Summary of Safety and Clinical Performance

Of

Automated External Defibrillator

Drafted by:		Date:	2025-09-30
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Documents Revision History

Rev.	Date	Revision History	Signature
A	2025.09.30	Initial version	Jie Hui, XuWang, Yuxi Wang

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Summary of Safety and Clinical Performance

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

According to the MDCG 2019-9 Rev.1 section 'Relevant SSCP information for patients', AED is not implantable devices, or class III devices that are intended to be used directly by patients, therefore this summary will not be provided to the patient.

The following information is intended for users/healthcare professionals.

1. Device Identification and General Information

1.1 Device Name

Device Name: Automated External Defibrillator

Trade Name: iAED-M2

Device Model: iAED-M2S, iAED-M2F

1.2 Manufacturer's name and address

Manufacturer: Jousing Medical Co., Ltd.

Address: 301&401, Building 21, 200 Xingpu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215000, China

1.3 Manufacture's Single Registration Number

CN-MF-000008915

1.4 Basic UDI-DI

697331555iAED2QE

1.5 Medical device nomenclature description / text

Device Name	Model	EMDN Code	Description
Automated External Defibrillator	iAED-M2S	Z12030501	Automated external defibrillators (AEDs) are portable, life-saving devices designed to treat people experiencing sudden cardiac arrest, a medical condition in which the heart stops beating suddenly and unexpectedly. - For iAED-M2S: When the device detects a shockable rhythm, it prompts the user to press the

	iAED-M2F	Z12030503	defibrillation button. If the user presses the button within the specified time, the device delivers a shock. - For iAED-M2F: When the device detects a shockable rhythm, it alerts the user not to touch the patient and automatically delivers a shock.

1.6 Class of device

Class Ⅲ

1.7 Year when the first certificate (CE) was issued covering the device

NA. The iAED-M2 is a new product.

1.8 Authorised representative if applicable; name and the SRN

Name:	Wellkang Ltd
Contact Person	Dr Edward Wang
Add:	Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland.
Tel:	+44(33)3303 1126 & +44(20)32876300
E-mail/Fax:	AuthRep@CE-marking.eu
SRN	XI-AR-000001836
DIMDI Code	NA

1.9 NB's name and the NB's single identification number

Notified Body: BSI Group The Netherlands B.V.

Notified body number: 2797

This document which is Summary of safety and clinical performance has been validated by BSI, and validation language is English.

2. Intended use of the device

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.

2.1 Intended user

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.

2.2 Indication and Target Patient Population

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

Population of Patients

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.

2.3 Contraindications and/or Limitations

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

- Responsive
- Breathing normally

3. Device Description

3.1 Description of the Device

3.1.1 Operating principles and mode(s) of action

➢ Operating principle
After turning on the iAED, it will instruct the user by audio prompts to connect the electrode pads to the patient. Once the pads are attached, everyone should avoid touching the patient so as to avoid false readings by the unit. The pads allow iAED's patient analysis system to examine the electrical output from the heart and determine if the patient is in a shockable rhythm (either ventricular fibrillation or ventricular tachycardia). If the device determines that a shock is needed, it will use the battery to charge its internal capacitor in preparation to deliver the shock.
When charged, iAED will instruct the user to ensure no one is touching the patient and then to press a button to deliver the shock (applicable to iAED-M2S) or automatcally deliver the shock afera warning prompt (applicable to iAED-M2F). This process avoids the possibility of accidental injury to another person. After the shock is delivered, iAED

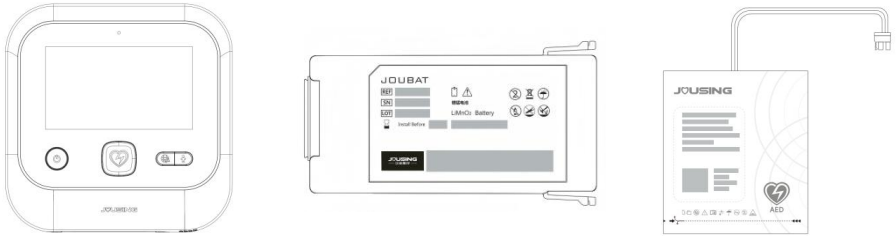
will prompt the CPR mode and instruct operator to give CPR. After the CPR is done, iAED will automatically get to rhythm analysis mode again.

