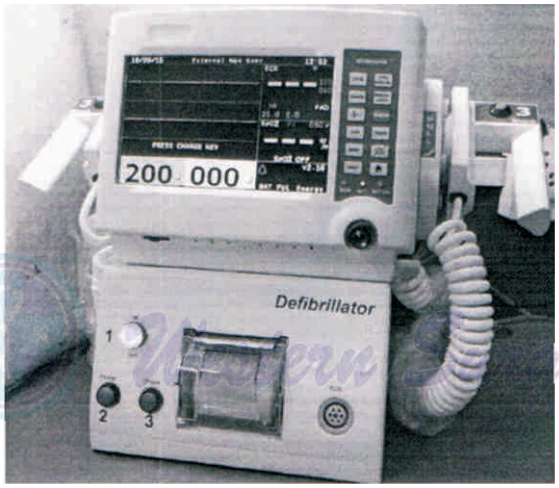

2008(P)
(Biphasic Defibrillator with ECG & Printer)

USER MANUAL

Western® Surgical

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* Due to constant upgradation design, price and features are subject to change any time without prior notice.

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- Device operation guidelines

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✦ CONTENTS OF MANUAL:

This Operator's manual contains all the information a user needs to operate the defibrillator properly. This defibrillator has been designed to analyze the ECG of a patient in ECG mode and to deliver a defibrillation shock as per user selected mode.

In case you have any problems regarding the operation of the device, please feel free to contact us right away.

This user manual contains information on a device that is subject to upgrades to incorporate additional features. Specifications and information herein are subject to change without prior notice.

Contents of this manual will be updated by us from time to time to reflect changes in features and design.

✦ DEVICE OPERATION GUIDELINES:

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

OPERATING CONDITIONS:

Temperature	0 °C to 50°C
Humidity	5 % to 95 % (non-condensing)

STORAGE CONDITIONS:

Temperature	-20°C to 70°C
Humidity	5 % to 95 % (non-condensing)

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.

✦ TESTING PROCEDURE FOR BIPHASIC DEFIBRILLATOR:

Since biphasic defibrillator is delivering energy after measuring of patient impedance, normally in the range of 35ohm to 250 ohm to test the shock delivery. It required set up of 50ohm/25W resistor.

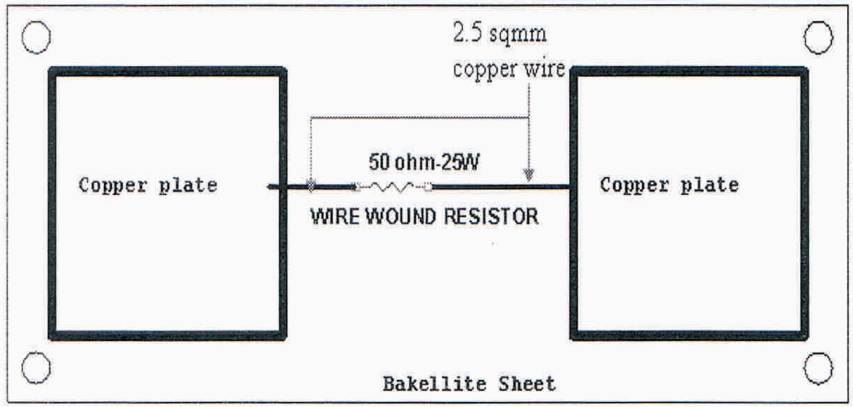
PROCEDURE BELOW GIVES DETAILS OF ENERGY DELIVER TEST:

1. Make set up of 50 ohm/25W Wire wound resistor with copper Plate as shown in diagram of "set up for Defibrillator testing".
2. Switch ON Defibrillator with the help of **"1" (ON) Indication button**
3. Remove both (Apex & Sternum) Pads from cradle & place on copper Plate of setup. Make Contact properly.
4. Press charge key on Apex handle(Top) or **"2"(Charge) indication button**

5. Wait until charge energy equal to selected energy then press discharge button simultaneously on Apex(Side) & Sternum handle or "**3" (Discharge) indication button**.

6. Shock Delivered message will be displayed on Screen & energy delivered to load will be displayed on Delivered energy.

Set up for defibrillator Testing



Note:- Mount M3x15 spacer(N+S) at bottom side each corner by M3 Screw

Connect Resistor to Copper plate with the help of 2.5 sqmm Copper Cable

NOTE: Shorting of paddles/paddles in open air, to check shock delivery is not recommended and it may damage the unit.

1. INTRODUCTION TO THE UNIT

A Biphasic Defibrillator is a battery powered, lightweight and portable device designed to deliver a biphasic shock.

It can be used in following operating modes:

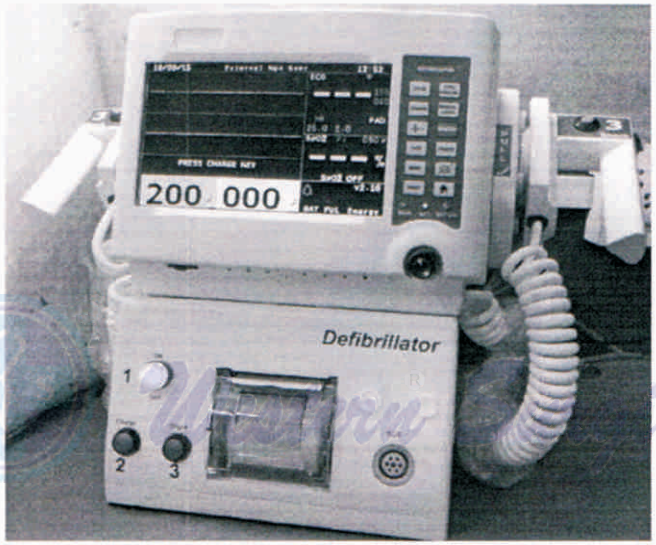
1. Monitoring the ECG of a patient in monitor mode.
2. When the patient shows following symptoms like
   a) Unconsciousness
   b) Abnormal breathing and
   c) Lack of a detectable pulse,

User can switch the operation to Defibrillator mode by manually pressing the **'DEFIB'** button on the keypad.

