Defibtech DDU-120
Fully-Automatic
External Defibrillator

Operating Guide

For concise guidance on
set-up, use, maintenance
and technical specifications

ELECTRONIC
DISTRIBUTION

DAC-E571-EN-CE

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.

For more detailed information regarding the Defibtech DDU-120 AED, please refer to the User Manual at www.defibtech.com.

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.

Copyright

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.

IMPORTANT: This Operating Guide only applies to DDU-120 AEDs running software version 3.2 or higher that include the marking shown at left on the rear panel AED pad holder label as shown at right.

Please refer to **www.defibtech.com/support** for information about DDU-120 AEDs running earlier software versions.

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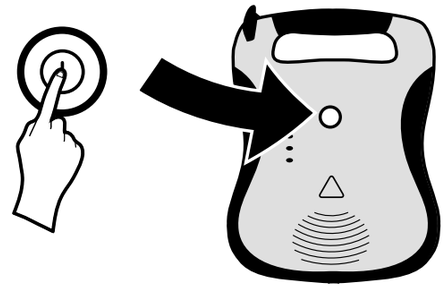
This Operating Guide is to be used for concise guidance on set-up, use, maintenance and technical specifications on DDU-120 AEDs.

For comprehensive training on set-up, use and maintenance as well as complete technical specifications, refer to the User Manual at www.defibtech.com

QUICK USE INSTRUCTIONS

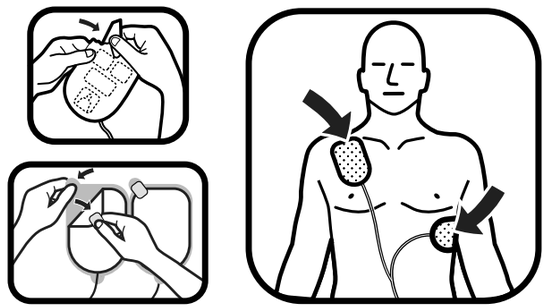
PRESS "ON" BUTTON

1



APPLY PADS

2



FOLLOW AED INSTRUCTIONS

3

WHEN TO USE

INDICATIONS

The DDU-120 Automated External Defibrillator (AED) is indicated for use on victims of sudden cardiac arrest (SCA) who are:

- Unconscious and unresponsive
- Not breathing or not breathing normally

For patients under 8 years old, or weighing less than 55 lbs (25 kg), use child/infant defibrillation pads, if available. Do not delay therapy to determine exact age or weight. Apply the pads as shown for a child/infant and use the AED.

Federal Law (USA) restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

None.

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.

