Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

K970074

APR -3 1997

510(k) Summary

January 6, 1996

Applicant:

Hill-Rom, Inc.
1069 St. Route 46 East
Batesville, IN 47006
Reg. No: 1824206

Contact Person:

James G. Carpenter
Ph: (812)934-1671
Fx: (812)934-1675

Device trade/proprietary name:

" Stabilet™"

Device common/usual/classification name:

Infant Radiant Warmer

Classification:

General Hospital and Personal Use Device, 21 CFR 880.5130 , Infant Radiant Warmer, 80FMT, Class III

Predicate (Current) Device:

Hill-Rom " Stabilet™" Infant Radiant Warmer, K942948

Device Description

The Hill-Rom Stabilet™ is a device consisting of an infrared heating element positioned over an infant to maintain the infant's body temperature by means of radiant heat. Available features include a warming/lighting module which provides heat through two stainless steel heater tubes, manual or servo heat control with a temperature monitoring sensor and temperature alarms, procedural Apgar timer, bassinet with mattress and spring loaded fold down sides, trendelenburg/reverse trendelenburg, x-ray cassette tray, retractable Mayo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

tray, slide through storage drawer, resuscitation equipment, storage bin and casters with front locking brakes, optional scale and hilo feature.

Intended Use:

The Stabilet™ Infant Radiant Warmer maintains the infant's body temperature at a level determined by the caregiver through the use of an infrared radiant heating element and is designed to be used in those areas of the healthcare facility that provide neonatal and infant care.

Federal law restricts this device to sale by or on the order of a licensed health care practitioner and its use is restricted to health care facilities.

Design and construction:

Both the new and predicate warmers utilize the same materials and methods of construction. The warmers are fabricated from steel, aluminum, and plastic. The submitted warmer's most highly stressed areas utilize only steel and aluminum. Plastics are used in less stressed areas. Steel and aluminum warmer components are welded or assembled with commercially available fasteners. Plastics used in less stressed areas are assembled with fasteners.

The subject warmer and predicate warmer in this submission are substantially equivalent. There is some variation in the available features of the warmers, but the variations do not significantly affect the safety or efficacy of the warmers.

This submission is a result of the introduction of several improvement modifications Hill-Rom has introduced to the existing product. The principal changes are:

Modification of the heater lamp housing

- Bare quartz element changed to a stainless steel element.

  The new element eliminates tube breakage as a hazard to the patient or caregiver. The electrical contacts have been changed from a spring compression socket arrangement to an insulated wire with a screw. This provides a positive locking electrical connection to the power supply.

- One heating element to two.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

- **Heating element length increased from 12" to 16"**
- **Change parabolic reflector from pebbled to smooth to optimize irradiance pattern with new dual heating elements**

Two 375W elements centered over the bassinet replace the single 760W element in the predicate warmer. In conjunction with the increased length and the changes to the parabolic reflector, the irradiance pattern is more evenly distributed and the time required to warm the infant to the caregiver- selected skin temperature is reduced.

Height adjustability for the 1500C and 2000D.

This is a customer preference feature and does not impact the safety of the device to the user or patient. The heater lamp housing to bassinet surface relationship is maintained.

Quartz Halogen task light replaces the florescent task light.

The light is balanced to 3200°K. This more closely approximates natural ambient light and eliminates the color bias imparted by florescent lighting.

Accessories

Resusitation and Suction modules are offered as options on all current and previous models and the 1250C and 1500C Stabilet-. This does not represent an increased risk to the user or patient as these options are already standard features on the Predicate 2000C.

A scale option (Premarket Notification K926174) is also available on the P1500C and P2000D models.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 1997

Mr. James G. Carpenter
Manager, Regulatory Affairs
Hill-Rom, Incorporated
1069 State Route 46 East
Batesville, Indiana 47006-9167

Re: K970074
Trade Name: Stabilet Freestanding/CC Infant/200C Infant Warmer (1250C) CC Infant Warmer (15000C) 2000D Infant Warmer
Regulatory Class: III
Product Code: FMT
Dated: January 6, 1997
Received: January 8, 1997

Dear Mr. Carpenter:

This letter corrects our substantially equivalent letter of January 6, 1997, which contains an incorrect spelling of the trade name.

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

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) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note that the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food And Drug Administration

4/17/97

Memorandum

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s) K970074/A1

To: Division Director HO/DD16

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission. 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. Feel free to note any additional comments below.

Thank you for your cooperation.

X Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TRANSFER OF OWNERSHIP, PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS].

_____ Additional information requires a new 510(k), however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD 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 or 510(k) statement)

SE letter correction

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

Reviewed by HUNG TRINH / PTC

Date 4/25/97

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

K970074/A

Hill-Rom®
A HILLENBRAND INDUSTRY

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
Document Mail Center
9200 Corporate Blvd.
Room 20N
Rockville, MD 20850

April 14, 1996

FDA/CDRH/OCE/DMC
17 APR 97 14 08

Re: K970074

Dear Mr. Ulatowski,

We have received clearance on the above referenced 510(k). The trade name of the device on the clearance letter was misspelled. Could you please provide a corrected copy of the letter for our files.

From: Stanilet

To: **Stabilet**

I appreciate your efforts in this matter. Thank you.

Sincerely,

William D Jordan

William D. Jordan
Regulatory Specialist
Ph. 812-934-7471
Fax 812-934-1675

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1069 STATE ROUTE 46E, BATESVILLE, INDIANA 47006-9167 812-934-7777 Telefax International: 812-934-7191 Telefax Domestic: 812-934-8189

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1997

Mr. James G. Carpenter
Manager, Regulatory Affairs
Hill-Rom, Incorporated
1069 State Route 46 East
Batesville, Indiana 47006-9167

Re: K970074
Trade Name: Stanilet Freestanding/CC Infant/2000C Infant Warmer (1250C) CC Infant Warmer (15000C) 2000D Infant Warmer
Regulatory Class: III
Product Code: FMT
Dated: January 6, 1997
Received: January 8, 1997

Dear Mr. Carpenter:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

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) 594-4618. 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" (21 CFR 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 at (301) 443-6597.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Indications for Use

510(k) Number: Unknown

Device Name: Stabilet™ Infant Radiant Warmer

Indications for Use:

The Stabilet™ Infant Radiant Warmer maintains the infant's body temperature at a level determined by the caregiver through the use of an infrared radiant heating element and is designed to be used in those areas of the acute care hospital that provide neonatal and infant care.

Federal law restricts this device to sale by or on the order of a licensed health care practitioner and its use is restricted to health care facilities.

(Division Sign-Off) Patricia Cucerite
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970074

Prescription Use ✓
(Per 21 CFR 801.109)

3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

510(K) ROUTE SLIP

510(k) NUMBER K970074 PANEL HO DIVISION DDIG BRANCH

TRADE NAME STANILET FREESTANDING/CC INFANT/2000C INFANT WARMER (1250C

COMMON NAME INFANT RADIANT WARMER

PRODUCT CODE ___

APPLICANT HILL-ROM, INC.
SHORT NAME HILLROMA
CONTACT JAMES G CARPENTER
DIVISION
ADDRESS 1069 STATE ROUTE 46 EAST
BATESVILLE, IN 470069167
PHONE NO. (812) 934-1671 FAX NO. (812) 934-1675

MANUFACTURER UNITED MEDICAL MFG. CO. REGISTRATION NO. 1832726

DATE ON SUBMISSION 06-JAN-97 DATE DUE TO 510(K) STAFF 24-MAR-97

DATE RECEIVED IN ODE 08-JAN-97 DATE DECISION DUE 08-APR-97

DECISION __ DECISION DATE _____

Is this 510(k) identified as a Class III device X YES ____NO

FMT

CLASS III

CLASS III

CLASS III

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

K970074

Class III Certification

I certify, in my capacity as Manager of Regulatory Affairs, of Hill-Rom, Inc. that I have conducted a reasonable search of all information known or otherwise available about the types and causes of reported safety and/or effectiveness problems that have been reported for the Infant Radiant Warmer. I further certify that I am aware of the types of problems to which the Infant Radiant Warmer is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the Infant Radiant Warmer is complete and accurate.

James G. Carpenter
Manager, Regulatory Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CLASS III SAFETY AND EFFECTIVENESS SUMMARY

1.0 SUMMARY OF SAFETY AND EFFECTIVENESS PROBLEMS ASSOCIATED WITH INFANT RADIANT WARMERS

1.1 Hyperthermia or Burning of Infant.

Typical Causes:

a. Temperature sensor not in complete contact with skin.
b. Poor placement of temperature sensor.
c. Failure of alarms.
d. Inappropriate operator resetting of alarms.
e. Unmonitored uses of manual heating mode.
f. Temperature sensor failure.
g. Control circuit failure.
h. Incorrect Sensor Type.
i. Miscalculation of Control Circuitry.
j. Failure of Sensor Connection.
k. Non-uniform Heat Distribution.
l. Manufacturing Defect in Control Electronics.
m. Infant too close to heater.

1.2 Heat Loss from Infant to surrounding environment.

Typical Causes:

a. Insensible water loss due to evaporation.
b. Convection, especially from forced air ducts.
c. Radiation to cool surfaces.
d. Sidewalls too low to protect against drafts.

1.3 Mechanical Failure of Heater Mechanism

Typical Causes:

a. Breakage of Quartz Heater Bulb allowing hot material to fall on infant.
b. Heat aging of wire insulation.
c. Mechanical Failure of Support Mechanism.
d. Debris falling from heater element contact area

1.4 Hypothermia or Underheating of Infant

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Typical Causes:

a. Sensor artifact due to improper application on infant.
b. Miscalculation of Control Circuitry.
c. Heater Power cutback due to overheating or alarms.
d. Heater Element Burn-out.
e. Failure of Sensor Connection.
f. Loss of Primary Power.
g. Incorrect Temperature Sensor
h. Non-uniform Heat Distribution
i. Manufacturing Defect in Control Electronics.
j. Infant too far away from heater.

1.5 Patient Falls

Typical Causes:

a. Mechanical Failure of Side Panel Latch.

2.0 CITATION OF THE INFORMATION UPON WHICH THE SUMMARY WAS BASED:

2.1 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT FDA DATA

ACCESSION NUMBER	DESCRIPTION OF PROBLEM
145931	Failure of Hi/Lo Set Point Alarm.
150899	Failure of Safety Panel Latch.
160080	Heater Element's envelope shattered & fell on bed.
162463	Overheating of patient due to Probe Misplacement.
171013	Burning Piece of foreign material fell on mattress.

2.2 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT ABSTRACTS

ACCESSION NUMBER	DESCRIPTION OF PROBLEM
17887	Adel Model 986 Warmers, overfill of water tray.
18012	User & Technical evaluation of Ohmeda 3300 Warmer
18195	Transformer failed overheating test.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

18457	Manufacturing Problem with Probe Jack Mounting resulting in failure of probe connection. Ohmeda Models 3000, 3300, 3500, and 5000 Warmers.
18632	Electrical System not Double Insulated.
18715	Evaluation of Viamed Thermocot TC400.
19536	Failure of the Crib's Hydraulic Tilt Mechanism.
19537	Heater Quartz Envelope Chipping and pieces falling on patient.
19945	Failure of Power/Mode Switch.

2.3 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT ACTION ITEMS

ACCESSION NUMBER	DESCRIPTION OF PROBLEM
A1338	Possibility of wrong disposable probe connection with older interface cables.
A1736	Power/Mode Switch Failure & Control Panel Not Properly Calibrated.

2.4 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT CITATIONS FROM ECRI DATABASE PRIOR TO MARCH 1985

ACCESSION NUMBER	DESCRIPTION OF ARTICLE
00154	FDA Recall T-133-7, and T-134-7 of certain models of KDC warmers.
00350	Another potential hazard of radiant warmers.
00383	Committee on environment hazards: infant radiant warmers.
00518	FDA Recall T-084-8 of Emerson Heat Lamps.
00612	FDA Recall T-039-8 of Ohio radiant warmers.
00877	Potential hazard in infant resuscitator-aspirator
00913	Proper use of radiant warmers.
01244	Reduction of insensitive water loss in premature infants under the radiant warmer.
01378	Combined effect of radiant warmers and phototherapy on insensible water loss in low birth weight infants.
02216	Heat balance in premature infants: comparative effects of convectively heated incubators and radiant warmers, with and without plastic heat shield.
02298	FDA Recall T-074-0 of Cavitron temperature sensors.
02315	FDA Recall T-083/084 of Air-Shields radiant warmers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

02788	Heat balance in premature infants.
03208	Oxygen consumption and insensible water loss in premature infants under radiant warmers.
04211	White tape indicates burn hazard.
04769	Effect of heat shielding on convective and evaporative heat losses and on radiant heat transfer in the premature infant.
05370	Physiologic implications of two different heat shields for infants under radiant warmers.
06864	Radiant patient warmers - possible hazards.
06907	FDA Recall T-208-3 of Healthdyne radiant warmers .
07383	Letter from manufacturer concerning certain Air-Shields ICS and FS warmers.
07613	Letter from manufacturer concerning solder flux contamination in certain Air-Shields warmers.
07756	FDA Recall Z-106-4 of certain Air-Shields infant heater controller modules used in ICS and FS warmers.
07757	FDA Recall Z-140-4 of control switches in certain models of Air-Shields warmers.
08242	FDA Alert M-008-4 on asbestos used in Air-Shields warmers manufactured between 1972 and 1977.

MISCELLANEOUS ARTICLES CONCERNING RADIANT WARMERS

DATE	TITLE OF ARTICLE - AUTHOR - PUBLICATION
1970	The Optimum Thermal Environment for Naked Babies, E.H. Ney and G. Katz - Archives of Disease in Childhood Vol. 45
1971	Observations of Body Temperature in Young Premature and Full Term Newborns While Being Connected to a Servo Control Temperature Unit. - A. Fenner & M. List - Biological Neonate
1971	A Dangerous Situation Encountered in the Administration of Oxygen to an Infant in a Baby Warmer - Leonard Indyk - Pediatrics
03-1971	Temperature Control in Newborn Babies - L. Lutz & P. Perlstein, MD - Nursing Choices of North America Vol 6, No. 1
03-1973	Emergency Care Research Institute, ``Evaluation: Infant Warmers,'' Health Devices, 3:4-25, 1973.
12-1973	``Evaluation of Optical Radiation Hazards,'' Sliney, D. H., and B. C. Freasier, Applied Optics, 12:1-24, 1973

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

10-1974 Effects of Radiant Warmer on Insensible Water in Newborn Infants - Paul Williams, MD & William Oh, MD, American Journal of Diseases in Children.

10-1974 The Effects of Four Different Radiant Warmer Temperature Set-Points used for Rewarming Neonates - K. Motil, MD, M. Blackburn, MD, and J. Pleasuer, MD - Journal of Pediatrics Vol 85, No. 4

12-1974 Insensible Water Loss in Preterm Infants: Changes With Postnatal Development and Non-Ionizing Radiant Energy - Paul Wu, MB, BS & Joan Hodgman, MD - Pediatrics Vol. 54, No. 6

12-1974 Ahlgren, E. W., ``Environmental Control of the Neonate Receiving Intensive Care,'' International Anesthesiology Clinic, 12:173-215, 1974 .

02-1976 Iatrogenic Problems in Neonatal Intensive Care - Ross Conference on Pediatric Research

1976 Emergency Care Research Institute, ``The Development of a Standard for Infant Warmers and Incubators,'' final report, FDA Contract No. 223-75-5012, Plymouth Meeting, PA, 1976.

1976 ``Increased Insensible Water Loss in New Born Infants Nursed under Radiant Heaters,'' Jones, R. W. A., M. J. Rochefort, and J. D. Baum, British Medical Journal, 1:1347-1350

03-1977 Advantages and Disadvantages of Overhead Radiant Warmers - Dr. R. O. Robinson and Dr. R. Jones - Proc. Roy.Soc.Med. Vol. 70

1977 ``Evaluation of the Effects of Infrared Radiation on the Eyes of Infants under Radiant Warmers,'' Johns, R., D. Schaffer, and G. Peckham, Unpublished, 1977.

1978 ``Minimal Oxygen Consumption in Infants Cared for under Overhead Radiant Warmers Compared with Conventional Incubators,'' Darnall Jr., R. A., and R. L. Ariagno, Journal of Pediatrics, 93:283-287, 1978.

03-1980 Heat Balance in Premature Infants: Comparative Effects of Convectively Heated Incubator and Radiant Warmer, with and without Plastic Heat Shield. - E. Bell, MD & W. Oh, MD Pediatrics Vol 96, No. 3

1980 ``A Simple Device for Reducing Insensible Water Loss in Low-Birth Weight

10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Infants,'' Marks, K. H., Z. Freidman, and M. B. Maisels, Pediatrics, 60:223-226.

1980 ``Safety with Lasers and Other Optical Sources,'' Engel, W. D., 23. Sliney, D., and M. Wolbarsht, Plenum Press, New York, 1980, pp. 144-149.

1980 ``Oxygen Consumption and Insensible Water Loss in Premature Infants under Radiant Heaters,'' Marks, K. H., R. C. Gunther, J. A. Rossi, and M. J. Maisels, Pediatrics, 66:228-232, 1980.

1981 ``Insensible Water Loss in the Critically Ill Neonate,'' S. Baumgart, J. G. Schwartz, W. W. Fox, and R.A. Polin, American Journal of Diseases in Children, 135:516-520.

1981 ``Effect of Heat Shielding on Convective and Evaporative Heat Losses and on Radiant Heat Transfer in the Premature Infant,'' Baumgart, S., W. D. Engel, W. W. Fox, and R. A. Polin, Journal of Pediatrics, 99:948-956

04-1982 Relative Efficacy of an Incubator and an Open Warmer in Producing Thermoneutrality for the Small Premature Infant, Michael Le Blanc, MD - Pediatrics, Vol. 69, No. 4

06-1982 The Heat Balance of Small Babies Nursed in Incubators and under Radiant Warmers - A. E. Wheldon & N. Rutter - Early Human Development - Elsevier Biomedical Press

08-1982 Noise in the Intensive Care Nursery - Neil Kellman, MD - Neonatal Network

11-1982 The Neonatal ICU - A High Risk Environment, Susan Blackburn - American Journal of Nursing

1982 ``Fluid, Electrolyte, and Glucose Maintenance in the Very Low Birth Weight Infant,'' Baumgart, S., C. B. Langman, W. W. Fox, and R. A. Polin, Clinical Pediatrics, 32:199-206

1982 ``Physiologic Implications of Two Heat Shields for Infants under Infant Radiant Warmers,'' Baumgart, S., W. W. Fox, and R. A. Polin, Journal of Pediatrics, 100:787-790.

1982 ``Effect of Increased Radiant Power Output on State of Hydration in the Critically Ill Neonate,'' Critical Care Medicine, Engel, W. D., S. Baumgart, W. W. Fox, and R. A. Polin, 10:673-676.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

09-1982. "Radiant Energy and Insensible Water Loss in the Premature Newborn Infant Nursed under a Radiant Warmer," Baumgart, S., Clinics in Perinatology, 9:483-503,

05-1983 Infant Incubators and Radiant Warmers - Edward Bell , Early Human Development Pages 351-375 Elsevier Science Pub.

1983 American Academy of Pediatrics and American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care, Evanston and Washington, DC, respectively.

09-1984 Medical Technology for the Neonate - AAMI Technology Report

11-1984 Thermal Support for the very low birth weight infant: Role of Supplemental Conductive Heat. - William Topper, MD & Thomas Stewart, PHD - Pediatrics

1984 ``Heat Shield Reduces Water Loss,'' Fitch, C. W., and S. B. Korones, Archives Disease in Childhood, 59:886-888,

1984 Emergency Care Research Institute, ``Evaluation: Infant Warmers,'' Health Devices, 13:119-145.

12-1984 Reduction of Oxygen Consumption, Insensible Water Loss, and Radiant Heat Demand with use of a Plastic Blanket for Low Birth-Weight Infants under Radiant Warmers. - Stephen Baumgart, MD - Pediatrics Vol. 74, No. 6

1984 ``Relative Efficacy of Radiant and Convective Heat in Incubators in Producing Thermoneutrality for the Premature,'' LeBlanc, M., Pediatric Research, 18:426-428.

01-1985 Partitioning of Heat Losses and Gains in Premature Newborn Infants under Radiant Warmers. - Stephen Baumgart, MD - Pediatrics, Vol. 75, No. 1

02-1986 Classical Conditioning in Neonatal Intensive Care Nurseries, Beverly Hyde & Darlene McCown - Pediatric Nursing Vol 12, No. 1

08-1986 Axillary and Rectal Temperatures of Full Term Neonates: Are They Different? - B. Haddock, MSN, P. Vincent, RN, D. Merror, RN - Neonatal Network

09-1986 Energy Metabolism and Substrate Utilization in Low Birth Weight Neonates Under Radiant Warmers, Marks, Nardis, and Momin - Pediatrics, Vol. 78 No. 3

1986 ``Energy Metabolism and Substrate Utilization in Low Birth Weight Neonates

12

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

under Radiant Warmers,'' Pediatrics, Marks, K. H., E. E. Nardis, and M. N. Momin, 78:465-472.

01-1988 Essential Background for the Design of a Neonatal Bed - Michael H. Donnely - Perinatal Research Institute - Cincinnati, OH

04-1988 Comparison of Axillary and Rectal Temperatures in the Preterm Infant - Betty Haddock, MSN, Pauline Vincent, RN, Dorothy Merrow, RN - Neonatal Network.

1988 ``Controversies in Fluid and Electrolyte Therapy for the Premature Infant,'' Costarino, A. T., and S. Baumgart, Clinical Perinatology, 15:863-878,

04-1989 Body Surface Temperature - Joseph Looney, Jr. - Medical Electronics, April 1989.

1993 ``Infrared Eye Injury Not Due to Radiant Warmer Use in Infants,'' Baumgart, S., A. Knauth, F. X. Casey, and G. E. Quinn, American Journal of Diseases in Childhood, 147:565-569.

1994 International Electrotechnical Commission, ``Medical Electrical Equipment, Part 2: Particular requirements for the safety of infant radiant warmers'',.

05-1995 Association for the Advancement of Medical Instrumentation, Infant Radiant Warmers (draft standard),.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BLANK PAGE

14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) HUNG TRINH

Subject: 510(k) Number K970074

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ 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

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

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

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

80 FMT Infant Radiant Warmer

Review: Patricia Cronin acting (Branch Chief) OHDB (Branch Code) 4-2-97 (Date)

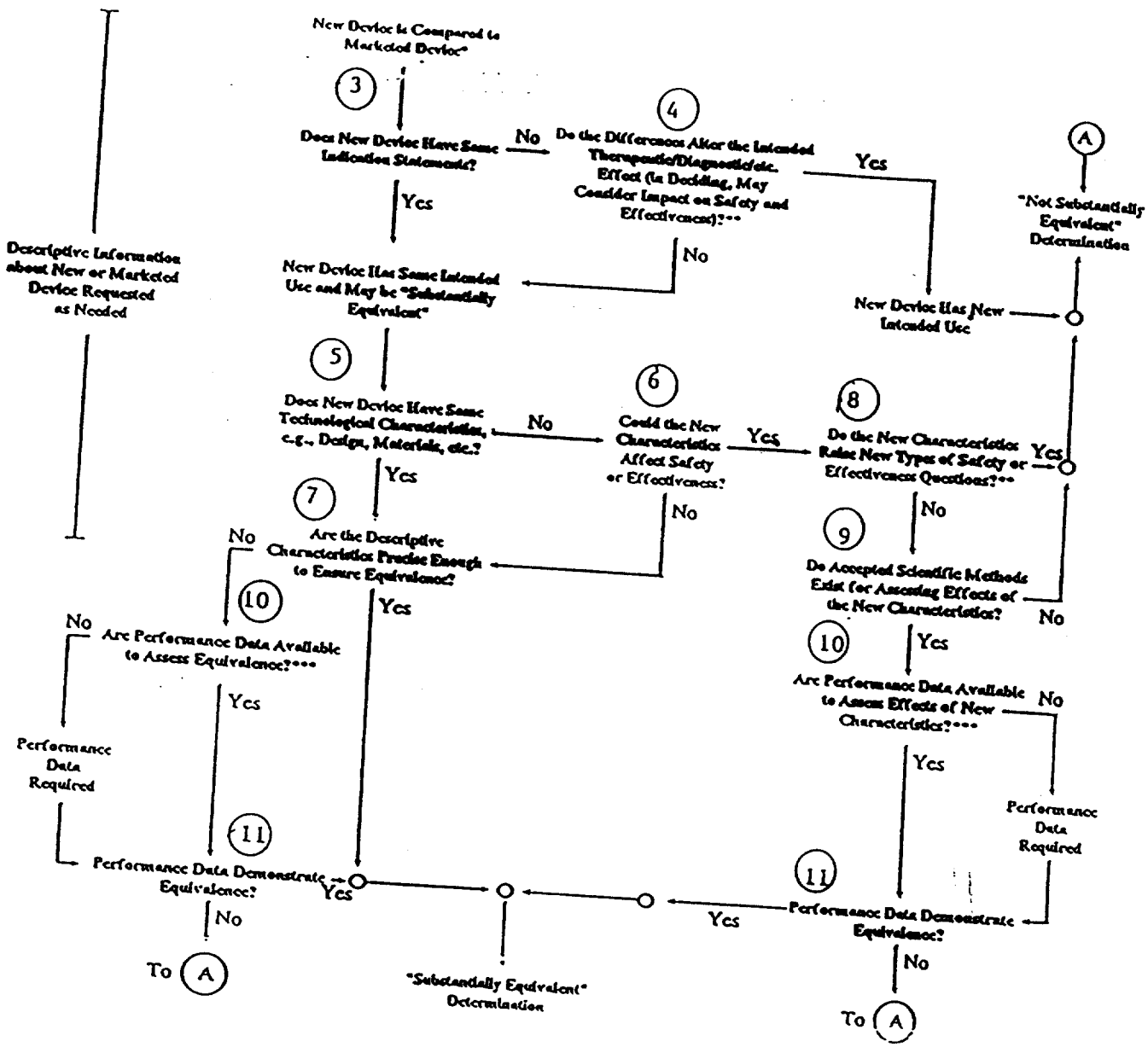
Final Review: _____
(Division Director) (Date)

Revised: 11-20-96

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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 testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

MEMO TO THE RECORD
510(K) REVIEW

DATE: 3/27/97 **OFFICE:** HFZ-480
FROM: Hung Trinh **DIVISION:** DDIG/GHDB

DOCUMENT: K970074
COMPANY NAME: Hill-Rom
DEVICE NAME: Stabilet™ Infant radiant warmers:
Freestanding Infant Warmer and Clinical Bassinet (1250C)
CC Infant Warmer (1500C)
2000D Infant Warmer

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE SUBMISSION UNDER REVIEW:
The firm intends to make modifications to the existing Stabilet Infant Radiant Warmers. The modifications include the number and type of heating element, height adjustability, task light. Accessories that will be made as available options will be a resuscitation and suction assembly and a scale.

2. INTENDED USE:
The device is used to maintain the infant's body temperature at a level determined by the care giver through the use of an infrared radiant heating element and is designed to be used in on those areas of the acute care hospital that provide neonatal and infant care.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: no
B. Implant (short-term or long-term): no
C. Is the device sterile? No
If yes, is sterility information provided? n/a

D. Is the device for single use? no
E. Is the device for prescription use? Yes
If yes, is prescription labeling included? Yes
F. Is the device for home use or portable? No
Whether the answer is yes or no, is adequate environmental testing, including EMC, performed for the intended environment, and are results provided, including test protocols, data, and a summary?
G. Does the device contain drug or biological product as a component? no
H. Is this device a kit? no
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? n/a
I. Software-driven: no

17

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Estimated level of concern: (Major, Moderate, Minor)? n/a

Has the firm provided a hazard analysis, software requirements and design information, adequate test plans/protocols with appropriate data and test reports, documentation of the software development process including quality assurance activities, configuration management plan, and verification activities and summaries, commensurate with the level of concern, as discussed in the Reviewer Guidance for Computer Controlled Medical Devices?

Software version:

J. **Electrically Operated:** yes

If yes, are AAMI or IEC leakage currents met and is the test protocol, data, and results provided?

K. **Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.):**

If applicable, has test data been provided to demonstrate conformance (protocol, data, and results)

L. **Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:**

K913945 Stabilet 2000C Infant radiant warmer
K942904 Stabilet Infant radiant warmer
K850069 Stabilet Infant radiant warmer

M. **Submission provides comparative specifications** yes
comparative in vitro data no
performance data No
animal testing no
clinical testing No
biocompatibility testing no

N. **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. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.**

The devices consist of an infrared heating element positioned over an infant to maintain the infant's body temperature by means of radiant heat. Available features include a warming/lighting module which provides heat through two stainless steel heater tubes, manual or servo heat control with a temperature monitoring senosr and temperature alarms, procedureal Apgar timer, bassinet with mattress and spring loaded fold down sides, trendelenburg/reverse trendelenburg, x-ray cassette tray, retractable mayo tray, slide through storage drawer, resuscitation equipment, storage bin and casters with front lockling brakes, optional scale and hilo feature.

Modification to the devices include:

1) heater lamp housing

a. The bare quartz element is replaced with a stainless steel element to eliminate tube breakage. The electrical contacts have been changed from a spring compression socket arrangement to an insulated wire with a screw. With a new and more rigid connection the concern regarding fretting corrosion is eliminated. Fretting corrosion occurs when two metal surface are in contact under slight pressure and are subjected to slight motion.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

b. Heating element length is increased from 12" to 16".
c. Two heating element (375 W) are used instead of one previously (760 W) to provide a more evenly distributed irradiance pattern.
d. Parabolic reflector is changed from pebbled to smooth to maximize irradiance pattern.

2) Height adjustability for the 1500C and 2000D without modifying the heater lamp housing to bassinet surface relationship. This is intended for customer convenience.
3) The florescent task light is replaced with a quartz halogen light to provide a more natural ambient lighting.

4) The resuscitation and suction modules are offered as options on all current and previous models.

5) A scale option (K926174) is also available on the P1500C and P2000D models.

Telephone conversation with Mr. (b)(6) [redacted] (b)(4) [redacted] : (on 3/27/97)
I asked Mr. (b)(4) [redacted]
(b)(4) [redacted]

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 OF REVIEW FORM AS NEEDED (DELETE QUESTIONS WHICH ARE NOT APPLICABLE)

7. IF THE ANSWER TO QUESTION 7 IS NO, EXPLAIN HOW THE DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH.

Changes to the heater lamp can affect the ability of the device to provide heating to the infant.

11. THE ANSWER TO QUESTION 11 IS YES OR NO, EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT.

A comparative irradiance plot of the subject device and the predicate device is provided. It shows that the new device has a more even distribution of temperature. The maximum irradience level is 38-40 mW/cm^2 which is within the AAMI recommended range of 60 mW/cm^2.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes
If not, does the submission include a certification that such information will be made available to interested persons upon request? N/a

9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FMT

Classification should be based on:

880.5130 Infant radiant warmer **Class:** III

If the device is substantially equivalent to a class III device, does the submission include: (1) certification that a reasonable search of all information known, or otherwise available, about the generic type of device has been performed and (2) a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description? Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Hill-Rom®
A HILLENBRAND INDUSTRY

Food and Drug Administration
Center for Devices and Radiological Health
Attention: Hung Trinh (HFZ-480)
Document Mail Center
9200 Corporate Blvd.
Room 20N
Rockville, MD 20850

March 31, 1997

Re: K970074

Dear Mr. Trinh,

Per our conversation 3/27/97, attached please find:

(b)(4)

[redacted]

If I can be of further assistance, please contact me.

Sincerely,

William D Jordan

William D. Jordan
Regulatory Specialist
Ph. (812) 934-7471
Fax: (812) 934-1675

121

1069 STATE ROUTE 46E, BATESVILLE, INDIANA 47006-9167 812-934-7777 TELEPHONE TOLL FREE 800-234-7193 Telex Domestic 812-934-8189

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-Connect@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

(b)(4)

[redacted]

(b)(4)

Stabilet I.R. pattern mw/sq. cm

PREDICATE DEVICE

ATTACHMENT C

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ATTACHMENT B

Sheet1 Chart 1

Stabilet radiant warmer (b)(4) [redacted]

(b)(4) [redacted]

NEW DEVICE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ATTACHMENT A

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

AAMI/DS 1152
(AAMI/WD II52)
1996-11-01

Proposed Draft

(Working Draft)

American National Standard

NOTE-This document is still under study and subject to change.
It should not be used for reference purposes.

Infant radiant warmers

Abstract: This standard delineates requirements for infant radiant warmers labeling and performance, which are intended to minimize risks to patient and operator, and establishes referee tests by which the requirements can be verified.

Keywords:

Association for the Advancement of Medical Instrumentation
3330 Washington Boulevard, Ste 400, Arlington, VA 22201-4598
Phone 703/525-4890 Fax 703/276-0793

21

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

AAMI
Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

Published by

Association for the Advancement of Medical Instrumentation
3330 Washington Boulevard, Suite 400
Arlington, VA 22201-4598

© 1996 by the Association for the Advancement of Medical Instrumentation
All Rights Reserved

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without prior written permission of the publisher.

Printed in the United States of America

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

21

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Contents **Page**

Committee representation v

Foreword vi

1 Scope 1

2 Normative references 2

3 Definitions 3

4 Requirements 5
- 4.1 Labeling 5
  - 4.1.1 Device markings 5
  - 4.1.2 Operator's manual 8
  - 4.1.3 Service manual 10
- 4.2 Performance 11
  - 4.2.1 Environmental performance 11
  - 4.2.2 Thermal characteristics 11
  - 4.2.3 Alarms 12
  - 4.2.4 Sound levels 13
  - 4.2.5 Fire prevention 13
  - 4.2.6 Mechanical/construction requirements 13
  - 4.2.7 Electrical characteristics 15

5 Tests 19
- 5.1 Labeling 20
  - 5.1.1 Device markings 20
  - 5.1.2 Operator's manual 20
  - 5.1.3 Service manual 23
- 5.2 Performance 23
  - 5.2.1 Environmental performance 23
  - 5.2.2 Thermal characteristics 23
  - 5.2.3 Alarms 24
  - 5.2.4 Sound levels 25
  - 5.2.5 Fire prevention 25
  - 5.2.6 Mechanical/construction requirements 25
  - 5.2.7 Electrical characteristics 27

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

26

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Annex

A Rationale for the development and provisions of this standard 32

AA General guidance and rationale from IEC document..... 51

B Cited references..... 55

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Association for the Advancement of Medical Instrumentation

Infant Incubator Committee

This standard was developed by the Infant Incubator Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of the standard does not necessarily imply that all committee members voted for its approval. The committee currently has the following members:

Cochairperson: Robert H. Stiefel, CCE

Members:
Joe Bagnell, Air-Shields
Michael M. Donnelly, University of Cincinnati Medical Center
Joseph F. Dyro, PhD, CCE, Biomedical Resource Group
Charles Goldberg, Hill-Rom Company
Gary H. Harding, Greener Pastures, Inc.
Robert J. Kopotic, RN, RRT, University of California at San Diego Medical Center
Jerome Korten, Vitaltrends Technology, Inc.
Michael H. LeBlanc, MD, American Academy of Pediatrics
Nancy Pressly, Center for Devices and Radiological Health, U.S. Food and Drug Administration
Dan Poole, International Biomedical
Wayne Shockloss, Arbo Medical
Alexander S. Sinclair, PhD, Bureau of Radiological Medical Devices, Canada
Robert H. Stiefel, CCE, Johns Hopkins Hospital, Baltimore, MD
Jeff Taylor, Ohmeda
Glynn E. Waechter, CBET, Loudoun Hospital Center, Leesburg, VA

Alternates:
Larry Krasley, Air-Shields
Vladimir Kremenchugsky, PhD, Ohmeda
Mike Mackin, Ohmeda
Janet L. Scudiero, Center for Devices and Radiological Health, U.S. Food and Drug Administration

---

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Foreword*

This standard was developed by the Infant Incubator Committee of the Association for the Advancement of Medical Instrumentation (AAMI). The objective of this standard is to provide minimum labeling, performance, and safety requirements that will help assure a reasonable level of clinical efficacy and patient safety. The standard is not intended to address matters of medical management and/or prescription, which are the responsibility of the medical personnel.

No standard can fully assure that a device will be totally safe and effective. Known risks associated with the use of infant radiant warmers are addressed in this standard, but this does not preclude the possibility of harm as a result of improper use, random component failures, or other unanticipated hazards.

As with many other medical devices, it is inherent in the design and function of infant radiant warmers that to be effective for one patient a device may be potentially harmful to another, even when the device is performing to the manufacturer's specifications and in conformance with a published standard. It is possible that an absolutely "safe" device would be ineffective for at least a portion of the patient population for which its use is intended.

Performance requirements have been established in this standard where a parameter is known to affect safety and efficacy *and* where sufficient data are available to establish specific performance criteria. Technological feasibility alone has not been considered a valid basis for establishing performance requirements.

Disclosure requirements have been established in this standard where a parameter is known to affect safety and efficacy, but where sufficient data are *not* available to permit the establishment of performance criteria. Where disclosure requirements have been defined, sufficient information has been provided to permit the user to knowledgeably compare and evaluate the parameters on available warmers when disclosure is made.

Referee test methods have been made part of the standard to assure that a valid comparison of information required for the disclosure can be made, and that conformance with the performance requirements can be verified.

The rationale statement of Appendix A, while not an "official" part of the standard, explains the committee's reasons for establishing the disclosure and performance requirements and provides important technical and clinical data underlying these provisions. It is essential that the rationale be read and understood by all who choose to use the standard as a reference.

---

*This foreword is not a part of the standard, *Infant radiant warmers*, AAMI II52-D-1995.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

It should be recognized that because a radiant warmer currently in use does not fully comply with all of the labeling, performance, and safety requirements of this standard, it does not necessarily mean that the device cannot be used safely and effectively. Nonconformance with the standard should not be the sole basis for a decision to replace a radiant warmer. The decision on whether or not to continue use of an infant radiant warmer should be based on careful consideration of the extent and nature of nonconformance, on how it has been and will continue to be used, and on what costs, risks, and/or benefits will result from the decision.

In the development of this standard, an attempt was made to achieve harmonization with the standard for infant radiant warmers which has been completed by Subcommittee SC 62D (Electromedical Equipment) of the International Electrotechnical Commission (IEC). Lastly, to ascertain the current clinical consensus on many of the safety and performance issues that required resolution, the committee relied heavily on the recommendations of the Infant Incubator Advisory Task Force of the American Academy of Pediatrics (AAP). The assistance of the AAP Task Force and Food and Drug Administration support of the Task Force's work are gratefully acknowledged.

The requirements incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be periodically reviewed and updated to reflect medical and/or technological advances and to address safety and performance issues not previously identified. To remain relevant, the standard must be revised or updated as technological innovation occurs and as new data are brought forward.

IMPORTANT: It is recommended that reviewers of this standard study the definitions (Section 3) prior to reviewing the requirements and tests, since many of the terms in the standard are used in a very specific context. (When terms are so similar they could cause confusion, the text refer readers back to the appropriate definitions number.)

As used within the context of this standard, "shall" indicates requirements strictly to be followed in order to conform to the standard; "should" indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action is discouraged but not prohibited; "may" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations.

As the standard is used, reference should also be made to Annex A. which explains the need for the standard and provides the rationale for each of its specific provisions. For each requirement in Section 4, the applicable test method is found in Section 5 and the rationale in Annex A. For ease of reference, the paragraph numbering has been designed so that the number of the requirement corresponds with that of the applicable test and rationale statement: for example, conformance of the device with the requirements of 4.1.2 a) can be verified by the referee test methods of 5.1.2 a), and the rationale is provided in A4.1.2 a).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

This standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses and other health care professionals, working with government representatives and device manufacturers, to define those safety and performance criteria that could reasonably be achieved at this time. Suggestions for improving the standard are invited. Comments and suggested revisions should be sent to AAMI, 3300 Washington Boulevard, Suite 400, Arlington, VA, 22201, Attn: Standards Department.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Infant radiant warmers
(Draft standard)

1 Scope

1.1 General

This standard applies to infant radiant warmers, those electrically powered devices with a radiant heating source intended to maintain a thermal balance of an infant patient by direct radiation of energy in the infra-red region of the electromagnetic spectrum.

1.2 Inclusions

Infant radiant warmers are defined for purposes of this standard into two classes, on the basis of the temperature variable which is controlled. Included within the scope of this standard are manual and infant temperature controlled (ITC), freestanding, integral bed, separate bassinet, and wall mounted warmers.

1.3 Exclusions

This standard specifies requirements for infant radiant warmers as defined in section 3. Requirements for infant radiant warmers intended for use outside a hospital environment, infant radiant warmers having a heated mattress, and infant radiant warmers powered by an internal electrical power source are not included in this particular standard.

2 Normative references

The following documents are normative to the extent specified herein:

2.1 AMERICAN NATIONAL STANDARDS INSTITUTE, CANADIAN STANDARDS ASSOCIATION AND COMPRESSED GAS ASSOCIATION. standard for *Compressed Gas Cylinder Valve Outlet and Inlet Connections*, ANSI B57.1; CSA B96; CGA V-1-1987.

2.2 COMPRESSED GAS ASSOCIATION. *Diameter index safety system*, ANSI/CGA V-5-1989.

2.3 AMERICAN SOCIETY OF HEATING, REFRIGERATING, AND AIR CONDITIONING ENGINEERS, INC. *1987 ASHRAE Handbook - HVAC Systems and Applications*, Atlanta (GA): ASHRAE, 1987.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

2.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe Current Limits for Electromedical Apparatus*, ANSI/AAMI ES1-1993. Arlington (VA): AAMI, 1993. American National Standard.

2.5 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Electromagnetic compatibility for industrial process measurement and control equipment*, IEC 1000-4 series. Geneva: IEC. (In US, Available from ANSI.)

-IEC 1000-4-2:1994 *Electrostatic discharges requirements*

-IEC 1000-4-3:1993 (ENV 50140) *Immunity to radiated radio frequency electromagnetic fields*

-IEC 1000-4-4:1994 *Electrical fast transient burst requirements*

-IEC 1000-4-5:1995 (ENV 50142) *Voltage surge immunity requirements*

-IEC 1000-4-6:199x (ENV 50141) Currently document 77B/144/DIS, *Immunity to conducted disturbances induced by RF fields* (draft International Standard)

2.6 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Part 2: Collateral standard: Electromagnetic compatibility: Requirements and test*, IEC 601-1-2, 1993. (Available from ANSI).

2.7 INTERNATIONAL ELECTROTECHNICAL COMMISSION. *Medical electrical equipment - Part 1: General requirements for safety*, IEC 601-1, 1988.

2.8 INTERNATIONAL SPECIAL COMMITTEE ON RADIO INTERFERENCE. *Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical(ISM) radio frequency equipment*, CISPR 11. 2nd Edition. 1990 (available from ANSI).

2.9 NATIONAL FIRE PROTECTION AGENCY. American National Standard, *National Electrical Code*, ANSI/NFPA No. 70. Boston, MA: National Fire Protection Association, 1993.

2.10 NATIONAL TRUCK EQUIPMENT ASSOCIATION. *Oxygen Tank Retention System*, AMD Standard 003. Livonia (MI): NTEA, 1991.

2.11 UNDERWRITERS LABORATORIES. *Standard for Safety, Medical and Dental Equipment.* UL 2601.1. Melville, NY: Underwriters Laboratories, 1994.

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 Applied part: All parts of the radiant warmer accessible to the infant.

3.2 Control temperature: The temperature set at the temperature control.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

83

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

3.3 Indicated temperature: The temperature displayed by the readout of the SKIN TEMPERATURE SENSOR.

3.4 Infant accessible region: Area surrounding an infant that includes anything on a level with the infant that could be reached without going over a partition at least 10 cm in height and that is within 30 cm of the mattress itself. Objects that are within 20 cm of the mattress that could be accessed by sticking a small arm or leg through a convenient hole or slit in the partition are considered infant accessible if they are within 20 cm of the infant compartment and did not contain angulations or barriers that would be impossible for a small arm or leg to negotiate.

3.5 Infant simulator: Device which was designed to approximate the thermal and heat exchange characteristics of infants. The INFANT SIMULATOR is described in United States Patent 5,409,382. It has the correct surface to mass ratio for small and large infants. The small simulator is representative of a 650 gram infant and the large simulator is representative of a 2500 gram infant.

3.6 Infant simulator skin or core temperature (reference figure 1)**:** The average temperature reading taken of an INFANT SIMULATOR during a STEADY TEMPERATURE CONDITION at regular intervals.

3.7 Infant simulator temperature equilibrium: The condition when the warmer TEST DEVICE surface temperature does not vary by more than 0.2°C in one hour.

3.8 Infant temperature controlled radiant warmer: A radiant warmer whose power output varies automatically in response to the temperature of the infant's skin to achieve a temperature close to a value set by the user.

3.9 Inspection: Any examination, such as a visual or auditory one, which does not require the use of special laboratory applications or procedures and/or verification of manufacturing and test records.

3.10 Irradiance: Radiant flux in infant area measured in mW/cm^2 with a thermopile referenced to ambient temperature.

3.11 Irradiance uniformity: The amount by which the irradiance at each of the five individual points as specified in figure 1 varies from the average irradiance of the five points.

3.12 Manual controlled radiant warmer: A radiant warmer whose heater output is controlled either at a fixed level or a proportion of its maximum output set by the user.

3.13 Overshoot: The amount by which the INFANT SIMULATOR SKIN OR CORE TEMPERATURE exceeds the average INFANT SIMULATOR TEMPERATURE at temperature equilibrium as a result of an increase in CONTROL TEMPERATURE.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

34

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

3.14 Single fault condition: Condition in which a single means for protection against a safety hazard in the equipment fails, including (but not limited to) failure of a skin temperature sensor, disconnection of the skin temperature sensor from the equipment, or failure of the heater control circuit.

3.15 Skin temperature sensor: A sensing device including the link with the equipment intended to measure the infant's skin temperature.

3.16 Steady temperature condition: A condition which is reached when the temperature measured at the core of the INFANT SIMULATOR (see figure 1) positioned on the mid point of the equipment mattress does not vary by more than 1°C over a period of one hour.

3.17 Temperature variability: The variability of the INFANT SIMULATOR SKIN OR CORE TEMPERATURE that will be observed over a one-hour period after temperature equilibrium has been reached.

3.18 Undershoot: The amount by which the INFANT SIMULATOR SKIN OR CORE TEMPERATURE falls below the average INFANT SIMULATOR at temperature equilibrium as a result of a decrease in CONTROL TEMPERATURE.

4 Requirements

4.1 Labeling

In addition to the information required by applicable federal regulations, the device or its accompanying documentation shall provide the information specified in 4.1.1, 4.1.2, and 4.1.3.

4.1 Device markings

4.1.1 General

Device markings shall withstand the cleaning, disinfecting and sterilizing procedures recommended by the manufacturer and shall not peel or wear off during normal use.

4.1.1.2 Product identification

Each device shall be plainly marked in a place where the following information will be visible or readily accessible for reference by the operator:

a) type of product (e.g., infant radiant warmer), and trademark name if applicable;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

35

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

b) name and location of manufacturer, and first importer of foreign manufacture, if applicable;

c) model number, catalog number, part number, or other unique identifying designation;

d) serial number, lot number, or other unique traceable identification;

e) nominal voltage, frequency, and wattage or current;

f) abbreviated instructions as required for correct operation;

g) any attachable assemblies intended for use with the device shall identify the model of the equipment with which they may be used;

4.1.1.3 Controls, displays and switches

Connectors whose function are obvious (e.g., the power cord) are exempt from this labeling requirement. In addition, the following requirements shall apply:

a) all switches and controls shall be clearly labeled to identify their functions;

b) the manual/ITC switch shall produce an auditory, visual or tactile indication of change of state and means shall be provided to unambiguously indicate which control mode is operational;

c) the direction of control(s) adjustment shall be clearly indicated. Minimum and maximum markings, if provided, shall be located to prevent confusion with regard to the position of the control and the indicated value. Any radiant warmer control, if it has a rotary action, shall be so arranged that a clockwise rotation produces an increase in output;

d) temperature controls shall be clearly marked with temperature settings on or adjacent to the control. The markings shall be provided at intervals of not greater than 0.25°C for servo control settings;

e) heater output control shall be clearly marked with power level settings on or adjacent to the control. The markings shall be provided at intervals such that when the first interval is indicated, the mattress irradiance shall be less than 10 mW/cm^2.

4.1.1.4 Infant temperature sensors

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

36

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Identification of the manufacturer's recommended sensor shall be posted at the sensor's point of connection. Both the sensor and the device shall be labeled to identify the sensor intended for use with the device. Sensors used to indicate rather that control temperature shall also be identified.

4.1.1.5 Overcurrent protection

Overcurrent protection devices shall be clearly and permanently marked as per UL 2601.1 (see normative reference 2.11).

4.1.1.6 Important notices, cautions, and warnings

The following statements, as applicable, shall be clearly displayed on the exterior of each device:

a) a warning of the possible effects of external heat sources on infant temperature, temperature control, and alarm functions;

b) a warning of the possible consequences of inadequately attaching the infant temperature sensor to the skin and of improperly locating it on the infant;

c) a notice to routinely check infant temperature and, if applicable, infant temperature sensor attachment;

d) a warning if the equipment is not suitable for use in the presence of flammable anesthetics;

e) a warning of the possible adverse consequences to the infant if blankets, diapers, or other objects obstruct or alter radiant energy delivery;

f) a warning that the use of an open bed warmer can increase insensible water loss;

g) a warning that is inadvisable to leave an infant unattended under a radiant warmer;

h) warmers without integral bed areas shall be permanently and clearly marked with an indication of the permissible distances between the equipment heating systems and any mattress;

i) maximum recommended loads on shelves and mounting brackets.

4.1.2 Operator's manual

Adequate instructions for the installation and proper operation of the warmer shall be provided with each warmer. Instruction for the installation and proper operation of accessories intended

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Auditory alarm indications which are required by this standard shall have a sound level of at least 65 dBA measured 3 meters from the warmer and at a height of 1.8 meters. See also 4.1.2 b)7).

4.2.4.2 Mattress center alarm

Alarm sound levels at the mattress center shall not exceed 80 dBA.

4.2.5 Fire prevention

Components which in normal use or in a single fault condition may be a source of ignition shall be separated from any oxygen-enriched environments by a barrier which will prevent the O_2 concentration from exceeding ambient by no more than 4 percent. Alternatively, if the O_2 concentration can exceed 4 percent above ambient, the product of load voltage and short circuit current shall not exceed 10 volt amperes.

4.2.6 Mechanical/construction requirements

4.2.6.1 Infant mattress area

The infant mattress area shall be constructed to facilitate observation of the infant:

a) provide means for containing the infant while providing for the introduction of monitoring cables or gas lines;

b) be constructed such that means of access intended to be opened or removed to allow access to the infant shall not be capable of being inadvertently opened or disengaged during normal use or as a result of infant activity;

c) be constructed such that means of barriers to the infant shall not be capable of appearing to be latched, but not actually latched.

4.2.6.2 Stability and transportability

The warmer shall meet the following requirements:

a) Tip-over. 1) The tip-over angle shall be at least 10 degrees from the vertical. 2) Tip-over force shall be at least 100 Newtons while in the worst case configuration of parts and accessories recommended by the manufacturer.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

38

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

2) Thresholds. Latches, doors, and barriers shall remain closed and ancillary equipment supplied by or available from the manufacturer shall remain secure after impact with thresholds typically found in a hospital.

4.2.6.3 Shelves and mounting brackets

Shelves and mounting brackets shall withstand three times the manufacturer's recommended load without evidence of damage to the shelf or mounting bracket.

4.2.6.4 Supplementary gas supply

1) If the device is designed to hold a supplementary air, oxygen or other gas supply, each supply shall be capable of being firmly secured to the unit (normative reference 2.10).

2) Gauges shall be clearly visible, and valves and regulators which are intended to be adjusted shall be readily accessible. If attached to a medical gas system, these shall conform to normative reference 2.1.

4.2.6.5 Switches, controls, and knobs

The following requirements shall apply:

a) indicating knobs shall incorporate means which will provide reasonable protection against inadvertent readjustment of the knob;

b) all switches and controls accessible to the operator under normal conditions of use shall be securely fastened to prevent inadvertent repositioning;

c) each temperature control, if it has a rotary action, shall be so arranged that a clockwise rotation produces an increase in temperature or power.

4.2.6.6 Ingress of liquids

The following requirements shall apply:

a) liquids shall not enter the electrical compartment of the device to the detriment of the performance or safety of the device;

b) the infant area shall be so constructed that liquid deposited on its inside surface cannot penetrate to electrical components during normal use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

for use with the warmer shall be provided and may be included in the operator's manual for the accessory. These shall include a description of the functional characteristics and use of all controls, indicators, displays and alarms, and a procedure for operator checks of the proper functioning of visual and auditory alarms. An explanation of the temperature control methodology, how and where these temperatures are measured, and how they relate to indicated temperature and control temperature, shall be provided. Definitions of the applicable terms as defined in this standard shall be included. As a minimum, the following additional information shall be included, when applicable:

a) a statement of the device's intended application;

b) the following performance specifications (and statements), as determined in accordance with the tests of section 5.1.2 b):

1) CONTROL TEMPERATURE range for infant temperature control (ITC). See also 4.2.2 a) and 4.2.2 d);

2) IRRADIANCE UNIFORMITY with mattress in normal and extreme positions of use;

3) infant INDICATED TEMPERATURE accuracy for ITC;

4) CONTROL TEMPERATURE vs INDICATED TEMPERATURE correlation for ITC (see also 4.2.2 c));

5) the deviation of INDICATED TEMPERATURE from CONTROL TEMPERATURE which will activate the infant temperature alarm, for ITC only;

6) range, accuracy, testing procedures, and other pertinent functional characteristics of other controls, alarms and indicators, for both manual and ITC;

7) maximum sound level with alarm(s) activated;

8) maximum center mattress sound level with alarms activated, for both manual and ITC;

9) maximum recommended loads on shelves and mounting brackets;

10) the permissible distances between the heating system and any mattress used with it and a statement on the effects which any changes in this distance may have;

40

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

11) a statement that the user regularly inspect latches, closing devices, or barriers if applicable to prevent the infant from falling out;

12) a statement to explain why the user should use the ITC mode;

13) a statement that the equipment cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and skin temperature (hypothermia), and a recommendation to monitor the temperature of the patient;

14) a statement that environmental conditions (e.g. air movement) can effect the thermal balance of the infant;

15) the manufacturer shall state in the accompanying documents the conditions under which the source of radiant heat should be replaced due to aging;

16) a statement that an infant radiant warmer should be used only by appropriately trained personnel and under the direction of qualified medical personnel being familiar with currently known risks and benefits of radiant warmer use;

17) a statement that infant radiant warmer can increase the patient's insensible water loss;

18) under normal conditions, overshoot, undershoot, and temperature variability;

19) time to maximum irradiance;

20) intervention temperature drop/recovery.

c) The following warnings, if applicable:

1) a warning regarding the possible consequences of inadequately attaching the infant temperature sensor to the skin and of improperly locating it on the infant's skin. The proper location and method of attachment shall be identified;

2) a warning that infant temperature sensors should not be used to control rectal or axillary temperature;

3) a warning of the possible effects of external heat sources (e.g. phototherapy, light sources on infant temperature, temperature control, and alarm functions;

4) a warning to routinely check infant temperature, infant temperature sensor attachment and warmer function;

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

41

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

5) a warning if the warmer is not suitable for use in the presence of flammable anesthetics;

6) a warning that it is inadvisable to leave an infant unattended.

d) Cleaning, disinfecting, and sterilizing methods and materials suitable for use on the warmer and, if separate instructions are not provided, for its accessories.

e) An explanation of the control methodology for ITC mode shall be disclosed, giving the relationship between infant temperature, control temperature, and other warmer controlled parameters (e.g., heater status).

4.1.3 Service manual

A service manual shall be available from the manufacturer and shall include:

a) care, preventive maintenance, and repair instructions for the equipment;

b) theory of operation;

c) schematics and wiring diagrams;

d) complete parts lists;

e) procedures for calibration of controls and for testing alarm systems;

f) recommended intervals for preventive maintenance and skill level required;

g) information on how to obtain authorized repair.

4.2 Performance

4.2.1 Environmental performance

The warmer shall meet the requirements of this standard when operated over the following range of ambient conditions:

a) Temperature: 20°C - 30°C;

b) Barometric pressure: 86 - 106 kPa (645 - 795 mm Hg);

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

c) Relative humidity: 0 to 95%, non-condensing;

d) Air velocity: 10 - 15 cm/sec.

4.2.2 Thermal characteristics

The warmer shall exhibit the following thermal characteristics:

a) the maximum irradiance level at any point on the mattress shall not exceed 60 mW/cm^2 in the total infra-red spectrum. The maximum irradiance level shall not exceed 10 mW/cm^2 in the near infra-red spectrum (760 to 1400 nm);

b) the temperature measured by the skin temperature sensor shall be continuously displayed and clearly visible. The temperature displayed shall have an accuracy of ± 0.3°C. If the temperature display is used to present any other parameter, this shall only be obtained on demand using a momentary action switch. The range of displayed temperature shall be at least 30°C to 40°C;

c) if the heater element surface temperature exceeds 85°C in normal use, heater guards are required and shall be below 85°C. The heater guard shall not touch the heater element (normative reference 2.7);

d) the equipment shall not permit the skin temperature of the infant to exceed 40°C under any operating mode and any single fault condition;

e) with the equipment working in the ITC with horizontal mattress orientation the temperature as measured by the skin temperature sensor shall not differ from the control temperature by more than 0.5°C during steady state;

f) the temperature of surfaces within the INFANT ACCESSIBLE REGION shall not exceed 40°C for metal surfaces and 42°C for other materials when the equipment is operating under steady temperature condition at its maximum control temperature. Under conditions of warm-up to steady temperature condition or that of a single fault condition these surfaces shall not exceed 43°C for metal or 45°C for other materials;

g) the range of the control temperature for an ITC controlled infant radiant warmer shall be from 36°C or less to at least 37°C but not more than 38°C.

4.2.3 Alarms

4.2.3.1 Infant temperature (ITC)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

VB

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

For ITC controlled devices, auditory and visual alarms shall be activated if the infant's indicated temperature differs from the control temperature by more that the preset amount specified by the manufacturer. This difference shall not exceed 1 °C.

4.2.3.2 Manual mode alarm (irradiance greater than 10 mW/cm^2)

In the case of infant radiant warmers which are operated in the manual mode an auditory and visual alarm should be given at least every 15 minutes. In addition, if the heater output is greater than 10 mW/cm^2, this alarm will cause the heater output to be reduced below 10 mW/cm^2. Adjustment of the manual temperature control may reset the alarm.

4.2.3.3 Temperature sensor failure

a) The equipment shall be provided with an auditory and visual alarm which operates in the event of the skin temperature sensor having open circuit or short circuit leads in the ITC. Both open and short circuit leads shall disconnect the supply to the heater. Manual controlled equipment which have a means to indicate the infant temperature shall provide a visual indication of failure of the infant temperature sensor when either electrically open- or short-circuited, or if the sensor is improperly connected; a blank display may be used for this purpose.

b) The visual and auditory alarms should be provided if the skin temperature probe is dislodged.

4.2.3.4 Power failure

The warmer shall incorporate an auditory alarm and visual indicator to signal complete failure of the input electrical power or inadvertent disconnection from the power source. The auditory alarm and visual indicator shall be capable of being sustained for at least 3 minutes. A five minute or shorter interruption and subsequent restoration of input electrical power shall not change the mode of operation nor the control temperature.

4.2.3.5 Silencing

Any deliberately silenced auditory alarm shall automatically sound again within 15 minutes unless the alarm condition has been corrected. The silencing of one alarm shall not disable or in any way inactivate any other alarm. Visual alarms shall not be extinguished until the alarm condition has been corrected. This requirement applies only to alarms covered in this standard.

4.2.4 Sound levels

4.2.4.1 Auditory alarm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

44

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

4.2.6.7 Mercury thermometers and thermostats

Thermometers or thermostats using mercury shall not be used.

4.2.6.8 Infant temperature sensors

Sensors intended for different functions in the same device shall be designed to prevent use in incorrect receptacles.

4.2.6.9 Wheels

If a warmer is equipped with wheels for transportation at least two of them shall be capable of being locked by the user.

4.2.7 Electrical characteristics

4.2.7.1 Risk current

The device shall meet the applicable requirements as specified in the American National Standard, *Safe Current Limits for Electromedical Apparatus* (Normative reference 2.3).

4.2.7.2 Overcurrent protection

Overcurrent protection shall be provided. See also 4.1.1.5.

4.2.7.3 Power switch

The power control switch shall simultaneously interrupt both power conductors.

4.2.7.4 Power cord and strain relief

The power cord shall be of a size and type to comply with the *National Electrical Code* (Normative reference 2.9) for the requirements of the unit. The plug shall be Hospital Grade or equivalent and the strain relief provided shall be in compliance with UL 2601.1 (Normative reference 2.11).

4.2.7.5 Power indicator

There shall be a visual indication when the power switch is on and electrical power is being delivered to the warmer.

4.2.7.6 Supply voltage variation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Devices with rated nameplate alternating current voltages between 115 to 120 V root mean square (rms) shall meet all requirements of this standard, except for 4.1.2 b)1), 4.1.2 b)3), 4.1.2 b)4), 4.1.2 b)6), 4.1.2 b)12), and 4.1.2 b)13), at line voltages ± 10 percent of the rated voltage. These devices shall not be damaged by operation on input voltages from 95 to 135 V rms. Where the nameplate voltage is other than the range specified, the voltage limits shall be the limits specified above, multiplied by a number which is the ratio of the device nameplate voltage to 120V.

4.2.7.7 Dielectric withstand

The insulation and spacing shall be capable of withstanding without breakdown the application for one minute of 1000 V plus twice the maximum rated voltage, or the application for one second of 1200 V plus 2.4 times the rated voltage.

4.2.7.8 Grounding impedance

The impedance between the point of any connection grounding means and any other metal part required to be grounded shall comply with UL 2601.1 and NFPA requirements (Normative references 2.7 and 2.11).

4.2.7.9 Electromagnetic compatibility (EMC) requirements

These EMC requirements were developed on the basis of reference standards 2.5, 2.6, and 2.8.

4.2.7.9.1 Electromagnetic emissions

4.2.7.9.1.1 Radiated and conducted electromagnetic emissions

The radiant warmer shall comply with the requirements of CISPR 11 Group 1 Level B in the worst cast configuration and operating mode.

Emission levels measured 10 meters from the radiant warmer shall not exceed 30 dB μV from 30 Hz to 230 MHz and shall not exceed 37 dB μV from 230 to 1000 MHz.

4.2.7.9.1.2 Magnetic field emissions

The unit shall not emit a magnetic field greater than 0.5 millitesla (5 gauss) at any point on the surface of the radiant warmer under normal operating conditions.

4.2.7.9.2 Electromagnetic immunity

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

4.2.7.9.2.1 Immunity to radiated RF electromagnetic fields

All requirements of this standard shall be verified over the entire range of carrier and modulation frequencies specified for the level 2 tests (3 V/m), when all faces of the instrument are sequentially exposed to a modulated RF electromagnetic field. For the level 3 tests, field strength of 20 V/m shall be used (rather than 10 V/m). The equipment shall continue to meet its specifications or fail in such a way that all high and low temperature alarms and thermal cut-outs (e.g., HIGH TEMPERATURE THERMOSTAT) continue to function according to the requirements of this standard, and the proper incubator settings shall be maintained.

4.2.7.9.2.2 Immunity to conducted electromagnetic fields

No unintentional change of state shall occur when an RF field is injected into the line cord. No degradation of system performance or loss of functionality is allowed.

4.2.7.9.2.3 Immunity to magnetic fields

No unintentional change of state shall occur when the equipment is exposed on all faces to an AC magnetic field. Some display jitter is allowed, however the displayed information must be readable.

4.2.7.9.2.4 Immunity to electrostatic discharge (ESD)

There shall be no noticeable change in equipment operation for open air discharges or direct contact discharges of test condition 1 (4 kV and 2 kV respectively). The equipment shall operate within normal limits of its specifications. No degradation of system performance or loss of functionality is allowed. However, display glitches or momentary LED flashes are acceptable during any electrostatic discharge (ESD). For open air discharges or direct contact discharges of test condition 2 (8 kV and 4 kV respectively), the equipment may exhibit momentary loss of functionality, but shall recover within two seconds without user intervention.

4.2.7.9.2.5 Power line transients

Only transient loss of functionality is allowed when the equipment is subjected to fast transient/bursts (1 kV) at the mains plug. The device shall return to its condition just prior to the burst without operator intervention. No unintentional change of state is allowed when the equipment is subjected to surges line to line (1 kV) and line to ground (2 kV). The device shall return to its prior condition without operator intervention.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

See 5.1.1.2.

5.1.1 Device markings

See 5.1.1.2.

5.1.1.1 General

Conformance can be determined by inspection.

5.1.1.2 (a-g) Product identification

Conformance can be verified by inspection.

5.1.1.3 (a-e) Controls, displays and switches

Conformance can be verified by inspection.

5.1.1.4 Infant temperature sensors

Conformance can be verified by inspection.

5.1.1.5 Overcurrent protection

Conformance can be verified by inspection.

5.1.1.6 (a-i) Important notices, cautions, and warnings

Conformance can be verified by inspection.

5.1.2 Operator's manual

a) Conformance can be verified by inspection.

b) (The following test must be conducted separately for the small and the large simulators.) Performance Specifications graph of temperature and/or irradiance.

1) Control temperature range. (following test must be conducted separately for the small and the large simulators)
With the INFANT SIMULATOR prewarmed to 34°C ± 0.1°C allow the INFANT SIMULATOR to reach INFANT TEMPERATURE EQUILIBRIUM first at the maximum, at 36°C and then at the minimum CONTROL TEMPERATURE

48

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

settings. Measure and record the INFANT SIMULATOR SKIN OR CORE TEMPERATURES and the irradiance 5 cm to the left of the INFANT SIMULATOR. The results of this test should be reported as a graph of INFANT SIMULATOR SKIN AND CORE TEMPERATURES and irradiance versus time.

2) Thermopyle test. Divide mattress into regions as defined in figure 2. Insert test procedure using a thermopyle, perform irradiance measurements under the following set-up conditions. Allow warmer to stabilize for 10 minutes before performing measurements at each set-up condition. Record data at each position as shown in figure 2.

a) 100% Heater Power at 117 VAC (Nominal Line Voltage).
b) 50% Heater Power at 117 VAC (Nominal Line Voltage).

3) Verified from results of 5.2.2 b)2).

4) Control temperature/indicated temperature correlation. During INFANT SIMULATOR TEMPERATURE EQUILIBRIUM at the maximum, at 36°C and minimum CONTROL TEMPERATURES note the maximum difference between the INDICATED TEMPERATURE and the CONTROL TEMPERATURE. If it can be demonstrated that an alternative test method is as relevant for this test, the manufacturer may use this method to verify the performance requirement; disclosure of this shall be made.

5) During test device temperature equilibrium at a control temperature of 36°C (i.e., ITC mode, infant temperature sensor attached to the warmer test device per figure 1), gradually increase the control temperature until the low temperature alarm is activated and note the difference between the indicated temperature and the control temperature to the nearest 0.1°C. For high temperature alarm activation repeat while gradually decreasing the control temperature.

6) The manufacturer's specified values are verified by test methods provided by the manufacturer in the service manual.

7) See 5.2.4.1.

8) See 5.2.4.2.

9) Conformance can be verified by inspection. See also 5.2.6.3.

10) to 17) Verified by inspection.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

18) Dynamic response, overshoot, and undershoot. (following test must be conducted separately for the small and the large simulators)
With the INFANT SIMULATOR prewarmed to a surface TEMPERATURE EQUILIBRIUM of 34°C increase the CONTROL TEMPERATURE to 37°C and allow the INFANT SIMULATOR to reach TEMPERATURE EQUILIBRIUM, then increase the CONTROL TEMPERATURE to maximum CONTROL TEMPERATURE and allow the INFANT SIMULATOR to reach TEMPERATURE EQUILIBRIUM then decrease the CONTROL TEMPERATURE to 36°C. Measure and record the INFANT SIMULATOR SKIN AND CORE TEMPERATURE and the irradiance 5 cm to the left of the INFANT SIMULATOR. The results of this test should be reported as a graph of INFANT SIMULATOR SKIN AND CORE TEMPERATURE and irradiance versus time.

19) Begin with warmer off and cold. Record irradiance at point of maximum irradiance. Turn warmer on to maximum power, and record till it reaches steady state (change in irradiance less than 5% of maximum value in 10 minutes). Record time to achieve 90% of maximum value. This is time to maximum irradiance.

20) Intervention temperature drop/recovery. (following test must be conducted separately for the small and the large simulators)
Operating at INFANT SIMULATOR TEMPERATURE EQUILIBRIUM at a CONTROL TEMPERATURE of 36°C, place a material which blocks the infrared energy midway between the heater and the mattress such that all the infrared energy from the heater is blocked from reaching any part of the mattress. Leave the material in place for 5 minutes and then remove. Allow the INFANT SIMULATOR to reach INFANT SIMULATOR TEMPERATURE EQUILIBRIUM. Measure and record INFANT SIMULATOR SKIN AND CORE TEMPERATURE to the nearest 0.1°C, irradiance 5 cm to the left of the INFANT SIMULATOR at mattress level and the recovery time to the start of the subsequent INFANT SIMULATOR TEMPERATURE EQUILIBRIUM after removing the infrared blocking material. The results of this test should be reported as a graph of INFANT SIMULATOR SKIN AND CORE TEMPERATURE and irradiance versus time.

c) (1 to 6) Important notices, cautions, and warnings. Conformance can be verified by inspection.

d) Conformance can be verified by inspection.

e) Compliance will be by inspection.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

80

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

5.1.3 Service manual

Conformance can be verified by inspection.

5.2 Performance

5.2.1 Environmental performance

Manufacturer is to certify compliance.

5.2.2 Thermal characteristics

a) Compliance is checked by measurement.

b) Compliance shall be checked by inspection and the following test:

Immerse the skin temperature sensor in a water bath maintained at 36 ± 0.1 °C. Position a calibrated thermometer accurate to within 0.05°C with its bulb adjacent to the skin temperature sensor. The reading of the standard thermometer shall be compared with the displayed temperature and their difference shall not exceed 0.3°C less the standard thermometer error.

c) Guards shall be tested by inspection and appropriately tested for temperature (see 2.11).

d) Place a test device at the center of the mattress, and with the equipment operating under steady temperature conditions at the maximum control temperature, and any single fault condition. The test device shall not exceed 40°C without the auditory and visual alarms operating and the heater being disabled.

e) Compliance shall be checked during the test for 4.1.2 b)4).

f) Compliance shall be checked by inspection and measurement.

g) Compliance shall be checked by inspection.

5.2.3 Alarms

5.2.3.1 Infant temperature (ITC)

Test 1:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Set the control temperature to 36°C and immerse the skin temperature sensor in a water bath maintained at 36 ± 0.1°C. Position a calibrated thermometer accurate to within 0.05 °C with its bulb adjacent to the skin temperature sensor. After a steady temperature indication is achieved and maintained for at least 10 min, increase the water bath temperature control setting to 38°C. Report whether the auditory and visual alarms operate at a water bath temperature not exceeding the manufacturer's alarm limit and that the heater switches off.

Test 2:

As for Test 1, but in this instance the temperature control setting of the water bath is reduced from 36 ± 0.1°C to 34 +0.1°C. Report whether the auditory and visual alarms operate above 35 ± 0.3°C and at the manufacturer's specified limit, verify that the equipment heater remains in operation.

See 5.1.2 b)5).

5.2.3.2 Manual mode alarm (irradiance greater than 10 mW/cm^2)

Select manual mode and set control temperature to produce an output of 11 mW/cm^2 measured by the thermopyle. Verify the auditory and visual alarms activate within 15 minutes and the heater is deactivated. Reset the alarm. Verify alarm activation and heater deactivation within 15 minutes.

NOTE: Run this test with the unit at maximum voltage.

5.2.3.3 Temperature sensor failure

a) The manufacturer shall certify that a shorted (<5 ohm) or open (>1 megohm) sensor will sound an alarm. Slowly insert connector into its receptacle to determine if any intermediate positions will inhibit alarm activation.

b) To be provided by the manufacturer.

5.2.3.4 Power failure

Compliance shall be checked by simulating both fault conditions and observing the effect. With the warmer turned on, disconnect the power cord from the line voltage receptacle and verify that auditory alarm is activated for at least 3 minutes. After being disconnected for five minutes, the power cord shall be reconnected to verify that the operating mode and control temperature are unchanged.

5.2.3.5 Silencing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Compliance shall be checked by inspection, operating the equipment and timing the alarm. An alarm condition is simulated for all alarm functions as recommended by the manufacturer. The time(s) for the alarm(s) to reactivate after silencing is measured with a stopwatch. Proper functioning of visual alarms can be verified by inspection.

5.2.4 Sound levels

5.2.4.1 Auditory alarm

With the alarm sound level adjusted to minimum (if operator adjustable), measure the sound level at a height of 1.8 meters and at a distance 3 meters from the front for the warmer. If more than one alarm sound means is provided, each shall be checked.

5.2.4.2 Mattress center alarm

With each alarm sound means activated, measure the sound level at a point 5 cm above the center of the mattress. The alarm sound level shall be adjusted to maximum, if operator adjustable.

5.2.5 Fire prevention

With warmer operating as recommended by the manufacturer for highest O_2 concentration, measure the O_2 concentration in all compartments which may be a source of ignition. Alternatively, if the O_2 concentration can exceed 4 percent above ambient, measure the no-load voltage and short-circuit current of components which may be a source of ignition under normal use or single fault conditions.

5.2.6 Mechanical/construction requirements

5.2.6.1 Infant mattress area

a) Conformance can be verified by inspection.

b) With barriers latched apply at the center of each barrier, a horizontal outward force gradually increasing over a period of 5-10 seconds to a maximum of 20 Newtons. Maintain for 5 seconds.

c) Conformance can be verified by inspection.

5.2.6.2 Stability and transportability

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

B

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

a) Tip-over. With the casters in the worst case position and prevented from rolling with all movable parts, doors, supports and accessories recommended by the manufacturer positioned to minimize the warmers stability, apply at the highest point of the warmer or 1.5 meters from the floor (whichever is lower), a horizontal force great enough to tip the warmer. The horizontal force shall be greater than 100 Newtons and the warmer shall not tip over at an angle of 10 degrees from the vertical.

b) Thresholds. Pull the warmer in the direction of its long axis at a constant velocity of 0.5 ± 0.1 m/s until its leading wheels meet a 20 mm thick plate. The test shall be carried out (a) with the incubator's long axis at right angles to the edge of the plate, and (b)with the edge of the plate parallel to a line from the leading edge of one front wheel to the trailing edge of the other front wheel (see figure 1). The two types of movement are repeated two times with each pair of wheels first. Following these tests, the warmer shall be fit for further normal use. The warmer's mechanical and structural integrity shall be verified, e.g., latches and doors shall remain closed and ancillary equipment that is recommended by the manufacturer.

5.2.6.3 Shelves and mounting brackets

With each support and/or mounting bracket in its worst case configuration, apply at its center a vertically downward force, gradually increasing over a period of 5-10 seconds to a maximum equal to three times the manufacturer's recommended maximum weight. Maintain for 1 minute. The tray or bracket shall not tilt more than 5° and its structural integrity shall not be adversely affected.

5.2.6.4 Supplementary gas supply

1) Test the capability of the supplementary air (normative reference 2.10), oxygen or other gas supply to be firmly secured to the unit according to AMD standard 003.

2) Conformance with the requirement for indexing, visibility and accessibility of gauges, valves and regulators can be verified by inspection. If attached to medical gas systems, these shall conform to the requirements of normative reference 2.1.

5.2.6.5 Switches, controls, and knobs

a) Brush a vertically held straight edge along the side(s) of the warmer where the control(s) are accessible. There shall be not contact with switches, controls, or knobs which could result in a change in setting.

b) Conformance can be verified by inspection.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

84

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

c) Compliance shall be checked by inspection.

5.2.6.6 Ingress of liquids

a) The warmer shall be positioned as for normal use with all accessories. 200 ml of water is poured steadily on the center top of the mattress. After this test the warmer shall comply with the requirements of this standard.

b) 200 ml of water shall be sprayed on all inner surfaces of the infant accessible region such that drops coalesce and flow down the walls. In addition, 200 ml of water shall be poured steadily on the infant tray. After this test the warmer shall satisfy all requirements of this standard.

5.2.6.7 Mercury thermometers and thermostats

Conformance can be verified by inspection.

5.2.6.8 Infant temperature sensor

Conformance can be verified by inspection.

5.2.6.9 Wheels

Compliance with 4.2.6.9 will be verified by inspection (see also 5.2.7.3).

5.2.7 Electrical characteristics

5.2.7.1 Risk current

Risk current levels can be determined by the methods provided in normative reference 2.3 for verifying conformance with the requirements for devices with isolated or non-isolated patient connections.

5.2.7.2 Overcurrent protection

Conformance can be verified by inspection.

5.2.7.3 Power switch

Conformance can be verified by inspection.

5.2.7.4 Power cord and strain relief

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

The power cord, plug and strain relief are inspected to verify conformance with normative reference 2.11.

5.2.7.5 Power indicator

Conformance can be verified by inspection.

5.2.7.6 Supply voltage variation

The effects of input voltage variation can be determined by using a variable transformer and verifying the performance and operation of alarms, temperature indicators, and controls.

5.2.7.7 Dielectric withstand

A 50- or 60-Hz sinusoidal potential of 1000 V plus twice the maximum rated voltage is applied (1) between live parts conductively connected to the supply circuit and dead metal parts, and (2) across each capacitor, winding separation, or other insulation in the primary circuit which is required for the elimination of shock hazard or, if short-circuited, would involve a fire hazard either directly or indirectly. The test potential is to be:

a) 1000 V for an appliance rated 250 V or less, provided that (a) any motor used is rated 1/2 horsepower or less and (b) the appliance, in normal use, is not applied to or in contact with personnel; or

b) 1000 volts plus twice the maximum rated voltage for (a) an appliance which, in its intended use, is applied to or in contact with personnel, (b) an appliance rated more than 250 volts, or (c) an appliance which uses a motor rated at more than 1/2 horsepower.

5.2.7.8 Grounding impedance

The voltage is measured when a current, of 25 A for 1 minute, derived from a 50- or 60-Hz source with no load voltage not exceeding 6 volts, is poised between the grounding connection and any exposed metal part which is likely to be energized due to an electrical fault. The measured voltage shall not exceed 2.5 V.

5.2.7.9 Electromagnetic compatibility

Radiant warmers are complex instruments because they use patient-coupled devices which markedly affect electromagnetic emissions and immunity. Equipment configurations for the tests will be determined by the manufacturer but the equipment shall be tested in a sufficient variety of configurations and operating modes that might be encountered in normal operation, so that the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

worst case may be determined and successfully tested. The infant temperature sensor cables shall be tested both in an unterminated mode and in a patient simulated (test device) terminated mode.

5.2.7.9.1 Electromagnetic emissions

5.2.7.9.1.1 Radiated and conducted electromagnetic emissions

The instrument shall comply with CISPR 11 Group 1 Level B (normative reference 2.8). The detailed test methods are outlined in CISPR 11 and CISPR 16.

The equipment shall be tested on all faces in all expected configurations and operating states. The infant temperature sensor shall be tested in both an unterminated and a patient simulated (test device) terminated mode.

5.2.7.9.1.2 Magnetic field emissions

Use a gauss meter probe to verify that the instrument does not emit a magnetic field greater than 0.5 millitesla (5 gauss) at any point on the surface of the instrument under normal operating conditions.

5.2.7.9.2 Electromagnetic immunity

5.2.7.9.2.1 Immunity to RF electromagnetic fields

The test methods and instruments specified in IEC 1000-4-3 (normative reference 2.5) apply.

The radiant warmer is exposed to a modulated RF field with the following characteristics:

Field strength: 3 V/m (Level 2); 20 V/m (Level 3)
Carrier frequency range: 26 MHz to 1 GHz
AM modulation, 80% index, at 3 frequencies: 1, 5 and 20 Hz.

The infant temperature sensor is attached to a TEST DEVICE. The radiant warmer is tested with all its faces sequentially exposed to the RF field.

NOTE - Certain temperature sensor cable configurations may cause failure to meet these immunity requirements. In such a case, the manufacturer shall disclosed the reduced immunity levels which are met.

5.2.7.9.2.2 Immunity to conducted electromagnetic fields

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

The test methods and instruments specified in the current draft of IEC 1000-4-6 (normative reference 2.5) apply.

When radiant warmer can be operated from line power as well as battery, an RF noise voltage with the following characteristics is injected into the input power cord:

Noise voltage amplitude: 1 V RMS
Carrier frequency: 150 KHz to 230 MHz
AM modulation, 80% index, at 1, 5 and 20 Hz.

5.2.7.9.2.3 Immunity to magnetic fields

The equipment is exposed on all faces to an external AC magnetic field with the following characteristics:

Magnetic field strength: 10^{-4} tesla peak to peak (1 gauss)
Frequency range: 47.5 to 1320 Hz

The equipment is exposed on all faces. The infant temperature sensor is replaced with a TEST LOAD that simulates a temperature of 36 ± 1 °C at the instrument.

5.2.7.9.2.4 Immunity to electrostatic discharge (ESD)

The test methods and instruments specified in IEC 1000-4-2 (normative reference 2.5) apply.

The radiant warmer is exposed, at any point on its surface accessible to the operator or patient, to open air discharges or direct contact discharges, both positive and negative.

Condition 1. Open air discharges up to 4 kV and direct contact discharges up to 2 kV.

Condition 2. Open air discharges up to 8 kV or direct contact discharges up to 4 kV.

5.2.7.9.2.5 Power and transients

a) first transients/burst -- The test methods and instruments of IEC 1000-4-4 (normative reference 2.5) apply. Instruments shall meet a 1 kV immunity level at the mains plug.

b) surge immunity -- The test methods and instruments of IEC 1000-4-5(normative reference 2.5) apply. Instruments shall meet an immunity level of 1 kV line to line and 2 kV line to ground.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Annex A
(Informative)

Rationale for the development and provisions of this standard

A1 Introduction

This appendix provides the rationale for the development of a standard for infant radiant warmers, as well as the rationale for each of the specific provisions of the standard.

The findings of an ECRI (originally Emergency Care Research Institute) study on infant incubators and radiant warmers, carried out under contract with the Food and Drug Administration (Dyro 1977), served as a point of departure for this standard. Additionally, various drafts of the International Electrotechnical Commission's (IEC) "601-2 Particular Requirements for the Safety of Baby Incubators" were also considered during the AAMI Infant Incubator Committee's deliberations. Lastly, to ascertain the current clinical consensus on many of the safety and performance issues that required resolution, the AAMI committee relied heavily on the recommendations of the Infant Incubator Advisory Task Force of the American Academy of Pediatrics (AAP 1983).

A2 Need for the standard

Infant radiant warmers have been successfully used in infant care since 1925. In appropriate applications, the benefits of the use of this device are numerous. Although the device is life-sustaining and life-supporting, sufficient scientific and medical data exist to establish a standard to provide reasonable assurance of the safety and effectiveness of the device and to help control the risks associated with the use of the device. These risks include: (1) electrical shock from improper design and/or construction or device malfunction, (2) hypothermia or hyperthermia if the device is not adequately controlled, and (3) potentially high levels of insensible water loss due to the open bed design of warmers.

The provisions of this standard reflect the committee's effort to address these potential risks and to provide for means of minimizing or eliminating these risks.

