4. Check the fixed internal **Airway Pressure Relief** Control by setting the desired Airway Pressure Limit and blocking the exhalation valve port exhaust and the patient port of the Exhalation Valve.
5. Observe the **Airway Pressure** Gauge to check pressure limit.
6. Turn on the **AutoBreath** Infant Resuscitator circuit.
7. Adjust the **Rate (BPM)** Control to 18 breaths per minute.
8. Set the **PEEP** threshold by blocking the patient port of the Patient Breathing circuit. Do not block the exhalation valve exhaust port. Observe the Positive End Expiratory Pressure indicated on the **Airway Pressure** Gauge and adjust the desired PEEP using the **PEEP** Control.
9. Check the I:E ratio by measuring the Inspiratory and Expiratory Phase Times and dividing the Expiratory Phase Time by the Inspiratory Phase Time. The result should be approximately 2.0.
10. Check the desired Breath Rate by counting the number of breath cycles per minute.

AUXILIARY FLOW (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the **Auxiliary Flow** circuit to the **Aux Outlet** Connector.
2. Adjust the desired Auxiliary Flow using the **Aux Flow (LPM)** Control and check for flow.

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PRIMARY FLOW (provides blended gas if optional blender is installed; 100% oxygen if no blender is installed)

1. Connect the desired device to be supplied by the **Primary Flow** circuit to the **Primary Outlet** connector.

2. Adjust desired primary flow using the Primary **Flow Rate (LPM)** control and check flow.

4.5 CONTROLLER OPERATION

WARNING: Connect the power cord only to a properly grounded wall receptacle that is approved for hospital-use and of the correct voltage. DO NOT use extension cords or an ac Receptacle Box for this device.

Connect the unit to the ac line. Turn on the **CIRCUIT BREAKER** on the Rear Panel and the **Power** Switch on the Front Panel. Observe the Functional Test.

4.5.1 PRE-WARM MODE

After the Functional Test is complete, the **Pre-Warm Mode** will activate. The **Heater Power** Indicator will be at 100% (all lights on) for three minutes, reduce to 60% (six lights on) for 12 minutes and then be reduced to 30% (three lights on).

NOTE: *Selection of **Manual** or **Baby** and then returning to **Pre-Warm** during the three minutes of 100% or 12 minutes of 60% power will automatically reduce the power to 30%.*

During **Pre-Warm** Mode, the **Chk Patient** Alarm is disabled.

4.5.2 MANUAL MODE

WARNING:

To avoid overheating or underheating, observe the infant constantly and monitor the temperature using the skin temperature probe supplied with the equipment or other electronic thermometer.

Inspect infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Use the Mode key to select **Manual Mode**.

2. Use only for short-term warming with nursing personnel in constant attendance.

3. Do not use warmer in **Manual Mode** if **Manual** Indicator is not on.

4. Set the **Heater Power** Indicator to the desired level. The heater power will be maintained for 10 minutes.

5. After 10 minutes, the **Chk Patient** Alarm will sound one time. Press the **Silence/Reset** Key to initiate another 10-minute warming period.

6. If the **Chk Patient** Alarm is not acknowledged, the heater will be automatically disabled after an additional 5 minutes of operation.

7. Heater power output must be adjusted manually to maintain Baby Temperature within the desired range.

8. Check infant's temperature and condition at least every 15 minutes. When initially setting or when changing heater power output, check Baby Temperature more frequently to be sure it is maintained within the desired range.

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CAUTION: A change in heater power output will not result in an immediate change in Baby Temperature. Wait for results. Large changes in heater power output will cause a more rapid change in Baby Temperature.

9. Use Skin Temperature Probe to continuously monitor Baby Temperature whenever possible.

   Refer to paragraph 4.5.3 to attach the probe to the patient.

IMPORTANT: *In **Manual Mode**, the Skin Temperature Probe monitors only -- it does not control.*

NOTE: *It is not necessary that the Skin Temperature Probe be connected to the Controller for **Manual Mode**.*

4.5.3 BABY MODE

WARNING:

To avoid hazards of overheating or underheating, the infant should not be left unattended. Use only with the Hill-Rom Air-Shields' Skin Temperature Probe supplied with the unit. Inspect the infant's skin for reddened areas which may result from heating of materials in contact with the skin (plastic diapers, pins, etc.).

