	KF-0654-6-0069-04		
	0654		

Summary of safety and clinical performance

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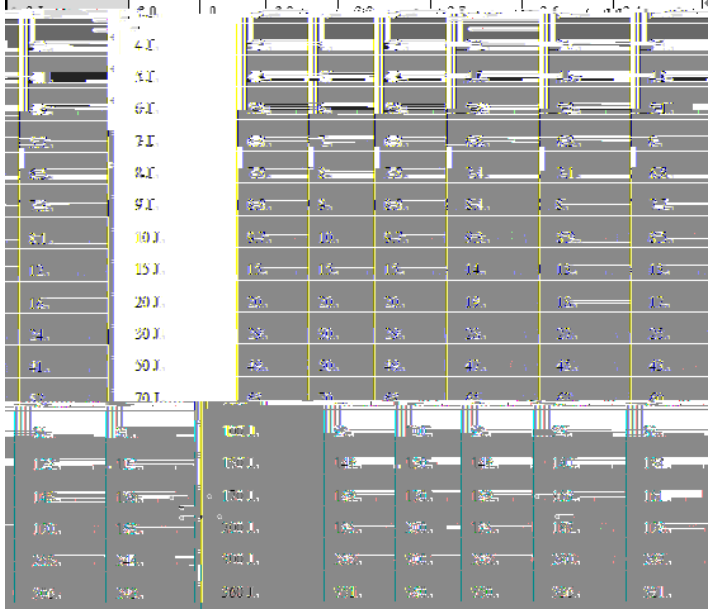
1. Technical Characteristics			
Technical characteristics	**Device 1 (subject device) Description of characteristics and reference to specifying documents**	**Device 2(marketed device) Description of characteristics and reference to specifying documents**	**Technical characteristics**
1.1 Device is of similar design			hardware design hardware design
1.2 Used under similar conditions of use			The subject device is the subset of the marketed device
1.3Similar specifications and properties including			Beneheart C

physiochemical properties			which Beneheart D1 has. Beneheart C &S series Beneheart C &S series Intended Medical Conditions. Beneheart C &S series have 25J and 120J energy level which Beneheart D1 does not have. But these two energy levels 2021 ERC guidence which the scope is in 1-360J range. Also, 25J and 120J are same with certified Beneheart D6 in MDR.

Energy \ Impedance	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω
10 J	9.7	10	9.7	9.3	8.9	8.5	8.1
15 J	15	15	15	14	13	13	12
20 J	20	20	20	19	18	17	16
25 J	24	25	24	23	22	21	20
30 J	29	30	29	28	27	25	24
50 J	49	50	49	47	45	43	41
70 J	68	70	68	65	62	60	57
100 J	97	100	97	93	89	85	81
120 J	116	120	116	111	106	101	97
150 J	146	150	146	140	134	128	122
170 J	166	170	166	159	151	145	138
200 J	195	200	195	187	178	170	163
300 J	292	300	292	280	267	255	244
360 J	351	360	350	336	321	306	293

Energy \ Impedance	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω
1 J	1	1	1	0.9	0.9	0.9	0.8
2 J	2	2	2	1.9	1.8	1.7	1.6



So Beneheart C &S series defibrillator energy level is the similar with marked device.

The measurement

			The subject device can provide CPR feedback of CPR rate through CPR sensor based on CPR movement measurements which is the same as the marketed device and is a class IIa functionality. The subject device can also provide a subset (CPR rate only) feedback of CPR movement based on the change of thoracic impedance which is a developed technology as discussed in the SOTA.
1.5 Critical performance standards			The subject device is the subset of the marketed device

			The of the subject device is same with the marketed device.

2.1 Uses the same materials or substances in contact with the same human tissues or body fluids	Not applicable There are no accssories contact with human tissues or body fluids included in this MDR submission.	Not applicable	Same.
2.2 Similar kind and duration of contact with the same human tissues or body fluids	Not applicable There are no accssories contact with human tissues or body fluids included in this MDR submission.	Not applicable	Same.

