JOUSING
久心医疗

iAED-S1

Automated External Defibrillator

User Manual

About this Edition

The instructions for use applies to the iAED-S1 Automated External Defibrillator.

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Copyright Statement

Responsibility Statement

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1. Introduction to iAED-S1

1.1 Overview

The iAED-S1 is an automated External Defibrillator (AED) that is used to treat patients in sudden cardiac arrest (SCA) and designed to be portable and battery powered, for simple and reliable operation. Voice prompts and visual indicators provide a simple interface for the operator. After pads are applied to the patient's chest, the iAED-S1 will automatically analyze the patient's heart rhythm. If a shockable rhythm is detected, the iAED-S1 will direct the responder to deliver a shock through the pads for defibrillation.

1.2 Device Appearance

1.2.1 Unpacking and Inspecting

Check the product box and the handbag. Make sure it contains the followings items:

- 1 iAED-S1 Defibrillator (REF: iAED-S1)
- 1 Battery JOUBAT (REF:JXB1242)
- 1 Pads Package JOUPAD (REF:F7952W/J)
- 1 User Manual
- 1 Quick Reference Guide
- 1 Product Certification
- 1 Warranty Card
- 1 Package List

Perform the initial inspection as follows:

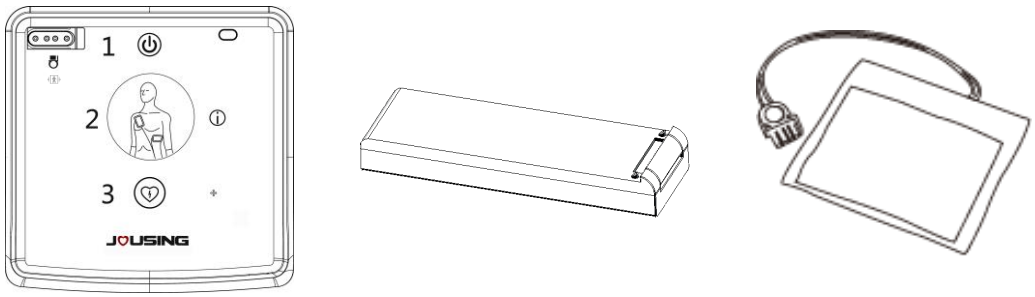
- Examine the surface of the device for signs of possible damage that might have occurred during shipping.
- Check the expired date of the pads and battery.

If there is any damage or expired parts, please contact your local distributor

or Jousing Medical.

1.2.2 Device Parts

The device's parts are as shown in Figure 1. Installing and removing the parts refer to section 3.1 Installing the Battery to 3.4 (Optional) Replacing the Battery.



① ② ③

Figure 1 Parts of the device

① The iAED-S1 defibrillator.

② Battery: Non-rechargeable battery, JOUBAT.

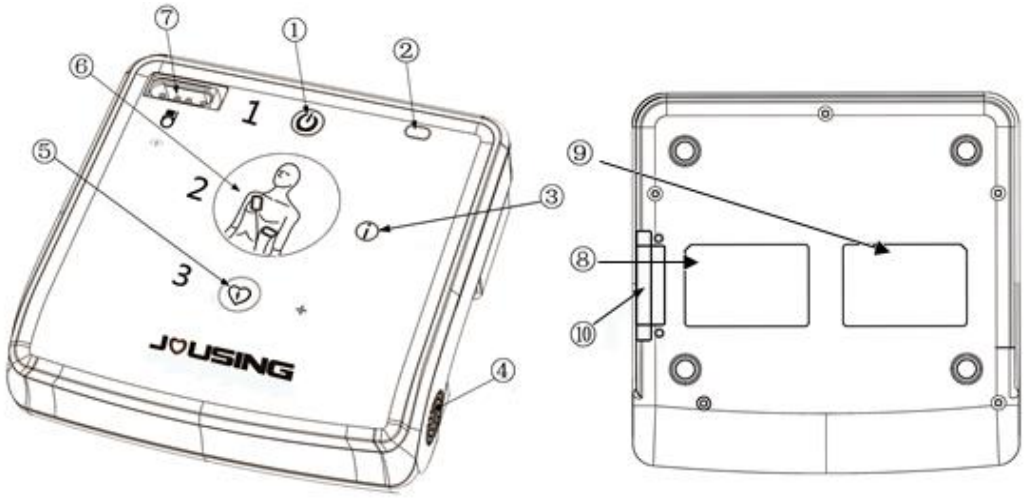
The iAED-S1 defibrillator is powered by JOUBAT.

③ Pads: Disposable pads, JOUPAD.

JOUPAD and its cables are the applied parts. They are applied to the patient's bare chest and used to detect the patient's heart rhythm and to transfer the defibrillation shock.

1.2.3 Controls, Indicators and Labels

The controls, indicators and labels on the iAED-S1 are shown in Figure 2 and the corresponding functions are described in Table 1.



a) Front view b) Back view

Figure 2 Controls and indicators on the iAED-S1

Table 1 Functions

No.	Name	Function
①	ON/OFF Button	The ON/OFF Button turns on or off the iAED-S1. The light of the button turns green when the defibrillator is on. Press button to turn on the iAED-S1, light turns green. Press button again to turn off the iAED-S1, light turns off.
②	Status indicator	Green light flashes – device is ready for use. Green light turn on– device is under using. Red light turns on or flashes – device operates abnormally.
③	Information Button	Press button for 3 seconds at least to enter Data administration Mode, light turns green. Green light flashes - data under transmitting. Green light turns on - in standby status. Press button for 3 seconds at least to exit the Data administration Mode, light turns off.
④	Speaker	To prompt use instructions to the user.

⑤	Shock Button	Press this button on iAED-S1 defibrillator to deliver a shock when the red light is flashing.
⑥	Pads Attachment Indicator	Pads Attachment Indicator flashes – pads are not applied to patient or pads connector is not connected to the defibrillator. Pads Attachment Indicator will turn off after pads are correctly applied to patient.
⑦	Pads Socket	Connect the pads to the defibrillator.
⑧	Safety Warning	Provide warning information about how to use the device.
⑨	Product Label	Product Label includes the defibrillator serial number.
⑩	Battery Holder	Store battery.