A3 Definitions

A4 Rationale for the specific provisions of the standard

A4.1 Labeling requirements

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

There are basically two factors which control the label content of a medical device. First, there are the requirements defined in Part 810, Chapter 1, Title 21, of the Code of Federal Regulations--Good Manufacturing Practice for Medical Devices--specifically sections 820.120, 820.121. and 820.130. These regulations establish requirements for proper handling, legibility, expiration dating, and many other aspects of labeling as they pertain to good manufacturing practices. Second, Part 201, Chapter 1, Title 21, of the *Code of Federal Regulations*, and Section 502 of the Federal Food, Drug and Cosmetic Act (as amended October 1976) specifically state what constitutes proper labeling and misbranding for a drug or device. These two groups of requirements comprise the federal regulations referred to in 4.1 of the standard. All labeling pertaining to infant radiant warmers must comply with these regulations.

In addition, there are other critical facts which shall be set forth in the labeling in order to assure that the device is used safely and effectively in controlling the thermal environment of the infant, and to assist the user in selecting a device most appropriate for the intended use. The provision of this additional information is specified in 4.1.1, 4.1.2, and 4.1.3 of this standard.

A4.1.1 Device markings

A4.1.1.1 General

All requirements concerned with markings or labels on the device itself ensure that important identification information, warnings, and instructions are displayed on the warmer and/or its accessories to minimize hazards and promote proper operation and that functional detachable components and accessories are used with the warmer(s) for which they are intended.

A4.1.1.2 Product identification

Permits the user to obtain service, order parts and/or accessories, and identify the device in case of problems. Identification of electrical specifications is essential to the safe and effective use of the device.

A4.1.1.3 Controls, displays and switches

Identification of all controls, connectors, alarms, and indicators is necessary to avoid improper use and to alert the user to operating conditions and control settings.

A4.1.1.4 Infant temperature sensors

Use of a sensor for purposes other than that recommended by the manufacturer could result in incorrect patient temperature indication and/or control and hazardous operating conditions (Freeman and Linder 1934).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

60

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

A4.1.1.5 Overcurrent protection

The use of improper fuses could result in unsafe operating conditions and/or damage to the infant radiant warmer.

A4.1.1.6 Important notices, cautions, and warnings

The inclusion of important labeling will promote proper use of the infant radiant warmer and related instrumentation (e.g., oxygen delivery and control systems), and make the user aware of outside factors that may affect patient care and safety.

a) External radiant heat sources, (e.g., the sun, phototherapy lights) can affect the temperature control and alarm functions of the radiant warmer (Hey and Mount 1967). Patient temperature and insensible water loss may also be affected by external radiant heat sources(Bell and Rios 1983 (a), 1983(b); Bell, Gray et al 1980; Bell, Weinstein et al 1980).

b) Improper placement of the patient probe (e.g., under the infant) can result in uncontrolled warming. If the patient probe is not placed and does not remain in good contact with the patient's skin, the probe can sense the temperature of the cooler surroundings and cause the infant's temperature to rise above the desired level.

c) Many factors which can influence thermal warming may not be readily apparent to the operator (Adamsons et al 1965; Bell and Rios 1983 (a); Bell, Gray et al 1980). Frequent checks of infant temperature, radiant warmer temperature, and warmer function can help detect unwanted temperature fluctuations from misuse or outside interference and allow operators to take corrective action before those fluctuations become hazardous.

d) Special requirements with respect to electrical safety and explosion hazards are necessary for safe use owing to the possible use of explosive anesthetics.

e) The proper performance of an infant warmer is dependent upon the direct delivery of radiant energy to the infant area. Objects obstructing or altering this energy could affect the thermal performance of the warmer and thus the patient temperature.

f) Evaporative water losses are much higher in radiant warmers than in incubators as shown by Wu (1988), Bell (1974), Baumgart (1984), and many others. In clinical practice, especially in infants under 1000 grams and less than 28 weeks gestation, these evaporative water losses can result in massive derangements of hydration and electrolyte status if the clinician is not careful to frequently check the baby's fluid and electrolyte status and make appropriate changes in his fluid and electrolyte management.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

g) An infant's temperature can change rapidly under an infant warmer. Users need to frequently observe the condition and status of an infant to avoid over or under heating.
h) Infants placed too close to the heater can expose the infant to higher than specified irradiance levels that could lend to overheating or skin burns. Infants placed too far from the heater can cause underheating.

i) This information enables the user to determine whether the maximum shelf loading recommended by the manufacturer is suitable for the extended application.

A4.1.2 Operator's manual

It is necessary that the user be provided with adequate instructions for proper use, user maintenance, and cleaning/ sterilizing, and that the performance characteristics and specifications disclosed by the manufacturer are adequate to permit user evaluation of the appropriateness of a particular device for the intended application. The parameters called out in 4.1.2b) are generally recognized as important variable in defining incubator performance. However, clinical evidence to support the establishment of specific numerical values for these parameters is lacking. The inclusion of these parameters in the labeling/disclosure section of the standard, rather than in the performance requirements section, allows the manufacturer to state in numerical terms the performance of the device and, in the absence of clinical consensus on what this performance should be, allows the user to evaluate the appropriateness of a particular device for the intended application. At such time as clinical evidence dictates specific performance levels, the standard will be amended accordingly.

a) Intended application. Needed to help prevent unintentional misuse.

b) Performance specifications

1) Control temperature range. Enables the user to determine whether the control temperature range is suitable for the intended application (Hey 1975; Sauer, Dane et al 1984; Scopes and Ahmed 1965).

2) Irradiance uniformity. During normal operation, the radiant warmer irradiance can be expected to differ at sites across the mattress. Since the location of the infant on the mattress can vary, non-uniformity should be minimized in order to maintain the infant as close to the prescribed warmer temperature as possible (Adamsons et al 1969; Avery 1981; Bell and Rios 1983.

3) Indicated temperature accuracy. This information enables the user to determine whether the maximum difference which can exist between the indicated temperature and the actual temperature is suitable for the intended application and

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

within the performance requirements of this standard [4.2.2 b)] (Adamsons et al 1965; Avery 1981; Day 1941; Perlstein et al 1976).

4) Control temperature/indicated temperature correlation. This information enables the user to determine whether the difference between the prescribed temperature (control temperature) and the indicated temperature are suitable for the intended application and within the performance Requirements of this standard [4.2.2 c)] (Adamsons et al 1965; Avery 1981; Perlstein et al 1976).

5) Infant temperature alarm. This information enables the user to determine whether the temperature deviation from the ITC control temperature which will activate a high or low temperature alarm is suitable for the intended application (Bell, Weinstein et al 1980; Hey and Katz 1970; Scopes and Ahmed 1966; Silverman et al 1966).

6) Other controls/alarms. This information enables the user to determine whether the performance characteristics are suitable for the intended application.

7) Nursery alarm sound level. This information enables the user to determine whether the maximum alarm sound level in the nursery is suitable for the intended use environment and that the minimum level is within the performance requirements of this standard.

8) Maximum center mattress sound level. This information enables the user to determine whether the maximum infant area sound level during normal use is within the performance requirements of this standard (4.2.4.1).

9) Shelf loading. This information enables the user to determine whether the maximum shelf loading recommended by the manufacturer is suitable for the intended application.

10) Radiant energy varies by the inverse square of the distance, small variances in the distance from the heater to the bed can cause dramatic changes in irradiance.

11) n/a

12) An infant radiant warmer operating in the manual mode continuously emits a preset amount of energy to the infant regardless of his/her temperature. If this energy is at a maximum in order to rapidly warm up the infant, its skin can become dangerously hot. A considerable source of risk is that there is not necessarily an automatic monitoring of the infants temperature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

13) The equipment cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and skin temperature (hypothermia). Therefore in all unclear situations the temperature of the patient shall be monitored.

14) Open bed warmers are susceptible to changes in the nursery environment.

15) Provide user with information to perform product maintenance to keep equipment within specification.

16) n/a

17) Jones JWA, et al.: Increased insensible water loss in infants nursed under a radiant heaters. Br. Med. J. 2:1347, 1976.

18) Comparable to incubators, radiant warmers have instabilities (Baumgart *et al*, 1984) in use which will result in variations in operative temperature with time. Perlstein *et al* (1970; 1976) have shown that rapid variations, especially rising environmental operative temperatures, will cause an increase in apnea and a decrease in survival rate among infants. Since we do not have an adequate way of measuring operative temperature in a radiant warmer, we are left with measuring the components of operative temperature, the most important of which is irradiance. Although we cannot quantitate how much instability in irradiance and steady state is dangerous for the infant with regard to amplitude or frequency, in general a more stable device should be a better device. The instability is from both variations during steady state, that is, variance, and from overshoot and undershoot when the device is made unstable.

19) The user needs to know how long it takes for the warmer to achieve full power output.

20) The user needs to know the effect of temporarily removing or blocking the radiant heat source.

c) Important notices, cautions, and warnings. The rationale for these requirements is as follows:

1) and 2) Oxygen consumption in infants has been shown to be related to infant skin temperature (Adamsons et al 1965; Kajtar et al 1976; Silverman et al 1966). Controlling infant temperature with a rectal probe or a skin temperature sensor which is not accurately sensing the skin temperature (loose or misplaced probe) can result in adverse effects on oxygen consumption (Silverman et al 1966).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

3) See A4.1.1.6.a)

4) See A4.1.1.6.c)

5) See A4.1.1.6.d)

6) See A4.1.1.6.g)

d) **Cleaning, disinfecting and sterilizing.** Provision of recommended sterilization/disinfection procedures will help assure an effective cleaning method which will not degrade device performance.

e) ITC algorithm. This information is required to provide clinicians with an understanding of the interrelation of the various parameters controlled and affected by the radiant warmer in ITC mode.

A.4.1.3 Service manual

Necessary to enable service personnel to perform preventive maintenance, calibration and repairs in conformance with the manufacturer's recommended procedures.

A4.2 Performance requirements

A4.2.1 Environmental performance

This requirement reflects the limits of the range of ambient environmental conditions normally encountered in a hospital environment.

A4.2.2 Thermal characteristics

a) The maximum radiance of a radiant warmer determines how quickly under maximum heat conditions it could warm up a baby. That is, it determines the safety margin that is allowed between the time an alarm sounds and a nurse can correct a single fault condition that could result in over heating of the infant. Thus, for safety's sake, the lowest maximum heat capacity that is effective should be used. Baumgart's data (Baumgart *et al*, 1981) in small babies suggests that in steady state any infant could be maintained with a maximum radiance of 25 mW/cm^2. The existing radiant warmers have a maximum radiance of no more than 55 mW/cm^2. These seem to be adequate in clinical experience, thus setting the maximum radiance at 60 mW/cm^2 will allow plenty of effective power without compromising the safety of the device by providing power in excess of what is needed to keep babies warm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

b) Infant indicated temperature accuracy. Clinical judgments concerning the adequacy of thermal control and infant well being are based in great part, on the skin temperature measurements. Small changes in skin temperature have been shown to affect O_2 consumption (LeBlanc 1983; Silverman et al 1966). An accuracy of ± 0.3°C is considered clinically acceptable and is capable of attainment with current technology. There may be additional variance between actual skin temperature and that measured by the sensor caused by the site and method used for attaching the sensor to the skin.

c) Maximum operator contact temperature on 0.3 second exposure to a metal surface at 85°C will result in pain. Roughly two and one-half times as long is required to cause tissue injury (Stoll, *et al*, 1979). Quick removal of the tissue from the heated surface in response to the pain sensation can prevent a reversible injury to the skin.

d) see below (g)

e) The user of the equipment must be confident that the temperature that is set will be the actual temperature achieved within + 0.5°C.

f) Maximum infant contact temperature. Potential damage to human skin from hot surfaces can be divided into two parts. Acute changes due to thermal transfers of heat already stored in the material to the skin and chronic changes due to the conduction of heat from the heat source to the infant's core. Safe levels of acute exposure can be calculated from the equation of Stoll (1979, 1982) assuming skin thickness approaches 0.

$$TmPt = .494(t)^{-.412}\left(\frac{0.239}{\sqrt{k\rho c_p}} + 31.5\right) + 41^\circ C$$

where TmPt is the temperature of a material at the pain threshold, t is the time of exposure, k is the thermal conductivity of the material (Joules/sec·cm·°C), ρ is the density of the material (gm/cm^3), and c_p is the specific heat of the material (Joules/gm·°C). The time to produce skin damage is approximately 2.5 times that to produce pain. Five seconds is chosen for the end of acute events. Thus, the allowable temperature of the surface TmPt is:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

$$TmPt = 0.494\,(5)^{.412}\left(\frac{0.239}{\sqrt{k\rho\, c_p}} + 31.5\right) + 41^{\circ}C$$

$$TmPt = 0.25\left(\frac{0.239}{\sqrt{k\rho\, c_p}} + 31.5\right) + 41^{\circ}C$$

$$TmPt = \frac{0.06}{\sqrt{k\rho\, c_p}} + 48.9^{\circ}C$$

For chronic exposure the skin temperature must exceed 43 °C to produce damage. Forty degrees is used for the standard to provide a margin of safety. We use the equation for heat flow by conduction, $(T_1-T_2)k/X$, where k is the thermal conductivity and X is thickness. If the thermal conductivity of skin is 2.1×10^{-3} Joules/sec·cm·°C (Cohen 1973), and the effective thickness from skin to core is 1 cm (Brock 1992), and if the thermal conductivity of the material is k, and its thickness is X, then

$(T_{core} - T_{skin})\, k_{skin}/X_{skin} = (T_{source} - T_{skin})\, k/X$

and if
$T_{core} = 37$ °C, $T_{skin} < 40$ °C, $k_{skin} = 2.1 \times 10^{-3}$ Joules/sec·cm·°C,

$X_{skin} = 1$ cm then

$$T\,source < \frac{6.3 \times 10^{-3} X}{k} + 40$$

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Or looking only at the right side of the equation, the heat flow to a 37 °C heat sink shall not exceed (T_{core} - T_{skin}) k_{skin}/X_{skin} or 6.3×10^{-3} Joules/sec·cm^2.

Example:

For Teflon, k = 2.42 x 10^{-3} Joules/sec·cm·°C, ρ = 2.15 gm/cm^3, Cp = 1.05 Joules/gm·°C.

$$k\rho c_p = 5.46 \times 10^{-3} \ Joules^2 / cm^4 \, C$$

$$\sqrt{k\rho c_p} = 0.0739 \ Joules / cm^2 \, C$$

For acute exposure of 5 sec, the allowable surface temperature TmPt shall be:

$$\frac{0.06}{0.0739} + 48.9^\circ C = 49.7^\circ C$$

If the heat source is not directly on the other side of the Teflon and a more complicated geometry exists, the heat flow to a 37 °C heat sink shall not exceed 6.3 x 10^{-3} Joules/sec·cm^2, after a 5 sec stabilization.

g) Radiant warmer temperature control range. The neutral thermal zone for infant skin temperature under radiant warmers is approximately 36 to 37 °C (Malin, 1987). Due to artifacts in the measurement of skin temperature under low humidity environment (Belgaumkar and Scott, 1975) which may result in the skin temperature measured by the warmer being substantially higher than the baby's mean skin temperature, a slightly higher upper limit was included in this standard than in previous standards. Overheating the infant can result in increased apnea (Daily, *et al*, 1969).

A4.2.3 Alarms

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

A4.2.3.1 High temperature (ITC)

Failure of the primary radiant warmer temperature control system could cause the infant to be exposed to dangerously high air temperatures. A high temperature alarm will minimize the degree and duration of exposure of the infant to high temperature in the event of such failure. Experience has shown that adjustable high temperature thermostats are misadjusted to their maximum position, and that such adjustments have resulted in excessively high radiant warmer temperatures without an alarm.

A4.2.3.2 Manual mode alarm

An infant radiant warmer in the manual mode of operation emits a preset amount of energy to the child continuously, regardless of the temperature of the infant. If the heater is set at the maximum in order to warm up the infant rapidly, the skin of the infant can become overheated. It is therefore essential to attend equipment operation and infant condition at frequent intervals.

A4.2.3.3 Infant temperature sensor failure

A failed sensor or one which is not properly connected to its receptacle could cause the infant to be exposed to high operative temperatures. A failed alarm provides a rapid alert to prevent this occurrence. Deviation of the indicated temperature from the control temperature may indicate that the warmer is not appropriately controlling the baby's temperature. Were this situation allowed to continue, hypothermia or hyperthermia might result. Causes of deviation of the indicated temperature from the controlled temperature include dislodgement of the skin probe (Mayock, 1976), the placement of the skin probe on the infant after it has become dislodged and the infant has become overheated, malfunctioning of the warmer or probe, and warming of a cold baby or cooling of an overheated baby. In practice, this provides the only alarm for probe dislodgement. The most common fault condition in caring for babies in infrared warmers is the detached skin probe. If the skin probe becomes detached and the user does not become aware of the detached probe in a timely fashion, the infant can be dangerously overheated. Although the alarm for deviation of the indicated temperature from the control point picks up most of the skin probe dislodgement, if the probe becomes dislodged gradually so that the temperature changes gradually, it will not be picked up by this particular alarm system. Similarly, if the probe falls to a region that has a temperature similar to that of the infant, its dislodgement will not be picked up. This has the potential to result in hyperthermia of the infant and frequently does in clinical practice. Thus, if a better means becomes available to detect skin probe dislodgement directly incorporating it into the device design of the radiant warmer will result in a safer and more effective device. Although several such devices have been designed, none had been tested in a practical environment at the time this standard was written.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

A4.2.3.4 Power failure

To help assure that personnel will be alerted when the warmer is not being powered, due to dislodgement of the power cord plug or to a general power outage, radiant warmers should incorporate an auditory alarm to signal complete failure of input electrical power. Inadvertent temporary power loss for any reason should not alter the operating mode or settings when power is restored.

A4.2.3.5 Alarm silencing

A 15-minute alarm silence will provide for reactivation of the alarm in a reasonable period of time, without creating such an annoyance that the attending personnel will be disposed to permanently disable the alarm. The visual indication that an auditory alarm is disabled serves as a reminder to personnel that an alarm condition which is potentially harmful to the infant may exist and may require resolution. An exception was not allowed for initial warm-up of the device, even though warm-up time commonly exceeds 15 minutes, since overheating with a radiant warmer can occur very quickly.

A4.2.4 Sound levels

A4.2.4.1 Auditory alarm

A minimum alarm sound level is necessary to reasonably assure that an alarm will be heard in a typical nursery environment.

A4.2.4.2 Mattress center alarm

In a number of studies, warmer noise levels have been measured and potentially harmful effects on the hearing of prematurely born infants have been suggested. Studies demonstrating a harmful synergistic effect of continued noise and ototoxic drugs in guinea pigs have added to concern about potential risks to infants (Dayal et al 1971). (However, the only studies involving infants nursed in conventionally available incubators have failed to establish a synergism between incubator noise and kanamycin, or a correlation between deafness and duration of noise exposure [Winkel et al 1978; Abramovich et al 1979; Stennert et al 1978].) Based on the available evidence, the committee judged that a maximum interior sound level of 60dBa, which represents performance met by currently available incubators, provided reasonable assurance of safety.

A4.2.5 Fire prevention

The increase in flammability which could occur at oxygen concentrations of 4% (above ambient) or less was considered acceptable in terms of safety. An energy level of 10 VA is sufficiently low that ignition will not occur in high (<4%) concentrations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

70

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

A4.2.6 Mechanical/construction requirements

A4.2.5.1 Infant mattress area

The device shall contain the infant within the mattress area in such a way as to prevent the infant from falling, while also providing a means for observation and nursing management.

A4.2.6.2 Stability and transportability

a) Tip-over - The required values are based on established industry practice for evaluation of stability (UL 2601.1).

b) Thresholds - It is important that the warmer continue to operate as specified by the manufacture following impacts with obstacles normally encountered in the health care facility (e.g. elevator thresholds).

A4.2.6.3 Shelves and mounting brackets

This requirement is intended to assure safe mechanical construction under normal use.

A4.2.6.4 Supplementary gas supply

Extreme mechanical shock presents a hazard due to the nature of compressed gases.

A4.2.6.5 Switches, controls, and knobs

a) Inadvertent changes to control setting can be detrimental to infant safety.

b) Rotation of controls and switches on the panel could result in improper setting of a control.

c) Ergonomic standard - *Human factors engineering and preferred practices for the design of medical devices*, second edition (HE48-1999). American National Standard. AAMI.

A4.2.6.6 (1 & 2) Ingress of liquids

Ingress of liquids that may contact electrical circuitry can degrade performance, reliability, or cause a hazardous condition.

A4.2.6.7 Mercury thermometers and thermostats

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

The exposure of infants to the potential toxicity of mercury vapor was judged by the committee's clinical participants to represent an unnecessary risk. Technically there are other means by which the referenced functions can be accomplished.

A4.2.6.8 Infant temperature sensor

A rectal probe if improperly used to control an infants temperature could result in unstable and/or undesirable skin temperatures because of the response time differences between rectal and skin temperature.

A4.2.6.9 Wheels

Means to allow the user to prevent the warmer from moving are necessary for the safety of the user, infant, and equipment.

A4.2.7 Electrical characteristics

A4.2.7.1 Risk current

Limiting risk current reduces the potential for inadvertent electric shock from the device.

A4.2.7.2 Overcurrent protection

Overcurrent protection minimizes electrical and fire hazard and/or damage to other components. Interruption of power to other equipment is also minimized.

A4.2.7.3 Power switch

This requirement helps assure that primary power will be interrupted if used on isolated power sources or if polarity is reversed.

A4.2.7.4 Power cord and strain relief

The *National Electrical Code* is a recognized standard.

A4.2.7.5 Power indicator

Any illuminated indicator helps provide the user with visual conformation that the switch an power are on.

A4.2.7.6 Supply voltage variation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

72

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

This requirement provides assurance that the warmer operate as specified will over a range of voltage fluctuation typically seen in the hospital. Voltage variation beyond the normal range should not damage the device.

A4.2.7.7 Dielectric withstand

This requirement provides assurance that typical high voltage transients will not cause electrical breakdown.

A4.2.7.8 Grounding impedance

Low impedance is required to assure that the ground path is adequate to handle large currents that may occur during electrical faults.

A4.2.7.9 Electromagnetic compatibility requirements

With the proliferation of digital and computer instruments working at close range in the hospital, for instance in the ICU, there are a growing number of instances where one instrument emits radiation which interferes with the performance of another instrument. EMC must therefore be considered, in the expectation that compliance with EMC standards, on both emission and immunity, will minimize detrimental interferences between instruments.

EMC performance and validation tests are very complex and require sophisticated instrumentation. It is not practical to make the infant radiant warmer standard a stand alone document by including all the pertinent information, particularly concerning test methods and instrumentation. Instead, we reference a number of IEC documents which specify in detail the appropriate EMC test methods and instruments. Two of these documents are still in draft stage, hence are subject to possible change. However, drafts of these documents are available and are routinely used by development and test engineers; it is therefore reasonable to reference and use these documents, and we have no alternative at this time. Clearly, if the final documents differ from the current drafts, the committee will have to examine the impact on the present standard and consider possible revisions.

The standard addresses two complementary subjects: emission, i.e., the intensity and characteristics of electromagnetic radiation emitted or conducted by an operating device, and immunity, i.e., the ability of an instrument to perform satisfactorily while exposed to external electromagnetic radiation. The standard sets maximum levels on electromagnetic emission and defines the levels of external radiation which the device shall tolerate and still perform satisfactorily.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

The maximum levels of emission stated in the general standards have been adjusted to the specific device considered, i.e. infant radiant warmer, and require a design effort by the manufacturer. At the same time, the levels are achievable with good design, may be different for different operating modes, and may also be waived when they cannot be achieved during certain operating modes.

The IEC collateral standard 601-1-2 on EMC in medical devices recognizes that measurement and control of EMC is particularly difficult for patient coupled devices, such as infant radiant warmers, where the infant temperature sensor acts as an antenna which both emits and receives rf signals, with an antenna gain which depends on the layout of the infant temperature sensor. The IEC standard makes allowance for this situation by providing limited exemptions from the immunity requirements. These exemptions are extended to the present standard, on condition that the reduced immunity levels be measured and disclosed by the manufacturer.

The EM levels stated in the immunity subsection represent a compromise between the infant radiant warmer design state-of-the-art and the almost infinite variety of EM environments that a portable device may encounter. The general documents quoted in reference (CISPR, IEC) have standardized on approximately four levels which represent increasingly harsh environments. Level 2 environments are commonly encountered, hence full immunity to Level 2 fields is required. Level 3 environments are rare but may be found (e.g., in the OR or near power lines, etc.) and it is important to indicate the performance of the instrument in a Level 3 environment. However, based on CDRH test data for EMI in ambulances (FDA, 1995), the 10 V/m field strength specified in the reference documents was replaced with 20 V/m.

For EMC requirements it is a generally accepted practice to define standardized and progressively more severe EM environments and specify the device response to these standardized environments. There is of course an almost infinite variety of field environments which differ from the standardized environments covered in this standard, they are asked to test their devices in these environments, seek to achieve the highest possible immunity and disclose any observed degradation in performance, so that the user will have appropriate warnings.

Finally, EMC is a rapidly developing subject where standards are evolving. This section of the transport infant incubators standard is likely to be revised and improved in the future.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

74

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Annex AA
(Informative)

General guidance and rationale from IEC document

Note to AAMI Members: These were "left over" rationale statements from the IEC document that did not immediately fit in with the "AAMIzed" version of the IEC Warmer Standard.

2.1.103 The aluminum 500 g test devices were developed in 1984 on the basis that they were simple to reproduce to specific dimensions and respond to temperature changes due to variations in warmer output. Different manufacturers of infant warmers have considered them to be a suitable reference for tests of their products. Other test devices of this nature tended to be more complicated to reproduce and relatively more expensive.

This test load configuration is not intended to represent a specific infant size, but only to test the operation of a radiant warmer.

This test load configuration is intended to demonstrate the radiant warmer temperature control mechanism, and indicates the uniformity of heating across the mattress.

A matt black finish of the test loads should provide a high emissivity value for consistent test data reproduction.

3.6 The additional specified single fault conditions apply specially to this PARTICULAR STANDARD.

4.5 Infant Radiant Warmers are commonly used in areas where ambient temperatures range from 18°C to 30°C.

6.8.2 aa (8) It is desirable that the equipment should be provided with an auditory alarm and visual indication which operates when the SKIN-TEMPERATURE SENSOR is detached from the infant's skin, since it has not been reliably achieved technically. This has not been made a requirement of this standard.

6.8.2 aa (17) There have been reports of hot fragments (e.g. metal oxide particles) from aged warmer heaters falling onto the mattress.

33. Infant radiant warmers provide thermal support by directing invisible infrared light to the infant's body. The source of this infrared light is an overhead heater whose electrical power input is limited by design, thereby limiting the amount of infrared energy output that can be directed at the infant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

The limits proposed in this standard are based upon a review of literature regarding the effect of infrared radiation upon the eyes and skin of humans.

Infrared measurements can be made in both the 760 to 1400 nm wavelength (IR-A region) as well as the 1400 to 4500 nm segment of the wavelength IR-B and IR-C regions.

The IR-A region is associated with the potential for damage to the crystalline lens which may lead to a cataract. The IR-B and IR-C regions are almost completely absorbed by the cornea, (the outermost layer of the eyes) with a resulting potential for burn.

From this review of the literature the following statements can be made:

a) There have been no reports from any sources describing any harmful effects of infrared radiant energy on either the eyes or skin in infants nursed under infant radiant warmers. Retrospective examinations specifically looking for any eye effects have produced no evidence of harmful effects for either the short-term or long-term evaluations. The long-term evaluations were performed from 30 days to 6 years after the infants were nursed under radiant warmers.

Similar levels of irradiate have been used in neonatal intensive care units for at least the last 15 years to provide thermal support to premature infants.

No reports have identified a corneal opacity or skin inflammation caused by the nursing of the infant under a radiant warmer.

Both cataracts and retinal lesions have been documented as being caused by IR-A wavelengths. Absorption of the infrared energy by the iris which indirectly heats the lens (and forms opacities) has been identified as the most likely cause of infrared induced cataracts. Infant radiant warmers possess very little IR-A energy when compared to source that have caused cataract formation.

Retinal lesions have been reported to be caused primarily by shorter-visible light wavelengths and the actual IR-A component may be a negligible contributor to any retinal damage that would occur.

The proposed radiant warmer threshold values put forth by Emergency Care Research Institute in 1973 have been observed and maintained by manufacturers of radiant warmers on the market today. These limits of less than 300 mW/cm^2 for the IR-B and IR-C regions and less 40 mw/cm^2 for the IR-A region are based on data that since has been updated and re-evaluated and confirms that these are also appropriate.

Photobiologists have not yet determined absolute minimum safe levels of incoherent infrared light in the IR-A, B, and C regions. It has been proposed that for IR-A wavelengths, a safe, chronic

76

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

exposure level probably is on the order of 10 mW/cm² with allowances for incidental exposures for several minutes up to 100 mW/cm². In a 1980 publication from one of these same authors (Sliney), it was concluded that 100 mW/cm² for IR-B and IR-C regions is the safe threshold limit for chronic exposure to the cornea. Since the time these limits were proposed, these authors have documented that more recent investigations indicate that infrared radiation may not be as hazardous as was once thought.

Since no harmful effect from the irradiance levels now present in radiant warmers have been reported, these levels can serve as a maximum threshold limit until further data are made available.

Although further study of threshold levels could be useful to further define limits, the actual benefits derived from the use of radiant warmers far outweigh the potential, unreported, and theoretical risks associated with radiant infrared energy from infant radiant warmers. No reports of any harmful infrared energy induced effects have been documented in the medical literature after nearly 15 years of clinical use.

c) The spectral characteristics for human eye and skin media have been documented in the literature. No studies of the neonatal eye spectral characteristics have been reported. Only the spectral characteristics of neonatal skin with respect to visible light has been reported.

Although the neonatal eye is not completely developed at birth, the spectral characteristics are believed to be similar to an adult. Examinations of neonatal eyes after being nursed in radiant warmers has not shown any harmful effects with the level of IR-A delivered by the radiant warmers.

Neonatal excised skin specimens have been shown to have similar spectral absorption characteristics to adult skin in the visible light regions. However, the IR-A regions the skin absorption can vary with skin thickness.

Since the skin's reflectance is greatest in the IR-A regions, much of the incident light will be reflected away and only a small portion of the total incident light would actually penetrate the skin.

Most infrared energy is in the IR-B and IR-C regions and is absorbed by the top 1-2 mm of skin. No harmful effects of absorption of the radiant energy from a radiant warmer have been reported. Since infrared energy is not energetic enough to enter into photochemical reactions with skin components, the only effect of the absorption of the energy is heating, which is the primary reason the infant is under a radiant warmer.

d) The associated hazards from exposure to infrared energy have been documented in the literature for humans and animals, using both coherent and incoherent light. The hazards reported in the literature from exposure of humans to incoherent infrared light are cutaneous skin burns,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

corneal opacities and inflammation, lenticular opacities (cataracts), retinal lesions, and skin inflammation. Recent reports have shown that the cutaneous skin burns, corneal opacities and inflammation, and skin inflammation are due entirely to the IR-B and IR-C portions of the infrared spectrum because the outermost layer of the skin and eye absorb all of the incident radiation in the wavelength regions they do not transmit any significant portion of incident energy below this outermost layer. Skin pain thresholds have been documented at approximately 45°C. Several commercially available radiant warmers have skin temperature limits to prevent the skin temperature from exceeding 40°C. Corneal opacities have been reported in neonates, but usually are associated with other pathological conditions (in association with congenital glaucoma, or as a result of an infection from either congenital rubella or herpesvirus).

42.3 The requirements of this clause can be based upon the BSI publication (23) and the drafting committee noting the potential risk of babies under warmers coming into contact with hot metallics or other surfaces, hence the stated limits.

46.104 It is necessary to have in the manual mode a mode of operation without alarm function on a low heater output level to keep the equipment previously warmed (as a stand-by-function) or to provide only a small proportion of heat to the baby (usually bigger ones). The experts of this working group and the pediatrics doctors from the German National Committee are of the opinion that at a level of 10 mW/cm2 is no risk for babies under radiant warmers. Long experience with the use of radiant warmers with low output-levels confirm this statement. There are no safety hazards known.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

78

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Annex B
(Informative)

References

AMERICAN ACADEMY OF PEDIATRICS. *Safety and performance of infant incubators.* A report to the Food and Drug Administration, Bureau of Medical Devices, by the Infant Incubator Advisory Task Force of the American Academy of Pediatrics. AAP, Nov. 1983.

ABRAMOVICH, et. al. Hearing loss in very low birthweight infants treated with neonatal intensive care. *Archives of Diseases in Childhood*, 1979, vol. 54, p. 421.

ADAMSONS, K. Jr., GANDY, GM., and JAMES, LS. The influence of thermal factors upon oxygen consumption of newborn human infant. *J. Pediatr.*, 1965, vol. 66, p. 495.

AVERY, GB., ed. *Neonatology.* Philadelphia: JB. Lippincott Co., 1981, p. 1192.

BAUMGART, S. Reduction of oxygen consumption insensible water loss and radiant heat demand with use of a plastic blanket for low birth weight infants under radiant warmers. *Pediatrics*, 1984, vol. 74, p. 1022-1028.

BAUMGART, S., LAVANIER, J., SCHWARTZ, JG., *et al.* Attenuation of warming and cooling cycles by shielding thermistor probes in infants nursed under radiant warmers. *Advances in Therapy*, 1984, vol. 1, p. 19-25.

BAUMGART, S., ENGLE, WD., FOX, WM, and POLIN, RA. Radiant warmer power and body size as determinate of insensible water loss in the critically ill neonate. *Pediatr. Res.*, 1981, vol. 15, p. 1495-1499.

BELGAUMKAR, TK., and SCOTT, KE. Effects of low humidity on small premature infants in servo control incubators. *Biol. Neonate*, 1975, vol. 26, p. 337-347.

BELL, EF., and RIOS, GR. A double-walled incubator alters the partition of body heat loss of premature infants. *Pediatr. Res.,* 1983 (a), vol. 17, p. 135.

BELL, EF., and RIOS, GR. Performance characteristics of two double-walled infant incubators. *Crit. Care Med.*, 1983 (b), vol. 11, p. 663.

BELL, EF., GRAY, JC., and WEINSTEIN, WOH. The effect of thermal environment on heat balance and insensible water loss in low birth weight infants. *J. Pediatr.*, 1980, vol. 96, p. 452.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BELL, EF., WEINSTEIN, MR., and OH, W. Heat balance in premature infants: comparative effects of connectively heated incubator and radiant warmer, with and without plastic heat shield. *J. Pediatr.*, 1980, vol. 96, p. 460-465.

BLIGH, J., and JOHNSON, KG. Glossary of terms for thermal physiology. *Journal of Applied Physiology*, 1973, vol. 35, p. 941-961.

BUETOW, KC., and KLEIN, SW. Effect of maintenance of "normal" skin temperature on survival of infants of low birth weight. *Pediatrics*, 1964, vol. 34, p. 163-170.

DAILY, WJ., KLAUS, M., and MEYER, HB. Apnea in premature infants. *Pediatrics*, 1969, vol. 43, p. 510.

DAY, RL. Regulation of body temperature during sleep. *Amer. J. Dis. Child*, 1941, vol. 61, p. 734.

DAY, RL., CALIGUIRI, L., KAMENSKI, C., and EHRLICH, F. Body temperature and survival of premature infants. *Pediatrics*, 1965, vol. 34, p. 171-181.

DAYAL, et. al. Combined effects of noise and kanamycin. *Ann. of Oto-Rhino-Laryngology*, 1971, vol. 80, p. 897.

DYRO, JF. *The development of standard for infant warmers and incubators*. FDA/DMDDP-77/43, Springfield (Vir.): National Technical Information Service PB-263 250/3WV, 1977, p. 346.

FREEMAN, H., and LINDER, FE. Some factors determining the variability of skin temperature. *Arch. Int. Med.*, 1934, vol. 54, p. 981-987.

HARDY, JD. The radiating power of human skin in the infrared. *Amer. J. Physiol.*, 1939, vol. 127, p. 454.

HEY, EN. Thermal neutrality. *Brit. Med. Bull.*, 1975, vol. 31, pl 69-74.

HEY, EN., and KATZ, G. The optimum thermal environment for naked babies. *Arch. Dis. Childh.*, 1970, vol. 45, p. 328-334.

HEY, EN., and MOUNT, LE. Heat losses from babies in incubators. *Arch. Dis. Childh.*, 1967, vol. 42, p. 75.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

KAJTAR, P., JEQUIER, E., and PROD'HOM, LS. Heat losses in newborn infants of different body size measured by direct calorimetry in a thermoneutral and a cold environment. *Biol. Neonate*, 1976, vol. 30, p. 55-65.

LEBLANC, MH. Oxygen consumption in premature infants in an incubator of proven clinical efficacy. *Biol. Neonate*, 1983, vol. 44, p. 76.

MALIN, S., and BAUMGART, S. Optimal thermal management of low birth weight infants nursed under high-powered radiant warmers. *Pediatrics*, 1987, vol. 79, p. 47-53.

MARKS, KH., LEE, CA., BOLAN, CD., and MAISELS, MJ. Oxygen consumption and temperature control in premature infants in a double-wall incubator. *Pediatrics*, 1981, vol. 68, p. 93-98.

MAYOCK, DE., and McMILLAN, DD. Neonatal hyperthermia secondary to a plastic thermal blanket. *Crit. Care. Med.*, 1986, vol. 14, p. 817-818.

MCLAUGHLIN, JF., TELZROW, RW., and SCOTT, CM. Neonatal mercury vapor exposure in an infant incubator. *Pediatrics*, 1980, vol. 66, p. 988-990.

OKKEN, A., JONXIS, JHP., RISPENS, P., and ZIJLSTRA, WG. Insensible water loss and metabolic rate in low birthweight newborn infants. *Pediatric Res.*, 1979, vol. 13, p. 1072-1075.

OLIVER, TK. Temperature regulation and heat production in the newborn. *Pediatr. Clin. North Am.*, 1965, vol. 12, p. 765.

PERLSTEIN, PH., EDWARDS, NK., ATHERTON, HD., et al. Computer assisted newborn intensive care. *Pediatrics*, 1976, vol. 57, p. 494.

PERLSTEIN, PH., EDWARDS, NK., and SUTHERLAND, JM. Apnea in premature infants and incubator air temperature changes. *N. Engl. J. Med.*, 1970, vol. 282, p. 461-466.

RAHILLY, PM. Effects of 2% carbon dioxide, 0.5% carbon dioxide, and 100% oxygen on cranial blood flow of the human neonate. *Pediatrics*, 1980, vol. 66, no. 5, p. 685-689.

SAUER, PJJ., DANE, HJ., and VISSER, HKA. New standards for neutral thermal environment of healthy very low birthweight infants in week one of life. *Archives of Disease in Childhood*, Jan. 1984, vol. 59, no. 1, p. 18-22.

SCOPES, JW., and AHMED, I. Range of critical temperature in sick and premature newborn babies. *Arch. Dis. Child.*, 1966, vol. 41, p. 417.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

SILVERMAN, WA., SINCLAIR, JC., and AGATE, FJ. The oxygen cost of minor changes in heat balance of small newborn infants. *Acta Paediatr. Scand.*, 1966, vol. 55, p. 294-300.

STENNERT, et. al. The etiology of neurosensory defects in premature children. *Archives of Oto-Rhino-Laryngology*, 1978, vol. 22, p. 171-182.

STOLL, AM., CHIANTA, MA., and PIERGALLINI, JR. Thermo conduction effects in human skin. *Aviat. Space and Environ. Med.*, 1979, vol. 50, p. 778-787.

TALBOT, FB. Skin temperatures of children. *Amer. J. Dis. Childh.*, 1931, vol. 42, p. 965-1050.

WAFFARN, F., and HODGEMAN, JE. Mercury vapor contamination of infant incubators: A potential hazard. *Pediatrics*, 1979, vol. 64, p. 640-642.

WHELDON, AE. Energy balance in the newborn baby: Use of a mannequin to estimate radiant and convective heat loss. *Phy. Med. Biol.*, 1982, vol. 27, p. 285.

WINKEL, et. al. Effects of Kanamycin & incubation in LBW newborns. *Acta. Paed. Scand.*, 1978, vol. 67, p. 709-715.

WU, YK., and HODGEMAN, JE.. Insensible water loss in preterm infants: Changes with postnatal development and non-ionizing radiant energy. *Pediatrics*, 1974, vol. 54, p. 704-712.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Checklist for Premarket Notifications [510(k)s]

Device Trade Name: Stanilet Freestanding/CC Infant/Doric Infant warmer	K#: 970074
Submitter Name: Hill-Rom, Inc	
Date Received: 1/8/97 90 Day Due Date: 4/8/97	

Review Tier (circle one): 1 2 (3)

Question	Yes	No
A. Is the product a device?	✓	
B. Is the device exempt from 510(k)?		✓
C. Expedited Review Status: Requested by sponsor,		✓
or identified by PILOT Division		
Granted by Pilot Division?		
D. Has this device been the subject of a previous NSE decision?		✓
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?		
E. Has the sponsor been the subject of an integrity investigation?		✓
If yes, has the ODE Integrity Officer given permission to proceed with the review?		

Decision: ACCEPT ✓ REFUSE TO ACCEPT _____

Administrative Reviewer Signature: L. Ran Date: JAN 22 1997

Supervisory Signature: _____ Date: _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Screening Checklist for Premarket Notifications [510(k)s]
ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: Stanlet Freestanding/CC Infant/ 2000C Infant Warmer K970074

Submitter Name: Hill-Rom, Inc.

General Content of a 510(k)	MISSING INFORMATION
1.* General Information: a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, i) applicant's name and address. COMMENT:	
2.* Safe Medical Device Act of 1990 Requirements: a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices). d) Indication for use statement COMMENT:	
3.* Proposed Labeling: a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device. COMMENT:	
4.* Description of Device (or modification): diagrams, engineering drawings, or photographs. COMMENT:	
5.* Comparison Information: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness. COMMENT:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

6.	Biocompatibility Data: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use. COMMENT:	
7.	Sterilization Information: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method. COMMENT:	
8.	Software Validation & Verification: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification. COMMENT:	
9.	Information Recommended in FDA Guidance: There is an FDA guidance document for this device that recommends additional data. COMMENT:	
10.	Kit Information: see attachment if this device is a kit. COMMENT:	

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

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

January 08, 1997

HILL-ROM, INC.
1069 STATE ROUTE 46 EAST
BATESVILLE, IN 47006
ATTN: JAMES G. CARPENTER

510(k) Number: K970074
Received: 08-JAN-97
Product: STANILET FREESTANDING/CC INFANT/2000C INFANT WARMER

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 DSMO@FDADR.CDRH.FDA.GOV or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

K970074

Stabilet™ Infant Radiant Warmer

BY

HILL-ROM•

PREMARKET NOTIFICATION
510(K)

January 6, 1997

RECEIVED
8 JAN 97 11 06
FDA/CDRH/OCE/DMC

SK=17

HOM III

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

TABLE OF CONTENTS

TAB	PAGE	ITEM
A	1	Truth and Accuracy Statement
B	2 - 4	Premarket Submission Cover Sheet
C	5	Indications Statement
D	6	Product Comparison Matrix
E		Engineering Specification: Product and Performance Requirements
	7 - 36	E1 1250C Freestanding Warmer
	37 - 67	E2 1500C Stabilet CC
	68 - 104	E3 2000D Stabilet
F	105 - 142	Hazard Analysis
G	143	Performance Testing: (b)(4) [redacted]
H	144 - 146	Performance Testing: (b)(4) [redacted]
I	147 - 174	Product Labels
J	177	Draft In-Service Manual
	175 - 193	I1 1250C Freestanding Warmer
	194 - 215	I2 1500C Stabilet CC
	216 - 239	I3 2000D Stabilet
K		Predicate: Hill-Rom Stabilet Infant Radiant Warmer Literature
	240 - 263	K1 1250B Freestanding Warmer
	264 - 287	K2 1500B Stabilet CC
	288 - 311	K3 2000C Stabilet
L	312 - 321	Class III Certifcation and Class III S&E Summary
M	322 - 325	510(K) Summary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Premarket Notification

Truthful and Accurate Statement

(As Required by 21 CFR 807.87(j))

I certify that, in my capacity as Manager of Regulatory Affairs of Hill-Rom, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

James G. Carpenter
Manager of Regulatory Affairs
January 6, 1997

90

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

B

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: **January 6, 1997**

FDA Document Number:

Section A — Type of Submission

- ☒ 510(k)
- ☐ 510(k) Add'l information
- ☐ IDE
- ☐ IDE Amendment
- ☐ IDE Supplement
- ☐ IDE Report
- ☐ PMA
- ☐ PMA Amendment
- ☐ PMA Report
- ☐ PMA Supplement - Regular
- ☐ PMA Supplement - Special
- ☐ PMA Supplement - 30 day
- ☐ 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: **80 General Hospital and Personal Use Devices**

Section D — Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 **FMT**	2	3	4
5	6	7	8

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 **K942948**	1 **Stabilet Infant Radiant Warmer**	1 **Hill-Rom, Inc.**
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

	FDA Document Number:

Section E Product Information - Applicable to All Applications

Common or usual name or classification name: **Infant Radiant Warmer**

Trade or proprietary or model name	Model Number
1 **Stabilet™ Freestanding Warmer**	1 **1250C**
2 **Stabilet™ CC Infant Warmer**	2 **1500C**
3 **Stabilet™ 2000C Infant Warmer**	3 **2000D**
4	4
5	5
6	6

FDA document numbers of all prior related submissions (regardless of outcome): **Not Applicable**

1 **K942904**	2 **K913945**	3 **K850069A**	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Indications (from labeling):

The Stabilet™ Infant Radiant Warmer maintains the infant's body temperature at a level determined by the caregiver through the use of an infrared radiant heating element and is designed to be used in those areas of the healthcare facility that provide neonatal and infant care.

Section F Manufacturing / Packaging / Sterilization Sites

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: (b)(4) [redacted]	☐ Manufacturer ☒ Contract manufacturer	☐ Contract sterilizer ☐ Repackager/relabeler

(b)(4)

[redacted]

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

	FDA Document Number:
Section G	**Applicant or Sponsor**
Company / Institution name: **Hill-Rom, Incorporated**	FDA establishment registration number: **1824206**
Division name (if applicable): **Not applicable**	Phone number (include area code): **(812) 934 - 1671**
Street Address: **1069 State Route 46 East**	FAX number (include area code): **(812) 934 - 1675**

City:	State / Province:	Country:	ZIP / Postal Code:
Batesville	**Indiana**	**United States**	**47006**

Signature: James Carpenter

Name: **James G. Carpenter**

Title: **Manager, Regulatory Affairs**

Section H - Not Applicable

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Indications for Use

510(k) Number: Unknown

Device Name: Stabilet™ Infant Radiant Warmer

Indications for Use:

The Stabilet™ Infant Radiant Warmer maintains the infant's body temperature at a level determined by the caregiver through the use of an infrared radiant heating element and is designed to be used in those areas of the acute care hospital that provide neonatal and infant care.

Federal law restricts this device to sale by or on the order of a licensed health care practitioner and its use is restricted to health care facilities.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CONFIDENTIAL

Comparison Matrix

Features	Predicate 1250B	New 1250C	Predicate 1500	New 1500C	Predicate 2000C	New 2000D
Overall dimensions:						
Height	69"	71"	71"	73"	71.5"	73.5"
Width	28"	32"	27"	31"	27"	31"
Length	34"	34"	34"	34"	41"	41"
Overhead arm:						
Floor to heater	65"	67"	67"	69"	67.5"	69.5"
Heater to mattress	29"	31"	29.5"	31.5"	29.5"	31.5"
# Of heater(s)	1	2	1	2	1	2
Heater length	12"	16"	12"	16"	12"	16"
Type of heater(s)	Quartz	S.S. Tubular	Quartz	S.S. Tubular	Quartz	S.S. Tubular
Heater wattage (ea.) @ 120VAC	760	375 X 2	760	375 X 2	760	375 X 2
Heater Reflector	Dimpled	Smooth	Dimpled	Smooth	Dimpled	Smooth
# Of task light bulb(s)	2	1	2	1	2	1
Type of task light bulb(s)	Fluorescent	Quartz Halogen	Fluorescent	Quartz Halogen	Fluorescent	Quartz Halogen
Bassinet:						
Mattress to floor	N/A	N/A	37.5"	37.5"	38"	38"
Bassinet length	N/A	N/A	28"	28"	28"	28"
Bassinet height: Floor to side rail top	N/A	N/A	42"	42"	42"	42"
Bassinet width	N/A	N/A	24"	24"	24"	24"
Base:						
Electric hi / low drive	N/A	N/A	N/A	Optional	N/A	Optional
Options/accessories:						
Scale	Optional	Optional	Optional	Optional	Optional	Optional
Resusitation	Optional	Optional	Optional	Optional	Standard	Standard
Suction	Optional	Optional	Optional	Optional	Standard	Standard

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CONFIDENTIAL

1.0 SPECIFICATION PURPOSE

(b)(4)

[redacted]

101

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4) [redacted]	DRAFT	DATE EFF.: 5/3/97	

TITLE: SPECIFICATION FOR STABILET FREESTANDING WARMER

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4)	DRAFT	DATE EFF.: 5/3/97	

TITLE: SPECIFICATION FOR STABILET FREESTANDING WARMER

RECORD OF CHANGE

DATE	REV	DESCRIPTION OF CHANGE	APPROVED

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FIGURE A

(b)(4) Drawing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FIGURE C CHASSIS PANEL DESCRIPTION (b)(4) [redacted]

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FIGURE D (b)(4) Schematic Drawings

(b)(4) Schematic [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FIGURE F

(b)(4) Schematic Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FIGURE F (b)(4) Schematic Drawings

(b)(4) Schematic Dra

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BLANK PAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4) Specifications	DRAFT	DATE EFF.: 5/3/97	CONFIDENTIAL

TITLE: SPECIFICATION FOR STABILET CC

(b)(4) Specifications

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BILL-ROM ENGINEERING SPECIFICATION (b)(4) Specificatio	DRAFT	DATE EFF.: 5/3/97
TITLE: SPECIFICATION FOR STABILET CC		

FIGURE A

(b)(4) Diagram

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b [redacted]	DRAFT	DATE EFF.: 5/3/97	
TITLE: SPECIFICATION FOR STABILET CC			

FIGURE D

(b)(4) Schematic Drawings

(b)(4) Schematic Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4) [redacted]	DRAFT	DATE EFF.: 5/3/97	
TITLE: SPECIFICATION FOR STABILET CC			

(b)(4) Schematic Drawings

[redacted]

160

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4)	DRAFT	DATE EFF.: 5/3/97	

TITLE: SPECIFICATION FOR STABILET CC

(b)(4) Schematic Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BLANK PAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

VB

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4)	DRAFT	DATE EFF.: 5/03/97	CONFIDENTIAL
TITLE: SPECIFICATION FOR STABILET			

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

(b)(4) Specifications

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4) (b)(4) Specifi	DRAFT	DATE EFF.: 5/03/97	
TITLE: SPECIFICATION FOR STABILET			

FIGURE B

(b)(4) Schematic Drawings

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4)	DRAFT	DATE EFF.: 5/03/97	
TITLE: SPECIFICATION FOR STABILET			

(b)(4) Specifications

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b[redacted]	DRAFT	DATE EFF.: 5/03/97	
TITLE: SPECIFICATION FOR STABILET			

(b)(4) Specifications

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4)	DRAFT	DATE EFF.: 5/03/97	
TITLE: SPECIFICATION FOR STABILET			

FIGURE E

(b)(4) Specifications

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

HILL-ROM ENGINEERING SPECIFICATION (b)(4) (b)(4)	DRAFT	DATE EFF.: 5/03/97	
TITLE: SPECIFICATION FOR STABILET			

FIGURE E

(b)(4) Specifications

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BLANK PAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CONFIDENTIAL

HAZARD ANALYSIS

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

BN

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

G

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Stabilet radiant warmer, I.R. power distribution plot

(b)(4)

[redacted]

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

H

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ZM

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Radiolucent Panels

Testing and procedures have been implemented to assure compliance with performance standards established under 21 CFR Part 1020, "Performance Standard for Ionizing Radiation Emitting Products".

Functional/Operational Characteristics

The panels do not generate any electronic or radiation emissions. The panels provide a radiolucent surface for patient support and are incorporated into the Stabilet as the bassinet sleep surface support.

Performance Standards Category (21 CFR 1020.30n)

Tabletop, moveable without articulated joint(s): Aluminum equivalent: 1.5 mm

Attached is an example of the testing lab report.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Third Party Testing

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BLANK PAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Labels

The following labels do not represent a significant change from the predicate device in the recommendations for the safe and effective operation of the Stabilet Infant Radiant Warmer. The new device is substantially equivalent to the predicate device.

Label	P1250C	P1500C	P2000D
Mfr. ID label	Yes	Yes	Yes
X-Ray label	No	Yes	Yes
Caution: Shock	Yes	Yes	Yes
Chassis	Yes	Yes	Yes
Blender Label	No	No	Optional
O2 Flow/Airway pressure	Optional	Optional	Yes
Probe Placement	Yes	Yes	Yes
Suction	Optional	Optional	Yes
Airway Pressure	Optional	Optional	Yes
O2 Supply	Optional	Optional	Yes
Pressure Gauge	Optional	Optional	Yes
O2 Supply T-handle	Optional	Optional	Yes
Volume	Optional	Optional	Yes
Trend Release	No	Yes	Yes
23" Grid	No	Yes	Yes
X-ray Grid	No	Yes	Yes
Chassis Label - Fuse	Yes	Yes	Yes
Fuse Label	Yes	Yes	Yes
Mattress Height Label	Yes	No	No
Warning - Open Cylinder Valve	Optional	Optional	Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

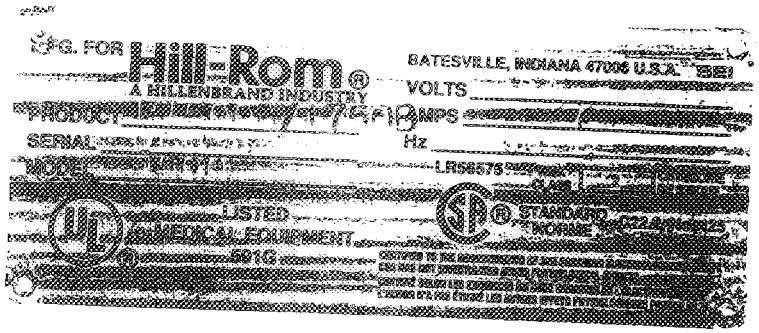
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Label	P1250C	P1500C	P2000D
Prescription Label	Yes	Yes	Yes
Halogen Bulb Label	Yes	Yes	Yes
Warning - Positioning Label	No	Optional	Optional
Heater Element Label	Yes	Yes	Yes
Hilo Arrows	No	Optional	Optional
Infant Scale Labels	Optional	Optional	Optional
Patient Probe Label	Yes	Yes	Yes
Probe Package Label - Single Use	Yes	Yes	Yes
Probe Package Label - Single Use	Yes	Yes	Yes
Probe Package Label - Single Use	Yes	Yes	Yes
Zip-Loc Bag - Probe	Yes	Yes	Yes

Note: All Optional labeling is placed on the optional accessory or is installed when the feature is selected by the customer.

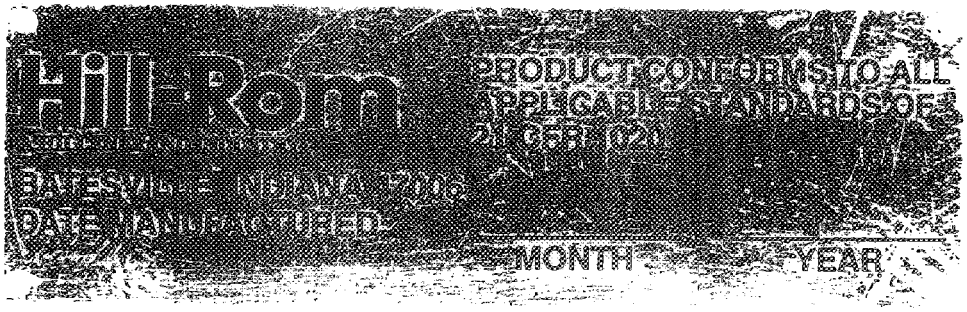
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



X-Ray Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CAUTION: ELECTRIC SHOCK HAZARD.
Do not remove cover. Refer servicing to qualified personnel. Fuses are located internally.
Reliable grounding is achieved only by connection to receptacles marked "HOSPITAL GRADE".

DANGER: POSSIBLE EXPLOSION HAZARD
If used in the presence of flammable anesthetics.

DANGER: RISQUE D'EXPLOSION. Ne pas employer en présence d'anestésiques inflammables.

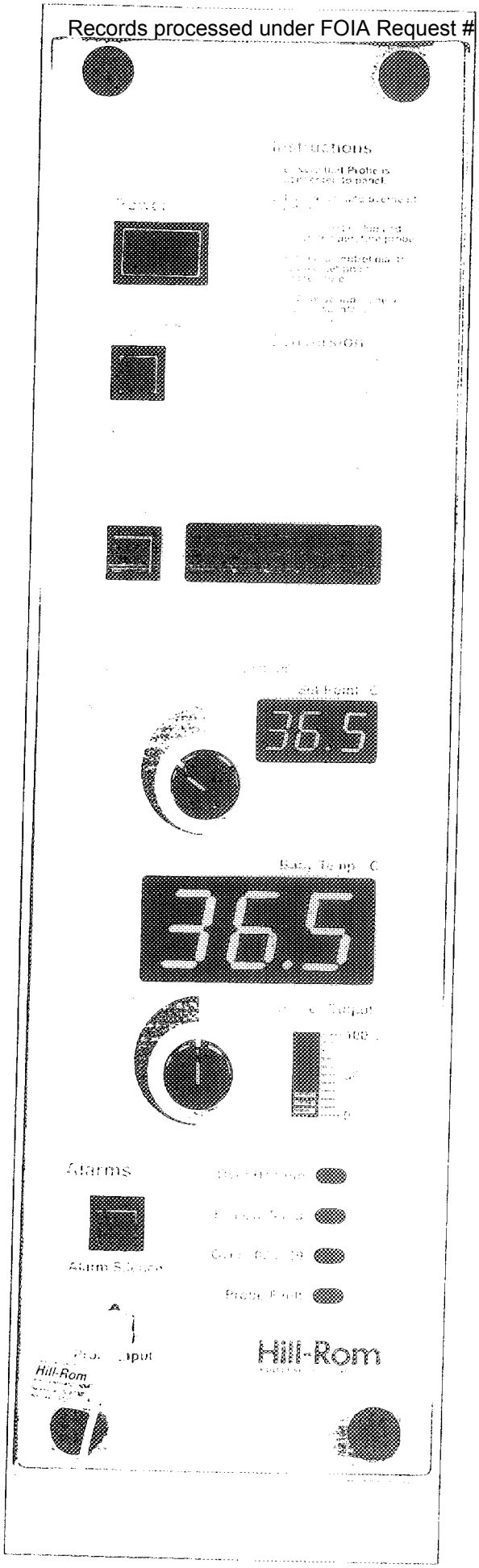
WARNING: FIRE HAZARD. Keep matches, lighted cigarettes, and all other sources of ignition out of the room in which the incubator is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

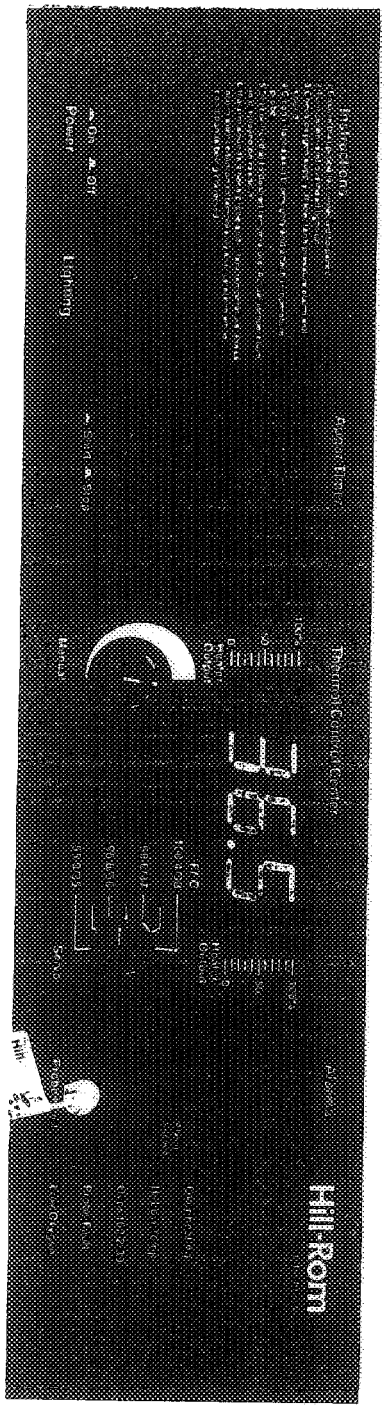
For service/product support information please contact a Hill-Rom representative at 1-800-445-3720.

Caution Decal

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

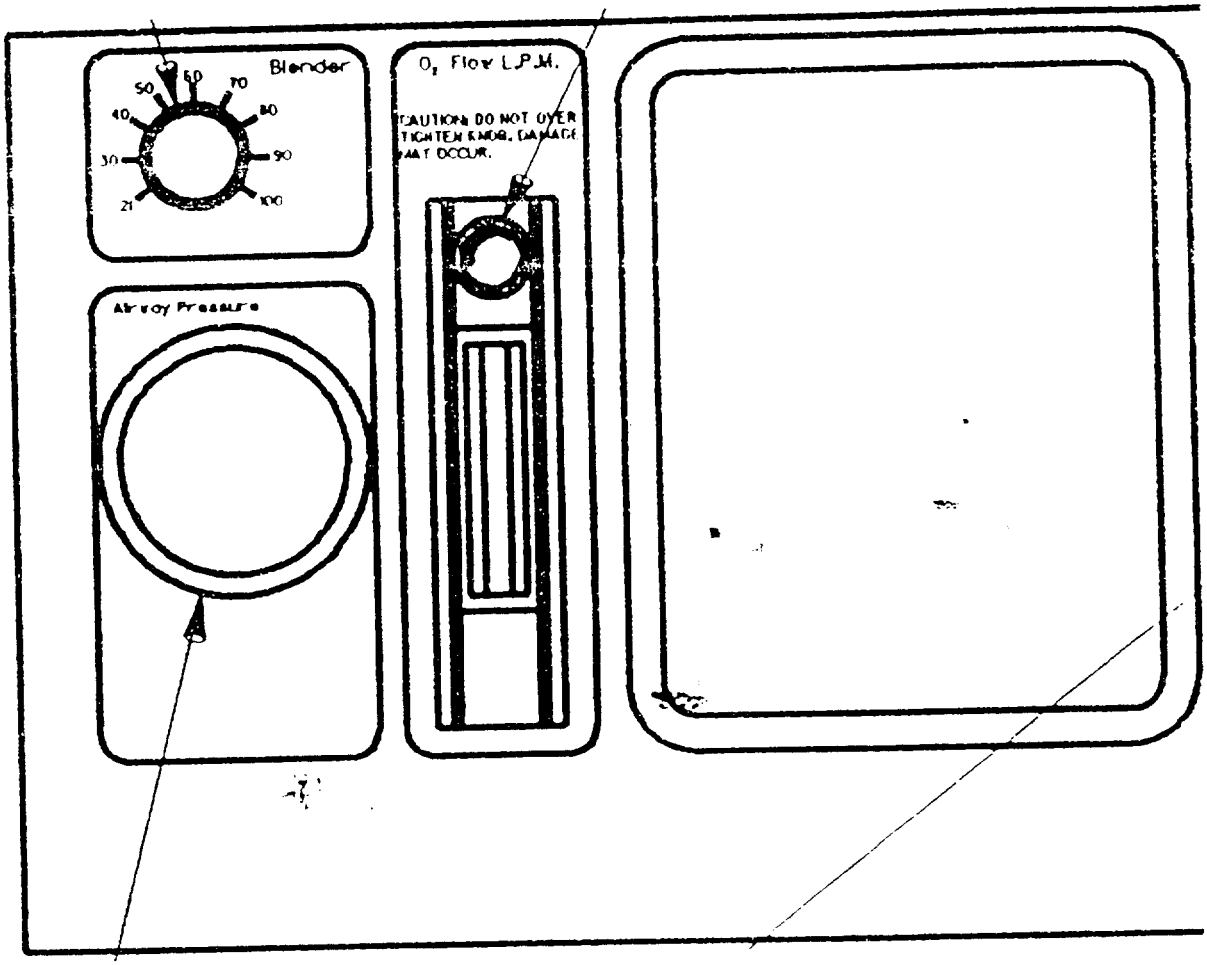
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

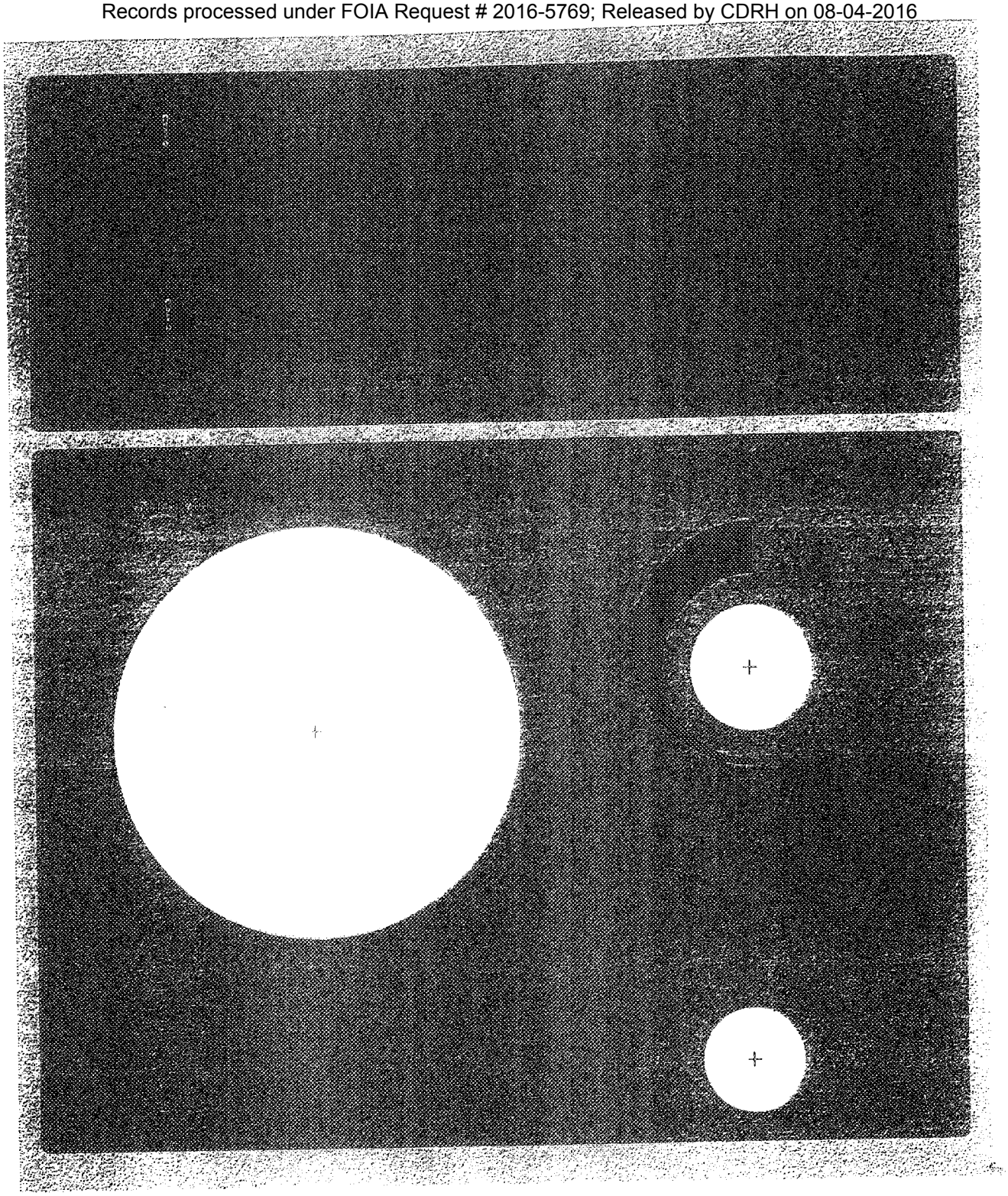


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

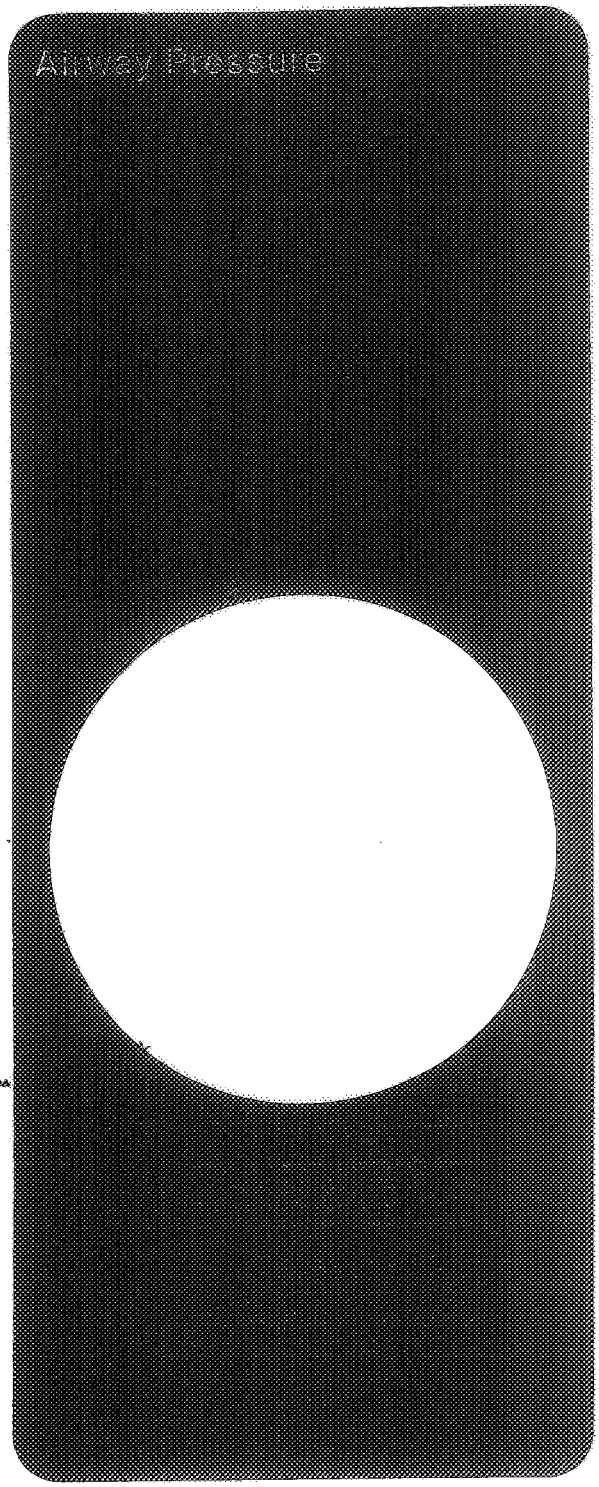
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Airway Pressure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Supply

O2 Supply

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Pressure Gauge

Pressure Gauge

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

O2 T-Handle

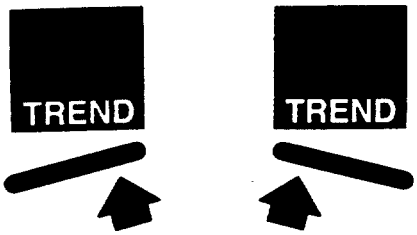
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Volume - Green white

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

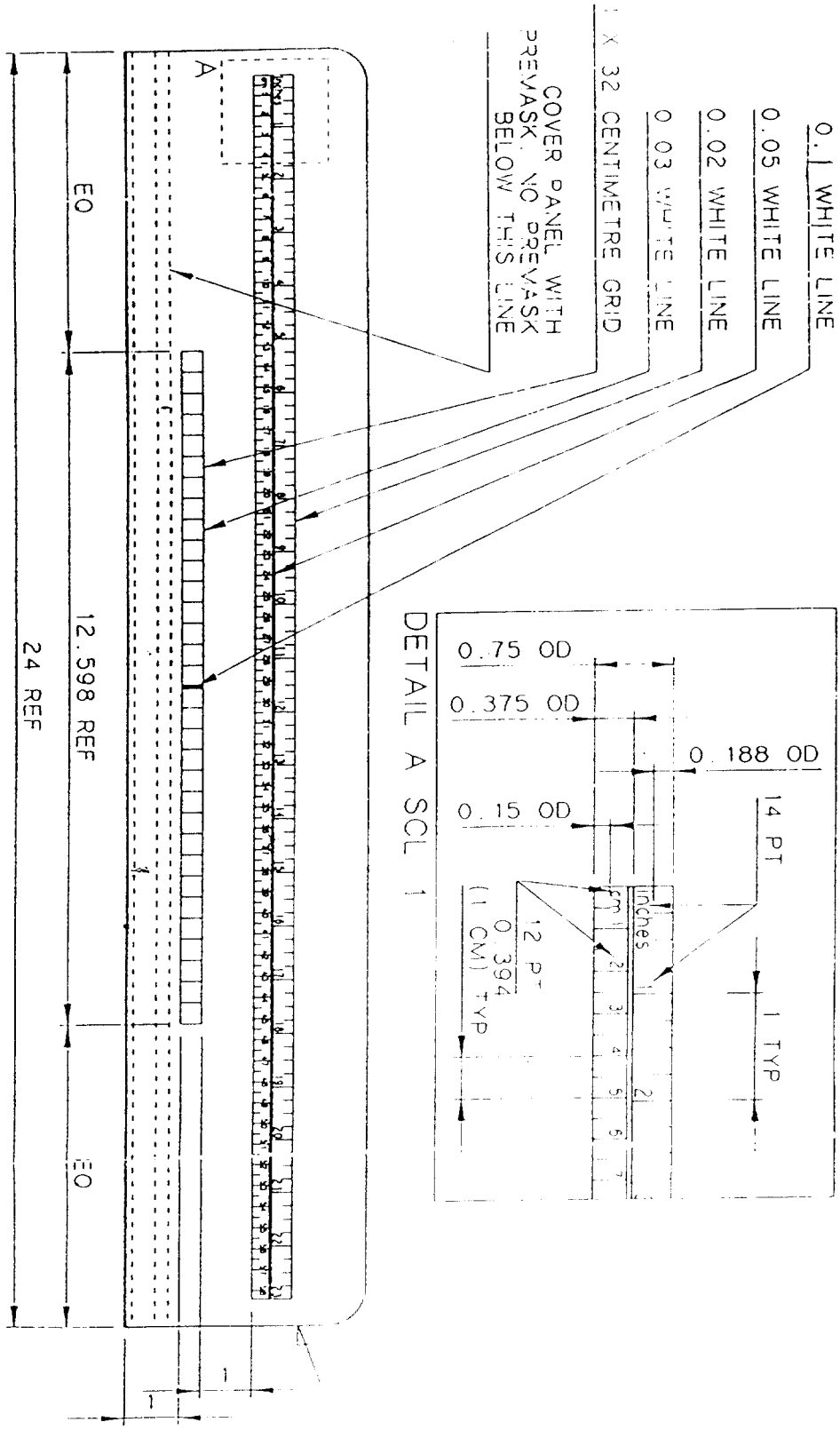
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Trend Release

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

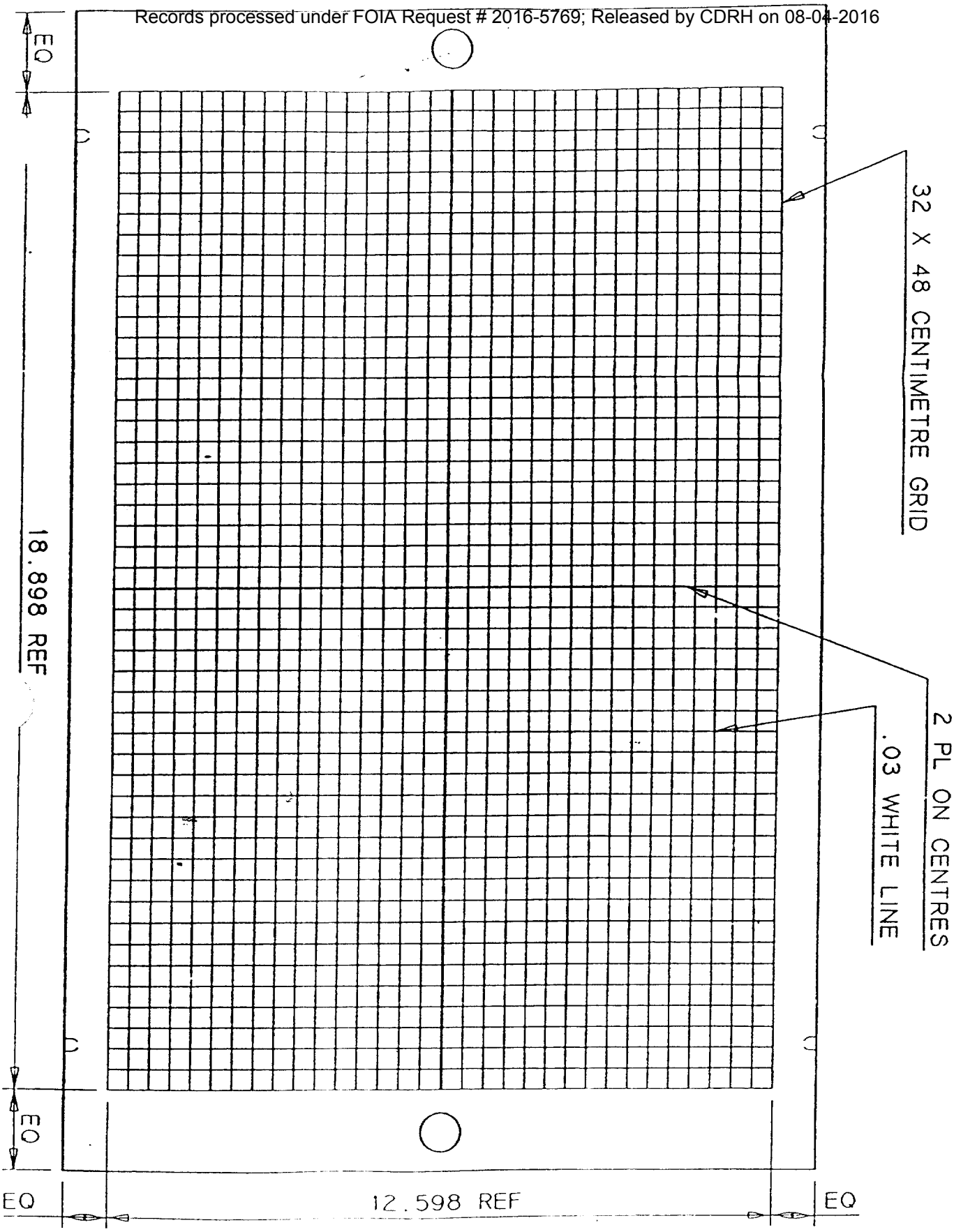
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



23" Grid

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



X-Ray Grid

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

WARNING - RISK OF FIRE
- REPLACE FUSE AS MARKED

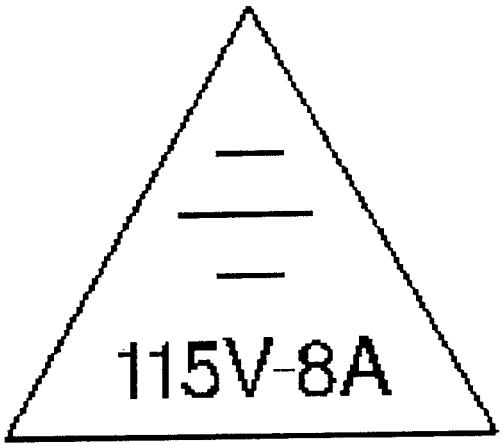
FUSE F1: 250V, 8 AMP, FAST ACTING
FUSE F2: 250V, .25 AMP, TIME DELAY

- DISCONNECT LINE CORD
BEFORE SERVICING.

Chassis Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



REPLACE
FUSES
AS MARKED

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Warning:

Mattress surface should not be above this line.

Warning:

Mattress surface should not be below this line.

Mattress Height Label

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Open cylinder valve slowly!

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Caution: Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

STABILET REFRESH LABELS

USE SYLVANIA XXXXXX/XX HALOGEN BULB

WARNING: Check space above and below the warmer so that repositioning the unit will not be obstructed.

WARNING: Do not transport warmer with the bed in the high position. Lower the bed surface before transport.

REPLACE HEATER ELEMENT WITH HEATER PART# XXXXX-XX

HI/LOW ARROWS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

WARNING: DISCONNECT SUPPLY BEFORE SERVICING.

CAUTION: TO PREVENT ELECTRICAL SHOCKS DO NOT REMOVE BACK. NO USER SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.

AVERTISSEMENT: COUPLER L'ALIMENTATION AVANT L'ENTRETIEN ET LE DEPANNAGE.

DANGER: EXPLOSION HAZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS. RISK CLASS 2B C22.2 NO. 125

DANGER: RISQUE D'EXPLOSION. NE PAS EMPLOYER EN PRESENCE D'ANESTHESIQUES INFLAMMABLES.

H

DO NOT REMOVE

Hill-Rom.
A HILLENBRAND INDUSTRY
INFANT SCALE

CAUTION:
TO ENSURE GROUNDING RELIABILITY MATE ONLY WITH HOSPITAL GRADE RECEPTACLE. H

DO NOT REMOVE

Hill-Rom.
A HILLENBRAND INDUSTRY
INFANT WARMER

CAUTION:
TO ENSURE GROUNDING RELIABILITY MATE ONLY WITH HOSPITAL GRADE RECEPTACLE. H

GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN THE EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED HOSPITAL ONLY OR HOSPITAL GRADE.

Hill-Rom.
A HILLENBRAND INDUSTRY
BATESVILLE, IN. 47006 USA

MODEL HR
S/N 0111
105-120 VAC
50/60 Hz
6 WATTS

H

E118797 LR84978

MANUFACTURED FOR
Hill-Rom.
A HILLENBRAND INDUSTRY
BATESVILLE, IN. 47006

THIS DEVICE COMPLIES WITHIN THE REQUIREMENTS OF PART 15 OF THE FCC RULES AND THE CLASS A LIMITS OF THE CANADIAN DEPARTMENT OF COMMUNICATIONS STANDARD ICES-003 FOR DIGITAL APPARTUS. OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS: (1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE. (2) THIS DEVICE MUST ACCEPT ANY INTERFERENCE RECEIVED, INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRABLE OPERATION.