Avoid placement of objects (equipment, blankets, or clothing) between the infant and Warmer Module that can block heat transfer or absorb heat. This can cause underheating or overheating.

Radiant warming increases insensible water loss. Appropriate measures to maintain fluid balance should be considered.

1. Plug Skin Temperature Probe into Controller **Skin Temp Probe** Connector.

2. Use the Mode key to select **Baby Mode**.

3. Attach the Skin Temperature Probe to the infant. The probe should be located on the infant's abdomen, halfway between the xyphoid and the umbilicus (Figure 4.13). The metal side of the probe should be placed in direct contact with the skin (when using the reusable probe).

FIGURE 4.13A ATTACHING SKIN PROBE

FIGURE 4.13B ATTACHING SKIN PROBE

WARNING:

The location of the Skin Temperature Probe must be such that the skin around the Sensor is in direct line with the heat from the Warmer Module. If the location is shadowed, for example, by the infant's body, overheating and possible burning of the infant's skin can result. Do not use a rectal probe. Use of a rectal probe can result in overheating or underheating of the infant.

The Skin Temperature Probe must be in intimate contact with the skin to provide accurate monitoring of the infant's skin temperature. Failure to maintain intimate skin contact can result in overheating and possible burning. Check infant's condition at least every fifteen minutes for correct Sensor attachment and feel infant's skin for signs of overheating.

The Skin Temperature Probe should be placed at least 1.5 inches from any transcutaneous monitor ($TcPO_2$ or $TcPCO_2$) probe to prevent false temperature indications. The Skin Temperature Probe should not be placed on an area previously used by a $TcPO_2$ or $TcPCO_2$ probe.

4. When the infant is prone, the Skin Temperature Probe should be located on the infant's back.

5. The skin area around the probe should be thoroughly cleansed and dried before the probe is placed on the skin.

6. To obtain an accurate reading of the infant's skin temperature, place the probe in position and cover with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or tape the probe into position, cover it with a small piece of cotton just large enough to cover the tip of the probe, and then place a second piece of tape over the cotton. If it is desired to reduce tape contact on the infant's skin, the cotton can be applied directly to the probe tip without the first piece of tape. To stabilize the attached probe, a third piece of tape may be placed over the probe wire approximately three to four centimeters from the probe tip.To minimize the effect of direct radiation on the Skin Temperature Probe, in order to obtain a more accurate **Baby Temperature** measurement, cover the Sensor with a Critter Covers® Disposable Probe Cover, Care-For-Me Cover or an equivalent insulating cover with a reflective surface facing the Warmer Module.

7. Baby Mode should be used for long-term warming and when attending personnel cannot be in constant attendance.

8. Set the **Set Temperature** Display to the prescribed temperature. A higher Set Temperature setting does not increase rapid warming.

9. Verify that **Baby Temperature** Display reading stabilizes within 0.2 °C of **Set Temperature** Display. Fluctuations in the **Heater Power** Indicators or the **Baby Temperature** Display reading can result from air currents, obstruction of radiation to the infant or the Skin Temperature Probe not being in intimate contact with the skin.

10. **Baby Temp** Alarms can be silenced for 10 minutes by pressing the **Silence/Reset** Key.

11. **Probe, High Temp** and **Baby Temp** (39.0 °C) Alarms are automatically reset after the alarm condition is corrected. The **High Temp** Alarm may be silenced for 2 minutes by pressing the **Silence/Reset** Key.

NOTE: *In the event of a **Probe** Alarm, **Manual Mode** can be used temporarily until a replacement Skin Temperature Probe is available and only if nursing personnel are in constant attendance.*

4.5.4 EXAMINATION LIGHT

The light is turned on and off by the **Exam Light** Switch. Turn the light on only as required for optimum bulb life.

4.6 X-RAY PROCEDURES

1. Swing the Warmer Module (Figure 4.9) to the right or left of center as required to position the X-ray machine.

2. Lift the Left or Right Bassinet Side Panel up, slide the X-ray Tray out (Figure 4.10); place the X-ray Cassette on the tray and return the tray to the Bassinet. Align the cassette as desired with the markings on the X-ray Cassette Tray and relative markings on the inside of the Bassinet panels.

3. When the X-ray is complete, remove the X-ray Cassette Tray and return the X-ray Tray. Place the Warmer Module in its normal operating position.

