User manual

i.on pro AUTOMATED EXTERNAL DEFIBRILLATOR WITH MANUAL FUNCTION

i.on 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.

I.on/I.on PRO User Manual R2.0 English 2022-05-26

Battery use

ATTENTION: observe the battery charge maintenance instructions.

Rechargeable batteries first use

The batteries of the I.on or I.on PRO are rechargeable Lithium-Ion (Li-Ion) batteries. Before the first use, the equipment must receive a full battery charge. For this, it needs to be connected to the electric current for at least 8 hours.

To charge the battery, disconnect it from the I.on/I.on PRO and connect the charger at the back of the battery and then connect it to the mains supply.

Time to battery full charge = 5 hours.

ATTENTION: the equipment may not be connected to the patient when communicating via USB with the SoftDEA app.

ATTENTION: the equipment blocks patient operation when communicating via USB with a PC.

See chapter 2 – SAFETY INFORMATION
I.on/I.on PRO devices only operate on battery power.

Occasional use

Even when disconnected (stand-by), the I.on/I.on PRO executes internal routines checking the status of the equipment. Despite of this procedure entailing a low power consumption, the battery charge may be consumed. Therefore, it is recommended that the battery be fully charged every 8 months.

Rechargeable batteries 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The battery can be withdrawn through the rear opening through a quick-release system. Remove the old battery and replace the new battery, observing the correct docking position.

Battery replacement is recommended every 02 (two) years or when the runtime is less than 01 (one) hour.

Package contents

Included items

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

- An I.on/I.on PRO automated defibrillator.
- A pair of disposable adult size adhesive pads.
- One first-aid kit containing 1 pair of surgical gloves, 1 scissor and 1 CPR mask.
- A transport bag.
- A USB cable.
- CD with instructions manual and SOFTDEA management PC software.

Optional items

- A power supply for charging the battery.
- A cable for connecting the power supply to the electric current.
- A pair of disposable child size adhesive pads.
- 3 Lead ECG cable.
- Accessory for chest compression (CPR Maestro).

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: +55 (51) 3073-8200.

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Introduction

1

The I.on/I.on PRO is a new generation semi-automatic external defibrillator (AED), which, through a care protocol, guides by voice, performs the diagnosis, considers the clinical variables and applies the treatment safely with the touch of only button.

Designed for emergency care, it is compact, light, resistant and easy to use.

only I.on PRO

I.on PRO

In its PRO version, the equipment offers the flexibility of the manual mode, which allows the health care professional to select the parameters of shock delivery treatment, such as selecting charge up to 360 Joules.

Through a touch screen with excellent contrast and visualization area, the user selects the operation mode and charge, while visualizing the ECG curve. The interface is simple and self-explanatory.

Characteristics

- Semi-automated.
- 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.
- Audio recording (optional).
- PC connection via USB.
- Software for connection, download and data management via PC.
- Biphasic shock.
- Automatic self-diagnosis of functions and battery.
- Easy access to pads for use and replacement.
- ECG Monitoring (optional).
- Chest compression performance feedback, with the use CPR Maestro (optional).
- Patient selection button (optional).

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 are 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

biphasic SHOCK

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

The I.on/I.on PRO 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 defibrillation.

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

Use criteria

The I.on/I.on PRO, as well as any other Automated External Defibrillator, must only be used if the following circumstances, as a whole, are presented:

- **Unconscious victim.**
- **Not breathing.**
- **No pulse (for professionals).**

Other important considerations regarding the use of the I.on/I.on PRO:

- 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 I.on/I.on PRO 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 I.on/I.on PRO 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.

I.on/I.on PRO ONLY works with battery.

Warnings

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

WARNING: not recommended for patients younger than one (01) year old.

ATTENTION: the patient's movements can confuse the correct detection of rhythm and delay therapy. Do not perform maneuvers with the patient and keep him still during rhythm analysis.

WARNING: I.on/I.on PRO can be used by patients over 01 (one) year old, regardless of their weight.

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: 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 I.on/I.on PRO 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.

NOTICE: do not modify this equipment without authorization from instramed.

ATTENTION: the equipment may not be connected to the patient when communicating via USB with the SoftDEA app.

ATTENTION: the equipment blocks patient operation when communicating via USB with a PC.

ATTENTION: the I.on/I.on PRO was designed to have no loose parts or small parts, but if any come loose, there is a risk of asphyxiation by swallowing or inhalation, so keep the equipment and its materials out of reach of children.

WARNING: the I.on/I.on PRO and its accessories are free of latex and allergy-causing components.

ATTENTION: the I.on/I.on PRO may experience problems or have its performance affected if it is near sources of heat or humidity, for example near heaters, cooking equipment, or open areas. For this reason, try to keep the I.on/I.on PRO in areas protected from these conditions to ensure that it functions perfectly.

Adverse events or side-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.

Possibility of superficial skin burns. To minimize the effect, in the case of adhesive pads, apply them immediately after removal of the protective envelope and securely attach to the patient's skin. The patient's skin must be dry.

Possibility of reduction of treatment efficiency. The patient's skin must be dry, otherwise the electric discharge may leak. Never apply conductive gel.

Possibility of reddish and/or bruised skin at the application place (thorax) by the use of CPR MAESTRO. It is recommended for cases of resuscitation maneuvers of long duration, the use of a gauze between the skin and the CPR MAESTRO.

Possible BURNED/REDNESS SKIN, due to the HIGH VOLTAGE and HIGH CURRENT delivered. But it becomes more severe damaged as the progressive counting of the delivered shocks. These side-effects depend also on the quantity of delivered shocks.

ECZEMAS on the skin, due to a bad biocompatibility of the adhesive pads or ECG electrodes. The accessories supplied with the product are biocompatible according the ISO 10993 standard.

Degraded or loose electrodes can affect the performance of the equipment, with the possibility of reduced efficiency or inability to provide treatment.

Animals or pests, such as birds, rodents and others, can cause perforations, break connections, or lead to loss of contact, compromising the performance of the equipment. For this reason, try to keep the I.on/I.on PRO in areas protected from these conditions to ensure that it functions perfectly.

The I.on/I.on PRO has bright colors to make it easy to identify in an emergency, on the other hand, it may attract the attention of children. To avoid the risk of suffocation or degradation of the equipment's performance, keep it out of reach of children.

Standards

I.on/I.on PRO was designed following performance and safety national and international standards. Among them are:

- IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- 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.
- IEC 60601-1-6 - Medical Electrical Equipment - Part 1-6: General requirements for basic safety - Collateral Standard: Usability.
- IEC 60601-1-8 - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standards: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- NBR IEC 60601-1-9 - Electromedical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for design and compliance.

- NBR IEC 60601-1-11 - Electromedical equipment Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for electromedical equipment and electromedical systems used in domestic health care environments.
- NBR IEC 60601-2-4 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators.

Or equivalent IECs.

The current versions of technical standards can be verified on the Product Conformity Certificate, available at www.instramed.com.br/certificates.

All instramed equipments that has AED mode are manufacture with current AHA protocol.

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

Instramed recommends cleaning the equipment monthly and its accessories at each patient exchange, or in shorter periods whenever the existence of dirt or contamination is evident.

CLEANING THE EQUIPMENT

- Disconnect the equipment from the mains supply before cleaning it.
- Wipe the external part of the device with a cloth moistened with water (almost dry) and neutral liquid soap until the entire surface is free of dirt. Never allow cleaning agents or water to enter the cabinet slits, display, and openings for connectors.
- Repeat the procedure only with the cloth moistened with water (almost dry) to remove soap residue.
- Dry the equipment with a clean and dry cloth.
- Perform the procedure in room temperature.

CLEANING THE ACCESSORIES

For the ECG cable

- Clean the cable, the connection box and the surfaces of contact with the patient with a soft cloth moistened with water or neutral disinfection solution, dry the cable to use again.
- The cleaning must be periodic.
- Keep the plugs dry.

For the CPR MAESTRO

- Moisten a cloth with clean water and neutral detergent and clean the device until all dirty is removed.
- Use a second dry cloth to remove excess of liquid and/or foam.
- Moisten a third cloth with Alcohol 70º and pass lightly on the product.

IMPORTANT RECOMMENDATIONS

- Never immerse in liquid and never spill liquid of any kind on any part of the equipment.
- Do not use any other cleaning products not recommended by this manual.

NEVER sterilize any parts of the equipment, regardless of the sterilization method, as this would damage the mechanical structure and compromise the product's operation.

The above recommendations ensure that the device will support, without damage or deterioration of safety factors, the cleaning and disinfection process necessary.

Connection to other equipment

When connecting the I.on/I.on PRO to any device, ensure that the equipment is operating correctly before clinical use.

Disposing of the device

As provided in Brazilian environmental legislation, equipment and parts that do not have more use conditions should be referred to the manufacturer for proper final destination, thus preserving natural resources and contributing to the conservation of the environment.

For the disposal of Instramed products, contact us through the telephones available on the website “www. instramed.com.br” or by e-mail “qualidade@instramed.com.br”.

Avoid contamination of the environment, humans, or other equipment by make sure to properly 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 I.on/I.on PRO 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	Description
	Follow the instructions for use.
	ATTENTION.
	General WARNING symbol.
	WARNING: dangerous voltage.
	Power supply connector.
	Non-ionizing radiation.
	USB connector.
	This side up.
	Fragile equipment.
	Maximum stacking of 4 units.
	Keep away from rain.
	Storage temperature limits.
	Operation temperature limits.
	Minimum and maximum atmospheric pressure.
	Minimum and maximum relative humidity.
	Recyclable paper.
	Remains of electrical and electronic equipment. Dispose of separately from other disposables.
	Mark of conformity according to the European Community. “2460” stands for the number of the Notified Body.
	Internal exclusive use.
	Direct current.
	CF applied part - Defibrillation proof .
	On/Off (push-push).

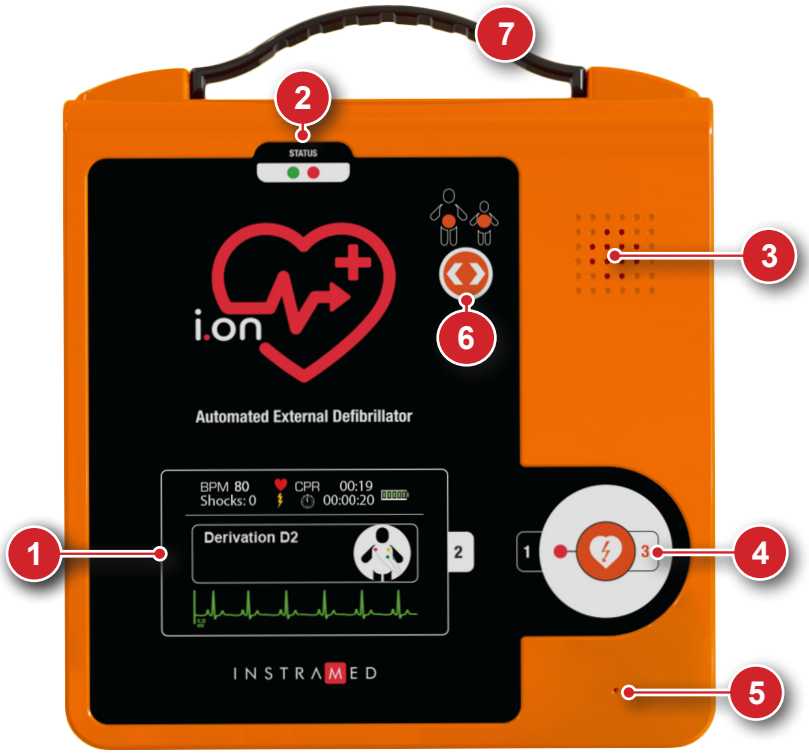
	Manufacturer.
	European representative.
	Serial Number.
	Electric polarity of the rechargeable battery power supply.
	Does not contain natural rubber LATEX.
	Do not reuse.
	Non-sterile.
	Do not use if the packaging is damaged.
	Keep away from sunlight.
	Adhesive pads operation temperature limits.
	Check instructions for use.
	Lot code.
	Catalog number.
	Date after which the product cannot be used.

The norms EN 60601-1 and ISO 15223 are used as reference to the symbols.

The equipment

3

Front Panel - Models I.on and I.on PRO with LCD screen



1. Touch screen: presents operational information and allows for manual interaction with the device.
2. Operational status indicator.
3. Speaker.
4. Start button.
5. Microphone (optional).
6. Patient selection button (optional).
7. Handle set (optional).

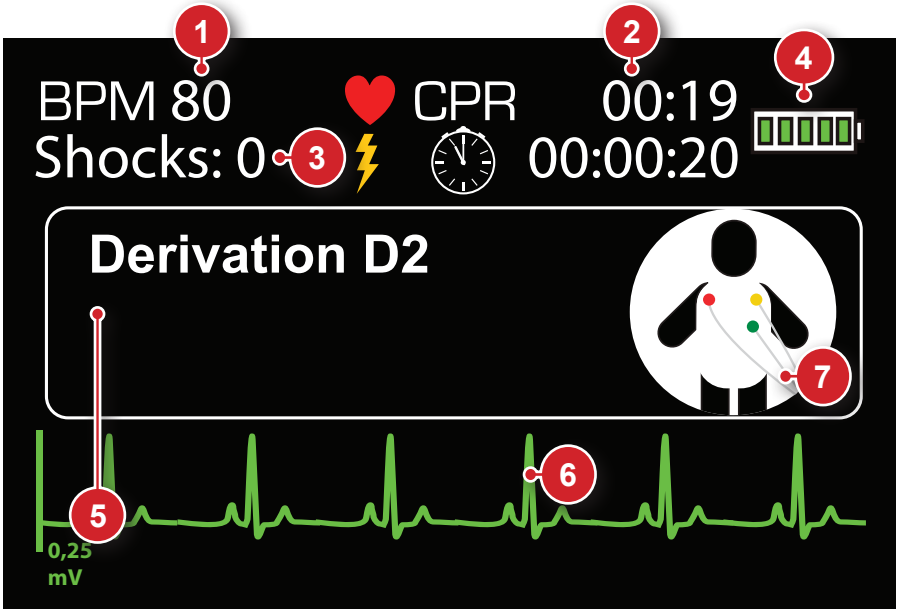
On the next pages you will find the detailed description of each component of the front panel.

