USER'S MANUAL

FANEM®
SÃO PAULO – BRASIL

NEONATAL INCUBATOR
1186 MODEL

Segurança
OCP-0004 Compulsório INMETRO

Norma Técnica - NBR IEC 60601-1
NBR IEC 60601-1-2
NBR IEC 60601-2-19
NBR IEC 60601-2-49

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CONTENT

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1186 NEONATAL INCUBATOR

1 - Equipment Identification

The FANEM® 1186 Neonatal Incubator has been developed to fulfill the most varied requests for models, enabling the assembly from a basic equipment up to an assortment of optionals.

By using a high technological level in its operation platform, it provides an easy interaction, ensuring the user a higher control of all operating parameters. Having three kinds of control panels, one may choose an intensive care incubator with the possibility to install all available optionals, or an intermediary incubator with led's display or even a basic incubator only with air and skin control and led's display.

The 1186 Neonatal Incubator aims at the following purposes:

- Effective insulation of the newly born regarding the contaminant agents which are transported through the air; this insulation is performed through the supply of a micro-filtered air which is admitted in the incubator.
- To enable the full visualization and access to the newly-born by means of a transparent acrylic dome of optical quality. The dome has front and back access panels.
- The newly-born warming by means of a controlled air circulation environment and uniform distribution of heat. There are two possible temperature control systems, one by means of the internal air temperature monitoring and another one by means of the skin temperature monitoring of the newly born. The user may also use an auxiliary temperature sensor (optional).
- To enable different concentrations of oxygen under the integral way, or simultaneous mixture with the ambient air, via two modes, the oxygen limiting valve or micro processed control (optional) using oxygen sensors on the dome.
- To enable the ambient humidification where the newly born is, by means of two possible manners, through the humidity passive system or through integrated micro control active system (optional).
- Another possible optional is the integrated pulse oxymeter to be used as a continuous non-invasive monitor of arterial oxygen saturation (SpO2) and the pulse frequency of neonatal patients. Its use in the 1186 incubator jointly with other monitoring and control instruments provides easier way to check the vital signs of the newly-born.
- To enable the newly-born weight monitoring in the internal ambient of the dome with the Scales Kit (optional), without the need to remove or handle the patient from the incubator for that control.

This User's Manual provides general instructions for installation, use, operator's maintenance and failure diagnosis of the 1186 Model Incubator. Fanem® will not be responsible if the user does not operate the unit according to its instructions, if the maintenance recommendations in this manual are not followed or if any repair is made with unauthorized parts. Calibration and repairs must only be performed by qualified servicing. Any additional information may be evaluated by your local distributor.

This manual must be fully read and understood and must be accessible to any person who will work with the unit. When not in use, the User's Manual should be kept with the Incubator. Should there be further clarifications, please, contact the Fanem® representatives for additional information.

2 - Technical Specifications

2.1 - 1186 Neonatal Incubator

2.1.1 - Definitions

- **Control Zone:** Central Point located at 10 cm on the center of the mattress surface.
- **Incubator Temperature:** Air Temperature, measured in the Control Zone.
- **Control Temperature:** Controller's temperature setting selected by the user.
- **Incubator Stability Condition:** It is a condition reached when the Incubator temperature does not vary to over 1,0 °C for a period of 1 hour. These measures are read in Control Temperature of 32 °C and/or 36 °C.
- **Temperature Rising Time:** The time necessary for the Incubator to raise the temperature in 11°C, when the Air Control Temperature is less 12°C higher than the ambient temperature.
- **Temperature Uniformity:** The quantity by which the average temperature in each one of the four points at 10 cm above the mattress surface, it differs from the Incubator Average Temperature under the condition of the Incubator stability.
- **Temperature Variation:** The difference between the Incubator Temperature and the temperature average during the Temperature Stability Condition.
- **Excess Temperature:** The internal temperature that surpasses the Incubator average temperature under the Temperature Stability Condition, as a result of the change of the temperature control.
- **Measurements Points:** Measurements performed in 5 points in a parallel plan at 10 cm above the mattress surface. A point is found at 10cm above the mattress center, the other 4 points are found in the center of 4 areas formed by lines, which divide both the width and the height in two parts.
- **ATC:** Control mode where the temperature is automatically controlled by the Air Temperature Sensor at a value set by the user.
- **ITC:** Control mode where the Air Temperature is controlled and which has the additional capacity to automatically control the Incubator Air Temperature so as to maintain the temperature as it was measured by a Skin Sensor, close to the value set by the user.
- **Routine Calibration:** The act of calibrating the Incubator or its other functions, as per the manufacturer's pre- established standards.

2.1.2 - Electrical Specifications

♦ Feeding Tension	127V~ or 220V~ or 240V~
♦ Network Frequency	50/60 Hz
♦ Nominal Current	5A -127V~ / 3A -220 and 240V~
♦ Scape Current	< 100 µA
♦ Inlet Power	
➢ LED panel with no optionals	300 W
➢ LCD panel with optionals	350 W
♦ Network Outlet Power (Auxiliary Switches)	150 W (each switch)
♦ Motor Group Power	50 W
♦ Humidifier Group Power	120 W
♦ Ergometric Support Power	180 W
♦ Rechargeable Battery	9V ⎓

Fuses

Model / Use	Fuse
♦ Incubator 1186 - 127V~	5 A – F Type
♦ Incubator 1186 - 220V~ or 240V~	3 A – F Type
♦ Ergometric Support 127V~	3 A – F Type
♦ Ergometric Support 220V~ / 240V~	2 A – F Type
♦ 4 Auxiliary Switch Set – 127V~	7 A – F Type

Model / Use	Fuse
♦ 4 Auxiliary Switch Set 220V~ / 240V~	3 A – F Type
♦ 6 Auxiliary Switch Set 127V~	10 A – F Type
♦ 6 Auxiliary Switch Set 220V~ / 240V~	5 A – F Type

2.1.3 - Classifications and Characteristics

♦ Insulation Class	Class I
♦ Applied Part	BF Type
♦ Protection Against Water Inlet	IPX4
♦ Protection Against Explosive Atmospheres	Non AP / Non APG
♦ Maximum % of CO_2	< 0,2%
♦ Air Speed on mattress	< 0,35 m/s
♦ Internal Noise (ambient <45 dBA)	< 50 dBA

NOTE: Values and classifications as per the NBR IEC 60601.1and NBR IEC 60601.2.19 norms

2.1.4 - Control Characteristics

Air Temperature and Skin Temperature

♦ Performance Range of Air Temperature and Skin Temperature Display	17,0 – 50,0 °C
♦ Temperature Indication Resolution	0,1ºC
♦ Control Precision – Air and Skin Mode	± 0,2 °C
♦ Temperature Rise Time	30 min
♦ Excess Temperature	0,8ºC
♦ Temperature Uniformity	< 0,6ºC
♦ Temperature Variation	± 0,2ºC
♦ Control Range – Air Mode	20,0 - 39,0 °C Key > 37 °C
♦ Control Range – Skin Mode	34,0 – 38,0 °C Key > 37 °C

Oxygen System

♦ Display Resolution	1%
♦ O_2 Display Performance Range	18% to 100%
♦ Control Range – O_2	21% to 65%
♦ Control Precision – O_2 (Calibration in 100%)	3%
♦ Control Precision – O_2 (Calibration at 21%)	5%
♦ O_2 Inlet Maximum Flow	30 lpm
♦ O_2 Sensor Calibration (ServoControlled Mode)	7 days
♦ O_2 Sensor Calibration Pressure	600 a 900 mm Hg
♦ O_2 Sensor Operation Temperature Range	20 °C - 41 °C
♦ O_2 Inlet Nipple(ServoControlled Mode)	Thread 9/16" – 18UNF

Humidity System

♦ Display Resolution	1%
♦ Humidity Display Performance Range	20% to 100%
♦ Control Range – Relative Humidity	30 % to 95 %
♦ Control Precision – Relative Humidity	± 5 %
♦ Reservoir Capacity	950 ml
♦ Operation Time* – Maximum Capacity Reservoir	24 $\pm$ 1 h @ 85% Relative Humidity

* For ambient temperature 23º+/- 1ºC and Control Temperature 34ºC

Weighing System - Scales

♦ Display Resolution	0,2g
♦ Performance Range - Weight	0 to 10Kg
♦ Indication Precision	± 0,4 g

2.1.5 - Physical Characteristics

Incubator on Fixed Support

♦ Width	107 cm
♦ Depth	56 cm
♦ Height	138 cm
♦ Height – Mattress Level	98 cm
♦ Weight with Rods and Shelves	77 kg
♦ Weight without Rods and Shelves	65 kg
♦ Rotating Wheel 4" - Brake with brake (5" - with optional brake)	4 units

Incubator on Ergometric Support

♦ Width	107 cm
♦ Depth	56 cm
♦ Height (Min. and Max.)	134 to 154 cm
♦ Height – Mattress Level (Min. and Max.)	94 to 114 cm
♦ Weight with Rods and Shelves	80 kg
♦ Weight without Rods and Shelves	68 kg
♦ Rotating Wheel 4" - Brake with brake (5" - with optional brake)	4 unit.

Dome/ Bed Specifications

♦ Oval Ports*	5 units
♦ Iris Sleeve	1 unit
♦ Access Panel*	Front + Rear
♦ Diffuser for Pipe Passage *	4 left + 4 right
♦ Mattress Dimensions	34 cm x 63 cm
♦ Mattress/ Access Panel Passage Height	21 cm
♦ Mattress Elevation (Trendelenburg and Reverse)	± 10º

* Variations according to dome models.

2.1.6 - Maximum Loads

♦ Serum Support	2 kg
♦ Auxiliary Shelves	10 kg per shelf
♦ Bed	7 kg

2.1.7 - Alarms

System Alarms

♦ Power Failure	Actuate if power failure occurs for the Incubator or if the power wire i accidentally disconnected from the system.
♦ Air Circulation Failure	Actuated when the internal air flow is interrupted. Performance Time afte the failure up to 120 seconds.
♦ System Failure	Actuated when an internal failure occurs in the control microprocessor.

Attention: When the incubator is turned on, the Air Circulation Failure Alarm remains unactuated during 40 minutes, becoming active after this period is elapsed.

Attention: The temperature setting values will remain memorized.

Temperature Alarms

♦ High Temperature	Actuated at 38,0°C for temperature settings lower than 37 ºC. Actuated at 40,0°C for temperature settings higher than 37 ºC.
♦ Low Air Temperature	Actuated if the Air Temperature on the dome is 3,0 ºC below the settin point.
♦ High Air Temperature	Actuated if the Air Temperature on the dome is 1,5 ºC higher than the settin point.
♦ Skin Temperature High	Actuated if the NB Skin Temperature is 1,0 ºC higher than the setting point.
♦ Skin Temperature Low	Actuated if the NB Skin Temperature is 1,0 ºC below the setting point.
♦ Sensor Failure	Actuated when the Patient Sensor plug is disconnected or when the sensor wire has a poor contact or even if the sensor is loosened off the Patient skin. It only actuates on Skin Mode.

Oxygen Alarms (optional)

♦ Low Oxygen %	Actuated when the internal concentration of O^2 is higher than 3% below th setting point.
♦ High Oxygen %	Actuated when the internal concentration of O^2 is higher than 3% above th setting point.
♦ Calibration Failure O^2	Actuated when an operational failure occurs during the Oxygen Sensc calibration process.
♦ Sensor Failure	Actuated when the Oxygen Sensor/UR plug is disconnected or when th sensor wire has poor contact or when one of the cells has its date expired.

Humidity Alarms (optional)

♦ H2O Low Level	Actuated if the water level is reduced below the pre--determined level.
♦ High Humidity - % UR	Actuated if the internal relative Humidity % UR is higher than 10% above th setting point.
♦ Sensor Failure	Actuated when the Oxygen/UR Sensor Plug is disconnected, or when th sensor wire has poor contact.
♦ Alarm of Low Concentration of UR	Activated if internal relative humidity % UR it is lesser of what 10% below of the adjustment point (Version 1186 Panel LCD).

2.1.8 - Alarms – Silencing / Restoring

Press to Silence	Alarm Type
For standard, the time of duration of the suspension of sonorous alarm of the incubadora is of 15 minutes. However, in case that he has been requested, the incubadora will come adjusted of plant with time of equal suspension the 5 minutes. • Pressures the keyboard key To inhibit sound to silence per 15 minutes (or 5 minutes, case this configuration has been requested). • It pressures the keyboard key To inhibit sound one more time to desinibir the sonorous alarms.	♦ Low Air Temperature/ Skin ♦ High Air Temperature / Skin ♦ Low Water Level ♦ Oxygen High Concentration ♦ Low Oxygen Concentration ♦ Low SPO2/BPM Level ♦ High SPO2/BPM Level

Press to Restore	Alarm Type
♦ Restore	♦ Skin Sensor Dislodging ♦ Water Shortage

Note: Cancel the alarm if the alarm mode does not exist any longer.

During first the 40 minutes after to bind the incubadora, will have sonorous and visual alarm for all the alarm conditions, except the following ones:

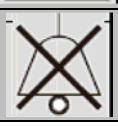
- Lack of Air circulation: sonorous nor visual alarm does not occur
- Low Air temperature: sonorous nor visual alarm does not occur
- Low skin temperature: sonorous nor visual alarm does not occur
- Low concentration of Humidity: sonorous nor visual alarm does not occur
- Water lack in the reservoir: sonorous nor visual alarm does not occur

After the ending of 40 minutes, the alarms above cited come back to operate completely (sonorous and visual detonation). Such conditions serve to prevent constant alarms while the incubadora reaches the stabilization.

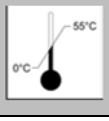
2.1.9 - Circumstantial Requirements

♦ Operation Temperature Range	19 ºC to 28 ºC – Ambient
♦ Storage Temperature Range	0 ºC to 55 ºC – Ambient
♦ Operation Humidity Range	15% a 95% - Non Condensing
♦ Storage Humidity Range	0% a 90% - Non Condensing
♦ Humidity Sensor Operation Range	20 °C to 42 °C
♦ Oxygen Sensor Operation Range	20 °C to 41 °C
♦ O^2 Sensor Calibration Pressure	600 to 900 mm Hg
♦ O^2 Inlet Maximum Pressure, Servo	3,5 kgf/cm2

2.1.10 - Symbols

	BF Type Applied Part	IPX4 Equipment Protected Against Liquid Dripping	
	Class I Equipment		Attention: Electric Shock Risk
O	OFF (Without Feeding Electric Tension)		ON (With Feeding Electric Tension)
	Attention: Potential risk for people		Alternate Current
	Obligatory Grounding		Protection Grounding
	Attention: Hot Surface		Equipment not adequate with inflammable anesthetic mixtures
	Attention: Refer to Manual		Attention: Potential Damage to the equipment and its parts
	Inhibit Sound		Contrast

2.1.11 - Symbols – Packaging

	Fragile		This side up
	Protect against Sun Light		Protect from Rain
	Stacking Limit		Attention: Refer to accompanying documentation
	Temperature Limit for transport and storage		Hooks or bores prohibited

2.2 - Technical Specifications - Kit for Integrated Pulse Oxymetry

Indication:

♦ SpO^2 Measures	1 to 100%
♦ Pulse Measures	20 to50 bpm

Alarms:

♦ SpO^2 High	Set 0 to 100%.
♦ SpO^2 Low	Set 0 to 100%.
♦ High BPM	Set 0 to 250.
♦ Low BPM	Set 0 to 250.
♦ Disconnected Sensor	when the sensor is not plugged to the device.
♦ Dislodged Sensor	when the sensor is plugged to the device but disconnected from the patient.
♦ Movement	indicates that the sensor is moving.

Alarm Sound Inhibition: The sound is inhibited by pressing the "INHIBIT SOUND" key, the heart beat BIP may only be inhibited being on the oxymeter screen; a graphic information of the inhibited sound will be displayed on the oxymeter screen.

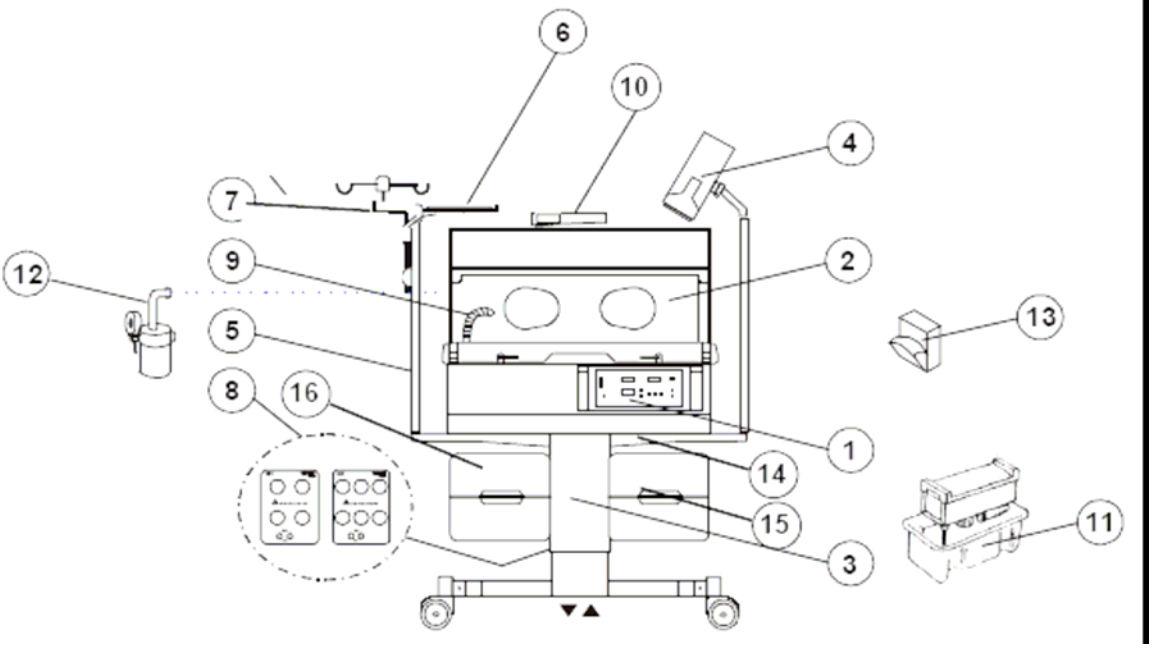
Attention: All alarms, when actuated, turn on the red led on the control panel.

Attention: Whenever the oxymeter is used, check for the alarm limits to ensure that the are appropriate for the patient that is being monitored.

Attention: Optional item.

3 - Parts, Pieces and Accessories

Code	Tension	Description
093.004.700 093.004.800 093.004.850	127V~ - 50/60Hz 220V~ - 50/60Hz 240V~ - 50/60Hz	Dome with 5 oval ports / 1 iris sleeve / 2 Access Doors (Front and Rear) / 8 Pipe Conductor. Basic Control Panel with no optionals
093.006.700 093.006.800 093.006.850	127V~ - 50/60Hz 220V~ - 50/60Hz 240V~ - 50/60Hz	Dome with 05 oval ports / 1 iris sleeve / 2 Access Doors (Front and Rear) / 8 Pie Conductor. LCD Graphic Control Panel (enables installation of all accessories)



ITEM	DESCRIPTION	CODE
1	Control Unit 1186 Panel LED (without optionals) – 127V~ - 50/60Hz Control Unit 1186 Panel LED (without optionals) – 220V~ - 50/60Hz Control Unit 1186 Panel LED (without optionals) – 240V~ - 50/60Hz	093.051.700 093.051.800 093.051.850
	Control Unit 1186 Panel LCD with (optionals) – 127V~ - 50/60Hz Control Unit 1186 Panel LCD with (optionals) – 220V~ - 50/60Hz Control Unit 1186 Panel LCD with (optionals) – 240V~ - 50/60Hz	093.053.700 093.053.800 093.053.850
2A	2PA Dome with 05 oval ports / 1 iris sleeve / 2 Access Doors (Front and Rear) / 8 Pipe Conductor / Compartment (enables installation of all accessories)	093.053.600
2B	Dome Double Wall 2PA	093.100.321
	Access Panel Double Wall	092.116.321
3	Fixed Support - SFV	092.146.600
	Ergometric Support – SEV – 127V~ -50/60Hz	092.063.700
	Ergometric Support – SEV – 220 / 240V~ -50/60Hz	092.063.800
4	Bilispot® Phototherapy 006BB – 127V~ -50/60Hz	006.020.700
	Bilispot® Phototherapy 006BB – 220V~ -50/60Hz	006.020.800
5	Right Left Vertical Rod Kit G3 G3 - without arm (for bumper)	094.052.600
	Left Vertical Rod Kit G3 G3 - without arm (without bumper)	094.050.600
	Right Vertical Rod Kit G3 G3 - without arm (without bumper)	094.051.600
6	Rotating Shelf G3 for Breathers	094.054.600
7	Column Serum Support G3	094.053.600

8	4 Auxiliary Switches Kit	090.051.600
	6 Auxiliary Switches Kit	090.082.600
	4 Electric Auxiliary Plugs Set IEC Snap-Fit type	094.058.900
	6 Auxiliary Switches (Schuko Type) Kit	090.147.600
9	Breather Adapter "Goose Neck"	013.050.600
10	Bilitron® Phototherapy 3006 BTI	006.001.900
11	Motor group cleaning and disinfection tank – EMA model	086.100.321
12	Recirculating humidifier (only applicable on 1186-STD)	087.000.600
13	Adhesive Box for patient's sensor (50 units)	086.076.600
	Adhesive Box for patient's sensor (100 units)	086.068.600
14	Surrounding Bumper Kit	094.055.600
	Lateral Bumper Kit	094.056.600
15	Big Drawer Set - GV (Right)	090.078.600
16	2 Drawers Set –GG (Left)	090.079.600
17	Manual Reanimator with Mask 0 (not illustrated)	020.010.600
18	Oxygen Servocontrol Kit 127V~ (not illustrated)	093.054.700
	Oxygen Servocontrol Kit 220 / 240V~ (not illustrated)	093.054.800
19	Humidity Servocontrol Kit 127V~ (not illustrated)	093.055.700
	Humidity Servocontrol Kit 220V~ (not illustrated)	093.055.800
	Humidity Servocontrol Kit 240V~ (not illustrated)	093.055.850
20	Integrated Pulse Oxymetry Kit (not illustrated)	093.054.900
21	Integrated Scales Kit (not illustrated)	093 056.900
22	Box with disposable sensor (50 units)	092.162.600

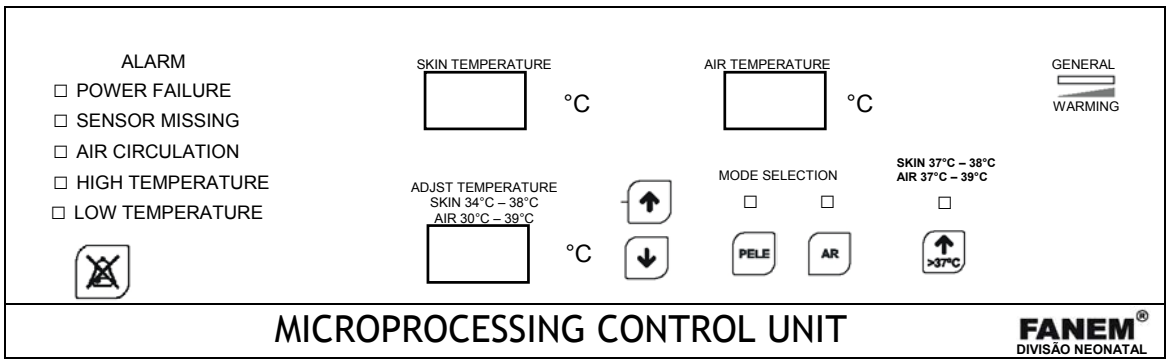
3.1 - 1186 Control Unit

In order to make the installation of optionals flexible, different Control Unit Models have been devised. Therefore, the 1186 Neonatal Incubator may be supplied with 2 types of Control Unit:

- 1186 Control Unit LED Panel LED without optionals;
- 1186 Control Unit LCD Penel with optionals.

