DE100

Electroshock

User Manual – V5

Change history					
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DE100

Electroshock

User Manual

CE 2195

D00008-V5

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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 Users

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
August 2025	D00008-V5

- Read this manual carefully before using the monitor.
- All of the images in this manual are for example; Therefore, it should not necessarily reflect the settings of your device or the data displayed on it.
- URUK Co. reserves the right to make changes to this manual and improvements to the product it describes at any time without notice obligation.
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Contents

1. Introduction

Overview

DE100 defibrillator is an automated external defibrillator (AED) that is designed to be used for both adult and child victims of sudden cardiac arrest (SCA).

DE100 uses audio and visual prompts to guide the rescuer through a resuscitation sequence that may include defibrillation and/or cardiopulmonary resuscitation (CPR) based on AHA guideline.

The DE100 AED defibrillator incorporates the Rectilinear Biphasic Defibrillation waveform.

When the rescuer attaches defibrillation pads to a patient's chest, the AED monitors and analyzes the electrocardiographic (ECG) rhythm of the patient's heart to determine whether or not the ECG rhythm is shockable. If the AED detects a shockable rhythm, it either issues instructions to deliver the shock (semi-automatic) or automatically delivers the shock (fully automatic). The DE100 AED then prompts the rescuer to perform CPR for a period of time, after which the AED automatically initiates a new ECG analysis.

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

Intended use

DE100 AED is indicated for defibrillation of adult and child victims of sudden cardiac arrest with obvious circulatory insufficiency (which is as follows):

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

The device can also be used for ECG monitoring to evaluate the patient's heart rate or ECG morphology.

Contraindications

- Never use the DE100 AED if the victim is responsive, conscious, breathing, or has a detectable pulse or other signs of circulation.
- DE100 is not intended for resuscitation of newborns and under 1-year-old patients. Resuscitation of pregnant women should be done provided that it is under an expert (including an obstetrician and neonatologist) supervision.

Intended Users

The DE100 AED device is intended to be used by personnel who are qualified by training in the use of the DE100 AED device, basic life and/or advanced life support, or other physician-authorized emergency medical training.

Operation environment

- Clinical places
  - Hospitals
  - Ambulances
  - Clinics
  - Other clinical centers
- Public places
  - Offices
  - Police and firefighter vehicles
  - Religious places
  - Schools and universities
  - Trade centers
  - Airports
  - Subway stations
  - Hotels and residencies
  - Any crowded building

Warnings and safety information

⚠ Warnings

- Read User manual carefully before operating the AED system. Improper use of the device can cause death or serious injury.
- The DE100 AED unit detects ECG electrical signals only and does not detect a pulse (effective circulatory perfusion). Always verify pulse and heart rate by physical assessment of the patient. Never assume that the display of a nonzero heart rate means that the patient has a pulse.
- Inappropriate defibrillation of the patient (eg, without the arrhythmia required to deliver a shock) can precipitate ventricular fibrillation, asystole, or other dangerous types of arrhythmias.
- RISK OF ELECTRIC SHOCK - Never attempt to modify, repair, or open the device. Leave any device service to personnel approved by the manufacturer.
- The DE100 AED defibrillator is not intended for use in fixed or rotary wing aircraft.
- The DE100 AED defibrillator should only be used by properly trained individuals.
- Before using the device, keep the patient away from electrically conductive surfaces.
- Don’t use the DE100 AED defibrillator near or within puddles of water.

- Don’t use the DE100 AED in an oxygen-rich environment, near anesthetic and flammable gases. During shock administration, turn off the gas source or keep it away from the patient.
- MR Unsafe - Keep the DE100 AED defibrillator away from magnetic resonance imaging (MRI) equipment.
- Turn off cell phones and radio equipment to avoid frequency interference that may cause erroneous cardiac signal analysis.
- Disconnect non-defibrillation protected electronic devices or equipment from victim before defibrillation.
- Before using the defibrillator, remove all equipment that interferes with the operation of the defibrillator from the patient.
- The DE100 AED defibrillator rejects implanted pacemaker pulses.
- Don’t use the DE100 AED defibrillator on/together with another equipment. If the defibrillator must be used with/on other equipment, verify proper operation prior to use.
- Don’t connect the DE100 AED defibrillator to a flash memory or other devices (using the USB port) while the defibrillation pads are still connected to the victim.
- The USB port of the defibrillator is included only for flash use. Do not connect wireless adapters or any unauthorized devices to the USB port.
- In order to prevent environmental pollution, the destruction of accessories (batteries and pads) should be done according to the relevant regulations.
- Don’t use the device with electrosurgery simultaneously.
- Maintenance of the device should be done according to the manufacturer's recommendations given in this manual.
- Before using the device, remove the patient from very humid environments and conductive surfaces (metal), because it may lead to incorrect operation of the device and burns
- Keep any sharp objects such as stones and knives away from the treatment environment.
- In order to perform resuscitation for pregnant patients, contact the relevant expert (including obstetrician and pediatric and newborn specialist) and ensure correct and high-quality chest compressions with minimal interference.

تحذيرات ومعلومات السلامة

⚠ تحذيرات

- اقرأ دليل المستخدم بعناية قبل تشغيل جهاز AED. قد يؤدي الاستخدام غير الصحيح للجهاز إلى الوفاة أو الإصابة الخطيرة.
- وحدة DE100 AED تكشف الإشارات الكهربائية لتخطيط القلب فقط ولا تكشف النبض (إرواء الدورة الدموية الفعال). تحقق دائمًا من النبض ومعدل ضربات القلب عن طريق التقييم البدني للمريض. لا تفترض أبدًا أن عرض معدل ضربات القلب غير الصفر يعني أن المريض لديه نبض.
- يمكن أن يؤدي إزالة الرجفان غير الصحيح للمريض إلى التعجيل بالرجفان البطيني أو توقف الانقباض أو أنواع خطيرة أخرى من عدم انتظام ضربات القلب.

- خطر التعرض لصدمة كهربائية - لا تحاول أبدًا تعديل الجهاز أو إصلاحه أو فتحه. اترك خدمة أي جهاز للموظفين المعتمدين من قبل الشركة المصنعة.
- جهاز إزالة الرجفان DE100 AED غير مخصص للاستخدام في الطائرات ذات الاجنحة الثابتة أو المتحركة.
- يجب استخدام جهاز إزالة الرجفان DE100 AED بشكل صحيح فقط من قبل الأفراد المدربين.
- قبل استخدام الجهاز، أبعد المريض عن الأسطح الموصلة للكهرباء.
- لا تستخدم جهاز إزالة الرجفان DE100 AED بالقرب من أو داخل برك الماء.
- لا تستخدم جهاز DE100 AED في بيئة غنية بالأكسجين، وبالقرب من مواد التخدير والغازات القابلة للاشتعال.
- أثناء إدارة الصدمة، قم بإيقاف تشغيل مصدر الغاز أو إبقائه بعيدًا عن المريض.
- MRI غير آمن - احتفظ بجهاز إزالة الرجفان DE100 AED بعيدًا عن معدات التصوير بالرنين المغناطيسي (MRI).
- قم بإيقاف تشغيل الهواتف المحمولة وأجهزة الراديو لتجنب تداخل التردد الذي قد يتسبب في تحليل خاطئ لإشارات القلب.
- افصل الأجهزة أو المعدات الإلكترونية المحمية غير القابلة لإزالة الرجفان عن المريض قبل إزالة الرجفان.
- قبل استخدام مزيل الرجفان، قم بإزالة جميع المعدات التي تتداخل مع تشغيل مزيل الرجفان من المريض.
- يرفض جهاز إزالة الرجفان DE100 AED نبضات جهاز تنظيم ضربات القلب المزروع.
- لا تستخدم جهاز إزالة الرجفان DE100 AED مع جهاز آخر. إذا كان من الضروري استخدام جهاز مزيل الرجفان مع/على معدات أخرى، فتحقق من التشغيل السليم قبل الاستخدام.
- لا تقم بتوصيل جهاز إزالة الرجفان DE100 AED بذاكرة فلاش أو غيرها من الأجهزة (باستخدام منفذ USB) بينما لا تزال منصات إزالة الرجفان مرتبطة بالمريض.
- لا تقم بتوصيل اي جهاز في منفئ ال USB لانها مخصصة فقط ل USB Flash Memory.
- من أجل منع التلوث البيئي، يجب أن يتم تدمير الملحقات (البطاريات والوسادات) وفقًا للوائح ذات الصلة.
- لا تستخدم الجهاز مع الجراحة الكهربائية في وقت واحد.
- يجب أن تتم صيانة الجهاز وفقًا لتوصيات الشركة المصنعة.
- قبل استخدام الجهاز، أبعد المريض عن البيئات شديدة الرطوبة والأسطح الموصلة (المعدنية)، لأن ذلك قد يؤدي إلى تشغيل غير صحيح للجهاز ويسبب الحروق.
- أبعد أي أدوات حادة مثل الحجارة والسكاكين عن بيئة العلاج.
- من أجل إجراء الإنعاش للمرضى الحوامل، اتصل بالخبير المعني (بما في ذلك طبيب التوليد وأخصائي الأطفال وحديثي الولادة) وتأكد من الضغط على الصدر بشكل صحيح وعالي الجودة بأقل قدر من التدخل.

Device Labels and Symbols

	Waste equipment is disposed of in compliance with environmental requirements
CE 2195	CE sign & NB identification number

IP44	Protection against ingress of small solid foreign bodies (diameter greater than 1mm). Water splashed against the enclosure from any angle shall have no harmful effect.
SN	Serial Number
	Consult instructions for use
	General warning
	Address of manufacturer
 **yyyy**	Manufacture Date country code
	BF-type applied parts
EC REP	European Community Representative
	Dangerous voltage
UID	Equipment has a unique identifier.
MD	Equipment is medical.

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. Product Overview

Overview

DE100 provides two operation modes:

1- **Rescue mode**: In this mode, DE100 defibrillator provides the necessary measures to save the patient. DE100 could be configured as fully automated or semi-automated which could be decided according to customer requirement.
2- **ECG Monitoring Mode**: The DE100 AED defibrillator provides nondiagnostic ECG display of the patient's heart rhythm when the ECG cable is connected and the electrodes are applied.

