

USER MANUAL  
IT-158 TS TRANSPORT INCUBATOR

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IT-158 TS TRANSPORT INCUBATOR

Fanem Ltda.



Technical Standard - NBR IEC 60601-1

NBR IEC 60601-1-2

NBR IEC 60601-1-6

NBR IEC 60601-1-8

NBR IEC 60601-2-20

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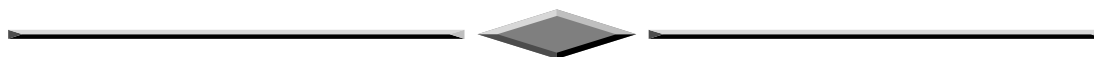
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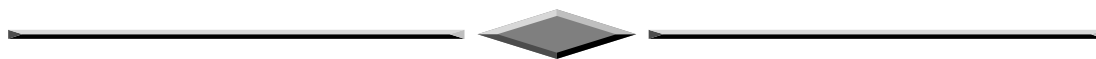
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## **Presentation of the Manual**

This User Manual provides general instructions for installation, use, operation, maintenance and troubleshooting of the IT-158 TS Transport Incubator, manufactured by Fanem Ltda.

Prior reading of this manual is an essential condition for proper use of the equipment.

According to current regulations, Fanem Ltda will not be held liable in cases where:

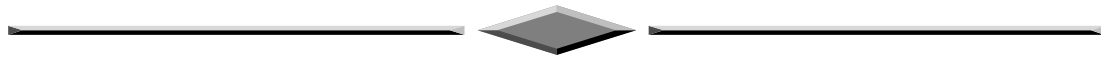
- The equipment is not used according to the instructions contained in the User Manual;
- Maintenance recommendations are not followed, such as any calibration or repairs done with components and/or personnel not authorized by Fanem Ltda.

The recommendations in this manual should be followed in whole and always be accessible to all those who use the equipment.

In case of questions, Fanem Ltda and its representatives are available for further clarifications.

Good reading!

**Warning! Carefully read this manual before using this equipment.**



## 1. Identification of the Equipment

The IT-158 TS Transport Incubator is a mobile medical electrical device which consists of a rigid transparent compartment, in the form of a box, providing a closed and controlled environment for heating newborns through the circulation of heated air on the skin during transport. The equipment includes monitoring sensors, a system of audible and visual alarms, a heating element to provide heating to the incubator, a fan for circulating heated air, a water tank for adding humidity, a control valve through which oxygen can be administered, access hatches that enable handling patients while limiting the entry of cold air, a safety belt for securing the patient, a place for gas cylinders, coupling for a cart/stretchers to be installed in emergency transport vehicles, and an additional electrical power source for an internal battery, with an external DC inlet to keep the equipment operating when it is not connected to an AC power source.

Its function is to provide a thermal neutral environment through adequate control of the temperature inside the compartment of the incubator. This environment allows newborns that are premature and/or have complications to maintain a normal body temperature with low metabolic rates, which helps them develop faster, with a lower incidence of clinical complications.

This equipment is especially designed for safe transport of newborns of different gestational ages and clinical conditions, including high-risk cases, such as premature births and serious diseases, receiving care and treatment while being moved internally between different sectors of a hospital or moved externally to other services or hospitals.

The IT-158 TS Transport Incubator has an operating module with an automatic charger and two 12 V rechargeable batteries, which enables transport for up to four hours. It also has an additional 12 V inlet for ambulances and another 28 V inlet (optional) for aircraft, enabling the equipment to be powered by a DC power source during transport.

The IT-158 TS Transport Incubator has a control panel that provides easy viewing and operation of the functions and parameters of the equipment, such as: Air temperature (ATC), Skin temperature (ITC), with operating mode indicators (AC mode - mains, and DC mode - batteries), heating power and battery charge, in addition to audible and visual alarms, such as Power Failure; Air Circulation, High and Low Temperature, No Sensor and Battery.

This incubator provides a protective insulated microclimate through the admission and circulation of microfiltered air and internal positive pressure, heating in Air Mode and Skin Mode, different microfiltered oxygen concentrations and passive relative humidity to create a neutral thermal environment for receiving and caring for newborns.

The transparent, optical quality hood provides full viewing and has a double wall to provide better thermal insulation and less calorie loss in newborns.

Patients can be treated by up to three professionals through the following openings in the hood:

- ♦ Three access doors, where the two on the front and rear fold down and can be fully opened, and the one on the side, at the head of the hood, is equipped with two silicone double tubing ports for introducing and positioning ventilation circuits adapted to the newborn, with no need for disconnection and without changing the microclimate.
- ♦ Four hatches (two front and two rear accesses), outfitted with elastic cuffs which enable hand and forearm entry for performing procedures with newborns, without affecting the microclimate conditions of the incubator.
- ♦ Four single tubing port for introducing, directing and attaching sensor cables and drains in relation to patients and sources, thereby avoiding folds, discomfort or disconnection.

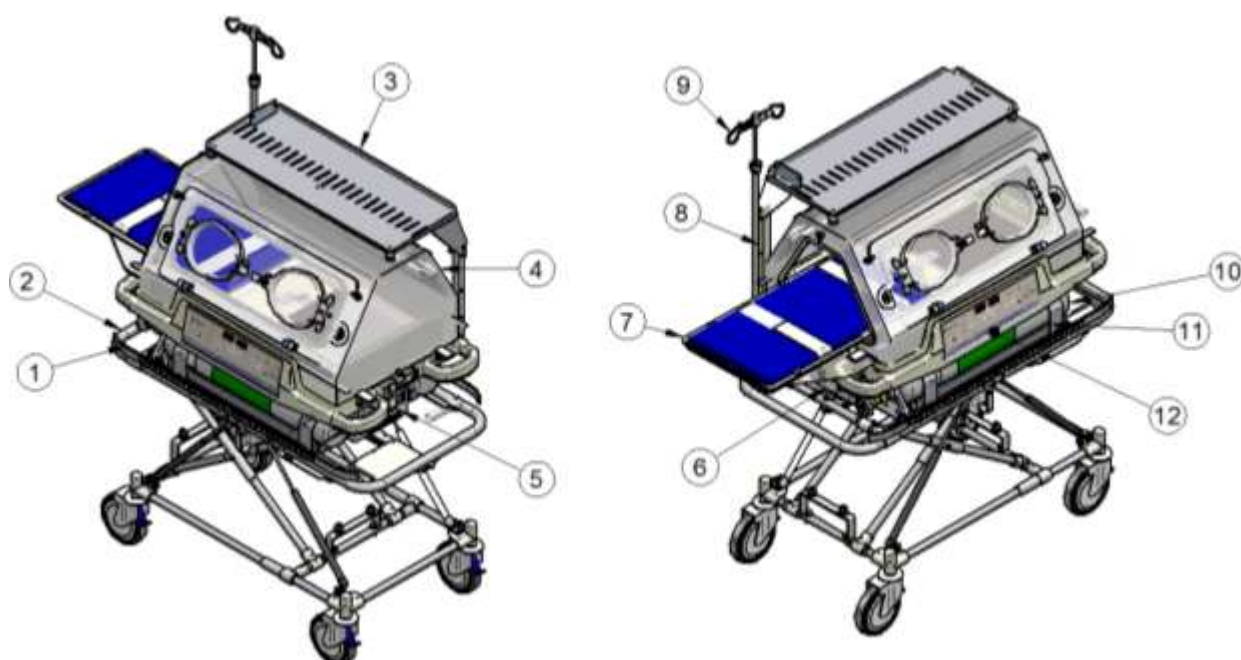
The bed can be slid out through the side door on rails and supported outside the hood (to a distance of up to 24 cm) enabling access to the head and trunk of the newborn, in emergency situations for performing special procedures, while continuing to supply heat to the patient. The bed has a safety belt which can be adapted to the newborn's body and provides safety during transport.

The mattress has a self-extinguishing, non-toxic, seamless cover which is easy to clean and disinfect, and its edges facilitate procedures.

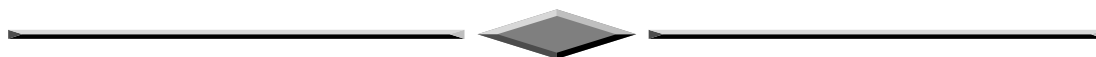
The incubator is equipped with LED lighting to observe patients in low-light environments.

The IT-158 TS Transport Incubator can be operated in 100 V~ to 240 V~ power systems.

Depending on the type of transport or vehicle that will be used, it can be adapted and attached to different types of carts and/or stretchers, such as: an X-shaped transport cart, with an aluminum structure and shock absorbers, and four 6" casters, with brakes, and adjustable height in three positions: upper, intermediate and low; or flat ambulance stretchers, with four 7.5" casters.



1	Bumper	7	Tray with mattress
2	Transport cart	8	Dual strip
3	Auxiliary shelf	9	IV Pole
4	Acrylic hood	10	Cylinder
5	Battery module (Vital Module)	11	Cylinder bracket
6	Power module	12	Front control panel



The main features of this equipment are:

- ♦ Audible and visual safety alarms;
- ♦ Independent air and oxygen inlets, with filters;
- ♦ Indication of the proportional power level of the heating element;
- ♦ Set points saved in the memory;
- ♦ Automatic auto-test system;
- ♦ Programmable T1 skin temperature servocontrol system;
- ♦ Redundant safety system, with auto shutdown of the heating system in the event of high temperature;
- ♦ Specific valve for oxygen admission to the hood.

The IT-158 TS Transport Incubator also has a number of optional items, comprised of features and devices (integrated and/or joint use), which can configure and optimize the equipment for real conditions of use, such as:

- ♦ Babypuff® 1020 Neonatal Resuscitation Device;
- ♦ Blender;
- ♦ Air and O<sub>2</sub> cylinders with air and O<sub>2</sub> reducing valves;
- ♦ IV Pole;
- ♦ Auxiliary LED lighting;
- ♦ Adhesive kit for temperature sensors;
- ♦ Infant pillow.

The IT-158 TS Transport Incubator and all its accessories were designed according to the highest standards of technology, quality and safety, to ensure safe transport and patient comfort in all newborn care situations. The equipment can also be fully disassembled for cleaning purposes.

This equipment should only be used by properly trained and qualified health professionals in order to achieve the desired results for internal and external transport, with quality and safety for both patients and users.

This equipment was manufactured in compliance with the following technical standards:

ABNT NBR IEC 60601-1	General Requirements for Basic Safety and Essential Performance;
ABNT NBR IEC 60601-1-2	Electromagnetic Compatibility – Requirements and Tests;
ABNT NBR IEC 60601-1-6	Usability;
ABNT NBR IEC 60601-1-8	General requirements, tests and guidelines for alarm systems in medical electrical equipment and medical electrical systems;
ABNT NBR IEC 60601-2-20	Specific requirements for basic safety and essential performance of transport incubators for newborns.

Considering the characteristics of use of this equipment, special care is needed with its handling and operation, to achieve optimum clinical effectiveness. This User Manual provides general instructions for installation, use, operation, maintenance and troubleshooting of the IT-158 TS Transport Incubator, manufactured by Fanem®.


Provided that the equipment undergoes the preventive and/or corrective maintenance procedures recommended in this manual, its actual useful life can be extended. The average useful life of this equipment is estimated to be approximately eight years, taking into account factors such as technological obsolescence of the product or improved technical standards related to its development.

## 2. Technical Specifications

### 2.1 Definitions

- ♦ **ATC:** Control mode where the heating of the air is automatically controlled to maintain the air temperature set by the user. It is measured by the air temperature sensor and is equivalent to control in Air Mode.
- ♦ **Routine Calibration:** Calibration of the equipment and its functions, according to standards previously established by the manufacturer.
- ♦ **Stable Incubator Condition:** Condition achieved when the incubator temperature does not vary by more than 1°C in a one-hour period. Taken at a control temperature of 32°C and/or 36°C.
- ♦ **ITC:** Control mode where heating of the air is automatically controlled to maintain the skin temperature set by the user. It is measured by the T1 skin temperature sensor and is equivalent to control in Skin Mode.
- ♦ **Measurement Points:** Measurements taken at five points on a parallel plane 10 cm above the mattress surface. One point is located 10 cm above the center of the mattress and the other four points are located in the center of four areas formed by lines that divide both the width and length into two parts.
- ♦ **Temperature Overshoot:** Amount by which the internal temperature exceeds the incubator temperature during stable incubator condition, after a change in the temperature set point.
- ♦ **Incubator Temperature:** Air temperature, measured in the control zone.
- ♦ **Control Temperature:** Temperature set point of the controller selected by the user.
- ♦ **Temperature Rise Time:** Time required for the incubator temperature to rise 11°C, when the air control temperature is set at least 12°C above room temperature.
- ♦ **Temperature Uniformity:** Measurement of the difference between the temperature at the control points and the average temperature in the stabilized incubator.
- ♦ **Temperature Variation:** Difference between incubator temperature and average incubator temperature during the stable incubator condition.
- ♦ **Control Zone:** Central point located 10 cm over the center of the mattress surface.

### 2.2 Electrical Specifications

Rechargeable Sealed Lead Acid Battery (two units)	12 V <sub>---</sub> 26 Ah
Leakage Current (for the cabinet)	< 100 µA
Rated Current	1.4 A (127 V~) and 0.82 A (220 V~)
Mains Frequency	50/60 Hz
Power (AC)	150 VA
Power (DC)	80 W
Supply Voltage (AC)	100 - 240 V~
Supply Voltage (DC)	12 V <sub>---</sub>   12 - 28 V <sub>---</sub> (optional)
Polarity of connector for direct current (DC) source	
Minimum Battery Charging Time (for fully discharged batteries)	30 hours
Duration (when fully charged)	4 hours
Battery Life Expectancy	200 (charges and discharges)



## 2.3 Fuses

Supply voltage	Fuse
External Supply Voltage 100 to 240 V~	2x 3 A - L – Type F 250 V~
External Supply Voltage 12 V---	1x 16 A - L – Type F 250 V~
External Supply Voltage 28 V---	1x 16 A - L – Type F 250 V~
12 V Internal Battery---	1x 16 A - L – Type F 250 V~

## 2.4 Classification and Characteristics

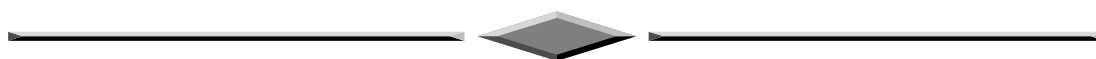
Oxygen Enriched Atmosphere	Yes
Protection Class against Electric Shock	Class I
Maximum % of CO <sub>2</sub>	< 0,4%
Operating Mode	Continuous
Applied Part	BF Type
Protection against Explosive Atmospheres	Non-AP / Non-APG
Protection against Penetration of Solid and Liquid Particles	IP33
Internal Noise (external ambient <45 dBA)	< 55 dBA
Air Velocity over Mattress	< 0.1 m/s
Audible Alarm Volume	55 - 65 dBA

*Note: Values and classifications according to NBR IEC 60601-1 and NBR IEC 60601-2-20*

## 2.5 Control Features

Oxygen Concentration (% O <sub>2</sub> )	21% to 85%
Temperature Display Resolution	0.1°C
Control Accuracy – Air Mode	± 1.5°C
Skin Temperature Sensor Accuracy	± 0.3°C
Temperature Overshoot	< 2°C
Temperature Rise Time*	50 min
Temperature Uniformity	< 1.5°C
Air Temperature Variation	< 0.5°C

*(\*) Consult definition in Section 2.1 "Glossary of Terms".*



## 2.6 Typical Set Points

Air Temperature	34°C
Skin Sensor Temperature	36°C

### 2.6.1 Temperature Adjustment Range

Air Mode	20 – 37.5 - 39°C *
Skin Mode	34 – 37.5 - 38°C *

(\*) Air temperatures ranging from 20°C to 30°C are used as a preheating parameter for the incubator. The Transport Incubator normally uses air temperatures from 30°C to 39°C. The equipment can accommodate a range from 20°C to 39°C. Determining the control temperature is a clinical decision.

### 2.6.2 Reading Range of the Temperature Displays

Air Mode (ATC)	20°C to 45.5 °C
Skin Mode (ITC)	20°C to 45°C

## 2.7 Physical Characteristics

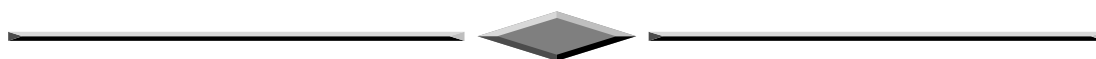
### 2.7.1 Hood / Bed Specifications

Internal Height between Mattress and Hood	23 cm
Mattress Passage / Access Door Height	18 cm
Mattress Size	32 cm x 63 cm
Tubing port	4 units
Double Tubing port	2 units
Access Doors	Front / Rear / Side
Oval Access Hatches	4 units

### 2.7.2 Incubator on Transport Cart

Height with cart in upper position	118.7 cm
Height with cart in low position	88.3 cm
Width	56.5 cm
Maximum weight with accessories	75 kg*
Maximum packaged weight	110 kg
Depth	102 cm
Four 6" swivel casters – with brake	4 units

(\*) Equipment weight without considering the maximum loads in Section 2.8



### 2.7.3 Incubator on Transport Stretcher

Maximum height with stretcher - 8 positions	160 cm
Minimum height with stretcher - 8 positions	94 cm
Width	57 cm
Maximum weight with accessories	120 kg*
Maximum packaged weight	140 kg
Depth	200 cm
Four 7.5" swivel casters – with brake	4 units

(\*) Equipment weight without considering the maximum loads in Section 2.8

### 2.7.4 Total Weight of the Equipment under Normal Use

Total weight of the equipment on transport cart = maximum weight of the equipment + maximum weight of the loads	95 kg
Total weight of the equipment on transport stretcher = maximum weight of the equipment + maximum weight of the loads	140 kg

## 2.8 Maximum Loads

IV Pole	Single (2 hooks)	2 kg
	Double (4 hooks)	4 kg
Auxiliary Shelf		10 kg
Bed		7 kg

## 2.9 Integrated Babypuff Neonatal Resuscitation Device (optional item)




Operating Range of the Manovacuometer	- 20 to 80 cmH <sub>2</sub> O (mbar)
Accuracy of the Manovacuometer	+/- 2% (upper range limit)
Maximum Pressure of the Manovacuometer	65 to 80 cmH <sub>2</sub> O (mbar)*
Input Flow	0 - 15 lpm

(\*) Depending on the intake flow

## 2.10 Blender (optional)















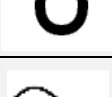

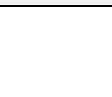
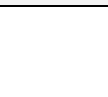
Range of % oxygen	21 to 100%
Accuracy of % oxygen	± 5% of the complete scale
Intensity of the audible warning	80 dB @ 1 m






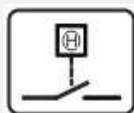








## 2.11 Indicators

 (Green)	Indicates that the equipment is ready for use.
 (Yellow)	Indicates a special situation that requires the operator's attention, but the equipment can continue to operate normally.
 (Red)	Indicates the occurrence of critical situations that require the operator's immediate intervention.

















## 2.12 Symbols



All of the following symbols are conventional and their purpose is to warn the user about conditions involving installation, functioning, operation and use of the equipment.