Features:

1. Defibrillator has variable energy level selection : **2, 3, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200 Joules**
2. It uses advanced logic to deliver equal energy in both the phases, regardless of patient impedance.
3. Charging time is less than 8 sec.
4. The internal battery can deliver up to 75 shocks.
5. In its Synchronous Cardio Version the energy delivery begins with 60 ms of the QRS (R wave).
6. The DEFIBRILLATOR mode can be operated in two modes: Synchronous and
7. Non-Synchronous Mode
8. There is a Manual Check facility for checking proper functioning of the Defibrillator.
9. Displays ECG waveform, heart rate (HR), Easy access to all the functions and setting of parameter through encoder.

2. DEVICE PARTS ILLUSTRATION AND ACCESSORIES



Note:

Always use Front button (ON/OFF) to make unit ON. Given Optional ON/OFF at rear panel is used only when unit is not get ON with Front knob.
Keep Optional ON/OFF switch always in OFF position.
If "Optional ON/OFF" switch, is ON then "Front Knob (ON/OFF)" will not under operation.

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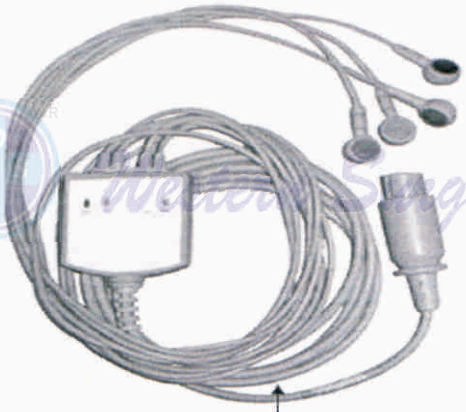
ACCESSORIES



4 Lead ECG Cable

Note:

Use only ECG cable with Defibrillator protection.

Discharge Button

Sternum Paddle

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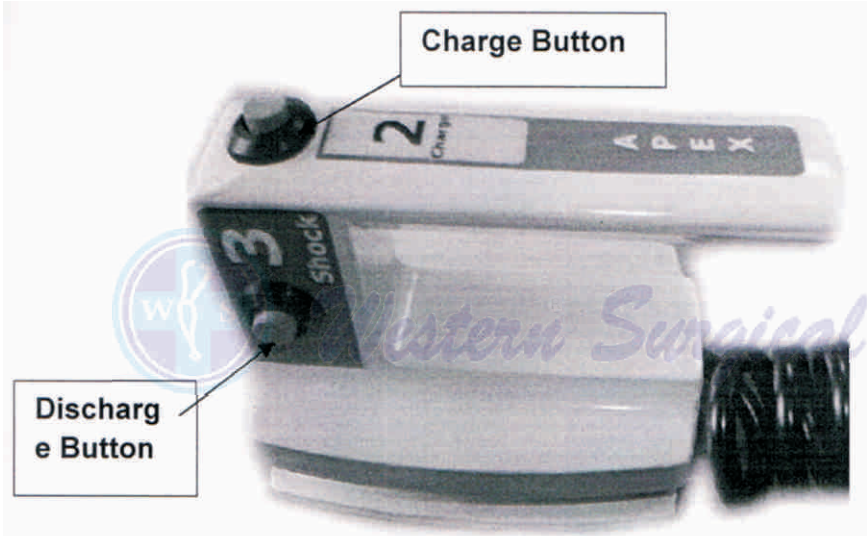

Apex Paddle

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3. OPERATING CONTROLS AND INDICATORS

The operating panel of the unit is as shown in the following figure.

Fig 3.1: Front Panel

Encoder is used for easy browsing through menus.

In Monitor mode, Press the encoder to enter in to parameter setting. Rotate encoder clockwise or anticlockwise to increase or Decrease highlighted setting. Press encoder to save setting. Rotate encoder to move to the Next menu option. To cancel a setting option, press Encoder till highlighted bar disappears.

In DEFIBRILLATOR mode energy will not change by encoder if encoder position is on highlighted HR limit value. Press Encoder till highlighted bar disappears.

Rotate encoder clockwise or anticlockwise to select energy value in DEFIB mode.

Keypad Description:

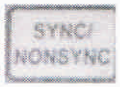
This key is used to work in Defibrillator mode.

To switch from MONITOR to "DEFIB CHECK" mode, first press "Defibrillator" key on the keyboard and then press "DEFIB CHECK" key to start the operation in 'Defib check' mode.

Use "Defibrillator" key on the keyboard while switching from

"DEFIB CHECK" to "Defib-Non Sync" mode, to start the operation in Non sync OR Sync mode.

If unit previously operates in 'Monitor' mode and HR value is valid then in 'Defibrillator' mode ECG from ECG cable(Lead II) is selected otherwise ECG from 'PAD' is selected automatically. If required, User can select ECG from PADS OR Lead II by pressing Lead key.



SYNC / NON SYNC

Press **SYNC / NON SYNC** key to switch the mode to Synchronous mode. The Defibrillator operation starts in Synchronous mode. Refer "Operation in Synchronous Mode" section 4.2 for detail operation. Press '**SYNC / NON SYNC** key to switch the mode to Non-Synchronous mode. Refer "Operation in Non-Synchronous Mode" section 4.1 for detail operation.

DISARM

Press "**DISARM**" key to discharge capacitor through internal circuit. "Press discharge key" message is displayed.

MANUAL (DEFIB) CHECK

Press 'Manual CHECK' key to check proper functioning of

Defib in manual mode. Refer "Operation in Manual Check Mode" for detailed operation.

PRINT

Monitor Mode: Prints last 10 Seconds of ECG data.

ECG in Defibrillator Mode: Prints last 10 Seconds of ECG data.

Press 'Monitor' key to check proper functioning of Defib in monitor mode. Refer "Operation in Monitor Check Mode" for detailed operation.