To guide the operator through rescue protocols, the DE100 AED unit issues instructions through text messages displayed on its screen and by voice prompts played through a speaker.

Rescue Mode

As the defibrillator pads are plugged into the connector, DE100 AED is automatically set to Rescue mode and applying a shock to the patient is possible. In this mode, DE100 AED analyses the patient's ECG through the defibrillator pads attached to the patient. If the unit detects a shockable rhythm, it automatically charges the appropriate (preconfigured) energy level. Once the defibrillator is fully charged, considering the system settings, acts as one of the following:

- Semiautomatic Mode Defibrillation
  The *Shock* button begins flashing. The unit also emits a charge-ready tone, and directs the rescuer to press the *Shock* button. the rescuer must deliver the shock within 30 seconds of full charge, otherwise the defibrillator automatically disarms itself, and the unit resumes ECG analysis.

- full-automatic Mode Defibrillation
  The shock is delivered to the patient automatically and with a countdown in three seconds.

After delivering a shock to the patient, the rescuer will be guided to apply the CPR. after the time of the CPR is over, the signal will be analyzed again to deliver additional shocks, if needed.

ECG Monitoring

As the ECG cable is plugged into the connector, DE100 AED is automatically set to ECG Monitoring mode. The ECG monitoring mode provides ECG rhythm display, as well as performing background ECG analysis to detect shockable rhythms. If the DE100 AED unit detects a shockable rhythm during monitoring, it immediately alerts the rescuer through displayed text and voiced prompts; defibrillation pads are attached, the unit automatically switches to semiautomatic mode.

Note

After the device is charged while in rescue mode and semi-automatic AED mode, if the shock button is not pressed within 30 seconds, the device automatically discharges the charged circuits internally.

All ECG monitoring is performed in the lead II configuration. The operator cannot select another lead.

Data Transfer

The DE100 AED unit includes nonvolatile memory, which automatically records:

- Device history which is a summary of the whole self-test results (serial number, the software version, the date and time of the self-test, battery percentage, errors occurred during self-tests)
- Clinical data (A summary of the patient's information, the events that occurred and the time of the events, ECG)

Stored information can be transferred to a remote device (such as a computer) through a USB device. The clinical data format is compatible with *URUK Rescue Event Eژ Summary* software, which can be used to review and analyze the patient data.
The unit retains the device history and clinical data even when powered off or when the battery pack is removed. Clinical data is erased only when the device is powered on and electrodes are attached to a new patient. If configured to do so, the unit can store data for more than one patient (two patients).

Standby State

When the unit is turned off with a good battery installed, the unit enters standby state. While in standby, the unit periodically starts up automatically to perform a self-test, and then returns to standby. The  indicates the success of the self-test.

Automatic Shutdown

The unit automatically powers off if no patient connection is detected within 10 minutes.

Accessories

Table 2-1: list of DE100 AED accessories

Accessory	Manufacturer
Adult PAD	FIAB
Child PAD	FIAB
Battery Pack	URUK
3 Wire ECG Cable	URUK

⚠ Warnings

- Do not use accessories (pads and batteries) which are not approved by the manufacturer.
- If the electroshock device, battery and pads are stored in environmental conditions other than those mentioned in this manual, there is a possibility of performance loss, damage and reduction of their lifespan.

Battery placement

The DE100 device supports two types of rechargeable batteries (Li-Ion) and non-rechargeable (LiMnO2). Along with the rechargeable battery, the charger stand is also supplied.

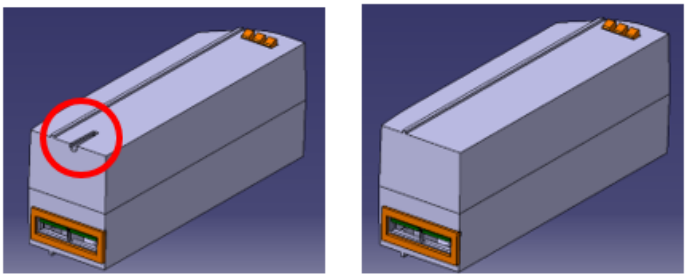


Figure 2-1 : Battery pack, left: rechargeable, right: non-rechargeable

Note

Power saving and run-time of the battery decreases over time.

⚠ Warnings

- The LiMnO2 battery packs are non-rechargeable. Do not attempt to recharge them as this may result in fire or explosion.
- If, for any reason, the working time with a fully charged battery is less than what you need, contact the after-sales service to replace the battery.
- Do not immerse the battery pack in water or other liquids as this may cause fire or explosion.
- To avoid the risk of fire and explosion, do not expose the battery pack to fire or heat.
- Battery disposal must be done in accordance with relevant laws.
- Replace the empty non-rechargeable battery with a new one immediately. If using a rechargeable battery, charge it.
- Check the expiration date of non-rechargeable batteries. Do not use the battery after its expiration date.
- Use only batteries approved by the manufacturer.
- Always keep an extra and healthy battery pack with the device.
- When you see the battery replacement message on the device, replace the battery pack with a new battery as soon as possible.

Note

The exact amount of battery charge is shown on the screen after inserting it into the device.

Charging stand

Figure 2-2 : Charging stand with battery

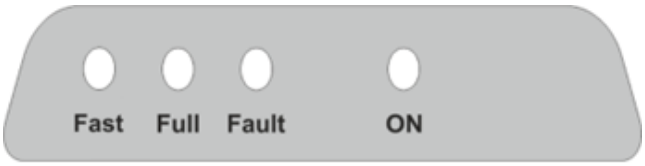


Figure 2-3 : indicators of charger stand

- Fast: When the battery is charging (fast), this indicator will light up.
- Full: When the battery charge reaches about 90%, this indicator will turn on and the Fast Charge indicator will turn off. When the battery is fully charged, this indicator will also turn off.
- Fault: If charging is not done for any reason, this indicator will light up.
- ON: Indicator of connecting the charger to the power mains through the adapter.

Note

Causes of the reduction of battery power maintenance:

- Full discharge of the battery
- Continuous charging of the battery
- Time passage

Pads and ECG cable

The DE100 device comes with two adult and child defibrillation pads (as shown in Figure 3-3) as well as a 3-wire ECG cable if ordered so (as shown in Figure 4-3).

A B

Figure 2-4 : Defibrillation pads, A: Adult, B: Child

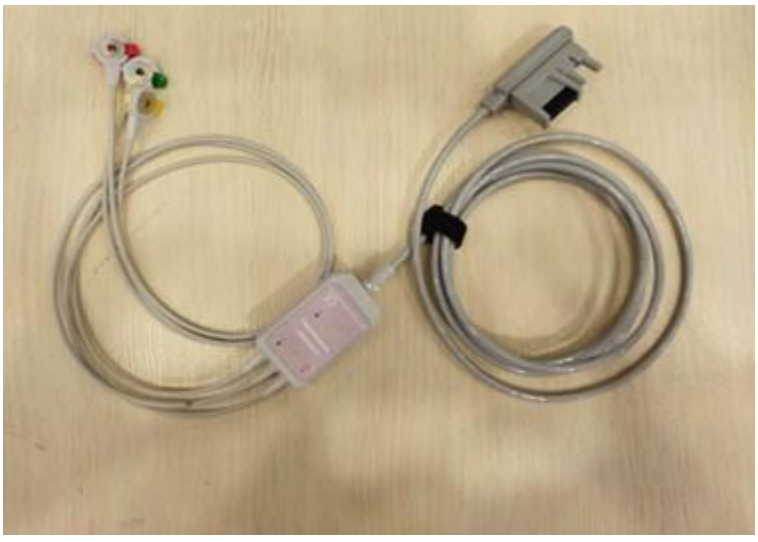


Figure 2-5 : 3-wire ECG cable of DE100 AED

⚠ Warnings

- Do not reuse disposable pads in order to prevent the transfer of contamination and inappropriate shock.
- Pay attention to the expiration date of the pads and do not use expired pads.
- When using the children's pad, the device automatically selects the Child mode.
- 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 pads. Do not delay therapy to determine exact age or weight.

- Avoid connecting two pads to each other because it leads to electric arc.
- Do not move the pads after placing them. If you need to displace the pads, remove them and replace them with new pads.
- Damaged or dry pads may cause burns to the patient's skin during shock. Do not use pads that have been opened for more than 24 hours. Also, avoid continuous contact of the pads with the patient's skin for more than 24 hours.
- Make sure the electrodes are glued correctly.
- Replace the pads after giving 50 shocks.
- Defibrillator pads do not contain any harmful substances and can be disposed of like normal waste as long as they are not contaminated with pathogens. In case of contamination with pathogenic substances, be careful when destroying the pads.

View of DE100 AED

Figure 2-6 : DE100 AED Front Panel

Figure 2-7 : DE100 AED bottom view

Figure 2-8 : DE100 AED top and rear view

Control Functions of SHHOKA AED

Table 2-2: DE100 AED Control Functions

	Item	Description
1	Defibrillation pads or ECG connector	This connector is used to attach the defibrillation pads or 3 wire ECG electrodes to the DE100 AED defibrillator.
2	Touch screen	A 5-inch touch screen for display and user input. It displays information below: • Visual and text according to rescue situation • Adult or Child mode selected • Elapsed time • CPR countdown time • battery charge • Number of shocks applied In settings mode, touch screen provides required control menu for configuration of the device.
3	On/Off button	Press to turn power ON or hold 3 seconds to turn OFF
4	Shock button	In semi-automatic mode, when the device is ready to transmit shock energy to the patient, the LED indicator under this key lights up. Pressing this button will transfer energy to the patient **Note**: In the automatic mode, shock discharge is performed automatically and the indicator does not light up.
5	Self-test indicator	Illustrates the status of the last self-test. A green check indicates that the DE100 AED defibrillator passed its last self-test and is ready for use. A red cross indicates that the AED has a problem or battery with sufficient power has not been installed.
6	Child button	If a universal pad is installed, pressing the button activates Child mode.
7	Battery compartment	Holds the battery pack used to power the AED
8	Speaker	Provides audio prompts to guide rescuers during a rescue in rescue and monitoring mode; also provides the specific service required for the system
9	USB connector Compartment	The area used to connect a USB flash drive when exporting files from the DE100 AED defibrillator.

