Defibtech Automated External Defibrillator

- Lifeline/ReviveR DDU-100
- Lifeline/ReviveR AUTO DDU-120

Operating Guide

For concise guidance on set-up, use, maintenance and technical specifications
This manual applies to the following models and trade names

<table>
<thead>
<tr>
<th>Trade Names</th>
<th>Model Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifeline/ReviveR</td>
<td>DDU-100</td>
</tr>
<tr>
<td>Lifeline/ReviveR AUTO</td>
<td>DDU-120</td>
</tr>
</tbody>
</table>

The Lifeline/ReviveR is referred to as the DDU-100 from this point forward in this manual. The Lifeline/ReviveR AUTO is referred to as the DDU-120 from this point forward in this manual. Statements that apply to all trade names/model numbers listed above are referred to in this manual as “DDU-100 Series.”

**Notices**

Defibtech shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

Information in this document is subject to change without notice. Names and data used in any examples are fictitious unless otherwise noted.

**Limited Warranty**

The “Limited Warranty” shipped with Defibtech AED products serves as the sole and exclusive warranty provided by Defibtech, L.L.C. with respect to the products contained herein.

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**Tracking**

U.S.A. federal regulations require Defibtech to maintain records for each AED it distributes (reference 21 CFR 821, Medical Device Tracking). These requirements also apply anytime there is a change in the AED’s location, including if you move, sell, donate, give away, export or even throw it away. We depend on AED owners/users to contact us when these things happen to ensure the tracking information remains accurate in the event we need to share important product notices. If your location is outside the U.S.A., we ask you share your information for exactly the same reasons. To keep your information up to date, please visit www.defibtech.com/register.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.
QUICK USE INSTRUCTIONS

1. Press “ON” button
2. Apply pads
3. Follow AED instructions

WHEN TO USE

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.

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.

IMPORTANT
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.

OPERATOR TRAINING REQUIREMENTS
In order to safely and effectively operate the DDU-100 Series AED, a person shall have met the following requirements:

- Defibtech DDU-100 Series AED and/or defibrillation training as required by local, state, provincial, or national regulations.
- Any additional training as required by the authorizing physician.
- Thorough knowledge and understanding of the material presented in the User Manual (available for viewing/download at www.defibtech.com).

Refer to User Manual Section 8.1.6 for Summary of Primary Clinical Studies and User Manual Section 8.1.7 for Potential Adverse Effects of the Device on Health.
A. **Speaker.** The speaker projects the voice prompts when the AED is on. The speaker also emits a “beep” when the unit is in standby mode and has detected a condition that requires operator attention.

B. **SHOCK button** *(DDU-100 ONLY).* This button will flash when a shock is recommended - push this button to deliver the shock to the patient. This button is disabled at all other times.

**IMPORTANT:** On the fully-automatic DDU-120, a **SHOCK Required Indicator** which flashes when a shock is recommended and the unit has charged and is to deliver a shock is in the SHOCK button location. **Do not touch the patient while this indicator is flashing.**

C. **“analyzing” LED (Light Emitting Diode).** This green LED flashes when the AED is analyzing the patient’s ECG rhythm.

D. **“do not touch patient” LED.** This red LED flashes when the AED detects motion or other interference that prevents analysis of the signal or when the user should not be touching or moving the patient.

E. **“check pads” LED.** This red LED flashes when the AED detects that the pad connection to the patient is poor or pads are not applied.

F. **ON/OFF button.** Push button to turn the AED on. Push again to disarm and turn the AED off.

G. **Pads connector port.** Insert Patient Pads Connector (item O) into this port to connect pads to the AED.

H. **Battery pack.** The battery pack provides a replaceable main power source for the AED.

I. **Battery pack opening.** Insert the battery pack firmly into this opening until the latch clicks into place.

J. **Battery pack eject button.** This button releases the battery pack from the AED. To remove the battery pack, push the button until the battery pack is partially ejected from the unit.

K. **Active Status Indicator (ASI).** The ASI indicates the current status of the AED. This indicator flashes green to indicate the unit has passed its last self-test and is ready for use. It flashes red to indicate unit needs attention from the user or needs servicing.