2.3 Similar release characteristics of substances including
de0 1 5.4 279.Tf1

		The equipment is also intended for use in public places and facilities by personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or other emergency medical response.	
3.5 Patient population			**Same**
3.6 Clinical		In manual defibrillation mode, asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. Synchronous defibrillation is intended for termination of atrial fibrillation. The ECG monitoring function is used	The subject device is the subset of the marketed device.
Summary Based on the comparison from technical, biological and clinical perspectives, slight differences are found, which cannot affect the safety and clinical performance of the device			

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3.3.1

3.3.2

3.3.2.1

3.3.2.2

3.4

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4.1

Item	Energ	Sequence of events	Hazardous situation	Harm	Control Measure	Risk level

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-
-
-
-

4.3

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2.

	2
	245
	247

Number of total Cases	success cases	success
161	154	95.7%

$$p \pm \quad _{/2}\sqrt{\quad (1 - \quad)/}$$

$_{/2}$ = 1.96

$$p \pm \quad _{/2}\sqrt{\quad (1 - \quad)/}$$

$_{/2}$ = 1.96

$$p \pm \quad _{/2}\sqrt{\quad (1 - \quad)/}$$

$_{/2}$ = 1.96

5.2

5.3

5.4

Factor	Assessment
Assessment of Benefits of Devices	
Type of benefit(s)	**Using real world data or other available data, what is t** **impact on clinical management and patient health?** The automated external defibrillator is intended for semi-automated external defibrillation and automated external defibrillation. Automated external defibrillation (AED) can directly improve patient survival, relieve symptoms and improve patient quality of life. During defibrillation, the CPR could standardize the chest compression procedure based on the measurement of compression depth range and compression rate.
Magnitude of the benefit(s)	**management?**

	Defibrillator are life-saving devices used in emergency situations. They have been shown to have a high benefit for patients with underlying diseases that remain undetected until sudden cardiac arrest occurs. The time from collapse to defibrillation is critical in-patient survival. For every minute that passes between collapse and defibrillation, survival rates from VF SCA decrease 7% to 10%. The magnitude of this benefit is either life or death.
Probability of the patient experiencing one or more benefit(s)	**From the data of PMCF:** The result of defibrillation success rate is 95.7% (95%Cl: 92.6%, 98.8%), the lower limit 92.6% is upper than the target value 87.9%. The result of sensitivity rate is 98.4% (95%Cl: 97.3%, 99.5%), the lower limit 97.3% is upper than the target value 90%. The result of specificity rate is 99.4% (95%Cl: 99.0%,99.8%), the lower limit 99.0% is upper than the target value 95%. The clinical performance of the AED function of the product in question has been proved to meet the requirement of recognized level in the industry.
Duration of effect(s)	N/A.
Assessment of risks of Devices	
	The risk management report has assessed the severity and probability of hazard occurrence and the combined residual risk is acceptable and the product is safe and effec104 4 44g(t)5(hts)3(as56 Tf1 0 0 1 182.78 432.91 Tm0 G[The ri)7(sk

Conclusion	Defibrillator are life-saving devices used in emergency situations. They have been shown to have a high benefit for patients with underlying diseases that remain undetected until sudden cardiac arrest occurs. The time from collapse to defibrillation is critical in-patient survival. For every minute that passes between collapse and defibrillation, survival rates from VF SCA decrease 7% to 10%. In conclusion, given the available information above, the defibrillator's support for patients in cardiac arrest who are unconscious, not breathing, or without circulation the probable benefits outweigh the probable risks.

