Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 03.07.2023

Solicitantul **FCPC „DataControl" S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

INSTRAMED INDUSTRIA MEDICO HOSPITALAR

Product: Defibrilator
Model:
1. **I.ON**
2. **Cardiomax Basic**

Se anexează următoarele acte:

1. Certificat CE
2. Declaratie de conformitate
3. Actul prin care producătorul își desemnează reprezentantul
4. Declarație pe propria răspundere.

Data **03.07.2023** Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Grabazei Alexandru
Date: 2023.07.03 10:16:06 EEST
Reason: MoldSign Signature
Location: Moldova

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. ”DataControl” S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscînd prevederile art. **352[1]** , Codul Penal al republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

INSTRAMED INDUSTRIA MEDICO HOSPITALAR

Product: Defibrilator
Model:

1. **I.ON**
2. **Cardiomax Basic**

Sunt autentice și corespund realității

Alexandru Grabazei, director Semnătura _____
Data: **03.07.2023**

INSTRAMED

To: Whom It May Concern

Date: 09/06/2023.

Authorization

We, Company-manufacturer, Instramed Indústria Médico Hospitalar Ltda herby appoint following company:

F.C.P.C. "DataControl" S.R.L.,

17/6, N.Testimiteanu street,

MD-2025, Chişinau, Republic of Moldova,

to be our official representative at the responsible authorities of the Republic of Moldova for registration, renewal, variation of registration etc.

Signed: Isabella Fernandes da Costa

Instramed Ltda.
Isabella Costa
Export Specialist

Name: Isabella Fernandes da Costa

Address: Beco José Paris, 339 – PAV 19, Sarandi, Porto Alegre, Brasil.
comex@instramed.com.br

Title: Export Specialist

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
289758-2019-CE-BRA-NS-PS Rev. 0.0	PRJC-531733-2015-MSL-BRA	27 May 2024

This is to certify that the quality system of:

INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.

Beco José Paris, 339. Pavilhão 19. Condomínio Empresarial Mont'Serrat – Bairro Sarandi. Porto Alegre – RS – Brazil. 91140-310.

For design, production and final product inspection/testing of:
BIPHASIC MONITOR DEFIBRILLATORS

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 02 December 2019

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Sholeh Gheissar

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2019-12-02

Products covered by this Certificate:

Product Description	Product Name	Class
BIPHASIC MONITOR DEFIBRILLATORS	CARDIOMAX DUALMAX	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Instramed Indústria Médico Hospitalar Ltda	Beco José Paris, 339. Pavilhão 19. Condomínio Empresarial Mont'Serrat – Bairro Sarandi. Porto Alegre – RS – Brazil. 91140-310.

EU Representative
OBELIS S. A. Bd. Général Wahis 53, B-1030
Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
289757-2019-CE-BRA-NA-PS Rev. 0.0	PRJC-531733-2015-MSL-BRA	27 May 2024

This is to certify that the quality system of:

INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.

Beco José Paris, 339. Pavilhão 19. Condomínio Empresarial Mont'Serrat – Bairro Sarandi. Porto Alegre – RS – Brazil. 91140-310.

For design, production and final product inspection/testing of:
AUTOMATIC EXTERNAL DEFIBRILLATORS

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 27 November 2019

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Sholeh Gheissar

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2019-11-27

Products covered by this Certificate:

Product Description	Product Name	Class
AUTOMATIC EXTERNAL DEFIBRILLATORS	i.on i.on pro	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Instramed Indústria Médico Hospitalar Ltda	Beco José Paris, 339. Pavilhão 19. Condomínio Empresarial Mont'Serrat – Bairro Sarandi. Porto Alegre – RS – Brazil. 91140-310.

EU Representative
OBELIS S. A. Bd. Général Wahis 53, B-1030
Brussels, Belgium

Certificate No.:
289757-2019-CE-BRA-NA-PS Rev. 0.0

Project No.:
PRJC-531733-2015-MSL-BRA

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

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- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

INSTRAMED

DECLARATION OF CONFORMITY CE

Directive and Regulation to which conformity is declared:
93/42/EEC Annex II excl. section 4 - Medical Device Directive and amendment 2007/47/EC on Medical Device.
Transitional provisions of Regulation (EU) 2017/745 Of the European Parliament and Of The Council of 5 April 2017, for legacy devices in accordance with Directive 93/42/EEC.

