

Title:

Biphasic Defibrillator

Instructions For Use

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Biphasic Defibrillator

with ECG, Printer

Optional - SpO₂, NIBP, AED, Pacer, Internal paddle, EtCO₂, Code Ready, Respiration, Temperature

USER MANUAL

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NASAN MEDICAL FLECTRONICS PVT. LTD

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INTRODUCTION

Thank you for choosing the biphasic defibrillator. The biphasic is designed to meet your monitoring and resuscitation needs by providing advanced, ECG-parameter monitoring functions, a full range of defibrillation therapies. This guide provides instructions for safe and proper operation. Be sure to familiarize yourself with the features and operation of your biphasic prior to its use.

<u>Overview</u>

The biphasic is a lightweight, portable, defibrillator. It provides four modes of operation: Defibrillation, Monitoring and optional: Pacer& AED.

In Monitor Mode you can monitor three ECG waveforms, acquired through a5-lead ECG Set, Optional monitoring of pulse oximetry (SpO_2), noninvasive blood pressure (NIBP), and measurements from these parameters is presented on the display. Alarms are available to alert you to changes in the patient's condition.

A Vital Signs Trending Report can be viewed for all key parameters and their measurements over time.

Defib Mode offers simple, 3-step defibrillation. You analyze the patient's ECG and, if appropriate:

- 1. Select an energy setting
- 2. Charge
- 3. Deliver the shock.

Defibrillation is performed using paddles.

DEFIB Mode also allows you to perform defibrillation in synchronized and non-synchronized mode. It incorporates slow energy Biphasic waveform for defibrillation. The biphasic is powered by rechargeable lead acid battery. Available battery power is easily determined by viewing the convenient battery power indicators located on the device keypad.

Additionally, an external Power cord may be applied as a Primary power source and for continual battery charging. The battery acts as the Secondary power source.

The biphasic automatically stores critical event data, such as Event History, Heart Rate and Vital Signs Trending, in its internal memory.

<u>Intended Use</u>

Itis intended for use in hospital and pre-hospital settings by qualified medical person trained in the operation of the device and qualified by training in basic life support, advance Cardiac life support or defibrillation.

When operating in Monitor and DEFIB Mode, it is suitable for use by healthcare professionals trained in advanced cardiac life support.

Defibrillation

Non-Synchronous defibrillation is the initial treatment for ventricular fibrillation which is a condition in which there is uncoordinated contraction of the cardiac muscle of the ventricles in the heart, making them quiver rather than contract properly. Ventricular fibrillation is the most identified arrhythmia in cardiac arrest patients. Ventricular tachycardia is very fast heartbeat caused by a malfunction in one of the heart's ventricles. It is a pulse of more than 100 beats per minute with at least three irregular heartbeats in a row. VT can occur with or without heart disease. Synchronous defibrillation is indicated for termination of certain atrial and ventricular arrhythmias.

5-lead ECG

The 5-lead ECG function is to provide a conventional 5-lead ECG, which includes Heart Rate and seven different leads such as Lead I, II, III, aVL, aVR, aVF, V.

Pulse oximeter, NIBP(optional)

It can be used as a monitoring device to monitor Electrocardiogram, Saturated percentage of oxygen in blood (SpO2) and Non-invasive blood pressure.

Indications for Use

It is for use for the termination of ventricular tachycardia and ventricular fibrillation. The device is for use by qualified medical person trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician.

Safety Considerations

General warnings and cautions that apply to use of defibrillator are provided in 'Safety Consideration'. Additional warnings and cautions specific to a particular feature are provided in the appropriate section of this guide.

WARNING:

- Electric shock hazards exist internally. Do not attempt to open the device. Refer to servicing section of the manual.
- Use only supplies and accessories approved for use with your unit.
- Use of non-approved supplies and accessories could affect performance and results, refer 'Accessories'.
- Use the defibrillator on one patient at a time.
- Use single use supplies and accessories only once

DEVICE OPERATION GUIDELINES

Do not operate or store the device in conditions that are beyond the following specified limits.

DO'S

- ✓ Do read the user manual carefully before operating the defibrillator.
- ✓ Do recharge battery when LOW BATTERY condition occurs.
- ✓ Do keep the paddles always clean.
- ✓ Do exercise CAUTION while using the instrument in DEFIBRILLATOR mode.

DONT'S

- Do not open the cover of the unit. Lethal voltage is present inside.
- Do not expose the defibrillator to sunlight.
- Do not operate or store the device in areas with highly fluctuating temperatures.
- Do not operate or store the device near heating equipment.
- Do not operate or store the device in areas where there is high vibration.
- Do not operate or store the device in environments with high concentration of flammable gas or anesthetics.
- Do not operate or store the device in areas with high concentration of dust.

Only our authorized service personnel should open the device for servicing. There are no user serviceable components inside the device

<u>GETTING</u> ACQUAINTED

Itis designed with your needs in mind. Controls, indicators, and menus are carefully organized to facilitate easy use. Display information is tailored to the current task.

This chapter acquaints you with defibrillator operational modes, display views, controls, and indicators. It also provides general information on device use.

Basic Orientation

Defibrillator controls, indicators, and connections are carefully organized.

<u>NOTE</u>: Pictures of defibrillator appearing in this manual are for illustration purposes only.

<u>Front Panel</u>

The Front Panel and all its parts are as show in the figure below:

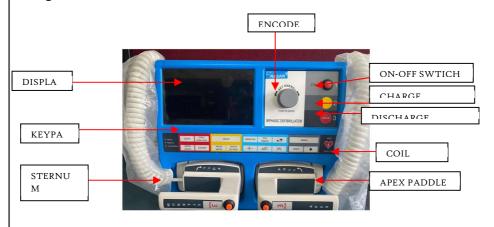


Fig.1

Side Panels

The left side of defibrillator has ports for monitoring cables such as ECG cable, Voice volume and QRS volume controls and Printer on the right-side panel.

LEFT SIDE PANEL

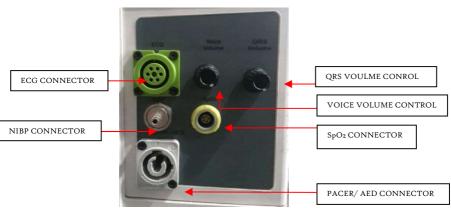


Fig. 2

RIGHT SIDE PANEL

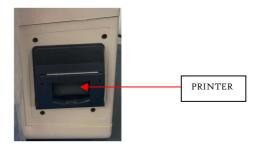


Fig.3

Paddles

There are two paddles on defibrillator, APEX and STERNUM. The paddles are connected to the front panel and to the coil cord; the coil cord is not removable. These two paddles are connected to the patient's body and shock is delivered through them. Apex paddle contains two buttons 'Charge' and 'Shock' and Sternum paddle only contains 'Shock' button. One can charge defibrillator by using the charge button on the Apex paddle and discharge the unit by pressing the shock buttons on both paddles simultaneously.

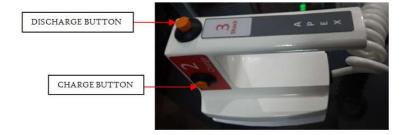




Fig.5

The lower part of the paddles contains a removable plate known as an 'Adult Plate' this plate is used to deliver shock to adults. The adult plate is removed to use the 'Child Plate' which is used deliver shock to children.

Following paddle indicator shows proper body contact to user

- 1) sternum Paddle indicator green LED turns ON for good contact.
- 2) Red LED in sternum glows when shock is delivered

<u>NOTE</u>: The paddles cannot be inserted into the front panel without the adult plate. Child plate is not removable it is attached to the paddles.

Adult plate



Fig.6

NOTE: To remove the adult plate; turn the plate towards the left side by 90 degrees and pull it in the outward direction.

Child Plate

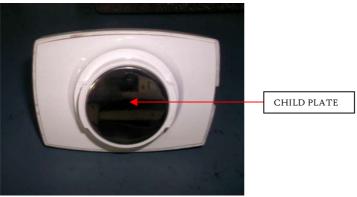


Fig.7

Back Panel

The back panel consists of ventilation ducts and an optional on-off switch, power cord/Adapter connector and fuse holder.

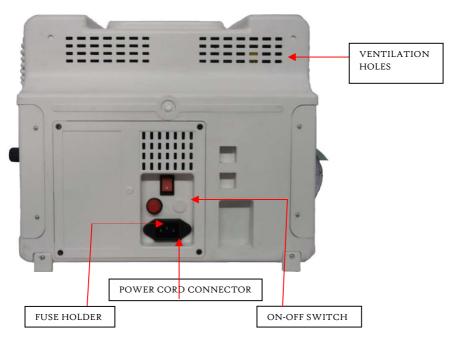


Fig.8a

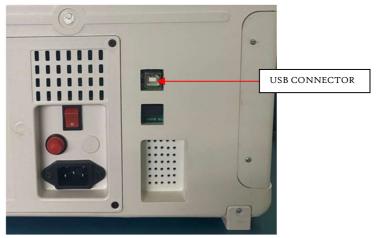


Fig.8b

NOTE: For Code ready only: Always use the front On-Off switch to turn on defibrillator and the rare switch on back panel should be ON.

Always keep the rare On-Off switch on the back panel in the ON position, if it is in the OFF position then defibrillator will not be turned on by the front panel On-Off switch.

NOTE: Defibrillator is a high voltage device, during transport, the 8 Amp fuse which is to be inserted in the back panel is removed for safety concerns. After the box is opened insert the fuse into the fuse holder on the Back Panel to start defibrillator.

<u>Power</u>

Defibrillator is powered by Battery or AC power. A fully charged batteryshould always be installed so the device is ready for use whether power is available at the point of care, keep your battery charged. Limit settings for the parameter and Event history are restored when power is turned on. But parameter display trend is lost when unit is turned off.

Do not remove back panel to change the Battery, to replace the battery refer to the servicing instructions of this manual.

CAUTION: A battery should be used as the secondary power source. Power cord should be used as a primary source, if desired. If an AC/DC power module is used as the only power source, defibrillator takesless time to charge to the desired energy level.

Lead Acid Battery

We use a Sealed lead acid Battery; it is fitted inside the back panel of defibrillator.

To remove or replace the battery refer to the servicing section of the manual.

<u>Installation procedure (With code ready feature)</u>

This chapter explains the Start-up and Turn-Off procedure of the defibrillator.

Once all the packing material from the box is removed, Insert fuse in the back panel. Connect the power cord at the backside of the unit.
The connectors for the parameters and printer are on the side panel.
After completing all these connections and checking your unit is ready to use!
On the back panel there is a rare switch, switch it on.
Set the RTC and for this refer page number-28- <u>Set</u> RTC – To Change Date and Time
By pressing the red colour push button from the front panel unit turn it ON.
When the unit is switched ON, It will open in the default screen 'External NON- SYNC'.
Using the keys on the Keypad, press 'Defib-Check' key and 'Press Charge Key' is displayed in the message window.
Press the Blue Charge button on the front panel
The capacitor charges and 'Press Discharge Key'is displayed in the message window. Press the Red Discharge button on the front panel.
The capacitor discharges internally and the internal circuit is checked and a Print- Out describing that the Manual Defib Check mode is completed is generated.

