JOUSING
久心医疗

Control
Sealed

iAED-S1

Automated External Defibrillator

User Manual

About this Edition

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

Edition History

Edition: L

Publication date: Nov. 2024

Responsibility Statement

No responsibility need to be taken by Jousing Medical Co., Ltd. for any injury caused by any action in violation of the instruction for use, cautions, warning or the application instructions of this publication.

For any information about the product, please contact your local distributor or Jousing Medical Co., Ltd.

Technical Support & Customer Service

Company name: Jousing Medical Co., Ltd.

Company Address: 301&401, Building 21, 200 Xingpu Road, Suzhou Industrial

Park, Suzhou, Jiangsu 215000, China

Tel: 400-820-9952

Fax: +86-0512-62995351

Email: service@jousing.com

Authorized EU representative

Company name: Wellkang Ltd

Address: Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland, UK.

Tel: +44(33)33031126

Email: AuthRep@CE-marking.eu

Summary of Safety and Clinical Performance (SSCP):https://en.jousing.com/product/iaed-s1

CE 2797

Important Note

Sudden Cardiac Arrest (SCA) is the main cause of sudden cardiac death. Time is critical in treating sudden cardiac arrest! Survival rates are directly related to how soon victims are defibrillated. For every minute of delay, the chance of survival drops by 7%-10%. It is critical for SCA patients to receive CPR and defibrillation as soon as possible.

Although defibrillation is currently the only effective treatment for SCA, it is important to understand that defibrillation cannot always assure survival. In some cases, the cause of SCA is simply not survivable despite any available care.

CONTENTS

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 Main Unit (Model: iAED-S1)
- 1 Battery (Model: JXB1242)
- 1 Pads Package (Model: F7952W/J, F7952PW/J)
- 1 User Manual
- 1 Quick Reference Guide
- 1 Warranty Card
- 1 Package List

Perform the initial inspection as follows:

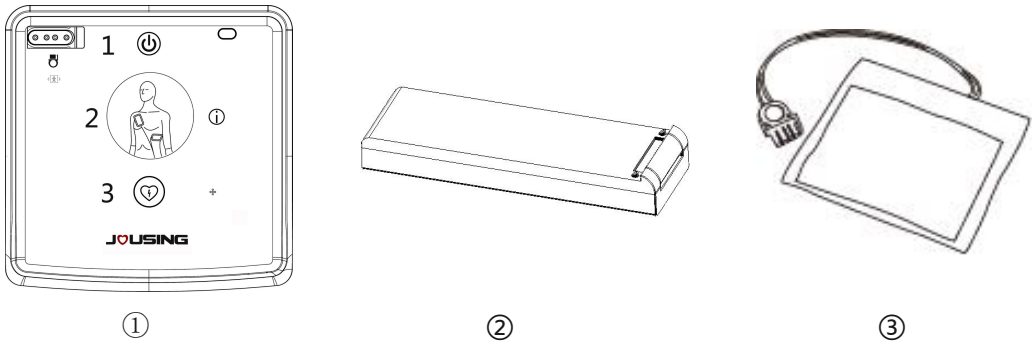
- Examine the surface of the device for signs of possible damage that might have occurred during shipping.
- Check the expired date of the pads and battery.

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 Main Unit (Model: iAED-S1)

② Battery (Model: JXB1242), which is non-rechargeable.

The iAED-S1 defibrillator is powered by battery.

