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What is a medical stethoscope?

A stethoscope is “doctor’s earphones” that allow auscultating a patient during a visit. The stethoscope helps a doctor detect sounds such as rhonchi, wheezes, or rattle, all of which may be symptoms of diseases such as pneumonia, bronchitis, or asthma. The creator of the current standard of the most popular traditional stethoscopes, characterised by featuring a membrane, is Dr David Littmann.

StethoMe® is a revolutionary, wireless stethoscope combined with an application and AI algorithms that help doctors diagnose respiratory system diseases such as bronchitis, asthma, bronchial asthma, and pneumonia - which may be caused by e.g. coronavirus. Thanks to this examination you have a control over your health and you can contact your doctor using online consultation.

What is StethoMe® system and how does it work?

1. What is the StethoMe® system?

StethoMe® is the first system that detects abnormalities in the respiratory system. StethoMe® relies on StethoMe® AI algorithms working together with a wireless StethoMe® stethoscope and a dedicated application.



Both products are certified medical device in EU member states and other countries that recognise this certificate (e.g. Switzerland, Australia). Their safety and value are confirmed by the CE2274 mark awarded to verified medical devices under Council Directive 93/43/EEC (MDD) binding in EU.

StethoMe® is intended for telemedical applications, enabling quick and easy integration with, among others, HIS, EDM, or telemedical systems.

Thanks to using unique technologies that ensure control over examination quality, StethoMe® can be used by patients at their homes.

2. Where can I buy StethoMe®?

The StethoMe® system consisting of a StethoMe® stethoscope and StethoMe® AI artificial intelligence algorithms is available only to medical facilities, doctors, telemedicine service providers, and hospitals.

At present, StethoMe® is not available for individual needs. You can find the list of current partners of StethoMe® at this website.

If you are a doctor, you can see the offer [on the website](#).

3. How much does StethoMe® cost?

The StethoMe® system is available only to medical facilities, doctors, telemedicine service providers, and hospitals. The price is agreed upon individually and depends on the contract signed.

If you are a representative of a medical facility or a hospital, or if you are a doctor and you would like to cooperate with us, contact us via e-mail at kmak@StethoMe.com

If you are a doctor, you can see the offer [on the website](#).

4. Intended use of the medical device StethoMe®?

The StethoMe® medical device enables recording the respiratory sounds or heart sounds by a physician, other medical personnel, or a person without medical education, and remote transmission of such records. The StethoMe® medical device can be combined with the StethoMe® AI medical device 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..

5. What kind of examinations can I carry out using StethoMe®?

StethoMe® enables remote auscultation of lungs and heart without leaving home, making a recording, and sending it directly to a doctor.

Additionally, in case of lung auscultation, it allows obtaining automatic notification of presence of any abnormal auscultation sounds appearing in the course of various respiratory system diseases, such as bronchitis, pneumonia, or obstruction in the lower respiratory tract. The system does not diagnose these diseases, but detects pathological sounds characteristic of their course. StethoMe® can also be used like a traditional stethoscope (without the analytical module) after connecting earphones to the mini jack socket.

See also Item 4 Intended use of the StethoMe® medical device.

6. Is the device a medical device and does it feature CE and FDA certificates??



StethoMe® stethoscope and the StethoMe® AI algorithms feature the CE 2274 European mark and have a certificate awarded to medical devices (both in IIa class) under the Council Directive 93/42/EEC (MDD). It is the world's first certification of artificial intelligence algorithms for the purposes of analysing respiratory system sounds. StethoMe® and StethoMe® AI have been designed and are produced according to the highest worldwide quality standards, which is confirmed by the certificate for the Quality Management System for Medical Device Manufacturers, in line with the ISO 13485:2016-04 standard, which has been implemented in the company.



StethoMe® has also the safety and quality certificate of TÜV. The certificate can be verified at: www.certyfikat.tuv-nord.pl

StethoMe® is now in the course of preparations to obtain the FDA certificate (USA) and PMDA certificate (Japan), but does not have them at this moment.