DE100 AED display

In the rescue mode, the display is as one of the following:

(DE100 automatically enters rescue mode as defibrillation pads are installed.)

- Lay user
    - The user gets step-by-step instructions.

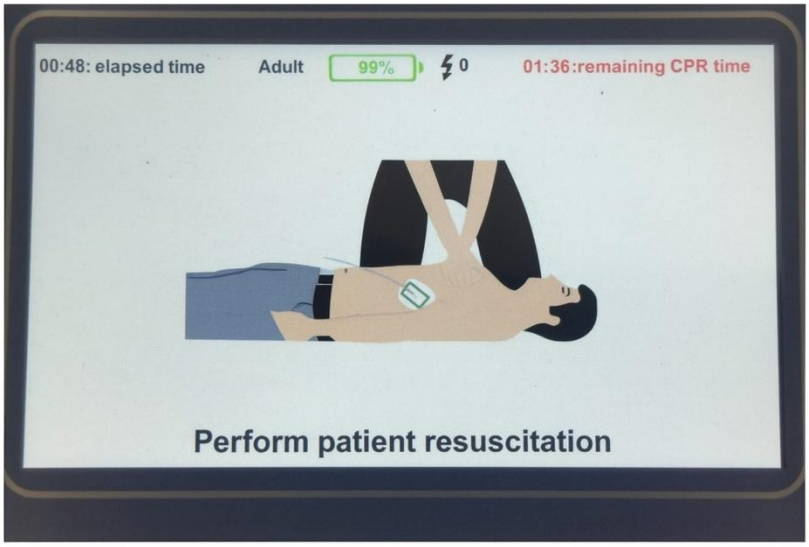


Figure 2-9 : DE100 AED display screen elements.

- ECG
    - ECG signal is displayed.

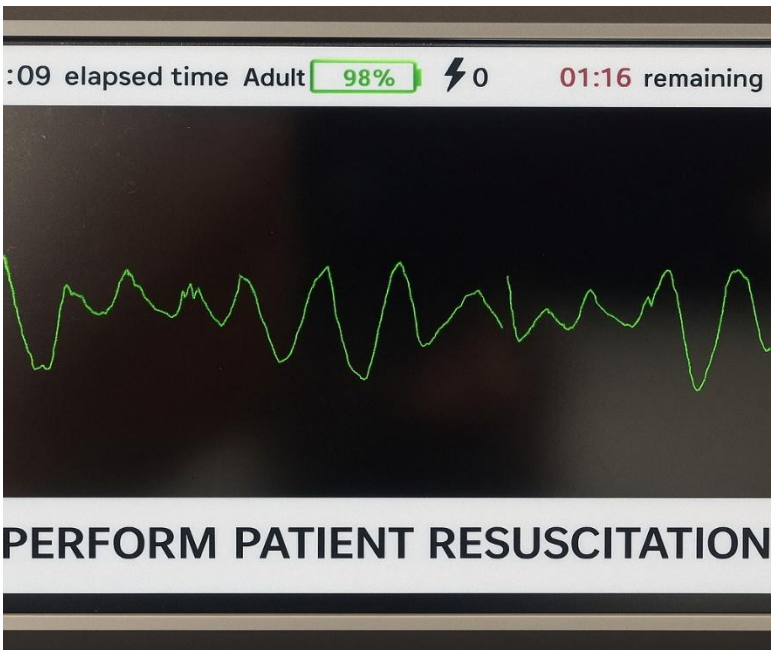


Figure 2-10 : DE100 AED display screen in Lay user.

In the ECG Monitoring mode, display is as following:

(DE100 automatically enters ECG Monitoring mode as ECG cable is installed.)

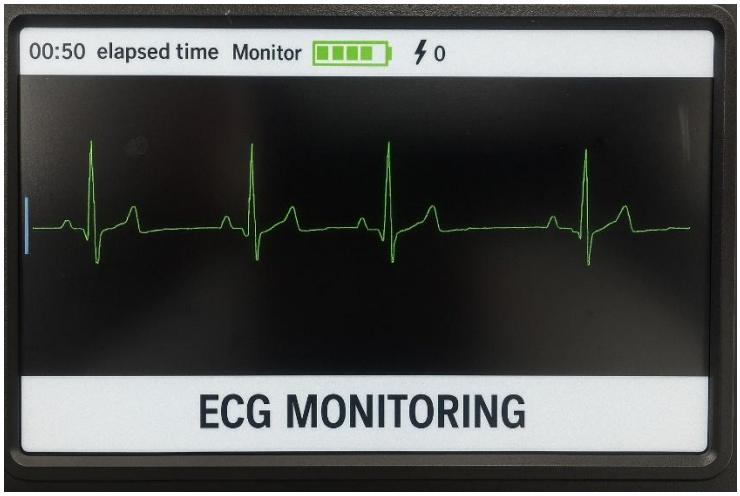


Figure 2-11 : DE100 AED display screen in Lay user

DE100 AED display elements

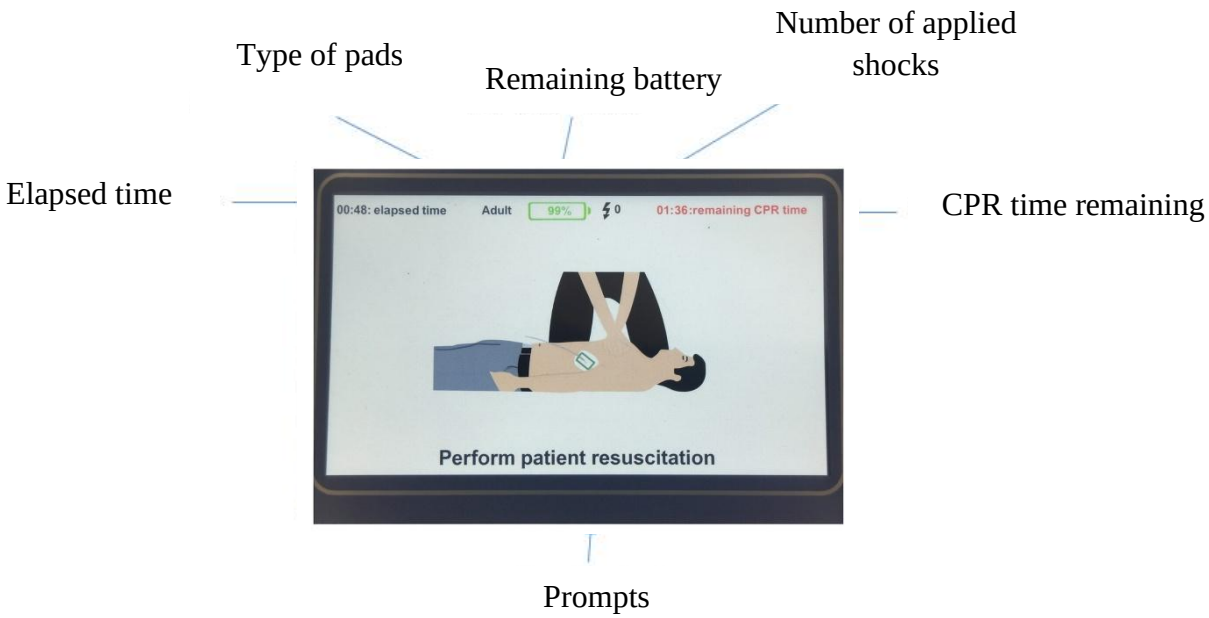


Figure 2-12 : DE100 AED display screen in Lay user

The following parameters are shown on the display:

- **Elapsed time:** Indicates the amount of time that has lapsed since the device was turned on.
- **CPR countdown time:** Indicates the amount of time remaining in the CPR interval.

- **Battery charge indicator:** Indicates the amount of battery power remaining as bar graph or percentage.
- **Number of shocks:** Indicates the total number of defibrillation shocks since the resuscitation pads were installed.
- **Type of installed pad:** Indicates the type of the defibrillation pad attached to the patient which can be *Adult* or *Child*. While the ECG Monitoring cable is installed, *Monitor* is displayed.
- **User instructions:** Displays a visual message on the screen while simultaneously issuing an audio prompt.

3. Setting Up the DE100 AED Defibrillator

DE100 AED Shipping Contents

Check the DE100 AED shipping container for the following contents:

- 1 DE100 AED defibrillator
- 1 DE100 AED battery pack
- 1 package containing defibrillation pads (adult and child pad)
- 1 package containing 3 wire ECG cables (adult and child electrode)
- 1 DE100 AED documentation packet

Note

If the contents are incomplete or damaged, contact URUK Medical Corporation's Technical Service Department.

Setting up the Defibrillator

Follow the steps below to prepare the DE100 AED for use.

1. Remove the defibrillation pads package from the cardboard box in the shipping container.

⚠ Warnings

- Do not open sealed defibrillation pads until immediately prior to use.

2. Plug the defibrillation pads cable connector into the defibrillation pads port.

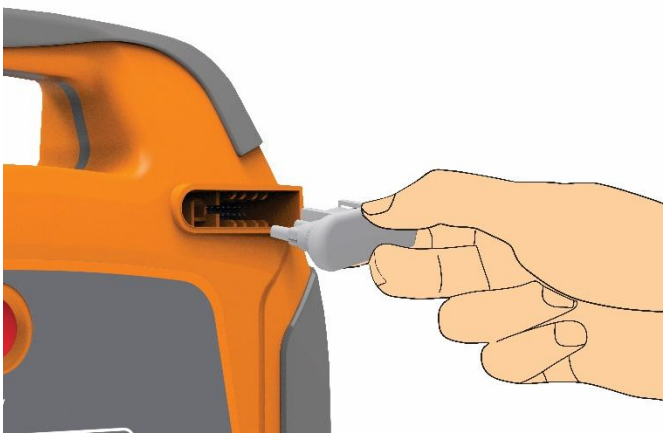


Figure 3-1 : Connecting the defibrillator pad to the connector

⚠ Warnings

- To prepare for an emergency, it is better to always have the pad and battery connected to the device.
- Connect the defibrillator pads to the system before installing the battery.