1.3 Indications

The iAED-S1 is indicated for use on victims of sudden cardiac arrest when the patients showing both of:

- Unresponsive
- Not breathing or not breathing normally

1.4 Contraindications

The iAED-S1 should not be used if the patient shows any of the following signs:

- Responsive
- Breathing normally

1.5 User Training Requirement

The iAED-S1 is intended to be used by persons who are qualified by training in basic life support (CPR/AED certification) and the use of this device.

2. Safety Information

This section provides important information about safely operating the defibrillator. Many of these messages are repeated elsewhere in this manual and on the iAED-S1 or accessories.

DANGER：Immediate hazards that will result in serious personal injury or death.

WARNING：Hazards or unsafe practices that could result in serious personal injury or death to the user and/or the patient.

CAUTION：Hazard or unsafe practices that could result in minor personal injury to the user and/or the patient or damage to the device.

2.1 Warnings

⚠ **Shock Hazard**

- Disconnect all medical electrical equipment without defibrillation protection from patient before delivering a shock.
- Do not touch the patient or connect the patient with other equipment or metal objects in contact with patient during defibrillation. The electrical energy could potentially cause death or injury if it is discharged improperly.

⚠ **Skin burns**

- The pads should be kept clear of other electrodes, lead wires, dressings, medicine patches in contact with patient, etc. Such contact can cause electrical arcing and skin burns during defibrillation and may also divert the electrical current away from the patient’s heart.
- During defibrillation, air pockets between the skin and pads can cause skin burns.
- To help prevent air pockets, body hair needs to be removed then make

sure no other object sticking to the gel or on the pads and pads stick well to the skin.

- Do not use dried out pads, because they will not provide good contact with the skin.
- Do not wipe patient's skin with alcohol, it may cause skin burns.

⚠ **Incorrect Rhythm analysis**

- Place the pad on the patient's bare skin and press the pads down firmly, improper place the pad will affect the analysis.
- Be sure not to place the pads over an implanted device. An indication of an implant is a protrusion in the chest skin and a scar.
- Moving or transporting the patient during the rhythm analysis may cause incorrect or delayed diagnosis. Be sure to follow all instructions in this manual.
- Avoid operating the device in close proximity to the equipment which may emit strong electromagnetic. Electromagnetic interference may result in improper device operation or failure to detect shock rhythm.

⚠ **Explosion danger**

- Do not use this device in the presence of flammable gases or oxygenated environment.
- Do not recharge battery.
- Do not burn or incinerate the battery.

⚠ **Improper operation**

- An electrical shock hazard will be resulted from unauthorized repair or modification.
- Do not open the iAED-S1, remove its covers, or attempt repair or modification. There are no user-serviceable components in iAED-S1.
- If repair is required, contact Jousing Medical for service.
- Do not immerse the device in water or any fluids. Avoid any fluids to spill or enter the device.
- Do not immerse the pads in alcohol or any fluids. Aggressive or prolonged

cardiopulmonary resuscitation (CPR) to a patient with pads attached can cause damage to the pads and the device.

⚠ **Usage caution**

- Do not use the device on patient under 8 years old or weighing less than 25kg (55lb).
- Use only Jousing Medical-approved accessories. The iAED-S1 may perform improperly if it is used with other manufacturer's accessories.
- The improper operation can result in damage to the device. Be sure to follow the instructions in this manual.
- Keep patient from touching with conductive liquid or metal conductor. Conductive liquid or metal conductor may cause unexpected current bypass.
- The device should not be close to or superimposed with other equipment. It should be observed and verified that the device is normally operating in this configuration.
- The iAED-S1 is an equipment for infrequent use.
- During rescue, do not service or maintain the equipment and its parts.

⚠ **Usage environment**

- The device should be used for rescue within the temperature 0℃~ 50℃.
- When the essential performance of the device is lost or degraded due to electromagnetic disturbances, please turn off the device and keep away from strong electromagnetic environment and contact Jousing Medical for service.

2.2 Cautions

⚠ **Device Damage**

If the device appears damage in any way, please contact Jousing Medical for service.

⚠ Label

Please note all cautions and warning signs on the device and the accessories.

⚠ Performance

The device may not in good performance if it is stored, transported or used beyond the range of environmental conditions specified in the technical specifications.

3 Setting up the iAED-S1

This section describes how to set up the defibrillator for use. A few steps are required to set up the iAED-S1 before using. (The *Quick Reference Guide* provides illustrated instructions for set up).

3.1 Installing the Battery

To make sure the defibrillator in operation, the first step is to insert the battery into the battery holder.

Procedure

Insert a new battery into the defibrillator and push until the user hears it clicked into position, as shown in figure 3.

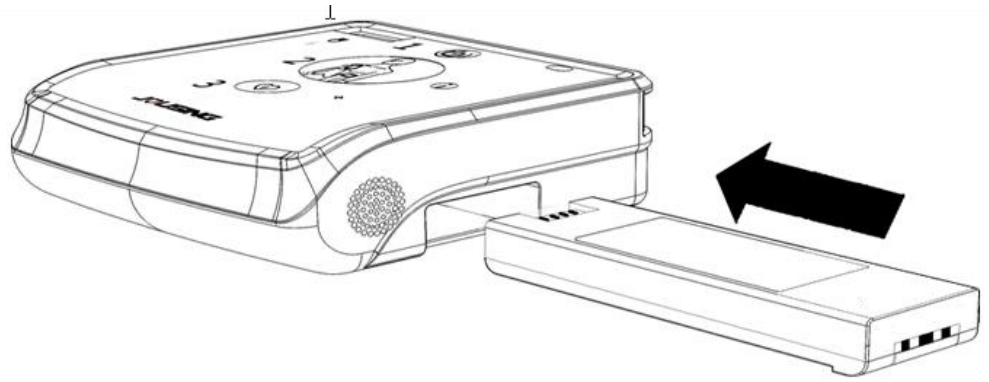


Figure 3 Installing the battery schematic

⚠ Warning: Use only the battery approved by Jousing Medical, the battery specified in the 1.2 Device Appearance.

Verification

If the battery is installed successfully, the device will prompt “Beep”, “Self-test started, press the green ON/OFF button for emergency”.

※ Press the ON/OFF button in case of an emergency.

3.2 Battery Insertion Self-Test

Procedure

Wait for battery insertion self-test completion.

If there are some prompts during the self-test, be sure to follow the prompts and press corresponding buttons and let the self-test run until it completes.

