User manual

DUALMAX

Cardioverter/Biphasic Defibrillator Monitor

INSTRAMED

Manufacturer

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ATTENTION: Instramed assumes no responsibility for any damage caused to individuals or property brought by failure to use this product in accordance with the information, recommendations and warnings presented in the user manual, alterations made in the device, attempts of repair not provided by authorized technical assistance centers, operation by unqualified personnel, use of defective device or use of accessories and parts not supplied by the manufacturer.

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

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Manual Dualmax R3.2 English 2025-05-21

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.

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).

Storage

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

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 batteries can be replaced following the procedures described on the chapter “Care and maintenance”.

Batteries replacement are 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.

Package contents

Included items

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

Optional items

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

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** or directly contact Instramed by telephone at:
+55 (51) 3073 8200.

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

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Introduction

1

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_2 / Monitor mode measures the oxygen saturation of blood by a Non-Invasive method.

The $EtCO_2$/Monitor mode presents the partial pressure of exhaled CO_2 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_2).
- Pressure monitoring (Non-Invasive method - NIBP).
- Invasive pressure monitoring (IP).
- Monitorng of expired carbon dioxide at the end of expiration ($EtCO_2$) and inspired carbon dioxide at the end of inspiration ($FiCO_2$)
- Charge Auto-Sequencing mode (CAS).
- Real Time Check (RTC).
- Complex freeze (COMPLEX).
- Analysis of arrhythmias (ARRHYTHMIAS).
- Printer.
- 2 removable and rechargeable batteries.

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.

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.

Safety information

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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.

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_2, NIBP and $EtCO_2$, 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 radiofrequency, 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 is 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.

If any monitor module has a permanent failure, the message in the damaged parameter will be "COMMUNICATION ERROR"

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 (non-compliance with the ISO 10993 standard). 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 affect 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 $EtCO_2$ monitoring. Some patients have been with nausea or headaches due to the cannula smell or discomfort with the cannula positioning. In these 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 connection.
	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.

ATTENTION: this product and its accessories that come into contact with the patient do not contain LATEX.

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 60601-1-8 - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standards: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

- NBR IEC 60601-1-9 - Electromedical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for design and compliance.
- NBR IEC 60601-2-4 - 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 60601-2-34 - Medical Electrical Equipment - Part 2-34: Particular Requirements For The Basic Safety And Essential Performance Of Invasive Blood Pressure Monitoring Equipment.
- 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.
- NBR ISO 80601-2-55 - Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.
- NBR ISO 80601-2-56 - Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- NBR ISO 80601-2-61 - Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter 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.

All instramed equipments that has AED mode are manufacture with the 2020 American Heart Association (AHA) Guidelines.

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.
- Do not silence the monitor's audible alarm if patient safety could be compromised.
- Always respond immediately to any system alarm because the patient may not be monitored during certain alarm conditions.
- Before each use, verify if the alarm limits are appropriate for the patient that is being monitored.

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, equipment 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** or by the e-mail **comex@instramed.com.b**r.

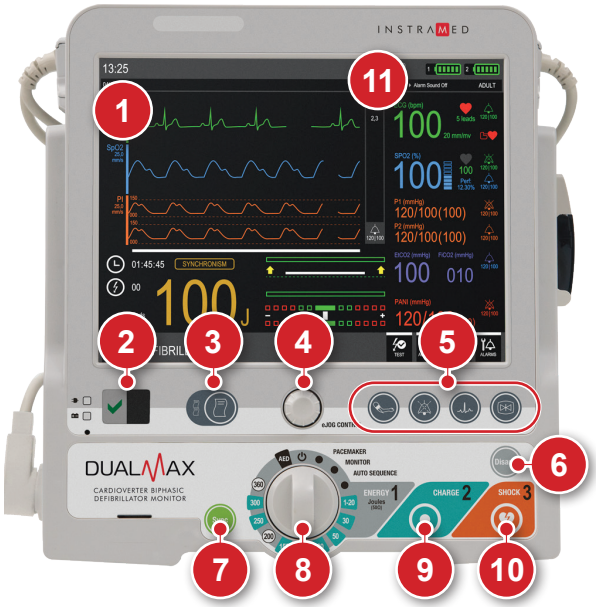
Avoid contamination of the environment, humans, or other equipment by making sure to properly decontaminate the equipment before disposing of it.

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_2, 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_2, NIBP, $EtCO_2$ 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.

OP (*) 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..

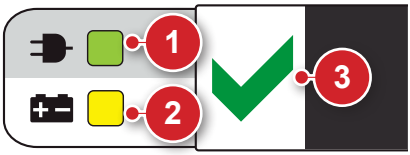
Freeze: freezes the graphical signals on the screen for closer examination

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.configuração do equipamento, esta tecla não tem função.*

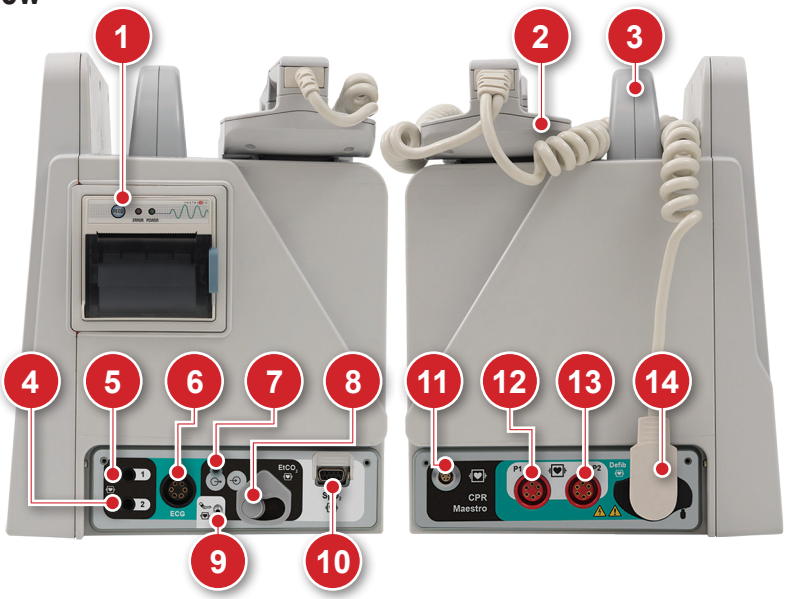
Power and battery charging indications



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

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

2 - Defibrillation 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

OP Temperature connector YSI 400 standard (channel 1).

5 - Temperature connector

OP 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 OP - 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

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

8 - Capnography connector

OP Connector for the capnography sampling line.

9 - NIBP connector

OP Connector for direct use with the armband.

10 - SpO_2 connector

OP BCI standard oximetry connector. Adult and child oximetry sensors.

11 - CPR Maestro connector

OP CPR help device connector.

12 - P1 connector

Invasive pressure connector (channel 1)

13 - P2 connector

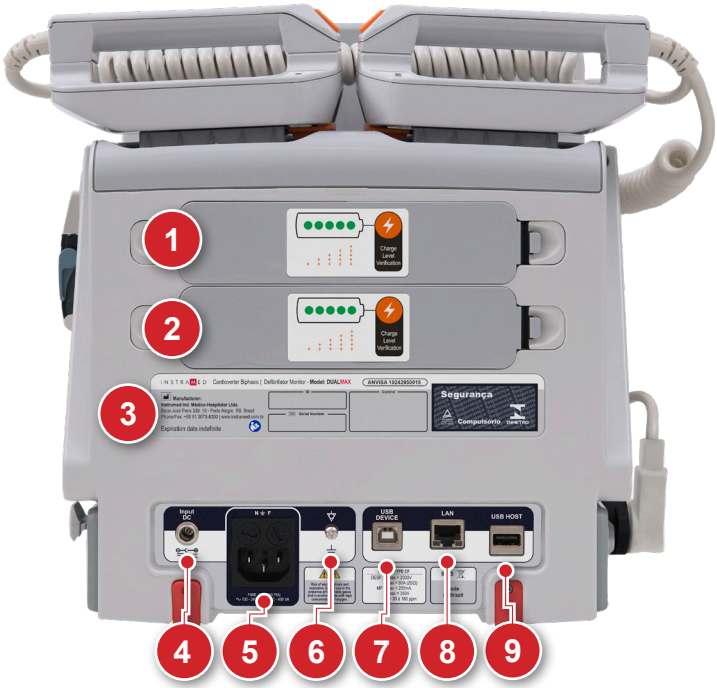
Invasive pressure connector (channel 2).

14 - Defibrillation electrodes (pads) connector

Multifunctional: adhesive pads for defibrillation, 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

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

8 - LAN connector

OP Connector for wired network connection.

9 - USB host connector

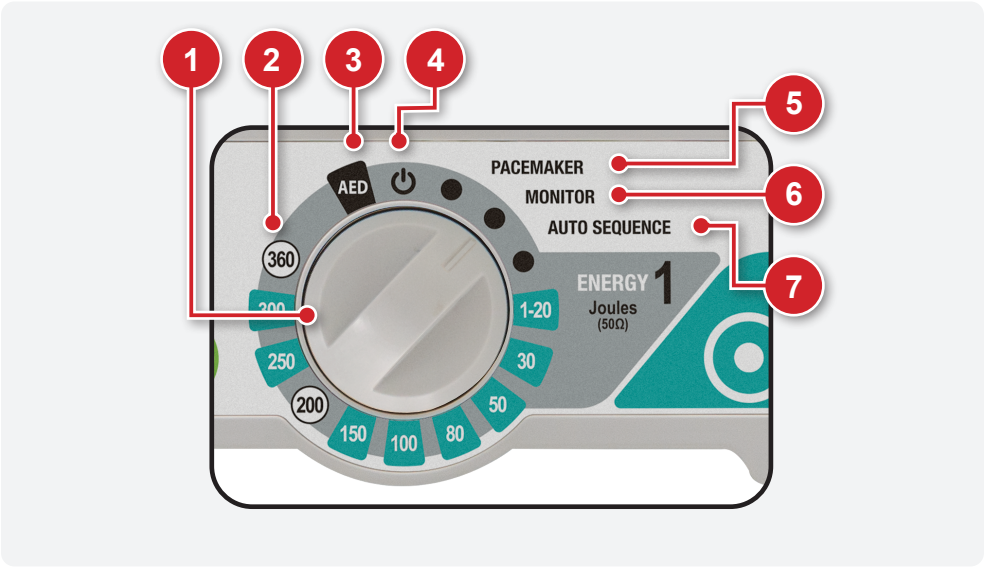
OP Connector for pendrive connection.

Screen and view

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 counterclockwise to select the operation mode. On "Off" position the equipment is turned off.

2 - Selector switch

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

3 - AED mode

OP 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

OP 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_2, NIBP, $EtCO_2$ and RESP. In this position the DualMax works as a multiparametric monitor.

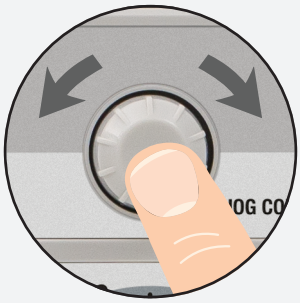
ECG and SpO_2 limit alarms continue operating. ECG and SpO_2 messages are enabled.

7 - Auto Seq mode

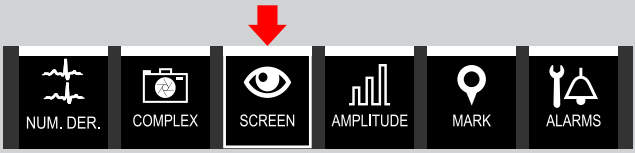
In this mode, it is possible to deliver shocks in a sequence of energy levels preset by the user. (See the "Defibrillator mode" chapter).

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

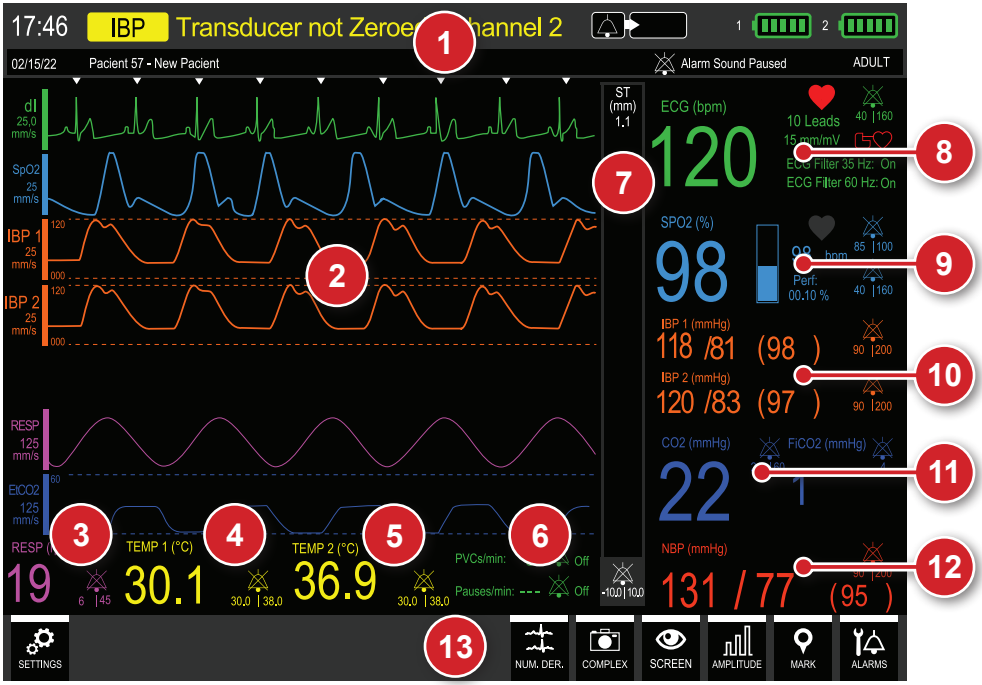
Quick access bar

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.

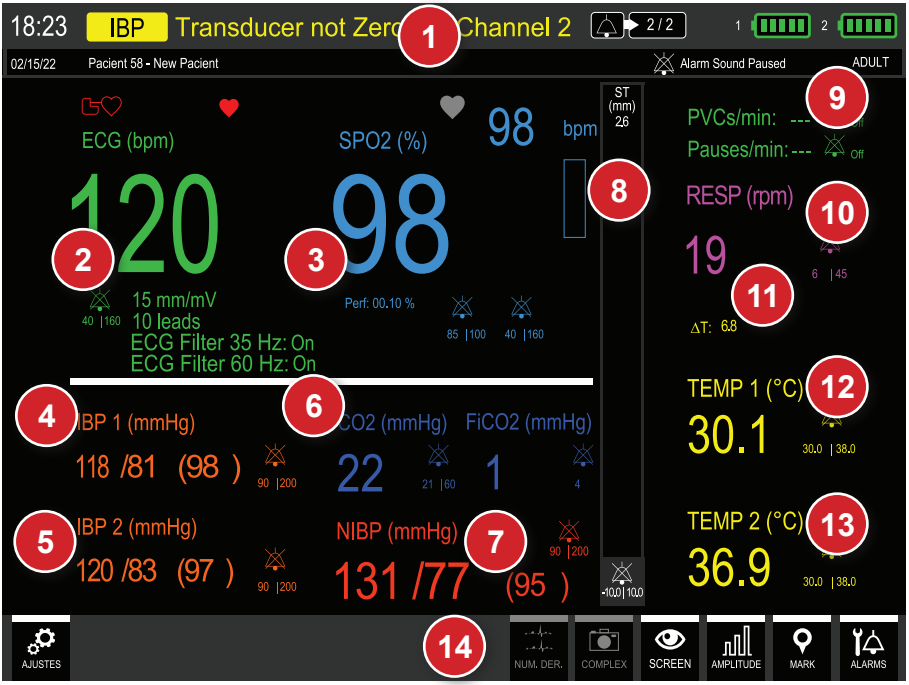
1. Button to access the configuration menu.
2. Operating mode active.
3. Changes the number of ECG curves displayed on the screen.
4. Complex freezing.
5. Button for changing the visualization mode of the screen.
6. Button for amplitude adjustment.
7. Mark event.
8. Alarm sound status.

Monitor mode screen - Variation A (with curves exhibition)



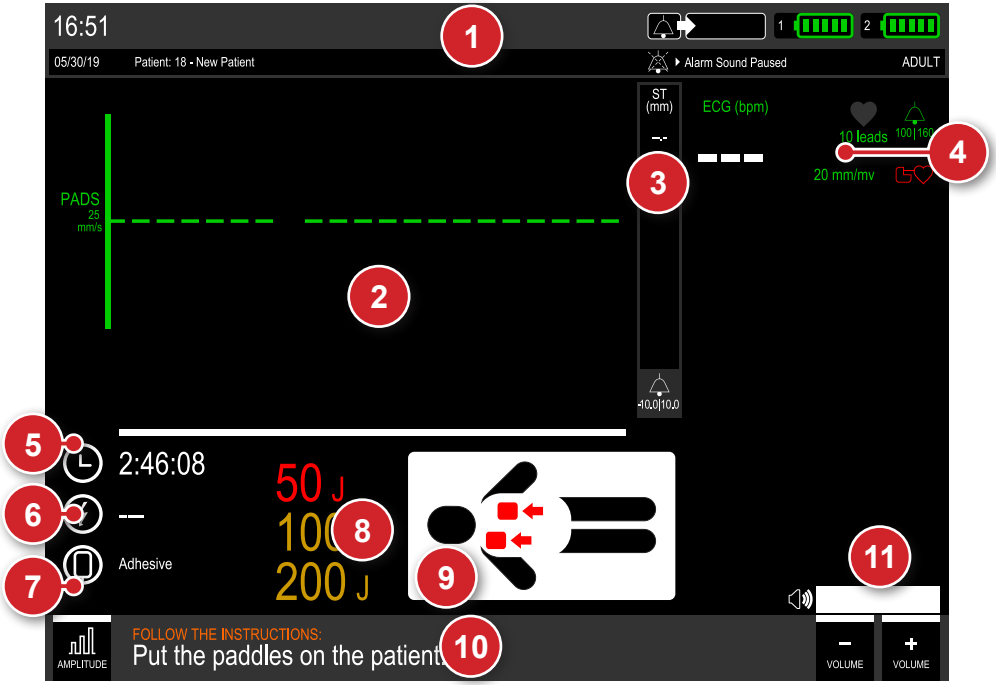
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. RESP data.
4. Temperature 1 data.
5. Temperature 2 data.
6. Arrhythmia data.
7. ST segment data.
8. ECG data.
9. SpO_2 data.
10. Invasive Pressure data.
11. Capnography data.
12. NIBP data.
13. Quick access bar.

Monitor mode screen - Variation B (without curves exhibition)



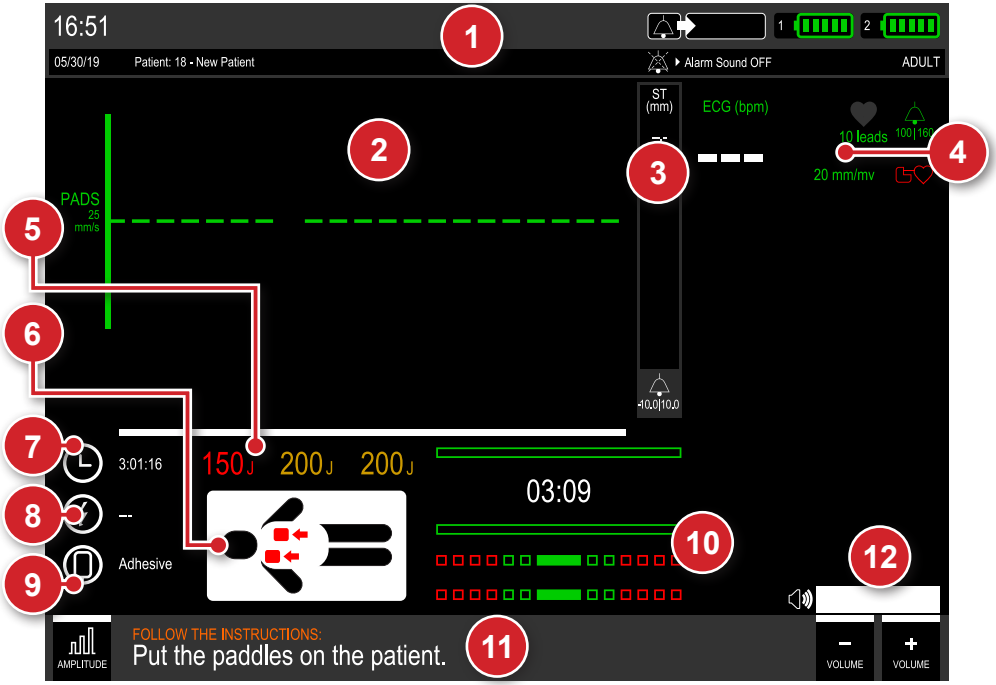
1. Information bar.
2. ECG data.
3. SpO_2 data.
4. Invasive pressure 1 data.
5. Invasive pressure 2 data.
6. Capnography data.
7. NIBP data.
8. ST segment data.
9. Arrhythmia data.
10. RESP data.
11. ΔT value.
12. Temperature 1 data.
13. Temperature 2 data.
14. Quick access bar.

AED mode screen - Variation A (without CPR)



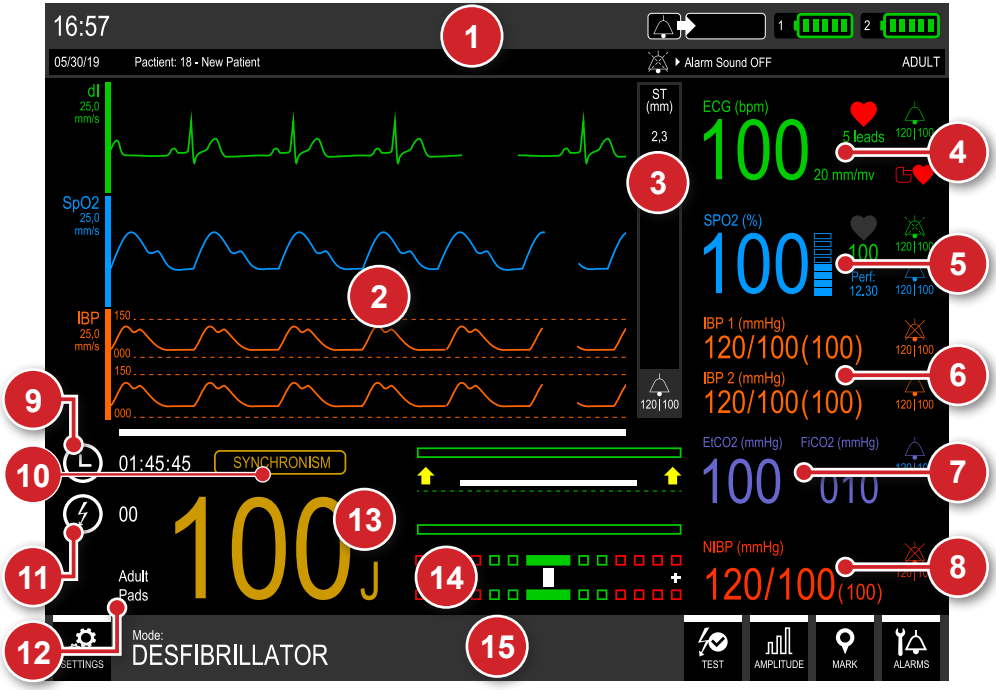
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. Treatment duration.
6. Number of applied shocks.
7. Type of pads selected and defibrillation mode.
8. Charges selected for the first, second and third shocks.
9. Illustrative image of the treatment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

AED mode screen - Variation B (with CPR)



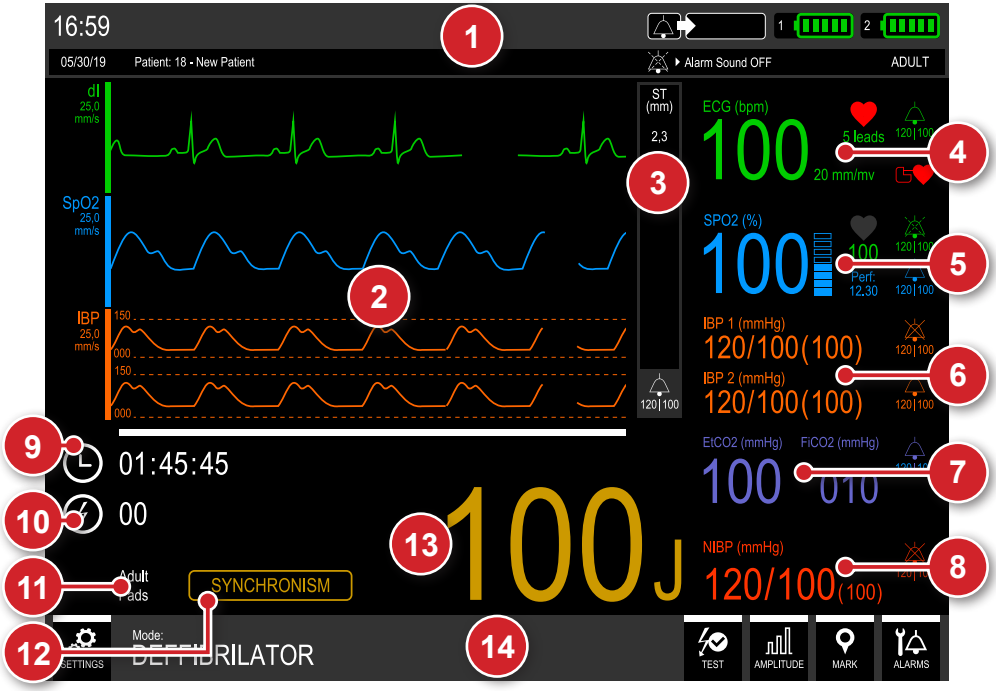
1. Information bar.
2. Graphic area for ECG curves exhibition.
3. ST segment data.
4. ECG data.
5. Value of energy to be applied.
6. Illustrative image of the treatment stage.
7. Treatment duration.
8. Number of applied shocks.
9. Type of pads selected and defibrillation mode.
10. CPR indicative graphic.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

Defibrillator mode screen – Variation A (with CPR)



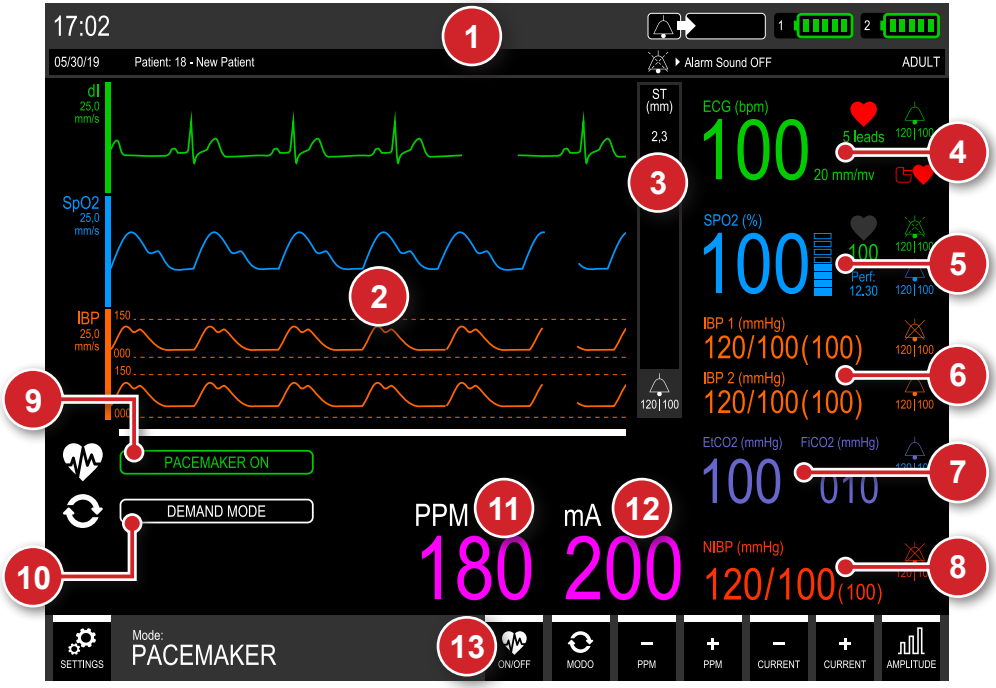
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO2 data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Treatment duration.
10. Indication of active synchronism.
11. Number of applied shocks.
12. Type of pads selected (adult/child).
13. Selected charge.
14. CPR indicative graphic.
15. Quick access bar.

