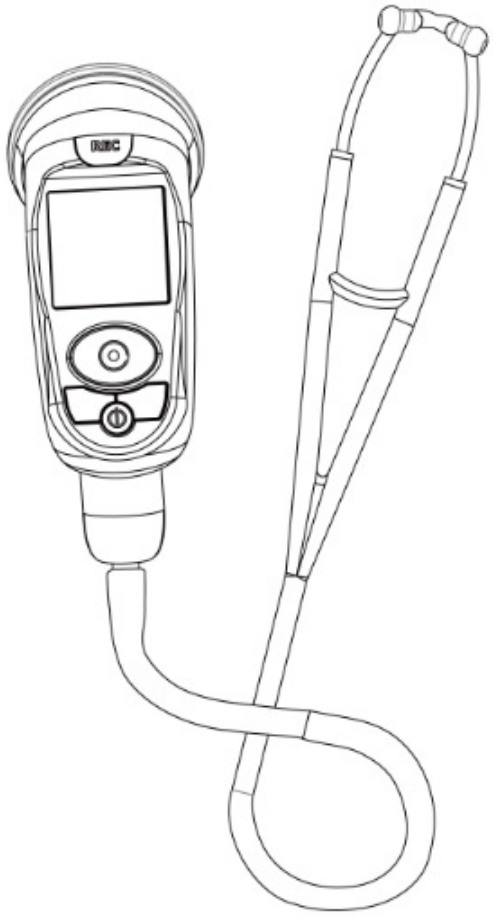


Omni-Steth Electronic Stethoscope
Model name: Omni-Steth
USER MANUAL

Feature

Auscultation for heart, Anterior/Posterior chest, neck, bowel, limbs arteries, veins and internal organs.
Heart rate detection.
Real time recording and playing of auscultation sounds.
Recording multiple sounds from patient and saving up to 160 10-second auscultation sound tracks.
Clear acoustic performance.
With auscultation sound amplify ability and 10 volume level adjustable.
Ergonomic Design.
Easy to use.

Content

1. Introduction

Thank you for choosing our Electronic Stethoscope Omni-Steth.

This useful stethoscope will be a great aid to your auscultation.

It has several smart and friendly features, which makes it easy to use and to properly fit user needs. The design, with an easy-to-use interface, enables the users to approach the patient with one hand. The ear-tips with the soft texture are comfortable to wear. They also provide a sealant for reducing environmental noise, offering a good sound quality for users.

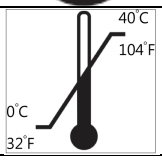
Electronic Stethoscope Omni-Steth was innovated by a group of healthcare professionals. What's more, the user experience is an important factor in designing the stethoscope. We appreciate your selection of our Electronic Stethoscope Omni-Steth and look forward to your valuable feedback.

2. Safety Information

Please read, understand, and follow all safety information contained in these instructions prior to using this electronic stethoscope. Retain the user manual for future reference.

Rx only.

2.1 Symbol Definitions

Explanation of Safety Markings and Symbols	
	Warning.
	Consult instructions for use.
	Indicates Type BF Equipment: The equipment provides protection against electrical shock and electrical current leakage. Applied parts are considered to be the complete chest-piece with diaphragm.
	This product and packing does not contain natural rubber latex.
	Temperature Limits.
	This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.
	Bluetooth transmission
Rx only	Federal law restricts this device to sale by or on the order of a physician.
IPX4	Protected against splashing liquid.

Explanation of Signal Word Consequences	
NOTICE	Indicates hazards, if not avoided, may result in property damage.

WARNING	Indicates hazards, if not avoided, could result in minor injury and/or property damage.

2.2 Important Safety Information

NOTICE
● Please follow local applicable regulations concerning proper disposal and recycling of electronic devices and batteries to avoid polluting the environment. ● No modification to the device is allowed; repair could only be conducted by authorized IMEDIPLUS personnel. If there's any modification, the user is solely responsible for the consequence. ● The Electronic Stethoscope Omni-Steth is MR unsafe. Do not use the Electronic Stethoscope Omni-Steth in Magnetic Resonance Imaging (MRI) environment.