Verification

- If the status indicator flashes green from fast to slow and the voice prompts “self-test completed device normal”, it means the device is ready for use.
- If the status indicator flashes red, the device will prompt:
  - “Self-test completed, replace battery now” User should replace a new battery immediately after performing this rescue if a rescue is needed, or replace a new battery immediately.
  - “Self-test completed, battery low”. User should replace the battery immediately.
  - “Self-test completed, temperature abnormal”. You can also perform rescue if needed. Or place the device in room temperature and wait for 10 minutes, then reinstall the battery to eliminate equipment failure alarm.
  - “Self-test completed, service required”. That means error is detected and user should contact Jousing Medical for service.

3.3 Checking the Pads Connection

Procedure

1. Make sure the pads package is intact and within expired date. Replace the pads if it is expired or the pads package is damaged.
2. Insert the pads connector into the device if it’s not fully inserted into the

device, as shown in figure 4.

⚠ **Warning:** Use only the pads approved by Jousing Medical, the pads specified in the 1.2 Device Appearance.

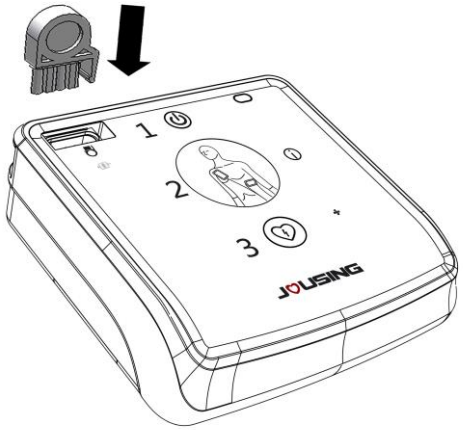


Figure 4 Pads Connector Insertion

3.4 (Optional) Replacing the Battery

Scenarios

Replace the battery when the device prompts “Replace the battery” or “Battery low”.

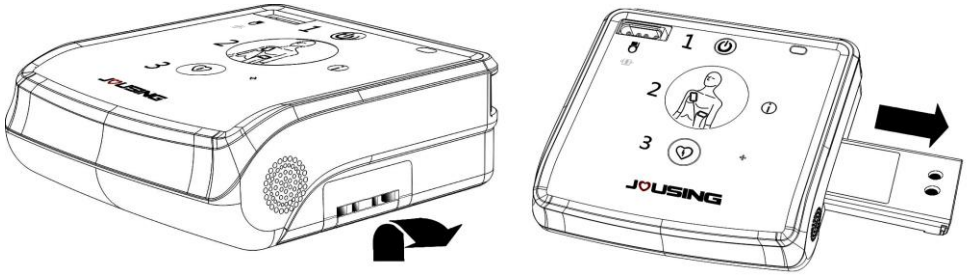
⚠ **Warning:**

- Do not remove the battery from the device optionally.
- Battery lifetime will be shortened if the defibrillator turns on frequently.

Procedure

Press up the spring button on the right side of the device and pull out the battery, as shown in Figure 5 a). Remove the battery from the battery holder as shown in figure 5 b). After removing the old battery, wait at least 30 seconds before reinstalling a new battery.

Verification



a) Step one b) Step two

Figure 5 Removing the battery

4. Using the iAED-S1

4.1 Overview

This chapter describes how to use the iAED-S1. The device provides voice prompts and indications for users throughout the rescue.

If you think someone is in SCA, follow these steps:
1. If other rescuers are available, ask them to call for emergency medical assistance. Check the patient and get the iAED-S1.
2. If you are the only rescuer, first call the emergency services, quickly get the iAED-S1 and bring it to the patient. If there is any delay in getting the defibrillator, perform cardiopulmonary resuscitation (CPR) until the iAED-S1 is available.

There are three basic steps to use the iAED-S1 to treat someone who may be in SCA:
1. Press the ON/OFF button.
2. Apply pads on the patient's chest.
3. Press the shock button as instructed by the iAED-S1 voice prompts.

4.2 Preparation

Make sure all the steps in 3 Setting up the iAED-S1 are already finished.
The pads should be kept clear of other electrodes, lead wires, dressings, medicine patches in contact with patient, etc.

4.3 Steps

The iAED-S1 is designed to be easily use. Users can use it according to the following figure. To learn more about detailed steps instructions, please refer to the sections 4.3.1 Turning on the iAED-S1 to 4.3.9 Terminate Operation.

