

BeneHeart D1

Automated External Defibrillator

Operator's Manual

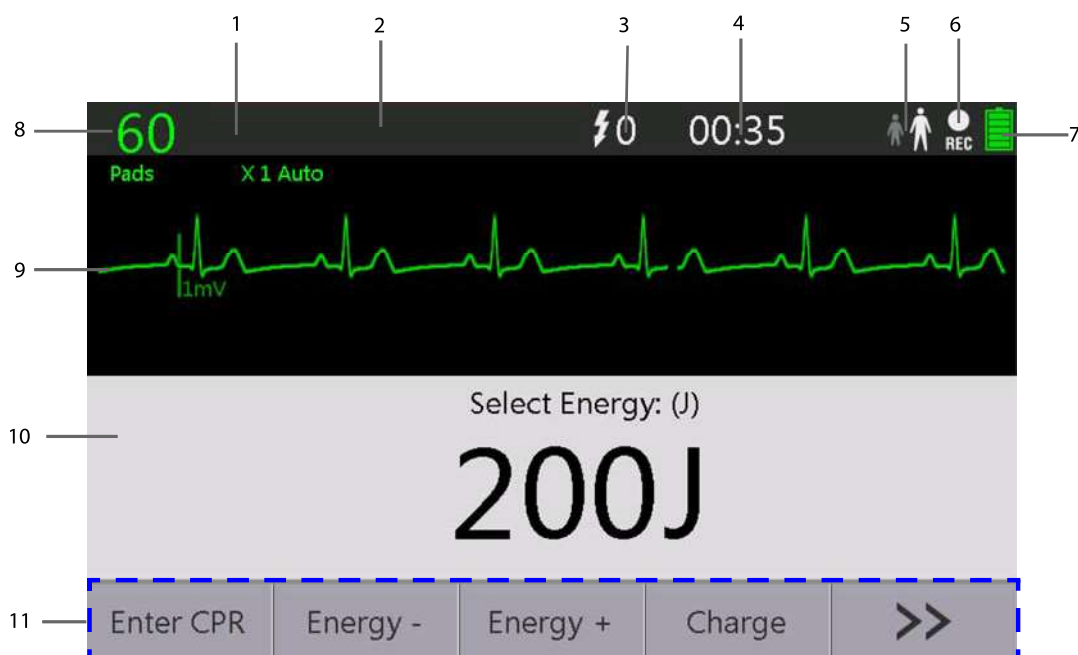


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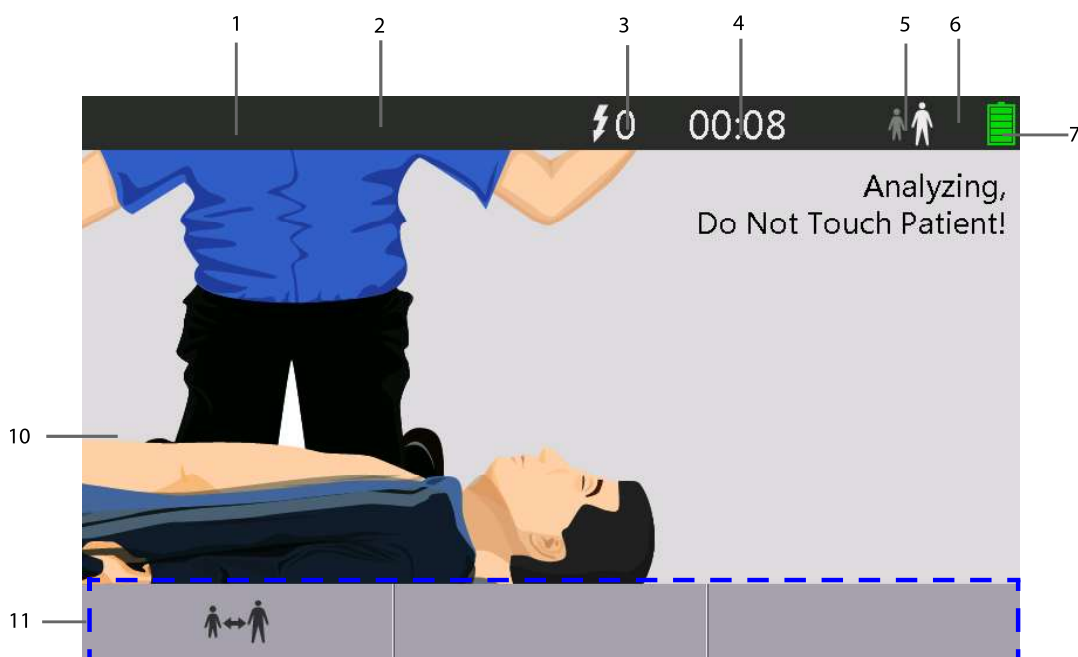
- Release time: January 2019
- Revision: 9.0