WARNING
● **To reduce the risks associated with an incorrect result, personal injury and equipment damage,** stethoscope shall be stored and operated by medical professionals only as instructed in this manual. ● **To reduce the risks associated with infection** follow all cleaning and disinfecting instructions included in this manual. Establish and follow a cleaning and disinfecting schedule. ● **To reduce the risks associated with a damage to ear canal,** please hold the device tight to avoid sudden falling and make sure that the soft sealing ear-tips are snapped firmly into position. ● **To reduce the risks associated with very strong electromagnetic fields,** avoid using the stethoscope near strong radio frequency signals or portable and/or mobile RF devices. Otherwise, the stethoscope might be damaged. If you hear sudden or unexpected sounds, move away from any radio transmitting antennas. ● **To reduce the risk associated with an electrical shock,** do not use the stethoscope on patients without the original diaphragm.

WARNING

- **The electronic stethoscope Omni-Steth contains a Bluetooth Class 2 wireless data link.** The maximum radio frequency field strength generated by the stethoscope is below three volts per meter, a level that is considered safe to use with other medical devices. However, audio, video, and other similar equipment may cause electromagnetic interference. If such devices are encountered and cause interference, immediately move Electronic Stethoscope Omni-Steth away from that device and/or turn the Bluetooth OFF.
- **To reduce the risks associated with a damage of stethoscope,** please put the device into the pocket of a physician gowns to avoid sudden falling when hanging the device around the neck.
- **Do not use the unauthorized accessories,** which would cause hazards. Use the accessories provided by IMEDIPLUS only.
- **Do not immerse the stethoscope in a liquid or subject it to any sterilization process**. The device might be damaged.
- **Do not use the Electronic Stethoscope Omni-Steth in Magnetic Resonance Imaging (MRI) environment** because Electronic Stethoscope Omni-Steth contains conductive, metallic and magnetic materials, including headset, wire, connectors and inductors, which are assembled in Electronic Stethoscope.
- **Do not use for children under two years old.** The stethoscope chest-piece is designed to be used for child, adolescent and adult patients.
- **To prevent causing battery leaks or damaging their terminals**, carefully follow all instructions regarding the use of batteries.
- **When the battery is not in use for a long time,** remove it to avoid corrosion of the battery connector in the battery charger.
- **If battery fluid gets into your eyes**, flush your eyes immediately with clear, cold running water and seek medical attention immediately.
- **This device should not be used adjacent to or stacked with other equipment.**
- **This device is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.**

3. Product Description

When turning on the Electronic Stethoscope Omni-Steth for the first time, your authorization to operate this handheld electronic stethoscope is necessary for regular operation.

The Electronic Stethoscope Omni-Steth picks up the sounds from the heart, lungs, anterior/posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs from a patient's body. By pressing the buttons ‘OK’ or ‘REC’ to pick up the sounds, the phonogram of sounds could be simultaneously displayed. The sounds are also delivered to the user’s ears bilaterally through the active speaker embedded at the bottom of the Omni-Steth, while at the same time sound processing is conducted with the aid of a digital signal processor.

The one-hand user interface includes a full-color OLED display, record button, arrow keys, OK button, and a tubing connector to output sounds via the headset tubing to the user’s ears.

After turning on the Electronic Stethoscope Omni-Steth and connecting with a wireless device via Bluetooth 4.0, the digital data of the recordings could be transmitted. The effective range of Bluetooth transmission will be influenced by objects blocking the signal between the Electronic Stethoscope Omni-Steth and the connected laptop, such as a wall, humans and other barriers. Reducing the distance or allowing a line of sight between the Electronic Stethoscope Omni-Steth and the connected laptop will improve the Bluetooth connection.

The Omni-Steth does not incorporate any off-the-shelf (OTS) software. The recorded audio data can only be replayed by the Electronic Stethoscope, and the software installed in the laptop or tablet with the speaker of effective range from 20 to 1000Hz. The Omni-Steth operates on two AAA 1.2V rechargeable batteries with a power management system to prolong the battery life.

4. Intended Use

The Omni-Steth Electronic Stethoscope is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. The stethoscope chest-piece is designed for use with child, adolescent and adult patients. It is used for any subject undergoing a physical examination and intended only for medical diagnostic purposes in clinic or hospital.

5. Operator Profile

The Electronic Stethoscope Omni-Steth is designed to be used by anyone who wishes to listen to the sounds as described in the Intended Use section above. The user manual provides complete information on how to operate the Electronic Stethoscope Omni-Steth. Additional operating training is not proposed.

