



User manual

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1. Introduction

1.1 About the manual

This manual is a part of a medical product - the StethoMe electronic stethoscope.

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.
- The user manual should be kept in a safe place for the whole duration of using the medical product.
- It should be provided to every subsequent owner or user of this 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 electronic stethoscope – taking into account the following in particular:

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

1.2 Index of revisions

This user manual is valid for the below specified version of the StethoMe electronic stethoscope.

Medical product version: 2.x

Status: 2020.02

1.3 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

The StethoMe medical product enables recording the respiratory sounds or heart sounds by a doctor, other medical personnel, or a person without medical education, and remote transmission of such recordings. The StethoMe medical product can be combined with

the StethoMe AI medical product for the purposes of auscultation sound analysis..



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

2.2 Contraindications

Do not perform auscultation if there are any wounds or abrasions within the spot examined.

2.3 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.

2.4 Precautions and warnings



- This medical product is an electronic stethoscope. It is certified and should be used solely for recording the respiratory system or heart auscultation sounds, and transmitting them remotely. This medical product does not analyse the sounds recorded. This medical product may but does not have to be used in combination with the StethoMe AI medical product, enabling analysis of the sounds transmitted within the ranges specified for presence of certain abnormal additional sounds indicated in the user manual for this medical product.
- Using this medical product is not a substitute for visiting a physician and may not delay obtaining medical assistance in sudden pathological conditions.
- This medical product can be operated by adults only.
- Do not perform auscultation with this medical product if there are any wounds or abrasions within the spot examined.
- In the event when the user of this medical product has a pacemaker implanted, the admissibility of using this medical product should be consulted with a physician.
- We underline that this medical product is sensitive to external factors – noises or murmurs may have a negative impact on the quality of recordings.

- Prior to commencing examination it is necessary to become familiarised in detail with this medical product's user manual available at the address: www.StethoMe.com.
- This medical product is not intended for diagnostics in emergency conditions! Remember! If you suspect any hazard to life or health (e.g. trouble breathing, impaired consciousness, significantly increased respiratory rate, panic), do not use this medical product! In such a situation, contact a doctor urgently or report the problem using the 112 emergency line.
- In case of any questions related to how this medical product should be used (e.g. regarding the spot where this medical product should be put to the body), please consult a physician.
- A recording made using this medical product may be transmitted only via applications approved by StethoMe. The recordings made using any applications other than those specified below may not be reliable, which may lead to their content being interpreted incorrectly by a doctor or StethoMe AI and, in consequence, to incorrect diagnosis. The list of approved applications is available at the www.StethoMe.com website.

- The application has been tested only on the mobile phone models listed. Although it is possible that the application may work on other mobile phone models, the manufacturer does not guarantee correct functioning in such cases. Using the application with any mobile phone other than those listed in this manual should be considered inconsistent with the intended use. The list of mobile phone models supported is available at the website: www.StethoMe.com.
- This medical product includes small elements that can be ingested or aspirated: keep the product and its accessories away from children.
- The power supply cable may constitute a strangulation hazard: any examination of children should be conducted under supervision.
- Only a special USB [type A] - 3.5 mm mini jack [4-pin] cable paired with a charger provided by the manufacturer – or a charger with parameters consistent with those specified in Item 8 of this manual – should be used for charging the device.
- The USB [type A] - 3.5 mm mini jack [4-pin] cable provided by the manufacturer and the charger provided by the manufacturer features electronic elements inside the USB type A plug and constitutes a part of the complete set.
- Do not perform examinations with the stethoscope or put it to the body while it is being charged.
- When charging, do not place the stethoscope in a manner that would make disconnecting it from the power socket difficult.
- Do not attempt to replace the battery on your own.

- Prior to commencing examination it is **ABSOLUTELY** necessary to disconnect the charging cable from the stethoscope!
- ⓘ • This medical product should be used in compliance with the intended use.
- The product should be used in ambient temperature from 15 to 40°C.
- Do not expose the stethoscope to temperatures greater than 50°C or lower than 0°C.
- Do not use the product when the relative humidity exceeds 90%.
- Do not expose the product to impact of any chemical substances, sunlight, or high temperature.
- It is always necessary to adhere to the fundamental principles of safety, particularly when this medical product is used near children.
- Prior to using the stethoscope it is necessary to make sure that it has no visible damage.
- The stethoscope should not be opened or modified.
- The stethoscope should not be immersed in water or other liquids.
- Protect the stethoscope against shocks and falls.
- The stethoscope should be stored in closed original packaging, in a place beyond the sight and reach of children.
- In case of noticing any irregularities in functioning of the stethoscope or any damage to it, stop using it immediately and contact the manufacturer.