1 - Touch screen

I.on – with LCD screen only

A) Model I.on (with LCD screen)

The I.on displays the following items on screen when connected to the patient:

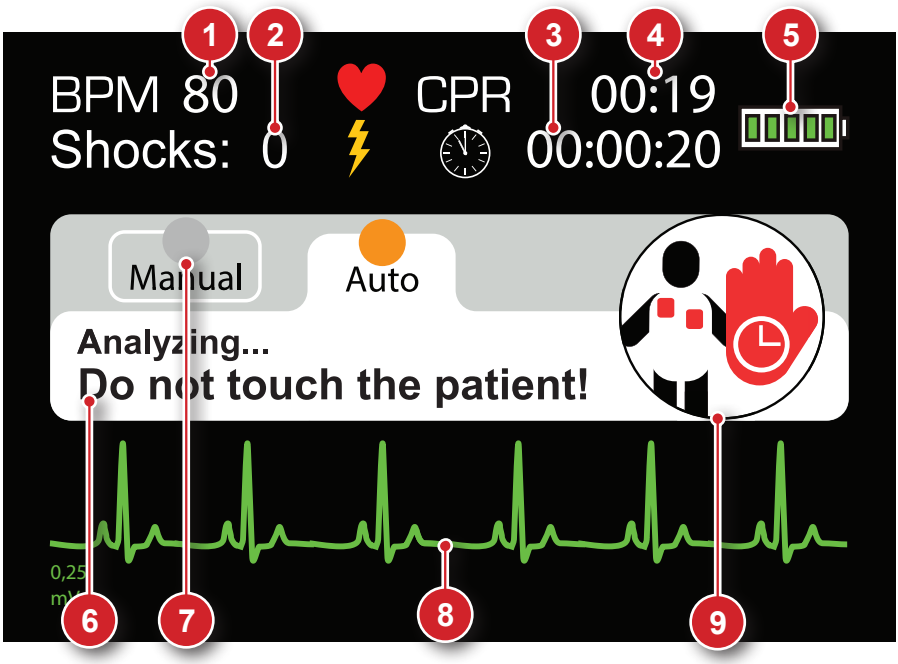


1. Heart beats per minute.
2. CPR interval counter: counts the interval between discharge delivery, helping in the CPR.
3. Shocks counter: shows the total number of defibrillations successfully executed.
4. Battery status.
5. Orientation message.
6. ECG curve.
7. Icon indicating the defibrillation stage.

only I.on PRO

B) Model I.on PRO - Automatic mode

As default, the device starts operating in AUTOMATIC MODE. In this configuration, the I.on PRO presents the following items on the screen when connected to the patient:

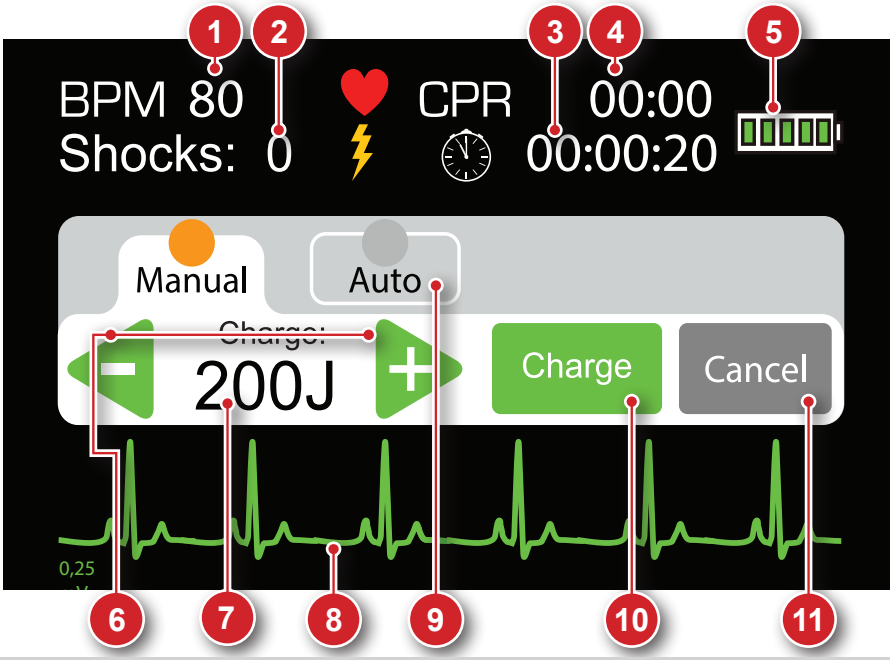


1. Heart beats per minute.
2. Shocks counter: shows the total number of defibrillations successfully executed.
3. General timer: shows the total time of the equipment being on.
4. CPR interval counter: counts the interval between discharge delivery, helping in the CPR (Cardiopulmonary resuscitation) massage.
5. Battery status.
6. Orientation message.
7. Manual mode button.
8. ECG curve.
9. Icon indicating the defibrillation stage.

only I.on PRO

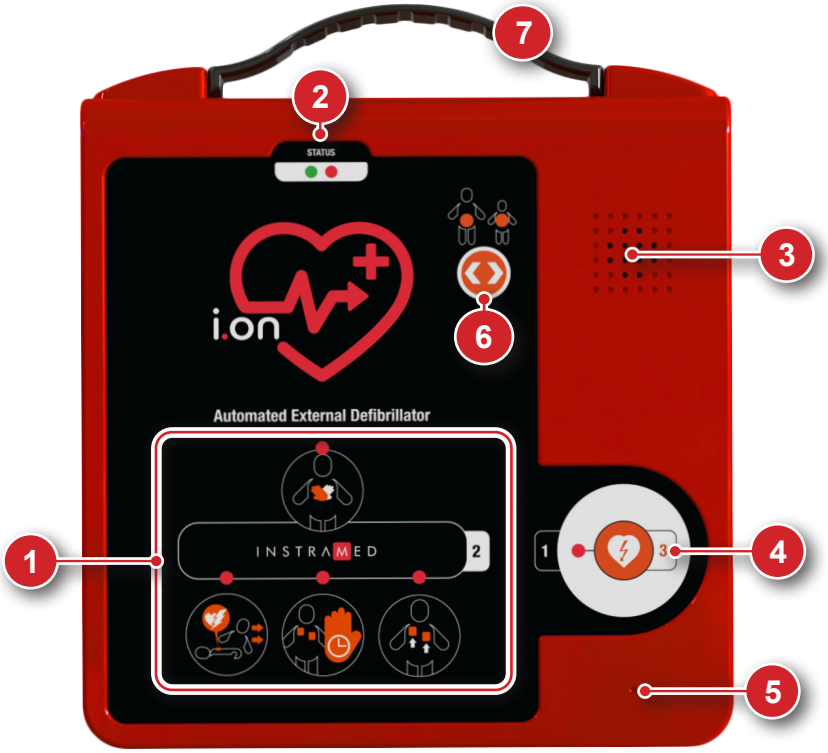
C) Model I.on PRO - Manual mode

If the user decides to switch to manual mode, the equipment will function as a standard defibrillator. In this situation, it will be necessary to select the appropriate charge according to the type of patient without the I.on PRO's intervention or orientation. Energy charging, delivering the shock and CPR interval counting will be the user's entire responsibility.



1. Heart beats per minute.
2. Shocks counter: shows the total number of defibrillations successfully executed.
3. General timer: shows the total time of the equipment being on.
4. CPR interval counter: in manual mode this indicator shows the continuous counting since the beginning of the operation.
5. Battery status.
6. Charge selector: allows the user to select the desired energy charge.
7. Selected charge.
8. ECG curve.
9. Automatic mode button.
10. Charge button: charges the defibrillator to the selected energy setting.
11. Cancel button: disarm the stored charge. Charge may be disarmed at any time, whether the charge is ready or not.

Front panel - Model I.on without LCD screen

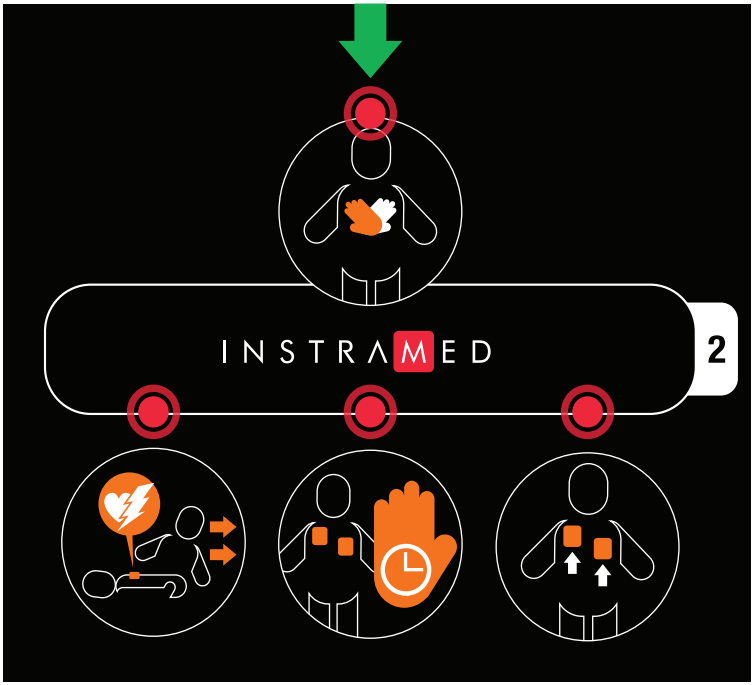


1. Indicative LEDs of the care stage.
2. Operational status indicator
3. Speaker.
4. Start button.
5. Microphone (optional).
6. Patient selection button (optional).
7. Handle set (optional).

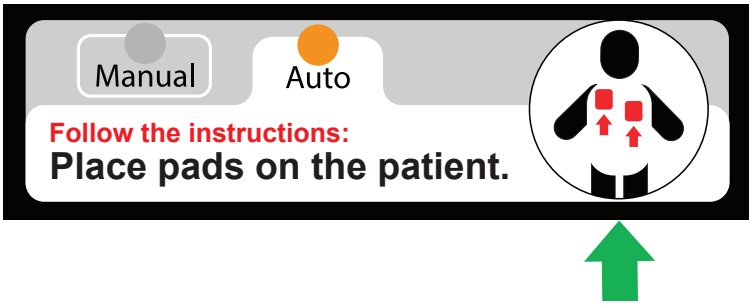
On the next pages you will find the detailed description of each component of the front panel.

1 - Instruction pictograms

In the I.on, the assistance step is shown by the LED indication above the pictogram.



In the I.on PRO, the pictogram will be displayed on the LCD screen.



2 - Operational status indicator

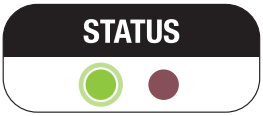
The I.on/I.on PRO performs a weekly complete auto test as standard* allowing the user to know the operational status of the device. This status is informed by a visual indicator (see picture below), voice messages and sound signals.

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.

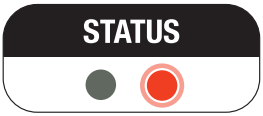
***Check availability for daily, weekly or monthly auto-test configuration.**

VISUAL INDICATOR

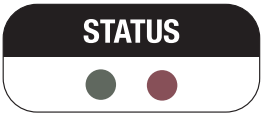
The visual indicator LEDs flash at a 5-second interval to report the following status.



Indicates that the equipment is operational and ready for use.



It indicates that the device **DOES NOT HAVE ENOUGH CHARGE IN THE BATTERY TO OPERATE** or presents another internal defect. In case of non-rechargeable battery, change the battery immediately. In case of rechargeable battery, charge the battery immediately. After changing or recharging the battery, turn on the equipment to perform the auto test. If the indicator remains red, contact Instramed Technical Support or an authorized representative. It indicates that the device **DOES NOT HAVE ENOUGH CHARGE**.



It indicates that the device **DOES NOT HAVE ENOUGH CHARGE IN THE BATTERY TO OPERATE** or presents another internal defect. In case of non-rechargeable battery, change the battery immediately. In case of rechargeable battery, charge the battery immediately. After changing or recharging the battery, turn on the equipment to perform the auto test. If the indicator remains red, contact Instramed Technical Support or an authorized representative. It indicates that the device **DOES NOT HAVE ENOUGH CHARGE**.

NOTE: EVEN AFTER THE BATTERY HAS BEEN COMPLETELY CHARGED, the operational status indicator may continue to show an 🔴 or some time.

The display will only change from 🔴 to 🟢 when the I.on/I.on PRO performs the auto test routine or if the device is turned on/off by the user.

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

SOUND INDICATOR

Along with visual indication, the I.on/I.on PRO emits electronic beeps.

ATTENTION: the device will not turn on in case of low battery or presenting general failure. In this case only the audible beep warning will be issued.

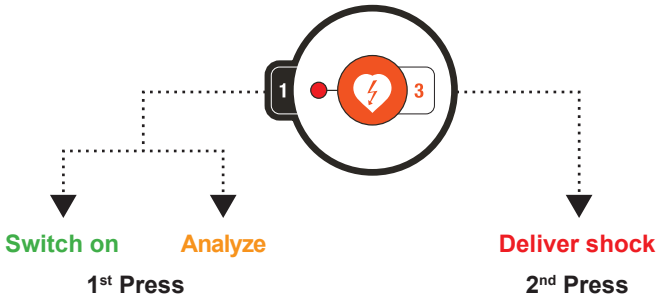
3 - Speaker

The I.on/I.on PRO 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 I.on/I.on PRO 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.

4 - Start button

The I.on/I.on PRO offers a unique technology that allows the operation of the device to be performed with just one button, completely safe.



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 I.on/I.on PRO 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".

Even so, there are two ways to manually switch off: press the start button for three seconds and remove the pads (after 30 seconds without the pads the equipment will automatically shut down).

5 - Microphone (optional)

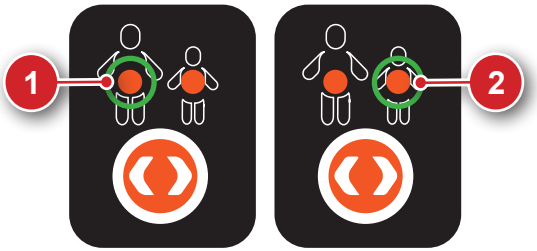
The I.on/I.on PRO has the functionality of storing ambient sound. The maximum storage capacity of ambient sound is 10 hours.

Stored audios can be transferred to the computer using SoftDEA (see section "Operating SoftDEA).

6 - Patient selection button (optional).

When using electrodes intended for adults, it is possible, through the patient selection button, to switch the equipment's operating mode to adult or child.

Selection of the patient type is indicated by the LEDs in the center of the pictograms, followed by the Adult mode/Child mode confirmation message.



1. Adult mode.
2. Child mode.

If the I.on/I.on PRO identifies the child electrode connection, the child mode is automatically selected and the patient selection button is inhibited from working.