6. Patient Privacy

The privacy of patient health information would be protected by state, federal, or international/foreign laws that regulate how such information can be used, stored, transmitted, and disclosed. This system employs security features that are compliant with HIPAA policies. Third party access may be prohibited to such information without obtaining written authorization from the patient.

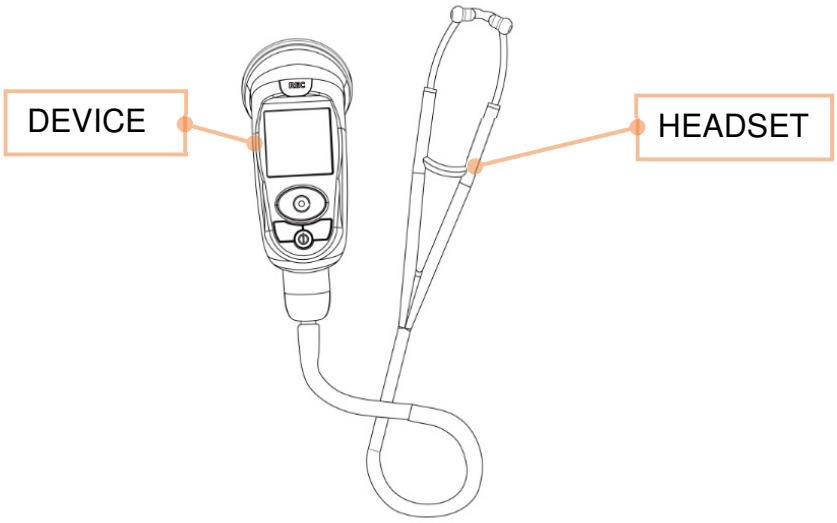
The user is fully responsible for understanding and following all laws that regulate storage, transmission, and disclosure of any patient data through the use of software. If the user is unable to comply with the law or restriction that applies to use and disclosure of such data, the user should not proceed to collect or save such information.

This application may require entry of individually identifiable health information in order to function. Records are stored and recalled through the use of patient name, date of birth, and/or patient ID #. By entering this information, the user assumes any and all risks and liabilities incurred with using or transmitting such information.

7. Instructions for Use

Please read through the user manual carefully before using the product and operate it according to the user manual. It is advised to keep this manual for reference.

7.1 Stethoscope Interface



7.2 Changing Battery

According to Figure 1, open the battery compartment cover by push the notch on the cover, and remove the old batteries by lifting it. Replace the batteries with two new AAA rechargeable batteries. Make sure inserting the new batteries in the right direction as the notice marked inside, then remount the cover after replacement.

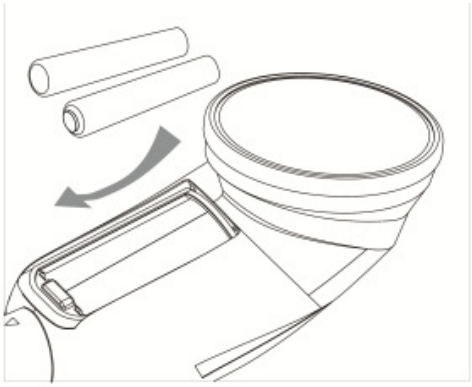


Figure 1

IMPORTANT!
Please turn off the system before taking out the battery.

NOTICE:
The Electronic Stethoscope Omni-Steth can be installed with alkaline or Ni-MH batteries. The chart below shows the voltage specifications for the alkaline and Ni-MH battery. We highly recommend the use of rechargeable batteries for longer operational time.

	Alkaline	Ni-MH
Voltage	1.5 V	1.2 V

⚠ **WARNING: Do not use a battery if it is cracked or broken.**

7.3 Removing and applying the eartube.

As shown in Figure 2, please tightly hold the device while removing/ applying the eartube. Twist the tubing connector in counterclockwise direction to remove the eartube. Please put the eartube on a safe platform to avoid unnecessary damage from falling. Align the new eartube with the two triangle marks on each side and directly insert it into the device. Make sure

the eartube is completely inserted into the device with the arrow marks aligning.

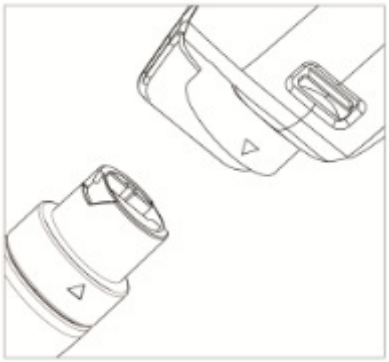


Figure 2

7.4 Removing and applying the ear-tip.

The ear-tips should point in the forward direction as you insert them into your ear canals. When ear-tips are properly positioned, the diaphragm will face towards your body, as shown in Figure 3.