Exclusive use with the 1186 Neonatal Incubator

3.1.1 1186 Control Unit Panel with LED's – Air and Skin Mode Control - No Optionals



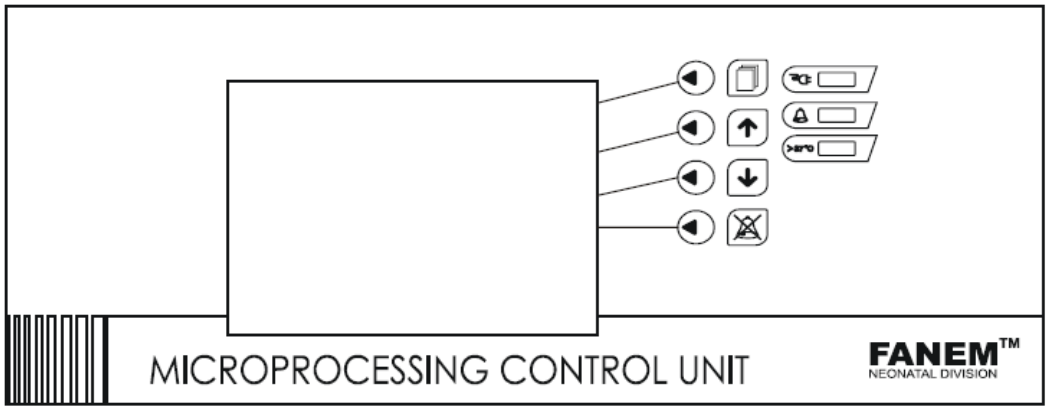
This Control Unit will always accompany the basic 1186 Neonatal Incubator. Its front panel is made up of numeric displays and led's, which inform in a single manner and aims at the programmed and controlled parameters.

As it is a basic Model, the installation of the Humidity ServoControl, Oxygen ServoControl, Integrated Scales and Pulse Oxymeter optionals **IS** not possible.

Description		Code
1186 Control Unit Panel	(LED w/no optionals) – 127V~ - 50/60Hz	093.051.700
1186 Control Unit Panel	(LED w/no optionals) – 220V~ - 50/60Hz	093.051.800
1186 Control Unit Panel	(LED w/no optionals) – 240V~ - 50/60Hz	093.051.850

Attention: The Humidity Servocontrol, Oxygen Servo Control, Integrated Scales an Pulse Oxymeter Optional Items MUST not be installed in this Control Unit.

3.1.1 - 1186 Control Unit Panel with Graphic LCD Display Air, Skin Mode Control and Servo-Active Humidity with all optionals available



This Control Unit may accompany the 1186 Neonatal Incubators with all kinds of available optionals. Its front panel contains a graphic LCD Display, which fully informs the programmed and controlled parameters such as the temperature graphs, Humidity, oxygen, weight (optional), saturation, beats and plestimographic curves (Integrated Oxymeter – optional). It also has the advantages of preventive maintenance control, integrated clock, language selection, etc.

Description		Code
1186 Control Unit Panel	(LCD w/ optionals) – 127V~ - 50/60Hz	093.053.700
1186 Control Unit Panel	(LCD w/ optionals) – 220V~ - 50/60Hz	093.053.800
1186 Control Unit Panel	(LCD w/ optionals) – 240V~ - 50/60Hz	093.053.850

Attention: All optional items may be installed in this Control Unit.

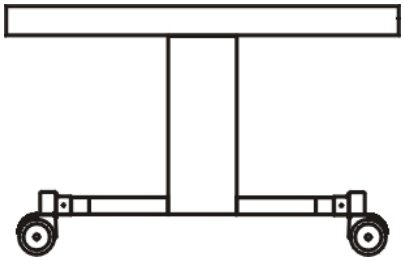
3.2 - Supports

The 1186 Neonatal Incubator may be supplied with two support options, the Fixed Support – SFV and the Ergometric Support – SEV.

Attention: The Ergometric Support – SEV is an optional item.

3.2.1 - Fixed Support – SFV – Re.: 090.050.600

Fixed height support SFV model (Re. 090.050.600), made up of 4 rotating wheels with brake. This support may optionally be supplied with a set of drawers or cabinets, as per item 3.4 Drawers and Cabinets.

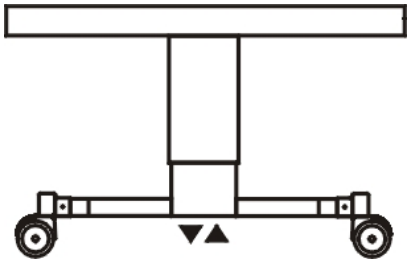


092.146.600

Exclusive use with the 1186 Neonatal Incubator

3.2.2 - Ergometric Support – SEV

Optional Support, of variable height, SEV model, electrically actuated, with a total course of 200mm, having 4 rotating wheels with brake. See reference chart below:



Support Type	Voltage (Volts) V~	Frequency Hertz (Hz)	Re: FANEM Code
Ergometric	127	50/60	092.063.700
Ergometric	220 / 240	50/60	092.063.800

Exclusive use with the 1186 Neonatal Incubator

3.3 - 5" (127mm) wheels with brake – RE.:090.191.600

It raises the incubator at 12,5mm, in addition to providing lesser effort to move the equipment.

Attention: Optional Item.

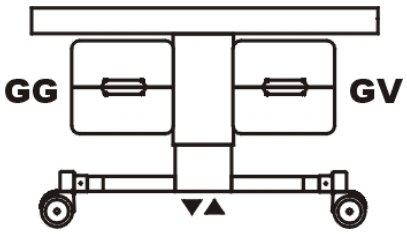
Exclusive use wit the 1186 Neonatal Incubator

3.4 - Drawers and Cabinets

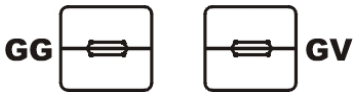
The may be installed on the two types of supports, the fixed one and the ergometric one. Both on the right and left sides.

There are two chest of drawers type, one with two drawers and other with a big drawer. Of these can just be chosen one model for each side, in other words, one right and one left. The references are:

Drawers



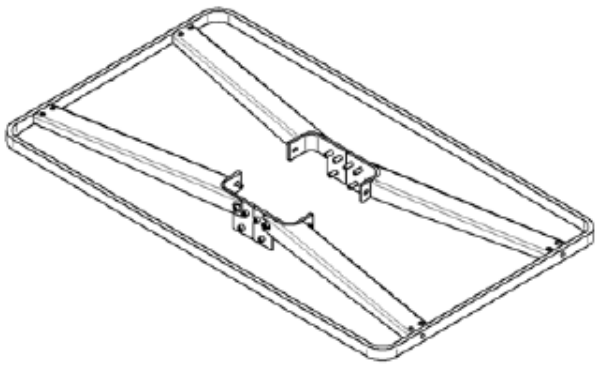
Drawer/Cabinet	Re. FANEM
1 Big Drawer Set GV - Right	090.078.600
2 Drawers GG - Left	090.079.600



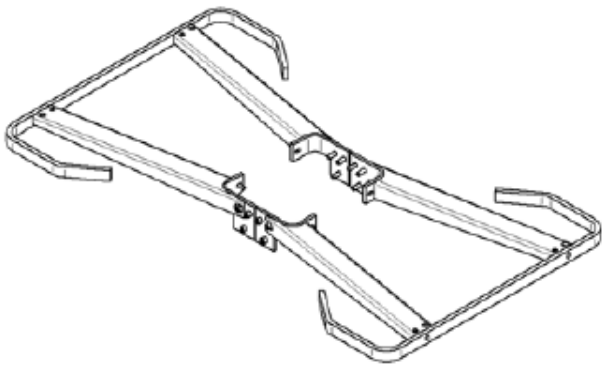
Attention: Optional Item.

3.5 - Bumpers

In order to protect the 1186 Neonatal Incubator, mainly during its transportation, two types of bumpers may be installed. One Surrounding Model, which protects the entire Incubator perimeter, and another lateral one, which protects the sides of the Incubator.



Surrounding Re.:093.070.600



Lateral Re.:093.069.600

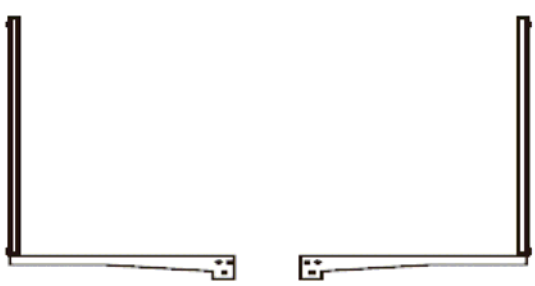
Attention: Optional Item.

Attention: When installing the Bumper Kit in the 1186 Neonatal Incubator, if th installation of a Vertical Rod is required, use Right or Left Rod (without arm RE.:094.052.600.

Exclusive Use with the 1186 Neonatal Incubator

3.6 - Vertical Rods

The 1186 Neonatal Incubator may have Vertical Rods, one Right and One Left one, which may support the Rotating Shelf and the Serum Support Kit. The installation of the rods is independent of the support configuration, and may be installed on the fixed and ergometric supports, such as any configuration of drawers and cabinets.



094.050.600 (LEFT with arm)

094.051.600 RIGHT(with arm)

094.052.600 (RIGHT OR LEFT (without arm)

Attention: Optional Item.

Attention: The Right or Left Rod (no arm) RE.:094.052.600 may only be requested if Bumper Kit is installed. If there is not a bumper installed, request Rod Kit (with arm).

Exclusive use with the 1186 Neonatal Incubator

3.7 - Rotating Shelf

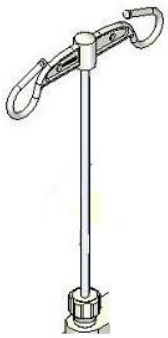
Rotating Shelf that can be fixed on the top of the Vertical Rods, one per rod. Ideal for monitor coupling, breathers and infusion pumps, each shelf supports the maximum load of 10kg.

Right Rotative Shelf	094.054.600
Left Rotative Shelf	094.065.600

Attention: Optional Item. Each shelf depends on a Vertical Rod to be installed.

Exclusive use with the 1186 Neonatal Incubator.

3.8 - Saline Solution Support – REF: 094.053.600



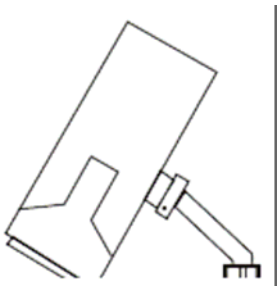
Saline solution support of adjustable height , fixed close to column of the vertical pole.

Attention: Optional item that depends on the installation of a Vertical Rod.

Exclusive use with the 1186 Neonatal Incubator

3.9 BILISPOT 006 BB Phototherapy

Halogenous lamp phototherapy that provides high beam intensity, it has two filtering systems for infrared rays and ultraviolet rays, which are harmful to the skin. The BILISPOT® 006 BB Phototherapy Unit is fixed on a Vertical Rod providing higher mobility to the unit. See reference chart below.



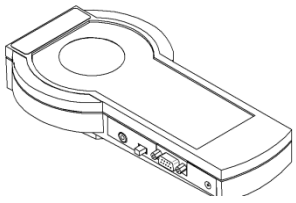
	Voltage (Volts) V~	Frequency Hertz (Hz)	Re: FANEM Code
006 BB	127	50/60	006.020.700
006 BB	220	50/60	006.020.800

Attention: Optional item that depends on the installation of a Vertical Rod.

Product registered at ANVISA nr. 10.224.620.002

3.10 BILITRON® 3006 BTI Phototherapy - RE:006.001.900

Phototherapy with a luminous fountain formed by 5 Super Led´s of high intensity, which provide an irradiation of centralized light in the blue spectrum of the wave length of 460nm. The BILITRON® 3006 BTI Phototherapy Unit has anti -sliding supports, which allow placement on dome in a practical manner, without damaging it.



Attention: Optional Item.

Product registered at ANVISA under nr. 10.224.620.049

3.11 Humidity Servo System

The Humidity Servo System controls the dome internal Humidity as it has an immersed sensor in this ambient. With a boiling system to generate vapor, it provides programmed Humidity by the user.

	Voltage (Volts) V~	Frequency Hertz (Hz)	Re. FANEM Code
Humidity System	127	50/60	093.055.700
	220	50/60	093.055.800
	240	50/60	093.055.850

Exclusive use with the 1186 Neonatal Incubator

3.12 Oxygen Servo System

Servocontrolled oxygen system that constantly monitors the internal O2 concentration by means of two O2 sensors. The O2 inlet flow is automatically adjusted by means of a control valve.

	Voltage (Volts) V~	Frequency Hertz (Hz)	Re. FANEM Code
Servo Controlled Oxygen System	127	50/60	093.054.700
	220 / 240	50/60	093.054.800

Attention: Optional Item. It may be installed in the 1186 Neonatal Incubator only wit graphic LCD display panel.

Attention: The O_2 Servo System may be provided upon request for installation in plant

Exclusive use with the 1186 Neonatal Incubator

3.13 Auxiliary Switch Kit

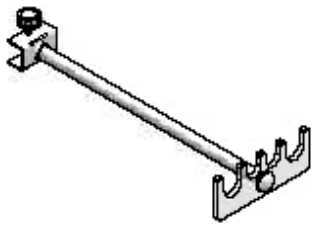
A set of Auxiliary Switches, directly fixed to the Incubator supports. This Kit may be supplied in the 4 switch configuration (Re. 090.051.600) or in the 6 switch configuration (Re.090.082.600), or even in 4 switch configuration (Schuko type) (Ref.:090.147.600) or 4 snapfit switches with 12V outlet – For auxiliary lighting and Bilitron.

Attention: Optional Item.

Exclusive use with the 1186 Neonatal Incubator

3.14 "Goose Neck" Breather Adaptor – Re.:013.050.600

The "Goose Neck" breather adaptor is fixed to the dome internal deflector, helping the fixation and directing the breather pipe towards the patient. Made of flexible metallic rod, the Breather Adaptor facilitates the direction of the breather pipes.



Attention: Optional Item.

Exclusive use with the 1186 Neonatal Incubator

3.15 Head Positioner RAM-1 Type – RE.:013.000.600

The RAM-1 Head Positioner is aimed at fixing the newly-born head, providing higher safety in the maneuvers when using the breather piping.

It accommodates the patient according to the anatomy of each head comfortably, as it has auricular protectors with horizontal adjustments. It also has height adjustment, adapting to the most varied models of breathers.

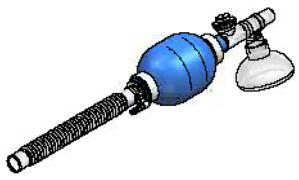
The piped patient is better fixed and it prevents the patient from abrupt movements during the medical and nursing assistance, which should cause loosening of the breathing coupling. A Flexible Adaptor comes together for the "Intubation Support" "Goose Neck".

Attention: Optional Item.

Exclusive use with the 1186 Neonatal Incubator

3.16 20 Manual Reanimator – REF: 020.010.600

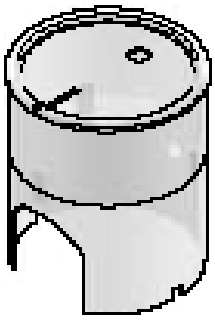
020 Model Reanimator, totally constituted in silicon, with accumulative tube of oxygen, mask "0" size, safety valve of 40 cm H2O, supplied in plastic case.



Attention: Optional Item.

Product Registered at ANVISA under number 10.224.620.036

3.17 Acrylic Helmet Mod. 016



Made of optical quality transparent acrylic, it guarantees the newly-born visualization during treatment. It enables oxygen concentrations of 90% with a small volume. Its asepsis may be easily and quickly made. It has 2 sizes that can be used in the 1186 Neonatal Incubator, as per the following table:

Size	Reference	Newly Born Weight	Total Dimensions		Front Opening for Neck	
			Diameter	Height	Width	Height
1	016.000.600	< 1000g	150mm	105mm	77mm	83mm
2	016.001.600	≥ 1000g ≤ 3600g	198mm	128mm	87mm	87mm

Attention: Optional Item.

Product registered at ANVISA under number 10.224.620.003

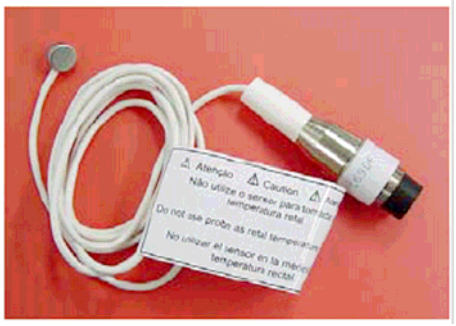
3.18 Reusable Patient Sensor - Re.:092.059.600

Put in contact with the newly-born skin, it provides the temperature control.

Attention: Optional Item.

Exclusive use with the 1186 Neonatal Incubator

3.19 Auxiliary Sensor - Re.:092.072.600



Auxiliary Sensor that may be used for monitoring of the other desired temperature.

Attention: Optional Item

Exclusive use with the 1186 Neonatal Incubator

3.20 Disposable Patient Sensor (Box with 50 units) - Re.:092.162.600

Place in contact with the newly-born skin, it provides the temperature control.

Attention: Consumption Item. Not supplied with the incubator.

Exclusive Use with the 1186 Neonatal Incubator

3.21 Adhesive Kit

Antiallergic Adhesive specially developed for the perfect fixing of the Patient Sensor to the NB skin. Provided with 50 or 100 units.

Adhesive Box	Re. FANEM
50 units	086.076.600
100 units	086.068.600

Attention: Consumption item. It is not provided with the incubator.

Exclusive Use with the 1186 Neonatal Incubator

3.22 Integrated Pulse Oxymetry Monitor Kit Re.: 093.054.900

The Pulse Oxymetry Kit - OXIMAX® - NELLCOR (Re.: 090.068.900) has been exclusively developed for the 1186 NEONATAL INCUBATOR and integrated to the 1186 Control Unit - Graphic LCD Display Panel. It is a pulse oxymeter to be used as a continuous non-invasive monitor, of arterial oxygen saturation (SpO2) and pulse frequency for neonatal patients. Its use in the 1186 neonatal incubator jointly with other monitoring and control parameters, such as Air and Skin Temperature, oxygen concentration control and monitoring , relative Humidity control and monitoring , it provides better ways to check the newly-born signs.

Attention: This kit must only be used as a complement in the medical evaluation of the patien
It must be used together with clinical symptoms and signs.

This kit uses pulse oxymetry to measure the functional oxygen saturation in the blood. The pulse oxymetry works with the use of a sensor to a pulsating arterial vascular bed, such as, for example, a finger. The sensor contains a luminous dual fountain and a photo detector.

The bones, tissues, pigmentation and venous vases normally absorb a constant volume of light during the time. the arteriolar bed pulses and normally absorbs variable amounts of light during pulsations. The absorbed light ratio is converted into a functional oxygen saturation measure (SpO_2).

Note: Once the measure of SpO2 depends on the sensor light, the excess lighting of the ambient may interfere in this measure.

Attention: Optional Item.

Exclusive use with the 1186 Neonatal Incubator

3.22.1 OXIMAX® Accessories- NELLCOR (a Tyco Co)

♦ **D-YS Sensor - Re.: 090.137.600**

reusable sensor used in babies (3 - 15kg) and in a newly-born.

For use in babies the ideal area for application is the foot big toe, with the cable along the sole of the foot.
For application in a newly-born, the ideal area for application is the anterior part of the foot sole; another alternative area would be the palm of the hand, below the fingers, with the cable along the palm.

♦ **DEC4 Extension Cable - Re.: 090.138.600**

Used when it is necessary to increase the sensor cable useful length, it actuates as a sensor extension cable.

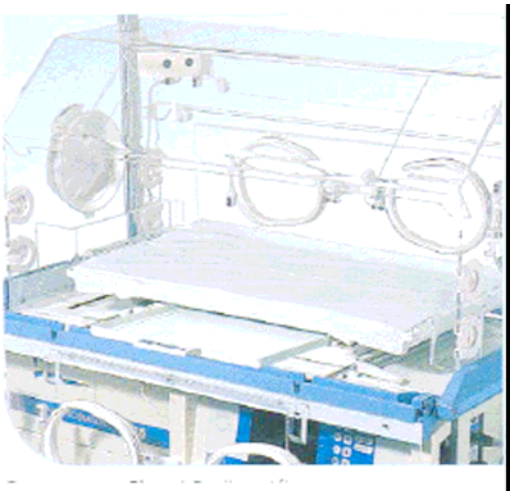
♦ **Bandages FOAN P/I sensor WRAPS - Re.: 090.151.600**

♦ **Bandages ADH-P/I sensor WRAPS - Re.: 090.152.600**

Products Registered at ANVISA under number 10.139.810.074

3.23 Scales Kit - RE.:093.056.900

Optionally, the Incubator 1186 – Display LCD may be supplied with the Scales Kit integrated with drawer for X-Rays. The weighing function is performed by means of 4 charge cells internally contained to the bed platform, thus preventing more handling with the newly-born.



ttention: Optional Item.

Exclusive Use with the 1186 Neonatal Incubator

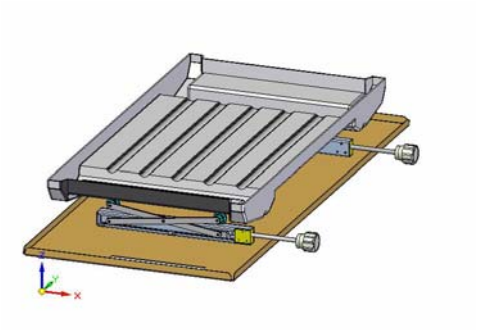
3.23.1 - Electronic Scale Microprocessada PN-91 TS - REF.: 019.007.900

Attention: Optional item

Exclusive Use with the 1186 Neonatal Incubator

3.24 Soft Inclination Bed Set – REF: 093.088.600

Manual command, with a displacement of the patient's bed for the positioning in Trendelenburg and Proclive ($\pm$ 10°) in a continuous and soft way, without clattering or abrupt movements.

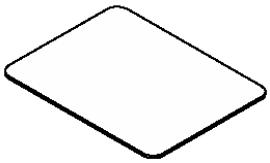


⚠	**Attention: Optional Item.**

Exclusive use with the 1186 Neonatal Incubator

3.25 Silicone Mattress – RE.:090.242.321

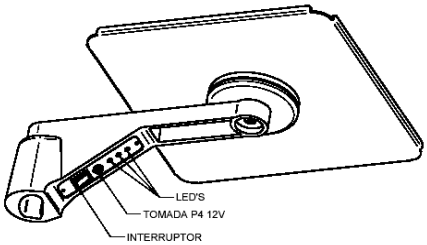
Produced with atoxic silicone of medical degree, it provides higher comfort to the newly-born, in addition to improving the thermal stability.



⚠	**Attention: Optional Item.**

Exclusive use with the 1186 Neonatal Incubator

3.26 Auxiliary illumination with LEDS – REF: 094.053.700 / 800 / 850



Coupled close to left shelf, with visualization of the Infant, it can to turn on and to turn off the illumination through the switch.

It accompanies source for Bilitron 3006 (BTI), extension cable with plug P4 for Bilitron and 4 plugs IEC Snap-Fit type.

OBS: For 4 plugs Schuko type – REF:094.054.700 / 800 / 850

⚠	**Attention: Optional item. It requests Left Shelf.**

Exclusive use with the 1186 Neonatal Incubator

3.27 Network Communication Kit – RE.:090.098.900

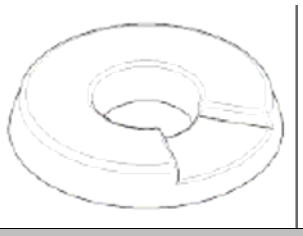
Communications system in which the neonatal information and control information present in the incubator are sent to a processing center. This may enable the storage of information of each newly-born, such as the general monitoring of the nursery in only one point. And to do so, each incubator will have a network communication kit installed plus the software.

