USER MANUAL

AMPLA® 2085 INTENSIVE CARE UNIT

FANEM®

Technical Standard - NBR IEC 60601-1
NBR IEC 60601-1-2
NBR IEC 60601-2-21
NBR IEC 60601-2-49

Review: 02/14

Edition: 05/19

SMTs: 8092/10237/10416

REF: 004.001.550

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Notes

1. Identification of the Equipment

The AMPLA® 2085 Infant Warmer Intensive Care Unit and all its accessories were designed according to the highest technology and safety standards. It has excellent versatility for use in the care and treatment of newborns in Neonatal Intensive Care Units, Obstetric Centers, Surgery Centers, Children's Emergency Rooms, Pediatrics, Nurseries and rooming-in situations.

The AMPLA® 2085 Infant Warmer, with its accessories, constitutes an Intensive Care Unit, for use in stationary or internal transport mode, for the integrated treatment and care of newborns of different weights (up to 7 kg) and gestational ages, in order to perform clinical, surgical and diagnostic procedures in the bed itself.

This equipment has a radiant heat system, designed to care for newborns during their first moments of life or for longer periods of time, in addition to providing patient access for more than one professional and full viewing for observational purposes, in a wide variety of uses. Most of all, it provides patients with comfort and enables the monitoring of clinical parameters.

The reflector, located on the upper part of the central column, has a radiant heat system, with a heating element coated with quartz and a protective guard for the patient. Through its directional fins, it provides uniform heat to every area of the mattress. The radiant reflector has auxiliary lighting for better viewing and can be shifted from its central position to either side of the warmer, in order to permit other functions, such as: access to the portable X-ray device to perform radiological procedures on the bed; and heating support in the kangaroo mother care mode.

The control panel, located on the front part of the column, has different configurations, according to the three distinct options for the microprocessor-controlled monitor:

- **Microprocessor-based 8.4" Graphic Color Monitor**

  It has 20 functions and 19 graphic parameters.

- **Microprocessor-based 5.5" Graphic Monochrome Monitor**

  It has 20 functions and 11 graphic parameters.

- **Microprocessor-based LED panel**

  It has 10 basic functions.

According to the microprocessor-controlled monitor option, the following configurations of functions and parameters can be applied: skin T1 sensor; auxiliary skin T2 sensor; pulse oximetry sensor; toolbar access buttons; rotary dial with Enter function; bed inclination buttons; LED indicators for power failure and alarms; ambient temperature indicator; APGAR timer function; timer alarm function; current date and time display; trend line graph; electronic medical record (patient); preventive maintenance; oxygen concentration monitor; servo controlled thermal mattress; charging of batteries in the transport module; in-bed scale; and data communication.

The reinforced metal structure base has four 5" casters, with brakes, for internal transport, in addition to a vertically adjustable ergometric column with side activation pedals, to provide greater comfort to the professional during procedures with the patient (optional).

The bed table, located on the middle front part of the column, is spacious and radio-transparent, made out of non-toxic plastic material, with transparent acrylic protectors, three of which fold open to provide frontal and side access, enabling up to three professionals to work at the same time on the newborn in critical procedures. It has four tube inserts installed on the bed protectors, with front and rear access, for introducing cables, in addition to two hooks to support and attach the collector bag for better positioning in relation to the patient, avoiding folds, discomfort, disconnection and other possible nonconformities. The bed can also be supplied in the acrylic bassinet configuration, with manual movement.

The position of the bed table can be regulated electrically, with smooth and steady external activation, and/or automatic adjustment (optional), and/or manual adjustment of the bed inclination (±12ºC) for the following positions: Trendelenburg, Reverse Trendelenburg and Horizontal. It also has an X-ray cassette drawer, with external access on either side, to avoid patient handling and contact during the procedure for taking X-rays in the bed. The appropriately dense, anti-stress foam mattress has a self-extinguishing,

seamless cover made out of non-toxic material, which is easy to clean and disinfect for added patient comfort.

The following accessories, some included with the line and other optional ones, can be coupled to the central column: serum holder; side rotating shelf; cord reel; power cord connector; ambient temperature sensor; auxiliary handle for transporting the Infant Warmer; side support for infusion pumps; auxiliary sockets in different configurations; cable router hook; transport battery module; ergometric column with side pedals, tray and drawer sets for accessories; compressed air and O_2 cylinder brackets; pressure control valve; gas inlet panel; O_2 flow meter; front gas panel for: aspiration, oxygenation, blender, oxygen analyzer, manual resuscitation device with controlled pressures, humidifier with bubble generator bottle and CPAP circuit and oxygen analyzer.

The AMPLA® 2085 Infant Warmer can be used in combination with a number of other devices, as optional items, which can be coupled to the equipment in modular form, configuring and optimizing the product for its actual applications and conditions of use as a Neonatal Intensive Care Unit, such as: in-bed scale; pulse oximeter (SpO_2); BILITRON® 3006 Phototherapy; BILITRON® BED 4006 Reverse Phototherapy and transparent mattress for reverse phototherapy; transport kit with thermal mattress, transparent mattress and batteries; ergometric column with side pedals; front gas panel with configuration options for an aspirator, blender, BABYPUFF®, Neonatal water-seal CPAP, etc.

To preserve the efficiency and characteristics of use of this equipment, special care is needed with its handling and operation. This User Manual provides general instructions on installation, use, maintenance, operation and troubleshooting for the AMPLA® 2085 Infant Warmer, manufactured by FANEM®.

According to current legislation, FANEM® will not be held liable if the user does not operate this equipment in accordance with its instructions or fails to follow the maintenance recommendations in this manual or makes repairs to the equipment by anyone not authorized by the company and/or uses unauthorized components. Calibration and repairs should only be performed by duly trained and qualified personnel. Any additional issues can and should be assessed by the local distributor.

This manual should be read and understood, as well as be readily accessible to all those who use the equipment. If there is any information you do not understand, please contact a FANEM® representative for further clarifications.

Warning: Carefully read this manual before turning on the unit.

2. Technical Specifications

2.1 Electrical Specifications

Supply Voltage	127 V~ ± 5%	220/240 V~ ± 5%
Mains Frequency	50/60 Hz	
Power	800 W	
Rated Current	7 A for 127 V~ 4 A p for 220/240 V~	
Leakage current	< 300 μA	
Ergometric Power	75 W	
Rechargeable Battery (Panel)	9 VDC	
Rechargeable Battery (Transport Kit)	12 VDC – 9 Ah	
Auxiliary Electrical Socket – Maximum Power per Socket	150 W	

2.1.1 Fuses and Circuit Breakers

Power Supply 127 V~	10A – Type F
Power Supply 220/240 V~	5A – Type F

2.2 Classification and Characteristics

Type of Protection against Electric Shock	Class I Equipment
Degree of Protection against Electric Shock	BF Type Applied Part
Degree of Protection against Water Penetration – 2085 AMPLA® Infant Warmer	IPX0
Equipment not suitable for use in the presence of flammable anesthetics, such as air, oxygen or nitrous oxide	Non-AP / Non-APG
Operating Mode	Continuous Operation
Type of Protection against Electric Shock	Class I Equipment
Degree of Protection against Electric Shock	BF Type Applied Part
Degree of Protection against Water Penetration – 2085 AMPLA® Infant Warmer	IPX0

Note: Values and classifications according to NBR IEC 60601-1 and NBR IEC 60601-2-21 standards

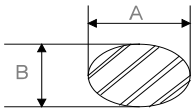
2.2.1 BILITRON® 3006 - Classification and Characteristics

Degree of Protection against Water Penetration	IPX0	Converted Irradiance *
Total Irradiance for Bilirubin – Distance 30 cm	6.75 to 9.75 mW/cm^2	45 to 65 $\mu W/cm^2nm$
Irradiation Setting Range	10% to 100% of maximum irradiation (±10%)	
Effective Surface Area	150 x 105 cm	
Maximum Noise Level (ambient 45 dBA)	< 52 dBA	

(*) Irradiance stated in mW/cm^2 is presented as converted irradiance in $\mu W/cm^2nm$ when measured using the THOR Multitester 3620 Radiometer with a spectrum band of 400 to 500 nm

To take better advantage of the light on the patient, it is recommended that the light source be adjusted so that an elliptical shape is formed, i.e., **the light should fall on the chest until the root of the thighs**. See Table 1.

Table I

Distance of the reflector from the patient D (mm)	**Total irradiance for bilirubin Ebi $\mu W/cm^2.nm$ (in the center of the light focus)**	 **Elliptical Focus**	
Distance	**Radiation**	**A (mm)**	**B (mm)**
300	45 - 65	200	140
400	30 - 45	220	160
500	20 - 30	260	180

Note: The shape of the ellipse will depend on the angle of incidence of light on the patient.

Patients weighing more than 2500 g should be positioned approximately 40 cm from the phototherapy device to create a "light focus" that covers the entire trunk and root of the thighs of the newborn. For preterm infants and those with very low birth weights, this height could occasionally be lower provided the incidence of the "light focus" covers the entire chest and root of the thighs. The radiation intensity will be greater the smaller the distance between the light source and the patient, and vice versa. See Table 1, Figure 1 and Figure 2.

Always keep the light focus on the trunk and root of the thighs of the newborn.

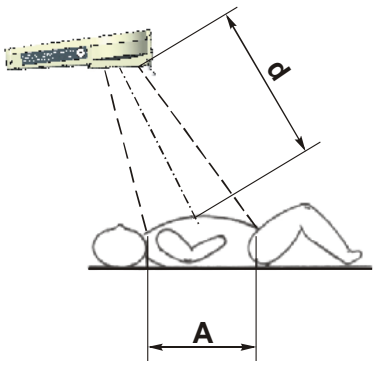


Figure 1

Warning: It is recommended to keep patients at a minimum distance of 30 mm from the light source.

Warning: Do not use the Bilitron® with the Power Module in direct contact with the patient's body.

SPECTRAL IRRADIANCE VERSUS DISTANCE

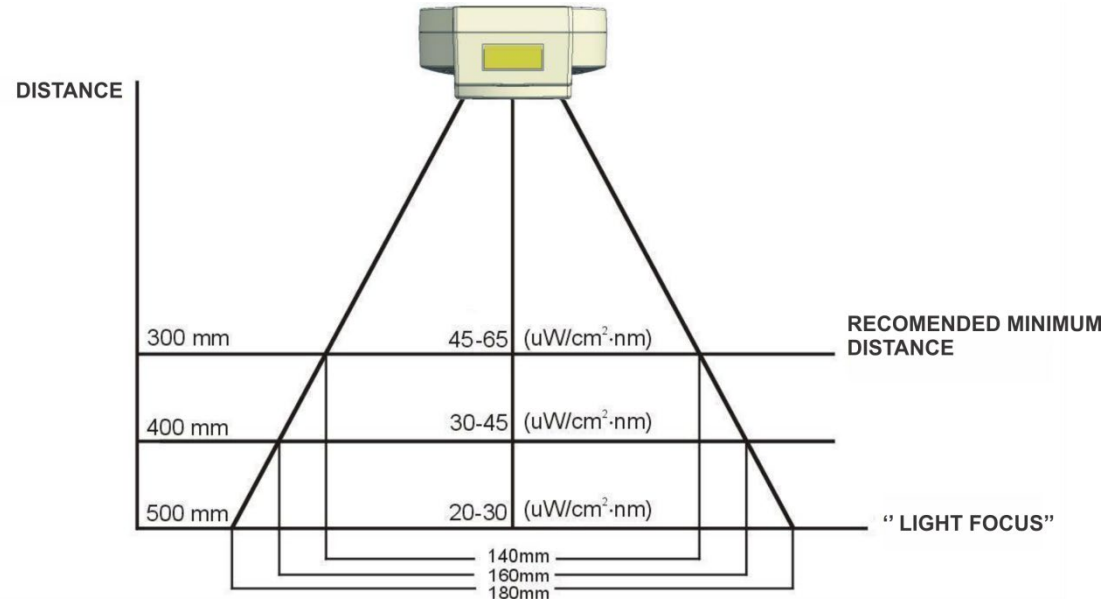
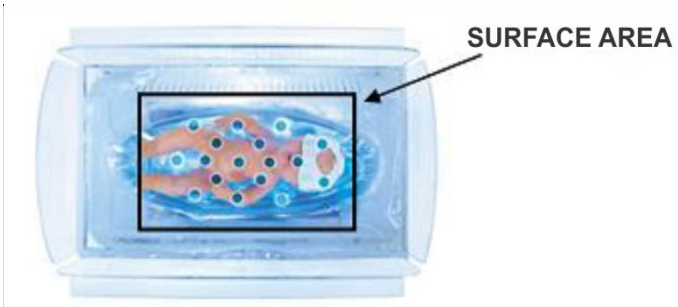


Figure 2

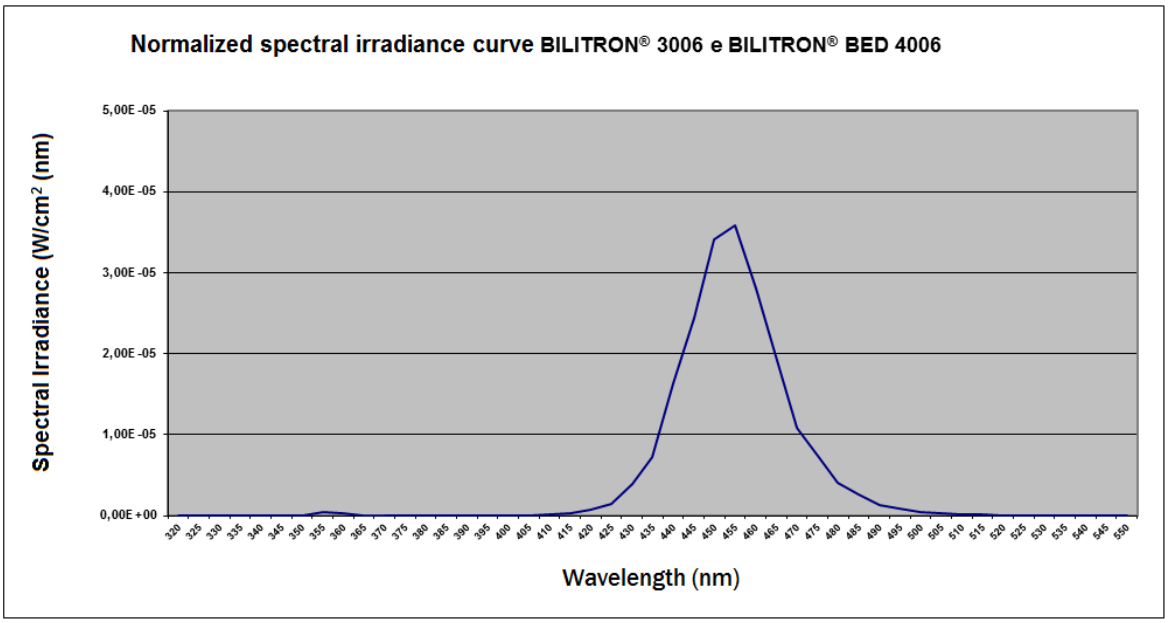
2.2.2 BILITRON® BED 4006 - Classification and Characteristics

Degree of Protection against Water Penetration	IPX4	**Converted Irradiance ***
Total Irradiance for Bilirubin	3.6 mW/cm^2	36 μW/cm^{2}nm
Average Total Irradiance (Ebimax)	3 mW/cm^2	30 μW/cm^{2}nm
Average Minimum Irradiance (Ebimax)	1.7 mW/cm^2	17 μW/cm^{2}nm
Distance between the Irradiance Source and Effective Surface	127 mm	
Effective Surface Area – Fixed distance	25 x 30 cm	
Maximum Noise Level (ambient 45 dBA)	< 52 dBA	

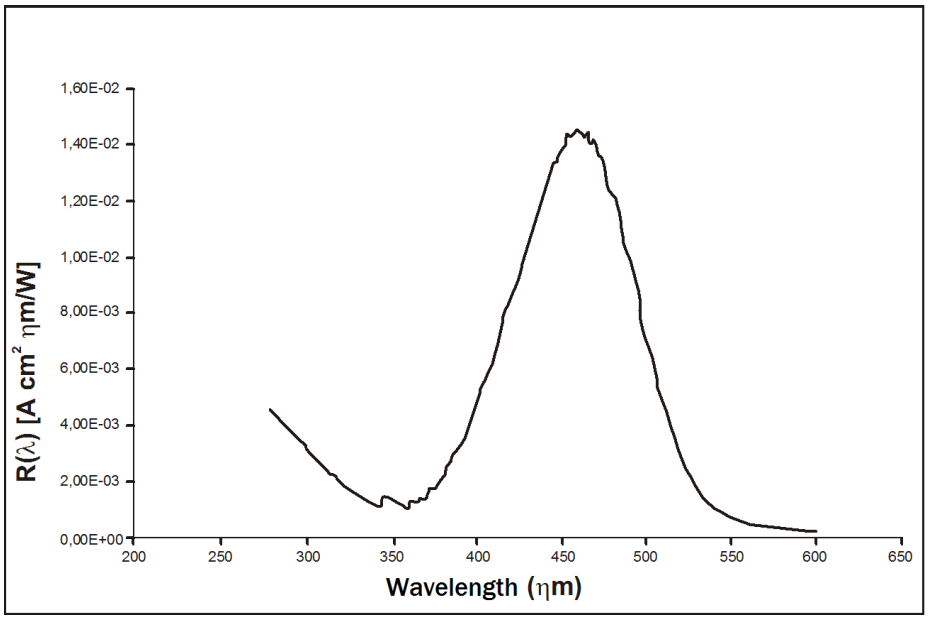
(*) Irradiance stated in mW/cm^2 is presented as converted irradiance in μW/cm^{2}nm when measured using the THOR Multitester 3620 Radiometer with a spectrum band of 400 to 500 nm



♦ Total Spectral Irradiance Graph – Interval 320 nm to 550 nm



♦ Calibration Curve for radiation measurement of the THOR® Multitester 3620



2.2.3 Pulse Oximeter – Characteristics

Indication:

SpO_2 Measurements	1% to 100%
Pulse Measurements	20 to 250 BPM

Accuracy:

Saturation (%SpO_2 + 1 SD)	70% to 100% + 2 Digits 60% to 80% + 4 Digits
Low Perfusion	70% to 100% + 2 Digits
Heart Rate	20 to 250 BPM + 3 digits
Low Perfusion	20 to 250 BPM + 3 digits
Perfusion Index	0.03% to 20%
% SpO_2 Measurement Variation	1% to 100%
Heart Rate	20 to 250 BPM

2.2.4 Thermal Mattress – Classification and Characteristics

Degree of Protection against Electric Shock	BF Type Applied Part
Low Heat Transfer Heating Device	
Power (Watts)	50 W
Equipment not suitable for use in the presence of flammable anesthetics, such as air, oxygen or nitrous oxide	Non-AP / Non-APG

2.3 Control Features

Temperatures

Temperature Monitor Resolution	0.1ºC
Control Range	25 - 38ºC
Control Accuracy	± 0.2ºC
Operating Range of the Temperature Monitor	20 - 45ºC

Weighing System

Monitor Resolution	2 g
Operating Range - Weight	0 to 10 kg
Indication Accuracy	±4 g

2.4 Physical Specifications

Bed in Fixed Support

Width	63 cm
Length	112 cm
Total height	200 cm
Height - Mattress Level	100 cm
5" Swivel Caster - Brake	4 units

Bed in Ergometric Support

Width	63 cm
Length	112 cm
Length (w/ resuscitation support)	200 cm
Maximum height	210 cm
Minimum height	190 cm
Height - Mattress Level	100 cm $^{+10}/_{-10}$
5" Swivel Caster - Brake	4 units

2.5 Gas Module

O_2 Inlet and Outlet Nipple	Thread 9/16" – 18 UNF
Compressed Air Inlet and Outlet Nipple	Thread 3/4" – 16 UNF

Vacuum Nipple for Gas Network (Optional). Special configurations upon request, according to customer requirements and local laws.

2.6 Maximum Loads

Serum Holder	2 kg
Auxiliary Shelves	10 kg
Bed	7 kg
Intermediate Tray	7 kg

2.7 Audible Alarms

System Alarms

Power Failure	Activated if power is not being supplied to the equipment, or if the power cord is inadvertently disconnected from the system. If it has the transport module (optional item), the power failure alarm will be activated when the transport batteries run out. A red LED will light up on the panel (indicating a power failure) and a loud and continuous audible signal will be heard.
Radiant Heater Failure	Activated when there is a failure in the radiant heater (burned resistor or no power is being supplied). Visual alarm and intermittent audible alarm.
Heating Power Remains at 100%	Activated when the radiant heater remains at 100% power for over 15 minutes. Occurs both in Manual Mode and Skin Mode (servocontrolled). Visual alarm and intermittent audible alarm. When the alarm is activated, the radiant heating is cut off. When the Silence key is pressed, the alarm is canceled, the radiant heating is resumed, and the 15-minute counting period starts again.
Alarm when in Manual Mode for 15 minutes	Activated every 15 minutes, when the system is operating in Manual Mode, with heating power set at less than 100%. Unlike the alarm when power remains at 100%, the radiant heating, in this case, is not cut off. Visual alarm and intermittent audible alarm. When the Silence key is pressed, the alarm is canceled, and the 15-minute counting period starts again.
Low Transport Battery Charge	Alarm associated with the transport module (optional item). Activated when the system is operating with the transport batteries (power failure or system disconnected from the mains) and the voltage in the batteries is less than 11.3 V. Visual alarm and intermittent audible alarm.

Skin Temperature T1 Sensor Alarms

High Temperature (*Only Skin Sensor T1*)	Activated if skin temperature T1 is 1ºC or more above the skin temperature set point. When this alarm occurs, the radiant heating is cut off. Visual alarm and intermittent audible alarm.
Low Temperature (*Only Skin Sensor T1*)	Activated if skin temperature T1 is 1ºC or more below the skin temperature set point. Visual alarm and intermittent audible alarm.
No Skin T1 Sensor (*Only Skin T1 Sensor*)	Activated if the Skin T1 Sensor is disconnected or there is a failure in the sensor (broken wires, damaged pins, etc.). When this occurs, the system will automatically cut off the radiant heating and shift into Manual Mode. Visual alarm and intermittent audible alarm.
Dislodged Skin Sensor (*Only Skin T1 Sensor*)	Activated if the Skin T1 sensor is dislodged from the patient's skin. Visual alarm and intermittent audible alarm. It will be activated whenever an abrupt variation, whether negative or positive, is detected in the Skin T1 Sensor temperature. The following points must be observed: - When the system is first turned on, this alarm is silenced for 10 minutes (for the Skin T1 Sensor temperature to stabilize on the baby's skin), after which the discharged sensor alarm will start operating. - Detection of a dislodged sensor occurs as follows: if within 7 seconds a positive variation greater than or equal to 0.5ºC or a negative variation greater than or equal to 0.3ºC is detected in the Skin T1 Sensor, the alarm is triggered. - Once triggered, the alarm will only be canceled if the Skin T1 Sensor temperature returns to the temperature prior to the variation, or if the user presses the Silence key. - When the alarm is canceled through the Silence key, it will remain silenced for 2 minutes, after which dislodged sensor monitoring will be resumed. - Every time the user shifts from Manual (or Preheating) Mode to Skin Mode, the alarm will be silenced for 1 minute, after which dislodged sensor monitoring will be resumed. - If the Skin T1 Sensor is lacking, as soon as the sensor is restored, the alarm will be silenced for two minutes, after which dislodged sensor monitoring will resume. - If after performing any of the actions listed below the system goes into Skin Mode (servocontrolled), the alarm will be silenced for two minutes, after which dislodged sensor monitoring will be resumed. - Turn off the thermal mattress - Return the radiant heater to the central position - Go from battery power to wall power.

Operation Indicator Alarms

Servo	Automatically activated when the Skin T1 Sensor is connected.
Manual	Automatically activated when the Skin T1 Sensor is disconnected, or when the sensor or sensor wire is damaged.
Silence Alarm	Indicates that the sound of the alarm that is activated will be silenced for 15 minutes or for the interval specified for the corresponding function. The sound will be automatically restored after this period of time has elapsed.
Heating	Indication of heating power from 0 to 100% of total power, shown in the power bar, in 10% increments.

Oxygen Monitor Alarms

High O_2 Concentration (*Adjustable from 16 to 100%*)	Activated if the oxygen concentration is above the high O_2 concentration limit. Visual alarm and intermittent audible alarm.
Low O_2 Concentration (*Adjustable from 15 to 99%*)	Activated if the oxygen concentration is below the low O_2 concentration limit. Visual alarm and intermittent audible alarm.
No O_2 Sensor	Activated if the oxygen sensor is disconnected from the system or there is a failure in the sensor (broken wires, damaged pins, etc.). Visual alarm and intermittent audible alarm.

Blender Mixer Alarm

Network Pressure Audible Alarm	The Blender will activate an internal alarm, characterized by a continuous whistling sound, if an imbalance greater than 20 psi (1.4 Kgf/cm^2) occurs between the Air and Oxygen inlet pressures.

Pulse Oximeter Alarms

High SpO_2 Saturation *(Adjustable from 21 to 100%)*	Activated if the patient's oxygen saturation is above the high SpO_2 saturation limit. In the versions with color and monochrome LCD monitor, the pulse oximeter has the SatSeconds[1] SpO_2 alarm management function (See the Pulse Oximetry section in the chapter on Infant Warmer functions). Visible alarm in the Information and Alarms section and an intermittent audible alarm.
Low SpO_2 Saturation *(Adjustable from 20 to 99%)*	Activated if the patient's oxygen saturation is below the low SpO_2 saturation limit. In the versions with color and monochrome LCD monitor, the pulse oximeter has the SatSeconds[1] SpO_2 alarm management function (See the Pulse Oximetry section in the chapter on Infant Warmer functions). Visible alarm in the Information and Alarms section and an intermittent audible alarm.
High Heart Rate (HR) Level *(Adjustable from 11 to 250)*	Activated if the patient's BPM (beats per minute) level is above the high HR limit. Visual alarm and intermittent audible alarm.
Low Heart Rate (HR) Level *(Adjustable from 10 to 249)*	Activated if the patient's BPM (beats per minute) level is below the low HR limit. Visual alarm and intermittent audible alarm.
Sensor in Movement	Activated when there are variations in SpO_2 readings by the pulse oximeter sensor. It is automatically deactivated when SpO_2 is once again stable. Visual alarm and intermittent audible alarm.
Dislodged Sensor	Activated if the pulse oximeter sensor is dislodged from the patient. It is automatically deactivated once the sensor is reattached. Visual alarm and intermittent audible alarm.
Disconnected Sensor	Activated if the pulse oximeter sensor is disconnected from the panel or there is a failure in the sensor (broken wires, damaged pins, etc.). Visual alarm and intermittent audible alarm.
Pulse Oximeter Failure	Occurs when there is a communication failure with the pulse oximetry module. Visual alarm and intermittent audible alarm.

In this module, the alarm will be silenced for up to 2 minutes.

1 SatSeconds is a trademark of Covidien AG.

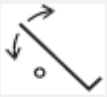
Note: If the SpO_2 alarms are set at below 85% and the equipment is restarted, the low SpO_2 alarm level will automatically be changed to 85%, while the high SpO_2 alarm level will automatically be changed to 100%.

Warning: Whenever the oximeter is used, check the alarm limits to make sure they are appropriate for the patient being monitored.

FOG® 1140 Humidifier Alarms

High Temperature (*"HI TEMP" - ERROR*)	Indicated on the FOG® 1140 Humidifier by a red LED, an intermittent beep and "Ht" displayed on the monitor. It is activated whenever the gas temperature registered by the patient circuit temperature sensor is greater than or equal to 36ºC.
Internal Temperature Sensor Failure (*"Sensor Failed" - ERROR*)	Visual alarm indicating that there was damage or a connection failure in the internal temperature control sensor of the humidifier. Such a failure is indicated by the letters "SF" on the monitor. When activated, all the humidifier's operations are blocked, and heating is cut off. The monitor will continue to indicate "SF" intermittently, as long as the equipment is being energized and the failure has not been corrected.
Low Water in the Humidifier Tank (*"Low Level" - ERROR*)	Audible and visual alarm activated whenever the water level of the humidifier tank is at a low level. It is indicated by the letters "LL" on the humidifier monitor and by an intermittent beep.
No patient circuit temperature sensor	If the humidifier is used without the patient circuit temperature sensor, the monitor will alternately show the Power Level and the letters "nS" – "*No Sensor"*, indicating that the sensor is disconnected from the device.

2.8 Symbols

	Note: Consult accompanying documents		BF Type Applied Part
	OFF (No Power Supply Voltage)		ON (With Power Supply Voltage)
	ON (Only a part of the equipment)		OFF (Only a part of the equipment)
	Tare		Printing
	Timer - APGAR		Silence Alarm
	Alternating Current		Grounding Terminal for Protection
	Warning: Heat Emission through Radiation		Protection for the patient's eyes
	Ergometric Up		Ergometric Down
	Tilting Movement of the Table		Movement in both directions

2.9 Symbols – Packaging

	Fragile		This Side Up
	Protect from Sunlight		Protect from Rain
	Stacking Limit		Note: Consult accompanying documents

2.10 Environmental conditions

Operating Temperature Range	20°C to 30°C – Ambient
Operating Humidity Range	15% to 95% – Non-condensing
Ambient air velocity	< 0.3 m/s

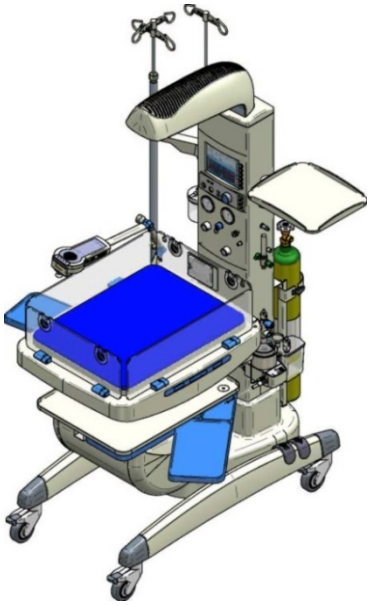
2.11 Environmental Conditions for Transport and Storage

Storage Temperature Range	0°C to 55°C – Ambient
Storage Humidity Range	30% to 75%

Note: Specified conditions with properly packaged equipment.

3. Parts, Pieces and Accessories

3.1 Assembly Configurations / Optional Items

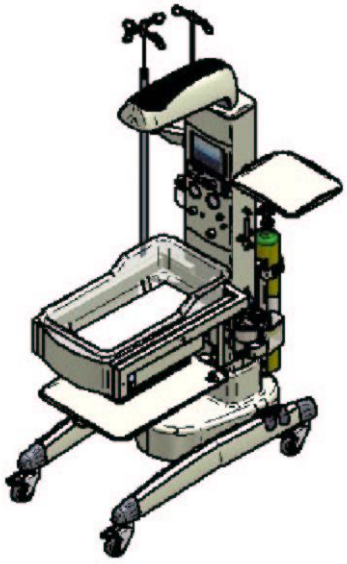


AMPLA® 2085 Infant Warmer

Complete with Accessories

Color/Monochrome Monitor, Scale, Ergometric Column, ICU Table

Illustration 1 – Configuration Example

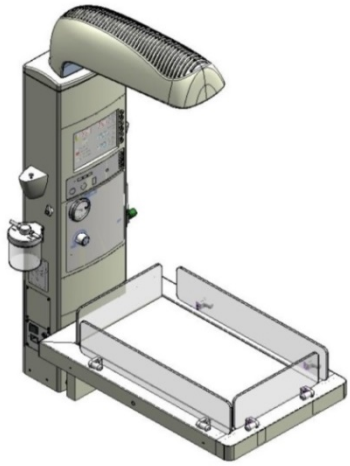


AMPLA® 2085 Infant Warmer

Complete with Accessories

Color/Monochrome Monitor, Scale, Ergometric Column, Acrylic Bed Table, with Manual Trendelenburg

Illustration 2 – Configuration Example



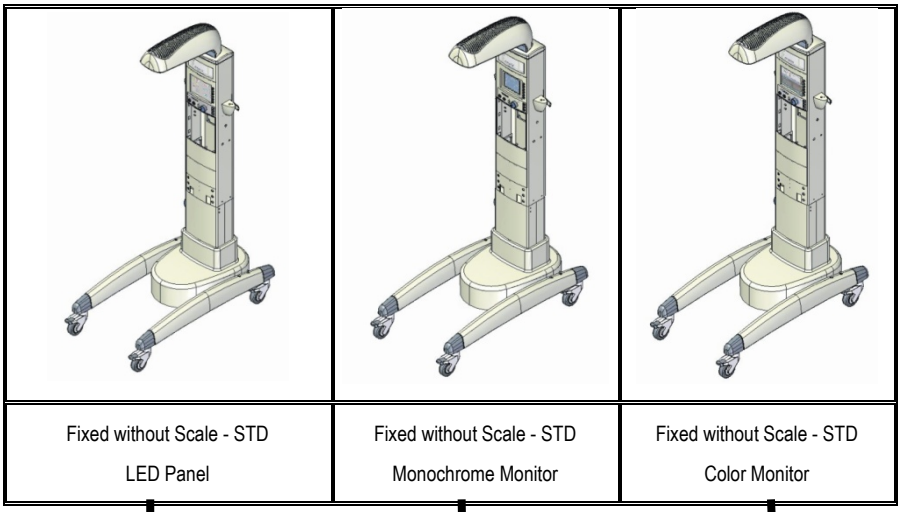
AMPLA® 2085 Infant Warmer

Wall Unit with Accessories

LED Panels, Compact LDR Table, with Aspiration Set

Illustration 3 – Configuration Example

AMPLA® 2085 Infant Warmer



Fixed without Scale - STD LED Panel	Fixed without Scale - STD Monochrome Monitor	Fixed without Scale - STD Color Monitor

Microprocessor-based Graphic Color Monitor

Microprocessor-based Graphic Monochrome Monitor

Microprocessor-based LED Panel

	LED Panel		Monochrome Monitor		Color Monitor	
Accessories	**STD**	**OPTIONAL ITEMS**	**STD**	**OPTIONAL ITEMS**	**STD**	**OPTIONAL ITEMS**
Swivel Radiant Reflector	√		√		√	
Auxiliary Lighting	√		√		√	
Adjustable Serum Holder		√		√		√
Side Shelf – 10Kg		√		√		√
Electric Table		√		√		√
Manually Adjustable Table		√		√		√
Acrylic Bed Table		√		√		√
Transport Handle	√		√		√	
5" Casters with Brake (4x)	√		√		√	
Cable Reel	√		√		√	
Ergometric Side Pedals		√		√		√
Gas Inlet Panel		√		√		√
1.5 m Extension for O_2 (1x)		√		√		√
1.5 m Extension for Compressed Air (1x)		√		√		√
Ambient Temperature Sensor	√		√		√	
Hook for Collector Bag and Cable Router (3x)	√		√		√	
Air Cylinder DOT 3AL (aluminum) w/ stop valve		√		√		√
Oxygen Cylinder DOT 3AL (aluminum) w/ stop valve		√		√		√
Cylinder Bracket - Right/Left		√		√		√
Complete Cylinder Set		√		√		√
O_2 Flow Meter (0-15 lpm)		√		√		√
O_2 Flow Meter (0-15 lpm)		√		√		√
Humidifier Bottle for Flow Meter		√		√		√

Accessories		LED Panel		Monochrome Monitor		Color Monitor	
		STD	OPTIONAL ITEMS	STD	Optional Items	STD	OPTIONAL ITEMS
Gas Panel – Aspiration (Vacuum Gauge; Bottle; Meconium Aspirator)			√		√		√
Gas Panel with Blender			√		√		√
Gas Panel – Aspiration + Babypuff®			√		√		√
Gas Panel – Aspiration + Babypuff® + Blender			√		√		√
Humidifier + Bubble Generator Bottle + CPAP Circuit No. 0			√		√		√
In-bed Scale	#		√		√		√
Pulse Oximeter with Plethysmographic Curve		*NA*	*NA*		√		√
Bilitron® 3006 Phototherapy with Articulated Arm			√		√		√
Bilitron® BED 4006 Reverse Phototherapy			√		√		√
Transparent Mattress Reverse Phototherapy/Surgery ICU Table and Acrylic Bed			√		√		√
Thermal Mattress Available upon request	#		*NA*		√		√
Transport Kit - Batteries, Thermal Mattress (upon request) + Transparent Mattress	#		*NA*		√		√
Infusion Pump Support			√		√		√
Accessory tray			√		√		√
Accessory tray 2 drawers			√		√		√
Accessory tray 4 drawers	#		√		√		√
Tray for accessories 2 Articulated Shelves and Bypass Drawer	#		√		√		√
Side Shelf with Adapter			√		√		√
Auxiliary Sockets – 2P+T NBR 14136 (4X)			√		√		√
Auxiliary Sockets – Shucko (2x)			√		√		√
Auxiliary Sockets – 3P SNAP FIT IEC 9 (4X)			√		√		√

	LED Panel		Monochrome Monitor		Color Monitor	
CABLES AND SENSORS	**STD**	**OPTIONAL ITEMS**	**STD**	**OPTIONAL ITEMS**	**STD**	**OPTIONAL ITEMS**
Oxygen Analyzer Cable with Cell	*NA*	*NA*		√		√
Oxygen Analyzer Cable with Connector	*NA*	*NA*		√		√
Oxygen Analyzer Oxygen Cell	*NA*	*NA*		√		√
Temperature Sensor Skin T1 Sensor	√		√		√	
Temperature Sensor Skin T2 Sensor		√		√		√
Temperature Sensor Rectal		√		√		√
Pulse Oximeter – SpO_2 D-YS Sensor	*NA*	*NA*		√		√
Heated Humidifier – CPAP FOG® Temperature Sensor		√		√		√
Heated Humidifier – CPAP FOG® Water Level Sensor		√		√		√

	LED Panel		Monochrome Monitor		Color Monitor	
SENSOR ADHESIVES	**STD**	**OPTIONAL ITEMS**	**STD**	**OPTIONAL ITEMS**	**STD**	**OPTIONAL ITEMS**
Skin Sensor Adhesive		√		√		√
Spo_2 Sensor Adhesive	*NA*	*NA*		√		√

"#" - Not available in the "Acrylic Bed" configuration

"NA" - Item not applicable to the model

3.2 Wall Unit Configuration

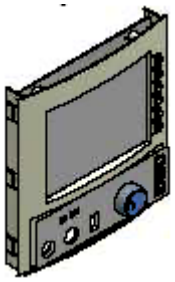
The AMPLA® 2085 Infant Warmer Intensive Care Unit can be configured as a wall unit, with the same monitor options, i.e., graphic color monitor, graphic monochrome monitor and LED panel. It has only one basic bed option and different options for accessories, and can be used on a counter, hospital crib or together with a cabinet in humanized delivery rooms.

