

Automated External Defibrillator

HR-501

User manual



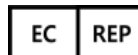
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IMPORTANT

- ☑ 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 Radian
- ☑ Data without any quotation mark may be different from estimated data as compared to actual data



#1610, Halla-Sigma Valley, 53, Gasan Digital 2-ro
Geumcheon-gu Seoul, Korea
+82-2-1670-1980
Info@radian.co.kr
www.radian.co.kr













S.B. PHARMA GMBH
Max-Planck Str. 39a D-50858, Koln, Germany
Tel) +49 (0) 2234 988 1521








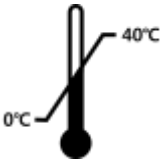






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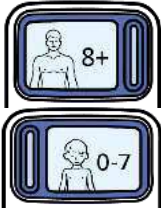

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1 Symbol Descriptions

- ☑ 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 RADIANT 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
	EC Representative European authorized representative		Serial Number
	LOT Batch code		Product Model Number
	Do not use if package is damaged		Single time use only Do not reuse AED pads

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		CE Mark This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC
	Date of Manufacture 4 digits of the year and 2 digits of month and day which indicate the manufacturing date		Manufacture Name and address of manufacturer
	Bluetooth AED supports Bluetooth wireless communication		LATEX Free
	Power Button Press the button to operate AED		Electric Shock Button Audio and LED guidance will notice to press the shock button when it is needed
	Adult/Child mode switch Confirm Adult/Child mode switch prior to AED pads attachment		i-button A dummy button for system check-up

2 Warning and Caution

- ☑ Please refer to the following for safety use of HR-501
- ☑ Certain contents may be indicated delicately in other part



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

HR-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

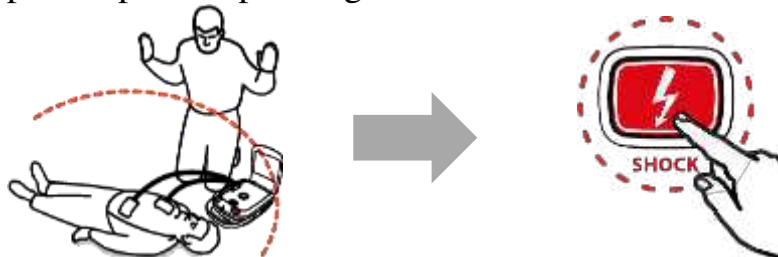
In adult mode, AED delivers about 150J of electric shock to patient. In child mode, about 50J of electric shock is set to be delivered, if patient is under the age of 7 or weighting below 25kg, please set "Child Mode" by moving Adult/child mode switch to the left and attach the pads firmly to appropriate 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 (BT-303)

Recharge or heat/damage on battery(BT-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 RADIANT

RADIANT 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 HR-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), RADIANT 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.



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

IP54



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

HR-501 is only used for sudden cardiac arrest patient.
Any HR-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



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

3 Limited warranty

3.1 Customer requirement and product registration

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

3.2 Warranty details

RADIAN Corp., provides warranty to original purchaser of HR-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 RADIAN's sales policy. Please contact sales representatives for more details.

Following cases are exceptions of warranty coverage:

3.2.1 Defect caused by improper operation not following the user manual

3.2.2 Defect caused by unauthorized repair or modification

3.2.3 Defect caused by external shock including drop

3.2.4 Defect caused by natural disaster such as fire, earthquake, flood, and thunder stroke

3.2.5 Defect caused by use/storage in extreme temperature or humidity environment, please refer to 'Chapter 5 Guidance for maintenance'

3.2.6 Unauthorized alternation of purchase date, purchaser name, vender, and serial number

3.2.7 Products that warranty period is expired

3.2.8 Un-registered AED

3.3 Warranty period

3.3.1 HR-501 (Main Body, excluding battery and AED pads)

- 5 years from date of manufacture (indicated on product label)

