JOUSING

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iAED-M2

Automated External Defibrillator

User Manual

About this Edition

The instructions for use apply to the iAED-M2 Automated External Defibrillator.

Edition History

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Copyright Statement

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.

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Summary of Safety and Clinical Performance (SSCP):
https://en.jousing.com/product/iaed-m2

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.

Table of Contents

1 Overview

This section describes the iAED-M2's intended purpose, indications, contraindications, models, and software information.

1.1 Intended Purpose

The iAED-M2 is indicated for the treatment of patients with suspected cardiac arrest (unresponsive, not breathing or breathing abnormally).

The adult mode is indicated for use on patients aged 8 years of age or older or weighing 25 kg or more. And the child mode is indicated for use on patients under 8 years of age or weighing less than 25 kg.

The iAED-M2 is intended for use in public, home, healthcare facilities, during transportation, and emergency medical services environment.

The iAED-M2 is intended for use by personnel trained in basic life support/AED and advanced life support, or under the guidance of emergency medical dispatchers

1.2 Indications

The iAED-M2 is indicated for patients with suspected cardiac arrest who simultaneously meet all of the following conditions:

- Unresponsive
- Not breathing or breathing abnormally

1.3 Contraindications

The iAED-M2 should not be used if the patient shows any of the

following signs:

- Responsive
- Breathing normally

1.4 Models

The iAED-M2F is a fully automatic defibrillator. Once the pads are attached, iAED-M2F will analyze the rhythm. If a shockable rhythm is detected, the device will audibly warn and then automatically deliver a shock, requiring no intervention from the responder.

The iAED-M2S is a semi-automatic defibrillator. After analyzing the rhythm, if a shockable rhythm is detected, the device will prompt the responder to press the shock button to deliver therapy.

1.5 Intended Clinical Benefits

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

1.6 Software Information

Name: AED-JouSoftM2

Version: V01

2 Safety Information

This section describes the iAED-M2's warnings, cautions, the production date, and the service life.

2.1 Warnings

⚠Shock Hazard

Disconnect non-defibrillation protected electronic devices or equipment from the patient before defibrillation.

Do not touch the patient, the sickbed, or any conductive material connected to the patient during defibrillation.

⚠Skin Burns

Apply unexpired, undamaged electrodes to clean and dry skin to minimize burning.

Do not let the pads touch each other or other electrodes, lead wires, etc.

Verify that the pads are applied firmly in the right position to prevent skin burns.

⚠Inaccurate Rhythm Analysis

Place the pads on the patient's bare skin, excluding where the skin is folded (e.g., below the chest or on fat deposits), because improperly placed pads may disrupt rhythm analysis and shock delivery.

Keep the patient as motionless as possible during rhythm analysis, or the diagnosis can be delayed or inaccurate. Please operate exactly as the instructions in this Manual suggest.

Do not place the electrode pads directly over the patient's implanted pacemaker. Otherwise, it may degrade the accuracy of rhythm analysis or damage the pacemaker. Despite its function to detect pacemaker artifacts of a certain width and amplitude, the iAED-M2 may turn out incorrect diagnosis when the pads are placed that way.

Do not use the device near any strong electromagnetic source, such as high-voltage lines, transformer substations and radio base stations, because electromagnetic interference may lead to wrong

diagnosis by causing the defibrillator to incorrectly interpret heart rhythms.

⚠Explosion Danger

Do not use this device in the presence of flammable gases or an oxygen-rich atmosphere, as this may cause an explosion or fire.

Do not try to recharge the battery, or it may explode or catch fire.

Do not burn or incinerate batteries, or it may explode or catch fire.

⚠Improper Operation

Do not use accessories (batteries, pads, etc.) from other manufacturers, or it may impair the iAED-M2's normal functioning. Please use accessories provided by Jousing Medical, and ensure their models are compatible with the main unit.

Do not open the iAED-M2, remove its covers, or attempt repair or modification. Doing so may result in high-voltage electric shock. There are no user-serviceable components in the iAED-M2. If repair is required, contact Jousing Medical or authorized personnel for service.

Do not modify the device.

Do not use the device if it has been immersed in fluids. The conductive parts should not touch each other or any other conductive material (including the ground).

Do not immerse the pads in or clean them with alcohol or any other solutions.

Do not press the pads when they are attached, or it may damage the pads and the normal functioning of the unit.

If the device is stored outside the recommended environmental

conditions, it can be damaged or its useful life reduced.

⚠Usage Cautions

This device should be used by properly trained individuals only.

Use the device only as described in this Manual. Improper use may cause death or injury.

Electrode pads are disposable. Discard after use.

Verify that the pads are properly connected to the main unit in any case.

Ensure the patient's chest is dry before attaching electrode pads.

If the patient has excessive chest hair, shave the hair before attaching the pads.

Move the patient away from electrically conductive surfaces prior to the use of the unit to prevent any part of the body (skin of the head or limbs) from touching conductive liquids (sewage, conductive gels, blood, or saline solutions) and metal (bed frames or stretchers).

Do not touch the electrode pads, the patient, or any conductive material touching the patient during rhythm analysis or defibrillation.

When using the device, ensure the pads cable is not wrapped around the patient's neck to prevent the risk of strangulation.

The pads have passed the skin sensitization test; however, some patients may still experience allergic reactions. Avoid unnecessary prolonged skin contact with the pads.

Always stand clear of the patient when delivering a shock. Defibrillation energy delivered to the patient may be conducted

through the patient's body and cause a lethal shock to those touching the patient.

Place the patient on a firm surface before performing CPR.

Do not use the iAED-M2 near or in combination with other equipment, or it may cause malfunctions. If the device has to be used near or in combination with other equipment, verify proper operation prior to use.

Dispose of the main unit, battery and pads in accordance with local regulations for waste disposal.

If the device is connected to the internet. The device consumes more power in areas with poor network signals.

2.2 Cautions

Damage

If the device shows any damage, please contact Jousing Medical for service.

Label

Pay attention to all caution and warning labels on the device and its accessories.

Performance

The device's performance may be degraded if stored, transported or used outside the recommended conditions.

Maintenance

Please maintain the device as this Manual suggests to ensure that it is always ready for use.

2.3 Production Date and Service Life

Refer to the device label for production date and service life

information.

2.4 Special Instructions for Safe Use

For consumer use in a home setting, users should note the following:

- Join the training on safe operation provided by Jousing Medical or the local distributors after purchasing the device.
- Keep the device in a dry, cool and well-ventilated places without direct sunlight and moisture.
- Keep the device out of the reach of children to avoid accidents.
- Check the device status regularly according to Section 6.1. When the Status Indicator is flashing red or other anomalies have been detected, please contact Jousing Medical or the local distributor immediately for repair. Do not disassemble the device without any professional assistance;
- Operate the device exactly as Section 4 suggests.
- Timely contact Jousing Medical or the local distributor to replace the pads after 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.

2.5 Probable Adverse Effects

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

- 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 Installation and Preparation

This section describes device unpacking and inspection, device description, battery installation/removal, pad connection, and battery insertion self-test.

3.1 Unpacking and Inspection

Check the product box to ensure all items listed in the packing list are included.

If any items are missing, please contact your local distributor or Jousing Medical.

If the contents are complete, please follow the steps below for inspection:

1) Check the defibrillator's case for damage.

2) Check the electrode pads:

- Verify that the pads package is intact;
- Ensure the pads are within the expiration date.

Note: The pads plug is pre-connected to the main unit. Do not disconnect it during unpacking or inspection.

3) Check the battery to verify that its shelf life is within the expiration date.

If there is any abnormality, please contact your local distributor or Jousing Medical.

Note: Jousing Medical provides optional accessories for the iAED-M2. For more detailed information, please refer to Appendix A.

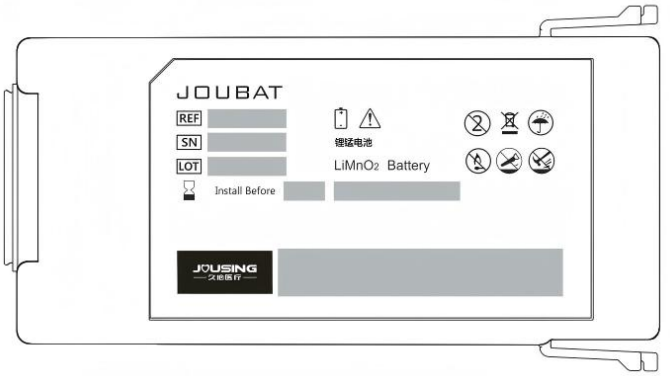
3.2 Device Description

This section describes the device's components, appearance, indicators, buttons, and screen functions.

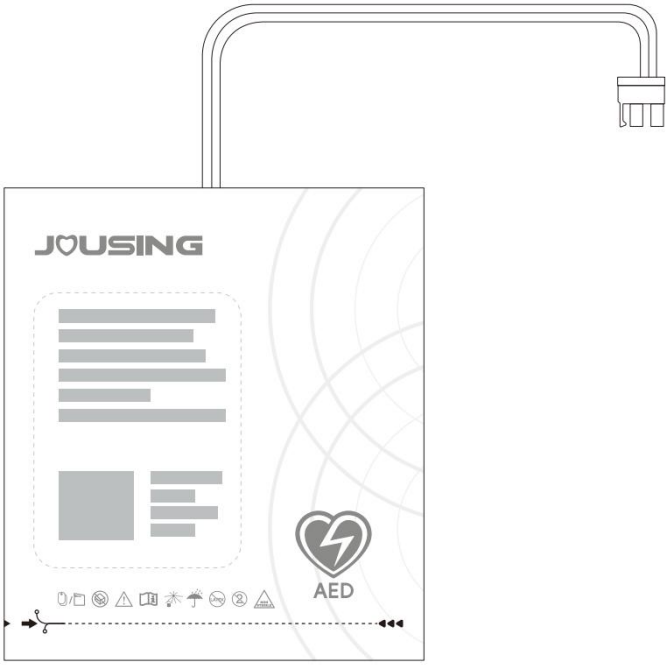
3.2.1 Components

The iAED-M2 consists of a main unit, a battery and electrode pads. To install and remove these components, refer to Sections 3.3 and 3.4. Please ensure that the components are complete according to Figure 3-1 prior to use.