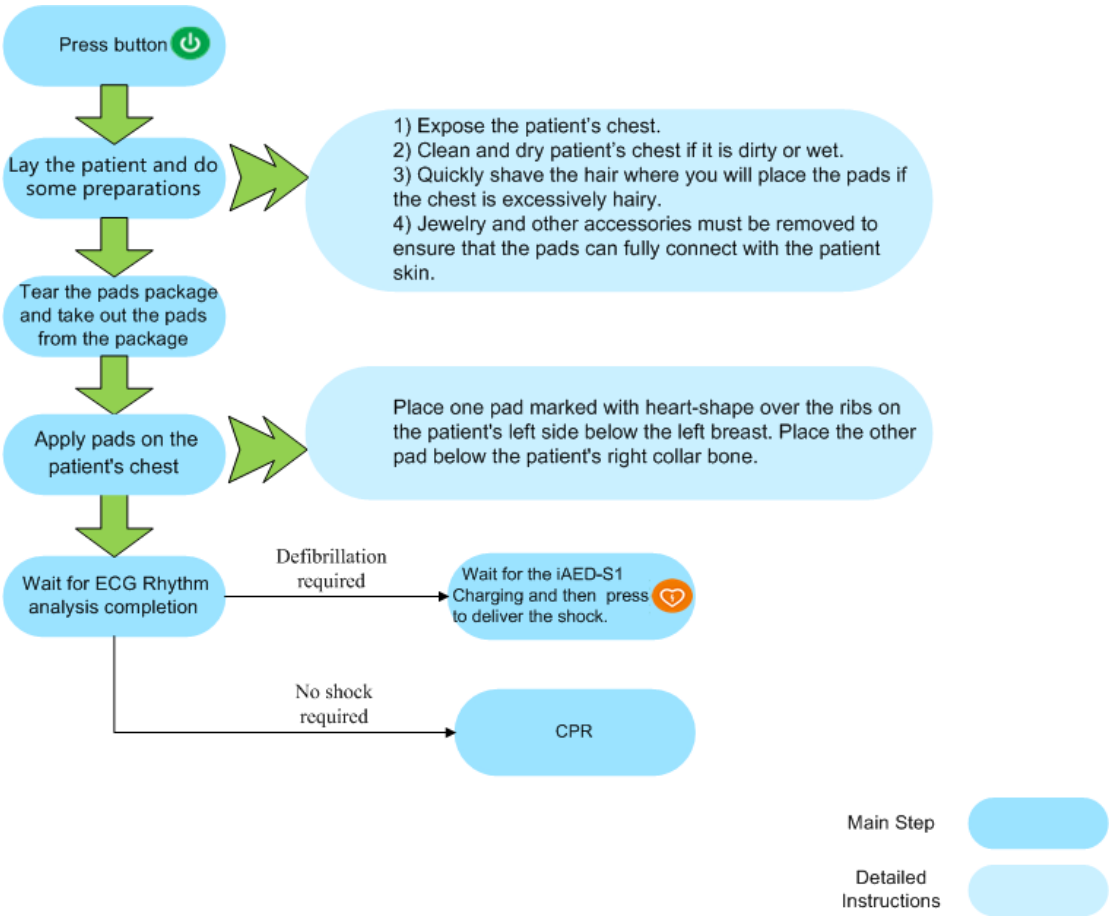


Figure 6 Step Procedure

4.3.1 Turning on the iAED-S1

Procedure

1. Press button .
2. Call emergency medical assistance.

Verification

The device turns on and performs self-test. Once it passes the self-test, it will prompt “Beep, call for help now.”

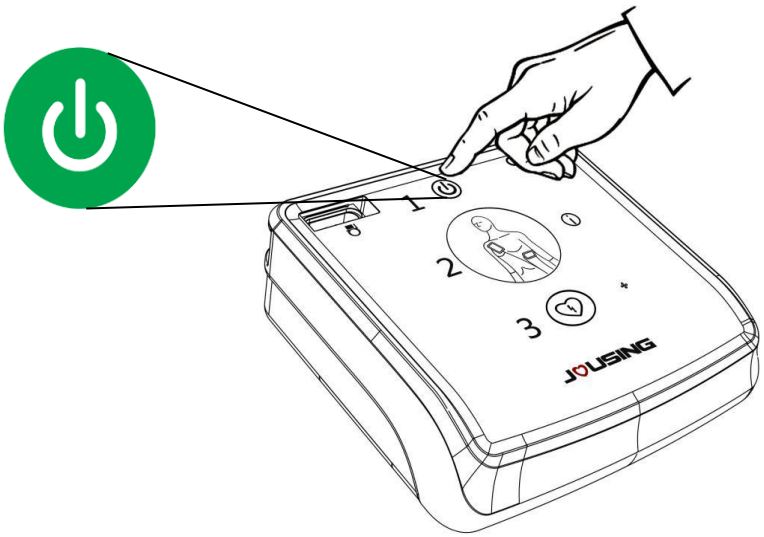


Figure 7 Power on the Device

4.3.2 Preparing the Patient

Procedure

Lay the patient down and do the followings if necessary:

※The device prompts “Remove all clothing from patient’s chest”.

1) Expose the patient’s chest, as shown in figure 8,
2) Clean and dry patient’s chest if it is dirty or wet.
3) Quickly shave the hair where the pads will be placed if the chest is excessively hairy.
4) Remove the jewelry and other accessories to ensure that the pads can fully attach to the patient skin.

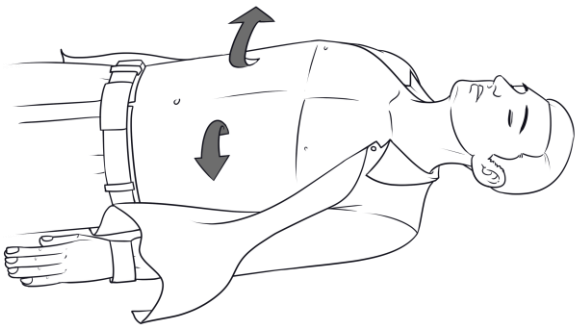


Figure 8 Removing all clothing from the patient's chest

4.3.3 Tearing the Pads Package

Procedure

1. Tear the pads package and take out the pads from the package, as shown in figure 9 and figure 10.

   ※ The device prompts "Tear open pads package and remove pads".

⚠ **Warning:** Do not tear the pads package until you need to use the pads.

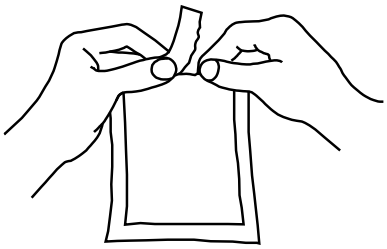


Figure 9 Tear the pads package

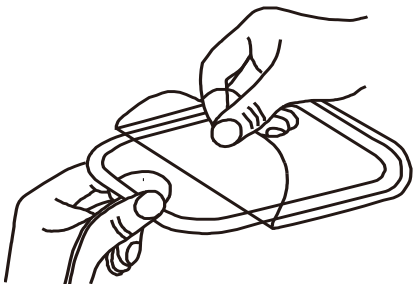


Figure 10 Peel the pad from plastic liner

2. Check the pads as follows:

- Signs of damage.
- With other substance (like dust).
- Dried out (the gel cannot fully stick on patient's chest).
- Expired.

If any of the cases occurs, please replace it with a pair of new pads.

4.3.4 Placing the Pads to the Patient

Procedure

Place one pad marked with heart-shape over the ribs on the patient's left side below the left breast and the other pad below the patient's right collar bone as shown in figure 11.

⚠ **Warning:** The pads should be placed on a flat surface of the patient's skin. Otherwise it may cause incorrect rhythm analysis and false defibrillation decision.

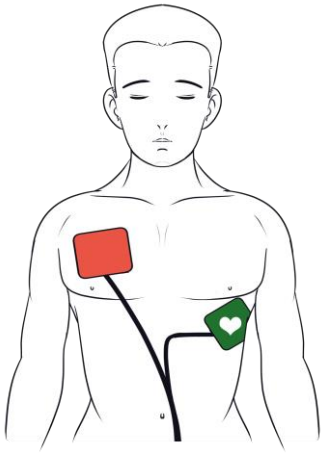


Figure 11 Place the Pads

Details

If the pads are properly placed, the defibrillator will prompt “Beep Beep” and the Pads Attachment Indicator will stop flashing and the device will get into rhythm analysis.