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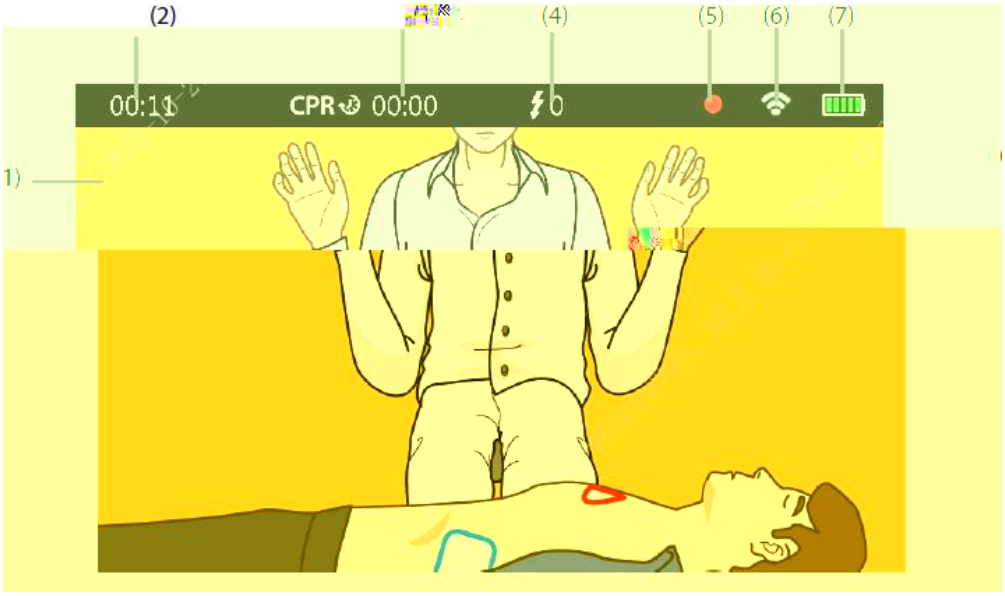
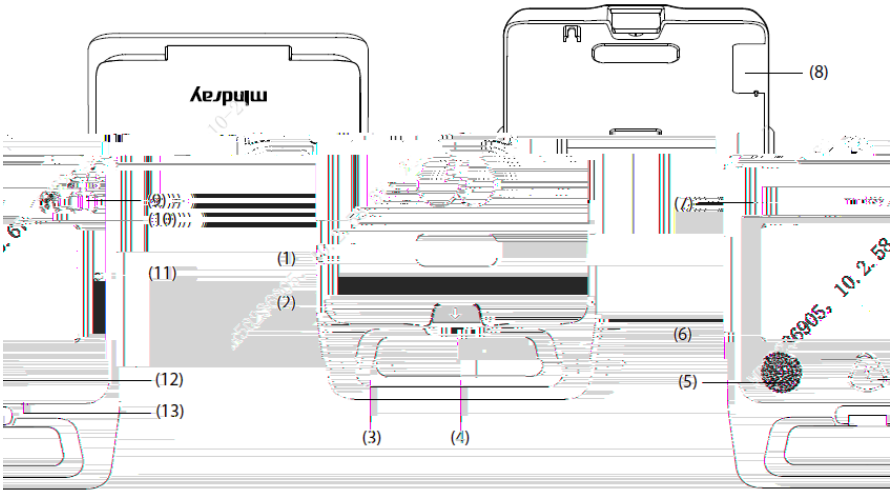
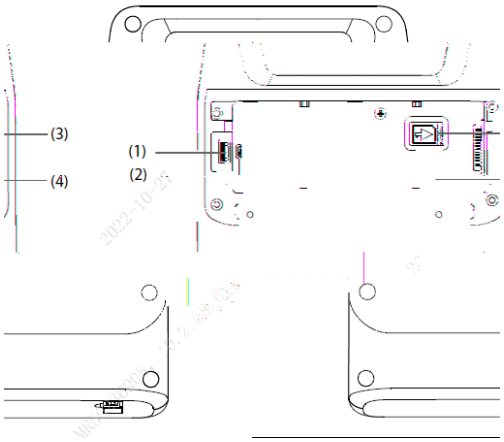