Side connectors

1. ECG connector (only in the models with LCD screen).
2. CPR Maestro connector.
3. Disposable pads connector.

1 - ECG connector

Only models with LCD screen

Used for ECG cable connection
(see chapter 8).

2 - CPR Maestro connector

Used for connection of CPR Maestro accessory
(see chapter 9).

3 - Disposable pads connector.

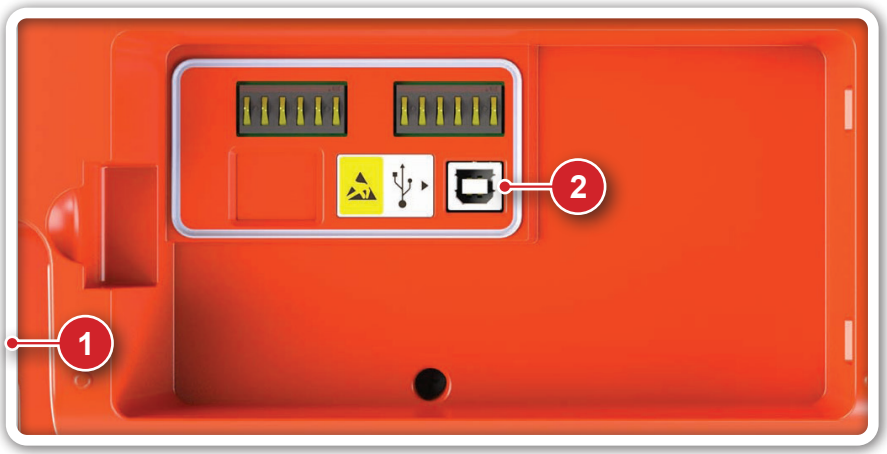
Used for connection of disposable pads to the equipment.

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

ATTENTION: disposable pads have defined expiration date. Check the enclosure for limit date for use and, if it is not used within this time, replace them with a new pair.

ATTENTION: only use original pads, supplied by Instramed. Failure to do so may result in malfunction.

Rear connectors



1. Battery compartment.
2. USB connector.

1 - Battery compartment

It holds the batteries of the equipment.

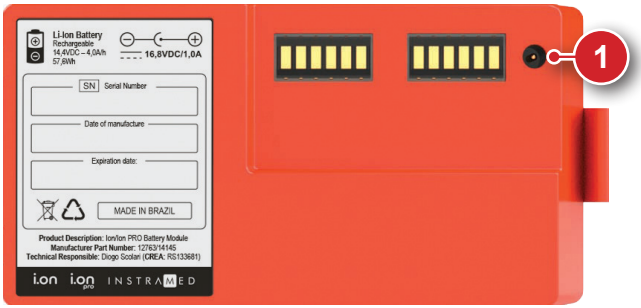
ATTENTION: in case of battery replacement, use original replacements from Instramed supplied by its authorized distributors.

2 - USB Connector

Used for connecting the equipment to a PC (see chapter 10).

Charging the battery

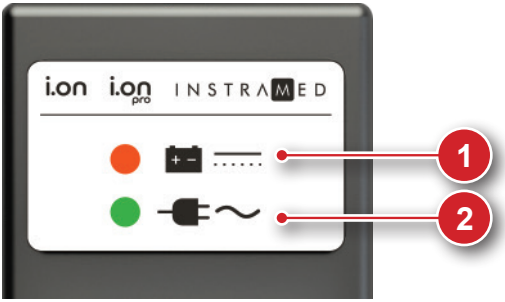
To recharge the rechargeable battery, only remove it from the equipment and connect it to the charger, using the input indicated below.



1. Battery charger connector.

VISUAL INDICATOR

Visual indicators of the charging process may be found in the charger.



1. BATTERY LED.

   ON: indicates that the battery is being charged.

   OFF: indicates complete charge.

2. MAINS LED.

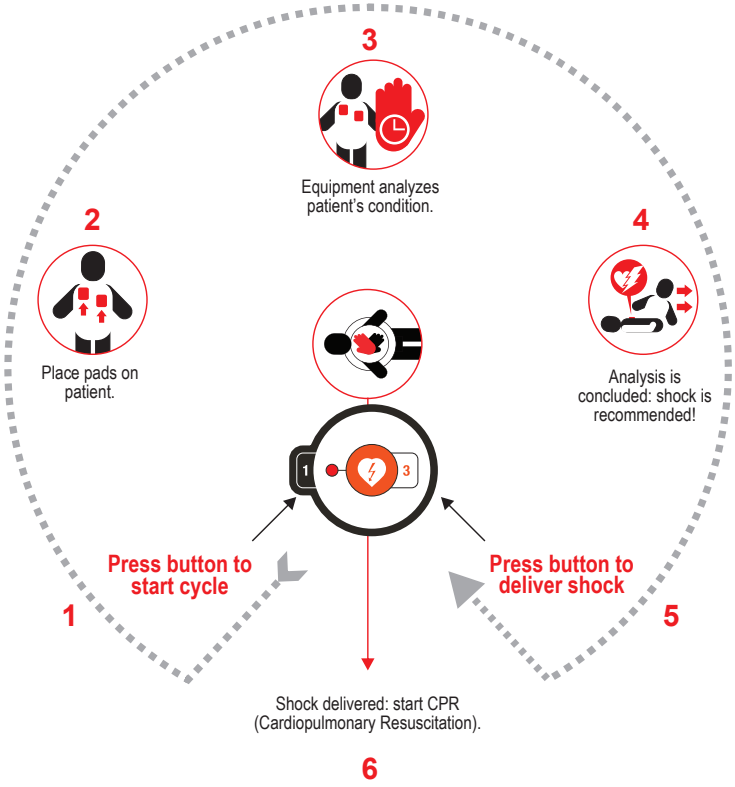
   ON: indicates that the equipment is connected to the mains supply.

Operating in AED mode

4

When in AED mode (Automated External Defibrillator), the I.on/I.on PRO identifies arrhythmias and selects the energy charge automatically. I.on/I.on PRO, on AED mode, is in accordance with American Heart Association 2015 Guidelines.

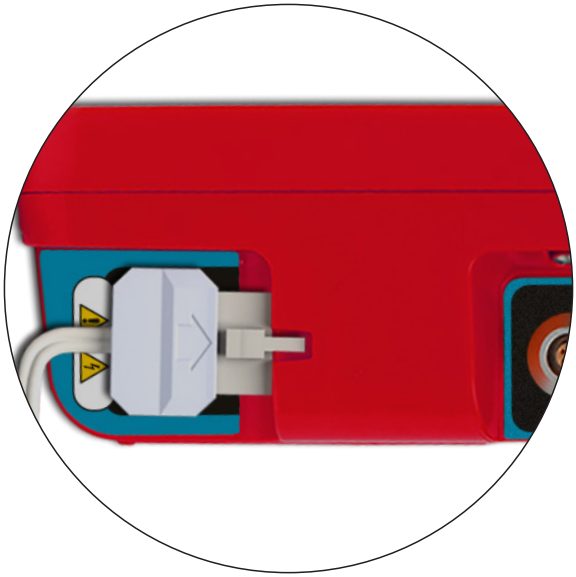
Below you will find a simplified introduction to how the I.on/I.on PRO operates. Be sure to carefully memorize the detailed guide on the next pages before operating the equipment.



The energy delivered is pre-adjusted at the factory according to the values below. The operator can only change this protocol using SoftDEA (see chapter 11).

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

Step 1



Before starting the operation, please call the emergency service.

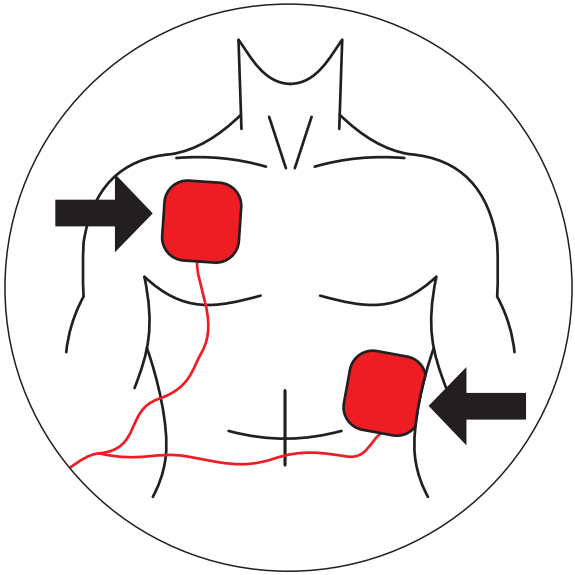
If the disposable pads have not been connected to the I.on/I.on PRO yet, attach the connector to the plug on the right side of the equipment.

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.

ATTENTION: 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: the pads are disposable and for single use, cannot be reused under any circumstances.

ATTENTION: after opening the wrapping, the pads should be used within 24 hours.

ATTENTION: in case of use for long periods, the pads should be replaced every 24 hours.

Step 3

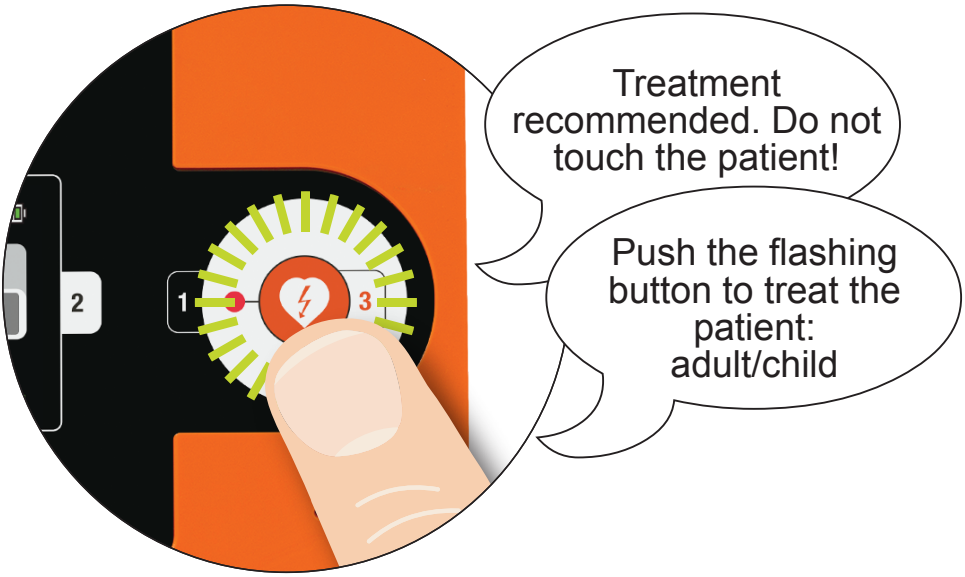
Press “START” button.

The I.on/I.on PRO will automatically enter the heart rate analysis mode and initiate the vocal commands, clearly and paused, so that the user can fully understand. Visual indications of each step will also be shown on the LCD screen or indicated by means of indicative LEDs, according to the model.

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 I.on/I.on PRO will announce: "TREATMENT NOT RECOMMENDED".

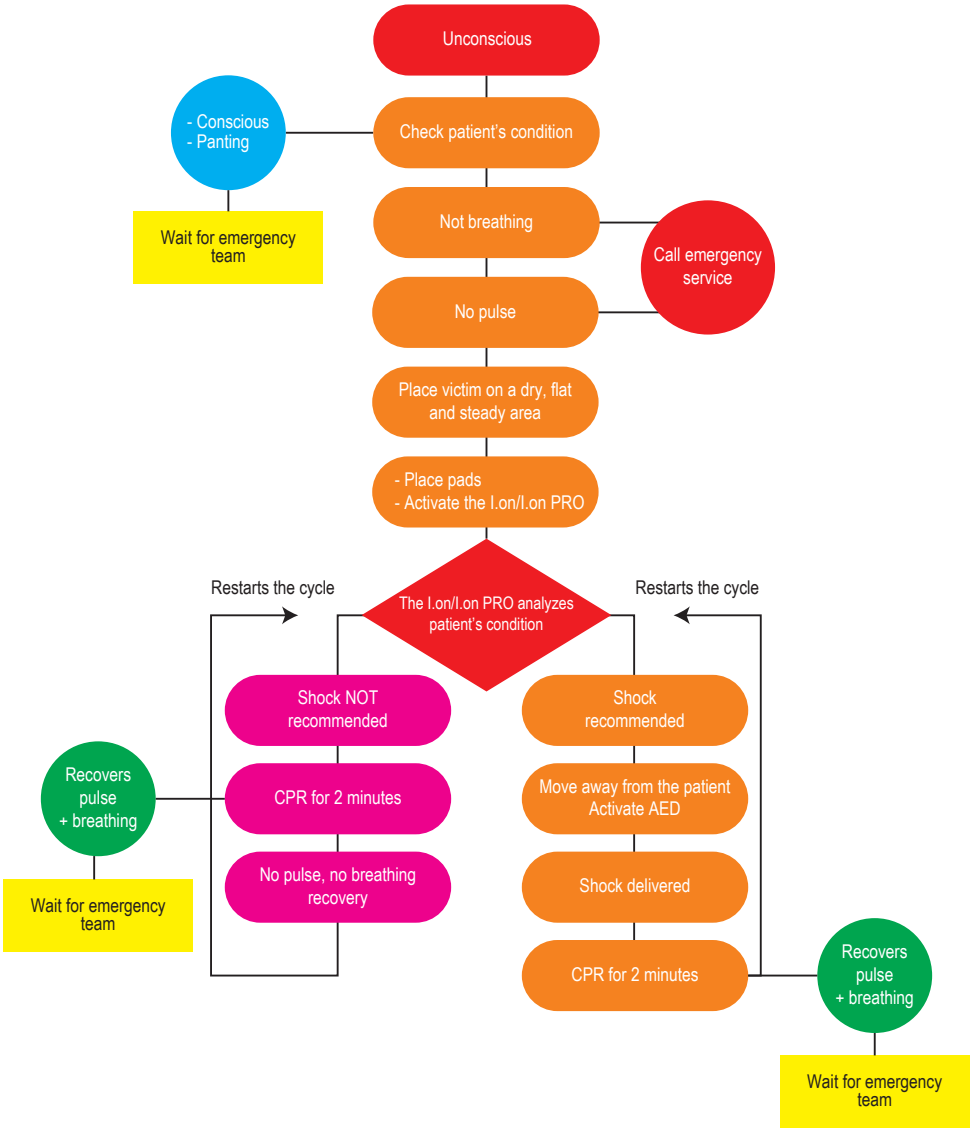
Check that the patient did not move during the analysis period. If so, restart the process. Otherwise, start the CPR procedure - cardiopulmonary resuscitation. Details in the next section.