① Main Unit



② Battery: Non-rechargeable



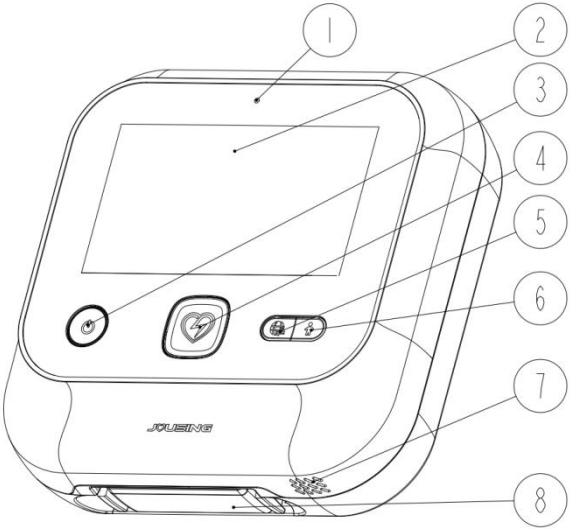
③ Pads: Disposable

Figure 3-1 Device components (① main unit, ② battery, and ③ pads)

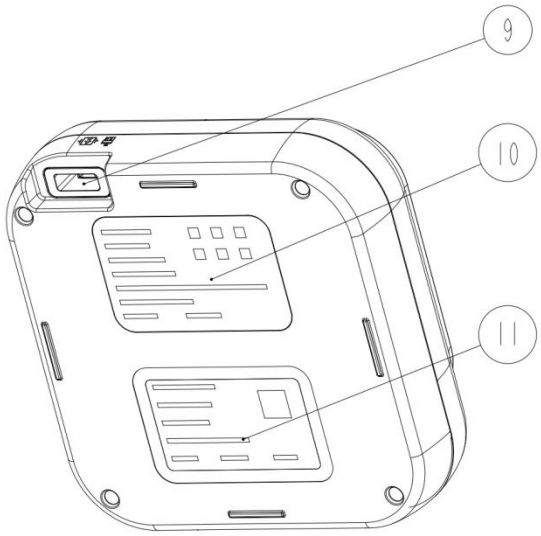
In addition to the essential components listed above, an optional back clip or case can be used to make the device easier to carry and to conveniently store the electrode pads.

3.2.2 Appearance

The buttons, indicators, and labels on the iAED-M2 are shown in Figure 3-2 and their respective functions are listed in Table 3-1:



a) Front



b) Back

Figure 3-2 Buttons, indicators, and labels on the iAED-M2

Table 3-1 Functions of buttons, indicators, and labels

No.	Item	Description
1	Status indicator	Indicates whether the device status is normal: In standby mode: flashing green light for normal status, flashing red light for abnormal status. In rescue mode: solid green light for normal status, solid red light for abnormal status. In management mode: solid green light for normal status, solid red light for abnormal status.
2	HD color screen	Displays operational steps and status information to guide the operator during first aid. It can be configured to display ECG, remaining battery capacity, wireless signal quality, text prompts, and other information.
	Color touchscreen (optional)	Displays operational steps and status information to guide the operator during first aid. It can be configured to display ECG, remaining battery capacity, wireless signal quality, text prompts, and other information. In management mode, the device can be configured via the touchscreen.
3	ON/OFF	In standby or management mode, press the button to

	button/indicator	turn on the device; when the green light is on, the device has entered rescue mode. To switch back to standby mode, hold the button for at least 3 seconds, and the light turns off.
4	SHOCK button/indicator	For fully automatic defibrillators (iAED-M2F), the SHOCK indicator flashes when the defibrillator is preparing to deliver a shock. For semi-automatic defibrillators (iAED-M2S), press the flashing SHOCK button to deliver a shock to the patient.
5	LANGUAGE button/indicator	By pressing this button, the device can switch between up to three configured voice languages. This indicator remains illuminated during rescue mode.
6	CHILD MODE button/indicator	Press this button to switch the device to defibrillation mode. The indicator is off in adult mode and illuminated in child mode.
7	Speaker	Instructs the operator with voice prompts.
8	Battery	Powers the device.
9	Pads socket	Connects the pads to the defibrillator.
10	Information label	Displays information on the registrant, manufacturer address, as well as usage cautions.
11	Barcode label	Provides the product production information.

3.3 Install or Remove the Battery

3.3.1 Install the Battery

The iAED-M2 has a non-rechargeable battery with an output voltage of DC9V. Suitable battery is the JXMB0942. Do not use any other battery.

Before installing the battery, inspect its shelf life. To ensure the battery's standby life, install it within its shelf life, as shown in Figure 3-3.

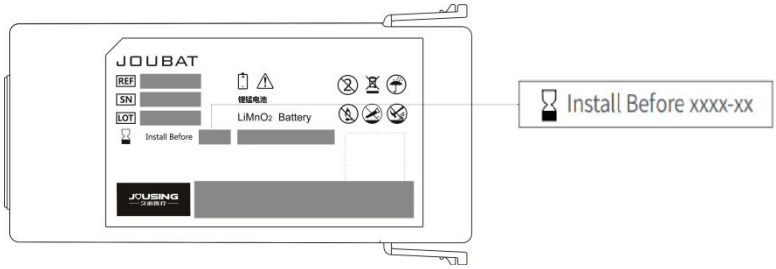
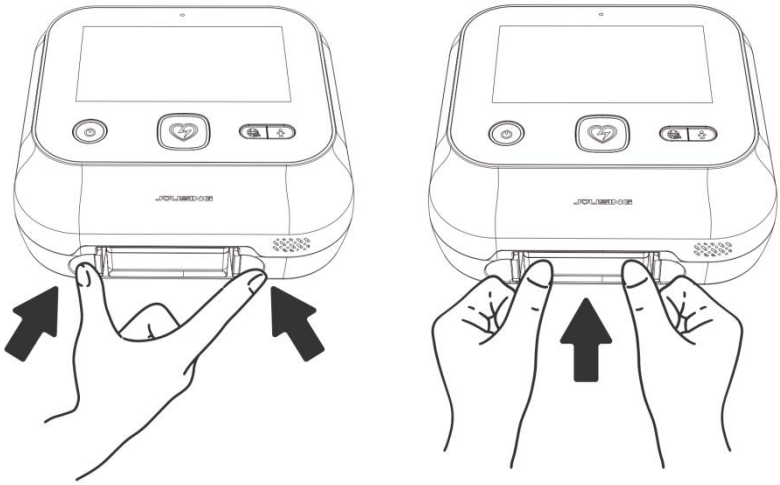


Figure 3-3 Shelf life of the battery

Follow the steps shown in Figure 3-4 a): lay the device flat, orient the battery with its label facing upward, and insert it into the battery compartment in the direction indicated by the arrow. Then, follow the step shown in Figure 3-4 b): push the battery into the compartment until you hear a “click” sound, which indicates that the side clips have engaged and the battery is securely in place.



a) Step 1: Press clip to open compartment

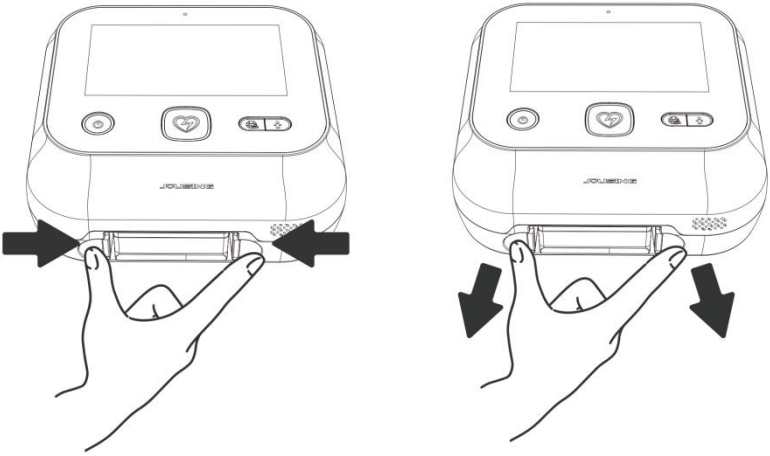
b) Step 2: Push battery into compartment

Figure 3-4 Inserting the battery

After the battery installation, the unit performs post-battery installation self-test. Refer to Section 3.5 for more details. If there are audio prompts during the self-test, follow the prompts to help complete the test, after which the device enters standby mode.

3.3.2 Remove the Battery

Replace the battery when the device prompts "*Battery low*" or "*Replace battery now*". To remove the battery, follow the steps shown in Figures 3-5 a) and b): place the device flat, press the clip, and pull out the battery from the compartment.



a) Step 1: Press clip

b) Step 2: Pull out the battery

Figure 3-5 Removing the battery

⚠ Caution: Do not remove the battery from the device unless required, nor frequently switch the device on and off. Verify that the device has sufficient battery power and is in normal standby mode. Replace the battery only when the device prompts "*Battery low*" or "*Replace battery now*" in standby mode.

⚠ Caution: When replacing the battery, wait at least 30 seconds after removing it before any further operation.

3.4 Check the Pads Connection

The pads socket of the iAED-M2 is designed to be foolproof. Use only the pads specified in this Manual.

Before connecting the pads, verify that the pads package is intact and within the expiration date. Replace the pads if otherwise.

Insert the pads connector vertically into the pads socket on the main unit, as shown in Figure 3-6, and ensure it is inserted right to the bottom. Do not remove the pads after connection unless required.

