USER MANUAL

DEFIBRILLATOR MONITOR
Mod. 3850B-BIPHASIC

Rx Only

IMPORTANT!
DEFIBRILLATOR MONITOR Mod. 3850B-BIPHASIC is intended for use by physician/medical trained in the operation of the equipment and expertise in advance cardiac life support, defibrillation procedures, cardioversion, monitoring vital signs and pacing. It can also be operated by a paramedic or nurse, under the direct supervision and order of a physician/medical, and who has, at a minimum, the following skills and training:

- CPR training.
- ACLS training equivalent to that recommended by the American Heart Association.
- Training in the use of the DEFIBRILLATOR MONITOR Mod. 3850B-BIPHASIC.

This device is rated IPX2 per IEC529.

RESPONSIBILITY FOR INFORMATION
It is the responsibility of our customers to ensure that the appropriate person(s) within their organization have access to this information; including general safety information provided in section ***"NOTES AND WARNINGS"***.

VERSION HISTORY
This User Manual (ref. 16184/0916A - MANUAL DE USO DESFIBRILADOR 3850 B BIFÁSICO) describes the Defibrillator Monitor Mod 3850B-Biphasic with software version 3.28.1
You can verify the software version of the device during power up. The software version is displayed on screen.
Edition date: 2023/07/25

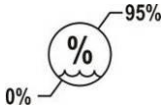
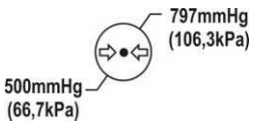
MANUFACTURER

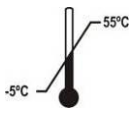
Av. Colón 5756/60 – C.P. X5003 DFP – Bº Quebrada de las Rosas - CÓRDOBA – REPÚBLICA ARGENTINA.Tel.: +54 351 484 8016 – Cel.: +54 351 156 750048.
E-mail: *soporte@feaselectronica.com.ar*
Web: *www.feaselectronica.com.ar*

TM: Eng. Jorge F. Feas - PM: 12341991 and
Eng. Julio Brezzo - PM: 18015606.
The equipment is authorized by A.N.M.A.T. PM 1125-15.
The equipment is exclusively use for medical professionals and medical institutions.

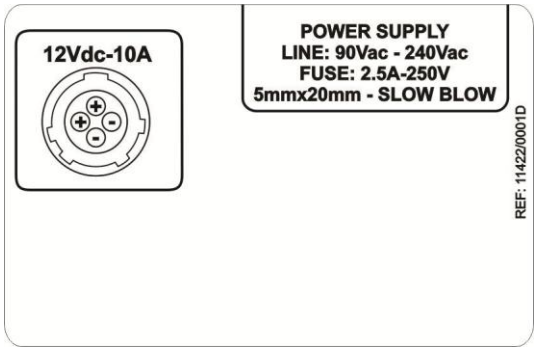
TABLE OF CONTENTS

SYMBOLS AND REFERENCES LIST

	Attention! Consult accompanying documents.
Rx Only	Prescription Only. U.S. federal law restricts this device to sale by or on the order of a physician.
CLASS I	Protection against electric shock: "CLASS I" (with protective earth (ground)).
REF	Reference code.
EC REP	Authorized representative.
	Line/Battery charge.
	Manufacture date.
	Not suitable for explosive atmosphere.
	Connected to line or external 12 Vdc.
	Right.
	Left.
	Protective earth (ground).
	Protect from rain.
	Fragile.
	Charge button.
	Sync key.
	Disarm key.
	Manufacture.
	Alarm silence.
	Storage and transport relative humidity (non-condensing), maximum and minimum.
	Storage and transport pressure, maximum and minimum.

	Defibrillation-proof type CF.
	MR (Magnetic Resonance) Unsafe
SN	Serial number.
IPX2	Protected against vertical waterfalls with a maximum inclination of 15 degrees.
	Battery fully charged.
	Low battery.
	Battery discharged.
	Sound volume.
	Screen contrast.
	Up.
	Down.
	Warning! High voltage.
	Do not pile more than 3 boxes.
	Box orientation.
	Shock button.
	Recorder.
	Alarm key.
	Follow the instructions.
	For disposal follow local regulations.
	Storage and transport temperature, maximum and minimum.

Label according to Annex III.B of Disp. A.N.M.A.T. 2318/02 (T.O. 2004) and Disp. A.N.M.A.T. No. 9688/2019.



Back label

NOTES AND WARNINGS

WARNING! The followings are descriptions of the general dangers and unsafe usage of the **Defibrillator Monitor Mod 3850B-Biphasic**, which can lead to death or severe damage to the user or the equipment.

- You should read this manual before beginning installation and use of equipment.
- This equipment is meant to be used by persons trained in professional health care.
- Defibrillator Monitor Mod. 3850B-Biphasic use is limited to a single patient at a time.
- This equipment must be used in conjunction with signs and symptoms of the patient. The equipment is designed to be an aid in clinical diagnosis.
- Do not reuse any element disposable or single use. The time limit of use thereof is that indicated by the manufacturer.
- The expiration date of this equipment is of 5 years from its purchase, when that time is over, dismiss the equipment and its accessories following the local regulations in force.
- In case of discarding the equipment or one of its accessories, at the end of its useful life, do it according to the local regulations, normative or laws in force.
- In order to take care of the environment, you can send the equipment to feas ELECTRÓNICA for its disposal.
- RISK OF ELECTRICAL SHOCK, if you remove the equipment's lead. Do not remove the equipment's lead. Ask for assistance from qualified and authorized personnel.
- There is a risk of Electrical Shock and death. Do not use this equipment if you doubt of the integrity of any cable. Check the cables periodically (disconnect them before) to verify their integrity; paying special attention to cable points close to connectors and paddles. In case you find an irregularity, request the part to our Customer's Service.
- Do not touch the Power Line connectors with wet hands.
- The Defibrillator Monitor Mod 3850B-Biphasic is designed with covers and plastic handles to minimize the risk of electrical shock. When it is not plugged to the line power its energy will be provided by the battery, without ground reference.
- The multi-outlet power extension cord shall not be placed on the floor.
- The multi-outlet power extension cord should only be used to power equipment that is part of the system.
- All combinations of medical equipment with non-medical equipment must comply with the total leakage current specified in IEC 60601-1, Cl. 16.
- When combined instruments, the sum of the leakage currents can be dangerous for both the patient and the operator. If you can't determine the leakage current of each team on the specifications of each, technical staff will take measurements to ensure the installation complies with the requirements of EN 60601-1, Cl. 16. In any case, the user should consult the manufacturer to ensure that the sum of leakage currents will not jeopardize patient safety.
- The device is intended to be connected to:
  - Installations in medical rooms belonging to Groups 0, 1, 2a and 2b, according to AEA90364-7-710 (IEC 60364-7-710).
  - Installations according to AEA90364-7-771, installations in buildings in general, to grounded outlets according to IRAM 2071.
  - Mobile units, to the cigarette lighter connector of the vehicle.
- The equipment must be connected to an approved electrical installation that includes a correct grounding according to the local legislation in force. Do not use adapters or replace the device's original cables. If the plug does not match the installation, please contact our Customer Service for the provision of a suitable cable.
- You must make sure that the AC outlet, to which you will plug the device, has a groundling and is in good condition.
- Do not connect this device to an outlet controlled by a switch on/off.
- Verify the AC voltage range matches the voltage at which the equipment is to be connected. If does not match, contact feas ELECTRÓNICA's Service Customer.
- Verify the AC frequency indicated on the back panel matches the AC frequency which the device is to be connected. If does not match, contact feas ELECTRÓNICA's Service Customer. Do not use the device in those conditions. The ECG waveform will be affected by noise and will not be able to use SYNC mode.
- If you have any doubts about the integrity of the ground, either the cable or the installation of the building, use the device from the internal battery. In case that the battery is discharge or damage, don't use the equipment.
- The disconnection of the equipment from the Power Line does not de-energize it, since it has an internal battery, so you must also set the selector switch to OFF.
- Caution, leave one end of the power cord accessible so that in the event of an emergency, it is easy to disconnect the equipment from the Power Line.
- Do not disconnect power by pulling the cord. Disconnect the connector firmly grasping.
- Do not excessively bend the plug or power cord or place heavy objects on them, which could cause damage.
- Do not immerse the electrical connector in liquids. This can damage the cable or connector by corrosion.
- RISK OF FIRE AND/OR EXPLOSION: do not use this equipment in the presence of flammable gases (anesthetics, oxygen, etc.).
- Not use or store inflammable substances near the equipment.
- Avoid installing this equipment in places where liquids can be spilled on it. Avoid direct exposure to splatter, sprayer or air vented from nebulizers or humidifiers.
- Do not place containers with water, chemicals or any small metal objects on the equipment.
- Do not use this equipment under the rain. You have to make sure that the equipment, the cables and paddles are dry before you start using them.

- Do not place the equipment on the patient or where it can fall over the patient. Place it next to the patient where it's comfortable for its use.
- Never attempt to introduce sharp, metallic or other objects into any aperture on the equipment.

CAUTION! The followings are the general descriptions of precautions and unsafe usage that could cause slight injuries, damage or wrong performance of the equipment.

- The equipment is not suitable to be used for extra-hospital transport either by air.
- The operation of the equipment can be affected by the presence of CAT scanner.
- The operation of the equipment can be affected by the presence of portable and mobile RF communications equipment.
- Do not use this equipment near Magnetic resonance imaging equipment (MR o MRI).
- The operation of the equipment below the specified amplitudes can cause inaccurate results.
- The Defibrillator should not be used adjacent or stacked with other equipment, if it is necessary to use it adjacent or stacked with other equipment, the Defibrillator should be observed to verify its normal functioning in the configuration in which it is being used.
- To attach wires and sensors always use hypoallergenic tape.
- Do not store the equipment in deposits or between periods of use in places where the sun shine directly on it. Risk of damage to the cover of the equipment, parts and accessories.
- Avoid installing this equipment in those places where the sun hits directly.
- Do not place heavy objects on the equipment.
- Do not drop the equipment when moving it.
- Use the equipment on a flat and stable surface.
- Important!! If using a bracket, make sure that the bracket holds at least twice the weight of the equipment. If you have any questions, please contact feas ELECTRÓNICA.
- Do not push the keys of the frontal panel with pushing or slicing elements. This will produce permanent damage to the keypad. Only push the keys of the frontal panel with your fingers. Do not press the buttons with your nails.

ACCESSORIES MESSAGES

WARNINGS

- The proper operation of the equipment and protection against the effects of the discharge of a cardiac defibrillator requires the use of original accessories intended for this equipment. Only use original accessories provided with the equipment or those accessories specially indicated for this equipment.
- The use of accessories, transducers and cables other than those specified, with the exception of the transducers and cables sold by the equipment manufacturer as replaceable parts of internal components, may cause an increase in emissions or a decrease.
- The user shall be responsible to check the compatibility between the accessories used and this medical device.

CAUTIONS

- Do not clean or disinfect the accessory's cable, accessories, and parts of the equipment or its main body with sodium hypochlorite, solvents, acids or abrasive products. For cleaning and disinfection of equipment follow the instructions given in this manual.
- Risk of equipment breakdown. Do not sterilize this equipment or its parts or accessories in autoclave or ethylene oxide. Do not submerge any part of this equipment in water or other liquids or use abrasive cleaners. Do not spray or spill liquids on the equipment or its accessories. Do not allow any liquid entering the connectors or other openings of the housing. If you accidentally spill liquid on the equipment, turn the energy switch OFF (because the equipment has internal battery) and disconnect it the power line (in case it is connected to the power line), clean it and dry it before reuse. If in doubt about equipment security, send it to an authorized technical service.

BATTERY MESSAGES

WARNINGS

- The battery must be replaced by an original battery for this equipment. Replacement with another type of battery can result in an unacceptable risk of temperature rise, fire and/or explosion of the battery or the equipment.

CAUTIONS

- The equipment has rechargeable battery type must remain connected to the power line during periods when it is not used.
- If the capacity of the internal battery is below 80% the equipment will be able to function from line power or Ext +12 Vdc.
- Do not discharge the battery completely.
- Recharge the battery immediately after it's been used.
- The internal battery of this equipment cannot be replaced by the user. It has to be replaced by qualified and authorized personnel.
- In case you replace the battery follow the local instructions to dispose Ni-Mh batteries or send them to feas ELECTRÓNICA for disposal.
- When the device is stored in warehouse, should be put to charge at least once every 60 days for at least 3 hrs. at 25ºC ±3ºC temperature, to prevent battery damage.

DEFIBRILLATOR MESSAGES

WARNINGS

- Discharging a defibrillator directly to a healthy person's chest can be lethal.
- In order to decrease the time pre-shock should follow the specific CPR protocols of the place.
- Neonatal and pediatric defibrillation energy levels should be set based on the specific clinical protocols.
- Conscious patients must be anesthetized or sedated before performing synchronized cardioversion.
- Before performing cardioversion, correct synchronism with R wave must be assess.
- When defibrillating the patient be careful to avoid the contact between patient's body parts (exposed skin, head, arms and legs) with metallic objects (such as parts of the bed) that might generate non desired paths for the defibrillation current.
- Rescuers performing chest compressions during external defibrillation are exposed to leakage currents.
- Do not touch the bed, patient's body, or any equipment connected to the patient during defibrillation. A severe electrical shock can result.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- This equipment is protected against the effects of defibrillation.
- Make sure you know where and how to position the paddles for monitoring and defibrillation. See section **External paddles positioning**.
- When defibrillating with paddles, use your thumbs to operate the SHOCK buttons in order to avoid inadvertent operator shock.
- When positioning the paddles on the patient for energy discharge, make sure no one is near or in contact with the patient.
- During the preparation of the paddles, avoid spilling conductive paste or gel over hand or in the paddles handles as this might cause and electric shock to the operator.
- Avoid the excess of conductive paste or gel over the patient's thorax as it could generate and electric path over the patient's skin.
- After use, you should keep the paddles clean, free of conductive gel and dirt in general, since using uncleaned paddles can lead to uncontrolled conduction paths that lead to an unwanted electric shock to the operator, either during a typical procedure or during an energy test.
- Take special care to keep the paddles pressing firmly on the patient, since a poor contact with the patient may cause interference (noise) resulting in a false trigger and shocks the patient, as well as cause burns at the shock time.
- Never defibrillate a patient with the paddles wet.
- Never defibrillate a patient on a wet surface.
- More than 10 energy discharges should not be performed during the Test of Energy Delivered; considering that the minimum waiting time is 1 minute, between discharges.

CAUTIONS

- For safety reasons, after completion of the energy charge and elapsed the "automatic disarm time", the defibrillator will discharge the energy internally automatically. By default, the "automatic disarm time" is 60 seconds. For more information on how to configure the "automatic disarm time" refer to **SETUP MENU** section.
- Verify that the devices connected to the patient are protected against defibrillation before shock to the patient. If necessary, disconnect the patient from those devices that are not protected against defibrillation so that they are not damaged by the shock.
- It is recommended **DO NOT USE** Xylocaine to apply a shock.
- Be sure to know the methods used to discharge the energy charged in the Defibrillator Monitor Model 3850B.
- Do not discharge the Defibrillator Monitor placing paddle against paddle or in the paddle support.
- It is suggested to perform the Test of Energy Delivered according to the domestic policy of the Institution Health or at least once a week.
- Before performing the Test of Energy Delivered, external paddles must be connected and place on the paddle's holder. Perform the verification with the equipment connected to line power.

ELECTROSURGERY MESSAGES

WARNINGS

- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- The neutral electrode of the electrocautery must have adequate contact with the patient, otherwise it may cause burns to the patient.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- The use of an electrocautery it can cause interference in the operation of this device.

CAUTIONS

- Operation of this equipment may be affected by the presence of strong electromagnetic or radio frequency fields such as those produced by electrocautery.

ECG MESSAGES

WARNINGS

- Conductive parts of electrodes and associated connectors for applicable parts shall not contact with other conductive parts of equipment (metal part), including metal parts of equipment connected to ground.
- Make sure you know where and how to position the electrodes for monitoring. See section **"Placing electrodes"**.
- After the delivery of a defibrillator shock, if monitoring is undertaken with a combination of gel and patch/paddle, the ECG may initially display no signal or asystole, regardless of the true rhythm.
- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- The heart rate may be affected in the presence of arrhythmias. The cardiotachometer uses an algorithm to determine the heart rate.
- This equipment may reject pacemaker pulses of the following characteristics: with amplitude of ±2 mV to ±700 mV and a pulse width of 0.1 ms to 2 ms, anyway keep the patients with pacemaker under close surveillance.
- Electrocardiographic monitoring equipment and its accessories shall not be considered life-supporting medical equipment.
- PATIENTS WITH PACEMAKERS. The rate meter may continue to count the pacemaker rate during some occurrences of cardiac arrest or some arrhythmias. Not based entirely on the rate meter alarms. Keep patients under close surveillance.
- Be careful when making a temporary suspension audible alarm signal (silence), keep the patient under close surveillance at all times. If the alarm signals are selected, the visual alarm signal will continue to indicate an alarm condition if this occurs.
- Maximum channel height: 21.2 mm. Suitable for use as a monitor up to 2 meters away.
- Carefully route the patient cables, extension cables, oximetry sensors and/or pacemaker electrodes to reduce the possibility of patient entanglement or strangulation.

CAUTIONS

- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- During monitoring, the ECG electrodes should be re-positioned every 48 hours to maintain good signal quality. After 48 hours, the electrode's conductive paste or gel begins to dry and the patient's skin may begin to chafe.
- For ECG monitoring using hypoallergenic adhesive electrodes. The company recommends 3M ECG electrodes.

PACEMAKER MESSAGES

WARNINGS

- Conductive parts of electrodes and associated connectors for applicable parts shall not contact with other conductive parts of equipment (metal part), including metal parts of equipment connected to ground.
- Make sure you know where and how to position the pacer electrode for monitoring. See section **Transcutaneous pacer usage**.
- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- To avoid risk of electrical shock, do not touch the gelled area of the pads while pacing.
- Use demand mode whenever possible. Use asynchronous mode when the presence of motion artifacts or other sources of artifacts, of the ECG, render the R-wave detection is not reliable.
- To change the pacing mode is necessary that the pacemaker is off.
- When pacing in demand mode is performed, the patient cable must be connected from the patient to the equipment. If you do not connect the cable patient cannot turn on the pacemaker. If the pacemaker is on and disconnect the patient cable, the pacemaker will turn off.
- If you will shock the patient, at move the selector switch from the MONITOR position to the selected energy value, the pacemaker will turn off.
- Carefully route the patient cables, extension cables, oximetry sensors and/or pacemaker electrodes to reduce the possibility of patient entanglement or strangulation.
- Verify mechanical capture by radial pulse when electrical stimulation (pacing) is applied. Consider the use of sedation or an analgesic, in case the patient experiences discomfort or pain during the application of electrical stimulation (pacemaker).

CAUTIONS

- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- If the pacemaker function is used in demand mode for extended periods of time, may be necessary to apply new ECG electrodes.

OXIMETRY MESSAGES

WARNINGS

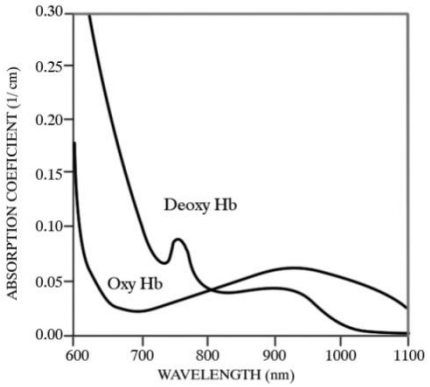
- This is a functional measuring cannot be used to evaluate the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter cannot measure the contribution to total error of a probe/monitor system.
- The oximeter is calibrated to display the visualization of functional oxygen saturation.
- Significant dysfunctions of hemoglobin affect the accuracy of the SpO_2 measurement.
- SpO_2 measurement can be affected by excessive ambient light. If necessary, cover the sensor area with an opaque material (e.g., surgical gauze).
- Contrast inks introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine and fluorescent, can affect the accuracy of SpO_2 reading.
- Any condition that may reduce the blood flow, like the usage of cuff to measure the blood pressure or extreme systemic vascular resistance might cause an improper result in the SpO_2 and pulse rate measurements.
- Avoid using the Oximetry sensor in any extremity were a baumanometer or any type of catheter is placed.
- Before placing the Oximetry sensor remove nail polish or fake nails, they might cause mistakes in the SpO_2 reading.
- If the extremity is in an elevated position, could compromise venous return and provide lower saturation measurements. Therefore, it is recommended to keep the Oximetry sensor at the height of the heart.
- Do not place the Oximetry sensor across the foot of a pediatric patient or on the foot itself.
- All necessary information regarding the toxicity and/or action on the tissues of the materials with which the patient or anyone else can contact is indicated in each attachment
- It should be noted that values between 70% and 100% SpO_2 measured by the pulse oximeter will be within ± 2% of the value measured by a co-oximeter, due to the statistical distribution.
- If the equipment power is interrupted, when returning energy, the equipment will start with the last configuration set by the operator, except for the minimum oximetry alarm limit, that if it was off or set to less than 85%, will be adjusted to 85%, by regulatory requirement, and if has been set to more than 85% will retain the value set by the operator.
- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- Be careful when making a temporary suspension audible alarm signal (silence), keep the patient under close surveillance at all times. If the alarm signals are selected, the visual alarm signal will continue to indicate an alarm condition if this occurs.
- Carefully route the patient cables, extension cables, oximetry sensors and/or pacemaker electrodes to reduce the possibility of patient entanglement or strangulation.

CAUTIONS

- Only use the Oximetry sensor provided with the equipment or those specially indicated for this equipment.
- The user is responsible for ensuring compatibility between the sensor, extension cable and this equipment.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- When placing the Oximetry sensor "Y" with tape does not stretch or tighten it. If the tape is too tight can cause inaccurate readings and blisters on the skin of the patient (the blisters are caused by lack of skin breath, not by heat).
- Replace the Oximetry sensor every 2 hours to allow the patient's skin to breathe.
- The operation of the Oximeter can be affected by the presence of Computed Tomography equipment.
- In the presence of strong electromagnetic fields, the reading of SpO_2 may not be stable, displaying different values in every second. The device reading will stabilize after the interference ceases or when the device moves away from the emission source.
- The maximum time of application of the Oximetry sensor is indicated in its own manual.
- The specific use of the Oximetry sensor concerning: the patient population (e.g., age, weight), body part or tissue type to which it applies and application (e.g., environment, frequency of use, anatomical place, mobility) is indicated in its own manual.
- Be sure to know where and how to position the Oximetry sensor. Refer to the user manual that accompanies the sensor.

MEASUREMENT PRINCIPLES

The SpO_2 module measures the SpO_2 content with a continuous non-invasive method to measuring oxyhemoglobin saturation. The principle of measurement is determining SpO_2 under cyclic congestion status of the tissues during pulsation. The method determines how much light emitted by the sensor light source penetrates the patient's tissue (finger or ear, for example) and reaches the receiver. The amount of light penetrating the tissue depends on many factors, many of them are constant; but one of them, the blood flow, varies with time as it is pulsed, therefore, the oxygen saturation of arterial blood can be calculated by measuring light absorption during pulsation. The pulsation control system provides a pulse waveform and a pulse signal. For the measurement, the wavelength of red light is 660 nm and 940 nm for infrared light. The optical power delivered to the patient is 4 mW (milliwatts).



Absorption spectral characteristic of hemoglobin

ALARM WARNINGS

- Because the patient is monitored but not attended continuously by an operator, it is for this reason that the alarms must be configured and adjusted appropriately.
- If an alarm limit is set to "---" (inhibited), the alarm condition for that limit will not be detected neither manifested by the alarm signals (visual and auditory).
- According to the intended use of the device, the user is considered a medical professional trained in the operation of the device and knowledge, among others, in the monitoring and surveillance of vital signs, so any adjustment made alarm limits by an operator (paramedics or nurse) should be carried out under the direct supervision and user commandment.

MAINTENANCE MESSAGES

WARNINGS

- Before any cleaning, make sure the device is turned off. REMEMBER: The device has internal battery, so even disconnected from the AC line, may be turn on. Verify the selection switch is in the OFF position and the display doesn't contain instructions and is turned off.
- Risk of explosion or fire! Do not allow spill water or other liquid on the device. Unplug the power cord before cleaning or disinfecting equipment.
- It is not allowed to modify the equipment.
- Not modify this equipment without authorization from the manufacturer.
- If you modify this equipment must perform appropriate tests and inspections to ensure continued safe use of equipment.

CAUTIONS

- Risk of equipment breakdown. Do not sterilize this equipment or its parts or accessories in autoclave or ethylene oxide. Do not submerge any part of this equipment in water or other liquids or use abrasive cleaners. Do not spray or spill liquids on the equipment or its accessories. Do not allow any liquid entering the connectors or other openings of the housing. If you accidentally spill liquid on the equipment, turn the energy switch OFF (because the equipment has internal battery) and disconnect it the power line (in case it is connected to the power line), clean it and dry it before reuse. If in doubt about equipment security, send the same to an authorized technical service.
- Risk of equipment breakdown. No sterilize defibrillation paddles of this device in autoclave or ethylene oxide.
- Do not clean the external cover, the cables or the paddles with abrasive or acid products.
- Do not clean or disinfect accessory cables, accessories and parts of the equipment or the main body thereof with sodium hypochlorite (bleach water), solvents, acids or abrasive products. For cleaning and disinfection of the equipment and its accessories, follow the instructions in this manual.
- During storage in warehouses and between uses, respects the conditions of temperature, pressure and humidity as defined in this manual and periods of recharge the internal battery specified.
- It suggests an annual contrasting against calibrated simulators.

- In case of fuses are damage replace with fuses of the same type and value. If the failure persists, please contact our Customer Service.
- This equipment has line fuses in both the neutral pole and Phase Line.
- This equipment is not sterile or sterilizable, in the case of accessories; refer to the user manual corresponding to that accessory.
- The user shall be responsible to check the compatibility between the accessories used and this medical device.
- When the device is stored in warehouse, should be put to charge at least once every 60 days for at least 3 hrs at 25ºC ±3ºC temperature, to prevent battery damage.

Screen visualization

The data visualized in the screen are updated once every second, same for SpO_2 and pulse rate. The visualized data is the measured values; they are not averaged and are not perform any other process.
The alarm gets activated at the first pulse rate or SpO_2 value, out of range, it might have one second delayed to generate and display the alarm signal.

