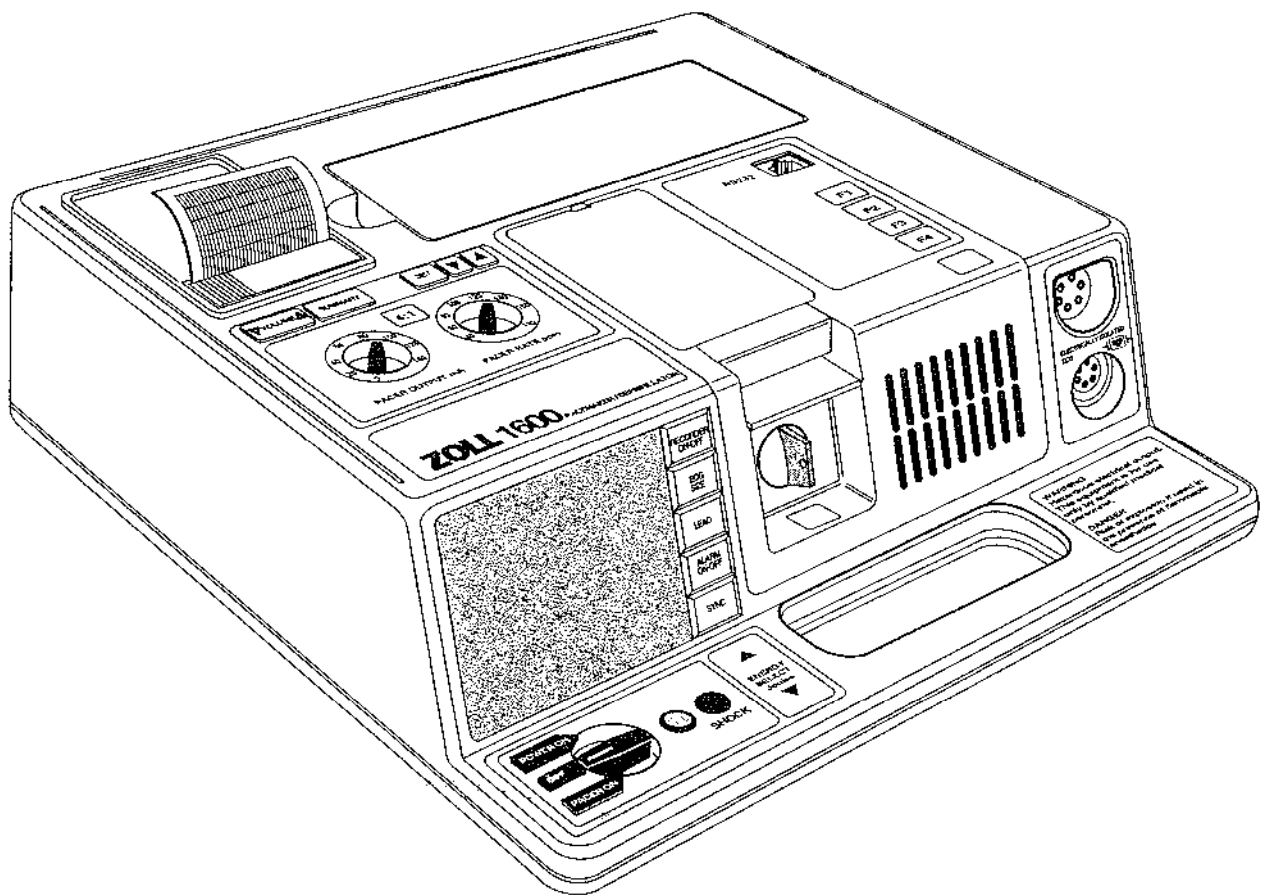


ZOLL 1600 Operator's Guide



An issue or revision date for this manual is shown on the back cover

In the event that three years or more have elapsed between this date and the product's use, contact ZOLL Medical Corporation to determine if additional product information updates are available.

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Section 1

General Information

Product Description

The ZOLL 1600, designed for EMS and hospital use, is a semiautomatic defibrillator with a non-fade monitor and a medical report module. The ZOLL 1600 may be equipped with optional noninvasive pacemaker, annotating strip chart recorder, manual mode of operation, audio recorder and telecommunication ports. Power is provided by a rechargeable battery pack or an optional AC Adaptor/Charger.

The ZOLL 1600 may operate in two user selectable modes. In semiautomatic mode, the operator selects ECG analysis and the ZOLL 1600's integrated algorithm analyzes the patient's ECG through a pair of disposable defibrillation electrodes which are also used to deliver defibrillation shocks or pacing stimuli. The ZOLL 1600 analyzes the patient's ECG, determines if a shockable arrhythmia is present, charges and prompts the operator to shock the patient. Configuration options allow the operator to customize unit features according to local protocols.

The ZOLL 1600 is easily switched from semiautomatic mode to optional manual mode with a keyswitch. In manual mode, the operator determines and delivers appropriate therapies. Noninvasive temporary pacing is an available option in manual mode.

Patient ECG, unit status, operating and warning messages are displayed on the monitor. The ZOLL 1600 also provides voice prompts via a speaker to alert the operator about patient ECG and unit status. The ZOLL 1600 performs self-diagnostic tests when the instrument is turned on and periodically during operation.

Defibrillation shocks are delivered to the patient via a single pair of anterior/anterior defib/monitoring electrodes or anterior/posterior ZOLL Multi-Function Electrodes. Both types of electrodes provide hands-off defibrillation and ECG monitoring. In manual mode, Multi-Function Electrodes may also be used for noninvasive pacing. Standard ECG electrodes may be used for patient ECG monitoring in either semiautomatic or manual mode.

A removable PCMCIA data card begins recording ECG and machine data when the unit is turned on. The ZOLL 1600 will record and store patient ECG, system status and audio activity (optional). Data stored on the PCMCIA card can be reviewed and archived on a properly equipped personal computer.

An optional annotating strip chart recorder provides immediate event documentation as well as a summary function.

The ZOLL 1600 uses ZOLL 4410 replaceable battery packs. The 1600 alerts the operator when the battery voltage indicates inadequate capacity for continued operation. Battery packs are charged using ZOLL supplied charging devices.

The ZOLL 1600 is intended for use in the semiautomatic mode by first responders and emergency medical technicians certified by an appropriate federal, state or local government authority. The ZOLL 1600 is intended for use in manual mode by personnel certified to provide advanced life support care by appropriate federal, state or local authority.

The ZOLL 1600 is intended for use in the prehospital emergency medical care setting, indoors and outdoors, including first response vehicles, fire vehicles, basic and advanced level ambulances.

How to Use This Manual

The ZOLL 1600 Operator's Guide provides information operators need for the safe and effective use and care of the 1600. It is important that all persons using this device read and understand all the information contained within.

This manual is organized for semiautomatic mode operators and manual mode operators. If you will only use the 1600 in semiautomatic mode you do not need to read sections 3 and 4. If you will use the 1600 in manual mode, you must read the complete manual. Section 4 and Appendix B describe optional features. If your device is not equipped with these options, you do not need to read these sections.

Please read thoroughly the safety considerations and warnings on page 6.

Procedures for daily checkout and unit care are found in Section 6.

Manual Updates

ZOLL Medical provides Manual Updates to inform customers of changes in device information and use. The updates are mailed to each registered ZOLL 1600 purchaser automatically. All users should carefully review each manual update to understand its significance and then file it in its appropriate section within this manual for subsequent reference.

Unpacking

Carefully inspect each container for damage. If the shipping container or cushion material is damaged, it should be kept until the contents have been checked for completeness and the instrument has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, or if the instrument does not pass its electrical self-test, U.S.A. customers should call ZOLL Medical Corporation (1-800-348-9011). International customers should contact the nearest ZOLL authorized representative. If the shipping container is damaged, also notify the carrier.

Accessories Available Separately

- Adult, Multi-Function pacing/defibrillation electrodes (12 pair/box)
- Pediatric Multi-Function pacing/defibrillation electrodes (6 pair/box) (For manual mode use only)
- Multi-function cable
- 3-lead ECG cable
- PCMCIA Data Card - (Package of two)
- Rechargeable battery pack
- PD 4420 Battery Support System
- Single Battery Charger
- PowerCharger AC Power/Charger Module
- ECG Simulator

- MFC Test Port
- Output verification unit for noninvasive pacer
- Service manual

Save all shipping materials for future use.

Locate the battery pack and the battery charger supplied with the unit. See Section 5 for battery charging and installation. Before using, fully charge the battery pack.

Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:



Type B patient connection.



Type BF patient connection.



Type CF patient connection.



Defibrillation protected Type BF patient connection



Defibrillation protected Type CF patient connection



ATTENTION Refer to manual for more information



Fusible link.



Protective (earth) ground terminal



DANGER High voltage present



Alternating current.



DANGER Risk of explosion if used in the presence of flammable anesthetics.



Conformité Européenne Complies with the Medical Device Directive 93/42/EEC.

Defibrillator Function

Indications – Semiautomatic Operation

The ZOLL 1600 is designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the operator of the device controls the delivery of the shock to the patient. It is specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated in a medically-approved patient care protocol.

The ZOLL 1600 must be prescribed for use by a physician or medical advisor of an emergency response team.

Use of the ZOLL 1600 in the semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

Contraindications – Semiautomatic Operation

Semiautomatic defibrillation is contraindicated on patients showing the following responses:

- Consciousness
- Presence of breathing
- Presence of pulse.

The ECG analysis may not reliably identify ventricular fibrillation in the presence of an implanted pacemaker. Inspection of the ECG and clinical evidence of cardiopulmonary arrest should be the basis of any treatment of patients with implantable pacemakers.

Do not use the ECG analysis during patient movement on a stretcher or in an ambulance or other conveyance. **A patient must be motionless during ECG analysis. Do not touch the patient during analysis.**

Do not defibrillate pediatric patients (weighing less than 80 lbs./36 kg) in semiautomatic mode. (AHA standard)

Indications – Manual Operation

Use of the ZOLL 1600 in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

The ZOLL 1600 contains a standard DC defibrillator capable of delivering up to 360 joules of energy. In manual mode, it may also be used for synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference.

This product is to be used only by qualified medical personnel for the purposes of converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

Inappropriate defibrillation or synchronized cardioversion of a patient (e.g., with no malignant arrhythmia) may precipitate ventricular fibrillation, asystole, or other dangerous arrhythmias.

Defibrillation without proper application of electrodes may be ineffective and cause burns, particularly when repeated shocks are necessary. Erythema or hyperemia of the skin under the electrodes often occurs; this effect is usually enhanced along the perimeter of the electrode. This reddening should substantially clear within 72 hours.

Defibrillator Output Energy

The ZOLL 1600 delivers up to 360 joules into a 50 ohm impedance. The actual energy delivered through the chest wall, however, is controlled by skin impedances.

Synchronized Cardioversion

Applies to manual operation only.

Ventricular Tachycardia (VT), atrial fibrillation, atrial flutter and other arrhythmias resistant to drug therapy require synchronizing the defibrillator discharge with the ECG R-wave to prevent the induction of ventricular fibrillation. In this case, a synchronizing (SYNC) circuit within the instrument detects the patient's R-waves. When the Shock button is pressed and held, the unit will discharge with the next detected R-wave, thus avoiding the vulnerable T-wave segment of the cardiac cycle. A qualified operator must decide when synchronized cardioversion is appropriate.

Pacemaker Function

Applies only to ZOLL 1600 configured with a pacemaker.

Noninvasive Temporary Pacing (NTP) is an established and proven technique. This therapy is safe and is easily and rapidly applied in both emergency and non-emergency situations when temporary cardiac stimulation is indicated.

The ZOLL 1600 contains a demand pacemaker consisting of a pulse generator and ECG sensing circuitry. The output current of the pacemaker is continuously variable from 0 mA up to 140 mA and the rate is continuously variable from 30 to 180 pulses per minute (ppm).

The pacing output pulse is delivered to the heart via ZOLL Multi-Function Electrodes placed on the back and the precordium.

The characteristics of the output pulse, together with the design and placement of the electrodes, minimize cutaneous nerve stimulation, lower cardiac stimulation thresholds, and reduce discomfort due to skeletal muscle contraction.

During external pacing the unique design of the ZOLL 1600 allows clear viewing and interpretation of the electrocardiogram (ECG) on the monitor without offset or distortion.

Proper operation of the ZOLL 1600, together with correct electrode placement is critical to obtaining optimum results. The operator must be thoroughly familiar with these operating instructions.

Intended Use — Pacemaker

This product may be used for cardiac pacing in conscious or unconscious patients for up to a few hours duration as an alternative to endocardial stimulation. The purposes of pacing include:

1 Resuscitation from standstill or bradycardia of any etiology:

Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, β -blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

2 As a standby when standstill or bradycardia might be expected:

As a stand-by when arrest or symptomatic bradycardia might be expected, the external pacer is used especially in pacemaker procedures (e.g., acute myocardial infarction, drug toxicity, anesthesia, or surgery, especially when disturbances of rhythmicity or conduction are present). Prophylactic placement of endocardial electrode, which carries risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis, and mechanical or electrical stimulation of ventricular tachycardia and fibrillation, can be avoided.

3 Suppression of tachycardia:

An increase in heart rate from external pacing often suppresses ventricular ectopic activity and may prevent tachycardia.

Pacemaker Complications

Ventricular fibrillation will not respond to pacing and requires immediate defibrillation. The patient's dysrhythmia must therefore be determined immediately, so that appropriate therapy can be employed. If the patient is in ventricular fibrillation and defibrillation is successful, but cardiac standstill ensues (asystole), the pacemaker should be used.

Ventricular or supraventricular tachycardias may be interrupted with pacing but in an emergency or circulatory collapse, synchronized cardioversion is faster and more certain. (See Section 3 for Synchronized Cardioversion Procedure.)

Electromechanical dissociation may occur following prolonged cardiac arrest or in other disease states with myocardial depression. Pacing may then produce ECG responses without effective mechanical contractions, and other treatment is required.

Pacing may evoke repetitive responses, tachycardia, or fibrillation in the presence of generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance, or other cardiac diseases.

Pacing by any method tends to inhibit intrinsic rhythmicity. Abrupt cessation of pacing, particularly at rapid rates, can cause ventricular standstill and should be avoided.

Noninvasive Temporary Pacing may cause discomfort of varying intensity, which may occasionally be severe and preclude its continued use in conscious patients. Similarly, unavoidable skeletal muscle contraction may be troublesome in very sick patients and may limit continuous use to a few hours. Erythema of the skin under the electrodes often occurs but is inconsequential.

There have been reports of burns under the anterior electrode when pacing adult patients with severely restricted blood flow to the skin. Prolonged pacing should be avoided in these cases and periodic inspection of the skin is advised.

There are reports of transient inhibition of spontaneous respiration in unconscious patients with previously available units when the anterior electrode was placed too low on the abdomen.

This device may not be connected to internal pacemaker electrodes in contact with the myocardium.

Pediatric Pacing

Pacing can be performed on pediatric patients (15kg or less) using special pediatric Multi-Function Electrodes.

Monitor Function

The ZOLL 1600 contains a non-fade monitor for observation of the patient's cardiac rhythm. The monitor displays the ECG in moving trace mode at 25 mm/sec for a period of 3.4 seconds. In addition, the monitor displays:

- defibrillator output in joules
- number of shocks delivered during the event
- operational prompts, messages, and diagnostic codes

In manual mode the monitor displays:

- defibrillator output in joules
- heart rate, derived from measuring averaged R to R intervals.
- operational prompts, messages, and diagnostic codes
- ECG lead selections - I, II, III, or ELECTRODES.
- ECG size - .5, 1.0, 1.5, 2.0, 3.0 cm/mV
- pacemaker output in milliamps

The ZOLL 1600 has built-in protection circuitry that allows patient monitoring to continue during a defibrillation attempt. Monitoring electrodes may become polarized during defibrillator discharge, causing the ECG waveform to briefly go off the display area. High quality silver/silver chloride (Ag/AgCl) electrodes minimize this effect, and circuitry in the instrument will return the trace to the monitor display within a few seconds.

Medical Report Module

The 1600 stores event report data and provides convenient means of transferring the event to a database for review, training or storage. The 1600 begins recording data when the unit is turned on.

Removable PCMCIA Data Card

A removable 4 megabyte PCMCIA data card stores up to two hours of incident data (continuous patient ECG and unit status) or up to one hour of incident data and simultaneous audio recording. Data can be reviewed on a personal computer. (See Appendix A)

Strip Chart Recorder Function

A thermal strip chart recorder (optional) prints patient ECG, unit status and event information. The recorder operates in delay mode (i.e. ECG data is printed 6 seconds after its acquisition). Certain events will start the recorder automatically depending on the configuration. Manual operation is controlled by the Recorder On/Off button.

Summary Report

Summary Report allows the operator to store and later retrieve a printed copy of critical ECG event information. The 1600 internal memory automatically records defibrillation and cardioversion segments, **Pacer On** mode, heart rate alarm, analysis initiation, shock advised, no shock advised, and recorder activated ECG events. The Summary Report records all associated event information including 1600 control settings, patient ECG, time and date. (Refer to Appendix B for more information)

Electrode Options

ZOLL approved defibrillation only electrodes provide anterior/anterior placement, hands-off defibrillation and ECG monitoring. ZOLL Multi-Function Electrodes provide anterior/posterior placement, hands-off defibrillation, synchronized cardioversion, ECG monitoring and noninvasive pacing.

Safety Considerations

Persons using the ZOLL 1600 should be appropriately trained, skilled personnel familiar with the use of this device. Training appropriateness, such as Basic Life Support, should be the determination of the prescribing physician. (The semiautomatic mode of operating the ZOLL 1600 reduces the level of, but does not eliminate the need for training required to use the device.)

WARNINGS

General

- Federal (U.S.A.) law restricts this device to use by or on the order of a physician.
- The use of external pacing/defibrillation electrodes and adapter devices from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used in conjunction with pacing/defibrillation electrodes and adapter devices from other sources. If device failure is attributable to pacing/defibrillation electrodes or adapter devices not manufactured by ZOLL, this may void ZOLL's warranty.
- Proper operation of the ZOLL 1600, together with correct electrode placement is critical to obtaining the optimum results. The operator must be thoroughly familiar with proper ZOLL 1600 operation.
- Do not use the ZOLL 1600 in semiautomatic mode during patient movement on a stretcher or in an ambulance or other conveyance. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle to analyze the ECG. If using the device in an emergency vehicle, bring the vehicle to a halt before using the ZOLL 1600 in semiautomatic mode.
- The ZOLL 1600 is protected against interference from radio frequency emissions typical of two-way radios and cellular phones (digital and analog) used in emergency service/public safety activities. Users of the ZOLL 1600 should assess the device's performance in their typical environment of use for the possibility of radio frequency interference from high-power sources. Radio Frequency Interference (RFI) may be observed as shifts in monitor baseline, trace compression, or transient spikes on the display.
- Keep a fully charged spare battery pack with the ZOLL 1600 at all times. Replace the battery immediately when a low battery message is displayed.
- Emergency defibrillation should be attempted only by appropriately trained, skilled personnel who are familiar with equipment operation. Training appropriateness, such as Advanced Cardiac Life Support (ACLS) or Basic Life Support (BLS) certification, should be the determination of the prescribing physician.
- Synchronized cardioversion should only be attempted by skilled personnel trained in Advanced Cardiac Life Support (ACLS) and familiar with equipment operation. The precise cardiac arrhythmia must be determined before attempting defibrillation.
- Prior to attempting to perform a synchronized cardioversion, ensure that the ECG signal quality is good to minimize risk of synchronizing on artifact.
- These operating instructions describe the functions and proper operation of the ZOLL 1600. They are not intended as a substitute for a formal training course. Operators should attend a formal training course conducted by an appropriate authority.
- Do not disassemble the ZOLL 1600. A shock hazard exists. Refer all problems to ZOLL Technical Service.
- Follow all recommended maintenance instructions. If a problem occurs, obtain service immediately. Do not use the ZOLL 1600 until the unit has been inspected by the appropriate personnel.
- Do not install batteries into Monitor/Defibrillators when storage may exceed 90 days. Battery damage may occur.
- Do not use the ECG out signal as a sync pulse to another Defibrillator because of the delay in the signal path.

Operator Safety

- Do not use the ZOLL 1600 in the presence of flammable agents (such as gasoline), oxygen-rich atmospheres, or anesthetics. Using the instrument near the site of a gasoline spill may cause an explosion.
- Do not discharge with paddles or electrodes shorted together or in open air. Stand clear of patient when defibrillating.
- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Do not use the instrument near or within puddles of water.
- Do not touch patient, or any equipment connected to the patient other than the defibrillator during defibrillation.
- Do not allow electrolyte gel to accumulate on hands.
- Do not touch the gelled area of the electrodes while pacing.
- Excessive body hair or wet, sweaty skin may interfere with electrode adhesion. Remove the hair and/or moisture from the area where the electrode is to be attached.
- Do not discharge the defibrillator except as indicated in the instructions. Do not discharge the defibrillator if the electrodes are not properly placed on the patient.
- The user must check that the equipment functions properly and see that it is in proper condition before being used.

WARNINGS (Continued)

- Disconnect any other medical electrical equipment that is not specifically defibrillation protected from the patient prior to defibrillation.

Patient Safety

- Do not defibrillate pediatric patients (weighing less than 80 lbs./36 kg) in semiautomatic mode (AHA standard).
- The ZOLL 1600 detects ECG electrical signals only. It will not detect a pulse. Always verify rate and pulse by physical assessment of the patient. Never assume a rate display indicates a patient has a pulse.
- Use only high quality ECG electrodes. ECG electrodes are for rhythm acquisition only. Defibrillation or pacing cannot be accomplished with ECG electrodes.
- Do not use electrodes with gel that is torn or split from the foil.
- Multi-Function electrodes should be used no longer than eight (8) hours for continuous pacing.
- Pacer output current (mA) must be set to 0mA when connecting and disconnecting a patient from the ZOLL 1600.
- Prolonged pacing (in excess of 30 minutes), particularly in neonates and adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.
- Internal implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Pacemaker patients should be carefully observed. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect and display all implanted pacemaker spikes; patient history and physical exam are important in the determination of the presence of an implanted pacemaker.

Restarting the Device

Certain events require the ZOLL 1600 to be re-started after it has shut off or become inoperative. One example is when the battery runs down and the unit shuts off. The selector switch should always be turned to the OFF position before removing the battery. The selector switch may then be turned to the desired operating mode to resume operation after insertion of a new battery. This sequence is needed to restart the device, and can also be used to clear some "Status XX" messages, if immediate use of the device is required. Note that some settings (for example, alarm settings, lead selection, ECG size) may need to be restored from their default values when operation is resumed.

FDA Regulations

Tracking

Federal law (21 CFR 821) requires tracking of defibrillators. As an owner of this device, you have the responsibility under this law to notify ZOLL Medical Corporation if this product has been received, lost, stolen or destroyed; or has been donated, resold, or otherwise distributed to a different organization.

If any of the events described above occur, please contact ZOLL Medical Corporation in writing with the following information:

1. Originator's organization- Company name, address, Contact name and Contact phone number
2. Part number/Model number and Serial number
3. Disposition of device (e.g., received, lost, stolen, destroyed, distributed to another organization)
4. New location and/or Organization (if different from number 1 above) - Company name, address, contact name, and contact phone number
5. Date change took effect
6. Other information or comments

Please address your information to:

ZOLL Medical Corporation
32 Second Avenue
Burlington, MA 01803-4420
Attn: Tracking Coordinator

Fax 617 272-5578 Phone 617 229-0020

Notification of Adverse Events

As a health care provider, you may have responsibilities under the SMDA, for reporting to ZOLL and possibly to the FDA the occurrence of certain events. These events, described in 21 CFR Part 803, include device related death and serious injury or illness.

In any event, as part of our Quality Assurance Program, ZOLL should be notified of any device failures or malfunctions. This information is required to assure that ZOLL provides only the highest quality products.

Warranty (U.S.A. Only)

(a) ZOLL Medical Corporation warrants to the Customer that from the date of installation, or thirty (30) days after the date of shipment from ZOLL Medical Corporation's facility, whichever first occurs, the Equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period of one (1) year. Accessories and electrodes shall be warranted for 90 days from date of shipment. During such period ZOLL Medical Corporation will, at no charge to the Customer, either repair or replace (at ZOLL Medical Corporation's sole option) any part of the Equipment found by ZOLL Medical Corporation to be defective in material or workmanship. If ZOLL Medical Corporation's inspection detects no defects in material or workmanship, ZOLL Medical Corporation's regular service charges shall apply. (b) ZOLL Medical Corporation shall not be responsible for any Equipment defect, the failure of the Equipment to perform any specified

function, or any other nonconformance of the Equipment, caused by or attributable to: (i) any modification of the Equipment by the Customer, unless such modification is made with the prior written approval of ZOLL Medical Corporation; (ii) the use of the Equipment with any associated or complementary equipment, accessory or software not supplied by ZOLL Medical Corporation; (iii) any misuse or abuse of the Equipment; (iv) exposure of the Equipment to conditions beyond the environmental, power or operating constraints specified by ZOLL Medical Corporation; or (v) installation or wiring of the Equipment other than in accordance with ZOLL Medical Corporation's instructions. (c) This warranty does not cover items subject to normal wear and burnout during use, including but not limited to lamps, fuses, batteries, patient cables and accessories. (d) The foregoing warranty does not apply to software included as part of the Equipment (including software embodied in read-only memory, known as "firmware"). (e) The foregoing warranty constitutes the exclusive remedy of the customer and the exclusive liability of ZOLL Medical Corporation for any breach of any warranty related to the Equipment supplied hereunder. THE WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND ZOLL MEDICAL CORPORATION EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE.

For additional information, please call ZOLL Medical Corporation at 1-800-348-9011 (in Massachusetts: 1-617-229-0020). International customers should call the nearest authorized ZOLL Medical Corporation service center.

Service

The ZOLL 1600 should provide trouble-free operation without periodic calibration or adjustment. Appropriately trained and qualified personnel should perform periodic routine tests of the device to verify proper operation. (See Section 6.) Refer to the 1600 Service Manual for semi-annual tests to be performed on the device.

U.S.A. Customers

Should the ZOLL 1600 require service, it should be returned, in its original container, to same address listed in previous column, Attn: Technical Service Department

Loaner instruments are available for use while repairs are being completed. To request loan equipment, contact ZOLL Medical at 1-800-348-9011 (in Massachusetts: 1-617-229-0020). Please try to have the following information available to expedite service:

- The unit serial number.
- A description of the problem.
- The name of the department where the equipment is in use.
- Sample ECG strips documenting problem (if available).
- A Purchase Order to allow tracking of loan equipment.

International Customers

Should the ZOLL 1600 require service, it should be returned, in its original container, to the nearest authorized ZOLL Medical Corporation service center.

Section 2

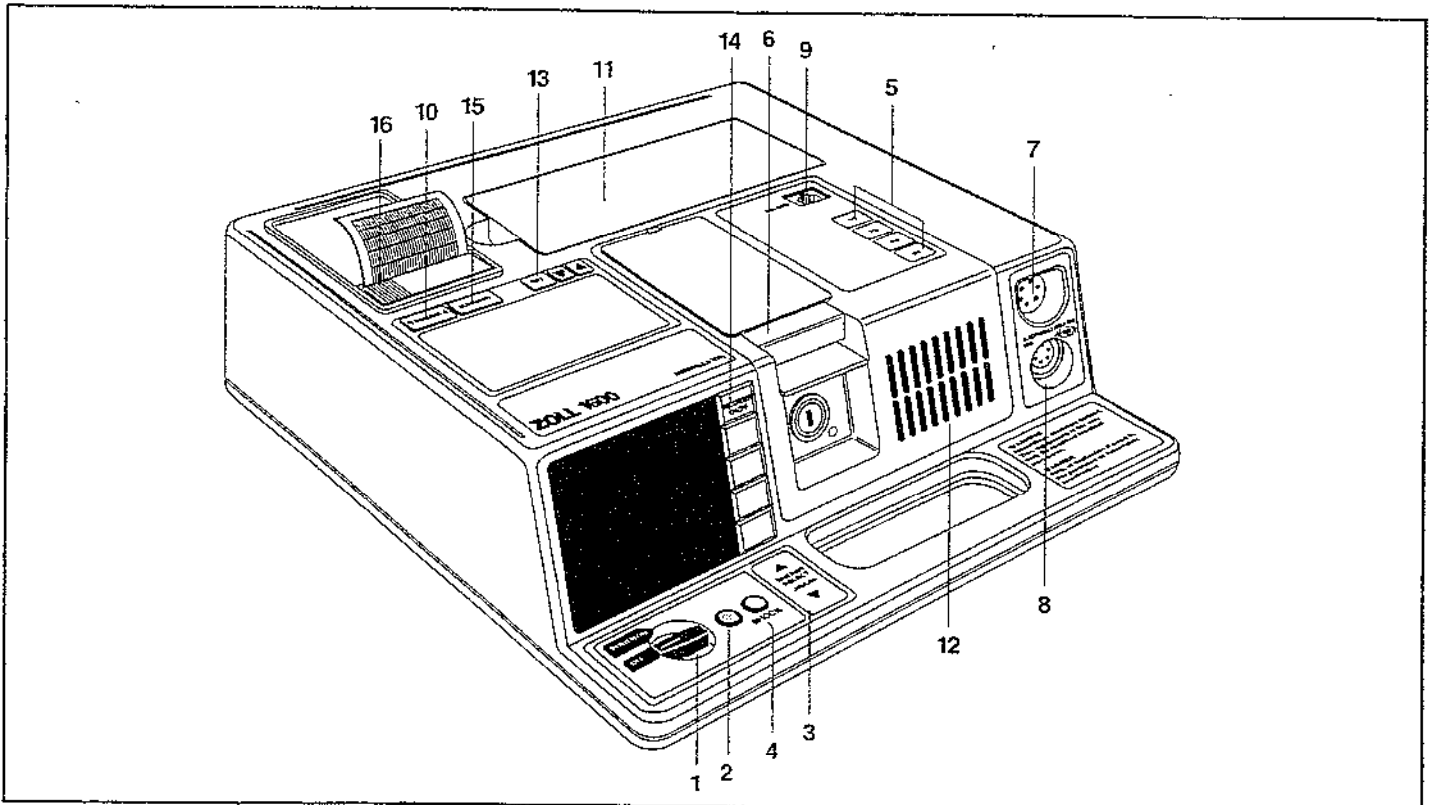
Operating Controls and Indicators Semiautomatic Mode



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.



The controls and indicators described are active in semiautomatic mode. Also described are the optional strip chart recorder controls. Many ZOLL 1600 features and controls are user configurable to better facilitate local protocols. **Some configuration options affect controls and indicators. See Appendix D for additional information.**

1. Selector Switch

The selector switch powers on the unit.

If the selector switch is turned to Power On and only the ECG cable is connected, the 1600 will operate in monitor mode only.



The device will always power on in the semiautomatic mode. To select manual mode, the manual mode key must be used after the unit has been turned on.

2. Analyze Button


An ANALYZE  message appears on the monitor when the


unit is ready for active analysis mode. Pressing the Analyze button initiates an active analysis causing the unit to analyze the patient ECG and determine if a shockable rhythm exists. If a shock is advised, the 1600 will charge to the preconfigured energy level and prompt the operator to shock the patient.

3. Energy Select Button

A set of up-down arrow buttons located on the front panel allow changing the preconfigured defibrillator energy level. Pressing the up  button will increase the energy level to the next preconfigured energy level and pressing the down  arrow button will decrease the energy level to the next preconfigured energy level. (200J and 360J are the preconfigured (default) energy levels available in semiautomatic mode.) The energy level selected is displayed on the monitor. These up-down arrow buttons are disabled after the 1600 begins charging preventing further changes in the selected energy.

4. Shock Button

The Shock button is active only after the ECG analysis has been completed and a shockable rhythm has been detected. The monitor displays the message **PRESS SHOCK** . Pressing and holding the Shock button delivers the shock.

The shock button is operational for 15 seconds after the defibrillator is charged. If the button is not pressed within the 15 second interval, the energy is discharged internally and the **PRESS SHOCK**  message disappears.

5. Event Keypad

The 4 keypad buttons, F1, F2, F3, F4, control medical report module data downloading functions, and event annotation. (See Appendix A)

6. PCMCIA Data Card

A ZOLL recommended PCMCIA card should be installed in the memory card slot during device operation. The PCMCIA card stores patient ECG, 1600 status and optional audio data. The data can be retrieved via a personal computer. (See Appendix A)

7. Multi-Function Cable Connector

The Multi-Function cable connector on the right front of the ZOLL 1600 is used to connect the Multi-Function cable to the instrument.

Multi-Function Cable (Not Shown)

Connects the ZOLL Multi-Function Electrodes or defib only electrodes to the 1600. To install the cable into the 1600, simply plug it into the connector. To remove the cable, depress the black button on the cable and pull the cable out of the unit.

8. ECG Cable Connector

Used to connect a standard 3-lead ECG cable and electrodes to the 1600. The cable is keyed.

9. Communications Port

The communications port (RS-232) is used to transfer recorded incident (ECG and audio) data from the medical report module (memory card) to the ZOLL Data Control System. (See Appendix A)

10. Volume

The Volume control allows audio level adjustment of the voice prompts. The voice prompts cannot be made inaudible even if the volume is turned to the minimum setting. The QRS beep is inaudible in semiautomatic mode. (The charge ready and warning beep volumes are not adjustable.)



11. Battery Pack

The ZOLL 1600 uses a rechargeable, sealed lead-acid battery pack (PD 4410).

12. Speaker

The speaker provides audio prompts to reinforce monitor messages. The volume is adjusted by the Volume control.

13. Set

This control is used to set the time. The up  button increments the displayed value. The down  button decrements the displayed value (See Section 6).

Strip Chart Recorder Controls

The following controls are active only if a strip chart recorder is installed.

14. Recorder On/Off

Press this button and the strip chart recorder starts, press again and the recorder stops.

15. Summary

Initiates the print out of Summary reports. (See Appendix B)

16. Paper Compartment

Opens the strip chart recorder paper storage compartment. (See Section 6)

Audio and Monitor Display Messages

The ZOLL 1600 uses both audio and visual prompts to present critical information to operators. (The following information describes the 1600 default configuration. If your device has been custom configured some of the information may be different. Check with your Medical Control Authority.)

There are 8 voice prompts used in semiautomatic mode. These prompts are accompanied by a message displayed on the monitor. The voice prompts are given only once, but the monitor continues to display the message until new action is taken by the operator or the device status changes.

The ZOLL 1600 also provides a beeper tone to indicate unit status. Four beeps immediately after turning the 1600 on signifies the self diagnostics are complete and 1600 is ready for operation. Additional tone signals are described later.

The display has fields where messages appear. The messages that appear depend upon the functions the 1600 is performing, the mode selected, and the ECG information from the patient.

The 1600 will alternately display two different messages in the same field of the monitor when two conditions are detected at the same time. For example, a "LOW BATTERY" message may alternately display on the same line of the monitor as a "CABLE FAULT" message.

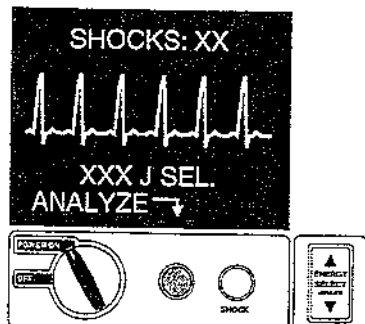
The upper portion of the monitor displays the elapsed time (if enabled) and the number of shocks delivered during the incident (SHOCKS: XX). The center portion of the monitor displays approximately 3.4 seconds of ECG trace and the lower portion of the monitor displays operator prompts, energy levels selected, button function labels and error messages.

Additional unit status information is also displayed on the monitor. See sections 6, 7 and appendices A, B, and C.

Operating Messages

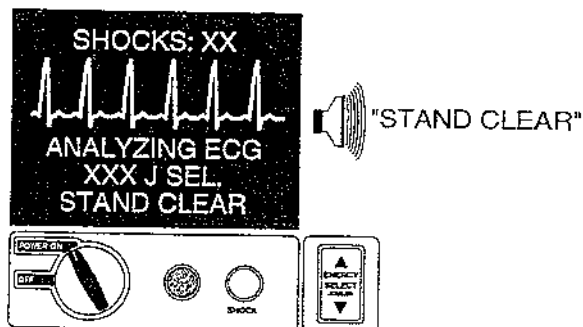
Following are monitor displays and voice prompts that can occur during ZOLL 1600 use. Each subsequent paragraph contains a brief explanation of the message (and applicable user action if necessary).

ANALYZE

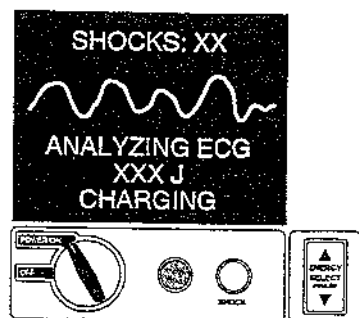


If the 1600 has been turned on with Multi-Function or defibrillation electrodes attached to the patient, the monitor will display an analyze prompt.

ANALYZING ECG/STAND CLEAR



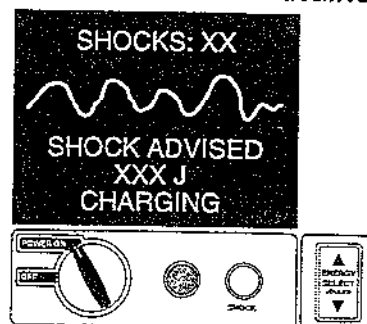
This message appears after pressing the Analyze button. It indicates that an active ECG analysis is starting. Touching or moving the patient can create artifact that interferes with the analysis process. Remain clear of the patient until after the shock has been delivered or no shock advised is determined.



ANALYZING ECG/CHARGING

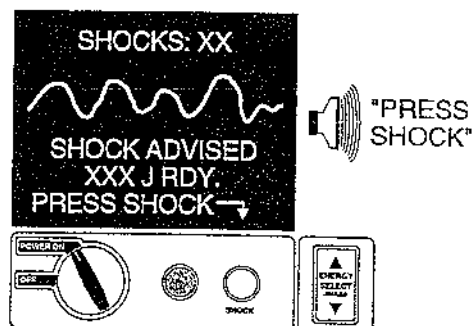
Active analysis is still in progress and a potentially shockable rhythm has been detected. The current charge level and a message that the 1600 is charging are displayed.

SHOCK ADVISED/CHARGING



Active analysis determined that a shock is advised. The selected charge level has not yet been reached. The current charge level and a message that the 1600 is charging are displayed.

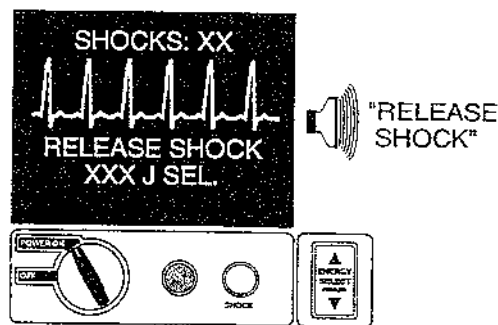
PRESS SHOCK



Active analysis determines that a shock is advised. The selected charge level is ready to be delivered and a message to press the Shock button is displayed. Pressing and holding the Shock button on the front panel delivers the shock to the patient.

The 1600 provides a continuous 10 second steady tone after the defibrillator is fully charged. After the 10 seconds the unit will beep intermittently for 5 seconds. If the Shock button is not pressed during this 15 seconds the unit will discharge the energy internally and the PRESS SHOCK message will disappear.

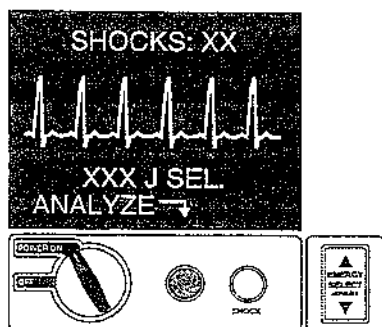
RELEASE SHOCK



If the Shock button is pressed during charging (before the XXX J RDY message), a RELEASE SHOCK message is displayed and the 1600 beeps. If the Shock button is not released and remains depressed for 15 seconds the unit discharges the energy inter-

nally. If the Shock button is released before 15 seconds has elapsed the PRESS SHOCK → message will appear and the shock can be delivered.