SECTION 5
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 Hill-Rom service personnel.

WARNING:

If oxygen is in use, make sure that the oxygen supply to the equipment is turned off and that it 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 cleaning and maintenance procedures; make sure that the Power Cord is disconnected from the wall receptacle.

5.2 CLEANING

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and 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

1. Remove both Bassinet Side Panels (Figure 5.1) by pulling them straight up.

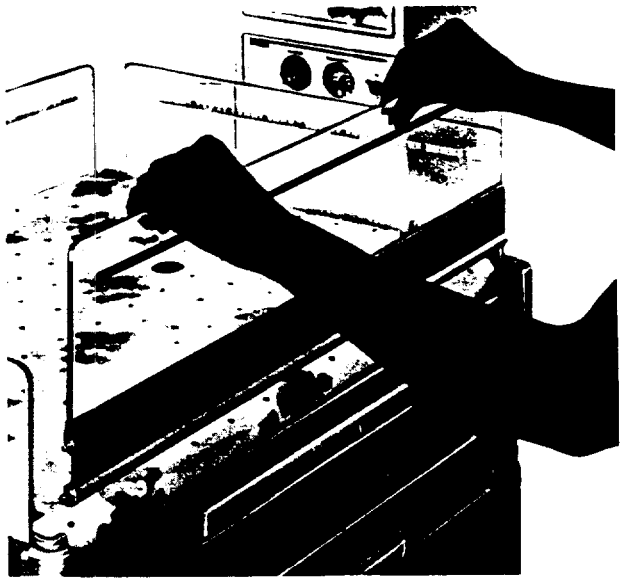

FIGURE 5.1 REMOVING BASSINET SIDE PANELS

2. Remove the Bassinet Back Panel (Figure 5.2) by raising it straight up until the bottom pins are adjacent to the slots in the corner brackets.

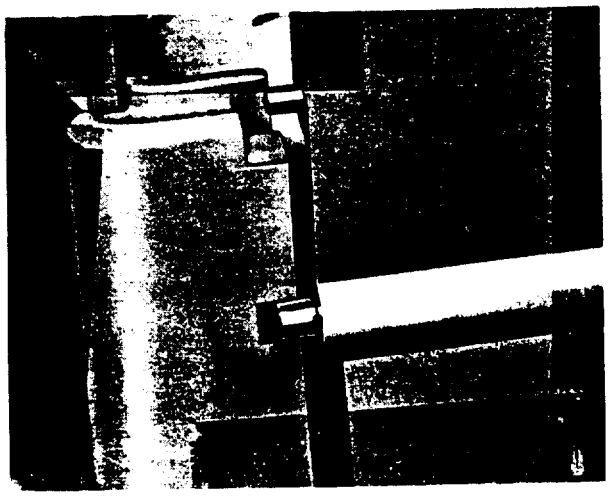

FIGURE 5.2 REMOVING BASSINET BACK PANEL

3. Remove the Bassinet Front Panel (Figure 5.3) by raising it and then swiveling it down. At the corners, press up on the release buttons and pull the panel straight out (Figure 5.4).

