URUK Co.

User Manual

DE100

Electroshock

CE 2195

D00008-V3

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Manual Purpose

This manual provides the necessary instructions to operate Automated External Defibrillator (AED) system based on its intended use. It also describes all adjustable and measurable parameters by the system, defined maneuvers, alarms and briefly all capabilities of the DE100 AED.

Observance of this manual is a prerequisite for proper operation and assures patient and operator's safety. If you have any questions about the AED, please contact our customer service department. This manual is an essential part of the AED system and should always be kept close to it, so that it can be obtained conveniently when necessary.

Intended Audience

This unit is intended to be used by trained rescuers to provide emergency defibrillation.

Version Information

This manual has a version number. The version number changes whenever the manual is revised due to software or technical specification changes. The version information of this manual is as below:

Release date	Version number
April 2022	D00008-V2

Contents

1 Introduction

1-1 Description

DE100 is an easy to use, battery operated, automated external defibrillator (AED). DE100 automatically analyses patient's ECG signal and identifies sudden cardiac arrest (SCA) and advises if the electrical shock is needed. DE100 provides audible and visual prompts during operation which simplify system usage. DE100 is manufactured based on CPR guideline of AHA revised in 2010.

DE100 provides an internal automated self-test and indicates the device is ready to use or not. DE100 operates with disposable battery and detects low battery condition and produces related prompts for battery exchanging.

DE100 is designed to operate in two different modes: Adult and child.

1-2 Intended use

DE100 is designed to use in clinical environments and public places and used by trained user with appropriate technical and clinical trainings.

DE100 automated external defibrillator (AED) are indicated for use on victims of sudden cardiac arrest who are:

- Unconsciousness
- Absence of breathing
- Absence of pulse and other sign of circulation

When the victim is less than 8 years old or less than 25 Kg weight (newborns and under 1 year old are not included), use child pad. Do not delay therapy to determine exact age or weight. If child pads are not available, apply adult pads in the position as shown for a child and set AED on child mode and use the AED.

Contraindications

Never use the DE100 Automated External Defibrillators (AED) if the victim

- Is responsive or conscious,
- Is breathing, or
- Has a detectable pulse or other sign of circulation.

DE100 is not intended for resuscitation of newborns and under 1-year-old patients.

Also, resuscitation of pregnant women should be done provided that it is under an expert (including an obstetrician and neonatologist) supervision.

1-3 Warnings and safety information

⚠ Warning

- Read User manual carefully before operating the AED system.
- The system function can be affected by using unapproved accessories.
- The AED should only be operated and maintained by trained person.
- Use only standard pads.
- The device maintenance should always be accomplished in conformity with safety regulations.
- The AED must be repaired, assembled, and used by trained personnel.
- There will be some risks to the environment pollution associated with the disposal of the device accessories and parts (e.g., pads). The device and accessories shall be disposed in compliance with relevant regulations. Contact your municipality to check where you can safely dispose the pads.
- Do not use this equipment in presence of electro-surgery.
- Maintenance of the device should be conducted due to the manufacturer recommendations in the user manual.
- Do not connect the AED to a PC or other devices while the device is connected to patient.
- Check the expiration date of electrodes.
- Check the expiration date of battery pack.
- Remove patient from strongly wet environment and conductive (metal) surface because it may lead to disfunction and burn.
- Remove any sharp object from the treatment area such as rock and knife.
- Make sure there is no direct contact between user and patient during shock.
- Do not use DE100 AED in the presence of flammable gases or anesthetics. Turn off gas source or move source away from patient during defibrillation. Do not defibrillate in an oxygen-enriched atmosphere.
- For pregnant patients, call for expert help (including an obstetrician and neonatologist) and start basic life support, ensure good quality chest compressions with minimal interruptions.

1-4 Device Labels and Symbols

Table 1: Symbols

	Waste equipment is disposed of in compliance with environmental requirements
CE	Compliance with CE standard requirements
IP22	Under 12.5 mm diameter protection from particles and vertically dripping water have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position
S/N	Serial Number
	Caution
	Consult instructions for use
	General warning
	Address of manufacturer
 **20XX**	Date of manufacture

	BF-type applied parts
	European representative
	Dangerous voltage

1-5 Guarantee and responsibilities

The manufacturer will not take any responsibility if operator:

- Misuses the device
- Fails to follow operating instructions
- Disregards any warning or technical information
- Modifies the device in any way
- Uses accessories that are not approved or recommended by manufacturer

2 Overview of DE100 AED

DE100 provides two operation modes:

1- **Rescue mode**: This is default operation mode of the device when it turns ON. In this mode AED provides rescue measures. DE100 could be configured as fully automated or semi-automated which could be decided by customer requirement.
2- **Management mode**: This mode is intended for service and troubleshooting of the device.

