# User manual


isis

AUTOMATED EXTERNAL DEFIBRILLATOR

INSTRAMED

# Manufacturer

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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.**



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# Battery use

**ATTENTION: Observe the battery charge maintenance instructions**

## First use:

The batteries are rechargeable Lithium-Ion (Li-ion). 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 an electric current for at least eight hours.

To charge the battery connect the charger to the lateral connector in the device (⇉–) and then to the electric current.

Time for full battery charge = 5 hours.

**The device blocks any operation on the patient when connected to the electric current.**

## Occasional use:

Even when disconnected (stand-by), the Isis 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.

Therefore, whenever the device has not been connected to an electric current for more than 20 days, 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 Isis in its portable configuration (not connected to the electric current).

## Replacement:

Every battery has a determined shelf life, which is the possible quantity of full charge and discharge cycles, without loss of performance (see battery specifications in chapter 8). When the device presents a drop in battery performance, with low autonomy, please request a new unit from Instramed's technical assistance.

The batteries are rechargeable Lithium-Ion (Li-ion). The battery can be removed by the side opening, in the lower left part identified by the symbol (⇉–) (see picture on page 22). Remove the screw, unplug the connectors from the battery, remove it and replace it with the new set, observing the correct position of the connectors and making sure the lid remains steady.

The battery's shelf life is at least 500 cycles (full charges and discharges).

# Package contents

## Included items:

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

- An Isis Automated External Defibrillator
- A power supply for charging internal battery
- A cable for connecting the power supply to the electric current
- A pair of disposable adult size adhesive pads
- A pair of disposable child size adhesive pads
- A user manual
- A first-aid kit
- A transport bag
- A USB cable
- A CD with the Soft DEA management Software

## Replacement parts:

You can ask Instramed for replacements of the following items (consult Instramed for prices. Shipping costs may be applied):

- Batteries replacement
- Adult/child adhesive pads replacement

To request pieces and services please contact Instramed.

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# Introduction

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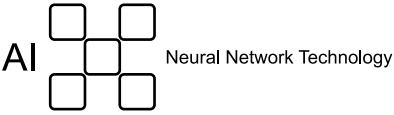


Given the complexity of the clinical variables involved, for many years only doctors and experienced paramedics could use defibrillators to reverse a cardiac arrest.

Nowadays, however, with the evolution of artificial intelligence (AI), the Isis, using its Neural Network Technology, is capable of analyzing the state of the patient, considering the clinical variables and applying, automatically, the most suitable shock therapy.

This allows any individual with proper training to perform assistance to a victim in the process of fibrillation, multiplying and making life-saving possibilities easier.

## Characteristics

- Semi-automatic.
- Artificial Intelligence: accurate diagnosis of the patient's conditions, indicating shock delivery or not.
- Safety precautions: prevents accidental use in cases in which shock treatment is not advisable or in healthy people.
- Operation with just one button.
- Orientation by voice and indicator lights.
- Internal recording of events.
- PC connection via USB.
- Software for connection, download and data management via PC.
- Biphasic shock.
- Automatic self-diagnosis of functions and battery.
- Use in hospital or extra-hospital environments including emergency rescue units.

## Purpose

The defibrillator is a device used for treating cardiac arrhythmias, situations in which the heart loses the ability of keeping steady heartbeats, blood stops being pumped and oxygen and nutrients do not get to the organs, starting a degenerative process known as biological death.

Among the most common cases of cardiorespiratory arrest are ventricular fibrillation (VF) and ventricular tachycardia (VT), and the most efficient treatment for these kinds of cardiac dysrhythmia is electrical defibrillation, a technique by which electrical shocks are applied to the anterior thoracic wall.

Obviously, the success of defibrillation depends on the metabolic conditions of the myocardium. The more the ventricular fibrillation lasts, the greater the metabolic deterioration is and, consequently, the fewer chances of the electrical shock converting it into a steady rhythm.

However, if it lasts shortly, as in the cases of quickly assisted cardiac arrests, shock response is almost always positive.

Therefore, the most important factor in survival is how fast treatment is delivered. Ideally, treatment should not be delayed for more than four minutes from the beginning of the defibrillation.

## Principle


Defibrillation is the electrical shock therapy responsible for reversing cardiac arrest caused by ventricular fibrillation or ventricular tachycardia without a pulse.

The Isis uses the BIPHASIC SHOCK technology, which is characterized by a current which is released in a direction and, after a very short time, reverts in the opposite direction.

During the defibrillation the whole myocardium is briefly depolarized by a strong positive impulse and a negative one, of adjustable intensity (Biphasic Truncated Exponential Shock). This impulse is used for eliminating atrial and ventricular fibrillation and ventricular disturbances.

Compared to monophasic shock, the following advantages can be mentioned regarding biphasic technology:

- Greater efficiency at ending ventricular fibrillation.
- Lesser damage to the myocardium, through the use of lesser energy intensity, with attenuation of subsequent myocardial dysfunction.
- Fewer incidence of refibrillation.

*Source: Sociedade de Cardiologia do Estado de São Paulo – SOCESP, Revista Socesp V.11, no 2.*

## Use criteria

**The Isis, as well as any other Automated External Defibrillator, must only be used if the following circumstances, as a whole, are presented:**

- **Unconscious victim or unresponsive to verbal or physical stimulus**
- **Not breathing**
- **No pulse (for professionals)**

Other important considerations regarding the use of the Isis:

- Not recommended for children under one year old.
- Pacemakers may affect the device's efficiency.
- Medicines in adhesive form must be removed before starting defibrillation.
- Hypothermic patients may not respond well to defibrillation.
- 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.

## About the manual

The function of this guide is to explain how the Isis Automated Defibrillator series works, alerting the user to safety risks.

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

Instramed has the right to make any changes to improve this guide and the product without prior notice.

This guide is a part of the Isis and must be kept for further reference.

# Safety Information

# 2

## ATTENTION

The following factors may cause ECG misinterpretation:

- Wrongly placed pads.
- Patient's movements.
- Pacemaker (it may lessen the precision of the cardiac arrest detector).
- Radio frequency interference, including mobile phones.
- Excessive hair or wet skin in the application area of the electrodes.
- Pieces of clothing between skin and pads.

## Warnings

**IMPORTANT: This equipment may only be operated by qualified technical personnel. Read this guide carefully before using the equipment.**

**WARNING: THE PATIENT MUST BE PLACED ON NON CONDUCTIVE SURFACES. DO NOT USE WET OR METALLIC SURFACES AND, IF NECESSARY, DRY THE CHEST BEFORE APPLYING THE SHOCK.**

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

**WARNING: DO NOT CONNECT THE PATIENT TO THE ISIS WHEN THE EQUIPMENT IS CONNECTED TO THE ELECTRIC CURRENT.**

**WARNING: THE PATIENT MUST BE COMPLETELY STILL DURING THE CARDIAC RHYTHM ANALYSIS PHASE. DO NOT GIVE CARDIAC MASSAGE AT THIS POINT.**

**WARNING: risk of explosion if the equipment is operated in the presence of flammable liquids or gases.**

**WARNING: always check the general state of the equipment, the battery and the accessories before using it.**

**NOTICE: each and every repair to the equipment can only be done by Instramed's authorized technical assistance centers.**

**NOTICE: The use of the Isis is restricted to one patient at a time.**

**NOTICE: The applied parts are protected against defibrillation discharge; during discharge there may be baseline variation.**

**NOTICE: Avoid connecting the patient to several items of equipment at the same time. The limits of current leakage may be exceeded.**

**NOTICE: The applied parts intended to come into contact with the patient have been evaluated and comply with the directives and principles of ISO 10993-1.**

**NOTICE: when removing the equipment from the 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.**

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

## Adverse effects

Superficial burns may occur to the patient's skin on the area in contact with the electrodes. To minimize this effect, apply the pads soon after removing their protective envelope and press them firmly to the patient's skin.

The skin should be dry, or electrical current leakage may happen, enlarging burn area and reducing treatment efficiency.

## Standards

The Isis was designed according to safety and performance standards, such as:

- NBR IEC 60601-1:1997 (IEC 60601-1:1995), Medical electrical equipment – Part 1 – General Requirements for Safety.
- EN 60601-1:1990, (Amendment, A1:1993, A2:1995, A13:1996) (IEC 60601-1:1988, A1:1991, A2:1995), Medical electrical equipment - Part 1 - General Requirements for Safety.
- NBR IEC 60601-1-2:2006 (IEC 60601-1-2:2004), Medical electrical equipment – Part 1-2 - General Requirements for Safety – Collateral standard: Electromagnetic compatibility - Requirements and tests.
- EN 60601-1-2:2007 (IEC 60601-1-2:2007), Medical electrical equipment. General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility - Requirements and tests.
- ABNT NBR IEC 60601-1-4:2004 (IEC 60601-1-4:2000) Medical electrical equipment - Part 1-4: General Requirements for Safety – Collateral standard: Programmable electrical medical systems.

- IEC 60601-1-4:2000 - Medical electrical equipment - Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems.
- NBR IEC 60601-2-4:2005 (IEC 60601-2-4:2002), Medical electrical equipment - Part 2 - Particular requirements for the safety of cardiac defibrillators.
- EN 60601-2-4:2003 (IEC 60601-2-4:2002), Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of cardiac defibrillators.
- ANSI/AAMI DF80:2003: Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators).
- NBR IEC/CISPR11:1995, Electromagnetic compatibility: Irradiated and Conductive.