OR

Installation procedure (Without code ready feature)

This chapter explains the Start-up and Turn-Off procedure of the defibrillator

Once all the packing material from the box is removed, Insert fuse in the back panel.
Use the 'Green On-Off' switch on the front panel to switch on the unit.
DO NOT USE THE ON-OFF SWITCH ON THE BACK PANEL. (USE IT ONLY IF THE GREEN SWITCH IN THE FRONT PANEL IS NOTWORKING).
When the unit is switched ON, It will open in the default screen 'External NON- SYNC'.
Set the RTC and for this refer page number-28- <u>Set</u> RTC – To Change Date and Time
Using the keys on the Keypad, press 'Defib - Check' key and 'Press Charge Key' is displayed in the message window. Press the Blue Charge button on the front panel
The capacitor charges and 'Press Discharge Key' is displayed in the message window. Press the Red Discharge button on the front panel.
The capacitor discharges internally and the internal circuit is checked and a Print- Out describing that the Manual Defib Check mode is completed is generated.

Note: If the paddles are not placed in the cradles, then Defib Check mode will not be completed. 'Place Pads in Cradle' message is displayed in the message window.

- ✓ To go to Defibrillation mode, press the Defib'key on the keypad.
- ✓ Use the paddles to deliver selected amount of the energy.
- ✓ To go to Monitor mode, press the 'Monitor' key on the keypad. You can monitor ECG, SpO2, and NIBP in this mode.
- ✓ The connectors for the parameters and printer are on the side panel.
- ✓ After completing all these connections and checks your unit is ready to use.
- ✓ When the device is not in use, switch off the unit using the front panel On-Off switch on the front panel
- ✓ If device is not in use for a long time, then charge the device regularly.

Note: Contact the person designated by the MANUFACTURER as qualified to perform the installation

Operating Modes

Defibrillator has four modes of operation, modes are: Defibrillation, Monitor and optional: AED, Pacer.

Operating Modes and Views

Mode of Operation	Display View	Description	
Monitor Mode	Monitoring View, Single Lead ECG.		Used to monitor ECG, take an optional 5-lead ECG, and Monitor ECG For viewing Vital Signs And Trending data.
Defibrillator Mode	DEFIB View		Used to perform non-synchronous and synchronous Defibrillation.
Pacer Mode	Pacer view		Used to perform external pacing in Demand and Non-Demand mode.
Automated External Defibrillator Mode	AED View		Used to analyze the patient's ECG and decide whether the rhythm is shockable or non-shockable.

Display Views

Defibrillator display layout is segmented as shown in Figure.

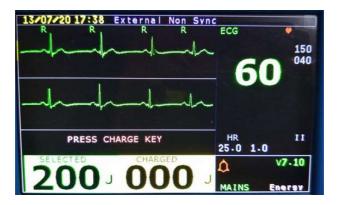


Fig.9

<u>NOTE</u>: Pictures of defibrillator display appearing in this manual are for illustration purposes only. The content of these areas varies with the display view, the options on your device and the function being performed.

General Status

The general status area of the display contains:

- 1. Version number.
- 2. Battery power indicator.
- 3. At the right bottom corner of the display 'BAT-FUL' for full battery and 'BAT-MED' for medium battery and 'BAT-LO' for low battery indication.
- 4. ECG/HR alarm status Alarm messages communicate Hi-Low limit alarms as well as overall alarm status (alarms off) as well as overall alarm status (alarms off)

General Status Window

This window displays messages such as 'PAPER OUT' and 'SAVING'. 'Paper Out' message denotes that the printer paper is out of paper and the 'Saving' message is displayed after a shock is delivered and it denotes that defibrillator is saving the shock details, which can be viewed later in Event History.

In Monitor Mode:

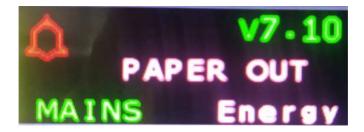


Fig.10

In Defibrillator (External-non sync) mode:



Fig.11

Energy window

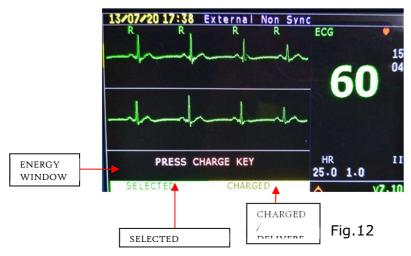


Fig.12

There are two parts in the Energy window

- Selected Energy: This Energy is selected by trained Medical professional. It is displayed in Joules. The selected energy is in the following intervals: 2,3,5,7,10,20,30,50,70,100,150,200.
- Charged Energy: This Energy changes to match the selected energy once the charge button is pressed.
- Delivered Energy: The Charged Energy window turns to Delivered Energy window once discharge button is pressed and the shock is delivered.

<u>NOTE</u>: The default selected energy is 200J and once the desired energy is selected 'PRESS CHARGE KEY' message is displayed.

After the charge button is pressed, the selected energy and charged energy become equal and then 'PRESS DISCHARGE KEY' message is displayed and "*Press Discharge Button*" voice prompt is also generated

Wave Sector:

When you Power defibrillator the default screen is,

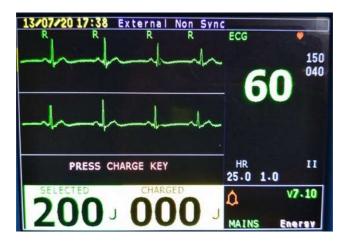


Fig.13

<u>NOTE:</u> The text 'External on-Sync' on the top of the screen shows the defibrillator is in Default mode.

Operations in default mode:

- 1. ECG by paddles
- 2. Shock Delivery

You can set it to PADS to detect an ECG signal from paddles or LEADS to detect an ECG signal from an ECG patient cable. If you select LEADS, default lead II is selected and can be changed by pressing the lead key on the keypad. If the primary ECG is PADS, one can switch to the default lead selection by pressing the lead button.

When switched to monitor mode

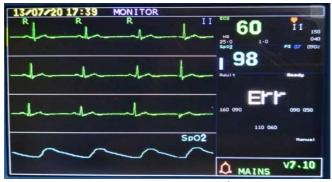
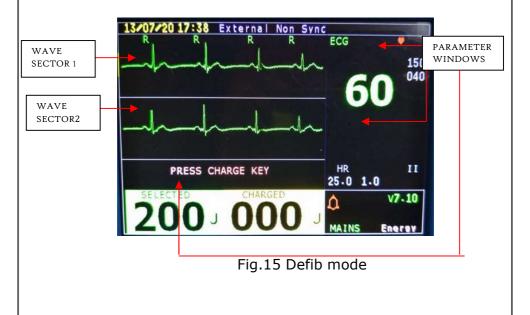


Fig.14 Monitor mode

<u>NOTE</u>: The text 'Monitor' on the top of the screen shows the defibrillator is in monitor mode.



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WAVE SECTOR 1

In monitor mode, Wave Sector 1 only contains an ECG waveform. Lead II is selected by default. You can select any lead by pressing Lead button. Lead II ECG waveform is used for heart rate derivation

WAVE SECTOR 2

In Defib mode, Wave Sector 2 contains a 4 second delayed ECG waveform of the same lead.

In monitor mode, if the pulse oximeter NIBP is being monitored then the waveform is displayed as per above image in Monitor mode.

NOTE: When monitoring using a 5-lead ECG patient cable, defibrillator displays 1 ECG lead at a time.

Parameter Windows

Measurements for monitored parameters are provided in the parameter windows. ECG window (parameter window 1)always contains the Heart Rate, Pulse Rate and HR limits. It also displays the 'Gain', 'Sweep Speed' and 'Lead'. The other parameter windows display 'Pulse Oximeter' and 'Non-invasive blood pressure'. The SpO₂ parameter window displays 'Perfusion Index' and 'SpO₂ percentage limit'. The NIBP parameter window displays 'Patient type', 'Mode', Limits of 'Systolic, Diastolic and Mean' values, Status of measurement.

Menu

Menu with controls and options of defibrillator are easily accessible using the Menu key located on the keypad and Encoder located on the front panel. Menus are used to select Display trend, and a variety of other tasks. Menu and submenu are organized to allow you to conveniently make selections. To display a menu, press the Menu key and then use the Encoder to scroll through the available choices until the desired selection is highlighted.

Following Screen is displayed when the Menu key is pressed.



Fig.16

Event History

Select 'Event History' option and press it with the help of encoder. The details of completed shock will be seen in event history option and it contains Sr no., Date, Time, Energy delivered in Joules and status Pass or Fail.



Fig.17

The last shock details will be replaced with latest shock details in the memory. Shock history of only 10 latest shocks is available. Print out of desired shock waveform is obtained by bringing the 'P' option on the desired shock waveform & pressing encoder.

USB (Optional):

'Defib utility' Software is used to check the impedance value and shock status.

For this installing 'Defib utility' Software on PC and connecting USB cable between Defib unit & PC.

Steps for Data downloading through USB-

- 1. Install 'Defibrillator utility ' Software on the PC.
- 2. Connect the Unit to the PC, through a USB cable.
- 3. Switch ON the unit
- 4. Press 'MENU' key for 5-6 seconds.
- 5. Run the "Defib utility" software.
- 6. Go to Edit→Communicate in software.
- 7. Check that 'data stored in file Event.txt successfully' message appears on the PC screen.
- 8. Check the event.txt file in Program Files (x86)\Nasan\DefibUtility\ folder.
- 9. Event report is printed with following column-Event No, date, time, Del joules ,P/F, battery, mains status, impedance value.

E	vent Report	
		Date: 26-10-2023 16:58

Event No.	Date	Time	Del Joules	P/F	Battery	Impedence
1	26-10-23	16:48	O O	F	Mairra	70
2	26-10-23	16:47	0	F	Mains	25
3	26-10-23	16:46	0	E.	Mains	26
4	26-10-23	16:46	0	F.	Meine	25
5	26-10-23	16.46	0	E	Mains	47.
ri.	26-10-23	16.45	0	6.	Mains	25
7	26-10-23	16:45	0	F	Mains	25
8	26-10-23	16.21	360	P	Full Bat	47
9	26-10-23	16.21	300	p	Full Bat	47
10	26-10-23	16:20	266	P	Full Bat	47
.11	26-10-23	16:20	230	P	Full Bat	47
12	26-10-23	16:19	183	p	Full Bat	47
13	26-16-23	16:19	200	р	Full Bat	47
14	26-10-23	15:19	150	P	Full Bat	47
15	26-10-23	10:19:	100	ip.	Full Bat	47
to	26-10-23	10.19	70	р	Full Bat	47
17	26-19-23	16.18	60	#	Full Bat	47
18	26-10-23	10.18	30	P	Full Bat	90
19	26-10-23	16.15	20	P	Full Bat	47
20	26-10-23	16:18	10	p	Full Bat	70
21	26-10-23	10:17	7	P	Full Bat	47
22	26-10-23	16.17	5	24	Full Bat	47
23	26-10-23	16:17	3	p	Full Bat	47
24	26-10-23	10:16	2	р	Full Bat	47
25	26-10-23	16.15	360	To.	Mains	47

Event report

Display Trend

Select 'Display Trend' option with the help of encoder. Press encoder to enter into it.



Fig.18

Select 'Graphical' option using encoder. Press encoder then following Graphical trend window will be displayed.



Fig.19

Page will display current time data with previous 6 hrs. Rotate encoder to view next page data or last 24 hours data of all parameters with time.

The parameter value which goes out of limit will be seen in Red colour.

Press 'home' key to exit from graphical trend. Again press 'menu' key. Select 'display trend', Select "Tabular" using encoder. Full Screen Tabular Trend will be displayed as shown below:

```
Pg-001

TIME 15:40 15:39 15:38 15:37

HR/PR 60 60 60 ---

Sp02 97 98 --- 98

TIME 15:36 15:35 15:34 15:33

HR/PR --- --- ---

Sp02 98 98 97 ---

TIME 15:32 15:31 15:30 15:29

HR/PR --- --- ---

Sp02 --- ---
```

Fig.20

Rotate encoder to view last 24 hours data. Each tabular trend Page contains 12minutes data. The parameter which is out of specified limit will be displayed in red color in tabular trend. Press 'home' key to exit from tabular trend.