L. **Patient pads.** The defibrillation pads that are placed on the patient. The pads should be stored in the pad storage area on the back of the unit.

M. **Defibtech Data Card (DDC).** This optional plug-in card provides enhanced storage capabilities to the AED.

N. **Active Status Indicator (ASI) battery.** This 9V lithium battery provides power to the Active Status Indicator (ASI). It is inserted into a compartment in the battery pack.*

O. **Patient pads connector.** Insert into Pads Connector Port (item G) to connect pads to the AED.

P. **Operating Guide.** Quick reference information for the DDU-100 and DDU-120 AED. *(The full DDU-100 Series AED User Manual can be found at www.defibtech.com.)*

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*DDU-100 series AEDs will continue to perform standby and ASI functions without the 9V ASI battery installed, but battery pack standby life will be reduced.*
The DDU-100 Series AED is designed to be stored in a “ready” state so that few steps are required to begin using the AED.

1. **CONNECT THE PADS TO THE AED**
   - Ensure that the pads package has not expired. Expired pads must not be used.
   - For more information, refer to page 14.

2. **INSTALL THE LITHIUM 9V ASI BATTERY INTO THE BATTERY PACK**
   - Ensure that the lithium 9V battery has not expired.
   - For more information, refer to page 15.

*NOTE: DDU-100 series AEDs will continue to perform standby and ASI functions without the 9V ASI battery installed, but battery pack standby life will be reduced.*

3. **INSTALL THE BATTERY PACK INTO THE AED**
   - Ensure that the battery pack has not expired. Expired battery packs must not be used.
   - When the battery pack is installed, the AED will turn on and run a battery pack test.
   - Wait for the test to complete and for the unit to turn off.
   - For more information, refer to page 15.

4. **CHECK THE STATUS**
   - When the AED is off, the Active Status Indicator (ASI) should flash green. If the ASI flashes red, is solid red, or if there is no flashing light, the unit requires service.
   - For more information, refer to page 17.

5. **READ THE USER MANUAL**
   - Comprehensive information about the DDU-100 Series AED can be found in the User Manual (at www.defibtech.com).

For more detailed information, refer to the User Manual (at www.defibtech.com).
USING THE AED

If the patient is unconscious or unresponsive, and is not breathing or not breathing normally, ensure emergency medical assistance has been called and start using the AED.

1. **TURN AED ON**
   - Press ON/OFF button to turn AED on.
   - Follow the voice prompt instructions.
   - **NOTE:** To power off the AED at any time, press and hold the ON/OFF button for approximately two seconds.

2. **PREPARE THE PATIENT**
   - Remove clothing from patient’s chest.
   - If necessary, dry chest and remove excess chest hair.

3. **PREPARE PADS**
   - Peel adhesive pads from blue liner.
   - Tear open pads package.

4. **PLACE PADS**
   - Apply pads to patient’s bare chest.
   - For more information, refer to page 14.

   *ADULT PATIENT*

   *CHILD/INFANT PATIENT*

   **OR**

For more detailed information, refer to the User Manual (at www.defibtech.com).
USING THE AED (continued)

5 STAND CLEAR

When instructed, do not touch the patient.

6 IF INSTRUCTED, PRESS SHOCK BUTTON

If instructed, press “SHOCK” button.

IMPORTANT: The semi-automatic DDU-100 AED will deliver the shock after the SHOCK button has been pressed; the fully-automatic DDU-120 AED will shock the patient automatically without any user intervention. Do not touch the patient while the SHOCK Required (“auto”) indicator is flashing.

7 PERFORM CPR

Follow instructions to perform CPR, if needed.

8 CONTINUE TO FOLLOW INSTRUCTIONS

Continue to follow the voice prompt instructions.

For more detailed information, refer to the User Manual (at www.defibtech.com).
HOW TO CONNECT THE PADS

Insert the connector end of the defibrillation pad cable into the pads connector socket on the top-left corner of the DDU-100 Series AED as shown at left. Insert the pads connector firmly until it is fully seated in the unit. The connector will only fit in one way – if the connector does not fit, rotate the connector before trying again.