7. Who can see the results of my examinations? Is data security ensured?

If the user account was added by a doctor or telemedicine service provider, then the doctor you are registered with can see the results of your examinations.

If you shared your visit, the people to whom you send the link can see its content.

What are the technical requirements for using StethoMe®?

1. What do I need to be able to use StethoMe®?

- a StethoMe® wireless stethoscope
- the StethoMe® application (available at [Google Play](#) and [App Store](#))
- active Bluetooth communication and localisation service, and online access on the device where the above application is installed.

2. How to sign in to the StethoMe® application?

After downloading the application to your mobile, you need to click the “sign up” or “sign in” button (if you already have an account). If the “sign up” option is not available, make sure that the application you use is the most recent version available at the application store.

Remember that the applications works only in combination with a StethoMe® stethoscope.

3. Which phones and tablets are compatible with StethoMe®?

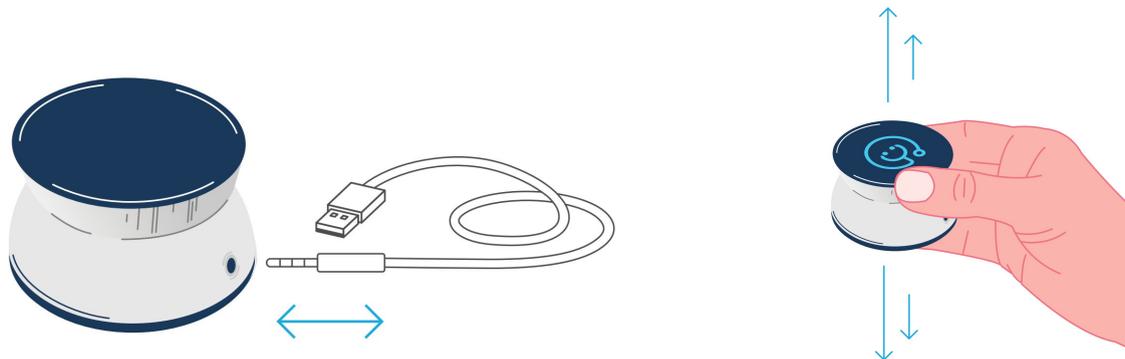
You can find the list of supported devices at StethoMe.com/devices.

4. How often should the stethoscope be charged and how long does the battery last?

The stethoscope should be charge once the red discharged battery symbol appears on its screen. After the battery is discharged completely, the device should be charged for at least 15 minutes before it is turned on again. The time required to charge the battery full is about 4 hours. The stethoscope can work continuously for approximately 8 hours on a fully charged battery.

5. How to turn the StethoMe® device on and off?

The stethoscope is turned on for the first time by inserting the jack plug into the socket and then removing it. If the stethoscope is not used, it will enter the standby mode (you do not have to turn it off). You will be able to wake it up by shaking it vigorously upwards or downwards.



6. Messages when launching the application - request for authorisation.

When the application is launched for the first time, it is necessary to grant it permission to use the location service*, establish connections and access the photos and multimedia. The settings are saved and this step is a one-time action. During every subsequent launch of the application these screens will not be shown again. In order for the application to work correctly in all the three cases (location, establishing connections, and photos and multimedia) it is necessary to click the ALLOW button. If you refuse to grant permission in case of any of these requests, the application will not be functioning correctly.

*The location data is not collected by StethoMe®. It is necessary only because of the technology used for communication between the stethoscope and the application.

Technical problems.

1. Information on no stethoscopes having been found.

This message will appear in case when the mobile phone or other mobile device has been unable to find any stethoscope via the wireless connection.