Note: For definition of the installation and accessories, consult with the Technical Assistance department.

3.3 Microprocessor-Controlled Monitor

The microprocessor-controlled monitor can be supplied in the following different options, according to the applications and requirements of use.

- Microprocessor-based 8.4" Graphic Color Monitor – 20 functions and 19 graphic parameters
- Microprocessor-based 5.5" Graphic Monochrome Monitor – with 20 functions and 11 graphic parameters
- Microprocessor-based LED Panel – 10 basic functions.

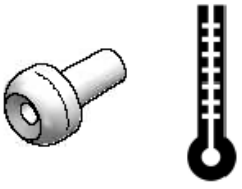


- These models monitor the temperature programmed/set for the patient, electronically controlling the amount of heat radiated by the heating element, according to the skin temperature of the newborn receiving care in the Infant Warmer, with a variation of ± 0.2°C. The amount of heat is reported to the device via the Skin Temperature T1 Sensor, which must be in contact with the newborn's skin, preferably in the abdominal area, fastened with the proper adhesive.
- It has alarms for high and low patient temperature depending on the set points, as well as for disconnection of the sensor plug and dislodging of the sensor, with different sounds and visual indications on the monitor screen.
- The silence alarm key for hypothermia automatically reverts the system to the set point through automatic reset.
- The temperature setting to be controlled is displayed on the monitor under TEMPERATURE SET POINT, and the level of radiant power can be viewed on the LED bar or bar diagram, according to the monitor. The temperature indicated on the monitor under SKIN TEMPERATURE is that of the newborn, in the sensor region.
- These monitors also allow for manual control mode, where the proportional heating power can be adjusted by the operator. In this case, the patient's body temperature should be monitored frequently, by a professional, using a clinical thermometer in the axillary region.

According to the configuration of the monitor and its respective accessories, other patient monitoring parameters may also be applied, such as: two skin temperatures, oxygen saturation, heart rate and weight; plus oxygen concentration administered to the patient, temperature of the thermal mattress and ambient temperature where the Infant Warmer is installed.

3.3.1 Ambient Temperature Sensor

On the back upper part of the column, this sensor measures the ambient temperature where the Infant Warmer is installed and constantly informs this temperature on the Control Monitor, as additional information for the user.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.4 Radiant Reflector

It supplies the necessary heat to the patient, through indirect infrared radiation derived from a 560 W heating element, made with nickel chromium wire encapsulated in a special quartz tube. The reflector has directional fins that evenly distribute the heat over the mattress region, concentrating it only in this region.

3.4.1 Swivel function of the radiant reflector to either side, at +90˚/ -90˚ to enable and facilitate

♦ **Access to the portable X-ray equipment** for exam procedures in the bed. During this operation, a safety device will be activated, cutting off the heat from the heating element, which will resume normal operation immediately after being restored to its original position.

♦ **The kangaroo mother function** keeps heating the newborn, held on the lap of its mother, who is seated on a chair next to the Infant Warmer, with the swivel radiant reflector at 90º and the kangaroo function programmed on the panel, at a heating power of 30%.

Note: Estimated useful life of the heating element is 18 months. (Under normal conditions of use).

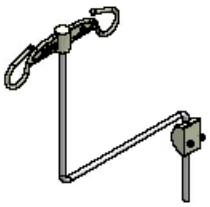
3.5 Auxiliary Lighting

It provides lighting over the patient, for use in settings with reduced lighting. It has a light source comprised of a battery with three white LEDs and a diffuser lens. It is activated by a light switch located on the lower part of the radiant reflector.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.6 Adjustable Serum Holder

Consisting of a metal rod and hook made out of engineering plastic, it is coupled on the lower part of the column. It can be pivoted to either side of the Infant Warmer and its height is adjustable. It can also be coupled in a dual crossed manner. It enables at least two intravenous and/or enteral infusion bottles to be used, when operated as an Infant Warmer in a stationary position, or during transport.

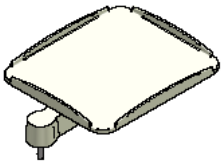


Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional item.

3.7 Side Shelf

Fastened midway up on the adjustment blocks on the side of the column, for coupling peripherals, such as fans, multiparameter monitors and other items being used with the patient. Each shelf can support a load of up to 10 kg, with maximum permitted height of up to 30 cm, for peripherals, which should be centered on the shelf.



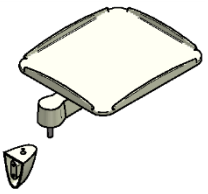
Up to three shelves can be coupled.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

	Warning: Maximum shelf load of 10 kg.
	Note: Optional item.

3.8 Side Shelf with Adapter

Rotating side shelf fastened halfway up the column, ideal for coupling fans, multiparameter monitors and other peripherals.
Additional shelf supplied with adapter block.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

	Warning: Maximum shelf load of 10 kg.
	Note: Optional item.

3.9 Patient's Bed

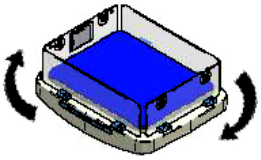
Patient's bed: two models to meet different needs and provide access to perform procedures with the patient or to observe and keep the newborn warm, during transitory stages in its care.

3.9.1 ICU Bed Table

More spacious intensive care unit, equipped with three transparent acrylic side walls that completely fold open, facilitating the access of medical and nursing teams to perform procedures on the newborn. It also has a bypass-type drawer on the lower side part for placing an X-ray cassette drawer, in addition to four silicone tube and cable inserts and a patient identification holder. Maximum load of 7 kg. It has two systems for bed movement and inclination:

3.9.1.1 Electric Table

With a system that operates electrically, providing smooth bed movement, without noise or jolts to the patient. It is activated via access keys located on the column, on the panel, for the Trendelenburg (-12º), Reverse Trendelenburg (+12º) or automatic Horizontal positions.

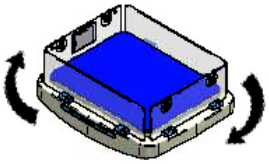


Note: Optional item.

Note: in the LED Display Monitor version it does not execute Automatic Horizontal Return.

3.9.1.2 Mechanical Table

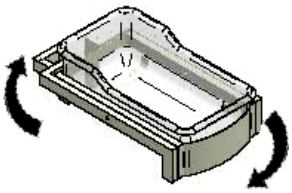
With a system that operates mechanically via manual adjustments, using a locking device, on the lower front part of the table, which when pulled enables the bed to be placed in the Trendelenburg (-12º), Reverse Trendelenburg (+12º) and Horizontal positions.



Note: Optional item.

3.9.2 Acrylic Bed

Acrylic bassinet with rounded corners, which rests on a support platform, able to support a maximum load of 7 kg. Totally removable and operated mechanically through manual adjustments which enable the bed to be placed in the Trendelenburg (-10°), Reverse Trendelenburg (+10°) or Horizontal positions. It has a patient identification holder.



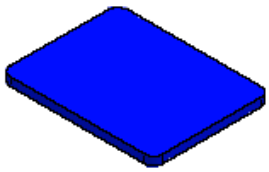
Note: Optional Item.

Warning: The bed can support a maximum weight of 7 kg.

3.10 Bed mattress

3.10.1 Memory Mattress

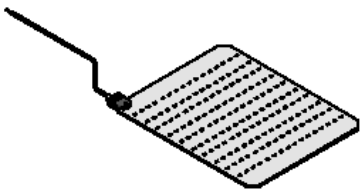
It is made out of special self-extinguishing polyurethane foam, with the appropriate density and composition, providing patients with superior softness and comfort. It has "memory effect" and a non-toxic sealed PVC cover that is malleable and resistant to cleaning and disinfection procedures, with pressed edges to prevent deposits of dirt and secretions. It comes in two sizes: one for the two types of ICU Table Bed and another one for the Acrylic Bed.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.10.2 Thermal Mattress

To be coupled to the ICU bed table of the Infant Warmer. It has a safety thermostat and temperature programming and control via the control monitor of the Infant Warmer. It also generates indirect heat, which is conducted to the patient. Recommended for use during intra-hospital neonatal transport, in surgical procedures or in situations where radiant heating is inappropriate and may interfere with procedures being performed by the medical team. It must be used together with a transparent mattress to accommodate the newborn and enable its body temperature to be maintained.



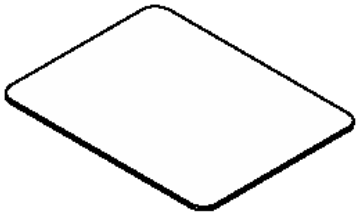
Accessory for exclusive use with the AMPLA®2085 Infant Warmer

⚠	**Note: Optional Item. Available upon request.**
⚠	**Note: Item only available for the AMPLA® 2085 Infant Warmer - ICU Table configuration.**

3.10.3 Transparent Mattress

Transparent gel mattress with appropriate density to provide excellent softness and patient comfort. Recommended for use with two different functions of the Infant Warmer:

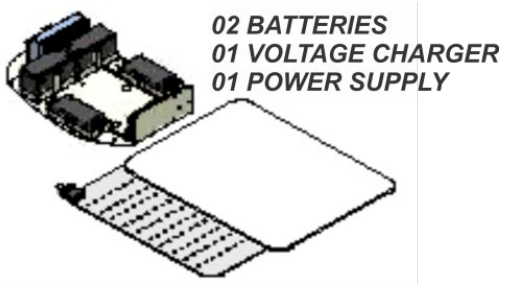
- On top of the thermal mattress (optional item, upon request), to accommodate the newborn and maintain its body temperature, especially by conduction, when the Infant Warmer is used for surgical procedures and during neonatal transport.
- Joint use with the Bilitron® Bed 4006, the reverse phototherapy coupled to the bed table of the Infant Warmer to enable the desired irradiation dose for neonatal jaundice treatment.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.11 Transport Kit

Comprised of two batteries, a voltage charger, thermal mattress (optional item, upon request) and transparent mattress, it enables autonomous intra-hospital transport of newborns, under appropriate thermal conditions, with the support of other accessory devices, such as the Babypuff® Neonatal Resuscitation Device, the aspirator for removing secretions and the Babypap®. It is used in transport situations, between normal newborn care sectors, such as the Delivery Room, ICU and Surgery Center, where it is necessary to maintain the patient's body temperature. Available only for the AMPLA® 2085 Infant Warmer - ICU Table configuration.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

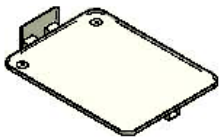
⚠	**Note: Optional Item.**
⚠	**Note: Item only available for the AMPLA® *2085 Infant Warmer* - ICU Table configuration.**

3.12 Accessories Tray and Drawers

Resources, with different combinations, that can be installed in the area underneath the patient's bed and serve for setting, storing or protecting different materials, such as extra mattresses (standby mode), the patient's medical chart, clothing and materials for hygiene and comfort.

3.12.1 Accessory Tray

Installed underneath the patient's bed, it can be used to properly store up to two of the three different mattress models, where one will be in use and the others on standby between uses. The tray can support a maximum weight of 7 kg.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

Warning: Maximum tray load: 7 kg.

3.12.2 Accessories Tray and Two Drawers

Installed underneath the patient's bed along with two drawers for storing clothing and/or different utensils.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

Warning: Maximum tray load: 7 kg.

3.12.3 Accessories Tray and Four Drawers

Installed underneath the patient's bed, along with four drawers, for storing clothing and/or different utensils.

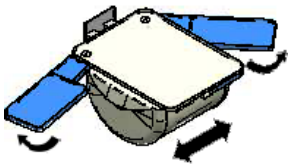
Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Item only available for the AMPLA® 2085 Infant Warmer - ICU Table configuration.

Warning: Maximum tray load: 7 kg.

3.12.4 Accessories Tray with Two Articulated Shelves and Bypass-type Drawer

Installed underneath the patient's bed. This unit contains two articulated shelves to provide assistance and support during routine procedures, as well as one bypass-type drawer for storing clothing and/or different utensils.

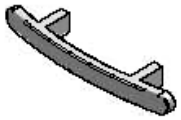


Accessory for exclusive use with the AMPLA®2085 Infant Warmer

⚠	**Note: Item only available for the AMPLA® 2085 Infant Warmer - ICU Table configuration.**
⚠	**Warning: Maximum tray load: 7 kg.**

3.13 Protector and Handle for Transport

Comprised of two vertical handles located on the upper part of the column for users to place their hands on to safely move or transport the equipment, operating from the back part to the front.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.14 Gas Inlet

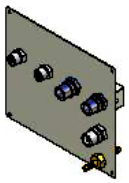
3.14.1 Gas inlet panel: located on the back of the column, it has separate gas and aspiration modules

The gas module consists of a strip with: one O_2 inlet nipple, one O_2 outlet nipple, one compressed air inlet nipple and one compressed air outlet nipple.

The aspiration module consists of one compressed air inlet nipple and one aspiration nipple.

The supply connection is made through using standardized hoses for O_2 and compressed air, between the reducing valves (of the cylinders or network) and the respective inlet nipples of the gas inlet panel. The outlet supply for use in therapeutic procedures in oxygen therapy is done through O_2 and compressed air flow meters and/or mixture, from the Blender, according to the applications involved in the use of other built-in or external ventilation devices, such as the BABYPUFF® and/or BABYPAP® CPAP.

The supply connection for the aspiration module is made through using a standardized hose for compressed air, between the reducing valve (of the cylinder or fixed network) and the respective inlet nipple of the gas inlet panel. The outlet is done through a transparent silicone hose, equipped with a hydrophobic filter, which is connected to the outlet nipple and intermediate aspiration bottle, from which issues another transparent silicone connection, for the single-use universal device for individual aspiration of the patient.



Note: Special configurations can be made according to the gas installation and/or customer's needs and local laws.

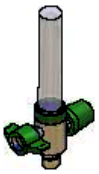
Note: All the connections, valves, meters and tanks may vary according to the customer's need and local laws.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.14.2 O2 Flow Meter

O_2 flow meter: 0-15 LPM, coupled to the side of the column, controls the supply flow for the configured therapeutic options and others, such as: manual resuscitation devices, CPAP, nasal catheters and hoods and tents, etc.



Accessory for exclusive use with the AMPLA® 2085 Infant Warmer

Note: Additional, optional flow meters can be incorporated into the system, as needed for use.

Note: Optional Item.

3.14.3 Humidifier for Flow Meter

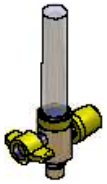
Made out of plastic and able to hold 230 ml, to be coupled to the base of the flow meter in order to supply humidified oxygen, in a wide range of options for therapeutic use with oxygen therapy.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.14.4 Compressed Air Flow Meter

Compressed air flow meter: 0-15 LPM, which can be used with the outlet nipple of the gas module on the rear panel, providing flow control for a wide range of options for therapeutic use.

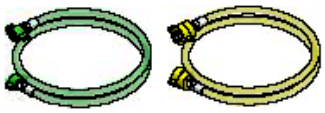


Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.14.5 Extensions for O_2 and Compressed Air

Specific extensions for O_2 and compressed air, in 1.5 m, non-toxic, braided, high-pressure (250 PSI) hoses and standard female connectors for connecting the respective gas sources (cylinders or gas network) to the gas inlet panel. Green for O_2 and yellow for compressed air.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

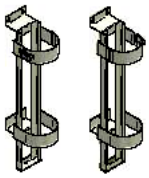
Note: Optional Item.

3.15 Cylinder Bracket and Cylinders

Installed on the rear of the column of the Infant Warmer, it is used to safely fasten the gas cylinders during internal transport or in situations where there are no medical gas supply sources.

3.15.1 Right/Left Cylinder Bracket

Fits one cylinder on each side, such as: a compressed air cylinder and an O_2 cylinder to administer mixtures and concentrations recommended in therapeutic procedures and for use with oxygen therapy devices whether built-in or not to the Infant Warmer.



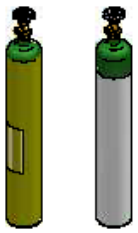
Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.15.2 Oxygen and Compressed Air Cylinders

Oxygen Cylinder Aluminum oxygen cylinder, with stop valve, type E in accordance with standard DOT 3AL, reference volume 4.6 L (H_2O).

Compressed Air Cylinder Aluminum compressed air cylinder, with stop valve, type E in accordance with standard DOT 3AL, reference volume 4.6 L (H_2O).

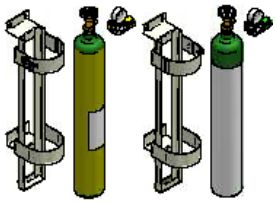


Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item. Reducing Valve not included.

3.15.3 Complete Cylinder Set

Complete set consisting of right/left cylinder brackets, 1 oxygen cylinder with stop valve, type E in aluminum, as per the standard DOT 3 AL, reference volume 4.6 L (H_2O) and 1 compressed air cylinder with stop valve, type E in aluminum as per the standard DOT 3 AL, reference volume of 4.6 L (H_2O).

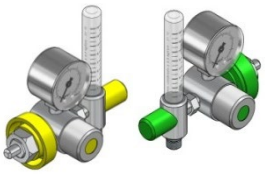


Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.15.4 Reducing Valves for Cylinders

Compatible for use with compressed air and oxygen cylinders, with connections in accordance with the standards ABNT 204-1 (compressed air) and ABNT 218-1 (oxygen).



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

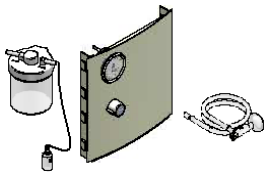
Note: Optional Item.

3.16 Front Gas Panel – Configurations

The AMPLA® 2085 Infant Warmer offers modular configuration options to meet specific requirements for aspiration, oxygenation, resuscitation and neonatal CPAP, in accordance with the applications involved in the use of an Aspirator, Flow Meter, Blender, Babypuff® Neonatal Resuscitation Device, Neonatal water-seal CPAP and Oxygen Concentration Monitor.

3.16.1 Front Gas Panel – Aspiration

Modular panel containing a vacuum gauge, intermediate aspiration bottle, silicone aspiration hose and meconium aspirator, fed by a specific compressed air inlet and a silicone hose equipped with a hydrophobic filter for outlet and connection to the intermediate aspiration bottle.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.16.2 Front Gas Panel – Oxygenation

Side modular panel containing up to two flow meters and connections for supplying dry and humidified oxygen, fed by the oxygen inlet on the rear gas inlet panel, to be used for administering oxygen with masks, helmets and tents.

3.16.3 Front Gas Panel with Blender

Modular panel containing a blender-type gas mixer to supply precise O_2 concentrations from 21% to 100%, integrated with the functions of the Babypuff® and Babypap®.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

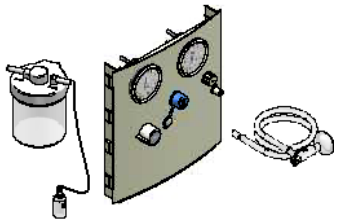
Note: Optional Item.

3.16.4 Babypuff® Front Gas Panel

Modular panel containing an oxygenation module, blender and Babypuff®, consisting of a pressure-vacuum gauge, safety pressure valve, inspiratory pressure (PIP) valve, gas inlet hose, corrugated tube with Ayre's T-Piece, expiratory pressure (PEEP) valve and test lung.

3.16.5 Front Gas Panel – Aspiration + Babypuff®

Modular panel containing an aspiration module with vacuum gauge, aspiration bottle, silicone aspiration hose and meconium aspirator, plus the Babypuff® Neonatal Resuscitation Device, comprised of a pressure-vacuum gauge, safety pressure valve, inspiratory pressure (PIP) valve, gas inlet hose, corrugated tube with Ayre's T-Piece, expiratory pressure (PEEP) valve and test lung.

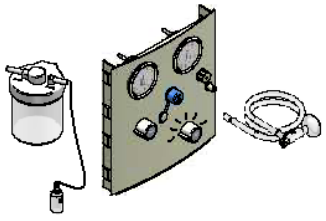


Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.16.6 Front Gas Panel – Aspiration + Babypuff® + Blender

Modular panel containing all the complete modules, i.e., aspiration module with vacuum gauge, aspiration bottle, silicone aspiration hose and meconium aspirator, plus the Babypuff® Neonatal Resuscitation Device, comprised of a pressure-vacuum gauge, safety pressure valve, inspiratory pressure (PIP) valve, gas inlet hose, corrugated tube with Ayre's T-Piece, **expiratory pressure (PEEP) valve** and test lung, in addition to the blender-type gas mixer – 21% to 100% oxygen concentration.

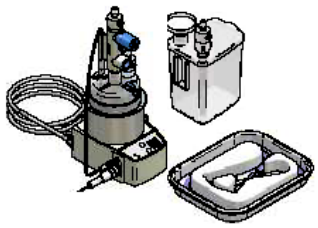


Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.16.7 Humidifier + Bubble Generator Bottle + CPAP Circuit

This adapted optional item which fits on the side of the column of the Infant Warmer is comprised of the FOG® 1140 Heated Humidifier, bubble generator bottle and CPAP Circuit No. 0, to be used together with the oxygenation module and blender from the gas inlet panel for carrying out therapeutic procedures that use heated and humidified gases, especially Neonatal water-seal CPAP. Available in (127 V~ 50/60 Hz) and (220 V~ 50/60 Hz)



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.16.8 General Purpose Oxygen Analyzer Monitor

Located on the side of the column, with connector and complete cable and oxygen cell kit, for measuring and monitoring O_2 concentration, on the monitor screen, for the different therapeutic ways to administer gases in the Infant Warmer. Only available in the versions with color or monochrome LCD monitor for specific or continuous monitoring of the O_2 concentration used by the patient.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.17 Side Support for Infusion Pump

Metal rod unit fastened to the right side of the column, for coupling infusion pumps, with adjustable height to provide greater or less gravitational pressure, and four hooks on the top for attaching bottles and bags containing intravenous and gastroenteral solutions.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.18 Hooks – Collector Bags and Cable Router

Hooks made out of engineering plastic used to support collector bags (two hooks located on the sides next to the patient's bed), and for routing the sensor cables connected into the control panel (one hook located on the side of the column).

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.19 Auxiliary Sockets

Installed in a box, on the side of the column, the set of auxiliary sockets is for connecting monitors and auxiliary devices that comply with the medical electrical equipment standard IEC 60601.

The voltage supplied in the auxiliary sockets is the same as the input voltage for operating the AMPLA® 2085 Infant Warmer.

Warning: Output voltage = Mains voltage
Maximum power per socket is 150 W

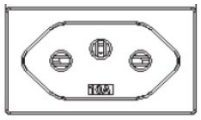
The auxiliary sockets are equipped with a cover fastened by screws. Removal of this cover should be done by the person in charge of the area, with sufficient qualifications to check which equipment is authorized to be connected into the auxiliary sockets of the AMPLA® 2085 Infant Warmer.

Warning: Make sure that the equipment to be connected complies with the standard IEC 60601-1 and its particular standards, in addition to the electrical specifications of the auxiliary sockets.

NOTE: *The configuration of the sockets may vary according to local regulations.*

3.19.1 Standard Auxiliary Socket 2P+T NBR 14136

Set of auxiliary sockets with protective cover, comprised of four standard sockets 2P+T 10 A, in accordance with the standard NBR 14136.

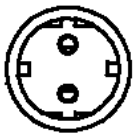


Note: Optional Item.

NOTE: *Item designed in accordance with local regulations*

3.19.2 Standard Shucko Auxiliary Socket

Set of auxiliary sockets with protective cover, comprised of two standard Shucko sockets



Note: Optional Item.

NOTE: *Item designed in accordance with local regulations*

3.19.3 Standard Auxiliary Socket 3 P SNAP FIT

Set of auxiliary sockets, comprised of four standard 3P sockets, in accordance with the standard SNAP FIT IEC.

Note: Optional Item.

NOTE: *Item designed in accordance with local regulations*

3.20 Cable Reel

Made of malleable rubber and installed on the side of the column, to partially or totally stow or secure the power cord, when used in transport mode or for storing excess cable when the Infant Warmer is used in a stationary position.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.21 In-bed Scale

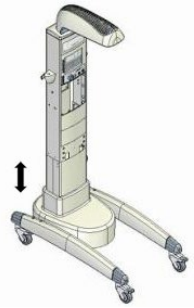
Table bed with in-built neonatal scale, to weigh patients without removing them from the heat source and enabling weight to be monitored on the monitor screen. This results in minimum handling and enhances the clinical evaluation of the newborn. The weighing function is performed through load cells contained inside the platform of the table. Able to weigh up to 10 kg with an accuracy of ±4 g.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.
Available only for the AMPLA® 2085 Infant Warmer - ICU Table configuration.

3.22 Ergometric Column with Pedal

The ergometric column with pedals on both sides of the AMPLA® 2085 Infant Warmer can be adjusted in height and is operated electrically with a total extension of 200 mm (+100 / -100 mm), smoothly adjusting to the height of the bed, according to the need and best ergonomic body position of the user.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.23 BILITRON® 3006 Phototherapy with adapter

Microprocessor-based phototherapy device, with compact dimensions, that uses five blue Super LEDs as its light source. It is directly coupled via a flexible articulated arm to the structure of the patient's bed, so that the irradiation intensity set for the treatment does not vary in intensity and focus, due to interference in the patient/source distance when the position of the bed table is changed, whether Trendelenburg, Reverse Trendelenburg or Horizontal.

ANVISA Registration No.: 10.224.620.049

	**Note: Optional Item. Exclusive use adapter.**

3.24 Bilitron® Bed 4006 Reverse Phototherapy

Microprocessor-based phototherapy device in the format of a compact bassinet, which uses a set of 17 blue Super LEDs, arranged at the base of the Infant Warmer bed, in a space bound by transparent acrylic side protectors, approximately 9 cm away from the light source. This set of Super LEDs emits light upwards that passes through the underside of the acrylic bed and transparent gel mattress, to reach the skin of the newborn who is comfortably lying down and positioned to receive phototherapy treatment

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

	**Note: Optional Item.**

3.25 Pulse Oximeter

Nellcor Pulse Oximetry features priorities in alarm management and contains the SatSeconds® system.

Application: Babies from 3 to 15 kg:

Ideal application area: on the big toe, with the cable running along the sole of the foot

Newborns from 1 to 3 kg:

Ideal application area: Front part of the sole of the foot.

	**Warning: Use adhesive wraps only once.** **Alternate the application area every four hours.**
	**Warning: Since SpO_2 measurement depends on the light of the sensor, excessive ambient light can interfere with this measurement. Surgical lights, phototherapy lamps, infrared heating lamps and direct sunlight can affect SpO_2 sensor performance. To avoid light interference, ensure that the sensor is properly applied and cover the sensor site with opaque material**

Note 1: The pulse oximeter reading is automatically updated in one second intervals.

Note 2: This oximeter measures functional saturation – oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of non-functional hemoglobin, such as carboxyhemoglobin or methemoglobin.

On the other hand, instruments called hemoximeters, report fractional saturation – oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured non-functional hemoglobins.

To compare functional saturation measurements with those from an instrument that measures fractional saturation, the fractional measurements need to be converted as follows:

Functional saturation = [Fractional saturation/100 - (% carboxyhemoglobin + % methemoglobin)] x 100

Note 3: To identify the oxygen saturation of arterial hemoglobin, the oximeter uses the pulsatile nature of the arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (that is, measurements at systole and diastole). By doing so, it focalizes light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone and venous blood.

Note 4: Reading accuracy ranges

Saturation	
Newborn	70% to 100% ± 3 digits
Low perfusion *	70% to 100% ± 2 digits
Pulse Rate	
Newborn	20 to 250 BPM ± 3 digits
Low perfusion *	20 to 250 BPM ± 3 digits

(*) The accuracy of the reading in the presence of low perfusion (infrared pulse modulation amplitude <1.5% was detected) was validated with signals provided by the patient simulator. The SpO_2 and pulse rate values varied during monitoring when compared with a range of weak signal conditions and compared with the real saturation and pulse rate of the input signals.

3.26 Cables, Sensors and Adhesives

3.26.1 Pulse Oximeter Sensor – SpO2 – D-YS Sensor

Reusable, latex-free sensor, for patients weighing between 3 and 15 kg. For use with newborns, the recommended area of application is the big toe, with the cable fastened along the sole of the foot, or the front of the sole of the foot. Another alternative would be the palm of the hand, below the fingers, with the cable fastened on the palm.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item. Comes with the optional pulse oximeter

3.26.2 Adhesive for SpO2 Sensor

Foam-P/I, latex-free sensor wraps – 10 units

ADH - P/I, latex-free sensor wraps – 10 units

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item. Comes with the optional pulse oximeter

Oximax® – Trademark of Nellcor Puritan Bennett

3.26.3 Skin Temperature T1 Sensor

It is the main sensor for monitoring and controlling the newborn's skin temperature. It is through the skin T1 sensor that the patient's temperature is controlled through the radiant heater in Skin Mode. It should be placed and attached, preferably in the abdominal region, with the skin temperature set point for the newborn ranging from 36ºC to 36.4ºC. The monitoring of temperature by this sensor will determine the activation of Skin Mode alarms.

The sensor is made out of latex-free material and comes with the different configurations of the AMPLA® 2085 Infant Warmer.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

3.26.4 Auxiliary Skin Temperature T2 Sensor

It is an auxiliary skin temperature sensor for a different area of the patient's body, or for another location in the bed. The equipment can be used only to indicate the temperature of the location where it is installed, without interfering with the radiant heating of the patient.

Sensor made out of latex-free material, used as an optional item.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.26.5 Rectal Temperature Sensor

Latex-free sensor for measuring rectal temperature, encapsulated in 304 stainless steel, used as optional item to indicate the peripheral temperatures of the patient. It is not involved in controlling the heating of the Infant Warmer.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.26.6 Skin Sensor Adhesives

Anti-allergic, latex-free adhesive specially designed to properly attach the temperature sensor to the skin of the newborn.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.26.7 Oxygen Analyzer Sensor

Complete kit with cable and oxygen cell to monitor O_2 concentration via the Oxygen Analyzer of the AMPLA® 2085 Infant Warmer monitor. The full kit can be provided, or just the cable with connector, without the cell, or just the Oxygen Cell – MAXTEC® MAX 13 or ANALYTICAL PSR –11-917-J5

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.26.8 Heated Humidifier of the CPAP Kit

3.26.8.1 Cable with Connector

Cable with connector, without the cell.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.26.8.2 Oxygen Cell

Oxygen Cell – MAXTEC® MAX 13 or ANALYTICAL PSR –11-917-J5.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

MAXTEC® – Trademark of Maxtec Inc.

3.26.8.3 Temperature Sensor

Used with the heated humidifier of the CPAP Kit to indicate the temperature of the gas mixture that is delivered to the patient in heated and humidified form.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item. Comes with the optional Heated Humidifier.

3.26.8.4 Water Level Sensor

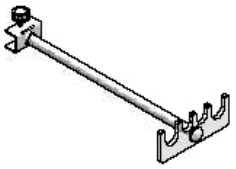
Used in the heated humidifier bottle of the CPAP Kit to monitor the water level in the humidification compartment.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item. Comes with the optional Heated Humidifier.

3.27 Flexible Goose Neck Adapter for Circuit Support

It is made out of a flexible metal rod that can be coupled to the rear protection wall of the bed, to help secure and route the tubing of the connections of the respirator for the patient.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.28 Accessory Basket

Wire structure basket to stow different materials and implements.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.29 Stethoscope and Thermometer Holder

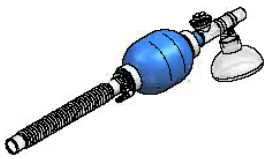
Attached to the column of the AMPLA® 2085 Infant Warmer, the stethoscope and thermometer holder is for storing these individual use instruments.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.30 Pediatric Resuscitator Model 020

Made entirely of silicone, it has a corrugated oxygen accumulator tube, mask No. "0" and safety valve calibrated at 40 cmH_2O.