3.3.2 Battery (BT-303)

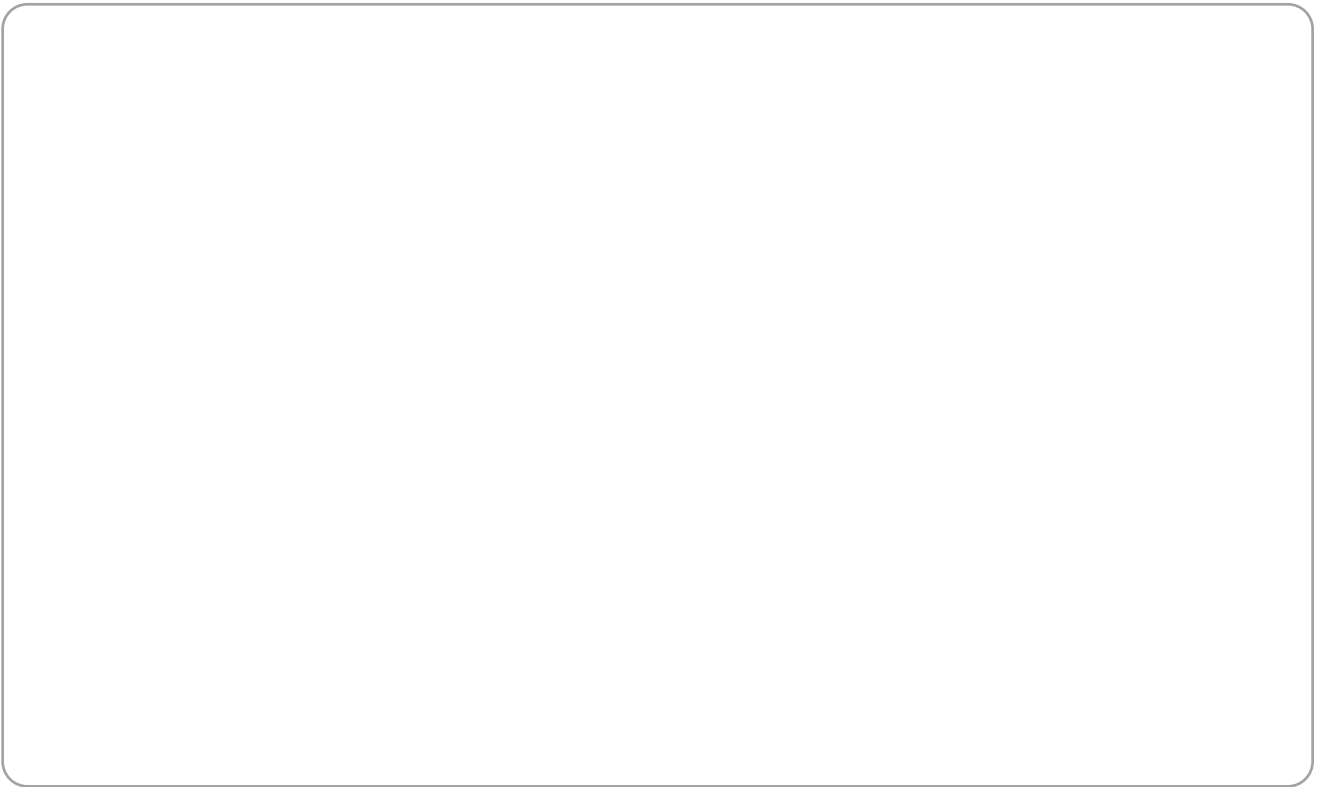
- 4 years from date of manufacture (indicated on product label)

3.3.3 AED Pads (P-303)

- 2 years from date of manufacture (indicated on the surface of pads)

3.4 Product repair/exchange

An inspection can be performed by Radian (or regional representative) to check the warranty period and trace the defect. Once Radian confirm the defect is caused by one of the manufacturing, development or delivery procedure, repair/exchange may be provided without any shipping charge. Shipping will be completed within maximum of 50 days from the day the product arrives at RADIAN Corp., which are automatically added up to remaining warranty period



4 Product introduction



Please consult the quick manual and user manual prior to AED operation



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

4.1 Product overview

HR-501, a portable electric device operated by battery power, is an easy-to-use Semi-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, HR-501 is manufactured based on CPR guideline of AHA revised in 2010

4.1.1 Functions





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

4.1.2 Specification

Product Type	Semi-automated External Defibrillator
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 (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 (BT-303)	LiMnO ₂ (12V DC 4.2A)
Number of shock	At least 200 times (New battery)
AED Pads Type (P-303)	AED electric prods(single-use), 2 lead wire(2m), 4-hole plug
Product Size (mm)	225(W) x 320(L) x 85(H)mm
Product Weight (kg)	2.2kg (battery included, AED case and electric pads excluded)
Product Color	Red
Basic Components	AED portable case(HR-B1), AED pads(P-303), Battery(BT-303), User Manual, Quick guide

4.1.3 Accessories

HR-B1 (Portable AED case)



Model : **HR-B1**

Usage ; Storage and protection

Type : Plastic, Artificial Leather

Size : 235(W) x 330(H) x 95(T)mm

Weight : 370g

Life time : 1 year(Portable)
10 years(Storage)

P-303, AED Pads



Model : **P-303**

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)

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

BT-303, HR-501 Battery



Model : **BT-303**

Usage ; Electric power supply to AED

Type : LiMnO₂ (DC 12V 4.2Ah)

Size : 60(H) x 175(W) x 25(T)

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

-
- 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.
 - AED is able to use 200 times of electric shock at the immediate usage starting from purchase and HR-501 guarantee 5 years life-time. If you only use electric shock function after 1 year of purchase, we guarantee the remaining 4 years life time.