- Mode of action

When a patient experiences cardiac arrest, the heart is unable to produce normal contractions to supply blood to organs. This leads to organ dysfunction or even necrosis due to ischemia. Defibrillation is currently the only effective treatment method. A defibrillator delivers a high-voltage, high-current, short-duration electrical pulse to the heart. This causes simultaneous depolarization of myocardial cells throughout the heart, terminating the heart's irregular electrical activity—such as ventricular fibrillation or ventricular tachycardia—which may then allow normal cardiac contractions to resume.

3.1.2 key functional elements

The device is composed of three parts: main unit, battery and pads.



① ② ③

① Main unit (Model: iAED-M2S, iAED-M2F).
② Battery (Model: JXMB0942), which is non-rechargeable.
③ Disposable Defibrillator Electrode Pads (Model: JOUPAD-A01, JOUPAD-A02), simplified as pads. One pair of pads coated by gel is sealed in an aluminum foil bag. Once torn open, it cannot be reused.
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.

The pads (including connected wires) are applied parts. The surface of the defibrillator and battery are accessible parts.
The pads are for single use.
Pads are attached to patient's skin. The pad has passed the skin sensitization test; however, some patients may still experience allergic reactions. Avoid unnecessary prolonged skin contact with the pads.

Expected lifetime
Service life of products: 12 years when the device is stored and maintained according to directions provided in the user manual
Battery: 5 years from date of manufacture when stored and maintained according to directions provided in the user manual.

Disposable defibrillation electrode pads: 3 years for Model JOUPAD-A01 and 5 years for Model JOUPAD-A02 from date of manufacture when stored and maintained according to directions provided in the user manual.

3.1.3 Identification of Material

N/A

3.1.4 Identification of Any Tissues, blood components or Cells of Human or Animal origin

N/A

3.1.5 Whether it incorporates a medicinal substances

N/A

3.1.6 Whether devices composed of substances that are absorbed by or locally dispersed in the human body

N/A

3.1.7 Whether devices containing CMR or Endocrine-disrupting substances

N/A

3.1.8 Materials that could result in sensitisation or an allergic reaction by the patient

N/A

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

- Previous generation
  Automated External Defibrillator (model: iAED-S1) obtained CE Certificate (MDR 806471 R000) under MDR in 2025 and is the previous generation of iAED-M2.
  The iAED-M2 and iAED-S1 share identical defibrillation waveforms, defibrillation energy, and related software design. Based on iAED-S1, iAED-M2 features reduced dimensions, an integrated screen, and introduces a fully automation level.
- Variants
  iAED-M2S and iAED-M2F are two variants of iAED-M2.
  They both share the same intended purpose.
  According to IEC 60601-2-4: 2018, AEDs may provide varying levels of automation and be referred to by various terms. A semi-automatic defibrillator requires manual shock activation. A fully automatic defibrillator will provide shock without operator intervention.
  iAED-M2S is a semi-automatic external defibrillator and iAED-M2F is a fully automatic external defibrillator.

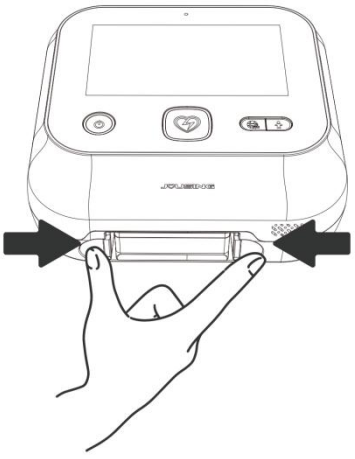
3.3 Description of any accessories which are intended to be used in combination with the device

Battery and pads are the accessories of iAED-M2.

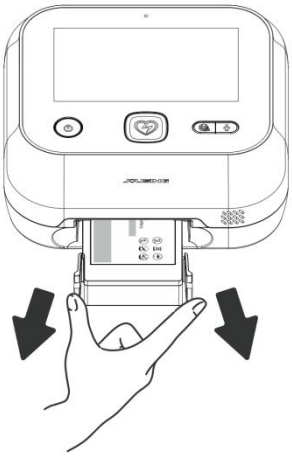
Battery

The model of battery is JXMB0942.