ANVISA Registration No.: 10.224.620.036

Note: Optional Item.

3.31 Infant pillow

Infant pillow with anti-allergic TNT pillow case, with a format tailored to the anatomy of the head of the newborn. Helps secure the newborn's head during intubation, oxygen therapy, phototherapy and other procedures. Available in different sizes.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

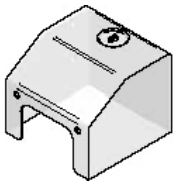
3.32 Tents and Hoods

Devices made out of transparent, non-toxic and anti-allergic material to administer oxygen in higher concentrations and in specific therapeutic procedures. The hoods and tents come in different sizes.

3.32.1 Hoods

ANVISA Registration No.: 10.224.620.003

3.32.2 Tents



ANVISA Registration No.: 10.224.620.003

Note: Optional Item.

3.33 Hydrophobic Filter

Filter installed on the suction line to prevent the transmission of pathogenic viruses, in accordance with the Guidelines for Perioperative Practice by AORN (Association of Perioperative Registered Nurses - USA).

It contains microporous membranes of "Teflon" and polytetrafluoroethylene (PTFE) capable of retaining aerosol and microorganisms in accordance with ULPA standards, and thereby captures 99.9% of all particles from 0.1 to 0.5 microns in size or larger.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item. Consumable Item.

3.34 Babypuff® 1020 Neonatal Resuscitation Device

Separate or built into the Front Gas Panel of the AMPLA® 2085 Infant Warmer, it consists of a pressure-vacuum meter to set, measure and monitor pressure; three mechanical valves to regulate and control Maximum or Safety Pressure, Peak Inspiratory Pressure (PIP) and Positive End Expiratory Pressure (PEEP); two quick coupling connections - one smooth one for the gas inlet/supply, to the device, and the other one for the gas outlet/supply to the patient adapted to an Ayre's T-piece, for connection to the tracheal tube or silicone mask (round and transparent, in three sizes); and a test lung for simulation and setting parameters.

The built-in Babypuff® Neonatal Resuscitation Device operates directly and solely through a gas source: Oxygen at 100%, Compressed Air at 100% and/or a mixture of Air/O_2 controlled through a blender or another type of mixer at the gas inlet.

ANVISA Registration No.: 10.224.620.065

Note: Optional Item.

3.35 Meconium Aspirator

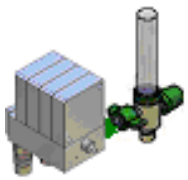
Made of transparent polycarbonate, in adapter format for tracheal tube aspiration probe, used in resuscitation procedures, after birth, for newborns who aspirated meconium.

Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

3.36 Blender Mixer

Separate or built into the Front Gas Panel of the AMPLA® 2085 Infant Warmer, it adjusts and supplies concentrations of compressed air and oxygen mixtures, through an outlet flow meter (0 to 15 LPM) to supply a Babypuff® 1020 Neonatal Resuscitation Device and/or another form for administering oxygen to newborns.



Accessory for exclusive use with the AMPLA®2085 Infant Warmer

Note: Optional Item.

4. Precautions, Restrictions and Warnings

Warning: This section of the User Manual contains extremely important information to ensure the safety and integrity of the patient, user and equipment. Read it CAREFULLY!

Check whether the electrical network to which the equipment will be connected is compatible with the electrical specifications of the equipment, such as voltage and power, as indicated on the label affixed to the unit.

The power cord must be plugged into a grounded outlet that is permanently attached to the wall, in accordance with the rules and legislations for low voltage electrical installations and electrical legislation for Health Care Establishments.

Warning: To avoid risk of electric shock, this equipment should only be connected into a socket grounding to provide proper protection. Do not use extension cords or multiple sockets.

Check that the caster brake levers are positioned downward, keeping the unit locked.

Connect the oxygen supply hose to the hospital gas network, or an oxygen cylinder, checking beforehand that all the valves on the strip are totally closed (clockwise direction).

Warning: When oxygen is administered in the Infant Warmer, it is also necessary to use an oxygen monitor.

When an Infant Warmer is incorrectly used, it can cause serious risks to newborns. This equipment should only be operated by trained and qualified personnel who understand the risks and benefits of its use.

Warning: Explosion Hazard. Do not use the Infant Warmer in the presence of flammable anesthetics or cleaning agents which could cause combustion.

This equipment cannot be used if any of its functions are not operating properly. A qualified service technician should be requested.

The AMPLA® 2085 Infant Warmer was designed for use with only one patient at a time.

Warning: It is not recommended to use this equipment with more than one patient at a time, since it will only be possible to monitor one of them. There is also a risk of cross infection.

The operator must constantly monitor the Infant Warmer and newborn, regardless of the patient's temperature.

This equipment cannot be used if any of its functions are not operating properly. A qualified service technician should be requested.

Warning: Any and all set point parameters must be according to medical instructions.
FANEM® and its representatives shall not be held liable for any damages resulting from the improper use of these parameters.

When in Skin Mode control, the Skin T1 sensor must remain in direct contact with the skin, so that through exact monitoring of the patient’s skin temperature, the right amount of heating can be supplied to the Infant Warmer for the patient. If the Skin T1 sensor is incorrectly positioned on the patient, this could result in overheating or cooling of the newborn, since the sensor that controls the heating system of the Infant Warmer would not be registering the real temperature.

Regularly check the newborn’s condition and that the sensor is correctly positioned in order to avoid activating the dislodged sensor and/or Skin T1 sensor failure alarms.

It is not advisable to leave a newborn in an Infant Warmer without constant observation and proper clinical care.

The Skin T1 temperature sensor is exclusively intended to monitor the surface temperature of the patient's skin and must be placed on a part of the body that is exposed to the heat from the radiant heater.

Never use the Skin T1 sensor, placing it underneath the newborn's body.

Never use any material that would constitute an obstacle between the Skin T1 sensor and the radiant heat source. For example, never use the Skin T1 sensor underneath diapers, blankets or any other similar type of protection.

Never use the Skin T1 or T2 sensors to measure the patient's rectal or axillary temperature.

The sensors described in this manual are not designed to measure the patient's axillary temperature. A clinical thermometer should be used for this purpose.

Warning: Rectal temperatures are not suitable for controlling the power of the Infant Warmer heater.

Controle de Temperatura - Precauções
Temperature Control - Precautions
Control de Temperatura - Precauciones

- **Quando em modo manual, para prevenir hipertermia ou hipotermia, controlar intensivamente a temperatura do RN de forma independente, atráves de um termômetro de precisão;**
  Para prevenir hipertermia, acople o sensor paciente somente na superfície da pele diretamente exposta ao aquecimento, fixando com o adesivo refletivo apropriado;
  O aquecimento por radiação pode causar aumento de perda insensível de água (IWL).
  Medidas apropriadas devem ser consideradas para manter o balanço hídrico desejado;
  Condições ambientais (movimentação, fluxo de ar, etc) podem afetar o balanço térmico do paciente;
- *In manual mode, to prevent hyperthermia or hypothermia, control the temperature of the newborn intensively in an independent way, using a precision thermometer.*
  To prevent hyperthermia, connect the patient sensor in the surface of the skin directly exposed to the heating only, fastening with the appropriate reflective sticker;
  The heating by radiation may cause increase of insensitive water loss (IWL).
  Appropriate measures should be considered to maintain the desired hydric balance;
  Environmental conditions (movement, air flow, etc) may affect the patient´s thermal balance;
- *Cuando en el modo manual, para prevenir hipertermia o hipotermia, controlar intensivamente la temperatura del RN de una manera independiente, através del termómetro de precisión;*
  Para prevenir hipertermia, acople el sensor paciente en la superficie de la piel directamente expuesta a la calefacción, atando con el adhesivo reflexivo apropiado;
  La calefacción por radiación puede causar aumento de pérdida insensible de agua (IWL).
  Medidas apropriadas deben considerarse para mantener el balanceo hídrico deseado;
  Condiciones ambientales (movimento, flujo de aire, etc) pueden afectart el balanceo termal del paciente;

The distance between the heating system and mattress is standardized and fixed. Therefore, any change in this distance could create serious hazards to the patient.

It is recommended to constantly inspect the condition of the latches of the bed's side protection walls, to ensure that they lock properly as a protective measure against patient falls.

When using the shelves, take the following precautions:

- Always place the monitor in the center of the shelf.
- Make sure the monitor fits within the boundaries of the shelf.
- Avoid putting one monitor upon another one already installed on the shelf.
- Respect the maximum load limits of each one of the shelves.

Any peripheral equipment which may be connected to the patient and powered through a set of auxiliary sockets must be properly grounded, as well as comply with the electrical safety standards for medical electrical equipment contained in IEC 60601-1 and its particular standards.

Never exceed the specified power range for the set of auxiliary sockets, when peripheral equipment is being powered through these sockets.

Additional equipment such as phototherapy devices, heated mattresses, etc., used with the Infant Warmer, can alter its performance in relation to the temperatures measured.

Warning: When using conventional Phototherapy Device, such as the 006OFL or BILITRON®, together with an Infant Warmer, make sure that it does not encroach upon the area of heat radiated by the Infant Warmer.

For the Trendelenburg and Reverse Trendelenburg positions, where there is an inclination of the bed in relation to the unit's heating element, this inclination can change the performance of the equipment.

Ambient conditions, such as air movement and flow or incidence of sunlight can affect the patient's thermal balance.

Warning: This equipment cannot differentiate between a condition of increased internal body temperature with cold skin (fever) and low internal temperature of cold skin (hypothermia). It is recommended to constantly monitor the patient's temperature with a clinical thermometer.

When using radiant heating, never put blankets or any type of cover on the patient. This affects the heating control of the Infant Warmer and may expose the patient to serious or even fatal risks due to overheating of the system.

When operating in Manual Mode, the Infant Warmer continuously sends the patient a preset amount of energy/heat, regardless of the patient's temperature. When operating in Servo Controlled Mode, the Infant Warmer monitors the patient's temperature using the Skin T1 sensor, electronically commanding the amount of energy/heat emitted, according to the patient's real need. Therefore, it is preferable to use Servo Mode.

Warning: The Skin T2 sensor only serves to indicate temperature and does not electronically command the amount of energy/heat supplied to the patient.

The AMPLA® 2085 Infant Warmer was designed for use with only one patient at a time.

The AMPLA® 2085 has protective filters designed to meet the specifications of electromagnetic compatibility standards but may be adversely affected by and suffer interference from certain equipment, such as high frequency surgical equipment, defibrillators, short wave therapy equipment, cardiac pacemakers and other electrical stimulators connected to the patient.

Before starting to monitor a physiological parameter, take note of all the information and precautions regarding the operation and application of the accessories, since incorrect use could cause patient injury, such as burns and/or electric shock, arising from a possible defibrillator discharge.

Warning: Patient cables and sensors are not protected against the effects of defibrillation.

Although the patient's bed is made of engineering plastic, which is fully insulated electrically, it is not recommended to use high frequency surgical equipment together with the AMPLA® 2085 Infant Warmer;

In the housing structure of the AMPLA® 2085 Infant Warmer, all its physiological parameter modules are equalized to the same potential, with no external potential equalization conductor.

To prevent the Infant Warmer from sliding when it is stopped on a ramp, make sure the casters are locked and that there is no slippage.

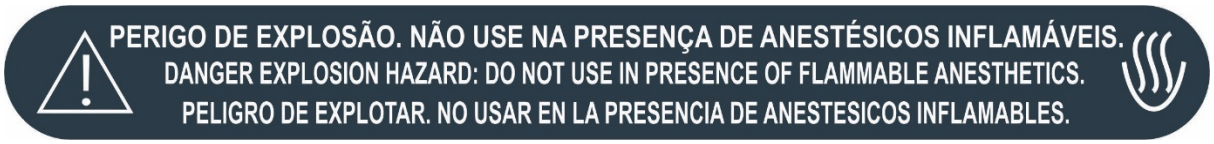
For greater safety, do transport the Infant Warmer with its shelves loaded.

When using the optional ergometric column, always transport the Infant Warmer at its lowest height, to make the equipment stabler.

♦ Do not activate the control keys using one's fingernail or any other sharp object.

Only use original FANEM® parts and accessories to ensure optimum equipment performance and safety.

Explosion Hazard: Precautions



♦ Never use the Infant Warmer in the presence of flammable anesthetics.

♦ Make sure that the oxygen supply to the Infant Warmer is turned off and that it is disconnected from the oxygen supply when during cleaning or maintenance procedures. There is a risk of fire or explosion when cleaning and/or maintenance procedures are performed in an oxygen enriched environment.

♦ Do not keep matches, lighted cigarettes and all other possible ignition sources in the location where the equipment is operating. Textiles, oils and other combustibles easily ignite and burn in oxygen enriched air.

♦ Flammable agents left in the equipment can cause a fire when in contact with oxygen.

♦ Equipment that may cause sparks, such as defibrillators or electrocautery devices, should not be used when the Infant Warmer is operating with oxygen supply.

Warning: Small quantities of flammable agents left in the equipment, such as alcohol, may cause a fire when in contact with oxygen. Never use the equipment in the presence of flammable anesthetics.

Oxygen: Precautions

♦ Improper use of supplemental oxygen may be linked to serious side effects, including blindness, brain damage and death. The risks vary with each newborn. The method, concentration and duration of oxygen administration must be prescribed by a physician.

♦ Oxygen concentrations should be continuously monitored to meet patient needs, comply with the medical prescription and to avoid potential risks.

♦ Oxygen concentrations should be measured with a calibrated oxygen analyzer, at regular intervals established by the physician.

Warning: Always use an oxygen analyzer to check the oxygen concentration that is being administered to the patient. It is recommended to use the THOR® 3620 Oxygen Analyzer for this purpose.

♦ The oxygen concentration inspired by the newborn does not accurately determine the partial pressure of oxygen (pO_2) in the blood. When deemed necessary by the physician, the pO_2 of the blood should be measured using appropriate clinical techniques.

♦ If it is necessary to administer oxygen to a patient, in an emergency situation, the physician should be notified immediately.

♦ When the arterial oxygen levels of the patient cannot be maintained, even when the oxygen concentration is set to the maximum, the change in procedures should be prescribed by the physician.

Warning: There is a risk in administering oxygen at high concentrations for extended periods of time to newborns. Strictly follow the medical prescription and frequently monitor and evaluate the concentrations supplied in relation to the clinical conditions and parameters of the patient.

♦ The use of separate cylinders for the supply of gases, such as oxygen, presents risks and should not be used without taking the recommended precautions.

4.1 Precautions – Integrated Pulse Oximetry Kit (optional)

Biocompatibility testing was conducted on NELLCOR sensors in accordance with ISO 10993-1, Biological evaluation of medical devices, Part 1: Evaluation and testing. The sensors passed the recommended biocompatibility testing and comply, therefore, with ISO 10993-1.

Warning: Pulse oximetry and pulse rate readings can be affected by certain ambient conditions, sensor application errors and specific patient conditions.

Inaccurate pulse oximetry and pulse rate readings can be caused by:

♦ Incorrect application of the sensor;

♦ Placing the sensor on a member with a pressure gauge cuff, arterial catheter or intravascular access;

♦ Ambient lighting;

♦ Extended movement by the patient.

Loss of the pulse rate reading can be caused by:

♦ Sensor is too tight;

♦ Pressure gauge cuff is blowing on the same member where the sensor is connected;

♦ Arterial occlusion close to the sensor.

Clean and remove any substances, such as adhesives, from the application area. Periodically check that the sensor continues to be properly positioned on the patient.

Strong ambient lighting, through surgical lamps, phototherapy or sunlight, can interfere with the performance of an SpO_2 sensor. Make sure that the sensor is correctly applied and cover the area of the sensor with opaque material.

Do not use a damaged sensor or sensor cable. Do not use a sensor with exposed optical components.

Warning: Only use NELLCOR™ sensors and cables with this monitor. Other sensors or cables can result in unsatisfactory performance of the Integrated Pulse Oximetry Kit.

Do not use a sensor cable to increase the length of the sensor (if unsure. contact FANEM). Use, if necessary, the Nellcor™ extension for the Kangaroo Mother procedure.

Warning: The use of another sensor cable could have an adverse effect on performance. Do not plug any cable designed for use with computers into the input port of the sensor. Do not plug any device into the sensor connector that has not been approved by FANEM.

Warning: The incorrect application or extended use of an SpO_2 sensor may cause tissue damage. Regularly check the area of the sensor and adopt the recommended procedure for safe use.

4.2 Precautions in reference to the Phototherapy Devices BILITRON® 3006 and BILITRON® BED

Check whether the mains into which the Phototherapy Devices BILITRON® 3006 and/or BILITRON BED® 4006 will be connected is compatible with the voltage and power marked on the label attached to each device.

Warning: Do not use the Phototherapy Device in the presence of flammable anesthetics, combustible gases or cleaning agents that could cause combustion.

The power cord must be plugged into a grounded outlet that is permanently attached to the wall, in accordance with the rules and legislation for low voltage electrical installations and electrical legislation for Health Care Establishments.

Warning: If there is no evidence of grounding, do not use the Phototherapy Device.

In cases where no radiant heat is being provided by an Infant Warmer, the BILITRON®3006 and BILITRONBED® 4006 Phototherapy Devices should be used in settings with an ambient temperature between 24 and 26°C, recommended as comfortable, to enable the newborn to remain totally unclothed during treatment, in neonatal care units.

Ensure that the maximum noise level generated around the patient's bed is 60dBA, for an environment with a level of noise of 45dBA.

Heat therapy devices (Infant Warmer, thermal mattress or others) used in combination with Phototherapy Device can raise body temperature, placing the newborn at risk. The patient's temperature should be constantly monitored, using a clinical thermometer.

The useful life expectancy of the Super LEDs is approximately 20,000 hours of use. However, it is recommended to periodically use the FANEM THOR® Radiation Monitor to measure the actual effectiveness of the Super LEDs, through checking the radiation status of the sources. Any lamps from

the radiant source (Super LEDs) should always be replaced once 25% of their total irradiance for Ebi-bilirubin has been lost.

It is also recommended to check for any darkening or fluctuation in the Super LEDs, in which case they should be replaced to ensure proper treatment.

Always use original parts. The use of other types of radiation sources could alter the specified radiance conditions (radiation intensity) and temperature for BILITRON® phototherapy devices.

When using BILITRON® Phototherapy Device for newborns receiving care in Infant Warmers, it is recommended to operate the equipment in servo-controlled mode, so that the heating is controlled through the patient. When used in manual mode, reduce the heating power of the radiant heater and continuously control the patient's body temperature.

Protection devices designed to maintain the patient within the effective treatment surface of the light source should be inspected regularly to ensure that their safety function is working properly.

Do not use reflective plates or sheets in the Phototherapy Device, since this could raise the patient's body temperature to dangerous levels and, in combination with the radiant heat unit, cause serious injury to the patient.

4.2.1 Suggestions to Improve Phototherapy Effectiveness

To improve the effectiveness of the treatment, the newborn should be totally unclothed, using only an open diaper and/or one that only covers the perineal region to collect urine and fecal eliminations. The use of large diapers prevents the light from acting on the newborn's skin and considerably reduces the effectiveness of the phototherapy treatment.

The larger the area exposed to the light, the more effective the treatment is.

However, if it is decided to use diapers, they should be as small as possible, only covering a small part of the perineum of the newborn. Large diapers, since they block the action of the light on the newborn's skin, considerably reduce the effectiveness of the phototherapy.

Eye comfort protection is necessary to block the light and protect the patient from the disagreeable effects of prolonged exposure to it, in addition to enabling the newborn to benefit from the positive effects of sleep during the treatment.

A good dose of irradiance combined with larger body surface exposure will make the phototherapy treatment more clinically effective, as well as significantly reduce treatment time and the need for hospitalization, thereby helping to reduce costs and associated risks.

4.2.2 Taking care of the Mattress

The transparent gel mattress is an indispensable, important and delicate component of the BILITRON® BED phototherapy unit and should be handled, cleaned and stored according to the following recommendations:

- ♦ Do not fold or roll up the transparent gel mattress to avoid ripping its protective film and to prevent risk of leakage of the gel.
- ♦ Do not use pointed or sharp objects when handling the gel mattress to avoid irreversible damage to its protective film.
- ♦ Do not use medicinal products and/or disinfectants that could result in altering the transparency (yellowish/amber color) of the gel mattress and interfere with the irradiance dose administered.
- ♦ To clean the transparent gel mattress, it is recommended to use a soft pad, water and neutral detergent. Chemicals or alcohol can damage the mattress and reduce its useful life.
- ♦ Prolonged use of the mattress can cause a photoreaction, which should be assessed through measurement and control of the irradiance to determine the interference and whether the mattress needs to be replaced.

♦ If the mattress is accidentally punctured, do not attempt to reuse it, since the spilled gel could be contaminated or even ingested by the patient. Please contact our Technical Assistance team to replace the damaged mattress with a new one.

4.2.3 Physiological Effects

Phototherapy is used to treat indirect neonatal hyperbilirubinemia, through exposure of the patient to concentrated radiation in the blue spectrum of visible light. The irradiance dose and length of treatment is determined by the physician, according to each clinical case.

The BILITRON® 3006 and BILITRON® BED 4006 phototherapy units rapidly reduce the serum levels of indirect bilirubin, thereby reducing the need for exchange transfusion and the duration of the treatment.

During phototherapy treatment, the following transitory physiological effects may be noted in the patient: increased peripheral blood flow with subsequent vasodilation, erythema, increased insensible water loss and changes in intestinal transit.

The light emitted by the Phototherapy Device may affect the visual comfort of other patients in the vicinity of the treatment area, requiring attention and care to reduce this undesirable effect.

During the use of Phototherapy Device, the water balance of the newborn undergoing treatment should be monitored.

Constant attention needs to be given to the Phototherapy Device used and the newborn receiving phototherapy requires individualized nursing and medical care.

Warning: In order to avoid eye injuries, the newborn must use eye protection whenever exposed to radiation from the Phototherapy Device.

The operator's eyes can also be impaired if exposed for long periods of time to the patient's treatment area. During patient care, the operator can turn off the phototherapy device, if so desired.

During treatment, it is important to eliminate the photosomers of indirect bilirubin, through the urine and feces, by providing the newborn with appropriate nutrition.

It is recommended to regularly measure and control the patient's serum levels with a bilirubinometer.

It is not recommended to store liquid infusions or drugs in general within the radiation area, to avoid alteration of the substances by the radiation emitted.

4.3 Thermal Mattress Precautions (optional item, upon request)

To ensure safe and efficient use of the thermal mattress, the following recommendations and guidelines must be obeyed:

♦ The thermal mattress and transparent gel mattresses are accessories for exclusive use with the FANEM AMPLA® 2085 Infant Warmer.

♦ The thermal mattress can only be used with the patient together with the specific corresponding transparent gel mattress.

♦ For safe use, the thermal mattress must be directly installed and stretched out (without creases) upon the bed of the Infant Warmer, be plugged into the monitor and overlaid with its transparent gel mattress.

♦ The patient must be placed directly on the gel mattress in the central demarcated area, which marks the area that will be heated during treatment.

♦ When not in use, the thermal mattress should be stored away, preferably on the lower shelf of the bed, connected to the Infant Warmer, but turned off, with the gel mattress laid on top, ready for use.

♦ The thermal mattress and gel mattress require special care during handling, conservation and cleaning and/or disinfection, as explained in the AMPLA® 2085 Infant Warmer Manual, to avoid

possible safety risks caused by bending, crushing or puncturing, with loss of material due to contact with pointed and sharp objects.

♦ Never use materials with good thermal insulation, such as pillows and blankets to wholly or partially cover the patient when using the thermal mattress, due to the safety risks caused by overheating.

♦ Never place the patient directly in contact with the surface of the thermal mattress, due to risk of discomfort and overheating, and the clinical consequences thereof.

Warning: Before using the thermal mattress, confirm that the transparent gel mattress is also there. The thermal mattress can only be used with the patient together with the specific corresponding transparent gel mattress.

Warning: The patient must be placed directly on the gel mattress in the central demarcated area, which marks the area that will be heated during treatment.

Warning: Before each use of the thermal mattress, check the integrity of the mattress. If the thermal mattress is not in perfect condition, do not use this function of the Infant Warmer.

Warning: When not in use, the thermal mattress must be stored according to the instructions printed on its surface and in this manual.

♦ The thermal mattress module does not have its own sensor to use with patients in order to control of the temperature of the mattress. It is only possible to use the temperature sensors provided by the AMPLA® 2085 Infant Warmer to monitor the patient's temperature. The temperature of the thermal mattress is manually selected by the operator on the control monitor of the AMPLA® 2085 Infant Warmer.

♦ The thermal mattress already comes properly calibrated from the factory and does not require additional calibration. Routine maintenance and calibrations should be performed by technicians accredited by FANEM.

♦ The thermal mattress has an internal safety thermostat that cuts off heating if there is an insulation failure, in order to prevent the temperature of the contact surface between the patient and the transparent gel mattress from exceeding 42°C, in accordance with standard NBR IEC 60601-2-35. The proper functioning of the safety thermostat can be checked through a test set forth in Section 52.5.102 of this standard.

4.4 Electromagnetic Compatibility and Immunity

This deals with the ability of equipment and/or systems to operate in an electromagnetic environment, without introducing unacceptable electromagnetic disturbances to anything in the environment and, on the other hand, to perform without degradation in the presence of an electromagnetic disturbance.

This equipment was designed and tested to comply with the following electromagnetic compatibility standards.

- IEC 60601-1-2
- CISPR11
- IEC 61000-3-2
- IEC 61000-3-3
- IEC 61000-4-2
- IEC 61000-4-3
- IEC 61000-4-4
- IEC 61000-4-5
- IEC 61000-4-6
- IEC 61000-4-8
- IEC 61000-4-11

Found within the parameters established for RF Emissions; Immunity; Electrostatic Discharge; Irradiated Radio Frequency Electromagnetic Fields; and Transient (Bursts and Voltage Surges).

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

Warning: The use of non-original accessories, transducers, sensors and network cables can result in increased emissions or decreased immunity of the equipment.

The AMPLA® 2085 Infant Warmer requires special precautions in relation to its electromagnetic compatibility and needs to be installed and started up according to the information on Electromagnetic Compatibility and Immunity, which are supplied in the following tables.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The AMPLA® 2085 Infant Warmer is intended for use in the electromagnetic environment specified below. **It is recommended that the customer or user of this equipment ensure that it is used in such an environment.**		
Emissions Tests	Compliance	Electromagnetic environment - guidelines
RF Emissions **CISPR 11**	**Group 1**	The Infant Warmer uses RF energy only for its internal functions. However, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions **CISPR 11**	**Class A**	The Infant Warmer is suitable for use in all establishments other than domestic and can be used in all residential establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is observed: **Warning: This equipment is intended for use only by health professionals.** This equipment may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to adopt mitigation procedures, such as reorient or relocate the Infant Warmer or provide local shielding.
Harmonic Emissions **IEC 61000-3-2**	**Class A**	
Emissions due to voltage fluctuations/flicker **IEC 61000-3-3**	**Compliant**	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The AMPLA® 2085 Infant Warmer is intended for use in the electromagnetic environment specified below. **It is recommended that the customer or user of this equipment ensure that it is used in such an environment.**			
Immunity Test	Test Level ABNT NBR IEC 60601	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 V ms 150 KHz - 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the AMPLA® 2085 Infant Warmer, including cables, than the recommended separation distance, calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 0.35\ P^{1/2}$ $d = 0.35\ P^{1/2}$ 80 MHz - 800 MHz $d = 0.7\ P^{1/2}$ 800 MHz - 2.5 MHz where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). It is recommended that the field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-3	3 V ms 80 MHz - 2.5 GHz	10 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio, cellular/cordless telephones, land-mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed-RF transmitters, an electromagnetic site survey is recommended. If the measured field strength in the location in which the AMPLA® 2085 Infant Warmer is used exceeds the RF compliance level utilized above, observe the equipment to confirm normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AMPLA® 2085 Infant Warmer. [b] Over a frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Warning: Infant Warmers are often used together with other Phototherapy Devices or other health care products, such as incubators, hospital bassinets or pulmonary ventilators, etc. Therefore, it is recommended that such equipment be monitored to ensure that they are operating normally according to the configuration used.

Guidelines and Manufacturer's Declaration – Electromagnetic Immunity			
The AMPLA® 2085 Infant Warmer is intended for use in the electromagnetic environment specified below. **The customer or user of the Infant Warmer should ensure that it is used in such an environment.**			
	Test Level NBR IEC 60601	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge IEC 61000-4-2 (ESD)	± 6 kV by contact	± 6 kV	The floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	± 8 kV by air	± 8 kV	
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV in the power supply lines	± 2 kV for the power supply line	Mains power quality should be that of a typical hospital or commercial environment.
	± 1 kV in the input and output lines	± 1 kV for the input and output line	
Surges IEC 61000-4-5	± 1 kV line to line	± 1 kV line to line	Mains power quality should be that of a typical hospital or commercial environment.
	± 2 kV line to ground	± 2 kV line to ground	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% voltage dip in U_T) for 0.5 cycles	< 5% U_T (> 95% voltage dip in U_T) for 0.5 cycles	Mains power quality should be that of a typical hospital or commercial environment. If the user of the AMPLA® 2085 Infant Warmer needs to continue using it during a power failure, it is recommended to power the equipment using an uninterruptable power supply or battery.
	40% U_T (60% voltage dip in U_T) for 5 cycles	40% U_T (60% voltage dip in U_T) for 5 cycles	
	70% U_T (30% voltage dip in U_T) for 25 cycles	70% U_T (30% voltage dip in U_T) for 25 cycles	
	5% U_T (95% voltage dip in U_T) for 5 seconds	5% U_T (95% voltage dip in U_T) for 5 seconds	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic fields should be at the level characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to the application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the AMPLA® 2085 Infant Warmer.

The AMPLA® 2085 Infant Warmer is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AMPLA® 2085 Infant Warmer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of the transmitter W	Separation distance according to the frequency of the transmitter m		
	150 kHz - 80 MHz $d = 0.35\ P^{1/2}$	80 MHz - 800 MHz $d = 0.35\ P^{1/2}$	800 MHz - 2.5 GHz $d = 0.7\ P^{1/2}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.11	1.11	2.21
100	3.50	3.50	7.00

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

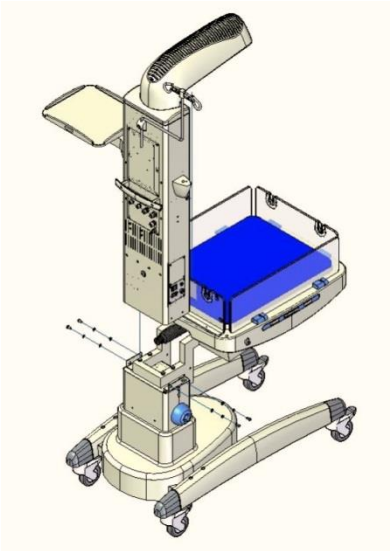
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5. Installation of the Equipment

Unpack the AMPLA® 2085 Infant Warmer, ensuring that all the parts are in perfect condition. Also make sure that all its accessories are complete. Follow the equipment drawing in the "Parts, Pieces and Accessories" section in the User Manual, to proceed with mounting the sets, pieces and accessories.

To assemble and transport the equipment, use an appropriate number of qualified people to perform the procedures.

The AMPLA® 2085 Infant Warmer has components located on three parts: the column, main structure and accessories. Following is an exploded view drawing for its assembly.



To assemble the equipment, place the structure of the base on the ground in its normal condition of use and lock the casters using the brakes.

With the help of two people, tip the column into its fitting located on the structure of the base. Locate, inside the column, two cables with their respective connectors. Plug these cables into their respective connectors located on the structure of the base. Make sure that the connectors of the cables of the column and base have their respective male and female connectors, to avoid any wrong connections.

Use a Phillips tip screwdriver to attach the four screws (M6 x 16 mm), the four spring washers (6.4 mm) and the four flat washers (6.4 mm) to the sides of the column.

For devices that have the configuration with electric table, and/or scale, and/or humidifier, and/or phototherapy, and/or heated mattress, identify and connect the respective connection cables to their connectors located on the column, on the lower part of the patient's bed.

⚠	**Warning: The connectors from the base (structure) should be connected to the connectors from the column. Make sure that the connectors of the cables of the column and base have their respective male and female connectors, to avoid any wrong connections.**

⚠	**Warning: The column of the Infant Warmer must be perfectly attached to the base (structure). Incorrect attachment can result in the column becoming detached and falling, creating risks for the patient and operator.**

For transport and internal displacement of the Infant Warmer, steer it from the rear. Grip the transport handle on the column.

⚠	**Warning: Do not transport the Infant Warmer with any load on its shelves.** **Do not transport the Ergometric Infant Warmer (optional) in the high position.**

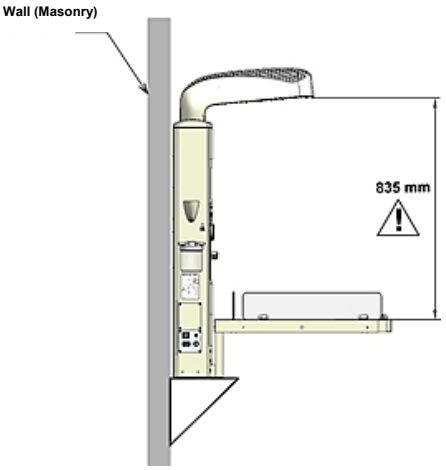
Warning: Before using the equipment, it should be first cleaned and disinfected according to the instructions contained in this manual.

Wall Unit Configuration

For installation of the equipment, place the main structure, column and radiant reflector against the wall, **with a minimum distance of 835 mm between the heating element and mattress surface**, level the unit and mark the attachment points on the wall. Drill holes in the wall, insert the plugs in the holes, couple the structure and attach it using the supplied screws and washers.

Warning: Make sure that the wall is solid (masonry). Dry-Wall type installations should not be used for fastening the Infant Warmer. Make sure that the structure is firmly attached. Use S-10 bushings and screws.

The AMPLA® 2085 Infant Warmer wall unit can be used on a counter, hospital bassinet or together with a cabinet in humanized delivery rooms. For any and all applications, the minimum distance of 835 mm between the heating element and mattress surface must be obeyed, due to the danger of exposing the patient to serious risks.



Warning: Do not use additional heaters or other thermotherapy equipment along with the Infant Warmer. Risk of overheating.

5.1 Installation of the Accessories

This section provides basic instructions on how to install parts, pieces, accessories and optional items that are supplied with the AMPLA® 2085 Infant Warmer and that, due to their packaging process, come separately from the equipment.

Other pieces, accessories and optional items are pre-determined in the order and installed in the factory, coming already assembled in the Infant Warmer, according to the configuration defined in the order.

- Serum Holder

Locate the attachment base for the serum holder on the rear of the column and install the bottom tip, making sure it fits perfectly and pressing it downwards.