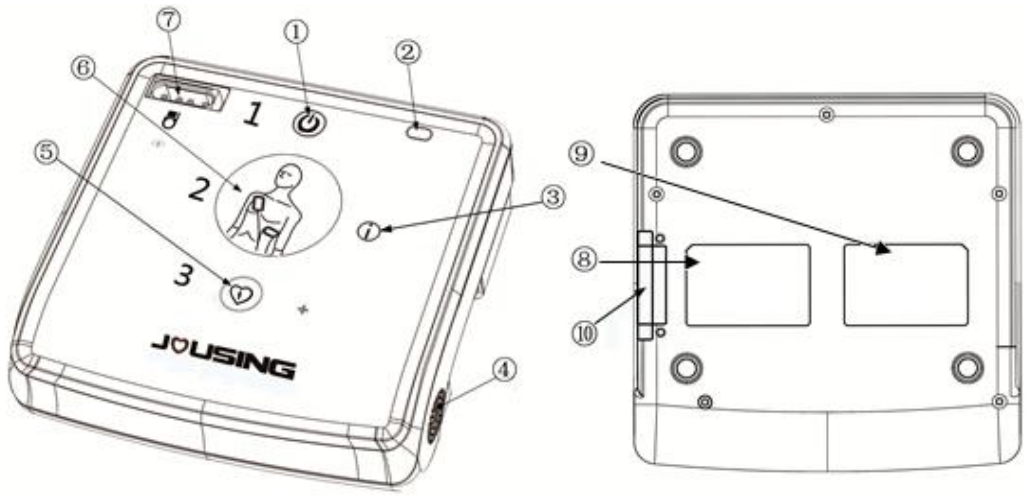
③ External cardioversion defibrillation electrode pads (Model F7952W/J for adult, F7952PW/J for pediatric).

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.

Embedded software for the device: AED-JouSoft2000 (Version: V01)

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	In standby mode, press the information button for at least 5 seconds to enter the management mode of the device; In management mode, press the button continuously for 3 seconds to exit the management mode of the device; In rescue mode, press the information button to switch the device to another language; When the device is in management mode, the information key indicator light is on.
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	Warning Label	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 Intended Purpose

iAED-S1 is an automated external defibrillator used to treat victims with suspected cardiac arrest (unresponsive or not breathing normally).
After defibrillation electrodes are applied to the victims' chest, iAED-S1 will analyzes the victims' heart rhythm. If a shockable rhythm (either ventricular fibrillation or pulseless ventricular tachycardia) is detected, iAED-S1 will direct the responder to deliver a shock across the heart in order to try and restore a normal heart rhythm. Use the adult pads for adults over 25 kg to deliver a 150 J shock, and use pediatric pads for pediatric under 25 kg or 0-8 years old to deliver 50 J shock.
The product should be used in public, home, or medical settings by personnel trained in cardiopulmonary resuscitation and automated external defibrillator use, or by medical personnel trained in basic life support and advanced life support courses, or under the guidance of emergency center dispatchers.

1.4 Indications

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

- Unresponsive
- Not breathing normally

1.5 Contraindications

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

- Responsive
- Breathing normally

1.6 User Training Requirements

The product should be used by personnel trained in cardiopulmonary resuscitation and automated external defibrillator use, or by medical personnel trained in basic life support and advanced life support courses, or under the guidance of emergency center dispatchers.

1.7 Intended Clinical Benefits

Helps early electrical defibrillation and improves survival for individuals with sudden cardiac arrest.

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 pads on the patient's bare skin (excluding wrinkled skin surfaces such as the lower part of the chest and obese patients' fat accumulation areas). Improper placement of the pads will affect the analysis and result in incorrect or no shock delivery.
- 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

- Do not use other manufacturers' accessories (batteries or pads), or it may result in improper functioning. Please use accessories provided by Jousing Medical, and ensure their models are compatible with the main unit.
- 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

- 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.
- When using the device, be careful not to wrap the electrode wire around the patient's neck, which may cause suffocation.

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.

Maintenance

Please adhere to the maintenance requirements and schedules detailed in the manual to ensure the device remains in a state of readiness for use at all times.

2.3 Safety precautions

For home use, please heed the following precautions:

- Upon purchasing the device, ensure you receive safety training provided by Jousing Medical or your local distributor.
- Store the device in a location that is dry, cool, and well-ventilated. Avoid direct sunlight and do not store it in dark, damp areas.
- Keep the device out of children's reach to prevent accidents.
- Regularly inspect the device's status as detailed in Chapter 6 of the instruction manual. If the status light turns red or any other abnormality is detected, contact Jousing Medical or your local distributor immediately. Do not disassemble the device without authorization.
- Strictly adhere to the guidelines outlined in Chapter 4 of the instruction manual for use.
- If any serious incident occurred in relation to the device, please report to us and the competent authority of the Member State in which you are established.