	General warning symbol		Warning!
	Operating instructions		Follow instructions for use
	General prohibition symbol		Do not exceed maximum weight
	Hot surface		Crushing of hands due to movement of mechanical parts
	Warning! Hot surface		Warning! Potential hazards for people
	Warning! Risk of electric shock		Warning! Potential damage to the equipment and its parts
	Single-use		Type BF, Class I equipment
	OFF: with no power supply voltage		ON: with power supply voltage
	Alternating current		Direct current











	Protective grounding		Functional grounding required
	Lighted indicator for equipment powered by the mains		Total equipment weight See Section 2.7
	Auxiliary lighting		Thermal switch set point temperature
	Fuse		Polarity of connector for direct current (DC) source
	Oxygen inlet		Air outlet for patient
	Part Code		Serial Number
	Manufacturer		European Representative Authorized

### 2.12.1 Symbols – Control Panel

	LED indicator for Power Failure		OFF key of the control panel
	Air Circulation Failure LED indicator		ON key of the control panel
	High Temperature LED indicator		Key for selecting Temperature Set Point
	Low Temperature LED indicator		Increase Temperature Set Point key
	No Sensor LED indicator		Decrease Temperature Set Point key
	Low Battery Level LED indicator		Mode selection key >37.5°C
	Battery Charging LED indicator		Heating Power LED indicator
	Skin Mode selection key		Silence alarm key

	Air Mode selection key		Locked key / Locked Access
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### 2.12.2 Symbols – Packaging


	Warning! Risk of damage to the equipment if the storage and transport specifications are not followed		Fabrication date
	This side up		Prohibited to use a hook or to drill
	Fragile		Protect from rain
	Stacking limit		Protect from sunlight
	Temperature limit for transport and storage		Humidity limit for transport and storage

### 2.13 Circumstantial Requirements

Operating Temperature Range (Normal)	0°C to 30°C – Ambient
Operating Temperature Range (Limited)**	-5°C to 0°C and 30°C to 40°C – Ambient
Temperature Range for Transport and Storage*	0°C to 55°C – Ambient
Operating Humidity Range	15% to 95% – Non-condensing
Humidity Range for Transport and Storage*	0% to 90% – Non-condensing
Operating Pressure Range	700 hPa to 1060 hPa
Pressure Range for Transport and Storage*	500 hPa to 1060 hPa

(\*) Note: Specified conditions for properly packaged equipment.

(\*\*) Note: In the limited operating temperature range, temperature control in the incubator can be affected by external ambient temperature conditions.

	<b>Warning! During external transport, expose the incubator the least time possible to adverse conditions. In extreme ambient temperatures, the incubator may not be able to maintain the desired temperature.</b>
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## 2.14 Alarm Condition

The IT-158 TS Transport Incubator has an alarm system to indicate the occurrence of probable hazardous situations, arising from a failure. When alarms occur simultaneously, all the messages are presented separately at the same time on the monitor, to inform the operator of the cause of the alarm condition. Therefore, if two distinct alarms occur in the equipment, the monitor will display the two messages at the same time, in addition to issuing an audible alarm.

All alarms are high priority and immediately trigger a visual message upon detection, along with an audible alarm after the visual message is activated.

Individual or combined alarms also activate a red indicator light on the front control panel of the equipment, to serve as a warning that an alarm condition has occurred.



**Warning! All the alarms, when triggered, also activate a red LED warning on the front control panel.**

The panel presents all the control, set point and alarm information for the parameters of the transport incubator, which can be seen by the operator at a distance of one meter from the equipment. The alarm limits are automatically defined by the software, according to the control value set by the operator, and these limits cannot be adjusted.






The following tables describe each of the alarms according to the parameter being monitored and provide an explanation about the alarm limits and how each one behaves. Chapter 7.11 of this manual describes how to check the equipment's alarm systems.

### 2.14.1 System Alarms

Symbol	Alarm	Description
	Power Failure	Activated when the electricity is cut.
	Air Circulation Failure	Activated when the internal air flow is interrupted. Operating time after the malfunction, up to 120 seconds.
	Low Battery Level	Activated when the voltage of the batteries reaches a minimum level of 10.5 V <sup>----</sup> .
	Air Sensor - Failure	Air Temperature Sensor Failure Activated when there is a short or malfunction in the air sensor connection of the incubator. When this alarm occurs, three underscores “_ _ _” will appear on the air temperature screen and the heating of the transport incubator will be cut off.

### 2.14.2 Temperature Alarms

Symbol	Alarm	Description
	High Temperature (Safety)	Activated when the air temperature in the hood exceeds 40°C. Heating of the transport incubator is cut off.
	High Temperature (Air)	Activated when the air temperature in the hood (Air Mode) is 1°C above the set point.

	High Temperature (Patient)	Activated when the patient's skin temperature (Skin Mode) is 1°C above the set point.
	Low Temperature (Air)	Activated when the air temperature in the hood (Air Mode) is 1°C below the set point.
	Low Temperature (Patient)	Activated when the patient's skin temperature (Skin Mode) is 1°C below the set point.
	Patient Sensor Failure	Activated when the skin temperature sensor is not present, or the skin temperature sensor is disconnected, or when there is a bad connection in the sensor cable. Operates only in Skin Mode.
	Patient Sensor Failure (Dislodged)	Activated when the skin temperature sensor is dislodged, or when there is a sudden temperature variation in the patient skin temperature sensor, which is common when the sensor gets disconnected from the patient's skin. Operates only in Skin Mode.

### 2.14.3 Description of the Operation of the Alarms

#### 2.14.3.1 Power Failure Alarm

This alarm will be activated when there is no supply of 100 V~ to 240 V~ power from the mains, or internal battery voltage of 12 V\_-, or external voltage of 12 - 28 V\_ to power the incubator.



**Note: This alarm will be activated for at least 10 minutes and can be turned off by pressing the "Off" key on the front control panel.**  
**The temperature set point will be saved and stored in the memory of the microprocessor.**

#### 2.14.3.2 Air Circulation Alarm

This alarm will be activated when the air flow circulating within the hood is interrupted, or when the motor stops working or the ventilation circuit of the equipment is obstructed.

The alarm will be triggered within 120 seconds of the failure. When this alarm is activated, the supply of power to the heating element will be cut off

The "Air Circulation" LED indicator and icon will remain on and the sound can be silenced for 15 minutes by pressing the "Silence" key. This alarm will automatically cease once air circulation returns to normal.



**Warning! During the heating cycle, whenever the incubator is turned on, the "air circulation" alarm will be disabled for 40 minutes to avoid constant and/or nuisance alarms until the temperature stabilizes.**

#### 2.14.3.3 Low Battery Level Alarm

This alarm will be activated when the battery voltage reaches a critical level of 10.5 V---. The "Battery Voltage" LED indicator and icon will remain on and the sound can be silenced for 15 minutes by pressing the "Silence" key. Both the LED indicator and sound are intermittent.



**Warning! After the battery voltage level alarm has been activated, the incubator will continue functioning for another 15 minutes, maintaining its control functions. After this time elapses, the temperature of the incubator will continue to drop until the operating controls completely shut down.**



#### **2.14.3.4 High Temperature Alarm**

##### **2.14.3.4.1 Safety**

This alarm is monitored by a circuit and a temperature sensor that are independent from the control circuit. The air temperature is constantly being monitored, and if this temperature exceeds 40°C, the alarm will be triggered, activating the LED with the high temperature" icon, and the supply of power to the heating element will be cut. This LED indicator will remain on until the air temperature is restored.

##### **2.14.3.4.2 In Air Mode**

The alarm is activated when the air temperature is 1°C or higher than the temperature set point. The sound can be silenced for 15 minutes by pressing the SILENCE key.

##### **2.14.3.4.3 In Skin Mode**

The alarm is activated when the skin temperature is 1°C or higher than the temperature set point. The sound can be silenced for 15 minutes by pressing the SILENCE key.

#### **2.14.3.5 Low Temperature Alarm**

##### **2.14.3.5.1 In Air Mode**

The alarm is activated when the air temperature is 1°C or lower than the temperature set point. The sound can be silenced for 15 minutes by pressing the SILENCE key.

##### **2.14.3.5.2 In Skin Mode**

The alarm is activated when the skin temperature is 1°C or lower than the temperature set point. The sound can be silenced for 15 minutes by pressing the SILENCE key.

#### **2.14.3.6 Sensor Failure Alarm**

##### **2.14.3.6.1 No Skin Temperature Sensor**

Activated when the skin temperature sensor connector is disconnected, or when there is a short in the sensor cable. In such situations, the operating mode will automatically switch to Air Mode and the skin temperature indicator will show three underscores " \_ \_ \_".

##### **2.14.3.6.2 Skin Temperature Sensor Dislodged**

If the sensor disconnects from the patient's skin, the alarm will be triggered when there is an abrupt temperature variation in a short lapse of time. The skin temperature display will continue indicating a temperature.



**Warning! The "No Sensor" alarm is only activated when the incubator is in "Skin Mode".**


To restore the normal alarm detection mode, press SILENCE and reattach the sensor to the patient. The alarm will stop and no skin sensor detection will be reactivated.

##### **2.14.3.7 Air Sensor Failure**

Activated when the connector of the air temperature sensor inside the hood of the incubator is disconnected, or when the cord of this sensor has a short, whether in Air Mode or Skin Mode. In such situations, the air temperature indicator will show three underscores " \_ \_ \_".

## 2.15 Alarms – Disable / Silence

During an audible and visual alarm situation in the equipment, the purpose of the Silence function is to pause only the audible part of the alarm, whereas the visual alarm message and indicator will remain on the screen.

Press  to Silence	Type of Alarm
<p>The default duration time for suspending the equipment's audible alarms is 15 minutes.</p> <p>Press SILENCE to disable them for 15 minutes*. To reactivate them, simply press SILENCE again.</p> <p>This is the case with the following alarms:</p>	<ul style="list-style-type: none"> <li>♦ Air Circulation Failure</li> <li>♦ High Temperature (Air)</li> <li>♦ High Temperature (Patient)</li> <li>♦ Low Temperature (Air)</li> <li>♦ Low Temperature (Patient)</li> <li>♦ Patient Sensor Failure</li> <li>♦ Low Battery Level</li> <li>♦ Air Sensor - Failure</li> </ul>
<p>Dislodged sensor alarms will only be disabled for two minutes after pressing SILENCE.</p> <p>Press SILENCE to disable them for 2 minutes*. To reactivate them, simply press SILENCE again.</p> <p>This is the case with the following alarms:</p>	<ul style="list-style-type: none"> <li>♦ Patient Sensor Failure (Dislodged)</li> </ul>

(\*): The silencing time and sound characteristics of the alarms are factory-set and cannot be adjusted.

Even if the alarm is silenced, if a new alarm condition arises, the corresponding audible and visual alarm will be triggered. This happens to warn the operator about the occurrence of an alarm condition.

Since their purpose is to alert, whenever the equipment is not properly monitoring or treating the patient, as in the case of alarm conditions indicating a power failure and high safety temperature, the audible alarms cannot be silenced by the operator.

During the first 40 minutes after switching on the incubator, in the waiting and initial heating stage (see definition of **Temperature Rise Time** in Chapter 2.1), there will be audible and visual alarms for all alarm conditions, except for the following:

- ♦ Air Circulation Failure: there will be no audible or visual alarm.
- ♦ Low Air Temperature: there will be no audible alarm, only a visual one.

After 40 minutes, the aforementioned alarms will resume full operation (audible and visual). The reason for this is to avoid constant and/or nuisance alarms while the equipment is in the stabilization process.

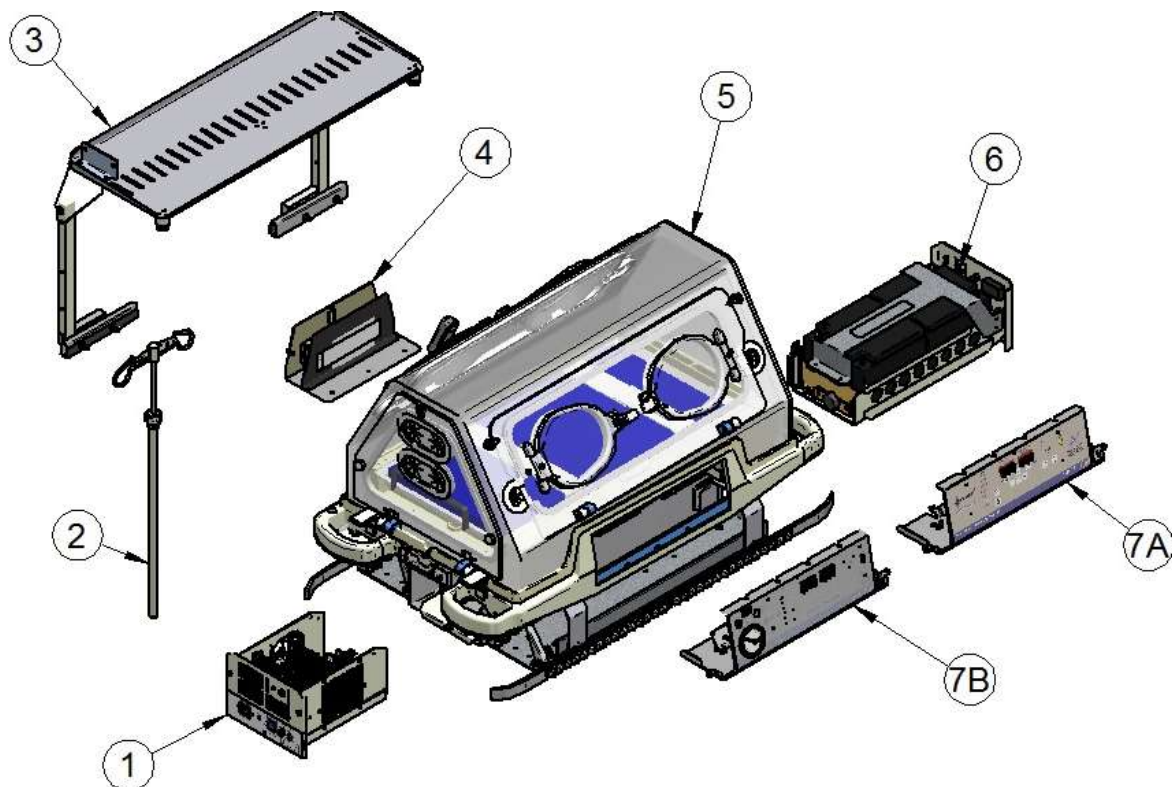
## 2.16 Informational Messages

The purpose of the following messages, presented on the temperature display of the incubator, is to provide information on the operating status of the equipment. For this reason, there is no audible indication and the red LED on the control panel does not light up.

Message	Description
HHH	Indicates temperature measured above the sensor reading range.
LLL	Indicates temperature measured below the sensor reading range.

### 3. Parts, Pieces and Accessories

All the materials used in the parts, pieces, accessories and consumables of the IT-158 TS Transport Incubator are designed to ensure optimum operation of the equipment according to its original features, as well as safety in terms of toxicity, flammability and biocompatibility of the materials used.



Item	Description
1	Power Module
2	Assembled IV Pole
3	Auxiliary Shelf
4	Air Filter Support
5	Acrylic Hood with Incubator Base
6	Battery Module (Vital Module)
7a	Front Control Panel
7b	Front Control Panel with integrated Babypuff

### 3.1 Goose Neck Respirator Adapter

Made out of a flexible metal rod, this adapter can be coupled to the four corners of the bed to help secure and guide the tubing of the connections of the respirator used by the patient.

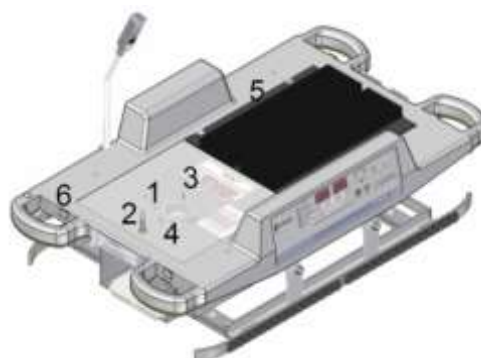


### 3.2 Base

The base of the IT-158 TS Transport Incubator is comprised of two parts: upper base and lower base.

The upper base contains the bed, bed displacement latch and passive humidification foam. This base can be removed by loosening the four side latches.

The lower base contains the heating element, air circulation fan, air temperature and safety temperature sensor and the sensor indicating no air circulation. This base is attached to the structure of the incubator.



Item	Description
1	Inlet nozzle for air and/or mixture of air with oxygen
2	Temperature sensor and safety temperature sensor
3	No air circulation sensor
4	Air circulation fan
5	Finned heating element.
6	Latches to fasten the upper base



**Warning! The upper base must be removed by the user during terminal cleaning procedures to enable the components of the lower base of the incubator to be accessed for cleaning and/or disinfection.**

### 3.3 Hood

The hood of the IT-158 TS Transport Incubator is acrylic, with a double wall and three access doors: front, rear and side.

The front and rear access doors fold downward to facilitate access and positioning of the patient in the bed. Each door has two hatches for hand insertion and access by operators during procedures with the newborn. They also have two openings with single silicone fittings and membrane systems that enable tubes and sensor cables in use with the patient to be inserted and positioned. They also allow bed movement without interfering with these tube connections and with no changes to the internal microclimate of the incubator.

The side door has a protected opening with a double tubing port and silicone fitting and membrane system located close to the point of access to the newborn's head, which enables inserting and positioning devices, such as ventilator circuits, CPAP circuits and other applications.

To open the front, rear and side doors, turn the latches on the upper part of the door, as shown in "A" in the drawing.

To remove the acrylic hood from the base of the incubator, move the auxiliary lighting back and loosen the two rubber rings that secure it to the two sides of the lower base, as shown in "B" in the drawing. With the help of two professionals, one on each side, slowly lift the hood until it is totally removed and place it on another surface that is able to support it. The same procedure is applied to the inner wall of the hood that rests on the base of the incubator.

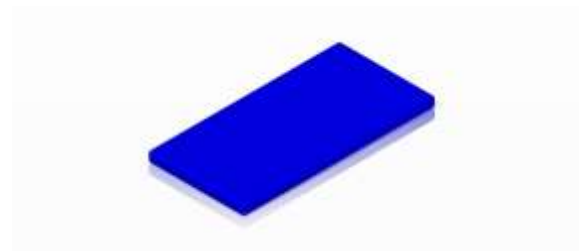
Special hood configurations in relation to openings, doors and tubing ports can be provided through a technical analysis.



**Warning!** After putting the acrylic hood back on the base of the incubator, it must be fastened with the rubber rings that secure it to the two sides of the lower base.

### 3.4 Memory mattress

The mattress of the bed of the IT-158 TS Transport Incubator provides patient comfort and safety during transport. It is made out of a special self-extinguishing polyurethane foam, with the appropriate density and composition, and with "memory effect". The cover is made out of non-toxic, resistant, malleable PVC, with pressed edges that prevent deposits of dirt and facilitates cleaning.