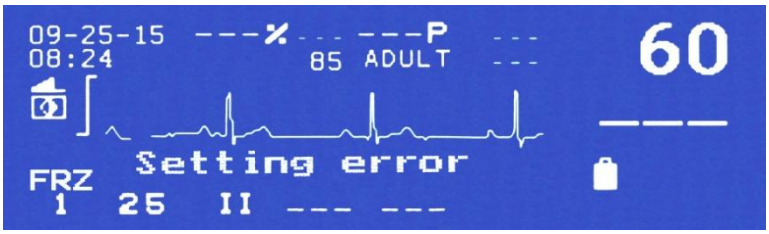
Calibration

An annual contrasting the equipment with calibrated simulators is suggested.

SCREEN MESSAGES

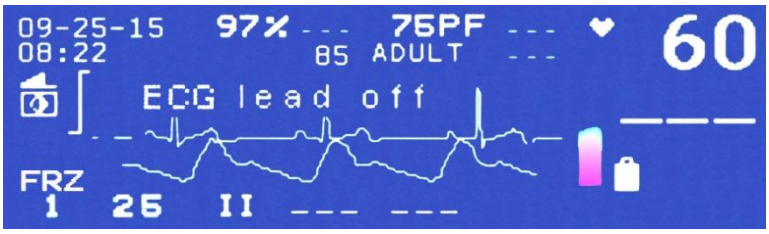
Warning messages from Configuration

"Setting error" This message is displayed when, turning on the device, is located that there are differences between the stored configuration of factory and the current configuration.



Warning messages from the ECG

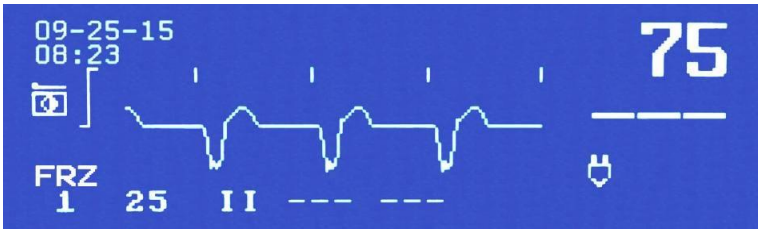
"ECG lead off" This message is shown when one of the ECG electrodes loses connection with the patient. When this message is displayed can be selected only the leads DI, DII and DIII.



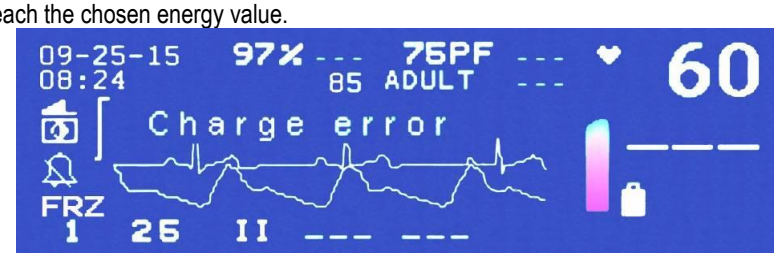
"ECG Saturated" This message is displayed when, for some reason, ECG channels receive more than ±5 mV signal at its inputs, making inoperative ECG monitoring (Paddles or Patient ECG Cable). This can happen during defibrillation.

Indicator of pacemaker spike detection

The following figure shows the indication of the presence of pacemaker's spikes on screen:



"Charge error" This message is shown when, once the charging command is started, for some reason and after a certain time the charged energy does not reach the chosen energy value.

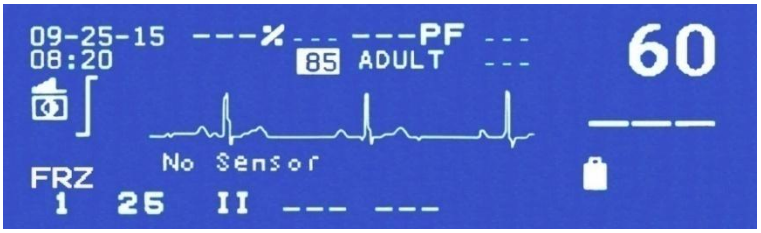
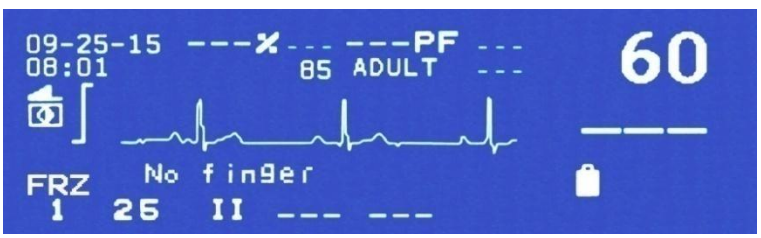


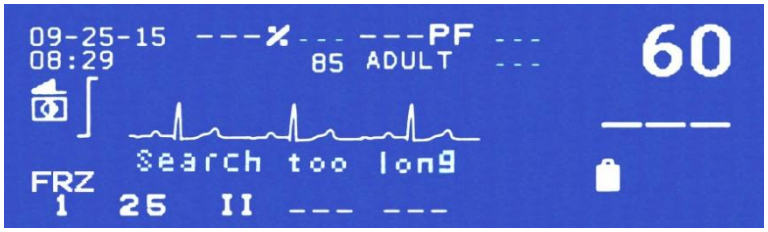
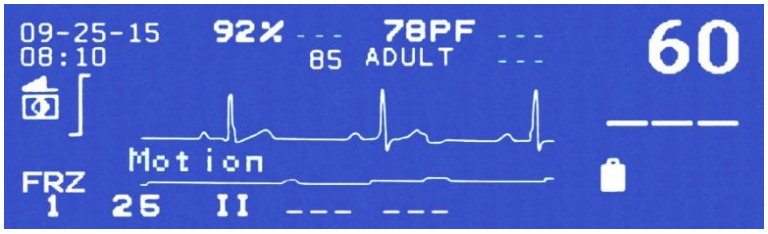
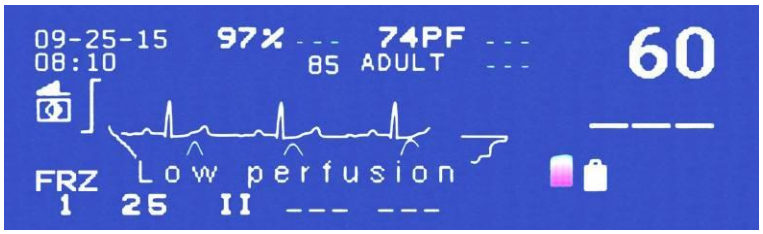
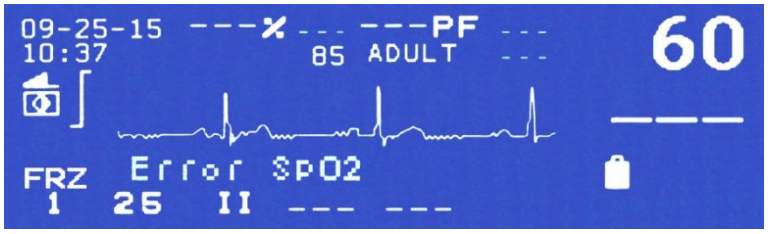
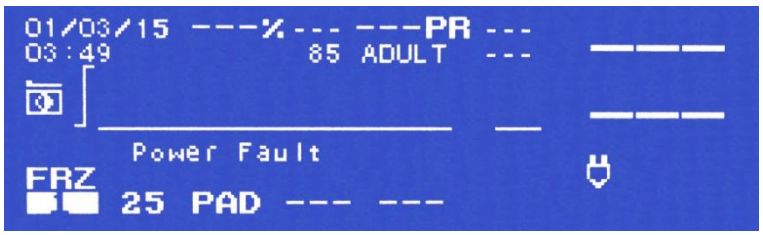
Test messages of energy delivered

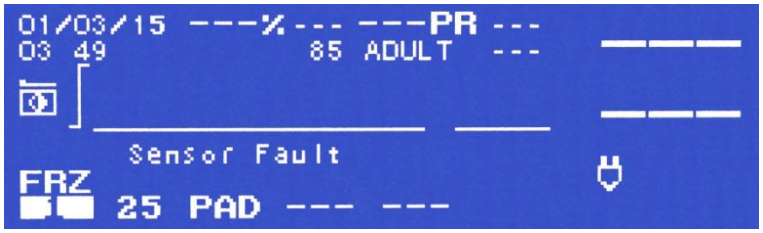
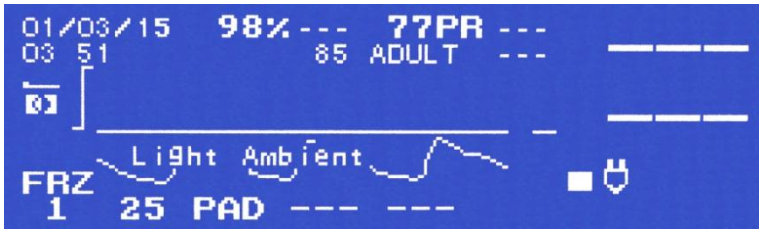
"Pass": This message is displayed upon completion of the energy test in the event of a successful outcome.

"Fail": This message is displayed upon completion of the energy test in case of a failed result.

Warning messages from the oximeter

No sensor	This message will be displayed while the Oximetry sensor is not plugged to the device. 
No finger	Once connected the Oximetry sensor, this message will be displayed while the sensor is not placed to the patient. 

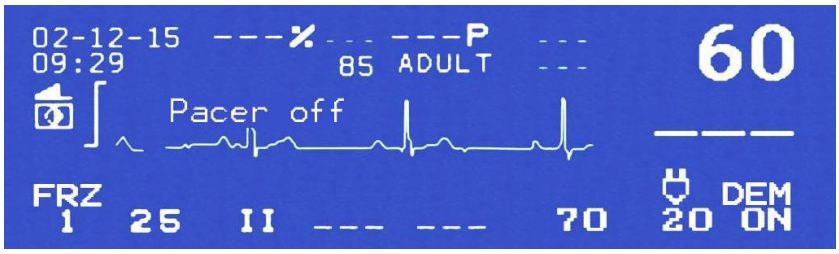
Searching	After placing the sensor on the patient, the message **"Searching"** is displayed while the oximeter detects pulse.
	
Search too long	If pulse is not found after a long period of time, the message **"Search too long"** will be displayed.
	
Motion	Once connected the Oximetry sensor and if the device detects patient movement, this message will be displayed.
	
Low perfusion	In the presence of a weak signal or low perfusion will display the message **"Low perfusion"**.
	
Error SpO_2	If there is no communication with the Oximeter module the message **"Error SpO_2"** will be displayed.
	
Power fault	Indicates a power supply failure in the Oximeter module.
	

Sensor fault	Indicates that there is a problem with the Oximetry sensor.
	
Interference by ambient light	When interference is detected by ambient light, the message "Light Ambient".
	

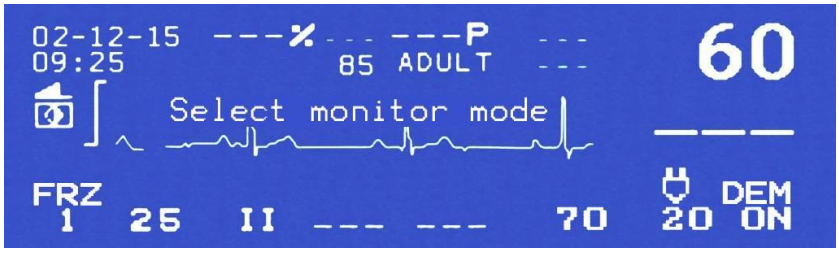
Warning messages Transcutaneous Pacer (TPM)

"Pacer lead off" This message is displayed when an electrode pacer loses contact with the patient and pacer pulse is not applied.

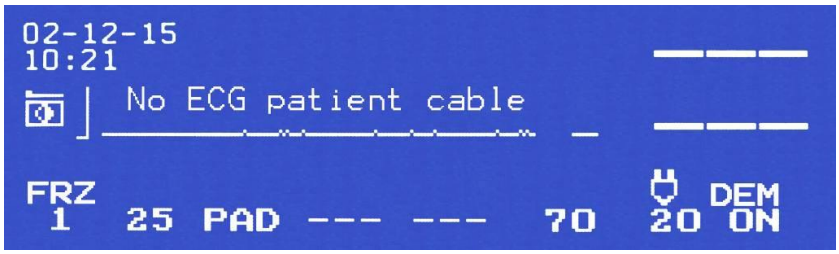
"Pacer Off" This message is displayed when the pacemaker is on and the selector switch moves from position "MONITOR" to the "2 Joules" position, or when the pacemaker is on and mode demand (DEM), and the patient cable is disconnected from the equipment.



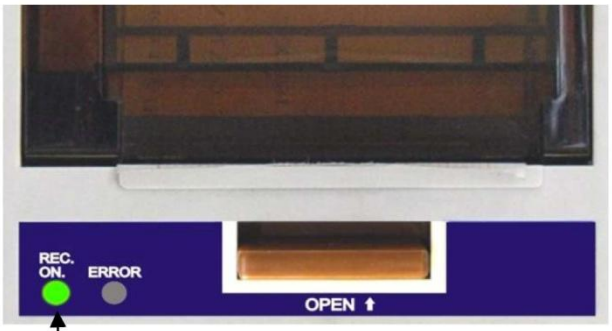
"Select monitor mode" This message is displayed when you try to turn on the pacemaker, regardless of the selected mode, and the selector switch is in a position of energy selection.



"No ECG patient cable" This message is displayed when you try to turn on the pacemaker in demand mode (DEM) and patient cable is not connected to the equipment.



Warning messages RECORDER module



The green light on indicates that the recorder is powered up and ready to RECORD.

The red light on indicates an error in the recorder module.
This may be due to 3 reasons:
- The gate is open.
- There is no paper.
- The driver threw a recorder error.

The error message will continue as long as the cause or causes that generate it.

Warning messages BATTERY

When the device's battery is fully discharged and the device is about to power down, the screen will display messages **"Battery discharged"** and **"Powering down"** (see figure below), and in 120 seconds the device automatically turns off. These messages are accompanied with auditory alarms signal of high priority as described in section **"AUDITORY ALARM SIGNALS OF HIGH PRIORITY"**.

1. INTRODUCTION

This user's manual provides instructions for the installation, operation and basic maintenance, also for safe and appropriate use of the DEFIBRILLATOR MONITOR 3850B-Biphasic.

BEFORE YOU START USING THE DEVICE, READ THE MANUAL AND GET FAMILIAR WITH ITS CONTENT.

1.1. DEVICE DESCRIPTION AND INTENDED USE

1.1.1. Description

The model 3850B-Biphasic of feas ELECTRÓNICA is an external defibrillator monitor of rectilinear biphasic waveform capable of delivering up to 200 Joules of energy, selectable by steps; it may be used in asynchronous or synchronous mode to perform synchronized cardioversion by using the R-wave of the patient ECG as a timing reference. The manual defibrillation implies that the operator must set the energy, initiate charge and press shock button. The energy delivery is made through external paddles.

It also allows ECG monitoring, with measure of Heart Rate, through paddles, or through 5 wires or 3 wires patient ECG cable allowing the selection of I, II, III, aVR, aVL, aVF and C(precordial) leads depending on the cable. Optional pulse oximetry (SpO_2) monitoring is also available, plotting plethysmography waveform and a bar graph indicating the pulse amplitude, indicating SpO_2 and pulse rate values on display. Both, ECG and SpO_2, allows alarms settings of heart rate, SpO_2 and pulse rate.

It is portable, powered by an internal rechargeable battery, by ac line 90 Vac - 240 Vac, 50 Hz or 60 Hz, or an external supply of 12 Vdc.

Optional transcutaneous pacer is available, to apply temporarily pacing a patient's heart in external non-invasive way, in fixed mode (asynchronous) or demand (synchronous) through electrodes.

A thermal recorder is also optionally available. Two real time waveforms can be registered: an ECG lead and the plethysmography waveform, optionally. The record can be initialized in manual mode by the operator when decided or in automatic mode during energy charge and energy shock.

The optional parameters combination is detailed in the next table:

Ref.	Description
14634	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY 3850B BIPHASIC.
14635	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY AND RECORDER 3850B BIPHASIC/R.
14636	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY AND PACER 3850B BIPHASIC/TPM.
14637	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY, RECORDER AND PACER 3850B BIPHASIC/R/TPM.
14638	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY AND SpO_2 3850B BIPHASIC/SpO_2.
14639	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY, RECORDER AND SpO_2 3850B BIPHASIC/R/SpO_2.
14640	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY, PACER AND SpO_2 3850B BIPHASIC/TPM/SpO_2.
14641	DEFIBRILLATOR MONITOR WITH INTERNAL BATTERY, RECORDER, PACER AND SpO_2 3850B BIPHASIC/R/TPM/SpO_2.

1.1.2. Intended Use

Place: It is intended to be used in a great variety of clinical/hospital ambient such as Intensive Care, Shock Rooms, Coronary Care Units, Operating Rooms, Emergency Room, Hospital Wards and also Out-Of-Hospital or in mobile units such as ambulances.

Operator/User: To be used only by qualified medical staff trained in the operation of the equipment and expertise in advanced cardiac life support, procedures defibrillation, cardioversion, cardiac pacing and monitoring vital signs. It can also be used by paramedics or nurses under the direct supervision and order of a physician.

Patient: It is intended for used in patient neonates, pediatric, adults and senior adults; victims of cardiac arrest, ventricular fibrillation, ventricular tachycardia, supraventricular tachycardia, atrial fibrillation, bradycardia or other fatal arrhythmias.

1.2. INDICATIONS AND CONTRAINDICATIONS

1.2.1. Defibrillation and Cardioversion

Indications:

Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients who are pulse less, unconscious and not breathing on their own. The synchronous fibrillation or cardioversion is indicated for termination of atrial fibrillation, atrial flutter or atrial tachycardia.

Contraindications:
Asynchronous defibrillation therapy is contraindicated in patients that exhibit one or any combination of the following:

- Responsiveness.
- Spontaneous breathing.
- Palpable pulse.

Inappropriate defibrillation or cardioversion of a patient (e.g., without malignant arrhythmia) can cause ventricular fibrillation, asystole or other dangerous arrhythmias.
The defibrillation asystole may inhibit recovery of the heart's natural pacemaker and completely eliminate any possibility of recovery. Energy should not be applied routinely during asystole.
The incorrect application of the paddles or gel pad (see section "**EXTERNAL PADDLES PREPARATION**") in defibrillation can lead to inefficacy and produce burns, particularly when multiple shocks are delivered.
Erythema or hyperemia of the skin under the paddles can often be caused; this redness should decrease in term of 72 hours.

1.2.2. Transcutaneous pacing therapy (optional)
The Biphasic Defibrillator Monitor 3850B with TPM allows transcutaneous electrical stimulation to the heart by delivering a monophasic stimulus in demand mode or in asynchronous mode. This stimulus is intended to cause cardiac depolarization and myocardial contraction. The medical care provider selects the stimulus current and rate settings. The energy is delivered through electrodes applied to the patient's bare chest.
In demand mode, the pacemaker delivers pulses only when the patient's heart rate is lower than the selected pacing rate.
In asynchronous mode, the pacemaker delivers pulses at the selected frequency.

Indications:
Non-invasive pacing is one method of treating patients with symptomatic bradycardia or hemodynamically unstable, particularly in patients who do not respond to drug therapy.
Hemodynamically significant bradyarrhythmias requiring temporary pacemaker are due to various types of AV block, sinus node dysfunction or bifascicular block symptomatic.
The transcutaneous cardiac pacing is useful in reversible or transient conditions or when it is not possible transvenous cardiac pacing. It can also be helpful in patients with asystole, if performed early.

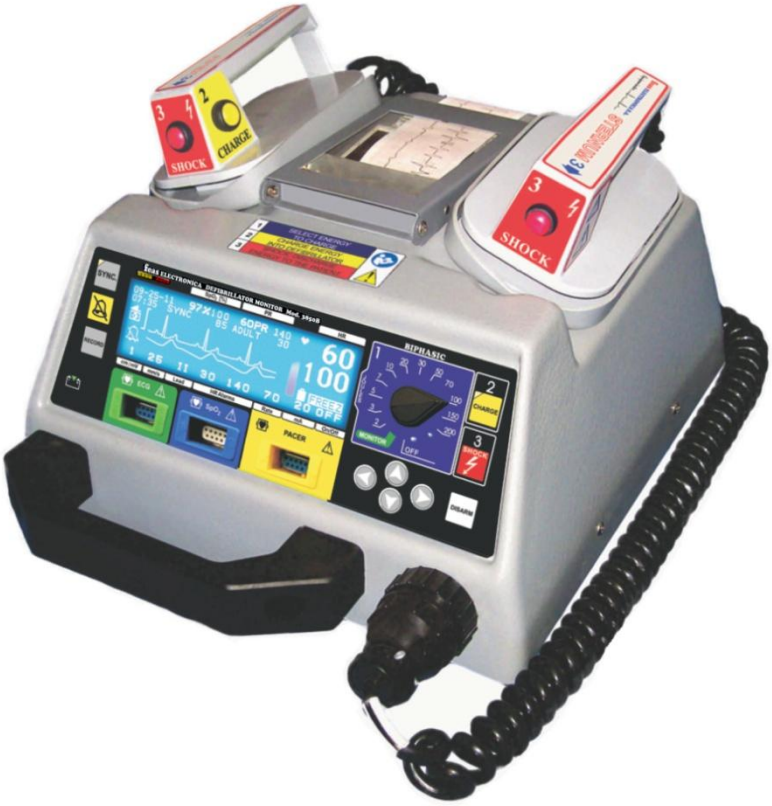
Contraindications:
Non-invasive electric pacing is contraindicated in the treatment of ventricular fibrillation, it not responds to electrical stimulation and requires immediate defibrillation. For that reason, the patient arrhythmia should be immediate determinate to apply the correct treatment.
If the patient is suffering ventricular fibrillation and the defibrillation was successful but asystole is produced, pacing should be applied.
Electrical stimulation is contraindicated in patients with asystole by cardiac arrest, especially if the resuscitation were delayed more than 20 minutes, by the poor performance of these patients.
Ventricular or supraventricular tachycardia could be interrupted with pacing, but synchronized cardioversion is quicker and safer during emergency to circulatory collapse. An electromechanical dissociation can occur after a prolonged cardiac arrest; in this case effective ECG response without mechanical contractions can be produced by pacing, whereby another treatment is required.
Undesirable repetitive responses, tachycardia, fibrillation with generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance or other heart diseases can be caused by electric pacing.
Stimulation by any method tends to inhibit the intrinsic rhythm. Abrupt rate, especially in high heart rates, may cause ventricular stop.
Non-invasive Temporary Pacing may cause discomfort of varying intensity, which can sometimes be serious and oppose the continued use in conscious patients.
Similarly, inevitable muscle contraction can be problematic in very ill patients and may limit continuous use to a few hours.
It can often cause erythema or hyperemia of the skin under the electrodes.
The non-invasive pacing in the presence of severe hypothermia may be contraindicated; the bradycardia in these patients is a physiological phenomenon.

1.2.3. Pulse Oximeter (optional)

Indications:
SpO_2 monitoring is indicated for use when it is beneficial to assess a patient's oxygen saturation level. It is indicated for use in any patient who is at risk of developing hypoxemia.

Contraindications:
There are no known contraindications for SpO_2 monitoring through a Pulse Oximeter.

1.3. FRONT PANEL



1.3.1. MONITOR SECTION

- Connector for patient ECG cable.
- Liquid Crystal Display with backlight.
- CURSOR keys that let you use the monitor menu.
- **RECORDER**  **key:** To start or stop the paper record (just the device that has the optional recorder).
- **SILENCE**  **key:** To cancel the alarm sound for 2 minutes. Silence for two minutes is commonly used to move the patient, reposition or change sensors and/or electrodes or any activity that involves moving the patient or temporarily disconnected. Keep the patient under close surveillance during periods of off alarm signals. If the alarm signals are selected, the visual alarm signal will continue to indicate the alarm condition if it occurs even though the sound is muted.

1.3.2. DEFIBRILLATOR SECTION

- **SELECTOR**  **SWITCH**: The selector switch allows the device turn on or turn off, selecting mode MONITOR (which doesn't allow energy charge) and selecting the desired energy.
- **CHARGE**  **Key:** Initiates energy charge.
- **DISARM**  **Key:** disarm energy charge.
- **SYNC**  **key:** For SYNCHRONOUS mode selection.
- The shock is performed using the  keys placed in the paddles (you must press both them simultaneously) or from the front panel with the  key.

1.3.3. RECORDER SECTION

- Cover.
- Cover open button.

- Deposit of Paper of the recorder.
- Paper for the recorder.

1.3.4. OXIMETRY SECTION

- Connector for SpO_2 sensor.
- Indication of saturation percentage (SpO_2) and pulse rate (PR).
- Plethysmography waveform.
- Pulse intensity bar.
- Function of alarms SpO_2.
- Function of pulse rate Alarm.

1.3.5. TRANSCUTANEOUS PACER SECTION

- CF pacer output type.
- Through external stimulation electrodes.
- Pacer output connector polarized.
- Selection and indication of pulses delivery mode, demand or asynchronous.
- Selection and display of current and programmed pacing rate.
- Frequency Range: 40 ppm to 180 ppm ±5%.
- Output Current: 10 mA to 200 mA ±5%.
- Pulse Width: 20 ms ±5%.

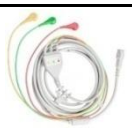
1.4. BACK PANEL

BAT: With Internal Battery.
REC: With Thermal Recorder.
TPM: With External Transcutaneous Pacer.
SpO_2: With Pulse Oximeter.

1.5. ACCESSORIES

WARNING! The proper operation of the equipment and protection against the effects of the discharge of a cardiac defibrillator requires the use of original accessories intended for this equipment. Only use original accessories provided with the equipment or those accessories specially indicated for this equipment.
WARNING! The use of accessories, transducers, and cables other than those specified, except for the transducers and cables sold by the equipment manufacturer as replaceable parts of internal components, may result in increased emissions or decreased immunity of this medical device.
WARNING! The user shall be responsible to check the compatibility between the accessories used and this medical device.
ATTENTION! Do not clean or disinfect the accessory's cable, accessories, and parts of the equipment or its main body with sodium hypochlorite, solvents, acids, or abrasive products. For cleaning and disinfection of equipment follow the instructions given in this manual.
ATTENTION! There is a risk that the equipment will break. Do not sterilize this equipment or its parts or accessories in autoclave or ethylene oxide. Do not submerge any part of this equipment in water or other liquids or use abrasive cleaners. Do not spray or spill liquids on the equipment or its accessories. Do not allow any liquid entering the connectors or other openings of the housing. If you accidentally spill liquid on the equipment, turn the energy switch OFF (because the equipment has internal battery) and disconnect it the power line (in case it is connected to the power line), clean it and dry it before reuse. If in doubt about equipment security, send the same to an authorized technical service.