CET APPAREIL NUMERIQUE RESPECTE LES LIMITES DE BRUITS RADIOELECTRIQUES APPLICABLES AUX APPAREILS NUMERIQUES DE CLASSE A PRESCRITES DANS LA NORME SUR LE MATERIEL BROUILLEUR: "APPAREILS NUMERIQUES", NMB-003 EDICTEE PAR LE MINISTRE DES COMMUNICATIONS DU CANADA.

m127_054

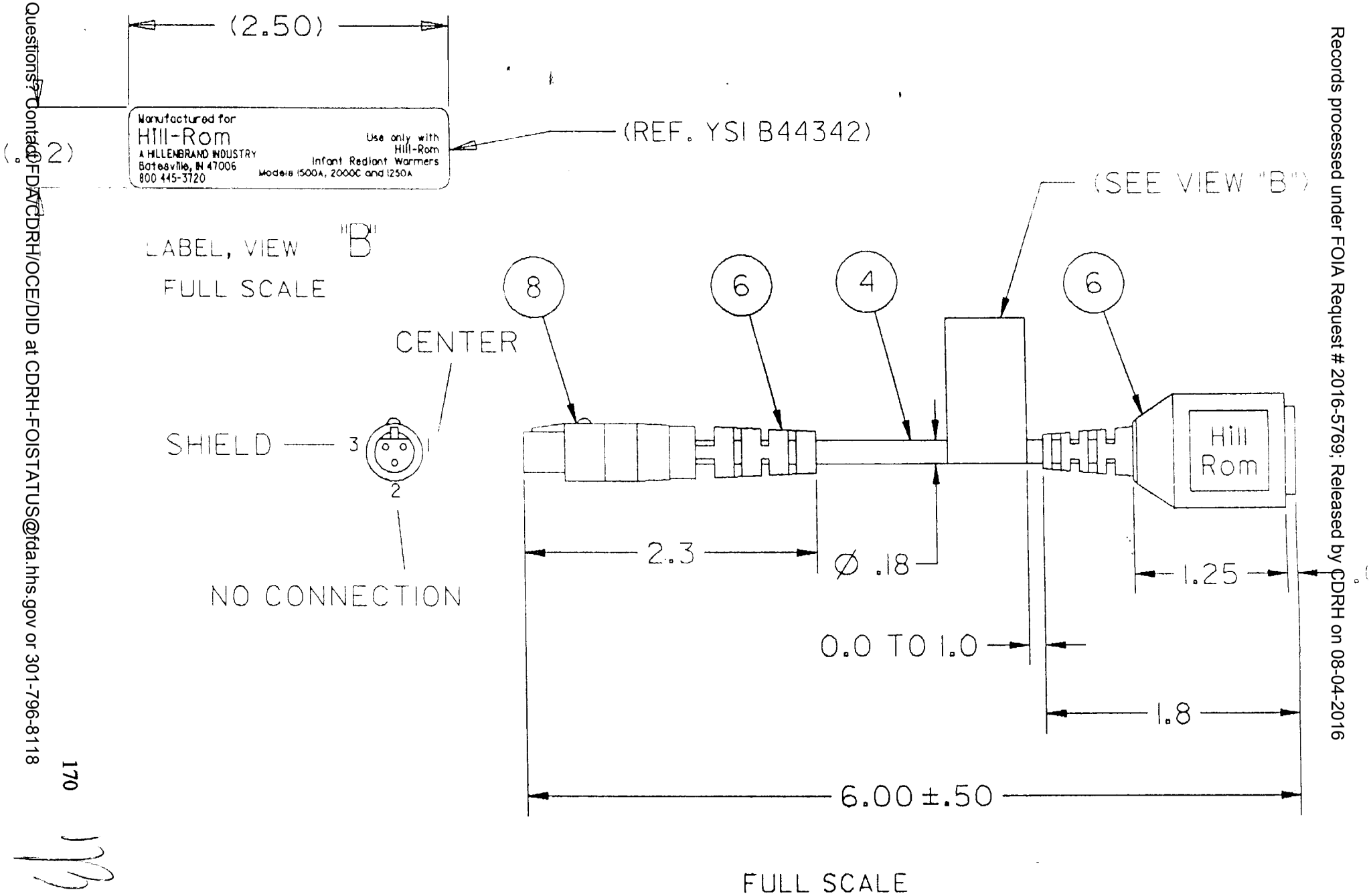
CAUTION: Risk of Electrical Shock

This unit recieves power from more than one source. Disconnection of the A/C sources is required to de-energize the unit before servicing.

m127_070

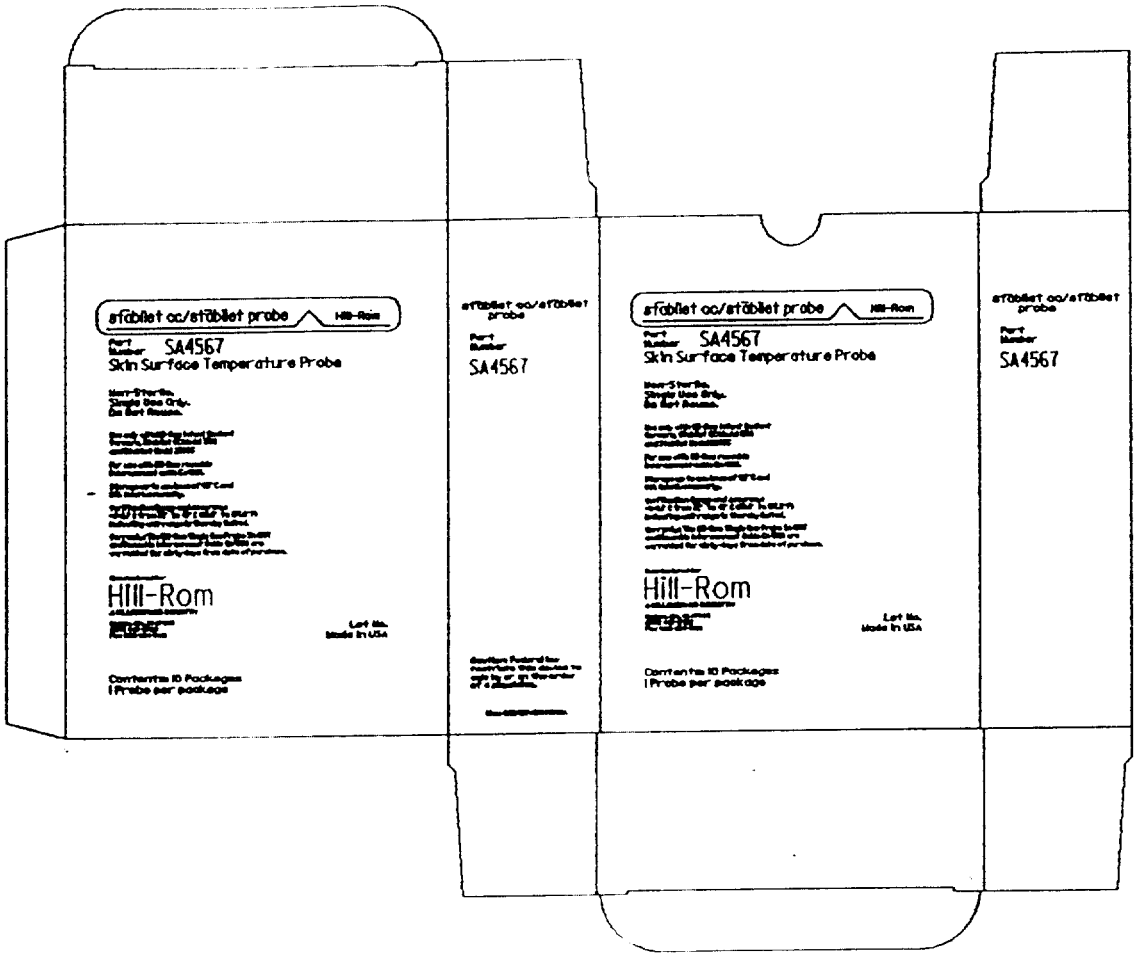
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

NTERED ON
IEAT SEAL.

HEAT SEAL MUST
BE CONTINUOUS.

Peel apart to open

stabilet cc/probe Hill-Rom

Part Number SA4567

Skin Surface Temperature Probe

Non-Sterile.
Single Use Only.
Do Not Reuse.

Use only with Hill-Rom Infant Radiant Warmers, Stabilet CC Model 1500 and Stabilet Model 2000C

For use with Hill-Rom reusable Interconnect cable SA4566.

Storage up to maximum of 65° C and 80% Relative Humidity.

Verification Range and Accuracy: ±0.1° C from 32° to 42° C (89.6° to 107.6° F) Indicating unit range is thereby limited.

Warranty: The Hill-Rom Single Use Probe SA4567 and Reusable Interconnect Cable SA4566 are warranted for sixty days from date of purchase.

Manufactured for

Hill-Rom

A HILLENBRAND INDUSTRY

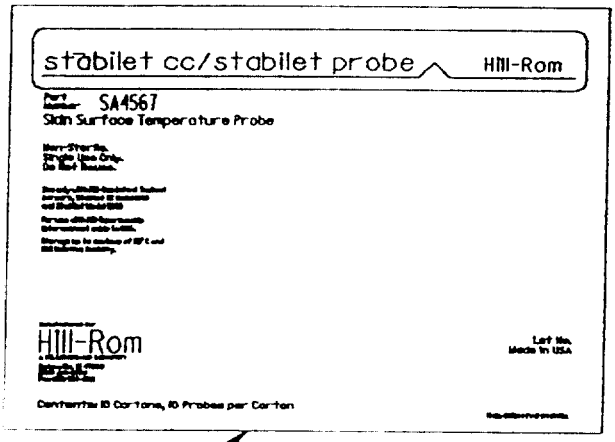
Batesville, IN 47006
(800) 445-3720
Fax (812) 934-8189

Lot No.
Made In USA

Item 061242 P/N C44361A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

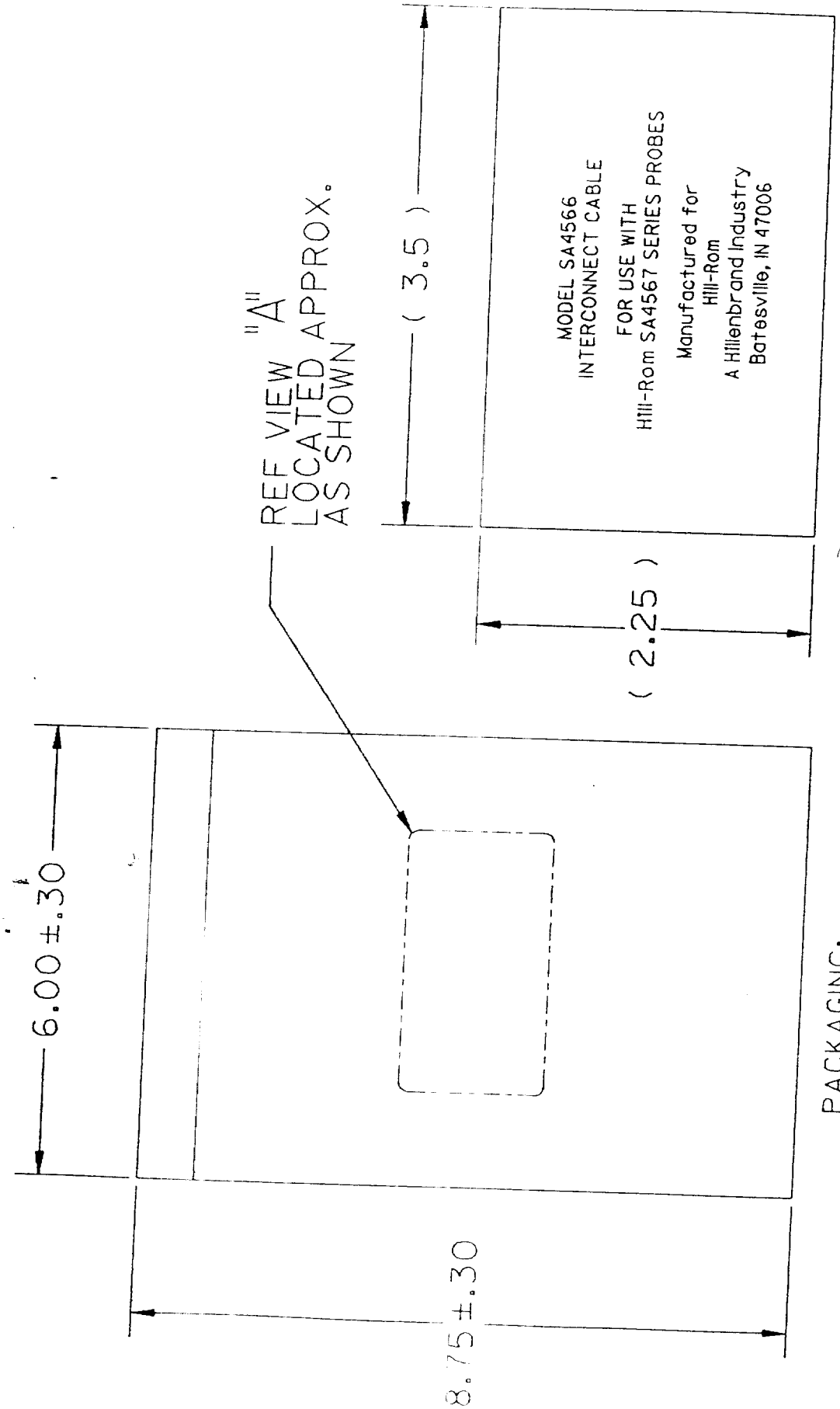
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



ART FOR SIDES "A", "B", "C", AND "D"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

5

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Labeling

In-Service Manuals

The enclosed copies of the Draft In-Service Manual for the 1250C, 1500C and 2000D Model Stabilets will be have revised photographs which reflect the look and features of the new Stabilet Infant Radiant Warmers.

All references to earlier model/versions of the Stabilet will be revised to reflect the new Stabilet Model/version.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

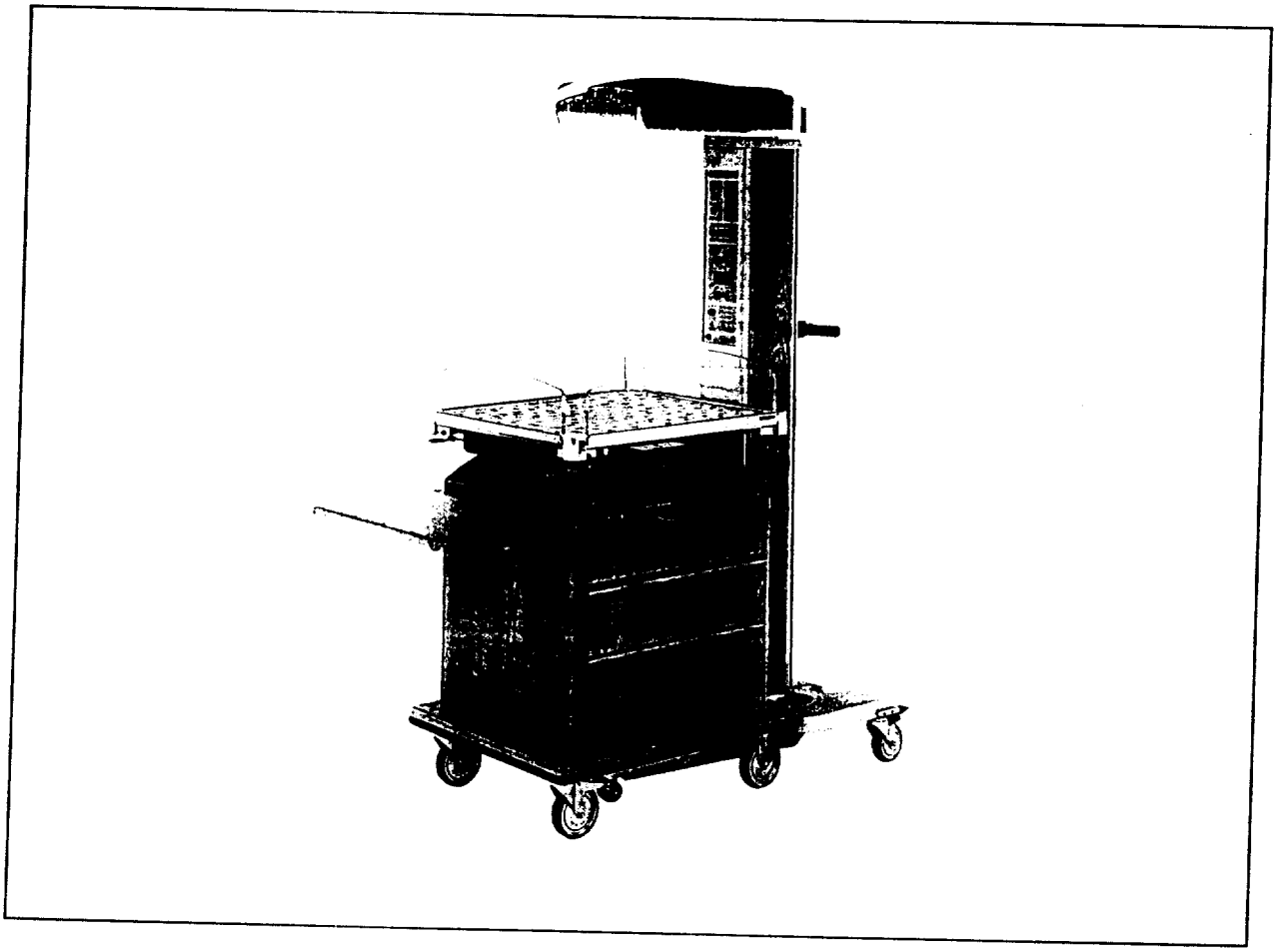
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016.

IN-SERVICE MANUAL

Stabilet™ Freestanding Infant Warmer and Clinical Bassinet

From Hill-Rom®



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE OF CONTENTS

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

FEATURES 1
SPECIFICATIONS 1
FEATURES – WARMER
Two Position Warmer Module 2
Over Center of Bassinet 2
X-Ray, Mother/Baby Bonding, and Storage 2
Apgar/Procedure Timer 2
Lighting Button Module 2
Accessory Tracks 3
Thermal Control Center 3
Manual Mode 3
Servo Control Mode 4
Alarm Descriptions 5
Overheating Alarm 5
Hi-Low Temperature Alarm 5
Over 102.2°F/39°C Alarm 5
Probe Fault Alarm 6
System Fault Alarm 6
Loss of AC Power Alarm 6
FEATURES – BASSINET
Bassinet 7
Trendelenburg/Reverse Trendelenburg/Level Sleep Surface 7
Drop Leaf Work Surface/Chart Holder 8
Built-In X-Ray Cassette Holder/Radiolucent Mattress 8
Storage Drawers 9
Docking Mechanism 9
ACCESSORIES
Resuscitation Modules 10
Oxygen Module (Flow and Airway Pressure) 11
Oxygen Module (Flow Only) 12
Suction Module (Wall Only) 13
Suction Module (Venturi Only) 14
CLEANING 15
SAFETY TIPS 16

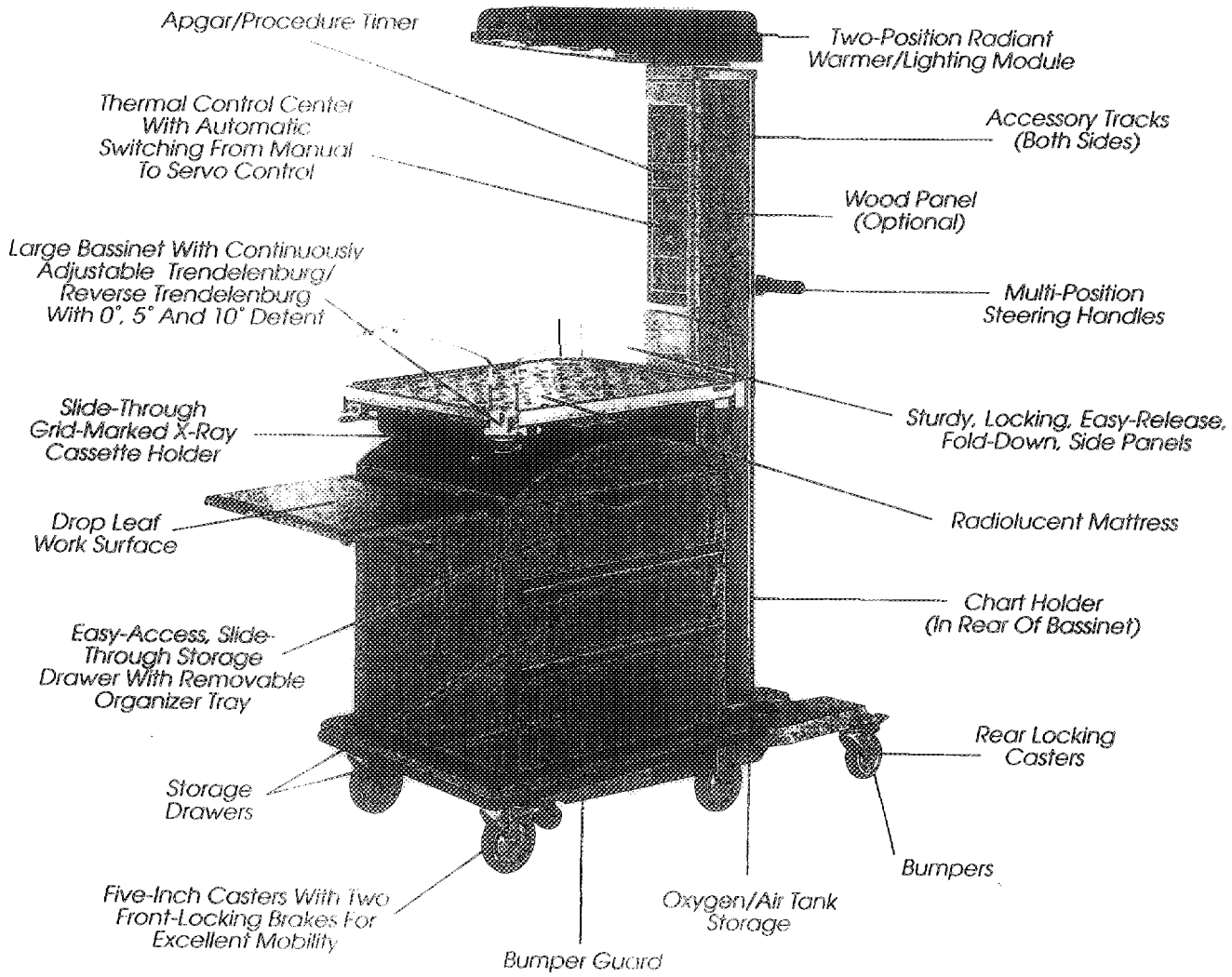
FOR SPECIAL ASSISTANCE:

Hill-Rom Account Manager _____ Phone _____
Perinatal Consultant _____ Phone _____
Field Service Technician _____ Phone _____
Customer Service Representative _____ Phone _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES



U.S. Patent 5,162,038

SPECIFICATIONS

Stabilet Freestanding Infant Warmer

Height – Floor to top of unit	72"
Front Caster	2"
Rear Casters	4"
Width	27½"
Length	33½"

Stabilet Clinical Bassinet

Height – Floor to top of Side Panel	42"
Width – Overall	24¾"
Length – Overall (drop-leaf work surface down)	30"
Length – Overall (drop-leaf work surface up)	43½"
Bassinet Size	28" x 24"
Mattress Size	26" x 22" x 1"
Casters	5"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Response Provided Under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

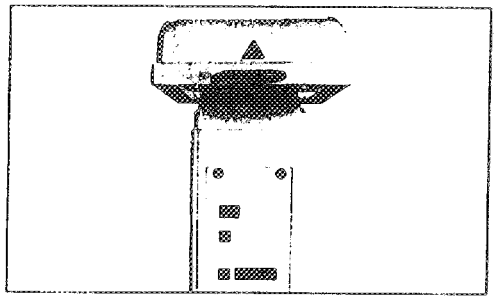
TWO-POSITION WARMER MODULE

The Radiant Warmer Module provides a controlled source of radiant heat to unit through (2) 375 Watt Stainless Steel Tubes and a smooth parabolic reflector.

er Center of Bassinet

- To place the heater into the standard operating position, rotate the heater 90°, placing it centrally over the Bassinet.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.

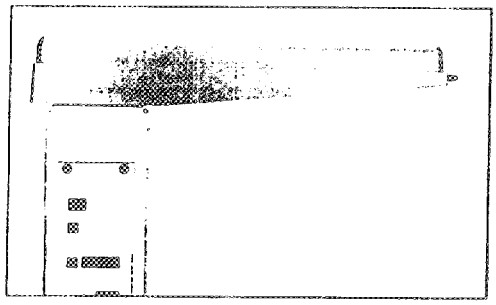
WARNING Do not place any objects on top of the Warmer Housing. This could cause overheating of the unit and/or combustion of the objects placed on top of the warmer.



X-Ray, Mother/Baby Bonding and Storage

- Fold down Front and Side panels if applicable.
- Rotate the heater from the center position 90° to the right.
- For Mother/Baby Bonding positions, verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.
- The heater may be rotated to allow the X-Ray machine to be properly positioned over the infant.

NOTE In this position, the Warmer Module will continue to deliver heat.

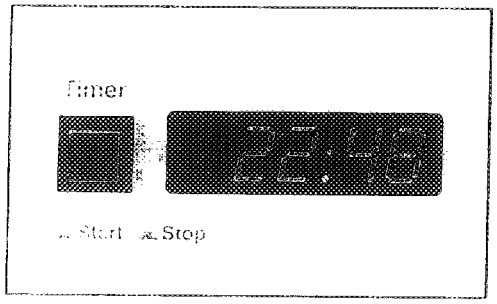


APGAR/PROCEDURE TIMER

Located on the unit's Control Panel is a one-hour electronic Apgar/ Procedure Timer. The Main Power Button must be on to activate the Timer.

- To start the Apgar/Procedure Timer, depress the Start/Stop Button located on the Control Panel.
- A visible four-digit display in minutes and seconds will appear on the Control Panel. The timer will begin at 00:00 and run to 59:59.
- A one-second audible tone will sound at one, five, and ten minutes.
- Depress the Start/Stop Button again to reset the timer.

NOTE Power Switch must be ON to operate timer.



LIGHTING BUTTON MODULE

A Lighting Button located on the unit's Control Panel activates one halogen Light. The Main Power Button must be on to activate the lighting.

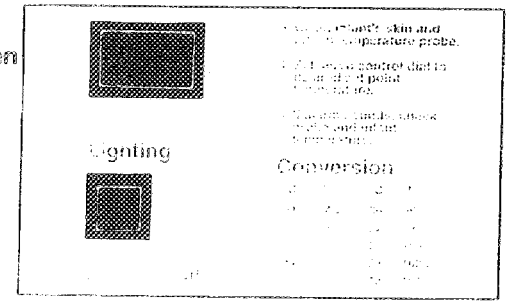
To Activate Lighting

- Depress the Lighting Button, located on the Control Panel.

To Turn Lighting Off

- Depress Lighting Button.

NOTE To extend bulb life, turn the examination light on only as required.

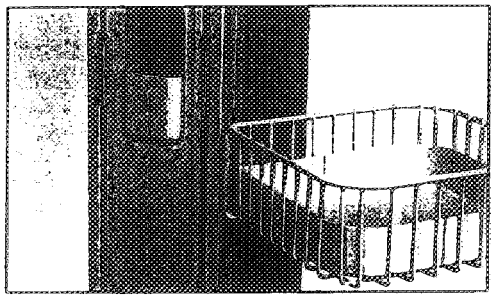


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

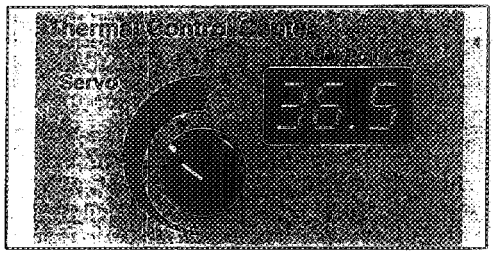
ACCESSORY TRACKS

Accessory Tracks allow convenient placement of numerous accessories at comfortable working heights. The Accessory Tracks improve access to equipment and save valuable floor space.



THERMAL CONTROL CENTER

Thermoregulation Controls are centrally located on the Control Panel.



Manual Mode

Manual Mode is intended primarily for warming the Bassinet and blankets in preparation for an Infant or when it is impractical to attach a skin Probe to the Infant.

NOTE Before placing the Infant in the Bassinet, pre-heat the Thermistor Probe, face up, in the Bassinet, prior to connecting the Probe into the Jack.

NOTE To avoid overheating or underheating of the Infant, Hill-Rom recommends that a Probe be attached to the Infant at all times while in an Infant Warmer and the Infant not be left unattended.

- Plug the power cord into a standard 115V AC receptacle.

CAUTION Connect the power cord to a properly grounded receptacle that is approved for hospital use. Do not use an extension cord or AC receptacle box.

DANGER Possible explosion hazard if used in the presence of flammable anesthetics. This unit is not intended for use in hazardous Class 1, Group C locations.

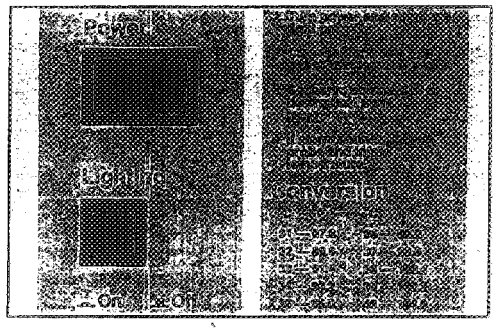
- Turn the power on by depressing the Power Button located on the upright Control Panel.

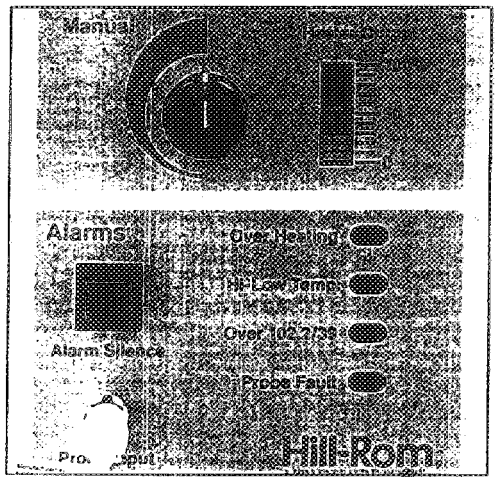
CAUTION The use of radiant warmers may cause insensible water loss.

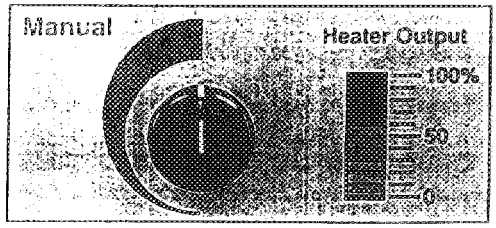
NOTE The Infant Warmer will function in the Manual Mode without a Thermistor Probe inserted in the jack. The Probe Fault LED Display will remain lit during this time.

NOTE Skin temperature alarms are not functional during Manual Mode when a Thermistor Probe is not inserted in the Probe Jack or when the Probe is inserted in the Probe Jack but senses temperature less than approximately 31°C.

- Set the desired heater output using the Heater Output Control Dial located on the Thermal Control Center.
- Heater output is shown on the unit in terms of percentage of power and can be from 0% to 100%.
- The unit will remain at the set heater output you choose until you manually readjust it unless the Overheating Alarm is activated (See Overheating Alarm description).



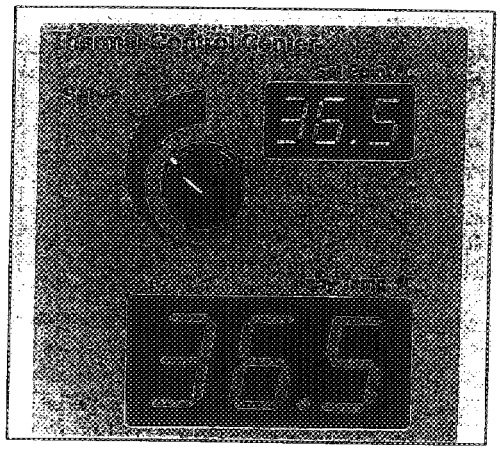




NOTE In Manual Mode, when no heater output lights appear, it is an indication that heater output is 0%.
Green LEDs indicate approximately 10%-30% heater output.
Yellow LEDs indicate approximately 40%-70% heater output.
Red LEDs indicate approximately 80%-100% heater output.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016



Servo Control Mode

When the Thermistor Probe is inserted into the Probe Jack and senses a mperature of approximately 31°C (88°F), the unit automatically converts the Servo Control Mode.

The Servo Control Mode allows the LED Heater Output Grid to indicate the amount of energy delivered to the warmer to keep the infant's skin temperature at the predetermined set point temperature.

Heater output is shown on the unit in terms of approximate percentage of power and ranges from 0% to 100%.

As the infant's skin temperature approaches the set point, the heater output will modulate to maintain the infant's skin temperature at the set point temperature.

Once the infant's skin temperature and the set point temperature are equal, only gradual changes in the heater output are needed to maintain the desired infant skin temperature.

A temperature readout displays the infant's skin temperature when the unit is in Servo Control Mode.

- Set the infant desired target temperature using the Servo Temperature Control Dial and the setpoint digital display. Turn the dial until the selected setting is indicated on the setpoint digital display.
- Attach the Thermistor Probe to the infant. The Probe should be pre-heated before registering the baby's skin temperature.

NOTE Placement of the Probe is vital because it is the Probe that senses the baby's skin temperature and regulates warmer output.

SUPINE INFANTS...place the flat stainless steel side of the Probe down on the infant's abdomen below the rib cage.

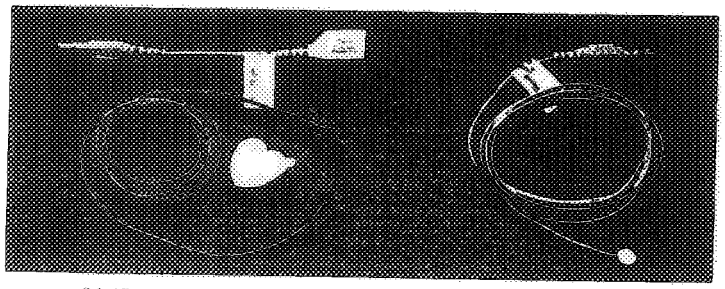
PRONE INFANTS...place the flat stainless steel side down on the infant's back below the rib cage, but away from the kidneys.

CAUTION Always attach the Probe with a reflective Probe cover. Serious temperature and control errors can occur if anything other than the recommended Probes and Probe covers are used. Do not use tape to attach the Probe.

CAUTION Inspect the infant's skin for reddened areas which may result from the heating of materials in contact with the skin.

CAUTION Avoid placement of objects (equipment, blankets, clothing) in the Bassinet that can block heat or absorb heat away from the infant.

NOTE Only the following Thermistor Probes should be used with the Stablet Freestanding Infant Warmer:



SA4567 Disposable Probe (Requires Reusable Adapter Cable SA4566)

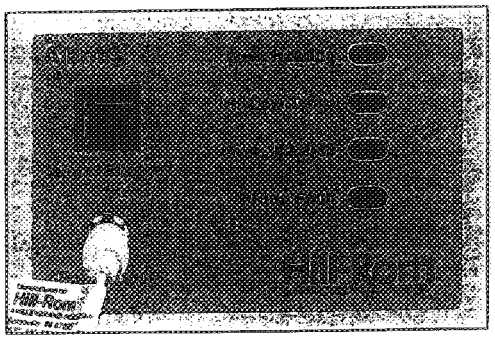
BCZ009 Reusable Probe

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

ALARM DESCRIPTIONS

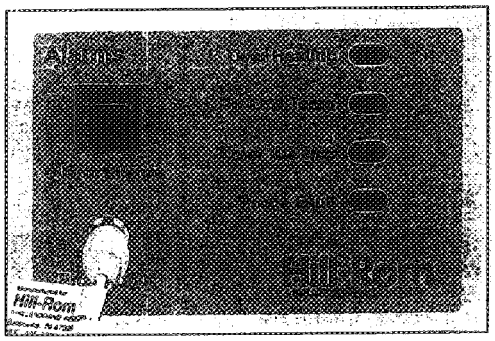
Overheating Alarm (Manual Mode Only)



- An Overheating Alarm will sound if there is constant heater output of 100% for approximately 15 minutes or approximately 30% (1 or 2 LEDS) for 70 minutes or any combination thereof of power and time.
- When the Overheating Alarm is triggered, power to the heater is reduced to approximately 30%.
- The Overheating Alarm can be silenced by depressing the Alarm Silence Button located on the left side of the Control Panel.
- The unit will continue to operate in Manual Mode and no Overheating Alarm will sound as long as the heater output is kept under approximately 30% (1 or 2 LEDS) and a Thermistor Probe is not inserted into the Probe Jack or is inserted but does not sense a temperature of over approximately 31°C.
- Once the Probe is inserted in the Probe Jack and the Probe senses a temperature of approximately 31°C, the Infant Warmer becomes a Servo-Controlled Unit, controlled by the skin temperature of the infant.

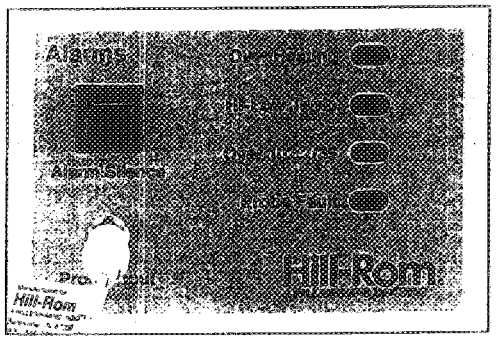
WARNING Do not leave the infant unattended.

Hi-Low Temperature Alarm



- If the infant's temperature has fluctuated more than ± .5°C from the set point temperature, a solid, visible Hi-Low Temperature LED Display will appear immediately on the Infant Warmer Control Panel.
- If after four minutes the high-low temperature has not been rectified, an audible Hi-Low Temperature Alarm will sound.
- During the (audible) alarm condition, heater output will change to approximately 30% until the alarm is silenced.
- The Hi-Low Temperature Alarm can be silenced by depressing the Alarm Silence Button; however, the Hi-Low Temperature LED Display will remain lit until the infant's skin temperature returns to within the target range. If the infant's temperature remains outside of the ± .5°C setpoint for another 4 minutes the audible alarm will again sound.
- When the Hi-Low Temperature condition is rectified, the Hi-Low Temperature Alarm will automatically reset.

Over 102.2°F/39°C Alarm

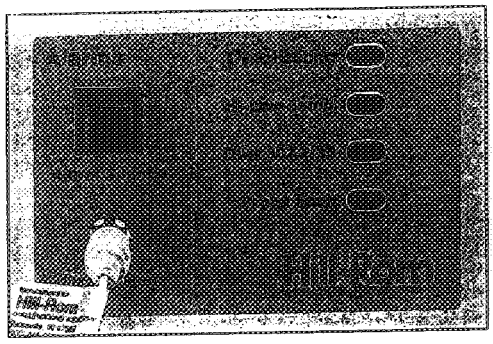


- An audible and visible Over 102.2°F/39°C Alarm will sound immediately if the Thermistor Probe senses that the infant's skin temperature exceeds 102.2°F/39°C.
- Heater output is reduced to 0% and will not resume until the Thermistor Probe senses that the infant's temperature has fallen below 102.2°F/39°C.
- The alarm will not silence until the condition is rectified.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

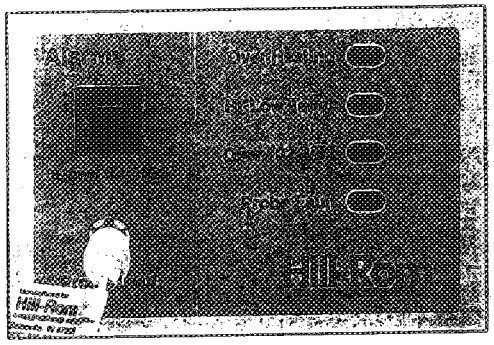
Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

Probe Fault Alarm



- In the Manual Mode when the Probe is not inserted in the Probe Input Jack, the Probe Fault LED will remain lit.
- In the Servo Mode, whenever the Probe senses a temperature of less than approximately 31°C for approximately one minute, the Probe Fault LED will come ON, an audible alarm will occur, and heater output will drop to approximately 30%.
- When the alarm is silenced by depressing the Alarm Silence Button: If sensed temperature is still below 31°C, the Probe Fault LED will remain lit and the unit will revert to manual mode. If the sensed temperature is above 31°C, the Probe Fault LED will go off and the unit will revert to Servo Mode.

System Fault Alarm



- A System Fault Alarm has occured when an audible alarm sounds and all alarm LED displays illuminate.
- The system continually monitors itself electronically to ensure complete thermoregulation integrity. If, at any time, the Heater Control Signal and the actual Heater Current Signal do not agree, AC power/heater output is immediately terminated and a System Fault Alarm is activated.
- The System Fault Alarm may also be activated by connecting an incompatible temperature Probe or when the Probe is shorted or when there is an open heater element.
- The alarm cannot be silenced until the condition is rectified.
- The alarm may indicate a system failure and require maintenance by a qualified technician.

Loss of AC Power Alarm

- If the unit becomes unplugged or AC power is interrupted to the unit when the Power Switch is ON, a pulsating alarm will sound. This Loss of AC Power Alarm will fade after approximately 3 minutes, or will automatically reset if power is restored to the unit.
- The Loss of AC Power Alarm works off a capacitor that will recharge when AC power is restored to the unit and the Power Switch is turned on.
- No batteries are required for the operation of this alarm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

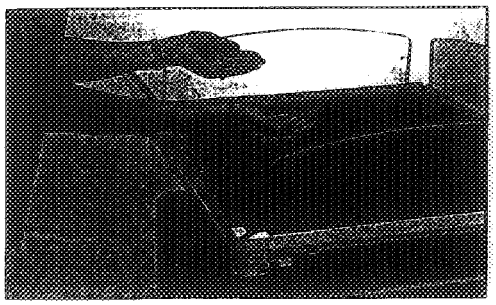
BASSINET

The Stabilet Clinical Bassinet has Fold-Down Front, Rear and Side Panels to allow greater access to the Procedure Table.

To Lower

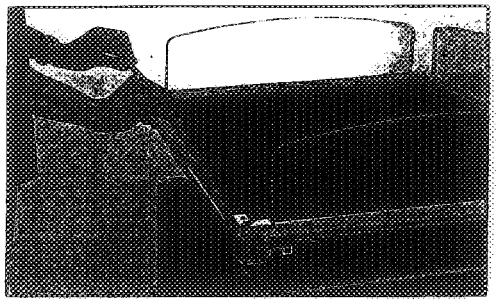
- To lower the Front, Back, or Side Panels, press down and pivot panel out and down with forearm or hands.

CAUTION: Do not leave infant unattended when Panels are lowered.



To Raise

- To raise the Panels, grasp the panel and rotate up and towards the Bassinet.
- Move the panel gently to ensure that it is securely locked in the upright position.

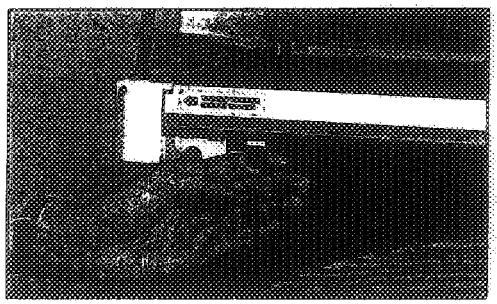


To Lock (So that the Side Panels cannot be accidentally lowered)

- Locate locking mechanism, positioned under each panel, and gently pull out until it stops.
- Push down gently to ensure that it is locked.

To Unlock

- Locate locking mechanism, positioned under each panel, and push in until it stops.



TRENDELENBURG/REVERSE TRENDELENBURG/LEVEL SLEEP SURFACE

Trendelenburg

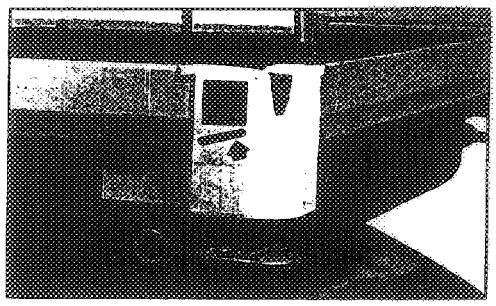
- Depress either of the handles located beneath the Front Panel of the Bassinet and lift. The Bassinet will rotate from 0° to 10° Trendelenburg, with a 0°, 5° and 10° detent.

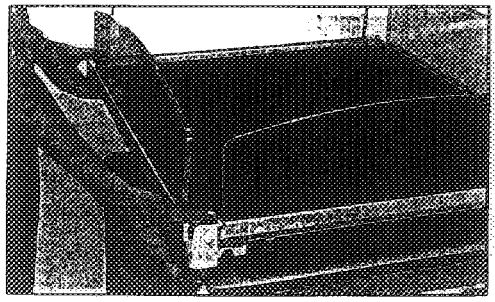
Reverse Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet.
- Push down on the Bassinet from the front using the Trendelenburg Mechanism.
- Lift the Bassinet from the end opposite of the handles. The Bassinet will rotate from 0° to 10° Reverse Trendelenburg, with a 0° and 5° detent.

Level Sleep Surface

- Depress either of the handles located beneath the Front Panel and guide the Bassinet to a center position.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

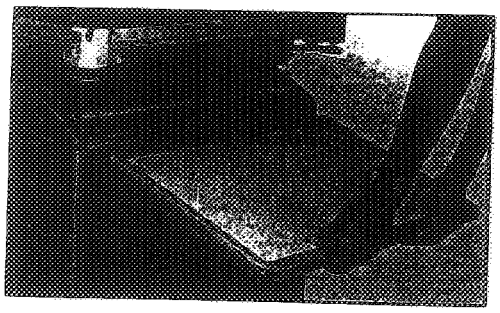
Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

DROP LEAF WORK SURFACE/CHART HOLDER

A built-in Drop Leaf Work Surface can be used as an instrument shelf ring procedures as well as a surface for charting. Do not overload work face. Also located on the Bassinet is a built-in Chart Holder which allows you to store the infant's records within easy reach.

To Access

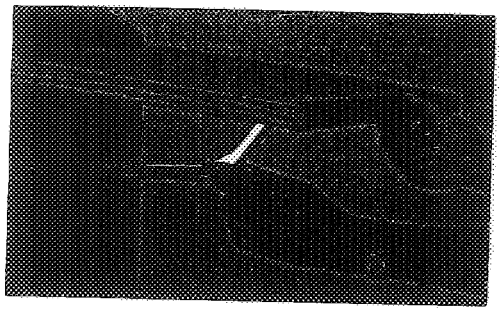
- Grasp the work surface and pivot up until it locks into place.



To Store

- Grasp the ring located directly beneath the work surface and pull downward while supporting it with your hand.
- The shelf will lower to a flush position against the Bassinet.

WARNING Do not place the infant on the Drop Leaf Work Surface. The surface has a load rating of 25 lbs.

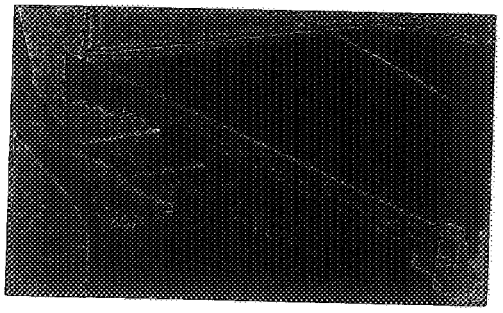


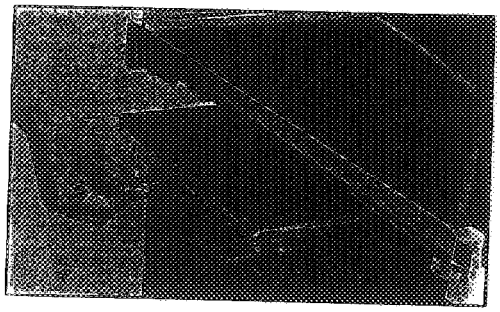
BUILT-IN X-RAY CASSETTE HOLDER

e X-Ray Cassette Holder accomodates cassettes up to 12" x 14".

oading X-Ray Cassettes

- Working from either side of the Bassinet, locate the X-Ray Cassette Tray directly beneath the Sleep Surface.
- Release the X-Ray Cassette Tray by lifting the tray up and pulling out.
- While supporting the X-Ray Cassette Tray, place the film cassette on the tray.
- Slide the cassette and X-Ray Cassette Tray in toward the Bassinet until it rests securely and flush beneath the Bassinet.
- A slight detent will be felt indicating that the tray is "locked" into place.
- The Heating Element may be pivoted 90° away from the Mattress to provide easy access over the Sleep Surface, by an X-Ray Machine.

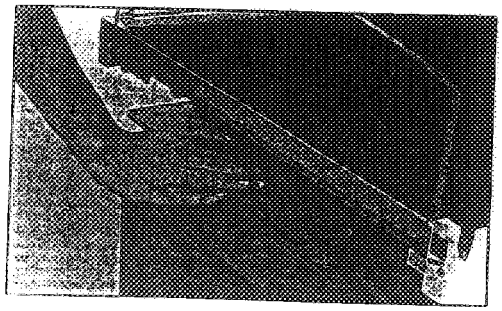




Unloading X-Ray Cassettes

- When X-Ray is complete, lift the X-Ray Cassette Tray up and pull it gently away from the Bassinet.
- Remove the X-Ray cassette and slide the tray back in toward the unit to a normal operating position.

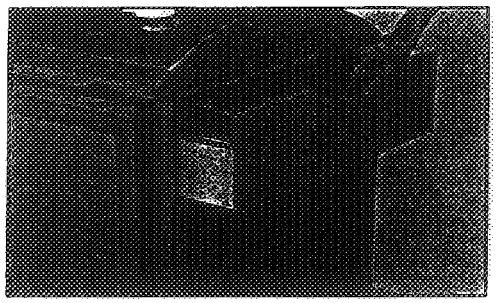
OTE The mattress is radiolucent.



Document processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

STORAGE DRAWERS

A built-in Slide-Through Storage Drawer is accessible from either side of the unit and has a removable plastic tray (compartmentalized) for small equipment and disposable items. Two additional Storage Drawers, located on the right side of the unit, slide out for easy access.



To Access

- Grasp the Drawer Handle and pull drawer out and away from unit.

To Close

- Slide the drawer in until it is flush with the Bassinet.

DOCKING MECHANISM

The Stabilet Freestanding Infant Warmer and Bassinet will dock together to create an attractive infant care station. A steering handle, located on the Warmer Column, allows easy movement of the care station.

To Dock

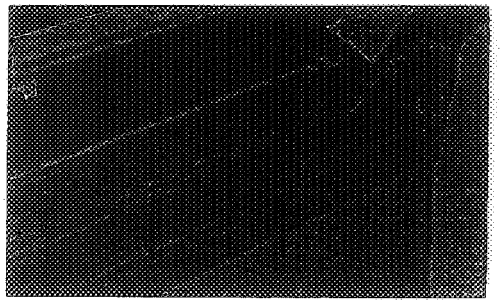
- Position the Stabilet Freestanding Infant Warmer and ensure that the two rear locking casters are in the locked position.

CAUTION After setting the brakes, gently rock the unit to check for movement of the unit.

- Align the Bassinet with the Warmer and slowly push the Bassinet toward the unit until the two units lock together, with the Chart side toward the Warmer.
- Release Infant Warmer's brakes. The Warmer and Bassinet will now move together as one unit.
- To achieve positive braking of both units, ensure that the two rear locking casters on the Infant Warmer and the two front locking casters on the Bassinet are in the locked position.

To Disengage

- Ensure that the two rear locking casters on the Infant Warmer are in the locked position.
- Release Bassinet brakes.
- Release the docking mechanism lever located on Bassinet, and hold while slowly pulling Bassinet away from Infant Warmer.
- Release Infant Warmer brakes. The Infant Warmer and Bassinet will now operate as two separate units.



CAUTION The Infant Warmer and Bassinet brakes should **ALWAYS** be set when the unit is occupied. Brakes should be periodically tested and adjusted if necessary.

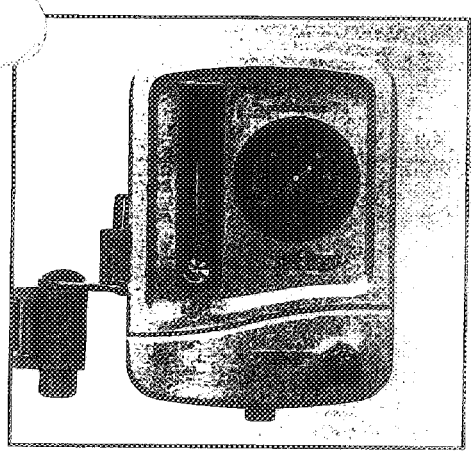
CAUTION The Thermistor Probe must be detached from the infant before separating the Infant Warmer and the Bassinet.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

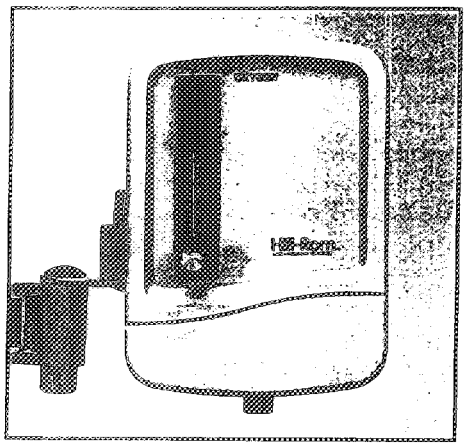
Records Processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

RESUSCITATION MODULES

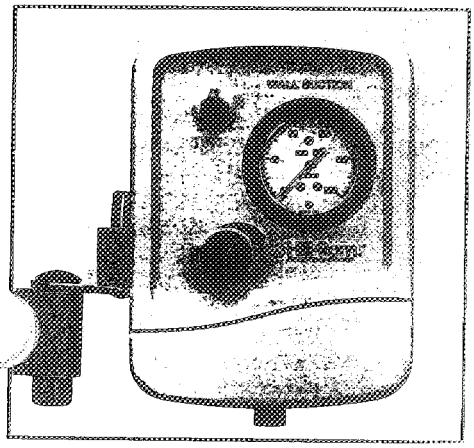
The Resuscitation Modules for the Stabilet Infant Warmer products include:



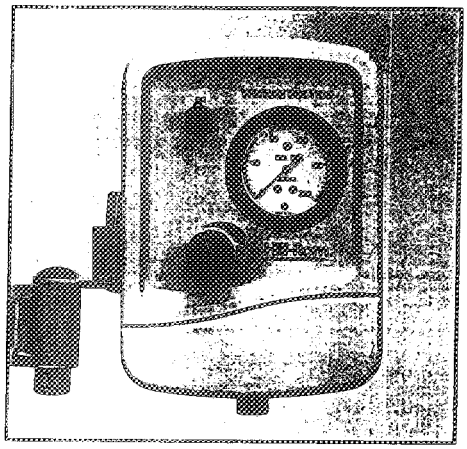
P1276 Oxygen Module (Flow and Airway Pressure)



P1278 Oxygen Module (Flow Only)



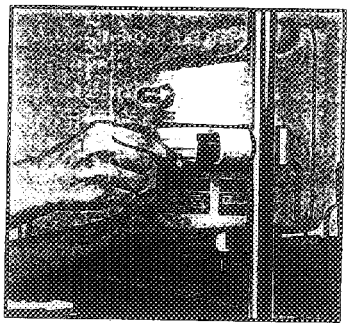
P1280 Suction Module (Wall Only)



P1281 Suction Module (Venturi Only)

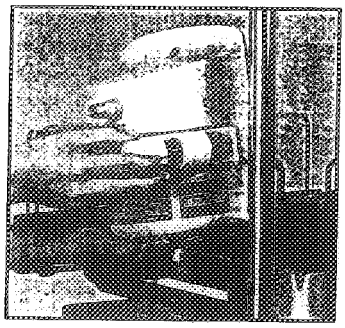
NOTE Resuscitation Modules are intended for use only on the Stabilet Infant Warmers.

To Mount The Resuscitation Modules



- Position the module on the pole at the desired height.
- Tighten the module knob by turning it counter-clockwise.
- Shake the module gently to ensure it is properly mounted.

To Remove The Resuscitation Modules



- Disconnect all tubing from the module.
- Loosen the module knob by turning it clockwise.
- Lift the module gently away from the pole.

NOTE You must have a Hill-Rom Infusion Pump Holder accessory or Post Utility Mount accessory in order to mount the Resuscitation Modules on the Stabilet Infant Warmers.

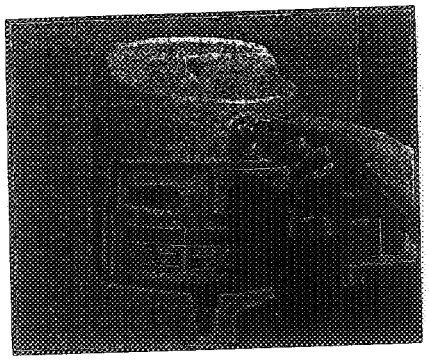
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

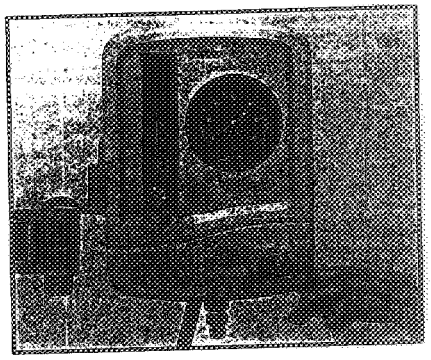
ACCESSORIES

To Use Oxygen Source (Cylinder or Wall)
Oxygen can be administered from a regulated wall source or from oxygen cylinders. Using cylinders permits the module to be used in transport situations.

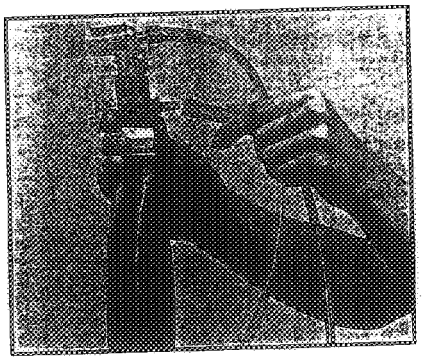
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module.



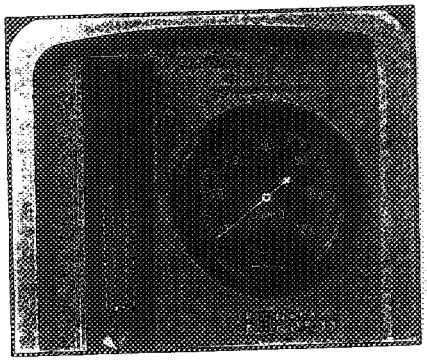
OXYGEN MODULE (FLOW AND AIRWAY PRESSURE)
To Utilize Oxygen Module (Flow and Airway Pressure)



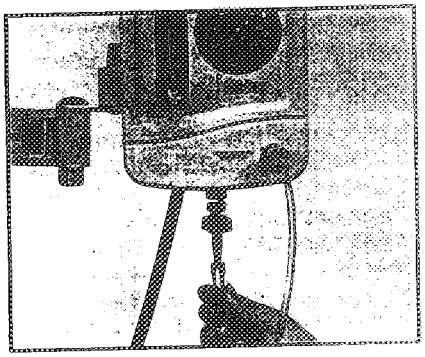
Connect one end of the Oxygen Tubing to the nipple located on the front of the oxygen module. This measures the amount of pressure being delivered during resuscitation.



Connect the opposite end of the Oxygen Tubing to the Manometer Connector located on the Resuscitation Bag and Mask.



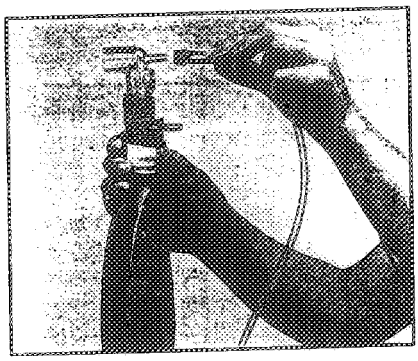
The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the front of the module. Airway Pressure is measured from 0 to 120 cm H_2O.



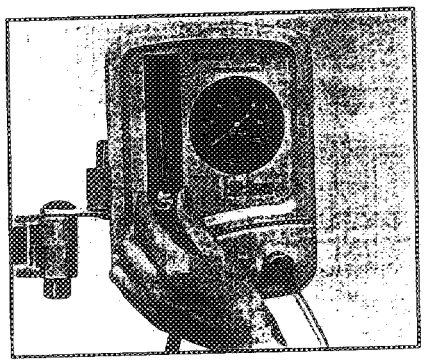
Using an appropriate adaptor, connect one end of a Second Oxygen Tubing to the DISS fitting located underneath the oxygen module.

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing

CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.

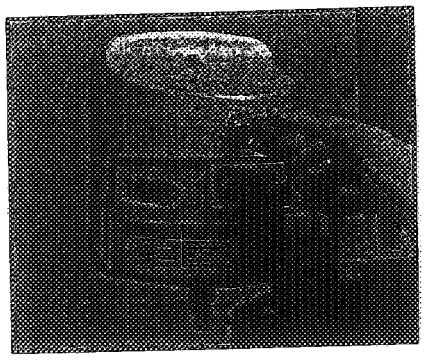


Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

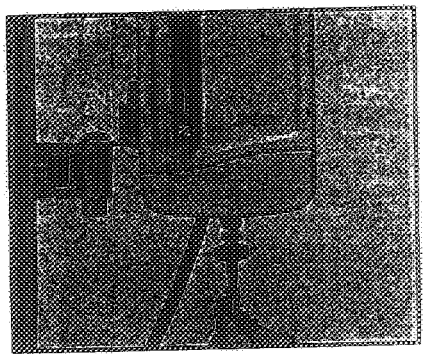
Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016



To Use Oxygen Source (Cylinder or Wall)
Oxygen can be administered from a regulated wall source or from oxygen cylinders. Using cylinders permits the module to be used in transport situations.

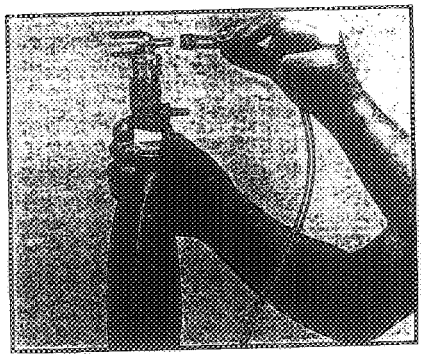
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module.

OXYGEN MODULE (FLOW ONLY)
To Utilize Oxygen Module (Flow Only)

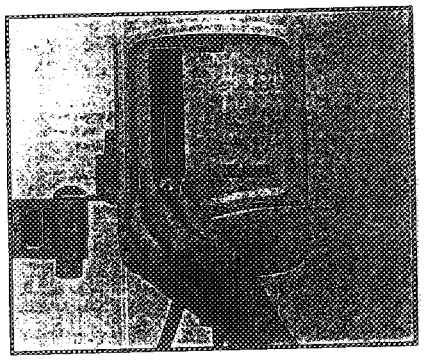


Using an appropriate adaptor, connect one end of the Oxygen Tubing to the DISS fitting located underneath the oxygen module.

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing.



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.



Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

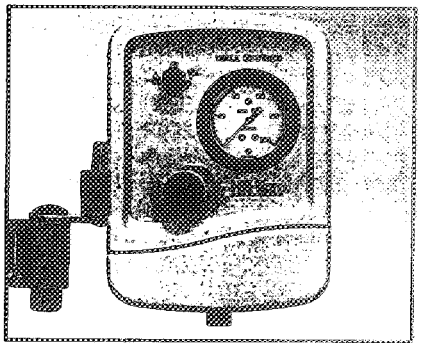
CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.

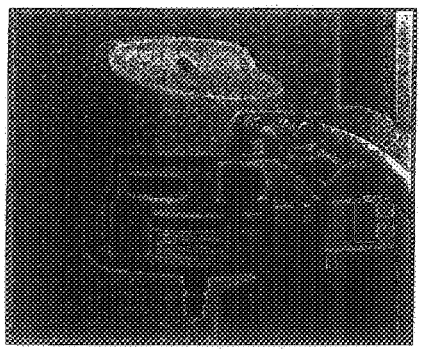
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

SUCTION MODULE (WALL ONLY)



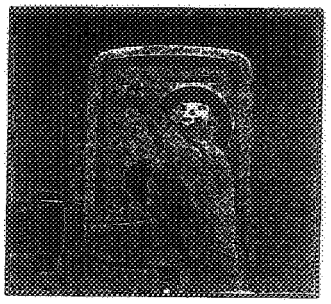
Suction is accomplished by the use of Wall Suction and is variable from 0 to 160 mm Hg.



To Use Wall Suction Source

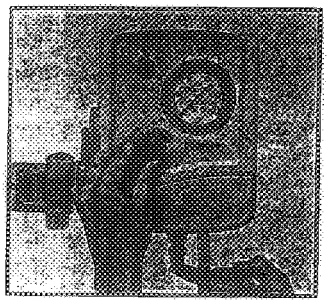
- Connect one end of vacuum hose to wall source of vacuum using a gas outlet adaptor.
- Connect second end of vacuum hose to DISS fitting located on the back of the suction module.

Set Rate

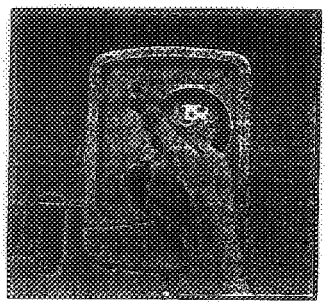


Turn the suction on with the On/Off Switch located on the front of the module.

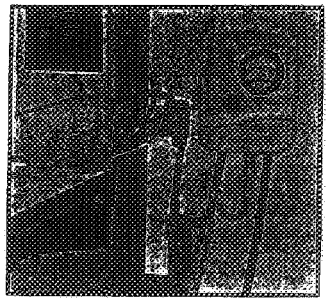
NOTE Properly occlude the Suction Port located underneath the suction module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the suction Module) to the desired setting while occluding the Suction Port.



Turn the suction off with the On/Off Switch located on the front of the module.

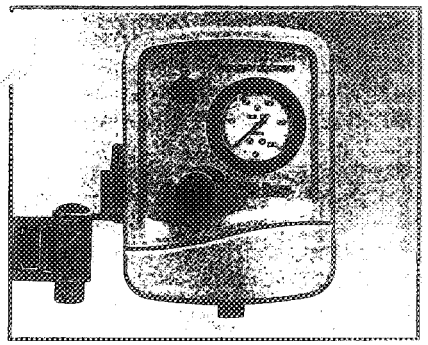


Attach Disposable Suction Canister to the Port located underneath the module.

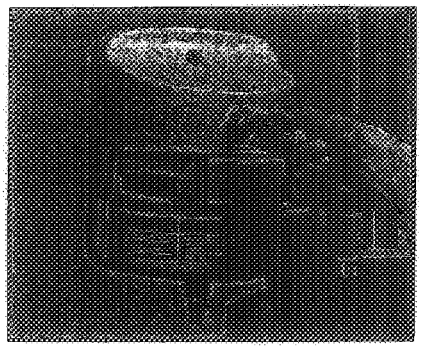
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

SUCTION MODULE (VENTURI ONLY)



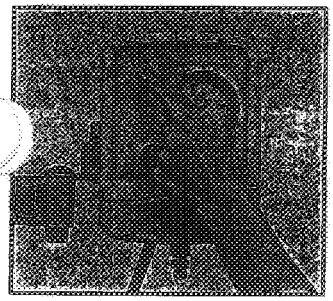
Venturi Suction is accomplished by the use of either Wall or Cylinder Oxygen and is variable from 0 to 160 mm Hg.



To Use Oxygen Source for Venturi Suction (Cylinder or Wall)

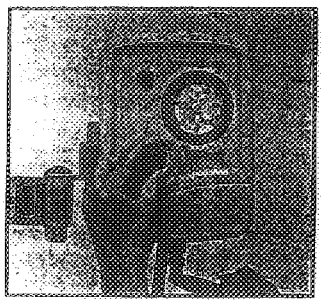
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting located on the back of the suction module.

Set Rate

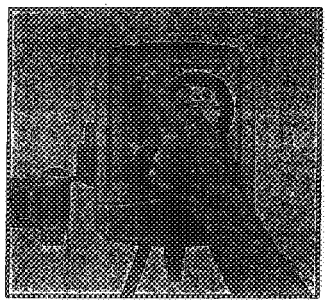


Turn the suction on with the On/Off Switch located on the front of the module.

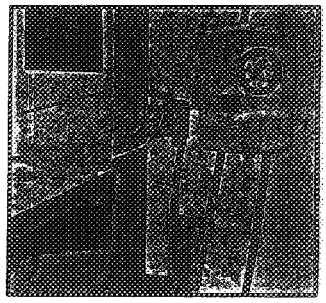
NOTE Properly occlude the Suction Port located underneath the Suction Module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the Suction Module) to the desired setting while occluding the Suction Port.



Turn the suction off with the On/Off Switch located on the front of the module.



Attach Disposable Suction Canister to the Port located underneath the module.

NOTE To increase Oxygen Cylinder life:

1) Turn the cylinder off when not in use or when utilizing Wall Source of oxygen.

2) Do not set suction level any higher than necessary to complete procedure.

3) Turn suction off when not in use.

4) Connect unit to Wall Oxygen Source when available and practical.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

This file processed under FOIA Request # 2016-5709, Released by CDRH on 08-04-2016

STERILIZATION
The Centers for Disease Control recommend EPA approved hospital disinfectants, used at manufacturers' suggested dilutions.

Cleaning should be done by wiping a soft dampened cloth over the surface, followed by wiping with a dry cloth.

Quartenary ammonium disinfectants may be used to reduce the contamination level between patients.

Alcohol, strong or abrasive cleaners and hydrocarbon solvents are not necessary and should not be used on plastic surfaces.

MATTRESS CARE
The mattress cover may be cleaned with a mild detergent, rinsed, and cold sterilized. The following products have been tested by the Herculite Laboratory and have been found not to have a harmful effect on StaphChek® fabrics WHEN USED IN ACCORDANCE WITH MANUFACTURERS' RECOMMENDED DILUTION.

TRADE NAME	TYPE	MANUFACTURER
A33	Quartenary	Airwick
Absolute	Quartenary	Walton-March
Beaucoup	Phenolic	Huntington
Blue Chip	Quartenary	S.C. Johnson
Coverage 256	Quartenary	Vestal
El Dorado Plus	Quartenary	Puritan/Churchill
Elimstaph	Quartenary	Walter G. Legge
Forward DC	Quartenary	S.C. Johnson
Franklin Sentinel	Quartenary	Purex
Galahad	Phenolic	Puritan/Churchill
Hi-Tor	Quartenary	Huntington
Insurance	Quartenary	Vestal
LPH	Phenolic	Vestal
Matar	Phenolic	Huntington
Omega	Quartenary	Airwick
Quanto	Quartenary	Huntington
Sanikleen	Quartenary	West Chemical
Sanimaster 111	Quartenary	Service Master
Surfacide	Quartenary	Walton-March
Tri-Quat	Quartenary	Vestal
Vesphene 11	Phenolic	Vestal
Virex	Quartenary	S.C. Johnson

Betadine stains may be removed from the mattress by doing the following:

- Use a 5.25% sodium hypochlorite solution (Clorox® brand bleach).
- Apply 3 drops of the solution per square inch immediately and scrub lightly. The stain should start to fade almost immediately and within 15 minutes should be totally gone.
- Stubborn stains may need further applications. No more than 3 applications on any one area are recommended.
- When completely dry, rinse area with clear water and wipe dry.
- If solution comes into contact with skin, wash off with water and follow manufacturer's label instructions.

CLEANING OF THERMISTOR PROBE
Several precautions must be observed when cleaning and sterilizing to protect Probe from damage.

Avoid contact with strong, aromatic, chlorinated, ketone ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the cable to lose flexibility.

Probe may be disinfected and sanitized by washing with 3% hydrogen peroxide, 70% isopropanol, 70% ethanol, or 100% alcohol. Dakin's solution (sodium hypochloride in neutral buffer) is also suitable. Activated dialdehyde solutions, such as Cidex, are also effective.

Probe plug should not be immersed.

STERILIZATION OF THERMISTOR PROBE
Ethylene oxide sterilization is the preferred method. After sterilization, Probes must be safely and thoroughly ventilated before handling or use.

CAUTION: Autoclaving may cause Probe insulation to fail, and may also cause the Probe to give inaccurate reading.

CLEANING OF CASTERS
The Stabilet Freestanding Infant Warmer will be used both in and outside aseptic surgical areas. Care should be taken to assure the casters do not carry contamination into the surgical suite. Removal of accumulated debris and treatment of the caster tread with a spray of disinfectant solution as the unit is transferred into the surgical suite is recommended.

CLEANING OF SIDE PANELS
The Clinical Bassinet side panels are made of clear polycarbonate plastic and can be damaged by cleaning with alcohol, abrasive agents, hydrocarbon solvents or phenolic disinfectants. Use only gentle detergents for cleaning and polish with a soft cloth to return clarity.

MAINTENANCE
The Stabilet Freestanding Infant Warmer and Resuscitation Modules need regular care and maintenance, as detailed in the Service Manual. Please request your maintenance technician to follow the preventive maintenance section in the Service Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SAFETY TIPS

Records processed under FOIA Request # 2016-5709, Released by CDRH on 08-04-2016

For over 65 years, Hill-Rom has set the standard for quality in patient room equipment. During this time, with input from many of our customers, we have acquired useful tips which may contribute to the safety of the infant and staff.

SIDE PANELS
To provide maximum protection for the infant, the side panels should always be in a full, upright position and latched when an infant is unattended. To ensure the side panels are latched, give the side panels a gentle tug.

TRANSFERRING THE STABILET FREESTANDING INFANT WARMER
Although the unit is lightweight and easy to move, be sure to keep hands and feet clear of the wheels when moving to prevent destabilization of the unit or injury to hands or feet.

BRAKES
Brakes should always be set when the Clinical Bassinet is occupied. After setting the brakes, push and pull the unit to ensure they are engaged.

X-RAY CASSETTE HOLDER
If using the X-Ray Cassette Holder accessory, always secure the holder to the unit when not in use. This will avoid possible damage to the unit and holder.

RESUSCITATION MODULES
Warmer Module should always be kept over the center of the Bassinet when Modules are attached.

PREVENTIVE MAINTENANCE
Quarterly preventive maintenance must be performed to ensure all features are functioning as originally designed. Particular attention must be addressed on safety features, including but not limited to:

- Side Panel Latching Mechanisms
- Caster Braking Systems
- Electrical Cords and Components
- **Stainless Steel Tubular Heater**
- Temperature Alarm System
- Scheduled Recalibration

Please refer to your Service Manual for specific details on preventive maintenance.

PARTS AND ACCESSORIES
Use only Hill-Rom parts and accessories. Do not modify the unit without authorization from Hill-Rom.

CAUTION
Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

DIRECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Hill-Rom®
A HILLENBRAND INDUSTRY

Batesville, IN 47006 USA • 800-638-2546
International • 812-934-8173 • FAX 812-934-7191

Manufactured for Hill-Rom under a quality system certified to **ISO 9001/EN46001** by TÜV Product Service of San Diego, CA.

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.

© Hill-Rom 1996

W6133A RC1096

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

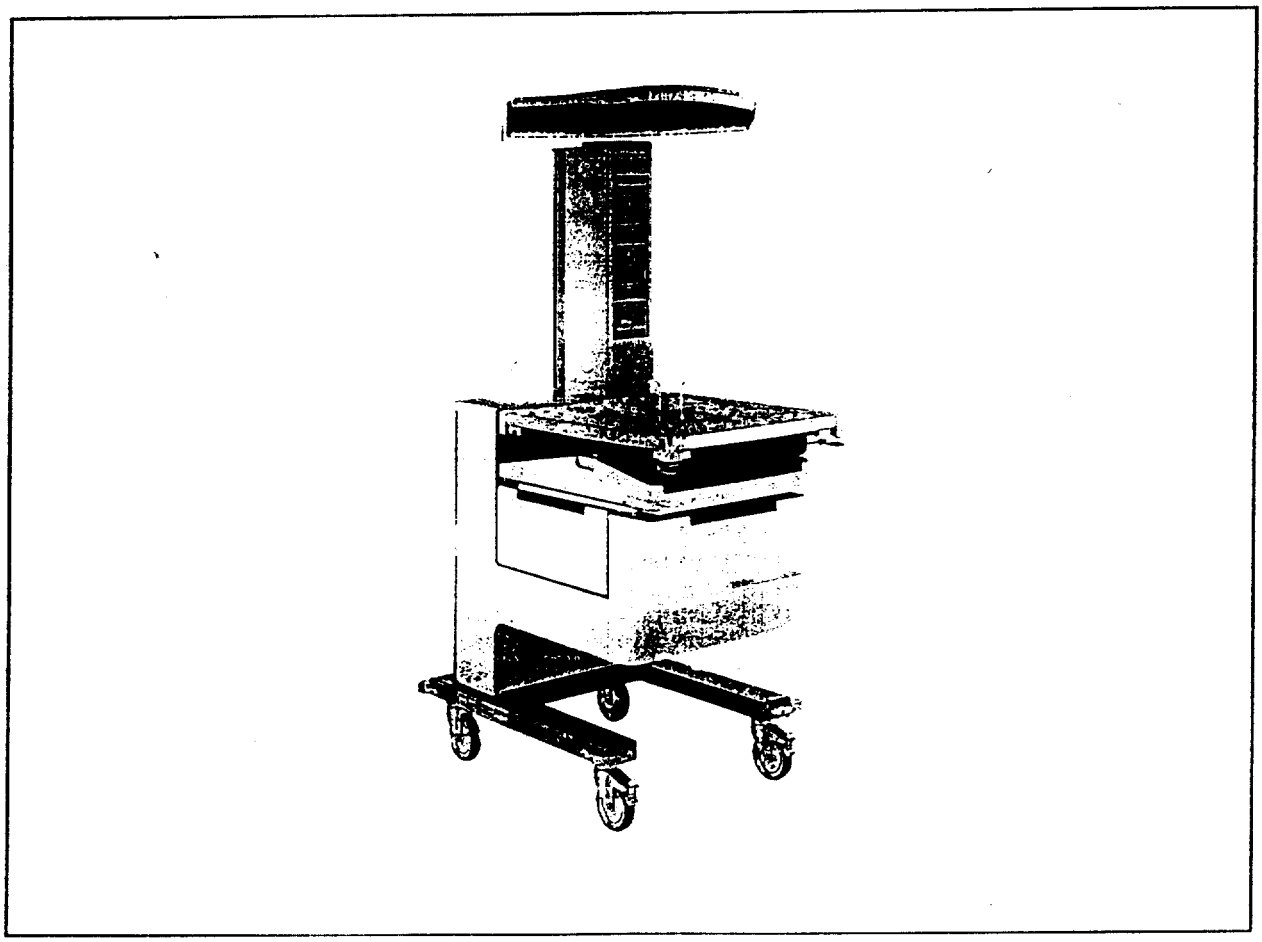
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

IN-SERVICE MANUAL

Stabilet™ CC Infant Warmer

From Hill-Rom®



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records released under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

TABLE OF CONTENTS

FEATURES 1
- IFICATIONS 1
- JRES
- Two-Position Warmer Module 2
  - Over Center Of Bassinet 2
  - X-Ray And Mother/Baby Bonding 2
- Bassinet 2
- Retractable Mayo Tray 2
- Slide-Through Storage Drawer 3
- Trendelenburg/Reverse Trendelenburg/ Level Sleep Surface 3
- Apgar/Procedure Timer 3
- Lighting Button Module 3
- Tilt-Out Front Storage Compartment 3
- Built-In X-Ray Cassette Holder/Radiolucent Mattress 4
- Accessory Tracks 4
- Tank Storage 4
- Thermal Control Center 5
  - Manual Mode 5
  - Servo Control Mode 6
- Alarm Descriptions 7
  - Overheating Alarm 7
  - Hi-Low Temperature Alarm 7
  - Over 102.2°F/39°C Alarm 7
  - Probe Fault Alarm 8
  - System Fault Alarm 8
  - Loss Of AC Power Alarm 8

OPTIONS
- **Hi-Low Height Adjustment**
- Scale 9
- Patient Weighing 10

ACCESSORIES
- Resuscitation Modules 11
  - Oxygen Module (Flow and Airway Pressure) 12
  - Oxygen Module (Flow Only) 13
  - Suction Module (Wall Only) 14
  - Suction Module (Venturi Only) 15

CLEANING 16

SAFETY TIPS 17

SPECIAL ASSISTANCE:

ill-Rom Account Manager _____ Phone _____

Perinatal Consultant _____ Phone _____

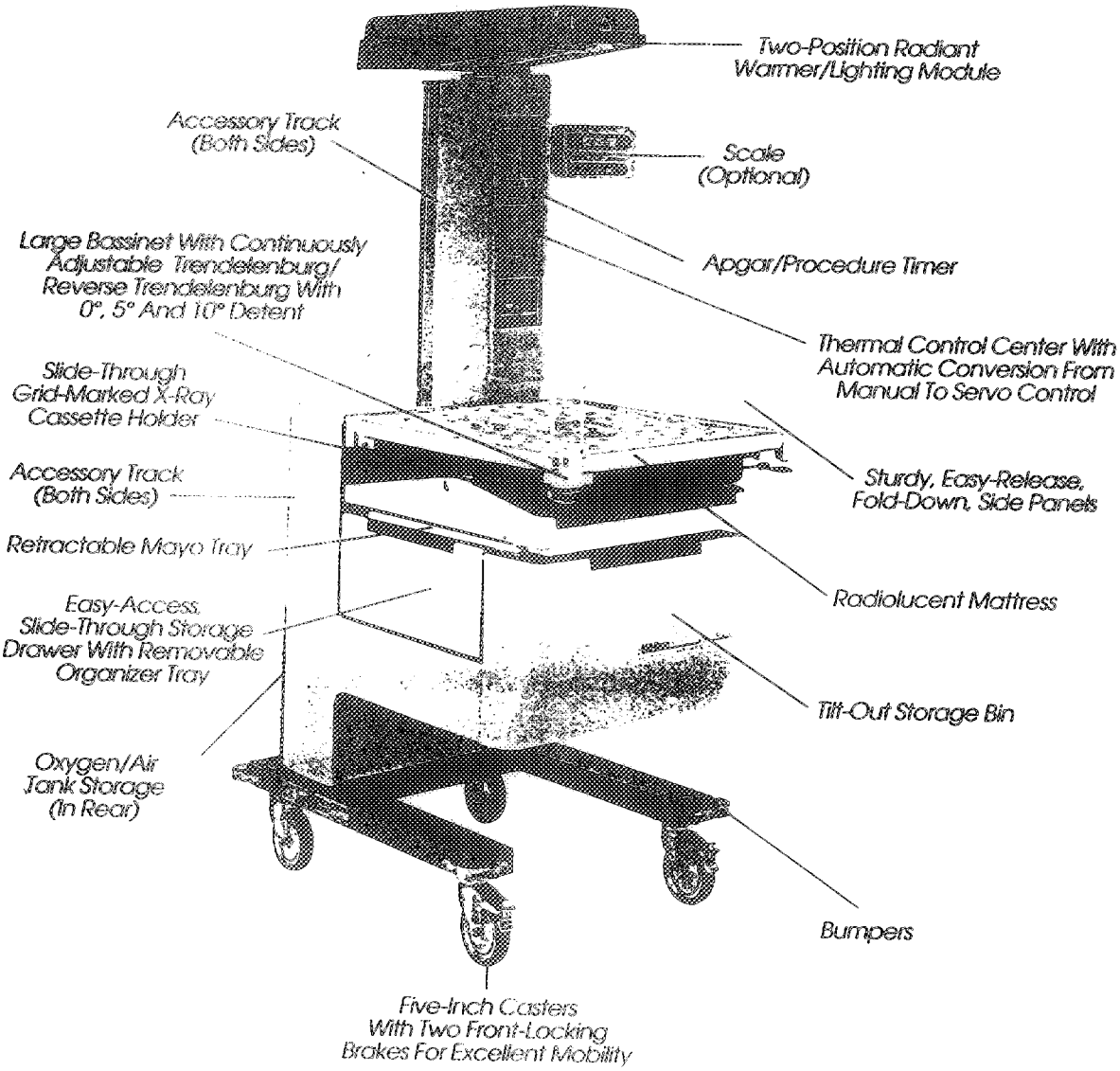
Field Service Technician _____ Phone _____

Customer Service Representative _____ Phone _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES



SPECIFICATIONS

Height – Floor to top of unit ..... 73" - 82" with Height Adjustment
Height – Floor to top of side panel ..... 42" - 51"
Side panel height ..... 5½"
Caster ..... 5"
Width – Overall ..... 27"
Width – Bassinet ..... 24"
Length – Bassinet ..... 28"
Mattress size ..... 26" x 22" x 1"
Mattress height – Floor to top of mattress ..... 37.5" - 46.5" from floor with Height Adjustment
Weight with Hi/Low Height Adjustment approx. 325 lbs.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

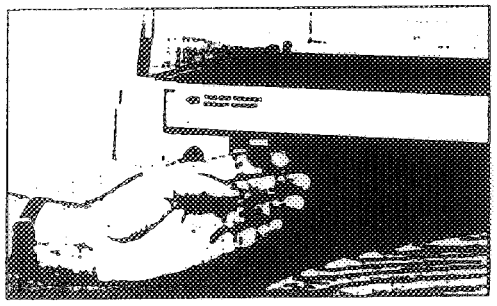
TO BE LISTED UNDER BASSINET

To Lock (So that the Side Panels cannot be accidentally lowered)

- Locate locking mechanism, positioned under each panel, and gently pull out until it stops.
- Push down gently to ensure that it is locked.