⚠	**Attention: Optional item.**

Exclusive use of 1186 Neonatal Incubator

3.28 Neonatal Pillow – REF: 094.070.600

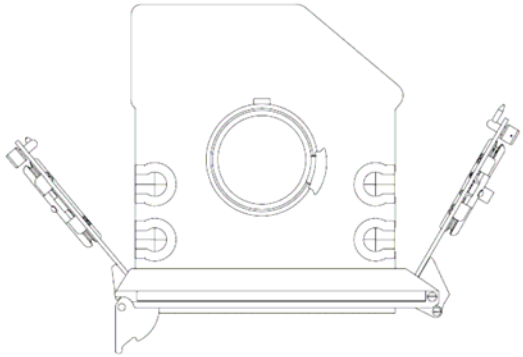
Special Density Circular Pillow, it distributes the NB head weight and releases the tensions accommodating the head on the desired condition during the CPAP procedure or phototherapy application.
It facilitates the works of the operator to avoid cranial deformity originating from lateral decubitus of the newly-born.



	**Atenção: Article of only use. Packing with 10 units. Optional item.**

Pillow Kit – Re. 094.070.600 (Package with 10 units)
Exclusive use with the 1186 Neonatal Incubator

3.29 Acrylic Dome

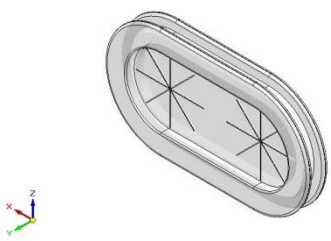


Made of optical quality transparent acrylic, the dome allows the total visualization of the newly born. It has five oval ports, it allows the neonatal manipulation both from the front part (two ports), and the rear part (two ports), in addition to having a lateral port for the outlet of materials. In the other side, in the direction of the head of the infant, there is a manga-iris for the fixation of necessary tubes in certain procedures, it possesses 2 access doors, one frontal and other back and eight tubes passages. The double intern wall of the 1186 Incubator is formed by three parts, one installed in the body of the cupola and two in the front and back access doors. The double walls optimize and improve the control of the temperatures inside the cupola.

Model	Description	Reference	Quantity
1186	Dome Internal Double Wall	090.237.321	1
	Access Door Internal Double Wall	092.116.321	2

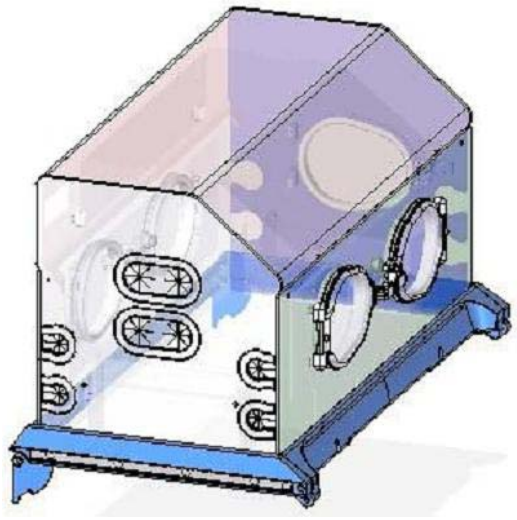
Exclusive use with the 1186 Neonatal Incubator

3.30 – Double Stuffy – REF: 090.112.322



Installed in factory close to lateral of the cupola, in the destined place the manga-iris, provides total easiness of passage and positioning of cables, fans circuits, CPAP circuits or other several applications.

Made in silicon, it is easily removable facilitating the procedures for cleaning and asepsis.



Model	Descrição	Referência
1186	Cupola with double stuffy (2X) – 1186 Incubator–Display	093.089.600
	Cupola with double stuffy (2X) – 1186 Incubator 1186–LCD Display	093.090.600

Attention: Optional item.

4 Precautions, Restrictions and Warnings

4.1 1186 Model Neonatal Incubator

Attention: This User's Manual Chapter contains information, whic are highly important to guarantee the patient's, user' and equipment safety and integrity. Read it wit ATTENTION!

- Check if the network to which the equipment will be connected has the characteristics to support the equipment electrical conditions indicated on the label that is fixed in the equipment, as well as tension and power.
- The feeding cable plug must be connected to a grounded switch, permanently fixed on the wall, according to the legislations and norms in force, for electrical installations of lower tension and electrical legislations for Health Assistance Facilities, never use extension.

Attention: Do not use multiple extensions or switches. If there is not perfect groundinç do not use the equipment.

- An incubator that is poorly used may cause serious risks to the newly-born. This incubator must be operated solely by trained and qualified personnel, who may know the risks and benefits of its use, under medical guidance.
- This incubator may not be used if any of its functions is not operating properly. The qualified technical service must be required.
- The 1186 Vision Incubator was developed for restricted use to an only patient;

Attention: The use of the incubator with more than one patient can cause infection risks crossed to the same.

- The 1186 Vision Incubator possesses filters of protection to assist the specifications of the norms of electromagnetic compatibility, however, it can be affected adversely and to suffer interferences of certain equipments, such as, surgical equipments of high frequency, defibrillators, therapies with short waves, pacemaker and other connected electric stimulators to the patient;
- Before beginning the monitorization of a physiologic parameter to observe all information and cares about operation and application of the accessories, because the incorrect use of these it can cause damages to the patient, such as burns e/ou electric discharge, in an eventual defibrillator discharge;

Attention: Patient's cables and sensor are not protected against the defibrillator effects.

- Although the patient's bed made of engineering plastic, totally electrically isolated, the use of surgical equipments of high frequency is not recommended in united use with the 1186 Vision Incubator;
- The 1186 Vision Incubator possesses in your constructive form all modules of parameters physiologic equalized to a same potential, not existing external driver of potential equalization;
- In order to prevent accidents to the patient, the dome must not be raised while it remains in the incubator or the need to raise the dome while the patient is taken care of in the incubator. All necessary accesses to the newly-born may be performed by means of the front and rear Access Panel as well as through the Ports.
- Check if the door (iris sleeve) is correctly installed, if not, the internal temperature will not stabilize.
- The Temperature Display may not reflect precisely the INCUBATOR TEMPERATURE when the Front Access Panel is open. Do not leave the Access Panel open more than necessary.
- All Access Doors and Ports locks must be perfectly safe to avoid accidental openings.
- For the patient safety, DO NOT leave the patient unaccompanied when the Access Panel or the Ports are open. DO NOT raise the dome with the patient.
- The use of infantile seats or other accessories inside the incubator, which may alter the air flow standard, may affect the temperature uniformity, the temperature variability and the incubator temperature reading correlation of the child's skin.
- Do not use mattress with heights that are different from the original mattress.
- The patient's safety and the incubator operation may be compromised if the air flow passage is not kept without obstructions (blankets, diapers, etc.) during clinical use.
- In order to avoid over heating of the patient due to direct radiation, do not position the incubator directly under solar light or under other sources of radiant heat. In those cases, the functioning condition by the air control may be compromised.
- Do not place surgical lids or blankets on the patient, neither hot air forced currents at the same time. This may cause induced heat injury and burns.
- Phototherapy units located close to the incubator may affect the dome wall temperature, incubator air temperature and the child's skin temperature.
- Never place the Skin Temperature Sensor on the child, or use it to sensor the rectal temperature.
- When in Skin Control the Skin Temperature sensor must be in direct contact with the skin to provide the patient's skin perfect temperature monitoring. If the Skin Temperature Sensor fails or is poorly positioned on the patient, it may result in over heating. Routinely, check the child's conditions for the correct positioning of the sensor and feel and observe the child's skin for overheating signs.
- When the X-Ray is taken through the dome, the acrylic dome may be shown on the image as a radiolucent shade, and may result in an incorrect diagnosis.
- For a better stability of the incubator, always lock the support wheels during use.
- For better safety, do not transport the incubator with its shelves loaded and with the Bilispot® phototherapy coupled.
- When using the Ergometric Support, always transport the incubator in its lowest height to improve stability of the set.

- For the assembly and transport of the Incubator, the procedure is recommended with a person of sufficient strength.
- When using the Incubator's shelves, take the following precautions:
  Always place the monitor on the corner of the shelf.
  Check if the monitor fit the shelf edge.
  Avoid over placing the monitors, installed on the shelf.
  Respect the maximum load limits of the shelves.
- Do not place equipment or other accessories on the dome. During an emergency it may be opened quickly.
- The additional equipment that may be connected to the patient and eventually energized through the auxiliary switch set shall be perfectly grounded and be in conformity with the electric safety norms for electro medical equipment, NBR IEC 60601.1 and its private norms or equivalent norms which are in force in the country.
- Never surpass the power range specified by the set of Auxiliary Switches, when additional equipment is energized through those switches.
- Do not actuate the command keys with your nails and do not use sharpened objects to actuate them.
- Use only original FANEM parts and accessories to ensure better safety and performance in the equipment.

Attention: Do not raise the acrylic dome while the patient is in the incubator.

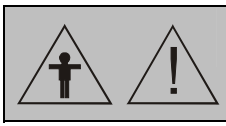
4.1.1 Danger of Explosion: Precautions

- Never use the incubator in the presence of inflammable anesthetics.
- Ensure that the supply of oxygen for the incubator is off and that the incubator is disconnected from the oxygen supply when executing the cleaning or maintenance procedures; there is risk of fire or explosion when making the cleaning and/or maintenance procedures in an environment containing oxygen.
- Keep matches, cigarettes and other sources of ignition away from the location where the incubator is located. Fabrics, oils and other combustibles ignite very easily and burn when the air is enriched with oxygen.
- Small amounts of inflammable agents, such as ethylic and alcohol left in the incubator may cause fire in contact with oxygen.

4.1.2 Oxygen: Precautions

- Improper use of supplementary oxygen may be associated with serious side effects including blindness, damage to the brain and death. The risks may vary depending on each patient. The method, concentration and duration of oxygen administration must be prescribed by a qualified medical doctor.
- If oxygen intake is deemed necessary in an emergency, the doctor in charge should be notified immediately.
- The oxygen concentration breathed by the newly-born will not determine the oxygen partial pressure in the blood (pO_2). The oxygen pressure shall be measured with appropriate techniques.
- The oxygen flow measured in the inlet valve may not be used as an accurate indication of oxygen concentration in the Incubator.

The oxygen concentration must be measured with a calibrated oxymeter, in intervals as determined by the medical doctor in charge.



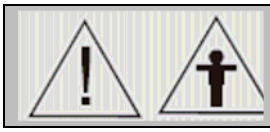
Attention: The amount of flow of oxygen marked in the back panel, is not valid when it is working in way Servocontrolado de Oxigênio. Not to connect hoses of oxygen in both niples of oxygen entrance at the same time.

- Dirt in the air filter may affect the oxygen concentration in the Incubator and/or cause the formation of carbon dioxide (CO_2). Ensure that the filter is changed in the specific periods or whenever it is necessary.
- The oxygen levels in the dome ambient may be affected when the Ports or Access Panel are open. Ensure that all dome fixtures and pipe conductors are appropriately installed. Any opening on the incubator dome may reduce the incubator internal oxygen.

Attention: Use an oxygen monitor during the intake of oxygen

4.1.2.1 Oxygen Intake – Precautions

- If oxygen intake is deemed necessary, it must fulfill the parameters as set by the medical doctor.
- Whenever there is oxygen intake, one should as a standard procedure, perform routine proofs with an Oxygen Analyzer.
- The manufacturer's instructions should be strictly followed for the use of Monitors/ Oxygen Controllers.
- The Monitors / Oxygen Controllers must be tested routinely, taking samples from the ambient and of pure oxygen, and to do so the manufacturer's instructions should be followed. If the instruments indications are correct on the two extremes, the intermediary readings will be reliable, within the required exact limits.
- The Air filter must be changed routinely, at least every three months. If the filter element is saturated, the oxygen and CO_2 concentration will increase; if the incubator is run with no air filter, the oxygen concentration will decrease and the newly-born insulation will be violated. Both cases may cause risks to the patient.
- By the time of oxygen intake, no Humidity oxygen should be used as the FANEM® incubator provides sufficient Humidity.
- Accessories that are not manufactured by FANEM®. should not be used in the incubator. The use of parts that are not manufactured by FANEM® may negatively affect the adequate operation of the incubator and may cause serious risks to the patient.



Attention: The risk of incidence of RETROLENTAL FIBROPLASIA (Retinopathy c Prematurity) is maximized when oxygen concentrations that are highe than 40% to the newly-born with cardio respiratory diseases.

- Oxygen concentrations higher than 40% are likely to be dangerous to some newly-born infants. There are also cases in which in order to raise the oxygen pressure to normal levels, it is necessary to raise the concentration to values that are higher than 60%. For this reason, it is highly important to make the analysis of gases of the arterial blood to set the concentrations of oxygen intake.

Attention: During the oxygen administration, the increase of the noise level may occur for th patient inside the incubator.

4.2 - Precautions – Kit for Integrated Pulse Oxymetry (optional)

- Biocompatibility tests have been accomplished in NELLCO^{RTM} sensors according with ISO 10993-1, biologic Assessment of medical devices. Part 1: assessment and test. Sensors have been well succeeded in the advised biocompatibility tests and, thus they are in accordance with ISO 10993-1.

Attention: Readings of pulse oxymetry and pulse frequency can be affected by some environmental conditions, errors in sensor application and specific conditions of patient.

- Inaccurate measurements can be caused by:
  - Incorrect application of sensor.
  - Placement of sensor in an extremity with a sleeve of pressure gauge, arterial catheter orintravascular access.
  - Environmental illumination.
  - Prolonged movement of patient.
- Loss of pulse can be cause by the following reasons:
  - Sensor is very tightened.
  - Sleeve of pressure gauge is inflating in the same extremity as the connected sensor.
  - There is arterial occlusion next to the sensor.
- Clean and remove any substance like adhesives from the application ares. Check periodically if sensor continues placed in a suitable mode in the patient.
- A strong illumination in the environment like surgical lamps, phototherapies Bilitron^{TM} like, or sun light can interfere in the performance of a SpO_2 sensor. Be sure the sensor is correctly applied and is covering the sensor area with opaque material, however not opening the sensor of skin temperature.
- Do not use a damaged sensor or sensor cable. Do note use a sensor with exposde optical components.

Attention: Only use NELLCOR™ sensors and sensor cables with this monitor. Other sensors and cables can offer an unsatisfactory performance in the kit for Integrated Pulse Oxymetry.

- Do not use a sensor cable to increase the sensor length (exceto o DEC 4 REF:090.138.600).

Attention: The use of more than one sensor cable can has adverse effect on the performance. Do not connect to the input port of sensor any cable suitable for use in computer. Do not connect any not yet approved device to the sensor connector FANEM.

Attention: The incorrect application or prolonged use of a sensor of SpO_2 can damage tissues. Note the regularly the sensor area according to indication in their instructions.

4.3 Spare Parts

For possible spare parts, refer to section 3 of this manual: Parts, Pieces and Accessories with the respective references.
To obtain schemes, parts, components or other additional references, please contact Fanem Ltda. or its commercial representatives.

The function and safety of this equipment are only guaranteed if the checking, maintenance and repair services are performed by the Fanem Technical Assistance or by duly trained and qualified personnel by Fanem Ltda.

Fanem Ltda. holds harmless for damages that possibly occur in the device and with consequences to the patients due to improper maintenance which are not performed by our Technical Assistance or when spare parts/accessories which are not original have been used.

The materials used in the development of the parts and accessories as well as consumption and wear items aims at guaranteeing the perfect operation of the equipment according to its original characteristics as well as the safety relative to inflammability and biocompatibility of the employed materials.

Attention: Use only FANEM original parts.

4.4 Electromagnetic Compatibility and Immunity

It is the capacity of an equipment and/or system to operate in an electromagnetic environment, without introducing intolerable electromagnetic disturbances to anything in the environment and, on the other hand, operate without degradation in the presence of an electromagnetic disturbance.

This equipment was projected, tested, and complies with the following electromagnetic norms of compatibility.

- EN 60601-1-2
- NBR 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

According to parameters approved for RF Emissions, Immunity; Electrostatic Discharge; Electromagnetic fields of Radiofrequency Irradiated and Transients (Gusts of Winds and Voltage Changings).

Attention: Mobile and portable RF equipments can damage Electromedical Equipments.

Attention: The use of accessories, transducers, sensors and not-oroginal net cables can cause increase of Emissions or decrease of immunity for the equipment.

Guidelines and the manufacturer's declaration - electromagnetic emissions		
The neonatal Incubator1186 model is destined for use in specified electromagnetic environment below. We Recommend that to the customer or user of the neonatal Incubator1186 model guarantees that it is used in such environment.		
Assays of emissions	**Conformity**	**Electromagnetic environment - Guidelines**
RF emissions CISPR 11	Group 1	The neonatal Incubator1186 model uses energy of RF only for its internal functions. However, its emissions of RF are very low and it is not probable that they cause any interference in next electronic equipment.
RF emissions CISPR 11	Class A	The neonatal Incubator1186 model is adjusted for use in all the establishments that are not domestic servants and can be used in residential establishments and those directly hardwired to the public net of distribution of electric energy of low tension that feed constructions for domestic use, since that the following acknowlent be understood: **Attention:** This equipment is destined for use only for the professionals of the equipment health area. It can cause radio interference or interrupt equipment operations in the neighborhoods. It can be necessary to adopt procedures of reduction, such as reorientation or replace of the neonatal Incubator 1186 model or local shield.
Emissions of harmonic IEC 61000-3-2	Class A	
Emissions due the tension flotation /flicker IEC 61000-3-3	Comply	

Guidelines and manufacturer statement – Electromagnetic Immunity

The neonatal Incubator1186 model is destined for use in specified electromagnetic environment below.
We Recommend that to the customer or user of the neonatal Incubator1186 model guarantees that it is used in such environment.

Immunity Essay	Essay Level ABNT NBR IEC 60601	Level of Conformity	Electromagnetic environment - guidelines
RF Conducted IEC 61000-4-6 RF Conducted IEC 61000-4-3	3 V ms 150 KHz until 80 MHz 3 V ms 80 MHz until 2,5 GHz	10 V 10 V/m	Mobile or portable equipments of RF communication should not be used near any part of the Incubator1186, including cables with separation distance smaller than the specified, estimated from the equation applicable to the transmitter frequency. Distance of Specified Separation $d = 0,35.P^{1/2}$ $d = 0,35.P^{1/2}$ 80MHz until 800 MHz $d = 0,7.P^{1/2}$ 800MHz until 2,5 MHz where P is maximum nominal power for output of transmitter in watts (W), according to the transmitter manufacturer, and d is the specified separation distance in meters (m) It is recommended that the field intensity established by the RF transmitter, according to determination through an in loco [a] electromagnetic inspection, is lower than the level of accordance in each frequency [b]. Some interference around the equipment can occur marked with the following symbol: 

NOTE 1: At 80 MHZ and 800 MHZ, applies to high frequency range.
NOTE 2: These guidelines may not apply in all situations. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Itensities of field established by fixed transmitters such as radiostations, telephone (mobile/ wireless) and terrestrial mobile radios, amateur radio, FM radio transmission and TV transmission can be theoretically provided with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, we advise an electromagnetic inspection of the place. If the measurement of field intensity of the place in which the the Incubator1186 is used overpasses the level of accordance used above, the cradle need to be observed in order to verify if the operation is normal. If an anormal performance is observed, aditional procedures can be necessary, such as reorientation or replacememnt of the Incubator1186.

[b] Above the frequency band of 150 kHz until 80 MHz the field intensity should be below 10 V/m.

Distances of separation indicated between mobile and portable RF communication equipments and the Incubator1186			
The Incubator1186 is used for electromagnetic environment in which RF disturbances radiated are controled. The user can help to prevent electromagnetic interference keeping a minimum distance between mibile and portable RF communication equipments (transmitters) and the Incubator1186as indicated below, according to the maximum power of output for communication equipments.			
Maximum nominal power of output of transmitter W	Distance of separation according to the transmitter frequency m		
	150 kHz until 80 MHz $d = 0,35\ P^{1/2}$	80 MHz until 800 MHz $d = 0,35\ P^{1/2}$	800 MHz until 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 with maximum norminal power of output not mentioned above, the "d" distance of separation indicated in meters (m) can be determined through equation applicable for the transmitter frequency, where P is the maximum nominal power of output for the transmitter. **NOTE 1:** At 80 MHZ and 800 MHZ, applies to high frequency range. **NOTE 2:** These guidelines may not apply in all situations. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

5 Equipment Installation

5.3 1186 Model Neonatal Incubator

Unpack the Incubator, checking that all parts are in good condition. Also check if all accessories are complete.

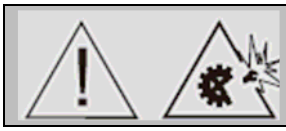
Remove the red lables that protect the panel for transport, loosening it and removing them. Follow the guide drawing of the equipment to perform the assembly of the sets, parts and accessories.

General Accessories such as the drawer set, vertical rods, shelves, serum support, etc. are supplied with their own instructions.

Assembly of Incubator on Support

The Base and Dome Sets are packed in a separate box, the Support Set is packed in another separate box.

In order to assemble the Incubator, lock the Support Set wheels, carefully couple the Base Set to the support upper part and fix the two sets through the 4 provided bolts.



Attention: The incubator should be perfectly fixed to the support; failure in its fixing may result in the separation and drop of the Incubator from the support, mainly in leaned surfaces and specially with the dome open.

General Instructions

Before turning on the incubator, see the description of your control panel in section "EQUIPMENT OPERATION" and get acquainted to it .

To turn on the Incubator, follow the orientation described in section "TURNING ON THE INCUBATOR".

More detailed instructions of the incubator general operation can be found in section "EQUIPMENT OPERATION".

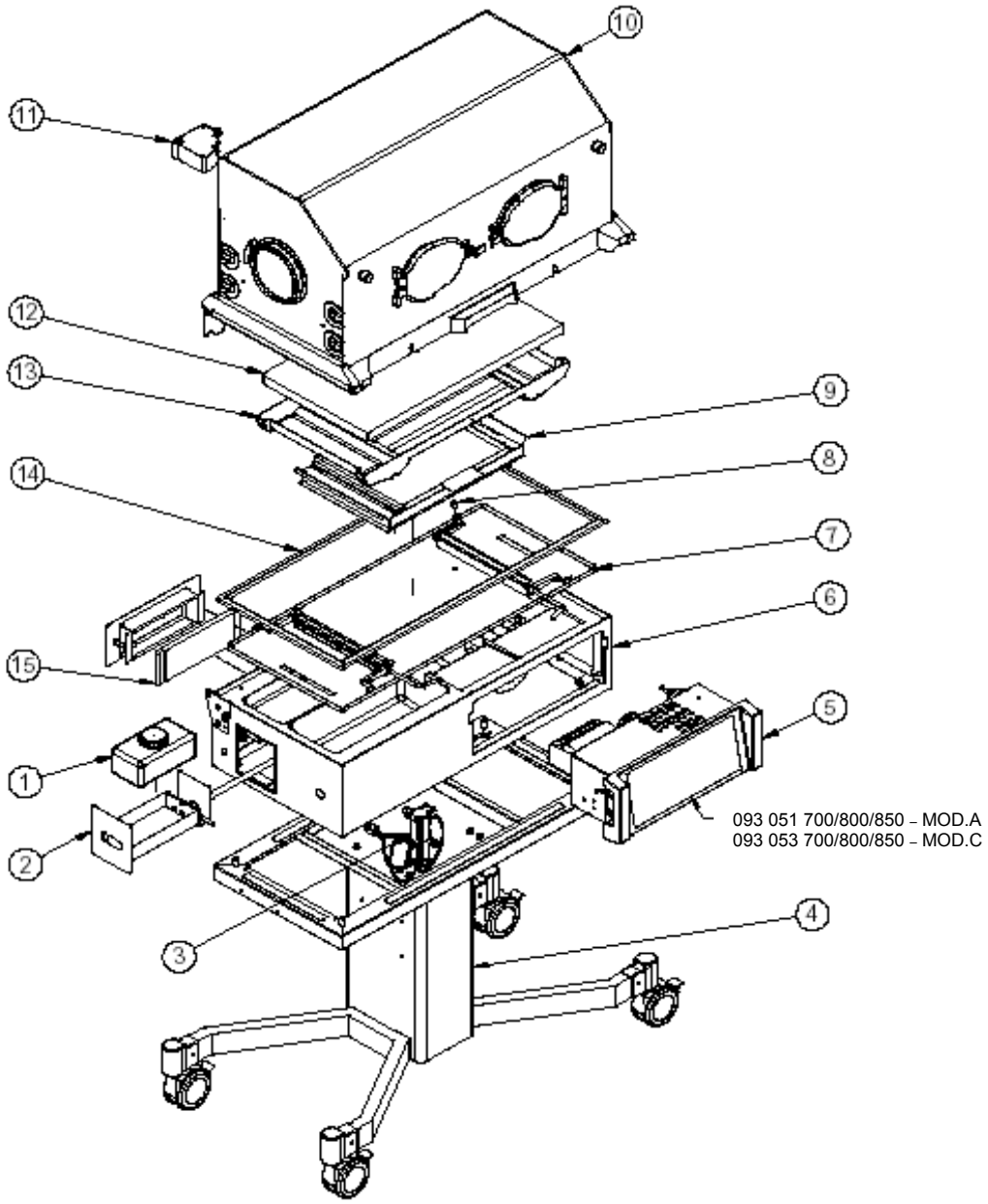
If some error occurs in the equipment operation, try to solve it by using the section "FAILURE DIAGNOSIS", that describes the possible failures and its corrections. Even though this is not possible to solve them, consult a FANEM authorized technical assistance.

