INTRODUCTION

Approximately 130,000 out-of-hospital cardiac arrest (OHCA) cases occur annually in Japan, and although the survival rate is increasing each year, it remains low [1,2]. In order to improve post-OHCA outcomes, the chain of survival has been emphasized [3], especially cardiopulmonary resuscitation (CPR) and automated external defibrillators (AEDs), which can be performed within a short period after the onset of OHCA [4].

Objective: To evaluate whether automatically adjusting the volume of automated external defibrillator (AED) audio guidance to match the environmental noise level made hearing in noisy environments easier for AED users.

Methods: A pilot usability study was conducted. We included three emergency life-saving technicians and nine university students who assigned medical support to spectators at the Japan Rugby League One match. Participants first used the AED without a volume-change function (no-change) and then used the AED with a volume-change function (change) in a noisy environment. The primary outcome was subjective audibility (7-point Likert scale). Secondary outcome was recognition of audio guidance (yes/no).

Results: The mean point in subjective audibility was 4.83 in change and 2.50 in no-change; high subjective audibility was shown in change (difference, 2.33; 95% confidence interval, 1.02 to 3.64). The number of participants who were able to recognize audio guidance was 11 in the change group and six in the no-change condition, indicating that a large number of participants were able to recognize audio guidance (κ=0.36; 95% confidence interval, −0.16 to 0.88).

Conclusion: The results of this study indicate that this function increased subjective audibility, and 91.2% of participants recognized the AED’s audio guidance. In the future, it will be necessary to develop and disseminate AEDs that are easy to use in any environment.

Keywords: Automated external defibrillator; Basic life support; Audibility, Usability; Bystander effect
While the rates of bystander CPR and public access defibrillation (PAD) in Japan have been increasing annually [5,6], the PAD implementation rate in 2022 was only 4.2% [1]. Furthermore, the COVID-19 pandemic has negatively impacted the PAD implementation rate, necessitating a nationwide effort to increase PAD implementation.

Some AEDs provide visual and audible operational guidance, which simplifies their use [7]. However, there have been instances where the shock was not delivered despite the announcement [8,9]. The effectiveness of AED operational guidance can be compromised by environmental factors at the scene of a cardiac arrest and the user’s skill level. Public places, for example, tend to be noisier than residential areas, increasing the likelihood that the user may not hear the AED’s audio instructions and may operate the device incorrectly. Despite these challenges, OHCA occurrences in public places are expected to have favorable outcomes [6,10-12]. Therefore, reliable and rapid defibrillation is crucial.

To address this problem, ClearVoice technology was developed (Stryker). This technology adjusts the frequency of voice guidance and modifies the volume incrementally to adapt to environmental noise during AED use, with the goal of improving the audibility of AED audio guidance in noisy settings, such as those encountered during medical support at sporting events—an area that has gained increasing importance in recent years [13,14]. However, there has been no research on whether altering the volume of the AED’s audio guidance actually improves its audibility in real-world noisy environments. As AED installations continue to increase, this study could provide valuable insights into which AED functions are best suited for specific environments.

We aimed to assess whether automatically adjusting the volume of AED audio guidance to match the environmental noise level would facilitate easier auditory comprehension for AED users in noisy settings.

**METHODS**

**Study design**

We conducted a pilot usability study. This study was approved by the Ethics Committee of Kokushikan University (No. 23001).

**Study setting**

The study periods were April 8, 16, and 22, 2023. Measurements were conducted during the warm-up period before the Japan Rugby League One match, where Kokushikan University was responsible for providing medical support to spectators. Additionally, emergency life-saving technicians (ELST) and ELST students from Kokushikan University were tasked with offering medical assistance. The measurement setting was an outdoor rugby stadium, accompanied by background music and announcements. The mean sound pressure level recorded was 80 dB (range, 60–98 dB). Weather conditions during the measurement times included sunny skies on April 8 and intermittent rain on April 16 and April 22.

**Participants**

Medical staff from Kokushikan University who provided medical support to spectators were eligible for inclusion. The exclusion criteria were as follows: (1) lack of consent to participate in the study; (2) inability to use an AED due to health or mental status; (3) failure to perform the measurement properly due to equipment malfunction; and (4) improper administration of questionnaire responses. Due to the constraints of the pilot study and the limited opportunities to use AEDs in a sports event environment, where real noise was present and proper randomization and collection of participants were not feasible, measurements were conducted on a small number of participants.

