User Manual

apolus

Biphasic Defibrillator

INSTRAMED

Manufacturer

Instramed Indústria Médico Hospitalar Ltda.

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ATTENTION: Instramed assumes no responsibility for any damage caused to individuals or property brought by failure to use this product in accordance with the information, recommendations and warnings presented in the user manual, alterations made in the device, attempts of repair not provided by authorized technical assistance centers, operation by unqualified personnel, use of defective device or use of accessories and parts not supplied by the manufacturer.

For information about warranty or technical assistance, please contact Instramed's technical support.

Apolus User Manual R2.0 2022-06-06

Battery use

ATTENTION: observe the instructions of the maintenance of the battery charge.

First use

The batteries are rechargeable Nickel-Metal Hydride (Ni-MH). Before using it for the first time, the device must receive a full battery charge. In order to do this, the equipment needs to be connected to the electric current for at least eight hours.

Occasional use

Even when disconnected (stand-by), the Apolus executes internal routines checking the status of the equipment. In spite of this procedure entailing a low power consumption, the battery charge may be consumed, except when the rear power switch is turned off.

Therefore, whenever the device has not been connected to an electric current for more than 20 days, and with the power switch at the position on, it is advisable to execute a full battery charge. If this procedure is not performed, there is a risk of draining the battery and consequently being unable to use the Apolus in its portable configuration (not connected to the electric current).

Replacement

Every battery has a determined lifetime, which is the possible quantity of full charge and discharge cycles, without loss of performance. When the equipment presents a decrease in battery performance, with low autonomy, request a new unit from Instramed's technical assistance.

The lifetime of the battery is of at least 500 cycles (full charges and discharges).

Package contents

Included items

When opening the package, please check whether all items below are present:

- Apolus Biphasic Defibrillator
- Instructions manual
- 3-pin professional power cable
- External defibrillation pads set – adult and child

Replacement parts

You can call Instramed for replacements of consumable items, parts and accessories.

Consult Instramed for prices.

Shipping may apply.

To request pieces and services please contact the representative of your region (the list may be found on www.instramed.com.br) or directly Instramed by the telephone +55 51 3073-8200.

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Introduction

1

Purpose and application

The Apolus uses electrical defibrillation and cardioversion therapy to reverse ventricular fibrillation arrhythmia or ventricular tachycardia without a pulse in adult and pediatric patients, as well as cardioversion of arrhythmias when necessary.

Characteristics

The Apolus is a lightweight and compact biphasic defibrillator with a modern design. It has an internal battery, therefore it is practical and suitable for emergency situations and transport within hospitals or in ambulances.

WARNING: The Apolus must be used by qualified personnel on patients who need defibrillation therapy or as a complement in assessing the patient's physiological conditions. The use must happen in conjunction with the patient's clinical signs and symptoms.

About the Manual

This manual explains the functioning of the Apolus defibrillators series, alerting the user to safety risks. This manual is part of the Apolus and must be kept for further reference.

The information contained in this manual belongs to Instramed and cannot be copied fully, or in part, without expressed written consent.

Instramed has the right to make any changes to improve this manual as well as the product without prior notice.

Safety Information

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Attention

The following factors can cause bad contact, causing burns on the patient.

- **Misplaced pads;**
- **Excessive hair or wet skin in the area of the electrodes application;**
- **Pieces of clothing between skin and pads.**

Warnings

CAUTION: To perform a direct defibrillation (not synchronized), the synchronized defibrillation indicator LED must be off. Otherwise the defibrillator will not apply the energy discharge on the patient due to absence of ECG signal or electrical connection between the defibrillator and a cardiac monitor for acquisition of the ECG signal.

For synchronized (cardioversion) discharge, the device must detect the ECG signal with QRS.

IMPORTANT: This device must only be operated by qualified technical personnel. Before using it, read the user manual attentively.

ATTENTION: risk of explosion if the equipment is operated in the presence of flammable liquids or gases

ELECTRICAL SHOCK HAZARD: never open the device. Each and every repair must be performed by Instramed's authorized technical centers.

ATTENTION: THE PATIENT MUST BE PLACED ON NON CONDUCTIVE SURFACES. DO NOT USE WET OR METALLIC SURFACES AND, IF NECESSARY, DRY THE PATIENT'S CHEST BEFORE SHOCK DELIVERY.

ATTENTION: DURING THE DEFIBRILLATION, DO NOT TOUCH THE PATIENT, THE EQUIPMENT, THE ACCESSORIES NOR ANY METALLIC OR CONDUCTIVE SURFACE IN CONTACT WITH THE PATIENT.

Do not use Apolus in the presence of MRI equipment.

This equipment was projected to offer resistance to electromagnetic interferences. However, the functioning of this device can be affected in the presence of strong sources of electromagnetic-interference or radio-frequency, such as mobile phones, communicator radios, etc.

ATTENTION: always check the general state of the equipment and its accessories before using it.

Before installing the equipment verify if there are any abnormalities or damage caused by mishandling during transportation.

WARNING: The use of the Apolus is restricted to one patient at a time.

WARNING: the conductive parts of the electrodes and connectors associated with the applied parts, including the neutral electrode, must not come into contact with other conductive parts, including the ground wire.

WARNING: avoid connecting the patient to several equipments at the same time, because the limits of current leakage may be exceeded.

WARNING: In general, the parts of the EQUIPMENT and ACCESSORIES of the Apolus defibrillator intended to come into contact with biological tissues, cells or fluids are tested and analyzed according to the directives and principles of ISO 10993-1, which deals exclusively with the biocompatibility test of the applied parts.

WARNING: When removing the equipment from its package, carefully verify if there is any abnormality or visible damage in the device or its accessories, caused by impact or mishandling during transportation. In case of irregularities, please contact Instramed.

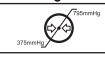
WARNING: disposable accessories and any other components must be disposed according to the hospital waste disposal norms.

Adverse effects

Superficial burns may occur on the patient's skin in the area in contact with the electrodes. To minimize the effect of the disposable paddles, apply them directly after removal from the protection envelope and attach them firmly to the patient's skin.

The skin must be dry, or electric current leakage may occur, increasing the burn's area and reducing the efficiency of the treatment.

Classification and symbols

Symbol	Standard	Description
	IEC TR 60878	Defibrillation proof insulated CF type equipment
	IEC 60601-1	Follow the instructions for use
	IEC 60601-1	General warning symbol
	IEC 60601-1	Warning: dangerous voltage
	IEC TR 60878	Terminal for equalization of potential
	IEC TR 60878	Terminal for general ground
Off	-	Disconnects the equipment
	IEC TR 60878	Alternate current
	IEC TR 60878	Direct current
	IEC TR 60878	Non-ionizing radiation
	IEC TR 60878	Input connection
	ISO 780	Maintain this side upwards
	ISO 780	Fragile equipment
	ISO 780	Maximum stacking of 4 units
	ISO 780	Maintain protected from the rain
	ISO 7000 ISO 780	Minimum and maximum temperature
	ISO 7000	Minimum and maximum atmospheric pres-sure
	ISO 7000	Minimum and maximum relative humidity
	IEC TR 60878	Recyclable paper
	Directive 2002/96/CE	Remains of electrical and electronic equipment - separate disposal from other objects
	EN 980	Manufacturer
	EN 980	Manufacturing date
SN	EN 980	Serial number

Standards

Apolus was designed following performance and safety standards. Among them are:

NBR IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

NBR IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirement for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and test.