The connected pads package should then be stored in the pad storage area on the back of the DDU-100 Series AED (see diagram at right). After connecting the pads connector to the unit, push the pads package, rounded end first, with the pictures on the package facing out, into the pad storage area. When the pads package is fully inserted, press the pad cable into the groove in the back of the unit to hold the cable in place and tuck any excess cable behind the pads package.

WHICH PADS TO USE

ADULT PADS
For adults and children 8 years or older or over 55 pounds (25 kg), use adult pads

CHILD/INFANT PADS
For infants and children under 8 years or less than 55 pounds (25 kg), use child/infant pads (NOTE: Child/infant pads can be identified by their blue connector and blue pads package)

WHEN TO REPLACE THE PADS

The Defibtech defibrillation pads are intended for one-time use only. The pads must be replaced after each use or if the package has been damaged.

It is important to check the expiration date of the pads. The expiration date is printed on the outside of the sealed package. Do not use pads past their expiration date. Discard expired pads. Use only Defibtech defibrillation pads.

IMPORTANT: DDU-100 Series AEDs that carry the marking shown at left on the pad holder label on the unit’s rear panel (see top of page 3) should use battery packs that also include this marking. Earlier model battery packs without this marking will function during a rescue, but should not be used for standby. If an earlier model battery pack is installed, the AED will prompt the user on shut down that an unknown battery type is present. The battery pack should be replaced with one that includes the marking shown at left.

INSTALLING THE ACTIVE STATUS INDICATOR 9V BATTERY

To meet battery pack specifications (see pages 24-25), a lithium 9V battery should be installed into the battery pack. NOTE: While DDU-100 Series AEDs will operate rescue and standby functions with a battery pack that does not contain 9V battery, battery pack standby life will be reduced.

The 9V battery is installed into the battery pack in the 9V battery compartment.
To install, remove the cover covering the 9V battery compartment by pushing it sideways. The cover will slide and detach from the battery pack. Insert the 9V battery into the 9V battery compartment so that the contacts on the battery touch the contacts in the battery pack. Replace the 9V battery compartment door by placing it in the almost closed position and then sliding it closed. Only a fresh 9V lithium battery should be used as a replacement.

INSTALLING AND REMOVING THE BATTERY PACK

The lithium battery pack provides power to the DDU-100 Series AED. Before inserting the battery pack into the AED, the 9V lithium battery should be installed in the battery pack itself as described in the previous section. Do not install the battery pack after the expiration date printed on the label.

The battery pack is non-rechargeable.
To insert the battery pack into the AED, orient the battery pack so that the label faces up. Make certain that the battery opening in the side of the AED is clean and clear of any foreign objects. Insert the battery pack into the opening in the side of the AED. Slide the battery pack all the way in until the latch clicks. If it does not slide all the way in, it is most likely inserted upside down. Once fully inserted, the battery pack surface should be flush with the side of the AED. To remove the battery pack, push the battery eject button on the side of the AED. After the battery pack is partially ejected, pull the battery pack out.

Within moments of insertion, the AED will turn on and run a battery pack insertion self-test. The AED will announce "Battery OK" after successful completion of the test. The unit will automatically shut off after the test is run. Afterwards, the Active Status Indicator on the top corner of the AED will periodically flash. If the indicator flashes green, the AED and battery pack are functioning properly; if this does not happen, there is a problem. Refer to page 17 for more details on the meaning of the indicator.

For more detailed information, refer to the User Manual (at www.defibtech.com).
**THE DEFIBTECH DATA CARD (optional)**

**INSTALLING AND REMOVING THE DEFIBTECH DATA CARD (DDC CARD)**

Each time the AED is used, an event file is created on the Defibtech Data Card (if installed). If the unit was used to treat a patient, the DDC in the unit should be removed and provided to the patient’s care provider. A new DDC should be installed before the next use.

To remove the DDC, first remove the battery pack by pressing the battery pack eject button on the side of the unit. The DDC card is located in a slot directly above the battery pack opening in the unit. To remove the DDC card, press the DDC in all the way and then release. The DDC will be partially ejected and can be removed by pulling it the rest of the way out. To install a new DDC, insert the DDC, label side up, in the thin slot on the top of the opening for the battery pack. The card should click into place and be flush with the surface of the slot. If the card does not push in all the way, it may have been inserted upside down. In that case, remove the card, flip it over and try inserting it again.