Sports medical support at Kokushikan University is provided by ELSTs and individuals trained in basic life support (BLS). We selected this participant due to our keen interest in exploring the potential integration of the LIFEPAK CR2 (CR2; Stryker) into our university’s sports medical support framework. Additionally, it is anticipated that the device will be adopted in various sports settings, where nurses, ELSTs, athletic trainers, and others with BLS training frequently operate. Therefore, we considered the usability of CR2 by BLS-trained participants to be of substantial interest to them.

**Intervention**

We utilized the CR2 (Fig. 1), which automatically activates the AED upon opening the lid. Operational instructions are provided on the back of the lid and on the defibrillation pad. The CR2 is capable of recognizing environmental sounds, and the frequency of the voice guidance can be adjusted. Additionally, the volume of the audio guidance can be incrementally increased to a maximum of 95 dB. Adjusting the sound volume takes time to assess the environmental noises and may require several seconds to a dozen seconds to reach the desired volume. The study commenced after obtaining oral and written informed consent from the participants. Initially, participants operated the AED in a noisy environment without the volume-change function (no-change). Subsequently, they completed a questionnaire (Supplementary Material). Then, they used the AED with the volume-change function (change) and completed the same questionnaire after the session.
In this study, participants activated the AED, listened to the audio guidance, and prepared to apply the AED pad in a noisy setting. However, they did not actually apply the AED pad to a mannequin or perform defibrillation. Participants were not previously informed that the volume of the AED would be adjusted.

Outcomes
The primary outcome was subjective audibility (7-point Likert scale). The secondary outcomes were subjective usability (7-point Likert scale) and recognition of audio guidance (yes/no). CR2 is anticipated to be extensively utilized in noisy settings. Therefore, to determine whether audio guidance is audible to AED users in these environments, we concentrated on subjective audibility in a real-world setting.

Statistical analysis
The characteristics of the participants are summarized using means and standard deviations (SDs) for continuous variables, and counts and percentages for categorical variables. We calculated mean differences and 95% confidence intervals (CIs) for outcomes involving continuous variables, and kappa coefficients and 95% CIs for outcomes involving categorical variables. The sample size of the pilot study was small; consequently, we conducted an exploratory analysis instead of a superiority test [15]. R (R Foundation for Statistical Computing, version 4.1.2) was used for all analyses.

RESULTS
Participant flow and recruitment
The flow chart of the study participants is shown in Fig. 2. All 12 participants provided consent for participation. No participants met the exclusion criteria.

Participants’ characteristics
Participants’ characteristics are presented in Table 1. The mean age of the participants was 24.1 years. The participants included three ELSTs and nine ELST students, all of whom had received CPR training within the past 2 years.

Outcomes
The results of this analysis are shown in Table 2. For subjective audibility in the primary outcome, the mean ± SD score was 4.83 ± 2.12 in the change group and 2.50 ± 1.83 in the no-change group; higher subjective audibility was observed in the change group (difference, 2.33; 95% CI, 1.02 to 3.64). For subjective us-

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**Table 1. Participants’ characteristics (n=12)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Age (yr), mean ± SD</td>
<td>24.1 ± 9.0</td>
</tr>
<tr>
<td>Qualification</td>
<td></td>
</tr>
<tr>
<td>Emergency life-saving technician</td>
<td>3 (25)</td>
</tr>
<tr>
<td>University student</td>
<td>9 (75)</td>
</tr>
<tr>
<td>Previous CPR training within 2 yr</td>
<td>12 (100)</td>
</tr>
<tr>
<td>SD, standard deviation; CPR, cardiopulmonary resuscitation.</td>
<td></td>
</tr>
</tbody>
</table>

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Fig. 1. LIFEPAK CR2. Image provided by Stryker K.K.

Fig. 2. Participant flow diagram and study sequence.
ability, the mean ± SD score was 4.92 ± 1.51 in the change group and 5.00 ± 1.35 in the no-change group, indicating nearly identical subjective usability for both functions (difference, –0.08; 95% CI, –0.77 to 0.61). In terms of recognizing audio guidance, 11 participants (91.2%) in the change group and eight participants (66.7%) in the no-change group were able to do so, demonstrating that a significant number of participants could recognize audio guidance (κ = 0.36; 95% CI, –0.16 to 0.88).

### DISCUSSION

We assessed whether automatically adjusting the volume of the AED’s audio guidance based on the environmental noise level improved audibility for users in noisy settings. The results indicated that this feature increased subjective audibility, with 91.2% of AED users reporting clear recognition of the audio guidance.