Application of the Standards:
IEC 60601-1:2005+AMD1:2012+AMD2:2020
IEC 60601-1-2:2014+AMD1:2020
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020
IEC 60601-1-8:2006+AMD1:2012+AMD2:2020
IEC 60601-2-4:2010+AMD1:2018
IEC 60601-2-27:2011
IEC 80601-2-30:2018
IEC 80601-2-49:2018
IEC 62304:2006+AMD1:2015
IEC 62366-1:2015
ISO 14971:2019
EN ISO 13485:2016
ISO 10993-1:2018
EN ISO 10993-5:2009
ISO 10993-10:2021

Manufacturer's name: **Instramed Indústria Médico Hospitalar LTDA.**
Manufacturer's address: **Beco José Paris, 339, Pavilions 18 and 19, Condomínio Empresarial Mont'Serrat - Bairro Sarandi, 91140-310, Porto Alegre, RS, Brazil**

Authorized Representative name: **Obelis S.A.**
Authorized Representative address: **Bd. Général Wahis 53, 1030 Brussels - Belgium**

Type of equipment: **Biphasic Monitor Defibrillator**

Trade mark / Model: **CARDIOMAX**

Accessories (parts) manufactured by Instramed:

- **(27009) Set of paddles for adult external defibrillation and pediatric.**
- **(80208) Pacemaker cable.**
- **(11066) CPR Maestro.**

Accessories are part of the system, they are not intended to be sold separately.

Accessories manufactured by third party with EC Declaration of Conformity:

- **(79005) 5 leads ECG Cable, Class I.**
- **(25671) Adult Cuff, Class I.**
- **(79032) ETCO2 Sample Line Kit, Class I.**

INSTRAMED

DECLARATION OF CONFORMITY CE

- **(21669) ECG electrodes adult, Class I.**
- **(23897) ECG electrodes pediatric, Class I.**

Accessories manufactured by third party with CE certified:

- **(79047) Multifunctional Adhesive Pads.**
- **(71854) SPO2 Sensor, Class IIb.**
- **(12475) SPO2 Y model, Class IIb.**

Classification:

- **Class IIb in compliance with Rule 9 of annex IX of the directive 93/42/EEC: Defibrillation, Cardioversion and Pacemaker parameters.**
- **Class IIb in compliance with Rule 10 of annex IX of the directive 93/42/EEC: Monitor parameters that detect variations and hazards to the patient.**

Notified body: **DNV Product Assurance AS**
Veritasveien 1, 1363 Høvik, Norway
CE 2460

This declaration of conformity is issued under the sole responsibility of the Instramed and we, the undersigned, hereby declare that equipment specified above conforms to the above Directives and Standards.

December 02, 2022.

Arthur J. A. Moraes
CEO
Instramed

Rev.8

INSTRAMED

DECLARATION OF CONFORMITY CE

Directive and Regulation to which conformity is declared:
93/42/EEC Annex II excl. section 4 - Medical Device Directive and amendment 2007/47/EC on Medical Device.
Transitional provisions of Regulation (EU) 2017/745 Of the European Parliament And Of The Council of 5 April 2017, for legacy devices in accordance with Directive 93/42/EEC.

Application of the Standards:
EN 60601-1:2006 / A1:2013
EN 60601-1-2:2015
EN 60601-1-6:2010
EN 60601-1-8:2007 / A11:2017
IEC 60601-2-4:2010
IEC 62304:2015
EN 62366:2008
EN ISO 14971:2012
EN ISO 13485:2016
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
ISO 10993-10:2010

Manufacturer's name: **Instramed Indústria Médico Hospitalar LTDA.**
Manufacturer's address: **Beco José Paris 339/19, Porto Alegre, RS - Brazil**

Authorized Representative name: **Obelis S.A.**
Authorized Representative address: **Bd. Général Wahis 53, 1030 Brussels - Belgium**

Type of equipment: **Automated External Defibrillator**

Trade mark / Model: **i.on and i.on Pro**

Accessories:
- **Power source internal battery charger – Class II, Code 79051;**
- **CPR Maestro – Code 11066 (Optional);**
- **Multifunctional Adhesive Pads – Code 79047;**
- **3-leads ECG Cable - Code 26005 – Class I, third party.**

Classification: **Class IIb in compliance with Rule 9 of annex IX of the directive 93/42/EEC.**

Notified body: **DNV Product Assurance AS**
Veritasveien 3, 1363 Høvik, Norway
CE 2460

INSTRAMED

DECLARATION OF CONFORMITY CE

This declaration of conformity is issued under the sole responsibility of the Instramed and we, the undersigned, hereby declare that equipment specified above conforms to the above Directives and Standards.