The battery is inserted into main unit to supply power to the AED, which is a necessary part for the AED to perform its functions.



a) Step 1: Press and hold the buckle



b) Step 2: Pull outward and take out the battery

The battery is not medical device, so there is no classification.

The battery, main unit, and pads are packaged together in a box for sale.

The battery is a non-rechargeable LiMnO2 battery. If the battery runs out, user can also buy a separate battery for replacement.

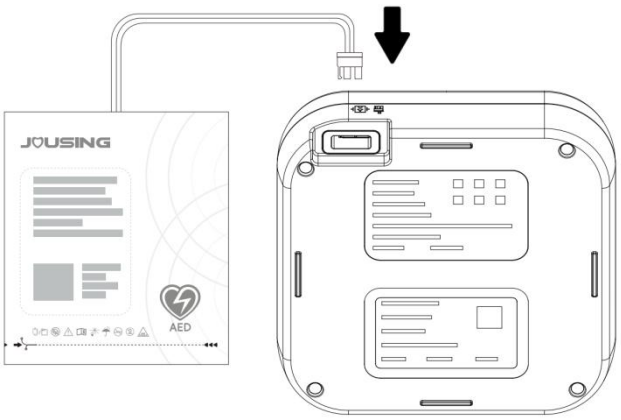
iAED-M2 can only use model JXMB0942. The JXMB0942 battery is only compatible with iAED-M2.

Pads

The model of Disposable Defibrillator Electrode Pads are JOUPAD-A01 (shelf-life is 3 years) and JOUPAD-A02 (shelf life is 5 years).

The main unit collects impedance and rhythm, and delivers an electric shock through the pads.

The pads connector is insert into the device as shown in figure below.



The pads are classified as class IIb. According to Regulation (EU) 2017/745 on medical devices (MDR) ANNEX VIII Rule 9, all active therapeutic devices whose characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.
The battery, main unit, and pads are packaged together in a box for sale.
The pads are for single use. When the pads expired or used, user can buy them separately for replacement.
iAED-M2 can only use model JOUPAD-A01 and JOUPAD-A02. The JOUPAD-A01 and JOUPAD-A02 pads are only compatible with iAED-M2.

3.4 Description of any other devices and products which are intended to be used in combination with the device

There is no device or product which is intended to be used in combination with the device.

4. Risks and warnings

4.1 Residual risks and potential side-effects

4.1.1 Description of residual risks and potential side-effects

Side-effects and complications identified from literature search were reviewed and summarized as follows. Side-effect identified in this review include:

- 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

4.1.2 Quantitative data & Qualitative data

Quantitative data on side-effects or residual risks relate to clinical data and vigilance data that were obtained proactively, the expected frequencies come from a systematic review of the scientific literature.

We searched the current available scientific literatures of the similar device in NCBI and other literature database. We searched literatures by using the key words in these databases, e.g. PubMed, embase or cochrane library to prove its safety and efficiency.

By searching 6 literatures of similar devices, the quantitative data from CER are as follow:

Recourse	Side-effect/	Probability

	complications/ AEs	
SOTA-P4-43, SOTA-P4-55, SOTA-P4-64, SOTA-P4-78, SOTA-P4-111, SOTA-G1-5	False positive	1.55% (72 in 4679)
	False negative	6.22% (844 in 13578)

In literature searched in Clinical evaluation report, 'Skin burn' and 'Myocardial damage' is mentioned in 4 articles, which are basically qualitative descriptions, while quantitative data such as incidence rate are not described in the searched literature found so far.

Table 4.1.2-1 Qualitative description of AED clinical safety

Endpoint type	Clinical endpoints	Ref No.	Description / Quantification
Safety	Skin burn	SOTA-P2-30	Then defibrillation gel is released to minimize skin-pad impedance and prevent skin injury during shock delivery.
		SOTA-E1-14	Compliance problems caused by skin itching and rash have been reported.
		SOTA-P3-79	There was significantly less erythema in patients receiving biphasic cardioversion at the edge of the sternal site (p = 0.046; 95% CI 0.41—4.5). There was no difference in any other variable at any site between biphasic and monophasic cardioversion. The use of a biphasic waveform for DC cardioversion reduces the inflammation and pain of burns as measured by erythema index and visual analogue scale.
	Myocardial damage	SOTA-P2-30	This energy level required large capacitors and inductors, was sometimes associated with cardiac injury after shock, and in some, cases second- and third-degree burns.
		SOTA-P3-163	Moreover, biphasic waveform, which provided shocks with smaller energy level, was at least as effective for successful resuscitation and

			produced significant lesser impairment in postresuscitation myocardial function.