2.5 Additional information

-  In order for this medical product to offer the whole range of its functions, an Internet connection is required.
- This medical product is intended for repeated use.
- It is intended for both home and professional use.
- The product should be stored in a clean and dry place.
- This medical product is not sterile and must not be sterilised.
- The stethoscope should be charged only by means of the charger included in the set supplied. In any other case, use a charger that meets the requirements described in Item 8 of this manual.
- When the product is being charged, all its functions, including data transmission, are blocked.
- The stethoscope does not include any parts that can be replaced by the user on their own.
- This manual should be retained so that it can be consulted again in the future if necessary.

2.6 Classification of the medical product

- The StethoMe 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.

- The stethoscope is powered internally: lithium-ion battery, non-replaceable.
- Type of application parts applied: BF.
- Protection class: IP22.
- Does not require sterilisation.
- Mode of operation: continuous.

2.7 Marks



Manufacturer



Direct current



Serial number



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



Disposal of waste electric and electronic equipment - this medical product should be disposed of in line with the national regulations regarding waste electric and electronic equipment



Protect against humidity

IP22 Degree of watertightness



Please familiarise yourself carefully with the user manual prior to using the product.



Relative humidity



Application parts of the BF type Caution - fragile



Easily breakable load



CAUTION! IMPORTANT!
Please read the manual



Temperature



Atmospheric pressure

2.8. Label



StethoMe



StethoMe sp. z o.o.
www.StethoMe.com



2274

Smart Stethoscope

61-633 Poznań, Poland
ul. Winogrody 18A

SVDC --- 250mA
IP22

SN 00000018



3. Equipment and structure

3.1 Equipment

The set includes:

1. StethoMe stethoscope,
2. special USB - mini jack 3.5 mm cable,
3. user manual,
4. Quick start guide [abridged User Manual],
5. charger [available in selected sets].

3.2 Structure

The main elements of the stethoscope are presented on Fig. 1a and Fig. 1b.



Fig. 1a



Fig. 1b

1. LCD display.
2. 3.5 mm mini jack socket - used for connecting headphones and for charging.
3. Membrane.
4. Ventilation openings.

i **IMPORTANT!** In order to take advantage of all features of StethoMe, it is required to have a device [e.g. phone, tablet, computer] with an approved application installed and with Internet access.

The table below includes the description of the most important symbols displayed on the stethoscope screen:

	StethoMe logo
	The stethoscope is connected to the application
	Stethoscope battery charge indicator
	Headphones are connected to the stethoscope

	The stethoscope is connected to the charger
	Lung auscultation filter is active
	Heart auscultation filter is active
	Maintain silence
	Excessive noise or the stethoscope is not applied to the body in a stable manner [red icon]

3.3 Connectors

The StethoMe stethoscope is fitted with a single 3.5 mm mini jack socket intended for:

- connecting earphones,
- connecting the USB - 3.5 mm mini jack cable, included in the set supplied, in order to charge the stethoscope [the stethoscope is inactive while being charged].

The description of 3.5 mm jack plug sections is included on Fig. 4.

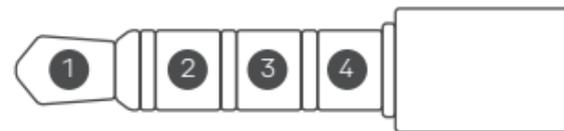


Fig. 4 1 - left headphone channel [inactive while charging], 2 - right headphone channel [inactive while charging], 3 - GND (ground), 3 - ground [headphones] / 4V [charging].

4. Preparations for use

4.1 Application

Prior to using the stethoscope it is necessary to download an approved application and install it on e.g. a phone, tablet, or computer. The list of approved applications is available at www.StethoMe.com.

- i The lists of the devices supported by our partner should be available at their websites.
- i Always use the most recent version of the application. You can download it from Google Play or App Store.

4.2 StethoMe stethoscope

1. When using the stethoscope for the first time, and after it was turned off, it is necessary to switch it on using the cable included in the set by inserting the the 3.5 mm jack cable provided into the stethoscope's jack socket [Fig. 2] and then removing it.