**Warning! Optional item.**

### 3.5 Carts and Stretchers

#### 3.5.1 X-shaped transport cart

X-shaped transport cart with aluminum structure and shock absorbers. Equipped with four 6" casters, with brake. Ideal for internal and external transport, since its height is adjustable in three positions: upper, intermediate and low.



**Warning! Optional item. When purchasing the kit, the height between the ground and the floor of the vehicle must be provided in order to correctly define the stretcher.**

### 3.5.2 Fixed-height transport cart

Transport cart with aluminum structure. Equipped with four 6" casters, with brake. Ideal for internal transport, due to its high-only position.

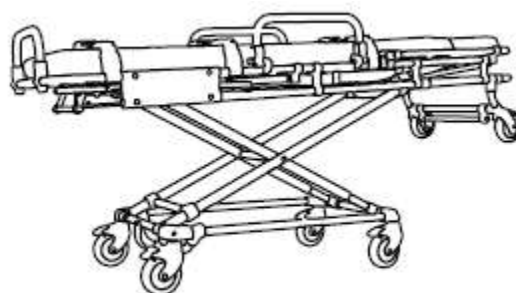


**Warning! Optional item.**

### 3.5.3 Retractable X-shaped stretcher with pantograph system

Retractable X-shaped stretcher with pantograph articulation system for eight height levels. It is equipped with four 7.5" rubberized casters with brakes to facilitate transport on uneven terrain, as well as a set of casters designed to help insert and remove the equipment from vehicles.

The incubator is fastened to the stretcher.



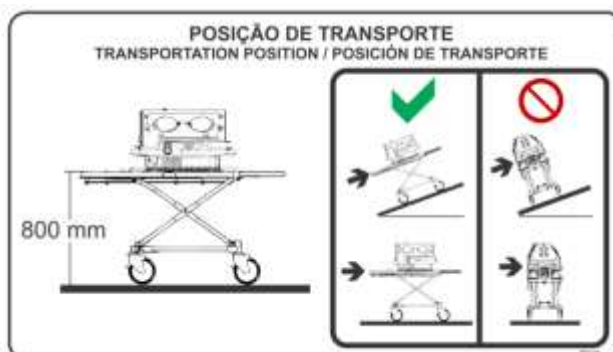
**Warning! Optional item. When purchasing the kit, the height between the ground and the floor of the vehicle must be provided in order to correctly define the stretcher.**



**Warning! The movement and articulation operations of the stretcher must be done by two or more rescue professionals during transport of the equipment.**

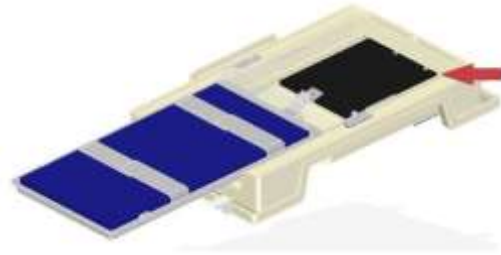


**Warning! Follow the recommendations for positioning the stretcher on inclined terrains to avoid possible instability of the equipment during transport.**



### 3.6 Humidifier Foam

The single-use, disposable foam is part of the passive humidification system of the IT-158 TS Transport Incubator and must be moistened with distilled water to supply humidity to the microclimate of the incubator. Only use original Fanem® foam and be sure to replace it between uses with patients.



### 3.7 Air Filter

The air filter of the IT-158 TS Transport Incubator is made out of a synthetic fabric and is placed in the compartment on the rear part. Its cover has two openings for admission of ambient air to the microclimate of the equipment.

The filtration system of the air that is admitted to the incubator, together with the positive pressure of the microclimate, provides protective insulation to the newborn.



*Note: Consumable item. Exclusive size for IT-158 TS.*



**Warning! The air filter should be changed every 45 days.**  
In more contaminated environments, it is recommended to change it more frequently or whenever necessary.  
Check the filter regularly.



**Warning! A dirty air filter can affect the volume per minute of ambient air admitted to the incubator and consequently contribute to carbon dioxide (CO<sub>2</sub>) buildup in the microclimate.**  
Always check the condition of the air filter whenever the equipment is sanitized for new use and make the necessary changes according to the instructions contained in this manual.



**The two openings on the filter cover are for admission of air to the incubator. Make sure they are never blocked.**



### 3.8 Babypuff Rail Fastener

It consists of a fastening mechanism located on the auxiliary shelf of the IT-158 TS Transport Incubator for safe attachment of the Babypuff neonatal resuscitation device.



Front view

Rear view



Babypuff attached



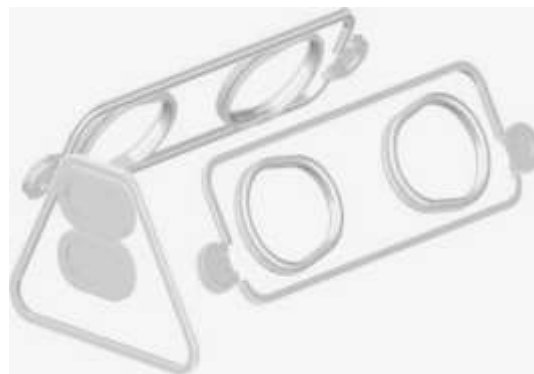
**Warning! Optional item.**

### 3.9 Protective Fitting and Elastic Cuffs

The IT-158 TS Transport Incubator has a removable protective fitting around the openings of the access hatches on the hood that seals them when closed. They are fully removable for cleaning between uses of the equipment.

The four hatch openings are protected with elastic cuffs made out of a plastic material, which are inserted into the hatch fittings, enabling hand and forearm entry for carrying out procedures without affecting the microclimate of the incubator.

If the parts are dried or damaged through use, change them, always using original Fanem® parts. Replacement time depends on usage, the products used for cleaning and/or disinfection, and carefulness handling the parts.





### 3.10 IV Pole

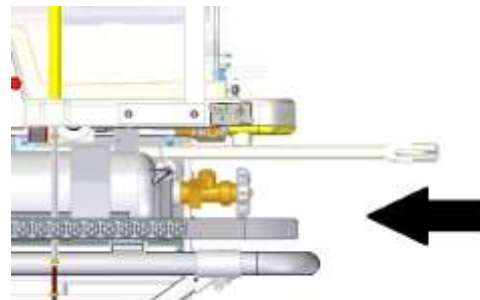
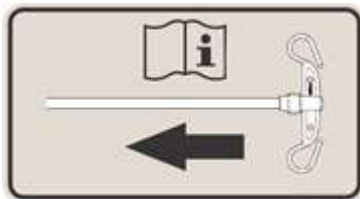
The IT-158 TS Transport Incubator has an adjustable IV pole with single (2 hooks) or double (4 hooks) sets of hooks, inserted into the opening on the handle of the base. Its purpose is to hold bottles and bags with solutions for administration to patients.



**Warning!** The maximum load of the IV pole must not exceed 2 kg for single sets (2 hooks) or 4 kg for double sets (4 hooks).

**Optional item.**

On the rear part of the equipment, close to the place for insertion of the gas cylinder, there is a compartment for stowing the IV pole when not being used. This lower region is identified by the marking below.



### 3.11 Auxiliary Lighting

#### 3.11.1 Auxiliary LED Lighting on a Rod

The auxiliary lighting is mounted on a flexible rod and is composed of high-intensity white LEDs, for the purpose of illuminating patients in low-light environments.

It works on both AC power and batteries, and has its own switch.



#### 3.11.2 Auxiliary LED Lighting with Spiral Cord (optional)

The IT-158 TS Transport Incubator has an optional auxiliary lighting kit to assist in viewing the newborn,

The lighting is supplied by white high intensity LEDs.

Its spiral cord provides greater flexibility for positioning and securing it to the hood.

Simply connect the cord into the 12 V outlet\_ \_ \_ on the upper panel of the panel module and turn it on using the switch.



**Warning! Optional item.**

### 3.12 Bed

The bed of the IT-158 TS Transport Incubator is coupled and attached to the upper base through a safety latch that controls its movement, as shown in "C" in the drawing.

The bed has two adjustable safety straps with a Velcro® system that cross over the patient and the oval recess, in preparation for being transported, as shown in "D" in the drawing.

The bed and mattress can be slid 24 cm outside the hood, through the opening on the side access door, until reaching the safety latch.

To completely remove the bed, open the side and front doors and slide it through the side access door, while pressing the safety latch downward.



**Warning! The maximum load on the bed must not exceed 7 kg.**

### 3.13 Iris Door

Plastic device for adaptation in the access door where the newborn's head is located, on the side wall of the incubator, which enables regulating the opening and closing the area for tubing portion and support.

The iris door is an optional item, which may be ordered upon request and replaces one of the two double tubing ports that are standard items.



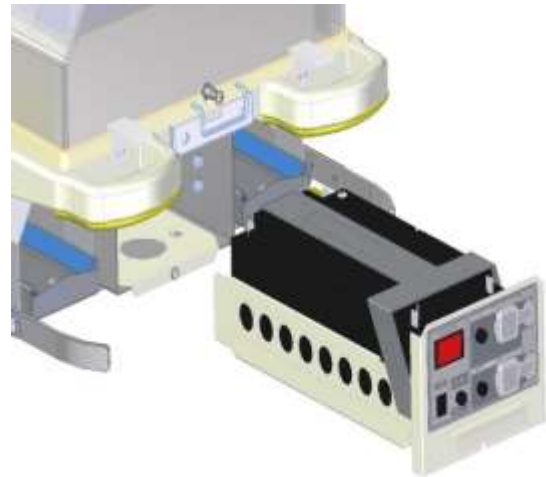
**Warning! Optional item.**

### 3.14 Battery Module (Vital Module)

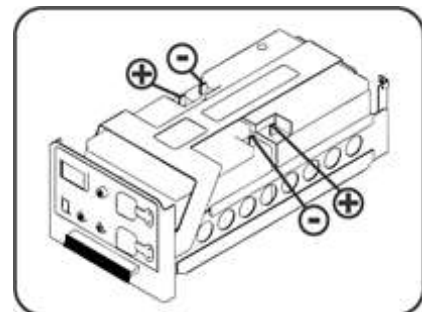
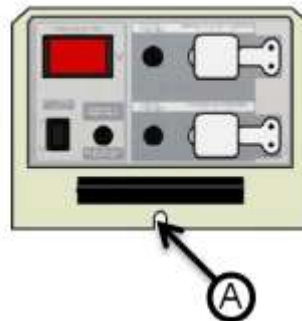
The battery module is comprised of a rack which contains two 12 V rechargeable batteries --- and a charger. The module is connected via a comb-type connector to facilitate its removal.

The side panel of the battery module of the incubator contains the fuses for the internal batteries and external power source, a 12 V --- and/or 12 - 28 V --- socket for connecting the power cord (optional), and a voltmeter for registering battery charge.

The charger keeps the batteries constantly charged. The green "battery charge" LED on the front panel indicates that the batteries are being charged. The automatic circuit of the charger allows the device to remain plugged in the wall indefinitely without damage to the batteries.



To remove the battery module, remove screw "A", as shown in the drawing. Slowly and carefully pull the module out around 15 cm. Hold the module firmly with both hands and completely remove it.

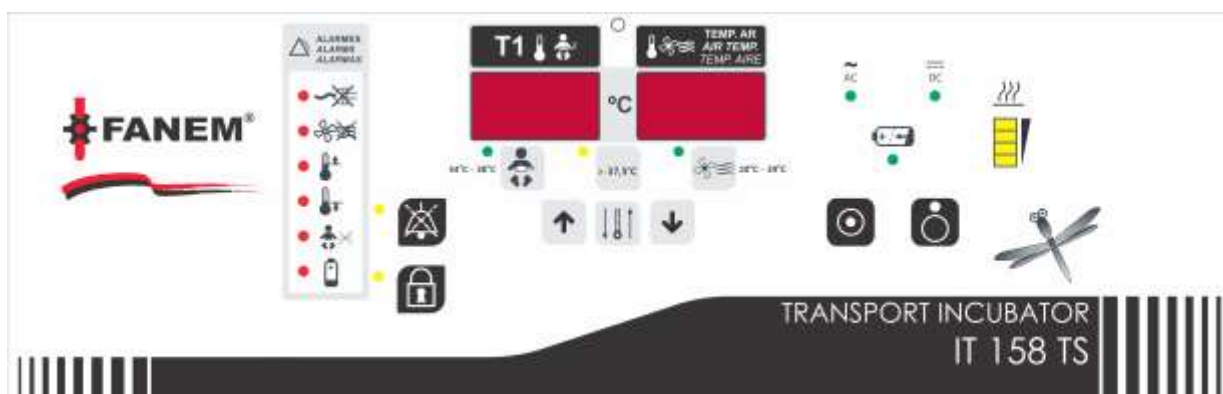


### 3.15 Front Control Panel

The IT-158 TS Transport Incubator has a control panel located on the front part of the base, with two numerical displays whose commands enable establishing air and skin temperature set points, as well as the operating mode used (AC mode - mains, and DC mode - battery), battery charge and indication of the heating power of the equipment.

The operation is done through keys with indicative icons: On and Off, Locked, Silence, UP and DOWN arrows, and Temperature  $>37^{\circ}\text{C}$ . The audible and visual alarms are identified by LEDs with the following indicative icons: Power Failure, Air Circulation, High and Low Temperature, No Skin Sensor and Low Water Level.

In an optional model, this control panel can be equipped with the Babypuff® Neonatal Resuscitation Device.



### 3.16 Double Tubing port

The IT-158 TS Transport Incubator has silicone double tubing port located on the side door that facilitate the insertion and positioning of devices, such as ventilation circuits, CPAP circuits and other applications, in addition to providing access to the newborn's head.

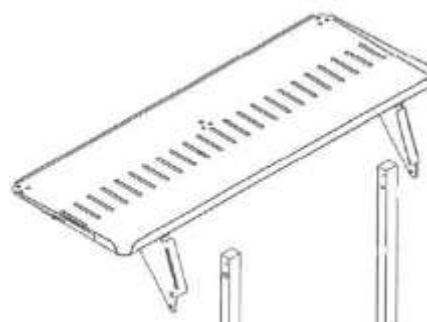
These double tubing ports are easy to remove, facilitating cleaning and/or disinfection procedures.



### 3.17 Auxiliary Shelf

The IT-158 TS Transport Incubator has a stainless steel auxiliary shelf installed on the hood that enables safe support and attachment of equipment such as monitors, infusion pumps, ventilators and other items. It can support a maximum weight of 10 kg.

The shelf is equipped with suction cups so that it can rest on the hood without damaging it or producing friction or noise. It also has an articulator that allows it to be easily moved out of the way for full access to the hood, especially for its removal.





**Warning! Optional item.**



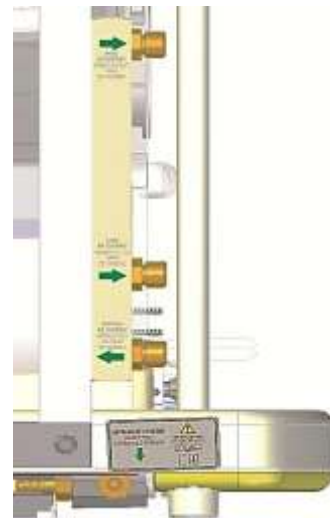
**Warning! Do not use the articulator to shift the shelf when there are objects being used on it.**



**Warning! The tray can support a maximum weight of 10 kg.**

### 3.18 Dual Oxygen Distribution Strip

The IT-158 TS Transport Incubator has a dual strip for oxygen distribution, which is mounted on the rod of the auxiliary shelf and enables simultaneous supply of oxygen to the incubator. It also serves as an inlet for the blender to be used with the Babypuff 1020 Neonatal Resuscitation Device.



**Warning! Optional item.**

### 3.19 T1 skin temperature sensor

The IT-158 TS Transport Incubator has a T1 skin temperature sensor, where the applied part is designed to make contact with the patient. The sensor measures, monitors and servocontrols the skin temperature set for the patient, in conjunction with the equipment's heating system. This sensor can be cleaned and/or disinfected and reused.



The metal surface of the sensor, available in large (10 mm), medium (9.5 mm) and small (5.5 mm) diameters, must remain attached and in direct contact with the newborn's skin through the use of adhesive. This helps to avoid mistakes that result in reading errors and various operational alarms.



**Warning! Optional accessory.**



**Warning!** Before attaching the skin temperature sensor to the patient, make sure that the body of the sensor is clean and does not contain any bits of adhesive, in order to avoid readings errors and contamination.



**Warning!** Never place the skin temperature sensor underneath the newborn, or use it to measure rectal and/or axillary temperature.



**Warning!** Improper positioning of the skin temperature sensor can cause increased heat to be delivered to the patient, possibly resulting in overheating and harmful consequences.

Constantly monitor the newborn's condition to check the temperature measured and that the sensor is properly attached.



**Warning!** Never remove the skin temperature sensor from the newborn by pulling on the cable. First remove the adhesive and then the sensor.



**Warning!** Only use FANEM® sensors.

The use of another type of sensor can result in temperature reading errors and harm to the patient. FANEM® sensors are tested and controlled to ensure repeated use and accuracy.

### 3.20 Disposable T1 skin temperature sensor

This more delicate skin temperature sensor is directly attached to the newborn's skin (applied part) and registers skin temperature. It is a single-use item, since it cannot be cleaned and/or disinfected and reused.



**Warning!** The manufacturer recommends single-use. The product is not sterilized and comes ready for use.

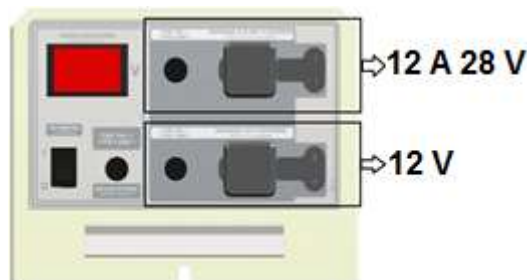


**Warning!** Optional accessory.

### 3.21 External 12 V\_ \_ \_ and/or 12 - 28 V Inlet\_ \_ \_

The incubator can be optionally configured with the following external inlets for providing DC power to the incubator during transport in aircraft or ambulances:

- External inlet with only 12 V\_ \_ \_;
- Independent external inlet from 12 to 28 V\_ \_ \_ (optional).





### 3.22 Blender

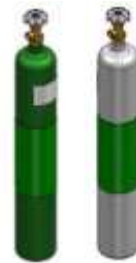
Precision instrument for mixing compressed air and oxygen, mounted with an output flow meter (0 to 15 lpm) and supply hoses for patient oxygen administration devices. The oxygen concentration can be set from 21% to 100%. It can be used in conjunction with other newborn ventilation devices, such as the Babypap® and Babypuff®.



**Warning! Optional accessory.**

### 3.23 Compressed Air or Oxygen Cylinders

To supply gas to the equipment, during transport, compressed air and oxygen cylinders are provided with connections according to the standards ABNT 204-1 (compressed air) and ABNT 218-1 (oxygen). The cylinders are stowed and fastened in the compartments for this purpose, located on the lower part of the base of the incubator.



**Warning! Optional item.**

### 3.24 Pediatric Resuscitator 020

Pediatric Resuscitator Model 020, made of silicone, with an oxygen accumulator tube, Rendell-Baker round mask (sizes 00, 0, 1) and 40 cm H<sub>2</sub>O safety valve, supplied in a plastic case.