Defibrillator mode screen – Variation B (without CPR)



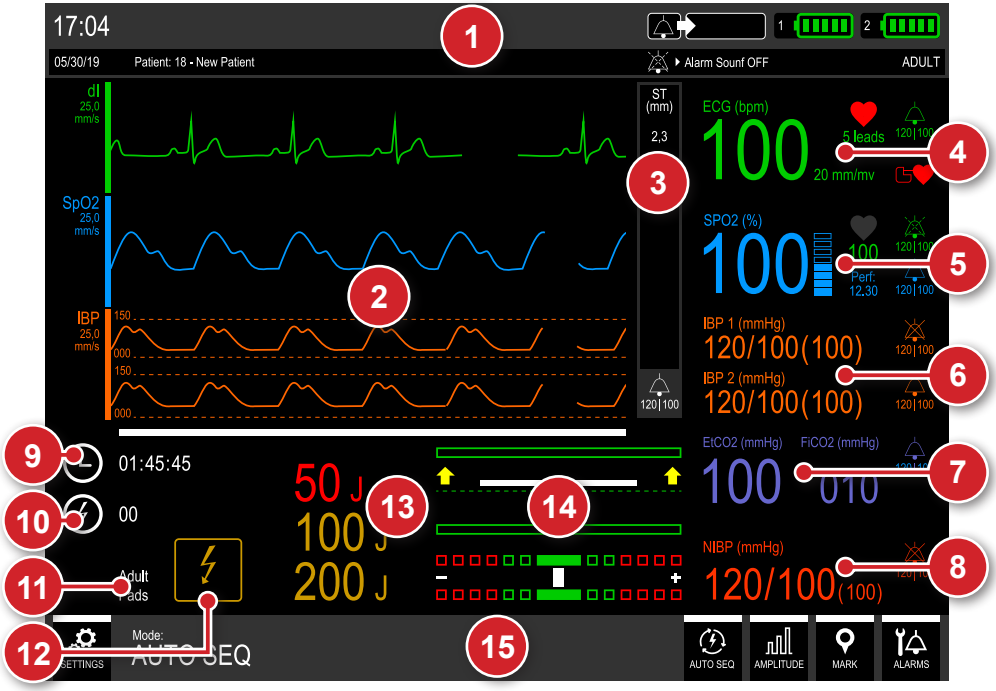
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO2 data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Treatment duration.
10. Number of applied shocks.
11. Type of pads selected
12. (adult/child).
13. Indication of active synchronism.
14. Selected charge.
15. Quick access bar.

Pacemaker mode screen



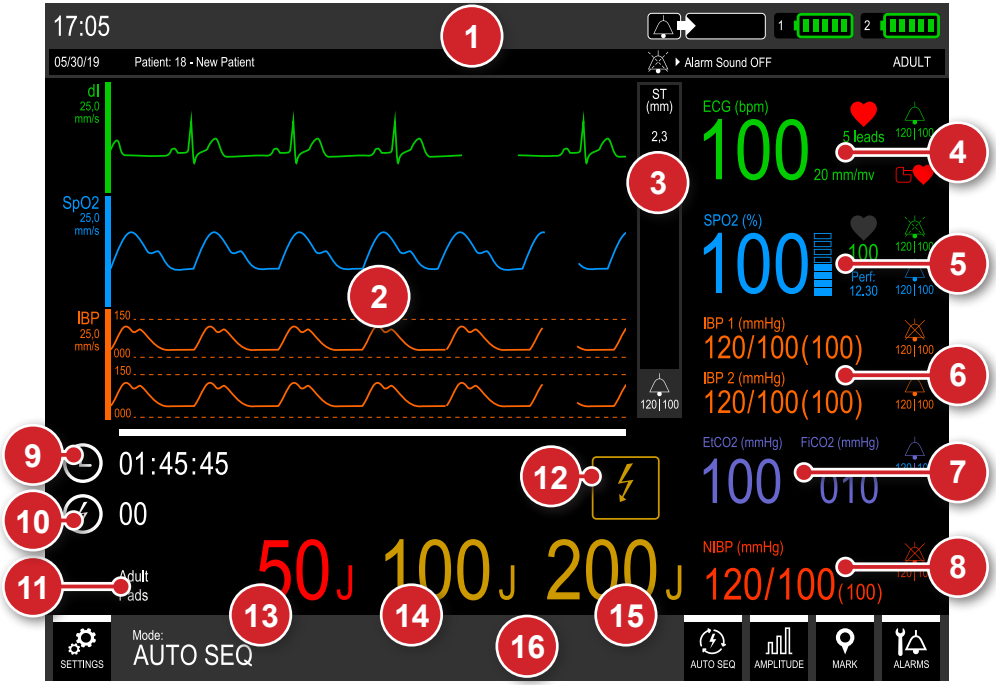
1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO2 data.
6. Invasive pressure data.
7. Capnography data.
8. NIBP data.
9. Pacemaker operating status.
10. Pacemaker operating mode.
11. BPM measure value.
12. mA measure value.
13. Quick access 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. SpO2 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.

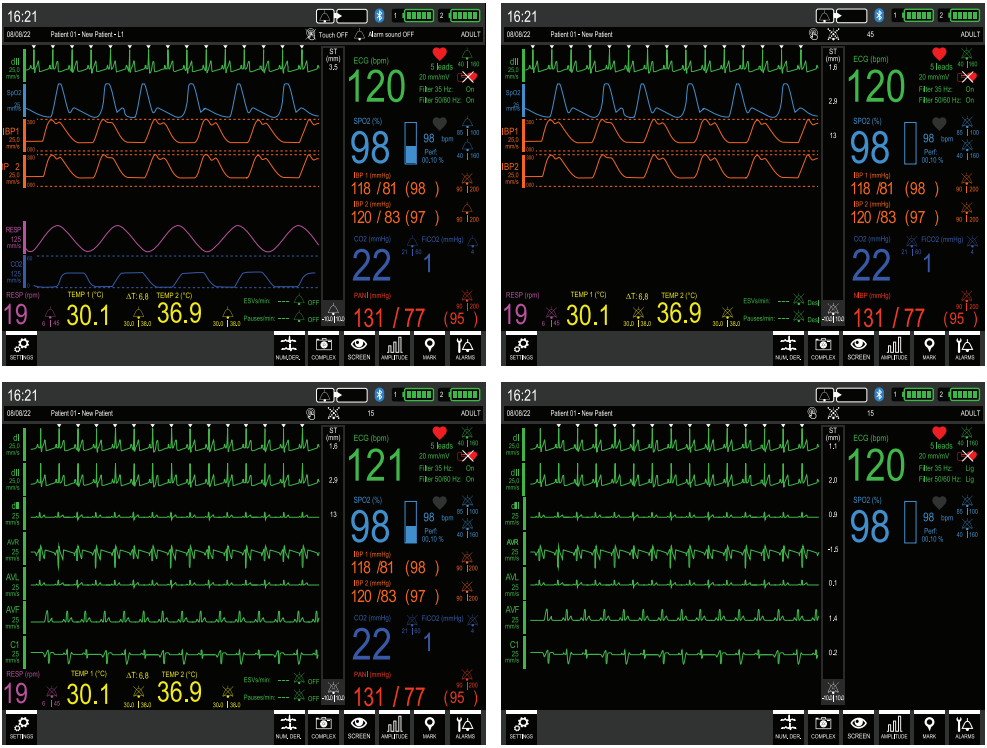
Charge auto-sequencing mode screen – Variation B (without CPR)



1. Information bar.
2. Graphic area for parameter curves exhibition.
3. ST segment data.
4. ECG data.
5. SpO_2 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.

Smart screen

Example of different presentations of parameters and curves:



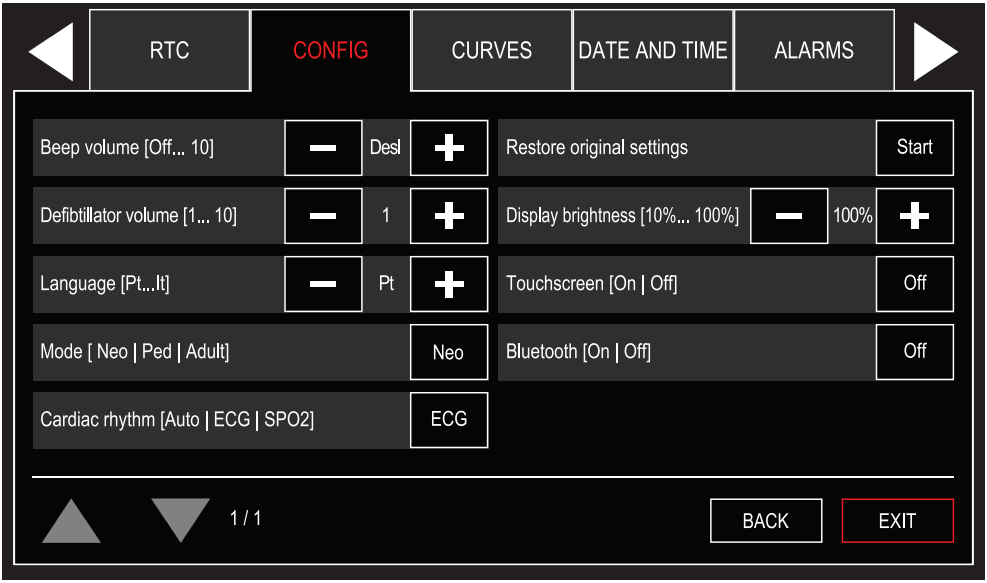
The Dualmax offers a smart screen feature that automatically adjusts to the number of parameters present. When one parameter is not being used, the equipment turns off the specific alarm for that function and inhibits the visualization of the curve and numeric values, making the characters and curves in use larger, which allows a better visualization

It is possible to present till 12 ECG curves OP simultaneously on the main screen. The selection is made through the “Main Menu > ECG > Number of Derivations”. The number of ECG curves to be displayed is preset in 01, 02, 03, 07 or 12 curves OP. Due to limited screen space, as the number of ECG curves increases, the curves for other parameters are disabled.

Basic operations

5

The DualMax has general configuration settings that can be accessed through the menu SETTINGS > CONFIG.



Pulse volume

The heart rate pulse volume can come from the ECG or SpO_2, depending on the selected setting.

To change the pulse volume, select the menu SETTINGS > CONFIG > Beep volume. It's possible to select as OFF, 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10.

Defibrillator volume

To change the defibrillator volume, select the menu SETTINGS > CONFIG > Defibrillator volume. It's possible to select as OFF, 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10.

Language configuration

To change the language, select the menu SETTINGS > CONFIG > Language. Select the desired language. It is not necessary to restart the equipment for the change to take effect.

Type of patient

The type of patient is determined by the operating mode of the equipment. To change the type of patient, select menu SETTINGS > CONFIG > Mode. You can select Neo Mode, Pediatric Mode and Adult Mode.

These definitions change the minimum and maximum values of alarms and initial pressure in the NIBP measurement according to the type of patient.

Heart rate

Heart rate beep auditory signal and heart rate indicator can be set between ECG and SpO_2, if both parameters are turned on, heart rate will automatically set ECG as priority. To change it, select menu SETTINGS > CONFIG > Cardiac rhythm.

Restoration of original settings

If you want to restore all alarm limits and reset all recorded information, select menu SETTINGS > CONFIG > Restore original settings. ALL changed values and information will be set to default.

Screen brightness adjustment

To change the screen brightness, select the menu SETTINGS > CONFIG > Display brightness. Select the most suitable setting for your screen brightness which can range from 10% (least bright), 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% and 100% (brightest).

Touchscreen

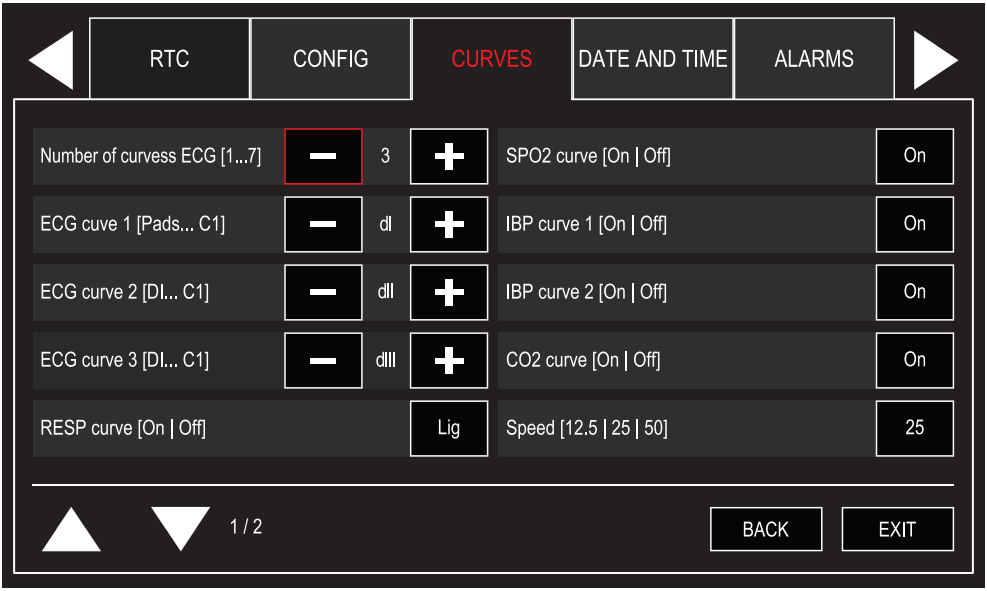
To enable or disable the touchscreen, select the menu SETTINGS > CONFIG > Touchscreen. It is possible to turn on or off.

Bluetooth

To access, select the menu SETTINGS > CONFIG > Bluetooth. It is possible to turn on or off. This function allows the transmission of patient data to SoftDEA using Bluetooth. On the main screen, in the Upper right corner, you can check whether Bluetooth is on or off.

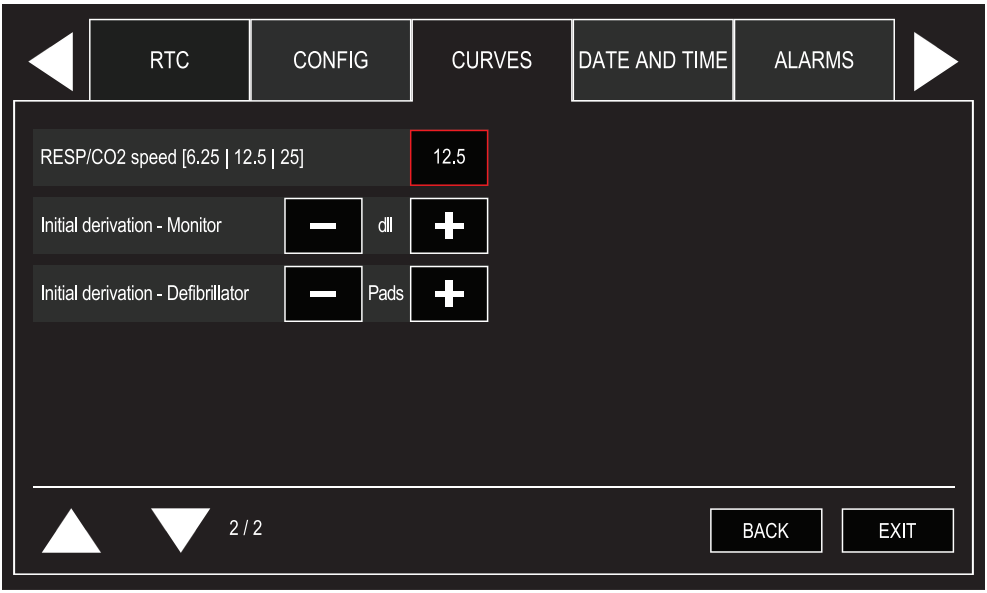
Curves

The DualMax has custom curve displays, which can be accessed on the menu SETTINGS > CURVES.



It is possible to select the ECG curves and/or oth.er parameters to be displayed on the screen.

Sweep speed can be selected as 12.5, 25 or 50 mm/s.

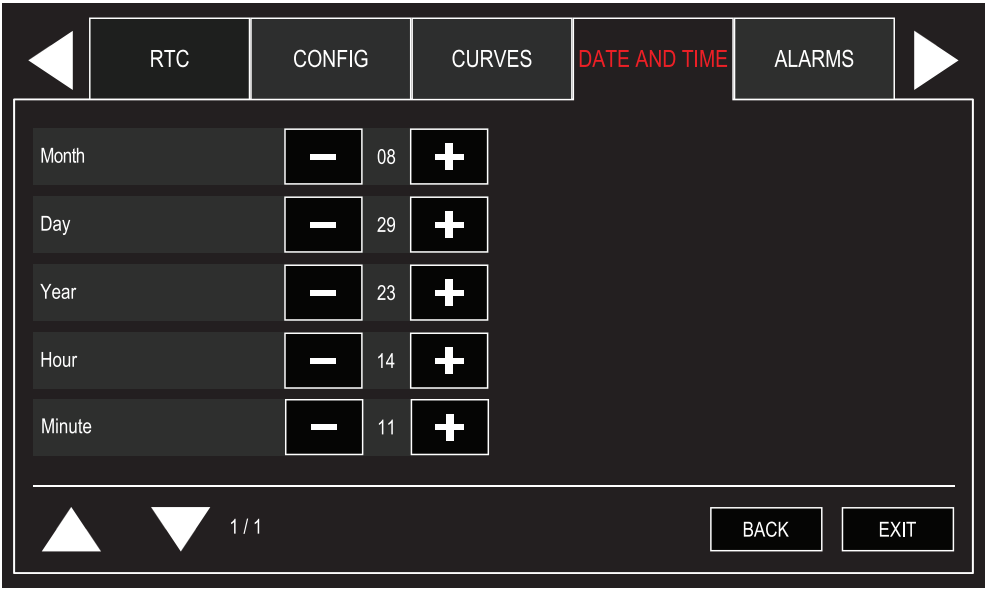


The RESP/CO_2 speed can be selected as 6.25, 12.5 or 25 mm/s.

The initial derivation to the Monitor mode and Defibrillator mode can be selected between PAS, DI, DII, DIII, aVR, aVL, aVF, C1, (C2, C3, C4, C5 and C6 if available).

Date and time

The date and time settings can be changed through the menu SETTINGS > DATE AND TIME.



Warning

Changing the date and time will affect the storage of trend and event data and may cause data loss

Alarms and limits

6

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 - Asystole - The DualMax cannot detect valid heartbeats for over 4 seconds.

ARRHYTHMIA - Ventricular tachycardia - When the Dualmax detects beats above 120 BPM (adjustable parameter in the ARRHYTHMIA menu).

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_2 - Pulse loss - When the DualMax identifies that it has lost the pulse in the SPO_2 sensor.

Violation of MAXIMUM or MINIMUM limits - When the Oximetry, ECG, NIBP, $EtCO_2$ 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_2, NIBP, RESP or $EtCO_2$ (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 asystole, 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_2 Saturation: 4 seconds.
  - $EtCO_2$: 9 seconds.
  - $FiCO_2$: 9 seconds.
- NIBP (systolic, diastolic, average): 1 second.
- For others parameters (RESP, TEMP, ST, PI): 5 seconds
- 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

CO_2	
$EtCO_2$ Max.	60 mmHg
$EtCO_2$ Min.	21 mmHg
$FiCO_2$ Max.	4 mmHg

SpO_2	
Response	Normal
SPO_2 Max.	100%
SPO_2 Min.	85%
Pulse Max.	160
Pulse Min.	40

Temperature (channels 1 and 2)	
Max.	38.0 °C
Min	30.0 °C
Max.	100.4 °F
Min	86.0 °F

NIBP	
Systole Max.	200 mmHg
Systole Min.	90 mmHg
Diastole Max.	150 mmHg
Diastole Min.	50 mmHg
Average Max.	170 mmHg
Average Min.	50 mmHg

Respiration	
Max.	45 RPM
Min.	6 RPM

ST segment	
Max.	45 RPM
Min	6 RPM

IBP (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, the 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_2 Saturation: 4 seconds.
- $EtCO_2$: 9 seconds.
- $FiCO_2$: 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). These 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.

If the equipment is operating with a duplicated screen (VGA interface), the delay in generating the alarm signal in the distributed system is less than 1 second.

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 category	Color	Frequency	Sound alert volume	Sound alert description
Physiological HIGH PRIORITY	RED	1,4 Hz to 2,8 Hz	74 to 83 dB	Triple beep - double beep - triple beep - double beep. Repeated at 3 second intervals.
Technical MEDIUM PRIORITY	YELLOW	0,4 Hz to 0,8 Hz	73 to 82 dB	Triple beeps. Repeated at 6 second intervals.

Alarm message characteristcs:

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 ▼.			

Arritmia			
Alarm	**Priority**	**Color**	**Possible cause**
Paus.	MEDIUM PRIORITY	YELLOW	When the interval between beats is less than the value defined in the alarm settings.
Sinus bradycardia.	MEDIUM PRIORITY	YELLOW	When the BPM < 60.
Tachyarrhythmia.	MEDIUM PRIORITY	YELLOW	When the BPM > 100.
Ventricular bigeminy	MEDIUM PRIORITY	YELLOW	When we have a normal heartbeat followed by a ventricular extrasystole and so on.
Ventricular trigeminy.	MEDIUM PRIORITY	YELLOW	When we have 2 normal beats and a ventricular extrasystole and so on.
ESV R over T.	MEDIUM PRIORITY	YELLOW	When a ventricular extrasystole occurs with an ultrashort coupling interval (R over T phenomenon).
Succession of ESVs.	MEDIUM PRIORITY	YELLOW	When more than two ventricular extrasystoles occur in a row between beats.
ESV duo.	MEDIUM PRIORITY	YELLOW	When two ventricular extrsystole occur in a row between beats.
ESVs above the limit.	MEDIUM PRIORITY	YELLOW	When the amount of ventricular extrasystoles exceeds the amount per minute defined in the alarm setting.
Ventricular tachycardia.	HIGH PRIORITY	RED	When the BPM is above the value set in the alarm setting (120 default value).

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_2			
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_2 signal.
Too long search.	MEDIUM PRIORITY	YELLOW	The equipment is searching a valid signal of SpO_2 for more than 20 seconds.
SpO_2- Disconnected sensor.	MEDIUM PRIORITY	YELLOW	Sensor or SpO_2 extension disconnected or incorrectly placed.
SpO_2 - 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_2 - Sat above the limit.	HIGH PRIORITY	RED	Saturation is above the value defined on the alarm configuration.
(↓) SPO_2 - Sat below the limit.	HIGH PRIORITY	RED	Saturation is below the value defined on the alarm configuration.
(↑) SPO_2 - BPM above the limit.	HIGH PRIORITY	RED	Pulse value is above the value defined in the alarm configuration.
(↓) SPO_2 - BPM below the limit.	HIGH PRIORITY	RED	Pulse value is below the value defined in the alarm configuration.

NIBP			
Alarm	**Priority**	**Color**	**Possible cause**
Artifact.	MEDIUM PRIORITY	YELLOW	Muscle tremor detected
Excessive pressure.	MEDIUM PRIORITY	YELLOW	The cuff´s maximum pressure has been exceeded.
Cuff problems.	MEDIUM PRIORTY	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 inaccurateness.
(↑) 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.

CO_2			
Alarm	**Priority**	**Color**	**Possible cause**
No filter lines.	MEDIUM PRIORITY	YELLOW	The capnography sampling line is not connected.
Occlusion.	MEDIUM PRIORITY	YELLOW	There is no airflow in the $EtCO_2$ sensor. Change the sampling line (filter line).
Starting sensor.	MEDIUM PRIORITY	YELLOW	The $EtCO_2$ 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.
Insufficient airflow: purging.	MEDIUM PRIORITY	YELLOW	Air passage in the CO_2 sensor is partially obstructed or flow is out of normal use condition.
(↑) CO_2 above the limit.	HIGH PRIORITY	RED	CO_2 EXP is above the value defined on the alarm configuration.
(↓) CO_2 below the limit.	HIGH PRIORITY	RED	CO_2 EXP is below the value defined on the alarm configuration.
Communication failure	HIGH PRIORITY	RED	Communication failure of $EtCO_2$ module.
(↑) $FiCO_2$	HIGH PRIORITY	RED	The $FICO_2$ measurement value is above the alarm limit

Defibrillator			
Alarm	**Priority**	**Color**	**Possible cause**
Connect pads.	MEDIUM PRIORITY	YELLOW	Pads are not connected.
Informative messages			
Adhesive pads - DualMax detected adhesive pads connected.			
Adult pads - DualMax detected adult pads connected.			
Children pads - DualMax detected paddles connected, but the adult electrode is disconnected. The same message is also exhibited when DualMax detects children adhesive pads.			
Charging - The load is not yet complete.			
Charge ready - The energy has been charged.			

Shock Delivered - Indicates that energy has been delivered to the patient. Just below this message, the energy values delivered in Joules (J), current in Amperes (A) and impedance in Ohms (Ω) are displayed.
Shock disarmed - The energy was canceled by the operator.
Shock disarmed (automatic internal discharge) - The energy was automatically canceled because the shock button was not pressed before the internal discharge time selected by the operator.
Shock disarmed (bad contact) - The energy was canceled because the impedance of the patient is not satisfying the applicable shock conditions.
Bad Contact - 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.
Informative message			
PM: Pause - The outbreak of pacemaker pulses is paused.			
PM: On - The outbreak of pacemaker pulses is on.			
Mode: Asynch - The pacemaker is in asynchronous mode.			
Mode: Dem - The pacemaker is in demand mode.			

Printer
Informative message
Without paper - Printer is out of paper.
Printing - 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.

ATTENTION: 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.

ATTENTION: for simultaneous alarms of the same priority, the DualMax will intercalate the alarm signals and messages.