**Note:** A DDC card is not required for the AED to operate. Even if a DDC card is not installed, relevant event information will still be recorded internally. The AED will still operate properly even after a “replace data card” message.

To install a new DDC, insert the DDC, label side up, in the thin slot on the top of the opening for the battery pack. The card should click into place and be flush with the surface of the slot. If the card does not push in all the way, it may have been inserted upside down. In that case, remove the card, flip it over and try inserting it again.

**CAUTION**
Using non-Defibtech Data Cards (DDC cards) may damage the unit and will void the warranty.

**ACTIVE STATUS INDICATOR (ASI)**

Once a fully-functional battery pack with a non-discharged 9V battery is installed in the AED, an LED indicator located in the corner of the unit actively indicates unit status. If the unit is fully operational, the Active Status Indicator ("ASI") will blink green and if the unit needs attention, the ASI will blink red. When the ASI blinks red, the unit will also “beep” periodically to call attention to itself.

**SELF-TESTS**

Power-on self-tests are performed every time the unit is turned on to test the basic operation of the unit. The unit also performs daily, weekly, monthly and quarterly self-tests automatically to check the integrity of the unit's hardware and software.

Manually-initiated self-tests may be run at any time by the user to test the AED’s systems, including the charging and shocking functions (the shock is internally dissipated and no voltage will be present at the pads).

**Note:** Every time the manually initiated self-test is run, the unit does an internal shock test. This test reduces the capacity of the battery pack by one shock.

To perform a manual self-test, begin with the unit powered off. Press and hold the ON/OFF button until the unit announces that it is performing a self-test – this should take approximately 5 seconds. Once you hear the announcement, release the ON/OFF button and follow the AED’s spoken instructions until the test is complete. The unit will run a series of internal tests, including charge and shock tests. The manually initiated self-test can be aborted by pressing the ON/OFF button again to turn the unit off. When the self-test is complete, the unit will announce its status and power off.

- **If the self-test passes:** The unit will announce: “AED OK” and power off. The unit may then be immediately used by pressing the ON/OFF button again.
- **If the self-test fails:** The unit will announce the symptom. Refer to the “Troubleshooting” section on page 20.

**CHECKING AED STATUS**

**ACTIVITY STATUS INDICATOR**

- **Off:** Battery pack not installed or the AED is defective. Install a functional battery pack in the AED.
- **Steady-on green:** The AED is ON and operating normally.
- **Blinking green:** The AED is OFF and ready to operate normally.
- **Blinking red:** The AED is OFF and the AED or battery pack needs attention. Refer to “Troubleshooting” on page 20 or call Defibtech for service.

For more detailed information, refer to the User Manual (at www.defibtech.com).

DAC-AS81-EN-DG
ROUTINE MAINTENANCE

The DDU-100 Series AED is designed to be very low maintenance. Simple maintenance tasks are recommended to be performed regularly to ensure its readiness (see sample maintenance table below). Different maintenance intervals may be appropriate depending on the environment where the AED is deployed, and ultimately the maintenance program is at the discretion of the emergency response program’s medical director.

<table>
<thead>
<tr>
<th>Daily</th>
<th>Monthly</th>
<th>After Each Use</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>•</td>
<td>•</td>
<td>Check that Active Status Indicator (ASI) is flashing green</td>
</tr>
<tr>
<td>•</td>
<td>•</td>
<td>•</td>
<td>Check the condition of the unit and accessories</td>
</tr>
<tr>
<td>•</td>
<td>•</td>
<td>•</td>
<td>Run manually-initiated self-test</td>
</tr>
<tr>
<td>•</td>
<td>•</td>
<td>•</td>
<td>Replace pads</td>
</tr>
<tr>
<td>•</td>
<td>•</td>
<td>•</td>
<td>Check pads and battery pack expiration dates</td>
</tr>
<tr>
<td>•</td>
<td>•</td>
<td>•</td>
<td>Check the DDC, if one was installed</td>
</tr>
</tbody>
</table>

Note: If the unit has been dropped, mishandled, or abused, a manually-initiated self-test should be performed.

If the unit still requires attention after a manually-initiated self-test has been performed, refer to “Troubleshooting” on page 20 or call Defibtech for service (refer to “Contacts” section on page 30).