Step 5

After the shock, start the CPR procedure (see more in section 6).

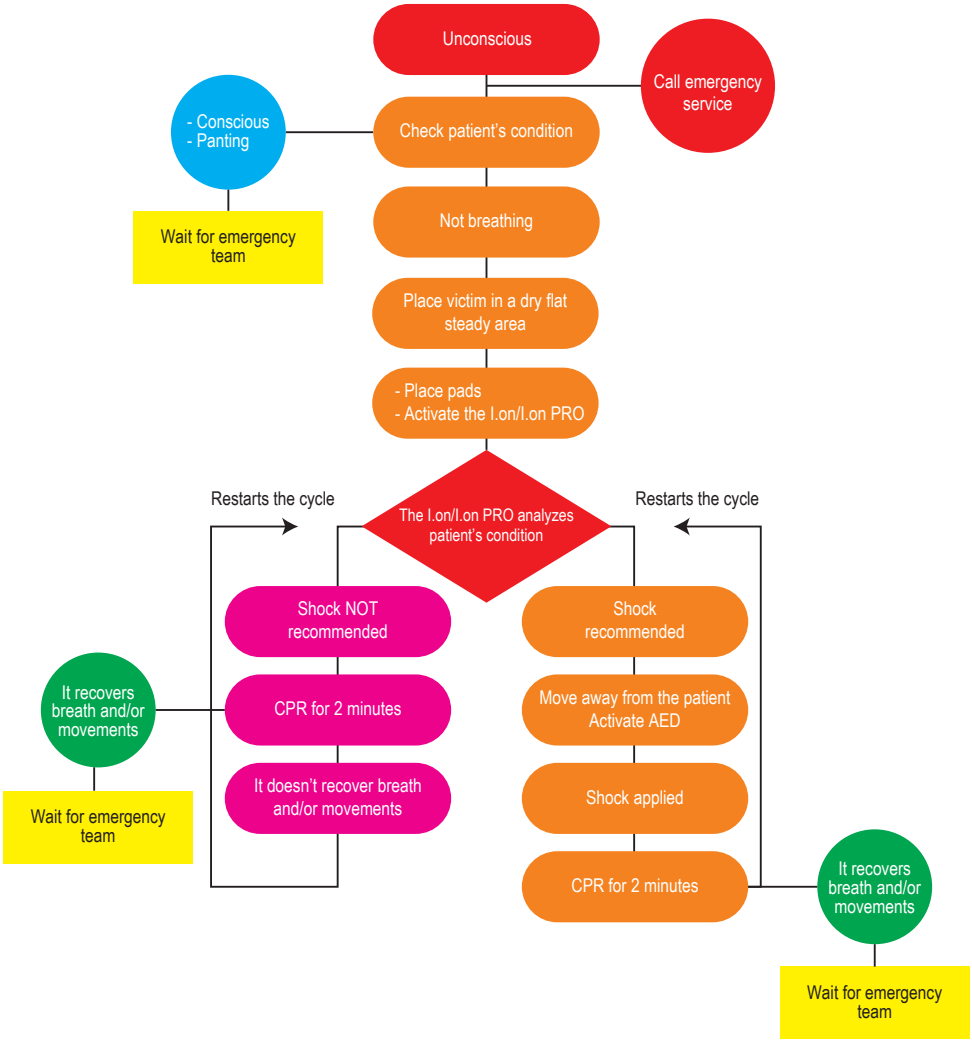
Simplified diagram of procedure in adults

Healthcare professional.



Simplified diagram of procedure in adults

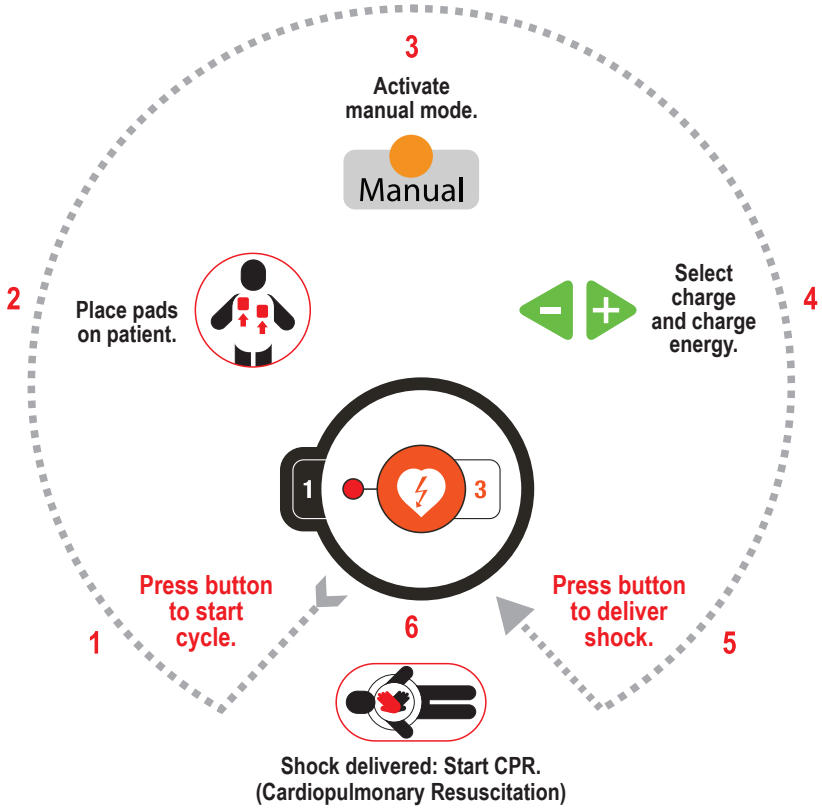
User without a degree in medicine, with previously training in the use of automatic defibrillators (AED) and CPR techniques.



Operating in manual mode

5

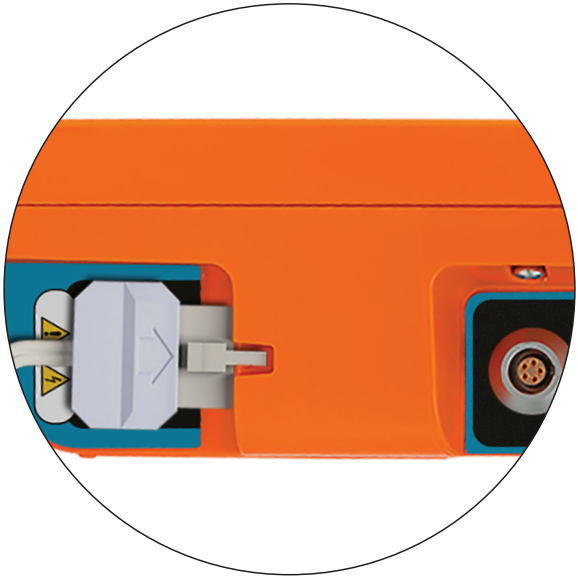
The I.on/I.on PRO enables manual mode operation, as a conventional defibrillator. In this situation, the device does not interfere with the treatment, and the user is responsible for choosing the energy, charging the charge and delivering the shock. After confirming the mode change, the I.on/I.on PRO ceases to emit sound and visual orientation, in addition to the automatic safeguards against shocks.



ATTENTION: the use of the manual mode is the user's entire responsibility. The use by non-qualified professional may cause severe damage and even the patient's death.

only I.on PRO

Step 1



Before starting the operation, please call the emergency service.

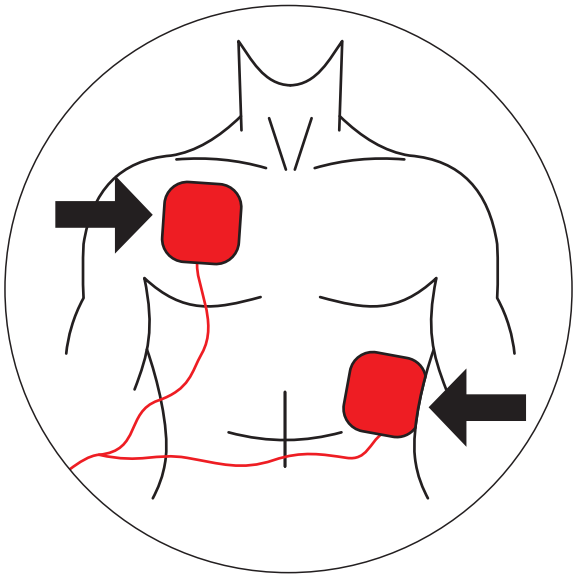
If the disposable pads have not been connected to the I.on or I.on PRO yet, attach the connector to the plug on the right side of the equipment.

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.

ATTENTION: 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: the pads are disposable and for single use, cannot be reused under any circumstances.

ATTENTION: after opening the wrapping, the pads should be used within 24 hours.

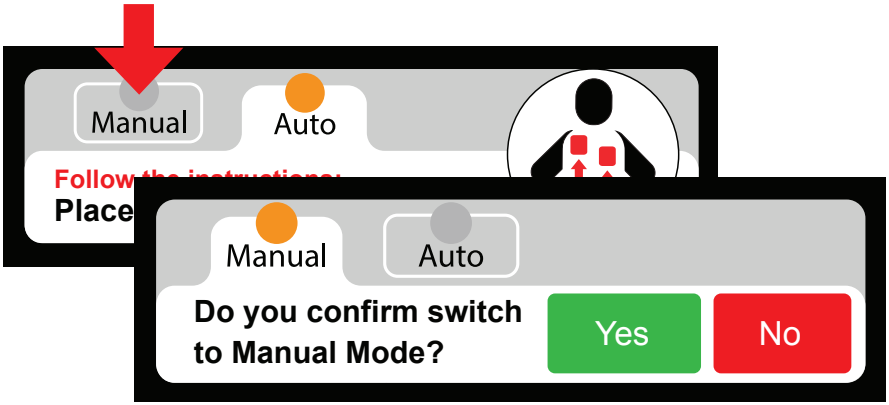
ATTENTION: in case of use for long periods, the pads should be replaced every 24 hours.

only I.on PRO

Step 3

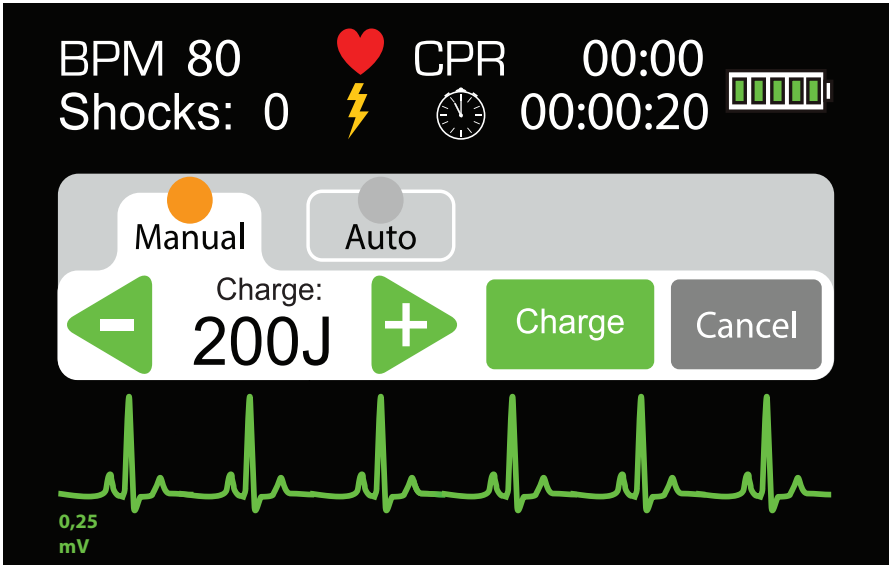
Press “START” button.

Press the MANUAL button on the device’s screen. Confirm this choice on the following screen. The I.on/I.on PRO will switch to manual mode.



If the user does not confirm the switch in 5 seconds, the device will return to automatic mode.

Step 4



Use − **and** + **buttons to select the desired charge.**

Use Charge **button to store the charge.**

Press .

The shock will be delivered.

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

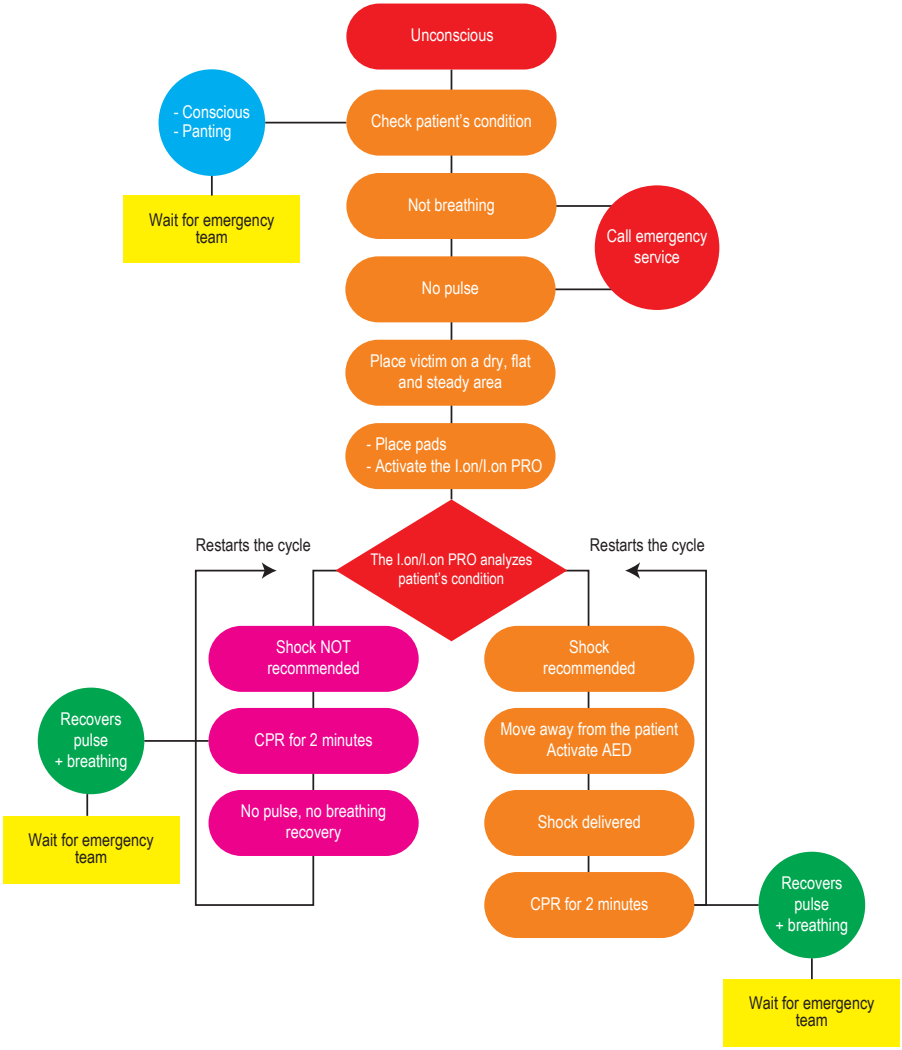
ATTENTION: disconnect other equipment which do not have defibrillation protection before defibrillating the patient.