NBR IEC 60601-1-6 - Medical Electrical Equipment - Part 1-6: General requirements for basic safety - Collateral Standard: Usability.

NBR IEC 60601-2-4 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators.

Device care

Do not place the equipment where it may fall on the patient. Do not lift the equipment by its cables or connections.

Place cables connected to the patient in order to restrict the possibility of strangulation.

Keep the defibrillator in a dry environment, avoiding places that allow liquids to spill over the monitor. Do not use the defibrillator if it is wet or excessively humid.

Always keep the equipment and its accessories clean and well maintained.

If you suspect a fall or external damage, do not use the equipment.

Connection to other equipment

When connecting the Apolus to any device, ensure that the equipment is operating correctly before clinical use. The equipment or accessories connected to the device must be certified according to the IEC 950 standard for data processing equipment or according to the IEC 60601-1-1 for medical equipment.

Grounding

GROUNDING IS ESSENTIAL TO PROTECT THE OPERATOR AND PATIENT AGAINST ELECTRICAL DISCHARGE ACCIDENTS. IN THE ABSENCE OF ADEQUATE GROUNDING, DANGEROUS CURRENTS MAY CIRCULATE FROM THE EQUIPMENT BOX IF THERE IS AN INTERNAL ELECTRICAL DEFECT. GROUNDING MUST BE PERFORMED ACCORDING TO ABNT NORMS FOR ELECTRICAL INSTALLATIONS (NBR 13534/1995).

The potential equalization is performed by the Mains Supply cable connector with 3 pins (accompanying the product) and / or with the earthing cable (optional).

Electromagnetic compatibility

The installation of the Apolus requires special precautions concerning Electromagnetic Compatibility in compliance with the information contained in this manual (see the chapter Care and Maintenance).

Disposing of the device

According to the Brazilian environmental legislation, equipments and parts that are no longer in conditions of use should be referred to the manufacturer for the final destination, thus preserving the natural resources and contributing to the conservation of the environment.

For disposal of products from Instramed, contact us by the telephone numbers available on the website www.instramed.com.br or by the e-mail qualidade@instramed.com.br.

To avoid contamination of the environment, humans, or other equipment, make sure to properly sterilize and decontaminate the equipment before disposing of it.

For countries that follow European Guidelines, refer to 2002/96/CE. For other, countries, refer to local regulations for the proper disposal of trash in your area.

The equipment

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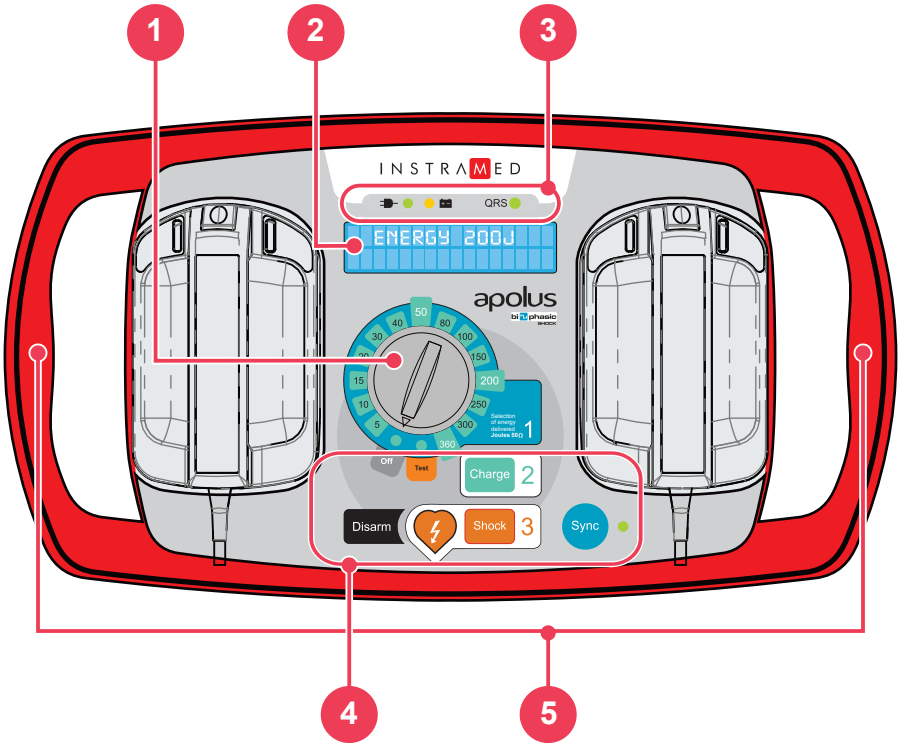
Front panel



1 - Selector switch: turns the equipment on and off; selects the energy

2 - LCD display

3 - Power, battery charge and QRS indications

4 - Operation buttons

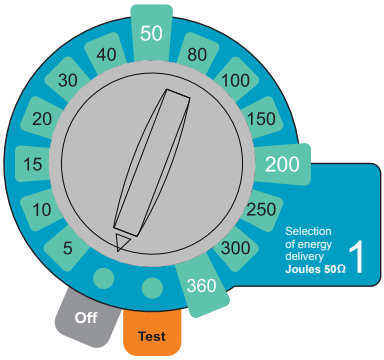
5 - Transport handle

1 - Selector switch

Scale from 5 to 360 Joules: allows the user to turn the equipment on and select the desired energy.

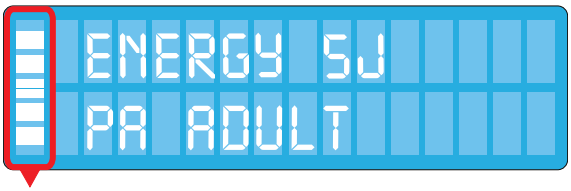
Position "Off": turns off the equipment.

Position "Test": functional test.



2 - LCD Display

The LCD screen of the Apolus shows numeric information related to the defibrillation process, as well as the battery level indicator (5 levels). For further information, see chapter "Defibrillation operation".



Battery charge level:

- 5 lines – 100% of charge
- 4 lines – 80% of charge
- 3 lines – 60% of charge
- 2 lines – 40% of charge
- 1 line – 20% of charge

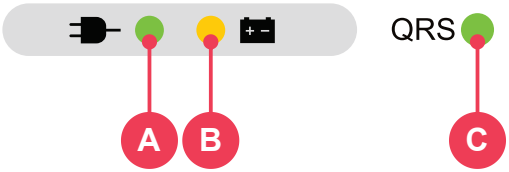
Battery status with the AC power source cable disconnected.