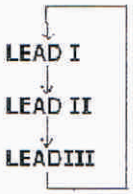
Press 'ECG FREEZE' key to freeze last 4 seconds ECG.

The upper part will show online ECG and lower section will show frozen waveform of ECG i.e. 4 second delayed waveform. To unfreeze the waveform, press 'ECG Freeze' key again. The screen will start showing ECG delayed by 4 second as that of the above.

LEAD

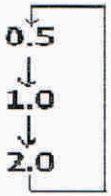
Press 'LEAD' key to change the ECG lead. Current selected

lead is displayed on the top of ECG waveform. Default lead selection is Lead 'II'. There are three lead selection options viz. Lead 'I', 'II', 'III'. Pressing the 'LEAD' key once will select the lead 'III'. Pressing it again will move the selection in the following order: -



GAIN

Press 'GAIN' key to adjust the amplitude of the waveform as required. The selected Gain is displayed in ECG Parameter window. Default gain setting is **'1'**. Other gain options are **'0.5'** and **'2'**. Pressing the **'GAIN'** key once will select next gain setting viz. **'2'**. Pressing the **'GAIN'** key will move the gain selections in the following order: -

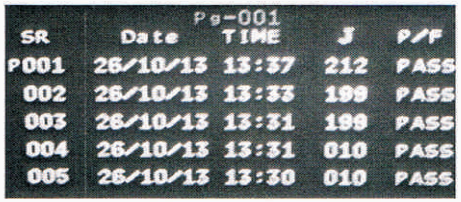


MENU

'Menu' key is used to enter in 'menu' OR 'Setting' mode. Press one time 'Menu' key to enter in 'Menu' mode as shown below. Rotate encoder clockwise for moving to the next menu and anticlockwise for previous menu.

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 in joules and status pass or Fail.



The last shock details will be replaced with latest shock details in the memory.

Procedure to print the stored events in Memory:

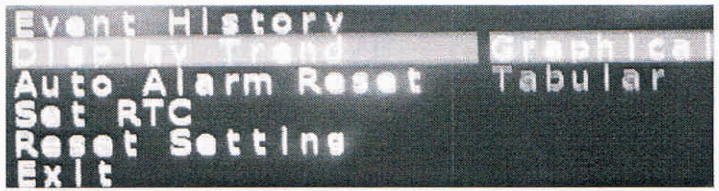
- Rotate encoder it will show the last 10 stored events on display. Select the event to be printed with the help of

encoder. Rotate the encoder and letter 'P" in yellow colour is displayed before sr no column and press "Print" button to take the print of shock status

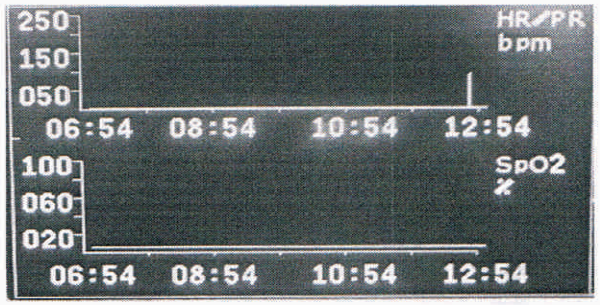
- Selected shock status will be printed on paper with date, time, charge, defib mode, shock status.
- Use 'Home' key to come out from event history.

DISPLAY TREND:

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



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



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.

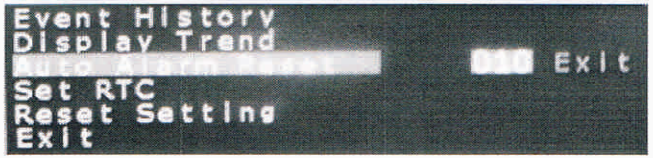
The parameter value which goes out of limit will be marked with red lines.

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:

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 display on the screen.

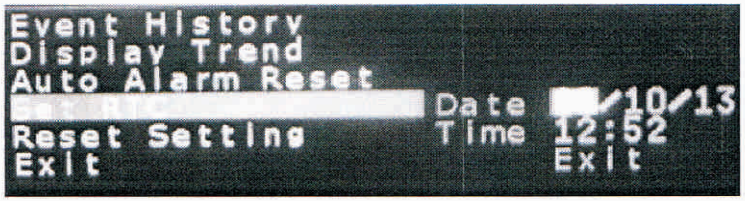


Rotate encoder to set the required reset time interval & press encoder, selected auto reset time interval will be

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.

Set RTC-TO CHANGE CURRENT DATE AND TIME:

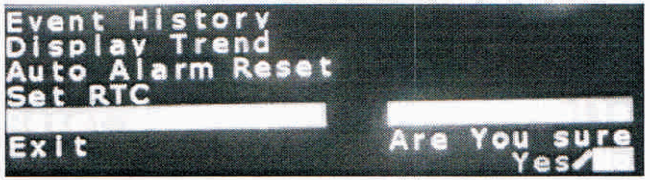
Select the 'Set RTC' menu using encoder. Following menu will be display on the screen. Real time clock and Date is displayed at upper right corner.



Change date and time using encoder. Selected time will be saved. Selected time will be updated on Trend and on upper right corner on main screen. Select 'EXIT' or Press home key to exit from Set RTC.

Reset Setting:

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



'All parameters set to default values' message displays on screen, if 'yes' option is selected then all parameter value

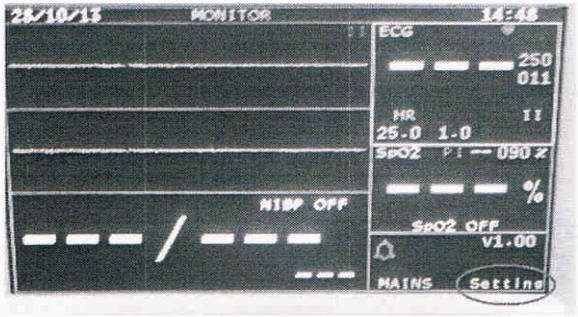
will change to default value and for 'NO' option change value will be remain as it is.

