INSTRUCTION FOR USE

StethoMe® AI

Artificial Intelligence Algorithms

1. INTRODUCTION

1.1. About the Manual

This instruction for use (IFU) is part of a medical device, i.e., the StethoMe® AI artificial intelligence algorithms, hereinafter referred to as StethoMe® AI.

StethoMe Sp. z o.o. bears no liability and provides no guarantee with regard to damage (including indirect damage) arising due to lack of compliance with this user manual.

- Prior to using the medical device, you should read this user manual carefully.
- This user manual should be kept in a safe place for the entire lifecycle of the medical device.
- This user manual should be provided to every subsequent owner or user of the medical device.
- This user manual should be updated on the basis of every supplement received from the device manufacturer.

The aim of this instruction is to describe a medical device – the StethoMe® AI artificial intelligence algorithms – taking account of the following in particular:

- Description of the medical device
- Safety of use
- Troubleshooting
- Maintenance service

Before commencing the examination, it is necessary to thoroughly read the medical device's (stethoscope) IFU supplied with the product and the instructions for the StethoMe® AI product available at www.stethome.com.

1.2. Scope of Application

The instruction for use applies to the most recent version of StethoMe® AI artificial intelligence algorithms (version available in the application).

1.3. Symbols and Marks Used in the Instruction for Use

Warnings and safety measures that must be followed in order to avoid personal injury!

Warnings and safety measures that must be followed in order to avoid damage to property!

Tips/additional information.

2. CHARACTERISTICS

2.1. Intended Use of the Medical Device

StethoMe® AI is a medical device that detects abnormal additional respiratory system sounds (wheezes, coarse crackles, fine crackles, and rhonchi) in recordings originating from supported certified electronic stethoscopes. StethoMe® AI determines the heart rate, as well as respiratory rate, and the inspiration/expiration ratio in recordings originating from supported certified electronic stethoscopes.

The device may be used for analysing wheezes and rhonchi, respiratory rate, heart rate, and the inspiration/expiration ratio in the course of asthma.

This medical device is intended for users with a medical education background, as well as those without.

Any other application of the medical device is considered to be inconsistent with the intended use and must be exclude

2.2. Recommendations for Using StethoMe®AI

StethoMe® AI is used to detect auscultatory changes in the respiratory system, including asthma patients, and to determine the classes and intensity of pathological phenomena. The following classes of pathological phenomena are detected: wheezes, fine crackles, coarse crackles, and rhonchi. Severity of phenomena is presented on a scale from 0 to 100.

StethoMe® AI is also intended for determining the heart rate (heart beats per minute, BPM), respiratory rate (breaths per minute, RR) and the inspiration/expiration ratio (i/e).

Based on detected additional abnormal auscultatory sounds, it is possible to present reliable demonstrative information about the algorithm's response for the entire visit and alert the StethoMe® AI user if any significant auscultatory changes in the respiratory system are detected. In addition the system informs about exceeding the standard values in case of respiratory rate and heart rate measurement.

2.3. Contraindications

Although StethoMe® AI is equipped with a module for analysing recording quality and content of interference, it should be remembered that in order for the analysis to work correctly, it is necessary to exclude recordings of poor quality that include interference such as crying, conversation, coughing, ambient noise, etc.

Due to the high physiologic variability of measured parameters, results for children under 1 year may be unreliable and the device is not recommended for use in this age group.

2.4 Potential Adverse Effects and Safety of the Medical Device

This medical device is completely safe for humans, provided that it is used in accordance with the user manual.

2.5 Precautions and Warnings

- The StethoMe® AI medical device is not intended for diagnostics in emergency conditions! Remember that if you suspect any hazard to your patient's life or health (e.g., acute breathing disorders, impaired consciousness, loss of consciousness, cardiac arrest, suspicion of acute coronary syndrome, panic attack, or trauma) it is forbidden to either recommend them to use the StethoMe® AI medical device or wait for the results of analysis performed by the StethoMe® AI medical device. In the said situation, the patient should urgently consult a physician or report the problem to the emergency number;

- No analysis carried out by the medical device – including in particular the cases where the result of the analysis performed by the medical device is the non-identification of abnormal additional sounds in the respiratory system or non-detection of heart murmurs or heart rate – should delay or substitute seeking medical attention by the patient or reporting the problem by calling to the emergency number;

