

# User manual



**DUALMAX**  
Cardioverter/Biphasic Defibrillator Monitor

INSTRAMED

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# Manufacturer

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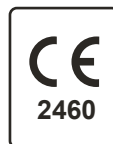
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**For information about warranty or technical assistance, please contact Instramed's technical support.**

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# Battery use

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

## First use

Before using the DualMax for the first time, the equipment must receive a full battery charge. In order to do this, the equipment needs to be connected to an electric current for at least eight hours.

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## Occasional use

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

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

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## Storage

The battery must be removed from the equipment in case it is stored or not used.

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## Replacement

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

The battery can be replaced following the procedures described on the chapter "Care and maintenance".

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



**ATTENTION: the equipment is capable of operating with only one battery connected.**



**ATTENTION: when servicing the batteries, it is obligatory to change only one battery at a time, leaving the other battery in the device, so that it can continue to operate at that moment.**

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# Package contents

## Included items

- 1 Dualmax and accessories listed in **Accessories** chapter.
- 

## Optional items

- Optional items listed in **Accessories** chapter.

**Consult availability.**

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# Replacement parts

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

Consult Instramed for prices.

Shipping may apply.

To request parts and services, contact your local representative (the list can be found at [www.instramed.com.br](http://www.instramed.com.br)) or directly contact Instramed by telephone at: +55 (51) 3073 8200.

**The items already included may be acquired for replacement as extra items.**

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## Purpose and application

The DualMax uses electrical defibrillation and cardioversion therapy to reverse ventricular fibrillation arrhythmia or ventricular tachycardia without a pulse in adult and pediatric patients. Cardioversion of arrhythmias is also used when necessary.

In the external pacemaker mode, the DualMax uses monophasic electrical stimulation in order to reproduce or regulate the cardiac rhythm.

The equipment is also used for monitoring vital signs in adult, pediatric and natal patients.

The ECG/Monitor mode shows the ECG signal and the heart rate value on the screen.

The NIBP/Monitor mode indicates the blood pressure value measured by a Non-Invasive method on the screen.

The SpO<sub>2</sub> / Monitor mode measures the oxygen saturation of blood by a Non-Invasive method.

The EtCO<sub>2</sub>/Monitor mode presents the partial pressure of exhaled CO<sub>2</sub> at the end of expiration as well as inhaled value.

The RESP/Monitor mode displays the respiratory rate measured by ECG electrodes or by the capnograph.

---

## Characteristics

The DualMax is a modern, practical, lightweight, compact and portable device that can be used in emergency situations.

The DualMax offers the following parameters and/or characteristics (some parameters are optional):

- Biphasic Defibrillator (DEF).
- Automatic defibrillator mode (AED).
- Non-Invasive Pacemaker (NIP).
- ECG and cardiac frequency monitoring.
- Respiratory rate monitoring (RESP).
- Sudden Death Prevention Mode (SDP).
- ST segment value monitoring.
- Temperature (TEMP) monitoring.
- Functional artery oxygen saturation monitoring (SpO<sub>2</sub>).
- Pressure monitoring (Non-Invasive method - NIBP).

- Invasive pressure monitoring (IP).
- Exhaled carbon dioxide monitoring (EtCO<sub>2</sub>).
- Charge Auto-Sequencing mode (CAS).
- Real Time Check (RTC).
- Printer.
- 2 removable and rechargeable batteries.

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## Optional items



This manual refers to all of DualMax's functions, however, some of them are optional and may not be present in your equipment. The icon beside will appear next to the text, whenever an optional characteristic is mentioned.



**WARNING: the DualMax must be used by qualified professionals on patients who need defibrillation therapy or as a complement in assessing the patient's physiological conditions. It must be accompanied by constant analysis of the patient's clinical status and symptoms.**

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## About the manual

This guide explains the functioning of the DualMax defibrillator/monitor series, alerting the user to possible safety risks. This manual is part of the DualMax and must be kept for further reference.

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

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

## Attention



The following factors can 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.

DualMax does not have support system and its carrying handle must not be used for this purpose.

This equipment does not have reminder signals.

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## Warnings



**IMPORTANT:** this device must only be operated by qualified technical personnel. Before using, read the manual attentively.

**WARNING:** for defibrillation, cardioversion, pacing and AED modes, we do not recommend the use in patients under 01 (one) year old. For monitoring modes such as ECG, SpO<sub>2</sub>, NIBP and EtCO<sub>2</sub>, it's use is possible with suitable accessories to these patients.

**WARNING:** DualMax can be used by patients over 01 (one) year old, regardless of their weight.

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

**ELECTRICAL SHOCK HAZARD: NEVER OPEN THE DEVICE.** Each and every repair must be performed by Instramed's authorized technical centers.

**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 (aed mode). do not give cardiac massage at this point.

**ATTENTION:** do not use DualMax or its accessories in the presence of MRI equipment.

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

If the precision of measurements seems to be incorrect, first check the vital signs of the patient and then check the functioning of the DualMax.

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

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

**NOTICE:** the DualMax must only be used as a complement to assess the patient's physiological conditions. It must be accompanied by constant analysis of the patient's clinical status and symptoms.

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

**NOTICE:** the applied parts (electrodes, sensors, armbands, etc.) are protected against defibrillation discharge; during discharge there may be baseline variation.

**WARNING:** when the DualMax is operated in monitor mode, it can be used with other electromedical equipment simultaneously connected to the patient, provided that the other equipment are in compliance with the safety standards.

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

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

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

**WARNING:** Do not modify this equipment without authorization from Instramed.

## Adverse or side effects

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

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

Possibility of reddish skin at the defibrillation electrodes exposition place, due to the high voltage applied.

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. Do not apply conductive gel outside the area of contact with the pads to avoid electrical leakage.

Do not apply conductive gel outside the area of contact with the pads to avoid electrical leakage.

Possibility of erythematous skin at the pacemaker electrodes exposition place, especially during prolonged use.

Possibility of discomfort and pain, with the use of high levels of pacemaker current. In case of high levels of current, it is recommended that the patient is anesthetized or unconscious.























Possibility of eczematous skin, due to the use of non-biocompatible electrodes. Always use accessories with technical recommendation described in this User Guide.













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 DISCOMFORT and REDUCED BLOOD CIRCULATION in NIBP measuring.** The operator should always ensure that the applied pressure or the quantity of measures did not effect in the blood circulation or discomfort to the user. In this case, the quantity of measures should be decreased and the arm should be changed.

**DISCOMFORT or COMPLICATIONS DUE TO THE PRODUCT SMELL in EtCO<sub>2</sub> monitoring.** Some patients have been with nausea or headaches due to the cannula smell or discomfort with the cannula positioning. In this cases, it's reversible with just changing the cannula or readjusting the positioning.

## Classification and symbols

Symbol	Description
	Equipment and its isolated defibrillation proof applied parts of CF type.
	Follow the instructions for use.
	General warning symbol.
	Warning: dangerous voltage.
	Terminal for equalization of potential.
	Terminal for general ground.
Desl	Disconnects the equipment.
	Alternate current.
	Direct current.
	Non-ionizing radiation.
	Input and output connection.
	Maintain this side upwards.
	Fragile equipment.
	Maximum stacking of 4 units.
	Maintain protected from the rain.
	Storage temperature limits The norms EN 60601-1 (IEC 60601-1) and ISO 15223 are used as reference for the symbols.
	Operation temperature limits The norms EN 60601-1 (IEC 60601-1) and ISO 15223 are used as reference for the symbols.
	Minimum and maximum atmospheric pressure.
	Minimum and maximum relative humidity.
	Recyclable paper.
	Remains of electrical and electronic equipment - Separate disposal from other objects.
CE 2460	Mark of compliance with European Community. "2460" stands for the number of the Notified Body.
	Manufacturer.
	Manufacturing date.

	European representative.
	Serial number.
	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.
	Consult instructions for use.
	Lot code.
	Catalog number.
	Date after which the product cannot be used.

## Standards

**DualMax was designed following performance and safety national and international standards. Among them are:**

- NBR IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- NBR IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirement for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and test.
- NBR IEC 60601-1-4 - Medical electrical equipment - Part 1-4: General requirements for the safety - Collateral Standard: Programmable electrical medical systems.
- NBR IEC 60601-1-6 - Medical Electrical Equipment - Part 1-6: General requirements for basic safety - Collateral Standard: Usability.
- NBR IEC 60601-2-4 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators.
- NBR IEC 60601-2-27 - Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.
- NBR IEC 80601-2-30 - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-



invasive sphygmomanometers.

- NBR IEC 60601-2-49 - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.

Or equivalent IECs.

**The current versions of the Standards can be verified in the Certificate of Conformity of the product, available at [www.instramed.com.br](http://www.instramed.com.br).**

## Device care

- Do not place the equipment where it may fall on the patient. Do not lift the equipment by its cables or connections.
- Place cables connected to the patient in order to restrict the possibility of strangulation.
- Keep the defibrillator in a dry environment, avoiding places that allow liquids to spill over the monitor. Do not use the defibrillator if it is wet or excessively humid.
- Always keep the equipment and its accessories clean and well maintained.
- If you suspect a fall or external damage, do not use the equipment.

---

## Grounding



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

## Electromagnetic compatibility

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

---

## Disposing of the device

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

For disposal of products from Instramed, contact us by the telephone numbers available on the website [www.instramed.com.br](http://www.instramed.com.br) or by the e-mail [qualidade@instramed.com.br](mailto:qualidade@instramed.com.br).

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

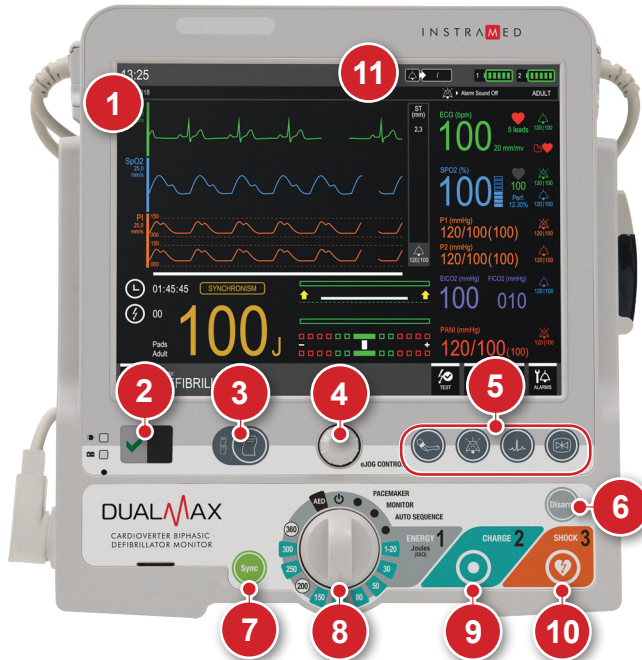


For countries that follow European Guidelines, refer to 2002/96/CE. For other, countries, refer to local regulations for the proper disposal of trash in your area.

# The equipment

# 3

## Front panel



1. Touch screen.
2. Indication of AC Mains, battery charging and product operation status (see item "Indication of AC Mains, battery charge and product status" forward, in this chapter).
3. Print: quick access button (see item "Quick access buttons", forward, in this chapter).
4. E-Jog control: access to the equipment's general settings and menu navigation.
5. Quick access buttons (see item "Quick access buttons" forward, in this chapter).
6. Disarm: disarms the stored charge.
7. Sync: activates synchronization.
8. Selector key: turns the equipment on and off; selects the operation mode (see following chapters).
9. Charge: charges the electrodes with the selected charge.
10. Shock: applies shock.
11. Alarm LEDs: indicate HIGH PRIORITY ALARM (RED) OR MEDIUM PRIORITY (YELLOW).

## Screen

The LCD screen displays graphic and numeric information used in ECG and SpO<sub>2</sub>, defibrillation and others. For more information about the configurations and screen information, see the “Screen and operation” section.

## e-Jog control

The e-Jog control is used to access all of the DualMax's functions, such as set alarms, define information displayed on the screen, alter parameters, etc.

**ROTATE:** rotating allows the user to select or change information and navigate all menus. It operates similarly to a computer mouse.

**PRESS:** works similarly to the enter button on a computer, confirming the selection.



## Selector switch

**Scale from 1 to 360 J:** Allows the user to select the desired energy charge.

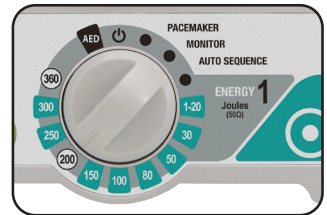
**Monitor mode:** used to monitor ECG, SpO<sub>2</sub>, NIBP, EtCO<sub>2</sub> and RESP parameters, as in a multiparametric monitor.

**Pacemaker mode (\*)**: enables external pacemaker.

**Off:** Turns off the equipment.

**AED position:** enables external automatic defibrillator mode.

**Auto Seq mode:** enables charge auto-sequencing.



**NOTE:** the equipment does not defibrillate in pacemaker and monitor modes. The pacemaker will only work in pacemaker mode.



(\*) Check your equipment's configuration. This item is optional and may not be present in all commercialized equipment.

## Quick access buttons



**Fast lead change:** enables quick access to change ECG leads.



**Fast sensitivity change:** enables quick change of ECG sensitivity.



**Print (when available):** press once to print a quick report. For continuous printing, simply press the button for 3 seconds. For further information, see the “Printing” section.



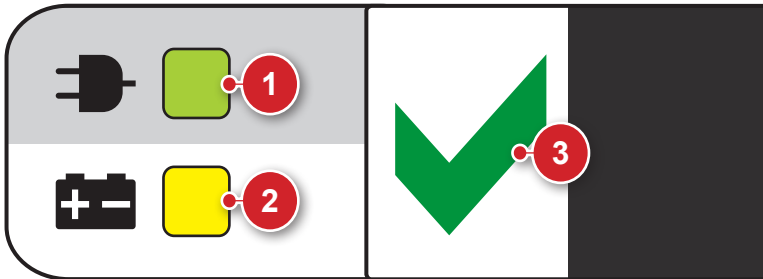
**Pause audio:** press the button quickly to deactivate ALL sound alarms for a previously programmed

period of time. Press for 3 seconds to deactivate ALL sound alarms for an INDETERMINATE period. For more information, see the “Alarms and limits” section.



**NIBP (when available):** starts or suspends the functionality of the Non-Invasive Blood Pressure Measurement. *When the NIBP (optional) parameter is not present in the device, this button has no function.*

## Power and battery charging indications

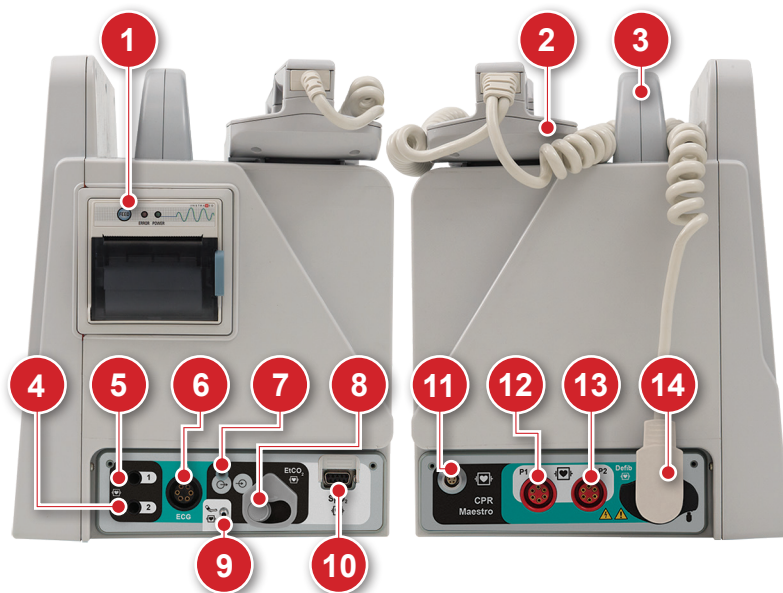


1. Power connected: when the LED is on, it indicates that the equipment is connected to a power source or an external battery.
2. Battery charging: when the LED is on, it indicates that the battery is charging.

3. Indicates that the equipment is ready to be used.

**OBS:** when the equipment is connected to an electric current, the LEDs will light up indicating the beginning of charging, even if the DualMax is inoperative.

## Side view



### 1 - Printer



Printer for thermosensitive paper. It prints electrocardiograms and events. For more information view the "Printing" chapter.

### 2 - Pads

The pads accompanying the DualMax must be placed on top of the equipment and must be properly connected to the adult adapter.

### 3 - Transport handle

Handle used to carry the equipment.

### 4 - Temperature connector



Temperature connector YSI 400 standard (channel 1).

## 5 - Temperature connector



Temperature connector YSI 400 standard (channel 2).

---

## 6 - ECG connector

Connector for ECG cables. Depending on the parameters present in the equipment, it may be available in the following settings:

- 3 or 5-wire - AAMI standard. Protected against defibrillation.
  - 10-wire (optional) - allows up to 12 simultaneous leads. This connector substitutes the standard connector and is not compatible with the 3 or 5-wire cables.
- 

## 7 - Capnography exhaust connector



Connector used for the removal of the gases collected by capnography. For more information, see chapter 12 - "Capnography".

---

## 8 - Capnography connector



Connector for the capnography sampling line.

---

## 9 - NIBP connector



Connector for direct use with the armband.

---

## 10 - SpO<sub>2</sub> connector



BCI standard oximetry connector. Adult and child oximetry sensors.

---

## 11 - CPR Maestro connector



CPR help device connector.

---

## 12 - P1 connector

Invasive pressure connector (channel 1).

## 13 - P2 connector

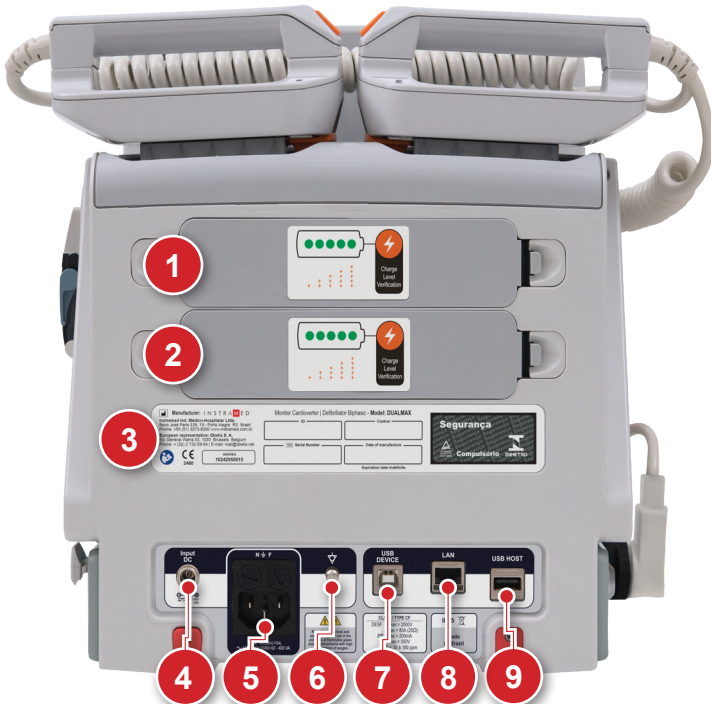
Invasive pressure connector (channel 2).

## 14 - Defibrillation electrodes (pads) connector:

**Multifunctional:** adhesive pads for desfibrillation, pacemaker and monitoring.

**Adult/child external pads:** accompany the equipment, may be used in adults and children. Cannot be used for pacemaker mode.

## Rear panel





## 1 - Removable battery 1

The battery can be easily replaced by simply pressing both side tabs one against the other. The battery will unlock and automatically detach itself from the equipment.

**NOTE: do not remove the battery when the equipment is operating in battery mode. Connect it to an electric current first.**

---

## 2 - Removable battery 2

The battery can be easily replaced by simply pressing both side tabs one against the other. The battery will unlock and automatically detach itself from the equipment.

**NOTE: do not remove the battery when the equipment is operating in battery mode. Connect it to an electric current first.**

---

## 3 - Identification tags

The identification tags have important information about the product, such as the model, serial number and manufacturer information. This information may be requested if technical assistance is needed. Therefore, do not remove or damage the identification tags.

---

## 4 - External DC socket

For battery connection or external DC source connection in a range of 11 to 16 VDC.

---

## 5 - 3-pin power connector

Input of 100 to 240 VAC, with central pin for grounding.  
5 A fuse (20 mm 20 AG F5A GLASS FUSE).

---

## 6 - Grounding and potential equalizer

Potential equalization and general grounding connector.

## 7 - USB connector



USB connector for access to data stored by the AED mode. It can be plugged directly to a Windows PC.

---

## 8 - LAN connector

Connector for wired network connection.

---

## 9 - USB host connector



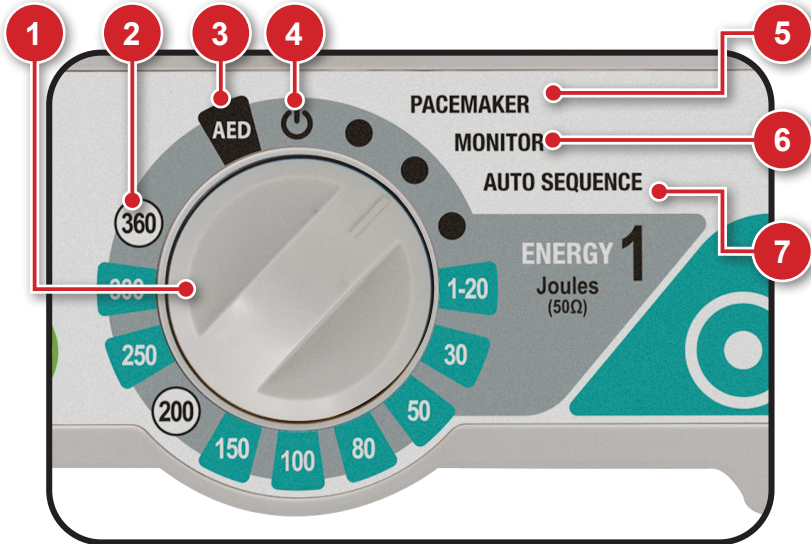
Connector for pendrive connection.

# Screen and operation

# 4

## Turning on and operating

Use selector switch (1) for turning DualMax on and off. When turning on, the operator must immediately select an operation mode.



### 1 - Selector switch

Turn clockwise or counter-clockwise to select the operation mode. On "Off" position the equipment is turned off.

### 2 - Defibrillator mode

Enables to set the time of the automated internal discharge of the energy stored in the device.

### 3 - AED mode



Enables the Automated External Defibrillator (AED).

In this situation, the DualMax is capable of assessing, through sophisticated sensors, the patient's state, consider the clinical variables and apply, automatically, the most indicated shock therapy. At the same time, the device guides the user by verbal commands and screen indications which can be warnings, instructions or status messages.

**The DualMax's Automated External Defibrillator will only function if the multifunctional pads (adhesive) are connected to the equipment.**

---

### 4 - Turns equipment off

In this position, the DualMax is turned off. After the device is turned off, only the circuit that charges the battery remains in operation. (This is indicated by a green LED in the base of the equipment's front).

---

### 5 - Pacemaker mode



Enables the external pacemaker.

**The external pacemaker will only work if the multifunction pads (adhesives) are connected to the equipment.**

---

### 6 - Monitor mode

Used to monitor the patient's ECG, SpO<sub>2</sub>, NIBP, EtCO<sub>2</sub> and RESP. In this position the DualMax works as a multiparametric monitor.

**ECG and SpO<sub>2</sub> limit alarms continue operating. ECG and SpO<sub>2</sub> messages are enabled.**

---

### 7 - Auto Seq mode

In this mode, it is possible to deliver shocks in a sequence of energy levels preset by the user. (See the "Defibrillator mode" chapter).

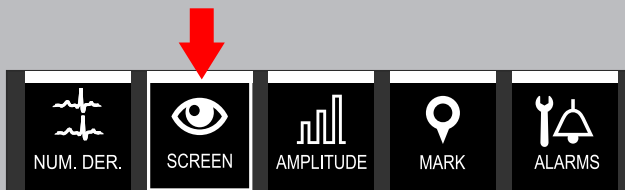
## Operating e-Jog control

To access the configuration menus and equipment operation use the rotating e-Jog control as indicated below:



### STEP 1

**ROTATE:** rotate the button to the desired item observing the highlighted icons on the equipment screen.



### STEP 2

**PRESS:** press to select the highlighted item. The menu for the chosen function will appear.

### STEP 3

**ROTATE:** rotate the button to the corresponding value desired in the selected item's menu.

### STEP 4

**PRESS:** press to confirm the new selected value.

## Information bar

The information bar is present in all operating modes of the equipment. In it are present the following information:



- |                         |                                |
|-------------------------|--------------------------------|
| 1. Time.                | 6. Date.                       |
| 2. Patient status.      | 7. Patient data.               |
| 3. Alarms total number. | 8. Alarm messages.             |
| 4. Battery 1 charge.    | 9. Patient type (adult/child). |
| 5. Battery 2 charge.    |                                |

## Quick access bar

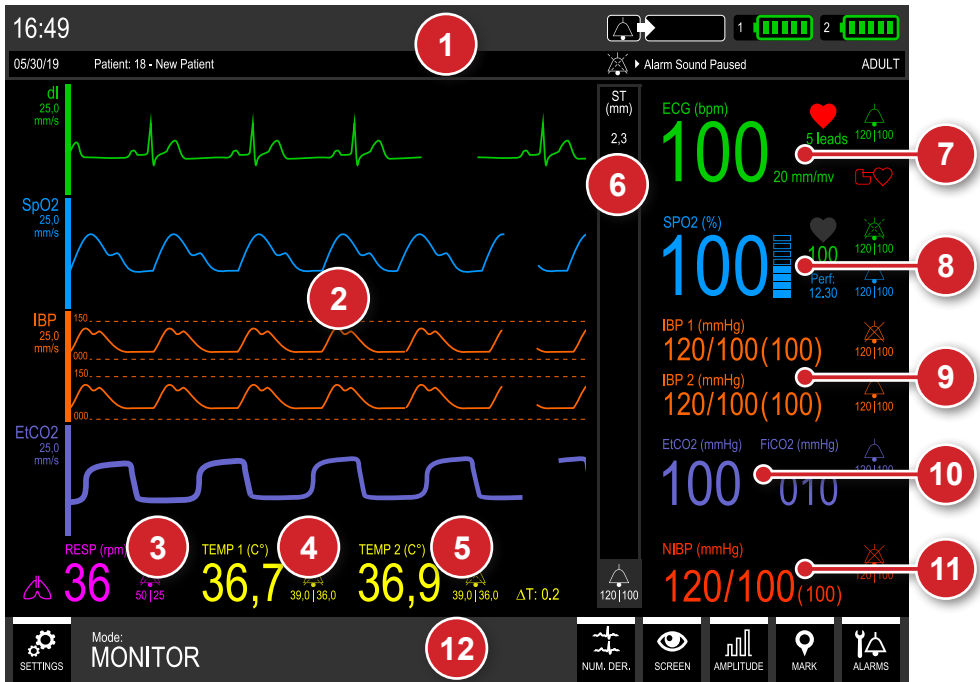
The quick access bar is present in all operating modes of the equipment. In it are present access buttons to different functions.

**NOTE:** the available functions may vary according to the parameters installed and according to the operating mode selected. The buttons shown below are only an example and may vary.



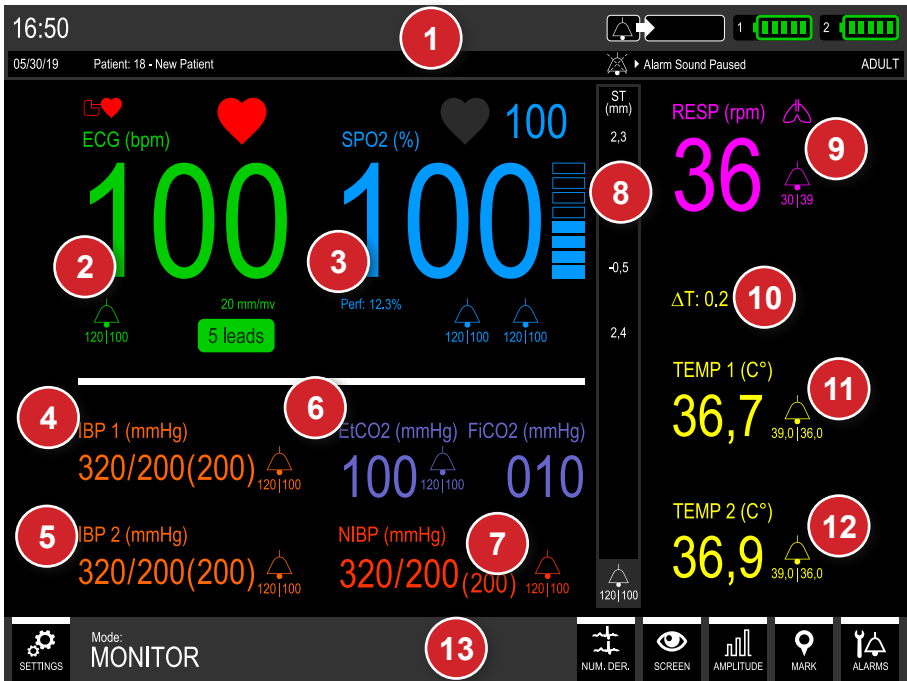
- |  |                                     |
|--|-------------------------------------|
| 1. Button to access the configuration menu.                  | 5. Button for amplitude adjustment. |
| 2. Operating mode active.                                    | 6. Mark event.                      |
| 3. Changes the number of ECG curves displayed on the screen. | 7. Alarm sound status.              |
| 4. Button for changing the visualization mode of the screen. |                                     |

## Monitor mode screen – Variation A (with curves exhibition)



1. Information bar.
2. Graphic area for parameter curves exhibition.
3. RESP data.
4. Temperature 1 data.
5. Temperature 2 data.
6. ST segment data.
7. ECG data.
8. SpO<sub>2</sub> data.
9. Invasive Pressure data.
10. Capnography data.
11. NIBP data.
12. Quick access bar.

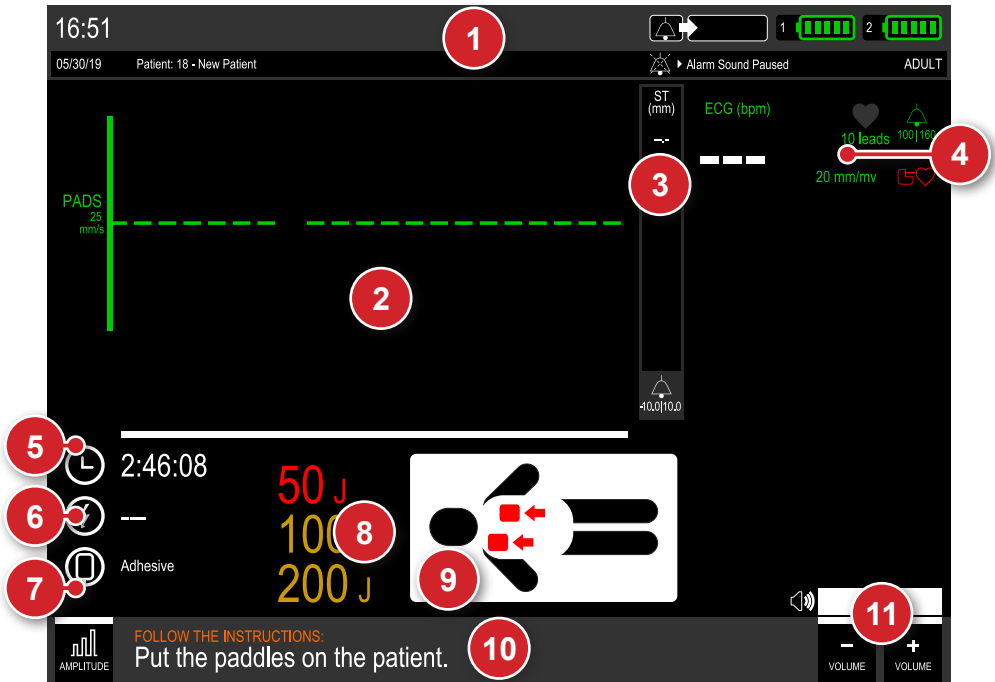
## Monitor mode screen – Variation B (without curves exhibition)



1. Information bar.
2. ECG data.
3. SpO<sub>2</sub> data.
4. Invasive pressure 1 data.
5. Invasive pressure 2 data.
6. Capnography data.
7. NIBP data.
8. ST segment data.
9. RESP data.
10. ΔT value.
11. Temperature 1 data.
12. Temperature 2 data.
13. Quick access bar.