3. Remove the battery pack from the shipping container.

   Hold the battery pack by the side tabs with the label facing out. Insert the battery pack into the battery placement of the AED until it clicks into place, lining up the notch on the end of the battery to the corresponding recess in the battery well.

Figure 3-2 : Insert the battery

Note

- A self-test is performed by connecting a new battery or turning it on.

⚠ Warnings

- If the self-test is successful, the status indicator will be displayed as  .In order to ensure the correct operation of the electroshock, check its condition weekly. Make sure the device status indicator shows  .
- If the self-test is not successful, its indicator will be marked with a  sign and when the device is turned on, the message "Internal test failed" will be announced. In this situation, remove the device's battery once and install it again. If the automatic test fails again, contact the company's after-sales service.

4. Turn off the device by holding the On/Off button for 3 seconds.
5. Put the device in an accessible place according to the relevant regulations.

Note

- To ensure adequate power availability during an emergency, monitor the device status weekly. Verify that the AED has passed its periodic self-test by confirming that the green check is displayed in the status indicator window.
- If you change the battery while the AED is in Rescue Mode (with the defibrillation pads cable connected), the AED automatically restart.

Self-test

DE100 AED conducts series of test to ensure proper function of the system in the emergency condition. The tests are as followed:

- Battery capacity
- ECG recorder circuit
- Charge and de-charge of the High-voltage circuit
- Motherboard software and hardware
- Function of the buttons

When the self-test is conducted:

- Every time the system is powered on
- Automatically at a certain length of time (7 days as default, can be set to 1 day)

If all of the tests are successfully passed, the indicator displays  . This shows that DE100 is ready to operate. If the tests are not passed, the indicator displays ;  which means the system is not ready to operate and the problem must be solved.

If the self-test is failed, a text prompt will be shown on the display depending on the problem each part of the device may have (figure **3-3**) and the system will turn off in 30 seconds. The issues that may cause the self-test to fail are as following:

- Connection problem with and lack of data acquisition from the SAE board
- Connection problem with high voltage circuit
- Problem in charge and discharge of the high voltage shoch circuit
- Problem in ECG record circuit
- Problem in the function of the buttons
- Problem in the battery pack

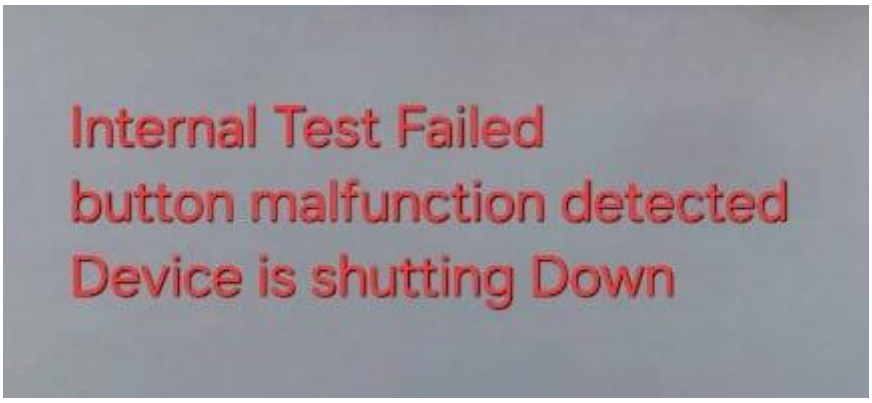


Figure 3-3 : Text prompt indicating the failure of the self-test

Battery condition during self-test

The remaining energy of the battery is one of the parameters verified during self-tests. System does one of the following things depending on the battery charge level:

- Less than 20% of battery power for non-rechargeable battery (10% for rechargeable battery)
    - Emits an audible alarm for 80 seconds and then turns off.
- Battery power between 20% and 30% for non-rechargeable battery (between 10% and 20% for rechargeable battery)
    - Emits an audible alarm for 40 seconds and then turns off.
- More than 30% of battery power for non-rechargeable battery (20% for rechargeable battery)
    - Returns to standby.

Battery condition during system function

The remaining energy of the battery is verified during general function and system dos one of the following things depending on the battery charge level:

- Less than 20% of battery power for non-rechargeable battery (10% for rechargeable battery)
    - Displays “Battery low. System shutting down” and turns off after 30 seconds.

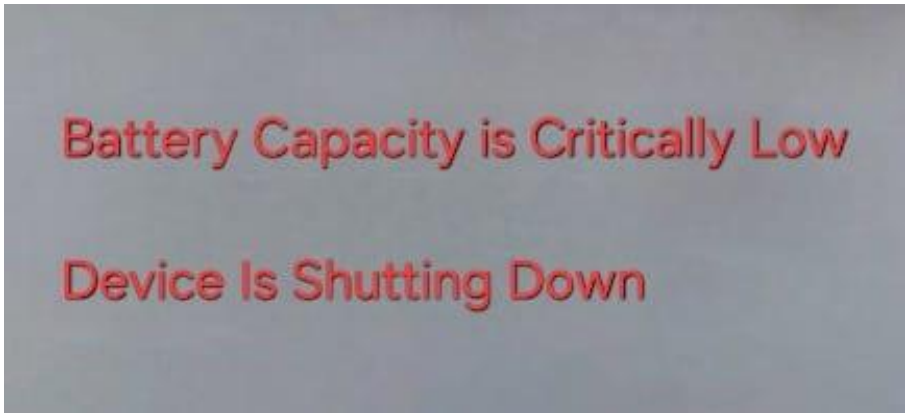


Figure 3-4 : Text prompt indicating low battery

- Battery power between 20% and 30% for non-rechargeable battery (between 10% and 20% for rechargeable battery)
    - Displays “Change battery” at the start up and during the resuscitation process and the system continues its normal function. The battery icon becomes red and keeps flashing.

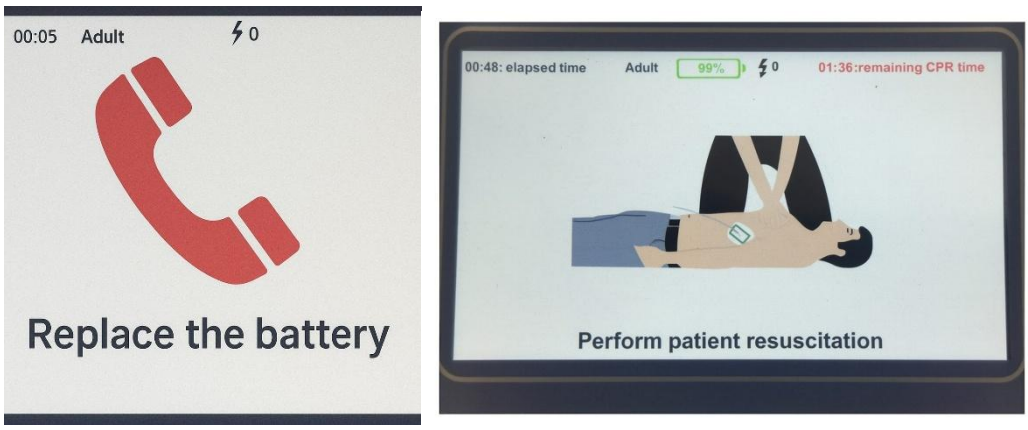


Figure 3-5 : Change battery prompt

- More than 30% of battery power for non-rechargeable battery (20% for rechargeable battery)
    - Continues normal function.

4. Using the DE100 AED Defibrillator

Overview

The DE100 AED defibrillator is used for cardiac arrest victims with obvious lack of blood circulation (without breathing and pulse). Call for help, retrieve the defibrillator, and bring it to the patient's side. Follow the basic steps on the following pages to treat the suspected cardiac arrest patient:

1. Press the On/Off button to turn on the defibrillator and follow the voice prompts.
2. Remove the pads from the package and attach them to the patient. (Follow the audio and visual prompts of the device).
3. If the device detects the need to apply a shock, give a shock to the patient.
4. Start CPR.

STEP 1 Turn on DE100 AED Defibrillator

Press the On/Off button in the bottom right side of the AED to turn it on.

Figure 4-1 : On/Off button

STEP 2 Place defibrillation pads on patient

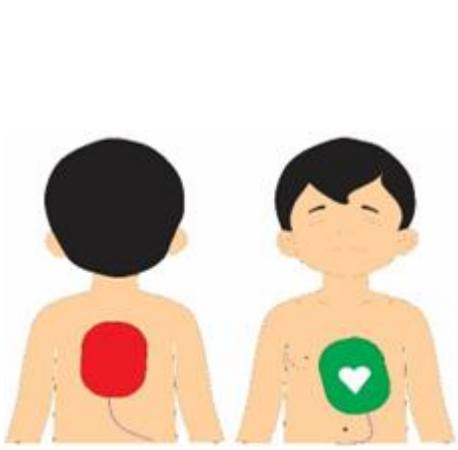
- At first, it is necessary to remove the person's clothes from the chest. Electrodes must be attached directly to the skin. Use scissors if needed.
- Make sure the person's chest is dry and clean. If necessary, shave the chest hair.
- Remove the pads from the package, remove the protective layer of the sticker from the pads and place the pads according to the instructions on the pad package, the **green** pad on the **lower left** side of the person's chest, and the **red** pad on the **upper right** side of the person's chest. The visual prompts of the device also show the installation location of the pads.

Note

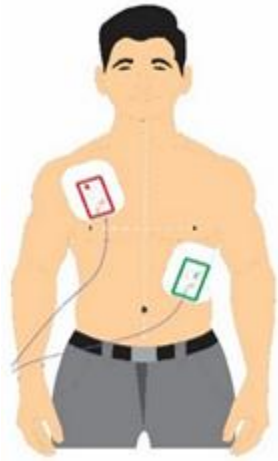
- If you use the child pad, the child patient will be selected automatically.
- If you use the universal pad and the patent is a child, press the child button.

Note

- For children who are small and the distance between the pads is too short, attach the red pad to the back of the chest.
- By the displaced attachment of the pads to the patient, the resuscitation probability decreses. Pay attention to the package illustrations.



