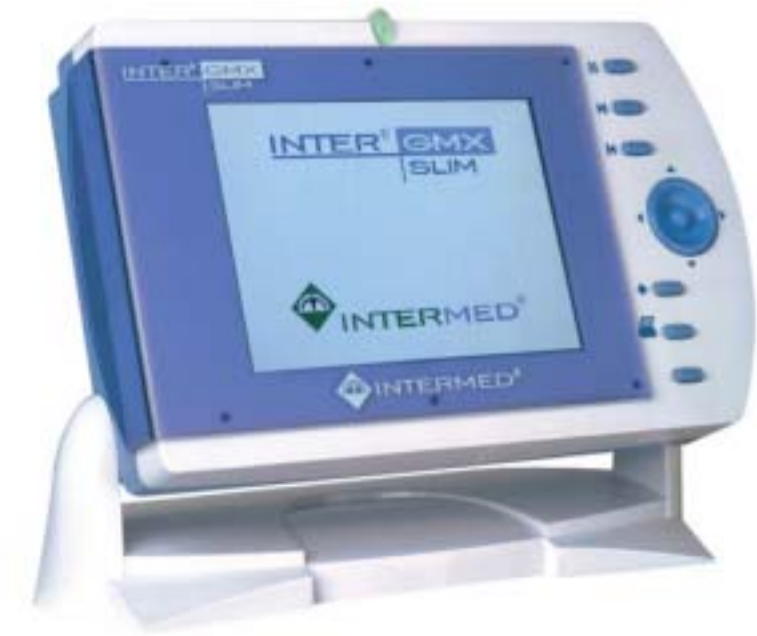
Operation Manual

INTERMED®
desde 1982



INTER® GMX
GRAPHICAL MONITOR

MOP Code 806.00223

Operation Manual

INTER® GMX
GRAPHICAL MONITOR

CAUTION:

Read this manual completely before using **Inter® GMX Slim** on patients.
This equipment can be changed without any previous notice to the user.

Foreword

This Operation Manual presents the information required for the correct utilization of Intermed® ventilation graphical monitor, model **Inter® GMX Slim**. Always use the Operation Manual as reference.

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ANVISA Product Registration:
Technical name: Ventilation Monitor
Business Name: Graphical Monitor **Inter® GMX Slim**
Registration Nr.: 10243240040

Product Classification:
CEE 93/42 - Medical Device - IIb rule 9
NBR IEC 60601-1:1994 and 1997 amendment;
NBR IEC 60601-1-2:2006; NBR IEC 60601-2-12:2004;
EN 60601-1:1990/A1:1993/A2:1995 and EN 60601-1-2:2001/A1:2004; EN 60601-2-12:2006;

Equipment Class I / Internally energized
Type B applied part - IP24 - Continuous Operation
Equipment not appropriate for utilization in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Technical Responsibility:
Eng. Jorge Bonassa
CREA 137.189/D

Legal Responsibility:
Milton Rubens Salles

Table of Contents

Chapter 1: Introduction

Always use the Operation Manual as reference

This Chapter Contains:

- Description

Description

- **Inter® GMX Slim** is a microprocessor-based graphical monitor, coupled and integrated to the **Inter® Plus** ventilation system ventilators for use on neonatal, pediatric and adult patients. It is recommended for the monitoring of the respiratory mechanics on patients under mechanical ventilation or breathing spontaneously. **Inter® GMX Slim** uses a high-contrast liquid crystal graphical display enabling excellent visualization both on monochromatic and colorful versions.

- **Inter® GMX Slim** measures the flow and pressure respiratory parameters by a pneumotachograph with fixed orifice.
  From the measured signals of flow and pressure, many other relevant parameters are calculated, including inspired and exhaled volumes, complacency, airways resistance, weaning rate, negative inspiratory pressure, among others.

- **Inter® GMX Slim** incorporates an automatic system to prevent water condensation within pneumotachograph tubes. A self-calibration routine is periodically performed to enable its continuous utilization.

- **Inter® GMX Slim** presents the graphical and digital monitoring of the ventilation parameters. Pressure, Flow and Volume Curves due to Time, Pressure vs. Volume, Flow vs. Volume and trend curves facilitate the ventilation monitoring and optimization.

- **Inter® GMX Slim** also presents an O_2 analyzer. Its operation depends on the ventilator controls and cell utilization, and on the optional O_2 sensor cable.

Chapter 2: Precautions and Notes

This Chapter Contains:

- Caution
- Warning
- Notes

Inter® GMX Slim shall be handled and operated by qualified and trained personnel, under the direct supervision of a licentiate physician.

You must READ THE OPERATION MANUAL COMPLETELY BEFORE using the **Inter® GMX Slim** on patients.

The use of this equipment before its characteristics and functions are fully understood may result in risk conditions to the operator, the patient and the equipment itself.

All paragraphs preceded by the following terms deserve special attention:

CAUTION: Indicates those conditions that may adversely affect the operator or the patient.

WARNING: Indicates those conditions that may affect and/or damage the equipment or its accessories.

NOTE: Indicates additional information for a better understanding of equipment operation.

CAUTION:

- Before the first utilization and after using on every patient, or more frequently if required, clean the monitor and sterilize the sensor, according to Chapter 7.
- DO NOT use the equipment in the presence of flammable anesthetic gases, because there is RISK OF EXPLOSION.
- ELECTRIC SHOCK HAZARD: do not disassemble the equipment cabinet. In case of doubts, call Intermed® or the Authorized Technical Service.
- For safety, the screws used for closing are SEALED OFF. Breaking this seals by unauthorized personnel may result in the equipment WARRANTY lost.
- The equipment must be perfectly coupled to a ventilator of **Inter® Plus** system.
- ALWAYS USE the equipment IN COMPLIANCE WITH THE SPECIFICATIONS included in the manual. In case of doubts, call Intermed® or the Authorized Technical Service.
- NEVER trust the equipment MAINTENANCE to NON-AUTHORIZED TECHNICAL PERSONNEL. Contact Intermed® or the Authorized Technical Service in case of any problem or difficulty.
- In case of replacement always use ORIGINAL ACCESSORIES, COMPONENTS AND PARTS, otherwise you can impair equipment performance, patient and operator's safety, and the warranty validity.
- When **Inter® GMX Slim** and the respiratory circuit are connected to the patient, a QUALIFIED PROFESSIONAL must be READY to take the required actions whenever an alarm or problem occurs. An ALARM indicates a situation that requires operator attention and SHALL NEVER BE IGNORED.

WARNING:

- Perform the FUNCTIONAL VERIFICATION TEST (FVT), specified in the Chapter 9 - Preventive Maintenance, BEFORE THE FIRST UTILIZATION and at least ONCE A MONTH, or always there are DOUBTS on the equipment operation. In case of problems during the FVT, stop the equipment utilization and request corrective maintenance by an authorized technician.
- Do not sterilize the **Inter® GMX Slim**. The internal components are not compatible with sterilization techniques.
- Follow correctly the instructions for cleaning and sterilizing the components.
- Sterilizing agents containing phenol, ammonium chloride, dimethyl and solutions with a glutaraldehyde concentration higher than 2% can damage the plastic components.
- **Inter® GMX Slim** maintenance must be performed only by Intermed® or the Authorized Technical Service.

NOTES:

- The circuit diagrams, component lists, technical descriptions, adjustment and calibration instructions and other required information for the equipment maintenance can be supplied to the customer upon request.
- **Inter® GMX Slim** is a medical equipment that must be used by specialized personnel under the direct supervision of a physician.
- The use of **Inter® GMX Slim** in **Inter® 3 Plus** and **Inter® 5 Plus** models require optional up grade in this equipment. For further information please contact Intermed® 0800 770 3357.

Chapter 3: Controls and Indicators

Always use the Operation Manual as reference

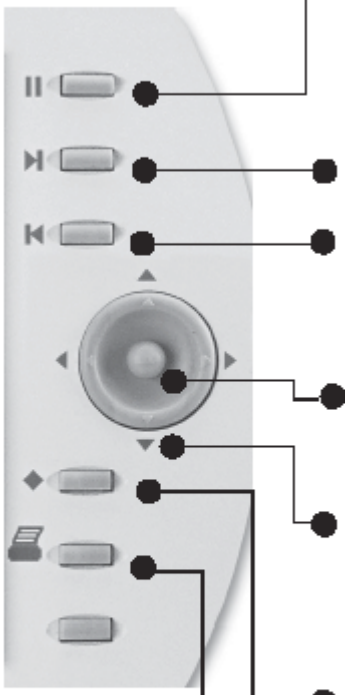
This Chapter Contains:

- Front Panel
- Controls
- Graphical Display
- ON/OFF Indicator - Power-ON/Power-OFF

FRONT PANEL

Figure 3.1 . **Inter® GMX Slim** Front Panel

CONTROLS



FREEZE / STAND BY
This key enables *freezing* (stop) the graphic drawing. If it is momentarily pressed (a single touch), the drawing will remain frozen. Press it again to return the graphic monitoring.

SCREEN SCROLL FORWARD

SCREEN SCROLL BACKWARD
These keys enable selecting the monitoring screens available in the **Inter® GMX Slim**.

CONFIRM
This key enables confirming the option or adjustment selected.

POSITION
These keys control the up, down, left and right cursor movement, in order to adjust the monitoring screen.

MENU
This key accesses the selection menu (task bar). When the menu is accessed, the movement across the various options must be made by the position keys.

PRINT *(not applicable for the Inter ® GMX Slim model)*
This key enables printing the selected screen.

GRAPHICAL DISPLAY

The **Inter® GMX Slim** graphical display presents the control and monitoring screens.