For assembly and transport of the Incubator, use people with enough strength for the applicable procedures.

Attention: Before using the Incubator, the initial cleaning and disinfection of th equipment should occur as per instructions in section PREVENTIVI CORRECTIVE MAINTENANCE", as well as the procedures adopted b the Client's Hospital Infection Control Committee (CCIH).

Attention: Never forget to fix the Cabinet Fixing Device to the Incubator body so as to prever imbalance of the set when in use.

Guidance Drawing

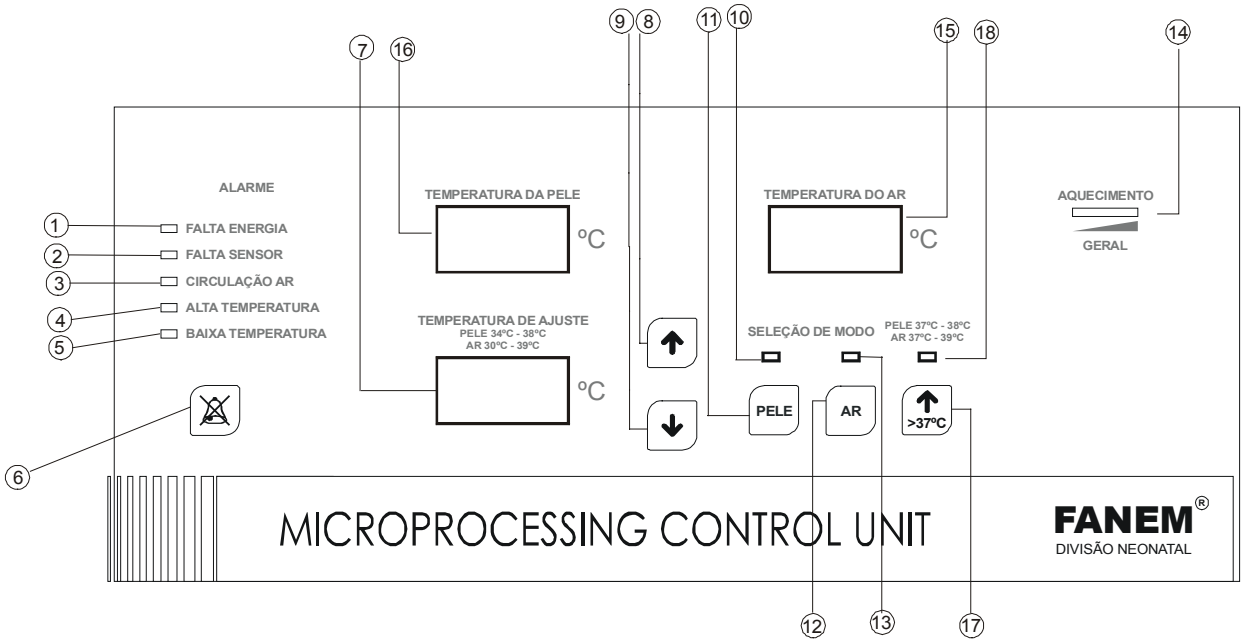


ITEM	CODE	NAME	QTY.
1	093 071 600 1	WATER RESERVOIR SET - 1186 LCD DISPLAY	1
2	093 055 600	RESERVOIR DRAWER KIT - 1186 LCD DISPLAY	1
3	093 056 700/800/850	ASSEMBLE BOILER FOR 1186 - 1186 LCD DISPLAY	1
4	092 146 600	FIXED SUPPORT V2 P/ C 186	1
5	See Drawing	1186 CONTROL UNIT	1
6	093 054 600	INTERMEDIARY BOX SET	1
7	026 059 600	TRAY SET	1
8	093 121 300	TRAY LOCK BUTTON	1
9	093 056 600	SCALES KIT - 1186 LCD DISPLAY (OPTIONAL)	1
10	See Drawing	ACRYLIC DOME SET	1
11	090 158 600	02 CELLS SET COMPARTMENT–LCD DISPLAY (OPTIONAL)	1
12	158.320.023	FOAM MATTRESS	1
	158.615.023	MATTRESS LAYER	1
13	093 122 321	TRAY FOR MATTRESS SEAT FOR 1186	1
14	086 117 320	BASE FIXTURE	1
15	090 058 600	AIR FILTER KIT WITH 4 UNITS	1

6 Equipment Operation

6.1 1186 Model Neonatal Incubator

6.1.1 Microprocessed Controlled Unit 1186 Control Unit 1186 Panel with LED's – Air and Skin Mode Control – With No Optionals



1) - "POWER FAILURE" Alarm Indication Led
2) - "SENSOR MISSING" Alarm Indication Led
3) - "VENTILATION MISSING" Alarm Indication Led
4) - "HIGH TEMPERATURE" (Skin/Air) Alarm Indication Led
5) - "LOW TEMPERATURE" (Skin/Air) Alarm Indication Led
6) - "INHIBIT SOUND" alarm key
7) - "TEMPERATURE SETTING" DisplAy (Skin/Air)
8) - "INCREASE" temperature setting key
9) - "DECREASE" temperature setting key
10) - "SKIN MODE"Indication Led
11) - "SKIN MODE" Selection key
12) – "AIR MODE" Selection key
13) - "AIR MODE" Indication Led
14) - Resistance I "WARMING" Indication Led
15) - "AIR TEMPERATURE" Indication display and/or auxiliary sensor
16) - "SKIN TEMPERATURE" Indication Display
17) – Temperature Setting key (higher than 37ºC)
18) - Temperature Setting Indication Led (higher than 37ºC)

6.1.2 Turning on the 1186 Incubator with 1186 Control Unit Panel with LED's Air/Skin Mode Control, without optionals

- Connect the appropriate feeding cable to the lateral panel switch.
- Conect the other end to a hospital installtion power switch.

Feeding cable Ref: 092.064.600

Feeding cable Ref: 000.208.600

	Check if network voltage where the feeding cable is connected corresponds to the same voltage indicated on the incubator lateral panel label, 127V~ ; 220V~ ou 240V. Never turn on the Incubator if the hospital switch does not have a reliable grounding. Never disconnect the feeding cable with the panel.

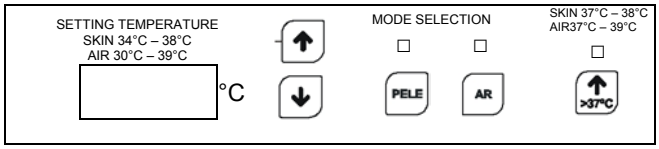
- Connect the patient sensor plug (Re.: 092.059.000) to the appropriate switch on the lateral panel. To connect the plug, check the matching of chamfers in the plug and switch, after connection, thread lock nut clockwise.

	Never remove the plug by pulling the wire.

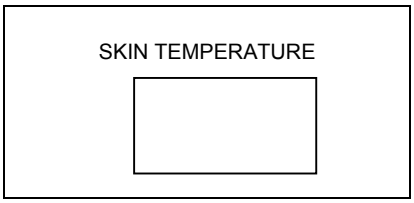
- Turn on the incubator by pressing key "I" ON located in the lower part of the front panel.

- When the incubator is turned on, all displays and identification leds (except the power failure led) will be on during 5 seconds. The sound alarm will also sound during this period. After the "auto check-up" the incubator begins to operate.

- The initial condition will automatically place the mode selection in AIR at and the AIR setting temperatures at 34,0ºC and skin setting at 36,1ºC. Set AIR temperature, reading it on display, by means of the increase and decrease keys, as needed.



- The Incubator internal air current temperature will be displayed on the air temperature display in Celsius degree.
- The patient skin current temperature willl be displayed on the skin temperature display in Celsius degrees and lack of air circulation.
- The low temperature alarm will remain with the inhibited sound during 40 minutes as from the moment in which the incubator is turned on to allow initial warming, it will be uninhibited after this time has elapsed.



- The incubator will begin the air temperature warming process and the amount of power supplied for the resistance may be seen by means of the "Warming" Led's. The air temperature will gradually increase until this equals the set temperature (Air Mode). In the first warming cycle, the air temperature surpasses 1,0ºC beyond the set temperature (Over Shoot) and decreases in less than 10 minutes becoming equal to the set temperature.
  When the two temperatures are the same the first warming Led will remain on, indicating that the system is controlling the temperature. (1/4 of power)

6.1.3 Alarm and Safety System

Five Led's indicate the safety alarm conditions of the Incubator with the 1186 Controller. The sound of each alarm may be inhibited (or not) during 15 minutes, by pressing the "INHIBIT SOUND" key.

Each Alarm:

Alarm Specifications:

- Dome air high temperature: .....> 38,0ºC or 40,0ºC
- Air High Temperature: .....+1,5ºC in relation to temperature set.
- Air Low Temperature: .....-3,0ºC in relation to temperature set.
- Skin High Temperature:.....+1,0ºC in relation to temperature set.
- Skin Low Temperature:.....-1,0ºC in relation to temperature set.
- Lack of ventilation:.....120 seconds after the motor stops or ventilation blockage.
- Lack of sensor: .....patient's cable disconnected or damaged or loosened sensor off patient's body.
- LLL:.....indicates temperature below the reading scale on display.
- HHH:.....indicates temperature above reading scale on display.

- **Power Failure Alarm**: Audio visual, it indicates when the electric power is cut off or if the cable is disconnected, or when the fuse located on the lateral panel is out.

  This alarm actuates due to a auto-rechargeable battery located in the microprocessed unit box.

  Turning off the incubator is necessary by means of the on/off swtich whenever this alarm is actuating in order to increase the useful life of the battery.

- **Lack of Ventilation Alarm**: Audio visual, it indicates when the air flow is interrupted , in case of motor stop or air ventilation duct obstruction. The alarm will actuate up to 120 seconds after the occurrence of the failure.

  When this alarm is actuated, the warming is interrupted and the sound may be inhibited during approximately 15 minutes.

  When the incubator is turned on, this alarm will remain innactive for 40 minutes, going back to the stand -by status (active) after this period has elapsed.

  Sensor Missing Alarm: Audio Visual- it indicates when the plug of patient sensor is disconnected from the lateral panel switch or in case of sensor failure when the sensor wire is broken or in short circuit or the sensor will become off the patient's skin. Under this condition, the alarm will be actuated when a temperature variation higher or qual to 0,3ºC occurs in a short period of time.

  The audio visual indication Sensor Missing alarm is differentiated under the following conditions:

  a) Sensor disconnected from the switch or damaged: Sound and Led constantly actuated.

  b) Sensor that may come off the patient's skin: Intermitent Sound and Led.

  To reset the normal stand-by condition of the alarm (active), when this may come off the patient skin, press, "Inhibit Sound" key.

Attention: The "Sensor Missing" alarm is only actuated when the mode selection is at "Skin".

- **High Temperature Alarm:** This alarm actuates in three different situations:

  a) <u>When the mode selection is at Air:</u>

  The alarm is actuated when the air temperature is higher or equal to 1,5ºC in relation to the set temperature and will go back to the normal condition after the temperature is reestablished.

  The sound may be inhibited during 15 minutes by pressing the "Inhibit Sound" key.

  b) <u>When the mode selection is at Skin:</u>

  The alarm is actuated when the skin temperature is higher or equal to 1,0ºC in relation to the set temperature and will go back to normal condition after the reestablishment of the temperature. The sound may be "Inhibited" during 10 minutes, pressing the "Inhibit Sound" key.

  c) <u>Dome Air Safety High Temperature</u>:

  (Yellow Led Off) – The High Temperature Alarm will actuate when the air temperature reaches 39ºC.
  (Yellow Led On) – The High Temperature Alarm will actuate when the temperature reaches 40ºC.

Attention: The High Temperature Alarm Sound – Dome Safety can not be inhibited.

Attention: In all conditions of high temperature the supply of power for the warming resistance i interrupted by means of a safety relay.

- **Low Temperature Alarm:** This alarm actuates in two different conditions:

  a) When the mode selection is at Air:

  The alarm is actuated when the Air temperature is lower or equal to 3,0ºC in relation to the set temperature and will go back to the normal condition after the restablishment of the temperature.

  The sound may be inhibited during 15 minutes, by pressing the "INHIBIT SOUND " key.

  b) When the mode selection is at Skin:

  The Alarm is actuated when the Skin Temperature is lower or equal to 1,0ºC in relation to the set temperature and will go back to the normal condition after the reestablishment of temperature.

  The sound may be inhibited during 15 minutes by pressing the "Inhibit Sound" Key.

Attention: In the initial period of pre-heating of the Incubator the low temperature and lack of circulation alarm sound will remain inhibited during 40 minutes and will go back to normal condition after this time has elapsed.

6.1.4 Temperature Indication Display

- **Skin Temperature:** This display indicates the temperature constantly (in Celsius Degrees) measured by the patients sensor (Re.: 092.059.600), in any operatiom mode, air or skin.

  The reading range of this display is 25,0ºC up to 43,0ºC.

  When the patient sensor is removed from the lateral panel switch, the display will indicate "__ __ __" ºC and the sensor missing alarm will be actuated, only if operation mode is in "Skin".

- **Air Temperature**: This display will indicate the temperature constantly (in Celsius Degrees) measured by the internal air sensor in any operation mode, air or skin. The reading range of this display is 25,0ºC up to 43,0ºC.

6.1.5 Temperature Sensors

- **Temperature Auxiliary Sensor:**

When this sensor (Re.: 092.060.600) is connected to the lateral panel, the indicated temperature by this sensor will be that one shown on the air temperature display, only when this sensor has a temperature of over 20,5ºC.

Attention: The temperautre auxiliary sensor is only used in cases of dome air temperature measurements. The temperature cnotrol and the alarm levels will continue to be made by the temperature measured through the internal sensor.

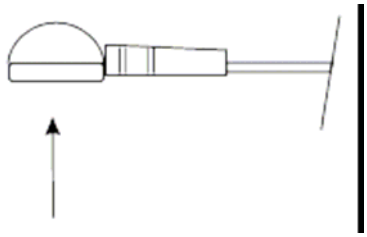
Attention: Use only FANEM® brand sensors, Re.: 092.059.600 patient sensor, Re.: 092.060.600 auxiliary sensor.

The use of other type of sensor may cause error in the reading of the temperature and damage to the patient. The FANEM® sensors are tested and controlled, for perfect repeatability and precision.

FANEM® also produces adhesives which are especially developed for the fixing of sensor to the patient's skin. Thise adhesives are made of atoxic material and are antiallergic and make the removal of the sensor easier, without damaging them.

The box contains 100 units Re. 086.068.600

Patient Sensor - Re.: 092.059.600



Postion the metallic surface in contact with the patient's skin

Attention: Never remove the sensor from the patient's skin pulling it by the wire. First remov the adhesive and then, the sensor.

Attention: Before installing the sensor on the patient, check if the sensor body is clean and ha no adhesive remains.

Attention: Do not use the sensor to rectal temperature reading.

6.1.6 Operation Mode with Newly –Born Infants

Turn on the incubator 1 (one) hour before using it with the newly -born.

Position the incubatore to heat up to the necessary temperautre for the newly-born.

After the temperature stability of the internal air in the dome, open the front accesss door, pull the patient bed forward, place the newly-born on the mattress, return the bed to the original position and close the access door.

Then, connect the cutaneous temperature sensor on the skin of the newly-born, preferably on the abdominal region waintg for the registered temperature to reach the pre-selected temperature.

Attention: Keep the front door and the ports open the least time possible to aoivd temperature loss. Position the patient sensor preferably on the abdominal region of the newly born and fix it with appropriate adhesive .

Before turning the operation mode to "Skin", wait for the temperature indicated on the "Skin Temperature" Display to stabilize, that is, it reaches the body temperature (for a normal patient, the expected value would be 36,1ºC), after this temperature stabilization, press the "Skin Mode". key.

From this moment on, the incubator begins to control the temperature according to the need of the newly-born.

Attention: If the monitored temperature by the sensor of the patient varies, it will indicate that a sensor dislodgging occurred in relation to the newly-born body. In this situation, the lack of sensor alarm wil be actuated intermitently and may stop if the sensor comes back to its original condition, if this does not occur, check the correct positioning of the sensor to the patient and then press "Inhibit Sound" key to cancel the sensor missing alarm.

- **Operation with Hypothermal Patient:**

This incubator has a safety system that controls the air temperature at 0,5ºC above the temperature set to the patient skin (only for the operation mode at Skin).

When the newly-born reaches the expected temperature (Set Temperature) the control becomes proportional again according to the need of the newly born.

6.1.7 Temperature Control:

- **Air Mode**: In this mode of operation, the incubator temperature may be kept between 30,0ºC and 39,0ºC selected through "Set Temperature" located on the front panel.

The incubator temperature is monitored through the air sensor, located on the inferior deck and the temperature will be read on the "Air Temperature" display.

- **Auxiliary Sensor:** When this sensor is connected to the incubator, the temperature indicated on the "Air Temperature" display will be read by this sensor (only when the temperautre is higher or the same as 20,5ºC).

Attention: The "Auxiliary Sensor" only serves to monitor the air temperature or the patient peripheral temperature and being that the resistance heating control and the alarm levels will continue to be referenced by the " internal air sensor" located in the lower deck (control panel).

- **Skin Mode**: In this operation mode, the newly-born temperature may be controlled between 34,0ºC and 38,0ºC, selected by means of the "Set Temperature" located on the front panel.

The newly-born temperature is monitored by the "Patient Sensor ".

The heating is proportionally controlled through the newly-born cutaneous temperature to keep it in the pre- set value.

When the "Skin Mode" is selected, the temperature control and the alarm levels will be referenced to the cutaneous temperature of the newly-born. The air temperautre will be monitored by the "Air Temperature' display.

6.1.8 Dome with Double Wall

The Double Wall dome was developed to provide to the incubator a better temperature stability.

Its unique format provides an adequate thermal insulation, involving the newly-born in air circulation with perfectly homogenous temperatures in all its extensions. The main characteristic of the Double Wall is the thermal insulation.

Attention: Do not use the incubator without the internal walls – The internal temperatur may be changed.

♦ **Assembly and disassembly of the Double Wall:** To disassemble the Double Wall of the dome, follow the instructions:

A) Keep the dome lowered.

B) Open the front access door.

C) Press the double wall acrylic located on the upper front part until this comes out of the dome.

D) With both hands, hold the double wall rear lower part and with the forearms support the front part.

E) With the two hands, raise the rear part of the wall until it is released from the two locking ports. Remove the double wall through the access door.

F) To remove the double wall from access door.

G) Keep it supported and raise the acrylic from the door on the lower central part of door where the lock pin is located. Push the acrylic upwards using the two bores until it is released from the two lock points located at the ports.

G) For assembly, follow the inverse procedure.

The FANEM® incubator with intensive care dome allows quick and total access to the newly-born that may want treatment or special exam. The access ports for the arms , in oval form, allows better mobility.

The five ports are provided with automatic locks that silence any noise coming from the opening and closing procedure. The opening locks have larger dimensions providing better opening with the elbows, to keep the hands free.

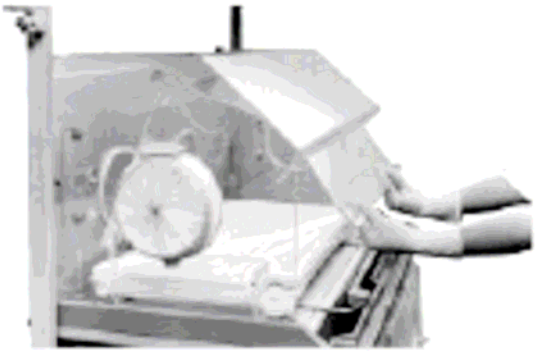
The doors may receive elastic handles of easy application that reduce the caloric loss with the access to patient.

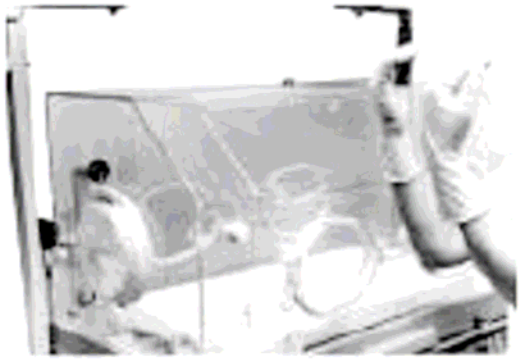
The access door opens, the front panel basculating.

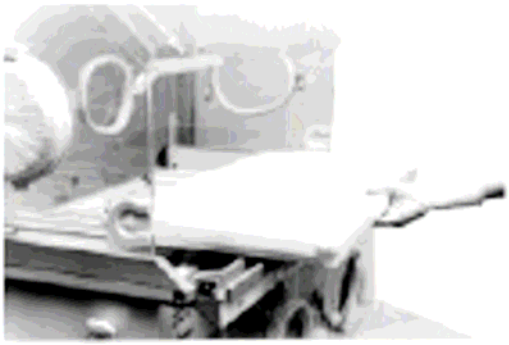
To open the access door, rotate the two buttons located in the upper corners of the door , rotating them inwards .

The patient bed may be slided forward with safety as it is supported on rails which are locked on the dome.

H) Due to safety reasons, the patient bed may not be slided outwards when it is in Trendelenburg position.







Attention: The maximum loa recommended on the patier bed is 7,0 Kg.

6.1.9 Operation with Humidity

For its use, fill up the Humidity Chamber with distilled and sterilized water adding 0,5 ml of Lunar Caustic per liter of water (solution 1 to 10.000), it helps to prevent the development of microorganisms. Only one charge of water from the Humidity chamber is sufficient , for at least 24 hours of operation of the Incubator. In order to empty the Humidity chamber, rotate the plastic lever to the left, putting the water in an appropriate recipient.

The incubator is manufactured with a passive moist system which provides to the patient an ambient in the range of 40% to70% of relative humidity (depending on envirnomental conditions) but without the effective control of these parameters.

Attention: The maximum recommended load on the patient's bed is 7,0 Kg.

6.1.10 – Safety Hinge and Lock

The transparent domes may be inclined to provide better access to the newly-born and make cleaning easier. A hinge with a safety lock is used for this operation. To open the dome, raise it until you feel the safety device is coupled. In this position there will be no chance of unnatentively closing the dome.

To close the dome, hold it firmly and push the safety lock lever down (located on the right hinge).