**Warning! Optional accessory.**

### 3.25 Babypuff® 1020 Neonatal Resuscitation Device

This portable manual resuscitation device enables the operator to adjust, execute and monitor pressure and parameterize the resuscitation process of the newborn, through three valves: safety or relief; PIP (peak inspiratory pressure) control and PEEP (positive end expiratory pressure) control – in a single precision manovacuometer on a scale up to 80 cm/H<sub>2</sub>O, providing greater safety, efficacy and effectiveness for the patient, as well as operator comfort.

The Babypuff® 1020 Neonatal Resuscitation Device can provide up to 15 liters/min of oxygen or compressed air through a flow meter, or a blender can be used for precise administration of the prescribed oxygen concentrations.

It comes with a gas inlet hose, a corrugated tube with an Ayre's T-piece, a set of three round, transparent, silicone masks (sizes 00/0/1) and a lung for testing the device and setting parameters.

The Babypuff® 1020 Neonatal Resuscitation Device can be coupled to the IT-158 TS Transport Incubator through a rail fastener on the auxiliary shelf, in addition to the dual oxygen distribution strip installed on its rod and the blender kit.



**Warning! Optional accessory.**

### 3.26 Relief Valves for Cylinders

To use the cylinders, pressure relief valves (3.5 kgf) compatible with the compressed air and oxygen cylinders and connections are provided, in accordance with the standards ABNT 204-1 (compressed air) and ABNT 218-1 (oxygen).

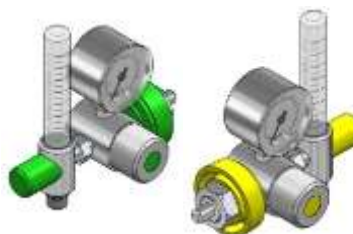


**Warning! Optional item.**

*\*Note: Item designed in accordance with local regulations. The gas connection configurations may vary according to local laws.*

### 3.27 Control Valves with Flow Meter for Cylinders

To use the cylinders, control valves compatible with the compressed air and oxygen cylinders and connections are provided, in accordance with the standards ABNT 204-1 (compressed air) and ABNT 218-1 (oxygen).



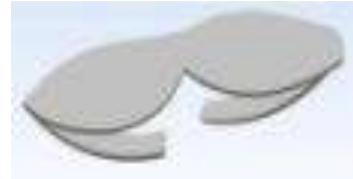
**Warning! Optional item.**

***Note:** Item designed in accordance with local regulations. The gas connection configurations may vary according to local laws.*



### 3.28 Eye Protection for Phototherapy

This ergonomic piece, with its anatomical design and integrated blackout pad, is seamless and adjustable to cover and perfectly fit the eyes, without obstructing or compressing the nose. Made out of a soft hypoallergenic elastic material, it can be easily adjusted and fastened to the patient's head with two adhesive straps, protecting the eyes from the light of the phototherapy equipment.



**Warning! The manufacturer recommends single-use. The product is not sterilized and comes ready for use.**



**Warning! Optional item.**

### 3.29 Cap-band for joint application of CPAP and phototherapy

One-piece item that wraps around the head of the newborn, made out of hypoallergenic fabric, with technology that absorbs skin perspiration, and is adjusted using two adhesive straps. It comes in small, medium and large sizes, and serves two purposes: there is a cap for routing and attaching ventilation circuits to the patient and a band with an inner blackout pad to provide eye protection to the newborn during phototherapy treatment.



**Warning! The manufacturer recommends single-use. The product is not sterilized and comes ready for use.**

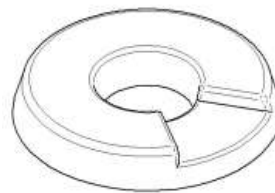


**Warning! Optional item.**

### 3.30 Infant Pillow

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This anti-allergic infant pillow has a TNT (nonwoven fabric) pillow case and a circular shape with a special density that distributes weight and helps supports the head of the newborn. This item helps secure the newborn's head during intubation and oxygen therapy procedures, and also prevents cranial deformity resulting from the patient being in a prolonged lateral position.



**Warning! Optional item.**



**Warning! The manufacturer recommends single-use. The product is not sterilized and comes ready for use.**

## 4. Precautions, Restrictions and Warnings

For safe use of the IT-158 TS Transport Incubator, it is necessary to know and comply with all the precautions, restrictions and warnings which must be respected during installation, operation and maintenance of the equipment.

The precautions provide information that indicate the need for greater care and are usually associated with hazardous situations. Restrictions, in turn, refer to attitudes or actions that cannot occur under any pretext. Warnings call attention to certain situations that can lead to harm or explicit injury.



**WARNING! This section of the User Manual contains extremely important information to ensure the safety and integrity of the patient, user and equipment.**

These include:

- 1) Check whether the mains into which the equipment will be connected is compatible with the electrical specifications, such as voltage and power, as indicated on the label affixed to the unit. This equipment has a switching mode. If it does not comply with the specifications, it can affect the operation of the equipment and cause damage to it.



**Warning! Before plugging the power cord into the mains, check whether its voltage matches the one on the equipment, shown on the label next to the power inlet, power voltage range 100 -240 V~.**

- 2) Before plugging the equipment into the mains, make sure the outlet is grounded and permanently attached to the wall, in accordance with the standards and laws for low voltage electrical installations and electrical laws for health care establishments.
- 3) Never use extension cords or multiple sockets.



**Warning! Do not use extension cords or multiple sockets. If not properly grounded, do not use the equipment.**



**Warning! To avoid risk of electric shock, this equipment should only be plugged into a grounded outlet for proper protection.**

- 4) To assemble and transport the equipment, it is recommended that the procedure be performed by a person with sufficient physical strength.



**Warning! Assembly and transport of the IT-158 TS Transport Incubator requires a trained professional with sufficient physical strength.**



**Warning! Before use, this equipment must be sanitized, through a preliminary cleaning and/or disinfection, according to the instructions in this manual.**

- 5) Before plugging the equipment into the gas cylinder, make sure all the valves are closed, to avoid leakage and risk of explosion.



**Warning! Do not use the equipment in the presence of flammable anesthetics or cleaning agents which could cause combustion.**

- 6) This equipment should only be operated by health professionals (physicians, nurses, and nursing technicians and assistants) who have been properly trained with regard to its operation and understand the risks and benefits of its use, under medical supervision. Improper use of the IT-158 TS Transport Incubator can expose the newborn to serious risks.
- 7) Provided that it is operated according to its intended use, there are no contraindications for clinical application.



**Warning! Fully clean the equipment and its parts and pieces before first use and between uses by the patient, as a required infection control measure.**

- 8) The IT-158 TS Transport Incubator should not be used if any of its functions or components are impaired. In such cases, a qualified service technician should be contacted.



**Warning! If, during the visual inspection, any of the parts show evident signs of wear, corrosion or mechanical defects, stop using the equipment and change the respective item.**

- 9) The IT-158 TS Transport Incubator was designed for the patient to rest only on the mattress, with use restricted to one patient at a time.



**Warning! This equipment can only monitor one patient at a time. For this reason, shared use is not recommended. Furthermore, single use prevents risk of cross infections.**

- 10) The IT-158 TS Transport Incubator has filters for electromagnetic protection designed to meet the specifications of electromagnetic compatibility standards. However, this equipment may be adversely affected and suffer interference from other equipment, such as high-frequency surgical devices, defibrillators, shortwave therapy equipment, cardiac pacemakers and other electrical stimulators.



**Warning! The equipment can be used with saturation monitors, ventilators, infusion pumps and other hospital equipment. It is recommended to observe these devices to confirm that they are operating normally in accordance with the configuration used.**

- 11) Before starting to monitor any of the physiological parameters, check all the information and precautions regarding the operation and application of the accessories. In a possible electric discharge, the incorrect use of these accessories can cause harm to patients, such as burns and electric shock.



**Warning! Cables and sensors are not protected against the effects of defibrillation.**



**Warning! If the transport incubator will be disconnected from the mains and not used for a long period of time, the battery fuses in the panel of the battery module should be removed to avoid discharge of the batteries.**



**Warning! It takes at least 30 hours to fully charge the batteries (in the case of totally discharged batteries).**



**Warning! Always keep the transport incubator plugged into the wall with the master switch in the "ON" position so that the batteries remain charged.**



**Warning!** If the power cord is disconnected from the socket, the transport incubator will automatically start operating in DC (battery) Mode.



**Warning!** When the skin temperature sensor is disconnected from the side power supply input, the display will indicate “\_ \_ \_” °C and the operating mode will automatically switch to Air Mode.



**Warning!** On the air temperature display, the decimal point of the temperature value that keeps blinking indicates the temperature that is programmed.



**Warning!** The air temperature set point will be saved even after the incubator is switched off.



**Warning!** It is necessary to wait for the air temperature inside the incubator to stabilize before receiving the patient.



**Warning!** After receiving the patient in Air Mode, it is necessary to wait for the patient's skin temperature to stabilize before switching the control to Skin Mode.



**Warning!** During the heating cycle, whenever the incubator is turned on, the "air circulation" alarm will be disabled for 40 minutes to avoid constant and/or nuisance alarms until the temperature stabilizes.



**Warning!** All the setting parameters of this equipment must be accordance with the medical prescription. Fanem and its representatives cannot be held liable for any harm resulting from the improper use of these parameters.

- 12) All the latches of the front, rear and side access doors of the hood and hatches must be properly closed to prevent accidental opening.
- 13) For patient safety, the front, rear and side access doors of the hood and hatches should only remain open if a professional is present.
- 14) The tubing port and fittings must be properly installed; otherwise, the internal temperature of the incubator will not stabilize.
- 15) The use of additional resources/accessories with the IT-158 TS Transport Incubator, whether for heating (heated mattresses, hot water bottles, blankets, covers or clothing, etc.) or comfort (infant seats, oval recesses or towels, etc.) may affect air circulation patterns and/or functioning of control parameters. This could modify the conditions established for the temperature of the incubator's microclimate.
- 16) Patient safety and proper operation of the incubator may be compromised if air circulation is interfered with, due to obstruction of openings inside the hood caused by diapers, towels and covers, etc.
- 17) The hood of the incubator should not be covered to avoid hindering direct observation of the patient.

- 18) To avoid overheating the patient due to thermal radiation, do not place the equipment in direct sunlight or under other radiant heat sources. In such cases, temperature control can be compromised.
- 19) If necessary, the use of phototherapy units, together with the transport incubator, can affect the temperature of the incubator and/or heating of the newborn.



**Warning! During external transport, expose the incubator the least time possible to adverse conditions. In extreme ambient temperatures, the incubator may not be able to maintain the desired temperature.**

- 20) During internal transport, the transport incubator cart should always be in the upper position.
- 21) To prevent the equipment from sliding when stopped on an incline, make sure the casters are locked.
- 22) While boarding or removing the IT-158 TS Incubator from aircraft and ambulances, as well as during the duration it is on board, the incubator cart should be kept in the low position and locked. The casters should also be locked. Adequate fastening conditions for the incubator in different types of vehicles is the responsibility of the user in charge of the transport operation.



**Warning! To move the transport incubator cart requires two operators positioned on each side of the equipment, with both hands placed on the support of the upper rim of the cart.**

- 23) Do not place devices or other accessories on the transport incubator unless it is equipped with an auxiliary shelf on the hood and an attachment system that prevents unwanted movement and damage. Always comply with the maximum shelf load.



**Warning! Do not use the articulator to shift the shelf when there are objects being used on it.**



**Warning! The tray can support a maximum weight of 10 kg.**

- 24) When using the auxiliary shelf of the incubator, take the following precautions:

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



**Warning! The maximum load for each IV pole is up to 2 kg.**

- 25) Any additional equipment connected to the patient must be properly grounded and comply with the electrical safety standards for medical electrical equipment contained in NBR IEC 60601-1 and its particular norms.



**Warning! The use of accessories, transducers, sensors and network cables that are not originals can result in increased emissions or decreased immunity of the equipment.**



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

- 26) The skin temperature sensor should never be used loose underneath the newborn or to monitor rectal and/or axillary temperature. Incorrect positioning of the sensor can cause reading errors as well as temperature and heating errors, placing the patient at risk.



**Warning! The skin temperature sensor should never be used to measure rectal and axillary temperature, since these temperatures are not suitable for controlling the heating of the equipment.**

- 27) The skin temperature sensor should only be attached to and kept in direct contact with the patient's skin. This will enable adequate heating of the equipment and thereby avoid overheating or cooling of the newborn.



**Warning! Before attaching the skin temperature sensor to the patient, make sure that the body of the sensor is clean and does not contain any bits of adhesive, in order to avoid readings errors and contamination.**



**Warning! Improper positioning of the skin temperature sensor can cause increased heat to be delivered to the patient, possibly resulting in overheating and harmful consequences.**

**Constantly monitor the newborn's condition to check the temperature measured and that the sensor is properly attached.**



**Warning! Place the skin temperature sensor preferably in the abdominal area of the newborn, securing it with suitable adhesive.**

- 28) During use of the skin temperature sensor, it is necessary to frequently check the newborn's temperature with a clinical thermometer.



**Warning! Only use Fanem® sensors.**

**The use of another type of sensor can result in temperature reading errors and harm to the patient. FANEM® sensors are tested and controlled to ensure repeated use and accuracy.**



**Warning! Never remove the skin temperature sensor from the newborn by pulling on the cable. First remove the adhesive and then the sensor.**

- 29) During use of the incubator in Skin Mode, check for attachment errors and dislodging of the skin temperature sensor which will activate the alarms.



**Warning! The "Sensor Failure" alarm is only activated when the incubator is in "Skin Mode".**



**Warning! If the temperature monitored by the skin temperature sensor fluctuates rapidly, an alarm will indicate that the sensor has shifted in relation to the newborn's body. In such situations, the No Sensor alarm**

will be triggered in an intermittent fashion. Press the "Silence" key to cancel the No Sensor alarm and check that the sensor is correctly positioned and attached to the patient.

- 30) The transport incubator has an air filter that enables the admission of microfiltered ambient air to the microclimate.



**Warning!** The air filter should be changed every 45 days. In more contaminated environments, it is recommended to change it more frequently or whenever necessary. Check the filter regularly.



**Warning!** A dirty air filter can affect the volume per minute of ambient air admitted to the incubator and consequently contribute to carbon dioxide (CO<sub>2</sub>) buildup in the microclimate.

Always check the condition of the air filter whenever the equipment is sanitized for new use and replace it according to the specifications of this manual.



**The two openings on the filter cover are for admission of air to the incubator. Make sure they are never blocked.**

- 31) The transport incubator has a passive system for humidifying the microclimate through foam moistened with distilled water.



**Warning!** The humidification foam is a single-use item and should be discarded in the cleaning and/or disinfection process of the incubator performed after use of the equipment.



**Warning!** In order to reduce risk of infection, only use the humidification foam when passive humidification is used. Never place humidification foam inside the incubator if it is not being used for its established purpose.



**Warning!** High relative humidity concentration may cause condensation to form on the inner walls of the hood if there is a significant difference between temperatures inside and outside the incubator.

- 32) To clean the IT-158 TS Transport Incubator, it is necessary to follow the recommendations in this user manual to ensure the patient, users and equipment safety.



**Warning!** This equipment must be sanitized through cleaning and/or disinfection, according to the instructions contained in this manual.



**Warning!** Before starting any maintenance and/or cleaning procedure, ensure that the equipment is disconnected from the mains.



**Warning!** Make sure the oxygen supply to the incubator is turned off and that the equipment is disconnected from the oxygen cylinder whenever cleaning or maintenance procedures are performed. There is a risk of fire or explosion in oxygen enriched environments.





**Warning!** The heating element may be hot enough to cause burns; avoid touching the heater until the equipment has been switched off and the heating element is cold.



**Warning!** The transport incubator must be fully disassembled between uses, regardless of the length of time of use, to undergo cleaning and eliminate any contamination in its inner parts.



**Warning!** The lower base of the structure of the incubator must be cleaned after every use of the equipment.

- 33) To clean and/or disinfect the IT-158 TS Transport Incubator, use products and materials that are non-toxic to patients and users and have been proven not to damage the different materials that make up the parts of the equipment and the acrylic, plastic and metal pieces in general.



**Warning!** In any cleaning procedure for this equipment, never use products that contain alcohol, abrasives, sodium hypochlorite, dyes and/or abrasive sponges or steel wool, since they will damage the acrylic hood and other parts.

- 34) The skin temperature sensors must be cleaned and/or disinfected like the other components and parts, by gently wiping the entire sensor cable and encapsulated part with a pad and cleaning product. Before using the sensor again with the patient, the cleaning product used needs to be fully removed.



**Warning!** The skin temperature sensors and their parts must not be immersed in the products used for the cleaning and/or disinfection procedures, since this could damage them.



**Warning!** After putting the acrylic hood back on the base of the incubator, it must be fastened with the rubber rings that secure it to the two sides of the lower base.

- 35) Reassembly of the transport incubator after cleaning must include attachment of the upper base with the four latches, and the hood with the rubber rings.



**Warning!** After putting the acrylic hood back on the base of the incubator, it must be fastened with the rubber rings that secure it to the two sides of the lower base.

- 36) Use of the IT-158 TS Transport Incubator under environmental conditions subject to strong air currents or direct exposure to sunlight can affect the heating and thermal balance of the patient.
- 37) Do not use your fingernails or sharp objects to activate the command keys of the front control panel.
- 38) Only use original Fanem® parts and accessories to ensure optimum equipment performance and safety.



**Warning!** This equipment should only be operated by trained and qualified personnel who understand the risks and benefits of its use, and under medical supervision.



**Warning! To avoid overheating the patient due to thermal radiation, do not place the transport incubator in direct sunlight or under other radiant heat sources. In such situations, temperature control may be adversely affected.**



**Warning! During transport, the protective devices designed to protect the patient while in bed should be inspected regularly to ensure that they are functioning properly.**



**Warning! This equipment cannot distinguish between a condition of increased internal body temperature with cold skin (fever) and low internal temperature with cold skin (hypothermia).**

**To more accurately detect hypothermia or hyperthermia during use of the incubator, it is recommended to frequently measure the patient's temperature with a clinical thermometer.**

#### 4.1 Explosion Hazard: Precautions

- 1) Never use the IT-158 TS Transport Incubator in the presence of flammable anesthetics.
- 2) To clean or perform maintenance procedures on the IT-158 TS Transport Incubator, the oxygen supply must be turned off and disconnected from the equipment, because there is a risk of fire or explosion in an oxygen enriched environment.
- 3) Keep matches, cigarettes and all other possible ignition sources away from the site where the equipment is operating, since oils and other combustibles easily ignite and burn in oxygen enriched air.
- 4) Ensure that no flammable product comes into contact with the equipment, because there is a risk of fire and explosions in oxygen enriched environments.
- 5) Equipment that can cause sparks, such as defibrillators or electrocautery devices, should not be used on the patient when the IT-158 TS Transport Incubator is using oxygen.