SHOCKS: XX



indicates the number of shocks that have been delivered by the 1600 during this incident. Resets to 0 after the 1600 has been off for more than 10 seconds. (This allows for replacing a battery and still maintaining shock number information).

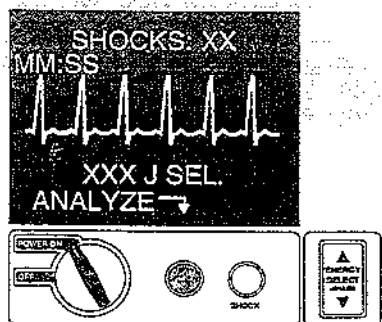
NO SHOCK ADVISED

If during active analysis no shockable rhythm is detected this message will appear.



A 10 second message indicating the 1600 has completed an active analysis of the patient and has not detected a shockable rhythm. Press the Analyze button to start another active analysis or perform other actions as specified by the treatment protocol.

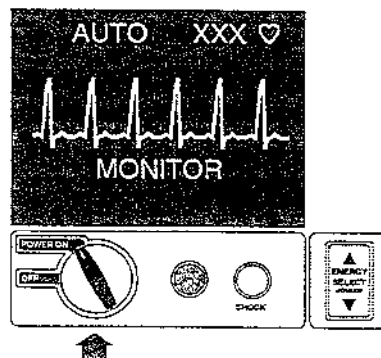
ELAPSED TIME



When enabled, this feature indicates the elapsed time from when the unit is first turned on. It is displayed in the upper left corner of the CRT display in both Semi-Automatic and Manual modes. The elapsed time is displayed in MM:SS form up to 99:59. If the unit is on for over 100 minutes, the elapsed time will roll over to 0. The

elapsed time will be maintained for up to 10 seconds after power down. This will give the operator adequate time to change the battery without resetting the elapsed time.

MONITOR



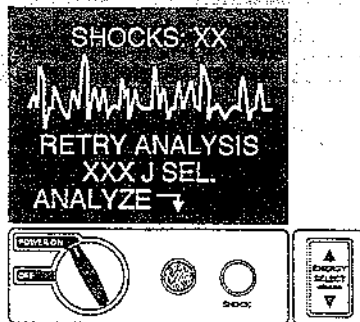
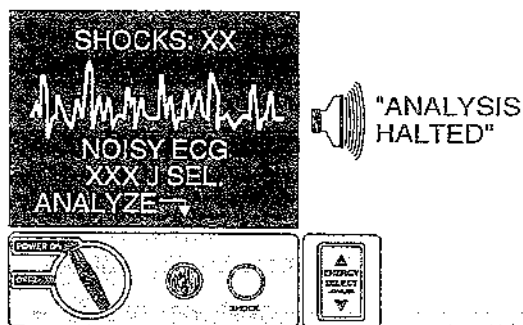
This screen appears when the patient ECG cable is connected to the ECG input connector and the multi-function cable is not installed. The MONITOR message is displayed as well as the patient ECG waveform. The AUTO message indicates the 1600 has selected lead II and set the ECG size automatically (Lead and ECG size cannot be changed by the operator).

Warning Messages

Warning messages prompt the operator to check the patient or the 1600, the electrodes and/or connections.

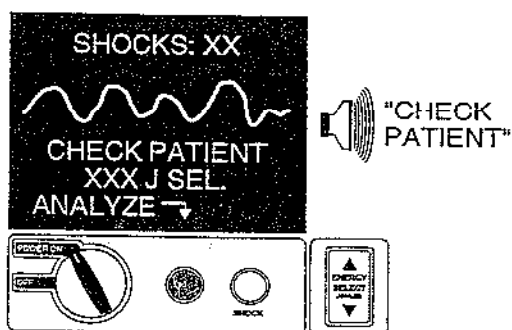
Note: The ZOLL 1600 does not warn the operator of patient asystole, as it is not a shockable rhythm.

NOISY ECG



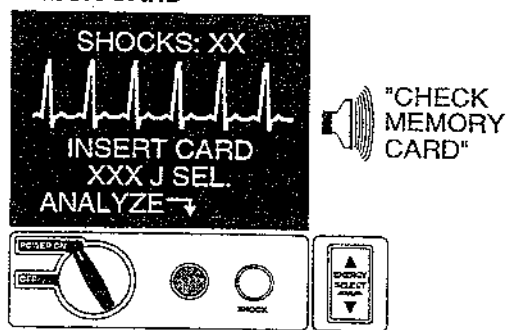
A 5 second NOISY ECG message alternating with a RETRY ANALYSIS message is displayed when the 1600 detects a noisy ECG signal. Check and adjust electrode placement and cable connections to help eliminate the source of noise. Press the Analyze button again to begin active analysis.

CHECK PATIENT



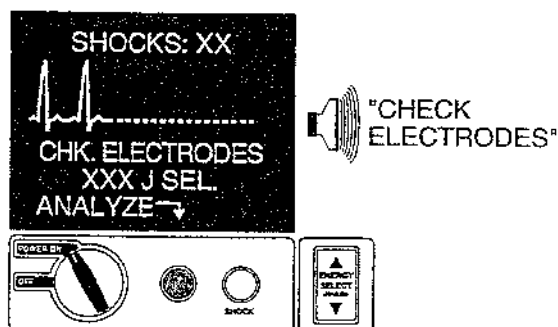
The 1600 detects a shockable rhythm during continuous analysis (i.e. without initiating an analysis). The prompt is given only when the 1600 first detects a shockable rhythm or if the rhythm goes from non-shockable to shockable. The screen message persists as long as a shockable rhythm is being detected. Press the Analyze button to activate the defibrillation functions.

CHECK CARD



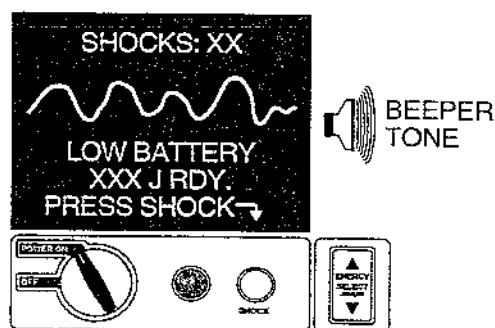
The memory card is not installed or not seated properly in the unit. A "REPLACE CARD" message will appear on the screen when the wrong card type is installed or the card is defective. The ZOLL 1600 will operate, but no data will be stored. This prompt is only given when the 1600 is not analyzing or charging.

CHECK ELECTRODES



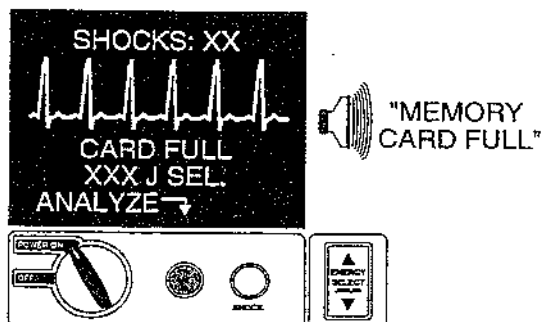
The Multi-Function defibrillation electrodes are no longer properly attached to the patient or the cable connections have become loose. Check that the electrodes are making good contact with the patient's skin and that the cables are all securely connected. The voice prompt will not sound if the electrodes were not previously connected to the patient.

LOW BATTERY



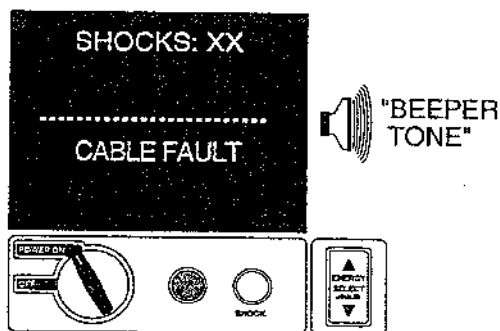
This message indicates the battery charge is low. Immediately replace the battery with a fully charged spare battery.

CARD FULL



The PCMCIA Data Card is full. No more data will be stored on the card but the ZOLL 1600 will continue to operate. This prompt is only given when the 1600 is not analyzing or charging. Insert another card or print event data on strip chart recorder (if so equipped).

CABLE FAULT



This message indicates the connection from the Multi-Function cable and the unit has been interrupted.

Semiautomatic Defibrillation



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.

When using the ZOLL 1600 in the semiautomatic mode, this section describes the recommended method of operation. If your local protocol requires a different procedure, follow that protocol.

In semiautomatic mode, pressing the Analyze button causes the 1600 to perform an active analysis of the patient's ECG and determine if a shockable rhythm is present. An active analysis consists of three 3-second ECG rhythm analyses. If at least two of the three analyses determine that the patient has a shockable rhythm, the 1600 will automatically charge and prompt the operator to shock the patient. If two or more of the three 3-second ECG analyses do not detect a shockable rhythm, the 1600 will alert the operator that no shock is advised. Continuous analysis is disabled for 60 seconds after the completion of analysis (either "NO SHOCK ADVISED" or "SHOCK ADVISED"). This inhibits the "CHECK PATIENT" voice prompt and CRT message during the 60 second interval when the operator is performing CPR. If during continuous analysis, which consists of continuous 18 second segments of ECG analysis, the 1600 detects a shockable rhythm, the 1600 prompts the operator via an audio prompt and visual display message to check the patient. (See Appendix E for data on the ECG analysis system).

1 Determine patient condition following medical protocols

Verify:

- Unconsciousness
- Absence of breathing
- Absence of pulse

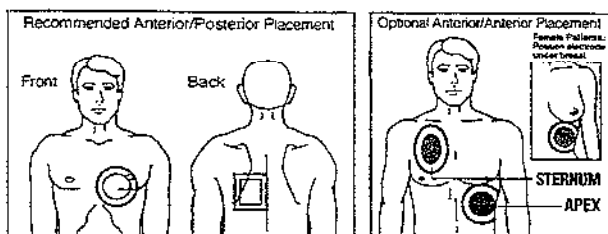
2 Begin CPR following medical protocols

Request additional assistance.

3 Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

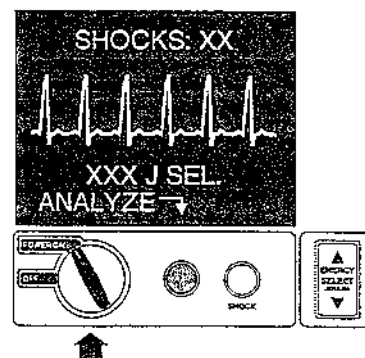
Attach the defibrillation electrodes according to instructions on electrode packaging.



Ensure that all of the electrodes are making good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the multi-function cable if not preconnected

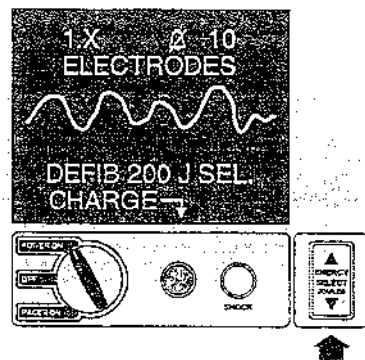
4 Select Power On



The 1600 will beep 4 times to indicate that it has passed the power-on self-test. If the audio recorder is present, the unit will begin recording audio data immediately.

The 1600 displays ANALYZE → on the monitor. The arrow on the monitor will flash to draw attention to the Analyze button below it. This message is displayed until an active analysis is started by the operator.

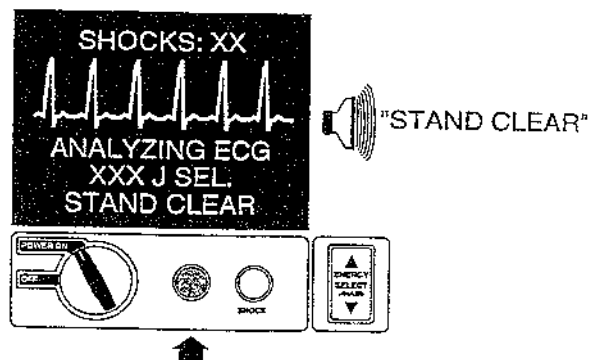
5 Select Energy Level



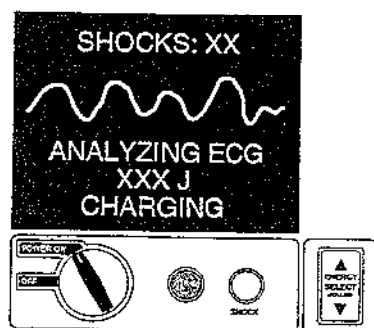
Shock number 1 is set at 200 joules, shock 2 is set at 200 joules and shock 3 and up is set at 360 joules (default setting) (Contact your Medical Control Authority for configuration options). If local protocols allow, the operator may select a different preconfigured energy level using the Energy Select up ▲ and down ▼ arrow buttons. The new energy level will display on the monitor.

6 Press Analyze Button

Avoid touching or moving the patient. If the patient is in a vehicle, bring the vehicle to a stop.

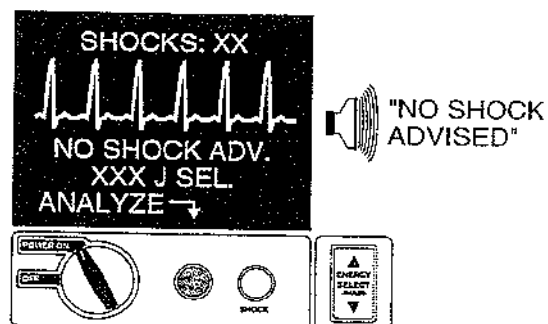


Press the Analyze button to begin the active analysis of the patient's ECG. The unit will advise everyone to "STAND CLEAR". The ECG analysis will last 9 seconds.

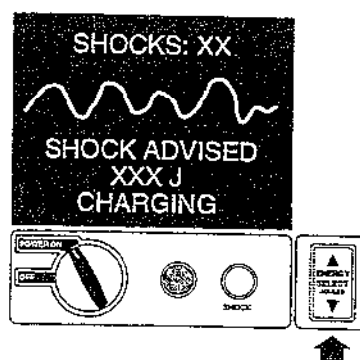


The 1600 may begin charging during the analysis. The monitor shows the CHARGING message.

Once the analysis is completed, the 1600 determines whether or not a shock is advised.



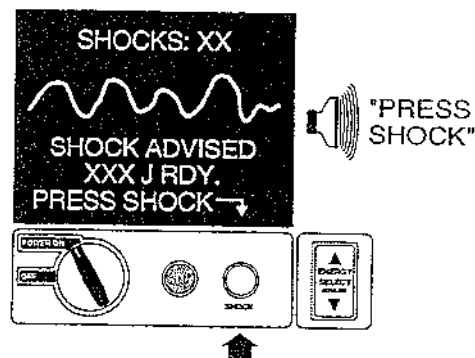
If shock is not advised, the 1600 announces and displays a NO SHOCK ADVISED message on the monitor. Immediately check pulse and breathing and resume other recommended protocol measures.



If a shockable rhythm is identified during analysis, the 1600 displays a SHOCK ADVISED message, indicates the preconfigured energy level and that it is charging – XXX J or charged – XXX J RDY.

7 Press Shock

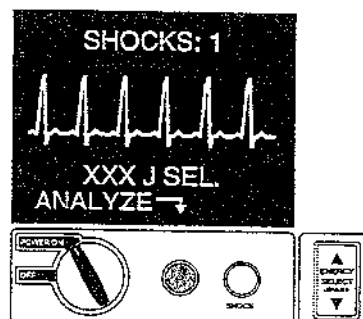
Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential electrical current pathway.



Once the 1600 has charged to the selected level, it announces "PRESS SHOCK" and flashes PRESS SHOCK → on the monitor. A continuous tone will sound for 10 seconds, followed by an intermittent beeping for 5 seconds. The shock must be delivered within this 15 second interval.

Press and **hold** the Shock button on the front panel to deliver the energy to the patient.

Observe the patient or ECG response to be certain that the shock has been delivered.



After the energy is delivered to the patient, the display returns to XXX J SEL. and indicates the number of shocks administered to the patient – SHOCKS 1.

8 Reanalyze Patient

Press the Analyze button to restart an active analysis to determine if a second shock is required.

9 Continue Patient Care

Continue patient care according to local protocols.

ECG Monitoring



ECG leads are a defibrillation protected Type CF patient connection.

ECG electrodes are for rhythm acquisition only. Defibrillation cannot be accomplished with ECG electrodes.

The ZOLL 1600 detects ECG electrical signals only. It will not detect a pulse. Always verify rate and pulse by physical assessment of the patient. Never assume a rate display indicates a patient has a pulse.

In addition to defibrillator electrodes and multi-function electrodes, the 1600 can monitor the patient ECG through standard electrodes. To monitor patient ECG using three (3) ECG electrodes, the ECG cable and electrodes must be properly connected and the multi-function cable must be disconnected from the 1600. If one of the three (3) electrodes or the ECG cable become disconnected the 1600 automatically switches to defibrillation mode and the CHECK ELECTRODES message appears.

If the multi-function cable is connected and defibrillation only or Multi-Function electrodes are attached to the patient the 1600 will operate in defibrillation mode and will monitor the ECG through the defibrillation only or Multi-Function electrodes even if 3-lead electrodes are properly attached.

Monitoring electrodes may become polarized during defibrillation discharge, causing the ECG waveform to briefly go off display. ZOLL 1600 circuitry will return the trace to the monitor display within a few seconds.

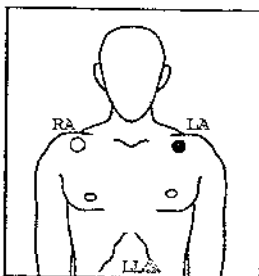
Monitoring Procedure

Follow prescribed medical protocols in your area to determine if ECG monitoring is required.

1 Prepare the patient.

Remove all clothing covering the patient's chest. Dry chest if necessary.

2 Attach Monitoring Electrodes.



RA/White Electrode (R/Red Electrode)

Place near right mid-clavicular line, directly below clavicle.

LA/Black Electrode (L/Yellow Electrode)

Place near left mid-clavicular line, directly below clavicle.

LL/Red Electrode (F/Green Electrode)

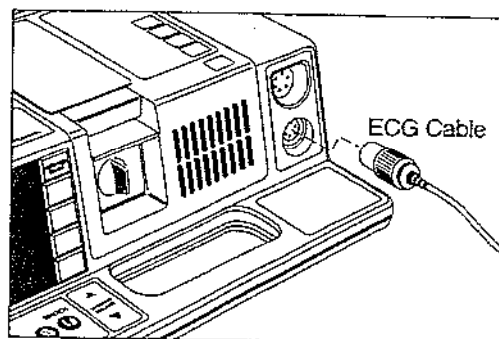
Place between 6th and 7th intercostal space on left mid-clavicular line.

Peel the protective backing from the ECG electrodes. Be careful to keep adhesive surface free of electrolyte gel.

Apply the electrodes firmly to the patient's skin, pressing around the entire perimeter of the electrodes.

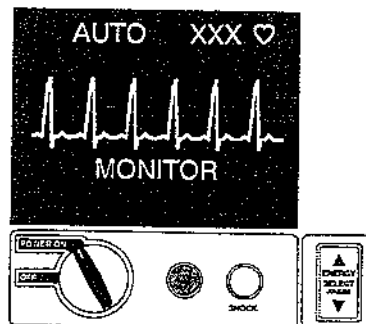
Attach snap-on leads and check for good contact between the electrode and the lead termination.

Plug the patient ECG cable connector into the ECG input connector.



3 Turn to Power On

Observe the monitor.



The message MONITOR should be displayed as well as the patient ECG waveform.

The 1600 automatically selects lead II and sets the ECG size.

Lead and ECG size cannot be changed by the operator.

The patient's heart rate and heart symbol (flashes each time a R-wave is detected) will be displayed in the upper right corner.

1. The first step is to check the battery level. If the battery is low, the device will not work properly. To check the battery level, press the power button and look at the battery icon on the screen. If the battery is low, you will need to charge it.

2. The second step is to check the signal strength. If the signal is weak, the device will not work properly. To check the signal strength, press the power button and look at the signal strength icon on the screen. If the signal is weak, you will need to move to a location with a stronger signal.

3. The third step is to check the device settings. If the settings are incorrect, the device will not work properly. To check the settings, press the power button and go to the settings menu. Make sure that the settings are correct for your location and device.

4. The fourth step is to check the device hardware. If the hardware is damaged, the device will not work properly. To check the hardware, press the power button and look at the device status icon on the screen. If the hardware is damaged, you will need to contact the manufacturer for a replacement.

5. The fifth step is to check the device software. If the software is outdated, the device will not work properly. To check the software, press the power button and go to the software update menu. Make sure that the software is up to date.

Section 3

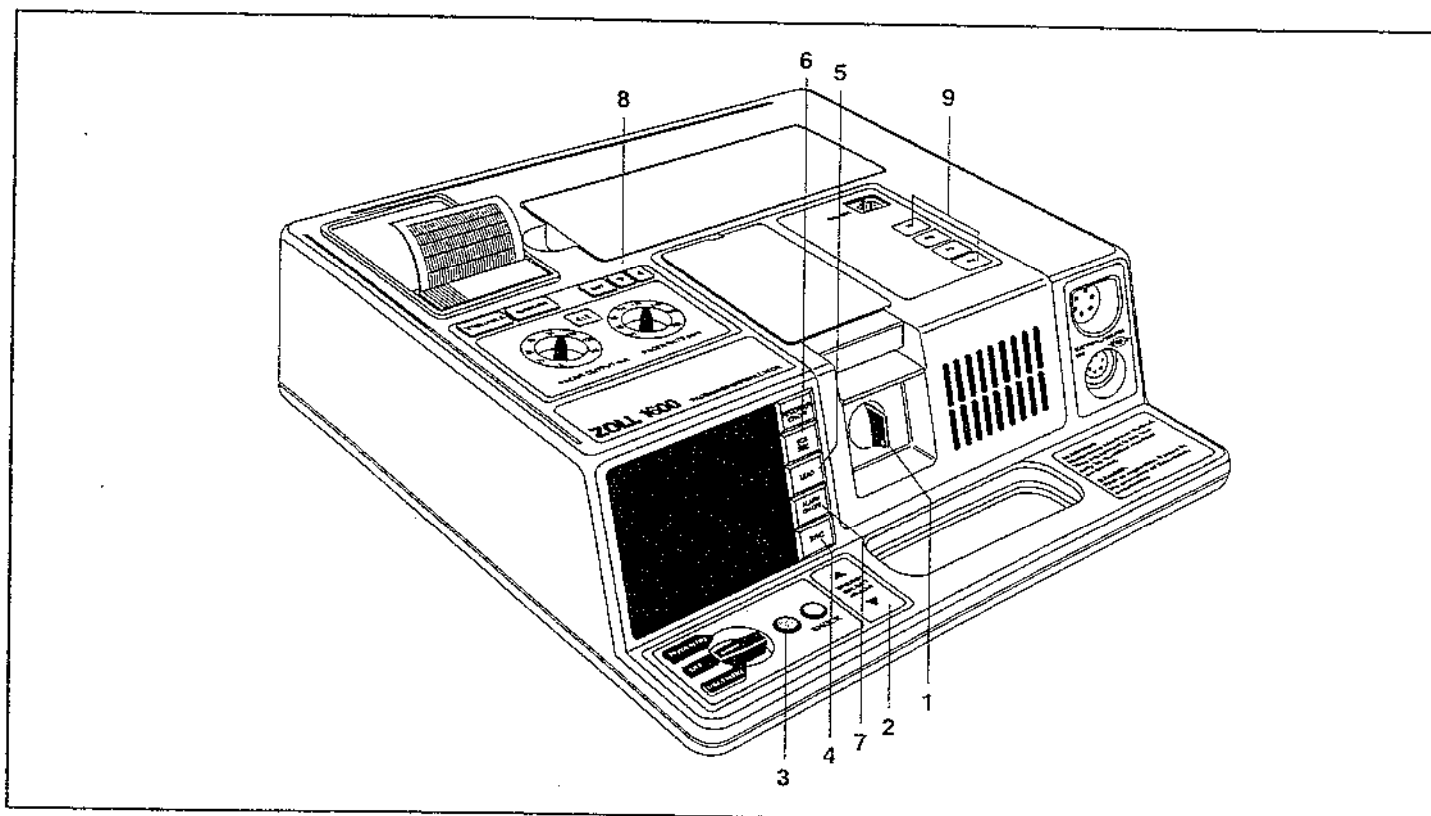
Operating Controls and Indicators Manual Mode



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.



The controls and indicators described below are only active in manual mode. For other controls active in both semi-automatic and manual mode, see the controls and indicators listed in Section 2.

1. Manual Mode Key Switch

The key is used by an authorized operator to switch the ZOLL 1600 into manual mode. The key has 3 positions, 9 o'clock, 12 o'clock and 3 o'clock. Turning the key once to 3 o'clock (right) will prompt a mode change confirmation request (monitor message). Turn the key to 3 o'clock a second time within 5 seconds to confirm the mode change. The 1600 will remain in manual mode until turned off for more than 10 seconds. Turn the 1600 off and then on to return to semiautomatic mode. To remove the key from the key slot turn the key to the 9 o'clock position (left) (unless the key has been permanently installed—contact your Medical Control Authority).

2. Energy Select Buttons

Two up-down arrow buttons located on the front panel control the defibrillator energy level. Press and **hold** the appropriate up ▲ or down ▼ arrow button until the desired energy level is displayed on the monitor.

3. Charge

Press the Charge button to charge the defibrillator to the energy level displayed on the monitor. To change the charged energy level, use the Energy Select buttons to select a new energy level.

4. Sync

In sync mode, the unit synchronizes defibrillator discharge with the first detected R-wave after the shock button is pressed. This mode is used for synchronized cardioversion procedures.

The ZOLL 1600 is configured by default to leave sync mode and revert to standard defibrillation mode after each discharge. (The 1600 can also be reconfigured to remain in sync mode for repeated synchronized shocks—contact your Medical Control Authority).

5. Lead

Pressing the button sequentially selects and displays the ECG source on the monitor. ELECTRODES (Multi-Function electrodes) is automatically selected when the instrument is turned on. Pressing the button sequentially switches the source to lead I, lead II, lead III or ELECTRODES.

If attached to monitoring electrodes in Semi-Auto mode, the default setting remains lead II when converting to manual mode.*

6. ECG Size

This control changes the ECG signal size. Size options are .5, 1.0, 1.5, 2.0, 3.0 cm/mv and are indicated in the upper left of the monitor.

7. Alarm On/Off

The Alarm On/Off button activates and deactivates the heart rate alarms.

8. Set Button

Use this button and the adjacent up ▲ and ▼ down arrows to change the heart rate alarm limit settings.

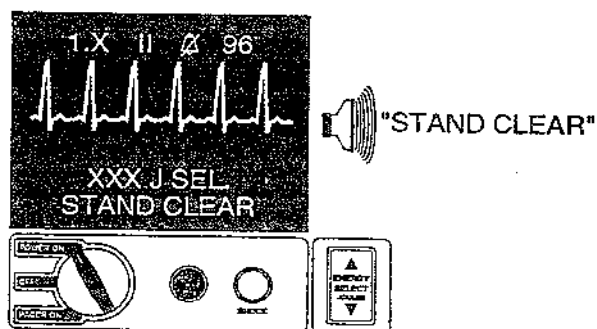
9. Event Keypad

These four buttons are event markers that place a distinctive mark (Event 1, Event 2, Event 3, and Event 4) on the recorder margin the instant the button is pressed. They also trigger a 15 second recorder run if the 1600 is configured to Automatically Generate strips.

Voice and Monitor Display Messages

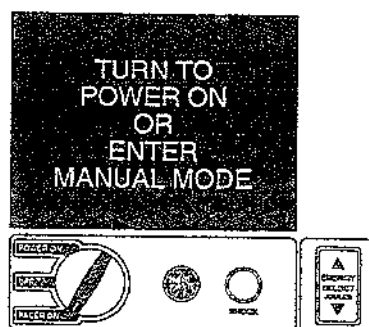
Manual mode monitor messages are similar to semiautomatic mode monitor messages except that the ECG size, ECG lead selected, alarm status, and heart rate replace the SHOCK: XX information on the top line. There are 2 voice prompts in manual mode, "STAND CLEAR" and "CHECK PATIENT". For additional messages that apply to manual mode see Section 2.

STAND CLEAR



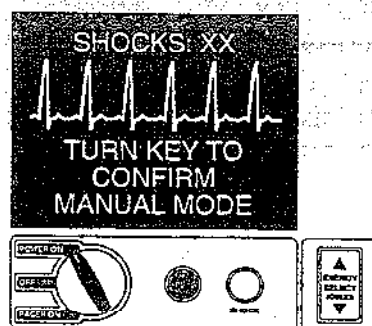
The charge button has just been pressed. Remain clear of the patient until after the shock has been delivered.

TURN TO POWER ON OR ENTER MANUAL MODE



The 1600 has just been turned to Pacer On from semiautomatic mode or from Off. Turn the key to select manual mode operation.

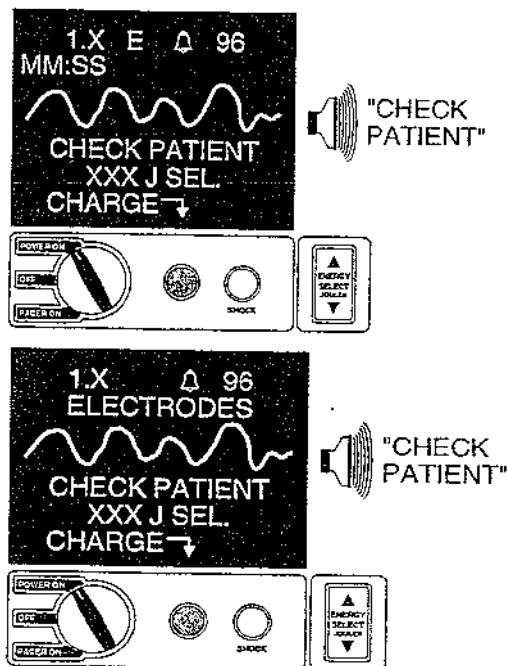
TURN KEY TO CONFIRM




The key has been turned to the 3 o'clock position once to switch to manual mode. Turn to 3 o'clock again within 5 seconds to confirm mode change.

Heart Rate Alarms

The SmartAlarms™ feature automatically analyzes ECG for shockable ventricular fibrillation or wide complex tachycardias whenever Heart Rate Alarms are enabled. The 1600 will display and announce the message, "CHECK PATIENT" to indicate that the source of the alarm was due to the analysis of the rhythm. If the 1600 has a strip chart recorder it will be printed as an annotation at the end of the 15 second strip recorder printout. When the Elapsed Time display is enabled and Electrodes are selected as the input, the letter "E" is displayed on the first line where the ECG Lead is normally displayed. If the Elapsed Time display is disabled the word "ELECTRODES" is displayed on the second line.



the violation tone and the flashing bell  and reactivates the heart symbol to flash with each detected R-wave.

Set the Heart Rate Alarm Limits

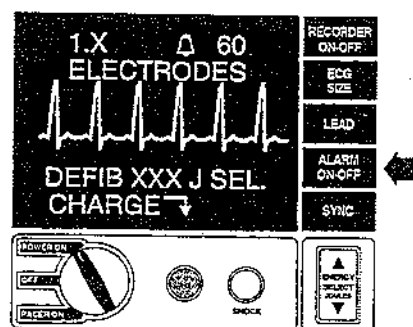
Heart rate alarms are preset at 30 (low) and 150 (high) when turned on.


To change the lower limit or upper limit alarm set points:

1. Push SET button. Low alarm limit value flashes in place of heart rate. To change value, push ▲ to raise, push ▼ to lower.
2. Push SET button again. High alarm limit value flashes in place of heart rate. To change value, push ▲ to raise, push ▼ to lower.
3. Push SET button again to return to monitoring.

To Enable the Heart Rate Alarm

Press the Alarm On/Off switch to enable the heart rate limit alarm and "Smart Alarms." When the alarm is on, the line crossing out the bell-shaped character will disappear.



When an alarm occurs the bell-shaped symbol  will flash (the heart symbol freezes for easier identification), and the audible alarm tone will sound. If the 1600 has a strip chart recorder, it will automatically run for 15 seconds. Turning the alarms off, turns off

Manual Mode Defibrillation

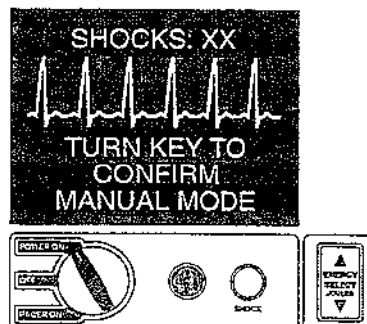


Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.

In manual mode the ZOLL 1600 ECG rhythm analysis algorithm is inactive. The operator determines the appropriate therapy. The operator can select the defib energy level and apply shocks according to the local protocol.



Turn the key clockwise again within 5 seconds to confirm manual mode operation.

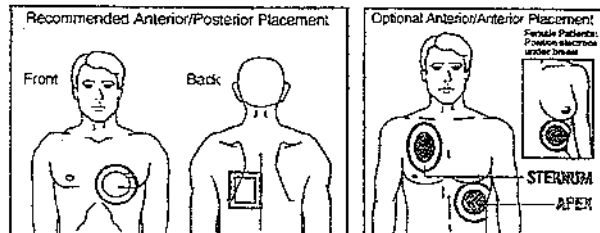
The 1600 will now be in manual defibrillation mode.

ELECTRODES will be selected as the ECG lead.

Verify that the patient requires a shock.

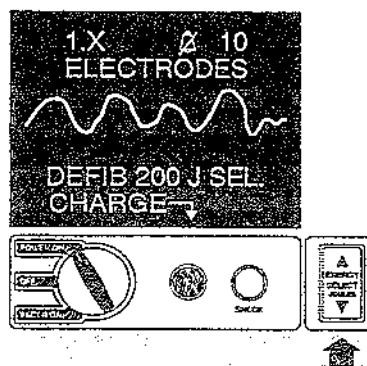
6 Select Defib Energy Level

Apply the electrodes according to the instructions on electrode packaging.



Ensure that the electrodes are in good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the Multi-function cable unless preconnected.



To change the pre-selected defib energy level (200J) press the up ▲ or down ▼ arrow located on the Energy Select button. The selected energy level is displayed digitally as DEFIB-XXX J SEL on the monitor.

4 Select Power On

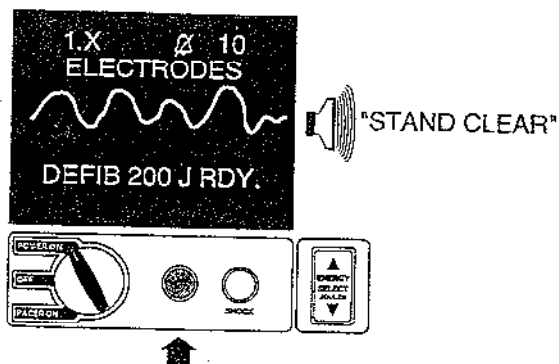
Turn the selector switch to Power On. The ZOLL 1600 will power on in semiautomatic mode.

The 1600 will beep 4 times to indicate power-on self-test has passed. If the audio recorder is present, the unit will begin recording audio data immediately.

5 Switch to Manual Mode

Insert the manual mode key if not already installed in the 1600. Turn the manual mode key clockwise and release. The 1600 displays a message, "Turn Key To Confirm Manual Mode".

7 Charge Defibrillator



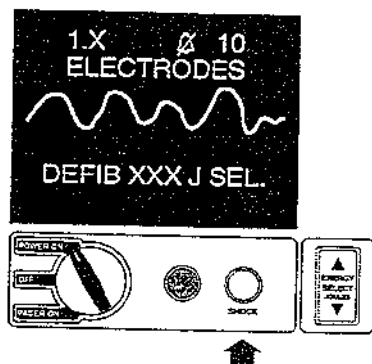
Press the Charge button on the front panel. The "STAND CLEAR" prompt will sound.

After 6-10 seconds of charging to the selected level, the DEFIB XXX J RDY message displays on the monitor. A distinctive charge ready (continuous) tone sounds. The defibrillator is now ready.

To abort the charging and increase or decrease the selected energy after the Charge button has been pressed, use the Energy Select button to select a new energy level. Press the Charge button again to charge the unit.

8 Discharge Defibrillator

Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential current pathway.



Press and **hold** the Shock button on the front panel to shock the patient.

Observe that the energy is delivered by observing the patient and checking the ECG response. The display will return to DEFIB XXX J SEL.

If the defibrillator is not discharged within 60 seconds of reaching the selected energy level, or the **Energy Select** button is pressed, the 1600 automatically discharges the stored energy internally.

During the 10 seconds prior to this internal discharge, the charge ready tone will beep intermittently. The charge ready tone will then stop and the monitor message will change to DEFIB XXX J SEL.

9 Determine Patient Condition

Repeat procedure if necessary according to local protocol.

Synchronized Cardioversion



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.

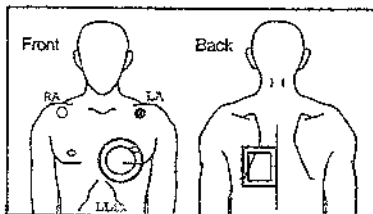
During synchronized cardioversion, the defibrillator discharge occurs when triggered by a patient R-wave. The ZOLL 1600 shows a marker pulse on the patient ECG to indicate the point in the cardiac cycle where discharge will occur. This marker pulse appears as an intensified "dot" or "line" on the ECG waveform. For documentation, a (↓) marker also designates this discharge point above the waveform on the strip recorder printout.

- 1 Determine patient condition following medical protocols**
- 2 Provide patient care following medical protocols**

Request additional assistance.

3 Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.



Attach ECG electrodes.

A standard ECG cable and ECG electrodes are recommended for use during cardioversion. Multi-Function electrodes may be used as an ECG source and signal quality will be equal to that of standard leads except immediately following a discharge when there may be more noise due to muscle tremors, especially if an electrode is not in complete contact with the skin. The use of a standard ECG cable also provides the choice of three different leads for ECG source; Multi-Function electrodes provide only one.

Apply Multi-Function electrodes to the patient according to the instructions on electrode packaging.

Ensure that the electrodes are in good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the multi-function cable unless preconnected.

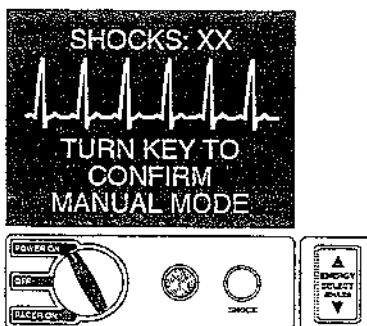
4 Select Power On

Turn the selector switch to Power On. The ZOLL 1600 will power on in semiautomatic mode.

The 1600 will beep 4 times to indicate power-on self-test has passed. If the audio recorder is present, the unit will begin recording audio data immediately.

5 Switch to Manual Mode

Turn the manual mode key clockwise. The 1600 displays a message, "Turn Key To Confirm Manual Mode".

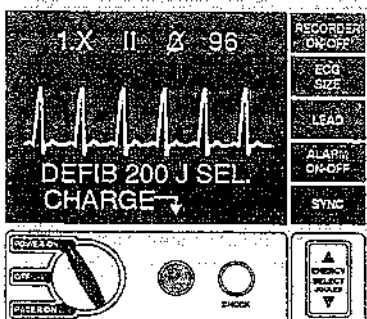


Turn the key clockwise again within 5 seconds to confirm manual mode operation.

The 1600 will now be in manual defibrillation mode.

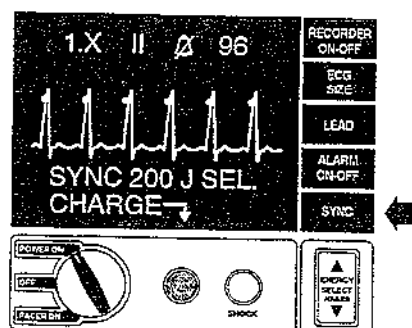
Verify that the patient requires a shock.