- The use of StethoMe® AI medical device should never substitute a consulting physician and only constitutes a supplement to the care provided by a physician. The results obtained should never delay or substitute seeking medical attention. The process of diagnostics and treatment, including using the StethoMe® AI medical device, should be supervised by medical personnel;

- StethoMe® AI is intended for users with a medical education background and also those without, however, using it is not a substitute for consulting a physician;

- NEVER diagnose a patient on your own based exclusively on the results obtained with the device;

- ONLY your physician may prescribe treatment and diagnose respiratory diseases;

- Consult your physician with the results obtained from the device;

- The established respiratory rate (RR) and heart rate (BPM) values are compared with the ranges indicated in medical literature. On this basis, the results of the examination are checked to see whether they are within the norm. It should be kept in mind that the limit values for these parameters for individuals may differ from the ranges specified in the literature and may be considered, by a doctor, to be physiologically correct, even though the device may indicate that the accepted normative range is exceeded;

- Each time you are in doubt with the result, repeat the test, remembering to clear your airways, blow your nose, and keep the room quiet during the examination;

- Please remember that the medications used or the disease itself may accelerate the patient's heart rate or alter breathing;

- You can find the symbols used in the examination result in the Quick Start guide provided with the StethoMe® product;

- The complete StethoMe manual is delivered with the StethoMe product. You can also find it at www.stethome.com.

- StethoMe® AI should be used in accordance with the user manual. If you notice any abnormalities in the operation of StethoMe® AI, please contact the manufacturer;
- StethoMe® AI supports only the recordings coming from the StethoMe® electronic stethoscope;
- NOTE: Do not modify files in a manner that changes the acoustic properties of the signal recorded (e.g., reduction in sampling frequency, decrease in resolution, addition of other signals, filtration, etc.). It is not recommended to use files originating from other devices – the analysis of such files may turn out unsuccessful.

2.6 Additional Information

For more information visit www.stethome.com.

2.7. Medical Device Classification

The StethoMe® AI medical device has been classified according to Annex IX to Council Directive 93/42/EEC as class IIa, and is subject to rule 10.

2.8. Markings

	Manufacturer
	Please read the user manual carefully before using the device
CE 2274	The medical device is CE certified and complies with the European market guidelines
	CAUTION! NOTE! Please read the manual

2.9. Compliance with Standards

The medical device meets the requirements of IEC 62304 International Standard.

3. MEDICAL DEVICE FUNCTIONING

3.1. Technical Parameters

- The medical device is constituted by software available via WebAPI with the use of REST protocol, described in the technical documentation available to integrators or through supported applications;
- The WebAPI address where the service is available is provided together with the software license;
- StethoMe® AI uses neural network architecture.

3.2 Sound Analysis Algorithms

The medical device enables analysis of sounds from supported certified electronic stethoscopes in the following cases:

- analysis of respiratory system sounds - wheezes, fine crackles, coarse crackles, and rhonchi;
- determination of respiratory rate (breaths per minute, RR) and calculation of the inspiration to expiration ratio (i/e);
- analysis of heart sounds – determination of the heart rate (BPM)

The following sections describe the forms of presenting the results.

3.3 Patient Auscultation Mode Using the Application Connected to the StethoMe® Medical Device

To commence examination, you require an active StethoMe® licence in the application, which you purchased with the device. If you have not yet activated the licence, find the message with instructions for licence activation in your email inbox and proceed in accordance with the instructions.

Launch the application and follow the instructions in the application.

Available test modes:

Asthma control

Quick examination performed in one location. You can use it to measure the respiratory rate, inspiration/expiration ratio, heart rate and the intensity of rhonchi and wheezes.

Complete lung examination

The examination is performed on 6-8 locations on the chest (depending on the patient's age). Detects and determines the intensity of abnormal auscultation sounds such as: wheezes, rhonchi, fine and coarse crackles. The following are also measured: respiratory rate, inspiration to expiration ratio and heart rate.

1. Select the mode in which you want to start the examination in the application;

2. Performing the recording involves applying the stethoscope's membrane (Fig.1) to the patient's body at the points indicated in the application/on the stethoscope screen and holding the stethoscope at a point until a progress bar is filled. The recording starts and ends automatically;

IMPORTANT! After placing the stethoscope on the body, the stethoscope automatically commences recording.