Step 5

After the shock, start the CPR procedure.
(see more in section 6).

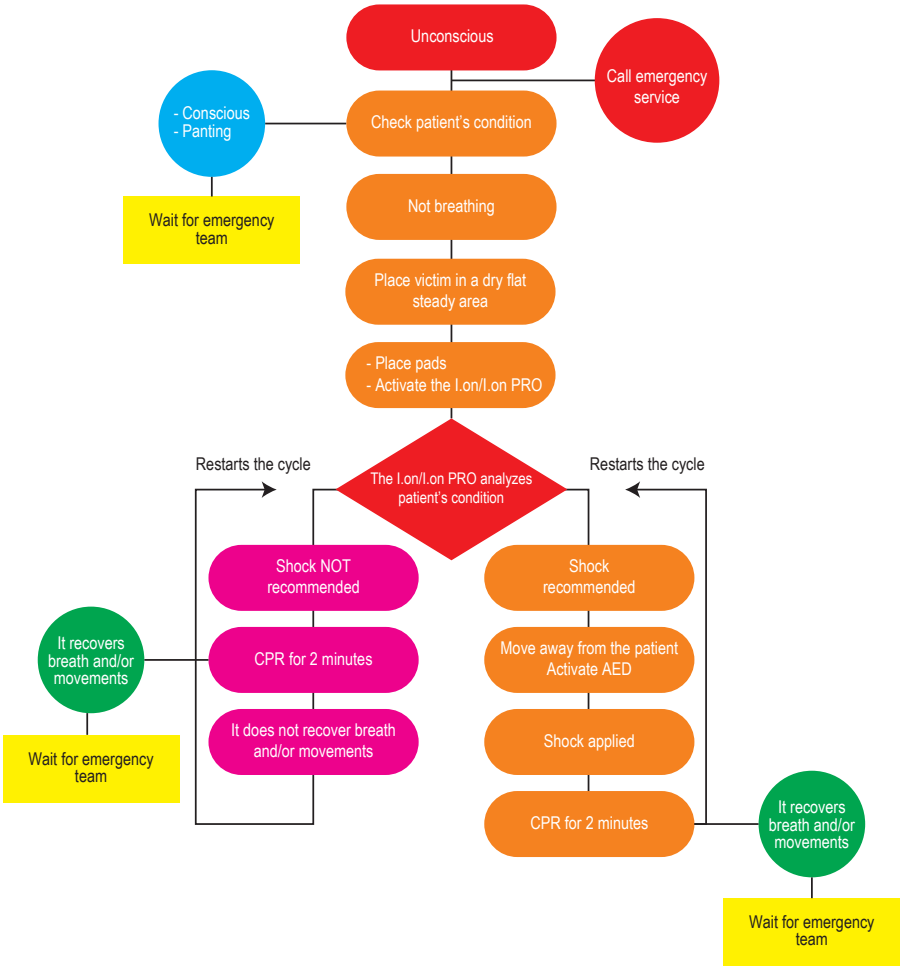
Simplified diagram of procedure in adults

Healthcare professional.



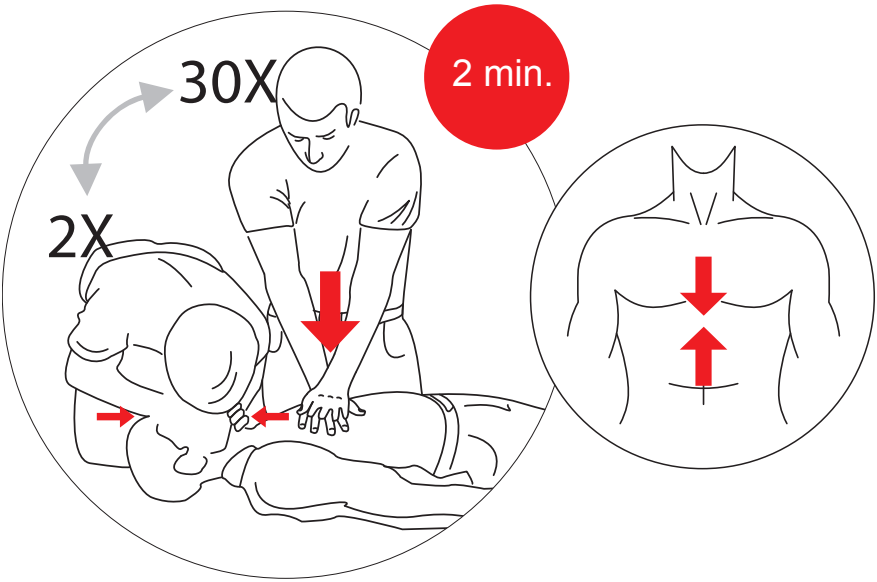
Simplified diagram of procedure in adults

User without a degree in medicine, with previously training in the use of automatic defibrillators (AED) and CPR techniques.



Applying CPR

6



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.

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 I.on/I.on PRO, 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 I.on/I.on PRO.

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

ATTENTION: the CPR techniques shown in this manual are only referential and do not substitute the specialized presential training which is mandatory for emergency care professionals.

ATTENTION: when using the mask to perform first aid breathing mouth to mouth, observe the statement "THIS SIDE UP", indicating the side that is facing up.

WARNING: the first aid mask and the surgical gloves are disposable, single use and cannot be reused under any circumstances.

Use in children

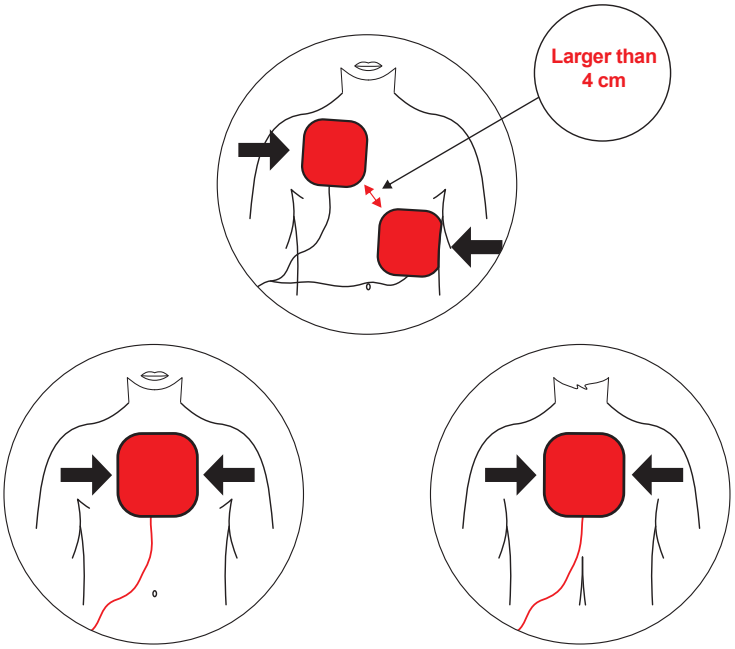
7

Using the I.on/I.on PRO on children under 8 years old

The I.on/I.on PRO 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 25 Kg, 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.**

ATTENTION: if using paddles intended for use in adult patients, select the CHILDREN'S OPERATING MODE using the PATIENT SELECTION BUTTON (optional).



(Chest) **Shorter than 4 cm** (Back)

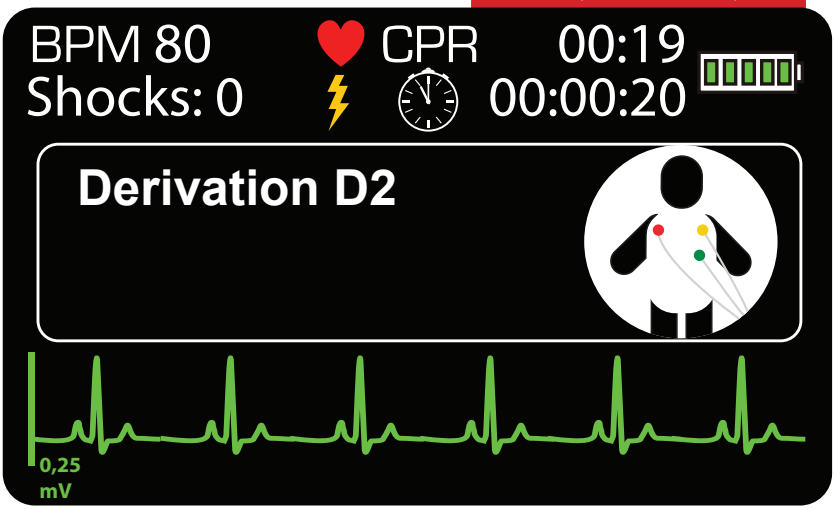
ECG monitoring

OP 8

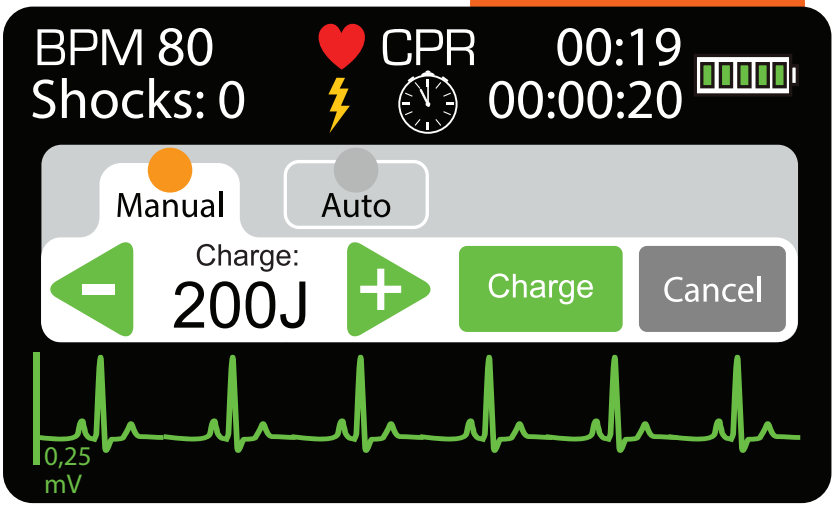
models with LCD screen only

ECG monitoring is available with the use of the 3-leads ECG cable (optional) on models with an LCD display. The I.on/I.on PRO monitors only the DII ECG derivation. The ECG sweep speed is fixed at 25 mm/s. The displayed ECG amplitude scale is automatic and shown in mV, according to images below.

I.on (with LCD screen)



I.on PRO

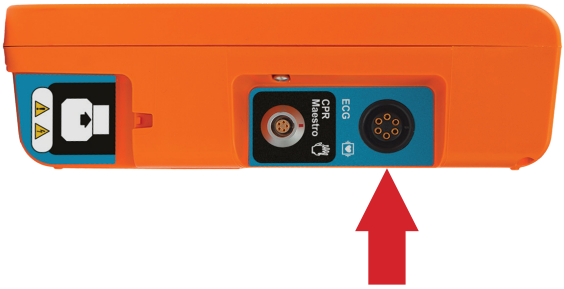


The device may operate in 3 distinctive ways:

- **Only adhesive pads connected:** the device works as an automated external defibrillator, using the AHA protocol.
- **ECG cable and adhesive pads connected:** the device will give priority to use of adhesive pads, operating as an automated external defibrillator, using AHA protocol.
- **Only ECG cable connected:** the equipment silently monitors the patient's ECG (always in DII derivation) and alarms when it detects a cardiac arrest situation. In this situation and in case of shock indicated, the adhesive pads must be connected.

Using ECG

Connect the ECG patient cable to the equipment, using the input indicated below, located on the side of the equipment.



Electrode technical description: adhesive conductor with hydrogel and silver sensor (Ag/AgCl), free of latex, biocompatible according to ISO 10993-1.

only models with LCD screen

CPR Maestro

OP 9

The CPR Maestro is an accessory from I.on/I.on PRO, created to help rescuers perform compressions in accordance with the latest CPR recommendations. Its sensors measure the frequency and depth of chest compressions, providing the user with real-time feedback. These information are displayed on CPR Maestro and I.on/I.on PRO screens and through sound recommendations.

NOTE: because it is an accessory, it cannot be used by itself. Only connected to I.on/I.on PRO.

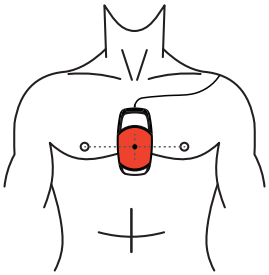
The on-screen and audible messages will only be displayed after the guidance "Perform CPR for 2 minutes".

To turn off the CPR Maestro, simply press the ON/OFF button for 3 seconds.

Using the CPR Maestro

1 - Connect the CPR Maestro to I.on/I.on PRO, using the input indicated below, located on the side of the equipment.

2 - Place the device on the patient's chest, according to the image below:



3 - Press the ON/OFF button, on the side of the equipment. At this moment, the equipment is not ready to be used yet.

This step is important and must always be followed. When the device is initialized, the sensors of the CPR Maestro are calibrated, allowing the evaluation of the compressions. Initialization with the device out of the recommended position may cause incorrect compression evaluations.

CAUTION: for long-lasting CPR in naked chest, place a gauze between the skin and the CPR MAESTRO to avoid risk of skin abrasion.

ATTENTION: do not use CPR MAESTRO on patients under 8 years old or under 25 Kg.

4 - A message on the CPR MAESTRO will be displayed to confirm that the device is positioned correctly in the patient's chest, where compressions will be performed. If it is, press the ON/OFF button again and start compressions.

Feedback

The user receives CPR feedback in the following ways:

- CPR indicative graphic on the CPR Maestro screen.

- Audio message.

Messages

The following messages can be displayed during the CPR Maestro use:

Compress harder: the rescuer did not reach the minimum depth required which is of 50 mm.

Allow full chest expansion: the rescuer is not allowing the patient's chest to return to total relief position.

Compress softer: the rescuer exceeded the limit of chest compression which is of 60mm.

Compress faster: the rescuer is performing the compressions at a frequency below the ideal limit, which is of 100 to 120 compressions per minute.