3 - Power, battery charge and QRS indications

A - Power connected: when the LED is on, it indicates that the equipment is connected to a power source or an external battery.

B - Battery charging: when the LED is on, it indicates that the battery is charging.

C – Systole visual indication: this LED lights up during each heartbeat, indicating the recognition of the R wave peak.



Obs.: The LEDs light up even with the equipment turned of.

4 - Operation buttons

Together with the energy selector, use the operation buttons to complete the defibrillation process. For more information, see chapter “Defibrillation operation”.

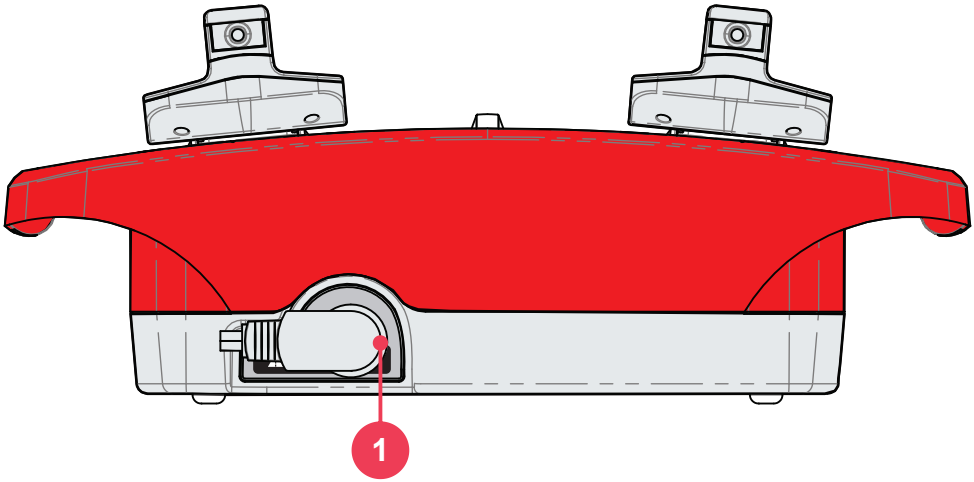
Sync: used to enable the synchronized discharge. When the LED is on, it indicates that the function is active. At the same time, the QRS LED blinks according to the heartbeat.

Charge: its activation triggers the accumulation of the internal energy that will be used in the shock treatment.

Shock: its activation releases, through the pads, the stored energy, resulting in an electric pulse applied to the patient’s heart.

Disarm: disarms the stored internal energy after activation of the “charge” button.

Side view

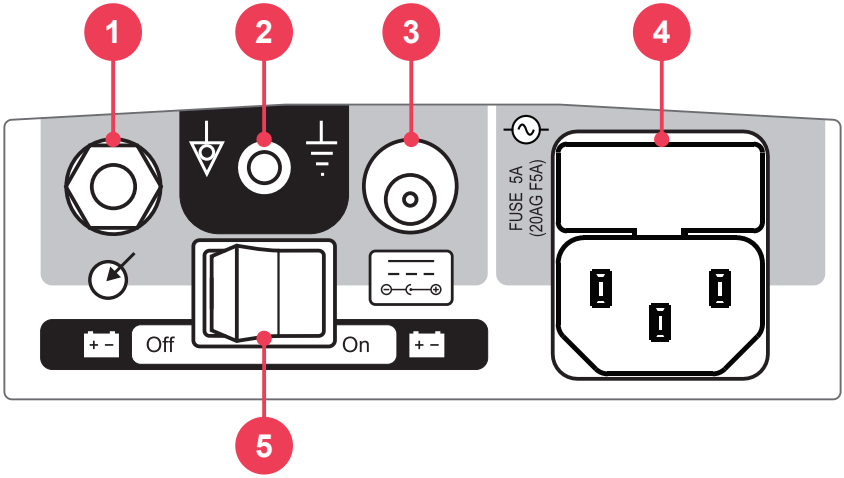


1 - Connector for defibrillation electrodes (pads)

Adult/child external: included with the equipment, may be used on adults and/or children.

Internal: Used in surgeries.

Rear pannel



1. **ECG signal socket:** ECG input connector (1V/mV) for synchronized defibrillation.

2. **Grounding and potential equalizer:** potential equalization and general grounding connector.

3. **External DC socket:** for battery connection or external DC source in a range of 11 to 16 VDC.

4. **3-pin power connector:** input of 100 to 265 VAC, with central pin for grounding. 5A fuse (20mm 20AG F5A GLASS FUSE).

5. **Battery on/off switch:** internal battery on/off switch. Used to turn off the battery when the equipment is not used for a long period.

Defibrillation operation

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Physics principle used

The cardiac defibrillator is an instrument that delivers energy previously stored in a capacitor to a patient, whether in the form of external defibrillation (when the capacitor discharge is delivered through the patient's chest) or internal defibrillation (applying the capacitor discharge directly to the heart, with with an open chest and during a surgical procedure).

The Apolus uses biphasic shock technology, which is characterized by a current liberated in one direction and, after a brief period of time, reverted in the opposite direction.

During the defibrillation the entire myocardium is briefly depolarized by a strong positive and negative impulse of adjustable intensity (Truncated Exponential Biphasic Shock). This impulse is used to eliminate ventricular fibrillation and pulseless ventricular tachycardia. It can also be used to perform cardioversion (synchronism) of arrhythmias such as atrial fibrillation and others that may be electrically cardioverted.

Direct defibrillation

The application of shocks without a monitor or without ECG rhythm diagnosis is called direct defibrillation, it can be applied at any time with no need of sychronism with the ECG signal. It is used to eliminate ventricular fibrillation.

Synchronized defibrillation

Among the functions of the defibrillator one of the most important is the stimulation commanded by the R wave of the ECG, known as synchronized defibrillation.

Synchronized defibrillation or cardioversion is done by synchronizing the discharge with the patient's ECG pulse. The capacitor discharge occurs from 20 ms to 60 ms after the R wave peak, to ensure that the current pulse does not occur during a vulnerable phase of the cardiac cycle.

A normal sinus rhythm has two vulnerable phases, and if the heart is electrically stimulated during one of these phases, the corresponding cardiac sector will, with very high probability, enter into fibrillation. In the case of an arrhythmia due to atrial fibrillation, electrical stimulation controlled by the cardiac phase avoids the vulnerable phase of the ventricle that would cause ventricular fibrillation.

Warnings

The Apolus has a patient impedance meter, it delivers shocks in impedances of 25 to 300 ohms.

If a cable or conductor is suspected of being ruptured, avoid using the equipment due to possible risk to the operator.

Ensure that the defibrillation electrodes of the Apolus are at an appropriate distance from other electrodes so that the power applied does not flow through these electrodes.