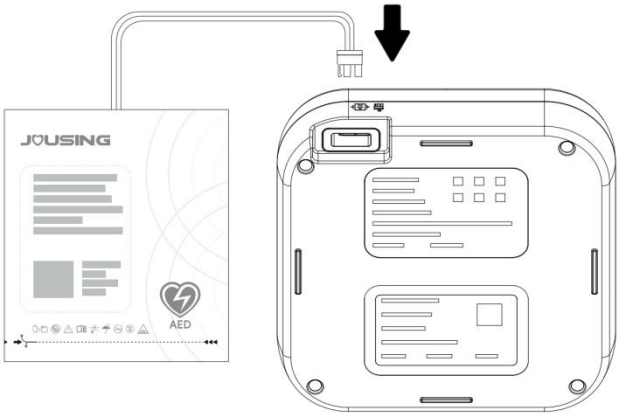


Figure 3-6 Inserting the pads connector

3.5 Battery Insertion Self-Test

After battery insertion, the iAED-M2 prompts "*Self-test initiated, press the green On/Off button in an emergency*". Then, the device performs the post-battery insertion self-test.

During the self-test, the device gives instructions for the users to perform button operation. Press buttons accordingly within 30 seconds after hearing a voice prompt, and the device immediately

provides the corresponding test result.

When the self-test is complete, the status indicator shows a solid green light, and the device prompts "*Device is ready for use*" if the test results are normal.

If any anomaly is detected, the status indicator shows an illuminated red light, and the voice prompts are:

1) "*Battery low*" or "*Replace battery now*" – The device battery runs low and needs to be replaced.

2) "*Defective operating temperature*" – The ambient temperature is abnormal, please relocate the device to a room temperature environment and remove the battery. Wait until the device returns to room temperature and put the battery back in. The device then runs another post-battery insertion self-test without the device failure alarm.

3) "*Service required*" – There are other errors, please contact Jousing Medical for service.

If the recommended actions are not followed, the device will announce "*Button test failed. Please reinstall the battery, and follow the voice instructions to complete the button test*." Reinsert the battery and comply with the voice instructions.

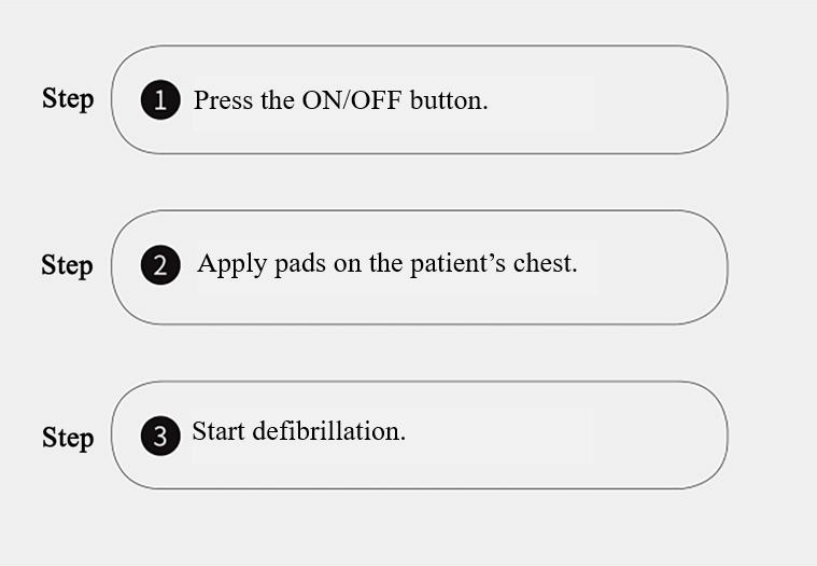
Upon the completion of the test, the device switches to standby mode. Do not remove the battery unless instructed to do so.

4 Operation

This section describes how to use the iAED-M2. The device guides the operator with voice prompts, indicators, and on-screen instructions throughout the rescue sequence.

When encountering a collapsed patient, first check their symptoms to see whether there is any suspicious symptom of SCA, such as unresponsiveness, absence of normal breathing or pulse, call the emergency medical services, and quickly get the AED and bring it to the patient's side. If there is any delay in getting the defibrillator, perform CPR immediately until the AED is available.

Three basic steps to use the AED:



4.1 Step 1: Turn on the Device

Press the ON/OFF Button to turn on the device. See Figure 4-1. After the device performs its self-test, the status indicator is illuminated: a solid green light indicates that the device is fully functional and has entered rescue mode. When a "*Di*" tone sounds and the voice "*Call for help now*" prompts, make sure that a phone call for emergency medical assistance has been made. The device screen will display the startup screen.

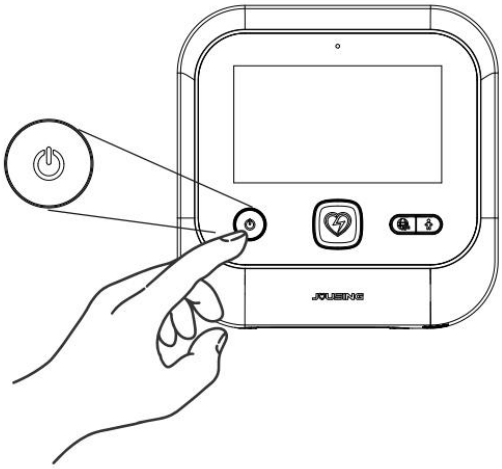


Figure 4-1 Turning on the device

If the operator is a healthcare professional, the device can be configured, upon request, to provide simplified prompts and to disable the voice prompt "***Call for help now***".

To change the spoken language, press the language-selection button (Figure 4-2). The device can switch among up to three

preconfigured voice languages.

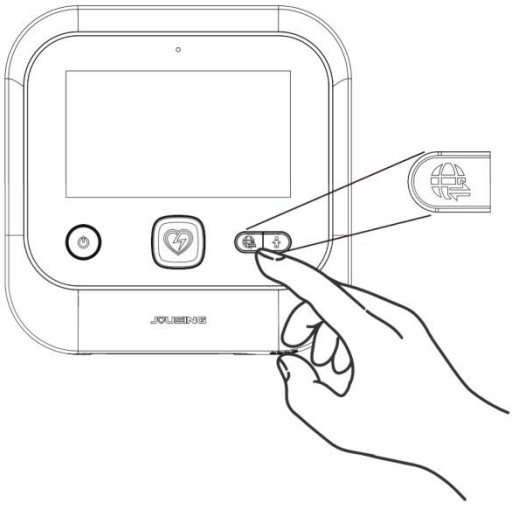


Figure 4-2 Language selection

4.2 Step 2: Apply the Pads

4.2.1 Patient Preparation

When the device prompts "*Remove all clothing from patient's chest*", do as follows:

- Remove all clothing covering the patient's chest, as shown in Figure 4-3.
- Clean and dry the patient's chest if it is wet.
- If the patient has excessive chest hair, shave the hair to bare the chest.
- Remove the jewelry and other accessories over the chest to avoid unwanted conductive paths.

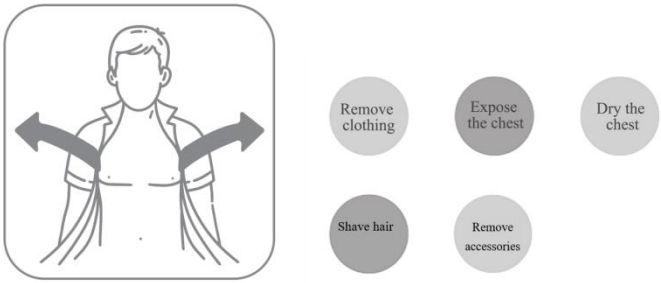


Figure 4-3 Removing all clothing from patient's chest

4.2.2 Insert the Pads Plug

In most cases, the pads are pre-connected, and the connector is plugged into the AED. Please check whether the pads connector is plugged into the socket; if not, insert the connector immediately. See Section 3.4 for proper operation. If the connector is plugged in, make sure it is inserted right to the bottom.

⚠ The device is equipped with universal pads suitable for both adult and child patients.

⚠ The device is in adult mode by default. For adult patients, no switching is required. For pediatric patients, press the CHILD MODE button to switch to child mode (see Figure 4-4); the child mode indicator will illuminate.

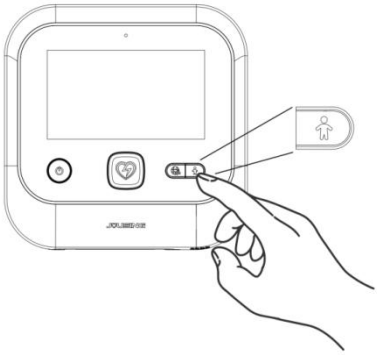


Figure 4-4 Changing shock mode

4.2.3 Tear Open the Pads Package

When the device prompts "*Tear open pads package and remove pads*", check the package to see if it is:

- Damaged;
- Within the expiration date (see Section 6.1.2).

If everything is fine, tear open the package as shown in Figure 4-5 and take out the pads. Then check the pads for:

- Damage;
- Impurities in the gel (such as dust);
- Dried-out gel or loss of contact with the skin when applied.

If any of the cases occurs, please replace the pads with new ones. (Only one pair for each device. A backup pair is recommended.)

Figure 4-5 Tearing open the pads package

4.2.4 Apply the Pads

The device prompts "*Peel one pad from the plastic liner*", "*Place the pad exactly as shown in the picture; press firmly onto the patient's bare skin*", "*Peel the second pad from the plastic liner*", "*Place the pad exactly as shown in the picture; press firmly onto the patient's bare skin*". See Figure 4-6 for how to separate the pads from the liner and Figures 4-7 and 4-9 for where to apply the pads. Place the pads on the patient exactly as the audio prompts suggest, and press firmly to ensure full contact with the skin. Once the pads are correctly applied, the device emits a "*DiDi*" tone.

⚠Caution: If the recommended placement area on the patient's body has a wound or other special situations, apply the pads on

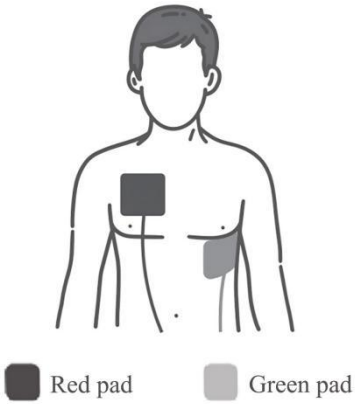
alternative areas instead. See Figures 4-8 and 4-10.

⚠Caution: If the patient has an implanted pacemaker, angle the pads accordingly to avoid placing them over the device.