Otherwise, the device will prompt “Pad must not be touching clothing or each other, make sure the liner is completely removed from both pads, make sure pad connector is plugged into the AED”. At this time, please replace the pads:

- If pads are replaced correctly, the voice prompt will stop repeating, and the device will get into rhythm analysis.
- If the pads are not placed properly until timeout, the device will turn off.

4.3.5 ECG Rhythm Analysis

Procedure

Keep the patient's body position steady and wait for the ECG Rhythm analysis completion.

⚠ **Warning:** Do not touch or shake the patient during the rhythm analysis otherwise it will affect the rhythm analysis results.

Details

※The defibrillator analyzes the patient's ECG signal and determines whether the rhythm is shockable or nonshockable. Meanwhile the AED will continue to monitor the pads connections and will abort analysis if it detects any connection problems.

- If the iAED-S1 has determined that the pads are poorly contacted to the patient, the device will prompts "Poor pad contact to patient, press pads firmly, check connector" The user should place pads correctly on the patient following instructions on pad package.
- If the pads are properly placed, the defibrillator will prompt "Do not touch patient! Analyzing heart rhythm." At this time, the user should not touch the patient.
- If the iAED-S1 has detected motion in the patient the defibrillator will stop analysis for up to 10 seconds. The defibrillator notifies the responder of the problem. The defibrillator will resume analysis after 10 seconds, even if motion is still present.
- Rhythm analysis takes about 10 seconds. Observe the patient through the whole process. If the patient is awake, stop the defibrillation immediately by pressing the ON/OFF button to turn off the defibrillator.

⚠ **Warning:** Do not touch or shake the patient during the rhythm analyzing

process, otherwise it may affect the rhythm analysis results.

4.3.6 Defibrillation Required

Procedure

1. Wait for the iAED-S1 charging completion.
2. Press  to deliver the shock as the instructions.

※The device detects a shockable rhythm, it will prompt “Shock Advised, stand clear, charging”.

Details

Do not touch the patient while the device is charging. While the iAED-S1 is charging, it will continue to analyze the patient’s heart rhythm.

- If the device detects the heart rhythm has changed to nonshockable state, it will prompts “Rhythm changed, shock cancelled”, then it will disarm the charged energy and guide the user to perform CPR.
- The iAED-S1 will stop charging if it detects any connection problem and guide user to place the pads again.

When the iAED-S1 finishes charging, the iAED-S1 defibrillator will prompt “Press flashing shock button”. Press the flashing shock button to deliver the shock. If the shock button is not pressed within 30 seconds , “Shock button not pressed,shock cancelled” will be prompted, the unit will automatically cancel the shock and guide the user to perform CPR.

“Shock delivered” will be prompted after shock button been pressed. After each shock, the iAED-S1 will guide the user to perform CPR, refer to 10. After CPR, the device will restart rhythm analysis. Once it detects that the shockable rhythm still presents, it will be ready for another shock.

⚠ **Warning:** Do not touch the patient during the defibrillation process.

4.3.7 No Shock Required

If the iAED-S1 determines that no shock is required, the device will prompt “No shock advised”, The user will be prompted to begin CPR, refer to 4.3.8 CPR.

4.3.8 CPR

Procedure

1. Compress the patient’s chest when the device prompts “da, da” beat.
2. Make artificial respiration to the patient when the device prompts “Breath”.

Details

Rescue cardiac arrest patients with artificial respiration and chest compression.

When rhythm analysis has determined no shock is required or a shock has been delivered, the device will prompt “It is now safe to touch the patient, begin CPR, da, da...” user should compress the patient’s chest following the beat.

When the device prompts “Breath”, user should make artificial respiration to the patient.

When the device prompts “Stop CPR”, it will restart to analyze the heart rhythm, no one should touch the patient during that time.

The CPR coaching protocol can be changed. Only the authorized person can change the CPR protocol by using specific software. Refer to Annex A for more information.

4.3.9 Terminate Operation

For any reason you want to turn off the defibrillator during the operation, press the ON/OFF button and hold for at least 3 seconds to turn it into standby mode.

5. After Using the iAED-S1

5.1 Replacing Pads

After rescuing, press the ON/OFF button to turn the device into standby mode. Change the pads into new ones: Insert the pads plug into the pads socket(see 3.3 Checking the Pads Connection.) and put the pads package in the carrying bag.

⚠ **Warning:** The disposable pads must be discarded and replaced after use.

5.2 Checking the Battery Capacity

Remove the battery and wait for at least 30 seconds to reinsert and run self-test.

- If the device prompts “Self-test completed, battery low” or “Self-test completed, replace battery now”. Replace the battery immediately and ensure that the new battery is within the expired date.
- If the battery insertion self-test result is normal, no action needs to be taken.

6. Maintenance and Troubleshooting

The iAED-S1 is very simple to maintain. The defibrillator performs a self-test every day and its extensive automatic self-test features eliminate the need for any manual calibration. The iAED-S1 has no user-serviceable parts.

6.1 Routine Maintenance

To ensure that the device is ready for use at any time, routine maintenance must be performed by users, who should fill in the periodic inspection table (see Annex H.). Table 2 shows the recommend routine maintenance plan.

Table 2 Periods of routine maintenance

Check Items	Daily	Monthly	After Each Use
Checking the status indicator	●	●	●
Checking the expired date of the pads		●	
Checking the Completeness of Parts		●	●

6.1.1 Checking the Status Indicator

Procedure

Automatically perform daily/weekly/monthly self-test.

Verification

- The status indicator is green: ready for use.
- The status indicator is red: abnormal. Do the followings:

  Press  (the information button) to get detailed information:

  - If it prompts “Battery low”, replace the battery immediately.
  - If it prompts “Service required”, contact Jousing Medical for service.

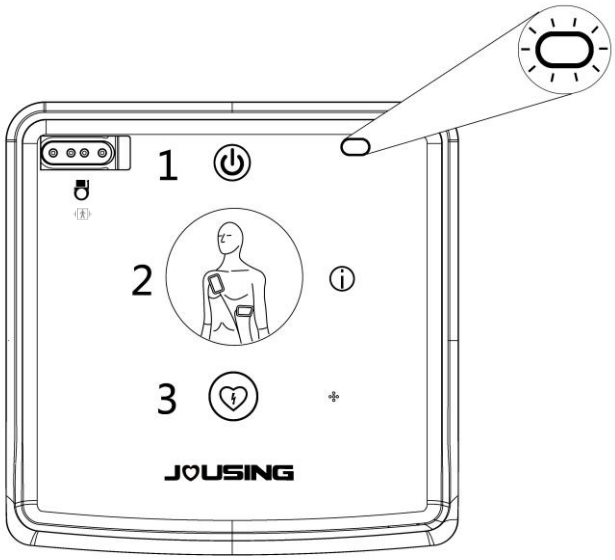


Figure 12 The Status indicator

6.1.2 Checking the Expired Date of the Pads

Procedure

The expired date of pads is shown in the dashed box on the packing bag label, as shown in figure 13.The pads are disposable product, so they must be replaced if the package has been damaged or the pads have been used.