In FDA TPLC device report database, the recalls for the device group (product code: MKJ) were screened:

Table 4.1.2-2 Side-effects from vigilance data

Recourse	Side-effect/ complications/ AEs	MDRs with this Patient Problem (2020-2024)
FDA TPLC[1]	Superficial (First Degree) Burn	36/78389 (0.046%)
	Myocardial Infarction	12/78389 (0.015%)

4.2 Warnings and Precautions

➢ **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

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=928&min_report_year=2020

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.

➢ **Safety precautions**

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.

4.3 Other Relevant Aspects of Safety, Including a Summary of Any Field Safety Corrective Action (FSCA including FSN)

Not applicable

5. Summary of Clinical Evaluation and Post-Market Clinical Follow-Up (PMCF)

5.1 Summary of Clinical Data related to Similar Device

Quantitative data on side-effects or residual risks relate to clinical data that were obtained proactively, the expected frequencies come from a systematic review of the scientific literature.

We searched the current available scientific literatures of iAED-S1, previous generation and other similar AED products in NCBI and other literature database. We searched literatures by using the key words in these databases, e.g. PubMed, PMC, or Embase to prove its safety and efficiency.

By searching literatures of iAED-S1 previous generation and other similar AED products on the market, the quantitative data from clinical evaluation report are as follow:

Table 5.1-1 Clinical Benefit Endpoints of AED

Clinical Benefit	Outcome parameter	SOTA criteria		Similar device clinical data
		Acceptance criterion	Literature	
Helps early	Performance			

electrical defibrillation and improves survival for individuals with sudden cardiac arrest.	Sensitivity	93.78% (95%CI 91.68%-95.89%)	SOTA-P4-43, SOTA-P4-55, SOTA-P4-64, SOTA-P4-78, SOTA-P4-111, SOTA-G1-54	96.84% (95%CI 94.39%-99.28%)
	Specificity	98.45% (95%CI 95.37%-100.00%)	SOTA-P4-43, SOTA-P4-55, SOTA-P4-78	98.11% (95%CI 96.18%-100.00%)
	Successful defibrillation*	73.58% (95%CI 67.98%-79.18%)	SOTA-P1-11, SOTA-P1-22, SOTA-P3-72, SOTA-P3-98, SOTA-P3-119, SOTA-P3-141, SOTA-P3-150，SOTA-P3-152, SOTA-P3-173, SOTA-E1-49	80.00% (95%CI 73.37%-86.63%)
	Return of spontaneous circulation (ROSC)	48.42% (95%CI 41.79%-55.04%)	SOTA-P1-11, SOTA-P1-22, SOTA-P1-135, SOTA-P3-72, SOTA-P3-98, SOTA-P3-119, SOTA-P3-141, SOTA-P3-147, SOTA-P3-152, SOTA-E1-49, SOTA-E1-33	65.00% (95%CI 52.93%-77.07%)
	Safety			
	False positive	1.55% (95%CI 0.00%-4.63%)	SOTA-P4-43, SOTA-P4-78, SOTA-P4-55	1.89% (95%CI 0.00%-3.82%)
	False negative	6.22% (95%CI 4.11%-8.32%)	SOTA-P4-43, SOTA-P4-55, SOTA-P4-64, SOTA-P4-78, SOTA-P4-111, SOTA-G1-5	3.16% (95%CI 0.00%-5.61%)

	Skin burn	0.046%	TPLC database	0.00%
	Myocardial damage	0.015%	TPLC database	0.00%

* Successful defibrillation: a successful defibrillatory shock was defined as the absence of VF 5 seconds after shock delivery.[2]

5.2 Summary of Clinical Data from Conducted Investigations of the Device before the CE-Marking

N/A. No pre-marketing clinical investigation was conducted

5.3 Summary of Clinical Data from Other Sources

Based on the analysis and evaluation, the safety and performance of Automated External Defibrillator have met the intended use of the product claimed by the company. According to the current level of medical/scientific knowledge and the medical options available, risk and benefits are acceptable. The information provided by the manufacturers is sufficient, intended purpose and risk reduction measures are sufficient. IFU and equipment is suitable and intended users and available area are appropriate. Manufacturer's declaration is sufficient. Evaluation of clinical data, the information provided by manufacturer and risk management documents are consistent. File and the current level of knowledge/science are consistent. Description of the residual risks, unknown or uncertain issues is acceptable.

