

LIFE  **ARK**

ARK-501

"LIFE ARK"

**AUTOMATED EXTERNAL
DEFIBRILLATOR AND ACCESSORIES**

User Manual

Be sure to read the user manual and
follow the instructions before use



DBi Dermacare Biomed Inc.

IMPORTANT

- Operators are recommended referring the quick-manual provided with the original manual carefully for quick and adequate product operation.
- Contents of the manual may be changed without prior notification or agreement by Dermacare.
- Data without any quotation mark may be different from estimated data as compared to actual data.
- Be sure to read the user manual and follow the instructions before use.



Applicant's Name : Dermacare Biomed Inc.
Applicant's Add : 5F., NO. 88-5, Minquan Rd., Xindian Dist., New Taipei City 23141, Taiwan
Manufacturer's Name : Dermacare Biomed Inc. STSP Branch.
Manufacturer's Add : 4F., NO. 3, Nanke 3rd Rd., Xinshi Dist., Tainan City 74147, Taiwan
Web : www.dermacare-asia.com.tw
Tel : +886 2 2218 6321
Mail : services@dermacare.com.tw

Contents

Product Introduction.....	Chapter 1
Product overview	1.1
Indications of use	1.2
Getting started	1.3
Symbol Descriptions.....	Chapter 2
Warning and Caution.....	Chapter 3
Limited Warranty.....	Chapter 4
Customer Requirement and product registration.....	4.1
Warranty details.....	4.2
Warranty period.....	4.3
Product repair/exchange	4.4
Guidance for maintenance.....	Chapter 5
AED location and periodical maintenance.....	5.1
After first-time use	5.2
Cleaning	5.3
Troubleshooting.....	Chapter 6
Self-diagnosis	6.1
AED conditional alarm.....	6.2
Troubleshooting.....	6.3
Technical data.....	Chapter 7
Physical parameters.....	7.1
Environmental parameters.....	7.2
Functionality	7.3
Applicable standards	7.4
Parameters for P-303TW(AED Pads).....	7.5
Parameters for DBT-303 (Battery).....	7.6

1 Product introduction



Please consult the user manual prior to AED operation.



It is highly recommended for every potential user to complete periodic training for CPR and ARK-501 operation. Please contact national/local representative for Heart Guardian series to find out detailed CPR and AED operating training schedule.

1.1 Product overview

ARK-501, a portable electric device operated by battery power, is an easy-to-use Automated External Defibrillator. The AED automatically analysis patient's ECG and identifies and advise electric shock if it is necessary. Nearly every procedure for AED operation is guided through voice message and beep sound, as well as the visual guidance with picture description with LED. Heart Guardian, ARK-501 is manufactured based on CPR guideline of AHA revised in 2010.

1.1.1 Functions





(M) Speaker	Speaker for Audio guidance
-------------	----------------------------

(A) Power Button		Used to turn on or off the product
(B) Summarized Instruction		Simple Instruction for CPR and AED use
(C) Status indication light		LED light informs about product status to user by blinking to various color
(D) Handle		For carrying AED safely
(E) Cover		Prevents external substances exposure to AED
(F) Battery		Provides electric to AED
(G) AED Pad Connector		Connect the AED pads prior to attaching the pads to patient
(H) Shock Button		Press the button when guidance indicates to deliver charged electric shock to patient
(I) Adult/Child Switch	Mode	Select Adult/Child mode, default is Adult mode
(J) Procedure Guidance	LED	LED light informs CPR and AED operating procedure to user
(K) Bluetooth Port		Communication port for maintains of AED
(L) Battery Slot		Mount the battery correctly to this slot

1.1.2 Specification

Product Type	Automated External Defibrillator (The AED automatically analysis patient's ECG, if it is necessary, user have to press the shock button)
Auto/Manual Diagnosis	Automatic diagnosis (battery power, circuit power, button operation checks)
ECG complete analysis	FFT ECG Analysis
Step by Step Audio Guidance	Voice record (Chinese 、 English)