2-1 Defibrillation

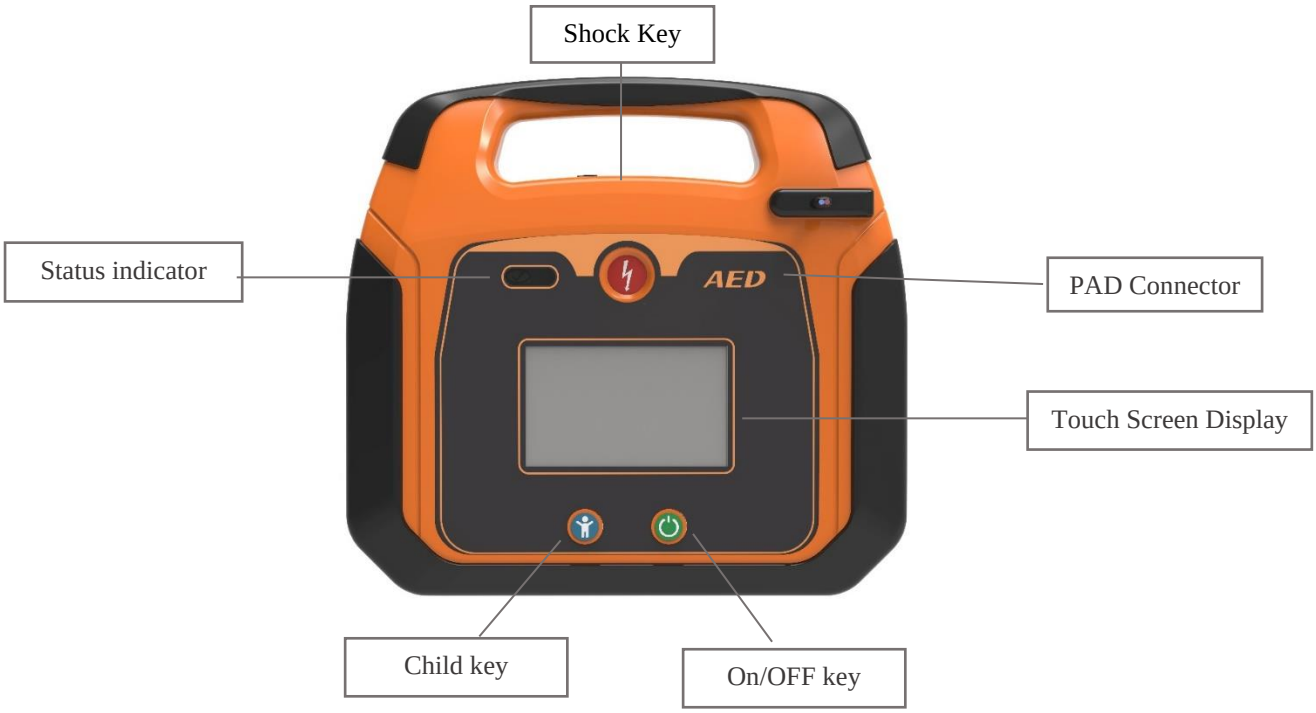
DE100 uses rectilinear biphasic waveform for defibrillation. DE100 automatically applies shock energy according to the table below:

Table 2: shock energy

	First shock	Second shock	Third shock
Adult	120	150	200
Child	50	70	85

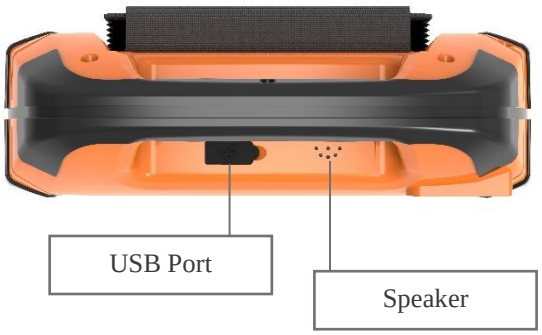
2-2 Device views

Front View



Back view

Top View



Battery Pack

Table 3: Controls

	Title	Description
1	Status indicator	Indicate the last self-test status
2	ON/OFF key	Used for turning device on or off
3	Child key	This button set AED for child mode.
4	Shock key	In semi-automatic versions, this button is used to deliver shock to patient after hearing appropriate voice alarm. When device is ready to deliver energy to patient, the LED indicator beneath this button turns on.
5	5” TFT Display and Touch screen	In rescue mode operation, LCD shows information below: • CPR help guide according to rescue situation • Displays child or adult mode is selected • Elapsed time

		In management mode, touch screen provides required control menu for configuration of the device.
6	PAD connector	PAD connection
7	Battery placement	Battery placement
8	USB Connector	USB connection for export data

3 Accessories

Only use manufacturer recommended accessories. These accessories are listed in the below table.

Table 4: Accessories

Accessory	Manufacturer	Manufacturer Part Number
Adult PAD	FIAB	F7958W
Child PAD	FIAB	F7958P
Battery Pack	SAADAT	P41021

3-1 Battery

DE100 uses non-chargeable lithium-ion manganese Dioxide battery (LiMnO2) pack for operation. Install battery pack according to below steps:

1. 

2. 

3. 

⚠ Warning

- Lithium manganese dioxide battery packs are non-rechargeable. Do not attempt to recharge the battery pack, it may result in fire or explosion.
- Do not immerse battery pack in water or other liquids It may result in fire or explosion.
- To avoid fire and explosion hazard, do not burn or incinerate the battery pack.
- Do not use the battery after its expiration date. A depleted battery shall be removed and replaced as soon as possible.
- Disposal of the battery shall be in compliance with relevant regulations.
- Extract the battery if the device is not to be used for a long period of time.

3-2 Pads

DE100 AED always has a connected pad. If the pad is not compatible with patient (Adult/child) change the pad with suitable pad according to below steps:

- **Adult**

Connect adult pad as picture below:

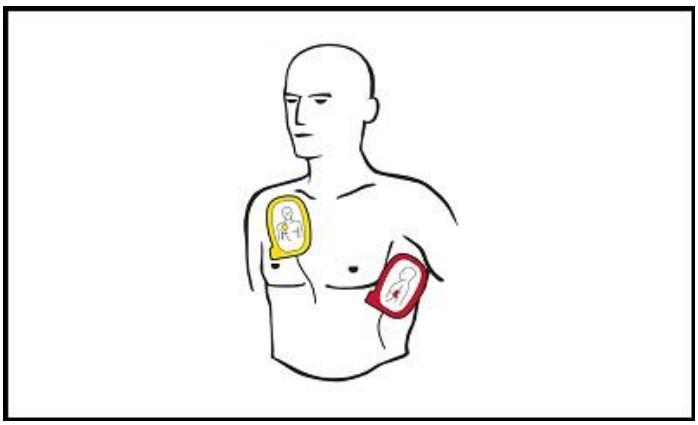


Figure 2: Adult pad placement

- **Child**

Connect child pad as picture below:

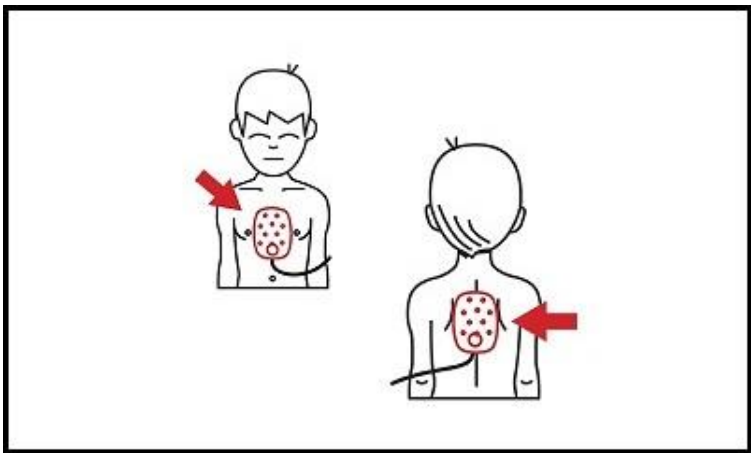


Figure 3: Child pad placement

⚠ Warning

- To prevent possible cross-contamination and inappropriate shock delivery, single-use accessories (such as pads) should not be reused.
- Pay attention to expiration date of the accessories and avoid using outdated accessories.
- When using Child pad, the Child mode will be selected automatically.
- When using Adult pad for a child patient, the rescuer must press the Child button.
- For men with hairy chest, after removing clothes, shaving is required. Make sure to remove any water and air bubble between pads and patient.
- Do not connect two pads to each other, it will result in electrical arcing.

4 Operation

4-1 Use of the AED

⚠ **Warning**

- The AED must be operated by trained rescuers.
- Be sure battery is installed and pad's cable is connected.

When DE100 is turned on in rescue mode, operators should follow below sequences:

Table 5: AED mode user prompts

Step	Action	Result
1	Turn ON AED by Press and release ON/OFF button.	AED turns ON and applies a self-test and visually shows: **SELF TEST…** If self-test result is true, AED visually shows: **UNIT OK** and plays audio prompt as below: **UNIT OK** **CALL EMS** **PRESS CHILD BUTTON IF NEEDED**
3	Apply pads to the patient's body according to visual prompts	**ATTACH DEFIBRILLATOR PADS TO PATIENT'S BARE CHEST** **(Audio prompt)**
4	Wait until ANALYZING is completed	If AED detects connected PAD, displays and plays this prompt: **DON'T TOUCH PATIENT,** **ANALYZING HEART RHYTHM** **(Audio prompt)** **ANALYZING HEART RHYTHM**

Step	Action	Result
		(Audio prompt will be repeated after 4 seconds)
5	After ANALYZING, AED decides whether a shock is needed	AED determines that patient has a shockable rhythm or not: If rhythm is shockable plays: **SHOCK ADVISED** **DON'T TOUCH PATIENT** If rhythm is not shockable Plays: **SHOCK NOT ADVISED**
6	According to previous step: If shock advised, AED automatically go to next step If no shock advised, AED automatically go to CPR help step 10	AED goes to charging mode or CPR help mode according to previous step.
7	Wait until charging is completed	Charging is started and AED displays: **CHARGING… "x" J** while charging is completed, then AED display this prompt **CHARGE COMPLETED** **STAND CLEAR**
8	In semi-automated mode press the shock button, unless go to step 9	**PRESS SHOCK BUTTON** **(Audio prompt)**
9	Stay away from the patient because the shock is delivering	AED delivers the shock and update the shock counter on display and following voice prompt will be heard: **SHOCK DELIVERED**
10	Apply CPR for 1 minute and 30 seconds, until the next prompt is played	Help prompts of the CPR is displayed until AED's next prompt **Perform CPR** **(Audio prompt)**

Step	Action	Result
		Perform CPR **(Audio prompt will be repeated each 30 seconds)** **CPR Remaining Time MINUTE: SECOND** **After 30 Pushes, Give Two Breaths** **(Visual prompt GIVE 2 RESCUE BREATHS**
11	Wait until AED determines next step	**ANALYZING HEART RHYTHM,** **DON'T TOUCH PATIENT** **(Audio prompt)** AED determine next action according to analysis and specify continue with step 7 or 10

⚠ Warning

- The defibrillator delivers up to 200 J of electrical energy. When discharging the AED, do not touch the disposable pads.
- If a person is touching the patient, bed, or any other conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Clear everyone away from contact with the patient, bed, and other conductive material before shock delivery.
- During defibrillation, air pockets between the skin pads may cause skin burns for the patent. Apply pads so that entire electrode adheres to skin. Do not reposition the electrodes once applied. If the position must be changed, remove and replace with new pads.
- Pads that are dried out or damaged may cause patient skin burns during defibrillation. Do not use pads that have been removed from foil package for more than 24 hours. Also, pads should not be in continuous contact with the patient's skin for more than 24 hours. Do not use electrodes beyond expiration date. Check that electrode adhesive is intact and undamaged. Replace pads after 50 shocks.
- Defibrillation may cause implanted devices to malfunction. Place pads away from implanted devices if possible. Check implanted device function after defibrillation, if possible.
- Do not analyze in a moving vehicle. Motion artifact may affect the ECG signal resulting in an incorrect shock or no shock advised message. Stop vehicle and stand clear of the patient during analysis.

- Do not move the AED during analysis. Moving the AED during analysis may affect the ECG signal resulting in an inappropriate shock or no shock advised decision. Do not touch the patient or the AED during analysis.
- Before using this defibrillator, disconnect all equipment that is not defibrillator-protected from the patient.
- If malfunctions could not be solved with the help of the user manual during the resuscitation, do use an alternative AED device.