CHECKING THE CONDITION OF THE UNIT AND ACCESSORIES

Inspect the unit for cracks or other signs of damage on the case, as well as dirt or contamination, especially in the areas around the connector socket and battery pack opening. If any cracks or other signs of damage are observed, remove the unit from service and contact an authorized service center. If any dirt or contamination is observed, refer to the “Cleaning” section of the full User Manual (available at www.defibtech.com).

It is important that the patient pads and the battery packs not be used past their expiration dates. The expiration date of the pad package is printed on the outside of the sealed package. The expiration date of the battery pack is printed on the label on the pack. The battery pack should be removed and replaced by this date; when the battery pack is used up, the unit will indicate “battery low” or “replace battery now” and the Active Status Indicator will flash red.

Once an accessory is past its expiration date, it should be replaced immediately. Follow the instructions in the “Installing and Removing the Battery Pack” and “How to Connect the Pads” sections of this guide to replace the part with an unexpired part. Patient pads should be discarded. Battery packs should be appropriately recycled.

CLEANING

Periodically clean the AED of any dirt or contaminants on the case and connector socket. The following are important guidelines to be adhered to when cleaning the device:

- The battery pack should be installed when cleaning the AED.
- Do not immerse the AED in fluids or allow fluids to enter the unit. Use a soft cloth to wipe the case clean.
- Do not use abrasive materials or strong solvents such as acetone or acetone-based cleaning agents. The following cleaning agents are recommended for cleaning the AED case and the connector socket:
  - Soapy water
  - Ammonia based cleaners
  - Hydrogen peroxide
  - Isopropyl alcohol (70 percent solution)
  - Chlorine bleach (30 ml/liter water)
- Ensure that the connector socket is completely dry before reinstalling the pads cable. After cleaning the device and before returning it to service, always turn the unit on for a few seconds, which will cause the unit to run a standard power-on self-test.

Please note that none of the items provided with the DDU-100 Series AED (including the AED itself) are sterile or require sterilization.
The following table lists the common causes for problems, the possible cause, and the possible corrective actions. Refer to the User Manual (available at www.defibtech.com) for detailed explanations on how to implement the corrective actions.

To have the unit report what the root cause of the problem is, power the AED on and then power it off by pressing the ON/OFF button for approximately two seconds. While powering off, the unit should issue a voice prompt that details the cause of the problem. Use the chart below to determine the appropriate corrective action based upon what prompt was spoken by the unit.

If the unit continues to be non-functional, call Defibtech for service (refer to the “Contacts” section on page 30).

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Possible Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unit will not turn on</strong></td>
<td>Battery pack not inserted</td>
<td>Insert battery pack</td>
</tr>
<tr>
<td></td>
<td>Battery pack depleted or needs servicing</td>
<td>Replace battery pack or call for service</td>
</tr>
<tr>
<td></td>
<td>Unit needs servicing</td>
<td>Call for service</td>
</tr>
<tr>
<td><strong>Unit immediately turns off</strong></td>
<td>Battery pack depleted</td>
<td>Replace battery pack</td>
</tr>
<tr>
<td></td>
<td>Unit needs servicing</td>
<td>Call for service</td>
</tr>
<tr>
<td><strong>ASI flashes red and/or unit makes periodic “beep” sound</strong></td>
<td>Unit may need servicing</td>
<td>Power unit on and then power off by pressing ON/OFF button for approximately two seconds; note problem indicated by voice prompt and, if necessary, call for service</td>
</tr>
<tr>
<td></td>
<td>Battery pack non-functional</td>
<td>Replace battery pack</td>
</tr>
<tr>
<td></td>
<td>Defibrillation pads are not pre-connected to unit</td>
<td>Connect defibrillation pads to unit</td>
</tr>
<tr>
<td><strong>ASI does not flash at all while the unit is in standby (powered off)</strong></td>
<td>Battery pack not inserted</td>
<td>Insert battery pack</td>
</tr>
<tr>
<td></td>
<td>Battery pack is low or needs servicing</td>
<td>Replace battery pack or call for service</td>
</tr>
<tr>
<td></td>
<td>Unit needs servicing</td>
<td>Call for service</td>
</tr>
<tr>
<td><strong>“Power on test failed, service code “xxx”” prompts</strong></td>
<td>Unit needs servicing</td>
<td>Record code number and call for service</td>
</tr>
<tr>
<td><strong>“Battery test failed, service code “xxx”” prompts</strong></td>
<td>Battery pack needs servicing</td>
<td>Record code number and replace with new battery pack</td>
</tr>
<tr>
<td><strong>“Service required” prompt</strong></td>
<td>Unit needs servicing</td>
<td>Call for service</td>
</tr>
<tr>
<td><strong>“Replace battery now” prompt</strong></td>
<td>Battery pack capacity is critically low</td>
<td>Unit may not deliver a shock, replace battery pack immediately</td>
</tr>
<tr>
<td><strong>“Battery low” prompt</strong></td>
<td>Battery pack capacity is getting low</td>
<td>Replace battery pack as soon as possible</td>
</tr>
</tbody>
</table>