- Auxiliary Shelves

The shelves are attached to the shelf adjustment blocks, located on the side of the column. To fasten a shelf, position its pivot pin on the adjustment block, align the guide pin with its respective hole and insert the unit, pressing it downwards.

Warning: The maximum permitted load for each shelf is 10 kg. Do not exceed this limit. Do not transport the Infant Warmer with any load on its shelves.
Maximum permitted height of peripherals is 30 cm.

- Bumper and Feet Plastic Protector

Check the correct positioning of the bumpers and plastic protectors for the feet, according to their internal cuts and assembly positions, for the right and left feet of the base of the Infant Warmer.

Once this positioning is confirmed, fit the protector parallel to the foot, gently pressing it downwards.

Warning: Make sure that the plastic protectors are properly coupled, above the support for the casters.

- **BILITRON® 3006 Phototherapy Device**

Locate a marking on the face of the structure of the patient's bed that identifies the hole for coupling the BILITRON® 3006 phototherapy device. Position the pivot pin of the articulated arm on the adjustment hole, align the guide pin and fit the unit, pressing it downward directly onto the structure of the patient's bed.

- **FOG® 1140 Heated Humidifier and Bubble Generator Bottle**

Through the fitting guide, couple the Bubble Generator Bottle to the side fitting of the humidifier and couple this unit to the lower part of the side of the column, with the column guide found there.

6. Operation of the Equipment

6.1 Operating Functions of the Infant Warmer

This section of the User Manual describes, in general terms, the operating functions of the AMPLA® 2085 Infant Warmer.

6.1.1 Heating Operation Modes using Radiant Heat:

The AMPLA® 2085 Infant Warmer has three distinct operating modes for the supply of radiant heat:

Preheating Mode

The AMPLA® 2085 Infant Warmer has a preheating function which uses radiant heat to warm up the bed before the patient is placed in the Infant Warmer.

When it goes into preheating mode, the radiant heat power level is set between 10% and 30%, depending on the ambient temperature. The higher the ambient temperature, the lower the radiant heat power level is, as shown in the table below.

Preheating Power	Ambient Temperature
30%	< 23ºC
20%	23ºC ≤ T_{amb} < 26ºC
10%	T_{amb} ≥ 26ºC

If the user does not select another operating mode and leaves preheating mode, the heat level will remain steady indefinitely.

Warning**:** Preheating mode should be not be used to heat newborn patients. In this mode, unlike Manual Mode, there are no warning alarms to check the patient's temperature every 15 minutes.

Manual Mode:

Function for initial care and immediately after the patient has been placed in the Infant Warmer, always under the direct supervision of the user alongside the bed. The radiant heat level can be set by the user from 0 to 100%, minutes before receiving the newborn for care and heating in the Infant Warmer. The radiant heat level will remain steady, regardless of the patient's temperature, and should be readjusted to lower levels as the clinical conditions indicate that the patient is already properly warmed, in order to avoid overheating and its consequences.

Warning: When operating in Manual Mode, constantly check the patient's skin temperature. Risk of overheating.

When operating in Manual Mode with the radiant heat level at 100%, after 15 minutes the heating will be cut off and an audible and visual alarm will sound to alert the professional to review the need to use this heating level and, after silencing the alarm, to lower the heat setting, if necessary.

When operating at a heating level lower than 100%, every 15 minutes an audible and visual warning alarm will sound to check the patient's temperature and, if necessary, after silencing the alarm, to readjust the heating according to each situation. The heating, in this case, is not cut off.

During Manual Mode operation, Skin Temperature T1 and auxiliary Skin Temperature T2, when the sensors are properly connected, continue to be displayed on the screen. The Skin Temperature Set Point parameter is not shown, to avoid any possible misinterpretation that the patient's temperature is being controlled by the system.

Skin or Servo Controlled Mode:

Function for prolonged patient care, following manual use and initial heating, where the desired skin temperature T1 (set point) is programmed by the user and the system controls the radiant heating with the power needed to keep the patient's skin temperature (T1) the same as the set point temperature.

Warning: The auxiliary Skin T2 sensor only provides a temperature reading and does not have any influence on radiant heating or the activation of safety alarms.

Skin temperature is monitored by the Skin T1 Sensor, which must be attached to the newborn's skin and participates in the radiant heating process of the Infant Warmer in Skin Mode. The auxiliary Skin T2 sensor only provides a supplementary temperature reading, in another location chosen by the user, and does not have influence on the radiant heating or activation of the safety alarms.

The difference between the Skin Temperature set point and temperature T1 determines the radiant heat level from 0 to 100% that will be applied to the patient, i.e.: the farther the temperature set point is from temperature T1, the higher the radiant heat power applied to the patient.

When skin temperature T1 is below the set point, a radiant heat power greater than 0% will immediately be applied and likewise, if skin temperature T1 is higher than the skin temperature set point by 1º, the radiant heating will be cut off and an alarm will be triggered, requiring the user to take measures to adjust the heat.

Warning: When using radiant heating, never put blankets or any type of cover on the patient. This affects the heating control of the Infant Warmer and may expose the patient to serious or even fatal risks due to overheating of the system.

♦ **Monitoring the patient's Skin Temperature (T1**)

The Skin Temperature T1 Sensor is the main sensor for monitoring and controlling the skin temperature of the newborn. It is through the skin T1 sensor that the patient's temperature is controlled through the radiant heater in Skin Mode. It should be placed and attached, preferably in the abdominal region, with the skin temperature set point for the newborn from 36ºC to 36.4ºC. The monitoring of temperature by this sensor will determine the activation of Skin Mode alarms.

♦ **Auxiliary Skin Temperature (T2) indicator**

The auxiliary Skin Temperature T2 sensor is a secondary sensor for monitoring the temperature of another area of the patient's body and/or place in the equipment, used only as a reference for viewing the temperature of the location where it is installed, without interfering with the radiant heating of the patient.

♦ **Ambient Temperature Indicator**

Thermometer located on the rear middle part of the column that measures and informs the control monitor of the ambient temperature of the location where the Infant Warmer is installed, without interfering with the radiant heat, in order to determine appropriate conditions of use for the newborn and adjustment of radiant heat power in preheating mode.

♦ **APGAR Timer Function**

Timer in minutes and seconds, with an audible beep every minute and a prolonged beep every five and ten minutes, which informs the control monitor of the time in minutes and seconds that has elapsed since the patient's birth, for determination of the APGAR score to assess the newborn's vital signs.

♦ **Timer Alarm Function**

For indicating schedules to give medication and perform procedures.

♦ Display of current date and time

Only available in the versions with color or monochrome LCD monitors.

♦ Trend line graph

Only available in the versions with color or monochrome LCD monitors. Eleven parameters (monochrome) and 19 parameters (color) monitored graphically: skin temperature (T1), auxiliary skin temperature (T2), difference between T1 and T2, ambient temperature, SpO_2 (%), BPM, power (%), relative weight, temperature of the thermal mattress, bilirubin (mg/dl) and oxygen concentration (%). On the color monitor, in addition to the aforementioned parameters, it also monitors high and low SpO_2, high and low BPM, thermal mattress set point, skin temperature set point, and high and low O_2%. The trend lines are stored in the memory for five days.

♦ **Electronic medical record (patient)**

Patient identification and information: name, gestational age (weeks), initial weight, current weight, start of treatment, use of phototherapy or not, phototherapy treatment time, bilirubin level (mg/dl). Only available in the versions with color or monochrome LCD monitors.

♦ **Preventive Maintenance**

Record of preventive maintenance data for the most critical parts of the equipment. Only available in the versions with color or monochrome LCD monitor.

♦ **Oxygen concentration monitor for general use (optional item)**

Measurement and monitoring of O_2 concentration, on the control monitor, for the different therapeutic ways to administer gases in the Infant Warmer. Only available in the versions with color or monochrome LCD monitor.

♦ **Metabolic Bed with Scale (optional item)**

Weighs patients, without needing to remove them from the equipment and radiant heat source, and monitors weight on the control monitor. Available in the three monitor versions and used exclusively for the bed table.

♦ **Data Communication**

The AMPLA® 2085 Infant Warmer, in the versions with color or monochrome LCD monitor, has a port for data communication with the computer, enabling the monitored parameters to be transferred for recording, analysis or printing.

	**Note: Optional Item. Available upon request.**

♦ **Servo Controlled Thermal Mattress (optional item)**

It is used for heating patients during surgical procedures or internal transport in the Infant Warmer. Available in the versions with color or monochrome LCD monitor. The thermal mattress is placed under the patient's mattress which is warmed through conduction and provides indirect heating to the newborn, through a gel mattress, without the patient having direct contact with the thermal mattress.

The temperature of the thermal mattress can be set from 30 to 38ºC, on the monitor of the Infant Warmer. The temperature of the thermal mattress displayed on the control monitor screen refers to the temperature of its contact surface.

The temperature of the thermal mattress displayed on the control monitor screen refers to the temperature of the contact surface between the newborn and the transparent gel mattress.

	**Warning: Never place the patient directly on the thermal mattress, due to the risk of causing burns.**
	**Warning: During the use of the thermal mattress, the patient's temperature must be constantly monitored by qualified and trained personnel.**
	**Note: Optional Item. Available upon request.**

When the thermal mattress is turned on, the radiant heating is cut off, i.e., the Skin, Manual and Preheating Mode operations are disabled.

If there is a sensor failure for internal temperature of the thermal mattress, a visual message will be displayed on the control panel. Available in the versions with color or monochrome LCD monitor. When the thermal mattress is turned off, the system will return to the previous operating mode (Skin, Manual and Preheating Mode).

If, at the time the thermal mattress is turned on, the system was operating in Manual or Preheating Mode, when the thermal mattress is turned off, the radiant heating will return to the level set before the thermal mattress was turned on. This applies even if during the period in which the mattress was turned on the system was switched off.

If, when turning on the thermal mattress, the BILITRON® 4006 reverse phototherapy unit (optional item) is on, it will be automatically switched off.

While the thermal mattress is turned on, the patient's temperature can be monitored using the auxiliary Skin Temperature T2 Sensor, adjusted and attached to the newborn's skin in the abdominal region.

Warning: Only use the transparent gel mattress (specified by Fanem) for use on top of the thermal mattress to help heat the newborn.

♦ Transport module with batteries to power the Infant Warmer during transport (optional item)

The transport module contains two 12 V batteries that keep the Infant Warmer operating during transport or when a power failure occurs. The duration of the battery charge can vary from 2-3 hours, depending on the Infant Warmer functions being used. The battery charge level is displayed on the control panel of the Infant Warmer.

When the equipment is being energized by wall power, the transport batteries start being charged automatically, as shown by the battery bar in movement. When the battery charge is complete, i.e., with voltage over 12 V, the battery bar on the screen will be full, with no movement.

The Infant Warmer automatically starts working on batteries if the power cord is disconnected from the socket or if there is a power failure. If the system is being powered by batteries, this will be displayed on the control panel. If it is operating by batteries and the battery charge is low, an audible and visual alarm will be triggered.

When it goes into battery power mode, the radiant heating is cut off, i.e., the Skin, Manual and Preheating Mode operations are disabled.

When operating by batteries, the thermal mattress (optional item, upon request) will function normally. When it leaves battery power mode, the system will return to its previous operating mode (Skin, Manual or Preheating). If before going into battery power mode the system was operating in Manual or Preheating Mode, when it returns to being powered by the mains, the radiant heating will return to the level it was previously at before being operated by batteries. This applies even if during the period of operation by batteries the system was switched off.

During battery power mode, the patient's temperature can be monitored by using the auxiliary Skin Temperature T2 sensor.

♦ Shifting the Radiant Reflector

To facilitate the access of X-ray equipment to the patient, the radiant reflector which contains the heating element can be shifted 90º to either side. The shifted reflector mode will be displayed on the control panel.

When the reflector is shifted from its central position, radiant heating is cut off, i.e., the Skin, Manual and Preheating Mode operations are disabled. When it returns to its central position, the system will return to its previous operating mode (Skin, Manual or Preheating).

The Kangaroo Mother radiant heating function can be used when the radiant reflector is shifted to a side position, to provide radiant heat to the newborn sitting in the lap of its mother who, in turn, is seated on the same side of the Infant Warmer.

If, before shifting the reflector, the system was operating in Manual or Preheating Mode, once the reflector is restored to its central position, the radiant heat power will return to the level it was at before the reflector was shifted. This applies even if during the period in which the reflector was shifted to the side the system was switched off.

While the radiant reflector is shifted to the side, the patient's temperature can be monitored using the Skin Temperature T1 Sensor and/or auxiliary Skin Temperature T2 Sensor. Only the skin temperature set point will not be shown on the screen.

Pulse Oximeter (optional)

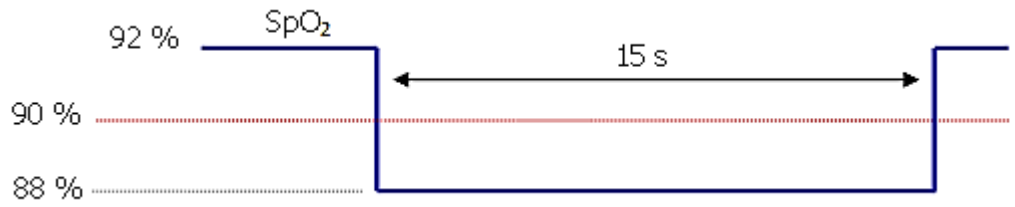
Optional item, only available in the versions with color or monochrome LCD monitor, which monitors oxygen saturation levels (SpO_2) and heart rate (HR) - beats per minute (BPM) of the newborn.

In the AMPLA® 2085 Infant Warmer versions with color or monochrome LCD monitor, SpO_2 monitoring comes with a SatSeconds[1] alarm management function which reduces the occurrence of clinically insignificant alarms, that is, nuisance alarms which only cause disturbance in the treatment area.

SatSeconds[1] is an adjustable parameter which can be set at 0 (off), 10, 25, 50 or 100.

The high or low saturation SpO_2 alarm will only be triggered if the number of SpO_2 percentage points exceeds the alarm threshold, multiplied by the time in seconds by which the limit was exceeded, whether greater than or equal to the number of SatSeconds[1].

For example, suppose the low SpO_2 saturation limit is set at 90% and that the SpO_2 percentage has dropped from 92% to 88% and remains so for 15 seconds, as shown in the figure below:



The number of percentage points that it has dropped below the limit is 90% - 88% = 2%. If the number of SatSeconds is set at 10, the low SpO_2 saturation alarm will be triggered 5 seconds after dropping below the limit, since 2% x 5 s = 10. If SatSeconds is set at 25, the alarm will go off 12.5 seconds after dropping below the limit, since 2% x 12.5 s = 25. However, if SatSeconds is set at 50, the alarm will not go off, since 2% x 15 s = 30 is the total amount observed during the limit violation period.

When SatSeconds is turned off, any violation of high and low SpO_2 saturation limits will trigger the alarm.

Warning: Whenever the equipment is switched off or there is a power outage, the SatSeconds parameter returns to Off mode.

Warning: The decision to use SatSeconds alarm management and setting the appropriate figure for this parameter is the responsibility of the physician, based on the clinical conditions of the patient.

SatSeconds is a trademark of Covidien AG.

♦ BILITRON® BED 4006 Reverse Phototherapy

The Bilitron Bed® 4006 phototherapy unit should only be used together with the transparent gel mattress, which has a high level of transparency for the radiation emitted by the phototherapy unit. Therefore, the memory mattress on the bed should be removed and replaced by the gel mattress.

If, when switching on the Bilitron® Bed 4006 in combination with the AMPLA® 2085 Infant Warmer, the thermal mattress (optional item, upon request) is also turned on, the Bilitron® Bed 4006 will automatically be disabled.

Inside the Bilitron® Bed 4006 there are two safety thermometers that cut off the radiation if the internal temperature exceeds the safety limit.

Note: Optional Item.

♦ BILITRON® 3006 Phototherapy

Microprocessor-based phototherapy comprised of five Super LEDs, directly coupled via an articulated arm to the structure of the patient's bed, so that the irradiation intensity set for the treatment does not vary in intensity and focus, due to inclination of the bed and changes in patient/source distance when in the Trendelenburg, Reverse Trendelenburg or Horizontal positions.

Note: Optional Item.

Warning: When using the BILITRON® 3006 phototherapy unit, together with the Infant Warmer, make sure that the Phototherapy Device is operating in a peripheral area, not encroaching upon the area of heat radiated by the Infant Warmer.

♦ Adjustable bed height

Through an ergometric column with pedals on both sides of the Infant Warmer, its height is adjustable. Operated electrically with a total extension of 200 mm (+100 / -100 mm), it smoothly adjusts to the height of the bed, according to the stature and/or position of the user.

♦ Inclination of the bed table

Through an electrical activation system (via access keys located on the column, on the panel) or a mechanical one involving manual adjustments (through the locking device, on the lower front part of the table), the bed can be gently and noiselessly moved, without jerking the patient, into the Trendelenburg, Reverse Trendelenburg or Horizontal positions.

Note: Optional Item.

♦ Use during the “Kangaroo Mother” procedure

The color or monochrome LED monitor versions of the AMPLA® 2085 Infant Warmer Intensive Care Unit enable the humanization technique referred to as “Kangaroo Mother” to be used. In this format, the Kangaroo Mother function should be selected on the monitor, which will shift the radiant reflector to one of the sides to provide heating outside the Infant Warmer. The radiant reflector will be directed toward the newborn held on the lap of its mother who is seated in a chair on the same side as the radiant reflector. In this format, the auxiliary Skin Temperature T2 sensor will be attached to the newborn’s skin to check and monitor the patient’s temperature, while the power of the heating element will be automatically controlled and limited to 30%.

The Kangaroo Mother function is only available when the radiant reflector is shifted to the side. When the Kangaroo Mother function is turned on, the radiant heat power will initially be set at 30%, but the

user can adjust the power level from 0 to 30%. If the user does not select another operating mode and exit the Kangaroo Mother function, the heat level will remain steady indefinitely.

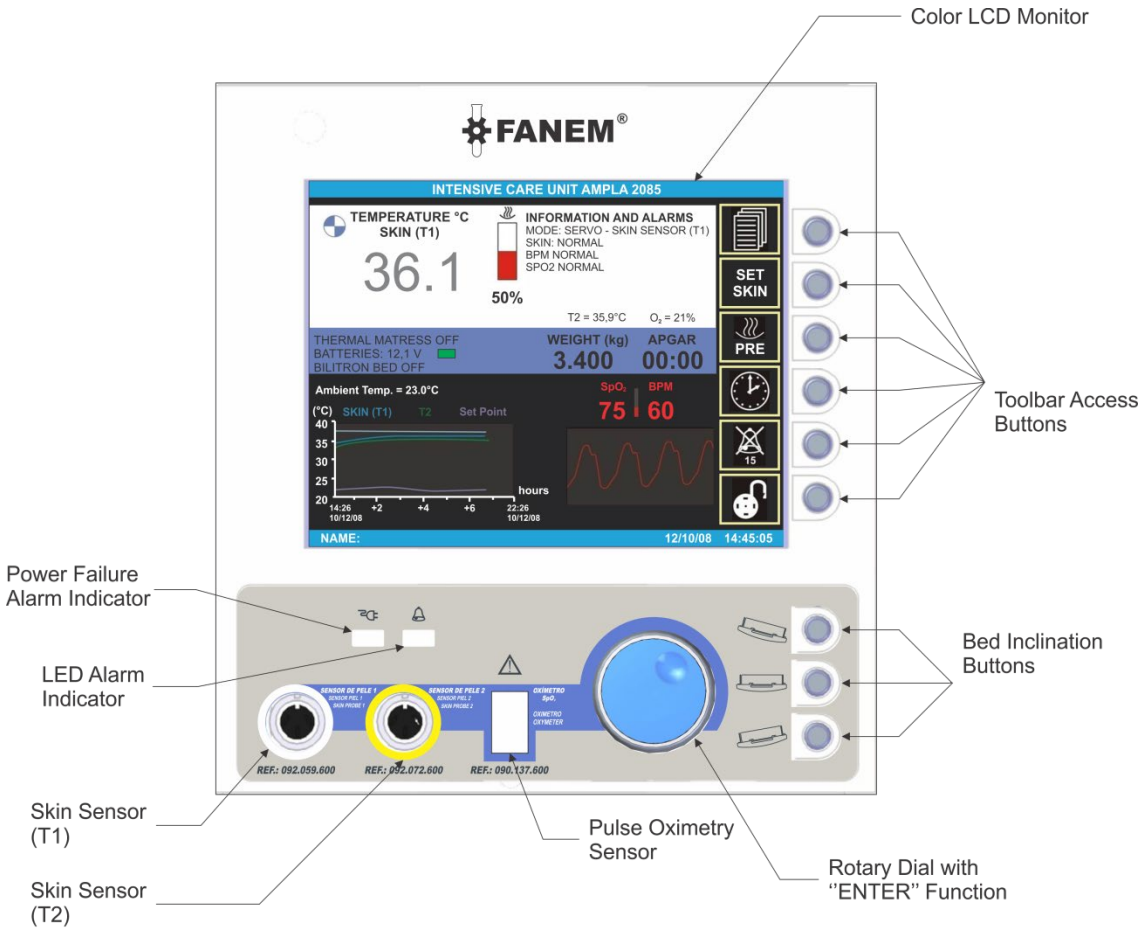
While operating in Kangaroo Mother mode, the patient's skin temperature can be monitored using the auxiliary Skin Temperature T2 sensor.

⚠	**Note: Line item for graphic and monochrome monitors. Not available for LED monitors.**
⚠	**Warning: While using the Kangaroo Mother function, constantly check the patient's temperature, since contrary to Manual Mode, there are no warning alarms in Kangaroo Mother mode to check the patient's temperature every 15 minutes.**
⚠	**Warning: When using the BILITRON® 3006 phototherapy unit, together with the Infant Warmer, make sure that the Phototherapy Device is operating in a peripheral area, not encroaching upon the area of heat radiated by the Infant Warmer.**

6.2 Monitors

6.2.1 Color LCD Monitor

The control panel of the AMPLA® 2085 Infant Warmer is organized as seen in the figure below.



Color LCD Monitor: screen which shows all the parameters, graphs and functions controlled by the control panel.

Toolbar access buttons: access buttons to the functions of the Infant Warmer commanded by the control panel.

Rotary dial with Enter function: knob used to change the values of parameters through a rotational movement and to confirm the change through pressing Enter.

Bed inclination buttons: adjustment of the inclination of the patient's bed. The upper and lower buttons cause the bed to incline (Trendelenburg or Reverse Trendelenburg), and the middle button automatically returns the bed to a horizontal position.

LED alarm indicator: Red LED that remains lit whenever an alarm is activated, associated with the functions controlled by the control panel.

Power failure alarm indicator: Red LED that remains lit when no power is being supplied to the system (power failure or disconnected power cord). When the transport module is present (optional item), the LED will light up if, in the event of a power failure, the charge of the transport batteries runs out.

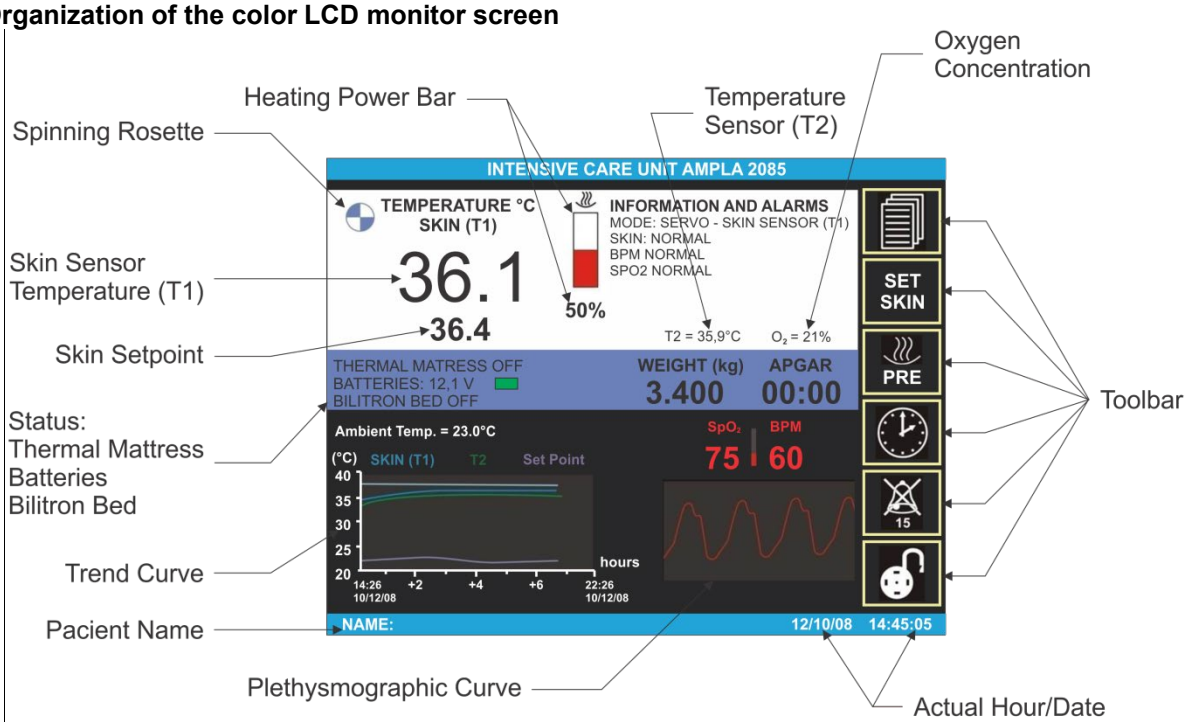
Skin T1 Sensor: main sensor for monitoring and controlling the newborn's skin temperature. It is via the Skin T1 sensor that the patient's temperature is controlled through the radiant heater (Skin Mode). The monitoring of temperature by this sensor will determine the activation of Skin Mode alarms (See section AMPLA® 2085 Infant Warmer Alarms).

SkinT2 Sensor: auxiliary skin temperature sensor may be used to indicate the temperature of peripheral regions of the newborn's body (members) and/or parts of the equipment for reference purposes. It may also be used as a rectal thermometer sensor.

> **Warning: The auxiliary Skin T2 sensor only provides a temperature reading and does not have any influence on radiant heating control or the activation of safety alarms.**

Pulse Oximetry Sensor: sensor used to measure oxygen saturation and heartbeats per minute (optional item).

Organization of the color LCD monitor screen



Information and Alarms: the information and alarms section displays informational messages about the operating system and alarms that have been set.

Spinning rosette: symbol that remains spinning throughout the operation of the system, indicating that the processing unit of the control panel is functioning. If the rosette has stopped moving, this means that the processing unit is stuck and that the system needs to be rebooted.

Heating power bar: indicates the proportional heating level of the radiant heater (0 to100%).

Toolbar: provides access to the functions and function menus of the Infant Warmer.

Navigating the functions on the screen

Navigation is done through the toolbar. A toolbar icon can take the user directly to a parameter setting or to a menu with more options.

Main toolbar: contains the icons in the figure to the right. Whenever the screen is displaying another toolbar or menu screen, if no other button is pressed, the screen will automatically return to the main toolbar after two minutes.

Use the Menu icon to switch between different toolbars.

Use the Enter icon or press the rotary dial knob to change a parameter.

Use the Back icon to return to the previous menu or main toolbar.

Use the Right Arrow icon to move the cursor to the right.

Use the Left Arrow icon to move the cursor to the left.

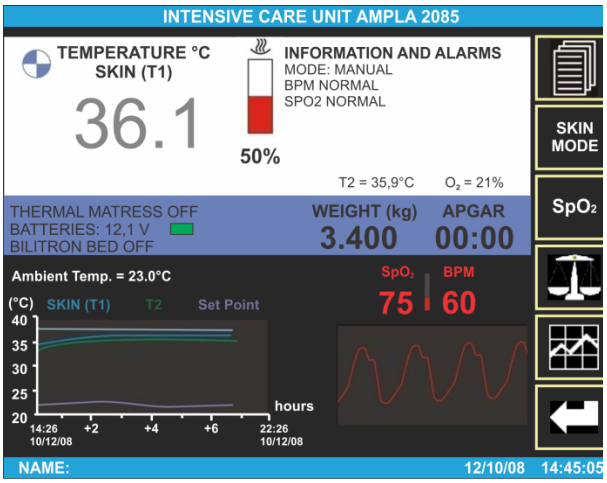
Adjusting the Heating Mode

Press the Menu icon to go the second toolbar.

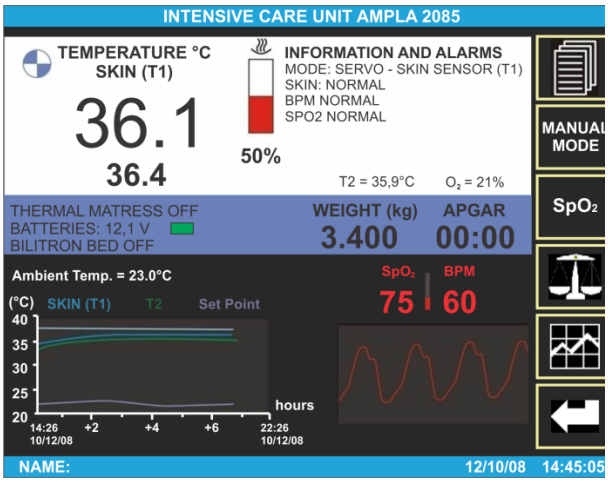
If the system is in Skin Mode, the Manual Mode icon will appear. Select to go to Manual Mode. In Manual Mode, when the Skin T1 and auxiliary T2 sensors are properly connected, the respective values for Skin Temperature T1 and auxiliary Skin Temperature 2 will continue to be shown on the screen. However, to prevent the user from misinterpreting that the patient's temperature is being controlled by the system, the Skin Temperature Set Point will not be shown and the Skin T1 temperature parameter will be displayed with a grayish color, a different color font than Skin Mode (black).

If the system is in Manual Mode, the Skin Mode icon will appear. Select to go to Skin Mode.

Manual mode

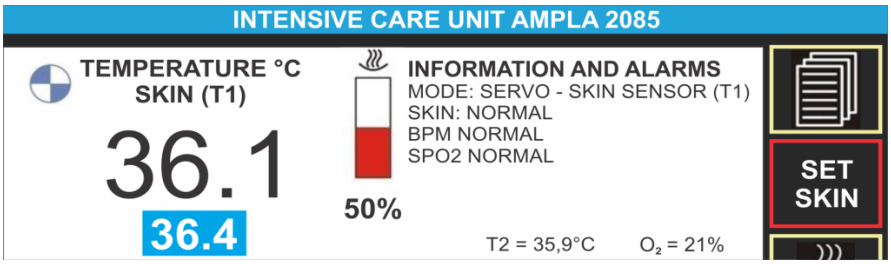


Skin Mode



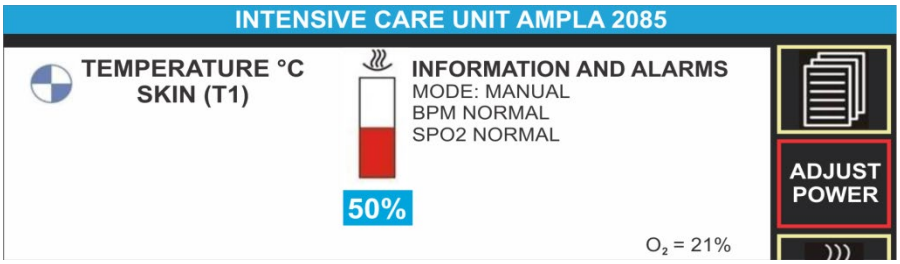
Adjusting the Skin Set Point

With the system in Skin Mode, select the Skin Set Point icon [SET SKIN] on the main toolbar. Change the Skin Set Point (from 20 to 38ºC) through the rotary dial knob. Select the Skin Set Point icon again or press the rotary dial knob to leave adjustment mode.



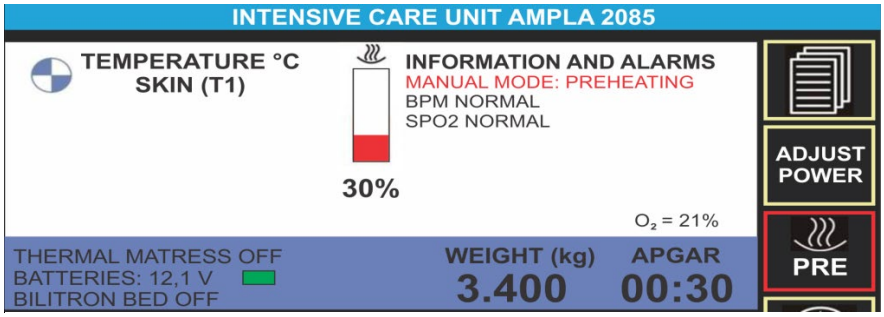
Adjusting the heating power

With the system in Manual Mode, select the Adjust Power icon [ADJUST POWER] on the main toolbar. Change the power level (from 0 to 100%) through the rotary dial knob. Select the Adjust Power icon again or press the rotary dial knob to leave adjustment mode.



Adjusting Preheating

Select the Preheating icon  on the main toolbar. The radiant heat power level will be adjusted according to the ambient temperature, as explained in Section 6.1.

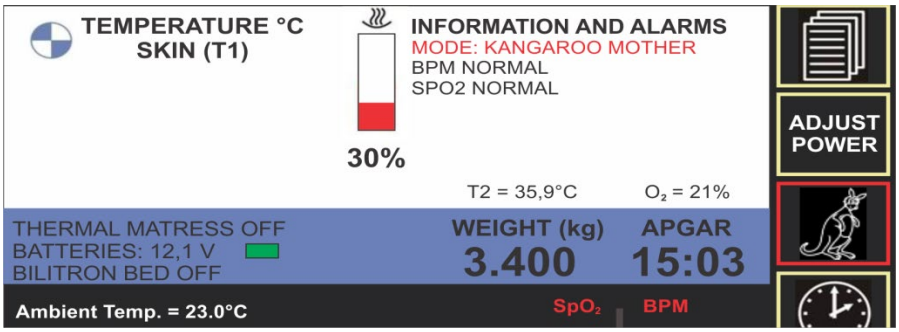


Kangaroo Mother Function

To activate the Kangaroo Mother function, shift the Radiant Reflector from its central position, to the desired side position. The Information and Alarms section of the monitor will indicate that the radiant heater has been shifted and, if there is radiant heating, it will be cut off. On the main toolbar, the preheating icon will be replaced by the kangaroo icon  . When this icon is selected, the radiant heat will be activated, with initial power set at 30%. The power level can be set from 0 to 30% (see explanation in Section 6.1).

The patient's temperature can be checked and monitored through the Skin T1 and auxiliary Skin T2 sensors.

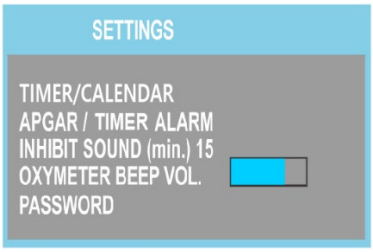
Warning: While using the Kangaroo Mother function, constantly check the patient's temperature, since unlike Manual Mode, there are no warning alarms in Kangaroo Mother mode to check the patient's temperature every 15 minutes.