The device is provided with the following accessories:

Ref.	Description	Quantity	Image	Adult	Pediatric	neonatal
1879	Patient ECG cable DB9M/G - 3 wires.	1 unit (patient ECG cable that might be chosen by the client).		✓	✓	---
1880	Patient ECG cable DB9M/G - 5 wires.			✓	✓	---
16474	Patient ECG cable DB9M/G - 5 mini clip 60 cm.			✓	✓	✓
16475	Patient ECG cable DB9M/G - 3 mini clip 60 cm.			✓	✓	✓
238	Power cord 220 V Iram connector.	1 unit.		✓	✓	✓
1846	External battery power cord 12 Vdc for vehicle.	1 unit.		✓	✓	✓
14520	Thermal paper for ECG: width 55 mm x 25 m (optional).	1 unit.		✓	✓	✓
1261	Pacer electrodes (optional).	1 set.		✓	✓	---
10024	Pacer electrode cable 2 pines 2 mm - DB9M/G (optional).	1 unit.		✓	✓	---

Ref.	Description	Quantity	Image	Adult	Pediatric	neonatal
6467	Velcro belt for pacer (optional).	1 unit.		✓	✓	---
12138	Adult oximeter finger sensor DB9M/G feas ELECTRÓNICA 512F (optional).	1 unit (sensor cable that might be chosen by the client).		✓	✓	---
15463	Pulse oximeter sensor, pediatric, finger, DB9M/G, feas ELECTRÓNICA, 512H (optional).			---	✓	---
17364	Pulse oximeter sensor, adult, disposable, DB9M/G, feas ELECTRÓNICA, 520A (optional).			✓	✓	---
17365	Pulse oximeter sensor, pediatric, disposable, DB9M/G, feas ELECTRÓNICA, 520P (optional).			---	✓	---
17366	Pulse oximeter sensor, infant (3 kg-20 kg), disposable, DB9M/G, 520I (optional).			---	✓	✓
17367	Pulse oximeter sensor, neonatal (< 3 kg), disposable, DB9M/G, 520N (optional).			---	---	✓
15037	Pulse oximeter reusable “y” sensor, neonatal, foot, feas ELECTRÓNICA, 518B (optional).			---	---	✓
10629	SpO_2 adapter cable DB9MG-DB9F (optional).	1 unit.		✓	✓	✓
1684	External paddles for Defibrillator 3850B. Note: Composed of pediatric paddles (Code 20180) plus adult adapters (Code 20172)	1 set.		✓	✓	---

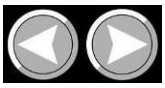
NOTE: The images of accessories are for illustrative purposes.

Additionally, the equipment requires the following commercially available accessories to perform its functions:

Description	Image	Adult	Pediatric	Neonatal
Disposable electrodes x 10 units.		✓	✓	✓

1.6. CONTROL AND INDICATORS

1.6.1. CONTROL



Cursor movement keys.

Selection keys of menu items.

Alarm silence key. Activates and deactivates the alarm sound.

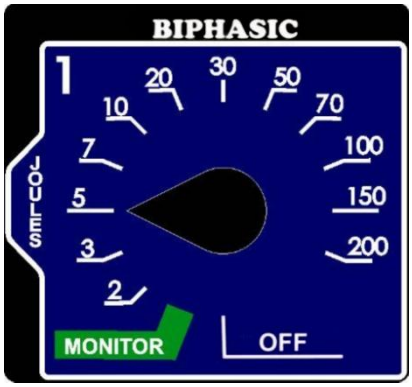
Key to RECORD on thermal paper.

Mode key SYNCHRONOUS/ASYNCHRONOUS: Determines if the shock is synchronized with the patient's QRS (synchronous) or not.

Discard the energy stored in the capacitor, internally.

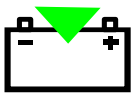
The charger starts charging the capacitor until it reaches the energy value selected by the selector switch. The indicator flashes until it reaches the value of energy and then stays on.

Shock key: Discharge the stored energy in the device over the patient through external paddles, internal paddles or self-adhesive patches.



Selector switch: Energy Selection, Monitoring and Off: The energy positions are graded in joules. In the MONITOR position, the device is inhibited to store energy.
In the OFF position turns off the device.
The energy values indicated are for patient impedance of 50 Ω.

1.6.2. INDICATORS



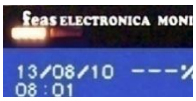
GREEN LED:
Indicates AC power line presence or external +12 Vdc. When on, the internal battery is charging. When is off, the device is operating at internal battery.

YELLOW LED:
When on, indicates that the device is in synchronous mode and stay on until the energy is discharged.

YELLOW LED:
Off: Indicates no charge on the capacitor of the device.
On: Indicates energy is being stored, during this process an intermittent beep will be heard; or that the energy selected from the selector switch is ready to be discharged onto the patient, the latter is accompanied by a continuous beep.
Indicates energy is being stored, during this process an intermittent beep will be heard; or that the energy selected from the selector switch is ready to be discharged onto the patient, the latter is accompanied by a continuous beep.

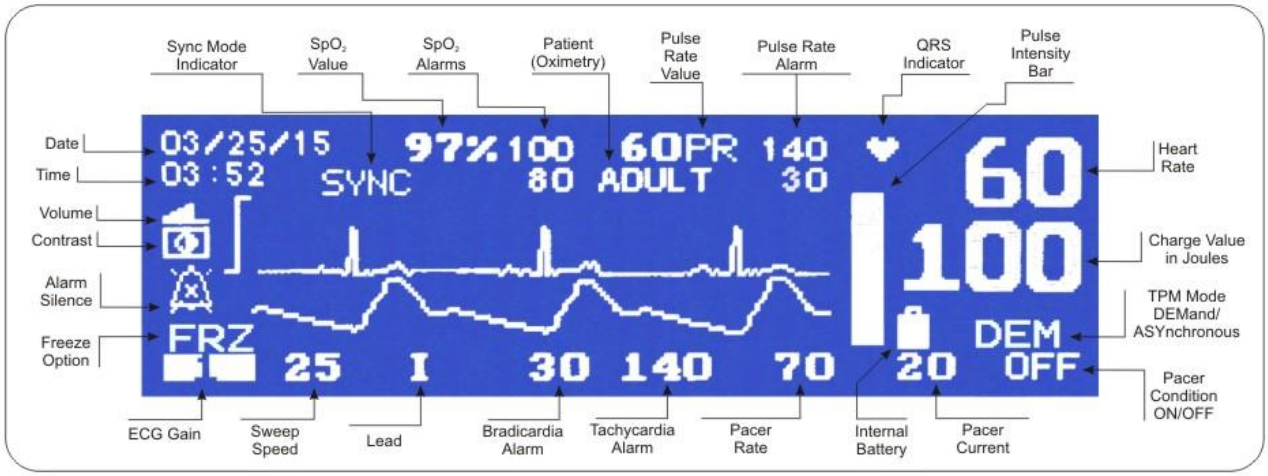
ALARM INDICATORS

HIGH PRIORITY alarm indicator: is indicated by a flashing red indicator, located in the upper left corner of the display.

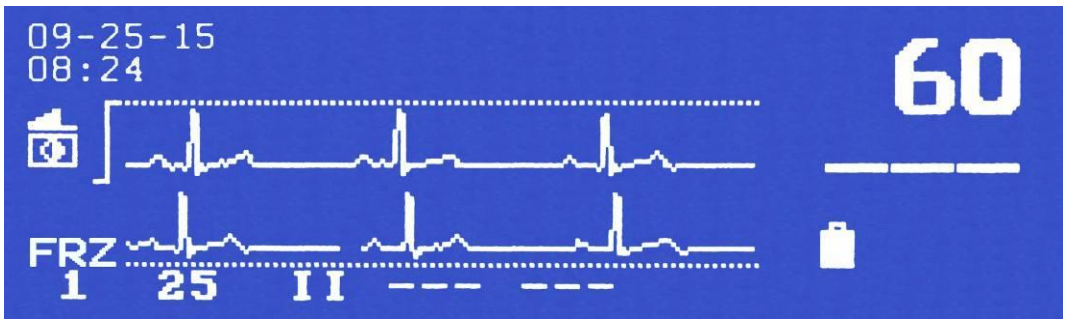


MEDIUM PRIORITY Alarm indicator: indicated by a yellow flashing indicator located in the upper left corner of the display
LOW PRIORITY alarm indicator: indicated by a yellow continuous light indicator.

STANDARD SCREEN



ECG SCREEN CASCADED



To display the cascade ECG see section **"CONFIGURATION MENU"**.

2. INSTALLING AND TURNING ON THE DEVICE

2.1. INSTALLING

WARNING

- You should read this manual before beginning installation and use of equipment.
- This equipment is meant to be used by persons trained in professional health care.
- Defibrillator Monitor Mod. 3850B-Biphasic use is limited to a single patient at a time.
- This equipment must be used in conjunction with signs and symptoms of the patient. The equipment is designed to be an aid in clinical diagnosis.
- Do not reuse any element disposable or single use. The time limit of use thereof is that indicated by the manufacturer.
- The expiration date of this equipment is of 5 years from its purchase, when that time is over, dismiss the equipment and its accessories following the local regulations in force.
- In case of discarding the equipment or one of its accessories, at the end of its useful life, do it according to the local regulations, normative or laws in force.
- In order to take care of the environment, you can send the equipment to feas ELECTRÓNICA for its disposal.
- RISK OF ELECTRICAL SHOCK, if you remove the equipment's lead. Do not remove the equipment's lead. Ask for assistance from qualified and authorized personnel.
- There is a risk of Electrical Shock and death. Do not use this equipment if you doubt of the integrity of any cable. Check the cables periodically (disconnect them before) to verify their integrity; paying special attention to cable points close to connectors and paddles. In case you find an irregularity, request the part to our Customer's Service.
- Do not touch the Power Line connectors with wet hands.
- The Defibrillator Monitor Mod 3850B-Biphasic is designed with covers and plastic handles to minimize the risk of electrical shock. When it is not plugged to the line power its energy will be provided by the battery, without ground reference.
- All combinations of medical equipment with non-medical equipment must comply with the total leakage current specified in IEC 60601-1, Cl. 16.
- When combined instruments, the sum of the leakage currents can be dangerous for both the patient and the operator. If you can't determine the leakage current of each team on the specifications of each, technical staff will take measurements to ensure the installation complies with the requirements of EN 60601-1, Cl. 16. In any case, the user should consult the manufacturer to ensure that the sum of leakage currents will not jeopardize patient safety.
- The device is intended to be connected to:
    - Installations in medical rooms belonging to Groups 0, 1, 2a and 2b, according to AEA90364-7-710 (IEC 60364-7-710).
    - Installations according to AEA90364-7-771, installations in buildings in general, to grounded outlets according to IRAM 2071.
    - Mobile units, to the cigarette lighter connector of the vehicle.
- The disconnection of the equipment from the Power Line does not de-energize it, since it has an internal battery, so you must also set the selector switch to OFF.
- Caution, leave one end of the power cord accessible so that in the event of an emergency, it is easy to disconnect the equipment from the Power Line.
- Do not disconnect power by pulling the cord. Disconnect the connector firmly grasping.
- Do not excessively bend the plug or power cord or place heavy objects on them, which could cause damage.
- Do not immerse the electrical connector in liquids. This can damage the cable or connector by corrosion.
- RISK OF FIRE AND/OR EXPLOSION: do not use this equipment in the presence of flammable gases (anesthetics, oxygen, etc.).
- Not use or store inflammable substances near the equipment.
- Avoid installing this equipment in places where liquids can be spilled on it. Avoid direct exposure to splatter, sprayer or air vented from nebulizers or humidifiers.
- Do not place containers with water, chemicals or any small metal objects on the equipment.
- Do not use this equipment under the rain. You have to make sure that the equipment, the cables and paddles are dry before you start using them.
- Do not place the equipment on the patient or where it can fall over the patient. Place it next to the patient where it's comfortable for its use.
- Never attempt to introduce sharp, metallic or other objects into any aperture on the equipment.

CAUTION

- The performance of equipment might be affected by the presence of CAT scanner.
- Do not use this equipment near Magnetic resonance imaging equipment (MR o MRI).
- To attach wires and sensors always use hypoallergenic tape.
- Do not store the equipment in deposits or between periods of use in places where the sun shine directly on it. Risk of damage to the cover of the equipment, parts and accessories.
- Avoid installing this equipment in those places where the sun hits directly.
- Do not place heavy objects on the equipment.
- Do not drop the equipment when moving it.

- Use the equipment on a flat and stable surface.
- Important!! If using a bracket, make sure that the bracket holds at least twice the weight of the equipment. If you have any questions, please contact feas ELECTRÓNICA.
- Do not push the keys of the frontal panel with pushing or slicing elements. This will produce permanent damage to the keypad. Only push the keys of the frontal panel with your fingers. Do not press the buttons with your nails.

Opening the package and verification
Remove the device and its accessories from the packaging carefully and properly keep packaging materials in case of future transportation or storage.
Check the accessories with the list of accessories purchased. Check if there is any mechanical damage, check the status of all cables and plug some accessories to review its operation, in case of any problems observed please contact immediately to feas ELECTRÓNICA's Customer Service.

Equipment transfer to the usage location
When transferring the equipment, please use the plastic handle and ensure that the equipment is turned off.
Prior to the relocation, please confirm that the paddles are correctly positioned and securely fixed.

Installing the device
When installing the device makes sure that the distance from to the wall is 5 cm or more, for adequate ventilation.
If the device is installed in a cubicle, you must ensure that the distance between the equipment and any of the walls is 10 cm or more.
The device must be supported on a surface capable of supporting twice its weight, with an angle no greater than 10º inclination.
The company guarantees that the device will operate properly and meet all specifications, only if properly installed, as is described in this User Manual.

2.2. CONNECTIONS AND TURNING ON THE DEVICE

Before connecting any cables, ensure the value of the mains voltage is within the voltage range of the device, also check that the power frequency indicated on the back panel matches the network's frequency that will connect the device, if it is different, please contact immediately with feas ELECTRÓNICA's Customer Service. Do not use the device in these conditions, the ECG waveform will be affected by noise and cannot use the SYNC mode.
Also verify that the output jack of the power cord matches the wall power outlet to which it will connect and possesses electrical energy.

WARNING! The equipment must be connected to an approved electrical installation that includes a correct grounding according to the local legislation in force. Do not use adapters or replace the device's original cables. If the plug does not match the installation, please contact our Customer Service for the provision of a suitable cable.
WARNING! You must make sure that the AC outlet, to which you will plug the device, has a groundling and is in good condition.
WARNING! Do not connect this device to an outlet controlled by a switch on/off.
WARNING! Verify the AC voltage range matches the voltage at which the equipment is to be connected. If does not match, contact feas ELECTRÓNICA's Service Customer.
WARNING! Verify the AC frequency indicated on the back panel matches the AC frequency which the device is to be connected. If does not match, contact feas ELECTRÓNICA's Service Customer. Do not use the device in those conditions. The ECG waveform will be affected by noise and will not be able to use SYNC mode.
WARNING! If you have any doubts about the integrity of the ground, either the cable or the installation of the building, use the device from the internal battery. In case that the battery is discharge or damage, don't use the equipment.
WARNING! The multi-outlet power extension cord shall not be placed on the floor.
WARNING! The multi-outlet power extension cord should only be used to power equipment that is part of the system.

Once completed these checks, connect the input jack of the power cord to the device, firmly pressing the jack until it stops at the bottom of the device connector. Then connect the output jack to the wall outlet. Verify that the connection is correct by observing the green triangular light "Battery Charge".

Do not attempt to operate this device unless you are thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

Turn on the device by turning the selector switch to the MONITOR position (if you only want to use this function) or to the position of some energy value (if you want to defibrillate). The MONITOR is set initially with ECG input PADDLES (if you do not have the cable connected to the patient, if you have the cable connected to the patient will start showing the waveform of the lead **I (DI)** on display), OFF ALARMS (except the lower limit of SpO_2 alarm which defaults to 85%), 25 mm/s in sweep speed and 1 V/cm in gain.

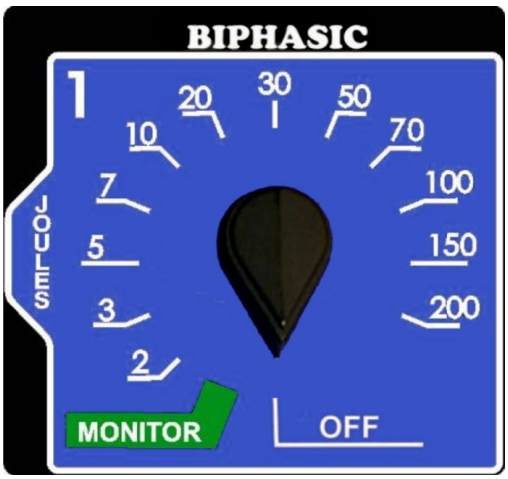
> **"Setup error"** This message is displayed when, turning on the device, is located that there are differences between the stored configuration of factory and the current configuration.

The defibrillator has three power modes:

- 90 Vac - 240 Vac (automatic selection) and notch filter 50 Hz or 60 Hz, factory selectable.
- Internal rechargeable battery 12 Vdc.
- External 12 Vdc battery.

2.3. TURN OFF THE EQUIPMENT

To turn the equipment off, turn the selector switch to the OFF position (see next figure).



2.4. INTERNAL BATTERY

2.4.1. WARNING MESSAGES

WARNINGS

- The battery must be replaced by an original battery for this equipment. Replacement with another type of battery can result in an unacceptable risk of temperature rise, fire and/or explosion of the battery or the equipment.

CAUTIONS

- The equipment has rechargeable battery type must remain connected to the power line during periods when it is not used.
- If the capacity of the internal battery is below 80% the equipment will be able to function from line power or from External +12 Vdc.
- Do not discharge the battery completely.
- Recharge the battery immediately after it's been used.
- The internal battery of this equipment cannot be replaced by the user. It has to be replaced by qualified and authorized personnel.
- In case you replace the battery follow the local instructions to dispose Ni-Mh batteries or send them to feas ELECTRÓNICA for disposal.
- When the device is stored in warehouse, should be put to charge at least once every 60 days for at least 3 hrs at 25ºC ±3ºC temperature, to prevent battery damage.

2.4.2. DESCRIPTION

The device has rechargeable battery type must remain connected to the power line during periods when it is not used.
In case of disconnection or failure of the Power Line or external 12 Vdc, the equipment may still be operated via the internal battery.
If, in addition, the internal battery is discharged or damaged, the unit will shut down. It will remain off until the operator turns it back on (move the power selector switch to any position except OFF) by restoring the power. The Power Line presence is indicated on the front of the equipment with a green light on the symbol. When you reconnect the equipment to the Power Line or external 12 Vdc (no matter the elapsed time), will remain off until you turn on the device. Moreover, the device will turn on with the same setup which was shut down with, except for the minimum alarm limit SpO_2, which if it was off or set to less than 85%, will be adjusted to 85%, by regulatory requirement. If there been set to more than 85%, it retains the value set by the operator.
When connected to the power line or external 12 Vdc, is charging the internal battery, whether the device is off or on. This condition is expressed in the green light over the symbol.
There is no need disconnecting and reconnecting the device periodically. This device has an automatic charging system that allows you to keep the battery at full charge state.
To power the device with external 12 Vdc (ambulance or other vehicle), you have to use the cable with lighter plug. In this condition, it also recharges the battery and is expressed in the green light over the symbol.
The state of battery charge is indicated on the screen and, therefore, requires the device have to be switched on (in MONITOR mode or selection of energy), and operating from the internal battery (disconnected from AC line and from external 12 Vdc). When battery is fully charged, the display shows the symbol. When the display shows the symbol indicates that the battery is partially charged and should be charged as soon as possible to preserve battery life.

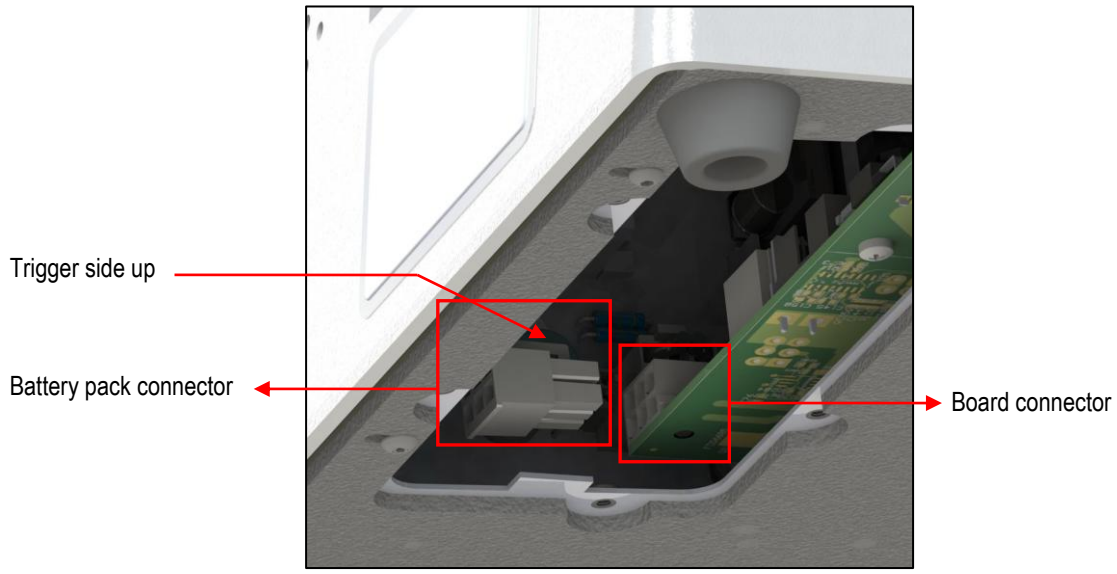
When battery is discharged, the display shows the symbol and the low battery technical alarm condition will activate the visual and auditory signal. This alarm is of low priority and allows the operator to perform at least three discharges at maximum energy, before the equipment is turned off.
When battery is fully discharged the high-priority discharged battery technical alarm will be activated, and the message **"Battery Discharged – Power is down"** will also be displayed. The device will automatically turn off 120 seconds after the message, to avoid damaging the battery. You should recharge the battery as soon as possible to preserve its life.
The auditory indication of the technical alarms, mentioned above, is detailed in the section **"AUDITORY ALARM SIGNALS"**.
In the latter case, the device will operate correctly from AC line or external 12 Vdc, in both conditions, the display shows the symbol.

The internal battery should be checked visually once a year to ensure their safety.
Check monthly its autonomy, if it decreases to 80% of the value indicated the technical specifications; the battery should be replaced with another battery of the same type.

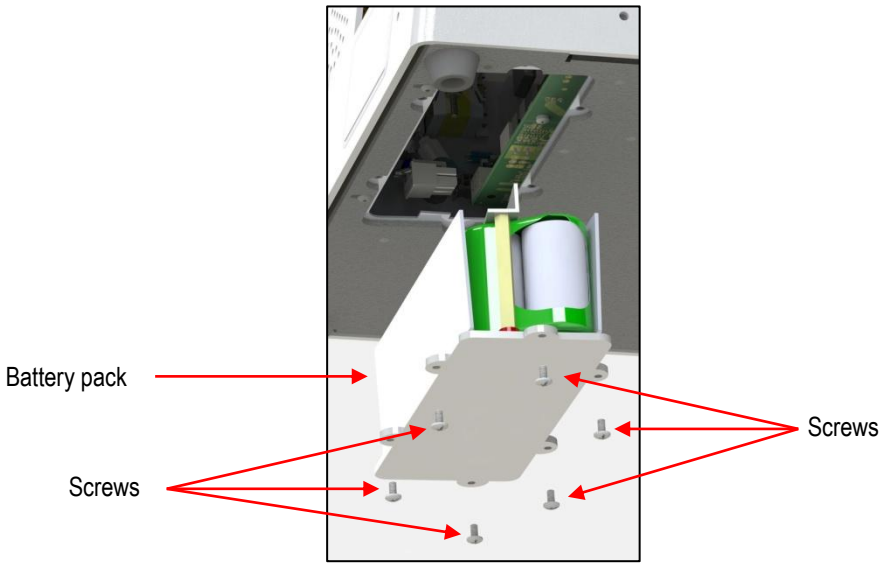
2.4.3. INSERTING THE BATTERY.

The procedure for inserting the battery is described below:

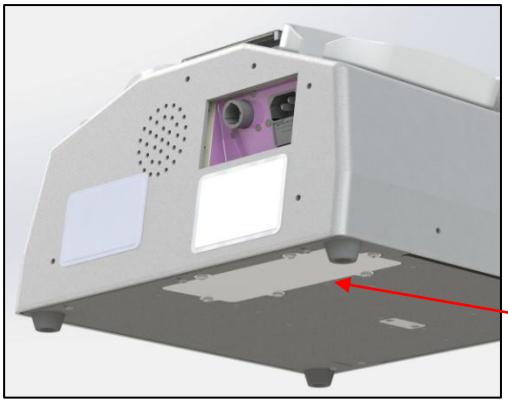
1) Connect the battery to the internal board connector (see figure below) by pressing the trigger and inserting the battery pack connector.



2) Insert the battery pack into the receptacle intended for it (see following figure), aligning the cover by its shape.



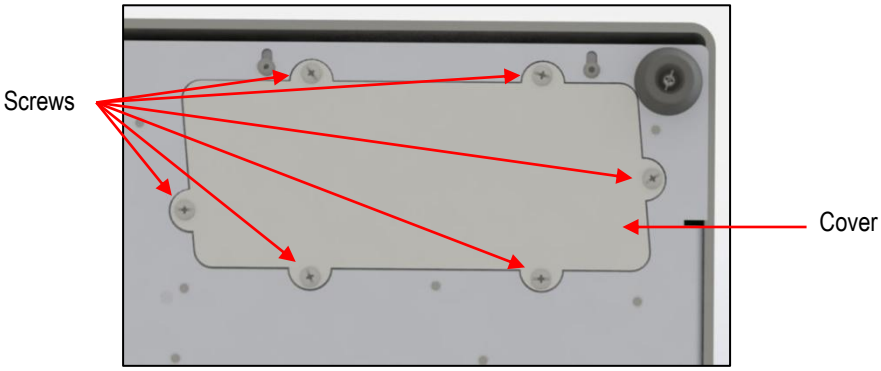
3) Make sure the cover is properly seated and proceed to install the six screws of the set, making sure they are tight (see figure below).