Type : Liquid Crystal Display of active matrix (**TFT**)
Visible area : 115 x 86 mm
Resolution : 320 x 240 points

ON/OFF INDICATOR - POWER-ON/POWER-OFF

In the center top of the **Inter® GMX Slim** graphical monitor front panel there is the indicator (green led) that will remain lit while the equipment is connected to a power supply.

Chapter 4: Assembly

The correct assembly of Inter® GMX Slim is essential for the perfect equipment operation.

This Chapter Contains:

- Connection of the flow sensors to an **Inter® Plus** system ventilator.

WARNING:

The assembly and the operation start-up of this equipment must be performed by an Intermed® qualified technician or by the Authorized Technical Service.

NOTE:

The correct operation of **Inter® GMX Slim** depends on the perfect connection of flow sensors in an **Inter® Plus** system ventilator.

FLOW SENSOR CONNECTIONS

Figure 4.1 - Detail of the flow sensors connection on the side panel of an **Inter® Plus** system ventilator.

Chapter 5: Operation

Follow correctly the instructions included in this manual to achieve the best equipment performance.

This Chapter Contains:

- Introduction
- Initial Screen
- Operation

INTRODUCTION

1. Clean the monitor and sterilize the sensor, according to Chapter 7.

2. Select the proper flow sensor - neonatal, pediatric or adult:

Sensor	**Patient**
Neonatal - Clearance 0.8mL	Flow: 0.2 to 9 L/min
Pediatric - Clearance 0.8mL	Flow: 2 to 24 L/min
Adult - Clearance 7mL	Flow: 6 to 120 L/min

3. Connect the sensor to an **Inter® Plus** system ventilator and to the "Y" connection of the patient circuit, according to Figures 4.3 or 4.5 contained in the Assembly Chapter of the Manual for this equipment.

4. Power-on the ventilator according to the instructions in the Operation Manual.

CAUTION:

- The equipment must be handled and operated by qualified and trained personnel under the direct supervision of a licentiate physician.
- The use of this equipment before its characteristics and functions are fully understood may result in risk conditions for the operator, the patient and the equipment itself.

INITIAL SCREEN

When the equipment is powered-on, the initial screen informs the software revision, the flow sensor connection condition and the type used, with the following information:

- ***DISCONNECTED SENSOR***
  Indicates that there is no sensor connected to the monitor.
- ***NEONATAL SENSOR CONNECTED***
  Indicates that the neonatal sensor is connected to an **Inter® Plus** system ventilator. In this case, the monitor assumes the calibration configurations and the neonatal range scale.
- ***PEDIATRIC SENSOR CONNECTED***
  Indicates that the pediatric sensor is connected to an **Inter® Plus** system ventilator. In this case, the monitor assumes the calibration configurations and the pediatric range scale.
- ***ADULT SENSOR CONNECTED***
  Indicates that the adult sensor is connected to an **Inter® Plus** system ventilator. In this case, the monitor assumes the calibration configurations and the adult range scale (not applicable to **Inter® 3 Plus/NEO** ventilators).
- ***TRANSMISSION OFF***
  Indicates that there is no signal between the **Inter® GMX Slim** ventilator and monitor. Contact Intermed® or the authorized technical service.

If the sensor is connected, the monitor will leave the initial screen after 5 seconds and will start the Cleaning and Auto Zero resources.

NOTE:

After exhibiting the initial screen, the equipment presents the last screen displayed before it has been powered-off.

CLEANING

At every 5 minutes the equipment eliminates eventual liquids existing within both sensor measurement duct paths.

CAUTION:

Perform the cleaning of the sensor duct when there are solid residues inside it, in order to prevent that the sensor accuracy is affected.

AUTO ZERO

At every 5 minutes the equipment repositions the flow zero indication in order to assure the accuracy during the monitoring period.

NOTE:

During the Cleaning and Auto Zero routine (25 seconds), an interval in the monitoring occurs.

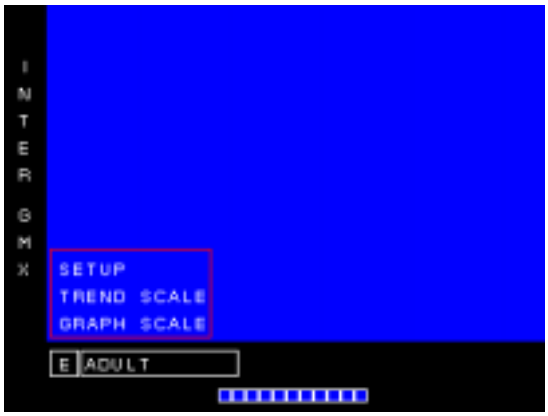
OPERATION

Respiratory parameter screen

Parameter Screen

Press *FORWARD or BACKWARD* keys to display the parameter change screen.

This screen displays all information related to the patient in terms of the respiratory mechanics, as well as the indication of the oxygen alarm cause (low or high concentration).

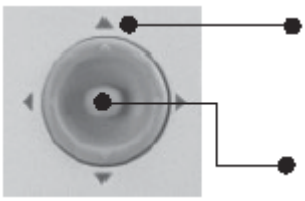


Menu Screen

Press the *MENU* key to start the access to the controls and screens available in the **Inter® GMX Slim**.

The menu screen presents the available control functions:

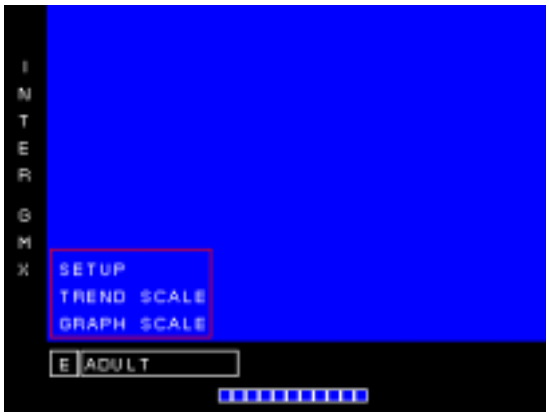
FUNCTION	DESCRIPTION
SET UP	Enables configuring date and time, the digital visualization of the flow and pressure for calibration purposes, the patient data and data cleaning.
TREND SCALE	Enables configuring the trend graphical scales.
GRAPH SCALE	Enables configuring the pressure, flow, volume and time scales, and the loop of graphics displayed on the screens.



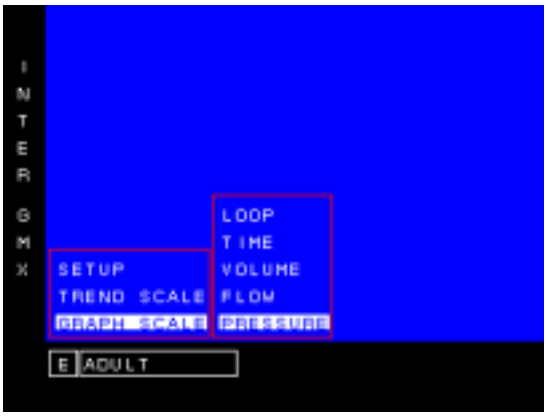
Press the direction keys to access each command.

Press the center key in the command area (*CONFIRM*) to select the commands.

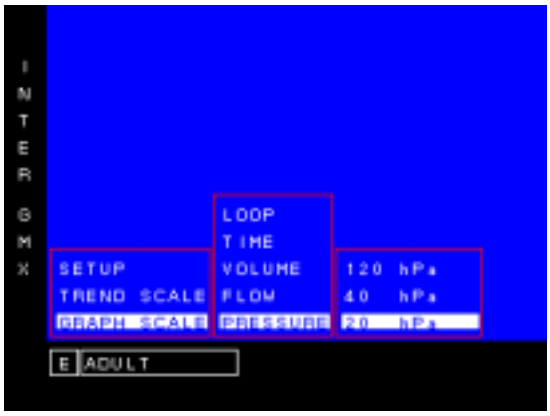
CONFIGURING GRAPHICAL SCALES



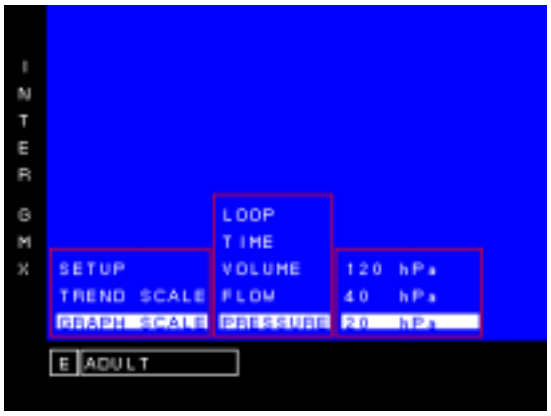
1. Press the *MENU* key to activate the function.



2. Press the direction key ▶ to to open the scale options: PRESSURE, FLOW, VOLUME, TIME or LOOP.



3. Press the direction key ▲ to select the scale: 20, 40 or 120 hPa.



4. Press CONFIRM key to validate the selected scale.

5. Adjust the other scales following the steps above for every function of item 2, using the direction keys ◀ and/or ▲ in order to select, and ▶ when selected.

