



Operating manual

Electronic stethoscope with a dedicated app

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1. Introduction

1.1 About the manual

This manual is part of the medical device called the StethoMe® electronic stethoscope.

Instructions for StethoMe® AI [sound analysis algorithms] and additional materials are available on the www.StethoMe.com website.

StethoMe sp. z o.o. bears no responsibility nor grants any warranty for any damages (also indirect damages) which may occur as a result of not following this operating manual.

- Carefully read the operating manual before using the medical product.
- For the entire period of use of the medical device, the operating manual should be kept in a safe location.
- The operating manual should be handed over to each subsequent user or owner of the medical device.
- The operating manual should be updated on the basis of each supplement received from the manufacturer.

The goal of this manual is to describe the medical device, called the StethoMe® electronic stethoscope, taking into account in particular:

- the description of the medical device,
- safety of use,
- maintenance,
- troubleshooting,
- servicing.

1.2 Index of changes

This operating manual is valid for the following version of the StethoMe® electronic stethoscope:

Version of the medical device: StethoMe® 2.3.x and StethoMe® AI 3.3.x.
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1.3 Symbols and markings used in the manual



Warnings and safety measures, which if not followed, could result in personal injuries.



Warnings and safety measures, which if not followed, could result in material damage.



Additional tips/information.

2. Characteristics

2.1 Intended use of the medical device

The StethoMe® medical device enables auscultation of the patient and recording of respiratory sounds or heart sounds by a doctor, by other medical personnel, or by a person without medical education, and transmission of the recordings. The device may be used for recording of respiratory tract sounds in the course of asthma. The StethoMe® device may be combined with the StethoMe® AI medical device for analysis of auscultation sounds.



NOTE! Any other use of the medical device is considered to be contrary to its intended purpose and should be avoided.

2.2 Contraindications

Auscultation should not be performed in the presence of wounds or abrasions. When using StethoMe® with the StethoMe® AI medical device, it should be remembered that due to the significant physiological variability of the established parameters, results for children below the age of one provided by StethoMe® AI should always be consulted with a doctor. It is recommended to be particularly cautious with this age group.

2.3 Safety of the medical device and possible adverse effects

The medical device is completely safe for humans, on the condition that it is used in accordance with the operating manual.

2.4 Precautions and warnings



- The medical device specified below is a certified electronic stethoscope and should be used in accordance with its intended use [described in item 2.1].
- Use of the medical device is not a substitute for a doctor's visit and should not delay obtaining medical attention for a sudden medical emergency.
- The medical device should only be operated by adults.
- Auscultation with the use of a medical device should not be performed in the presence of wounds or abrasions in the examined location.
- If the user of the medical device has an implanted pacemaker, a doctor should be consulted as to whether it is possible to use the medical device.
- It should be noted that the medical device is sensitive to external factors – noises or murmurs may negatively impact the recording's quality.
- Before commencing the examination, it is necessary to thoroughly read the medical device's operating manual supplied with the product and also available at the www.StethoMe.com address.
- It should be remembered that the medical device is not intended for emergency diagnostics!

- If you suspect risk to health and life (e.g. breathing difficulties, impaired consciousness, significantly increased respiratory rate, symptoms of increasing panic) do not use the medical device! In such situations, call an emergency number or contact a doctor urgently.
- If you have any doubts related to use of the medical device (e.g. where to apply the medical device to the body) consult a doctor.
- Transmission of recordings from the medical device can only be performed using StethoMe app. Recordings made with the use of other apps may not be reliable, which may lead to misinterpretation of their content by a doctor or StethoMe AI, resulting in a misdiagnosis.
- StethoMe application is available on both Android and iOS platforms. Supported software versions: Android 9 [and newer], iOS 15 [and newer].
- The medical device contains small parts which can be swallowed or ingested. Children should not have access to the product and its accessories.
- The power cord may pose a strangulation hazard; therefore, children should be examined under adult supervision.
- Only the special USB [type A] 3.5 mm mini jack [4-pole] cable supplied by the manufacturer and a charger with parameters which meet the parameters specified

in this manual should be used for charging.

