

Defibtech Lifeline AED Semi-Automatic Defibrillator

TECHNICAL SPECIFICATIONS†

DEFIBRILLATOR

TYPE

Semi-automatic external defibrillator

MODEL

DDU-100A, DDU-100E

WAVEFORM

Biphasic Truncated Exponential (Impedance compensated)

ENERGY

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

CHARGE TIME*

4 seconds or less
(from shock advised)

VOICE PROMPTS

Extensive voice prompts guide user through operation of the unit

CPR PACING

Metronome

CONTROLS

Lighted On/Off button
Lighted Shock button

INDICATORS

- "check pads"
- "do not touch patient"
- "analyzing"
- AED Status LED

RESCUE PROTOCOL

AHA/ERC (default);
supports protocol updates

*Typical, with new battery at 25°C

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

BATTERY PACK

| MODEL DBP-2800 | MODEL DBP-1400 |
|---|---|
| POWER 15VDC, 2800 mAh | POWER 15VDC, 1400 mAh |
| CAPACITY 300 shocks or 16 hours continuous operation* | CAPACITY 125 shocks or 8 hours continuous operation* |
| STANDBY LIFE 7 years (installed in AED with 9V ASI battery)* | STANDBY LIFE 5 years (installed in AED with 9V ASI battery)* |

TYPE

Lithium/Manganese Dioxide
Disposable, recyclable,
non-rechargeable

LOW BATTERY INDICATORS

Visible
Audible

*Typical, with new battery at 25°C

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

DEFIBRILLATION / MONITORING PADS

MODEL

Adult: DDP-100
Child / Infant: DDP-200P

TYPE

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

SURFACE AREA**

Adult: 16 inches² (103 cm²)
Child / Infant: 7.75 inches² (50 cm²)

**Nominal, each pad

EVENT DOCUMENTATION

INTERNAL EVENT RECORD

Critical ECG segments and rescue event parameters are recorded 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 12 hours of ECG and event data storage (no audio option) or up to 1 hour and 40 minutes of audio (audio option). ECG and event storage on a removable data card. Actual length of storage is dependent on card capacity.

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 (1 meter, any edge, corner, or surface, in standby mode)

SEALING / WATER RESISTANCE

IEC 60529 class IP54;
Dust Protected, Splash Proof (battery pack installed)

ESD

EN 61000-4-2 (15kV or direct contact up to 8kV)

EMC (Emission)

EN 55011 Class B Group 1 and FCC Part 15

EMC (Immunity)

EN 61000-4-3 (20V/m)

***From room temperature to temperature extreme, one hour duration

PHYSICAL

SIZE

8.5 x 11.8 x 2.7 inches
(22 x 30 x 7 cm)

WEIGHT (Approximate)

With DBP-1400: 4.2 lbs (1.9 kg)
With DBP-2800: 4.4 lbs (2.0 kg)

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 DDU-100 and Lifeline/ReviveR AUTO DDU-120 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 DDU-100 and Lifeline/ReviveR AUTO DDU-120 AEDs may be used with Defibtech adult defibrillation pads (model number DDP-100). For patients under 8 years old, or weighing less than 55 lbs (25 kg), use Defibtech child/infant defibrillation pads (model number DDP-200P), if available.

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

Lifeline/ReviveR DDU-100 and Lifeline/ReviveR AUTO DDU-120 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 post-shock 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-100 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-100 Series AED is not to be used in the presence of flammable substance/air mixtures.
- Improper maintenance can cause the DDU-100 Series AED not to function. Maintain the DDU-100 Series AED only as described in the User Manual and Operating Guide. The AED contains no user-serviceable 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-100 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-100 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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ELECTRONIC DISTRIBUTION

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