Summary of Safety and Clinical Performance

Of

Automated External Defibrillator

Drafted by:		Date:	2025-07-07
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Documents Revision History

Rev.	Date	Revision History	Signature
A	2024.07.31	Initial version	Jie Hui, XuWang, Yuxi Wang
B	2024.11.27	Updated the file	Jie Hui, XuWang, Yuxi Wang
C	2025.3.18	Updated Table 5.1-1 Clinical Benefit Endpoints of AED, Table 5.4-1 and Table 5.4-2 according CER updated.	Jie Hui, XuWang, Yuxi Wang
D	2025.7.7	Updated 'Summary of Safety and Clinical Performance', 5.3 'Summary of Clinical Data from Other Sources' according CER updated.	Jie Hui, XuWang, Yuxi Wang

Table of Content

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

Device Model: iAED-S1

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

697331555iAED1QC

1.5 Medical device nomenclature description / text

Device Name	EMDN Code	Description
Automated External Defibrillator	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.

1.6 Class of device

Class Ⅲ

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

NA. The iAED-S1 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

iAED-S1 is an automated external defibrillator used to treat victims with suspected cardiac arrest (no response, no breathing or abnormal breathing).

After defibrillation electrodes are applied to the victims' chest, iAED-S1 will analyzes the victims' heart rhythm. If a shockable rhythm (either ventricular fibrillation or pulseless ventricular tachycardia) is detected, iAED-S1 will direct the responder to deliver a shock across the heart in order to try and restore a normal heart rhythm. Use the adult pads for adults over 25 kg to deliver a 150 J shock, and use pediatric pads fo rpediatric under 25 kg or 0-8 years old to deliver 50 J shock.

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

2.1 Intended user

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

2.2 Indication and Target Patient Population

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

- No response
- No breathing or not breathing normally

Population of Patients

Victims with suspected cardiac arrest (no response, no breathing or abnormal breathing).

Use the adult pads for adults over 25 kg, and use pediatric pads for under 25 kg or 0-8 years old.

2.3 Contraindications and/or Limitations

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

- Responsive
- Breathing normally

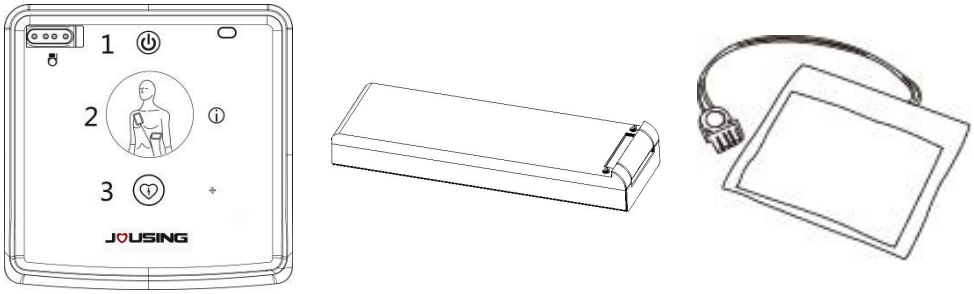
3. Device Description

3.1.1 Description of the Device

Operating principles and mode(s) of action:
The iAED-S1 automated external defibrillator is a device used in cases of life-threatening cardiac arrhythmias which lead to cardiac arrest. It has voice guidance and signal indicator, so can be used by laypersons after receiving the AED training. The iAED will automatically analyze the victim's heart rhythm after the electrode pads are attached to the victim's chest. When a life-threatening rhythm is recognized, such as pulseless ventricular tachycardia and ventricular fibrillation, iAED will instruct the user to deliver a shock for defibrillation.
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. 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.

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



① ② ③

① Main Unit (Model: iAED-S1)
② Battery (Model: JXB1242), which is non-rechargeable.
The iAED-S1 defibrillator is powered by battery.
③ External cardioversion defibrillation electrode pads (Model F7952W/J for adult, F7952PW/J for pediatric).
JOUPAD and its cables are the applied parts. They are applied to the patient's bare chest and used to detect the patient's heart rhythm and to transfer the defibrillation shock.

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 pads have obtained CE certificate under MDR and passed ISO 10993 related tests, but there may still be some patients who have an allergic reaction to the pads, and non-essential prolonged application should be avoided.

Expected lifetime
Service life of products: 10 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 this manual.
Defibrillation electrode: 30 months from date of manufacture when stored and maintained according to directions provided in this manual.

3.1.2 Product Structure and specifications, Principle of operation

The iAED-S1 automated external defibrillator is a device used in cases of life-threatening cardiac arrhythmias which lead to cardiac arrest. It has voice guidance and signal indicator, so can be used by laypersons after receiving the AED training.

The iAED will automatically analyze the victim's heart rhythm after the electrode pads are attached to the victim's chest. When a life-threatening rhythm is recognized, such as pulseless ventricular tachycardia and ventricular fibrillation, iAED will instruct the user to deliver a shock for defibrillation.

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. 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.

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

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

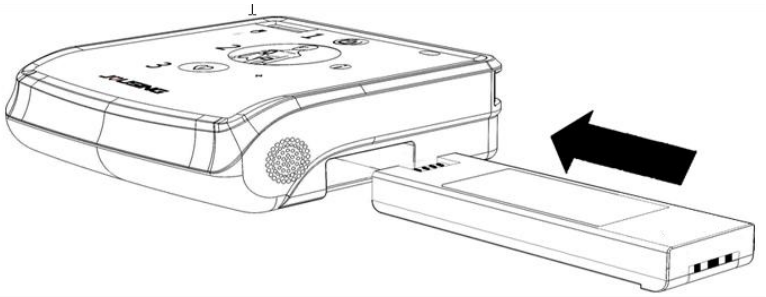
No previous generation(s) or variants for the product.