2.4 Display Views

For the equipment configured with AED manual defibrillation and ECG monitoring functions



For the equipment configured with only AED function



1. Alarm status symbols
 - ◆ indicates alarms are paused.
 - ◆ indicates alarm sounds are turned off.
2. Alarm area

This area shows alarm messages. When multiple alarms occur, they will be displayed circularly.
3. Number of delivered shocks
4. Runtime area

This area shows the equipment's operating time since it is turned on.
5. Patient type

6. Record icon
It is displayed if the sounding recording function is enabled.
7. Battery Status indicator
It indicates battery status. Refer to chapter 11 *Battery* for details.
8. Heart rate
9. Waveform area
This area shows the ECG waveforms.
10. Therapy information area
11. Soft Key area
The three soft key labels correspond to the soft key buttons located immediately below. The labels of the soft keys changes according to the current display view and function. Soft key labels appearing as blank indicate that the soft key is inactive.

2.5 Soft Key Symbols

Below is the description of symbols displayed in the soft key label area:

	Return to the previous page		Enter/Confirm
	Move to the previous item/page		Move to the next item/page
	Display more options		Confirm selection
	Switch to Adult or Pediatric mode		Start archive
	Power off		Maintenance
	Show more instructions		Change the compression/ ventilation rate
	Audio Language softkey Switch the language of audio prompts. The symbol changes if the system language is changed. The larger symbol indicates the current language while the smaller one indicates the target language. This symbol is for the equipment configured with only AED function. It is displayed only when [Bilingual Option] is set to [On]		

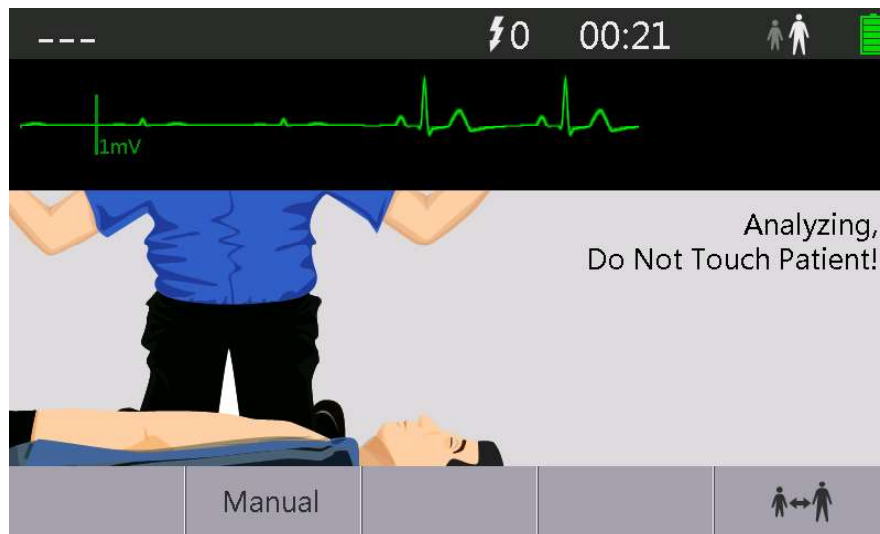
NOTE

- If needed, perform CPR when there is delay or interruption in using of the equipment.
- Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient event. Failure to have a successful patient outcome is not a reliable indicator of defibrillator/monitor performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or device performance.