ıed With lid closed With lid open


(3)
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(1)
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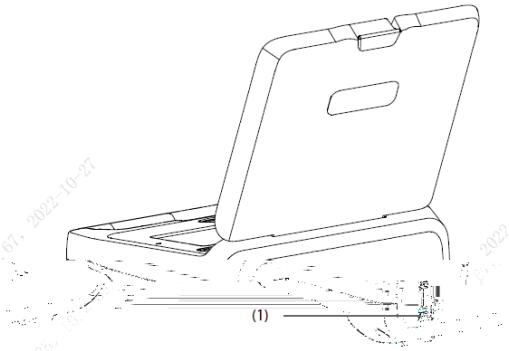
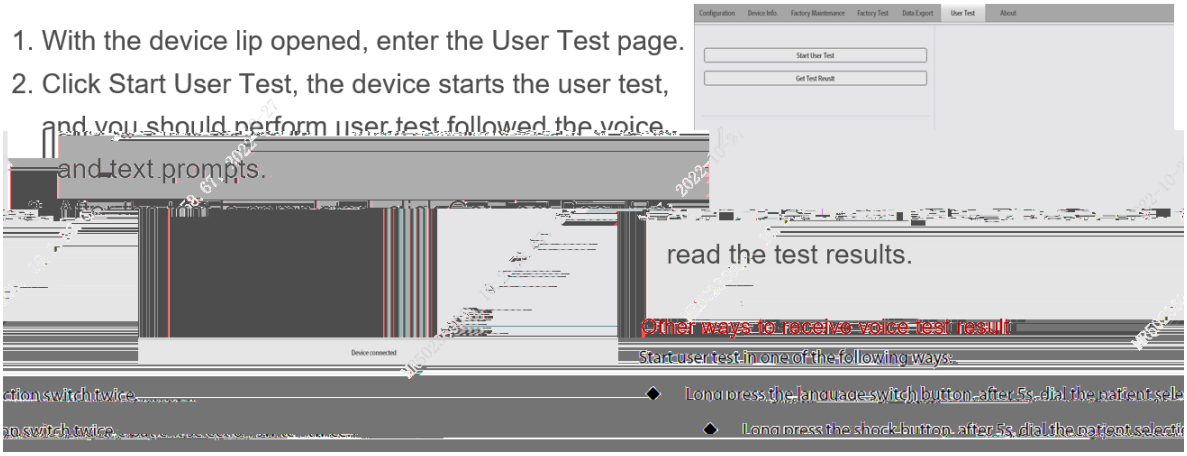


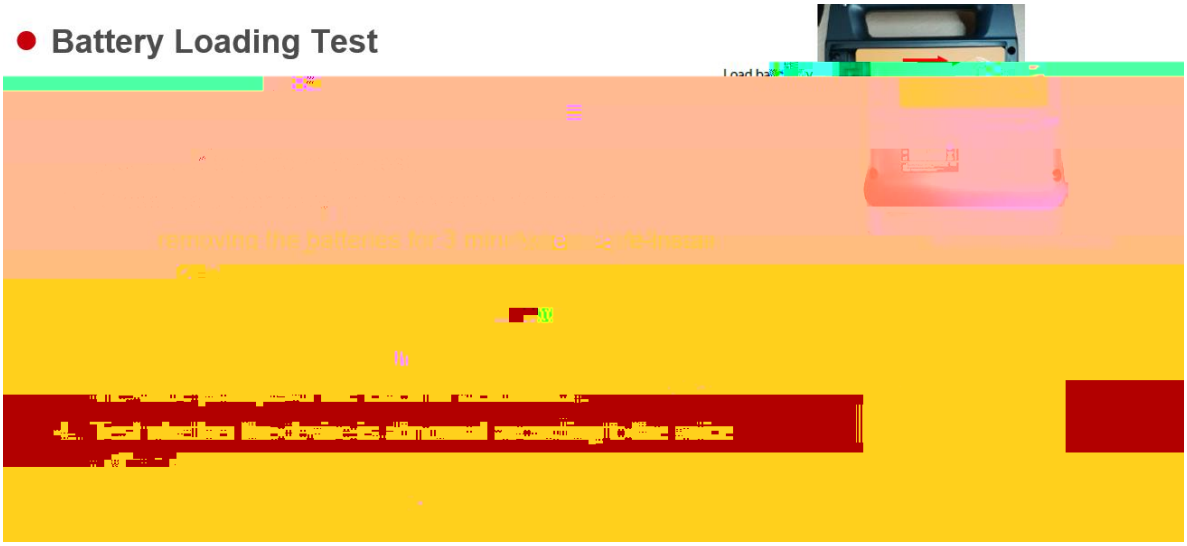
Modify Configuration — AED Tool Installation and Use Guide