6 Select Desired ECG lead



Use the Lead button to select the desired lead. The lead selected is displayed on the top of the monitor.

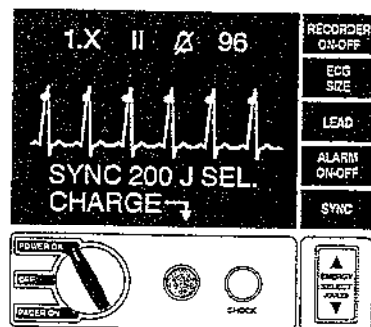
7 Press Sync Button



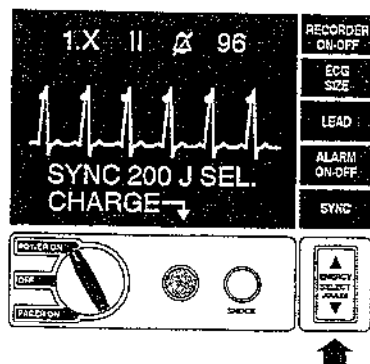
SYNC XXX J will display on the monitor.

An intensified dot or line will appear on the monitor at each detected R-wave to indicate where discharge will occur.

Verify that the intensified dot or line marker is clearly visible on the monitor and is consistent from beat to beat. If necessary, use the Lead button or ECG Size button to select the lead which yields the best display.



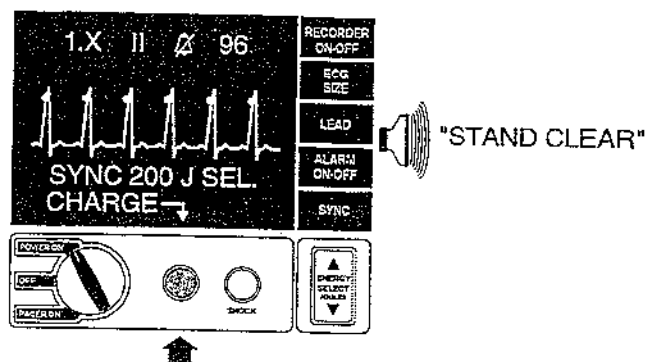
8 Verify Energy Level



The energy level selected will be the level set when the 1600 is powered on. This energy level is displayed on the monitor, SYNC XXX J SEL. If necessary, change the defib energy level using the Energy Select up ▲ and down ▼ arrow buttons. The selected energy level is displayed digitally on the monitor.

If DEFIB XXX J SEL. appears, press the Sync button.

9 Charge Defibrillator



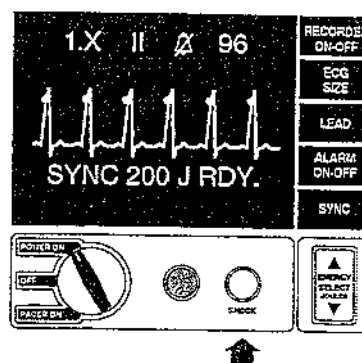
Press the Charge button on the front panel. The "STAND CLEAR" prompt will sound

After 6-10 seconds of charging to the selected energy level, a distinctive audible tone will sound and the energy ready SYNC XXX J RDY. will be displayed on the monitor. The defibrillator is now ready.

To abort charging and increase or decrease the selected energy after the Charge button has already been pressed, use the Energy Select buttons to select a new energy level. Press the Charge button again to charge the unit.

10 Discharge Defibrillator

Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential current pathway.

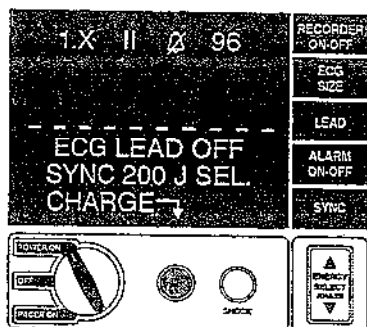


Verify again that the ECG waveform is stable and that a marker pulse appears **ONLY** with each R-wave of the cardiac cycle.

Press and **hold** the Shock button until discharge occurs. The defibrillator will discharge with the next detected R-wave.

After each discharge, the 1600 reverts to standard (non-synchronized) defibrillation. To reactivate sync mode, press the Sync button again. (The 1600 can be configured to remain in sync mode for multiple discharges. Contact your Medical Control Authority).

If additional countershocks are necessary, adjust the energy level as necessary and repeat the procedure.



An ECG LEAD OFF condition (if standard leads are selected as ECG source) will prevent synchronized discharge.

Should you need to disarm the charged defibrillator (if countershock is not needed), change the selected energy level using the Energy Select button. Any stored energy will be discharged internally. The monitor display will change to SYNC XXXJ SEL.

If the defibrillator is not discharged within 60 seconds of reaching the selected energy level, it will automatically discharge the stored energy internally.

During the 15 seconds just prior to this internal disarm, the charge ready tone will beep intermittently. The charge ready tone will then stop and the monitor message will be SYNC XXX J SEL.

Section 4

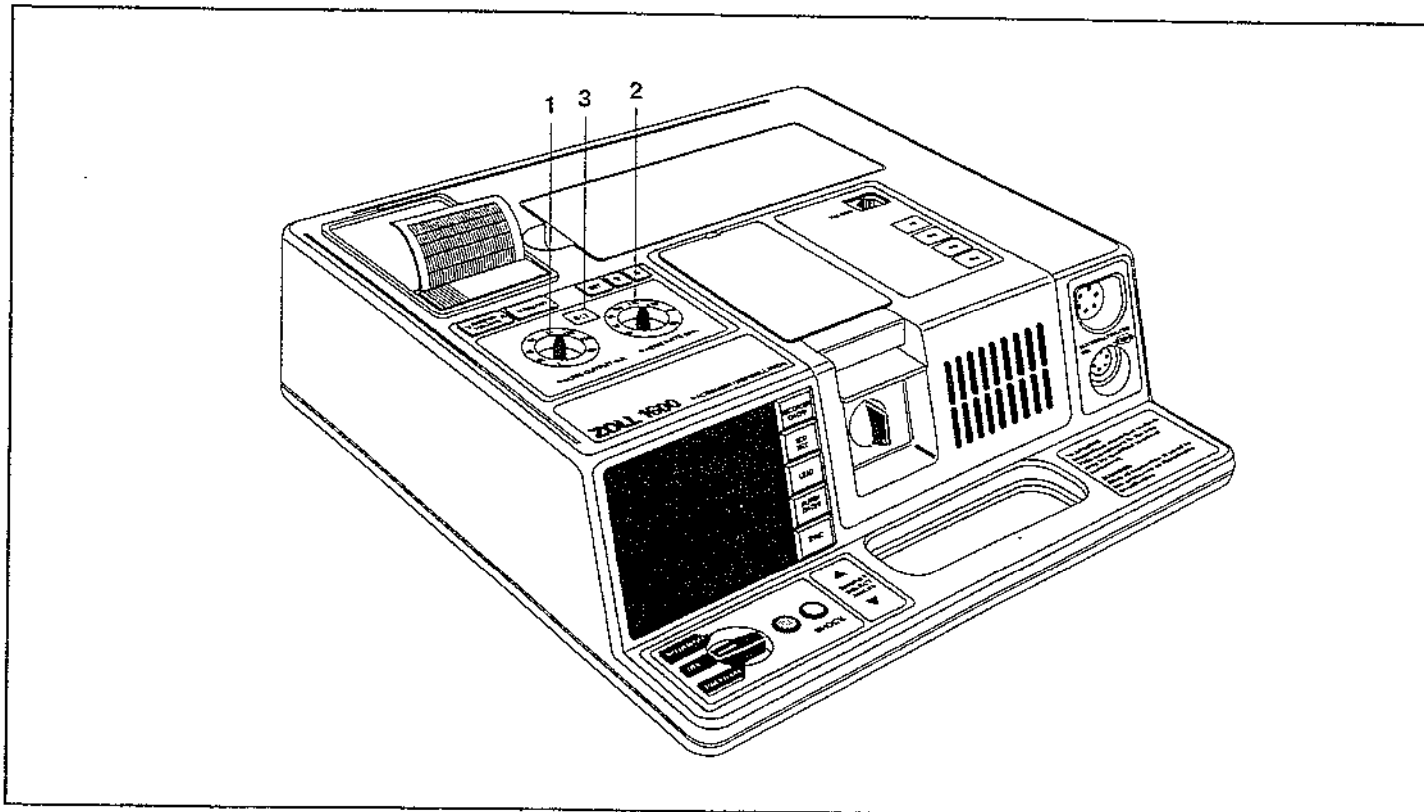
Noninvasive Temporary Pacing



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.



The controls and indicators described below are incorporated in ZOLL 1600's equipped with an external pacer and operating in the manual mode. For other controls active in both semi-automatic and manual modes see Sections 2 and 3.

1. Pacer Output mA

The Pacer Output controls the amount of current (mA) to the pacing electrodes. For conscious patients it should be gradually increased until capture is recognized. The output is displayed digitally on the monitor.

2. Pacer Rate ppm

The Pacer Rate control sets the rate (in pulses per minute) at which the PD 1600 will operate. It must be set above the patient's intrinsic rate in order for the pacemaker to provide stimulation.

3. 4:1 Button

The 4:1 function is used optionally to test for threshold or to determine the patient's underlying rhythm. When depressed, 3 of every 4 pace pulses are suppressed. Releasing the control causes the instrument to resume normal operation.

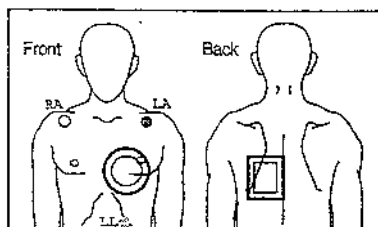
Noninvasive Temporary Pacing

1 Determine patient condition following medical protocols

2 Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary.

3 Apply Electrodes



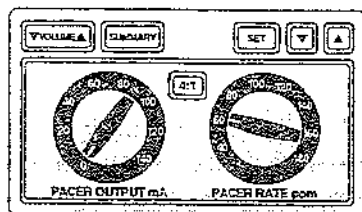
Attach ECG electrodes.

Apply Multi-Function electrodes according to the instructions on electrode pouch.

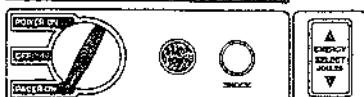
Ensure that all of the electrodes are making good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the ECG and Multi-function cables.

4 Set Pacer Output to 0mA



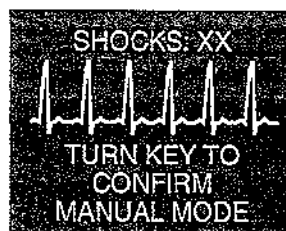
5 Select Pacer On



The ZOLL 1600 will prompt to switch to manual mode.

6 Switch to manual mode

Turn the manual mode key clockwise. The 1600 displays a message, "Turn Key To Confirm Manual Mode."

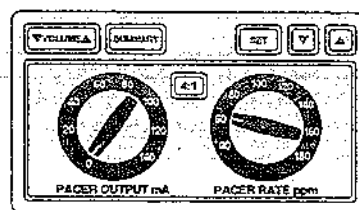


Turn the key clockwise again within 5 seconds to confirm manual mode operation.



Adjust ECG size and lead for a convenient waveform display. Verify proper R-wave detection. The heart-shaped R-wave detector flashes on the monitor when proper detection of R-waves is taking place.

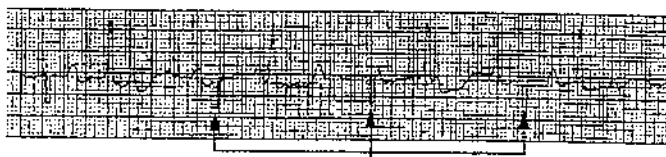
7 Set Pacer Rate



Set pacer rate to a value 10-20 ppm higher than patient's intrinsic rate. If no intrinsic rate exists, use 60 ppm.

8 Observe Pacing Artifacts

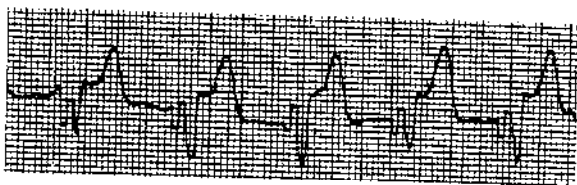
Pacing Below Threshold



Observe the pacing artifact (stimulus markers \square) and verify that it is well positioned in diastole.

Pacing Above Threshold

Effective pacing has been established.

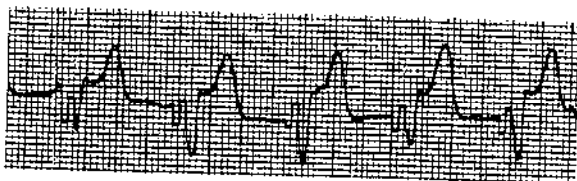


Increase pacer output mA until stimulation is effective (capture). Pacer output mA value is displayed digitally on the lower right of the monitor.

9 Determine Capture

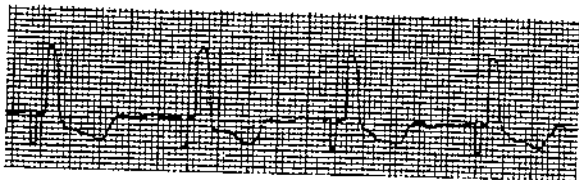
It is important to recognize when stimulation has produced a ventricular response. Ventricular response is normally characterized by suppression of the intrinsic QRS complex. The following traces are typical.

Effective Pacing



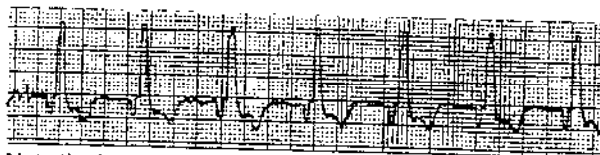
Note negative R-wave and large T-waves.

Effective Pacing



Note the widened positive QRS which looks like an ectopic beat. A paced beat is by definition an ectopic beat.

Effective Pacing



Note the inverted T-waves and the absence of P-waves.

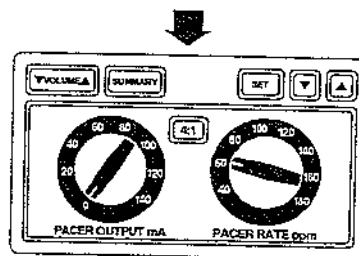
Changing ECG leads and size can sometimes be helpful in determining capture.

Note Shape and size of the stimulated waveforms can vary depending on lead chosen; variation from patient to patient can be expected.

10 Determine Optimum Threshold

The ideal output current is the lowest value that will maintain capture. This is usually about 10% above threshold. Typical threshold currents are usually between 40 and 80 mA. The electrode placement that offers the most direct current pathway to the heart while avoiding large chest muscles will usually produce the lowest threshold. Low stimulation currents produce less skeletal muscle contraction and are better tolerated. Placement of the electrodes will affect the current required to obtain ventricular capture.

After adjusting the electrodes to determine the best location for optimum threshold, the area should be cleaned of salt or other conductive materials (such as defibrillator gel). The electrodes may then be secured.

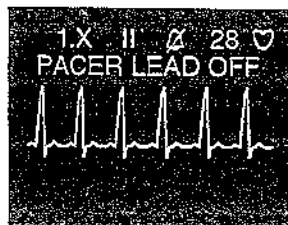


4:1 Test Mode

The 4:1 test mode can be used optionally to test for threshold. In this mode a stimulus is delivered to the patient approximately every fourth pace beat. (The stimulus is demand-synchronized to the patient's intrinsic beat.) Releasing the control causes the instrument to resume normal operation.



PACER LEAD Fault



The message "PACER LEAD OFF" appears on the monitor (in PACER ON mode) whenever the Multi-Function electrodes do not make good skin contact. "CABLE FAULT" will be the monitor message if the Multi-Function cable is not connected properly.

SPECIAL PACING APPLICATIONS

Standby Pacing

For certain patients at risk of developing symptomatic bradycardia, it may be advisable to use the ZOLL 1600 in standby. When used in standby mode, the 1600 automatically provides a pacing stimulus whenever the patient's heart rate drops below a predetermined level. To use the ZOLL 1600 in standby mode:

1. Establish effective pacing (see instructions on previous pages). Note the mA output at capture and run an ECG strip to document ECG morphology at capture.
2. Set the mA output 10% higher than the minimum mA output necessary to effect consistent ventricular capture.
3. Turn the pacing rate below the patient's heart rate. This suppresses pacing unless the patient's own rate drops below the set pacing rate. The pacing rate should be set at a level needed for adequate cardiac output.
4. Check the threshold periodically.

Asynchronous Pacing

The ZOLL 1600 is a VVI demand pacemaker—the safest and most effective design for Noninvasive Temporary Pacemakers. Proper demand pacing requires a reliable high quality surface ECG. If ECG electrodes are not available or there is some circumstance which prevents or interferes with the surface ECG, it may be necessary to operate the pacemaker asynchronously.

To pace asynchronously, simply detach the surface ECG electrodes or remove the ECG cable and set the rate and mA at the

known capture level or high enough (100mA) to presume capture. You should be aware that there will be no ECG activity on the ZOLL 1600 monitor and other means of determining capture such as the patient's pulse will be necessary. Asynchronous pacing should only be performed in emergency situations where there are no other alternatives.

Pediatric Pacing

Noninvasive pacing on pediatric patients is done in an identical manner to adult pacing. Smaller size pediatric Multi-Function Electrodes are available for patients less than 15 kg. Continuous pacing of neonates can cause burns. If it is necessary to pace for more than 30 minutes, caution and periodic inspection of the underlying skin is strongly advised. Carefully follow all instructions on electrode packaging.

Section 5

Battery Management

Safe, reliable use of the ZOLL 1600 system requires a well designed battery management program to ensure that adequate battery power is always available.

ZOLL Medical has developed the ZOLL Battery Management Program. It includes information for determining your particular battery requirements and program implementation steps to setup a comprehensive, effective and safe program.

The 7 key steps to developing a battery program are:

- A. Obtaining proper equipment.
Plan to have a sufficient number of battery packs and chargers to insure an adequate supply of fully charged primary use and spare use batteries.
- B. Assign a responsible individual.
Assign the responsibility to an individual who can oversee all aspects of the program as well as educate other ZOLL 1600 users.
- C. Define battery exchange and charging routines.
Clinical and technical staff should determine desired use patterns and an optimum sequence to insure consistent charging and exchange routines.
- D. Ensure sufficient spare battery capability.
A fully-charged spare battery should be kept immediately available with the ZOLL 1600. The availability of more than one spare battery is recommended in cases where prolonged or repeated use of the device may be required, such as long transport situations.
- E. Develop backup procedures.
Procedures to maintain appropriate life support (such as cardiopulmonary resuscitation) should be pre-planned in the event of a device failure and another battery or device must be sought.
- F. Test batteries regularly.
Develop a testing schedule as part of your organization's battery management. The appropriate frequency of testing depends on the age of the battery pack and the frequency and type of use. As the battery ages, testing should be more frequent since failure will occur rapidly at the battery's end-of-life. At a minimum, ZOLL recommends testing every three months.

PD 4410 Battery Pack

The ZOLL PD 4410 Battery Pack is a five-cell assembly of sealed lead-acid batteries specifically designed for use with the ZOLL 1600, 2000, and 1400 devices.

Lead acid battery packs require full recharging after use. Continuous short cycle recharging will result in reduced capacity and early battery pack failure.

Battery Life Expectancy

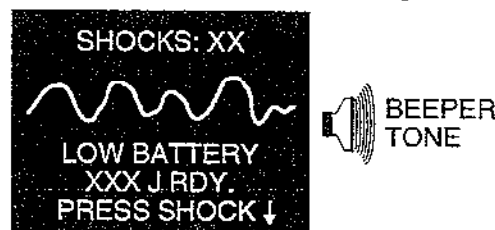
Frequency of use, number of batteries used for ZOLL 1600 operation, and the pattern of discharging and recharging batteries contribute to the loss of battery charge capacity. Because of this ZOLL recommends that operators replace and discard used batteries on a preventive, scheduled basis. The most effective preventive replacement interval should be based on anticipated use patterns, battery pack testing results and experience with the device in actual operation. ZOLL recommends battery replacement every eighteen months or sooner.

For more information about such a schedule, contact your ZOLL Technical Service Representative.

Low Battery Message

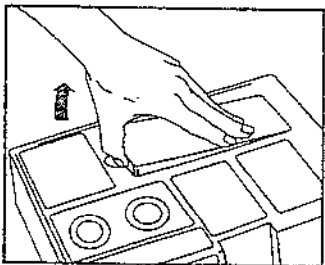
As individual battery capacity diminishes, the amount of operating time remaining after a 1600 LOW BATTERY message also diminishes. For newer or lesser-used batteries, the operating time remaining after this warning will be significantly longer than the operating time remaining on batteries having seen more use. In either case, this warning will ultimately lead to defibrillator shut-off, and consequently, the low battery should be replaced with a fully-charged battery as soon as possible.

When a LOW BATTERY message is displayed on the 1600 monitor, replace the battery pack immediately to ensure continuous operation. With a newer or lesser used battery the unit will beep twice every 20 seconds before shutting off due to a low battery.



Changing the Battery Pack

The ZOLL 1600 is designed for quick removal and replacement of the battery pack. To remove the battery pack, turn the unit off. Insert a finger into the recess at the left end of the battery pack, press against the battery pack to disengage the battery pack locking clip and lift the battery pack out. To install a battery pack, align the "D" shaped recess molded into the battery pack case with the battery pack removal finger recess in the 1600. Set the battery pack into the battery pack well. The shape of the battery pack will allow the battery pack to seat itself. Turn the defibrillator back on to the selected mode of operation.



It is recommended that the selector switch be turned to the OFF position before changing the battery. The selector switch may then be turned to the desired operating mode to resume operation.

This sequence is recommended as general good operating practice for any ZOLL device and is required to restart the device after a LOW BATTERY shutdown has occurred. Note that some settings, for example, alarm settings, lead selection, and ECG size, may need to be restored from their default values when operation is resumed.

Charging PD 4410 Battery Packs

PD 4410 batteries are designed to be charged in a four-compartment battery charger. They may also be recharged by other accessory chargers designed for use with ZOLL devices.

The following general practices will ensure the longest life from PD 4410 Battery Packs:

- Charge batteries completely. When a battery pack exchange is required, place a fully-charged battery in the ZOLL 1600. In an emergency, if no fully-charged batteries are available, a partially-charged battery may be used, but may result in very short 1600 operating times. If a partially-charged battery is used, complete a full charge cycle before its next use. Repeated use after partial charging will quickly diminish the battery's charge capacity, shortening the life of the battery.
- Do not leave batteries uncharged. Once a battery is removed from the 1600 it should be immediately placed in a charge or test well. Idle batteries will lose some of their charge and may suffer damage to charge capacity if left in a discharged state.
- Do not discharge batteries completely. Battery life will be improved if batteries are recharged before complete discharge of

capacity.

- Understand LOW BATTERY implications. As individual battery capacity diminishes, the amount of operating time remaining after a 1600 LOW BATTERY message also diminishes. For newer or lesser-used batteries, the operating time remaining after this warning will be significantly longer than the operating time remaining on batteries having seen more use. In either case, this warning will ultimately lead to defibrillator shut-off, and consequently, the low battery should be replaced with a fully-charged battery as soon as possible.
- Test batteries periodically. Your organization must determine an appropriate testing schedule. Adherence to this schedule is critical in achieving satisfactory results from your 1600 and batteries.
- Complete a shift check of the device. Your 1600 should be tested at the beginning of every shift. This procedure tests the readiness of the unit itself. If the 1600 shows a LOW BATTERY message during testing at the beginning of a shift, the battery currently in use is close to depletion and should be replaced and charged. The shift test does not test the battery for adequate charge to support extended use of the unit, which can only be determined by testing the battery in the PD 4420 Charger.
- Implement a means of indicating the charge status of battery packs. An effective battery management program includes a method of visually determining whether a battery pack is charged and ready for use or is in need of charging.

Single Battery Charger

The Single Battery Charger charges one battery to full capacity in a maximum of 24 hours while connected to AC power.

Battery Support System

Battery pack charging and charge capacity evaluation is easily performed with the ZOLL PD 4420 Battery Support System. Up to four battery packs can be charged simultaneously and testing is a simple one step operation.

PowerCharger AC Power/Charger Module

The ZOLL PowerCharger is an accessory for the ZOLL 1600. The PowerCharger recharges the battery while installed in the 1600 and provides operating power to the instrument even if the battery is removed. The PowerCharger is attached to the rear of the 1600 and plugs into a standard AC outlet.

Additional battery and charging information can be found in the PD 4420 Battery Charger Operator's Guide and the ZOLL PowerCharger Operator's Guide. It is recommended you read your charger instructions thoroughly.

Section 6

Recommended Daily Checkout

Resuscitation equipment must be maintained to be ready for immediate use. This section describes the post-operation maintenance and daily shift check you should perform on your ZOLL 1600. The maintenance can be completed in a few minutes and requires an ECG simulator. It is important that recommended post-operation checks be made after 1600 use since subsequent users may not be able to check the unit before an emergency situation.

At the end of the checkout procedure section is an Operator's Shift Checklist sheet for the ZOLL 1600. Copy and distribute this sheet to all individuals responsible for 1600 use and readiness.

Unit Care

Caution

- Do not sterilize the ZOLL 1600.
- Do not immerse any part of the 1600 in water.
- Do not use alcohol or ketones (MEK, acetone, etc.) on the 1600.
- Avoid using abrasives (e.g., paper towels) on the monitor window.
- Clean the ZOLL 1600 and cables with a soft cloth, mild soap and water. The recorder parts should be cleaned with a damp, soft cloth only.

Recommended Daily Checkout

This brief checklist is intended for non-technical personnel.

If a problem is discovered during the checkout procedure, call ZOLL Technical Service.

More thorough checkout procedures and troubleshooting information can be found in the *ZOLL 1600 Service Manual*.

1. Visual Inspections

- Check that the unit is clean (with no fluid spills) and nothing is stored on the unit.
- Inspect the unit and its accessories for physical damage. Check all cables, cords, and connectors for cuts in the insulation, or bent and broken connector pins.
- Make sure that all disposable supplies are available and in proper condition. (ECG electrodes, strip recorder paper, alcohol swabs, razors, antiperspirant, etc.)
- Check that two sets of defibrillation electrodes or Multi-

Function electrodes in sealed packages are available. Check expiration dates.

- Check that an empty memory card is installed in the unit and a second spare memory card is available.
- Check that a fully charged battery is installed in the unit.
- Check that a fully charged spare battery is with the unit.

Semi-Automatic Mode Testing

1. Power-up Sequence Check

Remove the memory card and install the Multi-Function cable before beginning tests. If the memory card is installed in the 1600 the following tests will be recorded but the available memory (on the card) will be limited. It is recommended that another card be installed before any further recordings are performed.

Turn the selector switch to Power On.

- A 4-beep tone indicates the power-up self-test is completed.

2. Defibrillator Test

Attach the Multi-Function cable to the ECG simulator. Set simulator to VF.

- Verify that within 30 seconds monitor displays CHECK PATIENT and voice prompt "CHECK PATIENT" is sounded. Press Analyze button
- Verify the unit charges to 200J or other preconfigured level.
- Verify PRESS SHOCK message appears and "PRESS SHOCK" voice prompt is heard.

Press SHOCK button.

- The SHOCK XX display message should change from 0 to 1.
- If the SHOCK XX stays at 0, contact your biomedical staff or ZOLL Technical Service immediately.

3. Strip Recorder Operation Check (Optional configuration)

Press the Recorder On/Off button.

While the recorder is running, press and hold the Set up (▲) arrow and Set down (▼) arrow buttons simultaneously.

- This will generate calibration pulses on the recorder paper and CRT.
- Inspect the recorder waveform for uniformity and darkness.

- Inspect for uniformity of annotation characters and completeness of words.
- Check recorder speed by verifying that a new calibration pulse appears approximately every 13 small divisions (13 mm).
- Check amplitude of recorder pulses to be 10 small divisions (10mm).

Check for adequate supply of paper.

A NO PAPER message appears on the monitor when the strip recorder is activated without paper. The strip recorder automatically shuts off when there is no paper.

Loading Strip Recorder Paper

Press the recorder door release button. The door and paper carriage will tilt up.

Remove the empty or low paper roll.

Place a new roll of thermal paper between the two side knobs with the paper coming off the top of the roll and the grid facing down.

Pull enough paper off the roll so that the paper extends out of the strip recorder when the strip recorder door is closed

Close recorder door.

Manual Mode Testing

Turn the selector switch to Power On. (Remove Memory Card)

- A 4-beep tone indicates the power-up self-test is completed

Switch to manual mode after turning on the power to see the following:

- READY message will be displayed briefly, followed by MONITOR, in the lower left of the display screen.
- The ECG size should be 1x.
- ELECTRODES should be displayed in the center of the display screen.
- The message ECG LEAD OFF will be displayed whenever leads I, II, or III have been selected and no ECG cable has been connected, or whenever the lead wires are not attached to a patient.
- Press ECG Size and Lead buttons to verify the following functions:
 - ECG Size for .5x, 1.0x, 2.0x, 3.0x
 - Lead Selection for I, II, III, or ELECTRODES when Multi-Function cable is connected.

4. Delivered Energy and Discharge Button Check

WARNING: Use extreme caution in performing the following tests. Make sure that the Multi-Function cable is plugged into the proper connector prior to discharging.

Install a Multi-Function cable.

Plug the Multi-Function cable into the MFC test port.

Turn the selector switch to Power On.

Switch the unit to manual mode.

Select 100J using the energy select up and down buttons on the front of the unit.

Press the Charge button.

- Charge Ready tone sounds within 10 seconds.
- DEFIB 100J RDY on display.

Press Shock button.

- Verify the monitor displays a "Test OK" message.

5. Maintenance After Use

- Inspect the defibrillator cables and electrodes for visible damage.
- Review your inventory checklist for accessories and supplies to ensure that all supplies are refilled and returned to their proper place after each use.
- Be sure the battery pack is fully charged and replace if in doubt.
- Be sure to keep the PD 4410 battery packs plugged into a ZOLL charger whenever they are not in use. This will keep the battery packs fully charged for future use. Battery packs left uncharged for excessive periods (4 to 6 months) may become damaged and require replacement.

6. Pacer Accuracy (Optional configuration)

Turn the unit on in manual mode.

Turn the selector switch to Pacer On.

Turn the Pacer Rate control to 150 ppm.

Press the Recorder On/Off button to generate a strip.

- The pace pulses should occur approximately every 10 small divisions (2 large divisions, 1 cm).

Press the 4:1 button.

- The frequency of pulses should decrease to 8 large divisions, 4 cm per pulse.

Turn the Pacer Output mA control to 0mA.

- There should be no PACE LEAD OFF message.
- Remove pacer cable from the unit.

Slowly turn the Pacer Output mA control to 15mA.

- The PACE LEAD OFF message should appear.

- The PACE LEAD OFF message should appear.

Replace the memory card.

Setting Time and Date

Check the time and date on the recorder annotation or go into Clock Set mode. If they are not correct, set the time and date as follows:

Turn the selector switch to Off.

Press and hold the Set button on the top of the 1600.

With the Set button pushed, turn the selector switch to the Power On position. When the date display appears on the monitor, release the Set button. Observe the DATE message on the lower portion of the screen with the current day flashing.

Use the Set up (▲) arrow to increase the value and use the down (▼) arrow to decrease the value. Observe that holding the ▲ arrow will increment repeatedly while holding the ▼ arrow will decrement repeatedly.

The range of acceptable values is 1 through 31. Set the value to the current day.

Press the Set button again and observe that the month is now flashing. Repeat above steps to set the correct month. The range of acceptable values is JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC.

Press the Set button again and observe that the current year now flashes. Repeat above steps to set the correct year. The range of acceptable values is 00 through 99.

Press the Set button again. The DATE message is replaced by a TIME message indicating the current hour and minute.

The displayed hour now flashes. Repeat above steps. The range of acceptable values is 00 through 23 (military clock). Set the value to the current hour.

Press the Set button again. The displayed minute now flashes. Repeat above steps. The range of acceptable values is 00 through 59.

Press the Set button again. The lower portion of the screen returns to the normal display.

If the ZOLL 1600 has a strip recorder, verify that the time and date are set correctly by generating a strip chart recording. Press the Recorder On/Off button and check that the strip chart is correctly annotated with the current time and date, selected ECG size,

source, and heart rate.

Verify that the real-time clock is operating correctly by waiting for several minutes before running the strip recorder again.

Note Time and date may require resetting if the 1600 has been without battery packs for more than 12 hours, or if the installed battery pack has been without a charge for more than 12 hours.

ZOLL 1600 Service

If the ZOLL 1600 fails any test, contact your biomedical staff or call ZOLL Medical.

U.S.A. Customers

If your instrument needs service, refer to the *ZOLL 1600 Service Manual* or contact ZOLL Service at 1-800-348-9011 (in Mass. 1-617-229-0020).

International Customers

If your instrument needs service, refer to the *ZOLL 1600 Service Manual* or contact your nearest authorized ZOLL service center. (Refer to page 8)

Operator's Shift Checklist For ZOLL 1600 Semi-Automatic Mode & ZOLL 1600 Manual Mode

Recommended checks and procedures to be performed at the start of each shift. For more detailed information, see the ZOLL 1600 Operator's Guide.

Date _____

Location _____

Unit Serial Number _____

1. ZOLL 1600 Condition

1st Shift 2nd Shift 3rd Shift

Remarks

Unit clean, no spills, clear of objects on top, case intact				
2. Defibrillator Pads				
Two sets present				
Package sealed, with appropriate expiration date				
3. Inspect cables for cracks, broken wires, connectors				
A ECG electrode cable, connector				
B Multi-function cable, connector				
4. Batteries (2)				
A Fully charged battery in unit				
B Fully charged spare battery available				
5. Memory Cards (2)				
6. Disposable Supplies				
A ECG electrodes				
B Recorder paper				
C Alcohol wipes				
D Razors				
E Antiperspirant				
6. Unit Tests (See Section 6 of User's Guide)				
A Power Up Sequence Test				
B Defibrillator Test (Semi-Automatic Mode)				
C Strip Recorder Operation Check (Optional)				
D Manual Mode Inspection				
E Delivered Energy and Discharge Button Check (Manual Mode)				
F Pacer Accuracy (Manual Mode Option)				
7. Maintenance After Use				

8. Please check the appropriate box after each use of this checklist

Signature _____

No Action Required				1st _____
Minor problem(s) corrected				2nd _____
Disposable supplies replaced				3rd _____
Major problem(s) identified - UNIT OUT OF SERVICE				

Section 7

Troubleshooting (Semi-Automatic and Manual Mode)

The troubleshooting guide provided on the following pages is intended for use by non-technical medical personnel during ZOLL 1600 operations. This section answers many of the common problems or questions that arise during operation. This Section is divided into Semi-Automatic Mode and Manual Mode.

If trouble persists after consulting this guide, contact the appropriate technical personnel or ZOLL Technical Service. A more detailed troubleshooting guide is found in the ZOLL 1600 Service Manual.

Semi-Automatic Mode

Defibrillator

<i>Symptom</i>	<i>Recommended Action</i>
1 A STATUS XX message appears on monitor display.	1 Contact ZOLL Technical Service Department immediately.
2 Defibrillator won't charge (energy level does not increment on display).	1 Check that Shock button is not stuck on. 2 Replace battery pack. 3 Turn unit off, then turn on and restart protocol.
3 Charge time to 360J exceeds 10 seconds.	1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.
4 Energy will not discharge when SHOCK button is pressed.	1 Fifteen (15) seconds had elapsed after initial charge. 2 Energy was internally discharged. 3 Unit not completely charged when SHOCK button is pressed. Wait for ready message and ready tone. 4 No shock is advised. 5 Turn unit off, then turn on and restart protocol. 6 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.
5 No apparent energy delivery to patient.	1 Check for CHECK ELECTRODES message on monitor. 2 Ensure proper placement and contact of Multi-Function Electrodes. 3 Under certain circumstances, some patients will not "twitch" when energy is delivered. 4 Turn unit off, then turn on and restart protocol. 5 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.
6 "NOISY ECG" "RETRY ANALYSIS"	1 Check for proper application and adhesion of Multi-Function Electrodes. 2 Check to make sure that nobody is touching the patient and that the patient is motionless.

<p>7 "CHK. ELECTRODES"</p>	<ol style="list-style-type: none"> 1 Ensure proper placement and contact of the Multi-Function Electrodes and that the patient does not have excessive hair beneath the electrodes. 2 If message persists, disconnect cable from electrodes and plug cable into test connector. "CHK. ELECTRODES" message will disappear.
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Monitor

<i>Symptom</i>	<i>Recommended Action</i>
<p>8 Unit does not turn on. (No 4 audible beeps).</p>	<ol style="list-style-type: none"> 1 Check that battery pack is properly installed. 2 Replace battery pack with a fully charged battery pack.
<p>9 Unit turns on with 4 beeps, but no display on monitor.</p>	<ol style="list-style-type: none"> 1 Replace battery pack with a fully charged battery pack. 2 Option to Display ECG may be turned off (Check with your Medical Control Authority)
<p>10 If a STATUS XX message appears on monitor display.</p>	<ol style="list-style-type: none"> 1 Contact ZOLL Technical Service immediately.
<p>11 SET CLOCK message appears on the monitor display.</p>	<ol style="list-style-type: none"> 1 Reset time and date information. (See Section 6.)
<p>12 ECG LEAD OFF message appears on the monitor display.</p>	<ol style="list-style-type: none"> 1 Check that the ECG cable is connected to patient and instrument. 2 Check that ECG electrodes are not dry. 3 Replace ECG cable.
<p>13 Poor ECG signal level, calibration pulse normal (10mm @ 1mV.)</p>	<ol style="list-style-type: none"> 1 Ensure ECG electrodes are not dried out and are making good contact. 2 Apply new electrodes using different placement.

Strip Chart Recorder

<i>Symptom</i>	<i>Recommended Action</i>
<p>14 NO PAPER message appears on monitor.</p>	<ol style="list-style-type: none"> 1 Recorder out of paper. 2 Remove paper, check paper type, check recorder for paper jam, reload paper. 3 Recorder needs replacement.
<p>15 Recorder makes a stuttering sound when activated.</p>	<ol style="list-style-type: none"> 1 Check paper path of recorder for paper jam.
<p>16 Light or poor quality tracings/annotations on paper.</p>	<ol style="list-style-type: none"> 1 Ensure correct paper is in use. 2 Ensure paper is installed grid side against recorder print head. 3 Recorder print head requires cleaning (trained personnel only).

Manual Mode

Noninvasive Pacing

WARNING

Be sure that pacer output current (mA) is set to "0mA" when connecting or disconnecting a patient from the ZOLL 1600.

<i>Symptom</i>	<i>Recommended Action</i>
1 PACER LEADS OFF message appears on monitor display.	<ol style="list-style-type: none"> 1 Check that Multi-Function Electrodes are connected to appropriate cable. 2 Ensure electrodes are not dry. Do not use ECG or defibrillator gel. 3 Replace electrode if necessary. 4 Ensure good electrode-to-patient contact—no buckling or falling off. 5 Check integrity of Multi-Function Cable - plug into test connector attached to the multi-function cable. PACER LEAD OFF message should disappear. 6 Replace Multi-Function Cable.
2 No stimulus marker present on ECG trace displayed on monitor	<ol style="list-style-type: none"> 1 Ensure ZOLL 1600 is in PACER ON mode. 2 Ensure pacing rate (ppm) dial is set greater than patient rate.
3 No ventricular capture beat after stimulus marker on ECG monitor display.	<ol style="list-style-type: none"> 1 Check for pulse of patient. 2 Increase output current level. 3 Change ECG Lead select. 4 Review pacing electrode placement. 5 Verify that pacemaker is delivering the proper current using the ZOLL NTP 4450 Pace Check, or have appropriate technical staff check output.
4 Patient on Standby pacing gets paced intermittently.	<ol style="list-style-type: none"> 1 If ECG lead wire comes off, pacer will automatically pace asynchronously. 2 Check ECG electrode connection and placement. 3 Check ECG cable for damage. 4 Patient R wave-to-R wave interval varying. Pace rate close to patient rate.
5 Heart rate is 0 with proper pacing capture displayed on ECG trace.	<ol style="list-style-type: none"> 1 Check patient's pulse. 2 Change ECG size. 3 Change ECG Lead selection.
6 Bedside/Central Station monitor display becomes erratic when pacing.	<ol style="list-style-type: none"> 1 Patients cannot be "double patch" ECG monitored while pacing.