Figure 13 Pads' expired dated

6.1.3 Checking the Condition of the Unit and Accessories

- Check the conditon of the unit and accessories, refer to 1.2 Device Appearance.
- Check the surface of the defibrillator's shell, especially in the connector

socket and pads connector.

- Check the device for damage.
- Check the scratches or signs of damage, especially near the connector and the connector socket. If there is any scratch or sign of damage, contact Jousing Medical for service.

6.2 Cleaning the Device Surface

Scenarios

Periodically clean the iAED-S1 and keep it away from dust or dirt.

Please use the household detergents of soapy water or chlorine bleach (10ml/liter). Do not use strong solvents such as isopropyl alcohol or acetone to clean the iAED-S1.

Follow the guidelines when cleaning the device:

- Remove the battery.
- Use a soft cloth dampened in the cleaning agent to clean the device surface. Do not immerse the iAED-S1 in water or allow fluids to spill onto it.
- If necessary, clean the excess agents on device with water or a dry cloth.
- Ensure the iAED-S1 is completely dry before reinstalling its accessories.

6.3 Storage Environment

The device should be stored near the emergency equipment (such as first aid kits) with suitable temperature. Keep it away from moisture and dust.

- The suggested storage temperature range is 5℃~ 35℃.
- The device should be stored in relative humidity of 5% ~ 95% (non-condensing).
- The pads only has 24 hours lifetime at the temperature: -30℃~ 0℃, 50℃~ 65℃, and the pads only has 4 months lifetime at the temperature: 35℃

~50℃.

- Do not store the device in direct sunlight.

6.4 Transportation Environment

If the device is returned for service, battery should be firstly removed(refer to Section3.4 (Optional) Replacing the Battery.) Pack the device and its accessories individually and transport them together. The device could be transported by general vehicle, but violent shock, vibration, rain and snow should be prevented from damaging the device during the transportation.

●The device should be transported at temperature between -30℃ and 65℃, volatility of temperature may significantly shorten the battery life and affect the performance of electrodes (the pads only has 24 hours lifetime at the temperature: -30℃~ 0℃, 50℃~ 65℃, and the pads only has 4 months lifetime at the temperature: 35℃~50℃).

●The device should be transported in relative humidity of 5% ~ 95% (non-condensing).

6.5 Disposal

In order to prevent hazardous waste, disposing the defibrillator and the battery should follow the regulations of the user's country. Dispose the pads as infectious waste. Contact Jousing Medical for consultation.

6.6 Data Management

The iAED-S1 will record data of operation in the internal memory, including ECG data, event logs and self-test data. Authorized person can download the

records. The viewing of the record needs to install the software **JouReview** on the computer. To get the **JouReview**, please contact Jousing Medical.

The types of the device data records are shown in table 3:

Table 3 Data Type

Type	Description
ECG Data	Patient's ECG data starting from pads attached
Event Log	Important events after the device power on , including: the device status, the pads application, the rhythm analysis, the charge and discharge, the CPR, etc.
Self-test Data	Device self-test data includes periodic self-test, battery insertion self-test

The iAED-S1 keeps ECG records of the last two rescues. Each record period can be 40 minutes maximum, starting from pads attached.

6.7 Troubleshooting

Table 4 Troubleshooting

Symptom	Possible Cause	Corrective Action
Device cannot be turned on.	Battery is not inserted.	Insert a battery.
	Battery is depleted.	Replace a new battery.
	The defibrillator needs repair.	Contact Jousing Medical for service.
Status indicator is off.	Battery is depleted.	Replace a new battery
	Status indicator is non-functional.	Contact Jousing Medical for service.
	The defibrillator needs repair.	
After turning on the iAED-S1, one or more lights do not light up.	One or more than one light damaged.	Do not use the iAED-S1, contact Jousing Medical for service.
	Battery is low or depleted.	Replace battery
Status indicator is solid in red, and the iAED-S1 prompts "battery low" during rescue.	Battery is low.	Replace a new battery immediately after performing this rescue.
Status indicator is solid	Battery is depleted.	Replace a new battery

in red, and the iAED-S1 prompts “replace battery now” in rescue.		immediately.
Status indicator is solid in red, and the iAED-S1 prompts “Service required” during rescue.	The defibrillator needs repair.	Contact Jousing Medical for service.
The iAED-S1 prompts “Poor pad contact to patient, press pads firmly”, “Check connector”.	Pads are not correctly applied to the patient.	Make sure the pads have been removed from the liner and place pads on patient to the right place.
	Pads are not making good contact with the patient.	Dry the patient’s chest and shave or clip any excessive chest hair, and make sure the pads are not touch the patient’s clothing.
	Connector is not inserted.	Make sure pads connector is inserted correctly
	Pads, pad cable or pad connector may be damaged.	Replace the pads.
	Pads socket may be damaged.	Contact Jousing Medical for service.
The iAED-S1 prompts “stop motion”,” analysis interrupted” during rescue.	Patient is moving.	Check patient’s breathing
	Someone is touching/moving the patient or doing CPR to the patient.	Stop touching/moving or doing CPR to the patient
	Vehicle is moving.	Stop the vehicle during analysis, if possible.
The iAED-S1 prompts “shock button not pressed, shock cancelled” during rescue.	Shock button is not pressed within 30 seconds.	Push shock button within 30 seconds
The shock cannot be delivered during rescue.	The pads may be damaged.	Replace the pads.
	Battery is depleted.	Replace a new battery.
Device turns off	Battery is depleted.	Replace a new battery