5 AED Management Mode

DE100 provides management mode for device configuration, self-test, data transferring and updates.

⚠ **Warning**

- Approved supplier must change the AED setting.
- In case the cross symbol is pressed in management mode, the device will autosave the data and changes and AED will be turn off.

5-1 Preparing DE100 for Management Mode

1- Check battery is available

2- Hold **ON/OFF** key for at least 5 seconds.

5-2 Settings

The below parameters could be set in management mode:

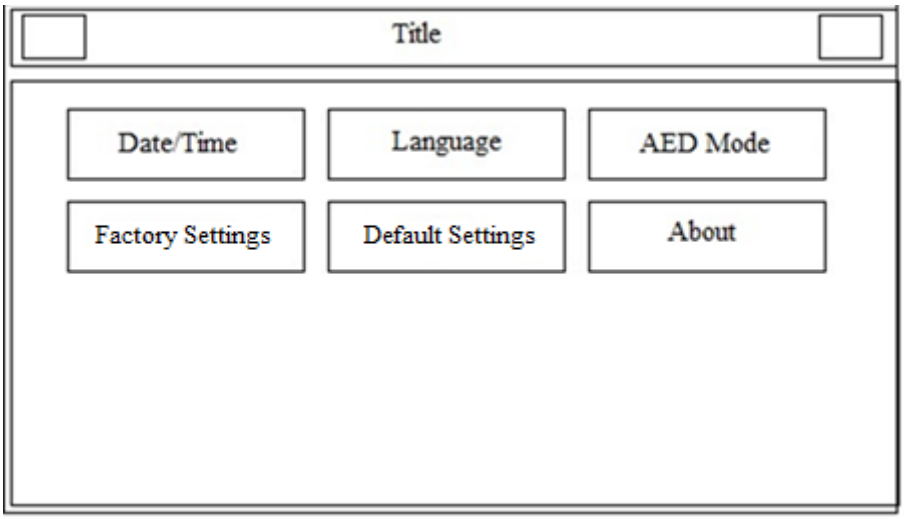


Figure 4: System setting menu

In this page, subsequent settings can be applied:

- **Date/Time**: user can adjust date or time by moving to Date/Time. Date/Time page is depicted in Figure 5

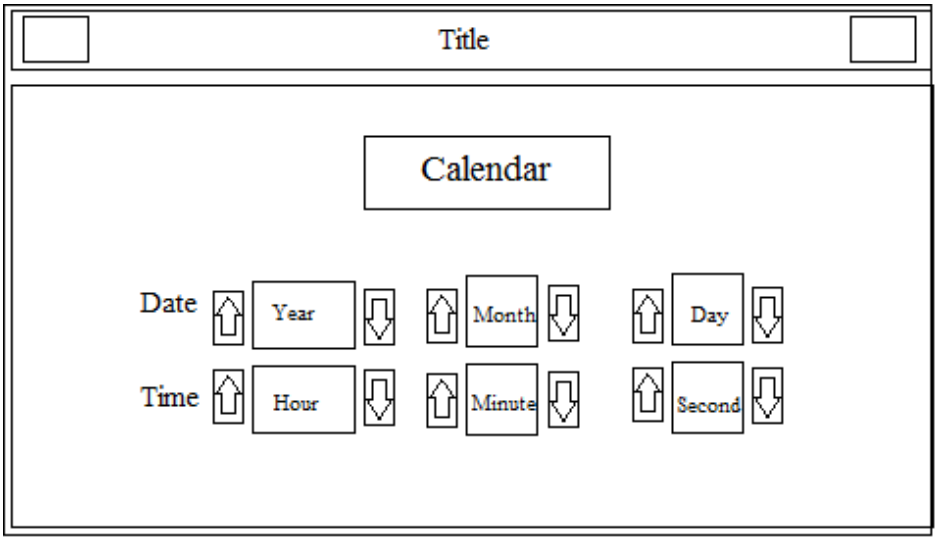


Figure 5: Date/Time page

Following changes can be done in this page:

- Calendar: Solar or Christian calendars can be selected
- Date: date can be adjusted by arrow buttons
- Time: time can be adjusted by arrow buttons

Language: English or Persian language can be selected

AED Mode: Semi or Full mode can be selected. Default state is Semi mode but if user wants to deliver shock automatically, he/she can select Full mode.

Factory Settings: Settings which should be performed by after sales service or qualified person. This menu is password-protected hence end-user should not enter this menu.

Default Settings: By pressing this button and confirmation (pressing "Yes" in subsequent menu), default settings for AED will be applied.

About: If the user opens this page, manufacturer information will be shown

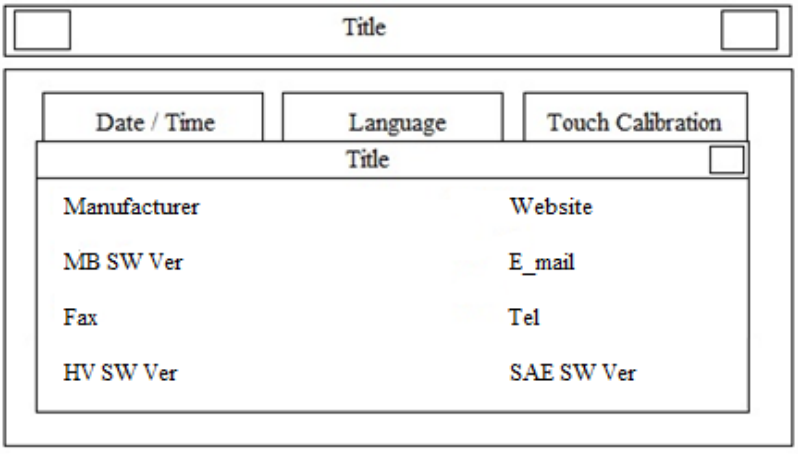


Figure 6 About page 1

6 Maintenance and Troubleshooting

In this section maintenance procedure of the DE100 AED is described:

6-1 Physical and Accessories

- Verify expiration date of pads
- Verify expiration date of battery
- Verify pad's cable is not damaged
- Verify case has no physical problem (broken...)
- Verify additional accessories are available

6-2 SELF-Test

DE100 provides self-test in order to verify device is ready to use or not.