Defibrillator

<i>Symptom</i>	<i>Recommended Action</i>
7 A STATUS XX message appears on monitor display.	<ol style="list-style-type: none"> 1 Contact ZOLL Technical Service immediately.
8 Defibrillator won't charge (energy level does not increment on display).	<ol style="list-style-type: none"> 1 Check that Shock button is not stuck on. 2 Replace battery pack. 3 Turn unit off, then on and restart protocol

9	Charge time to 360J exceeds 10 seconds.	<ol style="list-style-type: none"> 1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Have device serviced.
10	Energy will not discharge when SHOCK button is pressed.	<ol style="list-style-type: none"> 1 Sixty (60) seconds had elapsed after initial charge. 2 Energy was internally discharged. 3 Device is in SYNC mode and no QRS complex is detected. 4 Unit not completely charged when SHOCK button is pressed. Wait for ready message and ready tone. 5 Turn unit off, then on and restart protocol.
11	Unable to SYNC cardioversion discharge.	<ol style="list-style-type: none"> 1 Ensure SYNC is displayed on monitor. 2 Check for SYNC marker (high intensity dot or line on R-Wave). If not present, change ECG size, lead selection, or electrode placement. 3 Alter ECG placement.
12	No apparent energy delivery to patient.	<ol style="list-style-type: none"> 1 Check for CHECK ELECTRODES message on monitor. 2 Ensure proper placement and contact of Multi-Function Electrodes. 3 Under certain circumstances, some patients will not "twitch" when energy is delivered. 4 Turn unit off, then on and restart protocol. 5 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.

Monitor

<i>Symptom</i>	<i>Recommended Action</i>
13 Unit does not turn on. (No 4 audible beeps).	<ol style="list-style-type: none"> 1 Check that battery pack is properly installed. 2 Replace battery pack with a fully charged battery pack.
14 Unit turns on with 4 beeps, but no display on monitor.	<ol style="list-style-type: none"> 1 Replace battery pack with a fully charged battery pack. 2 Option to Display ECG may be turned off (Check with your Medical Control Authority)
15 If a STATUS XX message appears on monitor display.	<ol style="list-style-type: none"> 1 Contact ZOLL Technical Service Department immediately.
16 SET CLOCK message appears on the monitor display.	<ol style="list-style-type: none"> 1 Reset time and date information. (See Section 6.)
17 ECG LEAD OFF message appears on the monitor display.	<ol style="list-style-type: none"> 1 Check that the ECG cable is connected to patient and instrument. 2 Check that ECG electrodes are not dry. 3 Replace ECG cable.
18 Poor ECG signal level, calibration pulse normal (10mm @ 1mV).	<ol style="list-style-type: none"> 1 Change ECG size. 2 Change to another lead - I, II, III, or ELECTRODES. 3 Ensure ECG electrodes are not dried out and are making good contact. 4 Apply new electrodes using different placement.

- | | |
|--|--|
| 19 No systole sound (beat detection) or heart rate and flashing heart are not being displayed on monitor. | <ol style="list-style-type: none"> 1 Patient heart rate less than 20 BPM. 2 Increase beeper volume on top of unit. 3 Change ECG lead selection. 4 Change ECG size. 5 Alter ECG electrode placement. |
| 20 No sync marker displayed on ECG monitor signal or recorder printout, or intermittently displayed on R-wave. | <ol style="list-style-type: none"> 1 Ensure "SYNC" is displayed on the monitor. 2 Change ECG size. 3 Change ECG lead selection. 4 Alter ECG electrode placement. |

Strip Chart Recorder

<i>Symptom</i>	<i>Recommended Action</i>
21 NO PAPER message appears on monitor.	<ol style="list-style-type: none"> 1 Recorder out of paper. 2 Remove paper, check paper type, check recorder for paper jam, reload paper. 3 Recorder needs replacement.
22 Recorder makes a stuttering sound when activated.	<ol style="list-style-type: none"> 1 Check paper path of recorder for paper jam.
23 SYNC marker (↓) not annotating at top of paper	<ol style="list-style-type: none"> 1 Ensure SYNC is displayed on the monitor. 2 Ensure high intensity dot or line is displayed on ECG signal on monitor. 3 Change ECG lead selection. 4 Change ECG size. 5 Change electrode placement. 6 Paper too narrow. It should be 50mm wide.
24 Light or poor quality tracings/annotations on paper.	<ol style="list-style-type: none"> 1 Ensure correct paper is in use. 2 Ensure paper is installed grid side against recorder print head. 3 Recorder print head requires cleaning (trained personnel only).

Appendix A

Medical Report Capability

The ZOLL 1600 medical report capability automatically records incident information for subsequent review and archiving. Data is stored on a removable PCMCIA data card (memory card) for downloading to a properly equipped personal computer. (See the ZOLL Data Control System for information on PC equipment requirements and data retrieval procedures.) Stored data can also be downloaded to a PC via a ZOLL 1600 to serial port cable connection.

The medical report capability begins recording when the 1600 is turned on and continues until the unit is turned off. Patient ECG, unit status, date, time and 1600 control settings are recorded. Audio recording via a microphone located on the front of the 1600 is a configurable option on properly equipped units.

Data recorded during an incident is retained on the memory card until erased. Shutting the 1600 off with the memory card installed or removing the memory card from the unit will not erase the data.

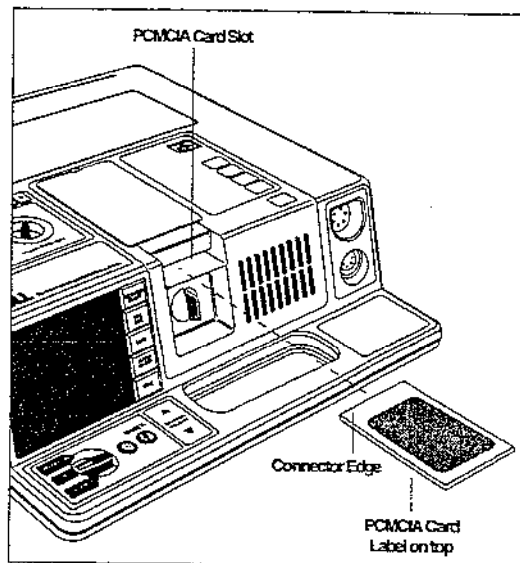
PCMCIA Data Card

The memory card is a self contained electronic storage device similar to a floppy disk. Do not subject the card to extreme temperatures, do not immerse the card in liquids, do not place the card near magnetic objects and do not place heavy objects on the card. Protect the connector located on one short edge of the card from physical damage.

Contact ZOLL Technical Service Department for the current list of supported PCMCIA cards.

Up to two hours of incident data (ECG and unit status) or up to one hour of incident data and simultaneous audio recording can be stored on one 4 megabyte memory card. ZOLL recommends that a spare memory card is always kept with the 1600 and that the memory card is changed after each incident.

Installing the PCMCIA Data Card



Check that there is no physical damage to the connector edge and that the connector edge is clean and free of dirt and debris. Insert the memory card into the slot located in the middle of the 1600. The label side should be up. Slide the card into the unit until it is firmly seated in the card slot.

To remove the card, lift the card slightly and pull the card out of the unit. If the memory card is removed while the 1600 is on, the unit will still operate properly but no event information will be recorded.

Transferring Data to a PC with a PCMCIA Data Card Reader

ZOLL Data Control software must be installed on the PC to access any information transferred from the medical report capability.

Remove the data card from the ZOLL 1600. Insert the card into the PCMCIA data card reader on the PC. See the ZOLL Data Control Guide for instructions on information retrieval procedures and PC equipment requirements.

Downloading Data to a PC via Serial Link

ZOLL Medical Report software must be installed on the PC to access any data downloaded from the medical report capability. (See the ZOLL Data Control System for information on PC equipment requirements and data retrieval procedures.)

Check that there is enough storage space on the personal computer to hold the data from the memory card. The minimum free hard disk space is 4 megabytes.

Connect the serial cable to the serial port on the front of the 1600 and to the PC serial port.

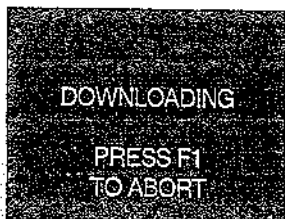
Check that the electrodes are not connected to a patient (or simulator) or that the Multi-Function cable is not connected to the ZOLL 1600. If an attempt is made to enter download mode with the electrodes connected to a patient (or simulator) and the Multi-Function cable connected to the ZOLL 1600, the unit will go into semi-automatic mode and the error message, "REMOVE ELECT." will be displayed.

Check that the correct memory card is installed in the ZOLL 1600.

Press and hold the F1 button on the top panel of the 1600 while turning the selector switch to Power On. The following message will appear on the display.



Release and press F1 again to confirm downloading. If F1 is not pressed within 10 seconds, the 1600 will return to normal operation in semiautomatic mode.



If no error messages appear on the display, the unit will begin to download the data. Transmitting may take several minutes.



To cancel the download press F1. To confirm the download abort, press F1 again. This will stop the data transfer. Press F3 to cancel the abort request. The 1600 will continue to download the data.



At the end of the transfer the display indicates the 1600 has successfully downloaded all the information stored on the memory card. Press F4 to erase the memory card or press F2 to exit the download without erasing the card. Erasing the memory card permanently removes all memory card information. To save the memory card information after a successful download, press F2. The card may then be removed from the 1600.



If F4 is pressed, a display message indicates the card is being erased.



Memory card has been erased and is now empty and can be used again to record a different incident.



If there is a problem with the memory card erasing procedure, the above message displays on the screen. Press F1 to exit or insert another card.



To save the memory card information after a successful download, press F2. The card may then be removed from the 1600 and a

new card inserted for downloading or you may exit the downloading sequence.

TURN TO
POWER OFF
OR PRESS F1
TO ENTER
SEMI-AUTO MODE

Press F1 for the 1600 to return to normal semi-automatic operation.

Error Messages

NO CARD

INSERT CARD
OR
PRESS F1
TO EXIT

The above message appears if there is no memory card installed. Following each message is a list of available options.

CARD PREVIOUSLY
DOWNLOADED
PRESS
F2 TO SKIP
F3 TO DOWNLOAD
F4 TO ERASE

The recorded information on the card has already been downloaded to a PC. The information can be downloaded again if necessary.

CARD EMPTY

REPLACE CARD
OR
PRESS F1
TO EXIT

The memory card installed in the 1600 is empty.

WRONG DATA TYPE

REPLACE CARD
OR
PRESS F1
TO EXIT

The card is a configuration card and not a memory card.

WRONG CARD TYPE

REPLACE CARD
OR
PRESS F1
TO EXIT

The card is not of the required type

CARD REMOVED

DOWNLOAD ABORTED
PRESS
F2 TO SKIP CARD
F3 TO RETRY

If an in progress download is interrupted because the memory card has been removed or dislodged the above message is displayed.

BAD CARD

DOWNLOAD ABORTED
PRESS
F2 TO SKIP CARD
F3 TO RETRY

The card has damaged data and cannot be downloaded.

HOST FAULT

DOWNLOAD ABORTED
PRESS
F2 TO SKIP CARD
F3 TO RETRY

The PC has aborted the download.

SERIAL FAULT

CORRECT FAULT
OR
PRESS F1
TO EXIT

The above message occurs if there is a serial fault. This indicates there is a problem with the cable, the cable connection, or the PC. Following each message is a list of available options.

Appendix B

Strip Chart Recorder Operation Summary Report

Strip Recorder Operation

If the ZOLL 1600 is configured to automatically generate strips, the strip chart recorder will automatically run for 15 seconds after a defibrillator discharge or a heart rate alarm in manual mode. This configuration is selectable (See Appendix D).

A NO PAPER message appears on the monitor when the Strip Chart Recorder is activated without paper. The strip chart recorder automatically shuts off when there is no paper. Press the Recorder On/Off button to start the strip chart recorder again after loading new paper. (See Section 6 for paper replacement)

The following annotations are printed on the top of the strip chart:

1. ANALYZE ECG: Printed when the Analyze button is pressed.
2. CHECK ELECTRODES: Printed when a poor connection of the Multi-Function Electrodes is detected.
3. ANALYSIS HALTED: Printed when the analysis is halted due to a fault condition.
4. NOISY ECG: Printed when excessive noise is detected.
5. SHOCK ADVISED: Printed at the end of user-initiated analysis when a shockable rhythm has been detected.
6. NO SHOCK ADVISED: Printed at the end of user-initiated analysis when no shockable rhythm has been detected.
7. "I": Printed at the end of each 3-second analysis sub-interval.
8. "***": Printed immediately following the last 3 second interval. Three characters are printed immediately following the "I" indicating the results of the analysis for the 3 analysis sub-intervals. A "*" indicates a shockable sub-interval while a "-" indicates a non-shockable interval.
9. "-": Indicates a non-shockable interval. (See 8 above.)

Summary Report

The Summary Report allows the operator to store and later retrieve a printed copy of critical ECG event information. The ZOLL 1600's internal memory automatically records significant events. The Summary Report records all associated event information including 1600 control settings, patient ECG, time, and date. The Summary Report functions independently of the Medical Report Capability to store these events.

The following events will trigger Summary Report to record information:

- Activation of the Heart Rate Alarm.
- Initiating analysis of the ECG.
- Discharging the defibrillator.
- Turning strip chart recorder on (or on and then off in rapid sequence).
- CHECK PATIENT message (when continuous analysis indicates a shockable condition).
- Pressing the "F" keys
- Entering Pacer Mode
- Entering Manual Mode

A Summary Report (header only) is stored when the unit is first powered on. The report will only be stored if the unit has been off for more than 10 seconds or was previously in configuration or download mode, and put into semi-automatic mode.

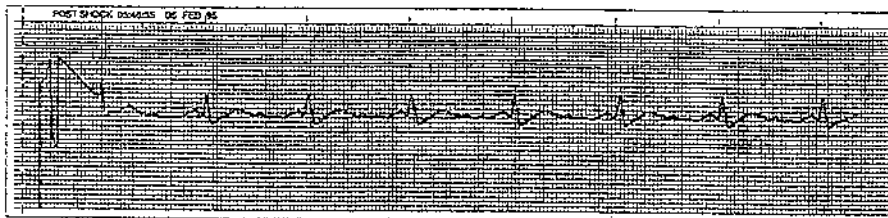
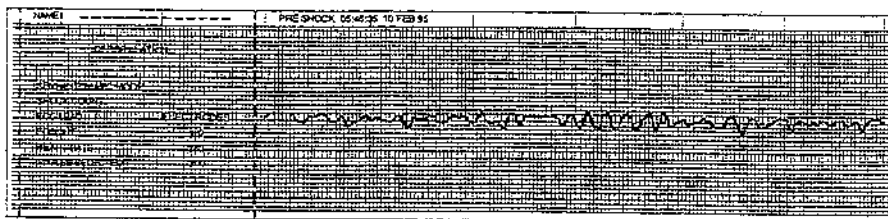
Summary Report records each event in chronological order and will store up to 33 defibrillation or 70 non-defibrillation events. All event data will remain in memory and be accessible until the 1600 has been off for five minutes or the data is manually erased.

If the memory is full and a strip chart recorder is installed, a REPORT FULL message will appear on the monitor and no further events will be recorded until the current memory is erased.

[illegible]

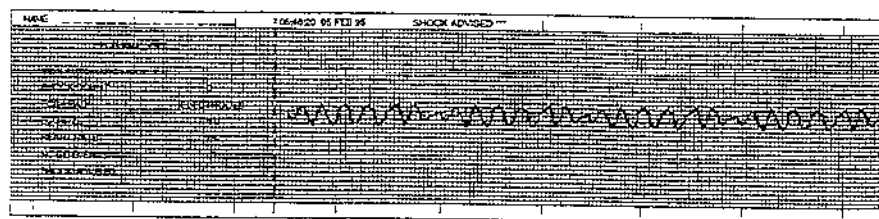
All segments have vertical dashed cut lines every 8.5 inches to facilitate easy mounting on 8.5" x 11" paper. On the last event recorded, SUMMARY COMPLETE will be printed at the bottom left of the strip chart.

Defibrillation Format



B2

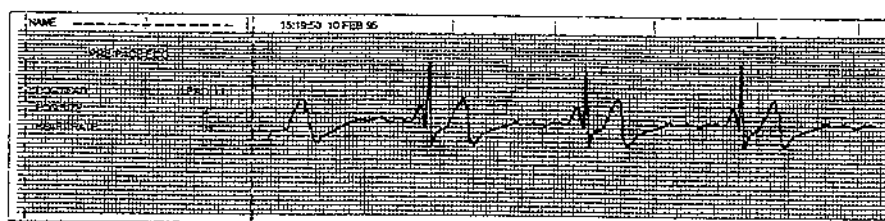
Analyze Format



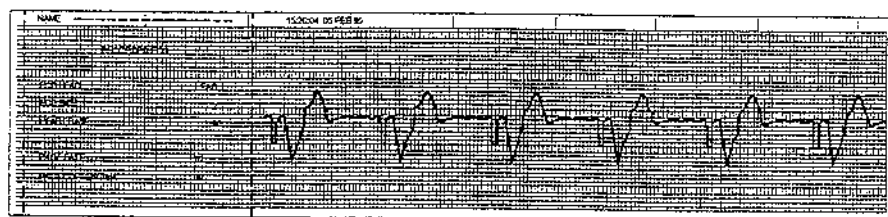
Summary Report records 6 seconds of pre-analysis patient ECG and 8 seconds of post-analysis ECG with the annotation SHOCK ADVISED or NO SHOCK ADVISED.

The following Summary Report formats are available in manual mode only.

Pacer On Format

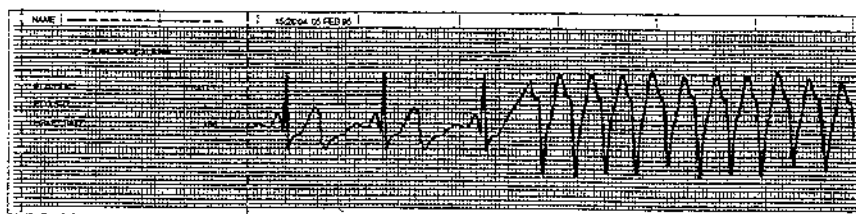


Summary Report records 6 seconds of pre-Pacer On patient ECG. Also recorded is the ECG lead, ECG size, patient's heart rate, time and date.



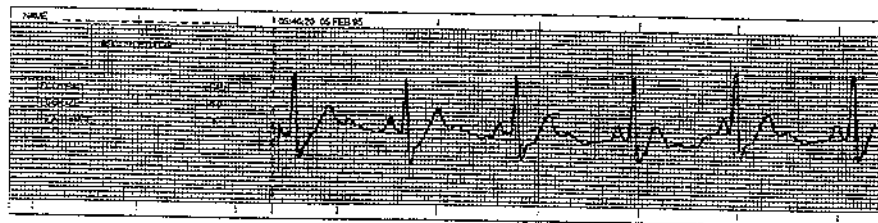
After establishing a paced rhythm, turn the recorder on briefly to record the paced rhythm in Summary Report.

Heart Rate Alarm Activated Format



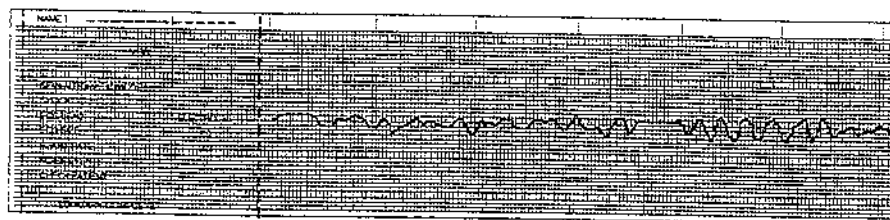
Summary Report records 6 seconds of pre-alarm patient ECG. Also recorded is the ECG lead, ECG size, patient's heart rate, time and date. If the pacer is on during this event, the pacing rate and pacing current is also recorded.

Recorder On Format



Summary Report records 6 seconds of patient ECG stored prior to recorder activation. Also recorded is the ECG lead, ECG size, patient's heart rate, time and date. If the pacer is on during this event, the pacing rate and pacing current is also recorded.

Continuous Analysis Report



Summary Report records 15 seconds of patient ECG data. Also recorded is the shock count, ECG lead, ECG size, patient's heart rate, and noise events.

Print a Summary Report on the Strip Chart Recorder

To retrieve recorded event reports, press the Summary button on the top of the ZOLL 1600. The strip chart recorder will print all events in chronological order currently in the 1600's internal memory.

If the strip recorder is on or the defibrillator is charging, the Summary button is inactive.

To stop printing a report, press the Summary button again or turn the unit off. You may print an unlimited number of copies of the report simply by pressing the Summary button once for each report and waiting until the printout is complete before pressing the Summary button for the next copy.

The 1600 will interrupt printing a report if the heart rate alarm activates, the Charge button is pressed, or the strip chart recorder turns on. If report printing is interrupted, press the Summary button again.

If the strip recorder is out of paper and the Summary button is pressed a NO PAPER message appears on the monitor. Load paper and press Summary again to print the report.

Erase a Summary Report from the Strip Chart Recorder

The report is automatically erased after 5 minutes when the unit is turned off but may be reconfigured to retain data as long as 90 minutes (See Appendix D). To manually erase all recorded summary information, press and hold the Set up arrow button ▲ and Summary button simultaneously for 4 seconds. An ERASING REPORT message will appear on the monitor.

Note that this does not affect the data stored on the PCMCIA card.

Appendix C

Specifications

General

Size	10.7 cm high x 33.5 cm wide x 31 cm long (4.2 in. x 13.2 in. x 12.2 in.).
Weight	5.9 kg. (13 lbs.) with Multi-function cable.
Power	Sealed lead acid battery - 2.0V/cell, 5 cells - wired in series.
Warranty	In North America: 1 year, including use of a loaner. Outside North America: consult ZOLL authorized representative.
Design Standards	Environmental tests include the following: RF immunity per IEC 801-3 to 20V/M, EMI emissions per CISPR 11 class A, Vibration per IEC 68-2-6 and IEC 68-2-34, Shock per IEC 68-2-27, and moisture per IEC 529 standard IPX4.
Patient Safety	All patient connections are isolated.
Environmental	Temperature: 0°C to 55°C (operating). -20°C to 70°C (storage and shipping). Humidity: 5% to 95% relative humidity, non-condensing.
Operating Modes	Semi-Automatic (default mode) Manual Diagnostic Configuration

Pacemaker

Type	VVI demand; asynchronous (fixed rate) when used without ECG leads.
Pulse Type	Rectilinear, constant current.
Pulse Duration	40 milliseconds.
Pulse Amplitude	Variable to 140 mA.
Pacing Rate	Variable from 30 to 180 ppm.
Output Protection	Fully defibrillator protected and isolated.
Pacer On	Message display on monitor.
Pacer Electrodes	Specifically designed adult anterior/posterior pre-gelled ZOLL electrodes, packaged in pairs. ZOLL pediatric electrodes are also available.

Defibrillator

Waveform	Damped sinusoid.
Output Energy	Selectable at 2, 3, 5, 7, 10, 20, 30, 50, 100, 150, 200, 300, 360 joules.
Energy Selection	Control on unit front panel.
Charge Time	Less than 10 seconds. Depleted battery packs will result in a longer defibrillator charge time.

*NOTE: Specifications subject to change without notice.

ZOLL, PD, *stat-pac*, PowerCharger, ConnectAlarm, SmartAlarms, ZOLL Data Control Software, *Speed Pack* and *Preconnect* are trademarks of ZOLL Medical Corporation.

Delivered Energy Display	CRT monitor displays delivered energy.
*Synchronized Mode	Synchronizes defibrillator pulse to patient's R-wave. SYNC message displayed on monitor. Marker on monitor and on recorder paper identifies R-wave.
Charge Controls	Control on front panel.
Multi-Function Electrodes	Specifically designed pre-gelled ZOLL electrodes, packaged in pairs, can be used in the anterior/posterior or anterior/anterior position. Adult Stat*Padz Electrodes with pre-connect (12 pair/box) 8900-4003 Adult Radiolucent Multi-Function Electrodes (12 pair/box) 8900-2755 Adult Multi-Function Electrodes (12 pair/box) 8900-2055 Pediatric Multi-Function Electrodes (6 pair/box) 8900-2065

Monitor and Display

Patient Connection	Via 3 lead ECG cable and electrodes. Lead configuration selectable by front panel switch.
Input Protection	Fully defibrillator protected. Special circuit prevents distortion of ECG by pacer pulse.
Bandwidth	0.5-35 Hz (-3dB) standard - .05-35 Hz Diagnostic (optional).
Display Format	Non-fade, moving trace.
Screen Type	High resolution CRT display.
Screen Size	4.5 inches diagonally (56 mm x 86 mm, viewing area).
Sweep Speed	25 mm/sec.
Viewing Time	3.4 seconds.
Heart Rate	Digital display on monitor 0-300 bpm + / - 5%.
*Pacer Output Current	Digital display on monitor 0-140 mA.
*Lead Selection	Display on monitor.
*ECG Size	.5, 1.0, 1.5, 2.0, 3.0 cm/mV - display on monitor.
*Alarm On/Off Status	Display on monitor. User selectable, High 60-280 bpm, Low 20-100 bpm.
ECG Lead Fault	Message display on monitor.
*Pacer Electrode Fault	Message display on monitor.
Defibrillator Electrode Fault	Message display on monitor.
Recorder Paper Out	Message display on monitor.
Low Battery Voltage	Message display on monitor.
*Strip Recorder	
Paper	Standard 40 mm thermal (grid width). 50 mm (paper width).
Speed	25 mm/sec.
Delay	6 seconds.
Annotations	Time, date, defib energy, heart rate, pacer output, QRS sync marker, ECG size, lead, alarm, defib test OK/Fail.
Writing Method	High resolution, thermal array print head.
Print-out Modes	Manual or automatic - user configurable.
Automatic Function	15 second recording initiated by alarm conditions and defibrillator discharge.

PCMCIA Card

Capacity	Standard series II flash card - 4 megabyte or 2 megabyte
*Audio Recording	Digital compressed audio data

Battery Packs

Type	Rechargeable, sealed lead acid
Voltage	2.0 V/cell; 5 cells wired in series.
Recharge Time	Charging systems require different charging times. See appropriate operator's guide for more information.
Service	Battery pack is easily removed as a unit.
Low Battery Indicator	Message displayed on monitor and 2-beep low battery tone sounds once a minute. For a new battery pack in good condition, the 1600 will beep twice every two seconds for the last 20 seconds before shut-off due to LOW BATTERY. The time from display of the LOW BATTERY message until the instrument shuts down will vary depending on the battery pack condition. For a new battery pack (fully charged prior to initiating battery pack operation), the message display-to-shut down time will be approximately 40 minutes in monitor mode. Defibrillator charge time may be extended when battery packs are depleted.
Operating Time	30 defibrillator chargings to maximum energy (360J), or 2 hours of continuous monitoring.
Chargers	Use ZOLL PD 4420 Battery Support System, ZOLL PowerCharger™ or ZOLL supplied single battery charger only for proper operation. See Battery Support System Operator's Guide for detailed information about battery charging and capacity evaluation. See PowerCharger™ Operator's Guide for detailed information about operation with AC line power.

* Indicates optional features

Appendix D

Configuration Mode

The ZOLL 1600 is designed with several user configurable features to allow each operator(s) to set the device according to their preferences.

A configuration strip can be printed without entering configuration mode by pressing and holding the SUMMARY and VOLUME

DOWN ▼ buttons for four (4) seconds while turning the unit to Power On.

This section lists the configurable features, the default settings and a description of the option. Some features are available to manual mode operators only.

General

Feature	Option	Default
Selected Language	English, French, Japanese	English
Notch Filter	50, 60 Hz	60 Hz
Summary Report erase delay	5, 15, 30, 90 min.	5 Min.
Serial Baud Rate (bps)	9600, 19200, 57600, 115200 bps	57,600 bps
Allow card erase without download	Yes/No	No
Display Elapsed Time	Yes/No	No

Semiautomatic Mode

Feature	Option	Default
Energy level: Shock 1	50, 100, 150, 200, 300, 360 J	200 J
Energy level: Shock 2	50, 100, 150, 200, 300, 360 J	200 J
Energy level: Shock 3	50, 100, 150, 200, 300, 360 J	360 J
Auto Analyze 3 Times	Yes/No	No
"NO SHOCK ADVISED" Prompt	"NO SHOCK ADVISED" "CHECK PULSE" BOTH	"NO SHOCK ADVISED"
"CHECK PATIENT" Prompt	"CHECK PATIENT" "PRESS ANALYZE"	"CHECK PATIENT"
Display ECG in semiautomatic mode	Yes/No	Yes
Display Heart Rate in semiautomatic mode	Yes/No	No
Record Card Data in Monitor Mode	Yes/No	Yes

Manual Mode

Feature	Option	Default
Automatically Generate Strips	Yes/No	Yes
Retain Sync after Defib	Yes/No	No
Initial QRS Volume	Off/Unchanged	Unchanged
Voice Prompts in manual mode	On/Off	On
Audio Recording Enabled in manual mode	On/Off	On
ECG Recording Enabled in manual mode *	On/Off	On

* This only applies to devices containing software release 2.07 or greater.

Appendix E

Algorithm Accuracy

Sensitivity, specificity, false positive rate and positive predictivity are expressions of the accuracy of an ECG analysis system when compared with clinicians or experts. The specifics of computations are detailed below. The accompanying data details the accuracy of the algorithm as tested by independent investigators.

Algorithm Sequence of Events:

1. The algorithm divides the ECG rhythm into 3-second segments.
2. The algorithm filters and measures noise, artifact, and baseline wander.
3. The algorithm measures baseline content ('waviness' at the correct frequencies-frequency domain analysis) of signal.
4. The algorithm measures QRS rate, width, and variability.
5. The algorithm measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
6. If 2-out-of-3 are shockable then "SHOCK ADVISED". Algorithm sequence thus takes approximately 9 seconds.

Clinical Performance Results

Applications:	<u># of analysis</u>	<u># of patients</u>
---------------	----------------------	----------------------

316

194

Shockable Rhythms

Overall Sensitivity	95.7%
Positive Predictability	100.0%

Non-shockable Rhythm

Overall Specificity	100%
False Positive Rate	0%

Sensitivity =

$\frac{\text{\# of "correct shock" decisions by algorithm}}{\text{Total \# of rhythms for which a shock is clinically advised}}$

Specificity =

$\frac{\text{\# of "correct no shock" decisions by algorithm}}{\text{Total \# of rhythms for which no shock is clinically advised}}$

False Positive Rate =

$\frac{\text{\# of "incorrect shock" decisions by algorithm}}{\text{Total \# of rhythms for which no shock is clinically advised}}$

Positive Predictivity =

$\frac{\text{\# of "correct shock" decisions by algorithm}}{\text{Total \# of rhythms for which shock is advised by unit}}$

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 11. 11. 2019

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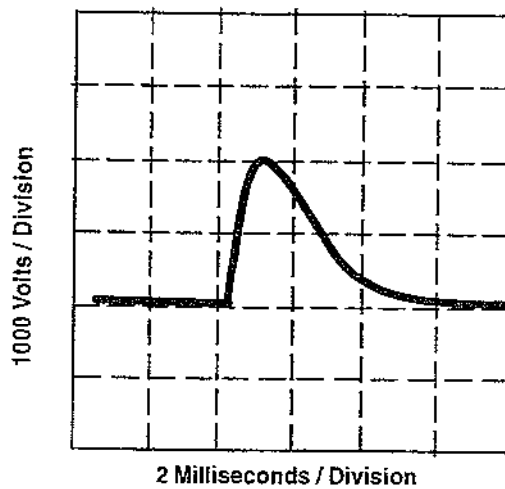
Appendix F

Waveform Information

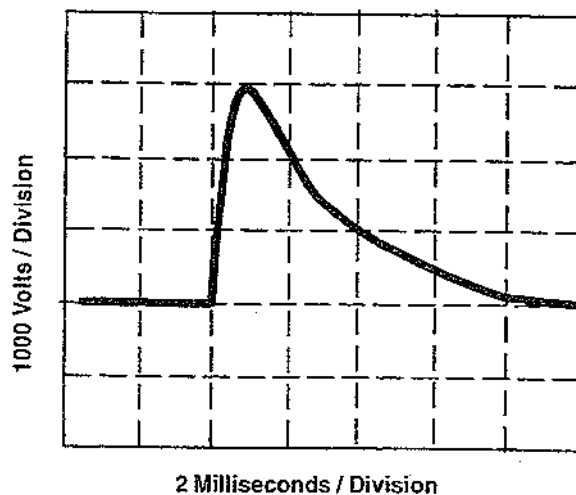
General

The ZOLL 1600 produces the following defibrillation waveforms when discharged into 25, 50, and 100 ohm loads at maximum energy. Each major vertical division equals 2 milliseconds.

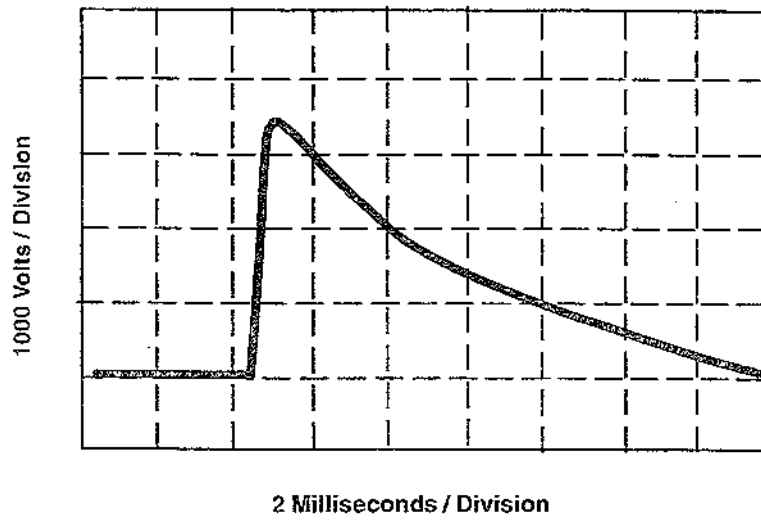
Discharge into a 25 ohm load



Discharge into a 50 ohm load



Discharge into a 100 ohm load



ZOLL

OPERATOR'S MANUALS

ZOLL 1600 #9650-0021 & 1700 #9650-0058

INTRODUCTION

This addendum provides information describing the operation of the ZOLL 1600 & 1700 devices. Please read this update carefully and add or change the affected pages of your manuals.

Please note the following changes:

ZOLL 1600 (#9650 - 0021)

Section 2: "Semiautomatic Defibrillation": Step 3 "Prepare Patient" (Page 14)

CHANGE FROM:

If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

CHANGE TO:

If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Section 3: "Manual Mode Defibrillation": Step 3 "Prepare Patient" (Page 22)

CHANGE FROM:

If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

CHANGE TO:

If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Section: 3: "Synchronized Cardioversion": Step 3 "Prepare Patient" (Page 24)

CHANGE FROM:

If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

CHANGE TO:

If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

ZOLL 1600 (#9650 - 0021) and ZOLL 1700 (#9650 - 0058)

Section 1: "Warnings": "Operator Safety" (Page 6)

CHANGE FROM:

- Do not discharge with paddles or electrodes shorted together or in open air. Stand clear of patient when defibrillating.

CHANGE TO:

- Do not discharge with electrodes shorted together or in open air. Stand clear of patient when defibrillating.

ZOLL

Section 3: "Manual Mode Defibrillation": Step 7 "Charge Defibrillator" (Page 23)

CHANGE FROM: After 6-10 seconds of charging of the selected level, the DEFIB XXX J RDY message displays on the monitor. A distinctive charge ready (continuous) tone sounds. The defibrillator is now ready.

CHANGE TO: After charging to the selected energy level, the DEFIB XXX J RDY message displays on the monitor. A distinctive charge ready (continuous) tone sounds. The defibrillator is now ready.

Section 3: "Synchronized Cardioversion": Step 9 "Charge Defibrillator" (Page 25)

CHANGE FROM: After 6-10 seconds of charging to the selected energy level, a distinctive audible tone will sound and the energy ready SYNC XXX J RDY. will be displayed on the monitor. The defibrillator is now ready.

CHANGE TO: After charging to the selected energy level, a distinctive audible tone will sound and the energy ready SYNC XXX J RDY. will be displayed on the monitor. The defibrillator is now ready.

Section 7: "Troubleshooting": Step 3 (Page 37)

CHANGE FROM:

<i>Symptom</i>	<i>Recommended Action</i>
3 Charge time to 360J exceeds 10 seconds	<ol style="list-style-type: none"> 1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Perform defibrillator self test as described in Section 6. If fails, have the unit serviced promptly.

CHANGE TO:

<i>Symptom</i>	<i>Recommended Action</i>
3 Charge time to 360J exceeds 10 seconds	<ol style="list-style-type: none"> 1 Charge or change battery pack. 2 Normal, if operating in low battery condition or battery with diminished capacity. 3 Perform defibrillator self test as described in Recommended Daily Checkout Section. If fails, have the unit serviced promptly.

ZOLL

Section 7: "Defibrillator": Step 10 (Page 40)

CHANGE FROM:

<i>Symptom</i>	<i>Recommended Action</i>
Charge time to 360J exceeds 10 seconds.	<ol style="list-style-type: none"> 1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Have device serviced.

CHANGE TO:

<i>Symptom</i>	<i>Recommended Action</i>
Charge time to 360J exceeds 10 seconds.	<ol style="list-style-type: none"> 1 Charge or change battery pack. 2 Normal, if operating in low battery condition or battery with diminished capacity. 3 Have device serviced.

Appendix C: "Defibrillator": (Page C1)

CHANGE FROM: **Charge Time** Less than 10 seconds. Depleted battery packs will result in a longer defibrillator charge time.

CHANGE TO: **Charge Time** Less than 10 seconds with a new, fully charged battery. Use of batteries with diminished capacity will result in a longer defibrillator charge time.

ZOLL

OPERATOR'S MANUALS

ZOLL 1600 #9650-0021 & ZOLL 1700 #9650-0058

INTRODUCTION

This addendum provides information describing the operation of the ZOLL 1600 & 1700 devices. Please read this update carefully and add or change the affected pages of your manuals.