User Test — AED Tool Installation and Use Guide

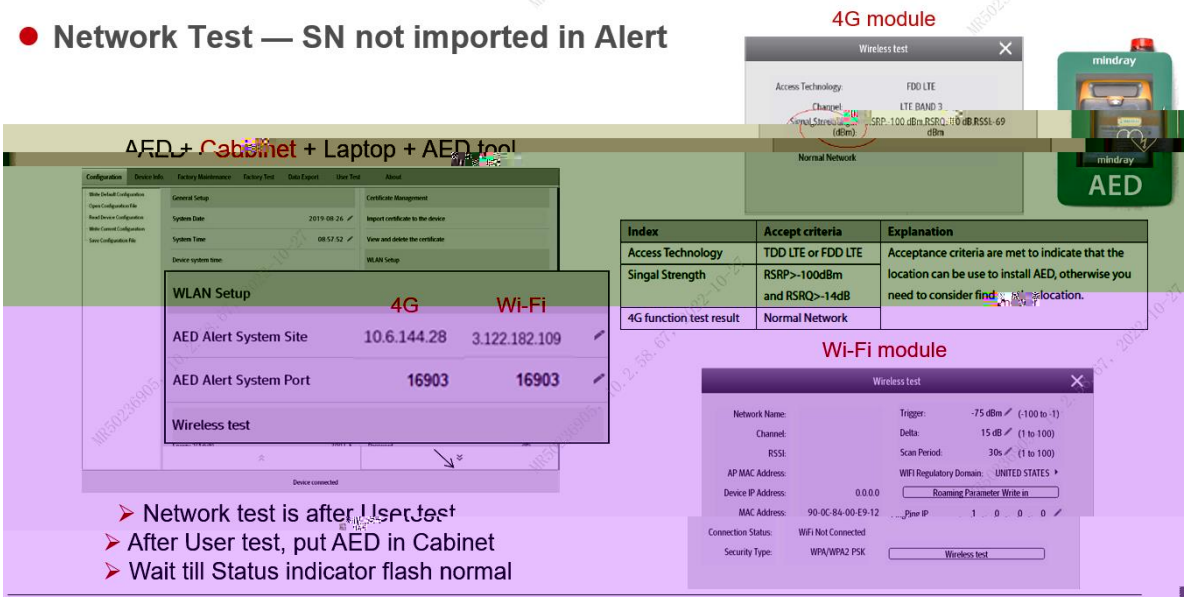
1. With the device lip opened, enter the User Test page.
2. Click Start User Test, the device starts the user test, and you should perform user test followed the voice and text prompts.