LOOP SCALE SCREEN:

This screen enables to select the loop scale, defining the period after which the loop is updated. It can be at every:

- 1 cycle
- 2 cycles
- 4 cycles

Select the desired scale and press *CONFIRM* key.
In order to view the graphic screen, press *FORWARD* or *BACKWARD* keys until this screen appears*:*

TIME SCALE SCREEN:

This screen enables to select the time scale, defining the window scanning period that can be:
- 5 sec
- 10 sec
- 20 sec

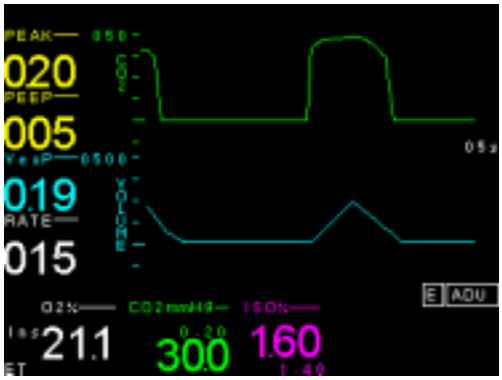
This configuration is applicable to Pressure vs. Flow and Pressure vs. Volume graphics. As lower the scanning time is, greater the graphic reading resolution will be.

VOLUME SCREEN:

This screen enables to select the proper volume scale in order to assure a better graphic visualization. The values depend on the sensor used:

Neonatal Sensor:	Pediatric Sensor:	Adult Sensor:
- 20 mL	- 100 mL	- 500 mL
- 40 mL	- 200 mL	- 1000 mL
- 80 mL	- 500 mL	- 2000 mL

Select the desired scale and press the *CONFIRM* key.



Pressure vs. Volume graphic screen

In order to view the graphic screen, press *FORWARD* or *BACKWARD* keys until the presented screen appears*:*

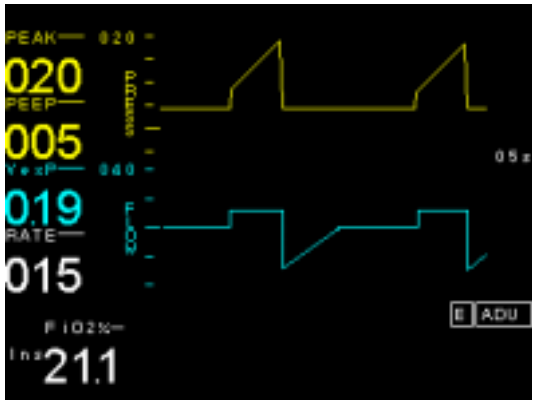
FLOW SCALE SCREEN:

This screen enables to select the most suitable flow scale, in order to assure a better graphic visualization. The values depend on the sensor used.

Neonatal Sensor:	Pediatric Sensor:	Adult Sensor:
- 3 L/min	- 8 L/min	- 40 L/min
- 6 L/min	- 16 L/min	- 80 L/min
- 9 L/min	- 24 L/min	- 120 L/min

Select the desired scale and press the *CONFIRM* key.

In order to view the graphic screen, press *FORWARD* or *BACKWARD* keys until the screen aside appears*:*



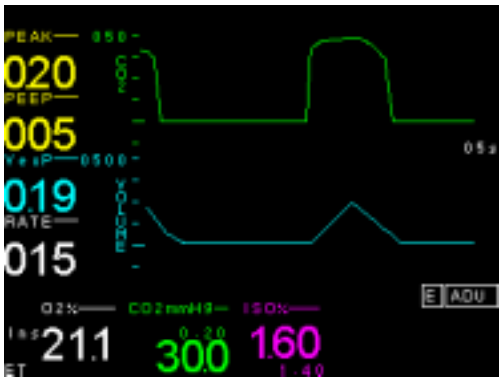
Pressure vs. Flow graphic screen

PRESSURE SCALE SCREEN:

This screen enables to select the most suitable pressure scale, in order to assure a better graphic visualization:

- 20 hPa, 40 hPa or 120 hPa
Select the desired scale and press the *CONFIRM* key.

In order to view the graphic screen, press *FORWARD* or *BACKWARD* keys until the screen aside appears:



Pressure vs. Volume graphic screen

CONFIGURING TREND GRAPHICAL SCALES

ZOOM Feature:

The trend graphs may be presented in scales from 15 minutes, 1, 2, 4, 8, 12 up to 24 hours, by using the ZOOM function. If the gathered data is not erased it remains in system memory for 24 hours.

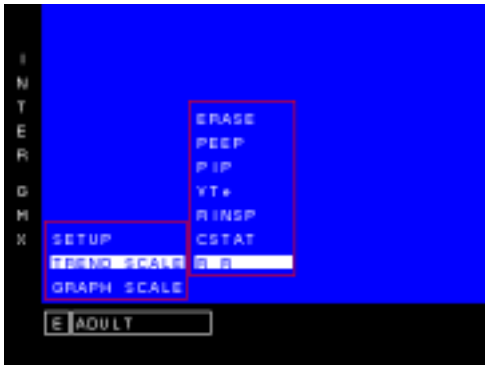
Open the trend graph by moving the ◀ or ▶ directional keys.

Use the ▲ or ▼ keys to open or close the time window of the trend graph intended.

1. Press the MENU key on the control panel to activate the functions.

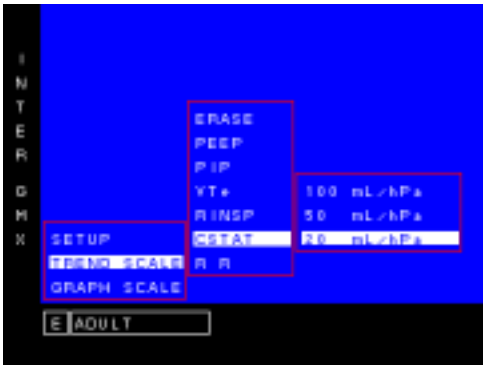
2. Press the directional key ▲ to select the TREND SCALE function.

3. Press the direction key ▶ to open the scale options menu: *ERASE, PEEP, PIP, VTe, RINSP, CSTAT or RR*



4. Press the directional key ▲ to select the parameter to be configured.

5. Press the CONFIRM key to confirm the selected scale.



6. Adjust the other scales, following the steps above for every function of item 2, using the direction keys ◀ and/or ▲ in order to select, and ▶ when selected.

PEEP (Positive End-Expiratory Pressure)

The PEEP function enables adjusting the expiratory pressure scale visualization mode in 10, 20 or 50 hPa.

PIP (Positive Inspiratory Pressure)

The PIP function enables adjusting the inspiratory pressure scale visualization mode in 20, 40 or 120 hPa.

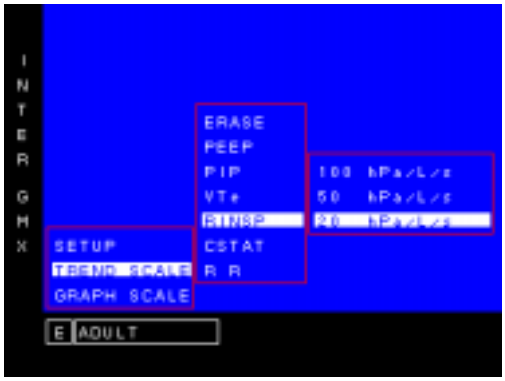
VTe (Total Expiratory Volume)

The VTe function enables adjusting the Total Expiratory Volume scale visualization mode according to the sensor used:

Neonatal Sensor:	Pediatric Sensor:	Adult Sensor:
- 80 mL	- 500 mL	- 2000 mL
- 40 mL	- 200 mL	- 1000 mL
- 20 mL	- 100 mL	- 500 mL

RISNP (Inspiratory Resistance)

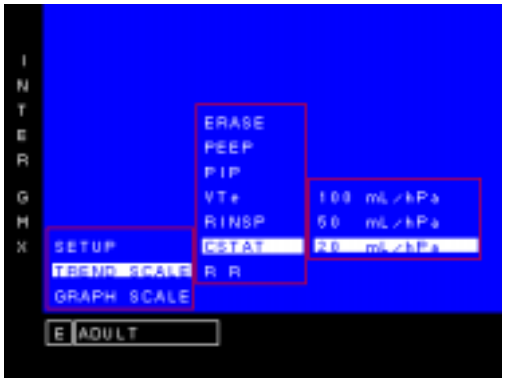
The RISNP function enables adjusting the inspiratory resistance scale visualization mode according to the sensor used:



Neonatal Sensor:	Pediatric Sensor:	Adult Sensor:
- 200 hPa/L/s	- 200 hPa/L/s	- 100 hPa/L/s
- 100 hPa/L/s	- 100 hPa/L/s	- 50 hPa/L/s
- 50 hPa/L/s	- 50 hPa/L/s	- 20 hPa/L/s

CSTAT (Static Compliance)

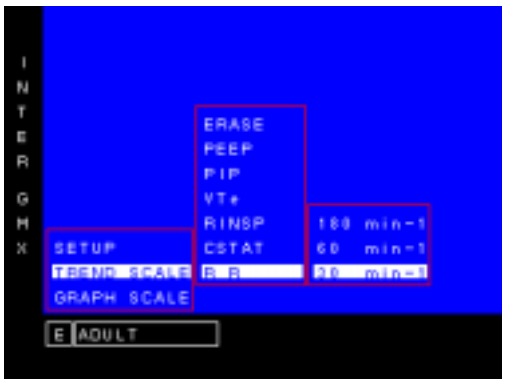
The CSTAT function enables adjusting the static compliance scale visualization mode according to the sensor used:

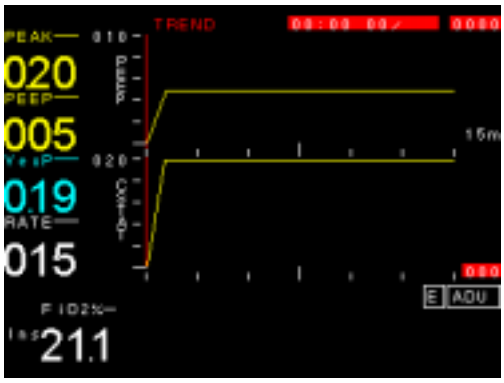


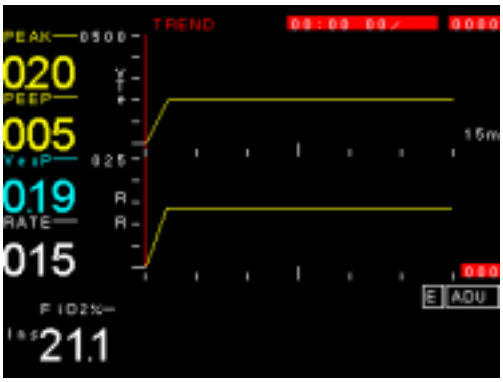
Neonatal Sensor:	Pediatric Sensor:	Adult Sensor:
- 5 mL/hPa	- 5 mL/hPa	- 20 mL/hPa
- 10 mL/hPa	- 10 mL/hPa	- 50 mL/hPa
- 20 mL/hPa	- 20 mL/hPa	- 100 mL/hPa

RR (Respiratory Rate)

The RR function enables adjusting the respiratory rate scale visualization mode in 30, 60 or 180 min^{-1}.



