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This side up

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1 INTRODUCTION

Milli pulse oximeter is an electro medical device manufactured by HI Technologies Brazil that indirectly monitors the oxygen functional saturation of patient's blood and cardiac frequency in patients who are in medical and hospital environment.

With a completely new design, this device has unique characteristics:

- It can be used as a table oximeter when connected to the docking station, or as a hand oximeter when separated of the base.
- It has its own operating system created by the company that permits the installation of medical applications, increasing the unit features.
- It can transmit patient's vital signals via Internet or through a wireless connection.
- It offers Internet and Intranet access with a browser like a computer.
- It has an integrated video camera.
- It allows that approved accessories are installed via USB or wireless connection (Bluetooth).

Intellectual Property (IP)

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Circuit diagrams, component lists, descriptions and other information are available by signing in a confidentiality agreement (NDA) with the company.

2 OVERVIEW

Intended Use

This device is indicated to monitor the oxygen functional saturation of patient's blood and cardiac frequency in patients who are in medical and hospital environment.

⚠ This equipment should not be used during Magnetic Resonance Exam (MRI) due to severe burns hazard.

⚠ This equipment should not be used to continuous monitoring if the audible alarms are permanently disabled.

⚠ The validity period of this equipment is UNDETERMINED, but its lifetime is 3 year average, since the manufacture date, and it may vary with the adequate use and preventive maintenance.

Operating Principles

Pulse oximetry is based on two main principles:

Spectrophotometry: The red and infrared light absorption is different between oxyhemoglobin and deoxyhemoglobin;

Plethysmography: The arterial blood volume in tissues varies with cardiac pulse, resulting in a variation of light absorption.

Based on mentioned principles, the pulse oximeter determines functional oxygen saturation in blood (SpO2) with a sensor with two light emitting diodes (LEDs) red and infrared, and a photodiode light receptor. This sensor is placed in a pulsating arterial vascular bed (e.g.: fingers and toes, ears and nose).

The LEDs emit infrared light (wavelength 905nm), and red light (wavelength 660nm) through a patient's arterial vascular bed. The light is converted in electronic signals by the photodiode. These signals are used to calculate the vital signals.

The calculus of functional saturation of blood oxygen (SpO2) is obtained using the equation figure 1, where ***A*** and ***B*** are calibration values, and ***R*** is obtained by the equation figure 2, where AC_V and DC_V are the ***AC*** and ***DC*** components of red light and AC_{IV} and DC_{IV} are the components ***AC*** and ***DC*** of infrared light. It is very important to remark that the equipment is enabled to measure the functional saturation, which means, the percentage of oxygenated hemoglobin related to total hemoglobin able to carry oxygen.

$$SpO2 = A - B * R$$

Figure 1

$$R = \frac{\frac{AC_V}{DC_V}}{\frac{AC_{IV}}{DC_{IV}}}$$

Figure 2

It is also important to report that comparing the calculated saturation (obtained with pulse oximeter) with the measured saturation (obtained with a gas sample of arterial blood), it may be different. These discrepancies are due to the calculated saturation is not properly corrected with some variables as: pH, carbon dioxide partial pressure, temperature and fetal hemoglobin. Moreover, a comparison can only be done in situations where the calculated saturation is stable for the duration of collecting blood for testing.

Commercial Presentation

This product consists of the following devices and accessories.

NOTICE: All parts, accessories and sensors are for EXCLUSIVE USE of Milli Pulse Oximeter.

Code	Name	Quantity
FOCA-DM-001	Pulse Oximeter	1
FOCA-BA-001	Docking station	1
See sensors table	Oximetry Sensor	1
FOCA-CA-001	Power Cord	1
FOCA-MU-001	User Manual	1

Table 1

Figure 3.
Milli Pulse Oximeter
(vertical position).

Figure 4.
Milli Pulse Oximeter
(horizontal position).

Figure 5.
Milli Pulse Oximeter
(detached from docking station).

Compatible Sensors

Table 2 shows the sensors compatible with the equipment.

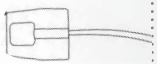
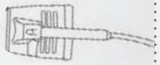
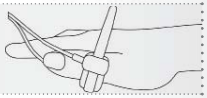
Code	*Use*	*Type*	*Image*
FOCA-SP-001	Pediatric	Soft	
FOCA-SA-001	Adult	Soft	
FOCA-CM-001	Adult	Clip	
FOCA-CP-001	Pediatric	Clip	
FOCA-JA-001	Adult	Clip	
FOCA-LC-001	Adult	LED	
FOCA-IN-001	Pediatric	Intermediate	

Table 2

NOTICE: The manufacturer recommends its disposal and replacement every 12 months.

Compatible Sensors

Table 3 shows the sensors compatible with the equipment.

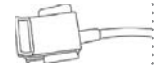
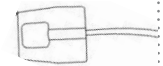
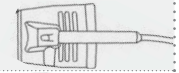
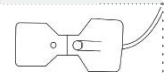
Code	*Use*	*Type*	*Image*
FOCA-PB-001	Pediatric	Clip	
FOCA-AB-001	Adult	Clip	
FOCA-PG-001	Pediatric	Soft Biogenesis	
FOCA-AG-001	Adult	Soft Biogenesis	
FOCA-MS-001	Neonatal	Multisite	
FOCA-DP-001	Pediatric	Disposable	
FOCA-DA-001	Adult	Disposable	

Table 3

NOTICE: The sensors are identified with a label that holds information about lot and expiry date, as follows:

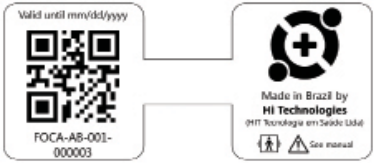


Figure 6.
Sensor identification label.

NOTICE: Every sensors use the same connector, as follows:

Figure 7.
Sensor Connector
(front view).

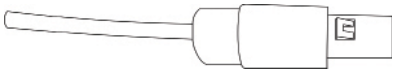


Figure 8.
Sensor Connector (lateral view).