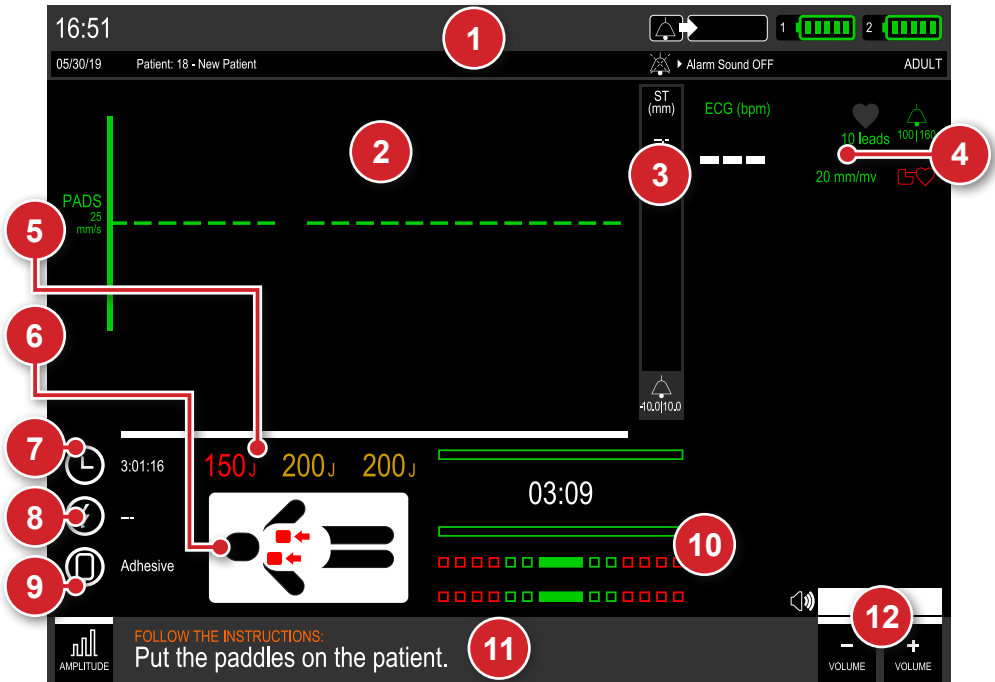


## AED mode screen - Variation A (without CPR)



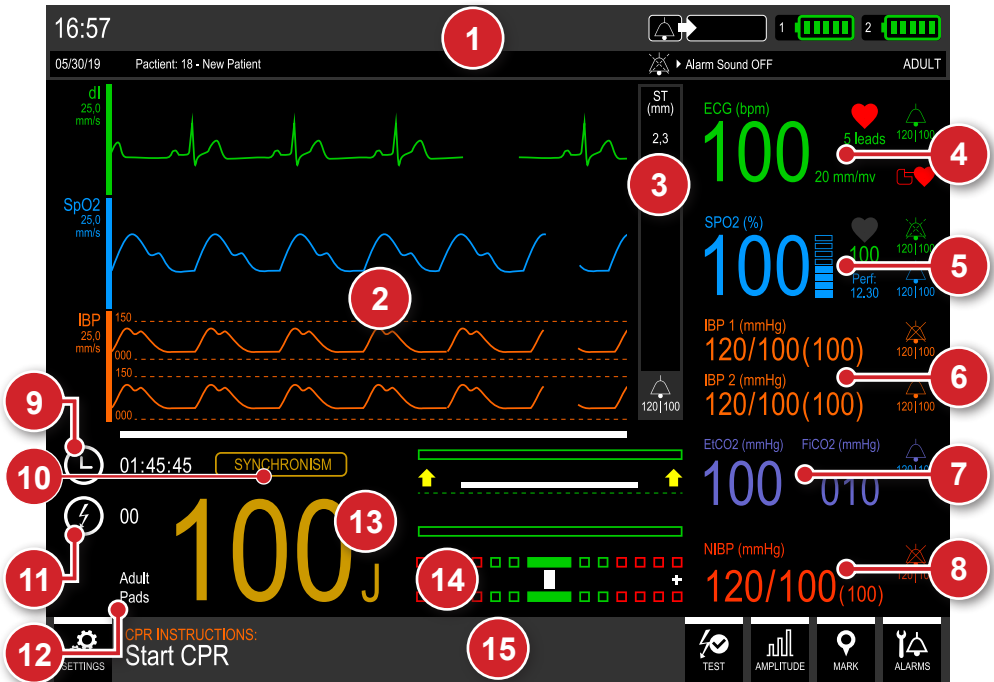
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. Treatment duration.
6. Number of applied shocks.
7. Type of pads selected and defibrillation mode.
8. Charges selected for the first, second and third shocks.
9. Illustrative image of the treatment stage.
10. Quick access bar and treatment stage information.
11. Automated External Defibrillator (AED) volume.

## AED mode screen - Variation B (with CPR)



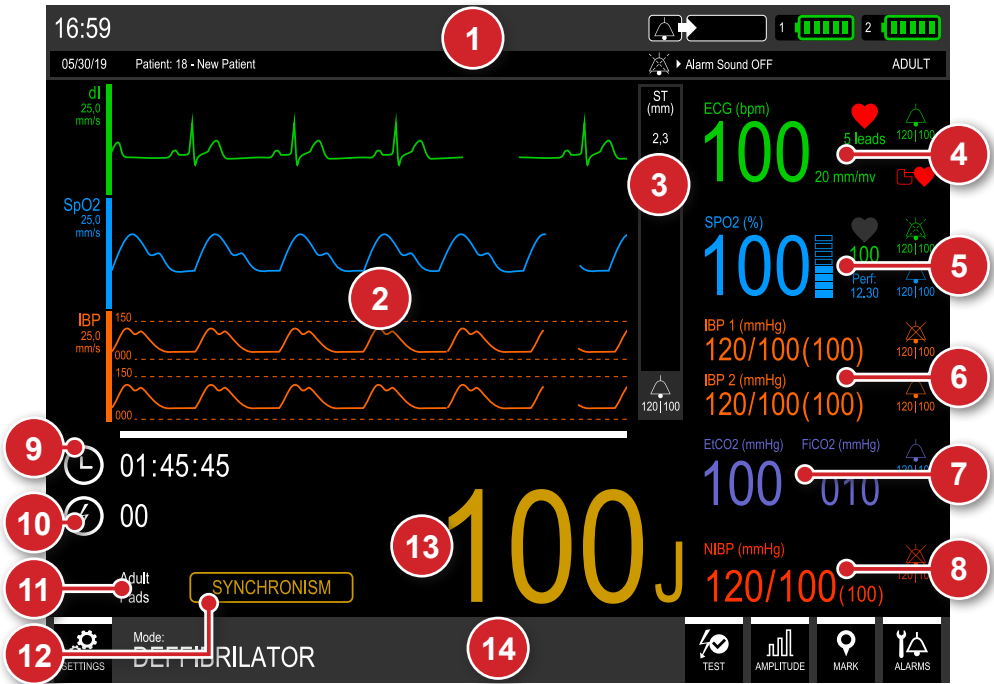
1. Information bar.
2. Graphic area for ECG curves exhibition.
3. ST segment data.
4. ECG data.
5. Value of energy to be applied.
6. Illustrative image of the treatment stage.
7. Treatment duration.
8. Number of applied shocks.
9. Type of pads selected and defibrillation mode.
10. CPR indicative graphic.
11. Quick access bar and treatment stage information.
12. Automated External Defibrillator (AED) volume.

## Defibrillator mode screen – Variation A (with CPR)



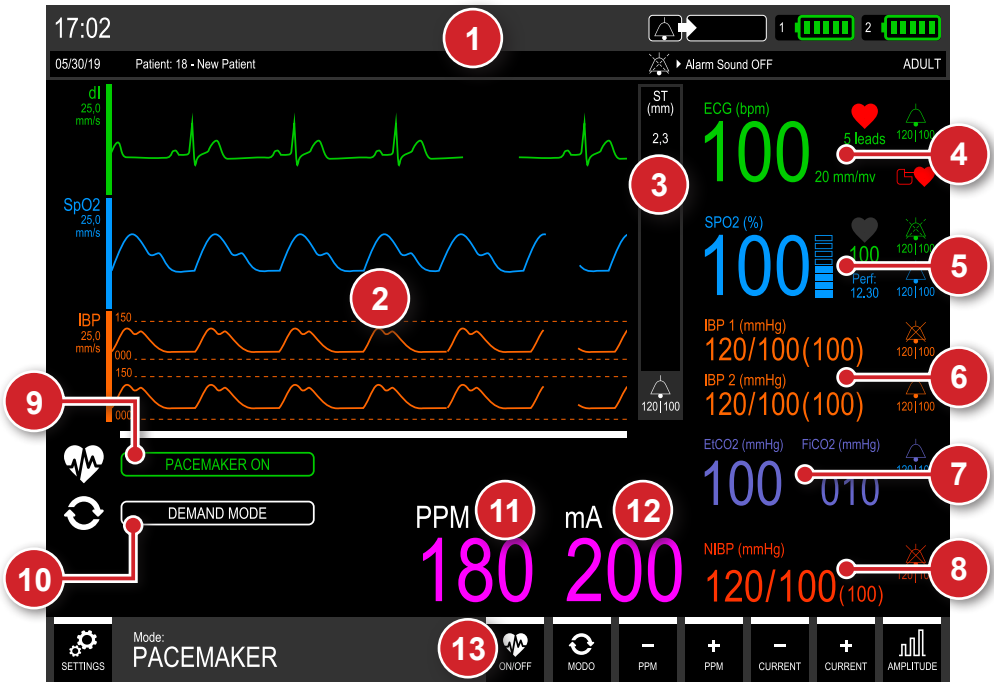
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO<sub>2</sub> data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Treatment duration.
10. Indication of active synchronism.
11. Number of applied shocks.
12. Type of pads selected (adult/child).
13. Selected charge.
14. CPR indicative graphic.
15. Quick access bar.

## Defibrillator mode screen – Variation B (without CPR)



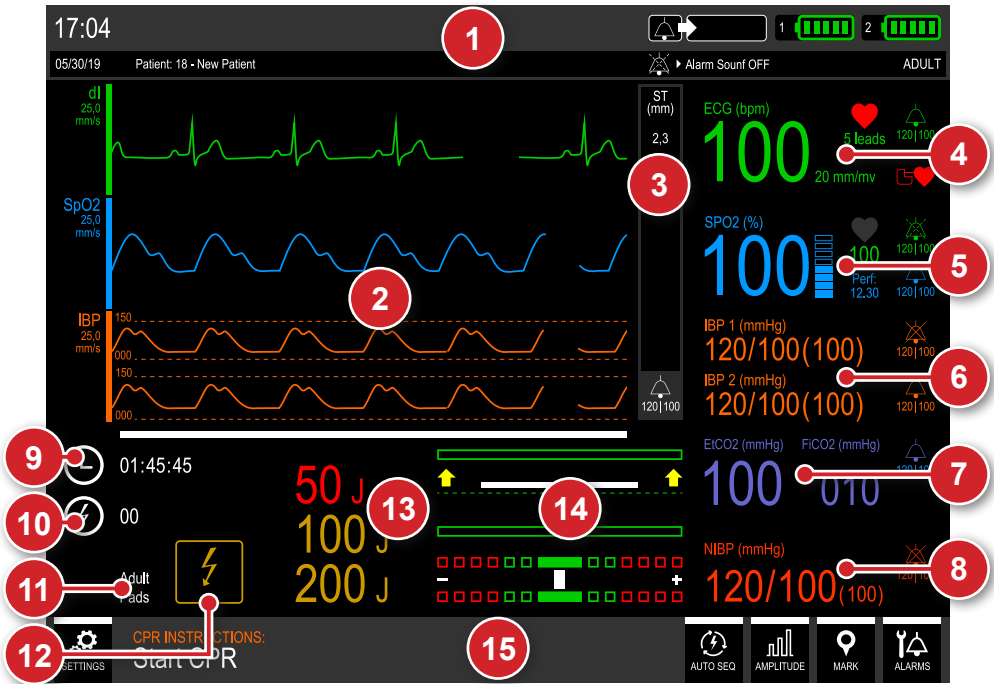
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO<sub>2</sub> data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Treatment duration.
10. Number of applied shocks.
11. Type of pads selected (adult/child).
12. Indication of active synchronism.
13. Selected charge.
14. Quick access bar.

## Pacemaker mode screen



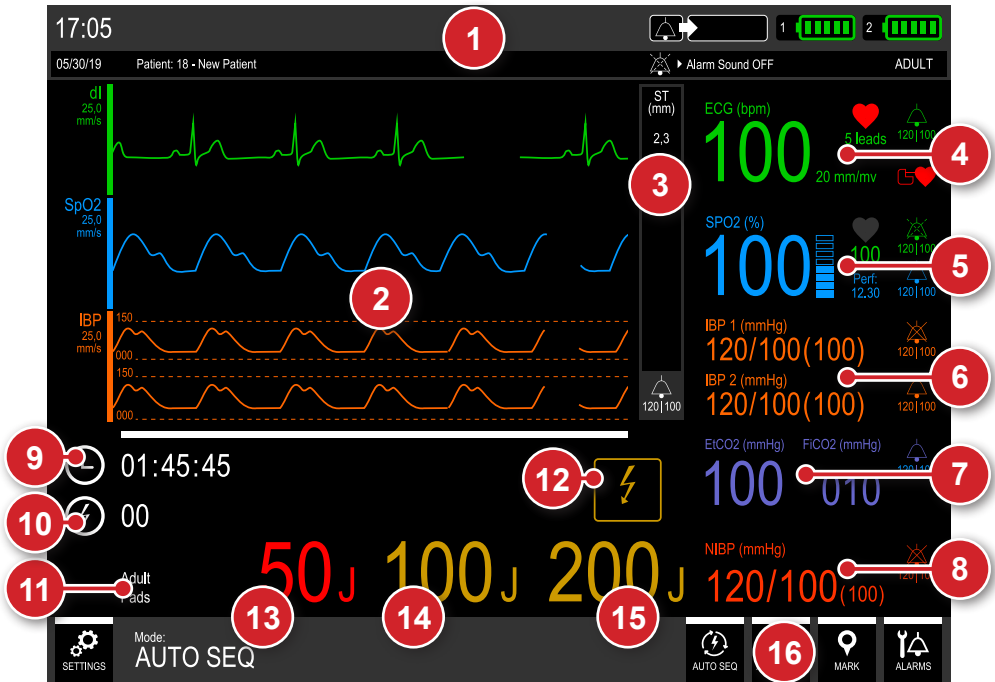
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO<sub>2</sub> data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Pacemaker operating status.
10. Pacemaker operating mode.
11. BPM measure value.
12. mA measure value.
13. Quick access bar.

## Charge auto-sequencing mode screen – Variation A (with CPR)



1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO<sub>2</sub> data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Treatment duration.
10. Number of applied shocks.
11. Type of pads selected (adult/child).
12. Indication of auto-sequencing active.
13. Charges selected for the first, second and third shocks.
14. CPR indicative graphic.
15. Quick access bar.

## Charge auto-sequencing mode screen – Variation B (without CPR)



1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO<sub>2</sub> data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Treatment duration.
10. Number of applied shocks.
11. Type of pads selected (adult/child).
12. Indication of auto-sequencing active.
13. Charge selected for the first shock.
14. Charge selected for the second shock.
15. Charge selected for the third shock.
16. Quick access bar.

The DualMax has audio and visual indications of physiological and technical alarm conditions.

## Physiological alarm (high priority)

There are five ways to enable the physiological alarm indications:

**ECG - Asistoly** - The DualMax cannot detect valid heartbeats for over 4 seconds.

**SDP - Shock Indicated** - When the DualMax identifies a rhythm that is liable to shock.

**RESP - Apnea** - When the DualMax identifies lack of respiration for a period of time longer than that set in the Adjustments menu.

**SpO<sub>2</sub> - Pulse Loss** - When the DualMax identifies that it has lost the pulse in the SPO<sub>2</sub> sensor.

**Violation of MAXIMUM or MINIMUM limits** - When the Oximetry, ECG, NIBP, EtCO<sub>2</sub> or RESP maximum or minimum alarm limits are not within the equipment's preset range.

The visual indications of physiological alarms will occur in any mode.



Sound indications will only occur in monitor mode. In other modes the sound indications will be disabled and the symbol beside here will be shown with the text **Sound alarm off**.

### FEATURES:

- ECG, SpO<sub>2</sub>, NIBP, RESP or EtCO<sub>2</sub> (except AED mode) alarm indicator: numerical value in white alternating with a red arrow. The direction of the arrow indicates (up or down) which limit has been exceeded. Together, red color text messages regarding the specific alarm condition are shown.
- Alarm indicative LED in the upper part of the front panel, flashing in red color.
- Text messages in RED in the upper part of the display for the alarms of asystolia, shock indicated, apnea and pulse loss.
- OBS: For visual indication related to violation of MAXIMUM and MINIMUM limits no text messages are shown.
- Maximum alarm delay (includes the delay of the alarm status and the signal generation delay):
  - Heart rate: 9 seconds.
  - SpO<sub>2</sub> Saturation: 4 seconds.
  - EtCO<sub>2</sub>: 9 seconds.
  - NIBP (systolic, diastolic, average): 1 second.



- Visual frequency: 2 Hz.
- Frequency of verification of the physiological alarms system by the user: monthly.

## STANDARD ALARM VALUE

The following tables provide the factory default values for the alarm limits:

ECG	
Bpm Max.	160 BPM
Bpm Min.	40 BPM

NIBP	
Medium Min.	50 mmHg
Initial pressure	140 mmHg

Capnography	
CO <sub>2</sub> Max.	60 mmHg
CO <sub>2</sub> Min.	21 mmHg

Respiration	
Max.	45 RPM
Min.	6 RPM

SpO <sub>2</sub>	
Answer.	Normal
SPO <sub>2</sub> Max.	100%
SPO <sub>2</sub> Min.	85%
Pulse Max.	160
Pulse Min.	40

ST segment	
Max.	10 mm
Min.	-10 mm

Temperature (channels 1 and 2)	
Max.	38.0°C
Min.	30.0°C

IP (channels 1 and 2)	
Systole Max.	200 mmHg
Systole Min.	90 mmHg
Diastole Max.	150 mmHg
Diastole Min.	50 mmHg
Average Max.	170 mmHg
Average Min.	50 mmHg

## Technical alarm (medium priority)

Sound and visual signals indicate that the DualMax is not able to accurately monitor the patient's status. The technical alarm indications are shown in the information bar (see item "Information bar").

In addition to the technical alarm conditions indicated in the information bar, there are two more conditions: "bad contact" and "battery charge level" (see following sections).

**These indications will be enabled when DualMax is in any mode except in AED Mode.**

## **FEATURES:**

Maximum alarm delay (includes the delay of the alarm status and the signal generation delay):

- Heart rate: 9 seconds.
- SpO<sub>2</sub> Saturation: 4 seconds.
- EtCO<sub>2</sub>: 9 seconds.
- NIBP (systolic, diastolic, average): 1 second.
- For other parameters: 5 seconds.
- Frequency of verification of the Technical Alarms System by the user: monthly.

It is possible for the operator to visualize the alarms from a 1 meter distance from the equipment.

DualMax has audible and visual indications of physiological alarm conditions (High priority) and technical alarm (Medium priority).

The alarms will sound according to their priority:





- High priority alarm (Physiological alarm): indicates the physiological changes of the patient and will be triggered when the value measured by the equipment exceeds the minimum or maximum limits set previously on the machine by the operator.
- Medium Priority alarm (Technical alarm): indicates that the equipment is not able to monitor the patient's condition.
- Information messages: they are displayed on equipment screen (in white or cyan colors). This messages are only indications and do not require immediate action from the operator.
- Sings and warning do not emit beeps; they are just visual changing its color to cyan.

If the equipment has different alarm priorities simultaneously occurring, the high priority alarm will overlap the medium priority.

The DualMax maintains the previous alarm settings in case of shutdown for a period of 30 seconds or less. After this time, the equipment returns automatically to the factory default settings to ensure safety in the event of patient exchange.

Alarm priority	Alarm description or audible alert	Alarm volume or audible alert
Physiological - High priority.	Two sets of five tons of short beeps, repeated at 2.6 second intervals.	74 to 83 dB (A).
Technical – Medium priority.	One sets of three tons of longs beeps, repeated at 6 second intervals.	73 to 82 dB (A).

Characteristics of alarm messages:

ECG			
Alarm	Priority	Color	Possible cause
Electrode loose.	MEDIUM PRIORITY	Yellow	Electrode disconnected.
Searching ECG sign.	MEDIUM PRIORITY	Yellow	Low ECG amplitude or saturated ECG signal.
PACEMAKER detected.	MEDIUM PRIORITY	Yellow	Pacemaker pulses detected.
(↑) ECG - BPM above the limit.	HIGH PRIORITY	RED	When the BPM is above the value set on the alarm configuration.
(↓) ECG - BPM below the limit.	HIGH PRIORITY	RED	When the BPM is below the value set on the alarm configuration.
Asystole.	HIGH PRIORITY	RED	DualMax cannot detect valid beats for more than 4 seconds.
Shock Indicated.	HIGH PRIORITY	RED	Ventricular fibrillation/ventricular tachycardia(VF/VT) was identified.
Pacemaker detected - Represented by a white vertical line at the point of the ECG curve, where the pacemaker pulse is detected. In addition, the figure   flashes.			
QRS detected - The indicator  is shown on the ECG curve, where the QRS complex is recognized. When the synchronism button has been pressed, this indicator will change to  .			

RESP			
Alarm	Priority	Color	Possible cause
Apnea alarm.	HIGH PRIORITY	RED	When detected the suspension of breathing (apnea) on specified times 5, 10, 15, 20, 25, 30, 35 or 40 seconds (set at Menu > RESP > Apnea alarm).

(↑) RESP - RPM above the limit.	HIGH PRIORITY	RED	When the RPM is above the value defined on the alarm configuration.
(↓) RESP - RPM below the limit.	HIGH PRIORITY	RED	When the RPM is below the value defined on the alarm configuration.

### ST segment

Alarm	Priority	Color	Possible cause
(↑) ECG - ST XX above the limit.	HIGH PRIORITY	RED	ST segment is above the value defined in the alarm configuration. XX represents the possible derivation shown.
(↓) ECG - ST XX below the limit.	HIGH PRIORITY	RED	ST segment is below the value defined in the alarm configuration. XX represents the possible derivation shown.

### Temperature

Alarm	Priority	Color	Possible cause
Sensor disconnected.	MEDIUM PRIORITY	Yellow	Temperature sensor disconnected or defective.
(↑) TEMP - T1 above the limit.	HIGH PRIORITY	RED	Temperature is above the value defined in the alarm configuration.
(↓) TEMP - T1 below the limit.	HIGH PRIORITY	RED	Temperature is below the value defined in the alarm configuration.
(↑) TEMP - T2 above the limit.	HIGH PRIORITY	RED	Temperature is above the value defined in the alarm configuration.
(↓) TEMP - T2 below the limit.	HIGH PRIORITY	RED	Temperature is below the value defined in the alarm configuration.

### SpO<sub>2</sub>

Alarm	Priority	Color	Possible cause
No finger on the sensor.	MEDIUM PRIORITY	Yellow	Connected sensor on the equipment, but without detection of patient's finger.
Searching signal.	MEDIUM PRIORITY	Yellow	The monitor is searching for valid SpO <sub>2</sub> signal.
Too long search.	MEDIUM PRIORITY	Yellow	The equipment is searching a valid signal of SpO <sub>2</sub> of more than 20 seconds.

SpO <sub>2</sub> - Disconnected sensor.	MEDIUM PRIORITY	Yellow	Sensor or SpO <sub>2</sub> extension disconnected or incorrectly placed.
SpO <sub>2</sub> - Artifact.	MEDIUM PRIORITY	Yellow	Muscle tremor detected.
Weak signal.	MEDIUM PRIORITY	Yellow	DualMax cannot identify the signal. Weak signal, possibly patient with low perfusion.
Loss of pulse.	HIGH PRIORITY	RED	Patient without heartbeats for more than 4 seconds.
(↑) SPO <sub>2</sub> - Sat above the limit.	HIGH PRIORITY	RED	Saturation is above the value defined on the alarm configuration.
(↓) SPO <sub>2</sub> - Sat below the limit.	HIGH PRIORITY	RED	Saturation is below the value defined on the alarm configuration.
(↑) SPO <sub>2</sub> - BPM above the limit.	HIGH PRIORITY	RED	Pulse value is above the value defined in the alarm configuration.
(↓) SPO <sub>2</sub> - BPM below the limit.	HIGH PRIORITY	RED	Pulse value is below the value defined in the alarm configuration.

NIBP			
Alarm	Priority	Color	Possible cause
Excessive pressure.	MEDIUM PRIORITY	YELLOW	The cuff's maximum pressure has been exceeded.
Cuff problems.	MEDIUM PRIORITY	YELLOW	The cuff is misplaced or there is leakage on measure circuit.
Weak signal .	MEDIUM PRIORITY	YELLOW	Pulse too weak for NIBP measurements. Check the cuff's position and tightening.
Excessive movement.	MEDIUM PRIORITY	YELLOW	There is noise due to the patient's movement.
Long measurement.	MEDIUM PRIORITY	YELLOW	The measurement of pressure is too long with possibility of inaccuracy.
(↑) NIBP - Sys above the limit.	HIGH PRIORITY	RED	Systolic pressure value is above the value set in the alarm setting.
(↓) NIBP - Sys below the limit.	HIGH PRIORITY	RED	Systolic pressure value is below the value set in the alarm setting.
(↑) NIBP - Dia above the limit.	HIGH PRIORITY	RED	Diastolic pressure value is above the value set in the alarm setting.
(↓) NIBP - Dia below the limit.	HIGH PRIORITY	RED	Diastolic pressure value is below the value set in the alarm setting.

(↑) NIBP - Mea above the limit.	HIGH PRIORITY	RED	Mean pressure value is above the value set in the alarm setting.
(↓) NIBP - Mea below the limit.	HIGH PRIORITY	RED	Mean pressure value is below the value set in the alarm setting.

IBP			
Alarm	Priority	Color	Possible cause
Initiating sensor.	MEDIUM PRIORITY	Yellow	The equipment is recognizing the sensor.
Non-cleared transducer.	MEDIUM PRIORITY	Yellow	The measures were initiated, but there was no clearing of the transducer. See chapter "Invasive Pressure".
Sensor disconnected.	MEDIUM PRIORITY	Yellow	IP sensor disconnected or defective.
(↑) IBP - P1 Sys above the limit.	HIGH PRIORITY	RED	Systolic pressure (port 1) value is above the value set in the alarm setting.
(↓) IBP - P1 Sys below the limit.	HIGH PRIORITY	RED	Systolic pressure (port 1) value is below the value set in the alarm setting.
(↑) IBP - P1 Dia above the limit.	HIGH PRIORITY	RED	Diastolic pressure (port 1) value is above the value set in the alarm setting.
(↓) IBP - P1 Dia below the limit.	HIGH PRIORITY	RED	Diastolic pressure (port 1) value is below the value set in the alarm setting.
(↑) IBP - P1 Mea above the limit.	HIGH PRIORITY	RED	Mean pressure (port 1) value is above the value set in the alarm setting.
(↓) IBP - P1 Mea below the limit.	HIGH PRIORITY	RED	Mean pressure (port 1) value is below the value set in the alarm setting.
(↑) IBP - P2 Sys above the limit.	HIGH PRIORITY	RED	Systolic pressure (port 2) value is above the value set in the alarm setting.
(↓) IBP - P2 Sys below the limit.	HIGH PRIORITY	RED	Systolic pressure (port 2) value is below the value set in the alarm setting.
(↑) IBP - P2 Dia above the limit.	HIGH PRIORITY	RED	Diastolic pressure (port 2) value is above the value set in the alarm setting.
(↓) IBP - P2 Dia below the limit.	HIGH PRIORITY	RED	Diastolic pressure (port 2) value is below the value set in the alarm setting.
(↑) IBP - P2 Mea above the limit.	HIGH PRIORITY	RED	Mean pressure (port 2) value is above the value set in the alarm setting.
(↓) IBP - P2 Mea below the limit.	HIGH PRIORITY	RED	Mean pressure (port 2) value is below the value set in the alarm setting.

EtCO <sub>2</sub>			
Alarm	Priority	Color	Possible cause
No filterline.	MEDIUM PRIORITY	YELLOW	The capnography sampling line is not connected.
Occlusion.	MEDIUM PRIORITY	YELLOW	There is no airflow in the EtCO <sub>2</sub> sensor. Change the sampling line (filterline).
Starting sensor.	MEDIUM PRIORITY	YELLOW	The EtCO <sub>2</sub> modulo is heating up its internal sensors (this occurs during the beginning of capnography and lasts about 15 seconds).
Auto-Zero.	MEDIUM PRIORITY	YELLOW	Necessary procedure for proper functioning of the equipment.
(↑) CO <sub>2</sub> above the limit.	HIGH PRIORITY	RED	CO <sub>2</sub> EXP is above the value defined on the alarm configuration.
(↓) CO <sub>2</sub> below the limit.	HIGH PRIORITY	RED	CO <sub>2</sub> EXP is below the value defined on the alarm configuration.

Defibrillator			
Alarm	Priority	Color	Possible cause
Connect pads.	MEDIUM PRIORITY	YELLOW	Pads are not connected.
<b>Informative message</b>			
<b>Adhesive pads</b> - DualMax detected adhesive pads connected.			
<b>Adult pads</b> - DualMax detected adult pads connected.			
<b>Children pads</b> - DualMax detected paddles connected, but the adult electrode is disconnected. The same message is also exhibited when DualMax detects children adhesive pads.			
<b>Charging</b> - The load is not yet complete.			
<b>Charge ready</b> - The energy has been charged.			
<b>Shock delivered</b> - The energy was delivered to the patient.			
<b>Shock disarmed</b> - The energy was canceled by the operator.			
<b>Shock disarmed (automatic internal discharge)</b> - The energy was automatically canceled because the shock button was not pressed before the internal discharge time selected by the operator.			
<b>Shock disarmed (bad contact)</b> - The energy was canceled because the impedance of the patient is not satisfying the applicable shock conditions.			
<b>Bad Contact</b> - Patient impedance measurement is not satisfying the applicable shock conditions.			

### Pacemaker

Alarm	Priority	Color	Possible cause
Connect adhesive pads.	MEDIUM PRIORITY	YELLOW	Adhesive paddles are disconnected.
<b>Informative message</b>			
<b>PM: Pause</b> - The outbreak of pacemaker pulses is paused.			
<b>PM: On</b> - The outbreak of pacemaker pulses is on.			
<b>Mode: Asynch</b> - The pacemaker is in asynchronous mode.			
<b>Mode: Dem</b> - The pacemaker is in demand mode.			

### Printer

<b>Informative message</b>
<b>Without paper</b> - Printer is out of paper.
<b>Printing</b> - Printer is printing.

## ATTENTION

There is a risk possibility if the alarm limits do not follow a pattern in the equipment or area, it means, if it is changed for each patient, or it is different for more than one equipment.

Confirm that the alarm limits are appropriate for the patient each time there is a new case of patient.








**ATTENTION**

Do not set alarm limits to such extreme values that make the alarm system useless.

For simultaneous alarms of the same priority, the DualMax will intercalate the alarm signals and messages.

## Battery charge level

Indication	Battery status*
	100% charged
	80% charged
	60% charged
	40% charged
	20% charged

\*Battery status when the AC power supply cable is not connected.

## Pause audio



By pressing the Pause Audio button RAPIDLY (less than 3 seconds), ALL sound alarms are silenced for a period pre-determined by the operator. Its visual indication is the "audio paused" icon in all parameters.

## Configuration of alarm limits

The DualMax maintains the previous alarm settings, in case of turning off for a period of 30 seconds or less. After this time, the device automatically returns to the factory default settings to ensure safety in case of patient exchange.

To change the alarm limits, the user must select the "ALARMS" menu. Then must press the "Edit" button to access the desired parameter.

◀		RTC	CONFIG	CURVES	DATE AND TIME	ALARMS	▶
---	--	-----	--------	--------	---------------	--------	---

ECG	ST	RESP	SPO2	PULSE	CO2	TEMP 1	TEMP 2
40 160	-10.0 10.0	6 45	40 160	85 100	21 60	30.0 38.0	30.0 38.0
Edit		Edit	Edit		Edit	Edit	

IBP 1			IBP 2			NIBP		
SIS	DIA	MEA	SIS	DIA	MEA	SIS	DIA	MEA
90 200	50 150	50 170	90 200	50 150	50 170	90 200	50 150	50 170
Edit			Edit			Edit		

1 / 2
BACK
EXIT


◀		RTC	CONFIG	CURVES	DATE AND TIME	ALARMS	▶
---	--	-----	--------	--------	---------------	--------	---

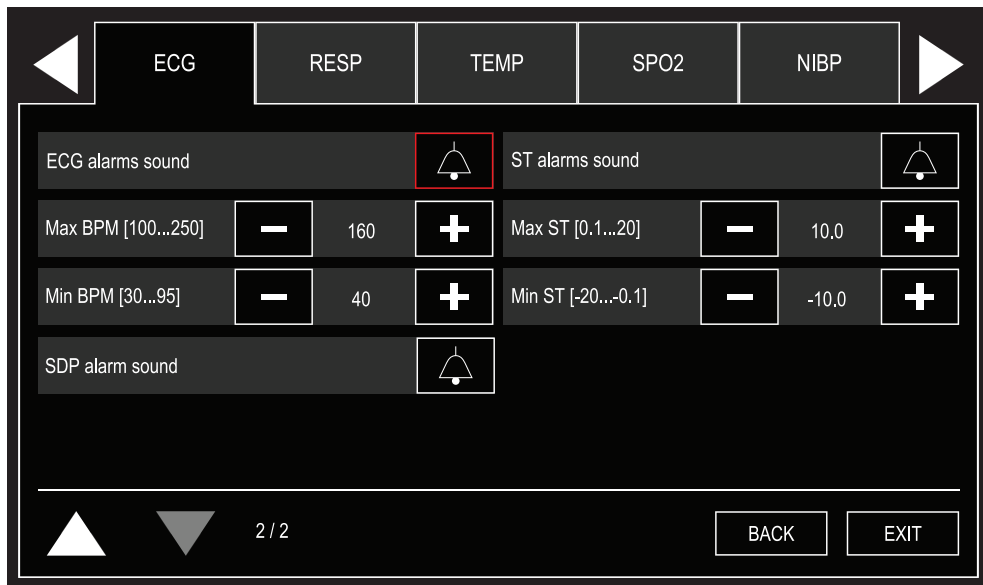
  

DEFIB/PM alarms sound	
BATTERY alarm sound	



  

2 / 2
BACK
EXIT

After editing an alarm, to return to the alarms menu, only select the button  present on the alarm configuration screens of each parameter.



## Minimum / Maximum limits adjustment

- 60  The adjustment of minimum and maximum values is done individually on each parameter by using the e-Jog Control. The operator must first select the limit and the parameter to be modified and then press it. Next, the desired value must be adjusted and then pressed again.
- 90 

**ECG:** it is possible to adjust the minimum ECG alarm to levels between 30 and 100 BPMs with intervals of 5 BPMs in “adult” mode and intervals of 1 BPMs in “neo” mode. It is possible to adjust the maximum ECG alarm to levels between 100 and 250 BPMs with intervals of 5 BPMs in “adult” mode and intervals of 1 BPMs in “neo” mode.

**SpO<sub>2</sub>:** it is possible to adjust the minimum SpO<sub>2</sub> alarm to levels between 40 and 99 BPMs with intervals of 5 BPMs in “adult” mode and intervals of 1 BPMs in “neo” mode. It is possible to adjust the maximum ECG alarm to levels between 41 and 100 BPMs with intervals of 5BPMs in “adult” mode and intervals of 1 BPMs in “neo” mode.

**NIBP:** it is possible to adjust the minimum NIBP alarm to levels between 50 and 290 mmHg to systolic, diastolic and mean pressure with intervals of 5 mmHg. It is possible to adjust the maximum NIBP alarm to levels between 60 and 300 mmHg to systolic, diastolic and mean pressure with intervals of 5 mmHg.

**CO<sub>2</sub>:** it is possible to adjust the minimum CO<sub>2</sub> alarm to levels between 18 and 96 mmHg, with intervals of 3 mmHg in "adult" mode and intervals of 1 mmHg in "neo" mode. It is possible to set the maximum CO<sub>2</sub> alarm to levels between 21 and 99 mmHg, with intervals of 3 mmHg in "adult" mode and intervals of 1 mmHg in "neo" mode.