Battery Loading Test



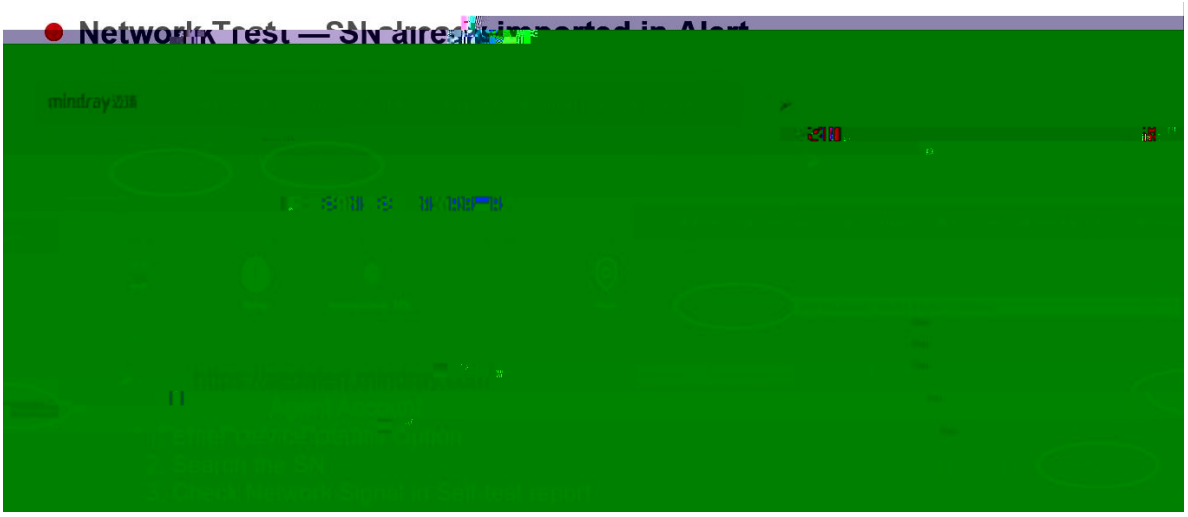
Network Test — SN not imported in Alert



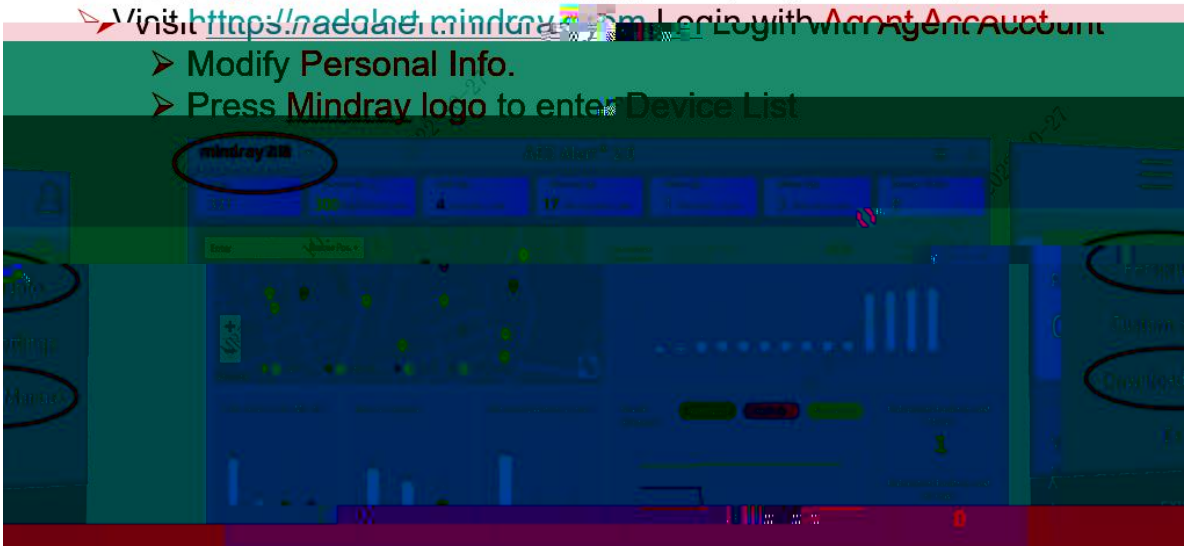
Index	Accept criteria	Explanation
Access Technology	TDD LTE or FDD LTE	Acceptance criteria are met to indicate that the location can be use to install AED, otherwise you need to consider find a new location.
Singal Strength	RSRP>-100dBm and RSRQ>-14dB	
4G function test result	Normal Network	

- Network test is after User test
- After User test, put AED in Cabinet
- Wait till Status indicator flash normal

- Network Test — SN are imported in Alert



- Import Device in AED Alert™ 2.0
  - Apply Agent Account with Mindray HQ (Only first time)
  - Visit https://aedalert.mindray.com, Login with Agent Account
    - Modify Personal Info.
    - Press Mindray logo to enter Device List



