StethoMe® AI

version 3.1.1

USER MANUAL

for users

with medical education

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1. INTRODUCTION

1.1. About the manual

This manual is a part of a medical product - the StethoMe AI artificial intelligence algorithms. StethoMe Sp. z o.o. bears no liability and provides no guarantee with regard to damage (including indirect damage) arising due to this user manual not being complied with.

- Prior to using the medical product it is required to read this user manual carefully.
- This user manual should be stored in a safe place for the whole duration of medical product use.
- It should be provided to every subsequent owner or user of the medical product.
- It should be updated on the basis of every supplementation received from the product manufacturer.

The aim of this manual is to describe a medical product – the StethoMe AI artificial intelligence algorithms – taking into account the following in particular:

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

1.2. Index of revisions

Medical product version	Issue date
3.1.1	2020/04
3.1	2020/01
3.x	2019/11
2.x	2019/05
1.1.1	2018/11

1.3. Scope of validity

This user manual is valid StethoMe AI artificial intelligence algorithms in the most recent version specified in item 1.2.

1.4. Symbols and marks used in the manual

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

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

Tips/additional information.

2. CHARACTERISTICS

2.1. Intended use of the medical product

StethoMe AI is a medical product that detects abnormal additional respiratory system sounds (i.e. wheezes, coarse crackles, fine crackles, and rhonchi) in recordings originating from supported certified electronic stethoscopes. StethoMe AI also determines the heart rate of adults in recordings origination from supported certified electronic stethoscopes.

This medical product is intended for users with medical education, as well as those without medical education.

> **Any other application of the medical product is considered inconsistent with the intended use and has to be excluded.**

2.2. Recommendations for using StethoMe AI

StethoMe AI is intended for detecting auscultatory changes in lungs and determining classes of pathological phenomena. The following classes of pathological phenomena are detected: wheezes, fine crackles, coarse crackles, and rhonchi.

StethoMe AI is also intended for determining the heart rate (heart beats per minute).

On the basis of changes detected at multiple points (visit) it is possible to present reliable demonstrative information on response of the algorithms for the whole visit (multiple points) and alarming the user of StethoMe AI in case of detecting significant auscultatory changes in lungs, or heart murmurs.

2.3. Contraindications

> Although StethoMe AI is fitted with a module for analysing recording quality and content of interference, it is necessary to remember that in order for the analysis to work correctly, it is necessary to exclude recordings of poor quality that include interference such as e.g. crying, conversation, coughing, ambient noise, etc.

2.4 Potential adverse effects and safety of the medical product

This medical product is completely safe for use by people, provided that it is used according to the user manual.

2.5 Precautions and warnings

StethoMe AI should be used according to the manual.
In case of noticing any irregularities in functioning of StethoMe AI it is necessary to contact its producer.

The StethoMe AI medical product 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 disturbances, 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 product or wait for the results of analysis carried out by the StethoMe AI medical product. In the situation described the patient should urgently consult a physician or report the problem using the 112 emergency line.

No analysis carried out by the medical product – including in particular the cases when the result of the analysis conducted by the medical product is lack of identification of any abnormal additional sounds in the respiratory system or lack of detection of heart murmurs or lack of determination of heart rate – should delay or substitute seeking medical attention by the patient or reporting the problem using the 112 emergency line.

Using the StethoMe AI medical product may never substitute consulting a physician - it provides only supplementation 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 product, should be supervised by medical personnel.

StethoMe is intended for users with medical education and also those without medical education, and using it is not a substitute for consulting a physician.

StethoMe supports only the recordings coming from the StethoMe electronic stethoscope and Littmann 3200 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 also not recommended to use files originating from other devices - the analysis of such files may turn out unsuccessful.

2.6 Additional information

You can find more information at www.StethoMe.com

2.7. Medical product classification

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

2.8. Markings

	![factory symbol]	Manufacturer
	![manual symbol]	Please familiarise yourself carefully with the user manual prior to using the product.
	CE 2274	The medical product features a CE certificate and complies with the guidelines of the European market.
	⚠	CAUTION! NOTE! Please read the manual

2.9. Label

Algorithms for detecting additional abnormal sounds in the respiratory system and heart rate (BPM).

Date of issue: 01.06.2020   Version: 3.1.1

CE 2274   ⚠   📖   🏭   StethoMe sp. z o.o.   61-633 Poznań, Poland
                                www.StethoMe.com | ul. Winogrady 18 A

2.10. Compliance with standards

The medical product meets the requirements of the IEC 62304 International Standard.
The medical product complies with European regulations and features the CE 2274 mark. The quality of the medical product has been verified and complies with provisions of the Council Directive (EC) 93/42/EEC on medical products of 14th of June 1993.