Slowly lower the dome on the fixture, which is found on the base

Attention: Do not lift the dome while th patient is in the incubator.

6.1.11- nclined Bed Operation

The two manipulators for the bed lifting are in the front part, close to the incubator base.

When rotating those manipulators down you will obtain Trendelenburg, proclive high horizontal positions, without violating the patient insulation. When there is not need to raise the bed, these manipulators should be in the horizontal position.

Attention: The high horizontal position must be used only for specific procedures or adjustments in the scales platform and X ray chassis, and then should return to the original positions.

6.1.12- Radiotransparency of Bed with Mattress

The bed and the mattress are manufactured with materials that allow the transparency to the X-Rays. There is a space under the bed for the introduction and positioning of the X-ray plates. The dome must be slightly open to introduce the X-Ray plates under the bed.

6.1.13- Inlet Bores for Pipes and Connections of Other Auxiliary Equipment

Located in the lower lateral close to the access doors. This location makes it easier and provides quick access to introduce connections and pipes for breathing, feeding and intravenous solution intake and monitoring cables. This

way, the bed with the newly-born may be slided forward over the access door, without the need to remove the pipes, probes or cables.

6.1.14- Use of the Incubator with the Neonatal Scales Mod. PN91-TS

The PN91-TS Neonatal Scales is used for the newly-born weighing.

Tthe weighing capacity of this Scales is up to 10kg with precision of 4g.

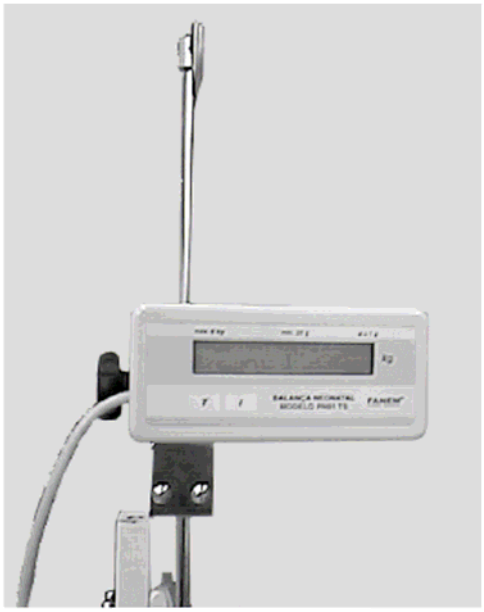
♦ **Scales Installation on the Incubator**

- Fix the scales box on the serum support as shown in the photo. Connect the feeding cable in a switch with grounding. Check the tension on the Scales Identification label.

♦ **Weighing Platform Installation:**

- Lift the mattress in high horizontal position.
- Open the dome access door.
- Position the platform under the mattress bed, as shown in the side photo.
- Pass the panel cable through the piping passage bore in the dome and connect the plug on the scales box..

  Check if the wire is not over the mattress rail or in another position which may hinders the platform movement.
- Connect the adaptor cable in the rear part of the panel, connecting the adaptor to corresponding the electrical network.
- Close the access door and lower the mattress in the low horizontal position. Check if the mattress is free and not touching in any side of the acrylic dome.

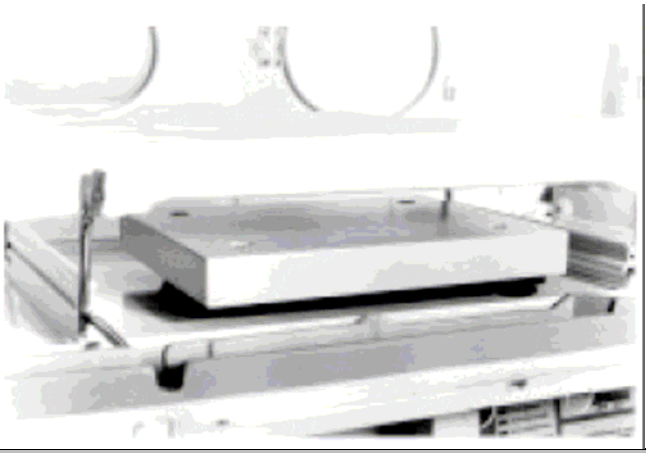


Ref.: 019.007.900

♦ **Tare and Weighing**

In order to promote the scales taring, two professionals are needed. While one nurse keeps the newly-born suspended out of the mattress, the other professional presses the "Tare" of the scales key.

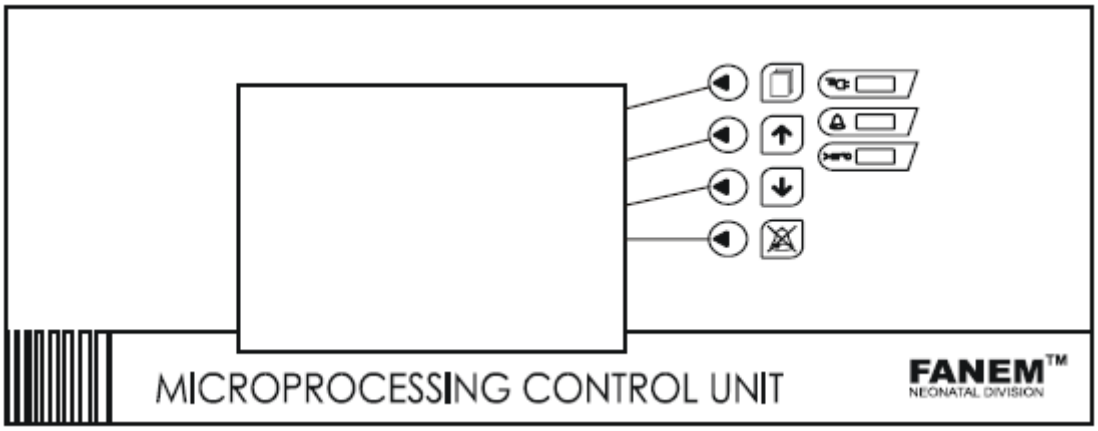
Place the newly-born again on the mattress and make the reading of his/her weight on the scales liquid crystal display.



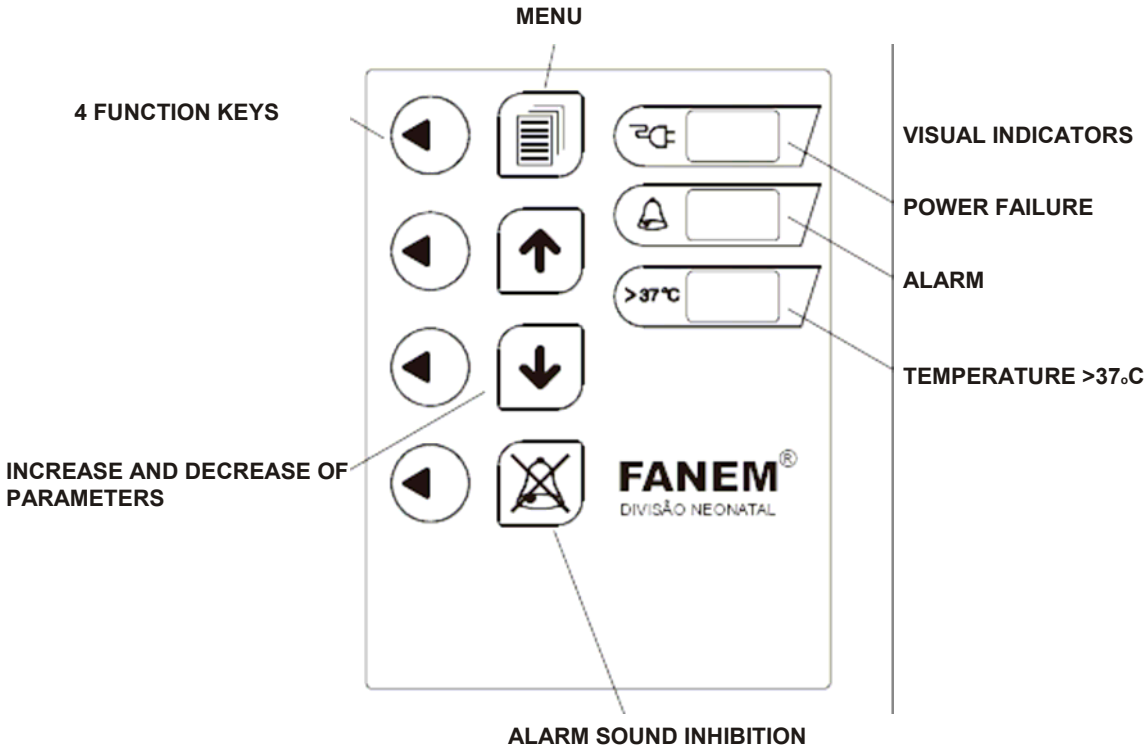
Attention: Before weight start-up, the scales should be turned on with a 20-minute advance so that th circuit reaches the working temperature and the scales provides the specified precision.

Attention: The dome may not be opened when the scales is installed.

6.1.15- 1186 Neonatal Incubator – LCD Graphic panel with all optional items



With an interactive display, the Control Panel of the 1186 NEONATAL INCUBATOR was configured in a simple manner and that can be easily operated;it is made up of 8 keys and 3 visual indications.



6.1.16- Turning on the 1186 NEONATAL INCUBATOR – LCD Graphic Panel

Connect the appropriate feeding cable in the power inlet of the 1186 NEONATAL INCUBATOR, located on the lateral side of the equipment.

Connect the other end of the feeding cable, its network plug, into a hospital installation power switch.

Attention: Check if th network voltage where the feeding cable is plugged correspond to the same equipment voltage indicated in the label close to the Incubator power inlet, 127V~; 220V~ ou 240V~.

Never turn on the Incubator if the hospital switch does not hav reliable grounding.

Never disconnect the feeding cable when the panel is on.

Connect the scales cable (scales – optional item) on the lateral panel.

Attention: If the scales cable is connected after the incubator is on, the scales will nc indicate the weight correctly.

On the lateral panel, connect the humidity and oxygen sensor cable (oxygen sensor – optional item), the skin sensor cable and the command cable on "Power Outlet" connector.

Turn on the incubator through its general switch which is located on the lower right front part of the equipment.

Position the general switch in " I " "ON" mode.

The LCD panel (liquid crystal) has contrast adjustment for better visualization. The contrast may be set by means of a rotating button which is located in the lower pleft art of the Control Panel.

When the Incubator is turned on, the screen will show the styled figure of an "owl". Afterwards, the display will go into the "auto check-up" process and the Incubator will begin to operate showing on the display its main screen to Control the Temperatures.

Attention: The "wheel" rotating on the display indicates which mode of operation and what functions are actuated.

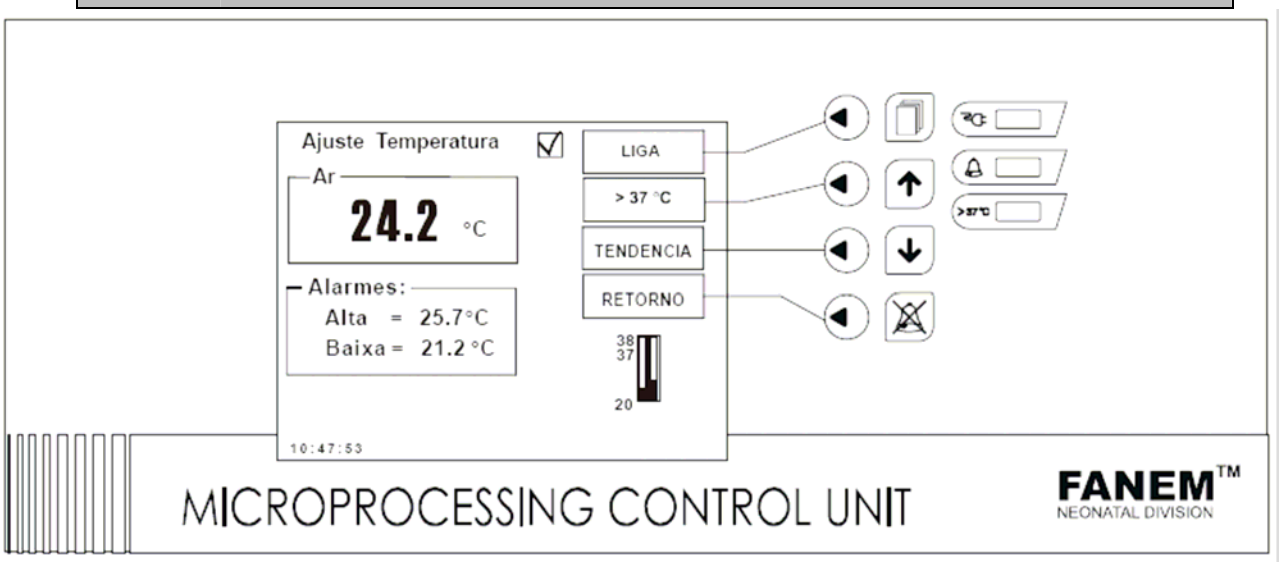
The constant visual observation of the "wheel" rotating is the user's and th medical doctor's obligaton.

6.1.17- Air Temperature Mode

In this operation mode, the air temperature may be kept from 20 to 37ºC, or from 37 to 39ºC in temperature surpassing mode, actuating the >37ºC condition.

By actuating on the Control Panel, press the function key corresponding to the AIR Mode, the display will show the AIR SET screen, through the INCREASE or DECREASE keys, Air Temperature Set, as needed.

Attention: During the Air Temperature Set operation, the system itself wi automatically select the High and Low Temperature alarm points.



Confirm the Air Mode condition, by actuating the "ON" function (√).

To release the Air Temperature setting upper keys, > 37oC, and for the BIAS graph of Air Temperature, actuate in the corresponding function keys and check on the display the actuation of the selected functions by means of a CHECK (√) confirming the function actuation.

With the RETURN function, the display will return to the Temperature Control initial key or then after 15 seconds the display will automatically revert to the initial screen.

In case of a power failure, the set point will be memorized and retained and will go back to the set value when the power is restored.

The Low Temperature Alarm will remain with the sound inhibited during 40 minutes as of the moment in which the Incubator is turned on to allow the initial warming, this alarm will be actuated after this time has elapsed.

The incubator will begin the warming process and the amount of supplied power to the resistance may be visualized by means of the POWER indication.

The air temperature in the inside of the incubator will gradually increase until this temperature becomes equal to the adjusted temperature (Air Mode). In the first warming cycle, the Air Temperature will surpass 1,0ºC above the set temperature (Over Shoot) and after that it decreases in less than 10 minutes becoming equal to the set temperature.

When the two temperatures are equal to the POWER indication for the system will be controlling between 0% and 10% of power.

Alarm Conditions

When an alarm condition occurs due to HIGH AIR TEMPERATURE or due to LOW AIR TEMPERATURE, the alarm indication will be shown by the display next to the AIR function, actuating the audiovisual alarm in the Control Panel.

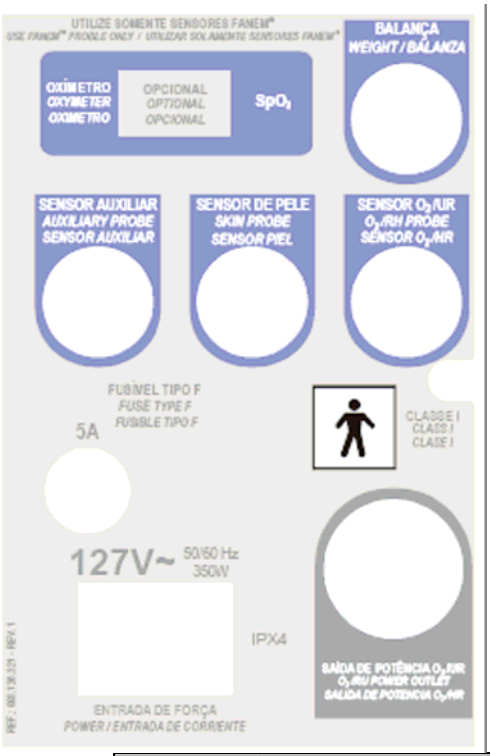
By Pressing the Inhibit Sound key, the alarm sound will silence for 15 minutes. See item 2.7 and 2.8 for further information.

Attention: In all conditions of High Temperature, the supply of power for th warming resistance is automatically interrupted.

6.1.18- Skin Temperature Mode

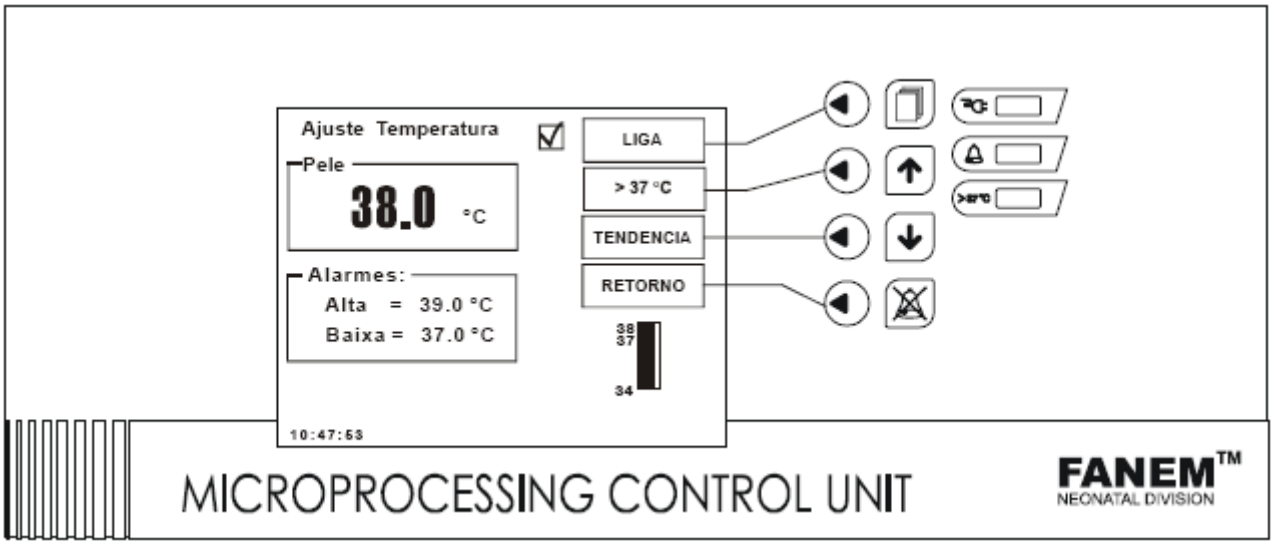
In this operation mode, the NB temperature may be kept from 34 to 37ºC or from 37 to 38ºC in temperature surpassing mode, actuating the >37ºC condition.

Connect the Patient Sensor plug (Re.: 092.059.600), into the switch for the Skin Sensor, located on the Incubator lateral panel.



Actuating on the Control Panel, actuate the function key corresponding to the SKIN SET, the display will show the SKIN SET screen, by means of the INCREASE or DECREASE keys, set Skin Temperature, as needed.

Attention: During the Skin Temperature Set operation, the system itsel automatically selects the High and Low Temperature alarm points.



Confirm the Skin Mode condition, by actuating the "ON" function (√).

To release the Skin Temperature higher Set keys, > 37oC, and for the Skin Temperature BIAS graph, actuate on the corresponding function keys, and check through the display of the actuation of the selected functions by means of a CHECK (√) confirming the actuation of the functions.

By means of the RETURN function, the display will go back to the Temperature Control initial screen or then after 15 seconds the display will automatically revert to the initial screen.

In case of a power failure the set point will be memorized and retained and will go back to the set value when the power is restored.

The Low Temperature Alarm will remain with the inhibited sound during 40 minutes as of the moment in which the Incubator is turned on. To allow the initial warming, this alarm will automatically actuate after this time has elapsed.

The Incubator will begin the warming process and the amount of power supplied for the resistance may be visualized by means of POWER inidication, close to the BIAS graph.

The temperature in the inside of the Incubator will gradually increase until it becomes equal to the set temperature (Skin Mode). In the first warming cycle, the temperature surpasses 1,0ºC above the set temperature (Over Shoot) and after that it decreases in less than 10 minutes becoming equal to the setting temperature.

When the two temperatures are equal to the POWER indication for the system, it will be controlling between 0% and 10% of power.

Attention: The Air Temperature is still displayed in the Skin Mode only fo information. If the Air Temperature Mode is selected while the Skin Senso is connected, the Skin Temperature Display will continue to show th current Skin Temperature but it will not control it.

Attention: Never place the Skin Temperature Sensor under the NB or use i to sensor rectal temperature. The Skin Temperature Sensor mus be in direct contact with the skin to provide precision in th monitoring of the newly-born skin temperature. Failure in keepin direc contact with the skin may result in over heating and possibl burns. Check the newly born condition at least every 15 minute for the right fixation of the sensor and feel the newly born ski with for no signs of overheating.

Placing the Skin Sensor

Before placing the sensor on the skin, deeply clean and dry well the area of the skin where the sensor wil be placed. When the newlly-born is lying on his back or is lying sideways, place the sensor on the abdomen, half between the xyphoid and the nipple. When the newly-born is lying with his face up, place the sensor on its back.

Couple the Patient's Sensor to the NB, using FANEM adhesive (Adesivo Kit Re. 086.068.600), as shown in figure on page 36.

Once the Skin Temperature is stabilized, the sensor will automatically control the system within +/- 0.3ºC of the Skin temperature setting.

Alarm Conditions

When an alarm condition occurs due to HIGH SKIN TEMPERATURE or due to LOW SKIN TEMPERATURE, the indication of the alarms will be shown by the display close to the SKIN function, actuating an audiovisual alarm on the Control Panel.

By pressing the Inhibit Sound key, the alarm sound will silence for 15 minutes. See items 2.7 and 2.8 for additional information.

Attention: In all High Temperature Conditions, the supply of power for th heating resistance is automatically interrupted.

When an alarm condition occurs due to the Sensor Failure, disconnected sensor , or in short circuit, or even off the NB skin, the alarm indication will be shown by the display close to the SKIN function, by actuating an audiovisual alarm in the Control Panel.

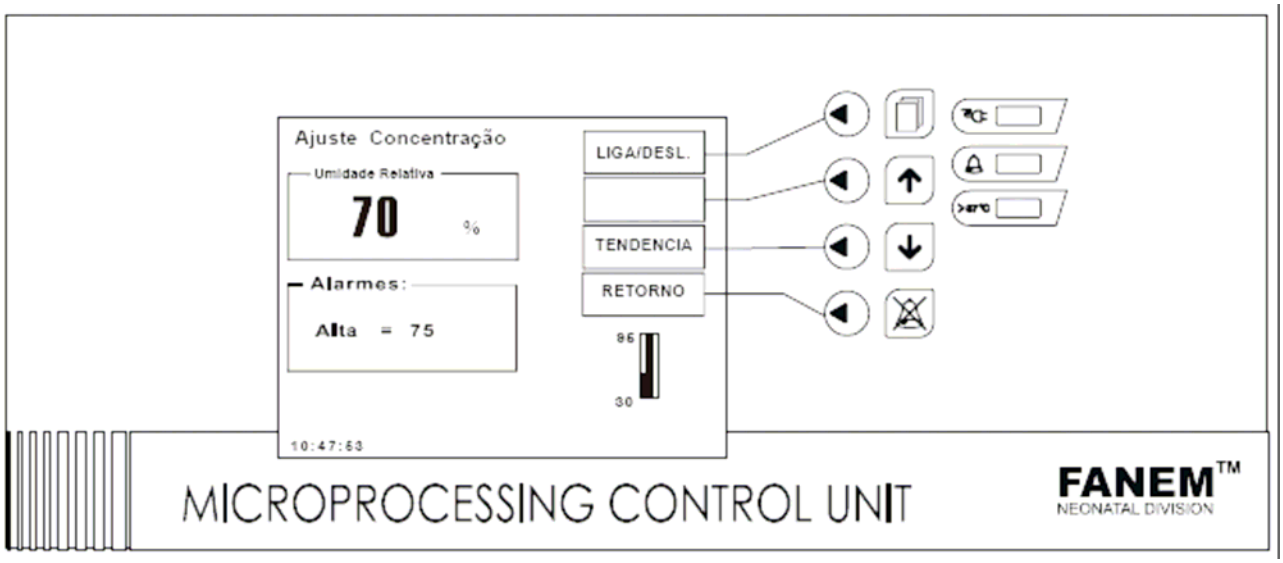
By pressing the Inhibit Sound key, the alarm sound will silence during 15 minutes. See item 2.7 and 2.8 for additional information.