**“Unknown battery type” prompt**
- Battery pack not recommended for use with unit (see top of page 15).
- Replace installed battery pack with recommended battery pack.

**“Pads missing” prompt**
- Pads not connected
- Make sure pads connector is oriented correctly and fully inserted into unit.

**“Plug in pads connector” prompt**
- Pads connector not plugged in
- Plug in pads connector
- Pads connector broken
- Replace pads
- Unit’s connector broken
- Call for service
- Pads not connected to patient
- Place pads on patient

**“Apply pads to patient’s bare chest as shown” prompt**
- Pads not making good connection to patient
- Check pad connection to patient
- Pads or pad cable damaged
- Replace pads

**“Poor pad contact to patient”, “Press pads firmly”, “Replace pads”, “Non-rescue pads” or “Warning” prompt**
- Dry pads
- Replace pads
- Partial pad connection
- Check that pads are placed securely on patient
- Pads touching
- Separate pads and place correctly on patient
- Non-rescue pads (e.g. trainer pads) connected while in AED (rescue) mode
- Replace non-rescue pads with rescue pads
- “Check pads” prompt
- Pads touching
- Separate pads and place correctly on patient

**“Stop motion” prompt**
- Patient motion has been detected
- Stop patient motion

**“Stop interference” prompt**
- External interference has been detected
- Stop external interference

**“Analyzing interrupted” prompt**
- Patient’s ECG rhythm changed
- No action necessary
- Shock button not pushed within 30 seconds (DDU-100 ONLY)
- Push shock button within 30 seconds (DDU-100 ONLY)

**“Shock cancelled” prompt**
- Low battery – insufficient to charge
- Replace battery pack
- Hardware failure
- Run manually initiated Self-Test, return unit for servicing
- Bad pad to patient connection
- Check that pads are placed securely on patient
- Dry pads
- Replace pads

**“Replace data card” prompt**
- DDC card is full
- Replace DDC card with a card that is not full
- DDC has failed
- Replace DDC card
WARNINGS:

- Do not sterilize the DDU-100 Series AED or its accessories.

- Use only Defibtech disposable self-adhesive defibrillation pads, battery packs, and other accessories supplied by Defibtech or its authorized distributors. Substitution of non-Defibtech approved accessories may cause the device to perform improperly.

- 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.

- Do not allow pads to touch metal objects or equipment in contact with the patient. Do not touch equipment connected to the patient during defibrillation. Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock hazard and potential damage to that equipment.

- Do not shock with defibrillation pads touching each other. Do not shock with gel surface exposed.

- Do not allow defibrillation pads to touch each other, or to touch other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart.

- The defibrillation pads are intended for one-time use only and must be discarded after use. Reuse can lead to potential cross contamination and skin burns around the defibrillation pads.

- The defibrillation pads should not be in continuous contact with the patient’s skin for more than 24 hours.

- Some very low amplitude or low frequency VF rhythms may not be interpreted as shockable. Some very low amplitude or low frequency VF rhythms may not be interpreted as shockable.

- Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis, especially if very low amplitude or low frequency rhythms are present. If the patient is being transported, stop vehicle before beginning ECG analysis.

- In patients with cardiac pacemakers, the DDU-100 Series AED may have reduced sensitivity and not detect all shockable rhythms. If you know the patient has an implanted pacemaker, do not place electrodes directly over an implanted device.