- i **IMPORTANT!** If the battery of the stethoscope is charged (the battery status icon is located in the upper right corner of the screen), the cable can be disconnected after the start screen [with StethoMe logo] appears.

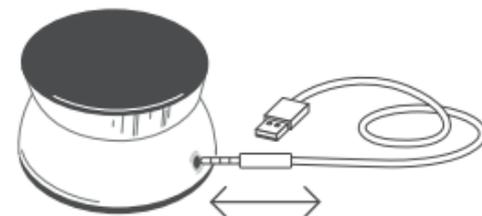


Fig. 2

2. In order to charge the stethoscope it is necessary to connect it to a charger using only the cable provided. If a charger was included in the set, it should be used for charging the stethoscope. In any other case the cable should be connected to a charger that meets the requirements described in Item 8 of this manual. After connecting the stethoscope to the charger, it should be left until fully charged [when the battery icon is full].

- i **IMPORTANT!** When the stethoscope is being charged, all its function are blocked.

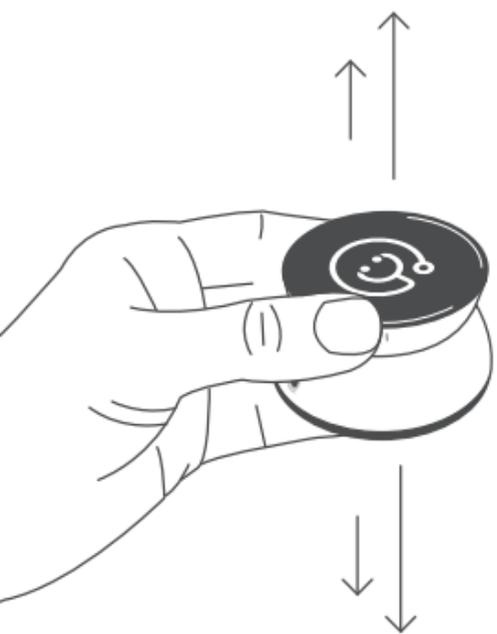


Fig. 3

When the stethoscope is charged, turned on, and in standby mode, it is necessary to shake it gently in vertical axis until the start screen (StethoMe logo, Fig. 3) appears.

3. The communication between the application and the stethoscope is possible after the Bluetooth and Location functions are activated on the device where an approved application has been installed.
4. It is necessary to launch the approved application, which will establish connection to the stethoscope after the type of examination is selected. Depending on the quality of connection between the devices, the connection time may differ and it usually takes about 5 seconds. After the connection is established, an icon meaning readiness to work will appear on the stethoscope screen - "The stethoscope is connected to the application" [see table item 3.2].



IMPORTANT! When launching, the application checks the version of the stethoscope and the software. If necessary, the application will carry out an automatic update process. A software update may take about 1 minute and the user will be notified of its progress on a current basis. When the update is in progress neither the device with the application installed nor the stethoscope should be used, as this may damage the stethoscope.

5. Activities during operation

The StethoMe stethoscope can be used in one of the three modes listed below:

- using the application without connection to the StethoMe AI medical product,
- using the application with connection to the StethoMe AI medical product,
- without the application.



CAUTION! When recording, make sure that the jack socket and the ventilation openings are not covered and do not knock on the casing. After putting the stethoscope to the body, it starts recording automatically. The stethoscope screen and the application will show information on the recording progress.

If during the recording the stethoscope detects excess ambient noise or that it is not put to the body in a stable manner, it will signal it with a red icon of the appropriate alarm (see the table in item 2 of this manual).

i IMPORTANT! In the first two cases the system requires connection to the Internet.

5.1 Patient auscultation mode using the application without connection to the StethoMe AI medical product

It is necessary to launch the application and proceed according to the instructions displayed in the application.

1. Select in the application whether you want to auscultate lungs or heart by touching the appropriate icon.
2. Making a recording consists in putting the stethoscope membrane (Fig. 4) to the patient's body at specific spots indicated in the application / on the stethoscope screen and holding the stethoscope at each spot until the progress bar is filled.