3. In the case of a complete lung examination, selection of the auscultation point may be also performed in the application by selecting a point other than the proposed one, as well as by vigorously moving the stethoscope to the right or left;

4. It is recommended to record all the points indicated in the application/on the stethoscope screen;

5. If the application indicates points which require correction, repeat the recording at these points;

6. After all points are correctly recorded or the examination is forced to end with a smaller number of recorded points, the recorded auscultation sounds are automatically transmitted for analysis by StethoMe® AI algorithms and then the results of this analysis are obtained (depending on transmission speed this will take just a few to several seconds). The results are recorded in the cloud, and can be accessed through a history of examinations in the application;

7. Once the examination ends, a short survey appears concerning the patient's condition. The results of the survey will be attached to the test results and recorded in the patient's history;

8. The survey and the test results along with the sounds can be made available to a doctor by sending a link for examination.

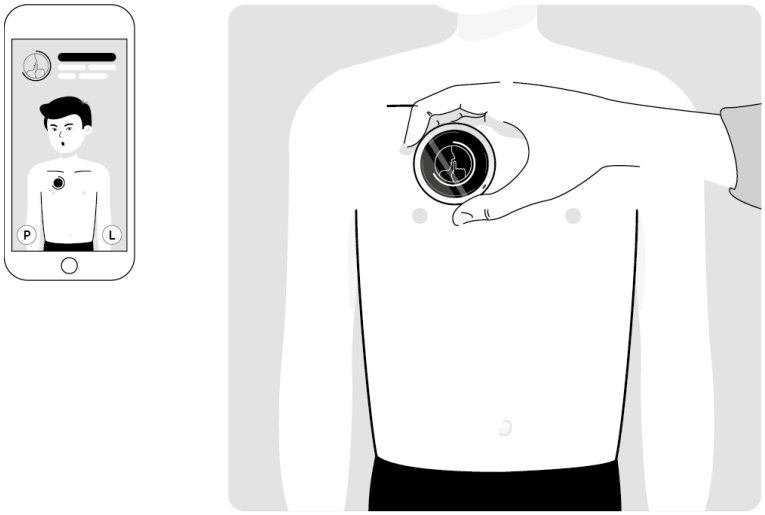

Fig.1

After the analysis, the result is presented graphically using graphic templates.

Symbols used in the results of the analysis of recorded auscultation sounds with StethoMe® AI:

Asthma control, examination status:

 no abnormal auscultation sounds have been detected

 a small number of abnormal auscultation sounds have been detected

 abnormal auscultation sounds detected

 test results cannot be determined

wheezes intensity scale from 0 to 100

rhonchi intensity scale from 0 to 100

 parameter value too high (BPM, RR)

 parameter value above normal (BPM, RR)

 parameter value below normal (BPM, RR)

Additional parameters:

 respiratory rate value

 heart rate value

 inspiration/expiration ratio

- The ‘Asthma control’ mode is particularly intended for patients diagnosed with bronchial asthma or with suspicion of asthma;
- The device detects symptoms such as abnormal auscultation sounds that occur in the course of asthma and other respiratory tract diseases;
- When the patient has symptoms of dyspnoea, shortness of breath, a strong cough, obstruction may be so strong that pathological sounds may not be present. First, administer the interventional medication prescribed by the

doctor and consult the doctor. In this case, you should always follow the doctor's instructions, regardless of the result indicated by the device;

- DO NOT use in the event of an acute asthma attack or respiratory failure;
- It should be remembered that medication used in the treatment of asthma may cause an accelerated heart rate;
- The established respiratory rate (RR) and heart rate (BPM) values are compared to ranges indicated in medical literature. On this basis, the results of the examination are checked as to whether they are within the norm. Down arrow is displayed for a lower value and an up arrow for a higher value.

Complete lung examination status:

 no abnormal auscultation sounds have been detected

 a small number of abnormal auscultation sounds have been detected

 abnormal auscultation sounds detected

 test results cannot be determined

 parameter value too high (BPM, RR)

 parameter value above normal (BPM, RR)

 parameter value below normal (BPM, RR)

Additional parameters:

 respiratory rate value

 heart rate value

 inspiration/expiration ratio

The recording and its detailed analysis are available in the application by clicking the 'Detailed Test Result' button. Instructions on how to read the result are available in the application by clicking the 'Help' button in the upper right corner of the screen.