Compatible Adult/Child	Adult/child mode switch (default)
Charge Method	Hi-Cap charge
Output Range	150J±10% (Adult) / 50J±10% (Child)
Data Storage	108 times of ECG log can be recorded
Control Button	Power, Analysis, Shock, Adult/child mode switch
Battery Type (DBT-303)	LiMnO ₂ (12V DC 4.2Ah)
Number of shock	At least 200 times (New battery)
AED Pads Type(P-303TW)	AED electric prods(single-use), 2 lead wire(2m), 4-hole plug
Product Size (mm)	312(L) x 223(W) x 85(H)mm
Product Weight (kg)	1.7kg (battery included)
Product Color	Yellow
Basic Components	AED portable case(ARK-501), Battery(DBT-303), User Manual
The proposed purchase	AED Pads (P-303TW)

- ARK-501 guarantee 5 years.
- Life of Battery is different from temperature and humidity during storage. Management is necessary to follow this guidance.
- While keep by wait mode, Life of Battery is decreasing as time goes by and is possible to reduce the number of electric shock.

1.1.3 Accessories

ARK-B1 (Portable AED case)



Model : **ARK-B1**
 Usage ; Storage and protection
 Type : Plastic, Artificial Leather
 Size : 330(H) x 235(W) x 95(T)mm
 Weight : 370g
 Life time : 1 year(Portable)
 10 years(Storage)

P-303TW (AED Pads) (**The proposed purchase**)



Model : **P-303TW**
 Usage ; Delivers electric shock to patient, Detect Patient's ECG signal
 Type : Adhesive pads for both adult/child
 Size : 145(H) x 98(W) x 1(T)mm
 Weight : 120g
 Warranty : 2 years (in case of damage caused by user's mistake, repair/ exchange will be charged)
 Life time : Single use only, 2 years for unpacked/sealed product since the manufacturing date

DBT-303 (AED Battery)



Model : **DBT-303**
 Usage ; Electric power supply to AED

Type : LiMnO₂ (DC 12V 4.2Ah)
 Size : 60(H) x 175(W) x 25(T)mm
 Weight : 285g
 Warranty : 4 years (in case of damage caused by user's mistake, repair/exchange will be charged)
 Life time : 4 years for standby mode

1.2 Indications of use

The Heart Guardian ARK-501 is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The Heart Guardian ARK-501 is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program.

The Heart Guardian ARK-501 is indicated for use with electric pads (on patients greater than 8 years old or over 25 kg when used with the adult mode and/or on children between 1 and 8 years of age or up to 25 kg when used with the kid mode).

It is highly recommended for every potential user to complete periodic training for CPR and ARK-501 operation. Please contact national/local representative for Heart Guardian series to find out detailed CPR and AED operating training schedule.

Heart Guardian, ARK-501 is an emergency medical device used for patient stops in breathing lapsed into unconsciousness due to sudden cardiac arrest.



No response



Unusual or no breath



AED is prohibited for use in case of response or consciousness of patient

Heart Guardian, ARK-501 may be used for both adult and child with the identical pads by separate button setting. Initial default setting is adult mode.

1.2.1 Contraindications for Use

Do not use the Heart Guardian ARK-501 when the patient:

1. is conscious; or
2. is breathing; or
3. has a detectable pulse or other signs of circulation.

1.3 Getting started

Once AED is powered on, every operation procedure is guided by voice recorded audio guidance and beep sound with picture description with LED. For a brief operation training, refer to quick guide provided with the product

1.3.1 Preparation

- ① Open the packing box and confirm product components. If the components are not prepared, inquiry contact national/local representative.
 - I. ARK-501 AED
 - II. ARK-501 User Manual
 - III. P-303TW AED Pads (The proposed purchase)
 - IV. DBT-303 Battery (Non-rechargeable)
- ② Insert a battery pack (DBT-303) into the battery slot



- ③ For safe storage, always keep AED in the portable case(ARK-B1)
- ④ Place AED at a highly visible and accessible location



Do not remove sealed package which contains AED pads (P-303TW).
Once the package is opened, the adhesive material on AED pads will get dry continuously and that would result improper pads attachment.