Suspending audible alarms

To temporarily suspend the audible signal of an alarm, select the Silence icon  on the main toolbar. The icon will become a crossed-out bell and the time remaining before reactivation of the alarm will appear, in minutes.

The time the audible alarm will be silenced can be set from 1 to 15 minutes. On the Settings menu (Settings icon ), set the password to 121 and change the silence time to the desired number of minutes.



Blocking changes to parameters

To block changes being made to the most important parameters, select the Lock icon  on the main toolbar, setting it to the closed lock.

Selecting the APGAR Timer or Timer Alarm function

In the Settings menu, select the desired function. 

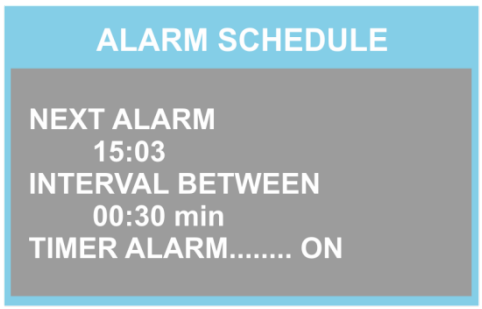
APGAR Timer

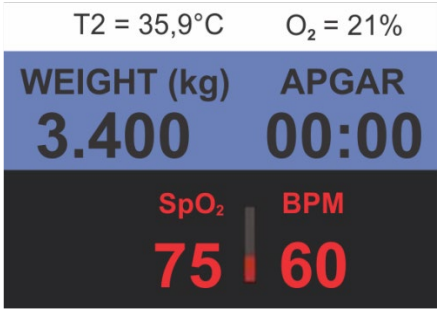
With the APGAR timer selected, press the Timer icon  on the main toolbar for the APGAR timer to start counting. The APGAR timer emits a beep after every minute and a prolonged beep at the five- and ten-minute marks.

To stop the counting, press the Timer icon again and to restart counting, press this same button one more time.

Adjusting the Timer Alarm

With the Timer Alarm selected, press the Timer icon on the main toolbar to open the Alarm Schedule menu. Set the time of the next alarm and the time interval between each alarm, and then activate the Timer Alarm. The schedule of the next alarm to go off will be displayed on the home screen. The alarm will emit an intermittent sound and, if it is not stopped, it will last around 40 seconds. To silence the alarm, press the Silence button. After the sound is silenced or 40 seconds have elapsed, the schedule for the next alarm will be displayed.





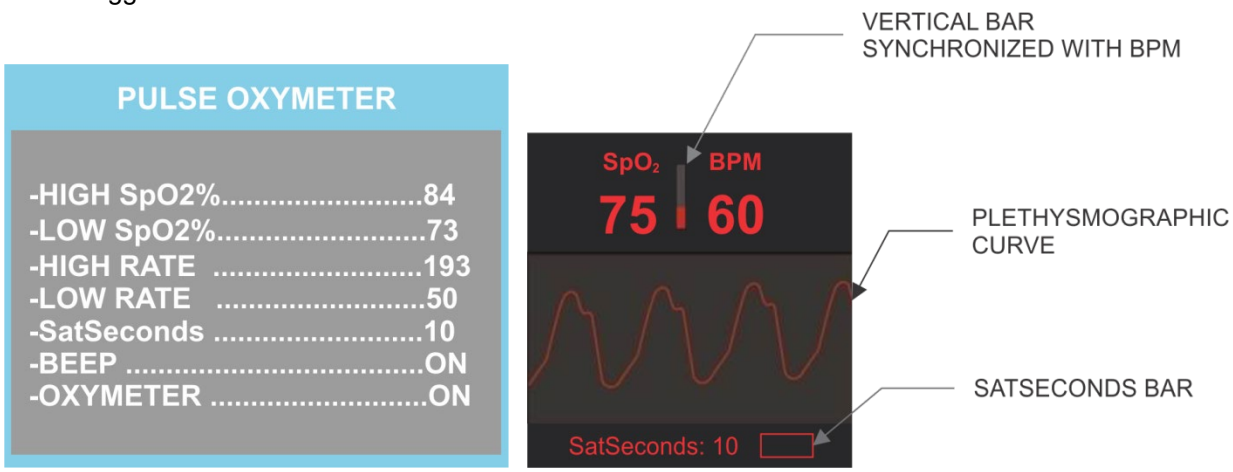
Adjusting the Pulse Oximetry parameters

Select the Heart icon  . The following parameters can be adjusted:

- High SpO_2 concentration limit, from 21% to 100%
- Low SpO_2 concentration limit, from 20% to 99%
- High BPM limit, from 11 to 250
- Low BPM limit, from 10 to 249
- SatSeconds: Turned off, 10, 25, 50 or 100 (See “Pulse Oximetry" Section 6.1)
- Audible beep synchronized with the beats: On/Off
- Pulse Oximeter On/Off.

Warning: The decision to use SatSeconds alarm management and setting the appropriate figure for this parameter is the responsibility of the physician, based on the clinical conditions of the patient.

The SpO_2 and BPM values, a vertical bar synchronized with BPM and the plethysmographic curve are displayed on the home screen. If SatSeconds is turned on, its value will be displayed below the plethysmographic curve, along with a bar that monitors the development of an event where high or low saturation limits are violated. When this bar is completely full, it means that the event has reached the number of SatSeconds (See Pulse Oximetry section), and the corresponding high or low saturation alarm will be triggered.

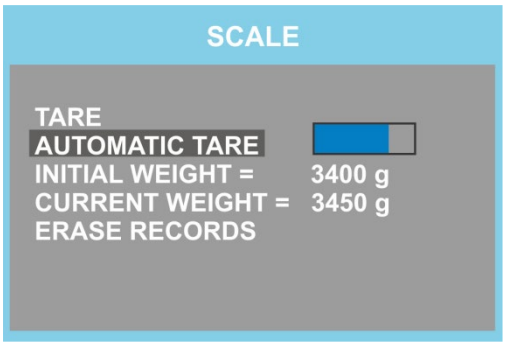


To set the volume of the audible beep synchronized with the beats, select the function "Oximeter beep volume" on the Settings menu.

Scale functions

Select the Scale menu  . The following functions are available:

- Tare: tares the scale.
- Automatic tare: when selected, a time count begins, synchronized with a horizontal bar. When the bar is completely full, an audible beep is emitted, and the tare is performed.
- Initial weight: when selected, it registers the weight that the scale is reading at that instant. It serves to register the weight of the newborn at the start of the treatment, to monitor the evolution of weight gain and loss through a trend line called "Relative weight".
- Current weight: when selected, it registers the weight that the scale is reading at that instant. It serves to register the weight of the newborn during the treatment, to monitor the evolution of weight gain and loss through a trend line called "Relative weight". It is recommended to update Current weight every time the newborn's weight is measured, so that the "Relative weight" trend line will be updated.
- Erase Records: erases the Initial weight and Current weight records.



Adjusting the trend lines

Select the Graphs menu  . The following functions are available:

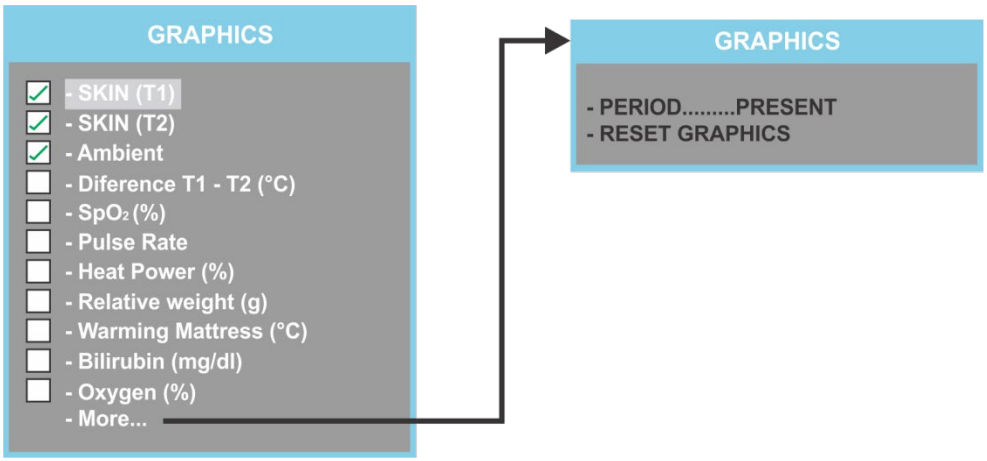
- Selection of the trend line
- View previous periods
- Erase graphs

The trend lines are displayed in 8-hour periods (except for the Relative Weight trend line, whose periods prior to the current period are displayed in 24-hour blocks) and stored in the memory of the control panel for a total of five days (120 hours) for each trend line.

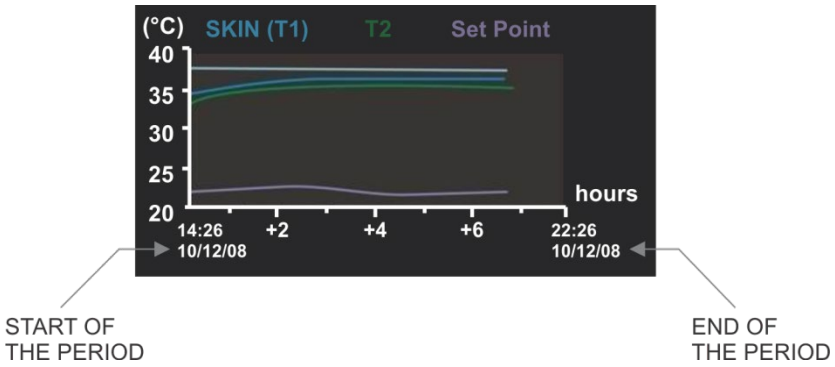
The selection of graphs related to optional accessories (pulse oximeter, scale and oxygen monitor) will be disabled if the corresponding optional item is not available in the equipment.

The following parameters are measured in the form of trend lines:

- SKIN (T1): skin temperature T1 (ºC). When the SKIN (T1) graph is selected, the Skin Set Point trend line (ºC) will also be displayed in the same graph. The SKIN (T1), SKIN (T2) and Ambient trend lines can be displayed on the same graph, in any combination, enabling simultaneous monitoring of the evolution of these parameters.
- SKIN (T2): auxiliary skin temperature T2 (ºC)
- Difference T1 – T2: difference between temperatures T1 and T2 (oC)
- Ambient: ambient temperature (ºC)
- SpO2 (%): oxygen saturation measured by the pulse oximeter. The high and low oxygen saturation limit trend lines are also displayed on the SpO2 graph, enabling the occurrence of violations of the limits in previous periods to be viewed.
- Heart Beat: BPM measured by the pulse oximeter. The high and low BPM limit trend lines are also displayed on the BPM graph, enabling the occurrence of violations of the limits in previous periods to be viewed.
- Heating Power (%): proportional power level of radiant heat.
- Relative weight (g): difference between Current weight and Initial weight, registered in the Scale menu. Represents weight gains or losses of the newborn throughout the period. Unlike the other trend lines, the previous periods in this graph are presented in 24-hour periods.
- Thermal mattress (ºC): temperature of the internal sensor of the thermal mattress.
- Bilirubin (mg/dl): bilirubin concentration as registered on the patient's medical record.
- Oxygen (%): oxygen concentration measured by the Oxygen Monitor. The high and low O2 concentration limit trend lines are also displayed on the O2 concentration graph, enabling the occurrence of violations of the limits in previous periods to be viewed.



To view trend lines of previous periods, select View Periods in the Graphs menu. The graphs are presented in 8-hour periods. Once a period has been selected, the time and date of the start and end of the period will be displayed under the horizontal axis of the graph.



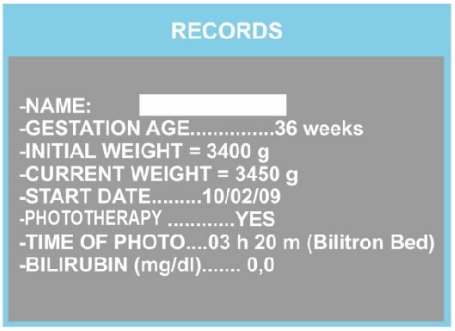
To erase the five days of stored graphs from the memory, select Restart Graphs in the Graphs menu. A confirmation will be requested. Once confirmed, the user must wait until the end of the graph deletion process which lasts approximately 35 s.

Patient's medical record

Select the Medical Record icon  . The following information about the patient is registered in the medical record:

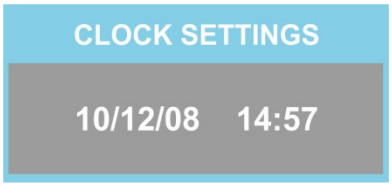
- Name: patient's name. To enter it, place the cursor over Name and press the Enter button. A virtual keyboard will appear, where the letters of the name can be selected.
- Gestational age of the patient. Adjustable parameter from 12 to 42 weeks.
- Initial weight: patient's weight at the start of the treatment, registered in the Scale menu. On the Medical Record screen, this parameter can only be viewed and cannot be changed.
- Current weight: most recent weight of the patient, registered in the Scale menu. On the Medical Record screen, this parameter can only be viewed and cannot be changed.
- Start: date the patient started treatment in the Infant Warmer.
- Phototherapy (Yes/No): indicates whether the patient is receiving phototherapy treatment.
- Phototherapy time: phototherapy treatment time that the patient has already received. If the Infant Warmer has the Bilitron® Bed 4006 phototherapy device (optional item), there will be an indication "(Bilitron Bed)" next to phototherapy time and this field will show the treatment time received in the Bilitron® Bed 4006, automatically tabulated by the system during use of the phototherapy device. If the Bilitron® Bed 4006 is not installed, there will be no indication, and the phototherapy treatment time will need to be inserted manually by the user.

♦ Bilirubin (mg/dl): bilirubin concentration level, inserted manually by the user (adjustable from 0 to 50 mg/dl). Based on the value that is recorded, the bilirubin trend line is built.



Setting current time and date

In the Settings menu  , select Clock/Calendar. In the Clock Settings menu, set the time and date.

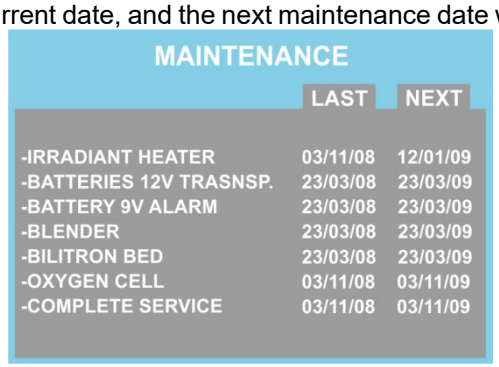


Selecting the language

In the Language menu  , select the desired language.

Preventive maintenance

Open the Maintenance menu  . The dates of the last and next preventive maintenance performed on parts of the system and the general check-up of the Infant Warmer will be displayed. After performing the maintenance, place the cursor on the item reviewed and press the Enter button, in order to change the last maintenance date to the current date, and the next maintenance date will be automatically calculated.



Viewing the optional items

Select the Optional Items icon [OPTIONALS]. A list of available optional items for the AMPLA® 2085 Infant Warmer will be displayed, with the selection boxes of those that are currently part of the device already marked.

Adjusting the parameters of the thermal mattress (optional item, upon request)

Access the Thermal Mattress menu [THERMAL MATTRESS]. The following parameters can be adjusted:

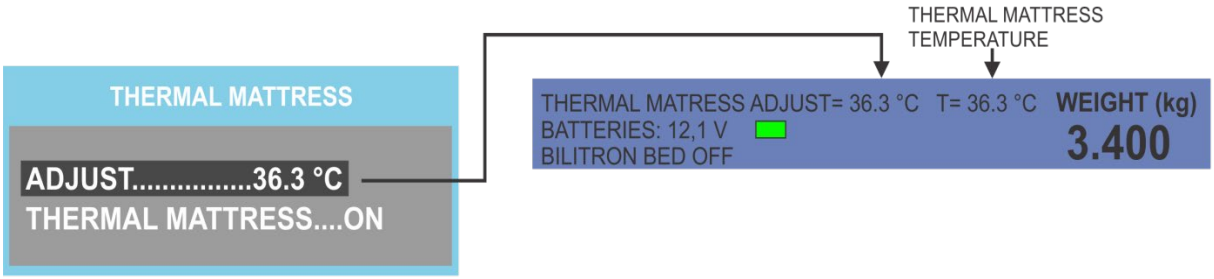
Set Point of the thermal mattress: temperature at which the thermal mattress should be maintained. Adjustable from 30 to 38ºC.

Turn thermal mattress On/Off.

When "On", the monitor will indicate "Thermal Mattress – ON", and track its operation, displaying the gradual increase in its temperature on the monitor.

> **Warning: Never place the patient directly on the thermal mattress, due to the risk of causing burns. The patient should remain on the transparent gel mattress.**

The thermal mattress conditions are shown on the home screen.

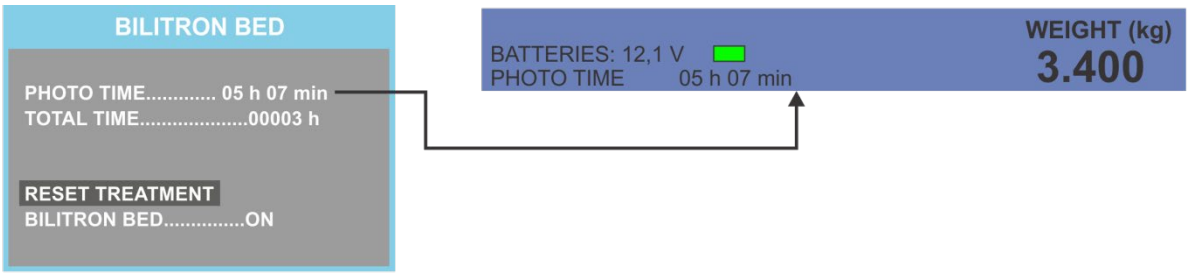


Adjusting the parameters of the BILITRON® BED 4006

Select the Bilitron Bed menu [Bilitron Bed]. At the top of the menu, the phototherapy treatment time performed thus far and the total time of use of the lamps (Super Leds) are displayed. Upon reaching 1,000 hours of use of the Super LEDs, there will be a message "Check Super LEDs", indicating that the radiation module should be checked to determine whether it needs replacement.

- The following functions are available:
- Restart treatment time
- Turn Bilitron® Bed 4006 On/Off

The conditions of the Bilitron® Bed are shown on the home screen. When turned on, total treatment time will be displayed.



Adjusting the parameters of the Oxygen Monitor

Select the Oxygen Monitor menu 

. The following functions are available:

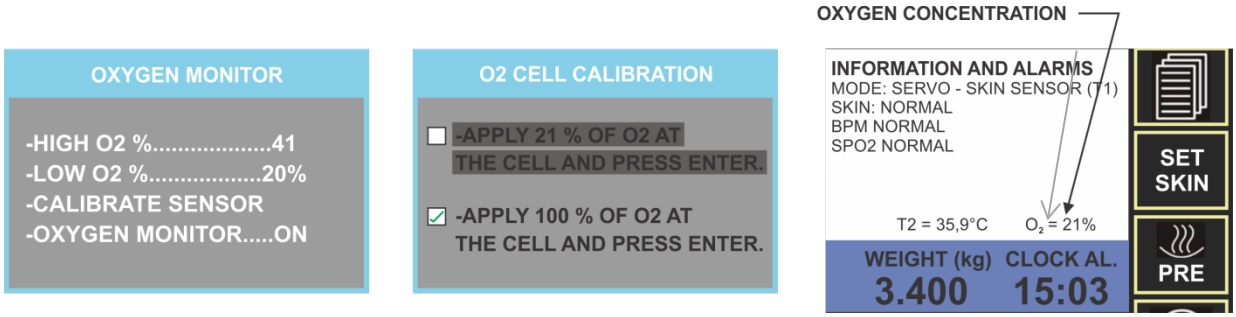
- Set the high O_2 concentration limit: adjustable from 16 to 100%
- Set the low O_2 concentration limit: adjustable from 15 to 99%
- Oxygen cell calibration
- Turn Oxygen monitor On/Off

To calibrate the oxygen cell, select the Calibrate Sensor option. The oxygen cell calibration menu can only be accessed if the oxygen monitor is turned on. Once in the calibration menu, in order to calibrate the cell, leave it exposed to the air (21% oxygen concentration) and wait two minutes for stabilization. Press the Enter key. Once the calibration is completed, the O_2 concentration shown on the home screen should be 21% (+/- 1%).

Warning: Calibration of the cell at 21% should always be done prior to using the Oxygen Monitor.

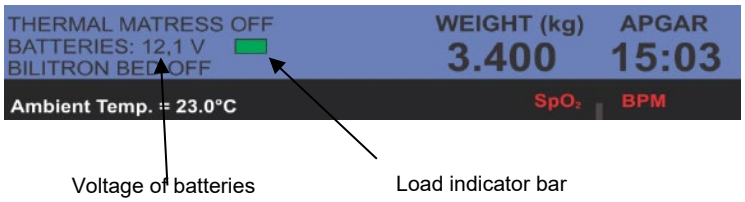
When an oxygen cell is used for the first time, it must also be calibrated at 100% O_2 concentration (contact Authorized Technical Assistance team).

The oxygen concentration is displayed on the home screen, under the Information and Alarms section.



Transport battery charge indicator

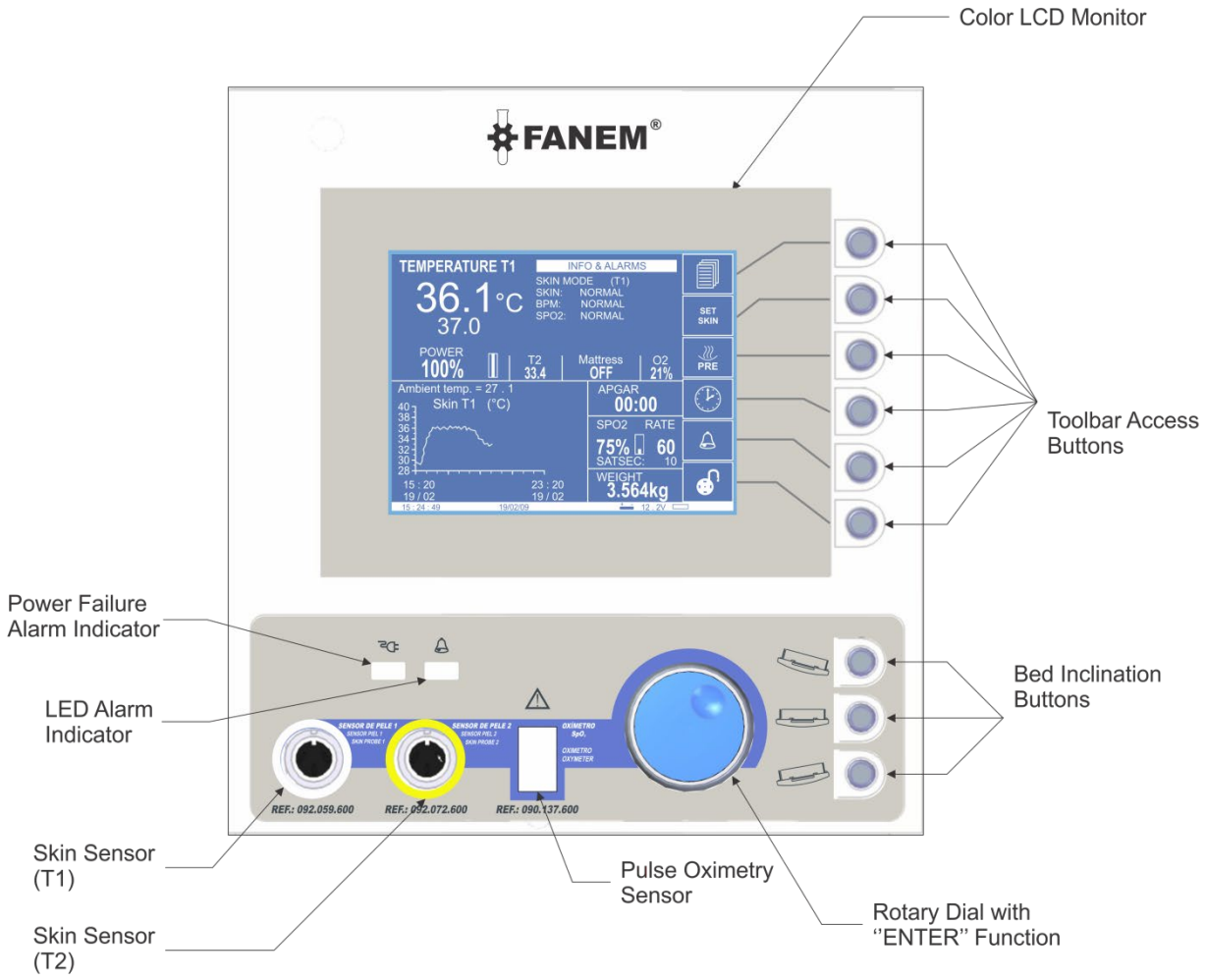
When the AMPLA® 2085 Infant Warmer is equipped with the optional Transport Module, the voltage of the transport batteries and a load indicator bar are displayed in the lower right-hand corner of the screen. The batteries are fully charged when the voltage is at 12 V and considered low when the voltage level is below is 11.3 V.



The operating mode of the AMPLA® 2085 Infant Warmer with transport kit is presented in the manual in the section Transport module with batteries for powering the Infant Warmer during transport (optional item).

6.2.2 Monochrome Monitor

The control panel of the AMPLA® 2085 Infant Warmer with Monochrome Monitor is organized as seen in the figure below.



Color LCD Monitor: screen which shows all the parameters, graphs and functions controlled by the control panel.

Toolbar access buttons: access buttons to the functions of the Infant Warmer, commanded by the control panel.

Rotary Dial Knob with Enter function: knob used to change the values of parameters through a rotational movement and to confirm the change through pressing Enter.

Bed inclination buttons: adjustment of the inclination of the patient's bed. The upper and lower buttons cause the bed to incline (Trendelenburg or Reverse Trendelenburg), and the middle button automatically returns the bed to a horizontal position.

LED alarm indicator: Red LED that remains lit whenever an alarm is activated, associated with the functions controlled by the control panel.

Power failure alarm indicator: Red LED that remains lit when no power is being supplied to the system (power failure or disconnected power cord). When the transport module is present (optional item), the LED will light up if, in the event of a power failure, the charge of the transport batteries runs out.

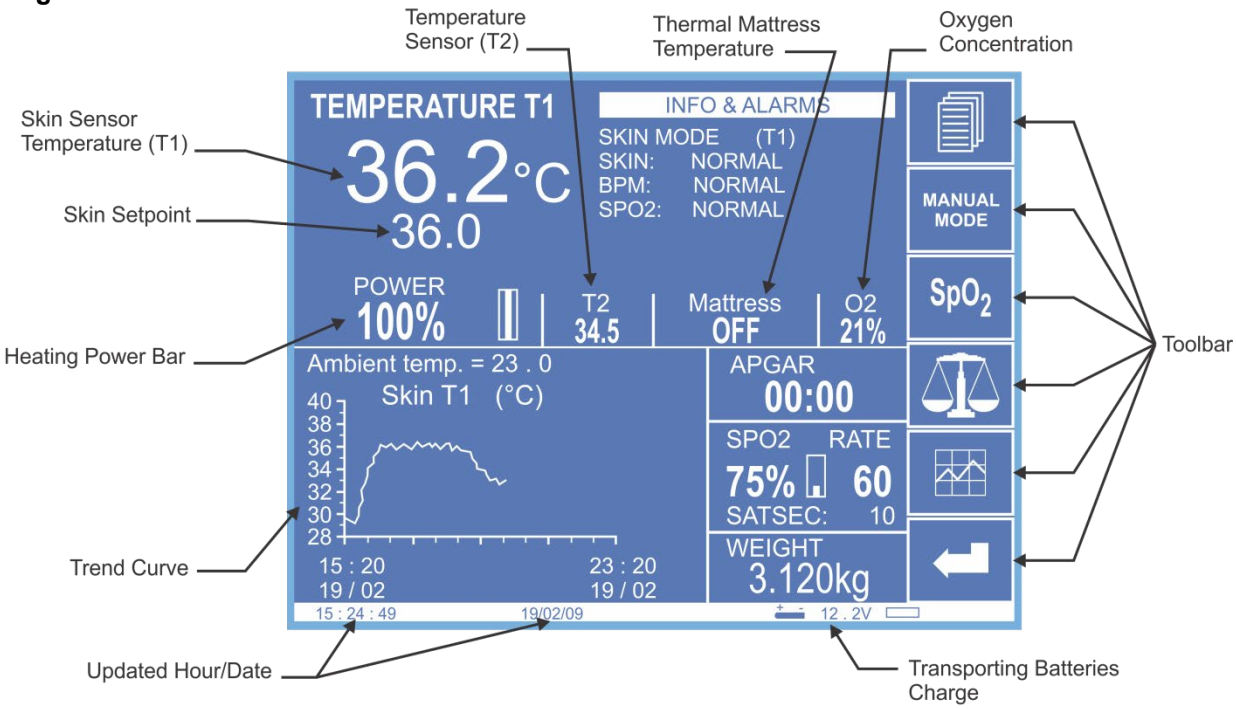
Skin T1 Sensor: main sensor for monitoring and controlling the newborn's skin temperature. It is via the Skin T1 sensor that the patient's temperature is controlled through the radiant heater (Skin Mode). The monitoring of temperature by this sensor will determine the activation of Skin Mode alarms (See section AMPLA® 2085 Infant Warmer Alarms).

SkinT2 Sensor: auxiliary skin temperature sensor, which can be used to indicate the temperature of peripheral regions of the newborn's body (members). It may also be used as a rectal thermometer sensor.

> **Warning: The auxiliary Skin T2 sensor only provides a temperature reading and does not have any influence on radiant heating or the activation of safety alarms.**

Pulse Oximetry Sensor: sensor used to measure oxygen saturation and heartbeats per minute (optional item).

Organization of the monochrome LCD monitor screen



Information and Alarms: The information and alarms section displays informational messages about the operating system and alarms that have been set.

Heating power bar: indicates the proportional heating level of the radiant heater (0 to100%).

Toolbar: provides access to the functions and function menus of the Infant Warmer.

Navigating the functions on the screen

Navigation is done through the toolbar. A toolbar icon can take the user directly to a parameter setting or to a menu with more options.

Main toolbar: contains the icons in the figure to the right. Whenever the screen is displaying another toolbar or menu screen, if no other button is pressed, the screen will automatically return to the main toolbar after two minutes.

Use the Menu icon  to switch between different toolbars.

Use the Enter icon  or press the rotary dial knob to change a parameter.

Use the Back icon  to return to the previous menu or main toolbar.

Use the Right Arrow icon  to move the cursor to the right.

Use the Left Arrow icon  to move the cursor to the left.

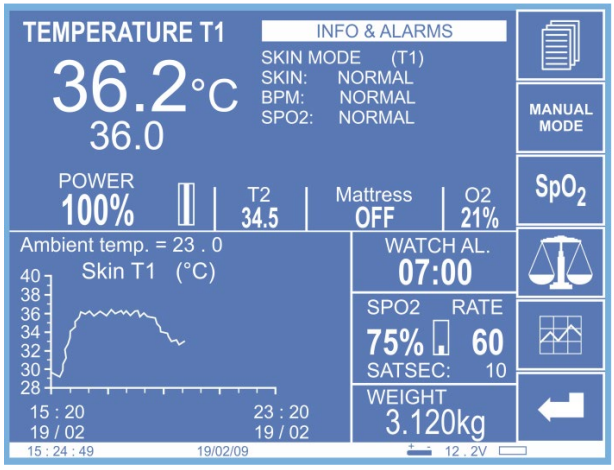
Adjusting the Heating Mode

Press the Menu icon to go to the second toolbar.

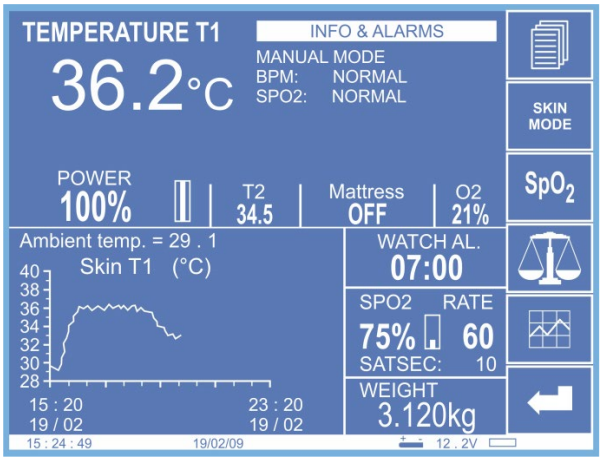
If the system is in Skin Mode, the Manual Mode icon  will appear. Select to go to Manual Mode. In Manual Mode, when the Skin T1 and auxiliary T2 sensors are properly connected, the respective values for Skin Temperature T1 and auxiliary Skin Temperature 2 will continue to be shown on the screen. The Skin Temperature Set Point parameter is not shown, to avoid any possible misinterpretation that the patient's temperature is being controlled by the system.

If the system is in Manual Mode, the Skin Mode icon  will appear. Select to go to Skin Mode.

Skin Mode

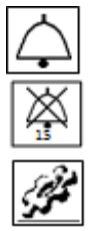


Manual Mode



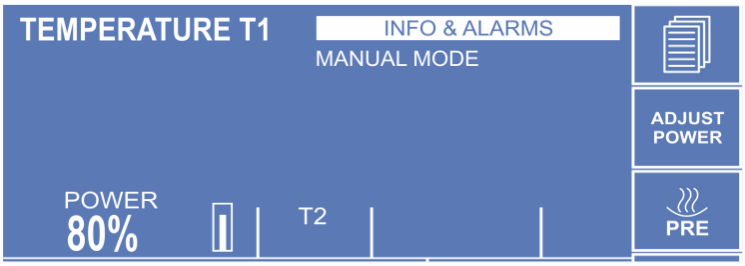
Adjusting the Skin Set Point

With the system in Skin Mode, select the Skin Set Point icon SET SKIN on the main toolbar. The Set Point and Adjust Skin icon will start blinking. Change the Skin Set Point (from 20 to 38ºC) through the rotary dial knob. Select the Skin Set Point icon again or press the rotary dial knob to leave adjustment mode.