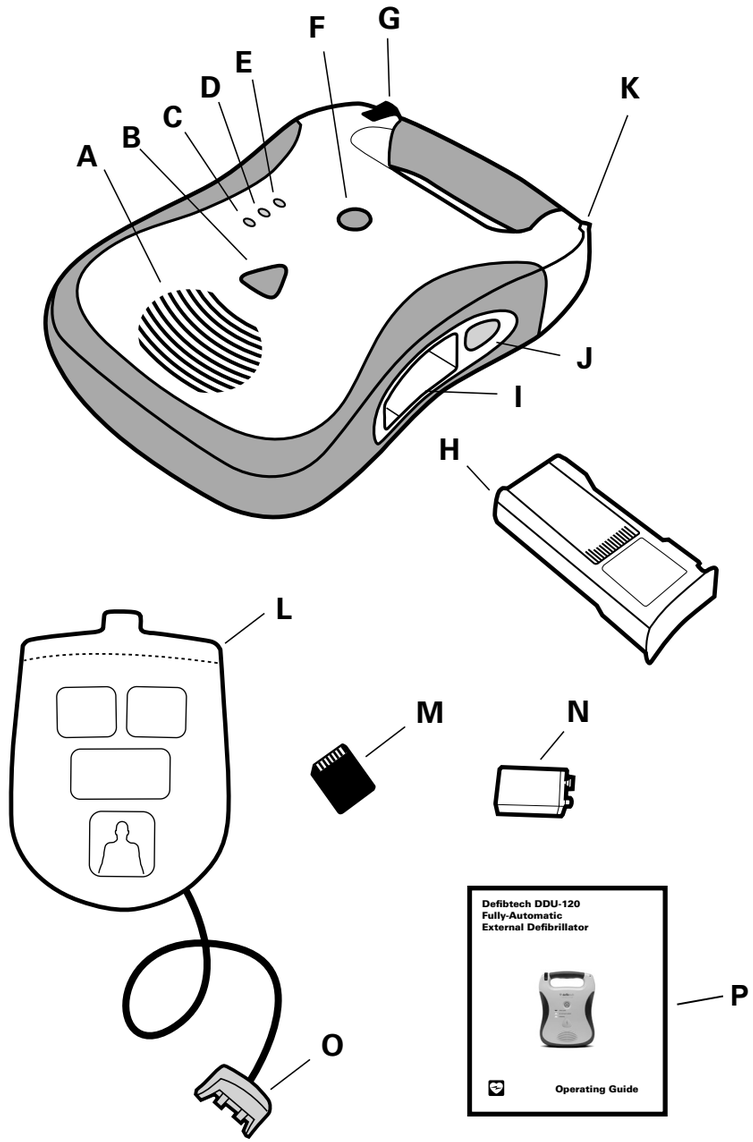
OPERATOR TRAINING REQUIREMENTS

In order to safely and effectively operate the DDU-120 AED, a person shall have met the following requirements:

- Defibtech DDU-120 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).

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

DIAGRAM OF COMPONENTS



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 Required Indicator.*** LED indicator that 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-120 AED.
(The full DDU-120 AED User Manual can be found at www.defibtech.com.)

*DDU-120 AEDs will continue to perform standby and ASI functions without the 9V ASI battery installed, but battery pack standby life will be reduced.

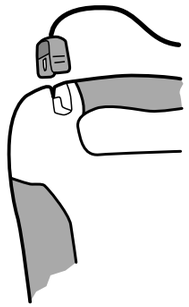
For more detailed information, refer to the User Manual (at www.defibtech.com).

SETTING UP THE AED

The DDU-120 AED is designed to be stored in a "ready" state so that few steps are required to begin using the AED.

CONNECT THE PADS TO THE AED

1

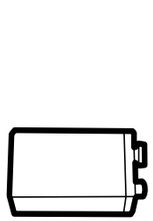


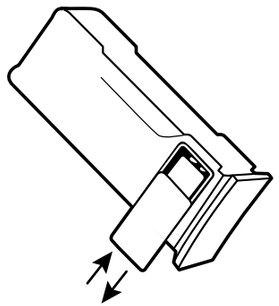
Ensure that the pads package has not expired. Expired pads must not be used.

For more information, refer to page 14.

INSTALL THE LITHIUM 9V ASI BATTERY INTO THE BATTERY PACK*

2





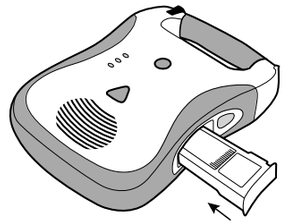
Ensure that the lithium 9V battery has not expired.

For more information, refer to page 15.

***NOTE:** DDU-120 AEDs will continue to perform standby and ASI functions without the 9V ASI battery installed, but battery pack standby life will be reduced.*

INSTALL THE BATTERY PACK INTO THE AED

3



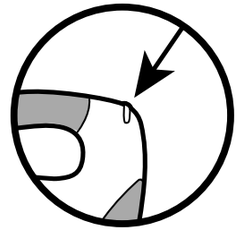
Ensure that the battery pack has not expired. Expired battery packs must not be used.

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.

CHECK THE STATUS

4



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.

READ THE USER MANUAL

(at www.defibtech.com)

5

Comprehensive information about the DDU-120 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.