The manufacturer also referred to the latest version of the clinical guidelines regarding AEDs currently available：

Table 5.3 Clinical Practice Guidelines related to AED

Guidelines	**Organization/ Author**	**Publish year**	**Description**

[2] AHA/ASA Journals, Part 4: The Automated External Debrillator:Key Link in the Chain of Survival

2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care[3]	AHA/ASA Journals	2020	Latest update: The AHA released the most recent updates in 2020, which include the latest guidance on the use of AEDs in adult and pediatric populations. The guidelines provide recommendations on the timing of defibrillation, the use of AEDs by both trained and untrained individuals, and the importance of early defibrillation in improving survival rates from sudden cardiac arrest.
European Resuscitation Council Guidelines 2021[4]	The European Resuscitation Council Guideline Collaborators	2021	The 2021 updates were essential for improving the quality of resuscitation practices, especially in terms of AED deployment and use by bystanders. The ERC provides detailed guidelines for resuscitation and the use of AEDs during adult and pediatric cardiac arrest scenarios. These guidelines stress early defibrillation and the accessibility of AEDs in public spaces.
ILCOR Consensus on Science and Treatment Recommendations (CoSTR) 2024[5]	International Liaison Committee on Resuscitation (ILCOR)	2024	These guidelines form the basis of many of the national and regional recommendations for AED deployment and use. This is the international standard for evidence-based recommendations, which includes AED usage in a variety of clinical scenarios, from public access to healthcare settings.
2021 Resuscitation Guidelines[6]	Resuscitation Council UK	2021	The UK Resuscitation Council follows guidelines similar to those of the AHA and ERC. Their recommendations include the importance of public access defibrillation (PAD), with AEDs being made widely available in public places.
ARC 2020	Australian Resuscitation Council (ARC)	2020	Similar to the AHA and ERC, the ARC provides guidelines on the use of AEDs in both adults and children, focusing on quick defibrillation and integration of AEDs in public and community

[3] https://cpr.heart.org/en/resuscitation-science/cpr-and-ecc-guidelines

[4] https://www.erc.edu/

[5] https://ilcor.org/publications

[6] https://www.resus.org.uk/professional-library/2021-resuscitation-guidelines

Guidelines[7]			spaces. The guide also provides specific instructions on the waveform and energy usage of the AED.
2020 Korean Guidelines for Cardiopulmonary Resuscitation[8]	Korean Guidelines for Cardiopulmonary Resuscitation	2020	Cardiopulmonary resuscitation (CPR) guidelines are a set of medical recommendations for cardiac arrest treatment based on scientific evidence. Korea has been updating its CPR guidelines every five years since the first CPR guidelines were established in 2006 by the Korean Association of CPR.

Conclusion:

The community response to cardiac arrest remains critical to saving lives. Bystander cardiopulmonary resuscitation (CPR) and use of an automated external defibrillator (AED) increase the chances of survival by two to four-fold.

Many studies of public access defibrillation have shown that AEDs can be used safely by bystanders and first responders. Although injury to the CPR provider from a shock by a defibrillator is extremely rare, do not continue chest compression during shock delivery.

Shock Energy for defibrillation separated as biphasic and monophasic, evidence from three studies of monophasic defibrillation suggest equivalent outcomes with lower and higher starting energies.For biphasic waveforms (rectilinear biphasic or biphasic truncated exponential), deliver the first shock with an energy of at least 150 J. For pulsed biphasic waveforms, deliver the first shock at 120-150 J.

Therefore low energy biphasic waveform AEDs in cardiac arrest patient is the practice of the State of the Art.