To Unlock

- Locate locking mechanism, positioned under each panel, and push in until it stops.



Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

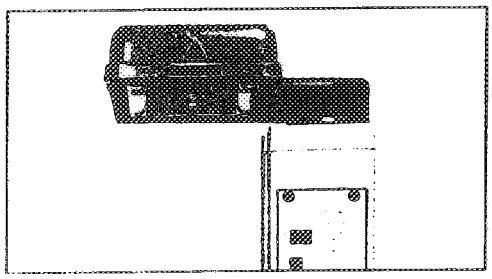
TWO-POSITION WARMER MODULE

e Radiant Warmer Module provides a controlled source of radiant heat to unit through (2) 375 Watt Stainless Steel Tubular Heaters and a smooth parabolic reflector.

Over Center Of Bassinet

- To place the heater into the standard operating position, rotate the heater 90°, placing it centrally over the Bassinet.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.

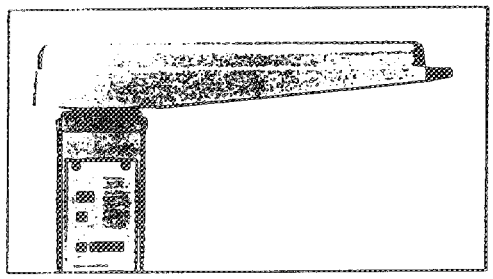
WARNING Do not place objects (equipment, blankets, clothing) on top of the Heater Housing. This could cause overheating of the unit and/or combustion of items placed on top of the warmer.



X-Ray and Mother/Baby Bonding

- Fold down front and side panels if applicable.
- Rotate the heater from the center position 90° to the right.
- For mother/baby bonding, verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.
- The heater may be rotated to allow the X-Ray machine to be properly positioned over the infant.

NOTE In this position, the warmer module will continue to deliver heat.



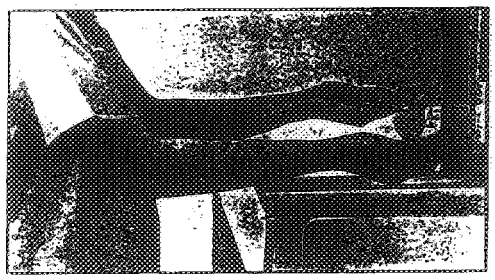
SSINET

Stabilet CC Bassinet has Fold-Down Front and Side Panels to allow greater access to the Procedure Table. An Infant Measurement Scale (in both inches and centimeters) and X-Ray Cassette Placement Grid are located on the Bassinet Panels.

To Lower

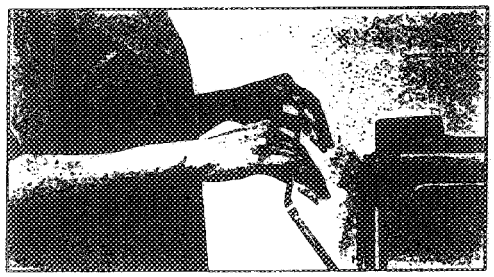
- To lower the Front or Side Panels, press down and pivot panel out and down with forearm or hands.

CAUTION Do not leave infant unattended when Front or Side Panels are lowered.



To Raise

- To raise the Front or Side Panels, grasp the panel and rotate up and towards the Bassinet.
- Move panel gently to ensure that it is secure.



RETRACTABLE MAYO TRAY

A built-in Retractable Mayo Tray can be used as an instrument shelf during procedures as well as a surface for charting. Do not overload the tray (25 lb. load weight capacity).

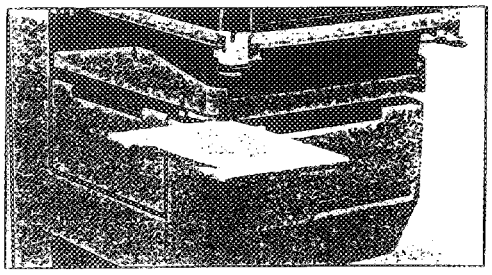
To Access

Grasp the tray and pivot out and toward the front of the unit until the tray stops.

Store

- Rotate the tray toward the left side of the unit until it is flush with the Bassinet.

WARNING Do not place the infant on the Mayo Tray.



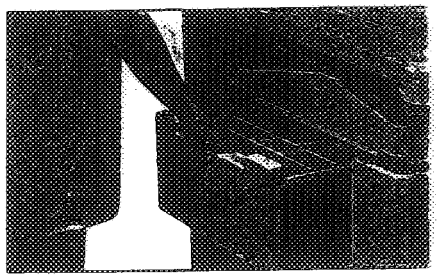
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

SLIDE-THROUGH STORAGE DRAWER

The built-in Slide-through Storage Drawer is accessible from either side of the unit and has a removable plastic tray (compartmentalized) for small equipment and disposable items.



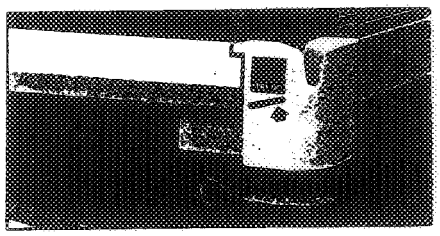
To Access

- Grasp the Cut-Out Drawer Handle and pull drawer out and away from the unit.

To Close

- Slide the drawer in until it is flush with the Bassinet.

TRENDELENBURG/REVERSE TRENDELENBURG/LEVEL SLEEP SURFACE

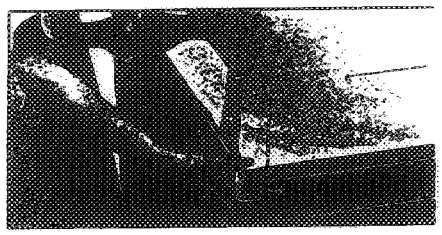


Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet and lift. The Bassinet will rotate from 0° to 10° Trendelenburg, with a 0°, 5° and 10° detent.

Reverse Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet.
- Push down on the Bassinet from the front, using the Trendelenburg Mechanism. The Bassinet will rotate from 0° to 10° Reverse Trendelenburg, with a 0°, 5° and 10° detent.

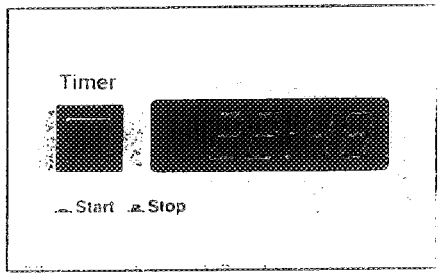


Level Sleep Surface

- Depress either of the handles located beneath the Front Panel and guide the Bassinet to a center position.

APGAR/PROCEDURE TIMER

Located on the Stabilet CC Control Panel is a one-hour electronic Apgar/Procedure Timer.

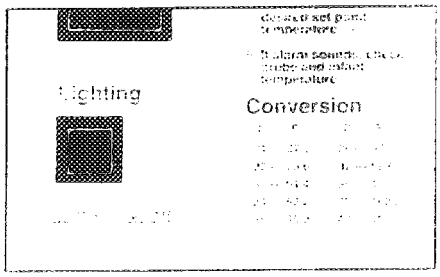


- To start the Apgar/Procedure Timer, depress the Start/Stop button located on the Control Panel.
- A visible four-digit display in minutes and seconds will appear on the Control Panel. The timer will begin at 00:00 and run to 59:59.
- A one-second audible tone will sound at one, five, and ten minutes.
- Depress the Start/Stop Button again to reset the timer.

NOTE Power switch must be ON to operate timer and Overhead Light.

LIGHTING BUTTON MODULE

A Lighting Button located on the Stabilet CC Control Panel actuates **one 35 Watt Halogen Light.** The Main Power Button must be ON in order to activate lighting.



To Activate Lighting

- Depress the Lighting Button, located on the Control Panel.

To Turn Lighting Off

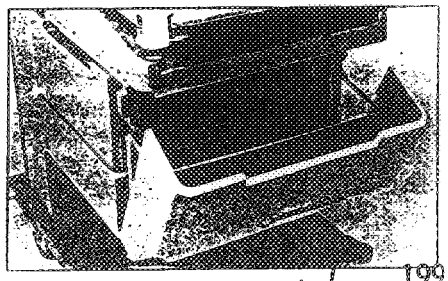
- Depress the Lighting Button again.

NOTE To extend bulb life, turn the ~~examination~~ TASK light on only as required.

NOTE Power switch must be ON to operate timer and Overhead Light.

TILT-OUT STORAGE COMPARTMENT

The Storage Compartment, located at the front of the unit, tilts out for easy access.



To Access

- Grasp Cut-Out Door handle at the front of the unit and pull the door gently toward you.

To Close

- Push the compartment door gently toward the unit. The Magnetic Catch will hold the door in place.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

06

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

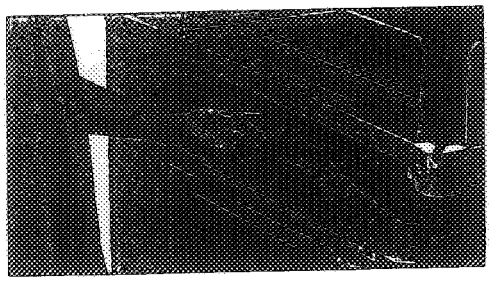
FEATURES

BUILT-IN X-RAY CASSETTE HOLDER

X-Ray Cassette Holder accommodates cassettes up to 12" x 14".

Loading X-Ray Cassettes

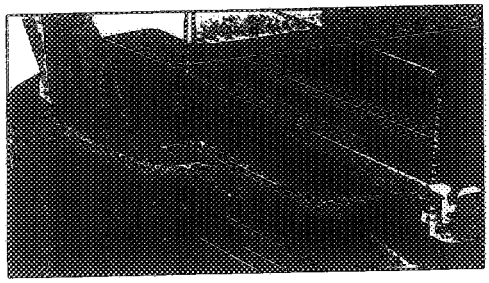
- Working from either side of the Bassinet, locate the X-Ray Cassette Tray directly beneath the Sleep Surface.
- Release the X-Ray Cassette Tray by lifting the tray up and pulling out.
- While supporting the X-Ray Cassette Tray, place the film cassette on the tray.



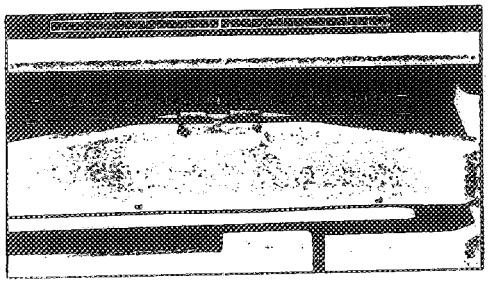
Unloading X-Ray Cassettes

- When x-ray is complete, lift the X-Ray Cassette Tray up and pull it gently away from the Bassinet.
- Remove the x-ray cassette and slide the tray back in toward the unit to a normal operating position.

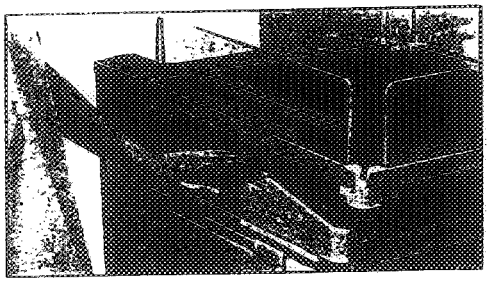
NOTE The mattress is radiolucent.



- To ensure proper cassette placement, align the X-Ray Cassette Tray Grid Markings with the markings located on the Bassinet Front and Side Panels. These grid markings allow you to position the cassette accurately relative to the infant's position in the Bassinet.



- Slide the x-ray cassette and X-Ray Cassette Tray in toward the Bassinet until it rests securely and flush beneath the Bassinet.
- A slight detent will be felt indicating that the tray is "locked" into place.
- The Heating Element may be pivoted 90° away from the Mattress to provide easy access over the Sleep Surface, by an X-Ray Machine.

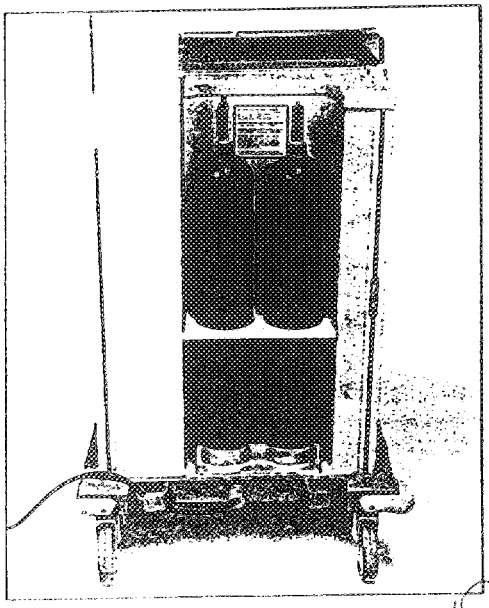


ACCESSORY TRACKS

Accessory tracks allow convenient placement of numerous accessories at comfortable working heights. The accessory tracks improve access to equipment and save valuable floor space.

TANK STORAGE

Two built-in Oxygen Tank Holders tuck out of the way in the rear of the unit.



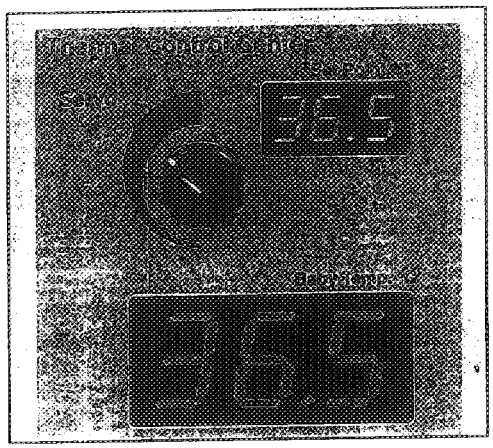
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

THERMAL CONTROL CENTER

Thermoregulation Controls are centrally located on the Control Panel between the Warmer Module and the Bassinet. Temperature may be set using the set point digital display once a Thermistor Probe has been inserted and senses a temperature of 31°C or greater.



Manual Mode

Manual Mode is intended primarily for warming the Bassinet and blankets in preparation for an infant or when it is impractical to attach a Thermistor Probe to the infant.

NOTE Before placing the infant in the Bassinet, pre-heat the Thermistor Probe, face up, in the Bassinet, prior to connecting the Probe into the Jack.

NOTE To avoid overheating or underheating of the infant, a Probe should be attached to the infant at all times while in a Radiant Warmer and the infant should not be left unattended.

- Plug the power cord into a standard 115V AC receptacle.

CAUTION Connect the power cord to a properly grounded receptacle that is approved for hospital use. Do not use an extension cord or AC receptacle box.

DANGER Possible explosion hazard if used in the presence of flammable anesthetics. This unit is not intended for use in hazardous Class 1, Group C locations.

- Turn the power on by depressing the Power Button located on the upright Control Panel.

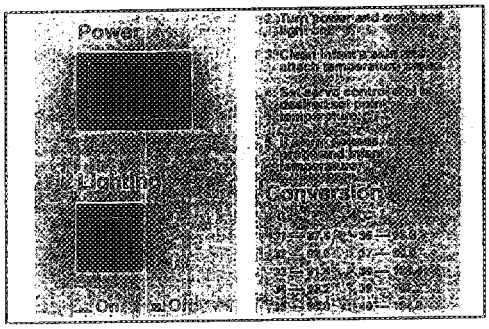
CAUTION The use of radiant warmers may cause insensible water loss.

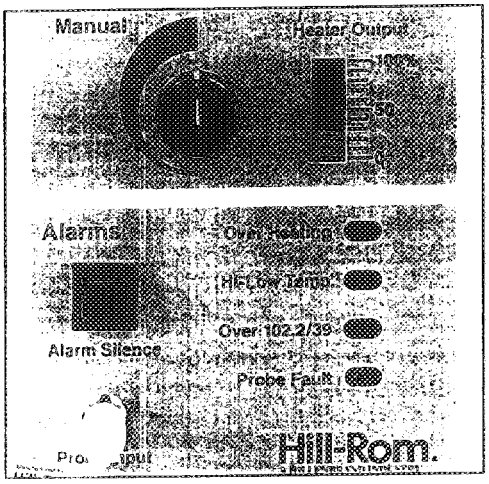
NOTE The unit will function in the Manual Mode without a Thermistor Probe inserted in the jack. The Probe Fault LED Display will remain lit during this time.

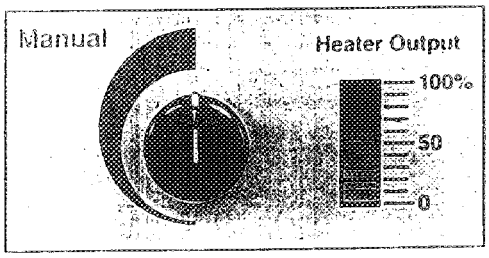
NOTE Skin temperature alarms are NOT functional during Manual Mode when the Thermistor Probe is not inserted in the Probe Jack or when the Probe is inserted in the Probe Jack but senses a temperature less than approximately 31° C (88° F).

- Set the desired heater output using the Heater Output Control Dial located on the Thermal Control Center.
- Heater output is shown on the unit in terms of percentage of power and can be from 0% to 100%.
- The unit will remain at the set heater output you choose until you manually readjust it unless the Overheating Alarm is activated (see Overheating Alarm description).

NOTE In Manual Mode, when no heater output lights appear, it is an indication that heater output is 0%.
Green LEDs indicate approximately 10%–30% heater output.
Yellow LEDs indicate approximately 40%–70% heater output.
Red LEDs indicate approximately 80%–100% heater output.

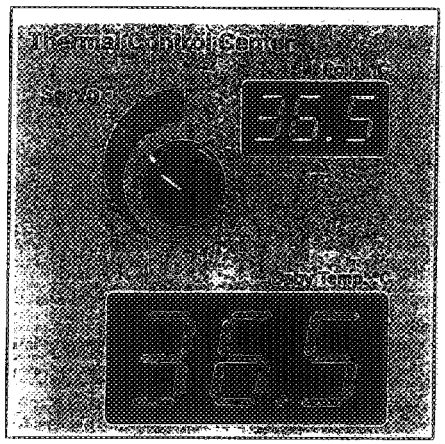






Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Servo Control Mode

When the Thermistor Probe is inserted into the Probe Jack and senses a temperature of approximately 31°C (88°F), the unit automatically converts to the Servo Control Mode.

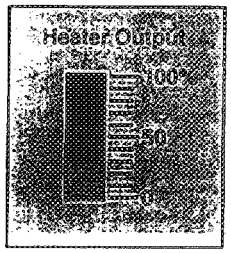
The Servo Control Mode allows the LED Heater Output Grid to indicate the amount of energy delivered to the warmer to keep the infant's skin temperature at the predetermined set point temperature.

Heater output is shown on the unit in terms of approximate percentage of power and ranges from 0% to 100%.

As the infant's skin temperature approaches the set point, the heater output will modulate to maintain the infant's skin temperature at the set point temperature.

Once the infant's skin temperature and the set point temperature are equal, only gradual changes in the heater output are needed to maintain the desired infant skin temperature.

A temperature readout displays the infant's skin temperature when the unit is in Servo Control Mode.



- Set the Infant desired target temperature using the Servo Temperature Control Dial and the setpoint digital display. Turn the dial until the selected setting is indicated on the setpoint digital display.
- Attach the Thermistor Probe to the infant. The Probe should be pre-heated before registering the baby's skin temperature.

NOTE Placement of the Probe is vital because it is the Probe that senses the baby's skin temperature and regulates warmer output.

SUPINE INFANTS...place the flat stainless steel side of the Probe down on the infant's abdomen below the rib cage.

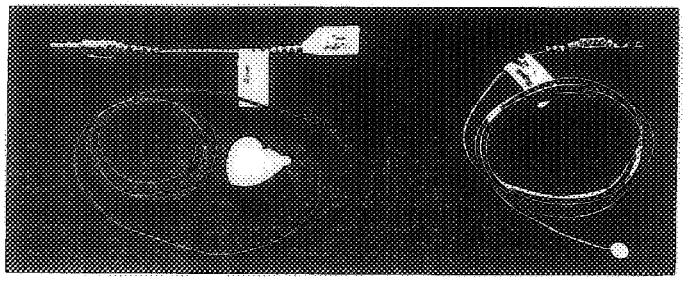
PRONE INFANTS...place the flat stainless steel side down on the infant's back below the rib cage, but away from the kidneys.

CAUTION Always attach the Probe with a reflective Probe cover. Serious temperature and control errors can occur if anything other than the recommended Probes and Probe covers are used. Do not use tape to attach the Probe.

CAUTION Inspect the infant's skin for reddened areas which may result from the heating of materials in contact with the skin.

CAUTION Avoid placement of objects (equipment, blankets, clothing) in the Bassinet that can block heat or absorb heat away from the infant.

NOTE Only the following Thermistor Probes should be used with the Stabilet CC Infant Warmer:



SA4567 Disposable Probe (Requires Reusable Adapter Cable SA4566)

BCZ009 Reusable Probe

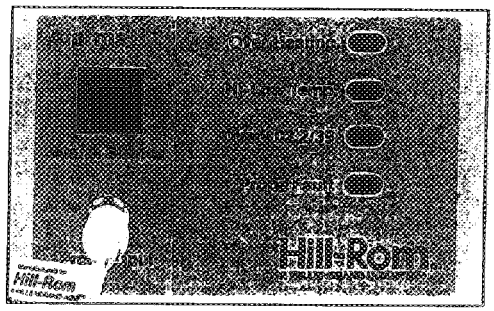
CAUTION Do not place the Warmer in areas near or beneath air conditioning or heating ducts. Drafts or forced air may cause a disruption in the heat distribution.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ALARM DESCRIPTIONS

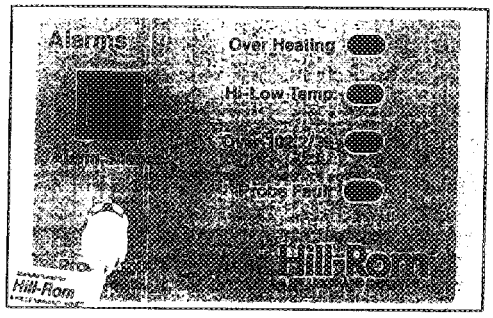
Overheating Alarm (Manual Mode Only)



- An Overheating Alarm will sound if there is constant heater output of 100% for approximately 15 minutes or approximately 25% (2 or 3 LEDS) for 73 minutes or any combination thereof of power and time.
- When the Overheating Alarm is triggered, power to the heater is reduced to approximately 30%.
- The Overheating Alarm can be silenced by depressing the Alarm Silence Button located on the left side of the Control Panel.
- The unit will continue to operate in Manual Mode and no Overheating Alarm will sound as long as the heater output is kept under approximately 30% (1 or 2 LEDS) and a Thermistor Probe is not inserted into the Probe Jack or is inserted but does not sense a temperature of over approximately 31°C.
- Once the Probe is inserted in the Probe Jack and the Probe senses a temperature of approximately 31°C, the Stabilet CC becomes a Servo-Controlled Unit, controlled by the skin temperature of the infant.

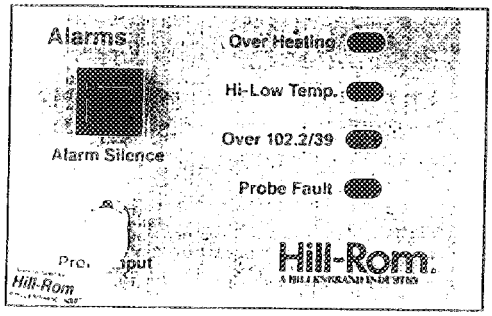
WARNING Do not leave the infant unattended.

Hi-Low Temperature Alarm (Servo Mode Only)



- If the Infant's temperature has fluctuated more than ± .5°C from the set point temperature, a solid, visible Hi-Low Temperature LED Display will appear immediately on the Stabilet CC Control Panel.
- If after four minutes the high-Low temperature has not been rectified, an audible Hi-Low Temperature alarm will sound.
- During the audible alarm condition, heater output will change to approximately 30% until the infant's skin temperature returns within the target range or until the alarm is silenced.
- The Hi-Low Temperature alarm can be silenced by depressing the Alarm Silence Button; however, the Hi-Low Temperature LED Display will remain lit until the infant's temperature returns to within the target range. If the infant's temperature remains outside of the ± .5°C setpoint for another 4 minutes the audible alarm will again sound.
- When the Hi-Low Temperature condition is rectified, the Hi-Low Temperature Alarm will automatically reset.

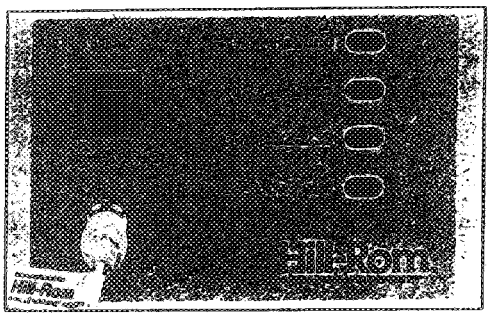
Over 102.2°F/39°C Alarm



- An audible and visible Over 102.2°F/39°C Alarm will activate immediately if the Thermistor Probe senses a temperature that exceeds 102.2°F/39°C.
- Heater output is reduced to 0% and will not resume until the Thermistor Probe senses that the infant's temperature has fallen below 102.2°F/39°C.
- The alarm will not silence until the condition is rectified.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

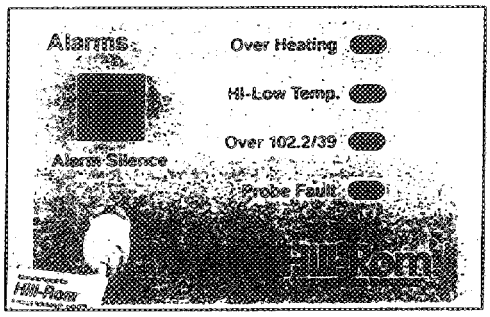
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Probe Fault Alarm

- In the Manual Mode when the Probe is not inserted in the Probe Input Jack, the Probe Fault LED will remain lit.
- In the Servo Mode, whenever the Probe senses a temperature of less than approximately 31°C for approximately one minute, the Probe Fault LED will come ON, an audible alarm will occur, and heater output will drop to approximately 30%.
- When the alarm is silenced by depressing the Alarm Silence Button:
  If sensed temperature is still below 31°C, the Probe Fault LED will remain lit and the unit will revert to Manual Mode.

  If the sensed temperature is above 31°C, the Probe Fault LED will go off and the unit will revert to Servo Mode.



System Fault Alarm

- A System Fault has occurred when an audible alarm sounds and all alarm LED displays illuminate.
- The system continually monitors itself electronically to ensure complete thermoregulation integrity. If, at any time, the Heater Control Signal and the actual Heater Current Signal do not agree, AC power/heater output is immediately terminated, and a System Fault Alarm is activated.
- The System Fault Alarm may also be activated by connecting an incompatible temperature Probe, or when the Probe is shorted or when there is an open heater element.
- The alarm cannot be silenced until the condition is rectified.
- The alarm may indicate a system failure and require maintenance by a qualified technician.

Loss Of AC Power Alarm

- If the unit becomes unplugged or AC power is interrupted to the unit when the Power Switch is "on", a pulsating alarm will sound. This Loss Of AC Power Alarm will fade after approximately 3 minutes, or will automatically reset if power is restored to the unit.
- The Loss Of AC Power Alarm works off a capacitor that will recharge when AC power is restored to the unit and the Power Switch is turned on.
- No batteries are required for the operation of this alarm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

OPTIONS

HI/LOW HEIGHT ADJUSTMENT

With a simple touch of the foot pedal, the mattress on the Stabilet 2000 and Stabilet CC may be adjusted anywhere between 37.5 and 46.5 inches from the floor to provide a comfortable work height for any caregiver.

Foot Pedals may be accessed from either side of the infant warmer.

Raise Bed

Depress and hold right foot pedal until desired height is achieved.

Lower Bed

Depress and hold left foot pedal until desired height is achieved.

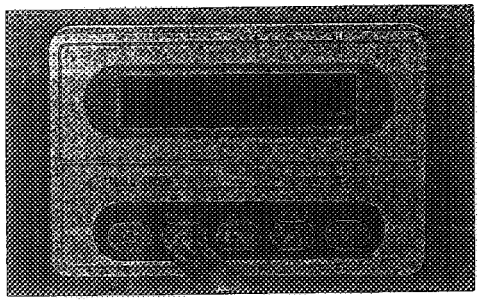
Warning: Check space above and below the warmer so that repositioning the unit will not be obstructed.

Warning: Do not transport warmer with the bed in the high position. Lower the bed surface before transport.

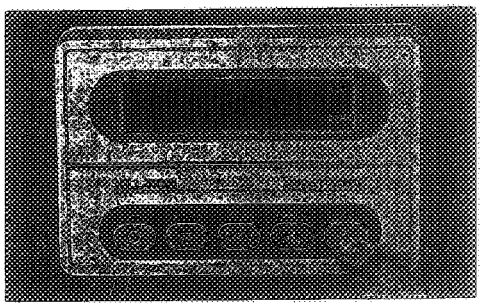
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

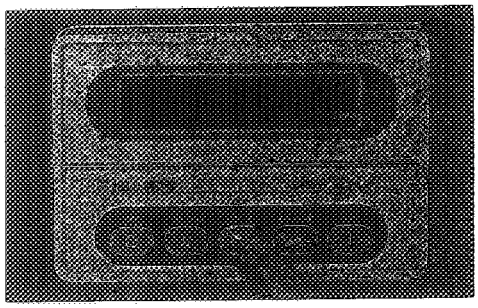
SCALE
The weighing capacity is approximately 17.6 lbs./8 kgs. The scale has five buttons and a display area. A caption appears above each button describing its function. Each control button is color-coded and graphically represented.



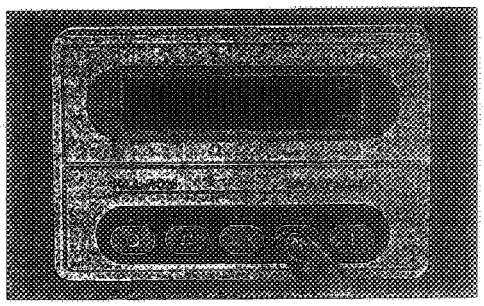
The LBS/KGS button is used to switch to lbs. or kgs.



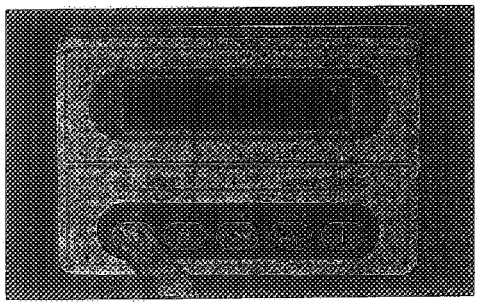
The ON button turns the unit on.



The ZERO button resets the scale to 0.000 prior to placing an infant on the scale.



The AVERAGE button compensates for an active infant, vibration or excessive air currents.



The OFF button turns the unit off.

Before Operating The Scale
For the most accuracy, follow these procedures:

Scale Setup
Prior to operating the Stabilet Scale, refer to the service manual for complete instructions on scale setup.

Sleep Surface Preparation
Before placing the infant on the sleep surface, it must be prepared. This includes placing articles on the surface such as linens, skin temperature probes, etc. that the infant will require. It can be helpful to place a list of these items near the warmer for future reference.

NOTE It is important to develop a protocol to determine what items belong on the Bassinet at the time of weighing.

Weight Interferences
Before operating the scale, be aware of the following:

- The entire surface of the Bassinet is weighed. It is also important that no one touch the Bassinet while the scale is operating. For example, leaning on the front or side panels can cause incorrect readings.
- The most accurate weight reading will be achieved if nothing is touching the Bassinet. This includes patient lines, temperature probes, ventilators, ECMO equipment, drainage bags and anything that could impact the weight and cause an incorrect weight to appear in the display.

Continuous Display
The infant's weight reading will appear continuously on the display until the OFF button is activated. Turning the unit off will not erase any weight readings but only deactivate the scale for a period of time.

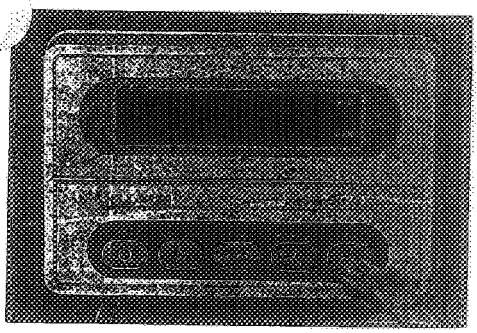
B

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

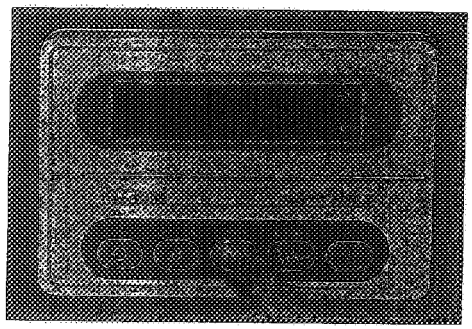
PATIENT WEIGHING

Step One – Turning the Scale On



- Connect the scale's power cord to a 120V electrical outlet.
- To turn the scale on, press and release the ON button on the front panel.
- When first turned on, all display indicators will light briefly, and then clear.

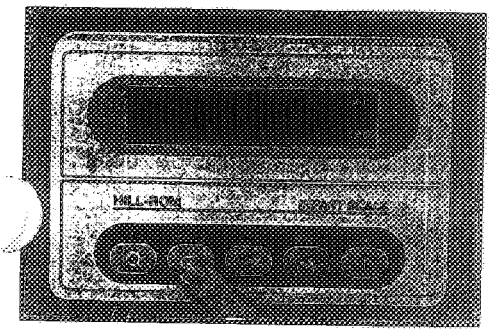
Step Two – Zeroing the Scale



Before placing the infant on the sleep surface, the bed weight must be zeroed.

- Press ZERO to obtain a zero reading on the display prior to weighing the patient for the first time.
- The scale will read 0.000 lbs./kgs.

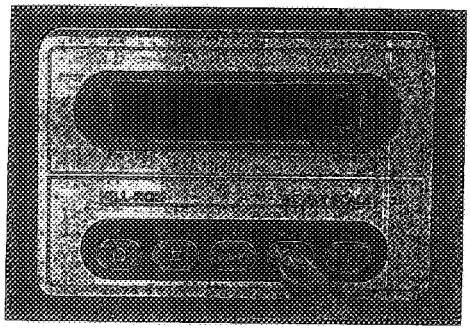
Step Three – Weighing the Patient



For the most accurate weight readings, the infant should be centered on the bed and lying still.

- Place the infant in the Bassinet.
- The patient weight will appear in the display. For lbs. to kgs., press the LBS/KGS button during weight display.

Step Four – Averaging Level



The AVERAGE button allows you to obtain an average weight when an active infant, excessive vibration and/or air currents cause the weight reading to fluctuate.

- Press and release the AVERAGE button. The display will begin a countdown – 02, 01, then a weight reading. This takes approximately four seconds. The scale will display an infant weight based on a statistical average. Do not press any other keys while the scale is in the averaging level mode.
- This statistical average weight will display for approximately 3½ minutes.
- The unit will then return to the original weighing mode.

NOTE This feature does not affect the accuracy of the unit.

LOW BATTERY INDICATOR

When the scale's battery power becomes low, the word "LO BAT" will appear in the scale's display. To recharge the battery, plug the unit into an outlet. The battery is charged when the "LO BAT" display disappears.

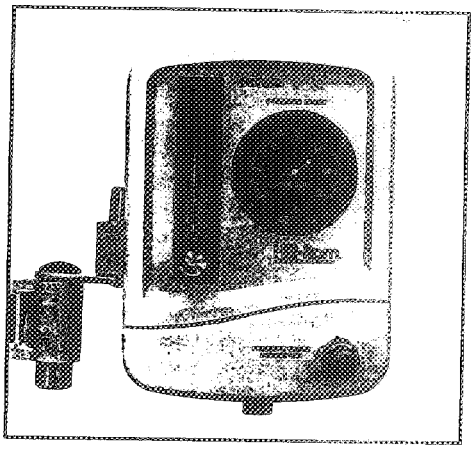
NOTE The Infant Scale receives backup power from six AA batteries contained in the scale indicator when the power cord is unplugged from the wall receptacle.

CAUTION The Infant Scale calibration information is not retained in the scale indicator memory in the event that total electrical power is lost. To prevent calibration information loss, ensure that the scale indicator batteries are adequately charged before unplugging the power cord from the wall receptacle. If the scale indicator displays "LO BAT" message, allow sufficient time for the batteries to recharge before unplugging the power cord from the wall receptacle. If the batteries do not accept charge, replace the batteries and recalibrate the Infant Scale.

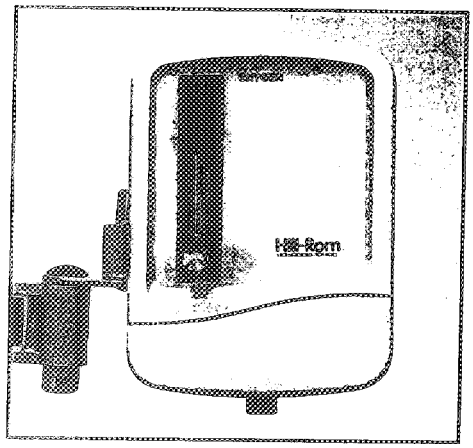
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

RESUSCITATION MODULES

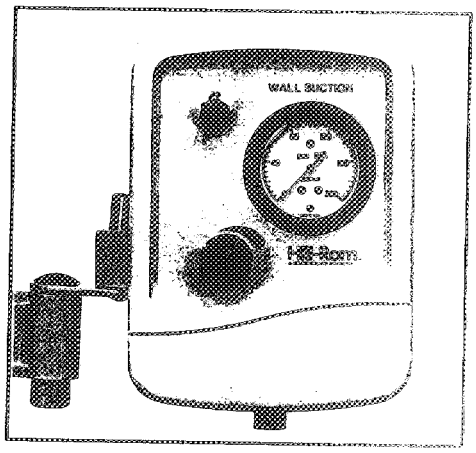
The Resuscitation Modules for the Stabilet Infant Warmer products include:



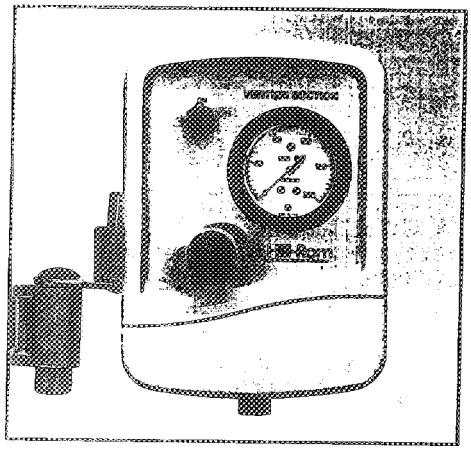
P1276 Oxygen Module (Flow and Airway Pressure)



P1278 Oxygen Module (Flow Only)



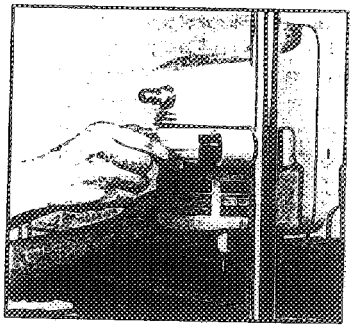
P1280 Suction Module (Wall Only)



P1281 Suction Module (Venturi Only)

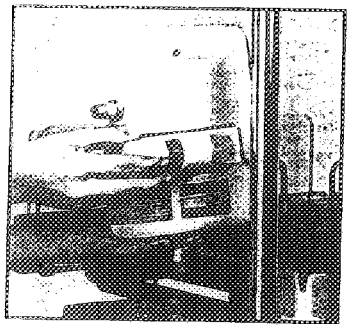
NOTE Resuscitation Modules are intended for use only on the Stabilet Infant Warmers.

To Mount The Resuscitation Modules



- Position the module on the pole at the desired height.
- Tighten the module knob by turning it counter-clockwise.
- Shake the module gently to ensure it is properly mounted.

To Remove The Resuscitation Modules



- Disconnect all tubing from the module.
- Loosen the module knob by turning it clockwise.
- Lift the module gently away from the pole.

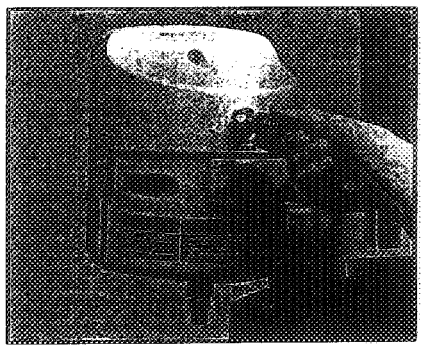
NOTE You must have a Hill-Rom Infusion Pump Holder accessory or Post Utility Mount accessory in order to mount the Resuscitation Modules on the Stabilet Infant Warmers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

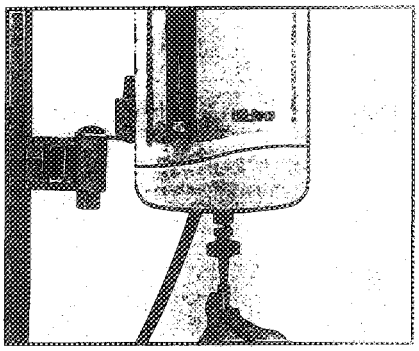
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

To Use Oxygen Source (Cylinder or Wall)
Oxygen can be administered from a regulated wall source or from oxygen cylinders. Using cylinders permits the module to be used in transport situations.

- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module.

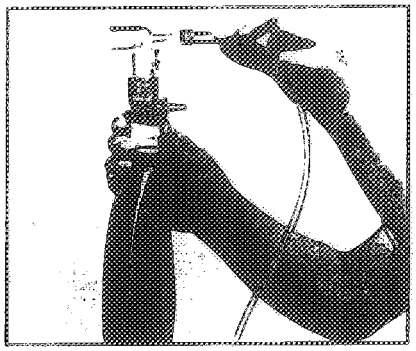


OXYGEN MODULE (FLOW ONLY)
To Utilize Oxygen Module (Flow Only)

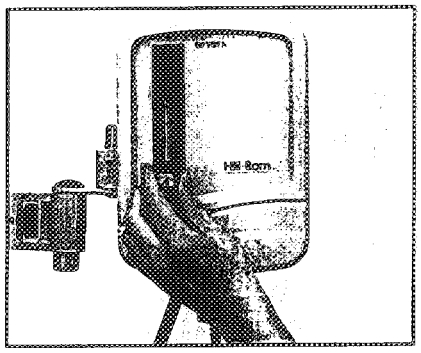


Using an appropriate adaptor, connect one end of the Oxygen Tubing to the DISS fitting located underneath the oxygen module

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing.



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.



Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.

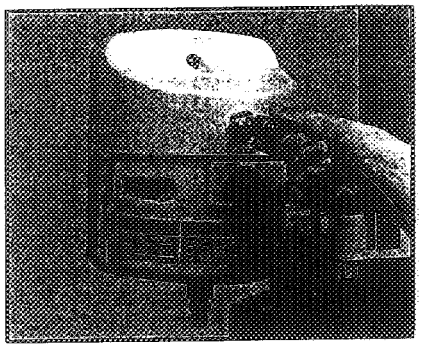
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

16

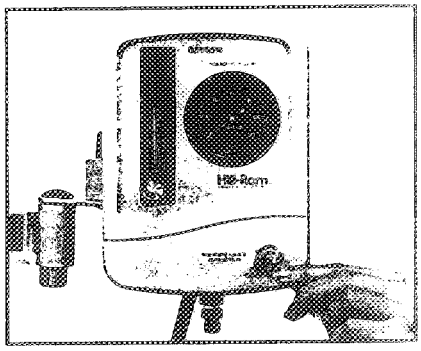
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

To Use Oxygen Source (Cylinder or Wall)
Oxygen can be administered from a regulated wall source or from oxygen cylinders. Using cylinders permits the module to be used in transport situations.

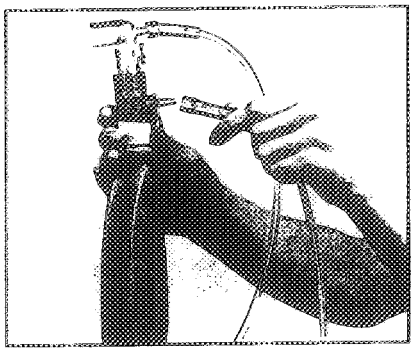
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module.



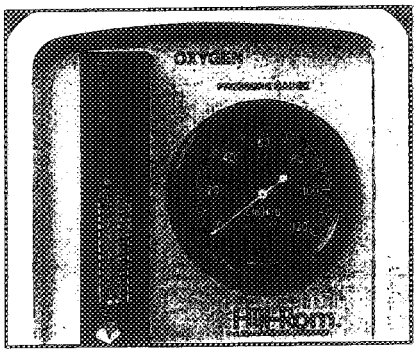
OXYGEN MODULE (FLOW AND AIRWAY PRESSURE)
To Utilize Oxygen Module (Flow and Airway Pressure)



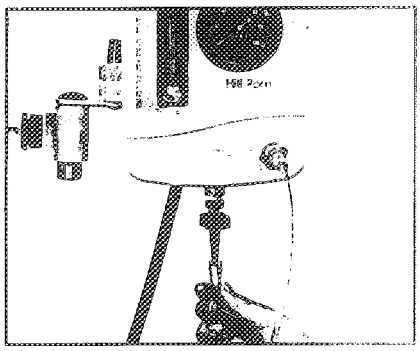
Connect one end of the Oxygen Tubing to the nipple located on the front of the oxygen module. This measures the amount of pressure being delivered during resuscitation.



Connect the opposite end of the Oxygen Tubing to the Manometer Connector located on the Resuscitation Bag and Mask

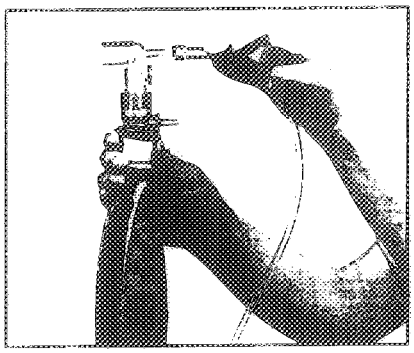


The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the front of the module. Airway Pressure is measured from 0 to 120 cm H_2O.

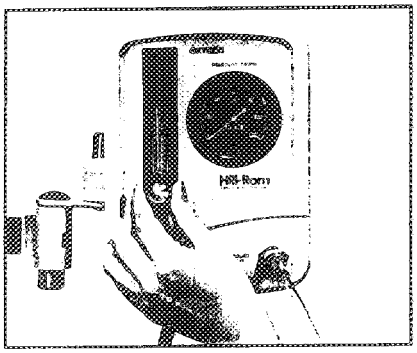


Using an appropriate adaptor, connect one end of a Second Oxygen Tubing to the DISS fitting located underneath the oxygen module.

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing.



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask



Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

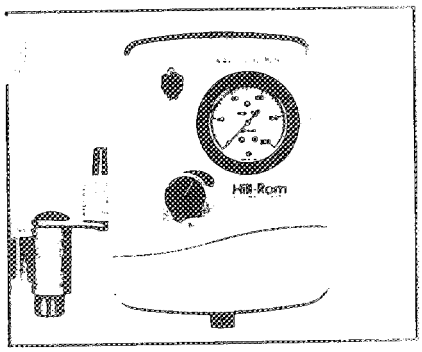
CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

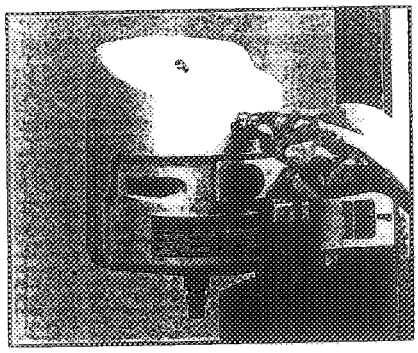
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ACCESSORIES

SUCTION MODULE (WALL ONLY)



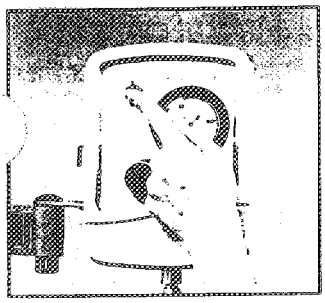
Suction is accomplished by the use of Wall Suction and is variable from 0 to 160 mm Hg.



To Use Wall Suction Source

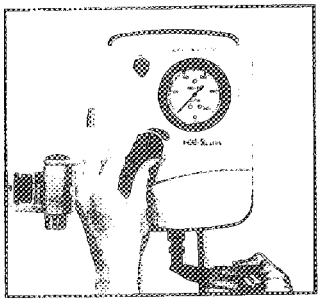
- Connect one end of vacuum hose to wall source of vacuum using a gas outlet adaptor.
- Connect second end of vacuum hose to DISS fitting located on the back of the suction module.

Set Rate

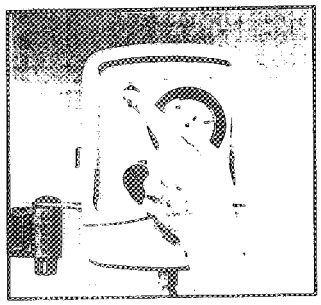


Turn the suction on with the On/Off Switch located on the front of the module.

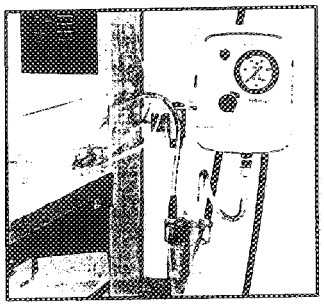
NOTE Properly occlude the Suction Port located underneath the suction module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the suction Module) to the desired setting while occluding the Suction Port



Turn the suction off with the On/Off Switch located on the front of the module



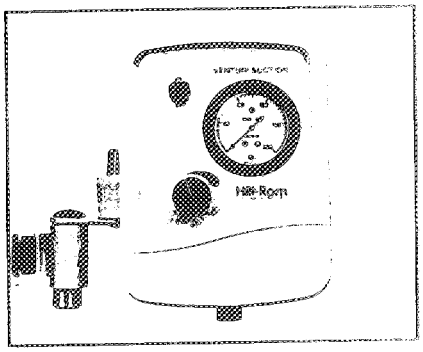
Attach Disposable Suction Canister to the Port located underneath the module.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

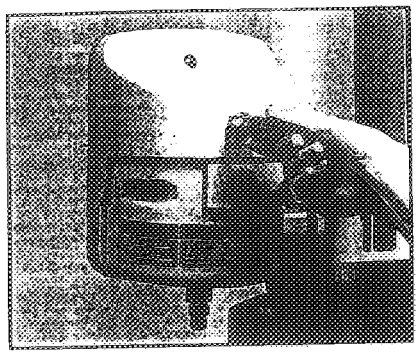
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ACCESSORIES

SUCTION MODULE (VENTURI ONLY)



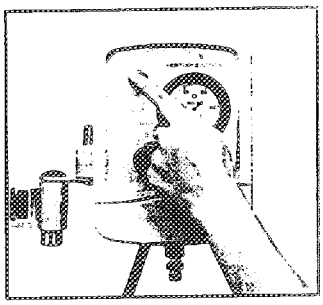
Venturi Suction is accomplished by the use of either Wall or Cylinder Oxygen and is variable from 0 to 160 mm Hg.



To Use Oxygen Source for Venturi Suction (Cylinder or Wall)

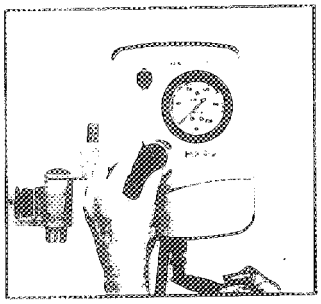
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting located on the back of the suction module.

Set Rate

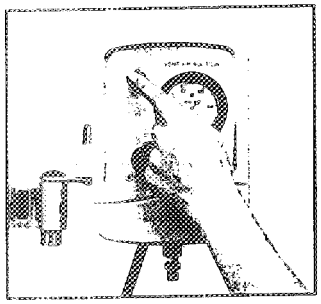


Turn the suction on with the On/Off Switch located on the front of the module.

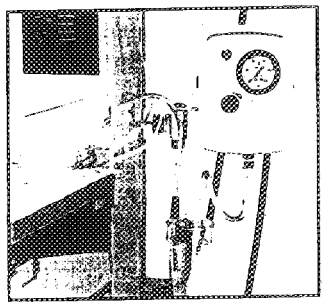
NOTE Properly occlude the Suction Port located underneath the Suction Module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the Suction Module) to the desired setting while occluding the Suction Port



Turn the suction off with the On/Off Switch located on the front of the module.



Attach Disposable Suction Canister to the Port located underneath the module.

NOTE To increase Oxygen Cylinder life

1)Turn the cylinder off when not in use or when utilizing Wall Source of oxygen.

2)Do not set suction level any higher than necessary to complete procedure.

3)Turn suction off when not in use

4)Connect unit to Wall Oxygen Source when available and practical.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

19

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CLEANING

STERILIZATION

The Centers for Disease Control recommend EPA approved hospital disinfectants, used at manufacturers suggested dilutions. Cleaning should be done by wiping a soft dampened cloth over the surface, followed by wiping with a dry cloth.

Quartenary ammonium disinfectants may be used to reduce the contamination level between patients.

Alcohol, strong or abrasive cleaners and hydrocarbon solvents are not necessary and should not be used on plastic surfaces.

MATTRESS CARE

The mattress cover may be cleaned with a mild detergent, rinsed, and cold sterilized. The following products have been tested by the Herculite Laboratory and have been found not to have a harmful effect on StaphChek® fabrics WHEN USED IN ACCORDANCE WITH MANUFACTURERS' RECOMMENDED DILUTION.

TRADE NAME	TYPE	MANUFACTURER
A33	Quartenary	Airwick
Absolute	Quartenary	Walton-March
Beaucoup	Phenolic	Huntington
Blue Chip	Quartenary	S.C. Johnson
Coverage 256	Quartenary	Vestal
El Dorado Plus	Quartenary	Puritan/Churchill
Elimstaph	Quartenary	Walter G. Legge
Forward DC	Quartenary	S.C. Johnson
Franklin Sentinel	Quartenary	Purex
Galahad	Phenolic	Puritan/Churchill
Hi-Tor	Quartenary	Huntington
Insurance	Quartenary	Vestal
LPH	Phenolic	Vestal
Matar	Phenolic	Huntington
Omega	Quartenary	Airwick
Quanto	Quartenary	Huntington
Sanikleen	Quartenary	West Chemical
Sanimaster 111	Quartenary	Service Master
Surfacide	Quartenary	Walton-March
Tri-Quat	Quartenary	Vestal
Vesphene 11	Phenolic	Vestal
Virex	Quartenary	S.C. Johnson

Betadine stains may be removed from the mattress by doing the following:

- Use a 5.25% sodium hypochlorite solution (Clorox® brand bleach).
- Apply 3 drops of the solution per square inch immediately and scrub lightly. The stain should start to fade almost immediately and within 15 minutes should be totally gone.
- Stubborn stains may need further applications. No more than 3 applications on any one area are recommended.
- When completely dry, rinse area with clear water and wipe dry.
- If solution comes into contact with skin, wash off with water and follow manufacturer's label instructions.

CLEANING OF THERMISTOR PROBE

Several precautions must be observed when cleaning and sterilizing to protect Probe from damage.

Avoid contact with strong, aromatic, chlorinated, ketone ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the cable to lose flexibility.

Probe may be disinfected and sanitized by washing with 3% hydrogen peroxide, 70% isopropanol, 70% ethanol, or 100% alcohol. Dakin's solution (sodium hypochloride in neutral buffer) is also suitable. Activated dialdehyde solutions, such as Cidex, are also effective.

Probe plug should not be immersed.

STERILIZATION OF THERMISTOR PROBE

Ethylene oxide sterilization is the preferred method. After sterilization, Probes must be safely and thoroughly ventilated before handling or use.

CAUTION Autoclaving may cause Probe insulation to fail, and may also cause the Probe to give inaccurate reading.

CLEANING OF CASTERS

The Stabilet CC Infant Warmer may be used both in and outside aseptic surgical areas. Care should be taken to assure the casters do not carry contamination into the surgical suite. Removal of accumulated debris and treatment of the caster tread with a spray of disinfectant solution as the Stabilet is transferred into the surgical suite is recommended.

CLEANING OF SIDE PANELS

The side panels are made of clear polycarbonate plastic and can be damaged by cleaning with alcohol, abrasive agents, hydrocarbon solvents or phenolic disinfectants. Use only gentle detergents for cleaning and polish with a soft cloth to return clarity.

CLEANING RESPIRATORY THERAPY PARTS

Remove and clean or discard all tubing, masks and control apparatus which have come in contact with patient secretions. Cleaning procedures should follow standard recommendations for respiratory therapy equipment and should include surveillance for residual pathogenic contamination. Respiratory therapy equipment tends to deteriorate with age and repeated cleaning and sterilization. Assure it is safe and functioning properly. Cracked rubber and plastic articles should be replaced.

MAINTENANCE

The Stabilet CC Infant Warmer and Resuscitation Modules need regular care and maintenance, as detailed in the Service Manual. Please request your maintenance technician to follow the preventive maintenance section in the Service Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

SAFETY TIPS

For over 65 years Hill-Rom has set the standard for quality in patient room equipment. During this time, with input from many of our customers, we have acquired useful tips which may contribute to the safety of the infant and staff.

SIDE PANELS
To provide maximum protection for the infant, the side panels should always be in a full, upright position and latched when an infant is unattended. To ensure the side panels are latched, give the side panels a gentle tug.

TRANSFERRING THE STABILET CC INFANT WARMER
Although the unit is lightweight and easy to move, be sure to keep hands and feet clear of the wheels when moving to prevent destabilization of the unit or injury to hands or feet.

BRAKES
Brakes should always be set when the unit is occupied. After setting the brakes, push and pull the unit to ensure they are engaged.

X-RAY CASSETTE HOLDER
If using the X-Ray Cassette Holder accessory, always secure the holder to the unit when not in use. This will avoid possible damage to the unit and holder.

RESUSCITATION MODULES
Warmer Module should always be kept over the center of the Bassinet when Modules are attached.

SCALE
The Display Unit may be attached to either side of the Thermal Control Center.

PREVENTIVE MAINTENANCE
Quarterly preventive maintenance must be performed to ensure all features are functioning as originally designed. Particular attention must be addressed on safety features, including but not limited to:

- Side Panel Latching Mechanisms
- Caster Braking Systems
- Electrical Cords And Components
- Stainless Steel Heater
- Temperature Alarm System
- Scheduled Re-calibration
- Air Flow Measurement Devices

Please refer to your Service Manual for specific preventive maintenance.

PARTS AND ACCESSORIES
Use only Hill-Rom parts and accessories. Do not modify the unit or module without authorization from Hill-Rom.

CAUTION
Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

DIRECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800-638-2546
International (812) 934-8173 • FAX (812) 934-7161

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

W6098A RC1096

Manufactured for Hill-Rom under a quality system certified to ISO 9001/EN46001 by TÜV Product Service of San Diego, CA.

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.

© Hill-Rom 1996

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

3

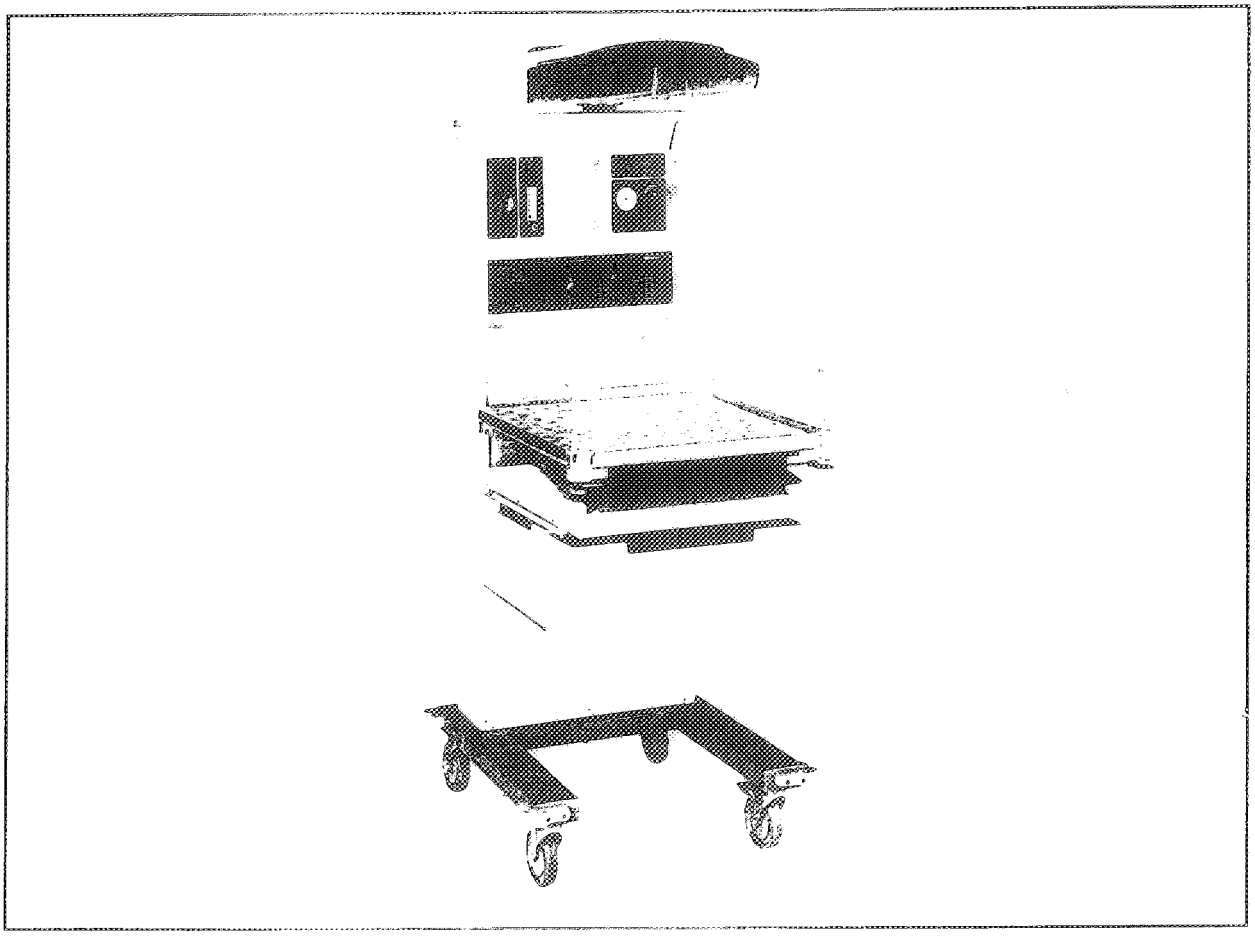
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

IN-SERVICE MANUAL

Stabilet™ 2000D Infant Warmer

From Hill-Rom®



DRAFT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

TABLE OF CONTENTS

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES 1
SPECIFICATIONS 1
FEATURES
Multi-Position Warmer Module 2
Storage 2
Over Center Of Bassinet 2
X-Ray And Examination 2
Mother/Baby Bonding 2
Bassinet 3
Trendelenburg/Reverse Trendelenburg /Level Sleep Surface 3
Retractable Mayo Tray 3
Slide-Through Storage Drawer 3
Built-In X-Ray Cassette Holder/Radiolucent Mattress 4
Apgar/Procedure Timer 5
Lighting Button Module 5
Tilt-Out Resuscitation Compartment 5
Resuscitation Package 5
Utilize Resuscitation Equipment 6
Oxygen Cross-Over System 7
Oxygen Cylinder Installation 7
Use Portable System 8
Use Wall Oxygen Source 8
Suction 9
Thermal Control Center 9
Manual Mode 10
Servo Control Mode 10
Alarm Descriptions 11
Overheating Alarm 11
High-Low Temperature Alarm 11
Over 102.2° F /39° C Alarm 12
Probe Fault Alarm 12
Low Oxygen Alarm 12
System Fault Alarm 12
Loss Of AC Power Alarm 12
OPTIONS
Air/Oxygen Blender Package 13
Air/Oxygen Blender Alarm 13
Installation 13
Use Package 14
Hi-Low Height Adjustment
Scale 15
Patient Weighing 16
CLEANING 17
SAFETY TIPS ..... Back Cover

FOR SPECIAL ASSISTANCE:

Hill-Rom Account Manager ..... Phone _____

Perinatal Consultant ..... Phone _____

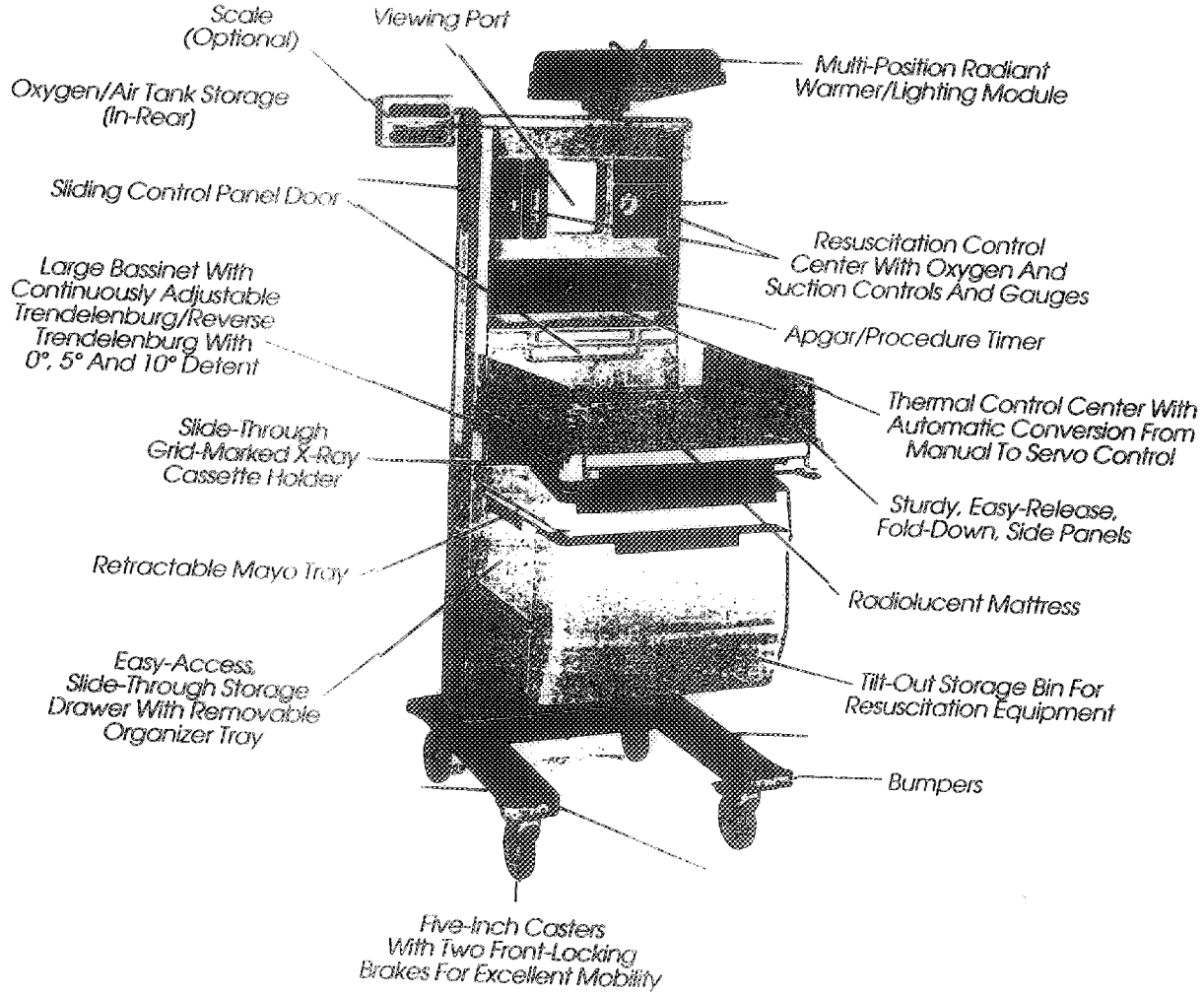
Field Service Technician ..... Phone _____

Customer Service Representative ..... Phone _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES



SPECIFICATIONS

Height – Floor to top of unit ..... **73" - 82" with Height Adjustment**
Height – Floor to top of side panel ..... 42" - 51"
Side Panel height ..... 5½"
Caster ..... 5"
Width – Overall ..... 27"
Width – Bassinet ..... 24"
Length – Bassinet ..... 28"
Mattress size ..... 26" x 22" x 1"
Mattress height – Floor to top of mattress ..... **38" - 47" with Height Adjustment**
Weight ..... 295 lbs

Weight with Hi/Low Height Adjustment approx. 335 lbs.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

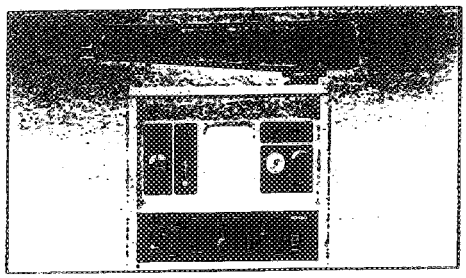
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

MULTI-POSITION WARMER MODULE
The Radiant Warmer Module provides a controlled source of radiant heat to the unit through (2) 375 Watt Stainless Steel Tubular Heaters and a smooth parabolic reflector.

Storage

- To store, pivot the heater 90° (parallel to unit housing).
- Grasp the Heater Handle and push the heater horizontally to the stored position.

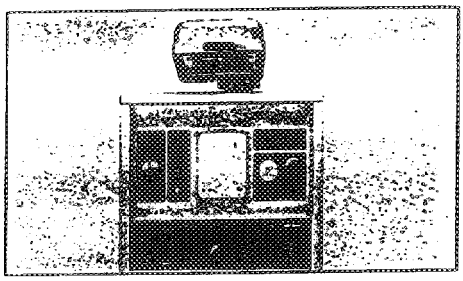
NOTE Internal microswitches turn the heater off if it is rotated from the central position over the Bassinet 45° from right, 35° from left. This safety feature prevents overheating of the Upper Control Panel Housing when the heater is in the stored position.



Over Center Of Bassinet

- To place the heater into the standard operating position, grasp the handle and pull horizontally, placing the base of the heater in the center of the unit.
- Rotate the heater 90°, placing it centrally over the Bassinet.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.

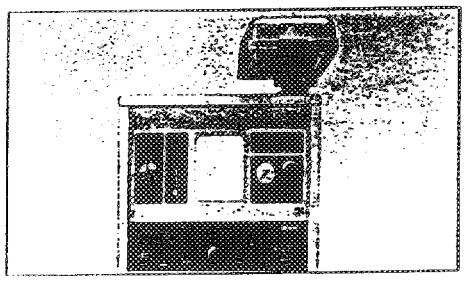
WARNING Do not place any objects on top of the Warmer Housing. This could cause overheating of the unit and/or combustion of items placed on top of the warmer.



X-Ray And Examination

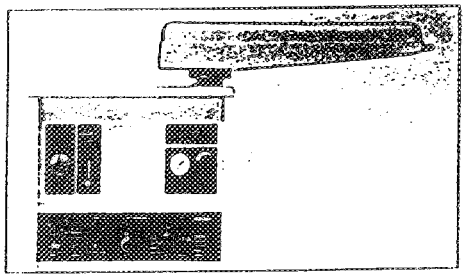
- Grasp the handle, lift and pull horizontally, placing the base of the heater on the right side of the unit.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.
- The heater may be rotated to allow the x-ray machine to be properly positioned over the infant.

NOTE In the x-ray position the Warmer Module will continue to deliver heat to the infant.



Mother/Baby Bonding

- Rotate the heater from the stored position to 180° over the mother's bed or chair.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.



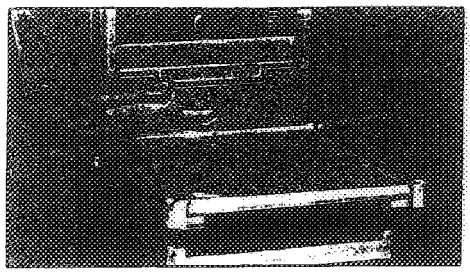
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BASSINET

Fold Down Front And Side Panels

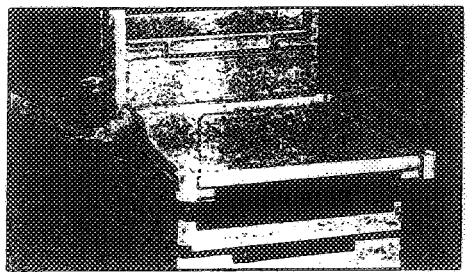
- The Bassinet has Fold-Down Front and Side Panels to allow greater access to the Procedure Table. An Infant Measurement Scale (in both inches and centimeters) and X-Ray Cassette Placement Grid are located on the Bassinet Panels.



To Lower

- To lower the Front or Side Panels, press down and pivot panel out and down with forearm or hands.

CAUTION Do not leave infant unattended when Front or Side Panels are lowered.



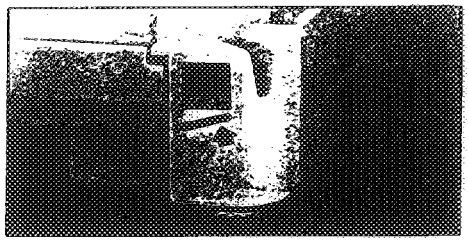
To Raise

- To raise the Front or Side Panels, grasp the panel and rotate up and towards the Bassinet.
- Move panel gently to ensure that it is secure.

TRENDELENBURG/REVERSE TRENDELENBURG/LEVEL SLEEP SURFACE

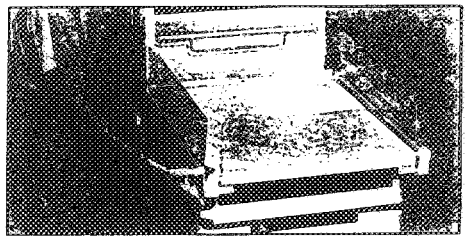
Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet and lift. The Bassinet will rotate from 0° to 10° Trendelenburg, with a 0°, 5° and 10° detent.



Reverse Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet.
- Push down or lift the Bassinet from the front, using the Trendelenburg Mechanism. The Bassinet will rotate from 0° to 10° Reverse Trendelenburg, with a 0°, 5° and 10° detent.

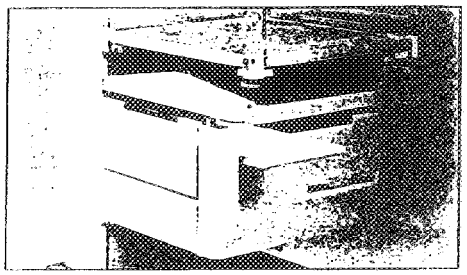


Level Sleep Surface

- Depress either of the handles located beneath the Front Panel and guide the Bassinet to a center position.

RETRACTABLE MAYO TRAY

A built-in Retractable Mayo Tray can be used as an instrument shelf during procedures as well as a surface for charting. Do not overload the tray (25 lb. load weight capacity).



To Access

- Grasp the tray and pivot out and toward the front of the unit until the tray stops.

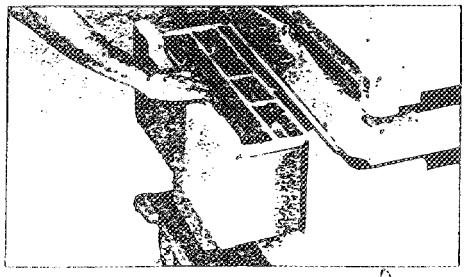
To Store

- Rotate the tray toward the left side of the unit until it is flush with the Bassinet.

WARNING Do not place the infant on the Mayo Tray.

SLIDE-THROUGH STORAGE DRAWER

The built-in Slide-Through Storage Drawer is accessible from either side of the unit and has a removable plastic tray (compartmentalized) for small equipment and disposable items.



To Access

- Grasp the Cut-Out Drawer Handle and pull drawer out and away from the unit.

To Close

- Slide the drawer in until it is flush with the Bassinet.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

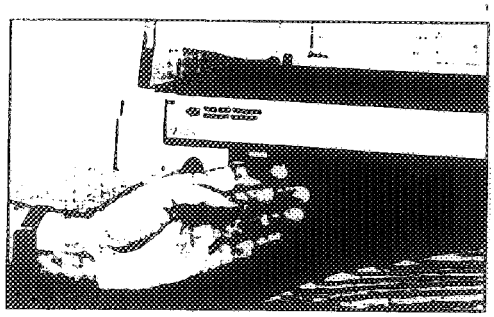
Bassinet

To Lock (So that the Side Panels cannot be accidentally lowered)

- Locate locking mechanism, positioned under each panel, and gently pull out until it stops.
- Push down gently to ensure that it is locked.

To Unlock

- Locate locking mechanism, positioned under each panel, and push in until it stops.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

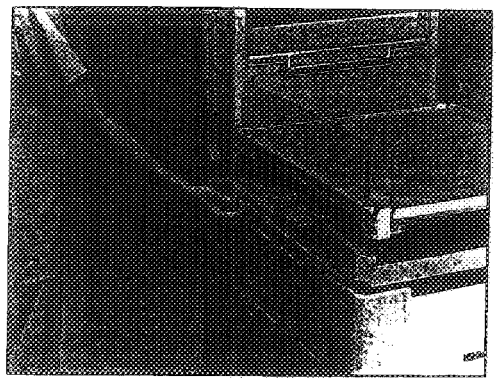
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BUILT-IN X-RAY CASSETTE HOLDER

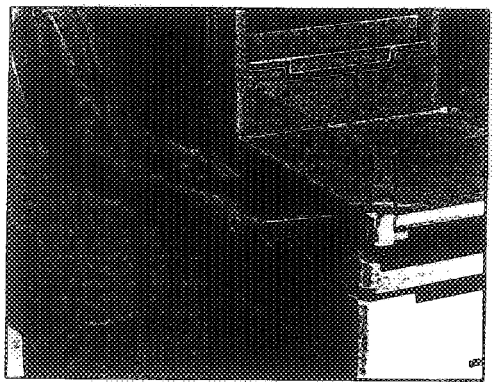
The X-Ray Cassette Holder accommodates cassettes up to 12" x 14".

oading X-Ray Cassettes

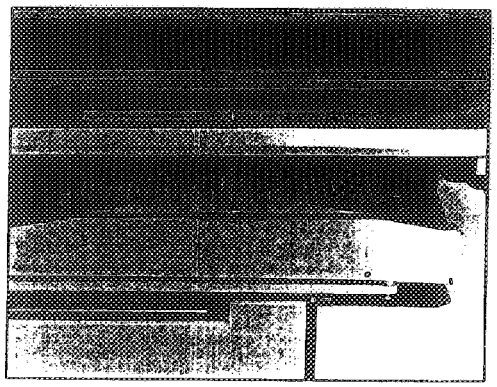
- Working from either side of the Bassinet, locate the X-Ray Cassette Tray directly beneath the Sleep Surface.
- Release the X-Ray Cassette Tray by lifting the tray up and pulling out.



- While supporting the X-Ray Cassette Tray, place the film cassette on the tray.



- To ensure proper cassette placement, align the X-Ray Cassette Tray Grid Markings with the markings located on the Bassinet Front and Side Panels. These grid markings allow you to position the cassette accurately relative to the infant's position in the Bassinet.

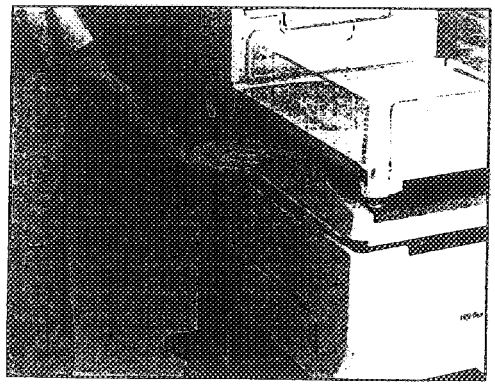


- Slide the cassette and X-Ray Cassette Tray in toward the Bassinet until it rests securely and flush beneath the Bassinet.
- A slight detent will be felt indicating that the tray is "locked" into place.
- The Heating Element may be pivoted 90° away from the Mattress to provide easy access over the Sleep Surface, by an X-Ray Machine.

Unloading X-Ray Cassettes

- When x-ray is complete, lift the X-Ray Cassette Tray up and pull it gently away from the Bassinet.
- Remove the x-ray cassette and slide the tray back in toward the unit to a normal operating position.

NOTE The mattress is radiolucent.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

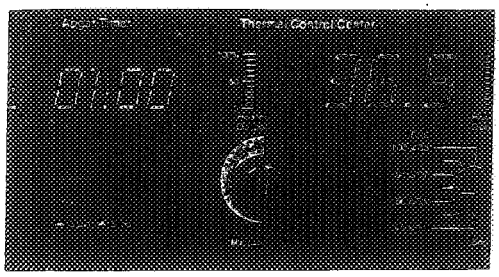
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

APGAR/PROCEDURE TIMER

Located on the Control Panel is a one-hour electronic Apgar/Procedure Timer.

- To start the Apgar/Procedure Timer, depress the Start/Stop Button located on the Control Panel.
- A visible four-digit display in minutes and seconds will appear on the Control Panel. The timer will begin at 00:00 and run to 59:59.
- A one-second audible tone will sound at one, five, and ten minutes.
- Depress the Start/Stop Button again to reset the timer.

NOTE Power Switch must be ON to operate timer.



LIGHTING BUTTON MODULE

A Lighting Button located on the Control Panel actuates one halogen light. The light can be activated without the main power on.

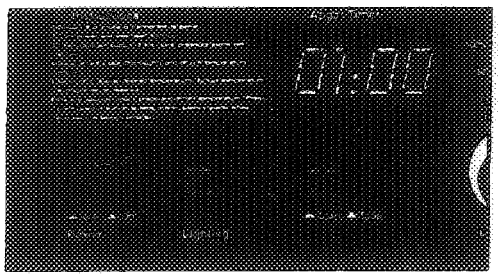
To Activate Lighting

- Depress the Lighting Button, located on the Control Panel.

To Turn Lighting Off

- Depress the Lighting Button again.

NOTE To extend bulb life, turn the Task Light on only as required.