Equipment Connections

9 Connection pins

Connection pins used to connect the docking station with handheld.

No other equipment should be connected here.

10 External batteries input

It should be used only to connect external batteries. Just certified batteries, tested and approved by the company can be used (IEC 60601).

11 USB input

This port should be used only to connect accessories approved by the company.

12 Power Supply

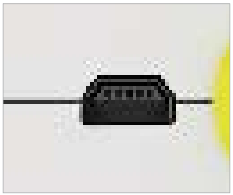
Power supply, it supplies electrical energy to the equipment (110V~ to 220V~).

13 Connection pins

Connections pins used to connect the handheld to docking station.

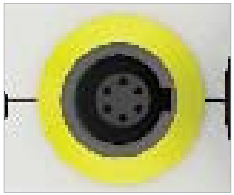
No other equipment should be connected here.

14 Connection pins



It should be used only to connect accessories approved by the company.

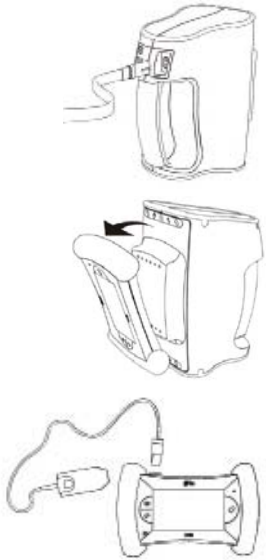
15 Sensor input



The oximetry sensor should be connected in this port. Only certified sensors, tested and approved by the company should be connected in this entry (IEC60601).

3 EQUIPMENT OPERATION

Installing the Oximeter



1. Connect the power cord to docking station.
2. Connect the handheld to docking station. The connection is electromagnetic, mechanical fittings are not needed.
3. Connect the sensor to the handheld.
4. To turn on the equipment press the MENU button by 3 seconds. The same procedure will be done to turn it off.
5. After turning on, register the patient (according to "Patient" section) then accompany the monitoring.

NOTICE: When the equipment is turned on, it emits a sound that indicates whether the speaker is operating properly and whether the alarm will sound normally.

Equipment Controls

Milli pulse oximeter can be controlled by two ways:

1. Touch buttons: buttons are lit when the device is on, but they are turned off momentarily during touch to indicate they are being activated;

2. Touch screen: press the buttons on the screen to activate functions.

Symbol	Name	Function
	Menu / Turn on /Turn Off	• Keep pressed to turn on/off the device. • Touching quickly activate the menu if the equipment is in vital signals monitoring screen.
	Return	• Returns to the previous screen.
	Silence Audible Alarms	• Turn off the audible alarms by 25 seconds. • Turn on the audible alarms if they are temporarily disabled • If one alarm (SpO2 or Pulse) is permanently disabled, it displays alarm settings screen.

Table 4

Light Indicators

Docking station has blue light indicators. When lit, this indicates some states of the equipment:

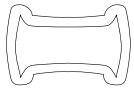
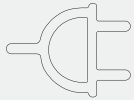
Symbol	Name	Meaning (when lit)	Meaning (when off)
	Handheld connection	Handheld is connected to docking station.	Handheld is not connected to docking station.
	Power grid connection	Docking station is connected to the power grid.	Docking station is not connected to the power grid.

Table 5

4 MONITORING THE PATIENT

Milli pulse oximeter starts with the patient's monitoring screen. The user has access to:

1. Patient's name;
2. Functional oxygen saturation in blood (SpO2) measured in %;
3. Heartbeat, measured in beats per minute;
4. Perfusion Index (IP) and Perfusion Variability (IVP) measured in %;
5. Plethysmographic curve proportional to the patient's heartbeat;
6. Heartbeats indicator. The quality of heartbeats signals can be verified by the size of the circumference. Bigger is better signal quality (SQ).

If user presses the MENU button, the MENU screen will be displayed.

If **SILENCE ALARMS** button is pressed, the alarms will be temporarily disabled by 25 seconds. If the button is pressed again during this period, the alarms will be enabled. But in case of alarms being permanently disabled, the **SILENCE ALARMS** button displays the alarm settings.

*To access to Alarm settings, the device request for a password. See page 21 Security Locks for more information.

Alarms can be disabled with a quick tap on the screen.

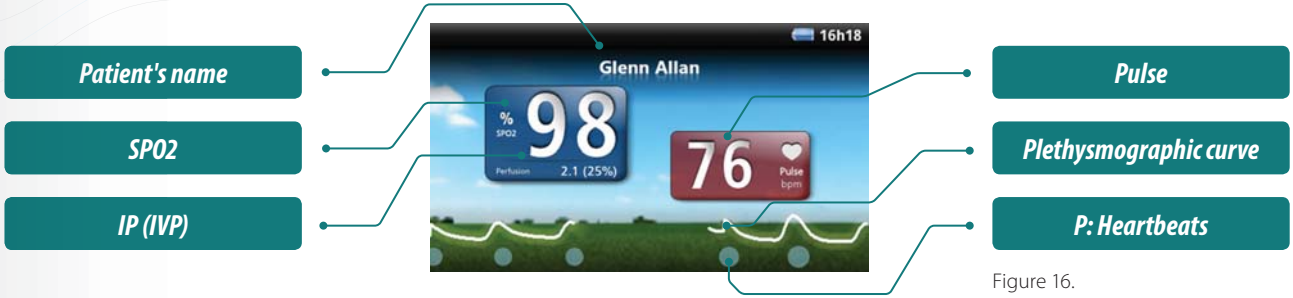


Figure 16.
Patient's vital signals monitoring.

Main Menu

Touch the menu button in the monitoring screen to access to MENU screen. Many functions of the oximeter are available in this screen by touching the icons (shortcuts) on screen surface (touch screen).

Figure 17.
Main menu.

Buttons and Widgets

Applications
Access the applications.

Settings
Access to personal settings.

Internet
Internet access.

Trends
Access to monitoring trends charts.

Patient
Register and access to patient's information.