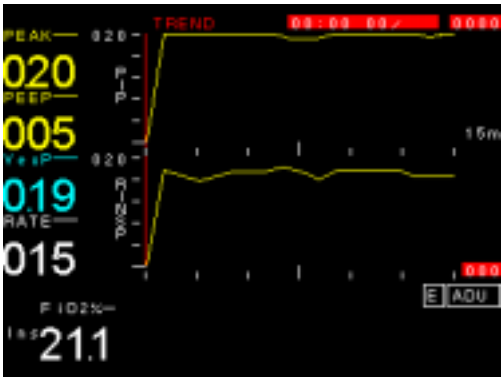




To view the trend screens, press the page FORWARD or BACKWARD keys until the following screens are displayed:

PEEP and CSTAT trend screen

VTe and RR trend screen



PIP and RINSP trend screen

CONFIGURING DATE AND TIME

1. Press the MENU key and use the direction key ▲ to select the SET UP option.
2. Press the direction key ▶ to access the SET TIME option in order to configure date and time, and open the configuration window.
3. Adjust each field (year, month, day, hour and minutes) using the direction key ▲.
4. Press the CONFIRM key to change field and to return to the previous menu.

The time can be configured in the formats:
- 12-hour (AM/PM)
- 24-hour (default)

Move the cursors ◀ and ▶ to select each field.
Move the cursors ▲ and ▼ to change them.

NOTE:

Keeping the ▲ or ▼ keys pressed, the values are changed more quickly.

The date can be configured in the formats:

month in the numeric format (01 to 12) (default).
months abbreviated in English:

JAN	- January
FEB	- February
MAR	- March
APR	- April
MAY	- May
JUN	- June
JUL	- July
AUG	- August
SEP	- September
OCT	- October
NOV	- November
DEC	- December

The exhibition order can be presented in the following options:

- mm/dd/yyyy
- dd/mm/yyyy

Where:
dd : day (2 digits)
mm : month (2 digits)
yyyy : year (4 digits)

To leave the configuration screen press the *MENU* key, or the *FORWARD* or *BACKWARD* keys.

CONFIGURING PATIENT DATA

1. Press the MENU key on the control panel to activate the menu on the monitor screen.

2. Press the directional key ▲ to select the SET UP option.

3. Press the direction keys ▶ and ▲ to select the PATIENT option (patient data configuration).

4. Open the data entry screen with the direction key ▶.

To enter data in the fields, select the characters to compose words or numbers using the direction keys, and confirm their entry with the CONFIRM key.

- NAME - up to 25 characters;
- AGE - up to 03 characters;
- SEX - M (male) or F (female) with the directional keys;
- WEIGHT - up to 03 characters.

Special characters:
- &: spaces between words in the same field
- <: backward movement to any field
- >: forward movement to any field
- *: Reset (clears all information. Confirm the option with the CONFIRM key).

NOTE:

Keeping the ▲and ▼ keys pressed, the values are changed more quickly.

Press the CONFIRM key to go to the next field.

Press the MENU key to return to main menu.

CONFIGURING THE O_2 ANALYZER

The **Inter® GMX Slim** presents an O_2 analyzer. This operation is made together with the ventilator controls and will only be performed when using the O_2 Cell (optional).

NOTE:

- For the perfect operation of this mode, install the O_2 Cell and proceed according to the Operation, Assembly and Calibration instructions described in this section.
- In order to operate correctly, the ventilator blender must be fed by one 100%-oxygen gas supply and one 21%-oxygen medical air supply.

INSTALLATION OF O_2 Cell

Install the O_2 Cell according to the drawing below:

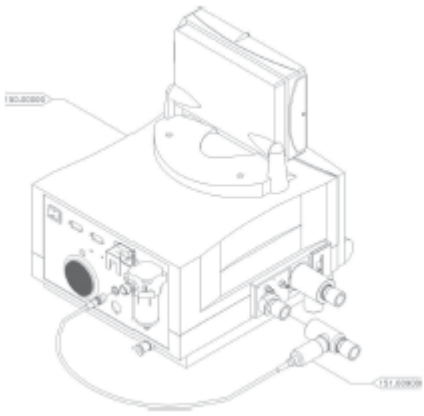


Figure 5.1 - Fitting diagram of O_2 Cell

1) Connect the cable terminal in the O_2 Cell entry located in the ventilator rear panel.
2) Connect the O_2 Cell in the ventilator side panel, fitting the female side in the Inspiratory branch output, before connecting the Insp. tube of the patient circuit.
3) Fit the Insp. tube of the patient circuit in the male side of the O_2 Cell.

PREPARATION FOR O_2 ANALYZER USE

NOTE:

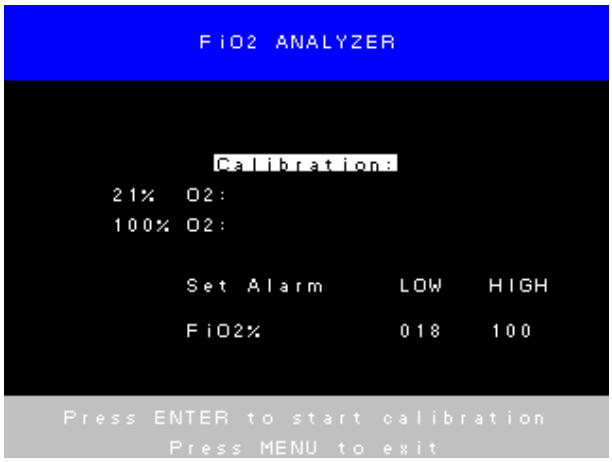
Keep the circuit disconnected from the patient.

1. Connect the O_2 Cell cable in the ventilator, according to previous description.
2. Make sure that the gas supplies are connected and under the working pressures described in the ventilator's Operation Manual.
3. Obstruct the patient circuit "Y".
4. Power-on the ventilator with the **Inter® GMX Slim** connected, and set the following parameters in the commands:

Mode	: Time Cycle A/C
Sensitivity by pressure	: (Exp. Flow: - -)
Insp. Time	: 1.00 sec
Flow	: 30 L/min
Resp. Rate	: 30 min^{-1}
P Limit	: 20 hPa (cmH_2O)

5. The ventilator starts to cycle.

CELL CALIBRATION



1. In the **Inter® GMX Slim** graphical monitor, press the MENU key and select the SET UP mode using the direction key ▲.

2. Use the direction keys ▶ and ▲ until select O_2 ANALYZER.

3. Use the direction key ▶ to access the calibration and adjustment screen.

4. Check the “PRESS ENTER TO START CALIBRATION” message in the information frame.

5. Press the CONFIRM key to start the calibration.

6. Adjust 21% in the ventilator blender and press the CONFIRM key. Wait until the end of the visualization bar course in the monitor. This time will be of approximately 1 min and 30 sec, after which the “OK” message will be displayed.

7. Now, adjust 100% in the ventilator blender and repeat the operation. The calibration is done.

NOTE:

The following failure conditions may occur during the calibration:

ERROR	Error occurrence due to wearing or O_2 Cell defect.
CELL Disconnected	Operation not feasible due to O_2 Cell disconnection.
ABORT	When you press MENU the calibration operation is aborted. In this case, the calibration will be kept with the data of the last calibration performed or the factory default.

CONFIGURING O_2 ANALYZER ALARMS

1. Still in the calibration screen, select the SET ALARM function using the direction keys ◀ or ▶.
In the monitor central command, adjust the LOW (low saturation) and HIGH (high saturation) alarms.

2. Once the alarm is chosen, use the direction keys ▲ or ▼ to select the alarm value for LOW and HIGH, according to the scale:

LOW: from 18 to 99%-concentration
HIGH: from 19% to OFF

3. Press the MENU key in the monitor command to finish.

NOTE:

- The O_2 analyzer alarm is presented by a visual indication $ in the monitor graphical display and by an audible signal in the ventilator.
  - medium priority signal: from 18% to 100% O_2 concentration
  - high priority signal: O_2 concentration equal or less than 18%
- To silence an alarm caused by the O_2 analyzer, press SILENCE/RESET in the ventilator.