1.3.2 AED Operation

1.3.2.1 Open the cover and set up the adult/child mode switch

Heart Guardian, ARK-501 may be used for both adult and child. If it is hard to define the patient's weight and age quickly, proceed further operation procedure with the default mode (adult mode)



Adult Mode
Above age of 8 or Minimum weight 25kg

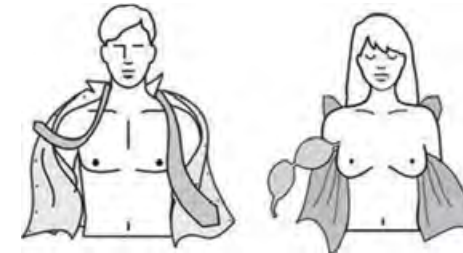


Child Mode
Below age of 7 or Maximum weight 25kg

1.3.2.2 Turn on the power by pushing power button



1.3.2.3 Prepare the patient for AED operation



AED shall be placed just next to the patient, and remove clothing from the patient chest, and make sure the patient's chest is clean and dry. Shaving hair may be necessary for better AED pads attachment



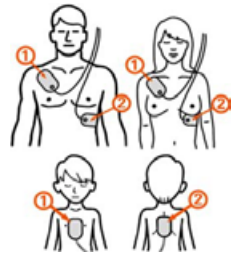
Saving time is very important for sudden cardiac arrest patient
Time shall not be wasted on taking off the clothes. Remove patient's top as quickly as possible even by cutting or ripping it

1.3.2.4 Attach AED Pads to the patient, and connect pads to AED.

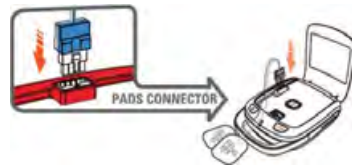


1. Take the AED pads out

2. Remove the covering package and tear off the covering stickers



3. Attach the pads to patient's chest



4. Connect the pads to AED

1.3.2.5 ECG Analysis

Once AED pads are clearly attached to the patient's chest and pads connector is connected to AED, AED starts ECG analysis for patient.



During ECG analysis, stay away from patient



For accurate and safe ECG analysis, during ECG analysis, do not physically contact the patient.

1.3.2.6 Electric shock and CPR

Once ECG analysis is completed, the AED operates as shown below

- **In case of Electric Shock is needed (Defibrillation is required)**

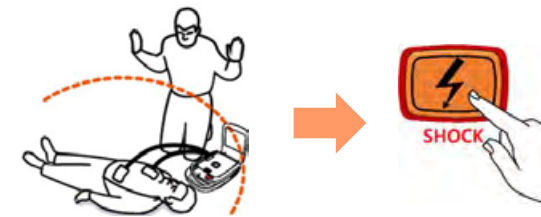
- ① Audio guidance: 'Electric shocks are needed'
- ② After a while, once recharging is completed, shock button blinks.

- ③ Audio guidance: 'Press the flashing orange shock button'
- ④ Electric shock delivers to the patient
- ⑤ After electric shock, perform CPR procedure following audio guidance
- ⑥ Audio guidance: 'Start CPR'
- ⑦ Audio guidance: 'Compress the chest 30 times'
- ⑧ Beeper: rings 30 times
- ⑨ Audio guidance: 'Start mouth to mouth CPR 2 times'
- ⑩ CPR guidance for ⑥ ~ ⑨ will repeat every 30 seconds and operates as shown below after repeat of 5 cycles.



Be careful of electric shock

Electric shock may be delivered to a person who is physically contacting with the patient. Before pushing the shock button, confirm and instruct others to stay away from the patient.