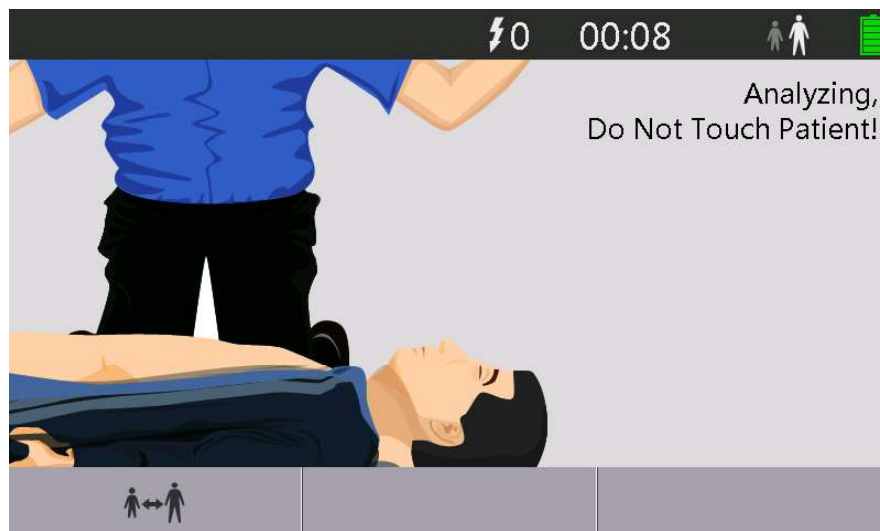
5.3 AED View

A typical screen in AED Mode is shown below.

For the equipment configured with AED, manual defibrillation and ECG monitoring functions



For the equipment configured with only AED function



In AED mode, the information area displays CPR instructions, pads connection instructions and AED prompt messages. For the equipment configured with AED, manual defibrillation and ECG monitoring functions, HR numeric and one ECG waveform acquired from the multifunction electrode pads are displayed above the information area if **[ECG Display]** is set to **[On]**.

- If MR60/MR61 multifunction electrode pads are used, the equipment automatically recognizes the patient type after power on. When the current patient type is found inconsistent with the pad type, you need to manually change the patient type.
 - The Shock button must be pressed to deliver a shock. The equipment will not automatically deliver a shock.
 - Impedance is the resistance between the defibrillator's pads that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin. If the "Impedance too high. Charge removed" message appears, make sure that the patient's skin has been washed and dried and that any chest hair has been clipped. If the message persists, change the pads.
 - Most pediatric cardiac arrests are asphyxial, and the resuscitation from asphyxial arrest is best accomplished by a combination of ventilations and chest compressions. Make sure proper CPR is performed on the patient when waiting for defibrillation equipment or advance life support. Or follow your local protocol.
-

5.5 Shock Advised

If a shockable rhythm is detected, the equipment automatically charges to the pre-configured energy level. A charging tone is sounded, and the Shock button flashes when the equipment is fully charged.

Heart rhythm analysis continues while the equipment charges. If a rhythm change is detected before the shock is delivered and a shock is no longer appropriate, the stored energy is removed internally.

If the patient type is changed or pads malfunction detected during charging, the charge will be removed.

Once you are prompted "**Do Not Touch Patient! Press Shock Button**", if you do not do so within the configured Auto Disarm time interval, the equipment disarms itself and resumes analyzing.

5.6 No Shock Advised (NSA)

If a shockable rhythm is not detected, the equipment will tell you "**No Shock Advised!**".

- If the [NSA Action] is set to [CPR]: the equipment enters CPR status.
- If the [NSA Action] is set to [Monitor]:

The equipment continues to monitor the ECG and automatically resumes analysis if a potentially shockable rhythm is detected. You will hear "No Shock Advised! Attend to patient". The message "No Shock Advised!" and "Monitoring" are shown circularly in the AED information area. You can define the frequency of these prompts by adjusting [Voice Prompt Interval] in [Config. Edit] menu.

5.7 CPR

If [Initial CPR] is set to [On], the system enters initial CPR after startup. You can set [Initial CPR] to [On] or [Off] in [Config. Edit] menu.

In CPR mode, voice instructions, pictures, and prompt messages needed for CPR are provided.

After the shock series, ECG analysis pauses and the equipment enters the CPR status. Analysis resumes at the completion of CPR.

CPR mode continues for 2 minutes.

WARNING

- Performing CPR with pads attached on the patient might damage the pads. In this case, replace the pads.
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5.7.1 CPR Metronome

The equipment provides a CPR metronome feature that can be used to encourage rescuers to perform chest compression and ventilation at AHA/ERC recommended rate.

You can press the  soft key repeatedly to change the compression/ventilation rate.