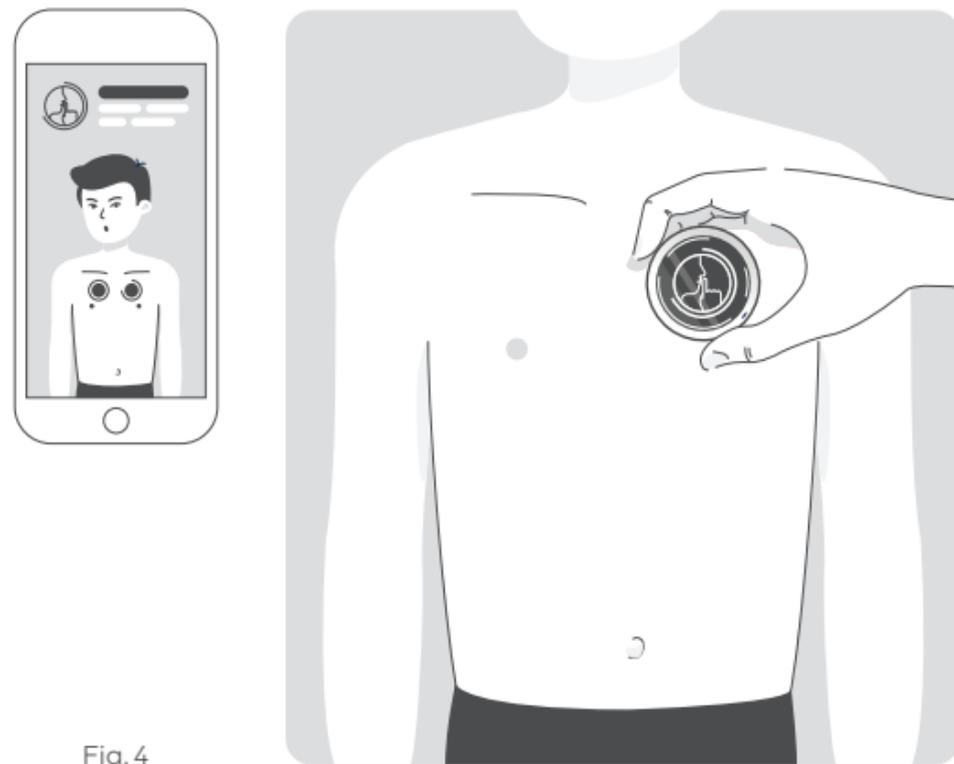


Fig. 4

The recording is started and finished automatically.

3. The active auscultation spot can also be selected without using the application. It is enough to make a gesture with the stethoscope by moving it to the right or to the left.
4. It is recommended to record sound at all the spots indicated in the application / on the stethoscope screen.

i **IMPORTANT! After putting the stethoscope to the body, it starts recording automatically.**

5.2 Patient auscultation mode using the application with connection to the StethoMe AI medical product

It is necessary to launch the application and proceed according to the instructions displayed in the application.

1. Select in the application whether you want to auscultate lungs or heart by choosing the appropriate mode of auscultation
2. Making a recording consists in putting the stethoscope membrane [Fig. 4] to the patient's body at specific spots indicated in the application / on the stethoscope screen and holding

the stethoscope at each spot until the progress bar is filled. The recording is started and finished automatically.

3. The auscultation spot can also be selected without using the application. It is enough to make a gesture of moving the stethoscope to the right or to the left.
4. It is recommended to record sound at all the spots indicated in the application / on the stethoscope screen.
5. If the application shows that the quality of sound recorded at some spots is poor, it is necessary to repeat recording at those spots.
6. After recording all the spots properly or after forcing the examination to end with not all of the spots recorded, the auscultation sounds recorded are automatically sent for analysis by StethoMe AI algorithms. After the analysis is completed, it is sent back to the user [depending on transmission speed this takes from several to several dozen seconds]. At the same time, the results can also be sent to a medical teleplatform.

i **IMPORTANT! After putting the stethoscope to the body, it starts recording automatically.**

Below you can find the tags employed in the results of StethoMe AI's analysis of the auscultation sounds recorded:

Spots on the silhouette:

- green colour - no abnormal auscultation sounds have been detected,
- orange colour - a small number of abnormal auscultation sounds has been detected,
- red colour - abnormal auscultation sounds have been detected,
- red circle - not recorded,
- red circle with a cross - analysis impossible (low quality of recording or excessive noise).