This study suggests that adjusting the volume of the operational audio guidance on an AED can be beneficial when the device is used in noisy environments. Typically, AEDs are equipped with visual aids, such as illustrations or LCD screens. However, given the urgency when using an AED, it can be challenging to focus on visual instructions. In these situations, audio guidance proves to be effective, facilitating the use of an AED without reliance on visual cues. Nevertheless, acute psychological stress, often experienced during AED use, can impair cognitive function. This decline, coupled with environmental noise, may make it even harder to hear audio instructions [16]. Moreover, with the increasing adoption of fully automated defibrillators in recent years [17,18], it has become increasingly important to provide clear and audible audio guidance to AED users to help prevent accidents, such as electrocution.

Although this study was limited to measurements at a sports event, its findings might support the use of AEDs in a variety of public places, including large sporting events such as the Olympic Games [19], as well as mid-sized community sporting events and general public gatherings. Since the noise level at crowded events can vary widely depending on the size and number of spectators, it is especially important for the AED audio guidance to be clearly audible. Psychological effects, such as anxiety, and technical inexperience can prevent laypersons from initiating BLS and AED use [20], and this stress can be particularly high in a noisy or crowded environment. However, confidence in the AED is expected to reduce anxiety. Thus, the audibility of the AED audio guidance is a very important feature. In recent years, OHCA in public places has been reported to be associated with favorable outcomes [6,10-12]. It is hoped that the widespread implementation of AEDs, featuring both easy-to-hear audio guidance and highly visible visual guidance, will enable everyone to use an AED safely and effectively, even during emergencies.

This study has several limitations. First, as this was a pilot study, it did not conclusively demonstrate the effectiveness of the function for adjusting the audio guidance volume. Further interventional studies based on the findings of this study are warranted. Second, the sound pressure level in the environment where this study was conducted was not constant and varied over time. Therefore, the noise level may have decreased at certain times, making the audio guidance easier to hear. Third, all participants in this study had completed a CPR course within the past 2 years. Thus, the results may not be representative of laypersons who have not undergone such training. It is crucial to include laypersons who are not trained in BLS in future studies. Fourth, the function used in this study to adjust the volume detects environmental sounds and changes the volume incrementally; thus, it may take time to reach a volume level that is sufficiently loud to understand the AED guidance. As a result, we cannot assert that this will lead to rapid defibrillation. Fifth, since all participants initially used AEDs without the volume change and then with the volume change, and because this study was not randomized, there may have been residual order effects.

We assessed whether adjusting an AED’s audio guidance volume based on ambient noise levels facilitated easier auditory reception for users in noisy settings. The study demonstrated that this feature improved subjective audibility, with 91.2% of participants able to discern the AED’s audio instructions. Moving forward, it will be essential to develop and distribute AEDs that are universally easy to operate in various environments.

### Table 2. The results of the usability measurements

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No-change (n = 12)</th>
<th>Change (n = 12)</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective audibility, mean ± SD</td>
<td>2.50 ± 1.83</td>
<td>4.83 ± 2.12</td>
<td>2.33 (1.02 to 3.64)</td>
</tr>
<tr>
<td>Subjective usability, mean ± SD</td>
<td>5.00 ± 1.35</td>
<td>4.92 ± 1.51</td>
<td>–0.08 (–0.77 to 0.61)</td>
</tr>
<tr>
<td>Audio recognition, No. (%)</td>
<td>8 (66.7)</td>
<td>11 (91.2)</td>
<td>0.366 (–0.16 to 0.88)</td>
</tr>
</tbody>
</table>

SD, standard deviation; CI, confidence interval.

*Kappa (κ).
FUNDING

None.

CONFLICT OF INTEREST

LIFEPAK CR2 used in this study was provided free of charge by Stryker K.K. for research use. Except for that, no potential conflict of interest relevant to this article was reported.

AUTHORS’ CONTRIBUTIONS

Conceptualization: KN; Data curation: KN; Formal analysis: KN; Investigation: all authors; Methodology: KN; Project administration: KN, ES; Software: KN; Supervision: HT; Visualization: KN; Writing-original draft: KN, MO; Writing-review & editing: HT; All authors read and approved the final version.

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SUPPLEMENTARY MATERIAL

Supplementary materials can be found via https://doi.org/jemsm.2024.00087

REFERENCES