If the pads are not properly applied, the device will repeat the voice prompts. If the pads are placed properly during any of these prompts, the device stops the prompts and starts to perform rhythm analysis. If the pads are not placed properly until timeout, the device will turn off.

Figure 4-6 Separating pads from plastic liner

- **Pads placement (adult)**

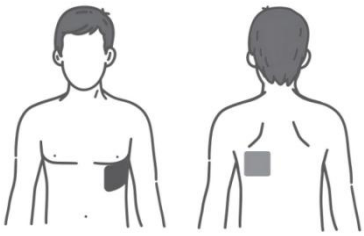


① Place the red pad on the patient’s right-side chest and below the collar bone.

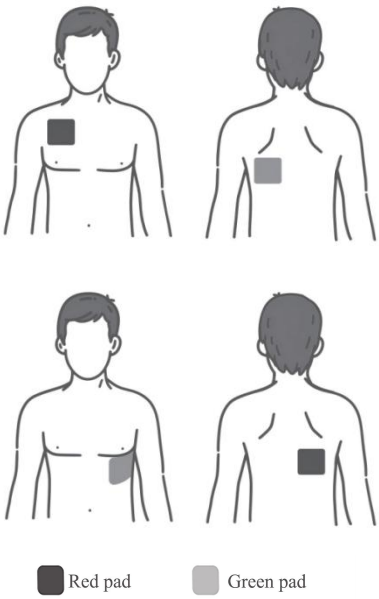
② Place the green pad on the patient's left rib and below the left-side chest.

Figure 4-7 Pads placement (adult)

If these placement areas are not available, choose one of the following.



① Front-back placement: Place the red pad on the 4th rib of the left sternum, and the green pad on the patient’s back and below the left scapula.

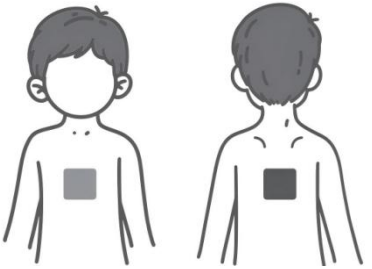


② Front-left scapula placement: Place the red pad on the patient's right-side chest and below the collar bone, and the green pad on the back, below the left scapula.

③ Front-right scapula placement: Place the green pad on the patient's apical area, and the red pad bellow the edge of the right scapula.

Figure 4-8 Alternative pads placement (adult)

- **Pads placement (child)**



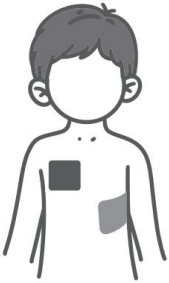
Red pad Green pad

① Place the green pad on the patient's chest and between the two nipples;

② Place the red pad on the patient's back and between the two scapulae.

Figure 4-9 Pads placement (child)

If the child is older or heavier, or these placement areas are not available, apply the pads as one of the following:



Red pad Green pad

① Place the red pad on the patient's right-side chest and below the collar bone;

② Place the green pad on the patient's left rib and below the left breast.

Figure 4-10 Alternative pads placement (child)

⚠ **Warning:** The pads should be placed squarely on the patient's bare skin, or it may cause inaccurate rhythm analysis or electrical burns.

⚠ **Note**: In an emergency, do not delay patient care due to voice prompts indicating pad expiration or malfunction, even if no spare pads are available.

4.3 Step 3: Initiate Defibrillation

4.3.1 ECG Rhythm Analysis

The defibrillator analyzes the patient's ECG signal and determines whether the rhythm is shockable or not. Meanwhile, the AED keeps monitoring the pads connection:

- When the device determines that the pads are not in good contact with the patient, the device prompts "*Poor pad contact to patient, press pads firmly*", "*Check connector.*" Rhythm analysis pauses, and the operator needs to re-apply the pads according to the diagram.
- When the pads are properly placed, the defibrillator prompts "*Do Not Touch Patient!*", "*Analyzing Heart Rhythm*." During the analysis, do not touch or shake the patient.
- When the device detects external interference (such as CPR being performed on the patient) that affects normal ECG acquisition, it voices the prompt "*Stop Motion*".

⚠ **Warning:** Do not touch or shake the patient during the rhythm analyzing process, or it may degrade the accuracy of the analysis results.

4.3.2 Shock Required

When the device detects a shockable rhythm, it prompts *"Shock*

advised", "Stand clear, Charging". Do not touch the patient while the device is charging.

While the device is charging, it continues to analyze the patient's heart rhythm. When the device detects a heart rhythm change to non-shockable state, it prompts "*Rhythm changed, shock cancelled*" and stops charging, and guides the operator to perform CPR.

The device stops charging if it detects any connection problem, and guides the operator to place the pads properly again.

If the patient's rhythm is shockable and charging is complete, there are two possible scenarios:

- The iAED-M2F (fully automatic model) will prompt the voice "Shocking will be delivered", "Move away from the patient immediately", "Deliver shock in 3, 2, 1", followed by the "DiDiDi...." tone. At this moment, do not touch the patient, the sickbed, or any conductive material connected to the patient. The device automatically delivers the defibrillation energy; no further action is required.

- The iAED-M2S (semi-automatic model) will prompt the voice "*Press flashing shock button*", and the defibrillation indicator will flash (as shown in the left figure). At this moment, follow the voice prompt and press the flashing shock button to deliver the shock.

After the shock is delivered, the device will issue the voice prompt "*Shock delivered*", and the defibrillation indicator will turn off.

⚠Caution: For the semi-automatic model iAED-M2S, if the operator

does not press the flashing Shock Button within 30 seconds, the device will prompt "*Shock button not pressed, shock cancelled*" and will then guide the operator to perform CPR. If the device detects that the patient's impedance exceeds the acceptable range, it will prompt: "*Make sure pad connector is plugged into AED*", and will prohibit energy output.

After each shock, the device guides the operator to perform CPR. See Section 4.3.4. After each CPR sequence, the device restarts rhythm analysis. If it still detects a shockable rhythm, it will be ready for another shock.

Watch the patient closely throughout the rescue. When the patient recovers consciousness, stop defibrillation immediately, and press and hold the ON/OFF Button to turn off the device.

If no shock is delivered after charging is complete, the device will internally and automatically discharge the energy to ensure the safety of the patient, the responder, and all nearby personnel.

⚠ **Warning:** Do not touch the patient during the charging and defibrillation processes.

4.3.3 No Shock Required

When the device determines that no shock is needed, it prompts "*No shock advised*", and instructs the operator to perform CPR. Refer to Section 4.3.4.

4.3.4 CPR

When the rhythm analysis result suggests no shock or a shock has been delivered, the device prompts "It is not safe to touch the patient, follow the rhythm for CPR", followed by the "Da, Da, Da"

tone and the operator should compress the patient's chest to the beat. After 30 compressions, the device prompts "Breath" twice and the user should perform artificial respiration two times for the patient. Repeat the compression-breath loop 5 times. The CPR prompts are set in line with the AHA guidelines by default, and can be set according to the ERC guidelines or customized. The compression-breath ratio can be set to 30:2 or 15:2, or keep the compression steps only.

During CPR, the device provides voice guidance and automatically adjusts prompts and the CPR Mode based on the patient type. CPR guidance is also displayed on the device screen, as shown in Figure 4-11.

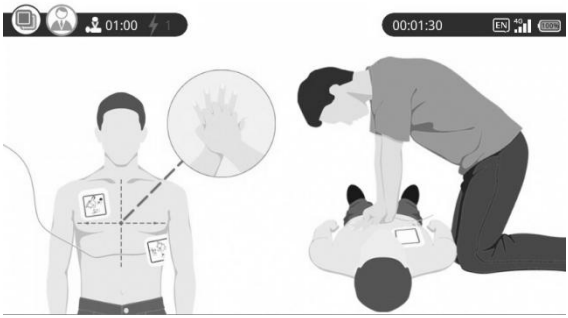


Figure 4-11 CPR screen display

When the CPR is complete, the device prompts "Stop CPR". After hearing two "DiDi" tones, the device will reinitiate rhythm analysis. Do not touch the patient during this time.

⚠Caution: Press the ON/OFF Button to activate rescue mode. If necessary, even when the device is in management mode, or under post-battery insertion self-test, periodic self-test etc.

⚠Caution: In rescue mode, the touchscreen is disabled and will not respond to touch.

⚠Caution: In the case that the device needs to be turned off during operation, press the ON/OFF Button and hold for at least 3 seconds until the device beeps three times in a "Di, Di, Di" pattern, and then powers off.

⚠Caution: There is no need to remove the attached pads during CPR.

5 Management Mode

This section mainly describes the functions available in management mode, including network settings, training mode, device maintenance, and advanced parameter configuration.

Press and hold the power button while inserting the battery to enter Administration Mode.

In management mode, device parameters can be configured. For devices equipped with the optional touchscreen, parameters can also be configured directly via the touchscreen interface. For non-touchscreen devices, users requiring parameter configuration can contact Jousing Medical After-Sales Service.

Upon entering Administration Mode on touchscreen models, four options are displayed: “Network Settings”, “Training Mode”, “Device Maintenance”, and “Advanced Param Config”. The functions and operating procedures for each option are described below.

After entering the management mode, devices with network capabilities will automatically upload internal data (refer to Section 6.6 “Data Management”) to the AED management platform.

5.1 Network Settings

Before shipment, devices are configured with mobile communications, Wi-Fi, or Bluetooth according to user requirements. Devices configured with cellular or Wi-Fi support network settings. Cellular is connected to the network automatically, while Wi-Fi requires users to manually configure the

Wi-Fi SSID and password.

For touchscreen models, after entering Administration Mode, select [Network Settings] to configure the [Wi-Fi SSID] and [Wi-Fi Password].

Users of the touchscreen model can configure the network connection toggle, self-test upload frequency, and rescue data upload schedule in the Network Settings interface. For details, refer to Appendix J-1.

5.2 Training Mode (applicable only to devices configured with touchscreens)

This device features a Training Mode that enables users to quickly learn the basic operation of the device through simulated procedures.