- During defibrillation, air pockets between the skin and defibrillation pads can cause patient skin burns. To help prevent air pockets, make sure self-adhesive defibrillation pads completely adhere to the skin. Do not use dry out or expired defibrillation pads.

- Defibrillation may cause skin burns around the defibrillation pads area.

- Use and store the DDU-100 Series AED only within the range of environmental conditions specified in the technical specifications.

- Some very low amplitude or low frequency VF rhythms may not be interpreted as shockable. Some very low amplitude or low frequency VF rhythms may not be interpreted as shockable.

- Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis, especially if very low amplitude or low frequency rhythms are present. If the patient is being transported, stop vehicle before beginning ECG analysis.

- In patients with cardiac pacemakers, the DDU-100 Series AED may have reduced sensitivity and not detect all shockable rhythms. If you know the patient has an implanted pacemaker, do not place electrodes directly over an implanted device.

- During defibrillation, air pockets between the skin and defibrillation pads can cause patient skin burns. To help prevent air pockets, make sure self-adhesive defibrillation pads completely adhere to the skin. Do not use dry out or expired defibrillation pads.

- Defibrillation may cause skin burns around the defibrillation pads area.

- Use and store the DDU-100 Series AED only within the range of environmental conditions specified in the technical specifications.

CAUTIONS:

- 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.

- The defibrillation pads should not be in continuous contact with the patient’s skin for more than 24 hours.

- Use and store the DDU-100 Series AED only within the range of environmental conditions specified in the technical specifications.

- 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.

- 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.
DEFIBRILLATOR

TYPE
Automated external

MODELS
DDU-100 and DDU-120

WAVEFORM
Impedance Compensated Biphasic Truncated Exponential

REScue PROTOCOL
AH/A/RC (default); future protocols via field updates

POWER rechargeable Lithium/Manganese TYPE DBP-2800 MODEL BATTERY PACK System integrity test on battery BATTERY INSERTION and quarterly circuitry tests

PATIENT ANALYSIS SYSTEM
SELF-TESTS
AUDIBLE INDICATIONS
*Typical, new battery, at 25°C

SENSITIVITY/SPECIFICITY
*Typical, new battery, at 25°C

BATTERY PACK (HIGH-CAPACITY)

MODEL DBP-2800
TYPE Lithium/Manganese Dioxide Disposable, recyclable, non-rechargeable
POWER 18VDC, 2800 mAh

CAPACITY* 300 shocks or 16 hours of continuous operation STANDBY LIFE* 7 years (installed in AED with 9V battery) LOW BATTERY INDICATIONS Visible, Audible

BATTERY PACK (STANDARD)

MODEL DBP-1400
TYPE Lithium/Manganese Dioxide Disposable, recyclable, non-rechargeable
POWER 18VDC, 1400 mAh

CAPACITY* 125 shocks or 8 hours of continuous operation STANDBY LIFE* 5 years (installed in AED with 9V battery) LOW BATTERY INDICATIONS Visible, Audible

DEFIBRILLATION / MONITORING PADS

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

EVENT DOCUMENTATION
INTERNAL EVENT RECORD
Select 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

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
-150 to 4500 meters (-500 to 15,000 feet) per MIL-STD-810F

VIBRATION
Ground (MIL-STD-810F 514.5 Procedure II)

SHOCK/DRop ABUSE TOLERANCE
MIL-STD-810F 516.5 Procedure IV (1 meter, any edge, corner, or surface, in standby mode)

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

WEIGHT
Approximately 4.2 lbs (1.9 kg) with DBP-1400 battery pack Approximately 4.4 lbs (2 kg) with DBP-2800 battery pack

SEALING/WATER RESISTANCE
IEC 60529 class IP54; Dust Protected, Splash Proof, (battery pack installed)

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

EMC (Separation Distances)
DDU-100 Series AEDs are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The AED user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED. Recommended separation distances can be found in the DDU-100 Series User Manual at www.delfibtech.com.