MESSAGES AREA

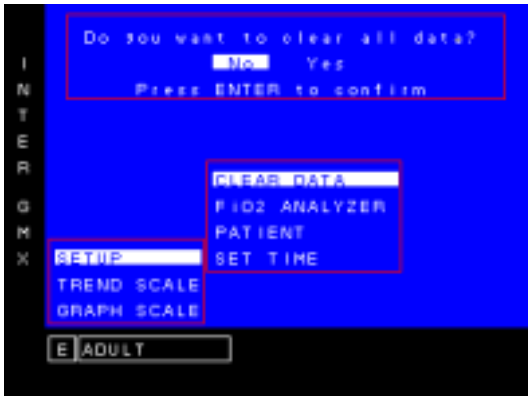
During the alarms calibration and configuration processes, the following information can be displayed in the message area:

OK	Indicates correct calibration
ERROR	Calibration out of the defined parameter
ABORT	Calibration aborted
MUST BE BELOW HIGH ALARM	Indicates that the minimum O_2 % alarm cannot be equal or greater than the maximum O_2 % alarm
MUST BE ABOVE LOW ALARM	Indicates that the minimum O_2 % alarm cannot be equal or greater than the minimum O_2 % alarm
Cell disconnected	Indicates that the O_2 cell is not connected

MONITORING O_2

The O_2 monitoring is displayed in the parameter screen of the Inter® GMX Slim graphical monitor.
The set alarms are indicated by the symbol in the lower right corner of the working screens. When an alarm is triggered, the letters “L” (LOW) or “H” (HIGH) will flash in the left side of the O_2 value, and an audible alarm in the ventilator will be activated until it is disabled by the SILENCE/RESET key in the ventilator.
When the alarm is silenced, the symbol will appear and the letters “L” (LOW) or “H” (HIGH) will stop flashing when the alarm cause is removed.
Press SILENCE/RESET in the ventilator to erase the signal.

ERASING DATA IN MEMORY



1.Press the MENU key on the control panel to activate the menu on the monitor screen.

2. To erase the data stored in the memory as patient data and TREND, select the CLEAR DATA option using the direction key ▲, and press CONFIRM.

3. Then, the “DELETE DATA? YES / NO?” confirmation request will appear. With the direction key ▶ select:
- “YES” to erase data
- “NO” to return to the main menu without erasing data.

4. When the YES option is pressed, the monitor will present the respiratory parameters monitoring screen with the default configuration.

NOTE:

The time and date data are not affected, but they return to the default exhibition format (24-hour time format, and date in the numeric format dd/mm/yyyy).

Chapter 6: Troubleshooting

Some problems can be solved by the user.

This Chapter Contains:

- Troubleshooting array

WARNING:

Whenever a problem cannot be solved by the operator, stop using the equipment and contact Intermed® 0800 770 3357.

PROBLEM	PROBABLE CAUSE	CORRECTIVE ACTION
The screen displays the message "TRANSMISSION OFF"	1. Monitor disconnected of the ventilator. 2. Electronic failure.	1. Check the connection fitting. 2. Contact the Authorized Technical Service.
The screen displays the message "DISCONNECTED SENSOR"	1. Misconnected or disconnected flow sensor in the ventilator.	1.Connect the appropiate flow sensor in the ventilator.
Monitor does not update therespiratory parameters; Monitor does not displayflow and/or pressurecurves; Monitor displaysflow and/or pressurecurves distortedand/or attenuated.	1. Flow sensor disconnected from the patient circuit. 2. Leakage in patient's circuit. 3. Leakage in the flow sensor connection. 4. Flow sensor tube blocked; secretion accumulation on the flow sensor or within the sensor tube. 5. Defective flow sensor. 6. Electronic problem.	1. Connect the sensor in the patient's circuit. 2. Remove the circuit leakage. 3. Reconnect the sensor in the monitor, replace the sensor. 4. Remove the blocking and/or clean the flow sensor tube. 5. Replace the flow sensor. 6. Stop using the equipment and contact the Authorized Technical Service.
The indicated values of flow and/or curves exceeded the scale limits.	1. Improper selection of the neonatal/pediatric flow sensor. 2. Secretion accumulation on the sensor.	1. Replace the sensor for the pediatric/ adult model. 2. Clean the flow sensor.

PROBLEM	PROBABLE CAUSE	CORRECTIVE ACTION
Exhaled volume less than the inspired volume.	1. Endotracheal tube leakage. 2. Water and/or secretion accumulation on the flow sensor and/or within the sensor tube. 3.Miscalibrated flow sensor. 4. Defective self-cleaning system. 5. Miscalibrated monitor.	1. Remove leakages. 2. Clean the flow sensor and/or the sensor tube. 3. Replace the flow sensor. 4. Contact Intermed® or the Authorized Technical Service. 5. Contact Intermed® or the Authorized Technical Service.
The pressure and/or flow curves present noises.	1. Water and/or secretion accumulation within the patient's circuit. 2. Secretion accumulation within the endotracheal tube.	1.Remove the water from the circuit; clean secretions. 2. Aspirate the secretions from the endotracheal tube.
Expiratory Flow Volume and Peak flashing. Inspiratory Flow Volume and Peak flashing.	1. Flow limit exceeded (e.g., using the neonatal/pediatric sensor).	1. Reduce the work flow. 2. Replace the neonatal/ pediatric sensor by the pediatric/ adult sensor.
Fail Calibration	1. Calibration out of the± 10 % range.	1.Contact Intermed® or the Authorized Technical Service.

Chapter 7: Cleaning and Sterilization

The components durability and the patient safety depend on the proper cleaning and sterilization.

This Chapter Contains:

- Monitor
- Flow sensor
- Oxygen Cell

WARNING:

- Before using the equipment for the first time and after its use on every patient, or more frequently when required, clean the equipment and sterilize the flow sensor.
- After the sterilization, rinse and dry properly the flow sensor in order to eliminate any residual chemical substances.

INTER® GMX SLIM MONITOR

Cleaning and disinfection of the monitor outer parts, except for the control panel, may be done with an appropriate germicidal or bactericidal agent.

The control panel may be cleaned with a gauze humidified with 70% Isopropyl Alcohol.

WARNING:

- **NEVER** sterilize the monitor.
- **NEVER** place the monitor in a liquid solution.
- **NEVER** use abrasives on the monitor surface.
- **NEVER** allow liquid to enter inside the monitor.
- **NEVER** use alcohol for the rear panel cleaning, because the lettering can be damaged.

THE *DISINFECTION* is a process capable of destroying pathogenic microorganisms, ***BUT IT CANNOT*** destroy the spores. The spores are only destroyed by ***STERILIZATION***.

OXYGEN CELL

WARNING:

- Use **ONLY** a clean and dry rag for the oxygen cell cleaning.
- **NEVER** use any substance for the cell cleaning, because it can be damaged.

FLOW SENSOR

Material	Processes
Neonatal Sensor - code 136.00347 (Silicone/Polycarbonate)	L, D, EQ, ETO
Pediatric Sensor - code 136.00311 (Silicone/Polycarbonate)	L, D, EQ, ETO
Adult Sensor - code 136.00310 (Silicone/Polycarbonate)	L, D, EQ, ETO

Caption:

L: Washing
D: Chemical Disinfection by Immersion
EQ: Chemical Sterilization by Immersion
ETO: Ethylene Oxide

WASHING

BEFORE performing any disinfection or sterilization process, washing by immersion should be carried out in a neutral solution with enzymatic detergent, at a temperature between 35°C and 65°C, for approximately 10 minutes. Rinse with distilled or filtered water to eliminate the high concentrations of chemical substances used. Leave to dry in a clean environment before proceeding with the disinfection or sterilization.

WARNING:

DO NOT USE	
Phenol (>5%)	Chlorinated Hydrocarbons
Ketones	Aromatic Hydrocarbons
Formaldehyde	Inorganic Acids
Hypochlorite	Ammonium Quaternary Compounds

These solutions may cause cracks on polysulfone components or disintegration of silicone tubes. Do not use these solutions in washing processes that precede sterilization in autoclave and pasteurization, since they can accelerate materials deterioration.

CHEMICAL DISINFECTION BY IMMERSION

Chemical disinfection by immersion can be performed using a 2% Glutaraldehyde solution (Cidex®) for a period of **40 MINUTES**. Rinse with distilled and sterilized water to eliminate the high concentrations of chemical substances used. Let it dry in a clean environment.

CHEMICAL STERILIZATION BY IMMERSION

Chemical sterilization by immersion can be performed using a 2% Glutaraldehyde solution (Cidex®) for a period of **12 HOURS**. Rinse with distilled and sterilized water to eliminate the high concentrations of chemical substances used. Let it dry in a clean environment.

ETO - ETHYLENE OXIDE (C_2H_4O)

The sterilization using Ethylene Oxide gas must comply with EN ISO 11135-1:2007 standard.

WARNING:

- After sterilizing in Ethylene Oxide, await from 24 to 48 hours before using the material, in order to enable aeration and exit of gas residues.

NOTE:

- Components submitted to sterilization suffer natural degradation due to the characteristics of the processes used. The sensor lifetime will depend on the care in its utilization and handling.
- Do not use sensors that have damage or deterioration signals.

Chapter 8: Accessories and Parts

Always use original accessories and parts.

This Chapter Contains:

- Accessories, Components and Parts.

CAUTION:

- In case of replacement always use ORIGINAL ACCESSORIES AND PARTS, otherwise you can impair the equipment performance, patient and/or user's safety, and warranty validity.

Accessories and Parts

The accessories and parts of Inter® Plus model ventilators used with the Inter® GMX Slim graphical monitor are listed below:

Code	Description
151.00000	**Inter GMX Slim Graphical Monitor**
	Optional Accesories
151.00900	O_2 sensor cable and oxygen cell
	Optional Accesories (ventilator)
136.00347	Neonatal Flow Sensor
136.00311	Pediatric Flow Sensor
136.00310	Adult Flow Sensor

NOTE:

- The accessories required for the Inter® GMX Slim operation are connected to the ventilator.