Nível de carga da bateria

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

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

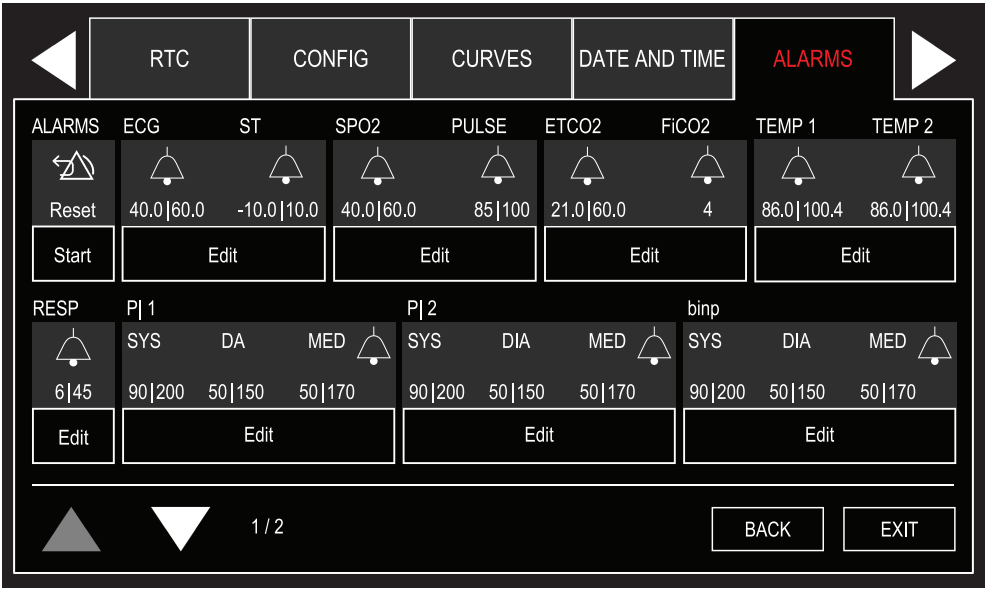
Pause audio

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

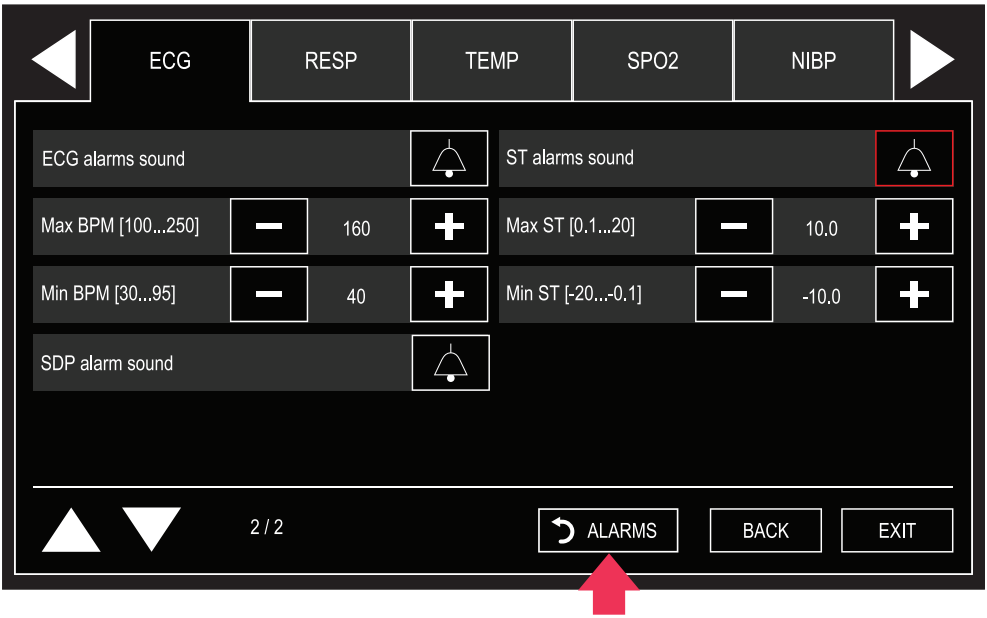
The DualMax maintains the previous alarm settings, in case of turning off for a period of 30 seconds or less. After this time, the device automatically returns to the factory default settings to ensure safety in case of patient exchange.

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
ALARMS
ECG
ST
SPO2
PULSE
ETCO2
FiCO2
TEMP 1
TEMP 2
Reset
40.0|60.0
-10.0|10.0
40.0|60.0
85|100
21.0|60.0
4
86.0|100.4
86.0|100.4
Start
Edit
Edit
Edit
Edit
RESP
P| 1
P| 2
binp
SYS
DA
MED
SYS
DIA
MED
SYS
DIA
MED
6|45
90|200
50|150
50|170
90|200
50|150
50|170
90|200
50|150
50|170
Edit
Edit
Edit
Edit
1 / 2
BACK
EXIT


RTC
CONFIG
CURVES
DATE AND TIME
ALARMS
DEFIB/PM alarms sound
BATTERY alarm sound
Sound Arrhythmias Alarms
2 / 2
BACK
EXIT

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



Minimum/Maximum limits adjustment

60 △
90 ▽

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.

ECG: it is possible to adjust the minimum ECG alarm to levels between 30 and 150 BPM, with an interval of 5 BPM when in “Adult and Pediatric” mode and 1 BPM interval when in “Neo” mode. It is possible to adjust the maximum ECG alarm at levels between 100 and 250 BPM, with intervals of 5 BPM in “Adult and Pediatric” mode and 1 BPM in “Neo” mode.

SpO_2: it is possible to adjust the SpO_2 minimum pulse alarm at levels between 30 and 95 BPM, with intervals of 5 BPM in “Adult and Pediatric” mode and 1 BPM in “Neo” mode. It is possible to adjust the maximum SpO_2 pulse alarm at levels between 100 and 250 BPM, with intervals of 5 BPM in “adult” mode and 1 BPM in “Neo” mode. It is also possible to adjust the minimum SpO_2 saturation alarm to levels between 40 and 95% with intervals of 5% in “Adult and Pediatric” mode and 1% in “Neo” mode. It is possible to adjust the maximum SpO_2 saturation alarm to levels between 45 and 100% with intervals of 5% in “Adult and Pediatric” mode and 1% in “Neo” mode.

NIBP: it is possible to adjust the minimum NIBP alarm to levels between 50 and 290 mmHg for systolic, diastolic and mean pressure with 5 mmHg intervals for “Adult, Pediatric and Neo” modes. Ir is possible to adjust the maximum NIBP alarm at levels between 30 and 300 mmHg for systolic, diastolic and mean pressure with 5 mmHg intervals for “Adult, Pediatric and Neo” modes.

CO_2: it is possible to adjust the minimum $EtCO_2$ alarm to levels between 18 and 94 mmHg, with an interval f 5 mmHg in “Adult and Pediatric” mode and every 1 mmHg In “Neo” mode. It is possible to adjust the maximum $EtCO_2$ alarm at levels 23 and 99 mmHg, with intervals of 3 mmHg in “Adult and Pediatric” mode and 1 mmHg in “Neo” mode. It is possible to adjust the maximum $FiCO_2$ alarm to levels between 1 and 99 mmHg

RESP: it is possible to adjust the minimum respiration alarm at levels between 3 and 145 RPM, with an interval of 5 RPM when in “Adult and Pediatric” mode and 1 RPM interval when in “Neo” mode. It is possible to adjust the maximum respiration alarm at levels between 8 and 150 RPM, with intervals of 5 RPM in “Adult and Pediatric” mode and 1 RPM in “Neo” mode. PI: It is possible to adjust the minimum PI alarm at levels between 0 and 290 mmHg for systolic, diastolic and mean pressure with 5 mmHg intervals for “Adult, Pediatric and Neo” modes. It is possible to adjust the maximum PI alarm at levels between 10 and 300 mmHg for systolic, diastolic and mean pressure with 5 mmHg intervals for “Adult, Pediatric and Neo” modes.

TEMPERATURE: it is possible to adjust the minimum temperature alarm to levels between 0 and 49.4 °C, with intervals of 0.2 by 0.2 °C or levels between 32 and 120.9 °F, with intervals alternating between 0.3 and 0.4 °F for “Adult, Pediatric and Neo” modes. It is possible to adjust the maximum temperature alarm to levels between 0.6 and 50 °C, with intervals of 0.2 by 0.2 °C or levels between 33 and 122 °F, with intervals alternating between 0.3 and 0.4 °F for “Adult, Pediatric and Neo” modes.

Alarm test

When turning on the DualMax with the cables and parameter sensors disconnected, a self-test of the alarm system is performed. It is necessary to check if the alarm indicator light turns on, the yellow light for the technical alarm is turned on, then the red light for the physiological alarm and the blue light (used in preventive and/or corrective maintenance). Then the monitor will emit an alarm sound, this indicates that the visual and audible alarm system is working properly.

If you want to carry out individual tests of the alarm system, follow the instructions below.

To perform the technical alarm test

1. Turn on the equipment with cables and parameter sensors disconnected. There should be a technical alarm indication (text messages in the information bar in yellow color), the DualMax will emit the medium priority alarm sound and the alarm indication light should flash yellow.

2. Once the visual and auditory informational message has been confirmed, correctly connect the sensor you want to test to the equipment and the other end to a parameter simulator or yourself (it can be the SpO_2 sensor, ECG cable, $EtCO_2$/$FiCO_2$ or temperature sensor) and check again. If the indication disappears, the resulting alarm is the same, the alarm system is probably faulty.

The parameter audio can be turned on and off individually in the “Alarm” menu and in the parameter menus.

To perform the physiological alarm test

1. Turn on the equipment, with the sensor or parameter cable to be tested properly connected to a parameter simulator or to yourself. Once connected, check the value read on the equipment and follow the instructions below:

2. a) For the test via ECG, using the e-Jog control key on the equipment panel or touch screen*, navigate to: ADJUSTMENTS > ECG > ALARMS. Select one of the limits and then vary its value until the initially measured value is outside the range, and return to the main screen.

2. b) For the test through SpO_2, using the e-Jog control key on the equipment panel or touch screen*, navigate to: SETTINGS > SPO_2 > ALARMS. Select one of the limits and then vary its value until the initially measured value is outside the range, and return to the main screen.

2. c) For the test through $EtCO_2$, using the e-Jog control key on the equipment panel or touch screen*, navigate to: ADJUSTMENTS > $ETCO_2$ > ALARMS. Select one of the limits and then vary its value until the initially measured value is outside the range, and return to the main screen.

2. d) For the test through Temperature, using the e-Jog control key on the equipment panel or touch screen*, navigate to: SETTINGS > TEMP > ALARMS. Select one of the limits and then vary its value until the initially measured value is outside the range, and return to the main screen.

2. e) For the test via $FiCO_2$, using the e-Jog control key on the equipment panel or touch screen*, navigate to: ADJUSTMENTS > CO_2 > ALARMS. Select the threshold and then vary its value until the initially measured value is outside the range, and return to the main screen.

3. Once this is done, there should be a physiological alarm indication (text messages in the information bar in red color), the DualMax will emit the high priority alarm sound and the alarm indication light should flash red. If any of the aforementioned warnings do not occur, the alarm system is probably defective.

*When touchscreen OP is available.

Alarm reset

Selecting the Alarms hotkey 

and then “Start”.

Restart of alarms you can reset the alarm system to recognize the alarms that are currently active, after reset, the following settings can be considered:

- No alarm sound will be emitted until a new occurrence of alarm arises.
- The icon  will be displayed in the area dedicated to the alarm indicator.
- For alarms that are currently active, visual indications will continue to be displayed.
- Alarm thresholds and numeric parameter values will continue to flash.

ATTENTION

By default, the sound of alarms is turned on when entering monitor mode and off when entering other modes - PACING, AED, DEFIBRILLATION (1 to 360 J) or AUTO SEQUENCE - if the user individually configures the sound of an alarm, this setting individual remains unchanged due to mode changes, thus prevailing the configuration selected by the user until a new patient is added, or there is a power interruption/equipment shutdown lasting more than 30 s.

In AED mode, the sounds of all parameter alarms remain off, considering that they can confuse or distract the operator, since the operation in this mode is guided by means of voice instructions.

When the alarm of any parameter is disabled, the monitor will not alarm even if an alarm occurs. To avoid putting the patient's life at risk, this function must be used with care by the operator.

Before starting monitoring, check that the alarm limits are suitable for the patient.

Setting alarm thresholds to extreme values can make the alarm system ineffective. It is recommended to use the default settings.

Defibrillator mode

7

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.

In this Defibrillation mode, only the SOUND of the HIGH PRIORITY and MEDIUM PRIORITY alarms are disabled.

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.

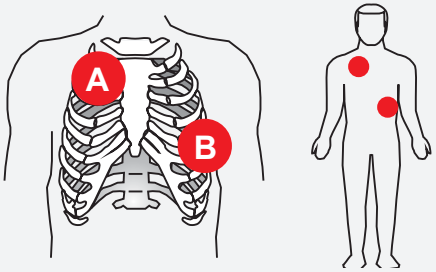
External pads use

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.

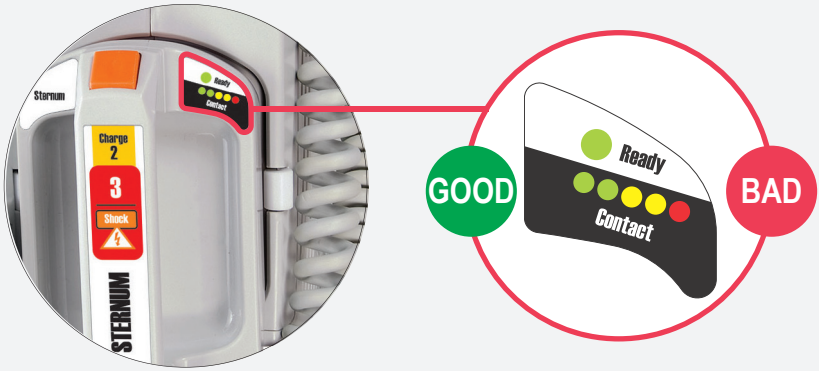
The electrodes must be placed in a position which will maximize the current thatpasses through the myocardium. The standard position is:

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.

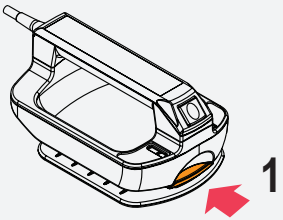
Patient's impedance	Shock	Message on screen after “Charge” key pressed	Values indicated on bargraph
Short circuit.	Shock inhibited.	Bad contact.	All LEDs blinking.
< 25 Ohms.	Shock inhibited.	Bad contact.	All LEDs blinking.
>25 Ohms and < 300 Ohms.	Shock delivered and the waveform is adjusted according 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.

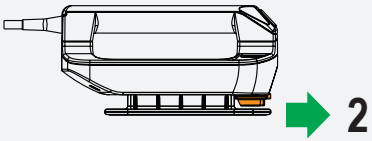
When only the RED LED is blinking, shock delivery will not be allowed.

Child pads use

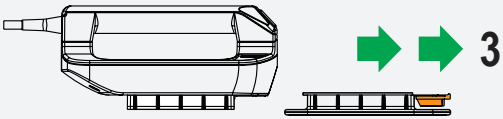
1. Fasten the lock in the front of the adult external pads.



2. Pull the pads base forward to remove them.



3. This exposes the smaller electrode for children.



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).

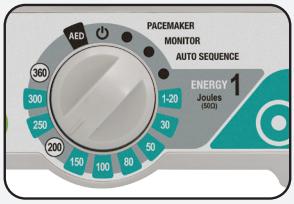
ATTENTION: after opening the wrapping, the pads should be used within 24 hours.

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

Defibrillation

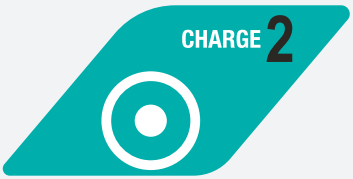
Follow the steps 1-2-3

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



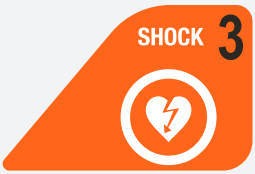
Press the “Charge” button (green) in the front panel or use the charge button in the external pads (orange). While the DualMax is charging, a sound will be emitted and the measurement of the charged energy will appear on the display.

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 values.

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

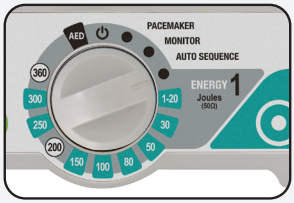
Indicates if the synchronism is on (beige). When turned on, the symbol flashes indicating the activation of the function.

5 - Energia selecionada e carregada

The energy SELECTED by the user is shown in this display area in BEIGE 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: "DefibrillationAUTO 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.

In this Auto Sequence Charge mode, only the SOUND of the HIGH PRIORITY and MEDIUM PRIORITY alarms are disabled.

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.

4 - Back/Exit

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

AED mode

Automatic External Defibrillator

OP 8

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.

Neural Network Technology

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 settings, 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.

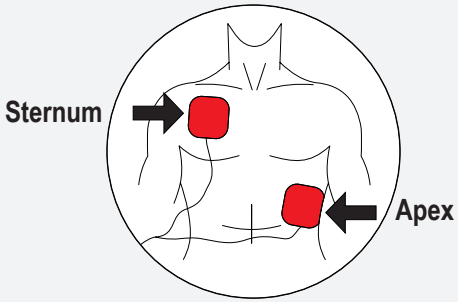
After disposing of used pads, always leave a replacement pair already connected to the equipment, avoiding having to replace them at the moment of the emergency.

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.

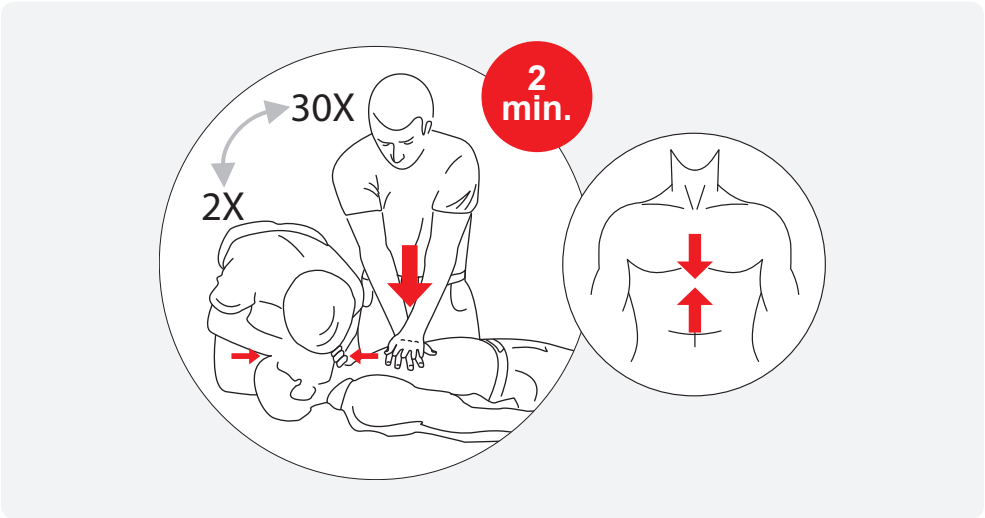
ATTENTION: the user must not touch the patient or conductive surfaces in contact with him/her during shock delivery, under risk of suffering a powerful electric discharge.

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.

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.

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.

ATTENTION: the RCP techniques shown in this manual are for reference only and do not replace the mandatory specialized training for professionals who perform emergency care.

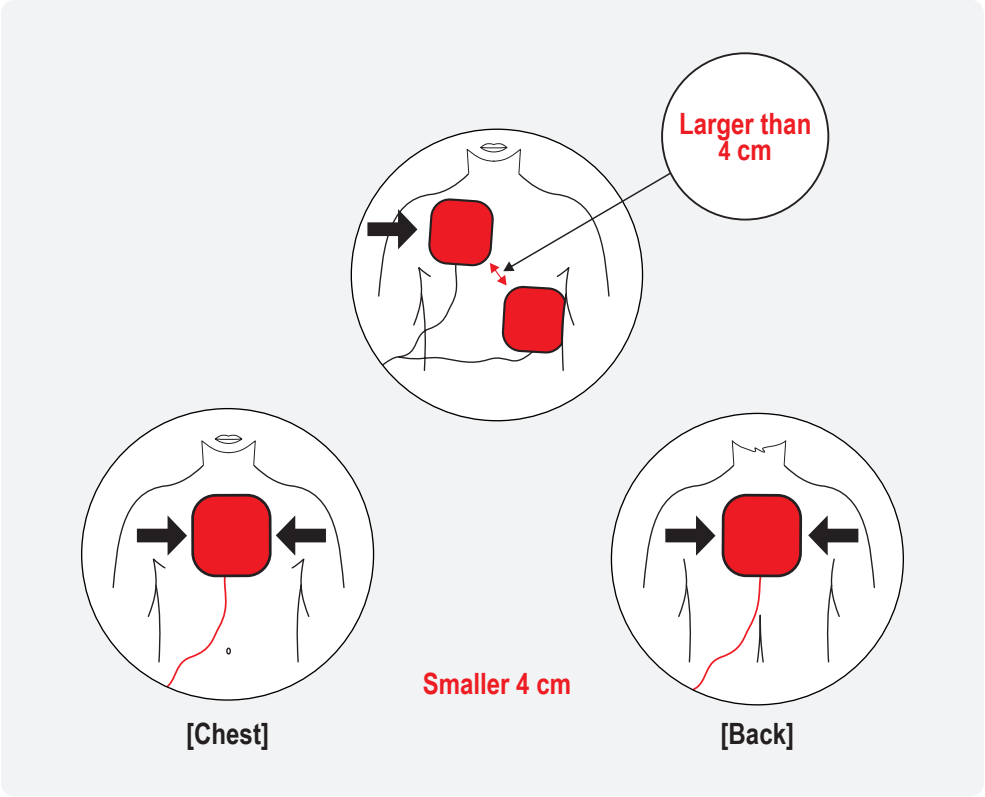
ATTENTION: when using the first aid mask to carry out ventilation, observe the instruction "THIS SIDE UP", which indicates which side should face upwards.

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

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. High.
VISUAL ALARM SIGN	Messages in Info center 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 reparation or pulse if you cannot detect either, perform CPR for two minutes.

CPR Maestro

OP 9

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 cannot be used by itself. Only connected to DualMax.

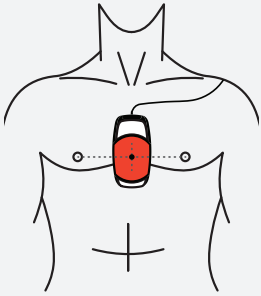
The CPR Maestro parameter must work on DEFRIBRILLATION, CHARGE AUTO SEQUENCE and AED modes. On AED mode, the messages on screen and the audible ones will only be presented after the orientation "Perform CPR for 2 minutes".

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.



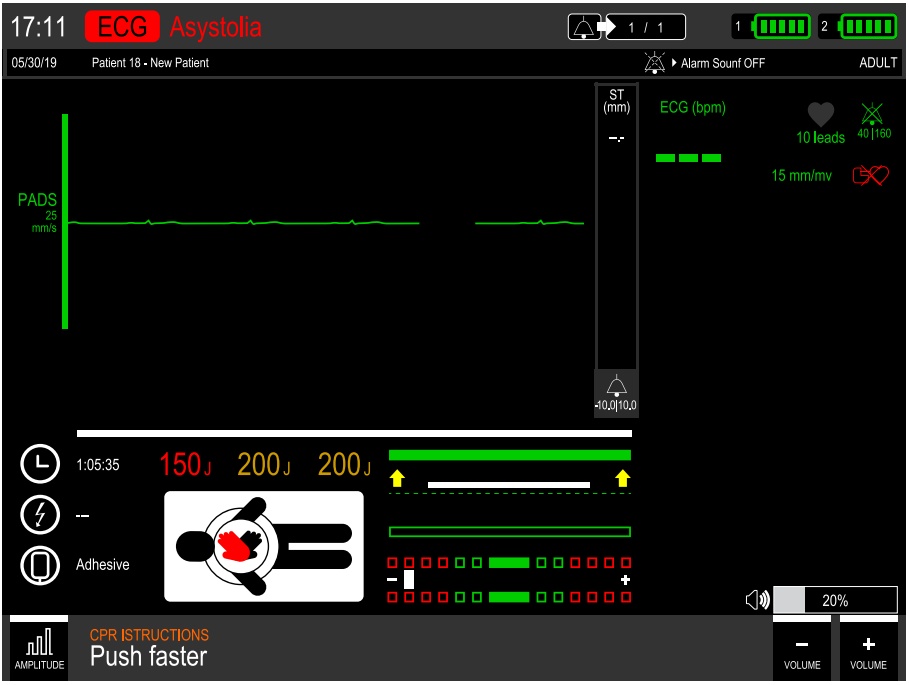
This step is important and must always be followed. When the equipment is initialized, the CPR sensors are calibrated, enabling the evaluation of the compressions. The initialization with the device out of the recommended position may cause incorrect evaluations.

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.

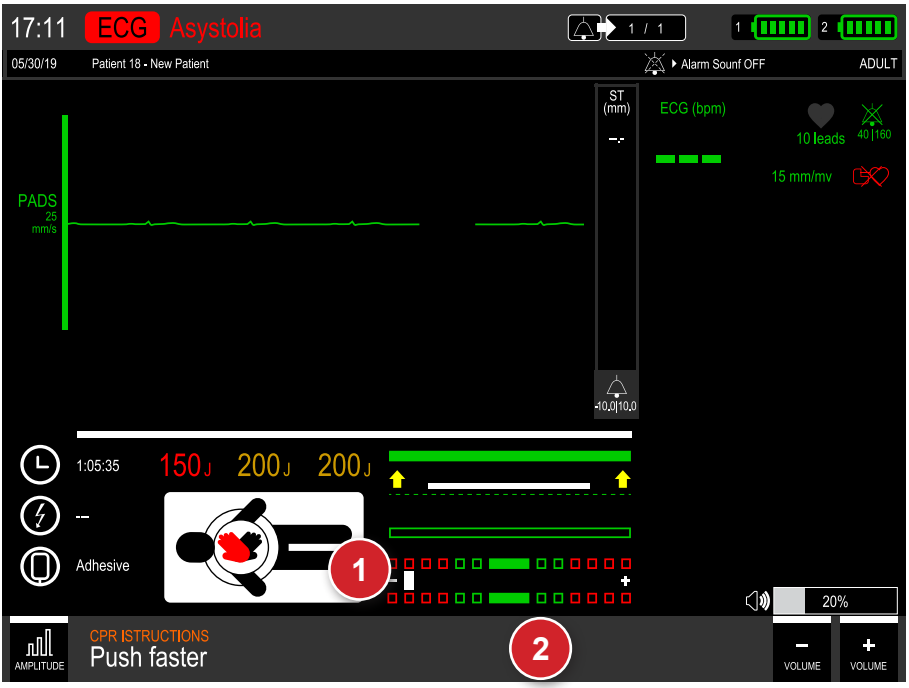
4. A message will be displayed to confirm if the device is correctly placed on the patient's chest, where the compressions will be performed. If yes, press the ON/OFF button again and start the compressions.



Feedback

The user receives CPR feedback in the following ways:

A - Message and CPR image on DualMax screen



1. CPR indicative graphic.
2. Messages.

B - CPR indicative graphic on the CPR Maestro screen

C - Audio message (bellow)

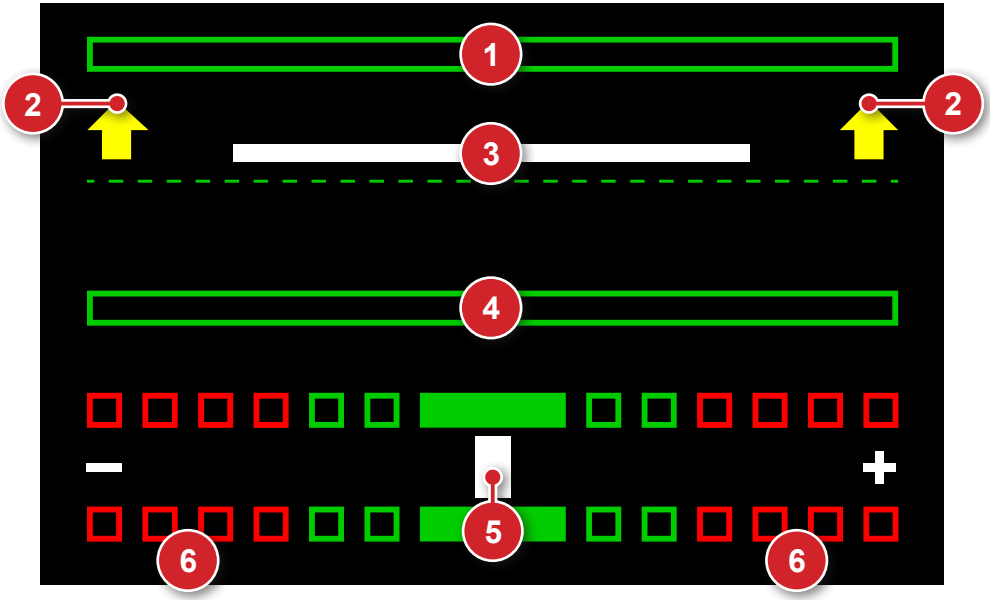
Messages

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

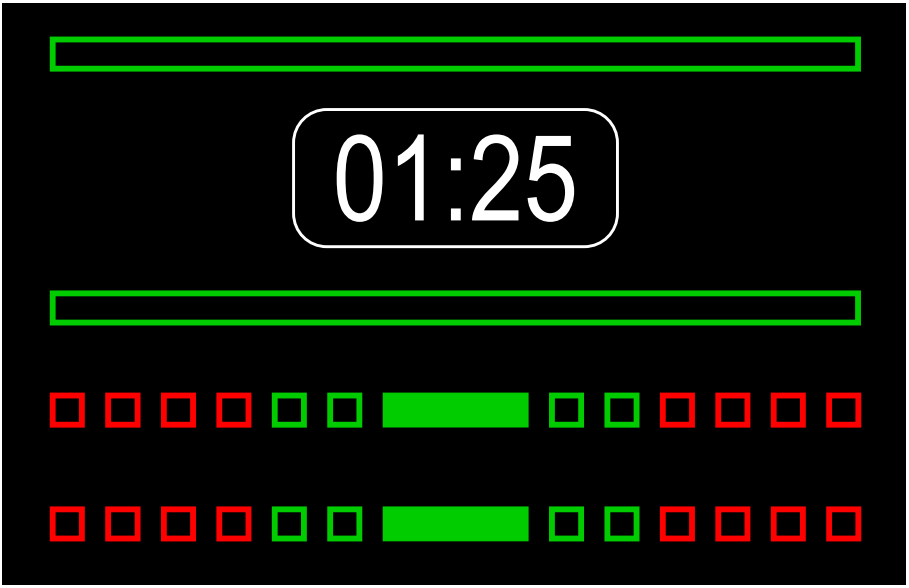
CPR graphic

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



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

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



Pacemaker mode

OP 10

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.