Auto Alarm Reset

Select the 'Auto Alarm Reset' menu using encoder. Following menu will be displayed on the screen.



Fig.21

Rotate encoder to set the required reset time interval & press encoder, selected auto reset time interval will be saved. When Master alarm is OFF, it gets switched ON automatically after set time interval. Select 'EXIT' option or Press 'Home' key to exit from Auto Alarm Reset.

<u>Set RTC - To Change Date and Time</u>

Select the 'Set RTC' menu using encoder. Following menu will be displayed on the screen.



Fig.19

Change Date and Time using encoder. To change press encoder selected parameter becomes red and then change it; selected time will be saved. Selected time will be updated on Trend and on the main screen. Real time clock is displayed in the upper right corner and Date is displayed in the upper left corner. Select 'EXIT' or Press home key to exit from Set RTC.

<u>Set RTC – To Change Date and Time(For code ready only)</u>

Select the 'Set RTC' menu using encoder. Following menu will be displayed on the screen.



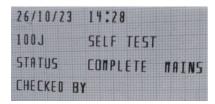
Fig.22

Change Date and Time using encoder. To change press encoder selected parameter becomes red and then change it; selected time will be saved. Selected time will be updated on Trend and on the main screen. Real time clock is displayed in the upper right corner and Date is displayed in the upper left corner. Select 'EXIT' or Press home key to exit from Set RTC.

Self test: This option is checked by selecting 'Set RTC' from the 'Menu'.

Turn OFF the back plate switch. Wait for 1 minute. Turn ON the back plate switch. Turn ON the unit. Goto RTC setting menu. Set time for Autocheck Hour and Minute from current time. Turn the unit OFF and do not switch off the rare switch on the back panel. Check that the unit wakes up after set time and then it performs

auto check operation. Check printout for date, time, autocheck status, and battery status.



Self test Printout on Mains



Self test Printout on battery

Reset Setting

Select "Reset setting" option using encoder as shown below.



Fig 23

'All parameters set to default values' message displays on screen, if 'YES' option is selected then all parameter value will change to default value and for 'NO' option change value will be remained as it is. All the parameter such as gain, sweep speed and parameter limits are restored to default values.

Alarm Priority: To set alarm priority of parameter.

- a. Select "alarm priority" from the menu. A window for alarm ECG,SPO2, NIBP & EtCO2 will open.
- b. Make the out of limit condition for each parameter.
- c. An Alarm will set ON. The Color of the alarm set are shown as below:

Level of Priority	Color Indication
High	Red with 3 stars
Medium	Yellow with 2 stars
Low	Yellow with 1 stars

Exit

To close 'MENU', select 'Exit' option with the help of encoder.

<u>NOTE:</u>In case of encoder inactivity more than 10 sec, defibrillator comes back to previous screen automatically.

Message Windows

Messages appear in the message window to provide additional status information and to alert you to an error or a potential problem or direct you to take action. Remain alert to these messages.



Fig.24

PLACE PADS IN CRADLE

Fig.25

CAPACITOR IS DISCHARGING NO QRS. INCREASE GAIN

Fig.26

Controls

The Green push button marked '1' is used to turn defibrillator; ON and OFF. Front panel keypad is used to select the desired mode of operation. Controls are organized by function, with Defibrillation function buttons at left side of the keypad, Monitoring controls in the middle of the keypad and General function keys at the right side of the keypad.

Control by Encoder

Rotate encoder clock wise or anti-clock wise to select

- 1. Select defibrillation energy level: 2,3,5,7,10,20,30,50,70,100,150 and 200 Joules
- 2. Scroll to desired option in Menu
- 3. Increase or decrease the value of parameter

Press Encoder

To confirm the selection of parameter in Menu or to Change set value. If a parameter is selected by the encoder to be changed it changes colour from grey to red. The user changes the parameter which is in red, to save the changed value. Press the encoder again and the colour changes back to grey.

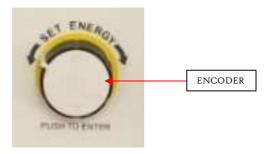


Fig.27

Controls by Front panel Keypad

Defibrillator comes in various models, with different parameters. There are different keyboards for different parameters. All the various keyboards are shown below along with the function of every key. Please refer to the keyboard which matches your defibrillator.



Fig.29

1. DEFIB:

This key is used to work in Defibrillator mode.

Again Press 'DEFIBRILLATOR' to operate the unit in Defibrillator INTERNAL mode

2. SYNC/NON-SYNC: SYNC/NONSYNC

To enable DEFIB Mode for Non-Synchronous or Synchronous defibrillation.

3. MONITOR:

To enable Monitor Mode for 5-lead ECG monitoring



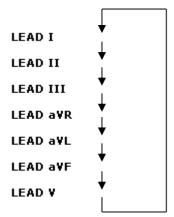
To check proper functioning of Defibrillator



This key is used to discharge capacitor through internal circuit

6. LEAD SELECT BUTTON:

Changes the ECG lead in Wave Sector 1.Pressing this button cycles through the available ECG waveforms, changing the displayed wave and label. Default lead is Lead II.





The Alarm key pauses audible alarms.

8. PRINT BUTTON:

The Print key initiates a print-out of last 10 sec ECGdata and Print out of the event history along with shock details and 5 second ECG data before shock and 5 seconds after the shock.

9. MENU SELECT KEY:

Pressing the Menu Select button brings up the menu



This key enables the users to come back directly to main screen from Menu or setting screen.

11. ECG FREEZE KEY: ECG FREEZE

ECG freeze key is pressed to freeze last 4 seconds ECG data in wave sector 2. To unfreeze the waveform, press 'ECG Freeze' key again. The freeze key is used only when ECG is the only parameter for monitoring.



Press 'GAIN' key to adjust the amplitude of the waveform as required. The available gain values are 0.5 – 1- 2.



NOTE: when double R is detected on traces, decrease the gain till you get single R.

<u>SETTING:</u> Double click on 'Menu' key to enter in 'Setting' mode as shown below. This setting option is used to change the parameter (ECG, SpO₂ and NIBP) setting in 'Monitor mode. Selected parameter window is highlighted with yellow color.

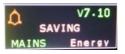


Fig.30

13. PACER(optional):



This key is used to switch to pacer mode. To enable external pacing to the patient

14. PACER MODE(optional):

There are two different types of modes for External Pacing, Demand mode and Non-Demand mode. This key is used to determine which mode is to be used for the pacing.

15. SHOCK BY PADS (optional): SHOCK BY PADS

If the pacer pads are connected to the patient and the patient is receiving external pacing, and the patient goes into cardiac arrest or ventricular fibrillations then we can give shock through the pacer pads already connected to the patient using this key.

16. NIBP: (optional)

This key is used to start the NIBP measurement.

Defibrillator keypad controls:



Fig.31

Monitor Keypad Controls:



Fig.32

General Keypad Controls:



Fig.33

Pacer Keypad Controls:

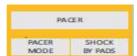


Fig.34 (optional)

AED control:



Fig.35(optional)

Defibrillation Controls

The defibrillation controls are shown in Figure.



Fig.36

- 1. Charge Button: The Defibrillator can be charged by
- Yellow key marked '2' on the front panel.
- Orange button on the Apex pad marked '2'.
- Charges the defibrillator to the selected Defib energy setting.
- 2. DischargeButton: The Defibrillator delivers the Shock by
- Red key marked '3' on the front panel.
- Orange buttons on both paddles marked '3'
- If shock is delivered through paddles then both discharge buttons should be pressed simultaneously.

<u>Indicators</u>

Defibrillator indicators provide a visual display of device status.

Power Indicator

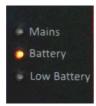


Fig.37

- Mains: Green LED is located at the left of the front panelkeypad. The green light on the front panel will glow indicating power is provided by external or internal AC/DC power.
- 2. Battery: Yellow LEDis located at the left of the front panelkeypad. The Yellow light on the front panel will glow indicating power is provided by internal battery.
- 3. Low Battery: Red LED is located at the left of the front panel keypad. Red light on the front panel will glow indicating power provided by internal battery is low.
- 4. Alarm: It indicates that Alarm is in ON condition.
- 5. Alarm Off: It indicates that Alarm is paused.

Parameter out of limit: The blinking of the parameter value indicates that the parameter value goes beyond set limit.

SETTING UP

This chapter provides the basic set-up information you need to prepare your defibrillatorfor operation.

NOTE: Defibrillator is a high voltage device, during transport, the 8 Amp fuse which is to be inserted in the back panel is removed for safety concerns. After the box is opened insert the fuse into the fuse holder on the Back Panel to start defibrillator.

To connect a 5-leadPatient cable

Align the ECG cable with the Green port, as shown in figure below the notchanything cable faces the top of the device. Push the ECG cable firmly into the ECG port, until the notch of the cable connector is no longer visible.



Fig.38

To connect power cord /adapter for battery charging

Connect the power cord on the back panel of defibrillator for charging the battery. The 'Mains' LED glows on the keypad when connected.



Fig.39

<u>To connect SpO2 probe (optional)</u>

Align the SpO2 probe with the notches on the connector side; Push the probe inside till you hear a 'Click'. Pull lightly on the probe to check it is connected properly.



Fig.40

To connect NIBP tube(optional)

Align the NIBP tube with the connector; Push the probe inside till you hear a 'Click'. Pull lightly on the probe to check it is connected properly.



Fig.41

To connect Pacer (AED) extension cable (optional)

Align the Pacer Extension cable with the notches on the connector side; Push the cable inside and rotate it towards the right side, you will hear a 'Click' when the connector is properly connected. Pull lightly on the probe to check it is connected properly.

To remove the connector, pull the silver notch on the connector away from the unit and rotate it towards the left and remove the connector.



Fig.42

To install thermal printer paper

- 1. Open the printer door by pulling the green flap.
- 2. If there is an empty or low paper roll in the printer, pull up on the tab holding the paper roll to remove it.
- 3. Examine a new roll of printer paper and remove any remaining adhesive residue from the outer layer of paper.
- 4. Place a new roll of printer paper into the paper well, positioning the roll so that the end of the roll is on the top and the grid faces up.
- 5. Pull the end of the paper out past the paper roller.
- 6. Close the printer door.

PRINTER ON THE SIDE PANEL OF BIPHASIC

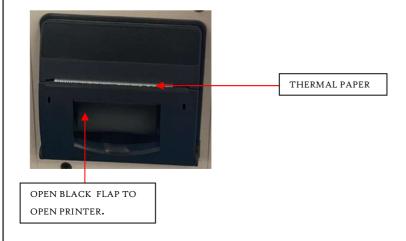


Fig.43

<u>MANUAL</u> <u>DEFIBRILLATION</u>

This chapter explains how to prepare for and perform nonsynchronous and synchronous defibrillation using patient cable or paddles.

<u>NOTE</u>: Defibrillation is always performed through paddles. However, during defibrillation you may choose to monitor ECG using 5-lead monitoring.

Overview

Defibrillation is the definitive method for termination of a variety of potentially fatal arrhythmias. Defibrillator provides defibrillation through the application of a brief biphasic pulse of electricity to the cardiac muscle. This electrical energy is transferred through the paddles attached to the patient's bare chest. In DEFIB Mode, one must assess the ECG, decide if defibrillation is required and select the appropriate energy, charge the defibrillator and deliver the shock. The entire defibrillation process is under your control. Voice prompts are present. However, text messages on the display provide relevant information throughout the process. It is important to be attentive to these messages when displayed. The ECG trace and Event Summary are easily annotated with event information using the Event History option.