Alarm
Alarm information.

Hints
Shows safety hints and use hints the first time the device is turned on.

Add widgets
Helps in widget settings.

Remove widgets
Helps in widgets settings.

Organizational folder
Helps in applications organization.

Edit
Edit patient data.

Release
Delete the patient.

Open Folder
Helps in applications organization.

Shortcuts
Allows the creation of shortcuts for applications.

Patient's Avatar
Identifies the patient, if not yet been set, whether male or female.

CONNECTIVITY SYMBOL

Bluetooth activated.

Bluetooth in activity.

Wi-Fi connection activated.

OTHERS BUTTONS

Zoom in
increases screen details.

Zoom out
Decreases screen details.

Enable audible alarms

VITAL SIGNALS SYMBOLS

IP
Perfusion index.

IVP
Variabillity perfusion index.

SPO2
Functional saturation of oxygen.

PULSE
Patient's cardiac frequency.

Security Locks

LOCK OF MEDICAL FUNCTIONS

To lock the access to all the medical functions of the device:

1. Go to MENU screen.
2. Click the Application shortcut
3. Click the Security and Lock shortcut.
4. Maintain the red button pressed to lock medical functions of the equipment. The appears in Status Bar while the device is in this state.

Note: Functions may be temporarily unlocked with individual password while equipment is locked.

Security Locks

UNLOCK OF MEDICAL FUNCTIONS

To unlock proceed as follows:

1. To unlock temporarily individual functions, or general lock, enter the password : **AMOR.**
2. Select a letter by dragging the column up or down until to reach to the correct letter.
3. If the password is correct, the red button "cancel" becomes green "proceed". Clicking on it, unlocking is done and disappear of Status Bar.

TECHNICAL FUNCTIONS

Technical functions of device (e.g. settings applications) are protected by the password: **KIRK.**

Alarms

In the alarms screen, the user can set the alarm limits. Touching the desired alarm, the window with the limits will appear. The sounds can be turned off permanently for each vital signal with alarm sounds controls on the right side of the screen. When SpO2 or pulse audible alarm is disabled, a visual notice will appear.

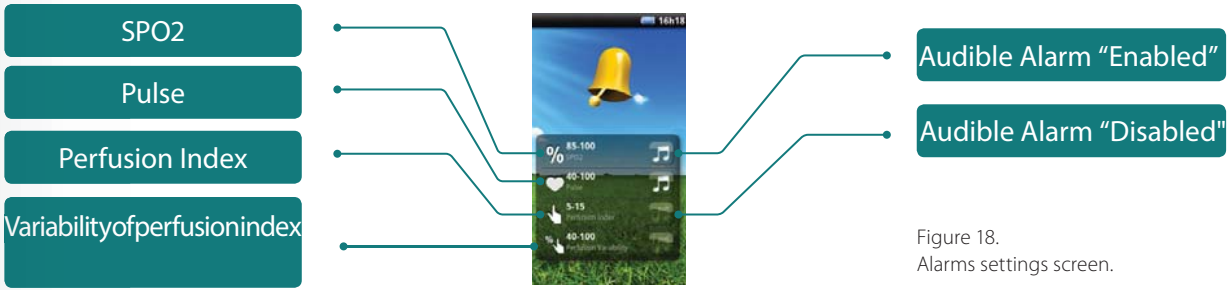


Figure 18.
Alarms settings screen.

Alarms are categorized into high, medium and low priority. Each priority has a different visual identification:

HIGH

MEDIUM

LOW

- Letter "x" indicates that any audible alarm (SpO2 or pulse) is permanently disabled.
- The clock indicates that the audible alarms are disabled by 25 seconds.

Table 6. Description of the alarm sounds.

Description	***Priority***	***Sound Sequence***
Sensor disconnected of the equipment	Medium	C4 C4 C4
Finger disconnected of the sensor	Medium	C4 C4 C4
Weak signal	Low	E4 C4
Errors in the oximetry module	Medium	C4 C4 C4
Sensor failure	Medium	C4 C4 C4
SpO2 out of limits	High	C5 B4 A4 - G4 F4
Pulse out of limits	High	C4 E4 G4 - G4 C5
Perfusion Index out of limits	High	C5 B4 A4 - G4 F4
Variation of perfusion out of limits	High	C5 B4 A4 - G4 F4

Table 7. Range of alarms values..

Alarm	*Min value*	*Max value*	*Factory enabled*	*Factory minimum value*	*Factory maximum value*
SpO2	0	100	Yes	85	100
Pulse	30	235	Yes	40	100
Perfusion index	0,02	20	No	5	15
Variability of perfusion index	0	100	No	40	100

Patient Data

Patient's data may be registered using the Patient's application, in the menu screen. If no patients are registered, a form will appear automatically. Touching in any field enables a virtual keyboard. The keyboard can be used by touching the touchscreen. When the patient is registered, the user may choose to "Release" (remove all patient data, including trend charts) or "Edit" (allows data editing).

Figure 19.
Patient data Editing.

Figure 20.
Display of Patient data.

Settings

The user can set up the oximeter in the "Settings" screen of the main menu, following the next steps:

*Password of Settings Screen: KIRK.

1. Go to *"Menu"* screen.
2. Click on *"Settings"* shortcut.
3. Choose one of the options to set.

BACKGROUND:

1. Select your preferred image.
2. Define it as background.

DATE AND TIME:

1. Define desired date and time, do necessary adjustments.

SELECT LANGUAGE:

Choose one of preinstalled languages: Portuguese, English and Spanish.

WIRELESS NETWORKS AND OTHERS:

1. Enable or disable the desired connections.
2. Do necessary adjustments

OPENVIDA NETWORK:

Milli pulse oximeter may be used in telemedicine applications using OpenVida Network. For more information, acquire OpenVida Central Monitoring.

APPLICATIONS.

Applications installed in the device can be removed. To do this, select one application and check available options.