2.4 Probable adverse effects of the deive on health

Following are the probable adverse effects of the device on heath.

- False positive: failure to identify non-shockable arrhythmia
- False negative: failure to deliver a defibrillation shock in the presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT), which may result in death or permanent injury
- Skin burn
- Myocardial damage

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.

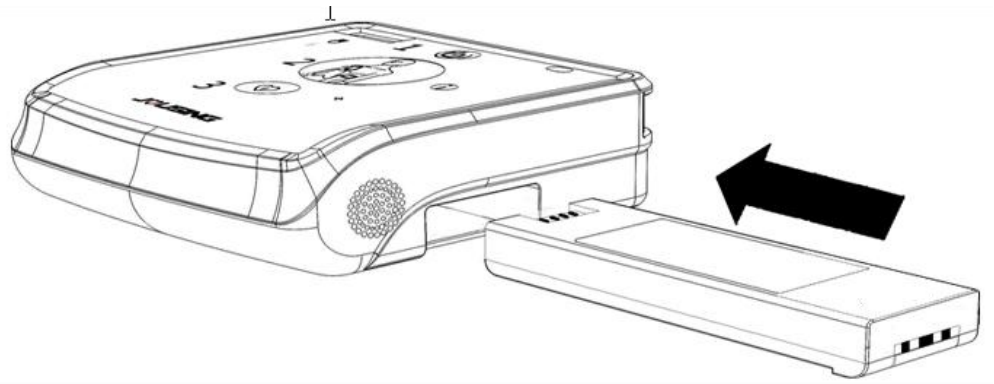


Figure 3 Installing the battery schematic

⚠ 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.

3. After turning on, the device will broadcast "adult mode" or "child mode" according to the plug type.

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

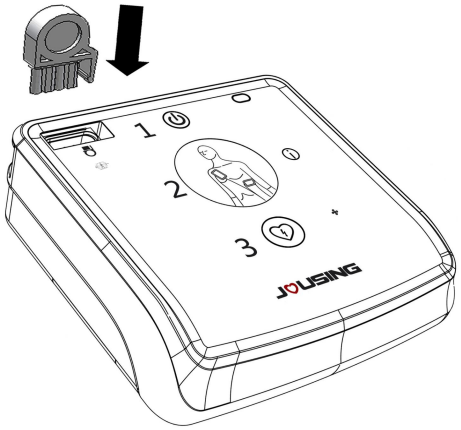


Figure 4 Pads Connector Insertion

3.4 (Optional) Replacing the Battery

Scenarios

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

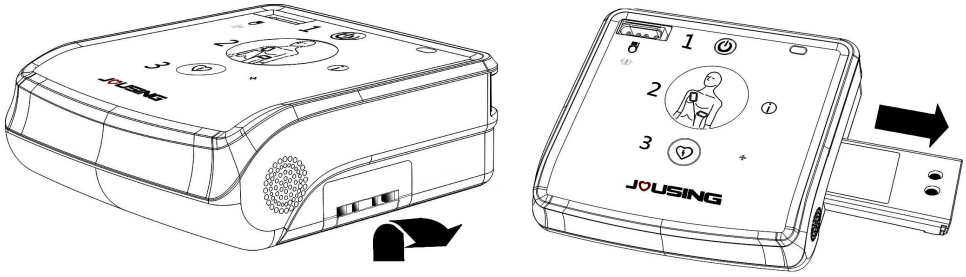
⚠ **Warning:**

- 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.