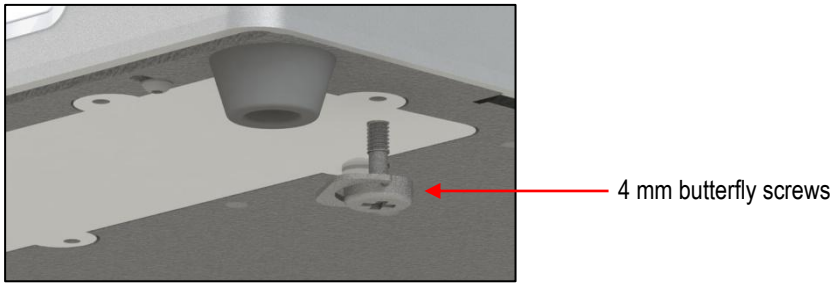
2.4.4. REMOVING THE BATTERY.

The procedure for removing the battery is described below:

1) Remove the six screws that make up the battery cover (see following figure).



2) Then, in one of the holes at the widest end of the cover, place the 4 mm butterfly screw and tighten it (see the following figure) until the battery is removed.



3) Finally disconnect the battery from the equipment by pressing the trigger of the battery connector and removing the pack out.
4) Remove the 4 mm butterfly screw and save it for later use.

2.4.5. CHECKING THE BATTERY STATUS

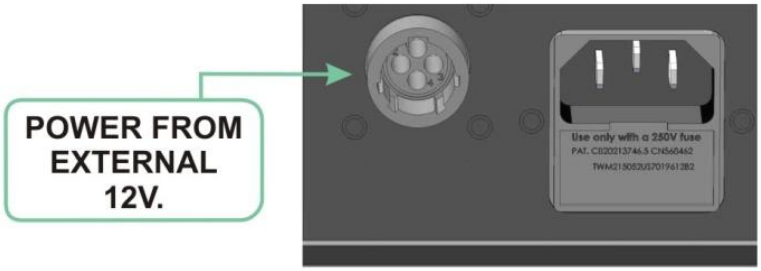
Procedure for check the battery status:

1) Connect the device to AC line (or external +12 Vdc) for 3 hours to achieve a full charge the internal battery.
2) Unplug the device from the AC line (or external +12 Vdc).
3) Turn the device on (this test requires the device cannot be used for two hours).
4) Register the time you turned on the device.
5) Verify that at 2 hours the device is still on. If the device is off, you must request the replacement of the internal battery.

This device, with a new internal battery, fully charged, at a temperature of 20ºC, can discharge at least 150 shots at 200 Joules without recharging the battery, with a maximum cadence of 3 shots/minute and 1 minute rest.

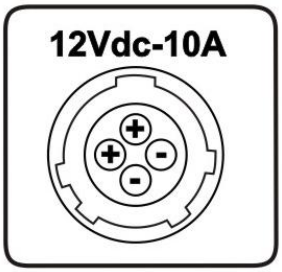
2.5. EXTERNAL POWER SOURCE

The feas ELECTRÓNICA Defibrillator has on the back a connector for receiving power from an external power source, as seen in the following figure:

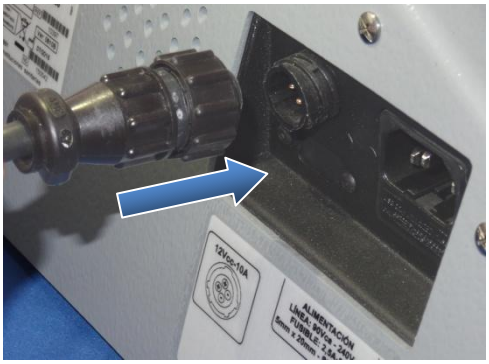


There you must connect the power cable reference 1846, to do this follow the following steps:

a) Position the cable so that the connectors face each other and the male connector guides match the grooves of the female connector, in the following figure you can see the female connector viewed from the front, where you can see the grooves for the male connector guides:



Once positioned, plug the cable until it stops, see following figure.



b) Finally turn the nut until it locks and make sure that the cable is firmly connected without the possibility of disconnect it, see next figure.

The external power source must meet the following requirements:

- Be medical grade and meet the requirements of standard IEC 60601-1 or come from a vehicle battery (cigarette lighter connector ambulance).
- Voltage: 12 Vdc.
- Current: 10 A.

3. USE MODE

3.1. DEFIBRILLATOR USE

Before you begin
Perform all operational checks described in chapter MAINTAINING THE EQUIPMENT every day or every turn.
These operational checks are intended to ensure that the equipment works properly and that necessary supplies and accessories are present and ready to use.

Turn the selector switch located to the right of the device, indicated with **"1"** until desired energy value.

WARNING! Discharging a defibrillator directly to a healthy person's chest can be lethal.
WARNING! This equipment is protected against the effects of defibrillation.
WARNING! Make sure you know where and how to position the paddles for monitoring and defibrillation. See section **External paddles positioning**.
WARNING! Neonatal and pediatric defibrillation energy levels should be set based on the specific clinical protocols.
WARNING! In order to decrease the time pre-shock should follow the specific CPR protocols of the place.

When you turn on the defibrillator starts in **asynchronous mode**.
Prepare the paddles and position them on the patient (see section "**EXTERNAL PADDLE POSITION**").
Then press the **CHARGE** button located below the selector switch and marked with the number **"2"** or the **CHARGE** button on the paddle.
The defibrillator will start to charge energy; this is indicated with an intermittent sound and a yellow light on the **CHARGE** button. The energy indicator will show the stored energy value (in Joules). When the charge is complete, the sound will be continuous, the yellow light will remain on, the red high priority alarm indicator will flash and the energy indicator will show the energy value to be delivered until the energy is discharged into the patient or internally discharged into the equipment.

> **"Charge error"** This message is displayed when, once started charge command, for some reason and after a certain time the charged energy does not reach the energy value selected.

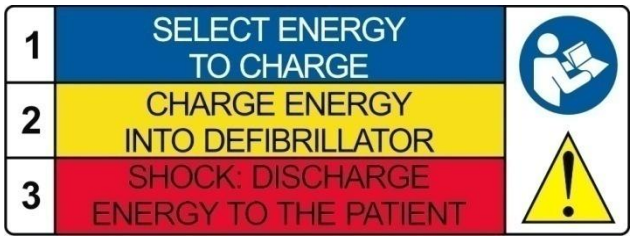
CAUTION! For safety reasons, after completion of the energy charge and elapsed the "automatic disarm time", the defibrillator will discharge the energy internally automatically. By default, the "automatic disarm time" is 60 seconds. For more information on how to configure the "automatic disarm time" refer to **SETUP MENU** section.

To shock the patient will need to press the two buttons simultaneously, located one on each paddle marked with the number **"3"**. If you do not press the two buttons at once, the discharge will not be made. You can also apply the discharge by pressing the **SHOCK** key indicated with the number **"3"** on the front of the device. The application of the discharge is carried out immediately according to section ***DEFIBRILLATOR: Waveform***.
After the discharge, the sound will stop, the indicator LED will turn off and the energy indicator, after a few seconds necessary for it to be updated on the screen, will show "**---**".

NOTE: The energy indicator will not show "**---**" immediately but, due to the on-screen update, a decrease in energy will be observed in "steps" until it reaches 0 Joule (indicated as "**---**").

WARNING! When defibrillating with paddles, use your thumbs to operate the **SHOCK** buttons in order to avoid inadvertent operator shock.
WARNING! Be especially careful to keep the paddles pressing firmly on the patient, since a poor contact with the patient's skin may cause interference (noise) resulting in a false triggering of the shock the patient and also could produce burns on the patient's skin at the shock time.

The three steps, mentioned above, are indicated on the label (see figure below) located on the top (front and middle) of the defibrillator.



When the defibrillator has been charged and not to apply the shock to the patient, this charge can be overridden internally as follows:

a) Pressing the key CANCEL CHARGE.
b) Let to elapse the "automatic disarm time" since the end of the full charge of energy, which by default is 60 seconds. For more details refer to SETUP MENU section.
c) Put the Selector Switch in the position "MONITOR" or in the OFF position.

In all cases no charge appears at the paddles.

3.1.1. EXTERNAL PADDLE PREPARATION

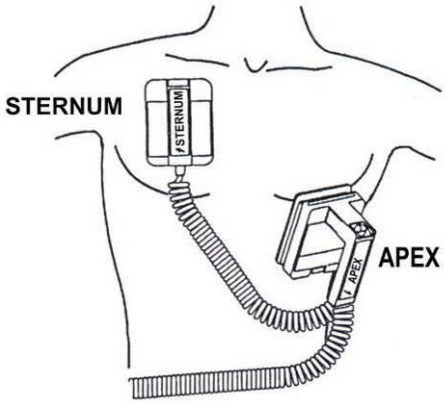
First connect the paddle cable to the defibrillator. Position the cable of the external paddles so that the connectors are facing each other and the guides of the male connector coincide with the grooves of the female connector. Once positioned, plug in the cable until it stops. Finally turn the thread clockwise until it stops and make sure that the cable is firmly connected without the possibility of disconnecting.

Remove paddles from their holders by pulling them upwards. You should verify that the paddles are clean and dry.
Apply a liberal amount of conductive paste or electrolyte gel to the electrode surface of each paddle.
Rub the electrode surfaces together to evenly distribute the applied conductive paste or gel. Hold the paddles firmly, as shown in the following figure, with your thumbs ready to press the "**SHOCK**" buttons.

The 3850B Biphasic Defibrillator external paddles can be detached and used as pediatric paddles. To do this, first make sure that the equipment is disarmed (without energy), then remove the paddles from the paddle holder, on the left side you will find a black lever, press hard where a square is displayed and remove the adult metal paddle forward to stay with a paddle with an area suitable for a pediatric patient. Perform the same procedure described above with the other paddle.
WARNING! During the preparation of the paddles, avoid spilling conductive paste or gel on the handles since it may cause electrical shock to the operator.
WARNING! Avoid excess conductive paste or gel on the patient's chest, which can form an electrical path on the patient's skin.
ATTENTION! It is recommended **DO NOT USE** Xylocaine to apply a shock.
ATTENTION! After use, you should keep the paddles clean, free of conductive gel and dirt in general, since using uncleaned paddles can lead to uncontrolled conduction paths that lead to an unwanted electric shock to the operator, either during a typical procedure or during an energy test.

3.1.2. EXTERNAL PADDLES POSITIONING

The figure below shows the positioning of the paddles on the patient.
Apply paddles firmly to the anterior wall of the chest.
Place the Sternum paddle to the right (patient's right) of the patient's sternum, just below the clavicle.
Place the Apex paddle on the chest wall, just below and to the left of the patient's left nipple, along the antero-axillary line.



Rub the paddles against the skin to maximize the paddle-to-patient contact.
The paddles may be used for ECG monitoring in emergency situations when time does not allow for connection of standard ECG monitoring electrodes.

3.1.3. MODE OF OPERATING

WARNING! There is a risk of Electrical Shock and death. Do not use this equipment if you doubt of the integrity of any cable. Check the cables periodically (disconnect them before) to verify their integrity; paying special attention to cable points close to connectors and paddles. In case you find an irregularity, request the part to our Customer's Service.
WARNING! It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
WARNING! When defibrillating the patient be careful to avoid the contact between patient's body parts (exposed skin, head, arms and legs) with metallic objects (such as parts of the bed) that might generate non desired paths for the defibrillation current.
WARNING! Rescuers performing chest compressions during external defibrillation are exposed to leakage currents.
WARNING! Do not touch the bed, patient's body, or any equipment connected to the patient during defibrillation. A severe electrical shock can result.
WARNING! When positioning the paddles on the patient for energy discharge, make sure no one is near or in contact with the patient.
CAUTION! Verify that the devices connected to the patient are protected against defibrillation before shock to the patient. If necessary, disconnect the patient from those devices that are not protected against defibrillation so that they are not damaged by the shock.
CAUTION! Be sure to know the methods used to discharge the energy charged in the Defibrillator Monitor Model 3850B.
CAUTION! Do not discharge the Defibrillator Monitor placing paddle against paddle or in the paddle support.

ELECTROSURGERY MESSAGES

WARNINGS

- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- The neutral electrode of the electrocautery must have adequate contact with the patient, otherwise it may cause burns to the patient.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- The use of an electrocautery it can cause interference in the operation of this device.

CAUTIONS

- Operation of this equipment may be affected by the presence of strong electromagnetic or radio frequency fields such as those produced by electrocautery.

3.1.3.1. ASYNCHRONIC MODE

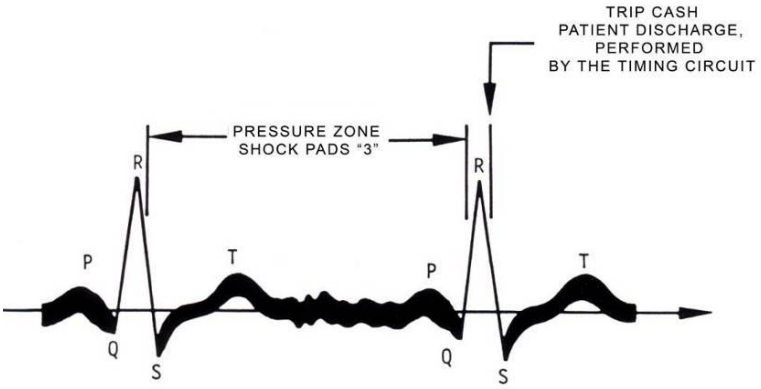
Turn on the device and/or select the desired energy by selector switch, marked **"1"**.
Prepare the paddles with conductive paste or gel (see section "**EXTERNAL PADDLES PREPARATION**").
Press the **CHARGE** key, marked with **"2"**, for energy charge.
Place the paddles on the patient (see section **"EXTERNAL PADDLE POSITIONING"**) and make sure no one is near or in contact with the patient.
Shock the patient pressing both buttons **RED** of the paddles, marked with **"3"**, or pressing the shock key, indicated by **"3"** in the front panel.

3.1.3.2. SYNCHRONIC MODE

WARNING! Conscious patients must be anesthetized or sedated before performing synchronized cardioversion.
WARNING! Before performing cardioversion, correct synchronism with R wave must be assess.

Turn on the device and/or select the desired energy by selector switch, marked **"1"**.
Select the appropriate lead and place the snaps (see section **"MENU MONITOR"**).
Prepare the paddles with conductive paste or gel (see section "**EXTERNAL PADDLES PREPARATION**").
Press the **SYNC** key, then the led will light indicating that it is in synchronous mode and also be displayed on the display the text **"SYNC"**.
Press the **CHARGE** key, marked with **"2"**, for energy charge.

Place the paddles on the patient (see section **"EXTERNAL PADDLE POSITIONING"**) and make sure no one is near or in contact with the patient.
Hold down both red buttons from the paddle, indicated with **"3"**, or press shock key on the front panel of the device, also indicated with **"3"**, and discharge energy over the patient will be made within 60 ms after detected the next R wave (see figure below), for SYNC mode, R wave must be at least 0.3 mV amplitude.
After shock it cancels the **SYNCHRONIC** mode, the led indicator goes off, and disappear the display the message **"SYNC"**. In case you need cardioverter again, you must press again the **SYNC** key.



3.1.4. TIME OF ENERGY CHARGE

The defibrillator charge time, from fully discharged till its full energy (200 Joules) is:

Powered from AC line:

a) With nominal line voltage (90 Vac - 240 Vac): 6 seconds.
b) With line voltage at 90% of the nominal: 7 seconds.

Powered from internal battery:

a) With the battery fully charged: 6 seconds.
b) After 15 shocks at maximum energy: 6 seconds.

The time from initial power up, or any operator programming mode till its full energy (200 Joules) is:

Powered from AC line:

a) With nominal line voltage (90 Vac - 240 Vac): 8 seconds.
b) With line voltage to 90% of nominal: 9 seconds.

Powered from internal battery:

a) With the battery fully charged: 9 seconds.
b) After 15 shocks at maximum energy: 9 seconds.

3.1.5. USE IN ADVERSE WEATHER CONDITIONS

In severe weather conditions, dry the device and accessories before use. If necessary, protect the device and its accessories from the rain.

WARNING! Never defibrillate a patient with wet paddles.
WARNING! Never defibrillate a patient on a wet surface.

3.2. MONITOR USAGE

3.2.1. SCREEN MESSAGES

"Setup error" This message is shown when in the **"turn on"** of the device founds differences between the manufacturer's configuration and the present one.

"Charge error" This message is shown when, once the charging command is started, for some reason and after a certain time the charged energy does not reach the chosen energy value.

"Lead off" This message is shown when one of the ECG electrodes loses connection with the patient. When this message is displayed can be selected only the leads DI, DII and DIII.

"ECG Saturated (Override)" This message is displayed when, for some reason, ECG channels receive more than ±5 mV signal at its inputs, making inoperative ECG monitoring (Paddles or Patient ECG Cable). This can happen during defibrillation.

3.2.2. SETUP MENU

This menu allows you to set the ECG view mode, standard or cascade, display or not display the plethysmography waveform (if this device have oximetry module), this also let you set the recording mode to automatic or manual (if this device have recorder module), and configure the automatic internal discharge time.

To enter into the SETUP menu, you must hold on one of the keys and turn on the device in MONITOR mode. Once you enter the menu, release the key and use the keys for select YES or NO and keys to select another menu option.
If the ECG display mode is cascade you can't enable the plethysmography waveform.
The "AUTOMATIC DISARM TIME" option, allows you set the time in which the defibrillator will automatically discharge the energy internally, from the time it reached to the selected energy value, if doesn't discharge the energy over the patient. It is expressed in seconds and can be selected between minimum values of 30 seconds up to 120 seconds, in 5 seconds steps.

3.3. ECG

3.3.1. WARNING MESSAGES

WARNINGS

- Conductive parts of electrodes and associated connectors for applicable parts shall not contact with other conductive parts of equipment (metal part), including metal parts of equipment connected to ground.
- Make sure you know where and how to position the electrodes for monitoring. See section "**Placing electrodes**".
- After the delivery of a defibrillator shock, if monitoring is undertaken with a combination of gel and patch/paddle, the ECG may initially display no signal or asystole, regardless of the true rhythm.
- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- The heart rate may be affected in the presence of arrhythmias. The cardiotachometer uses an algorithm to determine the heart rate.
- This equipment may reject pacemaker pulses of the following characteristics: with amplitude of ±2 mV to ±700 mV and a pulse width of 0.1 ms to 2 ms, anyway keep the patients with pacemaker under close surveillance.
- Electrocardiographic monitoring equipment and its accessories shall not be considered life-supporting medical equipment.
- PATIENTS WITH PACEMAKERS. The rate meter may continue to count the pacemaker rate during some occurrences of cardiac arrest or some arrhythmias. Not based entirely on the rate meter alarms. Keep patients under close surveillance.
- Be careful when making a temporary suspension audible alarm signal (silence), keep the patient under close surveillance at all times. If the alarm signals are selected, the visual alarm signal will continue to indicate an alarm condition if this occurs.
- Maximum channel height: 21.2 mm. Suitable for use as a monitor up to 2 meters away.
- Carefully route the patient cables, extension cables, oximetry sensors and/or pacemaker electrodes to reduce the possibility of patient entanglement or strangulation.

CAUTIONS

- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- During monitoring, the ECG electrodes should be re-positioned every 48 hours to maintain good signal quality. After 48 hours, the electrode's conductive paste or gel begins to dry and the patient's skin may begin to chafe.
- For ECG monitoring using hypoallergenic adhesive electrodes. The company recommends 3M ECG electrodes.

3.3.2. DESCRIPTION

On the left side on the front panel will find the following connector:

At the bottom on the front panel will find the section of the menu:

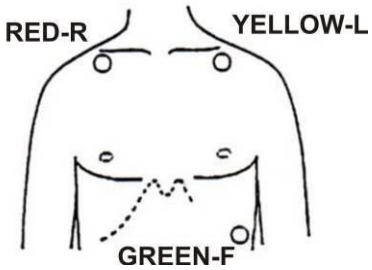
To connect the patient cable, only need to place the electrodes on the patient, connect the snaps to the electrodes and connect the other extreme to the device.

3.3.3. PLACING ELECTRODES

The ECG waveform quality depends on the contact of the electrodes with the patient's skin. To ensure lowest contact resistance, remember the following:

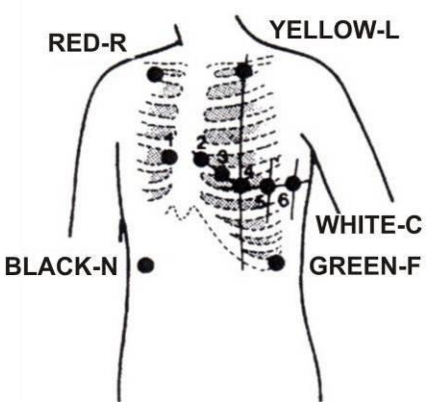
a) Shave the area where the electrode will position.
b) Clean the area with alcohol.
c) Place disposable electrodes.

3.3.3.1. THREE WIRE PATIENT ECG CABLE CONNECTION



COD	Snap Name	Snap color	Snap Position
R	Right Arm	RED	Right infraclavicular fossa.
L	Left Arm	YELLOW	Left infraclavicular fossa.
F	Left Leg	GREEN	Left antero-axillary line 6th rib.

3.3.3.2. FIVE WIRE PATIENT ECG CABLE CONNECTION

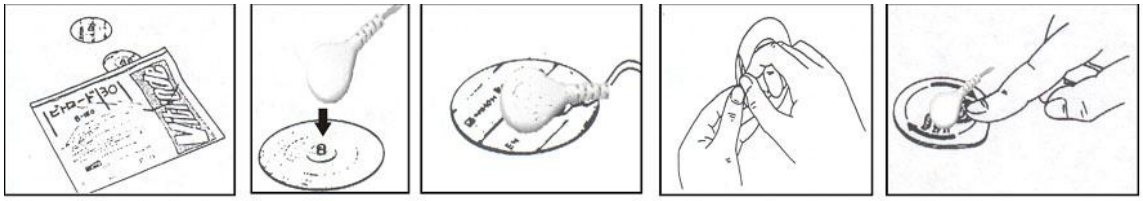


COD	Snap Name	Snap color	Snap Position
R	Right Arm	RED	Right infraclavicular fossa.
L	Left Arm	YELLOW	Left infraclavicular fossa.
F	Left Leg	GREEN	Left antero-axillary line on the last rib.
N	Right Leg	BLACK	Right antero-axillary line (at the same level of F).
C	Precordial	WHITE	Any precordial positions described below.

Precordial positions

1 (C1): Fourth intercostals space at the right edge of the sternum.
2 (C2): Fourth intercostals space at the left edge of the sternum.
3 (C3): Midway between 2 (C2) and 4 (C4).
4 (C4): Fifth intercostals space on left midclavicular line.
5 (C5): left antero-axillary line at the same level of 4 (C4).
6 (C6): Left midaxillary line at the same level of 4 (C4).

3.3.3.3. DISPOSABLE ELECTRODE PLACING



Remove the electrodes from the package | Put the snap in the electrode | Remove the adhesive backing | Position the snap on the patient, press gently, and in circular form, the edge of the electrode (not press the center) in order to achieve adherence sucesfully.

3.3.4. ECG MENU

At the bottom of the screen of the device is digital keyboard that can perform the following functions:

3.3.4.1. Select ECG waveform gain

Scroll the cursor with keys to highlight cm/mV and then press keys to select the ECG waveform gain. The selectable values are: 1/6 cm/mV, 1/4 cm/mV, 1/2 cm/mV, 1 cm/mV and 2 cm/mV.

3.3.4.2. To select leads

Scroll with keys to the area called Lead and press keys to select the desired lead.
With a 3-wire patient ECG cable, you can choose: DI, DII, DIII or paddles (onscreen I, II, III and PAD) and with a 5-wire patient ECG cable: DI, DII, DIII, aVL, aVR, aVF, C or paddles (onscreen I, II, III, aVL, aVR, aVF, C and PAD).
If not all the electrodes are connected to the patient, the ECG LEAD OFF technical alarm will be activated and the equipment will not be able to recognize the patient cable connected, therefore, it will allow the selection of all the leads until all the electrodes are connected to the patient. From here on, the allowed derivations will be according to the type of cable.
When the patient ECG cable is not connected, PAD (paddles) will automatically be selected.

NOTE: If you select a lead corresponding to the 5-wire cable and connect a 3-wire cable, the device will automatically select the DI lead after connecting the electrodes to the patient.

3.3.4.3. To select sweep speed

Scroll with keys until the area called mm/s and with the keys choose the sweep speed between 25 mm/s and 50 mm/s.

3.3.4.4. To vary limits of heart rate alarm

Press the keys and move the cursor to the area called ALARM. The number on the left is the BRADYCARDIA ALARM, and the right number is the TACHYCARDIA ALARM. Pressing the key increases the alarm limit and pressing the key decreases the alarm limit.
The adjustment range of the limits of heart rate alarm is from 20 1/min to 245 1/min for bradycardia, and from 25 1/min to 250 1/min, for tachycardia, in steps of 5 1/min.

3.3.4.5. To Mute sound alarm

Press the key (Mute) to mute the alarm sound for 2 minutes. If the alarm condition persists, the alarm sound is reactivated immediately after the two minutes of silence.

3.3.4.6. Date and time

Scroll with keys and move the cursor to the date field. Press the key or key to increase or decrease the date. Repeat the above steps to set the time.

3.3.4.7. Volume

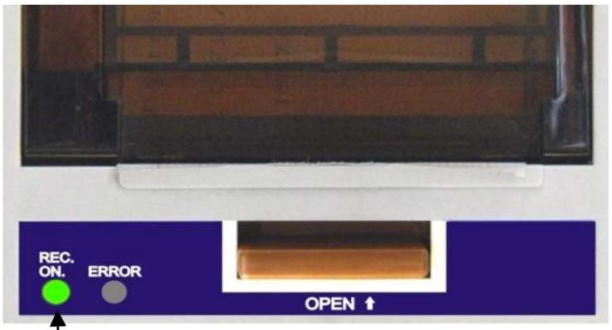
To adjust the QRS beep volume, scroll with keys and move the cursor to the volume icon. Press the key or key to increase or decrease the volume.

3.3.4.8. Contrast

To vary the angle of view, scroll to the contrast icon with keys. Press the key or key to increase or decrease the contrast.

