StethoMe® AI

v2.x

OPERATION MANUAL

for users without medical

education

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1. INTRODUCTION

1.1. About the manual

This manual intended for users without medical education is a part of a medical device - 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 this user manual not being complied with.

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

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

- medical device description
- Safety of use
- Troubleshooting
- Servicing

1.2. Index of revisions

medical device version	Issue date
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 device

The medical device detects abnormal additional sounds (i.e. wheezes, coarse crackles, fine crackles, and rhonchi) in the respiratory system of children up to the age of 18 in recordings originating from supported certified electronic stethoscopes. It is intended for users with medical education, as well as those without medical education.

> **i** **Any other application of the medical device 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 and determining classes of pathological phenomena.
The following classes of pathological phenomena are detected:
1) wheezes,
2) fine crackles,
3) coarse crackles,
4) rhonchi.

On the basis of changes detected at multiple points(visit) it is possible to present reliable general information on response of the algorithms for the whole visit (multiple points) and alert the StethoMe AI user in case of detecting significant auscultatory changes.

2.3. Contraindications

> **i** 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 medical device safety

This medical device is completely safe for 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 manufacturer.

This medical device is not intended for diagnostics in emergency conditions! Remember that if you suspect any hazard to life or health (e.g. trouble breathing, impaired consciousness, significantly increased respiratory rate, panic), do not use the medical device and do not wait for results of analysis carried out by the medical device! In the situation described, consult a physician or report the problem using the 112 emergency line.

No analysis carried out by the medical device – including in particular the cases when the result of the analysis conducted by the medical device is lack of identification of any abnormal additional sounds in the respiratory system – should delay or substitute consulting a physician or reporting the problem using the 112 emergency line.

Using the StethoMe AI medical device 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 device, should be supervised by medical personnel.

StethoMe AI 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 AI supports only the recordings originating from the StethoMe® Smart 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 device classification

The StethoMe AI medical device 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

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

2.9. Label

2.10. Compliance with standards

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

3. MEDICAL DEVICE FUNCTIONING

3.1. Technical parameters

- The medical device is a piece of software that is 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 medical device is available is provided together with the software license.
- StethoMe AI takes advantage of a neural network architecture.

3.2 Result of analysis

After carrying out the analysis, the result is presented visually using two 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 pointsin order to obtain the most reliable result.

3.2.1 Analysis result for a single auscultation points

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

🟢	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)
❗	insufficient signal quality (no breathing detected or too much interference)

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

3.2.2 Result of analysis of a whole visit

StethoMe AI presents results of analysis of the whole visit using an alarm icon. The icon displayed depends on the analysis result and may take forms described in Table 2.

	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 2. Templates of icons presenting the result of analysis of a whole visit.

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 device license.

4.2. User manual available online

The most recent version of the user manual is available at the www.StethoMe.com/manuals 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: https://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.

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 device'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 device, contact the maintenance service at the e-mail address: support@StethoMe.com

MANUFACTURER

StethoMe Sp. z o.o.
61-663 Poznań; ul. Winogrady 18a
Poland
www.StethoMe.com

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