Internet

The user may browse in Internet using the "Internet" application, from main menu screen. It is necessary to setup and enable a Wi-Fi connection before browsing. The steps are:

1. Go to "Menu" screen.
2.  Click on "Applications" shortcut.
4.  Click on "Internet" option.
5. Browse in Internet.

Batteries

This icons sequence shows the battery charge. When the charge level decreases, the blue color becomes yellow, followed by red, when the charge is finishing. When the battery is empty, the icon is black. While the battery is charging, icon color goes from red to blue, passing through yellow. To charge the handheld battery is necessary to connect it to docking station, and connect this to power grid. The average battery charge time is 10 hours.

Figure 21.
Sequence of battery charge.

Trends

The patient's vital signals are stored in pulse oximeter and can be seen as trend charts. The access to this screen is trough the "Trend" shortcut in the main menu.

1. Go to "Menu" screen.
2.  Click on "Applications" shortcut.
3.  Click on "Trends" shortcut.
4. Analyze the charts.

Figure 22.
Trends charts.

5 GENERAL GUIDELINESS

Biocompatibility

⚠ All parts of the equipment that remains in contact with the patient (sensors) are produced with biocompatible materials. The manufacturer has the documents that certify the sensors biocompatibility and it should be delivered signing a confidentiality agreement.

⚠ According to the kind of contact with patient (ISO 10993-1) it is classified as external communication equipment.

⚠ According to the duration of contact with the patient (ISO 10993-1) it is classified as limited or prolonged exposure equipment.

Essential Care

⚠ Maintain the equipment in a dry environment, protected of direct solar rays.

⚠ Avoid places where liquid spillage may occur.

⚠ Do not use the equipment if it is wet or with humidity excess.

⚠ Do not use if it shows external damage or in case of suspected fall.

⚠ Install the equipment always in places where the electrical installation corresponds to the conditions established on the equipment (voltage, current, power).

Essential Care

⚠ Never sterilize or immerse it in liquids.

⚠ Do not apply mechanical stress to the cables.

⚠ Do not expose the device to temperatures upper 131F (55°C) or lower 14F (-10°C).

⚠ Do not operate the device in temperatures upper 104F (40°C) or lower 32F (0°C).

⚠ Calibration is not required.

⚠ Functional measurers may not be used to determine the accuracy of the oximetry sensor.

Battery Care

⚠ Batteries may have longer lifetime if kept, whenever possible, its maximum load. Constant discharges decrease their lifetime. It must also be considered that elderly batteries have lower operating time.

⚠ The equipment's batteries (docking station and handheld) should not be changed and do not require maintenance. In case of problems, send the equipment to an Authorized Technical Support.

⚠ Batteries charging temperature varies between 32F (0°C) and 117F (47°C), and batteries discharging temperature is estimated between -4F (-20°C) and 149F (65°C). There is a protection circuitry that disables it partially in temperatures out of limits. During device operation, batteries may have temperatures varying between -4F (20°C) and 167F (75°C).

Packaging, Transportation and Storage.

⚠ The equipment is packaged in a Kraft box reinforced with internal polyurethane protector.

⚠ During transportation, handle with care to avoid damage.

⚠ During transportation or storage, the equipment should be maintained in temperatures between -40F (-40°C) and 158F (70°C), protected against liquid spillage, with relative air humidity between 10% and 90%, and atmospheric pressure between 500hPa and 1060hPa (375mmHg and 795mmHg).

Electrostatic Discharge

⚠ Electrostatic discharge (ESD) may cause damage to the Milli pulse oximeter if it happens inside of it. Because of the accumulation of electrons on the material surface, it may occur in many ways. For example after dragging feet on carpet floor (what causes electrons accumulation on your body), you may feel an electric shock while touching the metallic knob door. This shock is due to the static electricity accumulated on your body is discharged to ground through knob door. Eventually, the discharge may occur touching the car bodywork after it was driven for some time. Even these shocks are nothing more than a nuisance to people it may damage electronics circuits as Milli's circuits. Therefore it is important to take certain precautions to avoid these episodes:

Electrostatic Discharge

⚠ All professional who use Milli pulse oximeter should know the explanations contained in this manual about electrostatic discharge protection, so that:

- They can recognize the warning symbol ESD.
- They are trained in procedures to prevent electrostatic discharge.

⚠ Connection pins identified with the ESD warning should not be touched.

⚠ To connect these pins it is necessary to follow procedures against ESD.

⚠ Follow these precaution procedures:

- Connect to a grounding point to take the equipment.
- Increase the air relative humidity.
- Install specific protection items against ESD, as floors, bracelets and antistatic heel straps.

⚠ Avoid conditions that promote the accumulation of static electricity in the environment:

- Low relative humidity.
- Materials that accumulate static charge, e.g. synthetic materials accumulate more static energy than natural fiber as cotton.
- Touch or connect the equipment quickly.

Precautions

⚠ The equipment should be used by trained professionals. The operator should know the information contained in this user manual before proceeding to use it with the patient.

⚠ The operation of this equipment may be affected by presence of strong magnetic fields as electro surgery devices, computed tomography, magnetic resonance images (MRI) and others.

⚠ Always disconnect the equipment of power supply and remove the accessories before cleaning and disinfecting to avoid damaging and ensure the biosafety guidelines.

⚠ Always use sensors approved by the company. The use of other sensors can generate inaccurate measures or damage the equipment.

⚠ The results obtained with this device are a complement of the evaluation patient/client and should be used with a clinical evaluation of a qualified professional.

⚠ Hi Technologies's sensors do not contain latex in its composition, protecting patient and operator of possible allergic tissue reactions due to toxicity.

⚠ Do not use the sensor in temperatures above 106F (41ºC) in children under one year.

⚠ This equipment requires special precautions related to electromagnetic compatibility, for that it must be installed and operated in accordance with the electromagnetic compatibility information available in this manual.

⚠ Mobile and portable radio frequency devices may affect this equipment.

Restrictions

⚠ Any condition that restricts the peripheral blood flow (as non invasive pressure cuffs) may prevent accurate measurement of vital signals.