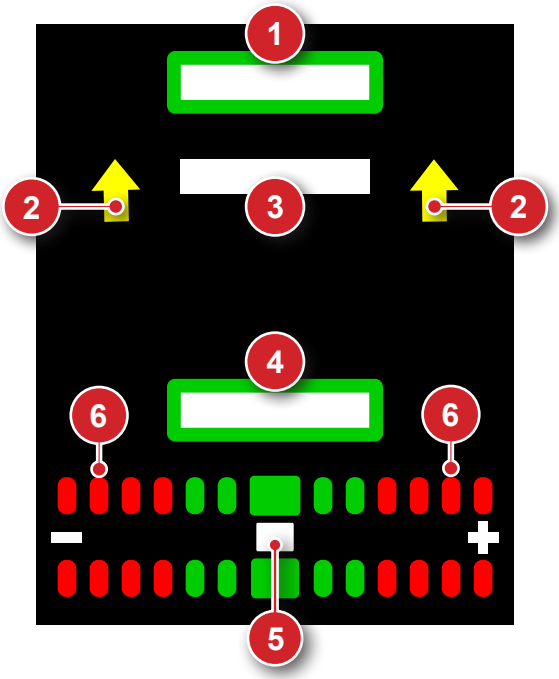
Compress slower: the rescuer is performing the compressions at a frequency beyond the limit.

Good compressions: the rescuer is performing an adequate massage.

Start CPR: the rescuer stopped doing the massages.

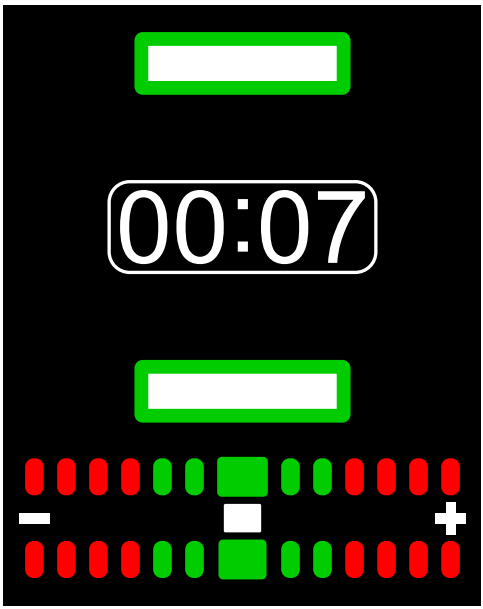
CPR graphic

The CPR graphic displays information about the frequency and depth of the compressions.



1. Chest full expansion indicator: when filled with the white indicates that the chest returned to the initial position of the compressions.
2. Indicative arrows of correction: when present, the arrows indicate that the movement must be wider in the indicated direction.
3. Depth indicative bar: indicates the current depth of the compression.
4. Maximum depth indicator: when filled with the white, indicates that the compression reached the ideal depth. When filled with the red, indicates too hard compression.
5. Frequency indicative bar: indicated the frequency of the compressions. When aligned with the red rectangles, indicates need of frequency adjustments.
6. Frequency indicators: the red rectangles indicate very low (on the left) or very high (on the right) frequency. The green rectangles indicate appropriate frequency.

When the rescuer stops the compressions, a chronometer is automatically displayed on the graphic area.



PC connection

10

Introduction

The I.on/I.on PRO 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 I.on/I.on PRO (only for authorized technicians).
- Check and update firmware version of the equipment (only for authorized technicians).

Requirements

Connecting the I.on/I.on PRO to a PC requires installation of the SoftDEA application in the computer to which a connection will be made. This software is in the CD which comes with the equipment.

To install SoftDEA, observe the following requirements:

- Windows 7 or Windows 10 operating system.
- CPU of 500 MHz or faster.
- Minimum 1 GB of RAM.
- Minimum 4 GB of free hard disk space.
- CD or DVD ROM reader unit.

For physical connecti on to the PC:

- One available USB port.

SoftDEA 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.

Installing the SoftDEA using the website

- Download the installer from the link: http://www.instramed.com.br/softwares.html
- Locate the downloaded file (the file name begins with the word SoftDEA and “exe” extension) in the “Downloads” folder on your computer and double-click it.
- Follow the installation instructions that appear on the screen.

Connecting the I.on/I.on PRO to a PC

- Connect the equipment only after installing SoftDEA.
- After the installation connect the equipment using the USB cable provided.

To access the USB connector, the user must remove the battery and plug the USB connector into the equipment and the PC. The equipment will use USB power to connect.

- Start the SoftDEA application.
- On the language selection screen, choose among Spanish, English, Polish or Portuguese. You only must select a language the first time you start the software.
- After the software reads the I.on/I.on PRO 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 SoftDEA application occurs.

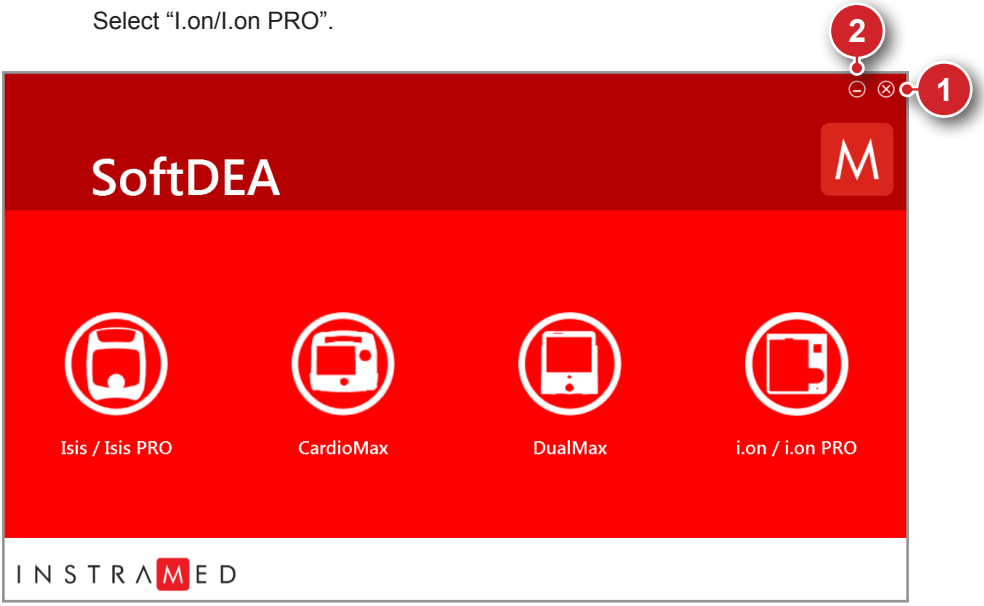
ATTENTION: the equipment blocks any operation on the patient when communication via USB with PC occurs.

Operating SoftDEA

11

Initial screen

Select “I.on/I.on PRO”.



1 – Close button

Press this button to close the application.

2 – Minimize button

Press this button to minimize the application.

Adjusts screen

To perform the operations on the adjusts screen it is necessary to connect the equipment to the PC, in which the SoftDEA is installed, using the USB cable provided.

1 – Options bar

Through the bar it is possible to access the software screens, just click on the desired option.

2 – Back button

Press this button to return to the initial screen, in which it is possible to choose the desired device.

3 – Clock button

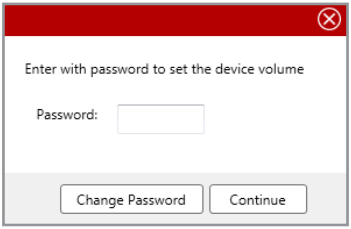
Press the “update” button so that the clock is synchronized with the time of the PC connected to the I.on/I.on PRO.

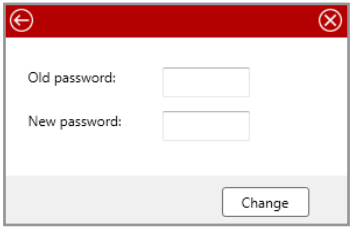
4 – Volume level

Using the mouse, select one of the five preset levels for the audio of the equipment. After clicking the desired volume level, a window requiring the password to perform the operation will open.

ATTENTION: level 1 is the lowest volume level (55 dB), and may be inaudible in a noisy environment.

In compliance with the standards of alarms (IEC 60601-1-8), the change of volume is performed by means of a secure password, to avoid misuse. The default SoftDEA password is 123456, but it can be changed by the user to have high security criteria.





Languages screen

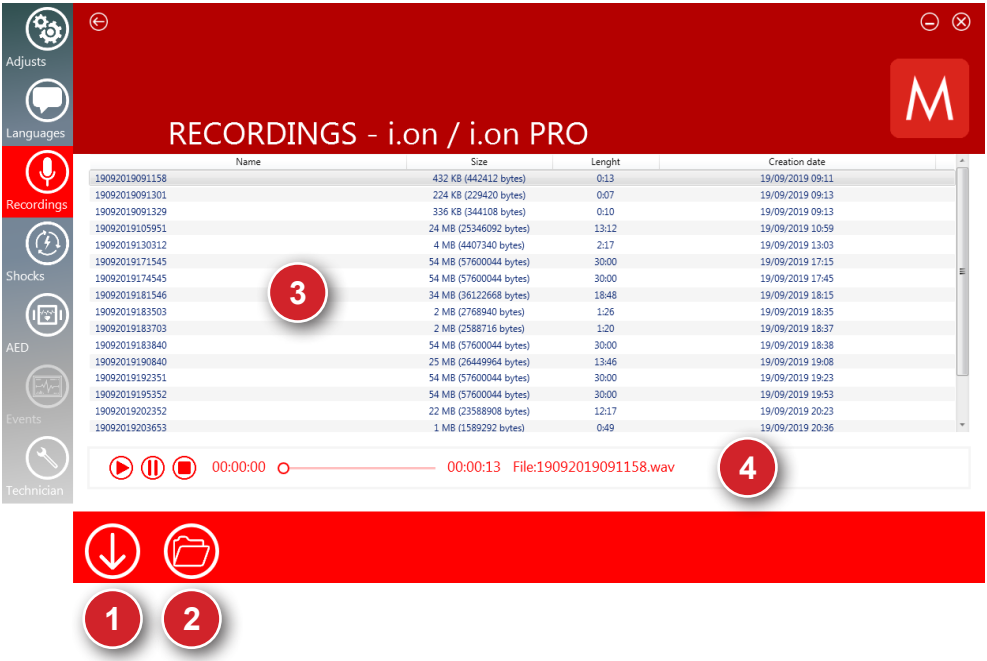
1 – On the application

Click on the desired language option. This feature alters the language of the voice warnings emitted through the speakers for the selected language.

2 – On the equipment

Connect the I.on/I.on PRO to the computer. Click on the desired language option. This feature alters the language of the voice warnings emitted through the speakers for the selected language.

Recordings screen



1 - Download

Press this button to save to the PC the currently displayed information set. A window will open allowing the user to choose the desired file storage location.

2 - Open

Press this button to open ".wav" files previously stored on your computer. One or more audio files can be opened at one time.

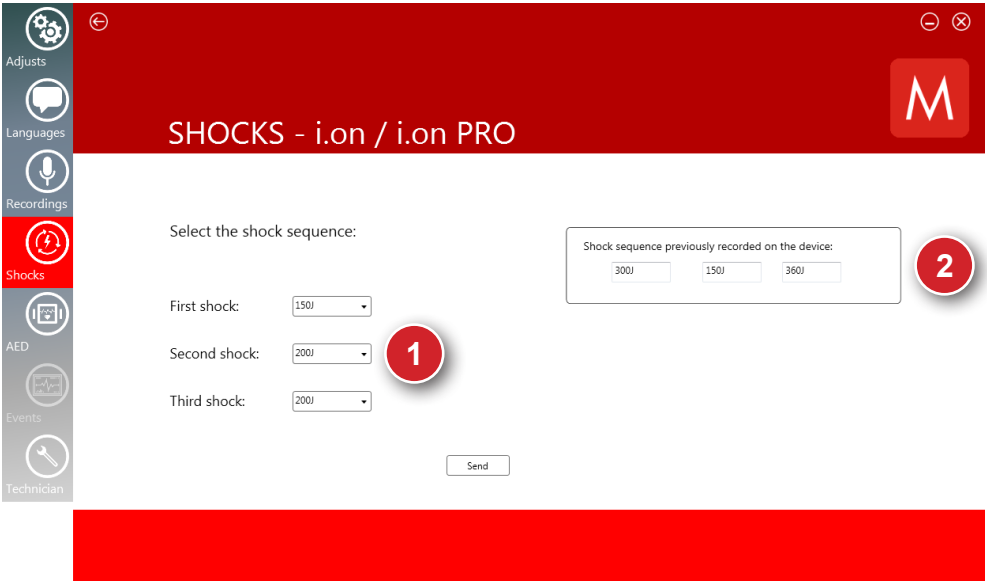
3 – List of audios

After downloading the audio recorded by the microphone contained in the memory of the I.on/I.on PRO, in this area the list will be displayed. The file names are equivalent to the date and time they were originally stored. For example: 19092019105951 is equivalent to day 19, month 09, year 2019, hour 10, minutes 59, and seconds 51.

4 – Player

Click on an audio, then it will be played on the player. There are the options to pause, start or stop. On the right side it appears the name of the audio being played.

Shocks screen



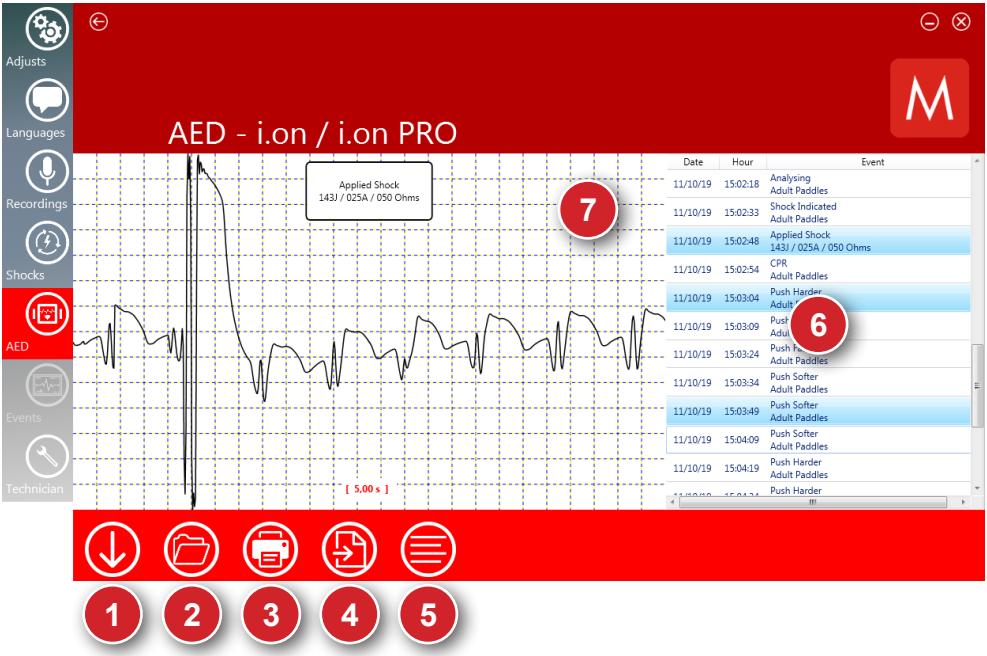
1 – Define shock sequence

Choose the energy value for the first, second and third shocks. Click the send button to send the values to the device. Through this window it is possible to set the values of the three shocks of the device's auto sequence in AED mode.