Porto Alegre, November 26, 2021.

Arthur J. A. Moraes
CEO
Instramed

Rev.8

INSTRAMED

- DEFIBRILLATOR •
- AED •
- PACEMAKER •
- ECG •
- RESPIRATION •
- OXIMETRY •
- NIBP •
- CAPNOGRAPHY •
- PRINTER •
- CPR MAESTRO •

CARDIOMAX 8 SERIES

Biphasic Defibrillator Monitor and Cardioverter

RTC
Real Time Check

Auto CAS Sequencing

SDP Sudden Death Prevention

bi phasic SHOCK

AVAILABLE PARAMETERS

- Real Time Check Technology (RTC)*
- Automated External Defibrillator Mode (AED)
- Sudden Death Prevention Mode (SDP)
- Cardiopulmonary Resuscitation Accessory (CPR Maestro)*
- Electrocardiogram (ECG) up to 12 derivations*

Complete, advanced, reliable and easy to use: definitely the best investment in emergency equipment.

*Some items are optional - Please verify availability.

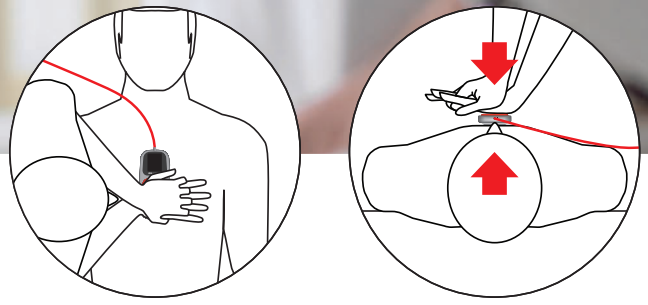
- Oximetry (SpO_2)*
- Non invasive pacemaker*
- Non-invasive pressure (NIBP)*
- Capnography ($EtCO_2$)*
- Printer*
- Removable rechargeable battery

THE IDEAL PARTNER FOR YOUR CARDIOMAX

Positioned on the patient's chest, the CPR Maestro provides real-time feedback on the rescuer's performance by guiding him through voice, LCD display and indications on the CardioMax screen about the procedure's optimal frequency, strength and interval.

The result is a much more effective and consistent performance of CPR, resulting not only in increased chances of patient survival, but reducing the occurrence of severe sequelae due to lack of oxygenation.

CPR Maestro



CARDIOMAX 8 SERIES

PRACTICAL

- Light.
- Ready to use in less than 6 seconds.
- Biphase power delivery of up to 360 J.
- AED Mode – Automated External Defibrillator.
- CPR Maestro assists in performing cardiopulmonary resuscitation by measuring the frequency and depth of the chest compressions applied (optional).
- Internal battery, easy to replace, allows more than 100 shocks.

EASY TO USE

- Easy to use - All operations centralized on just two buttons.
- Easy operation - 1, 2, 3 standard.
- Quick access to main functions.
- Easy-to-use user interface - automatically adjusts itself to the number of active parameters, presenting clear and organized information.
- Large 8.4" color display.

SMART

- Auto Sequencing Charge function - When enabled, applies charges pre-configured by the user for the first, second and third shocks without the need to change the selector manually.
- Smart monitoring alarms.
- Sudden Death Prevention (SDP) technology. This characteristic allows CardioMax to monitor the patient continually and identify the beginning of a Ventricular Fibrillation or Rapid Ventricular Tachycardia episode.

RELIABLE

- Reliability - Instramed is a brand present in hundreds of medical organizations on more than 60 countries.
- Dependable products developed for the reality of emergency care.
- A wide network of dealers providing sales and parts, along with the factory-certified technical assistance, provides excellent post-sales service.
- With more than 30 years in the business, Instramed is a manufacturer that maintains stock parts and components even for discontinued products.