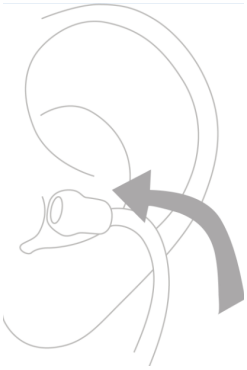


Figure 3

The user can pull ear-tips away from the eartube to remove the ear-tips, as shown in Figure 4.

The user can push ear-tip firmly onto the eartube to apply new ear-tips, as shown in Figure 4.

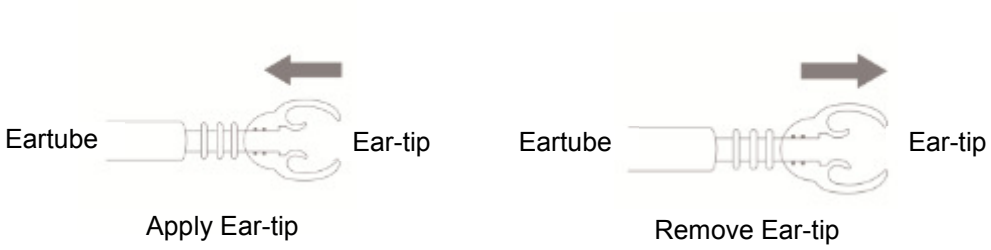


Figure 4

7.5 Adjust Headset for Comfort

To reduce the spring tension of the headset, hold each eartube at the bend part near the ear-tips and gradually pull apart until fully extended (180 degrees), as shown in Figure 5.

To increase spring tension, grasp the headset with one hand where the metal eartube enters the plastic tubing, and squeeze until the plastic tubing on one eartube touches the other, as shown in Figure 5.

Repeat the steps to adjust the headset to suitable tension.

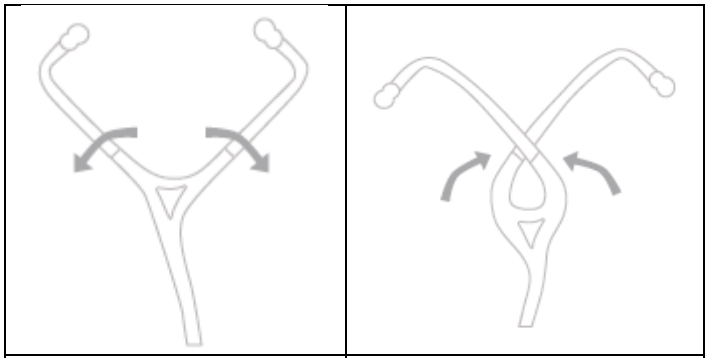


Figure 5

7.6 Changing the chestpiece

The location of the chestpiece is shown in Figure 6. Please tightly hold the device while changing the chestpiece. Twist the chestpiece in counterclockwise direction to remove it. Please put the chestpiece on a safe platform to avoid unnecessary damage from falling. Align the triangle marks on the device and the chestpiece to directly insert the chestpiece. Twist the chestpiece until hearing a click sound to make sure it is completely fixed into the device.

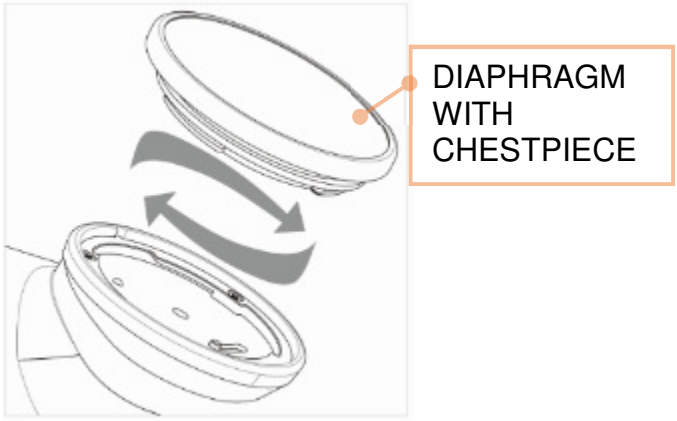


Figure 6

7.7 Replacing the diaphragm(Silicone and PS)

As shown in Figure 7, when changing the silicone diaphragm, please follow the directions below:

- To remove the diaphragm, place your nail under the rim of the stethoscope head and gently separate the rim from the head.

