User's Manual

LIFE 400 FUTURA DEFIBRILLATOR

MAN00001_04

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ATTENTION!

CMOS DRAKE is exempt from any and all liability for personal or material damage caused by incorrect use of the AED LIFE 400 FUTURA and its accessories. The following situations are considered incorrect use:

- Use outside the recommendations, information and warnings of the User's Manual.
- Application other than the intended purpose.
- Breakage of the security seal, which characterizes loss of warranty.
- Interventions, repairs or changes to the equipment outside the authorized network.
- Use of defective accessories or components, beyond the expiration date or not supplied by the Manufacturer;
- Equipment operation by unqualified person.

Only use the battery and charger supplied by the Manufacturer or its authorized agents, otherwise there may be a risk of explosion.

For more information on warranty or technical assistance, contact CMOS DRAKE technical support.

Congratulations on your purchase of the Life 400 Futura Defibrillator from CMOS DRAKE. This product incorporates state-of-the-art electrocardiogram monitoring technology to automatically identify cardiac arrhythmias that require early defibrillation.

All the information necessary for the safe and correct use of the Life 400 Futura Defibrillator can be found in this manual, in addition to information on essential care, conservation, clarifications related to Technical Assistance and the Warranty Certificate.

The complete reading of this manual must precede before using the equipment, as it is a mandatory and essential condition. Always keep the manual close to the equipment for consultation, doubts and clarifications.

TABLE OF CONTENTS

ACRONYMS

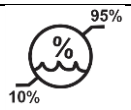
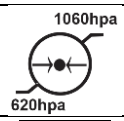
ACLS	Advanced Cardiology Life Support;
AHA	American Heart Association
BLS	Basic Life Support
CoHb	Carboxyhemoglobin
DEA	Automatic External Defibrillator
ECG	Electrocardiogram
ERC	European Resuscitation Council
VF	Ventricular Fibrillation
MetHb	Metahemoglobin
CRA	Cardiorespiratory Arrest
SCA	Sudden Cardiac Arrest
PPM	Pulses per minute
CPR	Cardiopulmonary Resuscitation
SpO_2	Oxygen Saturation
VT	Ventricular Tachycardia
PVT	Pulseless Ventricular Tachycardia
ICU	Intensive Care Unit

TERMINOLOGY

Watch Dog	Electronic device that resets the system when an error condition is identified.
Software	A program recorded in an electronic device that determines how it functions.
Hardware	The physical part of a device that contains the interconnected electronic circuits and components.
Equipment	It refers to the Life 400 Futura Defibrillator.
Service	Period in which the Equipment is in operation connected to an individual.
Patient	Individual who presents CRA and/or is under the Equipment's Service.
Operator	Person duly qualified to perform BLS/ACLS and to use Automatic External Defibrillators and who is operating the Equipment during a Service.

SYMBOLS

Figure	Relevant Standard	Description
	IEC 60878 - 5036	Hazardous Electric Potential Difference (Voltage)
	IEC 60878 - 5031	Direct Current
	IEC 60878 - 5032	Alternating Current
	IEC 60878 - 5172	Class II Equipment
	IEC 60878 - 5036	Attention!
	IEC 60601-1	It refers to the instructions manual
	IEC 60878 Safety 35	Do not sit
	IEC 60878 Safety 37	Do not step on the surface
	IEC 60878 - 5010	On/Off Key
	N/A	Shock trigger button for treatment
	N/A	Low battery indicator
	N/A	AED Battery Charger Polarity
	N/A	Heartbeat indicator on equipment display
	IEC 60878 - 5336	Defibrillator-proof CF type applied part
	IEC 60878 - 5334	Defibrillator-proof BF type applied part
	ISO 780	This side up: indicates the correct position in which the box should be transported

	ISO 780	Fragile: indicates that the package must be transported and handled with care
	ISO 780	Keep dry: indicates that the package should be kept in a dry place
	ISO 780	Number 5: indicates the maximum stacking of five overlapping units
	IEC 60878 - 0632	Minimum and maximum temperature
	ISO 7000 / IEC 60417	Minimum and maximum humidity
	ISO 7000 / IEC 60417	Minimum and maximum pressure
	N/A	It indicates that it is a medical equipment and, therefore, it deserves special handling
	EN 980	Manufacturer
	IEC TR 60878	It indicates that it is composed of recyclable raw material
	Directive 2002/96/CE	Wastes from electric and electronic equipment - Disposal separated from other objects

UNITS

Type	Unit	Name	Equivalence
Time	ms	Millisecond	10^{-3} s
	s	Second	1 s
	m	Minute	60 s
	h	Hour	3600 s
Frequency	Hz	Hertz	1 Hz
	kHz	Kilohertz	10^{3} Hz
	MHz	Megahertz	10^{6} Hz
	GHz	Gigahertz	10^{9} Hz
	bps	Beat per Second	1 bps
	rpm	Respiration per Minute	1 rpm
	bpm	Beat per Minute	1 bpm
	ppm	Pulses per Minute	1 ppm
Length	mm	Millimeter	10^{-3} m
	cm	Centimeter	10^{-2} m
	m	Meter	1 m
Area	mm^2	Square Millimeter	10^{-6} m^2
	cm^2	Square Centimeter	10^{-4} m^2
	m^2	Square Meter	1 m^2
Volume	dL	Deciliter	10^{-2} L
	L	Liter	1 L
	mm^3	Cubic Millimeter	10^{-9} m^3
	m^3	Cubic Meter	1 m^3
Speed	mm/s	Millimeter per Second	10^{-3} m/s
	m/s	Meter per Second	1 m/s
Flow	L/s	Liter per Second	1 L/s
	L/m	Liter per Minute	60 L/s
Mass	g	Gram	1 g
	kg	Kilogram	10^{3} g
Pressure	mmHg	Millimeter of Mercury	133.3 Pa
	hPa	Hectopascal	10^{2} Pa
	Pa	Pascal	1 Pa
Temperature	°F	Degree Fahrenheit	(1 °C – 32) 5/9
	°C	Degree Celsius	1 °C
Resolution	px	Pixel	N/A

Impedance	Ω	Ohm	1 Ω
	MΩ	Megaohm	10^{9} Ω
Electric Potential Difference / Voltage	mV	Millivolt	10^{-3} V
	V	Volt	1 V
	kV	Kilovolt	10^{3} V
Current	µA	Microampere	10^{-6} A
	mA	Milliampere	10^{-3} A
	A	Ampere	1 A
Current Density	A/m	Ampere per meter	1 A/M
Electric Charge	C	Coulomb	1 C
	mAh	Milliampere-hour	3.6 C
Power	W	Watt	1 W
Energy	J	Joule	1 J
Intensity	dB	Decibel	1 dB
Digital Storage	B	Byte	1 B
	MB	Megabyte	10^{6} B
	GB	Gigabyte	10^{9} B

SAFETY

General Warnings

Equipment maintenance must be performed exclusively by the Manufacturer or Authorized Technical Assistance, otherwise, the technical assistance warranty is interrupted and the equipment owner becomes solely responsible for possible physical, material and other damages.

Only use the equipment on one patient at a time.

Do not use the AED close to other equipment. If this occurs, it may affect the correct functioning of the equipment. Always check its functionality if this instruction is not followed.

Do not connect other equipment to the patient at once.

The equipment must be used by people duly trained in Basic Life Support or Advanced Life Support (BLS/ACLS).

The reading of this Manual does not in any way override the training of people in BLS/ACLS who will make use of the equipment.

The operator must check the condition of the equipment and its accessories (frequent and regular checks), especially regarding the validity of disposable electrodes and the battery charge level.

Keep the equipment stowed in its transport bag or in the Emergency Cabin (if it has), ensuring the integrity of the equipment.

When installing the equipment with the battery charger, make sure they are in a place with enough space for ventilation and away from heat radiation.

The equipment was developed to identify, through electrocardiogram monitoring, arrhythmias that require defibrillation (which require defibrillation) in patients who are victims of cardiorespiratory arrest. It can be used inside or outside the hospital environment, including rescue units, promoting life support.

The equipment must not be used adjacent to or on top of other equipment. Such a configuration may lead to improper operation.
Obs.: If use becomes necessary, it is advisable that the equipment involved be observed to certify their correct functioning.

Warnings about Electrodes

Prevent disposable electrodes (shock pads) from coming into contact with each other (short circuit).

Move ECG electrodes, bandages or any other metallic objects away from the disposable electrodes due to the risk of the patient suffering skin burns during defibrillation, an effect caused by deviation of the current to the heart.

Do not touch the patient, electrodes or any conductive material during ECG analysis as the result of ECG interpretation will be affected.

At the moment of shock, never touch the patient. Keep away from it.

During defibrillation, burns to the patient's skin may occur if there are air pockets between the skin and the pads. To prevent this from happening, make sure the pads are completely adhered to the skin. Use the pads within the expiration date recorded on the packaging, and only once.

Only open the package containing the disposable electrodes when using it on the patient. Once opened, use it or discard it.

Do not touch the patient, beds (stretcher), equipment or any accessory connected to the patient during defibrillation.

The patient should not have contact with metallic objects and/or conductive fluids, as this is capable of causing unintended currents through accessory pathways.

The electrodes may remain connected to the patient for up to 6 (six) hours, for ideal skin conditions (intact, without injuries, irritations, among others).

When using this equipment, disconnect other devices from the patient, as the high voltage of the electric shock can cause damage to them.

Warnings about Battery and Charger

When using the AED, immediately disconnect the battery charger from it.

Never use batteries not supplied by the Manufacturer and/or non-serial batteries. Cmos Drake is not responsible for damages caused by the use of batteries from unauthorized third parties, since they can cause several and serious damages, such as: non-functioning of the equipment, burning, loss of performance, incorrect indication of the battery level. and explosion risk.

The equipment does not start up with the battery charger connected to it.

Never use another battery charger that is not always the original supplied by Cmos Drake, as several and serious damages can occur, such as burning the equipment, incorrect operation, damage to the battery and risk of explosion.

Do not place the battery charger connected to extensions or additional MULTIPLE OUTLETS directly on the floor, in such a way as to prevent the ingress of liquids into the contacts and prevent electrical and mechanical damage.

Disposal of batteries must follow Environmental regulations. Consult your city's Environment Department.

Keep the battery away from fire and other heat sources and avoid dropping it when the battery is taken out for end-of-life disposal.

Do not place the battery near metallic objects that could cause a short circuit.

Never disassemble, puncture, crush or open the battery. Respect the safety circuit. Risk of explosion.

Warning about Watch Dog

The equipment has a Watch Dog circuit designed to activate the system reset if any unexpected error condition occurs, resetting the equipment. The Watch Dog circuit (hardware reset) is an additional security system that exists in any electronic device that uses embedded software.

The Watch Dog circuit is used to reset the main board circuit, without the need for operator intervention, in case the crash occurs due to external reasons.

The Watch Dog circuit during normal equipment operation is in Standby. Therefore, it has no active function on the equipment. It only comes into operation if the main board circuit crashes.

The Watch Dog circuit does not pose a risk to the patient and the user, does not influence stability and does not affect the performance of the product.

Warnings about Electromagnetic and Biological Compatibility

Avoid using a cell phone or any devices that pick up radio frequency near the equipment. The high level of electromagnetic radiation emitted by these devices can result in interference, impairing the normal functioning of the defibrillator, putting patient safety at risk.

In general, the EQUIPMENT Parts and ACCESSORIES of the Life 400 FUTURA Defibrillator intended to come into contact with biological tissues, cells or body fluids are tested and analyzed in accordance with the guidelines and principles of ISO 10993-1, which deals exclusively with testing of biocompatibility of the applied parts.

On Aircrafts / Ambulances / Vehicles in General:
- Low level of radiation from electromagnetic fields.
- High immunity to transients and external electromagnetic fields.
- High mechanical resistance to vibration.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) is not recommended to be used within 30 cm of any part of the AED or its accessories (including cables). Otherwise, performance degradation of this equipment may occur.

Warnings about Maintenance

Risk of electric shock if the equipment or battery charger cabinet is opened. Any type of technical service or future updates to the equipment and its parts may only be carried out by personnel duly trained and authorized by Cmos Drake.

Disposable materials must not be reused. They must be disposed of in appropriate places according to the special procedures for hospital wastes.

If any part of the equipment, battery, battery charger and disposable materials need to be replaced, contact the manufacturer or the authorized network to supply the material and replace it, when necessary. If accessories from suppliers other than those indicated by Cmos Drake are used, the company is not responsible for the operation of the equipment and will have its warranty nullified.

There is a risk of polluting the environment associated with the use of accessories and consumables at the end of their useful life. Accessories and consumables must be disposed of in hospital wastes in accordance with environmental law. Batteries must be delivered to appropriate environment or returned to the manufacturer or an appropriate collection center after replacement due to a defect or end of life.

No modifications to this equipment and its parts are permitted.

Warnings about Areas of Risk

This equipment is not designed to operate in environments containing flammable anesthetics and cleaning agents. Do not use it in the presence of flammable gases.

To prevent the risk of fire or undue shock, avoid operating or placing the equipment near water source or flammable products, do not leave liquid products on the cabinet and/or battery charger.

Risk of explosion if the equipment and battery charger are used in the presence of flammable anesthetic gases.

Do not use the Life 400 Futura Defibrillator in areas where there is a risk of explosion.

Do not use the Life 400 Futura Defibrillator inside x-ray and MRI rooms.

The Life 400 Futura Defibrillator does not have intentional electromagnetic interference.

The equipment must be stored in a ventilated place and free from moisture, dust, light (including sunlight) and fibers from other materials such as cotton. The mentioned components can interfere with the correct use or even lead to a total impairment of the equipment's functioning.

1 INTRODUCTION

The AED Automated External Defibrillator, model Life 400 Futura, is an electronic, compact, lightweight and portable device. This product incorporates state-of-the-art technology aimed at monitoring the electrocardiogram, to automatically identify cardiac arrhythmias that require early defibrillation in victims of cardiac arrest, in order to effectively and accurately combat sudden death.

The equipment is capable of delivering controlled electric shocks that are applied to the patient's chest using defibrillation electrodes (Disposable Adhesive Pads) with instructions to the rescuer by voice commands, text and icons (self-explanatory).

The equipment has microprocessed circuits that perform cardiac mapping and automatically identify shockable cardiac arrhythmias such as PVT – Pulseless Ventricular Tachycardia and VF – Ventricular Fibrillation.

The equipment can be used in adult and child patients, in different places and environments, allowing basic life support in this first care, considerably increasing the survival rate.

INDICATION FOR USE

- The Life 400 Futura Defibrillator has the basic function of automatically identifying cardiac arrhythmias to revert to sinus rhythm.
- The equipment can be used by the lay public (trained in BLS - Basic Life Support and medical professionals trained in ACLS). The equipment operates automatically, regardless of the operator's prior knowledge of cardiac arrhythmias.
- The equipment has voice commands, text, intuitive icons on the display and an audible beep, to guide the rescuer during the care procedure for victims of cardiorespiratory arrest.
- The AED is medically indicated for defibrillation of cardiac arrhythmias susceptible to shock (Ventricular Tachycardia and Ventricular Fibrillation). The equipment has voice and text commands that guide the operator through the patient resuscitation procedure. To use the AED just connect the equipment and follow the instructions.
- The AED has the patient population for indicated use:
  - Adults and Children, requiring the attention of rescuers as to the type of accessory to be used in each type of patient.
  - Patient status: Unconscious patients.
- Applied body part:

Shock pads are positioned on the patient as follows:
- Adult Patients: Patient's chest (demonstration on p. 31).
- Children patients: One pad on the chest and another pad on the back 31).

- The Defibrillator has as intended user profile:
  Education: Users fluent in the language configured on the equipment (Portuguese, English or Spanish).
  Knowledge: Basic first aid training.
  Experience: People with basic first aid training.
  Language comprehension: Comprehension of the language set on the equipment for quick understanding of the text and voice commands provided by the equipment.
  Inadmissible disabilities: Due to standard resuscitation procedure the equipment cannot be used by blind, deaf and dumb people.

- The equipment has as essential performance:
  - Perform the correct reading and analysis of the patient's ECG signal;
  - Perform shock treatment when user presses the trigger button;
  - Proper operation of voice and text commands;
  - Proper functioning of all equipment keys;
  - Proper functioning of all available accessories.

  The equipment may lose one or more functionalities when exposed to out-of-tolerable interference rates, such as:
  - Anomalies on the display;
  - Interference in the audio control;
  - Interference in electrocardiogram monitoring.

- Intended conditions of use:
  Use in places such as: stadiums and sports arenas, bus stations, shopping malls and commercial centers, ports and airports, hotels, temples, trains, subways, planes and boats, ambulances and air or ground rescue vehicles, police and fire events of any kind, and a hospital environment, enabling basic and advanced life support.

  It is not intended for use in damp sites.
  Limits of environmental conditions shown in Appendix B attached to this manual.
  Infrequent use - It is intended to carry less than 2500 discharges with a minimum interval of 30 seconds between discharges.

CONTRAINDICATIONS

- This equipment cannot be used in the presence of flammable agents, such as anesthetic gases, fuels, among others;
- This equipment should not be used by laypersons without proper qualification in Basic Life Support (BLS);
- Asynchronous defibrillation is not indicated for patients:
  - Conscious;
  - With spontaneous breathing;
  - With a palpable pulse.

- This equipment does not indicate shock treatment in asystole. Defibrillation in case of asystole can inhibit the recovery of natural pacemakers in the heart and reduce the chance of recovery.
- For patients under 8 years of age or weighing less than 25 kg, disposable infant shock pads must be used. In addition, if it is not possible to position the two paddles on the patient's chest with a spacing greater than or equal to 4 cm, one should be placed on the chest and the other on the back. More information in Chapter 6 – Mode of Use.

REGULATORY REQUIREMENTS

This equipment was designed in full compliance with all Standards and Guidelines relevant to defibrillation electromedical equipment, which are:

ABNT NBR IEC 60601-1	Electromedical equipment General requirements for basic safety and essential performance
ABNT NBR IEC 60601-2-4	Electromedical equipment Specific requirements for basic safety and essential performance of cardiac defibrillators
ABNT NBR IEC 60601-1-2	Electromedical equipment General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
ABNT NBR IEC 60601-1-6	Electromedical equipment General requirements for basic safety and essential performance - Collateral standard: Usability
ABNT NBR IEC 60601-1-12	Electromedical equipment Requirements for medical electrical equipment and medical electrical systems intended for use in emergency medical service environments
IEC 62304	*Medical device software* *Software life cycle processes*
Ordinance No. 350/10 **Ordinance No. 384/20**	INMETRO

ITEMS INCLUDED

- 1 (one) Life 400 Futura Defibrillator – AED;
- 1 (one) rechargeable battery or disposable battery;
- 1 (one) battery charger (if the battery is rechargeable);
- 1 (one) disposable shock pad (adult);

- 1 (one) USB cable;
- One (1) professional yellow BLS bag with compartments for AED and BLS accessory storage;
- 1 (one) AED Life 400 Futura warranty certificate;
- 1 (one) user manual containing:
  - All information necessary for the use and care of the equipment;
  - Link/QR code for downloading Phoenix software for device data acquisition.

OPTIONAL ITEMS

- **Medical Mode (Manual Mode):** Used for shock delivery by the medical rescuer, when he wants to deliver the shock.
- **PULSE OXIMETRY:** Used for reading Oxygen Saturation (SpO_2) in the patient's blood.
- **Electrocardiogram Monitoring by 3-Way ECG Cable:** Used to monitor the ECG signal through the 3-Way ECG cable.
- **CPR Feedback Device:** Used to assist the rescuer during CPR, indicating the frequency and depth of chest compressions, by voice command and graphic indicator that shows the level of compression depth in real time on the display.
- **Emergency Cabin:** Used to house and protect the equipment and its accessories on the wall at a predetermined height for easy access in case of an emergency. It has an audible alarm device when opening the cabin.

The description of each optional accessory is in Chapter 7 – Optional Accessories.

2 INSTRUCTIONS

PACKAGING

Upon receipt of the Life 400 Futura Defibrillator, inspect each box for damage to the physical integrity of the packaging or product and that all required accessories are present. If any product accessory and/or other requested additional accessory is not present or if there are damages to the equipment, any accessories is verified, contact Cmos Drake within thirty (30) days after receiving the product. After 30 (thirty) days of receipt, any claim will be evaluated by CMOS DRAKE, not guaranteeing the replacement of the product and its accessories.

If you identify damage to the physical integrity of the package, open it and record the physical state of the equipment and its accessories in the presence of the carrier. Please forward this incident immediately with knowledge of the carrier to CMOS DRAKE's customer support department for appropriate action.

ACCOMMODATING THE EQUIPMENT

- Remove the AED from the packaging box.
- Read without exemptions this manual, specifically Chapter 4 – Battery, which guides the correct connection of how to charge the battery.
- Immediately connect the battery charger into the AED (with rechargeable battery) and into the electrical outlet. Make sure that the charger is working.
- Keep the AED in a suitable and easily accessible place.
- Keep the AED away from equipment that generates strong magnetic fields such as radiological devices, air conditioning systems and others.
- Make sure that the installation location has adequate ventilation and is within the pressure and temperature ranges indicated in this manual (Appendix B - Technical Specifications of the Equipment).

GUIDELINES FOR USE

- Read without exemptions this Manual.
- This equipment must be used by people trained in BLS or ACLS.
- Only use accessories supplied exclusively by the manufacturer.
- Follow the voice control instructions, texts and intuitive icons of th equipment.
- The Life 400 Futura Defibrillator and its basic and optional accessories will promote safety if used for the correct purpose and according to the instructions described in this Manual.
- All those who need or wish to use the Life 400 Futura Defibrillator must be trained through training in basic life support, a course taught by accredited institutions, companies and/or accredited and accredited medical professionals. Guidance on the fundamentals of defibrillation, as well as on the indications and contraindications, are essential for the care of a victim of cardiorespiratory arrest.
- It is mandatory to read the user's manual and comply with the safety rules and warnings contained therein, especially regarding batteries, electrodes, battery charger and Technical Assistance.
- If the patient's chest is wet, it is recommended that the rescuer dry it before attaching the electrodes.
- It is recommended to keep some auxiliary materials such as surgical scissors, a disposable razor blade to remove hair from the chest and disposable gloves, in case they need to be used when there is an accident. The BLS bag has suitable housing to hold these materials.