## 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.

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

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

## 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. See the procedures for cleaning and disinfection below.

**External parts of the 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.
- Never immerse the defibrillator in liquids.

## Connection to other equipment

When connecting the Isis 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.

## Disposing of the device

Avoid contamination of the environment, humans, or other equipment by making sure to properly sterilize and decontaminate the equipment before disposing of it.

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

## Precautions:

**Danger of EXPLOSION: Do not use the Isis in the presence of flammable anesthetics.**

**Risk of ELECTRICAL SHOCK: Never open the equipment. When necessary, this must be done by authorized individuals.**

**Do not use the equipment in the presence of magnetic resonance devices.**

**This equipment was designed to be resistant to electromagnetic interference. However, equipment performance can be affected if in the presence of strong sources of electromagnetic interference or radio frequencies, such as mobile phones, radio communicators, etc.**

# Classification and Symbols

| Symbol | Standard | Description |
|---|---|---|
|  | IEC TR 60878 | Attention: only use according to the instructions of this manual |
|  | IEC TR 60878 | Careful: dangerous high electrical voltage |
|  | IEC TR 60878 | Power supply connector |
|  | IEC TR 60878 | Non-ionizing radiation |
|  | - | USB connector |
|  | ISO 780 | This side up |
|  | ISO 780 | Fragile equipment |
|  | ISO 780 | Maximum stacking of 4 units |
|  | ISO 780 | Keep away from rain |
|  | ISO 7000<br>ISO 780 | Minimum and maximum temperature |
|  | ISO 7000 | Minimum and maximum atmospheric pressure |
|  | ISO 7000 | Minimum and maximum relative humidity |
|  | IEC TR 60878 | Recyclable paper |
|  | Directive 2002/96/CE | Remains of electrical and electronic equipment - Dispose of separately from other disposables |
| CE<br>XXXX | Directive 93/42/EEC | Mark of conformity according to the European Community. “XXXX” stands for the number of the certification authority. |
|  | IEC 60417-5031 | Direct current |
|  | IEC 60417-5036 | CF applied part - defibrillation proof |
|  | IEC 60417-5010 | On/Off (push-push) |
|  | EN 980 | Manufacturer |
| EC REP | EN 980 | European representative |
| SN | EN 980 | Serial Number |

# The Equipment

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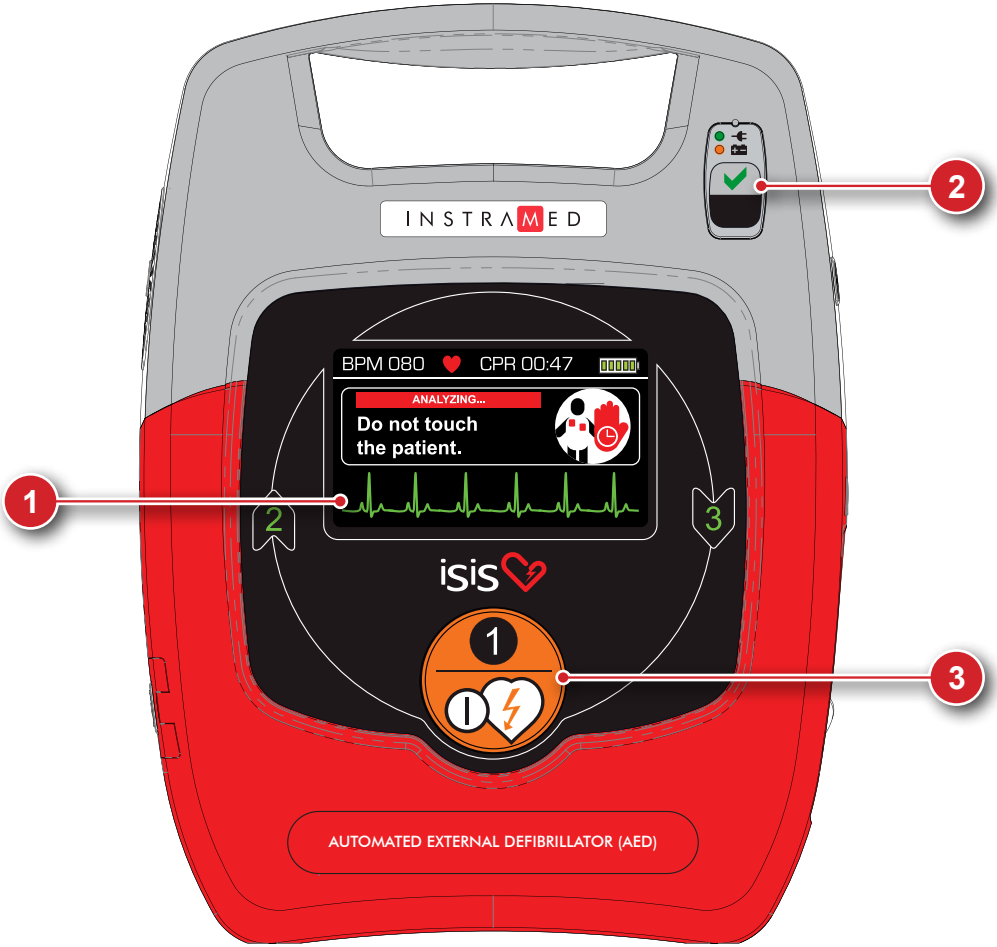
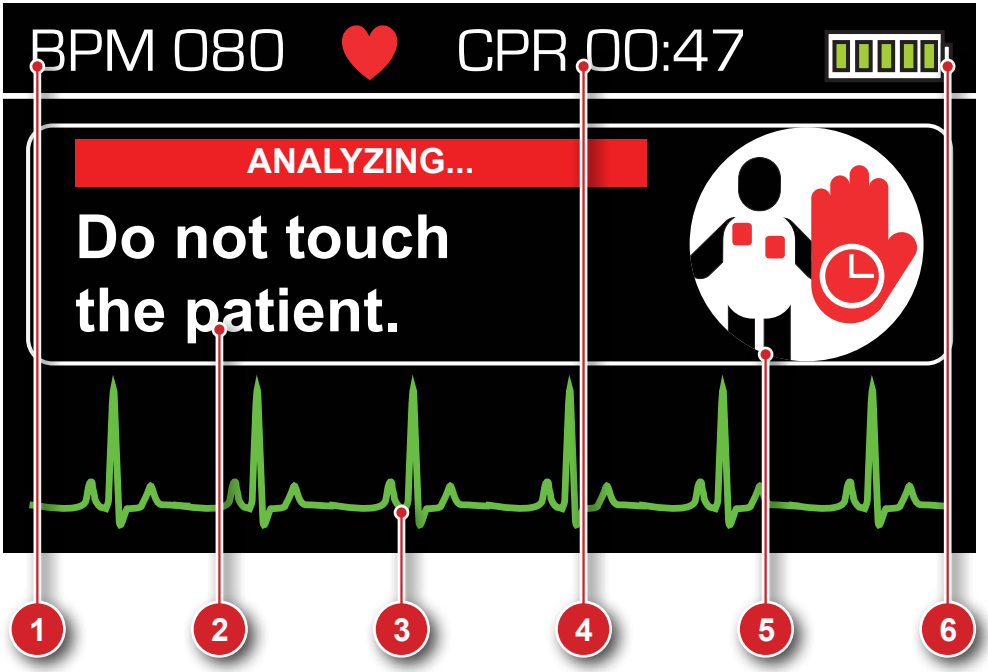
## Front panel




1. Screen indicating the stages of the defibrillation procedure and ECG curve.
2. Operational status indicator.
3. Start button.

## 1 - Screen

The Isis presents the following items on the screen when connected to the patient:



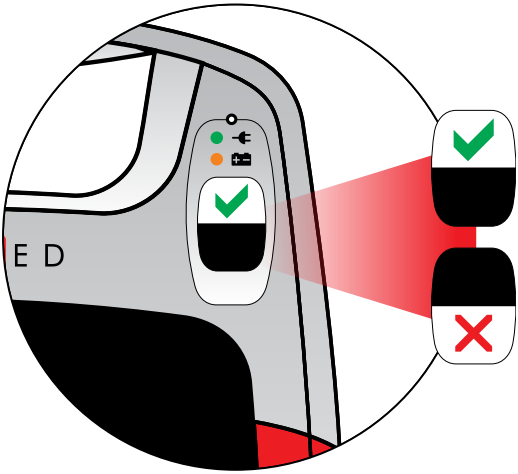

1. **Heart beats per minute.**
2. **Orientation message.**
3. **ECG curve.**
4. **CPR interval counter:** counts the interval between discharge delivery, helping in the CPR (Cardiopulmonary resuscitation) massage.
5. **Icon indicating the defibrillation stage.**
6. **Battery status.**

## 2 - Operational status indicator

The Isis performs a full auto-test weekly, allowing the user to know the operational status of the device. This status is informed by a visual indicator (see picture below), voice messages and sound signals.

The automatic test is also performed when the device is switched on. Should any problem be found, the voice message “problem with the automatic test” will be emitted with the visual indicator of failure.

**VISUAL INDICATOR**



Shows that the device is operating and ready for use.