3. MEDICAL PRODUCT FUNCTIONING

3.1. Technical parameters

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

3.2 Sound analysis algorithms

The medical product enables conducting analysis of sounds from supported certified electronic stethoscopes in two cases:

- analysis of respiratory system sounds
- analysis of heart sounds

The next items (3.3, 3.4) feature description of the form of result presentation.

3.3 Analysis of respiratory system sounds

After carrying out the analysis, the result is presented visually using one of the three templates:

1. analysis result for a single auscultation point;
2. general result for all the auscultation points recorded;
3. detailed analysis result for a single auscultation point.

It is recommended to record signals from all the auscultation points in order to obtain the most reliable result.

3.3.1 Analysis result for a single auscultation point

The template of result for a single auscultation point is represented by a green or red circle. The icon displayed depends on the analysis result and may take forms described in Table 1.

🟢	No abnormal auscultation sounds have been detected (green)
🔴	Abnormal auscultation sounds have been detected (red)
❗	Analysis is impossible. No breathing detected or excessive noise in the room.

Table 1. Templates of the icon presenting the analysis result for a single auscultation point.

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 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 on Figure 1.

Wheezes   Rhonchi

Fine crackles   Coarse crackles

Figure 1. Location of pathological phenomena around the analysis result icon.

	Minor intensity of all the abnormal auscultation sounds
	Major 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.

Table 2. Example look of auscultation point analysis result templates

Additionally, next to presentation of the intensity level for every auscultatory phenomenon, there is presented a percentage value (0-100) 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 are determined directly on the basis of the percentage scale and provide an overview of intensity of a given abnormal sounds in the recording. Thanks to the percentage value a doctor can differentiate with precision and track the changes in intensity of auscultatory phenomena in time.

3.3.2 General result for all the auscultation points recorded

StethoMe AI presents the analysis results for all the points recorded (e.g. collected within the framework of a single visit) using an alarm icon. The icon displayed depends on the analysis result and may take forms described in Table 3:

	No abnormal auscultation sounds have been detected (green)
	A small number of abnormal auscultation sounds has been detected (yellow)
	Abnormal auscultation sounds have been detected (red)
	It is impossible to determine the examination result

Table 3. Templates of icons presenting the result of analysis of a whole visit.

3.3.3 Detailed analysis result for a single auscultation point.

The template of detailed result description presented extended information on the results of analysis of a single recording from a visit. The view includes, among others:
1. A spectrogram of the recording analysed,
2. Possibility of playing back the sound recorded,
3. 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 inhalations and exhalations,
    c. occurrence of pathological phenomena
       (the height of markers corresponds to intensity of a given pathology in the whole fragment analysed, using a two-level scale),
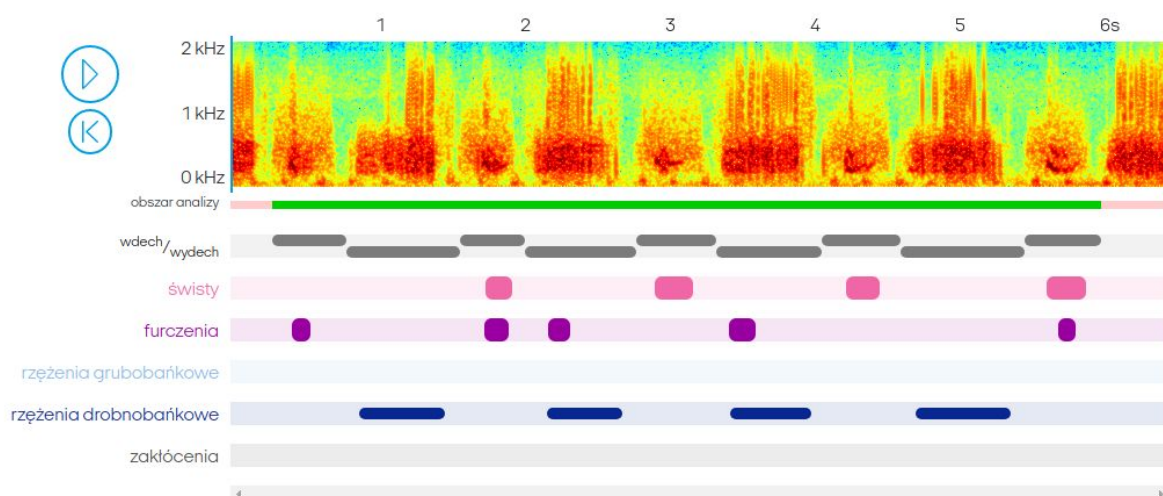   d. detected interference that may have impact on analysis results.