Status of the whole examination:

- green symbol - no abnormal auscultation sounds have been detected,
- orange symbol - a small number of abnormal auscultation sounds has been detected,
- red symbol - abnormal auscultation sounds have been detected,
- grey symbol - it is impossible to determine the examination result.



CAUTION! After obtaining in the application the results of analysis carried out by the StethoMe AI medical product, such results always have to be consulted with a physician.



Check the most recent possibilities at the address www.StethoMe.com. You can learn how to read the results from the StethoMe AI user manual, the most recent version of which is available at the www.StethoMe.com website.

5.3 Patient auscultation mode without using the application

In order to use the StethoMe stethoscope without the application, it is enough to connect headphones to the 3.5 mm mini jack socket – the stethoscope screen should then display a lung symbol indicating that the lung auscultation filter is active. After tapping the StethoMe stethoscope screen twice, the filter will be switched to the heart auscultation mode, which will be indicated by the heart symbol on the stethoscope screen.



IMPORTANT! Although it is possible to use various type of headphones, in view of the range of frequencies present in auscultation sound signals and levels thereof it is recommended to use headphones with minimum impedance of 16 Ohm and bandwidth of at least 20 - 20 000 Hz during auscultation.

5.4 Turning the stethoscope off

If the stethoscope is not used, it will automatically enter the sleep mode. It is not necessary to turn it off after each use. If it becomes necessary to turn off the stethoscope completely, this can be done by knocking six times on the device screen. In order to turn the stethoscope on again, it is enough to connect and disconnect the jack cable [see Fig. 2].



IMPORTANT! Automatic transition into standby mode (if no movement is detected): after about 30 s in case of lack of connection to the application; after about 5 minutes when the stethoscope is connected to the application.

6. Maintenance and cleaning

The stethoscope should be disinfected after each use. It should be disinfected using a cotton pad or swab moistened with non-alcoholic disinfectant intended for medical products.

- Please take care not to flood the 3.5 mm jack socket with the disinfectant.
- Please take care not to flood the ventilation openings with the disinfectant.
- Do not immerse the stethoscope in water or other cleaning liquids and do not clean it under running water.

- Make sure that the water does not reach the inside of the stethoscope.

7. Troubleshooting

You can find a list of solutions for the most frequently occurring issues at the www.StethoMe.com website.

8. 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-mini - 3.5 mm jack cable, user manual, Quick Start Guide [abridged user manual]
Power supply:	lithium-ion battery [non-removable]

Battery lifetime:	300 charging cycles or 12 months
Charging voltage/current:	5V DC / 250mA
Frequency range:	RF: ISM, 2.400 -2.4835 GHz
Modulation:	DSSS
Effective radiation strength:	+4dBm

8.1 Electromagnetic compatibility and compliance with standards

The stethoscope meets the requirements of the IEC60601-1-2 and IEC60601-1 International Standards. The stethoscope complies with European regulations and features the CE 2274 mark. The quality of the stethoscope has been verified and complies with provisions of the Council Directive [EC] 93/42/EEC on medical products of 14th of June 1993.

8.2 Storage, transport and operation conditions

Storage and transport conditions:

Temperature:	0°C do 50°C
Relative humidity:	0% do 85%

Atmospheric pressure:	700 hPa -1060 hPa
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Operation conditions:

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

9. Servicing

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

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.

10. Manufacturer



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



If the stethoscope is marked with the symbol of a crossed-out waste container, it means that this piece of equipment and the batteries included in it may not be disposed of together with other household waste after expiration of their useful life. The user is obligated to hand them over at a waste electric and electronic equipment collection point. The waste collection points, including local collection points, stores and municipal units, create an appropriate system enabling handing over of such equipment.



Date of issue of the manual: 24.02.2020
Version: 03

11. Warranty document

StethoMe sp. z o.o. company having its seat in Poznań in Poland at the address ul. Winogrody 18A, entered into the Entrepreneur Register kept by the District Court Poznań - Nowe Miasto i Wilda in Poznań, 8th Commercial Division of the Polish National Court Register (KRS) under the KRS number 0000558650, NIP [tax identification number]: 7831726542, register number BDO 000258860 grants warranty for the device.

The warranty-related information regarding warranty duration, its scope, its territorial range, and the rights in case of finding a defect are described in detail at the address: www.StethoMe.com.



StethoMe[®]

Smart Stethoscope