6.1.19- Humidity Control

In this operation mode, the Humidifier provides Humidity to the Incubator at the range of 30 to 95% UR, in increments of 1%. The Humidifier Reservoir is located in the laeral part of the Incubator, with easy access through a sliding rail system. Fill up the Water Reservoir, with distilled and sterilized water.

Actuating on the Control Panel, actuate the function key that corresponds to the HUMIDITY Mode, the display will show the HUMIDITY SETTING screen, by means of the INCREASE or DECREASE keys, set the Relative Humidity, as needed.

Attention: During the Relative Humidity Setting operation, the system itsel automatically selects the High humidity alarm point.



Confirm the Humidity Mode condition, by actuating the ON/OFF function in "ON"(√) position.

To release the BIAS graph of the Relative Humidity, actuate in the key of corresponding function and check through the display of the selected function actuation by means of a CHECK (√) confirming the actuation of the Bias graph.

By means of the RETURN function, the display will return to its initial screen of Temperature Control, or then after 15 seconds the display will automatically revert to the initial key.

In case of power failure the setting points will be memorized and retained.

Attention: In high humidity levels inside the Incubator Dome (typically higher thai 60%), the condensation may be formed on the dome internal walls. Th concentration on the walls is directly related to the internal humidity i the incubator and ambient temperature.

Attention: High relative humidity in the Incubator in a certain temperatur will reduce the loss of vapor heat of the newly-born and ma cause an increase in the temperature. This effect will be stronge in premature newly-born with too low weight. The Temperatur Control Mode, the Temperature Set and Humidity Level Settin shall be prescribed by the attendant medical doctor. The newl born armpit and rectal temperature should be routinely monitore according to the recommendations of the attendant doctor or th Nursery standards.

Attention: Only use distilled water to place in the reservoir. Tap water may contain organisms which may proliferate in the heated water of the humidifier.
Check that all fixtures of the access doors are perfectly installed. An opening in the Incubator Dome will reduce the internal relative humidity c the Incubator.

Alarm Conditions

When an alarm condition occurs due to HIGH HUMIDITY or due to LOW WATER LEVEL, the alarm indication will be shown by the display next to the HUMIDITY function (UR), actuating an audivisual alarm in the Control Panel.

By presing the Inibit Sound key, the alarm sound will silence for 15 minutes. See item 2 (alarms) for more information.

When an alarm condition occurs due to Sensor Failure, disconnected sensor or in short circuit , the alarm indication will be shown by the display next to the HUMIDITY function (UR), actuating an audiovisual alarm on the Control Panel.

By pressing the Inhibit Sound key , the alarm sound will silence for 15 minutes. See item 2 (alarms) for additional information.

6.1.20- Oxygen Control

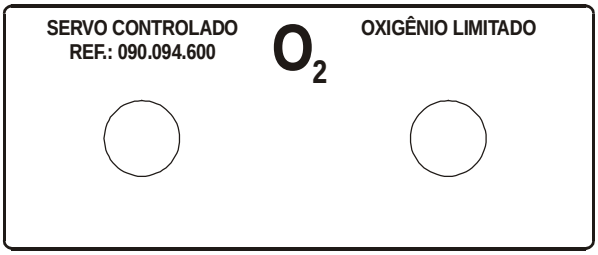
In this operation mode, the Oxygen intake may be performed by means of two different manners:

- Limited Intake
- Servocontrolled Intake (optional)

Attention: before performing the Oxygen Intake, revise the Operation Precautions – Oxygen, item 4.2 of this User's Manual.
Attention: During the Oxygen intake the increase in the noise level for th patient inside the incubator may occur.

Limited Intake

Through a silicone or latex hose 1/4", connect the outlet of the Oxygen Fluxometer of the line to the oxygen inlet nipple, which serves for the intake of LIMITED OXYGEN.



A guiding table of the oxygen concentration is supplied and is next to the Air Filter lid also located on the rear part of the incubator.

OXYGEN RANGES					O_2
INLET FLOW (LITERS PER MINUTE)	3	6	9	12	15
CONCENTRATION (%O_2)	30-45	45-60	50-70	55-75	60-85

ATENTION: THE OXYGEN FLOW RATES CAN NOT BE USED AS A PRECISI INDICATION IN THE OXYGEN CONCENTRATION IN AI INCUBATOR, THE OXYGEN CONCENTRATION MUST BI CONTINUALLY MOINTORED WITH A CALIBRATED OXYGEI ANALYSER.

Servo Controlled Inlet

By means of a 250 Psi □3/16" (Re.: 004.094.600) pressure woven nylon hose, connect the Oxygen Flowmeter outlet of the line to oxygen inlet niple aimed at the SERVO CONTROLLED OXYGEN inlet..

Attention: Inlet Maximum Pressure of O_2 = 3 kgf/cm2. O_2 Nipple, 9/16" Thread - 18UNF – as per NBR 11.906

This inlet nipple niple is found on the incubator rear part, right below its compartment to the Air Filter.

In this operation mode, the Oxygen concentration level inside the Incubator is controlled by a soleniod valve system, using an Oxygen Sensor (Ref.: 090.074.600) for control and another sensor for monitoring assembled in the O2 and humidity sensor compartments.

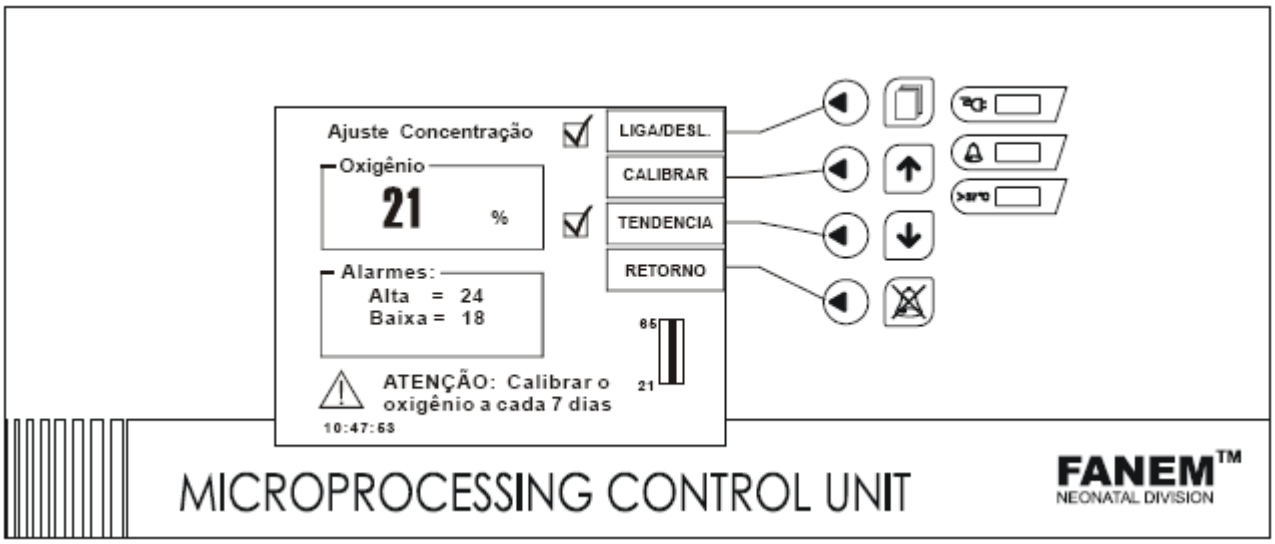
The oxygen concentration in the Incubator is set by a valve that usually interrupts the oxygen flow inside the Incubator, this way controlling the required concentration levels.

In the Oxgen Control Mode, the user may set the oxygen level from 21% to 65%, in increments of 1%.

Actuating on the Control Panel, actuate the function key that corresponds to the OXYGEN Mode, the display will show OXYGEN SETTING key, by means of the INCREASE AND DECREASE keys, set the required concentration as needed.

Attention: Check, on an usual basis, with a calibrated Oxygen Analyser, the internal concentration of the dome and comapre with the value indicated on the panel.

Attention: During the Oxygen Concentration setting operation, the system iself automatically selects the High and Low Concentration alarm points.



Confirm the Oxygen Mode condition, actuating the ON/OFF function to "ON" (√) position.

To release the BIAS graph of the Oxygen Concentration, actuatre in the corresponding function key and check through the display about the selected function actuation by means of a CHECK (√) confirming the BIAS graph actuation.

With the RETURN function, the display will return to the Temperature Control Initial screen or after 15 seconds the display will automatically revert to the initial screen.

In case of power failure the seting points will be memorized and retained.

Attention: During the oxygen intake, by using the Oxygen Servo-Controlled System the Oxygen Concentration Table is not valid.

Alarm Conditions

When the O_2 control is "on", one of the alarm indications described as follows may occur:

1- High Concentration: when the dome internal concentration value is higher than or equal to 3% above the set value.

2- Low Concentration: when the dome internal concentration value is lower than or qual to 3% below the set value. Under this condition, the sound alarm will be inhibited atomatically for 3 minutes.

3- Sensor Missing: when one or more cells are disconnected from the circuit, or the rear panel connector is disconnected. Under this condition, the control will be off.

4- Cell Failure: when one of the cells is uncalibrated in relation to the other one in more than 5% during 1 minute. Under this condition, the O_2 control will be off and one ATTENTION sign will appear instead of the O_2 values.

Alert Conditions

In Calibration

It indicates the the Oxygen Control System is performing the Calibration Procedure of 21%.

Calibration Concluded

It indicates that the Oxygen Control System was calibrated with success.

Failure in the Calibration

It indicates that the Oxygen Control System failed in the calibration. Repeat the Calibration Procedure. If the system fails in the second time, change the Oxygen Sensor.

Calibrating the Oxygen Sensor

The Oxygen Cells must be calibrated every 7 days or whenever the incubator is switched on. Daily calibrations are recommended. To keep system accuracy, a maximum cycle of calibration of 7 days is required.

Attention: During the operation, if the Sensor Module Cable is disconnected from the oxygen cell, the SENSOR MISSING message will be displayed and the oxygen flow will be interrupted.

Calibration at 21% - Ambient Air

Rotate the oxygen cell compartment outwards until its total opening. Wait for at least 2 minutes until the cells get an air ambient concentration at 21%.

Attention: If the compartment is open when the oxygen control is "on", an audiovisual alarm will indicate this occurrence. In this case, turn off the Oxygen control or inhibit the arlam sound.

Enter in the oxygen concentration setting table by pressing the key which corresponds to the oxygen. Press the CALIBRATE key to enter in Calibration Procedure key.

If the cell compartment is closed, the information "Open the Calibration Compartment" will remain blinking. If the compartment is already open, press the CALIBRATE key. The "Oxygen in Calibration" indication will be blinking until the "Calibration Performed Successsfully" information will appear indicating the end of the process.

Attention: If one of the cells has a problem or has expired, the ERROR2 information will be displayed indicating this occurrence. In this case, check the cell validity and their connections.

Attention: Never change one of the cells only. For the perfect functioning change the two cells as per the valdity indicated.

Attention: Every time the cells are calibrated, the control condition will be off, and the operator should turn it on again.

Checking at 100%

If a checking of the Oxygen Concentration at 100% is necessary, couple an oxygen hose into a plastic bag coming from a 100% medical degree O2 source in a flow of 3 to 5 lpm, insert the Oxygen Sensor cell in the plastic bag and check the concentration reached on the incubator display.

At the end of calibration, close the cell compartment , enter the oxygen concentration setting screen, set a desired concentration value and turn on the oxygen control.

6.1.21- Operation with Integrated Pulse Oxymetry Kit (optional)

6.1.21-1. Application

Babies weighing from 3 to 15 kg: Ideal area for application: the foot big toe, with the cable along the sole of the foot

Neonatal Infants weighing 1 to 3 kg:

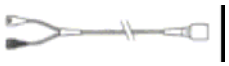
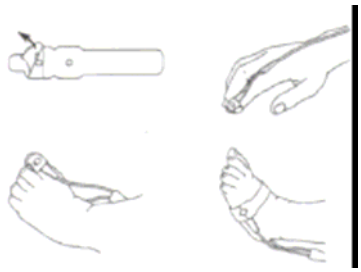
Ideal area for application:..... sole of the foot anterior part.

Alternate area:..... palm of the hand, below the fingers, with the cable along the palm.

Attention: Use the adhesive bandages only once.

Alternate the application area every 4 hours.

6.1.21-2. Sensors

Model Nr.	Quantity	Application
Dura-Y resusable multi-area sensor		
D-YS 	1 D-YS and 10 bandages.	Multi - area 

The sensor connector must be placed in the correspnding switch in the incubator lateral panel (sensor panel).

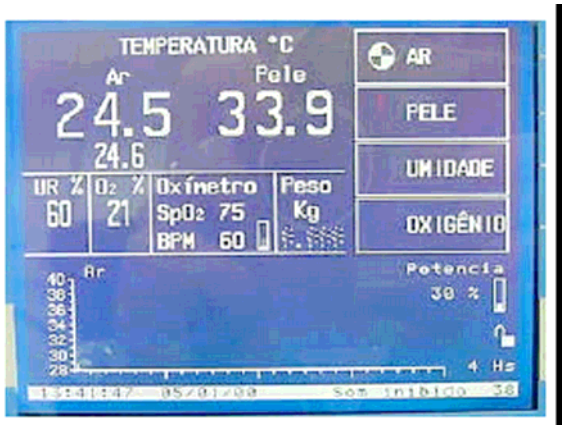
If necessary, the DEC4 extension cable may be used DEC 4 (090.138.600) to increase the sensor cable length.

Attention: The sensor recommended for use is the DURA-Y sensor (D-YS).
Re.: Fanem 090.137.600
This sensor may be used with the DEC4 extension cable.
Ref: Fanem 090.138.600.´

Attention: This sensor is reusable and its application is with bandage. The sensor kit has one DURA-Y sensor and 10 bandages.

6.1.21-3. Alarm Values

- Enter the oxymeter screen, press the "ALARMS" key.

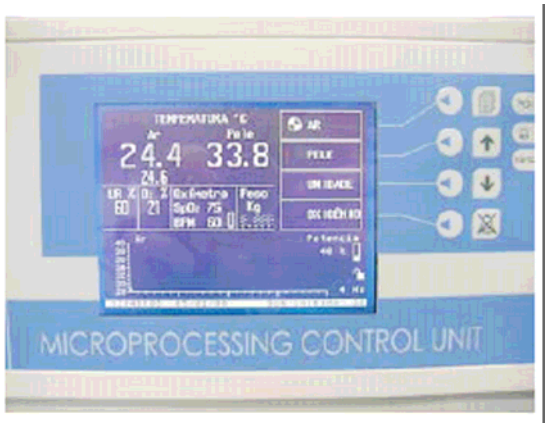


- Once on the alarm screen, the alarm values will be displayed.
- Press the "INCREASE" (left) to choose the value to be altered. An arrow indicates the alarm value for setting. Press the "INCREASE" or "DECREASE" (right) keys to set the desired value.
- Press "RETURN" to go back to the oxymeter screen.

6.1.21-4. Monitoring Mode

- The SpO2 is shown for values between 1% to 100%. The pulse frequencies are shown for values of 20 to 250 beats per minute and zero beats per minute.
- Pulse frequencies below 20 (except zero) are shown as 20 and above 250 will be shown as 250. A zero pulse frequency is used to indicate that the monitor is not monitoring the pulse.
- The SpO2 and BPM values information are shown in two manners: 1. On the main screen: the SpO2 and BPM values are shown in the "oxymeter" chart, together with the pulsation bar.

1. On the main screen: the SpO2 and BPM values are shown in the "oxymeter" chart, together with the pulsation bar.



2. On the oxymeter specific screen: the SpO_2 and BPM values are shown in big digits, the pulsation bar and the pletismographic curve.

On this screen the oxymeter alarms are also informed.

- The access to the ALARMS screens and the BIAS graph screens are performed by means of the indication keys on the left.

Attention: Before using the oxymeter, check if the alarm levels are compatible with the prescriiption for the newly born.

- To adjust the alarm levels, follow the instructions in item 6.3.
- Bias: On the BIAS screen, the SpO_2 and BPM graph wll be displayed for a period of 18 hours.
- The initial part of the graph is indicated in hours and minutes as from the moment in which the equipment is turned on.

Note:Check if the indicators, the information of the displays and the sound signs including the alarms are working, which indicate that the monitor is in operation. Observe the movement of the pulse amplitude indicator or the wave form and pay attention to the pulse bips to check if the measures are being made.

- Iin the monitoring mode, if the pulse perception is lost the monitor will go into the pulse search mode.
- pulse search: If the pulse perception is lost during monitoring, the oxymeter will go into the pulse search mode. During the pulse search, the monitor tries to detect a pulse to measure.
- Access keys:

To enter the OXYMETER screen, being on the main one, press the MENU key once. The left side keys will begin to indicate: SpO_2 , SCales, Settings and Retuin, respectively.

Press the corresponding key to SpO_2.

Being on the Oxymeter screen, press the BIAS key to enter the Bias graph screen.

6.1.22- Tare and Weighing

- Whenever it is necessary to weigh the newly-born, the scales must be tared.

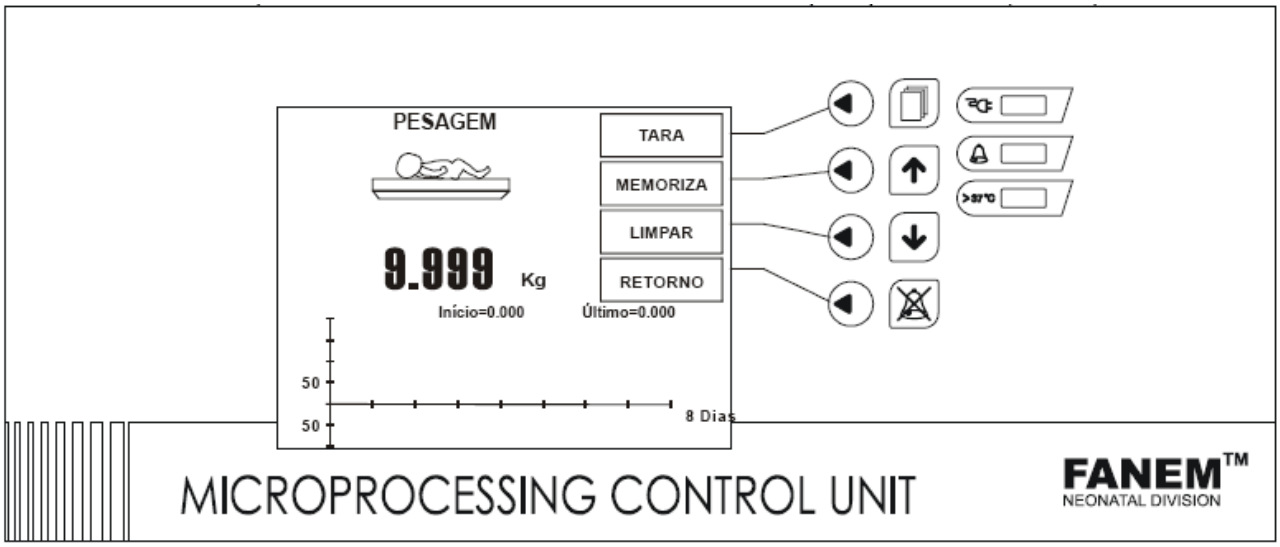
Procedure:

1- Place the mattress on the low horizontal position.

2- Enter the weighing screen. Press the hot key ▼ or press the MENU key once, and the scales indication will appear on the frames; press the corresponding key.

Note: when we enter the weighing screen, one information "Tare the Scales" will appear, together with an animation picture of this condition.

3- Pressing the TARE key during 3 seconds, the "Automatic Tare" information will be displayed and a bar will inform the time in which the scales will be tared. After the information appears on the screen, lift the newly-born off the mattress and wait for the automatic final tare. After the tare, place the newly-born on the mattress and memorize the weight in order to form a new relative graph.



Relative Graph:

When the incubator is turned off, the graph time will be zeroed the time counting begun in the period indicated by the clock.

This graph has a period of 8 days and the relative weight curve will be fed through the MEMORIZE key.

The initial weight of the newly-born must be memorized in order to have the zero reference of the graph. On the screen the information "Start" and "Last" weight will appear.

The graph may be fed as many times as necessary (pressing the MEMORIZE key).

Attention: Always tare the scales before and after reading the weight.

The difference between the initial and last weight will be indicated in the relative graph.

In order to earse the graph, press the CLEAN key, the initial and final weight will also be erased and the graph time counting will be zeroed.

- Position the NB on the bed, observing the initial weight on the display and through the corresponding function key, actuate the MEMORIZE function. In this moment, the NB initial weight will be memorized for future comparison and analyses;
- The weight bias graph will indicate the weight variation in relation to the initial weight in –100g to +200g.
- Through the corrresponding function key actuate the RETURN function, the system will go back to the temperature initial key, showing the actual NB weight on the display.

Attention: The NB must always be weighed in the center of the mattress. Maximum load on the bed /scales 7 g.

Attention: Toys or other objects on the mattress must not be supported on the Incubator walls or on Access Panel. Imprecise Readings may occur. In addition, the bed assembly must not be touching the Incubator Dome.

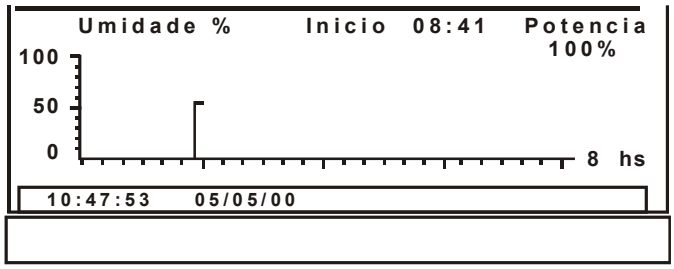
Instantaneous Weight Freezing:

With the option of freezing of the instantaneous weight, the weight in that instant is congealed, being possible to execute procedures of manipulation in the RN and later to reactivate the "unfreeze", the reading of the scale will return to the previous weight to the freezing having returned its normal functions.

Attention: Item of optional configuration and installation under consultation.

6.1.23- Bias Displays

The 1186 NEONATAL INCUBATOR has an exclusive parameter visualization system by means of the BIAS Graphs; these graphs are visualizaed on the main screen display in its lower part.



BIAS GRAPHS:

- Air Temperature
- Skin Temperature
- Relative Humidity

The additional BIAS GRAPHS can also be evaluated when the unit is equipped with any of the following options:

- Oxygen
- Weight (Scales)
- Oxymetry

The BIAS monitoring time is selected by the user in intervals of 4, 8, and 24 hours for all the parameters except the weight which provides a fixed time of eight hours and the oxymeter that is fixed at 18 hours.

For the configuration of the BIAS graphs, by actuating through the function keys select the corresponding function to visualize the graph, AIR; SKIN; HUMIDITY; OXYGEN, the display will show the corresponding SETTING screen regarding the selected function.

Actuate the BIAS corresponding function key and check through the display about the actuation of the selected function by means of a CHECK (√)confirming the graph actuation.

Generally, the BIAS graphs are configured in the following manner:

AIR Bias

The graph will display the Air Temeprature - °C (ordinate axis) along the Time – hs (abscissa axis).

SKIN Bias

The graph will display the Skin Temperature - °C (ordinate axis) along the Time – hs (abscissa axis).