- **Electric shock is not needed**

- ① Audio guidance: 'No shock is needed'
- ② Audio guidance: 'If there's no pulse, please start CPR immediately'

During AED conducts CPR guide, no ECG analysis is proceeded. Once CPR guidance completed, the product informs the rescue progress status via audio message and re-analyzes ECG.

- Other conditions

In case of AED pads' mis-attachment to the patient, the product operates as below:

Audio guidance: 'Firmly attach the pads to the patient's bare skin'.

Even though electric energy charge is completed, if user does not push blinking shock button for more than 15 seconds, AED will conduct discharge the electric energy instead of delivering electric shock to patient through AED pads:

Audio guidance: 'Shock button was not pressed'

1.3.3 Data management











1.3.3.1 ECG data record








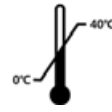





The product automatically saves ECG data based on every events of the AED operates. Those data can be transferred via Bluetooth 2.0 interface to a computer. Pairing may be required to connect AED to computer.

2 Symbol Descriptions

☑ Following symbols refer to the international standard, and are indicated on the surface of the product, battery, AED pads, and packing box

☑ Some symbols can be changed/modified/added by DERMACARE to follow up with the international standards update

Symbol	Explanation	Symbol	Explanation
	Warning The symbol implements serious hazards that may cause injury or death		Caution The symbol implements hazards that may cause an electric shock, product damage, and malfunction
	Reference Additional reference data is referred		Dangerous Voltage The defibrillator output has high voltage and may present a shock hazard
	Additional info Additional information is described on manual		Type BF Equipment Connected AED to the patient's chest by the AED pads, may withstand the effects of an externally applied defibrillation shock.
	Non-Sterile Product/Part is not sterilized		Non-Rechargeable Do not recharge the battery
	Keep Dry AED/Accessories shall be kept dry before or in use		Relative Humidity Humidity range to be maintained

Symbol	Explanation	Symbol	Explanation
	Keep away from ignition materials Do not operate or keep AED around ignition materials		Do not expose or incinerate to open flame
	Expiration date AED pads shall be replaced after marked date		Do not expose to sunlight Do not expose to direct sunlight
	WEEE Waste Electronic Electrical Equipment Separate collection for waste electrical and electronic equipment		Direct Current, DC Direct Current
	Battery Type Lithium manganese oxide Battery		Temperature Limit Product/Part shall be kept at marked temperature range
	Product Model Number		Serial Number
	LOT Batch code		Single time use only Do not reuse AED pads
	Do not use if package is damaged		

Symbol	Explanation	Symbol	Explanation
IP54	Protection Level Protection level that shows anti-dust and waterproof level		Maintenance required
	Recycling Dispose of properly in accordance with all state, province, and country regulations		Manufacture Name and address of manufacturer
 20XX-XX-XX	Date of Manufacture 4 digits of the year and 2 digits of month which indicate the manufacturing date		LATEX Free
	Bluetooth AED supports Bluetooth wireless communication	 SHOCK	Electric Shock Button Audio and LED guidance will notice to press the shock button when it is needed
	Power Button Press the button to operate AED		i -button A dummy button for system check-up
	Adult/Child mode switch Confirm Adult/Child mode switch prior to AED pads attachment		

3 Warning and Caution

☑ Please refer to the following for safety use of ARK-501.



Do not use if the patient shows any reaction or is consciousness

ARK-501 is a portable defibrillator manufactured for ventricular fibrillation patients. Prior to AED operation, it is very important to check patient's consciousness and respiration condition; do not use if the patient is conscious and reacting.



The AED is set to "Adult Mode" as default

In adult mode, AED delivers about 150J of electric shock to patient. In child mode, about 50J of electric shock is set to be delivered, if patient is under the age of 7 or weighting below 25kg, please set "Child Mode" by moving Adult/child mode switch to the left and attach the pads firmly to appropriate spots.