The steps for training are as follows:

- Enter management mode and tap [Training Mode] on the touchscreen;
- The device will automatically restart and display the training interface;
- Follow the instructions displayed on the screen;
- Tap  on the touchscreen to proceed to the next step;
- To exit training mode, press and hold the power button for 3 seconds.

⚠ Caution: To preserve readiness for real emergencies, do not open the pad package during training. The standard pads provided with the device are disposable defibrillation pads. Once opened,

they are valid for only 24 hours.

⚠ Caution: One hour of training mode use can consume approximately 8% of battery capacity. After completing the training, verify that the battery is in good condition.

5.3 Device Maintenance

In management mode on touchscreen models, tap [Device Maintenance] on the touchscreen to enter the device maintenance interface. This interface provides functions such as device activation, pad replacement (instantly updating the pad expiration date on the AED management platform), device information viewing, and access to self-test reports.

5.4 Advanced Param Configuration

In management mode on touchscreen models, tap [Advanced Param Configuration] on the touchscreen, and enter the password to access the device's advanced parameter configuration interface.

The device's default password is 251030, which can be modified under [Advanced Param Configuration] → [General] → [Password]. If the password is forgotten after modification, please contact Jousing Medical After-Sales Service.

Within Advanced Param Configuration, users can configure general parameters, rescue parameters, and self-test settings. For details, refer to Appendix J-2: Advanced Parameter Configuration.

⚠ **Warning**: Modifying default advanced parameters may affect data rescue efficiency and should be performed only by senior device administrators who have received professional training.

6 Maintenance

The device does not require any additional tests other than regular self-tests as it is thoroughly examined before leaving the factory. Please contact Jousing Medical if any additional testing is required according to local laws and regulations or as requested by licensed professionals.

Both routine maintenance and cleaning should be conducted on a regular basis. Users may conduct troubleshooting for common problems by following the instructions below.

6.1 Routine Maintenance

Perform regular maintenance to ensure device readiness. See Table 6-1 for the recommended frequency of routine maintenance.

Table 6-1 Routine maintenance checklist

Daily	Monthly	After Each Use	Action
●	●	●	Check the status indicator
	●		Check the expiration date of pads
	●	●	Check for the completeness of parts
		●	Replace the pads

6.1.1 Check Status Indicator

The device status indicator is located on the top of the device and indicates the operational status, as shown in Figure 6-1. The device automatically runs real-time self-tests whilst being used for rescuing and periodic self-tests whilst in standby mode (ready for use). Different colours of the status indicator imply different results of the self-test. If the status indicator is blinking in green, the device is ready for use. If blinking in red, the user should switch into the management mode, and receive voice prompts to address

the problem accordingly.

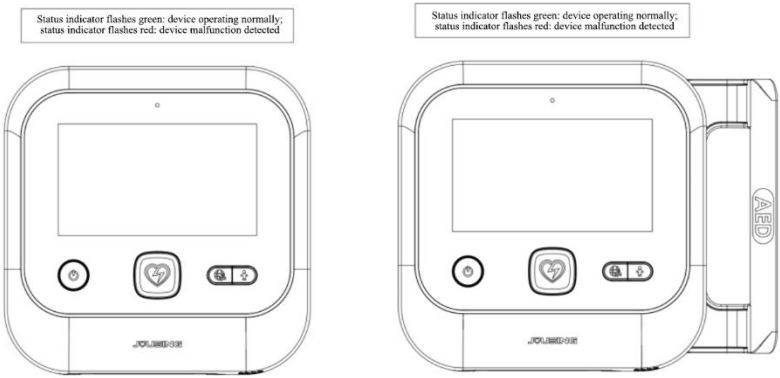


Figure 6-1 Status indicator

- If the device issues the voice prompt *"Battery low"*, replace the battery;
- If the device issues the voice prompt *"Service required"*, contact Jousing Medical immediately for service.

6.1.2 Check Pads Expiration Date

The pads are disposable. Check the expiration date of pads on outer packaging periodically. Pads expiration date is displayed next to the expiration symbol on the pad label.

6.1.3 Check Device Integrity

For inspection of device component integrity, refer to Section 3.2.1 for details.

Check whether the device is clean. If not, refer to Chapter 7 for cleaning instructions.

Check if the exterior of the device is damaged, especially near the

plug and the plug socket of the pads. If there are any signs of damage, contact Jousing Medical for technical support.

Check if the pads packaging is damaged. If there is any damage, contact Jousing Medical for replacement.

6.1.4 Post-Use Maintenance

After each use, press the ON/OFF button to switch the device into standby mode and perform maintenance for the pads and the battery according to the instructions below:

Remove the used pads. Place new pads into the pads socket of the main unit and make sure they are completely inserted according to Section 3.4.

Remove the battery and wait for at least 30 seconds. Then re-install the battery to run a self-test. If the device issues the voice prompt *"Battery low"* or *"Replace battery now"* , replace the battery with a new one. For battery removal and installation, refer to Section 3.3. If the result of the battery installation self-test is normal, no further action is required.

> ⚠ **Warning:** Only choose from approved pads and battery listed in Annex A.

6.1.5 Battery Maintenance

The battery provided is non-rechargeable. It may drain or deplete in standby mode and training mode or after defibrillation.

Check battery expiration date before installation. After the battery is installed, the AED device will perform self-tests on the battery to monitor the remaining power and provide users feedback via the status display and voice prompts. See Table 6-2 for battery

conditions and corresponding actions to take:

Table 6-2 Battery maintenance

Battery Condition	Device Indication & Prompt	Corrective Action
Low battery when device is on	The device issues the voice prompt *"Battery low"* or *"Replace battery now"*. Status indicator blinks in red.	If a rescue operation is required at the moment, replace the battery as soon as the rescue is over. Otherwise, replace the battery immediately.
Low battery when device is in standby mode	The device emits a *"DiDi"* sound every four minutes, and Status indicator blinks in red.	Replace the battery.
Low battery when device is in management mode	The device issues the voice prompt *"Battery low"*. Status indicator remains red.	Replace the battery.
Low battery when device is being used for rescuing	The device issues the voice prompt *"Battery low"*. Status indicator remains red.	Replace the battery after performing current rescue operation.
Battery depleted	Status indicator is off.	Replace the battery.

⚠ Caution: When the AED device issues the first low-power warning, it can still deliver at least 10 shocks or provide 30-minute continuous monitoring. However, for the device's proper long-term operation, please replace the battery immediately if a low battery condition occurs. Only one battery is provided with the device when delivered, and users are recommended to purchase an additional battery for backup

6.2 Storage Environment

Store the main unit and accessories (pads and the battery) in a well-ventilated area with a suitable temperature. Keep them away from direct sunlight, moisture, and dust. Specific requirements are as follows:

- Temperature for normal storage: 0 ℃ to 50 ℃;
- Temperature for temporary storage: -40 ℃ to 70 ℃, for ≤ 24 hours;
- Recommended storage temperature: 5 ℃ to 35 ℃
- Relative humidity: 5% RH to 95% RH (non-condensing);
- Do not store the device in direct sunlight;
- Do not store the device near high-voltage electrical lines, substations, and Wi-Fi base stations or other facilities with strong electromagnetic fields;
- During storage, ensure the battery is inserted into the main unit, and the pads are properly connected to the main unit.

6.3 Transportation Environment

The device can be transported by general vehicles but should avoid violent shocks and vibration, and prevent from getting wet by rain/snow. Specific requirements are as follows:

- Temperature: 0 ℃ to 50 ℃;
- Temperature limit: -40 ℃ to 70 ℃, for ≤ 24 hours;
- Relative humidity: 5% RH to 95% RH (non-condensing).

If the device is to be returned for maintenance, the battery should be removed (see Section 3.3.2), packed individually and transported with the device together.

6.4 Operating Environment

The device's operating conditions are:

- Temperature: 0 ℃ to 50 ℃;
- Relative humidity: 5% RH to 95% RH (non-condensing);
- Atmospheric pressure: 480 hPa (altitude 5920 m) to 1060 hPa

(altitude -390 m).

The device can operate for at least 60 minutes at a temperature of -20 °C.

The device requires 1 hour to reach normal operating conditions after being transferred from its minimum or maximum storage temperature to 20 °C.

Do not use the device in the presence of flammable gases or electrically conductive materials such as water below a patient's body, or in an oxygenated or strong electromagnetic environment.

When the device is operated in a 50 °C ambient environment, the maximum temperature of the applied part may reach 52 °C.

6.5 Disposal

To avoid environmental degradation, the device and its battery should be disposed of in accordance with local regulations. The pads should be treated as medical waste when disposed. When in doubt, contact Jousing Medical for assistance.

6.6 Data Management

The device records and stores operating data including rescue, self-test, and event log data in its internal memory. The stored data can be conveniently transferred to and reviewed on a PC with appropriate devices and software. The device supports wireless exporting of self-test and rescue reports. To access the stored data, please contact Jousing Medical. See Table 6-3 for types of stored data in the device:

Table 6-3 Types of data

Type	Description

Rescue Data	Patients' ECG, impedance, and recording data from rescue mode.
Self-test Data	Data generated during periodic self-tests, battery insertion self-tests and power-on self-tests. The maximum storage is 4,000 pieces.
Event Log Data	All event data during operation, including turn on/off, the device status (location included), rescue time, pads attachment, button operation, rhythm analysis, and charge/discharge. The maximum storage is 40,000 pieces.

The device stores data from the last 2 rescues, with a maximum time of 80 minutes. Rescue data can be selectively exported.

6.7 Self-Test Function

The device regularly performs a self-test to verify its usability. See Table 6-4 for self-test items.

The device performs battery insertion self-tests, user self-tests, and periodic self-tests. The monthly self-test covers all self-test components of the device.

When the self-test is completed, the indicator will automatically light up to show the results. A green light indicates good conditions for use. A red light indicates the device has failed its self-test and requires troubleshooting.

Users should check the status indicator in time. See Section 6.1 for the recommended frequency of routine maintenance.