HUMIDITY Bias

The graph will display the Relative Humidity - % (ordinate axis) along the Time – hs (abscissa axis).

OXYGEN Bias

The graph will display the Oxygen Concentration - % (ordinate axis) along the Time – hs (abscissa axis).

For those graphs the time distribution may be 4, 8, or 24 hours and is selected on the system MENU screen.

WEIGHT bias

The WEIGHT graph is accessed by means of WEIGHING procedures as decribed in item 6.5 in this manual, or through the MEMORIZE screen, the NB weight is followed during an interval of 8 consecutivre days.

The graph will show the weight variation (in grams) - (ordinate axis) along the Time – 8 Days (abscissa axis).

Attention: If the display is on the main screen, one may actuate the WEIGHING screen directly by pressing the Decrease key only.

6.1.24- RS 232 Serial Outlet

A related serial port is provided. This port is configured as Data Terminal Device and provides the RS232 outlet.

The following parameters are evaluated through this RS 232 outlet:

- Date of hours
- Air Current Temperature
- Skin Current Temperature
- Relative Humidity
- Oxygen Concentration (optional)
- Weight (optional)
- Oxymetry (optional)

This serial port may be connected to a matrix type printer and in pre-defined intervals by the user the system prints the date, time and control parameters.

To select the print time, do as follows:

- Press the MENU key twice the display will show the SYSTEM MENU screen;
- Actuating on the function keys, take the cursor to the CONFIGURATION item, press the corresponding function key to ENTER;
- The display will show the SYSTEM screen, actuating on the function keys, take the cursor to the PRINTER 001 MIN item;
- Actuating on the INCREASE or DECREASE keys, set the print time in minutes, performance range from 1 to 240 minutes.

6.1.25- Auxiliary Sensor

The Auxiliary Sensor (Re: 092.072.600), is only used for a routine checking of the Incubator internal temperature or having the patient temperature and having the function of simply operate as an indication thermometer.

Connect the Auxiliary Sensor plug into the swtich for the Auxiliary Sensor located on the Incubator lateral panel which is used to the sensor coupling in general.

The auxiliary temperature indication will be displayed on the left upper corner on the screen.

6.1.26- 1186 NEONATAL INCUBATOR Operation General Modes

6.1.26-1. Newly -Born Operation Mode

Turn on the Incubator 1 (one) hour before using it with the NB.

Set the Incubator to heat up to the necessary temperature for the NB.

After the Internal Air Temperature stability to the dome, open the front Access Panel, pull the bed forward, position the NB on the mattress, return the bed to its original position and close the Access Panel.

After that, position the Skin Sensor on the NB skin as per instructions in item 6.3, waiting for the temperature to reach the pre-selected temperature.

Attention: Keep the Access Panel and the Ports open the least time possible to avoid temperature losses. Position the Skin Sensor correctly with appropriate adhesive tape.

Before going to the SKIN operation mode, wait for the temperature indicated on the SKIN display to stabilize or the body temperature is reached (for a normal patient the expected value would be 36,1oC), after this temperature stabilization, actuate the SKIN operation mode.

From this moment on, the Incubator begins to control the temperature according to the newly-born needs.

Attention: If the temperature monitored by the Patient Sensor quickly osciliates, this will indicate that a disloging of the sensor occurred in relation to the NB body. In this condition, the SENSOR MISSING alarm will be actuated continously and may stop if the sensor goes back to its original condition; if this does not occur check the correct positioning of the sensor on the NB and after that press the "Inhibit Sound" key to cancel the alarm.

6.1.27- Operation with Hypothermal Patient

This Incubator has a safety system that controls the Air Temperature at 0,5oC above the set temperature for the NB skin (only for the SKIN operation mode).

When the newly born reaches the expected temperature (Set Temperature) the control becomes proportional according to the NB need.

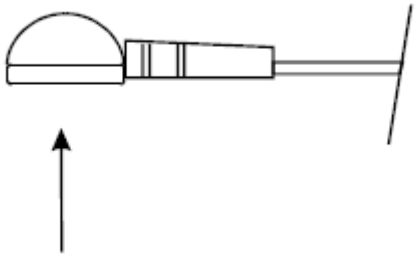
6.1.28- Operation with Sensors In General

The 1186 NEONATAL INCUBATOR sensors have been developed by FANEM especially to be used in their equipment.

The sensors, due to the use characteristics, are delicate parts and should be handled with care specially when they are uncoupled and they should not be pulled by the connection wiring.

FANEM also produces adhesives which are specially devised for the sensor fixing on the NB skin; these adhesives are made of atoxic and antiallergic material and the sensor removal is easy without damaging it. The box contains 100 units Re.: 086.068.600

The Patient Sensor (Re.: 092.059.600) must be placed with its metallic surface in direct contact on the NB skin and fixed with the FANEM sensor adhesive, thus preventing positioning errors, which result from reading failures and several operating alarms.



Position the metallic surface in contact with the patient skin, Patient Sensor - Re.: 092.059.600

Attention: Never remove the sensor from the NB skin by pulling it by the wiring. First remove the adhesive and then the sensor. Before installing the sensor in the patient, check if the sensor body is clean and does not have adhesive remains.

Attention: Never put the Skin Temperature Sensor on the NB or use it to measure the rectal temperature. The Skin Temperature Sensor must be in direct contact with the skin to provide precision in the temperature monitoring of the skin temperature of the NB. Failures to keep direct contact with the skin may result in over heating and possible burns. Check the NB condition for at least every 15 minutes for the correct fixing of the sensor and feel the NB skin regarding no signs of overheating.

6.1.29- Bores for Pipe Inlet

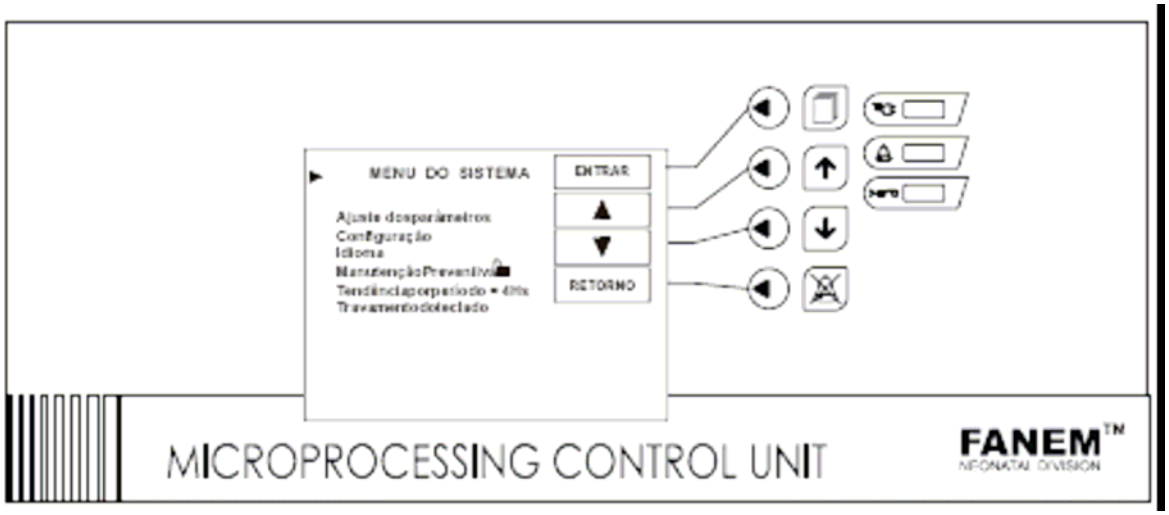
Located on the dome lateral walls, close to the Access Panel; the 1186 NEONATAL INCUBATOR has PVC membranes for the introduction of the breathers, feeding, intravenous solutions intake and monitoring cable piping.

Through this membrane system, the bed with the NB may be slided forwards on the Access Panel with no need to remove pipes, probes or cables.

Attention: All piping, intravenous solution intake, cables and monitoing introduction to the incubator must be performed through those membranes.

6.1.30- System Menus

By means of the MENU key the user has access to various functions and operation parameters of the 1186 NEONATAL INCUBATOR.



By pressing the MENU key, the display will show the SYSTEM MENU screen, the cursor may be moved by means of the function keys for the following topics:

- PARAMETER SETTING;
- CONFIGURATION;
- LANGUAGE;
- PERIOD BIAS 4 Hs;
- KEYBOARD LOCKING

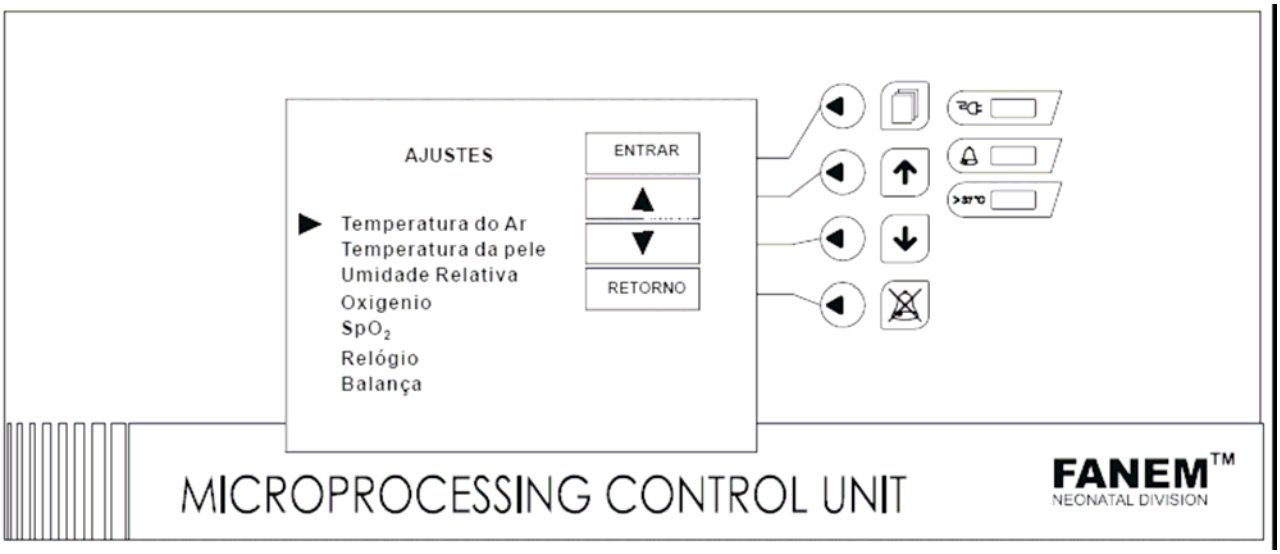
Selecting the desired item, press the function key to ENTER on the respective item:

PARAMETER SETTING

Actuating the PARAMETER SETTING, on this condition the display will show the following items, which may be set:

- AIR TEMPERATURE
- SKIN TEMPERATURE
- RELATIVE HUMIDITY
- OXYGEN
- SpO_2
- CLOCK
- SCALES

The items AIR TEMPERATURE, SKIN TEMPERATURE, RELATIVE HUMIDITY, OXYGEN and SCALES have already been reported in Chapter 6 of this User's Manual.



For the item relative to the CLOCK setting, one should proceed in the following manner:

By the function keys, take the cursor to the CLOCK item, press the function key which corresponds to ENTER, the display will show:

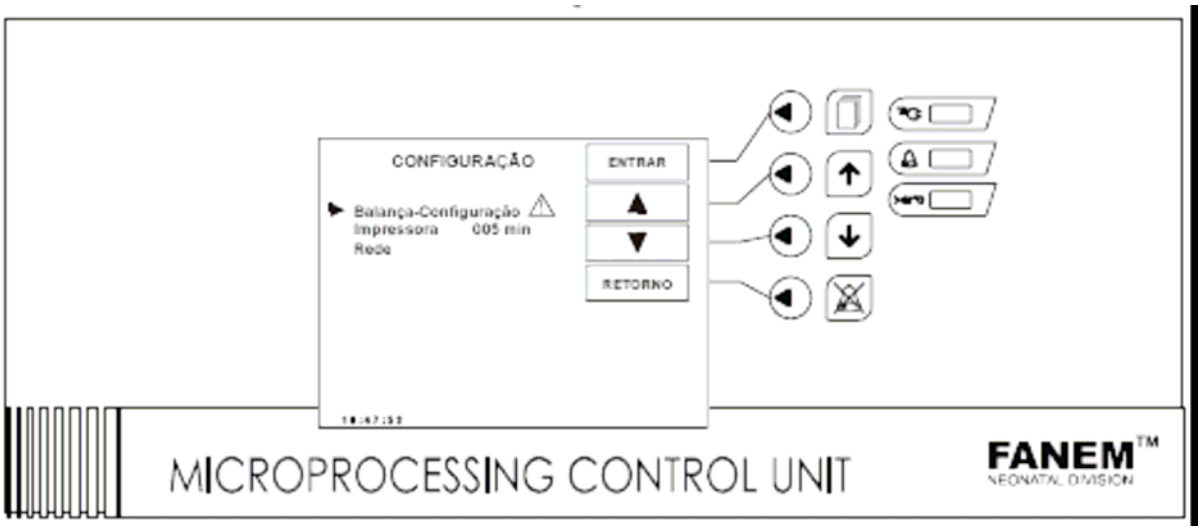
MINUTE
HOUR
DAY
MONTH
YEAR

Actuating on the corresponding INCREASE AND DECREASE keys, one can set the date and hour parameters, where the system will take reference.

CONFIGURATION

By actuating the CONFIGURATION parameter, under this condition the display will show the following items:

- SCALES
- PRINTER 005 min
- NETWORK



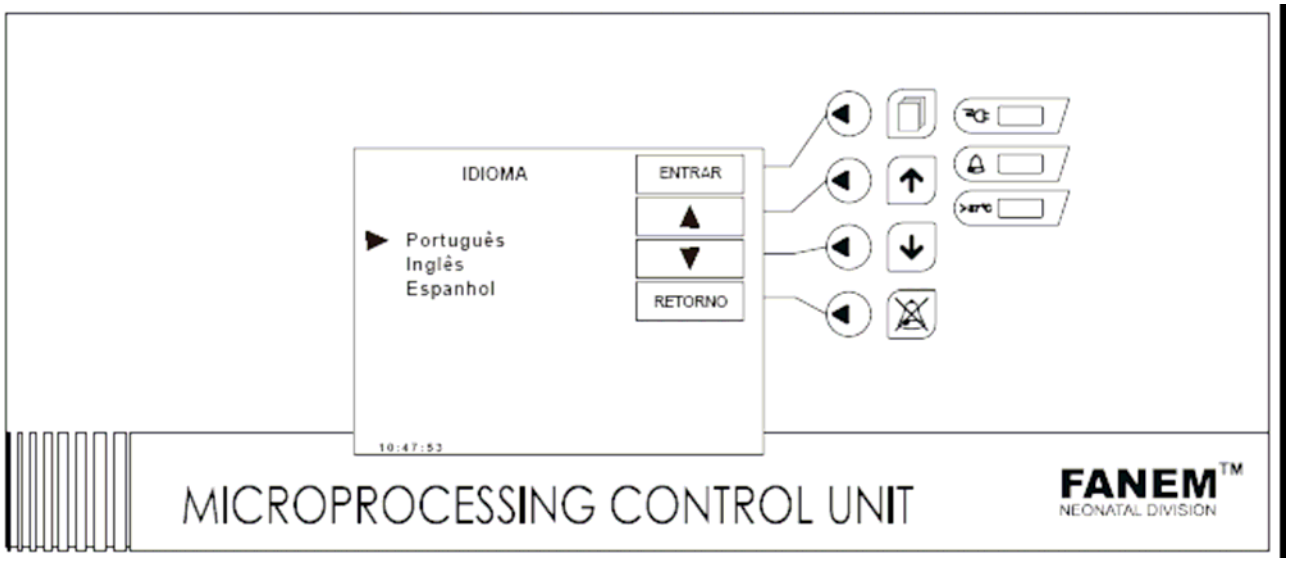
The items relative to the SCALES AND PRINTER parameters have already be reported in Chapter 6 of the USER's Manual.

The parameter for connection in NETWORK is not available for use yet.

LANGUAGE

Entering the SYSTEM MENU, under this condition, the display will show the following items to be selected by the user:

- PORTUGUESE;
- ENGLISH;
- SPANISH;



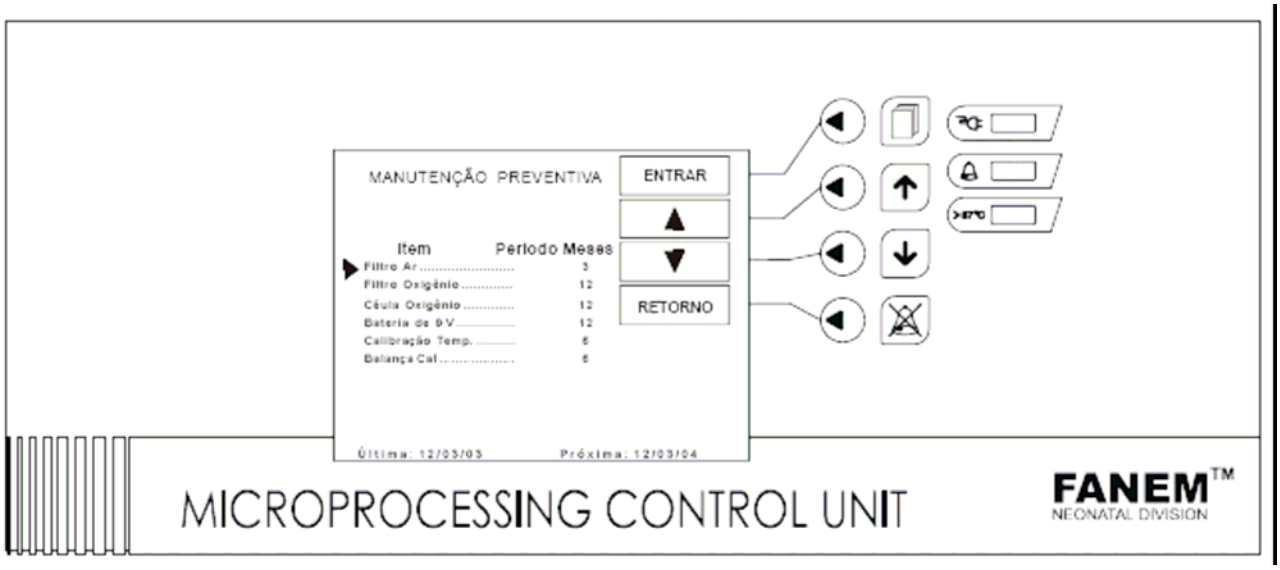
By using the function keys, you can select the language and the temperature grading that the system will adopt.

PREVENTIVE MAINTENANCE

By actuating the PREVENTIVE MAINTENANCE parameter, under this condition, the display will show the following basic items for the user information and warning:

1. AIR FILTER – Change the Air Filter every 3 months
2. OXYGEN FILTER – Wash the O2 Filter every 6 months
3. OXYGEN CELL – Change the O2 Cell every 6 months
4. 9V BATTERY – Change the battery every 12 months
5. TEMP CALIBRATION. – Every 6 months

After performing maintenance, such as for example the Air Filter substitution, by means of the function keys, select the repaired item and confirm by pressing its corresponding key; the current date will be recorded together with the date of the next intervention.



7. Preventive and Corrective Maintenance; Maintenance

7.1. 1186 Neonatal Incubator

7.1.1- Preventive and Corrective Maintenance; Maintenance

This section supplies leaning and maintenance instructions. Where necessary, disassembly instructions are provided. The maintenance not provided in this section must only be executed by the qualified authorized technical service.

On a routine basis, inspect the patient compartment and put the accessories again before putting the Incubator into service.

Attention: In order to start a cleaning or maintenance procedure, check if the incubator is disconnected from the electric power.

Attention: Ensure that the oxygen supply to the Incubator is off and that the Incubator is disconnected from the oxygen supply when performing cleaning and maintenance procedures; risk of fire and explosion exist when performing cleaning and/or maintenance procedures in an ambient with oxygen.

Attention: The Heater may be sufficiently hot to cause burns; avoid removing or touching the heater until the unit has been turned off for at least 45 minutes.

7.1.2- Instructions for Cleaning and Maintenance

By the time of the initial receipt of equipment and whenever the incubator is turned off, inactive, or when the newly-born is removed from the incubator, hospital release or even as per the procedures of the Hospital Infection Control Committee- CCIH, the procedure of a deep cleaning and disinfection in the Incubator is recommended. The most effective cleaning procedure is first by disassembling it and then group the parts in categories according to the required cleaning method.

♦ **Acrylic Dome**

Clean it carefully and use a soft fabric in all the surfaces of the dome inside and outside with water and neutral soap only with disinfectant for a fixed surface that does not contain agents that would damage the acrylic parts and the metallic parts in general.

Attention: do not expose the acrylic dome to direct radiation of lamps with any adequate filters. The ultraviolet radiation may cause cracks and may destroy the acrylic transparency.
We do not recommend disinfectants that contain alcohol as they may damage the acrylic dome.

♦ **Cleaning Standard Protocol**

Material used:

- Enzymatic detergent that does not contain alcohol, sodium hypochlorite or chlorexidine based products.
- Container to keep detergent.
- Cleaning Brush.
- 3 bandages – Operatory field – being one bandage for cleaning, one bandage for the removal of the excess product and another one for drying.
- 2 pairs of gloves for procedure.

1 - Cleaning:

Use a bandage to apply the solution removing the excess of dirt before soaking it again in the solution. Change the solution whenever you realize the presence of blood and secretion.

Procedure:

- Wash hands,
- Put on gloves for procedure,
- Put product in the container in the following dilution – 3 ml. For each liter of water.
- Disconnect and remove all extensions such as the skin sensor cable and scales cable,etc.
- Remove the fixtures,
- Begin cleaning by the outer part of the incubator.
- Disassemble and clean the equipment, by removing the mattress, bed, bed support, air pipe, humidity reservoir deflector, double wall and control unit (see "Controller Unit Panel Cleaning").
- Clean the cables and fixtures,
- Clean the internal part of the incubator with only one movement, upwards, downwards and from left to right.
- Remove the procedure gloves

2 – Removal of Excess Product and Drying:

Use a bandage humidified in water to remove the excess product and then apply the dry bandage.

Procedure:

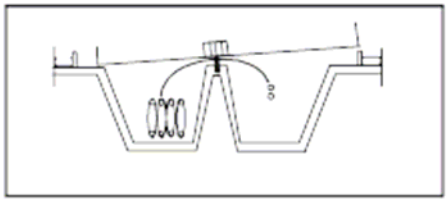
- Wash the hands.
- Put on the gloves for procedure.
- Remove the product excess with one humidity bandage and use another bandage to dry the internal and external part of the incubator.
- Remove the excess product and dry the components, following the assembly order, tray, bed support, mattress, double wall and controller unit (see "Reassembly of Incubator").
- Remove the excess product and dry the fixtures and cables, connecting them to the Incubator.
- Remove the gloves for procedure.
- Wash the hands

Connect the incubator to the electric power and keep it on, even without a patient, programming a pre-set temperature, for example, 34 or 36ºC, or as per the operational procedures of the sector. This is necessary in order to maintain the cleaning and aseptic conditions through the air filtering and forced circulation, until the next use.

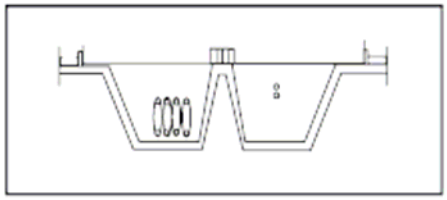
- **Reassembly of the Incubator**

a) Install the air pipe
b) Install the deflector of the humidity reservoir.
c) Install the control panel.
d) Reposition the water level.
e) Install the dome fixture.
f) Replace the internal tray, checking if it is in the right position, as it is shown in the figures below and press the Tray lock button.

Badly Positioned Tray
Tray placed on the fixture, in one of the side allowing air passage.



Correctly Positioned Tray
The tray must be seated directly on the base with the fixture around it.