2 – Previous sequence

Allows to view the last shock sequence recorded on the device.

AED screen



1 – Download

Press this button to save to the PC the information set currently being viewed on the device as well as previously generated events. A window will open allowing the user to choose the desired file storage location.

2 – Open

Press this button to open a “.dea” file previously stored on the computer.

3 – Print

Click this button to print the events selected on the screen. Use the Windows print dialog to choose your printer. Printing is only done in landscape mode with one page per sheet.

4 – Generate PDF

Click this button to generate a PDF file of the events selected on the screen. The user should select the desired directory for file storage. There is a maximum of 100 events for each PDF.

5 – Select events

Selects all listed events.

6 – List of events

After downloading the information contained in the memory of the Ion / Ion PRO, this area will display the list of events stored by the device in chronological order. To view an event in the curve area click on it. To select more than one event, click one of the desired events, then click the ctrl key, hold it down, and select other events. In addition, it is possible to select events in sequence by clicking the first event in the sequence, then clicking the shift key, holding it down, and clicking the last event in the desired sequence. To view how many events have been selected, hover the mouse over the event list.

7 – Curves area

In this area it is possible to view all the curve related to the event using the scroll bar. In addition, it is possible to use the zoom in curve feature by right-clicking on the curve area and selecting the zoom option.

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 events

COMPRESS HARDER - It is necessary to compress the patient's chest harder.

COMPRESS SOFTER - It is necessary to compress the patient's chest softer.

COMPRESS FASTER - It is necessary to compress the patient's chest faster.

COMPRESS SLOWER - It is necessary to compress the patient's chest slower.

GOOD COMPRESSIONS - Good compressions were performed on the patient's chest.

ALLOW FULL CHEST EXPANSION - It is necessary to allow the patient's full chest expansion.

Precautions, restrictions and warnings 12

The I.on/I.on PRO 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 I.on/I.on PRO may be affected by the presence of electromagnetic power supplies, such as electrosurgical equipment and computer tomography (CT).

Electromagnetic compatibility

Attention

Using the I.on/I.on PRO requires special precautions concerning Electromagnetic Compatibility in compliance with the information contained in this manual.

Mobile and portable RF communications equipment, such as a cellphone, may affect the functioning of the I.on/I.on PRO.

Maximum length of accessory cables in order to comply with the requirements of Electromagnetic Compatibility is 2.5 m.

All parts and accessories, listed below, follow the requirements for Electromagnetic compatibility.

- **Pair of disposable adhesive pads, adult size.**
- **Pair of disposable adhesive pads, child size (optional).**
- **Power supply for charging the battery (optional).**
- **USB cable.**

Warnings

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 I.on/I.on PRO must not be used too close to or piled over other equipment.

Electromagnetic emissions

Directives and manufacturer declaration - Electromagnetic emissions		
The I.on/I.on PRO 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 IEC CISPR11	Group 1	The I.on/I.on PRO 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 IEC CISPR11	Class B	I.on/I.on PRO is suitable for use in hospital and home environments.
Harmonics emissions EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions EN 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.		

WARNING: the I.on PRO is suitable for use in professional health care environments.

CAUTION: do not use the equipment in the presence of MRI devices. Measures must be taken to minimize interference from high frequency surgical equipment.

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

- Ensure minimum distance, according to the table on page 71, of an RF emitting source.
- The cables and accessories must also keep this distance.
- Do not use this product in conjunction with electrical scalpel.
- Do not use this product in conjunction with MRI devices.

The essential performance of the I.on PRO is understood as the ANALYSIS of the patient's heart rhythm and the DEFIBRILLATION applied to the patient, depending on the result of the analysis. The performance of the I.on PRO is designed and verified for the absence of an unacceptable risk.

If performance is lost or degraded due to electromagnetic disturbances, the ECG signal may be interfered with and cardiac rhythm analysis may be compromised as long as electromagnetic disturbances persist.

WARNING: portable RF communication equipment (including peripherals such as cables and external antennas) should not be used within 30 cm of any part of the I.on PRO, including cables specified by Instramed. Otherwise, performance degradation of this equipment may occur.

Electromagnetic immunity - General

Directives and declaration of the manufacturer - Electromagnetic emissions			
The I.on/I.on PRO 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 EN 60601**	**Compliance level**	**Electromagnetic environment Directives**
Electrostatic discharge (ESD) EN 61000-4-2	± 8 KV contact ± 15 KV air	± 8 KV contact ± 15 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 EN 61000-4-4	± 2 KV for power supply lines ± 1 KV for input/output lines	± 2 KV for power supply lines ± 1 KV for input/output lines	The quality of the power supply should be that appropriate for hospital and home health care environments.
Surge EN 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 appropriate for hospital and home health care environments.
Voltage dips, short interruptions, and voltage variations on power supply input lines EN 61000-4-11	< 5% U_T (> 95% dip in U_T) For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles < 5% U_T (> 95% dip in U_T) For cycle of 5 seconds	< 5% U_T (> 95% dip in U_T) For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles < 5% U_T (> 95% dip in U_T) For cycle of 5 seconds	The quality of the power supply should be that appropriate for hospital and home health care environments. During power outage, it is recommended that I.on/I.on PRO is recharged by an uninterruptible power supply. Because the equipment does not operate when connected to the charger.
Power frequency magnetic field (50/60 Hz) EN 61000-4-8	3 A/m and 30 A/m	3 A/m and 30 A/m	Magnetic fields at the frequency of the power supply should be those appropriate to hospital and home health care environments.
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 I.on/I.on PRO

The I.on/I.on PRO 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 EN 60601	Compliance level	Electromagnetic environment Directive
			Portable and mobile RF communications equipment should not be used near any part of the I.on/I.on PRO, 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:
Conducted RF EN 61000-4-6	3 Vrms 150 kHz up to 80 MHz outside bands[a] ISM	3 Vrms	$d=1,2.\sqrt{P}$
	10 Vrms 150 kHz up to 80 MHz outside bands[a] ISM	10 Vrms	$d=1,2.\sqrt{P}$
Conducted RF EN 61000-4-3	10 V/m 80 MHz up to 2.5 GHz	10 V/m	$d=1,2.\sqrt{P}$ 80 MHz até 800 MHz. $d=2,3.\sqrt{P}$ 80 MHz até 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 survey, [c] should be less than the compliance level in each frequency range[d]. Interference can occur around equipment marked with the following symbol: 

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

a - ISM bands (industrial, medical and scientific) between 150 kHz and 80 MHz are 6,765 MHz to 6.795MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
b - The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range between 80 MHz and 2.5 GHz 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 I.on/I.on PRO is used exceeds the level of RF compliance used above, the I.on/I.on PRO 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 I.on/I.on PRO.
d - Over the frequency range 150 kHz to 80 MHz, the field intensity should be less than V1 (3 V/m) .

Electromagnetic immunity - Equipment with life support functions

Advisable separation distances between mobile and portable RF communications equipment and the I.on/I.on PRO

The I.on/I.on PRO 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 I.on/I.on PRO 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 $d=1,2.\sqrt{P}$	150 KHz to 80 MHz outside ISM bands $d=1,2.\sqrt{P}$	80 MHz to 800 MHz $d=1,2.\sqrt{P}$	800 MHz to 2.5 GHz $d=2,3.\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	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 80 MHz and 800 MHz, the separation distance for the highest frequency range is applied.

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

NOTE 3: an additional factor of 10/3 is used in calculating the advisable separation distance for transmitters in the ISM frequency bands between 150 KHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to 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.

Testing specifications for cabinet interface immunity to RF wire communications equipment

The I.on PRO was designed to provide Basic Security with RF equipment by the following table:

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 Band LTE 1, 3, 4, 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.

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	No shockable rhythms
Shock INDICATED	A	B
Shock NOT RECOMMENDED	C	D

- Sensitivity = $\frac{A}{A+C}$
- 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 no shockable 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 **no shockable** rhythm.

A true positive (D) is the equipment's ability, in measurement units, to **correctly** recognize a **no shockable** rhythm.

Values measured with the AED using the specified database:

	VF/VT	No shockable rhythms
Shock INDICATED	329	23
Shock NOT RECOMMENDED	10	454

- Sensitivity = **97,05%**
- Specificity = **95,18%**

Types of arrhythmia analyzed

No shockable

- 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 I.on/I.on PRO meetsEN 60601-2-4 requirements for sensitivity > 90%.
Shock - VT	The I.on/I.on PRO meets IEC 60601-2-4 requirements for sensitivity > 75%.
No shockable rhythms	The I.on/I.on PRO meets IEC 60601-2-4 requirements for specificity > 95%.

Specifications

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General specifications

Dimensions:	225 mm (width). 225 mm (high). 69 mm (depth).
Weight:	1.2 Kg (basic) to 1,9 Kg (complete).
Display size (optional):	4.3”.
Non-rechargeable battery:	Type: Manganese Lithium Dioxide ($LiMnO_2$) 18V, 2800 mAh. Battery duration: more than 300 shocks in 200 J or 15 hours of continuous monitoring and 5 years of lifespan in standby. Note: discharge tests performed on the I.on/I.on PRO configuration with LCD.
Rechargeable battery:	Type: Li-Ion, 14.4 VDC 4.0 A/h. Duration: 18 hours of continuous monitoring or a minimum of 400 shocks at 200 J (battery at full charge). Shelf life: 2 years in standby. Time to fully charge the battery (fully discharged): 5 hours.
Battery power supply charger:	Power 100 - 220 V/50-60 Hz. Consumption (maximum): Mains supply 1 A. Output: 16.8 VDC, 1 A. Use only source manufactured by Instramed.
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:	Adult (automatic): 1º shock - 150 J. Following shocks: 200 J. Adult (manual): until 360 J. Child: 50 J.
Defibrillation scales adjusted by user (via SoftDEA):	Adult: scales between 120 J and 360 J.
Internal memory storage:	100 events or 2 hours of ECG recording.
Ambient sound storage:	Up to 10 hours (optional).
Degree of protection:	IP56 (this AED is protected against the possibility of dust entering and against strong water jets according to ABNT NBR IEC 60529).
Classification:	Class II, internally energized equipment.
Electrical insulation:	CF type.
Operating mode:	Continuous operation.
Maximum time from rhythm analysis beginning to full discharge readiness:	25 seconds.
Insulation method from main power supply (when with rechargeable battery):	Flexible cable with a mains plug.
Non-frequent use equipment:	Comply with the requirements for non-frequent use equipment as specified in EN 60601-2-4 standard.

Equipment lifetime:	9 years (excluding battery and adhesive pads).
Service life of parts and accessories:	Each accessory has its own service life. To consult it, please check the information on the tag or label.

NOTE: the environmental conditions of use and storage, the frequency of use and general care have a direct impact on the service life of parts and accessories.

Environmental specifications

Temperature:	Operational: 0 to 50 °C. Storage: -25 to 70 °C.
Humidity:	Operational: 10 to 95% RH, without condensation. Storage: 10 to 95% RH, without condensation.
Altitude:	Maximum of 79.48 kPa.

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. Only I.on PRO Touchscreen: allows for the selection of manual mode and defining energy scales
Scales for defibrillation:	Adult: 120 to 360 J. Child: 10, 20, 30, 40 or 50 J.

Adults/children selection:	Automatic due to the size of the pads Forced by patient selection button (optional).
Charge command:	Automatic after identifying arrhythmias that should receive shock.
Shock command:	Front panel button, when blinking.
Maximum time from rhythm analysis beginning to discharge readiness:	Maximum time from rhythm analysis beginning to discharge readiness (rechargeable battery and 200 J): 20 seconds. Maximum time from rhythm analysis beginning to discharge readiness (rechargeable battery and 360 J): 25 seconds. Maximum time from rhythm analysis beginning to discharge readiness (non-rechargeable battery and 200 J): 30 seconds. Maximum time from rhythm analysis beginning to discharge readiness (non-rechargeable battery and 360 J): 35 seconds
Maximum charging time:	Rechargeable battery: 50 J: < 2 seconds. 150 J: < 3 seconds. 200 J: < 4 seconds. 270 J: < 5 seconds. 360 J: < 6 seconds. Non-rechargeable battery: 50 J: < 2 seconds. 150 J: < 5 seconds. 200 J: < 6 seconds. 270 J: < 8 seconds. 360 J: < 10 seconds.

NOTE: charging times considering the product in full operating condition and fully charged battery.

The detector and rhythm recognizer does not continue to analyze the ECG after detecting a pace that is susceptible to defibrillation.

Pads size:	Adult = area: 82 cm^2 (32.3 in^2). Child = area: 30 cm^2 (11.8 in^2).
Pads cable length:	2 meters.
Maximum output voltage:	2000 V.
Maximum output current:	80 A (25 Ω).

CPR Maestro

Accuracy:	Depth = ± 98%. Frequency= ± 95%.
Minimum number of uses:	100 uses.

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%
360	344.0	363.0	370.5	370.0	363.0	345.0	322.0	±15%

Patient's impedance response table

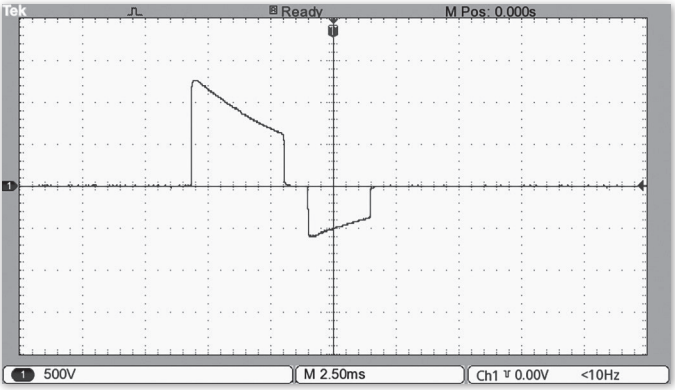
Patient's impedance	Shock
Short-circuit.	Shock inhibited.
< 25 Ohms.	Shock inhibited.
> 25 Ohms and < 300 Ohms.	Shock delivered with a waveform adjusted to the patient's impedance.
> 300 Ohms.	Shock inhibited.
Open circuit.	Shock inhibited.