Shows that the device **DOES NOT HAVE ENOUGH BATTERY CHARGE TO OPERATE** or has another internal defect. Charge battery immediately. If the indicator remains red, please call technical assistance.

- Mains supply LED on means device is connected to the electric current.
- Mains supply LED blinking when in normal use means the battery needs charging. **In this state the Isis guarantees at least 3 full energy discharges.**
- Battery LED on means internal battery is being charged. A blinking LED beside this symbol means full charge.

**Notice: EVEN WHEN THE BATTERY HAS BEEN FULLY CHARGED, the operational status indicator will still be showing ✗.**

**The display will only change from ✗ to ✓ when the Isis performs the auto-test routine or if the device is turned on/of by the user.**

**That is: to change the display from ✗ to ✓ user’s intervention is necessary after the battery has been completely charged.**

**ATTENTION: remember to check the status of the operational status indicator at least every 30 days.**

### SOUND INDICATOR

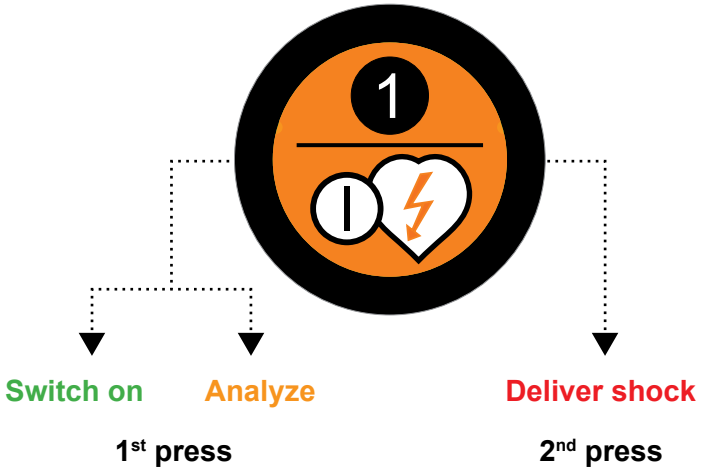
Along with visual indication, the Isis emits electronic beeps which can be identified by the user from a distance and can also be interpreted according to the frequency, as in the table below:

| Number of beeps | Failure description |
|---|---|
| Two | CPU failure |
| Three | Failure in defibrillation module |
| Four | Discharged battery |
| Five | General failure in battery module |

**ATTENTION: the device will not switch on if the battery is discharged or showing general failure. In this case only the sound warning of the respective failure will be emitted.**

## 3 - Start button

The Isis offers exclusive technology which allows to operate the device completely safely with a single button.




The start button has the functions of:

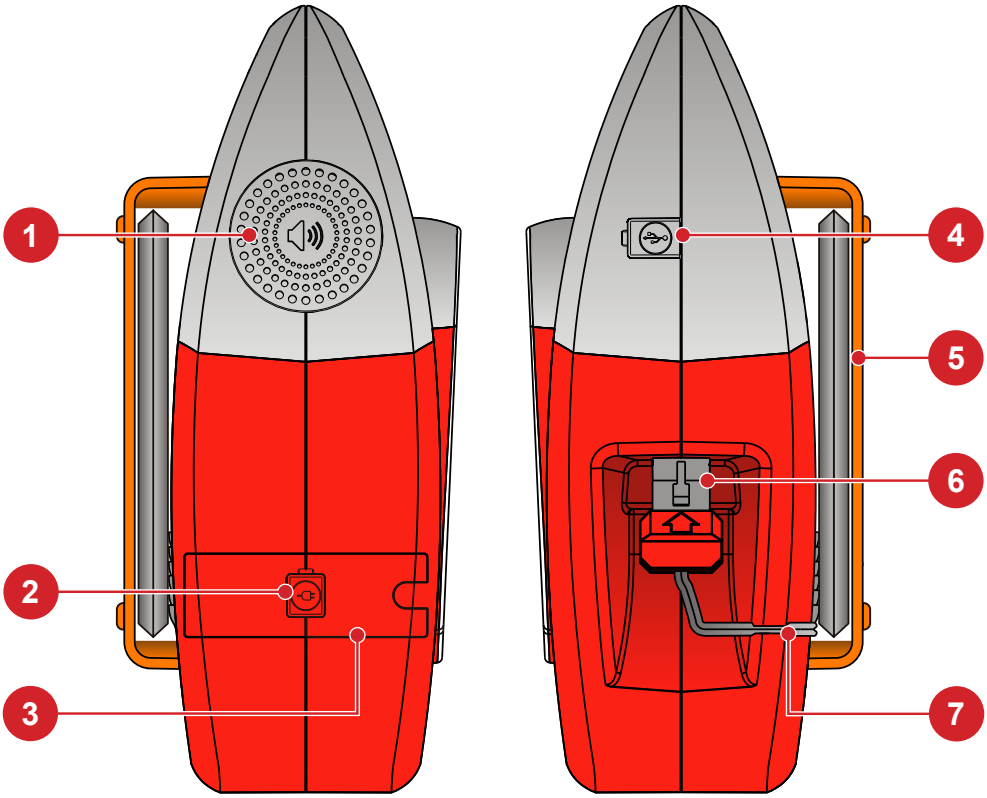
- Turning on the device
- Starting the automatic process of the patient's clinical analysis
- Applying shock therapy (active only when the automatic clinical analysis of the patient indicates the need for it)

More information in the "Operation" section.

NOTE: it is not necessary to switch the Isis off. Fifteen seconds after the removal of pads from the patient or disconnection of pads from the equipment, the device switches itself off, saving battery charge. In this moment the following message will be heard: "The device is being turned off. Press the button in order to turn the machine back on".

**Still, there are three ways of switching it off manually: pressing the start button for three seconds, removing the pads or plugging and unplugging the USB cable.**

## Sides




1. Speaker
2. Battery power supply connector
3. Battery compartment
4. USB connector
5. Disposable pads compartment
6. Disposable pads connector
7. Cabinet recess

## 1 - Speaker

The Isis is a highly complex equipment which, from the moment of activation, assesses the steps of the operation and the general state of the patient. Based on this analysis, the device guides the user through verbal commands which may be warnings, instructions or status messages. Therefore **it is extremely important that the speaker is unobstructed and the Isis is in a position which allows the user to hear its instructions.**

**ATTENTION: do not use the equipment inside bags which may prevent the user from hearing the spoken instructions.**

## 2 - Battery power supply connector

Connect the power supply to the electric current and then, to this connector in order to charge the internal battery. The equipment operates on voltage between 100 to 240 V in 50/60 Hz.

**ATTENTION: the device performs internal routine verifications which consume energy. Even when the equipment is not in use, a full charge is recommended every 20 days.**

## 3 - Battery compartment

It holds the internal batteries of the equipment. The reset button is also placed in this compartment, in case restarting the equipment is necessary.

**ATTENTION: in case of battery replacement, use original replacements from Instramed supplied by its authorized distributors.**

## 4 - USB Connector

Used for connecting the equipment to a PC (see chapter 5).

## 5 - Disposable pads compartment

Used for storage of disposable pads used in shock delivery.

**ATTENTION: the disposable pads have an expiration date. Check the expiration date on the wrapping, and in case they have not been used during this period, replace them with another pair.**

**ATTENTION: only use original pads provided by Instramed. Not following this observation may prevent the equipment from working.**

## 6 - Disposable pads connector

Used for connecting disposable pads to the Isis.

**ATTENTION: whenever the pads set is replaced, remember to keep a new pair already connected to the equipment.**

## 7 - Cabinet recess

Used for attaching the cord of the disposable pads to the equipment's body, preventing the cord from getting loose. When installing a new pair of pads, push the connector's cord in its narrowest part inside the cabinet recess and then twist to fix it.

# Operation

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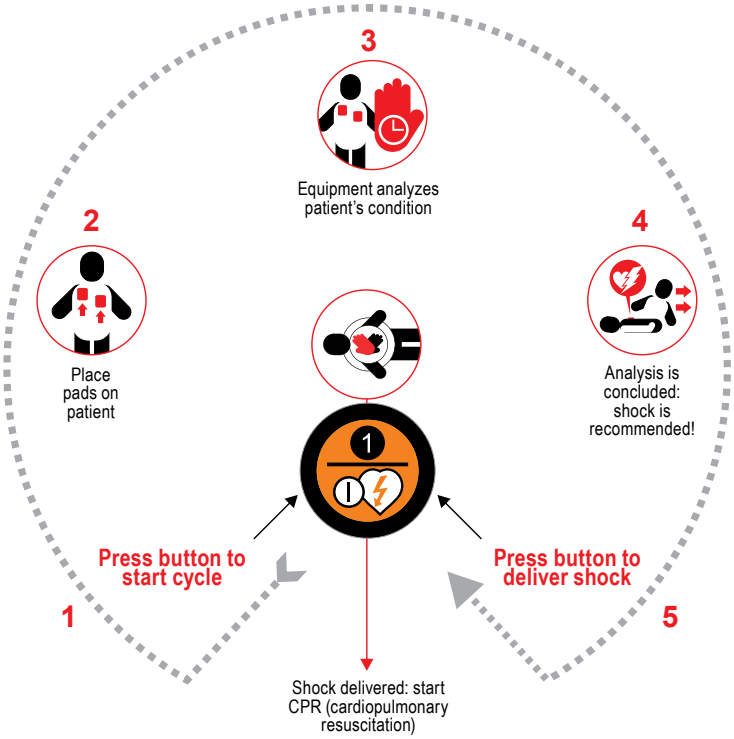
## Operation cycle of the Isis

