Defibtech Lifeline ECG Semi-Automatic Defibrillator with ECG Display

TECHNICAL SPECIFICATIONS[†]

OPERATING MODES

AED WITH VIDEO DISPLAY

High-resolution LCD displays full-motion animated instructions with CPR coaching.

AED WITH ECG DISPLAY

High-resolution LCD displays ECG data and event information.

DEFIBRILLATOR

TYPE

Semi-automatic external defibrillator

MODEL

DDU-2450

WAVEFORM

Impedance Compensated Biphasic Truncated Exponential

ENERGY*

Adult: 150 Joules Child / Infant: 50 Joules (Nominal into 50 ohm load)

CHARGE TIME

4 seconds or less (from shock advised)*

CONTROLS

Lighted On/Off button Lighted Shock button

DISPLAY

High-resolution color LCD

VIDEO PROMPTS

Full motion video On-screen text prompts

CPR COACHING

Video and voice coaching On-demand video help

VOICE PROMPTS

Extensive voice prompts guide user through operation of the unit

RESCUE PROTOCOL

AHA/ERC (default); supports protocol updates by the user (password protected)

PATIENT ANALYSIS SYSTEM

PATIENT ANALYSIS

Automatically evaluates patient impedance for proper pad contact. Monitors signal quality and analyzes patient ECG for shockable/ non-shockable rhythms.

SENSITIVITY/SPECIFICITY

Meets or exceeds IEC-60601-2-4 requirements; meets AAMI DF80 requirements and AHA recommendations

EVENT DOCUMENTATION

INTERNAL EVENT RECORD

Critical ECG segments and rescue event parameters are recorded (greater than 60 minutes) and can be downloaded to a removable data card

PC-BASED EVENT REVIEW

ECG with event tag display, and audio playback when available

REMOVABLE STORAGE

(optional) Up to 30 hours of ECG and event data storage (no audio option) or up to 3 hours of audio (audio option). ECG and event storage on a removable data card. Actual length of storage is dependent on card capacity.

USB PORT

Event download and maintenance operations

SELF TESTS

AUTOMATIC

Automatic daily, weekly, monthly and quarterly circuitry tests

BATTERY INSERTION

System integrity test on battery insertion

PAD PRESENCE

Pads preconnected tested daily

USER-INITIATED

Unit and battery pack system test initiated by the user

STATUS INDICATION

Visual and audible indication of unit status

STATUS SCREEN

Unit self-test results Pads and battery information (status and expiration)

DEFIBRILLATION / MONITORING PADS

MODEL

Adult: DDP-2001 Child / Infant: DDP-2002

SURFACE AREA**

Adult: 12 inches² (77 cm²) Child / Infant: 7.75 inches² (50 cm²)

TYPE

Pre-connected, single-use, non-polarized, disposable, self-adhesive electrodes with cable and connector

**Nominal, each pad

BATTERY PACKS

NON-RECHARGEABLE

MODEL

DBP-2003, DBP-2013 (aviation)

POWER

12V, 2800 mAh

TYPE

Lithium/Manganese Dioxide Disposable, recyclable Non-rechargeable

CAPACITY*

125 shocks or 8 hours continuous operation

STANDBY LIFE*

4 vears

LOW BATTERY INDICATORS

*Typical, with new battery, at 25°C

Visible & Audible

RECHARGEABLE

MODEL

DBP-2009

POWER

11.1 VDC, 2.0 Ah, 22.2 Wh

TYPE

Lithium Ion (Li-ON) Recyclable, Rechargeable

CAPACITY*

12 hours of operation in ECG monitoring mode or min. 250 shocks

STANDBY LIFE*

3 months

LOW BATTERY INDICATORS

Visible & Audible

CHARGING TIME*

Less than 3 hours

USEFUL LIFE

Replacement recommended every 3 years (~300 charge/discharge cycles)

ENVIRONMENTAL

TEMPERATURE

Operating: 0 to 50°C (32 to 122°F)
One Hour Operating Temperature
Limit (extreme cold):
-20°C (-4°F)***

Standby: 0 to 50°C (32 to 122°F)

RELATIVE HUMIDITY

Operating / Standby: 5%-95% (non-condensing)

ALTITUDE

-500 to 15,000 ft (-150 to 4500 m) per MIL-STD-810F 500.4 Procedure II

VIBRATION

Ground (MIL-STD-810F 514.5 Category 20)

Helicopter (RTCA/DO-160D, Section 8.8.2, Cat R. Zone 2, Curve G)

Jet Aircraft (RTCA/DO-160D Section 8, Cat H, Zone 2, Curves B & R)

SHOCK / DROP ABUSE TOLERANCE

MIL-STD-810F 516.5 Procedure IV 48 inches (1.2 meters), any edge, corner, or surface, in standby mode