Please note the following changes:

ZOLL 1600 (9650-0021) and ZOLL 1700 (9650-0058)

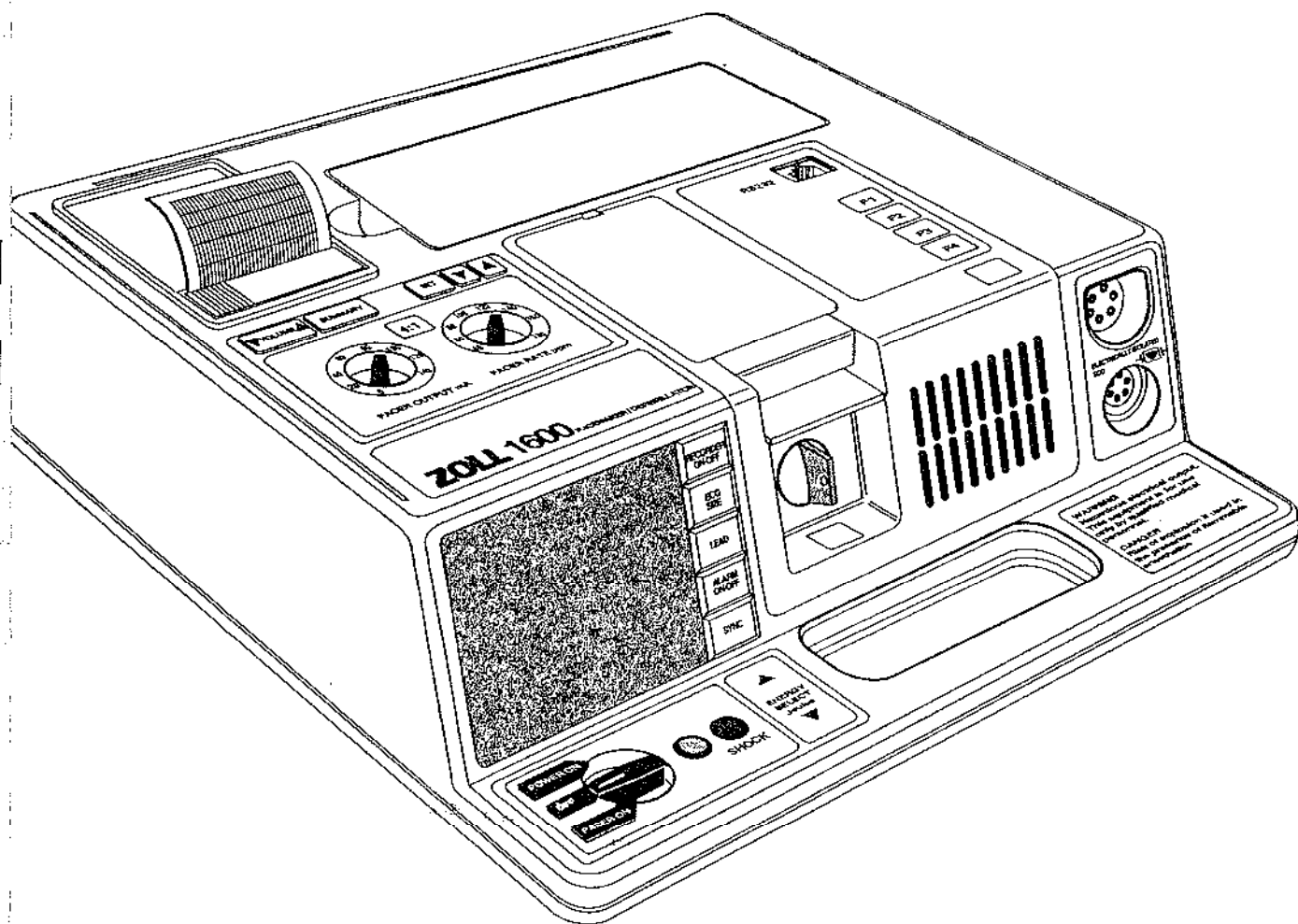
Section 7 : "TroubleShooting" : "Strip Chart Recorder" (Page 41)

ADD the following information as step 25 on page 41.

<i>Symptom</i>	<i>Recommended Action</i>
25. Period (.) appears at the top of the paper.	This marker indicates the occurrence of a recoverable recorder error. This error does not affect the ability to deliver therapy. If this error occurs repeatedly with use, contact ZOLL's Technical Service Department.

ZOLL

ZOLL 1600 Operator's Guide



An issue or revision date for this manual is shown on the back cover.

In the event that three years or more have elapsed between this date and the product's use, contact ZOLL Medical Corporation to determine if additional product information updates are available.

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Figure 1 consists of two parts, (a) and (b), illustrating experimental setups. Part (a) shows a quantum circuit with two qubits. The first qubit starts in state $|0\rangle$ and the second in state $|1\rangle$. They pass through a Hadamard gate (H), then a CNOT gate with the first qubit as control and the second as target. This is followed by another Hadamard gate (H) on the first qubit, and finally a measurement on both qubits. Part (b) shows a similar setup but with a different sequence of operations, including a Hadamard gate (H), a CNOT gate, and a Hadamard gate (H) on the first qubit, followed by a measurement on both qubits.

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Section 1

General Information

Product Description

The ZOLL 1600, designed for EMS and hospital use, is a semiautomatic defibrillator with a non-fade monitor and a medical report module. The ZOLL 1600 may be equipped with optional noninvasive pacemaker, annotating strip chart recorder, manual mode of operation, audio recorder and telecommunication ports. Power is provided by a rechargeable battery pack or an optional AC Adaptor/Charger.

The ZOLL 1600 may operate in two user selectable modes. In semiautomatic mode, the operator selects ECG analysis and the ZOLL 1600's integrated algorithm analyzes the patient's ECG through a pair of disposable defibrillation electrodes which are also used to deliver defibrillation shocks or pacing stimuli. The ZOLL 1600 analyzes the patient's ECG, determines if a shockable arrhythmia is present, charges and prompts the operator to shock the patient. Configuration options allow the operator to customize unit features according to local protocols.

The ZOLL 1600 is easily switched from semiautomatic mode to optional manual mode with a keyswitch. In manual mode, the operator determines and delivers appropriate therapies. Noninvasive temporary pacing is an available option in manual mode.

Patient ECG, unit status, operating and warning messages are displayed on the monitor. The ZOLL 1600 also provides voice prompts via a speaker to alert the operator about patient ECG and unit status. The ZOLL 1600 performs self-diagnostic tests when the instrument is turned on and periodically during operation.

Defibrillation shocks are delivered to the patient via a single pair of anterior/anterior defib/monitoring electrodes or anterior/posterior ZOLL Multi-Function Electrodes. Both types of electrodes provide hands-off defibrillation and ECG monitoring. In manual mode, Multi-Function Electrodes may also be used for noninvasive pacing. Standard ECG electrodes may be used for patient ECG monitoring in either semiautomatic or manual mode.

A removable PCMCIA data card begins recording ECG and machine data when the unit is turned on. The ZOLL 1600 will record and store patient ECG, system status and audio activity (optional). Data stored on the PCMCIA card can be reviewed and archived on a properly equipped personal computer.

An optional annotating strip chart recorder provides immediate event documentation as well as a summary function.

The ZOLL 1600 uses ZOLL 4410 replaceable battery packs. The 1600 alerts the operator when the battery voltage indicates inadequate capacity for continued operation. Battery packs are charged using ZOLL supplied charging devices.

The ZOLL 1600 is intended for use in the semiautomatic mode by first responders and emergency medical technicians certified by an appropriate federal, state or local government authority. The ZOLL 1600 is intended for use in manual mode by personnel certified to provide advanced life support care by appropriate federal, state or local authority.

The ZOLL 1600 is intended for use in the prehospital emergency medical care setting, indoors and outdoors, including first response vehicles, fire vehicles, basic and advanced level ambulances.

How to Use This Manual

The ZOLL 1600 Operator's Guide provides information operators need for the safe and effective use and care of the 1600. It is important that all persons using this device read and understand all the information contained within.

This manual is organized for semiautomatic mode operators and manual mode operators. If you will only use the 1600 in semiautomatic mode you do not need to read sections 3 and 4. If you will use the 1600 in manual mode, you must read the complete manual. Section 4 and Appendix B describe optional features. If your device is not equipped with these options, you do not need to read these sections.

Please read thoroughly the safety considerations and warnings on page 6.

Procedures for daily checkout and unit care are found in Section 6.

Manual Updates

ZOLL Medical provides Manual Updates to inform customers of changes in device information and use. The updates are mailed to each registered ZOLL 1600 purchaser automatically. All users should carefully review each manual update to understand its significance and then file it in its appropriate section within this manual for subsequent reference.

Unpacking

Carefully inspect each container for damage. If the shipping container or cushion material is damaged, it should be kept until the contents have been checked for completeness and the instrument has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, or if the instrument does not pass its electrical self-test, U.S.A. customers should call ZOLL Medical Corporation (1-800-348-9011). International customers should contact the nearest ZOLL authorized representative. If the shipping container is damaged, also notify the carrier.

Accessories Available Separately

- Adult, Multi-Function pacing/defibrillation electrodes (12 pair/box)
- Pediatric Multi-Function pacing/defibrillation electrodes (6 pair/box) (For manual mode use only)
- Multi-function cable
- 3-lead ECG cable
- PCMCIA Data Card - (Package of two)
- Rechargeable battery pack
- PD 4420 Battery Support System
- Single Battery Charger
- PowerCharger AC Power/Charger Module
- ECG Simulator

- MFC Test Port
- Output verification unit for noninvasive pacer
- Service manual

Save all shipping materials for future use.

Locate the battery pack and the battery charger supplied with the unit. See Section 5 for battery charging and installation. Before using, fully charge the battery pack.

Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:



Type B patient connection.



Type BF patient connection.



Type CF patient connection.



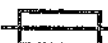
Defibrillation protected Type BF patient connection



Defibrillation protected Type CF patient connection



ATTENTION Refer to manual for more information



Fusible link.



Protective (earth) ground terminal



DANGER High voltage present



Alternating current.



DANGER Risk of explosion if used in the presence of flammable anesthetics.



Conformité Européenne Complies with the Medical Device Directive 93/42/EEC.

Defibrillator Function

Indications – Semiautomatic Operation

The ZOLL 1600 is designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the operator of the device controls the delivery of the shock to the patient. It is specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated in a medically-approved patient care protocol.

The ZOLL 1600 must be prescribed for use by a physician or medical advisor of an emergency response team.

Use of the ZOLL 1600 in the semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

Contraindications – Semiautomatic Operation

Semiautomatic defibrillation is contraindicated on patients showing the following responses:

- Consciousness
- Presence of breathing
- Presence of pulse.

The ECG analysis may not reliably identify ventricular fibrillation in the presence of an implanted pacemaker. Inspection of the ECG and clinical evidence of cardiopulmonary arrest should be the basis of any treatment of patients with implantable pacemakers.

Do not use the ECG analysis during patient movement on a stretcher or in an ambulance or other conveyance. **A patient must be motionless during ECG analysis. Do not touch the patient during analysis.**

Do not defibrillate pediatric patients (weighing less than 80 lbs./36 kg) in semiautomatic mode. (AHA standard)

Indications – Manual Operation

Use of the ZOLL 1600 in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

The ZOLL 1600 contains a standard DC defibrillator capable of delivering up to 360 joules of energy. In manual mode, it may also be used for synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference.

This product is to be used only by qualified medical personnel for the purposes of converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

Inappropriate defibrillation or synchronized cardioversion of a patient (e.g., with no malignant arrhythmia) may precipitate ventricular fibrillation, asystole, or other dangerous arrhythmias.

Defibrillation without proper application of electrodes may be ineffective and cause burns, particularly when repeated shocks are necessary. Erythema or hyperemia of the skin under the electrodes often occurs; this effect is usually enhanced along the perimeter of the electrode. This reddening should substantially clear within 72 hours.

Defibrillator Output Energy

The ZOLL 1600 delivers up to 360 joules into a 50 ohm impedance. The actual energy delivered through the chest wall, however, is controlled by skin impedances.

Synchronized Cardioversion

Applies to manual operation only.

Ventricular Tachycardia (VT), atrial fibrillation, atrial flutter and other arrhythmias resistant to drug therapy require synchronizing the defibrillator discharge with the ECG R-wave to prevent the induction of ventricular fibrillation. In this case, a synchronizing (SYNC) circuit within the instrument detects the patient's R-waves. When the Shock button is pressed and held, the unit will discharge with the next detected R-wave, thus avoiding the vulnerable T-wave segment of the cardiac cycle. A qualified operator must decide when synchronized cardioversion is appropriate.

Pacemaker Function

Applies only to ZOLL 1600 configured with a pacemaker.

Noninvasive Temporary Pacing (NTP) is an established and proven technique. This therapy is safe and is easily and rapidly applied in both emergency and non-emergency situations when temporary cardiac stimulation is indicated.

The ZOLL 1600 contains a demand pacemaker consisting of a pulse generator and ECG sensing circuitry. The output current of the pacemaker is continuously variable from 0 mA up to 140 mA and the rate is continuously variable from 30 to 180 pulses per minute (ppm).

The pacing output pulse is delivered to the heart via ZOLL Multi-Function Electrodes placed on the back and the precordium.

The characteristics of the output pulse, together with the design and placement of the electrodes, minimize cutaneous nerve stimulation, lower cardiac stimulation thresholds, and reduce discomfort due to skeletal muscle contraction.

During external pacing the unique design of the ZOLL 1600 allows clear viewing and interpretation of the electrocardiogram (ECG) on the monitor without offset or distortion.

Proper operation of the ZOLL 1600, together with correct electrode placement is critical to obtaining optimum results. The operator must be thoroughly familiar with these operating instructions.

Intended Use — Pacemaker

This product may be used for cardiac pacing in conscious or unconscious patients for up to a few hours duration as an alternative to endocardial stimulation. The purposes of pacing include:

1 Resuscitation from standstill or bradycardia of any etiology:

Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, β -blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

2 As a standby when standstill or bradycardia might be expected:

As a stand-by when arrest or symptomatic bradycardia might be expected, the external pacer is used especially in pacemaker procedures (e.g., acute myocardial infarction, drug toxicity, anesthesia, or surgery, especially when disturbances of rhythmicity or conduction are present). Prophylactic placement of endocardial electrode, which carries risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis, and mechanical or electrical stimulation of ventricular tachycardia and fibrillation, can be avoided.

3 Suppression of tachycardia:

An increase in heart rate from external pacing often suppresses ventricular ectopic activity and may prevent tachycardia.

Pacemaker Complications

Ventricular fibrillation will not respond to pacing and requires immediate defibrillation. The patient's dysrhythmia must therefore be determined immediately, so that appropriate therapy can be employed. If the patient is in ventricular fibrillation and defibrillation is successful, but cardiac standstill ensues (asystole), the pacemaker should be used.

Ventricular or supraventricular tachycardias may be interrupted with pacing but in an emergency or circulatory collapse, synchronized cardioversion is faster and more certain. (See Section 3 for Synchronized Cardioversion Procedure.)

Electromechanical dissociation may occur following prolonged cardiac arrest or in other disease states with myocardial depression. Pacing may then produce ECG responses without effective mechanical contractions, and other treatment is required.

Pacing may evoke repetitive responses, tachycardia, or fibrillation in the presence of generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance, or other cardiac diseases.

Pacing by any method tends to inhibit intrinsic rhythmicity. Abrupt cessation of pacing, particularly at rapid rates, can cause ventricular standstill and should be avoided.

Noninvasive Temporary Pacing may cause discomfort of varying intensity, which may occasionally be severe and preclude its continued use in conscious patients. Similarly, unavoidable skeletal muscle contraction may be troublesome in very sick patients and may limit continuous use to a few hours. Erythema of the skin under the electrodes often occurs but is inconsequential.

There have been reports of burns under the anterior electrode when pacing adult patients with severely restricted blood flow to the skin. Prolonged pacing should be avoided in these cases and periodic inspection of the skin is advised.

There are reports of transient inhibition of spontaneous respiration in unconscious patients with previously available units when the anterior electrode was placed too low on the abdomen.

This device may not be connected to internal pacemaker electrodes in contact with the myocardium.

Pediatric Pacing

Pacing can be performed on pediatric patients (15kg or less) using special pediatric Multi-Function Electrodes.

Monitor Function

The ZOLL 1600 contains a non-fade monitor for observation of the patient's cardiac rhythm. The monitor displays the ECG in moving trace mode at 25 mm/sec for a period of 3.4 seconds. In addition, the monitor displays:

- defibrillator output in joules
- number of shocks delivered during the event
- operational prompts, messages, and diagnostic codes

In manual mode the monitor displays:

- defibrillator output in joules
- heart rate, derived from measuring averaged R to R intervals.
- operational prompts, messages, and diagnostic codes
- ECG lead selections - I, II, III, or ELECTRODES.
- ECG size - .5, 1.0, 1.5, 2.0, 3.0 cm/mV
- pacemaker output in milliamps

The ZOLL 1600 has built-in protection circuitry that allows patient monitoring to continue during a defibrillation attempt. Monitoring electrodes may become polarized during defibrillator discharge, causing the ECG waveform to briefly go off the display area. High quality silver/silver chloride (Ag/AgCl) electrodes minimize this effect, and circuitry in the instrument will return the trace to the monitor display within a few seconds.

Medical Report Module

The 1600 stores event report data and provides convenient means of transferring the event to a database for review, training or storage. The 1600 begins recording data when the unit is turned on.

Removable PCMCIA Data Card

A removable 4 megabyte PCMCIA data card stores up to two hours of incident data (continuous patient ECG and unit status) or up to one hour of incident data and simultaneous audio recording. Data can be reviewed on a personal computer. (See Appendix A)

Strip Chart Recorder Function

A thermal strip chart recorder (optional) prints patient ECG, unit status and event information. The recorder operates in delay mode (i.e. ECG data is printed 6 seconds after its acquisition). Certain events will start the recorder automatically depending on the configuration. Manual operation is controlled by the Recorder On/Off button.

Summary Report

Summary Report allows the operator to store and later retrieve a printed copy of critical ECG event information. The 1600 internal memory automatically records defibrillation and cardioversion segments, **Pacer On** mode, heart rate alarm, analysis initiation, shock advised, no shock advised, and recorder activated ECG events. The Summary Report records all associated event information including 1600 control settings, patient ECG, time and date. (Refer to Appendix B for more information)

Electrode Options

ZOLL approved defibrillation only electrodes provide anterior/anterior placement, hands-off defibrillation and ECG monitoring. ZOLL Multi-Function Electrodes provide anterior/posterior placement, hands-off defibrillation, synchronized cardioversion, ECG monitoring and noninvasive pacing.

Safety Considerations

Persons using the ZOLL 1600 should be appropriately trained, skilled personnel familiar with the use of this device. Training appropriateness, such as Basic Life Support, should be the determination of the prescribing physician. (The semiautomatic mode of operating the ZOLL 1600 reduces the level of, but does not eliminate the need for training required to use the device.)

WARNINGS

General

- Federal (U.S.A.) law restricts this device to use by or on the order of a physician.
- The use of external pacing/defibrillation electrodes and adapter devices from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used in conjunction with pacing/defibrillation electrodes and adapter devices from other sources. If device failure is attributable to pacing/defibrillation electrodes or adapter devices not manufactured by ZOLL, this may void ZOLL's warranty.
- Proper operation of the ZOLL 1600, together with correct electrode placement is critical to obtaining the optimum results. The operator must be thoroughly familiar with proper ZOLL 1600 operation.
- Do not use the ZOLL 1600 in semiautomatic mode during patient movement on a stretcher or in an ambulance or other conveyance. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement via stretcher or vehicle to analyze the ECG. If using the device in an emergency vehicle, bring the vehicle to a halt before using the ZOLL 1600 in semiautomatic mode.
- The ZOLL 1600 is protected against interference from radio frequency emissions typical of two-way radios and cellular phones (digital and analog) used in emergency service/public safety activities. Users of the ZOLL 1600 should assess the device's performance in their typical environment of use for the possibility of radio frequency interference from high-power sources. Radio Frequency Interference (RFI) may be observed as shifts in monitor baseline, trace compression, or transient spikes on the display.
- Keep a fully charged spare battery pack with the ZOLL 1600 at all times. Replace the battery immediately when a low battery message is displayed.
- Emergency defibrillation should be attempted only by appropriately trained, skilled personnel who are familiar with equipment operation. Training appropriateness, such as Advanced Cardiac Life Support (ACLS) or Basic Life Support (BLS) certification, should be the determination of the prescribing physician.
- Synchronized cardioversion should only be attempted by skilled personnel trained in Advanced Cardiac Life Support (ACLS) and familiar with equipment operation. The precise cardiac arrhythmia must be determined before attempting defibrillation.
- Prior to attempting to perform a synchronized cardioversion, ensure that the ECG signal quality is good to minimize risk of synchronizing on artifact.
- These operating instructions describe the functions and proper operation of the ZOLL 1600. They are not intended as a substitute for a formal training course. Operators should attend a formal training course conducted by an appropriate authority.
- Do not disassemble the ZOLL 1600. A shock hazard exists. Refer all problems to ZOLL Technical Service.
- Follow all recommended maintenance instructions. If a problem occurs, obtain service immediately. Do not use the ZOLL 1600 until the unit has been inspected by the appropriate personnel.
- Do not install batteries into Monitor/Defibrillators when storage may exceed 90 days. Battery damage may occur.
- Do not use the ECG out signal as a sync pulse to another Defibrillator because of the delay in the signal path.

Operator Safety

- Do not use the ZOLL 1600 in the presence of flammable agents (such as gasoline), oxygen-rich atmospheres, or anesthetics. Using the instrument near the site of a gasoline spill may cause an explosion.
- Do not discharge with paddles or electrodes shorted together or in open air. Stand clear of patient when defibrillating.
- Warn all persons in attendance of the patient to STAND CLEAR prior to defibrillator discharge.
- Do not use the instrument near or within puddles of water.
- Do not touch patient, or any equipment connected to the patient other than the defibrillator during defibrillation.
- Do not allow electrolyte gel to accumulate on hands.
- Do not touch the gelled area of the electrodes while pacing.
- Excessive body hair or wet, sweaty skin may interfere with electrode adhesion. Remove the hair and/or moisture from the area where the electrode is to be attached.
- Do not discharge the defibrillator except as indicated in the instructions. Do not discharge the defibrillator if the electrodes are not properly placed on the patient.
- The user must check that the equipment functions properly and see that it is in proper condition before being used.

WARNINGS (Continued)

- Disconnect any other medical electrical equipment that is not specifically defibrillation protected from the patient prior to defibrillation.

Patient Safety

- Do not defibrillate pediatric patients (weighing less than 80 lbs./36 kg) in semiautomatic mode (AHA standard).
- The ZOLL 1600 detects ECG electrical signals only. It will not detect a pulse. Always verify rate and pulse by physical assessment of the patient. Never assume a rate display indicates a patient has a pulse.
- Use only high quality ECG electrodes. ECG electrodes are for rhythm acquisition only. Defibrillation or pacing cannot be accomplished with ECG electrodes.
- Do not use electrodes with gel that is torn or split from the foil.
- Multi-Function electrodes should be used no longer than eight (8) hours for continuous pacing.
- Pacer output current (mA) must be set to 0mA when connecting and disconnecting a patient from the ZOLL 1600.
- Prolonged pacing (in excess of 30 minutes), particularly in neonates and adults with severely restricted blood flow, may cause burns. Periodic inspection of the underlying skin is recommended.
- Internal implanted pacemakers may cause the heart rate meter to count the pacemaker rate during incidents of cardiac arrest or other arrhythmias. Pacemaker patients should be carefully observed. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect and display all implanted pacemaker spikes; patient history and physical exam are important in the determination of the presence of an implanted pacemaker.

Restarting the Device

Certain events require the ZOLL 1600 to be re-started after it has shut off or become inoperative. One example is when the battery runs down and the unit shuts off. The selector switch should always be turned to the OFF position before removing the battery. The selector switch may then be turned to the desired operating mode to resume operation after insertion of a new battery. This sequence is needed to restart the device, and can also be used to clear some "Status XX" messages, if immediate use of the device is required. Note that some settings (for example, alarm settings, lead selection, ECG size) may need to be restored from their default values when operation is resumed.

FDA Regulations

Tracking

Federal law (21 CFR 821) requires tracking of defibrillators. As an owner of this device, you have the responsibility under this law to notify ZOLL Medical Corporation if this product has been received, lost, stolen or destroyed; or has been donated, resold, or otherwise distributed to a different organization.

If any of the events described above occur, please contact ZOLL Medical Corporation in writing with the following information:

1. Originator's organization- Company name, address, Contact name and Contact phone number
2. Part number/Model number and Serial number
3. Disposition of device (e.g., received, lost, stolen, destroyed, distributed to another organization)
4. New location and/or Organization (if different from number 1 above) - Company name, address, contact name, and contact phone number
5. Date change took effect
6. Other information or comments

Please address your information to:

ZOLL Medical Corporation
32 Second Avenue
Burlington, MA 01803-4420

Attn: Tracking Coordinator

Fax 617 272-5578 Phone 617 229-0020

Notification of Adverse Events

As a health care provider, you may have responsibilities under the SMDA, for reporting to ZOLL and possibly to the FDA the occurrence of certain events. These events, described in 21 CFR Part 803, include device related death and serious injury or illness.

In any event, as part of our Quality Assurance Program, ZOLL should be notified of any device failures or malfunctions. This information is required to assure that ZOLL provides only the highest quality products.

Warranty (U.S.A. Only)

(a) ZOLL Medical Corporation warrants to the Customer that from the date of installation, or thirty (30) days after the date of shipment from ZOLL Medical Corporation's facility, whichever first occurs, the Equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period of one (1) year. Accessories and electrodes shall be warranted for 90 days from date of shipment. During such period ZOLL Medical Corporation will, at no charge to the Customer, either repair or replace (at ZOLL Medical Corporation's sole option) any part of the Equipment found by ZOLL Medical Corporation to be defective in material or workmanship. If ZOLL Medical Corporation's inspection detects no defects in material or workmanship, ZOLL Medical Corporation's regular service charges shall apply. (b) ZOLL Medical Corporation shall not be responsible for any Equipment defect, the failure of the Equipment to perform any specified

function, or any other nonconformance of the Equipment, caused by or attributable to: (i) any modification of the Equipment by the Customer, unless such modification is made with the prior written approval of ZOLL Medical Corporation; (ii) the use of the Equipment with any associated or complementary equipment, accessory or software not supplied by ZOLL Medical Corporation (iii) any misuse or abuse of the Equipment; (iv) exposure of the Equipment to conditions beyond the environmental, power or operating constraints specified by ZOLL Medical Corporation; or (v) installation or wiring of the Equipment other than in accordance with ZOLL Medical Corporation's instructions. (c) This warranty does not cover items subject to normal wear and burnout during use, including but not limited to lamps, fuses, batteries, patient cables and accessories. (d) The foregoing warranty does not apply to software included as part of the Equipment (including software embodied in read-only memory, known as "firmware"). (e) The foregoing warranty constitutes the exclusive remedy of the customer and the exclusive liability of ZOLL Medical Corporation for any breach of any warranty related to the Equipment supplied hereunder. THE WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND ZOLL MEDICAL CORPORATION EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, IMPLIED, OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE.

For additional information, please call ZOLL Medical Corporation at 1-800-348-9011 (in Massachusetts: 1-617-229-0020). International customers should call the nearest authorized ZOLL Medical Corporation service center.

Service

The ZOLL 1600 should provide trouble-free operation without periodic calibration or adjustment. Appropriately trained and qualified personnel should perform periodic routine tests of the device to verify proper operation. (See Section 6.) Refer to the 1600 Service Manual for semi-annual tests to be performed on the device.

U.S.A. Customers

Should the ZOLL 1600 require service, it should be returned, in its original container, to same address listed in previous column, Attn: Technical Service Department

Loaner instruments are available for use while repairs are being completed. To request loan equipment, contact ZOLL Medical at 1-800-348-9011 (in Massachusetts: 1-617-229-0020). Please try to have the following information available to expedite service:

- The unit serial number.
- A description of the problem.
- The name of the department where the equipment is in use.
- Sample ECG strips documenting problem (if available).
- A Purchase Order to allow tracking of loan equipment.

International Customers

Should the ZOLL 1600 require service, it should be returned, in its original container, to the nearest authorized ZOLL Medical Corporation service center.

Section 2

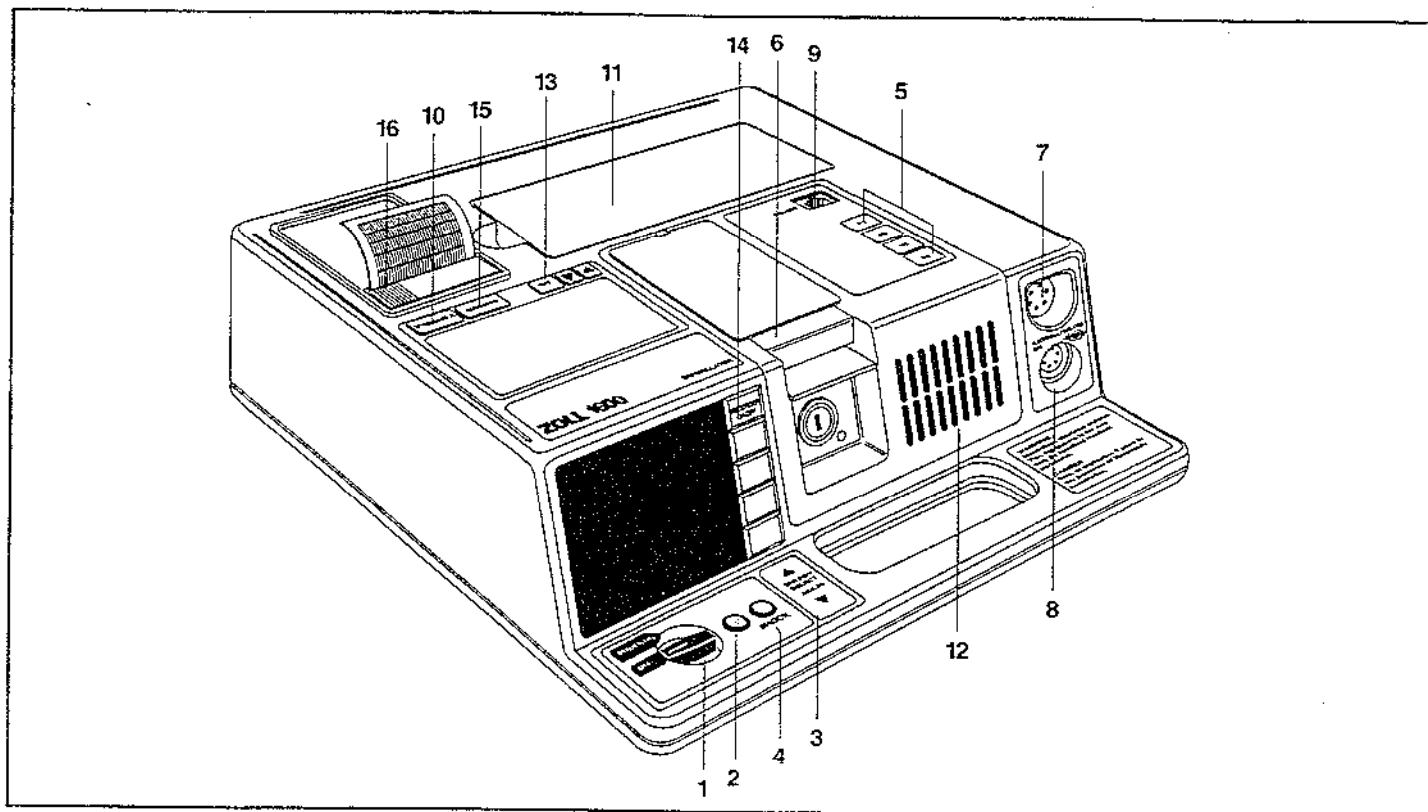
Operating Controls and Indicators Semiautomatic Mode



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.



The controls and indicators described are active in semiautomatic mode. Also described are the optional strip chart recorder controls. Many ZOLL 1600 features and controls are user configurable to better facilitate local protocols. **Some configuration options affect controls and indicators. See Appendix D for additional information.**

1. Selector Switch

The selector switch powers on the unit.

If the selector switch is turned to Power On and only the ECG cable is connected, the 1600 will operate in monitor mode only.



The device will always power on in the semiautomatic mode. To select manual mode, the manual mode key must be used after the unit has been turned on.

2. Analyze Button


An ANALYZE  message appears on the monitor when the


unit is ready for active analysis mode. Pressing the Analyze button initiates an active analysis causing the unit to analyze the patient ECG and determine if a shockable rhythm exists. If a shock is advised, the 1600 will charge to the preconfigured energy level and prompt the operator to shock the patient.

3. Energy Select Button

A set of up-down arrow buttons located on the front panel allow changing the preconfigured defibrillator energy level. Pressing the up  button will increase the energy level to the next preconfigured energy level and pressing the down  arrow button will decrease the energy level to the next preconfigured energy level. (200J and 360J are the preconfigured (default) energy levels available in semiautomatic mode.) The energy level selected is displayed on the monitor. These up-down arrow buttons are disabled after the 1600 begins charging preventing further changes in the selected energy.

4. Shock Button

The Shock button is active only after the ECG analysis has been completed and a shockable rhythm has been detected. The monitor displays the message **PRESS SHOCK** . Pressing and holding the Shock button delivers the shock.

The shock button is operational for 15 seconds after the defibrillator is charged. If the button is not pressed within the 15 second interval, the energy is discharged internally and the **PRESS SHOCK**  message disappears.

5. Event Keypad

The 4 keypad buttons, F1, F2, F3, F4, control medical report module data downloading functions, and event annotation. (See Appendix A)

6. PCMCIA Data Card

A ZOLL recommended PCMCIA card should be installed in the memory card slot during device operation. The PCMCIA card stores patient ECG, 1600 status and optional audio data. The data can be retrieved via a personal computer. (See Appendix A)

7. Multi-Function Cable Connector

The Multi-Function cable connector on the right front of the ZOLL 1600 is used to connect the Multi-Function cable to the instrument.

Multi-Function Cable (Not Shown)

Connects the ZOLL Multi-Function Electrodes or defib only electrodes to the 1600. To install the cable into the 1600, simply plug it into the connector. To remove the cable, depress the black button on the cable and pull the cable out of the unit.

8. ECG Cable Connector

Used to connect a standard 3-lead ECG cable and electrodes to the 1600. The cable is keyed.

9. Communications Port

The communications port (RS-232) is used to transfer recorded incident (ECG and audio) data from the medical report module (memory card) to the ZOLL Data Control System. (See Appendix A)

10. Volume

The Volume control allows audio level adjustment of the voice prompts. The voice prompts cannot be made inaudible even if the volume is turned to the minimum setting. The QRS beep is inaudible in semiautomatic mode. (The charge ready and warning beep volumes are not adjustable.)



11. Battery Pack

The ZOLL 1600 uses a rechargeable, sealed lead-acid battery pack (PD 4410).

12. Speaker

The speaker provides audio prompts to reinforce monitor messages. The volume is adjusted by the Volume control.

13. Set

This control is used to set the time. The up  button increments the displayed value. The down  button decrements the displayed value (See Section 6).

Strip Chart Recorder Controls

The following controls are active only if a strip chart recorder is installed.

14. Recorder On/Off

Press this button and the strip chart recorder starts, press again and the recorder stops.

15. Summary

Initiates the print out of Summary reports. (See Appendix B)

16. Paper Compartment

Opens the strip chart recorder paper storage compartment. (See Section 6)

Audio and Monitor Display Messages

The ZOLL 1600 uses both audio and visual prompts to present critical information to operators. (The following information describes the 1600 default configuration. If your device has been custom configured some of the information may be different. Check with your Medical Control Authority.)

There are 8 voice prompts used in semiautomatic mode. These prompts are accompanied by a message displayed on the monitor. The voice prompts are given only once, but the monitor continues to display the message until new action is taken by the operator or the device status changes.

The ZOLL 1600 also provides a beeper tone to indicate unit status. Four beeps immediately after turning the 1600 on signifies the self diagnostics are complete and 1600 is ready for operation. Additional tone signals are described later.

The display has fields where messages appear. The messages that appear depend upon the functions the 1600 is performing, the mode selected, and the ECG information from the patient.

The 1600 will alternately display two different messages in the same field of the monitor when two conditions are detected at the same time. For example, a "LOW BATTERY" message may alternately display on the same line of the monitor as a "CABLE FAULT" message.

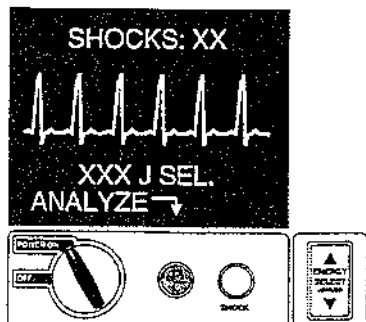
The upper portion of the monitor displays the elapsed time (if enabled) and the number of shocks delivered during the incident (SHOCKS: XX). The center portion of the monitor displays approximately 3.4 seconds of ECG trace and the lower portion of the monitor displays operator prompts, energy levels selected, button function labels and error messages.

Additional unit status information is also displayed on the monitor. See sections 6, 7 and appendices A, B, and C.

Operating Messages

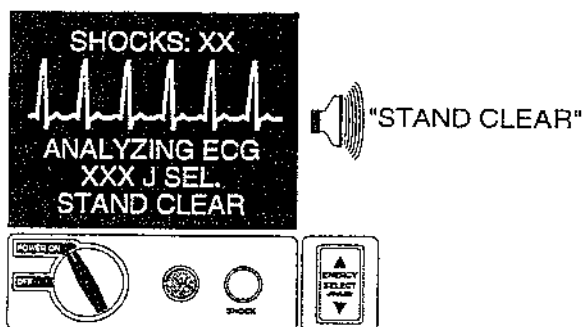
Following are monitor displays and voice prompts that can occur during ZOLL 1600 use. Each subsequent paragraph contains a brief explanation of the message (and applicable user action if necessary).

ANALYZE

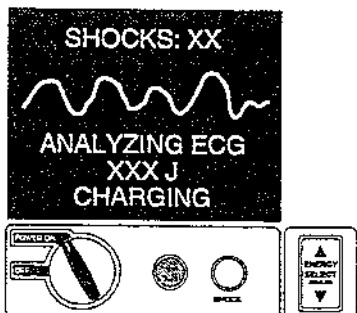


If the 1600 has been turned on with Multi-Function or defibrillation electrodes attached to the patient, the monitor will display an analyze prompt.

ANALYZING ECG/STAND CLEAR



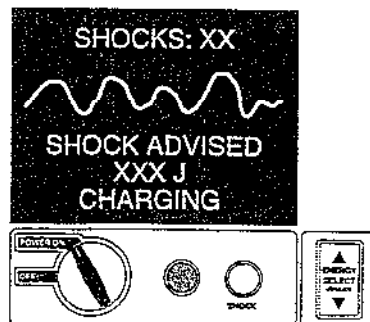
This message appears after pressing the Analyze button. It indicates that an active ECG analysis is starting. Touching or moving the patient can create artifact that interferes with the analysis process. Remain clear of the patient until after the shock has been delivered or no shock advised is determined.



ANALYZING ECG/CHARGING

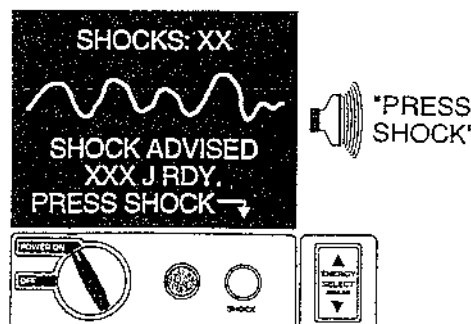
Active analysis is still in progress and a potentially shockable rhythm has been detected. The current charge level and a message that the 1600 is charging are displayed.

SHOCK ADVISED/CHARGING



Active analysis determined that a shock is advised. The selected charge level has not yet been reached. The current charge level and a message that the 1600 is charging are displayed.

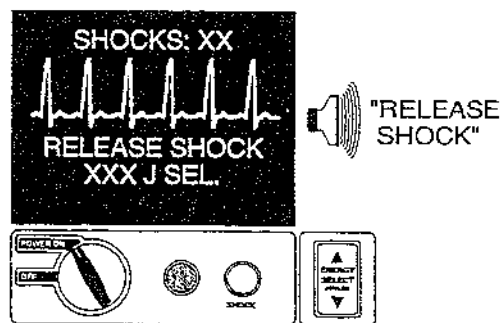
PRESS SHOCK



Active analysis determines that a shock is advised. The selected charge level is ready to be delivered and a message to press the Shock button is displayed. Pressing and holding the Shock button on the front panel delivers the shock to the patient.

The 1600 provides a continuous 10 second steady tone after the defibrillator is fully charged. After the 10 seconds the unit will beep intermittently for 5 seconds. If the Shock button is not pressed during this 15 seconds the unit will discharge the energy internally and the PRESS SHOCK message will disappear.

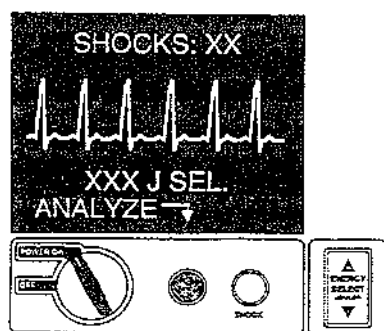
RELEASE SHOCK



If the Shock button is pressed during charging (before the XXX J RDY) message, a RELEASE SHOCK message is displayed and the 1600 beeps. If the Shock button is not released and remains depressed for 15 seconds the unit discharges the energy inter-

nally. If the Shock button is released before 15 seconds has elapsed the PRESS SHOCK → message will appear and the shock can be delivered.