Possible reasons:

- **the stethoscope being switched off (the display of the stethoscope is not lit):**
Turn on the stethoscope. The stethoscope is turned on for the first time by inserting the jack plug into the socket and then removing it. Later on you will be able to wake it up by shaking it vigorously upwards or downwards. See also question 2.6 How to turn the StethoMe® device on and off?
- **the stethoscope's battery is fully discharged:**
Charge the stethoscope using the cable and charger included in the set.
- **the wireless signal between the phone and the stethoscope may be disrupted or suppressed:**
It is necessary to check whether the transmission between the phone and the stethoscope is not disrupted in some manner. The stethoscope should be located near the device with the

- **StethoMe® application other causes**

After checking and removing the problems it is necessary to start the examination again, which will result in an attempt to establish connection with the stethoscope. It is necessary to remember to activate the Bluetooth module and the device location service in the settings of the device where the StethoMe® application is installed.

2. Where do I find the newest Manual instruction?

The newest instruction can be find on our website [here](#).

How to carry out lung auscultation?

1. What kind of conditions should be ensured in order to perform a lung examination correctly?

StethoMe® records the very silent sounds originating from the respiratory system and therefore it is important to maintain silence in the room during examination. Any additional sounds may make recording impossible or worsen its quality significantly. In extreme cases they may even have impact on the examination result. That is why it is necessary to turn off the television and other sources of sound and not to talk during recording. During the examination it is nor allowed to knock on the stethoscope, move it on the skin, or move fingers on its housing. It should be put to the skin gently and then held in a stable position during recording. The persons examined should not be moving or eating, and little children should not use a pacifier. During the examination it is necessary to take deep breath at a natural pace, best through mouth. If the person examined is a female, it is necessary to undo the bra during auscultation in the back.

2. How to prepare oneself to a lung auscultation?

Before being examined, the patient should blow their nose and expectorate mucus from the respiratory tract, to the extent possible. Children should not use a pacifier, eat, drink, or chew gum during the examination. The stethoscope should be put to the skin directly - the patient should have their upper body clothing taken off.

3. What position should be patient be in during lung auscultation?

The most important aspect is to maintain a stable, possibly stationary position during the examination, so that it is possible to apply the stethoscope in a stable manner to the points indicated and not move it while registering the signal from the chest. The positions preferred during the examination depend on the patient's age:

- infants may be in supine position or in parent's arms,
- for children able to sit on their own the sitting position is preferred,
- for older children and for adults the standing position is preferred.

4. How to breathe during lung auscultation?

It is best to take deep breaths through the mouth, at a natural pace. It is very important for the person examined to breathe in a natural way, without any forced - e.g. quicker - breathing, and not to hold their breath. The condition for obtaining a good quality recording is detecting breath, since any additional and abnormal respiratory system auscultation sounds appear and are audible only during breathing.

5. What should I do if the examination result is red lungs?

Abnormal auscultation sounds have been detected.

The red lungs result means that the algorithms detected some additional and abnormal auscultation sounds (irregularities in breathing). The reasons for appearance of the red lungs result may be one of the following:

- changes in breathing may appear in the course of various respiratory system diseases, such as bronchitis, pneumonia, or obstruction in the lower respiratory tract or
- on rare occasions, such a result may appear if proper examination conditions have not been provided: the respiratory tract secretions have not been expectorated, the nose have not been blown, the stethoscope has not been applied to the right place, or additional sounds have appeared (e.g. crying, speech) during the examination

WE RECOMMEND:

- Repeating the examination after cleaning the airways and in conditions of complete silence, to the extent possible.
- It is necessary to pay attention to the location of auscultation points on the picture and try putting the stethoscope to the body at exactly the same points. Lower points on the back are above the waist line and are located on the extreme right and left side, almost along the sides of the body. If the person examined is a female, it is necessary for her to take off the bra for the examination.
- If the same result is obtained repeatedly, consult a doctor immediately in order to have other further examinations carried out and to receive diagnosis.

6. What should I do if the examination result is orange lungs?

A small number of abnormal auscultation sounds has been detected.

This result means that the algorithms detected a small number of abnormal additional auscultation sounds. This result may also appear if proper examination conditions have not been provided, e.g. if the respiratory tract secretions have not been expectorated, the nose has not been blown, the stethoscope has been applied at a wrong place, or additional sounds have appeared (e.g. crying, speech) during the examination.