Be careful of electric shock hazard



Electric shock can be delivered to operator or bystander through unexpected ways. To avoid this hazard during AED operation, keep followings:

- Do not use AED in standing water, underwater, rain, snowing. Move patient to a dry area.
- Confirm and instruct anyone to stay away from the patient prior to pressing 'Shock Button'.



- When patient is contacted with any conductive materials such as metals, stay away from the conductive materials.



Do not use around flammable materials

To avoid possible fire or explosion hazard, do not use around the following situation/place.

- close to flammable materials
- close to hyperbaric oxygen tank (within 25m)
- close to hydrogen tank (within 25m)



Do not attempt to recharge or cause heat/damage the battery (DBT-303)

Recharge or heat/damage on battery(DBT-303) may cause an explosion or fire hazard. If the battery is low, please exchange to new one.



Do not attempt to disassemble or repair the AED

Disassembling AED may result electric shock hazard. RADIANT is not responsible for electric shock hazard resulted by unauthorized disassemble or repair. Please contact local/national sales representative for repair or replacement.



Do not use battery not provided by DERMACARE

DERMACARE is not responsible for damage/malfunction in operation caused by unofficial battery use. Uses of unofficial battery may cause serious damage / malfunction on AED.



Attach the AED pads clearly on the patient's bare chest

For accurate ECG analysis and proper electric shock delivery, AED pads shall be attached on the patient's bare chest firmly and tightly. Users shall make sure the patient's skin is clear and dry prior to the AED pad attachment.



During ECG analysis, stay away from the patient

Touching the patient during the ECG analysis phase can cause interference with the diagnostic process that may cause increased analysis time, or result analysis error. Avoid contact with the patient while analysis is on progress.



AED pads are single-use only

Do not reuse AED pads. Also always keep the AED package sealed prior to the actual use. If the sealed package is damaged or opened, exchange it to new one immediately.



Interference may be caused by implanted pacemaker

With some pacemakers, the AED may not advise an electric shock

- Do not attach the AED pads directly on an implanted device
- Attach the AED pads at least 5cm away from any implanted device



Temperature requirement for stable operation/storage

Battery and AED pads of ARK-501 can be stored from 0°C to 40°C for short term period(under 5 days), but recommends at least 1 hour of storage at 20°C~ 30°C temperature condition prior to actual AED operation. For long-term storage(over 5 days), DERMACARE recommends maintaining AED with temperature range from 20°C to 30°C. AED pads and battery may have significant performance degrade with the long-term storage(over 5 days) at out of range of 0°C~40°C temperature condition.



IP54

Do not expose AED to water or liquid directly

IP54 grade is not capable of blocking direct inflow of liquid completely. In case of water or liquid inflow inside the AED, there may cause malfunction or failure of the AED.



Operator is to be well-informed of method of AED operation and CPR in advance

Some national standards restrict AED to be sold by or on the order of a physician or practitioner licensed by law in which operator practices to use or order the use of the AED.



The AED requires periodic maintenance for followings:

- Status indication light check
- Battery manufacturing date check
- AED pads expiration date check



Do not use AED for CPR training, experiment, and demo

ARK-501 is only used for sudden cardiac arrest patient. Any ARK-501 operation on a simulator or a mannequin may cause serious malfunction or damage on AED.



Compliance with national and regional regulation

AED maintenance and authorization, responsibility of usage shall be followed by relevant national and regional regulation.



Product disposal

The AED is classified as electronic device. AED shall be disposed in a way required by the local guideline.



ARK-501's CPR guidance is consistent with 2010 guidelines defined by AHA

4 Limited warranty

4.1 Customer requirement and product registration

Product registration regarding the purchased product may be necessary based on the national regulations for AED.