3.4. RECORD IN PAPER

Warning messages RECORDER module



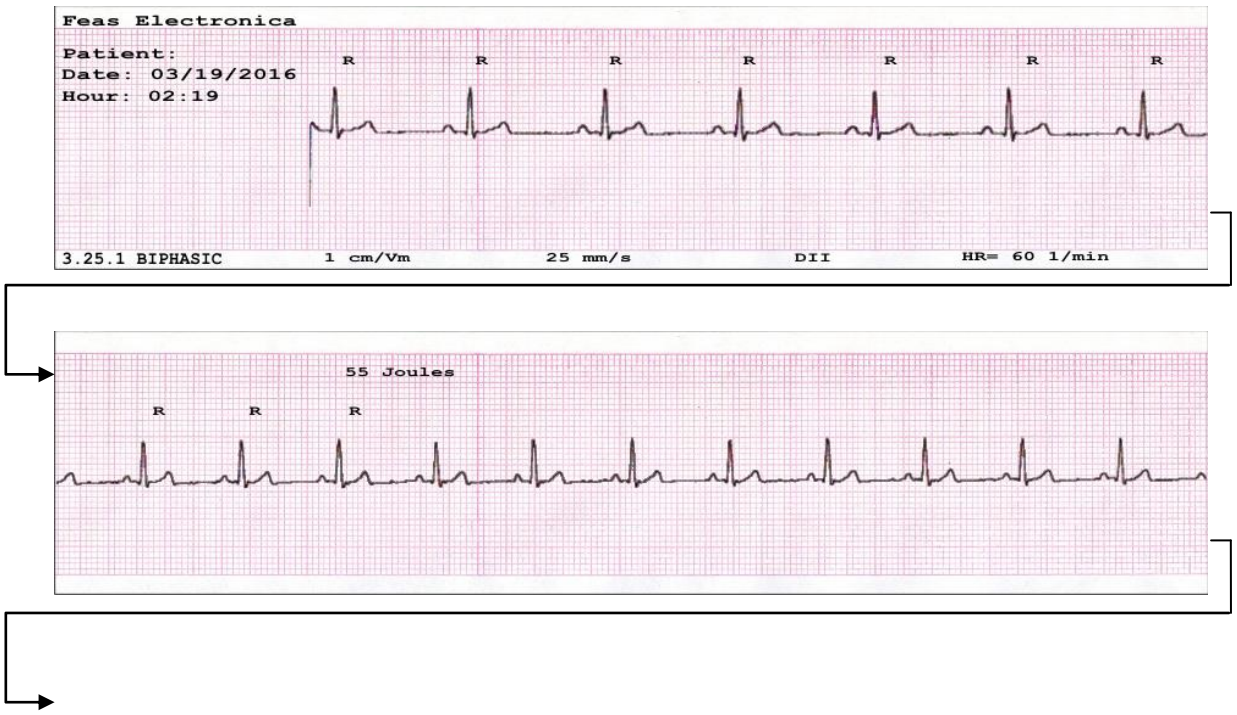
The green light on indicates that the recorder is powered up and ready to RECORD.

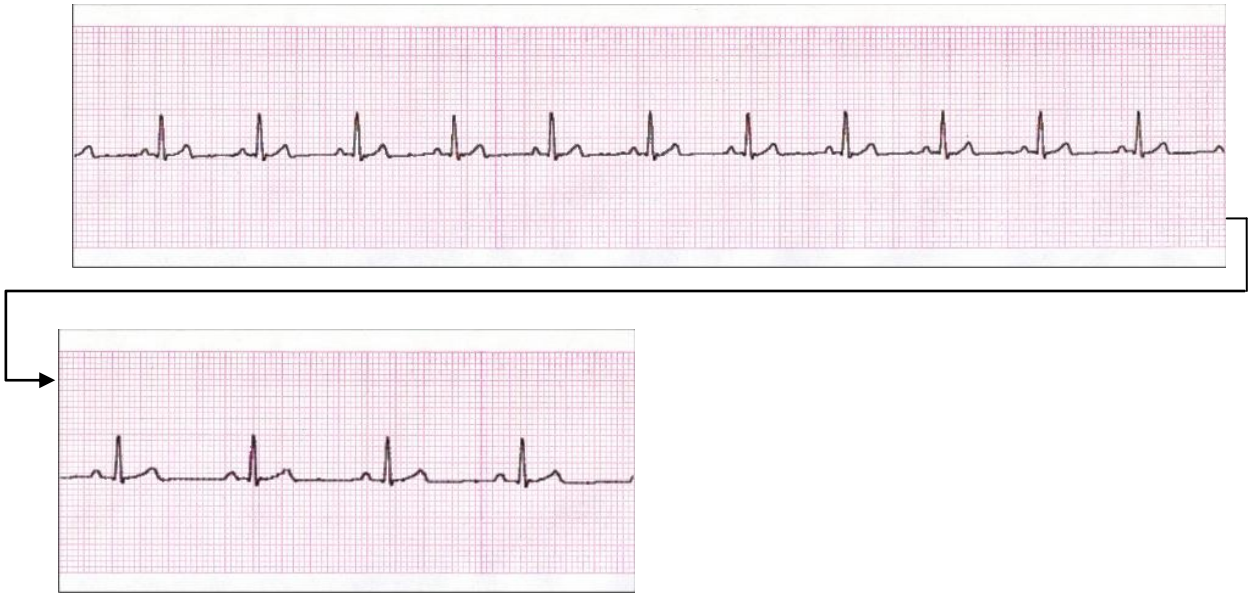
The red light on indicates an error in the recorder module.
This may be due to 3 reasons:
- The gate is open.
- There is no paper.
- The driver threw a recorder error.

The error message will continue as long as the cause or causes that generate it.

3.4.1. AUTOMATIC MODE

If in the setup menu, the AUTOMATIC REGISTRATION option is YES, then the paper record of the ECG and, optionally, plethysmography waveform will start immediately by pressing the **CHARGE** key. The recorder will stop 20 seconds after shock, or immediately after press button **DISARM** or RECORD **RECORD** key, located on the left of the front panel.



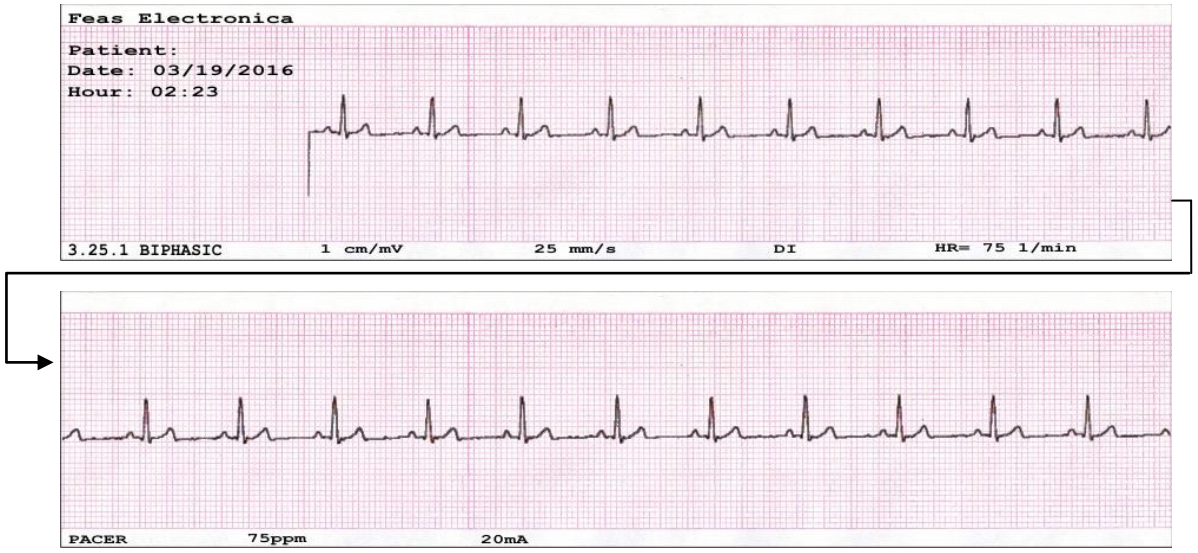


3.4.2. MANUAL MODE

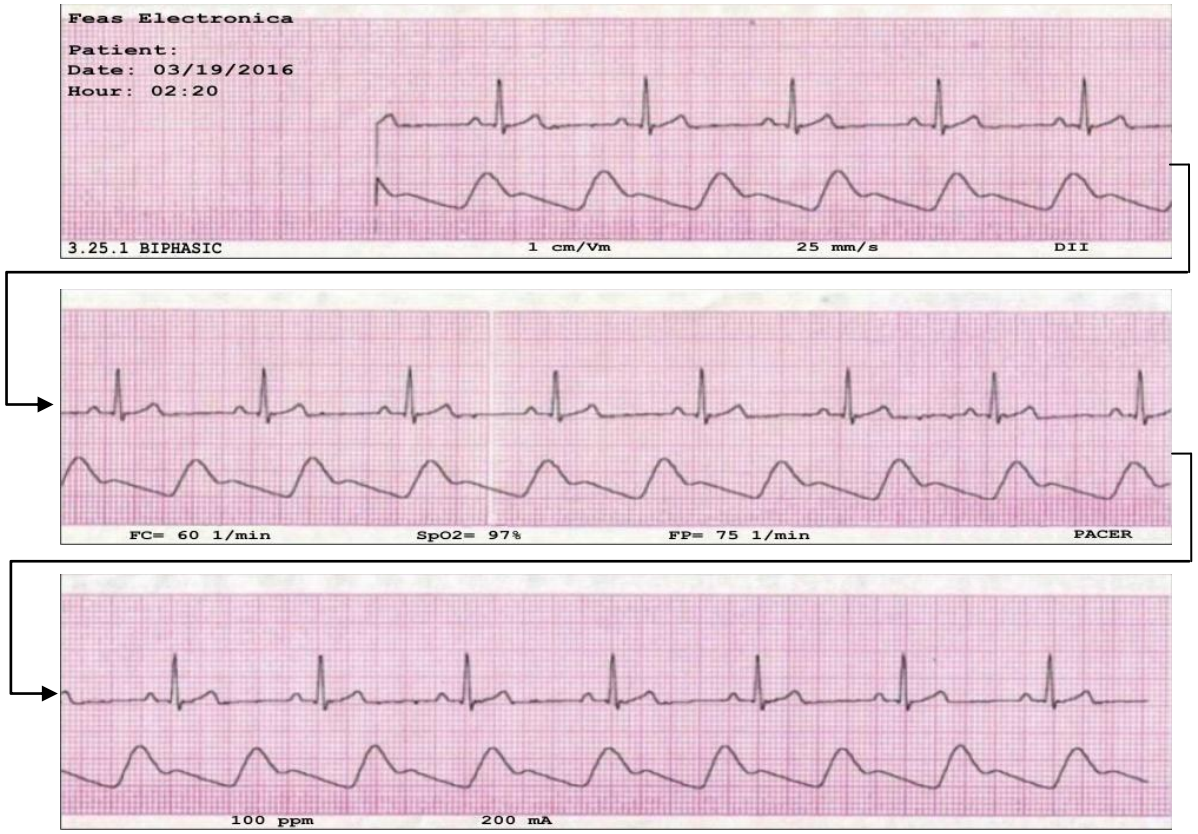
To obtain a paper record of the ECG and, optionally, plethysmography waveform that is being observed on the display, press RECORD **RECORD** key.

To stop recording, press again RECORD **RECORD** key.

One waveform registered

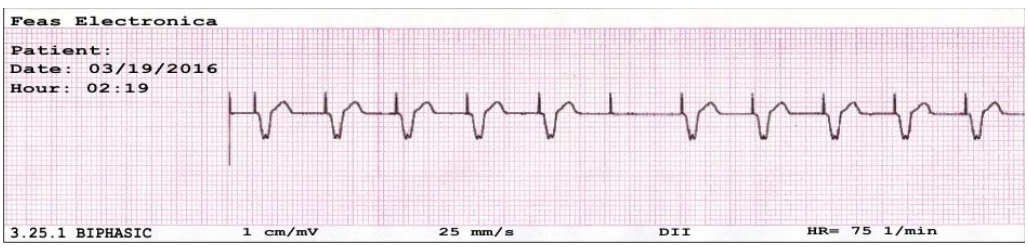


Two waveforms registered



3.4.3. Indicator of pacemaker spike detection

The following figure shows the indication of the presence of pacemaker's spikes on screen:



3.5. PACEMAKER

3.5.1. WARNING MESSAGES

WARNINGS

- Conductive parts of electrodes and associated connectors for applicable parts shall not contact with other conductive parts of equipment (metal part), including metal parts of equipment connected to ground.
- Make sure you know where and how to position the pacer electrode for monitoring. See section **Transcutaneous pacer usage**.
- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- To avoid risk of electrical shock, do not touch the gelled area of the pads while pacing.
- Use demand mode whenever possible. Use asynchronous mode when the presence of motion artifacts or other sources of artifacts, of the ECG, render the R-wave detection is not reliable.
- To change the pacing mode is necessary that the pacemaker is off.
- When pacing in demand mode is performed, the patient cable must be connected from the patient to the equipment. If you do not connect the cable patient cannot turn on the pacemaker. If the pacemaker is on and disconnect the patient cable, the pacemaker will turn off.
- If you will shock the patient, at move the selector switch from the MONITOR position to the selected energy value, the pacemaker will turn off.
- Carefully route the patient cables, extension cables, oximetry sensors and/or pacemaker electrodes to reduce the possibility of patient entanglement or strangulation.
- Verify mechanical capture by radial pulse when electrical stimulation (pacing) is applied. Consider the use of sedation or an analgesic, in case the patient experiences discomfort or pain during the application of electrical stimulation (pacemaker).

CAUTIONS

- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- If the pacemaker function is used in demand mode for extended periods of time, may be necessary to apply new ECG electrodes.

3.5.2. WARNING TRANSCUTANEOUS PACER USAGE

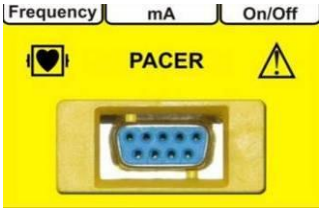
This option allows transcutaneous cardiac stimulation by electrical pulses, current controlled fixed-width 20 ms, applied in demand mode or asynchronous mode. The operator may adjust the frequency of the pulses between 40 ppm and 180 ppm in 5 ppm steps, and the applied current in a range of 10 mA to 200 mA in 5 mA steps.
The connector is polarized, which makes it impossible to connect, by mistake, in other connector.
In demand mode, should be used the patient cable of 3 leads or 5 leads for ECG monitoring, because the application of the pacemaker pulse is synchronous with respect to the QRS. Select the derivation which has the R waves more easily detectable.
In asynchronous mode, it is indistinct because the application of pacemaker pulses is asynchronous.

If your device has transcutaneous pacer, in the lower right corner of the display is the menu section dedicated to pacer.

To connect the pacer, follow the sequence:

1) Before starting the pacer connection sequence, make sure that it is turned off (OFF over the options on/Off).
2) Select the mode; demand (DEM) or asynchronous (ASY), when you turn on the equipment the default mode is demand. In demand mode verify that the QRS complexes are detected correctly, for which can be seen that the indicator of QRS complex detection is displayed, and the beep is heard in sync with the QRS.
   To change mode, you need to shut down the pacemaker before selecting it.
3) Select the frequency value to be applied (by default, is 70 ppm): Scroll with  keys to Frequency and then using the  keys may increase frequency to 180 ppm or decrease to 40 ppm in 5 ppm steps.
4) Set the current to a low value (by default, 20 mA): Scroll with  keys with the highlighted portion (cursor) to mA and then with the  keys you can adjust the current in steps of 5 mA.
5) Place the pacer's electrodes in position a) or b) (see the figure below).

6) Plug the pacer connector to the plug marked **"PACER"** in the front panel:



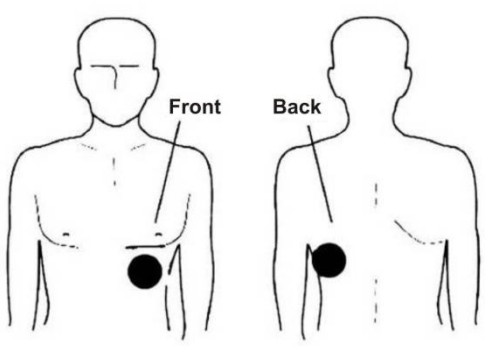
7) In demand mode (DEM) place the ECG electrodes to the patient and connect the ECG cable from the patient to the equipment. In asynchronous mode (ASY) this step is not necessary.
8) Turn on the pacer: Move with keys with the highlighted portion (cursor) until you reach ON/OFF and then, with the keys, choose ON.
9) Increase the current (in mA) to be observed on the monitor that has captured.

3.5.3 PREPARATION AND PLACEMENT OF PACING ELECTRODES

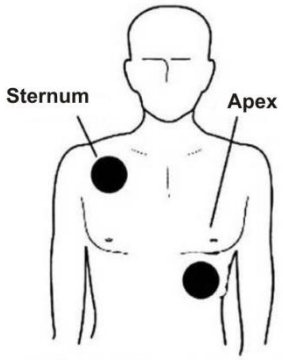
1) Connect the pacing electrodes to the cable.

2) Sanitize the area to be treated.
3) Application of the conductive gel.
   Apply the conductive gel homogeneously on the surface of the pacing electrodes.
   In case of prolonged use, renew the conductive gel and periodically clean the electrodes and the stimulation area.

4) Place the electrodes on positions a) or b) and fix them with the elastic belt. Make sure that conductive gel is not displaced and that the electrode makes homogeneous contact in the stimulation area.

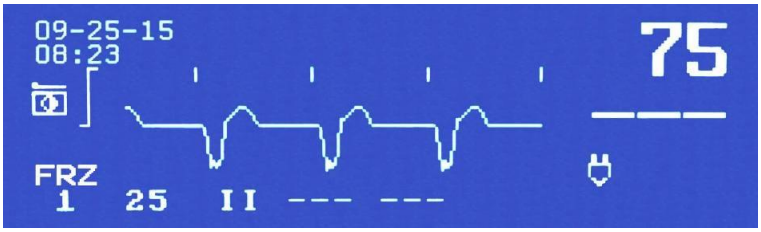


Position a) Front - Back



Position b) Sternum - Apex

Indicator of pacemaker spike detection
The following figure shows the indication of the presence of pacemaker's spikes on screen:



3.6. PULSE OXIMETER

It measures percentual oxygen saturation and peripheral pulse rate. It has alarms for tachycardia and bradycardia, QRS detection from pulse oximeter, with audio frequency ranging with the saturation percentage, and oxygen saturation alarms from 0% to 100%, where the default lower limit is 85%. It has a key that silences the alarm for 2 minutes.
The connector is polarized, which makes it impossible to connect, by mistake, in another connector.

3.6.1. WARNING MESSAGES

WARNINGS

- This is a functional measuring cannot be used to evaluate the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter cannot measure the contribution to total error of a probe/monitor system.
- The oximeter is calibrated to display the visualization of functional oxygen saturation.
- Significant dysfunctions of hemoglobin affect the accuracy of the SpO_2 measurement.
- SpO_2 measurement can be affected by excessive ambient light. If necessary, cover the sensor area with an opaque material (e.g., surgical gauze).
- Contrast inks introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine and fluorescent, can affect the accuracy of SpO_2 reading.
- Any condition that may reduce the blood flow, like the usage of cuff to measure the blood pressure or extreme systemic vascular resistance might cause an improper result in the SpO_2 and pulse rate measurements.
- Avoid using the oximeter sensor in any extremity were a baumanometer or any type of catheter is placed.
- Before placing the Oximetry sensor remove nail polish or fake nails, they might cause mistakes in the SpO_2 reading.
- If the extremity is in an elevated position, could compromise venous return and provide lower saturation measurements. Therefore, it is recommended to keep the Oximetry sensor at the height of the heart.
- Do not place the Oximetry sensor across the foot of a pediatric patient or on the foot itself.
- All necessary information regarding the toxicity and/or action on the tissues of the materials with which the patient or anyone else can contact is indicated in each attachment
- It should be noted that values between 70% and 100% SpO_2 measured by the pulse oximeter will be within ±2% of the value measured by a co-oximeter, due to the statistical distribution.
- If the equipment power is interrupted, when returning energy, the equipment will start with the last configuration set by the operator, except for the minimum oximetry alarm limit, that if it was off or set to less than 85%, will be adjusted to 85%, by regulatory requirement, and if has been set to more than 85% will retain the value set by the operator.
- It is recommended to place the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor away from the surgical field in the case in which it will use an electrocautery; this is to prevent burns on the patient's body in the area of the electrode.
- Be careful when making a temporary suspension audible alarm signal (silence), keep the patient under close surveillance at all times. If the alarm signals are selected, the visual alarm signal will continue to indicate an alarm condition if this occurs.
- Carefully route the patient cables, extension cables, oximetry sensors and/or pacemaker electrodes to reduce the possibility of patient entanglement or strangulation.

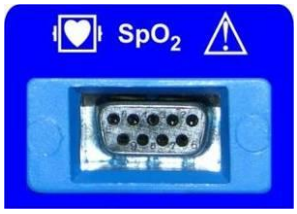
CAUTIONS

- Only use the Oximetry sensor provided with the equipment or those specially indicated for this equipment.
- The user is responsible for ensuring compatibility between the sensor, extension cable and this equipment.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **defibrillation** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- It is not necessary to disconnect the ECG electrodes, Pacemaker electrodes and/or Oximetry sensor for **electrosurgery** since the equipment is electrically isolated; although the paddles should not be positioned close to or on the electrodes or metal parts in contact with the patient, if this is not possible remove the electrodes or metal parts before positioning the paddles.
- When placing the Oximetry sensor "Y" with tape does not stretch or tighten it. If the tape is too tight can cause inaccurate readings and blisters on the skin of the patient (the blisters are caused by lack of skin breath, not by heat).
- Replace the Oximetry sensor every 2 hours to allow the patient's skin to breathe.
- The operation of the Oximeter can be affected by the presence of Computed Tomography equipment.

- In the presence of strong electromagnetic fields, the reading of SpO_2 may not be stable, displaying different values in every second. The device reading will stabilize after the interference ceases or when the device moves away from the emission source.
- The maximum time of application of the Oximetry sensor is indicated in its own manual.
- The specific use of the Oximetry sensor concerning: the patient population (e.g., age, weight), body part or tissue type to which it applies and application (e.g., environment, frequency of use, anatomical place, mobility) is indicated in its own manual.
- Be sure to know where and how to position the Oximetry sensor. Refer to the user manual that accompanies the sensor.

3.6.2. OXIMETER CONNECTION

If your device has an oximeter, in the middle of the front panel will find the following connector:



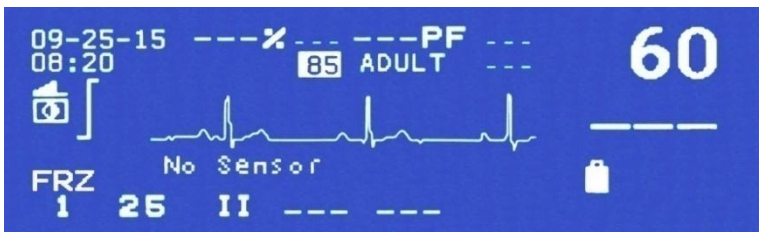
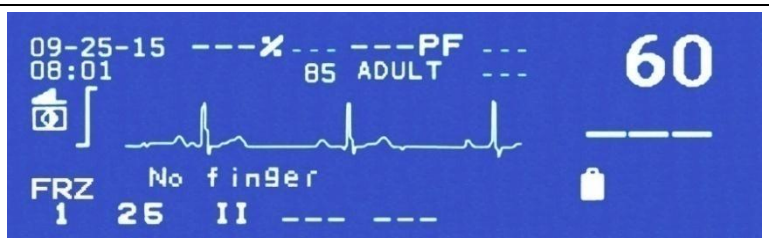
In the top of front panel, will find the menu section:

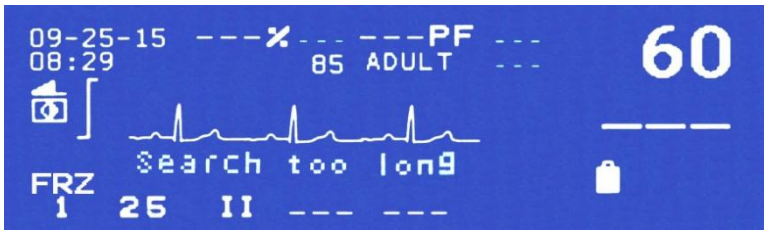
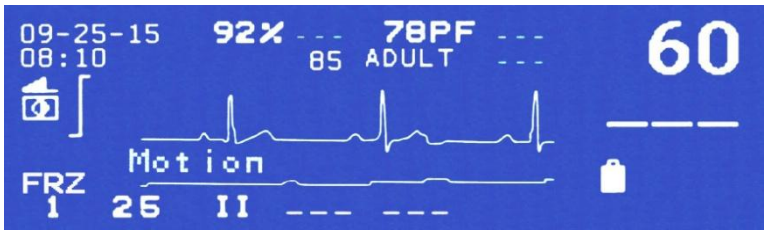
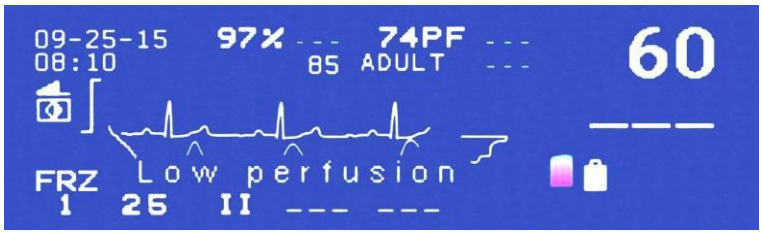
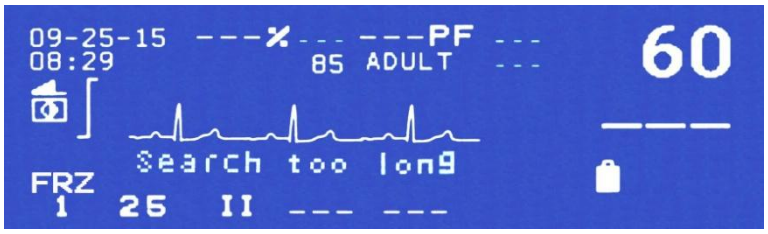
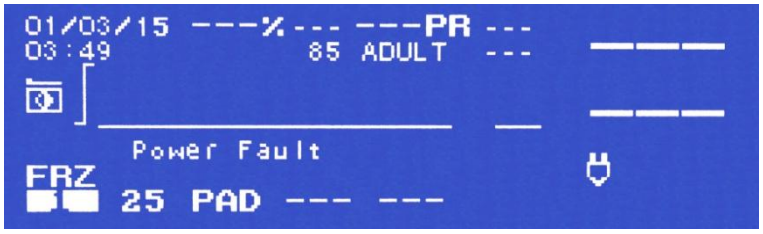
To connect the oximeter, only need to place the sensor on finger's patient and connect the sensor to the device. You also have to select the patient type between adult and neonatal.