In the event of improper use of the equipment, the user, patient or other people will be subject to the risk of electric shock or may suffer burns, due to the high voltage generated at the time of the shock.

AFTER USE TIPS

- Dispose of the accessories after service in an appropriate place.
- Replace the shock pads or any accessories on the AED necessary for the service, to speed up the next one.
- Keep the equipment with the battery charged.
- Keep the maintenance and cleaning routine always up to date to preserve the devices.

3 THE PRODUCT

GENERAL FEATURES

Functionalities

- ECG signal analysis and automatic detection of malignant arrhythmias (PLVT and VF) that require defibrillation.
- ECG monitoring via pads before, during and after the shock.
- Pacemaker detection.
- Detection of battery conditions (originality and validity) and record in equipment history.
- Detection of conditions of the disposable pads (originality and validity) and record in equipment's history.
- Patient's thoracic impedance analysis for automatic adjustment of timing and electrical current of the shock, increasing defibrillation effectiveness and reducing the risk of causing heart damage.
- Text and voice commands for guidance to the rescuer during service.

Defibrillation

- Truncated exponential biphasic waveform.
- Automatically limited energy protocol for adult or child patient, depending on shock pads inserted.
- Various power protocols provided at the user's discretion, up to a limit of 360 J (Joules). By default there are 150J shots in Adult Mode and 50J in Kid Mode.
- Automatic internal discharge after 30 seconds if there is no trigger.
- Charge time adjustable up to 4 seconds for 150 J and 5 seconds for 200 J.

Battery

- Capacity to perform up to 200 discharges or 10 hours of monitoring with 2850mAh rechargeable battery at full charge (new battery with full charge). Optional 300 discharges or 15 hours of monitoring with 3500mAh rechargeable or disposable battery.
- Battery status at various levels clearly visualized on the display (bar graph).

- Low battery indicator – audible and visual.
- Possibility of using rechargeable or disposable battery. Battery charger included for rechargeable batteries.
- The user himself can easily replace the battery (without the use of tools), and it is not mandatory to send the equipment to the manufacturer.

Recording of Events

- Dedicated software compatible with Windows environment for communication, recording and interpretation of collected data to PC, with interface cable.
- The equipment recognizes and records the status of the battery and disposable pads, such as: validity and originality of accessories.
- The equipment identifies its opening by third parties and records the events in the equipment's memory.
- Recording of events and service curves in 4GB continuous memory that provides more than 200 years of recording, with visualization and data transfer to computer via USB connection.

General

- ECG with beep.
- Beep for guidance of the rate of compressions during CPR.
- Shock counter, CPR time and clock.
- Daily self test.

Cabinet

- Ingress protection IP 56.
- High compression, electrically insulated ABS cabinet.
- Handle for transport integrated into the cabinet that facilitates handling and generates convenience in transport, preventing accidental falls.

Language

- Standard: Portuguese.
- Optional: English and Spanish.

Monitor

- Electroluminescent liquid crystal monitor, with real-time ECG tracing visualization.
- Intuitive icons on the monitor to assist the service.

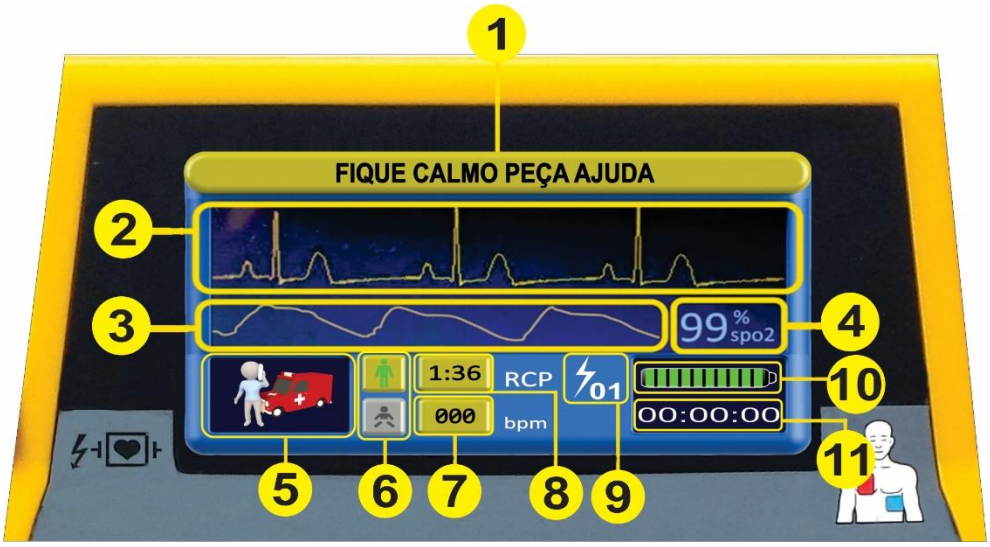
Option features

- Medical Mode (Manual Mode).
- Pulse Oximetry.
- Monitoring by 3-Way ECG Cable.
- CPR Feedback Device
- Emergency Cabin

MAIN PANEL

1	Connector of the shock pads (electrodes) and CPR Feedback Device.	2	Monitor: It shows the duration of the service, ECG trace, text commands to the user according to voice commands.
3	Weak battery indicator.	4	Treatment button: Used to trigger the shock. When flashing, it confirms that the shock is ready to be applied on the patient.
5	Carrying handle.	6	On / Off Button.

GRAPHIC DISPLAY



1	Text command.	2	ECG Curve.
3	Oximetry curve (Optional).	4	SpO_2 (%) level indicator in the blood (Optional).
5	Icons of measurements to be taken by the operator.	6	Icon that indicates the type of patient (adult or child).
7	Indicator of the patient's beats per minute.	8	2-minute countdown timer for CPR delivery.
9	Count of shocks applied during the service.	10	Battery level icon.
11	Timer that indicates the duration of the service.		

Guidance Icons During Service

Place the Electrodes on the Patient.

If there is no circulation, perform CPR for 2 min.

Move away from the Patient.

REAR PANEL

1 Charger input for rechargeable battery.

2 USB output.

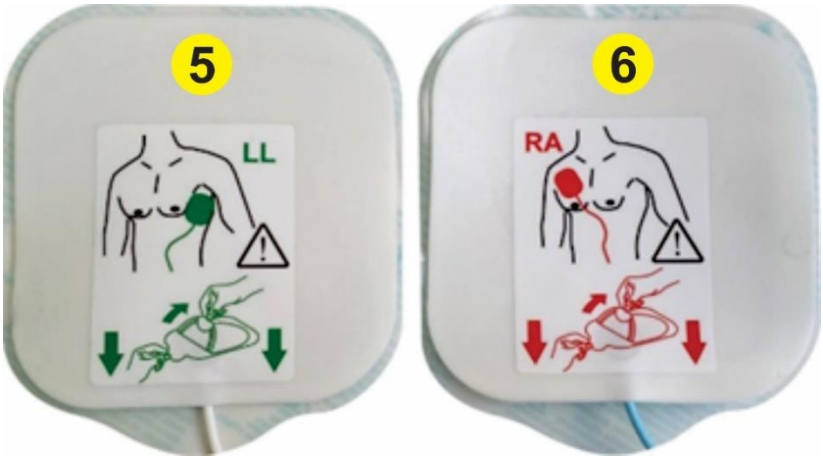
BATTERY CHARGER

1	Connection to the electric mains.	2	Connection at the back of the equipment.
3	Label with the charger's technical specifications and safety information.	4	Battery charge indicator light.

Never use a battery charger not supplied by the manufacturer, there may be a risk of equipment explosion.

DISPOSABLE ADHESIVE SHOCK PADS

1	Batch and expiry date of the pads (year/month).	2	Instructions for use.
3	Warnings.	4	AED input connector



www.cmosdrake.com.br

5 Apex Electrode.

6 Sternum Electrode.

The disposable adhesive shock pads are for single use and have a 24-month unopened packaging warranty and a 24-month post-billing shelf life.

The disposable adhesive shock pads have a maximum time of use of 8 hours in the same service. After this interval, the pads must be replaced.

The defibrillator has a disposable pad condition detection system (originality and validity) and record in equipment's history.

BLS PROFESSIONAL BAG FOR AED

The BLS Professional Bag is made of Cordura (400), a long-lasting material that is resistant to abrasion, cuts and tears. Cordura is a material with greater resistance compared to nylon, as its weave is tighter than the weft of polyester, in addition to not forming balls and presenting very high resistance to abrasion, tearing and perforation. It Is very light, easy to wash and dries quickly, doesn't mildew and looks like new for a long time.

The bag receives PVC resin to make it more full-bodied\, in addition to an antibacterial and water repellency. This helps protect your accessories. It features reinforced rubber details and resistant carrying handles. Coated with strategic electroluminescent reflective dots for easy viewing of the bag over long distances.

1 Hand carrying handle.

2 Electroluminescent fabric.

3 Compartment for accessories (Left and Right side).

4 Compartment for the AED.

5 Transparent cover for viewing the low battery alarm.

6 Support for adjustable shoulder strap.

7 Several compartments to house the materials used in BLS

Keep the equipment stowed in its carrying bag or in the optional Emergency Cabin to prevent damage and increase its durability.

SERIAL NUMBER

The Serial Number, identification located at the bottom of the equipment, is composed of the following sequence:

XX	XX	XX	XXXX
1	2	3	4

1: Formed by one or two numbers, it represents the equipment identifier;
2: Formed by two numbers, they represent the YEAR of manufacture of the equipment;
3: Formed by two numbers, they represent the MONTH of manufacture of the equipment;
4: Serial number, sequence formed by four numbers, from 0001 to 9999.

4 BATTERY

ABOUT LITHIUM BATTERIES

The batteries used in the equipment have lithium as a base element, as they have a higher energy capacity, are lighter and do not become addicted like standard nickel-cadmium batteries. Still, the lithium-based battery requires care to increase its lifespan.
The AED defibrillator has a battery status monitoring system
Identified if it is original and if it is within the validity of use, and when necessary, recording this data in the equipment history.

It is recommended that these batteries be stored and operated in a cool place, as extreme temperatures (high or low) accelerate the aging process and battery charge loss. In addition, the ideal is to keep lithium batteries always charged, as when the battery is fully charged, it can lose its ability to hold a charge.

TYPES OF BATTERY

The Life 400 Futura Defibrillator is, by factory default, supplied with the Lithium-Ion Standard 2850mAh battery. However, any of the battery options can be supplied as per customer's request.

Disposable battery option:

- **Lithium-Manganese Battery:** 3500 mAh battery, 5 years standby life, up to 15 hours of monitoring capacity or up to 300 shocks on a full charge.

Rechargeable battery options:

- **Standard Lithium-Ion Battery:** 2850 mAh battery, 5 years standby life, up to 10 hours of monitoring capacity or up to 200 shocks on a full charge.
- **Lithium-Ion Plus Battery:** 3500 mAh battery, 5 years standby life, up to 15 hours of monitoring capacity or up to 300 shocks on a full charge.
- **Lithium-Polymer Battery:** 2200 mAh battery, 5 years standby life, up to 5 hours of monitoring capacity or up to 140 shocks on a full charge.

Every product purchased with a rechargeable battery is accompanied by the appropriate battery charger. To obtain the monitoring time or the number of charges described, the battery must be fully charged (new battery with full charge).

When the low battery indicator is activated, the battery at this very moment still has the capacity to perform, by factory default, 15 shocks or 30 minutes of monitoring. The amount of shocks or residual monitoring time after low battery alert can be optionally changed at the user's discretion to higher or lower values.

The battery has a 12 month warranty after its billing. If the battery is damaged due to improper use or deviating from the instructions described in this manual, the loss of warranty will be occur.

Do not disassemble or dispose of in fire, as there is also a risk of explosion.

Never use batteries or battery charger that are not supplied by the Manufacturer.

If the battery shows a loss of performance, immediately contact the nearest Cmos Drake or Authorized Service Center for immediate replacement.

When the battery is discharged, the battery charger is not able to power the AED.

Do not short-circuit the battery.

Do not allow the battery to discharge completely.

Do not compress or disassemble the battery.

When using loads with the infant electrode (50 Joules) the amount of shocks will be proportionally higher.

There is loss of battery charge due to execution of the self test (decreasing the battery's useful life).

BATTERY REPLACEMENT

The user must request from the manufacturer or Authorized Technical Assistance the supply of a new battery for the due replacement at the end of its useful life or defect. The user can replace the battery himself, and it is not mandatory to send the equipment to the manufacturer, as it is a removable battery and the replacement time is less than 10 seconds. If you prefer the equipment, you can send it to the nearest Authorized Technical Assistance to replace the battery together with a check of the charging circuit and charger.

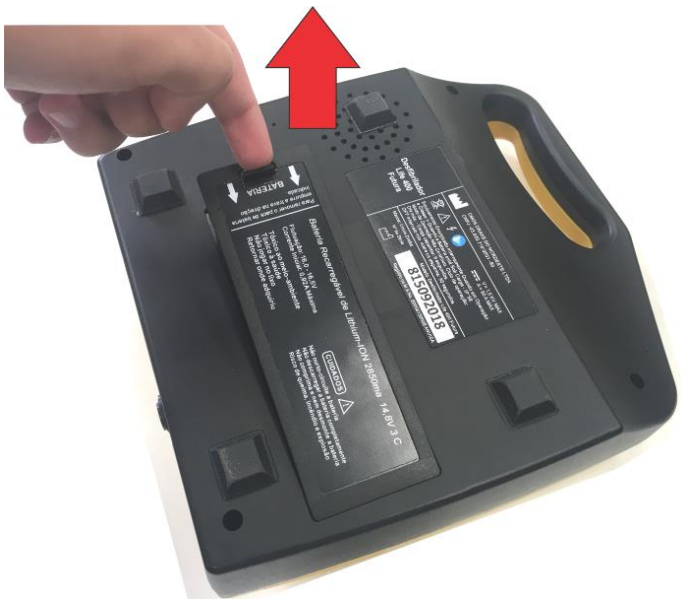
Whenever the battery is supplied by the manufacturer and/or authorized, check the authenticity through the serial number, as shown below.

To remove the battery, follow the steps described below.

1. Turn off the equipment.

2. Position the equipment with its lower part upwards as shown below.

3. Push the lock into the indicated position and lift the batttery pack to be replaced as shown below.



4 Position he new battery as indicated below and press downwards until a click is heard.

5 Turn on the equipment and wait for the voice and text commands up to the phrase:
Place the electrodes on the chest of the equipment. Observe the status of the battery charge through the battery level indicator on the display (bar graph).

6 Turn off the equipment.

7 **If the battery is rechargeable,** check the charger's operation and keep it connected to the electrical network and to the equipment until the use of the AED is necessary.

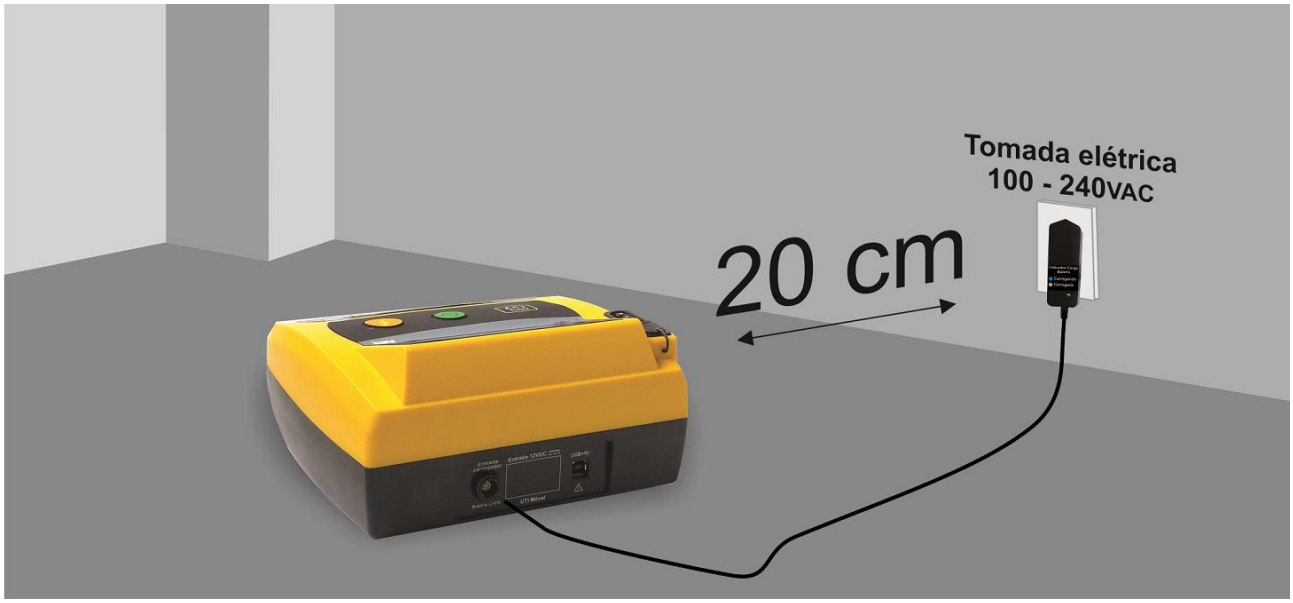
Very low level batteries can prevent the equipment from turning on. In this case, for rechargeable batteries, connect the equipment to the charger, wait for 4 hours and repeat the test procedure. If the problem persists, contact the Authorized Technical Assistance.

RECHARGABLE BATTERY

The battery charger is intended for the exclusive use of the Life 400 Futura Defibrillator.

1. Connect the battery charger to the equipment's rear panel as shown in the figure below. Note the position of the connector when attaching it. You will hear a click indicating secure connection when the position is correct. Do not force the connector as it may break.

2. Keep the rear of the equipment a minimum distance of 20 cm from any other device or from the wall, so that you do not run the risk of the battery charger plug being pressed or disconnected from the equipment.



3. Charging time for a fully depleted battery is approximately:

- **Initial charge:** 4 hours.
- **Other charges:** 1 hour to 4 hours depending on battery status.

4 The battery charger has a bicolor LED that indicates charging status:

- **Blue LED:** Battery Charging.
- **Green LED:** Battery Charged.

The rechargeable battery is already fully charged at the factory. When you receive the equipment, remove it from the packaging and connect the battery charger to keep the battery fully charged. If the battery is not connected to the battery charger within 60 days after receipt, there will be a loss of performance, compromising the charging capacity, resulting in the loss of the battery's warranty.

Do not connect the battery charger to MULTIPLE OUTLETS close to the floor, to prevent liquids from penetrating the power contacts and prevent electrical and mechanical damage.

The battery charger of the Life 400 FUTURA Defibrillator is intelligent and automatically monitors the recharge, being able to remain connected to the electrical network 24 hours, without having to disconnect the AED from the battery charger.

The equipment will not work for treatment while connected to the battery charger. This equipment is ready to run on battery power only. Disconnect the battery charger from the AED to begin use. When turning on the equipment with the charger connected, the message will appear on the screen: *"FOR USE, DISCONNECT THE CHARGER FROM THE EQUIPMENT!".*

It is recommended to replace the AED's rechargeable battery every 2 years, or when the battery life is less than 1 hour.

In the event of heavy rain and thunder and lightning storms, unplug the battery charger from the electrical outlet and the AED.

DISPOSABLE BATTERY

The disposable battery must be replaced when the equipment emits an audible (beep) and visual signal of a low battery and/or need for maintenance. For more information on alarm frequency see Chapter 5.

When the low battery indicator is activated, the battery at this very moment still has the capacity to perform, by factory default, 15 shocks or 30 minutes of monitoring. The amount of shocks or residual monitoring time after low battery alert can be optionally changed at the user's discretion to higher or lower values.

The device with a disposable battery performs a count of delivered shocks to show the level in the battery icon. When replacing the disposable battery with a new battery, it is necessary to perform the following steps below:

1. Turn on the equipment.
2. Press the treatment button for 5 seconds and wait for the text message “Battery replaced” on the equipment display. After this procedure, the AED can be used.

Disposable batteries have the capacity to deliver 300 shocks or monitor for 15 hours at full charge. Considering the fact that during the care of a patient in cardiac arrest, defibrillation is often indicated, it is inferred that in a care the disposable battery will be used up to perform the defibrillation and to monitor the patient during the care procedures. Assuming that a service lasts an average of 20 minutes and that 3 shocks will be triggered, disposable batteries significantly lose their charge. We recommend replacing the disposable battery with each service performed for total safety of the next use, since it is not possible to predict the time that the next service will demand as well as the number of shots.

When the low battery indicator comes on, replace the disposable battery immediately.

The disposable battery loses its capacity even when not used. We recommend periodically checking the device's battery level indicator.

Do not disassemble the battery or dispose of it in fire, as there is also a risk of explosion.

The AED has a clock powered by an independent internal battery – model CR 2032 3V – which must be replaced every 4 to 5 years. This exchange must be carried out at the factory or at an authorized technical service. After depleting this battery, the AED loses the ability to record the date and time of services.

5 SELF TEST

The Life 400 Futura Defibrillator performs self-tests, informing the AED status to the user. In this way, the user is always aware of the need to maintain the equipment, preventing it from being unloaded or defective during an emergency.

Even if the Equipment has a self-test capability, it is recommended that the User always keep the Equipment charged and carry out periodic checks of the battery status and its functioning.