4.2 Warranty details

DERMACARE provides warranty to original purchaser of ARK-501(including battery and AED pads but varies the covering time periods) that guarantees free replacement and repair service. Warranties and returning policies may vary by products and periods depends on regional regulations and DERMACARE's sales policy. Please contact sales representatives for more details.

Following cases are exceptions of warranty coverage:

- 4.2.1 Defect caused by improper operation not following the user manual.
- 4.2.2 Defect caused by unauthorized repair or modification.
- 4.2.3 Defect caused by external shock including drop.
- 4.2.4 Defect caused by natural disaster such as fire, earthquake, flood, and thunder stroke.
- 4.2.5 Defect caused by use/storage in extreme temperature or humidity environment, please refer to 'Chapter 5 Guidance for maintenance'.
- 4.2.6 Unauthorized alternation of purchase date, purchaser name, vender, and serial number.
- 4.2.7 Products that warranty period is expired.
- 4.2.8 Un-registered AED.

4.3 Warranty period

- 4.3.1 ARK-501 (Main Body, excluding battery and AED pads)
 - 5 years from date of manufacture (indicated on product label)
- 4.3.2 Battery (DBT-303)
 - 4 years from date of manufacture (indicated on product label)
- 4.3.3 AED Pads (P-303TW, The proposed purchase)
 - 2 years from date of manufacture (indicated on the surface of pads)

4.4 Product repair/exchange

An inspection can be performed by DERMACARE (or regional representative) to check the warranty period and trace the defect. Once DERMACARE confirm the defect is caused by one of the manufacturing, development or delivery procedure, repair/exchange may be provided without any shipping charge.

5 Guidance for maintenance

5.1 AED location and periodical maintenance

5.1.1 Please set AED at a place where AED can be easily detected and accessed. DERMACARE strongly suggests setting AED close to a telephone in order to call emergency aid service immediately in case of emergency

5.1.2 Always, battery shall be installed to AED

5.1.3 Periodically check AED operation and expiration date of battery and AED pads

5.1.4 The product shall be stored/operated in following environmental conditions

① Operating*

- Temperature Range : 0°C to 40°C (32°F to 104°F)
- Humidity: 5% to 95% (non-condensing)

② Standby**

- Temperature Range : 0°C to 40°C (32°F to 104°F)
- Humidity: 5% to 95% (non-condensing)

③ Storage and transport (up to 3 days)***

- Temperature Range: -20°C to 60°C (-4°F to 140°F)
- Humidity : 5% to 95% (non-condensing)

④ Avoid AED storage in below places

- Place where wide temperature changes happen frequently
- Place where is exposed to direct sunlight
- Wet or flood places
- Places close to heater or heavy electrical devices
- Places where excessive shock or shake may occur
- Places close to flammable materials

- Places exposed to the extreme environmental weather condition
- ↳*Operating*: AED with pads and battery installed and lid open.
- ↳Standby***: AED with pads and battery installed and lid closed.
- ↳Storage and transport***: AED with pads optionally connected and battery not installed.

5.1.5 Battery and AED pads maintenance

① Battery maintenance

If the battery is low, AED may not be operated properly in emergency situation. When status LED blinks 'RED', battery pack shall be replaced immediately. Periodically check manufacturing date indicated on battery label, and replace to new one if it is expired (4 years from manufacturing date).

- Replacing battery pack



- Pull out the battery pack to be replaced on backside of the AED, by pressing dual lever switch on each side of the battery pack.
- Push in the new battery pack facing the label below until 'clack' sound emits.



Do not attempt to recharge or cause heat/damage the battery (DBT-303)

To avoid possible fire or explosion hazard, do not use around the following situation/place.

- In the presence of flammable gases
- In the presence of hyperbaric oxygen tank (within 10m)
- In the presence of hydrogen tank (within 10m)



Do not use battery not provided by DERMACARE

DERMACARE is not responsible for damage/malfunction in product operation caused by use of unofficial battery. Since use of unofficial battery may cause trouble/malfunction.