SURFACE AREA
Adult: 16 inches2 (103cm2) (nominal, each pad) Child/Infant: 7.75 inches2 (50cm2) (nominal, each pad)

REMOVABLE STORAGE (optional)
Up to 12 hours of ECG and event data storage (no audio option) or up to 2 hours of audio (audio option). ECGs and event storage on a removable data card. Actual length of storage is dependent on card capacity. Data card must already be installed at the time of event.

AIRCRAFT
Meets RTCA/DO-160D, Section 8, Cat H, Zone 2, Curves B & R

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

*Typical, new battery, at 25°C

For more detailed information, refer to the User Manual (at www.delfibtech.com).
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚡️</td>
<td>High voltage present.</td>
</tr>
<tr>
<td>⚠️</td>
<td>Caution, consult accompanying documents.</td>
</tr>
<tr>
<td>SHOCK Button – Delivers defibrillation shock to the patient when the device is ready to shock.</td>
<td></td>
</tr>
<tr>
<td>SHOCK Required Indicator – Flashes to indicate that a shock is about to be delivered.</td>
<td></td>
</tr>
<tr>
<td>ON/OFF/DISARM Button –</td>
<td></td>
</tr>
<tr>
<td>Do not expose to high heat or open flame. Do not incinerate.</td>
<td></td>
</tr>
<tr>
<td>Recyclable.</td>
<td></td>
</tr>
<tr>
<td>Consult operating instructions.</td>
<td></td>
</tr>
<tr>
<td>Refer to instruction manual / booklet.</td>
<td></td>
</tr>
<tr>
<td>Do not damage or crush.</td>
<td></td>
</tr>
<tr>
<td>Follow proper disposal procedures.</td>
<td></td>
</tr>
<tr>
<td>Meets the requirements of the European Medical Device Directive.</td>
<td></td>
</tr>
<tr>
<td>Meets the requirements of the Radio Equipment and Telecommunications Directive, 1999/5/EC.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symbol</th>
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</tr>
</thead>
<tbody>
<tr>
<td>⚡️</td>
<td>Operational temperature limitation.</td>
</tr>
<tr>
<td>⌛️</td>
<td>Use by yyyy-mm-dd.</td>
</tr>
<tr>
<td>Defibrillation proof - Can withstand the effects of an externally applied defibrillation shock. Internally powered with defibrillator-proof BF-type patient applied parts (per EN 60601-1).</td>
<td></td>
</tr>
<tr>
<td>Manufacturer.</td>
<td></td>
</tr>
<tr>
<td>Date of manufacture.</td>
<td></td>
</tr>
<tr>
<td>Manufacturer and date of manufacture.</td>
<td></td>
</tr>
<tr>
<td>Do not reuse.</td>
<td></td>
</tr>
<tr>
<td>For USA users only.</td>
<td></td>
</tr>
<tr>
<td>Federal Law (USA) restricts this device to sale by or on the order of a physician.</td>
<td></td>
</tr>
<tr>
<td>Catalogue number.</td>
<td></td>
</tr>
<tr>
<td>Keep dry.</td>
<td></td>
</tr>
<tr>
<td>Handle with care.</td>
<td></td>
</tr>
<tr>
<td>Transportation and storage requirements. See environmental requirements on packaging.</td>
<td></td>
</tr>
</tbody>
</table>
Dust protected; Protected against water jets. Does not contain latex.

Lithium manganese dioxide battery.

Serial number.

Lot number.

Classified by TUV Rheinland of NA with respect to electric shock, fire, and mechanical hazard in accordance with UL 60601-1, CAN/CSA Standard C22.2 No. 601.1-M90. Conforms to IEC 60601-1, and IEC 60601-2-4. Product is not sterile.
Manufacturer

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reporting@defibtech.com  (Medical Device Reporting)
service@defibtech.com    (Service and Repair)

This product and its accessories are manufactured and sold under license to at least one or more of the following United States patents: 5,591,213; 5,593,427; 5,601,612; 5,607,454; 5,611,815; 5,617,853; 5,620,470; 5,662,690; 5,735,879; 5,749,904; 5,749,905; 5,776,166; 5,800,460; 5,803,927; 5,836,978; 5,836,993; 5,879,374; 6,016,059; 6,047,212; 6,075,369; 6,438,415; 6,441,582.

For additional patent information, please see:
www.defibtech.com/patents