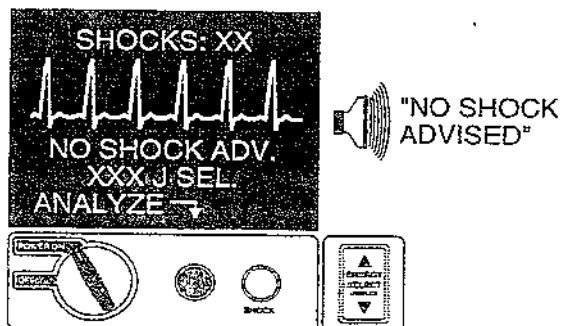
SHOCKS: XX



Indicates the number of shocks that have been delivered by the 1600 during this incident. Resets to 0 after the 1600 has been off for more than 10 seconds. (This allows for replacing a battery and still maintaining shock number information).

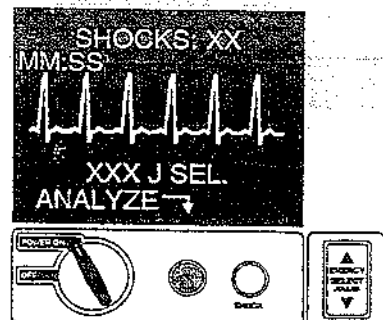
NO SHOCK ADVISED

If during active analysis no shockable rhythm is detected this message will appear.



A 10 second message indicating the 1600 has completed an active analysis of the patient and has not detected a shockable rhythm. Press the Analyze button to start another active analysis or perform other actions as specified by the treatment protocol.

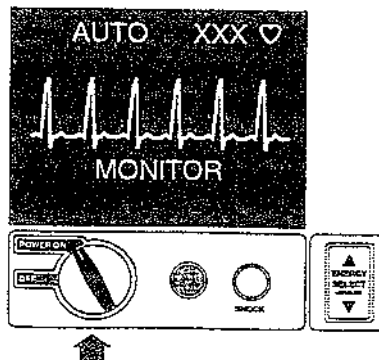
ELAPSED TIME



When enabled, this feature indicates the elapsed time from when the unit is first turned on. It is displayed in the upper left corner of the CRT display in both Semi-Automatic and Manual modes. The elapsed time is displayed in MM:SS form up to 99:59. If the unit is on for over 100 minutes, the elapsed time will roll over to 0. The

elapsed time will be maintained for up to 10 seconds after power down. This will give the operator adequate time to change the battery without resetting the elapsed time.

MONITOR



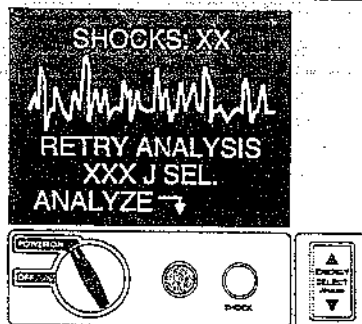
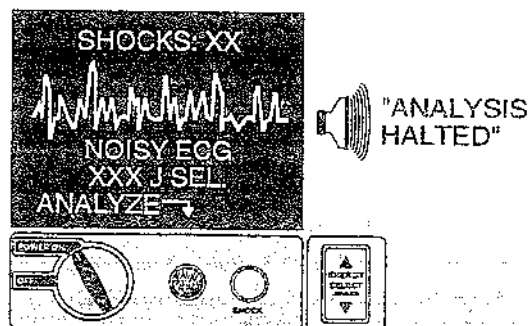
This screen appears when the patient ECG cable is connected to the ECG input connector and the multi-function cable is not installed. The MONITOR message is displayed as well as the patient ECG waveform. The AUTO message indicates the 1600 has selected lead II and set the ECG size automatically (Lead and ECG size cannot be changed by the operator).

Warning Messages

Warning messages prompt the operator to check the patient or the 1600, the electrodes and/or connections.

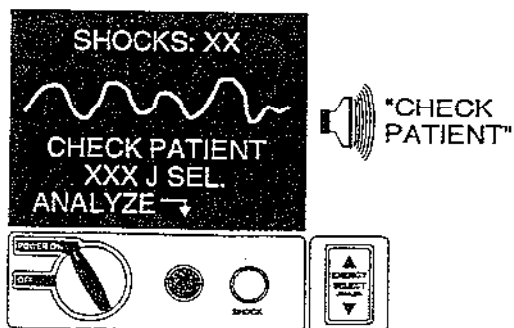
Note: The ZOLL 1600 does not warn the operator of patient asystole, as it is not a shockable rhythm.

NOISY ECG



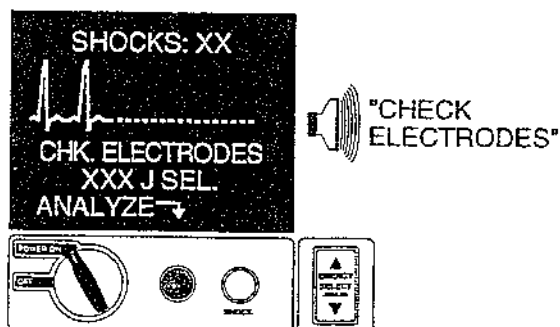
A 5 second NOISY ECG message alternating with a RETRY ANALYSIS message is displayed when the 1600 detects a noisy ECG signal. Check and adjust electrode placement and cable connections to help eliminate the source of noise. Press the Analyze button again to begin active analysis.

CHECK PATIENT



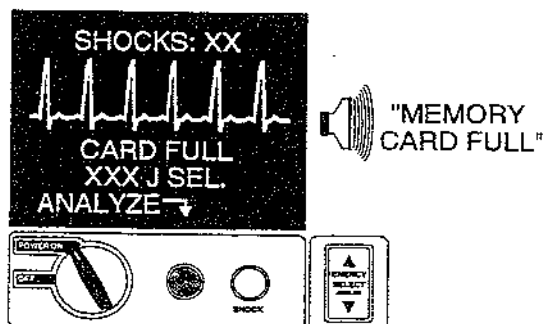
The 1600 detects a shockable rhythm during continuous analysis (i.e. without initiating an analysis). The prompt is given only when the 1600 first detects a shockable rhythm or if the rhythm goes from non-shockable to shockable. The screen message persists as long as a shockable rhythm is being detected. Press the Analyze button to activate the defibrillation functions.

CHECK ELECTRODES



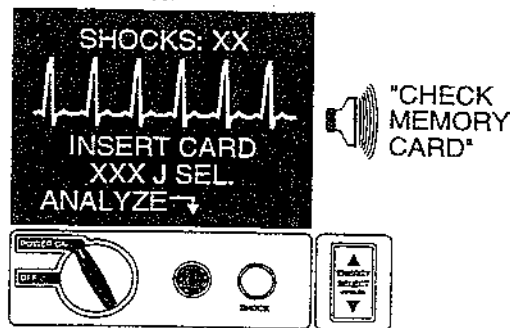
The Multi-Function defibrillation electrodes are no longer properly attached to the patient or the cable connections have become loose. Check that the electrodes are making good contact with the patient's skin and that the cables are all securely connected. The voice prompt will not sound if the electrodes were not previously connected to the patient.

CARD FULL



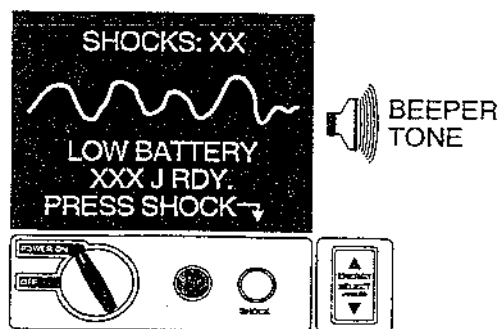
The PCMCIA Data Card is full. No more data will be stored on the card but the ZOLL 1600 will continue to operate. This prompt is only given when the 1600 is not analyzing or charging. Insert another card or print event data on strip chart recorder (if so equipped).

CHECK CARD



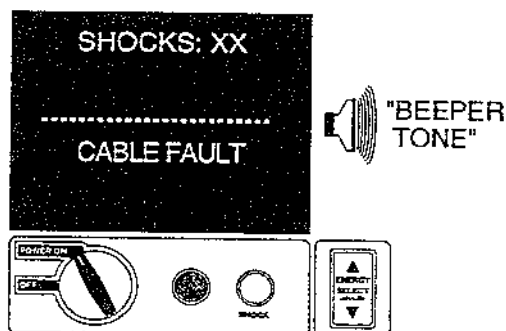
The memory card is not installed or not seated properly in the unit. A "REPLACE CARD" message will appear on the screen when the wrong card type is installed or the card is defective. The ZOLL 1600 will operate, but no data will be stored. This prompt is only given when the 1600 is not analyzing or charging.

LOW BATTERY



This message indicates the battery charge is low. Immediately replace the battery with a fully charged spare battery.

CABLE FAULT



This message indicates the connection from the Multi-Function cable and the unit has been interrupted.

Semiautomatic Defibrillation



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.

When using the ZOLL 1600 in the semiautomatic mode, this section describes the recommended method of operation. If your local protocol requires a different procedure, follow that protocol.

In semiautomatic mode, pressing the Analyze button causes the 1600 to perform an active analysis of the patient's ECG and determine if a shockable rhythm is present. An active analysis consists of three 3-second ECG rhythm analyses. If at least two of the three analyses determine that the patient has a shockable rhythm, the 1600 will automatically charge and prompt the operator to shock the patient. If two or more of the three 3-second ECG analyses do not detect a shockable rhythm, the 1600 will alert the operator that no shock is advised. Continuous analysis is disabled for 60 seconds after the completion of analysis (either "NO SHOCK ADVISED" or "SHOCK ADVISED"). This inhibits the "CHECK PATIENT" voice prompt and CRT message during the 60 second interval when the operator is performing CPR. If during continuous analysis, which consists of continuous 18 second segments of ECG analysis, the 1600 detects a shockable rhythm, the 1600 prompts the operator via an audio prompt and visual display message to check the patient. (See Appendix E for data on the ECG analysis system).

1 Determine patient condition following medical protocols

Verify:

- Unconsciousness
- Absence of breathing
- Absence of pulse

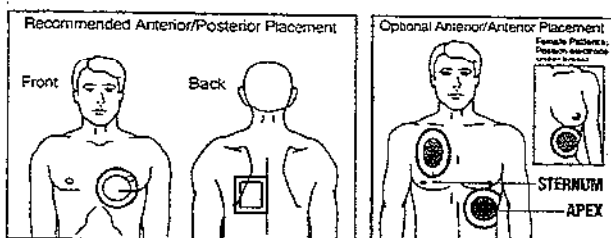
2 Begin CPR following medical protocols

Request additional assistance.

3 Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

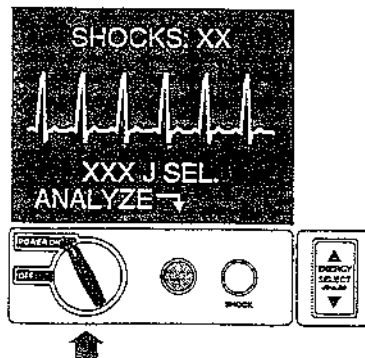
Attach the defibrillation electrodes according to instructions on electrode packaging.



Ensure that all of the electrodes are making good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the multi-function cable if not preconnected

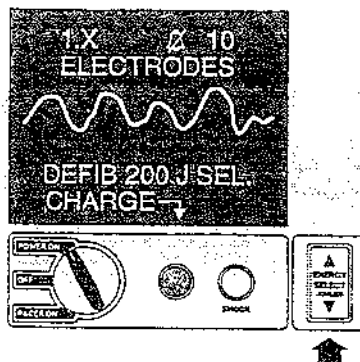
4 Select Power On



The 1600 will beep 4 times to indicate that it has passed the power-on self-test. If the audio recorder is present, the unit will begin recording audio data immediately.

The 1600 displays ANALYZE → on the monitor. The arrow on the monitor will flash to draw attention to the Analyze button below it. This message is displayed until an active analysis is started by the operator.

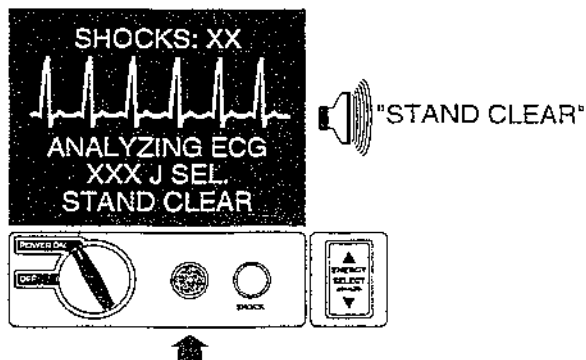
5 Select Energy Level



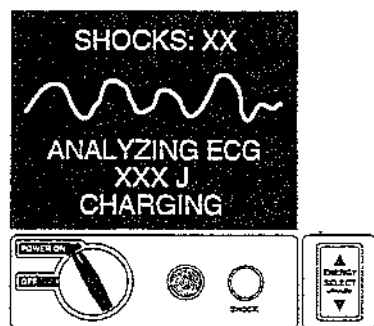
Shock number 1 is set at 200 joules, shock 2 is set at 200 joules and shock 3 and up is set at 360 joules (default setting) (Contact your Medical Control Authority for configuration options). If local protocols allow, the operator may select a different preconfigured energy level using the Energy Select up ▲ and down ▼ arrow buttons. The new energy level will display on the monitor.

6 Press Analyze Button

Avoid touching or moving the patient. If the patient is in a vehicle, bring the vehicle to a stop.

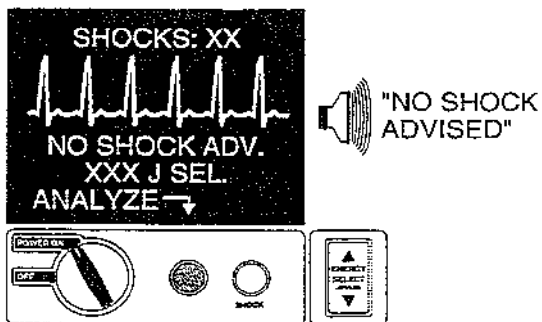


Press the Analyze button to begin the active analysis of the patient's ECG. The unit will advise everyone to "STAND CLEAR". The ECG analysis will last 9 seconds.

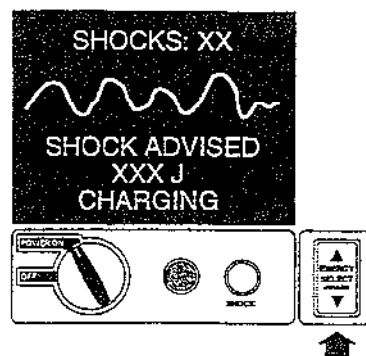


The 1600 may begin charging during the analysis. The monitor shows the CHARGING message.

Once the analysis is completed, the 1600 determines whether or not a shock is advised.



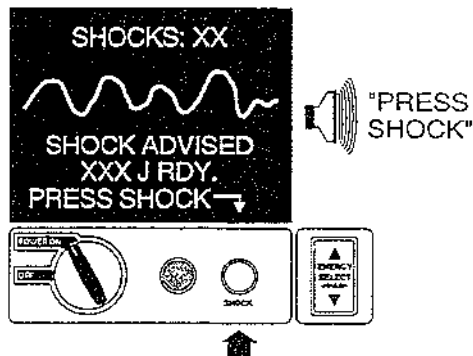
If shock is not advised, the 1600 announces and displays a NO SHOCK ADVISED message on the monitor. Immediately check pulse and breathing and resume other recommended protocol measures.



If a shockable rhythm is identified during analysis, the 1600 displays a SHOCK ADVISED message, indicates the preconfigured energy level and that it is charging – XXX J or charged – XXX J RDY.

7 Press Shock

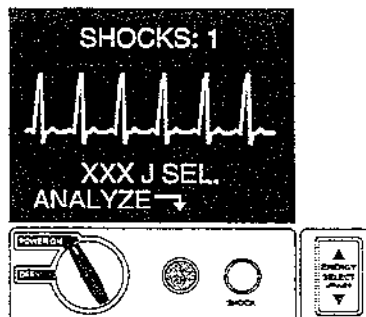
Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential electrical current pathway.



Once the 1600 has charged to the selected level, it announces "PRESS SHOCK" and flashes PRESS SHOCK → on the monitor. A continuous tone will sound for 10 seconds, followed by an intermittent beeping for 5 seconds. The shock must be delivered within this 15 second interval.

Press and **hold** the Shock button on the front panel to deliver the energy to the patient.

Observe the patient or ECG response to be certain that the shock has been delivered.



After the energy is delivered to the patient, the display returns to XXX J SEL. and indicates the number of shocks administered to the patient – SHOCKS 1.

8 Reanalyze Patient

Press the Analyze button to restart an active analysis to determine if a second shock is required.

9 Continue Patient Care

Continue patient care according to local protocols.

ECG Monitoring



ECG leads are a defibrillation protected Type CF patient connection.

ECG electrodes are for rhythm acquisition only. Defibrillation cannot be accomplished with ECG electrodes.

The ZOLL 1600 detects ECG electrical signals only. It will not detect a pulse. Always verify rate and pulse by physical assessment of the patient. Never assume a rate display indicates a patient has a pulse.

In addition to defibrillator electrodes and multi-function electrodes, the 1600 can monitor the patient ECG through standard electrodes. To monitor patient ECG using three (3) ECG electrodes, the ECG cable and electrodes must be properly connected and the multi-function cable must be disconnected from the 1600. If one of the three (3) electrodes or the ECG cable become disconnected the 1600 automatically switches to defibrillation mode and the CHECK ELECTRODES message appears.

If the multi-function cable is connected and defibrillation only or Multi-Function electrodes are attached to the patient the 1600 will operate in defibrillation mode and will monitor the ECG through the defibrillation only or Multi-Function electrodes even if 3-lead electrodes are properly attached.

Monitoring electrodes may become polarized during defibrillation discharge, causing the ECG waveform to briefly go off display. ZOLL 1600 circuitry will return the trace to the monitor display within a few seconds.

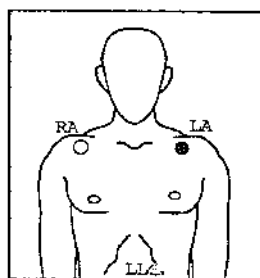
Monitoring Procedure

Follow prescribed medical protocols in your area to determine if ECG monitoring is required.

1 Prepare the patient.

Remove all clothing covering the patient's chest. Dry chest if necessary.

2 Attach Monitoring Electrodes.



RA/White Electrode (R/Red Electrode)

Place near right mid-clavicular line, directly below clavicle.

LA/Black Electrode (L/Yellow Electrode)

Place near left mid-clavicular line, directly below clavicle.

LL/Red Electrode (F/Green Electrode)

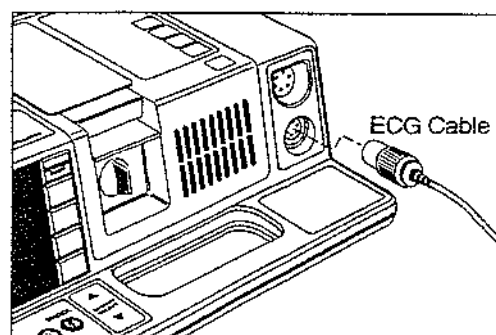
Place between 6th and 7th intercostal space on left mid-clavicular line.

Peel the protective backing from the ECG electrodes. Be careful to keep adhesive surface free of electrolyte gel.

Apply the electrodes firmly to the patient's skin, pressing around the entire perimeter of the electrodes.

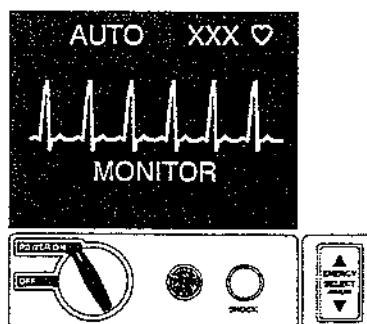
Attach snap-on leads and check for good contact between the electrode and the lead termination.

Plug the patient ECG cable connector into the ECG input connector.



3 Turn to Power On

Observe the monitor.



The message MONITOR should be displayed as well as the patient ECG waveform.

The 1600 automatically selects lead II and sets the ECG size. Lead and ECG size cannot be changed by the operator.

The patient's heart rate and heart symbol (flashes each time a R-wave is detected) will be displayed in the upper right corner.

Section 3

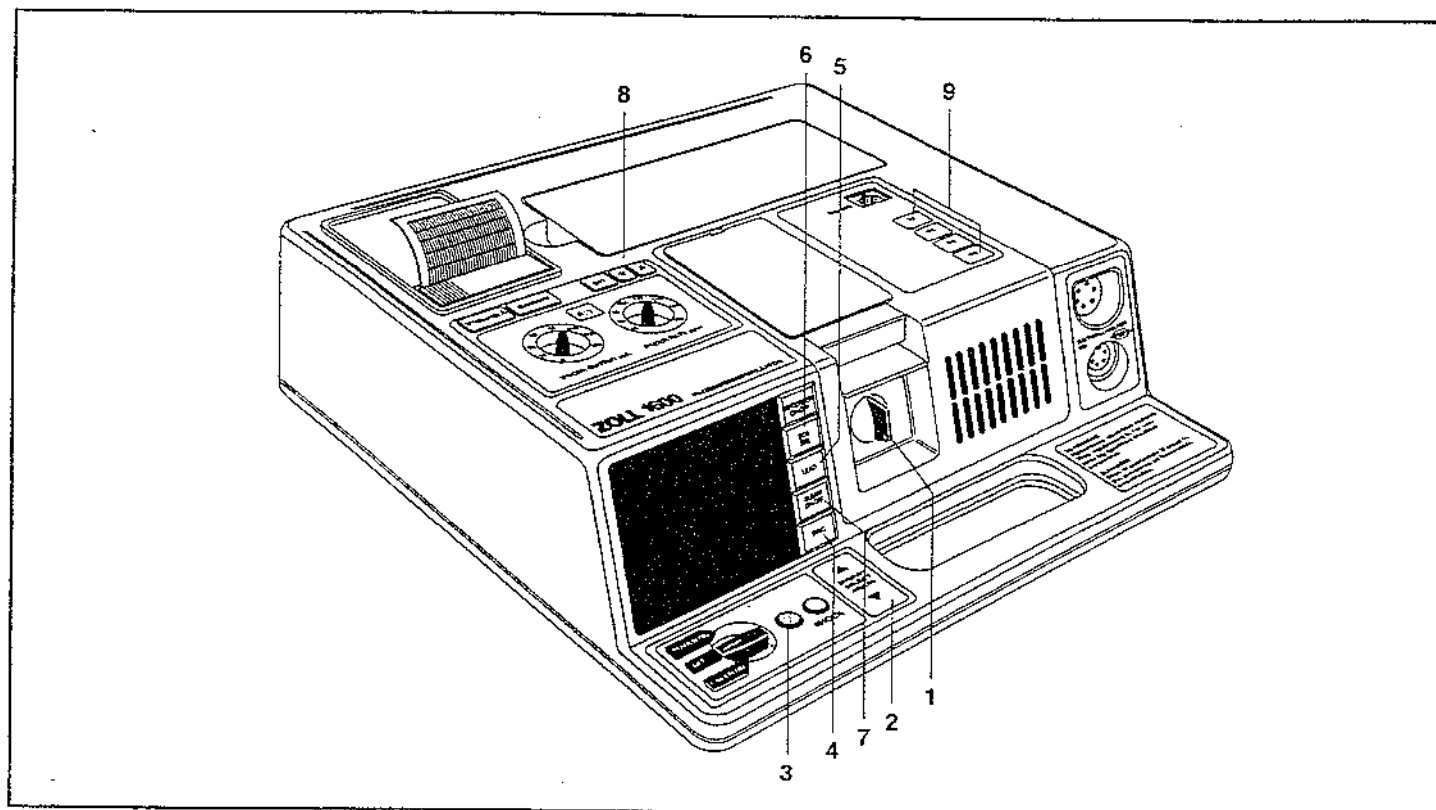
Operating Controls and Indicators Manual Mode



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.



The controls and indicators described below are only active in manual mode. For other controls active in both semi-automatic and manual mode, see the controls and indicators listed in Section 2.

1. Manual Mode Key Switch

The key is used by an authorized operator to switch the ZOLL 1600 into manual mode. The key has 3 positions, 9 o'clock, 12 o'clock and 3 o'clock. Turning the key once to 3 o'clock (right) will prompt a mode change confirmation request (monitor message). Turn the key to 3 o'clock a second time within 5 seconds to confirm the mode change. The 1600 will remain in manual mode until turned off for more than 10 seconds. Turn the 1600 off and then on to return to semiautomatic mode. To remove the key from the key slot turn the key to the 9 o'clock position (left) (unless the key has been permanently installed—contact your Medical Control Authority).

2. Energy Select Buttons

Two up-down arrow buttons located on the front panel control the defibrillator energy level. Press and **hold** the appropriate up ▲ or down ▼ arrow button until the desired energy level is displayed on the monitor.

3. Charge

Press the Charge button to charge the defibrillator to the energy level displayed on the monitor. To change the charged energy level, use the Energy Select buttons to select a new energy level.

4. Sync

In sync mode, the unit synchronizes defibrillator discharge with the first detected R-wave after the shock button is pressed. This mode is used for synchronized cardioversion procedures.

The ZOLL 1600 is configured by default to leave sync mode and revert to standard defibrillation mode after each discharge. (The 1600 can also be reconfigured to remain in sync mode for repeated synchronized shocks—contact your Medical Control Authority).

5. Lead

Pressing the button sequentially selects and displays the ECG source on the monitor. **ELECTRODES** (Multi-Function electrodes) is automatically selected when the instrument is turned on. Pressing the button sequentially switches the source to lead I, lead II, lead III or **ELECTRODES**.

If attached to monitoring electrodes in Semi-Auto mode, the default setting remains lead II when converting to manual mode.*

6. ECG Size

This control changes the ECG signal size. Size options are .5, 1.0, 1.5, 2.0, 3.0 cm/mv and are indicated in the upper left of the monitor.

7. Alarm On/Off

The Alarm On/Off button activates and deactivates the heart rate alarms.

8. Set Button

Use this button and the adjacent up ▲ and ▼ down arrows to change the heart rate alarm limit settings.

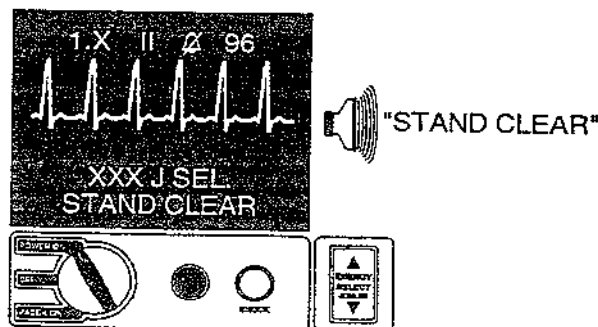
9. Event Keypad

These four buttons are event markers that place a distinctive mark (Event 1, Event 2, Event 3, and Event 4) on the recorder margin the instant the button is pressed. They also trigger a 15 second recorder run if the 1600 is configured to Automatically Generate strips.

Voice and Monitor Display Messages

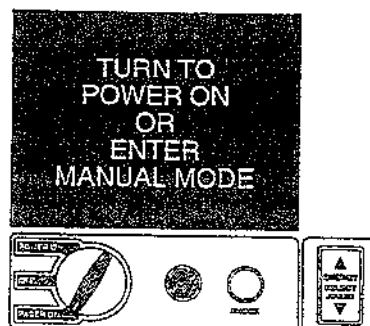
Manual mode monitor messages are similar to semiautomatic mode monitor messages except that the ECG size, ECG lead selected, alarm status, and heart rate replace the **SHOCK: XX** information on the top line. There are 2 voice prompts in manual mode, "STAND CLEAR" and "CHECK PATIENT". For additional messages that apply to manual mode see Section 2.

STAND CLEAR



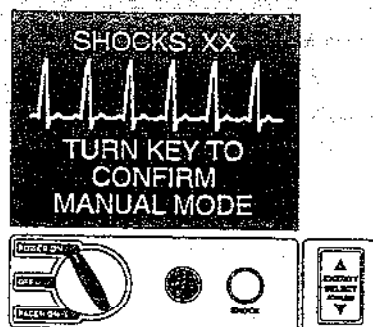
The charge button has just been pressed. Remain clear of the patient until after the shock has been delivered.

TURN TO POWER ON OR ENTER MANUAL MODE



The 1600 has just been turned to Pacer On from semiautomatic mode or from Off. Turn the key to select manual mode operation.

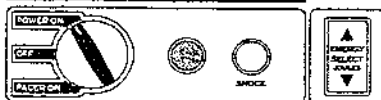
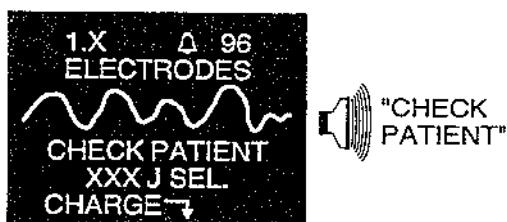
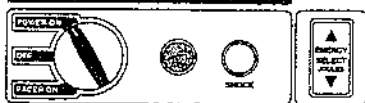
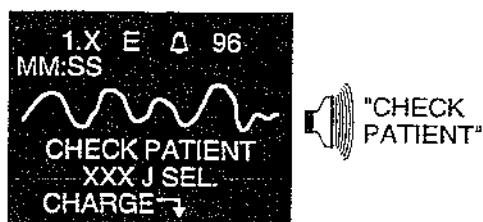
TURN KEY TO CONFIRM



The key has been turned to the 3 o'clock position once to switch to manual mode. Turn to 3 o'clock again within 5 seconds to confirm mode change.

Heart Rate Alarms

The SmartAlarms™ feature automatically analyzes ECG for shockable ventricular fibrillation or wide complex tachycardias whenever Heart Rate Alarms are enabled. The 1600 will display and announce the message, "CHECK PATIENT" to indicate that the source of the alarm was due to the analysis of the rhythm. If the 1600 has a strip chart recorder it will be printed as an annotation at the end of the 15 second strip recorder printout. When the Elapsed Time display is enabled and Electrodes are selected as the input, the letter "E" is displayed on the first line where the ECG Lead is normally displayed. If the Elapsed Time display is disabled the word "ELECTRODES" is displayed on the second line.



the violation tone and the flashing bell symbol and reactivates the heart symbol to flash with each detected R-wave.

Set the Heart Rate Alarm Limits

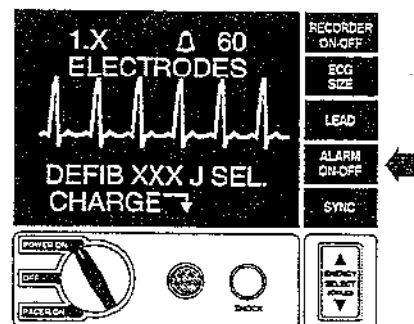
Heart rate alarms are preset at 30 (low) and 150 (high) when turned on.

To change the lower limit or upper limit alarm set points:

1. Push SET button. Low alarm limit value flashes in place of heart rate. To change value, push ▲ to raise, push ▼ to lower.
2. Push SET button again. High alarm limit value flashes in place of heart rate. To change value, push ▲ to raise, push ▼ to lower.
3. Push SET button again to return to monitoring.

To Enable the Heart Rate Alarm

Press the Alarm On/Off switch to enable the heart rate limit alarm and "Smart Alarms." When the alarm is on, the line crossing out the bell-shaped character will disappear.



When an alarm occurs the bell-shaped symbol will flash (the heart symbol freezes for easier identification), and the audible alarm tone will sound. If the 1600 has a strip chart recorder, it will automatically run for 15 seconds. Turning the alarms off, turns off

Manual Mode Defibrillation



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.

In manual mode the ZOLL 1600 ECG rhythm analysis algorithm is inactive. The operator determines the appropriate therapy. The operator can select the defib energy level and apply shocks according to the local protocol.

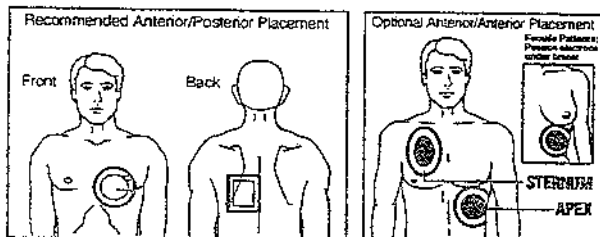
- 1 Determine patient condition following medical protocols**
- 2 Begin CPR following medical protocols**

Request additional assistance.

3 Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

Apply the electrodes according to the instructions on electrode packaging.



Ensure that the electrodes are in good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the Multi-function cable unless preconnected.

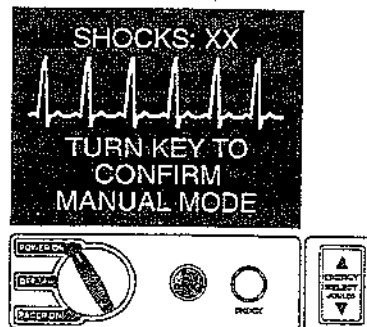
4 Select Power On

Turn the selector switch to Power On. The ZOLL 1600 will power on in semiautomatic mode.

The 1600 will beep 4 times to indicate power-on self-test has passed. If the audio recorder is present, the unit will begin recording audio data immediately.

5 Switch to Manual Mode

Insert the manual mode key if not already installed in the 1600. Turn the manual mode key clockwise and release. The 1600 displays a message, "Turn Key To Confirm Manual Mode".



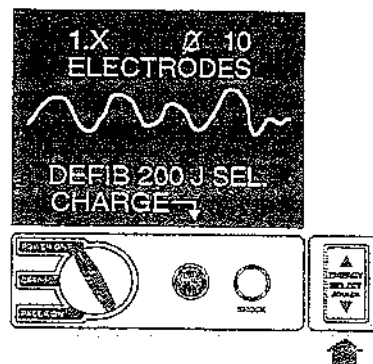
Turn the key clockwise again within 5 seconds to confirm manual mode operation.

The 1600 will now be in manual defibrillation mode.

ELECTRODES will be selected as the ECG lead.

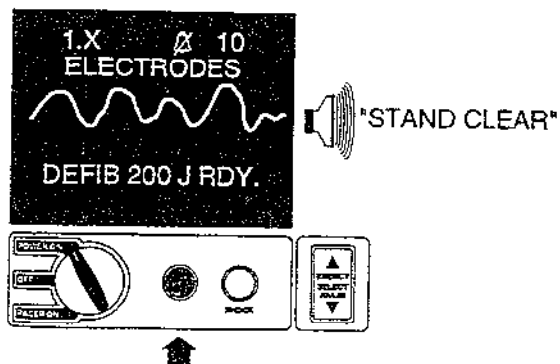
Verify that the patient requires a shock.

6 Select Defib Energy Level



To change the pre-selected defib energy level (200J) press the up ▲ or down ▼ arrow located on the Energy Select button. The selected energy level is displayed digitally as DEFIB XXX J SEL on the monitor.

7 Charge Defibrillator



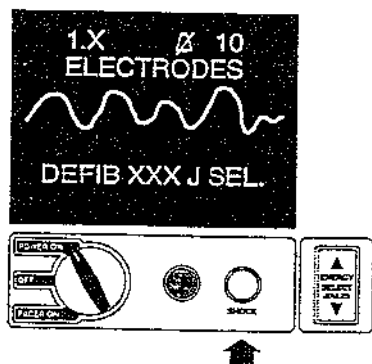
Press the Charge button on the front panel. The "STAND CLEAR" prompt will sound.

After 6-10 seconds of charging to the selected level, the DEFIB XXX J RDY message displays on the monitor. A distinctive charge ready (continuous) tone sounds. The defibrillator is now ready.

To abort the charging and increase or decrease the selected energy after the Charge button has been pressed, use the Energy Select button to select a new energy level. Press the Charge button again to charge the unit.

8 Discharge Defibrillator

Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential current pathway.



Press and **hold** the Shock button on the front panel to shock the patient.

Observe that the energy is delivered by observing the patient and checking the ECG response. The display will return to DEFIB XXX J SEL.

If the defibrillator is not discharged within 60 seconds of reaching the selected energy level, or the **Energy Select** button is pressed, the 1600 automatically discharges the stored energy internally.

During the 10 seconds prior to this internal discharge, the charge ready tone will beep intermittently. The charge ready tone will then stop and the monitor message will change to DEFIB XXX J SEL.

9 Determine Patient Condition

Repeat procedure if necessary according to local protocol.

Synchronized Cardioversion



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.

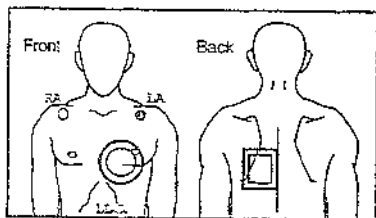
During synchronized cardioversion, the defibrillator discharge occurs when triggered by a patient R-wave. The ZOLL 1600 shows a marker pulse on the patient ECG to indicate the point in the cardiac cycle where discharge will occur. This marker pulse appears as an intensified "dot" or "line" on the ECG waveform. For documentation, a (↓) marker also designates this discharge point above the waveform on the strip recorder printout.

- 1 Determine patient condition following medical protocols**
- 2 Provide patient care following medical protocols**

Request additional assistance.

3 Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.



Attach ECG electrodes.

A standard ECG cable and ECG electrodes are recommended for use during cardioversion. Multi-Function electrodes may be used as an ECG source and signal quality will be equal to that of standard leads except immediately following a discharge when there may be more noise due to muscle tremors, especially if an electrode is not in complete contact with the skin. The use of a standard ECG cable also provides the choice of three different leads for ECG source; Multi-Function electrodes provide only one.

Apply Multi-Function electrodes to the patient according to the instructions on electrode packaging.

Ensure that the electrodes are in good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the multi-function cable unless preconnected.

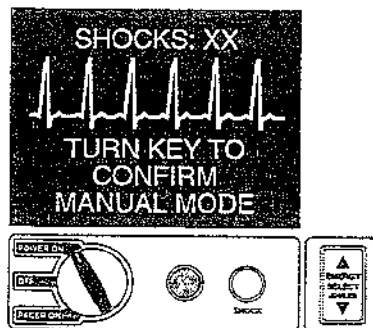
4 Select Power On

Turn the selector switch to Power On. The ZOLL 1600 will power on in semiautomatic mode.

The 1600 will beep 4 times to indicate power-on self-test has passed. If the audio recorder is present, the unit will begin recording audio data immediately.

5 Switch to Manual Mode

Turn the manual mode key clockwise. The 1600 displays a message, "Turn Key To Confirm Manual Mode".

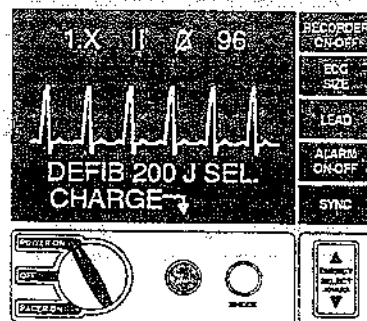


Turn the key clockwise again within 5 seconds to confirm manual mode operation.

The 1600 will now be in manual defibrillation mode.

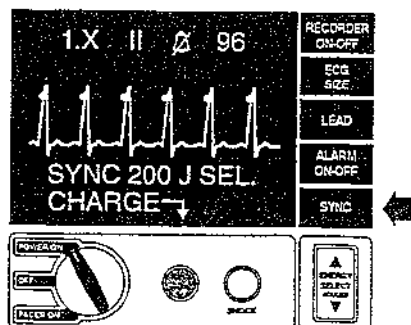
Verify that the patient requires a shock.

6 Select Desired ECG lead



Use the Lead button to select the desired lead. The lead selected is displayed on the top of the monitor.