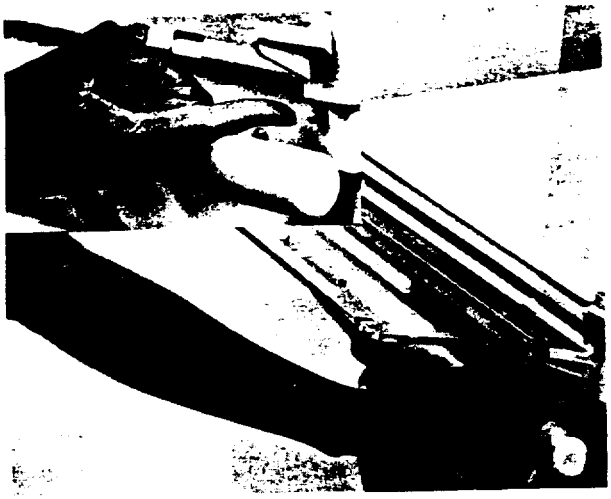

FIGURE 5.3 BASSINET FRONT PANEL RELEASE BUTTONS

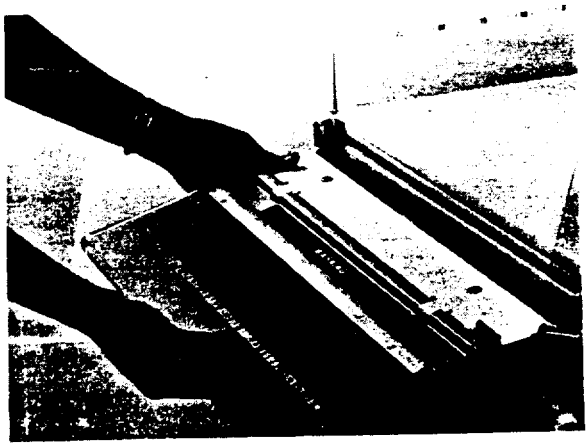

FIGURE 5.4 REMOVING BASSINET FRONT PANEL

4. Remove the Mattress from the Bassinet.
5. Remove the X-ray Tray (Figure 4.10).
6. Remove the Suction Bottle and Filter (Figure 4.12) from the front of the Bassinet.

5.4 CLEANING PROCEDURES

When an infant is discharged, or at least once a week, the equipment should be thoroughly cleaned and disinfected.

5.4.1 CLEANING AGENTS

An intermediate-level detergent/disinfectant registered by the U.S. Environmental Protection Agency should be used, but only when the equipment is not in use and disassembled as described elsewhere in this section. 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 PAINTED SURFACES

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

5.4.3 CLEAR PLASTIC AND ACRYLIC SURFACES

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

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.

Use a detergent/disinfectant to clean all surfaces thoroughly. Make sure to clean all holes, indentations, baffles, etc.; then dry with a clean cloth or paper towel.

5.4.4 METAL SURFACES

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

IMPORTANT: *After cleaning, a complete operational checkout should be performed before returning the unit to service.*

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5.4.5 SKIN TEMPERATURE PROBE, REUSABLE

CAUTION: Do not pull on the tip of the skin temperature probe when cleaning or drying; damage to the probe may result.

Use a detergent/ to thoroughly clean all surfaces; then dry with a clean soft cloth or paper towel.

5.5 STERILIZATION (IF DESIRED)

CAUTION: DO NOT STEAM AUTOCLAVE.

Sterilization can be accomplished by the following methods:

A. COLD (LIQUID) STERILIZATION

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

B. GAS STERILIZATION (ETHYLENE OXIDE). Prior to gas sterilization, the entire unit should be thoroughly cleaned as described elsewhere in this section. Remove and discard all used disposable elements. New disposable elements should be installed after sterilization.

Standard gas sterilization procedures are satisfactory as these do not normally exceed 54.4 °C (130 °F).

IMPORTANT: *After sterilization, a complete functional checkout procedure should be performed before returning the unit to service.*

5.6 REASSEMBLY AFTER CLEANING

1. Replace the Mattress on the Bassinet.
2. Replace the X-ray Tray (Figure 4.10).
3. Replace the Bassinet Back Panel by inserting the pins in the Corner Brackets (Figure 5.2).
4. Replace the Bassinet Side Panels by pushing them straight down into their slots (Figure 5.1).
5. Replace the Bassinet Front Panel by sliding it into the front of the Bassinet (Figure 5.4) until the release tabs catch. Raise the Panel into position.
6. Install a new Suction Filter if using a Reusable Bottle (Figures 3.1 and 4.12). Replace the Suction Bottle if using a Disposable Bottle.

5.7 CALIBRATION

The equipment should be completely checked and calibrated at least once a year by qualified service personnel. Refer to the appropriate Service Manual for details.

5.8 TROUBLESHOOTING

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

TABLE 5.1 TROUBLESHOOTING

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
No Power and **Power Fail** Alarm is not activated	a. Circuit Breaker not set to On.	a. Set Circuit Breaker to On.
Power Fail Alarm activated	a. Circuit Breaker tripped.	a. Reset Circuit Breaker (Figure 4.2).
	b. Power Cord unplugged.	b. Connect Power Cord to POWER connector (Figure 4.2) or wall socket.
	c. Defective Power Cord.	c. Replace Power Cord.
System Fail Alarm activated	a. Internal malfunction.	a. Refer to service.
Probe Alarm Activated	Possible Defective Skin Probe(s)	a. Check to ensure Skin Probe is in good contact with the skin.
		b. Replace Skin Probe(s). If condition is not corrected, refer to service.
Error Code Er02 through Er022 Er024 and Er025	a. Internal malfunction	a. Refer to service.
Error Code Er023	Ambient Temperature in excess of 32 °C (90 °F).	Verify ambient temperature with an external thermometer.