KNOW MORE ABOUT THIS PRODUCT IN WWW.INSTRAMED.COM.BR

TECHNICAL INFORMATION

EN

GENERAL SPECIFICATIONS

- **Pads dimensions**
  - 30.0 cm (11.81 in) length.
  - 21.5 cm (8.46 in) depth.
  - 28.0 cm (11.02 in) height..
- **Weight**
  - Device - 5.15 kg (11.35 lbs).
  - Li-Ion battery - 0.60 kg (1.32 lbs).
  - External pads - 0.85 kg (1.87 lbs).
  - Complete set (Li-Ion battery) - 6.60 Kg (15.66 lbs) (except NIBP).
- **Electrical**
  - AC: 100 to 220 VAC, 50/60 Hz.
  - DC external: 11 to 16 VDC.
- **Removable rechargeable battery**
  - Type: Li-Ion, 14.4 VDC 4 A/h.
  - Duration: battery with full charge - 3 hours in monitor mode, without printer, or a minimum of 140 shocks at 360 J or a minimum of 200 shocks at 200 J.
  - Battery full-charge time (when fully depleted): 4h 30min.
  - Type: Li-Ion, 14.4 VDC 6 A/h.
  - Duration: battery with full charge - 6.5 hours in monitor mode, without printer, or a minimum of 250 shocks at 360 J or a minimum of 400 shocks at 200 J.
  - Battery full-charge time (when fully depleted): 7h 20min.

  **Check availability.
- **Memory**
  - Type: Nand Flash.
  - Capacity: 2 Mbytes.
  - Patients stored: >150 patients.
  - ECG: 2 continuous hours of ECG curve recording, when in AED mode.
  - Storage: 15 seconds of ECG when in shock, physiological alarm and panel events.
- **RTC - Real Time Check (Available when equipped with optional Li-ion battery)**
  - Defibrillation self-test, battery level, connected pads, power source connection check. Check is performed 3 times which are set in advance. This information is wirelessly transmitted to a PC with RTC System software installed and within range of the network.

ENVIRONMENTAL SPECIFICATIONS

- **Temperature**
  - Operational: 0 to 50 ºC.
  - Storage: -20 to 50 ºC.
- **Humidity**
  - Operational: 10 to 95% RH without condensation.
  - Storage: 10 to 95% RH, without condensation.
- **IP rating**
  - IPX1 (standard) or IP44 (optional).

DEFIBRILLATOR

- **Waveform**
  - Biphasic truncated exponential. Waveform parameters adjusted in terms of patient's impedance.
- **Shock application**
  - By means of multifunctional pads (adhesive) or defibrillation pads.
- **Scales for adult/external defibrillation**
  - Scales: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 50, 80, 100, 150, 200, 250, 300 and 360 J (maximum power can be limited to 200 J). Maximum power limited to 50 J for children's pads.
  - Commands: On/Off button, charge, shock, synchronise.
  - Energy selection: selector switch in front panel.
  - Charge command: button in front panel or buttons in external pads.
  - Shock command: button in front panel or buttons in external pads.
  - Synchronized command: sync button in front panel.
- **Charge auto-sequencing**
  - When enabled, it charges power previously set by the user for the first, second and third shocks, with no need to manually adjust the selector.
- **Maximum charge time in maximum energy**
  - < 6 seconds with 90% to 100% of the minimum specified voltage.
  - < 6 seconds with a full charge.
  - < 13 seconds from equipment initialization.
- **Charge indicators**
  - Audio indication of equipment being charged.
  - Audio indication of charge completed.
  - LED on external pads and charge level indicated on display.
- **External pads size**
  - Adult = 10.3 cm x 8.5 cm. Contact area = 81.9 cm².
  - Children = 4.5 cm x 4 cm. Contact area = 18 cm².
- **Cardioversion**
  - < 60 ms.
- **Pads**
  - Adult and child external (included).
  - Adult and child external (optional).
  - Multifunctional for pacemaker, monitoring and defibrillation (optional).
  - Multifunctional extension (optional).

AED MODULE

- **Functional characteristics**
  - Voice instructions, visual indications, CPR instructions, USB 2.0. Multilanguage.
- **USB**
  - USB 2.0 for transfer of the electrocardiogram stored in AED mode to a compatible PC.
- **SoftDEA**
  - Software for viewing the data transferred to the PC.
- **Maximum charge time**
  - 50 J: 2 seconds.
  - 150 J: 4 seconds.
  - 200 J: 6 seconds.