TURN AED ON

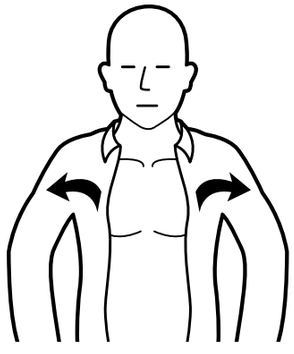
1

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.)*

PREPARE THE PATIENT

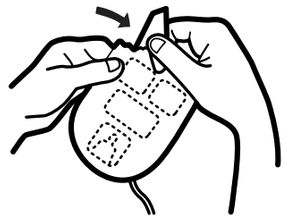
2



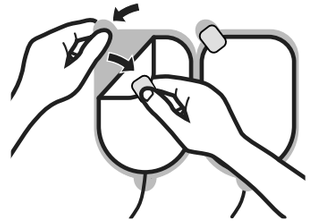
Remove clothing from patient's chest.
If necessary, dry chest and remove excess chest hair.

PREPARE PADS

3



Tear open pads package.

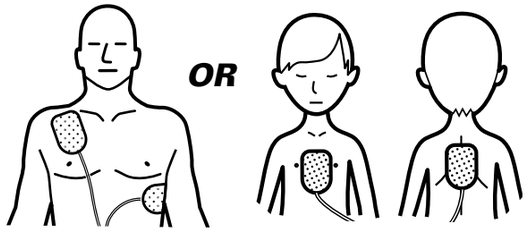


Peel adhesive pads from blue liner.

PLACE PADS

4

ADULT PATIENT **OR** **CHILD/INFANT PATIENT**



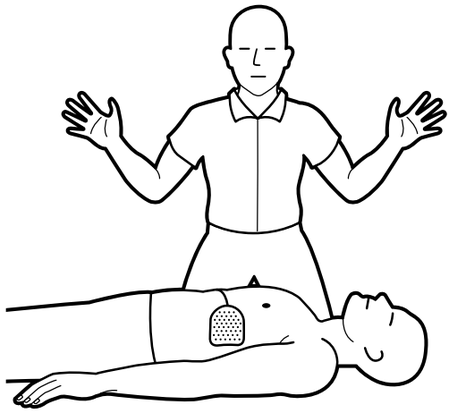
Apply pads to patient's bare chest.

For more information, refer to page 14.

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

STAND CLEAR

5



When instructed, do not touch the patient.

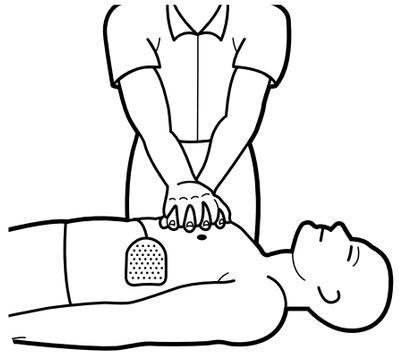
AUTOMATIC SHOCK DELIVERY (IF NEEDED)

6

If needed, 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.**

PERFORM CPR

7



Follow instructions to perform CPR, if needed.

CONTINUE TO FOLLOW INSTRUCTIONS

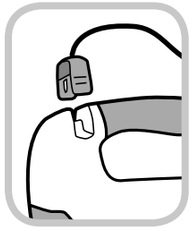
8

Continue to follow the voice prompt instructions.

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

THE DEFIBRILLATION PADS

HOW TO CONNECT THE PADS

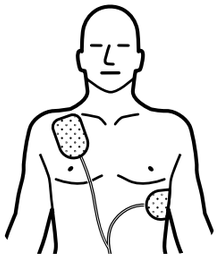


Insert the connector end of the defibrillation pad cable into the pads connector socket on the top-left corner of the DDU-120 AED as shown at left. Insert the pads connector firmly until it is fully seated in the unit. The connector will only fit in one way – if the connector does not fit, rotate the connector before trying again.

The connected pads package should then be stored in the pad storage area on the back of the DDU-120 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.

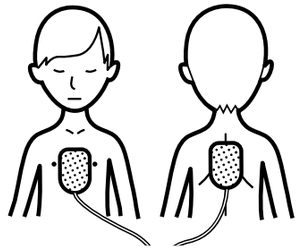
WHICH PADS TO USE

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

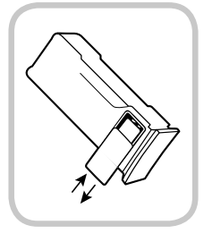
The Defibtech defibrillation pads are intended for one-time use only. The pads must be replaced after each use or if the package has been damaged.