**RESP:** it is possible to adjust the minimum respiration alarm to levels between 3 and 147 rpm, with intervals of 3 rpm in "adult" mode and intervals of 1 rpm in "neo" mode. It is possible to set the maximum respiration alarm to levels between 6 and 150 rpm, with intervals of 3 rpm in "adult" mode and intervals of 1 rpm in "neo" mode.

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## Technical alarm test


To perform the alarm test do the following steps:

1 - Turn the equipment on, without cables or sensors connected. It should occur indication of technical alarm (text messages in Infocenter) disconnected sensor.

2 - After confirming the visual indication, connect the sensor correctly. If the indication disappears, the alarm is working properly.


Otherwise, change the sensor and repeat the test. If the result is the same, the alarm will probably be defective.

3 - Repeat this procedure for the other modules, remembering to test with their respective sensor and parameters.

4 - With the indication of an active technical alarm, press the button PAUSE AUDIO  for 1s and check on screen the suspended alarm indication for all parameters.

Wait for 60 s and the alarm will activate. On the screen, the suspended alarm signal disappears, indicating the return of the alarm sound.

The time the alarm stays turned off is 60 s.

To turn the alarm sound on again, press the PAUSE AUDIO button  for 1 second.

The sound of the parameters of alarm can be turned on and off individually in the "Alarm" menu and in parameter menus.

## Physiological alarm test


To perform the alarm test do the following steps:

1 - Turn on the equipment, with the electrodes properly connected. Verify the BPM value on the equipment screen and that there are no alarms.

2 - Through the e-Jog Control key on the panel, navigate to: PARAMETER CONFIGURATION > ECG CONFIGURATION > ALARM. With this same key, select one of the limits and then change its value so that the initially measured value is outside the range. Then go back to the main screen.


3 - Having done this, the alarm should sound. If it does not, the alarm is probably defective.

4 - Repeat this procedure for the other modules, remembering to test with their respective sensor and parameters.

5 - With the indication of an active technical alarm, press the button PAUSE AUDIO  for 1s and check on screen the suspended alarm indication for all parameters.

Wait for 60 s and the alarm will activate. On the screen, the suspended alarm signal disappears, indicating the return of the alarm sound.

The time the alarm stays turned off is 60 s.

To turn the alarm sound on again, press the PAUSE AUDIO button  for 1 second.

The sound of the parameters of alarm can be turned on and off individually in the "Alarm" menu and in parameter menus.

### ATTENTION

**By default, alarm sound is turned on when the monitor is turned on and the alarm sound is turned off when entering other mode: PACEMAKER, AED, DEFIBRILLATION (1 to 360 J) or AUTO SEQUENCE. Individual settings remain unchanged due to mode switches, so the user-selected setting prevails until a new patient is added, or a power interruption/shutdown occurs that lasts longer than 30 seconds.**

**In AED mode, the sound of all parameter alarms remains off since they can confuse or distract the operator, once the operation of this mode is guided by voice instructions.**

## Physics principle used

The biphasic cardiac defibrillator is an instrument that delivers energy previously stored in a capacitor to a patient. The defibrillation is external (when the capacitor's discharge is delivered through the patient's thorax).

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

During the defibrillation the myocardium is briefly depolarized by a strong positive and negative impulse of adjustable intensity (Truncated Exponential Biphasic Shock). These impulses are used to eliminate arterial, ventricular fibrillation, and ventricular disturbances.



## Warnings

The DualMax has a patient impedance meter that delivers shocks in 25 to 300 Ohms impedances.

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

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

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

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

## **Use criteria**

In defibrillation mode, the DualMax must only be used if the following circumstances, as a whole, are presented:

- 1 - Unconscious victim.
- 2 - No breathing.
- 3 - No pulse.

Other important considerations regarding the use of the DualMax:

- 1 - Not recommended for children under one year old.
- 2 - Pacemakers may affect the device's efficiency.
- 3 - Medicines in adhesive form must be removed before starting defibrillation.
- 4 - Hypothermic patients may not respond well to defibrillation.
- 5 - Once the removal of the patient is started, the defibrillation must be interrupted.

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## **Qualified users**

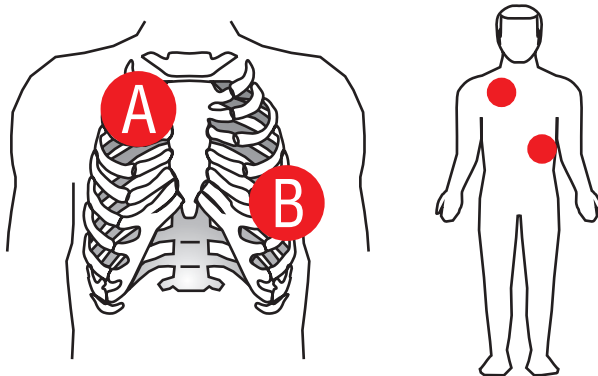
Shall be considered qualified users those who have a degree in Medicine.

## External pads use

1 - Verify if the pads are connected to DualMax. If they are not, connect the defibrillation cable to the pads socket located on the equipment's side. (according to the image). Press the quick release connector.



- 2 - Take both pads from their base pulling them up and out.
- 3 - Apply the conductive material to the pads' electrodes.
- 4 - Place pads as shown in the image below:



**A - Sternum.**

**B - Apex.**



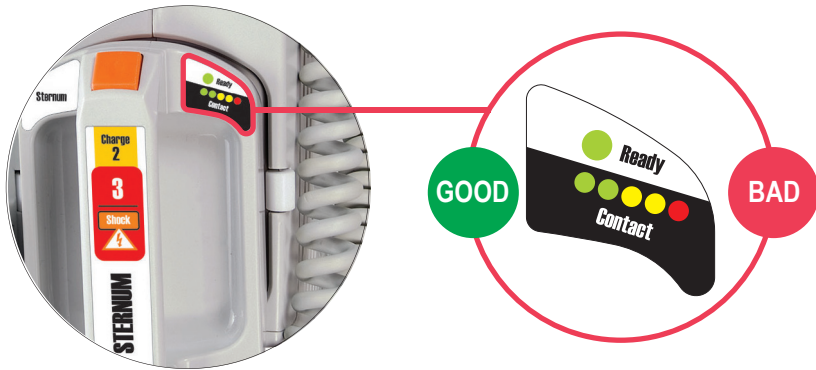
The electrodes must be placed in a position which will maximize the current that passes through the myocardium. The standard position is:

- a) **Electrode identified as “STERNUM”** on the right second intercostal space, mid-clavicular line.
- b) **Electrode identified as “APEX”** positioned on the left sixth intercostal space, midaxillary line.



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

**5** - Check contact with the patient.



The STERNUM pad has a patient contact indicator.

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

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

## About shock delivery

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

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

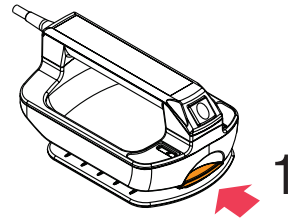
Patient's impedance	Shock	Message on screen after "Charge" key pressed	Values indicated on bargraph
Short circuit	Shock inhibited.	Bad contact.	All LEDs blinking.
< 25 Ohms	Shock inhibited.	Bad contact.	All LEDs blinking.
>25 Ohms and < 300 Ohms	Shock delivered and the waveform is adjusted according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

**When all LEDs blink simultaneously the pads have a short circuit, and shock delivery will not be permitted.**

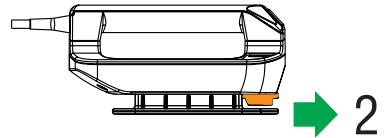
**When only the RED LED is blinking, shock delivery will not be allowed.**

## Child pads use

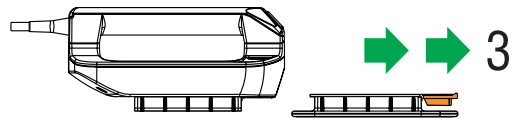
1 - Fasten the lock in the front of the adult external pads.



2 - Pull the pads base forward to remove them.



3 - This exposes the smaller electrode for children.



*Adult*

*Child*

**The DualMax will automatically identify that it is operating in pediatric mode. Energy is limited to 50 J in the pediatric mode.**

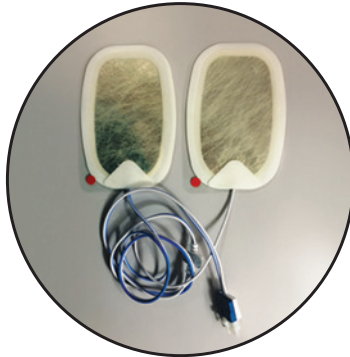
## Using multifunction pads

The use of the multifunction pads (disposable) requires that the operator uses the adapter provided (extension cable) in order to connect them to the standard socket of the external pads, as described below:

- 1 - Connect the AED/pacemaker extension cable to the equipment.



- 2 - Connect the adhesive multifunction pads to the extension cable.



- 3 - Remove the multifunction pads' protective film and apply them to the patient, using the same positions recommended for the external pads (Sternum and Apex).



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



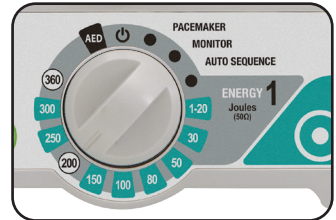
**ATTENTION:** in case of use for long periods, the pads should be replaced every 24 hours.

## Defibrillation

### Follow the steps 1-2-3

#### Step 1 - Select energy

Rotate the selection switch until you reach the energy desired. Energy options go from 1 to 360 J. In most cases, 200 J is recommended for adult use.



#### Step 2 - Charge



Press the “Charge” button (green) in the front panel or use the charge button in the external pads (orange).

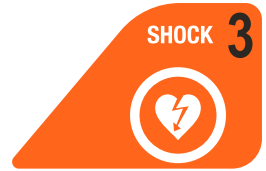
While the DualMax is charging, a sound will be emitted and the measurement of the charged energy will appear on the display.

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

To cancel the shock press “Disarm”.

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

## Step 3 - Shock



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

It is only possible to defibrillate using the pad buttons with the adult/child external pads.



**CAUTION:** make sure nobody is touching the patient! Tell passersby to stand clear of the patient!

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

## Synchronism - Synchronized discharge - Cardioversion

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



Monitor the patient with 3 or 5-leads ECG cables or with the defibrillation electrodes.

Press the “Sync” button in the front panel. Ensure that the synchronization marker is red and lined up with the “R” wave and the “SYNC” indication is displayed next to the selected energy value.

Follow steps 1-2-3 for defibrillation.



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



**IMPORTANT:** If DualMax does not identify a valid QRS it will not trigger the shock! For this reason, do not use the cardioversion in Ventricular Fibrillation rhythms.



Cardioversion can cause discomfort to the patient, as well as skin redness.

## Disarm key

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



Defibrillation display:



### 1 - Elapsed time

Indicates how long the equipment has been used for. The marker returns to zero if the equipment is turned off.

### 2 - Number of shocks

Shows number of shocks delivered. The counter is set to zero when the equipment is turned off.

### 3 - Defibrillation electrode type

Shows which defibrillation electrode is connected to the equipment: ADULT (adult external pads), CHILD (child external pads) or ADHESIVE.

### 4 - Synchronism

Indicates if the synchronism is on (beige). When turned on, the symbol flashes indicating the activation of the function.

### 5 - Selected and charged energy

The energy SELECTED by the user is shown in this display area in BLACK numbers.

During the equipment's charging cycle, the value of the energy that has already been stored is displayed in RED. When the charge is complete the numbers are displayed in RED and blink, indicating the equipment is ready and the shock can be delivered.

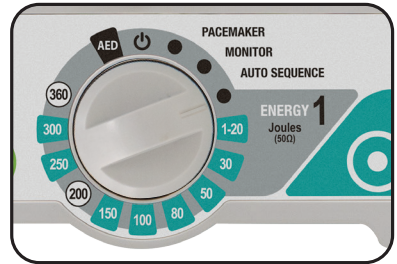
## Charge Auto-Sequencing mode (Auto Seq)

*In the Auto Seq mode, the shock energy levels will follow the order previously set by the user in: "Defibrillation > AUTO SEQUENCING CHARGE" (See "Defibrillation setup" below).*

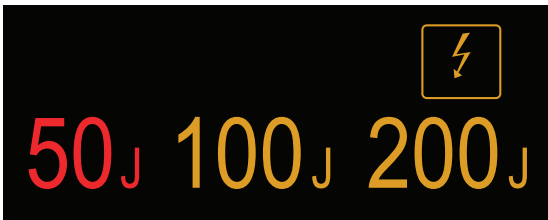
There are three sequential energy levels, being that, from the third shock on all subsequent shocks will use the same discharge value of the latter. The preset sequence will be interrupted in the following conditions:

- Equipment shutdown.
- Auto Seq mode exit.
- Reconfiguration of the Auto-Sequencing mode energy levels (available after the delivery of the third shock).

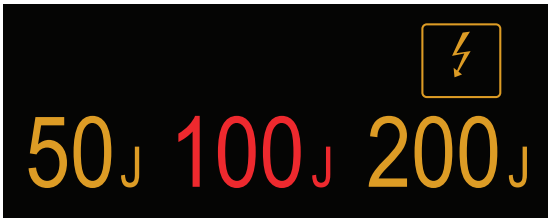
In case child pads are used, the equipment will automatically limit the charge value to 50 J.



*The energy to be charged is indicated in red.*

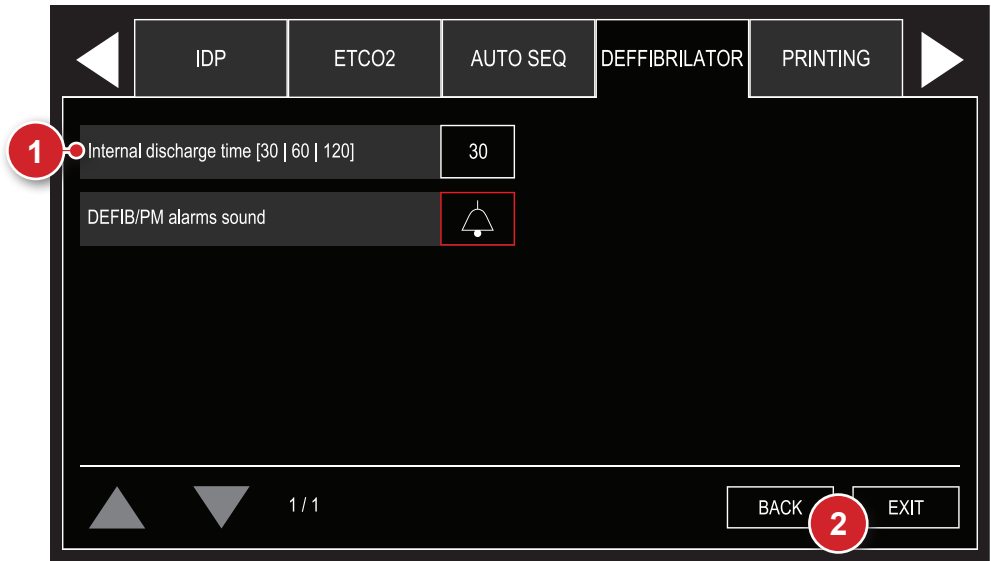


*After shock delivery, the energy is updated with the next energy level.*





## Defibrillation setup



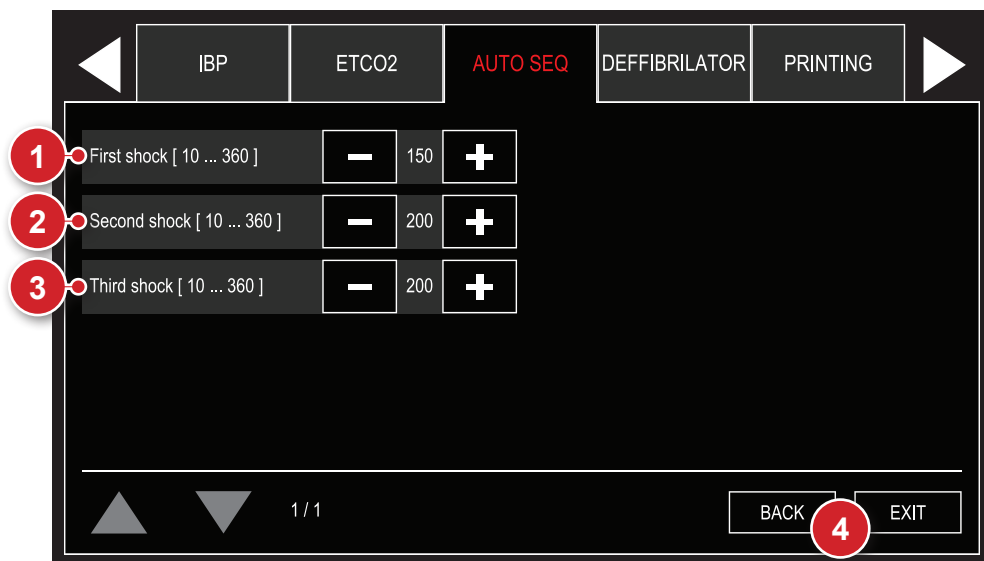
### 1 - Internal discharge time

Determines how long the equipment keeps the charge ready before discharging it internally.

### 2 - Back/Exit

“BACK” to configuration menu or “EXIT” to go to the monitoring screen.

## Auto-sequencing configurations



### 1 - First shock

Sets energy levels for the first shock of the Auto Seq mode. The user can select energy levels from 10 to 360 J. Preset values are 150 J for the first shock and 200 J for the next shocks.

In case child pads are used, the equipment will automatically limit the charge to 50 J. When there is use of child pads followed by the use of adult pads, the last configured values for adult pads will be recovered.

The charge and shock delivery processes are operated manually and after every delivery, the energy levels are updated.

### 2 - Second shock

Sets energy levels for the second shock of the Auto Seq mode. The user can select energy levels from 10 to 360 J. Preset values are 150 J for the first shock and 200 J for the next shocks.

In case child pads are used, the equipment will automatically limit the charge to 50 J. When there is use of child pads followed by the use of adult pads, the last configured values for adult pads will be recovered.

The charge and shock delivery processes are operated manually and after every delivery, the energy levels are updated.

### **3 - Third shock**

Sets energy levels for the third shock of the Auto Seq mode. The user can select energy levels from 10 to 360 J. Preset values are 150 J for the first shock and 200 J for the next shocks.

In case child pads are used, the equipment will automatically limit the charge to 50 J. When there is use of child pads followed by the use of adult pads, the last configured values for adult pads will be recovered.

The charge and shock delivery processes are operated manually and after every delivery, the energy levels are updated.

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### **4 - Back/Exit**

“BACK” to configuration menu or “EXIT” to go to the monitoring screen.

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# AED mode

Automatic External Defibrillator

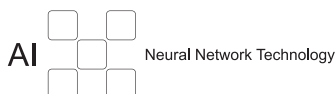


## Introduction

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

Nowadays, however, with the evolution of artificial intelligence (AI), the DualMax, using its Neural Network Technology, is capable of assessing, via sophisticated sensors, the patient's state, consider the clinical variables and deliver automatically the most indicated shock therapy.

This allows any individual with adequate training, to perform assistance to a victim in fibrillation process, facilitating and multiplying lifesaving possibilities.



---

## Characteristics

- Artificial Intelligence: accurate diagnosis of the patient's conditions, indicating shock delivery or not.
- Safety safeguards: avoids accidental use, in cases in which shock treatment is not indicated or in healthy people.
- Voice orientation and screen indications.
- Internal recording of events.
- PC connection via USB.
- Connection software, data download and management via PC.
- Biphasic shock.
- Automatic self-test.
- Use in hospital or out-of-hospital environment including emergency rescue units.

## Physics principle used

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

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

During the defibrillation the myocardium is briefly depolarized by a strong positive and negative impulse of adjustable intensity (Truncated Exponential Biphasic Shock). These impulses are used to eliminate arterial, ventricular fibrillation, and ventricular disturbances.



## Warnings

**The DualMax has a patient impedance meter that delivers shocks in 25 to 300 Ohms impedances.**

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

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

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

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

**In this AED mode, all of the HIGH PRIORITY and MEDIUM PRIORITY alarms are disabled, keeping only the VISUAL ALARM of the ECG HIGH PRIORITY and MEDIUM PRIORITY ALARM.**

## Use criteria

In defibrillation mode, the DualMax must only be used if the following circumstances, as a whole, are presented:

- 1 - Unconscious victim.
- 2 - No breathing.
- 3 - No pulse.

Other important considerations regarding the use of the DualMax:

- 1 - Not recommended for children under one year old.
- 2 - Pacemakers may affect the device's efficiency.
- 3 - Medicines in adhesive form must be removed before starting defibrillation.
- 4 - Hypothermic patients may not respond well to defibrillation.
- 5 - Once the removal of the patient is started, the defibrillation must be interrupted.

---

## Qualified users

Shall be considered qualified users those who have a degree in Medicine.

## Operation

Before starting the operation, call the emergency service.

### Step 1 - Connect disposable pads to the DualMax



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

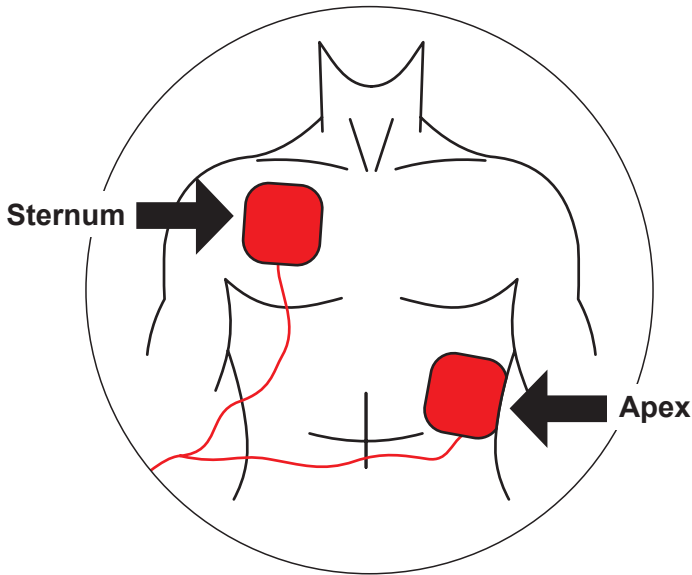
After disposing of used pads, always leave a replacement pair already connected to the equipment, avoiding having to replace them at the moment of the emergency.

**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.

**NOTE:** when using child pads, the shock will be set in 50 J.

## Step 2 – Apply pads to patient



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

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

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

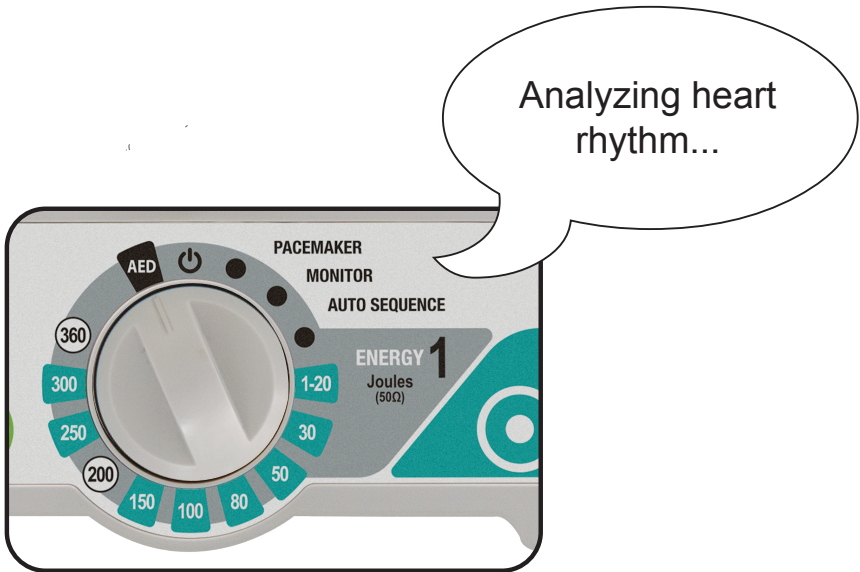
**ATTENTION:** the area in contact with the pads must be dry.

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

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



## Step 3 - Select AED



**Rotate the selector switch to the "AED" position.**

The DualMax will automatically enter cardiac rhythm analysis mode and will start giving vocal instructions clearly and pausedly, so that the user can perfectly understand them.

**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 - Deliver shock



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

**Press “SHOCK” button again.**

The shock will be delivered.

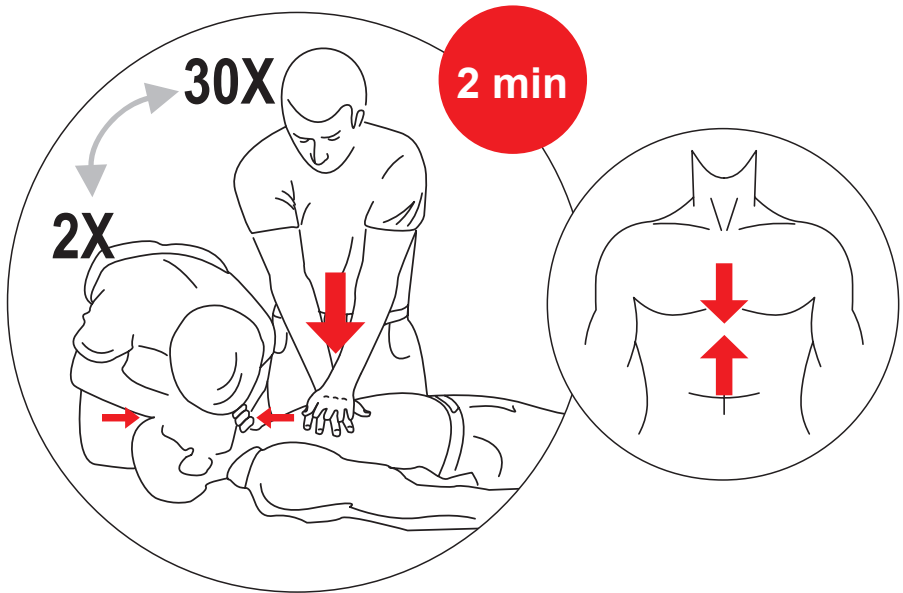
**ATTENTION: the user must not touch the patient or conductive surfaces in contact with him/her during shock delivery, under risk of suffering a powerful electric discharge.**

**NOTE: The energy delivered is pre-adjusted. The user cannot alter this protocol. For adult electrodes: 1st shock is 150 J and the following are 200 J; for child electrodes, all shocks are 50 J.**

If clinical scans show that defibrillation is not recommended, the DualMax will announce: “TREATMENT NOT RECOMMENDED”.

Check if there was no movement of the patient during the analysis. If so, restart the process. If not, remove pads and start the CPR (cardiopulmonary resuscitation) procedure. Details on the next section.

## Step 5 - Start CPR



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

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

## Applying CPR

- 1) Lay the victim on his back on a hard flat surface.
- 2) Run your fingers from the center of the victim's thorax, descending until finding a bone that comes to a tip in the middle of the chest (Sternum), right above the stomach.
- 3) Keep two fingers right below this point.
- 4) Place the palm of your other hand above the two fingers that indicate the base of the Sternum bone. This is the correct spot for the massage.

CONTINUES >

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 DualMax, 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 DualMax.

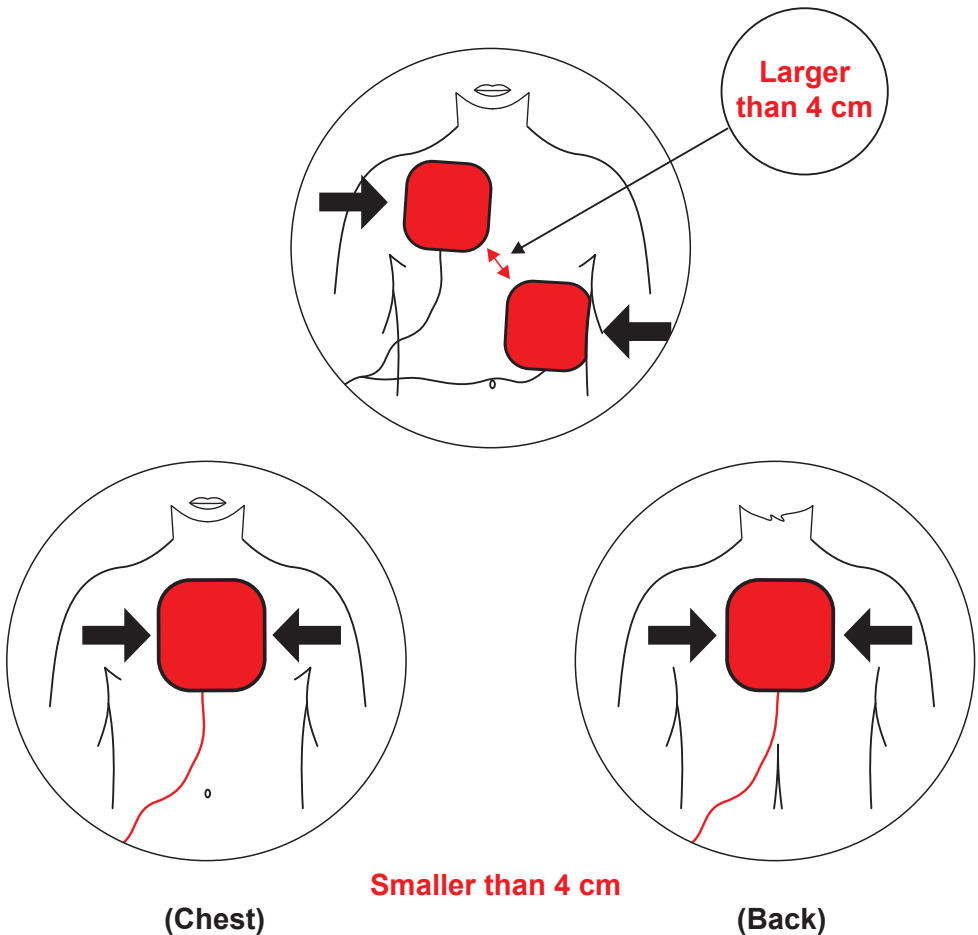
After the third complete CPR and shock cycle, chances of the patient's resuscitation are very slim.

**The DualMax also has the CPR Maestro accessory, to help in the efficient application of CPR. For more information, see the chapter "CPR Maestro".**

## Using the DualMax on children under 8 years old

The DualMax 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 40 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.**



## Alarm system

The alarm system in AED mode consists of a single alarm, as the table below:

ALARM CONDITION	The equipment is ready to shock the patient with the energy previously established in the algorithm, just waiting for the operator to press the shock button.
ALARM PRIORITY	High.
VISUAL ALARM SIGN	Messages in Infocenter flashes red at a frequency of 2 Hz which active cycle of 50%.
VERBAL ALARM SIGN	Voice statement with the following text: "press the button to treat the patient".
POWER SOUND	85 dB.
DELAY ON ALARM SIGNAL GENERATION	Less than 5 seconds.
OPERATOR POSITION	The operator should be at the frontal face of the equipment, a maximum distance of 1 m.

### Pause or inactivation of warning signs

According to NBR IEC 60601-2-4, it is not possible for the operator to pause or disable the alarm signals to the device **ALARM CONDITION**.

### Alarm checking

You can check the operation of alarm signals using an ECG simulator device, capable of generating signals of ventricular fibrillation. It is recommended that this check is done by a qualified technician, during preventative maintenance (see "Inspection and maintenance").

## Information signals

DualMax AED mode has information signals that can be visual, audio and verbal.

VISUAL INFORMATION SIGNAL	DESCRIPTION
Patient BPM	Number of heart beats per minute of the patient detected by the equipment.
ECG waveform	ECG waveform of the patient detected by the equipment.
CPR interval counter	Informs the elapsed time since the recommendation of the CPR procedure. In manual mode, reports the elapsed time since the entry on this mode.
Illustrative picture of the current procedure step	Picture illustrating to the operator which stage of the automatic procedure the equipment is performing at the moment.

AUDITIVE INFORMATION SIGNAL (BEEP)	DESCRIPTION
Metronome for CPR compressions	The equipment beeps at a frequency of 100 beeps per minute, helping the user in performing the cardiac compressions.

The equipment also has verbal information signals. The differentiation of verbal information signals and verbal alarm signal is given in two ways:

### **Sound power**

Verbal information signals will always be at least 6 dB(A) below the set to the alarm signal.

### **Messages content**

Verbal information signals have the following messages:

- Analyzing heart rhythm.
- Perform CPR for two minutes.
- Treatment recommended – do not touch the patient.
- Shock is not recommended.
- Put the paddles on the patient's chest.
- Energy is being discharged internally.
- Don't touch the patient.
- Children's paddles.
- Treatment successfully.
- Give two breaths.
- Check the patient respiration or pulse if you cannot detect either, perform CPR for two minutes.

The CPR Maestro is an accessory from DualMax, 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 DualMax screens and through sound recommendations.

**NOTE:** because it is an accessory, it can not be used by itself. Only connected to DualMax.

The CPR Maestro parameter must work on DEFIBRILLATION, CHARGE AUTO SEQUENCE and AED modes. On AED mode, the messages on screen and the audible ones will only be presented after the orientation “Perform CPR for 2 minutes”.

To turn off the equipment, simply press the ON/OFF button for 3 seconds. The parameter will be automatically turned off on the DualMax screen.

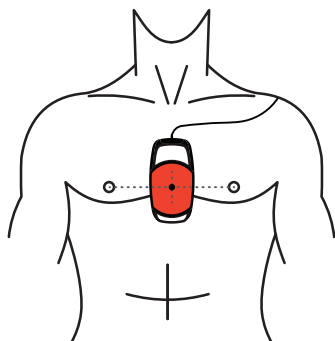
## Using the CPR Maestro

1 – Connect the CPR Maestro to DualMax, 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.