Disconnect all equipment devoid of protection against the discharge of defibrillators.

Ensure that the patient does not come into contact with any metallic parts.

Use criteria

The Apolus, in defibrillation mode, must only be used if the following circumstances, as a whole, are presented:

1 - Unconscious victim

2 - No breathing

3 - No pulse

Other important considerations regarding the use of the Apolus:

1 - Not recommended for children under one year old

2 - Pacemakers may affect the device's efficiency

3 - Medicines in adhesive form must be removed before starting defibrillation

4 - Hypothermic patients may not respond well to defibrillation

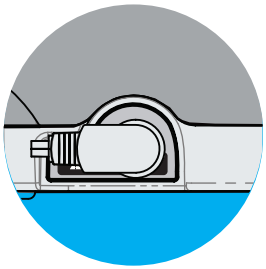
5 - Once the removal of the patient is started, the defibrillation must be interrupted

Qualified users

Shall be considered qualified users those who have had training in a recognized institution in the use of automated defibrillators and CPR techniques - Cardiopulmonary Resuscitation

External pads use

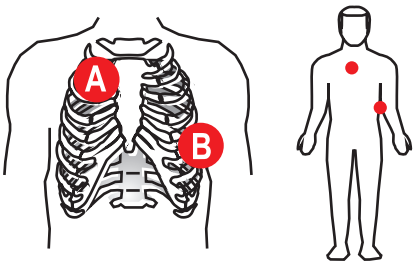
1 - Check if the pads are connected to the Apolus. If they are not, connect the defibrillation cable to the pads socket located on the equipment's side (as show in the image below). Turn the screw all the way.



2 - Take both pads from their base pulling them up and out.

3 - Apply the conductive material to the pads' electrodes.

4 - Place pads as shown in the image below:



A - Sternum.
B - Apex.

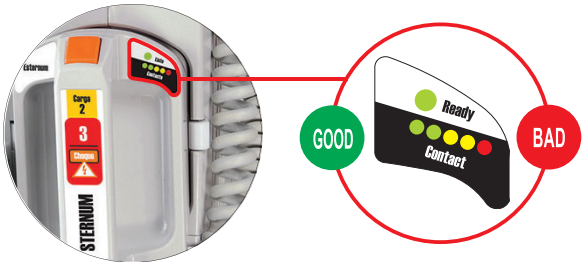
The electrodes must be placed in a position which will maximize the current that passes through the myocardium. The standard position is

A. Electrode identified as "STERNUM" on the right second intercostal space, midclavicular line.

B. Electrode identified as "APEX" positioned on the left sixth intercostal space, midaxillary line.

ENSURE that the electrodes are away from each other. DO NOT apply paste or gel to the thorax between the pads or the current may follow a superficial route along the thorax wall and not reach the heart.

5 - Check contact with the patient.



The STERNUM pad has a patient contact indicator.

The indicator goes from BAD contact (red flashing LED) to GOOD contact (at least one green LED on).

Make sure to adjust the pressure and the placement of the pads to optimize Contact with the patient, so that AT LEAST ONE GREEN LED remains on.

Considerations for shock delivery

Combining the pressure of the pads with the conductive material applied to the electrodes, different patient impedances are obtained.

The table below indicates the conditions in which the Apolus offers or inhibits the delivery of energy.

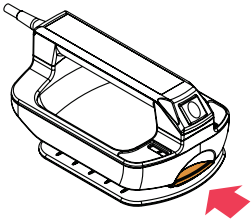
Patient's impedance	Shock	Message on screen after "Charge" key pressed	Values indicated on bargraph
Short circuit	Shock inhibited	Bad contact	All LEDs blinking
<25 ohm	Shock inhibited	Bad contact	All LEDs blinking
>25 ohm and <300 ohm	Shock delivered. Wave-form is adjusted according to the patient's impedance	No message	LEDs lit up indicating contact level
>300 ohm	Shock inhibited	Bad contact	Only the red LED is blinking
Short - open	Shock inhibited	Bad contact	Only the red LED is blinking

All LEDs blinking indicate short circuit in the pads. Shock delivery will not be allowed.

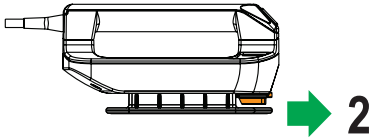
The red LED blinking indicates bad contact with the patient. Shock delivery will not be allowed.

Child pads use

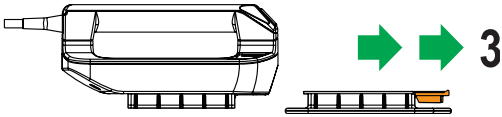
1 - Fasten the lock in the front of the adult external pads.



2 - Pull the pads base forward to remove them.



3 - This exposes the smaller electrode for children



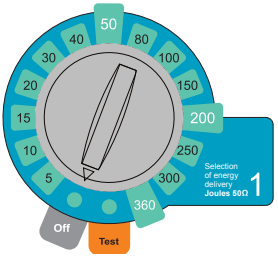
Adult *Child*

The Apolus will automatically identify that it is operating in pediatric mode. Energy is limited to 50 Joules in the pediatric mode.

Defibrillation

Follow the steps 1-2-3

Step 1 - Select energy



Rotate the selection switch until you reach the energy desired. Energy options go from 5 to 360 Joules. In most cases, 200 Joules is recommended for adult use

The Apolus automatically identifies that it is operating with internal pads. Energy in internal pads mode is limited to 50 Joules.

Step 2 – Charge

Press the “Charge” button (green) in the front panel or use the charge button in the external pads (orange). While the Apolus is charging, a sound will be emitted and the measurement of the charged energy will appear on the display

The energy selected can be increased or decreased at any time just by rotating the selector switch to the new charge.

To cancel the shock press “Disarm”.

When the charge is complete, the device sends a sound signal and displays “Charge Ready” on the screen.

Step 3 – Shock

After the “Charge Ready” warning, press the “Shock” 3 button (orange) in the frontpanel or use **the two buttons** (orange) in the external pads.

Only with the adult/child external pads it is possible to defibrillate using the pad buttons.

CAUTION: make sure nobody is touching the patient! Clearly warn everyone to stand clear of the patient!

The number of shocks and length of operation are indicated on the Apolus display.

Synchronism - Synchronized discharge - Cardioversion

Remember: the function “Synchronized Shock” is disabled after the shock is delivered.

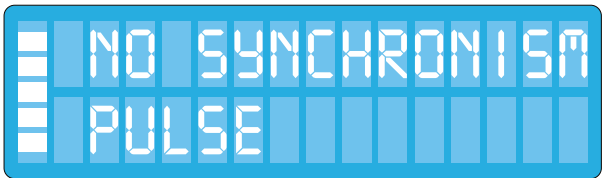
For synchronized defibrillation, a cardiac monitor with ECG output of 1 V/mV is required.

1 - Using a sync cable, connect the ECG input (), located on the rear panel of the Apolus, to the 1 V / mV ECG output of your cardiac monitor.