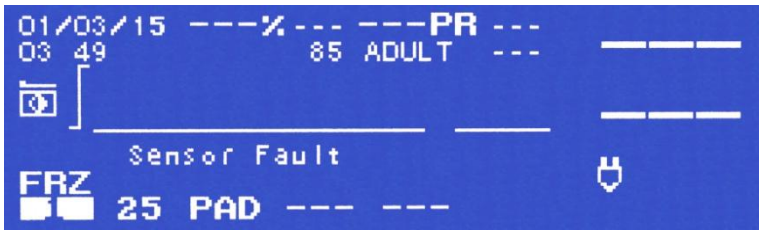
3.6.3. PATIENT SELECTION

To do this scroll with  keys to the patient sector and select the appropriate option with  keys: Adult or Neonate.

3.6.4. WARNING MESSAGES FROM THE OXIMETER

No sensor	This message will be displayed while the Oximetry sensor is not plugged to the device.
	
No finger	Once connected the Oximetry sensor, this message will be displayed while the sensor is not placed to the patient.
	
Searching	After placing the sensor on the patient, the message **"Searching"** is displayed while the oximeter detects pulse.

	
Search too long	If pulse is not found after a long period of time, the message **"Search too long"** will be displayed.
	
Motion	Once connected the Oximetry sensor and if the device detects patient movement, this message will be displayed.
	
Low perfusion	In the presence of a weak signal or low perfusion will display the message **"Low perfusion"**.
	
Error SpO_2	If there is no communication with the Oximeter module the message **"Error SpO_2"** will be displayed.
	
Power fault	Indicates a power supply failure in the Oximeter module.
	
Sensor fault	Indicates that there is a problem with the Oximetry sensor.

	
Interference by ambient light	When interference is detected by ambient light, the message **"Light Ambient"**.
	

3.6.5. CALIBRATION

The functional testers are not calibrated; however, an annual contrasting of the oximetry module with a calibrated simulator is suggested. To do this can send the device to feas ELECTRÓNICA or connect it to a simulator FLUKE-Index2 SpO_2 Simulator. If the set (SpO_2 sensor + SpO_2 adapter cable) does not meet the specified tolerances, directly connected to the oximeter, replace the sensor for a new one. If it still does not meet specifications, send the device to Technical Service.

The following table shows the values of measurements and tolerances.

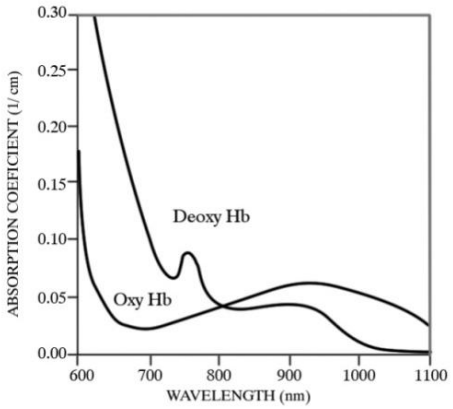
Oximeter FINAL TEST

	ITEM	DESCRIPTION	TO SIMULATE	TO MEASURE OR TO CONNECT IN	ADJUST	TARGET VALUE	MIN	MAX
OXIMETER	96	Oximetry: Simulate 76% SpO_2 - 40ppm. CHECK = OK.	--	--	--	--	--	--
	97	Register Pulse Rate	--	--	--	40ppm	37	43
	98	Register SpO_2	--	--	--	76%	74	78
	99	Look at the screen. If shows plethysmography waveform = OK	--	--	--	--	--	--
	100	Oximetry: Simulate 96% SpO_2 - 40ppm. CHECK = OK.	--	--	--	--	--	--
	101	Register Pulse Rate	--	--	--	40ppm	37	43
	102	Register SpO_2	--	--	--	96%	94	98
	103	Oximetry: Simulate 76% SpO_2 - 240ppm. CHECK = OK.	--	--	--	--	--	--
	104	Register Pulse Rate	--	--	--	240ppm	237	243
	105	Register SpO_2	--	--	--	76%	74	78
	106	Oximetry: Simulate 96% SpO_2 - 240ppm. CHECK = OK.	--	--	--	--	--	--
	107	Register Pulse Rate	--	--	--	240ppm	237	243
	108	Register SpO_2	--	--	--	96%	94	98
	109	Simulate "Low Perfusion" (with Cardiosat100, AMP=4%; with Index2, AMP=0,2%) (95% SpO2 - 75ppm) CHECK = OK	--	--	--	--	--	--
	110	Verify that displays the message "Low Perfusion". CHECK = OK.	--	--	--	--	--	--
	111	Register Pulse Rate with Low Perfusion.	--	--	--	75ppm	72	78
	112	Register SpO_2 with Low Perfusion.	--	--	--	95%	93	97
	113	If you have Cardiosat100 simulator, skip to Item122. CHECK = OK.	--	--	--	--	--	--
	114	Simulate Movement (95% SpO_2 - 75ppm). CHECK = OK.	--	--	--	--	--	--
	115	Verify that displays the message "Movement". CHECK = OK.	--	--	--	--	--	--
	116	Register Pulse Rate with Movement.	--	--	--	75ppm	70	80

	117	Register SpO_2 with Movement.	--	--	--	95%	93	97
	118	Simulate Neonatal (90% SpO_2 - 180ppm). CHECK = OK.	--	--	--	--	--	--
	119	Select PATIENT=NEONATE. CHECK = OK.	--	--	--	--	--	--
	120	Register Pulse Rate with NEONATAL.	--	--	--	180ppm	177	183
	121	Register SpO_2 with NEONATAL.	--	--	--	90%	87	93

3.6.6. MEASUREMENT PRINCIPLES

The SpO_2 module measures the SpO_2 content with a continuous non-invasive method to measuring oxyhemoglobin saturation. The principle of measurement is determining SpO_2 under cyclic congestion status of the tissues during pulsation. The method determines how much light emitted by the sensor light source penetrates the patient's tissue (finger or ear, for example) and reaches the receiver. The amount of light penetrating the tissue depends on many factors, many of them are constant; but one of them, the blood flow, varies with time as it is pulsed, therefore, the oxygen saturation of arterial blood can be calculated by measuring light absorption during pulsation. The pulsation control system provides a pulse waveform and a pulse signal. For the measurement, the wavelength of red light is 660 nm and 940 nm for infrared light. The optical power delivered to the patient is 4 mW (milliwatts).



Absorption spectral characteristic of hemoglobin

3.6.7. OXIMETER ALARMS

ALARMS Option: Select the alarms limits for SpO_2 and Pulse Rate. Position the cursor with the keys on the alarm limit to be changed and press the keys to adjust the desired value.

SpO_2 Alarm: Sets upper and lower limits of SpO_2 at which will alarm is activated.

Lower limit alarm for SpO_2:
ATTENTION! The lower limit alarm for SpO_2 is, by default, 85% and will be operational from the first pulse detection.
Using the keys, position the cursor over the lower limit (from SpO_2 alarm section, the bottom) and with the keys select the minimum value of oxygen saturation for the activation of the alarm; between 0% and 100% in 1% steps; if the upper limit alarm for SpO_2 is selected, the top value of the lower limit will be (upper limit alarm for SpO_2) - 1%.

Upper limit alarm for SpO_2:
Using the keys, position the cursor over the upper limit (from SpO_2 alarm section, the top) and with the keys select the maximum value of oxygen saturation for the activation of the alarm; between 0% and 100% in 1% steps; if the lower limit alarm for SpO_2 is selected, the lower value of the upper limit alarm for SpO_2 will be (lower limit alarm for SpO_2) + 1%.

PR ALARM: Sets the upper and lower limit for pulse rate at which alarm is activated.

Lower limit alarm for PR:
Using the keys, position the cursor over the lower limit alarm (from PR alarm section, the bottom) and with the keys select the minimum value of pulse rate for the activation of the alarm; between 30 1/min and 250 1/min in 5 1/min steps; if the upper limit alarm for PR is selected, the maximum top value of the lower limit will be (upper limit alarm for PR alarm) - 5 1/min.

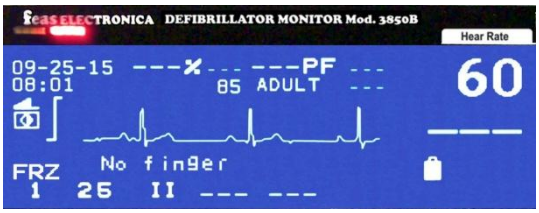
Upper limit alarm for PR:
Using the keys position the cursor over the upper limit (from PR alarm section, the top) and with the keys select the maximum value of pulse rate for the activation of the alarm; between 30 1/min and 250 1/min in 5 1/min steps; if the lower limit alarm for PR is selected, the lower value of the upper limit will be (lower limit alarm for PR) + 5 1/min.

The key  (Silence Alarm) also applied on oximeter alarms.

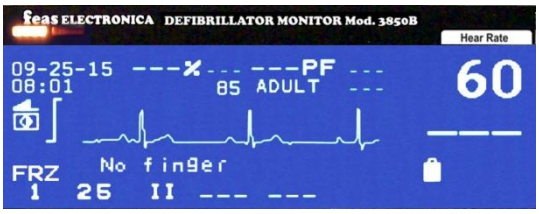
3.7. ALARM SYSTEM

WARNING! Maximum channel height: 21.2 mm. Suitable for use as a monitor up to 2 meters away.

The Biphasic 3850B Defibrillator Monitor has physiological and technical alarms and visual and audible alarm signals. Alarms are also classified according to their priority in High, Medium and Low.
A high priority alarm is indicated by a flashing red light indicator, located in the upper left corner of the display (see the figure below), and an audible signal (see AUDITORY ALARM SIGNALS OF HIGH PRIORITY).



A medium priority alarm is indicated by a flashing yellow light indicator, located in the upper left corner of the display (see figure below), and an auditory signal (see AUDITORY ALARM SIGNALS OF MEDIUM PRIORITY).



Finally, a low priority alarm is indicated by a yellow continuous light indicator, located in the upper left corner of the display (see previous figure), and an auditory signal (see AUDITORY ALARM SIGNALS OF LOW PRIORITY).
An audible alarm signal can be temporarily suspended by the SILENCE function.

SILENCE  **key:** To cancel the alarm sound for 2 minutes. Silence for two minutes is commonly used to move the patient, reposition or change sensors and/or electrodes or any activity that involves moving the patient or temporarily disconnected. Keep the patient under close surveillance during periods of off alarm signals. If the alarm signals are selected, the visual alarm signal will continue to indicate the alarm condition if it occurs even though the sound is muted.

WARNING! Be careful when making a temporary suspension audible alarm signal (silence), keep the patient under close surveillance at all times. If the alarm signals are selected, the visual alarm signal will continue to indicate an alarm condition if this occurs.

The alarm signals of the Defibrillator Monitor Mod. 3850B-Biphasic, are the class “not maintained”, meaning that the manifestation of alarm ceases when no longer exists the event that caused the alarm condition.

3.7.1. Physiological Alarms

WARNING! Because the patient is monitored but not attended continuously by an operator, it is for this reason that the alarms must be configured and adjusted appropriately.

A physiological alarm condition is visually indicated by the flashing red alarm indicator LED and on screen with the limit, which has been exceeded, blinking and aurally by a burst of pulses as specified in the AUDITORY ALARM SIGNALS section.
Physiological alarms can be inhibited by setting the limit(s) as “---”.

WARNING! If an alarm limit is set to “---” (inhibited), the alarm condition for that limit will not be detected neither manifested by the alarm signals (visual and auditory).

Physiological alarm limits are factory preset to “---”, except the lower limit of SpO_2 alarm which is preset to 85%.

The alarm system has a single preset by the user/operator, any change in one or more alarm limits will be stored so that when you turn off and on again the device, these modifications remain, except for the lower limit of SpO_2, the configuration is maintained if its value is greater than or equal to 85%, while if it is less than 85%, to turn off and turn on the device, the value will be set to 85%.

ATTENTION! According to the intended use of the device, the user is considered a medical professional trained in the operation of the device and knowledge, among others, in the monitoring and surveillance of vital signs, so any adjustment made alarm limits by an operator (paramedics or nurse) should be carried out under the direct supervision and user commandment.

3.7.2. Technical alarms

A technical alarm condition can be indicated by a visual signal, by indicator LED and text on the screen or symbol, plus an auditory signal, and can be of high, medium or low priority.
The technical alarm signals are the following:

Battery

Symbol	Visual alarm signal See section "VISUAL ALARM SIGNALS".		Auditory alarm signal See section "AUDITORY ALARM SIGNALS".	Priority
	Alarm led indicator	Message on screen		
	Yellow.	---	A pulse every 30 s.	Low
	red	"Low battery. The equipment will shut down."	Burst 10 pulses every 2.5 s.	High

DEFIBRILLATION

High priority alarm, with the exception that the auditory signal is not a high priority signal but is a continuous beep signal:
"Charge error" - This message is displayed when, once the load command has been started, for some reason and after a certain time the charged energy does not reach the selected energy value.

ECG

Low priority alarms:
"ECG lead off" - This message is displayed when one of the ECG electrodes loses connection with the patient. If the patient cable is removed, the alarm condition is disabled.
"ECG Satured" - This message is displayed when, for some reason, the ECG channels receive a signal greater than ± 5 mV at their inputs, rendering ECG monitoring (Palettes or Cable to Patient) inoperative. This can happen during defibrillation.

Oximetry

Low priority alarms:
"Search too long" - This message will be displayed if a pulse cannot be detected after a sufficiently long period.
"Error SpO2" - This message is displayed in case of loss of communication with the Oximetry module.

Medium priority alarms:
"Power fault" - Indicates a power failure of the Oximetry module.
"No finger" - Once the oxygen saturation sensor is connected, this message will be displayed as long as the sensor is not placed on the patient.
"No Sensor" - This message will be displayed while the oxygen saturation sensor is not connected to the Defibrillator.
"Sensor Fault" - Indicates that there is a problem with the Oximeter sensor.

Pacemaker

Medium priority alarm:
"Pacer lead off" - This message is displayed when an electrode of the TPM loses connection and there is no application of the pacemaker pulse to the patient.

Recorder

A fault in the thermal recorder is manifested by the light indicator, red color, located on the recorder panel.

4. MAINTAINING THE EQUIPMENT

Preventive maintenance
feas ELECTRÓNICA recommended that check the device by qualified and authorized personnel, at least every 12 months. We recommend contacting our Customer Service for the maintenance.
feas ELECTRÓNICA recommended periodic inspections of the power cords, patient ECG cable, SpO_2 sensor, defibrillation electrodes cables and pacer electrodes cables, looking for any breakage or cracks in the wires or conductors insulation.
Cleaning time is a good opportunity for a **GENERAL INSPECTION**.
feas ELECTRÓNICA recommends functional testing every time you start a new work shift.

Corrective Maintenance
When necessary, repair the equipment, request the assistance of qualified and authorised by feas ELECTRÓNICA to preserve the warranty conditions and electrical safety parameters.
In case to request assistance from Customer Service, will be asked the device serial number, for a faster and efficient assistance.
In case of sending the device to feas ELECTRÓNICA, if possible, use the original packaging. If is not possible, protect the device so well as possible.

4.1. GENERAL INSPECTION

Periodically, inspect the defibrillator case, the power cord and paddles cables, paying special attention to sectors of the cables near the connectors and paddles, as these are the sectors most likely to break due to rotations, tractions and bending at these points.
At any sign of deterioration require assistance to feas ELECTRÓNICA's Customer Service.
Cleaning time is a good opportunity for a **GENERAL INSPECTION**.

> ***WARNING! There is a risk of electrical shock and death.*** Do not use this equipment if you doubt of the integrity of any cable. Check the cables periodically (disconnect them before) to verify their integrity; paying special attention to cable points close to connectors and paddles. In case you find an irregularity, request the part to our Customer's Service.
> ***WARNING!*** *It is not allowed to modify the equipment.*
> ***WARNING!*** *Not modify this equipment without authorization from the manufacturer.*
> ***WARNING!*** *If you modify this equipment must perform appropriate tests and inspections to ensure continued safe use of equipment.*
> ***ATTENTION!*** *It suggests an annual contrasting against calibrated simulators.*

4.1.1. POWER CORD

If you notice the power cord is damaged, the ground is not correct; either by cable damage or the Power plug does not fit tightly into wall outlet, disconnect the device immediately and continue operating it from the internal battery. Contact the technical service to fix the problem.

4.2. CLEANING AND DISINFECTION

WARNING! Before any cleaning, make sure the device is turned off. REMEMBER: The device has internal battery, so even disconnected from the AC line, may be turn on. Verify the selection switch is in the off position and the display doesn't contain instructions and is turned off.

Please adhere to the following steps for thorough cleaning and disinfection of the equipment and its components as needed:

1) Visually inspect the condition of the equipment surfaces. Be sure to have sufficient lighting for the inspection. If there is substantial dirt or residue, use a cotton cloth, microfiber, or paper towel dampened with potable water to remove it. If no residue is present, proceed directly to step 2.
2) Clean the surface using a cotton cloth, microfiber cloth, or paper towel dampened with a cleaning and disinfection solution (One-Step Cleaner/Disinfectant) containing quaternary ammonium or hydrogen peroxide. Prepare the solution following the manufacturer's instructions.
DO NOT use abrasive cleaners or strong solvents such as acetone or acetone-based components.
DO NOT allow liquids to enter the device, and do not place liquids in the device while cleaning.
Be careful when cleaning the monitor display, is particularly sensitive to rough surfaces and susceptible to scratched.
3) Allow the solution to work for 10 minutes.
4) Rinse surfaces with a cotton cloth, microfiber cloth, or paper towel dampened with potable water.
5) Check that treated surfaces are visibly free of debris or dirt. Be sure to have sufficient lighting for the inspection. If needed, repeat the cleaning process.
6) Let the equipment air dry.

WARNING! Risk of explosion or fire! *Do not spill water or liquid on the device. Unplug the power cord and paddle before cleaning or disinfecting the device.*

ATTENTION! *Do not clean the outer casing, cables or paddles with solvents, abrasives or acids.*

ATTENTION! *Do not clean or disinfect accessory cables, accessories and parts of the equipment or the main body thereof with sodium hypochlorite (bleach water), solvents, acids or abrasive products. For cleaning and disinfection of the equipment and its accessories, follow the instructions in this manual.*

4.2.1. PADDLE CLEANING

NOT sterilize the external paddles with vapor or gas (ethylene oxide (ETO)), do not immerse in liquids or heat above 50ºC.
Clean and disinfect the paddles, including its handle by following the method previously described in section **"CLEANING AND DISINFECTION"**.

4.2.2. ECG ELECTRODES AND PATIENT CABLE

This device is intended for use disposable adhesive ECG electrodes. Do not reuse the electrodes. Replace them and repositioning them in accordance with the manufacturer's instructions. Check expiration date of disposable electrodes weekly, and their state, to ensure sealing integrity.
The ECG patient cable must be cleaned and disinfected by following the method previously described in section **"CLEANING AND DISINFECTION"**.

4.2.3 PACER ELECTRODES

NOT sterilize the pacer electrodes with vapor or gas (ethylene oxide (ETO)), do not immerse in liquids or heat above 50ºC.
Clean and disinfect the pacer electrodes by following the method previously described in section **"CLEANING AND DISINFECTION"**.

4.2.4. CLEANING OF PAPER CHAMBER AND PRINTHEAD

Press the gate release button, once ajar; raise it until it is fully opened. Take the roll of paper and pull it smoothly toward you.
With cloth moistened alcohol, clean the chamber; then with another clean cloth dampened with alcohol, clean the thermal array.
To replace the paper, see **PAPER REPLACEMENT** procedure.

4.2.5. OXIMETRY SENSOR CLEANING

To clean the oximetry sensor, disconnect it, clean it by following the method previously described in section "CLEANING AND DESINFECTION".

CAUTION! Do not sterilize with vapor in autoclave or immerse in water or other solutions.

4.3. STERILIZATION METHODS

ATTENTION! There is a risk of equipment breakdown. *Do not sterilize this device or its parts or accessories in autoclave or ethylene oxide. Do not submerge any part of this equipment in water or other liquids or use abrasive cleaners. Do not spray or spill liquids on the equipment or its accessories. Do not allow any liquid entering the connectors or other openings of the housing. If you accidentally spill liquid on the equipment, turn the energy switch OFF (because the equipment has internal battery) and disconnect it the power line (in case it is connected to the power line), clean it and dry it before reuse. If in doubt about equipment security, send the same to an authorized technical service.*

ATTENTION! There is a risk of equipment breakdown. *No sterilize defibrillation paddles of this device in autoclave or ethylene oxide.*

ATTENTION! *This equipment is not sterile or sterilizable, in the case of accessories; refer to the user manual corresponding to that accessory.*

Do not sterilize this device or its accessories. Refer to the cleaning and disinfection methods.

4.4. PAPER REPLACEMENT

a) Press the gate release button and lift the cover until fully open.
b) Take the paper support tube and pull smoothly towards you to remove it.
c) Place the new paper roll between the two round supports.
d) Pull out some paper. Make sure the paper sensitive side (brightest) is faced with the RECORD array. The brighter side of paper, generally, is inside the roll.
e) Align the paper with the roll at the cover.
f) Hold the paper against the roller and close the cover.
g) To verify the correct installation of paper, make a test RECORD. If the paper does not move, open the cover and repeat from **e)** step.

4.5. POWER SELECTOR

The defibrillator has three power modes:

- 90 Vac - 240 Vac (automatic selection) and notch filter 50 Hz or 60 Hz, factory selectable.
- Internal rechargeable battery 12 Vdc.
- External +12 Vdc.

WARNING! Verify the AC voltage range matches the voltage at which the device is to be connected. If does not match, contact feas ELECTRÓNICA's Service Customer.
WARNING! Verify the AC frequency indicated on the back panel matches the AC frequency which the device is to be connected. If does not match, contact feas ELECTRÓNICA's Service Customer. Do not use the device in those conditions. The ECG waveform will be affected by noise and will not be able to use SYNC mode.
WARNING! You must make sure that the AC inlet, to which you will plug the device, has a ground line and is in good condition.
WARNING! The equipment must be connected to an approved electrical installation that includes a correct grounding according to the local legislation in force. Do not use adapters or replace the device's original cables. If the plug does not match the installation, please contact our Customer Service for the provision of a suitable cable.
WARNING! Do not connect this device to an outlet controlled by a switch on/off.

In mobile units, you can power the Monitor Defibrillator from the lighter socket of the unit, through the external +12 Vdc power cable.
To connect the device, follow these steps:

1) Connect the output jack +12 Vdc power cable on the back panel.
2) Connect the plug on the lighter socket.
3) Verify that the connection is correct and the energy reaches the device, watching green triangular light over battery symbol, located on the front panel.

4.6. VERIFICATION OF ENERGY DELIVERED

Verification or energy test ensures that the equipment is able to deliver energy on paddles or determine that, due to a fault, does not allow delivery of energy on paddles. If the test failed, contact the feas ELECTRÓNICA´s Customer Service to arrange repair.
ATTENTION! It is suggested to perform the Test of Energy Delivered according to the domestic policy of the Institution Health or at least once a week.
ATTENTION! Before performing the Delivered Energy Test, verify that the external paddles are clean and dry.
ATTENTION! Before performing the Test of Energy Delivered, external paddles must be connected and place on the paddle's holder. Perform the verification with the equipment connected to line power.
WARNING! More than 10 energy discharges should not be performed during Test of Energy Delivered; considering that the minimum waiting time is 1 minute, between discharges.

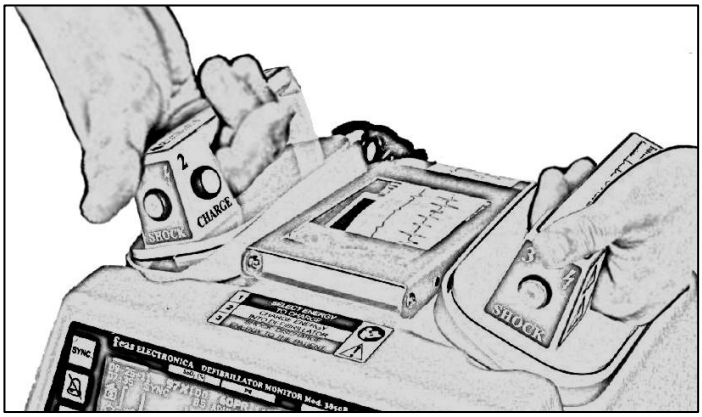
For verification of energy delivered perform the following steps:

i. Turn on the equipment, while pressing the DISARM key, then the equipment will start in energy delivered test mode and you should see the following message on screen:

ii. Place the Selector Switch in 200 Joules, as shown in figure above.

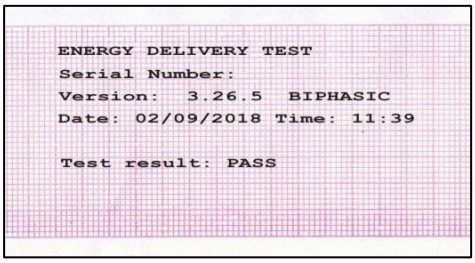
iii. When the Selector Switch is in 200 Joules, and the external paddles are connected to the equipment and placed on the paddle's holder, as indicated in the message of figure above, press the CHARGE key. Then begins a count that is increased up to the value of about 200 Joules, this number indicates the value of the stored energy, and then the following message is showed in the screen:

iv. Press the "**SHOCK**" button located on the front of the device or press, at the same time, the "**SHOCK**" buttons located on the paddles (in this case take the paddles firmly as shown in the following figure), without removing the paddles of the holders:



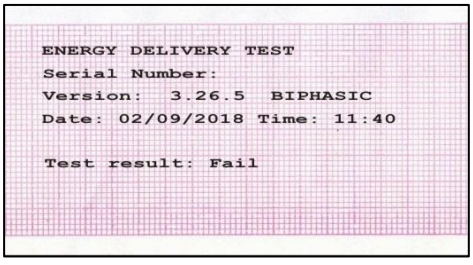
Then, if the verification result is correct and, therefore, the equipment delivered energy on paddles, you will observe the following message:

If the device has a thermal recorder, after the Test a report will be printed as follows:



v. If the verification result is wrong the following message is displayed onscreen:

If the device has a thermal recorder, after the Test a report will be printed as follows:



In case the equipment does not pass the energy test, please contact to the Customer Service of feas ELECTRÓNICA to agree on the repair.

vi. When the verification is complete, turn the power selector switch to the OFF position.

4.7. ALARM VERIFICATION

This device alarms are indicated audibly and visually. You must ensure, before checking the alarm function, the symbol does not appear on display.