4.2 Indications of use

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

- Unconscious
- Not breathing
- Without circulation

The Heart Guardian HR-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 HR-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 HR-501 operation. Please contact national/local representative for Heart Guardian series to find out detailed CPR and AED operating training schedule

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

4.2.1 Contraindications for Use

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

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

4.3 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

4.3.1 Preparation

- ① Open the packing box and confirm product components. If the components are not prepared, inquiry contact national/local representative. Manual and quick guide is available at 'www.radian.co.kr' for downloading
 - I. HR-501 AED
 - II. HR-501 User Manual
 - III. P-303 AED Pads
 - IV. BT-303 Battery (Non-rechargeable)
 - V. Quick Guide
- ② Insert a battery pack (BT-303) into the battery slot



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

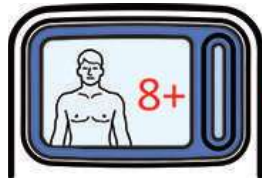


Do not remove sealed package which contains AED pads (P-303). Once the package is opened, the adhesive material on AED pads will get dry continuously and that would result improper pads attachment

4.3.2 AED Operation

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

Heart Guardian, HR-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



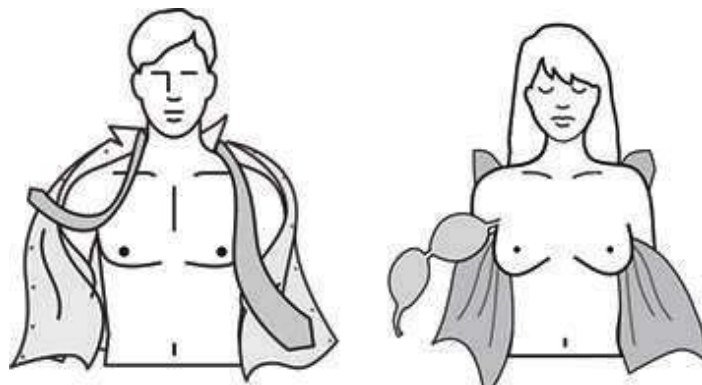
Child Mode

Below age of 7 or Maximum weight 25kg

4.3.2.2 Turn on the power by pushing power button



4.3.2.3 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



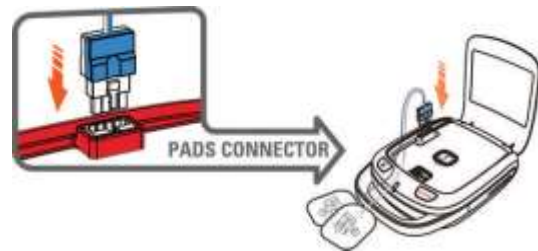
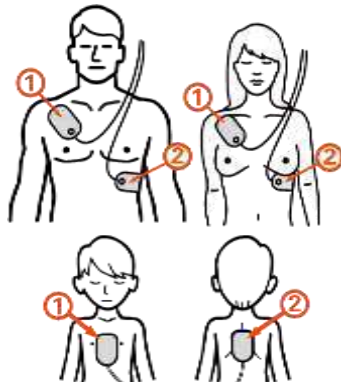
Saving time is very important for sudden cardiac arrest patient
Time shall not be wasted on taking off the clothes. Remove patient's top as quickly as possible even by cutting or ripping it

4.3.2.4 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

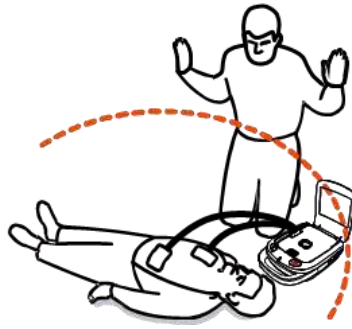
④ Connect the pads to AED

4.3.2.5 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

4.3.2.6 Electric shock and CPR

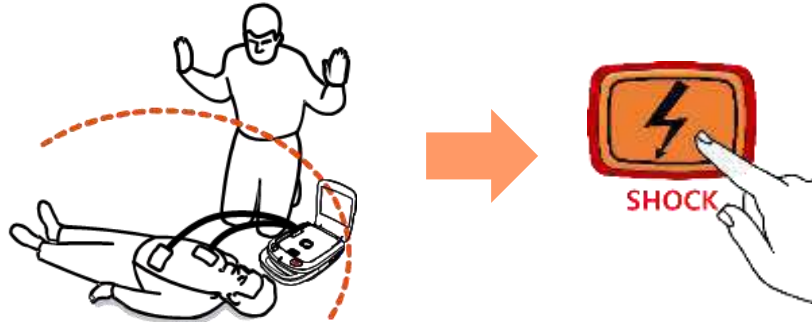
Once ECG analysis is completed, the AED operates as shown below