⚠ **HYPOPERFUSION**

The result of readings for low values may be altered due to the difficulty of the peripheral circulation.

⚠ **VENOUS CONGESTION**

Increased blood volume may produce capillaries pulses and promote reading errors in some equipment.

⚠ **MOVEMENTS**

The location for sensor placement should be analyzed according to patient's mobility to avoid compromising their anatomophysiology and reliability of sensor readings.

⚠ Significant rates of dysfunctional hemoglobin, as carboxyhemoglobin, may affect the accuracy of SpO2 measure.

⚠ **ANOMALOUS HEMOGLOBIN**

Genetic diseases, like falciform anemia, in acute conditions (lower than 5mg/dl) may have the value decreased.

⚠ **INTOXICATIONS**

(e.g. carbon dioxide) may alter the values.

⚠ **SKIN PIGMENTATION**

Darker skins may interfere in the readings.

⚠ **LIGHT INTERFERENCE**

When two or more sensors are placed near, mistakes may happen due to the exchange of light among them. Cover each of the sensors with opaque material to prevent light leakage.

Restrictions

⚠ ARTIFACTS

For example cell phones, may interfere in the correct operation of some electronic equipment causing reading mistakes.

⚠ AMBIENT LIGHT

Intense solar light, xenon light, fluorescent and infrared light may decrease the presented values.

⚠ BAD POSITIONING OF THE SENSOR:

May have unrealistic values regarding the patient's general condition.

⚠ Obstructions or dirt on the LEDs or photodiode may cause sensor failures. Always verify if the sensor is free and clean.

⚠ EXCESSIVE SECRETIONS

Interfere in the sensor reading allowing the reading of a lower value than reality. The problem is solved by cleaning the verification area (mechanical removal) or by changing the sensor position.

⚠ EPITHELIAL LESIONS

Skin problems (e.g. dermatitis, lesions, onicomycosis and necroses) may block the light input in the sensor, altering the reading result.

⚠ NAIL POLISH

May prevent the propagation of light sensor, altering the reading (mainly dark colors). It is not significant, but for complementary observation it is preferable to remove using nail polish remover.

⚠ FALSE NAILS

May interfere in the propagation of light sensor, altering the reading. It is preferable to remove them to perform complementary examination.

Warnings

⚠ Never use this device in presence of flammable anesthetic because of the risk of ignition that may result in an explosion.

⚠ Never use this device in the presence o Magnetic Resonance devices (MRI). MRI scanners can generate induced currents in the sensor, resulting in injuries and severe burns in the patient.

⚠ The autoclave use, ethylene oxide sterilization or immersion of the sensors in liquids may cause incorrect readings or irreversible damage to the equipment.

⚠ The prolonged use of the sensor may cause blisters, skin deterioration and discomfort. It is recommended to change the location of the sensor every 4 hours or as patient's needs.

⚠ When connecting the equipment in any instrument, verify proper operation before clinical use. See instrument manual for complete information. Accessories connected to the interface of the monitor should be certified in accordance with the respective standards.

⚠ Any connection of additional equipment in the input or output of signal will be classified as a medical system, so it should be in accordance with applicable technical standards.

⚠ Sensors used incorrectly may cause inaccurate readings. See manual for instructions about proper application.

Warnings

⚠ Damaged cables and sensors may cause incorrect readings, with possible injury or death of patient. Inspect each sensor and each cable and immediately discard if damaged. It is recommended to use another cable or sensor and contact the Technical Support for assistance.

⚠ Chemical products: petroleum based substances or substances used for disinfection (e.g. alcohol), for removing skin glue (e.g. benzine), removers (e.g. thinner) and other, may damage the material protection of the sensor, altering the reading results.

⚠ Do not connect USB devices not approved by the company because the use of other devices may cause irreparable damage to the equipment.

⚠ Do not insert any object into the docking station's power input connector.

⚠ Connectors identified with warning ESD symbol should not may not be touched directly neither with manual tools.

⚠ The equipment may generate imprecise results if operated out of amplitudes specified in this manual.

⚠ The use of accessories, transducers or cables not specified, approved and recommended by the manufacturer may adversely affect equipment operation, increasing the electromagnetic emissions or decreasing the electromagnetic immunity of the equipment.

⚠ The device may not be used near or stacked over other equipments.

⚠ This equipment is susceptible to other equipments, even being in conformity with CISPR emission prescription.

⚠ All discarded parts such as sensors, batteries, etc., should be sent to the manufacturer or delivered to one of the Technical Support Network, duly sterilized for proper disposal.

⚠ The equipment should be sent to the manufacturer or delivered to one of the Technical Support Network, duly sterilized for proper disposal.

6 MAINTENANCE

Cleaning and Disinfection

The instructions for cleaning and disinfection of the equipment and accessories should be strictly followed, as follows:

- Do not drop liquids onto the equipment, mainly in ventilation areas to prevent it from entering in the electronic components.
- If it happens, disconnect the equipment and call the Technical Support.
- Never immerse the equipment in any liquid.
- Do not sterilize with autoclave or any disinfectant immersion technique.
- Turn it off and disconnect from the power grid before start cleaning.
- Clean the external part with a smooth lint-free cloth, moistened with mild soap and water.
- Do not use chemical petroleum based products as thinner, benzine and other derivatives to clean the accessories and modules.
- Never wet connectors.

- LCD Touch Screen:

  In case of splashing or spilling liquids directly over LCD screen, clean immediately with a dry cloth and proceed to disinfection. Remember, any more fluid substance may enter in screen edges and damage the internal circuits.

  - Use a lint-free cloth.
  - The cloth should be used dry or moistened with a mild cleanser. Make sure the cloth is slightly damp, not wet.
  - Never apply the cleaner directly on the surface of the panel. If the cleaner is spilled on the touch panel, dry immediately with an absorbent cloth
  - Never use cleaning products with acid or alkaline base (use products with neutral pH).
  - When using the cleaner, avoid the contact with the edges of the film or glass and flexible parts.
  - Wipe the surface gently, if it has directional texture, wipe in the direction of texture.
  - Never use chemical organic products as thinner, acetone, propyl or isopropyl alcohol, toluene, xylene or kerosene.
  - Appropriate cleaning products are commercially available.