ECG rhythm recognition and detector table

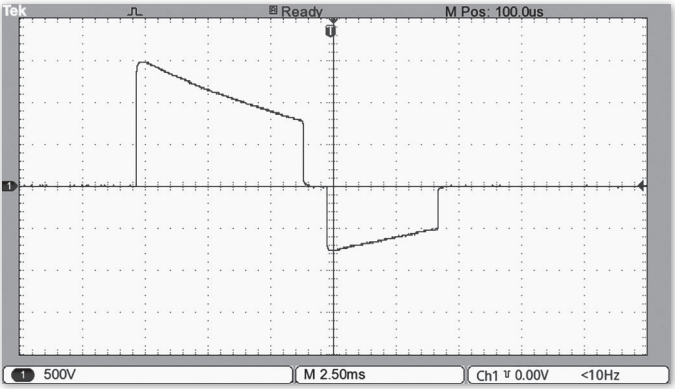
	VF and VT	All other ECG rhythms
Shock indicated.	329	23
Shock NOT RECOMMENDED.	10	454

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

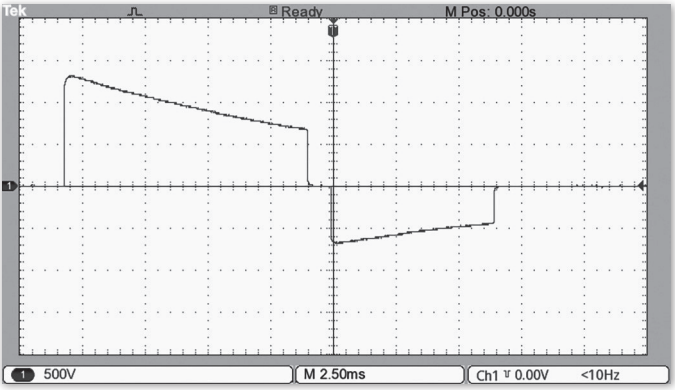
Values on the Y axis refer to voltage (volts) and values on the X axis refer to time (milliseconds).



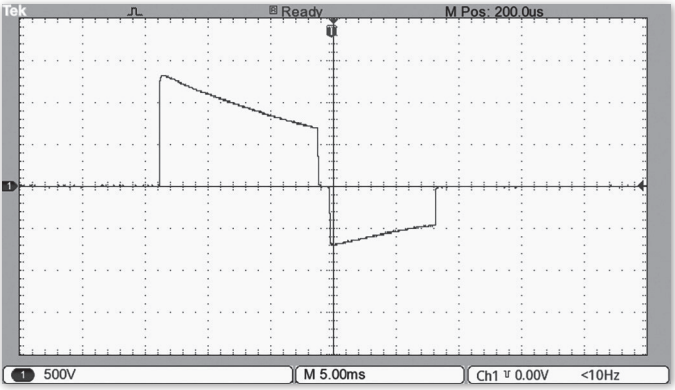
200 J of energy at 25 R impedance.



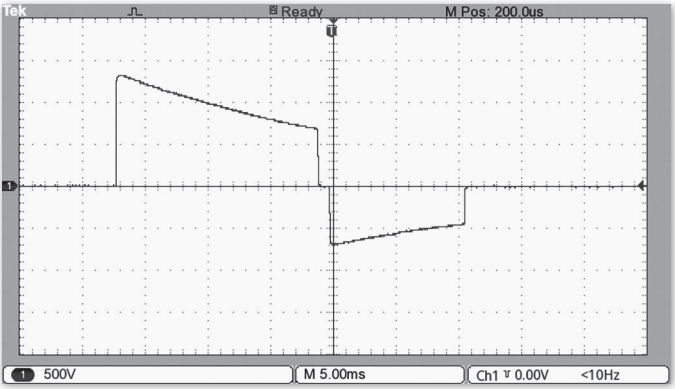
200 J of energy at 50 R impedance.



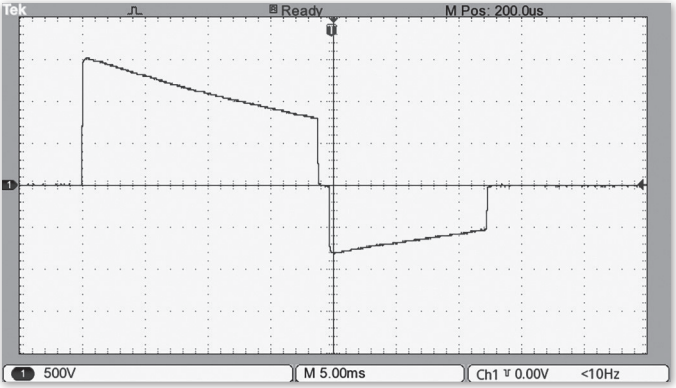
200 J of energy at 75 R impedance.



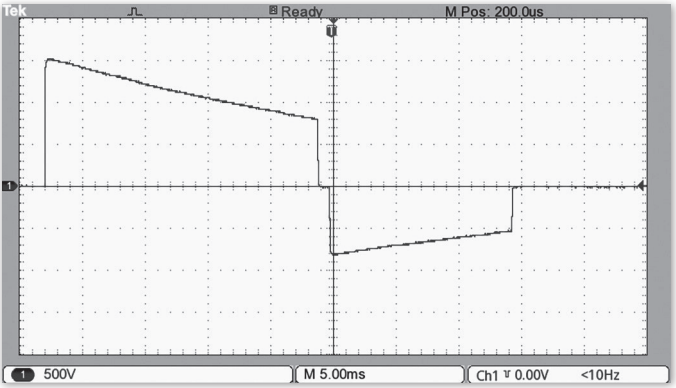
200 J of energy at 100 R impedance.



200 J of energy at 125 R impedance.



200 J of energy at 150 R impedance.



200 J of energy at 175 R impedance.

ECG

Only models with LCD srceen

Pacemaker stimulus rejection:	Pacemaker stimuli with widths between 0.1 ms and 2 ms and amplitude between ± 2 mV and ± 700 mV are rejected in the heart beats count. Regarding overshoot, it complies with Method A of the AAMI EC13 standard. In the range of 15 BPM to 350 BPM the pacemaker pulses are rejected.
Diagnostic signals applied to patient connections:	The electrical signal applied to the patient for diagnosis has DC voltage of 3, 3 V, current < 10 µA and impedance > 360 KOhms. The circuit of disconnected derivations / active noise detection suppression is < 0.2 µA.
T wave maximum amplitude:	Meets the recommended minimum rejection value of the T wave amplitude of 1.2 mV.
Minimum amplitude of the ECG signal:	The minimum amplitude of the patient's ECG signal is 0.05 mV (50 µV). Operation with ECG signals below this range may produce inaccurate results.
Heart rate meter response time:	Responds to a marked increase of 40 BPM in heart rate within 4.5 seconds. Responds to a sharp drop of 40 BPM within 4.0 seconds. The response time includes a screen refresh interval of 0.5 seconds.

Heart rate meter and heart rate response to irregular rhythm:	Ventricular bigeminism: 80 BPM (expected). Slow alternating ventricular bigeminism: 60 BPM (expected). Rapid Alternate Ventricular Bigeminism: 120 BPM (expected). Bidirectional systole: 45 BPM (expected).
Heart rate displayed:	Average of the last 5 intervals between the beats.
Maximum response time to tachycardia:	The I.on/I.on PRO has no alarms or alarm limits for ventricular tachycardia.

ECG electrodes (adult and child)

Composition:	Adhesive conductor with hydrogel and silver sensor (Ag/AgCl), latex free, biocompatible according to ISO 10993-1.
Use instructions:	1) Shave hairs, clean the spot and dry with gauze. 2) Before removing the protective film, attach the ECG wire to the electrode. 3) Remove the film from the electrode and put it in place by pressing firmly.
Precautions:	Do not open the packaging before use. Do not apply the electrodes on the nipples, bony protuberance, cuts, lesions, scars, only on intact skin. Store at temperatures between 15°C and 40°C. Non-sterile single use product. Discard after use.

Alarm system

I.on/I.on PRO's alarm system is made of a single alarm, as shown in the table below:

ALARM CONDITION	The device is ready to apply the shock treatment to the patient using the energy previously established by either the algorithm (AED mode) or the operator (manual override mode), waiting only for the operator to press the button.
ALARM PRIORITY	High.
VISUAL ALARM SIGNAL	Button blinks in red, at 2 Hz, and at a 50% duty cycle.
VERBAL ALARM SIGNAL	Voice indication with the following text: "Push the flashing button to treat the patient ".
SOUND LEVEL	Configurable between 55 and 80 dB(A) through PC software application: SoftDEA.
ALARM SIGNAL GENERATION DELAY	Lower than 5 seconds.
OPERATOR'S POSITION	The operator must be facing the front side of the device, at a maximum distance of 50 cm.

Pausing and turning off the alarm signals

Following the standard EN 60601-2-4, it is not possible to turn-off or pause the alarm signals for the device's ALARM CONDITION.

Verifying if the alarm system is functional

It is possible to verify if the alarm signals are functional with an ECG simulator capable of generating ventricular fibrillation signals. It is recommended that the verification be made by a qualified technician, during the preventive maintenance (see chapter "Inspection and maintenance").

Information signals

I.on/I.on PRO has information signals, which can be visual, audio or verbal.

VISUAL INFORMATION SIGNAL	DESCRIPTION
Operational status indicator.	*
Battery in charge/charge complete indicator.	*
Patient's BPM. Only models with LCD screen	Patient's BPM detected by the device.**
ECG wave. Only models with LCD screen	Patient's ECG waveform detected by the device.
CPR interval chronometer. Only models with LCD screen	Reports the elapsed time since the recommendation of the CPR procedures. In the manual mode, reports the time elapsed since the device entered the manual mode.**
Illustrative picture of the current step of the AED procedure. (AED mode only).	Picture that indicates to operator which stage of the automatic procedure the equipment is performing at the moment***
Battery level indicator. Only models with LCD screen	Indicates the approximate device's battery level.**
Energy selected (manual mode only). Only I.on PRO	Indicates the energy selected by the operator.**

* See section "The equipment", item "Operational status indicator".
** See section "The equipment", item "Touch screen".
*** See section "Operating in AED mode".

AUDIO INFORMATION SIGNALS (BEEP)	DESCRIPTION
Metronome for CPR compressions.	The device beeps at a rate of 100 per minute, helping the operator during the CPR compressions.
Failure indicator.	If the device is not operational, it beeps according to the detected failure.*
* See section "The equipment", item "Operational status indicator".	

IMPORTANT: all audio information signals have a sound level of 80 dB(A).

The device also has verbal information signals. They differ from the verbal alarm signal in two manners:

Sound level

The verbal information signals will always be at least 6 dB(A) lower than the previously configured level for verbal alarm signals.

Verbal content

The verbal information signals have the following messages:

- Analyzing heart rhythm.
- Press the illuminated button to shock the adult patient.
- Press the illuminated button to shock the child patient.
- Charging complete.
- Treatment recommended – do not touch the patient.
- Treatment is not recommended.
- Put the paddles on the patient's chest.
- Confirm the manual override mode? Only I.on PRO
- Internal energy discharge.
- Self-test failed.
- Limited to 200 Joules.
- Adult mode.
- Child mode.
- Manual override mode selected. Only I.on PRO
- Do not touch the patient.
- The equipment is turning off, press the button in order to turn the machine back on.
- Children's pads.
- Perform CPR for two minutes.
- Treatment performed.

- USB connected.
- Give two breaths.
- Check the patient's respiration or pulse. If you cannot detect either, perform CPR for two minutes.
- Check the pulse.

Care and maintenance

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Preventive Maintenance

Instramed recommends that the equipment 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 20 - 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.

Accessories

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Included

- **01 battery charger for charging the battery (code 13940).**
  Description: device to charge the rechargeable battery. This battery charger will accompany the product only when it has rechargeable battery.
- **01 Adult multifunctional adhesive pads (code 79047)*.**
  Description: adhesive pads to be used in the Adult patient's chest (skin). These adhesive pads will monitor and defibrillate the patient, it is necessary.
- **01 First aid kit (code 80023)*.**
  Description: first aid kit, containing 1 pair of non-reusable rubber gloves, 1 non scissor and 1 non-reusable CPR mask to be used by the operator.
- **01 Transport backpack (code 14015).**
  Description: transport bag, to transport the I.on/I.on PRO with all accessories.
- **01 USB cable A-B (code 10985)*.**
  Description: USB cable, to connect I.on/I.on PRO to the PC computer, in order to access log events and ECG waveforms.
- **01 CD manuals and software Instramed (code 25277).**
  Description: CD containing User Manual and software necessary to access the log events and ECG waveforms.
- **01 Quick Guide (code 14239).**
  Description: hardcopy of the Quick Guide with main functions to the operator.
- **01 of the following batteries:**
  - **Rechargeable Li-Ion.**
    I.on (code 14307).
    I.on PRO (code 14304).
  - **Non-rechargeable $LiMnO_2$ 2800 mAh.**
    I.on (code 14308).
    I.on PRO (code 14305).

Optional

- **CPR Maestro (code 13542).**
  Description: cardiopulmonary resuscitation (CPR) feedback device with visual information of depth and frequency of the compressions with the purpose of increase the quality of the CPR, through the operator.
- **Child multifunctional adhesive pads (code 79048)*.**
  Description: adhesive pads to be used in the Child's chest (skin). These adhesive pads will monitor and defibrillate the patient, it is necessary.
- **3-leads ECG cable (code 26005)*.**
  Description: ECG cable with 3 leads, with only the D2 derivation waveform with the purpose to only monitor the patient.
- **Charger for the battery (code 13940).**
  Description: device to charge the rechargeable battery. This battery charger will accompany the product only when it has a rechargeable battery.
- **Patient selection button (consult Instramed).**
  Description: allows you to switch the equipment's operating mode to adult or child.
- **I.on/I.on PRO handle set (consult Instramed).**

* Accessory with separate CE certificate.

Warranty certificate

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Instramed Indústria Médico Hospitalar Ltda. warrants the equipment described in this Certificate for 12 (twelve) months, starting from thedelivery 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: _____

i.on pro AUTOMATED EXTERNAL DEFIBRILLATOR WITH MANUAL FUNCTION

i.on AUTOMATED EXTERNAL DEFIBRILLATOR

INSTRAMED

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