eMurmur®

eMurmur Heart AI User Manual

Intellectual Property

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1 Introduction

eMurmur Heart AI is a medical device which serves as a decision support system in the evaluation of patient heart sounds. The Heart Sound Analysis Algorithm (HSAA) detects the presence of specific heart sounds that may be present, including S1, S2, physiological heart murmurs, pathological heart murmurs and the absence of a heart murmur.

eMurmur Heart AI interacts with either the eMurmur software platform or acts as a component of a supported third-party software platform. eMurmur is a non-medical device software platform which includes the eMurmur apps and eMurmur web portal. The platform is used to stream, record, display, replay, and store acoustic auscultation data, recorded by means of supported digital stethoscopes. Information on download and use of the eMurmur software platform can be found at https://emurmur.com.

CSD Labs assumes no responsibility for any injury to anyone, or improper use of the product, that may result from failure to use this product in accordance with the instructions, precautions, warnings, or statement of intended use published in this manual. Do not use eMurmur Heart AI before thoroughly reading the eMurmur Heart AI User Manual. eMurmur Heart AI is meant to provide clinical decision support to the user, and is not intended to be a sole diagnostic tool. Interpretations of analysis results must always be made by a qualified medical professional according to their clinical judgement.

2 Symbols

The following symbols are used in this manual:

Indicates the manufacturer's name and address.

Consult instructions for use or consult electronic instructions for use.

3 Cautions

The use of eMurmur Heart AI does not cause side effects. Follow the cautions below in order to minimize any potential residual risks of eMurmur Heart AI.

> CAUTION: eMurmur Heart AI is not intended to be the sole means of diagnosis; it is diagnosis-assisting only, i.e., to be used as an aid to the user during auscultation. The final diagnosis is always made by the qualified medical professional who must take into account the patient's whole medical history and any other relevant circumstances that might relate to heart conditions.

CAUTION: eMurmur Heart AI should not be used in an environment that would be considered especially noisy for auscultation. Care should be taken to reduce external noise as much as possible when recording heart sounds.

CAUTION: Keep a minimum distance of at least 1m (3 feet) between the recording device and Wi-Fi-routers or other devices that could potentially cause interference with wireless connections.

CAUTION: eMurmur Heart AI users must be trained in auscultation, i.e., must be able to identify an appropriate location for proper auscultation, and be able to instruct the patient as necessary to achieve the best possible recording quality.

CAUTION: eMurmur Heart AI is not intended to be used on patients in distress, in critical situations, in any acute critical/emergency state, such as atrial fibrillation, or under any physically threatening circumstances.

CAUTION: eMurmur Heart AI is to be used on patients who exhibit normal heart sound audibility. It is not intended to be used on patients with negatively altered heart sound audibility, e.g., excessive crying, intensive hiccupping, audible respiratory problems, intensive care patients or patients with severe health problems especially related to the cardio-vascular or respiratory system (e.g., patients receiving artificial respiration).

CAUTION: eMurmur Heart AI should not be used on patients where the user has difficulty performing a proper auscultation.

CAUTION: The use of a supported stethoscope for eMurmur Heart AI is critical. Using a different stethoscope could negatively impact analysis results.

CAUTION: The use of supported stethoscope cable adapters – if required - for eMurmur Heart AI is critical. Using a different adapter could negatively impact analysis results.

CAUTION: The stethoscope used for eMurmur Heart AI analysis must match the stethoscope selected in the auscultation software. A mismatch could negatively impact analysis results.

CAUTION: eMurmur Heart AI requires the correct input of the patient's age. Incorrect input could negatively impact analysis results.

CAUTION: eMurmur Heart AI is not intended to be used for analyzing anything but human heart sounds.

4 Intended Use / Indication for Use

eMurmur Heart AI software is a decision support system in the evaluation of recorded patient heart sounds. The automated analysis by eMurmur Heart AI identifies specific heart sounds that may be present, including S1, S2, physiological heart murmurs, pathological heart murmurs and the absence of a heart murmur. eMurmur Heart AI further determines

the average loudness of individual heart sound components, including S1, systole, S2, diastole, and their respective loudness ratios. These loudness ratios could be useful to providers when investigating potential changes among longitudinally recorded heart sounds.

eMurmur Heart AI is indicated for use in a setting where auscultation would typically be performed by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by eMurmur Heart AI are only significant when considered in conjunction with healthcare provider over-read and including all other relevant patient data.

USA only: Caution: Federal law restricts this device to being sold by or on the order of a healthcare provider.

5 Intended Users

Health care providers (doctors, nurses, midwives, specialists, etc.) who are trained in basic auscultation techniques are the intended users of eMurmur Heart AI. The eMurmur Heart AI user must be trained in auscultation, i.e., must be able to identify appropriate locations for proper auscultation and be able to instruct the patient accordingly to achieve the best possible recording quality.

6 Intended Patient Population

eMurmur Heart AI works on patients of all ages, sexes, and ethnicities. Patients must exhibit normal heart sound audibility.

7 Instructions for Use

7.1 Accessing eMurmur Heart AI

eMurmur Heart AI is accessed through:

- The eMurmur auscultation software platform, or
- a supported third-party software platform.