Chapter 9: Preventive Maintenance

Always use original accessories and parts.

This Chapter Contains:

- Functional Verification Test - FVT
- Routine Preventive Maintenance
- Annual Preventive Maintenance - APM

WARNING:

In order to prevent premature equipment wear and to achieve a safe performance within the required specifications, the following should be made:

- Routine Preventive Maintenance

It must be carried out DAILY or before each use, according to this chapter instructions.

- Functional Verification Test - FVT

It must be performed at least MONTHLY, or in case of doubts on the equipment operation.

- Annual Preventive Maintenance - APM

Request the equipment checking, adjustment and calibration ANNUALLY, performed by Intermed ® or by Authorized Service.

FUNCTIONAL VERIFICATION TEST - *FVT*

The FVT is a test that enables to verify if the equipment is operating in accordance with specifications.

The FVT must be performed by the operator at least once a month, or in case of doubts on the ventilator operation.

When detecting problems during the FVT, the equipment must be removed for corrective maintenance. Contact Intermed® 0800 770 3357.

The O_2 analyzer calibration must be done at every patient change, and must follow the conditions established in Chapter 5: Operation.

CAUTION

- The equipment must be DISCONNECTED FROM THE PATIENT for FCT conduction.
- The equipment that is not operating IN ACCORDANCE TO THE SPECIFICATIONS CONTAINED IN THE MANUAL SHOULD NOT BE USED. Contact Intermed® 0800 770 3357.
- NEVER TRUST the equipment maintenance to NON-AUTHORIZED PERSONNEL. Contact Intermed® 0800 770 3357 in case of any problem or difficulty.

REQUIRED EQUIPMENT

For the FVT conduction, the following equipment are required:

- Intermed® ventilator model Inter® Plus.
- Intermed® Lung Simulator model LS2000 or similar.

WARNING:

In order to assure the accuracy of the measures taken, it is required that the ventilator used is calibrated by traceable measurement equipment, under metrological standards worldwide recognized, and in compliance with the requirements of the ISO 9001:2008 Quality system rules. In case of doubts, please contact Intermed® 0800 770 3357.

INITIAL CONDITIONS

1. The **Inter® GMX Slim** graphical monitor and the ventilator must be properly assembled, according to Chapter 4;

2. The monitor and the ventilator must be disconnected from the patient;

3. Assemble the patient circuit in the ventilator.

4. Connect the ventilator to the power mains under the proper voltage, and to the grounding system for protection.

5. Connect the ventilator to the proper pneumatic pipeline (Air and oxygen pressure at 350 kPa).

TESTS SEQUENCE - NEONATAL SENSOR

1. Connect the neonatal sensor to the ventilator and to the patient's circuit (between the lung simulator and the circuit's Y connection), according to Chapter 4.

2. Power-on the ventilator. Check if the sensor ID on the **Inter® GMX Slim** initial screen is correct: *NEONATAL SENSOR CONNECTED*. Access the monitoring screen.

3. Adjust the simulator to 50 hPa (cmH_2O)/L/s of resistance and 20mL/ hPa (cmH_2O) of compliance. Adjust the following ventilator parameters:

Mode	: Controlled Time
Cycle	: Assisted/Controlled
Inspiratory Flow	: 6 L/min
Expiratory Flow	: 2 L/min
Inspiratory Time	: 1.00 sec
Respiratory Rate	: 30 min^{-1}
Resulting I:E Ratio	: 1:2
PEEP	: 0 hPa (cmH_2O)
Inspiratory Pressure (threshold)	: 80 hPa (cmH_2O) (maximum)

4. Check on the **Inter® GMX Slim** monitor if the indicated values for Inspiratory Pressure *Peak*, *PEEP*, Airways Average Pressure *MEAN*, Inspiratory Flow Peak *Pif,* Respiratory Rate *RATE*, Inspiratory Time *Tinsp*, and I:E Ratio (*I:E RATIO)* are in compliance with the values programmed and indicated in the ventilator.

5. Check if the values for *Vol insp* and *Vol exp* displayed on the **Inter® GMX Slim** monitor are 100ml ± 10ml.

6. Check if the pressure, flow and volume curves are compatible with the ventilation parameters and the ventilation mode selected in the ventilator.

7. Adjust the alarm thresholds compatible with the parameters adjusted in the ventilator. Change the parameters adjusted in the ventilator in order to generate alarm conditions, checking their actuation in the monitor.

TESTS SEQUENCE - PEDIATRIC SENSOR

1. Connect the pediatric sensor to the ventilator and to the patient's circuit (between the lung simulator and the circuit's Y connection), according to Chapter 4.

2. Power-on the ventilator. Check if the sensor ID on the **Inter® GMX Slim** initial screen is correct: *PEDIATRIC SENSOR CONNECTED*. Access the monitoring screen.

3. Adjust the simulator to 50 hPa (cmH_2O)/L/s of resistance and 20mL/cmH_2O of compliance. Adjust the following ventilator parameters:

Mode	: Controlled Time
Cycle	: Assisted/Controlled
Inspiratory Flow	: 15 L/min
Expiratory Flow	: 5 L/min
Inspiratory Time	: 1.00 sec
Respiratory Rate	: 20 min^{-1}
Resulting I:E Ratio	: 1:2
PEEP	: 5 hPa (cmH_2O)
Inspiratory Pressure (threshold)	: 120 hPa (cmH_2O) (maximum)

4. Check on the **Inter® GMX Slim** monitor if the indicated values for Inspiratory Pressure *Peak*, *PEEP*, Airways Average Pressure *MEAN*, Inspiratory Flow Peak *Pif,* Respiratory Rate *RATE*, Inspiratory Time *Tinsp*, and I:E Ratio (*I:E RATIO)* are in compliance with the values programmed and indicated in the ventilator.

5. Check if the values for *Vol insp* and *Vol exp* displayed on the **Inter® GMX Slim** monitor are 250mL ± 25mL.

6. Check if the pressure, flow and volume curves are compatible with the ventilation parameters and the ventilation mode selected in the ventilator.

7. Adjust the alarm thresholds compatible with the parameters adjusted in the ventilator. Change the parameters adjusted in the ventilator in order to generate alarm conditions, checking their actuation in the monitor.

TEST SEQUENCE - ADULT SENSOR

1. Connect the adult sensor to the ventilator and to the patient's circuit (between the lung simulator and the circuit's Y connection), according to Chapter 4.

2. Power-on the ventilator. Check if the sensor ID in the **Inter® GMX Slim** initial screen is correct: *ADULT SENSOR CONNECTED*. Access the monitoring screen.

3. Adjust the simulator to 20 hPa (cmH_2O)/L/s of resistance and 50mL/cmH_2O of compliance. Adjust the following ventilator parameters:

Mode	: Controlled Volume
Cycle	: Assisted/Controlled
Volume	: 500mL
Inspiratory Flow	: 30 L/min
Respiratory Rate	: 15 min^{-1}
PEEP	: 5 hPa (cmH_2O)

4. Check on the **Inter® GMX Slim** monitor if the indicated values for Inspiratory Pressure (*Peak)*, *PEEP*, Airways Average Pressure *MEAN*, Inspiratory Flow Peak *Pif,* Respiratory Rate *RATE*, Volume Exp. and I:E Ratio (*I:E RATIO)* are in compliance with the values programmed and indicated in the ventilator.

5. Check if the pressure, flow and volume curves are compatible with the ventilation parameters and the ventilation mode selected in the ventilator.

6. Adjust the alarm thresholds compatible with the parameters adjusted in the ventilator. Change the parameters adjusted in the ventilator in order to generate alarm conditions, checking their actuation in the monitor.

ROUTINE PREVENTIVE MAINTENANCE

Daily or prior to using:

1. Check the integrity of flow sensor, sensor tubes and power cable, and their proper connection, as per described in the Chapter 4;
2. Check the integrity of the patient circuit; eliminate possible leakages due to the assembly, or replace the circuit if necessary;
3. Check the equipment's general status so as to ensure that it did not suffer any falls or damages that might compromise its safe working; request for Intermed® or Authorized Technical Service technical support in case of doubts or problems;
4. Check the equipment's cleaning status proceeding in accordance with Chapter 7;
5. Sterilize the patient's circuit according to Chapter 7 and/or the institution's procedures;

Monthly:

Conduct the Functional Verification Test - FVT, requesting technical support from Intermed® 0800 770 3357 in case of problems.

Annually:

Request for the Annual Preventive Maintenance - **APM**, including verification, adjust and calibration of the equipment, to Intermed® or the Authorized Technical Service.

ANNUAL PREVENTIVE MAINTENANCE- *APM*

The Annual Preventive Maintenance - APM is an exclusive service provided by Intermed® in order to assure the safe operation of the equipment, in compliance with the original specifications and requirements of the NBR IEC 60601-1:1994 and 1997 amendment; NBR IEC 60601-2-12:2004; EN 60601-1:1990/A1:1993/A2:1995 and EN 60601-2-12:2006 rules.

The APM consists basically of the check of all equipment functions, replacement of defective parts or components that present wear or deterioration due to use, and adjustment and calibration of the equipment.

The calibration is performed with traceable measurement equipment under metrological standards worldwide recognized, and in compliance with the requirements of the ISO 9001/2008 Quality System rules.