These tests verify the following features:

- Self-test include:
  1- Battery charge
  2- ECG circuitry
  3- Defibrillator charge and discharge with low voltage (200V)
  4- Button test
  5- Pad detection

If DE100 passes each test successfully the status indicator shows (✓) symbol.

Otherwise displays (✕) symbol.

Problems and common errors of the device could be detected by troubleshooting procedure.

6-3 Troubleshooting

In the following table, issues which could be happen to DE100 AED and relative actions are described:

Table 6: Troubleshooting

Issue	Action
Status indicator shows X	when AED is OFF: Turn on the AED and wait until automated self-test is completed. If status indicator still shows X turn off the AED and replace the battery and repeat the procedure again. If issue continues, contact service department. when AED is ON: Turn the device OFF, after that turn the AED on and wait until automated self-test is completed. If status indicator still shows X turn off AED and replace the battery and repeat the procedure again. If issue continues, contact service department.
BATTERY IS TOO LOW!!! Device will shut down automatically Visual prompt	Replace the AED battery with a new battery pack. Device will perform self-test again. If visual prompt continue, contact service department.
SELF-TEST FAILED Visual prompt	Turn off the AED and then turn it on and wait until automated self-test is completed. If status indicator still shows X , turn off AED and replace the battery and repeat the procedure again. If issue continues, contact service department.
INTERNAL ERROR Voice prompt	Turn off the AED and replace the battery then press ON/OFF button. Let device performs a self-test. If issue continues, contact service department.
CHECK DEFIBRILLATOR PAD	Check defibrillator pad is correctly connected to patient and AED. Replace PAD with a new one. If issue continues, contact service department.
Connect AED Cable to the Device Visual prompt	Check defibrillator paddle connector is correctly connected to the socket. If issue continues, contact service department.

6-4 Periodic inspection

There is a periodic inspection procedure for the AED which is done every 1 years after sale by the company. All critical components are tested in this procedure and malfunctioning ones will be replaced.

⚠ **Warning**

- Do not open unit, remove casing or attempt to repair. Dangerous high voltages and currents are present. Refer servicing and periodic inspections to qualified service personnel.

7 Cleaning and disinfecting

Casing

- Exterior surface of the device, including battery pack, should be cleaned and disinfected after each use. Use a dampened cloth with soap and water, ammonia-based cleaners or 70% isopropyl alcohol in this case.
- Do not let the cleaning agent enter into the housing of the system. (And specially in the port of connector).
- Dry out the cleaning agents on any part of the device.

PADs

- The only parts of the AED which are in direct contact with patients are disposal PADs and because they are just for one-time use, they do not transfer any contaminants to patients. Thus, there is no need for cleaning and disinfecting,
- Do not sterilize the DE100 AED and its accessories.

LCD

- Do not wipe the display with dry cloth. It might cause scratch.
- Only use a soft sloth with IPA to wipe the polarizer, other chemicals might permanent damage to the polarizer.

The following table summarizes the methods of cleaning, disinfecting and sterilizing for different parts of the device:

<table>
<tr><th>Device parts</th><th>Single-use</th><th>Cleaning</th><th>Disinfection</th><th>Sterilization</th></tr>
<tr><td>External surface of device including battery pack</td><td>-</td><td colspan="2">Must be cleaned and disinfected after each use, using a dampened cloth with soap and water, ammonia-based cleaners or 70% isopropyl alcohol.</td><td rowspan="3">Do not sterilize the DE100 AED and its accessories.</td></tr>
<tr><td>PADs</td><td>disposable</td><td colspan="2">PADs are just for one-time use and there is no need for cleaning and disinfecting.</td></tr>
<tr><td>LCD</td><td>-</td><td colspan="2">Only use a soft sloth with IPA to wipe the polarizer.</td></tr>
</table>

8 Technical Specifications

Table 8: Specifications

General	Disposable Battery		
	Chemistry	LiMnO2	
	voltage	15V	
	Battery capacity	5Ah, 200 defibrillator discharges at maximum energy (200J) or 5 hours of continuous ECG Monitoring	
	Shelf-life	5 years	
	Environment		
	Operating Temperature	0° to 50° C	
	Storage Temperature	-30° to 70° C	
	Humidity	10 to 95% relative humidity	
	Altitude	-1,250 to 15,000 ft.; -381 m to 4573 m	
	Particle and Water Ingress	IP22	
Mother Board	User Interface		
	Display	Type	LCD with resistive touch
		Size	5 inches
		Resolution	400*800 pixel
		Parameters	Number of Shock, Time, Elapsed Time, Battery capacity and Menu
	ON/OFF Button		Turns Power ON or OFF
	Child Selection Button		Sets AED to child mode
	Speaker		Provides audio prompts and necessary alarms
	Shock Button		It used for semi-automated models (Illuminated button)
HV Board	Waveform		Rectilinear Biphasic
	Energy Selections		Automatic pre-programmed selection Adult mode: 120J, 150J, 200J Child mode: 50J, 70J, 85J
	Charge Time		Less than 15 seconds with new battery pack
	Self-Test		Internal self-test includes: charge circuit, shock circuit
	Patient Impedance Measurement		Yes
	Impedance Range		25-175 ohms
	Shock Delivery		Fully automated model Semi-Automated model
	Communication		UART Communication with Mother Board UART Communication with ECG Board
ECG Bo	ECG Bandwidth		1-30 Hz
	Shockable Rhythms		Algorithm spec