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Table 6-4 Self-test sheet

Category / Item	Battery Insertion	Power-on	Daily	Weekly	Monthly
Battery	√	√	√	√	√
Power Circuitry	√	√	√	√	√

Processor		√	√	√	√	√
Temperature Circuitry		√	√	√	√	√
LED Circuitry		√	/	√	√	√
LCD Circuitry		√	/	/	/	√
Buttons		√	/	√	√	√
ECG Circuitry		√	/	√	√	√
Impedance Circuitry		√	/	√	√	√
Relay Circuitry		√	/	/	/	√
High Voltage Circuitry	Charge Circuitry L1	√	/	/	√	√
	Discharge Circuitry L1	√	/	/	√	√
	Charge Circuitry L2	√	/	/	/	√
	Discharge Circuitry L2	√	/	/	/	√
Storage Circuitry		√	√	√	√	√
Voice Circuitry		√	/	/	/	√
Notes: 1. "√" indicates "included"; "—" indicates "excluded". 2. L1 indicates low-capacity; L2 indicates high-capacity.						

6.8 Battery Life Cycle Traceability Management Function

The life cycle of the device's battery can be traced and managed, as the information about its production, use and any abnormalities is monitored and recorded in real time to ensure its normal functioning. The following information is recorded by the battery

and can be exported.

a) Battery production: production date, serial number, model, and expiration date;

b) Battery usage: the number of uses, total operating time, power on/off time, remaining power, real-time voltage & current, and real-time temperature;

c) Battery abnormality detection: abnormal temperature, voltage, load status, and duration of abnormal voltage drops and low power.

6.9 Troubleshooting

Table 6-5 Troubleshooting

Symptom	Possible Cause	Corrective Action
Device cannot be turned on.	Battery is not inserted.	Insert a battery.
	Battery is depleted.	Replace with a new battery.
	Defibrillator malfunction.	Contact Jousing Medical for service.
Status indicator is off.	Battery is depleted.	Replace with a new battery
	Status indicator is non-functional.	Contact Jousing Medical for service.
	Defibrillator malfunction.	
After turning on the iAED-M2, one or more lights do not light up.	One or more lights are damaged.	Do not use the device, contact Jousing Medical for service.
	Battery is low or depleted.	Replace the battery.
Status indicator is solid in red, and the iAED-M2 prompts “battery low” during rescue.	Battery is low.	Replace with a new battery immediately after performing this rescue.
Status indicator is solid in red, and the iAED-M2 prompts “replace battery now” in rescue.	Battery is depleted.	Replace with a new battery immediately.
Status indicator is solid in red, and the iAED-M2 prompts “Service required” during rescue.	Defibrillator malfunction.	Contact Jousing Medical for service.

The iAED-M2 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 applied to the right location.
	Pads are not making good contact with the patient.	Dry the patient's chest and shave or clip excessive chest hair, and make sure the pads are not touching 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-M2 prompts "stop motion" during rescue.	Patient is moving.	Check patient's breathing.
	Someone is touching/moving the patient or doing CPR to the patient.	Stop touching/moving the patient.
	Vehicle is moving.	Stop the vehicle during analysis, if possible.
The iAED-M2 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 with a new battery.
Device turns off immediately during rescue.	Battery is depleted.	Replace with a new battery
	The defibrillator needs repair.	Contact Jousing Medical for service.
The iAED-M2 prompts "Service required" 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-M2	Battery is low.	Replace with a new battery immediately after

prompts “Battery low” in battery insertion self-test.		performing this rescue. Or, replace a new battery immediately.
Status indicator is solid in red, and the iAED-M2 prompts “Replace battery now” in battery insertion self-test.	Battery is depleted.	Replace with a new battery immediately.
Status indicator is solid in red, and the iAED-M2 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-M2 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 need. Or, place the device at room temperature, and wait for 10 minutes, then reinstall the battery. Self-test will run automatically to eliminate equipment failure alarm.
Status indicator flashes in red, and the iAED-M2 is chirping in standby mode.	Battery is low.	Replace with 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. Self-test will run automatically to eliminate equipment failure alarm.

⚠Warning: In an emergency, if the defibrillator cannot be turned on or has other problems which cannot be solved readily, continue the rescue with another defibrillator.

Possible case and its cause.

Table 6-6 Possible case

Symptom	Possible Cause	Corrective Action
The iAED-M2 prompts "rhythm changed, shock cancelled".	Patient's ECG changed from a shockable to non-shockable rhythm; no shock is advised. The device is functioning normally.	No action required.

6.10 Remote Management

Devices configured with network capabilities can be managed in the background through Wi-Fi or cellular, allowing device information to be viewed. This allows maintenance personnel and users to directly view information about the device status, the expiration date of pads, battery power, and device location. The backend management server will send warnings about abnormal device status, expired pads, or low-power battery to maintenance personnel for timely attention. The device's internal data (rescue data, self-test data and event log data) can be uploaded to the backend server after each rescue. The iAED-M1 also includes functions such as "maintenance request" and "inspection check-in".

Figure 6-3 Remote management

7 Cleaning

Regularly clean dust and dirt from the device surface.

Recommended cleaning products:

- Soapy water;
- Chlorine bleach (10%);
- Ethanol;
- Isopropyl alcohol;
- Hydrogen peroxide (3%).

Follow the steps below to clean the device:

(1) Turn off the device and remove the battery;

(2) Use a soft cloth dampened in the cleaning agent to clean the device surface. Do not immerse the device in water or allow fluids to spill onto it;

(3) Clean the excess agents with a dry cloth if necessary;

(4) Ensure the device is completely dry before reinstalling the battery;

(5) Do not use strong solvents (e.g. isopropyl ketone, acetone), abrasives, or other unauthorized chemicals to clean the device.

When necessary, you can clean the device according to the disinfection regulations of your local hospitals or other medical institutions.

⚠ Note: Residual cleaning agents may cause touchscreen malfunction. Wipe any cleaning agent from the touchscreen surface immediately after cleaning.

8 Product Warranty

The manufacturer provides a limited warranty in product warranty period.

Cases below are not in warranty:

- Violation of the instructions for use.
- Operating error.
- Improper use or handling.
- Disassemble the device by unauthorized personnel.
- Damage caused by force majeure, such as lightning, etc.
- Transport damage caused by improper packaging during return shipping.
- Failure to perform required device maintenance.
- Excessive wear of the device enclosure.

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

9 List of Parts

Table 9-1 List of parts

Item	Model	When to Replace	How to Replace
Battery	JXMB0942	Device prompts *"Battery low"*; Device prompts *"Replace battery now"*; Battery is damaged.	See Section 3.3
Pads	JOUPAD-A01 (3 years) JOUPAD-A02 (5 years)	Pads past expiration date; After use; Pad or packaging is damaged.	See Section 3.4

Note: To ensure the battery's standby life, do not place a network-configured AED in areas with poor signal reception, and avoid frequent power-on/off cycles.

10 Annex

A Optional Accessories

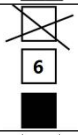
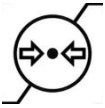
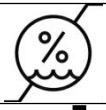
1. Back clip.
2. Device carrying bag.
3. Wall-mounted cabinet.
4. Standing cabinet.
5. Toolbox, containing scissors, a razor, a towel, etc.

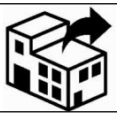
Contact Jousing Medical for accessory specifications.

B Device Symbols

The following symbols may appear on the device.

Symbol	Description	Symbol	Description
IP66	Protected against dust and jets of water		Defibrillation protected, type BF applied part
	ON/OFF button		SHOCK button (on semi-automatic devices) SHOCK indicator (on fully automatic devices)
	LANGUAGE button		CHILD MODE button
	Electrode pads plug		Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations.
	Lithium manganese dioxide battery		Do not place near an open flame, heat above 100 °C (212 °F), or incinerate
	Do not crush, puncture, or disassemble		Do not crush, puncture, or disassemble the battery
	Refer to instruction manual		Non-ionizing electromagnetic radiation
	Use-by date		Not made with natural rubber latex
	Do not use if package is damaged and consult		Non-sterile

Symbol	Description	Symbol	Description
	instructions for use		
	Do not reuse		Package contents: one set of two defibrillation pads
	Keep away from sunlight		Fragile, handle with care
	Keep dry		Stacking limit by 6
	Caution		This way up
	Atmospheric pressure limitation		Symbol for China RoHS indicating the Environmentally Friendly Use Period (EFUP) denoting the number of years before any substance is likely to leak out into the environment.
	Humidity limitation		Temperature limit
	Manufacturer		Authorized EC representative
	Date of manufacture		Unique device identifier
	Lot number		Serial number

Symbol	Description	Symbol	Description
	Model		Importer
	Distributor		Medical Device
	Mark of conformity to applicable European Directives		Warning, high voltage

C Glossary of Terms

GLOSSARY	Meaning
The device	The iAED-M2.
User	Person who operates the defibrillator.
Power-down status	Status of the device when the battery is not inserted.
Standby	Status of the device when it is installed with battery but not turned on.
Rescue status	Status of the device when the device is turned on (guide the user to perform rescue by voice and light prompts)
Turn on	The device switches 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 in standby mode. These tests check the battery, internal circuit, buttons, software, and other critical functions.
Sudden cardiac arrest, SCA	The abrupt termination of cardiac ejection function, ventricular fibrillation is the most common cause of 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 does not require a shock.
Sensitivity	If positive, the probability of detection is not missed.
Specificity	If negative, 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 parts. The pads are applied to the patient's bare skin and used to detect the patient's heart rhythm and to deliver the defibrillation shock.
Manufacturer	Jousing Medical Co., Ltd.
ECG	Electrocardiogram.
CPR	Cardiopulmonary Resuscitation. A lifesaving technique that is to rescue cardiac arrest patients with artificial respiration and chest compression.
bpm	Beat per minute.