CORRECTIVE MAINTENANCE

The equipment has a routine to check the need for maintenance. If a problem is identified, the system alerts the operator by text message and voice command as follows:

Message	Necessary Action
“Needs Maintenance Low battery”	**Recharge or replace** the battery.
“Needs Maintenance Hardware Failure”	**Restart** the system. If the problem persists, **contact** the **Authorized Technical Assistance**.

PREVENTIVE MAINTENANCE

The equipment performs periodic self-test, even when turned off. If detected that the battery charge is below 20% of its maximum capacity, the equipment will emit an audible signal (beep) and an alarm light, indicating the need for maintenance by text and voice command.

The interval between each automatic test varies proportionally to the battery level, getting smaller and smaller as the charge drops, that is, as the battery level decreases, alerts become more frequent indicating the urgency of replacing or recharging the battery (if it is rechargeable).

Battery Level	Interval	Alert
Above 50%	Every 24 hours	There is no alarm
Between 20% and 50%	Every 10 minutes	1 beep pulse; 1 low battery LED pulse.
Between 10% and 20%	Every 1 minute	
Below 10%	Turn off the Equipment.	There is no alarm

Below 2% battery charge it is not possible to turn on the equipment.

If the battery is disposable, as soon as the equipment starts the low battery alarm, contact CMOS DRAKE immediately for acquisition of a new battery.

6 MODE OF USE

ABOUT DEFIBRILLATION

The heart has a system that produces and transmits impulses throughout the heart muscle, which in turn is responsible for contracting and pumping blood throughout the body. These impulses can be measured on the surface of the body, generating the electrocardiogram (ECG).
The analysis of an ECG signal allows the detection of electrical and mechanical problems in the heart.

Cardiac arrhythmias can reflect disturbances in the initiation or conduction of impulses that, in the most severe cases, can manifest as Sudden Cardiac Arrest (SCA). During a PCS, there is a lack of adequate blood flow to the body and brain, which can quickly lead to death if not reversed. As a PCS rarely reverses spontaneously, the use of a defibrillator may be indicated to treat it. In this context, the application of a defibrillatory shock aims to restore the normal rhythm of the heart.

The most common arrhythmias that lead to Sudden Cardiac Arrest are Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). An Automated External Defibrillator (AED) is able to analyze a patient's ECG and recognize the presence or absence of VF and VT to indicate whether or not a shock should be delivered to the patient. It is important to point out that, according to the European Resuscitation Council (ERC), the use of an AED is only indicated in case of Sudden Cardiac Arrest (SCA) patients who are unconscious and not breathing normally - therefore, the AED should only be used if the patient has such conditions.

Before using the defibrillator, disconnect all equipment from the patient that does not have defibrillation protection.

Do not shock with short-circuited blades, as the triggering device may be damaged.

ANALYZER OF HEART RHYTHMS

The Life 400 Futura Defibrillator is able to analyze the patient's ECG and automatically identify the presence or absence of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). According to the American Heart Association (AHA), VF and VT are the arrhythmias that should be treated with shock (shockable) by the AED. Thus, if the Rhythm Class, when evaluating the ECG of the patient in PCS, identifies the occurrence of a VF or a VT, the equipment will issue a voice and visual command of the indicated treatment, signaling that a shock must be administered to the patient.

During the analysis of the patient's ECG, the equipment will issue the voice and visual command "Analyzing". During this period, for the analyzer to work correctly, the patient must not be touched, ensuring that the patient is still. At the end of the analysis, the AED will indicate the treatment (shock) or not, by sound and visual messages on the display. If treatment is indicated, move away from the patient before pressing the treatment button. If the AED does not indicate treatment, start CPR.

Validation of the Cardiac Rhythm Analyzer

The performance of the Rhythm Class algorithm was evaluated using defibrillator analyzers and ECG databases referenced worldwide, the MIT Arrhythmia Database and the CU Arrhythmia Database. According to the AHA, the performance of the rhythm analyzer should be evaluated in terms of Sensitivity (S_e) and Specificity (S_p):

$$S_e = \frac{VP}{VP + FN}$$

$$S_p = \frac{VN}{VN + FP}$$

Key:
FN: False Negative
FP: False Positive
VP: True Positive
VN: True Negative

The performance tests performed resulted in a sensitivity equal to 93.83% and a specificity equal to 95.01%.

EQUIPMENT DEFIBRILLATION ENERGY

As per the 2015 AHA Guidelines “Biphasic waveform shock settings differ by manufacturer, none of which have been directly compared in humans for relative effectiveness. Due to these differences in waveform configuration, practitioners should use the manufacturer's recommended power load (120 to 200J) for the respective waveform. If the manufacturer's recommended load is not known, consider defibrillation at full load.”
The Life 400 Futura Defibrillator is configured with the factory default shock sequence:

- **ADULT:** 150 J – 150 J – 150 J.
- **CHILD:** 50 J – 50 J – 50 J.

Optionally, it is possible to request alternative configurations for other energy sequences for adult patient shocks:

- 90 J – 130 J – 150 J.
- 150 J – 150 J – 200 J.
- 150 J – 200 J – 200 J.
- 150 J – 200 J – 360 J
- 120 J – 150 J – 200 J.
- 200 J – 300 J – 360 J.
- 150 J – 170 J – 200 J.
- Other settings may be provided.

In cases of pediatric use, the equipment automatically limits the energy, as soon as the pediatric pads are connected, through the sequences:

- 50 J – 50 J – 50 J.
- 50 J – 70 J – 70 J.
- 50 J – 70 J – 85 J.
- Other settings may be provided.

SERVICE SEQUENCE

The equipment automatically starts the sequence of commands and only proceeds to the next command when the user executes the procedure. The steps of care were designed in accordance with the chains of survival proposed by the AHA in its guidelines in the 2015 edition (also taking into account the 2020 updates), the sequence of which is shown below.

Recognition of CRA and activation of the emergency medical service;

Immediate high-quality CPR;

Rapid defibrillation;

Basic and advanced emergency medical services;

Advanced life support and post-CPA cares.

For all services, the following procedures must be carried out:

1. Check if the patient is unconscious.
2. Open the patient’s shirt.
3. Check if the patient’s skin is dry.
4. Perform trichotomy (shaving of the hair) if there is excess hair on the patient's chest for better contact of the electrodes with the patient's chest.
5. Check the expiry date of the electrodes.

STARTING THE EQUIPMENT

1. Disconnect the battery charger.
2. Press and release the on / off button.
3. Wait for the appearance of the **Cmos Drake** screen and, then the voice command and text **Ready for use.**

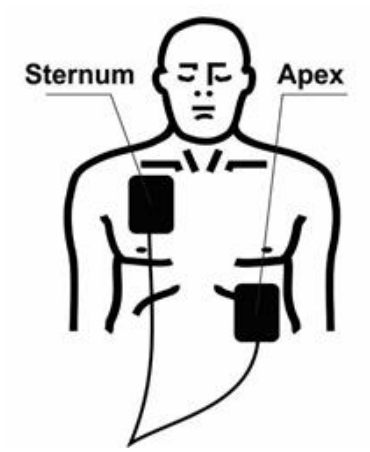
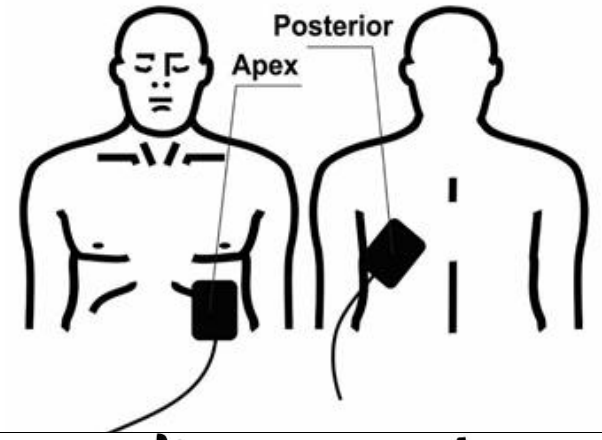
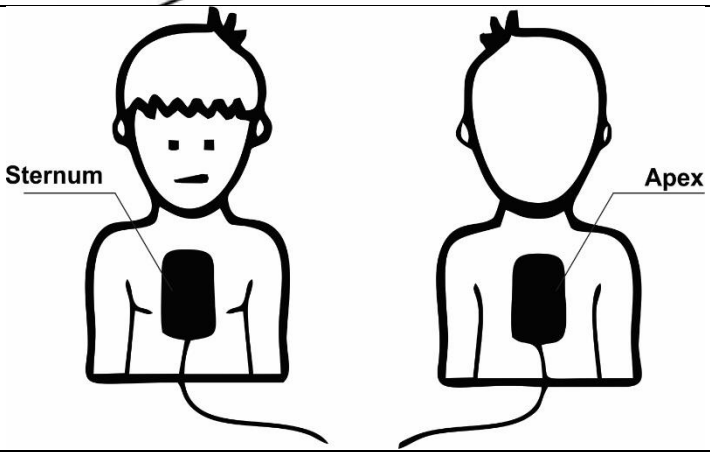
EQUIPMENT USE SEQUENCE

1. The AED must remain at a minimum distance of 20 cm from the operator and patient, according to the figure below.

2. Start the equipment.

3. Connect the electrodes into the equipment, as shown below, the voice and text commands “Plug the connector of the electrodes into the equipment” are activated on the equipment.

4 Fix the electrodes into the equipment, as shown below, the voice and text commands **“Place the electrodes on the patient’s chest”** are activated on the equipment.

Sternum-Apex	
OR	
Posterior-Apex	
Children with chest spacing less than 4 cm	

5 Move away from the patient when indicated by the voice and text commands **“Move away from the patient”** and **“Keep away”** from the equipment.

6 Wait for the analysis of the ECG signal when indicated by the voice commands and text “**Analyzing**” from the equipment.

7 Wait for the voice and text commands **“Treatment indicated”** or **“Treatment not indicated”** from the equipment.

8. When the treatment is indicated, press the treatment button indicated by the voice commands and text “**Press the treatment button**” of the equipment.

9. Wait for the voice and text prompts “Perform CPR 2 minutes on the patient”, at the first audible beep initiate chest compression in rhythm with the beep.

The 2015 AHA Guidelines say that the electrodes can be fixed in the anteroposterior, left anteroinfrascapular and anteroright infrascapular position with the same efficiency.

The user should take care to replace a new pair of transthoracic adhesive electrodes after use, so that the equipment is always ready for another emergency.

The user must check the expiration date of the electrodes in order to ensure prompt and prompt service. Expiration information can be found on the packaging label of the electrodes. If the electrodes are expired, replace them immediately.

Disposable electrodes are for *single use* and therefore should not be reused.

Do not use disposable electrodes if the packaging is damaged.

Do not touch the patient or any accessory connected to the patient during defibrillation.

If there is no triggering (pressing the Treatment Button) within 30 seconds, the shock capacitor will automatically discharge and the equipment will restart the analysis of the ECG signal.

Risk of burning the patient's skin when applying defibrillation.

Keep the patient away from conductive and wet surfaces and dry the patient's chest if necessary, before using the Life 400 FUTURA Defibrillator.

TURNING OFF THE EQUIPMENT

1. Press the on/off button for 3 seconds until the screen turns off.
2. Check the battery level. **For disposable battery,** its replacement is recommended when its level indicates 50%.
3. Disconnect the connector from the equipment's adhesive electrodes.
4. Disconnect the accessories from the patient (if it has been used) versions with ECG and/or SpO_2.
5. Carry out the cleaning of th AED and non-disposable accessories.
6. Reconnect the battery charger to the equipment and in the electrical oulet and keep it always connected so that the battery may remain fully charged.
7. Send the used adhesive electrodes for disposal.
8. Connect new adhesive electrodes to the equipment to speed up the next service.

7

OPTIONAL

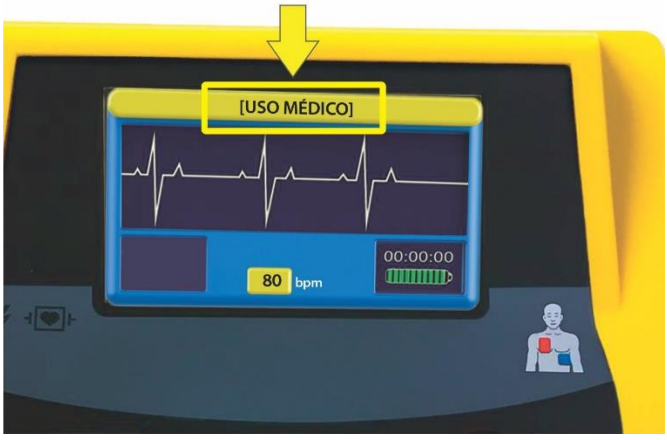
MEDICAL MODE

The clinical assessment of the patient's electrocardiogram (ECG) and the decision to deliver or not shock is determined by the medical rescuer. Therefore, the AED interrupts its main function of automatic analysis of shockable arrhythmias, starting to operate as a Manual Defibrillator. In this condition, the physician may deliver electrical shocks to the patient's chest at his or her discretion, based on his or her judgment.

The steps are simple. **Charging and shocking is performed only by the treatment button, through a command to charge and a command to trigger.** Also, the same disposable electrodes are used in Medical Mode, which must be used only once and then discarded.

Sequence of Use of the Medical Mode (Manual Mode)

1. Turn on the equipment.
2. Press the treatment button for 4 seconds and the message **MEDICAL USE** will be shown, according to the figure below.



3. Press the treatment button to load, move away the patient, following the equipment's voice and text commands.
4. **Wait for the treatment LED to blink and the voice and text command "Press treatment button".**
5. **Press the treatment button for application of the shock, the voice and text command "Treatment performed" are activated in the equipment.**
6. To exit the medical mode, simply turn off the equipment.

PULSE OXIMETRY

Pulse oximetry is a non-invasive method used to measure arterial blood oxygen saturation (SpO_2) and thus monitor and evaluate the functioning of the patient's respiratory and cardiac systems. Pulse oximetry is based on two basic principles: spectrophotometry and plethysmography.

Spectrophotometry measures the amount of light transmitted (or reflected) through the patient's capillaries, synchronized with the cardiac pulse, and plethysmography records the volume of arterial blood in the tissues (and, consequently, the absorption of light by this blood) that changes during pulsation. Therefore, functional saturation is calculated, where oxygenated hemoglobin is expressed as a percentage of the hemoglobin that can carry oxygen.

The result is provided immediately, where a saturation above 90% is satisfactory from the perspective of oxygen delivery to the tissues, provided that hemoglobin and cardiac output are adequate. SpO_2 is defined by:

$$SpO_2 = \frac{HbO_2}{100 - (CoHb + MetHb)}$$

Sensor Operation

The oximetry sensor transmits light beams, produced by two LEDs (diodes), which cross the patient's body and are captured by a photosensor positioned on the other side of the sensor. Diodes emit different wavelengths (red and infrared light) through peripheral regions of the body, such as the fingertips.

The amount of red and infrared light absorbed by oxygen-saturated hemoglobin (oxyhemoglobin) differs from the amount of light absorbed by oxygen-unsaturated hemoglobin. This difference in absorption of these wavelengths is measured by the photosensor, thus calculating the percentage of oxyhemoglobin by comparing the light absorbed during the pulsation. With all this you get an oxygen saturation reading.

Factors That Compromise SpO_2 Reading

Technical artifacts

- Improper sensor position, application or use.
- The emitter and the photosensor must be directly opposite.
- Excessive patient movement / vibrations.
- Intense ambient light (exposure to surgical lamps, infrared heating lamps, fluorescent lamps, or direct sunlight).

Patient-related artifacts

- Hemoglobinopathies (carboxyhemoglobin or methemoglobin).
- Hypothermia: Reading may be compromised by vasoconstriction.
- Anemia: there may be an underestimated reading when hemoglobin is less than 5 g/dL.
- Venous congestion: due to the presence of a venous pulse, the reading may be underestimated.
- Enamels: can compromise reading, especially in black, blue and green colors.
- Intravenous injections: some substances such as methylene blue, indocyanine green and indigo carmine have spectral activity at the wavelengths used for pulse oximetry. This interferes with the accuracy of the readings..

Prolonged Use of the Sensor

Oximetry sensors (adult, child or universal) are not indicated for prolonged use, due to the heat emitted by the sensor and the continuous pressure exerted on the patient. In case of monitoring for a longer period, it is recommended to reposition them in another location on the patient every 4 (four) hours.

Characteristics

- Pulse oximetry, with plethysmographic curve and numerical oxygen saturation indication in percentage; amplitude of the plethysmographic waveform adjusted on the screen.
- Pulse oximetry is used in situations where oxygen saturation (SpO2) is essential: in anesthesia, during surgery, in the postoperative period, in patients in intensive care, in ambulances and even in homes.

The use of the oximetry sensor is prohibited in the MRI room due to its constitution. Metallic parts cannot be used in the room.

Use of the Clip Type Sensor

Make use of the sensor on the index finger, if this is not possible, preferably use a small finger; do not use the thumb sensor.
Pay attention to the following guidelines:

- Check if the sensor is dry.
- Position the sensor as shown below.

- Keep cables connected to the mains supply away from sensor cables and connections.
- Avoid using the sensor in places with intense lighting. If necessary, cover the sensor region with opaque material.
- When selecting a sensor location, choose a device-free end such as: arterial catheter, blood pressure monitor, or intravascular infusion lines.

When reading errors are found, the user must accommodate the patient in order to correct his posture and return blood circulation normally, thus being able to restore the quality of the signals. Check the sensor application every two hours and the patient's skin. If skin quality is compromised, change sensor location.

We recommend changing the sensor placement every 4 hours. If the sensor fails to function, remove it from the patient immediately. Avoid applying tape or tape over the reusable sensor. This reduces the risk of venous pulsation, erroneous saturation measurements and the possibility of pressure damage to the area. However, applying a tape over the cable can help prevent the sensor from slipping out of place.

- Sensor expiry date: Indeterminate.

Use of the Y Type Sensor

The recommended sensor for infant/neonatal application is the Y-model. The fixation of this sensor is done by means of an adhesive tape around the foot; other sites may not provide acceptable results, due to incorrect perfusion or inadequate light.

Make sure that the fixation tape is securely fastened, but not too tight, thus avoiding interference with blood flow, which can cause incorrect readings or skin damage. If the

sensor is not positioned correctly (alignment between the emitter and the receiver), inaccuracies and instabilities in the reading and in the plethysmographic curve may occur. Prevent radiant light from radiotherapy equipment from reaching the tissue and interfering with the SpO_2 measurement.

Patient foot movements can misalign the transceiver assembly (Y sensor) and result in inaccuracies in SpO_2. Correct sensor placement is critical for good oximeter performance.

Important Features of the Y-Sensor:

- Pediatric patients: Weight from 15-40 kg;
- Change location every 4 hours;
- Sensor expiry date: Indeterminate.

When positioning the sensors, the integrity of the skin must always be observed. Patients with burns that may exhibit greater sensitivity to heat and pressure should receive special care, such as changing the applied area of the sensor more frequently.

Do not use the oximeter for continuous monitoring.

Warnings for Choice of Sensor

- Oximetry sensors are designed for weight ranges and for specific locations, so pay attention to the patient's weight when choosing the sensor and for proper sensor perfusion.

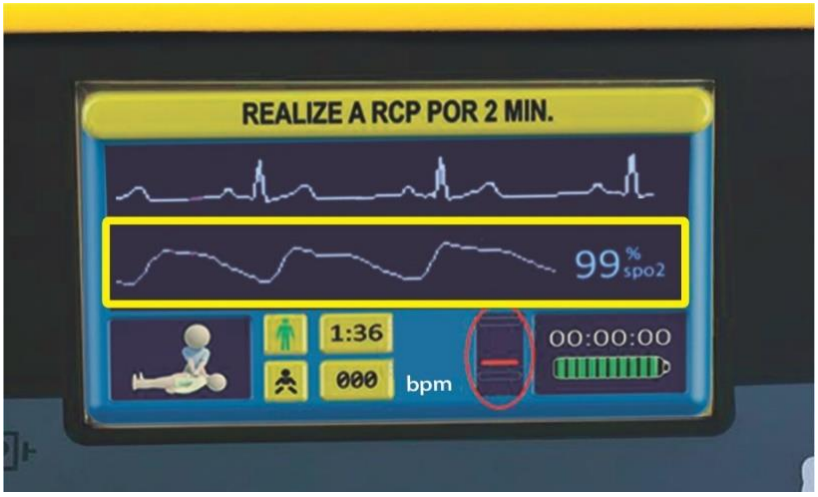
Never use alternative sensors not supplied by the Manufacturer.

Sequence of Use of the Oximetry Mode

1. **Connect the SpO_2 sensor to the left side SpO_2 connector of the equipment, as shown in the figure below.**

2 Place the sensor on the patient's finger, ensuring that the connector is properly seated.

3 The display shows the plethysmography curve and the patient's oxygen saturation value, as shown below.



4 To cancel the oximetry reading, simply disconnect the SpO_2 sensor from the equipment.

Use only SpO_2 sensors supplied by CMOS DRAKE. Other sensors may cause poor performance and/or non-functioning of the feature.

The oximetry reading does not interfere with the analysis of the ECG signal to determine whether or not treatment is indicated.

3-WAY ECG MONITORING

The Life 400 Futura Defibrillator offers an optional 3-way ECG cable input, so that the rescuer can use the ECG cable for continuous monitoring of the patient's electrocardiogram. This monitoring is done by 3 disposable ECG electrodes. If, during monitoring, the patient progresses from their sinus rhythm to a shockable arrhythmia, the AED will detect the need for immediate defibrillation and instruct the rescuer through text and voice commands.

When using the 3-way ECG cable, "MONITORING MODE" will appear on the equipment screen.

The AED must not be used in continuous monitoring and does not have an alarm system. The patient must be assisted by the rescuer.