In both cases, specific instructions for the combined use of eMurmur Heart AI with a software platform are made available to all users.

eMurmur Heart AI is only available using supported digital stethoscopes, listed here: https://emurmur.com/supported-stethoscopes.

7.2 eMurmur Heart AI Output

When heart sound analysis is performed by eMurmur Heart AI, possible outputs include:

- Murmur detection result
  a) AHA classification of the heart sound analysis algorithm: Class I or Class III.

b) Murmur type: likely no murmur; likely pathologic murmur; likely innocent murmur.
c) Heart AI Score: a measure that relates to the likelihood of a classification (a murmur finding) being correct. Score values can range between 50% and 100%. For probabilities <90 %, making another recording is recommended.

Important: All findings are diagnosis assisting only; the final diagnosis is always made by a qualified medical professional.

- Heart rate as determined by eMurmur Heart AI

  Note: If the heart rate displayed appears to be inaccurate, re-recording is recommended. The heart rate displayed in this context is not meant for any form of continuous heart rate monitoring. The heart rate is only intended to inform the user whether the heart sound should be re-recorded.

- S1 and S2 heart sound segmentation markers as determined by eMurmur Heart AI

  Note: if these markers (S1 and S2) appear to be inaccurate, re-recording is recommended. The segmentation markers are provided as a means for the healthcare provider to evaluate the performance of the product. It is not meant for any type of S1/S2 monitoring.

- Average loudness of individual heart sound components, including S1, systole, S2, diastole, and their respective loudness ratios.

If a recording could not be analyzed due to quality issues, the message **Insufficient quality for analysis** will be displayed.

7.3 Clinical Performance

To assess the clinical performance of eMurmur Heart AI, several blinded prospective clinical investigations have been performed. Published performance data is available through our website at https://emurmur.com/.

8 Notices

Follow the notices below in order to ensure the proper use of the device.

NOTICE: Reduce potential noise from the stethoscope (e.g., do not move the stethoscope while recording, do not tap on it, etc.)

NOTICE: In the event that eMurmur Heart AI malfunctions or changes in its performance occur, don't use eMurmur Heart AI. Report any problems to CSD Labs.

NOTICE: Follow the instructions of the digital stethoscope you are using. Ensure that it is fully functioning, that the cable is properly connected, and the battery is fully charged (if applicable).

NOTICE: eMurmur Heart AI is not intended for continuous monitoring and must not be used for that purpose. Where continuous monitoring is required, the appropriate equipment must be used.

9 Privacy

The eMurmur Privacy Policy is available through our website at https://emurmur.com

10 Cybersecurity

eMurmur safely stores patient health data for the user in an encrypted database. These sensitive data can only be accessed if the user logs into their eMurmur account using their access credentials.

In order to avoid cyber-attacks, it is highly recommended to consider the following:

- Users must keep their personal access credentials to eMurmur secret. Passwords should not be stored electronically in an unencrypted file or as an openly accessible hard copy.
- When accessing the eMurmur web portal, users must ensure the internet connection is secure. A secure connection is indicated by padlock icon in the browser address bar.
- eMurmur tracks user activity with an audit log, which is accessible in the eMurmur web portal. If users notice suspicious activity on their account, they should change their password immediately and contact the support team.
- Users will never be asked for their personal access credentials via email, phone or any electronic form other than in the eMurmur mobile app or the web portal.
- Wi-Fi access should always be secured with at least Wi-Fi Protected Access 2 (WPA2). Never connect to an open Wi-Fi hotspot or hotspots with unsecure protocols (WEP, WPA).
- Users shall not use a mobile device with privileged control activated ('rooted' device). They shall not install custom firmware, root management apps, root cloaking apps or other dangerous apps.
- Users shall only install apps from the Google Play Store or Apple App Store on their mobile device. They shall not allow the installation of unsafe apps on their device.
- Only TLS v1.2 or higher is supported to establish a connection to eMurmur servers. A connection via TLS v1.0 or TLS v1.1 will not allow the product to be used.

When operating eMurmur offline, PHI is temporarily stored on the user's mobile device. In order to maximize cybersecurity, users are strongly encouraged to take following steps:

- Accept all OS and app updates immediately. This is crucial to eliminate software or hardware vulnerabilities identified after an initial release.
- Never connect to unsecured Wi-Fi.
- Use discretion when downloading apps. Even legitimate-looking apps may be infected with malware that could compromise patient data, and cause a serious data breach.
- Users shall not jailbreak their device. Jailbreaking a device removes much of its built-in security and can leave it more vulnerable to attacks.

- Users shall ensure that the devices they plug their mobile device into (e.g., home computer, work laptop, etc.) are secure. If the computer/network isn't secure, it could act as a portal for hackers to gain access to a user's mobile device.
- Users should enable a password/pin to access their mobile device.
- Users should encrypt their data to ensure that it remains secure, even if malware steals it.

11 Software Lifetime

The eMurmur Heart AI lifetime ends with its next major release.

12 Help and Contact Information

- Product Reference and Information: https://emurmur.com/
- Direct Customer Contact: office@emurmur.com
- Contact regarding product inquiries or general product related comments, questions, or concerns, please use: https://emurmur.com/contact
- Report any injury or adverse event to CSD Labs via https://emurmur.com/contact or office@emurmur.com
- Please note that the information provided in this document may be modified without prior notice.

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