Adjusting the heating power

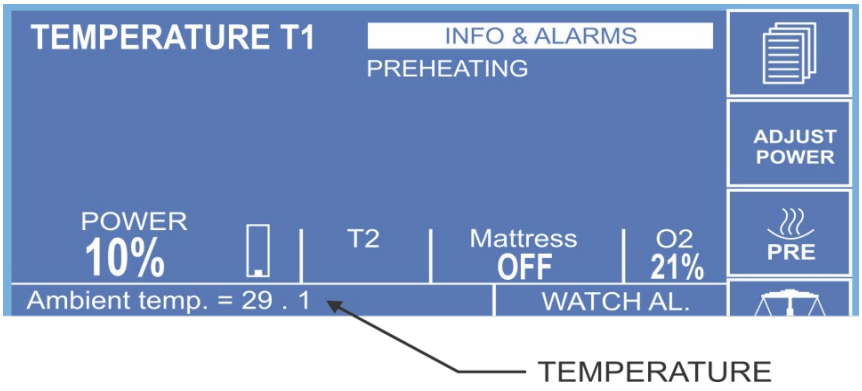
With the system in Manual Mode, select the Adjust Power icon ADJUST POWER on the main toolbar. The power level and Adjust Power icon will start blinking. Change the power level (from 0 to 100 %) through the rotary dial knob. Select the Adjust Power icon again or press the rotary dial knob to leave adjustment mode.



Adjusting Preheating

Select the Preheating icon PRE on the main toolbar. The Preheating icon will start blinking. The radiant heat power level will be set from 10% to 30%, depending on the ambient temperature, as shown in the table below.

Preheating power	Ambient temperature
30%	< 23ºC
20%	23ºC ≤ T_{amb} < 26ºC
10%	T_{amb} ≥ 26ºC

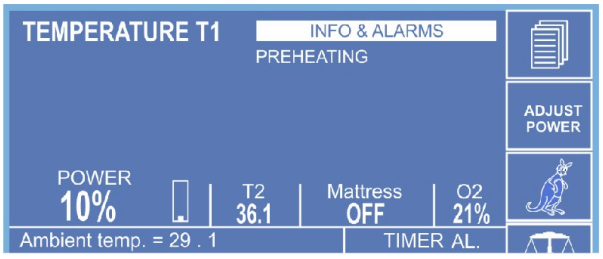


Kangaroo Mother Function

To activate the Kangaroo Mother function, shift the Radiant Reflector from its central position, to the desired side position. The Information and Alarms section of the monitor will indicate that the radiant heater has been shifted and, if there is radiant heating, it will be cut off. On the main toolbar, the preheating icon will be replaced by the kangaroo icon  . When this icon is selected, the radiant heat will be activated, with initial power set at 30%. The power level can be set from 0 to 30% (see explanation in Section 6.1).

The patient's temperature can be checked and monitored through the Skin T1 and auxiliary Skin T2 sensors.

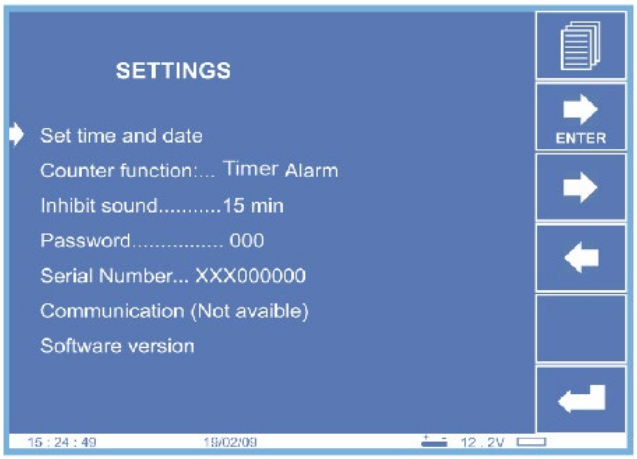
	**Warning: While using the Kangaroo Mother function, constantly check the patient's temperature, since unlike Manual Mode, there are no warning alarms in Kangaroo Mother mode to check the patient's temperature every 15 minutes.**



Suspending audible alarms

To temporarily suspend the audible signal of an alarm, select the Silence icon on the main toolbar. The icon will become a crossed-out bell and the time remaining before reactivation of the alarm will appear, in minutes.

The time the audible alarm will be silenced can be set from 1 to 15 minutes. On the Settings menu (Settings icon), set the password to 121 and change the silence time to the desired number of minutes.



Blocking changes to parameters

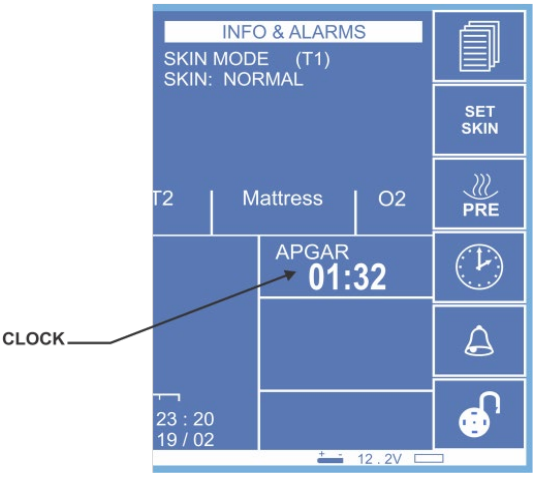
To block changes to the parameters, select the Lock icon  on the main toolbar, setting it to the closed lock. To enable the parameters to be adjusted again, select the Lock icon on the main toolbar, setting it to the open lock.

Selecting the APGAR Timer or Timer Alarm function

In the Settings menu, select the desired function. 

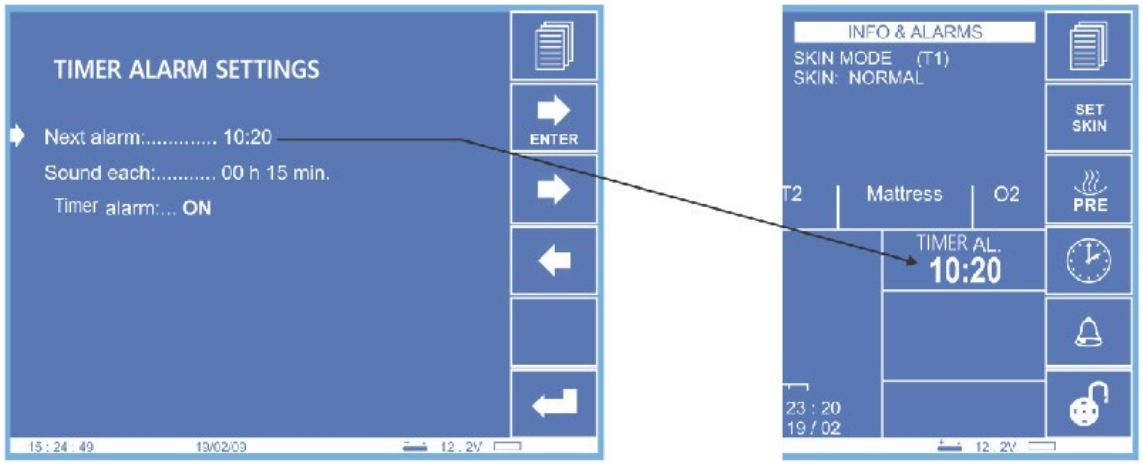
APGAR Timer

With the APGAR timer selected, press the Timer icon  on the main toolbar for the APGAR timer to start counting. The APGAR timer emits a beep after every minute and a prolonged beep at the five- and ten-minute marks. To stop the counting, press the Timer icon again and to restart counting, press this same button one more time.



Adjusting the Timer Alarm

With the Timer Alarm selected, press the Timer icon  on the main toolbar to open the Alarm Schedule menu. Set the time of the next alarm and the time interval between each alarm, and then activate the Timer Alarm. The schedule of the next alarm to go off will be displayed on the home screen. When it goes off, the alarm will emit an intermittent sound and, if it is not stopped, it will last around 40 seconds. To silence the alarm, press the Silence button. After the sound is silenced or 40 seconds have elapsed, the schedule for the next alarm will be displayed.



Adjusting the Pulse Oximetry parameters

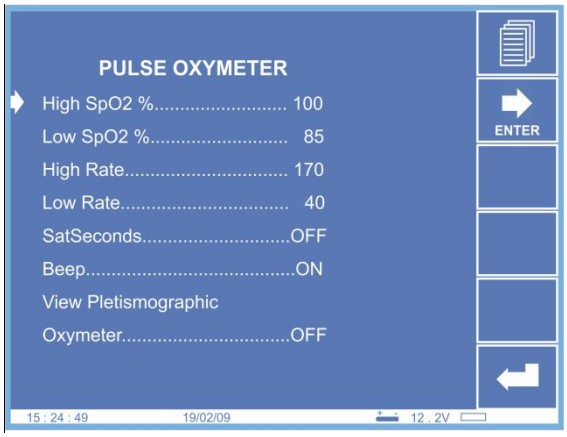
Select the SpO_2 icon  . The following parameters can be adjusted:

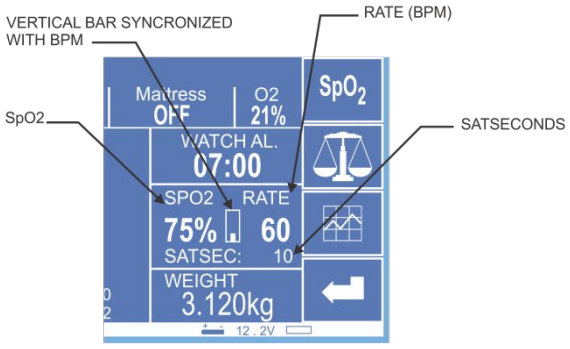
- High SpO_2 concentration limit, from 21% to 100%

- Low SpO_2 concentration limit, from 20% to 99%
- High BPM limit, from 11 to 250
- Low BPM limit, from 10 to 249
- SatSeconds: Turned off, 10, 25, 50 or 100 (See “Pulse Oximetry" Section 6.1)
- View the plethysmographic curve
- Audible beep synchronized with the beats: On/Off
- Pulse Oximeter On/Off.

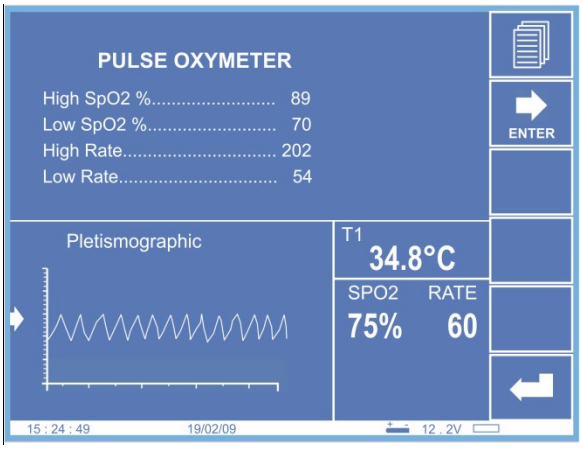
Warning: The decision to use SatSeconds alarm management and setting the appropriate figure for this parameter is the responsibility of the physician, based on the clinical conditions of the patient.

The SpO_2 and BPM values, as well as a vertical bar synchronized with BPM, are displayed on the home screen. If SatSeconds is on, its set point will also be displayed.





The plethysmographic curve can be viewed by selecting the function "See Plethysmographic" on the pulse oximeter screen. The curve will be displayed on the lower part of the pulse oximeter screen, along with Skin Temperature T1 and SpO_2 and BPM.



Scale functions

Select the Scale menu  . The following functions are available:

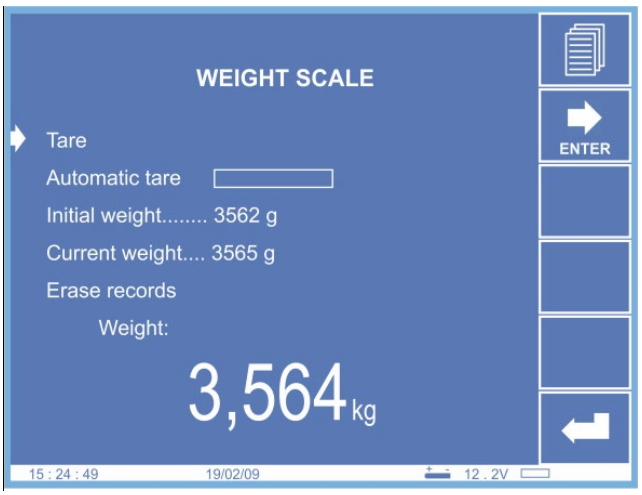
- Tare: tares the scale

♦ Automatic tare: when selected, a time count is started, synchronized with the filling in of a horizontal bar. During this period, the operator must lift the newborn from the bed. When the bar is full, an audible beep will be emitted indicating that the tare is complete, at which time the newborn's weight can be taken. The automatic tare is ideal for weighing a patient by one single operator.

♦ Initial weight: when selected, it registers the weight that the scale is reading at that instant. It serves to register the weight of the newborn at the start of the treatment, to monitor the evolution of weight gain and loss through a trend line called "Relative weight".

♦ Current weight: when selected, it registers the weight that the scale is reading at that instant. It serves to register the weight of the newborn during the treatment, to monitor the evolution of weight gain and loss through a trend line called "Relative weight". It is recommended to update Current weight every time the newborn's weight is measured, so that the "Relative weight" trend line will be updated.

♦ Erase Records: erases the Initial weight and Current weight records.



Adjusting the trend lines

Select the Graphs menu  . The following functions are available:

♦ Selection of the trend line

♦ View previous periods

♦ Erase graphs

The trend lines are displayed in 4-hour periods (except for the Relative Weight trend line, whose periods prior to the current period are displayed in 24-hour blocks) and stored in the memory of the control panel for a total of five days (120 hours) for each trend line.

The following parameters are measured in the form of trend lines:

♦ SKIN (T1): skin temperature T1 (ºC).

♦ SKIN (T2): auxiliary skin temperature T2 (ºC)

♦ Difference T1-T2: difference between temperatures T1 and T2 (ºC)

♦ Ambient: ambient temperature (ºC)

♦ SpO_2 (%): oxygen saturation measured by the pulse oximeter.

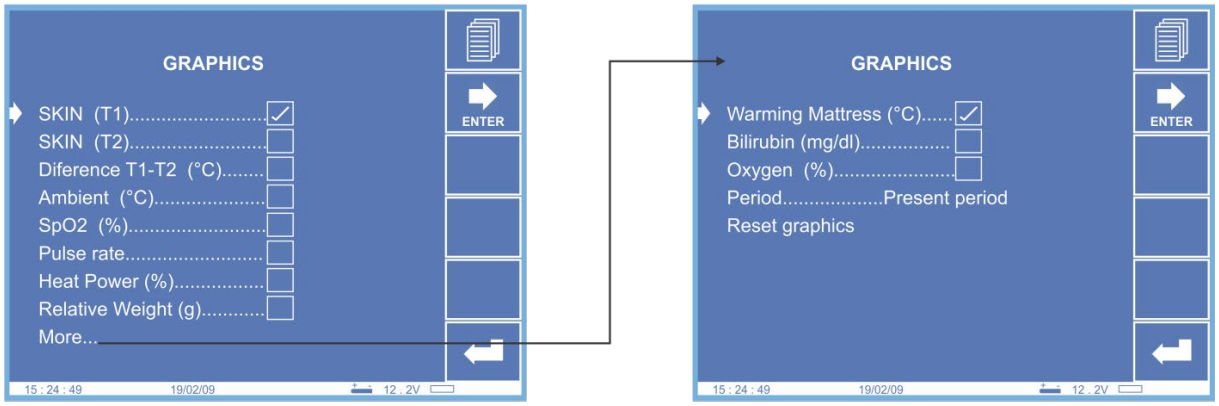
♦ Beats per minute: BPM measured by the pulse oximeter.

♦ Heating Power (%): radiant heat power level.

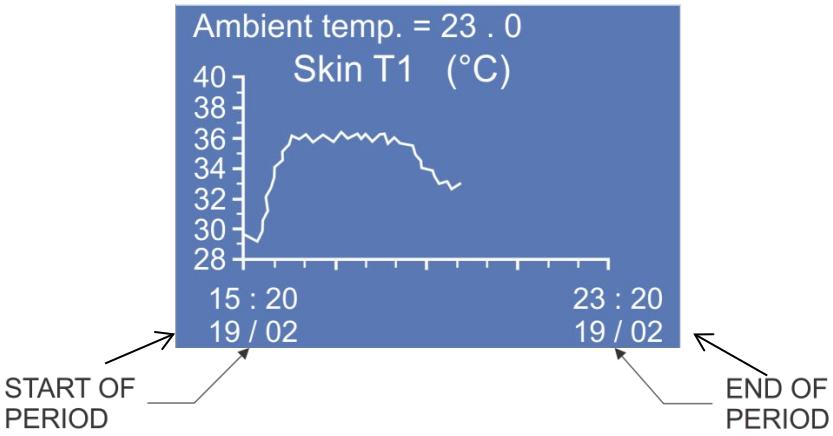
♦ Relative weight (g): difference between current weight and initial weight, registered in the Scale menu. Represents the weight gains or losses of the newborn throughout the period.

- Thermal mattress (ºC): temperature of the internal sensor of the thermal mattress.
- Bilirubin (mg/dl): bilirubin concentration as registered on the patient's medical record.
- Oxygen (%): oxygen concentration measured by the oxygen monitor.

The selection of graphs related to optional accessories (pulse oximeter, scale and oxygen monitor) will be disabled if the corresponding optional item is not available in the equipment.



To view trend lines from previous periods, select the desired time period through the "Period" option in the Graphics menu. Once a period has been selected, the time and date of the start and end of the period will be displayed under the horizontal axis of the graph.



To erase the five days of stored graphs from the memory, select Restart Graphs in the Graphs menu. A confirmation will be requested. Once confirmed, the user must wait until the end of the graph deletion process which lasts approximately 35 s.

Patient's medical record

Select the Medical Record icon  . The following information about the patient is registered in the medical record:

- Name: patient's name to enter it, place the cursor over Name and press the Enter button or the rotary dial knob. A virtual keyboard will appear, where the letters of the name can be selected.
- Gestational age of the patient. Adjustable parameter from 12 to 42 weeks.
- Start: date the patient started treatment in the Infant Warmer.
- Phototherapy (Yes/No): indicates whether the patient is receiving phototherapy treatment.

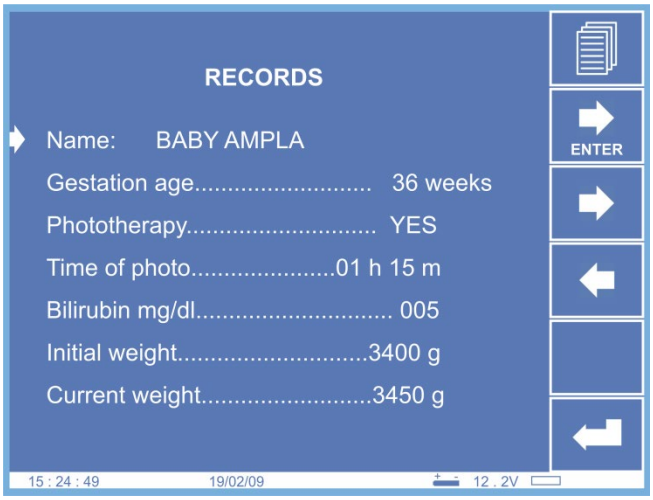
♦Phototherapy time: phototherapy treatment time that the patient has already received. If the Infant Warmer has the Bilitron® Bed 4006 phototherapy device (optional item), there will be an indication "(Bilitron Bed)" next to phototherapy time and this field will show the treatment time received in the Bilitron® Bed, automatically tabulated by the system during use of the phototherapy device. If the Bilitron® Bed 4006 is not installed, there will be no indication, and the phototherapy treatment time will need to be inserted manually by the user.

♦Bilirubin (mg/dl): bilirubin concentration level, inserted manually by the user (adjustable from 0 to 50 mg/dl). Based on the value that is recorded, the bilirubin trend line is built.

♦Note: This graph can be used in accordance with the local service protocol for defining this parameter.

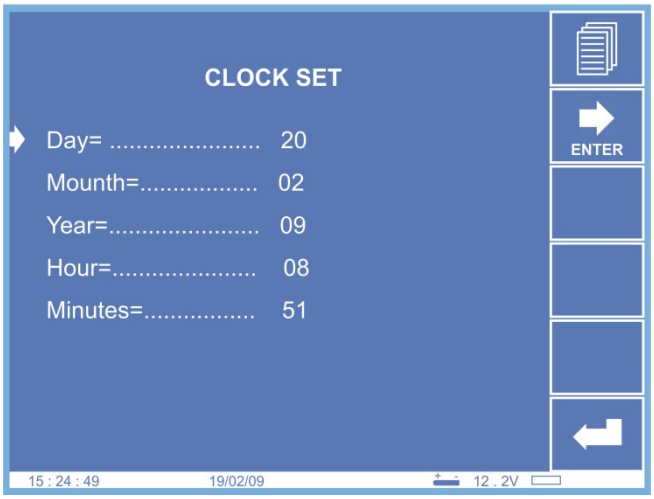
♦Initial weight: patient's weight at the start of the treatment, registered in the Scale menu. On the Medical Record screen, this parameter can only be viewed and cannot be changed.

♦Current weight: most recent weight of the patient, registered in the Scale menu. On the Medical Record screen, this parameter can only be viewed and cannot be changed.



Setting current time and date

In the Settings menu  , select Clock/Calendar. In the Clock Settings menu, set the time and date.

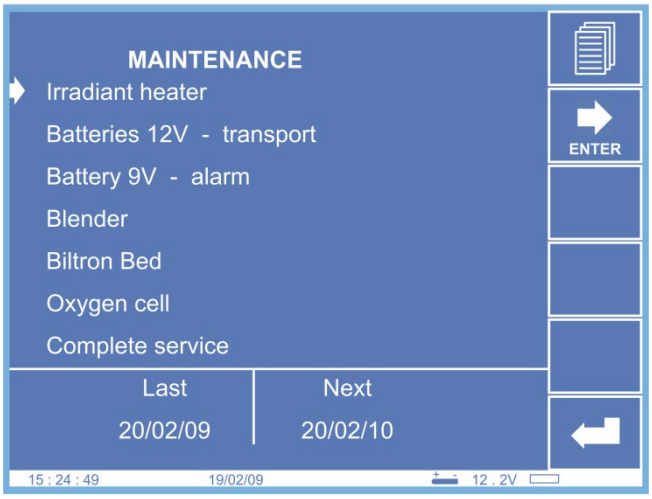


Selecting the language

In the Language menu  , select the desired language.

Preventive maintenance

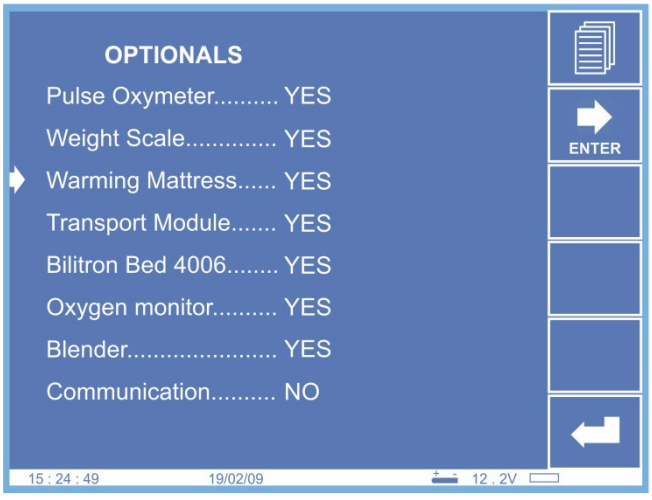
Open the Maintenance menu  . The dates of the last and next preventive maintenance performed on parts of the system and the general check-up of the Infant Warmer will be displayed. After performing the maintenance, place the cursor on the item reviewed and press the Enter button or rotary dial knob, in order to change the last maintenance date to the current date, and the next maintenance date will be automatically calculated.



Viewing the optional items

Select the Optional Items icon 

. A list of available optional items for the AMPLA® 2085 Infant Warmer will be displayed, whose functionality is related to the control panel. For each option, an indication is given (YES or NO) as to whether it already exists in the equipment.



Adjusting the parameters of the thermal mattress (optional item, upon request)

Access the Thermal Mattress menu 

. The following parameters can be adjusted:

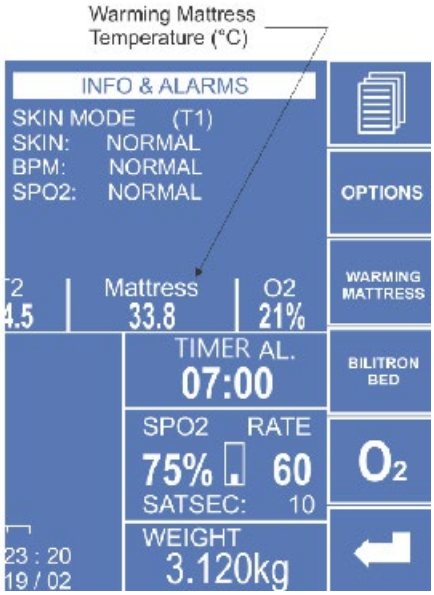
- Set Point of the thermal mattress: temperature at which the thermal mattress should be maintained. Adjustable from 30 to 38ºC.

♦ Turn thermal mattress On/Off.

Warning: Never place the patient directly on the thermal mattress, due to the risk of causing burns.

When "On", the monitor will indicate "Thermal Mattress – ON", and track its operation, displaying the gradual increase in its temperature on the monitor.

The temperature of the thermal mattress is shown on the home screen.



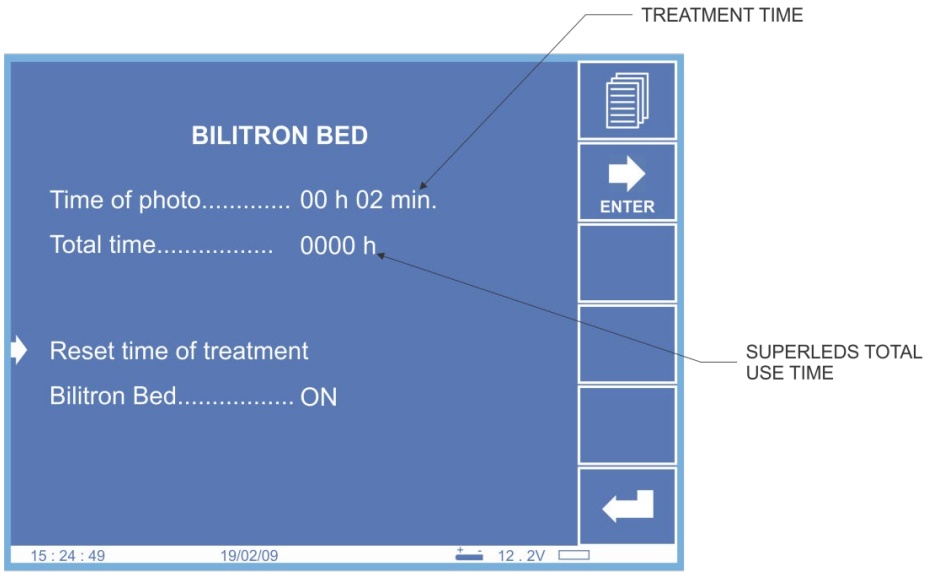
Adjusting the parameters of the Bilitron® Bed 4006

Select the Bilitron Bed menu. 

At the top of the menu, the phototherapy treatment time performed thus far and total time of use of the lamps (Super Leds) are displayed. Upon reaching 10,000 hours of use of the Super LEDs, there will be a message "Check Super LEDs", indicating that the radiation module should be checked to determine whether it needs replacement.

The following functions are available:

- Restart treatment time
- Turn the Bilitron Bed On/Off



Adjusting the parameters of the Oxygen Monitor

Select the Oxygen Monitor menu 

. The following functions are available:

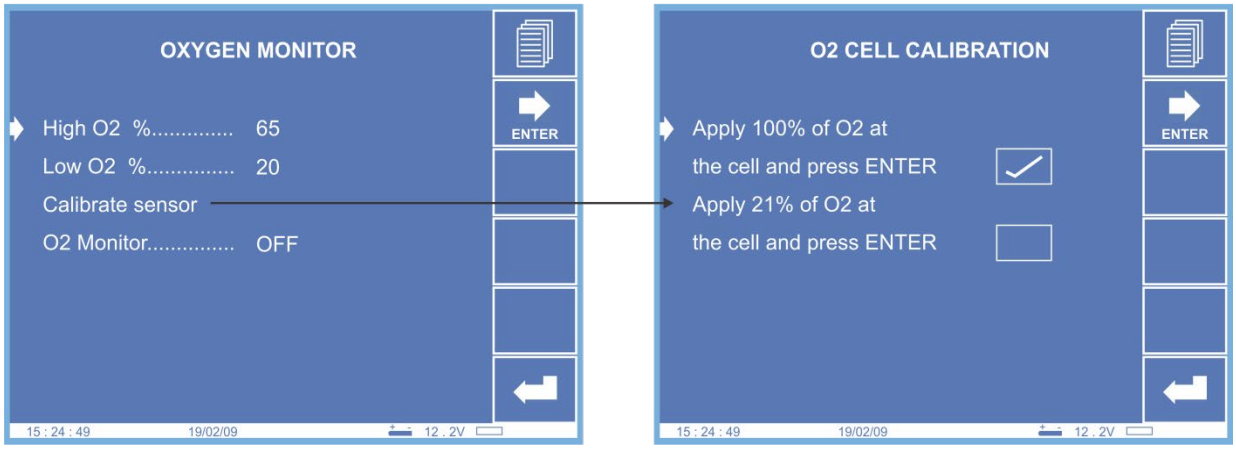
- Set the high O_2 concentration limit: adjustable from 16% to 100%
- Set the low O_2 concentration limit: adjustable from 15% to 99%
- Oxygen cell calibration
- Turn Oxygen monitor On/Off

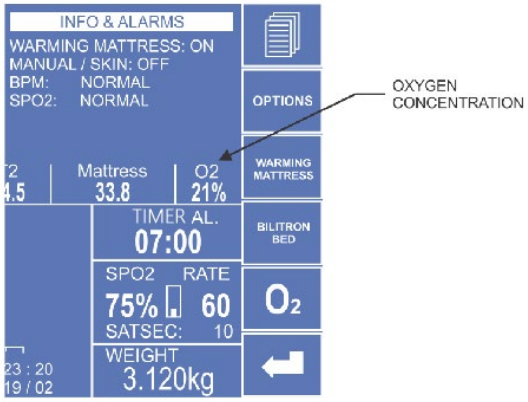
To calibrate the oxygen cell, select the Calibrate Sensor option. The oxygen cell calibration menu can only be accessed if the oxygen monitor is turned on. Once in the calibration menu, in order to calibrate the cell, leave it exposed to the air (21% oxygen concentration) and press the Enter key. Once the calibration is completed, the O_2 concentration shown on the home screen should be 21% (+/- 1%).

Warning: Calibration of the cell at 21% should always be done prior to using the Oxygen Monitor.

When an oxygen cell is used for the first time, it must also be calibrated at 100% O_2 concentration (contact Authorized Technical Assistance team).

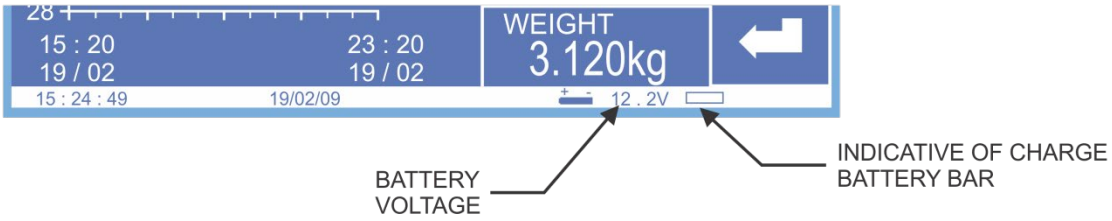
The oxygen concentration is displayed on the home screen, under the Information and Alarms section.





Transport battery charge indicator

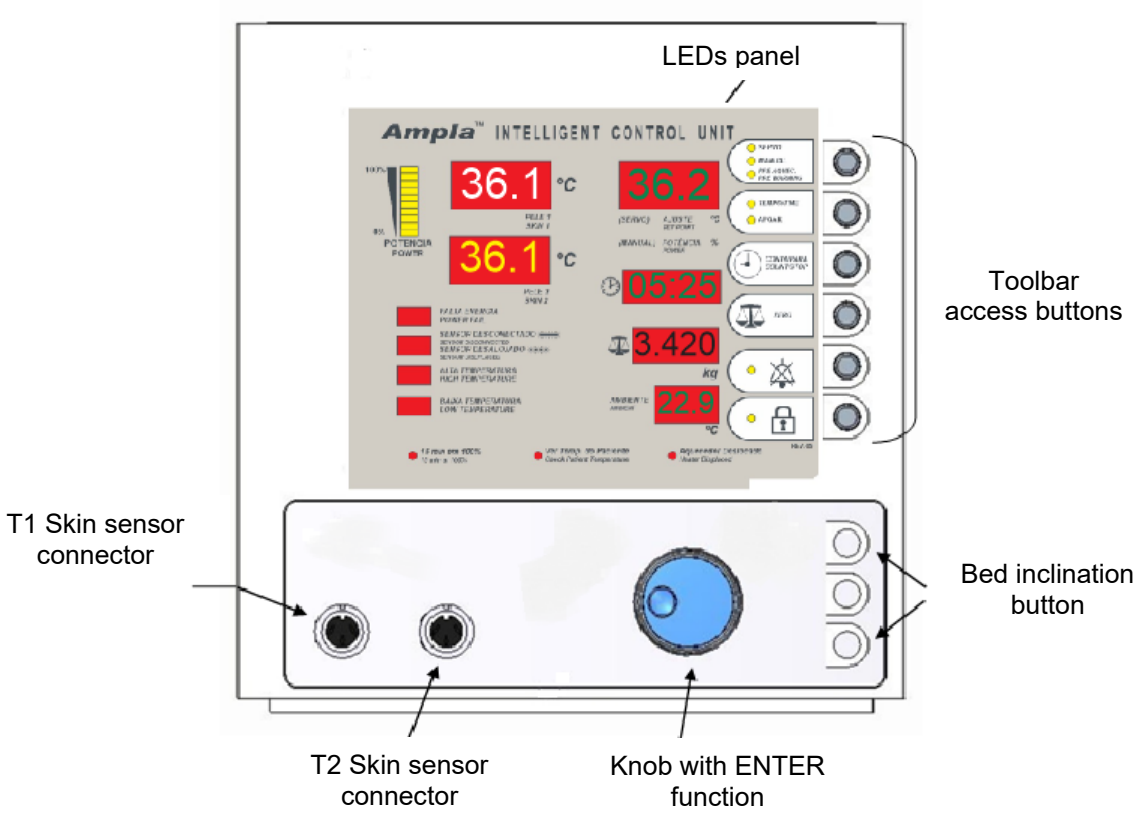
When the AMPLA® 2085 Infant Warmer is equipped with the optional Transport Module, the voltage of the transport batteries and a load indicator bar are displayed in the lower right-hand corner of the screen. The batteries are fully charged when the voltage is at 12 V and considered low when the voltage level is below is 11.3 V.



The operating mode of the AMPLA® 2085 Infant Warmer with transport kit is presented in the manual in the section Transport Module with batteries, for powering the Infant Warmer during transport (optional item).

6.2.3 LED Display Panel

The control panel of the AMPLA® 2085 Infant Warmer Intensive Care Unit with a LED panel comprised of seven segments is organized as seen in the figure below.