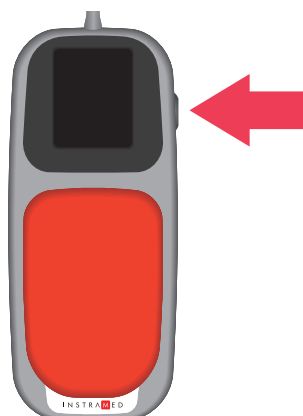


**This step is important and must always be followed. When the equipment is initialized, the CPR sensors are calibrated, enabling the evaluation of the compressions. The initialization with the device out of the recommended position may cause incorrect evaluations.**

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

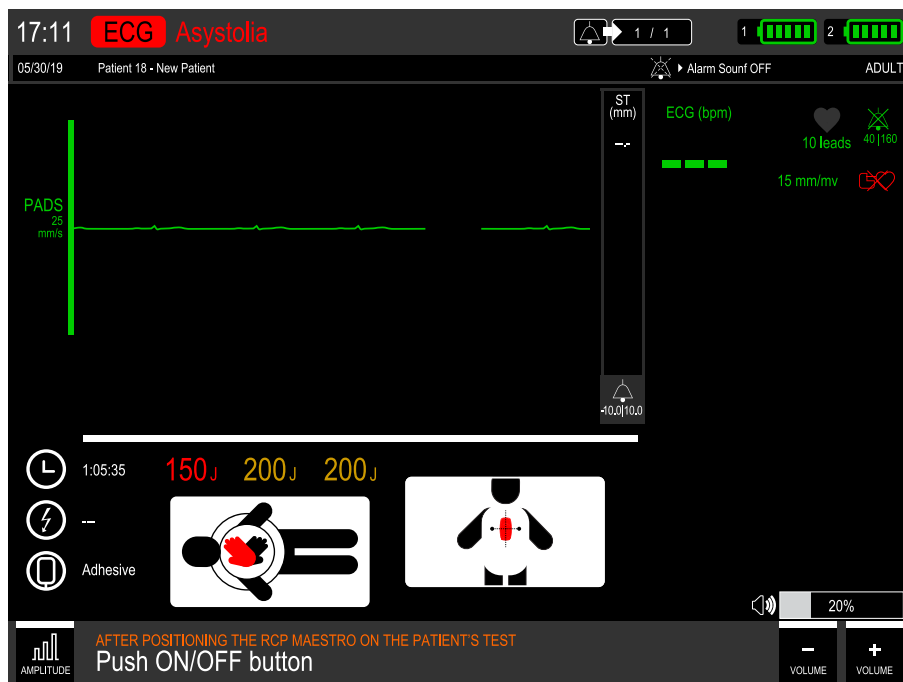
**ATTENTION:** do not use CPR MAESTRO on patients under 8 years old or under 25 Kg.

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



4 - A message will be displayed to confirm if the device is correctly placed on the

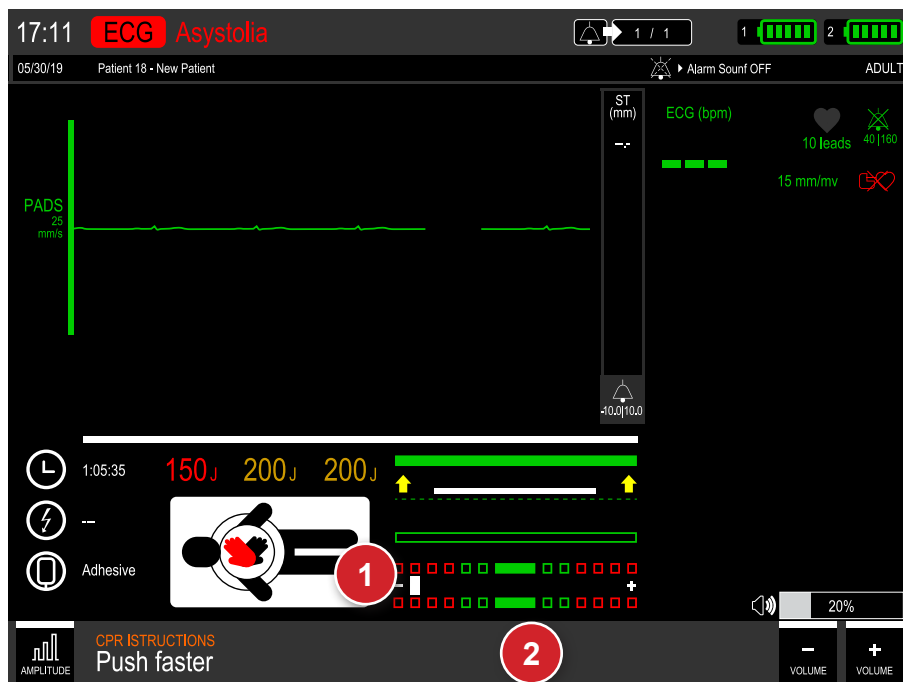
patient's chest, where the compressions will be performed. If yes, press the ON/OFF button again and start the compressions.



## Feedback

The user receives CPR feedback in the following ways:

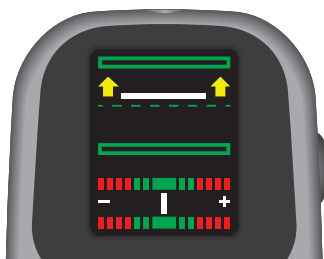
Message and CPR image on DualMax screen.



1. CPR indicative graphic.

2. Messages.

- 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 60 mm.

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

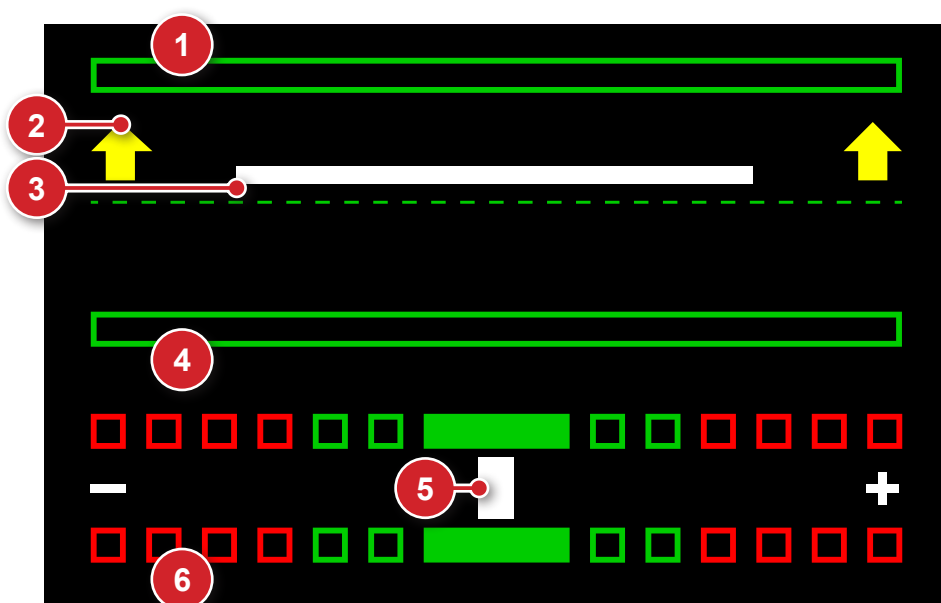
**Compress slower:** the rescuer is performing the compressions at a frequency beyond the limit.

**Good compressions:** the rescuer is performing a perfect message.

**Start CPR:** the rescuer stopped doing the massages.

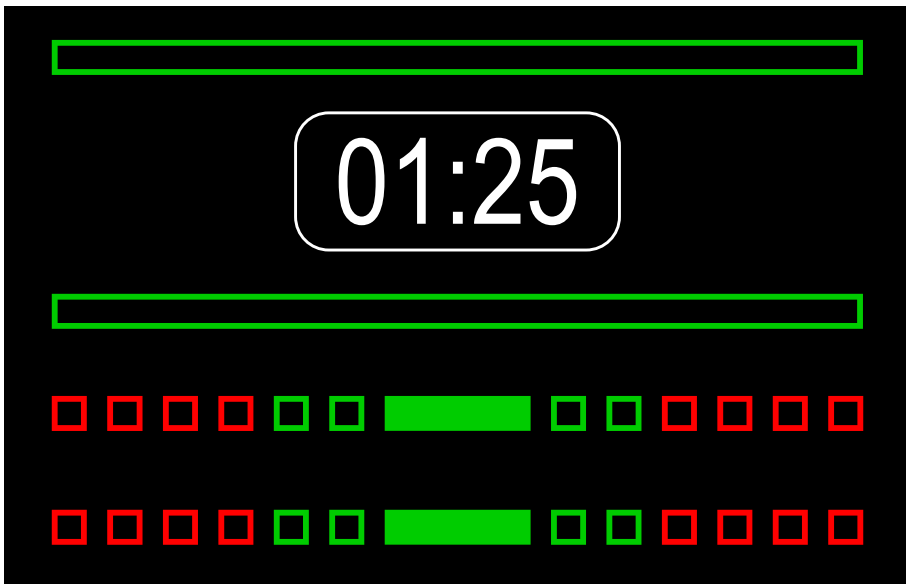
## CPR graphic

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



3. Chest full expansion indicator: when filled with the color green indicates that the chest returned to the initial position of the compressions.
4. Indicative arrows of correction: when present, the arrows indicate that the movement must be wider in the indicated direction.
5. Depth indicative bar: indicates the current depth of the compression.
6. Maximum depth indicator: when filled with the color green, indicates that the compression reached the ideal depth. When filled with the color red, indicates too hard compression.
7. Frequency indicative bar: indicated the frequency of the compressions. When aligned with the red rectangles, indicates need of frequency adjustments.
8. 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.



## Physics principle used

The external pacemaker applies a squared waveform of variable frequency and intensity to the heart in order to stimulate heartbeats. In a normal heart, the heart beats as follows: the sinoatrial node, located in the right atrium, stimulates the heart's contraction. It is controlled by the parasympathetic system that by freeing acetylcholine, performs a depressor effect while a sympathetic innervation, when stimulated, produces noradrenaline, which accelerates the rhythm. This potential is then propagated through the atrial myocardium and then reaches the second most important system center, the atrium-ventricular node, also located in the right atrium, which transmits the potential to the ventricles through the atrium-ventricular and its branches.

The pacemaker uses electrical stimulation to reproduce or regulate the heart's rhythm.

Its function is to supply pulses in order to stimulate the heart. These pulses have two characteristics that must be adjusted: The number of pulses per minute (PPM) and the strength of the current (mA). The pacemaker works in two modes: fixed or on demand (synchronous).



## Warnings

**The DualMax has a patient impedance meter that delivers shocks in 25 to 300 Ohms impedances.**

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

**Prolonged use of external pacemaker may cause erythematous skin.**

**In this Pacemaker mode, only the SOUND of the HIGH PRIORITY AND MEDIUM PRIORITY alarms are disabled.**

## **Fixed mode**

In this mode, the pacemaker does not consider the patient's heart frequency and applies the PPM number defined by the user.

---

## **Demand mode (synchronous)**

In this mode the DualMax assesses the patient's heart rate, applying the PPM number selected in the panel only when the heart rate is lower than the PPM value indicated. It must be within at least 5 BPM (the security margin) for the pacemaker to work.

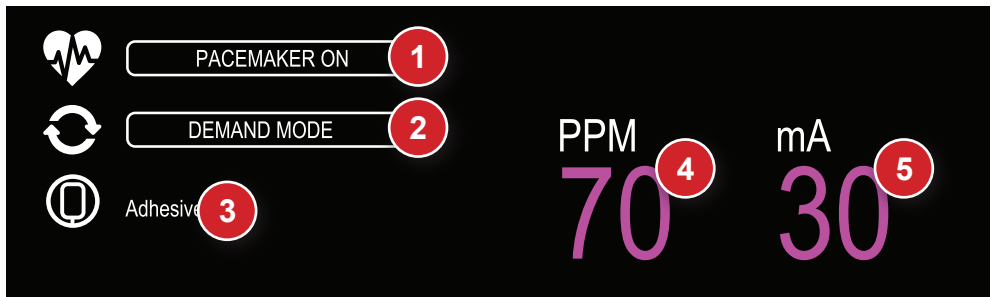
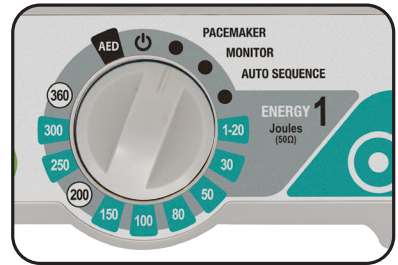
In this mode, the pacemaker uses the ECG signal captured by the electrodes (patient cable), synchronizing the pulses in order to prevent the heart's vulnerable phase.

## Operating in pacemaker mode

Place the selector switch on pacemaker mode.

The screen below will appear.

With the e-Jog, navigate on the yellow area to configure the pacemaker's parameters.



1. Changes between “PAUSE” and “ON” in the Pacemaker mode. In “PAUSE” mode, it does not emit any stimulation.
2. Allows the change between “FIXED” and “DEMAND” modes.
3. Type of pads selected (adhesive).
4. PPM: selection of the pacemaker's stimulation frequency. The user alters the “Pulses Per Minute” (PPM) value.
5. mA: alters the stimulation current in milliamperes.



## Starting stimulation

- 1 - If it not yet connected, connect the adhesive pads cable to the DualMax.
- 2 - Check if the multifunction adhesive pads package is intact and within the expiration date.
- 3 - Insert the adhesive pads connector into the equipment's extension cable.
- 4 - Put the adhesive pads on the patient according to package instructions.
- 5 - In case of demand mode stimulation, apply ECG monitoring electrodes.

---

## Fixed stimulation

- 1 - Rotate the dial to the pacemaker mode.

**The pacemaker starts in PAUSE, without stimulation pulses.**

**The mode must be changed to FIXED.**

- 2 - Select the leads for ECG viewing.
- 3 - With the e-Jog, adjust the initial current and frequency (PPM) values (see the previous page). The current value must be as low as possible.
- 4 - Go to "ON" with the e-Jog, in order to start stimulation. A message in the "Infocenter" will inform the pacemaker is active.
- 5 - Check if the pacemaker's pulse meter appears on the screen.
- 6 - Increase the stimulation current until the heart rate is captured. This is indicated by the presence of the QRS complex (Q, R and S waveforms) right after the pacemaker marker.

## Under demand stimulation

- 1** - Rotate the selector switch to the pacemaker mode. The pacemaker starts in PAUSE, without stimulation pulses.
- 2** - Select the leads for viewing the ECG. Check if the “R” wave indicators mark every “R” wave present on the screen. If not change the derivation.
- 3** - Adjust the initial current values and frequency (PPM) with the e-jog. The current value must be as low as possible.
- 4** - With the e-Jog, go to “ON” to start stimulation. A message in the “Infocenter” will warn that the pacemaker is active.
- 5** - Check if the pacemaker’s pulse meter appears on the screen.
- 6** - Increase the stimulation current until cardiac capture occurs. The capturing is indicated by the presence of a QRS straight after the pacemaker marker.

### NOTES

**There may be spontaneous beatings not related to the application of stimulation. If the patient's heart frequency is above the pulse's frequency, the stimulation pulses will not be applied and the stimulation markers will not appear.**

**Stimulation will not start if there is a problem with the multifunction (adhesive) paddles or contact with the patient.**

**The stimulated pulses will be applied in the asynchronous mode if there is a connection problem with the ECG monitoring electrodes or if the DualMax does not identify a valid QRS.**

## Defibrillation

If defibrillation is necessary, turn the switch to defibrillation mode. The DualMax automatically inhibits the pacemaker's stimulation pulse.

### Physics principle used

ECG is the measurement of electrical potential generated by the depolarization and re-polarization of heart cells, generating the bioelectrical impulse responsible for the heart's contraction. Heart impulses are detectable on the body surface by applying electrodes. Each electrode's potential is amplified and processed by the heart monitor, displayed on the screen and then used to calculate the heart's frequency (BPM).

The heart cycle period is the elapsed time from any point in the ECG cycle to the corresponding point in the next cycle. For example, the interval "R-R" is the time between two successive "R" waves. Using this measurement, it is possible to determine the beats per minute (BPM).



### Warnings

**Use only original Instramed cables and conductors. Other ECG cables may impede defibrillation or not work correctly.**

**If you suspect a cable or conductor is ruptured, avoid its use due to possible risk to operator.**

**If the patient has a pacemaker, do not rely solely on the equipment alarms. Keep the patient under observation.**

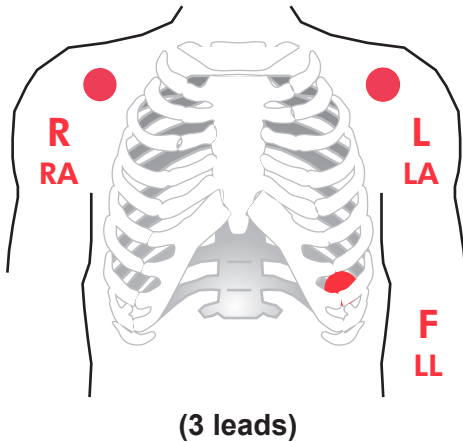
**The cardiac frequency measurement can be affected in the presence of a transcutaneous pacemaker.**

**The ECG electrodes are disposable and single-use and cannot be reused under any circumstances.**

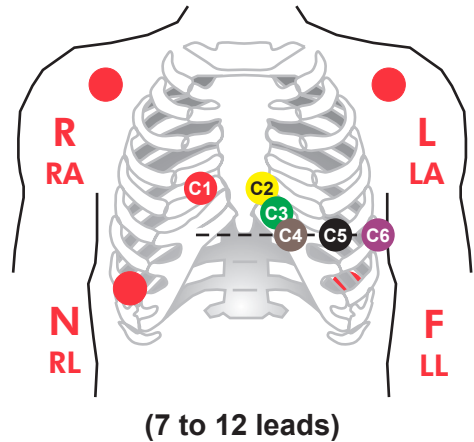
## Monitoring ECG

- 1 - Connect the ECG cable into the ECG socket in the equipment's side panel.
- 2 - Select the electrodes to be used on the patient. Use only one kind or brand of electrode. The electrodes must follow AAMI standards for electrode performance.
- 3 - Prepare the application area according to the manufacturer instructions.
- 4 - Apply the electrodes according to the images below, following the color pattern on the table on the following page.
- 5 - Connect the patient's ECG cable to the electrodes.

**3-wire cable**



**5-wire cable**



## Leads

Lead	Electrode differential	Reference
DI	LA - RA	LL
DII	LL - RA	LA
DIII	LL - LA	RA
aVR	RA - (LL+LA)	RL
aVL	LA - (LL+RA)	RL
aVF	LL - (LA+RA)	RL
C (V1 - V6)	C - (RA+LA+LL)	RL

## Color patterns

There are two color patterns for ECG cables. The DualMax uses the IEC pattern. See the table below.

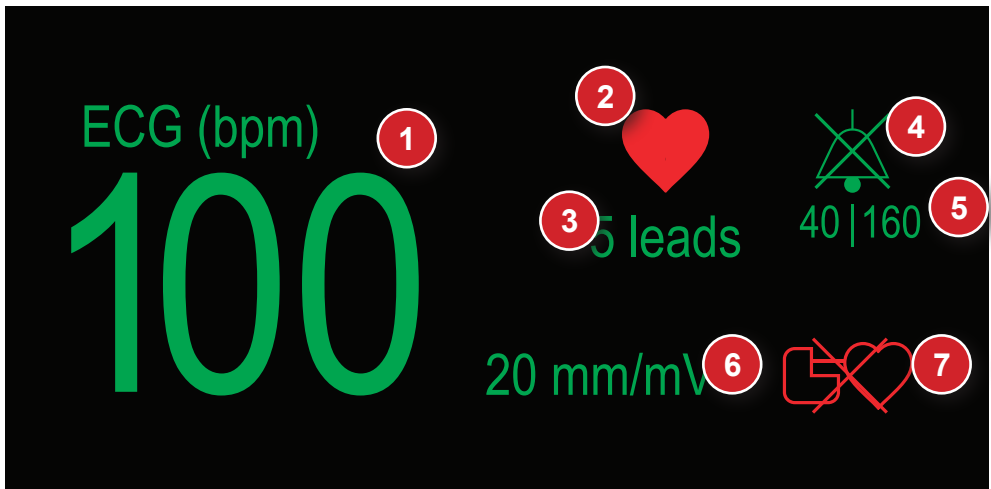
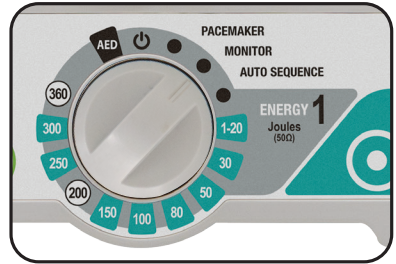
Position	IEC (European)	AHA (American)
Right Arm	R - Red	RA - White
Left Arm	L - Yellow	LA - Black
Left Leg	F - Green	LL - Red
Right Leg	N - Black	RL - Green
Thorax	C - White	V - Brown

## Operating in monitor mode - ECG

Turn the selector switch to the Monitor mode.

All ECG and SpO<sub>2</sub> alarms will be enabled.

The next screen will be displayed.



1. ECG numeric value and BPM measuring unit.
2. ECG Symbol - The ECG icon represents an expanding heart that indicates that the ECG's "R" wave peak has been detected.
3. Number of ECG leads selected.
4. The "BELL" Icon - Indicates audio in pause or off.
5. Maximum and minimum alarm values.
6. mm/mV value.
7. Pacemaker detector symbol - Represents a pacemaker generator that flashes when a pulse is detected. In case the symbol is overlaid by a red X, it means that the pacemaker detection is disabled.

## ECG Setup - Principal

The screenshot shows the ECG Setup - Principal screen. At the top, there are tabs for ECG (selected), RESP, TEMP, SPO2, and NIBP. Below the tabs, there are several settings:

- 1** ECG Response [Slow | Normal | Fast]: Set to Normal.
- 2** ECG Cable [3 leads | 5 leads]: Set to 5.
- 3** Pacemaker detector [On | Off]: Set to Off.
- 4** Amplitude [5 ... 40]: Set to 15.
- 5** Frequency range [Diag | Monitor]: Set to Monitor.
- 6** Mains filter 50/60 hz [On | Off]: Set to On.
- 7** ST [On | Off]: Set to Off.
- 8** SDP - Sudden Death Prevention [On | Off]: Set to Off.
- 9** A navigation bar at the bottom left with a triangle and the number 9, and a page indicator 1 / 2.
- 10** BACK and EXIT buttons at the bottom right.

### 1 - ECG response

Select the ECG numeric update response. You can select from “SLOW”, “NORMAL” and “FAST” responses.

**NORMAL:** used for most patients, this mode uses 16 beats to define the average.

**FAST:** used when the operator needs faster responses. It is affected by the patient's movements, using 8 beats to define the average.

**SLOW:** less affected by the patient's movements. However, you must pay attention to the slow response of the heart rate variation. This mode uses 32 beats to define the average.

### 2 - ECG cable

It allows selecting the ECG monitoring by cable with 3 lead, 5-lead or 10-lead.

**Using the 3-wire ECG cable in the SDP (Sudden Death Prevention) makes it functional only in the DII lead.**

### 3 - Detect pacemaker

Enables to turn the pacemaker detection mode on or off. When on, the equipment indicates on the screen the pacemaker's pulse moment. Detect pacemaker mode must only be used on patients with pacemaker.

---

### 4 - Amplitude

Selects the gain of the ECG amplification stage. Selectable in 5, 10, 15, 20, 30, 40 mm/mV.

---

### 5 - Frequency bandwidth selection

Filter selection for power interference. "Diag" or "Monitor".

---

### 6 - Mains supply filter

Enables to turn filter on or off to reduce mains supply interference with the ECG signal.

---

### 7 - ST

Turns on or off the ST segment monitoring.

---

### 8 - Sudden Death Prevention (SDP)

Allows to turn on or off the Sudden Death Prevention mode. When turned on, in monitoring through the adhesive pads or electrodes, the equipment alarms and indicates "shock indicated" if a ventricular fibrillation/tachycardia (VF/VT) is identified.

---

### 9 - Next page

Displays the next screen of the ECG menu.

---

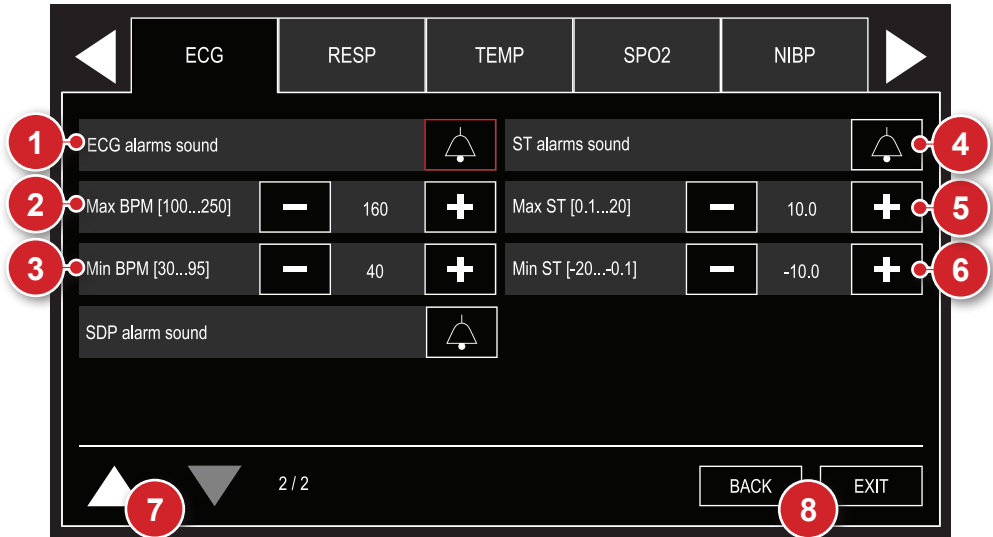
### 10 - Back/Exit

"Back" to Configuration menu and "Exit" to monitoring screen.

---



## ECG configurations - Alarm



### 1 - Alarm sound

Selection of ECG alarm status: active sound and disabled sound.

### 2 - Maximum limit

Selection of ECG alarm maximum limit.

### 3 - Minimum limit

Selection of ECG alarm minimum limit.

### 4 - Alarm sound

Selection of ST alarm status: active sound and disabled sound.

### 5 - Maximum limit

Selection of ST alarm maximum limit.

## 6 - Minimum limit

Selection of ST alarm minimum limit.


## 7 - Previous page

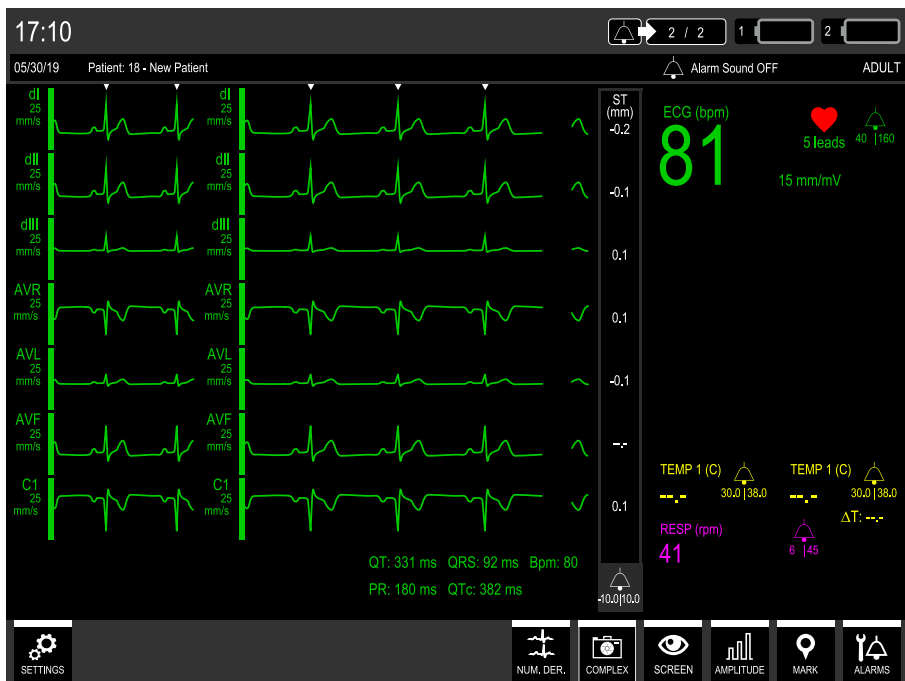
Returns to the previous page of the ECG menu.

## 8 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.



When pressing the key  only in Monitor Mode, the DualMax will freeze 1/3 of the screen and will keep displaying, in real time, the curves on the rest of the space. Additionally, the DualMax will calculate the intervals QT, QTc, QRS, BPM and PR to help the cardiologist.



## **NOTE**

For better calculation of ECG complex intervals, ECG electrodes must be positioned correctly, also avoiding noise.

The COMPLEX key will be disabled in MODE 12 DERIVATIONS, or when there is a LOOSE ELECTRODE, or when using the 3-lead CABLE.

If the clinical operator intentionally disconnects the ECG, SpO<sub>2</sub> and defibrillation module, it will appear the message ECG: COMMUNICATION ERROR, SpO<sub>2</sub>: COMMUNICATION ERROR, DEF: COMMUNICATION ERROR and the ALARM SIGNALS will be automatically disabled.

## Physics principle used

DualMax uses oscillometric mode to calculate Non-Invasive blood pressure. A armband is used to convey arterial pressure changes caused by blood flow. The armband is insufflated to a pressure higher than systolic pressure in order to occlude blood flow in extremities. Gradually, armband pressure is reduced generating little pulses or oscillations.

Mean pressure is the lowest pressure in the armband, in which detected oscillation peaks have higher amplitude. Systolic pressure occurs when oscillation increases quickly and diastolic pressure occurs when oscillation decreases in the same intensity. As a characteristic of oscillometric mode, mean pressure is the most precise one.



## Warnings

If you suspect a cable or conductor is ruptured, avoid using the equipment due to possible risk to the operator.

The armband must not be applied on the same limb or extremity where the SpO<sub>2</sub> sensor is. When inflating the armband, SpO<sub>2</sub> monitoring may be affected.

Do not place armband on limb or extremity which is being used for intravenous infusion, or in any area where circulation is compromised.

The DualMax shows the results of the last NIBP measurement until a new measurement is obtained. If the patient's conditions change between measurements, the monitor will not detect it.

Patient's excessive movements may cause imprecise measurements.

During NIBP monitoring, avoid compression or restriction of the pressure tubes.

The NIBP connection is protected against defibrillation discharges. It is not necessary to remove the armband from the patient or disconnect it in case of defibrillation.

In case the equipment is accidentally wet, dry it with a clean cloth.

A doctor should be consulted to interpret the non-invasive blood pressure measures.

Non-invasive Blood Pressure measurements are not intended for use during procedures with high frequency surgical equipment such as electro scalpel.

Non-invasive Blood Pressure measures are not intended for use during patient transportation, out of the medical environment.

## Monitoring Non-Invasive Pressure

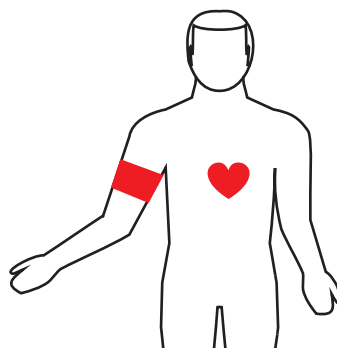
- 1 - Connect the end of the extension hose to the equipment's non-invasive pressure connector.
- 2 - Measure the limb in which the armband will be applied to and select an adequate type. See the chart below.
- 3 - Place the armband on the limb as it suggests "**Armband positioning**".
- 4 - Connect the armband to the extension hose.
- 5 - Select one of the measurement modes: manual or automatic.

### ARBAND SELECTION

Armband	Limb circumference (arm/leg)
Child	10 to 19 cm
Pediatric	18 to 26 cm
Adult	25 to 35 cm
Extra Large	33 to 47 cm

### PLACING THE ARMBAND

- 1 - Select the measurement place. Choose a place with good blood circulation, without skin problems and in which armband use does not harm the patient. Because of convenience and because of the fact that standard values are based on this location, give preference to the upper arm.
- 2 - Check the armband's appropriate size for the chosen area according to the previous chart.
- 3 - Make sure the limb is supported to guarantee that the armband is at the heart's level. Due to the hydrostatic effect, placement above or below the heart's level may cause incorrect measurements.
- 4 - Ensure the ARTERY Mark is above the brachial artery.



## Measurement modes

**1 - Manual:** Instantaneous measurement of systolic, diastolic and mean pressure.

To activate the manual mode, press NIBP MANUAL MEASUREMENT in the front panel or in the NIBP Menu Setup, select the Manual Measurement item.

**When pressing the NIBP MANUAL MEASUREMENT button while the monitor is exerting the NIBP measurement, it will immediately interrupt the measurement.**

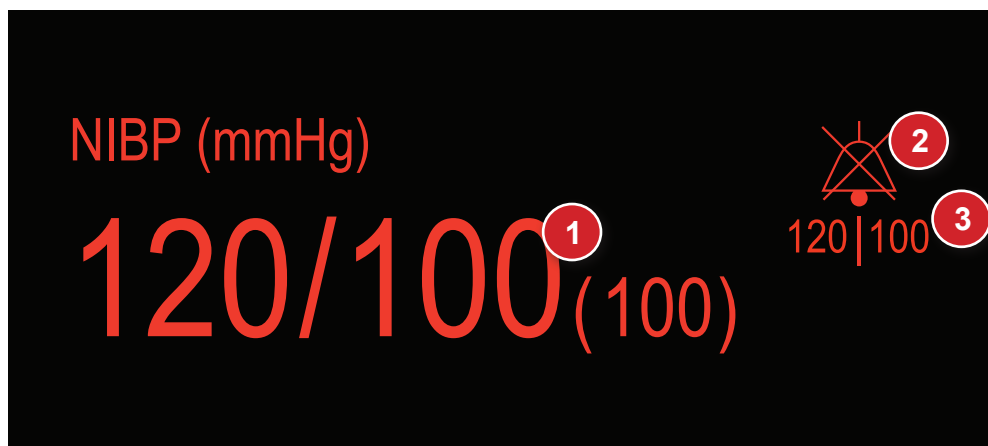
**2 - Long-term automatic:** automatic measurements of systolic, diastolic and mean pressures. Measurements are automatically repeated during the time set by the operator.

To activate the automatic mode select the desired time in the Configuration Menu > NIBP. Interval between measurements can be selected to:

1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes.

**Interrupting NIBP measurements: to cancel an ongoing pressure measurement, press “NIBP MANUAL MEASUREMENT”, located in the equipment’s front panel. The DualMax does not offer a short-term automatic measurement option.**

## NIBP numeric indicator



1. Numeric values for systolic/diastolic and mean pressures.
2. Icon "BELL" - Indicates if audio is active, paused or turned off.
3. Maximum and minimum alarm values.

## NIBP setup - Principal



## **1 - Manual measurement**

Start a NIBP manual measurement.

---

## **2 - NIBP On/Off**

Enables or disables the DualMax's NIBP function.