**Warning! The presence of flammable products, such as alcohol and cleaning products, may cause a fire when in contact with oxygen. Never use the incubator in the presence of flammable anesthetics.**

#### 4.2 Oxygen: Precautions

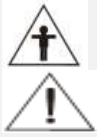
- 1) Improper use of supplemental oxygen can have serious side effects, including blindness, brain damage and death. The risks vary with each newborn. For this reason, the method, concentration and duration of oxygen administration should be prescribed by a physician.
- 2) The oxygen concentration administered should be continuously monitored to meet the patient's needs, comply with the medical prescription and avoid potential risks.



**Warning! Always use an oxygen analyzer to measure oxygen concentration in the equipment. It is recommended to use the THOR® 3620 multitester for this purpose.**

- 3) The oxygen concentration inspired by the newborn does not accurately determine partial pressure of oxygen (pO<sub>2</sub>) in the blood. Therefore, as per the medical prescription, pO<sub>2</sub> of the blood should be measured using other appropriate clinical techniques.

- 4) Whenever oxygen administration exceeds 21%, the concentration can be changed by opening the hatches and side walls of the hood or even due to improper installation of the fittings and protective tubing port.



**Warning! Administration of high concentrations of oxygen for extended periods of time exposes the newborn to risk. Therefore, strictly follow the medical prescription and monitor and frequently check the concentrations supplied, comparing them with other clinical parameters of the patient.**

- 5) If separate cylinders need to be used to supply the equipment with oxygen and compressed air, the standards and other precautions for fastening them must be followed.
- 6) Always check the condition of the air filter whenever the equipment is sanitized for new use. In addition, change it when necessary according to the instructions contained in this manual, since accumulated dirt in this filter can affect air intake and contribute to carbon dioxide (CO<sub>2</sub>) buildup in the microclimate of the incubator.
- 7) The oxygen analyzers that are used must be properly calibrated.



**Warning! During oxygen administration, the noise level may rise for the patient inside the incubator.**

### 4.3 Integrated Babypuff® 1020 Neonatal Resuscitation Device

The Babypuff® 1020 Neonatal Resuscitation Device integrated into the front control panel of the IT-158 TS Transport Incubator requires the same precautions and care as a separate Babypuff®, such as:



**Warning! The Babypuff® Neonatal Resuscitation Device should only be used by health professionals who are properly qualified and authorized to perform this procedure. It is the responsibility of the health professional to comply with current official safety standards and local service protocols when using this product for therapeutic procedures on patients.**



**Warning! Before using the Babypuff® Neonatal Resuscitation Device, all the parameters must be checked and calibrated, using the test lung, for network and usage flow conditions.**



**Warning! A gas flow of 5-8 lpm is normally used for newborns, and a flow of up to 15 lpm for pediatric use.  
Do not use flows greater than 15 lpm.**



**Warning! The Babypuff® Neonatal Resuscitation Device must be checked and set before each use. Make sure that the correct pressures were set before authorizing its use for each case and patient.  
Routine settings and checks must be in compliance with the resuscitation protocol adopted at the local service level.**

## 4.4 Blender

To properly operate the blender, it is necessary to provide continuous flow sources of O<sub>2</sub> and air, with a balanced network pressure at 3.5 kgf/cm<sup>2</sup>.

Humidity and dirt can affect the blender's operation; a clean and dry gas source must be used at all times.

Before and during use with the patient and whenever making any concentration adjustments, check the air/O<sub>2</sub> mixture (% FiO<sub>2</sub>) with an oxygen analyzer.



**Warning! If the pressure of the oxygen or air source increases or decreases, resulting in a difference of 1.4 kgf/cm<sup>2</sup> (138 kPa), this will affect the output flow and oxygen concentration.**

An audible warning from the blender will go off if there is a drop in the oxygen or air source, notifying the user that the oxygen concentration or flow may not be exact. The physician must determine the correct FiO<sub>2</sub> setting.

The audible warning must not be obstructed, removed or altered in any way.

## 4.5 Electromagnetic Compatibility and Immunity

Electromagnetic Compatibility and Immunity is the ability of equipment and/or systems to operate in an electromagnetic environment without introducing unacceptable electromagnetic disturbances to anything in the environment and, on the other hand, to operate without degradation in the presence of an electromagnetic disturbance.

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

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

This equipment is within the parameters recommended for RF Emissions; Immunity; Electrostatic Discharge; Irradiated and Transient Radio Frequency Electromagnetic Fields (Bursts and Voltage Surges).



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



**Warning! The use of accessories, transducers, sensors and network cables that are not originals can result in increased emissions or decreased immunity of the equipment.**



**Warning! Make sure that medical electrical equipment used close to and/or in conjunction with incubator complies with international electromagnetic compatibility standards.**



**Warning!** For proper operation of the incubator, make sure that it is installed and used according to the special precautions outlined in Section 4.5 on electromagnetic compatibility.



**Warning!** Avoid approximating and/or stacking equipment during its use. However, one characteristic of transport incubators is their use with phototherapy units, ventilators, infusion pumps, etc., i.e., they are used close to other health products.

Therefore, it is recommended to observe medical electrical equipment to confirm that it is operating normally in accordance with the configuration used.



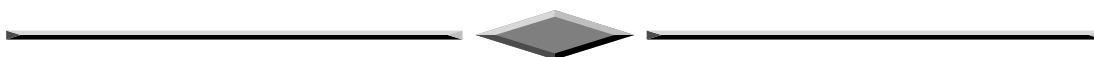
**Warning!** Although the patient's bed is made out of engineering plastic, which is fully insulated electrically, it is not recommended to use high frequency surgical equipment together with the IT-158 TS Transport Incubator.




**Warning!** The IT-158 TS Transport Incubator has protective filters designed to meet the specifications of electromagnetic compatibility standards, but may be adversely affected by and suffer interference from certain equipment, such as high frequency surgical equipment, defibrillators, short wave therapy equipment, cardiac pacemakers and other electrical stimulators connected to the patient.

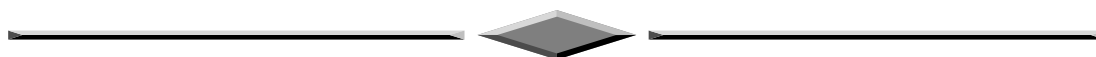


**Warning!** Before starting to monitor a physiological parameter, observe all the information and precautions related to the operation and application of the accessories, since incorrect use may cause patient injury, such as burns and/or electric shock, arising from a possible defibrillator or high frequency surgical equipment discharge.



Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The IT-158 TS Transport Incubator is intended for use in the electromagnetic environment specified below. It is recommended that the buyer or user of this incubator ensure that it is used in such an environment.		
Emissions tests	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The IT-158 TS Transport Incubator uses RF energy only for its internal functions. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The IT-158 TS Transport Incubator is suitable for use in all non-domestic establishments and those directly connected to the low-voltage mains which supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Emissions due to voltage fluctuations/flicker IEC 61000-3-3	Compliant	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The IT-158 TS Transport Incubator is intended for use in the electromagnetic environment specified below. It is recommended that the buyer or user of this incubator ensure that it is used in such an environment.			
Immunity Test	Test Level IEC 60601	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	<p>Portable or mobile RF communications equipment should not be used within a closer distance to any part of the IT-158 TS Transport Incubator, including cables, than the recommended separation distance, calculated by the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = 0.35 P^{1/2}$ <p><math>d = 0.35 P^{1/2}</math> 80 MHz - 800 MHz</p> <p><math>d = 0.7 \cdot P^{1/2}</math> 800 MHz to 2.5 MHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).</p> <p>It is recommended that the field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div></div>
Irradiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	
<p>NOTE 1: From 80 MHz to 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land-mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed-RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the incubator is used exceeds the RF compliance level defined above, the equipment should be observed to confirm normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IT-158 TS Transport Incubator.</p> <p><sup>b</sup> Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10V/m.</p>			



**Recommended separation distances between portable or mobile RF communication equipment and the IT-158 TS Transport Incubator**

The IT-158 TS Transport Incubator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The buyer or user of the incubator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the incubator as recommended below, according to the maximum output power of the communication equipment.

Maximum declared output power of the transmitter W	Recommended separation distance according to the frequency of the transmitter m		
	150 kHz to 80 MHz $d = 0.35 P^{1/2}$	80 MHz to 800 MHz $d = 0.35 P^{1/2}$	800 MHz to 2.5 GHz $d = 0.70 P^{1/2}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

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

*NOTE 1: From 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.*

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



Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The IT-158 TS Transport Incubator is intended for use in the electromagnetic environment specified below. It is recommended that the buyer or user of this incubator ensure that it is used in such an environment.			
Immunity Test	Test Level of IEC 60601	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge IEC 61000-4-2 (ESD)	± 6 kV by contact	± 6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	± 8 kV by air	± 8 kV	
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	The mains power quality should be that of a typical hospital or commercial environment.
	± 1 kV in input and output lines	± 1 kV in input and output lines	
Surges IEC 61000-4-5	± 1 kV line to line	± 1 kV line to line	The mains power quality should be that of a typical hospital or commercial environment.
	± 2 kV line to ground	± 2 kV line to ground	
Voltage dips, short interruptions and voltage variations in power supply input lines IEC 61000-4-11	< 5% $U_T$ (>95% voltage dip in $U_T$ ) for 0.5 cycles	< 5% $U_T$ (>95% voltage dip in $U_T$ ) for 0.5 cycles	The mains power quality should be that of a typical hospital or commercial environment. If the user of the IT-158 TS Transport Incubator needs to continue using it during a power failure, it is recommended to power the incubator using an uninterruptable power supply or battery.
	< 40% $U_T$ (>60% voltage dip in $U_T$ ) for 5 cycles	< 40% $U_T$ (>60% voltage dip in $U_T$ ) for 5 cycles	
	< 70% $U_T$ (>30% voltage dip in $U_T$ ) for 25 cycles	< 70% $U_T$ (>30% voltage dip in $U_T$ ) for 25 cycles	
	< 5% $U_T$ (>95% voltage dip in $U_T$ ) for 5 seconds	< 5% $U_T$ (>95% voltage dip in $U_T$ ) for 5 seconds	
Magnetic field generated by the frequency of the network (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic fields should be at the levels of a typical location in a commercial or hospital environment.
<b>NOTE:</b> $U_T$ is the AC mains voltage prior to the application of the test level.			

## 5. Installation of the Equipment

After confirming that the installation environment of the IT-158 TS Transport Incubator matches the one recommended in this user manual, unpack the equipment and ensure that all the parts are in perfect condition. Also make sure that all its accessories are complete.

To do so, follow the equipment description in the Parts, Pieces and Accessories section in the user manual, and then proceed to assemble the kits, pieces and accessories.



**Warning! Assembly and transport of the IT-158 TS Transport Incubator requires a trained professional with sufficient physical strength.**



**Warning! Before plugging the power cord into the mains, check whether its voltage matches the one on the equipment, shown on the label next to the power inlet, power voltage range 100 - 240 V~.**



**Warning! Before use, this equipment must be sanitized, through a preliminary cleaning and/or disinfection, according to the instructions in this manual.**

Note: No part or piece of the transport incubator comes sterilized from the factory. It is recommended to perform this process between uses by the same and/or different patient(s), in accordance with the standards of the Hospital Infection Control Committee where the equipment is being used.

### 5.1 Installation of the IT-158 TS Transport Incubator

#### 5.1.1 Raising the Transport Cart

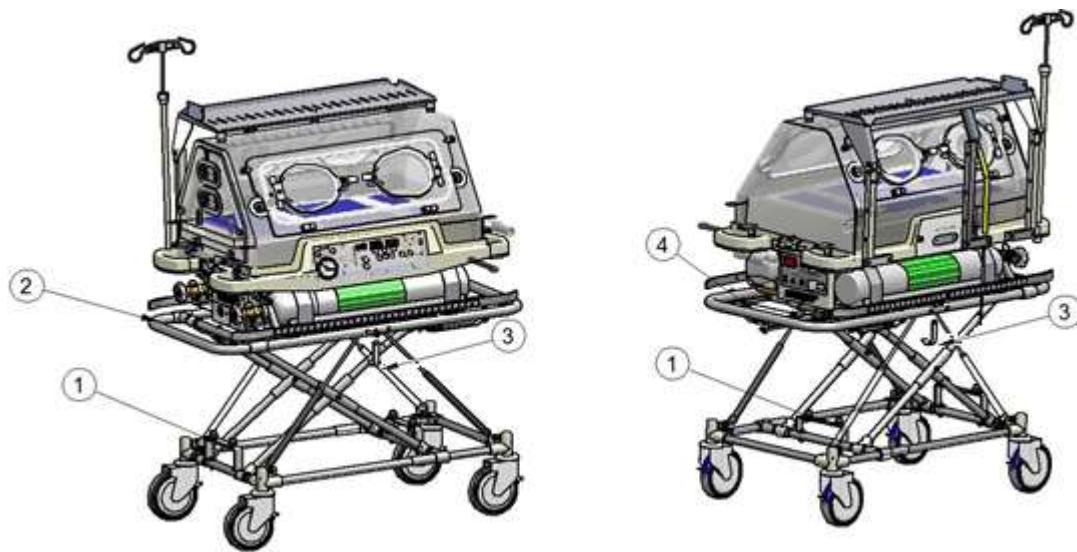
To raise the transport cart, place the incubator on a flat horizontal surface. Lock the casters of the transport cart and release the front and rear latches, located on the lower part of the cart.

To put the incubator in the upper position requires the joint action of two operators placed on each side of the equipment, with both hands placed on the support of the upper rim of the cart.

The operator on the side of the head of the incubator needs to place his right foot in the support located on the lower part of the transport cart to keep the casters of the incubator fixed to the floor. The operator on the other side needs to keep his feet planted on the floor and pull the safety lever of the transport cart with his left hand, pulling it horizontally toward the rim. It is the movement of pulling the safety lever that enables the transport cart to be raised to its upper position. Having taken these precautions, the incubator should be slowly raised to the upper position, under the direction of the person pulling the safety lever. The pressurized shock absorbers assist in the upward and downward movement of the transport cart, by alleviating the weight.



**Warning! To move the transport incubator cart requires two operators positioned on each side of the equipment, with both hands placed on the support of the upper rim of the cart.**

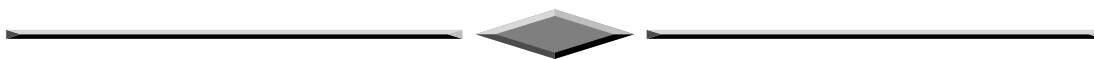


1	Foot support
2	Lift
3	Latches: Front and Rear
4	Safety Lever

### 5.1.2 Mounting the Gas Cylinders

The two cylinders for oxygen and/or compressed air need to be mounted in their respective supports located on the incubator on top of the transport cart. The cylinders should be positioned so that the gas outlet is aimed toward the head of the incubator, where the inlet nipple for feeding gas to the incubator is located, and the double tubing port for introducing and attaching tubes to the newborn, through the left door. To mount the oxygen and/or compressed air cylinders, open the bracket clasps by pressing the quick coupling buttons on each bracket. Install the cylinders into their respective oxygen (right) and compressed air (left) brackets, close the clasps around the neck of the cylinder, and attach the quick coupling screw to lock them in.

Oxygen and Compressed Air Cylinder Options	
Oxygen Cylinder Type E (DOT 3AL), without a control valve – ABNT 218-1.	
Compressed Air Cylinder Type E (DOT 3AL), without a control valve – ABNT 218-1.	
Compressed Air Cylinder Type E (DOT 3AL), without a control valve – ABNT 204-1.	
Oxygen Cylinder Type E (DOT 3AL), Yoke standard. Without a control valve.	
Compressed Air Cylinder Type E (DOT 3AL), Yoke standard. Without a control valve.	
Control Valve Options	
Oxygen Control Valve with a flow meter 0-15 l/min for O <sub>2</sub> and manometer.	
Compressed Air Control Valve with a flow meter 0-15 l/min for air and manometer.	
Control Valve for Compressed Air Cylinder with a manometer and flow meter – ABNT 204-1.	
Oxygen Control Valve, Yoke standard, with a flow meter 0-15 l/min for O <sub>2</sub> and manometer.	
Compressed Air Control Valve, Yoke standard, with a flow meter 0-15 l/min for air and manometer.	
Control Valve for Oxygen Cylinder calibrated at 3.5 kgf/cm <sup>2</sup> – ABNT 218-1.	
Control Valve for Compressed Air Cylinder calibrated at 3.5 kgf/cm <sup>2</sup> – ABNT 218-1.	
Control Valve for Compressed Air Cylinder calibrated at 3.5 kgf/cm <sup>2</sup> – ABNT 204-1.	



### **5.1.3      Installation of the Skin Temperature Sensor**

Connect the skin temperature sensor into the device on the side power inlet panel and observe the skin temperature reading on the corresponding display on the front panel.

During the heating and preparation stage of the transport incubator to receive the newborn, the skin temperature sensor should be kept inside the hood. The corresponding display on the front panel will indicate the temperature of the location where the sensor has been placed.

## 6. Operation of the Equipment

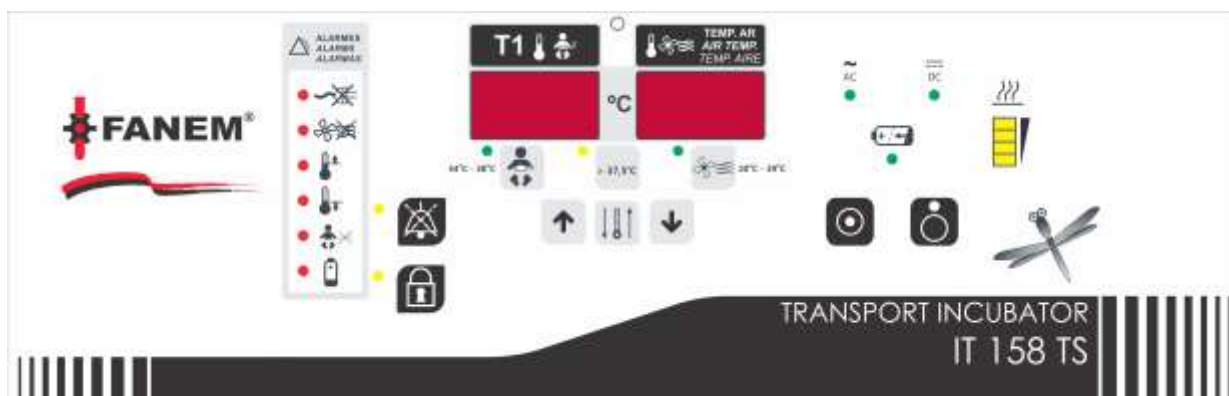
The IT-158 TS Transport Incubator provides a uniform microclimate with microfiltered, heated air that can be humidified and enriched with oxygen.

The forced air circulation system creates a slightly positive pressure within the hood, which promotes air flow from inside to outside and ensures protective insulation of the patient even when the hatches are open to perform a procedure on the newborn.

The microprocessor enables the temperature inside the hood to be accurately controlled, in addition to providing information such as heating power, alarms and operating voltage mode: AC ~ (mains) or DC --- (batteries) and battery charge.

On the front control panel, two numerical displays indicate the air temperature inside the incubator and the patient's skin temperature (fixed decimal point), as well as the set points for these temperatures (blinking decimal point).