immediately during rescue.	The defibrillator needs repair.	Contact Jousing Medical for service.
The iAED-S1 prompts “Service required”, “device is not ready for use”, “begin CPR now” during rescue.	The defibrillator needs repair.	Perform CPR and replace the device immediately, then contact Jousing Medical for service after this rescue.
Status indicator is solid in red, and the iAED-S1 prompts “Battery low” in battery insertion self-test.	Battery is low.	Replace a new battery immediately after performing this rescue. Or, replace a new battery immediately.
Status indicator is solid in red, and the iAED-S1 prompts “Replace battery now” in battery insertion self-test.	Battery is depleted.	Replace a new battery immediately.
Status indicator is solid in red, and the iAED-S1 prompts “Service required” in battery insertion self-test.	The defibrillator needs repair.	Contact Jousing Medical for service.
Status indicator is solid in red, and the iAED-S1 prompts “abnormal operating temperature” in battery insertion self-test.	The device has placed beyond the temperature range of 0℃~ 50℃.	You can also perform rescue if it needs of rescue. Or, place the device at room temperature, and wait for 10 minutes, then reinstall the battery, it will run a self-test again to eliminate equipment failure alarm.
Status indicator flashes in red, and the iAED-S1 is chirping in standby mode.	Battery is low.	Replace a new battery.
	The defibrillator needs repair.	Contact Jousing Medical for service.
	The device has placed beyond the temperature range of 0℃~ 50℃.	Place the device at room temperature, and wait for 10 minutes, then reinstall the battery, It will run a self-test again to eliminate equipment failure alarm.

Other phenomenon and its possible cause.

Symptom	Possible Cause	Corrective Action
The iAED-S1 prompts “rhythm changed, shock cancelled”.	Patient’s ECG converts from shock to no shock rhythms, no shock advised, the device is normal.	No action needed.

7. Product Warranty

Manufacturer provides a limited warranty in product warranty period.

Below cases are not in warranty:

- Violation of instructions.
- Operating error.
- Improper use or handling.
- Disassemble the device by unauthorized personnel.
- Force majeure, such as lightning, etc.
- Transport damage caused by improper packaging.
- Device has not been maintained.
- The enclosure of the device is heavy wear.

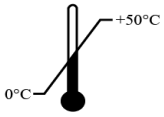
The manufacturer will not take any responsibility for the violation of instructions, operating error or any injury caused by improper use or handling.

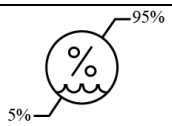
Annex

A Settings

Category	Parameters	Parameter Configuration	Default Configuration
Time	System Time / Date	/	Date of manufacture
Defibrillation	Discharge sequence Note: refers to analysis and shock up to N times before performing CPR	1 2 3	1
CPR	CPR assist type Note: tips on how to conduct CPR.	0- 30:2 (Pressing - ventilation ratio) 1-Chest compression alone	0
Device’s self-test time	Date Week Hour minute	1-31 1-7 0-60 0-60	1 1 24 0

B Symbols

Symbol	Description
	Manufacturer.
REF	Catalogue number.
SN	Serial number.
	Date of manufacture.
	Follow instructions for use
IP54	Dust protected, protected against splashing water.
	Defibrillation-proof type BF applied part.
	General warning sign.
	Dangerous voltage.
	Do not re-use.
	This way up.
	Fragile, Handle with care.
	Keep away from sunlight.
	Keep dry.
	The range of temperature is from 0℃ to 50℃.

	The range of humidity limitation from 5% to 95%.
	ON/OFF button.
	Expired dated.
	Authorized representative in the European Community.
	Non-sterile.
	Information button (i-button).
	Shock button.
	Dispose of in accordance with each country’s national law.
	Internally powered : $LiMnO_2$ battery
	Do not expose the battery to high heat or open flame. Do not incinerate.
	Do not crush, puncture, or disassemble the battery.
	Do not mutilate the battery or open the battery case.
	Package contents: one set of two defibrillation pads.
	Latex free.

C Glossary of Terms

GLOSSARY	Meaning
The device	The iAED-S1.
User	Person who operates the defibrillator.
Power-down status	A status of the device when the battery is not inserted
Standby	It's a status that the device is installed with battery but not turned on
Rescue status	A status of the device when the device is turned on (guide the user to perform rescue by voice and light prompts)
Power on	The device switch from standby mode to rescue state.
Self-test	A test automatically performed by the device to check the system modules and surrounding temperature.
Pacemaker	Implantable cardiac pacing generator that stimulates the heart by electrical pulses.
Periodic self-test	The device automatically performs a self-test daily, weekly, and monthly self-test in standby mode, test the battery, internal circuit, buttons and software, etc.
Sudden cardiac arrest, SCA	The abrupt termination of cardiac ejection function, ventricular fibrillation is the most common cardiac arrest.
Impedance	The device detects impedance between the two pads placed to the patient's skin.
Shock rhythm	The pulseless ventricular tachycardia or ventricular fibrillation that may cause cardiac arrest.
Non-shock rhythm	The rhythm detected by device which is non-shock.
Sensitivity	Positive that is the probability of detection is not missed.
Specificity	Negative that is the probability of detection is not misjudged.
Motion	The "noise" cause by muscle movement, cardiopulmonary resuscitation, or static electricity that may interfere the rhythm analysis.
New battery	Packing intact, unopened battery JOUBAT.
Pads	Pads and their cable are the applied part. The pads are applied to the patient's bare skin and used to detect the patient's heart rhythm and to transfer the defibrillation shock.
Manufacturer	Jousing Medical Co., Ltd is the manufacturer in this manual.
ECG	Electrocardiogram.
CPR	Cardiopulmonary Resuscitation. A technology that is to rescue cardiac arrest patients with artificial respiration and chest compression.
bpm	Beat per minute.

D Technical Specifications

Physical	
Size	198mm (L)×197mm (W)×67mm (H)
Weight (include battery and pads)	≤2kg
Environmental	
Temperature and relative humidity	Operating(with battery and pads installed) 0℃～50℃,5%～95% RH(non-condensing) Standby (with battery and pads installed) 5℃～35℃,5%～95% RH(non-condensing) Storage/shipping(with battery and pads) -30℃～65℃ for up to 24 hours, 5%～95% RH(non-condensing)
Altitude	0 to 15000 feet
Sealing	IP54
Vibration	Operating: meets EN1789 random, road ambulance. Standby: meets EN1789 swept sine, road ambulance.
shock/drop	Withstands 1 meter drop to any edge, corner, or surface.
EMC	Refer to Annex G for EMC Information
Defibrillator	
Waveform	Biphasic truncated exponential. Waveform parameters are automatically adjusted to patients′ impedances.
Energy	150 J nominal (±15%) delivered into a 50 ohm load. When the system detects impedance ≤ 20Ω or ≥ 200Ω, device will not deliver a shock.
Charge time from shock-advised	≤7s with a new battery
Pads	
Pads type	Disposable, pre-gelled self-adhesive defibrillation pads, latex free
Cable Length	120cm±12cm
Active gel surface area	100cm^2±10cm^2 each
Pads shelf life	2 years from date of manufacture when stored and maintained according to directions provided in this manual.
Battery	
Battery type	12VDC,4.2 Ah, $LiMnO_2$ battery
Battery capacity	New battery≥200 shocks (20℃±2℃). New battery≥100 shocks (0℃±2℃).