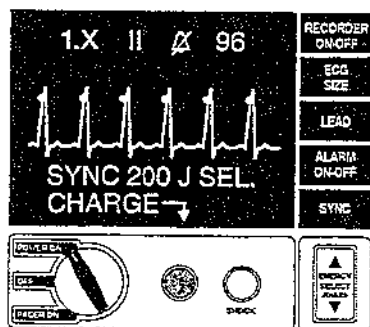
7 Press Sync Button



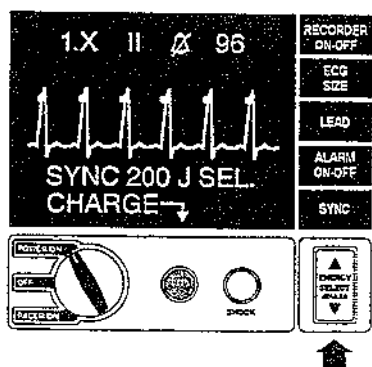
SYNC XXX J will display on the monitor.

An intensified dot or line will appear on the monitor at each detected R-wave to indicate where discharge will occur.

Verify that the intensified dot or line marker is clearly visible on the monitor and is consistent from beat to beat. If necessary, use the Lead button or ECG Size button to select the lead which yields the best display.



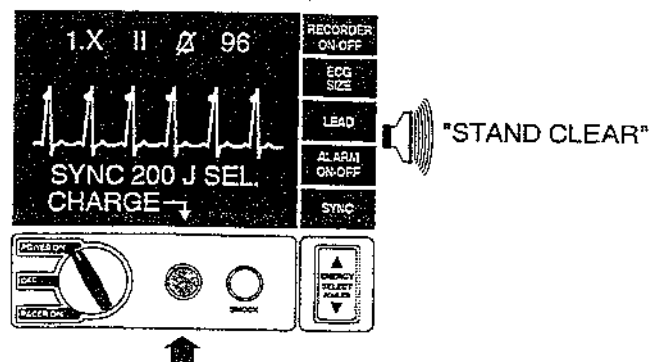
8 Verify Energy Level



The energy level selected will be the level set when the 1600 is powered on. This energy level is displayed on the monitor, SYNC XXX J SEL. If necessary, change the defib energy level using the Energy Select up ▲ and down ▼ arrow buttons. The selected energy level is displayed digitally on the monitor.

If DEFIB XXX J SEL. appears, press the Sync button.

9 Charge Defibrillator



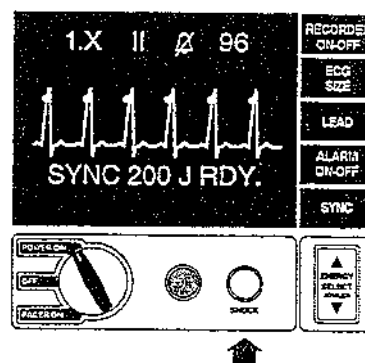
Press the Charge button on the front panel. The "STAND CLEAR" prompt will sound

After 6-10 seconds of charging to the selected energy level, a distinctive audible tone will sound and the energy ready SYNC XXX J RDY. will be displayed on the monitor. The defibrillator is now ready.

To abort charging and increase or decrease the selected energy after the Charge button has already been pressed, use the Energy Select buttons to select a new energy level. Press the Charge button again to charge the unit.

10 Discharge Defibrillator

Verify that no one is in contact with the patient, monitoring cable or leads, bed rails, or any other potential current pathway.

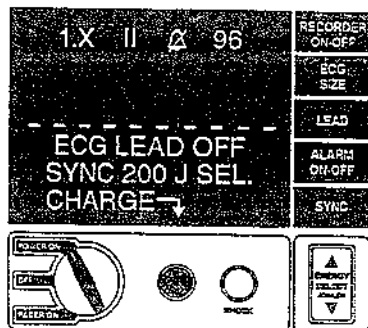


Verify again that the ECG waveform is stable and that a marker pulse appears **ONLY** with each R-wave of the cardiac cycle.

Press and **hold** the Shock button until discharge occurs. The defibrillator will discharge with the next detected R-wave.

After each discharge, the 1600 reverts to standard (non-synchronized) defibrillation. To reactivate sync mode, press the Sync button again. (The 1600 can be configured to remain in sync mode for multiple discharges. Contact your Medical Control Authority).

If additional countershocks are necessary, adjust the energy level as necessary and repeat the procedure.



An ECG LEAD OFF condition (if standard leads are selected as ECG source) will prevent synchronized discharge.

Should you need to disarm the charged defibrillator (if countershock is not needed), change the selected energy level using the Energy Select button. Any stored energy will be discharged internally. The monitor display will change to SYNC XXXJ SEL.

If the defibrillator is not discharged within 60 seconds of reaching the selected energy level, it will automatically discharge the stored energy internally.

During the 15 seconds just prior to this internal disarm, the charge ready tone will beep intermittently. The charge ready tone will then stop and the monitor message will be SYNC XXX J SEL.

Section 4

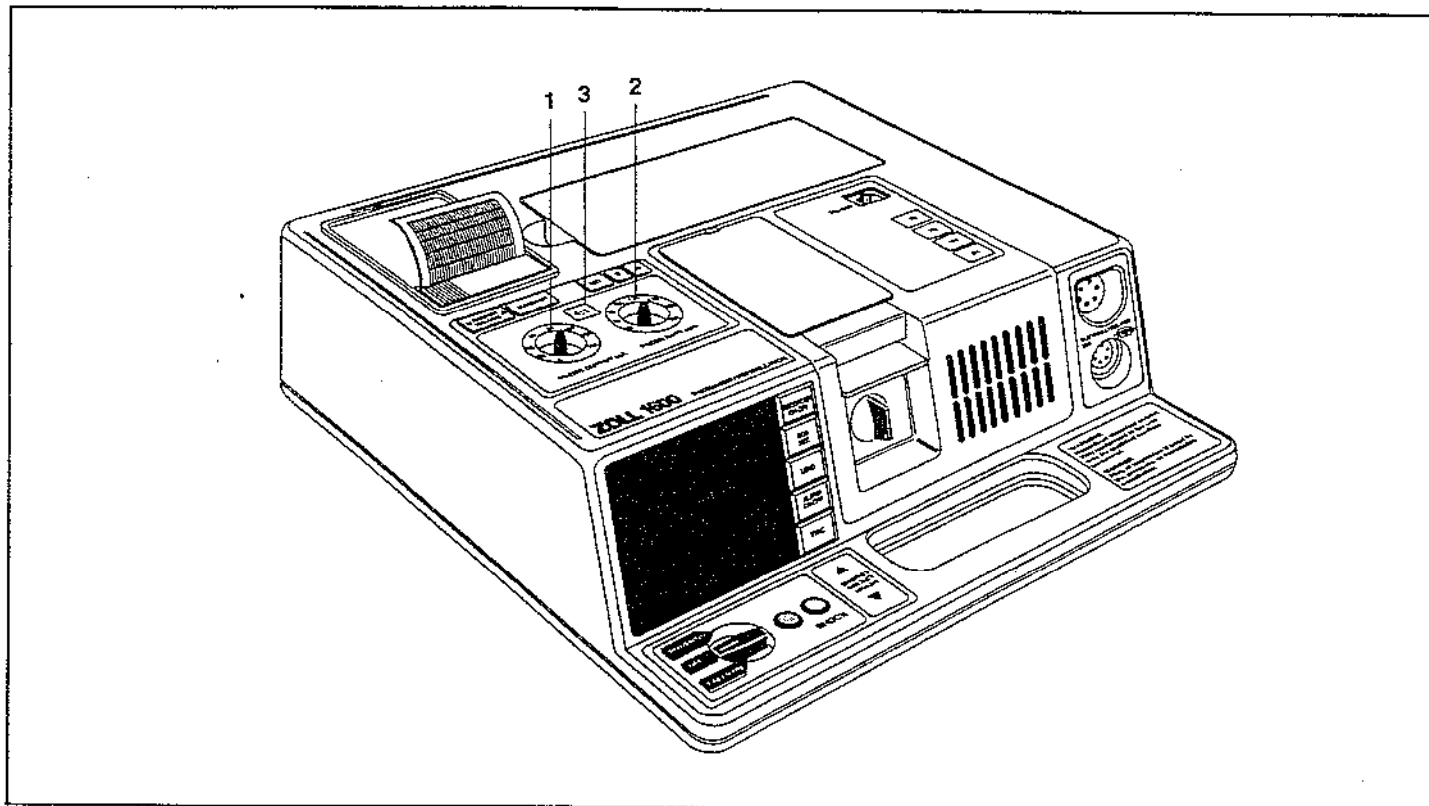
Noninvasive Temporary Pacing



Multi-Function Electrodes are a defibrillation protected Type BF patient connection.



ECG leads are a defibrillation protected Type CF patient connection.



The controls and indicators described below are incorporated in ZOLL 1600's equipped with an external pacer and operating in the manual mode. For other controls active in both semi-automatic and manual modes see Sections 2 and 3.

1. Pacer Output mA

The Pacer Output controls the amount of current (mA) to the pacing electrodes. For conscious patients it should be gradually increased until capture is recognized. The output is displayed digitally on the monitor.

2. Pacer Rate ppm

The Pacer Rate control sets the rate (in pulses per minute) at which the PD 1600 will operate. It must be set above the patient's intrinsic rate in order for the pacemaker to provide stimulation.

3. 4:1 Button

The 4:1 function is used optionally to test for threshold or to determine the patient's underlying rhythm. When depressed, 3 of every 4 pace pulses are suppressed. Releasing the control causes the instrument to resume normal operation.

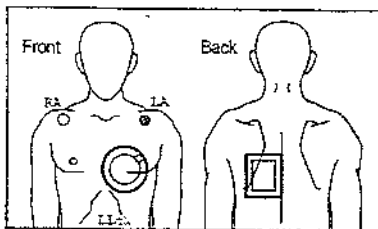
Noninvasive Temporary Pacing

1 Determine patient condition following medical protocols

2 Prepare Patient

Remove all clothing covering the patient's chest. Dry chest if necessary.

3 Apply Electrodes



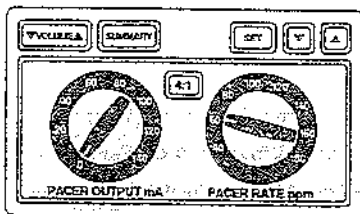
Attach ECG electrodes.

Apply Multi-Function electrodes according to the instructions on electrode pouch.

Ensure that all of the electrodes are making good contact with the patient's skin and are not covering any part of any other electrodes.

Connect electrodes to the ECG and Multi-function cables.

4 Set Pacer Output to 0mA



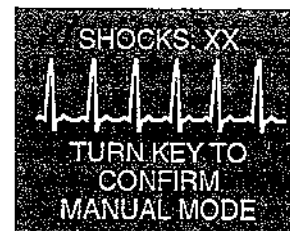
5 Select Pacer On



The ZOLL 1600 will prompt to switch to manual mode.

6 Switch to manual mode

Turn the manual mode key clockwise. The 1600 displays a message, "Turn Key To Confirm Manual Mode."

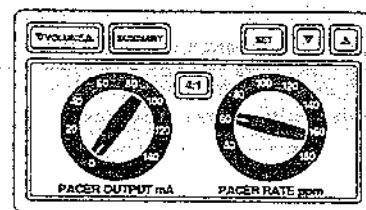


Turn the key clockwise again within 5 seconds to confirm manual mode operation.



Adjust ECG size and lead for a convenient waveform display. Verify proper R-wave detection. The heart-shaped R-wave detector flashes on the monitor when proper detection of R-waves is taking place.

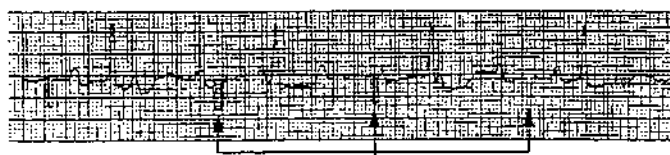
7 Set Pacer Rate



Set pacer rate to a value 10-20 ppm higher than patient's intrinsic rate. If no intrinsic rate exists, use 60 ppm.

8 Observe Pacing Artifacts

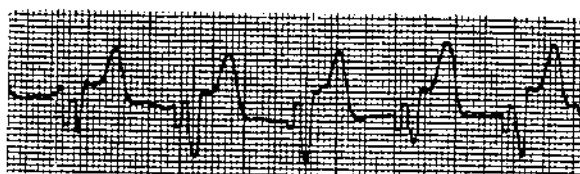
Pacing Below Threshold



Observe the pacing artifact (stimulus markers \square) and verify that it is well positioned in diastole.

Pacing Above Threshold

Effective pacing has been established.

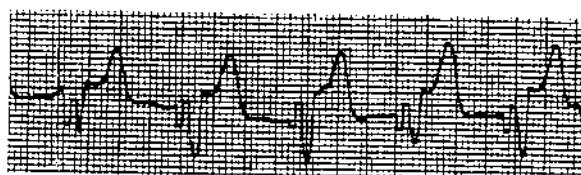


Increase pacer output mA until stimulation is effective (capture). Pacer output mA value is displayed digitally on the lower right of the monitor.

9 Determine Capture

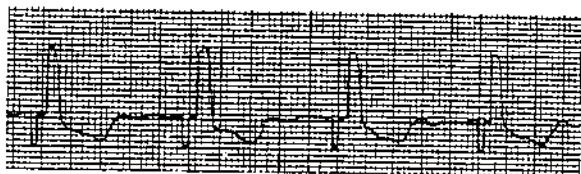
It is important to recognize when stimulation has produced a ventricular response. Ventricular response is normally characterized by suppression of the intrinsic QRS complex. The following traces are typical.

Effective Pacing



Note negative R-wave and large T-waves.

Effective Pacing



Note the widened positive QRS which looks like an ectopic beat. A paced beat is by definition an ectopic beat.

Effective Pacing



Note the inverted T-waves and the absence of P-waves.

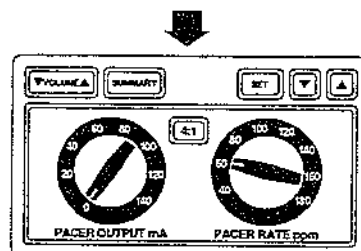
Changing ECG leads and size can sometimes be helpful in determining capture.

Note Shape and size of the stimulated waveforms can vary depending on lead chosen; variation from patient to patient can be expected.

10 Determine Optimum Threshold

The ideal output current is the lowest value that will maintain capture. This is usually about 10% above threshold. Typical threshold currents are usually between 40 and 80 mA. The electrode placement that offers the most direct current pathway to the heart while avoiding large chest muscles will usually produce the lowest threshold. Low stimulation currents produce less skeletal muscle contraction and are better tolerated. Placement of the electrodes will affect the current required to obtain ventricular capture.

After adjusting the electrodes to determine the best location for optimum threshold, the area should be cleaned of salt or other conductive materials (such as defibrillator gel). The electrodes may then be secured.

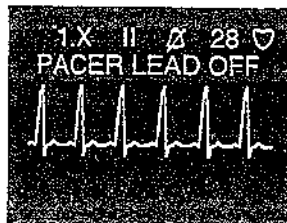


4:1 Test Mode

The 4:1 test mode can be used optionally to test for threshold. In this mode a stimulus is delivered to the patient approximately every fourth pace beat. (The stimulus is demand-synchronized to the patient's intrinsic beat.) Releasing the control causes the instrument to resume normal operation.



PACER LEAD Fault



The message "PACER LEAD OFF" appears on the monitor (in PACER ON mode) whenever the Multi-Function electrodes do not make good skin contact. "CABLE FAULT" will be the monitor message if the Multi-Function cable is not connected properly.

SPECIAL PACING APPLICATIONS

Standby Pacing

For certain patients at risk of developing symptomatic bradycardia, it may be advisable to use the ZOLL 1600 in standby. When used in standby mode, the 1600 automatically provides a pacing stimulus whenever the patient's heart rate drops below a predetermined level. To use the ZOLL 1600 in standby mode:

1. Establish effective pacing (see instructions on previous pages). Note the mA output at capture and run an ECG strip to document ECG morphology at capture.
2. Set the mA output 10% higher than the minimum mA output necessary to effect consistent ventricular capture.
3. Turn the pacing rate below the patient's heart rate. This suppresses pacing unless the patient's own rate drops below the set pacing rate. The pacing rate should be set at a level needed for adequate cardiac output.
4. Check the threshold periodically.

Asynchronous Pacing

The ZOLL 1600 is a VVI demand pacemaker—the safest and most effective design for Noninvasive Temporary Pacemakers. Proper demand pacing requires a reliable high quality surface ECG. If ECG electrodes are not available or there is some circumstance which prevents or interferes with the surface ECG, it may be necessary to operate the pacemaker asynchronously.

To pace asynchronously, simply detach the surface ECG electrodes or remove the ECG cable and set the rate and mA at the

known capture level or high enough (100mA) to presume capture. You should be aware that there will be no ECG activity on the ZOLL 1600 monitor and other means of determining capture such as the patient's pulse will be necessary. Asynchronous pacing should only be performed in emergency situations where there are no other alternatives.

Pediatric Pacing

Noninvasive pacing on pediatric patients is done in an identical manner to adult pacing. Smaller size pediatric Multi-Function Electrodes are available for patients less than 15 kg. Continuous pacing of neonates can cause burns. If it is necessary to pace for more than 30 minutes, caution and periodic inspection of the underlying skin is strongly advised. Carefully follow all instructions on electrode packaging.

Section 5

Battery Management

Safe, reliable use of the ZOLL 1600 system requires a well designed battery management program to ensure that adequate battery power is always available.

ZOLL Medical has developed the ZOLL Battery Management Program. It includes information for determining your particular battery requirements and program implementation steps to setup a comprehensive, effective and safe program.

The 7 key steps to developing a battery program are:

- A. Obtaining proper equipment.
Plan to have a sufficient number of battery packs and chargers to insure an adequate supply of fully charged primary use and spare use batteries.
- B. Assign a responsible individual.
Assign the responsibility to an individual who can oversee all aspects of the program as well as educate other ZOLL 1600 users.
- C. Define battery exchange and charging routines.
Clinical and technical staff should determine desired use patterns and an optimum sequence to insure consistent charging and exchange routines.
- D. Ensure sufficient spare battery capability.
A fully-charged spare battery should be kept immediately available with the ZOLL 1600. The availability of more than one spare battery is recommended in cases where prolonged or repeated use of the device may be required, such as long transport situations.
- E. Develop backup procedures.
Procedures to maintain appropriate life support (such as cardiopulmonary resuscitation) should be pre-planned in the event of a device failure and another battery or device must be sought.
- F. Test batteries regularly.
Develop a testing schedule as part of your organization's battery management. The appropriate frequency of testing depends on the age of the battery pack and the frequency and type of use. As the battery ages, testing should be more frequent since failure will occur rapidly at the battery's end-of-life. At a minimum, ZOLL recommends testing every three months.

PD 4410 Battery Pack

The ZOLL PD 4410 Battery Pack is a five-cell assembly of sealed lead-acid batteries specifically designed for use with the ZOLL 1600, 2000, and 1400 devices.

Lead acid battery packs require full recharging after use. Continuous short cycle recharging will result in reduced capacity and early battery pack failure.

Battery Life Expectancy

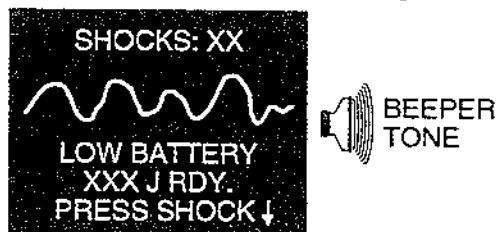
Frequency of use, number of batteries used for ZOLL 1600 operation, and the pattern of discharging and recharging batteries contribute to the loss of battery charge capacity. Because of this ZOLL recommends that operators replace and discard used batteries on a preventive, scheduled basis. The most effective preventive replacement interval should be based on anticipated use patterns, battery pack testing results and experience with the device in actual operation. ZOLL recommends battery replacement every eighteen months or sooner.

For more information about such a schedule, contact your ZOLL Technical Service Representative.

Low Battery Message

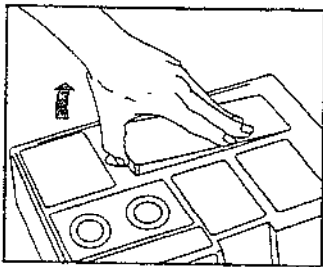
As individual battery capacity diminishes, the amount of operating time remaining after a 1600 LOW BATTERY message also diminishes. For newer or lesser-used batteries, the operating time remaining after this warning will be significantly longer than the operating time remaining on batteries having seen more use. In either case, this warning will ultimately lead to defibrillator shut-off, and consequently, the low battery should be replaced with a fully-charged battery as soon as possible.

When a LOW BATTERY message is displayed on the 1600 monitor, replace the battery pack immediately to ensure continuous operation. With a newer or lesser used battery the unit will beep twice every 20 seconds before shutting off due to a low battery.



Changing the Battery Pack

The ZOLL 1600 is designed for quick removal and replacement of the battery pack. To remove the battery pack, turn the unit off. Insert a finger into the recess at the left end of the battery pack, press against the battery pack to disengage the battery pack locking clip and lift the battery pack out. To install a battery pack, align the "D" shaped recess molded into the battery pack case with the battery pack removal finger recess in the 1600. Set the battery pack into the battery pack well. The shape of the battery pack will allow the battery pack to seat itself. Turn the defibrillator back on to the selected mode of operation.



It is recommended that the selector switch be turned to the OFF position before changing the battery. The selector switch may then be turned to the desired operating mode to resume operation.

This sequence is recommended as general good operating practice for any ZOLL device and is required to restart the device after a LOW BATTERY shutdown has occurred. Note that some settings, for example, alarm settings, lead selection, and ECG size, may need to be restored from their default values when operation is resumed.

Charging PD 4410 Battery Packs

PD 4410 batteries are designed to be charged in a four-compartment battery charger. They may also be recharged by other accessory chargers designed for use with ZOLL devices.

The following general practices will ensure the longest life from PD 4410 Battery Packs:

- Charge batteries completely. When a battery pack exchange is required, place a fully-charged battery in the ZOLL 1600. In an emergency, if no fully-charged batteries are available, a partially-charged battery may be used, but may result in very short 1600 operating times. If a partially-charged battery is used, complete a full charge cycle before its next use. Repeated use after partial charging will quickly diminish the battery's charge capacity, shortening the life of the battery.
- Do not leave batteries uncharged. Once a battery is removed from the 1600 it should be immediately placed in a charge or test well. Idle batteries will lose some of their charge and may suffer damage to charge capacity if left in a discharged state.
- Do not discharge batteries completely. Battery life will be improved if batteries are recharged before complete discharge of

capacity.

- Understand LOW BATTERY implications. As individual battery capacity diminishes, the amount of operating time remaining after a 1600 LOW BATTERY message also diminishes. For newer or lesser-used batteries, the operating time remaining after this warning will be significantly longer than the operating time remaining on batteries having seen more use. In either case, this warning will ultimately lead to defibrillator shut-off, and consequently, the low battery should be replaced with a fully-charged battery as soon as possible.
- Test batteries periodically. Your organization must determine an appropriate testing schedule. Adherence to this schedule is critical in achieving satisfactory results from your 1600 and batteries.
- Complete a shift check of the device. Your 1600 should be tested at the beginning of every shift. This procedure tests the readiness of the unit itself. If the 1600 shows a LOW BATTERY message during testing at the beginning of a shift, the battery currently in use is close to depletion and should be replaced and charged. The shift test does not test the battery for adequate charge to support extended use of the unit, which can only be determined by testing the battery in the PD 4420 Charger.
- Implement a means of indicating the charge status of battery packs. An effective battery management program includes a method of visually determining whether a battery pack is charged and ready for use or is in need of charging.

Single Battery Charger

The Single Battery Charger charges one battery to full capacity in a maximum of 24 hours while connected to AC power.

Battery Support System

Battery pack charging and charge capacity evaluation is easily performed with the ZOLL PD 4420 Battery Support System. Up to four battery packs can be charged simultaneously and testing is a simple one step operation.

PowerCharger AC Power/Charger Module

The ZOLL PowerCharger is an accessory for the ZOLL 1600. The PowerCharger recharges the battery while installed in the 1600 and provides operating power to the instrument even if the battery is removed. The PowerCharger is attached to the rear of the 1600 and plugs into a standard AC outlet.

Additional battery and charging information can be found in the PD 4420 Battery Charger Operator's Guide and the ZOLL PowerCharger Operator's Guide. It is recommended you read your charger instructions thoroughly.

Section 6

Recommended Daily Checkout

Resuscitation equipment must be maintained to be ready for immediate use. This section describes the post-operation maintenance and daily shift check you should perform on your ZOLL 1600. The maintenance can be completed in a few minutes and requires an ECG simulator. It is important that recommended post-operation checks be made after 1600 use since subsequent users may not be able to check the unit before an emergency situation.

At the end of the checkout procedure section is an Operator's Shift Checklist sheet for the ZOLL 1600. Copy and distribute this sheet to all individuals responsible for 1600 use and readiness.

Unit Care

Caution

- Do not sterilize the ZOLL 1600.
- Do not immerse any part of the 1600 in water.
- Do not use alcohol or ketones (MEK, acetone, etc.) on the 1600.
- Avoid using abrasives (e.g., paper towels) on the monitor window.
- Clean the ZOLL 1600 and cables with a soft cloth, mild soap and water. The recorder parts should be cleaned with a damp, soft cloth only.

Recommended Daily Checkout

This brief checklist is intended for non-technical personnel.

If a problem is discovered during the checkout procedure, call ZOLL Technical Service.

More thorough checkout procedures and troubleshooting information can be found in the *ZOLL 1600 Service Manual*.

1. Visual Inspections

- Check that the unit is clean (with no fluid spills) and nothing is stored on the unit.
- Inspect the unit and its accessories for physical damage. Check all cables, cords, and connectors for cuts in the insulation, or bent and broken connector pins.
- Make sure that all disposable supplies are available and in proper condition. (ECG electrodes, strip recorder paper, alcohol swabs, razors, antiperspirant, etc.)
- Check that two sets of defibrillation electrodes or Multi-

Function electrodes in sealed packages are available.

Check expiration dates.

- Check that an empty memory card is installed in the unit and a second spare memory card is available.
- Check that a fully charged battery is installed in the unit.
- Check that a fully charged spare battery is with the unit.

Semi-Automatic Mode Testing

1. Power-up Sequence Check

Remove the memory card and install the Multi-Function cable before beginning tests. If the memory card is installed in the 1600 the following tests will be recorded but the available memory (on the card) will be limited. It is recommended that another card be installed before any further recordings are performed.

Turn the selector switch to Power On.

- A 4-beep tone indicates the power-up self-test is completed.

2. Defibrillator Test

Attach the Multi-Function cable to the ECG simulator.

Set simulator to VF.

- Verify that within 30 seconds monitor displays CHECK PATIENT and voice prompt "CHECK PATIENT" is sounded.

Press Analyze button

- Verify the unit charges to 200J or other preconfigured level.
- Verify PRESS SHOCK message appears and "PRESS SHOCK" voice prompt is heard.

Press SHOCK button.

- The SHOCK XX display message should change from 0 to 1.
- If the SHOCK XX stays at 0, contact your biomedical staff or ZOLL Technical Service immediately.

3. Strip Recorder Operation Check (Optional configuration)

Press the Recorder On/Off button.

While the recorder is running, press and hold the Set up (▲) arrow and Set down (▼) arrow buttons simultaneously.

- This will generate calibration pulses on the recorder paper and CRT.
- Inspect the recorder waveform for uniformity and darkness.

- Inspect for uniformity of annotation characters and completeness of words.
- Check recorder speed by verifying that a new calibration pulse appears approximately every 13 small divisions (13 mm).
- Check amplitude of recorder pulses to be 10 small divisions (10mm).

Check for adequate supply of paper.

A NO PAPER message appears on the monitor when the strip recorder is activated without paper. The strip recorder automatically shuts off when there is no paper.

Loading Strip Recorder Paper

Press the recorder door release button. The door and paper carriage will tilt up.

Remove the empty or low paper roll.

Place a new roll of thermal paper between the two side knobs with the paper coming off the top of the roll and the grid facing down.

Pull enough paper off the roll so that the paper extends out of the strip recorder when the strip recorder door is closed

Close recorder door.

Manual Mode Testing

Turn the selector switch to Power On. (Remove Memory Card)

- A 4-beep tone indicates the power-up self-test is completed

Switch to manual mode after turning on the power to see the following:

- READY message will be displayed briefly, followed by MONITOR, in the lower left of the display screen.
- The ECG size should be 1x.
- ELECTRODES should be displayed in the center of the display screen.
- The message ECG LEAD OFF will be displayed whenever leads I, II, or III have been selected and no ECG cable has been connected, or whenever the lead wires are not attached to a patient.
- Press ECG Size and Lead buttons to verify the following functions:
 - ECG Size for .5x, 1.0x, 2.0x, 3.0x
 - Lead Selection for I, II, III, or ELECTRODES when Multi-Function cable is connected.

4. Delivered Energy and Discharge Button Check

WARNING: Use extreme caution in performing the following tests. Make sure that the Multi-Function cable is plugged into the proper connector prior to discharging.

Install a Multi-Function cable.

Plug the Multi-Function cable into the MFC test port.

Turn the selector switch to Power On.

Switch the unit to manual mode.

Select 100J using the energy select up and down buttons on the front of the unit.

Press the Charge button.

- Charge Ready tone sounds within 10 seconds.
- DEFIB 100J RDY on display.

Press Shock button.

- Verify the monitor displays a "Test OK" message.

5. Maintenance After Use

- Inspect the defibrillator cables and electrodes for visible damage.
- Review your inventory checklist for accessories and supplies to ensure that all supplies are refilled and returned to their proper place after each use.
- Be sure the battery pack is fully charged and replace if in doubt.
- Be sure to keep the PD 4410 battery packs plugged into a ZOLL charger whenever they are not in use. This will keep the battery packs fully charged for future use. Battery packs left uncharged for excessive periods (4 to 6 months) may become damaged and require replacement.

6. Pacer Accuracy (Optional configuration)

Turn the unit on in manual mode.

Turn the selector switch to Pacer On.

Turn the Pacer Rate control to 150 ppm.

Press the Recorder On/Off button to generate a strip.

- The pace pulses should occur approximately every 10 small divisions (2 large divisions, 1 cm).

Press the 4:1 button.

- The frequency of pulses should decrease to 8 large divisions, 4 cm per pulse.

Turn the Pacer Output mA control to 0mA.

- There should be no PACE LEAD OFF message.
- Remove pacer cable from the unit.

Slowly turn the Pacer Output mA control to 15mA.

- The PACE LEAD OFF message should appear.

- The PACE LEAD OFF message should appear.

Replace the memory card.

Setting Time and Date

Check the time and date on the recorder annotation or go into Clock Set mode. If they are not correct, set the time and date as follows:

Turn the selector switch to Off.

Press and hold the Set button on the top of the 1600.

With the Set button pushed, turn the selector switch to the Power On position. When the date display appears on the monitor, release the Set button. Observe the DATE message on the lower portion of the screen with the current day flashing.

Use the Set up (▲) arrow to increase the value and use the down (▼) arrow to decrease the value. Observe that holding the ▲ arrow will increment repeatedly while holding the ▼ arrow will decrement repeatedly.

The range of acceptable values is 1 through 31. Set the value to the current day.

Press the Set button again and observe that the month is now flashing. Repeat above steps to set the correct month. The range of acceptable values is JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC.

Press the Set button again and observe that the current year now flashes. Repeat above steps to set the correct year. The range of acceptable values is 00 through 99.

Press the Set button again. The DATE message is replaced by a TIME message indicating the current hour and minute.

The displayed hour now flashes. Repeat above steps. The range of acceptable values is 00 through 23 (military clock). Set the value to the current hour.

Press the Set button again. The displayed minute now flashes. Repeat above steps. The range of acceptable values is 00 through 59.

Press the Set button again. The lower portion of the screen returns to the normal display.

If the ZOLL 1600 has a strip recorder, verify that the time and date are set correctly by generating a strip chart recording. Press the Recorder On/Off button and check that the strip chart is correctly annotated with the current time and date, selected ECG size,

source, and heart rate.

Verify that the real-time clock is operating correctly by waiting for several minutes before running the strip recorder again.

Note Time and date may require resetting if the 1600 has been without battery packs for more than 12 hours, or if the installed battery pack has been without a charge for more than 12 hours.

ZOLL 1600 Service

If the ZOLL 1600 fails any test, contact your biomedical staff or call ZOLL Medical.

U.S.A. Customers

If your instrument needs service, refer to the *ZOLL 1600 Service Manual* or contact ZOLL Service at 1-800-348-9011 (in Mass. 1-617-229-0020).

International Customers

If your instrument needs service, refer to the *ZOLL 1600 Service Manual* or contact your nearest authorized ZOLL service center. (Refer to page 8)

Operator's Shift Checklist For ZOLL 1600 Semi-Automatic Mode & ZOLL 1600 Manual Mode

Recommended checks and procedures to be performed at the start of each shift. For more detailed information, see the ZOLL 1600 Operator's Guide.

Date _____

Location _____

Unit Serial Number _____

1. ZOLL 1600 Condition

1st Shift 2nd Shift 3rd Shift

Remarks

Unit clean, no spills, clear of objects on top, case intact				
2. Defibrillator Pads				
Two sets present				
Package sealed, with appropriate expiration date				
3. Inspect cables for cracks, broken wires, connectors				
A ECG electrode cable, connector				
B Multi-function cable, connector				
4. Batteries (2)				
A Fully charged battery in unit				
B Fully charged spare battery available				
5. Memory Cards (2)				
6. Disposable Supplies				
A ECG electrodes				
B Recorder paper				
C Alcohol wipes				
D Razors				
E Antiperspirant				
6. Unit Tests (See Section 6 of User's Guide)				
A Power Up Sequence Test				
B Defibrillator Test (Semi-Automatic Mode)				
C Strip Recorder Operation Check (Optional)				
D Manual Mode Inspection				
E Delivered Energy and Discharge Button Check (Manual Mode)				
F Pacer Accuracy (Manual Mode Option)				
7. Maintenance After Use				

8. Please check the appropriate box after each use of this checklist

Signature _____

No Action Required				1st _____
Minor problem(s) corrected				2nd _____
Disposable supplies replaced				3rd _____
Major problem(s) identified - UNIT OUT OF SERVICE				

Section 7

Troubleshooting (Semi-Automatic and Manual Mode)

The troubleshooting guide provided on the following pages is intended for use by non-technical medical personnel during ZOLL 1600 operations. This section answers many of the common problems or questions that arise during operation. This Section is divided into Semi-Automatic Mode and Manual Mode.

If trouble persists after consulting this guide, contact the appropriate technical personnel or ZOLL Technical Service. A more detailed troubleshooting guide is found in the ZOLL 1600 Service Manual.

Semi-Automatic Mode

Defibrillator

<i>Symptom</i>	<i>Recommended Action</i>
1 A STATUS XX message appears on monitor display.	1 Contact ZOLL Technical Service Department immediately.
2 Defibrillator won't charge (energy level does not increment on display).	1 Check that Shock button is not stuck on. 2 Replace battery pack. 3 Turn unit off, then turn on and restart protocol.
3 Charge time to 360J exceeds 10 seconds.	1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.
4 Energy will not discharge when SHOCK button is pressed.	1 Fifteen (15) seconds had elapsed after initial charge. 2 Energy was internally discharged. 3 Unit not completely charged when SHOCK button is pressed. Wait for ready message and ready tone. 4 No shock is advised. 5 Turn unit off, then turn on and restart protocol. 6 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.
5 No apparent energy delivery to patient.	1 Check for CHECK ELECTRODES message on monitor. 2 Ensure proper placement and contact of Multi-Function Electrodes. 3 Under certain circumstances, some patients will not "twitch" when energy is delivered. 4 Turn unit off, then turn on and restart protocol. 5 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.
6 "NOISY ECG" "RETRY ANALYSIS"	1 Check for proper application and adhesion of Multi-Function Electrodes. 2 Check to make sure that nobody is touching the patient and that the patient is motionless.

- | | | |
|---|-------------------|---|
| 7 | "CHK. ELECTRODES" | <ol style="list-style-type: none"> 1 Ensure proper placement and contact of the Multi-Function Electrodes and that the patient does not have excessive hair beneath the electrodes. 2 If message persists, disconnect cable from electrodes and plug cable into test connector. "CHK. ELECTRODES" message will disappear. |
|---|-------------------|---|

Monitor

<i>Symptom</i>		<i>Recommended Action</i>
8	Unit does not turn on. (No 4 audible beeps).	<ol style="list-style-type: none"> 1 Check that battery pack is properly installed. 2 Replace battery pack with a fully charged battery pack.
9	Unit turns on with 4 beeps, but no display on monitor.	<ol style="list-style-type: none"> 1 Replace battery pack with a fully charged battery pack. 2 Option to Display ECG may be turned off (Check with your Medical Control Authority)
10	If a STATUS XX message appears on monitor display.	<ol style="list-style-type: none"> 1 Contact ZOLL Technical Service immediately.
11	SET CLOCK message appears on the monitor display.	<ol style="list-style-type: none"> 1 Reset time and date information. (See Section 6.)
12	ECG LEAD OFF message appears on the monitor display.	<ol style="list-style-type: none"> 1 Check that the ECG cable is connected to patient and instrument. 2 Check that ECG electrodes are not dry. 3 Replace ECG cable.
13	Poor ECG signal level, calibration pulse normal (10mm @ 1mV.)	<ol style="list-style-type: none"> 1 Ensure ECG electrodes are not dried out and are making good contact. 2 Apply new electrodes using different placement.

Strip Chart Recorder

<i>Symptom</i>		<i>Recommended Action</i>
14	NO PAPER message appears on monitor.	<ol style="list-style-type: none"> 1 Recorder out of paper. 2 Remove paper, check paper type, check recorder for paper jam, reload paper. 3 Recorder needs replacement.
15	Recorder makes a stuttering sound when activated.	<ol style="list-style-type: none"> 1 Check paper path of recorder for paper jam.
16	Light or poor quality tracings/annotations on paper.	<ol style="list-style-type: none"> 1 Ensure correct paper is in use. 2 Ensure paper is installed grid side against recorder print head. 3 Recorder print head requires cleaning (trained personnel only).

Manual Mode

Noninvasive Pacing

WARNING

Be sure that pacer output current (mA) is set to "0mA" when connecting or disconnecting a patient from the ZOLL 1600.

<i>Symptom</i>	<i>Recommended Action</i>
1 PACER LEADS OFF message appears on monitor display.	<ol style="list-style-type: none"> 1 Check that Multi-Function Electrodes are connected to appropriate cable. 2 Ensure electrodes are not dry. Do not use ECG or defibrillator gel. 3 Replace electrode if necessary. 4 Ensure good electrode-to-patient contact—no buckling or falling off. 5 Check integrity of Multi-Function Cable - plug into test connector attached to the multi-function cable. PACER LEAD OFF message should disappear. 6 Replace Multi-Function Cable.
2 No stimulus marker present on ECG trace displayed on monitor	<ol style="list-style-type: none"> 1 Ensure ZOLL 1600 is in PACER ON mode. 2 Ensure pacing rate (ppm) dial is set greater than patient rate.
3 No ventricular capture beat after stimulus marker on ECG monitor display.	<ol style="list-style-type: none"> 1 Check for pulse of patient. 2 Increase output current level. 3 Change ECG Lead select. 4 Review pacing electrode placement. 5 Verify that pacemaker is delivering the proper current using the ZOLL NTP 4450 Pace Check, or have appropriate technical staff check output.
4 Patient on Standby pacing gets paced intermittently.	<ol style="list-style-type: none"> 1 If ECG lead wire comes off, pacer will automatically pace asynchronously. 2 Check ECG electrode connection and placement. 3 Check ECG cable for damage. 4 Patient R wave-to-R wave interval varying. Pace rate close to patient rate.
5 Heart rate is 0 with proper pacing capture displayed on ECG trace.	<ol style="list-style-type: none"> 1 Check patient's pulse. 2 Change ECG size. 3 Change ECG Lead selection.
6 Bedside/Central Station monitor display becomes erratic when pacing.	<ol style="list-style-type: none"> 1 Patients cannot be "double patch" ECG monitored while pacing.