When connecting the Adhesive Shock Pads, disconnect the ECG cable from the patient.

Do not trigger the shock through the pads with the ECG cable connected to the patient. This procedure can cause burns where the ECG electrodes are connected.

When monitoring via the 3-way patient cable, the AED does not automatically indicate treatment. However, the equipment starts performing another routine that monitors the patient's cardiac signal and searches for arrhythmias to alert the operator.

To use Monitoring Mode, make sure the shock pads are not connected to the AED.

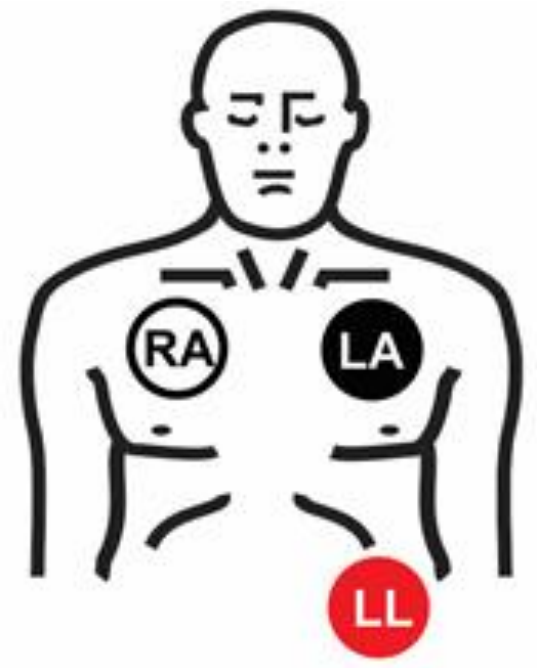
Sequence of Use of the Monitoring Mode

1. Connect the ECG cable to the left of the equipment as shown in the figure below.

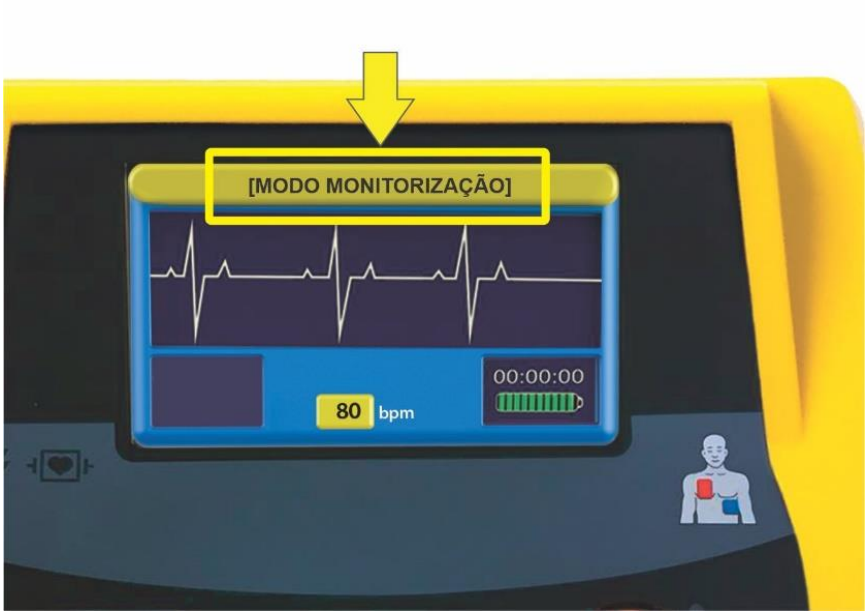
Perform trichotomy (shaving of the hair) if there is excess hair on the patient's chest for better contact of the disposable ECG electrodes with the patient's chest.

2. Check the expiry date of the disposable ECG electrodes.

3. Fix the disposable ECG electrodes on the chestt as shown in the figure below.



4 Connect the 3-Way ECG cable to the disposable ECG electrodes attached to the patient. The equipment shows on the **MONITORING MODE** screen as shown below.

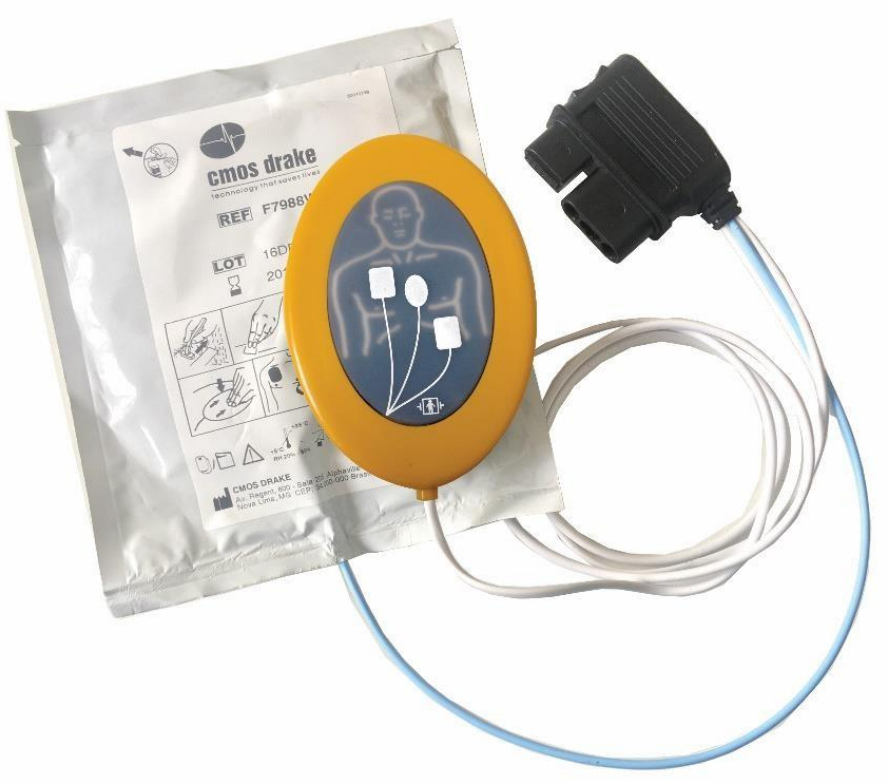


5 Upon identifying any arrhythmia, the voice and text commands **Arrhythmia detected** and **place the shock electrodes** will be issued.

6 To cancel he monitoring mode, simply disconnect the equipment's 3-Way ECG cable.

CPR FEEDBACK DEVICE

The feedback device is an accessory that provides feedback on the quality of compressions applied by the user. The product is optional, which is interconnected with disposable shock pads, and is also for single use.



Cardiopulmonary Resuscitation (CPR) is an emergency procedure used in unconscious, pulseless, and breathing patients. When the patient has these problems, there is a lack of oxygenation in the brain. Therefore, it is essential to apply quality CPR as soon as possible, because about 30 seconds after restriction of oxygen in the brain there is loss of consciousness, after 3 minutes there may be irreversible neurological sequelae and after 6 minutes without oxygen there are high chances. of death of the victim.

The application of high-quality CPR is essential for the survival of patients with cardiac arrest. In this sense, the American Heart Association in its 2015 Guidelines identified five essential components to perform quality CPR:

- Compression Rate from 100 to 120 compressions per minute;
- Compression Depth of 4 cm (infant) or 5 to 6 cm (adult);
- Allow full recoil of the chest between compressions;
- Avoid interruptions in CPR;
- Limit lung ventilation to 10 breaths per minute.

The incidence of sudden cardiac arrest is between 50 to 100 per 100,000 individuals. If CPR is immediately applied, the chance of survival increases significantly.

During the application of CPR there can be complications, the most common being: fracture of ribs or sternum, bleeding in the chest cavity, hematoma in the heart and damage to the lungs. In this sense, the CPR Feedback Device is essential to facilitate and improve the quality of CPR, reducing the chance of harm to the victim during CPR application.
The CPR Feedback Device is designed to assist the rescuer in delivering AHA Guidelines CPR to adult patients. Each device is equipped with intelligent circuitry capable of identifying the rate, depth of compressions and issuing, in real time, text and voice commands to the AED so that the operator adjusts CPR to the ideal parameters of the AHA.

In this way, both experienced rescuers and those performing first-time CPR will be able to continually improve the quality of care delivered in accordance with AHA definitions. The feedback device is also ideal for CPR instructors and their students to train in high quality CPR application.

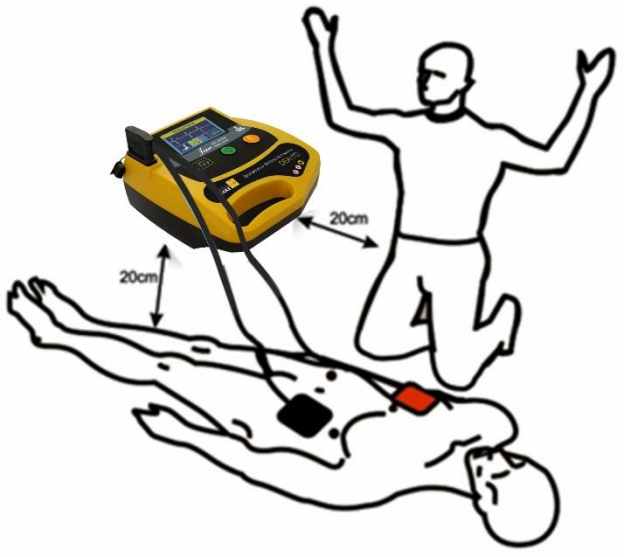
The device is operated in a simple way, just connecting it to the AED and placing it on the patient's chest for it to start working. It does not require any calibration or complicated assembly. Its compact, ergonomic, non-stick design allows for safer and more efficient CPR.

CPR Feedback Device Operating Parameters

Component	Recommended Value
Duration of CPR Cycle	2 minutes
Frequency of Compressions	100 to 120 compressions/min
Depth of Compressions	5 to 6 cm
Maximum Interruption	Interruptions less than 10 seconds

Sequence of Use of the CPR Feedback Device

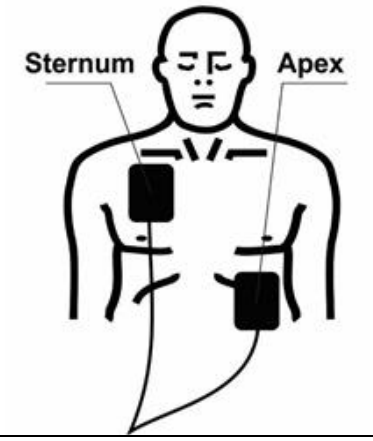
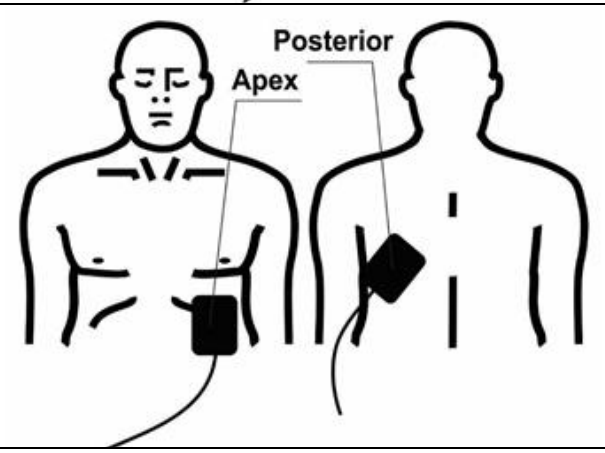
1. The equipment must remain at a minimum distance of 20 cm from the operator and patient, according to the figure below.



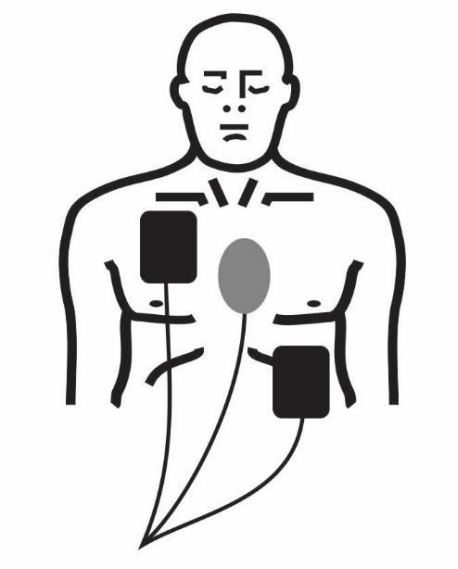
2. Start the equipment.

3. Connect the electrodes into the equipment, as shown below, the voice and text commands “Plug the connector of the electrodes into the equipment” are activated on the equipment.

4. Fix the electrodes **on the adult patient**, as shown below, the voice and text commands **“Place the electrodes on the patient’s chest”** are activated on the equipment.

Sternum-Apex	
OR	
Posterior-Apex	

5. Move away from the patient when indicated by the voice and text commands **“Move away from the patient”** and **“Keep away”** from the equipment.
6. Wait for the analysis of the ECG signal when indicated by the voice commands and text “**Analyzing**” from the equipment.
7. Wait for the voice and text command **“Treatment indicated”** or **“Treatment not indicated”** from the equipment.
8. If the treatment is indicated, press the treatment button when indicated by the voice commands and text “**Press the treatment button**” of the equipment.
9. Place the CPR feedback device as shown below, when indicated by the voice and text commands “**Place CPR feedback device on patient's chest**” on the equipment.



10 Perform CPR on the patient, the voice and text commands "**Perform CPR for 2 minutes**" are triggered on the equipment.

11 Follow the voice commands during CPR, as shown in the table below.

Voice Command	Description
Follow the beat of the beep	The device is indicating that the compression frequency is off-optimal
Compress harder	The device is indicating that the depth of compressions is below what is needed
Compress weaker	The device is indicating that the depth of compressions is above what is needed
Continue CPR	Device is indicating interruption in compressions
Good compressions	The device is indicating that the compressions are good

The AHA Guidelines establish that the electrodes can be fixed in the anteroposterior, left anteroinfrascapular and anteroright infrascapular position with the same efficiency.

The user should take care to replace a new pair of transthoracic adhesive electrodes after use, so that the equipment is always ready for another emergency.

The user must check the expiration date of the electrodes in order to ensure prompt and prompt service. Expiration information can be found on the packaging label of the electrodes. If the electrodes are expired, replace them immediately.

Disposable electrodes are for *Single Use* and therefore should not be reused.

Do not use disposable electrodes if its packaging is damaged.

Visual depth indicator

The CPR feedback device displays a graphical indicator on the screen to show the compression depth in real time, as shown below.

The colors indicate the compression performance, as shown below.


No compression


Almost without compression


Compression in progress


Almost ideal compression


Optimal compression


Overcompression

Display Icons for Guidance During Service

Ready to use.

Open the patient’s shirt.

Remove the electrodes from the packaging.

Fit the electrodes into the equipment.

Place the electrodes on the patient's chest.

Stay calm, ask for help.

Move away from the patient.

Keep away.

Analyzing.

Treatment indicated.

Press the treatment button.

Treatment performed.

Treatment not indicated.

If there is no circulation, perform CPR for 2 min.

Place the CPR feedback device on the patient's chest.

Follow the beat of the beep.

Perform CPR for 2 min.

Compress harder.

Compress weaker.

Continue CPR.

Good compressions.

EMERGENCY CABIN

The emergency cabin is designed for wall mounting to protect equipment and accessories and provide easy access during emergencies. When opening the cab, an audible alert will sound. The alarm will stop when the cab door is closed.

Made of steel and available in yellow or red, as shown below.

It is recommended that the Equipment and its accessories, when not in use, be properly stored in the BLS professional bag or in the emergency cabin in order to protect them.

8 MANAGING DATA

DESCRIPTION

The Phoenix software makes it possible to visualize all the events that occurred while using Cmos Drake products. Through the USB cable it will be possible to transfer the data to the Phoenix software and to analyze the events recorded during the use of the AED in detail. Phoenix also allows software upgrade of Cmos Drake equipment (authorized personnel only).

INSTALLATION OF THE DATA RECORDING SOFTWARE

Minimum Requirements

Operating System	Windows 7 or higher
Processor	1 GHz clock or higher
RAM Memory	1 GB or higher
Disc Space	200 MB free or higher
Others	Internet Access

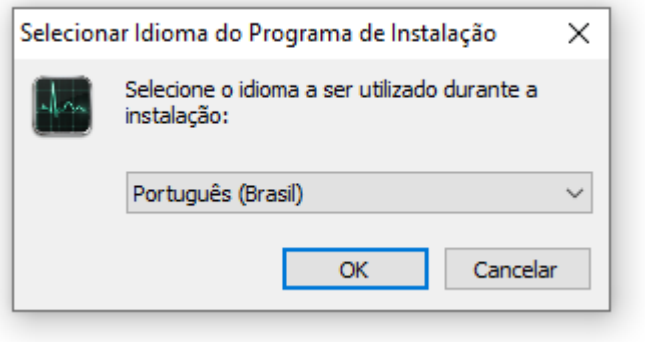
Installation Procedures

1. To perform the Phoenix Software download, access the following glink or use the QR CODE below: https://www.cmosdrake.com.br/content/uploads/manual/Phoenix.rar

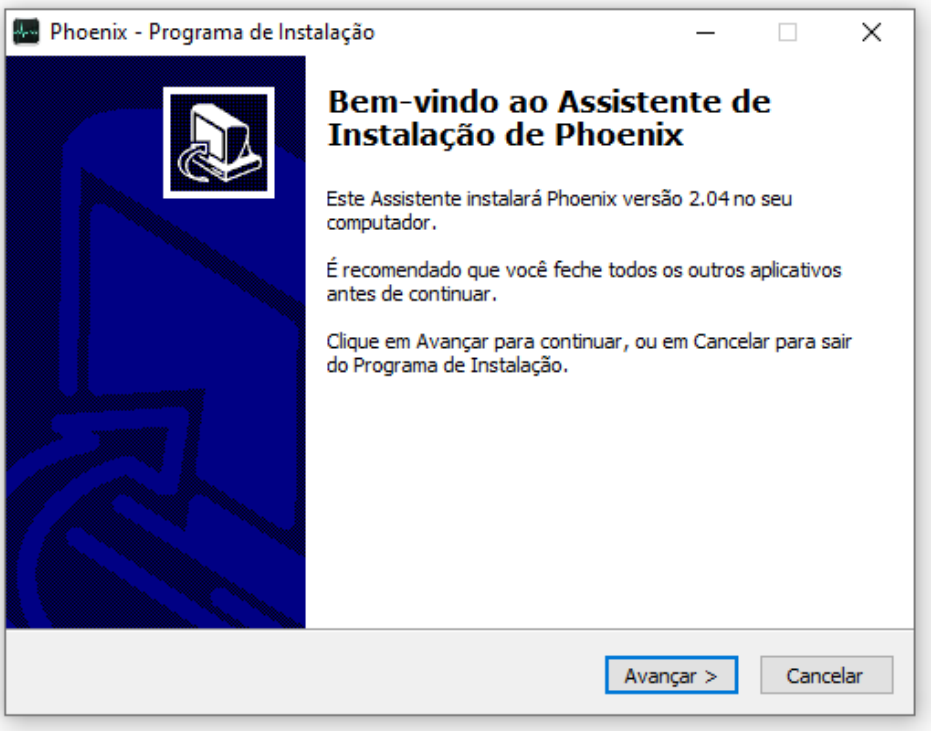
2 After conclusion of the download, decompress the file and run it.

3 Install the Software by following the procedures below:

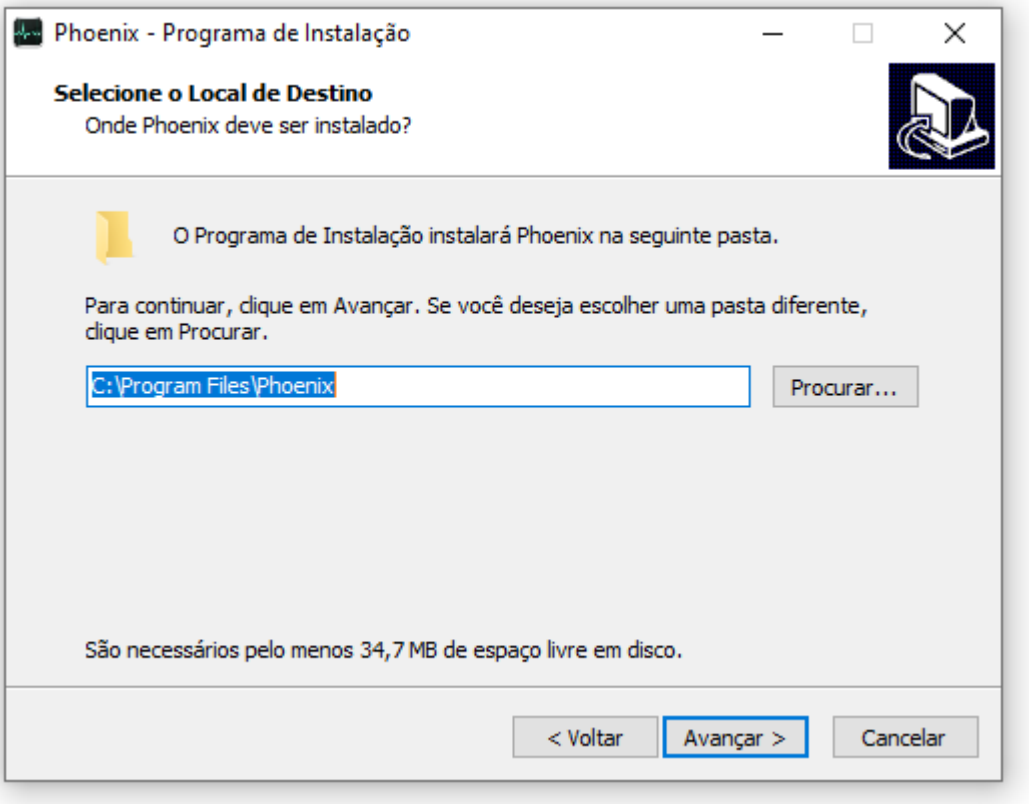
1. Select your language and press “OK”.