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SECTION 6
PARTS LIST

6.1 GENERAL

This section provides a listing of Operator replacement parts. Parts other than those listed here should be replaced by qualified service personnel. For an illustration of accessories, refer to Figure 1.1 of this manual.

	PART NUMBER
REPLACEMENT PARTS	
Bassinet Side Panel (Eng)	81 900 00
Bassinet Rear Panel (Eng)	81 900 01
Bassinet Front Panel (Eng)	81 900 02
Power Cord 220/240V Units	17 AZ 204
Skin Temperature Probe (Reusable)	81 300 05
Reusable Suction Bottle Kit (750 ml) (Bottle, Stopper, Tubing and Filter)	81 001 50
Reusable Suction Bottle Only	08 131 00
Filters (Box of 25)	81 001 50
40-Inch Power Cord	17 AZ 211
DISPOSABLES	
Premi-Probe® 3 Skin Temperature Probe (Box of 10)	81 300 08
Premi-Probe® 3 Skin Temperature Probe (10 Boxes of 10)	81 300 09
Autobreath Disposable Breathing Circuit and Exhalation Valve (Box of 25)	81 000 06
Autobreath Disposable Gas Supply Circuit (Box of 25)	81 001 27
Breathing Circuit Connector with Pressure Monitor Port (Box of 25)	81 001 29
Critter Covers® Probe Covers (Box of 100)	68 209 46
Critter Covers® Probe Covers (Box of 600)	68 209 45
Care-for-Me Probe Covers, 100 Large (10% discount when you order 5)	68 209 47
Care-for-Me Probe Covers, 100 Standard (10% discount when you order 5)	68 209 48
Neat Clips - 3/8" Diameter (Box of 100)	68 120 53
1.00" Diameter (50/Case)	68 120 54
Disposable Suction Bottle, 800 ml (Box of 100)	81 001 51
OPTIONS	
Instrument Tray - Right Hand	81 101 70R
Instrument Tray - Left Hand	81 101 70L
Pass-Through Drawer Organizer Tray	81 101 11
Air Hose Assembly, Green DISS	78 464 10
Oxygen Hose Assembly, Yellow DISS	78 465 10
Air Hose Assembly, Black NIST	81 501 45
Oxygen Hose Assembly, White NIST	68 507 50
Air Hose Assembly Black DISS	81 501 50
Oxygen Hose Assembly White DISS	68 507 30
Oxygen/Air Sealing Washer	81 502 02
X-ray Cassette Tray	81 100 44
IV Pole	82 001 53
Monitor Shelf	82 001 52

NOTES

LIMITED 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 Hill-Rom Air-Shields, Inc., 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 Hill-Rom Air-Shields, Inc. cannot be held liable for conditions resultant therefrom if:

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 Hill-Rom Air-Shields, Inc.
4. Sale or service is performed by a non-certified service/dealer agency.

THE FOREGOING WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE. HILL-ROM AIR-SHIELDS' OBLIGATION UNDER THESE WARRANTIES SHALL NOT INCLUDE ANY LIABILITY FOR LOSS OF PROFITS, DIRECT, INDIRECT OR CONSEQUENTIAL DAMAGES OR DELAYS. Some states, provinces, or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion or limitation may not apply. Any improper or negligent use, any alterations or repairs not in accordance with Hill-Rom Air-Shields' manuals or performed by others in such manner as in Hill-Rom Air-Shields' sole judgement affects the product materially and adversely, shall void these warranties. These warranties do not cover failures due to misuse, abuse, neglect, or lack of routine maintenance. No employee or representative of Hill-Rom Air-Shields is authorized to change these warranties in any way or grant any other warranty unless in writing and signed by a Hill-Rom officer. These warranties provide specific legal rights; but, there may be other available rights; which vary from state to state, province to province, or country to country.