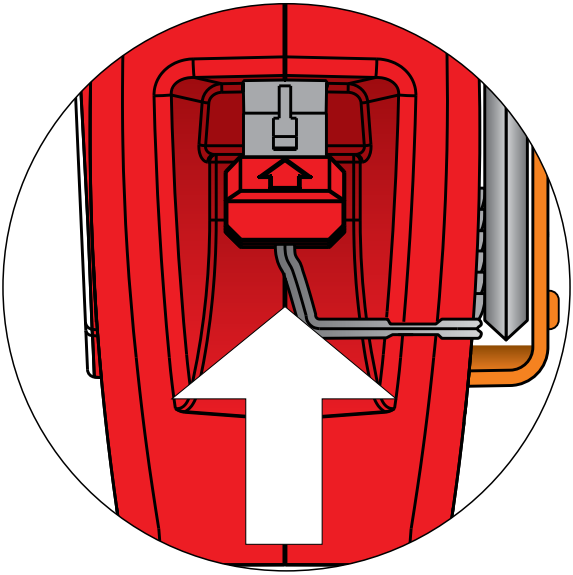
The Isis is an advanced and fully automated cardiac resuscitation equipment (defibrillator). See below a simplified introduction of its operation. Memorize the detailed guide on the next pages attentively before you operate the equipment.




The energy delivered is pre-adjusted. The user cannot change this protocol.

**For adult electrodes: 1st shock: 150J, the following: 200J.**
**For child electrodes: 50 J.**

## Step 1



**Before starting the operation, please call the emergency service.**

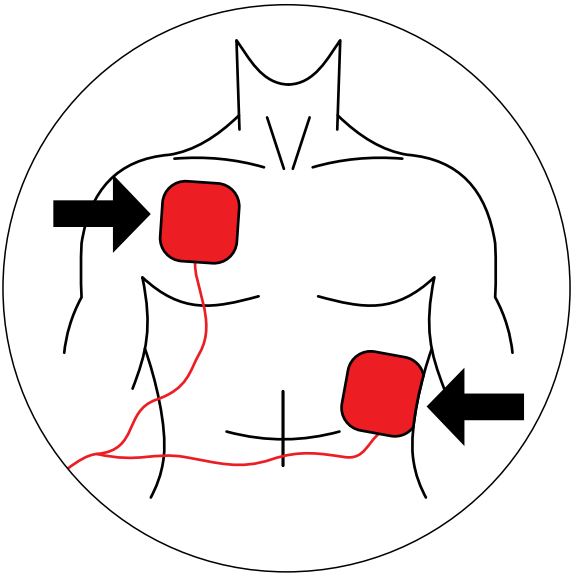
**If the disposable pads have not been connected to the Isis yet, attach the connector to the plug on the right side of the equipment.**

**After disposing of used pads, always leave a replacement pair already connected to the equipment, avoiding having to replace them at the moment of the emergency.**

**ATTENTION: this device has electronic safeguards and will not operate in inadvisable situations.**

**Check patient's condition. Only use the equipment if the patient is not breathing.**

## Step 2



**Remove pads from their wrapping and peel off the film protecting the adhesive.**

**Place pads on the patient according to the picture above, keeping adhesive area in contact with the skin.**

*This position allows the electric current to circulate from one pad to the other, thus reaching the whole thoracic cage.*

**ATTENTION: the area in contact with the pads must be dry.**

**The presence of too much hair in the contact area may affect scanning. In this case, shave hair.**

**ATTENTION: the pads must be applied directly over the skin. DO NOT place pads over clothes.**

**ATTENTION: only open the wrapping and remove adhesive electrodes immediately before use.**

**ATTENTION: a pair of adhesive electrodes can hold up to 50 defibrillation discharges. However, once used, even if only once, it is advisable to replace them after 24 hours.**

## Step 3

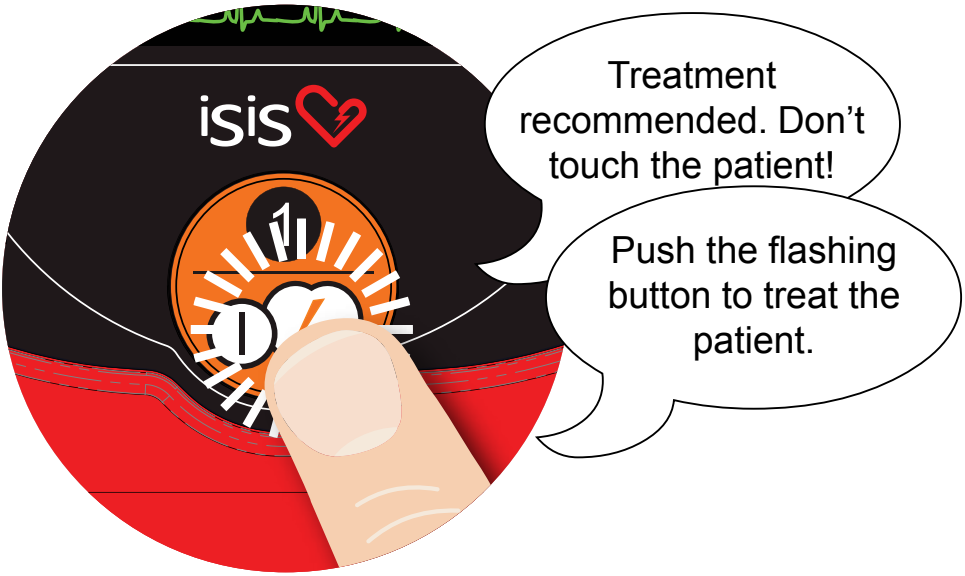

**Press “START” button.**

*The Isis will automatically enter cardiac rhythm analysis mode and will start giving vocal instructions clearly and pausedly, so that the user can perfectly understand them. Visual indications in each stage will also be demonstrated on an LCD screen.*

**ATTENTION: the patient must be on a steady surface. Any movement during the process of clinical analysis will result in mistaken scans.**

**ATTENTION: the pads are disposable and can be used in only one patient at a time. Remember to always keep extra ones with the equipment. For replacements, please contact Instramed.**

## Step 4




*If the need for shock is detected, the shock symbol will blink and the device will ask the user to press the start button again.*

**Press "START" button again.**

*The shock will be delivered.*

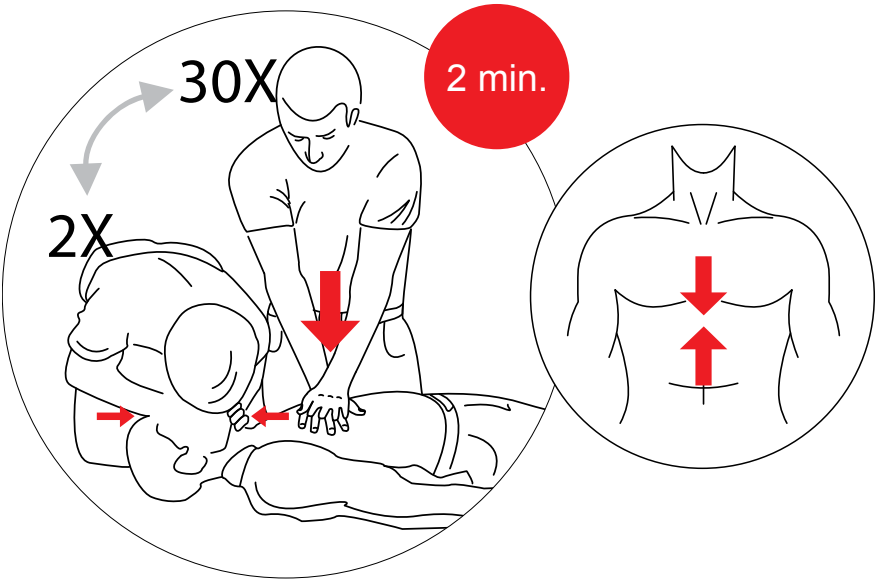
**ATTENTION: the user must not touch the patient or conductive surfaces in contact with him/her during shock delivery, under risk of suffering a powerful electric discharge.**

**ATTENTION: disconnect other equipment which do not have defibrillation protection before defibrillating the patient.**

*If clinical scans show that defibrillation is not recommended, the Isis will announce: "TREATMENT NOT RECOMMENDED".*

*Check whether there were patient's movements during the analysis. If there were, restart the process. If not, remove pads and start the CPR (cardiopulmonary resuscitation) procedure. Details on the next section.*

## Step 5




**After the shock, start the CPR procedure.**

*CPR (cardiopulmonary resuscitation) is a technique which consists in mechanical stimulation of the lungs and heart. Through simple actions, it aims to maintain the oxygenation of the brain, avoiding irreversible damage.*

## Applying CPR

1. Lay the victim on his back on a hard flat surface.
2. Run your fingers from the center of the victim's thorax, descending until finding a bone that comes to a tip in the middle of the chest (Sternum), right above the stomach.
3. Keep two fingers right below this point.
4. Place the palm of your other hand above the two fingers that indicate the base of the Sternum bone. This is the correct spot for the massage.
5. Put one palm on top of the other, keeping your fingers curled up without touching the thorax. In small children, however, use only your fingers. Apply force according to the victim's size.