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*.

THE BATTERY PACK

IMPORTANT: DDU-120 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-120 AEDs will operate rescue and standby functions with a battery pack that does not contain a 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 on 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-120 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.

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.

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

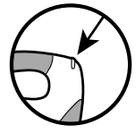
EVENT DATA

As part of Defibtech's on-going regulatory compliance activities, event data shared with Defibtech may be used by Defibtech to fulfill regulatory obligations. Any identifying personal data or health information received is considered confidential within Defibtech and will not be used for any other purpose. Please contact Defibtech at support@defibtech.com should there be any further questions.

CHECKING AED STATUS

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.

 **ACTIVE 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.

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.

MAINTENANCE

ROUTINE MAINTENANCE

The DDU-120 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.

Daily	Monthly	After Each Use	Action
●	●	●	Check that Active Status Indicator (ASI) is flashing green
	●	●	Check the condition of the unit and accessories
		●	Run manually-initiated self-test
		●	Replace pads
	●		Check pads and battery pack expiration dates
		●	Check the DDC, if one was installed

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-120 AED (including the AED itself) are sterile or require sterilization.

WARNING	Do not sterilize the DDU-120 AED or its accessories.

TROUBLESHOOTING

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).

Symptom	Possible Cause	Corrective Action
Unit will not turn on	Battery pack not inserted	Insert battery pack
	Battery pack depleted or needs servicing	Replace battery pack or call for service
	Unit needs servicing	Call for service
Unit immediately turns off	Battery pack depleted	Replace battery pack
	Unit needs servicing	Call for service
ASI flashes red and/or unit makes periodic "beep" sound	Unit may need servicing	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
	Battery pack non-functional	Replace battery pack
	Defibrillation pads are not pre-connected to unit	Connect defibrillation pads to unit
ASI does not flash at all while the unit is in standby (powered off)	Battery pack not inserted	Insert battery pack
	Battery pack is low or needs servicing	Replace battery pack or call for service
	Unit needs servicing	Call for service
"Power on test failed, service code 'xxx'" prompts	Unit needs servicing	Record code number and call for service
"Battery test failed, service code 'xxx'" prompts	Battery pack needs servicing	Record code number and replace with new battery pack
"Service required" prompt	Unit needs servicing	Call for service
"Replace battery now" prompt	Battery pack capacity is critically low	Unit may not deliver a shock, replace battery pack immediately
"Battery low" prompt	Battery pack capacity is getting low	Replace battery pack as soon as possible

Symptom	Possible Cause	Corrective Action
"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
"Apply pads to patient's bare chest as shown" prompt	Pads not connected to patient	Place pads on patient
	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	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	Motion or interference detected	Stop motion or interference
"Shock cancelled" prompt	Patient's ECG rhythm changed	No action necessary
	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

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

⚠ WARNINGS:

Immediate hazards that will result in serious personal injury or death.

- 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-120 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-120 AED is not to be used in the presence of flammable substance/air mixtures.

Conditions, hazards, or unsafe practices that may result in serious personal injury or death.

- Not intended to be used in an environment with high-frequency electrosurgical equipment.
- Improper use can cause injury. Use the DDU-120 AED only as instructed in the User Manual and Operating Guide. The DDU-120 AED delivers electrical energy that can potentially cause death or injury if it is used or discharged improperly.
- Improper maintenance can cause the DDU-120 AED not to function. Maintain the DDU-120 AED only as described in the User Manual and Operating Guide. The AED contains no user-serviceable parts — do not take the unit apart.
- No modification of this equipment is allowed.
- Electrical Shock Hazard. Dangerous high voltages and currents are present. Do not open unit, remove cover (or back), or attempt repair. There are no user serviceable components in the DDU-120 AED. Refer servicing to qualified service personnel.