*The Accreditation Manual for Hospitals requires each piece of equipment to be tested prior to initial use and at least annually thereafter. To comply with this standard, we recommend that you participate in our Preventive Maintenance 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. Technical Services representatives are located throughout the United States and Canada and are dispatched for required maintenance by calling USA (800) 445-3720 and Canada (800) 267-2337. Customers outside the U.S. and Canada should contact their local factory-authorized Hill-Rom Air-Shields' distributor for service.

Hill-Rom Air-Shields.
A HILLENBRAND INDUSTRY
330 Jacksonville Road, Hatboro, PA 19040

CAT NO. 82 990 15-8
E 1 2 3 4 5 6 7 8 9
A 1 2 3 4 5 6 7 8 9

Printed in USA 8/00

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DEVICE DESCRIPTIONS AND COMPARISONS

The Resuscitaire® Radiant Warmer is equivalent to the previously 510(k) approved device, RW Resuscitaire Infant Radiant Warmer K940951with the following exceptions:

- The addition of an optional resuscitation module that will use the existing resuscitation module with the following changes:
  - Changing the 15mm outlet to a tapered, barbed fitting that is consistent with currently accepted caregiver practice in the United States and Canada.
  - Replacement of the user adjustable airway relief valve with an internal fixed relief valve.
  - Appropriate modifications to module overlay and user manual.

Area Of Change	*EXISTING*	*NEW*
Gas Outlet Size/Type	15mm	Tapered Barbed Fitting
Airway Relief	User Adjustable	Fixed Internal
Overlay Markings	Patient Outlet	Primary Outlet

See attached RW Pneumatic Schematic.

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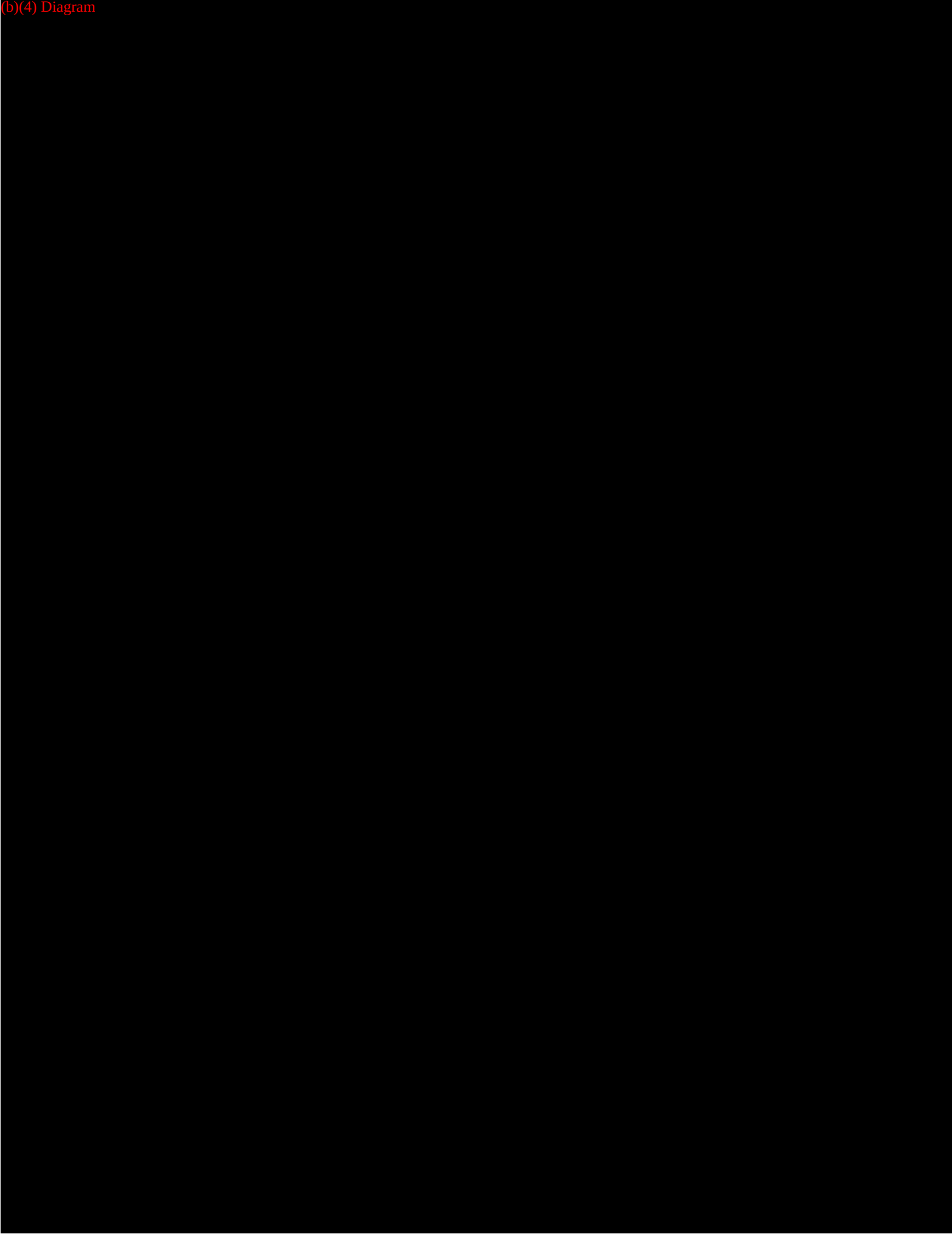
(b)(4) Diagram