2 - Press the “Sync” button on the panel for two seconds. The green indication next to the button will light up.

3 - Check if the QRS signal on your monitor triggers the Apolus synchronism circuit by checking for a visual (QRS LED) and audible QRS indication on the defibrillato

In case the Apolus is unable to identify the synchronism pulse, the following message will appear on the display of the device:



Check the connections and cable condition. If this does not resolve, it may be necessary to adjust the gain of the ECG input amplifier on the cardiac monitor. Consult the user manual or the monitor manufacturer.

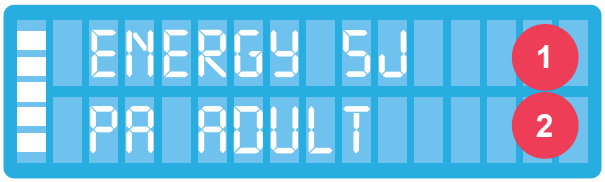
IMPORTANT: Keep key 3 (shock) or the two shock buttons on the pads pressed until the next “R” wave is identified. The Apolus will deliver the shock when the next “R” wave is identified.

IMPORTANT: If Apolus does not identify a valid QRS it will not trigger the shock!

Disarm key

Disarm the stored charge. Charge may be disarmed at any time, whether the charge is ready or not

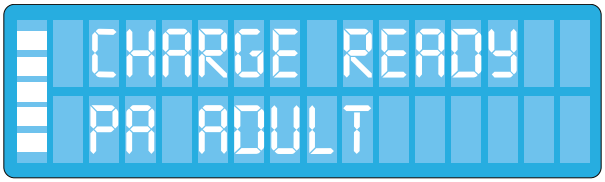
Pantalla de desfibrilación



1. Energy selected: from 5 to 360J.
2. Type of defibrillation electrode: adult pad, internal pad, adhesive pad or disconnected pad.

ENERGY CHARGED

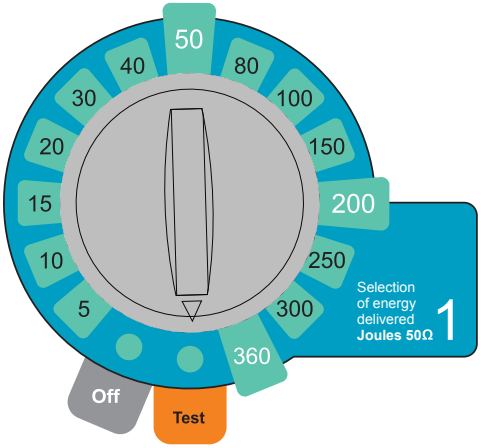
After selection and charging of the energy desired, the following message appears on the display.



Functional test

5

ATTENTION: The functional test must be performed daily, which ensures that the equipment is working perfectly and in a state of readiness.



Step 1

Put the selector switch in the functional test position.

Step 2

In case the pads are not connected, the display will show the message: CONNECT THE PADS ON THE EQUIPMENT. Follow the instruction

Step 3

In case the pads are not positioned in the support, the display will show the message: CONNECT THE PADS ON THE SUPPORT. Follow the instruction.

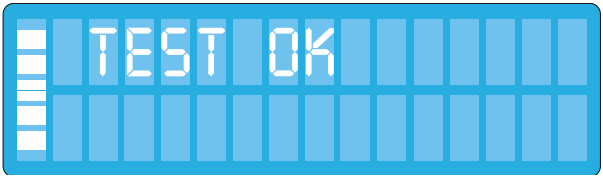
Step 4

The display will show the message: PRESS CHARGE. Press the “charge” key and wait until the equipment sends the charge ready signal.

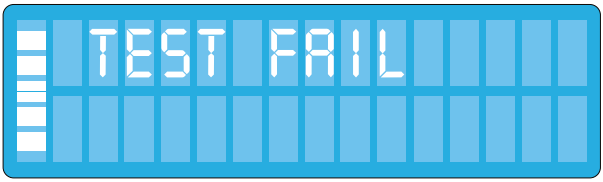
Step 5

The display will show the message: PRESS SHOCK. Press the “shock” button.

Indication of the functional tests results



Equipment passed functional test



Equipment failed functional test

ATTENTION: If Apolus fails the functional test, contact technical support immediately.

NOTE: the Apolus indicates failure in the functional test when the energy delivered presents an error higher than the allowed by standards

Care and maintenance

6

Preventive maintenance

Instramed recommends that the Apolus be examined by a qualified technician every 12 months. We recommend that you contact the manufacturer for more information about qualified and trained personnel to perform preventive maintenance.

It is recommended that periodic inspections be performed on the equipment's power supply charger, cables and connectors in order to determine possible isolation or internal conductor ruptures.

It is recommended that functional tests be performed at the beginning of every work shift.

Corrective maintenance

If the equipment needs repair, this can only be done by Instramed or its authorized representa-tive, otherwise this Warranty certificate may no longer be valid.

No internal parts are to be fixed by the user.

Cleaning and disinfection

Instramed recommends cleaning and disinfecting the equipment and its accessories every three months, or shorter periods whenever excessive dirt or contamination is noticed.

Equipment

- Remove the equipment from the electric current before cleaning it.
- Wipe the external part of the equipment with a cloth dampened with water and neutral soap or isopropyl alcohol.

Accessories

- Use a cloth dampened with isopropyl alcohol.
- Rub the surface to be cleaned for about 10 minutes.

Sterilization

Instramed recommends that the set of internal pads and their adult electrodes be sterilized using the "cold sterilization" method, making the right use of chemical ETO (ethylene oxide) ensuring quality control of sterilization process and handling by

specialized professionals. However, the connector of the internal pad set (which is connected to the equipment) should not be immersed with the entire length of this accessory.

ATTENTION: NEVER sterilize any parts of the equipment or its accessories using "dry heat sterilization", such as when using an autoclave. This will damage the mechanical structure and compromise functioning.

Battery

If Apolus is not used for a long period of time, the battery will need to be recharged. To recharge the battery, connect the monitor to an AC power source (110 or 220V outlet) or a DC power source.

There are no restrictions or limitations for using the Apolus while its battery is being recharged by an AC source or DC External source.

Returning componentes

If Apolus must be returned for repair, call Instramed for shipping instructions. Be prepared to provide the equipment's series number.

If possible, use the original equipment's packaging. If this is not possible, use an equivalent box that provides adequate protection for the monitor.

Precautions, restrictions and warnings

The Apolus is a device built according to NBR and IEC standards and therefore offers total safety for patient and operator. However, all safety precautions described below must be followed.

The equipment may have its operation affected by the presence of electromagnetic power sources, such as electrosurgical equipment and computer tomography (CT).

Electromagnetic compatibility

WARNING

Installing the Apolus requires special precautions concerning electromagnetic compatibility according to the information contained in this manual.

Mobile and portable RF communications equipment, such as mobile phones, can affect the Apolus' functioning.