### 6.1 Front Control Panel




	LED indicator for Power Failure		OFF key of the control panel
	Air Circulation Failure LED indicator		ON key of the control panel
	High Temperature LED indicator		Temperature Set Point selection key
	Low Temperature LED indicator		Increase Temperature Set Point key
	No Sensor LED indicator		Decrease Temperature Set Point key
	Low Battery Level LED indicator		Mode selection key >37.5°C
	Battery Charging LED indicator		Heating Power LED indicator
	Skin Mode selection key		Silence alarm key

	Air Mode selection key		Locked key / Locked Access
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### 6.1.1 Turning on the Incubator

Turn on the master switch located on the side power inlet panel.


Press the ON  key on the front control panel. The microprocessor will run an auto-test to verify that all the audiovisual information on the panel is in perfect condition, as follows: - two numerical displays will show the number 88.8 and all the LEDs will light up, except for the Power Failure and DC Mode LEDs, if power is supplied through the mains 100 to 240 V~ (automatic dual voltage 127 V~ or 220 V~).

Observe that immediately after the incubator is turned on, a series of numbers will appear on the front control panel, identifying the current version of the software installed.

After the auto-test, the air temperature numerical display will indicate the air temperature measured inside the incubator. The audible part of the Low Temperature alarm will be silenced for 40 minutes to avoid constant and/or nuisance alarms until the temperature stabilizes. If needed, the visual part of this alarm will continue being displayed. After this period of time, the audible part of the alarm will be automatically enabled.

This panel provides information from the battery charge indicator and, on the front control panel, the green LED indicates that the batteries are charging.

*NOTE: When the batteries are charged, the green LED indicator will remain off.*

To disconnect the transport incubator from the mains, it is necessary to press the Off  key on the front panel of the equipment and then place the master switch in the "O" OFF position. Also unplug the power cord from the socket.

## 6.2 Operational Indicators on the Control Panel

The IT-158 TS Transport Incubator displays the following operational indicators on the front panel:

### 6.2.1 Power Supply

Indicates the type of power source being provided to operate the transport incubator. This source can be AC power, internal batteries or external 12 V\_ \_ \_ and/or external 28 V\_ \_ \_ (optional).

Operating mode: AC mode – mains and DC mode – batteries are indicated through green LEDs that light up next to the respective AC and/or DC icons.

In AC mode, the green LED next to the battery icon lights up to indicate that the batteries are being charged. This LED turns off once the batteries are fully charged.



**Warning! Whenever possible, keep the transport incubator plugged into a socket so that the battery charge is not reduced unnecessarily.**

### 6.2.2 Battery Charge

Battery charge status is continually indicated by the volt meter (measures voltage), located on the side panel of the battery module. This screen informs in real time the current voltage of the batteries in volts and battery charge as a percentage, in addition to representing the battery level in the form of a colored indicator bar.






Following is an informational table on battery voltage values:

<b>Battery Voltage Gauge</b>
Over 12 V – Batteries totally charged
From 11.9 V to 11 V – Batteries partially charged
From 10.9 V to 10.6 V – Discharged batteries → Charge the batteries
Under 10.5 V – Battery low voltage alarm

To continually keep the batteries charging, it is necessary to complete the following steps:

- The power cord must be plugged into a socket.
- The master switch of the equipment must be turned on.

On the front control panel, the green LED next to the battery icon indicates that the batteries are being charged. This LED turns off once the batteries are fully charged.

	<b>Warning! It takes at least 30 hours to fully charge the batteries (in the case of totally discharged batteries).</b>
	<b>Warning! Always keep the transport incubator plugged into the wall with the master switch in the "ON" position so that the batteries remain charged.</b>
	<b>Warning! To prolong the time of use of the transport incubator by battery (DC Mode---), it is recommended not to use the batteries for the initial heating.</b>
	<b>Warning! When the transport incubator will be disconnected from the mains and stored for an extended period of time, the battery fuse holder, located on the battery module panel, should be removed. The incubator should be turned off using the key on the front control panel and master switch, located below the display, to avoid the batteries from discharging less quickly.</b>
	<b>Warning! Turn on the incubator upon receiving it, in order to preserve the batteries.</b>

### 6.2.3 Heating Indicator

The amount of heat supplied by the heating element is indicated by the four yellow LEDs on the front control panel.

The lower LED indicates 1/4 power, the second indicates 1/2 power, the third indicates 3/4 power and the fourth LED (upper) indicates full power. When the internal air temperature is equal to the temperature set point, the 1/4 power LED will remain on.

### 6.2.4 Numerical Temperature Display

#### 6.2.4.1 Air Temperature:

This numerical display constantly indicates the temperature measured by the internal air temperature sensor, in either Air or Skin operating mode. The reading range of this display is from 20°C to 45.5°C.

When the air temperature operating mode is activated, the green LED next to the selection key corresponding to the Air Mode icon will remain lit.

#### 6.2.4.2 Skin Temperature:

This numerical display indicates the temperature measured by the skin temperature sensor, in either Air or Skin operating mode. The reading range of this display is from 20°C to 45.5°C.


When the skin temperature operating mode is activated, the green LED next to the selection key corresponding to the Skin Mode icon will remain lit.






**Warning! When the skin temperature sensor is disconnected from the side power supply input, the display will indicate “\_ \_ \_” °C and the operating mode will automatically switch to Air Mode.**


### 6.3 Incubator Temperature Control

#### 6.3.1 Air Mode

In this operating mode, the temperature of the incubator can be set from 30°C to 39°C, selected via the Temperature Set Point  key on the front panel.

The temperature of the incubator is monitored through the air temperature sensor, and the temperature is indicated on the "Air Temperature" display.

To set the air temperature, press the Temperature Set Point  key. On the air temperature display, the decimal point of the value of this temperature will keep blinking to indicate the programmed mode, which enables setting the air temperature through the  or  keys.

To set the air temperature higher than 37.5°C press the  key to enable the system to accept settings up to 39°C.



**Warning! On the air temperature display, the decimal point of the temperature value that keeps blinking indicates the temperature that is programmed.**

After four seconds, if no key is pressed, the display will once again show the air temperature, followed by an audible notification.



**Warning! The air temperature set point will be saved even after the incubator is switched off.**


The power supplied to the heating element will be shown on the four heating LEDs. When the air temperature is equal to the temperature set point, the first LED will remain lit, indicating a 25% power supply.

Wait the time needed for the set air temperature to stabilize inside the incubator.



**Warning! It is necessary to wait for the air temperature inside the incubator to stabilize before receiving the patient.**

#### 6.3.2 Skin Mode




In this operating mode, the skin temperature of the newborn can be set from 34°C to 38°C, selected with the Temperature Set Point  key on the front panel.

Check that the skin temperature sensor is properly connected to the side power inlet panel.

The skin temperature of the newborn is monitored through the skin temperature sensor and the heating of the air of the incubator will be proportionally controlled to maintain the newborn's skin temperature at the set value.



When Skin Mode is selected, the control of the temperature and alarm levels will be based on the newborn's skin temperature. The air temperature will be continuously monitored by the air temperature display.

To set the skin temperature, press the Temperature Set Point  key. On the skin temperature display, the decimal point of the value of this temperature will keep blinking to indicate the programmed mode, which enables setting the skin temperature through the  or  keys.



**Warning! On the air temperature display, the decimal point of the temperature value that keeps blinking indicates the temperature that is programmed.**

After four seconds, if no key is pressed, the display will once again show the skin temperature, followed by an audible notification.



**Warning! The skin temperature set point will be saved even after the incubator is switched off.**

The power supplied to the heating element will be shown on the four heating LEDs. When the skin temperature is equal to the temperature set point, the first LED will remain lit, indicating a 25% power supply.

Wait the time needed for the set skin temperature to stabilize inside the incubator.



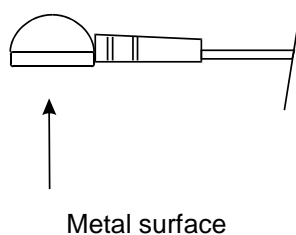
**Warning! After receiving the patient in Air Mode, it is necessary to wait for the patient's skin temperature to stabilize before switching the control to Skin Mode.**

### 6.3.3 Skin Temperature Sensor

After connecting the skin temperature sensor into the side power inlet panel of the transport incubator, the metal part of the head of the sensor should be attached to the intact skin preferably in the abdominal region of the newborn, with suitable adhesive.

Proper attachment of the skin temperature sensor helps avoid errors, reading errors and various operational alarms.

Skin Temperature Sensor



**Warning! Before attaching the skin temperature sensor to the patient, make sure that the body of the sensor is clean and does not contain any bits of adhesive, in order to avoid readings errors and contamination.**



**Warning! Never place the skin temperature sensor underneath the newborn, or use it to measure rectal and/or axillary temperature.**



**Warning! Improper positioning of the skin temperature sensor can cause increased heat to be delivered to the patient, possibly resulting in overheating and harmful consequences.**

**Constantly monitor the newborn's condition to check the temperature measured and that the sensor is properly attached.**



**Warning! Never remove the skin temperature sensor from the newborn by pulling on the cable. First remove the adhesive and then the sensor.**

#### **6.3.4     Standby Operating Mode**

The recommended procedures for the IT-158 TS Transport Incubator in standby mode, while waiting for the next newborn to transport are:

##### **6.3.4.1     Keeping the Batteries Charged**

Always keep the batteries fully charged, constantly checking the charge level indicator located on the side panel of the battery module.

The batteries will be in the charging process, when the battery charge indicator is lit up on the front control panel and:

- ◆ The power cord is connected into the electrical socket;
- ◆ The master switch of the equipment is in the ON position.



**Warning! If the transport incubator will be turned off and not used for a long period of time, remove the fuses from the battery fuse holder in the battery module panel and switch off the battery risk indicator, to avoid the batteries from discharging quickly.**

##### **6.3.5     Keeping the Incubator in AC Mode (mains)**

Always operate the incubator in AC Mode (mains) and check that the AC Mode LED indicator is lit up on the front control panel to ensure:

- ◆ Initial heating in Air mode and the necessary air temperature;
- ◆ Protective insulation of the microclimate for the patient;
- ◆ Full charge of the batteries and autonomous transport.



**Warning! It takes at least 50 minutes\* to reach the air temperature set point before the patient can be received in the incubator.**

\*See the definition of **Temperature Rise Time** in Chapter 2.1.

### 6.3.6 Transport Operating Mode

The recommended procedures for the IT-158 TS Transport Incubator in newborn transport mode are the following:

### 6.3.7 Receiving the Patient

To receive the patient in the transport incubator, proceed as follows:

- ◆ Assess and set the operating parameters of the incubator according to the patient's clinical condition and transport mode.
- ◆ Ensure that the patient is safely and comfortably settled in the bed, with the safety belt on.
- ◆ Disconnect the power cord to automatically enter into DC Mode (battery).
- ◆ Keep the power cord with the incubator to charge the batteries while waiting or in the actual vehicle.



**Warning! If the power cord is disconnected from the socket, the transport incubator will automatically start operating in DC (battery) Mode.**



**Warning! During transport, always keep the power cord with the incubator to charge the batteries while waiting or in the actual vehicle.**

### 6.3.8 Operating Mode with Newborns

With the incubator previously preheated, set the air temperature at the level indicated to receive the newborn that will be transported. For example: 37.5°C during transport from the delivery room, after the birth.

Once the air temperature inside the hood is stable, open the front access door, comfortably and safely position the newborn on the mattress with the safety belt attached, and close the access door.

Place and attach the skin temperature sensor to the newborn, preferably in the abdominal region. Monitor the measurement of the patient's skin temperature on the numerical display of the front control panel.

In the case of prolonged transport, once the patient's skin temperature reaches the set point and stabilizes, change heating control to Skin Mode. The skin temperature set point for newborns is approximately 36.2°C to 36.6°C.



**Warning! Keep the front access door and hatches open the least amount of time possible to avoid temperature losses. Place the skin temperature sensor preferably in the abdominal area of the newborn, fastening it with suitable adhesive.**



**Warning! If the temperature monitored by the skin temperature sensor fluctuates rapidly, an alarm will indicate that the sensor has shifted in relation to the newborn's body. In such situations, the No Sensor alarm will be triggered in an intermittent fashion. Press the "Silence" key to cancel the No Sensor alarm and check that the sensor is correctly positioned and attached to the patient.**

## 6.4 Additional functions

### 6.4.1 Humidification

The Transport Incubator has a passive humidification mode for the microclimate within the hood. Humidification is provided through foam that needs to be moistened with distilled water. Since humidification occurs through a natural process, this relative humidity concentration cannot be controlled by the equipment. Its use is recommended in situations where additional oxygen is used in the incubator.

To supply the microclimate with additional humidity, follow the instructions below:

- ◆ Unlatch and open the front and side access doors.
- ◆ Move the bed through the side door out of the hood to its maximum limit.
- ◆ Place new humidification foam in the appropriate location on the lower base beneath the bed, under the displacement latch, as shown in the drawing below.



- ◆ Wet the foam with sterile distilled water.
- ◆ Put the bed back in its original position and close the access doors.



**Warning! The humidification foam is a single-use item and should be discarded in the cleaning and/or disinfection process of the incubator performed after use of the equipment.**



**Warning! Only use original Fanem® parts.**



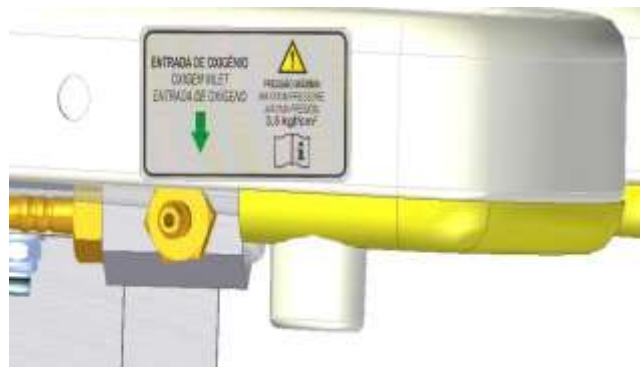
**Warning! In order to reduce risk of infection, only use the humidification foam when passive humidification is used. Never place humidification foam inside the incubator if it is not being used for its given purpose.**



**Warning! High relative humidity concentration may cause condensation to form on the inner walls of the hood if there is a significant difference between temperatures inside and outside the incubator.**

### 6.4.2 Oxygen Administration

The IT-158 TS Transport Incubator has a supplementary oxygen inlet located on the left side, next to the hood release latches, as shown in the drawing below. The supply of oxygen must be through an oxygen cylinder connected to a control valve and flow meter. The oxygen that enters is filtered and mixes with the air from the microclimate, to be heated and delivered to the hood, where it will be passively humidified.



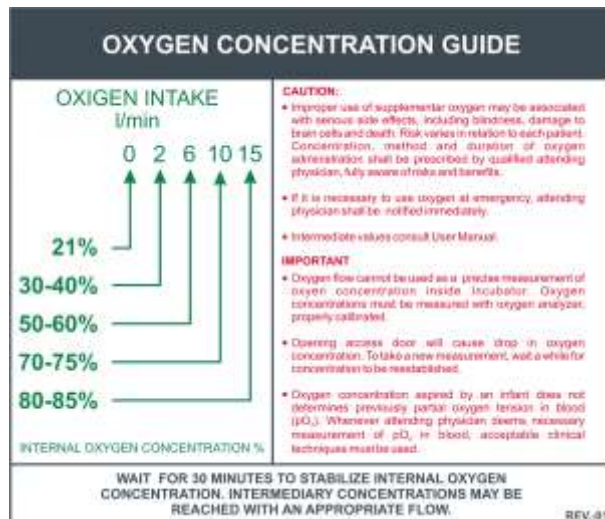
**Warning! Improper use of supplemental oxygen can have serious side effects, including blindness, brain damage and death. The risks vary with each newborn. The method, concentration and duration of oxygen administration must be prescribed by the physician.**

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



**Warning: Do not use the equipment in the presence of flammable anesthetics.**

**Keep all ignition sources (e.g.: example, matches, cigarettes, equipment that generates sparks, etc.) far from the site where the incubator is operating. Textiles, oils and other combustibles easily ignite and burn in oxygen enriched air.**



**ADVERTÊNCIA**  
**WARNING / ADVERTENCIA**

**PERIGO DE EXPLOÇÃO:** Não use na presença de anestésicos inflamáveis.

**PERIGO DE FOGO:** Mantenha qualquer fonte de ignição (ex.: Fósforos, cigarros, equipamentos que produzam faíscas, etc.) longe da sala onde a incubadora estiver operando. Tecidos, óleos ou outros combustíveis entram em ignição facilmente quando o ar está enriquecido com oxigênio.

**ATENÇÃO:** Radiação térmica pode causar um aumento excessivo da temperatura interna da incubadora. Não permita que a incubadora permaneça durante muito tempo sob as radiações diretas do sol ou outra fonte de calor.

**DANGER OF EXPLOSION:** Do not use in presence of flammable anesthetics.

**DANGER OF FIRE:** Keep any ignition sources (ex.: Matches, cigarettes, equipment producing sparks, etc.) away from room where incubator is operating. Textiles, oils and other combustibles are easily ignited when air is enriched with oxygen.

**CAUTION:** Thermal radiation may cause an excessive temperature increase inside incubator. Do not allow incubator to remain under direct sun light or other heat source for long time.

**PELIGRO DE EXPLOSIÓN:** No usar en la proximidad de anestésicos inflamables.

**PELIGRO DE FUEGO:** Mantener cualquier fuente de ignición (e.g.: Fósforos, cigarrillos, equipamentos que produzam faíscas, etc.) lejos de la sala donde está funcionando la incubadora. Tejidos, aceites o otros combustibles se ponen fácilmente en ignición cuando el aire está enriquecido de oxígeno.

**ATENCIÓN:** Radiación térmica puede causar un aumento excesivo de la temperatura interna de la incubadora. No se debe permitir que la incubadora quede demasiado tiempo expuesta a las radiaciones directas del sol o de otra fuente de calor.

REF: 158.252.321 - REV. 01

### OXYGEN CONCENTRATION REFERENCE TABLE

Intake flow (liters per minute)	0	2	4	6	8	10	12	15
Concentration (O <sub>2</sub> %)	21	30-40	40-50	50-60	60-70	70-75	75-80	80-85

## 6.5 Babypuff® Neonatal Resuscitation Device integrated into the control panel

The Babypuff® Neonatal Resuscitation Device is used in neonatal transport protocols to provide support in emergency situations requiring resuscitation.

To facilitate its use, the Babypuff® can be integrated into the control panel of the IT-158 TS Transport Incubator.

Whenever this transport incubator is ordered with the Babypuff® integrated into the control panel of the equipment, it will have a gas strip for simultaneous supply of oxygen to the Babypuff® and incubator.

When integrated into the control panel of the transport incubator, it contains an analog manovacuometer for setting, measuring and monitoring pressure. It uses three mechanical valves to regulate and control maximum pressure or safety pressure, peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP). It also has two quick coupler connections: a smooth one for the gas input/supply to the equipment and a corrugated one for the gas output/supply to the patient adapted to an Ayre's T-piece. The connection to the patient can be done using a tracheal tube or a round, transparent silicone mask, which comes in three sizes. The set comes with a test lung and parameter settings to define the parameters before use with the patient.