<u>NOTE</u>: Online print of the latest 10 second ECG data and Shock history will be printed after, shock is delivered.

Precautions for Manual Defibrillation

Defibrillating asystole can inhibit the recovery of natural pacemakers in the heart and completely eliminate any chance of recovery. Asystole should not be routinely shocked.

Defib-Check Mode

To check Charging and discharging of Defibrillator at selected level of energy DEFIB CHECK mode is used.

- 1. Press the DEFIB CHECK key on front panel keypad.
- 2. "Operating in Defibrillator-Check mode" sound message is generated.
- 3. "Defib-Manual check" text message is displayed on the top of the screen.100 Joule is the default value which is displayed in the Selected Energy window.
- 4. If paddles are not in cradle or loosely connected "PLACE PADS IN CRADLE" text message is displayed in message window and same voice message is also generated.
- 5. If the paddles are in cradle "PRESS CHARGE KEY "text message is displayed on message window. Press Charge key located on front panel or on Apex paddle.
- 6. Defibrillator capacitor is charged to 100 Joule.
- 7. While charging "CAPACITOR IS CHARGING "text message is displayed in message window and "Charging" voice message is also generated.
- 8. If Defibrillator Capacitor does not get charged or any other error occurred while charging "SYSTEM ERROR" message is displayed in message window.

- 9. If defibrillator capacitor gets charged to 100 Joule, 100Jvalue is displayed on the Charged Energy Window, "PRESS DISCHARGE KEY" Message is displayed in message window and 'Press Discharge Button to deliver shock' Voice Message is generated.'
- 10. Press Discharge Button located on the front panel or press discharge buttons on both paddles simultaneously.
- 11. "Discharging" voice message is generated and "CAPACITOR IS DISCHARGING" text message is displayed on the screen
- 12. When capacitor is discharged "Manual Defib Check Complete" Message is displayed on message window.

A print is generated after manual check is complete with the details as shown below:



Fig.44a



Fig.44b

NOTE: To switch from MONITOR to DEFIB CHECK mode you have to select DEFIB mode 1st then you are able to switch in DEFIB CHECK mode. If discharge key is not pressed within 20 seconds after display of "Press discharge key" message, the capacitor is discharged through internal circuit.

Defibrillator Keypad Controls



Fig.45

Preparing for Defibrillation

In preparation for defibrillation:

- 1. Connect the 5-lead ECG cable.
- 2. Paddles cord is pre connected always.
- 3. Apply the paddles as described below.

Connecting Paddles for Defibrillation

- 1. Remove the Paddle Set from the cradle. To remove paddles from cradle press the paddles slightly inwards and pull them out of the cradle tray. Verify there is no debris or residue (including dried electrode gel) on the surfaces of the paddles. Clean if necessary. Do not short paddles together.
- 2. Apply paddles to the patient's bare chest, using the anterior-anterior placement
- 3. Adjust paddle pressure and placement to optimize patient contact

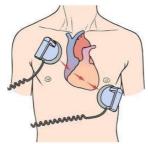


Fig.48

NOTE: Impedance is the resistance between the defibrillator's paddles when applied to the patient's body that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin. The low-energy Biphasic waveform is an impedance-compensating waveform that is designed to be effective across a wide range of patients. However, if you receive a "Shock Not Delivered" message, check that the patient's skin has been washed and dried and chest hair has been clipped.

Non-Synchronous Defibrillation

Once you have performed the necessary preparation for defibrillation, perform the following steps:

1. Select Energy- To select the energy setting, rotate the Encoder on the front panel of the defibrillator to the desired energy level as shown in Figure below. Energy choices range from 2 to 200; selected energy level is displayed on Selected Energy Window as below. By default selection is at 200 Joule.



Fig.46

30J is selected and press charge key message is displayed.

<u>WARNING</u>: Clinicians must select an appropriate energy level for defibrillation. Do not leave patients unattended when the Biphasic is in defibrillation mode with paddles attached to the patient.

2. Charge- Press the Charge button on the front panel or the charge button on the Apex paddle may be used instead. As the defibrillator charges, the Charged Energy Window changes to match the selected energy.

<u>NOTE</u>: One cannot increase or decrease the selected energy at any time during charging or after charging is complete. To disarm the defibrillator, press Disarm key on front Panel keypad. If the Shock button has not been pressed for 20 seconds after charging the defibrillator disarms automatically.

- 3. Discharge (Shock) When selected energy becomes equal to charged energy, "Press Discharge Key" message will be displayed on the message window and "Press discharge button" voice message is also generated. Confirm lead is displayed and the defibrillator has charged to the selected energy level. Make sure no one is touching the patient, or anything connected to the patient. Call out loudly and clearly, "Stay clear!" Press Discharge button on Front panel or press Discharge buttons simultaneously on both paddles. Delivered energy is displayed in Delivered Energy window.
- Display will show delivered energy till charge key is pressed to next shock.
- "Shock Complete" message is displayed in message window when shock is completely delivered.
- After Delivered energy, shock status will save and automatic print of shock event along with 10 seconds ECG data.
- When there is some error in charging of capacitor or delivering of shock, the message window displays following message; "PLACE PADS PROPERLY"

<u>WARNING</u>: Avoid touching any metal surface on the defibrillator and do not touch equipment connected to the defibrillator during shock. Dangerous high voltage exists on the paddles when the defibrillator is discharged. Contact with this high voltage can cause death or serious injury.

After the shock is delivered an online print is generated with the following details:



Fig.47

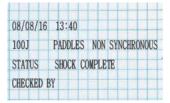


Fig.48

Synchronized Defibrillation

Defibrillator provides synchronized defibrillation by delivering a brief biphasic pulse of electricity to the cardiac muscle immediately following an R-wave detected in the ECG measurement.

NOTE: Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient. Failure to have a successful patient outcome is not a reliable indicator of defibrillator performance. The presence or absence of a muscular response to the transfer of energy during defibrillation is not a reliable indicator of energy delivery or device performance.

Use only approved patient cable with defibrillator; failure to do so may introduce noise and result in intermittent leads off messages.

Performing Synchronized Defibrillation

Synchronized defibrillation allows you to synchronize delivery of the shock with the R-wave of the ECG being monitored in Wave Sector 1. Synchronized cardio version is always through Paddles.

When using Paddles you should monitor the ECG through monitoring electrodes connected to a5-ECG patient cable.

Preparing for Synchronized Defibrillation

In preparation for synchronized:

- Perform the tasks as described in "Preparing for Defibrillation".
- 2. To monitor ECG, plug a 5-lead ECG cable, into the ECG port on BIPHASIC and apply monitoring electrodes to the patient.
- 3. Use the Lead Select button to select a lead from attached monitoring electrodes. The selected ECG source should have a clear signal and a large QRS complex.

Delivering a Synchronized Shock

- 1. BIPHASIC is in 'External-Non-Sync' mode by default.
- 2. Press Sync/Non-sync key on front panel keypad.
- 3. 'External-Sync' message is displayed on the top of the screen.
- 4. Rotate the Encoder to the desired energy level setting.
- 5. Press the Charge button on the front panel or, if using paddles, the orange charge button located on the Apex Paddle.

NOTE: To disarm the defibrillator, press Disarm key on front Panel keypad. If the Shock button has not been pressed within 20 sec the defibrillator disarms automatically. After charge button is pressed the selected energy cannot be changed. When selected energy becomes equal to charged energy, "Press Discharge Key" message will be displayed on screen and "Press discharge button" voice message is also generated. Confirm lead is displayed and the defibrillator has charged to the selected energy level. Make sure no one is touching the patient or anything connected to the patient. Call out loudly and clearly, "Stay clear!" Press Discharge button on Front panel or press Discharge buttons simultaneously on both paddles. Delivered energy is displayed in Delivered Energy window

- If 'R' wave is not detected the message "NO QRS INCREASE GAIN" and same voice message will also be generated increase gain and check if QRS is detected.
- If 'R' wave is still not detected the Defibrillator will switch to 'Non-Sync' Mode and 'PRESS DISCHARGE KEY' message is displayed on the message window and "Press Discharge Button" voice message is generated.
- After Delivered energy, shock status will save and automatic print of shock event along with 10 seconds ECG data.
- When there is some error in charging of capacitor or delivering of shock, the message window displays following message; "PLACE PADS PROPERLY"

<u>WARNING:</u> Avoid touching any metal surface on the defibrillator and do not touch equipment connected to the defibrillator during shock. Dangerous high voltage exists on the paddles when the defibrillator is discharged. Contact with this high voltage can cause death or serious injury.

<u>Delivering Additional Synchronized</u> Shocks

If additional synchronized shocks are indicated, perform the following steps:

- 1. Make sure the Sync function is still enabled, as indicated by the presence of the 'External-Sync' text on the top of the screen.
- 2. Repeat Steps for 'Non-Synchronous defibrillation'. Biphasic switches from synchronous to non-synchronous if 'R' wave is not detected.
- 3. To continue to give shock in synchronous mode press 'SYNC/NON SYNC' keypad button.

<u>Delivering shock using Internal Paddles</u> (<u>Optional</u>)

- 1. Check if the unit is in 'Internal-Non-Sync' mode.
- 2. 'Internal-Non-Sync' message is displayed on the top of the screen.
- 3. Rotate the Encoder to the desired energy level setting. Rotate Encoder to select the desired energy level by in the range of 2 to 50 Joule. By default selection is at 50 Joule
- 4. Press the Charge button on the front panel or, if using paddles, the orange charge button located on the Apex Paddle.

NOTE: To disarm the defibrillator, press Disarm key on front Panel keypad. If the Shock button has not been pressed within 20 sec the defibrillator disarms automatically. After charge button is pressed the selected energy cannot be changed.



Fig.49

ECG MONITORING

This chapter describes the monitoring of ECG (Electrocardiogram) through a 5- Lead patient cable.

Overview

Defibrillator can be used for ECG monitoring, allowing you to Monitor through:

- 1. 5-lead ECG patient cable.
- 2. Heart rate and alarms clearly communicate patient status, both audibly and visually.

Waveforms may be acquired through the paddles or 5-lead ECG Patient cable. Monitoring of ECG through paddles is not advised as only default lead 'II' can be selected for monitoring. And with the 5-lead Patient cable, 7 leads can be used for monitoring the ECG of the patient. The Heart rate is determined from the ECG lead II.

<u>WARNING</u>: Do not use defibrillator to monitor neonatal ECGs. Doing so could result in inaccurate measurements and alarms.

Monitoring View

Monitoring View appears on the display when your press Monitor key on front panel keypad shows the information displayed in Monitoring View

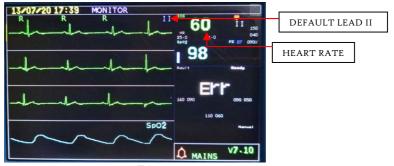


Fig.50



Fig.51

NOTE: In monitor mode 'MONITOR' text is displayed on top of the screen.

Lead II is selected by default. One can change Lead by pressing Lead Key.

Monitoring View can display only one ECG Trace at a time Numeric values for heart rate, sweep speed, gain and alarm limits.

<u>NOTE</u>: Wave sector 1 and 2 displays waveform of same Lead. Wave sector 1: It displays current wave form.

Wave sector 2: It displays Plethysmograph.