SUBSTANTIAL EQUIVALENCY STATEMENT

The modified Resuscitaire® Radiant Warmer has the following similarities to the device that previously received 510(k) concurrence (K940951 RW Resuscitaire Infant Radiant Warmer).

Both units:

- Have the same indicated use.
- Use the same operating principle.
- Performs same function.
- Incorporate the same basic warmer design.
- Incorporate the same construction materials.
- Have the same product life expectancy.
- Are packaged and shipped using the same materials and processes.

In summary, the Resuscitaire® Radiant Warmer described in this submission is substantially equivalent to the predicate device, the RW Resuscitaire Infant Radiant Warmer.

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Hazard Analysis Update For Resuscitaire® Radiant Warmer Resuscitation Module

The following section reflects the changes made to the System Hazard Analysis for the Resuscitaire® Radiant Warmer for the modified Resuscitation Module.

The Hazard Analysis is essentially a "Fault Tree Analysis". It consists of an identification of the possible risk, possible causes, minimum requirements to control risk, description of control/comments and verification method used.

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(b)(4) Hazard Analysis

Resuscitaire® Radiant Warmer Resuscitation Module Verification Test 13 Nov. 1999

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Resuscitaire Warmer Gas Delivery Module

Verification Test

Scope: Verification of the RW Gas Delivery Module

Purpose: (b)(4) Test Data

Test Procedur

(b)(4) Test Data

Test Setup:

(b)(4) Test Data

Test Data:

(b)(4) Test Data

(b)(4) Test Data

Manual Review
For
Resuscitaire® Radiant Warmer
Resuscitation Module

SECTION 3
FUNCTIONAL DESCRIPTION

3.1 GENERAL

This section provides a functional description of the equipment.

3.2 FUNCTIONAL DESCRIPTION

3.2.1 WARMER MODULE

The Warmer is controlled by a Controller which provides **Pre-Warm** Mode, **Manual** Mode heater control, or **Baby** Mode (automatic skin temperature control). An Examination Light provides added illumination of the mattress area. A Warmer Head Pivot permits the Warmer to be pivoted 90° to either side for X-ray procedures. In addition, when the Warmer is pivoted, it continues to provide heat.

3.2.2 BASSINET

The Bassinet is designed to provide maximum function and utility to aid in the care of the newborn. The side and front panels may be folded down to permit access to the infant. The mattress may be tilted up from the rear at a 5- or 10-degree angle. Openings are provided on each side of the Bassinet for the insertion of the optional X-ray Cassette Tray.

3.2.3 CONTROLLER

At power-up, the microprocessor within the Controller performs a series of diagnostic tests to confirm the proper operation of the system. During this time, all displays and indicators are lighted and an audible tone is sounded.

When powered up, the system initializes in **Pre-Warm** Mode, the Controller will start the heater at 100% power and maintain that setting for three minutes, reduce to 60% for 12 minutes and then reduce the heater power to 30%.

When operating the Controller in the **Manual** Mode, the operator can adjust the heater power from 0 to full power in 10% increments. After 10 minutes of operation in the Manual Mode, a **Chk Patient** Alarm occurs.

Failure to acknowledge the Check Patient Alarm within the next 5 minutes will cause the heater to be turned off.