	Defibrillator Electrode ECG Circuitry	Protected
	Analyzing Time	< 10s
	Communication	UART Communication with Mother Board UART Communication with HV Board
Operating Time	Time required for device to get ready at maximum energy from Power ON for all battery conditions	Less than 40s
	Time required for device to get ready at maximum energy from start of ECG analyzing for all battery conditions	Less than 30s
Compliance and Approvals	Classifications	Internally powered per EN 60601-1: 2006/A1: 2013, EMC related group and classification: Group 1, Class B
	Meets International Standards	Meets applicable requirements EN 60601-1: 2006/A1: 2013, EN 60601-1-2: 2015, IEC 60601-2-4:2010+AMD1: 2018

Appendix 1_ Rectilinear Biphasic Waveform

DE100 uses rectilinear biphasic waveform which reduces peak current of the shock. Below table shows the energy characteristics for different energy and loads.

Table 8: Delivered energy for different loads

Load	**Selected Energy**					
	Child			Adult		
	50 J	70 J	85 J	120 J	150 J	200 J
25	43	62	77	94	110	129
50	55	78	97	120	140	172
75	60	85	106	142	166	193
100	58	82	102	140	164	192
125	59	84	94	131	154	180
150	61	87	109	122	143	151
175	57	80	100	113	133	142
Accuracy	±15%	±15%	±15%	±15%	±15%	±15%

Rectilinear biphasic waveform has better performance in comparison with traditional Biphasic truncated exponential waveform according to clinical result. In the following rectilinear biphasic current graph, waveforms for different load are depicted.