- The USB (type A) 3.5 mm mini jack (4-pole) cable contains electronic components inside the type A USB plug and forms a part of the set.
- When charging the stethoscope, no examinations should be performed and the stethoscope should not be placed on the body.
- When charging the stethoscope, it should not be placed in a manner which would hinder disconnecting it from the electric socket.
- The battery should not be replaced by the user.
- Before commencing the examination, the charging cable **MUST** be disconnected from the stethoscope!
- If the stethoscope is used in combination with the StethoMe® AI medical device, the operating manual of this device has to be read as well as the warnings contained in this manual below section 5.1 'Patient auscultation mode, using the app in conjunction with the StethoMe® AI medical device'.



- The medical device should be used in accordance with its intended use.
- The product should not be exposed to any chemicals, sunlight or high temperatures.
- Basic safety precautions should always be followed, in particular when the medical device is used near children.
- Before use, make sure that the stethoscope has no visible damage.
- Do not modify nor open the stethoscope.
- Do not immerse the stethoscope in water or any other liquids.
- Protect the stethoscope against knocks and falls.
- The stethoscope should be stored in its original, closed packaging, in a location not visible and not accessible to children.
- If there are any irregularities in the operation of the stethoscope or any damage is observed, discontinue use of the device and contact the manufacturer.

2.5 Additional information



- **For full functionality of the medical device, an internet connection and an active Bluetooth module in a mobile device with an installed app are required.**
- **The medical device is reusable.**
- **The medical device is intended for home and professional use.**
- **The device should be stored in a clean and dry place.**
- **The medical device is not sterile and must not be sterilised.**
- **During charging, all functions of the stethoscope, including data transmission, are locked.**
- **The stethoscope does not contain user-replaceable parts.**
- **This manual should be kept, so it can be read as needed.**

2.6 Medical product classification

1. The StethoMe® medical device was classified in accordance with Annex IX of the Council Directive 93/42/EEC.
2. Internally powered stethoscope: lithium-polymer battery, non-replaceable.
3. Type of used applied parts: BF.
4. Protection rating: IP22.
5. Does not require sterilisation.
6. Operating mode: continuous.

2.7 Markings



Manufacturer



Serial number



Handle with care, breakable
Fragile



Water resistance rating



Before use, read the operating manual
carefully



Relative humidity



Meets the requirements of the 93/42/EEC directive and harmonised standards



Disposal of waste electric and electronic equipment – the medical device should
be disposed in accordance with national regulations on waste electric or electronic
equipment



Direct current



BF type applied parts



CAUTION! IMPORTANT!
Please read the manual



Protect against humidity



Temperature



Atmospheric pressure

3. Equipment and design

3.1 Equipment

The set contains:

1. StethoMe® stethoscope,
2. special USB (type A) 3.5 mm mini jack cable,
3. operating manual,
4. Quick start guide (abbreviated operating manual).

3.2 Design

The main elements of the stethoscope are presented in *Fig. 1a \ Fig. 1b*.



Fig. 1a







Fig. 1b

1. LCD display
2. The mini jack socket is used both for connecting the earphones and for charging
3. Membrane
4. Ventilation openings

i **IMPORTANT!** In order to make full use of StethoMe®, a mobile device with an installed, authorised app, internet access and an active Bluetooth module is required.

The table below contains the most important symbols displayed on the stethoscope screen:

	StethoMe® logo - stethoscope is active and ready to connect with the app
	Stethoscope is connected with the app
	Stethoscope battery charge level
	Stethoscope connected for charging
	Earphones connected to the stethoscope

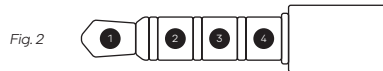
	Lung auscultation filter active (in earphones/no app connected mode)
	Heart auscultation filter active (in earphones/no app connected mode)
	Maintain silence in the room
	Excessive noise or stethoscope unstably placed on the body (red icon)

3.3 Connectors

The StethoMe® stethoscope is equipped with one mini jack socket intended for:

- connecting earphones,
- connecting the USB (type A) 3.5 mm mini jack cable supplied in the set for charging (the stethoscope is not active during charging).

A description of the 3.5 mm mini jack poles is presented in *Fig. 2*.