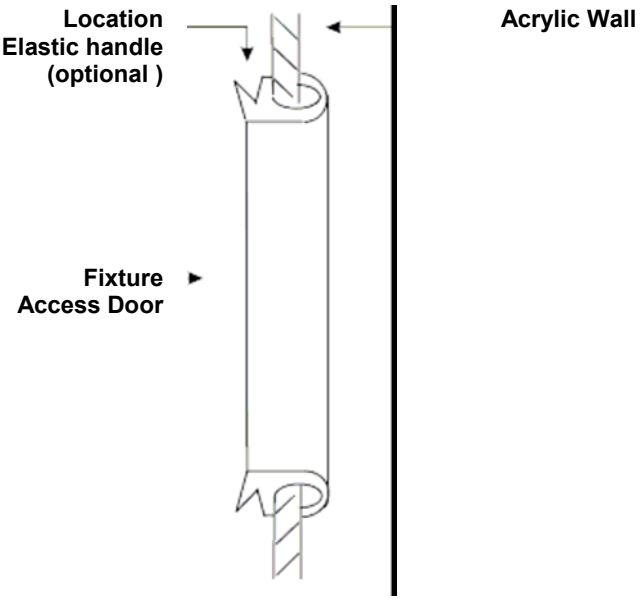


g) Replace the mattress bed on the elevator guides.
h) Place the mattress with the cover on the bed.
i) Install the ports fixtures. As in the figure below.
j) Close the dome.

- **Fanem® Humidifier (optional accessory)**

a) Remove the container.
b) Remove the Atomizer assembly, rotating it slightly and pulling it outwards.
c) Clean the metallic Atomizer in runnimng water using a small sponge or brush. Do not use metal parts to clean the bores.
d) Make the disinfection with the product adpoted by the Hospital Infection Control Committee, being careful not to leave residues.
e) Assemble the Humidifier and check that the Atomizer is in its correct position.

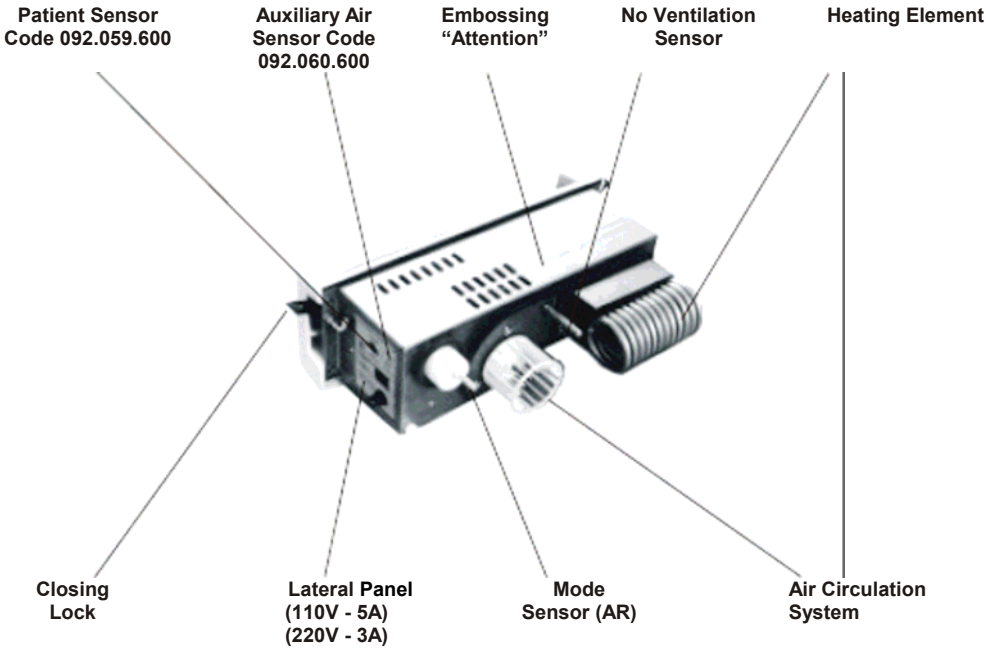
Port Fixture Correct Positioning



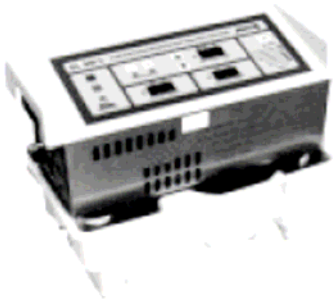
7.1.3- 1186 Microprocessed Controler Unit Panel

To remove the control panel, first turn off the incubator, take out the cables connected on the panel lateral, pull the two lock leverslocated on the panel lateral (black levers), upwards as shown in the figure and holding the panel, pull it softly outwards.

Attention: To begin a cleaning or maintenance procedure, check if the incubator is disconnected from electric power.



1186 Controller Unit Panel Cleaning



- **Cleaning and/or disinfection tank - EMA model**

For cleaning, proceed as follows:

1. Fill up the tank with 5,5 lters of clean water;
2. Add liquid neutral soap in the necessary amount;
3. Position the control panel as shown in the figure;
4. Connect the feeding cable to the switch and turn it on for 5 minutes;
5. Remove the panel supporting it on a surface;
6. Remove the water from the tank substituitng it for 5,5 liters of clean water;
7. Position the control panel again on the tank to make the rinsing, and keep it on for 5 minutes more;
8. Remove the panel drying it well before installing it in the incubator.

Re.: 086.100.321

Exclusive use with the 1186 Neonatal Incubator

Attention: We recommend the cleaning and disinfection of the controller unit at every change of patient or as per the norms of the Hospital Infection Control Committee.

7.1.4- Cleaning and Maintenance

The non-sterile reusable sensors require cleaning with agents such as alcohol at 70% or 1:10 water solution sodium hypochlorite), before being used in infected patients or by those who are more prone to infections.

7.1.5- Air Filter – Kit with 4 parts - Re: 090.058.600

Attention: Disposable consumption, Air Filter. It must not be cleaned or placed with the dirty face to the internal side. It must be changed whenever completely dirty or at the maximum of every 3 months.

- Remove the Filter lid by rotating the fixing buttons at 900;
- Remove the used Air Filter;
- Clean and dry all filter accommodation surfaces;
- Install the new filtering element and reinstall the rear panel.

Attention: A dirty air filter may affect the O2 concentration and/or cause carbon dioxide accumulation in the interior of the incubator. Check if the filter is checked in a routine that is compatible with the conditions of location. Especially, if the incubator is used in an environment that is usually dusty, more frequent changes may be deemed necessary.

Exclusive use with the 1186 neonatal Incubator

7.1.6- Humidity Reservoir

Open the access lid to the Humidity reservoir by rotating the fixing button and pulling the set.

Completely drain the reservoir through its hose for drainage.

Replace the drainage hose in its stand-by nipple and disconnect the system reservoir dislodging it towards the access lid.

Remove the reservoir by pulling it upwards.

After the set aseptic cleaning, put the reservoir back in its original position, coupling it to the system inlet. Check if the hose for drainage is perfectly installed and then add distilled and sterilized water by its lid.

Attention: Before performing the removal of the reservoir, Check if the humidifier system and its reservoir have no water so as to avoid undesirable spills.

Sterilization

The water reservoir set for 1186 Neonatal Incubator, may be sterilized by the process of disinfection with peracetic acid, or with a **gravity autoclave process**, or also sterilization with **Ethylene Oxide** and Low Temperature steam with formaldehyde (low temperature sterilization process), the health institutions using the **Peroxide Plasma STERRAD®** process shall validate the mentioned process.

It is important to mention that the gravity autoclave process does not use a vacuum pump for the sterilization cycle, since the autoclaves using this process may damage the water reservoir, together with various exiting packing types, such as cotton fabric, non woven, crepe paper, surgical degree paper and plastic filmand others.

Attention: The reservoir set shall not be sterilized in pre vacuum type autoclaves.

1- Sterilization Procedure with Autoclave:

To sterilize the set, first perform a manual cleaning of the parts in question with enzyme detergent, **with posterior rinsing with tap water and drying**. Pack the uncovered reservoir, in surgical degree paper packing, or crepe paper or SMS. The reservoir set shall be sterilized with the following parameters:

Temperature 121°C during 20 minutes – Clothes Cycle

Attention: Never overpass the maximum temperature of 121 °C for the sterilization. Validate your autoclave for the desired temperatures.

When using surgical degree paper packing and plastic film, certify the correct position of the reservoir inside the packing, this shall have the nozzle turned to permeable paper side, not the plastic film, in order to avoid nozzle obstruction and internal over pressure of the reservoir.

Remove the package from the autoclave and store it up to 30 days.

Attention: Never sterilize the reservoir set with closed cover.

We recommend the use of autoclave FANEM model 420 FKO according to its general use recommendations.

2- Procedure for Disinfection with Peracetic Acid:

- Receive the reservoir from the Intensive Neonatal Treatment Unit, disassemble it and wash with enzyme detergent.
- Remove the product excess with water.
- Rinse again with water and dry.
- Immerge the reservoir and its connections in the container with peracetic acid - STERILIFE®, and leave it there for 10 minutes.
- Remove the reservoir from the solution and rinse with sterile distilled water.
- Pack as appropriate.

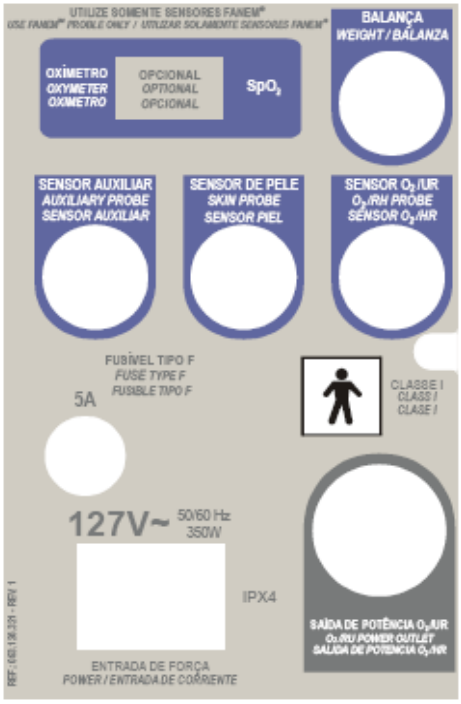
For safety and easy use we recommend the Kit **Ref: 093.071.600**, Water Reservoir Set. Thus you can have a unit in operation, another one at sterilization.

7.1.7- Shelf

To remove the shelf, remove the fixing bolt with a allen wrebch of 2mm; force it upwards with the two hands.

Attention: Never put weight higher than 10kg on the shelf.

7.1.8- Fuse Change



To change fuses, turn off the incubator from electric power.
With the help of a screwdriver introduce it on gap of fuse door and rotate counterclockwise until the lid is released.

127 V~	220 or 240 V~
5A	3A
F Type	F Type

7.1.9- Spare Parts

For possible spare parts, refer to section 3 of this Manual: Parts, Pieces and Accessories, with their respective references.

The function and safety of the 1186 Incubator will only be guaranteed if the checking, maintenance and repair services are performed by the Fanem Technical Assistance or by duly trained and qualified by Fanem Ltda.

Fanem Ltda. holds harmless from any responsibility for damages that may occur in the equipment and with consequences to the patients due to improper maintenance, not performed by our Technical Assistance or when original spare parts/ accessories are not used in a change.

The materials used in the manufacture of parts and accessories and consumption and wear items aim at guaranteeing the perfect operation of the equipment according to their original characteristics as well as the safety regarding toxicity and inflammability of the employed materials.

Attention: Use only FANEM original parts.

7.1.9-1. Consumption and Wear Parts

Reference	Description	Period	Performer
090.058.600	Air Filter Kit – 4pcs	3 months	User/Technician
092.100.026	Rechargeable Battery 9V	12 months	Technician
090.854.020		6 months	User/Technician
092.135.600	Elastic Handle with Oval Port	6 months	User/Technician
086.168.320	Iris Sleeve	6 months	User/Technician
086.068.600	Adhesive for Patient Sensor-100 Pcs	Disposable	User
086.117.320	Base Fixture made of atoxic PVC	12 months	User/Technician
092.107.320	Oval Port fixture made	12 months	User/Technician
090.111.322	Air Damper made of atoxic PVC	12 months	User/Technician
090.112.322	Air Damper made of atoxic PVC	12 months	User/Technician
158.320.023	Self-Extinguishable Foam	12 months	User/Technician
158.615.023	Mattress Cover made of atoxic PVC	12 months	User/Technician

7.1.10- Rechargeable Battery

The 1186 Neonatal Incubator control units have a NiCd - 9V ⎓ type rechargeable battery which has the function of feeding the power failure alarm in case of power break.

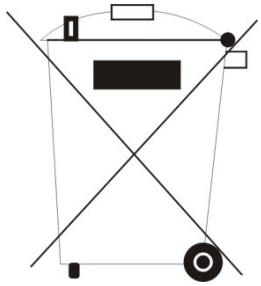
This battery is auto-rechargeable with the normal use of the equipment and its useful life is estimated for 12 months and once this period has elapsed the battery must be substituted for a new original part.

Attention: Danger of Explosion, do not use common or alkaline battery. Use only rechargeable battery FANEM. Re.: 092.100.026. Access and substitution of this battery must only be performed by a trained technician.

In order to perform the battery substitution, one should unscrew the control unit front panel, actuating on the 4 lateral bolts of the controller unit, uncouple the front panel, remove the battery from its container and perform the substitution. The battery connector is polarized, thus eliminating the risk of inattentive connections.

Battery charge: For the full operation of this battery, it should be totally charged. The battery charge is performed when the incubator is turned on and the initial charge time must be 10 hours.

7.1.11- Disposal



Don't throw devices or electronic pieces in the garbage when of the discard of the equipment or your pieces.
To minimize the pollution and to assure the maximum protection of the global atmosphere, please recycle. For larger information on the "Residues of Electrical and Electronic Equipments" it consults w-sites related to "Waste Electrical and Eletronics Equipment– WEEE."

If the equipment disposal is necessary, or even its parts, and they do not have a specific destination defined by the client, the referred item must be sent to the manufacturer or its legal representative for the due disposal measures as per the current national legislation.

Attention: The disposal of batteries must be performed as per the current legislation in the country.

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

The non-fulfillment of those conditions holds the supplier harmless from the responsibilities on possible impacts to the environment and/or people.

7.1.12- Maintenance Chart

It is the user's responsibility to establish a routine maintenance procedure in order to ensure one correct performance of the equipment, with due safety.

Part		Period	Performer
Air Filter	Re: 086.058.600	3 months (Substitution)	User / Technician
O_2 Imitator Filter	Re: 086.108.320	3 months (Washing)	User / Technician
Rechargeable Battery	Re: 092.100.026	12 months(Substitution)	Technician
Controller Unit Cleaning and Disinfection		Every patient change	User/Technician
Routine Calibration		4 to 6 months	Technician

7.1.13- Failure Diagnosis

SYMPTOM	CAUSE	SOLUTION
Unit Off	General key was not pressed	Press the "On" key
The unit will not star even by pressing the "On" key	Cable disconnected from electric network	Connect the cable correctly
The unit does will not turn off	"Turn off" key pressed in a wrong manner	Press "Turn off" key during 2 seconds until the effective turning off occurs in the unit.
"Power Failure" Alarm Actuated	Burned Fuse	Change fuse located on lateral panel: 5A F Type - 127V~ 3A F Type - 220V~
	Power Failure	Check voltage in the hospital network
	Disconnected Cable	Connect power cable on lateral panel
Air "High Temperature" Alarm	Badly positioned tray Opened access port or iris sleeve	Position the tray correctly see Fig. page 27 Close all access doors and iris sleeve correctly
Alarm Low Temperature	Badly positioned skin sensor in newly-born ("Skin" Mode)	Place the sensor on the newly-born correctly
Lack of Ventilation	No Air Circulation	Check the motor set fan or obstruction in the air inlet and outlet duct on tray.
	Resistance high temperature caused by positioning error of Patient Sensor when the access door is open	When the front access door is open, keep the Patient Sensor inside the Incubator or positioned on patient.
Oxygen low concentration	Opened Access Port or iris sleeve	Close all doors
	Badly positioned tray	Correctly position the tray
	Air filter not installed	Check if the air filter is correctly installed
Oxygen high concentration	Dirty Air Filter	Change Air filter
	Air Inlet pipe not installed	Correctly install the pipe
It does no heat even with heating indication on front panel	Burned heating resistance	Call the Authorized Technical Assistance
	Feeding Tension 127V~ or 220V~ below specification 127V~ or 220V~ ± 10%	Check voltage in hospital network
Front Panel Display with wrong, random, erased indication and alarm sound inappropriate time.	I.E.M excess in hospital network I.E.M – Electromagnetic irradiation	Turn off unit and turn it on again. If problems continue, call Technical Assistance

7.2. Integrated Pulse Oxymetry Monitor Kit

7.2.1- Consumption and Wear Items

Reference	Description	Period	Performer
090.152.600	ADH-P/I bandages WRAPS sensor	1 per patient	User
090.151.600	FOAN P/I bandages WRAPS sensor	1 per patient	User

7.2.2- Maintenance Chart

The user is responsible to establishing a maintenance routine procedure so as to ensure a correct performance of the equipment, with its due safety.

Intervention	Period	Performer
Cleaning/ Disinfection	Weekly / at every patient change	User / Technician
Routine Checking	12 months	Technician

7.2.3- Failure Diagnosis

Symptom	Cause	Solution
Reading is not performed	Processor	Turn on and off the incubator again
		Check the sensor positioning.
Unstable Reading	Sensor	Check if there is direct light on sensor.
		Check if the sensor optical window is clean.

Note: If the problems continue call the nearest Fanem Authorized Technical Assistance.

7.3. Alarm Checking – 1186 Incubator

This may be performed by means of simulation of the indicative alarm check up on the Control Panel.

Attention: When the "INHIBIT SOUND" key is actuated, inhibiting the alarm, the alarm will remain inactive during 15 minutes, and it goes into the active condition after this period of time has elapsed.

7.3.1- "Sensor Missing" Alarm

- ☑ **1186 Control Unit LED panel without optionals**
- ☑ **LED panel with optionals**
- ☑ **LCD panel with optionals**

With the "Patient Sensor" connected to the Incubator panel, select through the front panel the "Skin Mode" condition. Disconnect the "Patient Sensor" cable from the lateral panel and the " Sensor Missing" visual and sound alarm will immediately actuate.

7.3.2- "Air Circulation" Alarm

1186 Control Unit

- ☑ **LED Panel without optionals**
- ☑ **LED panel with optionals**
- ☑ **LCD panel with optionals**

On the Incubator front panel, select "Air Mode" condition, and actuating on the "Temperature Setting" display select the temperature of 36°C. Let the system stabilize for approximately 30 minutes. After this stabilization obstruct the inlet or outlet ventilation duct on the Incubator tray.
In an interval between 15 to 120 seconds, the visual and sound alarm "Lack of Ventilation" should actuate.

Attention: When the Incubator is turned on, this alarm remains unactuated during 40 minutes, going to the active condition after this period has elapsed.

7.3.3- "High Temperature Alarm"

1186 Control Unit

- ☑ **LED panel without optionals**
- ☑ **LED panel with optionals**
- ☑ **LCD Penal with optionals**

"Skin Mode"

Note: Trigger at +1°C in relation to the programmed temperature on the control point.

Select the condition in "Skin Mode", and actuating on the "Temperature Set" display, program the 36°C temperature. Insert the "Patient Sensor" inside the dome and after the system stabilization, actuate on the "Temperature Set" display and decrease at 1°C the previously programmed temperature. The "High Temperature" visual and sound alarm will be immediately actuated.

"Air Mode"

Note: Trigger at +1.5°C in relation to the programmed temperature on the control point.

Select the "Air Mode" condition and actuating on the "Temperature Set" Display, program the temperature of 36°C. After system stabilization, actuate on the "Temperature Set" and decrease the previously programmed temperature at 1,5°C. The "High Temperature" visual and sound alarm will be immediately actuated.

7.3.4- "Low Temperature" Alarm

1186 Control Unit

- ☑ **LED panel without optionals**
- ☑ **LED panel with optionals**
- ☑ **LCD panel with optionals**

"Skin Mode"

Note: Trigger at -1,0°C in relation to the programmed temperature in the control point.

Select the condition in "Skin Mode" and actuating on the "Temperature Set" display, set the temperature of 36°C. Insert the "Patient Sensor" inside the dome and after the system stabilization, actuate on "Temperature Set" display and increase the previously programmed temperature at 1,0°C. The visual and sound alarm of "Low Temperature" will be immediately actuated.

"Air Mode"

Note: Trigger at -3,0°C in relation to the programmed temperature in the control point.

Select the condition in "Air Mode" and actuating on the "Temperature Set" display, set the temperature at 34°C, after the system stabilization, actuate on "Temperature Set" display and increase the previously programmed temperature at 3,0°C. The visual and sound alarm of "Low Temperature" will be immediately actuated.

7.3.5- "Power Failure"Alarm

1186 Control Unit

- ☑ **LED panel without optionals**
- ☑ **LED panel with optionals**
- ☑ **LCD panel with optionals**

With the incubator in operation, disconnect the power cable off the electric power. The visual and sound alarm "Power Failure" will be immediately actuated.

7.3.6- "High Humidity" Alarm

1186 Control Unit

☐ **LED Panel without optionals**

☑ **LED Panel with optionals**

☑ **LCD Panel with optionals**

Note: Trigger at +10% in relation to the programmed humidity in control point.

Set a value of 70% of relative unit after system stabilization, actuate in control of humidity and increase previously programmed humidity at +10% the, now setting at 80%. The "High Humidity" sound and visual alarm should be immediately actuated".

7.3.7- "Water Shortage" Alarm

1186 Control Unit

☐ **LED Panel without optionals**

☑ **LED Panel with optionals**

☑ **LCD Panel with optionals**

Note: Trigger in -10% in relation to the programmed humidity in control point.

Set a value of 70% of relative unit, after system stabilization, remove water from humidifier reservoir. The alarm actuation will occur after 10 minutes on the concentration condition of 10% below the previously programmed value.

7.3.8- "High Oxygen Concentration " Alarm

1186 Control Unit

☑ **LED Panel without optionals**

☑ **LED Panel with optionals**

☑ **LCD Panel with optionals**

Note: Trigger in +3% in relation to the programmed concentration in control point.

Set a value of 50% oxygen concentration, after system stabilization, actuate on oxygen control and decrease 3% the previously programmed concentration. The " O_2 High Concentration sound and visual alarm will immediately actuate

7.3.9- "Low Oxygen Concentration" Alarm

1186 Control Unit

☐ **LED panel with optionals**

☐ **PLED panel with optionals**

☑ **LCD panel with optionals**

Note: Trigger in -3% in relation to the programmed concentration in control point.

Set a value of 50% oxygen concentration, after system stabilization, actuate on oxygen control and increase 3% the previously programmed concentration and interrupt the O_2. feeding. After 3 minutes the "O_2 Low Concentration sound and visual alarm will immediately actuate.

7.3.10- "Pulse Oxymetry" Alarms

1186 Control Unit

☐ LED Panel without optionals

☐ LED Panel with optionals

☑ LCD Panel with optionals

As it regards the NB physiological parameters, such as O_2 Saturation, Heart Beats per minute, etc, the checking of those alarms may be performed with the help of a specific simulator for application.

8. Guarantee and Technical Assistance

- Like all the Fanem® brand equipment, this equipment also has a total guarantee of 01 (one) year for possible defects in the parts (see Guarantee Term in the annex).
- For all types of maintenance, with or without the guarantee, always go to the Fanem Authorized Technical Assistance. Do not allow third parties, without suitable technical qualification to damage or change the original characteristics of your equipment.
- Always use the Fanem® Original parts.
- Registry at ANVISA nr. 10.224.620.054
- Technician In Charge

  Eng. Orlando Rossi Filho

  CREA/SP 98.435/D

EC REP

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