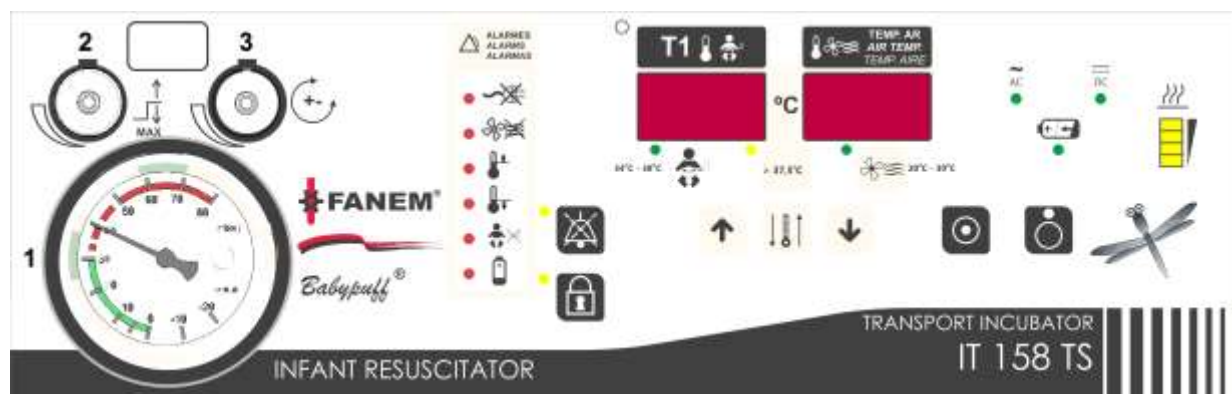
The integrated Babypuff® operates directly and exclusively through a gas source that can be oxygen, compressed air or an air/O<sub>2</sub> mixture controlled by a blender or another type of mixer.

The Babypuff® inlet and outlet gas connections are located on the side of the control panel and on the base of the incubator.

The device operates same way as the standard Babypuff® model. To adjust the pressure delivered to the patient, the maximum pressure relief and PIP valves are located next to the manovacuometer and PEEP valve, as in the standard model, is located on the Ayre's T-piece, of the corrugated tube.

### 6.5.1 Babypuff Integrated into the Panel

The drawing below shows the items that are integrated into the incubator and used for the resuscitation procedure:



Item	Description
1	Manovacuometer
2	Maximum Pressure Relief (Safety Pressure) Control Valve
3	Inspiratory Pressure (PIP) Control Valve

The Babypuff® gas inlet and outlet connections are located next to each other, on the side of the base, close to the power module, as shown below.





## 6.5.2 Items used with the Babypuff®

### 6.5.2.1 Gas Inlet Hose

Non-toxic, PVC hose (2.1 m), with connectors on the ends for quick coupling between the gas source (through a flow meter) and the Babypuff® gas inlet.



### 6.5.2.2 Corrugated Tube with Ayre's T-Piece

Connection circuit between the Babypuff gas outlet and the patient, composed of a quick coupler corrugated tube and Ayre's T-piece with a PEEP valve.



### 6.5.2.3 Round Masks

In sizes 00, 0 and 1, they are made of transparent silicone, which makes them easier to handle and enables full viewing of the patient's mouth and nostrils.



### 6.5.2.4 Test Lung

Made of silicone, with a polypropylene connector for coupling to the Ayre's T-piece.

Designed for running tests with this resuscitation device and setting individualized parameters.



## 6.5.3 Installation of the pieces used with the Babypuff

When the Babypuff® Neonatal Resuscitation Device is integrated into the IT-158 TS Transport Incubator, simply set up the gas circuit which is supplied through a flow meter and the test lung that will later be replaced by a mask or endotracheal tube for use with the newborn.



**Warning! Before using the Babypuff® Neonatal Resuscitation Device, all the parameters must be checked and calibrated, using the test lung, for network and usage flow conditions.**

The maximum pressure relief (safety pressure) valve comes from the factory at a 40 cmH<sub>2</sub>O opening.

Before using the Babypuff® Neonatal Resuscitation Device, all the parameters must be checked and calibrated, using the test lung, for network and usage flow conditions.

- ♦ **Gas Generation Source:** Identify and establish the gas generation source, whether compressed air, oxygen or an air/O<sub>2</sub> mixture, controlled through a blender or administered through another type of mixer or valve ("Y" type, example).
- ♦ Ensure that this gas generation source has a calibrated flow meter to control the inflow to the Babypuff®.
- ♦ Couple the corresponding connector of the gas inlet hose to the outlet of the flow meter of the gas generation source, and connect the other end of the gas inlet hose into the gas inlet port of the Babypuff®.
- ♦ Couple the corrugated tube to the gas outlet branch of the Babypuff®, with the Ayre's T-piece on the other end, to which the test lung should be coupled.
- ♦ Turn on the gas source and adjust the supply according to the desired flow, from 5 to 15 lpm.



**Warning! A gas flow of 5-8 lpm is normally used for newborns, and a flow of up to 15 lpm for pediatric use. Do not use flows greater than 15 lpm.**

- ♦ **Checking Safety Pressure:** Totally close the three valves, starting with safety pressure, and then inspiratory pressure (PIP) and PEEP, turning the knob clockwise, and then cover with your finger the aperture in the center of knob of the PEEP valve next to the Ayre's T-piece. Check maximum pressure relief (safety pressure) on the manovacuometer, obtained through the supply of gas (which should be around 50 cmH<sub>2</sub>O) and then set it, turning the knob counter clockwise. After this, adjust the opening pressure of the relief valve to the desired amount (up to 40 cmH<sub>2</sub>O is recommended).
- ♦ **Regulating PIP:** Keep the PEEP valve next to the Ayre's T-piece closed and covered with your finger on the aperture in the center of the setting knob. Then, turn the control knob of the inspiratory pressure valve counter clockwise, until the desired peak pressure is achieved. Monitor this setting on the manovacuometer.
- ♦ **Setting PEEP:** To set PEEP, remove your finger from the aperture in the center of the PEEP valve setting knob, located next to the Ayre's T-piece. Then, turn the knob counter clockwise and set the PEEP. Monitor the positive end expiratory pressure (PEEP) setting on the manovacuometer.



**Warning! The Babypuff® Neonatal Resuscitation Device must be checked and set before each use. Make sure that the correct pressures were set before authorizing its use for each case and patient.**

**Routine settings and checks must be in compliance with the resuscitation protocol adopted at the local service level.**

#### 6.5.4 Operating the Babypuff®

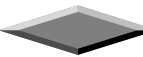
After installing and programming the Babypuff® Neonatal Resuscitation Device, according to the instructions in the previous section, uncouple the test lung from the Ayre's T-piece, attach the appropriate sized silicone mask or endotracheal tube, and proceed as follows for the mechanical ventilation process:

Using a silicone mask:

- Fit the mask over the mouth and nose of the patient, seeking to form a good seal. The PEEP setting will be displayed on the manovacuometer once the ideal seal has been achieved.

Using an endotracheal tube:



- 
- 
- 
- With the endotracheal and intermediary tube already attached to the patient, connect the intermediary to the Ayre's T-piece, seeking to form a good seal. The manovacuumeter will display the PEEP setting once the ideal seal has been achieved;

Start manual ventilation:

- Manually ventilate the patient by placing your thumb over the central aperture of the PEEP valve cover and then remove it, to enable inspiration and expiration.



**Warning! The Babypuff® Neonatal Resuscitation Device should only be used by health professionals who are properly qualified and authorized to perform this procedure. It is the responsibility of the health professional to operate in compliance with current official safety standards and local service protocols when using this product for therapeutic procedures on patients.**

## 6.6 Finalization procedure

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After completion of the patient's treatment with the equipment, turn it off using the off key on the front control panel and through the master switch and unplug the power cord from the socket to ensure that the equipment is not connected to the mains. Then, send the IT-158 TS Transport Incubator for the cleaning and disinfection process, following the instructions in Section 7 - Preventive and Corrective Maintenance and Conservation.

## 7. Preventive and Corrective Maintenance and Conservation

This chapter presents guidelines, recommendations and procedures related to Preventive and Corrective Maintenance and Conservation of the IT-158 TS Transport Incubator. Maintenance operations not covered in this section should only be carried out by properly qualified and trained professionals.

Routinely inspect the IT-158 TS Transport Incubator and put back the accessories before starting to operate the unit.



**Warning! Before starting any maintenance or cleaning procedure, ensure that the equipment is disconnected from the mains and not being used by a patient.**



**Warning! Make sure the oxygen supply is turned off and that the equipment is disconnected from it whenever cleaning or maintenance procedures are performed. There is a risk of fire or explosion in oxygen enriched environments.**



**Warning! The heating element may be hot enough to cause burns; avoid touching or removing the heater until the unit has been switched off for at least 50 minutes.**

### 7.1 Cleaning and Conservation

For cleaning the IT-158 TS Transport Incubator, only the cleaning and/or disinfection procedure established by the local Hospital Infection Control Committee can be adopted. It is recommended to use products and materials that are non-toxic to patients and users and that do not damage the different materials that make up the acrylic, plastic and metal parts and pieces of the equipment.

The incubator should be cleaned when it is first received and between uses with the same and/or next patient. It is recommended to completely disassemble the different compartments and parts. Therefore, it is necessary to have an appropriate physical location for setting down the parts and pieces, as well as a properly prepared and trained professional to comply with the recommendations from this manual.

To carry out the cleaning and/or disinfection, always use soft and preferably disposable pads.

For cleaning, use neutral detergent, diluted in water. Apply it with pads, wiping all the parts and surfaces. Remove the detergent with a damp pad, dry and then reassemble the parts and pieces.

For disinfection of the equipment, choose a product with low toxicity, whose composition and dilution enable removal of dirt and the load of microorganisms. Preferably choose a product that dispenses with prior cleaning of the equipment and apply it to all the surfaces and parts, according to the manufacturer's instructions. Leave the product for the specified exposure time and then totally remove it using pads dampened with water. Lastly, dry and reassemble the compartments and pieces.



**Warning! In any cleaning procedure for this equipment, never use products that contain alcohol, abrasives, sodium hypochlorite, dyes and/or abrasive sponges or steel wool, since they will damage the acrylic hood and other parts.**

### 7.1.1 Disassembly for Cleaning

The IT-158 TS Transport Incubator must be fully disassembled to perform the cleaning procedure to make the equipment safe and comfortable for the operator and patient. Disassembling the equipment permits individual access to all the compartments, parts and pieces.

Two properly trained professionals are necessary to safely disassemble the unit, according to the following steps:

- ♦ Make sure all the accessories have been removed to prevent possible damage to them;
- ♦ Disconnect the power cord and skin temperature sensor of the incubator;
- ♦ Check to see whether the cylinder is connected, turn off the oxygen supply and disconnect the supply hose;
- ♦ Completely remove all the hatch fittings and membranes for inserting tubes;
- ♦ Release the rubber rings, remove the outer acrylic hood, and place it on a suitable surface. Then, remove the inner acrylic hood;
- ♦ Remove the mattress and then the bed, moving it out through the side, pressing on the inner latch;
- ♦ If humidification was used in the last operation of the incubator, remove and discard the foam;
- ♦ Unlock the four side clamps and remove the upper base, taking care not to damage the air temperature sensor attached to the lower base;
- ♦ The cleaning and/or disinfection must be carried out up to this level of disassembly, including the finned heater, fan and thermal control switches.



**Warning! The transport incubator must be fully disassembled between uses, regardless of length of time of use, to undergo cleaning and eliminate any contamination in its inner parts.**

### 7.1.2 Acrylic Hood

To clean the hood, it is necessary to remove the hatch fittings and single and dual tubing port. Make sure that the product and materials used do not contain agents that could damage the acrylic, plastic and metal parts.



**Warning! In any cleaning procedure for this equipment, never use products that contain alcohol, abrasives, sodium hypochlorite, dyes and/or abrasive sponges or steel wool, since they will damage the acrylic hood and other parts.**

### 7.1.3 Structure of the Incubator

Clean the entire surface of the structure of the equipment, using the cleaning and/or disinfection procedures, products and materials, in accordance with the previous recommendations.

Completely remove the product used during the cleaning process with a damp pad, and then dry and reassemble the compartments and parts.



**Warning! The lower base of the structure of the incubator must be cleaned after every use of the equipment.**

#### 7.1.4 Heating Element, Fan and Thermal Switches

Clean and or disinfect using a soft pad and disposable spatula to remove dirt from the fan, finned heater and thermal switches.

Make sure that the product used does not contain agents that could damage the plastic and metal parts of these pieces.

Completely remove the product.



**Warning! The heating element may be hot enough to cause burns; avoid touching the heater until the equipment has been switched off and the heating element is cold.**



**Warning! Do not use products that contain alcohol and/or abrasives, or sodium hypochlorite.**



**Warning! Improper cleaning of the heating element and fan can result in lint buildup that could impair or affect the heating and air circulation in the incubator.**



**Warning! Do not use running water (hoses or showers) when cleaning and/or disinfecting the parts of the incubator.**

#### 7.1.5 Skin Temperature Sensor

Since the skin temperature sensor is a delicate device, it should be cleaned and/or disinfected like the other components and pieces, carefully applying the product with a pad along the cable and encapsulated part. After this, completely remove the product before new use with another patient.

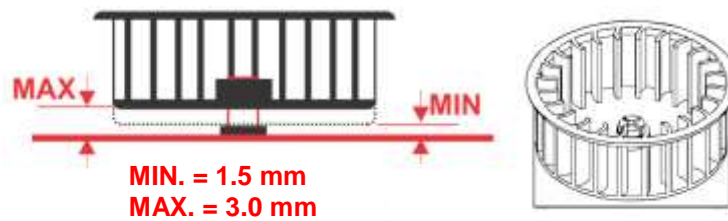


**Warning! The sensor should not be immersed in the products used for the cleaning and/or disinfection procedures, since this could damage it.**

#### 7.1.6 Reassembling the Equipment

To safely reassemble the IT-158 TS Transport Incubator for new use, two properly trained professionals need to carry out the following steps:

- ♦ If necessary, reinsert the fan in accordance with the maximum and minimum distances, as shown on the marking next to the motor-fan unit;



**Warning! The fan must be installed on the motor axle, in accordance with the established maximum and minimum distances, to enable proper air circulation and control the noise issued.**

- ♦ Insert the upper base, taking care not to damage the air temperature sensor attached to the lower base, and then lock the four side clamps;
- ♦ Put the bed back on along with the safety belts, inserting it through the side and sliding it over the safety latch;
- ♦ Put back the inner wall of the hood on the base;
- ♦ Put the hood back on the inner wall. The operator must place his hands on each side of the hood to raise it up above the inner wall and then insert it, carefully sliding it downwards until it rests completely upon the base. Fasten the hood with the rubber rings;
- ♦ Completely reinstall all the hatch fittings and membranes for inserting tubes;
- ♦ Put the mattress back on the bed;
- ♦ Connect the power cord and skin temperature sensor into the side power inlet panel;
- ♦ Check whether the cylinders are connected, turn off the oxygen supply and disconnect the supply hose;
- ♦ Check that the accessories that will be utilized in the next use of the incubator are installed;
- ♦ Connect the power cord and skin temperature sensor of the incubator;
- ♦ Plug the incubator into the mains and turn on the master switch to charge the batteries;
- ♦ Test that it works, keeping it preset and switched on to maintain the cleaning and/or disinfection conditions, heating and battery charge for next use.



**Warning! Check that the transport incubator and its accessories have been properly reassembled and that the devices for attachment to the hood are secured to ensure safe operation.**

#### 7.1.7 Integrated Babypuff® Neonatal Resuscitation Device – Parts

The cleaning and/or disinfection procedure for the resuscitation device is performed together with the one used for the control panel of the transport incubator.

The parts and pieces listed below are single-use items. They may be sterilized beforehand using ethylene oxide and/or gamma ray radiation.

- ♦ Gas inlet hose
- ♦ Corrugated tube
- ♦ Ayre's T piece
- ♦ Test lung
- ♦ Silicone masks



**Warning! Sterilization of single-use items after they have been used may affect the resistance of the materials and maintenance of their integrity, and operation of the Babypuff® Neonatal Resuscitation Device when next used.**

## 7.2 Cleaning and/or Disinfection Procedure

The IT-158 TS Transport Incubator can be cleaned and/or disinfected, and requires using suitable products and choosing an appropriate disinfectant that dispenses with pre-cleaning, which will help reduce the steps and time needed to carry out the procedure.



**Warning! In any cleaning procedure for this equipment, never use products that contain alcohol, abrasives, sodium hypochlorite, dyes and/or abrasive sponges or steel wool, since they will damage the acrylic hood and other parts.**



**Warning! This equipment must be sanitized through cleaning and/or disinfection, according to the instructions contained in this manual.**

After the terminal cleaning and/or disinfection procedure, the equipment must be plugged into the mains and continue operating in Air Mode at a preset temperature, such as 36°C, or according to the operational procedures in each department. This is necessary to maintain the heating, disinfection and cleaning conditions through filtration and forced circulation of the air, until the incubator is used again, and to keep the batteries charged.

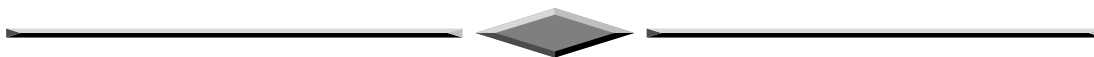


**Warning! After cleaning and/or disinfection, always keep the transport incubator plugged into the mains, at a preset temperature and in operation, to ensure internal protective insulation conditions, heating and battery charge, for next use of the equipment.**

### 7.2.1 Adoption of the Cleaning Procedure

Use:

- ◆ Good quality water
- ◆ Mild or enzymatic detergent
- ◆ Clean, soft and preferably disposable pads
- ◆ A suitable physical area for disassembling and laying down the components
- ◆ Procedure gloves



#### **7.2.1.1 When to perform a complete or terminal cleaning**

- ◆ Before first use.
- ◆ After each transport.

#### **7.2.1.2 How to perform the terminal cleaning procedure**

- ◆ Moisten the pad with a solution of water and recommended detergent.
- ◆ Wipe all the parts and pieces of the equipment with the pad to remove dirt.
- ◆ Replace the pad as often as necessary.
- ◆ Remove the product with another damp pad.
- ◆ Then dry and reassemble the parts and pieces of the equipment.

#### **7.2.2 Adoption of the disinfection procedure**

- ◆ Choose an appropriate disinfectant for fixed surfaces and the components of the equipment, such as a quaternary ammonia solution.
- ◆ Use clean, soft and preferably disposable pads.
- ◆ Use a suitable physical area for disassembling and placing the components.
- ◆ Use procedure gloves.

##### **7.2.2.1 When to perform a complete or terminal disinfection**

- ◆ Before first use.
- ◆ After each transport.

##### **7.2.2.2 How to perform the terminal disinfection procedure**

- ◆ Use the disinfectant in the recommended dilution for fixed surfaces.
- ◆ Moisten a dry pad with the disinfectant.
- ◆ Wipe all the parts and pieces of the equipment with the pad and disinfectant to remove dirt.
- ◆ Wait the indicated time for the disinfectant to work and then totally remove the product with another damp or dry pad, depending on the product used, preferably disinfectant. There is no need for rinsing. Then dry and reassemble the parts and pieces of the equipment.