6. Keep your arms stretched. Put pressure on the victim's thorax, compressing the chest and then releasing it. Follow the BEEPS emitted by the Isis, which mark the rhythm of the compressions. Every 30 compressions, apply 2 mouth-to-mouth ventilations.

7. **Performing mouth-to-mouth breathing:**

   - Place one hand on the back of the victim's neck and lift it; place your other hand on the victim's forehead and force the head back, in order to let the air through.
   - Close the victim's nostrils with the fingers which are on the forehead.
   - Take a deep breath, and place your open mouth on the victim's mouth (if it is a child, also cover the nose with your mouth).
   - Force air inside the victim's lungs, until the thorax inflates, as in normal breathing.
   - Allow the person to release the air by removing your mouth.

8. At every interval to perform mouth-to-mouth breathing, check if the patient's pulse is back..

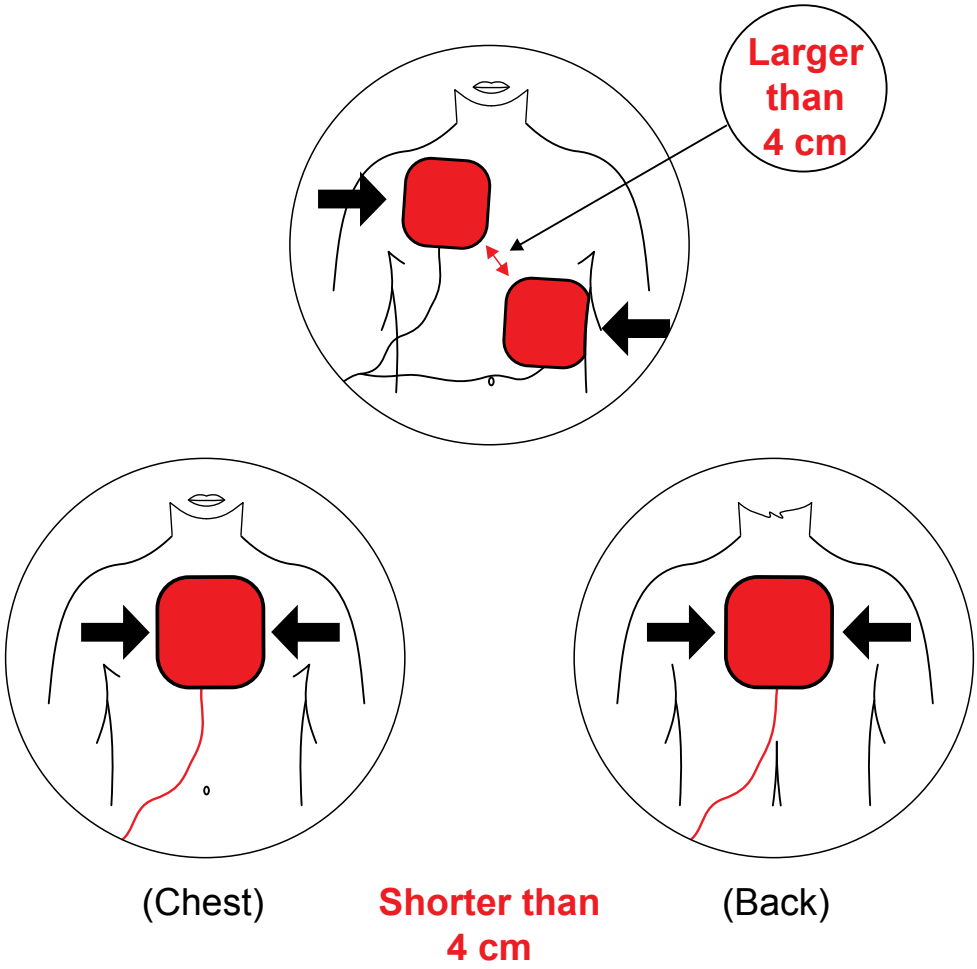
*The massage and ventilation cycle must be done for two minutes. If the patient's pulse does not return, restart shock procedure with the Isis.*

*After the third complete CPR and shock cycle, chances of the patient's resuscitation are very slim.*

## Using the Isis on children under 8 years old

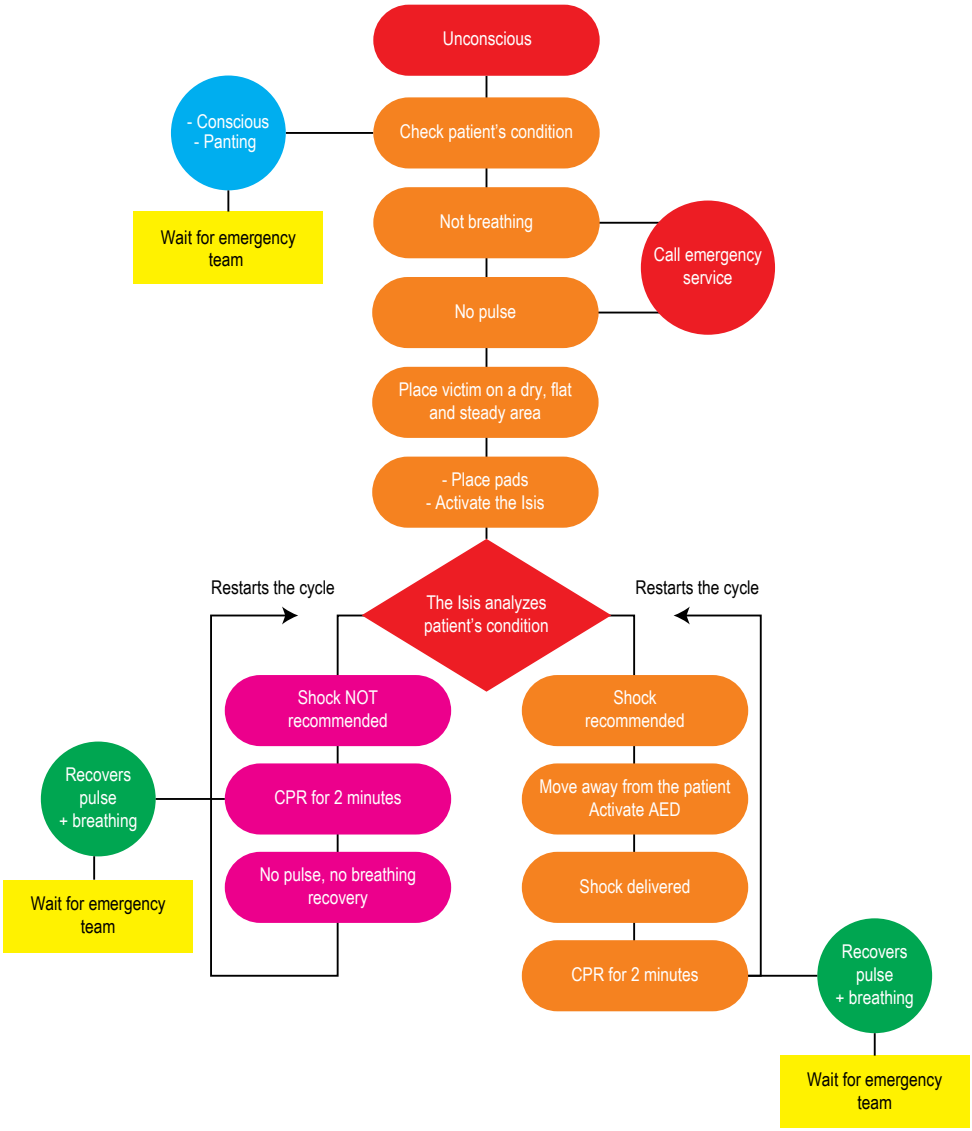
The Isis can be used on children from the age of one year onwards. However, on patients from one year of age to eight years of age or patients who weigh less than 25kg, some precautions must be taken:

- **Use child pads;**
- **If the pads cannot be placed within the minimal distance of 4 centimeters between them, place one of them on the child's chest and another on his back.**