Shelf life	5 years from date of manufacture when stored and maintained according to directions provided in this manual.
Standby life (after insertion)	5 years when stored and maintained according to directions provided in this manual.

E Waveform Specifications

The iAED-S1 delivers a Biphasic Truncated Exponential waveform, with its current and duration automatically adjusted to patient's impedance, as shown in figure E-1.

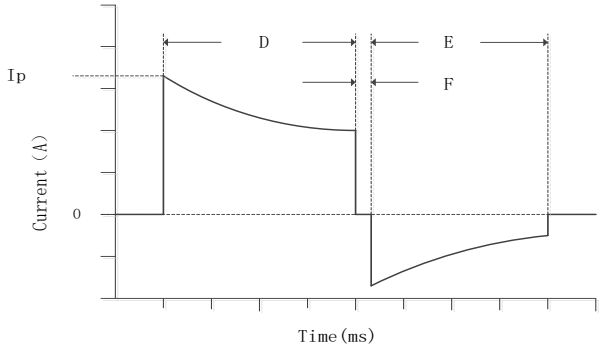


Figure E-1 Defibrillation energy waveform

Table 5 Defibrillation energy

load resistance(Ω)	phase 1 duration(ms)	phase 2 duration(ms)	phase 1 Peak current(A)	delivered energy(J)
25	2.8	2.8	55	128
50	4.5	4.5	32	150
75	6.3	5.0	22	155
100	8.0	5.3	18	157
125	9.7	6.4	14	159
150	11.5	7.7	12	160
175	12.0	8.0	11	158

Output energy accuracy: ±15%

F ECG Analysis Algorithm

Patient Analysis System

The iAED-S1 Patient Analysis System ensures that the pad/patient impedance is within the proper range and analyzes the patient's ECG rhythm to determine whether a shock is required. In the initial ECG signal conditioning stage, baseline wander and high-frequency noise is removed from the ECG signal and the ECG signal is digitized. In the ECG signal processing stage, artifacts is identified and removed from the patient's ECG signal (artifacts may arise from a variety of sources, including: noise, patient motion, respiration, muscular contractions, and pacemakers).

Rhythm analysis system consists of a number of parameters for making the ECG rhythm analysis, including ECG signal amplitude, consistency, period, spectrum etc.

Rhythm analysis is based on continuous segment of 3s ECG data. It needs at least three such ECG data segments to make a final shock or no-shock decision.

Shock Rhythm Criteria

When the patient's symptoms are consistent with suggested criteria, the iAED-S1 is designed to recommend a defibrillation shock when it detects proper pad impedance and the patient's rhythm for any one of the following table:

Ventricular fibrillation	Peak-to-peak amplitude reaches at least 200 μVolts ⚠ Warning: Some very low amplitude or low frequency VF rhythms may not be interpreted as shock.
Ventricular tachycardia	Cardiac rhythm rate reaches at least 180 bpm and peak-to-peak amplitude reaches at least 200 μVolts. ⚠ Warning: Some very low amplitude or low frequency VT rhythms may not be interpreted as shock.

Implantable pacemaker pulse signals may affect the correct determination of arrhythmia.

When any nonshockable rhythm (defined in IEC 60601-2-4:2018) is detected, the device will prompt the user to perform CPR.

Patient Analysis System Performance

Rhythm Class	**ECG Test Sample Size[1]**	**Algorithm Performance**		**Specifications**
		Performance	**90% Lower Confidence Limit**	
Shock Rhythm – Ventricular Fibrillation	273	99.6%	>99%	Sensitivity >90%
Shock Rhythm – Ventricular Tachycardia	69	91.3%	>85%	Sensitivity >75%
Non-Shock Rhythm – Normal Sinus Rhythm	546	100%	>99%	Specificity >99%
Non-Shock Rhythm – Asystole	109	100%	>99%	Specificity >95%
Non-Shock Rhythm – All other non-shock rhythms	159	98.7%	>97%	Specificity >95%

Jousing medical collects ECG samples from the industry recognized ECG databases, including MITDB、AHADB、CUDB、VFDB、SVDB、EDB、QTDB、SDDB and Jousing self-built ECG database.

According to the AHA recommendations and AAMI standard DF80, supraventricular is classified into nonshockable rhythm.

G EMC Test Results

Guidance and manufacturer's declaration-electromagnetic emissions for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic emission		
The iAED-S1 Automated External Defibrillator is intended for use in the electromagnetic environment specified below. The user of the iAED-S1 Automated External Defibrillator should assure that it is used in such environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The iAED-S1 Automated External Defibrillator uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The iAED-S1 Automated External Defibrillator is suitable for using in all establishments including domestic establishments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration-electromagnetic immunity-for all EQUIPMENT and SYSTEMS

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Radiated RF IEC 61000-4-3	20V/m 80MHz～2.7GHz	20V/m
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

⚠**WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iAED-S1, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (w)	Distance (m)	IMMUNITY TEST LEVE (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11	Pulse modulation	0.2	0.3	9
5500						

5785		a/n	217 Hz			

H Periodic Checklist

Periodic Checklist						
Date						
Check status indicator						
Check pads' expired dated						
Check Completeness of Parts						
Inspector signature						

I Device Tracking Table

In order to provide better services for users, we request users to provide important information including the specific address of the device and contact information. There are two ways users could send device tracking information to us.

Please record device information after you receive the equipment.

-Fax to +86 0512-62995391.

-Send an email to service@jousing.com.

If the device address or the user’s contact Information is changed, please send the updated information to us with the least delay possible.

Device tracking table	
User Information	
User name:	
Company name:	
Address:	
City:	Province:
Zip code:	Country:
Contact name:	
Tel:	Fax:
Email:	
Device Information	
Product name:	Serial number:
REF:	Installed Time:
Device Location:	