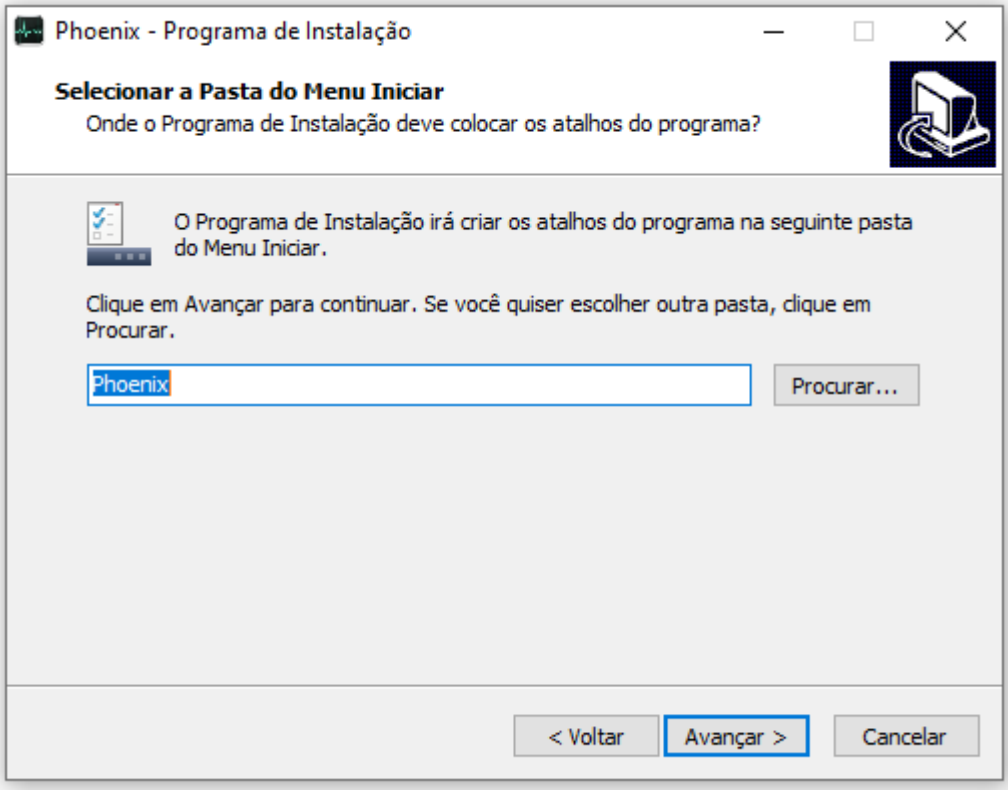
2. In the next window, click “Next”.



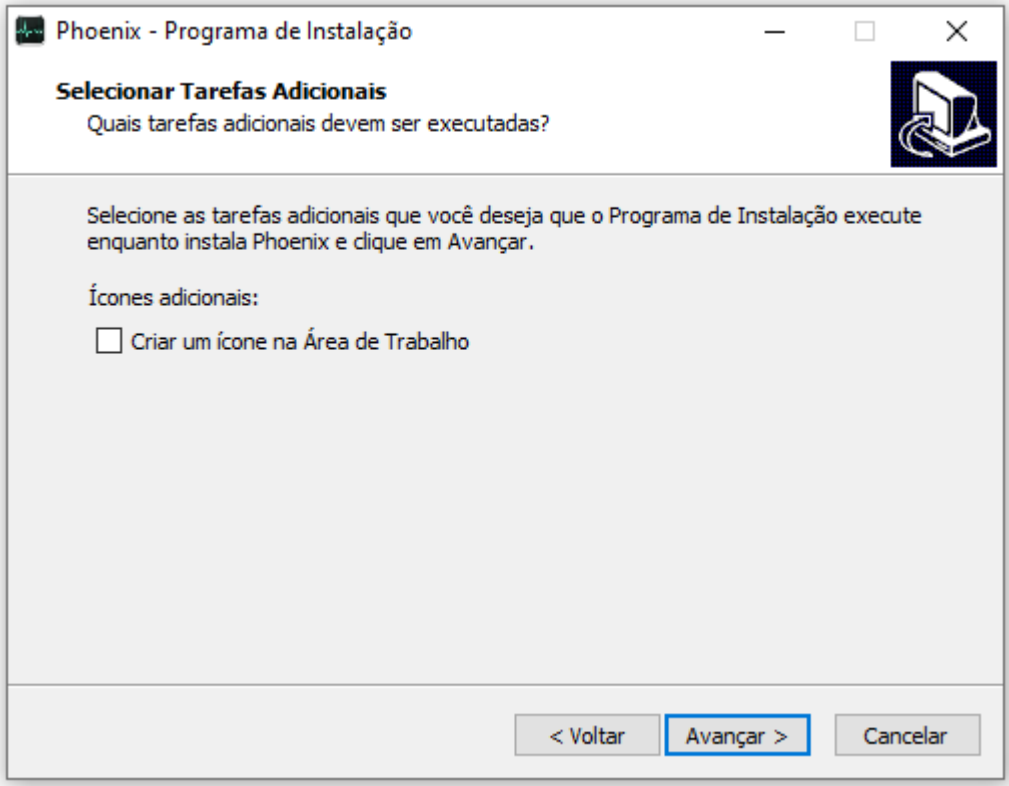
3. Select a directory of your choice



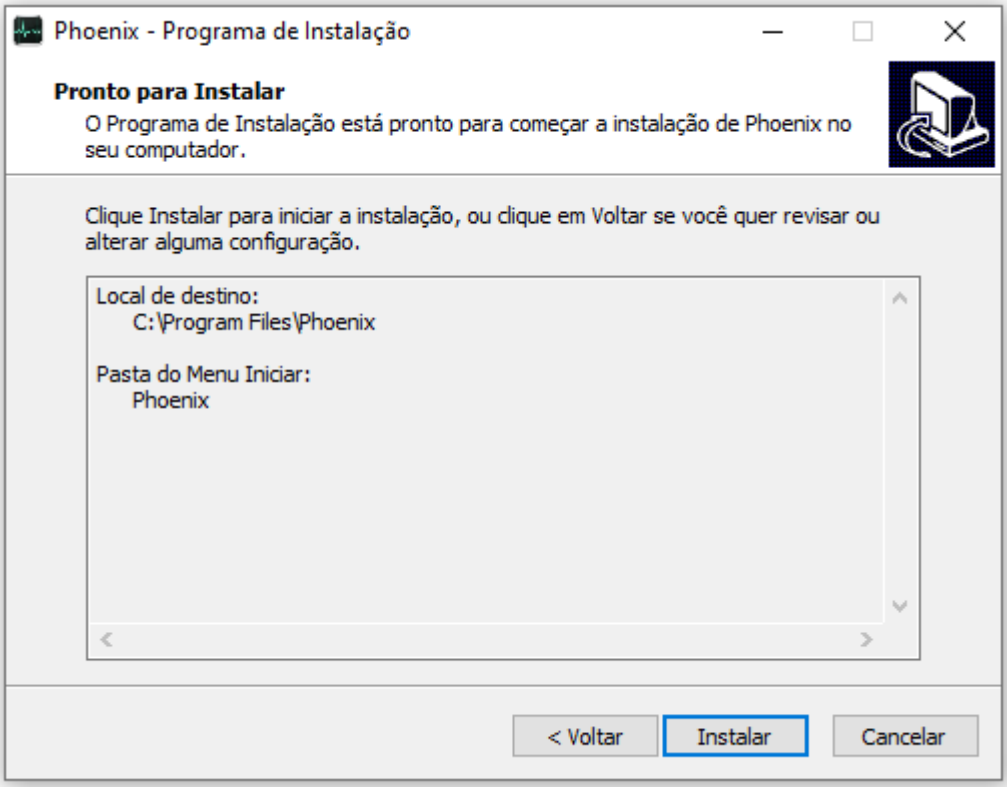
4. Click “Next” again



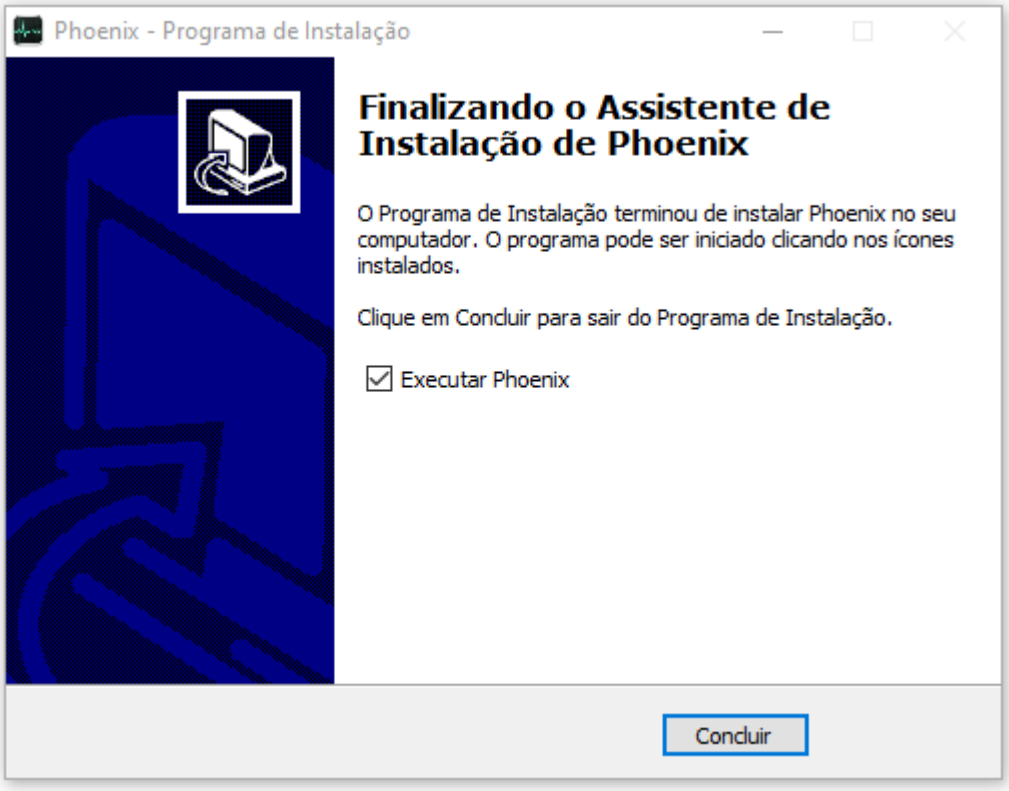
5. If you want a shortcut to be created on the desktop, check the text box. Then press “Next”



6. Click “Install”



7. Click “Finish”.

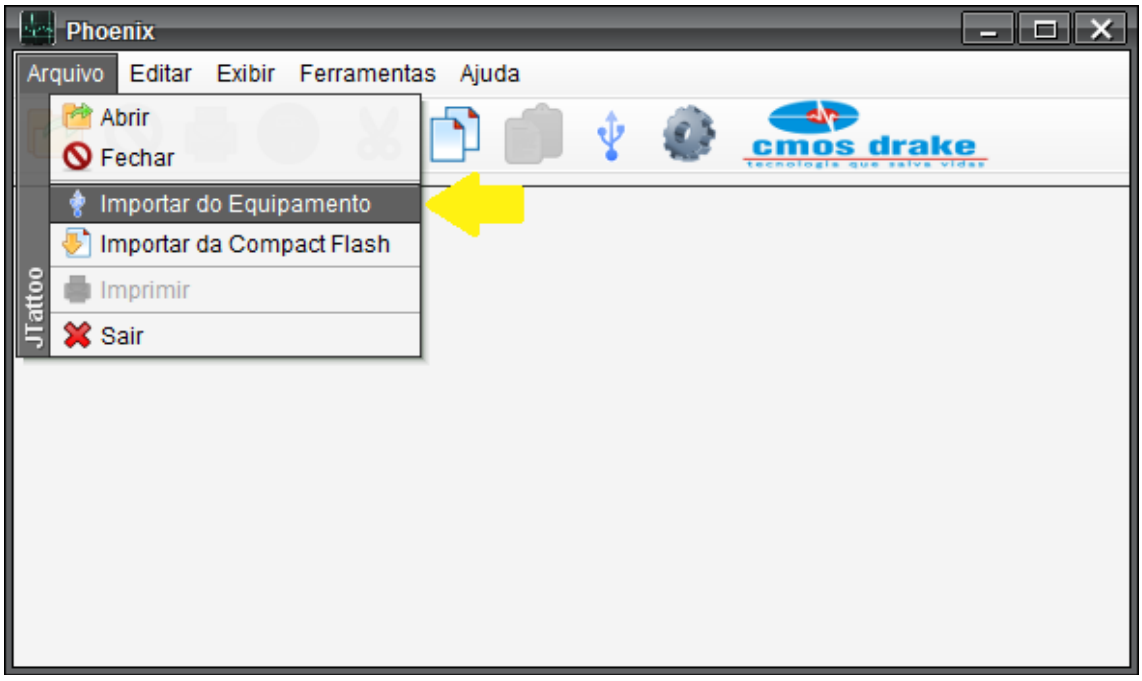


OPERATING THE PHOENIX SOFTWARE

Downloading AED Data

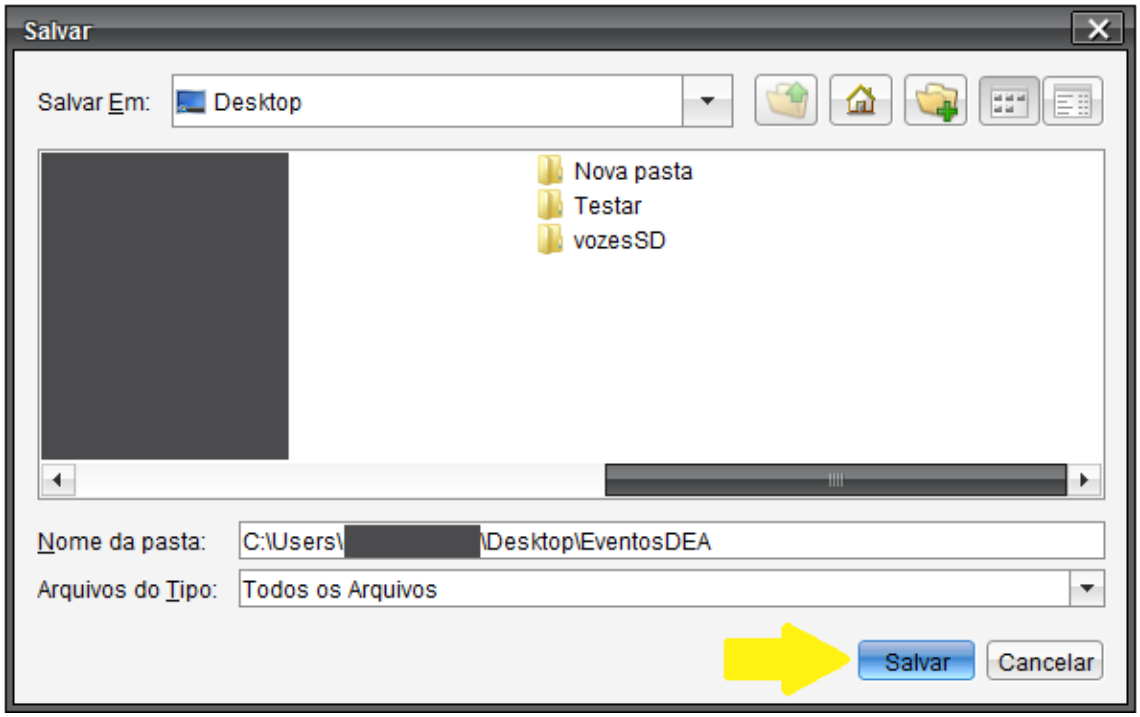
1. Start the Phoenix software
2. Connect the USB cable to the AED and to the computer as shown in the figure below.

3 Click on “File > Import from Equipment”.

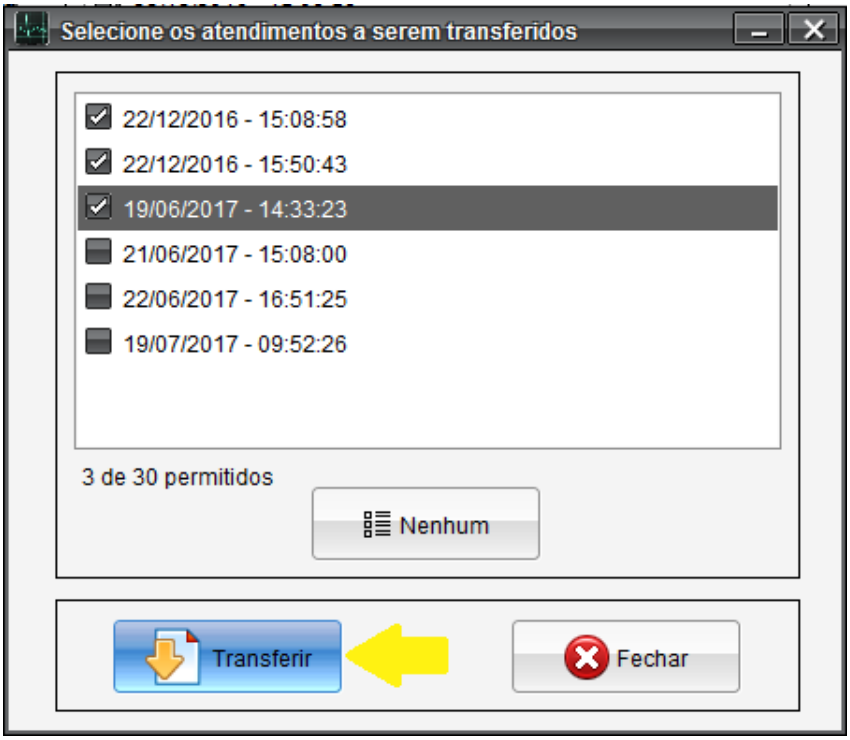


4 Mark the option “Receive data from the Equipment” and click on “Perform operation” ”.

5 Choose a folder to save the data and click “Save”.



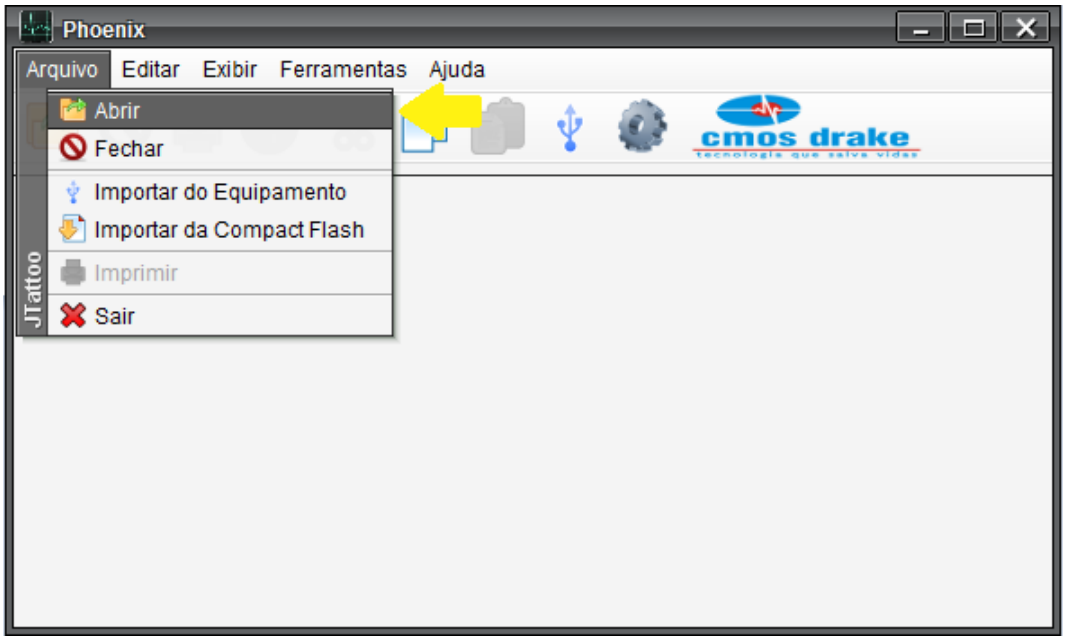
6 Mark the desired events and click “Transfer”.