5.4 An Overall Summary of the Clinical Performance and Safety

The Safety and Performance Endpoints of Automated External Defibrillator is list as follows:

[7] https://www.anzcor.org/home/adult-advanced-life-support/guideline-11-4-electrical-therapy-for-adult-advanced-life-support

[8] https://www.kdca.go.kr/board/board.es?mid=a20507000000&bid=0031&list_no=712117&act=view

Table 5.4-1 Safety and Performance Endpoints

Clinical Benefit	**Outcome parameter**	**SOTA criteria**	**Alternative method：ICD**
Helps early electrical defibrillation and improves survival for individuals with sudden cardiac arrest.	**Performance**		
	Sensitivity	93.78% (95%CI 91.68%-95.89%)[9]	95.85% (95%CI 94.35%-97.35%)[10]
	Specificity	98.45% (95%CI 95.37%-100.00%)[11]	93.00%[12]
	Successful defibrillation *	73.58% (95%CI 67.98%-79.18%)[13]	Not reported in SOTA literature
	Return of spontaneous circulation (ROSC)	48.42% (95%CI 41.79%-55.04%)[14]	Not reported in SOTA literature
	Safety		
	False positive	1.55% (95%CI 0.00%-4.63%)[15]	7.00%[16]
	False negative	6.22% (95%CI 4.11%-8.32%)[17]	4.15% (95%CI 2.65%-5.65%)[18]

[9] SOTA-P4-43, SOTA-P4-55, SOTA-P4-64, SOTA-P4-78, SOTA-P4-111, SOTA-G1-54

[10] SOTA-P4-06, SOTA-P4-18, SOTA-P4-84

[11] SOTA-P4-43, SOTA-P4-78, SOTA-P4-55

[12] SOTA-P4-02

[13] SOTA-P1-11, SOTA-P1-22, SOTA-P3-72, SOTA-P3-98, SOTA-P3-119, SOTA-P3-141, SOTA-P3-152, SOTA-P3-173, SOTA-E1-49

[14] SOTA-P1-11, SOTA-P1-22, SOTA-P1-135, SOTA-P3-72, SOTA-P3-98, SOTA-P3-119, SOTA-P3-141, SOTA-P3-147, SOTA-P3-152, SOTA-E1-49, SOTA-E1-33

[15] SOTA-P4-43, SOTA-P4-78, SOTA-P4-55

[16] SOTA-P4-02

[17] SOTA-P4-43, SOTA-P4-55, SOTA-P4-64, SOTA-P4-78, SOTA-P4-111, SOTA-G1-5

[18] SOTA-P4-06, SOTA-P4-18, SOTA-P4-84

	Skin burn	0.046%	Not reported in SOTA literature
	Myocardial damage	0.015%	Not reported in SOTA literature

Table 5.4-2 Clinical Benefit /Risk ratio

Clinical Benefit Ratio of Automated External Defibrillator							
Clinical Performance Parameter	Equivalent device PMCF data	Similar device / Automated External Defibrillator	State of the Art / Automated External Defibrillator	State of the Art / Automated External Defibrillator(Biphasic-150 J)	State of the Art / Automated External Defibrillator(Biphasic-200 J-350J)	State of the Art / Automated External Defibrillator Monophasic (200-360J)	State of the Art / Alternative method: ICD
Sensitivity	Patient: 144 Rate: 98.80% (95%CI 97.15%-100.00%)	Patient: 923 Rate: 96.84% (95%CI 94.39%-99.28%)	Patient: 13578 Rate: 93.78% (95%CI 91.68%-95.89%)	Patient: / Rate: /	Patient: / Rate: /	Patient: / Rate: /	Patient: 2586 Rate: 95.85% (95%CI 94.35%-97.5%)
Specificity	Patient: 144 Rate: 99.71% (95%CI 98.66%-100.00%)	Patient: 418 Rate: 98.11% (95%CI 96.18%-100.00%)	Patient: 4679 Rate: 98.45% (95%CI 95.37%-100.00%)	Patient: / Rate: /	Patient: / Rate: /	Patient: / Rate: /	Patient: 190 Rate: 93.00%
Successful defibrillation*	Patient: 144 Rate: 84.38% (95%CI 78.75%-90.00%)	Patient: 536 Rate: 83.07% (95%CI 75.53%-90.60%)	Patient: 2530 Rate: 73.58% (95%CI 67.98%-79.18%)	Patient: 817 Rate: 82.90% (95%CI 74.01%-91.80%)	Patient: 471 Rate: 82.07% (95%CI 71.59%-91.55%)	Patient: 1242 Rate: 64.23% (95%CI 61.56%-66.90%)	Patient: / Rate: /
Return of spontaneous circulation (ROSC)	Patient: 144 Rate: 68.57% (95%CI 57.70%-79.45%)	Patient: 553 Rate: 50.45% (95%CI 39.47%-61.44%)	Patient: 2665 Rate: 48.42% (95%CI 41.79%-55.04%)	Patient: 696 Rate: 58.76% (95%CI 48.65%-68.70%)	Patient: 351 Rate: 54.67% (95%CI 36.43%-72.90%)	Patient: 1058 Rate: 53.24% (95%CI 46.12%-60.36%)	Patient: / Rate: /
Clinical Risk Ratio of Automated External Defibrillator							
Clinical Safety Parameter	Equivalent device PMCF data	Similar device / Automated External Defibrillator	State of the Art / Automated External Defibrillator	State of the Art / Automated External Defibrillator (Biphasic, 150J)	State of the Art / Automated External Defibrillator (Biphasic, 200J-360J)	State of the Art / Automated External Defibrillator (Monophasic, 200-360J)	State of the Art / Alternative method: ICD