TILT-OUT RESUSCITATION COMPARTMENT

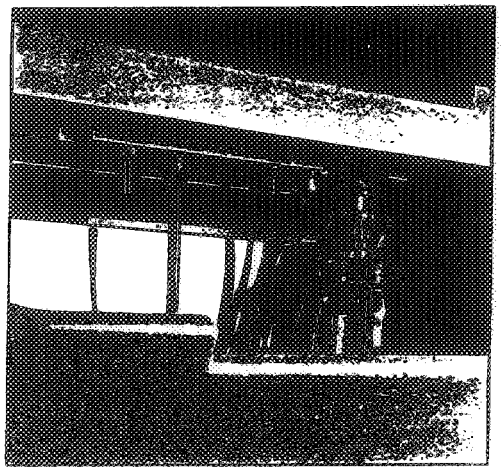
The Tilt-Out Resuscitation Compartment holds the Manometer (pressure gauge) Connector, Oxygen Connector, and Suction Canister. A tube gap at the top of the bin allows the compartment to be closed during use.

To Access

- Grasp Cut-Out Door handle at the front of the unit and pull the door gently toward you.

To Close

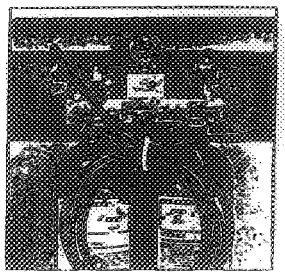
- Push the compartment door gently toward the unit. The Magnetic Catch will hold the door in place.

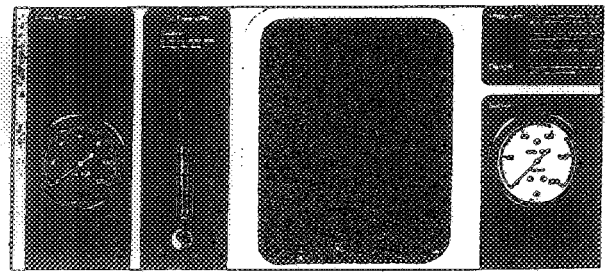


RESUSCITATION PACKAGE

The built-in Resuscitation Package includes:

- Automatic Oxygen Cross-Over System
- (2) Built-in Oxygen Flowmeters
- Airway Pressure Manometer
- Venturi Suction





Built-in Oxygen Flowmeter, Airway Pressure Manometer, and Venturi Suction

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Dual Oxygen (provides 100% Oxygen only)

1. Connect the desired device to be supplied by the Auxiliary Flow to the Auxiliary Outlet Port.

2. Adjust the desired Auxiliary Flow using the O2 Flow LPM 2 Control and check for flow.

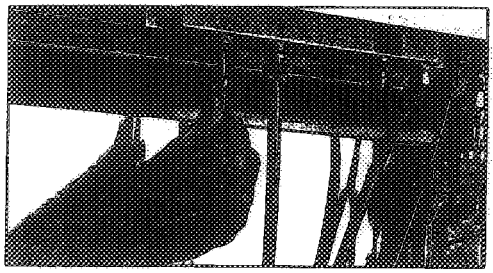
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

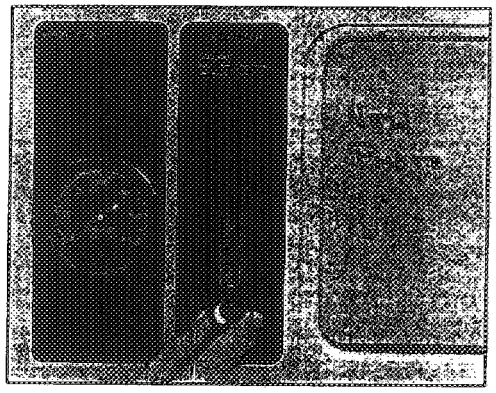
To Utilize Resuscitation Equipment

- Connect one end of the Oxygen Tubing to the nipple marked Pressure Gauge (located in Resuscitation Compartment). This measures the amount of pressure being delivered during resuscitation.
- Connect the opposite end of the Oxygen Tubing to the Manometer Connecter located on the Resuscitation Bag and Mask.

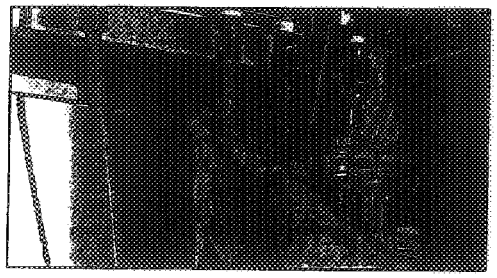
CAUTION The system must be vented or damage to the manometer will occur.



- The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the Control Panel.



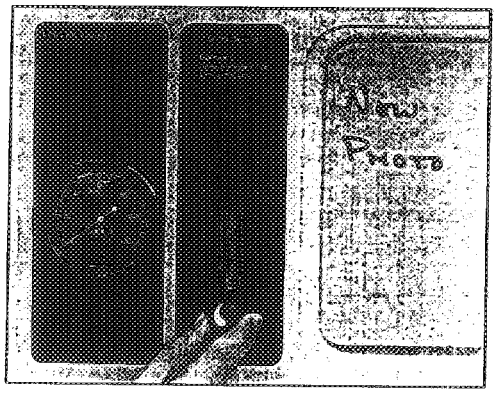
- Using an appropriate adapter, connect one end of a Second Oxygen Tubing to the DISS fitting marked Supply (located in Resuscitation Compartment.)
- Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.



- Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the Control Panel of the unit. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not over-tighten the knob.

CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.

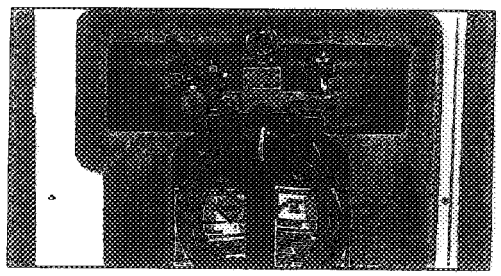


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

Oxygen Cross-Over System

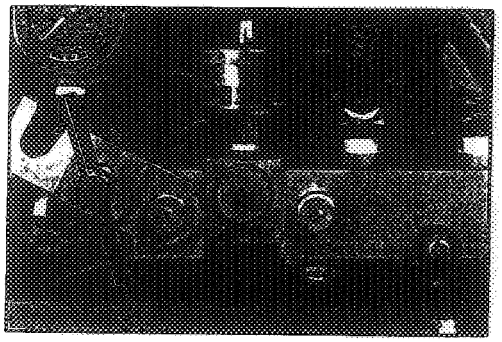
Oxygen can be administered from a regulated Wall Source or from Oxygen Cylinders mounted on the unit. When disconnected from the wall the unit will switch over to the cylinders (NOTE: cylinders must be turned on). When connected back in the wall the unit senses pressure and automatically switches to wall oxygen. A rear compartment contains an Oxygen Supply Hose and a manifold for two "D" or "E" size cylinders.



NOTE If the unit is equipped with an optional Air/Oxygen Blender Package, the rear compartment will be adapted to accommodate an "E" size cylinder for each gas type (refer to page 13 for more details on optional Air/Oxygen Blender Package).

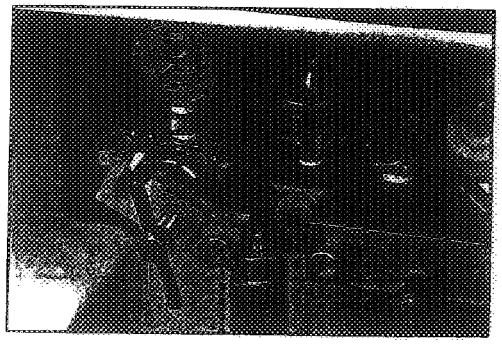
Oxygen Cylinder Installation

- Before installing the Oxygen Cylinders, ensure the built-in Flowmeter and Suction On/Off Switch are turned off.

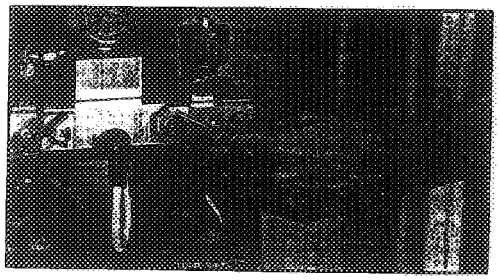


NOTE Before placing a new Oxygen Cylinder in the compartment, insert a new O_2 Cylinder Gasket (Part Number BBM409) on the brass stem to provide a tight seal and prevent cylinder leakage.

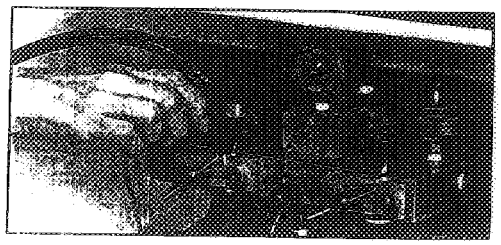
- Lift the Oxygen Cylinder up slightly and install it in the Retaining Ring.



- Tighten the T-Bar.



WARNING Turn the cylinder on by opening the valve slowly by using the cylinder wrench that is provided.



- Check pressure gauge on rear manifold to ensure sufficient gas pressure (approximately 2000 PSI for full "E" size cylinder).
- When the cylinder is turned off, bleed system pressure by turning on the built-in Flowmeter (clockwise turn) until the Flowmeter reads zero.
- Repeat the above steps to install and check the second cylinder.

NOTE Cylinders should be turned off when the unit is not in use.

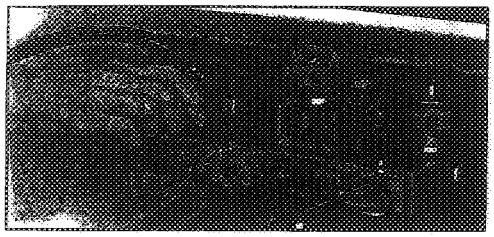
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

Use Portable System

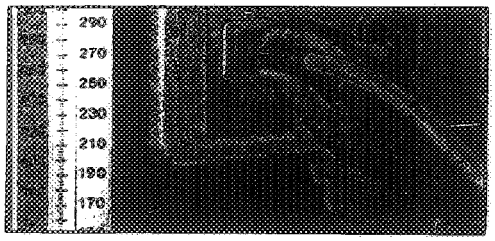
- To transfer an infant and continue to have oxygen and suction capabilities, turn the cylinder(s) on using the provided cylinder wrench.

WARNING To turn the Cylinder on, open the valve slowly.



- Disconnect the Wall Source of oxygen.

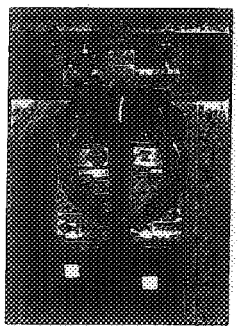
NOTE The unit will immediately begin using cylinder oxygen once the Wall Source is disconnected and the cylinder is turned on. This eliminates the need to manually switch from wall to cylinder gases and could save precious time during emergency transfer.

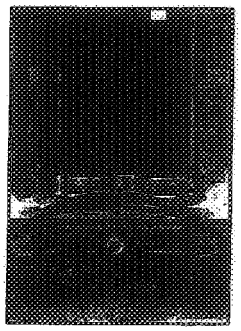


- If the unit has a Scale, it must be unplugged.
- Unplug the electrical cord. The AC Power Loss Alarm will sound if the Main Power Switch is turned on.
- Wind the Oxygen Hose and secure with the elastic cord which is attached to the Oxygen Manifold.
- Wind the electrical cord on the brackets at the base of the warmer.

NOTE It is recommended that one Oxygen Cylinder be kept closed to ensure a full Oxygen Cylinder is available at all times.

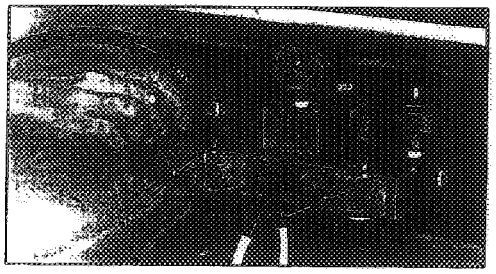
NOTE Before placing a new Oxygen Cylinder in the compartment, insert an O_2 Cylinder Gasket (Part Number BBM409) on the brass stem to provide a tight seal and prevent cylinder leakage.



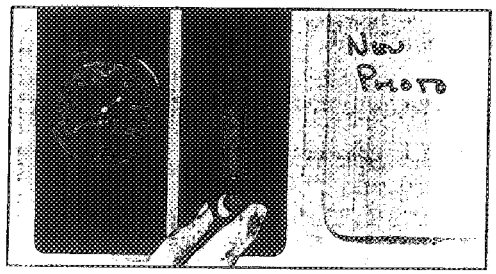


Use Wall Oxygen Source

- Turn the Oxygen Cylinders off.



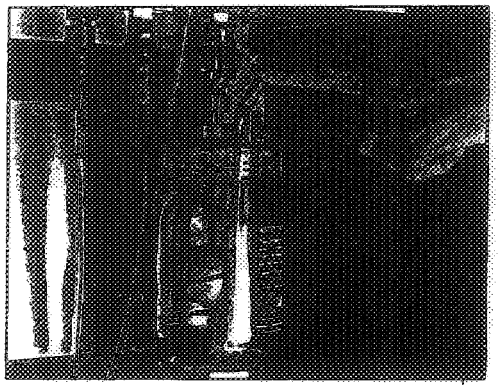
- Turn the built-in Flowmeter (located on the Front Control Panel) on.
- Bleed the O_2 Cylinder Gauge to zero.
- Turn the built-in Flowmeter off.
- Reconnect the Oxygen Hoses to the wall.
- Plug in the electrical cord.
- To begin using wall-supplied oxygen, turn the built-in Flowmeter back on.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Suction
Controls for Venturi-Operated Suction are built into the Control Panel. Venturi Suction is accomplished by the use of either Wall or Cylinder Oxygen and is variable from 0 to 180 mm Hg.



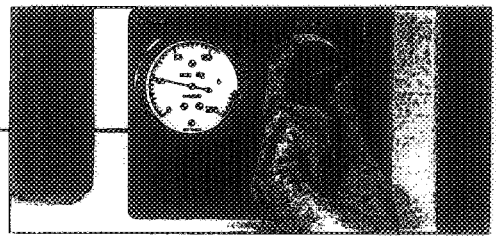
Set Rate

- Place the suction ON/OFF Toggle Switch to the ON position and occlude port.

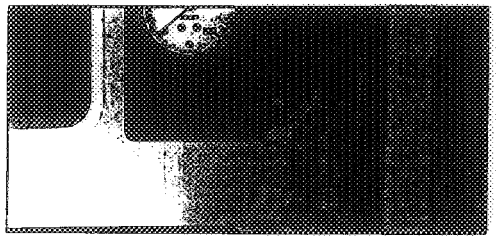
NOTE Properly occlude the Suction Port located on the canister to obtain the most accurate Suction Gauge reading.

- With the Suction Port occluded, rotate the Suction Dial (located on the Front Control Panel) to the desired setting.

New Photo



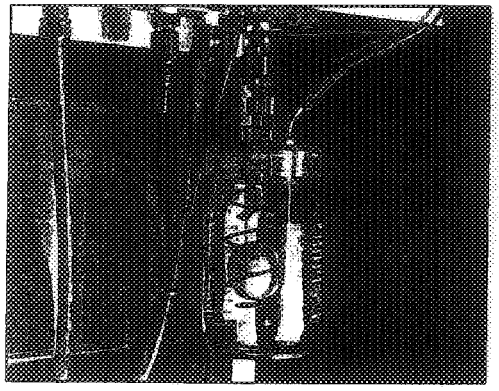
- Turn the suction off with the On/Off Switch located on the Front Control Panel.



NOTE A reusable Suction Canister with a stainless steel port is located in the Front Storage Bin.

NOTE To increase Oxygen Cylinder life:

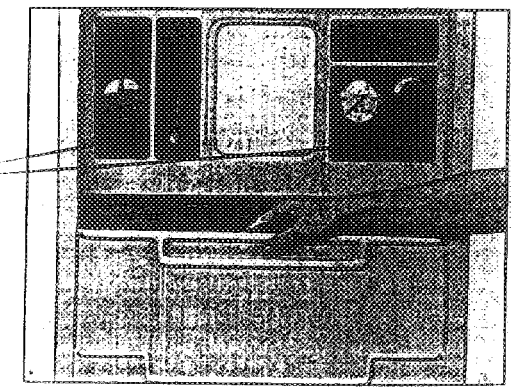
1) Turn the cylinder off when not in use or when utilizing Wall Source of oxygen.
2) Do not set suction level any higher than necessary to complete procedure.
3) Turn suction off when not in use.
4) Connect unit to Wall Oxygen Source when available and practical.



THERMAL CONTROL CENTER

Thermoregulation Controls are centrally located on the Control Panel between the Warmer Module and the Bassinet. A sliding door covers the Control Panel.

New Photos

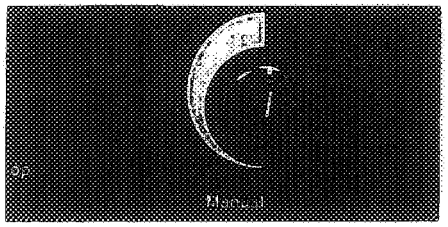


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Manual Mode

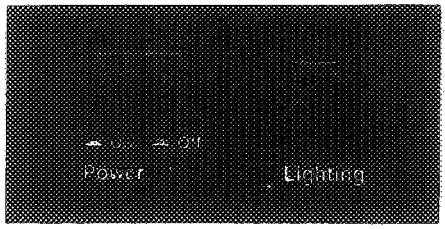
Manual Mode is intended primarily for warming the Bassinet and blankets in preparation for an infant or when it is impractical to attach a Thermistor Probe to the infant.



NOTE Before placing the infant in the Bassinet, pre-heat the Thermistor Probe, face up, in the Bassinet, prior to connecting the Probe into the Jack.

NOTE To avoid overheating or underheating of the infant, Hill-Rom recommends that a Probe should be attached to the infant at all times while in a Radiant Warmer and the infant should not be left unattended.

- Plug the power cord into a standard 115V Hospital Grade AC receptacle.



CAUTION Connect the power cord to a properly grounded receptacle that is approved for hospital use. Do not use an extension cord or AC receptacle box.

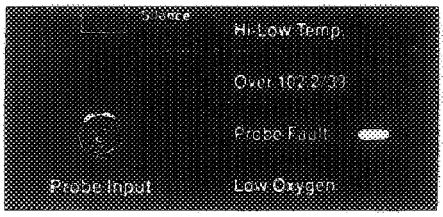
DANGER Possible explosion hazard if used in the presence of flammable anesthetics. This unit is not intended for use in hazardous Class 1, Group C locations.

- Turn the power on by depressing the Power Button located on the upright Control Panel.

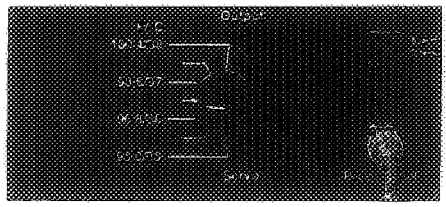
CAUTION The use of radiant warmers may cause insensible water loss.

NOTE The unit will function in the Manual Mode without a Thermistor Probe inserted in the jack. The Probe Fault LED Display will remain lit during this time.

NOTE Skin temperature alarms are not functional during Manual Mode when Thermistor Probe is not inserted in Probe Jack or when the Probe is inserted in Probe Jack but senses a temperature less than approximately 31°C (88°F).



- Set the desired heater output using the Heater Output Control Dial located on the left side of the Thermal Control Center.



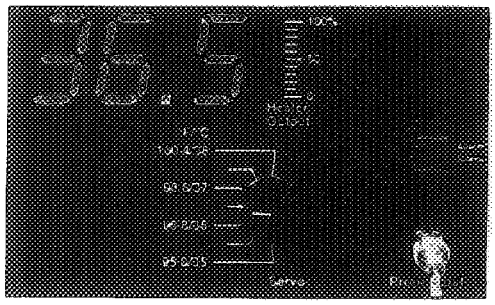
- Heater output is shown on the unit in terms of percentage of power and can be from 0% to 100%.
- The unit will remain at the set heater output you choose until you manually readjust it unless the Overheating Alarm is activated (see Overheating Alarm description).

NOTE In Manual Mode, when no heater output lights appear, it is an indication that heater output is 0%.

Green LEDs indicate approximately 10%–30% heater output.
Yellow LEDs indicate approximately 40%–70% heater output.
Red LEDs indicate approximately 80%–100% heater output.

Servo Control Mode

When the Thermistor Probe is inserted into the Probe Jack and senses a temperature of approximately 31° (88°F), the unit automatically converts to the Servo Control Mode.



The Servo Control Mode also has an LED Heater Output Grid to indicate the amount of energy delivered to the warmer to keep the infant's skin temperature at the predetermined set point temperature.

Heater output is shown on the unit in terms of approximate percentage of power and ranges from 0% to 100%.

As the infant's skin temperature approaches the set point, the heater output will modulate to maintain the infant's skin temperature at the set point temperature.

Once the infant's skin temperature and the set point temperature are equal, only gradual changes in the heater output are needed to maintain the desired infant skin temperature.

Temperature readout displays the infant's skin temperature when the unit is in Servo Control Mode.

- Set the infant's desired target temperature using the Temperature Control Point Dial. Turn the dial to the selected setting.
- Attach the Thermistor Probe to the infant. The Probe should be pre-heated before registering the baby's skin temperature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

NOTE Placement of the Probe is vital because it is the Probe that senses the baby's skin temperature and regulates warmer output.

SUPINE INFANTS...place the flat stainless steel side of the Probe down on the infant's abdomen below the rib cage.

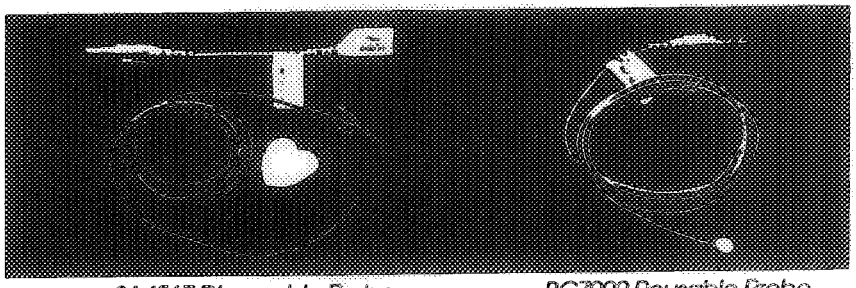
PRONE INFANT...place the flat stainless steel side down on the infant's back below the rib cage, but away from the kidneys.

CAUTION Always attach the Probe with a reflective Probe cover. Serious temperature and control errors can occur if anything other than the recommended Probes and Probe covers are used. Do not use tape to attach the Probe.

CAUTION Inspect the infant's skin for reddened areas which may result from the heating of materials in contact with the skin.

CAUTION Avoid placement of objects (equipment, blankets, clothing) in the Bassinet that can block heat or absorb heat away from the infant.

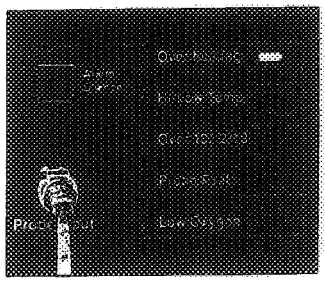
NOTE Only the following Thermistor Probes should be used with the unit.



SA4567 Disposable Probe *BCZ009 Reusable Probe*
(Requires Reusable Adapter Cable SA4566)

ALARM DESCRIPTIONS

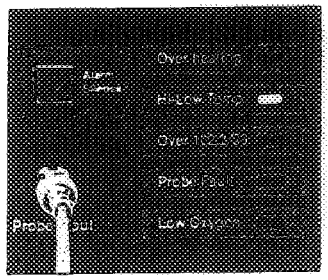
Overheating Alarm (Manual Mode Only)



- An Overheating Alarm will sound if there is constant heater output of 100% for approximately 15 minutes or approximately 25% (2 or 3 LEDS) for 70 minutes or any combination thereof of power and time.
- When the Overheating Alarm is triggered, power to the heater is reduced to approximately 30%.
- The Overheating Alarm can be silenced by depressing the Alarm Silence Button located on the right side of the Control Panel.
- The unit will continue to operate in Manual Mode and no Overheating Alarm will sound as long as the heater output is kept under approximately 30% (1 or 2 LEDS) and a Thermistor Probe is not inserted into the Probe Jack.
- Once the Probe is inserted into the Probe Jack and the Probe senses a temperature of approximately 31° C, the unit becomes a Servo-Controlled Unit, controlled by the skin temperature of the infant.

WARNING Do not leave the infant unattended.

High-Low Temperature Alarm (Servo Mode Only)



- If the infant's temperature has fluctuated more than +/- .5°C from the set point temperature, a solid, visible Hi-Low Temperature LED Display will appear immediately on the Control Panel.
- If after four minutes the high-low temperature has not been rectified, an audible Hi-Low Temperature Alarm will sound.
- During the audible alarm condition, heater output will change to approximately 30% until the infant's skin temperature returns within the target range or until the audible alarm is silenced.
- The Hi-Low Temperature Alarm can be silenced by depressing the Alarm Silence Button; however, the Hi-Low Temperature LED Display will remain lit until the infant's temperature returns to within the target range. If the infant's temperature remains outside of the .5°C setpoint for another four minutes the audible alarm will sound again.
- When the Hi-Low Temperature condition is rectified, the Hi-Low Temperature Alarm will automatically reset.

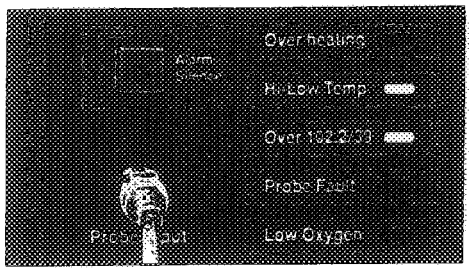
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Over 102.2°F/39°C Alarm

An audible and visible Over 102.2° F /39° C Alarm will activate immediately the Thermistor Probe senses a temperature that exceeds 102.2° F /39° C.

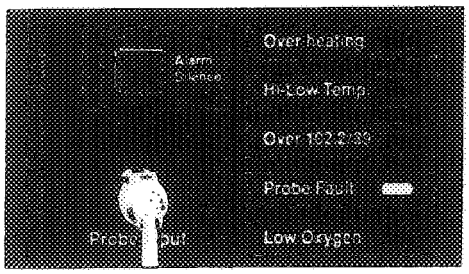
- Heater output is reduced to 0% and will not resume until the Thermistor Probe senses that the temperature has fallen below 102.2° F /39° C.
- The alarm will not silence until the condition is rectified.



Probe Fault Alarm

- In the Manual Mode when the Probe is not inserted in the Probe Input Jack, the Probe Fault LED will remain lit.
- In the Servo Mode, whenever the Probe senses a temperature of less than approximately 31°C, for approximately one minute, the Probe Fault LED will come ON, an audible alarm will occur and heater output will drop to approximately 30%.
- When the alarm is silenced by depressing the Alarm Silence Button:

If sensed temperature is still below 31°C, the Probe Fault LED will remain lit and the unit will revert to Manual Mode.
If the sensed temperature is above 31°C, the Probe Fault LED will go off and the unit will revert to Servo Mode.



Low Oxygen Alarm

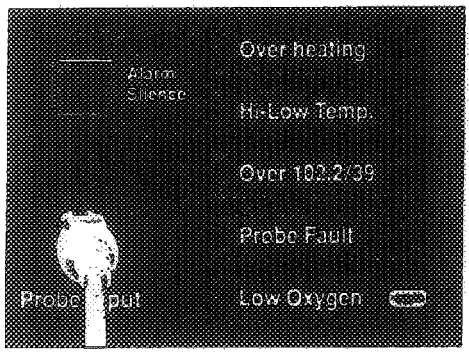
- The unit has a Low Oxygen Cylinder Pressure Indicator. An audible alarm will sound for one of three reasons:

1) Oxygen Cylinders are turned off,

No Oxygen Cylinders are hooked up to the unit, or

Oxygen Cylinders are hooked up to the unit and turned on but oxygen pressure has fallen below 750 PSI.

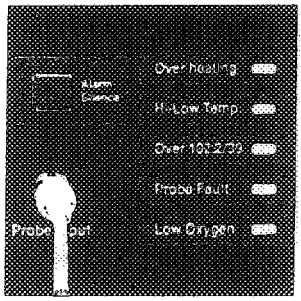
- The Low Oxygen Alarm can be silenced by depressing the Alarm Silence Button, however, the Low Oxygen LED Display will continue to flash until the situation is rectified.



NOTE The Low Oxygen Alarm must be silenced each time the Alarm Silence button is depressed in any other alarm situation.

System Fault Alarm

- A System Fault has occured when an audible alarm sounds and all Alarm LED Displays illuminate.
- The System continually monitors itself (electronically) to ensure complete thermoregulation integrity. If, at any time, the Heater Control Signal and the actual Heater Current Signal do not agree, AC power/heater output is immediately terminated, and a System Fault Alarm is activated.
- The System Fault Alarm may also be activated by connecting an incompatible temperature Probe, or when the Probe is shorted or when there is an open heater element.
- The alarm cannot be silenced until the condition is rectified.
- The alarm may indicate a system failure and require maintenance by a qualified technician.



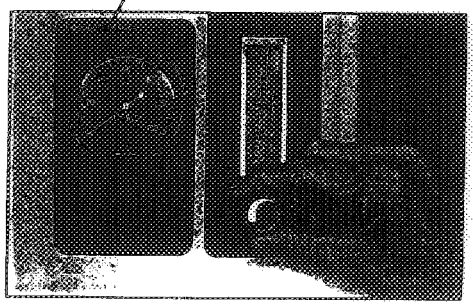
Loss Of AC Power Alarm

- If the unit becomes unplugged or AC power is interrupted to the unit when the Power Switch is "on", a pulsating alarm will sound. This Loss Of AC Power Alarm will fade after approximately **three minutes or will automatically reset if power is restored to the unit.**
- The Loss Of AC Power Alarm works off a capacitor that will recharge when AC power is restored to the unit and Power Switch is turned on.
- No batteries are required for the operation of this alarm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Photo



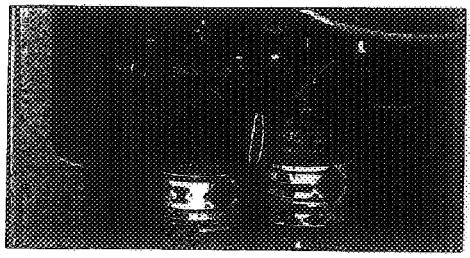
AIR/OXYGEN BLENDER PACKAGE

The optional Air/Oxygen Blender Package allows oxygen and medical air to be mixed. Oxygen and medical air can be administered from a regulated Wall Source or from the oxygen and Air Cylinders mounted on the unit. A Rear Compartment contains an air/O_2 Cylinder Manifold for two "D" or "E" size cylinders. The Air/Oxygen Blender Package also includes a built-in 30-Micron Filter and WaterTrap, Pipeline Air, and O_2 Pipeline/Cylinder Cross-Overs.

NOTE The Blender will only operate with Air and O_2 tanks turned on unless it is connected to a wall source.

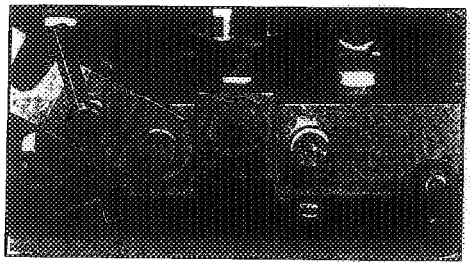
Air/Oxygen Blender Alarm

- The Air/Oxygen Blender is equipped with a continuous audible alarm which will sound when one gas source (either medical air or oxygen) has been depleted or failed, a difference of 20 PSI.
- The alarm will not silence until the depleted gas supply is restored.

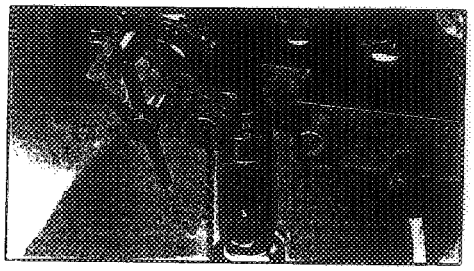


Installation

- Before installing air/O_2 Cylinders, ensure built-in Blender Selector Dial is set at 21% concentration (equivalent to ambient air).
- Ensure built-in Flowmeter and Suction On/Off Switch are turned off.



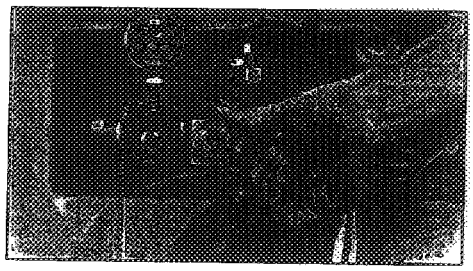
- Lift the Cylinders up slightly and install in the Retaining Rings.



- Tighten the T-Bars.

WARNING Turn on the Cylinders by opening slowly.

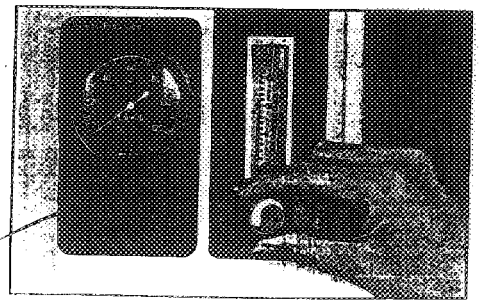
- Check individual high pressure gauges on Rear Manifold to ensure sufficient gas pressure (approximately 2000 PSI for full "E" size cylinder).



- When each cylinder is turned off, bleed the system pressure by turning on the built-in Flowmeter (clockwise turn) until the Flowmeter reads zero.

NOTE Before placing a new Oxygen or Air Cylinder in the compartment, insert a new Cylinder Gasket (Part Number BBM409) on the brass stem to provide a tight seal and prevent Cylinder leakage.

Photo

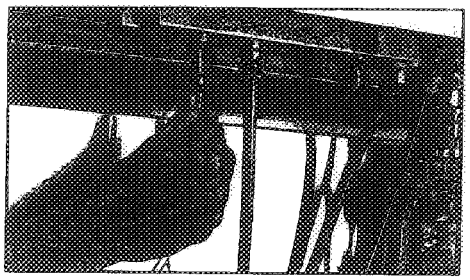


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

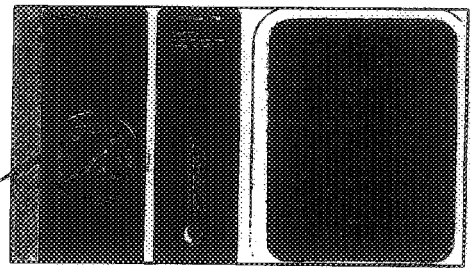
Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

Use Package To Utilize The Resuscitation Equipment With The Blender Package

- Connect one end of Oxygen Tubing to the nipple marked Pressure Gauge (located in Resuscitation Compartment). This measures the amount of pressure being delivered during resuscitation.

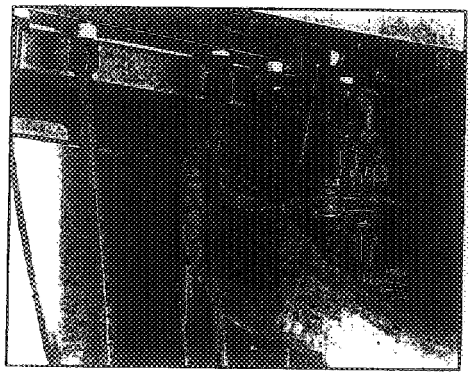


- Connect the opposite end of the Oxygen Tubing to the Manometer Connector located on the Oxygen Mask. The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the Control Panel.



Photo

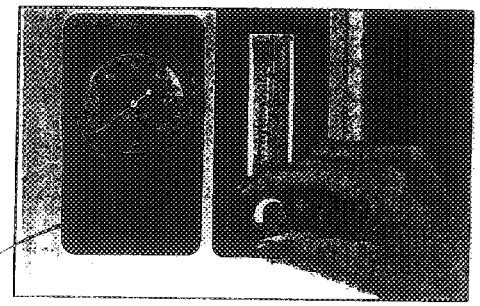
- Using an appropriate adapter, connect one end of a Second Oxygen Tubing to the DISS fitting marked Supply (located in Resuscitation Compartment).
- Connect the opposite end of this Oxygen Tubing to the supply fitting on the Mask.



- Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the Control Panel of the unit.

WARNING Analyze the delivered gases with a Calibrated Oxygen Analyzer.

NOTE Air/O_2 concentrations should be analyzed before each use.



Photo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

OPTIONS

HI/LOW HEIGHT ADJUSTMENT

With a simple touch of the foot pedal, the mattress on the Stabilet 2000 and Stabilet CC may be adjusted anywhere between 37.5 and 46.5 inches from the floor to provide a comfortable work height for any caregiver.

Foot Pedals may be accessed from either side of the infant warmer.

Raise Bed

Depress and hold right foot pedal until desired height is achieved.

Lower Bed

Depress and hold left foot pedal until desired height is achieved.

Warning: Check space above and below the warmer so that repositioning the unit will not be obstructed.

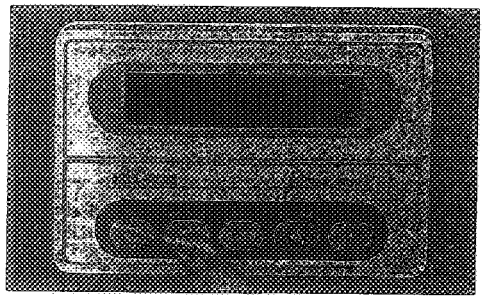
Warning: Do not transport warmer with the bed in the high position. Lower the bed surface before transport.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

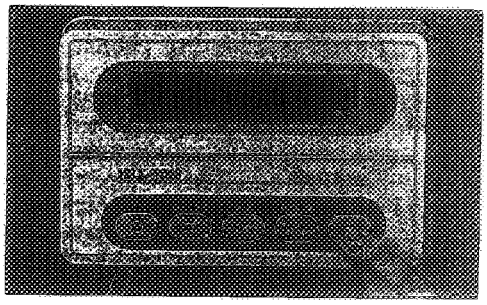
Records processed under FOIA Request # 2016-5769, Released by CDRH on 08-04-2016

SCALE

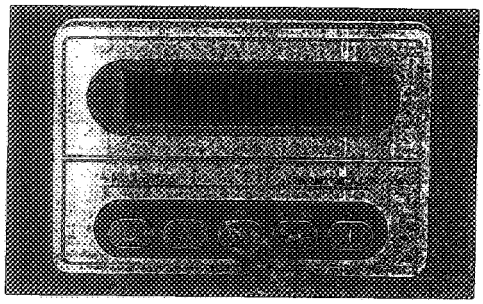
The weighing capacity is approximately 17.6 lbs./8 kgs. The scale has five buttons and a display area. A caption appears above each button describing its function. Each control button is color-coded and graphically represented.



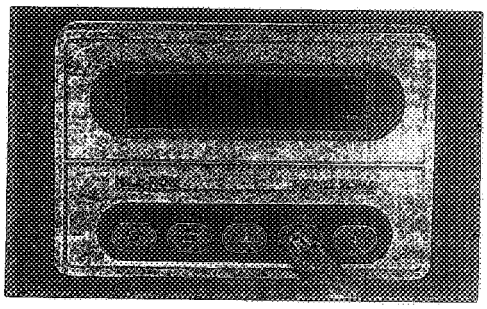
The LBS/KGS button is used to switch to lbs. or kgs.



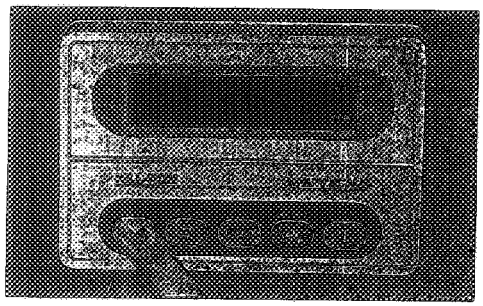
The ON button turns the unit on.



The ZERO button resets the scale to 0.000 prior to placing an infant on the scale.



The AVERAGE button compensates for an active infant, vibration or excessive air currents.



The OFF button turns the unit off.

Before Operating The Scale

For the most accuracy, follow these procedures:

Scale Setup

Prior to operating the Stabilet Scale, refer to the service manual for complete instructions on scale setup.

Sleep Surface Preparation

Before placing the infant on the sleep surface, it must be prepared. This includes placing articles on the surface such as linens, skin temperature probes, etc. that the infant will require. It can be helpful to place a list of these items near the warmer for future reference.

NOTE It is important to develop a protocol to determine what items belong on the Bassinet at the time of weighing.

Weight Interferences

Before operating the scale, be aware of the following:

- The entire surface of the Bassinet is weighed. It is also important that no one touch the Bassinet while the scale is operating. For example, leaning on the front or side panels can cause incorrect readings.
- The most accurate weight reading will be achieved if nothing is touching the Bassinet. This includes patient lines, temperature probes, ventilators, ECMO equipment, drainage bags and anything that could impact the weight and cause an incorrect weight to appear in the display.

Continuous Display

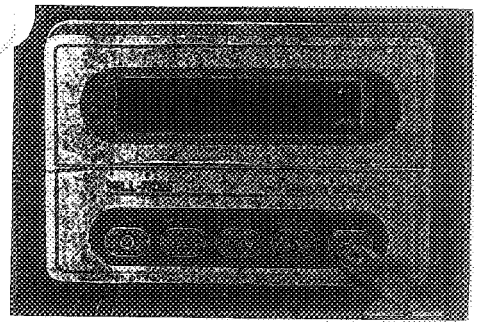
The infant's weight reading will appear continuously on the display until the OFF button is activated. Turning the unit off will not erase any weight readings but only deactivate the scale for a period of time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

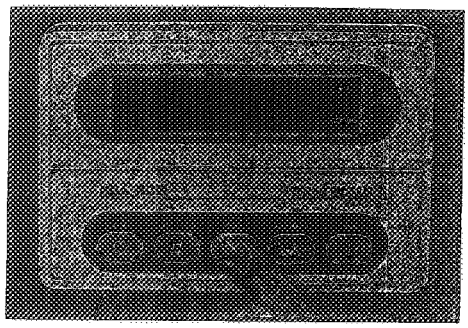
PATIENT WEIGHING

Step One – Turning the Scale On



- Connect the scale's power cord to a 120V electrical outlet.
- To turn the scale on, press and release the ON button on the front panel.
- When first turned on, all display indicators will light briefly, and then clear.

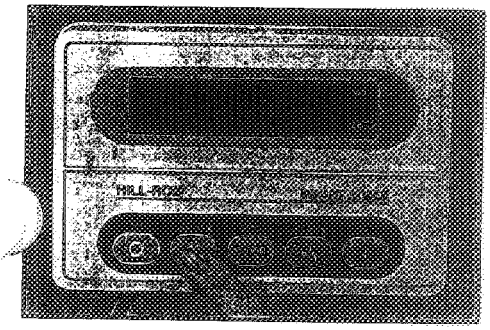
Step Two – Zeroing the Scale



Before placing the infant on the sleep surface, the bed weight must be zeroed.

- Press ZERO to obtain a zero reading on the display prior to weighing the patient for the first time.
- The scale will read 0.000 lbs./kgs.

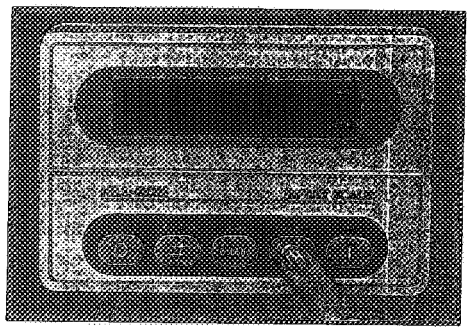
Step Three – Weighing the Patient



For the most accurate weight readings, the infant should be centered on the bed and lying still.

- Place the infant in the Bassinet.
- The patient weight will appear in the display. For lbs. to kgs., press the LBS/KGS button during weight display.

Step Four – Averaging Level



The AVERAGE button allows you to obtain an average weight when an active infant, excessive vibration and/or air currents cause the weight reading to fluctuate.

- Press and release the AVERAGE button. The display will begin a countdown – 02, 01, then a weight reading. This takes approximately four seconds. The scale will display an infant weight based on a statistical average. Do not press any other keys while the scale is in the averaging level mode.
- This statistical average weight will display for approximately 3½ minutes.
- The unit will then return to the original weighing mode.

NOTE This feature does not affect the accuracy of the unit.

LOW BATTERY INDICATOR

When the scale's battery power becomes low, the word "LO BAT" will appear in the scale's display. To recharge the battery, plug the unit into an outlet. The battery is charged when the "LO BAT" display disappears.

NOTE The Infant Scale receives backup power from six AA batteries contained in the scale indicator when the power cord is unplugged from the wall receptacle.

CAUTION The Infant Scale calibration information is not retained in the scale indicator memory in the event that total electrical power is lost. To prevent calibration information loss, ensure that the scale indicator batteries are adequately charged before unplugging the power cord from the wall receptacle. If the scale indicator displays "LO BAT" message, allow sufficient time for the batteries to recharge before unplugging the power cord from the wall receptacle. If the batteries do not accept charge, replace the batteries and recalibrate the Infant Scale.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

This page processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

STERILIZATION

The Centers for Disease Control recommend EPA approved hospital disinfectants, used at manufacturers suggested dilutions. Cleaning should be done by wiping a soft dampened cloth over the surface, followed by wiping with a dry cloth.

Quartenary ammonium disinfectants may be used to reducethe contamination level between patients.

Alcohol, strong or abrasive cleaners and hydrocarbon solvents are not necessary and should not be used on plastic surfaces.

MATTRESS CARE

The mattress cover may be cleaned with a mild detergent, rinsed, and cold sterilized. The following products have been tested by the Herculite Laboratory and have been found not to have a harmful effect on StaphChek® fabrics WHEN USED IN ACCORDANCE WITH MANUFACTURERS' RECOMMENDED DILUTION.

TRADE NAME	TYPE	MANUFACTURER
A33	Quartenary	Airwick
Absolute	Quartenary	Walton-March
Beaucoup	Phenolic	Huntington
Blue Chip	Quartenary	S.C. Johnson
Coverage 256	Quartenary	Vestal
El Dorado Plus	Quartenary	Puritan/Churchill
Elimstaph	Quartenary	Walter G. Legge
Forward DC	Quartenary	S.C. Johnson
Franklin Sentinel	Quartenary	Purex
Galahad	Phenolic	Puritan/Churchill
Hi-Tor	Quartenary	Huntington
Insurance	Quartenary	Vestal
LPH	Phenolic	Vestal
Matar	Phenolic	Huntington
Omega	Quartenary	Airwick
Quanto	Quartenary	Huntington
Sanikleen	Quartenary	West Chemical
Sanimaster 111	Quartenary	Service Master
Surfacide	Quartenary	Walton-March
Tri-Quat	Quartenary	Vestal
Vesphene 11	Phenolic	Vestal
Virex	Quartenary	S.C. Johnson

Betadine stains may be removed from the mattress by doing the following:

- Use a 5.25% sodium hypochlorite solution (Clorox® brand bleach).
- Apply 3 drops of the solution per square inch immediately and scrub lightly. The stain should start to fade almost immediately and within 15 minutes should be totally gone.
- Stubborn stains may need further applications. No more than 3 applications on any one area are recommended.
- When completely dry, rinse area with clear water and wipe dry.
- If solution comes into contact with skin, wash off with water and follow manufacturer's label instructions.

CLEANING OF THERMISTOR PROBE

Several precautions must be observed when cleaning and sterilizing to protect Probe from damage.

Avoid contact with strong, aromatic, chlorinated, ketone ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the cable to lose flexibility.

Probe may be disinfected and sanitized by washing with 3% hydrogen peroxide, 70% isopropanol, 70% ethanol, or 100% alcohol. Dakin's solution (sodium hypochloride in neutral buffer) is also suitable. Activated dialdehyde solutions, such as Cidex, are also effective.

Probe plug should not be immersed.

STERILIZATION OF THERMISTOR PROBE

Ethylene oxide sterilization is the preferred method. After sterilization, Probes must be safely and thoroughly ventilated before handling or use.

CAUTION Autoclaving may cause Probe insulation to fail, and may also cause the Probe to give inaccurate reading.

CLEANING OF CASTERS

The Stabilet 2000D Infant Warmer will be used both in and outside aseptic surgical areas. Care should be taken to assure the casters do not carry contamination into the surgical suite. Removal of accumulated debris and treatment of the caster tread with a spray of disinfectant solution as the unit is transferred into the surgical suite is recommended.

CLEANING OF SIDE PANELS

The Side Panels are made of clear polycarbonate plastic and can be damaged by cleaning with alcohol, abrasive agents, hydrocarbon solvents or phenolic disinfectants. Use only gentle detergents for cleaning and polish with a soft cloth to return clarity.

CLEANING RESPIRATORY THERAPY PARTS

Remove and clean all tubing, masks and control apparatus which have come in contact with patient secretions. Cleaning procedures should follow standard recommendations for respiratory therapy equipment and should include surveillance for residual pathogenic contamination. Respiratory therapy equipment tends to deteriorate with age and repeated cleaning and sterilization. Assure it is safe and functioning properly. Cracked rubber and plastic articles should be replaced.

MAINTENANCE

The Stabilet 2000D Infant Warmer requires regular care and maintenance, as detailed in the Service Manual. Please request your maintenance technician to follow the preventive maintenance section in the Service Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

SAFETY TIPS

For over 65 years Hill-Rom has set the standard for quality in patient room equipment. During this time, with input from any of our customers, we have acquired useful tips which may contribute to the safety of the infant and staff.

SIDE PANELS

To provide maximum protection for the infant, the side panels should always be in a full, upright position and latched when an infant is unattended. To ensure the side panels are latched, give the side panels a gentle tug.

TRANSFERRING THE STABILET 2000D INFANT WARMER

Although the unit is lightweight and easy to move, be sure to keep hands and feet clear of the wheels when moving to prevent destabilization of the unit or injury to hands or feet.

BRAKES

Brakes should always be set when the unit is occupied. After setting the brakes, push and pull the unit to ensure they are engaged.

X-RAY CASSETTE HOLDER

If using the X-Ray Cassette Holder accessory, always secure the holder to the unit when not in use. This will avoid possible damage to the unit and holder.

SCALE

The Display Unit may only be attached to the left hand side when facing the front of the unit.

PREVENTIVE MAINTENANCE

Quarterly preventive maintenance must be performed to ensure all features are functioning as originally designed. Particular attention must be addressed on safety features, including but not limited to:

- Side Panel Latching Mechanisms
- Caster Braking Systems
- Electrical Cords And Components
- **Stainless Steel Tubular Heater**
- Temperature Alarm System
- Scheduled Recalibration

Please refer to your Service Manual for specific details on preventive maintenance.

PARTS AND ACCESSORIES

Use only Hill-Rom parts and accessories. Do not modify the unit without authorization from Hill-Rom.

SAFETY TIPS

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

For over 65 years Hill-Rom has set the standard for quality in patient room equipment. During this time, with input from many of our customers, we have acquired useful tips which may contribute to the safety of the infant and staff.

SIDE PANELS
To provide maximum protection for the infant, the side panels should always be in a full, upright position and latched when an infant is unattended. To ensure the side panels are latched, give the side panels a gentle tug.

TRANSFERRING THE STABILET 2000D INFANT WARMER
Although the unit is lightweight and easy to move, be sure to keep hands and feet clear of the wheels when moving to prevent destabilization of the unit or injury to hands or feet.

BRAKES
Brakes should always be set when the unit is occupied. After setting the brakes, push and pull the unit to ensure they are engaged.

X-RAY CASSETTE HOLDER
If using the X-Ray Cassette Holder accessory, always secure the holder to the unit when not in use. This will avoid possible damage to the unit and holder.

SCALE
The Display Unit may only be attached to the left hand side when facing the front of the unit.

PREVENTIVE MAINTENANCE
Quarterly preventive maintenance must be performed to ensure all features are functioning as originally designed. Particular attention must be addressed on safety features, including but not limited to:

- Side Panel Latching Mechanisms
- Caster Braking Systems
- Electrical Cords And Components
- Stainless Steel Tubular Heater
- Temperature Alarm System
- Scheduled Recalibration

Please refer to your Service Manual for specific details on preventive maintenance.

PARTS AND ACCESSORIES
Use only Hill-Rom parts and accessories. Do not modify the unit without authorization from Hill-Rom.

CAUTION
Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

DIRECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800-638-2546
International • 812-934-8173 • FAX 812-934-7191

Manufactured for Hill-Rom under a quality system certified to ISO 9001/EN46001 by TÜV Product Service of San Diego, CA.

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.
©Hill-Rom 1996

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

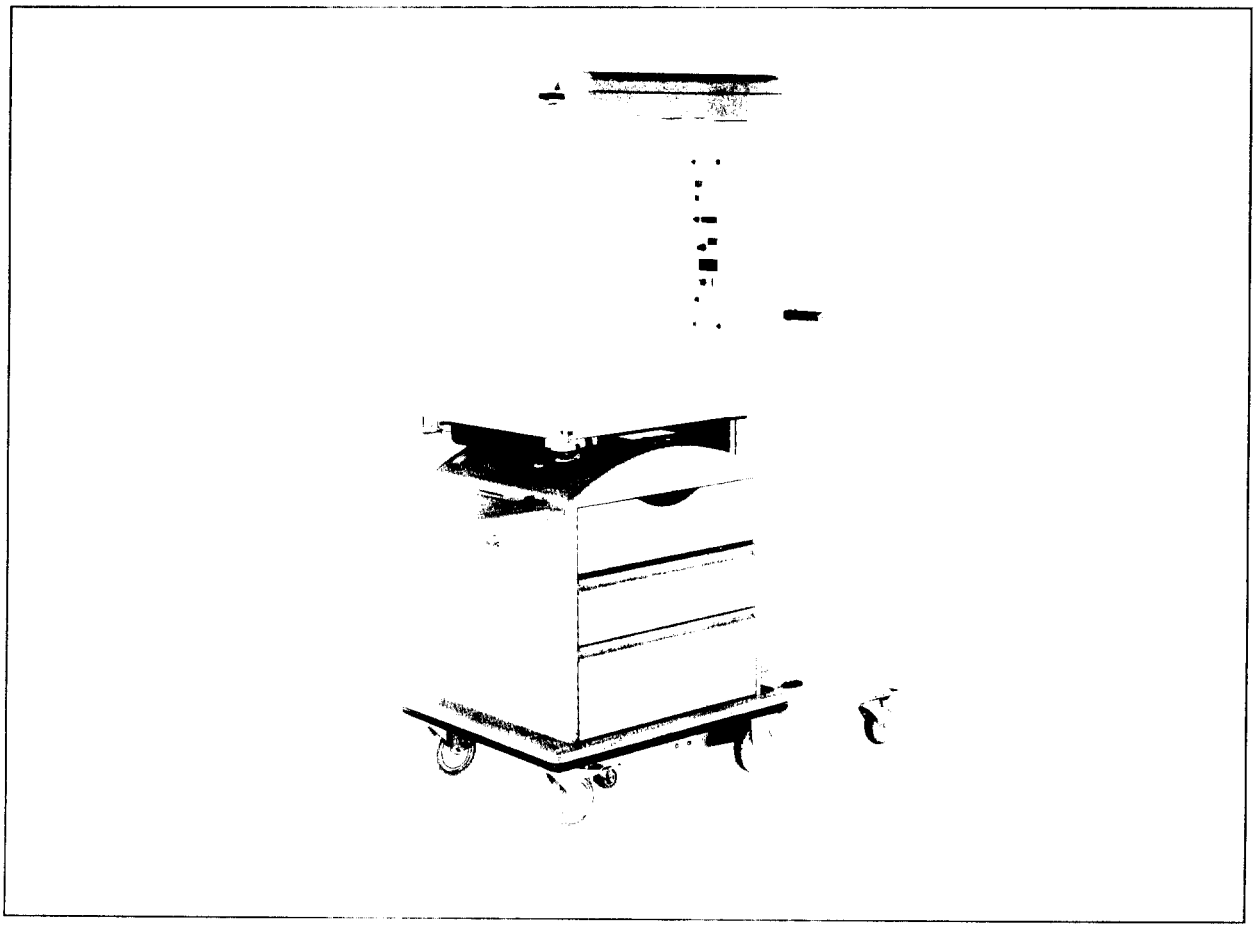
49

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

IN-SERVICE MANUAL

Stabilet™ Freestanding Infant Warmer and Clinical Bassinet

From Hill-Rom®



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

350

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

TABLE OF CONTENTS

FEATURES 1
ECIFICATIONS 1
ATURES – WARMER
Two Position Warmer Module 2
Over Center of Bassinet 2
X-Ray, Mother/Baby Bonding, and Storage 2
Apgar/Procedure Timer 2
Lighting Button Module 2
Accessory Tracks 3
Thermal Control Center 3
Manual Mode 3
Servo Control Mode 4
Alarm Descriptions 5
Overheating Alarm 5
Hi-Low Temperature Alarm 5
Over 102.2°F/39°C Alarm 5
Probe Fault Alarm 6
System Fault Alarm 6
Loss of AC Power Alarm 6
FEATURES – BASSINET
Bassinet 7
Trendelenburg/Reverse Trendelenburg/Level Sleep Surface 7
Drop Leaf Work Surface/Chart Holder 8
Built-In X-Ray Cassette Holder/Radiolucent Mattress 8
Storage Drawers 9
Docking Mechanism 9
ACCESSORIES
Resuscitation Modules 10
Oxygen Module (Flow and Airway Pressure) 11
Oxygen Module (Flow Only) 12
Suction Module (Wall Only) 13
Suction Module (Venturi Only) 14
CLEANING 15
SAFETY TIPS 16

FOR SPECIAL ASSISTANCE:

Hill-Rom Account Manager _____ Phone _____

Perinatal Consultant _____ Phone _____

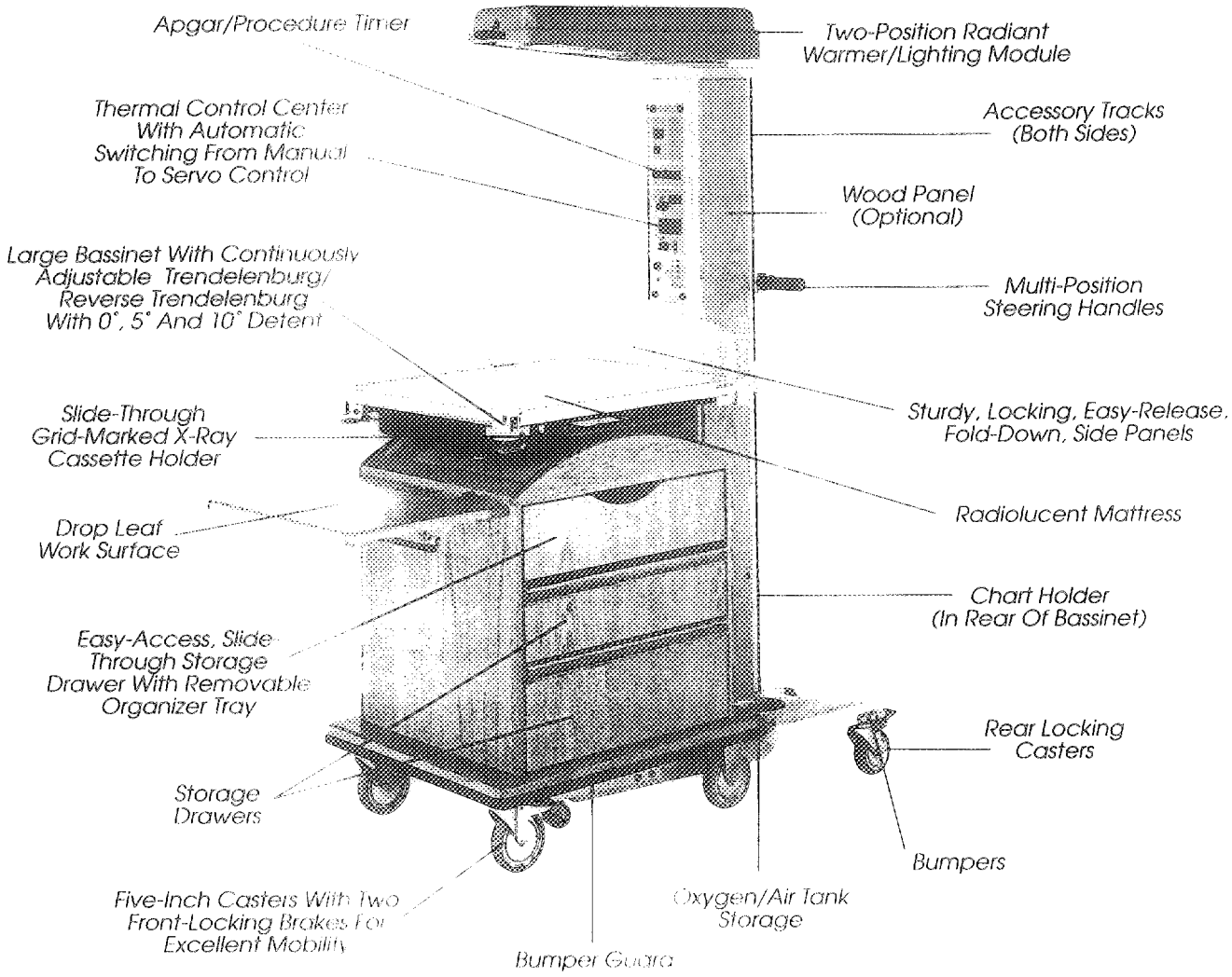
Field Service Technician _____ Phone _____

Customer Service Representative _____ Phone _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES



U.S. Patent 5,162,038

SPECIFICATIONS

Stabilet Freestanding Infant Warmer

Height – Floor to top of unit	72
Front Caster	2
Rear Casters	4
Width	27
Length	33

Stabilet Clinical Bassinet

Height – Floor to top of Side Panel	42"
Width – Overall	25"
Length – Overall (drop-leaf work surface down)	30'
Length – Overall (drop-leaf work surface up)	43½"
Bassinet Size	28" x 24"
Mattress Size	26" x 22" x 1"
Casters	5"

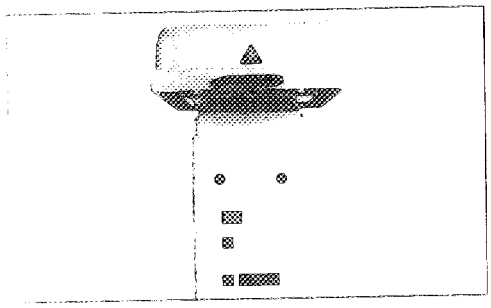
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES/WARMER

TWO-POSITION WARMER MODULE

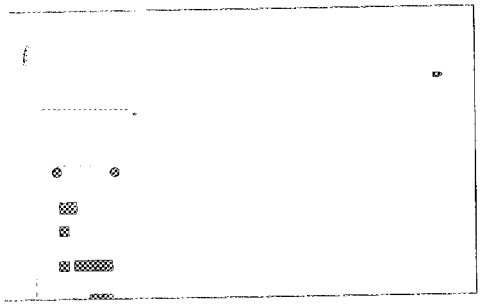
The Radiant Warmer Module provides a controlled source of radiant heat to unit through a 760 watt radiant quartz tube and a parabolic reflector



Over Center of Bassinet

- To place the heater into the standard operating position, rotate the heater 90°, placing it centrally over the Bassinet.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.

WARNING Do not place any objects on top of the Warmer Housing. This could cause overheating of the unit and/or combustion of the objects placed on top of the warmer.



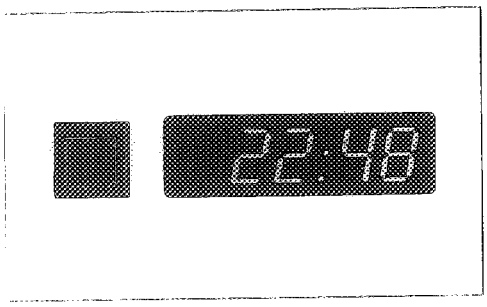
X-Ray, Mother/Baby Bonding and Storage

- Fold down Front and Side panels if applicable.
- Rotate the heater from the center position 90° to the right.
- For Mother/Baby Bonding positions, verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.
- The heater may be rotated to allow the X-Ray machine to be properly positioned over the infant.

NOTE In this position, the Warmer Module will continue to deliver heat

APGAR/PROCEDURE TIMER

Located on the unit's Control Panel is a one-hour electronic Apgar/Procedure Timer. The Main Power Button must be on to activate the Timer

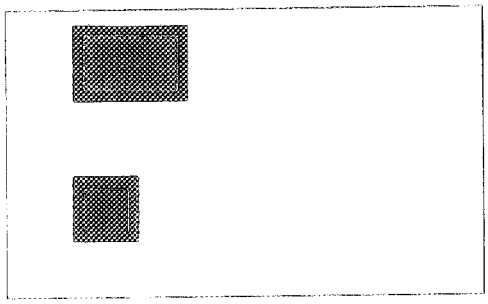


- To start the Apgar/Procedure Timer depress the Start/Stop Button located on the Control Panel.
- A visible four-digit display in minutes and seconds will appear on the Control Panel. The timer will begin at 00:00 and run to 59:59.
- A one-second audible tone will sound at one, five, and ten minutes
- Depress the Start/Stop Button again to reset the timer.

NOTE Power Switch must be ON to operate timer

LIGHTING BUTTON MODULE

A Lighting Button located on the unit's Control Panel activates two 15 Watt color correct fluorescent lights. The Main Power Button must be on to activate the lighting.



To Activate Lighting

- Depress the Lighting Button, located on the Control Panel.

To Turn Lighting Off

- Depress Lighting Button.

NOTE To extend bulb life, turn the examination light on only as required

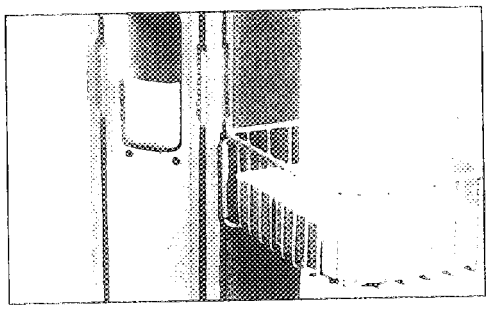
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

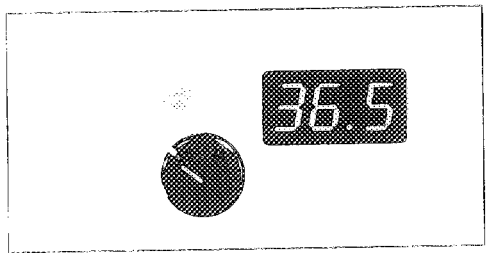
ACCESSORY TRACKS

Accessory Tracks allow convenient placement of numerous accessories at comfortable working heights. The Accessory Tracks improve access to equipment and save valuable floor space



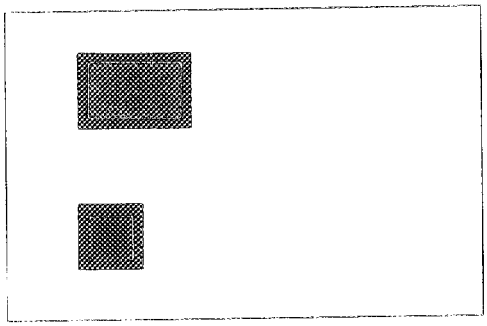
THERMAL CONTROL CENTER

Thermoregulation Controls are centrally located on the Control Panel.



Manual Mode

Manual Mode is intended primarily for warming the Bassinet and blankets in preparation for an infant or when it is impractical to attach a skin Probe to the infant.



NOTE Before placing the infant in the Bassinet, pre-heat the Thermistor Probe, face up, in the Bassinet, prior to connecting the Probe into the Jack

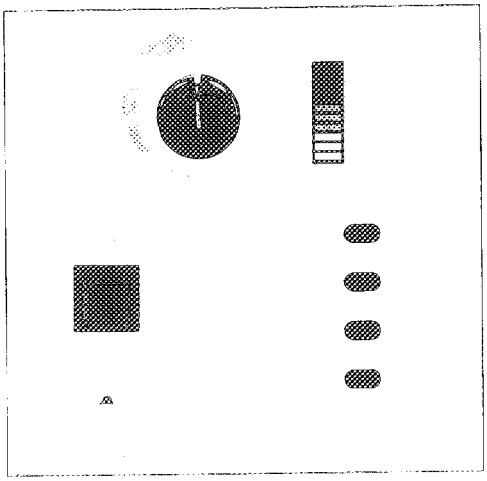
NOTE To avoid overheating or underheating of the infant, Hill-Rom recommends that a Probe be attached to the infant at all times while in an Infant Warmer and the infant not be left unattended.

- Plug the power cord into a standard 115V AC receptacle.

CAUTION Connect the power cord to a properly grounded receptacle that is approved for hospital use. Do not use an extension cord or AC receptacle box.

DANGER Possible explosion hazard if used in the presence of flammable anesthetics. This unit is not intended for use in hazardous Class 1 Group C locations.

- Turn the power on by depressing the Power Button located on the upright Control Panel.

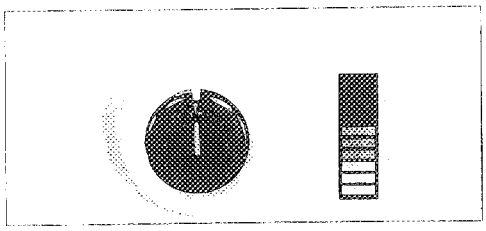


CAUTION The use of radiant warmers may cause insensible water loss.

NOTE The Infant Warmer will function in the Manual Mode without a Thermistor Probe inserted in the jack. The Probe Fault LED Display will remain lit during this time.

NOTE Skin temperature alarms are not functional during Manual Mode when a Thermistor Probe is not inserted in the Probe Jack or when the Probe is inserted in the Probe Jack but senses temperature less than approximately 31°C.

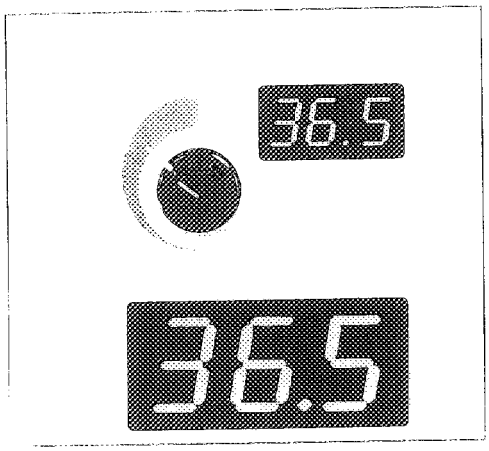
- Set the desired heater output using the Heater Output Control Dial located on the Thermal Control Center.
- Heater output is shown on the unit in terms of percentage of power and can be from 0% to 100%.
- The unit will remain at the set heater output you choose until you manually readjust it unless the Overheating Alarm is activated (See Overheating Alarm description).



NOTE In Manual Mode, when no heater output lights appear, it is an indication that heater output is 0%.
Green LEDs indicate approximately 10%-30% heater output
Yellow LEDs indicate approximately 40%-70% heater output
Red LEDs indicate approximately 80%-100% heater output

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



Servo Control Mode

When the Thermistor Probe is inserted into the Probe Jack and senses a temperature of approximately 31°C (88°F), the unit automatically converts to the Servo Control Mode.

The Servo Control Mode allows the LED Heater Output Grid to indicate the amount of energy delivered to the warmer to keep the infant's skin temperature at the predetermined set point temperature.

Heater output is shown on the unit in terms of approximate percentage of power and ranges from 0% to 100%.

As the infant's skin temperature approaches the set point, the heater output will modulate to maintain the infant's skin temperature at the set point temperature.

Once the infant's skin temperature and the set point temperature are equal, only gradual changes in the heater output are needed to maintain the desired infant skin temperature.

A temperature readout displays the infant's skin temperature when the unit is in Servo Control Mode.

- Set the infant desired target temperature using the Servo Temperature Control Dial and the setpoint digital display. Turn the dial until the selected setting is indicated on the setpoint digital display.
- Attach the Thermistor Probe to the infant. The Probe should be pre-heated before registering the baby's skin temperature.

NOTE Placement of the Probe is vital because it is the Probe that senses the baby's skin temperature and regulates warmer output.

SUPINE INFANTS...place the flat stainless steel side of the Probe down on the infant's abdomen below the rib cage

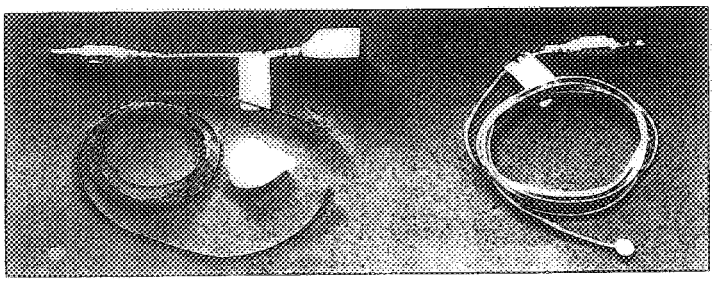
PRONE INFANTS...place the flat stainless steel side down on the infant's back below the rib cage, but away from the kidneys.

CAUTION Always attach the Probe with a reflective Probe cover. Serious temperature and control errors can occur if anything other than the recommended Probes and Probe covers are used. Do not use tape to attach the Probe.

CAUTION Inspect the infant's skin for reddened areas which may result from the heating of materials in contact with the skin.

CAUTION Avoid placement of objects (equipment, blankets, clothing) in the Bassinet that can block heat or absorb heat away from the infant.

NOTE Only the following Thermistor Probes should be used with the Stabilet Freestanding Infant Warmer:



SA4567 Disposable Probe (Requires Reusable Adapter Cable SA4566)

BCZ009 Reusable Probe

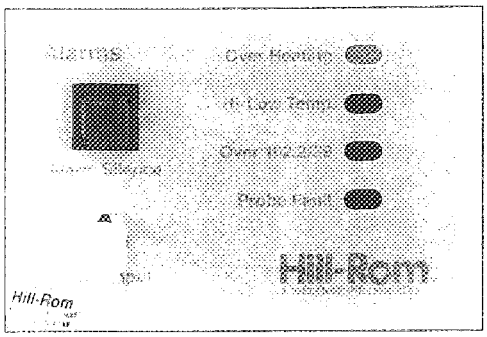
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

ALARM DESCRIPTIONS

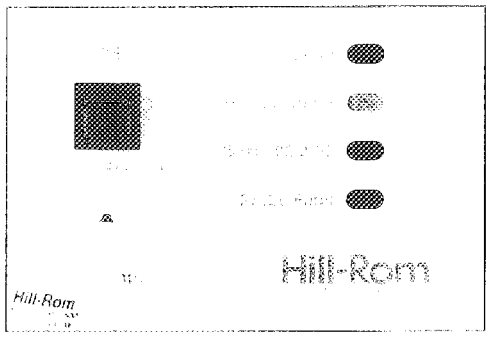
Overheating Alarm (Manual Mode Only)



- An Overheating Alarm will sound if there is constant heater output of 100% for approximately 18 minutes or approximately 30% (1 or 2 LEDS) for 73 minutes or any combination thereof of power and time.
- When the Overheating Alarm is triggered, power to the heater is reduced to approximately 30%.
- The Overheating Alarm can be silenced by depressing the Alarm Silence Button located on the left side of the Control Panel
- The unit will continue to operate in Manual Mode and no Overheating Alarm will sound as long as the heater output is kept under approximately 30% (1 or 2 LEDS) and a Thermistor Probe is not inserted into the Probe Jack or is inserted but does not sense a temperature of over approximately 31°C.
- Once the Probe is inserted in the Probe Jack and the Probe senses a temperature of approximately 31°C, the Infant Warmer becomes a Servo-Controlled Unit, controlled by the skin temperature of the infant.

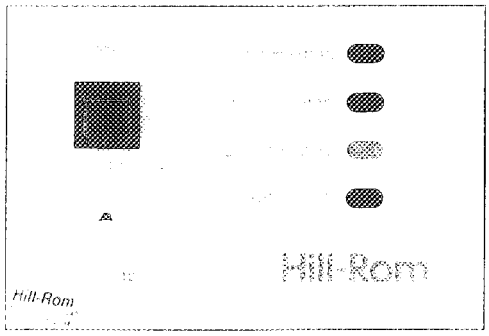
WARNING Do not leave the infant unattended.

Hi-Low Temperature Alarm



- If the infant's temperature has fluctuated more than ± .5°C from the set point temperature, a solid, visible Hi-Low Temperature LED Display will appear immediately on the Infant Warmer Control Panel.
- If after four minutes the high-low temperature has not been rectified, an audible Hi-Low Temperature Alarm will sound.
- During the (audible) alarm condition, heater output will change to approximately 30% until the alarm is silenced.
- The Hi-Low Temperature Alarm can be silenced by depressing the Alarm Silence Button; however, the Hi-Low Temperature LED Display will remain lit until the infant's skin temperature returns to within the target range. If the infant's temperature remains outside of the ± .5°C setpoint for another 4 minutes the audible alarm will again sound.
- When the Hi-Low Temperature condition is rectified, the Hi-Low Temperature Alarm will automatically reset.

Over 102.2°F/39°C Alarm



- An audible and visible Over 102.2°F/39°C Alarm will sound immediately if the Thermistor Probe senses that the infant's skin temperature exceeds 102.2°F/39°C.
- Heater output is reduced to 0% and will not resume until the Thermistor Probe senses that the infant's temperature has fallen below 102.2°F/39°C.
- The alarm will not silence until the condition is rectified

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

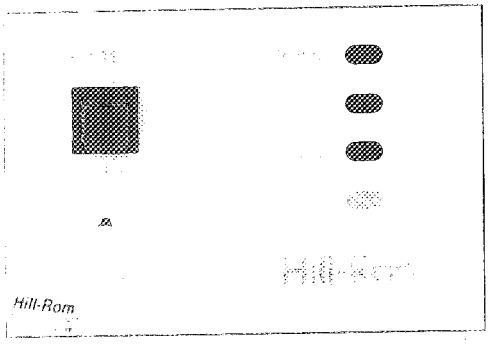
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

Probe Fault Alarm

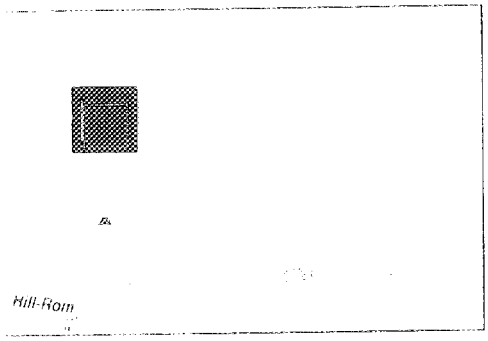
In the Manual Mode when the Probe is not inserted in the Probe Input Jack, the Probe Fault LED will remain lit.

- In the Servo Mode, whenever the Probe senses a temperature of less than approximately 31°C for approximately one minute, the Probe Fault LED will come ON, an audible alarm will occur and heater output will drop to approximately 30%.
- When the alarm is silenced by depressing the Alarm Silence Button. If sensed temperature is still below 31°C, the Probe Fault LED will remain lit and the unit will revert to manual mode. If the sensed temperature is above 31°C, the Probe Fault LED will go off and the unit will revert to Servo Mode



System Fault Alarm

- A System Fault Alarm has occured when an audible alarm sounds and all alarm LED displays illuminate.
- The system continually monitors itself electronically to ensure complete thermoregulation integrity. If, at any time, the Heater Control Signal and the actual Heater Current Signal do not agree, AC power/heater output is immediately terminated and a System Fault Alarm is activated.
- The System Fault Alarm may also be activated by connecting an incompatible temperature Probe or when the Probe is shorted or when there is an open heater element
- The alarm cannot be silenced until the condition is rectified.
- The alarm may indicate a system failure and require maintenance by a qualified technician.



s of AC Power Alarm

If the unit becomes unplugged or AC power is interrupted to the unit when the Power Switch is ON, a pulsating alarm will sound. This Loss of AC Power Alarm will fade after approximately 2 minutes, or will automatically reset if power is restored to the unit.

- The Loss of AC Power Alarm works off a capacitor that will recharge when AC power is restored to the unit and the Power Switch is turned on.
- No batteries are required for the operation of this alarm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES/BASSINET

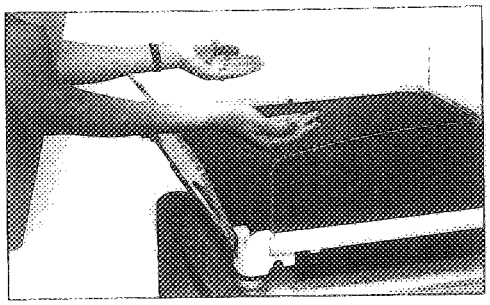
BASSINET

The Stabilet Clinical Bassinet has Fold-Down Front, Rear and Side Panels to allow greater access to the Procedure Table

To Lower

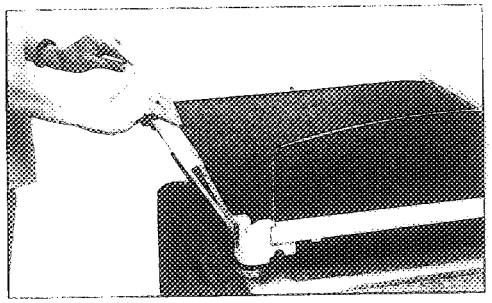
- To lower the Front, Back, or Side Panels, press down and pivot panel out and down with forearm or hands.

CAUTION: Do not leave infant unattended when Panels are lowered.



To Raise

- To raise the Panels, grasp the panel and rotate up and towards the Bassinet.
- Move the panel gently to ensure that it is securely locked in the upright position.

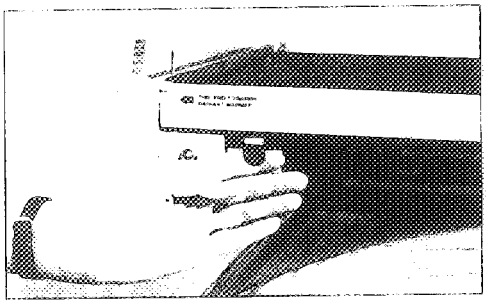


To Lock (So that the Side Panels cannot be accidentally lowered)

- Locate locking mechanism, positioned under each panel, and gently pull out until it stops.
- Push down gently to ensure that it is locked.

To Unlock

- Locate locking mechanism, positioned under each panel, and push in until it stops.



TRENDELENBURG/REVERSE TRENDELENBURG/LEVEL SLEEP SURFACE

Trendelenburg

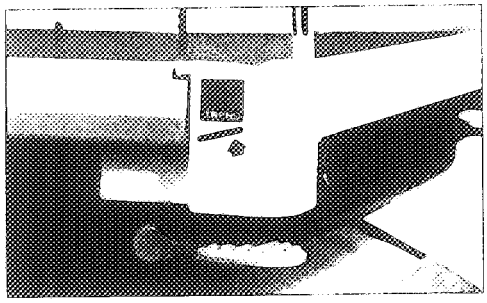
- Depress either of the handles located beneath the Front Panel of the Bassinet and lift. The Bassinet will rotate from 0° to 10° Trendelenburg with a 0°, 5° and 10° detent

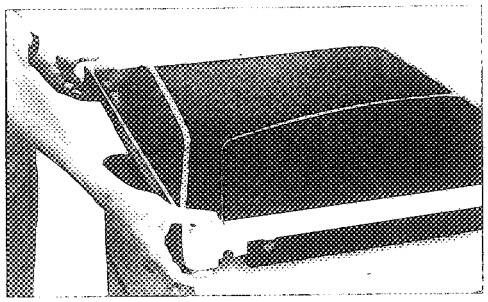
Reverse Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet.
- Push down on the Bassinet from the front using the Trendelenburg Mechanism.
- Lift the Bassinet from the end opposite of the handles. The Bassinet will rotate from 0° to 10° Reverse Trendelenburg, with a 0° and 5° detent

Level Sleep Surface

- Depress either of the handles located beneath the Front Panel and guide the Bassinet to a center position





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016.