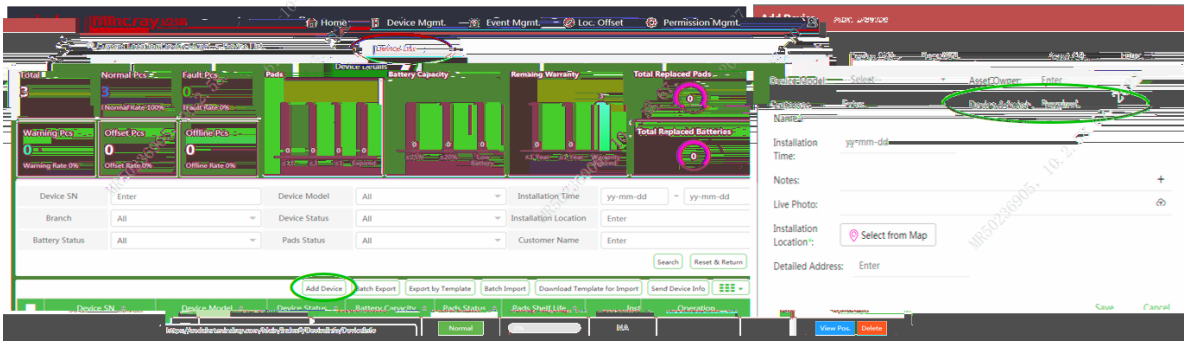
Import Device in AED Alert™ 2.0

Enter Permission Mgmt. -> User Mgmt. -> Create User

Admin Account ➢ Create Device

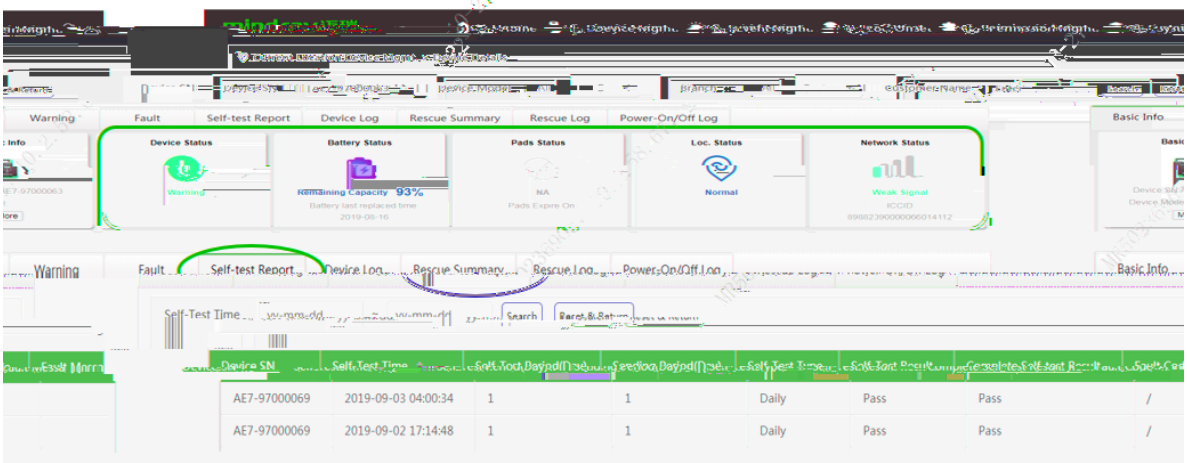
Import Device in AED Alert™ 2.0

- Enter Device Mgmt. -> Device List
- Press Add Device to import AED (Recommended)
- Associate Device with Device Admin



Import Device in AED Alert™ 2.0

- Enter Device Mgmt. -> Device Details
- Check All Device Status
- Check Self-test Report is received

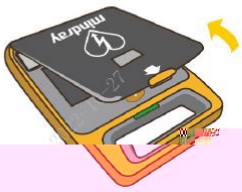


1 Assess the Patient

- Unresponsive,
- Not breathing or not breathing normally

CALL EMERGENCY MEDICAL SERVICE!

2 Turn on the Equipment



Open the lid.

You hear:
Powered on. Stay calm. Follow the instructions.

3 Check Patient Category

Flip the Adult/Child mode switch left or right:

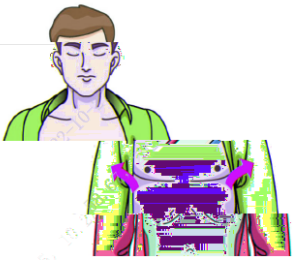
- For an adult: 8 years and older or over 25kg

You hear:
Adult mode.

- For a child under 8 years old or under 25kg

You hear:
Child mode.