D Specifications

Physical Specifications	Dimensions (L × W × H)	Without back clip: 170 mm × 169 mm × 54 mm (± 10 mm) With back clip: 170 mm × 208 mm × 65 mm (± 10 mm)
	Total weight (including battery, electrode pads, and back clip)	1.2 ± 0.2 kg
	Main unit weight	0.8 ± 0.2 kg
Environmental Specifications	Operating environment (with battery and pads)	Temperature: 0 °C to 50 °C (the device can operate for at least 60 minutes after being transferred from room temperature to a -20 °C environment); Relative humidity: 5% RH to 95% RH (non-condensing); Atmospheric pressure: 480 hPa (altitude 5920 m) to 1060 hPa (altitude -390 m).
	Storage environment (with battery and pads)	Storage temperature: 0 °C to 50 °C; Extreme temperature: -40 °C to 70 °C, for at least 24 hours; Recommended long-term storage temperature: 5 °C to 35 °C Relative humidity: 5% RH to 95% RH (non-condensing).
	Transportation environment (with battery and pads)	Temperature: 0 °C to 50 °C; Extreme temperature: -40 °C to 70 °C, for at least 24 hours; Relative humidity: 5% RH to 95% RH (non-condensing).
Defibrillation Specifications	Defibrillation waveform	Biphasic truncated exponential. Waveform parameters are automatically adjusted to patients' impedance.
	Energy level	With 50 Ω impedance, Adult mode output energy: 150 J; Child mode output energy: 50 J.
	Output control	iAED-M2S is a semi-automatic defibrillator; iAED-M2F is a fully automatic defibrillator
	Compensation range	25 Ω ~ 200 Ω
	Post-defibrillation recovery time	≤ 2 s

	Charge time	Under ambient temperature of 20 °C ± 2 °C, in Default Mode: a) With a new, fully charged battery, the time from the start of charging to readiness for a 150 J shock is within 10 seconds; b) With a battery discharged 6 times at maximum energy, the time from the start of charging to readiness for a 150 J shock is within 10 seconds; c) With a new, fully charged battery, the time from the start of rhythm analysis to readiness for a 150 J shock is within 14 seconds; d) With a battery discharged 6 times at maximum energy, the time from the start of rhythm analysis to readiness for a 150 J shock is within 14 seconds; e) With a new, fully charged battery, the time from turning on the AED to readiness for a 150 J shock is within 20 seconds; f) With a battery discharged 6 times at maximum energy, the time from turning on the AED to readiness for a 150 J shock is within 20 seconds. Under ambient temperature of 20 °C ± 2 °C, in simple prompt mode: a) With a new, fully charged battery, the time from the start of charging to readiness for a 150 J shock is within 10 seconds; b) With a battery discharged 6 times at maximum energy, the time from the start of charging to readiness for a 150 J shock is within 10 seconds; c) With a new, fully charged battery, the time from the start of rhythm analysis to readiness for a 150 J shock is within 10 seconds; d) With a battery discharged 6 times at maximum energy, the time from the start of rhythm analysis to readiness for a 150 J shock is within 10 seconds; e) With a new, fully charged battery, the time from turning on the AED power to completion of preparation for a 150 J shock is within 13 seconds; f) With a battery discharged 6 times at maximum energy, the time from turning on the AED power to readiness for a 150 J shock

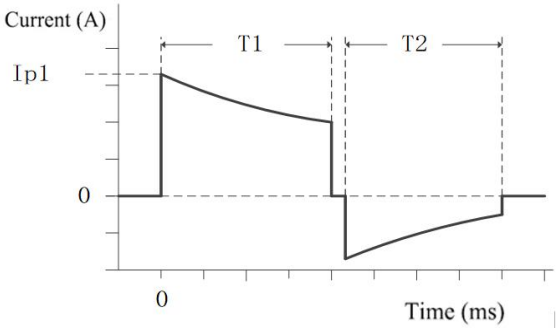
<table>
<tr><td></td><td></td><td>is within 13 seconds.</td></tr>
<tr><td rowspan="3">Safety Specifications</td><td>Electrical safety</td><td>Complies with IEC 60601-1, IEC 60601-2-4, IEC 60601-1-11, and IEC 60601-1-12.</td></tr>
<tr><td>Electromagnetic compatibility</td><td>Complies with IEC 60601-1-2 and IEC 60601-2-4.</td></tr>
<tr><td>Basic performance</td><td>Deliver defibrillation therapy
Accurately differentiate between shockable and non-shockable rhythms</td></tr>
<tr><td rowspan="3">Pad Specifications</td><td>Type</td><td>Self-adhesive disposable defibrillation pads</td></tr>
<tr><td>Length</td><td>120 cm ± 12 cm.</td></tr>
<tr><td>Active surface area</td><td>100 ± 10 cm^2;</td></tr>
<tr><td rowspan="4">Battery Specifications</td><td>Battery type</td><td>Non-rechargeable, lithium manganese dioxide ($LiMnO_2$) battery, DC12V;
Battery model: JXMB0942;
Capacity: 4.2Ah.</td></tr>
<tr><td>Number of shocks</td><td>With a new battery:<table><tr><td>Ambient temperature</td><td>150 J</td></tr><tr><td>20 ℃ ± 2 ℃</td><td>≥ 300 shocks</td></tr><tr><td>0 ℃ ± 2 ℃</td><td>≥ 250 shocks</td></tr><tr><td>-10 ℃ ± 2 ℃</td><td>≥ 150 shocks</td></tr></table></td></tr>
<tr><td>Continuous monitoring time</td><td>≥16 hours of non-shockable rhythm analysis and CPR guidance (using a new battery in 20 °C ± 2 ℃ environment); The product features CPR guidance (2 minutes per CPR period) by default. It is classified as an infrequently used device.</td></tr>
<tr><td>Shock times or monitoring time when battery is low</td><td>With a new battery at 20 °C ± 2 ℃, after the initial low-battery warning, the device allows ≥ 10 shocks and ≥ 30 minutes of continuous monitoring.</td></tr>
<tr><td colspan="2">Battery Life</td><td>Shelf life at ambient temperature (before battery installation): ≥ 5 years.</td></tr>
<tr><td colspan="2">Battery Standby Life (After Battery Installation)</td><td>At 20 ℃ ± 5 ℃, with a new battery installed, monthly self-tests are performed; the device is left powered off in standby; self-test results are not transmitted via network</td><td>≥ 7 years</td></tr>
</table>

	At 20 °C ± 5 °C, with a new battery installed, weekly self-tests are performed; the device is left powered off in standby; self-test results are not transmitted via network	≥ 6 years
	At 20 °C ± 5 °C, with a new battery installed, daily self-tests are performed; the device is left powered off in standby; self-test results are not transmitted via network	≥ 5 years
	At 20 °C ± 5 °C, with a new battery installed, daily self-tests are performed; the device is left powered off in standby; self-test results are transmitted via network monthly	≥ 4 years
	At 20 °C ± 5 °C, with a new battery installed, daily self-tests are performed; the device is left powered off in standby; self-test results are transmitted via network weekly	≥ 3 years
	Note: To ensure battery's standby life, do not place network-enabled AEDs in locations with poor network signals and do not turn them on and off frequently.	
Pad Life	JOUPAD-A01: 3 years; JOUPAD-A02: 5 years;	
Main Unit Life	12 years when stored and maintained according to the manual instructions.	
Wireless Communication	The device supports wireless communication: Bluetooth (BR/EDR and BLE), Wi-Fi (IEEE 802.11 b/g/n), and cellular (4G/5G).	
Positioning	Devices equipped with cellular or positioning modules support automatic location acquisition.	
CPR Prompts	During CPR, the device provides CPR guidance to the operator. The CPR mode defaults to the AHA guideline recommended mode and can be configured to the ERC guideline recommended mode and user-defined mode. The compression-to-ventilation ratio can be configured as 30:2,	

	15:2 or chest compressions only.
Case Protection	IP66
Drop	Complies with IEC 60068-2-31; each of the six surfaces is dropped from a height of 1.5 meters.
Shock	Complies with IEC 60601-1-11 and IEC 60601-1-12.
Vibration	Complies with IEC 60601-1-11 and IEC 60601-1-12.
Transport	Complies with IEC 60068-2-53.

E Defibrillation Waveform

The device delivers a Biphasic Truncated Exponential waveform, with its current and duration automatically adjusted to the patient's impedance.



Attached Figure E-1 Defibrillation energy waveform

Attached Table E-1 Defibrillation energy at various impedance levels

Operating Mode		Adult Mode	Child Mode
Energy Level		150 J	50 J
Impedance	25 Ω	128 J	43 J
	50 Ω	150 J	50 J
	75 Ω	155 J	52 J
	100 Ω	157 J	52 J
	125 Ω	159 J	52 J
	150 Ω	160 J	50 J
	175 Ω	158 J	48 J
	200 Ω	156 J	46 J
Accuracy		15%	

F Rhythm Analysis Algorithm

Patient Analysis System

The Patient Analysis System ensures that the pads are firmly attached to the patient and 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 are removed from the ECG signal and the ECG signal is digitized. In the ECG signal processing stage, artifacts are identified and removed from the patient's ECG signal (artifacts may arise from a variety of sources, including patients' motion, respiration muscular contractions, and pacemakers.).

Rhythm Analysis System uses a number of parameters to analyze the ECG rhythm, including ECG signal amplitude, consistency, period, spectrum, etc.

Shockable Rhythm Criteria

When the patient's symptoms are consistent with suggested criteria, the device is designed to recommend a defibrillation shock when it detects proper pad impedance and ventricular fibrillation or ventricular tachycardia. It can also detect normal sinus rhythm, asystole and all other non-shockable rhythms.

The device is designed to detect and analyze all shockable and non-shockable rhythms defined in GB 9706.8-2009, as shown below. When any non-shockable rhythm is detected, the device will prompt the user to perform CPR.

Patient Analysis System Performance

Jousing established the ECG database named Jousing_ECG_DB, which includes the world's recognized authoritative ECG database samples (MITDB, AHADB, CUDB and EDB, etc.), the ECG database with noise stress test (The MIT-BIH Noise Stress Test Database), and collected ECG data of various arrhythmias from Chinese patients.