WARNINGS (continued)

- Lithium metal battery packs are not rechargeable. Any attempt to recharge a lithium metal battery pack may result in fire or explosion. Do not attempt to recharge the primary battery pack or lithium 9V battery.
- Do not immerse battery pack in water or other liquids. Immersion in fluids may result in fire or explosion.
- Do not attempt to recharge, short-circuit, puncture, or deform battery. Do not expose battery to temperatures above 50°C (122°F). Remove battery when depleted.
- Do not let fluids get into the DDU-120 AED. Avoid spilling fluids on the AED or its accessories. Spilling fluids into the DDU-120 AED may damage it or cause a fire or shock hazard.
- Do not sterilize the DDU-120 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.

WARNINGS (continued)

- 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 infection, improper performance of the device, inadequate delivery of therapy, and/or injury to the patient or operator.
- Avoid contact between parts of the patient's body and conductive fluids such as water, gel, blood or saline, and metal objects, which may provide unwanted pathways for defibrillating current.
- Aggressive or prolonged CPR to a patient with defibrillation pads attached can cause damage to the pads. Replace the defibrillation pads if they become damaged during use.
- Possible Radio Frequency (RF) interference from RF devices such as cellular phones and two-way radios can cause improper AED operation. Normally using a cell phone near the AED should not cause a problem; however, a distance of 2 meters (6 feet) between RF devices and the DDU-120 AED is recommended.
- CPR during analysis can cause incorrect or delayed diagnosis by the patient analysis system.
- Do not place adult defibrillation pads in the anterior-posterior (front-back) position. A shock or no shock decision may be inappropriately advised. The DDU-120 AED requires that the adult defibrillation pads be placed in the anterior-anterior (front-front) position.
- Some very low amplitude or low frequency VF rhythms may not be interpreted as shockable. Some very low amplitude or low frequency VT rhythms may not be interpreted as shockable.

WARNINGS (continued)

- 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-120 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 dried out or expired defibrillation pads.
- Defibrillation may cause skin burns around the defibrillation pads area.
- User-initiated and automatic self-tests are designed to assess the DDU-120 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.
- Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator.
- In the event the voice prompts cannot be heard for any reason (e.g. noisy environment), follow the LEDs on the front of the AED to complete the rescue.
- It may be possible for the AED to not detect a shockable rhythm, not deliver a shock to a shockable rhythm or not deliver the intended energy during defibrillation.

Warnings continue on next page.

WARNINGS *(continued)*

- It may be possible that the AED recommends a shock for a non-shockable rhythm, and if a shock is delivered, VF or cardiac arrest may occur.
- Even if defibrillation occurs, the sudden cardiac arrest event may not result in survival.
- Defibrillation may cause myocardial damage or post-shock dysfunction.
- Therapy cannot be delivered while an AED software update is in process.
- Do not turn off the AED or remove the battery pack or the update data card until an AED software update process is complete as these actions may render the AED incapable of delivering therapy. If any of these interruptions occur, restart the update procedure from the beginning.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTIONS:

Conditions, hazards, or unsafe practices that may result in minor personal injury, damage to the DDU-120 AED, or loss of data.

- 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.
- Allergic dermatitis or a minor skin rash may result in patients that are sensitive to the materials used for the defibrillation pads. Remove the defibrillation pads from the patient as soon as practical.
- Recycle or dispose of lithium battery packs in accordance with local, state, provincial, and/or national regulations. To avoid fire and explosion hazard, do not burn or incinerate the battery pack. Do not crush.
- Use and store the DDU-120 AED only within the range of environmental conditions specified in the technical specifications.
- If possible, disconnect the DDU-120 AED from the patient prior to use of other defibrillators.
- Using non-Defibtech Data Cards (DDC cards) may damage the unit and will void the warranty.
- DefibView software is not intended for clinical use. Information presented by DefibView should not be used for making clinical decisions.
- Although the DDU-120 AED is designed for a wide variety of field use conditions, rough handling beyond specifications may result in damage to the unit.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