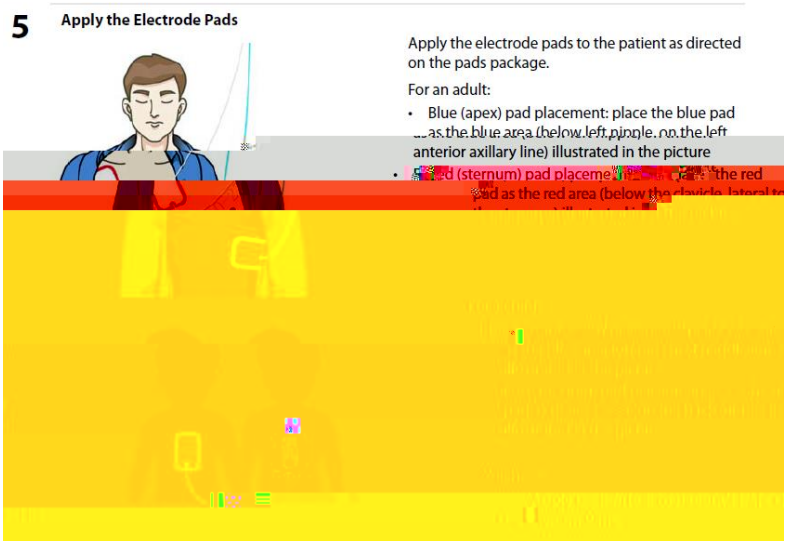
4 Prepare the Patient



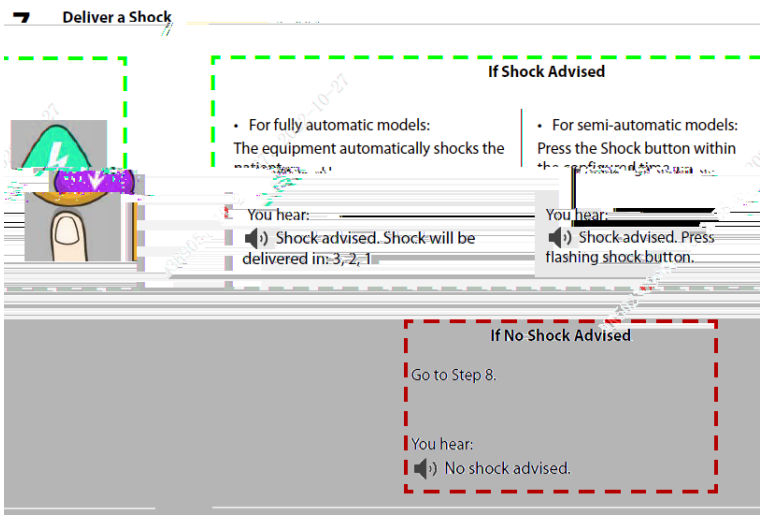
Expose the patient's bare chest:

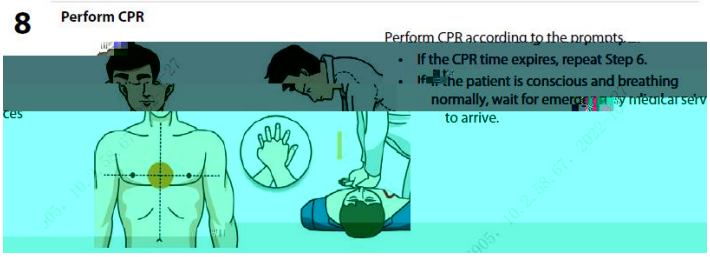
- Ensure the patient's skin is clean and dry.
- Trim excessive chest hair if necessary.

You hear:
Remove clothing from patient's chest.
Apply pads as shown on Pads.


5
Apply the Electrode Pads
Apply the electrode pads to the patient as directed on the pads package.
For an adult:
• Blue (apex) pad placement: place the blue pad as the blue area (below left nipple, on the left anterior axillary line) illustrated in the picture
• Red (sternum) pad placement: place the red pad as the red area (below the clavicle, lateral to


6
Analyze Heart Rhythm
You hear:
Do not touch the patient. Analyzing he rhythm.


Deliver a Shock
If Shock Advised
• For fully automatic models:
The equipment automatically shocks the
• For semi-automatic models:
Press the Shock button within
You hear:
Shock advised. Shock will be delivered in: 3, 2, 1
You hear:
Shock advised. Press flashing shock button.
If No Shock Advised
Go to Step 8.
You hear:
No shock advised.


8
Perform CPR
Perform CPR according to the prompts.
• If the CPR time expires, repeat Step 6.
• If the patient is conscious and breathing normally, wait for emergency medical serv to arrive.

8.

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