When operated in the **Baby** Mode, the Controller utilizes a Skin Temperature Probe, connected between the Controller input and the infant, to automatically adjust the heater output of the Warmer Module to maintain a digitally displayed preset **Set Temperature**.

The Apgar Timer displays the elapsed time and sounds an audible dual tone to alert the operator that 1, 5, and 10 minutes have elapsed since the timer was activated.

The **Keypad Lock** Key, when pressed, renders the Up/Down Arrows and Select Mode Keys inactive or active.

A Procedural Silence Timer prevents **Baby Temp** audible Alarms during routine procedures.

3.2.4 BLENDER MODULE (Optional)

The Blender Module provides blended oxygen from 21% to 100% to the **Patient Outlet** on the Resuscitation Module.

3.2.5 RESUSCITATION MODULE (Optional)

WARNING: Always monitor Airway Pressure and or/provide appropriate relief during infant resuscitation.

The Resuscitation Module contains pneumatic circuitry necessary for infant resuscitation. Controls and displays for the module are located above the rear of the Bassinet.

The Resuscitation Module is provided with AutoBreath or without AutoBreath and consists of the following factory installed components:

- **Suction** - The **Suction** Circuit is driven by a gas powered venturi actuated vacuum generator which provides a negative pressure for suctioning the patient's airway. The suction pressure is indicated on the **Suction** Gauge (Figure 3.1). Suction may be adjusted using the

Schematic Review
For
Resuscitaire® Radiant Warmer
Resuscitation Module

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(b)(4) Schematic drawing

(b)(4) Schematic drawing

Hill-Rom Air-Shields.
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Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modifications were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

Otho Boone
Business Director Infant Care
Hill-Rom Air-Shields

23-Oct-00
Date

Manufacturing Facility

The manufacturing facility, Hill-Rom Air-Shields, is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Bryan S. Overton
Quality Manager
Hill-Rom Air-Shields

24 October 2000
Date

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330 JACKSONVILLE ROAD, HATBORO, PA 19040 215-675-5200 Fax: 215-675-1859

510(k) Summary September 27, 2000

Applicant:

Hill-Rom Air-Shields
330 Jacksonville Road
Hatboro, PA 19040
Reg. No: 2510954

Contact Person:

James G. Carpenter
Ph: (215) 675-5200
Fx: (215) 682-8689

Device trade/proprietary name:

Resuscitaire® Radiant Warmer
Resuscitaire® Birthing Room Warmer
Resuscitaire® Wall Mounted Radiant Warmer

Device common/usual/classification name:

WARMER, INFANT RADIANT

Classification:

General Hospital
21 CFR 880.5130
Infant Radiant Warmer, FMT, Class II

Performance Standards:

None applicable.

Predicate (Current) Device:

K940951 RW Resuscitaire Infant Radiant Warmer

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Device Description

The Resuscitaire® Radiant Warmer is designed specifically for labor and delivery room use. The Resuscitaire® Radiant Warmer consists of a Bassinet, Warmer, and controller module, which provides heat control, monitoring of skin temperature and Apgar timing. The Resuscitaire® Radiant Warmer also includes an optional basic resuscitation package, which includes suction and oxygen delivery.

Intended Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.

This is the same intended use as previously cleared for the RW Resuscitaire® Infant Radiant Warmer, K940951 RW Resuscitaire Infant Radiant Warmer.

Description of Modifications:

The modifications that are the subject of this submission are summarized below:

- Addition of a new resuscitation module using the existing module with the following changes.
  - Change the 15mm outlet on the Gas Delivery Module to a tapered, barbed fitting that is consistent with currently accepted caregiver practice in the United States and Canada.
  - Replacement of the user adjustable airway relief valve with an internal fixed relief valve.
  - Appropriate modifications to module overlay and user manual.

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Hill-Rom Air-Shields.
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Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(k), I certify that, to the best of my knowledge and belief, the data and information submitted in this Premarket notification are truthful and accurate and that no material facts have been knowingly omitted from this submission.

Larry W. Krasley

Larry W. Krasley
Regulatory Affairs Specialist

Date: 10/23/00

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330 JACKSONVILLE ROAD, HATBORO, PA 19040 215-675-5200 Fax: 215-675-1859

Indications for Use

510(k) Number:

Device Name: Resuscitaire Radiant Warmer

Indications for Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, Apgar timing, and resuscitation of newborn infants.

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1/2/96)

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