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

Battery and pads are the accessories of iAED-S1.

Battery

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.



The battery is a non-rechargeable LiMnO2 battery.
The battery does not belong to medical device.
The battery, main unit, and pads are packaged together in a box for sale. If the battery runs out, user can also buy a separate battery for replacement. iAED-S1 can only use model JXB1242. The JXB1242 battery is only compatible with iAED-S1.

Pads

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.

Use the adult pads for adults over 25 kg to deliver a 150 J shock, and use pediatric pads for pediatric under 25 kg or 0-8 years old to deliver 50 J shock.

The 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 pads, main unit, and battery are packaged together in a box for sale.
The pads are single-use. If the pads are used, user need to replace new pads and they can buy separate pads for replacement. iAED-S1 can only use model F7952W/J and F7952PW/J. The F7952W/J and F7952PW/J pads are only compatible with iAED-S1.

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

⚠ Skin burns

- The pads should be kept clear of other electrodes, lead wires, dressings, medicine patches in contact with patient, etc. Such contact can cause electrical arcing and skin burns during defibrillation and may also divert the electrical current away from the patient’s heart.
- During defibrillation, air pockets between the skin and pads can cause skin burns.
- To help prevent air pockets, body hair needs to be removed then make sure no other object sticking to the gel or on the pads and pads stick well to the skin.

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

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

Incorrect Rhythm analysis

- Place the pads on the patient’s bare skin (excluding wrinkled skin surfaces such as the lower part of the chest and obese patients’ fat accumulation areas). Improper placement of the pads will affect the analysis and result in incorrect or no shock delivery.
- Be sure not to place the pads over an implanted device. An indication of an implant is a protrusion in the chest skin and a scar.
- Moving or transporting the patient during the rhythm analysis may cause incorrect or delayed diagnosis. Be sure to follow all instructions in this manual.
- Avoid operating the device in close proximity to the equipment which may emit strong electromagnetic. Electromagnetic interference may result in improper device operation or failure to detect shock rhythm.

Explosion danger

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

Improper operation

- Do not use other manufacturers’ accessories (batteries or pads), or it may result in improper functioning. Please use accessories provided by Jousing Medical, and ensure their models are compatible with the main unit.
- An electrical shock hazard will be resulted from unauthorized repair or modification.
- Do not open the iAED-S1, remove its covers, or attempt repair or modification. There are no user-serviceable components in iAED-S1.
- If repair is required, contact Jousing Medical for service.
- Do not immerse the device in water or any fluids. Avoid any fluids to spill or enter the device.
- Do not immerse the pads in alcohol or any fluids.
- Aggressive or prolonged cardiopulmonary resuscitation (CPR) to a patient with pads attached can cause damage to the pads and the device.

Usage caution

- Use only Jousing Medical-approved accessories. The iAED-S1 may perform improperly if it is used with other manufacturer’s accessories.
- The improper operation can result in damage to the device. Be sure to follow the instructions in this manual.
- Keep patient from touching with conductive liquid or metal conductor. Conductive liquid or metal conductor may cause unexpected current bypass.
- The device should not be close to or superimposed with other equipment. It should be

observed and verified that the device is normally operating in this configuration.
- The iAED-S1 is an equipment for infrequent use.
- During rescue, do not service or maintain the equipment and its parts.
- When using the device, be careful not to wrap the electrode wire around the patient's neck, which may cause suffocation.

Safety precautions

For home use, please heed the following precautions:

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

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

[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

			available in public places.
ARC 2020 Guidelines[7]	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 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

[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

follows:

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	Legacy 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: 118 Rate: 98.58% (95%CI 96.63%-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: 118 Rate: 99.49% (95%CI 98.91%-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: 118 Rate: 84.21% (95%CI 78.01%-90.96%)	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: 118 Rate: 66.10% (95%CI 54.02%-78.18%)	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	Legacy 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	
	118	0.51% (95%CI 0.00%-1.09 %)	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	
	118	1.42% (95%CI 0.00%-3.37 %)	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	Legacy 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	/		/		/		/		
	118	0.00%	N/A	0.00%	78389	0.046%									
Myocardial damage	Patient	Rate	Patient	Rate	Patient	Rate	/		/		/		/		
	118	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 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 cardiopulmonary resuscitation and automated external defibrillator use, or by medical personnel trained in basic life support and advanced life support courses, or under the guidance of emergency center dispatchers. 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

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 essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home	Full Compliance	July 2020

	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.	ISTA-2A:2011 ISTA Procedure	Full Compliance	January 2011

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.	MDCG 2019-9: Summary of Safety and Clinical Performance
4.	MDCG 2020-5 Guidance on clinical evaluation – Equivalence
5.	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
6.	MDCG 2020-7 Guidance on PMCF plan template
7.	MDCG 2020-8 Guidance on PMCF evaluation report template
8.	MDCG 2020-13 Clinical evaluation assessment report template
9.	MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
10.	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

8.2 Applied Common Specifications (CS)

NA. There is no applicable CS regarding the device.

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