Cleaning and Disinfection

- LCD Touch Screen:

  The wrong way to clean or use of not recommended products result in optical deterioration of the panel or functionality damage.

  It is recommended:

- Use a moistened cloth (not wet). In case the display has grease stains, use three drops of neutral soap.
- Gently wipe the screen without pressing.
- Immediately dry with a dry cloth.

NOTE: the majority of products have 1-3% of isopropyl alcohol per volume, which is in the acceptable limits for cleaning resistive touch screens.

CAUTION: many products contain ammonia, phosphates and or ethylene glycol and they are NOT RECOMMENDED. Carefully verify the content of the product in the label.

Preventive Maintenance

Every three months, the operator should check all equipment if there is no breaks in cables, drying of connections and metal parts oxidation.

Oximetry sensor should be inspected monthly for life, because handling may damage the LEDs and the internal wires of the cable.

To ensure the proper operation of the oximeter is recommended to send the equipment to an Authorized Technical Support annually.

Corrective Maintenance

Milli Pulse Oximeter corrective maintenance requires specific technical knowledge and software that only authorized people have. There are no internal parts that can be repaired by users. Therefore, if any repairs to the equipment are required, only Authorized Technical Support can do it.

In case on doubts about the equipment and its operation contact the manufacturer. The validity of the warranty and veracity of monitoring is only guaranteed when the corrective maintenance is performed in an Authorized Technical Support.

Problems and Solutions

This section shows possible solutions for some problems that may occur and can be solved by the operator. If the problem persists and the system does not work properly after the indicated verification, contact Hi Technologies or an Authorized Technical Support to solve the problem as soon as possible.

Problems	***Possible Causes***	***Solution***
The equipment does not turn on	1. Lack of energy. 2. Energy cable broken. 3.Battery discharged.	1. Verify the energy cable. 2. Change the energy cable. 3. Connect the equipment in the power grid.
Signals does not appear on screen	1. Sensor disconnected from the equipment. 2. Sensor disconnected from the patient. 3. Patient with very low perfusion. 4. Faulty sensor.	1. Connect the sensor to the equipment. 2. Place the sensor in the patient. 3. Change sensor position. 4. Substitute the sensor.

Supply of Sensors and Accessories

The company provides sensors and accessories that can be connected to the Milli pulse oximeter. If necessary, the sensors for replacement may be purchased directly from Hi Technologies.

Oximeter Manual Test

1. Connect oximeter to the power grid.
2. Connect sensor in the oximeter.
3. Turn the equipment on.
4. Wait the start up.
5. The equipment should play an alarm during start up.
6. Use the capacitive buttons and touchscreen to browse in menus.
7. Check if buttons and screen respond to commands.
8. Turn the oximeter in the 4 possible positions to check screen rotation.
9. The screen would rotate automatically after a few seconds.
   a) If screen does not rotate, tap it and wait 5 seconds until the rotation.
10. Connect the sensor in a patient or simulator and check if the vital signals are on screen.
11. Browse to alarm settings screen and setup the upper SpO2 limit to a value lower than current vital signal.
12. Check if the alarm is triggered.
13. Browse to alarm settings screen and setup the lower SpO2 limit to a value upper than current vital signal.
14. Check if the alarm is triggered.
15. Turn the SpO2 alarm off and check if the alarm is triggered.
16. Repeat steps 11 to 15 for:
    a) Cardiac frequency;
    b) Perfusion index;
    c) Perfusion variability.
17. Return to the initial settings for alarm limits.

Test Method for Accuracy Verification

Some models of functional testers or patient simulators (available on the market) may be used to check the functionality of the oximeter, cables and sensors. Read the specific operation manual of these equipments to perform the tests.

Even being useful for checking the oximeter, cables and sensors, **these testers ARE NOT CAPABLE of evaluate the accuracy of oximeter measurements.**

The full evaluation of the accuracy of Milli pulse oximeter requires at least a full reproduction of the optical interaction between the sensor and the patient. This level of technology is beyond the ability of the testers and simulators on the market, even those that say they have those resources.

Therefore, the Milli pulse oximeter accuracy may be evaluated with in vivo experiments through direct comparison with the values simultaneously measured with a lab co-oximeter.

The accuracy limits of the oximeter were established with a clinical study realized with healthy adult volunteers (SpO2 scale between 70% and 100%). The measured SpO2 values were statistically compared with the simultaneous results obtained with a certified and calibrated lab co-oximeter. Pulse measurements were statistically compared with simultaneous results obtained with a certified and calibrated cardiac monitor.

Validation of accuracy of measured values is the sole responsibility of the manufacturer and may only be guaranteed when the equipment is used according to the instructions in this manual.

Fuse Substitution

The docking station has 2 fuses that can be located in the Figure 23, which shows radial fuse 3.15A/250VAC (retarded) on the power circuit board. The fuse 1 (blue one) is visible without removing the cover of power supply. To see fuse 2 (yellow one) cover removal is necessary.

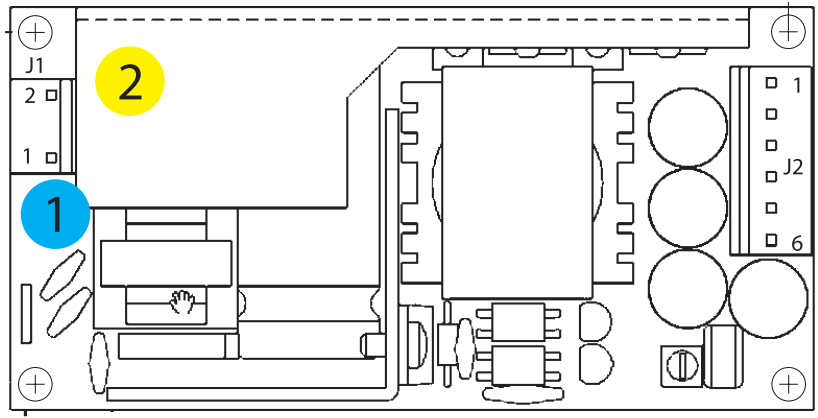


Figure 23.
Fuse localization inside the power supply of the Milli docking station.