The following conditions are applied:

1. The customer should send the equipment for APM to Intermed® or Intermed® Authorized Service after using the equipment for 12 months. In case of doubts, please contact Intermed® 0800 770 3357;

2. The APM should be performed at Intermed® or Intermed® Authorized Service facilities, with the customer being responsible for freight;

3. When performed within the WARRANTY period, the conditions established in Chapter 11 will be applicable.

4. APM is limited to the equipment; accessories are not included.

Chapter 10: Technical Description

Always use the Operation Manual as reference.

This Chapter Contains:

- Classification
- Flow Sensors
- Monitors
- Alarms
- Graphics
- Power Supply
- Dimensions and Weight

CLASSIFICATION	
According to the type of protection against electric shock	Class I / Internally Energized Equipment
According to the type of protection against electric shock	Type B applied part
According to the type of protection against noxious dripping water	IP24
According to the operation mode	Continuous Operation
Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.	
NBR IEC 60601-1:1994/A1:1997; NBR IEC 60601-1-2:2006; NBR IEC 60601-2-12:2004; EN 60601-1:1990/A1:1993/A2:1995; EN 60601-1-2:2001/A1:2004; EN 60601-2-12:2006;	
CEE 93/42 Medical Device - Class IIb rule 9	

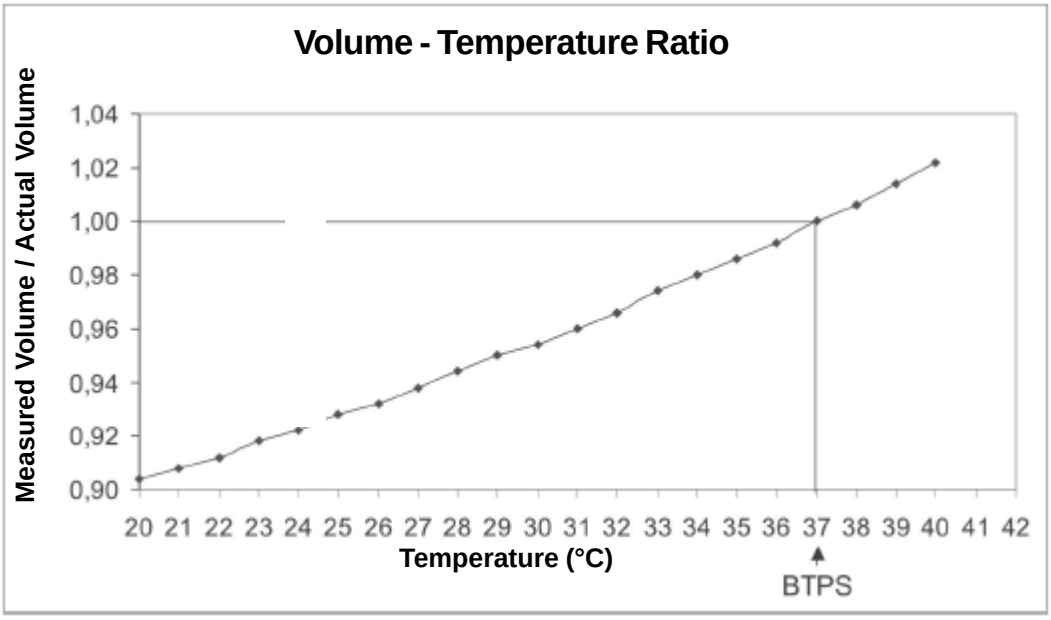
NOTE:

All measured values are expressed in BTPS (Body Temperature and Pressure, Saturated).

FLOW SENSORS		
	Range	**Tolerance**
Neonatal Clearance (internal volume): 0.8mL	0.2 to 9	±5% or 0.2 L/min
Pediatric Clearance (internal volume): 0.8mL	2 to 24	±5% or 0.5 L/min
Adult Clearance (internal volume): 7mL	6 to 120	±5% or 2 L/min
Maximum deviation according to gas composition (at 100% O_2, calibrated sensor to 21% O_2)	< 4%	
Maximum deviation according to gas temperature	See the graph below:	

NOTE:

Flow sensors are accessories of the Inter® Plus model.



Monitors	
Maximum Inspiratory Pressure	Peak
Plateau Pressure	Plateau
PEEP	PEEP
Mean Airway Pressure	Mean
Inspiratory Peak Flow	Pif
Expiratory Peak Flow	Pef
Tidal Inspiratory Volume	Vol insp
Tidal Expiratory Volume	Vol exp
Minute Volume	Vol min
Respiratory Rate	Rate
Inspiratory Time	Tinsp
I:E Ratio	I:E Ratio
Inspiratory Resistance	Rinsp
Expiratory Resistance	Rexp
Dynamic Compliance	Cdyn
Static Compliance	Cstat
Weaning Index	RSBI
Negative Inspiratory Pressure	NIP
Ventilation Work (ventilator)	WOBvent
O_2 Analyzer	
Alarms	
Visual signalling on the monitor and medium-priority audible alarm in the ventilator.	
Low oxygen concentration (Low $\%0_2$)	18% to 99%
High oxygen concentration (High $\%0_2$)	19% to OFF

Graphics - Curves
Pressure vs. Time
Flow vs. Time
Volume vs. Time
Pressure vs. Volume
Flow vs. Volume
Graphics - Trends (24 hours-maximum period of data)
Maximum Inspiratory Pressure
Expiratory Volume
Respiratory Rate
Inspiratory Resistance
Compliance
PEEP

Power Supply	
12 V Direct Current 0.25 A	
Dimensions and Weight	
Height (H)	175 mm
Width (W)	250 mm
Depth (D)	143 mm
Weight	1 kg

Accessory: O_2 Concentration Sensor		
Type of sensor		Galvanic Cell
Measurement Range		from 0 to 100%
Response Time	for 90% response	< 15s
	for 97% response	< 25s
Accuracy (% of full-scale)	Above the range of operating temperature	2.0%
	At constant temperature and pressure	1.0%
Operating Temperature		0° to 40° C (32° to 104° F)
Storage Temperature		-15° to 50° C (5° to 122° F)
Operating Humidity (non-condensed)		0 to 95%
Usage Time		900.000 h / % O2
Stability (above 8 hours of use, at constant temperature and pressure)		< 1

Electromagnetic Emission		
GMX® is designed for use in an electromagnetic environment as specified below. The **GMX®** client or user must assure that it is used in such environment.		
Emission Test	**Compliance**	**Guidelines - Electromagnetic Environment**
RF emission CISPR 11	Group 1	**GMX®** uses RF energy only for its internal functions. This RF emission is very low and must not cause any interference in electronic devices close to it.
RF emission CISPR 11	Class A	**GMX®** is appropriate to be used in all places, including domestic places and those directly connected to a short tension public power main supplying energy for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Tension Fluctuation/Flickers emission IEC 61000-3-3	Comply	

Electromagnetic Immunity			
GMX® is designed for use in an electromagnetic environment as specified below. The **GMX®** client or user must assure that it is used in such environment.			
Immunity Test	**Test Level IEC 60601**	**Compliance Level**	**Electromagnetic Environment Guide**
Electrostatic Discharge IEC 61000-4-2	± 6 kV	± 6 kV	The floor must be made of wood, concrete or ceramics. If the floor is made of a synthetic material, the relative humidity must be 30%, at least.
	± 8 kV	± 8 kV	
Electric Transient Fast/Surge IEC 61000-4-4	± 2 kV for power supply line	± 2 kV for power supply line	The power mains quality must be standard for commercial or hospital environment.
	± 1 kV for inlet and outlet line	± 1 kV for inlet and outlet line	
Surge IEC 61000-4-5	± 1kV from line to line	± 1kV Diferential Mode	The power mains quality must be standard for commercial or hospital environment.
	± 2kV from line to grounding	± 2kV Common Mode	
Tension Dips, Short Tension interruptions and differences in the power mains inlet tension IEC 61000-4-11	< 5 % U_T (>95% dip at U_T) for 0.5 cycle 40 % U_T (60% dip at U_T) for 5 cycles 70 % U_T (30 % dip at U_T) for 25 cycles <5 % U_T (>95% dip at U_T) for 5 seconds	< 5 % U_T (>95% dip at U_T) for 0.5 cycle 40 % U_T (60% dip at U_T) for 5 cycles 70 % U_T (30 % dip at U_T) for 25 cycles <5 % U_T (>95% dip at U_T) for 5 seconds	The power mains quality must be standard for commercial or hospital environment.
Electromagnetic field at the power supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	0.3 A/m	If a distortion occurs, **GMX®** may need to be positioned far from the magnetic sources or it will be necessary to place magnetic shields. The magnetic field must be measured in the place intended for the placement and it must be assured that it is weak enough.

NOTE FOR ELECTROMAGNETIC COMPATIBILITY:

This equipment was developed, tested and certified in accordance with the thresholds established in NBR IEC 60601-1-2:2006 and EN 60601-1-2:2001/A1:2004 for Class I / Internally Powered electromedical equipment, and CEE 93/42 - Medical Device Class IIb rule 9, following CISPR 11 normative conditions.

The thresholds are intended to offer protection against prejudicial interferences in its installation and operation, according to the immunity levels defined for electromagnetic interferences for the equipment connected on patient, as per technical description and use in conformity with this manual. When exposed to situations adverse to its specification, this equipment can produce or suffer electromagnetic interference.

In order to prevent prejudicial interferences it is mandatory to:

- Observe the distances between this equipment and other possible EMI emitters;
- Only connect the equipment to a grounded outlet for protection;
- Never disable the grounding terminal on the power cable plug of the equipment (ventilator).

In case of doubts, always contact Intermed® or the Authorized Technical Service.