Child pads position



Adult pads position

Figure 4-2 : AED pads attachment positions in child and adult

⚠ Warnings

- Do not place the pads on the patient's pacemaker site. Pacemaker signals lower the accuracy of the analysis. The pacemaker may also be damaged.
- The presence of water and air bubbles in the place where the pads are attached can cause sparks, burns, or reduce the transmission energy to the person. To reduce burns, the pads must be securely attached to clean, dry skin immediately after opening. When installing the pads, avoid creating any wrinkles on the gel-coated surface.
- Attach the pads in such a way that the entire surface of the electrode adheres to the skin. If the pad is incompletely connected to the patient, the energy transfer is not done completely and the possibility of reviving the patient decreases.

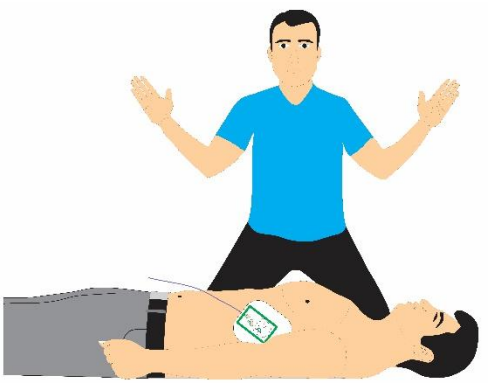


Figure 4-3 : Do not touch the patient. Analyzing the heart rhythm

The AED issues the voice and text prompt "Do not touch the patient. Analyzing the heart rhythm."

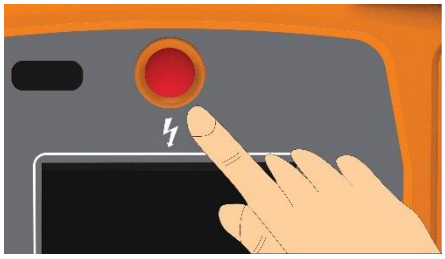
⚠ Warnings

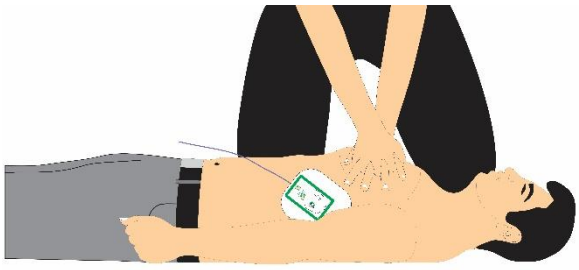
- During analysis and defibrillation, never touch the pads, the patient, or any conductive objects attached to the patient.
- During ECG signal analysis, the patient should not move as much as possible.
- Do not move the AED device during the analysis. Moving the device during analysis may affect the ECG signal and lead to inappropriate shock delivery or failure to deliver a shock. Do not touch the patient or the AED during analysis.
- Do not analyze the patient in a moving device. Artifacts related to movement may affect the ECG signal and lead to incorrect shocks or non-display and notification of shock messages. Stop the vehicle and stand away from the patient during the analysis.

STEP 3 Shock the Patient

DE100 uses Rectilinear Biphasic waveform to deliver shock. If the algorithm of the system detects a shockable heart rhythm, charges the capacitor and the up-coming actions are made according to the function mode of the system. If the patient does not need a shock, the corresponding prompt will be shown and the system enters resuscitation procedure.

When a shock is needed:

full-automatic	semi-automatic
You hear: Don't touch patient. Shock in 3, 2, 1.	**You hear:** Don't touch patient. Press shock button.
You see: First screen  Second screen  Third screen 	**You see:** 
Actions: Don't touch patient. Shock will be automatically delivered.	**Actions:** Don't touch patient. Press the flashing shock button.



The device issues the message “shock delivered” and this picture will be shown

After that, shows this picture and prompts the CPR procedure.

After the CPR procedure duration (90 or 120 seconds) is passed, ECG analysis will be done again to determine the necessity of applying shock.

When a shock is not needed:

This picure will be shown

If the AED determines that a shock is not needed, a voice prompt instructs you to start CPR for a period of time (configured by the AED Administrator), after which the AED automatically initiates a new ECG analysis. If a shock is needed at that time, refer to “When a Shock is Needed”.

⚠ Warnings

- Do not touch the disposable pads while the defibrillator is discharging.
- Giving shock may cause malfunction or failure of implanted devices. If possible, place the pads further away from the implantable device. After applying the shock, check the operation of the implantable device.
- Always stay away from the patient when applying the shock. Touching the patient while applying the shock may cause the energy to transfer through the patient's body and cause a fatal shock to people.
- If a person touches the patient, the bed or other conductive materials in contact with the patient during the shock, a part of the transferred energy may be discharged through that person. Before giving the shock, prevent other people from contacting the patient, pads, bed and other conductive materials around the patient.

The energy levels applied to the patient is either incremental (Sequential) in first three shocks or always maximum (MAX) according to the settings made in the device. The amount of energy is selected according to the type of pad connected to the device (adult or child).

In MAX mode, the maximum energy (Adult: 200J, Child: 85J) is delivered to the patient from the first shock.

The factory default energy levels in joules are described in Table 4-1.

Table 4-1: factory default energy levels in first three shock.

	Energy (J)		
	First shock	**Second shock**	**Third shock**
Adult	120	150	200
Pediatric	50	70	85

Note

- In sequential mode, after the first three shocks, all subsequent shocks with the same energy as the third shock are applied to the patient.
- The amount of energy delivered to the patient varies according to the load. See Appendix 2):

STEP 4 Start CPR

First, the patient should lie on a hard surface and on his back, then kneel next to the patient, then lock your hands and place your palms on the patient's chest. In this case, the fingers should not touch the patient's chest. Try to keep your arms straight. At this stage, bend forward and press vertically and downward on the last third of the patient's sternum. Then release the pressure but do not remove your hand from the chest. This action will cause blood circulation in the heart. Trained people will give two artificial breaths after every 30 chest compressions. If the person has not received full training, she/he will continue chest compressions with 100-120 times per minute until the rescue forces arrive. Open the airway by relaxing the patient's head and lifting his chin. In this case, slightly bend the head back and open the patient's mouth. Hold the patient's chin up and close his nostrils. Then take a deep breath and give artificial respiration to the patient. The rise of the patient's chest will indicate the success of artificial respiration. Then stop breathing and wait for the patient's chest to return to normal. Then immediately do the second breath as before. So, in general, after every 30 chest compressions, give two artificial breaths in 5 seconds. Vital signs should be checked every two minutes.

When emergency medical services arrive

When Emergency Medical Services (EMS) arrive, you can provide the following rescue information:

- Shock delivered count which is shown on the device screen
- The elapsed time from the beginning of the resuscitation and shock operation that is shown on the screen of the device.

You can transfer the patient event data to a USB flash drive if EMS personnel request the information.

Audio prompts

The following audio prompts will be issued while defibrillator is being used:

Table 4-2: list of Audio Prompt of DE100 AED.

Audio prompt	Definition/Action
UNIT OK	By pressing and releasing the ON/OFF key, the AED turns on and starts the automatic self-test, and if the test result is successful, it issues this message.
CALL EMS	Call the EMS for help.
PLUG IN PADS CABLE	According to the type of patient, connect the appropriate cable (child/adult) to the device.
ADULT PATIENT SELECTED.	The device selects the adult patient by connecting the adult cable.
CHILD PATIENT SELECTED	This message is issued if the child cable is connected.
ATTACH DEFIBRILLATOR PADS TO THE PATIENT'S BARE CHEST	Attach the pads to the patient according to the device's visual prompts.
DON'T TOUCH PATIENT, ANALYZING HEART RHYTHM	If the AED device detects the connected pad, it will announce these audio message. Wait until the analysis is done.
SHOCK NOT ADVISED	If the rhythm is non-shockable, this voice message will sound and the device enters the CPR phase.
SHOCK ADVISED. DON'T TOUCH PATIENT	After the analysis, the AED device decides if there is a need to perform a shock or not. If the rhythm is shockable, this voice message will sound. In this case, the AED will automatically go to the capacitor charging stage. Wait until charging is complete.
PRESS SHOCK BUTTON	In semi-automatic mode, press the shock button to deliver the shock to the patient.
SHOCK IN 3, 2, 1	In full-automatic mode, the shock is delivered to the patient automatically and with a countdown.
SHOCK DELIVERED	After the shock is delivered to the patient, the shock counter on the screen is updated and this voice message sounds. The device enters the CPR phase.
SHOCK NOT DELIVERED	This message will be issued if the rescuer does not press the shock button in semi-automatic mode, or if the shock is not delivered to the patient due to a fault in the device.
PERFORM CPR	After delivering the shock to the patient, or if shock is not advised, the AED automatically goes to the CPR stage. At this stage, according to the set time, continue the CPR procedure. After 30 chest compressions, take two breaths. This message is repeated every 10 seconds.
STOP CPR	The rescuer should stop the resuscitation of the patient and, a new analysis will begin. AED determines the next action according to the new analysis.
CHANGE BATTERY	This message is issued when the battery charge is below 20%. In this case, the device can still be used. But it is better to replace the battery.
BATTERY IS TOO LOW DEVICE IS SHUTTING DOWN	This message is issued when the battery charge is below 10%. In this case, the device will be turned off immediately after this warning.

5. ECG Monitoring (ECG Mode)

Overview

The DE100 AED defibrillator automatically enters ECG mode and displays ECG signal on the screen.

⚠ Warnings

- The frequency response of the screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for pacemaker pulse visibility, accurate measurements, such as QRS duration, and ST segment interpretation. For such purposes, use ECG monitors with an appropriate frequency response.

Note

You do not have to turn the defibrillator off before changing from therapy electrodes to the ECG cable or vice versa.

To monitor a patient's ECG

1. Connect the ECG cable.

Note

The ECG cable is connected to the same place as the shock pad.