False positive	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	
	144	0.29% (95%CI 0.00%-0.94 %)	418	1.89% (95%CI 0.00%-3.82 %)	4679	1.55% (95%CI 0.00%-4.6 3%)	/	/	/	/	/	/	190	7.00%	
False negative	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	Patient	Rate	
	144	1.42% (95%CI 0.00%-2.85 %)	923	3.16% (95%CI 0.00%-5.61 %)	13578	6.22% (95%CI 4.11%-8.32 %)	/	/	/	/	/	/	2586	4.15% (95%CI 2.65%-5.65 %)	
Clinical Safety Parameter	Equivalent device PMCF data		Similar device / Automated External Defibrillator[19]		State of the Art / Automated External Defibrillator[20]		/		/		/		/		
Skin burn	Patient	Rate	Patient	Rate	Patient	Rate	/		/		/		/		
	144	0.00%	N/A	0.00%	78389	0.046%									
Myocardial damage	Patient	Rate	Patient	Rate	Patient	Rate	/		/		/		/		
	144	0.00%	N/A	0.00%	78389	0.015%									

* **Successful defibrillation:** a successful defibrillatory shock was defined as the absence of VF 5 seconds after shock delivery.

[19] Data From CER Section 4.5 medical device vigilance data

[20] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=928&min_report_year=2020

5.5 Ongoing or Planned Post-Market Clinical Follow-up

The Medical Device Regulation (EU) 2017/745 (MDR) considers the post-market clinical follow-up (PMCF) as a continuous process that updates the clinical evaluation and that shall be addressed in the manufacturer's post-market surveillance (PMS) plan.

A summary table of the different PMCF activities foreseen by the manufacturer is provided below:

Item	Description of Input	Responsible Function	Aim of the activity	Rationale and known limitations of the activity	Timelines of the activity
C.1	Manufacturer device registry	R&D	Collect and analysis the device log for accuracy of cardiac rhythm recognition	Sampling bias	Annually
C.2	PMCF studies activities (if applicable)	Sales/RA/ Clinical	The PMCF study is aimed to confirm the clinical benefit of the Automated External Defibrillator throughout its expected lifetime	Perform the PMCF study to get the clinical data of the device. It is difficult to collect feedback on products exported abroad. clinical drop-out; etc.	One-Off activity, each indication will be carried out in stages (See below for detailed timeline)
C.3	Real-world evidence (RWE) Activities (if applicable)	N/A	N/A	N/A	N/A
C.4	Survey (Visit the hospital to collect clinical feedback corresponding to clinical experience of the device.)	R&D	Collect first-hand clinical feedback regarding to the clinical performance and safety	It is difficult to collect feedback on products exported abroad. Results affected response rate and data authenticity.	Annually

Item	Description of Input	Responsible Function	Aim of the activity	Rationale and known limitations of the activity	Timelines of the activity
C.5	Adverse Event report database info. (e.g. database of Competent Authorities in EU (EudaMed), UK (MHRA), Switzerland (Swissmedic), Germany (BfArM)), and US FDA MAUDE), China (NMPA)	R&D	Collect adverse events of equivalent device and similar devices	Reactive data collection with risk of missing critical data. Need to identified data relating to the product.	Annually
C.6	Feedback from users, distributors, information about use, etc.	R&D	Collect clinical use/operation information	Reactive data collection with risk of missing critical data	Annually
C.7	Literature screening and reviewing	R&D	Collect first-hand clinical feedback regarding to the clinical performance and safety	Reactive data collection with risk of missing critical data	Annually

6. Possible Diagnostic or Therapeutic Alternatives

Conventional CRP without AED is the therapeutic alternatives of AED.