---

## **3 - Automatic measurement**

Starts the NIBP automatic measurement mode. When selecting this function, a measurement is immediately exerted. Posterior measurements will be exerted in the time set by the user. Time can be selected to OFF, 1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes.

---

## **4 - Initial pressure**

Select the initial pressure for the armband's insufflation.

---

## **5 - Next page**

Displays the next screen of the NIBP menu.

---

## **6 - Back/Exit**

"BACK" to configuration menu or "EXIT" to monitoring screen.



## NIBP configurations - Alarm

The screenshot shows the NIBP configuration screen with the following elements:

- 1**: NIBP alarms sound (bell icon)
- 2**: Max Systole [30...300] (minus button, 200, plus button)
- 3**: Min Systole [20...290] (minus button, 90, plus button)
- 4**: Max Diastole [30...300] (minus button, 150, plus button)
- 5**: Min Diastole [20...290] (minus button, 50, plus button)
- 6**: Max Mean [30...300] (minus button, 170, plus button)
- 7**: Min Mean [20...290] (minus button, 50, plus button)
- 8**: Navigation arrows (up/down) and page indicator (2 / 2)
- 9**: BACK and EXIT buttons

### 1 - Alarm

Selection of alarm status: active sound and disabled sound.

### 2 - Maximum limit - Systole

Selection of systole alarm maximum limit.

### 3 - Minimum limit - Systole

Selection of systole alarm minimum limit.

### 4 - Maximum limit - Diastole

Selection of diastole alarm maximum limit.

### 5 - Minimum limit - Diastole

Selection of diastole alarm minimum limit.

## **6 - Maximum limit – Average**

Selection of average pressure maximum limit.

---

## **7 - Minimum limit – Average**

Selection of average pressure minimum limit.

---

## **8 - Previous page**

Returns to previous page on NIBP menu.

---

## **9 - Back/Exit**

“BACK” to configuration menu or “EXIT” to monitoring screen.

## Physics principle used

The DualMax measures oxygen saturation on arterial blood by the passage of two light wavelengths through the body tissue, a red one and an infrared one which are detected by a photo-sensor.

The oximeter processes these signals, separating invariable parameters (thickness of tissue, skin color, light intensity and venous blood) from the variable parameters (arterial volume and SpO<sub>2</sub>) in order to identify pulse frequency and calculate oxygen saturation. Calculation of oxygen saturation is precise due to the fact that blood saturated with oxygen absorbs less red light than blood with less oxygen.

The DualMax measures functional saturation, not detecting significant quantities of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin.



## Warnings

**Use only original SpO<sub>2</sub> sensors manufactured by Instramed. Other sensors may cause inadequate performance.**

**If you suspect a cable or conductor is ruptured, avoid using the equipment due to possible risk to the operator.**

**Before using the sensor carefully read instructions which accompany it.**

**Do not wet the SpO<sub>2</sub> sensor.**

**When handling the SpO<sub>2</sub> cable, be careful not to strangle the patient.**

**The SpO<sub>2</sub> sensor should be repositioned every 4 hours, alternating its location.**

**Any condition that may restrict blood circulation, such as the armband of the arterial pressure device or extremes of systemic vascular resistance may affect the precision of the pulse frequency and SpO<sub>2</sub> readings.**

**Position the SPO<sub>2</sub> sensor so that the cable rests against the palm of your hand. This places the light source on the side of the nail and the detector on the underside of the finger.**

**Remove nail polish, or artificial nails, if present.**

**The presence of too much ambient light may affect the operation of the sensor. In this case, block sunlight (with a surgical towel) if necessary.**

**Prolonged use or the condition of the patient may require replacement of the sensor. Replace the sensor every 4 hours and often check the integrity and circulatory condition of the skin as well as the correct alignment of the sensor.**

**If the finger cannot be positioned correctly, choose a smaller finger or use another sensor.**

## Factors which affect the SpO<sub>2</sub> measurement's precision

- Incorrect use of the sensor.
- Anemia.
- Use of vasoactive drugs.
- Patient in shock or cardiac arrest.
- Significant number of dysfunctional hemoglobins.
- Intravascular contrasts such as indocyanine green and methylene blue.
- Exposure to excessive lighting.
- Arterial occlusion next to the sensor.

## Sensor selection

Choose an appropriate sensor in the chart below. Check the instructions which accompany the sensor for application instructions.

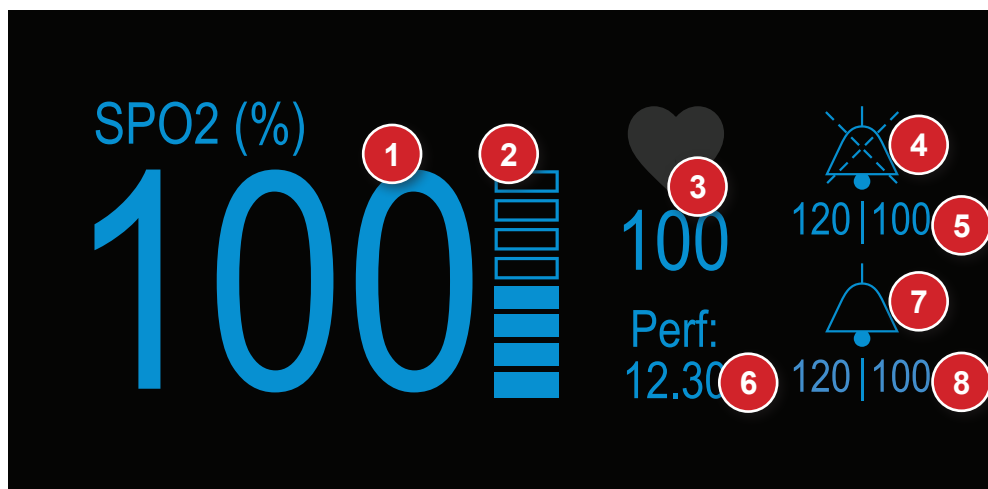
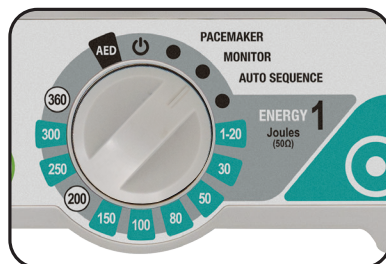
Patient	Place	Description
Adult/ Pediatric	Finger (hand). Finger or toe (hand or foot).	Sensor, adult. Sensor, "Y" universal.
Child	Finger or foot.	Sensor, "Y" universal.

## Operating in monitor mode - SpO<sub>2</sub>

Select the selector switch to Monitor mode.

All ECG and SpO<sub>2</sub> alarms will be enabled.

The following screen will be displayed.



1. SpO<sub>2</sub> numeric value.
2. Digital scale indicating pulse amplitude.
3. Patient's pulse frequency value, obtained by the oximetry sensor.
4. Icon "BELL" (saturation) - Indicates if audio is active, paused or turned off.
5. Maximum and minimum alarm values for saturation measurement.
6. Perfusion - Measurement value in percentage.
7. Icon "BELL" (pulse) - Indicates if audio is active, pause dor turned off.
8. Maximum and minimum alarm values for pulse frequency.

## SpO<sub>2</sub> setup - Principal



### 1 - SpO<sub>2</sub> (On/Off)

Allows to turn the parameter monitoring on or off.

### 2 - SpO<sub>2</sub> response

Selects the SpO<sub>2</sub> numeric update response. You can select among the SLOW, NORMAL and FAST options.

**NORMAL:** used for most patients.

**FAST:** used when the operator needs faster answers. The response is affected by the patient's movements.

**SLOW:** less affected by the patient's movements. However, you must pay attention to the SpO<sub>2</sub> slow response variations.

### 3 - Sensitivity

Allows to set the parameter sensitivity to "normal" or "high".

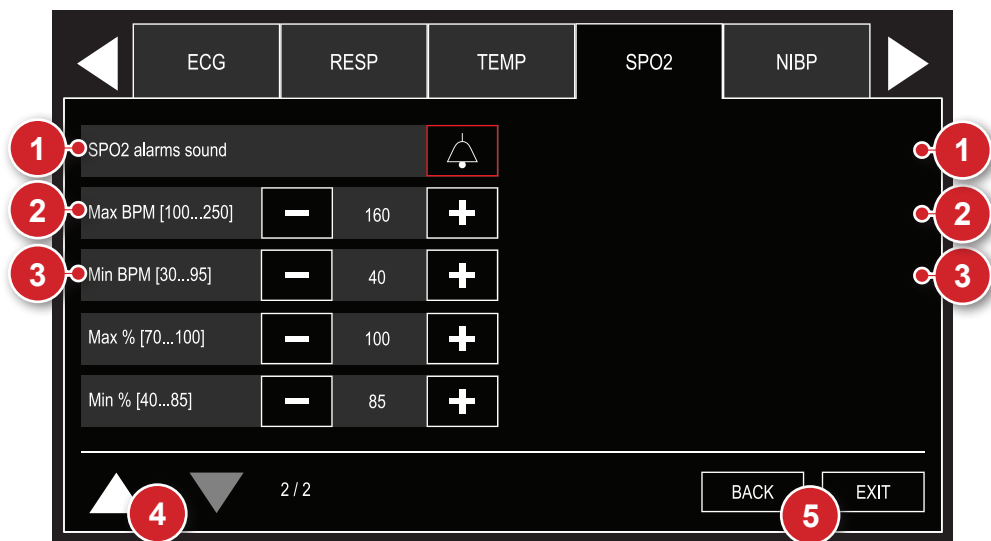
### 4 - Next page

Displays the next page of the SpO<sub>2</sub> menu.

## 5 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

## SpO<sub>2</sub> configurations – Alarm



### 1 - Alarm sound

Selection of alarm status: active sound and disabled sound.

### 2 - Maximum limit

Selection of BPM and SpO<sub>2</sub> saturation alarm maximum limit.

### 3 - Minimum limit

Selection of BPM and SpO<sub>2</sub> saturation alarm minimum limit.

## 4 - Previous page

Returns to the previous page of the SpO<sub>2</sub> menu.

## 5 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

## Physics principle used

Capnography is a Non-Invasive measurement usually presented by a graph of expiratory  $\text{CO}_2$  plotted against time.

The microstream method is used in intubated or non-intubated patients. A sample of the gas exhaled by the patient is collected by cannulas and sent to the Microstream chamber and sensor inside the DualMax.  $\text{CO}_2$  measurement is based on the characteristics of laser absorption by  $\text{CO}_2$  molecules.

Capnography consists of measuring and registering the carbon dioxide released at the end of expiration ( $\text{EtCO}_2$ ). The capnograph is an  $\text{EtCO}_2$  analyzer which displays its concentration or partial pressure both digitally and in graph record. The main information given by the capnograph are the exhaled  $\text{CO}_2$  partial pressure at the end of expiration, respiratory frequency and the capnogram.



## Warnings

**Never cut or bend the  $\text{EtCO}_2$  sample line. The use of folded or cut sample line can damage the equipment and prevent proper operation of the module.**

**The  $\text{EtCO}_2$  sample line is disposable and single-use and cannot be reused under any circumstances.**



## Capnography monitoring

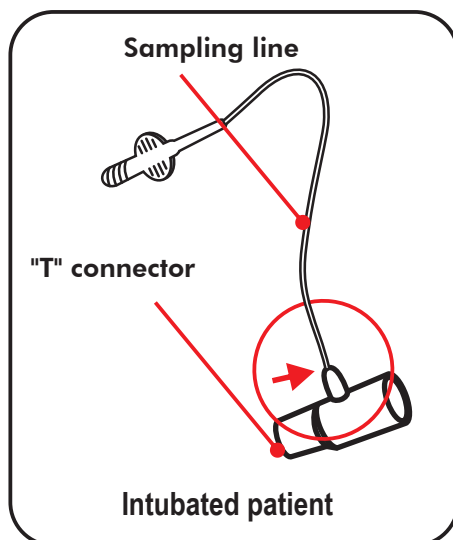
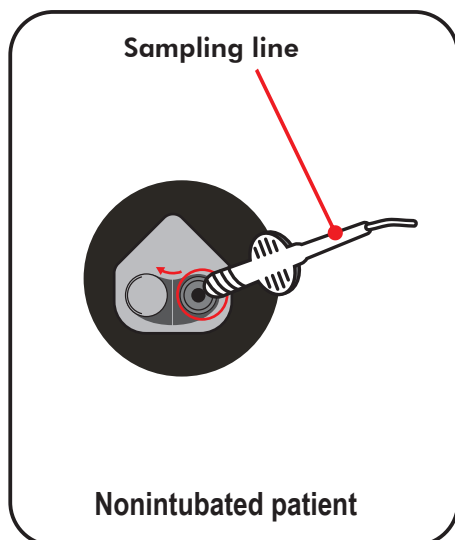
To start the EtCO<sub>2</sub> measurement, navigate through the “Configuration Menu - CO<sub>2</sub>” and set the “CO<sub>2</sub> - On/Off” item to ON.

**Right after the start, the EtCO<sub>2</sub> module performs a procedure called “auto-zero”, which is necessary for the proper functioning of the equipment. During this procedure, no measurements are exerted.**

The DualMax can monitor EtCO<sub>2</sub> in intubated or non-intubated patients. To do so, you just need to change the following accessories.

### Connect the following accessories

- **Intubated patient:** sampling line and “T” connector.
- **Non-intubated patient:** sampling line and nasal cannula.



### Sampling line

The sampling line collects a sample of the gas released by the patient.

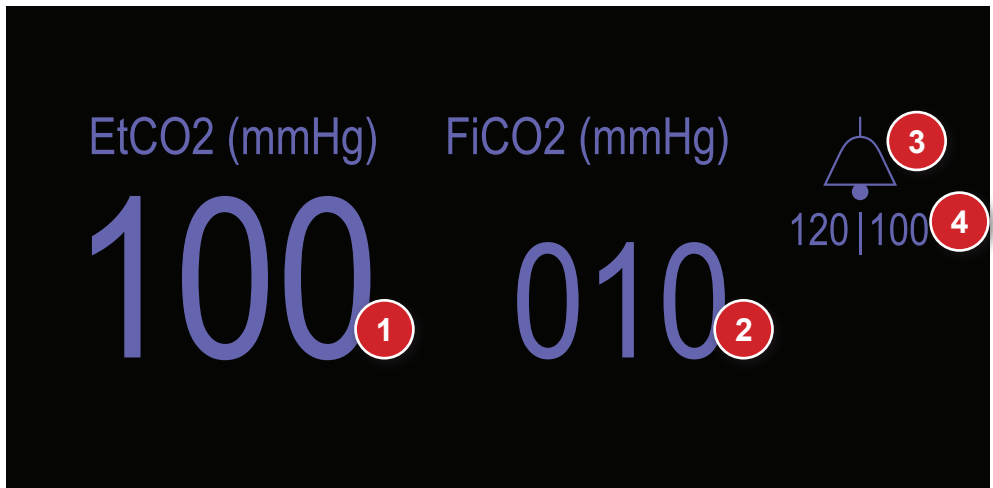
**In intubated patients** the sampling line is directly connected into the circuit via the “T” connector.

**In non-intubated patients** the sampling line is connected to the cannula and positioned on the patient.

### “T” connector

Connects the sampling line into the main ventilation circuit.

## EtCO<sub>2</sub> numeric indicator



1. Numeric value for the EtCO<sub>2</sub> expiration. The value of the EtCO<sub>2</sub> measured at the end of expiration is informed in mmHg or percents.
2. Numeric value for the FiCO<sub>2</sub> inspiration. It informs, in mmHg or percentage, the value of CO<sub>2</sub> measured at the end of the inspiration.
3. The “BELL” Icon - Indicates audio in pause.
4. Maximum and minimum alarm values.

## EtCO<sub>2</sub> setup - Principal

The screenshot shows the 'ETCO2' setup screen. At the top, there are navigation buttons: IBP, ETCO2 (highlighted in red), AUTO SEQ, DEFFIBRILATOR, and PRINTING. Below these are four configuration rows, each with a label and a value field:

- 1 - CO2 [On | Off] with a value of 'On'.
- 2 - Unit [mmHg | %] with a value of 'mmHg'.
- 3 - Scale [40 | 60 | 100] with a value of '60'.
- 4 - Calibration with a value of 'Start'.

Below the calibration field, a status bar shows 'Last calibration: 04/23/19 14:38'. At the bottom, there is a navigation bar with a left arrow, a right arrow, a page indicator '1 / 2', and two buttons: 'BACK' and 'EXIT' (highlighted with a red circle 7).

### 1 - CO<sub>2</sub> On/Off

Turns the CO<sub>2</sub> module on or off. When on, the sampling pump is also operating. The numeric values, graphs and CO<sub>2</sub> alarms will be activated.

### 2 - Units

Selects the measuring units of the CO<sub>2</sub> values. They can be displayed in mmHg (mercury millimeters) or % (the relative percent of the value measured in mmHg divided by the atmospheric pressure in mmHg).

### 3 - Scale

Alters the CO<sub>2</sub> gain graph on the screen.

## 4 - Calibration

The equipment is calibrated using a known gas sample, thus configuring its measuring curve.

**IMPORTANT: calibration must be performed when the equipment shows a message requiring this procedure during initialization. Calibration must be performed by QUALIFIED TECHNICAL PERSONNEL.**

## 5 - Calibration status

Displays the date of the last calibration or the current stage of calibration.

---

## 6 - Next page

Displays the next screen of the EtCO<sub>2</sub> menu.

---

## 7 - Back/Exit

“BACK” to Configuration menu or “EXIT” to monitoring screen.

## EtCO<sub>2</sub> configurations – Alarm



### 1 - Alarm sound

Selection of alarm status: active sound and disabled sound.

### 2 - Maximum limit

Selection of EtCO<sub>2</sub> alarm maximum limit.

### 3 - Minimum limit

Selection of EtCO<sub>2</sub> alarm minimum limit.

### 4 - Previous page

Returns to the previous page of the EtCO<sub>2</sub> menu.

### 5 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

## Physics principle used

The respiration waveform is generated by the measurement of the patient's bioimpedance. By means of a high frequency signal, which is applied to two electrodes (RA and LA), the thoracic impedance variation caused by the effort of breathing is detected and displayed on the monitor, in graph and numeric forms.

---



## Warnings

**If you suspect a cable or conductor is ruptured, avoid using them.**

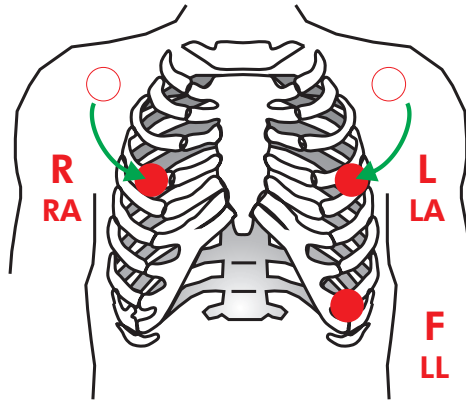
**The respiratory rhythm must be used to detect apnea.**

**Patient's excessive movements may cause imprecise measurements.**

## Respiration monitoring

The breathing signal is obtained by ECG electrodes. For more information on connections see the “ECG monitoring” chapter.

In order to improve breathing performance, you can change the position of the ECG electrodes, opting for alternative places. You must reposition RA and LA in a way so that they are applied below the nipples, as shown in the picture below:

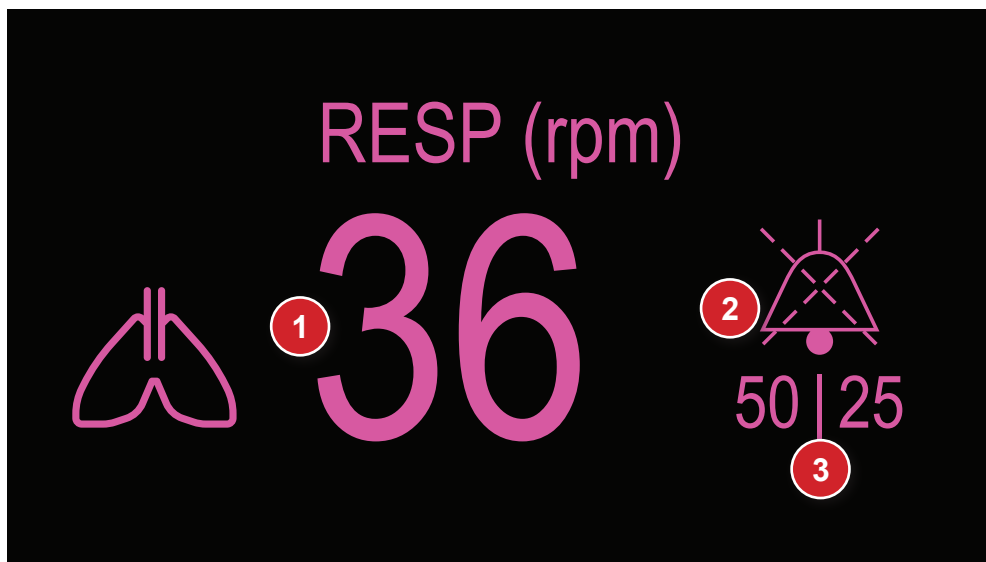


**WARNING:** when repositioning the electrodes, the ECG waveform and amplitude may change.

**WARNING:** only the respiration numeric value is obtained by the CO<sub>2</sub> module. The waveform is not.

**Capnography:** the monitor can also show the respiratory frequency calculated by the Capnography module. In order to this, set the function in the Configuration Menu (Menu > RESP > RESP Freq).

## Respiration numeric indicator

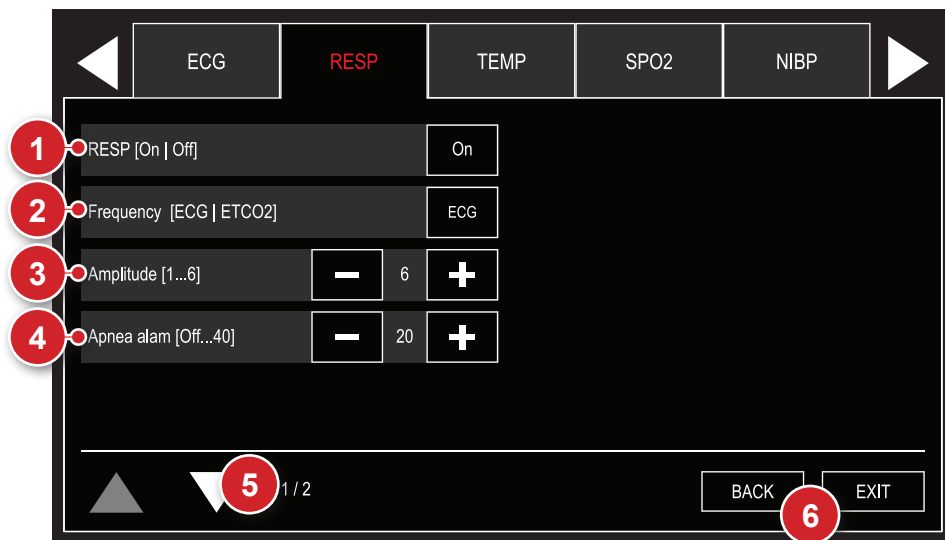


1. Numeric value of the respiration, measured in rpm.
2. Icon "BELL" - Indicates if audio is active, paused or turned off.
3. Maximum and minimum alarm values.



## Respiration setup

Using the e-Jog select the respiration function in the setup menu to access the respiration setup sub-menu.



### 1 - Respiration monitoring On/Off

When turned off, all visual and sound alarms will be inhibited and there will be no numeric indication for respiration.

### 2 - Respiratory frequency

Determines if the frequency shown by the equipment will be obtained by thoracic impedance (ECG cable) or by capnography (CO<sub>2</sub>).

### 3 - Respiration amplitude

Selectable in 1, 2, 3, 4, 5 and 6.

### 4 - Apnea alarm

The alarm emits a sound when a suspension of breathing is detected (apnea) in the specified times of 5, 10, 15, 20, 25, 30, 35 or 40 seconds.

### 5 - Next page

Displays the next page of the RESP menu.

## 6 - Back/Exit

“BACK” to Configuration menu or “EXIT” to monitoring screen.

## Respiration configurations – Alarm

Using the e-Jog, select the function respiration on the configuration menu to have access to the submenu of respiration configurations.



### 1 - Alarm

Selection of alarm status: active sound and disabled sound.

### 2 - Maximum limit

Selection of RESP alarm maximum limit.

### 3 - Minimum limit

Selection of RESP alarm minimum limit.

### 4 - Previous page

Returns to the previous page of the RESP menu.

### 5 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

---

# Temperature monitoring



# 15

## Physics principle used

The temperature is determined by measuring the resistance of the temperature sensor - a device called a thermistor whose impedance varies according to temperature.

The sensor signal is picked up by the input circuit that processes the signal and converts to values expressed as degrees Celsius ( $^{\circ}\text{C}$ ) or Fahrenheit ( $^{\circ}\text{F}$ ).

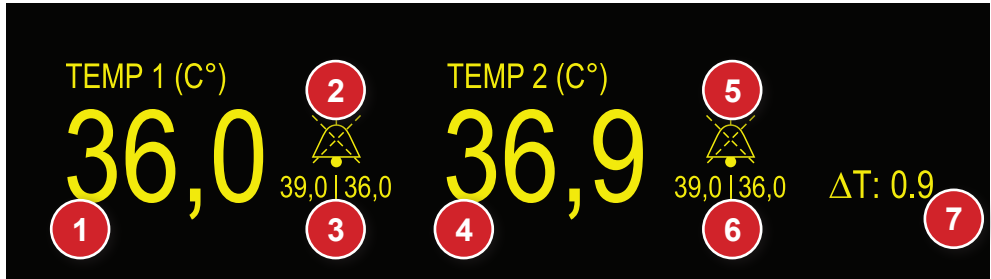
**OBS: “temperature sensor” not included with product.**

## Monitoring temperature

The DualMax uses YSI 400 standard temperature sensors.

The sensors can be for esophagus, rectum, skin, surface or temperature in the airways. In each type of sensor are found instructions for its proper use and maintenance.

## Temperature numeric indicator



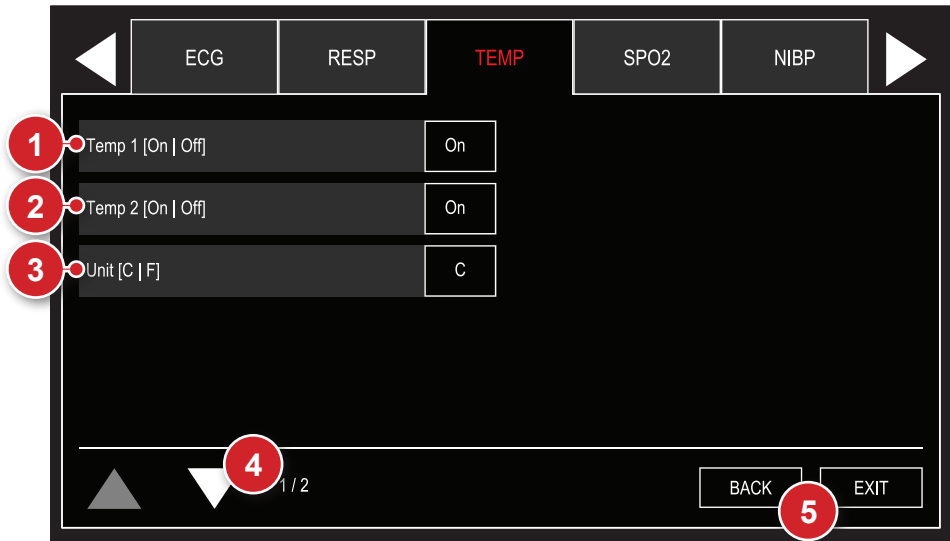
1. Channel 1 temperature numeric value.
2. Channel 1 “BELL” Icon - Indicates if audio is active, paused or off.
3. Channel 1 Maximum and minimum alarm values.
4. Channel 2 Temperature numeric value.
5. Channel 2 “BELL” Icon - Indicates if audio is active, paused or off.
6. Channel 2 Maximum and minimum alarm values.
7. ΔT numeric value.

## Temperature configuration

Using the e-Jog, select the function “Temperature” on the “Configuration menu” to have access to the submenu of temperature configurations.

**See image on the following page.**

## Temperature configurations – Principal



### 1 - Temperature 1

Turns the channel 1 temperature monitoring on or off. When turned off, all visual and sound alarms are disabled e there is no numeric indication for this parameter.

### 2 - Temperature 2

Turns the channel 2 temperature monitoring on or off. When turned off, all visual and sound alarms are disabled e there is no numeric indication for this parameter.

### 3 - Unit

Selection of the measurement unit for the temperature monitoring, selectable in °C (Celsius) or °F (Fahrenheit).

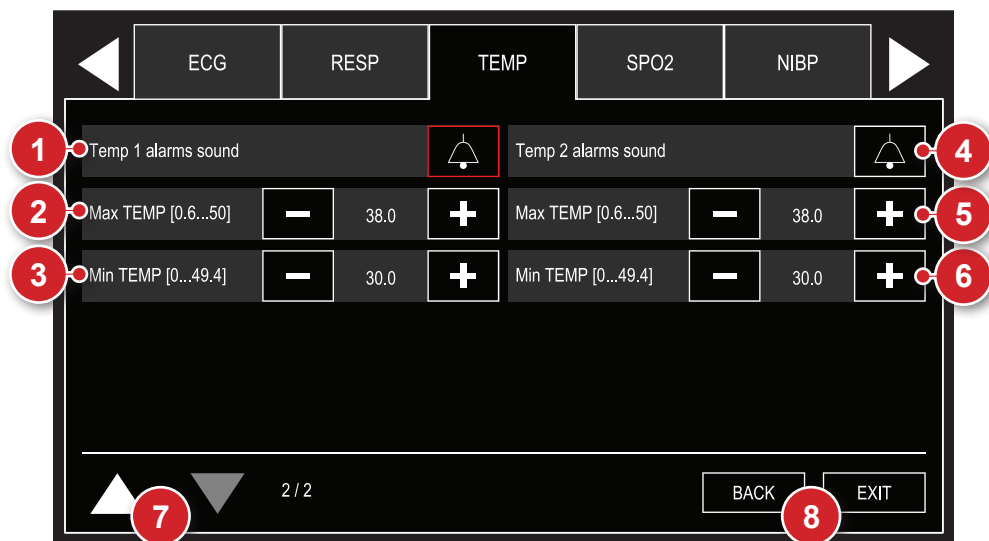
### 4 - Next page

Displays the next screen of the temperature menu.

### 5 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

## Temperature configurations – Alarms



### 1 - Temperature 1 alarm

Selection of channel 1 temperature alarm status: active sound and disabled sound.

### 2 - Maximum limit (temperature 1)

Selection of channel 1 temperature alarm maximum limit.

### 3 - Minimum limit (temperature 1)

Selection of channel 1 temperature alarm minimum limit.

### 4 - Temperature 2 alarm

Selection of channel 2 temperature alarm status: active sound and disabled sound.

### 5 - Maximum limit (temperature 2)

Selection of channel 2 temperature alarm maximum limit.

## **6 - Minimum limit (temperature 2)**

Selection of channel 2 temperature alarm minimum limit.

---

## **7 - Previous page**

Returns to the previous page of the temperature menu.

---

## **8 - Back/Exit**

“BACK” to the configuration menu or “EXIT” to monitoring screen.

## Physics principle used

The most accurate way to measure blood pressure is through the invasive method. This method is performed by means of a catheter inserted into the artery, which is connected to a liquid column. The pressure measurement is obtained through a pressure transducer. By this method, numeric values and curves corresponding to the blood pressure measurement are observed.

The invasive technique is regularly employed in intensive care medicine, anesthesiology and for research purposes.



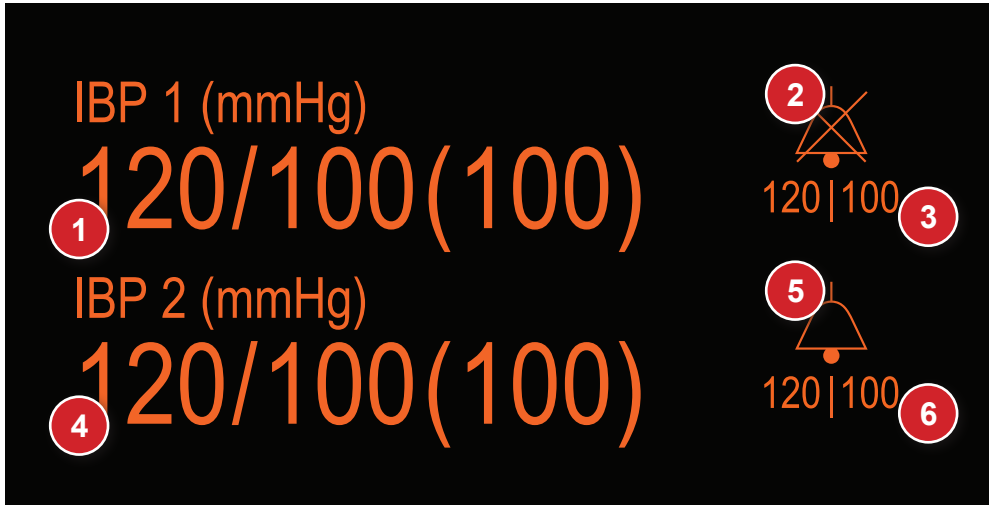
## Warnings

The following situations may cause inaccuracy or failure in the invasive pressure measurement:

- Cracked luer lock connections.
- Air bubbles in sampling line.
- Faulty infusion pump.
- Defective reusable transducer interface cable.
- Wrong readings caused by transducer problems.
- Problems associated with catheters. Tip of catheter contracted against wall.
- Transducer not reset.
- Loss of blood if the spigot is open.
- Fluid overload.