2. Apply ECG electrodes to the patient's chest as shown in figure 1-5.

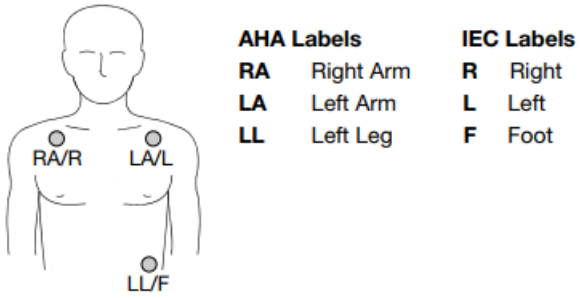


Figure 5-1 : Connecting the ECG Electrodes for ECG monitoring

After the ECG electrodes are connected, the defibrillator displays the patient's heart rhythm in a lead II configuration. Lead II is the only lead available with this cable.
While in ECG mode, the defibrillator's shock capability is disabled; however, the defibrillator continues to evaluate the patient's ECG for a potentially shockable rhythm. Remember that the presence of an ECG rhythm does not ensure that the patient has a pulse.
If shockable rhythm is detected, the message " CONNECT THERAPY ELECTRODES " will be displayed and the audio prompts of connecting the cable will be played. in this case:

1. Confirm the patient's condition: Not responsive? Not breathing? No signs of circulation?
2. Remove the ECG cable and connect the therapy electrodes to the defibrillator.
3. Follow the defibrillator's voice and text prompts

6. Settings Mode

Overview

DE100 provides this mode for configuation settings. Follow the steps below to enter the settings mode:

1- Make sure the battery is intstalled.
2- Hold the child button and the shock button and press the power button. Keep holding the two former buttons for 5 seconds. The device will enter the settings menu.

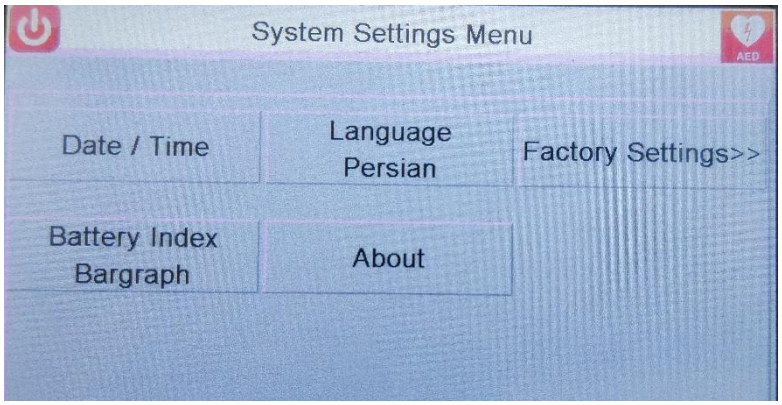


Figure 6-1 : System Settings Menu

The following parameters can be adjusted in settings menu:

- **Date/Time**: The user can enter the date and time setting page by selecting this option.

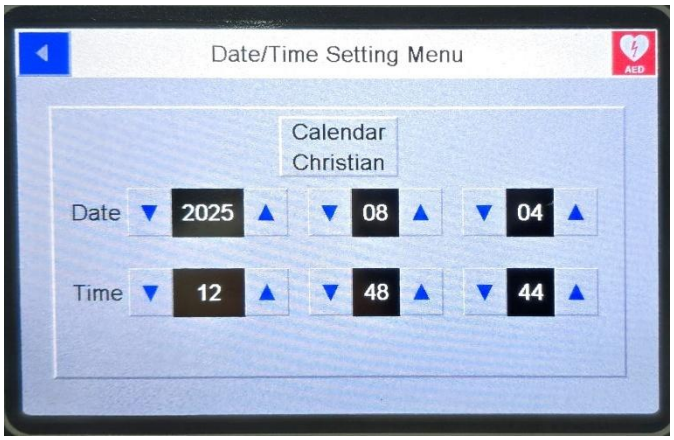


Figure 6-2 : Date and time Menu

  - **Calendar**: two available options are Solar and Cristian.
  - **Date**: can be set using the control keys in touch screen.
  - **Time**: can be set using the control keys in touch screen.
- **Language**: English .
- **Factory settings**: Entering the password is required to access this menu. The settings of this section must be performed by after-sales service personnel or a trained person.

- **Battery index**: The form of battery charge illustration, which can be selected as a bar graph or a percentage.
- **About**: The device and manufacturer information is shown in this page.

Note

- By pressing the  in settings menu, the information and changes will be automatically saved and the device turns off.
- By pressing the  in settings menu, the information and changes will be automatically saved and the device switches to Rescue mode

Factory settings

By selecting this option, a box to enter the factory code is displayed.

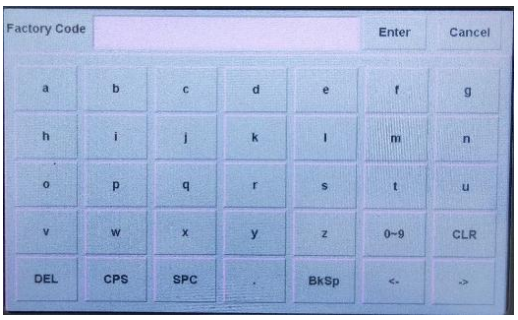


Figure 6-3 : Keyboard to enter the pass code

Type “dahsaa” in the box and press “Enter”. The factory settings menu will be displayed.

The following parameters can be adjusted in factory settings menu:

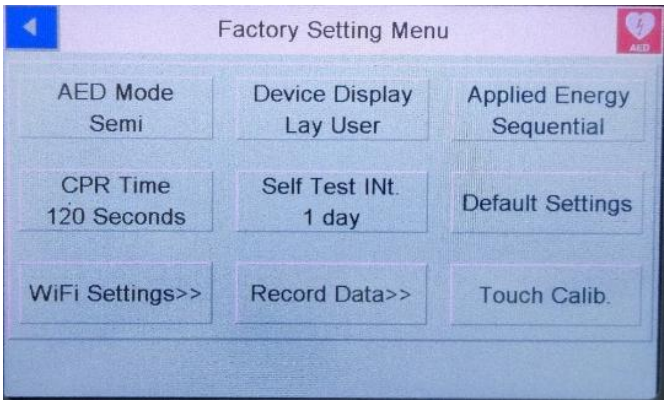


Figure 6-4 : Factory settings menu

AED Mode

In this section the function mode of the device in rescue mode is selected. “Full automatic” and “Semi-automatic” are available.

- In “semi-automatic” mode, the shock button starts flashing when the device detects a shockable rhythm and charges the capacitor. The rescuer must press the shock button and apply the shock within 30 seconds, otherwise the device automatically discharges the charged circuits internally.
- In “Full automatic” mode, if a shockable rhythm is detected, he shock is automatically delivered to the patient with a countdown in three seconds.

The system default is “semi-automatic”.

Device display

In this section, the display condition in rescue mode is configured. “lay user” and “ECG” are available.

- In “lay user”, the rescuer is instructed visually and step by step.
- In “ECG”, the patient’s ECG signal is displayed on the screen.

The system default is “lay user”

Note

It is not possible to select the “ECG” display mode and “full automatic” function mode simultaneously.

Applied energy

This option determines the shock delivery energy. “Sequential” and “MAX” are available.

- In “Sequential” mode, the energy delivered in first shock is 120 J. The energy of the next shocks will be set to 150 J and 200 J respectively (If the patient is child, Energies will be 50 J, 70 J, 80 J). After the first three shocks, all subsequent shocks with the same energy as the third shock are applied to the patient (200 J for Adult, 85 J for child).

“Sequential” is set as default.

The amounts of energies mentioned in this section are nominal, see appendix 333 for accurate energy amounts.

CPR time

In this section the CPR procedure duration is set. “90” or “120” seconds are available. The system default is “120” seconds.

Self-test interval

System self-test could be performed automatically at certain intervals. “1 Day” and “7 days” are available. System default is “7 days”.

Default settings

This option returns the device settings to its factory defaults.

Wi-Fi settings

No function.

Record data

Will be described.

Touch calib.

This option activates the touch screen calibration procedure which is done by touching the center and the four corners of the screen.

Record data

The following menu is displayed:

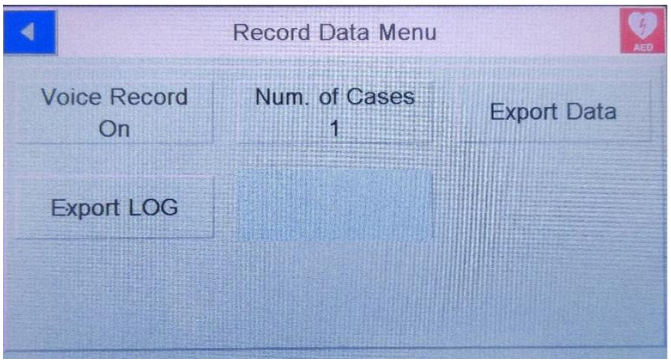


Figure 6-5 : Record Data menu

Voice record

By selecting this option, the environment voice recording is enabled and voice data is simultaneously recorded with the clinical data. DE100 is capable of recording 60 minutes of clinical data with environment voice. If the voice record is “off”, DE100 can record 120 minutes of clinical data.

Num of cases

DE100 can be set to record the information (voices and clinical data) of 1 or 2 patients.

Export data

In this section, the patient(s) clinical data and the results of the last self-test before recording the clinical data are transferred through the USB port. The exported file could be studied with URUK Rescue Event ECG Summary software.

Export Log

In this section the device history from the production time until the present time is transferred through the USB port. The exported file is a .txt file.

7. Information record

DE100 is capable of recording two types of information including a history of system condition and patient's clinical data.

Clinical Archive

- Continuous ECG data
- Number of applied shocks
- Time and amount of the applied shock
- Voice recording (if enabled)
- Date and time of turning on
- Type of the defibrillation pads
- Time and result of the ECG signal analysis
- Time of the attachment of the defibrillator pads to the patient
- Time of the connection of the defibrillator pads or ECG cable to the device
- Time spent (since turning on)
- All of the events with date and time

Device history

- Results of all of the performed self-tests
- Device serial number
- Software version
- Date and time of the self-test
- Battery charge percentage
- Errors occurred during self-tests

Note

- DE100 keeps the clinical data of the patient after turning off or even removing the battery pack.
- Clinical data is stored only by turning the system on and attaching defibrillation pads to new patient.
- In case of having previous records, the data of the earliest patient will be replaced with the new patient's data.
- DE100 records maximum 120 minutes of clinical data for one patient.
- If the number of cases is selected as "2", 60 minutes of clinical data will be recorded for each patient.