However, In European Resuscitation Council Guidelines 2021, it is recommended to carried out CPR until the Emergency Medical Service arrival. It is also recommended to apply AED as soon as possible, when AED is available.

7. Suggested Profile and Training for Users

In risk analysis, the relevant risks of users have been analyzed, and the Instructions for Use have provided sufficient clear and easy to understand instructions. The users of the product are personnel trained in basic life support/AED and advanced life support, or under the guidance of emergency medical dispatchers.. After reading the Instructions for Use, the users can know how to use the product, and at the same time, they have been confirmed by usability evaluation.

8. Reference to Any Harmonized Standards and CS Applied

8.1 Applied Harmonized standards, including Harmonized standards, international standards, partly applicable standards

Harmonised standards applied

No.	Standards	Full or Partial Compliance	Publication Date
1.	EN ISO 13485:2016/AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes	Full Compliance	March 2018
2.	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	Full Compliance	December 2019
3.	ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization	Full Compliance	November 2021

Other standards applied

No.	Standards	Full or Partial Compliance	Publication Date
1.	IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Full Compliance	August 2020
2.	IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Full Compliance	September 2020
3.	IEC 60601-2-4:2010+AMD1:2018 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	Full Compliance	February 2018
4.	IEC 60601-1-10:2007+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the development of physiologic closed-loop controller	Full Compliance	July 2020
5.	IEC 60601-1-11:2015+AMD1:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and	Full Compliance	July 2020

	essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment		
6.	IEC 60601-1-12:2014+AMD1:2020 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	Full Compliance	July 2020
7.	IEC 62304:2006+AMD1:2015 Medical device software-Software life cycle processes	Full Compliance	June 2015
8.	IEC 62366-1:2015+AMD1:2020 Medical devices - Application of usability Engineering to medical devices	Full Compliance	June 2020
9.	IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	Full Compliance	June 2020
10.	IEC 60068-2-31:2008 Environmental testing-Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens, IDT	Full Compliance	May 2008
11.	IEC 60529:1989+AMD1:1999+AMD2:2013 Degrees of protection provided by enclosures (IP Code)	Full Compliance	January 2019
12.	IEC 60068-2-53:2010 Environmental testing - Part 2-53: Tests and guidance - Combined climatic (temperature/humidity) and dynamic (vibration/shock) tests	Full Compliance	April 2010
13.	IEC 60086-2-64 ： 2008+AMD1:2019 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	Full Compliance	October 2019
14.	IEC 60068-2-13：2021 Environmental testing - Part 2-13: Tests - Test M: Low air pressure	Full Compliance	March 2021
15.	ISO 10993-1:2025 Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process	Full Compliance	November 2025
16.	ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro	Full Compliance	June 2009

	cytotoxicity		
17.	ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation	Full Compliance	January 2021
18.	ISO 15223-1：2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Full Compliance	July 2021

Common Specifications applied

No.	Common Specifications
1.	/

Other applicable Regulations & Directives

No.	Regulations & Directives
1.	Regulation (EU) 2017/745 on medical devices（MDR）
2.	Directive 93/42/EEC on medical devices（MDD）
3.	Directive 2011/65/EU Restriction of the Use of Certain Hazardous
4.	MDCG 2019-9: Summary of Safety and Clinical Performance
5.	MDCG 2020-5 Guidance on clinical evaluation – Equivalence
6.	MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
7.	MDCG 2020-7 Guidance on PMCF plan template
8.	MDCG 2020-8 Guidance on PMCF evaluation report template
9.	MDCG 2020-13 Clinical evaluation assessment report template
10.	MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
11.	MDCG 2023-7 Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on sufficient levels of access' to data needed to justify claims of equivalence
12.	MDCG 2025-10 Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices

8.2 Applied Common Specifications (CS)

NA. There is no applicable CS regarding the device.

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