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.

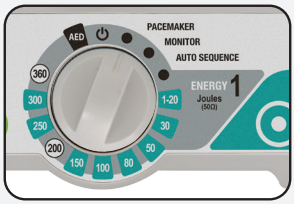
In this mode, the pacemaker uses the ECG signal captured by the electrodes (patient cable), synchronizing the pulses in order to prevent the heart’s vulnerable phase.

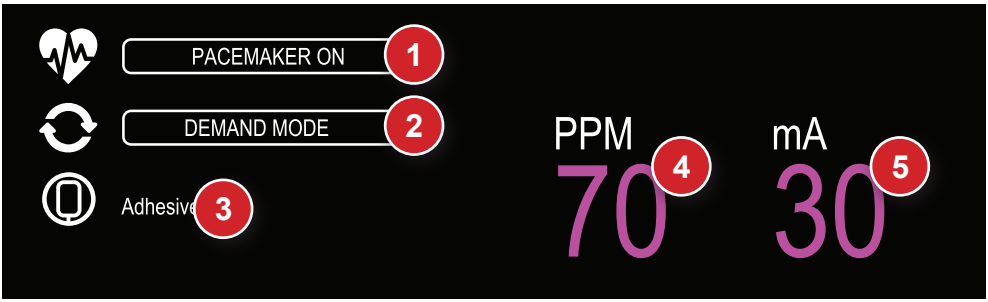
Operating in pacemaker mode

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 “Info center” 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 “Info center” 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.

Monitor mode - ECG

11

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).

The following factors can cause ECG misinterpretation:

- Poorly positioned pads.
- Excessive patient movements.
- Transcutaneous pacemaker present (may decrease the accuracy of the cardiac arrest detector).
- Excessive hair or wet skin in the region of the electrode application.
- Clothing between the skin and the pads.

ATTENTION: patient movements can confuse correct rhythm detection and delay therapy. Do not maneuver the patient and keep him or her still during rhythm analysis.

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.

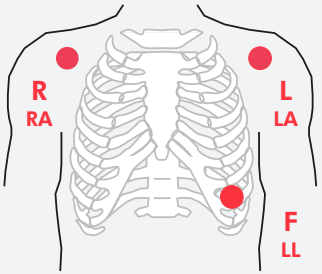
2. Select the electrodes to be used on the patient. Use only one kind or brand of electrode. The electrodes must follow AAMI standards for electrode performance.

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.

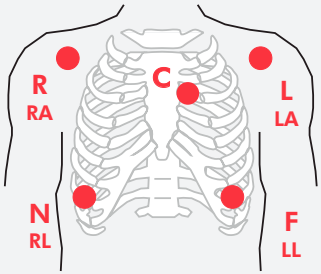
5. Connect the patient's ECG cable to the electrodes.

3-wire cable



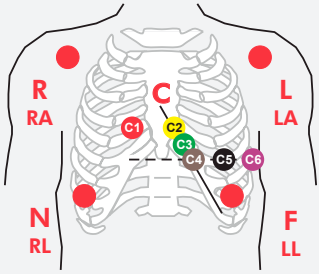
[3 leads]

5-wire cable



[7 leads]

10-wire cable



[12 leads]

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
V (V1 - V6)	V - (RA+LA+LL)	RL

Color patterns

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

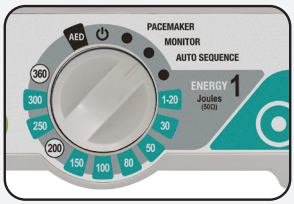
Position	IEC (European)	AHA (American)
Right Arm	R - Red	RA - White
Left Arm	L - Yellow	LA - Black
Left Leg	F - Green	LL - Red
Right Leg	N - Black	RL - Green
Thorax	C - White	V - Brown

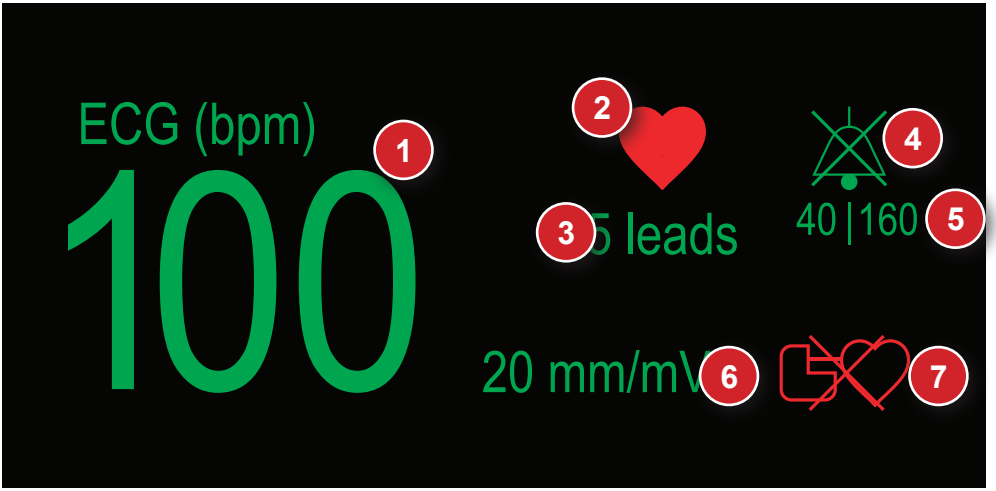
Operating in monitor mode - ECG

Turn the selector switch to the Monitor mode.

All ECG and SpO_2 alarms will be enabled.

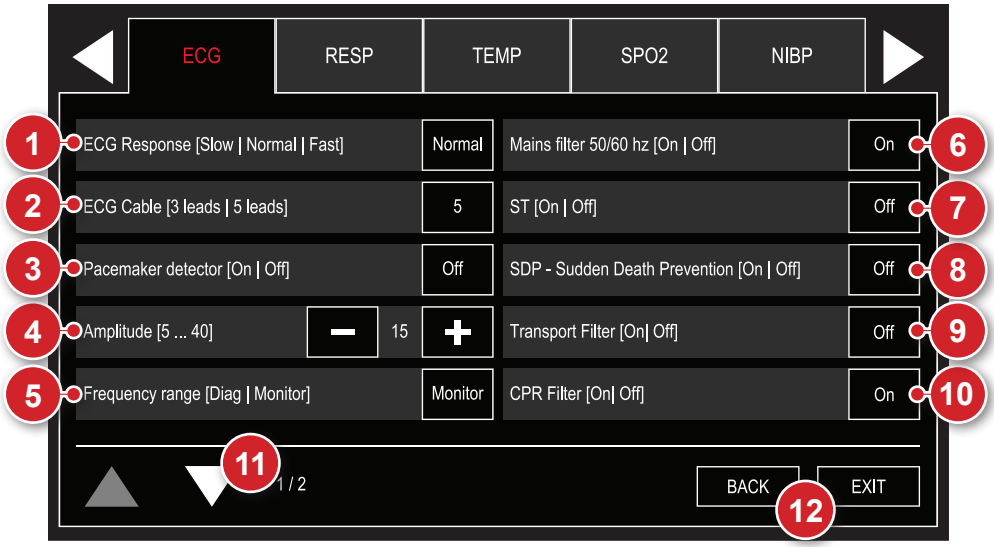
The next screen will be displayed.





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



1 - ECG response

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

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.

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.

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

Allows you to turn the pacemaker detection mode on or off. When turned on, the equipment indicates on the screen the moment of the pacemaker pulse. Detect pacemaker mode should only be used for pacemaker patients.

4 - Amplitude

Selects the gain of the ECG amplificaton step. Selectable from 5, 10, 15, 20, 30, 40 mm/mV.

5 - 35 Hz filter

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 - Transport filter

Allows enabling or disabling the ECG filter that prevents interference from motion during transportation.

10 - CPR filter

Allows turning on or off the ECG filter that prevents interference from cardiac compressions during the CPR process.

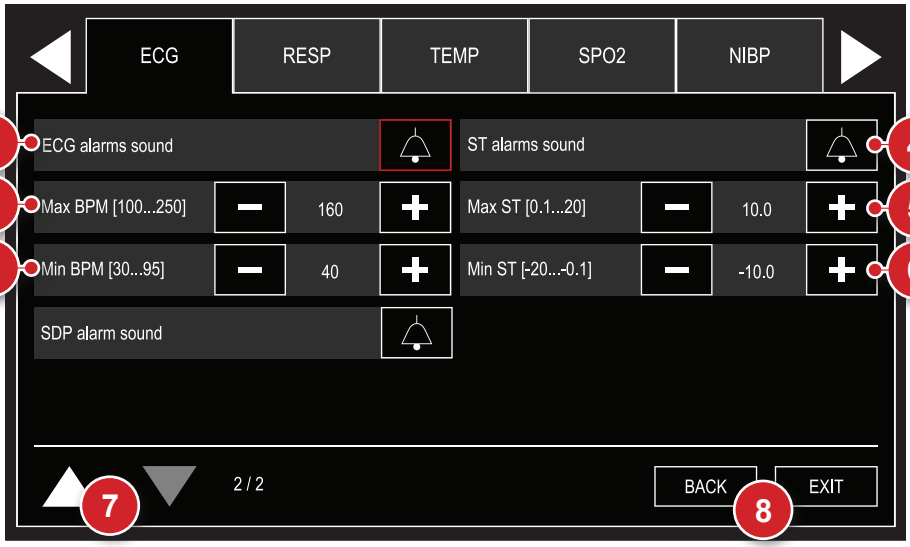
11 - Next page

Displays the next screen of the ECG menu.

12 - 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.

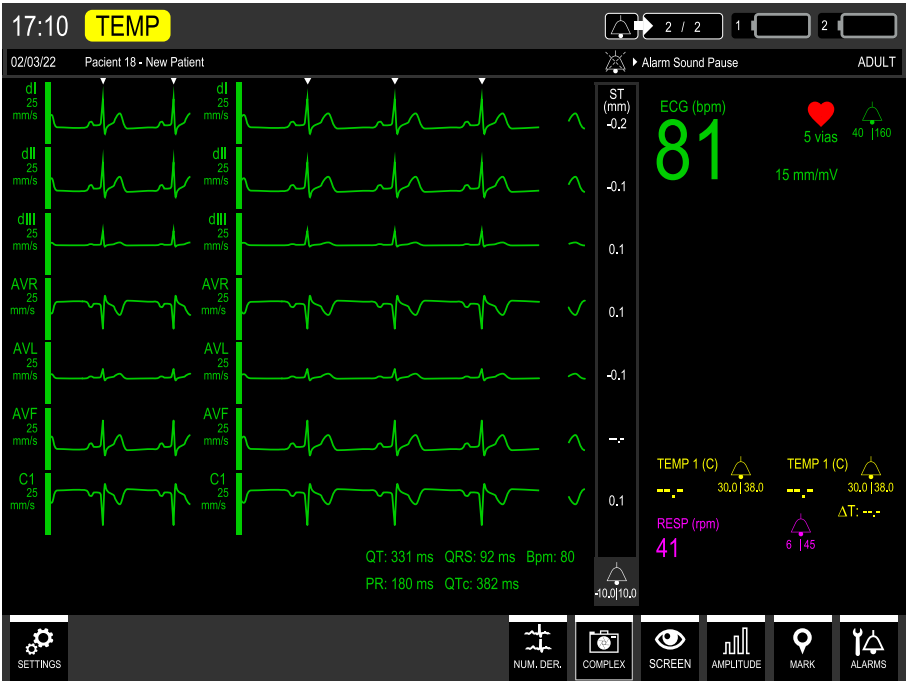
8 - Back/Exit

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

Freezing of complex

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.

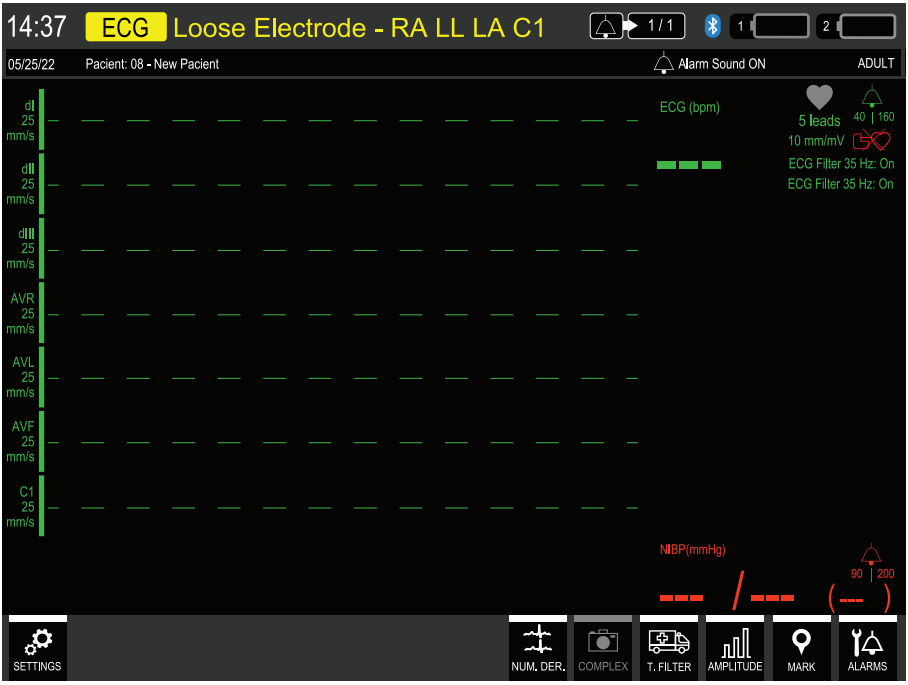
The COMPLEX key will be disabled in MODE 12 DERIVATIONS, or when there is a LOOSE ELECTRODE, or when using the 3-lead CABLE.

If the clinical operator intentionally disconnects the ECG, SpO_2 and defibrillation module, it will appear the message ECG: COMMUNICATION ERROR, SpO_2: COMMUNICATION ERROR, DEF: COMMUNICATION ERROR and the ALARM SIGNALS will be automatically disabled.

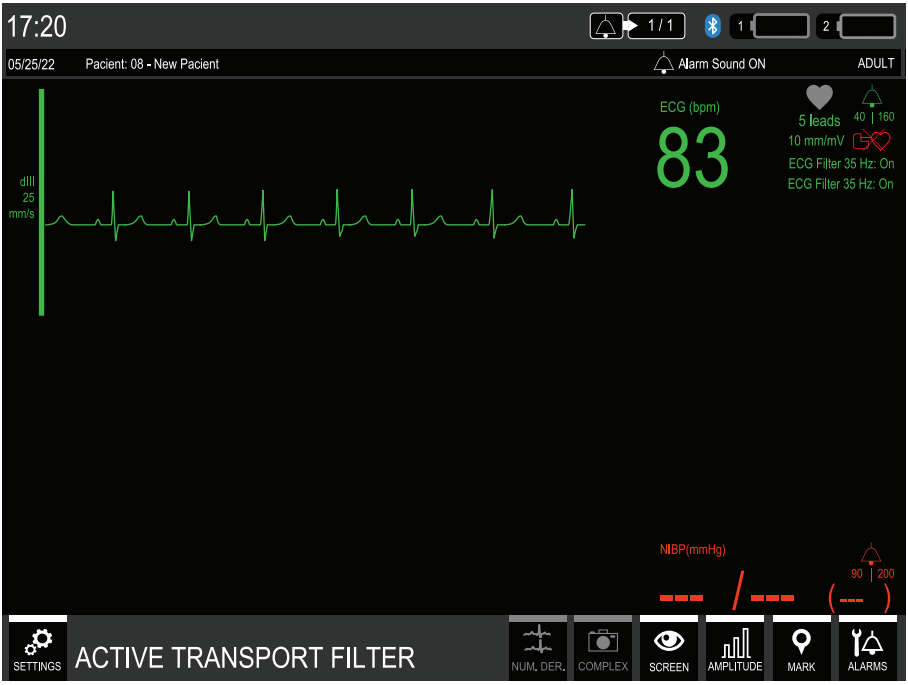
Transport filter

To enable the transport filter, select the SETTINGS icon on the shortcut buttons, navigate to the ECG tab and select "On" in the Transport Filter [On | Off] option.

After turning on the transport filter in the menu, the "T. FILTER" button will appear next to an emergency transport icon in the shortcut buttons. To actually activate this transport filter, click the "T. FILTER" button.



When this button is pressed, the equipment will show the informational message ACTIVE TRANSPORT FILTER and only one curve will be presented. In this mode it is possible to select the curve to be shown on the screen between DII or PADS..



To return to the previous screen and deactivate the transport filter, press the "SCREEN" button.

Monitor mode - NIBP

OP 12

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

Use only original Instramed clamps and conductors. Other brands may compromise the accuracy of the equipment.

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_2 sensor is. When inflating the armband, SpO_2 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.

ARMBAND SELECTION

Equipment operating mode	Armband	Limb circumference (arm/leg)
Neonatal	10 - 19 cm	3,30 cm - 15,0 cm
Pediatric	18 - 26 cm	14,0 cm - 25,0 cm
Adulto	25 - 35 cm	25,0 cm - 35,0 cm
Adult	33 - 47 cm	33,0 cm - 47,0 cm

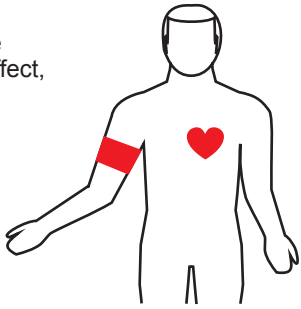
PLACING THE ARMBAND

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.

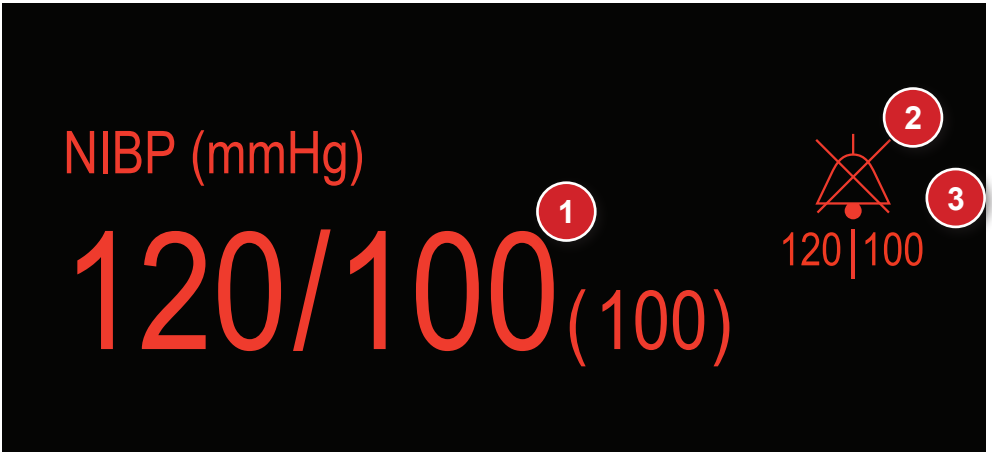
When pressing the NIBP MANUAL MEASUREMENT button while the monitor is exerting the NIBP measurement, it will immediately interrupt the measurement.

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.

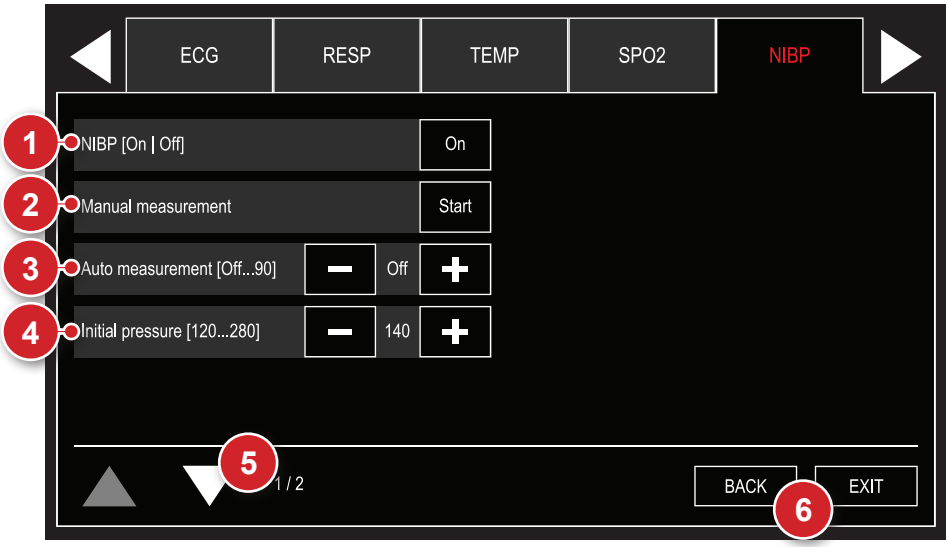
Interrupting NIBP measurements: to cancel an ongoing pressure measurement, press "NIBP MANUAL MEASUREMENT", located in the equipment's front panel. The DualMax does not offer a short-term automatic measurement option.

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 - NIBP On/Off

Enables or disables the DualMax's NIPB function.

2 - Manual measurement

Start a NIBP manual measurement.

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.

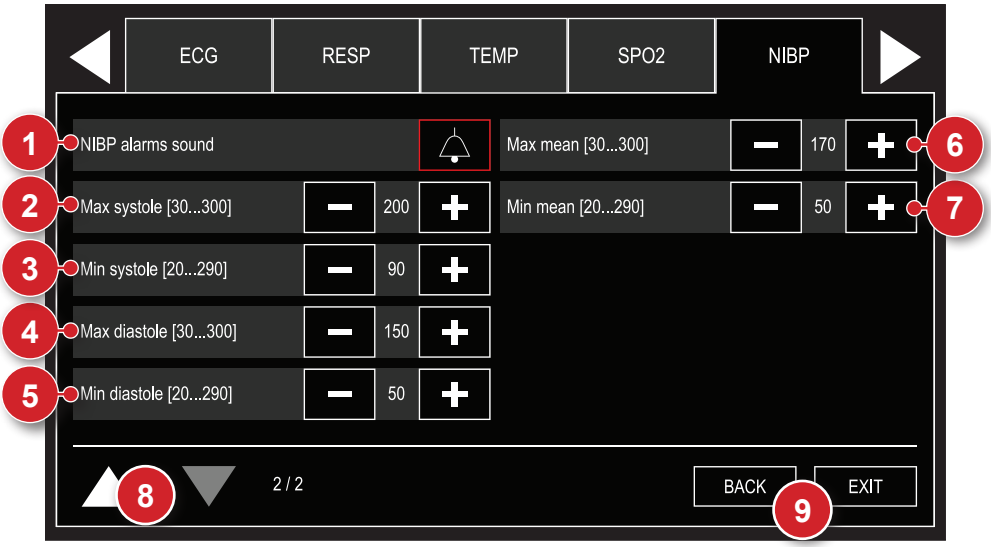
5 - Next page

Displays the next screen of the NIBP menu.

6 - Back/Exit

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

NIBP configurations - alarm



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 - mean

Selection of average pressure maximum limit..

7 - Minimum limit - mean

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.

Monitor mode - SpO_2

OP 13

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_2) 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 SpO_2 measurement is used to determine oxygen saturation, that is, if 98% of the hemoglobin molecules (the cell responsible for transporting oxygen) combine oxygen, the blood will have a saturation of 98%. Based on this, the value shown on the monitor will be 98%. During the SpO_2 measurement, it is also possible to check the pulse rate and plethysmographic waveform graph is generated.

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

Warnings

Prolonged use or the condition of the patient may require replacement of the sensor.

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_2 readings.

Position the SPO_2 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.

Use only original SpO_2 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_2 sensor.

Long cables (such as the sensor or its extender) can cause patient strangulation if incorrectly routed or handled. The SpO_2 sensor must be repositioned every 4 hours, alternating its location.

Prolonged use or patient condition may require sensor replacement. Replace the sensor every 4 hours and frequently check the integrity and circulatory condition of the skin, as well as the correct alignment of the sensor. If the sensor cannot be positioned correctly on the chosen finger, choose a smaller finger or use another sensor.

Materials that any patient, including children, pregnant and lactating women, or other people, may come into contact with without significant risk, as the SpO_2 sensor has been tested through biocompatibility testing (skin irritation, skin sensitivity, and cytotoxicity) according to ISO 10993.

When the SpO_2 value or pulse rate value is potentially incorrect, the "?" will be displayed (ISO 7000-0435, as a reference for the symbology).

It is recommended to periodically inspect extension cords and sensors for damage and discontinue use if damage is found.

Oximetry performance can be degraded when patient perfusion is low or signal attenuation is high.

NOTE: A functional tester or SpO_2 simulator cannot be used to determine the accuracy of SpO_2, the SpO_2 sensor, or the monitor's SpO_2 module itself.

Monitoring SpO_2 oxygen saturation

SpO_2 sensors do not require calibration, they are ready to use. The waveform of the curve is non-normalized.

1. Before use, the operator must check if the sensor and/or cables to be used are compatible with the DualMax, non-compatible sensors may cause risk of injury to the patient. Make sure the application site has pulsatile flow, with good circulation conditions.

2. Apply the sensor in the appropriate place, perfectly fitting the patient's finger.

3. Connect the other end of the sensor to the front panel of the equipment.

4. Periodically check the applied site, observing the correct fitting of the sensor and the conditions of the patient's skin to ensure a correct acquisition of the signal, if necessary, change the sensor location.

SpO_2 sensitivity and response

In DualMax it is possible to set the sensitivity to normal or high in the SpO_2 settings menu.

When the setting is selected for High sensitivity, signal handling is more sensitive to low signals. This setting is only recommended for patients with weak pulses.

When the setting is set to Normal, the signal is subjected to filters that ensure signal stability, that is, less susceptible to noise. This configuration is recommended for neonatal patients or patients who are not in critical health conditions, who may move and cause undue noise and signals.

It is also possible to change the SpO_2 response time through the SpO_2 settings menu. The value displayed on the screen corresponds to the average of the data collected over a period of time.

When the response is set to slow, the **longer** the averaging time will be, it will take longer for the monitor to update data on changes in oxygen saturation, but the measurements will be more accurate.

When the response is set to fast, the **shorter** the averaging time, the faster the data update of oxygen saturation changes, this mode is more suitable for patients in critical condition.