⚠ Warnings

➢ When defibrillation pads are attached to the patient, do not connect any flash memory or other devices to the USB port.

8. Maintaining the DE100 AED Defibrillator

Overview

The DE100 AED defibrillator requires little maintenance. It automatically performs a self-test every time you turn on the AED or install a battery, and it also performs a routine self-test based on the interval of days that you specify (default is 7 days). The test information is automatically collected from checking the status of the device and stored in the system history. This section contains procedures on how to maintain the defibrillator.

Appearance of the device and accessories

- Check the expiration date of the pads.
- Check the battery expiration date.
- Check the pads' cable for damage.
- Check the pad cable for damage.
- Check the device case for visible damage.
- Check for additional accessories.

Self-Test

DE100 defibrillator performs a series of tests to ensure system performance in emergency situations. These tests include the following:

- Battery Capacity
- Presence of pads and batteries in the system
- Defibrillation Pads Connection
- Defibrillation Pads/ Battery Expiration Verification
- ECG Circuitry
- Defibrillator Charge and Discharge Circuitry
- Microprocessor Hardware/Software
- Audio Circuitry
- 200 Joule Charge Test

The times when SELF-TEST is performed:

- Battery Installation: Automatically, after battery pack is installed or replaced
- Power On: Automatically, whenever the AED is turned on.
- Automatic: Once every 7 days (this interval can be configured to once a day)

When the defibrillator successfully completes its automatic self-tests, the device displays a green check  in the status indicator window to show that all tests passed and that it is ready to use; otherwise the device displays  .So the DE100 AED defibrillator is not ready for use and may be defective. Remove the defibrillator from service and consult "Troubleshooting" to determine the problem.

Periodic Inspection

The manufacturer performs a periodic inspection procedure for AEDs every year after sale. All critical parts will be tested in this inspection and malfunctioning parts will be replaced.

⚠ Warnings

- Never try to open and disassemble the body of the device or repair it because it has dangerous high voltage and current. To perform annual repairs and inspections, refer to the after-sales service personnel.

After Each Use

Perform the following steps after each time the AED is used.

1. Check that the AED is clean, undamaged, and free of excessive wear. If the AED needs to be cleaned, Clean the DE100 AED Defibrillator.
2. Obtain a new set of defibrillation pads (verify that the expiration date has not passed) and connect the defibrillation pads to the defibrillator.
3. Turn on the AED by pressing the defibrillator's On/Off button. Make sure the self-test passes and the battery has adequate power.
4. Turn off the device by holding the On/Off button for 3 seconds.
5. Place the AED system in the right place for the next use.

Cleaning the DE100 AED Defibrillator

After each use, clean and disinfect the defibrillator with a soft, damp cloth using either 70% isopropyl alcohol, or soap and water. You can also use a chlorine bleach and water mixture (30 ml/liter water) to clean the defibrillator (except on the contacts and connectors).

⚠ Warnings

- Do not immerse any part of the defibrillator in water.
- Do not use chlorine mixture on contacts or connectors; this will degrade the contacts over time.
- Do not use ketones (MEK, acetone, etc.) to clean the defibrillator.
- Do not use abrasives (e.g., paper towel) on the display window or graphic screen.
- Do not sterilize the defibrillator.

Case

- The external surface of the device, including the battery pack, must be cleaned and disinfected after each use. Use a cloth moistened with soap and water or cleaners containing ammonia or 70% isopropyl alcohol for this purpose.
- Do not allow the cleaning solution to enter the body of the device (especially inside the connector port).
- Dry the cleaning solution on the surface of the device.

Pads

- The only part of the AED device that comes into direct contact with the patient is the disposable pads. Because these pads are disposable, they do not transmit any contamination to the patient. Therefore, there is no need to clean and disinfect these pads.

Display Screen

- Do not wipe the screen with a dry cloth as it may cause scratches.
- Only use a soft cloth moistened with isopropyl alcohol to clean the screen as other chemicals may seriously damage it.

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

Table 8-1: summarizes the methods of cleaning, disinfecting and sterilizing for different parts of DE100 AED

<table>
<tr><th>Device parts</th><th>Single-use</th><th colspan="2">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>√</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>

9 Troubleshooting

The following table lists error indications that may occur on the DE100 AED defibrillator, and the associated corrective action. If the defibrillator is not working properly, contact URUK's Technical Service Department for assistance.

Table 9-1: Technical problem and recommended action of DE100 AED

Technical problem	Recommended Action
Status indicator shows 	when AED is OFF: Turn on the AED and wait until automated self-test is completed. If status indicator still shows  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  turn off AED and replace the battery and repeat the procedure again. If issue continues, contact service department.
Loss of audio prompts or display	Cycle power on the defibrillator by turning the AED off, and then on again. If the AED continues to fail, contact U**RUK** Technical Service.
The screen is blank and nothing is displayed.	Cycle power on the defibrillator by turning the AED off, and then on again. If the AED continues to fail, contact U**RUK** Technical Service.
Lack of shock delivery to the patient	The battery charge might be low. Change the battery. Let device performs a self-test. If issue continues, contact service department.
"BATTERY IS TOO LOW" Device will shut down automatically	Replace the AED battery with a new battery pack. Device will perform self-test again. If visual prompt continues, contact service department.
"SELF-TEST FAILED" Device will shut down automatically	Wait for shutting down, 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"	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.

Technical problem	Recommended Action
"CHECK DEFIBRILLATOR PAD"	Check defibrillator pad is correctly connected to patient. Replace PAD with a new one. If issue continues, contact service department.
ECG signal does not appear in Monitoring mode	Make sure there is a proper connection between the skin and the electrodes and the electrodes are not dry. Prepare the patient's skin before the attachment of electrodes. (Clean the skin or shave the chest hair if needed) Change the electrodes. If issue continues, contact service department.
Displays ECG signal with poor quality in Monitoring mode	Make sure there is a proper connection between the skin and the electrodes and the electrodes are not dry. Prepare the patient's skin before the attachment of electrodes. (Clean the skin or shave the chest hair if needed) Change the electrodes. If issue continues, contact service department.
Diversion of the ECG from the baseline in Monitoring mode	Make sure there is a proper connection between the skin and the electrodes and the electrodes are not dry. Prepare the patient's skin before the attachment of electrodes. (Clean the skin or shave the chest hair if needed) Change the electrodes. If issue continues, contact service department.
Noise on ECG signal in Monitoring mode	Make sure there is a proper connection between the skin and the electrodes and the electrodes are not dry. Prepare the patient's skin before the attachment of electrodes. (Clean the skin or shave the chest hair if needed) Change the electrodes. If issue continues, contact service department.
"Connect AED Cable to the Device"	Check defibrillator pad connector is correctly connected to the socket. If issue continues, contact service department.

Appendix 1. Technical specifications

Defibrillator	**Waveform**	Rectilinear Biphasic
	shock delivery	Fully automated model, Semi-Automated model
	defibrillator charge hold time	semi-automatic mode: 30 seconds full-automatic mode: 3 seconds prior to automatic shock delivery
	energy selection	sequential mode: Adult mode: 120J, 150J, 200J Child mode: 50J, 70J, 85J MAX mode: Adult mode: 200J Child mode: 85J
	patient safety	all patient connections are electrically isolated.
	charge time (time from first rhythm analysis to AED charged and ready to shock at 200 J)	less than 10 seconds to maximum energy with new battery pack. With a depleted battery pack, the charge time is longer.
	maximum time from power on to AED charged and ready to shock at 200 J	25 seconds
	electrodes	adult, child
	built in defibrillator self-test	included (verifies proper charging and discharging of the defibrillator)
	defibrillation advisory	evaluates defibrillation pads connection and patient ECG to determine if defibrillation is required.
	shockable rhythms	ventricular fibrillation with average amplitude >200 microvolts and wide complex ventricular tachycardia (with QRS duration > 120 msec) with rates greater than 150 bpm.
	electrode patient impedance measurement range	12-300 ohms
	defibrillator electrode ECG circuitry	protected
ECG	**ECG band width**	0.5-30 Hz

	implanted pacemaker pulses detection	detect and remove pacemaker pulses
Interface	**device display**	lay user (displays text prompts and graphics), ECG (displays text prompts, the patient's ECG rhythm)
	viewing Parameters	Number of Shock, Time, Elapsed Time and Battery capacity
	display type	high resolution LCD (400*800 pixel) with resistive touch panel
	viewable area (H*W)	5 inches
	ECG sweep speed	25 mm/sec
	ECG viewing time	3.8 seconds
	indicator	Display the result of last automated self-test by status indicator
	Speaker	Provides audio prompts and necessary alarms
	instructions	Step by step auditory and visual instructions, according to AHA/ERC CPR guidelines
	data transfer	USB connection to receive stored data (self-test, ECG and operation information)
	WI-FI	device status information can transfer over Wi-Fi
	language	Persian, English.
Data recording & storage	**Data recording & storage**	user configurable for 1 or 2 clinical events for a total for 120 minutes with audio recording disabled, or 60 minutes with audio recording enabled. Includes, ECG, patient impedance, audio prompts and optional audio recording.
Battery	**operating time (clinical mode) (non-chargeable battery)**	typical new battery running at an ambient temperature of +20 to +25 ˚C can provide: 200 defibrillator discharges at maximum energy (200J) or 6 hours of continuous ECG Monitoring (with 2-minute CPR periods). NOTE: CPR periods shorter than 2 minutes can decrease the operating time.
	standby life (years) when using battery stored for up to 2 years at 23 ˚C.	•auto self-test report: off self-test interval: 7 days -> 5 self-test interval: 1 day -> 3 •auto self-test report: on self-test interval: 7 days -> 3
Device	**size (H * W * D) [cm3]**	9.4 * 30.3 * 28.1
	weight	3.150 kg
	power	battery pack
	device classification	Internally powered per EN 60601-1: 2006/A1: 2013,
	design standards	Meets applicable requirements EN 60601-1: 2006/A1: 2013, EN 60601-1-2: 2015, IEC 60601-2 4:2010+AMD1: 2018
Environment	**Operating temperature**	0 to 50 ˚C
	Storage temperature	-30 to 70 ˚C
	Humidity	10 to 95% relative humidity