## IP numeric indicator



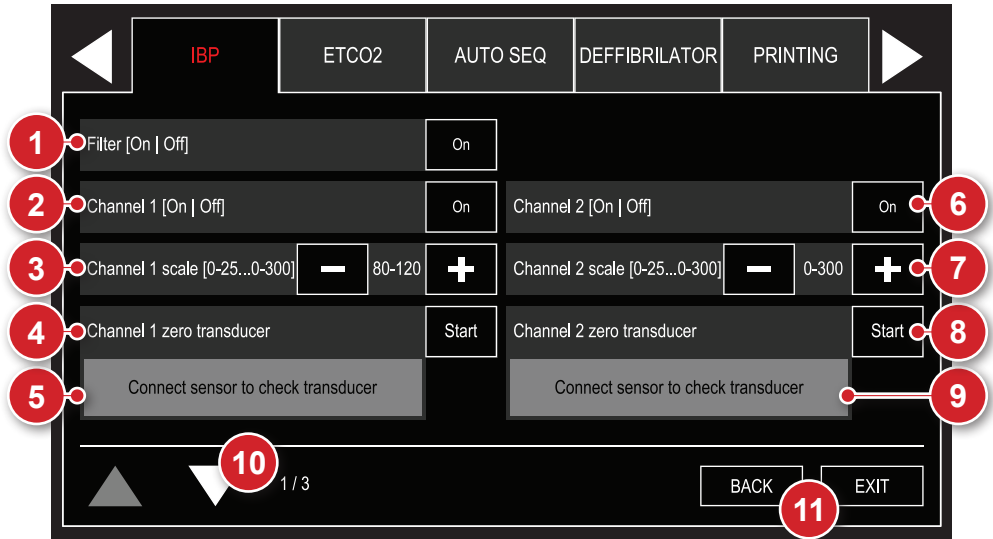
- |  |  |
|--|--|
| 1. Channel P1 invasive pressure numeric value. SYSTOLE/DIASTOLE (AVERAGE). | 4. Channel P2 invasive pressure numeric value. SYSTOLE/DIASTOLE (AVERAGE). |
| 2. Channel P1 "BELL" Icon - Indicates if audio is active, paused or off.   | 5. Channel P2 "BELL" Icon - Indicates if audio is active, paused or off.   |
| 3. Channel P1 Maximum and minimum alarm values.                            | 6. Channel P2 Maximum and minimum alarm values.                            |

## Invasive pressure configuration

Using the e-Jog, select the function "Invasive Pressure" on the "Configuration menu" to have access to the submenu of invasive pressure configurations.

**See image on the following page.**

## IP configuration - Principal



### 1 - 60 Hz filter

Selection of mains interference filter for both pressure channels.

### 2 - Channel 1 On/Off

Turns the channel 1 invasive pressure on or off.

### 3 - Channel 1 scale

Changes the scale of the channel 1 invasive pressure.

### 4 - Channel 1 clear transducer

Clears the channel 1 invasive pressure transducer.

**OBS: this operation must be performed in every new procedure. First position the transducer and then select “Start”.**

### 5 - Channel 1 reset status

Displays the date of the last reset or the current reset step of the channel 1 transducer.

## 6 - Channel 2 On/Off

Turns the channel 2 invasive pressure on or off.

---

## 7 - Channel 1 scale

Changes the scale of the channel 1 invasive pressure.

---

## 8 - Channel 1 clear transducer

Clears the channel 1 invasive pressure transducer.

**OBS: this operation must be performed in every new procedure. First position the transducer and then select “Start”.**

## 9 - Channel 1 reset status

Displays the date of the last reset or the current reset step of the channel 1 transducer.

---

## 10 - Next page

Displays the next screen of the IP menu.

---

## 11 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

### WARNING

- a. Harmful injury to the patient may be caused by the continuous pressure of the ARMBAND and resulting from twists in the connecting tubing.
- b. Very frequent measurements of blood pressure can cause injury to the patient, because of interference with blood flow.
- c. Injury to the patient can be caused if the ARMBAND is positioned on top of a WOUND.
- d. Injury to the patient and temporary interference in blood flow may be caused in the event of pressurization of the ARMBAND where there is an intravascular access or arteriovenous connection.

- e. Measuring blood pressure in the arm on the same side of a mastectomy can cause measurements to be inaccurate. In this case, use the contralateral arm.
- f. Pressurization of the ARMBAND may cause temporary loss of function of the equipment being used on the same limb.
- g. In patients where the measurement is FREQUENT, it must be checked if there is a prolonged reduction of blood circulation in the patient.

## WARNING

For a blood pressure measurement with greater precision, it is necessary:

- a. Patient at rest.
- b. User adjust pressure reduction rate when necessary.
- c. Patient must be:
  - Comfortably seated.
  - With legs uncrossed.
  - With feet flat on the floor.
  - With the back and arms propped up.
  - With the middle of the ARMBAND in the right atrium level of the heart.
  - Patient relaxed and avoiding speaking.
  - It is recommended that there be a 5-minute pause before the first reading is taken.
  - Operator position in NORMAL USE.
- d. Any reading of blood pressure may be affected by the location of the measurement, patient position, exercise or physiological condition of the patient.
- e. If the operator notices unexpected readings, he must check the positioning of the ARMBAND, the position of the patient, check if the patient's clothing sleeve is in the way and take a 5-minute break before the next measurement.

## IP configurations – P1 alarms

Option	Minus	Value	Plus	Status
IBP 1 alarms sound				Max Mean [10...300] 170
Max Systole [10...300]	–	200	+	Min Mean [0...290] 50
Min Systole [0...290]	–	90	+	
Max Diastole [10...300]	–	150	+	
Min Diastole [0...290]	–	50	+	

2 / 3

BACK EXIT

### 1 - IP alarms 1

Selection of channel 1 alarm status: active sound and disabled sound.

### 2 - Maximum limit - Systole

Selection of systole alarm maximum limit for channel 1.

### 3 - Minimum limit - Systole

Selection of systole alarm minimum limit for channel 1.

### 4 - Maximum limit - Diastole

Selection of diastole alarm maximum limit for channel 1.

### 5 - Minimum limit - Diastole

Selection of diastole alarm minimum limit for channel 1.

### 6 - Maximum limit - Average

Selection of average alarm maximum limit for channel 1.

## 7 - Minimum limit - Average

Selection of average alarm minimum limit for channel 1.

---

## 8 - Previous page

Returns to the previous page of the IP menu.

---

## 9 - Next page

Displays the next screen of the IP menu.

---

## 10 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

## IP configurations – P2 alarms

Menu Item	Option	Value	Status	
IBP	IBP 2 alarms sound	Max Mean [10...300]	170	
ETCO2	Max Systole [10...300]	200	Min Mean [0...290]	50
AUTO SEQ	Min Systole [0...290]	90		
DEFFIBRILATOR	Max Diastole [10...300]	150		
PRINTING	Min Diastole [0...290]	50		

3 / 3

BACK EXIT

### 1 - IP alarms 2

Selection of channel 2 alarm status: active sound and disabled sound.

### 2 - Maximum limit - Systole

Selection of systole alarm maximum limit for channel 2.

### 3 - Minimum limit - Systole

Selection of systole alarm minimum limit for channel 2.

### 4 - Maximum limit - Diastole

Selection of diastole alarm maximum limit for channel 2.

### 5 - Minimum limit - Diastole

Selection of diastole alarm minimum limit for channel 2.

### 6 - Maximum limit - Average

Selection of average alarm maximum limit for channel 2.

## 7 - Minimum limit - Average

Selection of average alarm minimum limit for channel 2.

---

## 8 - Previous page

Returns to the previous page of the IP menu.

---

## 9 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.



## Transducer connection and calibration accessories

**ATTENTION:** before monitoring the pressure, the system must be reset.

**CAUTION:** before connecting, make sure the connectors are dry and free of contaminated substances.

Assemble the transducer connections and the disposable kit in the operating position, with the zero-adjustment tap at the patient level, according to the rules or procedures of the hospital.

Expose the transducer to atmospheric pressure by turning the zero adjustment so the OFF points to the patient.

Set the monitor to zero the channel transducer used in the "Configuration menu" of the Monitor invasive pressure.

**CAUTION:** when not using the cable connectors, store them in the holder.

### PRECAUTIONS

Air bubbles in the system can result in significant distortion of the pressure waveform. Inspect the monitoring system in search for bubbles. Tap gently on areas that are not visible to locate any hidden bubbles. Tap slowly on the spot sample to remove all bubbles from the reservoir.

The operator must avoid a conductive connection between the part applied and the metallic parts of the equipment and accessories.

When monitoring in conjunction with a high-frequency surgical equipment, the transducer and cables must be prevented from touching conductive connections to protect the patient from burns.

The transducer/pressure system is resistant against the effects of the discharge of a cardiac defibrillator.

During monitoring, if a cardiac defibrillator is used in the patient, there may be a momentary variation of the pressure measurement. To minimize unwanted effects, keep the transducer as far as possible from the defibrillation cables.

Transducers/disposable systems must not be reused. They must be replaced in accordance with the norms and procedures from the hospital.

### Relation between ST elevation and myocardial infarction

Acute myocardial infarction is a necrosis process of part of the cardiac muscle due to the interruption of blood flow in the coronary arteries. Early diagnosis is a key factor in reducing mortality and possible sequelae for the patient.

One of the most precise forms for this diagnosis is the identification of anomalies on ST elevation, which can be identified in the electrocardiogram (ECG) evaluation.

When a ST elevation bigger than 2 mm is detected, the patient may be suffering the acute phase of a myocardial infarction.

When a ST depression of more than 2 mm is detected, the patient may be suffering from myocardial ischemia (malnutrition of a certain part of the myocardium).

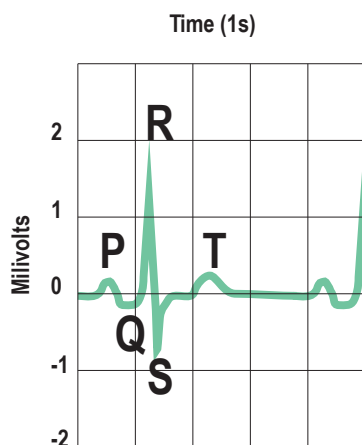
Ranges up to  $\pm 2$  mm are frequent and normal in healthy patients.

## ST elevation characterization

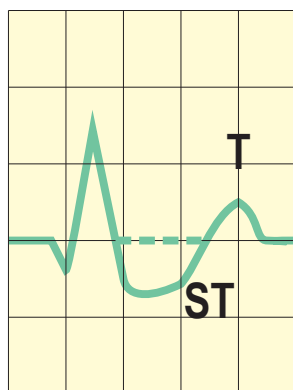
The waves recorded on the ECG are identified by the points ranging from P to T, as shown in figure 1.

The ST segment begins at the point at which the set Q-R-S ends, presenting upward curve in a normal situation.

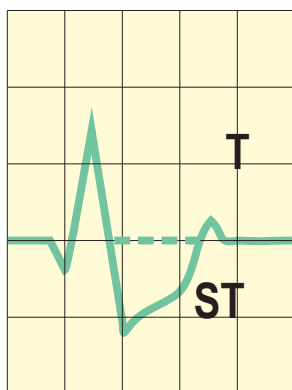
The indication of possible acute myocardial infarction is an evident decrease of the ST segment, represented by the decrease or inversion of the concavity of this region of the curve (other figures).



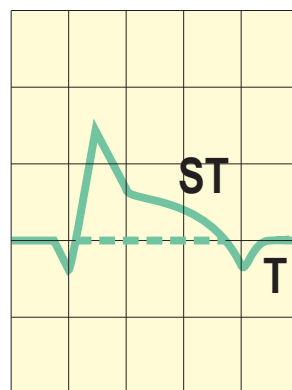
**Normal ST segment  
(Fig. 1)**



**ST depression**



**ST depression**

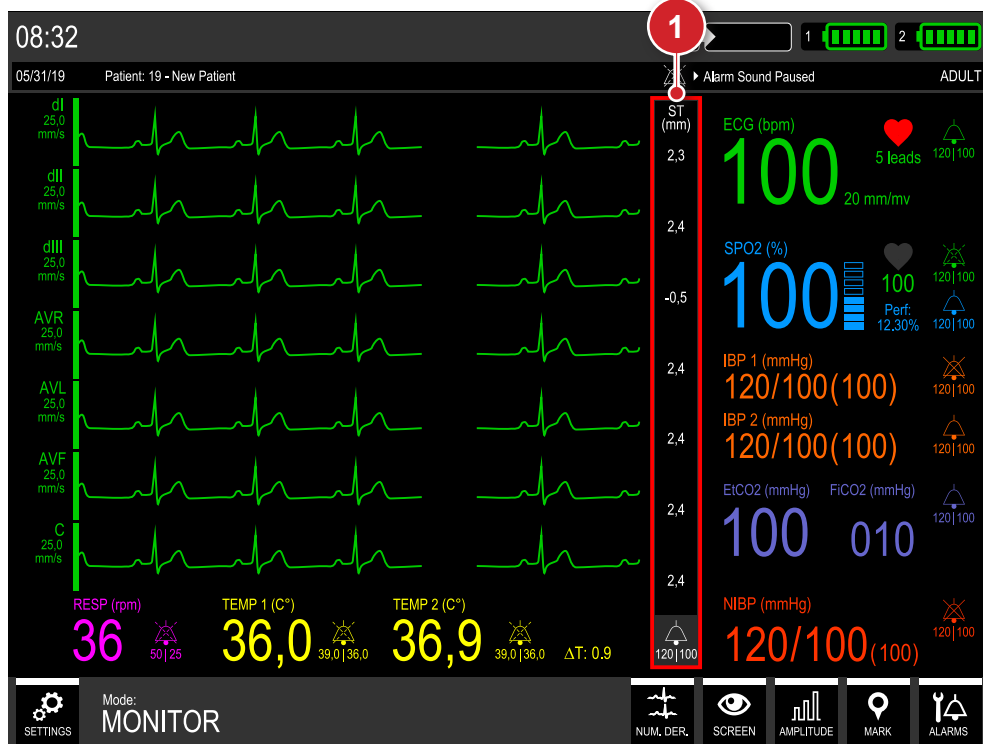


**ST elevation**

## ST levels detection

The DualMax has internal algorithms for measuring ST levels.

It will be measured seven ST segments of DI, DII, DIII, aVR, aVL, aVF and C derivations. These 7 ST gradients will be shown on the screen at the right end of each curve.



1. ST segment values exhibition area.

## ST segment configuration

Using the e-Jog, in the main menu, select the ECG parameter and in its submenu, the "ST Segment" function to turn on or off this analysis function.

See figure on next page.

## Turning ST segment on and off

The ST segment monitoring can be turned on or off through the item “ST” on the ECG configurations screen (see item “ECG configurations - principal”).

The screenshot shows the ECG configurations screen. At the top, there are tabs for ECG, RESP, TEMP, SPO2, and NIBP. The ECG tab is selected. Below the tabs, there are several configuration options. The 'ST [On | Off]' option is highlighted with a red box, and a red circle with the number '1' is next to it. Other options include ECG Response, ECG Cable, Pacer detector, Amplitude, Frequency range, Mains filter, and SDP - Sudden Death Prevention.

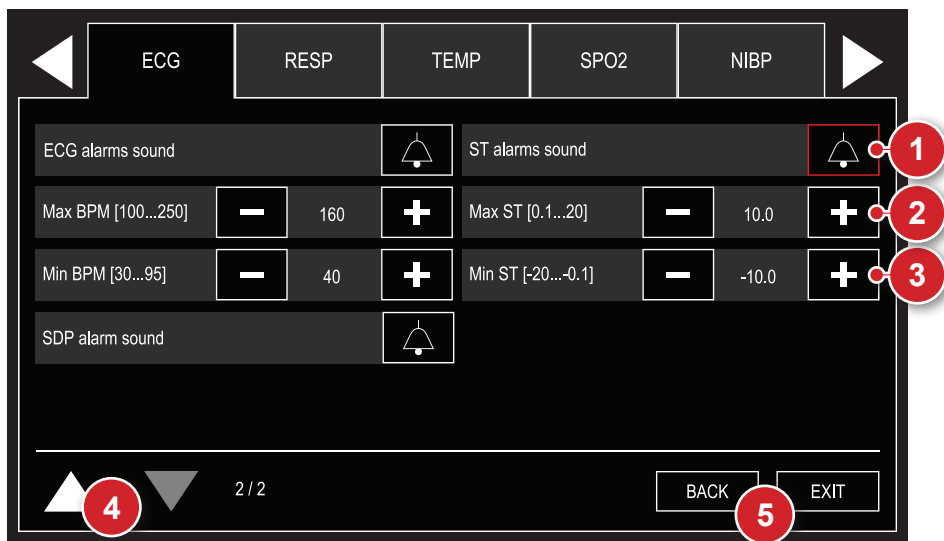
ECG		RESP	TEMP	SPO2	NIBP
ECG Response [Slow   Normal   Fast]	Normal	Mains filter 50/60 hz [On   Off]		On	
ECG Cable [3 leads   5 leads]	5	ST [On   Off]		On	
Pacer detector [On   Off]	Off	SDP - Sudden Death Prevention [On   Off]		Off	
Amplitude [5 ... 40]	- 15 +				
Frequency range [Diag   Monitor]	Monitor				

1 / 2

BACK EXIT

1. Turns the ST segment monitoring on or off.

## ST configurations – Alarms



### 1 - ST alarms

Selection of ST alarm status: active sound and disabled sound.

### 2 - Maximum limit

Selection of ST alarm maximum limit.

### 3 - Minimum limit

Selection of ST alarm minimum limit.

### 4 - Previous page

Returns to the previous page of the ECG menu.

### 5 - Back/Exit

“BACK” to the configuration menu or “EXIT” to monitoring screen.

## Data storage

The DualMax creates an event list for each patient observing the following criteria:

**Automatically** - If DualMax stays turned off for 30 seconds more.

**Manually** - Via the events setup menu.

The equipment stores data from up to 100 patients and 800 generated events. In each event it will be stored the ECG curve 12 seconds before and 12 seconds after the event generation.

When in AED mode, the equipment stores in its memory the last two ECG hours.

---

## Events stored

The DualMax stores the date, time, and ECG curve of the following situations:

- Defibrillation/cardioversion.
- Stimulation - Pacemaker On/Off.
- "Pause audio" key activation.
- Shock failure.
- Internal discharge.
- Manual event marking.
- Indicated shock or asystole (for equipment with SDP).
- Values out of the the alarm limits.
- Change of pads.
- The events continue to be stored, even when SOUND ALARM of a particular parameter is turned off. The shutdown time is not registered.
- In case of total loss of energy, the content of the records do not suffer modification.

## Patient configurations

The screenshot shows a software interface for patient configuration. At the top, there are five tabs: 'FUNC TEST', 'EVENTS', 'PATIENT' (highlighted in red), 'MAINTENANCE', and 'VERSION'. Below the tabs, the interface is divided into sections. On the left, there is a vertical list of options: 'Insert New Patient' (callout 1), 'Patient Number' (callout 2), and 'Age: 000' (callout 4). The 'Patient Number' field shows the value '20'. To the right of these fields, there are 'Edit' buttons (callout 3 for 'Insert New Patient', callout 4 for 'Patient Number', callout 5 for 'Age: 000', and callout 6 for 'Registration number: 0'). The 'Age: 000' field shows the value '000'. Below the 'Age: 000' field, there is a 'Sexo [Male | Female]' field with a 'Fem' button (callout 5). At the bottom, there is a 'Registration number: 0' field with an 'Edit' button (callout 6). At the very bottom, there are 'BACK' and 'EXIT' buttons (callout 7). The interface also includes a navigation bar at the bottom with a left arrow, a right arrow, and a '1 / 1' indicator.

### 1 - Insert new patient

Manual generation of a new patient.

### 2 - Patient number

Value between 1 and 100 automatically generated for each new patient.

### 3 - Name

Allows to change the patient's name through the keyboard displayed on screen. See item "Keyboards" in this chapter.

### 4 - Age

Allows to change the patient's age using the keyboard displayed on screen. See item "Keyboards" in this chapter.

### 5 - Gender

Allows selection of patient's gender.



## 6 - Register number

Allows to edit the patient's register number, using the keyboard displayed on screen.

## 7 - Back/Exit

"BACK" to the configuration menu or "EXIT" for the monitoring screen.

## Mark events

The "Mark events" menu allows the user to manually add pre-set events or configure personalized events. This menu is divided into two screens.

### PRE-SET EVENTS

The screenshot displays the 'PRE-SET EVENTS' menu. At the top, there is a navigation bar with five tabs: 'FUNC TEST', 'EVENTS' (highlighted in red), 'PATIENT', 'MAINTENANCE', and 'VERSION'. Below the tabs is a list of events, each with a plus sign icon to its right. The events are arranged in two columns. At the bottom of the screen, there is a status bar with a left arrow, a right arrow, the text '1 / 2', and two buttons labeled 'BACK' and 'EXIT'.

EVENTS	
Generic	+
Endotraqueal Access	+
Intravenous Access	+
Adrenaline	+
Lidocaine	+
Atropine	+
Morphine	+
Nitroglycerin	+
Aspirin	+
Epinephrine	+

Allows to manually mark the following events:

- Generic.
- Endotracheal access.
- Intravenous access.
- Adrenaline.
- Lidocaine.
- Atropine.
- Morphine.
- Nitroglycerin.
- Aspirin.
- Epinephrine.

## PERSONALIZED EVENTS

Navigation: ◀ FUNC TEST EVENTS PATIENT MAINTENANCE VERSION ▶

Personalized 1	Edit	+	Personalized 6	Edit	+
Personalized 2	Edit	+	Personalized 7	Edit	+
Personalized 3	Edit	+	Personalized 8	Edit	+
Personalized 4	Edit	+	Personalized 9	Edit	+
Personalized 5	Edit	+	Personalized 10	Edit	+

Navigation: ▲ ▼ 2 / 2 BACK EXIT

Allows to mark or edit up to 10 personalized events.

## VIEW EVENTS

Allows to view, print and transfer the generated events.

Navigation: ◀ VIS EVENTS ▶

1 Patient: 20 New Patient - 20/20 + Print Event List 3

2 Transfer patient data Start View curve associated with event Start 4

Date	Hour	Event	Data
31/05/2019	08:34	Out of Range	246 mmHg Systole IBP 2 - Level High
31/05/2019	08:34	Out of Range	0 mmHg Diastole IBP 2 - Level Low
31/05/2019	08:34	Out of Range	37.7 C TEMP 1 - Level Low
31/05/2019	08:34	Out of Range	36.5 C TEMP 2 - Level Low
31/05/2019	08:34	Out of Range	55 mmHg Diastole IBP 1 - Level Low
31/05/2019	08:34	Out of Range	186 mmHg Mean IBP 1 - Level High

Navigation: ▲ ▼ 1 / 1 BACK EXIT 7

## 1 - Patient selected

Allows to select the patient whose events will be displayed.

---

## 2 - Transfer patient data

Transfers the stores events data to a pendrive.


---

## 3 - Print

Prints data regarding the selected event or a list of all events of the patient selected. The printing will show 12 seconds of curve before the event and 12 seconds after the event.

---

## 4 - Visualize curve associated with event

Allows to visualize 8.5 of curve before an event and 8,5 seconds after a generated event. For it to be possible to view the curve, it is necessary that the selected event has the indication of associated curve .

---

## 5 - Events list

Displays the events of the selected patient.

---

## 6 - Roll list

Allows to select an event and roll the list.

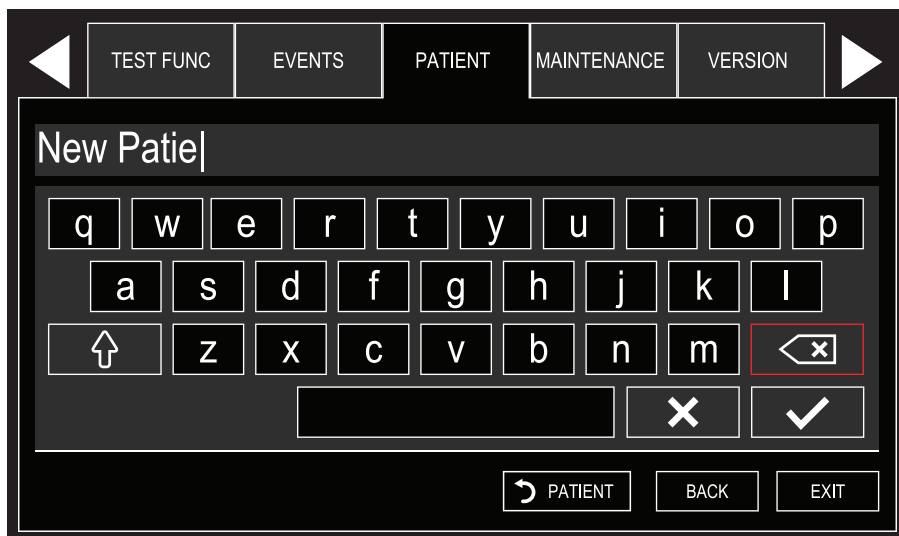
---

## 7 - Back/Exit

“BACK” to the configuration menu or “EXIT” to the monitoring screen.

## Keyboards

Personalizable information from the events menu (such as patient name, age and personalized events) are edited with the help of the keyboards below, according to the selected field:

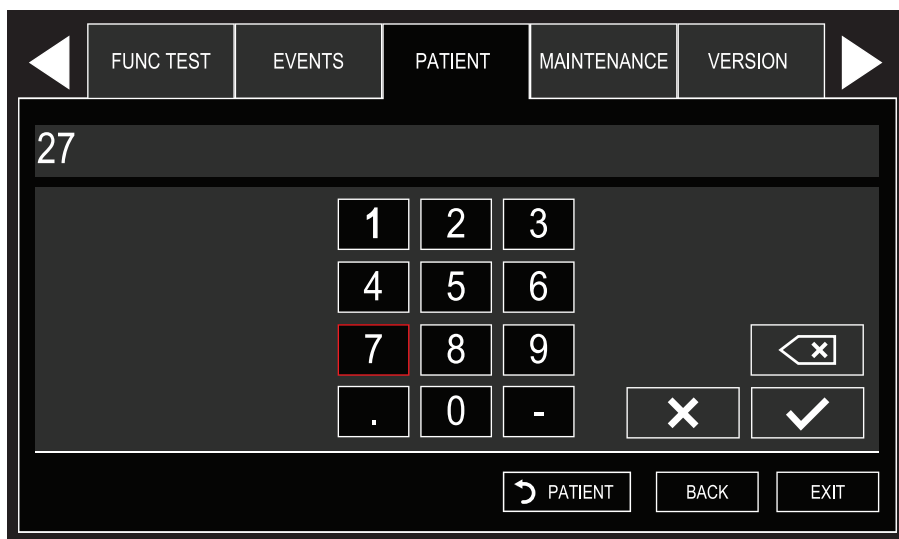


Navigation: ◀ TEST FUNC EVENTS PATIENT MAINTENANCE VERSION ▶

Field: New Patie|

q	w	e	r	t	y	u	i	o	p
a	s	d	f	g	h	j	k	l	
↵	z	x	c	v	b	n	m	⬅ x	
								✕	✓

Buttons: ↶ PATIENT BACK EXIT



Navigation: ◀ FUNC TEST EVENTS PATIENT MAINTENANCE VERSION ▶

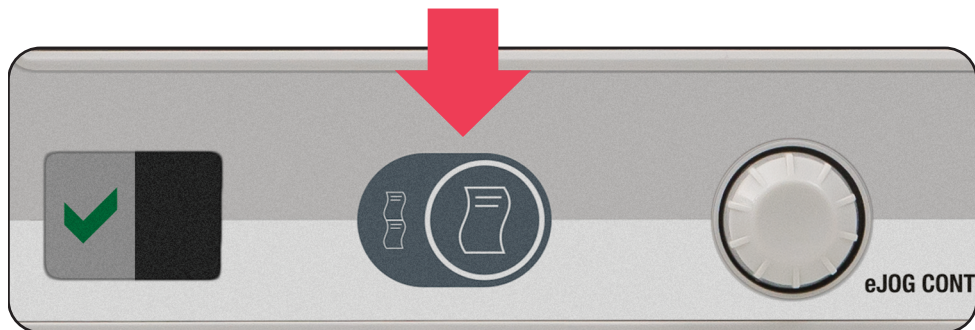
Field: 27

1	2	3		
4	5	6		
7	8	9		
.	0	-	✕	✓

Buttons: ↶ PATIENT BACK EXIT

## General

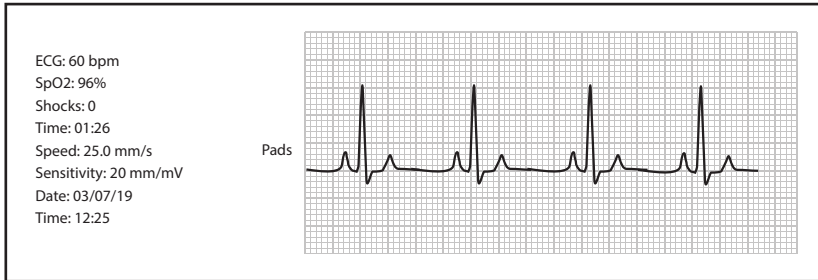
The thermal printer (optional item) allows you to manually or automatically print events, shock or electrocardiogram reports. To activate the printer, press the print button, located in the equipment's front panel or use the e-Jog control to enter the printing menu.



## Instant printing

When the print button is pressed for LESS than three seconds, the DualMax prints a fast report. The fast report prints the same curves being displayed at the moment. The numeric indicators for the following parameters are: date/time, trace speed and number of shocks. In the ECG report, the leads and corresponding amplitude will be printed.





*Instant printing*

## Continuous printing

When the print button is pressed for MORE than three seconds, the DualMax prints a continuous report for an indeterminate period of time or until printing is interrupted. The data in the continuous report is identical to the data in the quick printing. See the instructions below for more information on use.



## Stop printing

To interrupt continuous printing or instant printing, press the print key again.



## Configurations

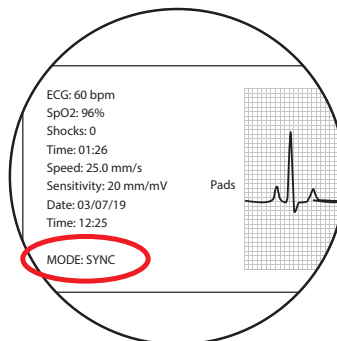


### 1 - Alarm printing

When the “alarm printing” option is enabled (in the printing setup menu), the DualMax prints an instant report whenever an alarm goes off.

### 2 - Shock printing

When the shock printing option is enabled (in the printing setup menu), the DualMax prints an instant report whenever the equipment identifies shock delivery. In this report you can see the equipment's operation mode at the moment of the defibrillation: MANUAL mode, SYNC mode and AED mode. See the pictures below.



### **3 - Paper size**

Shows the selected size of the report to be printed.

Large = length 30 m.

Medium = length 23 m.

Small = length 14 m.

---

### **4 - Electrocardiograph function**

To print a 7-lead electrocardiogram use the print Electro function, in the printing setup menu. When this function is selected, the equipment begins monitoring and printing the leads, starting by the DI lead. At the end of printing, it returns to its normal monitoring mode.

---

### **5 - Number of leads**

Select the number of leads to be printed simultaneously, in the electrocardiograph function. The DI, DII, DIII, AVR, AVL, AVF and C leads will be printed sequentially, individually or in groups, in this same sequence, according to the defined value. The C lead is always printed individually. In case the ECG cable used is a 3-wire one, it is not possible to print more than one lead simultaneously.

---

### **6 - Back/Exit**

“Back” to configuration menu or “EXIT” to go to the monitoring screen.



General

The functional test must be executed daily in order to guarantee that the equipment is in working order and ready to use.

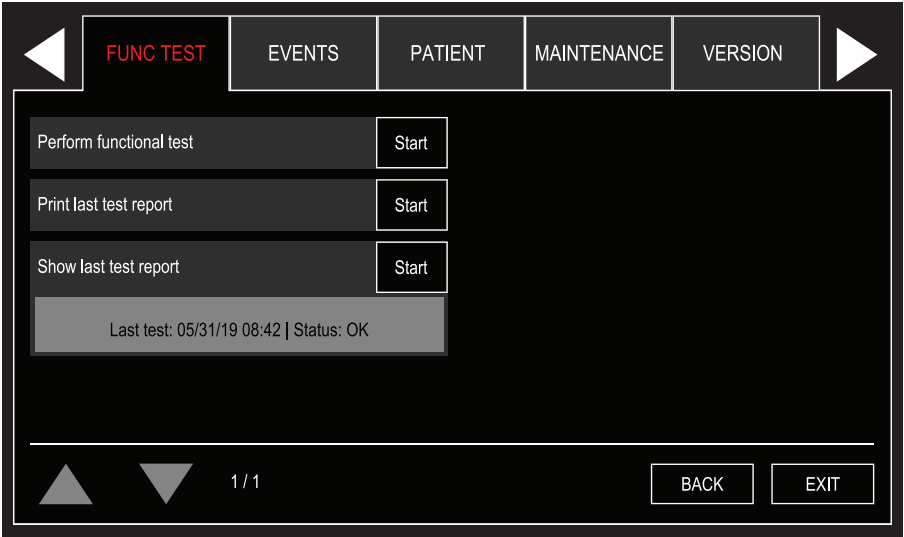
Performing the functional test

To perform the functional test, simply click on the TEST shortcut, or go to the menu and select the "TEST FUNC" option, following the instructions shown on the screen as follows:

Using the button "Perform functional test" it is possible to start the test, which takes place in a new window opened on the screen.

By using the "Print last test report" button it is possible to print the details and status of the last test performed.

Using the "Show last test report" button it is possible to view the details and status of the last test performed.



**ATTENTION:** if DualMax fails the functional test, contact technical support immediately.

**NOTE:** the option of printing the test results will only be available in the DualMax units equipped with printer.

**NOTE:** the DualMax indicates failure in the functional test when there is a failure in one of the 4 steps of the functional test or when the power delivered has an energy exceeding that allowed by standards.

The report is shown using the same pattern of images when the test is in progress, ie, all test steps are shown and next to each of them there is a checkbox showing its status. As well as it is possible to view the date and time data and the final result of the last test performed.

By using the "Print last test report" button it is possible to print the details and status of the last test performed.

The screenshot displays the 'FUNC TEST' screen of the DualMax device. At the top, there are navigation buttons: a left arrow, 'FUNC TEST', 'EVENTS', 'PATIENT', 'MAINTENANCE', 'VERSION', and a right arrow. The main area contains a list of test steps, each with a checkbox indicating its status:

Test Step	Status
Put paddles on base	<input checked="" type="checkbox"/>
Select 100J	<input checked="" type="checkbox"/>
Press CHARGE button	<input checked="" type="checkbox"/>
Press SHOCK button   102J (22A / 47R)	<input checked="" type="checkbox"/>
Test result	<input checked="" type="checkbox"/>

To the right of the steps, a summary box displays: 'Last test: 05/31/19 08:47 | Status: OK'. Below this, there is a 'Print last test report' button and a 'Start' button (highlighted with a red border). At the bottom of the screen, there are three buttons: 'F. TEST' (with a circular arrow icon), 'BACK', and 'EXIT'.