1. Left earphone channel (inactive during charging)
2. Right earphone channel (inactive during charging)
3. GND (ground)
4. Ground (earphones) / +5V (charging)

4. Preparing for use



4.1 App

Before using the stethoscope, you should download and install the StethoMe® app. A list of authorised apps can be found on the www.StethoMe.com website.

i Always use the latest version of the app. You can download it from Google Play or App Store.

4.2 Preparing the stethoscope

1. When the stethoscope is used for the first time, and after it has been turned off, it should be turned on by inserting the supplied USB mini jack cable in the stethoscope's mini jack socket and removing it [the cable does not have to be connected to the power] (Fig. 3).

i **IMPORTANT!** If the stethoscope's battery is charged (the battery charge level icon  is located in the upper right corner of the screen), after the start screen  appears, the cable may be disconnected.

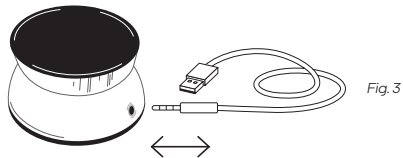


Fig. 3

2. To charge the stethoscope, connect it to a charger with the supplied cable only. The cable should be connected to a charger which meets the requirements specified in this manual [item 7]. The stethoscope should be connected to the power until it is fully charged [the battery icon is full].

i **IMPORTANT!** During charging, all stethoscope functions are locked.

3. When the stethoscope is charged, turned on and in standby mode, in order to activate, it is enough to gently shake it up and down until the start screen appears [the StethoMe® logo, Fig. 4].

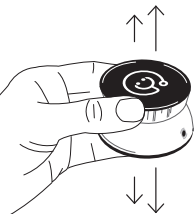


Fig. 4

- Internet access is required for the application to work. Communication between the app and the stethoscope is possible after the Bluetooth function is activated in a device with an installed app. During the first connection, for devices running Android 12 and above, an access to nearby devices is required. For devices with an older system - access to phone's location is needed.
- The StethoMe app should be started, which will automatically connect with the stethoscope after selecting the type of examination (no need to pair the devices). Depending on the quality of connection between devices, the time needed to form a connection may differ. Usually, this process takes about 5 seconds. After connecting, the icon will appear on the stethoscope's screen, which shows it is ready for operation - 'Stethoscope is connected with the app'.


i **IMPORTANT!** During activation, the app checks the version of the stethoscope and its firmware. If needed, the app will automatically perform an update process. This usually takes about 1 minute, and the user will be notified about its progress in an ongoing manner. During the update process, neither the device with the app nor the stethoscope may be used since this may result in damage to the stethoscope.

5. Actions to be taken when using the device

The StethoMe® stethoscope may be used in the following modes:

- with the use of the app combined with the StethoMe® AI medical device,
- without the app.



NOTE! Do not cover the mini jack socket and ventilation openings and do not tap on the enclosure during the recording. After placing the stethoscope on the body, it automatically commences recording. Information on the progress of the recording will be displayed on the stethoscope screen in the app. If during the recording the stethoscope detects excessive background noise or it is not placed on the body in a stable manner, it will notify this with the red  icon.



IMPORTANT! In the two first cases, an internet connection is necessary for the system to work.

5.1 Patient auscultation mode with the use of the app combined with the StethoMe® AI medical device

To commence examination in the app, you require an active StethoMe® licence, 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.



- You can find the symbols used in the examination result in the Quick Start guide.
- The full StethoMe® AI manual can be found on the www.StethoMe.com website.
- NEVER diagnose the patient on your own, based only on results obtained with the device.
- ONLY a doctor may diagnose and prescribe treatment of respiratory system illnesses.
- Consult the results obtained with the use of the device and StethoMe® AI with the doctor.
- 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 limit values for these parameters for individuals may differ from the ranges specified in the literature and may be considered to be physiologically correct by a doctor, even though the device may indicate exceeding the range assumed to be normal.

- Every time you have any doubts concerning the result, repeat the examination, remembering the cleaning of the respiratory tract, blowing the nose and maintaining silence in the room during the examination.
- An analysis conducted by the medical device, in particular in cases when its result will not identify any irregularities, should not be a reason to delay or substitute a doctor's consultation or not to call an emergency number to report a problem.
- StethoMe® AI is intended to be used by users without medical education. Its use does not replace a doctor's visit.
- It should be remembered that any medication taken or the illness itself may increase the heart rate or respiratory parameters.