Quick check
Before using the device for monitoring the patient through the alarm system, we recommend a quick check of the alarm signals. For this set the lower alarm limit of 20 1/min heart rate without connecting the cable to patient, is thereby activate the alarm system, the alarm condition manifested by auditory (see section **"AUDITORY ALARM SIGNALS"**) and visual signals (on screen, the lower limit of heart rate is highlighted with inverted text).

Technical check
It is recommended that a technical check at least once a year.
The verification method is analogous to SpO_2 alarms. We'll use as illustrative case the heart rate.
Connect the ECG simulator with 3 wires or 5 wires patient ECG cable, selecting in the simulator the following values: normal ECG, amplitude = 1 mV, frequency = 60 1/min.
Then, set alarm limits as follows: Lower Alarm Limit = 30 1/min; Upper Alarm Limit = 120 1/min and Detection of QRS from DII.
In that condition, shouldn't sound or be indicated any alarm and should indicate 60 1/min in the upper right corner of the screen.
Adjust the frequency of simulator to 29 1/min and observe the display. The heart rate indicator will diminish its value until 29. At that time, the lower alarm limit for heart rate (bradycardia) will activate and begin to hear the alarm sound. The heart rate lower limit is highlighted by presenting a white background. Check that pressing the mute key, the audible alarm went off at the lower left corner of the display shows the symbol, and it still indicates the visual alarm with white background in the lower limit. Press the mute key again and you will hear the alarm sound.
Adjust the frequency of the simulator to 60 1/min again and observe the display. The heart rate indicator will increase its value until it indicates 60. When indicating over 30 1/min the sound of the alarm and visual indication shall cease.
Now adjust the frequency of the simulator to 121 1/min and observe the display. The heart rate indicator will increase its value until it indicates 121. At that time, will activate upper alarm limit heart rate (tachycardia) and begin to hear the alarm sound. The upper limit heart rate is highlighted by presenting a white background. Check that pressing the mute key, the audible alarm went off and at the lower left corner of the display shows the symbol, and it still indicates the visual alarm with white background in the upper limit. Press the mute key again and you will hear the alarm sound.
Adjust the frequency of the simulator to 60 1/min again and observe the display. The heart rate indicator will diminish its value until 60. When indicating less than 120 1/min the alarm sound and visual indication shall cease.
Similarly, and with the corresponding patient simulators, can perform verification of alarm operation of each parameter.

4.8. FUSE CHANGE

Before starting operation, make sure the device is disconnected from the power line, and also is off. To perform the operation must have a small screwdriver and a set of replacement fuses.
You must enter a screwdriver to unlock the switch, pull the wire and cover will come out. Remove both fuses and check if are broken, by measuring electrical continuity between the terminals (broken = no continuity). Should you find one or two broken, you must replace them with new fuses.

ATTENTION! In case of fuses are damage replace with fuses of the same type and value. If the failure persists, please contact our Customer Service.
ATTENTION! This equipment has line fuses in both the neutral pole and Phase Line.

4.9. RECHARGEABLE BATTERY

The device is provided with an internal rechargeable battery allowing it to operate without connection to AC line voltage or external +12 Vdc. To charge the internal batteries, connect it to the AC line voltage or external +12 Vdc, permanently. It is not necessary that the device is turned on to charge the battery. The battery charge is indicated on the front panel by turning on the green triangular light over  symbol.
The state of charge of the battery is indicated on the screen, and therefore requires that the device is on (MONITOR or energy selection) and operating from the internal battery (disconnected from AC line or external +12 Vdc). If the battery is charged, the display shows the  symbol. When the display shows the  symbol indicates that the battery is partially charged and should be charged as soon as possible to preserve battery life.

When battery is discharged, the display shows the  symbol and the low battery technical alarm condition will activate the visual and auditory signal. This alarm is of low priority and allows the operator to perform at least three discharges at maximum energy, before the equipment is turned off.
When battery is fully discharged the high-priority discharged battery technical alarm will be activated, and the message **"Battery Discharged – Power is down"** will also be displayed. The device will automatically turn off 120 seconds after the message, to avoid damaging the battery. You should recharge the battery as soon as possible to preserve its life.
The auditory indication of the technical alarms, mentioned above, is detailed in the section **"AUDITORY ALARM SIGNALS"**.

In the latter case, the device will operate correctly from AC line or external +12 Vdc, in both conditions, the display shows the  symbol.

Battery Autonomy: This device, with new internal battery fully charged, at a temperature of 20ºC, can deliver a minimum of 150 shocks at 200 Joules without recharging the battery.

Battery Charging Time from exhausted till at least 90%: 2 hrs 15 min.

Charge Cycle: When is not used, the device must stay connected to AC line or external 12 Vdc to recharge the batteries. There is no need to disconnect from AC line or external 12 Vdc, because it has an automatic device to keep the battery fully charged.

The **internal battery** should be checked visually once a year to determine there are no damages.
Check monthly its autonomy, if it decreases to 80% of the value indicated the technical specifications; the battery should be replaced with another battery of the same type.

To ensure long battery life:

- ✓ **ATTENTION!** No fully discharge the battery.
- ✓ **ATTENTION!** Recharge the battery immediately after use.
- ✓ **ATTENTION!** When the device is stored in warehouse, should be put to charge at least once every 60 days for at least 3 hours at 25ºC ± 3ºC temperature, to prevent battery damage.
- ✓ **ATTENTION!** Do not store the device in deposits, or leave it between periods of use, in places where the sun shine directly into the device. Risk of damage to the cover device, parts and accessories.
- ✓ **ATTENTION!** During storage in warehouses and between uses, respects the conditions of temperature, pressure and humidity as defined in this manual and periods of recharge the internal battery specified.
- ✓ **ATTENTION!** The internal battery of this equipment cannot be replaced by the user. Necessarily must be replaced by a qualified technician.

ATTENTION! In case you replace the battery follow the local instructions to dispose Ni-Mh batteries or send them to feas ELECTRÓNICA for disposal.

5. TROUBLESHOOTING

GENERAL

Trouble	Probable cause	Action
Pushes the power on key, but the equipment no power on.	The equipment is disconnected from mains or +12 Vdc ext.	To connect firmly the cable to the mains and to the equipment.
The display is dark; the waveforms and characters are not sees.	The contrast is adjusted incorrectly.	Adjust the contrast as explained in "Contrast".
The date and/or time on screen and on the thermal paper is not correct.	The date and/or time are incorrect.	Set Date and Time according "Date and Time".
No sync sound (QRS beep).	The motherboard is faulty.	Send the equipment to our Customer Service for repair.
	Volume is too low.	Increase the sound volume.
No audible alarm signals.	The key (Alarm silence) is activated.	Pres the key (Alarm silence) again.
	The alarms are disabled "---" in all alarm limits.	Select, on screen, the upper and lower limits of each parameter alarm.
	The speaker, your cable or the motherboard is faulty.	If the problem persists, the motherboard is the cause, Send the equipment to our Customer Service for repair.

DEFIBRILLATOR

Trouble	Probable cause	Action
The defibrillator doesn't Charge energy. The message "Charge Error". Take more than 10 seconds to complete the charge.	Operating from the battery, it is almost empty.	Connect the equipment to an outlet and recharge the battery. The battery is charged automatically when the equipment is connected to the mains.
The defibrillator doesn't Charge energy. The message "Charge Error". Take more than 10 seconds to complete the charge.	Operating from the mains breakage in the power system charge.	Send the equipment to our Customer Service for repair.
Pressing paddle buttons don't discharge energy to the patient.	If discharge is performed from "Shock" key, then extern paddles are faulty.	Replace external paddles.
Pressing the "Shock" key, don't discharge energy to the patient.	Faulty keyboard.	Send the equipment to our Customer Service for repair.
Pressing paddle buttons or discharge front button, don't discharge energy to the patient.	Faulty equipment.	Send the equipment to our Customer Service for repair.

ECG

Trouble	Probable cause	Action
Selected ECG lead isn't properly viewed, and Lead Off message appear.	One of ECG electrodes is loose.	Check that the electrodes are perfectly attached and make contact with the patient's skin. If necessary, replace (the) electrode (s). Check that each pin of patient wire is correctly connected to its corresponding electrode. If problem persists, then motherboard is the cause, Send the equipment to our Customer Service for repair.
	One of the electrodes wires is disconnected from electrode.	
	One of the electrodes wires is faulty.	
	Faulty motherboard.	
Selected ECG lead isn't viewed, it's showing a straight line.	The ECG connecting wire is disconnected from the defibrillator.	Check patient wire connection to the equipment.
	ECG input signal greater than ± my, this can occur during defibrillation.	Wait a few seconds until the signal is restored automatically.
	Faulty motherboard.	Send the equipment to our Customer Service for repair.
Selected ECG lead isn't viewed and message "ECG Saturated" appear.	There is a very powerful source of electrical noise emission in patient vicinity.	Separate the patient and equipment of the noise source.
	Equipment isn't connected to ground because it uses an adapter plug.	Connect the equipment to the facility, without adapters, to a grounded outlet. Contact the After-sale customer assistance of feas ELECTRÓNICA to supply the appropriate wire for installation.
	The equipment isn't connected to ground because it uses a base of multiple sockets ungrounded.	In case of need to use a multi-socket basis, make sure that it´s earthed and connected to the facility. Contact After sale customer assistance of feas ELECTRÓNICA to providing multiple sockets base suitable for installation.
	The facility has no grounding or is faulty.	Contact a licensed electrician to normalize installation and outlets, and that they have normalized ground.
	None of the above.	Send the equipment to our Customer Service for repair.

SpO2

Trouble	Probable cause	Action
Not displayed SpO_2 value nor the PR and the message "Without sensor" appear.	The SpO_2 adapter cable is disconnected from the SpO_2 connector.	Connect the SpO_2 adapter to SpO_2 connector.
	The SpO_2 sensor is disconnected of SpO_2 adapter.	Firmly connect the SpO_2 sensor to the adapter.
	SpO_2 adapter cable or the sensor is cut.	Replace the SpO_2 adapter or sensor.
Not displayed SpO_2 value nor the PR and the message "Without Patient" appear.	Lost connection between sensor and patient.	Set firmly the sensor to the patient.
Not displayed SpO_2 value nor the PR and the message "Searching" appear.	This message should appear while the equipment is searching patient's pulse and disappears when waveform and values appears.	If the message "Not Found" appear change patient finger. If the problem persists, and has another sensor, replace it. If this solves the problem, send the sensor for repair; else send the sensor and equipment to our Customer Service for repair.
Not displayed SpO_2 value nor the PR and the message "Not Found" appear.	Appears if there is no pulse after a sufficiently long period.	See previous point.
Not displayed SpO_2 value nor the PR and the message "Movement" appear.	Indicates that patient is moving and the sensor isn't properly attached to him.	Attach the sensor to the patient with gauze or hypoallergenic tape without pressing too hard. If problem persists, and has another sensor, replace it. If this solves the problem, send the sensor for repair; else send the sensor and equipment to our Customer Service for repair.
The message "Low Perfusion" appears.	Indicates that where the sensor is placed have low perfusion.	Reposition the sensor. If problem persists, and has another sensor, replace it. If this solves the problem, send the sensor for repair; else send the sensor and equipment to our Customer Service for repair.
	The internal SpO_2 module is faulty.	Send the sensor and equipment to our Customer Service for repair.
Dotted lines appear in place of the pulse waveform.	Faulty SpO_2 sensor.	Replace SpO_2 sensor.
	Faulty SpO_2 adapter.	Replace SpO_2 adapter.

Printing

Trouble	Probable cause	Action
Printing is fuzzy. Missing points.	Not using the correct paper.	Use the specified paper for performed type printing.
	The thermal head is dirty.	Clean the thermal head with a head cleaning device. If the problem persists, the printer unit is faulty. Replace the print unit.
No prints.	No paper is loaded in the printer.	Load paper in printer.
	Printer compartment isn't properly closed.	Close the compartment until it clicks.
	Paper is loaded with the print side facing up.	Load the paper correctly.
	Faulty keys.	If the light does not turn on when you press the print key, make an impression through the System Maintenance. If printing is checked, then the key is faulty, replace it.
	Faulty printer.	If the light turns on when you press print key, check the printer with the maintenance system.
	Faulty motherboard.	
The printing light is on.	The printer temperature is too high.	Cool the printer. If the problem continues, the printer unit or the motherboard is faulty. Replace the print unit or the motherboard.

6. TECHNICAL SPECIFICATIONS

6.1. GENERAL

Device Class I and internally powered.
Degree of protection against electrical shock: Type CF.
Degree of protection against liquids: IPX2.
The equipment is not suitable for use in the presence of explosive atmosphere or flammable mixture.

• Safety Standards (certified):
- EN-60601-1.
- EN-60601-1-2. (Electromagnetic Compatibility).
- EN-60601-1-6.
- EN-60601-1-8.
- EN-60601-2-4.
- EN-60601-2-27.
- EN-60601-2-49.
- ISO 80601-2-61.

• Quality Standards (certified):
- CE marking, Dir. 93/42/CEE.
- ISO 13485.
- A.N.M.A.T. 3266/2013 Disp.: B.P.F.
- A.N.M.A.T. 2319/02 Disp.

TM: Eng. Jorge F. Feas - MP: 12341991 and Eng. Julio Brezzo - MP: 18015606.
The equipment is authorized by A.N.M.A.T. PM 1125-15.
The equipment is exclusively use for medical professionals and medical institutions.
Use Mode: Monitoring, Recording and Pacer: continuous use.
Defibrillator: intermittent use, maximum cadence of 200 J shock: 3 shock per minute and 1 minute rest.
In both cases, the device will be powered with 90 Vac - 240 Vac, 50 Hz/60 Hz.

Electrical Specifications

Power supply: 90 Vac - 240 Vac (automatic selection) and notch filter 50 Hz or 60 Hz, factory selectable.
External Power: 12 Vdc.
Internal Power Supply
- Battery.
- 12 Vdc - 4000 mAh Pack.
- Weight: 750 g.
- Ni-Mh battery.

Battery Autonomy: Continuous monitoring 8 hours or at least 150 shocks of 200 J.
4 hours of continuous monitoring with pacemaker.
Battery Charging Time from exhausted till at least 90%: 2 hrs 15 min.
Maximum power consumption during maximum energy charge: 180 W.
Power consumption during standby: 7 W.
Power supply in Ambulance
- Be medical grade and meet the requirements of standard IEC 60601-1 or come from a vehicle battery (cigarette lighter connector ambulance).
- Voltage: 12 Vdc.
- Maximum Current: 10 A.

Line fuse
- Quantity: 2 (two).
- Dimensions: 20 mm x 5 mm.
- Type: Slow Blow.
- Voltage: 250 V.
- Current: 2.5 A (I_{nom}).
- Speed: 100% of I_{nom} for 4 hours minimum.
  135% of I_{nom} for 1 hour maximum.
  200% of I_{nom} for 120 seconds maximum.
- Breaking capacity: 100 A to 250 Vac.

+12 V external fuse
- Dimensions: 20 mm x 5 mm.
- Type: Slow Blow.
- Voltage: 250 V.
- Current: 10 A (I_{nom}).
- Speed: 100% of I_{nom} for 4 hours minimum.
  135% of I_{nom} for 1 hour maximum.
  200% of I_{nom} for 120 seconds maximum.
- Breaking capacity: 100 A to 250 Vac.

Internal Battery fuse
- Dimensions: 20 mm x 5 mm.
- Type: Slow Blow.
- Voltage: 250 V.
- Current: 10 A (I_{nom}).

- Speed: 100% of I_{nom} for 4 hours minimum.
  135% of I_{nom} for 1 hour maximum.
  200% of I_{nom} for 120 seconds maximum.
- Breaking capacity: 100 A to 250 Vac.

Mechanical Specifications

Dimensions: 295 mm (width) x 200 mm (height) x 345 mm (length).
Weight: 6 Kg (including external paddles, battery and recorder).
Display: Type - High Brightness Liquid Crystal.
Dimensions: 132 mm x 38.5 mm.

Environmental Specifications

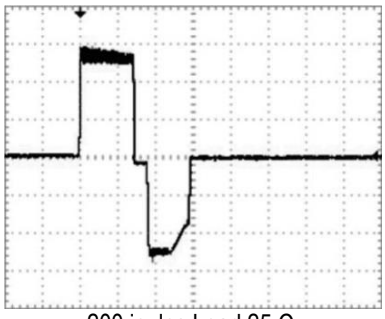
During storage and transportation
Ambient Pressure: 500 mmHg to 797 mmHg.
Ambient Humidity: 0% to 95% (non-condensing).
Temperature: -5ºC to 55ºC.
During operation
Ambient Pressure: 500 mmHg to 797 mmHg.
Ambient Humidity: 0% to 90% (non-condensing).
Temperature: 0ºC to 45ºC.

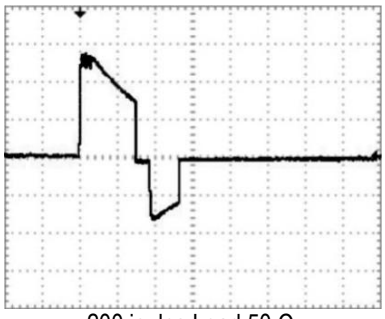
6.2. DEFIBRILLATOR

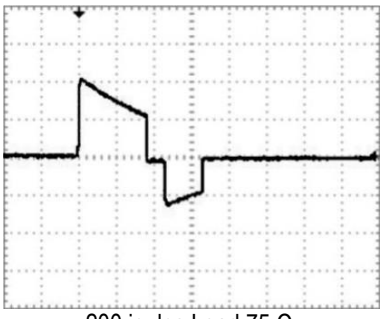
Capacitor: 196 µF x 2.30 KV.
Inductance: 7 mHy.
Internal resistance: 4 Ω.
Maximum charge energy: 200 Joules.
Waveform: Biphasic.
Charge time to 200 J
- Nominal Line: 6 s.
- 90% of nominal line: 7 s.
- Full battery: 6 s.
- After 15 shocks of 200 J: 6 s.

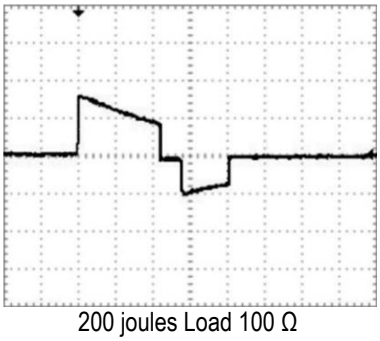
Number of shocks of 200 J with fully charged battery: 150 shocks at a rate of 3 shocks/minute and 1 minute rest.
Energy Values Selection: on steps of 2 J, 3 J, 5 J, 7 J, 10 J, 20 J, 30 J, 50 J, 70 J, 100 J, 150 J and 200 J.
Energy values are indicated in the selector for a patient impedance of 50 Ω.
Charging and Charged Indication: Visual and auditory.
Energy charge Indication: Visual and auditory.
Automatic Internal Disarm Time: 60 s.
SYNC: Started by keyboard, indicated on display.
Minimum amplitude detection of ECG R: 0.3 mV.
Trigger delay: Within 60 ms after detection of R-wave.

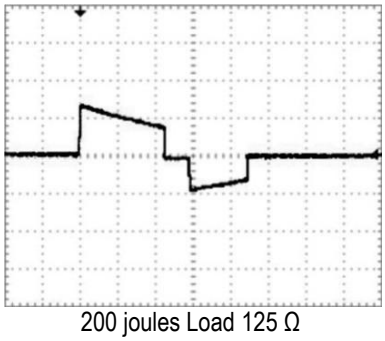
Waveform discharge at maximum energy

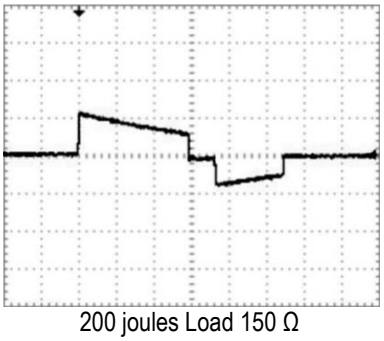

200 joules Load 25 Ω

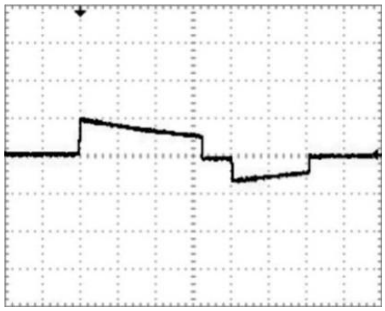

200 joules Load 50 Ω


200 joules Load 75 Ω


200 joules Load 100 Ω


200 joules Load 125 Ω


200 joules Load 150 Ω



200 joules Load 175 Ω

Scale on the vertical axis: 10 A/div.
Scale on the horizontal axis: 5 ms/div.

Precision of delivered energy

Energy [Joules]	Min.	Max.	25 Ω	50 Ω	75 Ω	100 Ω	125 Ω	150 Ω	175 Ω	PRECISION
2	0	5	1.8	2.1	2.1	2.2	2.0	2.1	1.8	±3 J
3	0	6	3.0	3.2	3.2	3.0	3.3	3.0	2.8	±3 J
5	2	8	4.6	5.3	5.3	5.2	5.3	5.1	4.9	±3 J
7	4	10	6.5	7.3	7.4	7.4	7.3	7.2	7.0	±3 J
10	7	13	9.3	10.4	10.5	10.4	10.5	10.2	10.4	±3 J
20	17	23	18.8	19.8	20.7	20.6	20.8	20.4	20.3	±15%
30	25.5	34.5	29.6	31.0	31.4	31.2	31.4	31.2	31.2	±15%
50	42.5	57.5	46.6	51.6	52.2	51.9	52.6	50.8	51.0	±15%
70	59.5	80.5	65.4	71.5	72.3	72.9	72.7	72.7	71.7	±15%
100	85	115	94.0	103.0	104.6	104.3	105.8	102.6	102.7	±15%
150	127.5	172.5	142.4	154.3	156.3	152.6	153.3	154.7	152.3	±15%
200	170	230	187.6	205.7	207.8	205.0	205.4	206.0	201.9	±15%

6.3. ECG

FUNCTIONAL SPECIFICATIONS

Input on Paddles: Type CF.
Patient ECG Cable: 3 wires or 5 wires.
Input Electrodes: Type CF.
Notch Filter: 50 Hz or 60 Hz (factory Determined).
Indication of QRS: QRS Beep and image (♥).
Alarm Silence: keyboard, 2 minutes.
Lead Selection: Keyboard DI, DII, DIII and PAD (Paddles) or DI, DII, DIII, aVR, aVF, aVL, precordial and PAD.
Amplitude Accuracy: ± 20% of reading or ± 100 µV (whichever is greater).
Input Noise Specification is <30 µVpp.
Input impedance
Common Mode: Greater than 10 MΩ at 50 Hz/60 Hz.
Differential Mode: Greater than 25 MΩ from direct current up to 60 Hz.
Common Mode Rejection Ratio: 90 dB minimum at 50 Hz or 60 Hz.
Sweep speed: 25 mm/s or 50 mm/s.
Gain Selection: 1/6 cm/mV, 1/4 cm/mV, 1/2 cm/mV, 1 cm/mV and 2 cm/mV.
Detection, rejection and indication of pacer pulse.

CARDIOTACHOMETER

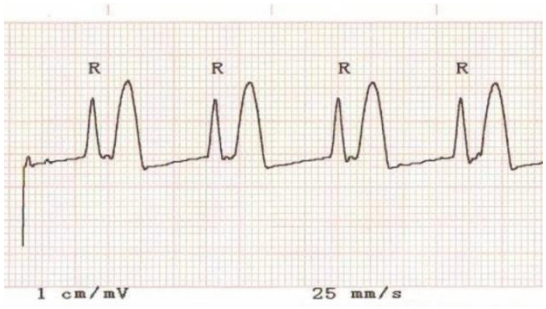
Precision and response of the heart rate monitor with regular rhythms:

Heart Rate Measurement:
Range = 20 1/min to 250 1/min.
Resolution = 1 1/min.
Calculation and display of heart rate: It is updated every 2 seconds, average of the last 4 values.
Heart Rate Accuracy: ± 10% of reading or ± 5 1/min (whichever is greater).
Bradycardia Alarm: 20 1/min to 245 1/min, in steps of 5 1/min.
Tachycardia Alarm: 25 1/min to 250 1/min, in steps of 5 1/min.
Maximum HR alarm system delay
Tachycardia: **3.8 s ± 0.1 s**.
Bradycardia: **6.13 s ± 0.1 s**.

Average HR alarm system delay

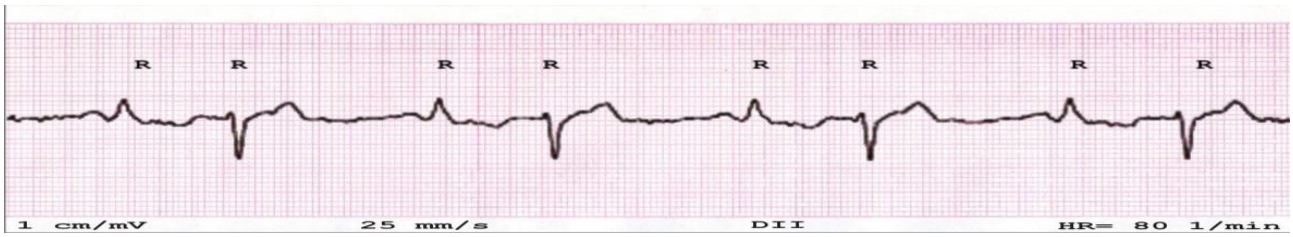
Tachycardia: **3.78 s ± 0.1 s**.
Bradycardia: **6.09 s ± 0.1 s**.

Maximum T-wave amplitude rejected: 1.2 times the amplitude of the QRS complex.