Preparing to Monitor ECG

To monitor ECG through 5-lead patient cable:

- 1. Prepare the patient's skin prior to applying monitoring electrodes. Skin is a poor conductor of electricity, so skin preparation is important in achieving good electrode-to-skin contact.
- 2. Identify the appropriate electrode sites.
- 3. If necessary, clip hair at the electrode sites (or shave sites if needed).
- 4. Clean and abrade the skin at the electrode site.
- 5. Dry the electrode sites briskly to increase capillary blood flow in the tissues and to remove oil and skin cells.
- 6. Apply some jelly to the electrode site and thoroughly rub the site with gauze till it becomes slightly red. This removes the horny non-conducting layer of the epidermis enabling a good electric contact with the body fluids.
- 7. Remove all the traces of jelly by wiping the abraded site with warm dry cloth and completely dry up the site with dry towel. The skin must be clean, dry and completely free of jelly for the electrodes to remain well in position till the end of ECG acquisition. If the jell has dried out, then discard the electrode.
- 8. Apply the electrode to the prepared site and run your fingers around the foam pad smoothing it from the center out. Repeat this procedure for all sites.
- 9. Connect 5-lead ECG patient cable to defibrillator and then connect it to the respective electrodes.

<u>WARNING</u>: Be sure that the electrodes do not come in contact with other conductive materials, especially when connecting or disconnecting the electrodes to/from the patient.

<u>NOTE</u>: Use only approved patient cable and electrodes with defibrillator failure to do so may introduce noise and result in intermittent leads off messages. If Monitoring of ECG is over long period of time then change the electrodes periodically.

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Electrode Placement

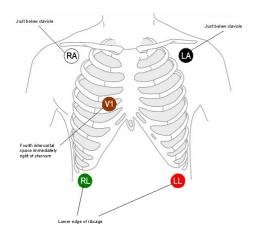


Fig.52

:Directly below the clavicle and near the RA/R placement

right shoulder.

LA/L placement

shoulder.

RL/N placement :On the right lower abdomen.

LL/F placement :On the left lower abdomen.

V/C placement : On the chest.

Heart Rate Alarms

Defibrillator detects Heart rate alarm conditions by comparing ECG data to a set of predefined criteria. The criteria are in format of limits; these limits can be changed on orders from a trained medical person.

HR Alarms can be generated when HR>High limit or HR<Low limit. The notification of an alarm is indicated by both an audible and visual. Heart rate parameter will start blinking to show alarm condition.

:Directly below the clavicle and near the left

Setting Alarms Limits

- 1. Confirm you are in monitor mode
- 2. Rotate the encoder until the ECG window is selected.
- 3. (Outline of the ECG window is Yellow.)
- 4. Press the encoder to confirm the selection.
- 5. Cursor will go to sweep speed parameter.
- 6. Rotate encoder until Hi-limit value or Low-limit value is selected.
- 7. Press the encoder to confirm the section of the parameter. Parameter values Red.
- 8. Rotate the encoder clockwise or anti-clockwise until the required limit is achieved.
- 9. Press the encoder to confirm the value.(Parameter value is Grey).
- 10. Sweep-speed parameter can be set in the same way.



Fig.53

Responding to HR

When an alarm is announced, pressing Alarm button on front panel keypad silences the alarm audio while you are attending to a patient. Parameter will blink if one pause's the alarm and alarm condition occurs within Auto reset alarm time in Menu option. Alarm will restart if conditions exist for more than set auto reset time in Menu option.

There are two ways to respond to an HR alarm:

- Acknowledge the alarm condition.
- Adjust the limits using the encoder

Respiration(optional):

Connect ECG cable leads to the patient. Respiration trace and respiration value will be displayed.

PULSE OXIMETRY (optional)

Pulse Oximetry (SpO_2) monitoring is one of the tools available to assist in assessing a patient's cardiac and respiratory systems. This chapter explains how pulse oximetry works and describes how to use defibrillator to monitor SpO_2 .

Overview

Pulse oximetry is a noninvasive method of continuously measuring functional oxygen saturation (SpO_2) in arterial blood. The resultant SpO_2 reading indicates the percentage of hemoglobin molecules in the arterial blood which are saturated with oxygen.

Understanding Pulse Oximetry

A pulse oximetry sensor sends light through patient tissue to a receiver on the other side of the sensor. Light emitting diodes transmit red and infrared light through peripheral areas of the body, such as a finger.

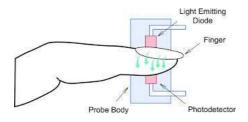


Fig.54

A photodetector positioned opposite the light emitting diodes compares light absorption before and after pulsation. The amount of light getting through reflects the blood flow in the arterioles. This measurement of light absorption during pulsation is translated into an oxygen saturation percentage and SpO2 value is displayed.

For accurate SpO₂ measurements, the following conditions must apply:

- The patient must have perfusion in that extremity.
- The light emitter and the photodetector must be directly opposite each other.
- All of the light from the emitter must pass through the patient's tissue.
- The sensor site should be free of vibration and excessive motion.
- Power cables should be kept away from the sensor cable and connector.

Monitoring SpO₂

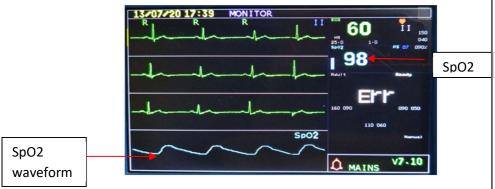


Fig.55

Applying the Sensor

Follow the manufacturer's directions for applying and using the sensor, making sure to observe any warnings or cautions. For the best results:

- Make sure the sensor is dry.
- If the patient is moving, secure the sensor cable loosely to the patient.

- Make sure the transducer is not too tight. Too much pressure can cause venous pulsation or can impede the blood flow, resulting in low readings.
- Keep power cables away from the sensor cable and connection.
- Avoid placing the sensor in an environment with bright lights. If necessary, cover the sensor with opaque material.
- Avoid placing the sensor on an extremity with an arterial catheter, blood pressure cuff, or intravenous infusion line.

SpO₂ Alarms

Defibrillator detects pulse oximeter alarm conditions by comparing the SpO_2 data to a set of predefined criteria. The criteria are in format of limits; these limits can be changed on orders from a trained medical person.

The notification of an alarm is indicated by both an audible and visual. SpO2 % parameter value will start blinking to show alarm condition.

Setting Alarms Limits

- 1. Confirm you are in monitor mode.
- 2. Rotate the encoder until the SpO₂ window is selected.
- 3. (Outline of the SpO₂ window is Yellow.)
- 4. Press the encoder to confirm the selection.
- 5. Rotate encoder until SpO₂ % limit is selected.
- 6. Press the encoder to confirm the section of the parameter. The value is in Red.
- 7. Rotate the encoder clock wise or anti-clock wise until the desired limit.
- 8. Press the encoder to confirm the value. (Parameter value is Grey).

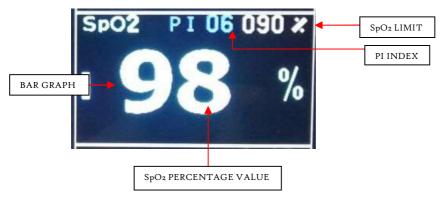


Fig.56

NON-INVASIVE BLOOD PRESSURE (optional)

This chapter describes how to monitor noninvasive blood pressure (NIBP) with defibrillator.

<u>Overview</u>

Defibrillator measures blood pressure for and adult, pediatric and neonatal patients using theoscillometric method. Systolic, diastolic, and mean measurements are provided, and alarms are available to alert you to changes in the patient's condition. NIBP measurements can be taken automatically on a schedule or manually on demand.

Once the measurement is complete, the values for systolic, diastolic, and mean pressure are displayed. If NIBP alarms are enabled, alarm limits appear next to the NIBP value and the alarm source (systolic, diastolic, or mean) is displayed above the NIBP alarm limits.

<u>Understanding NIBP</u>

Blood pressure (BP) is the pressure exerted by circulating blood upon the walls of blood vessels. When used without further specification, "blood pressure" usually refers to the arterial pressure in the systemic circulation. It is usually measured at a person's upper arm. Blood pressure is usually expressed in terms of the systolic (maximum) pressure over diastolic (minimum) pressure and is measured in millimeters of mercury (mm Hg). It is one of the vital signs along with respiratory rate, heart rate, oxygen saturation, and body temperature. Normal resting blood pressure in an adult is approximately 120/80 mm Hg. Blood pressure varies depending on situation, activity, and disease states. It is regulated by the nervous and endocrine systems. Blood pressure that is low due to a disease state is called

hypotension, and pressure that is consistently high is hypertension.

Both have many causes which can range from mild to severe. Both may be of sudden onset or of long duration. Long term hypertension is a risk factor for many diseases, including kidney failure, heart disease, and stroke. Long term hypertension is more common than long term hypotension in Western countries. Long term hypertension often goes undetected because of infrequent monitoring and the absence of symptoms.

Monitoring NIBP

Preparing to Measure NIBP

- 1. Attach the cuff to the NIBP tubing, making sure that air can pass through the tubing and that the tubing is not being squeezed or kinked.
- 2. Apply the blood pressure cuff to the patient's arm or leg as follows:
 - a. Ensure that the cuff is completely deflated.
 - b. The cuff should not be placed on the same extremity as a SpO₂ sensor. Wrap the cuff around the arm, making sure that the artery marker is aligned over the brachial artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities. Also ensure that the NIBP tubing from the defibrillator to the cuff is not compressed, crimped, or damaged.
- 3. Place the limb used for taking the measurement at the same level as the patient's heart.

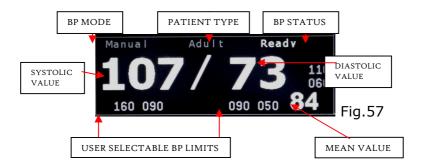
NOTE: Do not compress or restrict pressure tubes during an NIBP measurement. If a spill occurs and liquid appears to be inside the tubing, contact your service personnel

NIBP Alarms

Defibrillator detects noninvasive blood pressure alarm conditions by comparing the NIBP data to a set of predefined criteria. The criteria are in format of limits; these limits can be changed on orders from a trained medical person. The notification of an alarm is indicated by both in audio and display form. The systolic or diastolic value is out of the set limits; the value will start blinking to show alarm condition.

Setting Alarms Limits

- 1. Confirm you are in monitor mode.
- 2. Rotate the encoder until the NIBP window is selected. (Outline of theNIPB window is Yellow.)
- 3. Press the encoder to confirm the selection.
- 4. Rotate encoder until the diastolic or systolic limit is selected.
- 5. Each Diastolic and Systolic reading has a 'Hi' and 'Low' limit.
- 6. Press the encoder to confirm the section of the parameter. The value is in Red.
- 7. Rotate the encoder clock wise or anti-clock wise until the desired limit.
- 8. Press the encoder to confirm the value. (Parameter value is Grey).



TEMPERATURE(Optional):

The Monitor offers one channel of real-time continuous temperature monitoring. The device can monitor temperature using a surface temperature probe which can be displayed in either Fahrenheit or Celsius. The Temperature units can be changed to either Fahrenheit or Celsius, the temperature limits change according to the unit selected. The high level and low level limits are user defined. Applying the Sensor The temperature sensor used is surface temperature probe. Apply the temperature probe on the area of the human body where the temperature needs to be measured. Normally it is placed under the armpit or on the elbow. The placement is decided by trained medical professional.

Setting Alarms Limits

- Rotate the encoder until the Temperature window is selected. (Outline of the temperature window is Yellow.)
- Rotate encoder until the temperature limit is selected.
- Press the encoder to confirm the section of the parameter. The value is in Red.
- Rotate the encoder clock wise or anti-clock wise until the desired limit is set.
- Press the encoder to confirm the value. (Parameter value is Grey).