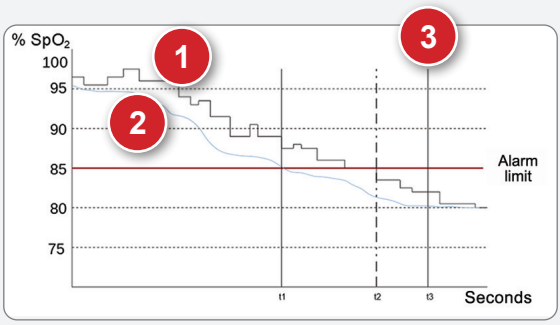
SpO_2 alarm delay

There is a delay between the physiological occurrence at the measurement site and the alarm to this occurrence in the DualMax, such delay varies according to the sensitivity configured by the operator added to the signal processing time. The lower the sensitivity and the slower the SpO_2 response, the longer will be the time between the physiological event and the monitor's alarm indication. The following illustration shows the delay components in alarm signal generation and their effects.

During traditional mono monitoring, the moment the alarm limits are violated, the DualMax will alarm immediately, with no delay in alarm generation. Alarms of this type, when they occur frequently, can be distracting. With the SpO_2 Hysteresis setting, it is possible to set a period of time below or above the alarm limit before it is triggered.

Time t2 - t1 is equivalent to the delay in the alarm condition, due to signal processing that may vary depending on the selected sensitivity level.

The t3 - t2 time is defined by the delay in alarm generation and depends on the selected SpO_2 Hysteresis setting.



1. SpO_2 displayed.
2. SaO_2.
3. Alarm signal generation.

The number of points the SpO_2 exceeds is multiplied by the number of seconds the SpO_2 level remains outside the stipulated limit. Therefore:

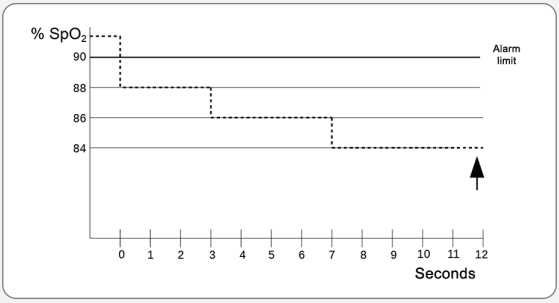
Points x Seconds = Hysteresis Limit.

Assuming the Hysteresis threshold is set to 50 and the lower alarm threshold is set to 90, the behavior will be as shown below.

Example, the SpO_2 level drops to 88 (being 2 points below the previously selected lower limit) and it remains in this condition for 3 seconds (2 points x 3 seconds = 6 hysteresis), then the SpO_2 drops to 86 for 4 seconds (4 points x 4 seconds = 16 Hysteresis), then SpO_2 drops to 84 for 5 seconds (6 points x 5 seconds = 30 hysteresis).

SPO_2	x	Seconds	=	Hysteresis
2	x	3	=	6
4	x	4	=	16
6	x	5	=	30
Total hysteresis limit			=	52

Based on the example shown, the delay in generating the alarm will be approximately 11.8 seconds, after this time, the alarm is triggered, as the Hysteresis limit has exceeded 50, as shown in the figure below:



The hysteresis limit can be configured as Off, 10, 25, 50 and 100. To configure it, just access the menu SETTINGS > SPO_2 > Page 2 > SPO_2 ALARM HYSTERESIS. Factors that affect the accuracy of the SpO_2 measurement.

Factors which affect the SpO_2 measurement's precision

- Incorrect use of the sensor.
- Anemia.
- Use of vasoactive drugs.
- Patient in shock or cardiac arrest.
- Significant number of dysfunctional hemoglobin.
- 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.

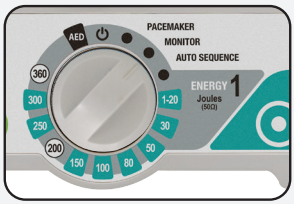
Patiente	Limb	Description	Code
Adult/Pediatric	Finger of the hand or foot	Finger Oximetry Sensor (S200A-300101, Solaris Medical)	12556

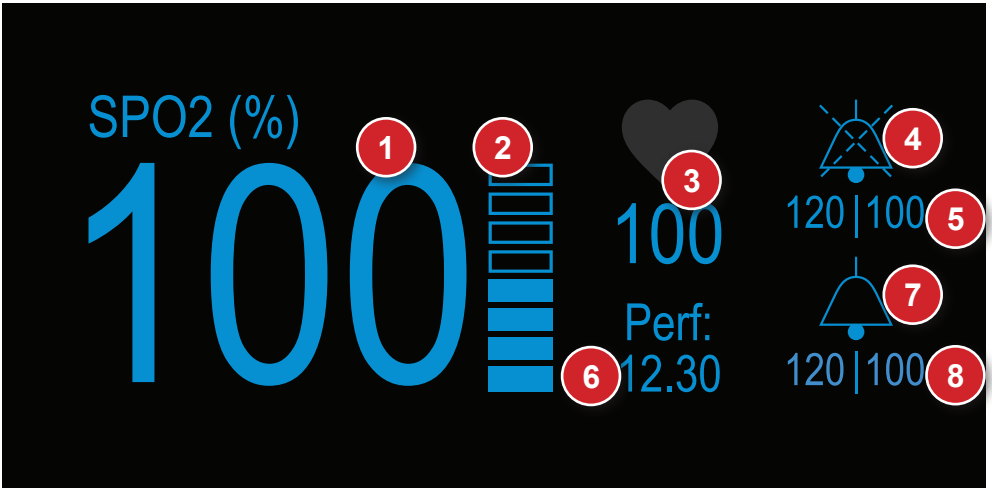
Operating in monitor mode - SpO_2

Select the selector switch to Monitor mode.

All ECG and SpO_2 alarms will be enabled.

The following screen will be displayed.





1. SpO_2 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, paused, or turned off.
8. Maximum and minimum alarm values for pulse frequency.

SpO_2 setup - principal

1 - SpO_2 On/Off

Allows to turn the parameter monitoring on or off.

2 - SpO_2 response

Selects the SpO_2 numeric update response. You can select among the SLOW, NORMAL and FAST options.

- **SLOW:** less affected by the patient's movements. However, you must pay attention to the SpO_2 slow response variations.
- **NORMAL:** used for most patients.
- **FAST:** used when the operator needs faster answers. The response is affected by the patient's movements.

3 - Sensitivity

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

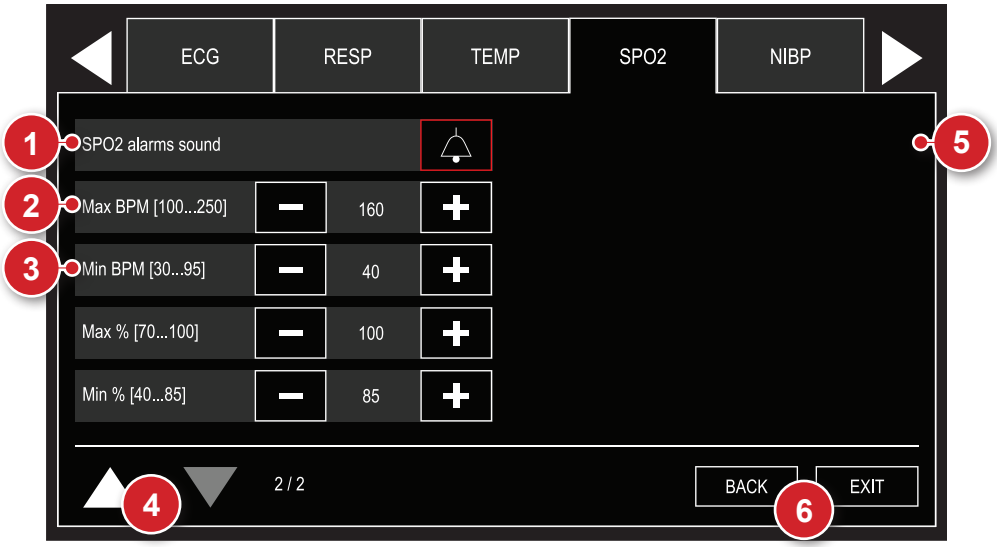
4 - Next page

Displays the next page of the SpO_2 menu.

5 - Back/Exit

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

SpO_2 configurations – alarm



1 - Alarm sound

Selection of alarm status: active sound and disabled sound.

2 - Maximum limit

Selection of BPM and SpO_2 saturation alarm maximum limit.

3 - Minimum limit

Selection of BPM and SpO_2 saturation alarm minimum limit.

4 - Previous page

Returns to the previous page of the SpO_2 menu.

5 - SpO_2 alarm hysteresis

SpO_2 alarm generation delay time selection: Off, 10, 25, 50 and 100

6 - Back/Exit

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

Monitor mode - Capnography

OP 14

Physics principle used

Capnography is a non-invasive measurement, whose graphic presentation is carried out as a function of the time of the CO_2 curve.

The capnography module used in the Dualmax is provided by Medtronic, which uses the Microstream™ method. The Microstream™ method is used in intubated or non-intubated patients. A sample of the patient's exhaled gas is collected by cannulas and sent to the chamber through the Microstream sensor inside the Dualmax. The CO_2 measurement is based on the absorption characteristics of the laser by the CO_2 molecules.

Capnography involves measuring the carbon dioxide exhaled at the end of expiration ($EtCO_2$) and the measurement of the fraction of carbon dioxide inhaled at the end of inspiration ($FiCO_2$). The capnograph is a CO_2 analyzer that displays its concentration or partial pressure both digitally and graphically.

The main information coming from the capnograph includes the partial pressure of CO_2 exhaled at the end of expiration ($EtCO_2$), fraction of carbon dioxide inhaled at the end of inspiration ($FiCO_2$), respiratory rate and the capnogram.

The capnography module provides CO_2 data in mmHg units. For displaying percentage data, the module uses the following formula to convert CO_2 readings:

$$\frac{CO_2\ (mmHg)}{Ambient\ pressure}\ x\ 100 \leftrightarrow CO_2\ (Vol\%)$$

The method used to calculate gas level readings is defined as a time window over which a new maximum CO_2 value is chosen. The measurement window controls both $EtCO_2$ values and $FiCO_2$ values. The maximum value read in the last 20 seconds is displayed.

Warnings

The CO_2 sampling line is disposable and single-use and cannot be reused under any circumstances. Its reuse can cause risk of contamination and compromise the accuracy of the measurement.

Periodically check for excessive moisture or secretion buildup in the tubing or flow sensors, which may change the CO_2 waveform. If necessary, purify or replace line and/or adapters.

The situations below may cause measurement inaccuracy or failure:

- **Leakage or internal exhaustion of sample gas.**
- **Cyclic pressure up to 10 kPa (100 cm H_2O).**
- **Crushing or mechanical shocks on the line.**
- **Other sources of interference, if any.**

In the case of a power outage, the batteries guarantee the operation of the equipment (including capnography monitoring) for approximately 4 hours.

There is no degradation in measurement accuracy due to respiration rate, as the module has automatic flow compensation.

Materials that any patient, including children, pregnant and lactating women, or others, may come into contact with without significant risk, as the CO_2 sampling lines do not have toxicity levels.

There is a risk of a possible leak in the gas passage between the sampling line and the equipment, due to the luer type connector. There is no leaching because there are no toxic gases. The gas entering the CO_2 module is breath-derived and does not physically affect the internal module mechanics.

Leakage is tested at manufacture, entering a known value of CO_2 and verifying the correct reading of this data by the monitor.

If you are unsure about the accuracy of any measurement, first check the patient's vital signs by alternate means, then make sure the monitor is functioning properly.

The device is not intended to be used as an apnea monitor.

To ensure patient safety, do not place the monitor in any position that could cause it to fall on the patient.

Carefully direct the FilterLine to reduce the possibility of patient entanglement or strangulation.

Do not lift the monitor by the FilterLine, as the FilterLine may become disconnected from the monitor, causing the monitor to fall onto the patient.

The use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.

CO_2 readings and respiratory rate can be affected by certain environmental conditions and certain patient conditions.

The monitor is a prescription device and should only be operated by qualified healthcare professionals.

If calibration does not proceed as instructed, the monitor may be out of calibration. An uncalibrated monitor can give inaccurate results.

Do not modify this equipment without authorization from the manufacturer.

Do not use the monitor with FilterLine H Set Infant/Neonatal during magnetic resonance (MR) scanning. Use of the Infant/Neonatal FilterLine H Set during an MRI scan may create an artifact on the MRI image.

When using the monitor with anesthetics, nitrous oxide or high concentrations of oxygen, connect the gas outlet to an exhaust system.

The monitor is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

The FilterLine can catch fire in the presence of O_2 when directly exposed to lasers, ESU devices or high temperatures. When performing head and neck procedures involving lasers, electrosurgical devices, or high temperature, use caution to avoid flammability of the FilterLine or surrounding surgical drapes.

Do not use the monitor with nuclear rotation tomography as the function of the monitor may be disturbed.

Operating high frequency electrosurgical equipment in proximity to the monitor may interfere with the monitor and cause inaccurate measurements.

In the event of a power outage, the batteries guarantee the operation of the equipment (including capnography monitoring) for approximately 4 hours.

There is no degradation in measurement accuracy due to respiration rate, as the module has automatic flow compensation.

CAUTION: during the MRI scan, the module must be placed away from the MRI site. When the module is used outside the MRI suite, $EtCO_2$ monitoring can be implemented using the FilterLine XL.

CAUTION: using a CO_2 sampling line with H in its name (indicating it is for use in humidified environments) during MRI may cause interference. Use of non-H sampling lines is advised.

CAUTION: In high altitude environments, $EtCO_2$ values may be lower than values observed at sea level, as described by Dalton's law of partial pressures. When using the monitor in high altitude environments, it is advisable to take this into account and consider adjusting the $EtCO_2$ alarm settings accordingly.

Capnography monitoring

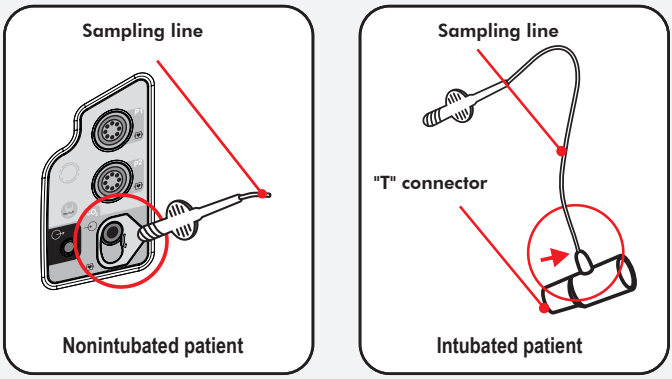
To start the $EtCO_2$ measurement, navigate through the "**Configuration Menu - CO_2**" and set the "**CO_2 - On/Off**" item to ON.

Right after the start, the $EtCO_2$ module performs a procedure called "auto-zero", which is necessary for the proper functioning of the equipment. During this procedure, no measurements are exerted.

DualMax can monitor $EtCO_2$ in intubated patients. To do this, just change the accessories.

Connect the following accessories:

- **Intubated patient:** lsampling line and "T" connector.
- **Paciente intubado:** sampling line and nasal cannula.



Sampling line

The sampling line colects 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.

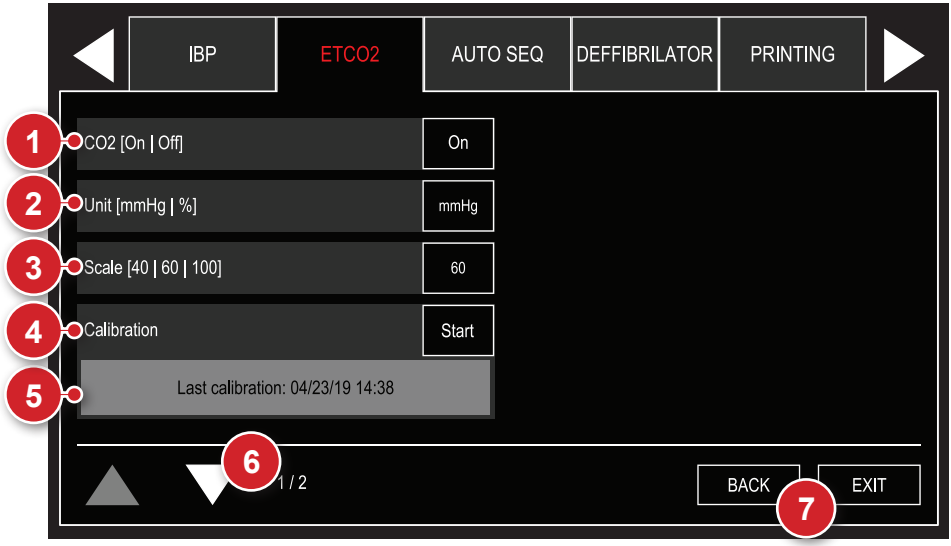
Sampling lines are disposables and non-washable.

$EtCO_2$ numeric indicator

1. Numeric value for the $EtCO_2$ expiration. The value of the $EtCO_2$ measured at the end of expiration is informed in mmHg or percent.
2. Numeric value for the $FiCO_2$ inspiration. It informs, in mmHg or percentage, the value of CO_2 measured at the end of the inspiration.
3. The “BELL” Icon - Indicates audio in pause.
4. Maximum and minimum alarm values.
5. Maximum $FiCO_2$ alarm values.

$EtCO_2$ setup - principal

Using the e-Jog select the respiration function in the setup menu to access the $EtCO_2$ setup sub-menu.



1 - CO_2 On/Off

Turns the CO_2 module on or off. When on, the sampling pump is also operating. The numeric values, graphs and CO_2 alarms will be activated.

2 - Units

Selects the measuring units of the CO_2 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_2 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.

After the patient monitor has been used for 4000 hours of operation or 12 months, a complete inspection must be performed by a QUALIFIED TECHNICIAN.

To run it manually, wait at least 1 minute after startup before starting the calibration.

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 $EtCO_2$ menu.

7 - Back/Exit

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

$EtCO_2$ configurations - alarm

1 - Alarm sound

Selection of alarm status: active sound and disabled sound.

2 - Maximum CO_2 limit

Selection of the maximum CO_2 alarm limit.

3 - Minimum CO_2 limit

Selection of the minimum CO_2 alarm limit.

4 - Maximum $FiCO_2$ limit

$FiCO_2$ upper alarm limit selection.

4 - Previous page

Returns to the previous page of the $EtCO_2$ menu.

5 - Back/Exit

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

Monitor mode - Respiration

15

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.

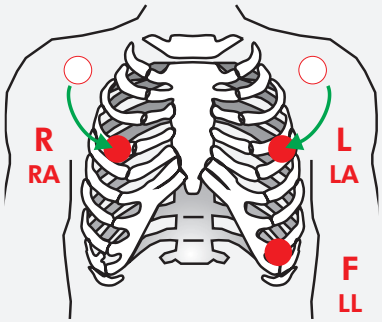
The respiratory rhythm must be used to detect apnea.

Patient's excessive movements may cause imprecise measurements.

Respiration monitoring

The breathing signal is obtained by ECG electrodes. For more information o 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 bellow the nipples, as shown in the picture below:

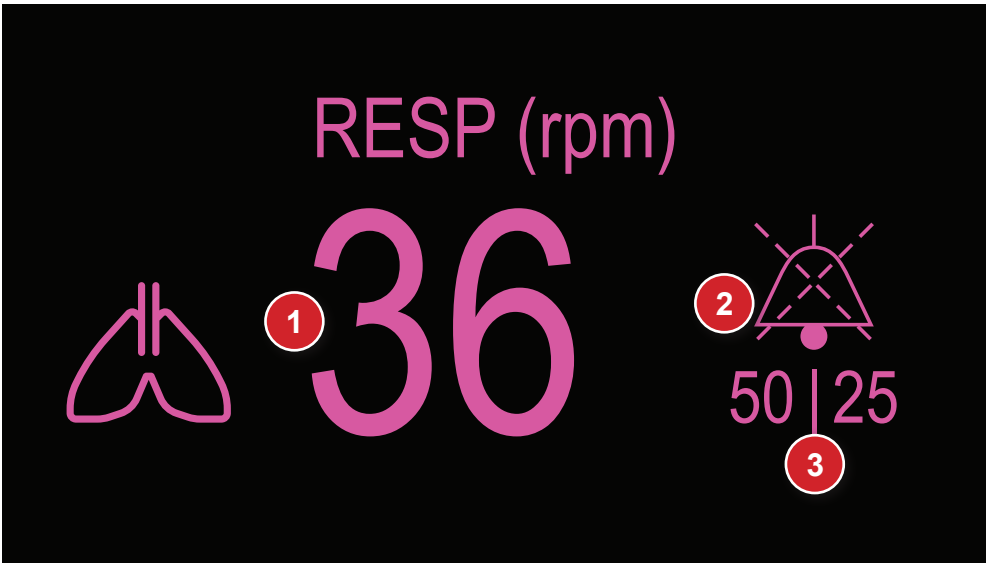


WARNING: when repositioning the electrodes, the ECG waveform and amplitude may change.

WARNING: only the respiration numeric value is obtained by the CO_2 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).

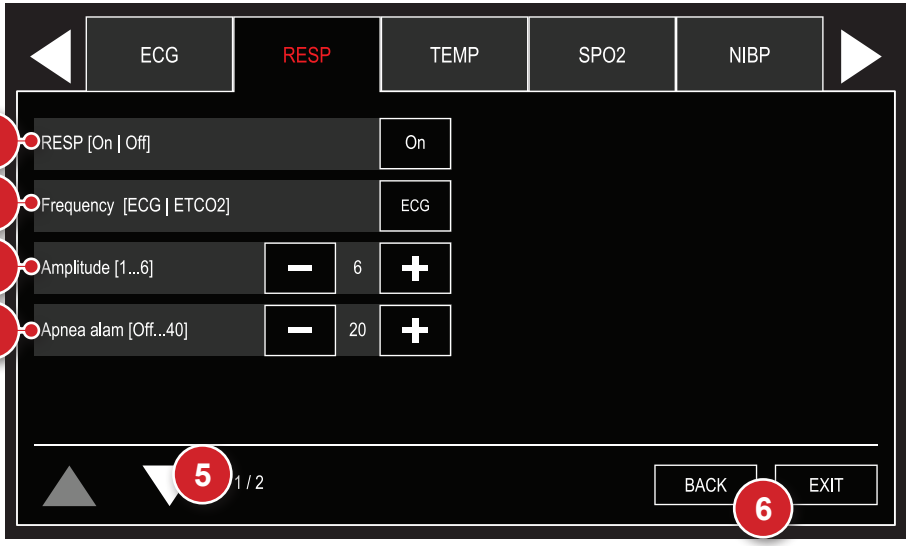
Respiration numeric indicator



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_2).

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

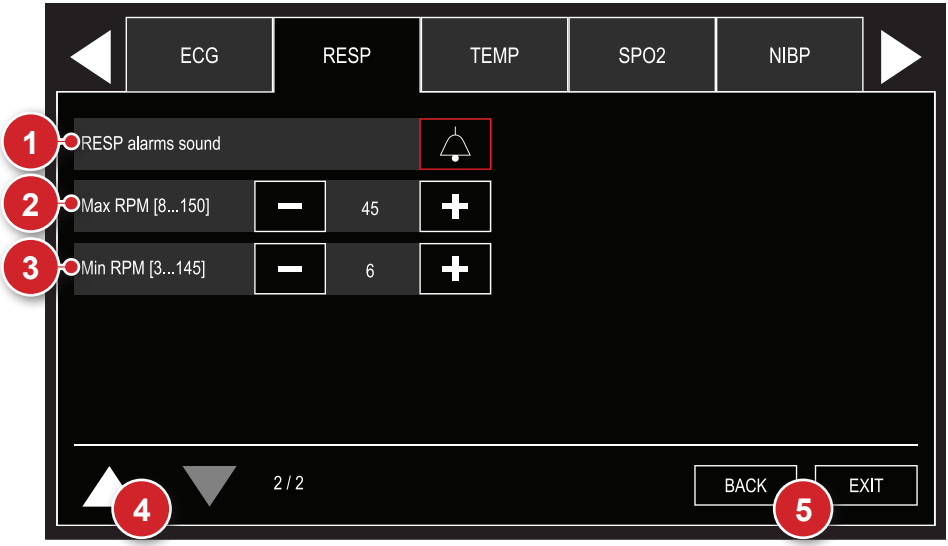
Displays the next page of the RESP menu.

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 sound

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 configuration menu or "EXIT" to monitoring screen.

Temperature monitoring

OP 16

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 (°C) or Fahrenheit (°F).

Monitorizando a temperatura

The DualMax uses YSI 400 standard temperature sensors.

In each type of sensor, instructions are found for its proper use and maintenance.

The sensors are for use on the surface of the skin and can be an adult or child model, **with direct contact**.

The temperature indicated by the equipment corresponds to the measurement location to which the supplied sensor is coupled.

For the temperature measurement, it is necessary to wait at least 5 minutes for the temperature to stabilize.

Between temperature measurements, it is necessary to wait at least 5 minutes for temperature stabilization.

Warnings

Materials that any patient, including children, pregnant and lactating women, or other people, may come into contact with without significant risk, as the temperature sensor has been tested through biocompatibility testing (skin irritation, skin sensitivity and cytotoxicity) according to ISO 10993.

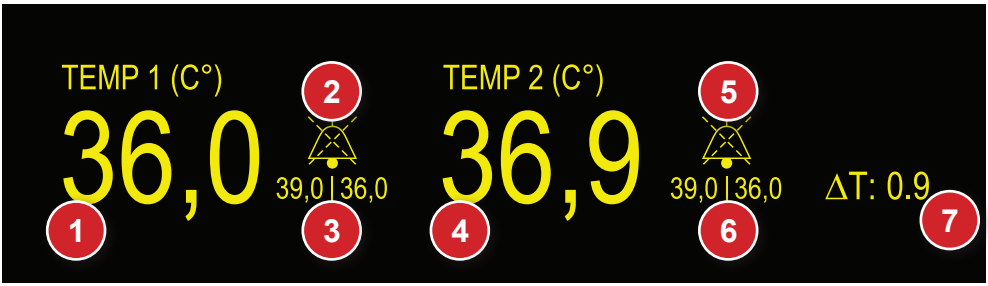
The temperature monitor can experience changes in environmental conditions which may affect the accuracy of the temperature reading, in which case it is recommended to use it in a controlled environment.

Environmental temperature or relative humidity conditions can affect temperature sensor performance.

To identify the temperature measurement location, refer to the probe manual that comes with the package.

The indication range adjustments must be configured according to the operating range indicated in the instruction manual that comes with the temperature probe, if the range is not in accordance, the monitor may display incorrect temperature readings or present values outside of accuracy.

Temperature numeric indicator



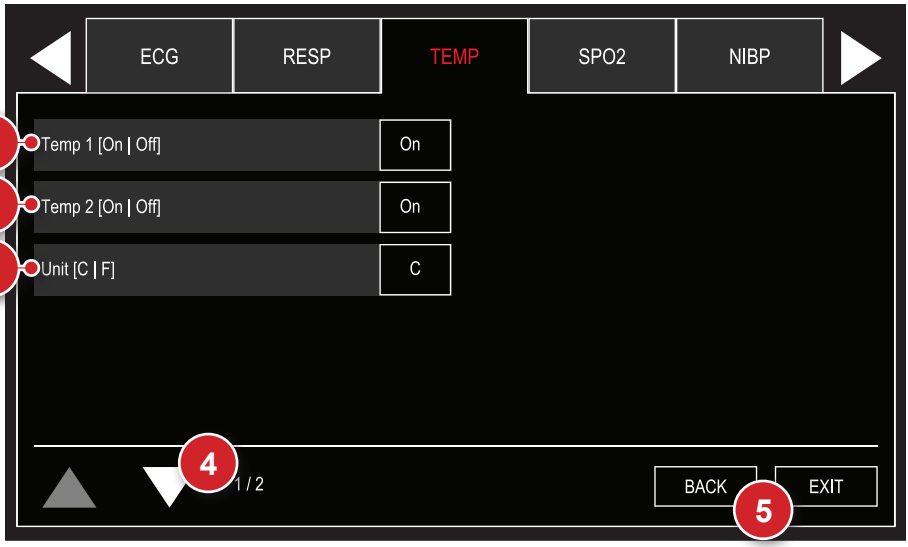
1. Channel 1 temperature numeric value.
2. Channel 1 “BELL” Icon - Indicates if audio is active, paused or off.
3. Channel 1 Maximum and minimum alarm values.
4. Channel 2 Temperature numeric value.
5. Channel 2 “BELL” Icon - Indicates if audio is active, paused or off.
6. Channel 2 Maximum and minimum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

Invasive pressure monitoring

OP 17

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.