- Place the new diaphragm inside the rim, making sure the diaphragm is properly and smoothly fitted into the rim groove.

- Place the combined diaphragm and rim over the edge of the chestpiece, then press the rim down with both thumbs until the whole rim is fitted onto the chestpiece groove.

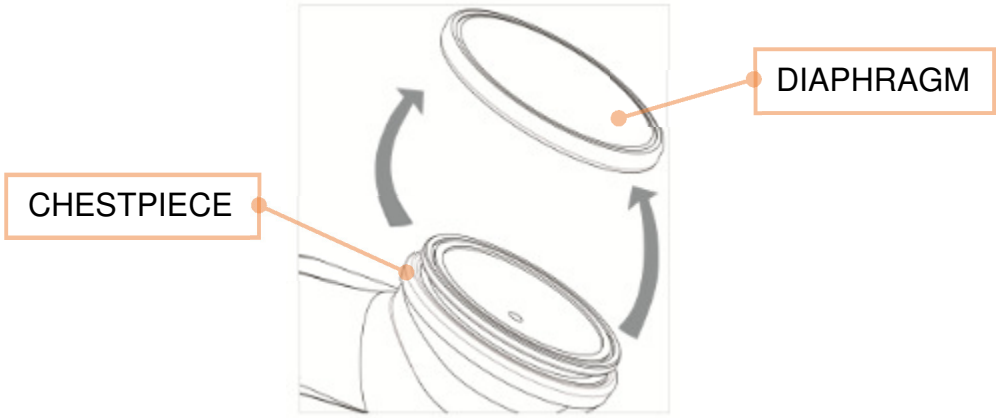


Figure 7

As shown in Figure 8, please hold the device and chestpiece tightly while removing the diaphragm. Pull down and remove the diaphragm (PS) and dispose of it into medical waste bucket. To mount the diaphragm, tear the new diaphragm package, pluck the device directly to the diaphragm, and make sure the diaphragm completely fits to the device until hearing the click sound.

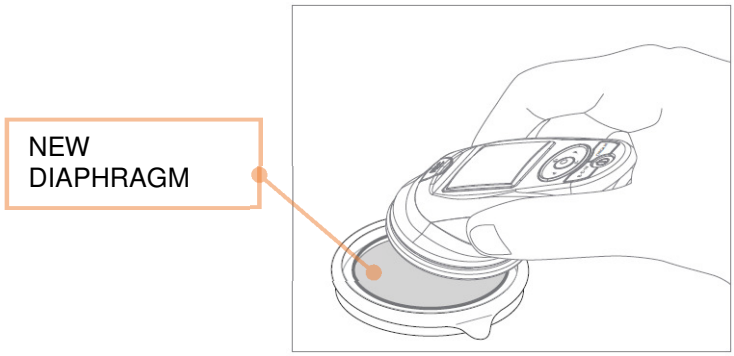
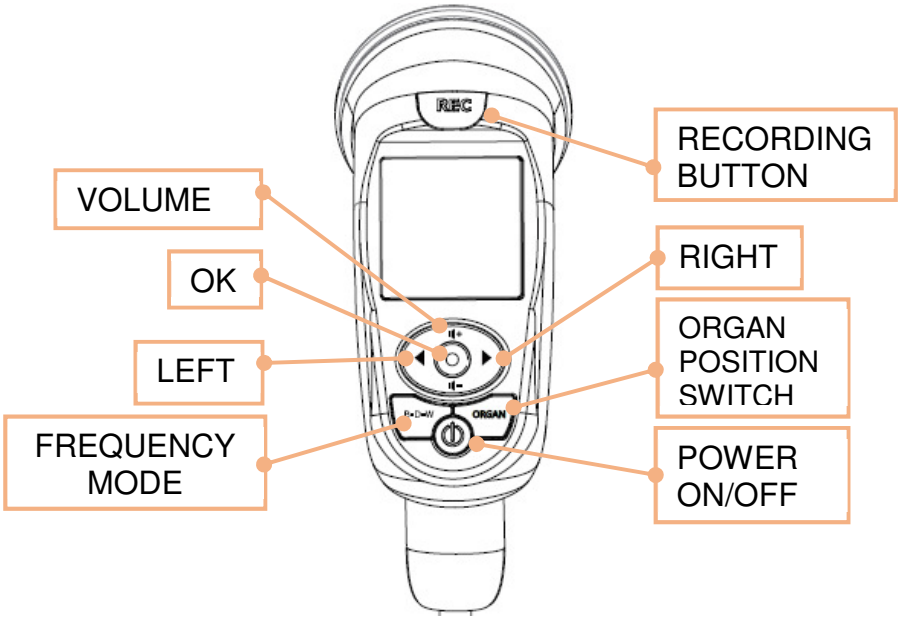