WARNING

- **The CPR metronome sounds do not indicate information regarding the patient's condition. Because patient status can change in a short time, the patient should be assessed at all times. Do not perform CPR on a patient who is responsive or is breathing normally.**
-

5.8 AED Sound Recording

The equipment include a sound recording function that can record the voice information during AED therapy. The sound recording function can be configured on or off.

To switch on or off the sounding recording,

1. Press the **Power On/Off** button and then select  → **[Config.]** → **[Config. Edit]** → enter the required password.
2. Select **[General Setup]** → **[Voice Recording]**, and toggle between **[On]** and **[Off]**.

The symbol  is shown at the top right corner of the screen if the sounding recording function is enabled.

The equipment can store up to 180 minutes of recording, and one recording for one patient.

5.9 AED Setup

1. Press the **Power On/Off** button and then select  → **[Config.]** → **[Config. Edit]** → enter the required password.
2. Select **[AED Setup >>]** to enter the AED Setup menu, and then change AED settings as desired.

Refer to *10 Configuration Management* for details.

10.6 List of Configuration Items

The following section lists of all the configuration items in the **[Config. Edit]** menu. Those marked with "*" are for the equipment with AED, manual defibrillation and ECG monitoring functions.

10.6.1 General Setup Menu

Menu Item		Options/Range	Default	Remark
System Date	Year	2007 to 2099	/	The selectable range for system date is 2007-01-01 to 2099-05-31.
	Month	01 to 12	01	
	Day	01 to 31	01	
Time	Hour	0 to 23	01	/
	Minute	0 to 59	01	
	Second	0 to 59	01	
Language		ENGLISH, SIM. CHINESE, FRENCH, GERMAN, ITALIAN, SPANISH, PORTUGUESE, RUSSIAN, CZECH, DUTCH, CROATIA, TRA. CHINESE	/	Three languages are available on your equipment, SIM. CHINESE, ENGLISH, and your local language. For English or Chinese speaking countries, the language options are SIM. CHINESE, ENGLISH, and FRENCH/TRA. CHINESE. For more information, contact the service personnel.
Bilingual Option		On, Off	Off	Disabled when [ECG Display] is set to [On]
Default Startup Mode*		AED, Manual	AED	/
Voice Recording		On, Off	Off	/
Voice Volume		On, Off	Auto	/
Brightness		Auto, Outdoor Mode, Indoor mode	Auto	/

10.6.2 AED Setup Menu

Menu Item		Options/Range	Default	Remark
Shock Series		1, 2, 3	1	/
Energy 1	Adult	100, 150, 170, 200, 300, 360J	200 J	≤Energy 2
	Pediatric	10, 15, 20, 30, 50, 70, 100J	50 J	
Energy 2	Adult	Energy 1 to 360J	300 J	≥ Energy 1, and ≤Energy 3
	Pediatric	Energy 1 to 100 J	70 J	
Energy 3	Adult	Energy 2 to 360J	360 J	≥ Energy 2
	Pediatric	Energy 2 to 100 J	100 J	
NSA Action		Monitor, CPR	CPR	/
Voice Prompt Interval		Off, 30s, 60s, 90s, 120s, 150s, 180s	30s	/
Initial CPR*		On, Off	Off	When set to [On] , the system enters CPR mode directly after startup.
ECG Display*		On, Off	On	When set to [On] , the [Bilingual Option] setting is disabled.

14.3 Physiological Alarm Messages

Physiological alarm messages are for the equipment with AED, manual defibrillation and ECG monitoring functions. Alarms marked with "*" are exclusive. They have identical alarm tones and alarm lights with normal high level physiological alarms, but their alarm messages are displayed exclusively. That is to say, when an exclusive physiological alarm and normal high level physiological alarms are triggered simultaneously, only alarm message of the exclusive physiological alarm is displayed.

Measurement	Alarm Message	Alarm Level	Cause and Solution
ECG	Asystole*	High	Arrhythmia has occurred to the patient. Check the patient's condition, and the pads, electrode, cables and leadwires.
	Shockable Rhythm*	High	
	Vtac*	High	
	Extreme Tachy*	High	
	Extreme Brady*	High	
	PVCs/min	Medium	
	Nonsus. Vtac	Medium	
	Vent. Rhythm	Medium	
	Tachy	Medium	
	Brady	Medium	
	VT>2	Medium	
	Couplet	Medium	
	Multif. PVC	Medium	
	R on T	Medium	
	Bigeminy	Medium	
	Trigeminy	Medium	
	PVC	Low	
	Irr. Rhythm	Low	
	PNP	Medium	The pacer appears abnormal. Check the pacer.
	PNC*	Medium	

14.4 Technical Alarm Messages

In this chapter, the "I" column indicates how indications of technological alarms are cleared after the **[Silence]** softkey is pressed: "A" means all alarm indications are cleared; and "B" indicates only alarm tone is disabled, but other indications remain presented.