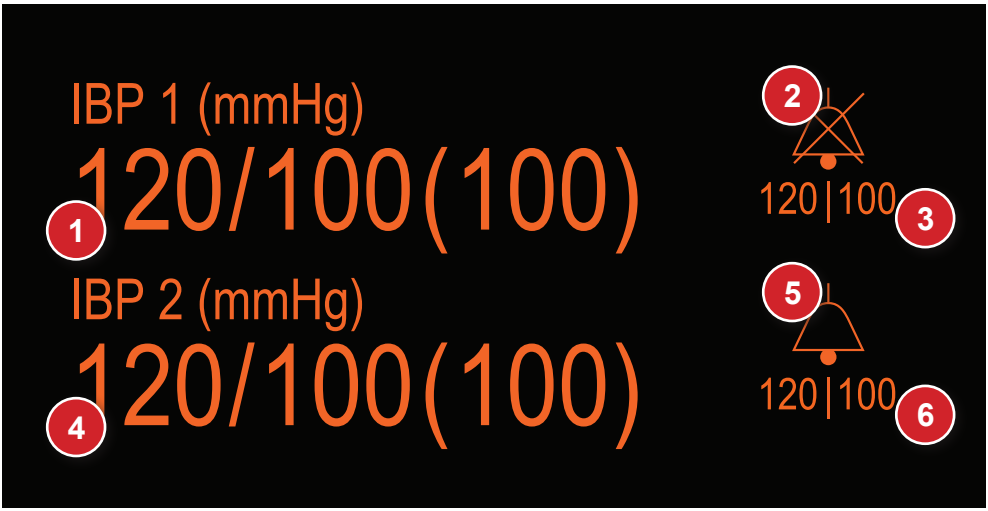
The invasive technique is regularly employed in intensive care medicine, anesthesiology and for research purposes.

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



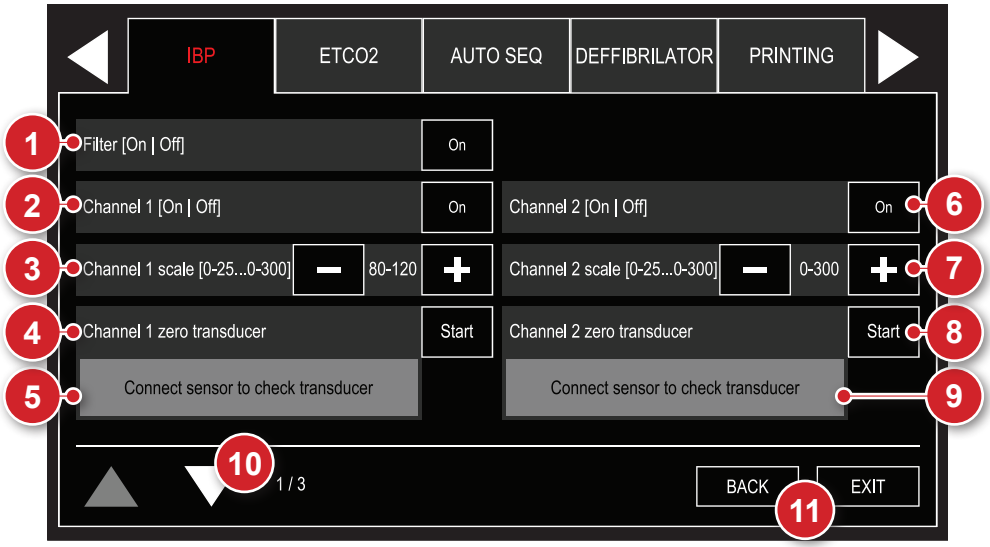
1. Channel P1 invasive pressure numeric value. SYSTOLE/DIASTOLE (AVERAGE).
2. Channel P1 “BELL” Icon - Indicates if audio is active, paused or off.
3. Channel P1 Maximum and minimum alarm values.
4. Channel P2 invasive pressure numeric value. SYSTOLE/DIASTOLE (AVERAGE).
5. Channel P2 “BELL” Icon - Indicates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

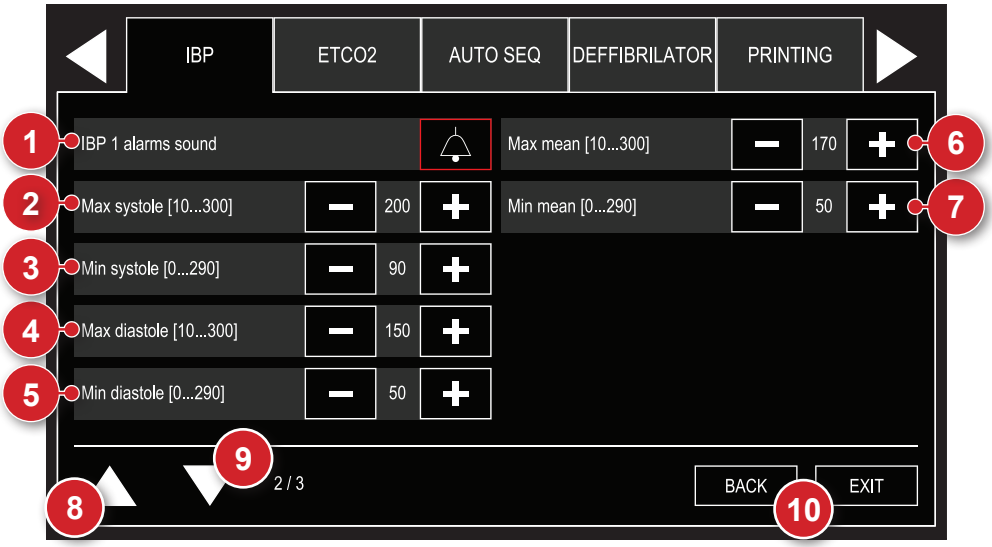
c. Patient must be:

- **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



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 - mean

Selection of average alarm maximum limit for channel 1.

7 - Minimum limit - mean

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

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 - mean

Selection of average alarm maximum limit for channel 2.

7 - Minimum limit - mean

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.

ST segment

18

Relation between ST elevation and myocardial infaction

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).

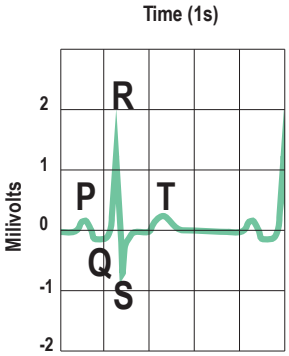
Ranges up to ± 2 mm are frequent and normal in healthy patients.

ST elevation characterization

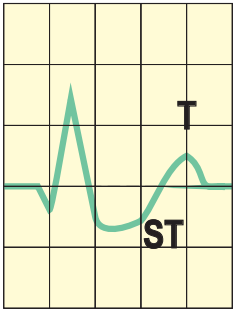
The waves recorded on the ECG are identified by the points ranging from P to T, as shown in figure 1.

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

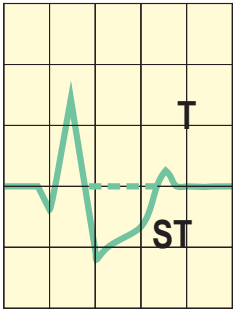
The indication of possible acute myocardial infarction is an evident decrease of the ST segment, represented by the decrease or inversion of the concavity of this region of the curve (other figures).



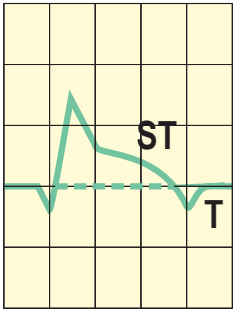
Normal ST segment (Fig. 1)



ST depression



ST depression

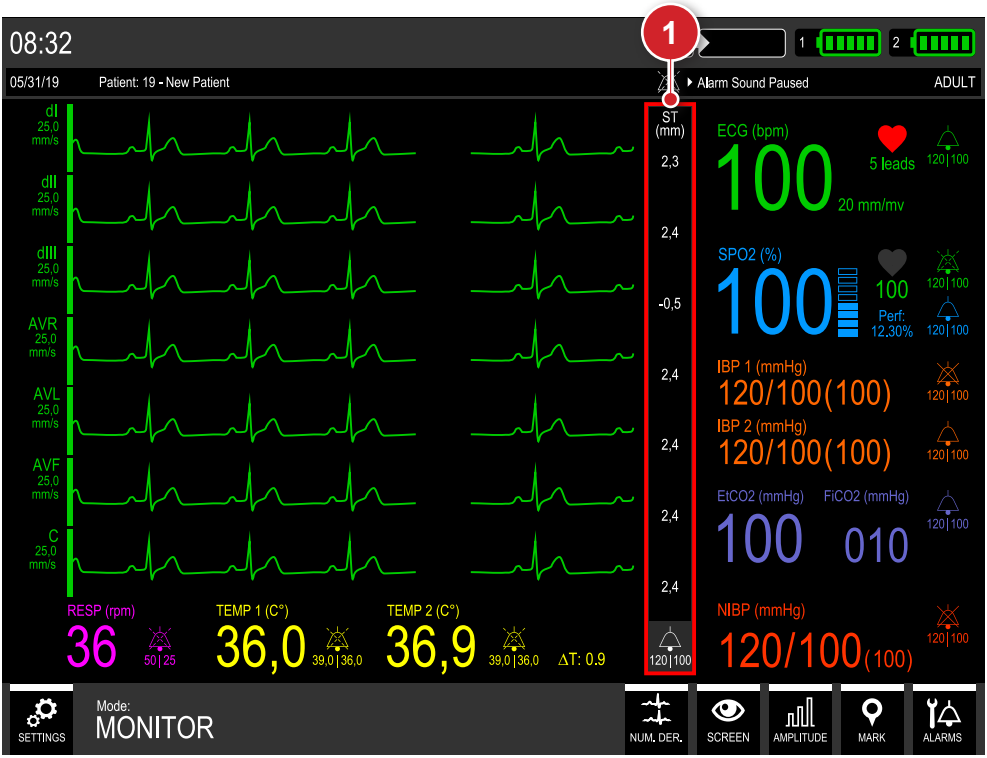


ST elevation

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.

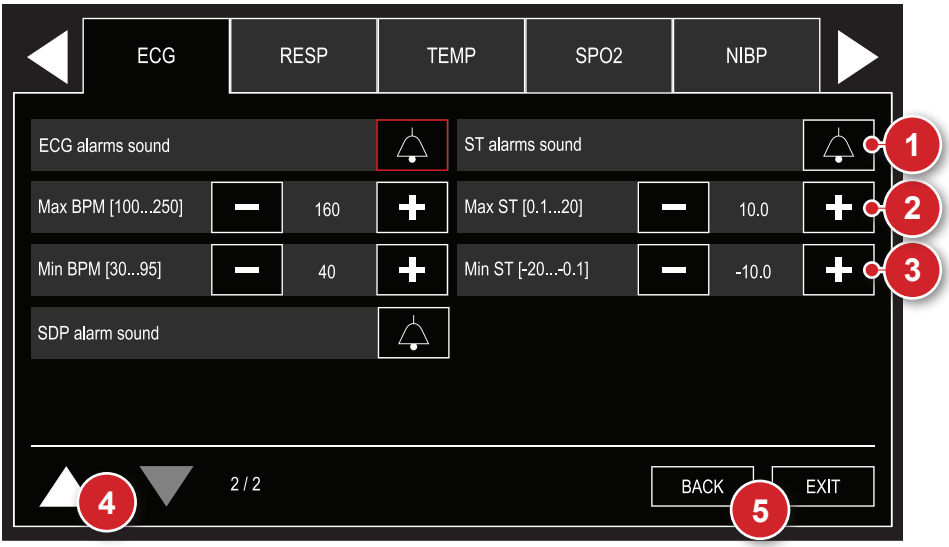
See figure on next page.

Turning 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”).

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.

Trendings

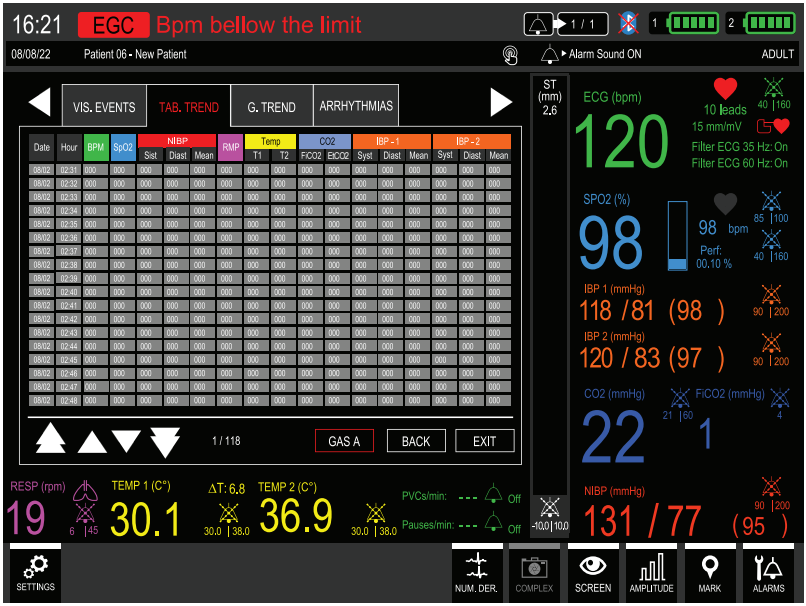
19

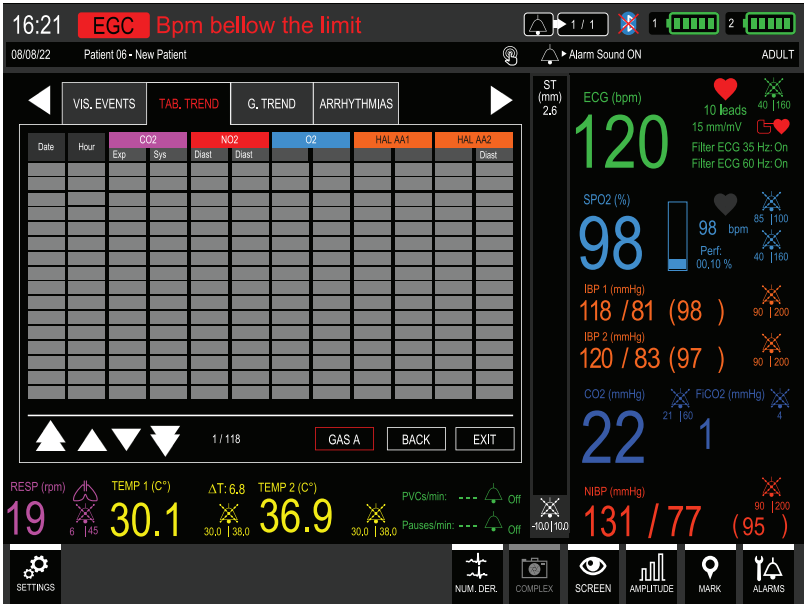
Data storage

Trend data is stored for all parameters, observing the average of the last 40 seconds, except NIBP. In this case, all measured values are stored. Along with parameter data, date and time are stored.

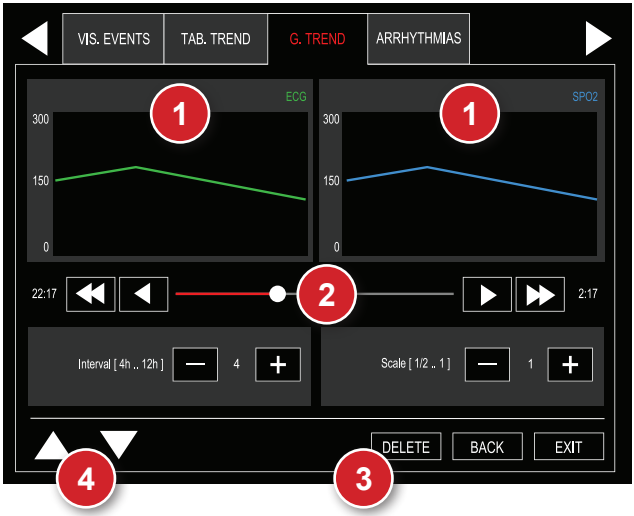
The DualMax has the capacity to store up to 168 hours of monitoring. When the volume of information exceeds this limit, the device will replace the oldest data with the most recent values.

Graph selection and trends

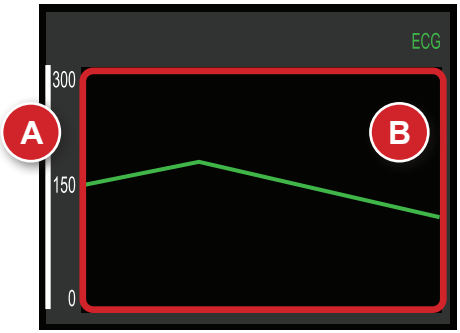




When selecting “Graphic Trend” in the “Configuration Menu”, the DualMax will show the graphic trend of all parameters, in four screens (two parameters per screen).



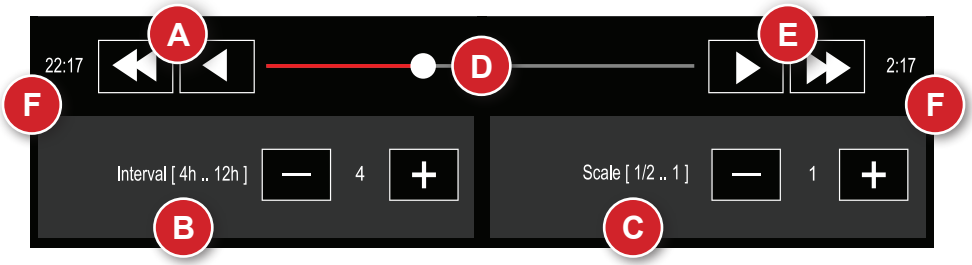
1 - Trend graph area



A - VERTICAL SCALE OF THE GRAPH: upper and lower limits of the measurement unit of the parameters.

B - GRAPHIC TREND AREA.

2 - Navigation of the trend graphic area



A - BACK POSITIONS: Return positions on the chart ◀. **START**: goes to the beginning of the chart ◀◀.

NOTE 1: It takes 4 hours of data storage to check graphs in graphical trends.

NOTE 2: On the left is the oldest data in memory and on the right is the newest data.

B - INTERVAL: configurable in 4, 6 or 12 hours. It also adjusts the size of the window visible on the graph (X axis).

C - SCALE: configurable in 1 (full parameter scale) or 1/2 (most significant half) (Y axis).

D - POSITION: the red bar indicates the amount of memory used. The white line and the numbers below it indicate the position of the view.

E - ADVANCE: advances positions on the graph [▶]. **END OF GRAPHIC**: goes to the end of the graph [▶▶].

F - TEMPORAL REFERENCE: start and end time of the graph plotting time.

3 - Delete trend

Clears all the DualMax's trend memory.

4 - Screens

Goes forward or back to the display of the screens:

- **Screen 1**: ECG and SpO_2.
- **Screen 2**: NIBP and TEMP.
- **Screen 3**: P1 and P2.
- **Screen 4**: $EtCO_2$ e RESP.

Arrhythmia analysis

20

Physical principle used

The analysis of arrhythmias in the DualMax is performed using an arrhythmia classifier algorithm. The purpose of the arrhythmia algorithm is to monitor the ECG of adult, pediatric, and neonate patients for heart rate and ventricular arrhythmias, and to generate events/alarms for one or more ECG leads. The arrhythmia algorithm is not capable of classifying the beats in situations such as: electrode loose, asystole, pacemaker present, and with a three-way cable with a curve different from DII.

Arrhythmia

The classifier algorithm detects the following arrhythmias:

- Ventricular tachycardia.
- Sinus bradycardia.
- Tachyarrhythmia.
- Ventricular bigeminy.
- Ventricular trigeminy.
- ESV R over T.
- Succession of ESVs.
- Pair of ESVs.
- Break.

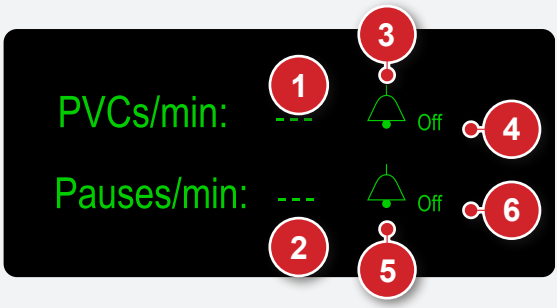
Warnings

It is not necessary for lead DII to be on the screen for arrhythmia analysis to be performed, except when using a 3-lead ECG cable. With a 5 or 10-lead ECG cable, it is sufficient for it not to be in a loose electrode condition. The analysis is also conducted with paddle signals.

The phenomenon of bundle branch block or any other type of fascicular block, which should be classified as a normal beat, poses a challenge to the arrhythmia algorithm. If, during block changes, the QRS complex varies significantly from the learned normal pattern, the blocked beat might be incorrectly classified as ventricular, leading to a false premature beat alarm.

The arrhythmia classifier performs analysis only on amplitudes starting from 0.10 mV.

Numeric indicator of arrhythmias per minute.



1. Numeric value of ventricular premature contractions quantity.
2. Numeric value of the quantity of pauses between beats.
3. "ESV" BELL icon - Indicates active audio, paused, or turned off.
4. Configured alarm value for the quantity of ventricular premature contractions (ESVs).
5. Pauses BELL icon - Indicates active audio, paused, or turned off.
6. Configured time value for detecting a pause between beats.

Arrhythmia setup - principal

Using the e-Jog, select the arrhythmia function in the “Configuration menu” to access the arrhythmia configuration submenu.

1 - Arrhythmias

Turns the arrhythmia analysis feature on or off. When turned off, all visual and audible alarms are inhibited and there is no numeric indication for this parameter.

2 - Tachycardia limit

Selection of the maximum beat limit for the tachycardia alarm.

3 - Pause limit

Selection of the maximum time limit (in seconds) for the pause alarm.

4 - ESV per minute

Selection of the upper limit of the amount of ventricular extrasystoles that can occur in one minute for the ESVs alarm.

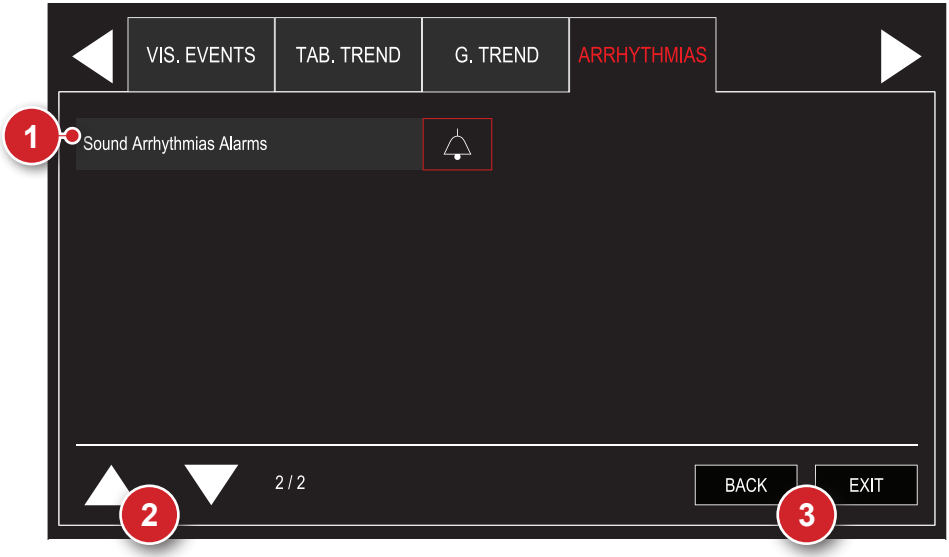
5 - Next page

Displays the next screen of the arrhythmia menu.

6 - Back/Exit

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

Arrhythmia configuration - alarms



1 - Arrhythmia alarm

Alarm status selection for arrhythmias: active sound and disabled sound.

2 - Previous page

Returns to the previous screen of the arrhythmias menu.

3 - Back/Exit

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

Event and data storage

21

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.

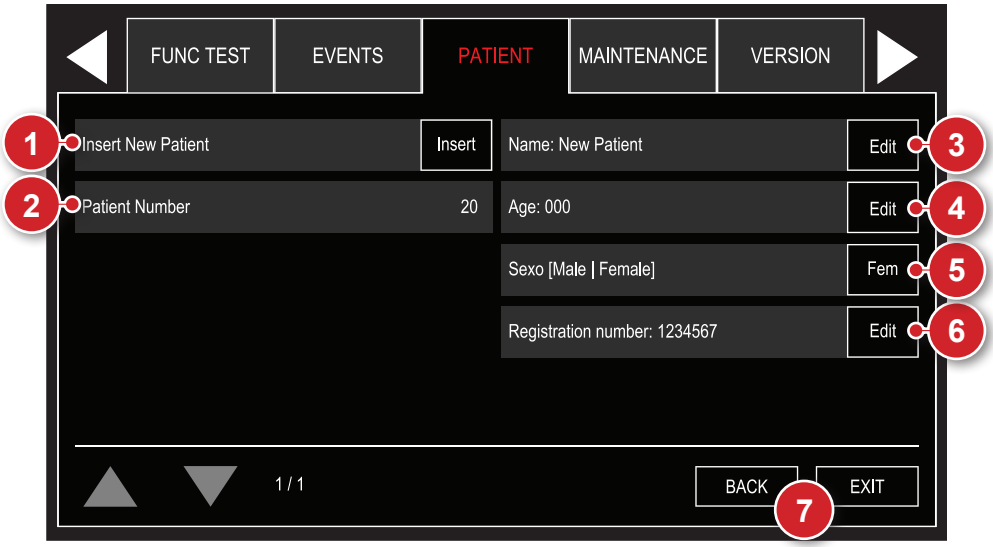
ATTENTION: when the events memory is fully filled, DualMax will begin to overwrite the oldest data.

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 does not suffer modification.

Patient configurations



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.