Exit:

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

Setting:

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 colour.



To change the high limit value of ECG parameter, selects the limit value 150 using encoder. Rotate encoder clockwise or anticlockwise to increase or Decrease the high limit value and press encoder. Selected value will be

updated on ECG panel. Similarly limits can be set for HR/PR-Lo-Limit.

To change the sweep speed of ECG parameter, select the sweep speed using encoder and change the value. Selected value will be updated on ECG panel.

AUDIO ALARM

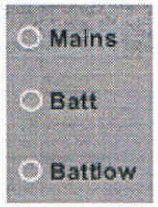
The Audio alarm ON/OFF key is provided to switch ON/OFF the audio alarm. The alarm sound can be switched ON/OFF with the ALARM ON/OFF key.

Volume Control knob--The heart rate beep sound can be controlled with volume control knob at front side.

Audio alarm starts ringing when any of the value goes out of specified limit values.

HOME

This key enables the users to come back directly to main screen from any other screen.



POWER AND BATTERY INDICATIONS

- The green light on the front panel will glow indicating 'POWER ON' condition.
- The yellow light on the panel indicates battery status.
- The red light on the panel indicates low battery status.
- At right bottom corner of screen "BAT FUL" for full battery and "BAT MED" for medium battery and "BAT LO" for low battery indication messages are displayed.
- When "BAT LO" message is displayed at right bottom corner of the screen then "Battery charging Required" message is also displayed on the screen. It is recommended that Defibrillator should keep on Mains for charging.

Note: Battery of our DEFIB unit tend to discharge slowly when the Product is kept unused for more than 10 days. So, charge the unit after every 10 days with a Charging interval of 15 hrs.

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4. OPERATION OF THE UNIT

4.1 Operation in Defib Non Synchronous Mode:

CAUTION: The equipment carries dangerous voltage at the paddle and cable during this mode, which are capable of causing serious injury or death. This equipment is to be used only by qualified medical personnel.

To deliver shock to patient in non synchronous mode:

Switch OFF the unit.

1. Remove ECG electrode or ECG cable from connector.
2. Remove paddle from the paddle holder by holding the paddle holders and lifting them straight up.
3. Hold both the paddles in one hand; apply electrolyte paste to metal surface of each paddle. **(Warning: Do not allow the electrolyte paste to accumulate on the paddle handles or on your hand to avoid risk of electric shock).**
4. Switch ON unit by push button on keyboard.
5. By default, unit is in "DEFIB Non Sync" or to change from synchronous mode to non synchronous press "Sync/Non sync" key.

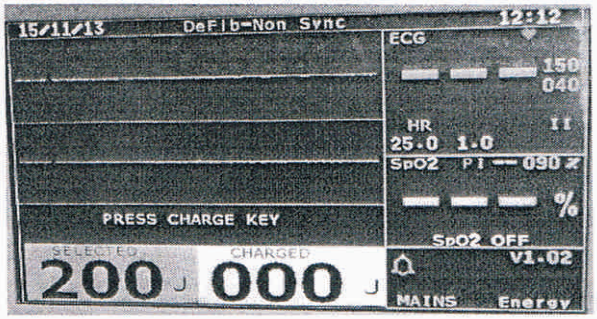


Fig 4.1: Acquisition screen in Non Sync Mode.

6. Rotate encoder (set energy knob) to select the desired energy level by in the range of 2 to 200 Joule. By default selection is at 200 Joule as shown in figure 4.1.
7. Remove both paddle form cradle.
8. Place pads on patient body as described below.

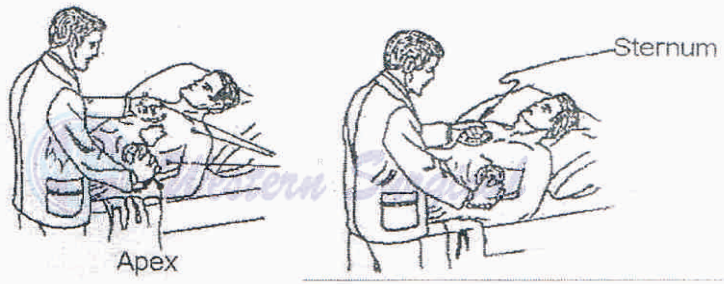


Fig 4.2: Paddle Placement In Non-Synchronous Mode

9. Place the Sternum paddle near the upper sternum in the patient's right midclavicular line, just below the

clavicle. Place the Apex paddle on the chest just below and to the left of the patient's left nipple, in the anterior auxiliary line.

10. Rub the paddle lightly against the skin to distribute the electrolyte paste and increase contact between the patient skin and the paddles.

CAUTION:

- **Do not rub the electrode surfaces together to spread the applied paste. Placing the paddles together increases risk of accidental shorted paddle discharge.**
- **Do not spread excess electrolyte paste between the paddle electrodes on the chest. The current will flow through this path and burn the patient skin.**

11. Press charge key on the apex paddle.
12. Apply pressure approximately 10kg on the paddles. The defibrillator starts charging and increasing energy available is displayed on the screen.
13. When selected energy become equal to charged energy and then 'press discharge key' message will be displayed on screen.
14. Press 'Discharge(shock) key' on paddle or keyboard
15. Delivered energy is displayed under "Delivered" title in yellow background box.

16. Display will show delivered energy till charge key is press. After Delivered energy, shock status will save and automatic print of shock event comes.
17. Adjust the paddle pressure and placement to optimize patient contact.
18. Press and hold both the discharge key located on the paddle simultaneously until the energy delivered to the paddle. **(Note if discharge key is not pressed within 15 seconds after display of "Press discharge key" message the capacitor is discharged through internal circuit).**
19. Wait for the Message "Shock Delivered".
20. When there is some error in charging of capacitor or delivering of shock, the acquisition screen displays following messages; "place PADS properly,"

WARNING:

- **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.**

21. To repeat shock, repeat from step 7.

4.2 OPERATION IN DEFIB SYNCHRONOUS MODE:

To deliver shock to patient in synchronous mode:

Switch OFF the unit.