Fig. 2 Example template of detailed analysis result for a single auscultation point.

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3.4 Analysis of heart sounds

After carrying out the analysis, the result is presented visually using one of the three templates:
1. general result of analysis for a single point;
2. general result of analysis for a single point, with details;
3. detailed analysis result for a single point.

3.4.1 General result of analysis for a single point;

The template of result for a single auscultation point is represented by an icon. The icon displayed depends on the analysis result and may take forms described in Table 4.

✔	Correctly recorded point
✖	Unrecorded point
❗	Point recorded in low quality

Table 4. Templates of the icon presenting the analysis result for a single auscultation point.

3.4.2 General result of analysis for a single point, with details

The template of general result of analysis for a single point looks as follows:
- Heart rate, represented in beats per minute (BPM), or a "-" sign in case when the recording quality makes it impossible to determine the BPM value.
- Recording quality description (Recording quality) that may take the form of one of the following values:
  - Good
  - Bad

An example general result of analysis for a single point, with details, is presented on Figure 3
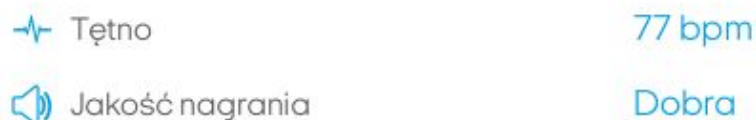

-\\- Tętno   77 bpm

🔊 Jakość nagrania   Dobra

Figure 3. Example general result of analysis for a single point

3.4.3 Detailed analysis result for a single point

The template of detailed result description presented extended information on the results of analysis of a single recording from a visit. The view includes, among others:
1. A spectrogram of the recording analysed,
2. Possibility of playing back the sound recorded,
3. Detailed description of the recording with heart beat phases (contraction and relaxation) marked in time, and the recording fragment subjected to analysis or suitable for analysis.
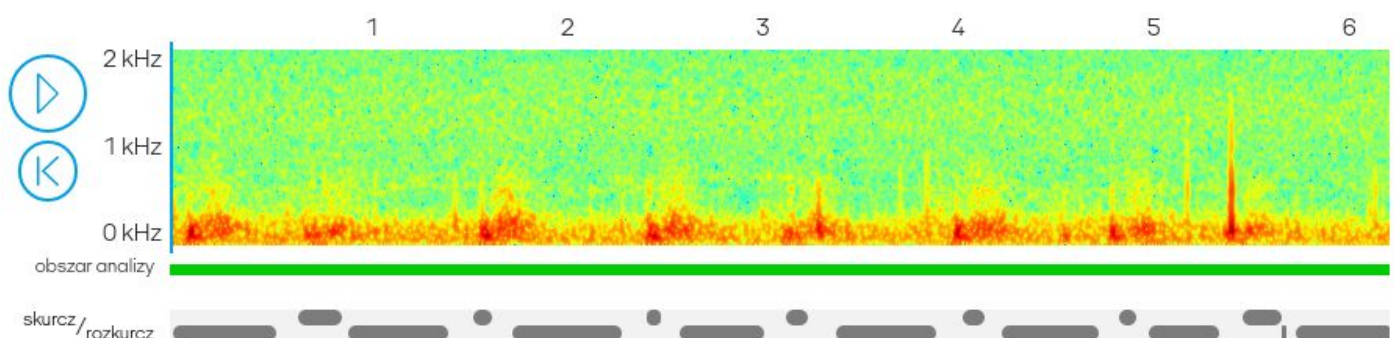
Fig. 4 Template of detailed analysis result for a single auscultation point.

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 a supported application or in the technical documentation provided with the software.
- In order to use StethoMe AI, an Internet connection is required.
- The WebAPI is available via the Internet, and its address and technical documentation are provided together with the medical product license.

4.2. User manual available online

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

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

5. TROUBLESHOOTING

In the event of encountering any problems while using StethoMe AI it is necessary to:
1) Make sure that the inquiries sent to StethoMe AI meet the requirements described in the medical product's technical documentation.
2) Analyse the result (error) obtained and compare it to the technical documentation.
3) If in spite of ensuring compliance with the technical documentation the issues keep occurring, please contact the manufacturer.

6. MAINTENANCE SERVICE

In case of noticing any irregularities in functioning of the medical product, contact the maintenance service at the e-mail address: support@StethoMe.com

7. MANUFACTURER

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Date of issue or last revision of the user manual

Date of issue of the manual: 2nd of April 2020
Version:3.1.1

CE 2274