② AED pads maintenance(The proposed purchase)

- AED pads' expiration date shall be checked periodically. Expired AED pads shall be replaced to new one immediately.
- If sealing package of AED pads is ripped or damaged, do not use the pads and replace it to new one.
- ARK-501 only accepts P-303TW AED pads, do not use any other AED pads not provided by DERMACARE.
- DERMACARE recommends preparing additional pads with different expiration dates for spare.



5.2 After first-time use

If AED were operated for an actual emergency situation, AED maintenance manager shall check-up followings to make AED ready to be used again anytime for everyone.

5.2.1 Exterior inspection after AED operation

- Check exterior appearance of AED, and if it is necessary, please remove contamination. For damage recovery on AED, please contact customer technical support.

5.2.2 Components management after AED operation

- If AED pads were used or unpacked, please replace the pads to new ones.
- If AED delivered electric shocks at least over 3 times, and life time is expired (2 years from manufacturing date), DERMACARE suggests replacing the battery to new one. Suggested battery life is 4 years for standby mode.

5.3 Cleaning

To clean the AED, wipe the AED with a soft cloth that has been dampened by one of the following:

- Soapy water
- Isopropyl alcohol (70% solution)

For cables and pads, follow cleaning instructions in the directions for use shipped with those components. Avoid spilling liquid on the AED, especially in connector areas. If liquid is accidentally spilled on the AED, clean and dry thoroughly before reuse. If in doubt about AED safety, refer the unit to qualified service personnel or your local supplier for checking.

6 Troubleshooting

6.1 Self-diagnosis

Power-On Self-test (Operation mode)	Every time when power button is pressed Flash ROM test Charge/ Discharge test Battery Output level test
Regular Self-test (Stand-by mode)	Automatically performed once per month on 1st day Flash ROM test Charge/ Discharge test Battery Output level test


If the product fails in self-diagnosis test, status light blinks in red and beeper sounds a warning. In this state, the product does not operate properly. If the product does not operate properly, users should refer to 6.3. Troubleshooting in the manual.



During periodic self-diagnosis, if product trouble is found, status light blinks in red; in case of power on by pushing power button, beeper sounds 3 times every second for warning with error audio guidance.

6.2 AED conditional alarm

Alarming Indication	Description
Status Indication Light Blue Blink	Prompts the state of proper use
Status Indication Light Red Blink 3 beep sounds/Min	Prompts when error is found during operation
Status Indication Light Green Blink	Prompts AED to conduct self-diagnosis test
Status Indication Light Off	Maintenance manager mode
Procedure LED guidance Orange Blink	Guides user current CPR procedure
Shock Button Light Orange Blink	Prompts the state of preparation for electric shock

6.3 Troubleshooting

Mode	Alarming Indication	Situation	To do
Standby	Status Indication light: Red blink 	AED is turned off after 8 to 10 times of electric shock or 10min later since power-on	Replace the battery to new one
		Audio message: The battery is low, please change the battery immediately	Replace the battery to new one
		Audio message: System error 000X	Contact the vender for A/S service
		Power button is not working, AED does not powered-on.	Replace the battery to new one, if the battery is already replaced within 3 years or new one. Please contact the vender for A/S service

Operating	Status Indication light: Red blink 	Audio message: The battery is low, please change the battery immediately	Replace the battery to new one
		Audio message: System error 000X	Contact the vender for A/S service
	Status Indication light: Blue 	Audio message: System will be terminated due to disconnection of the pads	Connect AED pads' connector to AED firmly and properly
		Audio message: Plug the connector of the pad to AED (repeat)	



Do not attempt to disassemble or repair the AED arbitrarily

Do not attempt to disassemble the AED arbitrarily due to danger of electric shock hazard when high voltage is recharged. DERMACARE is not responsible for electric shock resulted from unauthorized disassembly or attempt to repair. Please contact sales representative for defective AED.