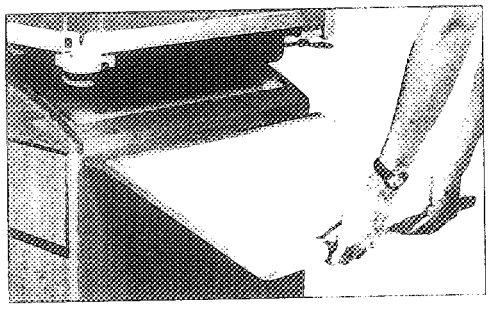
FEATURES

DROP LEAF WORK SURFACE/CHART HOLDER

built-in Drop Leaf Work Surface can be used as an instrument shelf ing procedures as well as a surface for charting. Do not overload work face. Also located on the Bassinet is a built-in Chart Holder which allows you to store the infant's records within easy reach.

To Access

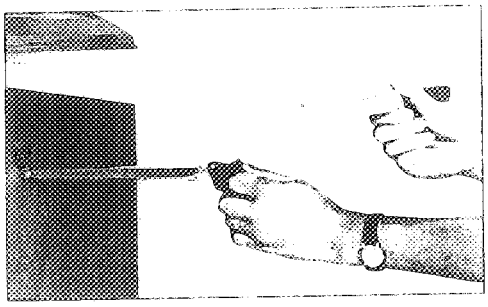
- Grasp the work surface and pivot up until it locks into place.



To Store

- Grasp the ring located directly beneath the work surface and pull downward while supporting it with your hand
- The shelf will lower to a flush position against the Bassinet.

WARNING Do not place the infant on the Drop Leaf Work Surface. The surface has a load rating of 25 lbs.

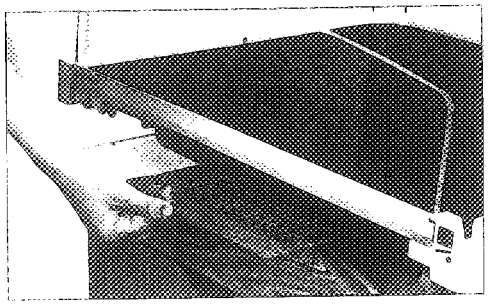


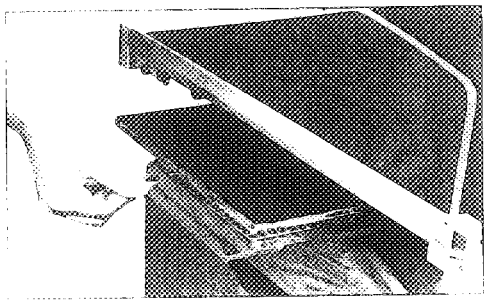
BUILT-IN X-RAY CASSETTE HOLDER

X-Ray Cassette Holder accomodates cassettes up to 12" x 14"

oading X-Ray Cassettes

- Working from either side of the Bassinet locate the X-Ray Cassette Tray directly beneath the Sleep Surface
- Release the X-Ray Cassette Tray by lifting the tray up and pulling out
- While supporting the X-Ray Cassette Tray place the film cassette on the tray.
- Slide the cassette and X-Ray Cassette tray in toward the Bassinet until it rests securely and flush beneath the Bassinet
- A slight detent will be felt indicating that the tray is "locked" into place
- The Heating Element may be pivoted 90° away from the Mattress to provide easy access over the Sleep Surface by an X-Ray Machine

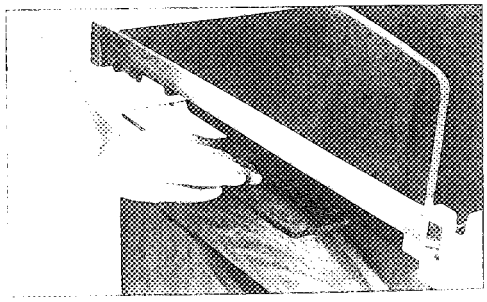




Unloading X-Ray Cassettes

- When X-Ray is complete, lift the X-Ray Cassette Tray up and pull it gently away from the Bassinet.
- Remove the X-Ray cassette and slide the tray back in toward the unit to a normal operating position.

OTE The mattress is radiolucent



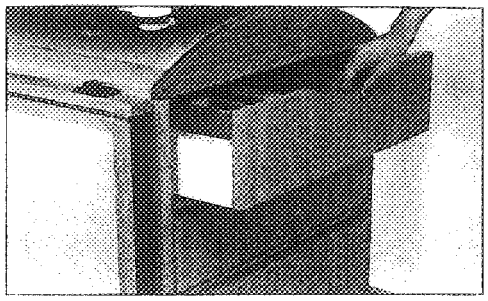
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

STORAGE DRAWERS

A built-in Slide-Through Storage Drawer is accessible from either side of the unit and has a removable plastic tray (compartmentalized) for small equipment and disposable items. Two additional Storage Drawers, located on the right side of the unit, slide out for easy access.



To Access

- Grasp the Drawer Handle and pull drawer out and away from unit.

To Close

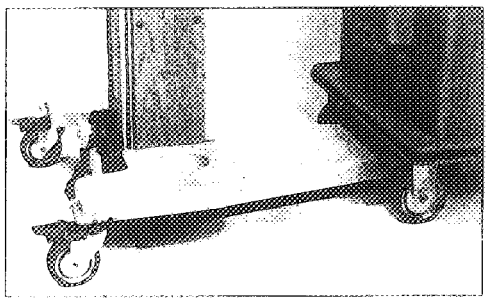
- Slide the drawer in until it is flush with the Bassinet.

DOCKING MECHANISM

The Stabilet Freestanding Infant Warmer and Bassinet will dock together to create an attractive infant care station. A steering handle, located on the Warmer Column, allows easy movement of the care station.

To Dock

- Position the Stabilet Freestanding Infant Warmer and ensure that the two rear locking casters are in the locked position.

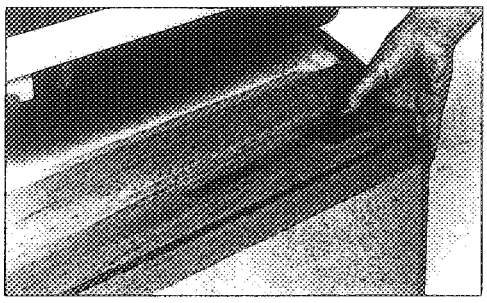


CAUTION After setting the brakes, gently rock the unit to check for movement of the unit.

- Align the Bassinet with the Warmer and slowly push the Bassinet toward the unit until the two units lock together, with the Chart side toward the Warmer.
- Release Infant Warmer's brakes. The Warmer and Bassinet will now move together as one unit.
- To achieve positive braking of both units, ensure that the two rear locking casters on the Infant Warmer and the two front locking casters on the Bassinet are in the locked position.

To Disengage

- Ensure that the two rear locking casters on the Infant Warmer are in the locked position.
- Release Bassinet brakes.
- Release the docking mechanism lever located on Bassinet and hold while slowly pulling Bassinet away from Infant Warmer.
- Release Infant Warmer brakes. The Infant Warmer and Bassinet will now operate as two separate units.



CAUTION The Infant Warmer and Bassinet brakes should **ALWAYS** be set when the unit is occupied. Brakes should be periodically tested and adjusted if necessary.

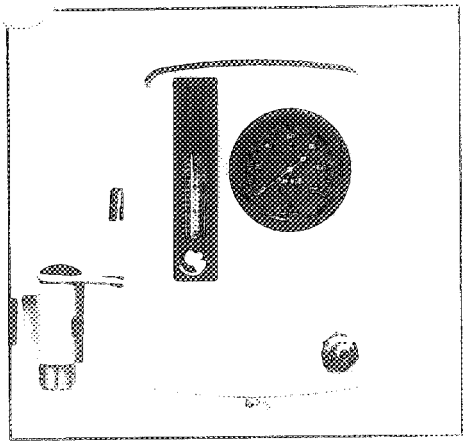
CAUTION The Thermistor Probe must be detached from the infant before separating the Infant Warmer and the Bassinet.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

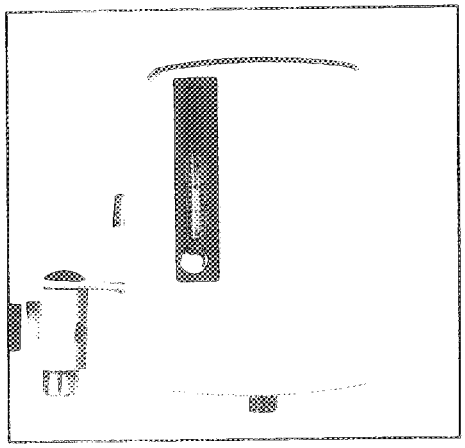
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

RESUSCITATION MODULES

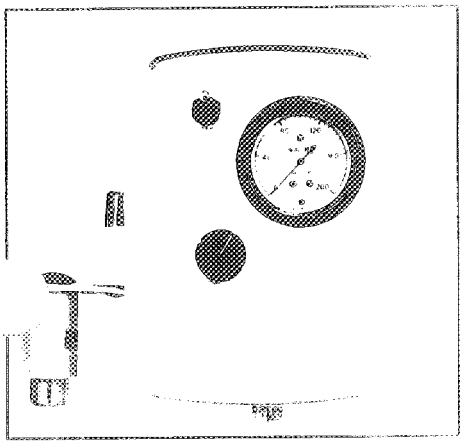
Resuscitation Modules for the Stabilet Infant Warmer products include:



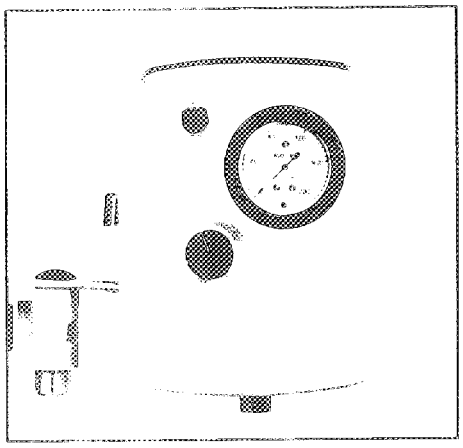
P1276 Oxygen Module (Flow and Airway Pressure)



P1278 Oxygen Module (Flow Only)



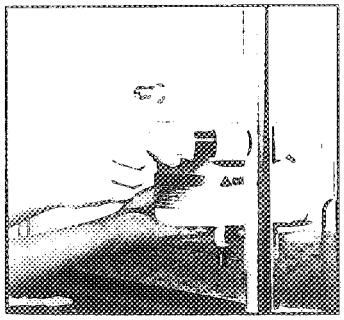
P1280 Suction Module (Wall Only)



P1281 Suction Module (Venturi Only)

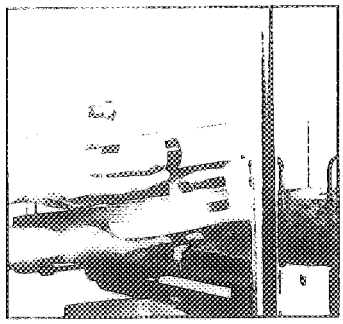
NOTE Resuscitation Modules are intended for use only on the Stabilet Infant Warmers.

To Mount The Resuscitation Modules



- Position the module on the pole at the desired height.
- Tighten the module knob by turning it counter-clockwise.
- Shake the module gently to ensure it is properly mounted.

To Remove The Resuscitation Modules



- Disconnect all tubing from the module.
- Loosen the module knob by turning it clockwise.
- Lift the module gently away from the pole.

NOTE You must have a Hill-Rom Infusion Pump Holder accessory or Post Utility Mount accessory in order to mount the Resuscitation Modules on the Stabilet Infant Warmers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

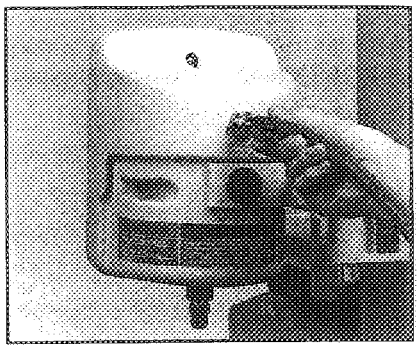
61

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

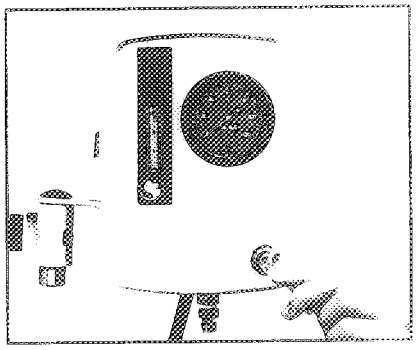
ACCESSORIES

To Use Oxygen Source (Cylinder or Wall)
Oxygen can be administered from a regulated wall source or from oxygen cylinders. Using cylinders permits the module to be used in transport situations.

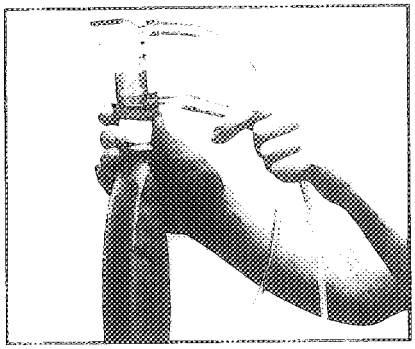
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module.



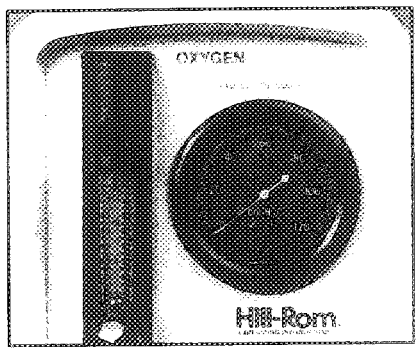
OXYGEN MODULE (FLOW AND AIRWAY PRESSURE)
To Utilize Oxygen Module (Flow and Airway Pressure)



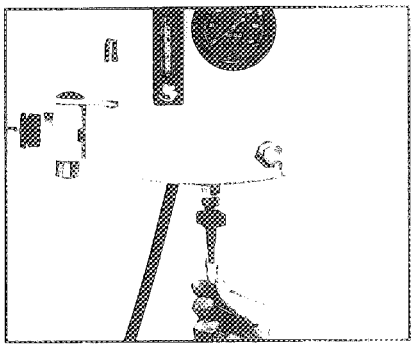
Connect one end of the Oxygen Tubing to the nipple located on the front of the oxygen module. This measures the amount of pressure being delivered during resuscitation.



Connect the opposite end of the Oxygen Tubing to the Manometer Connector located on the Resuscitation Bag and Mask.



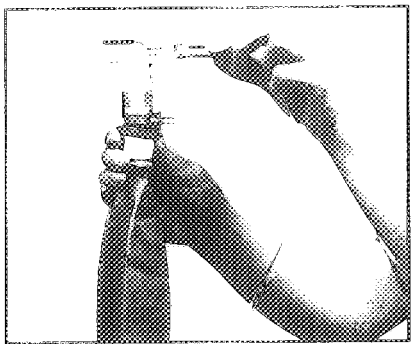
The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the front of the module. Airway Pressure is measured from 0 to 120 cm H_2O.



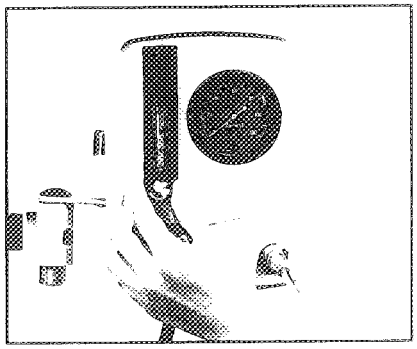
Using an appropriate adaptor, connect one end of a Second Oxygen Tubing to the DISS fitting located underneath the oxygen module.

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing.

CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.



Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

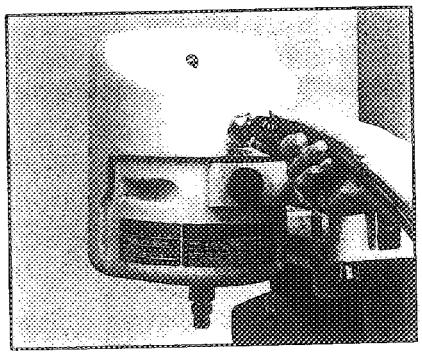
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

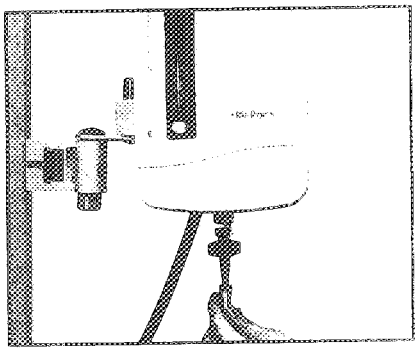
To Use Oxygen Source (Cylinder or Wall)

ygen can be administered from a regulated wall source or from oxygen nders. Using cylinders permits the module to be used in transport situations.

- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module.

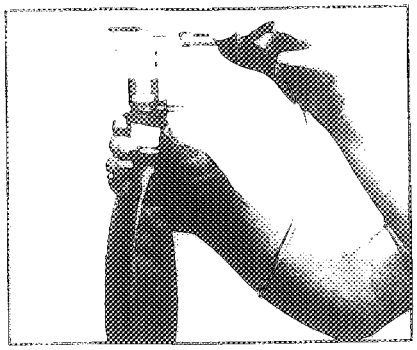


OXYGEN MODULE (FLOW ONLY)
To Utilize Oxygen Module (Flow Only)

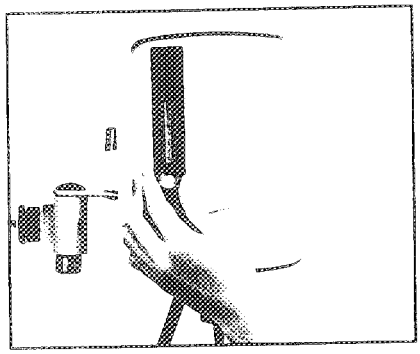


Using an appropriate adaptor, connect one end of the Oxygen bing to the DISS fitting located derneath the oxygen module.

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.



Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

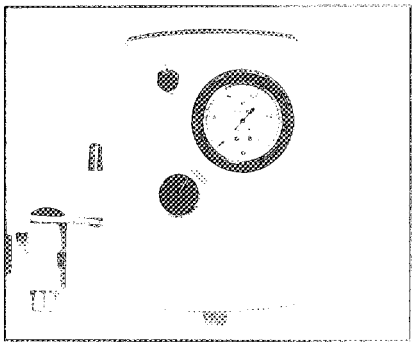
CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

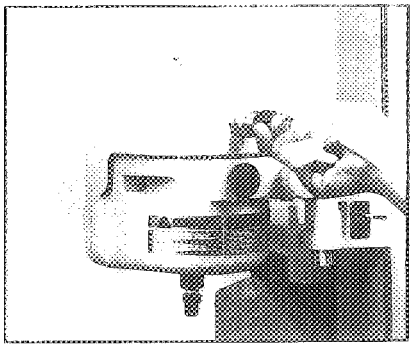
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ACCESSORIES

SUCTION MODULE (WALL ONLY)



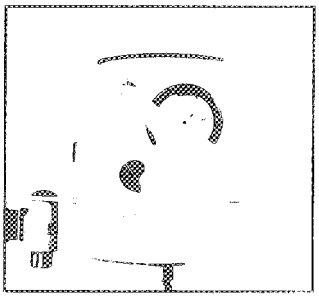
Suction is accomplished by the use of Wall Suction and is variable from 0 to 160 mm Hg.



To Use Wall Suction Source

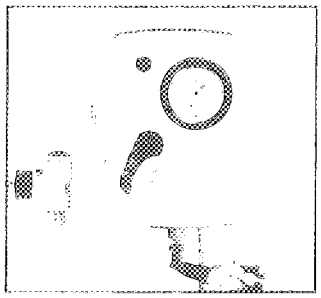
- Connect one end of vacuum hose to wall source of vacuum using a gas outlet adaptor
- Connect second end of vacuum hose to DISS fitting located on the back of the suction module

Set Rate

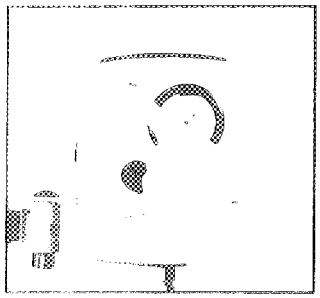


Turn the suction on with the On/Off Switch located on the front of the module.

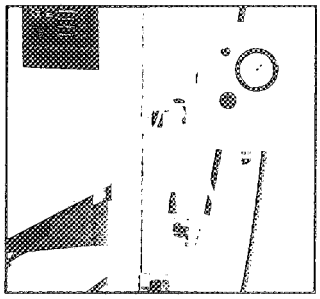
NOTE Properly occlude the Suction Port located underneath the suction module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the suction Module) to the desired setting while occluding the Suction Port.



Turn the suction off with the On/Off Switch located on the front of the module.



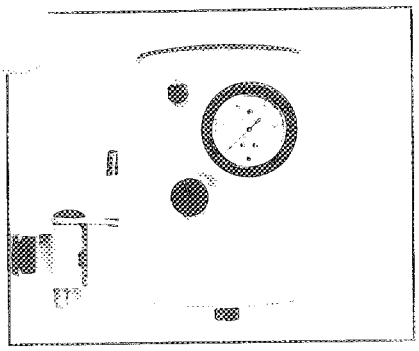
Attach Disposable Suction Canister to the Port located underneath the module.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

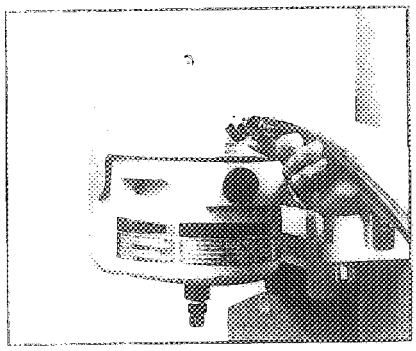
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ACCESSORIES

SUCTION MODULE (VENTURI ONLY)



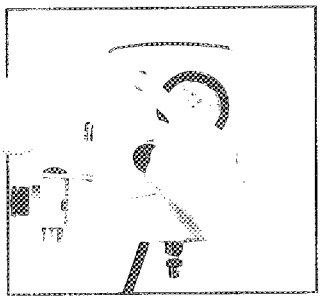
Venturi Suction is accomplished by the use of either Wall or Cylinder Oxygen and is variable from 0 to 160 mm Hg.



To Use Oxygen Source for Venturi Suction (Cylinder or Wall)

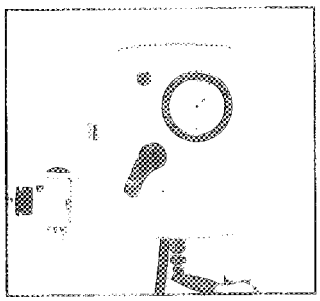
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting located on the back of the suction module.

Set Rate

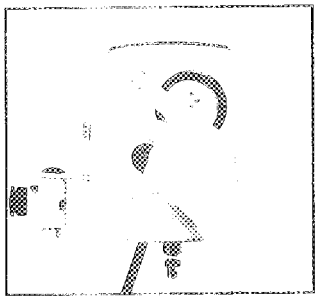


Turn the suction on with the On/Off Switch located on the front of the module.

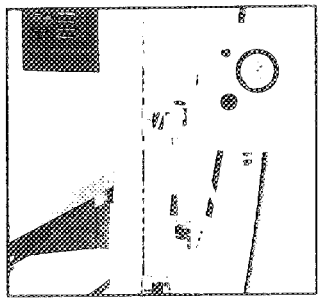
NOTE Properly occlude the Suction Port located underneath the Suction Module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the Suction Module) to the desired setting while occluding the Suction Port.



Turn the suction off with the On/Off Switch located on the front of the module.



Attach Disposable Suction Canister to the Port located underneath the module.

NOTE To increase Oxygen Cylinder life:

1) Turn the cylinder off when not in use or when utilizing Wall Source of oxygen.
2) Do not set suction level any higher than necessary to complete procedure.
3) Turn suction off when not in use.
4) Connect unit to Wall Oxygen Source when available and practical.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

STERILIZATION

The Centers for Disease Control recommend EPA approved hospital disinfectants, used at manufacturers suggested dilutions.

Cleaning should be done by wiping a soft dampened cloth over the surface, followed by wiping with a dry cloth.

Quartenary ammonium disinfectants may be used to reduce the contamination level between patients.

Alcohol, strong or abrasive cleaners and hydrocarbon solvents are not necessary and should not be used on plastic surfaces.

MATTRESS CARE

The mattress cover may be cleaned with a mild detergent, rinsed, and cold sterilized. The following products have been tested by the Herculite Laboratory and have been found not to have a harmful effect on StaphChek fabrics WHEN USED IN ACCORDANCE WITH MANUFACTURERS' RECOMMENDED DILUTION.

TRADE NAME	TYPE	MANUFACTURER
A33	Quartenary	Airwick
Absolute	Quartenary	Walton-March
Beaucoup	Phenolic	Huntington
Blue Chip	Quartenary	S.C. Johnson
Coverage 256	Quartenary	Vestal
El Dorado Plus	Quartenary	Puritan/Churchill
Elimstaph	Quartenary	Walter G. Legge
Forward DC	Quartenary	S.C. Johnson
Franklin Sentinel	Quartenary	Purex
Galahad	Phenolic	Puritan/Churchill
Hi-Tor	Quartenary	Huntington
Insurance	Quartenary	Vestal
LPH	Phenolic	Vestal
Matar	Phenolic	Huntington
Omega	Quartenary	Airwick
Quanto	Quartenary	Huntington
Sanikleen	Quartenary	West Chemical
Sanimaster 111	Quartenary	Service Master
Surfacide	Quartenary	Walton March
Tri-Quat	Quartenary	Vestal
Vesphene 11	Phenolic	Vestal
Virex	Quartenary	S.C. Johnson

Betadine stains may be removed from the mattress by doing the following:

- Use a 5.25% sodium hypochlorite solution (Clorox brand bleach).
- Apply 3 drops of the solution per square inch immediately and scrub lightly. The stain should start to fade almost immediately and within 15 minutes should be totally gone.
- Stubborn stains may need further applications. No more than 3 applications on any one area are recommended.
- When completely dry, rinse area with clear water and wipe dry.
- If solution comes into contact with skin, wash off with water and follow manufacturer's label instructions.

CLEANING OF THERMISTOR PROBE

Several precautions must be observed when cleaning and sterilizing to protect Probe from damage.

Avoid contact with strong, aromatic, chlorinated, ketone ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the cable to lose flexibility.

Probe may be disinfected and sanitized by washing with 3% hydrogen peroxide, 70% isopropanol, 70% ethanol, or 100% alcohol. Dakin's solution (sodium hypochloride in neutral buffer) is also suitable. Activated dialdehyde solutions, such as Cidex, are also effective.

Probe plug should not be immersed.

STERILIZATION OF THERMISTOR PROBE

Ethylene oxide sterilization is the preferred method. After sterilization, Probes must be safely and thoroughly ventilated before handling or use.

CAUTION: Autoclaving may cause Probe insulation to fail, and may also cause the Probe to give inaccurate reading.

CLEANING OF CASTERS

The Stabilet Freestanding Infant Warmer will be used both in and outside aseptic surgical areas. Care should be taken to assure the casters do not carry contamination into the surgical suite. Removal of accumulated debris and treatment of the caster tread with a spray of disinfectant solution as the unit is transferred into the surgical suite is recommended.

CLEANING OF SIDE PANELS

The Clinical Bassinet side panels are made of clear polycarbonate plastic and can be damaged by cleaning with alcohol, abrasive agents, hydrocarbon solvents or phenolic disinfectants. Use only gentle detergents for cleaning and polish with a soft cloth to return clarity.

MAINTENANCE

The Stabilet Freestanding Infant Warmer and Resuscitation Modules need regular care and maintenance, as detailed in the Service Manual. Please request your maintenance technician to follow the preventive maintenance section in the Service Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

SAFETY TIPS

For over 65 years, Hill-Rom has set the standard for ality in patient room equipment. During this time, with ut from many of our customers, we have acquired eful tips which may contribute to the safety of the infant and staff.

SIDE PANELS
To provide maximum protection for the infant, the side panels should always be in a full, upright position and latched when an infant is unattended. To ensure the side panels are latched, give the side panels a gentle tug.

TRANSFERRING THE STABILET FREESTANDING INFANT WARMER
Although the unit is lightweight and easy to move, be sure to keep hands and feet clear of the wheels when moving to prevent destabilization of the unit or injury to hands or feet.

BRAKES
Brakes should always be set when the Clinical Bassinet is occupied. After setting the brakes, push and pull the unit to ensure they are engaged.

X-RAY CASSETTE HOLDER
If using the X-Ray Cassette Holder accessory, always secure the holder to the unit when not in use. This will avoid possible damage to the unit and holder.

RESUSCITATION MODULES
Warmer Module should always be kept over the center of the Bassinet when Modules are attached.

VENTIVE MAINTENANCE
arterly preventive maintenance must be performed ensure all features are functioning as originally designed. Particular attention must be addressed on safety features, including but not limited to:

- Side Panel Latching Mechanisms
- Caster Braking Systems
- Electrical Cords and Components
- Quartz Heater
- Temperature Alarm System
- Scheduled Recalibration

Please refer to your Service Manual for specific details on preventive maintenance.

PARTS AND ACCESSORIES
Use only Hill-Rom parts and accessories. Do not modify the unit without authorization from Hill-Rom.

CAUTION
Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

'RECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Manufactured for Hill-Rom under a quality system certified to **ISO 9001/EN46001** by TÜV Product Service of San Diego, CA

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.

© Hill-Rom, 1996

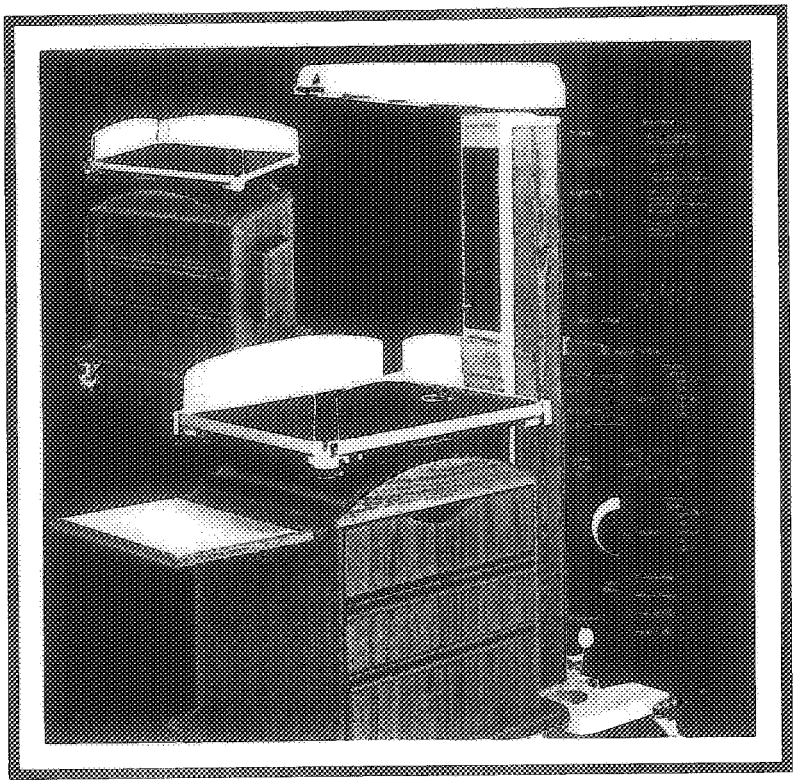
Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800-638-2546
International • 812-934-8173 • FAX 812-682-7101

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

W6133A RC996

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

A HILL-ROM SOLUTION



STABILET FREESTANDING
INFANT WARMER AND
CLINICAL BASSINET

Hill-Rom

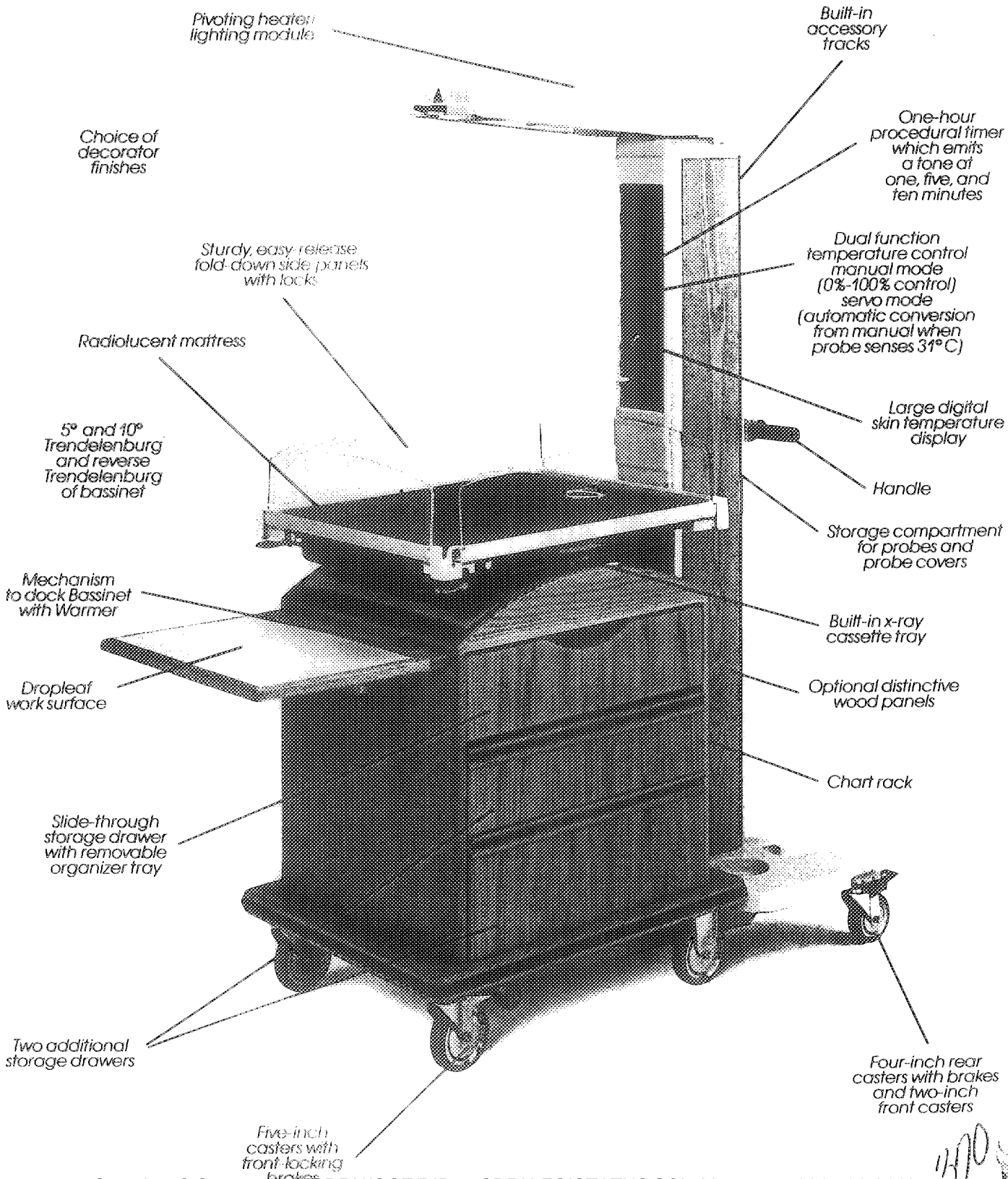
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

19

260

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

The Stabilet Freestanding Infant Warmer and Clinical Bassinet were designed to meet the ever changing demands of today's perinatal environments. The Infant Warmer can be used with Hill-Rom's bassinets and with other bassinets currently on the market. The Clinical Bassinet can be used with other warmers and as a functional rooming-in bassinet. Its sturdy construction is highlighted by a special Relplaz finish to minimize upkeep and to last in demanding perinatal environments. Together, these products offer you the solution to support a wide range of newborn care needs.

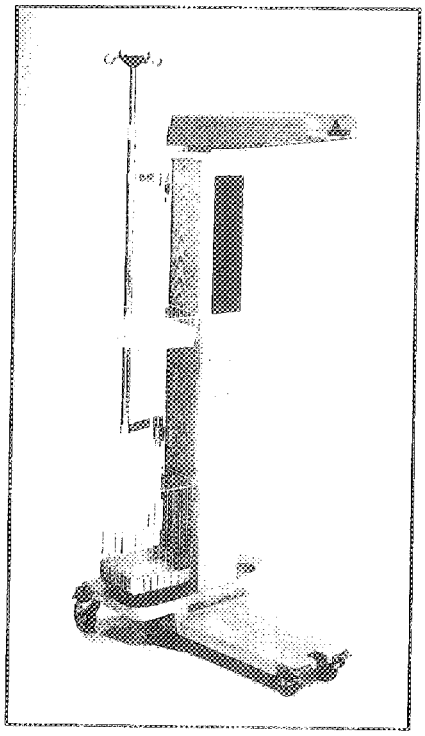


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

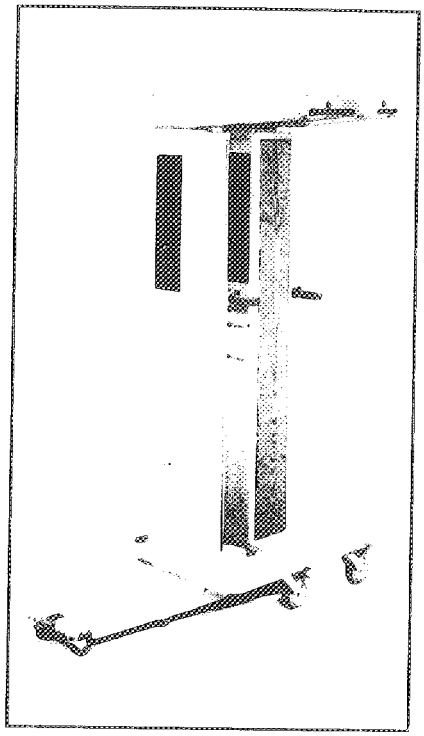
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Infant Warmer

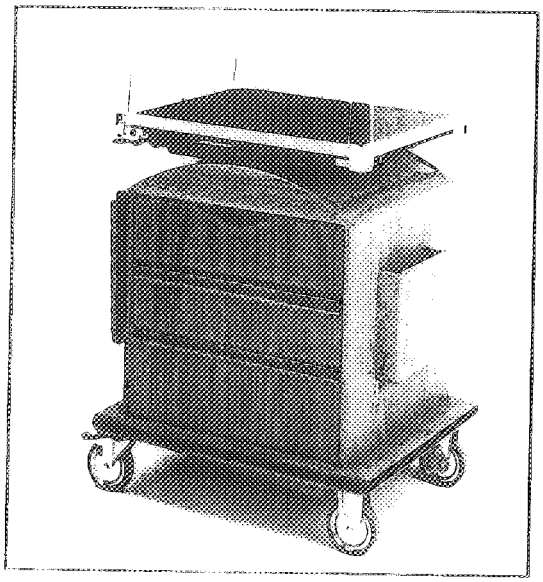
A large digital temperature display and automatic conversion from manual to servo-mode temperature control simplify the operation. A sophisticated alarm system can enhance infant safety. A procedural timer and exam light can facilitate medical procedures.



The specifically designed accessory tracks and accessories allow you to customize the Infant Warmer to meet your individual needs. The optional distinctive wood panels create a pleasing appearance for your unit.



The unique design of the Infant Warmer's base and heater housing significantly reduce storage space requirements. The Infant Warmer can also be used with other bassinets.



Clinical Bassinet

The Clinical bassinet features a unique chart rack and slide-through drawer (with an organizer tray) to further increase efficiency.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Specifications

Alarms
erheating
temperature
ver 102.2° F/39° C
Probe fault
System fault
Loss of AC power

Accessories/Options
Large and small storage baskets
Phototherapy light
IV pole
Utility mount, IV hanger

Decorator Finishes
Bleached Oak
Light Oak
Medium Oak
Dark Oak
Cherry

Electrical
760 Watt, 120 VAC heater
120+/-10% VAC, 60Hz, 7 Amps
Fully grounded through 3-wire power cord
Current leakage less than 50 mircoamps
Temperature display accuracy +/0.1°C

Warmer Dimensions
gth 34"
dth 28"
Height 69"
Floor to heater 65"
Weight 164 lbs.

Bassinet Dimensions
Length 27"
Width 24"
Height of mattress 36"
Mattress to heater 29"
Weight 162 lbs.

This product is supported by professional account executives, experienced perinatal consultants and technical specialists. We also provide educational seminars, featuring perinatal clinicians and consultants, to help you design and implement your perinatal system.

Service
Hill-Rom products should be serviced only by qualified technicians. Our fully trained Customer Service Representatives and Field Technicians stand ready to assist you with questions or problems. For more information on how we can meet your service requirements, please call us at 800-445-3720.

Warranty
Hill-Rom extends a limited warranty covering defects in workmanship and material under normal use for a period of one year from purchase. A 60-day warranty is applied to expendable parts such as overhead fluorescent tubes, heating element and probes.

DIRECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800 638-2546
International • 812-934-8173 • FAX 812-934-7101

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty accompanying the sale or rental of Hill-Rom products.
Hill-Rom 1999

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

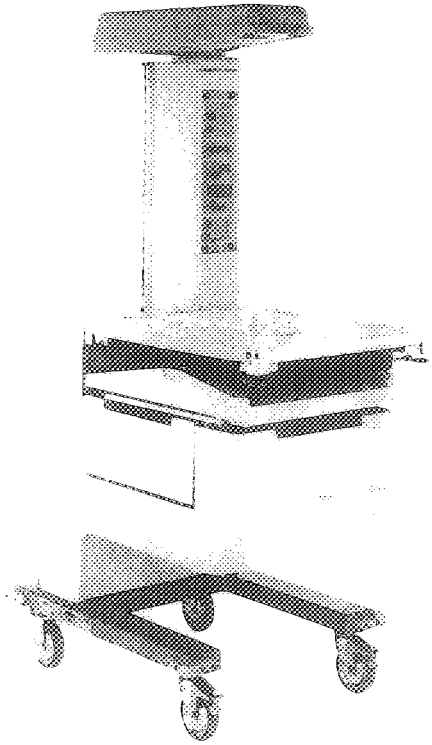
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

IN-SERVICE MANUAL

Stabilet™ CC Infant Warmer

From Hill-Rom®



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

TABLE OF CONTENTS

FEATURES 1

SPECIFICATIONS 1

FEATURES

Two-Position Warmer Module 2

Over Center Of Bassinet 2

X-Ray And Mother/Baby Bonding 2

Bassinet 2

Retractable Mayo Tray 2

Slide-Through Storage Drawer 3

Trendelenburg/Reverse Trendelenburg/ Level Sleep Surface .3

Apgar/Procedure Timer 3

Lighting Button Module 3

Tilt-Out Front Storage Compartment 3

Built-In X-Ray Cassette Holder/Radiolucent Mattress 4

Accessory Tracks 4

Tank Storage 4

Thermal Control Center 5

Manual Mode 5

Servo Control Mode 6

Alarm Descriptions 7

Overheating Alarm 7

Hi-Low Temperature Alarm 7

Over 102.2°F/39°C Alarm 7

Probe Fault Alarm 8

System Fault Alarm 8

Loss Of AC Power Alarm 8

OPTIONS

Scale 9

Patient Weighing 10

ACCESSORIES

Resuscitation Modules 11

Oxygen Module (Flow and Airway Pressure) 12

Oxygen Module (Flow Only) 13

Suction Module (Wall Only) 14

Suction Module (Venturi Only) 15

CLEANING 16

SAFETY TIPS 17

FOR SPECIAL ASSISTANCE:

Hill-Rom Account Manager ..... Phone .....

Perinatal Consultant ..... Phone .....

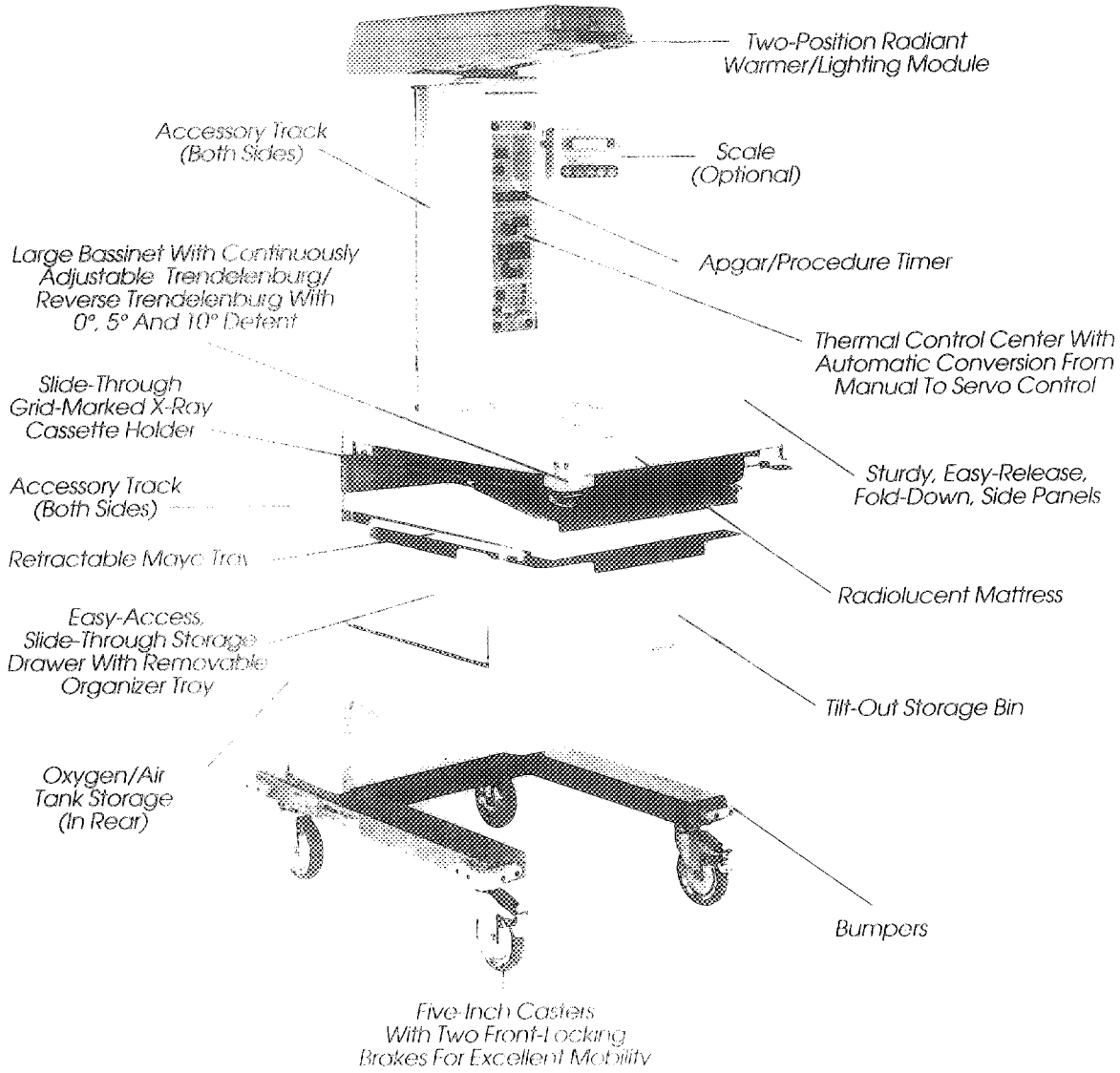
Field Service Technician ..... Phone .....

Customer Service Representative ..... Phone .....

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES



SPECIFICATIONS

Height – Floor to top of unit ..... 72"
Height – Floor to top of side panel ..... 42"
Side panel height ..... 57"
Caster ..... 5"
Width – Overall ..... 27"
Width – Bassinet ..... 24"
Length – Bassinet ..... 28"
Mattress size ..... 26" x 22" x 1"
Mattress height – Floor to top of mattress ..... 37 7/"
Weight ..... 285 lbs.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

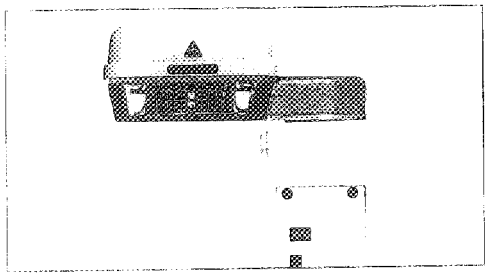
TWO-POSITION WARMER MODULE

Radiant Warmer Module provides a controlled source of radiant heat to unit through a 760 watt radiant quartz tube and a parabolic reflector.

Over Center Of Bassinet

- To place the heater into the standard operating position, rotate the heater 90°, placing it centrally over the Bassinet.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.

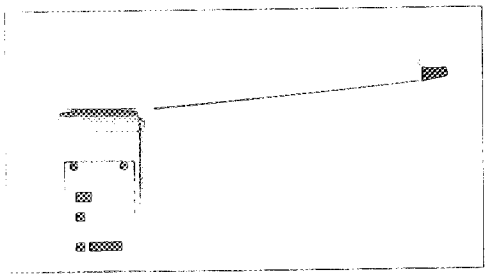
WARNING Do not place objects (equipment, blankets, clothing) on top of the Heater Housing. This could cause overheating of the unit and/or combustion of items placed on top of the warmer.



X-Ray and Mother/Baby Bonding

- Fold down front and side panels if applicable.
- Rotate the heater from the center position 90° to the right.
- For mother/baby bonding, verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.
- The heater may be rotated to allow the X-Ray machine to be properly positioned over the infant.

NOTE In this position, the warmer module will continue to deliver heat.



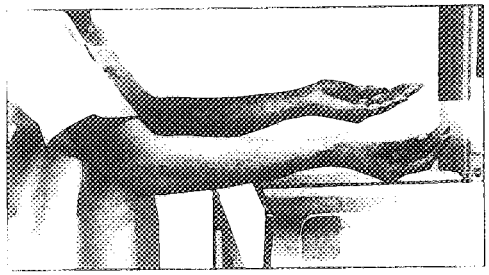
SINET

The Stabilet CC Bassinet has Fold-Down Front and Side Panels to allow greater access to the Procedure Table. An Infant Measurement Scale (in both inches and centimeters) and X-Ray Cassette Placement Grid are located on the Bassinet Panels.

To Lower

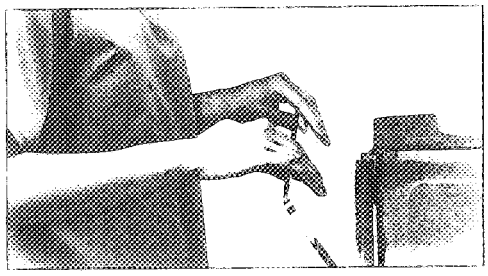
- To lower the Front or Side Panels, press down and pivot panel out and down with forearm or hands.

CAUTION Do not leave infant unattended when Front or Side Panels are lowered.



To Raise

- To raise the Front or Side Panels, grasp the panel and rotate up and towards the Bassinet.
- Move panel gently to ensure that it is secure.



RETRACTABLE MAYO TRAY

A built-in Retractable Mayo Tray can be used as an instrument shelf during procedures as well as a surface for charting. Do not overload the tray (25 lb load weight capacity).

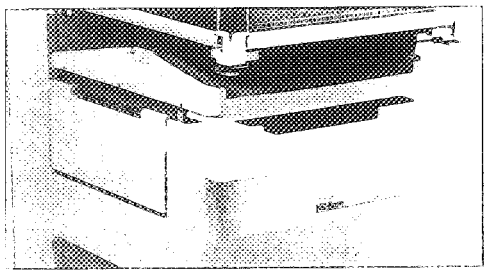
To Access

Grasp the tray and pivot out and toward the front of the unit until the tray stops.

To Store

- Rotate the tray toward the left side of the unit until it is flush with the Bassinet.

WARNING Do not place the infant on the Mayo Tray.



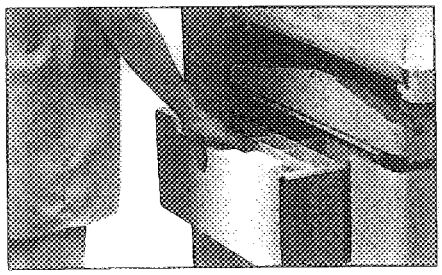
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

SLIDE-THROUGH STORAGE DRAWER

The built-in Slide-through Storage Drawer is accessible from either side of the unit and has a removable plastic tray (compartmentalized) for small equipment and disposable items.



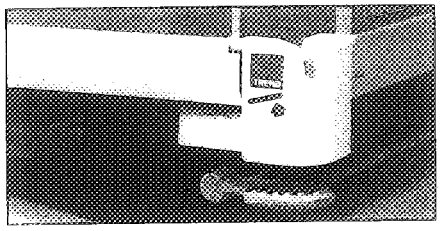
To Access

- Grasp the Cut-Out Drawer Handle and pull drawer out and away from the unit.

To Close

- Slide the drawer in until it is flush with the Bassinet.

TRENDELENBURG/REVERSE TRENDELENBURG/LEVEL SLEEP SURFACE

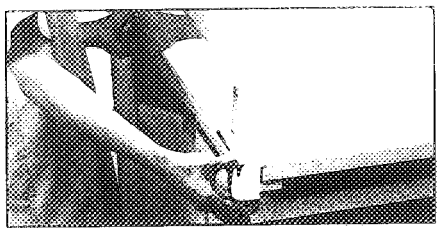


Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet and lift. The Bassinet will rotate from 0° to 10° Trendelenburg, with a 0°, 5° and 10° detent.

Reverse Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet.
- Push down on the Bassinet from the front, using the Trendelenburg Mechanism. The Bassinet will rotate from 0° to 10° Reverse Trendelenburg, with a 0°, 5° and 10° detent.

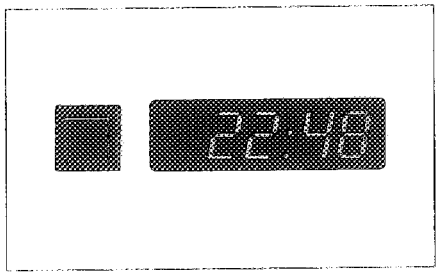


Level Sleep Surface

- Depress either of the handles located beneath the Front Panel and guide the Bassinet to a center position

APGAR/PROCEDURE TIMER

Located on the Stabilet CC Control Panel is a one hour electronic Apgar/Procedure Timer.

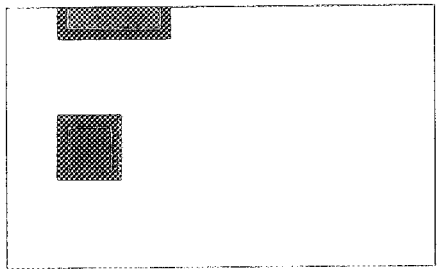


- To start the Apgar/Procedure Timer, depress the Start/Stop button located on the Control Panel.
- A visible four-digit display in minutes and seconds will appear on the Control Panel. The timer will begin at 00:00 and run to 59:59.
- A one-second audible tone will sound at one, five, and ten minutes
- Depress the Start/Stop Button again to reset the timer.

NOTE Power switch must be ON to operate timer and Overhead Light.

LIGHTING BUTTON MODULE

A Lighting Button located on the Stabilet CC Control Panel actuates two 15 Watt color correct fluorescent lights. The Main Power Button must be ON in order to activate lighting.



To Activate Lighting

- Depress the Lighting Button, located on the Control Panel

To Turn Lighting Off

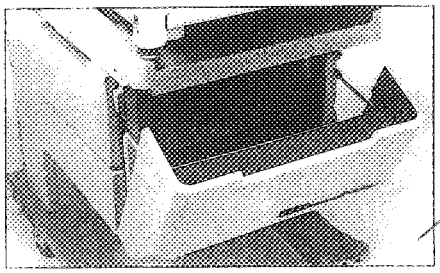
- Depress the Lighting Button again

NOTE To extend bulb life, turn the examination light on only as required.

NOTE Power switch must be ON to operate timer and Overhead Light.

TILT-OUT STORAGE COMPARTMENT

The Storage Compartment, located at the front of the unit, tilts out for easy access.



To Access

- Grasp Cut-Out Door handle at the front of the unit and pull the door gently toward you.

To Close

- Push the compartment door gently toward the unit. The Magnetic Catch will hold the door in place.

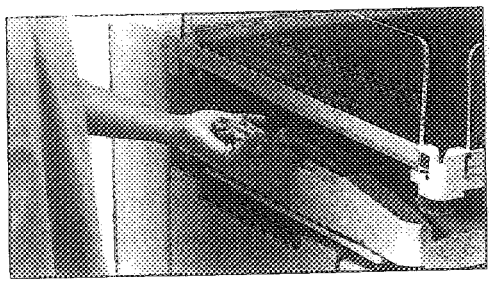
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

BUILT-IN X-RAY CASSETTE HOLDER

X-Ray Cassette Holder accommodates cassettes up to 12" x 14".



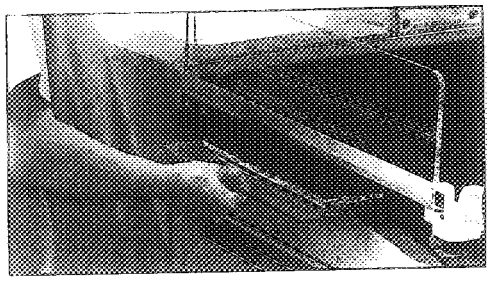
Loading X-Ray Cassettes

- Working from either side of the Bassinet, locate the X-Ray Cassette Tray directly beneath the Sleep Surface.
- Release the X-Ray Cassette Tray by lifting the tray up and pulling out.
- While supporting the X-Ray Cassette Tray, place the film cassette on the tray.

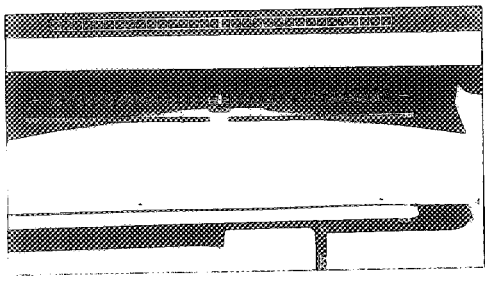
Unloading X-Ray Cassettes

- When x-ray is complete, lift the X-Ray Cassette Tray up and pull it gently away from the Bassinet.
- Remove the x-ray cassette and slide the tray back in toward the unit to a normal operating position.

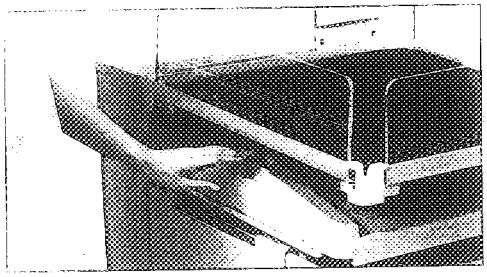
NOTE The mattress is radiolucent.



- To ensure proper cassette placement, align the X-Ray Cassette Tray Grid Markings with the markings located on the Bassinet Front and Side Panels. These grid markings allow you to position the cassette accurately relative to the infant's position in the Bassinet.

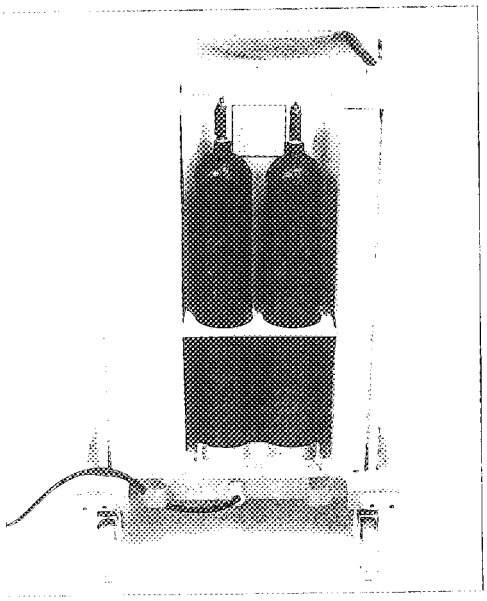


- Slide the x-ray cassette and X-Ray Cassette Tray in toward the Bassinet until it rests securely and flush beneath the Bassinet.
- A slight detent will be felt indicating that the tray is "locked" into place.
- The Heating Element may be pivoted 90° away from the Mattress to provide easy access over the Sleep Surface by an X-Ray Machine.



ACCESSORY TRACKS

Accessory tracks allow convenient placement of numerous accessories at comfortable working heights. The accessory tracks improve access to equipment and save valuable floor space.



TANK STORAGE

Two built-in Oxygen Tank Holders tuck out of the way in the rear of the unit.

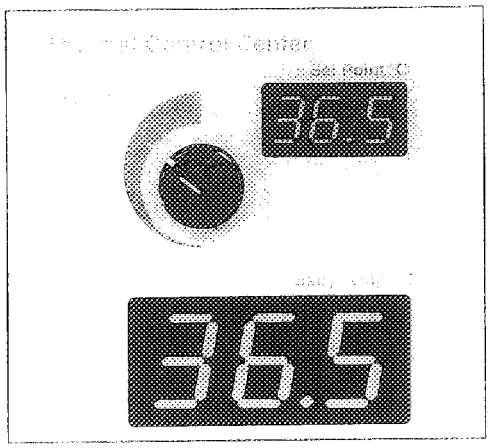
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

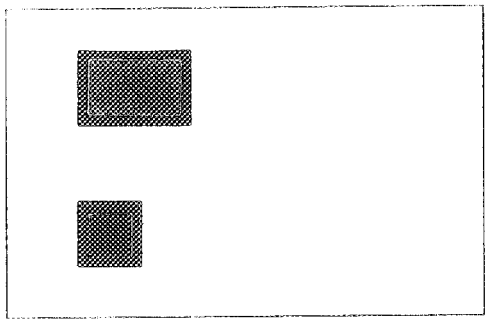
THERMAL CONTROL CENTER

Thermoregulation Controls are centrally located on the Control Panel between the Warmer Module and the Bassinet. Temperature may be set using the set point digital display once a Thermistor Probe has been inserted and senses a temperature of 31°C or greater.



Manual Mode

Manual Mode is intended primarily for warming the Bassinet and blankets in preparation for an infant or when it is impractical to attach a Thermistor Probe to the infant.



NOTE Before placing the infant in the Bassinet, pre-heat the Thermistor Probe, face up, in the Bassinet, prior to connecting the Probe into the Jack.

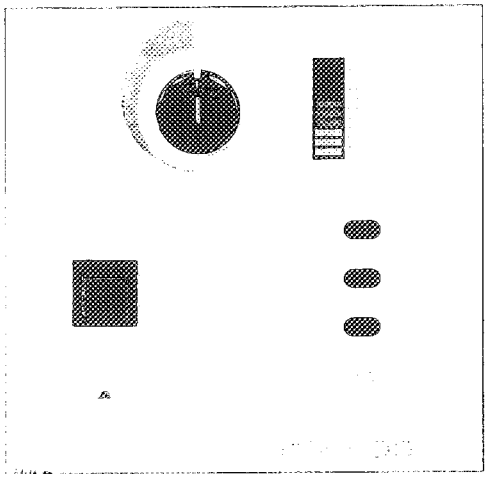
NOTE To avoid overheating or underheating of the infant, a Probe should be attached to the infant at all times while in a Radiant Warmer and the infant should not be left unattended.

- Plug the power cord into a standard 115V AC receptacle.

CAUTION Connect the power cord to a properly grounded receptacle that is approved for hospital use. Do not use an extension cord or AC receptacle box.

DANGER Possible explosion hazard if used in the presence of flammable anesthetics. This unit is not intended for use in hazardous Class 1, Group C locations.

- Turn the power on by depressing the Power Button located on the upright Control Panel.

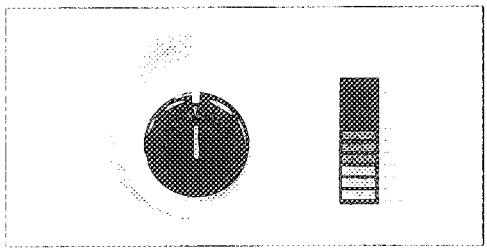


CAUTION The use of radiant warmers may cause insensible water loss.

NOTE The unit will function in the Manual Mode without a Thermistor Probe inserted in the jack. The Probe Fault LED Display will remain lit during this time.

NOTE Skin temperature alarms are NOT functional during Manual Mode when the Thermistor Probe is not inserted in the Probe Jack or when the Probe is inserted in the Probe Jack but senses a temperature less than approximately 31° C (88° F).

- Set the desired heater output using the Heater Output Control Dial located on the Thermal Control Center.
- Heater output is shown on the unit in terms of percentage of power and can be from 0% to 100%.
- The unit will remain at the set heater output you choose until you manually readjust it unless the Overheating Alarm is activated (see Overheating Alarm description).



NOTE In Manual Mode, when no heater output lights appear, it is an indication that heater output is 0%.
Green LEDs indicate approximately 10%-30% heater output.
Yellow LEDs indicate approximately 40%-70% heater output.
Red LEDs indicate approximately 80%-100% heater output.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

Servo Control Mode

When the Thermistor Probe is inserted into the Probe Jack and senses a temperature of approximately 31°C (88°F), the unit automatically converts to the Servo Control Mode.

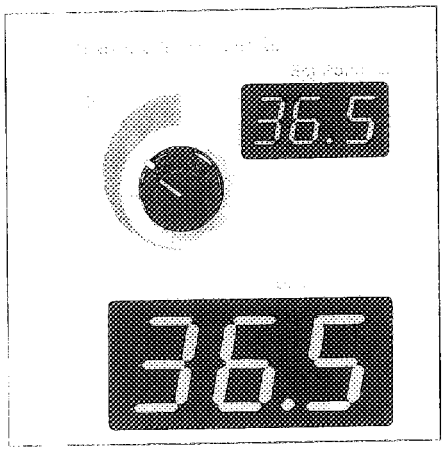
The Servo Control Mode allows the LED Heater Output Grid to indicate the amount of energy delivered to the warmer to keep the infant's skin temperature at the predetermined set point temperature.

Heater output is shown on the unit in terms of approximate percentage of power and ranges from 0% to 100%.

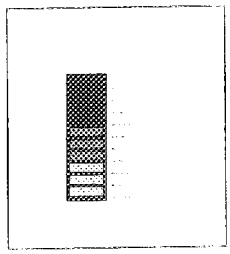
As the infant's skin temperature approaches the set point, the heater output will modulate to maintain the infant's skin temperature at the set point temperature.

Once the infant's skin temperature and the set point temperature are equal, only gradual changes in the heater output are needed to maintain the desired infant skin temperature.

A temperature readout displays the infant's skin temperature when the unit is in Servo Control Mode.



- Set the infant desired target temperature using the Servo Temperature Control Dial and the setpoint digital display. Turn the dial until the selected setting is indicated on the setpoint digital display.
- Attach the Thermistor Probe to the infant. The Probe should be pre-heated before registering the baby's skin temperature.



NOTE Placement of the Probe is vital because it is the Probe that senses the baby's skin temperature and regulates warmer output.

SUPINE INFANTS...place the flat stainless steel side of the Probe down on the infant's abdomen below the rib cage.

PRONE INFANTS...place the flat stainless steel side down on the infant's back below the rib cage, but away from the kidneys.

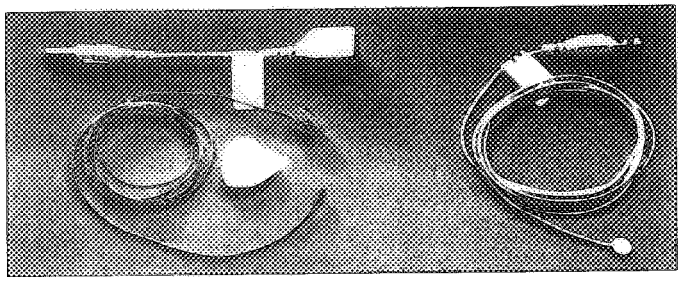
CAUTION Always attach the Probe with a reflective Probe cover. Serious temperature and control errors can occur if anything other than the recommended Probes and Probe covers are used. Do not use tape to attach the Probe.

CAUTION Inspect the infant's skin for reddened areas which may result from the heating of materials in contact with the skin.

CAUTION Avoid placement of objects (equipment, blankets, clothing) in the Bassinet that can block heat or absorb heat away from the infant.

NOTE Only the following Thermistor Probes should be used with the Stabilet CC Infant Warmer:

CAUTION Do not place the Warmer in areas near or beneath air conditioning or heating ducts. Drafts or forced air may cause a disruption in the heat distribution.



SA4567 Disposable Probe (Requires Reusable Adapter Cable SA4566)

BCZ009 Reusable Probe

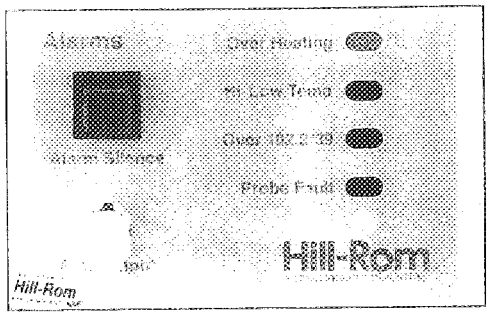
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

ALARM DESCRIPTIONS

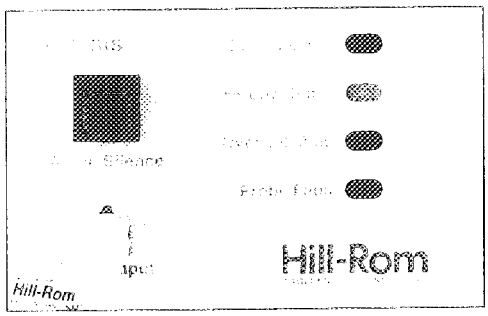
Overheating Alarm (Manual Mode Only)



- An Overheating Alarm will sound if there is constant heater output of 100% for approximately 18 minutes or approximately 25% (2 or 3 LEDS) for 73 minutes or any combination thereof of power and time.
- When the Overheating Alarm is triggered, power to the heater is reduced to approximately 30%
- The Overheating Alarm can be silenced by depressing the Alarm Silence Button located on the left side of the Control Panel.
- The unit will continue to operate in Manual Mode and no Overheating Alarm will sound as long as the heater output is kept under approximately 30% (1 or 2 LEDS) and a Thermistor Probe is not inserted into the Probe Jack or is inserted but does not sense a temperature of over approximately 31°C.
- Once the Probe is inserted in the Probe Jack and the Probe senses a temperature of approximately 31°C, the Stabilet CC becomes a Servo-Controlled Unit, controlled by the skin temperature of the infant.

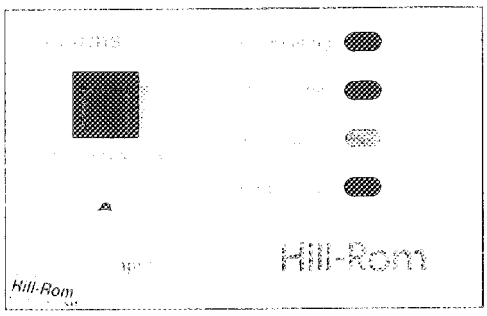
WARNING Do not leave the infant unattended.

Hi-Low Temperature Alarm (Servo Mode Only)



- If the Infant's temperature has fluctuated more than ± .5°C from the set point temperature, a solid, visible Hi-Low Temperature LED Display will appear immediately on the Stabilet CC Control Panel.
- If after four minutes the high-Low temperature has not been rectified, an audible Hi-Low Temperature alarm will sound.
- During the audible alarm condition, heater output will change to approximately 30% until the infant's skin temperature returns within the target range or until the alarm is silenced.
- The Hi-Low Temperature alarm can be silenced by depressing the Alarm Silence Button; however, the Hi-Low Temperature LED Display will remain lit until the infant's temperature returns to within the target range. If the infant's temperature remains outside of the ± .5°C setpoint for another 4 minutes the audible alarm will again sound.
- When the Hi-Low Temperature Condition is rectified, the Hi-Low Temperature Alarm will automatically reset.

Over 102.2°F/39°C Alarm



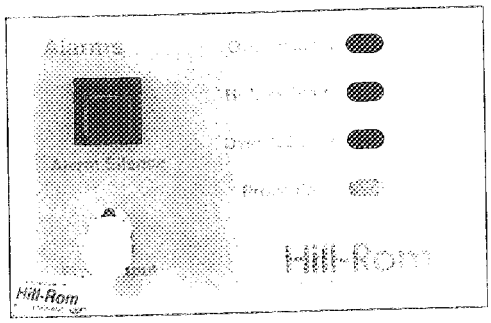
- An audible and visible Over 102.2°F/39°C Alarm will activate immediately if the Thermistor Probe senses a temperature that exceeds 102.2°F/39°C.
- Heater output is reduced to 0% and will not resume until the Thermistor Probe senses that the infant's temperature has fallen below 102.2°F/39°C.
- The alarm will not silence until the condition is rectified.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

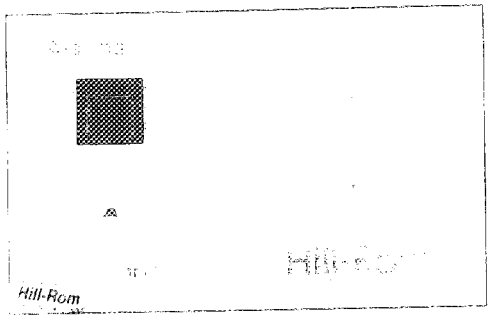
Probe Fault Alarm



- In the Manual Mode when the Probe is not inserted in the Probe Input Jack, the Probe Fault LED will remain lit.
- In the Servo Mode, whenever the Probe senses a temperature of less than approximately 31°C for approximately one minute, the Probe Fault LED will come ON, an audible alarm will occur, and heater output will drop to approximately 30%.
- When the alarm is silenced by depressing the Alarm Silence Button: If sensed temperature is still below 31°C, the Probe Fault LED will remain lit and the unit will revert to Manual Mode.

  If the sensed temperature is above 31°C, the Probe Fault LED will go off and the unit will revert to Servo Mode.

System Fault Alarm



- A System Fault has occurred when an audible alarm sounds and all alarm LED displays illuminate.
- The system continually monitors itself electronically to ensure complete thermoregulation integrity. If, at any time, the Heater Control Signal and the actual Heater Current Signal do not agree, AC power/heater output is immediately terminated, and a System Fault Alarm is activated.
- The System Fault Alarm may also be activated by connecting an incompatible temperature Probe, or when the Probe is shorted or when there is an open heater element.
- The alarm cannot be silenced until the condition is rectified.
- The alarm may indicate a system failure and require maintenance by a qualified technician.

Loss Of AC Power Alarm

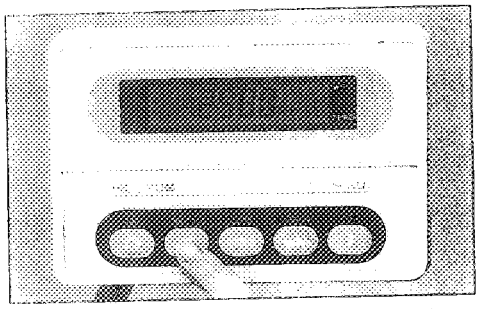
- If the unit becomes unplugged or AC power is interrupted to the unit when the Power Switch is "on", a pulsating alarm will sound. This Loss Of AC Power Alarm will fade after approximately 2 minutes, or will automatically reset if power is restored to the unit.
- The Loss Of AC Power Alarm works off a capacitor that will recharge when AC power is restored to the unit and the Power Switch is turned on.
- No batteries are required for the operation of this alarm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

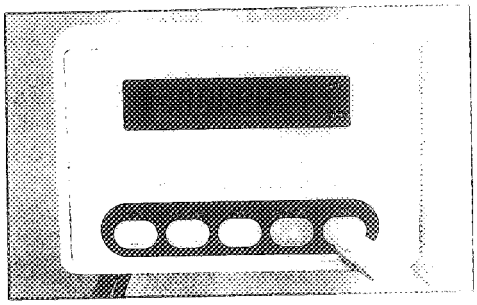
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

OPTIONS

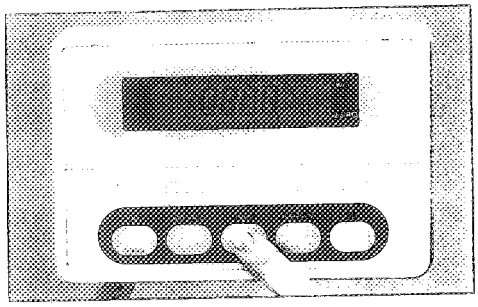
SCALE
The weighing capacity is approximately 17.6 lbs./8 kgs. The scale has five buttons and a display area. A caption appears above each button describing its function. Each control button is color-coded and graphically represented.



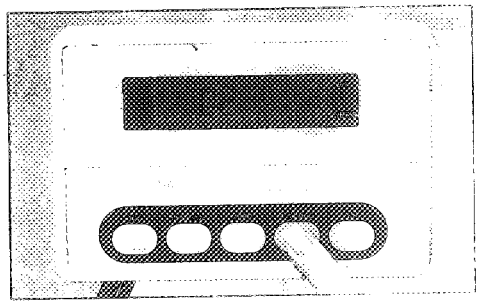
The LBS/KGS button is used to switch to lbs. or kgs.



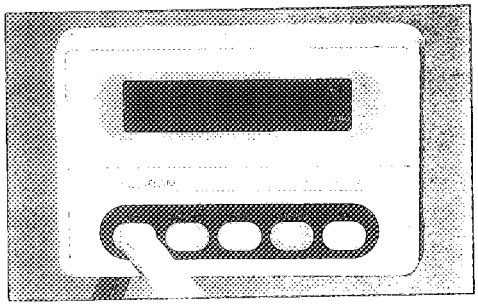
The ON button turns the unit on



The ZERO button resets the scale to 0.000 prior to placing an infant on the scale.



The AVERAGE button compensates for an active infant, vibration or excessive air currents



The OFF button turns the unit off.

Before Operating The Scale
For the most accuracy, follow these procedures:

Scale Setup
Prior to operating the Stabilet Scale, refer to the service manual for complete instructions on scale setup.

Sleep Surface Preparation
Before placing the infant on the sleep surface, it must be prepared. This includes placing articles on the surface such as linens, skin temperature probes, etc. that the infant will require. It can be helpful to place a list of these items near the warmer for future reference.

NOTE It is important to develop a procedure to determine what items belong on the Bassinet at the time of weighing.

Weight Interferences
Before operating the scale, be aware of the following:

- The entire surface of the Bassinet is weighed. It is also important that no one touch the Bassinet while the scale is operating. For example, leaning on the front or side panels can cause incorrect readings.
- The most accurate weight reading will be achieved if nothing is touching the Bassinet. This includes patient lines, temperature probes, ventilators, ECMO equipment, drainage bags and anything that could impact the weight and cause an incorrect weight to appear in the display.

Continuous Display
The infant's weight reading will appear continuously on the display until the OFF button is activated. Turning the unit off will not erase any weight readings but only deactivate the scale for a period of time.

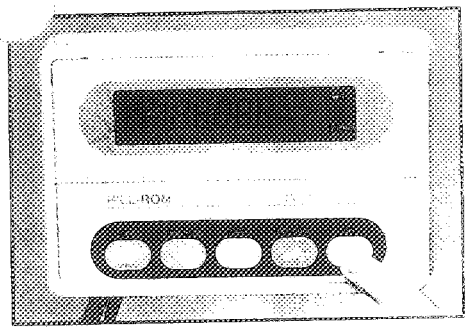
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

OPTIONS

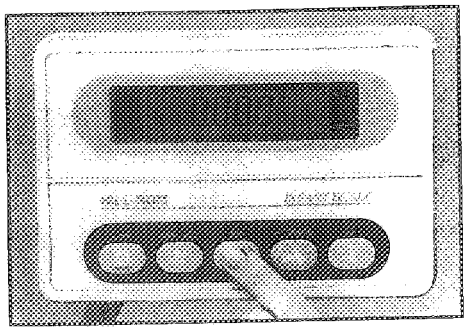
PATIENT WEIGHING

Step One – Turning the Scale On



- Connect the scale's power cord to a 120V electrical outlet.
- To turn the scale on, press and release the ON button on the front panel.
- When first turned on, all display indicators will light briefly, and then clear.

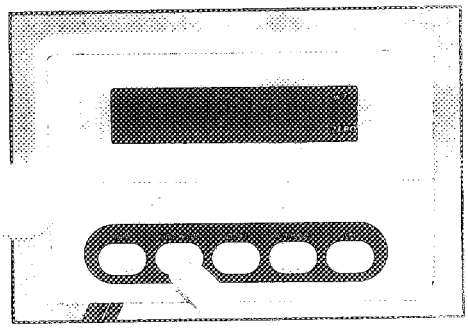
Step Two – Zeroing the Scale



Before placing the infant on the sleep surface, the bed weight must be zeroed.

- Press ZERO to obtain a zero reading on the display prior to weighing the patient for the first time.
- The scale will read 0.000 lbs./kgs.

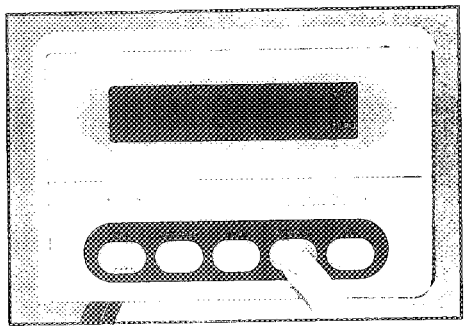
Step Three – Weighing the Patient



For the most accurate weight readings, the infant should be centered on the bed and lying still.

- Place the infant in the Bassinet.
- The patient weight will appear in the display. For lbs. to kgs., press the LBS/KGS button during weight display.

Step Four – Averaging Level



The AVERAGE button allows you to obtain an average weight when an active infant, excessive vibration and/or air currents cause the weight reading to fluctuate.

- Press and release the AVERAGE button. The display will begin a countdown – 02, 01, then a weight reading. This takes approximately four seconds. The scale will display an infant weight based on a statistical average. Do not press any other keys while the scale is in the averaging level mode.
- This statistical average weight will display for approximately 3/4 minutes.
- The unit will then return to the original weighing mode.

NOTE This feature does not affect the accuracy of the unit.

LOW BATTERY INDICATOR

When the scale's battery power becomes low, the word "LO BAT" will appear in the scale's display. To recharge the battery, plug the unit into an outlet. The battery is charged when the "LO BAT" display disappears.

NOTE The Infant Scale receives backup power from six AA batteries contained in the scale indicator when the power cord is unplugged from the wall receptacle.

CAUTION The Infant Scale calibration information is not retained in the scale indicator memory in the event that total electrical power is lost. To prevent calibration information loss, ensure that the scale indicator batteries are adequately charged before unplugging the power cord from the wall receptacle. If the scale indicator displays "LO BAT" message, allow sufficient time for the batteries to recharge before unplugging the power cord from the wall receptacle. If the batteries do not accept charge, replace the batteries and recalibrate the Infant Scale.