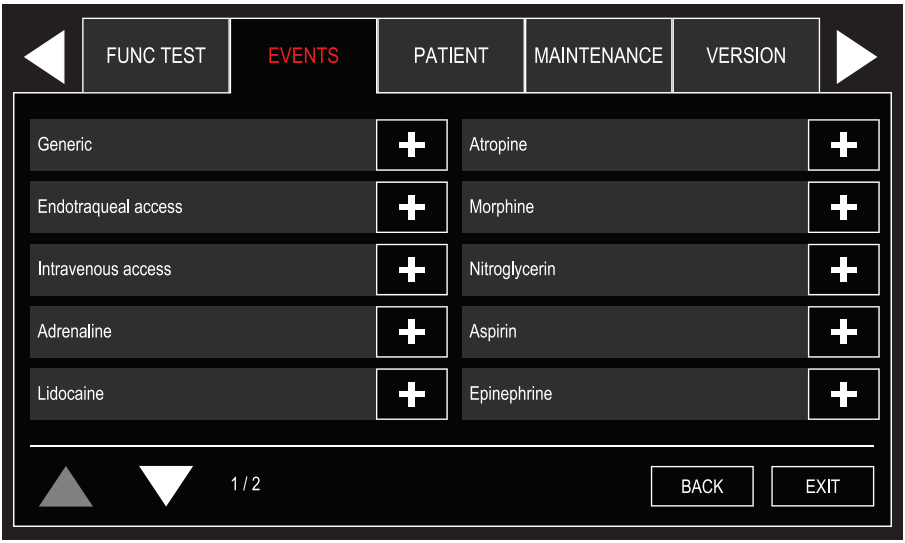
7 - Back/Exit

"BACK" to the configuration menu or "EXIT" to 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

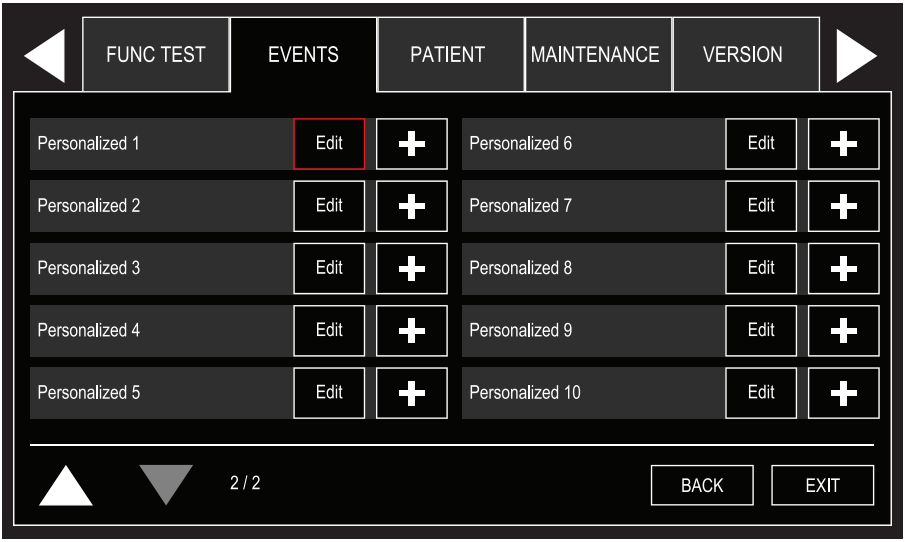


Allows to manually mark the following events:

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

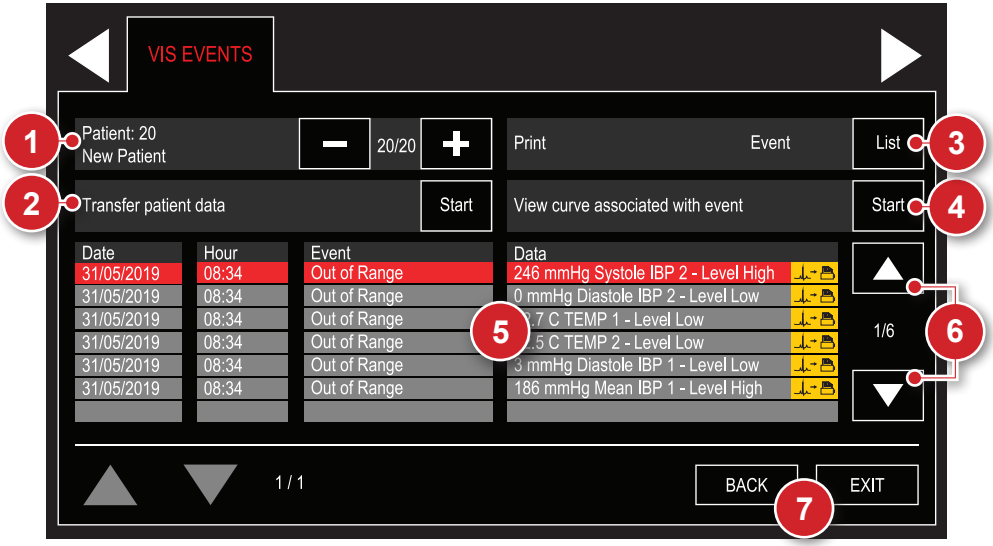
Personalized events

Allows to mark or edit up to 10 personalized events.



View events

Allows to view, print and transfer the generated events.



1 - Patient selected

Allows to select the patient whose events will be displayed.

2 - Transfer patient data

Transfers the stores events data to a flashdrive.

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

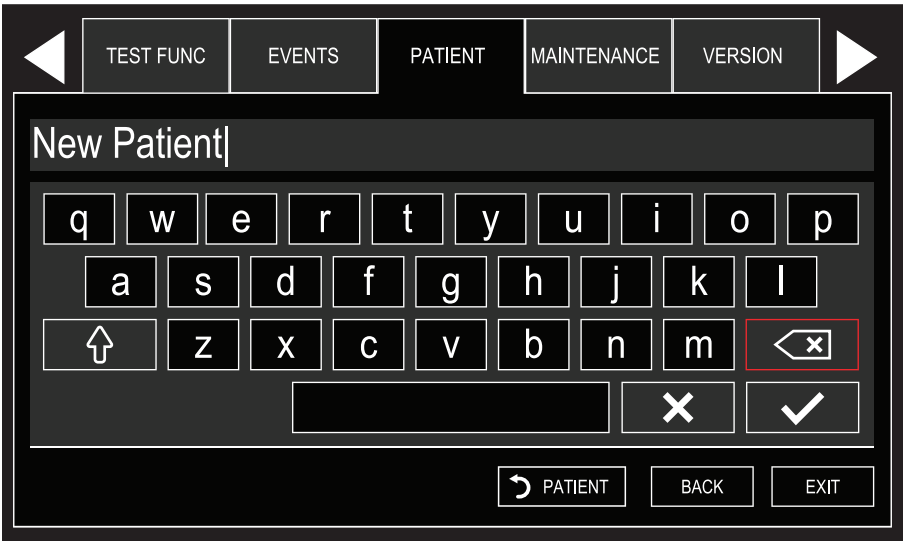
Allows to select an event and roll the list.

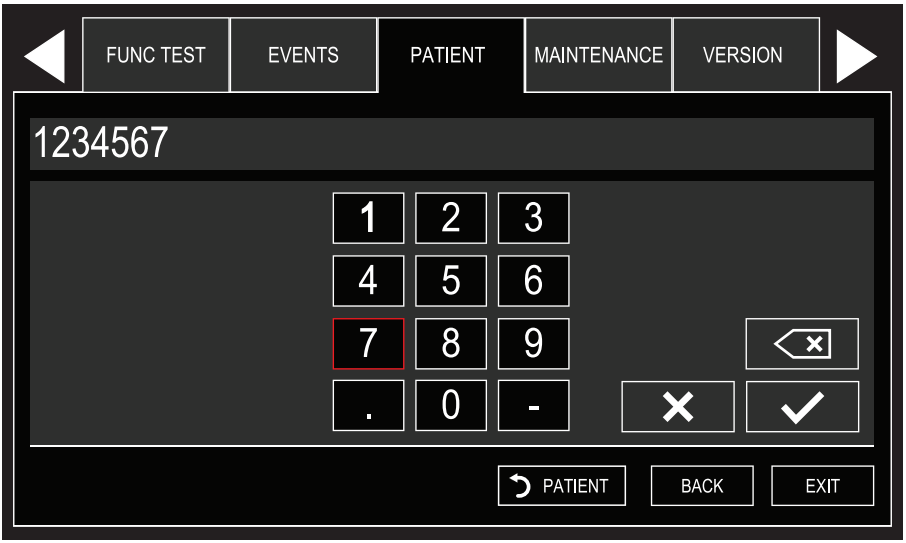
7 - Back/Exit

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

Keyboards

Personalized 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:



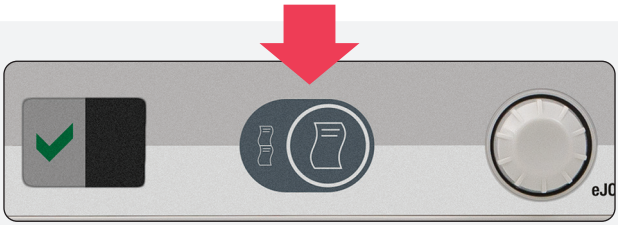


Printing

OP 22

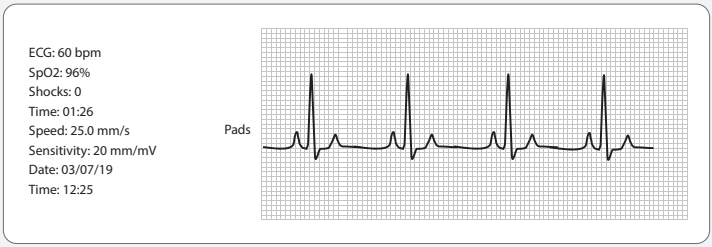
General

The thermal printer OP 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.

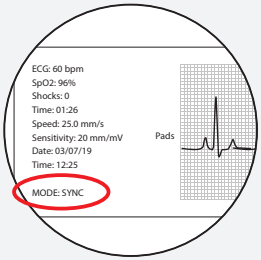
Configurations

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 picture below.



3 - Paper size

Informa ao equipamento quantos centímetros de papel serão impressos ao pressionar o botão impressão:

Large = length 30 m.

Medium = length 23 m.

Small = length 15 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.

*When equipped with the 12-lead ECG OP.

6 - Back/Exit

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

Functional test

23

General

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

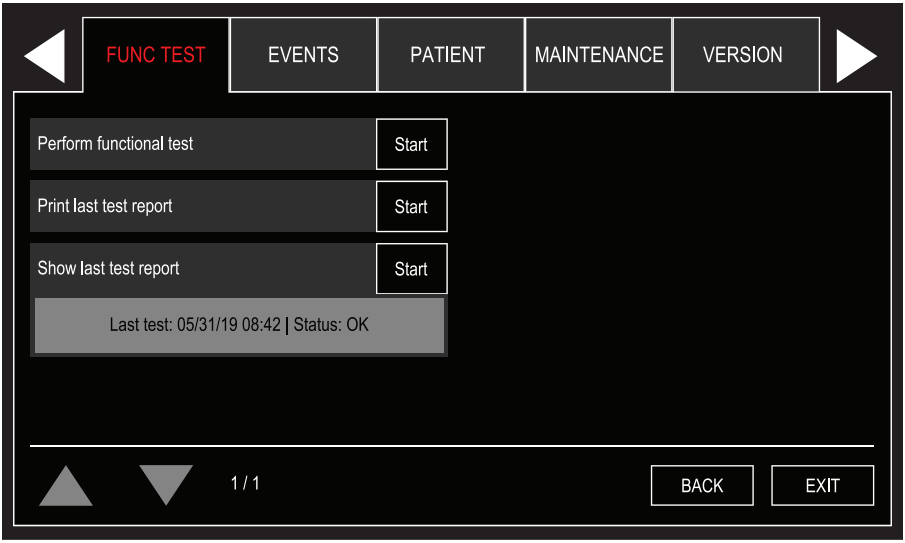
Performing the functional test

To perform the functional test, simply click on the TEST shortcut, or go to the menu and select the "FUNC TEST" 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.



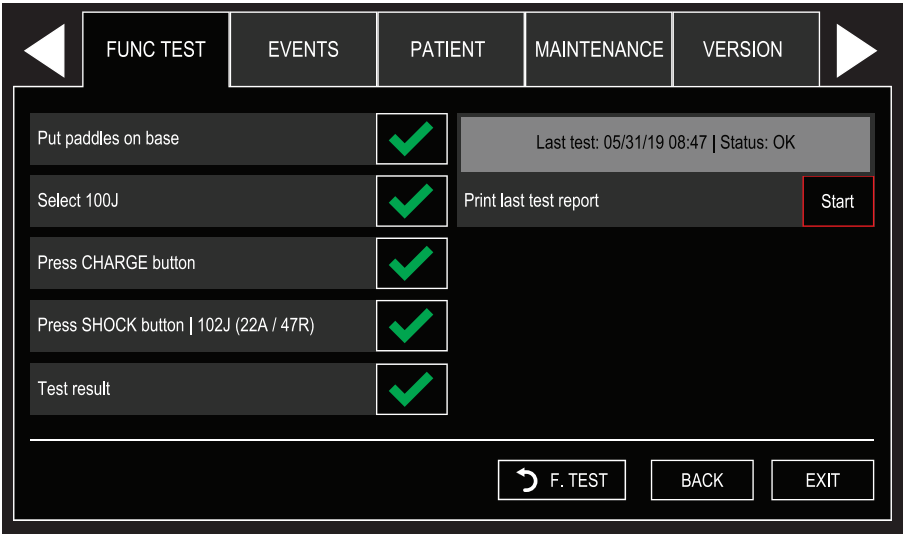
ATTENTION: if DualMax fails the functional test, contact technical support immediately.

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.



RTC - Real Time Check

OP 24

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. The diagnostic results are sent to the PC with the CTR System software installed and within network reach.

RTC operation on DualMax

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

PC connection

OP 25

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:

- Operating System Windows XP, Vista, 7 or higher version of Windows.
- 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

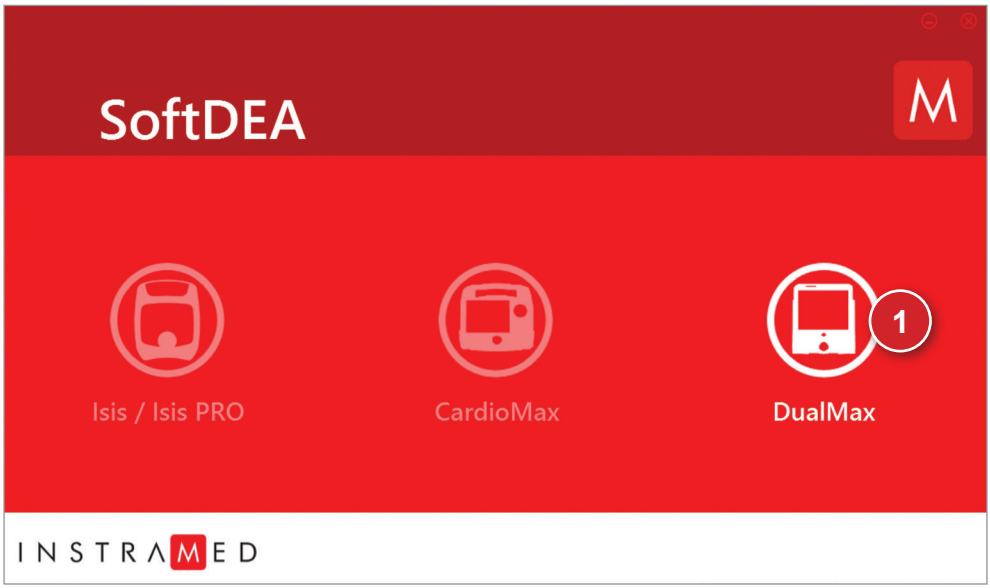
- Access **https://www.instramed.com.br/softwares.html** to download the software or insert the program CD in the CD/DVD ROM drive.
- If the autorun does not start automatically, find the **softdeasetup.exe** file in the CD and double-click it.
- Follow the installation instructions which will show up 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.

ATTENTION: accessories connected to the data interface must be certified according to IEC 60950 for data processing equipment.

Startup screen



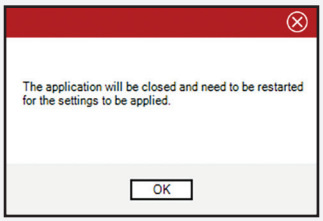
1 - DualMax services initialization button

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

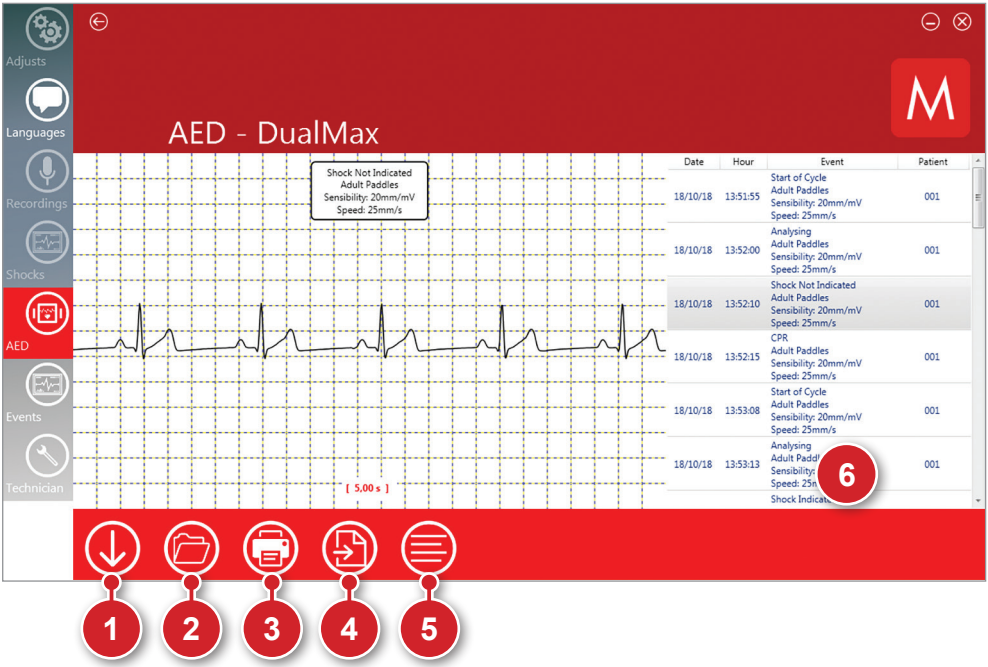
SoftDEA language selection screen

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.

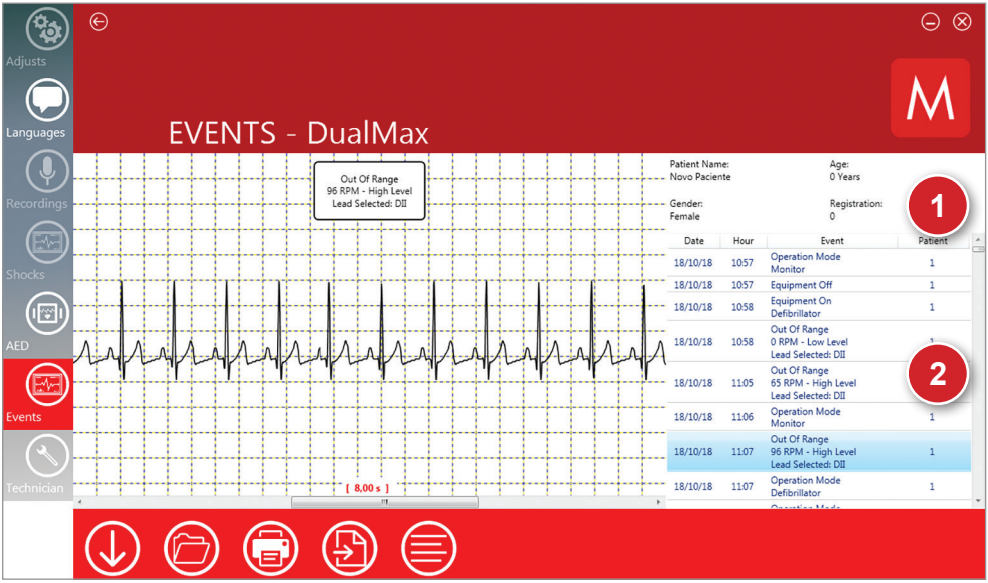
- TURNED ON - The equipment was turned on.
- CPR - Equipment indicating the CPR procedure.

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

- Access **https://www.instramed.com.br/softwares.html** to download the software or 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. Equipment that do not have the transmitter installed, will not have communication with the central station installed on the PC.

RTC software operation

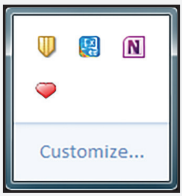
The RTC software runs in the background, with the minimized system awaiting a device to communicate with the "Real Time Check Control Center".

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:

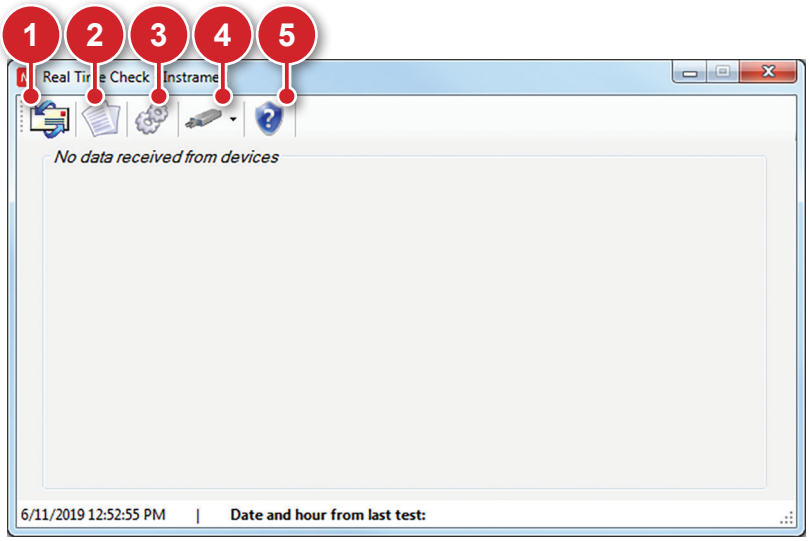
- Test of the connection with the ECG board.
- Test of the defibrillator module.
- Check of the battery level.
- Check of the connection with the power outlet.

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 following figure:



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



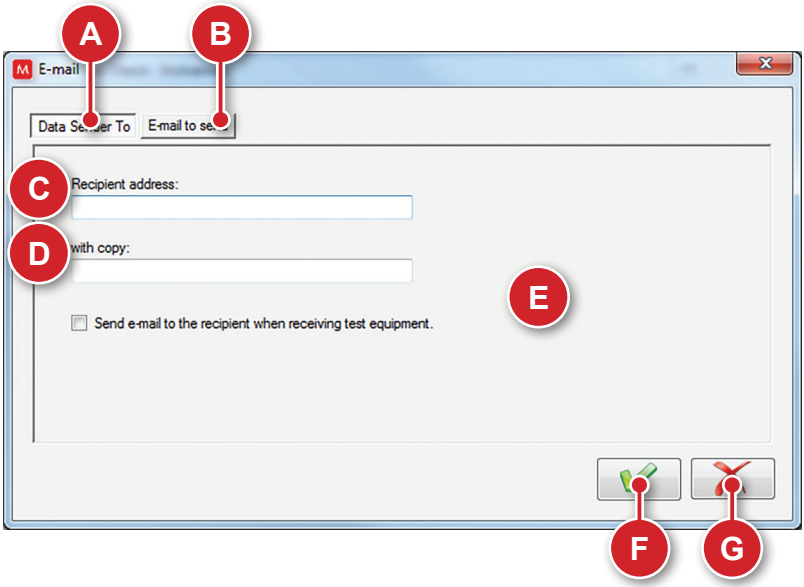
1 - Email configurations

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



A. Selected tab.

B. Opens the sender data tab.

C. Field for entering the recipient's address.

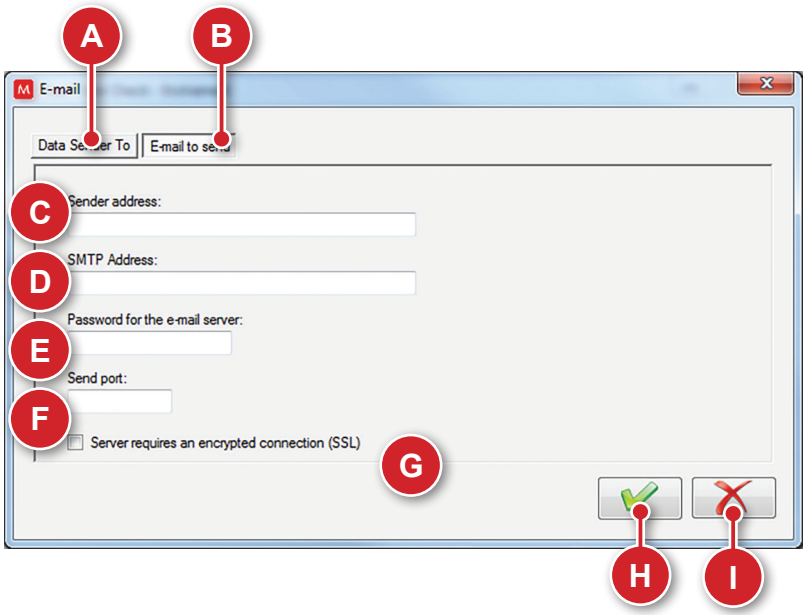
D. Field for entering the carbon copy recipients' addresses.

E. Enables or disables sending of the e-mail when new tests are received.

F. Confirms and saves the completed data.

G. Cancels changes and closes the e-mail configurations window.

"Sender Data" tab



A. Opens the "E-mail to send" tab.

B. Selected tab.

C. Field for entering the sender's address.

D. Field for entering the SMTP address.

E. Field for entering the e-mail server password.

F. Field for entering the sending portal.

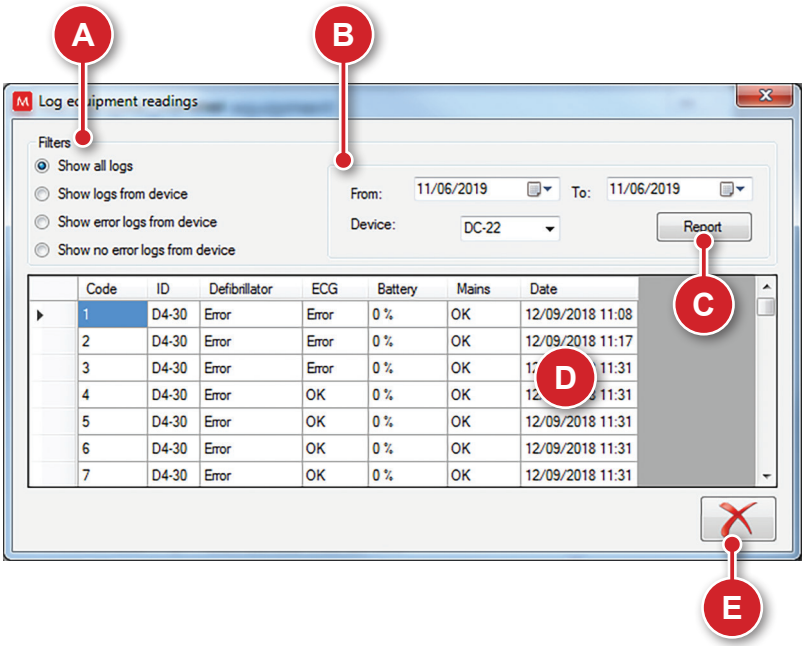
G. Select if the server requires an encrypted connection (SSL) or not.

H. Confirms and saves the completed data.

I. Cancels changes and closes the e-mail configurations window.

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.

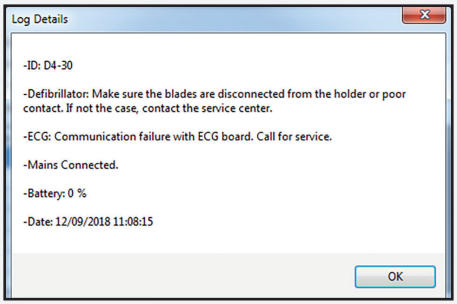
D. Log display area. This contains information about the tests conducted with the filters applied. A double-click on the content of a log will open a new screen with detailed information.

E. Closes the equipment reading log window.

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

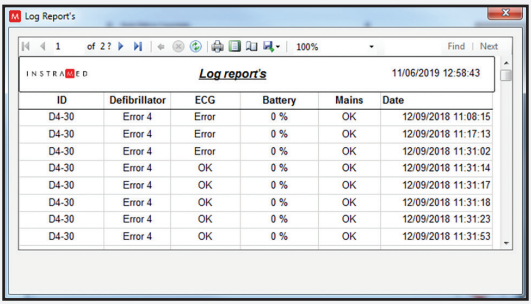
Log details

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.