WE RECOMMEND:

- Repeating the examination after cleaning the airways and in conditions of complete silence, to the extent possible.
- It is necessary to pay attention to the location of auscultation points on the picture and try putting the stethoscope to the body at exactly the same points. Lower points on the back are above the waist line and are located on the extreme right and left side, almost along the sides of the body. If the person examined is a female, it is necessary for her to take off the bra for the examination.
- If the same result is obtained repeatedly, it is best to consult it with a doctor (see also the important information for patients suffering from chronic diseases)

7. What does the message saying that the lung sounds are of insufficient quality mean?



It was impossible to determine the examination result. The number of points recorded is insufficient or the quality of points recorded is insufficient for determining the examination result.

It means that too much interference was present during the examination or that the patient was taking too shallow breaths and the algorithms have not detected the sufficient number of inhalations and exhalations required in order to perform analysis.

Such a message may also mean that the stethoscope was applied at a wrong place (e.g. too low on the back) and did not record any lung sounds (inhalation and exhalation). It is very important to apply the stethoscope precisely at the points on the body shown by the application.

8. During the examination the color of the icon and the point turns red - what does it mean?



StethoMe® automatically detects any excess ambient noise stethoscope movement that causes interference. If the conditions are too loud, the stethoscope will stop the examination for a moment and display a red icon. It is necessary to make sure that the examination room is sufficiently silent (TV and radio turned off, windows closed) and repeat the examination.

9. After placing the stethoscope onto the body the device do not start to record automatically.

One of the reason for the stethoscope not to start the recording is the thickness of the fat layer. In that case, just place the stethoscope a bit harder to your body and push it to the skin. Repeat this on each auscultation point.

How to carry out heart auscultation?

1. What kind of conditions should be ensured in order to perform a heart auscultation correctly?

StethoMe® allows recording and sending heart sounds and precise determination of the heart rate (BPM). It is very important to maintain silence in the room during examination. Any additional sounds may make recording impossible or significantly worsen the quality thereof. That is why it is necessary to turn off the television and other sources of sound and not to talk during recording. During the examination it is not allowed to knock on the stethoscope, move fingers on it, or move the stethoscope on the skin. It should be applied to the skin with gentle pressure, and then it is necessary to remain in a stable position during recording. During the examination, the person examined should not be moving or eating, and if they are a little child they should not use a pacifier. When a point is being recorded it is best to hold one's breath or to take as shallow breaths as possible.

2. How to prepare to a heart auscultation?

Immediately before the examination the patient should avoid any physical effort. The stethoscope should be applied directly to the skin – the patient should not be wearing any upper body clothing.

3. What position should be patient be in during heart auscultation?

The most important aspect is to maintain a stable, possibly stationary position during the examination, so that it is possible to apply the stethoscope in a stable and comfortable manner to the points indicated. Lying position is preferred during the examination, but the sitting one is also allowed. When a point is being recorded it is best to hold one's breath or to take as shallow breaths as possible.

4. During the examination the color of the icon and the point turns red - what does it mean?



StethoMe® automatically detects any excess ambient noise stethoscope movement that causes interference. If the conditions are too loud, the stethoscope will stop the examination for a moment and display a red icon. It is necessary to make sure that the examination room is sufficiently silent (TV and radio turned off, windows closed) and repeat the examination.

Important information regarding chronic diseases.

In case of certain diseases the auscultatory changes may be present permanently or exhibit certain characteristic variability. If you suffer from a chronic disease, remember to consult your results regularly with your doctor.

In case of persons suffering from cystic fibrosis the auscultatory changes may be present permanently.

In case of people suffering from asthma and chronic obstructive pulmonary disease, certain variability may occur. The auscultatory changes appear during the periods of disease aggravation. What is characteristic for it is the significant daily variability within several months.

Permanent auscultatory changes may also occur in case of bronchitis in patients who are chronically ill, remain in reclined position, suffer from cerebral palsy, experience hypersecretion in the respiratory tract, or suffer from central nervous system damage.