Source	Alarm Message	Alarm Level	I	Cause and Solution
ECG	ECG Noise	Low	A	The ECG signal is noisy. Check for any possible sources of signal noise from the area around the cable and electrode, and check the patient for excessive motion.
	ECG Lead Off	Low	A	The ECG electrode has become detached from the patient or the connector from the equipment. Check the connection of the electrodes and leadwires.
	ECG YY Lead Off (YY represents the leadwires LL, LA, and RA, as per AHA standard, or C, F, and L as per IEC standard.)	Low	A	
	ECG Signal Invalid	Low	A	ECG amplitude is so low that ECG signal is undetectable. Check for any possible source of interference from the area around the cable and electrode; check the patient's condition.

A.4 Monitor Specifications

ECG	
Patient connection	3-lead ECG cable or multifunction electrode pads
ECG inputs	Defibrillation electrodes: pads
	3-lead ECG set: I, II, III
Gain	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4) and Auto. Error less than ± 5%
Paper speed	25 mm/s, error no more than ± 10%
Bandwidth (-3dB, ECG lead set)	Monitor mode: 0.5 to 40 Hz
	Therapy mode: 1 to 20 Hz
Bandwidth (-3dB, defibrillation electrodes)	Therapy mode: 1 to 20 Hz
Common mode rejection (ECG lead set)	Monitor mode: >90 dB
	Therapy mode: >90 dB
Common mode rejection (defibrillation electrodes)	Therapy mode: >90 dB
Notch filter	50/60Hz, In Monitor and Therapy mode: notch filter turns on automatically
ECG signal range	With a sensitivity of 10 mm/mv, positive and negative signals between 0.2 mV to 8 mV can be detected and HR value be displayed.
Electrode offset potential tolerance (from ECG lead set and defibrillation electrodes)	±1 V
HR measurement range	Pediatric: 15 to 350 bpm
	Adult: 15 to 300 bpm
HR accuracy	±1% or ±1bpm, which ever is greater
HR resolution	1 bpm
Lead-off detection current	Measuring electrode: ≤0.1 µA
	Drive electrode: ≤1 µA
ESU protection	Baseline recovery time: ≤10 s
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (3a): 80±1 bpm Slow alternating ventricular bigeminy (3b): 60±1 bpm Rapid alternating ventricular bigeminy (3c): 120±1 bpm Bidirectional systoles (3d): 90±2 bpm
Response to change in heart rate	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s; From 80 to 40 bpm: less than 11 s;
Time to alarm for tachycardia	Meets the requirements of ANSI/AAMI EC13-2002: section 4.1.2.1 g). Waveform 4ah - range: 11 s 4a - range: 11 s 4ad - range: 11 s 4ah - range: 11 s 4bh - range: 11 s 4bd - range: 11 s

Heart rate averaging	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the screen is updated every second.
Arrhythmia Analysis Classifications	Asystole, Shockable rhythm (V-Fib/V-Tach), Vtac, Vent. Brady, Extreme Tachy, Extreme Brady, PVCs/min, PVC, Couplet, VT>2, Bigeminy, Trigeminy, R on T, Tachy, Brady, PNP, PNC, Vent. Rhythm, Multif. PVC, Nonsus. Vtac, Irr. Rhythm
ESU protection	Cut mode: 300 W Coagulate mode: 100 W Recovery time: ≤10 s In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27
Pace Pulse	
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs Input slew rate: 10V/s RTI