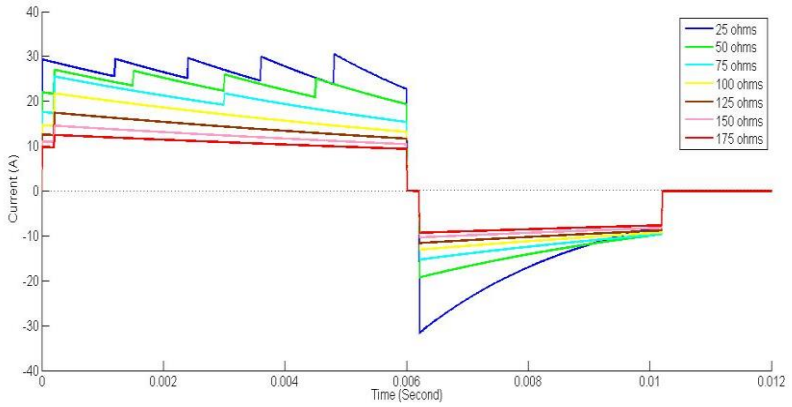


Figure 7: 200J Shock Current waveform

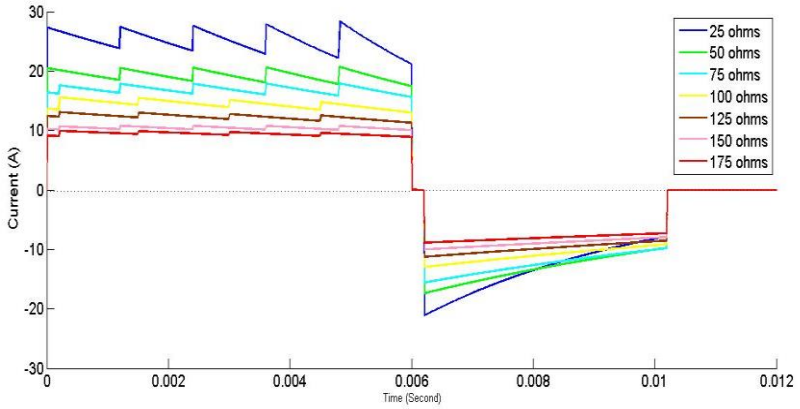


Figure 8: 150J Shock Current waveform

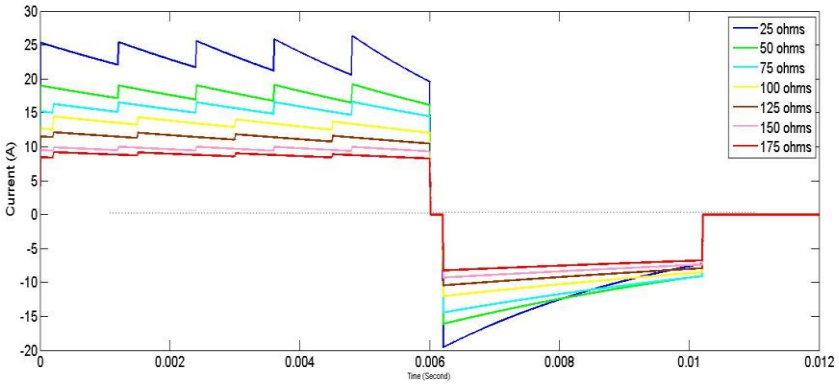


Figure 9: 120J Shock Current waveform

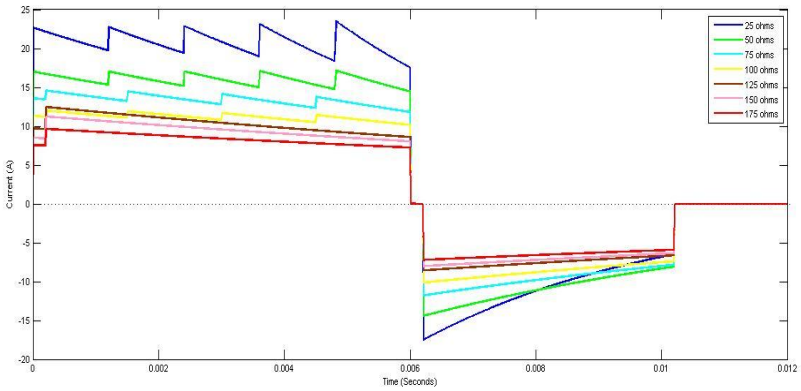


Figure 10: 85J Shock Current waveform

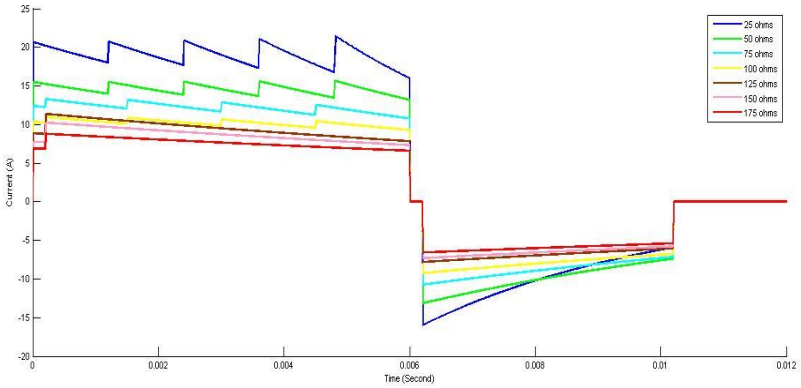


Figure 11: 70J Shock Current waveform

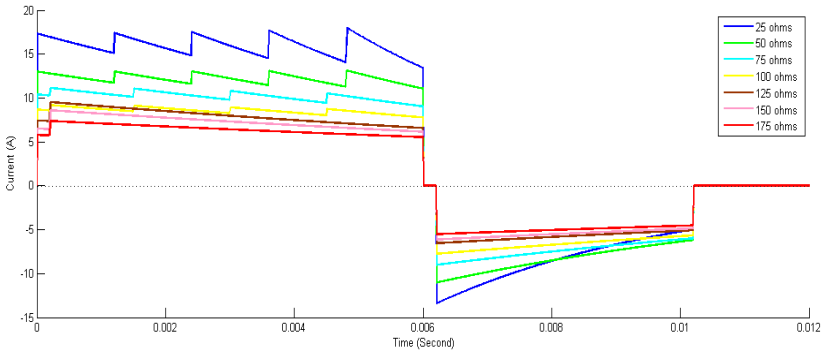


Figure 12: 50J Shock Current waveform

Appendix 2_ ECG Analysis Algorithm Accuracy

This appendix describes the basic function of the Shock Algorithm (SA).

Overview

Shock Algorithm (SA) is an ECG analysis program in the DE100 automatic external defibrillator that recommends whether or not a patient should be given a defibrillation shock. This algorithm makes it possible for individuals who are not trained to interpret ECG rhythms to provide potentially life-saving therapy to victims of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). The Shock Algorithm is used to analyze the ECG rhythm during the first rhythm analysis after the electrode pads have been placed on the patient when CPR is not being performed. It is also used during subsequent rhythm analyses when the user has been instructed to stop CPR.

Automated Interpretation of the ECG

The DE100 automatic external defibrillator recommends a shock if either of the following rhythms is detected:

- Ventricular fibrillation
- Rapid ventricular tachycardia (Rate >150 bpm, patient should be pulseless)

The DE100 automatic external defibrillator recommends no shock for non-shockable ECG rhythms as indicated in the Shock Algorithm Performance Report in this appendix.

The DE100 automatic external defibrillator is designed to detect and remove pacemaker pulses from the ECG so that an accurate decision can be reached while a pacemaker is functioning.

Shock Algorithm

The Shock Algorithm (SA) in the DE100 automatic external defibrillator was verified by inputting specific ECG waveform segments from databases through the electrode connector and recording the SA decision of 'shock' or 'no shock.' The 'shock' or 'no shock' decision made by the SA for each ECG waveform segment was compared to the databases reference annotations or treatment recommendation by similar device.

The main ECG database used to verify the performance of the DE100 automatic external defibrillator for SA is named the PhysioNet Test Set. In addition, the ECG database named Simulator Test Set was used to provide shockable and Non-shockable ECG segments for verification purposes. The following information about the test sets and the Summary Performance Report is provided in accordance with AHA recommendations[1] and IEC requirements[2] for reporting performance data for a rhythm recognition detector.

[1] Kerber RE, et al, "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety: A Statement for Health Professionals from the American Heart Association Task Force on Automatic External Defibrillation", Subcommittee on AED Safety and Efficacy. Circulation, 1997: Vol. 95: 1677-1682.

[2] Clause 201.7.9.3.103, "Essential Performance data of the Rhythm Recognition Detector," International Electrotechnical Association, IEC 60601-2-4, Medical Electrical Equipment – Part 2-4: Particular Requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators: 2018.

A. Acquisition and Annotation Methodology

This section includes recording methods, rhythm source, rhythm selection criteria, annotation methods, and annotation criteria for the databases.

PhysioNet Test Set

The PhysioNet Test Set includes 5891 ECG segments gathered from a variety of sources. Each ECG segment is 8 seconds in duration. Sources for the ECGs include:

- Creighton University Ventricular Tachyarrhythmia Database (CUDB):
  This database includes 35 eight-minute ECG recordings of human subjects who experienced episodes of sustained ventricular tachycardia, ventricular flutter, and ventricular fibrillation. Records was obtained from a long-term ECG (Holter) recording and from patient monitors. Five records were from paced patients. The reference annotation files supplied for this database have been included to aid users in locating VF segments.

- MIT-BIH Malignant Ventricular Ectopy Database (VFDB):
  This database includes 22 half-hour ECG recordings of subjects who experienced episodes of sustained ventricular tachycardia, ventricular flutter, and ventricular fibrillation. The reference annotation contains rhythm labels including atrial fibrillation, asystole, ventricular bigeminy, first degree heart block, high grade ventricular ectopic activity, normal sinus rhythm, nodal rhythm, noise, pacemaker (paced rhythm), sinus bradycardia, supraventricular tachyarrhythmia, ventricular escape rhythm, ventricular fibrillation, ventricular flutter and ventricular tachycardia.