	Altitude	-200 to 3000 m
	Particle & water ingress	IP44
	Drop	1 m

Appendix2. Battery specifications

Rechargeable battery	
type	lithium-ion (Li-ion)
weight	443 g
Nominal voltage	14.4 volt
Recharge time	5 hours
Operating time	For a new, fully charged battery pack at 20°C: 220 defibrillator discharges at maximum energy (200 joules) or 15 hours of continuous monitoring. The CHANGE BATTERY warning appears after 200 maximum-energy discharges
Standby life	Auto self-Test report OFF Self-Test Interval (1 day): 1.3 years Self-Test Interval (7 day): 1.4 years
Non-Rechargeable battery	
type	Lithium manganese dioxide (LiMnO2)
weight	476 g
Nominal voltage	15.0 volt
Operating time	For a new, fully charged battery pack at 20°C: 180 defibrillator discharges at maximum energy (200 joules) or 14 hours of continuous monitoring. The CHANGE BATTERY warning appears after 160 maximum-energy discharges
Standby life	Auto self-Test report OFF For Healthy battery: more than 5 years

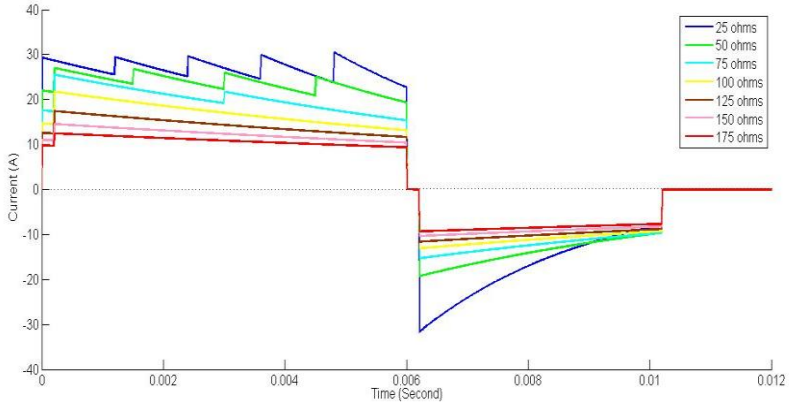
Appendix 3. Rectilinear Biphasic Waveform

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

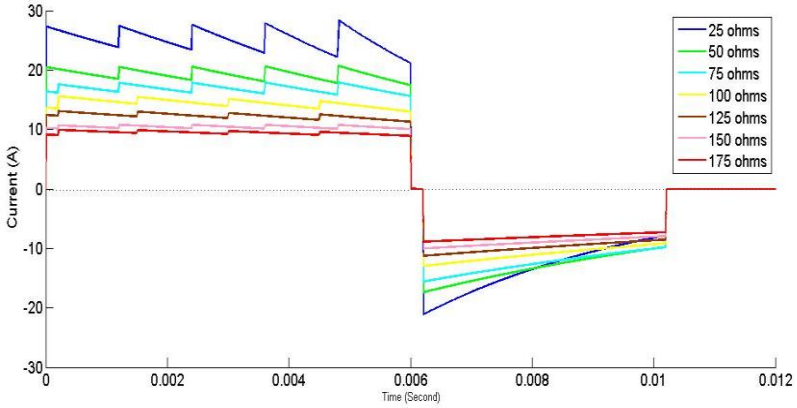
Delivered energy for different loads

Load (Ω)	Selected Energy [J]					
	Child			Adult		
	50	70	85	120	150	200
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%

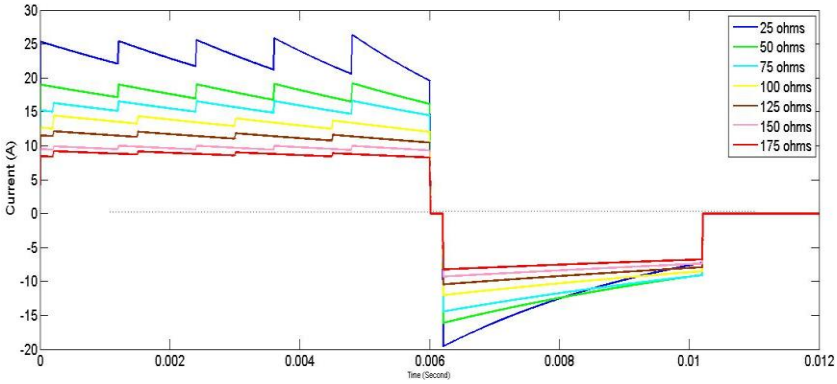
Rectilinear biphasic waveform has better performance in comparison with traditional Biphasic truncated exponential waveform according to clinical result. In the following rectilinear biphasic current graph, waveforms for different load are depicted.



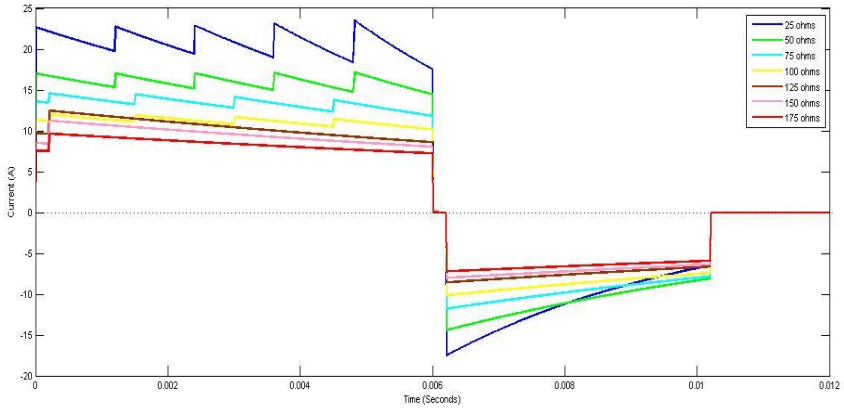
200J Shock Current waveform



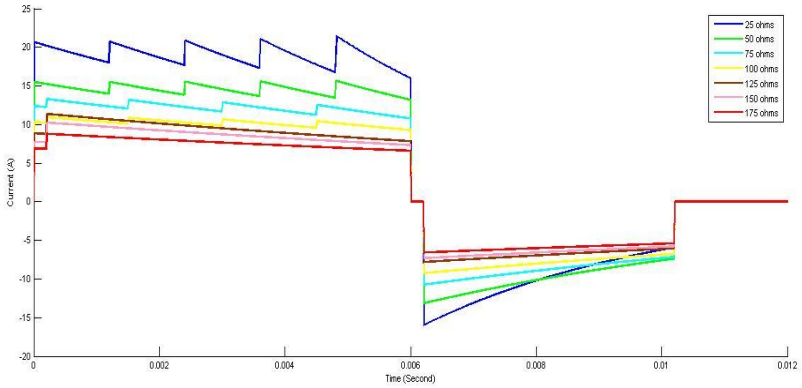
150J Shock Current waveform



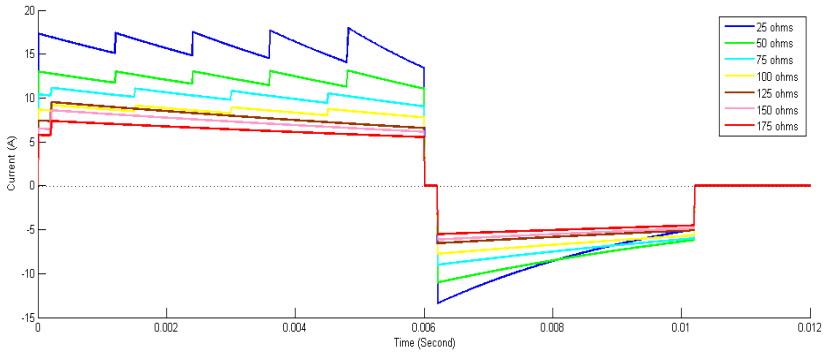
120J Shock Current waveform



85J Shock Current waveform



70J Shock Current waveform



50J Shock Current waveform

Appendix 4. 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 Physio-Net 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 and IEC requirements for reporting performance data for a rhythm recognition detector.

A. Acquisition and Annotation Methodology

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

Physio-Net Test Set

The Physio-Net Test Set includes 634 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 80 ECG segments gathered from the Fluke Impulse 7000DP Defibrillator Analyzer and 50 ECG segments gathered from the BC Biomedical Patient Simulator. Each ECG segment is 8 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.

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 Physio-Net Test Set 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%	 >91% >95%
Non-Shockable (Specificity)	>95%	>97%
Positive Predictive Value	Report Only	>97%
False Positive Rate	Report Only	<3%

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)	 >91% >95%	 200 50	 256 67

Non-Shockable			300 total	311 total
NSR	>99% (Specificity)	>97%	100	243
Other QRS	>95% (Specificity)	>98%	30	52
Asystole	>95% (Specificity)	>99%	100	16
Intermediate				Simulator test set
Fine VF	Report Only	>33% Shocked	25	9
Other VT	Report Only	>20% Shocked	25	15

Appendix 5. 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 manufacturer recommended accessories. Using the accessories other than in relevant chapter may cause to increase the EMISSION or decrease the IMMUNITY of system.
- Measurements can be affected by mobile phones 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="3">Guidance and manufacturer's declaration – DE100 emissions</td></tr>
<tr><td colspan="3">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>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>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>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>N.A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions

IEC 61000-3-3</td><td>N.A</td></tr>
<tr><td colspan="3">Guidance and manufacturer's declaration – electromagnetic immunity</td></tr>
</table>

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.			
Immunity test	Port	Compliance level	Electromagnetic environment - guidance
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	704- 787	LTE Band 13, 17		0.2	0.3	9
745						

780			Pulse modulation [b] 217 Hz			
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.