Maximum length of accessories cables - in compliance with electromagnetic compatibility requirements:

Set of external defibrillation pads (code 79001) 2.5m

WARNING

Using cables, transducers and accessories different from the ones specified above, except for the ones sold by Instramed as replacement pieces, may result in emission increase or immunity decrease of the equipment.

The Apolus must not be used too close to or piled over other equipment.

The actions to be taken to prevent adverse events to the patient and operator due to electromagnetic disturbances during the equipment's useful life are:

- Ensure minimum distance from an RF (Radio Frequency) emitting source, as per the table on the Electromagnetic Immunity - General page.
- Cables and accessories must also maintain this distance.
- Do not use this product in conjunction with electric scalpels.
- Do not use this product in conjunction with magnetic resonance apparatus.

The essential performance of Apolus means defibrillation and cardioversion therapies delivered effectively. The performance of Apolus is designed and verified to achieve the absence of an unacceptable risk.

If performance is lost or degraded due to electromagnetic disturbances:

- The LCD display may experience interference.
- Menu changes or equipment lock-up.
- Interference in the external synchronization signal.

Electromagnetic emissions

Directives and manufacturer declaration - electromagnetic emissions		
The Apolus is intended for use in the specific electromagnetic environment below. The customer or user of the defibrillator is advised to ensure that it is used in such an environment.		
Tests	Compliance	Electromagnetic environment - directives
RF Emissions ABNT NBR IEC CISPR11	Group 1	The Apolus only uses RF power for its internal functions. Nevertheless, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions ABNT NBR IEC CISPR11	Class B	The Apolus is suited for use in any establishment. This includes residential establishments and those directly connected to the public network of distribution of low voltage electricity which supply domestic use buildings.
Harmonics emissions IEC 1000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
NOTE: It is essential that the actual effectiveness of the RF shielding and the actual RF filter attenuation of the shielded location be checked to ensure that they meet or exceed the specified minimum values.		

Electromagnetic immunity - General

Directives and declaration of the manufacturer - electromagnetic emissions			
The Apolus is intended to be used in the specific electromagnetic environment below. The user or customer of the defibrillator should ensure that it is used in such an environment.			
Immunity Test	**Test Level ABNT NBR IEC 60601**	**Compliance Level**	**Electromagnetic Environment Directives**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 KV contact ± 8 KV air	± 6 KV contact ± 8 KV air	Floors should be made of wood, concrete or tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	± 2 KV for power supply lines ± 1 KV for input/output lines	± 2 KV for power supply lines ± 1 KV for input/output lines	The quality of the power supply should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 KV differential mode (phase - phase) ± 2 KV common mode (phase - ground)	± 1 KV differential mode (phase - phase) ± 2 KV common mode (phase - ground)	The quality of the power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	**Drop:** 0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT for 1 cycle and 70% UT for 25/30 cycles Monophasic A 0°. **Interruptions:** 0% UT for 250/300 cycles.	**Drop:** 0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT for 1 cycle and 70% UT for 25/30 cycles Monophasic A 0°. **Interruptions:** 0% UT for 250/300 cycles.	The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the Apolus requires continued operation during power interruption, it is advisable that the Apolus is supplied by an uninterrupted power source or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at characteristic levels of a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic immunity - Equipment with life support functions

Advisable separation distances between mobile and portable RF communications equipment and the Apolus

The Apolus is intended to be used in the electromagnetic environment specified below. The customer or user of the Apolus should ensure that it is used in such an environment.

Immunity Test	Test Level ABNT NB IEC 60601	Compliance Level	Electromagnetic Environment Directives
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz up to 80 MHz Modulation: AM 80% 5 Hz (sinusoidal).	[V_1]V	Portable and mobile RF communications equipment should not be used near any part of the Apolus, including cables, with a separation distance less than the one advised, calculated using the equation applicable to the frequency of the transmitter. Advisable distance of separation: $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{12}{V_2}\right]\sqrt{P}$ $d=\left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz up to 800 MHz $d=\left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz up to 2,5 GHz Where “P” is the maximum output power of the transmitter in watts (W), according to the transmitter manufacturer, and “d” is the advisable separation distance in meters (m)b. Field strengths established by RF transmitters, as determined by an electromagnetic site surveyc, shouldbe less than the compliance level in each frequency range.d Interference can occur around equipment marked with the following symbol:
	6 Vrms ISM and Amateur radio Modulation: AM 80% 5 Hz (sinusoidal).		
Conducted RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz Modulation: AM 80% 5 Hz (sinusoidal).	[E_1]V	

NOTE 1 - At 80 MHz and 800 MHz, the highest frequency range is applied.

NOTE 2 - These directives may not be applicable in all situations. Electromagnetic transmission is affected by the absorption and reflection of structures, objects and people.

CONTINUES >

a - ISM bands (industrial, medical and scientific) between 150kHz and 80MHz are 6,765MHz to 6.795MHz; 13.553Mhz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

The amateur radio bands between 150 KHz and 80 MHz are: 1.8 to 2.0 MHz; 3.5 to 4.0 MHz; 5.3 to 5.4 MHz; 7.0 to 7.3 MHz; 10.10 to 10.15 MHz; 14.0 to 14.2 MHz; 18.07 to 18.17 MHz; 21 to 21.4 MHz; 24.89 to 24.99 MHz; 28.0 to 29.7 MHz; and 50.0 to 54.0 MHz.

b - The compliance levels in the ISM frequency bands between 150kHz and 80MHz and in the frequency range between 80MHz and 2.5GHz are intended to reduce the likelihood of mobile and portable communications equipment causing interference if inadvertently brought into the patient areas. Therefore, an additional factor of 10/3 is used in calculating the advisable separation distance for transmitters in these frequency ranges.

c - Field strengths established by fixed transmitters, such as base stations for radio, telephones (cell phone/ wireless) mobile land radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with any accuracy. In order to evaluate the electromagnetic environment due to fixed RF transmitters, it is advisable to consider an electromagnetic site survey. If the measured field strength in the site where the Apolus is used exceeds the level of RF compliance used above, the Apolus should be observed to check if operation is normal. If abnormal performance is observed, additional procedures may be required, such as reorienting or repositioning the Apolus.

d - Over the frequency range 150kHz to 80MHz, the field intensity should be less than [V1]V/m

Electromagnetic immunity - Equipment with life support functions

Advisable separation distances between mobile and portable RF communications equipment and the Apolus

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

Maximum output power of the transmitter W	**Distance of separation according to the frequency of the transmitter (m)**			
	150 kHz to 80 MHz outside ISM bands $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	150 kHz to 80 MHz outside ISM bands $d=\left[\frac{12}{V_2}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{12}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{23}{E_1}\right]\sqrt{P}$
0,01	0,35	1,2	0,12	0,23
0,1	1,1	3,8	0,38	0,73
1	3,5	12	1,2	2,3
10	11	38	3,8	7,3
100	35	120	12	23

For transmitters with a maximum output power not listed above, the advisable separation distance “d” in meters (m) can be determined by using the equation applicable to the frequency of the transmitter, where “P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer..