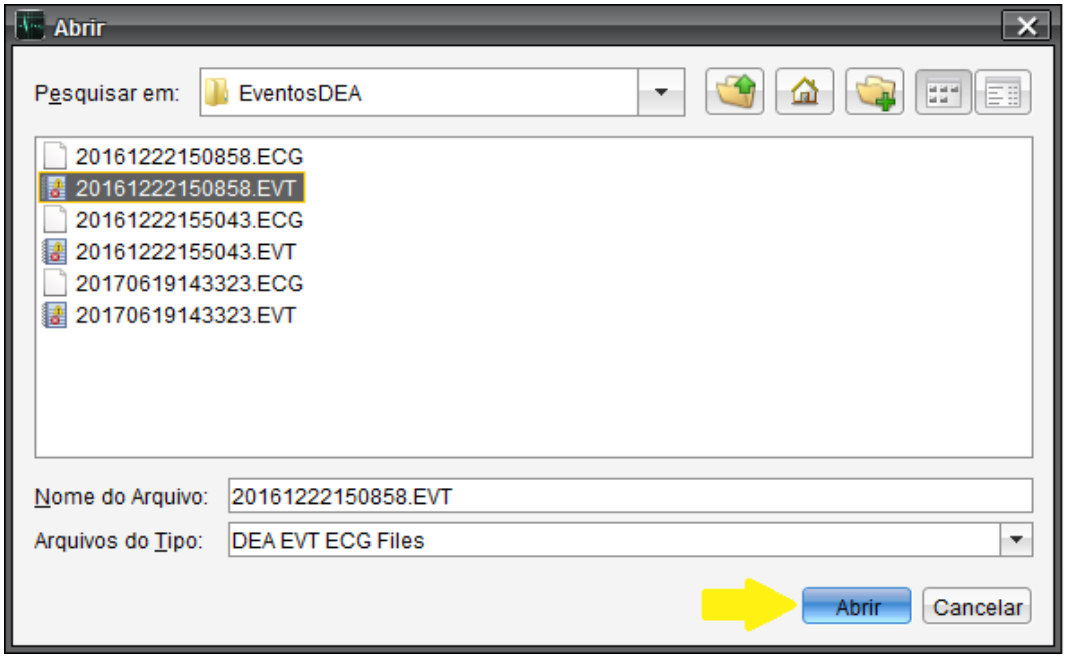
Viewing Stored Data

1 Start the Phoenix software

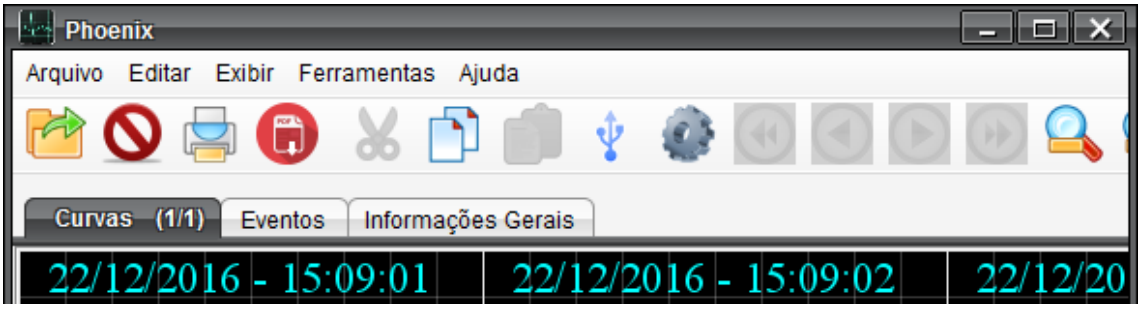
2 Click “’File > Open”.



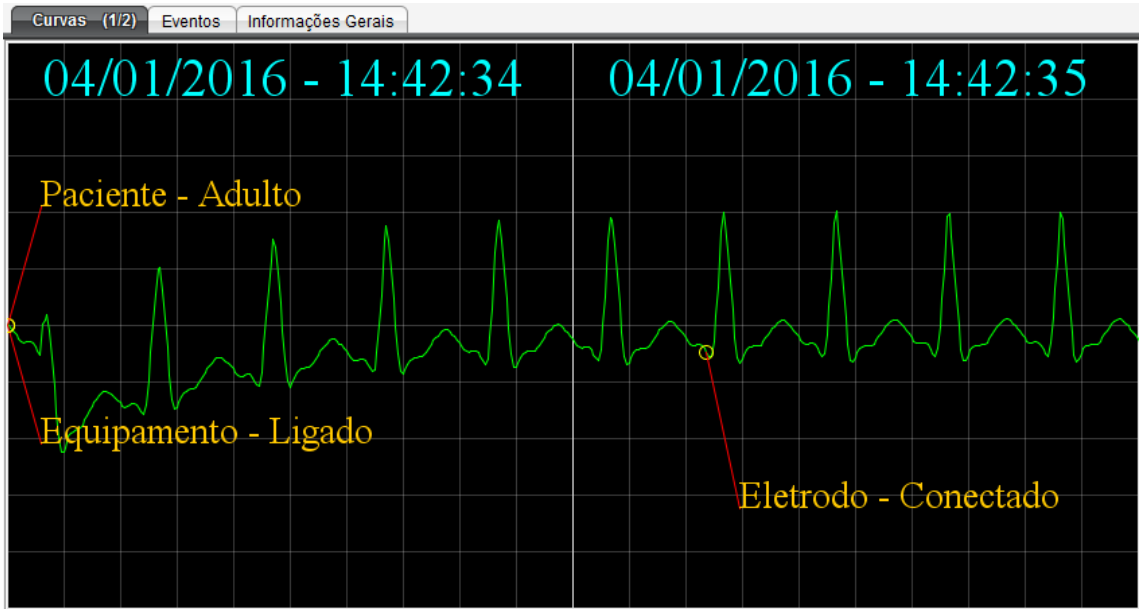
3 Open the folder containing the AED data, select the desired event and click “Open”.



4 3 tabs will appear on the screen: Curves, Events, General Information. To switch between tabs, simply click on the tab directly, or through the “View” menu.



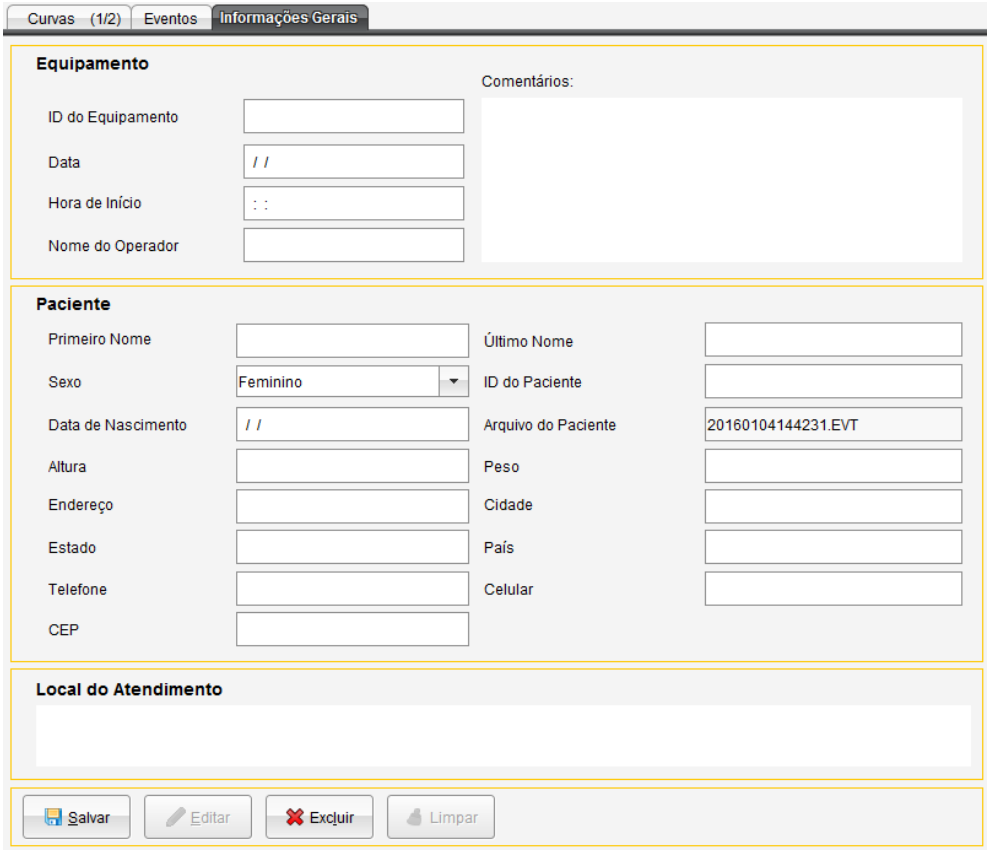
Curves: They display the patient's ECG curve as viewed during the service. In addition, the image is accompanied by a grid containing the date and time of each part of the ECG signal and the most relevant events are displayed by default on the ECG curve, for the purpose of analyzing the service.



Events: To view the events in detail, their period of occurrence and description, select the “Events” tab.

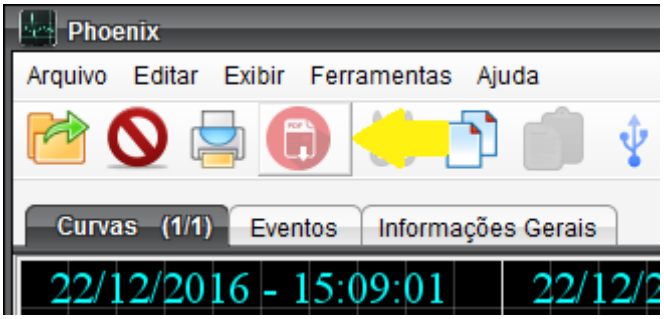
Período	Ocorrência	Evento
04/01/2016 - 14:42:34	Equipamento	Ligado
04/01/2016 - 14:42:34	Paciente	Adulto
04/01/2016 - 14:42:35	Eletrodo	Conectado
04/01/2016 - 14:42:42	Analise Cardiaca	Inicio
04/01/2016 - 14:42:56	Analise Cardiaca	Fim
04/01/2016 - 14:42:56	Tratamento	Nao Indicado

General information: On the General Information tab, the user can fill in patient and operator data. There is also a comment field that can be used to include additional information.

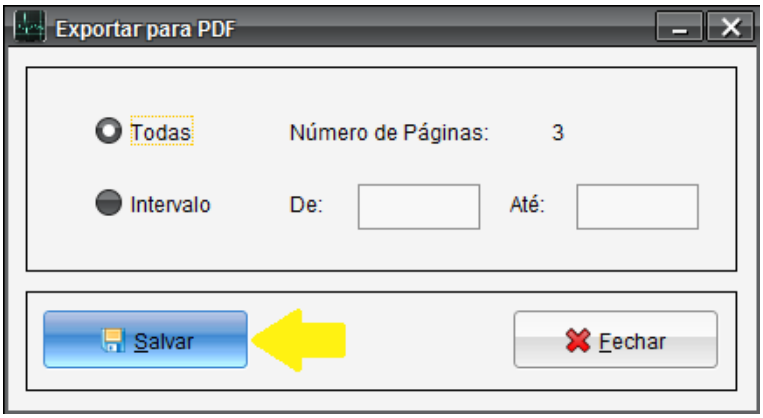


Exporting Service Data

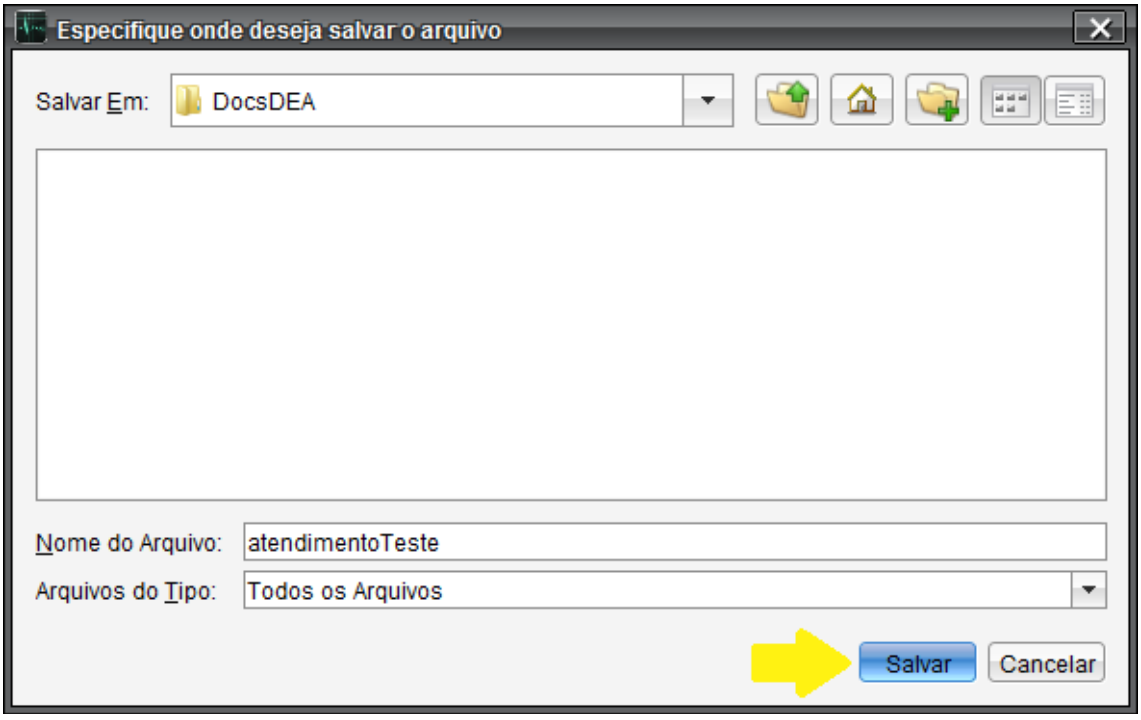
1 Click on the icon indicated on the figure below to save data in PDF.



2 Mark the interval of desired pages and click “Save”.

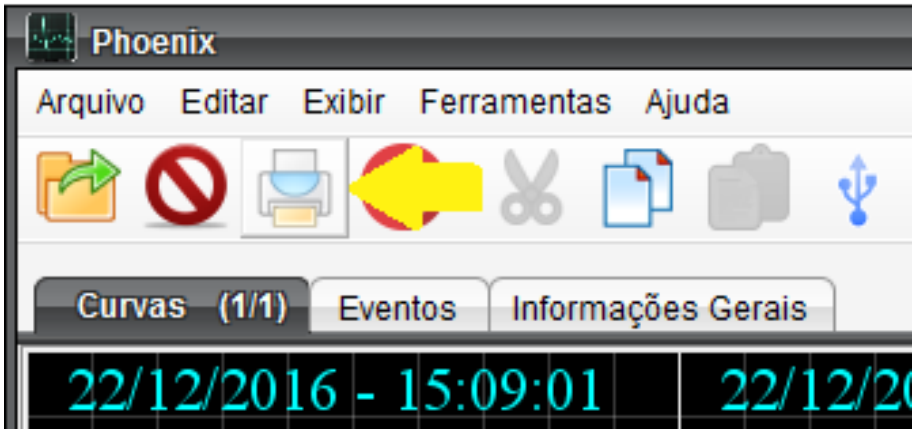


3 Choose a folder to save the PDF and click “Save”.



Printing Files

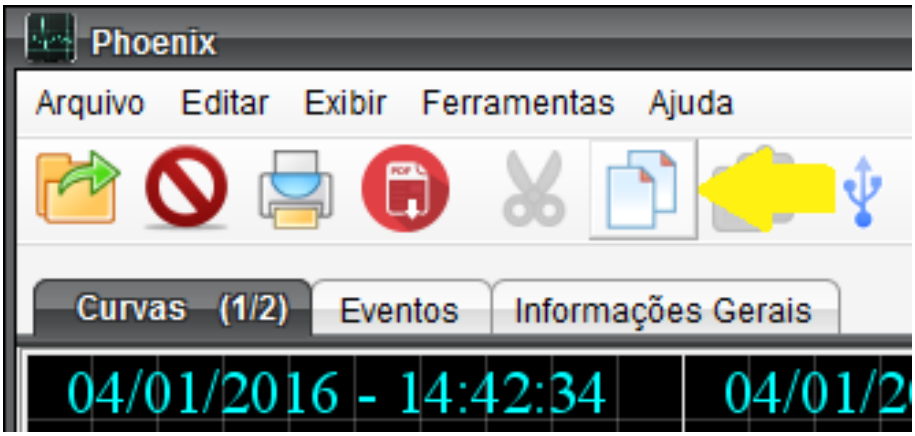
Click the icon shown below or click “File > Print” to print the document. Make sure your printer is properly configured on your computer.



Copying Phoenix Content

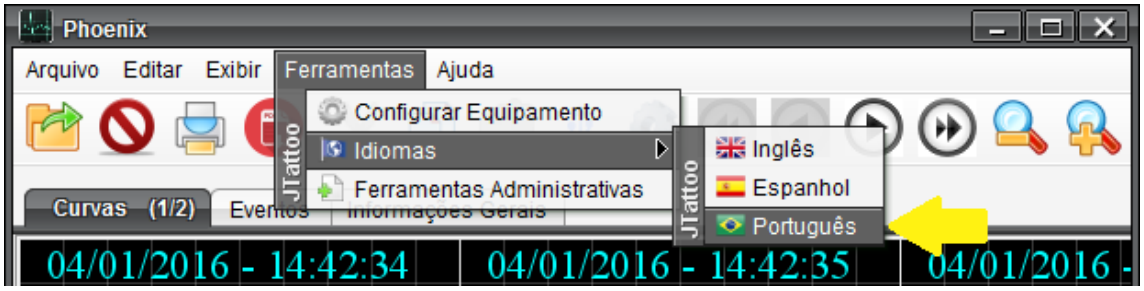
Click on the icon indicated below or click on “Edit > Copy” to copy the contents of the selected tab. This functionality operates as follows:

- ECG Tab – It will copy an image to the transfer area (clipboard).
- Events tab – It will copy text contained in the selected table cell.
- General Information tab – It will copy the text contained in the selected area.



Changing Language

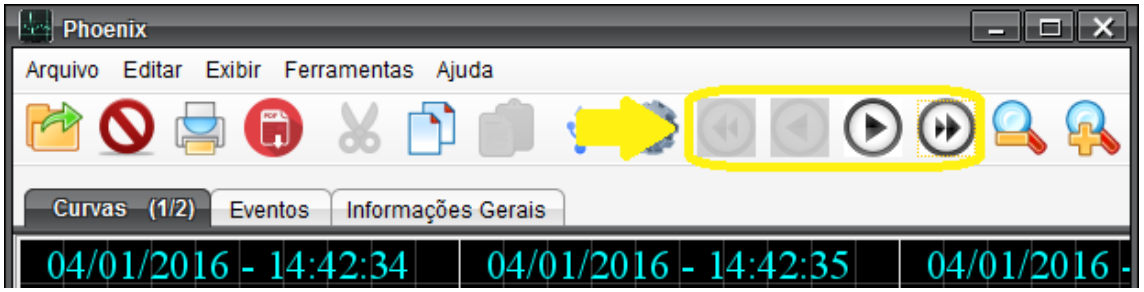
Click on “Tools > Languages” and select the desired language.



Switching Page

To advance to the next page, click on the icon  ;

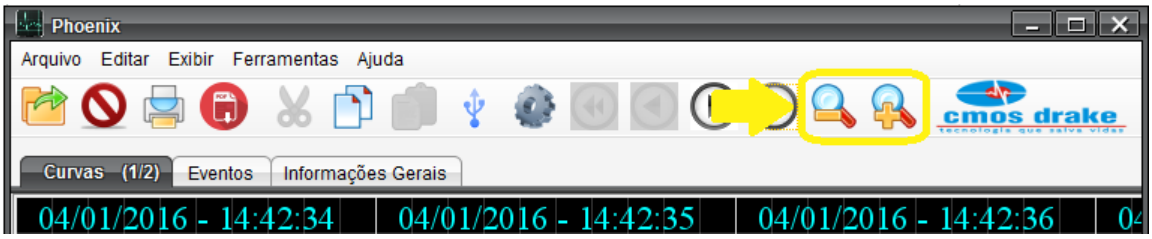
To return to the previous page, click on the icon  ;



Enlarging or Reducing the Screen

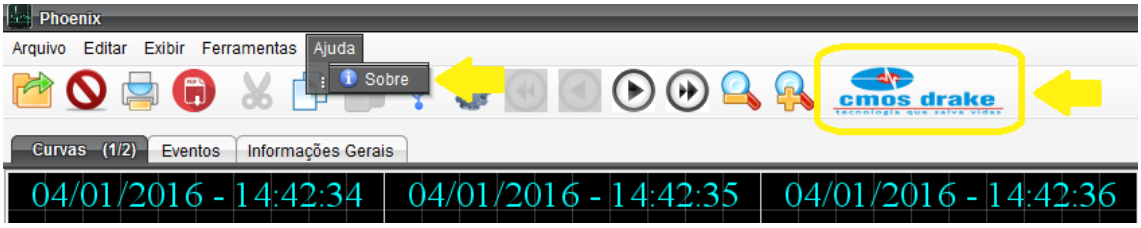
Click the icon  , or right click on the screen, select Zoom and slide the slider to the left, this will zoom out the screen.

Click the icon  , or right click on the screen, select Zoom and slide the slider to the right, this will zoom the screen.



Obtaining Information about Phoenix

Click on the icon shown below or click on “Help > About”.



A window will open with information about the software version and contact for support in case of doubts.

To download the latest software use the QR CODE below:

9 MAINTENANCE

PRECAUTIONS AND SPECIAL CARES

- Do not lean any type of material against the equipment;
- Do not reuse disposable materials, after use they must be discarded in appropriate places according to special procedures for hospital waste;
- We recommend keeping some auxiliary materials such as surgical scissors, a disposable razor blade for chest hair removal and disposable gloves, if necessary.

For greater durability of the Life 400 Futura Defibrillator and its accessories, we recommend that preventive inspections and cleaning be carried out periodically following the table below.

Applied Verification	Frequency
Cleaning	Weekly
Preventive Inspections	Biannual
Revision in Authorized Technical Assistance	Annual
Mandatory Calibration	Annual

For each process, make sure that the equipment is turned off and its electrodes are disconnected.

CLEANING OF EQUIPMENT AND ACCESSORIES

The equipment and its non-disposable accessories must be cleaned after each use or when visible dirt is detected. If it has not been used, it is recommended that cleaning be carried out quarterly. All cleaning procedures must be carried out at room temperature.

Do not spill any type of liquid and/or place needles and objects in general on the equipment and/or accessories.

Do not immerse the equipment and accessories in any type of liquid for cleaning.

Cleaning of the Equipment

1. Disconnect the equipment from the electric mains.
2. Gather together the equipment and the battery charger for cleaning.
3. Prepare a cloth slightly dampened with water and neutral liquid soap and a cloth dampened with 70% ethyl alcohol.

Do not use cleaning agents with abrasives, organic solvents, chlorine, alcohol or hydrocarbon solvents.