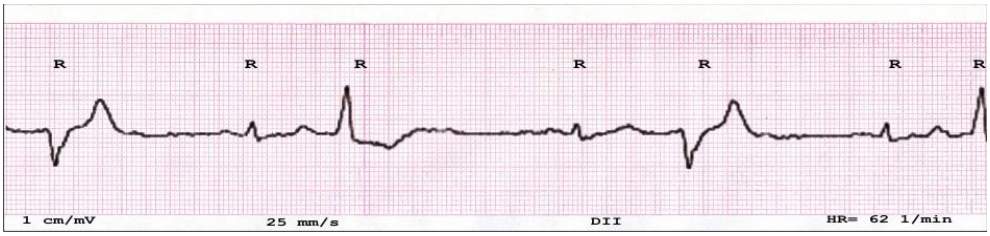
Precision and response of the heart rate monitor with irregular rhythms:

Signal A1: Ventricular Bigeminy



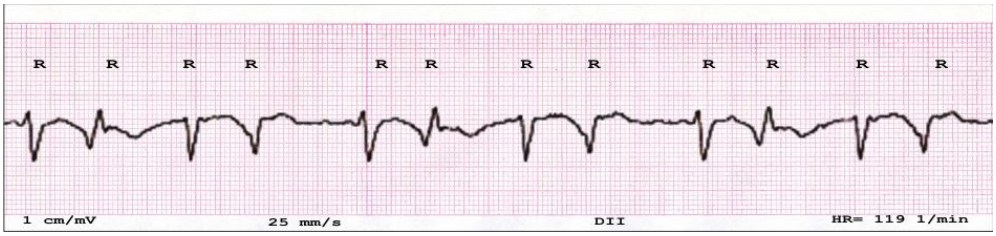
Measured and indicated frequency on display, after 20 s of establishment: **80 1/min ± 5 1/min.**

Signal A2: Slow alternating Ventricular Bigeminy



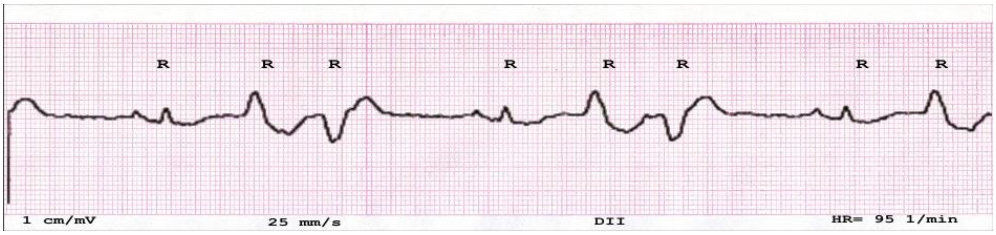
Measured and indicated frequency on display, after 20 s of establishment: **60 1/min ± 5 1/min.**

Signal A3: Fast alternating ventricular bigeminy



Measured and indicated frequency on display, after 20 s of establishment: **120 1/min ± 5 1/min.**

Signal A4: Bidirectional Systole



Measured and indicated frequency on display, after 20 s of establishment: **90 1/min ± 5 1/min.**

Maximum timing:

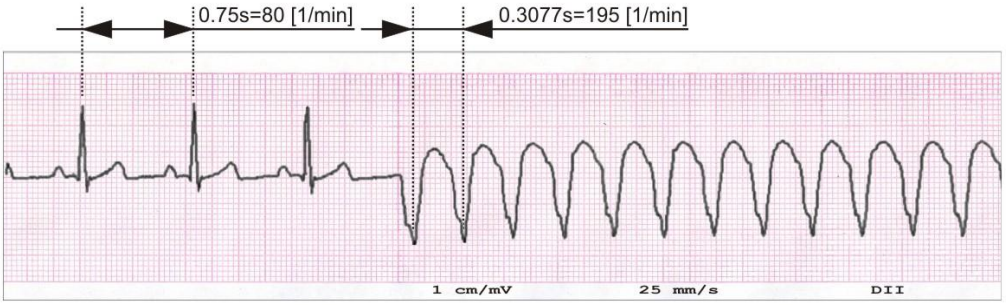
From 80 1/min to 120 1/min: **4 s ± 1 s.**
From 80 1/min to 40 1/min: **11 s ± 1 s.**

Response timing:

From 80 1/min to 120 1/min: **3 s ± 1 s**. This is the time from the first QRS complex of the new frequency to the time taken to indicate 105 1/min on the display (37% of 80 1/min + 63% of 120 1/min).
From 80 1/min to 40 1/min: **6 s ± 1 s**. This is the time from the first QRS complex of the new frequency to the time taken to indicate 55 1/min on the display (37% of 80 1/min + 63% of 40 1/min).

Tachycardia alarm time: 3 s ± 0.5 s, for the signal shown below.

Signal B2: ventricular tachycardia 2 mVpp, 195 1/min.

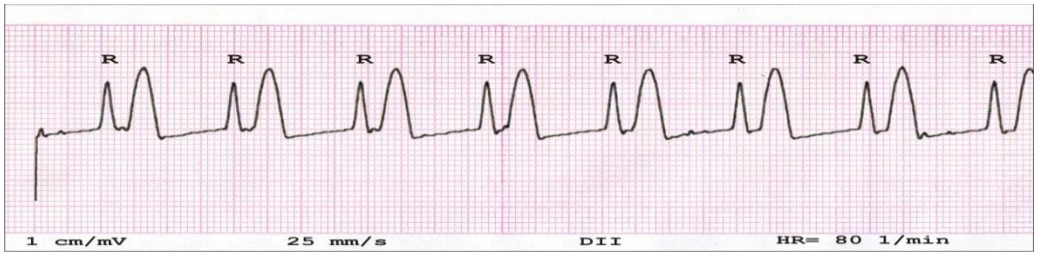


For signal B1: ventricular tachycardia 1 mVpp, 206 1/min the time **is the same**.

For different amplitudes of B1 and B2 (half and twice) the alarm time **is still the same**.

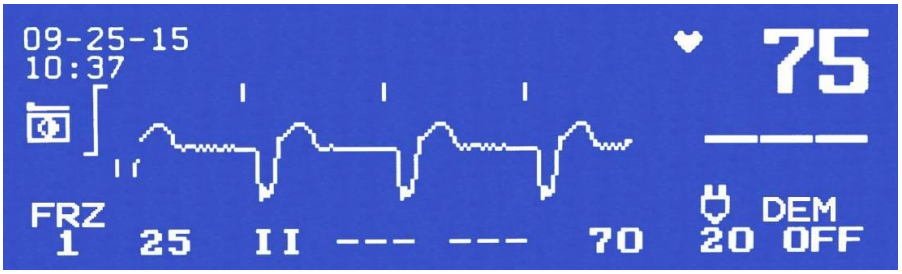
Rejection capacity of high T wave

Maximum T-wave amplitude rejected: **1.2 times the amplitude of the QRS complex**.



Detection, rejection and indication of pacemaker pulse

The cardiotachometer has a detector and rejecter of pacer pulse for measuring heart rate. In the next picture is showed the pacer pulse indication in the display:



This equipment may reject pacemaker pulses of the following characteristics: with amplitude of ±2 mV to ±700 mV and a pulse width of 0.1 ms to 2 ms, anyway keep the patients with pacemaker under close surveillance.

6.4. RECORDER

The writing method: Thermal array.
Registry speed: 25 mm/s.
Register mode: keyboard.
Resolution - Y Axis: 8 dots per mm.
X Axis: 16 dots per mm.
Print width: 48 mm.
Paper type: Width 50 mm and maximum diameter 45 mm.

6.5. TRANSCUTANEOUS PACER

Output pacer electrodes: Type CF.
Stimulation: External, trough electrodes.
Frequency range: 40 ppm to 180 ppm. – Choose it from keyboard, in 5 ppm steps.
Output current: 10 mA to 200 mA. – Choose it from keyboard, in 5 mA steps.
Pulse width: 20 ms ±5%.
Amplitude accuracy: within ±5% of displayed value.
Frequency accuracy: within ±5% of displayed value.
Mode: selectable, demand or asynchronous.
Refractory Period: 340 ms for frequencies less than or equal to 80 ppm; 240 ms for frequencies greater than 80 ppm.

6.6. PULSE OXIMETER

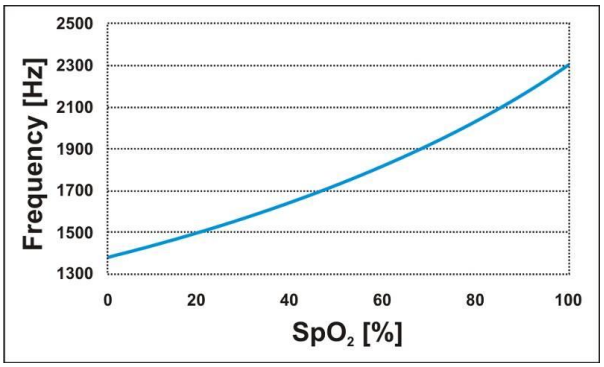
SpO_2 sensor input: Type CF.

LED
Wavelength: Red is 660 nm.
Infrared is 940 nm.
Optical Power: 4 mW.

SpO_2
Range: 0% to 100%.
Adult accuracy: ±2% from 70% to 100%, (<70% is not defined).
Neonatal accuracy: ±3% from 70% to 100%, (<70% is not defined).
Movement accuracy: ±3% from 70% to 100%.
Resolution: 1%.
The specified accuracy is the root mean square (RMS) difference between the measured values and reference values.

Pulse rate
Range: 30 1/min to 250 1/min.
Adult accuracy: ±3 1/min.
Neonatal accuracy: ±3 1/min.
Movement accuracy: ±5 1/min.
Resolution: 1 1/min.
Pulse Indicator: variable beep tone.
The specified accuracy is the root mean square (RMS) difference between the measured values and reference values.

Pulse's beep tone
The beep sound increases when the SpO_2 percentage does, as you can see in the image below:



Maximum delay of the SpO_2 ALARM system: **9.15 s ± 0.2 s**.
Medium delay of the SpO_2 ALARM system: **9 s ± 0.2 s**.

Maximum delay of the FP ALARM system
Tachycardia: **12 s ± 0.5 s**.
Bradycardia: **13.25 s ± 0.5 s**.

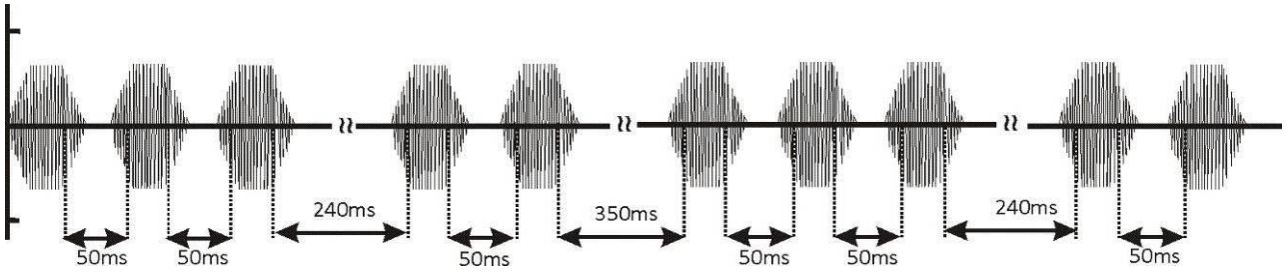
Medium delay of the FP ALARM system
Tachycardia: **11.72 s ± 0.5 s**.
Bradycardia: **12.74 s ± 0.5 s**.

6.7. AUDITORY ALARM SIGNALS

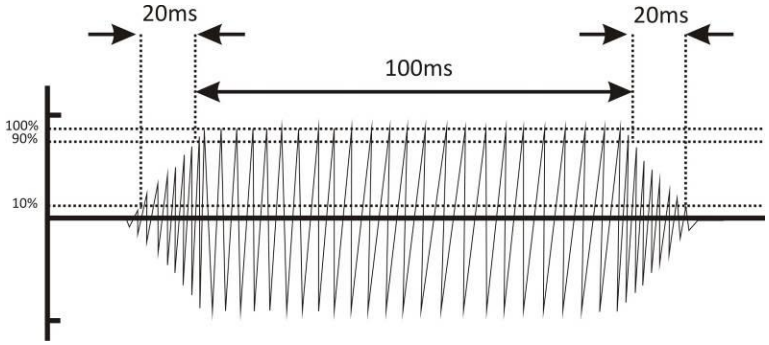
Sound pressure: Between 45 dB and 85 dB.

6.7.1. Auditory alarm signals of High priority

All physiological alarms are high priority.
The auditory alarm signal of a physiological alarm is composed of a burst of 10 pulses of 1000 Hz as show below.

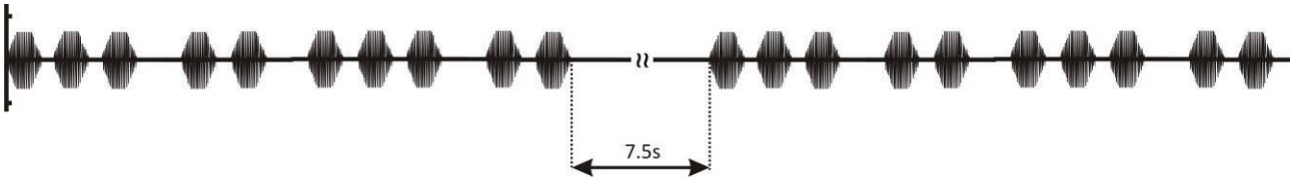


The detail of each one of the pulses is shown in the next figure.

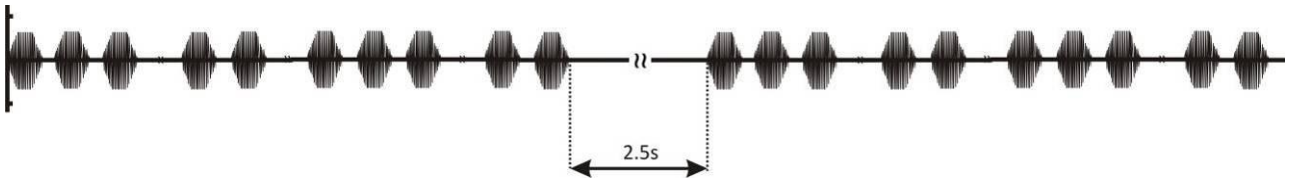


Rise time (from 10% to 90%) of pulse, t_r: 20 ms.
Effective duration time of pulse, t_d: 100 ms.
Fall time (from 90% to 10%) of pulse, t_f: 20 ms.

If the physiological alarm condition is maintained, the pulse burst is repeated every 7.5 s as shown in the next figure.

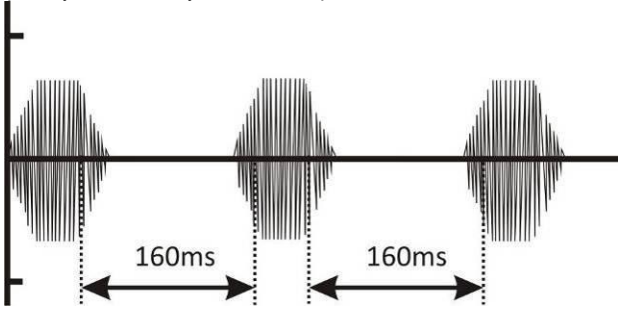


The auditory alarm signal of a technical alarm condition of high priority is equal to the auditory alarm signal of the physiological alarms, regarding the burst of pulses and pulse characteristics, but the repetition of the pulse burst is every 2.5 s as shown in the next figure.

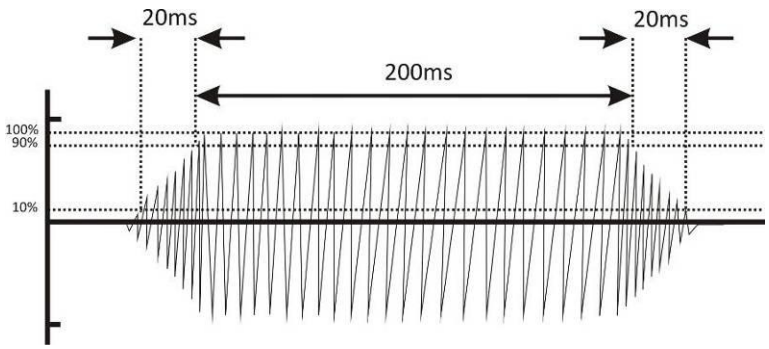


6.7.2. Auditory alarm signals of medium priority

The auditory alarm signal of medium priority is formed by a burst of 3 pulses of 1000 Hz, as shown below.

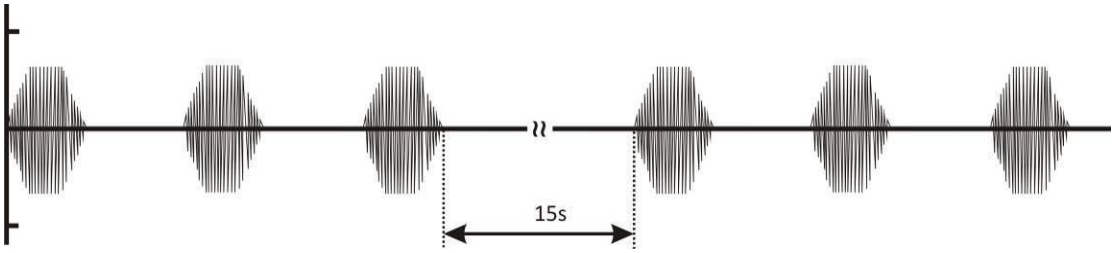


The characteristic of each pulse is shown in the next figure.



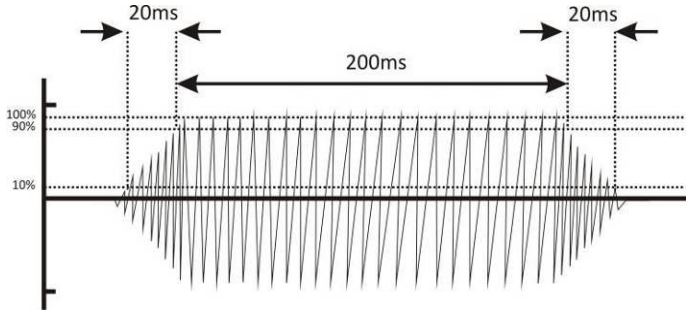
Rise time (from 10% to 90%) of pulse, t_r: 20 ms.
Effective duration time of pulse, t_d: 200 ms.
Fall time (from 90% to 10%) of pulse, t_f: 20 ms.

If the alarm condition of medium priority is maintained, the pulse burst is repeated every 15 seconds as shown in the next figure.



6.7.3. Auditory alarm signals of low priority

The auditory alarm signal of low priority is manifested by a single pulse of 1000 Hz.
The detail of the pulse shown in the next figure:



Rise time (from 10% to 90%) of pulse, t_r: 20 ms.
Effective duration time of pulse, t_d: 200 ms.
Fall time (from 90% to 10%) of pulse, t_f: 20 ms.

The pulse of the auditory alarm signal of low priority is repeated every 60 s.

6.8. VISUAL ALARM SIGNALS

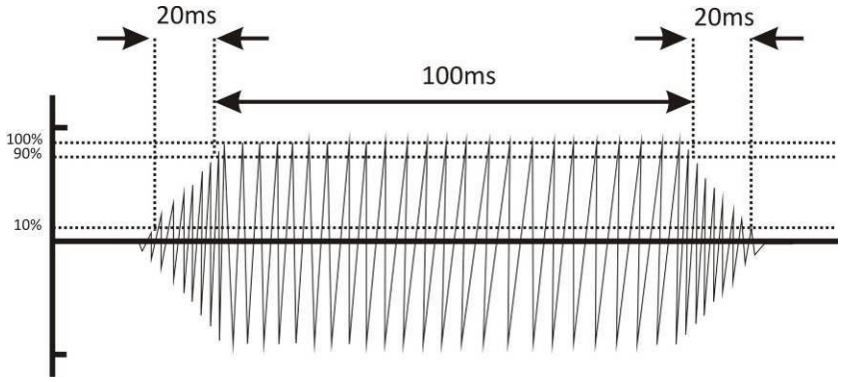
6.8.1. VISUAL ALARM SIGNALS OF HIGH PRIORITY
Intermittent light indication, red, with period 0.7 s, duty cycle 50% (0.35 s on / 0.35 s off).

6.8.2. VISUAL ALARM SIGNALS OF AVERAGE PRIORITY
Intermittent light indication, yellow, with period 1.4 s, duty cycle 50% (0.7 s on / 0.7 s off).

6.8.3. VISUAL ALARM SIGNAL OF LOW PRIORITY
Constant light indication, yellow.

6.9. QRS BEEP SOUND

The auditory indication of the presence of a QRS complex consisting of a 1000 Hz pulse whose characteristic is shown in the next figure:

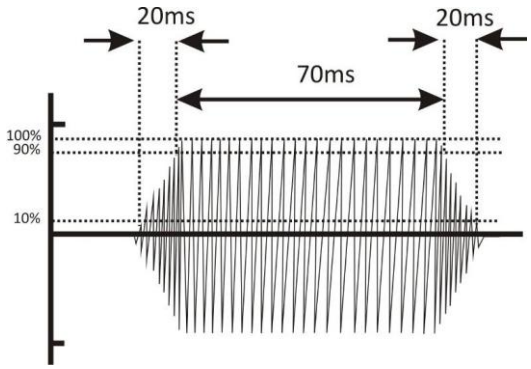


Rise time (from 10% to 90%) of pulse, t_r: 20 ms.
Effective duration time of pulse, t_d: 100 ms.
Fall time (from 90% to 10%) of pulse, t_f: 20 ms.

The sound pressure is adjusted from the volume adjustment function.

6.10. CONFIRMATION SOUND OF KEY PRESSED

Pressing a key generates a pulse of 1000 Hz confirming the activation of the key; this pulse has the following characteristics:



Rise time (from 10% to 90%) of pulse, t_r: 20 ms.
Effective duration time of pulse, t_d: 70 ms.
Fall time (from 90% to 10%) of pulse, t_f: 20 ms.

6.11. MANUFACTURER'S GUIDANCE AND DECLARATION REGARDING ELECTROMAGNETIC COMPATIBILITY

Electromagnetic emissions		
The feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Defibrillator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity			
The feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Defibrillator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
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 wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Power supply quality should be typical of commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Power supply quality should be typical of commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (dip >95% in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (dip >95% in U_T) for 5 s	<5% U_T (dip >95% in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (dip >95% in U_T) for 5 s	Power supply quality should be typical of commercial or hospital environment. If the user of the feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 requires continuous operation during power supply interruptions, it is recommended that the feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 be powered from an uninterruptible power supply or an internal battery.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity

The feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Defibrillator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.17 \cdot \sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 V	$d = 1.2 \cdot \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m of 80 MHz to 2.5 GHz	10 V/m	$d = 1.2 \cdot \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **feas ELECTRÓNICA**'s DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 is used exceeds the applicable RF compliance level above, the **feas ELECTRÓNICA**'s DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **feas ELECTRÓNICA**'s DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications and the feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2

The feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the feas ELECTRÓNICA's DEFIBRILLATOR Monitor Mod. 3850B-Biphasic REC/TPM/SpO_2 as recommended below, according to the maximum output power of the communications equipment.

Maximum output power assigned to transmitter [W]	**Separation distance according to transmitter frequency** [m]			
	150 kHz to 80 MHz $d = 1.17 \times \sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2 \times \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \times \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.117	0.12	0.12	0.23
0.1	0.37	0.379	0.379	0.727
1	1.17	1.2	1.2	2.3
10	3.7	3.79	3.79	7.27
100	11.7	12	12	23

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

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

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

feas ELECTRÓNICA S.A.
Equipamientos

WARRANTY OF FEAS DEVICE

feas ELECTRÓNICA S.A. guarantees the purchaser of this product by the following terms from the date of purchase, for 12 months.
This warranty covers normal operation against defects in workmanship and/or material defect, and will repair it at no charge to the purchaser when it fail in normal use situations and under conditions which are detailed below:

1- They are beneficiaries of it the original purchaser and subsequent purchasers within the aforementioned period.
2- In case of need to send the device to an authorized technical service, please contact **feas** ELECTRÓNICA's Authorized Technical Service nearest to coordinate shipping, along with a description of the problem, transportation will be made by the customer and will be responsible for the cost of transport and insurance. **feas** ELECTRÓNICA **S.A.** is not liable for damage caused during transport.
3- Service modality: **feas** ELECTRÓNICA **S.A.** may, at its choice, either repair or replace the product if it is damaged, so that the product or its replacement complies with the original equipment specifications. Any replacement product will be new or nearly new. In case at the time there were no available replacement product identical to replaced (either by discontinuation of production, lack of stock or otherwise), **feas** ELECTRÓNICA **S.A.** reserves the right to supply a product performance or functionality at least equal to the product being replaced. If after a reasonable time, not possible to **feas** ELECTRÓNICA **S.A.** repair or replace the product, the customer is entitled, as your sole remedy, to refund the purchase price against return of the product. The product must be sent to authorize technical service in the same condition it was provided, that is, packing materials, accessories, software and manuals complete and fall within the terms of this warranty.
4- Will cause the cancellation of this guarantee:
   a. Improper use or use other than specified.
   b. Excesses or electrical voltage drops involving use under abnormal conditions.
   c. Intervention to device by unqualified personnel and not authorized by **feas** ELECTRÓNICA **S.A.**
   d. Equipment operation in conditions not prescribed by the User manual.
5- Warranty void if it becomes apparent that:
   a. Amendments or deletions in the certificate data or purchase invoice.
   b. Lack of original purchase invoice or lack of date on purchase invoice.
6- This warranty doesn't cover the following case:
   a. The breaks, bumps, drops or scratches from any cause.
   b. Damage caused by the product interconnected to the equipment.
7- **feas** ELECTRÓNICA **S.A.** doesn't assume any responsibility for personal or property injury which may cause the misuse of the product.
8- **feas** ELECTRÓNICA **S.A.** ensures that this product complies with electrical safety standards in validity in the country.
9- In case of failure, **feas** ELECTRÓNICA **S.A.** assures the purchaser the repair and/or replacement of parts for proper operation within a period not exceeding 30 days.
10- Any intervention of our authorized technical services, conducted at the request of the purchaser within the warranty period, which was not caused by any failure or defect covered by this certificate, shall be paid by the applicant in accordance with the prevailing rate.
11- This certificate cancels any express or implied warranties, which and expressly not authorize any other person, partnership or association to take on our own liability with respect to our products.
12- Resource constraints: **feas** ELECTRÓNICA **S.A.** doesn't assume any responsibility for damage caused by the product including lost profits, loss of profits or consequential damages. This limitation applies whether try to claim compensation or submitting a claim for damages and perjury.

feas ELECTRÓNICA S.A.
Equipamientos

WARRANTY OF FEAS DEVICE

Device: _____ Serial Number: _____

PURCHASER INFORMATION:

Name: _____

Address: _____

City: _____ State: _____

ZIP Code: _____ Phone: _____

TO BE COMPLETED BY THE SALESMAN

Salesman: _____

Invoice Number: _____ Purchase Date: _____

City: _____ State: _____

Salesman Seal

MANUFACTURER

feas ELECTRÓNICA S.A.
Equipamientos

Tel.: +54 351 484 8016
Cel.: +54 351 156 750048
Email: *ventas@feaselectronica.com.ar*

IMPORTANT: *This warranty will only be valid if the Warranty Certificate was completed in full at the time of purchase by the salesman and submitted with the original commercial invoice of this device.*
The product must be returned in the same condition it was provided, that is, packing materials, accessories, software and user manual, complete.