- **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

- ① 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
- ② Audio guidance: ‘Shock button was not pressed’

4.3.3 Data management

4.3.3.1 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

4.3.3.2 Heart Guardian™

Heart Guardian™ is a viewing software provided by RADIANT for displaying and analyzing the ECG data transferred to computer. Heart Guardian software will be updated periodically and uploaded to RADIANT's website, www.radian.co.kr

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. RADIANT strongly suggests setting AED close to a telephone in order to call emergency aid service immediately in case of emergency
- 5.1.2 All components including P-303 electric pads shall be kept together
- 5.1.3 Always, battery shall be installed to AED
- 5.1.4 Periodically check AED operation and expiration date of battery and AED pads
- 5.1.5 The product shall be stored/operated in following environmental conditions

① Operating*

- Temperature Range : 0°C to 40°C (32 ~ 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% ~ 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

5.1.6 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 (BT-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 RADIANT

RADIANT 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

- 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
- HR-501 only accepts P-303 AED pads, do not use any other AED pads not provided by RADIANT
- RADIANT 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), RADIAN 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 1 st 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 blink		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. RADIANT 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	Semi-automatic external defibrillator
Dimensions	223(W) x 312(L) x 85(H)mm
Weight (Including battery)	2.2kg

7.2 Environmental parameters

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


* AED with pads stored over 5 days at temperatures condition between 0 ~ 20°C or 30 ~ 40°C, shall be kept in a place at room temperature range(20 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~ 30°C: 200 discharges at maximum energy or 10 hours of continuous ECG monitoring.
Automated Self-tests	Monthly (every 1 st day for each months): Battery, AED pads, 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	KGMP by KCL (KCLAAB-140053) 
Safety and performance	IEC60601-1H (Basic safety & essential performance) IEC60601-1-2CEMC (EMC) IEC60601-2-4:2011 EN 1041:2008 EN 980:2008
Shock	IEC60068-2-27
Vibration	IEC60068-2-64 (10Hz to 2,000Hz)
Free fall drop	IEC60068-2-32 (1m)
Enclosure (Particle and water ingress)	IEC 60529, IP54
EMC	IEC60601-1-2CEMC (EMC) Directive 2014/30/EU
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-303 (AED Pads)

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

7.6 Parameters for BT-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)

7.7 FFT ECG Analysis


FFT ECG Analysis algorithm is for efficient and accurate ECG detection algorithm that meets below requirements and recommendations

- 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%

Guidance and Manufacturer's Declaration – Electromagnetic emissions

Emissions test	compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1 , Class B	The HR-501 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. The HR-501 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The HR-501 uses interference detected and motion detected indicators to notify the user if conditions are not ideal. No other ESD requirements are necessary.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power line supply lines ±1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should not be greater than levels characteristic of a typical location in a commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2500 MHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HR-501, including cables, than necessary. The recommended separation distance calculated from the equation applicable to the frequency of the transmitter is shown in the following table. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HR-501 is used exceeds the applicable RF compliance level above, the HR-501 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the HR-501.

Separation Distances

The HR-501 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HR-501 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HR-501 as recommended below, according to the maximum output of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the HR-501

Rated maximum output power of the transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = 1.6 \times \sqrt{P}$	150 kHz to 80 MHz inside ISM bands $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2 \times \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \times \sqrt{P}$
0.01	0.01	0.12	0.12	0.23
0.1	0.1	0.37	0.38	0.73
1	1	1.17	1.20	2.30
10	10	3.69	3.79	7.27
100	100	11.67	12.00	23.00

For transmitters rated at the maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: As 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

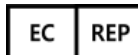


#1610, Halla-Sigma Valley, 53, Gasan Digital 2-ro
Geumcheon-gu, Seoul, Korea

+82-2-1670-1980

Info@radian.co.kr

www.radian.co.kr



S.B. PHARMA GMBH
Max-Planck Str. 39a D-50858, Köln, Germany
Tel) +49 (0) 2234 988 1521