The labels present on all items (AED, Accessories and Battery Charger) are important, and therefore must not be removed and must not be damaged when cleaning.

4. Clean the Equipment case and charger using the cloth with soap and water.
5. Disinfect the Equipment case and charger using the cloth with alcohol.
6. Carefully wipe the display with a dry flannel or, in case of dirt, a cloth slightly dampened with water to remove dust and dirt particles.

Cleaning of the Accessories

1. Disconnect the sensors of the equipment.
2. Gather together the non-disposable accessories for cleaning.
3. Prepare a fabric lightly moistened with demineralized water and neutral liquid soap, a soft fabric slightly moistened with demineralized water and a fabric moistened with 70% ethyl alcohol.
4. Clean the sensors using the cloth with soap and water.
5. Remove the soap from the sensors using the soft cloth with water.
6. Disinfect the sensors using the cloth with alcohol.
7. Disinfect or dispose of used cloths.

DISPOSAL OF EQUIPMENT AND ACCESSORIES

Electronic equipment and its parts that reach the end of their useful life must be sent to the manufacturer for proper disposal, thus preserving natural resources and contributing to the conservation of the environment.

Waste from electrical and electronic equipment. Dispose of separately from other objects in the establishment.

Disposal of Equipment at End of Useful Life

At the end of the equipment's useful life (period greater than 5 years), the customer must contact the Manufacturer to receive instructions for the disposal of the equipment, accessories and battery charger. Consult the local Environment Department in your city where the Equipment is installed, as it may dispose of it. Cmos Drake will also be able to receive the equipment, accessories and battery charger, will disassemble them by separating recyclable and non-recyclable parts.

The recyclable parts will be sent to companies duly accredited and qualified to recycle materials. The non-recyclable parts will be sent to accredited companies that follow the resolutions of CONAMA and the presidency of the republic for the disposal of non-recyclable materials.

Battery Disposal

Battery disposal

For batteries that are disposable, that have reached the end of their recommended life (more information in Chapter 4 – Battery) or that show any deterioration in charge capacity and/or

performance, contact the Manufacturer for disposal instructions. of the battery. Consult the local Environment Department in your city where the Equipment is installed, as it may dispose of it.

Disposal of Accessories

For disposable accessories such as shock pads, follow local regulations for medical waste.

PREVENTIVE INSPECTIONS

We recommend that the Life 400 Futura Defibrillator and its accessories be inspected every six months, regardless of whether the equipment has been used or not, following the instructions below:

- Check that the equipment has all the accessories and components necessary to carry out an eventual service that may occur.
- Check the expiry date/expiration of (disposable shock pads). The validity of the blades is in the format YYYY/MM (year/month) on the label affixed to their packaging, as shown below. If any of these accessories are close to expiration or are already expired or in poor condition, we request that you purchase new material from Cmos Drake or an authorized representative.

Never use alternative pads available on the market. This procedure will effectively compromise the analysis of the Patient's ECG.
Only purchase the original blades supplied by CMOS DRAKE as identified above.

- Check the conservation of the equipment and its accessories, if there is any irregularity in the equipment, it must be sent to the manufacturer for maintenance, and in the case of accessories, a new material must be purchased only by the manufacturer.

- Turn on the equipment and check the battery charge level (via the visual battery indicator on the display). If it is low, it will be necessary to recharge or replace the batteries (instructions on how to proceed in Chapter 4 - Battery).

Preventive Maintenances

Maintenance and periodic testing of the equipment and its accessories are preventive measures that help to prevent and detect possible electrical and mechanical failures. During the maintenance schedule recommended by CMOS DRAKE, if the test identifies a possible problem with the equipment, accessories and sensors, remove it from use immediately and contact the qualified technical area.

Programming of Tests and Maintenance

It is recommended that the following preventive inspection schedule be used in conjunction with the hospital's internal quality control program or any location where the AED is used. To record the results of the periodic inspection and help the operator to verify the recommended corrective action for simpler problems, a list to be followed, called **Checklist**, is provided, which must be kept close to the equipment and is available for highlight at the end of this user’s manual.

The electrical safety, performance and calibration tests of the equipment must be performed by qualified technical assistance authorized by CMOS DRAKE.

	Occasionally			Periodically				
Programming	Before Use	After Use	If Necessary	Every Day	Every Week	3 Months	6 Months	12 Months
Check the expiry date of the adhesive shock pads	X							
Inspect the equipment (visual and mechanical)	X	X						
AED cleaning		X	X					
Cleaning of accessories		X	X					
Check that all necessary materials are complete				X				
Check screen message and voice command						X		
Electrical safety test								X
Electrical safety test after technical intervention	X							
Test with Defibrillator Analyzer in 1st and 2nd year								X
Test with Defibrillator Analyzer in 3rd year onwards							X	
Turn on the AED, check “Ready to Use” and check battery charge level	X	X			X			

To test the equipment, follow the procedures below:

Partial Test

1. Turn on the equipment.
2. Observe the battery level on the display. **If low, charge immediately.**
3. Wait for voice and text commands until the phrase:
   Place the electrodes on the patient's chest.
4. Turn off the equipment.
5. Keep the battery charger plugged into the AED and electrical outlet.

Complete Test

1. Turn on the equipment.
2. Observe the battery level on the display. **If low, charge immediately.**
3. Connect your Defibrillator Analyzed into the AED.
4. Select th Ventricular Fibrillation (VF) or Ventricular Tachycardia (VT) ECG wave on the Defibrillator Analyzer.
5. Wait for voice and text commands of the indicated treatment.
6. Press the treatment button and the shock will be triggered in the Analyzer.
7. Check the energy delivered in the Analyzer.
8. Turn off the equipment.
9. Keep the battery charger plugged into the AED and electrical outlet.

Any eventual failure in the mentioned tests, contact the Authorized Technical Assistance immediately.

Equipment Calibration

Every 12 months the equipment must be sent to the authorized technical assistance for preventive maintenance and calibration. This procedure ensures that all equipment functionalities are in full working condition.

Periodic calibrations must be performed as follows:

- Advisable calibration after warranty: 3 months.
- Recommended calibration after warranty: 6 months.
- Mandatory calibration after warranty: 12 months.

The equipment calibration aims to keep the equipment with all its functionalities and within the technical standards of hardware and software. Calibration is understood as the measurement of electrical data and values, circuit waveforms, verification of circuit current and voltage levels, and the respective adjustments to correspond to the project's established standard values . During the measurement, if it is impossible to make the necessary adjustments, the replacement of parts and components will be made to guarantee the calibration. Therefore, calibration can only be performed by professionals trained by the manufacturer and who prove that they have the following equipment necessary for perfect calibration:

- Electrical safety analyzer.
- Defibrillator analyzer with display that visualizes the truncated exponential curve
- Pulse oximetry analyzer for version with SPO_2.

- Oscilloscope.
- Digital multimeter.

All the above equipment must be calibrated by an accredited body, within the validity periods and must be attached to the calibration report. Equipment that is calibrated by companies not authorized by CMOS Drake will lose its lifetime warranty and several risks of material damage due to incorrect intervention in the equipment may occur, directly impacting other risks.

Never forward the Life 400 Futura Defibrillator (high risk) to unauthorized Technical Assistance or hospital internal maintenance departments, whether for preventive, corrective or calibration maintenance, subject to penalties provided by the National Health Surveillance Agency - Anvisa.

The AED Life 400 Futura Defibrillator was designed and built within national and international regulatory and regulatory standards. Technical safety standards regarding technical intervention in the product must be applied.

The Authorized Technical Assistances undergo intense training for the correct technical intervention in the equipment, whether for corrective, preventive maintenance and calibrations. The factory applies intensive training, provides electronic diagrams, original parts and components, up-to-date software versions, and keeps authorized ones up-to-date for desired upgrades. The dedicated AED board is a multi-layer board with SMD and discrete components, manufactured following IPC (Association Connecting Electronics Industries) guidelines, assembled under careful technical procedures with controlled temperature, anti-static environment, lead free soldering, solder technology in ENIG bath (Electroless Nickel Immersion in Gold) among other modern techniques in electronic circuit design.

IPC Printed Board / Acceptance	IPC-DR-572	IPC-1601	IPC-6013	IPC-9151
	IPC-A-600	IPC-4761	IPC-6015	IPC-9194
	IPC-OI-645	IPC-6011	IPC-6017	IPC-9199
	IPC-1710	IPC-6012	IPC-6018	IPC-9241
	IPC-9252	IPC-9631	IPC-9641	IPC-9691

CMOS DRAKE advises owners of the AED defibrillator Life 400 Futura not to perform technical services in unauthorized technical assistance. Otherwise, the equipment may be damaged by undue interventions, compromising the correct functioning of the equipment, incurring serious errors in functionality, risk management, usability, and even more serious, it may fail during service.

TROUBLESHOOTING

Problem	Recommended Action
Equipment does not turn on.	• Press and hold the power button for at least 3 seconds; or • Check if the battery is installed incorrectly and, if necessary, fit it correctly; or • Check the condition of the battery and whether it is discharged. If necessary, recharge or replace the battery.
The Equipment turns on, but keeps repeating the message “Place the Electrodes on the Patient's chest”.	• Check if the electrodes connection to the AED is correct; or • Check if the adhesion of the electrodes to the Patient is adequate and if he is moving excessively; or • Check if the patient has hair on the chest, it will be necessary to perform Trichotomy (shaving the hair); or • Check that the electrodes are in good condition and, if necessary (and possible), replace the electrodes.
The Equipment does not display the SpO_2 curve, even with the sensor connected.	• Check that the connection of the SpO_2 sensor to the AED is correct; or • Check that the sensor is correctly positioned on the patient's finger and that it is moving excessively; or • Check for direct light on the SpO_2 sensor (light may interfere with the reading of the Patient's oximetry signal); or • Check that the sensor is in good condition and, if necessary (and possible), replace the sensor.
The Equipment beeps frequently.	• This is the self test, a sign that the battery is low and therefore needs to be recharged or replaced. If the battery has been recently charged and used little, but is not holding a charge, contact the Manufacturer to send it for disposal and replace it with a new one.

The Equipment emits a “beep” and turns off after indicating treatment.	➢ The AED had a very low battery before the treatment, a sign that the battery should be recharged or replaced. The process of charging the capacitor to deliver a shock is energy intensive and can cause the battery voltage to momentarily drop below the critical shutdown level.
The Equipment is not identified by the data recording software or the computer.	➢ Check if the USB cable was correctly inserted in the Equipment and in the computer; or ➢ Check if the computer has installed the Equipment driver correctly and, if necessary, wait for the complete installation of the computer; or ➢ Restart the computer.
Equipment is blocked for unknown reason.	➢ Wait for the device to automatically restart. If it does not occur within 3 seconds, press the equipment on/off key and check if it returns to normal operation; or ➢ Check if any adverse external events occurred in the environment where the equipment is being used.

OBSERVATION: *If the recommended actions are not sufficient to correct the problem, contact Cmos Drake Authorized Technical Support.*

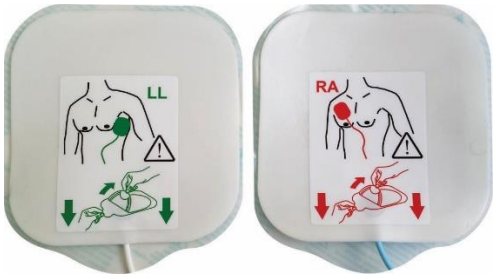
ADVERSE EFFECTS

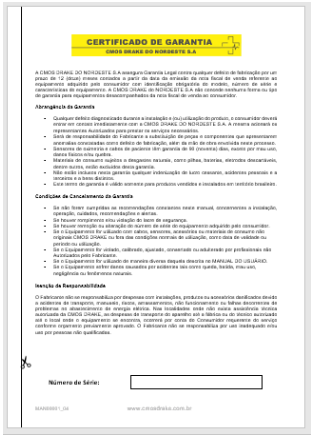
CMOS DRAKE, as a manufacturer of medical and hospital equipment, requests users to report possible defects or the occurrence of any undesirable event, in order to guarantee the quality of the equipment, accessories and battery charger. Therefore, any failure or malfunction, please contact the nearest authorized technical assistance or directly with the sales consultant at the telephone or website indicated below on the last page of this manual.

A

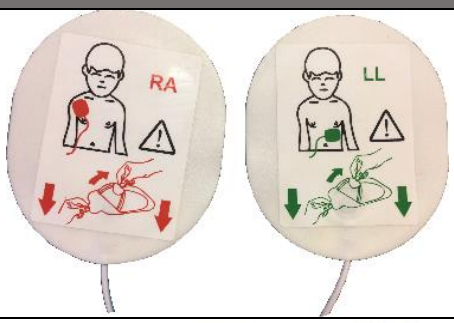
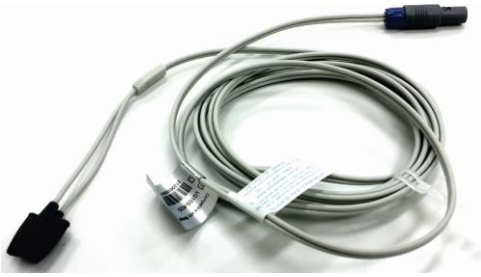
APPENDIX A

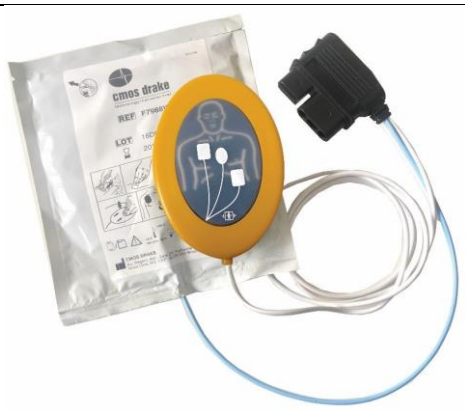
LIST OF BASIC ACCESSORIES

Description	Reference	Supplier	Image
Adhesive and Disposable Shock Pads (ADULT)	LT49131	Cmos Drake FIAB	
	LT72471	Cmos Drake OBS	
Battery Charger	**LiPo Battery** LT31651	Cmos Drake	
	LiOn Battery LT48509		
Shielded USB A/B Cable for Data Transfer	35375	Cmos Drake Computer Stores	

BLS Professional Bag for basic life support for AED	33940	Cmos Drake	
Printed User's Manual and Phoenix Software (Download via link in manual and QR code)	12486	Cmos Drake	
Certificate of Equipment Warranty	N/A	Cmos Drake	

LIST OF OPTIONAL ACCESSORIES

Description	Reference	Supplier	Image
Adhesive and Disposable Shock Pads (CHILD)	LT49147	Cmos Drake FIAB	
	LT72488	Cmos Drake OBS	
Oximetry Sensor Clip Type (ADULT)	LT218	Cmos Drake Biolight Nellcor	
	LT72460	Cmos Drake Orantech INC	
Oximetry Sensor Soft Type (CHILD)	LT247	Cmos Drake Biolight Nellcor	
Oximetry Sensor Y Type	LT231	Cmos Drake Biolight Nellcor	
	LT72465	Cmos Drake Orantech INC	
ECG Electrodes and Cable 3 Way	LT483	Cmos Drake	

Disposable ECG Electrodes (ADULT)	661	Cmos Drake	
CPR Feedbac Device and Adhesive and Disposable Shock Pads (ADULT)	LT56673	Cmos Drake	
Emergency Cabin for AED	54384	Cmos Drake	
BLS Rescue Bag	1815	Cmos Drake	
Cleaning Kit	23188	Cmos Drake Medical supply stores	Blunt tip scissors Gloves Depilatory wax Mask Blade for shaving hair.

Additional Rechargeable Battery	**LiPo Battery** LTSP32	Cmos Drake	
	LiOn Standard Battery LTSP33		
	LiOn Plus Battery LT57879		
Disposable Battery	**LiMn Battery** LT41170	Cmos Drake	

All accessories must be stored in a ventilated place and free from moisture, dust, light (including sunlight) and fibers from other materials such as cotton. The mentioned components can interfere with the correct use of the accessories or even lead to a total impairment of their functioning.

Before putting the equipment in contact with the patient, the operator must regularly check that it is in working conditions.

Use only the accessories, consumables and others listed in this manual. CMOS DRAKE does not guarantee the proper functioning of the equipment with the use of unknown accessories, in addition to not being responsible for failures in the operation of the equipment or possible damages caused by them.

In general, the EQUIPMENT Parts and ACCESSORIES of the Automatic External Defibrillator - AED, intended to come into contact with biological tissues, cells or body fluids are tested and analyzed in accordance with the guidelines and principles of ISO 10993-1, which deals exclusively with testing of biocompatibility of the applied parts.

Cmos Drake guarantees that all permanent and disposable materials in contact with the patient do not cause any type of damage or harmful physiological effect, provided that: the procedures described in this manual are followed; that they are installed in an appropriate medical place; that it is used with the correct accessories; be operated by trained personnel and that all precautions described in this User's Manual are followed.

B

APPENDIX B

EQUIPMENT TECHNICAL SPECIFICATIONS

Compliance with Standards and Certifications

In Compliance with the Standards	NBR IEC 60601-1:2010+Em.2016; NBR IEC 60601-1-2:2017; NBR IEC 60601-2-4:2014; NBR IEC 60601-2-27:1997; NBR IEC 60601-1-12:2020; MDD 93/42/EEC:2007; EN ISO 14971:2007; EN ISO 13485:2003; Among others
Relevant Certifications	Product Certification - INMETRO
Ministry of Health Registration	80058130008

General Specifications

Dimensions	295 mm x 225 mm x 155 mm
Weight	Approximately 3 kg
Internal Memory	**4 GB:** Recording capacity of data referring to 1000 events

Operation Specifications

Operating Temperature	0 °C to 50 °C
Operating Humidity	5% to 95%, without condensation

Operating Atmospheric Pressure	620 hPa to 1060 hPa (465 mmHg to 795 mmHg)
Operation Mode	Non-continuous operation mode ON – Capacitor average load: 6 seconds OFF – Min. interval between shots: 30 seconds
Maximum Cumulative Time of Operator/Patient Exposure to the Equipment	Approximately 6 hours (battery life)

Transitory Operation Specifications

Temperature	-20 °C to 50 °C
Humidity	15% to 90%, without condensation
Time of a transient condition	Period not less than 20 minutes

Storage and Transport Specifications

Storage Temperature	-10 °C to 45 °C
Transport Temperature	-10 °C to 45 °C
Storage Humidity	10% to 95%, without condensation
Storage Atmospheric Pressure	620 hPa to 1060hPa (465mmHg to 795mmHg)
Maximum Stacking	5 boxes
Box for Transport	Transport in original box of the equipment. CMOS DRAKE does not guarantee and is not responsible for any damage that occurs to equipment that is transported or stored in other packaging.

Safety Specifications

Classification of Applied Parts	**Shock Pads:** Defibrillator-proof CF type applied part **SpO_2:** Defibrillator-proof BF type applied part **ECG:** Defibrillator-proof CF type applied part **CPR Feedback:** Defibrillator-proof CF type applied part
Protection against Harmful Water and dust Penetration	IP56
Safety Degree of Use in Presence of Flammable Anesthetic Mixture	Equipment not adequate for use in the presence of flammable mixture with air, O_2 and N_2O
Degree of Protection Against Electric Shock	**Model with rechargeable battery:** Internally powered when operating and class II when battery is under load **Model with disposable battery:** Internally powered
Means of Separation between Equipment and Electricity Grid	Network plug

OBSERVATION: *Despite having different functions, the shock pads and ECG cable are the same applied part.*

Do not use both Permanent Shock Pads/Disposable Shock Pads and ECG electrodes at the same time, to avoid damage in case of discharge.