Changing the Temperature Unit

- Rotate the encoder until the Temperature window is selected. (Outline of the temperature window is Yellow.)
- Rotate encoder until the temperature unit is selected.
- Press the encoder to confirm the section of the parameter. The value is in Red.
- Rotate the encoder clock wise or anti-clock wise to select 'Celsius' or 'Fahrenheit'.
- Press the encoder to confirm the value. (Parameter value is Amber).

EXTERNAL PACING(optional)

This chapter explains the noninvasive transcutaneous pacing option available with defibrillator and describes how to perform pacing.

Overview

Noninvasive transcutaneous pacing therapy is used to deliver pace pulses to the heart. Non-invasive transcutaneous pacing is a technique of electrically stimulating the heart externally through a set of electrode pads. The stimulus is intended to cause cardiac depolarization and myocardial contraction. Pacing is one method of treating patients when their heart's own conduction system slows dangerously. Pacer pulses are delivered through multifunction electrode pads that are applied to the patient's bare chest. There are two modes of pacing; 'Demand mode' and 'Non-Demand mode'. An option for delivering shock through pacer pads is provided.

Understanding External Pacing

Transcutaneous pacing (also called external pacing) is a temporary means of pacing a patient's heart during a medical emergency. It is accomplished by delivering pulses of electric current through the patient's chest, which stimulates the heart to contract.

The most common indication for transcutaneous pacing is an abnormally slow heart rate. By convention, a heart rate of less than 60 beats per minute in the adult patient is called bradycardia. Not all instances of bradycardia require medical treatment. Normal heart rate varies substantially between individuals, and many athletes in particular have a relatively slow resting heart rate.

In addition, the heart rate is known to naturally slow with age. It is only when bradycardia presents with signs and symptoms of shock that it requires emergency treatment with transcutaneous pacing

MODES

There are two modes for external pacing. The certified physician will decide which mode is appropriate for the patient.

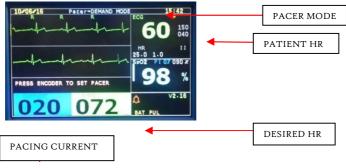


Fig. 58

Non demand Mode

In this operating mode, the module delivers pacing pulses with user-defined current at a user-defined rate. The selected rate remains constant and is not affected by intrinsic actions of the patient's heart. This is the preferred mode for cases of cardiac arrest.

Demand Mode

In demand mode, the pacemaker does not deliver pacing pulses as long as the patient's intrinsic heart rate exceeds the set pacing rate. When the heart rate drops below the pacing rate, the pacemaker starts emitting stimulation pulses. This can only be ensured by continued monitoring of the ECG. The pacemaker receives the necessary ECG signal via the ECG electrodes. If the module is not able to reliably identify QRS complexes, it will stimulate the heart permanently in demand mode. The demand mode is the recommended pacing mode when the patient is at risk of developing bradycardia or even asystole as a result of a critical event. As the pacemaker function is controlled by the patient's ECG, the harmful

competition between intrinsic and external stimulation, which could induce ventricular fibrillation, is excluded.

Attaching pacer pads

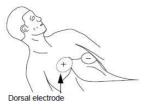


Fig. 59 - Anterior-posterior placement



Fig.60 - Anterior-anterior placement

- Connect pacemaker adaptor connector to side panel of unit and connector of pads cable to pacemaker adaptor connector.
- Connect pacer pads to patients. Connect ECG cable to patient.
- Select Pace maker mode with the help of pacer key. By default pacer is in Demand mode.
- Set the Pacer rate value to desired heart rate value.
- Now set current with the help of encoder.
- Rotate encoder to increase current value till pacemaker will captures myocardium, taking over pacemaker function of heart.
- Press key to change pacer mode from demand to NON demand mode.



Fig. 61 - Pacer window view

AED - AUTOMATED EXTERNAL DEFIBRILLATOR (optional)

Defibrillation therapy is the definitive method for termination of a variety of potentially fatal arrhythmias. Automated External Defibrillation (AED) Mode is designed to guide you through standard treatment algorithms for cardiac arrest. Defibrillatorprovides therapy through the application of a brief biphasic pulse of electricity to the cardiac muscle. This electrical energy is transferred through disposable multifunction electrode pads applied to the patient's bare chest.

Configuration choices allow you to customize AED Mode to better meet the unique needs of your organization or resuscitation team. This chapter describes how to use AED Mode. It explains the prompts that guide you through the defibrillation process and describes how prompts vary depending upon the condition of the patient and the configuration of your device.

NOTE: Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient incident. Failure to have a successful patient outcome is not a reliable indicator of defibrillator performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or device performance.

Preparation

Confirm that the patient is:

- Unresponsive
- Not breathing
- Pulse les
 - Remove clothing from the patient's chest. Wipe moisture from the patient's chest and, if necessary, clip or shave excessive chest hair.
 - Make sure the multifunction electrode pads packaging is intact and within the expiration date shown.
 - Apply multifunction electrode pads to the patient as directed on the pads packaging or according to your organization's protocol.

Operation in AED mode

Follow the below steps to operate defibrillator in AED mode.

1. Connect the disposable AED pads to the patient and the cable to the unit.

If the cable or the pads are not connected properly the unit will generate "Attach Pads" voice message and display the same message in the message window.



Fig.62(a) Adult mode

For Adult mode- Rotate encoder for adult mode to set 200J and Check voice prompt " Adult".



Fig.62(b) Pediatric mode

For Pediatric mode- Rotate encoder to set Joules to 50 J for Pediatric mode and Check voice prompt "Pediatric".

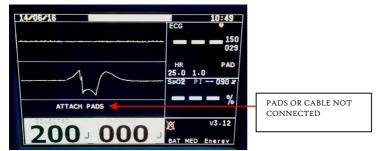


Fig.63

- 2. Then Press 'AED' mode button on the keypad.
- 3. The unit will start analyzing the ECG of the patient which is collected through the AED pads.

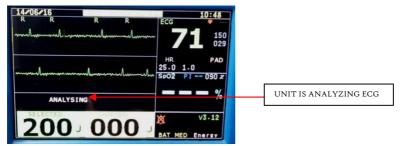


Fig.64

4. If the patient's HR is stable and shock is not required, the unit will generate a voice message "Shock not advised" and will display the message "Press analyze to reanalyze".

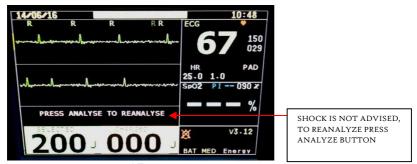


Fig.65

- 5. If the patient's HR is unstable and ECG waveform has fibrillations, the unit will generate a voice message "Shock advised" and it will automatically charge to 2001.
- 6. The user has to press the discharge key to deliver shock through the pads. The unit will generate voice message "Press discharge key to deliver shock" and display "Press discharge button" in the message window.

END-TIDAL CARBON DI-OXIDE EtCO2(optional)

Overview

ETCO₂ is the partial pressure or maximal concentration of carbon dioxide (CO₂) at the end of an exhaled breath, which is expressed as a percentage of CO₂ or mmHg. The normal values are 5% to 6% CO₂, which is equivalent to 35-45 mmHg. CO₂ reflects cardiac output (CO) and pulmonary blood flow as the gas is transported by the venous system to the right side of the heart and then pumped to the lungs by the right ventricles. When CO₂ diffuses out of the lungs into the exhaled air, a device called capnometer measures the partial pressure or maximal concentration of CO₂ at the end of exhalation. During CPR, the amount of CO₂ excreted by the lungs is proportional to the amount of pulmonary blood flow.

EtCO2 Setting

Select the 'Etco2 setting' menu using encoder. Following menu will be display on the screen.



Fig.66

- 1. O2 Comp: Use this setting to correct for the compensation of the oxygen in the gas mixture administered to the patient. Default value is 16%
- 2. <u>Balance:</u> Use this setting to correct for the compensation of the balance in the gas mixture administered to the patient

"Air", "N2O", "Helium", Default balance is Air

- 3. <u>Agent</u>: Use this setting to correct for the compensation of the anesthetic agent in the gas mixture administered to the patient.
- 4. <u>Temp:</u>This setting is used to set the temperature of gas mixture. The default value is 35.0 degree Celsius .0.0 to 50.0°C
- 5. <u>Baro-Pre</u>: User can set barometric pressure between 400 to 850mmhg and default value is 760mmhHg
- 6. <u>Wave -mod</u>: This setting is used to display CO₂ waveform in either Fill mode or line mode
- 7. EtCO₂ Probe zeroing: The Probe zero allows for the EtCO2 sensor to accommodate the optical characteristics of each of the different adapter types. A Probe zero should be performed whenever the type of adapter being used with the EtCO2 sensor is changed. Probe zeroing takes 10-15 seconds to complete.



<u>Note:</u> EtCO2 probe zeroing attempted and breaths have been detected in the last 20 seconds. Remove Sensor and Airway Adapter from presence of CO2 and wait for Breath Detected Status bit, to clear before attempting another Zero.



- 8. Exit: To exit from etco2 setting.
- EtCO₂ Scale-Select desired EtCO₂ scale option in Fi/EtCO₂ panel using encoder. Rotate encoder to select desired EtCO₂ scale. The height of EtCO₂ trace is changed according to the selected scale.

Setting Alarms Limits

- Rotate the encoder until the EtCO₂window is selected. (Outline of the temperature window is Yellow.)
- Rotate encoder until the EtCO₂ or FI limit is selected.
- Press the encoder to confirm the section of the parameter. The value is in Red.
- Rotate the encoder clock wise or anti-clock wise until the desired limit.
- Press the encoder to confirm the value. (Parameter value is Grey).



FEATURES

Printing Options:

Defibrillator has printer installed on the left side panel. There are various printing options.

Online print – After the shock is delivered; the last 10 second ECG data is printed along with shock details; (Sync/Non-Sync, Energy delivered, date and time).

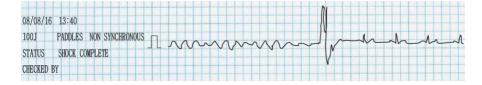


Fig.68

- Event history print –In Event history, one can select to print the history of the shock. This print includes all the shock details; (Sync/Non-Sync, Energy delivered, date and time).
- 3. ECG print In monitor mode, one can print 10 seconds of ECG data of the selected lead. To print data of another lead one has to select the lead on display and then print.



Fig.69

4. Paper out – The following message is displayed in the status window when the thermal printer paper is not loaded properly or the printer lid is open

Prompts:

These are the following voice and display prompts which are displayed during the operation of defibrillator.