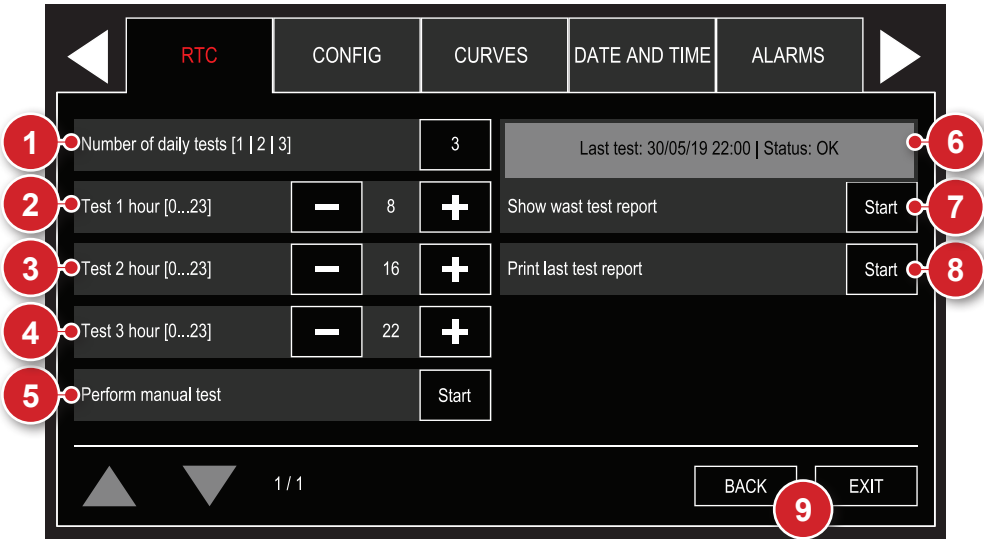
General

This function allows you to program up to three different times for the device to carry out a self-diagnosis of defibrillation, battery level, connected paddles, and verification of the device's connection to the power outlet.

RTC Operation on DualMax

The configurations for the RTC function can be accessed through the menu CONFIGURATION > RTC.

The configurations screen of the RTC function allows you to define the number of automatic daily tests to be performed, configurable in values from 1 to 3 tests. It is also possible to configure the time for each of these daily tests, carry out a manual test, or check the status of the last test carried out.



1 - Number of daily tests

Sets the amount of daily automatic tests. It can be configured with values from 1 to 3 tests per day.

2 - Test 1 time

Schedule of the first daily test. Configured by the user.

### 3 - Test 2 time

Schedule of the second daily test. Configured by the user. This item is disabled when the number of daily tests is 1.

---

### 4 - Test 3 time

Schedule of the third daily test. Configured by the user. This item will be disabled when the number of daily tests is less than 3.

---

### 5 - Perform manual test

Performs a manual test, with no prior configuration required.

---

### 6 - Last test

Displays data from the last test performed or the current step when a test is running.

---

### 7 - Show last test report

Shows the results of the last test performed.

---

### 8 - Print last test report

Prints the results of the last test performed.

---

### 9 - Back/Exit

"BACK" to the configuration menu or "EXIT" to the monitoring screen.

---

## Automatic test

To perform the automatic test, the equipment should be turned off at the programmed time.

At the configured time, the DualMax will automatically turn on and begin the test, composed of the following steps:

- Test of the connection with the ECG board.
- Test of the defibrillator module.
- Check of the battery level.
- Check of the connection with the power outlet.

It is possible to interrupt the test with a click on the e-Jog button.

After completing the test, the equipment will send the collected data to the RTC Control Center. At this time, it is not possible to turn off the device. If the connection with the RTC Control Center cannot be established, the device will cancel sending the data after 10 seconds. After this procedure, the device will save the collected data and turn off automatically.

**NOTE: the test of the defibrillator module will not be carried out if:**

- **The equipment is connected to the computer by USB cable.**
- **The paddles are not on the support or are disconnected from the device (external adult paddles).**
- **The battery has a charge of less than 10% and the equipment is not connected to a power outlet.**

---

## Manual test

Follow the instructions on screen to start the test. Or click "cancel" to cancel the test.

Once started, the manual test goes through the following steps:

- Test of the connection with the ECG board.
- Test of the defibrillator module.
- Check of the battery level.
- Check of the connection with the power outlet.

It is not possible to interrupt the manual test. After completing the test, the equipment will send the collected data to the RTC Control Center. At this time, it is not possible to turn off the device. If the connection with the RTC Control Center cannot be established, the device will cancel sending the data after 10 seconds. After this procedure, the device will save the collected data and return to the mode defined by the rotating switch on the DualMax.

---

## Error BEEPS

When there is an error in the last RTC test, the equipment emits three beeps in sequence, which can be identified by the user from a distance. This beeping sequence will be repeated every three minutes until the failure is solved.

## Introduction

The DualMax 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 DualMax (only for authorized technical personnel).
- Check and update firmware version of the equipment (only for authorized technical personnel).
- Real Time Check: self-diagnosis of defibrillation, battery level, connected pads, and verification of the device's connection to the mains supply.

---

## Requirements

The DualMax can be connected to a computer through the installation of two pieces of software: the SoftDEA application and the RTC application. This software is found on the CD that comes with the device.

To install the SoftDEA application and/or the RTC application, observe the following requirements:

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

For physical connection to the PC:

- An available USB port.

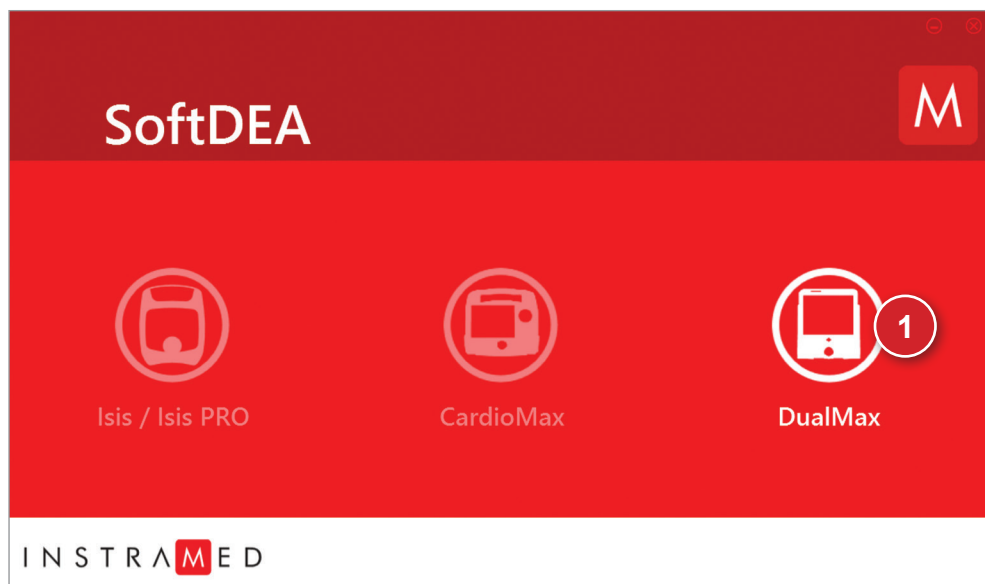
## SoftDEA installation

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

## Connecting the DualMax to a PC

- Connect the equipment only after installing SoftDEA.
- After the installation connect the device through an USB cable.
- The location of the device drivers to be installed will be required. They can be found in this folder: C:\Program Files\Instramed\SoftDEA\DRIVERS.
- Start the SoftDEA application.
- On the language selection screen, choose among Spanish, English or Portuguese. You only have to select a language the first time you start the software.
- Start the list of events and ECG waveform display following the steps in the next section.

## Startup screen



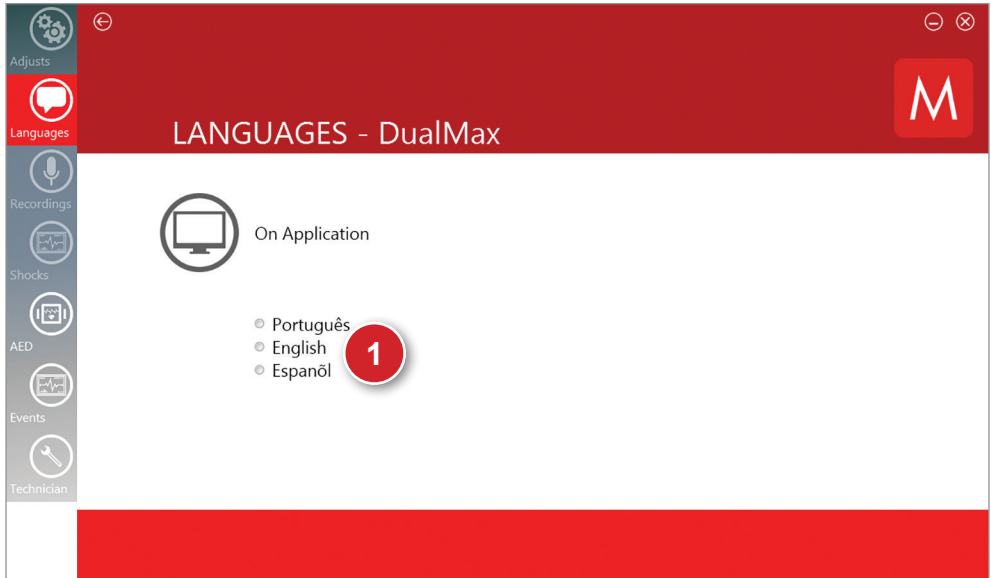
### 1 - DualMax services initialization button

Press this button to initialize the device's configuration screen and display of ECG curves and stored events on the device.



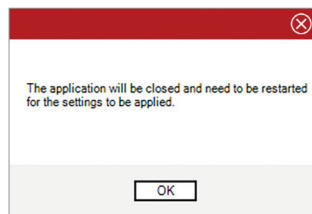


## SoftDEA language selection screen

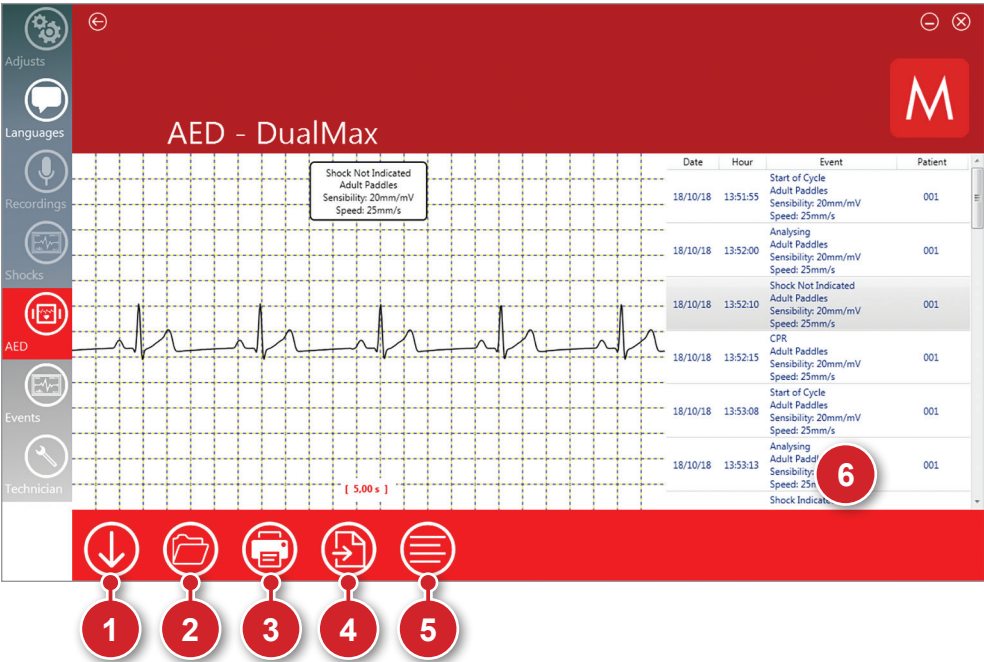


### 1 - Buttons of SoftDEA language selection

Click on the language option chosen. A warning message will appear, confirm clicking “OK”. Wait for the program to be closed and reopen it.



# Graphics generated by AED mode display screen



## 1 - Download

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



## 2 - Open

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



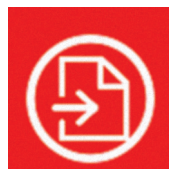
### 3 - Print

Click this button to print the information set regarding the event that is selected in the event list. Use the printer driver dialog box to set the printing options. It is possible to print more than one event, simply click the Ctrl key and click on the events desired in the events list.



### 4 - PDF

Click this button to generate a file showing the set of information that is currently displayed on the screen in pdf format. The user must select the desired directory in which to save the file. It is possible to print more than one event, simply click the Ctrl key and click on the events desired in the events list.



### 5 - Select all

Click this button to select all events from the list, this way it is possible to easily print or generate PDF of all events.



### 6 - Event viewer window

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

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

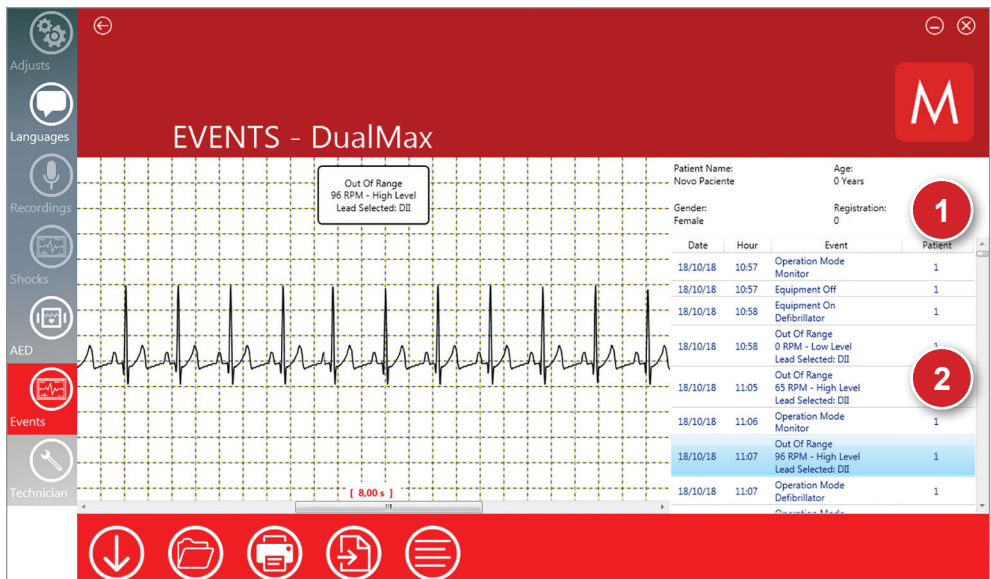
- ANALYZING - Analyzing heart rhythm.
- SHOCK INDICATED - Shock indicated due to the patient's ventricular fibrillation or ventricular tachycardia pattern.
- SHOCK NOT INDICATED - Shock not indicated on account of the electrocardiogram pattern not requiring a shock.
- ASYSTOLE - Asystole detected.
- 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.
- TURNED ON - The equipment was turned on.
- CPR - Equipment indicating the CPR procedure.

## Pads status definitions in the events in AED mode presented:

- PADS DISCONNECTED - The pads were disconnected.
- CHILD PADS - Child pads were connected to the device.
- ADULT PADS - Adult pads were connected to the device.

## Events graphics display screen

On the events screen the open files will be extension “.ev”.



## 1 - Patient data window

Information regarding the analyzed patient.

## 2 - Event view window

After downloading the information contained in the DualMax memory, this area will display the list of events stored by the device, in chronological order. To view an event on the main screen, double-click it.

## RTC software installation

- Insert the program CD in the CD/DVD ROM drive.
- If the installer does not initiate automatically, locate the "RTC" file or "Real Time Check" on the program CD and double click on it.
- Follow the installation instructions that appear on the screen.

**NOTE: check that the "Wireless Reception Unit" is connected to the computer by USB prior to installing the software. After completing the installation, links will be created to run the program on the Windows start menu and on the desktop.**

## RTC software operation

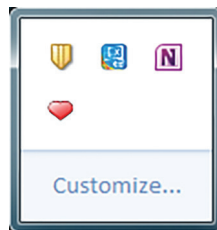
The RTC software runs in the background, with the minimized system awaiting a device to communicate with the "Real Time Check Control Center".

The DualMax can be configured to perform self tests at times specifically configured by the user. The device will send the results of the following tests to the RTC system:

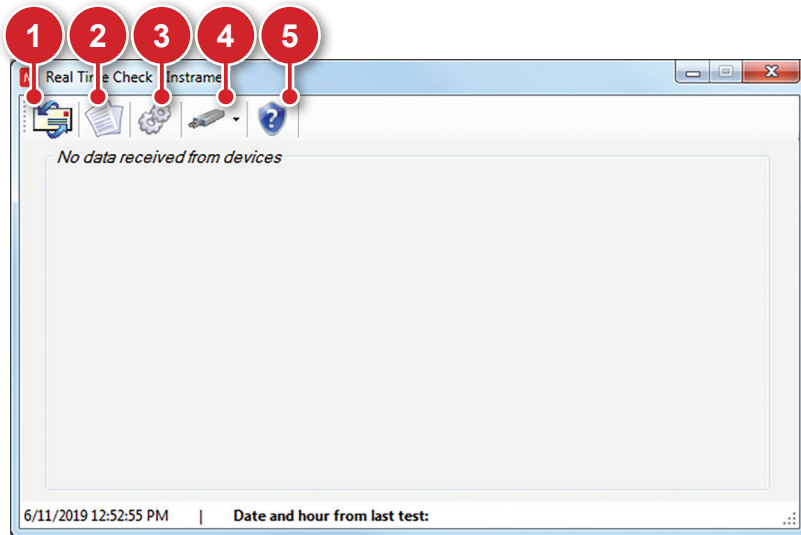
- Test of the connection with the ECG board.
- Test of the defibrillator module.
- Check of the battery level.
- Check of the connection with the power outlet.

Upon receiving the test results, the RTC software will open a screen showing this data. This information will also be stored in a log storage file. Optionally, the program can be set up to send e-mails with this data to determined recipients.

After the program is run for the first time, the software will be configured to automatically run after Windows starts up. The RTC icon is in the shape of a heart and will be shown on the task bar, next to the clock of the operating system, as shown in the figure below:



To see the software's main window, just click on the heart icon. This window will also be shown when receiving data via USB.

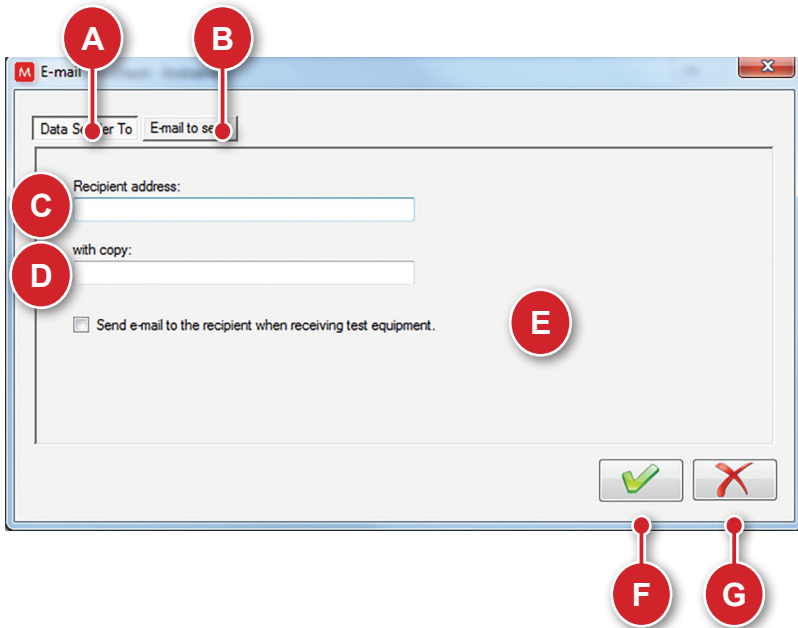


## 1 - E-mail configurations

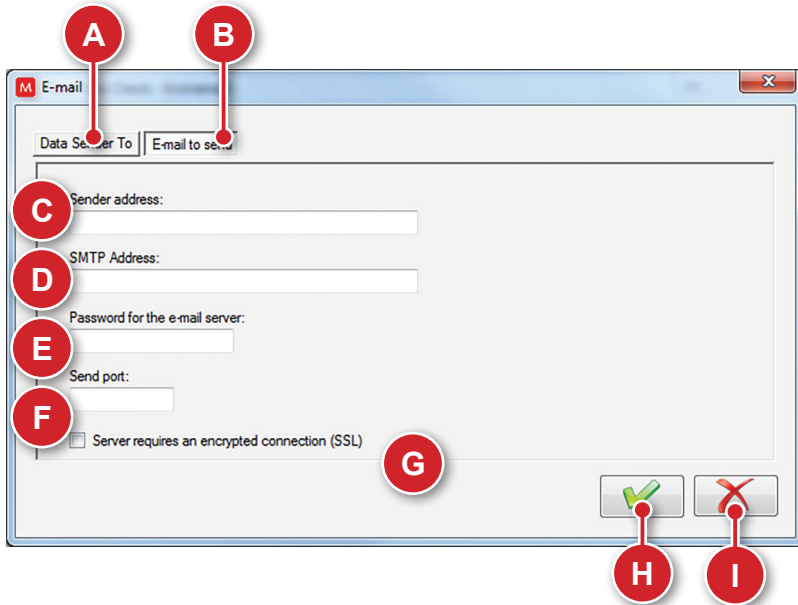
Click on this icon to open the e-mail configurations screen.

On this screen, it is possible to configure the sender, recipient and enable or disable sending e-mails when the software receives equipment tests.

**ATTENTION: when sending e-mails is enabled, the system will try to send 3 times, with intervals of 15 minutes between attempts. If sending is not possible, the e-mail will be discarded by the system after the third attempt.**

**"E-mail to send" tab**

- |   |   |
|---|---|
| <p>A. Selected tab.</p> <p>B. Opens the sender data tab.</p> <p>C. Field for entering the recipient's address.</p> <p>D. Field for entering the carbon copy recipients' addresses.</p> <p>E. Enables or disables sending of the e-mail when new tests are received.</p> | <p>F. Confirms and saves the completed data.</p> <p>G. Cancels changes and closes the e-mail configurations window.</p> |
|---|---|

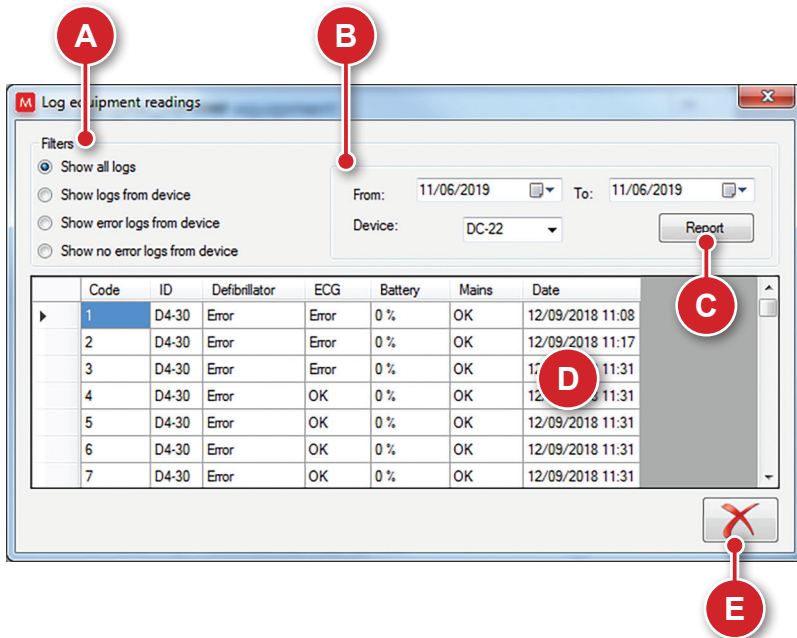
**"Sender Data" tab**

- |   |   |
|---|---|
| <p>A. Opens the "E-mail to send" tab.</p> <p>B. Selected tab.</p> <p>C. Field for entering the sender's address.</p> <p>D. Field for entering the SMTP address.</p> <p>E. Field for entering the e-mail server password.</p> <p>F. Field for entering the sending portal.</p> | <p>G. Select if the server requires an encrypted connection (SSL) or not.</p> <p>H. Confirms and saves the completed data.</p> <p>I. Cancels changes and closes the e-mail configurations window.</p> |
|---|---|



## 2 - Reading log of the equipment

Click on this icon to check the test logs stored in the system.



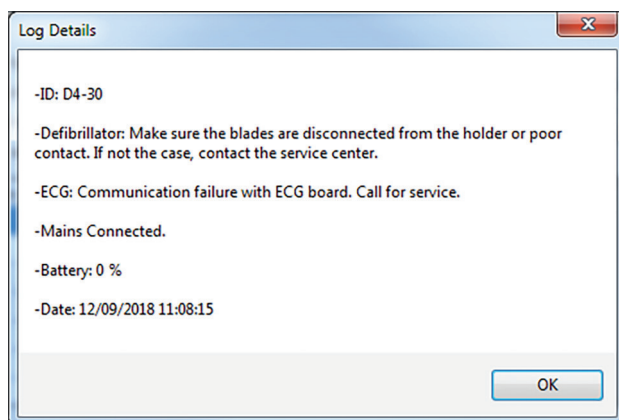
- A. Filter selection area. Allows you to select the criteria for displaying logs.
- B. Data selection and equipment ID area. Allows you to limit the log display to a time period and/or specific equipment.
- C. Opens a new screen with a detailed report of the selected log.

- D. Log display area. This contains information about the tests conducted with the filters applied. A double-click on the content of a log will open a new screen with detailed information.
- E. Closes the equipment reading log window.

**NOTE:** the equipment code is the ID value printed on the equipment.

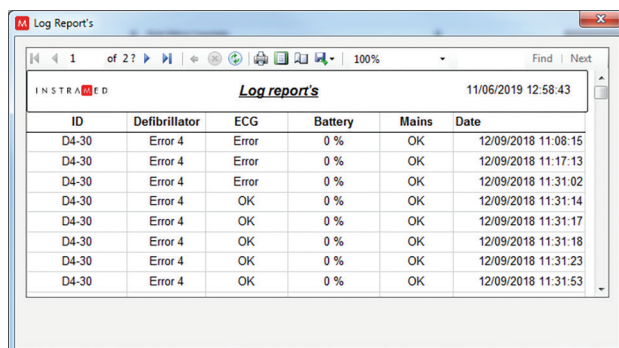
## Log details

Double-clicking on any line of the log will open a second window with more details.



## Report

To open this screen, click on the "Report" button. A complete report of the selected log will be generated. It is possible to save the content in Word or Excel, as well as print it.



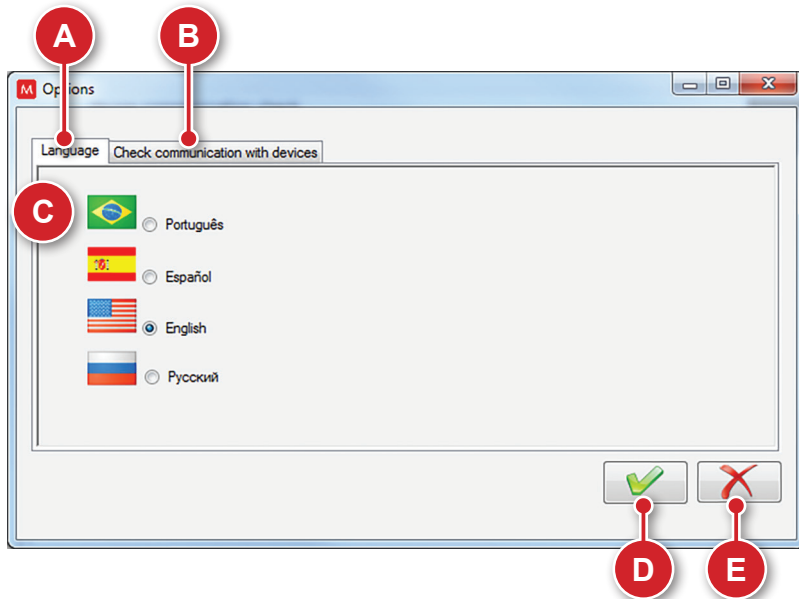
### 3 - Options

Click to open the options screen.

On this screen, it is possible to change the RTC software language and program the device communication check.

**NOTE: the system should be restarted for the changes to take effect.**

#### "Language" tab



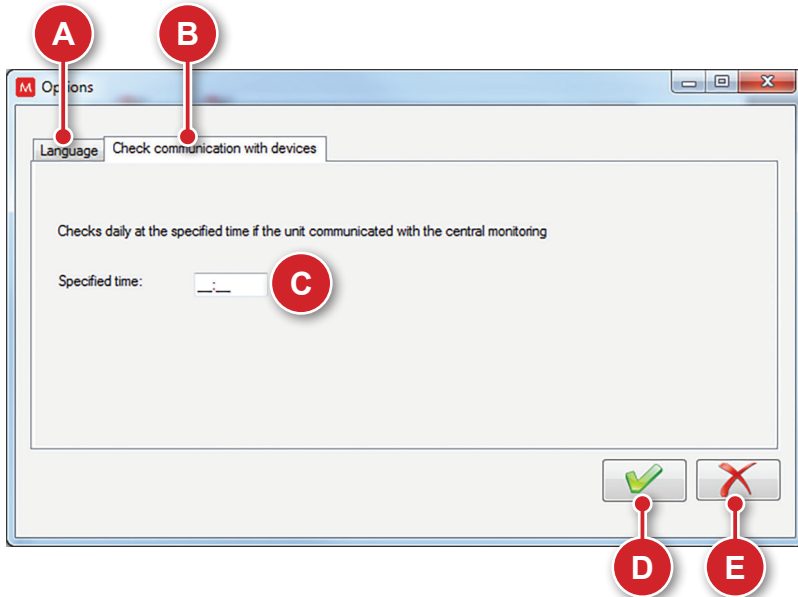
A. Selected tab.

B. Opens the "Check device communication" tab.

C. Selects the software language.

D. Confirms and saves the configurations.

E. Cancels changes and closes the window.

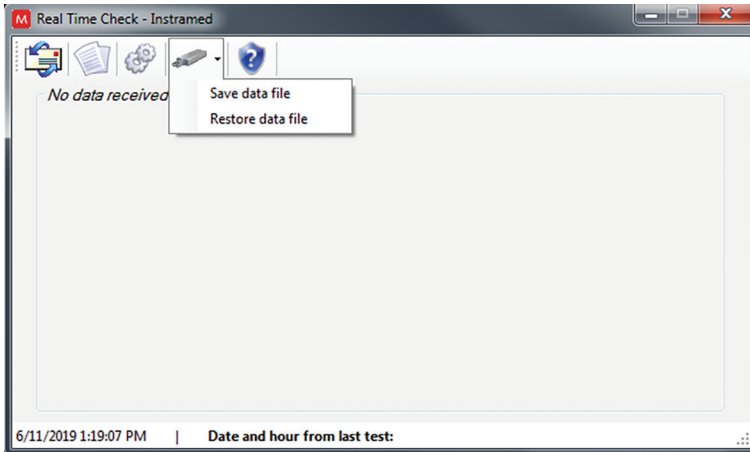
**"Check device communication" tab.**

- |   |   |
|---|---|
| A. Opens the "Language" tab.  | D. Confirms and saves the configurations. |
| B. Selected tab.  | E. Cancels changes and closes the window. |
| C. Field for entering the time to perform the device communication check. |   |

The system will perform a check at the selected time. If a device has not communicated with the control center for more than 24 hours, a notification will be shown on the screen.

## 4 - Backup

Click on this icon to select between the options "Save data files" and "Restore data files."

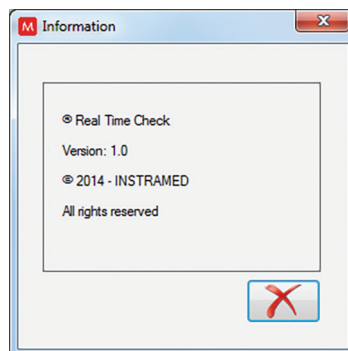


If a data file is lost, it is possible to restore the information from the last saved file. When restoring, all of the data obtained after the last backup file was saved will be lost.

**ATTENTION: it is the full responsibility of the final user to make data file backups.**

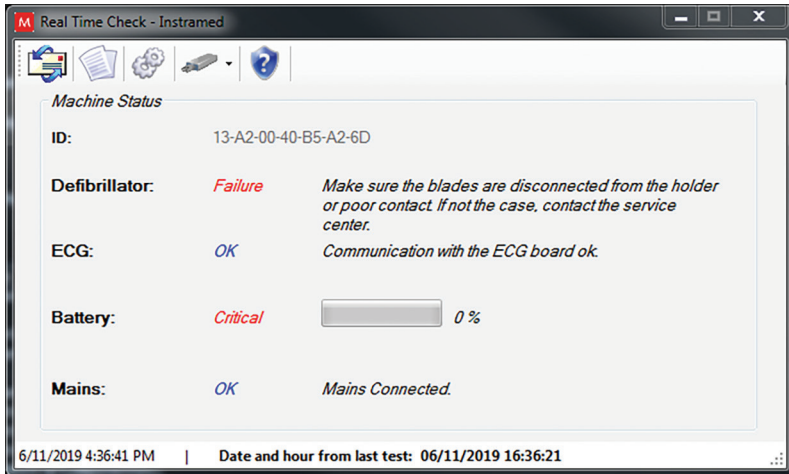
## 5 - Information

Click to see version and software developer information.



## Receiving data

When the DualMax performs the RTC test, the results will be sent to the control center and shown on the screen, along with the MAC ID code of the device.



## Closing the application

To close the RTC software, access the initial program screen and type "S".

## Preventive maintenance

Instramed recommends that the DualMax 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.

Functional tests must be performed at the beginning of every work shift.

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## 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.**

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## Cleaning

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

### 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 cable plugs dry, since a wet plug may cause some kind of failure.

### **For the SPO<sub>2</sub> sensor and cable:**

- The cleaning process is specified in the accompanying instructions.

### **For the NIBP armband:**

- The cleaning process is specified in the accompanying instructions.

### **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 70° and pass lightly on the product.

### **For the DEFIBRILLATION PADDLES set:**

- Dampen a cloth with clean water and mild detergent and wipe any accessories until all dirt is removed.
- Use a second dry cloth to remove excess liquid and/or foam.
- Moisten a third cloth with 70° alcohol and lightly wipe 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 recommendations above will ensure that the device will withstand, without damage or deterioration of safety factors, the necessary cleaning process.**



## Removable battery

Even when disconnected (stand-by), the DualMax executes internal routines checking the status of the equipment. In spite of this procedure entailing a low power consumption, the battery charge may be consumed. Therefore, whenever the device has not been connected to an electric current for more than 20 days, it is advisable to execute a full battery charge. If this procedure is not performed, there is a risk of draining the battery and consequently being unable to use the DualMax in its portable configuration (not connected to the electric current). To recharge the battery, connect the monitor to charge the battery, connect the monitor to an AC power source (110 or 220 V outlet) or a DC power source.