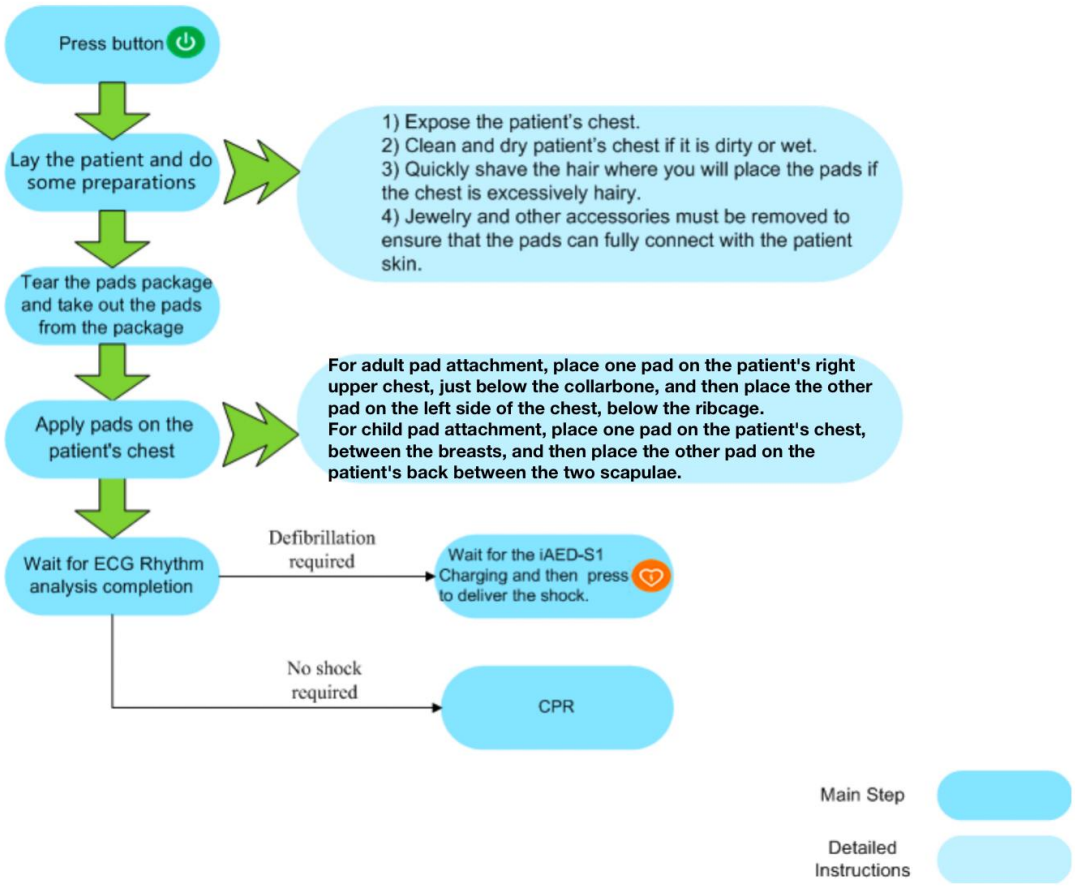


Figure 6 Step Procedure

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.”

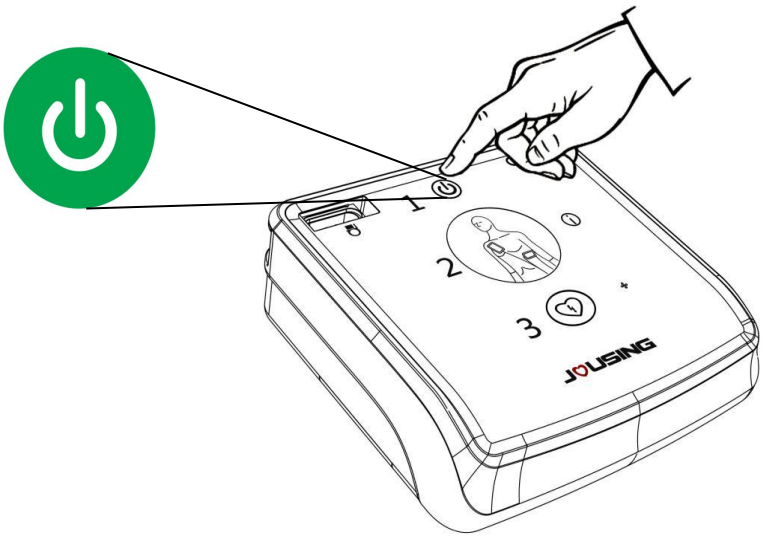


Figure 7 Power on the Device

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.