LED Panel with seven segments: Monitor that shows all the parameters, graphs and functions controlled by the control panel.

Toolbar access buttons: Access buttons to the functions of the Infant Warmer commanded by the control panel.

Rotary dial knob with Enter function: Knob used to change the values of parameters through a rotational movement and to confirm the change through pressing Enter.

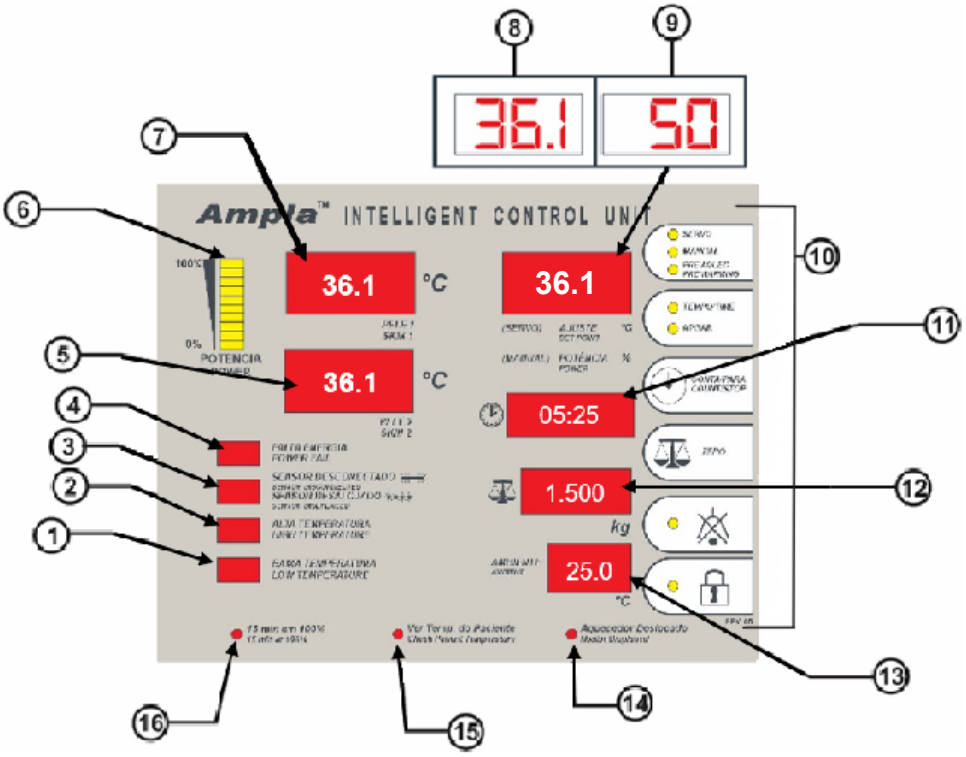
Bed inclination buttons: Adjust the inclination of the patient's bed. The upper and lower buttons cause the bed to incline (Trendelenburg or Reverse Trendelenburg), and the middle button automatically returns the bed to a horizontal position.

Skin T1 Sensor: Main sensor for monitoring and controlling the newborn's skin temperature. It is via the Skin T1 sensor that the patient's temperature is controlled through the radiant heater (Skin Mode - Servo Controlled). The monitoring of temperature by this sensor will determine the activation of Skin Mode alarms (See section AMPLA® 2085 Infant Warmer Alarms).

Skin T2 Sensor: Auxiliary skin temperature sensor, which can be used to indicate the temperature of peripheral regions of the newborn's body (members). The temperature read by the T2 sensor is only displayed if the temperature T1 sensor is also present and the system is operating in Skin Mode.

⚠	**Warning: The auxiliary Skin T2 sensor only provides a temperature reading and does not have any influence on radiant heating or the activation of safety alarms.**

Organization of the screen of the LED Monitor with seven segments



1	Low skin temperature LED alarm	9	Heating power indicator (manual mode)
2	High skin temperature LED alarm	10	User interface buttons
3	Dislodged sensor indicator (LED blinking) or no sensor indicator (continuously lit LED)	11	Operating time or APGAR timer
4	Power failure indicator	12	Weight on scale indicator
5	Peripheral skin temperature indicator	13	Ambient temperature indicator
6	Heating power indicator bar	14	LED indicator for shifted radiant reflector
7	Central Skin temperature indicator	15	LED indicator for patient temperature verification
8	Skin temperature set point indicator (servo controlled mode)	16	LED indicator for 15 minutes at 100% of heating power

Accessing the functions of the monitor

Adjusting the Heating Mode

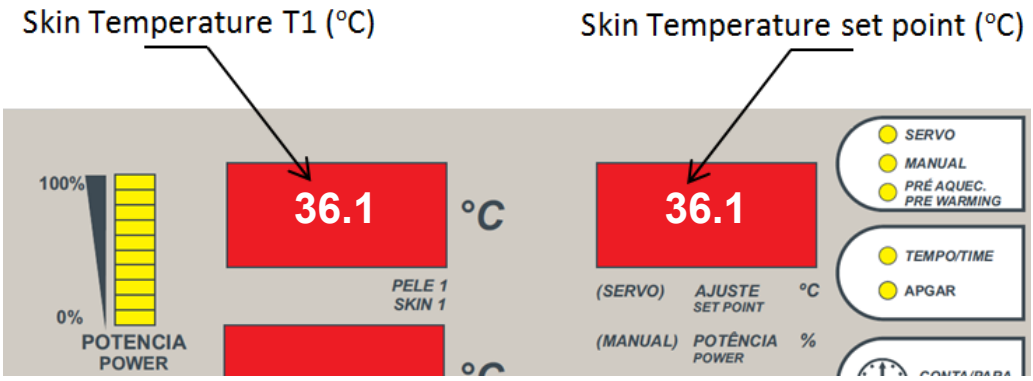
> **Warning: When using radiant heating, never put blankets or any type of cover on the patient. This affects the heating control of the Infant Warmer and may expose the patient to serious or even fatal risks due to overheating of the system.**

Skin Mode (Servo): Press the button on the toolbar corresponding to the heating modes, until the LED for the Servo (Skin Mode) option lights up. The system will go into Skin Mode only if the Skin T1 sensor is connected into the panel. If not, the system will enable selection of the Manual or Preheating Modes.

If the Infant Warmer is operating in Manual or Preheating Mode and the Skin T1 sensor is connected into the panel, the system will automatically switch to Skin Mode (Servo).

When operating in Skin Mode (Servo), the monitor displays the Skin T1 and Skin Set Point temperatures, as shown in the figure below.

Skin Mode (servo)

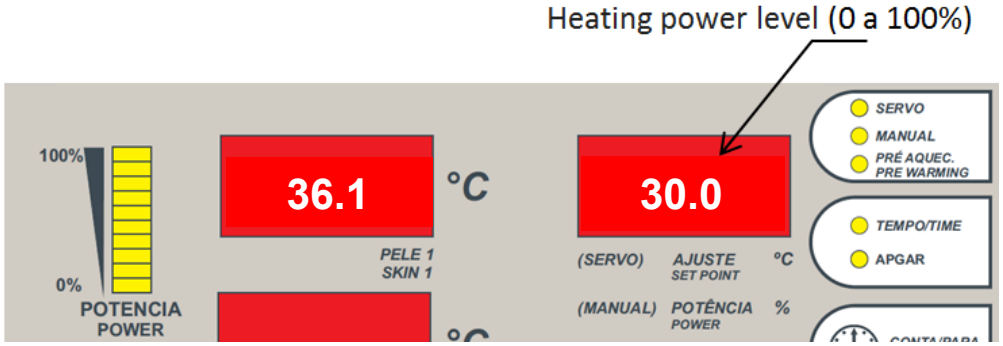


Manual Mode: Press the button on the toolbar corresponding to the heating modes, until the LED for the Manual option lights up.

If the system is operating in Skin Mode (Servo) and the Skin T1 sensor is disconnected from the panel, the system will automatically switch to Manual Mode, setting the heating power to 0% (heater turned off).

When operating in Manual Mode, the monitor displays the Skin T1 and auxiliary T2 temperatures, in addition to the power level (from 0 to 100%), as shown in the figure below.

Manual Mode



Preheating: Press the button on the toolbar corresponding to the heating modes, until the LED for the Preheating option lights up. The radiant heat power level will be set from 10% to 30%, depending on the ambient temperature, as shown in the table below.

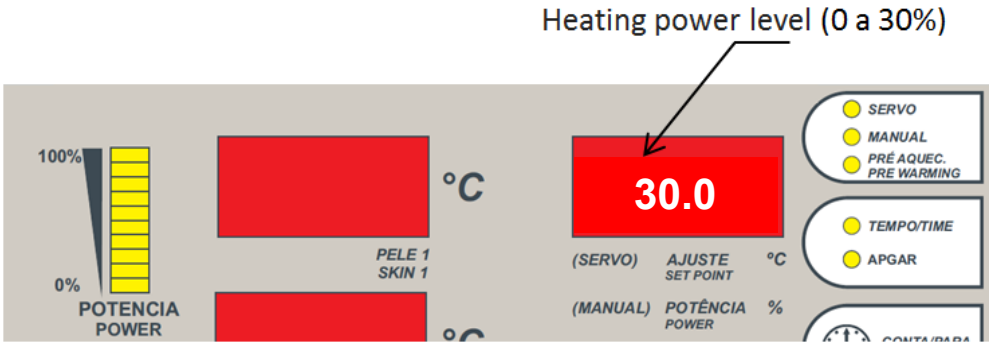
Preheating Power	Ambient Temperature
30%	< 23ºC
20%	23ºC ≤ T_{amb} < 26ºC
10%	T_{amb} ≥ 26ºC

Warning: The Preheating mode should not be used to heat the patient, but only to heat the bed before the patient's arrival, since unlike Manual Mode, there are no warning alarms in Preheating mode to check the patient's temperature every 15 minutes.

In Preheating mode, the operator cannot set the heating power level because the system automatically sets the power level according to the ambient temperature.

When operating in Preheating mode, the monitor does not display the Skin T1 and T2 temperatures, just the power level (from 0 to 100%), as shown in the figure below.

Preheating



Adjusting the Skin Temperature Set Point

With the system in Skin Mode (Servo), press the Rotary Dial Knob. The digits of the Skin Set Point will start blinking. Change the Skin Set Point (from 20 to 38ºC) through the Rotary Dial Knob. Press the Rotary Dial Knob again to leave adjustment mode.

Adjusting the heating power

With the system in Manual Mode, press the Rotary Dial Knob. The digits of the power level will start blinking. Change the power level (from 0 to 100 %) through the Rotary Dial Knob. Press the Rotary Dial Knob again to leave adjustment mode.

Suspending audible alarms

To suspend the audible signal of an alarm for 15 minutes, press the Silence icon on the toolbar. The corresponding LED will light up, indicating that the sound of the alarm has been silenced.

Blocking changes to parameters

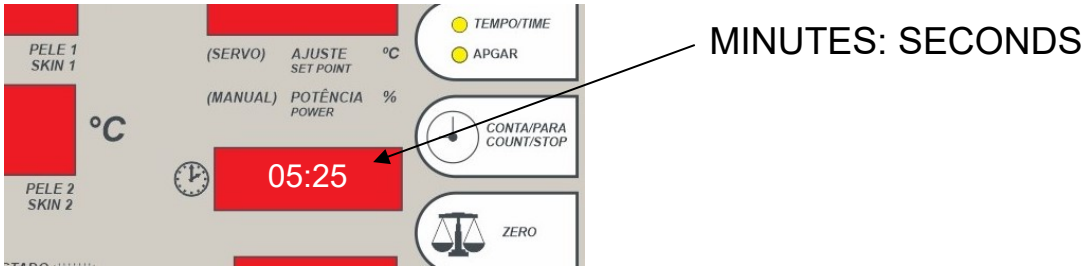
To block changes to parameters in the monitor (Power Level or Skin Set Point), press the Lock icon on the toolbar. The corresponding LED will light up, indicating that the option to change parameters has been blocked.

To enable the parameters to be adjusted again, press the Lock icon until the corresponding LED turns off.

APGAR Timer

To select the APGAR Timer function, press the "Timer/APGAR" button until the LED corresponding to APGAR lights up.

To start the count, press the Count/Stop button on the toolbar. The APGAR timer emits a beep after every minute and a prolonged beep at the five- and ten-minute marks. To stop the counting, press the Timer/Stop icon again and to restart counting, press this same button one more time.

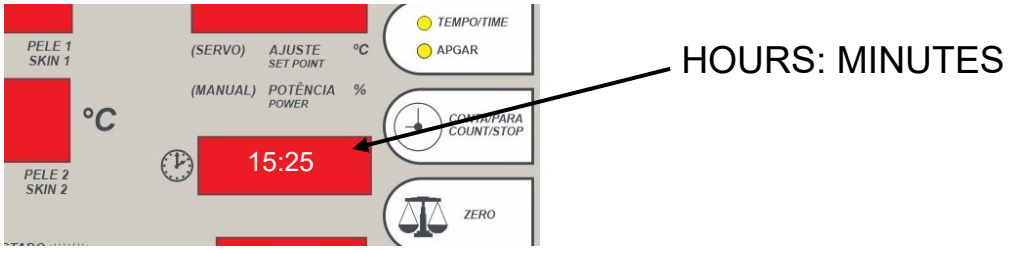


Clock (Current time)

The Timer Alarm function enables the time on the equipment to be adjusted. This function is ideal for informing the time during the application of medications or procedures. To select the Timer Alarm function, press the "Timer Al./APGAR" button until the LED corresponding to Timer Alarm lights up.

To adjust the time displayed, keep pressing the Count/Stop button for a few seconds When the two digits corresponding to the hour start blinking, adjust the hour through the Rotary Dial Knob.

To adjust the minutes, press the "Timer Al./APGAR" button. The two digits for minutes will start blinking. After adjusting the minutes, press the Rotary Dial Knob or Timer Al./APGAR button to leave adjustment mode.



Scale

To tare the scale, press the Tare button. A 10-second countdown will begin, in the field corresponding to Weight, at the end of which the scale will be tared. This countdown period serves to give the user time to lift the patient off the bed.

To perform the tare earlier, press the Tare button one more time before the countdown ends. The tare will be performed immediately.

After the tare is completed, 0.000 kg will be displayed on the screen and the patient can then be placed on the bed to be weighed.

6.3 Turning on the Monitor

Warning: Make sure that the voltage of the mains into which the power cord will be plugged corresponds to the stated voltage range of the equipment, as marked on the power cord label of the Infant Warmer – 127 V~ or 240 V~.
Do not switch on the Infant Warmer if the hospital grade socket is not reliably grounded.
Never disconnect the power cord while the monitor is turned on.

Plug the power cable into a hospital grade 3-way socket.

Make sure the hospital grade socket corresponds to the voltage and power required by the device, as marked on the identification plate next to the power cord.

Warning: Do not switch on the device if the socket is not reliably grounded.

Connect all the sensors and accessories in their appropriate sockets.

To connect the skin sensor plugs, check whether the chamfers on the plug and socket coincide. After connecting, screw the fastening nut counter-clockwise.

Warning: Never remove the plug by pulling on the cable.

Turn on the master switch of the device located on the rear part of the column, and the mains LED indicator on the front panel will light up.

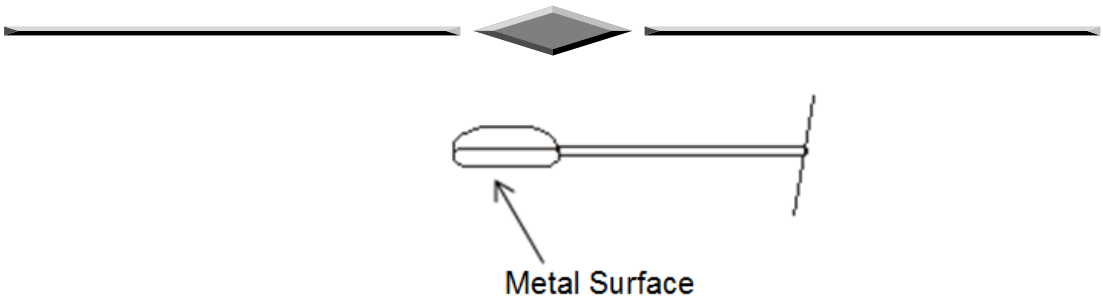
Set the control parameters as needed and according to the instructions in Section 6.2.

Place the metal surface of the Skin T1 sensor in contact with the newborn's skin, preferably in the abdominal region, and attach it with Fanem® sensor adhesive.

Note: *If the thermal contact between the sensor and the newborn's skin is inadequate, an incorrect skin temperature reading may occur, and consequently a false temperature will be recorded.*

The proper use of suitable adhesive, preferably non-allergenic, is highly recommended to avoid false readings.

Periodically checking the sensor is strongly recommended.



Warning: This sensor should be used exclusively for skin control and cannot be used to measure rectal temperature.

Warning: Only use FANEM® sensors. The use of another type of sensor can lead to temperature reading errors and harm patients. FANEM® sensors are individually tested and controlled.

The patient's current skin temperature will be shown on the SKIN TEMPERATURE screen.

The power supplied to the heating element will be displayed on the HEATING bar.

The high and low temperature alarms will only be activated if the skin temperature is greater than or equal to 1°C, or less than or equal to 1°C, respectively, in relation to the temperature set point.

Warning: The audible alarm can be silenced for 10 minutes by pressing the "SILENCE" key. It will be automatically restored after this period of time has elapsed. When the high temperature alarm is triggered, the heating power is cut off.

Warning: Never remove the sensor from the patient by pulling on the cable. First remove the adhesive and then the sensor.
Before attaching the sensor to the patient, make sure that the body of the sensor is clean and does not contain any bits of adhesive.

Warning: The set points will be memorized even when the device is turned off.

Warning: If the temperature monitored by the sensor fluctuates rapidly, this would indicate that the sensor has been dislodged from the body of the newborn. In such a case the Dislodged Sensor alarm will be intermittently activated and could stop if the sensor is restored to its original position. If this does not happen, attach the sensor properly to the patient and then press the Silence key to cancel the Dislodged Sensor alarm.

6.4 Operation with Scale (only available in the ICU table model)

To tare the scale, place the table in the horizontal position before receiving the newborn into the Infant Warmer, and perform the following steps:

Select the Tare function on the Scale menu. When the automatic tare function is selected, a time count begins, synchronized with a horizontal bar. When the bar is completely full, an audible beep is emitted, and the tare is performed.

Place the newborn on the bed and wait until the reading stabilizes.

Warning: The newborn should be weighed in the center of the mattress. Maximum load of 7 kg on the bed/scale.

Warning: Movements in the Infant Warmer during the weighing process can cause fluctuations in the weight indicator on the display monitor.

Warning: Toys or other objects on the mattress should not be leaning against the acrylic sides. Inaccurate readings may occur. In addition, the bed unit should not be touching the sides.

Warning: To tare the scale and weigh the patient, the bed must always be in the horizontal position.

Warning: Do not weigh newborn when the thermal mattress is being used.
A lack of complete symmetry in the thermal mattress could affect the weight measured by the scale.

6.5 Moving the Table

For procedures and treatments, the bed needs to be in the Trendelenburg or Reverse Trendelenburg position.

For the electric table configuration:

♦ Press the respective bed inclination buttons (Trendelenburg or Reverse Trendelenburg) on the front panel, until finding the desired position.

♦ To return the table to the horizontal position, simply press the Horizontal button on the front panel. The table will automatically return to the horizontal position.

Warning: Improper placement of the hands in areas of the equipment marked with the symbol to the right places them at risk of being crushed during the movement of the bed.

For the manual table adjustment configuration:

♦ Stand in front of the Intensive Care Unit.

♦ With the left hand gripping the support handle on the lower front part of the table, pull, with the right hand, the activation lever located on the lower right front part of the table. Move the bed upward or downward until finding the desired position.

♦ Release the activation lever and make sure the bed remains locked in the desired position.

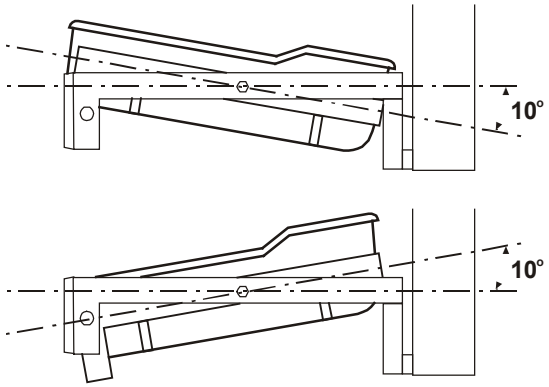
Note: If the scale is installed in the bed, it is necessary to put the bed in the horizontal position before taring the scale and weighing the patient.

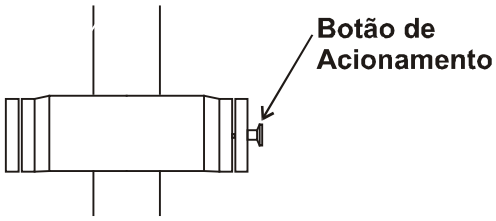
For the Acrylic Bed configuration:

♦ Stand in front of the Intensive Care Unit.

♦ With the left hand gripping the lower front part of the table, press, with the right hand, the activation button located on the right side of the table. Move the bed upward or downward until finding the desired position.

♦ Release the activation button and make sure the bed remains locked in the desired position.





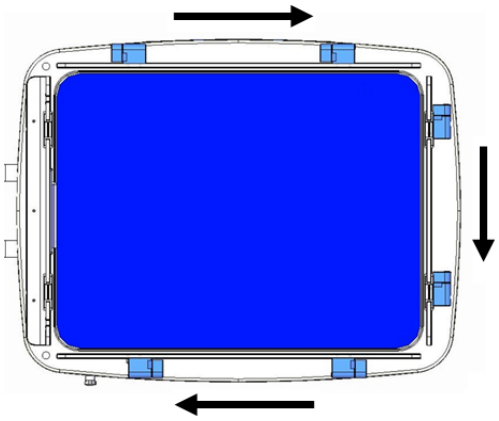
6.6 Opening the sides

Only for the Intensive Care Unit – ICU Table

Grip the side protection with one hand, press the side in the direction indicated by the arrows (figure to the right) until it unlocks. Move the side protection from inside to outside until it remains in the downward resting position.

The side protection located on the rear part of the bed can be removed by pulling it upward.

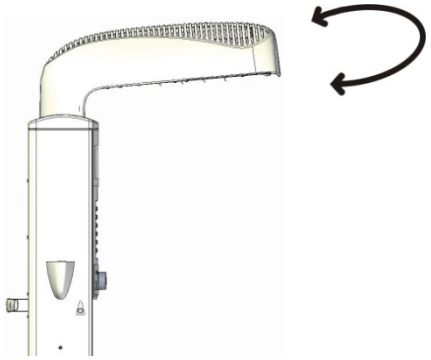
Note: It is recommended to lock the casters.



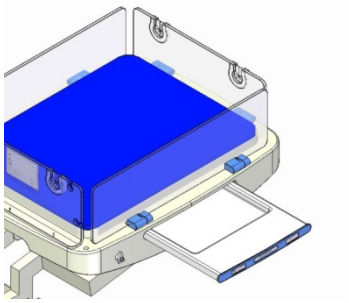
6.7 X-Rays

The reflector unit can be moved to either side of the equipment to permit space for the X-ray device.

To move it, simply shift the reflector unit by turning it to the right or left.

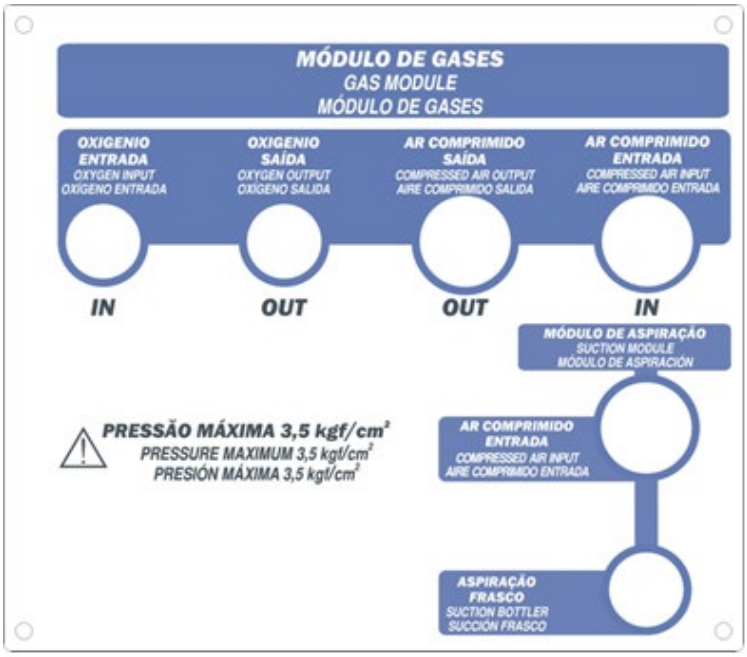


The bed and mattress are made of materials that provide transparency for X-rays. There is also an X-ray cassette drawer underneath the bed.



Note: The X-ray cassette drawer is only available for the Intensive Care Unit – ICU Table

6.8 Gas Module



6.8.1 Oxygen

The supply of oxygen can be provided two different ways: through oxygen cylinders or an oxygen line from the hospital gas network.

The administration of oxygen through the Gas Module is performed by connecting a braided nylon ∅3/16" 250 Psi pressure hose to the oxygen inlet nipple of the Gas Module.

This will supply the Gas Module and oxygen outlet nipple on the Gas Module. This oxygen outlet in the Gas Module is used to supply respirators, blenders, Babypap® and other peripherals.

Administration of Oxygen – Precautions:

- ♦ In the event it is necessary to administer oxygen, it should comply with the parameters set by the physician.
- ♦ Whenever oxygen is administered, routine tests should be performed with an oxygen analyzer, as a standard procedure.
- ♦ The manufacturer's instructions should be strictly followed when using the Oxygen Monitors / Controllers.

♦ These should be checked periodically, by taking pure ambient air samples, according to the manufacturer's instructions. If the indications of the instruments are correct on both ends, the intermediate readings will be reliable, within the limits of accuracy required.

Modo de Gases - Oxigênio - Precauções
Gases Module - Oxygen - Precautions
Módulo de Gases - Oxígeno - Precauciones

- Perigo: risco de incêndio - mantenha fósforos e qualquer outra fonte de ignição fora da sala na qual o oxigênio é usado. Materiais combustíveis entram facilmente em ignição e queimam quando o ar está enriquecido com oxigênio;
  Perigo: o uso de oxigênio suplementar pode estar associado a sérios efeitos, deve ser administrado somente por pessoal qualificado sob a direção do médico atendente;
  Perigo: pressão excessiva nas vias aéreas pode causar danos ao pulmão do paciente;
- ***Danger: risk of fire - maintains matches and any other ignition source out of the room in the oxygen is used. Combustible materials easily enter in ignition and burn when the air is enriched with oxygen;***
  Danger: the use of supplemental oxygen can be associated to serious effects, it should only be administered by qualified personnel under the direction of the assistant physician;
  Danger: excessive pressure in the respiratory tracts can cause damages to the patient´s lung;
- ***Peligro: riesgo de fuego - mantenga fósforos y cualquier otra fuente de ignición fuera del cuarto en que el oxígeno es usado. Los materiales combustibles entran fácilmente en la ignición y quemam cuando el aire se enriquece con oxígeno;***
  Peligro: el uso de oxígeno suplemental se asocia a efectos serios, sólo debe ser administrado por personal calificado bajo la dirección del médico atendente;
  Peligo: Presión excesiva en las vías aéreas puede causar daños y perjuicios al pulmón del paciente;

♦ It is likely that oxygen concentrations above 40% are dangerous for certain newborns. There are also cases where, to raise the oxygen pressure to normal levels, it is necessary to raise the concentration to over 60%. For this reason, it is extremely important to perform an analysis of the arterial blood gases, to regulate the concentrations of oxygen inspired

Note: Maximum O_2 intake pressure = 3.5 kgf/cm².
O_2 nipple, 9/16" thread size – 18 UNF

6.8.2 Compressed Air and Aspiration-Vacuum

The supply of compressed air can be provided two different ways: through compressed air cylinders or a compressed air line from the hospital gas network.

The administration of compressed air through the Gas Module is performed by connecting a braided nylon ∅ 3/16" 250 Psi pressure hose to the compressed air inlet nipple of the Gas Module, and another hose connected through the Aspiration Module.

This will supply the compressed air outlet for the use of respirators, blenders, Babypap®, etc., and in the Aspiration Module, the Venturi-type aspirator for removing secretions, where the vacuum can be adjusted from 0 to 200 mmHg through a button located on the vacuum gauge, on the front page of the column. There is also the bottle for secretions, with a level limiter, lid and vacuum hose,

Note: Maximum compressed air intake pressure = 3.5 kgf/cm².
Compressed air nipple – 3/4" thread size – 18 UNF

Warning: After normal medical procedures the bottle may contain contaminated wastes. Make certain that their disposal complies with current national laws, as well as the Hospital Infection Control Committee.
For instructions on how to sterilize the bottle for secretions, see Section 7 of this manual.

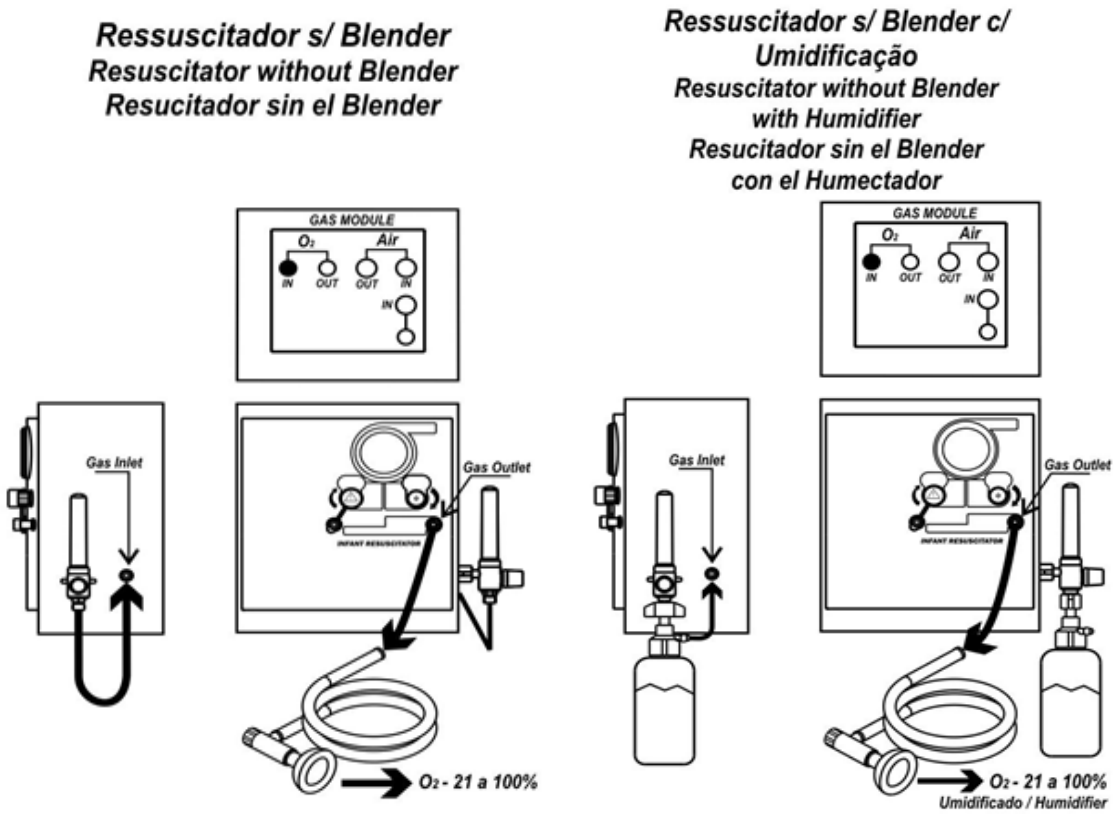
NOTE: As an option, a connection can be installed for direct coupling to the hospital's vacuum network. In this case, request this option from the factory.

6.9 Aspirator for Removing Secretions

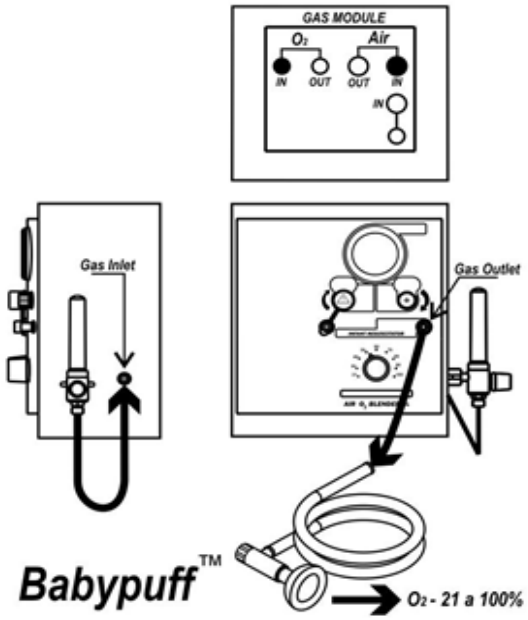
This Venturi-type aspirator works through a flow of compressed air.

The vacuum can be adjusted from 0 to 200 mmHg through the front button.