MODE/WINDOW	VOICE PROMPT	DISPLAY PROMPT
POWER ON	"UNIT IS READY"	NA
DEFIB-CHECK MODE (TEXT ON TOP OF THE SCREEN).	"OPERATING IN DEFIBRILLATOR CHECK MODE"	MANUAL DEFIB- CHECK
DEFIB-CHECK MODE (MESSAGE WINDOW)	NA	PRESS CHARGE KEY
DEFIB-CHECK MODE (MESSAGE WINDOW)	"OPERATING IN DEFIBRILLATOR CHECK MODE"	MANUAL DEIFB- CHECK COMPLETE
EXTERNAL NON- SYNC MODE (TEXT ON TOP OF THE SCREEN)	"OPERATING IN SHOCK BY PADDLES MODE"	EXTERNAL NON- SYNC
MONITOR (TEXT ON TOP OF THE SCREEN)	"OPERATING IN MONITOR MODE"	MONITOR
CHARGE (MESSAGE WINDOW)	NA	PRESS CHARGE KEY
CHARGING (MESSAGE WINDOW)	"CHARGING"	CAPACITOR IS CHARGING
DISCHARGE (MESSAGE WINDOW)	"PRESS DISCHARGE BUTTON TO DELIVER SHOCK"	PRESS DISCHARGE KEY
DISCHARGING (MESSAGE WINDOW)	"DISCHARGING"	CAPACITOR IS DISCHARGING
SHOCK DELIVERED (MESSAGE WINDOW)	"SHOCK DELIVERED"	SHOCK COMPLETE
EXTERNAL SYNC MODE (TEXT ON TOP OF THE SCREEN)	"OPERATING IN SYNCHRONOUS MODE"	EXTERNAL SYNC

DEFIBRILLATOR CHECK MODE (WHEN PADS ARE NOT PLACED PROPERLY)	"PLACE PADS IN CRADDLE"	PLACE PADS IN CRADDLE
"R" WAVE DETECTION (MESSAGE WINDOW)	"NO QRS INCREASE GAIN"	NO QRS INCREASE GAIN
BATTERY OPERATION	"UNIT OPERATING ON BATTERY"	NA
STATUS WINDOW	NA	SAVING
STATUS WINDOW	NA	PRINTING
STATUS WINDOW	NA	PAPER OUT
STATUS WINDOW	NA	BAT- FUL/MED/LO
PACER MODE (optional)	"SELECT PACER MODE,	PRESS ENCODER TO SET PACER
PACER DEMAND MODE PACER MODE (optional)(TEXT ON TOP OF THE SCREEN)	"OPERATING IN DEMAND MODE"	PACER – DEMAND MODE
PACER NON - DEMAND MODE PACER MODE (optional) (TEXT ON TOP OF THE SCREEN)	"OPERATING IN NON -DEMAND MODE"	PACER - NON DEMAND MODE
AED MODE (IF PADS ARE NOT CONNECTED)	"ATTACH PADS"	ATTACH PADS
AED MODE (WHEN ANALYSING)	"ANALYSING HEART RHYTHM "	ANALYSING
AED MODE	"SHOCK NOT ADVISED"	SHOCK NOT ADVISED
AED MODE	"SHOCK ADVISED"	SHOCK ADVISED
MONITOR (WAVE SECTOR 1)	NA	BATTERY CHARGING REQUIRED

ACCESSORIES

This chapter lists the various supplies and accessories for defibrillator.

<u>WARNING</u>: Use only supplies and accessories approved for use with your defibrillator. Use of non-approved supplies and accessories could affect performance and results. For example, some electrodes may be subject to large offset potentials due to polarization.

Only the accessories listed below should be used to provide the proper protection against burns and shock hazards. Use single-use supplies and accessories only once.

5-lead ECG cable set



Fig.70

NOTE: Use only ECG Cable with Defibrillator protection

SpO₂ Probe (optional)



Fig. 71

NIBP Cuff (optional)



Fig.72

Power Cord



Fig.73

The Power Cord is used to charge defibrillator ;it is connected on the back panel.

Pacer/AED Extension Cable (optional)



Fig. 74
Pacer/AED Pads (optional)



Fig.75

NOTE: The pacer extension cable and pacer pads can be used for AED too.

The AED pads are one time use only.

• Mainstream Sensor for EtCO₂(optional)



Fig.76

Temperature probe(optional)



Fig.77

TROUBLESHOOTING

This chapter describes all the problems that might occur during the operation of defibrillator.

<u>WARNING</u>: Product servicing and repair should only be performed by qualified service personnel. Refer to servicing instructions of the manual.

Symptom	Possible Cause	Possible Solution
Defibrillator does not turn on.	There is no power.	Connect the Power cord
Audio is too low or absent.	The QRS, Voice, volumes configured to a Very softer Off Setting.	Adjust the Voice volume POT and increase the volume using the knobs on the side panel.
External Power Interrupted.	AC/DC power was removed; now Operating from battery power.	Connect Power cord.
QRS beeper inaudible or beeps do not occur with teachers complex.	The amplitude of the QRS Complex is too small to detect.	Select a different lead.
Poor ECG signal quality (Noisy trace, wandering baseline, etc.) From signal acquired through monitoring electrodes.	The monitoring electrodes are not making proper contact with the patient.	Check that the monitoring electrodes are properly applied. If necessary, prepare the patient's skin and apply new electrodes.
Poor ECG signal quality (Noisy trace, wandering baseline, etc.) From signal acquired through monitoring electrodes.	The monitoring electrodes are outdated or driedout.	Check the date code on the electrodes. Do not open the electrode package until immediately prior to use

Poor ECG signal quality (noisy trace, wandering Baseline, etc.) From signal acquired through monitoring electrodes.	Radio frequency interference(RFI) is causing artifact.	Relocate or turn off equipment that may be causing RFI. Try repositioning cables/leads.
Poor ECG signal quality (noisy trace, wandering Baseline, etc.) From signal acquired through monitoring electrodes.	The ECG cable may be faulty.	Replace the cable with a new one.
Leads are Off (Message displayed in wave sector 1)	Electrode(s) are not making proper contact with the patient.	Check that monitoring electrodes are properly applied. If necessary, prepare the patient's skin and apply new electrodes.
Paper won't move in the printer.	Paper improperly loaded or jammed or paper is wet.	Reload paper or clear jam. If paper is wet, replace With fresh, dry roll.
Paper moves then stops in the printer.	Door improperly latched.	Check door latch.
Paper moves but printing is faint or absent.	Incorrect paper type.	Use only recommended paper type.
Paper out (Message displayed in status window)	The printer is out of paper or the door is open.	Load/reload the printer paper. Make sure the printer door is closed.

<u>MAINTENANCE</u>

OPERATIONAL CHECK

- 1. Check the power cord visually for wear and tear.
- 2. Check the ECG patient cable, paddles, retractable cables visually for wear and tear, cracks, insulation cuts and other damage.
- 3. Check that the electrolyte has not solidified on the paddle surface. Remove any residual electrolyte on the paddles.
- 4. Check that the cables do not have any cracks or cuts.
- 5. After each use, wait for 5 minutes and then clean Defib paddles metal plate using a soft, damp cloth moistened with any of the following solvents:
 - Mild Soap and water
- 6. Although there are no user serviceable parts inside the unit. The operator can perform the following preventive maintenance checks that will help ensure that the device stays in working condition.
 - Check the case of the device foray apparent damage.
 - Check the ports (power cord port) to see that they are tightly in place.
 - Check the accessories, especially the ECG cable, to see that they are in good condition.

BATTERYCHECK

- 1. A new fully charged battery provides approximately 70-100 shocks of 150J or approximately 180 minutes of continues monitoring before the device powers off.
- 2. As batteries age, their charge capacities diminish. It is recommended that Defibrillator battery should be replaced every two years as preventive maintenance measure.
- 3. When operating on battery power, the large current draw required for defibrillator charging, may cause the defibrillator to reach shutdown voltage levels with no low battery warning.
- 4. The time from display of the "BATT LOW" indication and the instrument shuts down will vary depending upon the battery age and condition.

VISUAL CHECK

Disconnect the defibrillator from AC power and inspect for the following:

- Loose or missing hardware.
- 2. Worn out or damaged wiring.
- 3. Mechanical damage.
- 4. Evidence of liquid spill.
- 5. Corroded or damaged electrodes.
- 6. Damaged patient cables or connectors.
- 7. Damaged paddle connector or retractable cable.

CLEANING INSTRUCTIONS

Listed below are recommendations for cleaning defibrillator and its associated accessories.

<u>CAUTIONS</u>: The BIPHASIC along with its accessories and supplies, may not be autoclaved, steam sterilized, ultrasonically cleaned, or immersed unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies. Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners. Do not mix the disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

Do not clean electrical contacts or connectors with bleach. Disinfect the device as determined by your institution's policy to avoid long-term damage to the device.

Defibrillator

The following cleaning products may be used to clean the exterior surfaces of the defibrillator.

- Min cream
- · Mild soap and water

Before cleaning, remove all adherent soil (tissue, fluids, etc.) and wipe thoroughly with a cloth dampened with water before applying the cleaning solution.

When cleaning, do not immerse. Wring any excess moisture from the cloth before cleaning. Be sure to avoid pouring fluids on the device, and do not allow fluids to penetrate the exterior surfaces of the device.

To prevent scratching the display, the use of a soft cloth is recommended

Paddles

If external non-sterilizing paddles were used during defibrillation, make sure you thoroughly clean the paddles and paddle tray after each patient event and before performing a Defibrillator Weekly Test. Verify that there is no debris or residue (including all conductive material) on the electrode surfaces of the paddles and paddle tray. External non-sterilizing paddles and the Therapy cables may be cleaned with a soft cloth moistened with:

- Mild soap and water.
- Min cream

<u>CAUTION</u>: The paddles and Therapy cables may not be ultrasonically cleaned or immersed. Nor may they be autoclaved or ETO sterilized.

Defibrillator weekly check

There should be a weekly check be performed on defibrillator. Perform the 'Defib-Check Mode' once a week to ensure the proper working of defibrillator.

SPECIFICATIONS

GENERAL

Dimensions without Paddles: 280mm (H) x 330mm (W) x 220mm (D);

Weight: Approx. 6.5 Kg (14.33lbs)

Power supply: Input: 150 - 270 VAC, 50 Hz, 1 Ø Battery: 12 V 4.5Ah,

Rechargeable, (Lead acid)

Types of the alarm

1. ORS BEEP

2. Beyond limit alarm

Standard Operator Position: Within one meter of device.

DEFIBRILLATOR

Waveform: Biphasic Truncated Exponential. Waveform parameters adjusted as a function of patient impedance.

CHARGE TIME

8 seconds to 200J with a fully charged lead acid battery.

PATIENTIMPEDENCERANGE (External Defibrillation)

Minimum : 25 Ohm Maximum : 250 Ohm

<u>NOTE</u>: Actual functional range may exceed the above values.

DEFIB MODE

Manual Defibrillation Energy (Selected):2,3,5,7,10,20,30,50,70,100,150 &200 Joules., and optional 230,300 & 360 Joules.

Controls

Encoder, Charge, Shock, Sync, Lead Select, Disarm, Print &Alarm.

Energy Selection

Encoder

Charge Control

Front panel button, button on Apex paddles.

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Shock Control: Front panel button, buttons on both Apex and Sternum Paddles.

Synchronized Control: Front panel SYNC/NON-SYNC keypad.

Indicators: Text Prompts, Audio Alerts, QRS Beeper, Battery Status, Mains, Sync Mode

Alarm Indicators: Flashing of parameter value, energy level indicated on Display.

Shock Delivery: Via Paddles.

Sr	Selected	Low	High Limit
No	Energy	Limit (Joules)	(Joules)
1.	2	1	5
2.	3	2	6
3.	5	3	8
4.	7	5	10
5.	10	8	13
6.	20	18	22
7.	30	28	32
8.	50	47	53
9.	70	66	74
10.	100	95	105
11.	150	142	158
12.	200	190	210
13.	230	218	242
14.	300	285	315
15.	360	342	378

ECG monitoring

Input: One ECG lead wave may be viewed on display and printed at a time.

With a 5-lead ECG cable, leads I,II,III, aVL, aVR, aVF, V can also be obtained.

Pads ECG is obtained through paddles.

Heart Rate Display: Digital readout on display from 10 to 250 bpm (resolution is 1 bpm) with an accuracy of \pm 2 bpm whichever is greater.

Heart Rate Alarms: HR

Alarm limit range : 10-250 Common Mode Rejection: Greater than 90 dB

ECG Size: 0.5, 1.0 and 2.0 mm/mV

(The size of the ECG traces can be by pressing the Gain button and changing the Amplitude of the ECG traces.)