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

TECHNICAL SPECIFICATIONS

DEFIBRILLATOR

TYPE
Fully-automatic external defibrillator

MODEL
DDU-120

WAVEFORM
Impedance Compensated Biphasic Truncated Exponential

RESCUE PROTOCOL
AHA/ERC (default); future protocols via field updates

ENERGY*
Adult: 150 Joules
Child/Infant: 50 Joules

CHARGE TIME
4 seconds or less (from shock advised)**
Charge time may increase at the end of battery life and for temperatures below 10°C

CONTROLS
Lighted ON/OFF button

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

CPR PACING
Metronome

VOICE PROMPTS
Extensive voice prompts guide user through operation of the unit

*Nominal (±15%) delivered into a 50 ohm load
**Typical, 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 IEC 60601-2-4 and AAMI DF80 specifications and AHA recommendations

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

BATTERY PACK (HIGH-CAPACITY)

MODEL
DBP-2800

TYPE
Lithium/Manganese Dioxide Disposable, recyclable, non-rechargeable

POWER
15VDC, 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

*Typical, new battery, at 25°C

BATTERY PACK (STANDARD)

MODEL
DBP-1400

TYPE
Lithium/Manganese Dioxide Disposable, recyclable, non-rechargeable

POWER
15VDC, 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

*Typical, new battery, at 25°C

Specifications subject to change without notice.

DEFIBRILLATION / MONITORING PADS

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

SURFACE AREA
Adult: 16 inches^2 (103cm^2) (nominal, each pad)
Child/Infant: 7.75 inches^2 (50cm^2) (nominal, each pad)

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

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

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). ECG 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.

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 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)

EMC (Separation Distances)
DDU-120 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-120 User Manual at www.defibtech.com.

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

*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
Approximately 4.2 lbs (1.9 kg) with DBP-1400 battery pack

Approximately 4.4 lbs (2 kg) with DBP-2800 battery pack

CE 0197

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

GLOSSARY OF SYMBOLS

Symbol	Meaning
	High voltage present.
	Caution, consult accompanying documents.
	SHOCK Required Indicator – Flashes to indicate that a shock is about to be delivered.
	ON/OFF/DISARM Button – - Turns the device ON when it is OFF. - Turns the device OFF when it is ON. - DISARMS the device when it is charged and then turns the device OFF.
	Do not expose to high heat or open flame. Do not incinerate.
	Recyclable.
	Consult operating instructions.
	Refer to instruction manual / booklet.
	Do not damage or crush.
	Follow proper disposal procedures.
	Meets the requirements of the European Medical Device Directive.
	Meets the requirements of the Radio Equipment and Telecommunications Directive, 1999/5/EC.

Symbol	Meaning
	Operational temperature limitation.
	Use by yyyy-mm-dd.
	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).
	Manufacturer.
	Date of manufacture.
	Manufacturer and date of manufacture.
	Do not reuse.
	For USA users only.
Rx ONLY	Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Catalogue number.
	Keep dry.
	Handle with care.
	Transportation and storage requirements. See environmental requirements on packaging.

GLOSSARY OF SYMBOLS *(continued)*

Symbol	Meaning
EC REP	Authorized European Representative: EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
LATEX	Does not contain latex.
LOT	Lot number.
IP54	Dust protected; Protected against water jets.
TÜVRheinland c us	Classified by TUV Rheinland of NA with respect to electric shock, fire, and mechanical hazard only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, IEC 60601-1, and IEC 60601-2-4. Conforms to UL Standard UL 60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.
SN	Serial number.
(xx)xxxxxxxxxxxxxxx (xx)xxxxxx (xx)xxxxxxxxx	Unique Device Identification (UDI) information. *(**NOTE:** Sample shown at left is for visual reference purposes only; actual UDI information specific to this device appears on a physical label affixed to the unit's components and/or its packaging.)*
Li/MnO2	Lithium manganese dioxide battery.
NON-STERILE	Product is not sterile.

WARRANTY INFORMATION

ORIGINAL END USER'S LIMITED WARRANTY*

COVERAGE

Defibtech, LLC provides a limited warranty that the defibrillator and its associated accessories (e.g., batteries and pads), whether purchased concurrently with the defibrillator as part of a configuration or separately, shall be substantially free from defects in material and workmanship. Defibtech's limited warranty shall only extend to the original end user, where the original end user purchased the items from an authorized Defibtech, LLC retailer. This limited warranty may not be assigned or transferred. The terms of the limited warranty in effect as of the date of original purchase shall apply to any warranty claims.