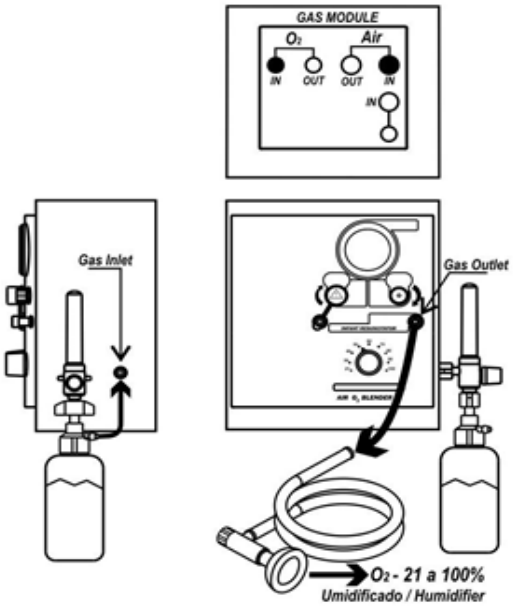
6.10 Connection Diagrams – Gas Module and Configurations of Accessories



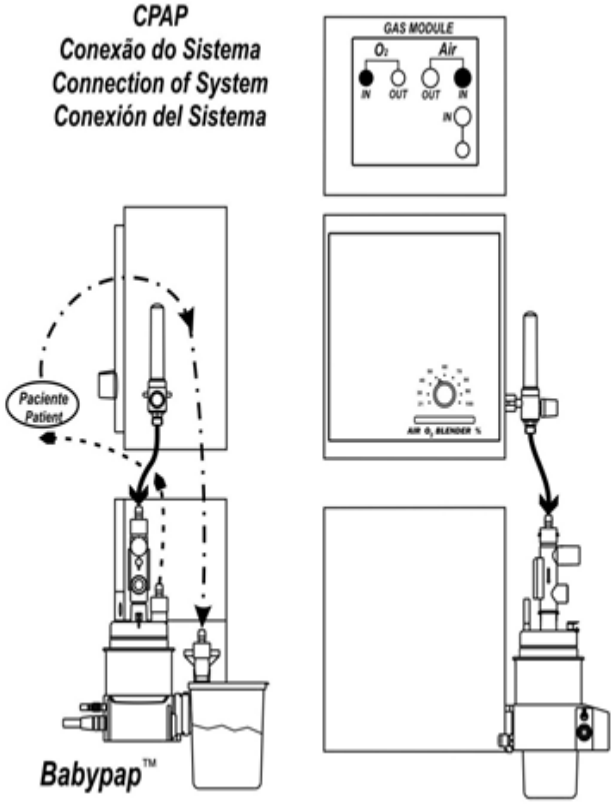
Ressuscitador c/ Blender
Resuscitator with Blender
Resucitador con el Blender



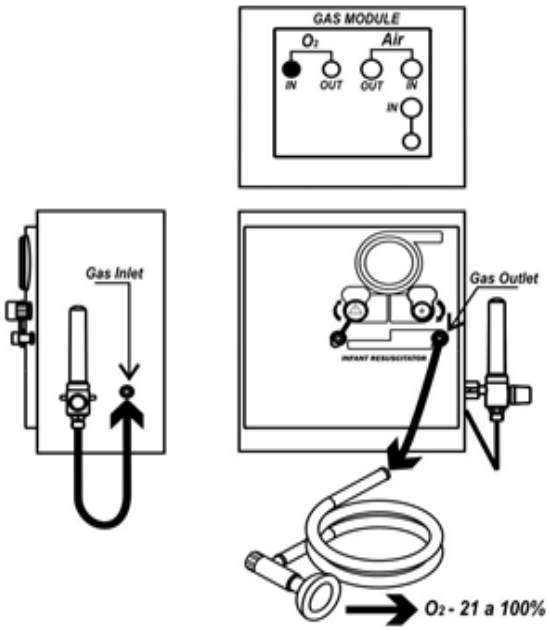
Ressuscitador c/ Blender c/ Umidificação
Resuscitator with Blender with Humidifier
Resucitador con el Blender con el Humectador



CPAP
Conexão do Sistema
Connection of System
Conexión del Sistema



Ressuscitador s/ Blender
Resuscitator without Blender
Resucitador sin el Blender



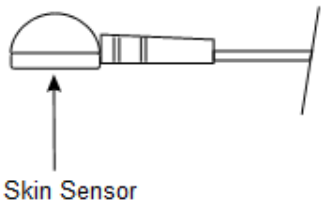
6.11 Operation with Sensor

The sensor of the AMPLA® 2085 Infant Warmer was specially designed by FANEM for use with its equipment.

The sensors, due to their characteristics of use, are delicate parts and must be handled with care. When detaching them, never pull on the connection cable.

FANEM also produces specially designed adhesives to attach the sensor to the newborn's skin. These adhesives are made from non-toxic, anti-allergic material which facilitates removal of the sensor without damaging it.

The Skin T1 Sensor must be positioned with its metal surface in direct contact with the newborn's skin and attached using FANEM sensor adhesives, in order to avoid positioning errors which can cause reading errors and set off different operational alarms.



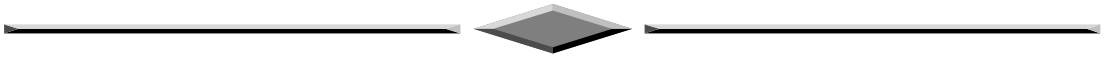
	**Warning: Place the metal surface in contact with the patient's skin, normally in the abdominal area.**
	**Warning: Never remove sensors from the newborn by pulling on the cable. First remove the adhesive and then the sensor.** **Before attaching the sensor to the patient, ensure that the body of the sensor is clean and does not contain any bits of adhesive.**
	**Warning: Never use the Skin T1 sensor to measure rectal, oral or axillary temperature.** **The Skin T1 sensor must be in direct contact with the skin for accurate monitoring of temperature. Failure to maintain direct contact with the skin can result in overheating and possible risks to the newborn. Check the newborn's condition at least every 15 minutes to ensure that the sensor is properly attached and to check the patient for any possible signs of overheating.**

6.12 Operation of the Bilitron® Bed 4006 Phototherapy Unit

Select the Bilitron® Bed 4006 menu. At the top of the menu, the phototherapy treatment time performed thus far and the total time of use of the lamps (SuperLeds) are displayed.

The following functions are available:

- Restart treatment time
- Turn on/Turn off the Bilitron® Bed 4006
- Turn on the Bilitron® Bed 4006 The conditions of the Bilitron® Bed conditions are shown on the home screen. When turned on, total treatment time will be displayed.
- Place the newborn on the phototherapy in the center of the mattress.
- Keep the air inlet and outlet fins unblocked to enhance the efficiency of the system.



Warning: To avoid eye injuries, the newborn must have eye protection.

Warning: Do not attach the reflective arch for this type of phototherapy.

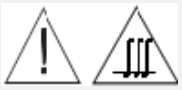
Warning: If the LEDs turn off, this means that the temperature has exceeded the set point. Check if there is any obstruction or if the fans have stopped.

7. Preventive and Corrective Maintenance and Conservation

Preventive and corrective maintenance and conservation should be performed only by duly qualified and trained professionals.

Warning: Before starting any maintenance or cleaning procedure, ensure that the equipment is disconnected from the wall.

Warning: Make sure the oxygen supply for the equipment is turned off and that the equipment is disconnected from the oxygen supply whenever cleaning or maintenance procedures are performed. There is a risk of fire or explosion in an oxygen enriched environment.



Warning: The heater may be hot enough to cause burns; avoid touching or removing the heater until the unit has been switched off for at least 45 minutes.

7.1 Monitor

Batteries
This monitor contains a 9 VCC - NiCd rechargeable battery for the Power Failure alarm.

This battery should be changed after every 12 months of use. To change the battery, it is necessary to turn off the Master Switch located on the side of the column and remove the monitor from the column. To take off the monitor, the six screws of the rear panel on the column must be removed to gain access to the panel of the monitor and its attachment clamps. Release the monitor by the front part of the column, loosening the attachment clamps.

The housing of the battery is in the rear part of the monitor on a platform above the display. Remove the battery from its receptacle port and replace it with a new one. The battery connector is polarized, thus eliminating the risk of inadvertent connections.

Warning: Explosion hazard. Do not use common or alkaline batteries. Only use FANEM rechargeable batteries.

Warning: The disposal of batteries must be done according to the laws of the country.

Calibration
Temperature calibration should be checked after every six months of use.

This procedure should be performed by accredited FANEM® technicians, in accordance with internal standards.

7.2 Replacement of Super LEDs in the BILITRON 3006 and BILITRON BED 4006 Phototherapy Units

	**Warning: Contact our FANEM® Technical Assistance or authorized customer service to request a properly trained technician.**
	**Warning: Never replace parts or pieces with the device plugged in and turned on.**
	**Warning: For the BILITRON® 3006 Phototherapy unit, total irradiance should be measured with the radiation level set at 100% perpendicular to the light source with a distance of 30 cm between the light source and optical sensor. The minimum expected level for the point of highest irradiance is 10 µW/cm2.nm. If below this level, all the lamps should be replaced.** **The estimated deterioration rate of the power module is 0.002 µW/cm²nm per hour of use, on average - a factor subject to a number of construction and operating characteristics.**
	**Warning: All the lamps should be replaced once 25% of their total irradiance for Bilirubin-Eli has been lost. The typical level or irradiance for the BILITRON® BED 4006 is 36µW/cm²ηm.** **The estimated deterioration rate of the power module is 0.0005 µW/cm².nm per hour of use, on average. This factor is subject to a number of construction and operating characteristics.**
	**Warning: It is recommended to use the FANEM THOR® 3620 Radiation Monitor to periodically check that the radiation conditions of the phototherapy sources are in perfect condition.** **It is also recommended to constantly check whether the Super LEDs are darkened or flickering, in which case they should be immediately replaced to ensure consistent adequate treatment.** **Only use original FANEM® parts, since they ensure appropriate radiance and temperatures within the specified levels.**

7.3 Protection Fuses

To change the fuses of the equipment, proceed as follows:

- Unplug the power cord from the socket.
- Make sure that the equipment and its accessories are de-energized.
- With the aid of a screwdriver, press and rotate to left the front of the fuse holder.
- The fuse holder cover will be disconnected, and the fuse will be attached to it.
- Replace it with a new fuse, according to its electrical specifications, and reassemble the set.

Application	Fuse
Power Supply 127 V~	10 A – Type F (3 cm)
Power Supply 220/240 V~	5 A – Type F (3 cm)

7.4 Cleaning and Conservation

To clean this equipment, only use the cleaning and/or disinfection procedure described in this section, with products and materials that are non-toxic to patients and users and have been proven not to damage the different materials that make up the parts of the equipment and acrylic, plastic and metals pieces in general.

It is recommended to completely remove the different compartments and parts that need to be checked during the terminal cleaning of the equipment to provide full access – which should be done when the equipment is first received and between uses with the same patient and/or different ones. For this purpose, it is necessary to have an appropriate physical area and location to set down the parts and pieces, as well as a properly prepared and trained professional to comply with the recommendations from this manual for this equipment.

Always use soft and preferably disposable pads to perform the cleaning and/or disinfection.

It is recommended that this be performed:

- By a professional properly prepared for the task;
- In a suitable location;
- Using one of the procedures and the appropriate products and materials;
- With the equipment unplugged from the wall;
- After removing all the components to access all the internal areas of the equipment.

To perform the cleaning, the following recommendations should be observed:

- Use neutral detergent, which should be diluted in water;
- Apply with a pad, rubbing it upon all the surfaces and parts;
- Remove with another damp pad;
- Then dry and reassemble the parts and pieces.

To perform the disinfection, the following recommendations should be observed:

- Select a product with low toxicity, whose composition and dilution enable the removal of dirt and load of microorganisms;
- Preferably choose a product that dispenses with precleaning of the equipment;
- Apply the product on all the surfaces and parts, according to the manufacturer's instructions;
- Leave the product for the specified exposure time;
- Then completely remove the disinfectant, using a pad dampened with water;
- Lastly dry and reassemble the parts and pieces.

Warning: Do not use disinfectants that contain alcohol and/or abrasives or sodium hypochlorite, because they will damage the acrylic and other parts used in the equipment. Do not use abrasive sponges and/or steel wool.

7.4.1 Cleaning the BILITRON BED 4006

Always keep the mattress, patient's bed and acrylic plates clean. For cleaning, use a soft cloth with warm water and neutral detergent.

Do not use chemicals or alcohol to do this cleaning.

Constantly check the conditions of the mattress and make sure there are no undesirable perforations.

7.4.2 Disassembling the Equipment for Cleaning

To disassemble the AMPLA® Infant Warmer for cleaning, proceed as follows:

- Unplug the equipment from the wall and turn off the connections and gas supply;
- Make sure that all the accessories have been removed to protect them from damage and to apply the specific recommended procedures for each one;
- Disconnect and remove the equipment's sensors to carry out individual cleaning;
- Remove the gas connection hoses;
- Remove the mattresses;
- Remove the drawer for the X-ray procedure;
- Remove the aspiration bottle;
- Open the side protections of the bed by moving them in the direction of the arrow indicator and folding them downwards.

All the surfaces of the equipment should be cleaned, using the procedures, products and materials for cleaning and/or disinfection, in accordance with the previous recommendations. Then, completely remove the product with a damp pad, dry and reassemble the compartments and pieces.

7.4.3 Skin Temperature T1 and T2 and Pulse Oximetry Sensors

Although they are delicate materials, they can be cleaned and/or disinfected like the other components and pieces, taking care to apply the product with a pad along the cable and encapsulated part. After this, the product should be completely removed before new use with a patient.

Warning: The sensors and their parts should not be immersed in the products used for the cleaning and/or disinfection procedures, since this could damage them.

7.4.4 Memory, Gel and Thermal Mattresses

The three mattresses are made of different and delicate materials, but they can be cleaned and/or disinfected like the other components and pieces, taking care to apply the product with a pad on the external protective covering. After this, the product should be completely removed before new use with a patient.

Warning: The memory, gel and thermal mattresses should not be immersed in the products used for the cleaning and/or disinfection procedures, since this could damage them.

7.5 Adoption of the Cleaning Procedure

Use:

- Good quality water;
- Neutral detergent and/or enzymatic detergent (if there is organic material present: blood, secretions, feces, etc.);
- Clean, soft and preferably disposable pads;
- Suitable physical area for disassembling and setting down the components;
- Procedure gloves.

7.5.1 How to perform the terminal cleaning procedure

With the equipment properly disassembled and its parts and pieces arranged:

- Moisten the pad with a solution of water and recommended detergent;
- Wipe all the equipment with the pad to remove dirt;
- Replace the pad as often as necessary;
- Remove the product with another damp pad;
- Dry and assemble the components.

7.6 Adoption of the Disinfection Procedure

- Choose an appropriate disinfectant for the fixed surface and components of the equipment, such as a quaternary ammonia solution – for example: Scotch-Brite Flex from 3M™.
- Use clean, soft and preferably disposable pads.
- Use a suitable physical area for disassembly and setting down the accessories;
- Use procedure gloves.
- Utilize the disinfectant according to the dilution recommended for use on fixed surfaces;
- Moisten a dry pad with the disinfectant;
- Wipe all the equipment with the pad and disinfectant to remove dirt;
- Wait the recommended exposure time before totally removing the product with another damp or dry pad, depending on the disinfectant. There is no need for rinsing. For example, in the case of SCOTCH-BRITE Flex™, exposure time is 10 minutes;
- Dry and assemble the components.

Warning:
The following should not be used:

- **Products proven to be inadequate (alcohol, solvents, antiseptics, chlorine, soaps and cleaning products in general)**
- **Fabrics that may harm or scratch the acrylic**
- **Sponges in general**
- **Equipment that generates hot steam**
- **Hose for wetting the equipment**
- **Cleaning the equipment while it is plugged into the wall**
- **Untrained employees to disassemble and assemble the equipment**

7.6.1 How to perform the terminal disinfection procedure:

- Utilize the disinfectant according to the dilution recommended for use on fixed surfaces;
- Moisten a dry pad with the disinfectant;
- Wipe all the equipment with the pad and disinfectant to remove dirt;
- Wait the recommended exposure time before totally removing the product with another damp or dry pad, depending on the disinfectant. There is no need for rinsing. For example, in the case of SCOTCH-BRITE Flex™, exposure time is 10 minutes.

Dry and assemble the components.

7.7 Aspiration Bottle

The bottle from the aspiration system should be removed and sent for cleaning and sterilization in the Material Center. The following procedures can be used: sterilization by autoclaving, ethylene oxide (ETO) and/or sterilization with hydrogen peroxide (Sterrad).

7.7.1 Tank sterilization procedure

- Disassemble and clean the tank with enzymatic detergent;
- Remove the excess product with water and then dry it;
- Wrap the uncapped tank in surgical grade paper or crepe paper;
- Then sterilize in ethylene oxide and/or with hydrogen peroxide (Sterrad);
- In the case of autoclaving, use a gravity autoclave - clothing cycle - 121ºC for 20 minutes;
- Obey the time period indicated on the packaging.

Warning: Do not sterilize the aspiration bottle with the cap on.

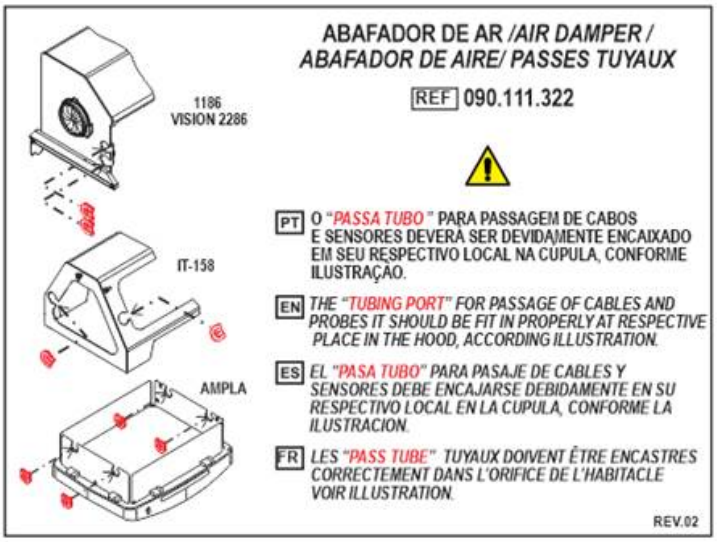
Warning: The aspiration bottle should not be sterilized in pre-vacuum type autoclaves.

The bottle of the aspiration system should only be installed when preparing the Infant Warmer for new use with a patient.

For your convenience and safety, we recommend having spare units of the bottle kit from the aspiration system to enable replacement and reprocessing between uses of the equipment.

7.7.2 Fitting the Tubing Port

The patient's bed, in the electric and mechanical table versions, consists of four silicone tubes and cable inserts. If these tubing ports need to be removed during the cleaning procedure of the bed or to be replaced, they need to fit properly into their respective locations.



7.8 Rechargeable Battery (Transport Kit):

Periodically check the condition of the batteries before using the transport mode (optional item) of the equipment. The charge level of this battery should be checked at each use. Its life cycle depends on frequency of use.

To verify whether the batteries are charged, plug in the Infant Warmer. When the battery bar on the screen is no longer moving, this means that the battery is no longer charging. Then, disconnect the equipment from the wall and check the battery charge level shown on the control panel. The batteries are fully charged if the voltage is above 12 V.

If the battery kit does not have a voltage of 12 V, briefly dipping below 11.3 V after being charged, the batteries need to be replaced, which should be done a qualified and trained technician.

Warning: Explosion hazard. Only use only 12 V rechargeable batteries supplied by FANEM Ltda.

7.9 Maintenance Chart

Part	Deadline	Performed by
Quartz Heating Element	12 months (replacement)	Technician
Rechargeable Battery	12 months (replacement)	Technician
Auxiliary Lighting Lamp	12 months (verification)	User/Technician
Operating Kit of the Trendelenburg	12 months (verification)	Technician
Routine Calibration	4 to 6 months	Technician
Ducts and Hoses	5 years (replacement)	Technician
Cleaning and Disinfection of the Aspiration Kit	With each new patient	User

7.10 Disposal

If the equipment or parts need to be disposed of, and the customer has not defined a specific destination for them, the item(s) in question should be sent to the manufacturer or its legal representative (with shipping paid by the customer), for appropriate disposal measures to be taken, in accordance with national laws.

Warning: The disposal of batteries must be done according to the laws of the country.

Note: The equipment and/or its parts must be sent in clean and aseptic conditions.

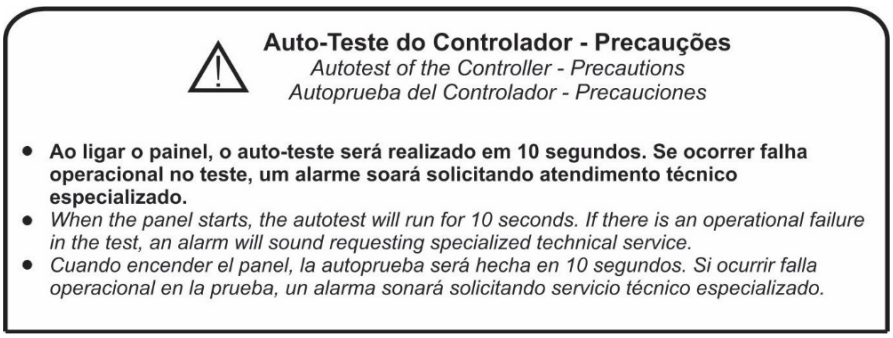
Failure to do so releases the supplier from liability for potential impacts on the environment and/or people.

7.11 Auto Check-up and Alarm Testing

When turning on the monitor, there are auto check-ups for visual indicators (LEDs and displays) and audible ones, except for the Power Failure LED. This check-up is done automatically to inform the user of any damaged displays/LEDs or audible alarms.

Warning: When the monitor is turned on, the audible Low Temperature alarm will be silenced for 15 minutes.

Warning: When the Silence key is pressed, the respective audible alarm(s) will be silenced for 15 minutes.



The procedures below describe the alarm verification tests that can be performed by the user.

System Alarms

- Power Failure

For systems without the transport module (optional item), disconnect the power cord from the socket with the system turned on. A red LED will immediately light up on the panel, indicating a power failure, and a loud and continuous audible signal will be heard.

For systems with the transport module, disconnect it from the system (consult a service technician authorized by Fanem to do this). With the system turned on, unplug the power cord from the socket. A red LED will immediately light up on the panel (indicating a power failure) and a loud and continuous audible signal will be heard.

- Alarm when Heating Power remains at 100%

Operation in Skin Mode: With the skin T1 sensor kept at a steady temperature, adjust the skin set point to a temperature at least 1.1 ºC over the T1 temperature, so that the heating power remains at 100%. After 15 minutes the alarm will be activated, cutting off the radiant heating (power bar at 0%), with a visible indicator in the Information and Alarms section and an intermittent audible signal.

Operation in Manual Mode: setting the heating power at 100%. After 15 minutes the alarm will be activated, cutting off the radiant heating (power bar at 0%), with a visible indicator in the Information and Alarms section and an intermittent audible signal.

Alarm when remaining in Manual Mode for 15 minutes

With the system in Manual Mode, set the heating power below 100%. After 15 minutes the alarm will be activated, with a visible indicator in the Information and Alarms section and an intermittent audible signal.

Low Transport Battery Charge Alarm

With the system turned on and disconnected from the wall, wait for the transport batteries to discharge, until the voltage drops to 11.3 V. The alarm will be activated, with a visible indicator in the Information and Alarms section and an intermittent audible signal.

Note: After the test, leave the system plugged into the mains to recharge the batteries.

Skin Mode Alarms

- High Skin Temperature

With the system in Skin Mode, adjust the skin set point to at least 1ºC below the skin T1 sensor temperature. The alarm will be activated immediately, with a visible indicator in the Information and Alarms section and an intermittent audible alarm.

- Low Skin Temperature

With the system in Skin Mode, adjust the skin set point to at least 1ºC above the skin T1 sensor temperature. The alarm will be activated immediately, with a visible indicator in the Information and Alarms section and an intermittent audible alarm.

- No Skin T1 Sensor

With the system in Skin Mode, disconnect the skin T1 sensor from the panel. The alarm will be activated immediately, with a visible indicator in the Information and Alarms section and an intermittent audible alarm.

- Dislodged Skin Sensor

With the system operating in Skin Mode, press the skin T1 sensor against the back of the hand until the temperature stabilizes. Then, remove the skin sensor, exposing it to the ambient air. Upon detecting the variation in temperature, the alarm will be activated, with a visible indicator in the Information and Alarms section and an intermittent audible alarm.

Pulse Oximeter Alarms*

♦ High SpO_2 Concentration

To test this alarm, it is necessary to have a Nellcor SRC-MAX pulse oximeter simulator. Set the high SpO_2 concentration limit at a level lower than the SpO_2 concentration displayed on the screen. The alarm will be activated after the time period set for SatSeconds[1] has expired (See Pulse Oximetry section in the chapter Ampla® 2085 Infant Warmer functions) in the versions with color or monochrome LED monitor, or immediately, in the case of the LED monitor version.

♦ Low SpO_2 Concentration

To test this alarm, it is necessary to have a Nellcor SRC-MAX pulse oximeter simulator. Set the low SpO_2 concentration limit at a level higher than the SpO_2 concentration displayed on the screen. The alarm will be activated after the time period set for *SatSeconds[1]* has expired (See Pulse Oximetry section in the chapter Ampla® 2085 Infant Warmer functions) in the versions with color or monochrome LED monitor, or immediately, in the case of the LED monitor version

♦ **High BPM Level**

To test this alarm, it is necessary to have a Nellcor SRC-MAX pulse oximeter simulator. Set the high BPM limit at a level lower than the BPM level displayed on the screen. The alarm will be activated immediately.

♦ Low BPM Level

To test this alarm, it is necessary to have a Nellcor SRC-MAX pulse oximeter simulator. Set the low BPM limit at a level higher than the BPM level displayed on the screen. The alarm will be activated immediately.

♦ Dislodged Sensor

With the pulse oximeter turned on, remove the sensor from the skin. The alarm will be activated within a few seconds.

♦ Disconnected Sensor

With the pulse oximeter turned on, disconnect its sensor from the panel. The alarm will be activated within a few seconds.

[1] SatSeconds is a trademark of Covidien AG.

**There are alarms only if the equipment has the corresponding optional item.*

Oxygen Monitor Alarms*

♦ High O_2 Concentration

Set the high O_2 concentration at a level lower than the O_2 concentration displayed on the screen. The alarm will be activated immediately.

♦ Low O_2 Concentration

Set the low O_2 concentration at a level higher than the O_2 concentration displayed on the screen. The alarm will be activated immediately.

♦ No Oxygen Sensor

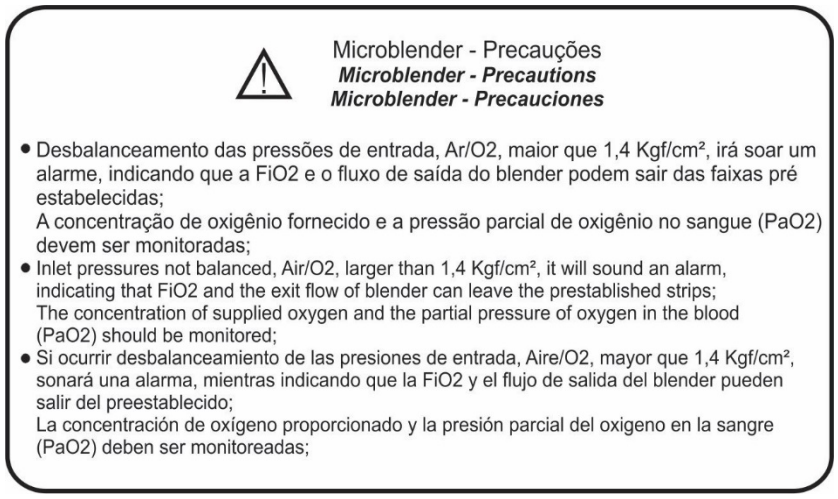
With the oxygen monitor turned on, disconnect its sensor from the side panel. The alarm will be activated immediately.

**There is an alarm only if the equipment has the corresponding optional item.*

CPAP Alarms

♦ Blender Alarm

With the Air and Oxygen flow sources from the gas supply network connected to the inlet of the Blender, open up the gas flow from the supply network and, via the manometer of the Air and O2 pressure valves, regulate intake pressure to 3.5 Kgf/cm^2.



With the end of the patient respiratory circuit connection free, open up the gas mixture flow (5 to 12 LPM) on the flow meter of the CPAP Module, and check whether anything comes out.

Disconnect one of the flow sources (air or oxygen) from the inlet of the Blender. The Blender alarm should go off.

FOG® 1140 Humidifier Alarms

♦ High Temperature – “HI TEMP” (ERROR)

With an ideal level of water in the tank and the Power Level of the humidifier set at 10, place the head of the temperature sensor of the patient circuit on the outer metal part of the tank (since this part reaches a temperature exceeding 36ºC). On the humidifier display, check the increase in sensor temperature as the tank is heated. Upon reaching 36ºC, the alarm will be activated.

♦ Low water in the humidifier tank – “*Low Level*” (ERROR)

With the humidifier tank empty, check whether the alarm is activated.

♦ No patient circuit temperature sensor

Disconnect the patient circuit temperature sensor from the humidifier. The alarm will be activated immediately.

Thermal Mattress (optional item, upon request)

♦ Safety Thermostat Operation

The proper functioning of the safety thermostat can be checked through a test set forth in Section 52.5.102 of the standard NBR IEC 60601-2-35.

7.12 Spare Parts

For possible spare parts, check Section 3 of this manual: Parts, Pieces and Accessories, with their respective references.

To obtain drawings, parts, components or other additional references, directly contact FANEM or its sales representatives.

The proper functioning and safety of this equipment are only ensured if the check-ups, maintenance and repair services are performed by the FANEM Technical Assistance team or those properly trained and qualified by FANEM.

FANEM is not liable for any damage that may occur with the equipment or for any consequences to the patient due to improper maintenance not performed by our Technical Assistance team, or in the event non-original spare parts / accessories were used as replacements.

The materials used in the design of parts and accessories and consumables and wear items, such as sensors, adhesives, mattress covers, etc., aim to ensure the perfect operation of the equipment according to its original features, as well as safety in terms of the toxicity and flammability and biocompatibility of the materials used.

Warning: Only use original FANEM® parts.

7.13 Troubleshooting for AMPLA® 2085 Infant Warmer with LED Display Monitor

Symptom	Possible Cause	Solution
Monitor does not turn on (system without the optional Transport Module) and power failure alarm is activated.	Blown fuse.	Check fuses in the side panel.
Monitor always turns on in battery power mode (system with the optional Transport Module), even when the system is plugged into the wall.		
Image is frozen on the screen and does not respond to any command. Rosette is not spinning.	Failure in the main microprocessor.	1. Reboot the system. 2. If the problem continues, contact an Authorized FANEM Service Technician.
Display monitor with incorrect and random indications and improper functions.	Excess EMI in the hospital electricity grid. Excess EMI due to electromagnetic radiation.	Turn off the unit and turn it on again. If the problem continues, contact an Authorized FANEM Service Technician.
Radiant heat not being supplied, even though the monitor indicates normal operation.	Mains supply voltage is below the voltage specifications.	Check the mains voltage. 127 V~ or 220 V~ ± 10%
The radiant heater continues heating (power bar not at 0%), even when the reflector has been shifted to the side.	Shifted reflector sensor failure	Contact the authorized FANEM Technical Assistance service team.
System does not accept moving into Skin Mode and remains in Manual Mode.	Skin temperature T1 sensor disconnected.	Connect the skin temperature T1 sensor.
Auxiliary temperature T2 sensor reading does not appear on the monitor.	Temperature T2 sensor disconnected or with a defect.	Connect the auxiliary temperature T2 sensor. If the problem continues, replace the sensor.
The transport battery charge lasts little (far less than two hours). Batteries do not recharge.	Batteries worn out.	Contact the authorized FANEM Technical Assistance service team.
Calibration of the oxygen cell at 21% results in a percentage other than 21% ±1%.	Oxygen cell has a defect. Oxygen cell is disconnected. Oxygen cell is saturated.	1. Check whether the cell is connected to the side panel of the Infant Warmer. 2. Replace the cell. 3. If the problem continues, contact the authorized Fanem Technical Assistance team to replace and fully calibrate the cell.
Bilitron Bed® does not emit radiation, even though the indicator shows that it is turned on.	Connector of the Bilitron Bed® disconnected or incorrectly connected to the system.	Check whether the connector of the Bilitron Bed® is connected to the column of the Infant Warmer.

Some Super LEDs of the Bilitron Bed® do not light up.	Super LED lamps are burned out.	Contact the authorized FANEM Technical Assistance team.
The Super LEDs of the Bilitron Bed® light up but are weak.	Radiation level is set on "low". Lifetime of the Super LEDs exceeds 10,000 hours.	Set the radiation level on high. If the problem continues, contact an Authorized FANEM Service Technician.
The thermal mattress does not heat up. Message "Thermal mattress with no sensor".	Connector of the thermal mattress disconnected or incorrectly connected to the system.	Check whether the connector of the thermal mattress is connected to the column of the Infant Warmer.
Pulse oximeter readings are unstable.	Sensor incorrectly positioned.	Check the positioning of the sensor.
Pulse oximeter is not functioning. Message "Pulse oximeter failure"	Communication failure with the oximeter module.	1. Reboot the system. 2. If the problem continues, contact an Authorized FANEM Service Technician.
Weight on the scale shows -8.888 kg.	Connection failure in the scale. Excess weight on the bed.	Check whether the connector of the scale is connected to the column of the Infant Warmer. Check whether the weight on the bed is over 10 kg. If the problem continues, contact an Authorized FANEM Service Technician.
Audible Alarm on the Blender (CPAP Module)	Gas inlet line with unbalanced pressure.	1. Check whether the Air/O_2 intake pressures on the CPAP are equalized at 3.5Kgf/cm^2 2. Check the difference in intake pressures, which should be less than 1.4Kgf/cm^2 3. If the problem continues, contact an Authorized FANEM Service Technician.
No Bubbles in the CPAP Bottle	Pressure Leak.	1. Check the flow set point parameters. 2. Check the circuit connections, close the cannula outlet with your fingers and check whether bubbles are generated. 3. Check for any leakage in the newborn's nostrils or mouth, in case the size of the cannula needs to be changed.
Alarm indicating low water level in the Fog 1140 humidifier, even though there is sufficient water in the tank.	Bad contact between the humidifier jar and the base.	Clean and/or dry the housing of the humidifier jar.

Troubleshooting for AMPLA® 2085 Infant Warmer with LED Display Monitor

Symptom	Possible Cause	Solution
Monitor does not turn on, with power failure alarm.	Blown fuse.	Check fuses in the side panel.
Image is frozen on the screen and does not respond to any command.	Failure in the main microprocessor.	1. Reboot the system. 2. If the problem continues, contact an Authorized FANEM Service Technician.
Display monitor with incorrect and random indications and improper functions.	Excess EMI (Electromagnetic Interference) from the hospital power supply. Excess EMI due to electromagnetic radiation.	Turn off the unit and turn it on again. If the problem continues, contact an Authorized FANEM Service Technician.
Radiant heat not being supplied, even though the monitor indicates normal operation.	Mains supply voltage is below the voltage specifications.	Check the mains voltage. 127 V~ or 220 V~ ± 10%
The radiant heater continues heating (power bar not at 0%), even when the reflector has been shifted to the side.	Shifted reflector sensor failure	Contact the authorized FANEM Technical Assistance service team.
System does not accept moving into Skin Mode and remains in Manual Mode.	Skin temperature T1 sensor disconnected or damaged.	Connect the skin temperature T1 sensor. If this does not work, replace the sensor.
Auxiliary temperature T2 sensor reading does not appear on the monitor.	Temperature T1 sensor disconnected or with a defect. Temperature T2 sensor disconnected or with a defect.	Check T1 sensor. Connect the auxiliary temperature T2 sensor. If the problem continues, replace the sensor.
Weight on the scale shows 8.888 kg.	Connection failure in the scale. Excess weight on the bed.	Check whether the connector of the scale is properly connected to the column of the Infant Warmer. Check whether the weight on the bed is over 10 kg. If the problem continues, contact an Authorized FANEM Service Technician.

Note: if the problem continues, call the closest Authorized FANEM Technical Assistance in your city.

8. Warranty and Technical Assistance

As with all FANEM® brand equipment, this one is also covered by a total one-year warranty against defects in materials and workmanship (see enclosed warranty statement).

For any type of maintenance, whether during or outside the warranty period, always contact an authorized FANEM Service Technician. Do not allow third parties, without the appropriate technical training, to accidentally damage or alter the original characteristics of your equipment.

Always use original FANEM® parts.

Registered with the Ministry of Health under No. 10.224.620.067

Technical Responsible

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