1. Remove ECG electrode or ECG cable from connector.
2. Remove paddle from the paddle holder by holding the paddle holders and lifting them straight up.
3. Hold both the paddles in one hand, apply electrolyte paste to metal surface of each paddle. **(Warning: Do not allow the electrolyte paste to accumulate on the paddle handles or on your hand to avoid risk of electric shock).**
4. Switch ON unit by push button on keyboard.
5. By default unit is in "DEFIB Non Synchronous Mode", to change from non synchronous mode to synchronous press "SYNC/NONSYNC" key.

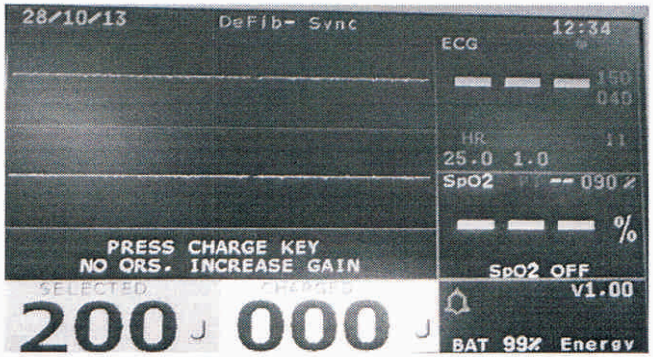


Fig 4.6: Acquisition screen for Sync Mode

6. Rotate encoder to select the desired energy level in the range of 2 to 200 Joule. By default selection is at 200 Joule
7. Remove both paddle form cradle. Press charge key on the apex paddle.
8. Place Pads on Patient body as described below.

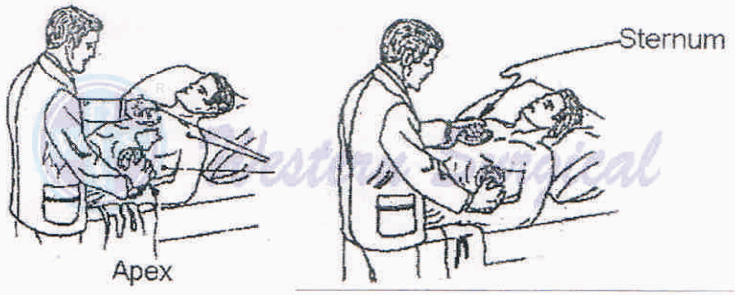


Fig 4.7: Paddle Placement In Synchronous Mode

9. Place the Sternum paddle near the upper sternum in the patient's right midclavicular line, just below the clavicle. Place the Apex paddle on the chest just below and to the left of the patient's left nipple, in the anterior auxiliary line.

10. Rub the paddle lightly against the skin to distribute the electrolyte paste and increase contact between the patient skin and the paddles.

CAUTION:

- **Do not rub the electrode surfaces together to spread the applied paste. Placing the Paddles together increases risk of accidental shorted paddle discharge.**
- **Do not spread excess electrolyte paste between the paddle electrodes on the chest. The current will flow through this path and burn the patient skin.**

11. Apply pressure approx 10kg on the paddles.
12. Press charge Key on apex paddle.

The defibrillator starts charging and increasing energy available is displayed on the screen.

Wait for 'selectable energy' and 'charge energy' to become equal and "press discharge key" message to be displayed on screen. In this mode the shock will be delivered only when the R wave is detected.

Delivered energy is displayed under "Delivered" title in yellow background box. Display will show delivered energy till charge key is press. After Delivered energy, shock status will save and automatic print of shock event comes.

(Note: If discharge key is not pressed within 20 seconds after display of "Press discharge key"

message, the capacitor is discharged through internal circuit).

13. The detection of R wave can be monitored by increasing Gain of ECG by pressing Gain key. If R wave is not detected, the unit will delivered shock as non-sync mode in second attempt.

14. Adjust the paddle pressure and placement to optimize patient contact.

15. Press and hold both the discharge keys located on the paddle simultaneously until the energy is delivered to the paddles.

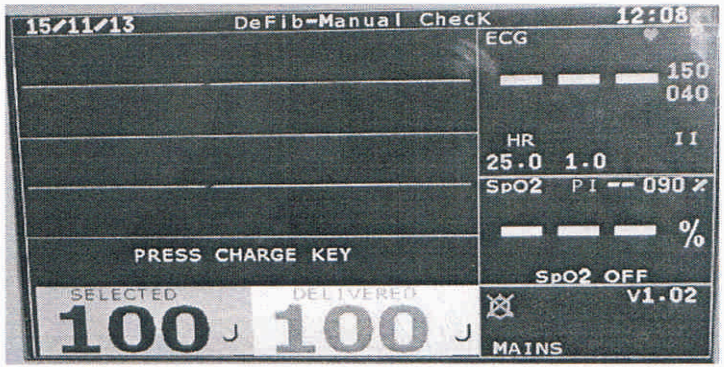
WARNING:

- **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.**

16. To repeat the shock repeat from step 7.

4.3 OPERATION IN DEFIB CHECK MODE:

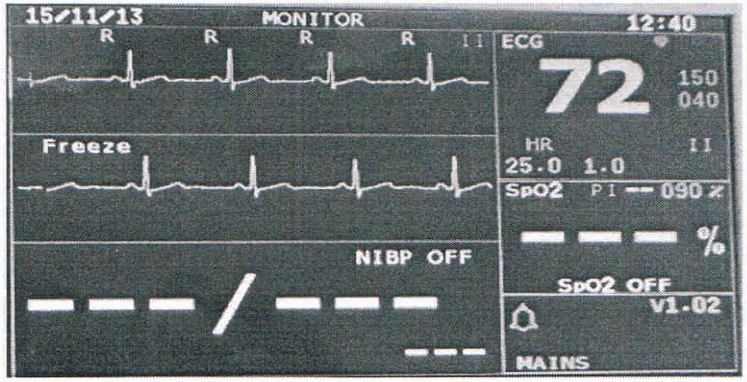
1. Pressing DEFIB CHECK key on the keypad will start the operation in Manual Check mode.
2. The default Joule value of 100 Joule is displayed on the lower left portion of the screen.
3. When pads are in cradle, "Press charge key" message is Displayed.
4. "Place Pads in Cradle" message is also displayed on the screen when PADS are removed.
5. After pressing charge key if the capacitor hasn't charged to the required voltage or if there is some error then the message "SYSTEM ERROR" is displayed.
6. When capacitor gets charged to required voltage, the message "Press Discharge Key" is displayed.
7. After pressing the Discharge key, message as "Manual check Complete" is printed.
8. While switching from MONITOR to "DEFIB CHECK" mode, first press "Defibrillator" key on the keyboard and then press "DEFIB CHECK" key to start the operation in Manual Check mode.



(Note: If discharge key is not pressed within 20 seconds after display of "Press discharge key" message, the capacitor is discharged through internal circuit).

4.4 OPERATION IN MONITOR MODE:

Press MONITOR key. The acquisition screen appears as follows:



The acquisition screen shows the default settings are gain (1.0mV), lead (lead II), speed (25 mm/s). User can

change the settings with the help of encoder or may continue with the same settings.

1. ECG

Connect the ECG cable leads to the patient and the round type connector to the unit (Refer Patient Preparation for ECG at the end in Appendix (C.b)).

User can change the HR limits settings with the help of encoder. The setting for parameters is:

Parameter Name	Limit Values	Increments in
HR Hi Limit	10 to 250	1 step
HR Lo Limit	10 to 250	1 step

5. MAINTENANCE

Operational Check:

- Check the power cord visually for wear and tear.
- Check the ECG patient cable, paddles, retractable cables visually for wear and tear, cracks, insulation cuts and other damage.
- Check that the electrolyte has not solidified on the paddle surface. Remove any residual electrolyte on the paddles.
- Check that the cables do not have any cracks or cuts.
- After each use, **wait for 5 minutes and then clean Defib pads metal plate** using a soft, damp cloth moistened with any of the following solvents:
  1. Soap and water
  2. 70% solution isopropyl alcohol
  3. Chlorine bleach and water mixture (30 ml bleach/liter of water) Ammonia-based cleaners.
  4. Hydrogen peroxide
- 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.
  1. Check the case of the device for any apparent damage.

2. Check the ports (Analog O/P port, adapter power port,) to see that they are tightly in place.
3. Check the accessories, especially the ECG cable, to see that they are in good condition.

Battery check:

1. A new fully charged battery provides approximately70-100 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 "Battlow" indication LED until 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.
- Worn out or damaged wiring.
- Mechanical damage.
- Evidence of liquid spill.
- Corroded or damaged electrodes.
- Damaged patient cables or connectors.

Damaged paddle connector or retractable cable.

APPENDIX-A

ABOUT DEFIBRILLATION:

1. What is Defibrillation?

Sudden cardiac arrest (SCA) associated with ventricular fibrillation (VF) remains a leading cause of unexpected death. It has been estimated that chances for survival from SCA decrease approximately 7% to 10% with each passing minute and that survival rates after 12 minutes are only 2% to 5%.

The most common cause of SCA is ventricular fibrillation (VF), a lethal heart rhythm, and survival depends on deploying a rapid treatment called *de*fibrillation, an electrical shock sent to the heart to resume normal and healthy heart rhythm.

So early defibrillation is the sole definitive determinant of survival and is a key factor in cardiopulmonary resuscitation.

2. How does Biphasic waveform Defibrillate?

For defibrillation to be successful, a sufficient amount of electrical current must be delivered to the heart muscle. How to deliver the electrical current to the heart muscle is the core technique to defibrillate the heart.

Successful defibrillation would be done when the cell membranes of the heart are "coated" with positive ions on one side and negative ions on the other side, enough to depolarize nearly 100 percent of the cardiac cells at the same instant. Optimal current is determined with the pressure (this means electric Voltage) that controls what an amount of current can be pushed and the duration of time the current flows. This defibrillation current is commonly described in Joules of energy. Energy is a measure of the amount of current, voltage, and duration of time the current flows.

Energy (Joules) =Current (Amps) x Voltage (Volts) x Time (Sec)

APPENDIX - B

PRODUCTION SPECIFICATION

GENERAL

Display	: 7″ colour TFT
Display area	: 150 mm x 90 mm
Dimensions without paddle	: H280 x W 330 x D220 mm (Max)
Weight	: Approx 6.5 Kgs. Max

POWER SUPPLY

Input	: 150 - 270 VAC, 50 Hz, 1 Ø
Battery	: 12 V 4.5Ah.
Back-up time	: 3 hours min. on full charge in ECG mode/ 75 shocks of 150 Joules in Defib mode
Power consumption	: 30 Watts (max.) in ECG mode

ENVIRONMENTAL

Operating Temp	: -5ºC to +50 ºC
Humidity	: up to 95 % non-condensing

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DEFIB

Operating Mode	: Manual
Waveform	: Biphasic
Energy selection	: 2 to 200 joules in 12 steps
Synchronous	: Energy delivery begins within 60 ms of the Cardio Version QRS Peak
Charging Time	: Less than 8 seconds
Paddle Assembly	: External paddle assembly with coil retractable high voltage cable. Adults & Pediatric paddle integrated to same handle
Check mode	: Manual test mode
Operation	: By front panel keyboard and through Encoder, Unit ON-OFF by push button on keyboard

ECG

Frequency response	: 0.5 Hz to 35 Hz
Patient isolation	: Optical isolation
Lead selection	: Lead I, II and III
Gain setting	: 0.5, 1.0 and 2.0
CMRR	: > 90 db
Sweep Speed	: 12.5, 25.0, 50.0 mm/sec

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Data Output	: Analog output of ECG
Digital filter	: Digital signal processing for good quality of ECG