LENGTH OF WARRANTY

The defibrillator's limited warranty is for a period of eight (8) years from the date of purchase. The battery's limited warranty is for a period of four (4) years from the date of purchase, but in no event shall the limited warranty period extend past the date printed on the battery. Single use accessories (e.g., the pads) shall have a limited warranty up to use or for a period up to the expiration date, whichever is earlier. The limited warranty for all other accessories is for a period of one (1) year from the date of purchase, or to the expiration date, whichever is earlier.

LIMITED WARRANTY LIMITATIONS

This limited warranty does not cover damage of any sort resulting from, but not limited to, accidents, improper storage, improper operation, alterations, unauthorized service, tampering, abuse, neglect, fire, flood, war, or acts of God. Additionally, this limited warranty does not cover damage of any sort to the defibrillator or its associated accessories resulting from the use of the defibrillator with unapproved accessories or use of the accessories with unapproved medical devices. The defibrillator and its associated accessories are not warranted to be compatible with any other medical device.

LIMITED WARRANTY VOIDED

The limited warranty is immediately voided if: the defibrillator or its associated accessories are serviced or repaired by any entity, including persons, not authorized by Defibtech, LLC; specified maintenance is not performed; the defibrillator is used with one, or more, unauthorized accessories; the associated accessories are used with an unauthorized defibrillator; or the defibrillator or associated accessories are not used in accordance with Defibtech, LLC approved instructions.

**Applicable to defibrillators and associated accessories having a date of manufacture on or after January 1, 2013. For all others, refer to warranty information in effect at the time of manufacture.*

EXCLUSIVE REMEDY

At Defibtech, LLC's sole discretion, Defibtech shall have the option to repair, replace, or provide a credit. In the event of replacement, Defibtech shall have the right at its sole discretion to replace the item with a new, or refurbished, same or similar item. Determination of a similar item shall be at the sole discretion of Defibtech. In the case of replacement, the replacement at a minimum shall reflect the prorated time remaining for the item based on the remaining limited warranty period. In the case of a credit, the credit shall be the prorated value of the item based on the lower of the original item cost of the same or similar item and the remaining limited warranty period. In no event, shall the limited warranty period of a replacement item extend past the limited warranty period of the item it is replacing.

WARRANTY SERVICE

In order to obtain warranty service, contact the retailer from whom the item was purchased, or Defibtech, LLC customer service. In the event an item must be returned, a Return Material Authorization (RMA) number is required. Items returned without an RMA number will not be accepted. The item shall be shipped at the original end user's expense to a destination specified by the retailer or Defibtech, LLC.

OBLIGATIONS AND WARRANTY LIMITS

THE FOREGOING LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND REPLACES, TO THE DEGREE PERMITTED BY APPLICABLE STATE LAW, ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

NO PERSON (INCLUDING ANY AGENT, DEALER, OR REPRESENTATIVE OF DEFIBTECH, LLC) IS AUTHORIZED TO MAKE ANY REPRESENTATION OR WARRANTY CONCERNING THE DEFIBRILLATOR OR ITS ASSOCIATED ACCESSORIES, EXCEPT TO REFER TO THIS LIMITED WARRANTY.

THE EXCLUSIVE REMEDY WITH RESPECT TO ANY AND ALL LOSSES OR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER SHALL BE AS SPECIFIED ABOVE. DEFIBTECH, LLC SHALL IN NO EVENT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, EXEMPLARY DAMAGES, SPECIAL, PUNITIVE, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR PERSONAL INJURY, EVEN IF DEFIBTECH, LLC HAS BEEN ADVISED OF THE POSSIBILITIES OF SUCH DAMAGES, HOWEVER OCCASIONED, WHETHER BY NEGLIGENCE OR OTHERWISE, UNLESS APPLICABLE STATE LAW DOES NOT ALLOW SUCH EXCLUSION OR LIMITATION.

Manufacturer

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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