A.5 Power Supply Specifications

Rechargeable Battery (new and fully charged, at 20 °C of ambient temperature)			
Battery type	Smart lithium ion battery, rechargeable and free of maintenance, one battery can be installed, two types of batteries can be configured Battery LI24I005A: 15.1V, 5600mAh Battery LI24I001A: 14.8V, 3000mAh		
Battery LI24I005A charge time	Less than 5 hours to 90% and less than 6 hours to 100% with BatteryFeed 20 charger station		
Battery LI24I001A charge time	Less than 2.5 hours to 90% and less than 3 hours to 100% with BatteryFeed 20 charger station		
Battery LI24I005A and LI24I001A run time	Work mode	Work time	Testing condition
	Monitoring	≥ 12 hours	LCD brightness set to low, wireless function off, not performing defibrillation charges or discharges, and audio off
	Defibrillation	≥300 discharges ≥200 discharges	200J discharges at a frequency of 3 times/min 360J discharges at a frequency of 3 times/min
Battery fuel gauge	5 LEDs indicating the current battery charge level		
Remaining charge after "Low Battery" is reported	At least 20 minutes of ECG monitoring (under the work condition of low LCD brightness, with wireless function turned off, not performing defibrillation charges or discharges, and audio off) and at least 10 200J discharges		

E Prompt Messages

This chapter lists the prompt audio and text messages that might appear on your equipment.

Source	Message	Audio
System	Battery Depleted! Replace Battery Now.	Battery Depleted! Replace Battery Now.
AED	/	Adult mode.
	/	Pediatric mode.
	Remove Clothing	Remove clothing from patient's chest.
	Take Out Pads Package	Take out pads package from back of AED.
	Plug in Pads Connector	Plug in Pads Connector
	Remove Pads	Tear open package and remove pads
	Peel Pads	Peel pads from plastic liner.
	Apply Pads	Apply pads to patient's bare chest as shown.
	Analyzing, Do Not Touch Patient!	Analyzing now. Do not touch the patient!
	Artifact Detected, Cannot Analyze	Artifact Detected.
	Motion Detected, Cannot Analyze	Motion Detected,
	Shock Advised! Charging to %sJ	Shock Advised! Charging
	Charge Failed!	Charge Failed!
	Do Not Touch Patient! Press Shock Button	Do Not Touch the Patient! Press the Shock Button
	Shock Delivered	Shock Delivered
	Impedance Too Low, Charge Removed	Impedance Too Low, Charge Removed
	Impedance Too High, Charge Removed	Impedance too high. Charge removed.
	Abnormal Energy Delivery	Abnormal Energy Delivery
	No Shock Advised!	No Shock Advised! It is safe to touch the patient.
	No Shock Advised! Monitoring	No Shock Advised! Attend to patient.
	Charge Removed	Charge Removed
	Shock Button Not Pressed, Charge Removed	Shock Button Not Pressed, Charge Removed
	Disarming Failed	Disarming Failed
CPR	Start CPR	Start CPR
	Interlock the Fingers Place Hands on Patient's Chest	Interlock the Fingers Place Hands on Patient's Chest
	Place One Hand on Patient's Chest	Place One Hand on Patient's Chest
	Keep Arms Straight	Keep Arms Straight
	Follow the Metronome to Compress	Follow the Metronome to Compress
	Give 2 Breaths	Give two Breaths
	Breathe	Breathe
	Continue	Continue
	Stop CPR Stop Now	Stop CPR Stop Now

Source	Message	Audio
Maintenance User test	Pediatric Pads, X/X Pads Expires, Replace Pads Advised.	/
	Selftest report trans. failed.	/
	Test Passed.	/
	AED is Ready for Use.	/
	Test Failed.	/
	Call for Service. Service Code:	/
	Pads Missing.	/
	Unknown Pads	/
	Pads Abnormal, Replace Pads Advised	/
	Pads Expires, Replace Pads Advised	/
	Replace Battery Advised. Service Code:	/
	Please Perform User Test to Confirm.	/
	Replace Battery Advised.	/
Configuration mode	Please enter password	/
	Password incorrect. Try again!	/
	Normal network.	/
	Connection failed. Check the network and setup.	/
	Cannot Reach the Site. Check the site and setup.	/
	Are you sure to restore to factory default?	/
	All settings restored to factory default	/
	Config. file not found.	/
	Are you sure to import the file and override the current config.?	/
	Config. updated successfully.	/
	USB memory not found!	/
	USB Memory Error. Data Export Failed!	/
	Config. file exported successfully.	/
System upgrade	Searching upgrade file.	/
	Server is busy. Please retry later.	/
	Upgrade file is not available. Upgrade cancelled.	/
Archive	USB memory not found!	/
	USB Memory Limited Space	/
	Exporting Data. Please Wait...	/
	Data Export Completed!	/
	USB Memory Error. Data Export Failed!	/