Internal Battery Specifications

Rated Voltage	**Rechargeable Lithium-Polymer:** 11.1 V_{DC} **Rechargeable Lithium-Ion Standard:** 14.8 V_{DC}

	Rechargeable Lithium-Ion Plus: 14.8 V_{DC}
	Disposable Lithium-Manganese: 15.0 V_{DC}
Rated Charge	**Rechargeable Lithium-Polymer:** 2200 mAh
	Rechargeable Lithium-Ion Standard: 2850 mAh
	Rechargeable Lithium-Ion Plus: 3500 mAh
	Disposable Lithium-Manganese: 3500 mAh
Operating Temperature	**Rechargeable Lithium-Polymer:** 0ºC to 45ºC
	Rechargeable Lithium-Ion Standard: 0ºC to 45ºC
	Rechargeable Lithium-Ion Plus: 0ºC to 45ºC
	Disposable Lithium-Manganese: 0 to 60ºC
Full Charge Time	**Rechargeable Lithium-Polymer:** 4 hours
	Rechargeable Lithium-Ion Standard: 4 hours
	Rechargeable Lithium-Ion Plus: 5 hours
	Disposable Lithium-Manganese: N/A
Charging / Discharging Cycles	**Rechargeable Lithium-Polymer:** 500
	Rechargeable Lithium-Ion Standard: 500
	Rechargeable Lithium-Ion Plus: 500
	Disposable Lithium-Manganese: N/A

Battery Charger Specifications

In Compliance with the Standards	FCC CE(EN55024,EN6100) C-TICK; UL1310; and EN55014
Relevant Certifications	CE; RoHS; and UL
Cabinet	ABS Plastic; and PA
Dimensions	74 mm x 28 mm x 42 mm
Weight	Approximately 60 g
Operating Temperature	10ºC to 40ºC
Operating Humidity	30% to 75%
Operating Atmospheric Pressure	700 Pa to 1060 Pa (525 mmHg to 795 mmHg)
Operation Mode	Continuous
Storage Temperature	0ºC to 50 ºC
Storage Humidity	10% to 95%, without condensation
Operating Atmospheric Pressure	700 hPa to 1060 hPa (525 mmHg to 795 mmHg)
Type of Protection Against Electric Shock	Class II
Protection against Harmful Water and dust Penetration	IPX0
Means of Separation between Equipment and Electricity Grid	Network plug, AC UE and 5.5 mm x 2.1 mm
Input Voltage	100/240 V_{AC}; 50/60 Hz
Maximum Input Current	1 A
Maximum Output Current	**Rechargeable Lithium-Polymer:** 12.6 V_{DC} **Rechargeable Lithium-Ion Standard:** 16.0 V_{DC} **Rechargeable Lithium-Ion Plus:** 16.0 V_{DC}
Output Current	800 mA

Defibrillation Specifications

Input impedance	> 10 MΩ
Frequency response	0.05 Hz to 100 Hz
Filters	**Electric mains:** Notch 60 - 50 Hz **Muscular:** Notch 35 Hz
Impedance detection range	25 Ω to 300 Ω
Gains	5 - 10 - 20 mm/mV
Beat reading range	10 BPM to 300 BPM
Tolerance	± 3%
Output	Analog ECG signal 1V/mV_{PP}
Calibration signal	1 mV_{PP} ± 3%
Shock application	By means of multifunctional adhesive pads
Limits for defibrillation	**Adult:** 150 J; 200 J (optional); 360 J (optional) **Child:** 50 J; 70 J (optional); 85 J (optional)
Area of the Shock Pads	**Adult:** 88.30 cm^2 **Child:** 38.46 cm^2
Length of the Cable of the Shock Pads	2 m
Adult/Child Selection	Automatic by type of pads
Defibrillator Output Features	1.5 KV Max; 50 A Max
Maximum Time from Start of ECG Analysis to Readiness for Discharge at Maximum Energy	Less than 20 seconds
Capacitor Charging Time	**50 Joules:** 3 seconds **150 Joules:**

	4 seconds **200 Joules:** 6 seconds
Maximum Time from Start of Operation to Readiness for Discharge at Maximum Energy (360 J)	Less than 30 seconds
Time to charge of the battery (fully discharged) with mains voltage at 90% to be able to deliver 6 shocks of 200 J	20 minutes
Waveform	Biphasic truncated exponential. Waveform parameters adjusted as a function of patient impedance.
Discharge Time	< 240 ms
Non-Shockable Arrhythmias	Atrial Fibrillation (AF); Premature Atrial Contraction (PAC); Premature Ventricular Contraction (PVC); Premature Ventricular Contraction with R on T (PVC_RonT); Multifocal Premature Ventricular Contraction (mfPVC); Supraventricular Tachyarrhythmia (SVTa); 2nd Degree Atrioventricular Block (BLKII); Right Bundle Branch Blockade (RBBB); Bigemia; and Asystole
Shockable Arrhythmias	Ventricular Fibrillation (VF); Fine Ventricular Fibrillation (FVF); Coarse Ventricular Fibrillation (CVF); Ventricular Tachycardia (VT); Multifocal Ventricular Tachycardia (MVT); and Polyfocal Ventricular Tachycardia (PVT)

Oximetry Specifications

Pulse Reading Range	10 BPM to 300 BPM
Tolerance	± 2%
Resolution	1 BPM

SpO_2 Reading Range	0% to 100%
Tolerance	**70% to 100% Saturation for Finger Clip:** ± 2 digits **70% to 95% Saturation for Neonatal:** ± 3 digits **Saturatiton < 70%:** Undefined for all sensors
Scan	25 mm/s
Update Reading Time	5 seconds

ECG Specifications

Leads	DII
ECG Cables	3 Way
Input impedance	> 10 MΩ
Frequency Response	**Monitor:** 0.5 Hz to 25 Hz **Diagnosis:** 0.05 Hz to 100 Hz
Rejection	In common mode greater than 90 dB
Sensitivity	ECG amplification step, 5, 10, 15, 20, 30 and 40 mm/mV
Filters	**Electric mains:** Notch 60/50 Hz **Muscular:** Notch 35 Hz
Gains	5 - 10 - 20 mm/mV
Beat Reading Range	10 BPM to 300 BPM; Accuracy of 1 BPM with numeric presentation
Tolerance	± 3%
Output	Analog ECG signal 1V/mV_{PP}
Offset (Potential)	± 300 mV

Leak Currentt	< 10 µA
Baseline Recovery	≤ 4s after defibrillation
Systolic Indicator (QRS)	Audible beep
Calibration Signal	1 mV_{PP} ± 3%
Operation Mode	Continuous operation
Internal Pacemaker Pulse	Detects the pacemaker pulse and rejects the pulse.
Synchronism	Does not synchronize shock with QRS. According to arrhythmia algorithm, this product indicates treatment in arrhythmias where the QRS complex is not identified. Does not display synchronism detection indicators on the screen.
Maximum Delay Time between Pulse Synchronization and Energy Delivery (After Output Activation)	Does not synchronize shock with QRS. According to arrhythmia algorithm, this product indicates treatment in arrhythmias where the QRS complex is not identified. Once the output has been activated, power is readily delivered.
Situations that May Disable Synchronism	This equipment does not synchronize shock with QRS.

Feedback Device Specifications for CPR

Cabinet	ABS Plastic; and Rubber
Dimensions	105 mm x 74 mm x 10.5 mm
Cable Length	1.30 m
Duration of CPR Cycle	2 minutes
Frequency of Compressions	100 to 120 compressions/min
Depth of Compressions	**Adult:** 5 cm to 6 cm
Maximum Interruption of Compressions	10 seconds

APPENDIX C

C

APPLIED TECHNOLOGY

Heart Rhythm Detector

The Life 400 FUTURA Defibrillator - AED is prepared to recognize and indicate defibrillation to the heart rhythms of Ventricular Tachycardia (VT) and Ventricular Fibrillation (VF), AUTOMATICALLY, leaving the operator to connect the pads to the patient's chest and follow their voice and text commands.

Recording Methods

Arrhythmias capable of defibrillation (VT and VF) are pre-programmed in the equipment, eliminating the need for operator configuration, resulting in a significant gain in treatment time.

Rhythm Selection Criteria

The selected rhythms are those notoriously known as the classic indication for defibrillation, namely: ventricular fibrillation and ventricular tachycardia.

Annotation Methods

The Life 400 FUTURA Defibrillator – AED is equipped with a liquid crystal display, or a color display (optional), where emergency care procedures and ECG tracings are plotted, allowing the graphic recording of heart rhythms.

Detector Performance Assessment Method

Rhythm	Classification
Ventricular Tachycardia	$\frac{A}{A+B}$
Ventricular fibrillation	

True Positive (A): Correct classification of rhythm susceptible of being defibrillated

False Negative (B): Organized or perfused rhythm or asystole that has been incorrectly classified as a rhythm susceptible of being defibrillated

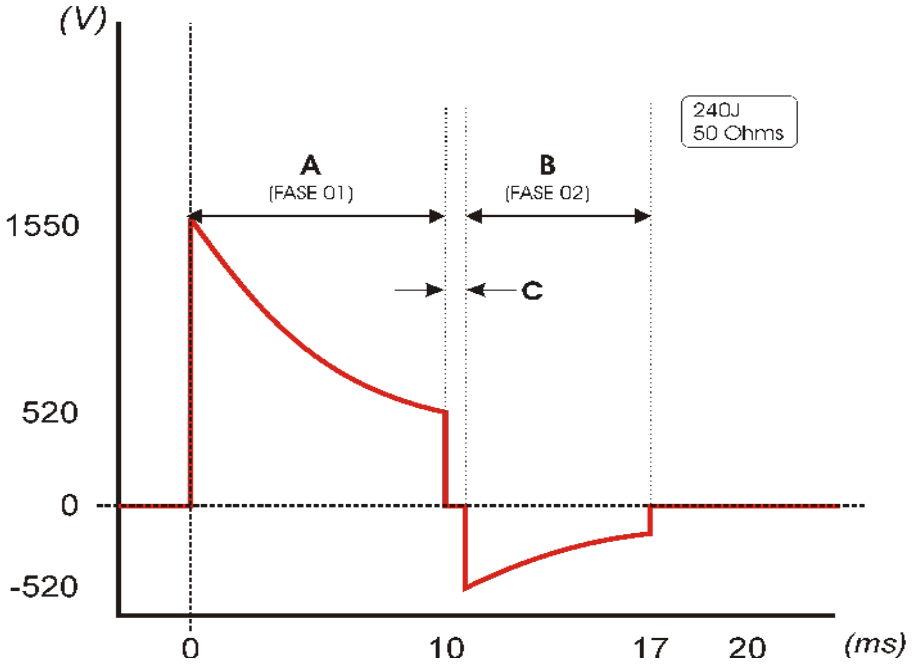
Shock Application as a Function of Impedance

< 25 Ω (and Short Circuit) Prevents application of shock

25 Ω to 300 Ω Allows application of shock

> 300 Ω (and Open Pads) Prevents application of shock

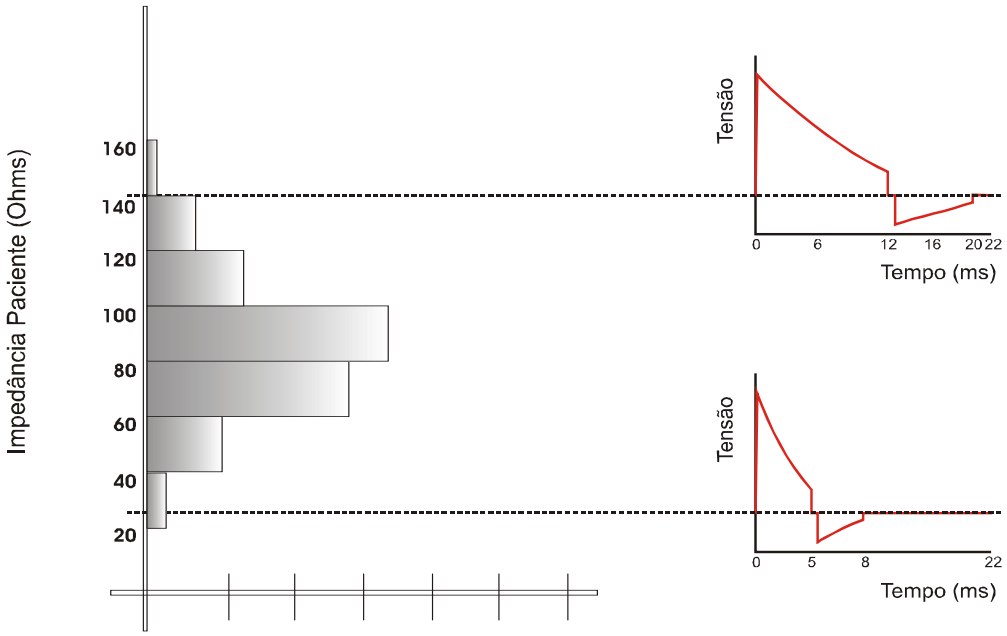
Truncated Exponential Biphasic Waveform



Variations According to the Patient's Thoracic Impedance

Impedance (Ω)	Phase A (ms)	Phase B (ms)
25	5	3.3
30	6	4
40	8	5.3
50	10	6.7
> 60	12	8

*OBSERVATION: Phase **B** corresponds to 2/3 of phase **A***
Maximum width (A+B+C): 20 ms
Dead-time (C): 0.5 ms



Selected Energy (J)	Impedance (Ω)						
	25	50	75	100	125	150	175
50	47.1	47.7	47.9	44.7	48.7	45.4	47.1
150	145.8	148.9	147.1	147.5	142.5	138.1	131.8
200	182.6	187.5	191.1	180.5	197.5	183.8	199.7
	Energy Delivered (J)						

D

APPENDIX D

ELECTROMAGNETIC EMISSIONS
CLASSIFICIATION AND COMPLIANCE WITH REGULATORY REQUIREMENTS

OBSERVATION: *The Life 400 Futura Defibrillator is designed to operate in any environment shown below. The owner or operator of this Equipment must use it in one of these environments.*		
TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The LIFE 400 FUTURA DEFIBRILLATOR – AED uses RF energy exclusively for its internal functions. Thus, its RF emission is very low and is not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class B	The Life 400 FUTURA Defibrillator – AED is suitable for use in all residential establishments and those directly connected to the public low-voltage electricity distribution network that supplies buildings for domestic use.
Harmonics Emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / scintillation emission IEC 61000-3-3	Not Applicable	

Interference Resistance Test			
TEST	**APPLIED LEVEL**	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**

Electrical discharge (lightning) **Static (ESD) according to IEC 61000-4-2**	± 2kV, ± 4 kV and ± 6kV by contact ± 2kV, ± 4 kV and ± 8kV by air	Conform	Floors must be made of wood or cement, and must have ceramic tiles. If the floor is made of synthetic material, relative humidity must be at least 30%
Fast transient electrical disturbances / discharges according to IEC 61000-4-4	±2 kV on power supply lines ±1 kV on input/output lines	Conform	Power supply quality should match the voltage supplied in a typical commercial or hospital environment.
Overvoltages according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Conform	
Voltage drops, **Brief interruptions and Voltage fluctuations Provided in accordance with IEC 61000-4-11**	< 5% Ut (>95% voltage drop in Ut) for 0.5 cycle. 40% Ut (60% voltage drop in Ut) for 5 cycles. 70% Ut (30% voltage drop in Ut) for 25 cycles. < 5% Ut (> 95% voltage drop in Ut) for 5 seconds.	Conform	The quality of the supplied voltage must correspond to the voltage Supplied in a typical commercial or hospital environment. If the user of the LIFE 400 FUTURA DEFIBRILLATOR - AED requires continuous operation even when there are interruptions in the energy supply, the LIFE 400 FUTURA DEFIBRILLATOR – AED must be powered without interruptions or with a battery.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	Conform	Magnetic fields at the power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

RF Conducted **IEC 61000-4-6**	3 V_{RMS} in entire range/ 6 V_{RMS} At the freq. ISM. 150 kHz up to 80 MHz	[V1] V Conform	Portable and mobile RF communication equipment should not be used near any part of the LIFE 400 FUTURA DEFIBRILLATOR - AED, including cables, with a separation distance less than the recommended one, this safe distance will be calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: d = [3.5 / V1] √P d = [3.5 / E1] √P 80 MHz to 800Mhz d = [7/E1] √P 800 MHz up to 2.5 Ghz where P is the rated maximum output power of the transmitter in Watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m) It is recommended that the field strength established by the RF transmitter, as determined through an electromagnetic on-site inspection a, be less than the compliance level in each frequency range. Interference may occur around equipment marked with the following symbol: 
RF Radiated **IEC 61000-4-3**	10 V/m 80 MHz up to 2.7 GHz	[E1] V/m Conform	

Note 1 Test levels defined according to ABNT NBR IEC 60601 guidelines.
Note 2 Ut is the AC supply voltage before the test level is applied
Note 3 At 80 MHz and 800 MHz, the higher frequency range applies.
Note 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] *Field intensities established by fixed transmitters, such as base stations, wireless (cellular) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with precision. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the field strength measurement at the location where the LIFE 400 FUTURA DEFIBRILLATOR - AED is used exceeds the compliance level used above, the LIFE 400 FUTURA DEFIBRILLATOR - AED should be observed to verify if the operation is normal. If abnormal performance is observed, additional procedures may be necessary, such as reorienting or relocating the LIFE 400 FUTURA DEFIBRILLATOR - AED.*
[b] *Over the frequency range 150 kHz to 80 MHz, the field intensity should be less than [V1] V/m.*

The Life 400 Futura Defibrillator does not have intentional electromagnetic interference.

TECHNICAL ASSISTANCE

CMOS DRAKE DO NORDESTE S.A

Mr./Mrs. Proprietor,

Cmos Drake do Nordeste has a large list of representatives and technical assistance throughout the Brazilian territory.
So that we can provide you with a personalized service, we ask that you send us the registration form on the next page, for updates on our database and better guidance of authorized technical assistance services for each region of Brazil, training and others.
Within Brazil, for additional information about the product or for any need to use the network of authorized workshops, complaints, doubts, suggestions, and technical assistance, contact our Customer Service below:

Site	www.cmosdrake.com.br
Telephone	(0XX31) 3547-3969
E-mail	sac@cmosdrake.com.br
Address	Av. Regent 600, Sala 205
District	Alphaville, Lagoa dos Ingleses
City / State	Nova Lima, MG
Zip Code	34.018-000
Office Hours	Monday to Friday, 08:00 AM - 06:00 PM

In special cases that are necessary, CMOS DRAKE makes available, by agreement, all technical material such as circuit diagrams, list of materials, technical information, component lists, instructions for calibration and gauging or whatever is necessary to that user-qualified technical personnel can carry out repairs on the parts designated repairable by the manufacturer. Authorization for maintenance must be formally expressed by CMOS DRAKE.

REGISTRATION FORM

CMOS DRAKE DO NORDESTE LTDA

Mr./Mrs. Proprietor,

Please fill in the fields below with your updated data and send it to us by fax so that we can register you in our system. This is necessary in order to provide the best service to our customers, keeping all contacts up to date for inquiries and technical assistance.

EQUIPMENT	SERIAL NUMBER
LIFE 400 FUTURA DEFIBRILLATOR	

CUSTOMER NAME	
ADDRESS	
CITY	**STATE**
TELEPHONE	**FAX**

MAINTENANCE CHECKLIST

CMOS DRAKE DO NORDESTE LTDA

Equipment	
Serial Number	
Location	

Start Date	/ /
End Date	/ /

This checklist allows 7 days of test. Insert a V in the field Day for each concluded instruction

Instruction	Recommended Corrective Action	Day						
		1	2	3	4	5	6	7
Check if the Equipment **cabinet** has **foreign substances**	**Clean** the Equipment							
Check the Equipment **cabinet** for **damage or cracks**	**Contact** the Qualified Technical Assistance							
Connect the Equipment to the electric mains. Check if the **charger's LED does not light up**	**Check the** chargers **connections** with the Equipment and the electric mains. If the problem persists, **contact** the Authorized Technical Assistance.							
Check if the **disposable shock pads** are **out of the expiry date**	**Replace** the shock pads							
Check if there are **spare electrodes available**	**Replace** the electrodes							
Check if the **cables and pins** of the Accessories have **damages or cracks**	**Replace** the damaged parts							
Disconnect the Equipment from the electric mains and turn it on. Check if the **battery charge level is low**	**Recharge or replace** the battery. If the battery cannot maintain the charge, **contact** the Qualified Technical Assistance.							

RECOMMENDATION

It is recommended that this device be inspected and tested daily according to checklist.

WARNING

Possibility of damage to the Equipment:
Do not clean any part of this Equipment or its Accessories with bleach, bleach dilution or phenol-based chemical compounds.
Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this Equipment or any of its Accessories.

CERTIFICATE OF
CMOS DRAKE DO NORDESTE S.A

CMOS DRAKE DO NORDESTE S.A guarantees Legal Warranty against any manufacturing defect for a period of 12 (twelve) months from the date of issuance of the sales invoice referring to the equipment purchased by the consumer with mandatory identification of the model, serial number and equipment characteristics. CMOS DRAKE do NORDESTE S.A does not grant any form or type of warranty for equipment unaccompanied by the sales invoice to the consumer.

Scope of Warranty

- Any defect diagnosed during the installation and (or) use of the product, the consumer must immediately contact CMOS DRAKE DO NORDESTE S.A. The same will activate the Authorized representatives to provide the necessary services.
- The Manufacturer will be responsible for replacing parts and components that present anomalies found to be manufacturing defects, in addition to the labor involved in this process.
- Oximetry sensors and patient cables are warranted for ninety (90) days, except for misuse, physical damage and/or breakage.
- Consumable materials subject to natural wear and tear, such as batteries, disposable electrodes, among others, are excluded from this warranty.
- This guarantee does not include any compensation for loss of profit, personal accidents and third parties and other goods.
- This warranty term is valid only for products sold and installed in Brazilian territory.

Warranty Cancellation Conditions

- If the recommendations contained in this manual regarding installation, operation, care, recommendations and warnings are not followed.
- If there is a breakage and/or violation of the security seal.
- If there is removal or alteration of the serial number of the equipment purchased by the consumer.
- If the Equipment is used with cables, sensors, accessories or consumables that are not original CMOS DRAKE or outside the normal conditions of use, such as expiration date or period or use.
- If the Equipment is tampered with, calibrated, adjusted, repaired or tampered with by professionals not Authorized by the Manufacturer.
- If the Equipment is used in a manner different from that described in the USER'S MANUAL.
- If the Equipment is damaged by accidents such as falling, knocking, misuse, neglect or natural phenomena.

Disclaimer

The Manufacturer is not responsible for expenses with installations, products or accessories damaged due to transport accidents, handling, scratches, dents, non-functioning or failures resulting from problems in the electricity supply. In locations where there is no authorized technical assistance from CMOS DRAKE, the costs of transporting the device to the factory or the authorized technician to the place where the equipment is located will be borne by the Consumer requesting the service according to a previously approved budget. The Manufacturer is not responsible for improper use and/or use by unqualified persons.

Serial Number:

CMOS DRAKE DO NORDESTE S.A
AV. REGENT 600, SALA 205; TÉRREO E 1º ANDAR
B. ALPHAVILLE, LAGOA DOS INGLESES
NOVA LIMA – MG – CEP: 34,018-000 – (0XX31) 3547-3969
TECHNICAL HEAD: BÁRBARA HELEN SOUZA MAIA
CREA/MG: 224055-D
LEGAL REPRESENTATIVE: MARCO AURÉLIO MARQUES FÉLIX

This manual was prepared by the Engineering and Quality departments of CMOS DRAKE, and approved by the Inmetro Certification Body.

CMOS DRAKE reserves the right to make any changes it deems necessary to the manual or product without any prior notice to the consumer. Any and all alterations/modifications are communicated to Inmetro and Anvisa.

MADE IN BRAZIL
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