Restrictions:

The non-authorized modification of any elements or components which operation can be affected by electromagnetic fields voids the product warranty and can produce adverse operating results.

Do not operate the equipment out of the described conditions and in a magnetic resonance environment, or near to high frequency surgical equipment, defibrillators or short wave therapy equipment. The electromagnetic interference may impair this equipment operation.

Manufacturer's guidelines and statement - electromagnetic immunity			
GMX® is designed for use in an electromagnetic environment as specified below. The **GMX®** client or user must assure that it is used in such environment.			
Immunity test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment - guidelines**
			Portable and mobile RF communication equipment must not be used close to any **GMX®** component, including cables with distance lower than that recommended, calculated from the equation applicable to the transmitter frequency. **Recommended Separation Distance**
RF Conducted IEC 61000-4-6	10 Vrms 150 kHz up to 80 MHz on ISM bands[a]	10 Vrms	$d = 1.2\,SP$
RF Radiated IEC 61000-4-3	10 V/m 80 MHz up to 2.5 GHz	10 V/m	$d = 1.2\,SP$ 80 MHz up to 800 MHz $d = 2.3\,SP$ 800 MHz up to 2.5 GHz
			where *P* is the maximum outlet nominal strength of the transmitter in watts (w), according to the manufacturer's transmitter, and d is the recommended separation distance in meters (m)[b]. It is recommended that the field intensity from the RF transmitter, as determined by electromagnetic inspection at the place[c], to be lower than the compliance level in each frequency range.[d] Interference may occur close to the equipment marked with the following symbol: 
NOTE 1	In 80 MHz and 800 MHz, the highest frequency range must be applied.		
NOTE 2	These guidelines may not be applied to all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.		
[a]	The ISM bands (industrial, medical and scientific) between 150 kHz and 80 MHz are 6.765 MHz up to 6.795 MHz; 13.553 MHz up to 13.567 MHz; 26.957 MHz up to 27.283 MHz; and 40.66 MHz up to 40.70 MHz.		
[b]	The compliance level in the ISM frequency bands between 150 kHZ and 80 MHz and in the frequency range between 80 MHz up to 2.5 GHz is intended to reduce the probability of mobile and portable communication equipment to cause interference if brought, inadvertently, to the patient environment. Therefore, an additional 10/3 factor is used to calculate the distance separation recommended to transmitters in those frequency ranges.		
[c]	The field intensity established by fixed transmitters, such as base radio station, telephone (mobile/wireless), land mobile radios, amateur radio, AM and FM radio transmission and TV transmission, cannot be accurately predicted. To evaluate the electromagnetic environment due to fixed RF transmitters, it is recommended to consider an electromagnetic inspection of the place. If the field intensity measurement at the place where GMX® is used exceeds the above applicable RF compliance level, the observation of GMX® is recommended to check if the operation is Normal. If an unusual performance is observed, additional procedures may be necessary, such as a new orientation or new positioning of GMX®.		
[d]	Above the frequency range from 150 kHz to 80 MHz, the field intensity is recommended to be lower than 3 V/m.		

Recommended separation distance between mobile and portable RF communication equipment and **GMX®**.				
GMX® is designed for use in an electromagnetic environment in which RF disturbances are controlled. The **GMX®** client or user may help preventing electromagnetic interference by keeping a minimal distance between mobile and portable RF communication equipment (transmitters) and **GMX®**, as recommended below according to the maximum outlet strength of the communication equipment.				
Transmitter maximum outlet strength W	Separation distance according to the transmitter frequency **m**			
	150 kHz up to 80 MHz out of ISM bands $d = 1.2\ SP$	150 kHz up to 80 MHz in the ISM bands $d = 1.2\ SP$	80 MHz up to 800 MHz $d = 1.2\ SP$	800 MHz up to 2,5 GHz $d = 2.3\ SP$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23
For transmitters with a maximum outlet nominal strength not listed above, the recommended separation distance *d* in meters (**m**) may be determined by using the equation applicable to the transmitter frequency, where *P* is the transmitter maximum outlet nominal strength in watts (**W**), according to the transmitter manufacturer.				
NOTE 1	In 80 MHz and 800 MHz, the separation distance for the highest frequency range is applied.			
NOTE 2	The ISM bands (industrial, medical and scientific) between 150 kHz and 80 MHz are 6.765 MHz up to 6.795 MHz; 13.553 MHz up to 13.567 MHz; 26.957 MHz up to 27.283 MHz; and 40.66 MHz up to 40.70 MHz.			
NOTE 3	An additional 10/3 factor is used to calculate the distance separation recommended to transmitters in the ISM bands between 150 kHZ and 80 MHz and in the frequency range between 80 MHz up to 2.5 GHz to reduce the probability of mobile and portable communication equipment to cause interference if brought, inadvertently, to the patient environment.			
NOTE 4	These guidelines may not be applied to all situations. The electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.			

Chapter 11: Warranty

Read the warranty conditions attentively. In case of doubts or problems, always request for assistance from the authorized representative.

Intermed Equipamento Médico Hospitalar Ltda. products are warranted against material and manufacturing defects and meet the published characteristics. The warranty and technical assistance are assured by Intermed Equipamento Médico Hospitalar Ltda. and its Authorized Service throughout Brazilian territory and in countries where the Authorized Service is instituted.

The responsibility for the warranty is limited to replacement, repair and labor, at the manufacturer's discretion, for components presenting defect or not meeting the characteristics published during the warranty period.

The warranty does not cover defects caused by accident, improper use, use conditions, improper installation or sterilization, service, installation, operation or alteration performed by non-authorized or unqualified personnel.

For safety, the screws used for closing are SEALED OFF. Breaking this seals by unauthorized personnel may result in the equipment WARRANTY lost.

Components subject to normal wear or degradation through use, adverse use conditions, negligent use or accidents are not covered by the WARRANTY.

The established warranty period is of 12 months for the equipment and 60 days for accessories, provided that their original characteristics are maintained, counted as of the equipment's delivery date or according to specific contractual conditions agreed upon.

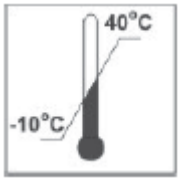
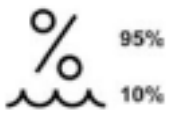
Annex A: Symbols and Terminology

Symbols

1. The meaning of standard symbols, printed on the equipment, is given below:

Symbol	Standard	Description
IP24	IEC60601-1:1994 Symbol nº. 529	Dip proof when bent up to 15° and protected against penetration of solid particles of 12.5mm diameter
	IEC60601-1:1994 Symbol No. 348	Warning! Consult ATTACHED DOCUMENTS
	IEC60601-1:1994 Symbol No.878-02-02	Equipment with Type B part applied
	IEC60601-1:1994 Symbol No. 878-03-01	Hazardous electrical voltage

2. The meaning of standard symbols, printed on the equipment package, is given below:

Symbol	Standard	Description
	ISO 780:1997(E) Symbol No. 1	FRAGILE: The package's contents are fragile, therefore, shall be handled with care.
	ISO 780:1997(E) Symbol No. 3	THIS SIDE UP: Indicates the package's upside position.
	ISO 780:1997(E) Symbol No. 4	PROTECT AGAINST DIRECT SUNLIGHT: The package shall remain sheltered from direct sunlight.
	ISO 780:1997(E) Symbol No. 6	PROTECT AGAINST RAIN: The package shall remain sheltered from rain.
	ISO 780:1997(E) Symbol No. 14	MAXIMUM PILING: Indicates the maximum number of identical package allowed to be superposed.
	ISO 780:1997(E) Symbol No. 17	TEMPERATURE LIMIT: It indicates the limit temperature for storage and handlling the package as cargo in transportation.
	ISO 7000:1998 (E/F) Symbol No. 0505	RELATIVE HUMIDITY: Indicates the relative humidity for storage and handling the package as cargo in transportation.

Symbol	Standard	Description
	BS EN 980:2008 Symbol No. 4.6	MANUFACTURING DATE: It indicates the date when equipment was manufactured.
	BS EN 980:2008 Symbol No. 5.2	MANUFACTURER: It indicates the the manufacturer of the equipment.
	BS EN 980:2008	LEGAL REPRESENTATIVE: It indicates the Authorised Representative in the European Community.
	CE Mark of Conformity	CE CONFORMITY: Its indicates that the system is in compliance with the European Council Directive (93/42/EEC) for Medical Devices. The xxxx is the certification number of the Notified Body used by equipment manufacturer.

TERMINOLOGY

The main terms used in this manual, defined by NBR-IEC 60601-1:1994 and 1997 amendment and EN 60601-1:1990/A1:1993/A2:1995 standards are given below:

1. ACCOMPANYING DOCUMENTS
Documents accompanying the equipament or on acessory and that contain all information that is important to the equipment user, operator and installer or assembler, mainly related to safety procedures.

2. CLASS I EQUIPMENT
Equipment in which the protection against electric shock is not based on its basic insulation, but rather incorporates an additional safety precaution consisting of a protection feature as to the equipment connection to a grounding conductor, for protection belonging to fixed installation wiring to prevent accessible metallic parts from being energized, in the event of a failure occuring in the basic insulation.

3. TYPE B APPLIED PART
Applied part in compliance with the provisions specified in standard NBR IEC 60601-1:1994 and 1997 amendment, to provide protection against electric shocks, particularly in connection with the admissible leakage current and marked by the 878-02-02 (NBR IEC 60601-1:1994 and 1997 amendment) symbol.

4. PROTECTIVE GROUNDING TERMINAL
A terminal connected to the conductive parts of a class I equipment for safety purposes, and intended to be connected to an external protective grounding system through a grounding conductor for protection.

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