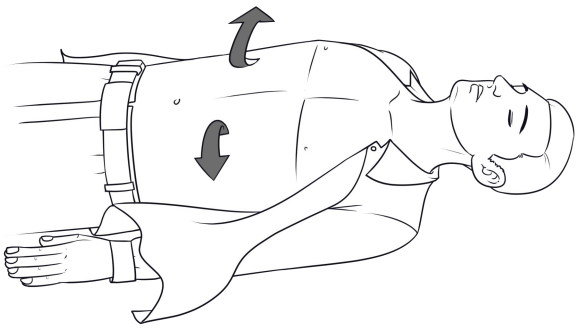


Figure 8 Removing all clothing from the patient’s chest

4.3.3 Checking pad connector

⚠ If the patient is an adult, make sure to use adult pads as specified.

⚠ If the patient is a child, make sure to use child pads as specified.

First, check whether the pad connector is properly inserted into the pad socket. If it is not inserted, immediately insert the connector into the socket. For detailed instructions, please refer to Chapter 3.3.

Once the connector is in place, please ensure that it is fully inserted to guarantee a secure connection. Upon powering on the device, it will announce the mode selection based on the type of connector inserted, either 'adult mode' or 'child mode'.

4.3.4 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.

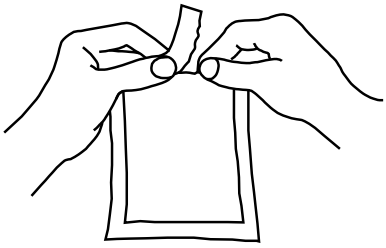


Figure 9 Tear the pads package

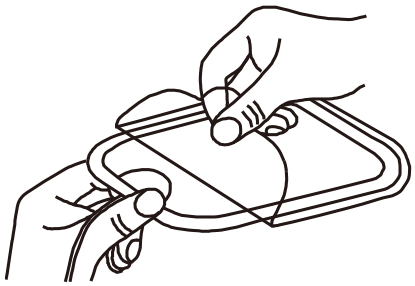


Figure 10 Peel the pad from plastic liner

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.

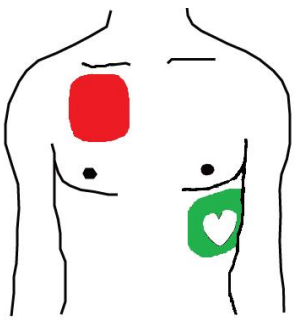
4.3.5 Placing the Pads to the Patient

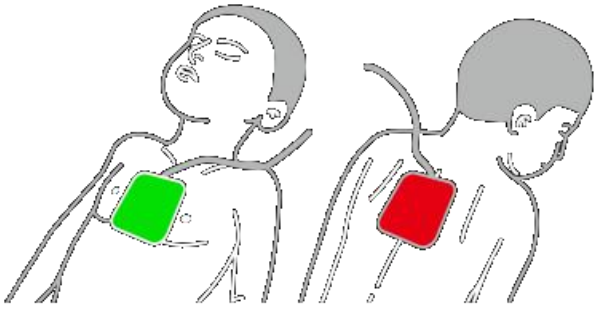
Procedure

For adult pad attachment, place the red pad on the patient's right upper chest, just below the collarbone, and then place the green pad on the left side of the chest, below the ribcage, as shown in the Figure 11 (a).

For child pad attachment, place the green pad on the patient's chest, between the breasts, and then place the red pad on the patient's back, between the two scapulae, as shown in the Figure 11 (b).