5-lead ECG

With a 5-lead cable, leads I, II, III, aVR, aVL, aVF and Vcan be obtained. The ECG traces can be viewed on the display one at a time. Press the Lead Button to change the lead to view on the display. All 7 leads can be printed on the ECG strip print.

Respiration(optional)

Parameter: Respiration rate

Measurement Method: Impedance between RA-LL

Measurement Range: 1 to 120 bpm

Accuracy: +/-2 bpm

Display

Size:7" in color TFT

Battery

Type: Rechargeable, Lead acid battery; (One Battery)

Capacity- 3 hours minimum on full charge in ECG mode, 70-100

shocks of 150J on full charged battery.

Note: As the battery ages its charging capacity and number of shocks delivered in a single shock also diminishes.

BATTERY INDICATIONS

'Operating in Battery mode' Voice message is generated while you are using Battery.

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'BAT FULL', 'BAT MED', 'BAT LO' messages are displayed in the Status Window indicating battery charged condition.

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THERMAL PRINTER

ECG Strip: The Print key starts the ECG print. The strip prints the displayed ECG lead. And the print includes details of the gain, sweep speed, ECG lead, date and time.

Auto Printing:

- An automatic print is generated after the shock is delivered which includes details of the energy delivered, complete/incomplete, sync/non sync, date and time and 10 seconds of ECG data.
- An automatic print is generated after a manual check is completed.

Reports: The Print button can be used to print a shock history from 'Event History' menu option which includes shock details and 5 seconds of ECG data.

Paper: Thermal Printer Roll size 55mm x 10mtr chemical coated.

- Printer paper may jam if paper is wet
- Thermal Printer may be damaged if wet paper is allowed to dry while in contact with printer elements

PATIENT TRENDING HISTORY

In the menu option there is an option of Display Trend which displays the history of the patient for 12 hours. There are two options

- Tabular Trend
- Graphical Trend

The trend displays Heart Rate value in Green colour and when the heart rate is out of the set limits it will appear in Red colour.

Environmental

Operating & Storage temperature : -5°C to 50°C

Humidity Up to 95% Relative Humidity

SpO2 (Optional)

Range: 0 - 100%

Accuracy : $\pm 2\%$ (70~100% SpO2)

± 3% (35~69% SpO2)

Pulse rate: Displayed in ECG window, when PR is selected.

Pulse beep: Yes, with volume control.

PR Range: 10 to 250 bpm (+/- 2 bpm) in step of 1 Pitch variation with change in oxygen saturation.

NIBP (NON-INVASIVE BLOOD PRESSURE)(Optional)

Method: Oscillometric Range: 10-250mmHg

Patient Type: Adult, Pediatric, Neonate

NIBP interval: User selectable, 2 min. to 250 min

Modes: Manual, auto
Cuff deflation: Automatic

Safety features: Automatic deflation if cuff pressure exceeds 280 mmHg

	Range
Adult type	
	40 ~ 270mmHg
SYS	10 270mmig
313	
	10 ~ 210mmHg
DIA	
51A	
	20 ~ 230mmHg
MEAN	
	Dange
	Range
Paediatric type	
	40 ~ 200mmHg
SYS	10 20011111119
313	
	10 ∼ 150mmHg
DIA	
DIA	
	20~ 165mmHg
MEAN	
	Range
	Kange
Neonatal type	
	40 ~ 135mmHg
SYS	====
313	
	10 ~ 95mmHg
DIA	
	20 10Fmamalla
	20 ~ 105mmHg
MEAN	

NIBP status display as:

TEMPERATURE(Optional) Parameter:

Temperature Measurement Range : 5 to 50 °C OR 41 to 122 °F

Temperature unit: Celsius OR Fahrenheit

[&]quot;Ready", when not taking reading

[&]quot;Measuring", when taking reading and

[&]quot;Error", if reading could not be taken due to some error while measuring

PACER(Optional)

Wave form: Monophasic

Modes: Demand or Non Demand

Pulse Current: From 10mA to 150 mA (resolution of 10 mA),

Pulse Duration: 40 ms (+/- 1ms)

Pacing rate: From 20 ppm to 250 ppm (increments of 1 ppm)

Refractory period: 340 ms (from 30 to 80 ppm); 240 ms(from 90 to 180

ppm).

Maximum output voltage: 150 V.

Impedance range: 200 ohm to 1 k ohm

AED (AUTOMATED EXTERNAL DEFIBRILLATOR) (Optional)

Wave form: Biphasic truncated exponential

AED Shock Series: Energy level 200J

Charge Command: Automatic after identifying shockable rhythm

Shock Command: Front panel button, shock

Controls: Analyze

Defibrillation Electrode: Self-adhesive, adult pads

Voice and Text prompts: Extensive text and audible messages to guide

user

INTERNAL PADDLES(Optional)

Operating Mode: Manual

Waveform: Biphasic Truncated Exponential Energy: 2 to 50 joules in 8 steps selection

Synchronous Cardioversion: Energy delivery begins within 60ms of the

QRS Peak

Charging Time: 6 seconds on Mains

Paddle Assembly: Internal paddle assembly with paddle extension cord.

EtCO2(Optional)

Parameters : EtCO2, FiCO2, RR

Measurement unit : mm Hg

Breath rate : 0~150 bpm

Measurement Range : 0 to 150 mmHg

Accuracy : $0 - 40 \text{ mm Hg } \pm 2 \text{ mm Hg}$

41 - 70 mm Hg $\pm 5\%$ of reading

 $71 - 100 \text{ mm Hg } \pm 8\% \text{ of reading}$

101 - 150 mm Hg ±10% of reading

Resolution : 0.1 mm Hg 0 to 69 mm Hg

0.25 mm Hg 70 to 150 mm Hg

Airway Adapter : Adult, Pediatric, Neonate

Measurement Mode : Mainstream & Side stream

FiCO2(optional)

Parameter : FiCO2

Measurement Range : 0-100 mmHg

^{*}Due to our continuous product improvement programme, features can be enhanced.

SAFETY CONSIDERATION

The following general warnings and cautions apply to use of defibrillator. Additional warning and cautions specific to a particular feature are provided in the appropriate section.

General

WARNING:

- Defibrillator is not intended to be deployed in settings or situations that promote use by untrained personnel.
 Operation by untrained personnel can result in injury or death.
- Biphasic service should only be performed by qualified service personnel, in accordance with the Biphasic Service Job Guide. Use of defibrillator is restricted to a single patient at a time. When transporting defibrillator, it is important to position it with the display facing away from the body.
- Remain attentive to the patient during the delivery of therapy. Delay in delivering a shock may result in a rhythm that was analyzed as shockable converting spontaneously to non-shockable and could result in inappropriate delivery of a shock.
- Use only 3-wire AC power cords with 3-pronged grounded plugs.
- Never operate defibrillator standing in water. Do not immerse, or pour fluids on, any portion of defibrillator. If the device does get wet, dry the device with a towel.
- Do not use defibrillator in the presence of a flammable anesthetic mixture or oxygen concentrations greater than 25% (or partial pressures greater than 27.5 kPa/206.27 mmHg). This can Cause an explosion hazard.
- Avoid connecting the patient to several devices at once. Leakage current limits may be exceeded.

- Does not use a second defibrillator on the patient while pacing with defibrillator. Do not remove assembly screws Refer to servicing instructions section of the manual.
- Operating defibrillator or its accessories in conditions outside the environmental specifications can result in device or accessory malfunction.
- Defibrillator should be allowed to stabilize within the operating temperature range for 30 minutes prior to operation.
- Defibrillator should not be used adjacent to or stacked with other equipment. Avoid touching monitoring electrodes and other measuring devices when they are applied to the patient. Doing so can degrade safety and may affect results.

CAUTION:

- Do not discharge the defibrillator with the paddles shorted together. Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact other conductive parts including earth.
- This device is suitable for use in the presence of high-frequency surgical equipment. Following electrosurgery interference, the equipment returns to the previous operating mode within 10 seconds without loss of stored data.
 Measurement accuracy may be temporarily decreased while performing electro surgery or defibrillation.
- This does not affect patient or equipment safety. See the electrosurgery devices Instructions for Use for information on reducing hazards of burns in the event of a defect in its equipment.
- Do not expose the equipment to x-ray or strong magnetic fields (MRI). Be aware of patient cables, including ECG monitoring equipment when used with high frequency surgical equipment.

<u>NOTE</u>: This device and its accessories are not intended for home use. Defibrillator can be operated with only AC/DC power and Sealed Lead-Acid Battery simultaneously.

Defibrillator does not require the practice of any special Electrostatic Discharge (ESD) precautionary procedures.

Defibrillation

WARNING:

- Keep hands and feet clear of paddles. Use your thumbs to depress the shock buttons on the paddle handle.
- Do not allow the paddles to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc.
- Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.
- During defibrillation, air pockets between the skin and paddles may cause patient skin burns. To help prevent air pockets, make sure the paddles completely adhere to the skin.
- Clean out the paddles for the dried electrode gel. Never touch the patient or any equipment connected to the patient (including the bed or gurney) during defibrillation.
- Avoid contact between the patient and conductive fluids and/or metal objects, such as the gurney.
- Contact with metal objects could cause unintentional current pathways. Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.

Battery WARNING:

- Do not expose batteries to temperatures greater than 50°C (122°F). Excess temperatures may result in battery damage.
- Keep batteries away from flame and other heat sources. Do not short circuit the battery. Avoid placing batteries around metal objects that may short circuit the battery.
- Avoid getting batteries wet or using batteries in high humidity environments.
- Do not crush, dent or allow any deformation of the batteries.
- Do not disassemble or open batteries. Do no attempt to alter or bypass the safety circuit
- Avoid extreme shock and vibration to the battery.
- Do not use or connect the battery to batteries of other chemistries.

Supplies and Accessories

<u>WARNING</u>: Use only the patient cable, battery, and accessories as listed in this guide. Substitutions may cause defibrillator to function improperly. If you wish to replace the accessories then contact our Service personnel (Refer Service Details).

Units and Abbreviations

Unit	Definition
bpm	Beats per minutes
°C	Degrees Celsius
mm/mV	Millimeter per millivolt
mmHg	Millimeters of mercury
mm	Millimeter
sec	Seconds
min	Minutes
Hz	Hertz
ppm	Pulses per Minute
J	Joules
%	Percentage

Above table lists units and abbreviations used.

SYMBOLS

\sim	Alternating current
(1)	Class I
	Power ON off
35%	Humidity
arc derc	Temperature
X	Dispose of in accordance with the requirements of your state
NON STERILE	Medical device that has not been subjected to a sterilization process.
- 	Defibrillation-proof type BF applied part
	Defibrillation-proof type CF applied part
<u> </u>	Caution
	Refer instruction manual/booklet
Ť	Keep dry
~	Manufacturer Date
	Manufacturer symbol
	D 444 -£444

SERVICING INFORMATION

The service life of machine is 7 years.

These are the following instructions to be followed for the servicing.

<u>WARNING:</u> Authorized personnel should only open the device as there are no user serviceable parts inside. The device is high voltage devices so do not disassemble the unit.

For servicing contact an authorized NASAN Medical Electronics Service Engineer.

Contact us:

All India Service (Mobile) : 09371039255

Email address : <u>service@nasanmedical.com</u>
Website : <u>www.nasanmedical.com</u>

Environmental protection

Disposal of the Equipment:

Then dispose of the device and supplies in accordance with your state regulations.



Disposal of the product: The product described in this user manual must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.