7 Technical data

7.1 Physical parameters

Parameter	Detail
Operation	Automated External Defibrillator
Dimensions	312(L) x 223(W) x 85(H)mm
Weight (Including battery)	1.7kg

7.2 Environmental parameters

Parameter	Condition	Detail
Temperature range	Operating*	0°C to 40°C (32°F to 104°F)
	Standby**	0°C to 40°C (32°F to 104°F)
	- Short-term (5 days)	20°C to 30°C (68°F to 86°F)
	- Long-term	20°C to 30°C (68°F to 86°F)
	Storage and transport***	-20°C to 60°C (-4°F to 140°F)
Humidity		5 to 95% (non-condensing)
Altitude		0 to 4,575m (0 to 15,000ft)

* AED with pads stored over 5 days at temperatures condition between 0°C to 20°C or 30°C to 40°C, shall be kept in a place at room temperature range(20°C to 30°C) at least 1 hour, prior to operation.

7.3 Functionality

Parameter	Detail
FFT ECG Analysis	The AED FFT ECG analysis system automatically analyzes the patient's ECG and advises you when defibrillation is required
Waveform	Biphasic Truncated Exponential (BTE)
Impedance range	25Ω to 175Ω
Electric shock energy	Adult mode: 150J±10% Child mode: 50J±10%
Charge time	Since the initiation of AED operation (Power On), 8 seconds with a new, fully charged battery; with low on battery, the charge time gets significantly longer.
Operating time	For a new, fully charged battery pack at 20°C to 30°C, 200 discharges at maximum energy or 10 hours of continuous ECG monitoring.
Automated Self-tests	Monthly (every 1st day for each months): Battery, internal electronics
Audible alerts	Voice recorded prompts Alarm beep sound
Indicators	Overall status light (Battery, AED condition) CPR procedure guidance LED CPR procedure guidance draws

ECG data record	13.75Mb (108 of ECG logs can be recorded)
Data communication	Bluetooth 2.0

7.4 Applicable standards

Type	Detail
General	GMP ISO13485 ISO9001
Safety and performance	IEC60601-1H (Basic safety & essential performance) IEC60601-1-2CEMC (EMC) IEC60601-2-4:2011
Sensitivity and Specificity of Rhythm Detection (FFT ECG Analysis)	<ul style="list-style-type: none"> • Shockable Rhythm-VF: (IEC 60601-2-4, AHA’s recommend: >90%) • Shockable Rhythm-VT: (IEC 60601-2-4, AHA’s recommend: >75%) • Non-shockable—Rhythm-NSR: (IEC 60601-2-4, AHA’s recommend: >95%) • Non-shockable-Asystole: (IEC 60601-2-4, AHA’s recommend: >95%) • Non-shockable-all other rhythms: (IEC 60601-2-4, AHA’s recommend: >95%)

7.5 Parameters for P-303TW (AED Pads) (The proposed purchase)

Parameter	Detail
Type	Pre-gelled, self-adhesive, disposable, nonpolarized defibrillation pads
Shelf life	2 years
Disposal	Abide by regional/national regulations

7.6 Parameters for DBT-303 (Battery)

Parameter	Detail
Type	Lithium Manganese Dioxide (LiMnO ₂)
Output Voltage	12 VDC 4.2Ah
Disposal	Abide by regional/national regulations
Shelf life	4 years from date of manufacture (can be reduced by temperature condition)



DBi Dermacare Biomed Inc.

Applicant's Name : Dermacare Biomed Inc.

Applicant's Add : 5F., NO. 88-5, Minquan Rd., Xindian Dist., New Taipei City 23141, Taiwan

Manufacturer's Name : Dermacare Biomed Inc. STSP Branch.

Manufacturer's Add : 4F., NO. 3, Nanke 3rd Rd., Xinshi Dist., Tainan City 74147, Taiwan

Web : www.dermacare-asia.com.tw

Tel : +886 2 2218 6321

Mail : services@dermacare.com.tw