 *Sections 3.4 and 3.5 are dedicated to the professional user*

3.4 Detailed Analysis Results for a Single Auscultation Point

The template with detailed results presents extended information on the analysis of a single recording from a visit. The view includes, among others:

1. The heart rate (pulse) expressed in beats per minute (BPM) or a "-" mark when the recording quality makes it impossible to determine the BPM;
2. Respiratory rate (RR);
3. Inspiration/expiration ratio (i/e);
4. A spectrogram of the recording analysed;
5. Possibility to play back the sound recorded;
6. A detailed description of the recording with indication of the following in time:
   a. the recording fragment subjected to analysis or suitable for analysis,
   b. occurrence of inspirations and expirations,
   c. occurrence of pathological phenomena,
   (the height of markers corresponds to the intensity of a given pathology in the whole fragment analysed, using a two-level scale),
   d. detected interference that may have an impact on the analysis of the results.

The information on the detected types of auscultation phenomena is presented using four ring fragments surrounding the above mentioned circle.
Each of the fragments represents a different type of pathological phenomenon.

The thickness of a ring fragment is proportional to the intensity of a given phenomenon, presented in a two-level scale. The absence of a given fragment means that a given phenomenon has not been detected. The locations of individual phenomena are described in Figure 2.

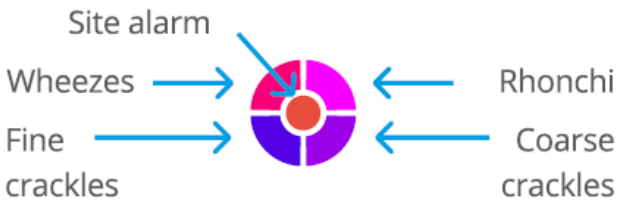

Fig.2 Location of pathological phenomena around the analysis result icon.

Table 1. Example view of auscultation point analysis result templates*

Minor intensity of all the abnormal auscultation sounds

DMajor intensity of all the abnormal auscultation sounds

- Major intensity of wheezes
- Major intensity of rhonchi
- Minor intensity of fine crackles
- No coarse crackles

- No wheezes
- Major intensity of rhonchi
- Minor intensity of coarse crackles
- Major intensity of fine crackles

*With asthma control, only wheezes and rhonchi are detected.

Possible markings of site alarm:

 No abnormal auscultation sounds have been detected,

 A small number of abnormal auscultation sounds have been detected,

 Abnormal auscultation sounds have been detected,

 Analysis is impossible. No breathing detected or excessive background noise.

In addition to the presentation of the intensity level for every auscultatory phenomenon, a percentage value (0–100) is presented, expressing the intensity of a given phenomenon in the recording, depending on the duration of the additional abnormal sound detected during respiratory cycles. The intensity levels provide an overview of intensity for a given abnormal sound in the recording. With the value, the physician may precisely differentiate and track the changes in intensity of auscultatory phenomena in time.

3.5. General Analysis Result for a Single Point with Details

The template for the general analysis results for a single point looks as follows:

- The heart rate (pulse) expressed in beats per minute (BPM) or a “-” mark when the recording quality makes it impossible to determine the BPM;
- Respiratory rate expressed in breaths per minute (RR) or a “-” mark when the recording quality makes it impossible to determine the RR.

4. ACTIVITIES DURING OPERATION OF STETHOME® AI

4.1 Using StethoMe® AI

The description of how to use StethoMe® AI is included in the user manual of the supported application or in the technical documentation provided with the software.

- In order to use StethoMe® AI, a smartphone is required with an installed, authorized application, internet access and an enabled Bluetooth mode.
- WebAPI is available via the Internet, and its address and technical documentation are provided together with the medical device license.

4.2. Instruction for Use Available Online

The most recent version of the user manual is available at www.stethome.com.

The user manual is available in PDF format. In order to read the content properly, it is recommended to use the Adobe Acrobat Reader DC software version 2019.008.20071 or newer. This software is available at its producer's website: www.adobe.com. In order to receive a printed version of the user manual, please send a request to our registered address: StethoMe sp. z o.o., 61-663 Poznań; ul. Winogrady 18a, Poland. The manual will be delivered within 7 days from the receipt of your request.

5. SERVICING AND REPORTING

If any irregularities are noticed in the operation of the medical device, contact the servicing department at the email address: support@stethome.com.

Each serious incident related to the device should be reported to StethoMe and the appropriate body of the member country where the user and/or patient reside.

6. ACCURACY

BPM – the mean absolute error is 4 units, the relative error is 4%.

RR – the mean absolute error is 2.2 units, the relative error is 9%.

7. MANUFACTURER

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CE 2274

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