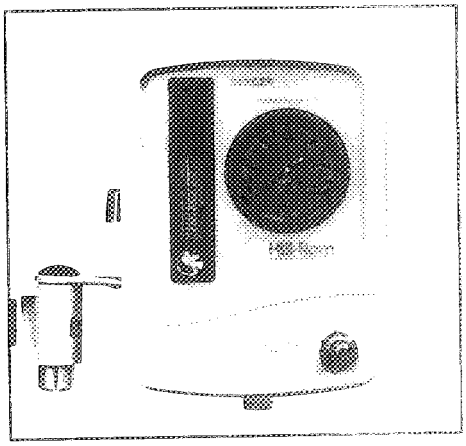
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

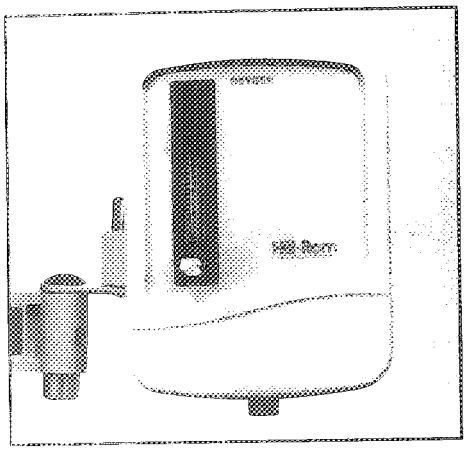
ACCESSORIES

RESUSCITATION MODULES

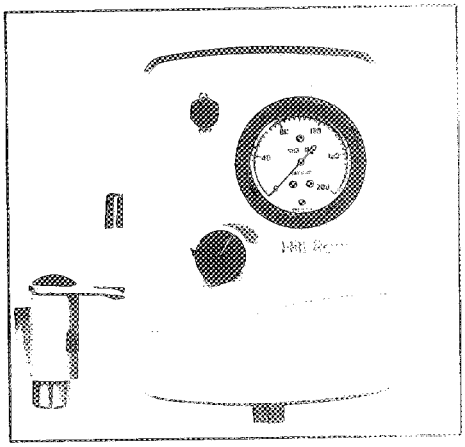
The Resuscitation Modules for the Stabilet Infant Warmer products include:



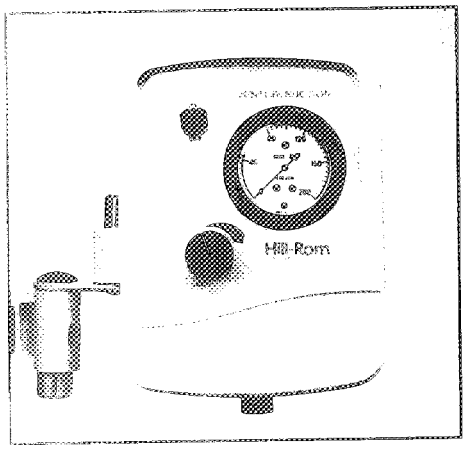
P1276 Oxygen Module (Flow and Airway Pressure)



P1278 Oxygen Module (Flow Only)



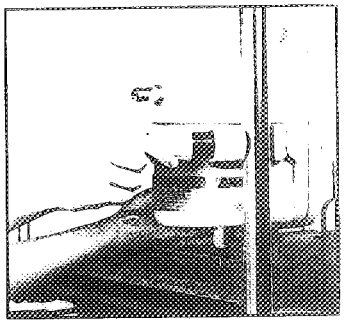
P1280 Suction Module (Wall Only)



P1281 Suction Module (Venturi Only)

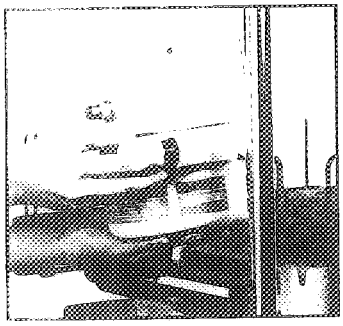
NOTE Resuscitation Modules are intended for use only on the Stabilet Infant Warmers.

To Mount The Resuscitation Modules



- Position the module on the pole at the desired height.
- Tighten the module knob by turning it counter-clockwise.
- Shake the module gently to ensure it is properly mounted.

To Remove The Resuscitation Modules



- Disconnect all tubing from the module.
- Loosen the module knob by turning it clockwise.
- Lift the module gently away from the pole.

NOTE You must have a Hill-Rom Infusion Pump Holder accessory or Post Utility Mount accessory in order to mount the Resuscitation Modules on the Stabilet Infant Warmers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

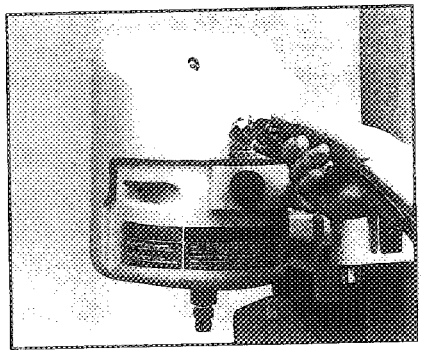
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ACCESSORIES

To Use Oxygen Source (Cylinder or Wall)

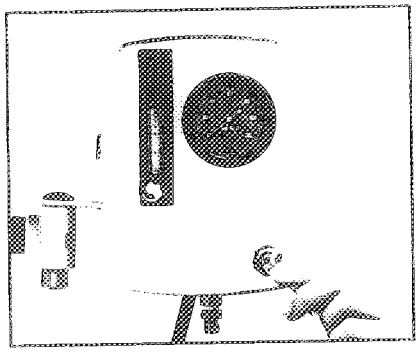
ygen can be administered from a regulated wall source or from oxygen nders. Using cylinders permits the module to be used in transport situations

- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module.

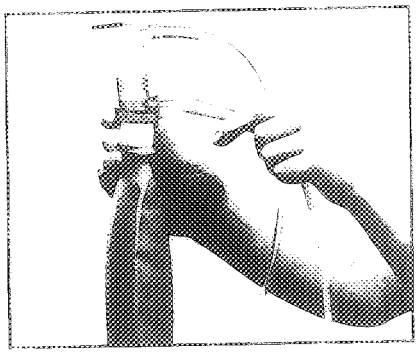


OXYGEN MODULE (FLOW AND AIRWAY PRESSURE)

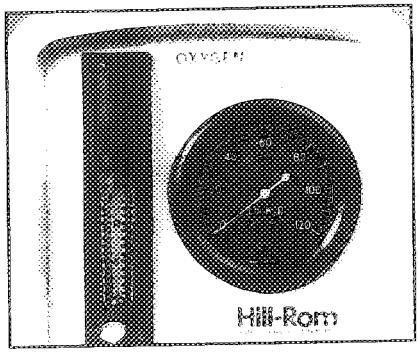
To Utilize Oxygen Module (Flow and Airway Pressure)



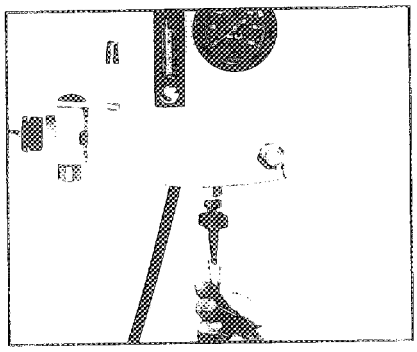
Connect one end of the Oxygen Tubing to the nipple located on front of the oxygen module. measures the amount of pressure being delivered during resuscitation.



Connect the opposite end of the Oxygen Tubing to the Manometer Connector located on the Resuscitation Bag and Mask



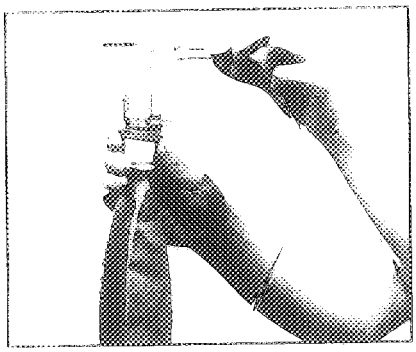
The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the front of the module. Airway Pressure is measured from 0 to 120 cm H.O.



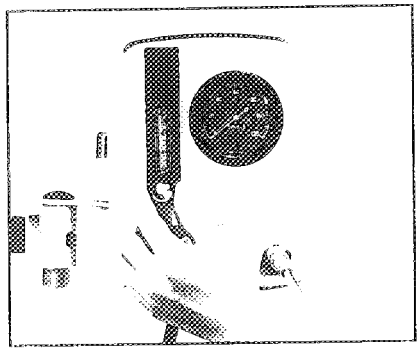
Using an appropriate adaptor, connect one end of a Second Oxygen Tubing to the DISS fitting located underneath the oxygen module.

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing.

TION Improper use of supplemental oxygen be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask



Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

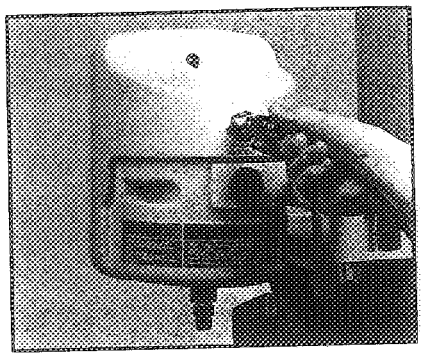
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

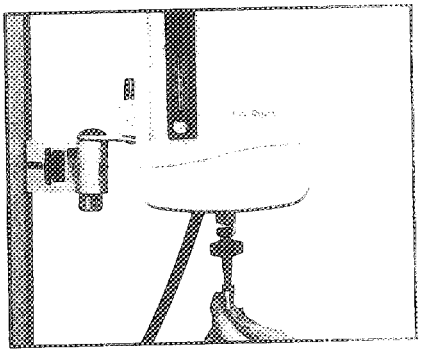
ACCESSORIES

To Use Oxygen Source (Cylinder or Wall)
Oxygen can be administered from a regulated wall source or from oxygen cylinders. Using cylinders permits the module to be used in transport situations.

- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder, using a gas outlet adaptor
- Connect second end of oxygen hose to the DISS fitting on the back of the oxygen module

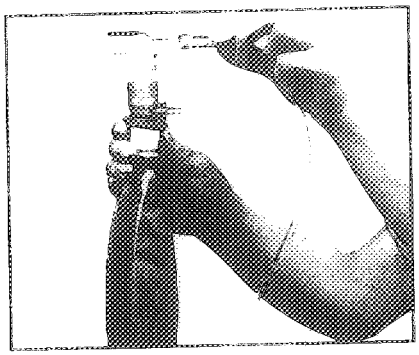


OXYGEN MODULE (FLOW ONLY)
To Utilize Oxygen Module (Flow Only)

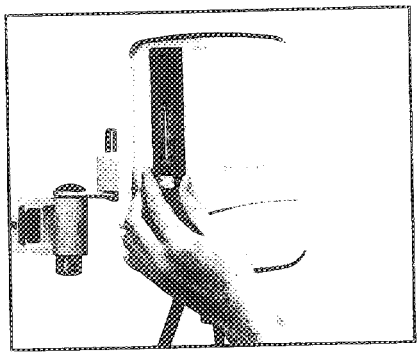


Using an appropriate adaptor, connect one end of the Oxygen Tubing to the DISS fitting located underneath the oxygen module.

NOTE A humidifier may be attached to the DISS fitting prior to connecting the Oxygen Tubing.



Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.



Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the front of the module. The flow is adjustable from 2 to 15 LPM. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not overtighten the knob.

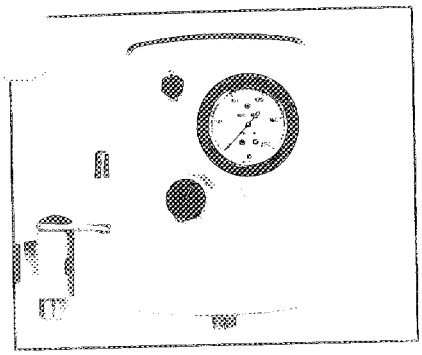
CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

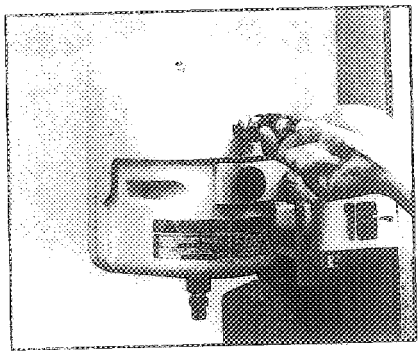
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ACCESSORIES

SUCTION MODULE (WALL ONLY)



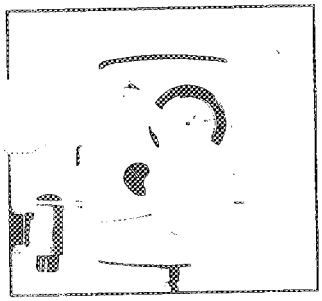
Suction is accomplished by the use of Wall Suction and is variable from 0 to 160 mm Hg.



To Use Wall Suction Source

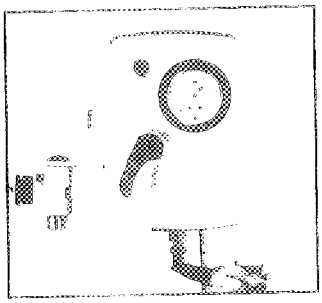
- Connect one end of vacuum hose to wall source of vacuum using a gas outlet adapter.
- Connect second end of vacuum hose to DISS fitting located on the back of the suction module.

Set Rate

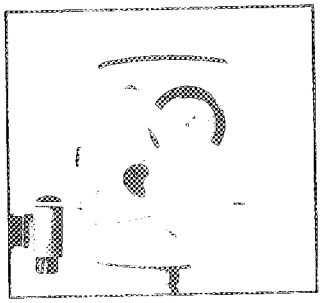


Turn the suction on with the On/Off Switch located on the front of the module.

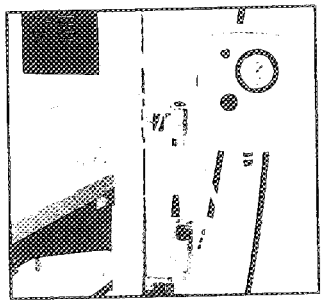
NOTE Properly occlude the Suction Port located underneath the suction module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the suction Module) to the desired setting while occluding the Suction Port.



Turn the suction off with the On/Off switch located on the front of the module.



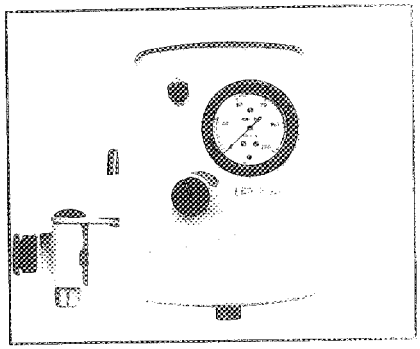
Attach Disposable Suction Canister to the Port located underneath the module.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

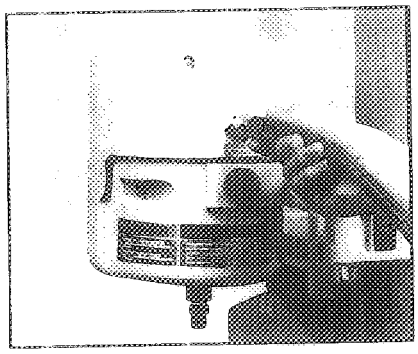
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

ACCESSORIES

SUCTION MODULE (VENTURI ONLY)



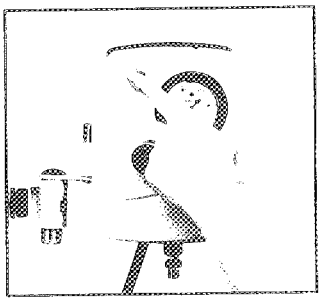
Venturi Suction is accomplished by the use of either Wall or Cylinder Oxygen and is variable from 0 to 160 mm Hg.



To Use Oxygen Source for Venturi Suction (Cylinder or Wall)

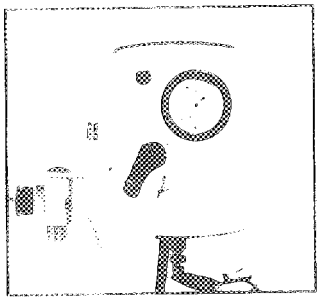
- Connect one end of oxygen hose to wall source of oxygen or oxygen cylinder using a gas outlet adaptor.
- Connect second end of oxygen hose to the DISS fitting located on the back of the suction module.

Set Rate

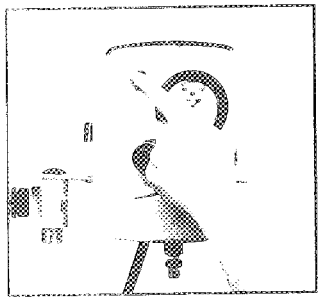


Turn the suction on with the On/Off Switch located on the front of the module.

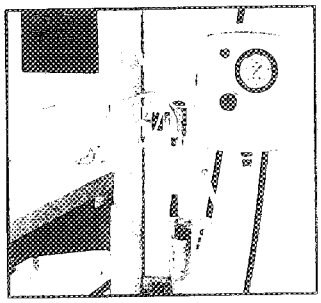
NOTE Properly occlude the Suction Port located underneath the Suction Module to obtain the most accurate Suction Gauge reading.



Rotate the Suction Dial (located on the front of the Suction Module) to the desired setting while occluding the Suction Port.



Turn the suction off with the On/Off Switch located on the front of the module.



Attach Disposable Suction Canister to the Port located underneath the module.

NOTE To increase Oxygen Cylinder life

1)Turn the cylinder off when not in use or when utilizing Wall Source of oxygen.

2)Do not set suction level any higher than necessary to complete procedure.

3)Turn suction off when not in use.

4)Connect unit to Wall Oxygen Source when available and practical.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CLEANING

STERILIZATION

The Centers for Disease Control recommend EPA approved hospital disinfectants, used at manufacturers suggested dilutions. Cleaning should be done by wiping a soft dampened cloth over the surface, followed by wiping with a dry cloth.

Quartenary ammonium disinfectants may be used to reduce the contamination level between patients.

Alcohol, strong or abrasive cleaners and hydrocarbon solvents are not necessary and should not be used on plastic surfaces.

MATTRESS CARE

The mattress cover may be cleaned with a mild detergent, rinsed, and cold sterilized. The following products have been tested by the Herculite Laboratory and have been found not to have a harmful effect on StaphChek fabrics WHEN USED IN ACCORDANCE WITH MANUFACTURERS' RECOMMENDED DILUTION.

TRADE NAME	TYPE	MANUFACTURER
A33	Quartenary	Airwick
Absolute	Quartenary	Walton-March
Beaucoup	Phenolic	Huntington
Blue Chip	Quartenary	S.C. Johnson
Coverage 256	Quartenary	Vestal
El Dorado Plus	Quartenary	Puntan/Churchill
Elimstaph	Quartenary	Walter G. Legge
[illegible]ward DC	Quartenary	S.C. Johnson
[illegible]klin Sentinel	Quartenary	Purex
[illegible]alahad	Phenolic	Puntan/Churchill
Hi-Tor	Quartenary	Huntington
Insurance	Quartenary	Vestal
LPH	Phenolic	Vestal
Matar	Phenolic	Huntington
Omega	Quartenary	Airwick
Quanto	Quartenary	Huntington
Sanikleen	Quartenary	West Chemical
Sanimaster 111	Quartenary	Service Master
Surfacide	Quartenary	Walter March
Tri-Quat	Quartenary	Vestal
Vesphene 11	Phenolic	Vestal
Virex	Quartenary	S.C. Johnson

Betadine stains may be removed from the mattress by doing the following:

- Use a 5.25% sodium hypochlorite solution (Clorox brand bleach).
- Apply 3 drops of the solution per square inch immediately and scrub lightly. The stain should start to fade almost immediately and within 15 minutes should be totally gone.
- Stubborn stains may need further applications. No more than 3 applications on any one area are recommended.

  [illegible]en completely dry, rinse area with clear water and [illegible]e dry.
- If solution comes into contact with skin, wash off with water and follow manufacturer's label instructions.

CLEANING OF THERMISTOR PROBE

Several precautions must be observed when cleaning and sterilizing to protect Probe from damage.

Avoid contact with strong, aromatic, chlorinated, ketone ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the cable to lose flexibility.

Probe may be disinfected and sanitized by washing with 3% hydrogen peroxide, 70% isopropanol, 70% ethanol, or 100% alcohol. Dakin's solution (sodium hypochloride in neutral buffer) is also suitable. Activated dialdehyde solutions, such as Cidex, are also effective.

Probe plug should not be immersed.

STERILIZATION OF THERMISTOR PROBE

Ethylene oxide sterilization is the preferred method. After sterilization, Probes must be safely and thoroughly ventilated before handling or use.

CAUTION Autoclaving may cause Probe insulation to fail, and may also cause the Probe to give inaccurate reading.

CLEANING OF CASTERS

The Stabilet CC Infant Warmer may be used both in and outside aseptic surgical areas. Care should be taken to assure the casters do not carry contamination into the surgical suite. Removal of accumulated debris and treatment of the caster tread with a spray of disinfectant solution as the Stabilet is transferred into the surgical suite is recommended.

CLEANING OF SIDE PANELS

The side panels are made of clear polycarbonate plastic and can be damaged by cleaning with alcohol, abrasive agents, hydrocarbon solvents or phenolic disinfectants. Use only gentle detergents for cleaning and polish with a soft cloth to return clarity.

CLEANING RESPIRATORY THERAPY PARTS

Remove and clean or discard all tubing, masks and control apparatus which have come in contact with patient secretions. Cleaning procedures should follow standard recommendations for respiratory therapy equipment and should include surveillance for residual pathogenic contamination. Respiratory therapy equipment tends to deteriorate with age and repeated cleaning and sterilization. Assure it is safe and functioning properly. Cracked rubber and plastic articles should be replaced.

MAINTENANCE

The Stabilet CC Infant Warmer and Resuscitation Modules need regular care and maintenance, as detailed in the Service Manual. Please request your maintenance technician to follow the preventive maintenance section in the Service Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

SAFETY TIPS

For over 65 years Hill-Rom has set the standard for quality in patient room equipment. During this time, with input from many of our customers, we have acquired useful tips which may contribute to the safety of the infant and staff.

SIDE PANELS
To provide maximum protection for the infant, the side panels should always be in a full, upright position and latched when an infant is unattended. To ensure the side panels are latched, give the side panels a gentle tug.

TRANSFERRING THE STABILET CC INFANT WARMER
Although the unit is lightweight and easy to move, be sure to keep hands and feet clear of the wheels when moving to prevent destabilization of the unit or injury to hands or feet.

BRAKES
Brakes should always be set when the unit is occupied. After setting the brakes, push and pull the unit to ensure they are engaged.

X-RAY CASSETTE HOLDER
If using the X-Ray Cassette Holder accessory, always secure the holder to the unit when not in use. This will avoid possible damage to the unit and holder.

RESUSCITATION MODULES
Warmer Module should always be kept over the center of the Bassinet when Modules are attached.

SCALE
The Display Unit may be attached to either side of the Thermal Control Center.

PREVENTIVE MAINTENANCE
Quarterly preventive maintenance must be performed to ensure all features are functioning as originally designed. Particular attention must be addressed on safety features, including but not limited to:

- Side Panel Latching Mechanisms
- Caster Braking Systems
- Electrical Cords And Components
- Quartz Heater
- Temperature Alarm System
- Scheduled Re-calibration
- Air Flow Measurement Devices

Please refer to your Service Manual for specific preventive maintenance.

PARTS AND ACCESSORIES
Use only Hill-Rom parts and accessories. Do not modify the unit or module without authorization from Hill-Rom.

CAUTION
Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

DIRECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Manufactured for Hill-Rom under a quality system certified to ISO 9001/EN46001 by TÜV Product Service of San Diego, CA.

Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800-638-2546
International • 812-934-8173 • FAX 812-934-7191

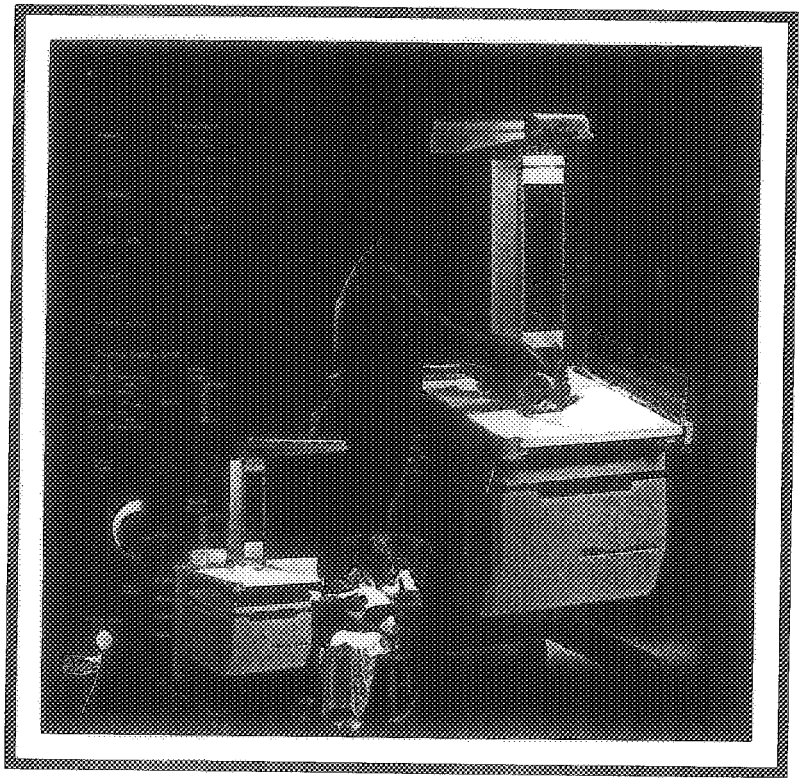
Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.
© Hill-Rom 1996

W6098A RC1096

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

A HILL-ROM SOLUTION

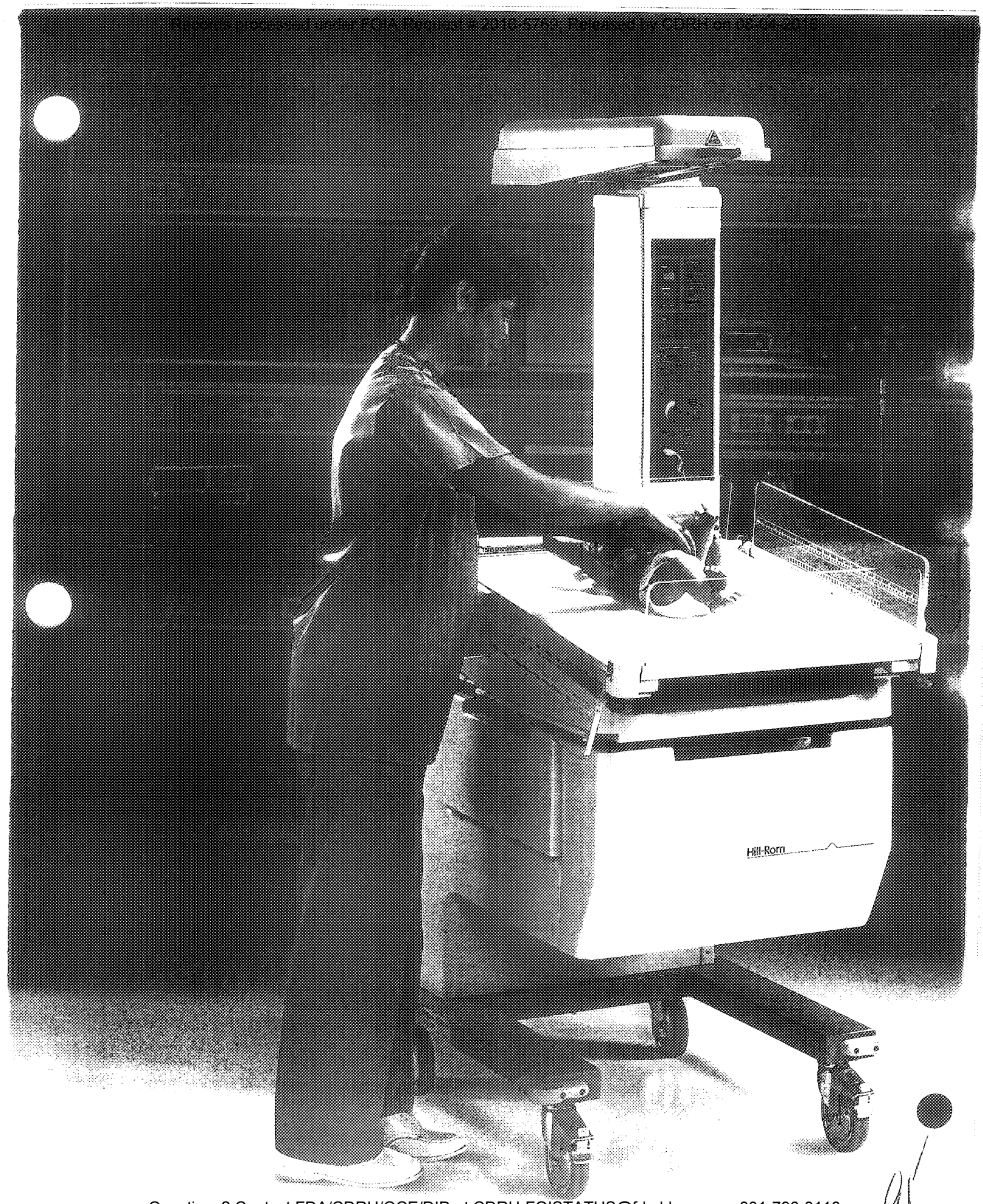


STABILET CC INFANT WARMER

Hill-Rom

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2018-5760, Released by CDRH on 08-04-2018



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2010-5769; Released by CDRH on 08-04-2016

Thermal Control Center

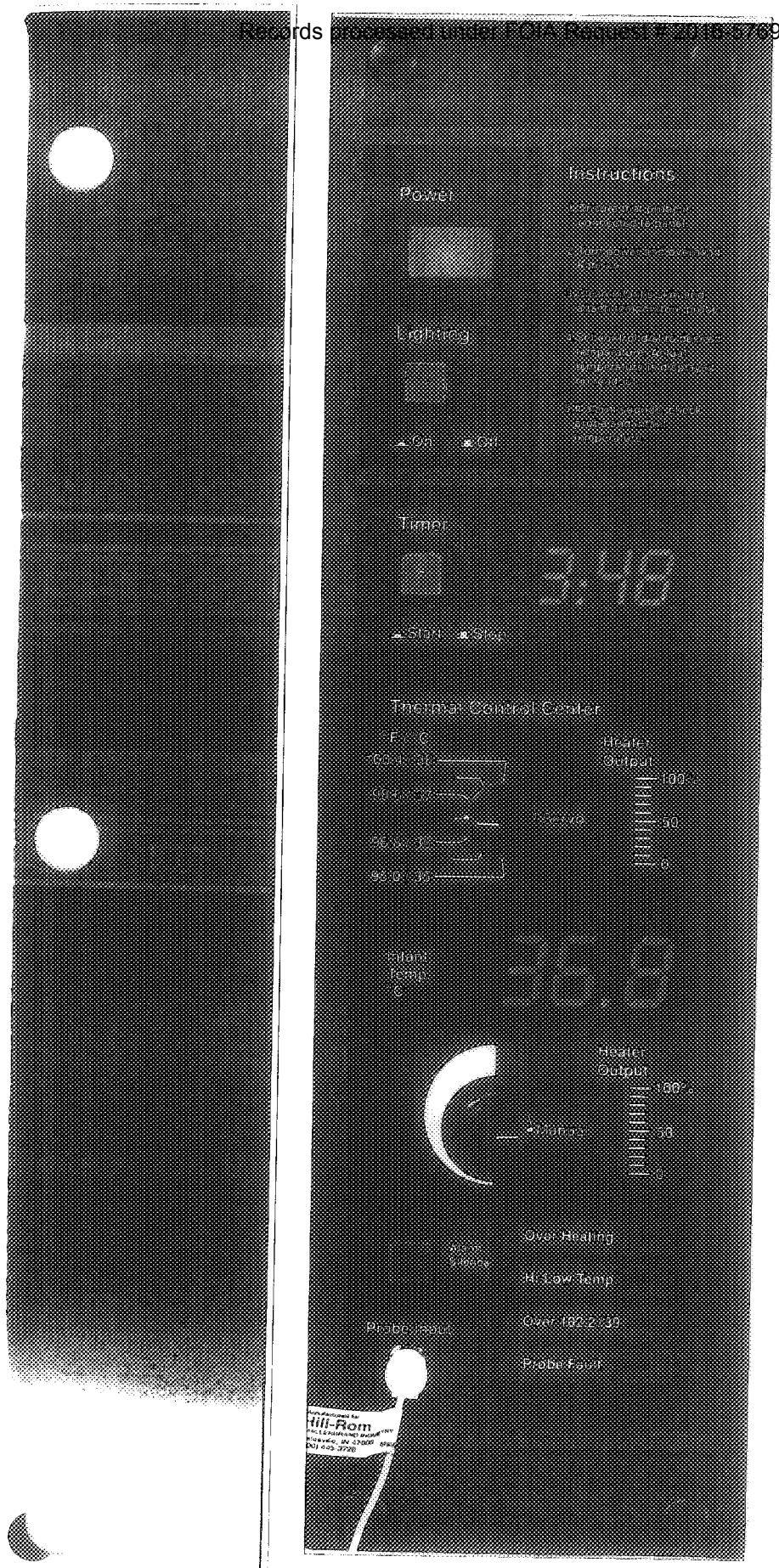
Built into the unit are state-of-the-art features, including automatic conversion from manual to servo control and a sophisticated alarm system.

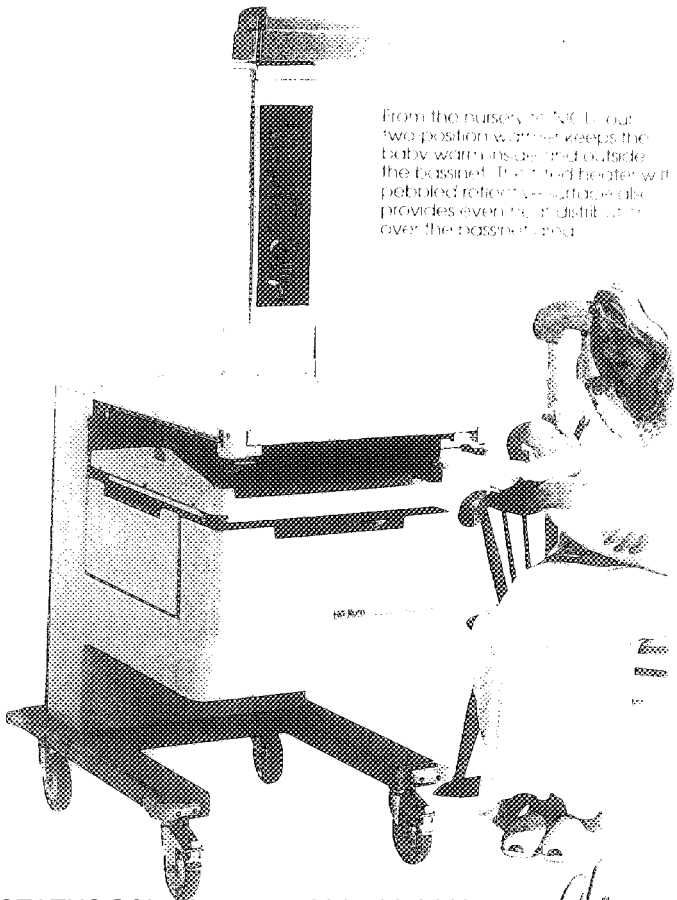
Easy operation saves nursing time and energy consumption.

Simply turn the power on and the unit is operational in manual mode. The caregiver can set the amount of heat coming from the warmer using a separate manual control. Heater output is indicated by the tricolor LED bar graph. Once the probe is attached and senses a skin temperature over 31 C, the unit automatically converts to servo control. In the servo mode, precise infant skin temperature is easily visible on the large digital display.

Sophisticated alarm system simplifies operation and enhances patient safety.

Our state-of-the-art alarm system is active in both the manual and servo modes.





Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5760. Released by CDRH on 08-04-2016

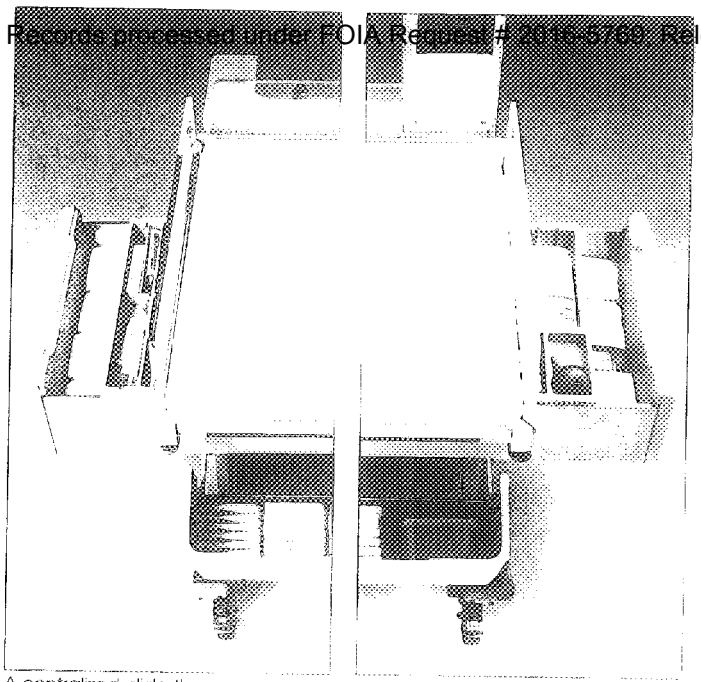
tures,
anual
alc

and

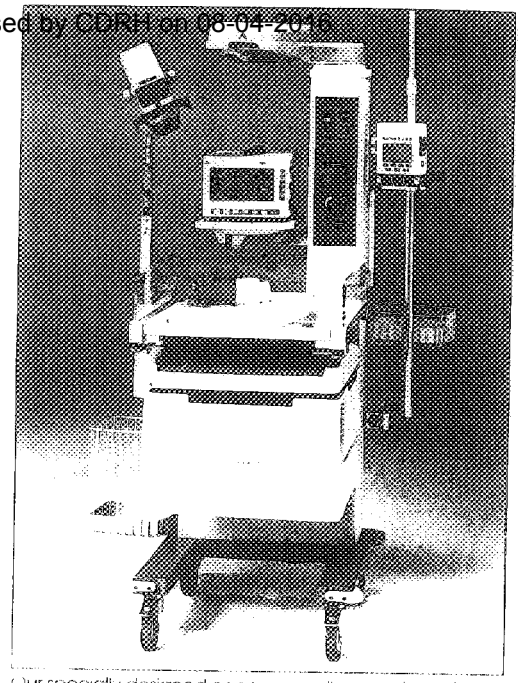
oper-
r can
n the
ntrol.
or LED
l and
, the
ntrol.
skin
arge

lities
fety.

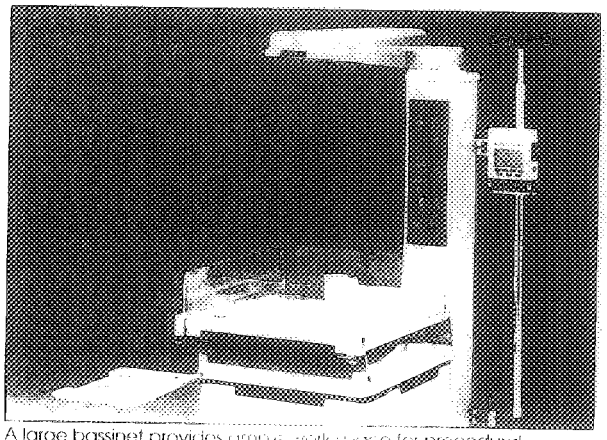
ctive



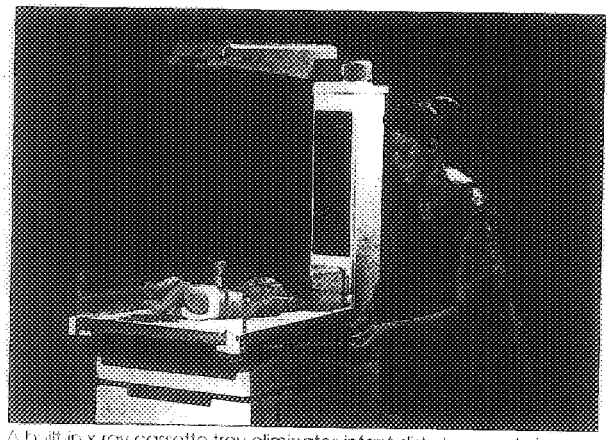
A centralized, slide-through storage drawer with removable organizer tray can be accessed from both sides of the unit. The front-opening bin provides additional storage.



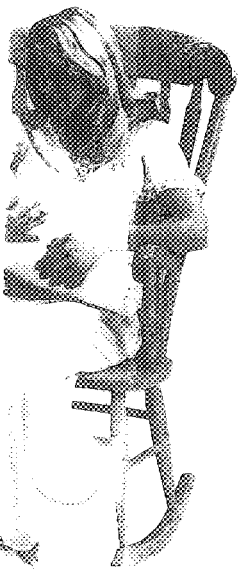
Our specially designed accessories allow you to customize the unit to meet your individual needs.

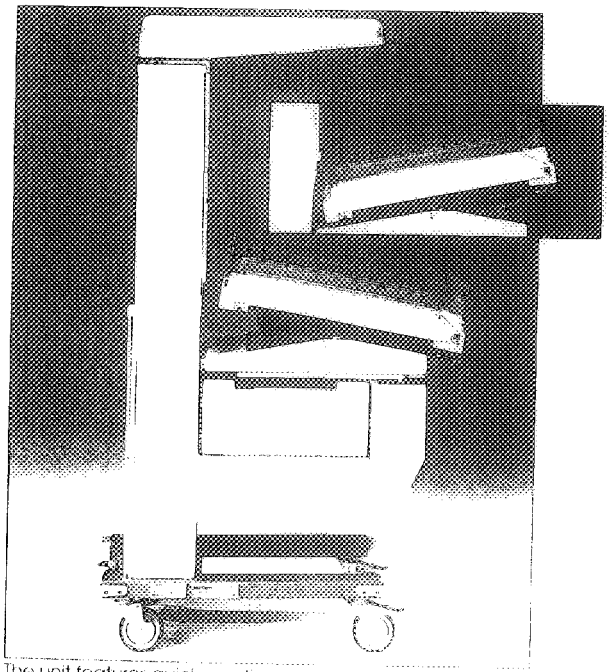


A large bassinet provides ample work space for procedural equipment in critical care environments. The swing out Mayo tray provides even more space for critical care procedures.

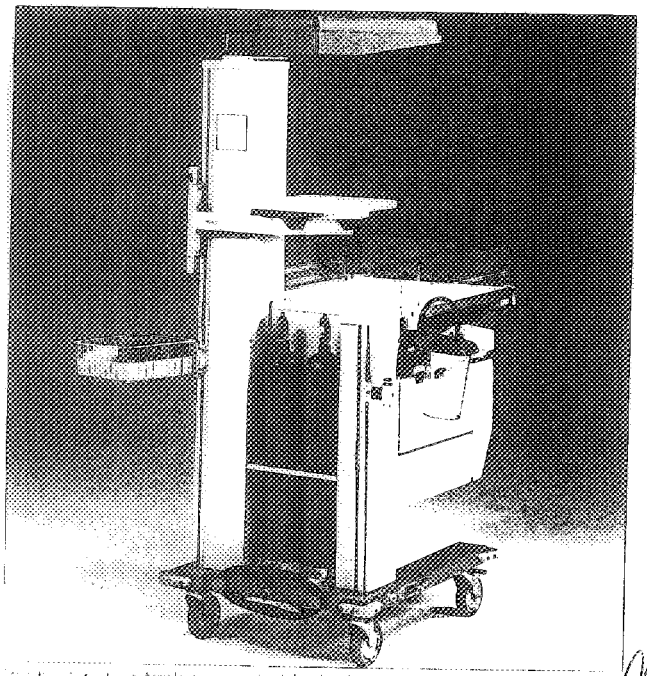


A built-in x-ray cassette tray eliminates infant disturbance during x-ray and reduces position errors.





The unit features quick, [illegible] Trendelenburg and reverse Trendelenburg [illegible] detent. [illegible] Easy to operate [illegible]



[illegible] two tank oxygen holder tucks out of the way in rear [illegible] convenient placement [illegible] accessory tracks [illegible] equipment and save valuable floor space.

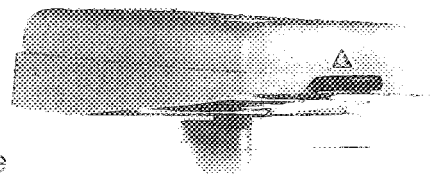
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

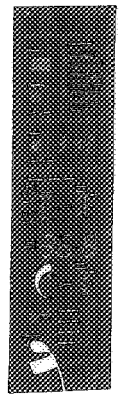
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

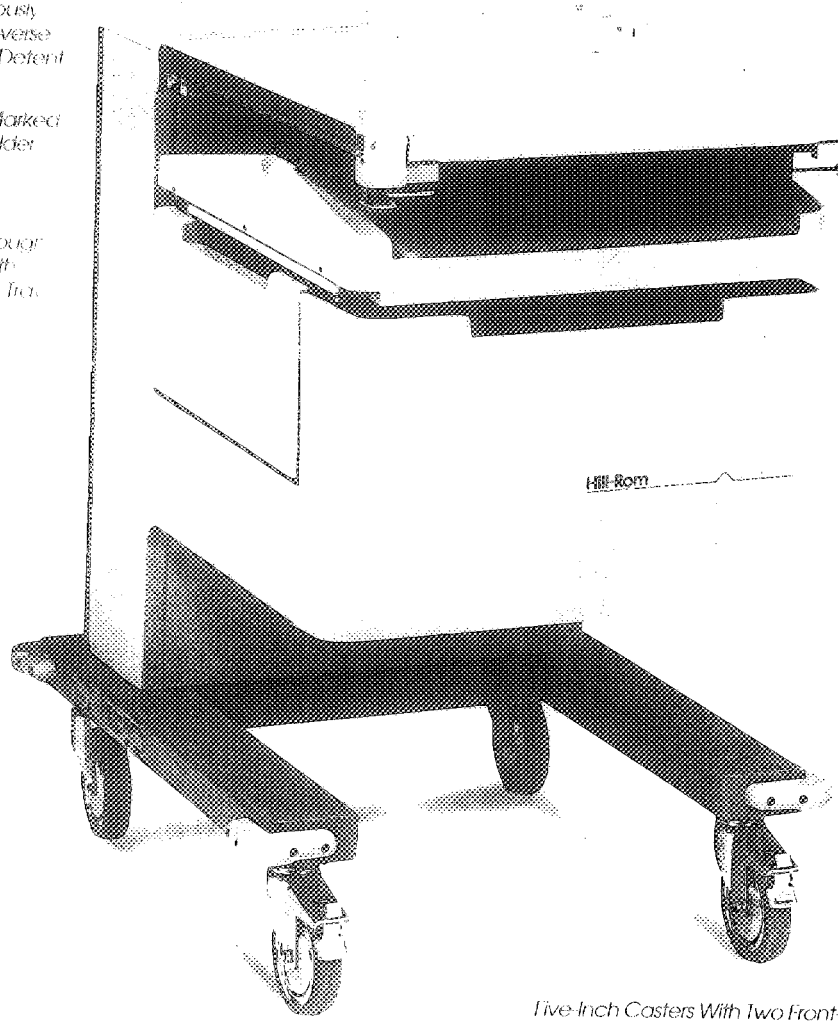
Every Hill-Rom Bassinet Infant Warmer from Hill-Rom has been designed to enhance the quality of infant care while providing the caregiver unparalleled infant accessibility and visibility.

Its sleek profile and ergonomic design conserve valuable space and optimize staff efficiency and organization.

From the NICU to the well-baby nursery, the unit provides features that make it the solution when the best possible infant care is the primary concern.







Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Specifications

Standard Equipment

Two-Position Warmer/Lighting Module

One-Hour Procedure Timer emits a tone at one, five and ten minutes

Manual Mode: 0%-100% Adjustable Heater Output

Servo Mode: Automatic conversion from manual when probe senses skin temperature over 31°C

Large digital Skin Temperature Display

Trendelenburg/Reverse Trendelenburg continuously adjustable Table Tilt with 5° and 10° Detent

Built-in X-Ray Cassette Holder

Retractable Mayo Tray

Slide-Through Storage Drawer with Removable Organizer Tray

Tilt-Out Front Storage Bin

Built-in Accessory Tracks

Five-Inch Casters with Front-Locking Brakes

Alarms

Overheating

Hi-Lo Temperature

Over 102.2°F/39°C

Probe Fault

System Fault

Loss of AC Power

Accessories

Large and Small Pivoting Shelves

Large and Small Storage Baskets

Phototherapy Light

IV Hanger, Utility Mount, Infusion Pump Holder

Infusion Support Arm with ISS Transfer Pole

Phototherapy/Exam Light

Chest Drainage Rail

Reusable or Disposable Probes

Storage Tray

Heater

760 Watts, 120 VAC Quartz Heater

DIRECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Electrical

120 +/- 10% VAC, 60 Hz, 7.0 Amps, 800 Watts

Fully grounded through 3-wire power cord

Current leakage less than 100 microamps

Temperature Display Accuracy:
+/- 0.1°C from 35-39°C with reusable probe (BCZ009)
+/- 0.2°C from 35-39°C with disposable probe (SA4567)

Irradiance at 100% power 25mW/cm²
(56 point grid average, measured 4" above and perpendicular to mattress).

Dimensions

Overall	
Length	34 in.
Width	27 in.
Height	71 in.
Weight	285 lbs.
Bassinet:	
Length	28 in.
Width	24 in.
Height	42 in. from floor, including sides
Mattress	
Length	26 in.
Width	22 in.
Height	37.5 in. from floor
Heater	
Length	30.25 in.
Width	09 in.
Height	67 in.
Heater Module to Mattress	29.5 in.

This product is supported by professional account executives, experienced perinatal nurse consultants and technical specialists. We also provide educational seminars, featuring perinatal clinicians and single-room maternity care consultants, to help you design and implement your perinatal system.

Service

Hill-Rom products should be serviced only by qualified technicians. Our fully trained Customer Service Representatives and Field Technicians stand ready to assist you with questions or problems. In addition, Hill-Rom is pleased to offer a Preventive Maintenance Program to ensure that recommended service is provided in a timely manner. For more information on how we can meet your service requirements, please call us at 800-445-3720.

Warranty

Hill-Rom extends a limited warranty covering defects in workmanship and material under normal use for a period of one year from purchase. A 60-day warranty is applied to expendable parts such as overhead fluorescent tubes, heating element and probes.

Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800-638-2546
International • 800-638-8133 • FAX 812-934-7

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.
Hill-Rom 1996

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

3

400

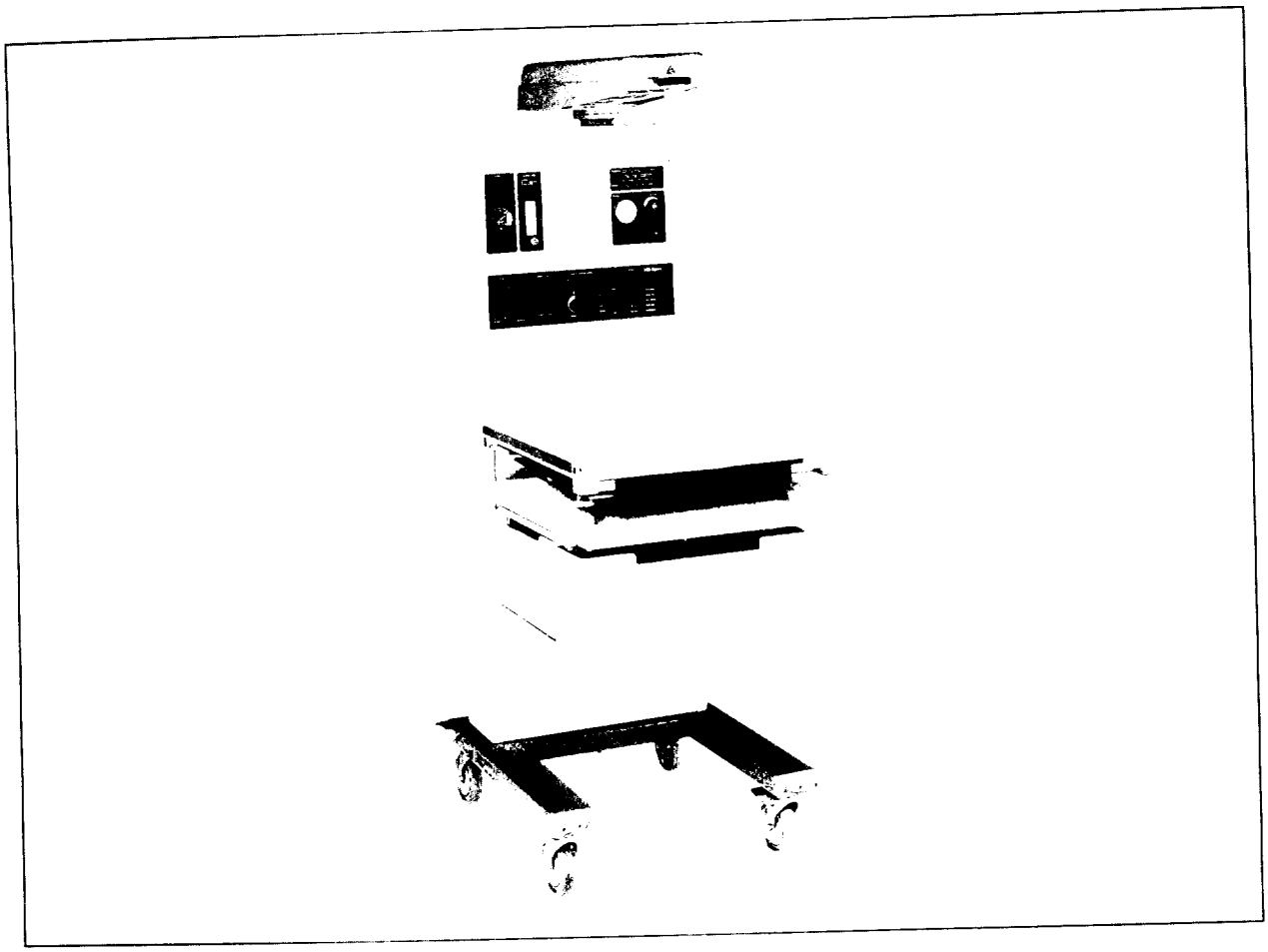
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

IN-SERVICE MANUAL

Stabilet™ 2000C Infant Warmer

From Hill-Rom®



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

01

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

TABLE OF CONTENTS

FEATURES 1

ECIFICATIONS 1

ATURES

Multi-Position Warmer Module 2

Storage 2

Over Center Of Bassinet 2

X-Ray And Examination 2

Mother/Baby Bonding 2

Bassinet 3

Trendelenburg/Reverse Trendelenburg /Level Sleep Surface 3

Retractable Mayo Tray 3

Slide-Through Storage Drawer 3

Built-In X-Ray Cassette Holder/Radiolucent Mattress 4

Apgar/Procedure Timer 5

Lighting Button Module 5

Tilt-Out Resuscitation Compartment 5

Resuscitation Package 5

Utilize Resuscitation Equipment 6

Oxygen Cross-Over System 7

Oxygen Cylinder Installation 7

Use Portable System 8

Use Wall Oxygen Source 8

Suction 9

Thermal Control Center 9

Manual Mode 10

Servo Control Mode 10

Alarm Descriptions 11

Overheating Alarm 11

High-Low Temperature Alarm 11

Over 102.2° F /39° C Alarm 12

Probe Fault Alarm 12

Low Oxygen Alarm 12

System Fault Alarm 12

Loss Of AC Power Alarm 12

OPTIONS

Air/Oxygen Blender Package 13

Air/Oxygen Blender Alarm 13

Installation 13

Use Package 14

Scale 15

Patient Weighing 16

CLEANING 17

SAFETY TIPS ..... Back Cover

R SPECIAL ASSISTANCE:

Hill-Rom Account Manager _____ Phone _____

Perinatal Consultant _____ Phone _____

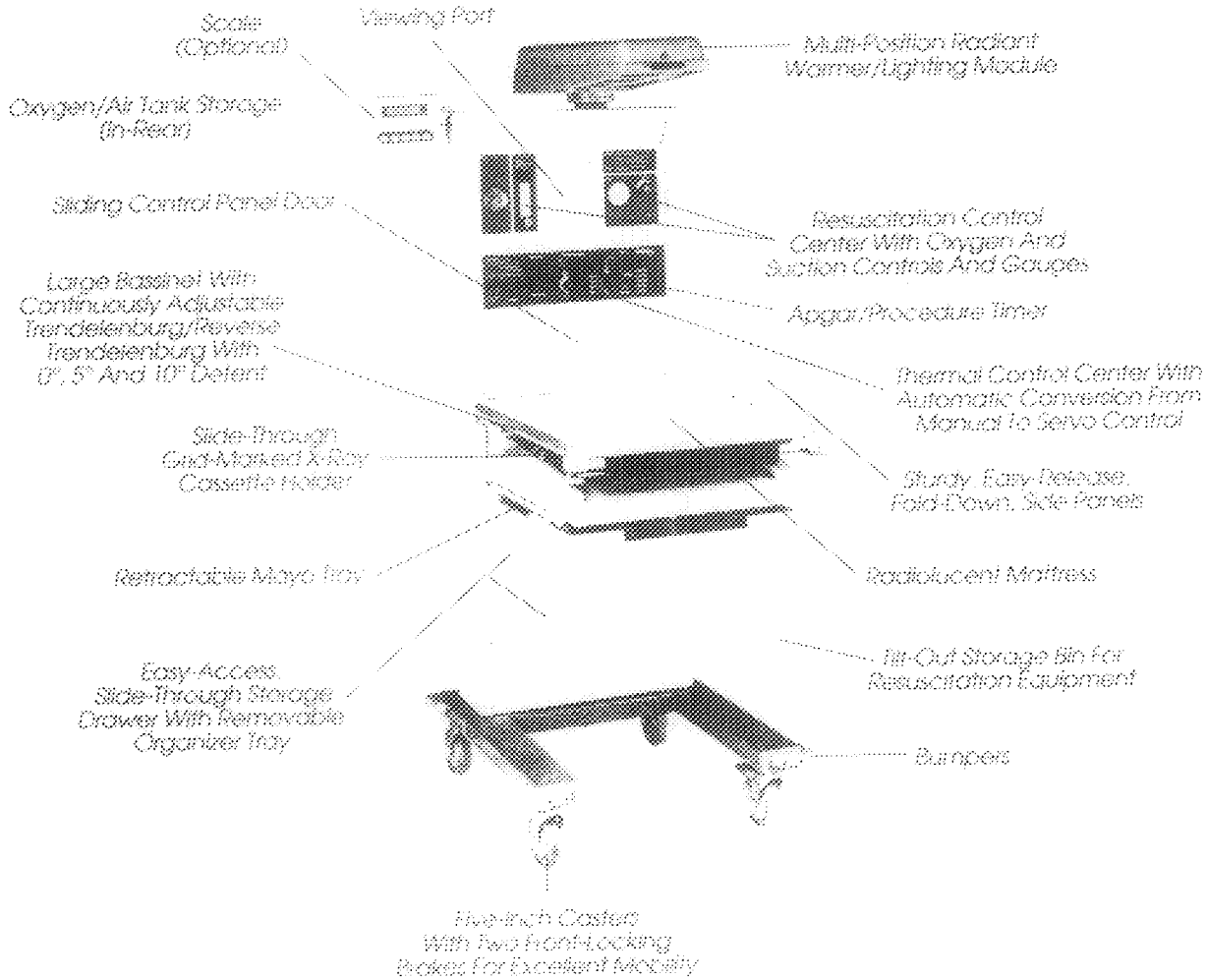
Field Service Technician _____ Phone _____

Customer Service Representative _____ Phone _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES



SPECIFICATIONS

Height – Floor to top of unit ..... 72"
Height – Floor to top of side panel ..... 42"
Side Panel height ..... 5½"
Caster ..... 5"
Width – Overall ..... 27"
Width – Bassinet ..... 24"
Length – Bassinet ..... 28"
Mattress size ..... 26" x 22" x 1"
Mattress height – Floor to top of mattress ..... 37½"
Weight ..... 295 lbs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

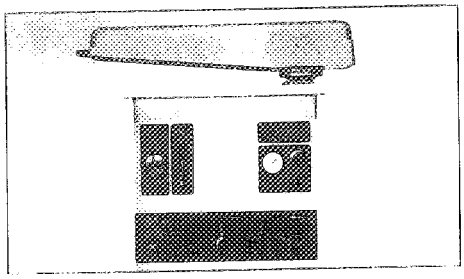
MULTI-POSITION WARMER MODULE

e Radiant Warmer Module provides a controlled source of radiant heat to
e unit through a 760 watt radiant quartz tube and a parabolic reflector

Storage

- To store, pivot the heater 90° (parallel to unit housing).
- Grasp the Heater Handle and push the heater horizontally to the stored position.

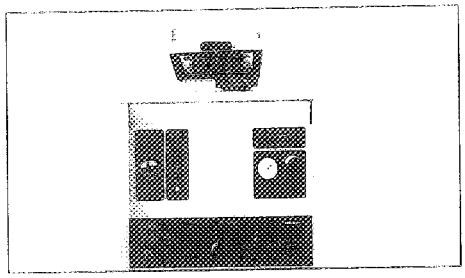
NOTE Internal microswitches turn the heater off if it is rotated from the central position over the Bassinet 45° from right, 35° from left. This safety feature prevents overheating of the Upper Control Panel Housing when the heater is in the stored position.



Over Center Of Bassinet

- To place the heater into the standard operating position, grasp the handle and pull horizontally, placing the base of the heater in the center of the unit.
- Rotate the heater 90°, placing it centrally over the Bassinet.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.

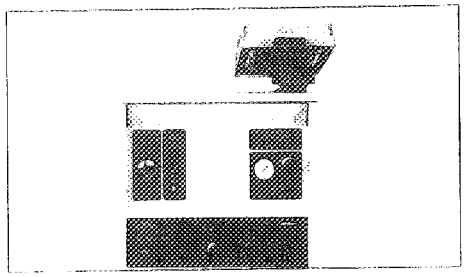
WARNING Do not place any objects on top of the Warmer Housing. This could cause overheating of the unit and/or combustion of items placed on top of the warmer.



-Ray And Examination

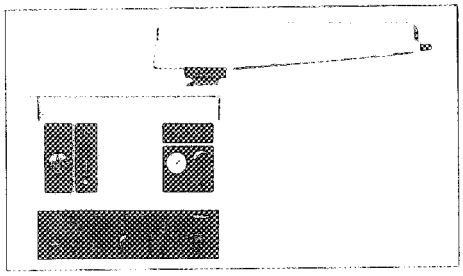
- Grasp the handle, lift and pull horizontally, placing the base of the heater on the right side of the unit.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.
- The heater may be rotated to allow the x-ray machine to be properly positioned over the infant.

NOTE In the x-ray position the Warmer Module will continue to deliver heat to the infant.



Mother/Baby Bonding

- Rotate the heater from the stored position to 180° over the mother's bed or chair.
- Verify that the LEDs on the Control Panel light up to signify that the heater is receiving power.



04

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

23

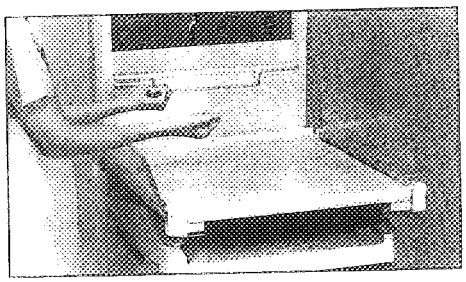
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

BASSINET

Fold Down Front And Side Panels

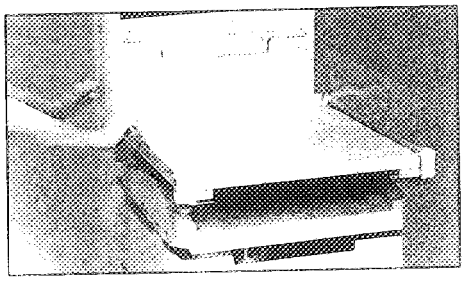
- The Bassinet has Fold-Down Front and Side Panels to allow greater access to the Procedure Table. An Infant Measurement Scale (in both inches and centimeters) and X-Ray Cassette Placement Grid are located on the Bassinet Panels.



To Lower

- To lower the Front or Side Panels, press down and pivot panel out and down with forearm or hands.

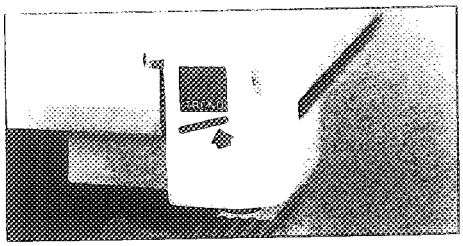
CAUTION Do not leave infant unattended when Front or Side Panels are lowered.



To Raise

- To raise the Front or Side Panels, grasp the panel and rotate up and towards the Bassinet.
- Move panel gently to ensure that it is secure

TRENDELENBURG/REVERSE TRENDELENBURG/LEVEL SLEEP SURFACE

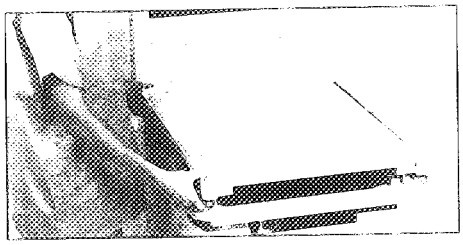


Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet and lift. The Bassinet will rotate from 0° to 10° Trendelenburg, with a 0°, 5° and 10° detent.

Reverse Trendelenburg

- Depress either of the handles located beneath the Front Panel of the Bassinet.
- Push down or lift the Bassinet from the front, using the Trendelenburg Mechanism. The Bassinet will rotate from 0° to 10° Reverse Trendelenburg, with a 0°, 5° and 10° detent

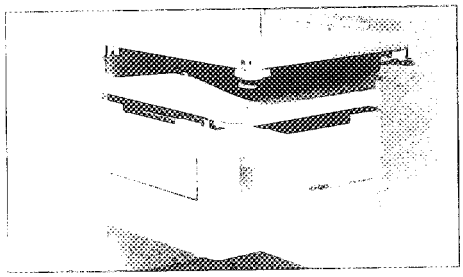


Level Sleep Surface

- Depress either of the handles located beneath the Front Panel and guide the Bassinet to a center position

RETRACTABLE MAYO TRAY

A built-in Retractable Mayo Tray can be used as an instrument shelf during procedures as well as a surface for charting. Do not overload the tray (25 lb load weight capacity).



To Access

- Grasp the tray and pivot out and toward the front of the unit until the tray stops.

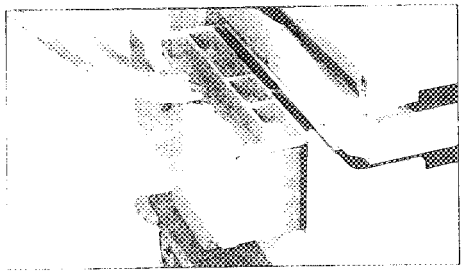
To Store

- Rotate the tray toward the left side of the unit until it is flush with the Bassinet.

WARNING Do not place the infant on the Mayo Tray.

SLIDE-THROUGH STORAGE DRAWER

The built-in Slide-Through Storage Drawer is accessible from either side of the unit and has a removable plastic tray (compartmentalized) for small equipment and disposable items.



To Access

- Grasp the Cut-Out Drawer Handle and pull drawer out and away from the unit.

To Close

- Slide the drawer in until it is flush with the Bassinet.

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

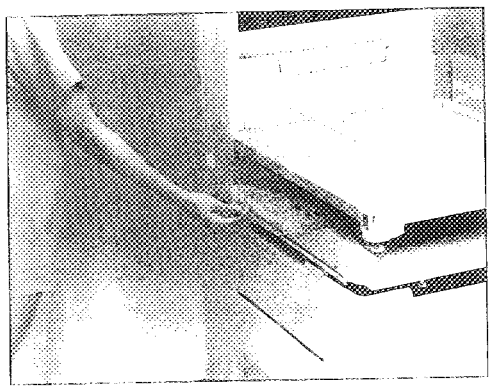
FEATURES

BUILT-IN X-RAY CASSETTE HOLDER

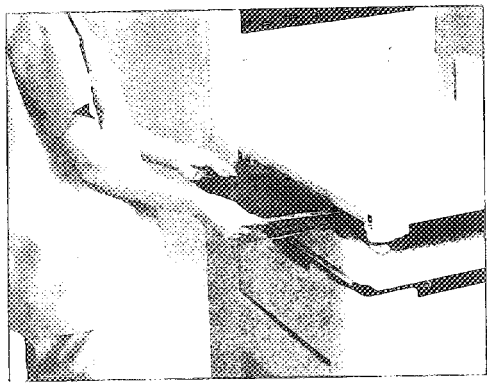
X-Ray Cassette Holder accommodates cassettes up to 12" x 14".

Loading X-Ray Cassettes

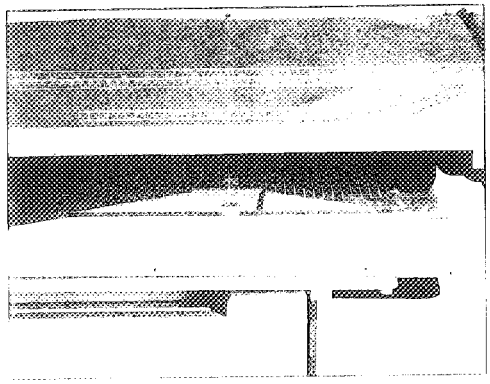
- Working from either side of the Bassinet, locate the X-Ray Cassette Tray directly beneath the Sleep Surface.
- Release the X-Ray Cassette Tray by lifting the tray up and pulling out.



- While supporting the X-Ray Cassette Tray, place the film cassette on the tray.



- To ensure proper cassette placement, align the X-Ray Cassette Tray Grid Markings with the markings located on the Bassinet Front and Side Panels. These grid markings allow you to position the cassette accurately relative to the infant's position in the Bassinet.

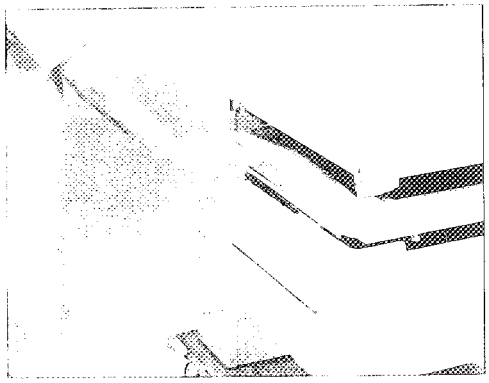


- Slide the cassette and X-Ray Cassette Tray in toward the Bassinet until it rests securely and flush beneath the Bassinet.
- A slight detent will be felt indicating that the tray is "locked" into place.
- The Heating Element may be pivoted 90° away from the Mattress to provide easy access over the Sleep Surface, by an X-Ray Machine.

Unloading X-Ray Cassettes

- When x-ray is complete, lift the X-Ray Cassette Tray up and pull it gently away from the Bassinet.
- Remove the x-ray cassette and slide the tray back in toward the unit to a normal operating position.

NOTE The mattress is radiolucent.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

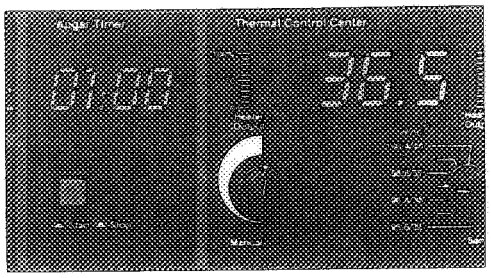
FEATURES

APGAR/PROCEDURE TIMER

Located on the Control Panel is a one-hour electronic Apgar/Procedure Timer.

- To start the Apgar/Procedure Timer, depress the Start/Stop Button located on the Control Panel.
- A visible four-digit display in minutes and seconds will appear on the Control Panel. The timer will begin at 00:00 and run to 59:59.
- A one-second audible tone will sound at one, five, and ten minutes.
- Depress the Start/Stop Button again to reset the timer.

NOTE Power Switch must be ON to operate timer.



LIGHTING BUTTON MODULE

A Lighting Button located on the Control Panel actuates two 15 Watt color correct fluorescent lights. The light can be activated without the main power on.

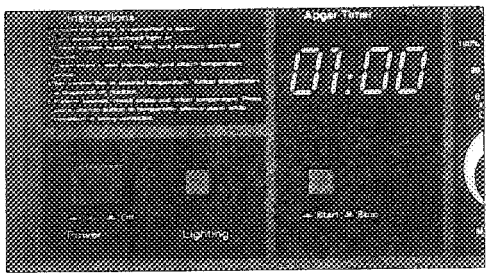
To Activate Lighting

- Depress the Lighting Button, located on the Control Panel.

To Turn Lighting Off

- Depress the Lighting Button again.

NOTE To extend bulb life, turn the examination light on only as required.



TILT-OUT RESUSCITATION COMPARTMENT

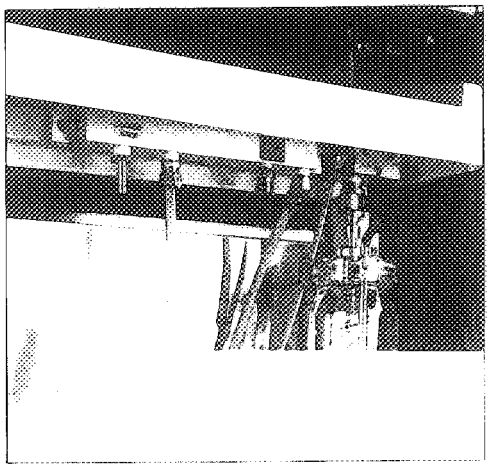
The Tilt-Out Resuscitation Compartment holds the Manometer (pressure gauge) Connector, Oxygen Connector, and Suction Canister. A tube gap at the top of the bin allows the compartment to be closed during use.

To Access

- Grasp Cut-Out Door handle at the front of the unit and pull the door gently toward you.

To Close

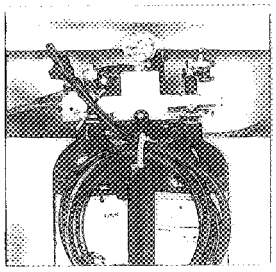
- Push the compartment door gently toward the unit. The Magnetic Catch will hold the door in place.

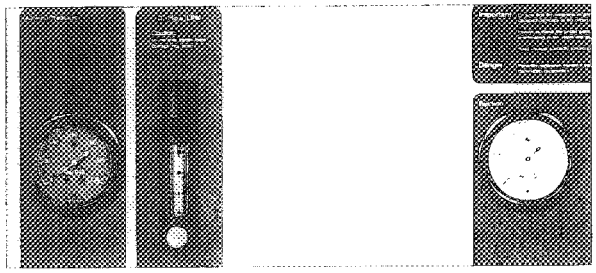


RESUSCITATION PACKAGE

The built-in Resuscitation Package includes:

- Automatic Oxygen Cross-Over System
- Built-in Oxygen Flowmeter
- Airway Pressure Manometer
- Venturi Suction





Built in Oxygen Flowmeter, Airway Pressure Manometer, and Venturi Suction

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

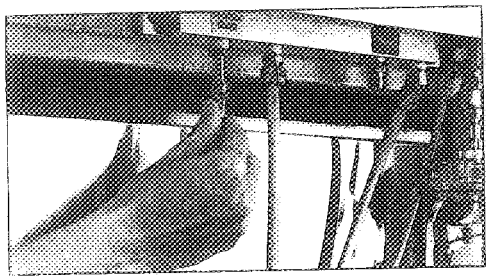
FEATURES

To Utilize Resuscitation Equipment

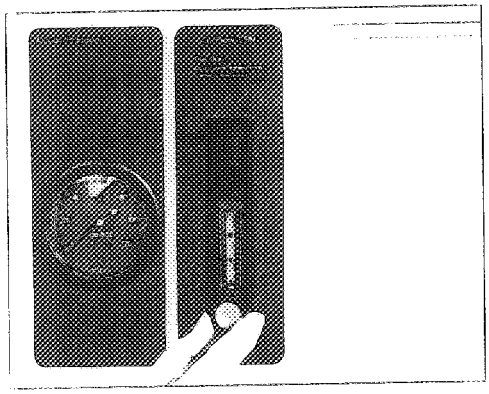
Connect one end of the Oxygen Tubing to the nipple marked Pressure Gauge (located in Resuscitation Compartment). This measures the amount of pressure being delivered during resuscitation.

- Connect the opposite end of the Oxygen Tubing to the Manometer Connecter located on the Resuscitation Bag and Mask.

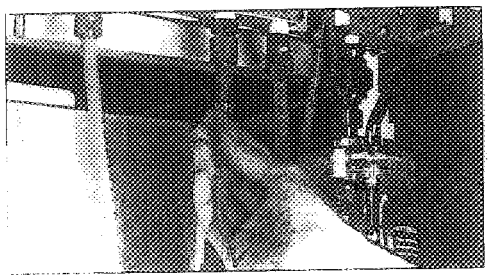
CAUTION The system must be vented or damage to the manometer will occur.



- The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the Control Panel.



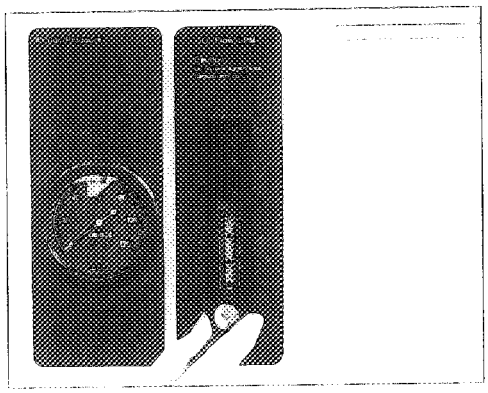
- Using an appropriate adapter, connect one end of a Second Oxygen Tubing to the DISS fitting marked Supply (located in Resuscitation Compartment.)
- Connect the opposite end of this Oxygen Tubing to the supply fitting on the Resuscitation Bag and Mask.



- Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the Control Panel of the unit. Because the Oxygen Flowmeter is back-pressured, a flowmeter should not be used at the Wall Oxygen Source.

CAUTION To avoid damage to the Flowmeter, do not over-tighten the knob.

CAUTION Improper use of supplemental oxygen may be associated with serious side effects for the infant including blindness, brain damage, and death. The method, concentration, and duration of oxygen administration should be prescribed by the attending physician.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

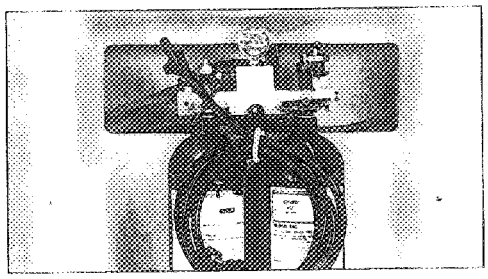
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

Oxygen Cross-Over System

Oxygen can be administered from a regulated Wall Source or from Oxygen Cylinders mounted on the unit. When disconnected from the wall the unit will switch over to the cylinders (NOTE: cylinders must be turned on). When connected back in the wall the unit senses pressure and automatically switches to wall oxygen. A rear compartment contains an Oxygen Supply Hose and a manifold for two "D" or "E" size cylinders.

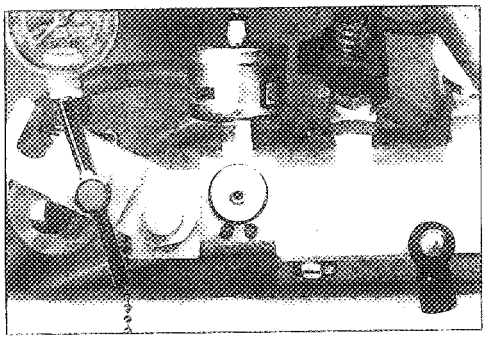
NOTE If the unit is equipped with an optional Air/Oxygen Blender Package, the rear compartment will be adapted to accommodate an "E" size cylinder for each gas type (refer to page 13 for more details on optional Air/Oxygen Blender Package)



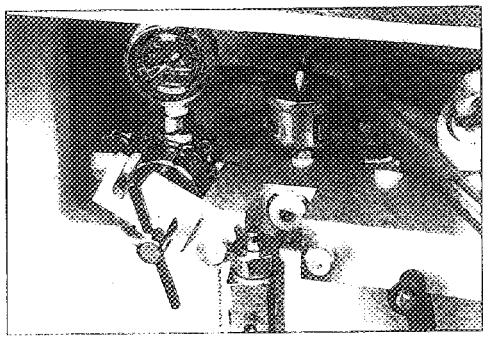
Oxygen Cylinder Installation

- Before installing the Oxygen Cylinders, ensure the built-in Flowmeter and Suction On/Off Switch are turned off.

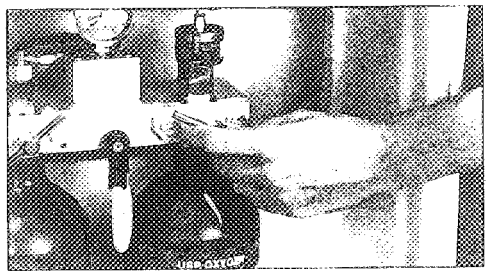
NOTE Before placing a new Oxygen Cylinder in the compartment, insert a new O_2 Cylinder Gasket (Part Number BBM409) on the brass stem to provide a tight seal and prevent cylinder leakage.



- Lift the Oxygen Cylinder up slightly and install it in the Retaining Ring.



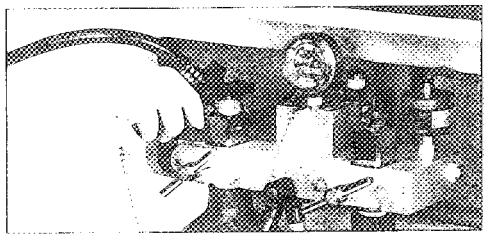
- Tighten the T-Bar.



WARNING Turn the cylinder on by opening the valve slowly by using the cylinder wrench that is provided.

- Check pressure gauge on rear manifold to ensure sufficient gas pressure (approximately 2000 PSI for full "E" size cylinder).
- When the cylinder is turned off, bleed system pressure by turning on the built-in Flowmeter (clockwise turn) until the Flowmeter reads zero.
- Repeat the above steps to install and check the second cylinder.

NOTE Cylinders should be turned off when the unit is not in use.



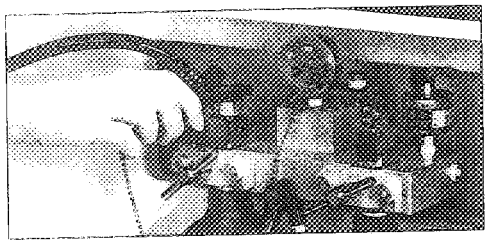
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

Use Portable System

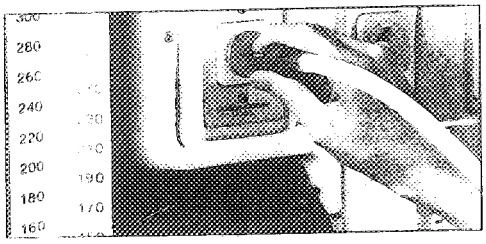
To transfer an infant and continue to have oxygen and suction capabilities, turn the cylinder(s) on using the provided cylinder wrench.

WARNING To turn the Cylinder on, open the valve slowly.



- Disconnect the Wall Source of oxygen.

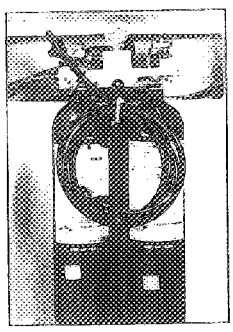
NOTE The unit will immediately begin using cylinder oxygen once the Wall Source is disconnected and the cylinder is turned on. This eliminates the need to manually switch from wall to cylinder gases and could save precious time during emergency transfer.