⚠ **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.





a) Adult pads attachment position b) Child pads attachment position

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.

4.3.6 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.

4.3.7 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.

⚠ **Note:** 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.

4.3.8 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.

4.3.9 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.

⚠ **Note:** No need to remove the pads during CPR.

4.3.10 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		●	●
Replacing pads			●

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.

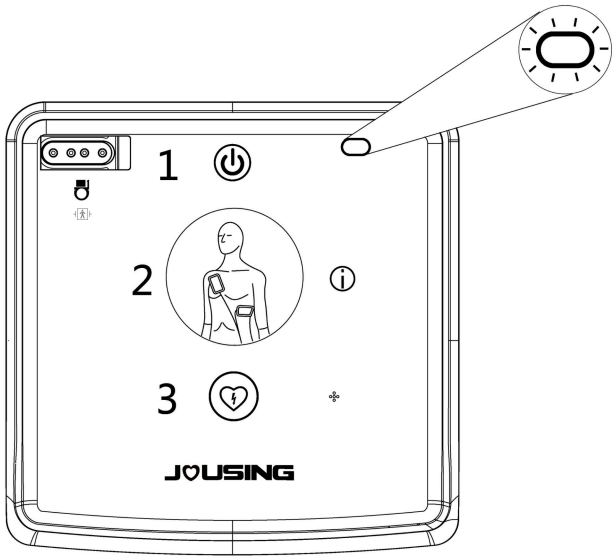


Figure 12 The Status indicator

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 condition 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.
- Check the device for any signs of contamination. In the event of contamination, proceed with the cleaning instructions outlined in 6.2 Cleaning the Device Surface.
- Check the pad packaging for any signs of damage. In the event of damage, contact Jousing Medical to request a replacement.

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 main unit and accessories (pads, batteries) should be stored in an environment with suitable temperature and good ventilation, avoiding sun

exposure and staying away from moisture and dust. The proper storage environment include:

- The suggested storage temperature range is 0℃~50℃.
- The suggested short-term storage temperature range is -30℃~ 65℃, within 24 hours.It takes 1 hour for the device to function properly after being transferred from the lowest storage temperature from -30 ℃ to 20 ℃, and take 30min from 65℃ to 50℃.
- The suggested storage temperature range is 5℃~35℃.
- The suggested relative humidity range is 5% to 95% (non-condensing).
- Do not store the device in direct sunlight.
- Do not store the device near strong electromagnetic fields, such as high voltage lines, substations, and wireless base stations.
- The device should be maintained in standby mode, ensuring that the battery is properly inserted into the main device unit and the pads are securely connected.

6.4 Transportation Environment

Transportation of the device is permitted using standard transportation vehicles. However, care must be taken to prevent severe impact, vibration, and exposure to rain and snow during transit. The transportation must adhere to the following guidelines:

- The suggested transportation temperature range is 0°C ~ 50°C.
- For extreme transportation conditions, the temperature should not exceed -30°C to 65°C, and such conditions should be limited to a maximum of 24 hours.
- The suggested relative humidity range is 5% to 95% (non-condensing).
- In the event the device requires transportation to a repair site, the battery must be removed from the device. Refer to Chapter 3.3.2 for instructions on

proper battery removal. The battery should be packaged separately and shipped together with the device.

6.5 Operating Environment

The operating environment should comply with the following requirements:

- The suggested temperature range is 0°C ~ 50°C.
- The suggested relative humidity range is 5% to 95% (non-condensing).
- The suggested air pressure range is 480hPa (altitude 5920m) ~ 1060hPa.

The device must not be operated in environments with high concentrations of flammable gases or oxygen, nor in areas with strong electromagnetic interference or where conductive materials, such as water, are beneath the patient. After transferring the device from the lowest storage temperature of -30° C to 20° C, allowing one hour for it to acclimate and function properly. Additionally, when the device is exposed to an environment of 50° C, the temperature of the application parts may rise to a maximum of 52° C.

6.6 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.