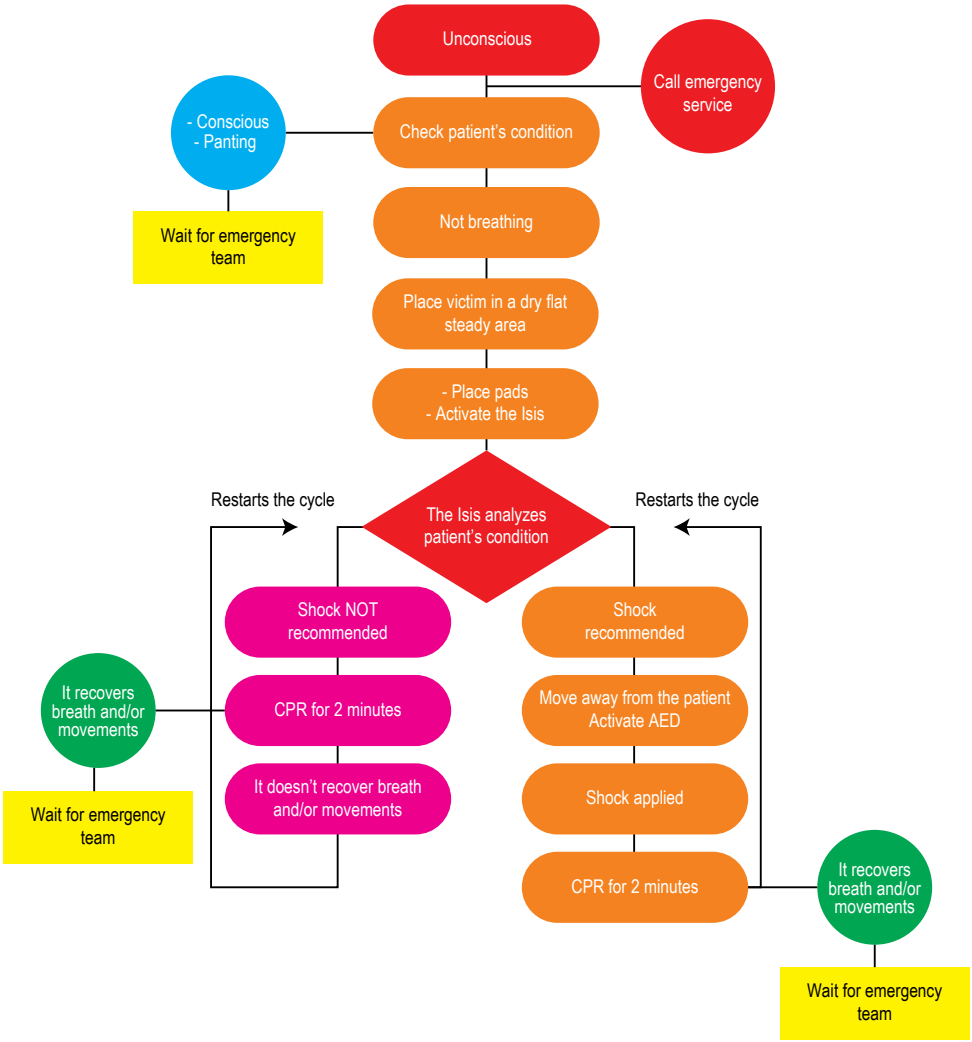
# Simplified diagram of procedure in adults

Healthcare professional



# Simplified diagram of procedure in adults

Layperson



# PC Connection

# 5

## Introduction

The Isis can be connected to a PC, allowing the user access to new functions as:

- View, save in external media or print list of the last 100 events.
- View, save in external media and print ECG activity of the last two hours.
- Change the operational configurations of the Isis (only for authorized technicians)
- Check and update firmware version of the equipment (only for authorized technicians)

## Requirements

Connecting the Isis to a PC requires installation of the Soft DEA application in the computer to which a connection will be made. This software is in the CD which comes with the equipment.

To install Soft DEA, observe the following requirements:

- Windows XP, Windows Vista or Windows 7 operating system
- CPU of 300 MHz or faster
- 02 GB free hard disk space
- Minimum 512 MB RAM (1 GB recommended)
- CD or DVD ROM reader unit

For physical connection to the PC:

- One available USB port

## Soft DEA Installation

- Insert the software CD in the CD/DVD ROM drive.
- If the autorun does not start automatically, find the “softdeasetup.exe” file in the CD and double-click it.
- Follow the installation instructions which will show up on the screen.

## Connecting the Isis to a PC

- Connect the equipment only after installing Soft DEA.
- After the installation connect the device through the USB cable given.
- The location of the device drivers to be installed will be required. They can be found in this folder: C:\Program Files\Instramed\Soft DEA\DRIVERS.
- Start the Soft DEA application.
- On the language selection screen, choose among Spanish, English or Portuguese. You only have to select a language the first time you start the software.
- After the software reads the Isis data (see following section), the ECG and the events list will appear on the software’s screen.

**ATTENTION: the equipment must not be connected to the patient when communication via USB with the Soft DEA application occurs.**

**ATTENTION: the equipment blocks any operation on the patient when communication via USB with PC occurs.**

# Operating Soft DEA

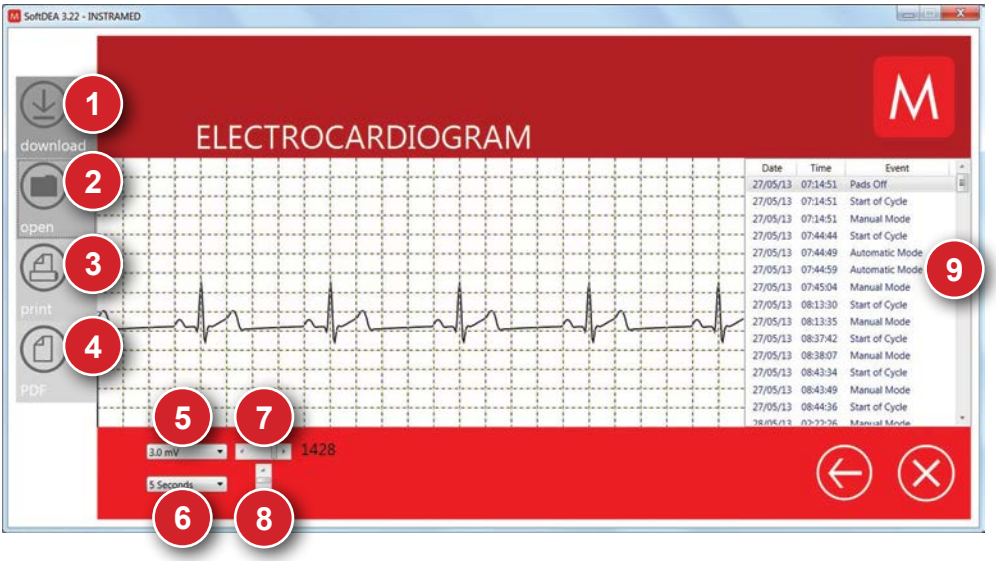
# 6

## Startup screen


## 1 - Graphic display button

Click this button to display the ECG waveforms and event list stored on the device. The displayed interval corresponds to the user-defined time frame (see item 7 on page 39 of this manual).

## Graphic display screen

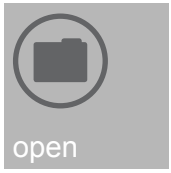



## 1 - Download

The set of information that is currently being viewed can be saved on the PC by clicking this button. A window will open enabling the user to select the desired location in which to store the file.


## 2 -Open

Click this button to open a ".dea" file that was previously saved on the computer.



## 3 - Print

Click this button to print the set of information that is currently displayed on the screen. Use the printer driver dialog box to set printing options.


## 4 - PDF

Click this button to generate a file showing the set of information that is currently displayed on the screen in pdf format. The user must select the desired directory in which to save the file.


## 5 - Amplitude selection

Allows the user to vary the ECG amplitude from 0.5 mV to 3.0 mV.

## 6 - Time frame

Allows the ECG to be viewed in time frames from 1 second to 60 seconds.

## 7 - Time frame scroll

Allows the ECG to be viewed throughout its time scale.

## 8 - Amplitude scroll

Allows the ECG to be viewed throughout its amplitude scale.

## 9 - Event viewer window

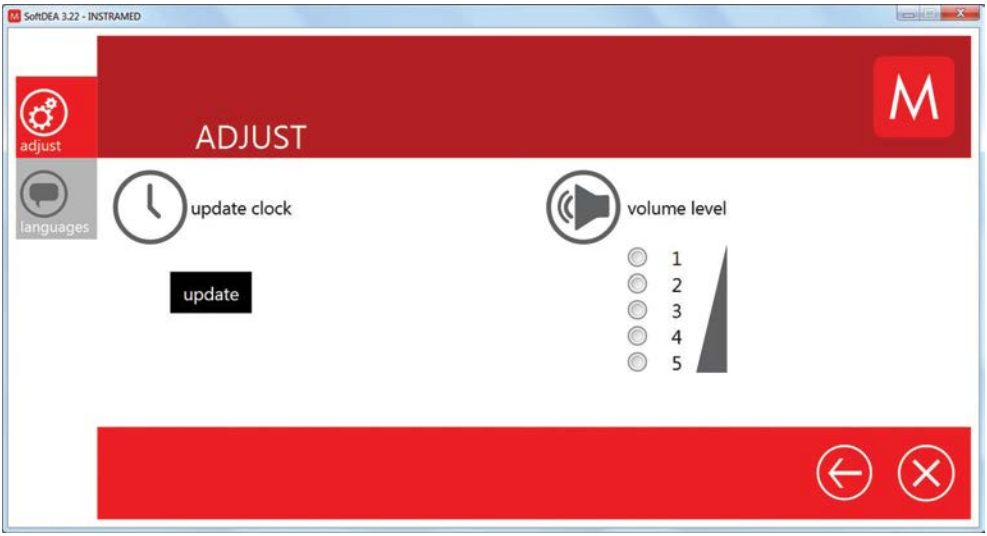
After downloading the information contained in the CardioMax memory, the list of events stored by the device will be displayed in this area in chronological order. Double click on an event to view it on the main screen.