#### **7.2.3 Required aspects for the cleaning and/or disinfection procedure**

- ◆ It should be performed by a professional who has been properly trained to carry out the procedure.
- ◆ There should be a suitable place for setting down the parts and pieces of the equipment.
- ◆ Use one of the procedures and the recommended products and materials between uses of the equipment.
- ◆ Unplug the equipment from the mains and the oxygen supply.
- ◆ Completely disassemble the equipment in order to access all the inner spaces.
- ◆ Reassemble the equipment and test it, keeping it preset at initial conditions for next use.
- ◆ Keep the incubator on and running after terminal cleaning or disinfection to maintain its internal sanitary conditions, through insulation, while waiting for next use.

### 7.3 Procedure for Changing the Air Filter

To change the air filter, proceed as follows:

- ◆ Open the lid of the air filter by releasing the clamp.
- ◆ Using procedure gloves, remove the used air filter and dispose of it.
- ◆ Clean and dry all the surfaces of the filter container.
- ◆ Using procedure gloves, install the new air filter. Close and latch the lid.
- ◆ Use a label to indicate the date the air filter was changed.



**Warning! Do not use very dirty air filters to avoid affecting oxygen concentration inside the incubator.**



**Warning! The air filter is a consumable and disposable item. It should not be cleaned or inserted with the dirty side facing inward. It should always be changed when completely dirty, or at least every 45 days.**



**Warning! Only use original filters and frequently check the conditions of the filter to ensure necessary replacements are made.**

### 7.4 Oxygen - Precautions

Improper use of supplemental oxygen can have serious side effects, including blindness, brain damage and death. The risks vary with each newborn. The method, concentration and duration of oxygen administration must be prescribed by the physician.

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



**Warning! Always use an oxygen analyzer to measure the concentration being administered. It is recommended to use the THOR® 3620 multitester for this purpose.**

When oxygen is supplied through a flow meter in liter/minute via the inlet nipple of the transport incubator, check the concentration table located on the front part of the incubator. This table only serves as a guide for variations of oxygen concentrations obtained in the microclimate of the incubator. Oxygen concentration should be frequently measured with a calibrated oxygen analyzer.



**Warning! Do not use a humidifier bottle on the flow meter supply outlet, to avoid wetting the oxygen filter, which can lead to a risk of contamination.**

The supply of oxygen concentrations above 21% in the internal environment of the incubator can be affected by opening the hatches or side walls of the hood, or even due to improper installation of the fittings and protective tubing port.

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

Accumulation of dirt in the air filter can affect the volume per minute of ambient air admitted to the incubator and consequently contribute to carbon dioxide (CO<sub>2</sub>) buildup in the microclimate. Always check the condition of the air filter whenever the equipment is sanitized for new use and replace it according to the specifications of this user manual.






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

## 7.5 Maintenance

### 7.5.1 Batteries of the Battery Module (Vital Module)

Check the state of the batteries before using the IT-158 TS Transport Incubator, or every three months.

To check whether the batteries are charged, turn on the transport incubator in DC mode using battery power (\_\_\_ indication), with the master switch in the ON position and the power cord disconnected from the AC power source. Press the ON  key on the front control panel. Set a temperature that is higher than room temperature so that all the LED power indicators will be lit. Turn on the auxiliary lighting and observe. If the "battery voltage" alarm is not triggered within five minutes, this means the batteries are charged.



**Warning!** Keep the transport incubator plugged into the mains with the master switch in the ON position so that the batteries remain charged. It can take up 30 hours to charge the batteries if they have been fully discharged.



**Warning!** Whenever the transport incubator is stored for a long period of time, remove the fuse for the batteries located in the battery module (Vital Module) and switch off the battery voltage indicator, to prevent the batteries from discharging quickly.

When the batteries need to be changed, this must be done by a qualified and trained technician. The procedure for removing the battery module is found in the section "Parts, Pieces and Accessories" of this user manual.



**Warning!** Always use original Fanem batteries when the batteries need replacement.

### 7.5.2 Battery Fuse

If the battery fuses need to be removed, use a tool for removing them from the fuse holders located on the side panel of the battery module, as shown in the drawing below:



### 7.5.3 Air Filter

The air filter of the transport incubator is a required item for the safe operation of the equipment in terms of the quality of air supplied to its internal environment. This filter, combined with positive pressure inside the hood, helps provide the newborn with protective insulation.

This filter is a disposable item that must be continuously monitored by the user, during terminal cleaning and/or disinfection of the equipment, between uses with newborns, to determine when it should be replaced. Replacement should be done by the user or the hospital's maintenance staff.

The air filter of the transport incubator should be changed whenever there is sufficient dirt buildup, i.e., when the outer layer is completely covered with the dirt. Clean the filter compartment and insert a new filter.



**Warning! Only use original Fanem® parts.**

The air filter should always be kept dry. If there are signs of moisture due to storage or misuse, the filter must be changed to avoid contamination of the inner layers of the filter and subsequent contamination of the inner environment of the incubator.

Use original filters specifically for the IT-158 TS Transport Incubator, since they have a particular area and thickness to properly cover the air flow duct. They cannot be cut or folded to be adapted to the equipment, or scraped off for reuse.

Not having a filter and/or using a saturated or inadequate filter affect: air circulation inside the incubator, heating uniformity, gas exchange levels and elimination of carbon dioxide, and oxygen concentration enrichment time, for the parameters established for this incubator.

### 7.5.4 Power cord

Before starting up the equipment, it is important to examine the power cord for any apparent signs of damage. If the power cord is damaged, do not start using the unit; contact the closest Fanem service technician.



**Warning! Only use the original Fanem® power cord, since it has been designed to comply with the electrical specifications of the equipment.**

### 7.5.5 Fittings and Elastic Cuffs

Regularly check the integrity and conditions of use of the fittings and elastic cuffs to ensure optimal equipment performance.

If the parts are dried or damaged through use, change them, always using original Fanem® parts. Replacement time depends on usage, the cleaning products used, and careful handling of the parts.

### 7.5.6 Humidification Foam

The single-use, disposable foam, when moistened with distilled water, provides passive humidification for the microclimate of the incubator. Only use original Fanem® foam and be sure to replace it between uses with patients.

### 7.5.7 Oxygen Cylinders and Valves

Use oxygen and compressed air cylinders that comply with the standards established by the ABNT or international equivalents.

The cylinders must be connected to the supply pressure control valves. For supplying oxygen to the incubator, a connection through a properly calibrated flow meter must be used. For connection with a blender, a hose must be used that provides a direct connection between the relief valves of the oxygen and compressed air cylinders and the gas inlets of the blender.

Be careful not to open the cylinder valves abruptly, as this could affect the diaphragm of the control valve.

When handling the cylinders and valves, check for the presence of grease, oil, paint or kerosene on gloves, rags or tools, since these products can instantly ignite when in contact with oxygen. Small amounts of flammable agents left on the equipment, such as alcohol, may cause a fire when in contact with oxygen.

Use properly calibrated valves. Never attempt to repair a damaged valve.



**Warning! Before handling cylinders or valves, always consult with the internal accident prevention committee (CIPA) for further clarifications and information.**



**Warning! It is recommended to use control valves with pressure set at 3.5 kgf/cm<sup>2</sup>.**

### 7.5.8 Calibration

The air temperature and safety temperature sensors should be calibrated regularly every 4 to 6 months.



**Warning! Calibration should be performed by a qualified technician who has been certified by Fanem Ltda.**

## 7.6 Spare Parts

For replacement of spare parts, consult Section 3 of this manual: Parts, Pieces and Accessories, to correctly mark them in the order.

The functions and safety of the IT-158 TS Transport Incubator are only guaranteed if the preventive maintenance and repair services are performed by the technical assistance team or people properly trained and qualified by Fanem Ltda.

FANEM assumes no responsibility for any damage that may occur with the equipment or for any consequences to patients or users due to improper maintenance not performed by our Technical Assistance team, or in the event non-original spare parts or accessories were used as replacements.

The materials used to design parts, accessories and consumables seek to ensure that the equipment operates in accordance with its original features, in addition to being safe in terms of toxicity and flammability of the materials used.



**Warning! No modifications to this equipment are permitted without authorization from Fanem Ltda.**  
**Only use original Fanem® parts.**

## 7.7 Consumables for Replacement

Description	Frequency	Performed by
Silicone tubing port (single)	24 months	User / Technician
Adhesive for Patient Sensor	With every new use	User
12 V Battery----	200 charges/discharges	Technician
NiMh 9 V----	12 months	Technician
Non-toxic PVC Mattress Cover	12 months	User/Technician
Safety Belt	6 months	Technician
Self-Extinguishing Foam Mattress	12 months	User/Technician
Humidification Foam	Single-use	User / Technician
Air Filter – kit with 10 units	45 days	User / Technician
Base Fittings (kit)	24 months	Technician
Hood Fittings (kit)	24 months	Technician
Hatch Fittings	24 months	User / Technician

## 7.8 Maintenance Chart

The user is responsible to establish a maintenance routine to ensure correct and safe performance of the equipment.

Part	Frequency	Performed by
Routine Calibration Tests	6 months	Technician
General Inspection of the Hood, Hatches and Fittings	6 months	Technician
Preventive Maintenance	12 months (preferably 6 months)	Technician
Terminal Cleaning / Disinfection	With each new patient	User
Calibration of the Blender	Every year between preventive maintenance	Technician
General Inspection, Cleaning and Calibration (Blender)	24 months	Technician

## 7.9 Power Failure Alarm Battery

The control unit of the IT-158 TS Transport Incubator has a rechargeable NiCd 9 V battery ---, designed to operate the power failure alarm when the transport batteries are running low.

This battery recharges through normal use of the equipment and its expected lifetime is 24 months, after which it should be replaced with a new original one.



**Warning! Do not use normal or alkaline 9 V batteries---, due to risk of explosion. Only use rechargeable NiCd batteries supplied by Fanem.**

To replace the power failure alarm battery, remove the support from the front cylinder, take out the screws on the front control module below the panel, and replace the battery. Perform the reverse operation to reassemble the units. There is no risk of inadvertent connections, since the connector is polarized.

## 7.10 Disposal

Do not throw electronic devices or parts in the trash when disposing of the equipment or its parts.

To minimize pollution and ensure the utmost protection of the environment, adopt the indicated recycling measures. For more information on the subject, research topics related to Waste Electrical and Electronics Equipment (WEEE).

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



**Warning! Batteries must be disposed of according to the laws of the country.**

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

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

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## 7.11 Checking the Alarms

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The checking of the audible and visual alarms of the control panel can be done through simulations to determine whether any LED or audible alarm is damaged.

Whenever the front control panel of the IT-158 TS Transport Incubator is turned on, the electronic circuit will perform an auto-test to check whether the visual indicators (LEDs and panel) and audible alarms, except for the "Power Failure" alarm, are functioning properly.

The procedures below describe the alarm verification tests that can be visually accompanied by the user of the transport incubator, after starting up the equipment. For system alarms not listed below, consult an authorized service technician.



**Warning! When the SILENCE key, the alarm will be disabled for 15 minutes, after which it will return to normal mode.**

### 7.11.1 No Sensor Alarm

With the skin temperature sensor (patient sensor) connected to the incubator panel, select "Skin Mode" on the front panel. Disconnect the skin temperature sensor cable from the side panel. The audible and visual "No Sensor" alarm should immediately be triggered.

### 7.11.2 Sensor Dislodged Alarm

Select "Skin Mode" and set the temperature at 37°C. Insert the skin temperature sensor (patient sensor) inside the hood and once the system has stabilized open the access door and quickly press the metal part of the sensor with your index finger. The sensor will register a rapid temperature change and conclude that the sensor has been dislodged, triggering the respective alarm.

### 7.11.3 Air Sensor Failure Alarm

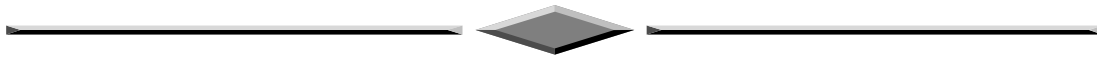
Select "Air Mode" and set the temperature at 36°C on the "Temperature Set Point" display. After the system stabilizes, disconnect the air temperature sensor cable from the mains. An audible and visual "Air Sensor - Failure" alarm should be activated. Note: Contact the service department of Fanem Ltda.

### 7.11.4 Air Circulation Alarm

Select "Air Mode" on the front panel of the incubator and set the temperature at 36°C on the "Temperature Set Point" display. Let the system stabilize for approximately 40 minutes. After stabilization, turn off / disconnect the motor of the incubator. Within 15 to 120 seconds, an audible and visual "Air Circulation" alarm should be activated. Note: Contact the service department of Fanem Ltda.



**Warning! When the incubator is switched on, this alarm will be disabled for 40 minutes, after which time it will move into active working mode.**



### **7.11.5     High Temperature Alarm**

#### **7.11.5.1     Skin Mode**

Note: This alarm is triggered by a +1°C difference in relation to the temperature set point.

Select "Skin Mode" and set the temperature at 36°C on the "Temperature Set Point" display. Insert the patient sensor inside the hood and once the system has stabilized, lower the previous temperature set point by 1°C on the "Temperature Set Point" display. The audible and visual "High Temperature" alarm should immediately be triggered.

#### **7.11.5.2     Air Mode**

Note: This alarm is triggered by a +1°C difference in relation to the temperature set point.

Select "Air Mode" and set the temperature at 36°C on the "Temperature Set Point" display. Once the system has stabilized, lower the previous temperature set point by 1°C on the "Temperature Set Point" display. The audible and visual "High Temperature" alarm should immediately be triggered.

### **7.11.6     Low Temperature Alarm**

#### **7.11.6.1     Skin Mode**

Note: This alarm is triggered by a -1°C difference in relation to the temperature set point.

Select "Skin Mode" and set the temperature at 36°C on the "Temperature Set Point" display. Insert the patient sensor inside the hood and once the system has stabilized, increase the previous temperature set point by 1°C on the "Temperature Set Point" display. The audible and visual "Low Temperature" alarm should immediately be triggered.

#### **7.11.6.2     Air Mode**

Note: This alarm is triggered by a -1°C difference in relation to the temperature set point.

Select "Air Mode" and set the temperature at 35°C on the "Temperature Set Point" display. Once the system has stabilized, increase the previous temperature set point by 1°C on the "Temperature Set Point" display. The audible and visual "Low Temperature" alarm should immediately be triggered.

### **7.11.7     Power Failure Alarm**

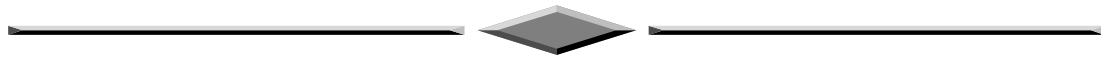
Remove the 10 A fuse of the batteries, located on the side panel of the incubator. Plug the power cord into a 100 V~ to 240 V~ socket. Wait for the system to stabilize and then unplug the power cord from the socket.

The audible and visual "Power Failure" alarm should immediately be triggered.

## 8. Troubleshooting

Failure	Cause	Solution
The incubator doesn't turn on.	Master switch in off position or discharged battery.	Turn on the master switch in the power module and press the "On" key in the front panel.
Air temperature does not increase.	Access door open.	Close the access doors.
	Power input is not properly connected.	Check the power supply voltage and voltage in the battery.
	Blocked air passage.	Unblock air circulation.
The AC mode LED indicator does not turn on.	Master switch in the off position.	Turn on the master switch in the power module and press the "On" key in the front panel.
	Fuse from the power module is burned out.	Change the fuse.
	Power cord not connected.	Check the power cord connection.
Low battery voltage alarm.	Discharged or damaged battery.	Turn on the incubator for 30 hours to ensure that the battery is fully charged or replace change the battery.
Panel with display and LEDs turned off.	Master switch turned off.	Turn on the switch in the lower panel.
	Burnt fuse.	Replace the fuses with others of the same rating as indicated on the lower panel.
Power Failure Alarm Triggered.	Burnt fuse.	Replace the fuses with others of the same rating as indicated on the lower panel.
	No power.	Check the mains voltage.
	Cord disconnected.	Connect the power cord.
Low Skin Temperature Alarm	Hatch open.	Properly close all the access doors.
	Skin sensor incorrectly attached to the newborn (Skin Mode).	Correctly reattach the sensor to the newborn.
No Ventilation.	No air circulation.	Check the fan unit or for an obstruction in the air inlet or outlet on the tray.
Low Oxygen Concentration.	Access doors open.	Close the doors.
	O <sub>2</sub> inlet tube with a leak.	Change the tube.
	Air filter not installed.	Install the air filter.
High Oxygen Concentration	Saturated air filter.	Change the air filter.

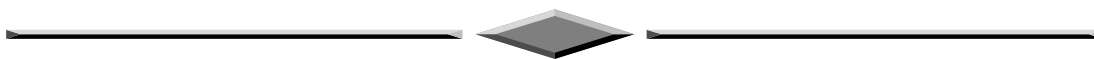




Failure	Cause	Solution
Display panel with incorrect and random indications, and improper functions.	Excess EMI in the hospital electricity grid.	Turn off the unit and turn it on again. If the problem continues, call an authorized service technician.
Oxygen analyzer does not correspond to the settings of the mixer.	Analyzer not calibrated.	Calibrate the oxygen analyzer.
	Mixer not calibrated.	Contact the Fanem service department.
	Supply of dirty gas.	Contact the Fanem service department.
	Air is flowing through a piece of the equipment being used and is diluting the concentration.	Correct the situation by stopping the air flow.
Mixer alarm is sounding.	Difference in pressures from the air and oxygen sources greater than 1.4 kgf/cm <sup>2</sup> (138 kPa).	Restore the pressure of the sources within the range of 1.4 kgf/cm <sup>2</sup> (138 kPa).
	Alarm system not calibrated.	Contact the Fanem service department.
	Dirty gas is contaminating the alarm system.	Contact the Fanem service department.
The mixer is only accurate when the pressures from the sources are exactly the same.	Pressure balance chamber is not functioning properly.	Contact the Fanem service department.



**Warning! If it is not possible to correct the malfunction, contact an authorized Fanem service technician.**



## 9. Warranty and Technical Assistance

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

For any type of maintenance, whether within or outside the warranty period, always contact an authorized Fanem Service Technician. Avoid using outsourced services, without appropriate technical training or authorization from Fanem Ltda, as this could result in damaging or altering the original features of your equipment.

Only use original Fanem parts.

ANVISA Registration No. 10.224.620.035

Technician in charge

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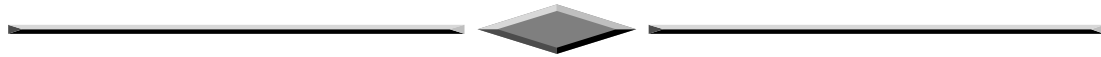
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Rua Arthur Carl Schmidt, 186

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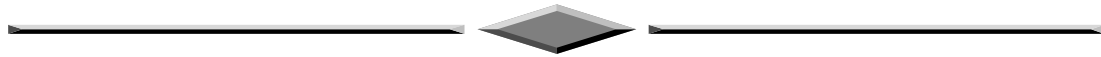
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