Turn on the app and then proceed in accordance with the instructions displayed in the app.

Available modes of examination:

-  **Asthma control**

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

-  **Full examination of the lungs**

Examination performed in 6-8 locations on the chest (depending on the patient's age). Detects abnormal auscultation sounds: wheezes, rhonchis, fine and coarse crackles. The following parameters are also measured: respiratory rate, inspiration/expiration time ratio and heart rate.

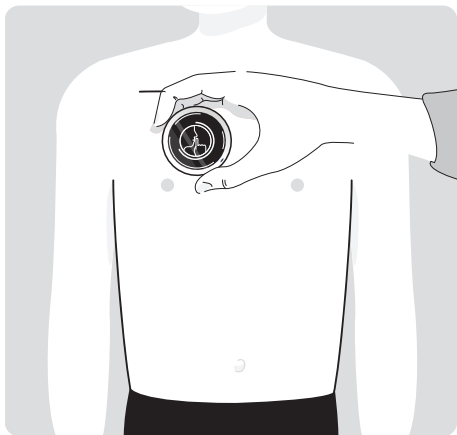
1. Select the mode in which you want to start the examination in the app.
2. Performing the recording involves applying the stethoscope's membrane (*Fig. 5*) to the patient's body at the points indicated in the app/on the stethoscope screen and holding the stethoscope at a point until a progress bar is filled. The recording starts and ends automatically.

i **IMPORTANT! After placing the stethoscope on the body, the stethoscope automatically commences recording. You should not perform a complete lung examination by yourself - examination of the points on your back requires the assistance of another person. Repeated auscultation may, in extreme cases, lead to hyperventilation of the examined person (manifested by, among others, dizziness and shallow breathing).**

3. For full examination of the lungs, selection of the auscultation point may be also performed in the app by selecting another point than the proposed one, as well as by vigorously moving the stethoscope right or left.
4. It is recommended to record all the points indicated in the app/on the stethoscope screen.
5. If the app indicates points which require correction, then the recording should be repeated at those points.
6. After correctly recording all the points or forcing the end of the examination 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 received (depending on transmission speed this will take just a few to several seconds). The results will be recorded in the cloud, and can be accessed through a history of examinations in the app.
7. Once the examination ends, a short survey appears concerning the patient's condition. The results of the survey will be attached to the results of the examination and recorded in the patient's history.
8. The survey and the results of the examination with the sounds may be made available to a doctor by sending a link for examination.



Fig. 5



Designations used in the results of analysis of recorded auscultation sounds by StethoMe® AI:




Status of the entire examination:  

- green symbol - no abnormal auscultation sounds were detected
- orange symbol - a small number of abnormal auscultation sounds were detected
- red symbol - abnormal auscultation sounds were detected
- grey symbol - the results of the examination could not be established

Asthma control:

- wheezes intensity scale from 0 to 100
- rhonchis intensity scale from 0 to 100






Other parameters:

-  respiratory rate value
-  heart rate value
-  inspiration/expiration time ratio



- The 'Asthma control' is particularly intended for patients diagnosed with asthma or with suspicion of asthma.
- The device detects these symptoms as incorrect auscultation sounds which appear in the course of asthma and other respiratory tract diseases.
- When the patient has symptoms of dyspnoea, shortness of breath, strong cough, obstruction may be so strong that pathological sounds may not be present. Firstly, administer the intervention medication prescribed by the doctor and consult the doctor. Always follow the doctor's recommendations, 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 RR and 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.