EXTERNAL (OPTIONAL)

- **Modes**
  - Demand or fixed.
- **Amplitude**
  - From 5 mA to 200 mA(resolution of 5 mA), accuracy 10%.
- **Pulse width**
  - 20 ms (tolerance of 10%).
- **Frequency**
  - From 30 PPM to 180 PPM (increments of 5 PPM), accuracy ± 2%.
- **Refractory period**
  - 340 ms (from 30 to 80 PPM).
  - 240 ms (from 90 to 180 PPM).

NIBP (OPTIONAL)

- **Operating principle**
  - Oscillometric.
- **Automatic mode**
  - 1, 2, 3, 4, 5, 10, 15, 30, 60 and 90 minutes.
- **Manual mode**
  - One measurement.
- **Measurement interval**

  Adult range
  - Systolic: 40 - 260 mmHg.
  - Mean: 26 - 220 mmHg.
  - Diastolic: 20 - 200 mmHg.

  Pediatric range
  - Systolic: 40 - 160 mmHg.
  - Mean: 26 - 133 mmHg.
  - Diastolic: 20 - 120 mmHg.

  Neonatal range
  - Systolic: 40 - 130 mmHg.
  - Mean: 26 - 110 mmHg.
  - Diastolic: 20 - 100 mmHg.
- **Overpressure limit by software**
  - Adult: 290 mmHg max.
  - Neonate: 145 mmHg max.
- **Overpressure protection by hardware**
  - Adult: 300 ± mmHg.
  - Neonate: 150 ± mmHg.
- **Resolution**
  - 1 mmHg.

CPR MAESTRO (OPTIONAL)

- **Accessory for Cardiopulmonary Resuscitation (CPR)**
  - Feedback of the thoracic compressions.

DISPLAY

- **Battery level indicator**
  - Yes.
- **Size**
  - 128.2 mm x 170.9 mm.
- **Diagonal**
  - 8.4".
- **Type**
  - Color LCD TFT.
- **Resolution**
  - 640 x 480 pixels (VGA).
- **Scan speed**
  - 6.25, 12.5, 25 e 50 mm/s.

ECG (supports up to 12 simultaneous derivations when equipped with optional module)

- **Inputs**
  - 3 or 5 lead ECG cable.
  - 10 lead ECG cable (optional).
  - External pads.
  - Multifunctional pads.
- **Range**
  - 15 to 350 BPM.
- **Precision**
  - ± 1 BPM from 15 to 350 BPM.
- **Rejection in common mode**
  - Higher than 90 dB, in compliance with the AAMI standards for heart monitors (EC 13).
- **Sensitivity**
  - 5, 10, 15, 20, 30 and 40 mm/mV.
- **AC line filter**
  - 60 Hz or 50 Hz.
- **ECG response frequency**
  - Diagnostic mode: 0.05 -100 Hz.
  - Monitor mode: 1 - 40 Hz.
- **Patient insulation**
  - Defibrillation proof.
  - ECG: CF type.
  - SpO_2: CF type.
- **Loose electrode**
  - Identified and shown with low level alarm.
- **Time to re-establish the ECG baseline after defibrillation:**
  - ≤ 3 seconds.

SpO_2 (OPTIONAL)

- **SpO_2 range**
  - 0 to 100%.
- **Pulse range**
  - 30 to 250 BPM.
- **SpO_2 precision**
  - ± 2% from 70 to 100%.
  - ± 3% from 50 to 69%.
- **Pulse precision**
  - ± 2 BPM.

CAPNOGRAPHY (OPTIONAL)

- **CO_2 measurement interval**
  - 0 - 99 mmHg.
- **Precision**
  - ± 2 mmHg (0 - 38 mmHg).
  - ± 5% + 0.08%. For each 1 mmHg above 38 mmHg (39 – 99mmHg).
- **Consumption**
  - 1.5 W.
- **Compensation**
  - BTPS, N_2O and O_2.

PRINTER (OPTIONAL)

- Prints up to three simultaneous derivations.
- **Type**
  - Thermal.
- **Weight**
  - 0,104 Kg.
- **Speed**
  - 25 or 50 mm/s with ± 5% precision.
- **Paper size**
  - 58 mm (width) x 15 m (maximum length).

