

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

**SIP** 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.





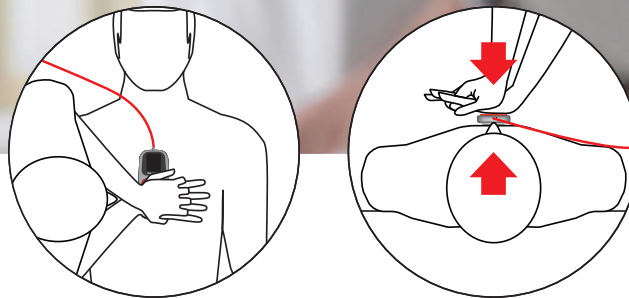
*\*Some items are optional - Please verify availability.*

- Oximetry (SpO<sub>2</sub>)\*
- Non invasive pacemaker\*
- Non-invasive pressure (NIBP)\*
- Capnography (EtCO<sub>2</sub>)\*
- 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.



## CARDIO MAX 8 SERIES

### PRACTICAL

- Light.
- Ready to use in less than 6 seconds.
- Biphasic 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](http://WWW.INSTRAMED.COM.BR)

## 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 °C.
- Storage: -20 to 50 °C.

### • 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  $\pm 2\%$ .

### • 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  $\pm$  mmHg.
- Neonate: 150  $\pm$  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

- $\pm 1$  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<sub>2</sub>: CF type.

### • Loose electrode

- Identified and shown with low level alarm.

### • Time to re-establish the ECG baseline after defibrillation:

- $\leq 3$  seconds.

## SpO<sub>2</sub> (OPTIONAL)

### • SpO<sub>2</sub> range

- 0 to 100%.

### • Pulse range

- 30 to 250 BPM.

### • SpO<sub>2</sub> precision

- $\pm 2\%$  from 70 to 100%.
- $\pm 3\%$  from 50 to 69%.

### • Pulse precision

- $\pm 2$  BPM.

## CAPNOGRAPHY (OPTIONAL)

### • CO<sub>2</sub> measurement interval

- 0 - 99 mmHg.

### • Precision

- $\pm 2$  mmHg (0 - 38 mmHg).
- $\pm 5\% + 0.08\%$ . For each 1 mmHg above 38 mmHg (39 - 99 mmHg).

### • Consumption

- 1.5 W.

### • Compensation

- BTPS, N<sub>2</sub>O and O<sub>2</sub>.

## PRINTER (OPTIONAL)

- Prints up to three simultaneous derivations.

### • Type

- Thermal.

### • Weight

- 0,104 Kg.

### • Speed

- 25 or 50 mm/s with  $\pm 5\%$  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.

Instamed Ltda.

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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.



ANVISA 10242950009

Folder CardioMax R5.7 Eng 2022

INSTRA MED

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
216869-2017-AQ-BRA-NA-PS

Initial certification date:  
18 October 2017

Valid:  
26 February 2022 – 25 February 2025

This is to certify that the management system of  
**INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR  
LTDA.**

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

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**DESIGN, MANUFACTURING, SERVICE, SALES AND DISTRIBUTION OF CARDIOVERTERS,  
DEFIBRILLATORS AND MULTIPARAMETER PATIENT MONITORS.**

Place and date:  
Høvik, 09 February 2022



For the issuing office:  
**DNV Product Assurance AS**  
Veritasveien 3, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
289758-2019-CE-BRA-NS-PS Rev. 0.0

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

Valid Until:  
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**



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](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



Certificate No.:  
289758-2019-CE-BRA-NA-PS Rev. 0.0

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

Valid Until:  
27 May 2024

## 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



Certificate No.:  
289758-2019-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:

- 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