Full examination of the lungs, points on the silhouette:

-  green colour – no abnormal auscultation sounds were detected
-  orange colour – a small number of abnormal auscultation sounds were detected
-  red colour – abnormal auscultation sounds were detected
-  the point was not recorded
-  analysis not possible [low recording quality or excessive background noise]

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

5.2 Patient auscultation mode without the use of the app

In order to use the StethoMe® stethoscope without the app, simply connect earphones to the mini jack socket. A lungs symbol will appear on the stethoscope screen, which indicates that the lung auscultation filter is activated. After a vigorous double tap on the StethoMe® stethoscope's screen, the filter will switch to the heart auscultation mode, which will be shown by a heart symbol on the stethoscope screen.

i **IMPORTANT! Even though it is possible to use various types of earphones, due to the range and levels of frequencies in auscultation sound signals, it is recommended to use earphones with a minimum impedance of 16 Ohm and frequency response of at least 20-20,000 Hz.**

5.3 Turning off and resetting the stethoscope

An unused stethoscope will switch to sleep mode by itself. It is not necessary to turn off the stethoscope after each use. If it is necessary to turn off the stethoscope completely, this can be done by vigorously tapping the screen of the device six times. In order to turn on the stethoscope again, it is sufficient to connect and disconnect the USB mini jack cable (see *Fig. 3*).

i **IMPORTANT! Automatic switching into standby mode when no movement is detected occurs after approx. 30 seconds when no connection with the app is made, and after approx. 5 minutes when the app is connected.**

If the stethoscope has stopped working and does not react to operations made in the app, first you should restart the app in the phone.

If this does not help, reset the stethoscope. Connect the USB mini jack cable to the power source. Then rapidly remove and put the mini jack plug back in the mini jack socket of the stethoscope three times. The stethoscope should turn off for a few seconds and then restart.

6. Maintenance, cleaning and disinfection

After each use, the stethoscope should be disinfected. For disinfection, use a swab or a gauze pad moistened with alcohol-free disinfectant for medical products.

- Pay attention to ensure that the mini jack socket and the ventilation openings are not flooded with disinfecting liquid.
- Do not immerse the stethoscope in water or any other cleaning liquids; do not clean it under running water.
- Make sure that water does not get into the stethoscope.

7. Technical specifications

Model:	StethoMe® stethoscope
Dimensions:	height 40 mm, base diameter 60 mm, membrane diameter 36.5 mm
Display:	TFT-LCD 240 x 240 pixels
Equipment:	stethoscope, USB [type A] 3.5 mm mini jack cable, operating manual, Quick Start Guide [abbreviated operating manual]
Power supply:	lithium-polymer battery [non-replaceable]
Battery life:	300 charging cycles or 5 years
Charging voltage/current:	5V DC / 250mA
Frequency range:	RF: ISM, 2.400-2.4835 GHz
Modulation:	DSSS
Effective radiation power:	+4dBm

7.1 Electromagnetic compatibility and compliance with standards

The stethoscope meets the requirements of IEC60601-1-2 and IEC60601-1 International Standards.

7.2 Operating, storage and transport conditions

Storage and transport conditions:

Temperature:	0°C to 50°C
Relative humidity:	0% to 85%
Atmospheric pressure:	700 hPa - 1060 hPa

Operating conditions:

Temperature:	15°C to 40°C
Relative humidity:	0% to 85%
Atmospheric pressure:	700 hPa - 1060 hPa

8. 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.

StethoMe sp. z o.o. bears no responsibility nor grants any warranty for any damages (also indirect damages) which may occur as a result of not following this operating manual.

9. Manufacturer



StethoMe sp. z o.o.
ul. Winogrody 18a
61-663 Poznań
Poland
www.StethoMe.com



The symbol of the stethoscope with a crossed-out waste bin indicates that this product and the batteries it contains may not be disposed of with other household waste after use. The user is required to dispose of this waste at electrical and electronic waste collection points. Collection points, including local ones, shops and municipal units operate an appropriate system to handle waste of this nature.



Date of first CE marking:
2019-03-26

10. Warranty document

StethoMe sp. z o.o. with its registered office in Poznań, at ul. Winogrody 18A, entered in the registry of entrepreneurs kept by the District Court Poznań, Nowe Miasto i Wilda in Poznań, 8th Commercial Division of the National Court Register under KRS No 0000558650, NIP [tax ID No] 7831726542, BDO registry No 000258860 grants a warranty for the device. Warranty information concerning the duration of the warranty, its scope and territorial range and the rights in the event of a defect are specified in detail on the website www.StethoMe.com.



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