STANDARD

- NBR IEC 60601-1
- NBR IEC 60601-1 2
- NBR IEC 60601-1 4
- NBR IEC 60601-1-6
- NBR IEC 60601-1-8
- NBR IEC 60601-2-4
- NBR IEC 60601-2-27
- NBR IEC 60601-2-30
- NBR IEC 60601-2-49 or equivalent IECs.

Instramed Ltda.
Beco José Paris, 339 - Pavilhões 18 e 19
CEP 91140-310 Porto Alegre RS Brasil
Tel.: +55 (51) 3073 8200

WWW.INSTRAMED.COM.BR

European Representative:
Obelis S.A.
Bd. Général Wahis 53, 1030 - Brussels, Belgium
Phone: + 32.2.732.59.54 | Fax: + 32.2.732.60.03
E-mail: mail@obelis.net

Some items are optional. Please verify availability.

CE 2460

ANVISA 10242950009

Folder CardioMax R5.7 Eng 2022

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INSTRAMED

- AED
- AED WITH MANUAL FUNCTION (I.ON PRO)
- ECG CURVE ON THE SCREEN (optional)
- CPR MAESTRO (optional)
- COMPATIBLE WITH 3-LEAD ECG CABLE FOR MONITORING
- AVAILABLE IN 3 VERSIONS

i.on pro i.on

Automated External Defibrillator With Manual Function

Automated External Defibrillator

biphasic SHOCK

Auto CAS Sequencing

Exclusive Technology 1 TOUCH

PRODUCT HIGHLIGHTS

- Compatible with 3-lead ECG cable.*
- Biphasic shock up to 360 J.*
- IP56 protection index.
- Weight of only 1.2 Kg.
- Rechargeable and non-rechargeable batteries.
- Ambient sound recording.*
- Autocheck of functions and battery.
- Storage of curves and events.

NEW! OPTIONAL TRANSPORT HANDLE

New generation of Automated External Defibrillators Instramed: the most complete line in the market.

i.on pro i.on

*Some items are optional.

- Much more economical disposable pads (and completely independent of battery replacement and/or the CPR feedback accessory).
- SoftDEA software included for connection, feature settings, data downloading and viewing using a PC (via USB).
- Easily switch between automatic and manual modes with a simple touch on the screen (I.on PRO).

THE IDEAL PARTNER FOR YOUR I.ON

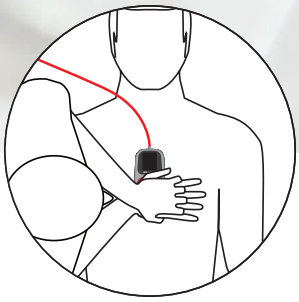
Positioned on the patient's chest, the CPR Maestro (optional) provides real-time feedback on the rescuer's performance by guiding him through voice and LCD display about the procedure's optimal frequency, strength and interval.

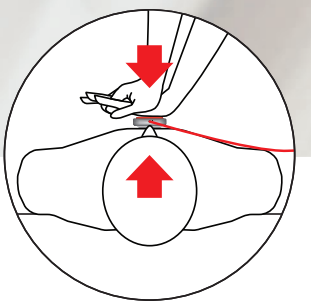
The result is a much more effective and consistent performance of CPR, resulting not only in increased chances of patient survival, but reducing the occurrence of sequelae due to lack of oxygenation.

CPR Maestro

NEW!
MANUAL SELECTION BUTTON ADULT/ CHILD

It allows the use of regular pads, even in child patients.





SIMPLE TO USE

- It evaluates, with sophisticated sensors, the patient's condition, considers the clinical variables and automatically applies the most appropriate shock therapy.
- It allows any individual with basic training to perform the care of a victim in cardiac arrest, facilitating and multiplying the possibilities of life-saving.
- Just press the single front button and follow the guidance by voice and visual indicators.

ADVANCED

- The I.on PRO model adds the flexibility of manual operation, thus allowing health professionals, based on their experience and in the ECG curve shown in the device screen, to personalize the parameters to be applied in the treatment.
- In the touch screen with excellent contrast and viewing area, the user selects the manual operation mode and then the charge up to 360 J.

INTELLIGENT

- Via the SoftDEA application (included), the Auto-Charge Sequence function can charge preset energies for the first, second and third shocks.
- Through the 3-lead ECG cable, the I.on can act as an Automated External Defibrillator or ECG monitor, alarming when it detects a cardiac arrest situation.
- It has built-in microphone and internal memory allowing digital storage of up to 10 hours of ambient sound (optional).