7 TECHNICAL SPECIFICATIONS

Equipment Classification

ANVISA hazard class of the device	III
Protection against harmful water penetration	IPXO - COMMON EQUIPMENT (closed equipment without protection against water penetration)
Equipment operation mode	CONTINUOUS OPERATION
Protection degree against electric shock	CLASS II
	Internally powered
	With BF applied part protected against defibrillator discharge
Equipment NOT SUITABLE for use in the presence of anesthetic flammable mixture with air, oxygen or nitrous oxide.	

Equipment Accuracy, Calibration and Resolution

Milli pulse oximeter is calibrated after the end of fabrication process. Therefore a new calibration is not necessary during oximeter lifetime. It was calibrated between 70 and 100%, being that for lower values is not possible to ensure the calibration accuracy. In the range of 70 to 100% there is an error of ±2% and during movement ±3%. The measurements done by the equipment, related to patient's pulse have an error of ±2 bpm between 20 and 100 beats per minute and 2% between 101 and 250 beats per minute.

Table 8. Oximeter accuracy.

SpO2 (70-100%)	± 2%
SpO2 (70-100%) (in movement)	± 3%
SpO2 (<70%)	Undefined

Table 9. Pulse accuracy.

Pulse frequency (20-100 bpm)	± 2 bpm
Pulse frequency (101-250 bpm)	± 2%

Table 9. Equipment resolution.

SpO2	1,00%
Pulse frequency	1 bpm
Reading update time	< 10 seconds Conditions: Oximeter powered, looking for the pulse and with the clip adult sensor.
	< 2 seconds Conditions: Oximeter powered, pulse detected and with the clip adult sensor.

Power Supply

Electric grid: 110 to 220 V~ (AC)

Frequency: 60 Hz / 50 Hz

Connector: 2 Pins

Power: 44 VA

Fuses: 2 units type of Radial T3.15A/250V~ (retarded)

External Power Supply

Connected to the docking station: 12 to 15Vcc (CC)

Current: 3.5A

Batteries

Docking station battery: 2 x Li-Polymer 2000mAh, 3.7V

Handheld battery: 2 x Li-Polymer 2000mAh, 3.7V.

Connectivity

Bluetooth:

Operating frequency: 2.4 – 2.4835 GHz

Power: < 1.1 mW

Modulation: Frequency Hopping Spread Spectrum (FHSS)

IEEE 802.11 b/g:

Operating frequency: 2.4 – 2.4835 GHz

Power: 500 mW

Modulation: Orthogonal Frequency Division Multiplexing (OFDM)

Electromagnetic Compatibility

Table 10. Electromagnetic emissions.

Guidelines and manufacturer declarations – Electromagnetic emissions		
Milli pulse oximeter is intended for use in the electromagnetic environment specified in this table. It is recommended the user or consumer to ensure that the equipment is used in such an environment.		
Test	***Conformity***	***Electromagnetic environment - Guidelines***
RF emissions ABNT NBR IEC CISPR 11	Group 1	Milli pulse oximeter uses RF energy only for internal functions. Its RF emissions are very low and it is not probable to cause any interference in near electronic equipments.
RF emissions ABNT NBR IEC CISPR 11	Class A	Milli pulse oximeter is suitable for use in all establishments other than domestic, and can be used in homes and establishments connected to the public power grid (low voltage) for domestic use whenever it has the following warning: **Warning:** This device/system is intended for use only by health professionals. This device/system may cause radio interference or disrupt operations of nearby equipment. It may be necessary to adopt certain proceduresuch as re-orientation and repositioning of the Milli pulse oximeter or local shielding to reduce the effects.
Limits for harmonics emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker in public low-voltage supply systems IEC 61000-3-3	Not applicable	

Table 11. Electromagnetic immunity (general).

Guidelines and manufacturer declarations – Electromagnetic immunity			
Milli pulse oximeter is intended for use in the electromagnetic environment specified in this table. It is recommended the user or consumer to ensure that the equipment is used in such an environment.			
Immunity test	***Test level ABNT NBR IEC 60601***	***Conformity level***	***Electromagnetic environment - Guidelines***
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	± 6 kV by contact ± 8 kV by air	Floors should be of wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Testing and measurement techniques - Electrical fast transient/burst immunity test. IEC 61000-4-4	± 2 kV in power supply lines ± 1 kV in input/output lines	± 2 kV in power supply lines Not applicable	The quality of power supply should be that of a typical commercial or hospital environment.
Testing and measurement techniques - Surge immunity test. IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV line(s) to line(s) Not applicable	The quality of power supply should be that of a typical commercial or hospital environment.

Table 11. Electromagnetic immunity (general).

Immunity test	***Test level ABNT NBR IEC 60601***	***Conformity level***	***Electromagnetic environment - Guidelines***
Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests. IEC 61000-4-11	< 5% UT (> 95% voltage drop in UT) for 0,5 cycle 40% UT (60% voltage drop in UT) for 5 cycles 70% UT) (30% voltage drop in UT for 25 cycles < 5% UT (> 95% voltage drop in UT) for 5 seconds.	Not applicable	Milli pulse oximeter is always operated with a backup battery. The user must ensure that the equipment battery is fully charged.
Testing and measurement techniques - Power frequency magnetic field immunity test 50/60Hz. IEC 61000-4-8	3 A/m	3 A/m	Milli pulse oximeter cannot be used near a Magnetic Resonance Unit (MRI).
Note: UT is the c.a. voltage before the application of test level.			

Table 12. Electromagnetic immunity (equipment that is not for life support).