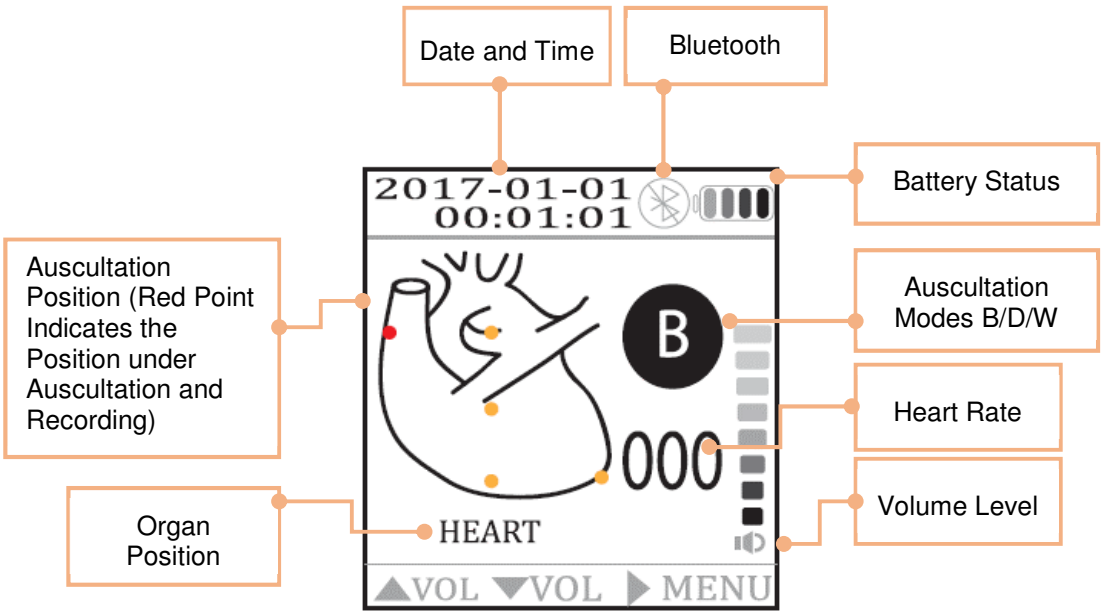
Figure 8

7.8 Stethoscope construction



Power Button To turn on the device or to enter the sleep mode.
Recording Button During auscultation (in the HOME page), press the recording button to record auscultation sounds of 10 seconds.
Filter Modes Switch During auscultation (in the HOME page) and playback of the recorded sound track, press this button to select the auscultation filter mode from “Bell”, “Diaphragm”, and “Wide” modes.
Arrow Keys and OK Button ● The “Arrow keys” is used for selection. ● The “Right” and “Left” keys are used to enter or exit the pages. ● The “Up” and “Down” keys are used to adjust the sound amplification level. Using the “Up” and “Down” to move the indicator upward and downward. ● The “OK” button is to set and confirm the selection item
Organ Position Switch The “Organ Position Switch” is used to change the organ positions among “Heart” “Lungs”, “Neck”, and “Bowel”.

7.9 OLED display shows information



8. Operation Description

➢ Power Button (Switch On / Sleep Mode)

Power ON/OFF: The position of power button is shown in Diagram 1. Pressing the power button for three seconds to turn on or off the stethoscope. The information shows up on the screen indicates the power is on. Turn off the device and the screen turns dark.