SEALING / WATER RESISTANCE

IEC 60529 class IP55; Dust Protected, Protected against water jets (Battery pack installed)

ESD

IEC 61000-4-2: (Open air up to 15kV or direct contact up to 8kV)

EMC (Emission)

CISPR 11 Group 1 Level B and FCC Part 15

EMC (Immunity)

IEC 61000-4-3 and IEC 61000-4-8

***From room temperature to temperature extreme, one hour duration, updated specification for DDU-2000 Series AEDs running software revision 2.4 or above

PHYSICAL

SIZE

 $7.3 \times 9.5 \times 2.3$ inches $(18.5 \times 24 \times 5.8 \text{ cm})$

WEIGHT (with battery)

Less than 3 lbs (1.4 kg)







^{*}Typical, with new battery, at 25°C

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS AND OTHER IMPORTANT SAFETY INFORMATION

When should the Defibtech Automated External Defibrillator (AED) be used - what are its indications?

Lifeline/ReviveR VIEW DDU-2300 and Lifeline/ReviveR ECG DDU-2450 Automated External Defibrillators (AEDs) are indicated for use on victims of sudden cardiac arrest (SCA) who are:

- Unconscious and unresponsive
- Not breathing or not breathing normally

Lifeline/ReviveR VIEW DDU-2300 and Lifeline/ReviveR ECG DDU-2450 AEDs may be used with Defibtech adult defibrillation pads (model number DDP-2001). For patients under 8 years old, or weighing less than 55 lbs (25 kg), use Defibtech child/infant defibrillation pads (model number DDP-2002), if available.

When should the Defibtech AED not be used - what are its contraindications?

Lifeline/ReviveR VIEW DDU-2300 and Lifeline/ReviveR ECG DDU-2450 Automated External Defibrillators (AEDs) should not be used if the victim is responsive or conscious.

What other information is important about using the AED?

Do not delay therapy to determine exact age or weight. If pediatric pads are not available, apply adult pads in the position as shown for a child/infant and use the AED.

What are the potential adverse health effects of using an AED?

The potential adverse effects (e.g., complications) associated with use of an automated external defibrillator include, but are not limited to, the following:

- · Failure to identify shockable arrhythmia.
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury.
- Inappropriate energy, which could cause failed defibrillation or postshock dysfunction.
- Myocardial damage.
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents.
- Incorrectly shocking a pulse sustaining rhythm and inducing VF or cardiac arrest.
- Bystander shock from patient contact during defibrillation shock.
- · Interaction with pacemakers.
- · Skin burns around the defibrillation pads placement area.
- Allergic dermatitis due to sensitivity to the materials used in the defibrillation pads construction.
- · Minor skin rash.

What are some of the relevant warnings related to the AED?

- Hazardous electrical output. This equipment is for use only by qualified personnel.
- Possible fire or explosion. Do not use in the presence of flammable gases or anesthetics. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation, if necessary.
- The DDU-2000 Series AED has not been evaluated or approved for use in hazardous locations as defined in the National Electric Code standard. In compliance with IEC classification, the DDU-2000 Series AED is not to be used in the presence of flammable substance/air mixtures.
- Improper maintenance can cause the DDU-2000 Series AED not to function. Maintain the DDU-2000 Series AED only as described in the User Manual and Operating Guide. The AED contains no userserviceable parts — do not take the unit apart.
- Do not open sealed pads package until pads are to be used. The
 packaging should be opened only immediately prior to use, otherwise
 the pads may dry out and become non-functional.
- Do not touch the patient during defibrillation. Defibrillation current can cause operator or bystander injury.
- The defibrillation pads are intended for one-time use only and must be discarded after use. Reuse can lead to potential cross infection, improper performance of the device, inadequate delivery of therapy, and/or injury to the patient or operator.
- CPR during analysis can cause incorrect or delayed diagnosis by the patient analysis system.
- User-initiated and automatic self-tests are designed to assess the DDU-2000 Series AED's readiness for use. However, no degree of testing can assure performance or detect abuse, damage, or a defect that occurred after the most recent test is completed.
- Even if defibrillation occurs, the sudden cardiac arrest event may not result in survival.

What are some of the relevant cautions related to the AED?

- Follow all battery pack labeling instructions. Do not install battery packs after the expiration date.
- Follow all defibrillation pad label instructions. Use defibrillation pads prior to their expiration date.
- Use and store the DDU-2000 Series AED only within the range of environmental conditions specified in the technical specifications.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Please refer to the Operating Guide provided with your AED for user instructions, complete list of warnings and cautions, operator training requirements, summary of primary clinical studies, technical specifications, and other important information. The Operating Guide, for concise guidance on set-up, use, maintenance and technical specifications, and User Manual, for comprehensive training on set-up, use and maintenance; and source for complete technical specifications, are also available at www.defibtech.com/support.



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