ID	Defibrillator	ECG	Battery	Mains	Date
D4-30	Error 4	Error	0 %	OK	12/09/2018 11:08:15
D4-30	Error 4	Error	0 %	OK	12/09/2018 11:17:13
D4-30	Error 4	Error	0 %	OK	12/09/2018 11:31:02
D4-30	Error 4	OK	0 %	OK	12/09/2018 11:31:14
D4-30	Error 4	OK	0 %	OK	12/09/2018 11:31:17
D4-30	Error 4	OK	0 %	OK	12/09/2018 11:31:18
D4-30	Error 4	OK	0 %	OK	12/09/2018 11:31:23
D4-30	Error 4	OK	0 %	OK	12/09/2018 11:31:53

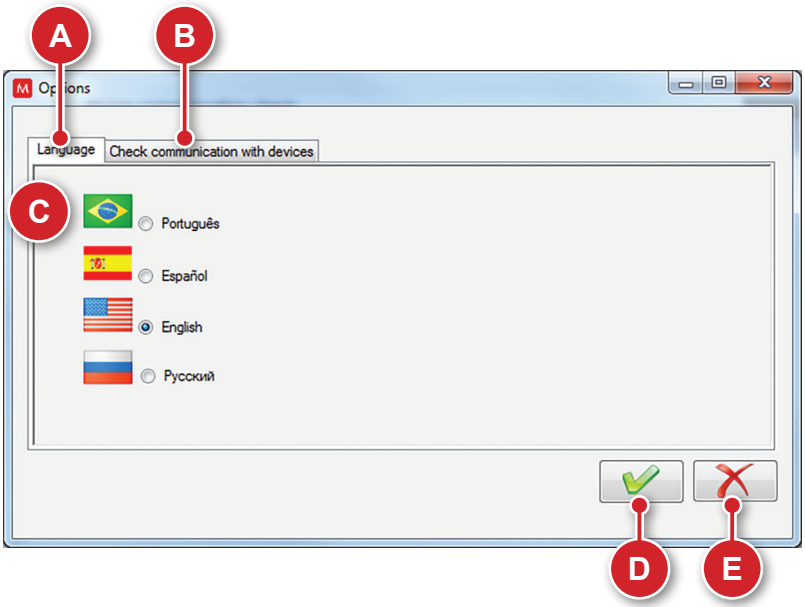
3 - Options

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.

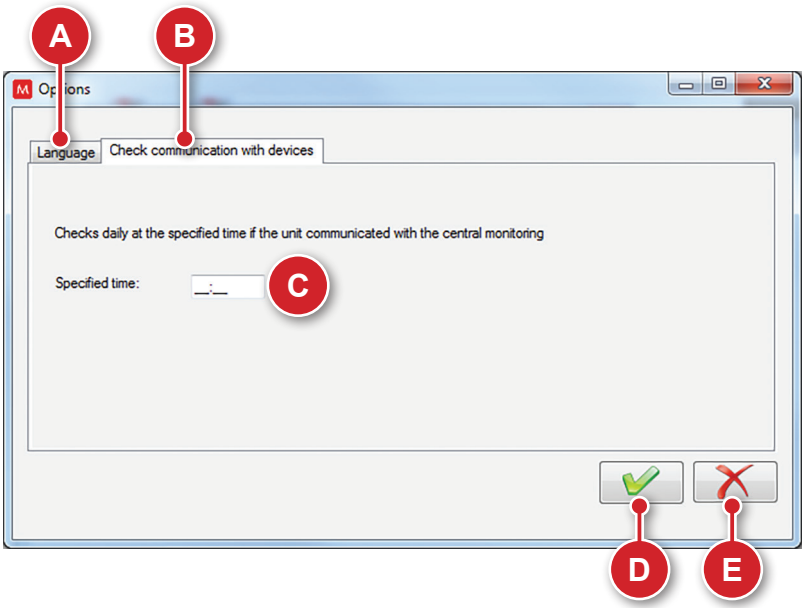
B. Opens the "Check device communication" tab.

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.

B. Selected tab.

C. Field for entering the time to perform the device communication check.

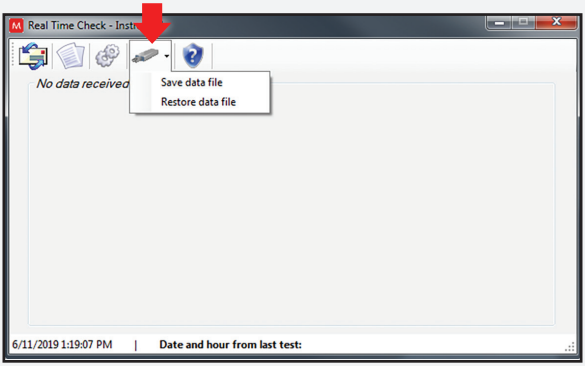
D. Confirms and saves the configurations.

E. Cancels changes and closes the window.

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."

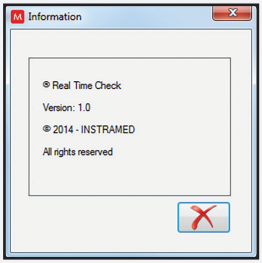


If a data file is lost, it is possible to restore the information from the last saved file. When restoring, all of the data obtained after the last backup file was saved will be lost.

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

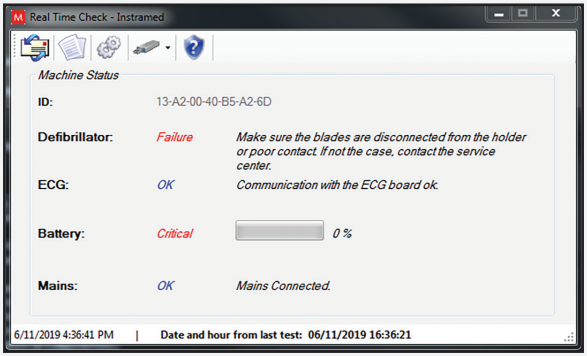
5 - Information

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**".

In.Track System and remote access

For more information and types of access permitted by the In.Track system, including remote data access, consult the Quick IoT Connectivity Guide for cardioverters.

Care and maintenance

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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.

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.

Cleaning

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

Only use substances approved by Instramed and the cleaning and disinfection methods mentioned in this chapter. The warranty does not cover damage resulting from the use of unapproved substances.

Instramed has validated the compatibility of the substances and cleaning and disinfection methods mentioned in this chapter and it is the responsibility of the hospital or responsible institution to ensure that the methods will be followed.

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_2 sensor and cable

- The cleaning process is specified in the accompanying instructions.

For cable and temperature sensor

- Moisten a cloth with clean water and mild detergent and wipe the device until all sweat is removed.
- Use a second dry cloth to remove excess liquid and/or foam.
- Moisten a third cloth with 70º alcohol and lightly wipe over the product.

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 70o and pass lightly on the product.

For the DEFIBRILLATION PADS 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 70o 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.

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** and **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).

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..

2 - SpO_2

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, lidocaine green, indigo carmine and fluorescein, may affect the SpO2 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_2 reading precision.

3 - Electromagnetic compatibility

Attention

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:

- **5-lead shielded ECG cable - 2.5 m. (code 79005)**
- **DualMax pads set for external defibrillation with quick coupling - 2.5 m. (code 13531)**
- **Oximetry sensor* - 2.5 m (code 12556 - BCI and code 13205 - NELLCOR)**
- **Oximetry sensor extensor - 2.5 m. (code 13208)**
- **DualMax pacemaker cable - 2.5 m. (code 13464)**

Warnings

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 SPO_2 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.
- The breathing curve may be disturbed.

EMC - General

Manufacturer's guidelines and declaration - Electromagnetic emissions		
The DualMax is intended for use in the specific electromagnetic environment as defined below. It is recommended that the DualMax customer or user ensure that it is used in such an environment.		
Tests	Compliance	Electromagnetic environment - guidelines
ABNT NBR IEC CISPR11 RF emissions.	Group 1	The DualMax uses RF energy only for its internal functions. However, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
ABNT NBR IEC CISPR11 RF emissions.	Class B	The DualMax is suitable for use in all establishments. Including residential establishments and those directly connected to the public low-voltage electricity distribution network that supplies buildings for domestic use.
IEC 61000-3-2 Harmonic emissions.	Class A	
IEC 61000-3-3 Emission due to voltage fluctuation/flicker.	According to	
NOTE: It is essential that the actual effectiveness of the RF shielding and the actual attenuation of the shielded location's RF filter are verified to ensure they meet or exceed the specified minimum values.		

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 ABNT NBR IEC 60601	Compliance level	Electromagnetic environment Directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 KV contact ± 2 KV, ± 4 KV, ± 8 kV, ± 15 KV by air.	± 8 KV contact ± 2 KV, ± 4 KV, ± 8 kV, ± 15 KV by 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 IEC 61000-4-4	± 2 KV for power supply lines. ± 1 KV for input/output lines.	± 2 KV for power supply lines ± 1 KV for input/output lines.	The quality of the power supply should be that 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	**Dips:** 0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT for 1 cycle and 70% UT for 25/30 cycles Single phase at 0°. **Interruptions:** 0% UT for 250/300 cycles.	**Dips:** 0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT for 1 cycle and 70% UT for 25/30 cycles Single phase at 0°. **Interruptions:** 0% UT for 250/300 cycles.	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 magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at characteristic levels of a typical commercial or hospital environment.
NOTE - UT 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 EN 60601 ABNT NBR IEC 60601	Compliance level	Electromagnetic environment Directives
RF conducted IEC 61000-4-6	3 Vrms 0,15 a 80 MHz Fora das faixas ISM AM[a] modulation, 80% index, at 1 kHz.	[V1]	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 Advisable distance of separation: $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d=\left[\frac{12}{V_2}\right]\sqrt{P}$ $d=\left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz 70 2.7 GHz Where “P” is the maximum output power of the transmitter in watts (W), according to the transmitter manufacturer, and “d” is the advisable separation distance in meters (m)[b]. Field strengths established by RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range[d]. Interference can occur around equipment marked with the following symbol:
	6 Vrms 0,15 a 80 MHz Within the ISM and Amateur Radio bands AM[a] modulation, 80% index, at 1 kHz.	[V2]	
RF radiated IEC 61000-4-3	10 V/m 80MHz to 2.7GHz AM[a] modulation, 80% index, at 1 kHz.	[E1]	
	20V/m 80MHz to 2.7GHz AM[a] modulation, index 80%, at 5 Hz.	[E1]	

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.

The radio amateur bands between 150 KHz and 80 MHz are: 1.8 to 2.0 MHz; from 3.5 to 4.0 MHz; from 5.3 to 5.4 MHz; from 7.0 to 7.3 MHz; from 10.10 to 10.15 MHz; from 14.0 to 14.2 MHz; from 18.07 to 18.17 MHz; from 21 to 21.4 MHz; from 24.89 to 24.99 MHz; from 28.0 to 29.7 MHz; and from 50.0 to 54.0 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 [V$_1$]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 $d=1,2.\sqrt{P}$	150 KHz to 80 MHz outside ISM bands $d=1,2.\sqrt{P}$	80 MHz to 800 MHz $d=1,2.\sqrt{P}$	800 MHz to 2.5 GHz $d=2,3.\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters with a maximum output power not listed above, the advisable separation distance “d” in meters (m) can be determined by using the equation applicable to the frequency of the transmitter, where “P” is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: at 80 MHz and 800 MHz, the separation distance for the highest frequency range is applied.

NOTE 2: the ISM (industrial, medical and scientific) frequency bands between 150 KHz 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

Testing frequency (MHz)	Band (MHz)	Service[a] (MHz)	Modulation[b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 -390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460 FRS 460	FM[c] deviation of ± 5KHz Sinusoidal 1 KHz	2	0.3	28
710 745 780	704 - 787	Band LTE 13,17	Pulse modulation[b] 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 Band LTE 5	Pulse modulation[b] 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT Band LTE 1, 2, 3, 25 UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9

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.

a - For some services, only the terminal's transmission frequencies are included.
b - The carrier must be modulated using a 50% service cycle square wave signal.
c - As an alternative to FM modulation, 50% to 18 Hz pulse modulation can be used because, although it does not represent actual modulation, this would be the worst case.

Troubleshooting

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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_2 curve.	SpO_2 curve turned off.	- Turn on SpO_2 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.

Accessories and parts

28

Included

Default		
Quantity	**Description**	**Code**
1	**Mains supply power cable (3 pins)*.**	5550
2	**Removable battery.**	13534
1	**CD of Instramed's manuals and softwares.**	25277
1	**DualMax pads set for external defibrillation with quick coupling**	13531
1	**Quick guide.**	13530

When Pacemaker or AED is present		
Quantity	**Description**	**Code**
1	**Dualmax pacemaker cable.** Description: cable to connect adhesive pads in the device.	13464
1	**Pair of adult multifunctional adhesive pads*.** Description: non reusable adhesive pads for monitoring, pacing, cardioverting and defibrillating.	79047

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

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

When Oximetry (SpO_2) of BCI is present		
Quantity	**Description**	**Code**
1	**Oximetry sensor (S200A-300101, Solaris Medical)*.** Description: SpO2 finger sensor.	12556

When Oximetry (SpO_2) of NELLCOR is present		
Quantity	**Description**	**Code**
1	**Oximetry sensor - NELLCOR*.** Description: SpO_2 finger sensor.	13205
1	**Oximetry sensor extensor - NELLCOR*.** Description: SpO_2 finger sensor extensor.	13208

When Temperature (TEMP) is present		
Quantity	**Description**	**Code**
1	**Adult skin sensor (TS-Y400S-AS30, Orantech)*.** Description: temperature sensor.	18384

When Non-Invasive Blood Pressure (NIBP) is present		
Quantity	**Description**	**Code**
1	**Adult armband (cuff) *.** Description: adult cuff.	25671
1	**Armband (cuff) extensor*.** Description: adult cuff extensor.	25900

When Invasive Blood Pressure (IBP) is present		
Quantity	**Description**	**Code**
1	**Utah Medical invasive blood pressure accessories kit*, consisting of:**	**70181**
1	**Organizer.** Description: labels to provide identification of the body access.	22558
1	**Clamp.** Description: clamp to provide strangulation of sampling line, limiting pressure.	22713
1	**Electrical cable.** Description: cable connecting the transducer to the device.	25134
1	**Sampling line.** Description: sampling line for blood pressure system.	39708
1	**Transducer.** Description: transducer that converts pressure to electrical signal..	80015

When Capnography ($EtCO_2$) is present		
Quantity	**Description**	**Code**
1	**Oridion capnography accessories kit*.** Description: non reusable $EtCO_2$ sampling line, consisting of:	79032
1	**Adult tracheal sampling line.** Description: adult tracheal access.	22686
1	**Child tracheal sampling line.** Description: child tracheal access.	22687
1	**Adult nasal sampling line.** 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

Optionals

CPR Maestro.	13542
Extension for BCI SpO_2 sensor*.	21176
Children Y model oximetry (SpO_2) sensor - BCI.	12475
Children oximetry (SpO_2) sensor - NELLCOR.	13207
Child skin sensor (TS-Y400S-PS30, Orantech)*.	19160
USB A-B cable - 1 m*.	10985
External grounding cable.	13231
Cable to external battery.	13203
Children multifunctional adhesive pads.	79048
Accessory bag.	12899
Adult disposable ECG electrode.	21669
Children disposable ECG electrode.	23897
ECG gel.	4529
3-lead ECG cable.	26005

* Accessory with separate CE certificate.

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

Specifications and safety

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General specifications

Dimension with pads:	31 cm (width). 24 cm (depth). 30 cm (high).
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 equipment with a battery - 6.6 Kg*. Complete equipment with two batteries - 7.2 Kg*. *Except NIBP, IP, $EtCO_2$, printer and accessories.
Power:	AC: 100 to 240 VAC, 50/60 Hz (automatic selection). 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.
Loudspeaker:	Alarm and QRS sounds, tone and volume modulation according to the 60601-1-8 standard.

Memória:	Type: SD card. Capacity: 4 Gb. Stored patients: 100 patients. Storage: 24 s 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 (protected against the possibility of dust ingress and against projection of water jets).
Classification:	Class I.
Electrical isolation:	Type CF and Type BF (check applied part).
Operating mode:	Continuous operation.
Isolating method from mains power supply:	Flexible cable with a MAINS PLUG.
Equipment lifetime:	110 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.
Optionals OP: (check availability)	Bluetooth. Audio recording.
Connectivity:	Refer to details in the Quick IoT Connectivity Guide.

Display

Battery level indication:	Yes.
Diagonal:	10.4" or 15" options.
Size:	Screen 10,4" OP 210,43 mm x 157,82 mm. Screen 15" OP 304,10 mm x 228,10 mm.
Resolution:	1024 x 768 pixels (XGA).
Scan speed:	6.25,12.5, 25 and 50 mm/s (varies according to the parameter presented).
Touchscreen:	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:	Maximum of 79.48 kPa.

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.

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 OP: 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 seconds. 360 J: mains and battery < 6 seconds.

Pads (options):	Adult and child external (included). Multifunctional for pacemaker, monitoring and defibrillation OP. Multifunction extension OP. NOTE: the adhesive pads provided by Instramed have a biocompatibility certificate in accordance with ISO 10993.
External pads size:	Adulto: 10,3 cm x 8,5 cm - Área: 81,9 cm^2. Infantil: 4,5 cm x 4,0 cm - Área: 18,0 cm^2.
Pads cable length:	2 meters
Cardioversion:	< 60 ms.
Maximum output voltage:	2000 V.
Maximum output electric current:	70 A (25 Ω).

AED mode OP

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 transferring electrocardiogram stored in AED mode to a compatible PC.
SoftDEA:	Software for viewing data transferred 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 seconds. 150 J: < 4 seconds. 50 J: < 2 seconds.
Maximum time from rhythm analysis beginning to discharge readiness:	20 seconds.
Maximum time from beginning of defibrillator operation to discharge readiness in maximum energy:	30 seconds.

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

Size of adhesive pads:	Adult = area: 82 cm^2. Child = area: 30 cm^2.

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%.

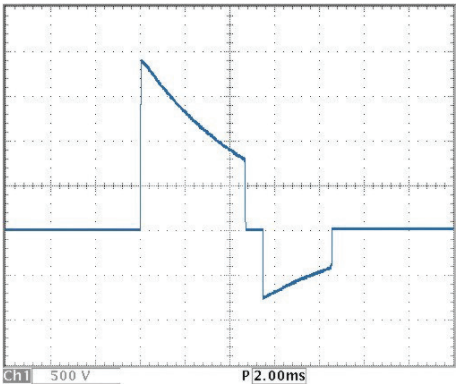
Precision of applied energy:

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%

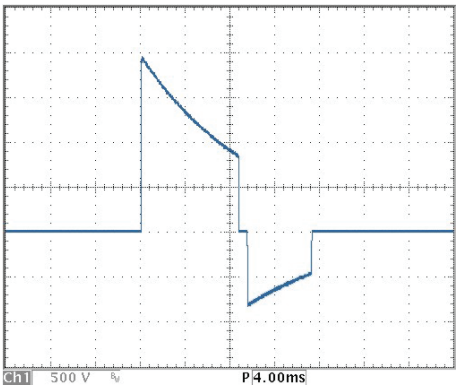
Patient's impedance response table:

Patient impedance	Schock
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.

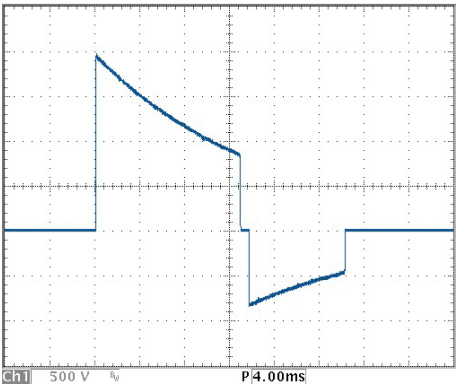
Values on the Y axis refer to voltage (volts) and values on the X axis refer to time (millis).



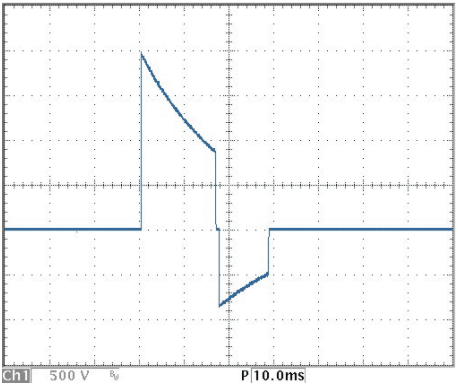
360 J of energy at 25 R impedance.



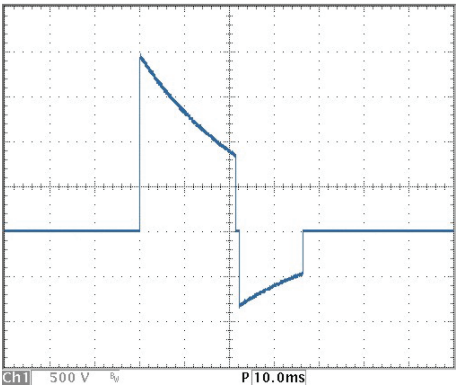
360 J of energy at 50 R impedance.



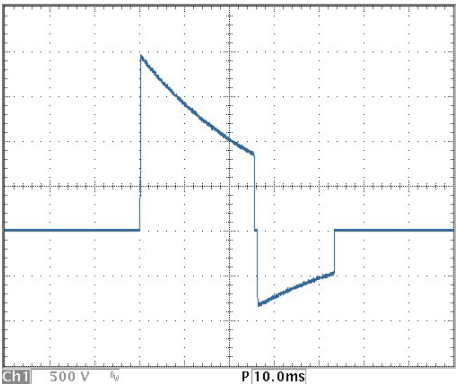
360 J of energy at 75 R impedance.



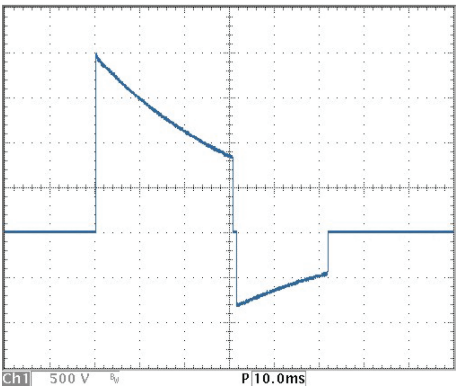
360 J of energy at 100 R impedance.



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 OP

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 (± 1 ms).
Frequency:	Between 30 ppm to 180 ppm (increments of 5 ppm), precision ± 2%.z

Refractory period:	340 ms (between 30 to 80 PPM). 240 ms (between 90 to 180 PPM).
Maximum output voltage:	350 V.

ECG

Input:	ECG patient cable and the corresponding derivations: - 03 leads OP: DI, DII and DIII. - 05 leads: DI, DII, DIII, aVL, aVR, aVF and C. - 10 leads OP: DI, DII, DIII, aVL, aVR, aVF, C1, C2, C3, C4, C5, C6. External defibrillation pads. Multifunctional adhesive pads. Supports up to 12 simultaneous derivations when equipped with the ECG OP of 12 derivations.
ECG electrodes (adult or child):	COMPOSITION: adhesive conductor with hydrogel and silver sensor (Ag/AgCl), latex free. USE INSTRUCTIONS: 1) Shave hairs, clean the spot and dry with gauze. 2) Before removing the protective film, attach the ECG wire to the electrode. 3) Remove the film from the electrode and put it in place by pressing firmly. PRECAUTIONS: do not open the packaging before use. Do not apply the electrodes on the nipples, bony protuberance, cuts, lesions, scars, only on intact skin. Store at temperatures between 15°C and 40°C. Non-sterile single-use product. Discard after use.
ECG gel:	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.

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:	Adult: 30 to 300 BPM. Neonatal/pediatric: 30 to 340 BPM.
Precision:	± 1 BPM.
Sensitivity:	5, 10, 15, 20, 30 and 40 mm/mV.
Scan speed:	12.5, 25 or 50 mm/s.
Filter:	35 Hz, 50 Hz and 60 Hz.
ECG response frequency:	Diagnostic mode: 0.05 - 100 Hz. Monitor mode: 1 - 40 Hz.
Patient isolation’s (defibrillation proof):	Defibrillation proof. ECG: 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:	≤ 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 ± 2 mV e ± 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 OP

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 and 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_2 BCI OP

SpO_2 range:	0 to 100%.
SpO_2 pulse range:	30 to 245 BPM.
SpO_2 precision:	±2 ARMS1 from 90 to 100%. Measured without adult/pediatric movement. ±3 ARMS1 from 90 to 100%. Measured without neonatal movement. ±3 ARMS1 from 70 to 100%. Measured with adult/pediatric movement.
Low perfusion accuracy:	Adult/pediatric: ±2 ARMS[1]. Neonatal ±3: ARMS[1].
Pulse precision:	± 3 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.
Patient isolation:	Isolated between applied part and mains. SPO_2: type BF.

NOTE 1: ARMS (Average Root Mean Square), measurement unit used according to the technical specifications of the BCI SpO_2 module.

OBSERVATIONS

The wavelength range information can be useful, especially for clinicians (e.g. when performing photodynamic therapy).

The sensor LED produces light of various curves in the red and infrared spectrums and falls into the exempt group with respect to photobiological risk according to IEC 62471.

Pulse rate accuracy is defined as the difference in pulse rate data recorded by the monitor versus a reference method. The reference method for calculating the pulse rate accuracy can be obtained by comparing the heart rate with an ECG or an electronic pulse simulator.

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 OP

Size:	60,5 x 41,2 x 25,7 ± 0,5 [mm].
Weight:	≈ 85 g.
CO_2 units:	mmHg.
CO_2 measurement interval:	0-99 mmHg
$EtCO_2$, $FiCO_2$ resolution:	1 mmHg.

Precision:	± 2 mmHg (0 - 38 mmHg). ± 5% + 0.08% for each 1 mmHg above 38 mmHg (39 – 99 mmHg).
Breath measurement range:	0 - 150 BPM.
Breath rate accuracy:	± 1 BPM at 70 BPM. ± 2 BPM to 120 BPM. ± 3 BPM above 120 BPM.
Flow rate:	50 (± 5) mL/min, flow measured by volume.
Waveform sampling:	20 samples/sec.
Startup:	30 seconds (includes power and startup time).
Calibration interval:	Once a year or 4000 hours of operation, whichever comes first.
Response time:	In $EtCO_2$ mode with a standard 200 cm long Microstream® FilterLine sampling line is specified as 4.3 seconds.
Compensation:	Automatic (barometric), BTPS, N_2O, O_2.

Printer OP

Type:	Thermal.
Weight:	200 g.
Speed:	12.5, 25 or 50 mm/s with precision of ± 5%.
Paper size:	White thermosensitive paper 58 mm x 15 m x 40 mm of external diameter.

CPR Maestro OP

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

Temperature

Technique:	Thermistor (serie YSI 400).
Range:	0 to 50°C (32 to 122°F).
Resolution:	± 0,1°C.
Temperature sensor:	It must be used reusable temperature sensor (adult or child), type YSI 400 (25oC @ 2.252 K Ohms).

Invasive pressure OP

Consumption:	350 mW.
Weight:	20 g.
Filter:	50 and 60 Hz.
Measures interval:	- 99 mmHg to 310 mmHg.
Clearing interval:	± 70 mmHg.
Precision:	± 1%, ±1 digit, whatever is bigger.
Transducer:	5 µV/V/mmHg, disposable or reusable.

Warranty Certificate

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Instramed Indústria Médico Hospitalar Ltda., guarantees the operation of the equipment described in this certificate for a period of 12 (twelve) months (except batteries and accessories), counted from the delivery date, against material or manufacturing defects that prevent its correct operation according to the specifications announced in this manual, as long as the conditions defined in this certificate are respected.

Exceptionally, the warranty periods foreseen in the previous paragraph may be extended through free commercial negotiation between the parties. To this end, the agreed terms must be stated in the contract and in this warranty certificate.

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

biphasic SHOCK

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