HEART RATE

Range	: 10 – 250 BPM
Accuracy	: +/- 2 BPM
Resolution	: 1 BPM
Tone	: Beep on every QRS detected
Low alarm limit range	: 10 – 250 (step of 1)
High alarm limit range	: 10 – 250 (step of 1)

Printer

Paper Type	: Thermal paper 50/55mm width, 20 meters length for 2 inch printer
Event Printing	: Prints 5 Seconds pre & post ECG with Date, Time, Energy and mode, Shock Status
ECG in Defib Mode paddle	: Prints last 10sec ECG through

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Print Annotates in Defib Mode: Time, Date, Mode, lead name, gain, sweep speed

ECG in Monitor Mode : Prints last 10 ECG through cable

Print Annotates in Monitor Mode: Time, Date, selected Lead name, Gain, Sweep speed

Manual Defib Check Mode: Prints the status of Shock, Energy, Date and Time

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

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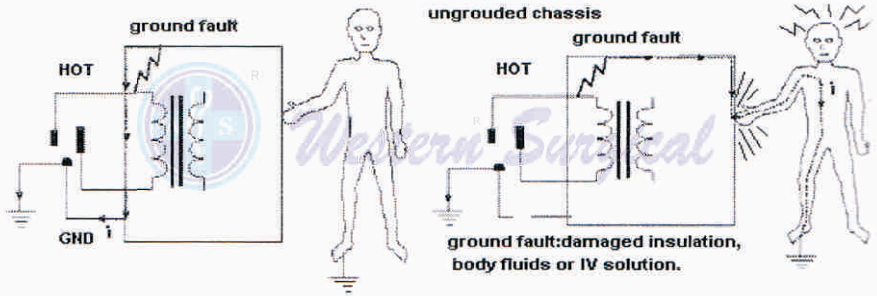
APPENDIX - C

SAFETY PRECAUTIONS:

A] Earthing.

The earthing for the system should be proper. This is to ensure patient safety and for no interference of line voltage fluctuations. For correct earthing procedure, refer to work order booklet and get it done and approved from licensed electrician only. If the earthing is not proper, leakage currents may pass from the enclosure / box to ground through the patient. If the magnitude of current is large, it can be harmful for the patient.



Danger in an unearthed system

- Read user manual carefully, before operating the monitor.
- Do not expose the LCD screen to high temperature (> 50□C), to thinner, or to trichloro ethylene.

- Protect LCD screen from sharp edges, impacts etc.
- Connect monitor to mains supply once in a week for battery charging, when not in use.
- Before cleaning the monitor, unplug power adaptor from mains.
- **To increase the durability of the battery, operate the monitor on battery once in 15 days. If this is not done, it may reduce the life of the battery.**
- Do not open the unit, as there are no user serviceable parts inside the monitor.

B] Safety Considerations while the Unit is used in Defib mode.

This product should be used by trained persons only. The hazards are labeled according to the seriousness of the resulting injury when an accident happens involving these hazards. The labels are the following:

1.  **DANGER –** Immediate hazards that will result in personal injury or death.
2.  **WARNING –** Conditions, hazards, or unsafe practices that can result in personal injury or death.
3.  **CAUTION** – Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the unit, or loss of data stored in the device.

4. **NOTICE!** – Notes items that are important during installations, operation, or maintenance of the device. When these notes are not followed, no injury to the patient happens.

HAZARD LEVEL	POSSIBLE HAZARDS
DANGER	There is a possibility of explosion if the Unit is exposed to concentrated oxygen or flammable anesthetics during use.
DANGER	The Unit should not be used in the presence of flammable substances/gas mixtures.
WARNING	Large voltages and currents are involved in the operation of the Unit.
CAUTION	The unit should be used by trained and qualified personal only.
CAUTION	Do not immerse the unit and its accessories in any liquid. Do not allow any fluid to enter the case of the device. Do not spill any liquid on any surface of the device and its accessories. Do not use strong acetone based cleaners in cleaning the device. Do not use abrasive

	materials for cleaning the device, especially on the LCD display.
WARNING	Using damaged equipment and its accessories in conjunction with the Defibrillator can cause it to perform improperly and it may injure the user or the patient.
WARNING	Radio frequency interference from radios, cellular phones, and other sources of electromagnetic energy may hamper the performance of Unit. Interference from these electromagnetic sources will introduce noise to the ECG signal acquired from the patient. This will make the analysis of the ECG signal more difficult. The Unit should be used at least 2 meters away from the interference sources.
DANGER	Large currents are involved during deliveries of defibrillation shock and this can injure the operator/user and bystanders. Nobody should touch the patient when the defibrillation shock is being delivered. Do not short the shock

	delivery system by making the defibrillator pads come into contact when it is in use.
WARNING	The patient should be still during the signal acquisition phase. If the patient is moving, motion artifacts will be introduced into the signal, which will make it more difficult to analyze.
WARNING	Do not allow the defibrillation pads to come into contact with any other materials such as other ECG electrodes, wires, dressings etc. This will cause arching and might burn the skin of the patient. This will also divert the defibrillation current away from the heart of the patient.
WARNING	Poor contact between the pads and the patient will increase the impedance at the juncture of the skin and the pads. This will cause burns due to higher energy dissipation at the skin-pad juncture. To prevent burns, good contact must be ensured by eliminating air pockets between the skin and the pads. Do not

	use pads that have dried-out gel.
CAUTION	Improper maintenance may result in device damage. Maintain the Unit only according to the instructions in 'Maintenance' section of this User Manual.
CAUTION	There are no user serviceable parts inside the Unit. Opening the device presents an electrical shock hazard. High voltage electrical energy is stored in the defibrillating capacitor, thus only trained service personnel should open the device for repair.
DANGER	Do not use the unit if it has been submerged in water. Call immediately for service assistance.
WARNING	During operation, the device should be placed away from the sources of electromagnetic interference such as motors, generator, cellular mobile telephones, etc as these might interfere with the signals being acquired and