- MIT-BIH Arrhythmia Database (MITDB):
  The MIT-BIH Arrhythmia Database contains 48 half-hour excerpts of two-channel ambulatory ECG recordings, obtained from 47 subjects. Two or more cardiologists independently annotated each record.

- AHA Ventricular Arrhythmia Database (AHADB):
  AHA database consisted of 80 two-channel excerpts of analog ambulatory ECG recordings. These 80 recordings are divided into eight classes of ten recordings each, according to the highest level of ventricular ectopy present. In this case, we use part 8 (ventricular flutter/fibrillation) of AHA database.

Simulator Test Set

The Simulator Test Set include 52 ECG segments gathered from the Fluke Impulse 7000DP Defibrillator Analyzer. Each ECG segment is 10 seconds in duration and including Ventricular Fibrillation (VF) rhythms of varying amplitudes, Ventricular Tachycardia(VT) rhythms of varying rates and QRS width, Normal Sinus Rhythms varying rates and amplitude and asystole. These segments are given to the ZOLL AED Pro and we consider the result of this device (shock/no shock) as a reference.

B. ECG Rhythm Types

The ECG rhythms were placed into the following categories:

Shockable

- Coarse ventricular fibrillation (VF) (≥0.20 mV peak-to-peak amplitude)
- Rapid ventricular tachycardia (VT) (Rate >150 bpm, patient should be pulseless)

Non-Shockable

- Normal sinus rhythm (NSR)
- Other Non-Shockable rhythms including atrial fibrillation/flutter, atrioventricular block, idioventricular rhythms, sinus bradycardia, supraventricular tachycardia, and premature ventricular contractions (PVC).
- Asystole (<0.1 mV peak-to-peak amplitude)

Intermediate

- Fine ventricular fibrillation (VF) (<0.20 and ≥0.1 mV peak-to-peak amplitude)
- Other VT (ventricular tachycardia that does not meet criteria for VT in the shockable rhythms category)

Also included rhythms with pacemaker pulses.

C. Shock Algorithm Performance Report

The results of tests with the Simulator and PhysioNet Test Sets in the DE100 automatic external defibrillator are shown below in the context of requirements from IEC 60601-2-4 and the recommendations from the American Heart Association.

Table 1 IEC 60601-2-4 Requirements and SA Performance

Rhythm Category	Requirement	Test Result
Shockable (Sensitivity) Coarse VF Rapid VT, pulseless	 >90% >75%	 >90% >89%
Non-Shockable (Specificity)	>95%	>96%
Positive Predictive Value	Report Only	>78%
False Positive Rate	Report Only	<4%

Table 2 AHA Recommendations and SA Performance

Rhythms	Performance Goal	Observed Performance	Minimum Test Sample Size	Sample Size Tested
Shockable Coarse VF Rapid VT, pulseless	 >90% (Sensitivity) >75% (Sensitivity)	 >90% >89%	 200 50	 457 199
Non-Shockable NSR Other QRS Asystole	>99% (Specificity) >95% (Specificity) >95% (Specificity)	>96% >97% >92%	300 total 100 30 100	5270 total 4123 1118 29
Intermediate Fine VF Other VT	Report Only Report Only	Same as Zoll AED Pro	25 25	10 7

Appendix 3_EMC

DE100 AED is intended for use in the electromagnetic environment specified below. The customer or the user of device, should ensure that it is used in such an environment.

⚠ Warning

- Use only the recommended manufacturer accessory. Using the accessory other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that the AED is used the electromagnetic environment specified.
- To prevent EMC effect on the AED, the system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- It is suggested to use another sensitive device in distance with the AED.

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration – DE100 emissions</td></tr>
<tr><td colspan="4">The DE100 is intended for use in the electromagnetic environment specified below. The customer or the user of the DE100, should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td colspan="2">Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td colspan="2">Group 1</td><td>The DE100 AED uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment</td></tr>
<tr><td>RF emissions
CISPR 11</td><td colspan="2">Class B</td><td rowspan="3">The DE100 is suitable for use in all establishments.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td colspan="2">N.A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td colspan="2">N.A</td></tr>
<tr><td colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The DE100 is intended for use in the electromagnetic environment specified below. The customer or the user of the DE100 should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>Port</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
</table>

Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ±2 kV, ± 4kV, ± 8kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling	N.A	
	Signal input/output parts	N.A	
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Surge IEC 61000-4-5	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Voltage dips, IEC 61000-4-11	Input a.c. power	N.A	
		N.A	
Voltage interruptions IEC 61000-4-11	Input a.c. power	N.A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The DE100 is intended for use in the electromagnetic environment specified below. The customer or the user of the DE100 should assures that it is used in such an environment.

Immunity test	Port	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	Input a.c. power	N.A	
	PATIENT coupling		
	Signal input/output parts		
Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m, 80 MHz - 2,7 GHz, 80% AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380- 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430- 470	GMRS 460, FRS 460	FM [C] ±5 KHz deviation 1 KHz sine	2	0.3	28

710 745 780	704- 787	LTE Band 13, 17	Pulse modulation [b)] 217 Hz	0.2	0.3	9
810 870 930	800- 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b)] 18 Hz	2	0.3	28
1720 1845 1970	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b)] 217 Hz	2	0.3	28
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b)] 217 Hz	2	0.3	28
5240 5500 5785	5100- 5800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	0.2	0.3	9

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Change history

Rev	Date	Description	Created By	Confirmed By	Approved By
1		Initial Release	Mohsen	Shima	S.Mohammad
2		European Authorized Representative was changed	Mohsen	Shima	S.Mohammad
3	2023/04/16	European Authorized Representative was changed	Mohsen	Shima	S.Mohammad