NOTE 1 - At 80MHz and 800MHz, the separation distance for the highest frequency range is applied.

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

NOTE 3 - An additional factor of 10/3 is used in calculating the advisable separation distance for transmitters in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80MHz to 2.5GHz to reduce the likelihood of interference that mobile/portable communications equipment could cause if taken inadvertently to patient areas.

NOTE 4 - These directives may not be applicable in all situation. Electromagnetic transmission is affected by the absorption and reflection of structures, objects and people.

Apolus was designed to provide **basic security** with RF equipment as per the following table:

Testing specifications for cabinet interface immunity to RF wire communications equipment

Testing frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM[c] deviation of ± 5 kHz Sinusoidal 1 kHz	2	0.3	28
710	704-787	Band LTE 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 920 CDMA 850 Band LTE 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT Banda LTE 1, 2, 3, 25 UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN, 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary, to reach the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the EM EQUIPMENT or EM SYSTEM may be reduced to 1 m. The test distance of 1 m is allowed by EN 61000-4-3.

a - For some services, only the terminal's transmission frequencies are included.
b - The carrier must be modulated using a 50% service cycle square wave signal.
c - As an alternative to FM modulation, 50% to 18 Hz pulse modulation can be used because, although it does not represent actual modulation, this would be the worst case.

Troubleshooting

7

Symptom	Probable cause	Probable solution
The Apolus does not turn on	There is no electricity	- Check connections: the Apolus/Power Cable/ Plug.
Does not select energy > 50J	Adult pads identification	- Check if the Apolus is equipped with adult pads and if adult electrodes are properly connected.
Does not deliver shock	Impedance measuringa	- Check the graph bar for the patient's impedance indication.
Low battery autonomy	Defective battery	- Replace battery.
No QRS audio indication	BEEP volume	- Turn on BEEP's volume in the configuration menu

Accessories

8

Accessories accompanying the equipment:

List of basic accessories

Quantity	Description	Code
01	Power supply cable	5550
01	A set of adult/child external defibrillation pads	79001
01	Quick guide	26173
01	CD with Instramed's manuals and softwares	25277

List of optional accessories

Description	Code
Auxiliary grounding cable	5495
External DC connection cable	79004
Set of internal pads	79013
Pair of electrodes for adult internal pads	8966
Pair of electrodes for child internal pads	8974
Synchronism cable	79138

Specifications and safety

9

General specifications

Dimension with pads:	44.5 cm (W). 24.5 cm (D). 20.0 cm (H).
Weight:	Device - 3.90 Kg. External set - 0.85 Kg. Complete set - 4.75 Kg.
Power:	AC: 100 to 240 VAC, 50/60 Hz. DC external: 11 to 16 VDC.
Removable rechargeable battery:	Type: NiMH, 14.4V DC 4.5 A/h Duration (fully charged battery): minimum of 140 shocks at 360 joules or a minimum of 200 shocks at 200 joules. Time to fully charge the battery (when fully depleted): 8 hours. Battery level indication on display.
Optional rechargeable battery*:	Type: Li-Ion, 14.8 VDC 4.4 A/h Duration: 3 hours (fully charged battery), without the printer or a minimum of 140 shocks at 360 joules or a minimum of 200 shocks at 200 joules. Time to fully charge the battery (when fully depleted): 8 hours. * Consult availability
Consumption (maximum):	AC: 400 W Battery 15 A
Fuse:	5 A power supply
Battery storage:	Storing the battery for long periods of time in temperatures higher than 35° C will reduce its capacity and lifetime.

Protection index:	IPX1.
Classification:	Class I, internally energized. CF Type.
Operating mode:	Continuous operation (frequent).
Screen:	Size: 99 mm x 19 mm. Type: alphanumeric LCD.

Environmental specifications

Temperature:	Operational: 0 to 50ºC. Storage: 0 to 70ºC.
Humidity:	Operational: 10 to 95% RH, without condensation Storage: 10 to 95% RH, without condensation

WARNING: if the Apolus is used outside these conditions, 15 through 30 minutes will be required to stabilize the system so that functioning failures do not occur.

Defibrillator

Waveform:	Biphasic truncated exponential. Wave shaped parameters adjusted according to the patient's impedance.
Shock application:	By means of multifunction pads or external adult/child pads.
Scales for adult/external defibrillation:	5, 10, 15, 20, 30, 40, 50, 80, 100, 150, 200, 250, 300 and 360 Joules. Maximum energy limited to 50 Joules in internal or child pads.
Operation:	Standard sequence "1-2-3"
Selector key:	Allows turning the equipment on and off, selecting energy scales and activating functional test mode.

Command keys:	Charge, Shock, Disarm and Sync (Synchronism)
Charge command:	CHARGE button in fron panel, button in external pads.
Shock command:	SHOCK button in front panel, buttons in external pads.
Disarm command:	DISARM button in front panel.
Synchronized command:	SYNC button in front panel.
Charge indicators:	Audio indication of equipment being charged, áudio indication of charge completed, LED on external pads and charge level indicated on display.
Maximum charge time in maximum energy:	< 6 seconds with 90% to 100% of the minimum specified voltage < 6 seconds with a full charge < 13 seconds from equipment initialization
External pads size:	Adult = 10.3 cm x 8.5 cm – Area: 81.9 cm² Children = 4.5 cm x 4 cm – Area: 18 cm²
Automatic internal discharge:	30 seconds.
Synchronism:	Synchronism circuit with external signal of 1V/mV of a cardioscope or electrocardiograph.
Time of synchronized discharge:	< 60 ms after R wave peak.
Maximum output voltage:	2000 V.
Maximum output electric current:	80 A (25 Ω).
Defibrillation pads:	External adult and child (included) Internal adult and child (optional)

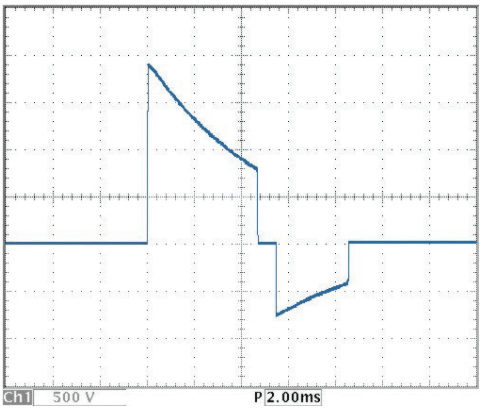
Precision of applied energy:

Energy selected	Impedance							Accuracy
	25	50	75	100	125	150	175	
5	4,8	5,1	5,1	5,0	5,0	5,0	4,9	±3J
10	8,8	9,8	10,2	10,4	10,3	10,2	9,8	±3J
15	13,4	16,0	16,7	17,2	17,5	17,7	17,2	±3J
20	19,0	20,5	21,0	21,0	20,5	19,5	19,0	±15%
30	27,5	30,0	31,0	31,5	31,0	29,5	27,5	±15%
40	37,4	42,0	44,4	44,9	44,1	45,4	44,2	±15%
50	49,0	52,0	53,0	52,5	51,5	48,0	45,5	±15%
80	77,5	81,5	82,5	83,0	80,5	76,5	74,5	±15%
100	96,0	101,0	102,5	103,5	101,0	96,5	92,0	±15%
150	143,0	151,5	155,0	153,0	148,0	141,0	137,0	±15%
200	191,5	201,5	205,5	206,0	203,5	192,0	177,0	±15%
250	240,0	250,5	256,5	256,0	254,0	241,5	224,0	±15%
300	284,0	302,0	305,5	306,0	305,0	290,0	270,0	±15%
360	344,0	363,0	370,5	370,0	363,0	345,0	322,0	±15%

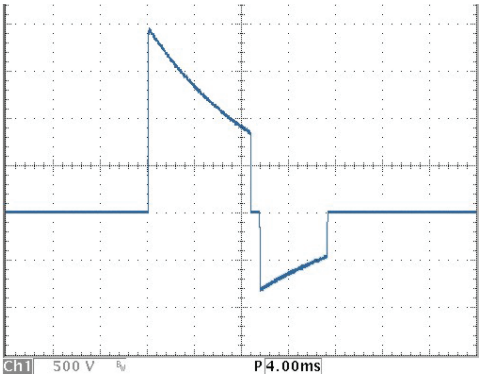
Patient's impedance response table:

Patient Impedance	Shock
Short-circuit	Shock inhibited
< 25 Ohms	Shock inhibited
> 25 Ohms and < 300 Ohms	Shock delivered with a waveform adjusted to the patient's impedance
> 300 Ohms	Shock inhibited
Circuito aberto	Shock inhibited

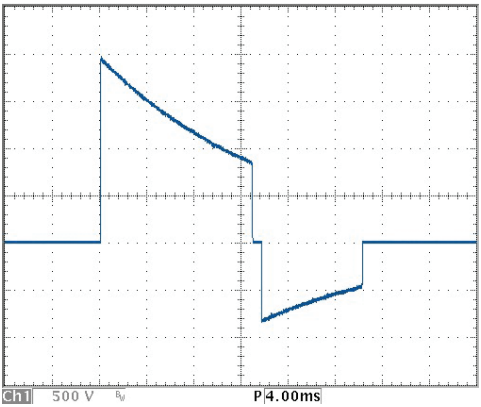
Values on the Y axis refer to voltage (volts) and values on the X axis refer to time (milliseconds).



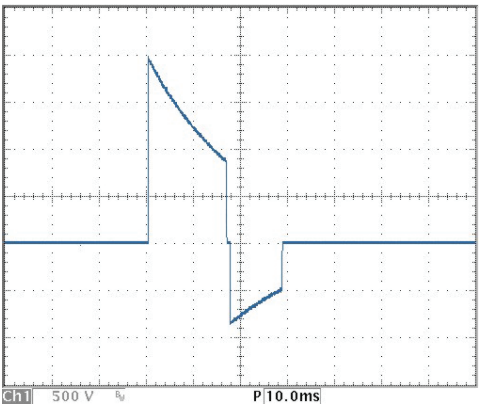
360J of energy at 25R impedance.



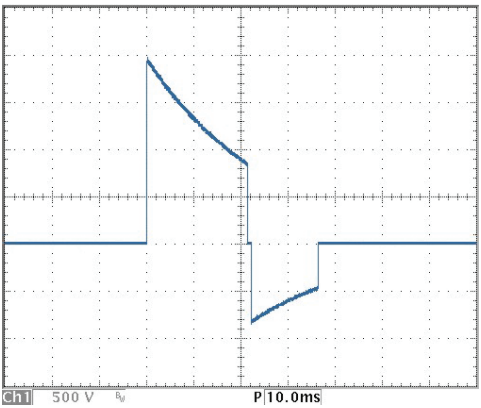
360J of energy at 50R impedance.



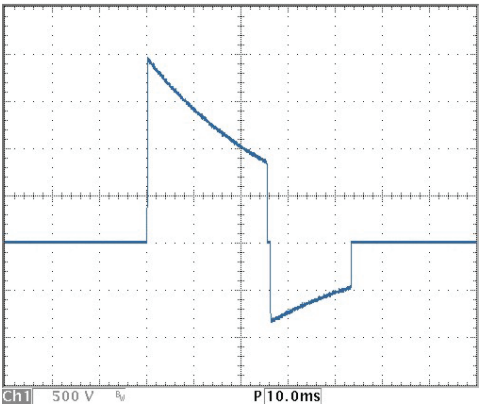
360 J of energy at 75 R impedance.



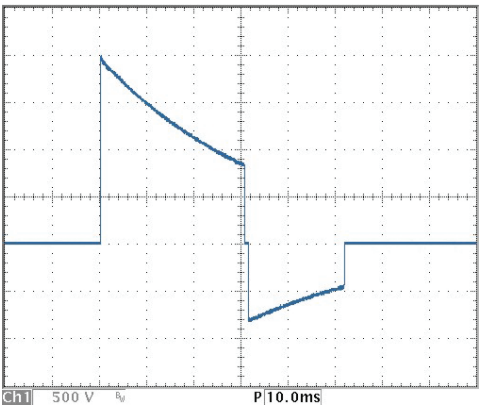
360 J of energy at 100 R impedance.



360 J of energy at 125 R impedance.



360 J of energy at 150 R impedance.



360 J of energy at 175 R impedance.

Warranty Certificate

10

Instramed Indústria Médico Hospitalar Ltda. warrants the equipment described in this Certificate for 12 (twelve) months, starting from the delivery date. This warranty covers manufacturing or material defects that prevents proper functioning according to the specifications stated herein, as long as the conditions presented in this Certificate are respected.

During the warranty period, Instramed Indústria Médico Hospitalar Ltda. or itsrepresentative will repair or replace defective parts, at no expense to the owner of the equipment.

This warranty will no longer be valid if any damage occurs due to accident, natural disaster, improper connection to a power source, use distinct from that described in the User manual, or irregular working conditions.

Any attempt to violate, adjust or repair this equipment by individuals not authorized by Instramed Indústria Médico Hospitalar Ltda. will automatically invalidate this warranty. This also applies in case of alterations made to this contract, the fiscal receipt, or to the serial number of the equipment.

Instramed Indústria Médico Hospitalar Ltda. is not responsible for the improper use of this equipment, by people who are not familiar with its function or the techniques recommend for its proper use.

EQUIPMENT: _____

SERIAL NUMBER: _____

PURCHASE DATE: _____

FISCAL RECEIPT NUMBER: _____

apolus

Biphasic Defibrillator

INSTRAMED

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