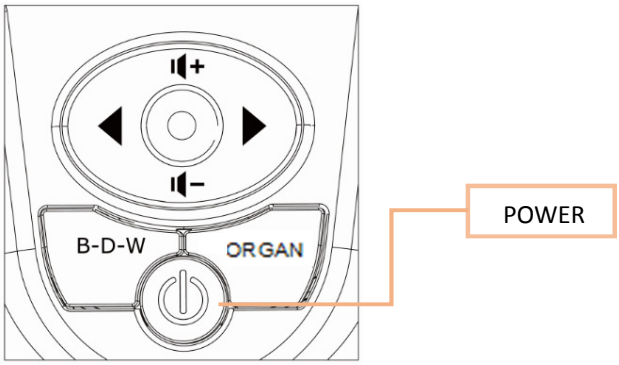


Diagram 1

➢ Sleep mode

In the menu, there are “two minutes” , ”five minutes” and ”ten minutes” of idle time you can choose for sleep mode. Use “UP”/”DOWN” to choose and then press the “OK” button to confirm. The stethoscope will enter the sleep mode after not being used within the time you select. Press “POWER ON/OFF” again to wake it up.

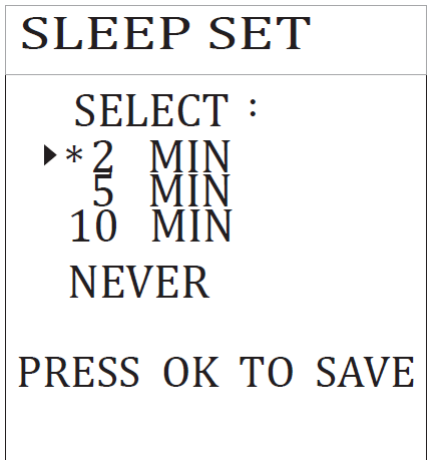


Diagram 2

➢ Enter the menu:

Press “RIGHT” for 3 seconds to enter the menu and the menu options become available as shown in Diagram 3.
Product information will be displayed on the screen.

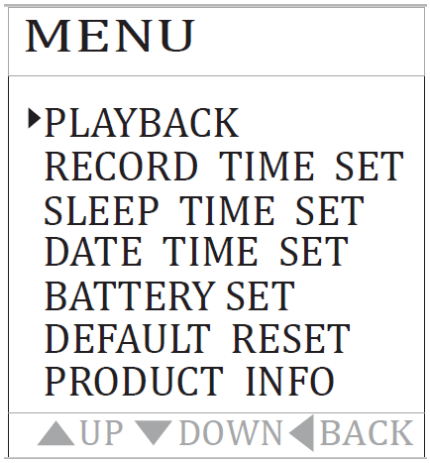


Diagram 3

➢ Record time set

In the menu, press “UP /DOWN” button to scroll to the “RECORD TIME SET”. As shown in Diagram 4, press “UP /DOWN” button to scroll to the record length then press ”OK”; the selections include “10 seconds”, “20 seconds”, “30 seconds” and “40 seconds”.

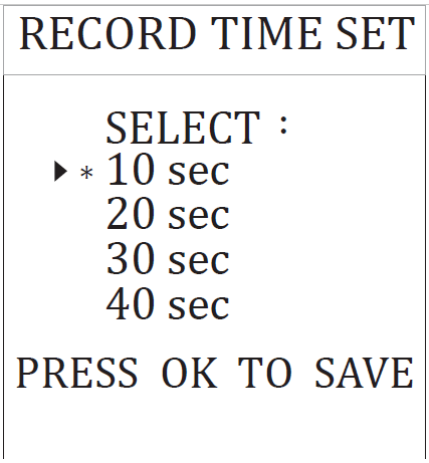


Diagram 4

➢ Date & Time Set

In the menu, press “UP /DOWN” button to scroll to the “DATE & TIME SET” then press “OK” to set the date and time. As shown in Diagram 5, “LEFT/RIGHT” buttons are used for moving position, “UP/DOWN” button for increase and decrease the numbers. Press “OK” to save the setting.

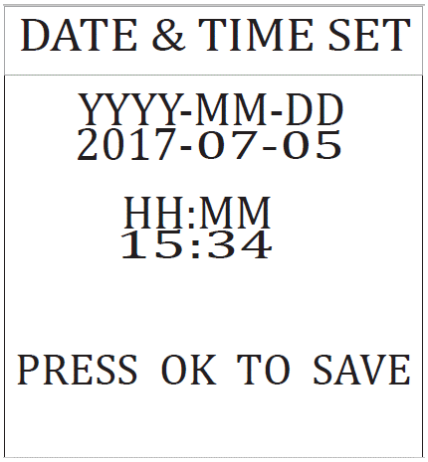


Diagram 5

➢ Battery set

In the menu, press “UP/DOWN” button to scroll to the “BATTERY SET” then press “OK” to set the battery. As shown in Diagram 6, “UP/DOWN” buttons are used for choosing the types of battery installed, “Alkaline” or “Ni-MH”. Press “OK” to save the setting. The batteries accessorized with the stethoscope are Ni-MH ones.