	analyzed. Electromagnetic interference will make analysis take longer.
CAUTION	It is important to have all the necessary accessories all the time. Make sure that you have the complete accessories during unpacking.
DANGER	Make sure that no one is touching the patient when you press the DISCHARGE button on the Defib pads.
NOTICE	The unit will not deliver the shock until the operator presses the DISCHARGE button.
WARNING	The patient should be kept motionless during signal acquisition and analysis. If the patient is being transported in an emergency vehicle, the vehicle should be stopped during ECG signal acquisition and analysis.
WARNING	Do not short-circuit the defibrillator pads. Do not place them very close to each other during operation. Do not let them touch lead wires and transdermal patches because these will cause electrical arching. Electrical arching will cause

	burns on the patient's skin.
WARNING	Do not let anybody touch the patient's body during shock delivery. Touching the patient will cause injury due to the high electrical currents involved during defibrillation.
NOTICE	Check the unit everyday to ensure that it has sufficient battery power to carry out rescue operations.
WARNING	During ECG MONITORING mode, the unit will not be able to deliver a defibrillating shock.
DANGER	Do not place the patient on a wet surface during defibrillation.

C] PREPARATION **FOR ECG.**

a. **PATIENT PREPARATION -**

Proper patient preparation is the most important factor in obtaining proper results from a system. If electrodes are applied to improperly prepared skin site then this may result in excessive base7 line shift and severe artifact while obtaining an ECG.

b. ELECTRODE PLACEMENT –

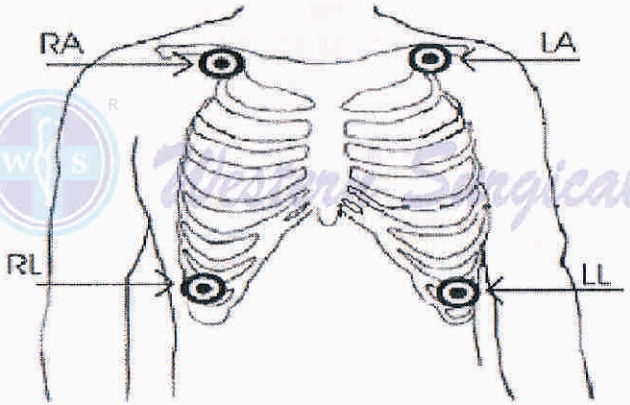


Fig 1: Electrode placement

- 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.
- 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.
- Take an electrode and peel it open from its plastic backing. Finger contact with the adhesive should be

minimized and jell in the foam pad should not be disturbed. If the jell has dried out then discard the electrode.

- 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.

NOTE –

- We recommend the use of good quality disposable electrode (With one time usage only).No assurance of quality result can be given if preparation is not good.
- We recommend the use of water soluble, easily removable, Non irritant and non toxic gel.
- Use the correct power supply during recharging. The correct power supply for the AC adapter is: 100V to 240V, SO to 60 Hz AC input. During recharging, do not place the device where the environmental conditions exceed the storage conditions specified in the Storage and Operating Environment Guidelines

STORAGE AND OPERATING ENVIRONMENT GUIDELINES:

- Avoid damp locations. Do not operate and store the device beyond the specified limits. Do not operate the device with wet hands. Do not conduct rescue

operations with patients on wet surfaces.

- Do not expose the device to direct sunlight during storage.
- Do not store the device in areas with highly fluctuating temperatures. Do not store the device close to heating equipment and appliances.
- Do not store the device near sources of vibration.
- Do not store and operate the device in locations that are exposed to chemicals, explosive gas and solvents.
- Keep the device away from dusty environments.
- There are no user serviceable parts inside the Defibrillator. Only our authorized service personnel should open the device for repairs.
- During recharging, when the device is connected and disconnected from the mains power connector, hold the plug and not the electrical cord.

Installation Commissioning report-cum Performance Certificate

Name of Dealer _____

1	Name of Customer(as per invoice/bill) :			
2	Name of Hospital/Clinic/Diagnostic Center :			
3	Address of the siteof Installation :			
4	Name of the person/s trained to use and operate the product/s :			
5	Name of the Product	Qty	Serial number of the product	Date of installation
a.				

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6	The product/s above named have been supplied in good and proper working condition and Installed successfully. **The performance of the product is satisfactory.** **Warranty:** For Electronic Manufacturing Defects - 12 Months from Date of Installation or 13 Months from Date of Dispatch whichever is earlier. For Accessories warranty will be 3 months from date of Installation or 4 Months from date of Dispatch.			

Note : (i) Training is given only once. Additional training will cost extra.

Name and Signature of customer (Please affix stamp / seal)

ONLY FOR DEALER

Manufactured by:

Note: All disputes are subject to Pune jurisdiction only. All other jurisdiction expressly barred.

Name and Signature of Dealer (Please affix stamp / seal)

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7.3 WARRANTY CERTIFICATE

western surgical product is warranted to be free from electrical and mechanical defects in material and workmanship, under normal use. The western surgical product must not have been moved from the site of original installation. A new or remanufactured part to replace the defective part will be provided without charge for the part itself, through an authorized western surgical service dealer. The replacement part assumes the unused portion of the warranty.

WESTERN SURGICAL WILL NOT BE RESPONSIBLE FOR:

1. Damage or repairs required as a consequence of faulty installation or application by others.
2. Damage or repairs needed as a consequence of any misapplication, negligent handling, improper servicing, unauthorized alteration, or improper operations.
3. Failure to start due to voltage conditions, blown fuses, open circuit breakers or other damages due to the inadequacy or interruption of electrical service.
4. Damage as a result of floods, winds, fires, lightning, accidents, corrosive atmosphere, or other conditions beyond the control of western surgical
5. Parts not supplied or designated by western surgical.

Date of Installation	**Installed By**
Model No.	**Serial No.**
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical
Sign. With Stamps

No Claim Warranty :

1) Any Defect Througut Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

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Date : 9-12-2015

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OUR OTHER PRODUCTS RANGE

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