6.7 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
Rescue data	All ECG and impedance data of the patient
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, power-on self-test

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

6.8 Self-Test

The device regularly performs a self-test to verify its usability. See Table 4 for self-test items.

If the device passes the self-test, the device status indicator light displays green, indicating that the device is in good condition and can be put into use; When the device fails the self-test, the device automatically shuts down and enters standby mode, and the device status indicator light displays red, indicating that the device may have errors and troubleshooting is needed. Users should check the status indicator in time. See Section 6.1 Routine Maintenance for the recommended frequency of routine maintenance.

Table 4 Self-test sheet of iAED-S1

Item \ Category		Battery insertion	Power-on	Daily	Weekly	Monthly
Processor system		√	√	√	√	√
Power circuitry		√	√	√	√	√
Temperature sensor		√	√	√	√	√
Ambient temperature		√	√	√	√	√
Battery level	Open circuit voltage self-test	√	√	√	√	√
	Charging voltage self-test	√	/	/	/	√
Voice circuitry		√	/	/	/	√
Button circuitry		/	/	√	√	√

Storage circuitry		√	√	√	√	√
ECG circuitry		√	/	√	√	√
Defibrillation charging and discharging circuit	Relay circuitry	√	/	/	√	√
	Charging circuit self-test (low energy)	√	/	/	√	√
	Charging circuit self-test (high energy)	√	/	/	/	√
	Self check of discharge circuit	√	/	/	√	√
Real Time Clock		√	/	√	√	√
Pilot lamp		√	/	√	√	√
⚠ *Notes: "√" indicates "included"; "—" indicates "excluded".*						

6.9 Troubleshooting

Table 5 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 in red, and the iAED-S1	Battery is depleted.	Replace a new battery immediately.

prompts “replace battery now” in rescue.		
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 immediately during	Battery is depleted.	Replace a new battery
	The defibrillator needs	Contact Jousing

rescue.	repair.	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 during return shipping.
- 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.

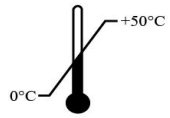
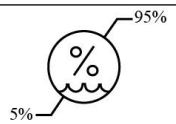
Annex

A Settings

Category	Parameters	Parameter Configuration	Default Configuration
CPR	CPR assist type Note: tips on how to conduct CPR.	Pressing - ventilation ratio 30:2 15:2 Chest compression alone	30:2

B Symbols

Symbol	Description
	Manufacturer.
	Catalogue number.
	Serial number.
	Date of manufacture.
	Follow instructions for use
	Medical Device
IP55	Dust protected, protected against jetting water.
CE 2797	Compliant with Medical Device Regulation (EU) 2017/745, Class Ⅲ，and Notified Body is BSI.
	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.
	Non-ionizing electromagnetic radiation.

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	98±10mm (L)×197±10mm (W)×67±10mm (H)
Weight (include battery and pads)	1.6±0.2kg
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)
Atmosphere pressure	480hPa（Wave height 5920m）～1060hPa
Sealing	IP55
Vibration	Operating: meets EN1789 random, road ambulance. Standby: meets EN1789 swept sine, road ambulance.
shock/drop	Withstands 1.2 meter drop to any edge, corner, or surface.
EMC	Refer to Annex G for EMC Information
Main Unit	
Waveform	Biphasic truncated exponential. Waveform parameters are automatically adjusted to patients＇impedances.
Energy	Adult mode: 150 J nominal (±10%) delivered into a 50 ohm load. Child mode: 50 J nominal (±10%) delivered into a 50 ohm load. When the system detects impedance ≤ 20Ω or ≥ 200Ω, device will not deliver a shock.
Charging Time	a) Time from the start of analysis to the completion of 150J shock preparation using a new battery with full capacity: ≤ 10 seconds; b) The time from the start of analysis to the completion of 150J shock preparation using a battery that has been discharged six times at maximum energy: ≤ 11 seconds; c) The time from turning on the AED power to the completion of 150J shock preparation using a battery that has been discharged six times at maximum energy: ≤ 15 seconds; d) The time from the start of charging to the completion of the 150J shock preparation using a new battery with full capacity: < 7 seconds;