RELIABLE

- Instramed technology with robust design used in hundreds of medical organizations, developed for the reality of emergency care.
- A wide network of distributors providing sales of products and parts, along with qualified technical assistance, that provides excellent post-sales service.
- With more than 30 years in the business, Instramed is a manufacturer that maintains stock parts and components even for discontinued products.

KNOW MORE ABOUT THIS PRODUCT AT WWW.INSTRAMED.COM.BR

GENERAL SPECIFICATIONS (I.on/I.on PRO)

- **Dimensions:**
  - 225 mm (W).
  - 225 mm (H).
  - 69 mm (D).
- **Weight:**
  - 1.2 Kg (basic) to 1,9 Kg (complete).
- **Non-rechargeable internal battery:**
  - Type: Manganese Lithium Dioxide ($LiMnO^2$) 18V, 2800 mAh.
  - Duration of battery: more than 300 shocks in 200 J or 15 hours of continuous monitoring.
- **Rechargeable internal battery:**
  - Type: Li-Ion, 14.4 VDC 4.0 A/h.
  - Duration: 18 hours of continuous monitoring.
  - Time for battery full charge (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 power supply charger 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: 1º shock - 150 J; following shocks - 200 J.
  - Child: 50 J.
- **Defibrillation scales adjusted by user (via SoftDEA):**
  - Adult (non rechargeable battery 2800 mAh or rechargeable): 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).
- **Protection rating:**
  - IP56.
- **Classification:**
  - Class II, internally energized equipment.
- **Electrical insulation:**
  - CF type.
- **Operating mode:**
  - Continuous operation.
- **Maximum time from rhythm analysis beginning to discharge readiness:**
  - 200 J: 20 seconds.
  - 360 J: 25 seconds.
- **Maximum time from start of operation beginning to full discharge readiness:**
  - 200 J: 25 seconds.
  - 360 J: 35 seconds.
- **Non-frequent use equipment:**
  - Comply with the requirements for non-frequent use equipment as specified in NBR IEC 60601-2-4 standard.
- **Connectivity**
  - In the cloud (consult availability).
  - IOT integration and dedicated app (consult availability).

ENVIRONMENTAL SPECIFICATIONS

- **Temperature:**
  - Operational: 0 to 50ºC.
  - Storage: -20 to 50ºC.
- **Humidity:**
  - Operational: 10 to 95% RH, without condensation.
  - Storage: 10 to 95% RH, without condensation.
- **Altitude:**
  - Recommended altitudes: lower than 2.000 meters.

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.
  - Manual selection button: adult/child.
- **Scales for defibrillation:**
  - Adult: adjustable from 120 up to 360 J (depending on the battery and via SoftDEA). 1º shock - 150 J; following shocks - 200 J.
  - Child: 50 J.
- **Adults/children selection:**
  - Automatic due to the size of the pads.
  - By manual selection button.
- **Charge command:**
  - Automatic after identifying arrhythmias that should receive shock.
- **Shock command:**
  - Front panel button, when blinking.
- **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.
- **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).

OTHER SPECIFICATIONS (I.on PRO)

- **Commands:**
  - Touchscreen: allows for the selection of manual mode and defining energy scales.
- **Scales for defibrillation (Manual mode)**
  - Adult: scales between 120 J to 360 J.
  - Child: 10, 20, 30, 40 or 50 J.

STANDARDS

- NBR IEC 60601-1
- NBR IEC 60601-1-2
- NBR IEC 60601-1-6
- NBR IEC 60601-1-8
- NBR IEC 60601-1-9
- NBR IEC 60601-1-11
- NBR IEC 60601-2-4 or equivalent IECs.

**Some items are optional.*

Instramed Indústria Médico-Hospitalar Ltda.
Beco José Paris, 339 - Pavilhão 19
CEP 91140-310 Porto Alegre RS Brasil
Tel.: (51) 3073-8200
E-mail: comercial@instramed.com.br
WWW.INSTRAMED.COM.BR

Representante da Comunidade Européia
Obelis S.A.
Bd. Général Wahis 53, 1030 - Brussels, Belgium
Phone: + 32.2.732.59.54 | Fax: + 32.2.732.60.03
E-mail: mail@obelis.net

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