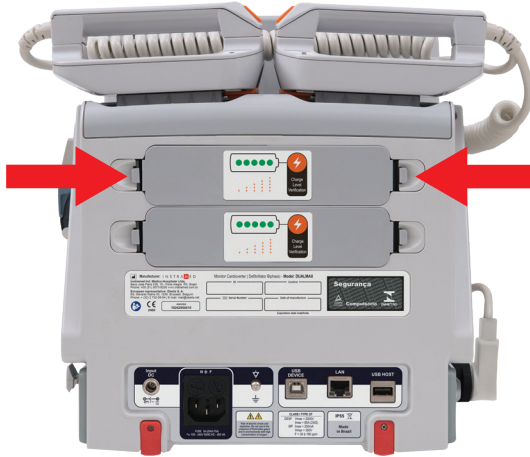
There are no restrictions or limitations for using the DualMax while its battery is being recharged by an AC source or DC External source.

Every battery has a determined lifetime, which is the possible quantity of full charge and discharge cycles, without loss of performance (see battery specifications in chapter 8). If the equipment presents a loss in battery performance, please request a new set to Instramed's technical assistance. To request pieces and services, please contact Instramed at +55 (51) 3073 8200.

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

## Removable battery replacement

The battery will automatically detach itself from the equipment as shown in the picture below.



- 1 - Press the side tabs to unlock the removable battery.
- 2 - Manually remove the battery from the equipment.
- 3 - Correctly position the new battery.
- 4 - Push the new battery until it firmly locks into the cabinet.

## Replacing the thermal paper

1 - Press the button to open the printer door.



2 - Remove the old paper bobbin, monitor well.



3 - Place the new bobbin, The bobbin must be positioned as shown in the picture above.

4 - Pull to unroll about 10 cm of paper.

5 - Align paper with the printer door.

6 - Close the printer door, The printer is ready for use.

## Repairs

If it is necessary to send the DualMax for repairs or to clarify other doubts, contact Instramed at +55 (51) 30738200 or by the e-mails: [assistencia@instramed.com.br](mailto:assistencia@instramed.com.br) and [suporte@instramed.com.br](mailto:suporte@instramed.com.br). Please, be prepared to inform the equipment's serial number.

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

---

## Precautions, restrictions and warnings

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



**The monitor's operation can be affected by the presence of electromagnetic power sources, such as electrosurgical equipment and computer tomography (CT).**

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### 1 - ECG

**1** - To guarantee protection against the effects of a defibrillation, use only the patient cable that accompanies the equipment.

**2** - If the monitor is used simultaneously with an electric scalpel, position the ECG electrodes as far as possible from the RF current route, between the surgical field and the neutral card. Do not use needle type ECG electrode during surgical procedures.

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### 2 - SpO<sub>2</sub>

**1** - The operation of this device may be affected by the presence of electromagnetic energy sources, such as electrosurgical or CT equipment. It also may be damaged by the presence of strong ambient light. If necessary, protect the area of the sensor with a surgical towel.

**2** - Any dyes injected into the blood stream, such as methylene blue, indocaine green, indigo carmine and fluorescein, may affect the SpO<sub>2</sub> reading precision. The presence of dyshemoglobin, such as carboxyhemoglobin (in consequence of carbon monoxide poisoning) or methemoglobin (in consequence of sulfonamide's treatment) may affect the SpO<sub>2</sub> reading precision.

### 3 - Electromagnetic compatibility



#### Warning

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

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

Portable RF communication equipment (including peripherals such as cables and external antennas) should not be used within 30 cm of any part of DualMax, including cables specified by Instramed. Failure to do so may cause performance degradation.

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

- ECG cable 5 leads (code 79005) 2.5 m.
- Set of external defibrillation pads (code 79001) 2.5 m.
- SpO<sub>2</sub> finger sensor cable (code 12556) + SpO<sub>2</sub> finger cable extensor (code 21176) 2.5 m.
- Pacemaker cable (code 79023) 2.5 m.



#### Warning

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

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

When the equipment is used in a surgical procedure simultaneously with an electric scalpel, there is a risk of burnouts if a defect in the connection of the neutral electrode of the high frequency equipment matches a defect in the DualMax's ECG socket. This type of accident will only occur when the defects occur simultaneously, as the DualMax's ECG socket is electrically protected against risks of burnouts, being completely insulated.

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 Electrical immunity - General, of an RF emitting source (radio frequency).
- 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 DualMax is understood as the ANALYSIS of the patient's heart rate, the DEFIBRILLATION, CARDIOVERSION and PACEMAKER applied to the patient, and the monitoring of the PATIENT in electrocardiogram, oximetry, non-invasive pressure, respiration, and invasive pressure, The performance of the DualMax 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.
- The SPO2 curve can be disturbed, besides the possibility of alteration in the measured value.
- Non-invasive pressure measurement may suffer alterations on the measured values.
- The Invasive pressure curve may suffer interferences.


# Electromagnetic immunity - General

Directives and declaration of the manufacturer - Electromagnetic emissions			
The DualMax 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 60601-1-2:2015 (IEC 60601:2014)	Compliance level	Electromagnetic environment Directives
Electrostatic discharge (ESD) IEC 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 IEC61000-4-4	± 2 KV for power supply lines ± 1 KV for input/output lines	± 2 KV for power supply lines ± 1 KV for input/output lines	The quality of the power supply should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 KV differential mode (phase - phase) ± 2 KV common mode (phase - ground)	± 1 KV differential mode (phase - phase) ± 2 KV common mode (phase - ground)	The quality of the power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 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 supply power should be that from a hospital or commercial environment, During power outage, it is recommended that DualMax is recharged by an uninterruptible power supply, Because the equipment does not operate when connected to the charger.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m and 30 A/m	3 A/m and 30 A/m	Power frequency magnetic fields should be at characteristic levels of a typical commercial or hospital environment.
NOTE: $U_T$ is the ac mains voltage prior to application of the test level.			

# Electromagnetic immunity - Equipment with life support functions

## Advisable separation distances between mobile and portable RF communications equipment and the DualMax

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

Immunity test	Test level of EN 60601-1-2:2015 (IEC 60601:2014)	Compliance level	Electromagnetic environment Directive
			<p><b>Portable and mobile RF communications equipment should not be used near any part of the DualMax, including cables, with a separation distance less than the one advised, calculated using the equation applicable to the frequency of the transmitter.</b></p> <p><b>Advisable distance of separation:</b></p>
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz up to 80 MHz outside bands <sup>a</sup> ISM.	3 Vrms 150 KHz up to 80 MHz outside bands <sup>a</sup> ISM.	$d=1.2\sqrt{P}$
	6 Vrms 150 KHz up to 80 MHz outside bands <sup>a</sup> ISM.	6 Vrms 150 KHz up to 80 MHz outside bands <sup>a</sup> ISM.	$d=1.2\sqrt{P}$
Conducted RF IEC 61000-4-3	3 V/m 80 MHz up to 2.5 GHz. 10 V/m 80 MHz up to 2.5 GHz.	3 V/m 80 MHz up to 2.5 GHz. 10 V/m 80 MHz up to 2.5 GHz.	$d=1.2\sqrt{P}$ $d=2.3\sqrt{P}$ 80% AM to 1 KHz. 80% AM to 1 KHz.
			<p>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)<sup>b</sup>.</p> <p>Field strengths established by RF transmitters, as determined by an electromagnetic site survey, <sup>c</sup> should be less than the compliance level in each frequency range<sup>d</sup>.</p> <p>Interference can occur around equipment marked with the following symbol:</p> 

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 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.6 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 DualMax is used exceeds the level of RF compliance used above, the DualMax 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 DualMax.

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



## Electromagnetic immunity - Equipment with life support functions

### Advisable separation distances between mobile and portable RF communications equipment and the DualMax

The DualMax 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 DualMax 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	150 KHz to 80 MHz outside ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d=1.2.\sqrt{P}$	$d=1.2.\sqrt{P}$	$d=1.2.\sqrt{P}$	$d=2.3.\sqrt{P}$
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 to 80MHz 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.

The DualMax was designed to provide **basic safety** with RF equipment by the following table:

Testing specifications for cabinet interface immunity to RF wire communications equipment						
The DualMax was designed to provide basic security with RF equipment by the following table:						
Testing frequency (MHz)	Band <sup>a</sup> (MHz)	Service <sup>a</sup>	Modulation <sup>b</sup>	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b</sup> 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM <sup>c</sup> deviation of ± 5 KHz Sinusoidal 1 KHz	2	0.3	28
710	704-787	Band LTE 13, 17	Pulse modulation <sup>b</sup> 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 <sup>b</sup> 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 <sup>b</sup> 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 <sup>b</sup> 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802,11 a/n	Pulse modulation <sup>b</sup> 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 IEC 61000-4-3.						
<div><div>a - For some services, only the terminal's transmission frequencies are included.</div><div>b - The carrier must be modulated using a 50% service cycle square wave signal.</div><div>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.</div></div>						

Symptom	Probable cause	Probable solution
The DualMax does not turn on.	There is no electricity.	- Check connections:the DualMax/Power Cable/ Plug.
Does not select energy > 50 J.	Adult pads identification .	- Check if is adult pads are connected to the equipment and if adult electrodes are properly connected.
Does not deliver shock.	Impedance measuring.	- Check the graph bar for the patient's impedance indication.
Does not capture ECG via electrodes.	Lead selection.	- Select a lead other than the "pads" lead.
No tracing.	Unstable since last shutdown.	- Restore initial configuration.
Low battery autonomy.	Defective battery.	- Turn off battery.
No QRS audio indication.	BEEP volume.	- Turn on BEEP's volume in the configuration menu.
No alarm sound indications.	Operation mode.	- Alarm indications are only active in the monitor mode.
No SpO <sub>2</sub> curve.	SpO <sub>2</sub> curve turned off.	- Turn on SpO <sub>2</sub> curve in waveform setup.
Pacemaker does not start.	Multifunction/Adhesive pads.	- Check if multifunction pads are connected. - Check if there is a "bad contact" message. - Check gel in multifunction pads.
Does not print.	No paper in the printer.	- Check if there is paper in the printer. - Check if paper is positioned properly.
Printer makes noises and does not print.	Too much paper on roll.	- Change roll's size.

## Included items

Default		
Quantity	Description	Code
1	Mains supply power cable (3 pins)*.	5550
2	Removable battery.	12883
1	CD of Instramed's manuals and softwares.	25277
1	Pads set for adult and child external defibrillation paddles.	13202
1	Quick guide.	13237

When Pacemaker or AED is present		
Quantity	Description	Code
1	<b>Dualmax pacemaker cable.</b> Description: cable to connect adhesive pads in the device.	13204
1	<b>Pair of adult multifunctional adhesive pads*.</b> Description: non reusable adhesive pads for monitoring, pacing, cardioverting and defibrillating.	20637

When 7 derivations ECG is present		
Quantity	Description	Code
1	<b>5-lead shielded ECG cable*.</b> Description: 5 leads ECG cable to monitor up to 7 derivations.	79005

When 12 derivations ECG is present		
Quantity	Description	Code
1	<b>10-lead shielded ECG cable*.</b> Description: 10 leads ECG cable to monitor up to 12 derivations.	80202

When Oximetry (SpO <sub>2</sub> ) of BCI is present		
Quantity	Description	Code
1	<b>BCI oximetry sensor*.</b> Description: SpO <sub>2</sub> finger sensor.	12556
1	<b>Oximetry sensor extensor*.</b> Description: SpO <sub>2</sub> finger sensor extensor.	21176

**When Non-Invasive Blood Pressure (NIBP) is present**

Quantity	Description	Code
1	<b>Adult armband (cuff) *.</b> Description: adult cuff.	25900
1	<b>Armband (cuff) extensor*.</b> Description: adult cuff extensor.	25671

**When Invasive Blood Pressure is present**

Quantity	Description	Code
1	<b>Utah Medical invasive blood pressure accessories kit*, consisting of:</b>	79181
1	<b>Organizer.</b> Description: labels to provide identification of the body access.	22558
1	<b>Clamp.</b> Description: clamp to provide strangulation of sampling line, limiting pressure.	22713
1	<b>Electrical cable.</b> Description: cable connecting the transducer to the device.	25134
1	<b>Sampling line.</b> Description: sampling line for blood pressure system.	39708
1	<b>Transducer.</b> Description: transducer that converts pressure to electrical signal.	80015

**When Capnography (EtCO<sub>2</sub>) is present**

Quantity	Description	Code
1	<b>Oridion capnography accessories kit*.</b> Description: non reusable EtCO <sub>2</sub> sampling line, consisting of:	79032
1	<b>Adult tracheal sampling line.</b> Description: adult tracheal access.	22686
1	<b>Child tracheal sampling line.</b> Description: child tracheal access.	22687
1	<b>Adult nasal sampling line.</b> Description: adult nasal access.	22688

**When PRINTER is present**

Quantity	Description	Code
1	White thermosensitive paper bobbin 58 mm x 15 m x 40 mm*	11858

**Optional items**

<b>Disposable adult ECG electrodes*.</b> Description: package (check quantity availability per package) with adult non reusable ECG electrode.	21669
<b>Y 3043 type oximetry sensor*.</b> Description: to use SpO <sub>2</sub> in pediatrics or in case of a body part in which can not use the finger sensor.	12475
<b>Child cuff*.</b> Description: child size cuff.	22503
<b>Cuff kit with 5 neonatal units.</b> Description: neonate size cuff.	79029
<b>Extra large cuff.</b> Description: extra large size cuff.	24500
<b>USB A-B shielded cable*.</b> Description: USB cable to use for data transmission.	10985
<b>Transport bag.</b> Description: transport bag to use for transport the device with all accessories.	13878
<b>Thermosensitive printer paper*.</b> Description: 58 mm width printer paper.	11858
<b>CPR Maestro.</b> Description: CPR feedback device to provide visual and audio informations about the quality of the CPR in the moment with purpose of increase the CPR's performance.	11066

\* Accessory with separate CE certificate.

**OBS: the items already included may be acquired for replacement as extra items.**

## General specifications

Dimension with pads:	31 cm (W). 24 cm (D). 30 cm (H).
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, IP, EtCO2, printer and accessories.
Power:	AC: 100 to 240 VAC, 50/60 Hz. DC external: 11 to 16 VDC.
Removable rechargeable battery:	Type: Li-Ion, 14.8 VDC 4.4 A/h.  Life (new fully charged battery): 7 hours in monitor mode, without the printer or a minimum of 280 shocks at 360 J or a minimum of 400 shocks at 200 J.  Time to fully charge the battery (when fully depleted): 4 hours.
Maximum consumption:	AC: 400 W. Battery 15 A.
Fuse:	Mains supply 5 A.
Battery storage:	Storing the battery for a long period of time in temperatures higher than 40°C will reduce its capacity and lifetime.
Memory:	Type: SD card. Capacity: 4 Gb. Stored patients: 100 patients. Storage: 24 seconds of ECG when the event is generated. ECG: 2 continuous hours recording of ECG curve when in AED mode.

RTC - Real Time Check:	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.
Protection index:	IP55.
Classification:	Class I.
Electrical isolation:	CF type.
Operating mode:	Continuous operation.
Isolating method from mains power supply:	Flexible cable with a MAINS PLUG.
Equipment lifetime:	10 years (excluding battery and adhesive pads). NOTE: each accessory has its own useful lifespan (specified by the manufacturers by the number of uses).
Adhesive pads lifetime:	2 years.

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## Display

Battery level indication:	Yes.
Diagonal:	10.4"
Size:	Screen 10.4" - 210.43 mm x 157.82 mm.
Resolution:	1024 x 768 pixels (XGA).
Scan speed:	6.25, 12.5, 25 and 50 mm/s (varies according to the parameter presented).
Touch screen:	Allows the user to interface with the product by touching directly on the device's screen.



## 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.
Altitude:	Recommended to use in altitudes lower than 2000 meters.



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

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## Defibrillator

Waveform:	Biphasic truncated exponential. Wave shaped parameters adjusted according to the patient's impedance.
Shock application:	By means of multifunction pads or external adult/child pads.
Scales for adult/external defibrillation:	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 50, 80, 100, 150, 200, 250, 300 and 360 J.  Energy option delivered limited to 200 J. Maximum energy limited to 50 J with child pads.
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.
Energy selection:	Selector switch in front panel.  **Optional: energy selection in the external pads (consult availability).
Charge command:	Button in front panel, buttons in external pads.
Shock command:	Button in front panel, buttons in external pads.

Synchronized command:	Sync key in front panel.
Charge indicators:	Audio indication of equipment being charged. Audio indication of charge completed. LED on external pads and charge level indicated on display.
Maximum charging time:	200 J: mains and battery < 4 s. 360 J: mains and battery < 6 s.
Pads (options):	Adult and child external (included). Multifunctional for pacemaker, monitoring and defibrillation (optional). Multifunction extension (optional).  NOTE: the adhesive pads provided by Instramed have a biocompatibility certificate in accordance with ISO 10993.
External pads size:	Adult = 10.3 cm x 8.5 cm (contact area = 81.9 cm <sup>2</sup> ). Children = 4.5 cm x 4 cm (contact area = 18 cm <sup>2</sup> ).
Pads cable length:	2 meters.
Cardioversion:	< 60 ms.
Maximum output voltage:	2000 V.
Maximum output electric current:	70 A (25 Ω).

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## **AED mode (optional)**

Functional characteristics:	Voice commands, visual indications, CPR instructions, USB 2.0 for PC connection, multi-languages, SDP (Sudden Death Prevention) technology.
USB:	USB 2.0 for tranfering electrocardiogram stored in AED mode to a compatible PC.
SoftDEA:	Software for viewing data tranferred to PC.

Waveform:	Truncated exponential biphasic pulse. Waveform parameters adjusted according to the patient's impedance.
Shock delivery:	By means of multifunctional pads (adhesive) or defibrillation pads.
Defibrillation scales:	Adult: 150 and 200 J. Child: 50 J.
Adult/children's selection:	Automatic due to the size of the pads.
Charge command:	Automatic after identifying an arrhythmia.
Shock command:	Frontal panel button, "shock".
Maximum charge time (with 100% of the minimum specified voltage):	200 J: < 6 s. 150 J: < 4 s. 50 J: < 2 s.
Maximum time from rhythm analysis beginning to discharge readiness:	20 s.
Maximum time from beginning of defibrillator operation to discharge readiness in maximum energy:	30 s.
<i>The rhythm detector and recognizer does not continue analyzing ECG after a shockable rhythm is detected.</i>	
Size of adhesive pads:	Adult = area: 82 cm <sup>2</sup> . Child = area: 30 cm <sup>2</sup> .

## 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.
- Creighton University.

### Types of Arrhythmia analyzed

#### Nonshockable:

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

#### Shockable:

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

Rhythm classes	Specifications
Shock - VF	The DualMax meets IEC 60601-2-4 requirements for sensitivity > 90%.
Shock - VT	The DualMax meets IEC 60601-2-4 requirements for sensitivity > 75%.
Nonshockable rhythms.	The DualMax meets IEC 60601-2-4 requirements for specificity > 95%.

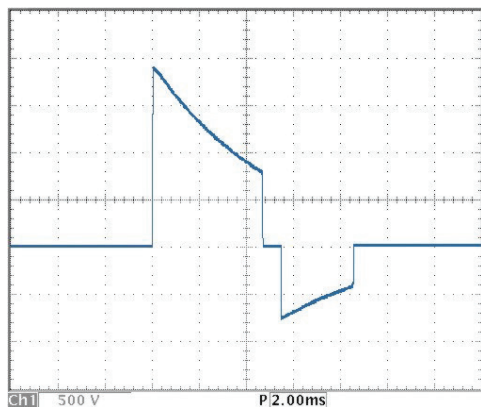
Precision of applied energy:

Energy selected	Impedance							Accuracy
	25	50	75	100	125	150	175	
1	0.9	1.0	1.1	1.1	1.0	0.9	0.8	±1J
2	1.8	1.9	2.0	2.0	2.0	2.0	1.9	±1J
3	2.8	3.0	3.0	3.0	3.1	3.2	3.2	±2J
4	3.6	3.9	3.9	4.0	4.0	3.9	3.9	±2J
5	4.8	5.1	5.1	5.0	5.0	5.0	4.9	±3J
6	5.5	5.8	5.9	6.0	6.0	6.0	6.0	±3J
7	6.5	6.9	7.2	7.2	7.1	7.0	7.0	±3J
8	7.2	7.9	8.1	8.2	8.3	8.1	7.7	±3J
9	7.8	8.6	8.9	9.0	9.0	9.0	8.8	±3J
10	8.8	9.8	10.2	10.4	10.3	10.2	9.8	±3J
20	19.0	20.5	21.0	21.0	20.5	19.5	19.0	±15%
30	27.5	30.0	31.0	31.5	31.0	29.5	27.5	±15%
50	49.0	52.0	53.0	52.5	51.5	48.0	45.5	±15%
80	77.5	81.5	82.5	83.0	80.5	76.5	74.5	±15%
100	96.0	101.0	102.5	103.5	101.0	96.5	92.0	±15%
150	143.0	151.5	155.0	153.0	148.0	141.0	137.0	±15%
200	191.5	201.5	205.5	206.0	203.5	192.0	177.0	±15%
250	240.0	250.5	256.5	256.0	254.0	241.5	224.0	±15%
300	284.0	302.0	305.5	306.0	305.0	290.0	270.0	±15%
360	344.0	363.0	370.5	370.0	363.0	345.0	322.0	±15%

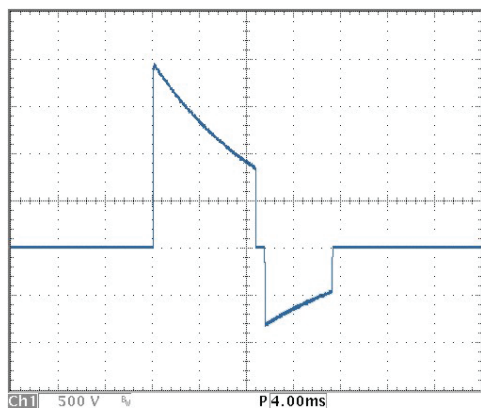
Patient's impedance response table:

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

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

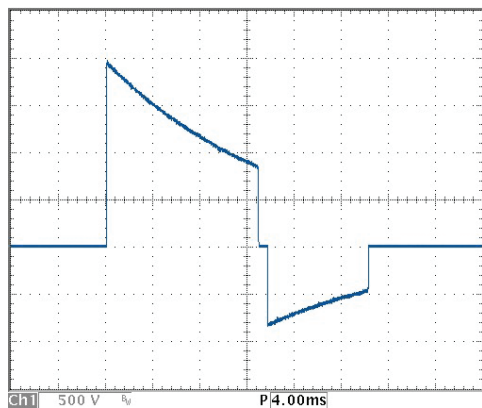


360 J of energy at 25 R impedance.

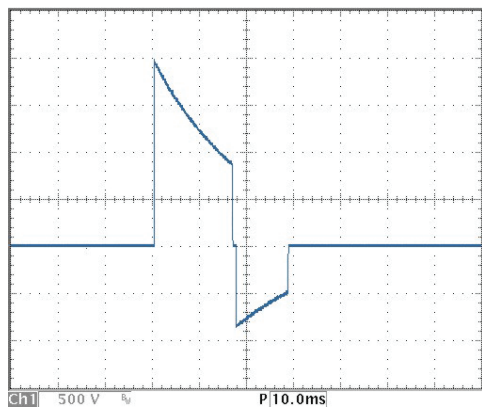


360 J of energy at 50 R impedance.

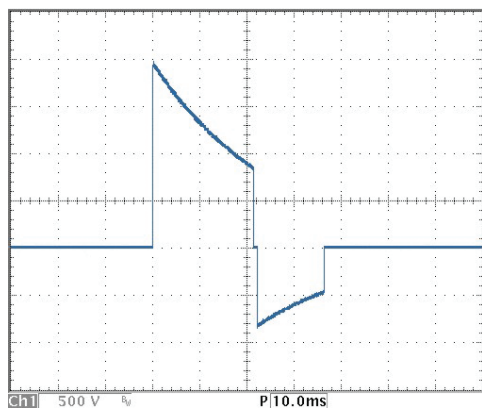
360 J of energy at 75 R impedance.



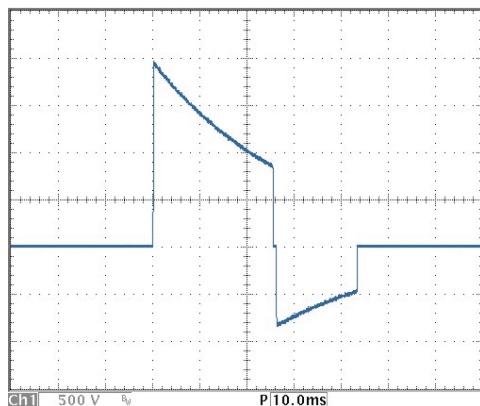
360 J of energy at 100 R impedance.



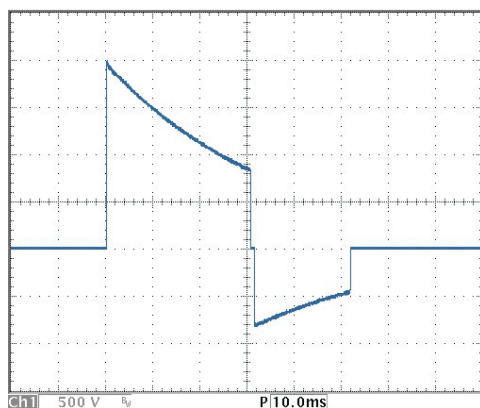
360 J of energy at 125 R impedance.



360 J of energy at 150 R impedance.



360 J of energy at 175 R impedance.



## External pacemaker (optional)

Waveform:	Single-phase rectangular pulse.
Modes:	Demand or fixed.
Amplitude:	Between 5 mA to 200 mA (resolution of 5 mA), precision 10%.
Pulse width:	20 ms ( $\pm 1$ ms).



Frequency:	Between 30 ppm to 180 ppm (increments of 5 ppm), precision $\pm 2\%$ .
Refractory period:	340 ms (between 30 to 80 ppm). 240 ms (between 90 to 180 ppm).
Maximum output voltage:	350 V.

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## ECG

Input:	<p>ECG patient cable and the corresponding derivations:</p> <ul style="list-style-type: none"><li>- 03 leads (optional): DI, DII and DIII.</li><li>- 05 leads: DI, DII, DIII, aVL, aVR, aVF and C.</li><li>- 10 leads (optional): DI, DII, DIII, aVL, aVR, aVF, C1, C2, C3, C4, C5, C6.</li></ul> <p>External defibrillation pads. Multifunctional adhesive pads.</p> <p>Supports up to 12 simultaneous derivations when equipped with the ECG optional of 12 derivations.</p>
ECG electrodes (adult or child):	<p>COMPOSITION: adhesive conductor with hydrogel and silver sensor (Ag/AgCl), latex free.</p> <p>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.</p> <p>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.</p>
ECG gel:	<p>It is recommended the use of a gel suitable for medical procedure, indicated for use in electrocardiography, defibrillators and similar. Used as a contact medium for the transmission of electrical impulses by means of an electroconductor. Biocompatible. After each use, clean the accessories according to cleaning recommendations.</p>

Electrode error:	NO ELECTRODES and a trace line will appear on the display if there is a disconnected cable or electrode.
Low ECG amplitude or saturated ECG signal:	The "Searching for ECG Signal" message will appear on the screen or printer (electrocardiograph mode) when the ECG 10mm/mV amplitude is less than 2.4 mm peak-to peak (or sensitivity proportional).
Multifunction pads error:	If an adhesive pad is disconnected, a trace line will appear on the display.
Range:	15 to 350 BPM.
Precision:	± 1 BPM of 15 to 350 BPM.
Rejection in common mode:	Higher than 90 dB, measurement in compliance with the AAMI standards for heart monitors (EC 13).
Sensitivity:	5, 10, 15, 20, 30 and 40 mm/mV.
Scan speed:	12.5, 25 or 50 mm/s.
Filter:	35 Hz or 60 Hz.
ECG response frequency:	Diagnostic mode (0.05 - 100 Hz). Monitor mode (1 - 40 Hz).
Patient isolation's (defibrillation proof):	ECG: type CF. SpO <sub>2</sub> : type CF.
Physiological alarm:	Alarm not locked. Minimum level (30-100). Maximum level (100-250). Visual indication. Sound indication.
Technical alarm:	Alarm not locked. Visual indication. Sound indication.

Time to re-establish the ECG baseline after defibrillation:  $\leq 3$  seconds.

Loose electrode: Identified and shown with low level alarm.

ECG amplifiers impedance input: 4.7 MOhms (Mega Ohms).

ST segment analysis: Performs the ST elevation measurement.

Pacemaker rejection stimulus: Pacemaker Stimuli with width between 0.1 ms and 2 ms, and amplitude between  $\pm 2$  mV e  $\pm 700$  mV, are rejected in the heart-beat counting. Regarding the overshoot, it meets the method A of the AAMI EC13: 2002 standard. In the range of 15 BPM the 350 BPM the pacemaker pulses are rejected.

Maximum amplitude of the T wave: It meets the minimum recommended value of 1.2 mV for the T wave amplitude rejection.

Accuracy of cardiac frequency in irregular rhythms: It complies with the AAMI standard for:  
Ventricular bigeminy (FC = 40 BPM)  
Slow alternating ventricular bigeminy (FC = 30 BPM).  
Fast alternating ventricular bigeminy (FC = 120 BPM).  
Bidirectional systoles (FC = 45 BPM).

Input dynamic range and offset differential voltage: The equipment complies with 50.102.2 standard IEC 60601-2-27.

50.102.15 standard of IEC 60601-2-27, heart rate range, accuracy and QRS detection range: To maintain accuracy at low heart rate and high heart rate, the equipment must be in diagnostic mode.

Heart rate response time: 80 to 120 BPM: maximum of 7 seconds.  
80 to 40 BPM: maximum of 9 seconds.

Tachycardia alarm time:	206 BPM (1 mV):	5 seconds.
	206 BPM (0.5 mV):	5 seconds.
	206 BPM (2 mV):	5 seconds.
	195 BPM (2 mV):	5 seconds.
	195 BPM (1 mV):	5 seconds.
	195 BPM (4 mV):	5 seconds.

## **NIBP - Non-Invasive Arterial Pressure (optional)**

Technique:	Oscillometric.
Armband:	Use only armband that has connector according to norm ISO 594-1.
Automatic mode:	1, 2, 3, 4, 5, 10, 15, 30, 60 e 90 minutes.
Manual mode:	One measurement.
Adult range:	Systolic: 40 to 260 mmHg. Mean: 26 to 220 mmHg. Diastolic: 20 to 200 mmHg.
Pediatric range:	Systolic: 40 - 160 mmHg. Mean: 26 - 133 mmHg. Diastolic: 20 - 120 mmHg.
Neonatal range:	Systolic: 40 to 130 mmHg. Mean: 26 to 110 mmHg. Diastolic: 20 to 100 mmHg.
Overpressure limit per software:	Adult: 290 mmHg max. Neonatal: 145 mmHg max.
Overpressure protection by hardware:	Adult: 300 ± mmHg. Neonatal: 150 ± mmHg.
Resolution:	1 mmHg.

## SpO<sub>2</sub> BCI (optional)

SpO <sub>2</sub> range:	0 to 100%.
Pulse range:	30 to 250 BPM.
SpO <sub>2</sub> 's precision:	± 2% (70 to 100%). ± 3% (50 to 69%).
Pulse precision:	± 2 BPM.
Scan speed:	12.5, 25 and 50 mm/s.
Physiological alarm:	Alarm not locked. Minimum level (40-95). Maximum level (45-100). Visual indication. Sound indication.
Technical alarm:	Alarm not locked. Visual indication. Sound indication.

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## Respiration

Technique:	Transthoracic impedance.
Range:	3 to 150 breaths per minute.
Precision:	± 3 breaths per minute.
Sensitivity:	1, 2, 3, 4, 5 and 6.
Electrodes:	RA-LA.
Scan speed:	6.25, 12.5 and 25 mm/s.

## Capnography (optional)

Weight:	160 gr.
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).
Calibration:	2 points.
Start:	10 seconds to start the CO <sub>2</sub> curve. Less than a minute for full functioning.
Consumption:	1.5 W.
Compensation:	BTPS, N <sub>2</sub> O, O <sub>2</sub> .

## Printer (opcional)

Type:	Thermal.
Weight:	0.2 Kg.
Speed:	12.5, 25 or 50 mm/s with precision of $\pm 5\%$ .
Paper size:	White thermosensitive paper 58 mm x 15 m x 40 mm of external diameter.

## CPR Maestro (optional)

Accessory for cardiac massage feedback, it presents visual and audible messages guiding the rescuer in relation to the speed and depth of the massage, providing a cardiac massage with greater efficiency.

CPR Maestro precision:      Depth:  $\pm 2\%$ .  
Frequency:  $\pm 16\%$ .

Minimum number of uses:      100 uses.

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## Temperature

Technique:      Thermistor (serie YSI 400).

Range:      0 to 50°C (32 to 122°F).

Precision:       $\pm 0.1^\circ\text{C}$ .

Temperature sensor:      It must be used reusable temperature sensor (adult or child), type YSI 400 (25°C @ 2.252 K Ohms).

## Invasive pressure (optional)

Consumption:      350 mW.

Weight:      20 g.

Filter:      50 and 60 Hz.

Measures interval:      - 99 mmHg to 310 mmHg.

Clearing interval:       $\pm 70$  mmHg.

Precision:       $\pm 1\%$ ,  $\pm 1$  digit, whatever is bigger.

Transducer:      5  $\mu\text{V/V/mmHg}$ , disposable or reusable.

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

During the warranty period, Instramed Indústria Médico Hospitalar Ltda. or its representative will repair or replace defective parts, at no expense to the equipment's owner.

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

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

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

**EQUIPMENT :** \_\_\_\_\_

**SERIAL NUMBER:** \_\_\_\_\_

**PURCHASE DATE:** \_\_\_\_\_

**FISCAL RECEIPT NUMBER:** \_\_\_\_\_



# DUALMAX

Cardioverter/Biphasic Defibrillator Monitor



# INSTRAMED

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