**Definition of events displayed in AED mode:**

- INTERNAL DISCHARGE - Power discharged internally due to pressing the start button for an excessive amount of time.
- TREATMENT PERFORMED - A shock was delivered to the patient.
- SHOCK INDICATED - Shock indicated due to the patient's ventricular fibrillation or ventricular tachycardia pattern.
- SHOCK NOT INDICATED - Shock not indicated on account of the electrocardiogram pattern not requiring a shock.
- ANALYZING AED - Analyzing heart rhythm.
- ASYSTOLE - Asystole detected.
- PADS DISCONNECTED - The pads were disconnected.
- CHILD PADS - Child pads were connected to the device.
- ADULT PADS - Adult pads were connected to the device.
- TURNED ON - The equipment was turned on.
- CPR - Equipment indicating the CPR procedure.

## Adjustments

Click the settings button to access the screen that allows you to update the clock and set the sound level emitted by the speaker on the equipment. In order to make changes, the Isis/Isis PRO device must be turned on and connected to the PC running Soft DEA, via the supplied USB cable.




## 1 - Update clock

Click the “update” button to synchronize the clock with the time on the PC connected to the Isis/Isis PRO device.

update

## 2 - Volume level

Using the mouse, simply select one of the five volume presets for the equipment audio.

## Changing languages


- **Under the "in the SoftDEA" option:** Change the language of the software interface. Does not require a device to be connected.
- **Under the "in the device" option (when an Isis/Isis PRO device is connected):** Change the language of voice prompts emitted by the speaker on the device to the selected language.
- **Under the "in the device" option (when a CardioMax device is connected):** The CardioMax language can be changed through the device's settings menu (see page 48 - "General setup"). However, if the voice prompts emitted by the CardioMax device show signs of degradation or defects, this function can be used to restore the equipment's speech synthesis files.

## Other buttons

### 1 - Back

Click this button to return to the previous page/menu.

## 2 - Exit

Click this button to close Soft DEA 3.

# Precautions, restrictions and warnings

7

The Isis is a device built according to NBR and IEC standards and therefore is completely safe for the patient and the user. However, all safety precautions described below must be followed.

**The operation of the Isis may be affected by the presence of electromagnetic power supplies, such as electrosurgical equipment and computer tomography (CT).**

## Electromagnetic Compatibility (warnings and notices)

**WARNING: Using the Isis requires special precautions concerning Electromagnetic Compatibility in compliance with the information contained in this manual.**

**Mobile and portable RF communications equipment, such as a cellphones, may affect the functioning of the Isis.**

**Maximum length of accessory cables in order to comply with the requirements of Electromagnetic Compatibility is 2,5 m.**

**All parts and accessories which go with the equipment, listed below, follow the requirements for Electromagnetic compatibility.**

- **Pair of disposable adhesive pads, adult size**
- **Pair of disposable adhesive pads, child size**
- **Power supply for charging internal battery**
- **USB cable**

**WARNING: using cables and accessories different from the ones specified above, except for cables and accessories sold by Instramed as replacement pieces, may result in emission gain or immunity decrease of the equipment.**

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

# Electromagnetic emissions

| Directives and manufacturer declaration - electromagnetic emissions | | |
|---|---|---|
| The Isis 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 Isis 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 Isis 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 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Complies | |
| NOTE: It is of paramount importance that the true efficacy of the RF shielding and the true attenuation of the RF filter of the shielded location are checked to ensure that they meet or exceed the minimum values specified. | | |

# Electromagnetic immunity - General

| Directives and declaration of the manufacturer - electromagnetic emissions | | | |
|---|---|---|---|
| The Isis 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<br>± 8 kV air | ± 6 kV contact<br>± 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<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>± 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)<br>± 2 kV common mode (phase – ground) | ± 1 kV differential mode (phase – phase)<br>± 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 | < 5% $U_T$<br>(> 95% dip in $U_T$) for 0,5 cycle<br>40% $U_T$<br>(60% dip in $U_T$) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$) for 25 cycles<br>< 5% $U_T$<br>(> 95% dip in $U_T$) for cycle of 5 seconds | < 5% $U_T$<br>(> 95% dip in $U_T$) for 0,5 cycle<br>40% $U_T$<br>(60% dip in $U_T$) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$) for 25 cycles<br>< 5% $U_T$<br>(> 95% dip in $U_T$) for cycle of 5 seconds | The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the defibrillator requires continued operation during power interruption, it is advisable that the Isis is supplied by an uninterrupted power source or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 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 Isis**

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

| Immunity Test | Test Level of ABNT NBR IEC 60601 | Compliance Level | Electromagnetic Environment – Directive |
|---|---|---|---|
| | | | **Portable and mobile RF communications equipment should not be used near any part of the Isis, including cables, with a separation distance less than the one advised, calculated using the equation applicable to the frequency of the transmitter.**<br>**Advisable Distance of Separation:** |
| Conducted RF IEC 61000-4-6 | 3 Vrms<br>150 kHz up to 80 MHz outside bands[a] ISM | $[V_1]V$ | $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$ |
| | 10Vrms<br>150 kHz up to 80 MHz outside bands[a] ISM | $[V_2]V$ | $d=\left[\frac{12}{V_2}\right]\sqrt{P}$ |
| Conducted RF IEC 61000-4-6 | 10V/m<br>80MHz up to 2,5GHz | $[E_1]V/M$ | $d=\left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz<br>$d=\left[\frac{23}{E_1}\right]\sqrt{P}$ 80 MHz 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]<br><br>Field strengths established by RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range[d].<br><br>Interference can occur around equipment marked with the following symbol:  |

NOTE 1: At 80MHz and 800MHz, 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

[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.
[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 Isis is used exceeds the level of RF compliance used above, the Isis 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 Isis.
[d] Over the frequency range 150kHz to 80MHz, the field intensity should be less than [V1]V/m.

# Electromagnetic immunity - Life support function equipment

**Advisable separation distances between mobile and portable RF communications equipment and the Isis**

The Isis is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the defibrillator can help to prevent electromagnetic interference by maintaining a minimum distance between the mobile and portable RF communications equipment (transmitters) and the Isis 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.

# ECG analysis algorithm

### Databases used for the VF/VT recognition algorithm tests:

- *MIT-BIH Arrhythmia Database.*
- *MIT-BIH Atrial Fibrillation Database.*
- *MIT-BIH Supraventricular Arrhythmia Database.*
- *European Society of Cardiology Arrhythmia Database.*
- *Creighton University Arrhythmia Database.*

### Test report:

- **Recording Methods: t**he files were acquired via internet through the MIT-BIH database and used via computer.
- **ECG Rhythm Sources:** MIT-BIH, on http://ecg.mit.edu/
- **Rhythm Selection Criteria:** rhythms were chosen according to notes present in the MIT-BIH database.
- **Criteria and Annotation Methods:** the rhythms were recognized and annotated in a separate file. Later they were recognized and compared for sensitivity and specificity calculations.

| | VF/VT | Nonshockable Rhythms |
|---|---|---|
| **Shock INDICATED** | A | B |
| **NO shock INDICATED** | C | D |

$$\text{Sensibility} = \frac{A}{A + C}$$

$$\text{Specificity} = \frac{D}{B + D}$$

Sensitivity is the equipment's percent ability to correctly identify a shockable rhythm.

Specificity is the equipment's percent ability to correctly identify a nonshockable rhythm.

**A** = True Positive

**B** = False Positive

**C** = False Negative

**D** = True Negative

A true positive (A) is the equipment's ability, in measurement units, to **correctly** identify a **shockable** rhythm.

A false positive (B) is the equipment's ability, in measurement units, to **wrongly** recognize a **shockable** rhythm.

A false negative (C) is the equipment's ability, in measurement units, to **wrongly** recognize a **nonshockable** rhythm.

A true positive (D) is the equipment's ability, in measurement units, to **correctly** recognize a **nonshockable** rhythm.

**Values measured with the AED using the specified database:**

| | VF/VT | Nonshockable Rhythms |
|---|---|---|
| **Shock INDICATED** | 329 | 23 |
| **NO shock INDICATED** | 10 | 454 |

**Sensibility = 97.05%**

**Specificity = 95,18%**

# Types of arrhythmia analyzed

**Nonshockable:**

- Sinus Rhythm/ Sinus Tachycardia/ Sinus Bradycardia;
- Atrial Tachycardia;
- Atrial Fibrillation;
- Atrial Flutter;
- Supraventricular Tachyarrhythmia;
- Normal Rhythm with Extrasystoles;
- Sinus Rhythm with Pacemaker;
- Asystole.