The heart rhythm analysis algorithm was tested according to the Jousing_ECG_DB. The results are as follows:

Table F-1 Rhythm analysis performance

Rhythm Type		Sample Size	Result Statistics	Result Interpretation [1]	Lower Limit of 90% Confidence Interval
Shockable Rhythms	Ventricular fibrillation (ventricular flutter)	214	Sensitivity 99.5%	Complies > 90%	98.7%
	Ventricular tachycardia	53	Sensitivity 94.3%	Complies > 75%	89.1%
Non-shockable Rhythms	Normal sinus rhythm	423	Specificity 100%	Complies > 99%	99.6%
	Other rhythms (including rhythms with premature ventricular contraction (PVC) features, supraventricular tachycardia, sinus bradycardia, atrial fibrillation, atrial flutter, cardiac conduction block, ventricular escape rhythm, and paced rhythm)	496	Specificity 99.2%	Complies > 95%	98.5%
	Asystole	125	Specificity 100%	Complies > 95%	99.4%

[Note 1] The criteria for result interpretation are based on the

requirements of IEC 60601-2-4:2018, Section 201.107.

Based on the statistics,

1. The false positive rate for non-shockable rhythms is 0.4%;
2. The positive predictive value is 98.5%.

According to the AHA recommendations and AAMI standard DF80, supraventricular is classified into non-shockable rhythms.

G Electromagnetic Compatibility

This appendix provides guidance and manufacturer's declaration of electromagnetic compatibility.

Electromagnetic Emissions

Table G-1 Guidance and manufacturer's declaration -electromagnetic emissions

The iAED-M2 is intended for use in the electromagnetic environment specified below. The user of the iAED-M2 should ensure that the device is operated within these conditions.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The iAED-M2 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-M2 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	

Electromagnetic Immunity

Essential Performance

The iAED-M2's essential performance (deliver defibrillation therapy, and accurately differentiate between shockable and nonshockable rhythms) is both clinically acceptable and meets basic safety when operated in the electromagnetic environment specified in the following tables.

Table G-2 Guidance and manufacturer's declaration - electromagnetic immunity

The iAED-M2 is intended for use in the electromagnetic environment specified below. The user of the iAED-M2 should ensure that the device is operated within these conditions.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment -Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	+1 kV line(s) to line(s) +2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T during 1/2 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 70% U_T during 25/30 cycles Single phase at 0°	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	
Note: U_T is the AC Mains voltage prior to application of the test level.			

Table G-3 Guidance and manufacturer's declaration - electromagnetic immunity

The iAED-M2 is intended for use in the electromagnetic environment specified

below. The user of the iAED-M2 should ensure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1] 6 Vrms 150 kHz to 80 MHz in ISM and amateur bands[1]	3 Vrms 10 Vrms ISM 6 Vrms amateur
Radiated RF IEC 61000-4-3	10 V/m 80 MHz ~ 2.7 GHz	10 V/m 80 MHz ~ 2.7 GHz

[1] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7.0 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14.0 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Separation Distances

The iAED-M2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the iAED-M2 can help prevent electromagnetic interference by maintaining a minimum distance of 30 cm (12 in) between portable and mobile RF communications equipment (transmitters) and the defibrillator.

Wireless Specifications

Table G-4 Wireless specification

The iAED-M2 meets the following specifications for wireless transmission and reception, in accordance with IEC 60601-1-2.			
IEEE Protocol 802.11	Center Frequency (MHz)	Bandwidth (MHz)	Effective Radiated Power (dBm)
802.11b	2412-2484	20	15
802.11g	2412-2484	20	14
802.11n	2412-2484	20	14

Table G-5 Wi-Fi communications

Quality of Service (QoS)	● Wi-Fi module QoS is based on lEEE 802.11e (implemented as WMM) ● The minimum recommended QoS required by the customer facility is as follows: ● WLAN access points are recommended to have minimum transmit power of 20 dBM ● Receive sensitivity of -97 dBM at 802.11b at 1 Mbps, -93 dBM at 802.11g at 6 Mbps, and -92 dBM at 802.11n at HT20 at MCS0
Module	● Espressif Sytems ESP32 ● Protocol: 802.11b/g/n
Operation Distance	30 m indoor office environment
Security	● WPA ● WPA2 ● WPA3 ● WPA2-Enterprise ● WPA3-Enterprise ● WAPI ● WPS and DPP
Certificate-based Authentication	● EAP-TLS ● EAP-TTLS/MSCHAPv2 ● PEAPv0/EAP-MSCHAPv2
Authentication Protocol	● EAP-TLS

Table G-6 Cellular specifications

The iAED-M2 meets the following specifications for cellular transmission and reception, in accordance with IEC 60601-1-2.				
Operating Band	Transmission Frequency (MHz)	Reception Frequency (MHz)	Maximum Transmit Power	Minimum Transmit Power

LTE-FDD B1	1920 - 1980	2110 - 2170	23 dBm ± 2 dB	<-39 dBm
LTE-FDD B3	1710 - 1785	1805 - 1880	23 dBm ± 2 dB	<-39 dBm
LTE-FDD B5	824 - 849	869 - 894	23 dBm ± 2 dB	<-39 dBm
LTE-FDD B7	2500 - 2570	2620 - 2690	23 dBm ± 2 dB	<-39 dBm
LTE-FDD B8	880 - 915	925 - 960	23 dBm ± 2 dB	<-39 dBm
LTE-FDD B20	832 - 862	791 - 821	23 dBm ± 2 dB	<-39 dBm
LTE-FDD B28	703 - 748	758 - 803	23 dBm ± 2 dB	<-39 dBm

⚠	Specific precautions must be taken to deal with electrical medical devices in accordance with EMC; and installation and maintenance should only be carried out in accordance with the EMC information mentioned in the Operating Manual.
⚠	Mobile phones and computers RF portable and mobile devices may interfere with medical devices. It is advised not to use communications equipment within the specified range while electrical medical devices are in use.
⚠	Increase in electromagnetic emissions or decrease in immunity to disturbances Using inappropriate accessories or cables, including those of the original components, may cause an increase in electromagnetic emissions or a decrease in immunity to disturbances.
⚠	Do not use or stack the device with other equipment, or it may result in improper operation. If the device has been used or stacked with other equipment, verify proper operation prior to use.

H Device Tracking Table

To provide better service and support, please provide important device information, including the specific installation address and user contact details. Submission methods:

-Fax: +86 0512-62995391.

-Email: service@jousing.com.

Please record and submit device information after receiving the equipment.

If the device address or the user contact information changes, submit the updated information to us as soon as 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:	

I Major Safety Features of the Product

- Classification - Internally powered equipment per IEC 60601-1;
- Applied parts - Electrodes are defibrillation-protected, type BF patient connection per IEC 60601-1;
- Liquid and Solid Ingress - IP66 per IEC 60529;
- 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 ($LiMnO_2$ battery) with a voltage of 9V and a capacity of 4.2Ah.
- Device input power - Not applicable.
- Signal output or input - Wireless communications.
- 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.

J Configuration Items

Annex J-1 Network Settings

Configuration Item	Description	Options/Range	Default
Wi-Fi SSID	Set Wi-Fi SSID	0 ~ 32 characters	/
Wi-Fi Password	Set Wi-Fi Password	0 ~ 32 characters	/
Net Switch	If disabled, the device will no longer attempt to connect to the network	On/Off	For 4G/5G network configuration, the default setting is On. For Wi-Fi configuration, the device is enabled by default after a password is set. If the device fails to connect to Wi-Fi four consecutive times, Wi-Fi will automatically disable and remain off until the next successful network configuration. For devices equipped with Bluetooth, Bluetooth is disabled by default and cannot be enabled.
Self-test Upload	Sets the self-test data upload frequency. When no malfunction is detected, the device transmits self-test reports at the configured interval. If a fault occurs, the device will transmit a self-test report	Do not upload, upload weekly, upload monthly	Upload monthly

Configuration Item	Description	Options/Range	Default
	in real time unless configured not to upload.		
ECG Upload	Configures the data upload time for rescue data.	Do not upload, upload immediately, upload the following day	Upload immediately
Net Test	Tests whether the Wi-Fi or cellular network connection is functioning properly.	Network connectivity test	/

Annex J-2 Advanced Parameter Configuration

Table J-2-1 General parameter

Configuration Item	Description	Options/Range	Default
Language	Sets the system prompt language.	3 default languages are available: Chinese, English, and Italian; 1 ~ 3 languages can be configured for cyclic switching. For custom language support, please contact Jousing Medical.	Chinese, English
Volume	Sets the device volume.	Low, medium, high	High
Backlight	Sets the screen brightness.	0~100	100
Password	Sets a password for parameter configuration.	0 to 6 digits	251030

Factory Reset	Restores to default settings.	/	/

Table J-2-2 Rescue parameter

Configuration Item	Description	Options/Range	Default
Express Mode	When Simple Mode is enabled, the device will not prompt “Please Call 120”.	On/Off	Off
Precharge	When turned on, the device charges while performing rhythm analysis to shorten the shock-ready time. When turned off, the device first performs rhythm analysis and only begins charging if the analysis result advises shock.	On/Off	On
Display Type	[Basic]: After powering on and entering Rescue Mode, the device displays guidance images; [Guidance]: After powering on and entering Rescue Mode, the device displays guidance images, text prompts, and real-time ECG; [Professional]: After powering on and entering Rescue Mode, the device displays impedance values, energy values, and real-time ECG.	Basic, Guidance, Professional	Basic
CPR Priority	Selects whether the device automatically enters CPR Mode after power-on.	On/Off	Off
CPR Metronome	When turned on, the device provides metronome tones and follows [CPR Mode] settings to perform chest compressions and ventilation.	On/Off	On
Adult C-V Ratio	Sets the compression-to-ventilation ratio for CPR.	30:2, 15:2, Compressions-Only	30:2
Child C-V			15:2

Ratio			

Table J-2-3 Self-test configuration

Configuration Item	Description	Options/Range	Default
Mo. Self-test	Perform a monthly self-test after startup	On/Off	On
Day of Month	Select monthly self-test date	1~28	/
Wk Self-test	Perform a weekly self-test after startup	On/Off	On
Day of Week	Select weekly self-test date	1~7	/
Day Self-test	Perform a daily self-test after startup	On/Off	On
Time of day	Select daily self-test time	(0–23) Hours and (0–59) minutes	/