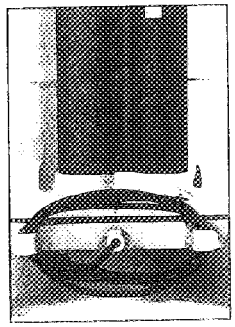


- If the unit has a Scale, it must be unplugged.
- Unplug the electrical cord. The AC Power Loss Alarm will sound if the Main Power Switch is turned on.
- Wind the Oxygen Hose and secure with the elastic cord which is attached to the Oxygen Manifold.
- Wind the electrical cord on the brackets at the base of the warmer.

NOTE It is recommended that one Oxygen Cylinder be kept closed to ensure a full Oxygen Cylinder is available at all times.

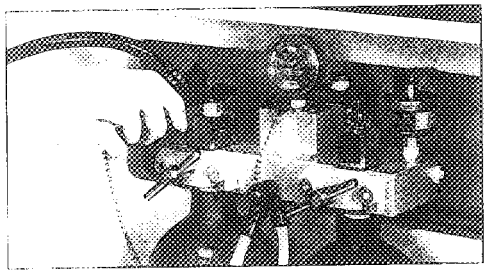
NOTE Before placing a new Oxygen Cylinder in the compartment, insert an Cylinder Gasket (Part Number BBM409) on the brass stem to provide a tight seal and prevent cylinder leakage.



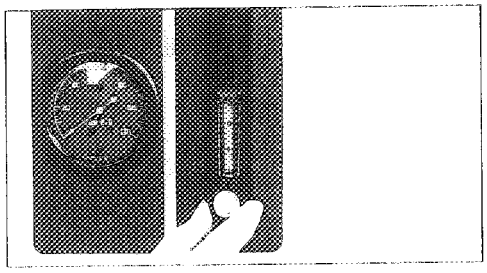


Use Wall Oxygen Source

- Turn the Oxygen Cylinders off.



- Turn the built-in Flowmeter (located on the Front Control Panel) on.
- Bleed the O_2 Cylinder Gauge to zero.
- Turn the built-in Flowmeter off.
- Reconnect the Oxygen Hoses to the wall.
- Plug in the electrical cord.
- To begin using wall-supplied oxygen, turn the built in Flowmeter back on.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

297

H10

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

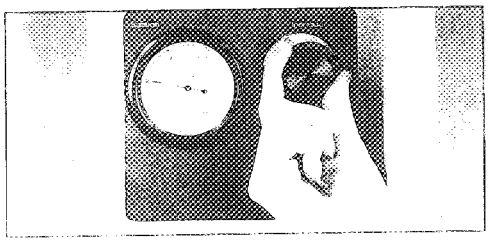
Suction
Controls for Venturi-Operated Suction are built into the Control Panel. Venturi Suction is accomplished by the use of either Wall or Cylinder Oxygen and is variable from 0 to 180 mm Hg.

Set Rate

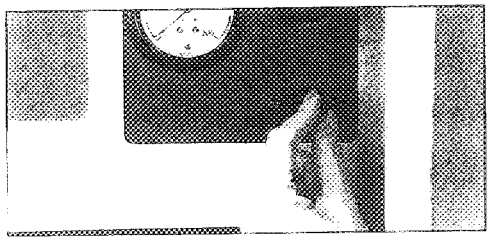
- Place the suction ON/OFF Toggle Switch to the ON position and occlude port.

NOTE Properly occlude the Suction Port located on the canister to obtain the most accurate Suction Gauge reading

- With the Suction Port occluded, rotate the Suction Dial (located on the Front Control Panel) to the desired setting



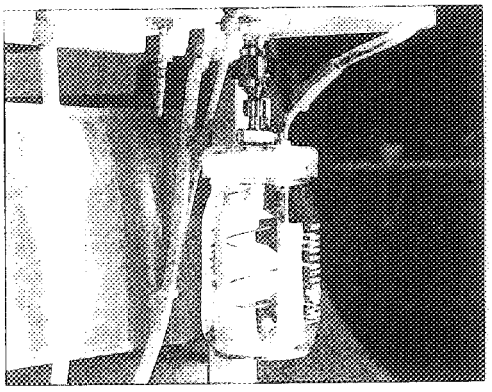
- Turn the suction off with the On/Off Switch located on the Front Control Panel.



NOTE A reusable Suction Canister with a stainless steel port is located in the Front Storage Bin.

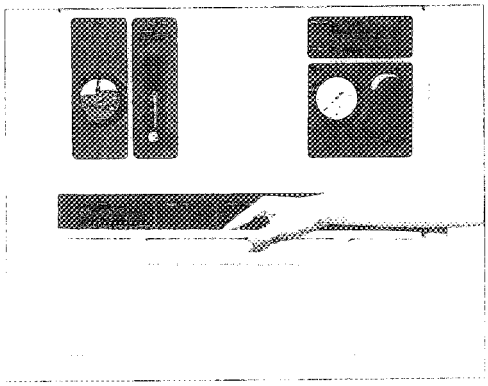
NOTE To increase Oxygen Cylinder life

1) Turn the cylinder off when not in use or when utilizing Wall Source of oxygen.
2) Do not set suction level any higher than necessary to complete procedure.
3) Turn suction off when not in use
4) Connect unit to Wall Oxygen Source when available and practical



THERMAL CONTROL CENTER

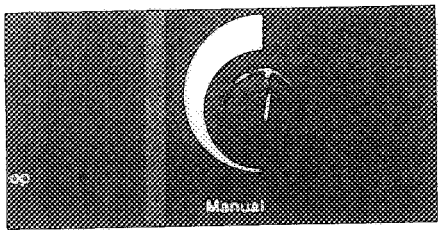
Thermoregulation Controls are centrally located on the Control Panel between the Warmer Module and the Bassinet. A sliding door covers the Control Panel.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

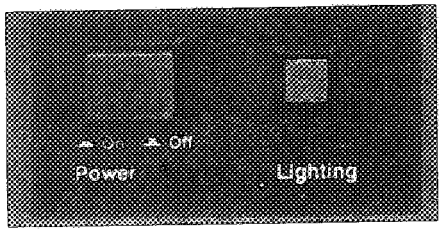
Manual Mode



al Mode is intended primarily for warming the Bassinet and blankets in preparation infant or when it is impractical to attach a Thermistor Probe to the infant.

NOTE Before placing the infant in the Bassinet, pre-heat the Thermistor Probe, face up, in the Bassinet, prior to connecting the Probe into the Jack.

NOTE To avoid overheating or underheating of the infant, Hill-Rom recommends that a Probe should be attached to the infant at all times while in a Radiant Warmer and the infant should not be left unattended.



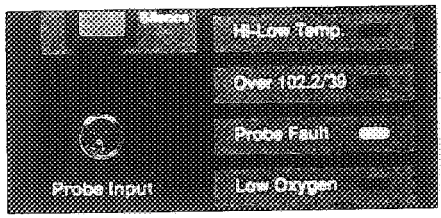
- Plug the power cord into a standard 115V Hospital Grade AC receptacle.

CAUTION Connect the power cord to a properly grounded receptacle that is approved for hospital use. Do not use an extension cord or AC receptacle box.

DANGER Possible explosion hazard if used in the presence of flammable anesthetics. This unit is not intended for use in hazardous Class 1, Group C locations.

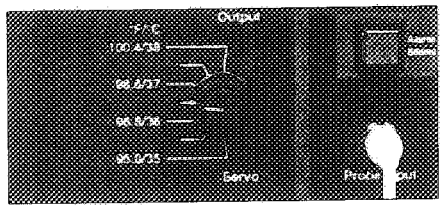
- Turn the power on by depressing the Power Button located on the upper Control Panel.

CAUTION The use of radiant warmers may cause insensible water loss.



NOTE The unit will function in the Manual Mode without a Thermistor Probe inserted in the jack. The Probe Fault LED Display will remain lit during this time.

NOTE Skin temperature alarms are not functional during Manual Mode when Thermistor Probe is not inserted in Probe Jack or when the Probe is inserted in Probe Jack but senses a temperature less than approximately 31°C (88°F).

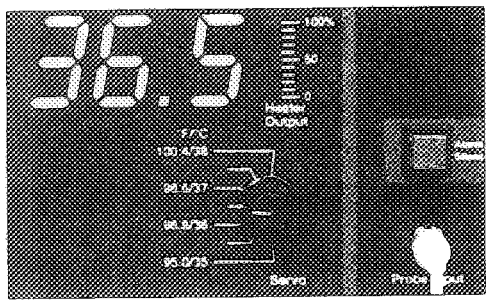


- the desired heater output using the Heater Output Control Dial located the left side of the Thermal Control Center.
- Heater output is shown on the unit in terms of percentage of power and can be from 0% to 100%.
- The unit will remain at the set heater output you choose until you manually readjust it unless the Overheating Alarm is activated (see Overheating Alarm description).

NOTE In Manual Mode, when no heater output lights appear, it is an indication that heater output is 0%.

Green LEDs indicate approximately 10%–30% heater output.
Yellow LEDs indicate approximately 40%–70% heater output.
Red LEDs indicate approximately 80%–100% heater output.

Servo Control Mode



When the Thermistor Probe is inserted into the Probe Jack and senses a temperature of approximately 31°C (88°F), the unit automatically converts to the Servo Control Mode.

The Servo Control Mode also has an LED Heater Output Grid to indicate the amount of energy delivered to the warmer to keep the infant's skin temperature at the predetermined set point temperature.

Heater output is shown on the unit in terms of approximate percentage of power and ranges from 0% to 100%.

As the infant's skin temperature approaches the set point, the heater output will modulate to maintain the infant's skin temperature at the set point temperature.

Once the infant's skin temperature and the set point temperature are equal, only gradual changes in the heater output are ed to maintain the desired infant skin temperature.

Temperature readout displays the infant's skin temperature when the unit is in Servo Control Mode.

- Set the infant's desired target temperature using the Temperature Control Point Dial. Turn the dial to the selected setting.
- Attach the Thermistor Probe to the infant. The Probe should be pre-heated before registering the baby's skin temperature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

17

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

NOTE Placement of the Probe is vital because it is the Probe that senses the baby's skin temperature and regulates warmer output.

SUPINE INFANTS...place the flat stainless steel side of the Probe down on the infant's abdomen below the rib cage

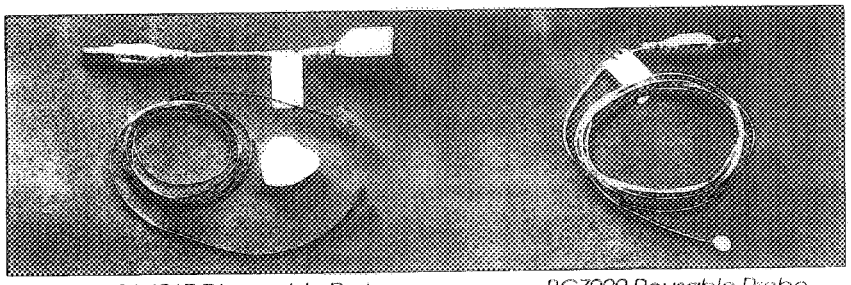
PRONE INFANT...place the flat stainless steel side down on the infant's back below the rib cage, but away from the kidneys.

CAUTION Always attach the Probe with a reflective Probe cover. Serious temperature and control errors can occur if anything other than the recommended Probes and Probe covers are used. Do not use tape to attach the Probe.

CAUTION Inspect the infant's skin for reddened areas which may result from the heating of materials in contact with the skin

CAUTION Avoid placement of objects (equipment, blankets, clothing) in the Bassinet that can block heat or absorb heat away from the infant.

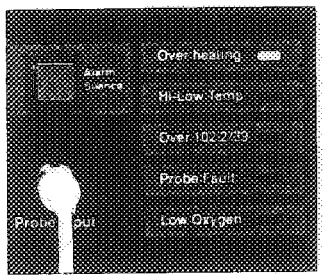
NOTE Only the following Thermistor Probes should be used with the unit.



SA4567 Disposable Probe *BCZ009 Reusable Probe*
(Requires Reusable Adapter Cable SA4566)

ALARM DESCRIPTIONS

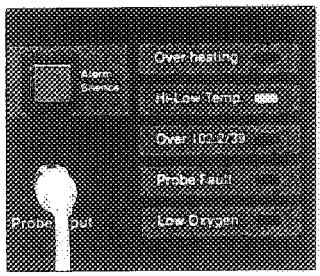
Overheating Alarm (Manual Mode Only)



- An Overheating Alarm will sound if there is constant heater output of 100% for approximately 18 minutes or approximately 25% (2 or 3 LEDS) for 73 minutes or any combination thereof of power and time.
- When the Overheating Alarm is triggered, power to the heater is reduced to approximately 30%.
- The Overheating Alarm can be silenced by depressing the Alarm Silence Button located on the right side of the Control Panel.
- The unit will continue to operate in Manual Mode and no Overheating Alarm will sound as long as the heater output is kept under approximately 30% (1 or 2 LEDS) and a Thermistor Probe is not inserted into the Probe Jack.
- Once the Probe is inserted into the Probe Jack and the Probe senses a temperature of approximately 31° C, the unit becomes a Servo-Controlled Unit controlled by the skin temperature of the infant.

WARNING Do not leave the infant unattended.

High-Low Temperature Alarm (Servo Mode Only)



- If the infant's temperature has fluctuated more than +/- .5°C from the set point temperature, a solid, visible Hi-Low Temperature LED Display will appear immediately on the Control Panel.
- If after four minutes the high-low temperature has not been rectified, an audible Hi-Low Temperature Alarm will sound.
- During the audible alarm condition, heater output will change to approximately 30% until the infant's skin temperature returns within the target range or until the audible alarm is silenced.
- The Hi-Low Temperature Alarm can be silenced by depressing the Alarm Silence Button; however, the Hi-Low Temperature LED Display will remain lit until the infant's temperature returns to within the target range. If the infant's temperature remains outside of the .5°C setpoint for another four minutes the audible alarm will sound again.
- When the Hi-Low Temperature condition is rectified, the Hi-Low Temperature Alarm will automatically reset.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

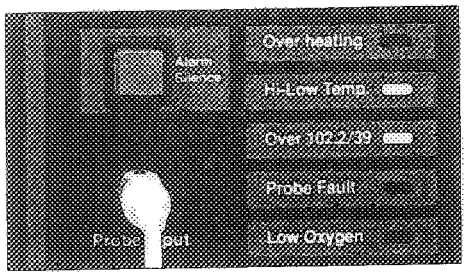
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

FEATURES

Over 102.2°F/39°C Alarm

An audible and visible Over 102.2°F/39°C Alarm will activate immediately when the Thermistor Probe senses a temperature that exceeds 102.2°F/39°C.

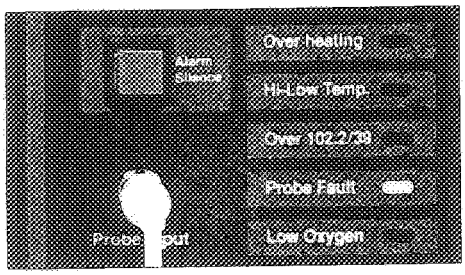
- Heater output is reduced to 0% and will not resume until the Thermistor Probe senses that the temperature has fallen below 102.2°F/39°C.
- The alarm will not silence until the condition is rectified.



Probe Fault Alarm

- In the Manual Mode when the Probe is not inserted in the Probe Input Jack, the Probe Fault LED will remain lit.
- In the Servo Mode, whenever the Probe senses a temperature of less than approximately 31°C, for approximately one minute, the Probe Fault LED will come ON, an audible alarm will occur and heater output will drop to approximately 30%.
- When the alarm is silenced by depressing the Alarm Silence Button:

  If sensed temperature is still below 31°C, the Probe Fault LED will remain lit and the unit will revert to Manual Mode.
  If the sensed temperature is above 31°C, the Probe Fault LED will go off and the unit will revert to Servo Mode.



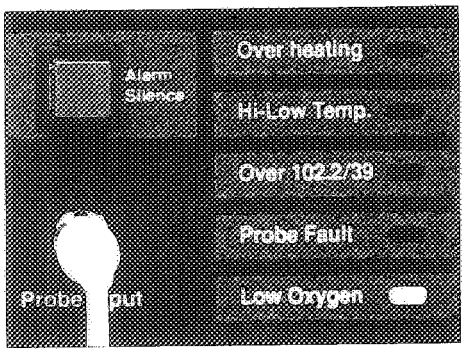
Low Oxygen Alarm

- The unit has a Low Oxygen Cylinder Pressure Indicator. An audible alarm will sound for one of three reasons:

  1) Oxygen Cylinders are turned off,

  2) No Oxygen Cylinders are hooked up to the unit, or

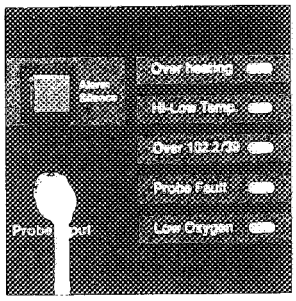
  3) Oxygen Cylinders are hooked up to the unit and turned on but oxygen pressure has fallen below 750 PSI.
- The Low Oxygen Alarm can be silenced by depressing the Alarm Silence Button, however, the Low Oxygen LED Display will continue to flash until the situation is rectified.



NOTE The Low Oxygen Alarm must be silenced each time the Alarm Silence Button is depressed in any other alarm situation.

System Fault Alarm

- A System Fault has occured when an audible alarm sounds and all Alarm LED Displays illuminate.
- The System continually monitors itself (electronically) to ensure complete thermoregulation integrity. If, at any time, the Heater Control Signal and the actual Heater Current Signal do not agree, AC power/heater output is immediately terminated, and a System Fault Alarm is activated.
- The System Fault Alarm may also be activated by connecting an incompatible temperature Probe, or when the Probe is shorted or when there is an open heater element.
- The alarm cannot be silenced until the condition is rectified.
- The alarm may indicate a system failure and require maintenance by a qualified technician.



Loss Of AC Power Alarm

When the unit becomes unplugged or AC power is interrupted to the unit when the Power Switch is "on", a pulsating alarm sound. This Loss Of AC Power Alarm will fade after approximately two minutes or will automatically reset if power is restored to the unit.

- The Loss Of AC Power Alarm works off a capacitor that will recharge when AC power is restored to the unit and Power Switch is turned on.
- No batteries are required for the operation of this alarm.

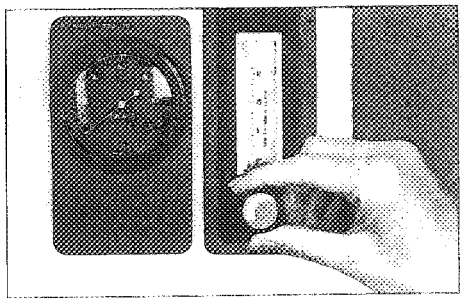
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

OPTIONS

AIR/OXYGEN BLENDER PACKAGE

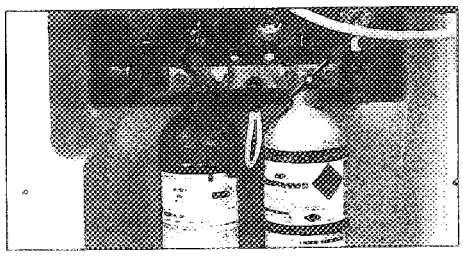
The optional Air/Oxygen Blender Package allows oxygen and medical air to be mixed. Oxygen and medical air can be administered from a regulated Wall Source or from the oxygen and Air Cylinders mounted on the unit. A Rear Compartment contains an air/O_2 Cylinder Manifold for two "D" or "E" size cylinders. The Air/Oxygen Blender Package also includes a built-in 30-Micron Filter and WaterTrap, Pipeline Air, and O_2 Pipeline/Cylinder Cross-Overs.



NOTE The Blender will only operate with Air and O_2 tanks turned on unless it is connected to a wall source.

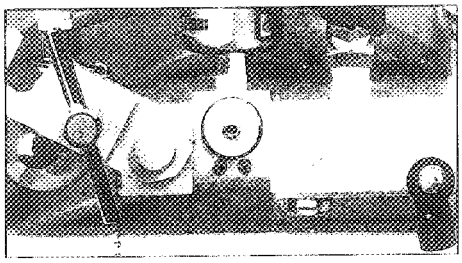
Air/Oxygen Blender Alarm

- The Air/Oxygen Blender is equipped with a continuous audible alarm which will sound when one gas source (either medical air or oxygen) has been depleted or failed, a difference of 20 PSI.
- The alarm will not silence until the depleted gas supply is restored.

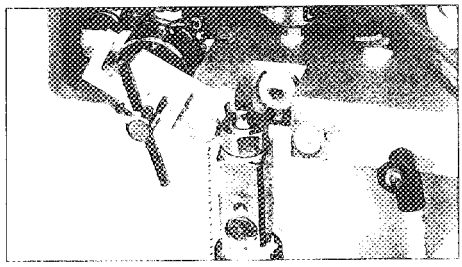


Installation

- Before installing air/O_2 Cylinders, ensure built-in Blender Selector Dial is set at 21% concentration (equivalent to ambient air).
- Ensure built-in Flowmeter and Suction On/Off Switch are turned off.



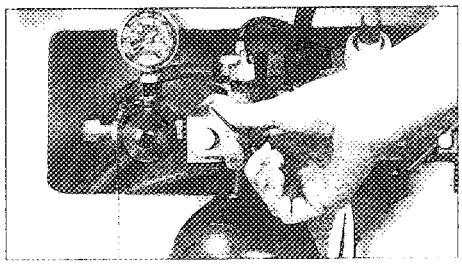
- Lift the Cylinders up slightly and install in the Retaining Rings.



- Tighten the T-Bars.

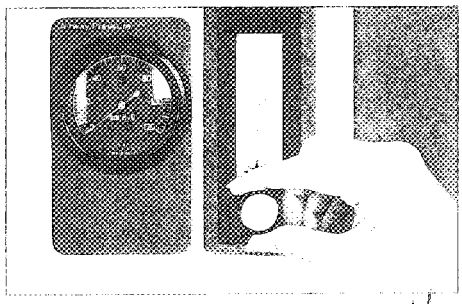
WARNING Turn on the Cylinders by opening slowly.

- Check individual high pressure gauges on Rear Manifold to ensure sufficient gas pressure (approximately 2000 PSI for full "E" size cylinder).



- When each cylinder is turned off, bleed the system pressure by turning on the built-in Flowmeter (clockwise turn) until the Flowmeter reads zero.

NOTE Before placing a new Oxygen or Air Cylinder in the compartment, insert a new Cylinder Gasket (Part Number BRM409) on the brass stem to provide a tight seal and prevent Cylinder leakage.



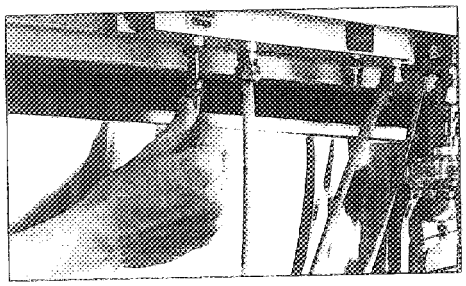
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

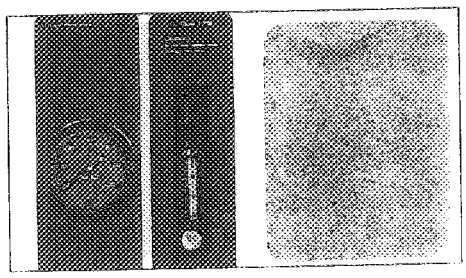
OPTIONS

Package To Utilize The Resuscitation Equipment With The Blender Package

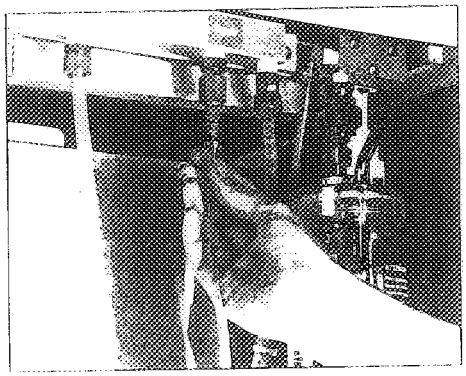
nnect one end of Oxygen Tubing to the nipple marked Pressure Gauge ocated in Resuscitation Compartment). This measures the amount of pressure being delivered during resuscitation



- Connect the opposite end of the Oxygen Tubing to the Manometer Connector located on the Oxygen Mask. The amount of pressure being delivered is indicated on the Airway Pressure Manometer built into the Control Panel.



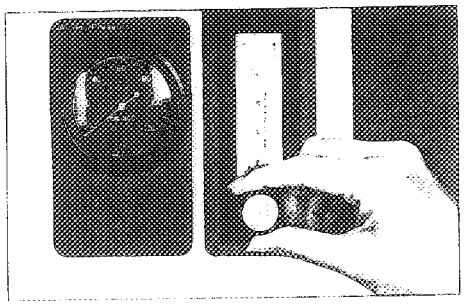
- Using an appropriate adapter, connect one end of a Second Oxygen Tubing to the DISS fitting marked Supply (located in Resuscitation Compartment).
- Connect the opposite end of this Oxygen Tubing to the supply fitting on the Mask.



- Dial in the appropriate flow rate of oxygen by using the built-in Oxygen Flowmeter, located on the Control Panel of the unit.

WARNING Analyze the delivered gases with a Calibrated Oxygen Analyzer.

NOTE Air/O_2 concentrations should be analyzed before each use



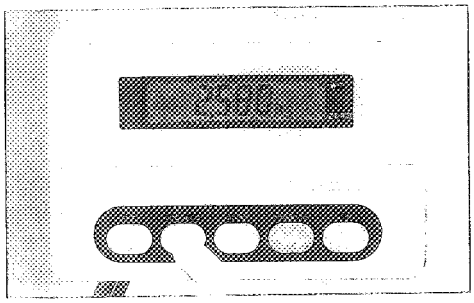
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

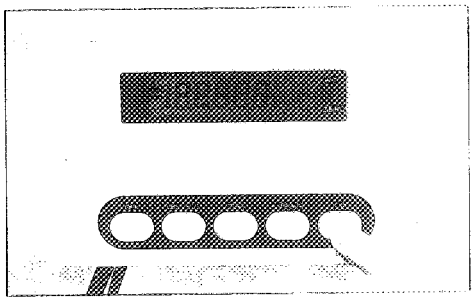
OPTIONS

SCALE

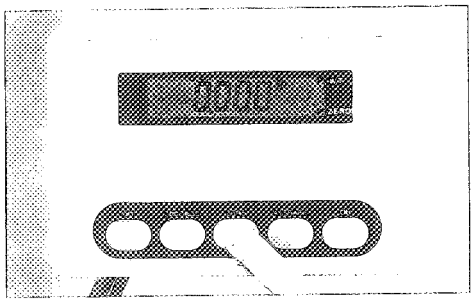
The weighing capacity is approximately 17.6 lbs./8 kgs. The scale has five buttons and a display area. A caption appears above each button describing its function. Each control button is color-coded and graphically represented.



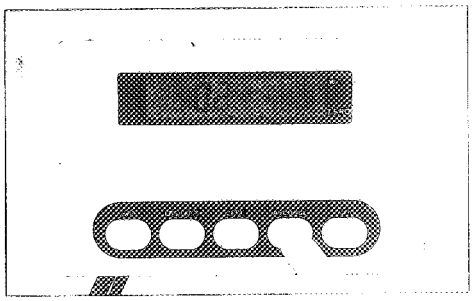
The LBS/KGS button is used to switch to lbs. or kgs.



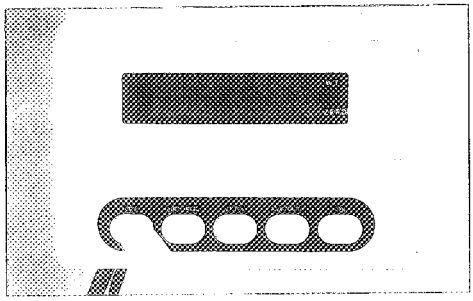
The ON button turns the unit on



The ZERO button resets the scale to 0.000 prior to placing an infant on the scale.



The AVERAGE button compensates for an active infant, vibration or excessive air currents.



The OFF button turns the unit off.

Before Operating The Scale

For the most accuracy, follow these procedures.

Scale Setup

Prior to operating the Stabilet Scale refer to the service manual for complete instructions on scale setup.

Sleep Surface Preparation

Before placing the infant on the sleep surface, it must be prepared. This includes placing articles on the surface such as linens, skin temperature probes, etc. that the infant will require. It can be helpful to place a list of these items near the warmer for future reference.

NOTE It is important to develop a protocol to determine what items belong on the Bassinet at the time of weighing.

Weight Interferences

Before operating the scale, be aware of the following:

- The entire surface of the Bassinet is weighed. It is also important that no one touch the Bassinet while the scale is operating. For example, leaning on the front or side panels can cause incorrect readings.
- The most accurate weight reading will be achieved if nothing is touching the Bassinet. This includes patient lines, temperature probes, ventilators, ECMO equipment, drainage bags and anything that could impact the weight and cause an incorrect weight to appear in the display.

Continuous Display

The infant's weight reading will appear continuously on the display until the OFF button is activated. Turning the unit off will not erase any weight readings but only deactivate the scale for a period of time.

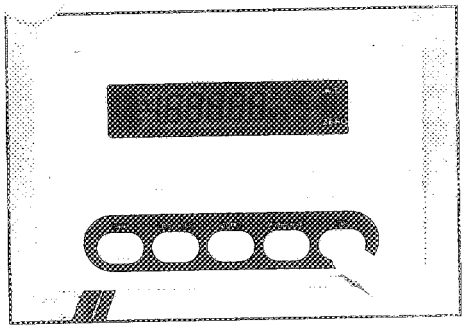
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

OPTIONS

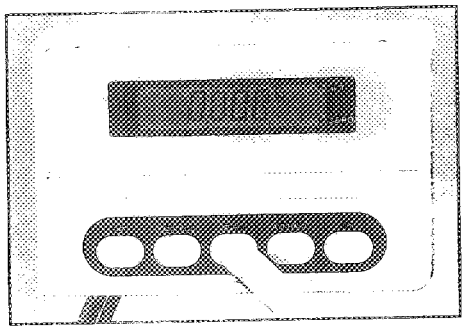
PATIENT WEIGHING

Step One – Turning the Scale On



- Connect the scale's power cord to a 120v electrical outlet.
- To turn the scale on, press and release the ON button on the front panel.
- When first turned on, all display indicators will light briefly, and then clear.

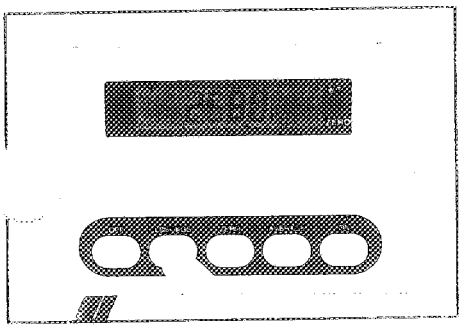
Step Two – Zeroing the Scale



Before placing the infant on the sleep surface, the bed weight must be zeroed.

- Press ZERO to obtain a zero reading on the display prior to weighing the patient for the first time.
- The scale will read 0.000 lbs./kgs.

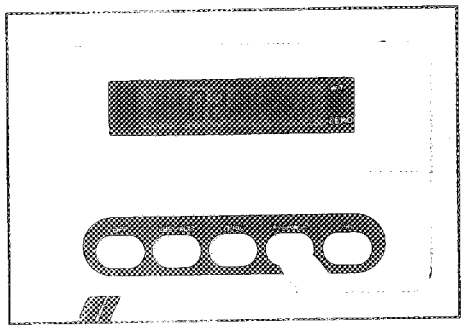
Step Three – Weighing the Patient



For the most accurate weight readings, the infant should be centered on the bed and lying still.

- Place the infant in the Bassinet.
- The patient weight will appear in the display. For lbs. to kgs., press the LBS/KGS button during weight display.

Step Four – Averaging Level



The AVERAGE button allows you to obtain an average weight when an active infant, excessive vibration and/or air currents cause the weight reading to fluctuate.

- Press and release the AVERAGE button. The display will begin a countdown – 02, 01, then a weight reading. This takes approximately four seconds. The scale will display an infant weight based on a statistical average. Do not press any other keys while the scale is in the averaging level mode.
- This statistical average weight will display for approximately 37 minutes.
- The unit will then return to the original weighing mode.

NOTE This feature does not affect the accuracy of the unit.

LOW BATTERY INDICATOR

When the scale's battery power becomes low, the word "LO BAT" will appear in the scale's display. To recharge the battery, plug the unit into an outlet. The battery is charged when the "LO BAT" display disappears.

NOTE The Infant Scale receives backup power from six AA batteries contained in the scale indicator when the power cord is unplugged from the wall receptacle.

CAUTION The Infant Scale calibration information is not retained in the scale indicator memory in the event that total electrical power is lost. To prevent calibration information loss, ensure that the scale indicator batteries are adequately charged before unplugging the power cord from the wall receptacle. If the scale indicator displays "LO BAT" message, allow sufficient time for the batteries to recharge before unplugging the power cord from the wall receptacle. If the batteries do not accept charge, replace the batteries and recalibrate the Infant Scale.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

19

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CLEANING

STERILIZATION

The Centers for Disease Control recommend EPA approved hospital disinfectants, used at manufacturers suggested dilutions. Cleaning should be done by wiping a soft dampened cloth over the surface, followed by wiping with a dry cloth.

Quartenary ammonium disinfectants may be used to reducethe contamination level between patients.

Alcohol, strong or abrasive cleaners and hydrocarbon solvents are not necessary and should not be used on plastic surfaces.

MATTRESS CARE

The mattress cover may be cleaned with a mild detergent, rinsed, and cold sterilized. The following products have been tested by the Herculite Laboratory and have been found not to have a harmful effect on StaphChek® fabrics WHEN USED IN ACCORDANCE WITH MANUFACTURERS' RECOMMENDED DILUTION.

TRADE NAME	TYPE	MANUFACTURER
A33	Quartenary	Airwick
Absolute	Quartenary	Walton-March
Beaucoup	Phenolic	Huntington
Blue Chip	Quartenary	S.C. Johnson
Coverage 256	Quartenary	Vestal
El Dorado Plus	Quartenary	Puritan/Churchill
Elimstaph	Quartenary	Walter G. Legge
Forward DC	Quartenary	S.C. Johnson
Franklin Sentinel	Quartenary	Purex
Galahad	Phenolic	Puritan/Churchill
Hi-Tor	Quartenary	Huntington
Insurance	Quartenary	Vestal
LPH	Phenolic	Vestal
Matar	Phenolic	Huntington
Omega	Quartenary	Airwick
Quanto	Quartenary	Huntington
Sanikleen	Quartenary	West Chemical
Sanimaster 111	Quartenary	Service Master
Surfacide	Quartenary	Walton-March
Tri-Quat	Quartenary	Vestal
Vesphene 11	Phenolic	Vestal
Virex	Quartenary	S.C. Johnson

Betadine stains may be removed from the mattress by doing the following:

- Use a 5.25% sodium hypochlorite solution (Clorox® brand bleach).
- Apply 3 drops of the solution per square inch immediately and scrub lightly. The stain should start to fade almost immediately and within 15 minutes should be totally gone.
- Stubborn stains may need further applications. No more than 3 applications on any one area are recommended.
- When completely dry, rinse area with clear water and wipe dry.
- If solution comes into contact with skin, wash off with water and follow manufacturer's label instructions.

CLEANING OF THERMISTOR PROBE

Several precautions must be observed when cleaning and sterilizing to protect Probe from damage.

Avoid contact with strong, aromatic, chlorinated, ketone ether or ester solvents. Prolonged immersion in alcohols or mild organic solvents, detergent solutions or highly alkaline solutions will cause the cable to lose flexibility.

Probe may be disinfected and sanitized by washing with 3% hydrogen peroxide, 70% isopropanol, 70% ethanol, or 100% alcohol. Dakin's solution (sodium hypochloride in neutral buffer) is also suitable. Activated dialdehyde solutions, such as Cidex, are also effective.

Probe plug should not be immersed.

STERILIZATION OF THERMISTOR PROBE

Ethylene oxide sterilization is the preferred method. After sterilization, Probes must be safely and thoroughly ventilated before handling or use.

CAUTION Autoclaving may cause Probe insulation to fail, and may also cause the Probe to give inaccurate reading.

CLEANING OF CASTERS

The Stabilet 2000C Infant Warmer will be used both in and outside aseptic surgical areas. Care should be taken to assure the casters do not carry contamination into the surgical suite. Removal of accumulated debris and treatment of the caster tread with a spray of disinfectant solution as the unit is transferred into the surgical suite is recommended.

CLEANING OF SIDE PANELS

The Side Panels are made of clear polycarbonate plastic and can be damaged by cleaning with alcohol, abrasive agents, hydrocarbon solvents or phenolic disinfectants. Use only gentle detergents for cleaning and polish with a soft cloth to return clarity.

CLEANING RESPIRATORY THERAPY PARTS

Remove and clean all tubing, masks and control apparatus which have come in contact with patient secretions. Cleaning procedures should follow standard recommendations for respiratory therapy equipment and should include surveillance for residual pathogenic contamination. Respiratory therapy equipment tends to deteriorate with age and repeated cleaning and sterilization. Assure it is safe and functioning properly. Cracked rubber and plastic articles should be replaced.

MAINTENANCE

The Stabilet 2000C Infant Warmer requires regular care and maintenance, as detailed in the Service Manual. Please request your maintenance technician to follow the preventive maintenance section in the Service Manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

SAFETY TIPS

For over 65 years Hill-Rom has set the standard for quality in ent room equipment. During this time, with input from ny of our customers, we have acquired useful tips which may contribute to the safety of the infant and staff

SIDE PANELS
To provide maximum protection for the infant, the side panels should always be in a full, upright position and latched when an infant is unattended. To ensure the side panels are latched, give the side panels a gentle tug

TRANSFERRING THE STABILET 2000C INFANT WARMER
Although the unit is lightweight and easy to move, be sure to keep hands and feet clear of the wheels when moving to prevent destabilization of the unit or injury to hands or feet.

BRAKES
Brakes should always be set when the unit is occupied. After setting the brakes, push and pull the unit to ensure they are engaged.

X-RAY CASSETTE HOLDER
If using the X-Ray Cassette Holder accessory, always secure the holder to the unit when not in use This will avoid possible damage to the unit and holder.

SCALE
The Display Unit may only be attached to the left hand side when facing the front of the unit.

PREVENTIVE MAINTENANCE
Quarterly preventive maintenance must be performed to ure all features are functioning as originally designed. rticular attention must be addressed on safety features, including but not limited to:

- Side Panel Latching Mechanisms
- Caster Braking Systems
- Electrical Cords And Components
- Quartz Heater
- Temperature Alarm System
- Scheduled Recalibration

Please refer to your Service Manual for specific details on preventive maintenance.

PARTS AND ACCESSORIES
Use only Hill-Rom parts and accessories Do not modify the unit without authorization from Hill-Rom

CAUTION
Federal law restricts this device to sale by or on the order of a licensed health care practitioner

ECT CUSTOMER SERVICE HOTLINE: 800-638-2546

Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800-638-2546
International • 812-[illegible]

Manufactured for Hill-Rom under a quality system certified to **ISO 9001/EN46001** by TÜV Product Service of San Diego, CA.

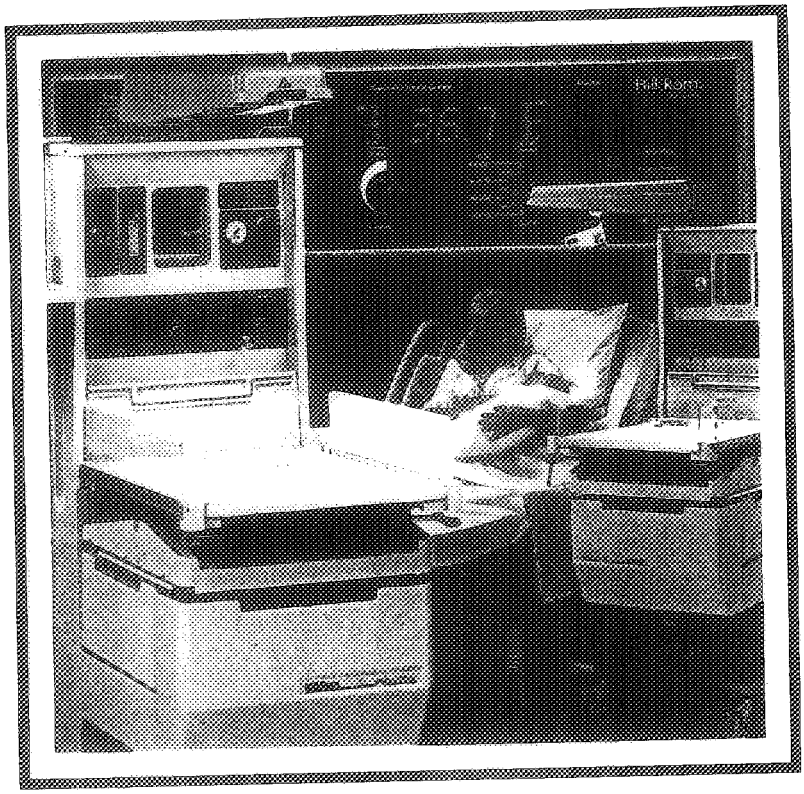
Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.
© Hill-Rom 1996

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

W6099A RC1096

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

A HILL-ROM SOLUTION

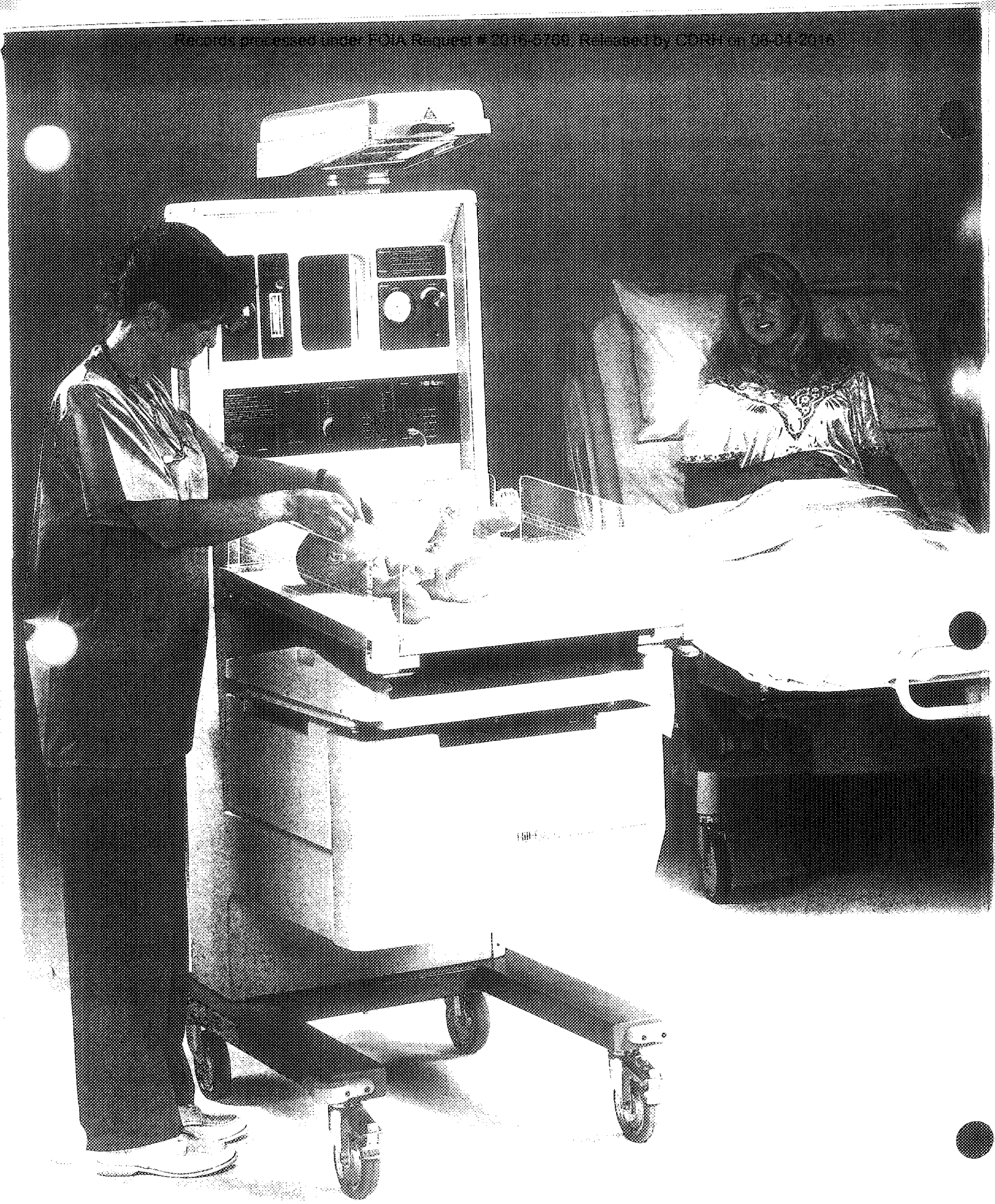


STABILET 2000C INFANT WARMER

Hill-Rom
A HILLENBRAND INDUSTRY

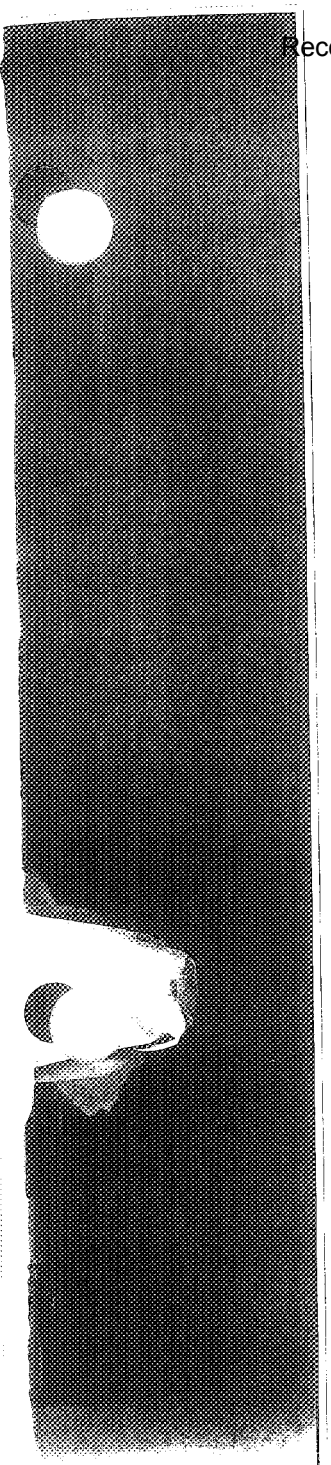
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

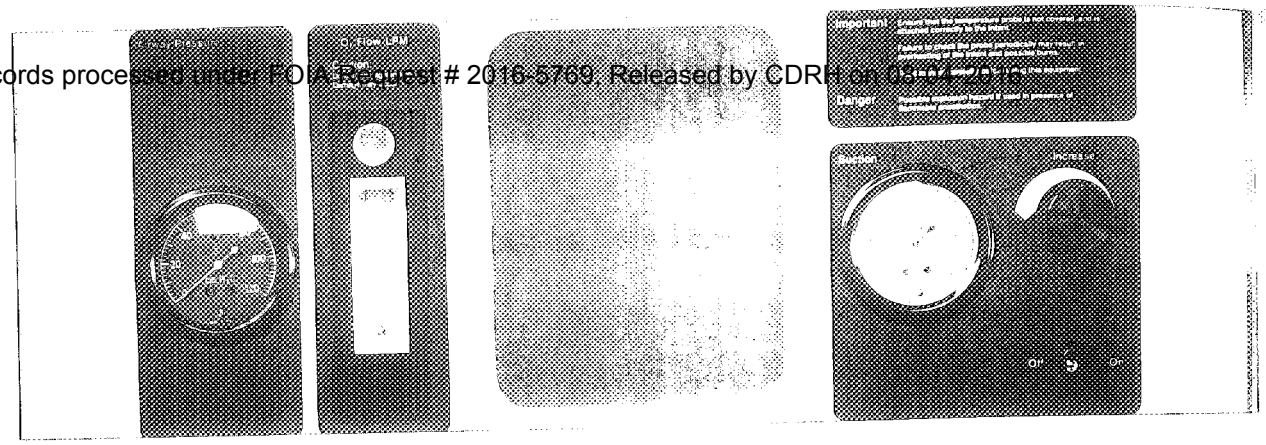
Records processed under FOIA Request # 2016-8700, Released by CDRH on 08-04-2016

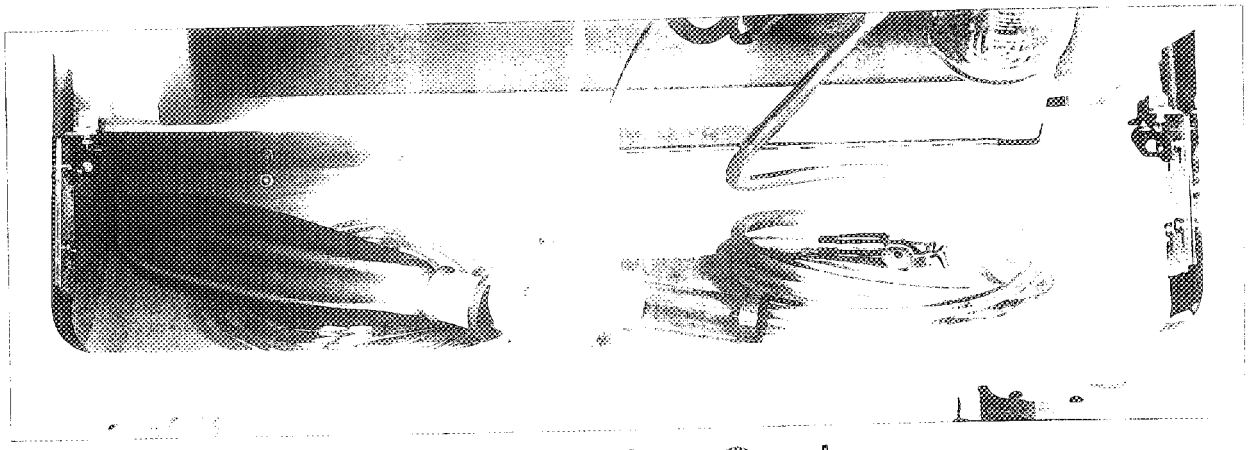


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769. Released by CDRH on 08-04-2016







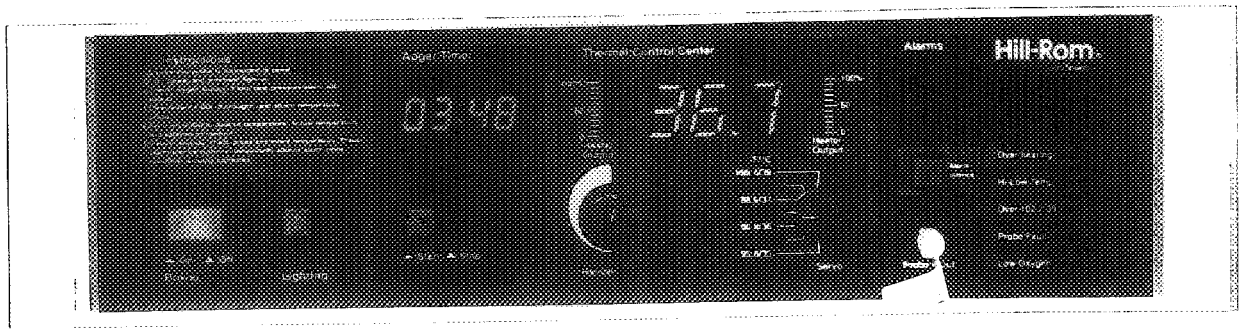
Resuscitation Center

The unit was carefully designed to allow resuscitation to be done as quickly and easily as possible.

Critical seconds saved by clearly-organized resuscitation panel.
Organized for speed, the resuscitation panel includes a built-in flowmeter, airway pressure manometer and a pediatric air/oxygen blender.

The panel also contains the controls for the suction or venturi operation. Suction can operate from either wall or cylinder oxygen.

Equipment always available when needed thanks to the special resuscitation compartment.
Just open the compartment, and you'll always be able to quickly access bag and mask, suction tubing and other crucial resuscitation equipment.



Thermal Control Center

Built into the unit are state-of-the-art features including automatic conversion from manual to servo control when a skin temperature of 31°C or above is sensed and a sophisticated alarm system.

Easy operation saves nursing time and energy consumption.
Simply turn the power on and the unit is operational in manual mode. The caregiver can set the amount of heat coming from the warmer using a separate manual control. Heater output is indicated by a color LED bar graph.

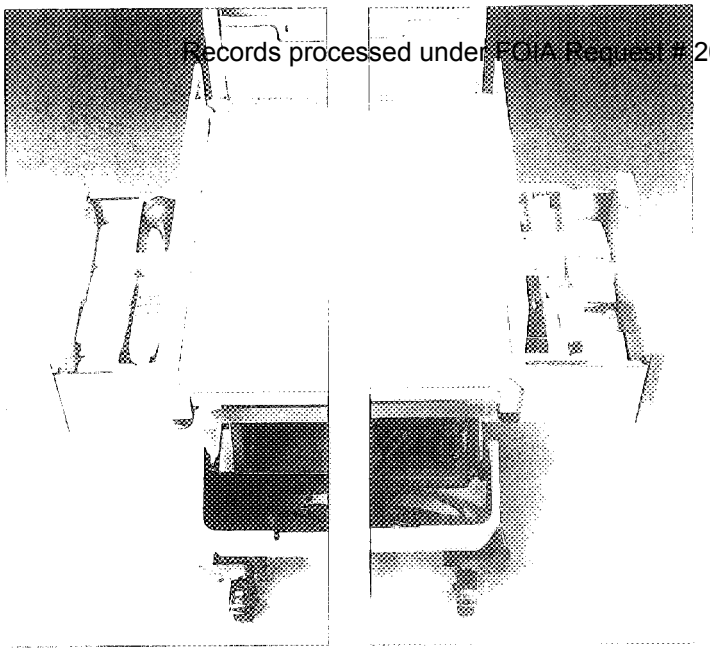
Once the probe is attached to the infant and senses a skin temperature of 31°C or above, the unit automatically converts to servo control, eliminating the need for a switch to change from manual to servo control. In the servo mode, the infant's skin temperature is easily visible on the large digital display.

Sophisticated alarm system simplifies operation and enhances patient safety.
The alarm system is active in both manual and servo modes.

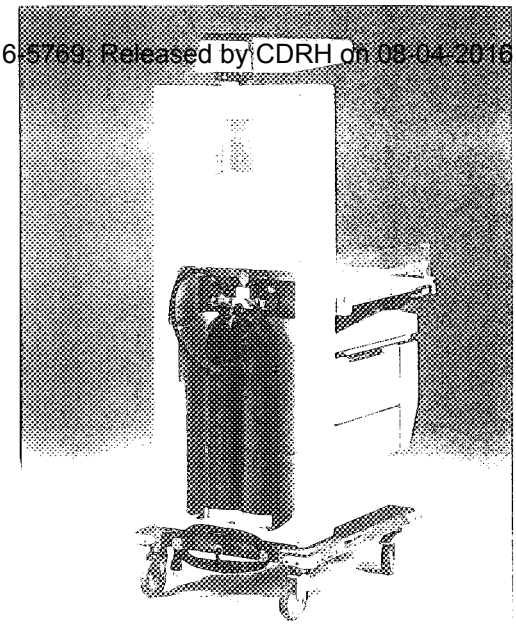
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

24

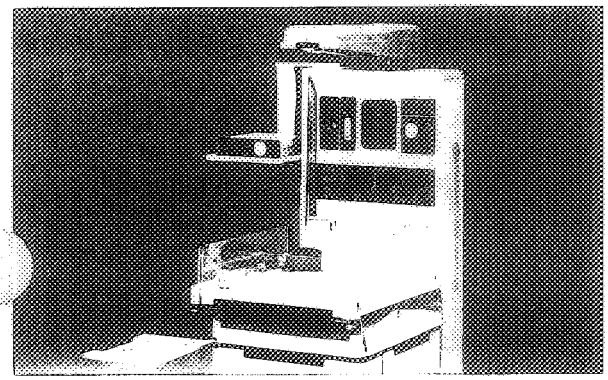
Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016



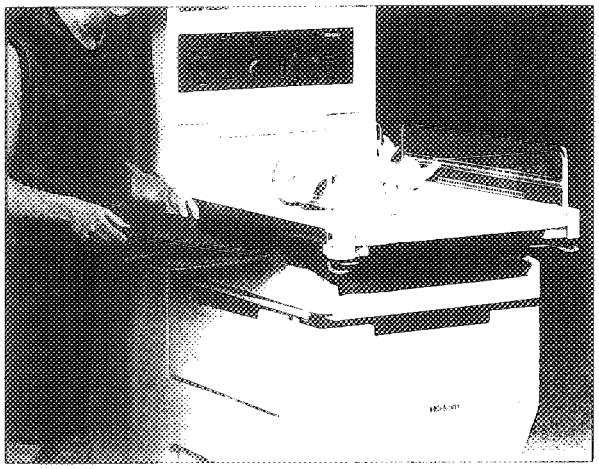
A centralized, slide-through drawer with removable [illegible] accessed from both sides of the unit. The front all[illegible] resuscitation equipment and supplies for [illegible]



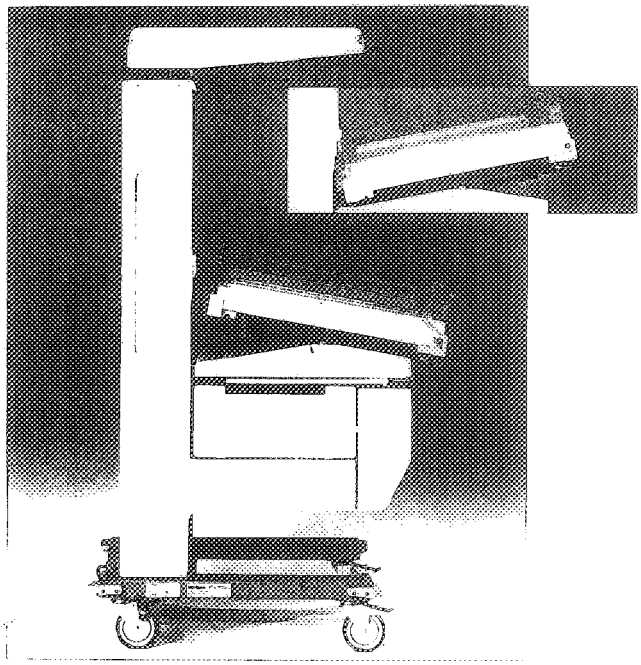
[illegible] the oxygen and optional [illegible] two E cylinders. An [illegible] allows oxygen from the cylin[illegible] hoses are disconnected. An [illegible] pressure [illegible] pressure



A large bassinet provides ample work space in delivery [illegible] operating room, and LDRP room environments. The [illegible] Mayo tray provides space for charting procedures [illegible] shelves provide even more space for [illegible]



A built-in [illegible] disturbance during [illegible] tray. The [illegible] bassinet sides reduce [illegible] position [illegible]



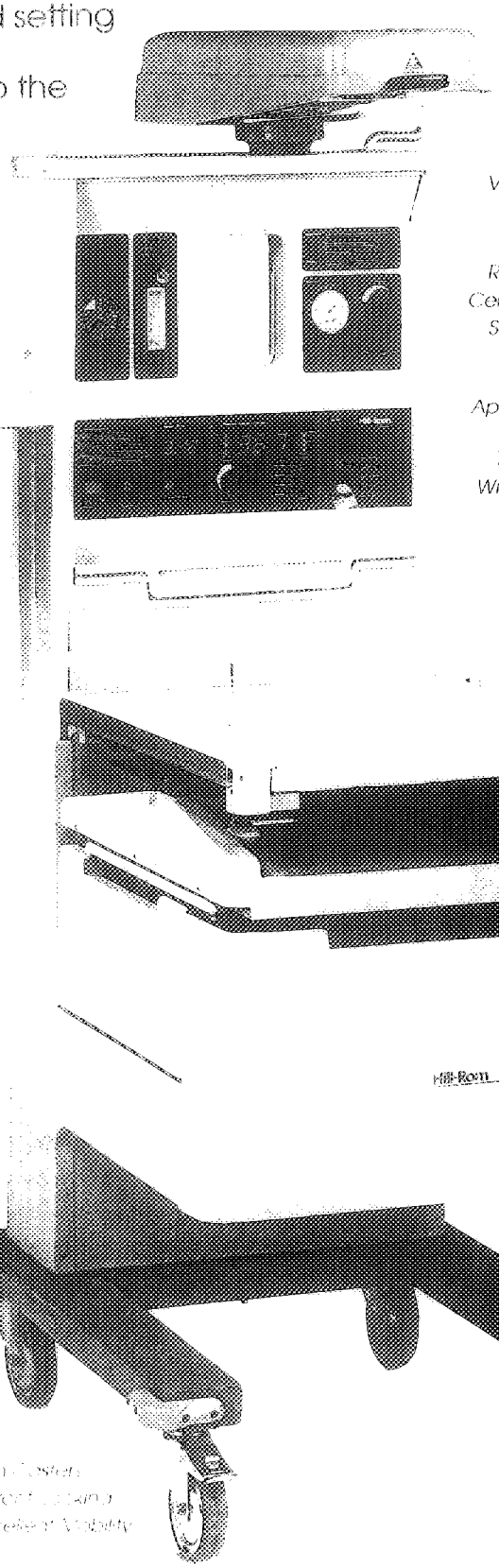
The unit provides quick continuously adjust[illegible] burg and Reverse Trendelenburg with 5° [illegible] The easy-to-operate, "no hands" activa[illegible] side panels ensures instant access to infan[illegible] for and without breaking sterile technique.

The two position warmer keeps the baby warm inside and outside the bassinet. The lifted heater with pebbled reflective surface also provides even heat distribution over the bassinet area.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

The Stabilet™ 2000C Infant Warmer from Hill-Rom is the solution to meet the needs of today's newborn care environments. Its built-in resuscitation equipment ensures that, when seconds count, valuable time will not be lost searching for and setting up resuscitation equipment. In fact, from delivery room to the nursery, the unit provides standard features available only as extra-cost options on other warmers.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Specifications

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Standard Equipment

Resuscitation Package

- DISS connector for oxygen tubing, humidifier or nebulizer
- Dual-yoke gas cylinder manifold
- Automatic pipeline/cylinder supply crossover
- Oxygen flowmeter (Canadian Model has a yellow dial)
- Airway pressure manometer
- Suction/venturi operated with gauge flowrate manometer and suction bottle

Sliding Control Panel Door

Multi-Position Warmer/Lighting Module

One-hour Apgar Procedural Timer which emits a tone at one, five, and ten minutes

Manual Mode: 0%-100% adjustable heater output

Servo Mode: automatic switch from manual to servo mode when probe senses skin temperature of 31°C or above

Large Digital Skin Temperature Display

Continuously Adjustable Trendelenburg/Reverse Trendelenburg of Bassinet with 5° and 10° Detent

Built-In X-Ray Cassette Holder

Retractable Mayo and Writing Tray

Slide-Through Storage Drawer with Removable Organizer Tray

Tilt-Out Resuscitation Compartment

Five-Inch Casters with Front-Locking Brakes

Alarms

Low O_2
Overheating
Hi-Lo Temperature
Over 102.2°F/39°C
Probe Fault
System Fault
Loss of AC power

Specifications

Accessories/Options

Oxygen/air blender package
Cylinder compartment door
Accessory tracks
- Large and small pivoting shelves
- Large and small storage baskets
- Phototherapy light
- IV pole, utility mount, infusion pump holder

Adjustable pole mounted shelves
Storage tray
Left/Right utility poles with AC outlets
Chest drainage rail
Infusion support arm with ISS transfer poles
Reusable and disposable probes

Electrical

760 Watt, 120 VAC Quartz Heater
115+/-10% VAC, 60Hz, 11 Amps, 800 Watts
Fully grounded through 3-wire power cord
Current leakage less than 100 microamps
Temperature display accuracy:
- +/- 0.1° C from 35-39°C with reusable probe (BCZ009)
- +/- 0.2°C from 35-39°C with disposable probe (SA4567)

Irradiance at 100% power 25mW/cm^2
(56 point grid average, measured 4" above and perpendicular to mattress).

Dimensions

Overall (l x w x h): 41" x 27" x 71"
Bassinet (l x w x h to top of sides): 28" x 24" x 42"
Mattress (l x w x h from floor): 26" x 22" x 38"
Heater (l x w x h from floor): 30" x 9" x 67"
Heater module to mattress: 29.5"
Weight: 295 lbs.

This product is supported by professional account executives, experienced perinatal nurse consultants and technical specialists. We also provide educational seminars, featuring perinatal clinicians and consultants, to help you design and implement your perinatal system.

Service

Hill-Rom products should be serviced only by qualified technicians. Our fully trained Customer Service Representatives and Field Technicians stand ready to assist you with questions or problems. For more information on how we can meet your service requirements, please call us at 800-445-3720.

Warranty

Hill-Rom extends a limited warranty covering defects in workmanship and material under normal use for a period of one year from purchase. No other warranties, expressed or implied, are given. The heating elements, probes and light bulbs are covered for 60 days.

Hill-Rom®
A HILLENBRAND INDUSTRY
Batesville, IN 47006 USA • 800-638-2546
International • 812-934-8173 • FAX 812-934-7191

Hill-Rom reserves the right to make changes without notice in design, specifications, and models. The only warranty Hill-Rom makes is the expressed written warranty extended on the sale or rental of its products.
© Hill-Rom 1995

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Class III Certification

I certify, in my capacity as Manager of Regulatory Affairs, of Hill-Rom, Inc. that I have conducted a reasonable search of all information known or otherwise available about the types and causes of reported safety and/or effectiveness problems that have been reported for the Infant Radiant Warmer. I further certify that I am aware of the types of problems to which the Infant Radiant Warmer is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the Infant Radiant Warmer is complete and accurate.

James G. Carpenter
Manager, Regulatory Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

CLASS III SAFETY AND EFFECTIVENESS SUMMARY

1.0 SUMMARY OF SAFETY AND EFFECTIVENESS PROBLEMS ASSOCIATED WITH INFANT RADIANT WARMERS

1.1 Hyperthermia or Burning of Infant.

Typical Causes:

a. Temperature sensor not in complete contact with skin.
b. Poor placement of temperature sensor.
c. Failure of alarms.
d. Inappropriate operator resetting of alarms.
e. Unmonitored uses of manual heating mode.
f. Temperature sensor failure.
g. Control circuit failure.
h. Incorrect Sensor Type.
i. Miscalculation of Control Circuitry.
j. Failure of Sensor Connection.
k. Non-uniform Heat Distribution.
l. Manufacturing Defect in Control Electronics.
m. Infant too close to heater.

1.2 Heat Loss from Infant to surrounding environment.

Typical Causes:

a. Insensible water loss due to evaporation.
b. Convection, especially from forced air ducts.
c. Radiation to cool surfaces.
d. Sidewalls too low to protect against drafts.

1.3 Mechanical Failure of Heater Mechanism

Typical Causes:

a. Breakage of Quartz Heater Bulb allowing hot material to fall on infant.
b. Heat aging of wire insulation.
c. Mechanical Failure of Support Mechanism.
d. Debris falling from heater element contact area

1.4 Hypothermia or Underheating of Infant

130

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Typical Causes:

a. Sensor artifact due to improper application on infant.
b. Miscalculation of Control Circuitry.
c. Heater Power cutback due to overheating or alarms.
d. Heater Element Burn-out.
e. Failure of Sensor Connection.
f. Loss of Primary Power.
g. Incorrect Temperature Sensor
h. Non-uniform Heat Distribution
i. Manufacturing Defect in Control Electronics.
j. Infant too far away from heater.

1.5 Patient Falls

Typical Causes:

a. Mechanical Failure of Side Panel Latch.

2.0 CITATION OF THE INFORMATION UPON WHICH THE SUMMARY WAS BASED:

2.1 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT FDA DATA

ACCESSION NUMBER	DESCRIPTION OF PROBLEM
145931	Failure of Hi/Lo Set Point Alarm.
150899	Failure of Safety Panel Latch.
160080	Heater Element's envelope shattered & fell on bed.
162463	Overheating of patient due to Probe Misplacement.
171013	Burning Piece of foreign material fell on mattress.

2.2 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT ABSTRACTS

ACCESSION NUMBER	DESCRIPTION OF PROBLEM
17887	Adel Model 986 Warmers, overfill of water tray.
18012	User & Technical evaluation of Ohmeda 3300 Warmer
18195	Transformer failed overheating test.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

18457	Manufacturing Problem with Probe Jack Mounting resulting in failure of probe connection. Ohmeda Models 3000, 3300, 3500, and 5000 Warmers.
18632	Electrical System not Double Insulated.
18715	Evaluation of Viamed Thermocot TC400.
19536	Failure of the Crib's Hydraulic Tilt Mechanism.
19537	Heater Quartz Envelope Chipping and pieces falling on patient.
19945	Failure of Power/Mode Switch.

2.3 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT ACTION ITEMS

ACCESSION NUMBER	DESCRIPTION OF PROBLEM
A1338	Possibility of wrong disposable probe connection with older interface cables.
A1736	Power/Mode Switch Failure & Control Panel Not Properly Calibrated.

2.4 ECRI HEALTH DEVICE ALERTS - (13-250) WARMERS, RADIANT, INFANT CITATIONS FROM ECRI DATABASE PRIOR TO MARCH 1985

ACCESSION NUMBER	DESCRIPTION OF ARTICLE
00154	FDA Recall T-133-7, and T-134-7 of certain models of KDC warmers.
00350	Another potential hazard of radiant warmers.
00383	Committee on environment hazards: infant radiant warmers.
00518	FDA Recall T-084-8 of Emerson Heat Lamps.
00612	FDA Recall T-039-8 of Ohio radiant warmers.
00877	Potential hazard in infant resuscitator-aspirator
00913	Proper use of radiant warmers.
01244	Reduction of insensitive water loss in premature infants under the radiant warmer.
01378	Combined effect of radiant warmers and phototherapy on insensible water loss in low birth weight infants.
02216	Heat balance in premature infants: comparative effects of convectively heated incubators and radiant warmers, with and without plastic heat shield.
02298	FDA Recall T-074-0 of Cavitron temperature sensors.
02315	FDA Recall T-083/084 of Air-Shields radiant warmers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

02788	Heat balance in premature infants.
03208	Oxygen consumption and insensible water loss in premature infants under radiant warmers.
04211	White tape indicates burn hazard.
04769	Effect of heat shielding on convective and evaporative heat losses and on radiant heat transfer in the premature infant.
05370	Physiologic implications of two different heat shields for infants under radiant warmers.
06864	Radiant patient warmers - possible hazards.
06907	FDA Recall T-208-3 of Healthdyne radiant warmers .
07383	Letter from manufacturer concerning certain Air-Shields ICS and FS warmers.
07613	Letter from manufacturer concerning solder flux contamination in certain Air-Shields warmers.
07756	FDA Recall Z-106-4 of certain Air-Shields infant heater controller modules used in ICS and FS warmers.
07757	FDA Recall Z-140-4 of control switches in certain models of Air-Shields warmers.
08242	FDA Alert M-008-4 on asbestos used in Air-Shields warmers manufactured between 1972 and 1977.

MISCELLANEOUS ARTICLES CONCERNING RADIANT WARMERS

DATE	TITLE OF ARTICLE - AUTHOR - PUBLICATION
1970	The Optimum Thermal Environment for Naked Babies, E.H. Ney and G. Katz - Archives of Disease in Childhood Vol. 45
1971	Observations of Body Temperature in Young Premature and Full Term Newborns While Being Connected to a Servo Control Temperature Unit. - A. Fenner & M. List - Biological Neonate
1971	A Dangerous Situation Encountered in the Administration of Oxygen to an Infant in a Baby Warmer - Leonard Indyk - Pediatrics
03-1971	Temperature Control in Newborn Babies - L. Lutz & P. Perlstein, MD - Nursing Choices of North America Vol 6, No. 1
03-1973	Emergency Care Research Institute, ``Evaluation: Infant Warmers,'' Health Devices, 3:4-25, 1973.
12-1973	``Evaluation of Optical Radiation Hazards,'' Sliney, D. H., and B. C. Freasier, Applied Optics, 12:1-24, 1973

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

10-1974 Effects of Radiant Warmer on Insensible Water in Newborn Infants - Paul Williams, MD & William Oh, MD, American Journal of Diseases in Children.

10-1974 The Effects of Four Different Radiant Warmer Temperature Set-Points used for Rewarming Neonates - K. Motil, MD, M. Blackburn, MD, and J. Pleasuer, MD - Journal of Pediatrics Vol 85, No. 4

12-1974 Insensible Water Loss in Preterm Infants: Changes With Postnatal Development and Non-Ionizing Radiant Energy - Paul Wu, MB, BS & Joan Hodgman, MD - Pediatrics Vol. 54, No. 6

12-1974 Ahlgren, E. W., ``Environmental Control of the Neonate Receiving Intensive Care,'' International Anesthesiology Clinic, 12:173-215, 1974 .

02-1976 Iatrogenic Problems in Neonatal Intensive Care - Ross Conference on Pediatric Research

1976 Emergency Care Research Institute, ``The Development of a Standard for Infant Warmers and Incubators,'' final report, FDA Contract No. 223-75-5012, Plymouth Meeting, PA, 1976.

1976 ``Increased Insensible Water Loss in New Born Infants Nursed under Radiant Heaters,'' Jones, R. W. A., M. J. Rochefort, and J. D. Baum, British Medical Journal, 1:1347-1350

03-1977 Advantages and Disadvantages of Overhead Radiant Warmers - Dr. R. O. Robinson and Dr. R. Jones - Proc. Roy.Soc.Med. Vol. 70

1977 ``Evaluation of the Effects of Infrared Radiation on the Eyes of Infants under Radiant Warmers,'' Johns, R., D. Schaffer, and G. Peckham, Unpublished, 1977.

1978 ``Minimal Oxygen Consumption in Infants Cared for under Overhead Radiant Warmers Compared with Conventional Incubators,'' Darnall Jr., R. A., and R. L. Ariagno, Journal of Pediatrics, 93:283-287, 1978.

03-1980 Heat Balance in Premature Infants: Comparative Effects of Convectively Heated Incubator and Radiant Warmer, with and without Plastic Heat Shield. - E. Bell, MD & W. Oh, MD Pediatrics Vol 96, No. 3

1980 ``A Simple Device for Reducing Insensible Water Loss in Low-Birth Weight

34

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

Infants,'' Marks, K. H., Z. Freidman, and M. B. Maisels, Pediatrics, 60:223-226.

1980 ``Safety with Lasers and Other Optical Sources,'' Engel, W. D., 23. Sliney, D., and M. Wolbarsht, Plenum Press, New York, 1980, pp. 144-149.

1980 ``Oxygen Consumption and Insensible Water Loss in Premature Infants under Radiant Heaters,'' Marks, K. H., R. C. Gunther, J. A. Rossi, and M. J. Maisels, Pediatrics, 66:228-232, 1980.

1981 ``Insensible Water Loss in the Critically Ill Neonate,'' S. Baumgart, J. G. Schwartz, W. W. Fox, and R.A. Polin, American Journal of Diseases in Children, 135:516-520.

1981 ``Effect of Heat Shielding on Convective and Evaporative Heat Losses and on Radiant Heat Transfer in the Premature Infant,'' Baumgart, S., W. D. Engel, W. W. Fox, and R. A. Polin, Journal of Pediatrics, 99:948-956

04-1982 Relative Efficacy of an Incubator and an Open Warmer in Producing Thermoneutrality for the Small Premature Infant, Michael Le Blanc, MD - Pediatrics, Vol. 69, No. 4

06-1982 The Heat Balance of Small Babies Nursed in Incubators and under Radiant Warmers - A. E. Wheldon & N. Rutter - Early Human Development - Elsevier Biomedical Press

08-1982 Noise in the Intensive Care Nursery - Neil Kellman, MD - Neonatal Network

11-1982 The Neonatal ICU - A High Risk Environment, Susan Blackburn - American Journal of Nursing

1982 ``Fluid, Electrolyte, and Glucose Maintenance in the Very Low Birth Weight Infant,'' Baumgart, S., C. B. Langman, W. W. Fox, and R. A. Polin, Clinical Pediatrics, 32:199-206

1982 ``Physiologic Implications of Two Heat Shields for Infants under Infant Radiant Warmers,'' Baumgart, S., W. W. Fox, and R. A. Polin, Journal of Pediatrics, 100:787-790.

1982 ``Effect of Increased Radiant Power Output on State of Hydration in the Critically Ill Neonate,'' Critical Care Medicine, Engel, W. D., S. Baumgart, W. W. Fox, and R. A. Polin, 10:673-676.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

09-1982. "Radiant Energy and Insensible Water Loss in the Premature Newborn Infant Nursed under a Radiant Warmer," Baumgart, S., Clinics in Perinatology, 9:483-503,

05-1983 Infant Incubators and Radiant Warmers - Edward Bell , Early Human Development Pages 351-375 Elsevier Science Pub.

1983 American Academy of Pediatrics and American College of Obstetricians and Gynecologists, Guidelines for Perinatal Care, Evanston and Washington, DC, respectively.

09-1984 Medical Technology for the Neonate - AAMI Technology Report

11-1984 Thermal Support for the very low birth weight infant: Role of Supplemental Conductive Heat. - William Topper, MD & Thomas Stewart, PHD - Pediatrics

1984 ``Heat Shield Reduces Water Loss,'' Fitch, C. W., and S. B. Korones, Archives Disease in Childhood, 59:886-888,

1984 Emergency Care Research Institute, ``Evaluation: Infant Warmers,'' Health Devices, 13:119-145.

12-1984 Reduction of Oxygen Consumption, Insensible Water Loss, and Radiant Heat Demand with use of a Plastic Blanket for Low Birth-Weight Infants under Radiant Warmers. - Stephen Baumgart, MD - Pediatrics Vol. 74, No. 6

1984 ``Relative Efficacy of Radiant and Convective Heat in Incubators in Producing Thermoneutrality for the Premature,'' LeBlanc, M., Pediatric Research, 18:426-428.

01-1985 Partitioning of Heat Losses and Gains in Premature Newborn Infants under Radiant Warmers. - Stephen Baumgart, MD - Pediatrics, Vol. 75, No. 1

02-1986 Classical Conditioning in Neonatal Intensive Care Nurseries, Beverly Hyde & Darlene McCown - Pediatric Nursing Vol 12, No. 1

08-1986 Axillary and Rectal Temperatures of Full Term Neonates: Are They Different? - B. Haddock, MSN, P. Vincent, RN, D. Merror, RN - Neonatal Network

09-1986 Energy Metabolism and Substrate Utilization in Low Birth Weight Neonates Under Radiant Warmers, Marks, Nardis, and Momin - Pediatrics, Vol. 78 No. 3

1986 ``Energy Metabolism and Substrate Utilization in Low Birth Weight Neonates

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

316

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

under Radiant Warmers,'' Pediatrics, Marks, K. H., E. E. Nardis, and M. N. Momin, 78:465-472.

01-1988 Essential Background for the Design of a Neonatal Bed - Michael H. Donnely - Perinatal Research Institute - Cincinnati, OH

04-1988 Comparison of Axillary and Rectal Temperatures in the Preterm Infant - Betty Haddock, MSN, Pauline Vincent, RN, Dorothy Merrow, RN - Neonatal Network.

1988 ``Controversies in Fluid and Electrolyte Therapy for the Premature Infant,'' Costarino, A. T., and S. Baumgart, Clinical Perinatology, 15:863-878,

04-1989 Body Surface Temperature - Joseph Looney, Jr. - Medical Electronics, April 1989.

1993 ``Infrared Eye Injury Not Due to Radiant Warmer Use in Infants,'' Baumgart, S., A. Knauth, F. X. Casey, and G. E. Quinn, American Journal of Diseases in Childhood, 147:565-569.

1994 International Electrotechnical Commission, ``Medical Electrical Equipment, Part 2: Particular requirements for the safety of infant radiant warmers'',.

05-1995 Association for the Advancement of Medical Instrumentation, Infant Radiant Warmers (draft standard),.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

87

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

BLANK PAGE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

38

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

M

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

510(k) Summary

January 6, 1996

Applicant:

Hill-Rom, Inc.
1069 St. Route 46 East
Batesville, IN 47006
Reg. No: 1824206

Contact Person:

James G. Carpenter
Ph: (812)934-1671
Fx: (812)934-1675

Device trade/proprietary name:

" Stabilet™"

Device common/usual/classification name:

Infant Radiant Warmer

Classification:

General Hospital and Personal Use Device, 21 CFR 880.5130 , Infant Radiant Warmer, 80FMT, Class III

Predicate (Current) Device:

Hill-Rom " Stabilet™" Infant Radiant Warmer, K942948

Device Description

The Hill-Rom Stabilet™ is a device consisting of an infrared heating element positioned over an infant to maintain the infant's body temperature by means of radiant heat. Available features include a warming/lighting module which provides heat through two stainless steel heater tubes, manual or servo heat control with a temperature monitoring sensor and temperature alarms, procedural Apgar timer, bassinet with mattress and spring loaded fold down sides, trendelenburg/reverse trendelenburg, x-ray cassette tray, retractable Mayo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

tray, slide through storage drawer, resuscitation equipment, storage bin and casters with front locking brakes, optional scale and hilo feature.

Intended Use:

The Stabilet™ Infant Radiant Warmer maintains the infant's body temperature at a level determined by the caregiver through the use of an infrared radiant heating element and is designed to be used in those areas of the healthcare facility that provide neonatal and infant care.

Federal law restricts this device to sale by or on the order of a licensed health care practitioner and its use is restricted to health care facilities.

Design and construction:

Both the new and predicate warmers utilize the same materials and methods of construction. The warmers are fabricated from steel, aluminum, and plastic. The submitted warmer's most highly stressed areas utilize only steel and aluminum. Plastics are used in less stressed areas. Steel and aluminum warmer components are welded or assembled with commercially available fasteners. Plastics used in less stressed areas are assembled with fasteners.

The subject warmer and predicate warmer in this submission are substantially equivalent. There is some variation in the available features of the warmers, but the variations do not significantly affect the safety or efficacy of the warmers.

This submission is a result of the introduction of several improvement modifications Hill-Rom has introduced to the existing product. The principal changes are:

Modification of the heater lamp housing

pistolen

- Bare quartz element changed to a stainless steel element.

  The new element eliminates tube breakage as a hazard to the patient or caregiver. The electrical contacts have been changed from a spring compression socket arrangement to an insulated wire with a screw. This provides a positive locking electrical connection to the power supply.

- One heating element to two.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

H1

Records processed under FOIA Request # 2016-5769; Released by CDRH on 08-04-2016

- **Heating element length increased from 12" to 16"**
- **Change parabolic reflector from pebbled to smooth to optimize irradiance pattern with new dual heating elements**

Two 375W elements centered over the bassinet replace the single 760W element in the predicate warmer. In conjunction with the increased length and the changes to the parabolic reflector, the irradiance pattern is more evenly distributed and the time required to warm the infant to the caregiver- selected skin temperature is reduced.

Height adjustability for the 1500C and 2000D.

This is a customer preference feature and does not impact the safety of the device to the user or patient. The heater lamp housing to bassinet surface relationship is maintained.

Quartz Halogen task light replaces the florescent task light.

The light is balanced to 3200°K. This more closely approximates natural ambient light and eliminates the color bias imparted by florescent lighting.

Accessories

Resusitation and Suction modules are offered as options on all current and previous models and the 1250C and 1500C Stabilet™. This does not represent an increased risk to the user or patient as these options are already standard features on the Predicate 2000C.

A scale option (Premarket Notification K926174) is also available on the P1500C and P2000D models.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118