Guidelines and manufacturer declarations – Electromagnetic immunity – Equipment that is not for life support.			
Milli pulse oximeter is intended for use in the electromagnetic environment specified in this table. It is recommended the user or consumer must ensure that the equipment is used in such an environment.			
Immunity test	***Test level ABNT NBR IEC 60601***	***Conformity level***	***Electromagnetic environment - Guidelines***
Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields. IEC 61000-4-6	3Vrms 150 kHz until 80 MHz	3V	RF communication equipment, portable or not, should not be used near any part of the Milli Pulse Oximeter, including cables, with a separation distance less than recommended. This distance is calculated from the equation applicable to the transmitter frequency. Recommended separation distance d=1.17√P d=1.17 from √P 80 MHz até 800 MHz d=2.33 from √P 800 MHz até 2.5 GHz

Table 13. Electromagnetic immunity (equipment that is not for life support).

Immunity test	***Test level ABNT NBR IEC 60601***	***Conformity level***	***Electromagnetic environment - Guidelines***
Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test. IEC 61000-4-3	3V/m 80 MHz until 2.5 GHz	3V/m	Where P is the maximum nominal output power of the transmitter in Watts (W) according to the transmitter manufacturer, and d the separation distance in meters (m). It is recommended that the field strength established by the RF transmitter and the field strength determined through an electromagnetic inspection in the place*, is less than the compliance level in each frequency range. ** Interference may occur around the equipment with the following symbol: 
NOTE 1: In 80 MHz and 800 MHz apply a higher frequency range. NOTE 2: These guidelines may be not applicable in every situation. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.			

* Field intensity established by fixed transmitters as radio base stations, telephone (cell and wireless) and land mobile radios, amateurs, transmission radio AM and FM and TV transmission theoretically cannot be predicted accurately. To evaluate the electromagnetic environment due to fixed RF transmitters, it is recommended an electromagnetic inspection of the place. If the measurement of the field strength where Milli pulse oximeter is used exceeds the level of conformity cited above, it should be observed to verify if the equipment is in normal operation. If it is observed an abnormal operation, some additional procedures such as reorientation or repositioning of the Milli pulse oximeter may be necessaries.

**Above frequency range of 150KHz until 80MHz, field strength should be lesser than 3V/m.

Table 14. Separation distances.

Recommended separation distances between RF communication portable and mobile equipment and Milli Pulse Oximeter			
Milli pulse oximeter is intended for use in the electromagnetic environment where radiated RF disturbances are controlled. The customer or user of the oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters) and the oximeter, as recommended in this table, according to the maximum power output of communication equipment.			
Nominal maximum power output of the transmitter W	***Separation distance according to transmitter frequency m***		
	From 150 kHz to 80 MHz $d=1.17\sqrt{P}$	From 80 MHz to 800 MHz $d=1.17\sqrt{P}$	From 800 MHz to 2,5 GHz $d=2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
For transmitters with a nominal maximum output power not listed in this table, recommended separation distance d in meters (m) may be determined by the equation applicable to the frequency of the transmitter where P is the maximum power output of the transmitter in Watts (W) according to the transmitter's manufacturer. NOTE 1: In 80 MHz and 800 MHz, separation distance for the higher frequency range is applied. NOTE 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8 WARRANTY

HIT Tecnologia em Saúde LTDA, within the limits specified in this certificate assures the consumer/purchaser of this product warranty against manufacturing defects (materials) if presented within one year for the equipment, and 90 (ninety) days on accessories (cables and sensors), counting from the date of invoice issuance of the product.

The responsibility of HIT Tecnologia em Saúde LTDA is limited to repair, replace defective parts, or at the discretion of the company, replace the products/equipments, since technical department or authorized representative check failures during normal use.

This warranty will be null and void if the product is damaged by accidents, natural agents, if it is operated in disagreement with the Operation Manual, use of accessories not approved by HIT Tecnologia em Saúde LTDA, not suitable electrical installations or excessive fluctuations of electricity supply, and if shows signs of having been violated, adjusted or repaired by people not authorized by HIT Tecnologia em Saúde LTDA.

Potential losses and damages of the buyer by the malfunctioning or standstill of product under any circumstances will not be manufacturer's liability.

HIT Tecnologia em saúde LTDA undertakes to provide both free and paid services only in localities which maintain its own workshops or authorized representatives.

Freight expenses, transportation, lodging and packaging are responsibility of the consumer/purchaser, except in cases covered by the warranty.

If the property of product is transferred during the warranty period, this will be transferred with all rights and will continue in force until the end of the period counting from the date of purchase by the first consumer/purchaser.

This warranty certificate is the only responsibility statement for HIT Tecnologia em Saúde LTDA, no representative is authorized to open exceptions on their behalf.

Claims for damage during transportation must be registered immediately with the carrier company. All correspondence relating to the product must specify product name, model and serial number, as described in the equipment.

Certifications of the Company and Product

Good manufacturing practice (GMP)

Issued: 07/13/2010
Renewed every 2 years

Health License

Certificado em: 04/19/2011
Renewed annually

INMETRO Certification

Issued: 03/10/2011.
Validity: 03/10/2016 .

NBR IEC 60601-1-4: 2004

Electro medical equipment
Parts 1-4 – General safety requirements
Collateral Standard: Programmable
electro medical systems.
Issued 10/03/2011
Validity: 10/03/16.

NBR IEC 60601-1: 1994 + Amendment:1997

Electro medical equipment
Part 1 – General safety requirements.
Issued 03/10/2011
Validity: 03/10/2016.

NBR IEC 60601-1-2: 2006

Electro medical equipment
Parts 1-2 – General safety requirements
Collateral Standard: Electromagnetic
Compatibility - Requirements and testing
Issued 03/10/2011
Validity: 03/10/2016.

NBR ISO 9919: 1997

Pulse oximeter for medical use
Prescriptions
Issued 03/10/2011
Validity: 03/10/2016.

Manufacturer Data

Register in ANVISA / MINISTRY OF HEALTH - Brazil: 80583710002

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Annotations

Annotations