Defibrillator

<i>Symptom</i>	<i>Recommended Action</i>
7 A STATUS XX message appears on monitor display.	<ol style="list-style-type: none"> 1 Contact ZOLL Technical Service immediately.
8 Defibrillator won't charge (energy level does not increment on display).	<ol style="list-style-type: none"> 1 Check that Shock button is not stuck on. 2 Replace battery pack. 3 Turn unit off, then on and restart protocol

9	Charge time to 360J exceeds 10 seconds.	<ol style="list-style-type: none"> 1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Have device serviced.
10	Energy will not discharge when SHOCK button is pressed.	<ol style="list-style-type: none"> 1 Sixty (60) seconds had elapsed after initial charge. 2 Energy was internally discharged. 3 Device is in SYNC mode and no QRS complex is detected. 4 Unit not completely charged when SHOCK button is pressed. Wait for ready message and ready tone. 5 Turn unit off, then on and restart protocol.
11	Unable to SYNC cardioversion discharge.	<ol style="list-style-type: none"> 1 Ensure SYNC is displayed on monitor. 2 Check for SYNC marker (high intensity dot or line on R-Wave). If not present, change ECG size, lead selection, or electrode placement. 3 Alter ECG placement.
12	No apparent energy delivery to patient.	<ol style="list-style-type: none"> 1 Check for CHECK ELECTRODES message on monitor. 2 Ensure proper placement and contact of Multi-Function Electrodes. 3 Under certain circumstances, some patients will not "twitch" when energy is delivered. 4 Turn unit off, then on and restart protocol. 5 Perform defibrillator self test as described in Section 6. If test fails, have the unit serviced promptly.

Monitor

<i>Symptom</i>	<i>Recommended Action</i>
13 Unit does not turn on. (No 4 audible beeps).	<ol style="list-style-type: none"> 1 Check that battery pack is properly installed. 2 Replace battery pack with a fully charged battery pack.
14 Unit turns on with 4 beeps, but no display on monitor.	<ol style="list-style-type: none"> 1 Replace battery pack with a fully charged battery pack. 2 Option to Display ECG may be turned off (Check with your Medical Control Authority)
15 If a STATUS XX message appears on monitor display.	<ol style="list-style-type: none"> 1 Contact ZOLL Technical Service Department immediately.
16 SET CLOCK message appears on the monitor display.	<ol style="list-style-type: none"> 1 Reset time and date information. (See Section 6.)
17 ECG LEAD OFF message appears on the monitor display.	<ol style="list-style-type: none"> 1 Check that the ECG cable is connected to patient and instrument. 2 Check that ECG electrodes are not dry. 3 Replace ECG cable.
18 Poor ECG signal level, calibration pulse normal (10mm @ 1mV).	<ol style="list-style-type: none"> 1 Change ECG size. 2 Change to another lead - I, II, III, or ELECTRODES. 3 Ensure ECG electrodes are not dried out and are making good contact. 4 Apply new electrodes using different placement.

- | | | |
|----|---|--|
| 19 | No systole sound (beat detection) or heart rate and flashing heart are not being displayed on monitor. | <ol style="list-style-type: none"> 1 Patient heart rate less than 20 BPM. 2 Increase beeper volume on top of unit. 3 Change ECG lead selection. 4 Change ECG size. 5 Alter ECG electrode placement. |
| 20 | No sync marker displayed on ECG monitor signal or recorder printout, or intermittently displayed on R-wave. | <ol style="list-style-type: none"> 1 Ensure "SYNC" is displayed on the monitor. 2 Change ECG size. 3 Change ECG lead selection. 4 Alter ECG electrode placement. |

Strip Chart Recorder

Symptom	Recommended Action
21 NO PAPER message appears on monitor.	<ol style="list-style-type: none"> 1 Recorder out of paper. 2 Remove paper, check paper type, check recorder for paper jam, reload paper. 3 Recorder needs replacement.
22 Recorder makes a stuttering sound when activated.	<ol style="list-style-type: none"> 1 Check paper path of recorder for paper jam.
23 SYNC marker (↓) not annotating at top of paper	<ol style="list-style-type: none"> 1 Ensure SYNC is displayed on the monitor. 2 Ensure high intensity dot or line is displayed on ECG signal on monitor. 3 Change ECG lead selection 4 Change ECG size. 5 Change electrode placement. 6 Paper too narrow. It should be 50mm wide.
24 Light or poor quality tracings/annotations on paper.	<ol style="list-style-type: none"> 1 Ensure correct paper is in use. 2 Ensure paper is installed grid side against recorder print head. 3 Recorder print head requires cleaning (trained personnel only).

Appendix A

Medical Report Capability

The ZOLL 1600 medical report capability automatically records incident information for subsequent review and archiving. Data is stored on a removable PCMCIA data card (memory card) for downloading to a properly equipped personal computer. (See the ZOLL Data Control System for information on PC equipment requirements and data retrieval procedures.) Stored data can also be downloaded to a PC via a ZOLL 1600 to serial port cable connection.

The medical report capability begins recording when the 1600 is turned on and continues until the unit is turned off. Patient ECG, unit status, date, time and 1600 control settings are recorded. Audio recording via a microphone located on the front of the 1600 is a configurable option on properly equipped units.

Data recorded during an incident is retained on the memory card until erased. Shutting the 1600 off with the memory card installed or removing the memory card from the unit will not erase the data.

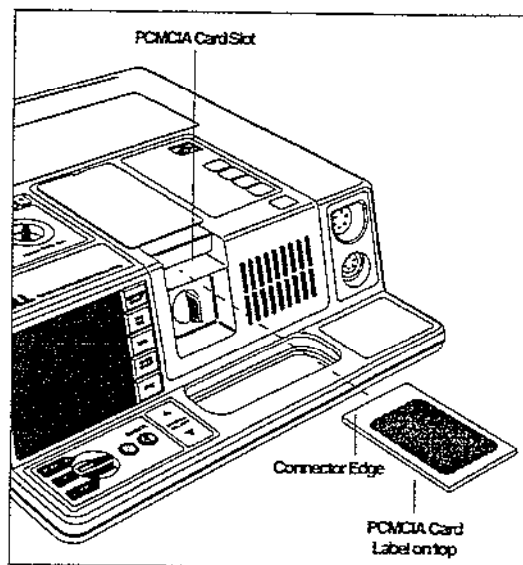
PCMCIA Data Card

The memory card is a self contained electronic storage device similar to a floppy disk. Do not subject the card to extreme temperatures, do not immerse the card in liquids, do not place the card near magnetic objects and do not place heavy objects on the card. Protect the connector located on one short edge of the card from physical damage.

Contact ZOLL Technical Service Department for the current list of supported PCMCIA cards.

Up to two hours of incident data (ECG and unit status) or up to one hour of incident data and simultaneous audio recording can be stored on one 4 megabyte memory card. ZOLL recommends that a spare memory card is always kept with the 1600 and that the memory card is changed after each incident.

Installing the PCMCIA Data Card



Check that there is no physical damage to the connector edge and that the connector edge is clean and free of dirt and debris. Insert the memory card into the slot located in the middle of the 1600. The label side should be up. Slide the card into the unit until it is firmly seated in the card slot.

To remove the card, lift the card slightly and pull the card out of the unit. If the memory card is removed while the 1600 is on, the unit will still operate properly but no event information will be recorded.

Transferring Data to a PC with a PCMCIA Data Card Reader

ZOLL Data Control software must be installed on the PC to access any information transferred from the medical report capability.

Remove the data card from the ZOLL 1600. Insert the card into the PCMCIA data card reader on the PC. See the ZOLL Data Control Guide for instructions on information retrieval procedures and PC equipment requirements.

Downloading Data to a PC via Serial Link

ZOLL Medical Report software must be installed on the PC to access any data downloaded from the medical report capability. (See the ZOLL Data Control System for information on PC equipment requirements and data retrieval procedures.)

Check that there is enough storage space on the personal computer to hold the data from the memory card. The minimum free hard disk space is 4 megabytes.

Connect the serial cable to the serial port on the front of the 1600 and to the PC serial port.

Check that the electrodes are not connected to a patient (or simulator) or that the Multi-Function cable is not connected to the ZOLL 1600. If an attempt is made to enter download mode with the electrodes connected to a patient (or simulator) and the Multi-Function cable connected to the ZOLL 1600, the unit will go into semi-automatic mode and the error message, "REMOVE ELECT." will be displayed.

Check that the correct memory card is installed in the ZOLL 1600.

Press and hold the F1 button on the top panel of the 1600 while turning the selector switch to Power On. The following message will appear on the display.



PRESS F1 TO CONFIRM
DOWNLOAD MODE

Release and press F1 again to confirm downloading. If F1 is not pressed within 10 seconds, the 1600 will return to normal operation in semiautomatic mode.



DOWNLOADING



PRESS F1
TO ABORT

If no error messages appear on the display, the unit will begin to download the data. Transmitting may take several minutes.



PRESS F1 TO
CONFIRM ABORT



PRESS F3
TO CONTINUE
DOWNLOAD

To cancel the download press F1. To confirm the download abort, press F1 again. This will stop the data transfer. Press F3 to cancel the abort request. The 1600 will continue to download the data.



DOWNLOAD
COMPLETE



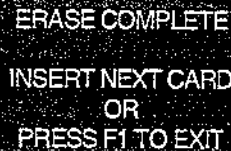
PRESS
F4 TO ERASE
F2 TO SAVE

At the end of the transfer the display indicates the 1600 has successfully downloaded all the information stored on the memory card. Press F4 to erase the memory card or press F2 to exit the download without erasing the card. Erasing the memory card permanently removes all memory card information. To save the memory card information after a successful download, press F2. The card may then be removed from the 1600.



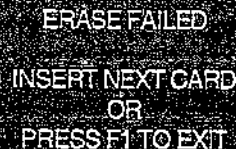
ERASING CARD

If F4 is pressed, a display message indicates the card is being erased.



ERASE COMPLETE
INSERT NEXT CARD
OR
PRESS F1 TO EXIT

Memory card has been erased and is now empty and can be used again to record a different incident.



ERASE FAILED
INSERT NEXT CARD
OR
PRESS F1 TO EXIT

If there is a problem with the memory card erasing procedure, the above message displays on the screen. Press F1 to exit or insert another card.



INSERT NEXT CARD
OR
PRESS F2 TO EXIT

To save the memory card information after a successful download, press F2. The card may then be removed from the 1600 and a

new card inserted for downloading or you may exit the downloading sequence.

TURN TO
POWER OFF
OR PRESS F1
TO ENTER
SEMI-AUTO MODE

Press F1 for the 1600 to return to normal semi-automatic operation.

Error Messages

NO CARD

INSERT CARD
OR
PRESS F1
TO EXIT

The above message appears if there is no memory card installed. Following each message is a list of available options.

CARD PREVIOUSLY
DOWNLOADED
PRESS
F2 TO SKIP
F3 TO DOWNLOAD
F4 TO ERASE

The recorded information on the card has already been downloaded to a PC. The information can be downloaded again if necessary.

CARD EMPTY

REPLACE CARD
OR
PRESS F1
TO EXIT

The memory card installed in the 1600 is empty.

WRONG DATA TYPE

REPLACE CARD
OR
PRESS F1
TO EXIT

The card is a configuration card and not a memory card.

WRONG CARD TYPE

REPLACE CARD
OR
PRESS F1
TO EXIT

The card is not of the required type

CARD REMOVED

DOWNLOAD ABORTED
PRESS
F2 TO SKIP CARD
F3 TO RETRY

If an in progress download is interrupted because the memory card has been removed or dislodged the above message is displayed.

BAD CARD

DOWNLOAD ABORTED
PRESS
F2 TO SKIP CARD
F3 TO RETRY

The card has damaged data and cannot be downloaded.

HOST FAULT

DOWNLOAD ABORTED
PRESS
F2 TO SKIP CARD
F3 TO RETRY

The PC has aborted the download.

SERIAL FAULT

CORRECT FAULT
OR
PRESS F1
TO EXIT

The above message occurs if there is a serial fault. This indicates there is a problem with the cable, the cable connection, or the PC. Following each message is a list of available options.

Appendix B

Strip Chart Recorder Operation Summary Report

Strip Recorder Operation

If the ZOLL 1600 is configured to automatically generate strips, the strip chart recorder will automatically run for 15 seconds after a defibrillator discharge or a heart rate alarm in manual mode. This configuration is selectable (See Appendix D).

A NO PAPER message appears on the monitor when the Strip Chart Recorder is activated without paper. The strip chart recorder automatically shuts off when there is no paper. Press the Recorder On/Off button to start the strip chart recorder again after loading new paper. (See Section 6 for paper replacement)

The following annotations are printed on the top of the strip chart:

1. ANALYZE ECG: Printed when the Analyze button is pressed.
2. CHECK ELECTRODES: Printed when a poor connection of the Multi-Function Electrodes is detected.
3. ANALYSIS HALTED: Printed when the analysis is halted due to a fault condition.
4. NOISY ECG: Printed when excessive noise is detected.
5. SHOCK ADVISED: Printed at the end of user-initiated analysis when a shockable rhythm has been detected.
6. NO SHOCK ADVISED: Printed at the end of user-initiated analysis when no shockable rhythm has been detected.
7. "I": Printed at the end of each 3-second analysis sub-interval.
8. "***": Printed immediately following the last 3 second interval. Three characters are printed immediately following the "I" indicating the results of the analysis for the 3 analysis sub-intervals. A "***" indicates a shockable sub-interval while a "-" indicates a non-shockable interval.
9. "-": Indicates a non-shockable interval. (See 8 above.)

Summary Report

The Summary Report allows the operator to store and later retrieve a printed copy of critical ECG event information. The ZOLL 1600's internal memory automatically records significant events. The Summary Report records all associated event information including 1600 control settings, patient ECG, time, and date. The Summary Report functions independently of the Medical Report Capability to store these events.

The following events will trigger Summary Report to record information:

- Activation of the Heart Rate Alarm.
- Initiating analysis of the ECG.
- Discharging the defibrillator.
- Turning strip chart recorder on (or on and then off in rapid sequence).
- CHECK PATIENT message (when continuous analysis indicates a shockable condition).
- Pressing the "F" keys
- Entering Pacer Mode
- Entering Manual Mode

A Summary Report (header only) is stored when the unit is first powered on. The report will only be stored if the unit has been off for more than 10 seconds or was previously in configuration or download mode, and put into semi-automatic mode.

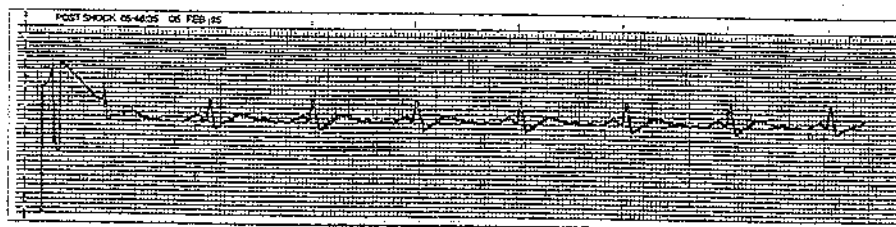
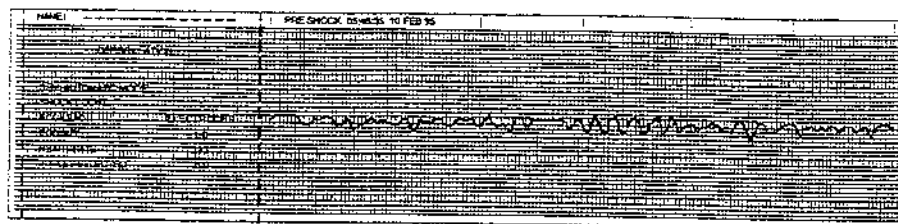
Summary Report records each event in chronological order and will store up to 33 defibrillation or 70 non-defibrillation events. All event data will remain in memory and be accessible until the 1600 has been off for five minutes or the data is manually erased.

If the memory is full and a strip chart recorder is installed, a REPORT FULL message will appear on the monitor and no further events will be recorded until the current memory is erased.

NAME	COMMENTS
1. NAME	
2. ADDRESS	
3. CITY	
4. STATE	
5. ZIP	
6. PHONE	
7. FAX	
8. E-MAIL	
9. COMMENTS	

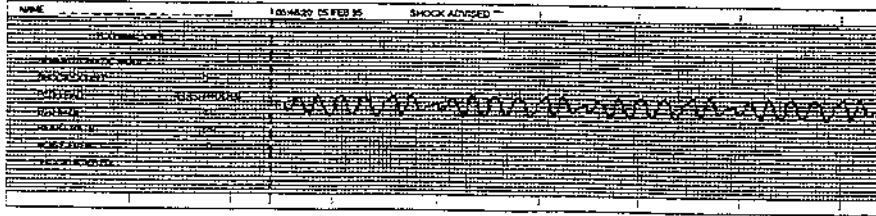
All segments have vertical dashed cut lines every 8.5 inches to facilitate easy mounting on 8.5" x 11" paper. On the last event recorded, SUMMARY COMPLETE will be printed at the bottom left of the strip chart.

Defibrillation Format



Summary Report records 6 seconds of pre-shock and 8 seconds of post-shock patient ECG data. It also records joules selected, sync (if on, including sync indicator marks), ECG lead, ECG size, time, and date.

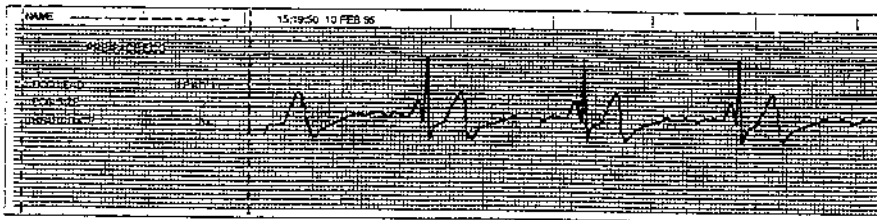
Analyze Format



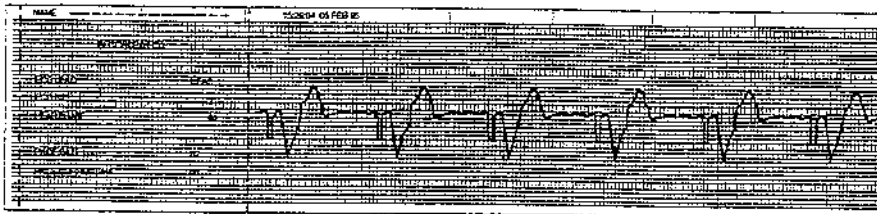
Summary Report records 6 seconds of pre-analysis patient ECG and 8 seconds of post-analysis ECG with the annotation SHOCK ADVISED or NO SHOCK ADVISED.

The following Summary Report formats are available in manual mode only.

Pacer On Format

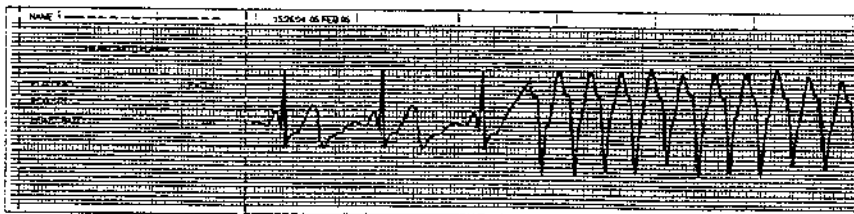


Summary Report records 6 seconds of pre-Pacer On patient ECG. Also recorded is the ECG lead, ECG size, patient's heart rate, time and date.



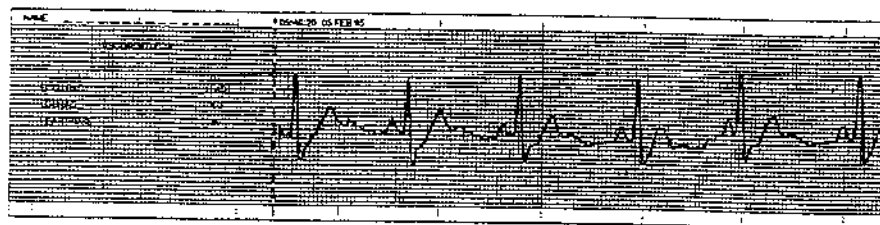
After establishing a paced rhythm, turn the recorder on briefly to record the paced rhythm in Summary Report.

Heart Rate Alarm Activated Format



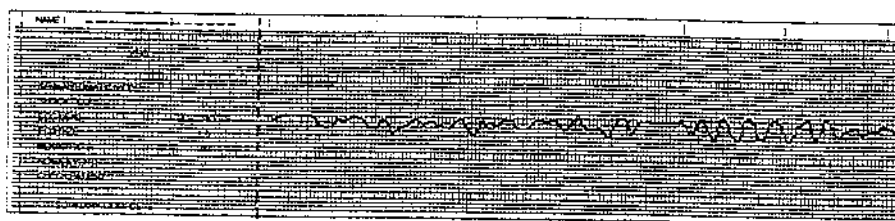
Summary Report records 6 seconds of pre-alarm patient ECG. Also recorded is the ECG lead, ECG size, patient's heart rate, time and date. If the pacer is on during this event, the pacing rate and pacing current is also recorded.

Recorder On Format



Summary Report records 6 seconds of patient ECG stored prior to recorder activation. Also recorded is the ECG lead, ECG size, patient's heart rate, time and date. If the pacer is on during this event, the pacing rate and pacing current is also recorded.

Continuous Analysis Report



Summary Report records 15 seconds of patient ECG data. Also recorded is the shock count, ECG lead, ECG size, patient's heart rate, and noise events.

Print a Summary Report on the Strip Chart Recorder

To retrieve recorded event reports, press the Summary button on the top of the ZOLL 1600. The strip chart recorder will print all events in chronological order currently in the 1600's internal memory.


If the strip recorder is on or the defibrillator is charging, the Summary button is inactive.

To stop printing a report, press the Summary button again or turn the unit off. You may print an unlimited number of copies of the report simply by pressing the Summary button once for each report and waiting until the printout is complete before pressing the Summary button for the next copy.

The 1600 will interrupt printing a report if the heart rate alarm activates, the Charge button is pressed, or the strip chart recorder turns on. If report printing is interrupted, press the Summary button again.

If the strip recorder is out of paper and the Summary button is pressed a NO PAPER message appears on the monitor. Load paper and press Summary again to print the report.

Erase a Summary Report from the Strip Chart Recorder

The report is automatically erased after 5 minutes when the unit is turned off but may be reconfigured to retain data as long as 90 minutes (See Appendix D). To manually erase all recorded summary information, press and hold the Set up arrow button  and Summary button simultaneously for 4 seconds. An ERASING REPORT message will appear on the monitor.

Note that this does not affect the data stored on the PCMCIA card.

Appendix C

Specifications

General

Size	10.7 cm high x 33.5 cm wide x 31 cm long (4.2 in. x 13.2 in. x 12.2 in.).
Weight	5.9 kg. (13 lbs.) with Multi-function cable.
Power	Sealed lead acid battery - 2.0V/cell, 5 cells - wired in series.
Warranty	In North America: 1 year, including use of a loaner. Outside North America: consult ZOLL authorized representative.
Design Standards	Environmental tests include the following: RF immunity per IEC 801-3 to 20V/M, EMI emissions per CISPR 11 class A, Vibration per IEC 68-2-6 and IEC 68-2-34, Shock per IEC 68-2-27, and moisture per IEC 529 standard IPX4.
Patient Safety	All patient connections are isolated.
Environmental	Temperature: 0°C to 55°C (operating). -20°C to 70°C (storage and shipping). Humidity: 5% to 95% relative humidity, non-condensing.
Operating Modes	Semi-Automatic (default mode) Manual Diagnostic Configuration

Pacemaker

Type	VVI demand; asynchronous (fixed rate) when used without ECG leads.
Pulse Type	Rectilinear, constant current.
Pulse Duration	40 milliseconds.
Pulse Amplitude	Variable to 140 mA.
Pacing Rate	Variable from 30 to 180 ppm.
Output Protection	Fully defibrillator protected and isolated.
Pacer On	Message display on monitor.
Pacer Electrodes	Specifically designed adult anterior/posterior pre-gelled ZOLL electrodes, packaged in pairs. ZOLL pediatric electrodes are also available.

Defibrillator

Waveform	Damped sinusoid.
Output Energy	Selectable at 2, 3, 5, 7, 10, 20, 30, 50, 100, 150, 200, 300, 360 joules.
Energy Selection	Control on unit front panel.
Charge Time	Less than 10 seconds. Depleted battery packs will result in a longer defibrillator charge time.

*NOTE: Specifications subject to change without notice.

ZOLL, PD, *statpads*, PowerCharger, ConnectAlarm, SmartAlarms, ZOLL Data Control Software, *Speed Pack* and *Preconnect* are trademarks of ZOLL Medical Corporation.

Delivered Energy Display	CRT monitor displays delivered energy.
*Synchronized Mode	Synchronizes defibrillator pulse to patient's R-wave. SYNC message displayed on monitor. Marker on monitor and on recorder paper identifies R-wave.
Charge Controls	Control on front panel.
Multi-Function Electrodes	Specifically designed pre-gelled ZOLL electrodes, packaged in pairs, can be used in the anterior/posterior or anterior/anterior position. Adult Stat*Padz Electrodes with pre-connect (12 pair/box) 8900-4003 Adult Radiolucent Multi-Function Electrodes (12 pair/box) 8900-2755 Adult Multi-Function Electrodes (12 pair/box) 8900-2055 Pediatric Multi-Function Electrodes (6 pair/box) 8900-2065

Monitor and Display

Patient Connection	Via 3 lead ECG cable and electrodes. Lead configuration selectable by front panel switch.
Input Protection	Fully defibrillator protected. Special circuit prevents distortion of ECG by pacer pulse.
Bandwidth	0.5-35 Hz (-3dB) standard - .05-35 Hz Diagnostic (optional).
Display Format	Non-fade, moving trace.
Screen Type	High resolution CRT display.
Screen Size	4.5 inches diagonally (56 mm x 86 mm, viewing area).
Sweep Speed	25 mm/sec.
Viewing Time	3.4 seconds.
Heart Rate	Digital display on monitor 0-300 bpm \pm 5%.
*Pacer Output Current	Digital display on monitor 0-140 mA.
*Lead Selection	Display on monitor.
*ECG Size	.5, 1.0, 1.5, 2.0, 3.0 cm/mV - display on monitor.
*Alarm On/Off Status	Display on monitor. User selectable, High 60-280 bpm, Low 20-100 bpm.
ECG Lead Fault	Message display on monitor.
*Pacer Electrode Fault	Message display on monitor.
Defibrillator Electrode Fault	Message display on monitor.
Recorder Paper Out	Message display on monitor.
Low Battery Voltage	Message display on monitor.
*Strip Recorder	
Paper	Standard 40 mm thermal (grid width). 50 mm (paper width).
Speed	25 mm/sec.
Delay	6 seconds.
Annotations	Time, date, defib energy, heart rate, pacer output, QRS sync marker, ECG size, lead, alarm, defib test OK/Fail.
Writing Method	High resolution, thermal array print head.
Print-out Modes	Manual or automatic - user configurable.
Automatic Function	15 second recording initiated by alarm conditions and defibrillator discharge.

PCMCIA Card

Capacity	Standard series II flash card - 4 megabyte or 2 megabyte
*Audio Recording	Digital compressed audio data

Battery Packs

Type	Rechargeable, sealed lead acid
Voltage	2.0 V/cell; 5 cells wired in series.
Recharge Time	Charging systems require different charging times. See appropriate operator's guide for more information.
Service	Battery pack is easily removed as a unit.
Low Battery Indicator	Message displayed on monitor and 2-beep low battery tone sounds once a minute. For a new battery pack in good condition, the 1600 will beep twice every two seconds for the last 20 seconds before shut-off due to LOW BATTERY. The time from display of the LOW BATTERY message until the instrument shuts down will vary depending on the battery pack condition. For a new battery pack (fully charged prior to initiating battery pack operation), the message display-to-shut down time will be approximately 40 minutes in monitor mode. Defibrillator charge time may be extended when battery packs are depleted.
Operating Time	30 defibrillator chargings to maximum energy (360J), or 2 hours of continuous monitoring.
Chargers	Use ZOLL PD 4420 Battery Support System, ZOLL PowerCharger™ or ZOLL supplied single battery charger only for proper operation. See Battery Support System Operator's Guide for detailed information about battery charging and capacity evaluation. See PowerCharger™ Operator's Guide for detailed information about operation with AC line power.

** Indicates optional features*

Appendix D

Configuration Mode

The ZOLL 1600 is designed with several user configurable features to allow each operator(s) to set the device according to their preferences.

A configuration strip can be printed without entering configuration mode by pressing and holding the SUMMARY and VOLUME

DOWN ▼ buttons for four (4) seconds while turning the unit to Power On.

This section lists the configurable features, the default settings and a description of the option. Some features are available to manual mode operators only.

General

Feature	Option	Default
Selected Language	English, French, Japanese	English
Notch Filter	50, 60 Hz	60 Hz
Summary Report erase delay	5, 15, 30, 90 min.	5 Min.
Serial Baud Rate (bps)	9600, 19200, 57600, 115200 bps	57,600 bps
Allow card erase without download	Yes/No	No
Display Elapsed Time	Yes/No	No

Semiautomatic Mode

Feature	Option	Default
Energy level: Shock 1	50, 100, 150, 200, 300, 360 J	200 J
Energy level: Shock 2	50, 100, 150, 200, 300, 360 J	200 J
Energy level: Shock 3	50, 100, 150, 200, 300, 360 J	360 J
Auto Analyze 3 Times	Yes/No	No
"NO SHOCK ADVISED" Prompt	"NO SHOCK ADVISED" "CHECK PULSE" BOTH	"NO SHOCK ADVISED"
"CHECK PATIENT" Prompt	"CHECK PATIENT" "PRESS ANALYZE"	"CHECK PATIENT"
Display ECG in semiautomatic mode	Yes/No	Yes
Display Heart Rate in semiautomatic mode	Yes/No	No
Record Card Data in Monitor Mode	Yes/No	Yes

Manual Mode

Feature	Option	Default
Automatically Generate Strips	Yes/No	Yes
Retain Sync after Defib	Yes/No	No
Initial QRS Volume	Off/Unchanged	Unchanged
Voice Prompts in manual mode	On/Off	On
Audio Recording Enabled in manual mode	On/Off	On
ECG Recording Enabled in manual mode*	On/Off	On

* This only applies to devices containing software release 2.07 or greater.

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Appendix E

Algorithm Accuracy

Sensitivity, specificity, false positive rate and positive predictivity are expressions of the accuracy of an ECG analysis system when compared with clinicians or experts. The specifics of computations are detailed below. The accompanying data details the accuracy of the algorithm as tested by independent investigators.

Algorithm Sequence of Events:

1. The algorithm divides the ECG rhythm into 3-second segments.
2. The algorithm filters and measures noise, artifact, and baseline wander.
3. The algorithm measures baseline content ('waviness' at the correct frequencies-frequency domain analysis) of signal.
4. The algorithm measures QRS rate, width, and variability.
5. The algorithm measures amplitude and temporal regularity ('auto-correlation') of peaks and troughs.
6. If 2-out of-3 are shockable then "SHOCK ADVISED". Algorithm sequence thus takes approximately 9 seconds.

Clinical Performance Results

Applications:	<u># of analysis</u>	<u># of patients</u>
	316	194

Shockable Rhythms

Overall Sensitivity	95.7%
Positive Predictability	100.0%

Non-shockable Rhythm

Overall Specificity	100%
False Positive Rate	0%

Sensitivity = $\frac{\text{\# of "correct shock" decisions by algorithm}}{\text{Total \# of rhythms for which a shock is clinically advised}}$

Specificity = $\frac{\text{\# of "correct no shock" decisions by algorithm}}{\text{Total \# of rhythms for which no shock is clinically advised}}$

False Positive Rate = $\frac{\text{\# of "incorrect shock" decisions by algorithm}}{\text{Total \# of rhythms for which no shock is clinically advised}}$

Positive Predictivity = $\frac{\text{\# of "correct shock" decisions by algorithm}}{\text{Total \# of rhythms for which shock is advised by unit}}$

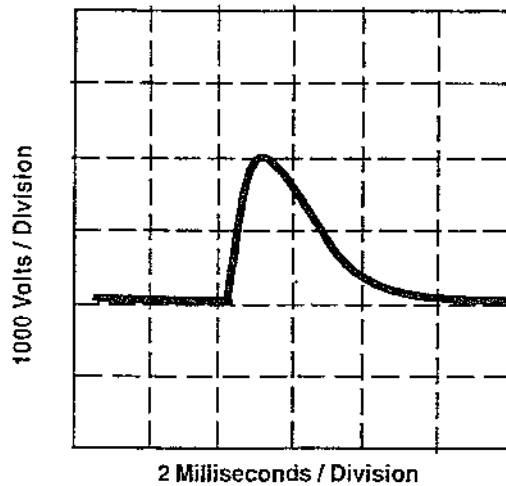
Appendix F

Waveform Information

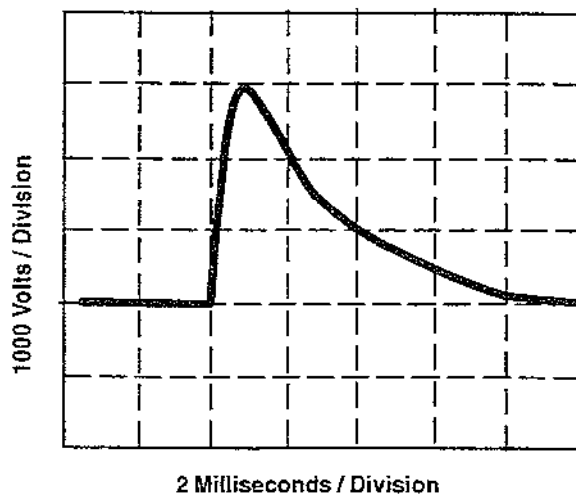
General

The ZOLL 1600 produces the following defibrillation waveforms when discharged into 25, 50, and 100 ohm loads at maximum energy. Each major vertical division equals 2 milliseconds.

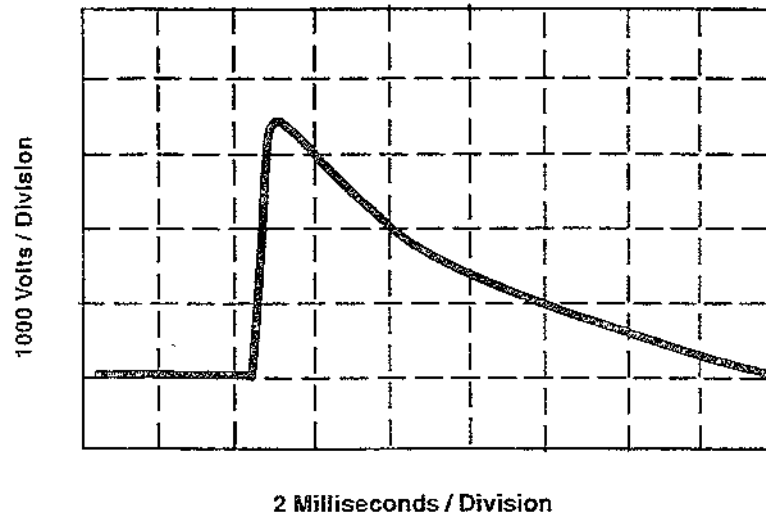
Discharge into a 25 ohm load



Discharge into a 50 ohm load



Discharge into a 100 ohm load



ZOLL**OPERATOR'S MANUALS****ZOLL 1600 #9650-0021 & 1700 #9650-0058****INTRODUCTION**

This addendum provides information describing the operation of the ZOLL 1600 & 1700 devices. Please read this update carefully and add or change the affected pages of your manuals.

Please note the following changes:

ZOLL 1600 (#9650 - 0021)**Section 2: "Semiautomatic Defibrillation": Step 3 "Prepare Patient" (Page 14)**

CHANGE FROM: If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

CHANGE TO: If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Section 3: "Manual Mode Defibrillation": Step 3 "Prepare Patient" (Page 22)

CHANGE FROM: If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

CHANGE TO: If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

Section: 3: "Synchronized Cardioversion": Step 3 "Prepare Patient" (Page 24)

CHANGE FROM: If the patient has excessive chest hair, shave it to ensure proper adhesion of electrodes.

CHANGE TO: If the patient has excessive chest hair, clip it to ensure proper adhesion of electrodes.

ZOLL 1600 (#9650 - 0021) and ZOLL 1700 (#9650 - 0058)**Section 1: "Warnings": "Operator Safety" (Page 6)**

CHANGE FROM:

- Do not discharge with paddles or electrodes shorted together or in open air. Stand clear of patient when defibrillating.

CHANGE TO:

- Do not discharge with electrodes shorted together or in open air. Stand clear of patient when defibrillating.

[illegible]

ZOLL

Section 3: "Manual Mode Defibrillation": Step 7 "Charge Defibrillator" (Page 23)

CHANGE FROM: After 6-10 seconds of charging of the selected level, the DEFIB XXX J RDY message displays on the monitor. A distinctive charge ready (continuous) tone sounds. The defibrillator is now ready.

CHANGE TO: After charging to the selected energy level, the DEFIB XXX J RDY message displays on the monitor. A distinctive charge ready (continuous) tone sounds. The defibrillator is now ready.

Section 3: "Synchronized Cardioversion": Step 9 "Charge Defibrillator" (Page 25)

CHANGE FROM: After 6-10 seconds of charging to the selected energy level, a distinctive audible tone will sound and the energy ready SYNC XXX J RDY. will be displayed on the monitor. The defibrillator is now ready.

CHANGE TO: After charging to the selected energy level, a distinctive audible tone will sound and the energy ready SYNC XXX J RDY. will be displayed on the monitor. The defibrillator is now ready.

Section 7: "Troubleshooting": Step 3 (Page 37)

CHANGE FROM:

<i>Symptom</i>	<i>Recommended Action</i>
3 Charge time to 360J exceeds 10 seconds	<ol style="list-style-type: none"> 1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Perform defibrillator self test as described in Section 6. If fails, have the unit serviced promptly.

CHANGE TO:

<i>Symptom</i>	<i>Recommended Action</i>
3 Charge time to 360J exceeds 10 seconds	<ol style="list-style-type: none"> 1 Charge or change battery pack. 2 Normal, if operating in low battery condition or battery with diminished capacity. 3 Perform defibrillator self test as described in Recommended Daily Checkout Section. If fails, have the unit serviced promptly.

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Section 7: "Defibrillator": Step 10 (Page 40)

CHANGE FROM:

<i>Symptom</i>	<i>Recommended Action</i>
Charge time to 360J exceeds 10 seconds.	<ol style="list-style-type: none"> 1 Charge battery pack. 2 Normal, if operating in low battery condition (up to 20 seconds). 3 Have device serviced.

CHANGE TO:

<i>Symptom</i>	<i>Recommended Action</i>
Charge time to 360J exceeds 10 seconds.	<ol style="list-style-type: none"> 1 Charge or change battery pack. 2 Normal, if operating in low battery condition or battery with diminished capacity. 3 Have device serviced.

Appendix C: "Defibrillator": (Page C1)

CHANGE FROM: **Charge Time** Less than 10 seconds. Depleted battery packs will result in a longer defibrillator charge time.

CHANGE TO: **Charge Time** Less than 10 seconds with a new, fully charged battery. Use of batteries with diminished capacity will result in a longer defibrillator charge time.

ZOLL

OPERATOR'S MANUALS

ZOLL 1600 #9650-0021 & ZOLL 1700 #9650-0058

INTRODUCTION

This addendum provides information describing the operation of the ZOLL 1600 & 1700 devices. Please read this update carefully and add or change the affected pages of your manuals.

Please note the following changes:

ZOLL 1600 (9650-0021) and ZOLL 1700 (9650-0058)

Section 7 : "TroubleShooting" : "Strip Chart Recorder" (Page 41)

ADD the following information as step 25 on page 41.

<i>Symptom</i>	<i>Recommended Action</i>
25. Period (.) appears at the top of the paper.	This marker indicates the occurrence of a recoverable recorder error. This error does not affect the ability to deliver therapy. If this error occurs repeatedly with use, contact ZOLL's Technical Service Department.

[illegible]

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