	e) The time from the start of charging to the completion of 150J shock preparation using a battery that has been discharged six times at maximum energy: ≤ 8seconds; f) The time from the start of charging to the completion of 150J shock preparation using a battery that has been discharged 15 times at maximum energy: ≤ 9 seconds; The time from turning on the AED power to the completion of 150J shock preparation using a battery that has been discharged 15 times at maximum energy: ≤ 17 seconds;
Lifetime	The expected service life of the main unit is 10 years （if stored and maintained as instructed).
Pads	
Pads type	Disposable, pre-gelled self-adhesive defibrillation pads, latex free
Cable Length	120cm±12cm
Active gel surface area	F7952W/J: 100cm^2±10cm^2 each F7952PW/J: 40cm^2±10cm^2 each
Pads shelf life	30 months from date of manufacture when stored and maintained according to directions provided in this manual.
Battery	
Battery type	12V DC, 4.2 Ah, $LiMnO_2$ battery, non-rechargeable
Battery capacity	New battery≥300 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.

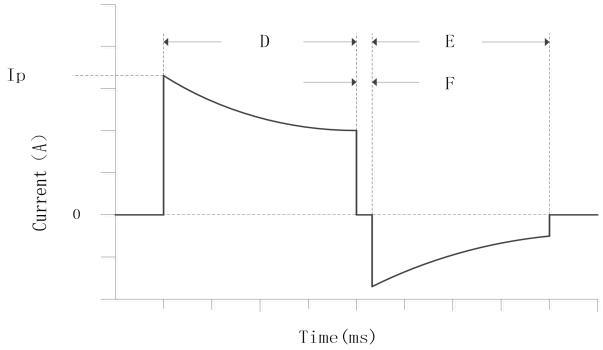


Figure E-1 Defibrillation energy waveform

Table E-2 Defibrillation energy (adult mode)

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
200	12.0	80	9	156

Table E-3 Defibrillation energy (child mode)

load resistance(Ω)	phase 1 duration(ms)	phase 2 duration(ms)	phase 1 Peak current(A)	delivered energy(J)
25	2.8	2.8	32	43
50	4.5	4.5	19	50
75	6.3	5.0	13	52
100	8.0	5.3	10	52
125	9.0	6.0	8	52

150	9.0	6.0	7	50
175	9.0	6.0	6	48
200	9.0	6.0	5	46

Output energy accuracy: ±10%

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	214	99.5%	98.7%	Sensitivity >90%
	Ventricular Tachycardia	53	94.3%	89.1%	Sensitivity >75%
Non-Shock Rhythm	Normal Sinus Rhythm	423	100%	99.6%	Specificity >99%
	Asystole	125	100%	99.4%	Specificity >95%
	All other non-shock rhythms	496	99.2%	98.5%	Specificity >95%

*Specification according to IEC60601-2-4:2018 201.107.

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

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration-electromagnetic emission</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment-guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>N/A</td></tr>
</table>

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 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

H Major Safety Features of the Product

Type of shock prevention: Internal power supply.
Degree of shock prevention: BF type.
Protection against liquid ingress: IP55.
Safety level in the presence of flammable anesthetic gases: The device should not be used in environments where flammable anesthetic gases are mixed with air, oxygen, or nitrous oxide.
Operating mode: Continuous operation.
Rated voltage and frequency: The device operates on a DC power source (LiMnO2 battery) with a voltage of 12V and a capacity of 4.2Ah.
Device input power: Not applicable.
Application part for shock discharge protection: There exists application part includes pads designed to protect against the effects of shock discharge.
Signal output or input: Wireless communication
Installation type: Non-permanent installation .
Use in emergency vehicles: Suitable for non-frequent use in road ambulances and fixed-wing aircraft, transferable for emergency situations.

I Periodic Checklist

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

J 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:	