**Shockable:**

- Ventricular Tachycardia with several QRS amplitudes and widenings.
- Ventricular Fibrillation with several amplitudes.

| Rhythm Classes | Specifications |
|---|---|
| Shock - VF | The Isis meets IEC 60601-2-4 requirements for sensitivity > 90% |
| Shock - VT | The Isis meets IEC 60601-2-4 requirements for sensitivity > 75% |
| Nonshockable rhythms | The Isis meets IEC 60601-2-4 requirements for specificity > 95% |

# Specifications

# 8

## General specifications

| | |
|---|---|
| Dimensions: | 22 cm (8.7 in ) (L)<br>13 cm (5.1 in) (W)<br>29 cm (11.4 in) (H) |
| Weight: | Equipment – 2.90 Kg (6.38 lbs) |
| Internal rechargeable battery: | Type: Li-ion, 14,4VDC 4,0 A/h<br>Life: 10 hours in cardiac rhythm recognition mode (fully charged battery), or a minimum of 200 shocks at 200 Joules.<br>Time to fully charge the battery (when fully depleted): 5 hours. |
| Battery power supply charger : | AC 100 – 240 V/50-60 Hz<br>Consumption (maximum): Electric mains supply 1A<br>Output: 24 VDC, 1,5 A |
| Battery storage: | Storing the battery for a long period of time in temperatures higher than 35° C (95° F) will reduce its capacity and shelf life. |
| Pre-adjusted defibrillation scales: | Adults: 1st shock: 150J; next shocks: 200J<br>Children: 50 J |
| Internal memory storage: | 100 events or 2 hours of ECG recording |
| Protection rating: | IPX0 |
| Classification: | Internally Energized Equipment<br>CF type |

| | |
|---|---|
| Functioning mode: | Continuous Operation |
| Maximum time from rhythm analysis beginning to discharge readiness: | 20s |
| Maximum time from rhythm analysis beginning to full discharge readiness: | 25s |

## Environmental specifications

| | |
|---|---|
| Temperature: | Operational: 0 to 50ºC (32 to 122 ºF)<br>Storage: 0 to 70 ºC (32 to 158ºF) |
| Humidity: | Operational: 10 to 95% RH, without condensation<br>Storage: 10 to 95% RH, without condensation |

## Defibrillator

| | |
|---|---|
| Waveform: | Biphasic truncated exponential. Wave shaped parameters adjusted according to the patient's impedance |
| Shock application: | By means of multifunctional adhesive pads |
| Commands: | Front Panel Button (on/off). |
| Scales for defibrillation: | Adult: 150 and 200 J<br>Child: 50 J |
| Adults/children Selection: | Automatic due to the size of the pads |

| | |
|---|---|
| Charge command: | Automatic after identifying an arrhythmia |
| Shock command: | Front panel button, when blinking |
| Maximum time from rhythm analysis beginning to discharge readiness: | 20s |
| Maximum charging time: | 50 Joules: < 2 seconds<br>150 Joules: < 4 seconds<br>200 Joules: < 6 seconds |

*The rhythm detector and recognizer does not continue analyzing ECG after a shockable rhythm is detected*

| | |
|---|---|
| Pads size: | Adult = area: 82 $cm^2$ (32.3 $in^2$)<br>Child = area: 30 $cm^2$ (11.8 $in^2$) |
| Maximum output voltage: | 2000V |
| Maximum output current: | 80A (25Ω) |

## Precision of applied energy:

| Selected energy | Impedance | | | | | | | Accuracy |
|---|---|---|---|---|---|---|---|---|
| | 25 | 50 | 75 | 100 | 125 | 150 | 175 | |
| 50 | 49,0 | 52,0 | 53,0 | 52,5 | 51,5 | 48,0 | 45,5 | ±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% |

## Patient's impedance response table:

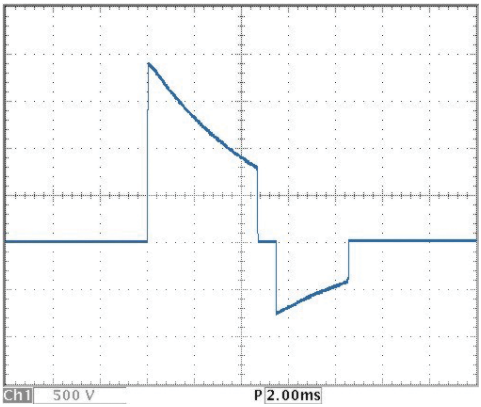
| Patient's impedance | Shock |
|---|---|
| Short-circuit | Shock inhibited |
| < 25 Ohms | Shock inhibited |
| > 25 Ohms e < 300 Ohms | Shock delivered with a waveform adjusted to the patient's impedance |
| > 300 Ohms | Shock inhibited |
| Open circuit | Shock inhibited |

## ECG rhythm recognition and detector table:

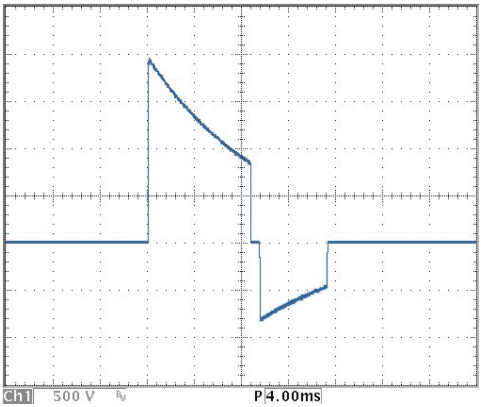
| | VF and VT | All other ECG rhythms |
|---|---|---|
| Shock indicated | 329 | 23 |
| No shock indicated | 10 | 454 |

Sensitivity: 97,05%
Specificity: 95,18%
Tests carried out with the MIT-BIH database.

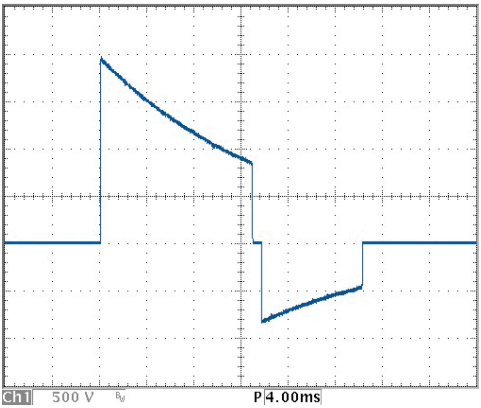
Values on the Y axis refer to voltage (volts) and values on the X axis refer to time (milliseconds).



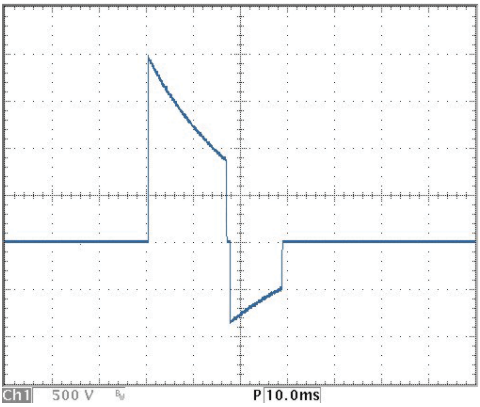

200J of energy at 25R impedance.



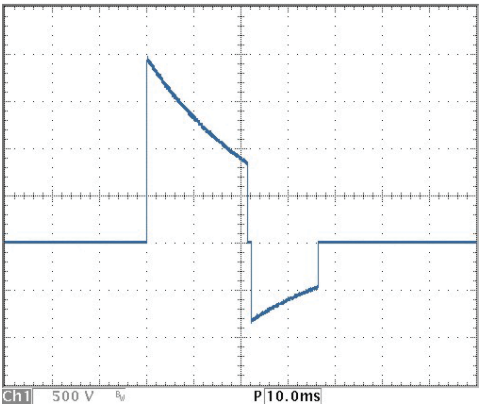

200J of energy at 50R impedance.



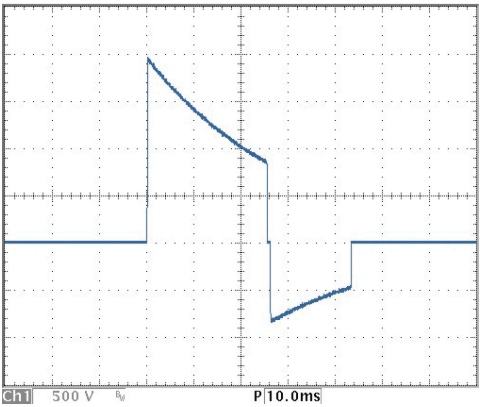

200J of energy at 75R impedance.



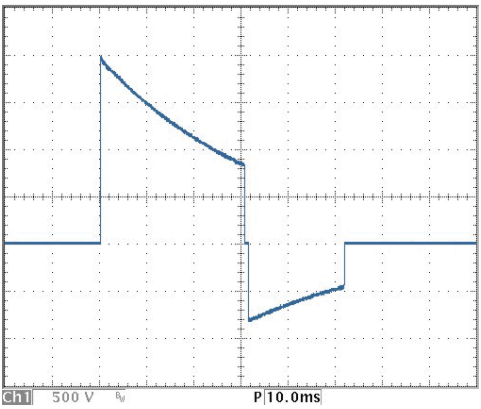

200J of energy at 100R impedance.




200J of energy at 125R impedance.




200J of energy at 150R impedance.




200J of energy at 175R impedance.

# Inspection and Maintenance

# 9

## Preventive Maintenance

Instramed recommends that the Isis be examined by a qualified technician every 12 months. We recommend that you contact the manufacturer for more information about qualified and trained personnel in your area 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.

Remember to check the status of the operational status indicator at least every 30 days (see page 18 - operational status indicator).

## Corrective Maintenance

If the equipment needs repair, this can only be done by INSTRAMED or its authorized representative, otherwise this Warranty certificate may no longer be valid.

**No internal parts are to be fixed by the user.**

**ATTENTION: periodic maintenance is needed independently of the equipment's use frequency.**

# Warranty Certificate

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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 its representative will repair or replace defective parts, at no expense to the equipment's owner.

**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 equipment's serial number.**

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:** _____

iSiS

AUTOMATED EXTERNAL DEFIBRILLATOR

INSTRAMED

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