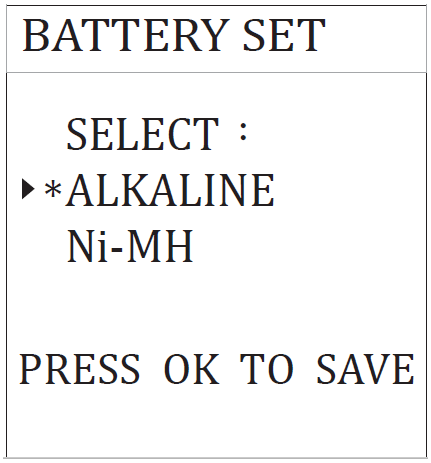


Diagram 6

NOTICE ：There are two selections of battery: Alkaline and Ni-MH.

The default selection of battery selection is Ni-MH battery. An inaccurate battery indicator will show on screen if you change the batteries without changing the setting.

➢ Default

In the menu, press “UP /DOWN” button to scroll to the “DEFAULT RESET” then press ”OK” to enter to default reset page, as shown in Diagram 7. Press “YES” if you want to reset to default settings. This is to help you avoid unexpected condition and reset.

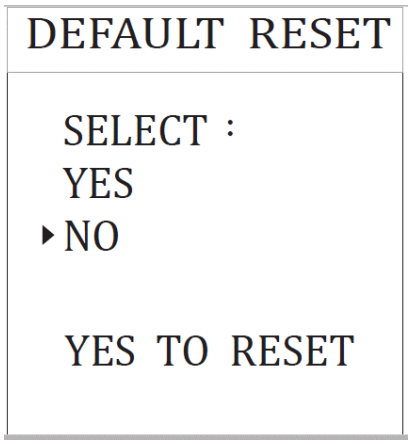


Diagram 7

Factory Default Setting Table

Parameters	Default
Idle time of “Sleeping Mode” before going to sleep	2MIN (2 minutes)
Auscultation organ position	HEART
Filter Mode	B Mode
Amplification level	Level 5
Recording time	10 seconds
Battery Setting	Ni-MH

➢ Product Information

The device version and product name are shown on the “PRODUCT INFO” page.

Diagram 8

➢ Organ settings

"ORGAN" button is used for organ settings. As shown in Diagram 9, press and release the "ORGAN" button to switch the organ patterns. For example: Heart → Anterior Chest → Posterior chest → Neck → Bowel。

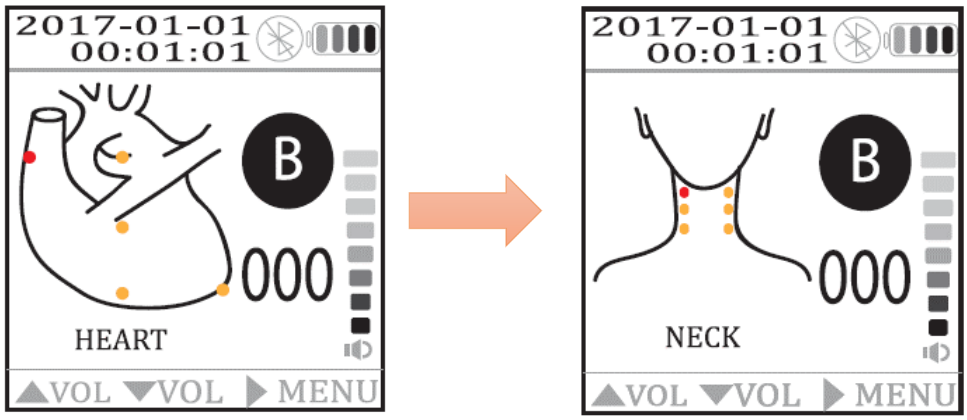


Diagram 9

➢ Sound frequency mode

The stethoscope allows the users to select these three different filter modes (B/D/W modes) for diverse application to different clinical scenario. Which can emphasize the specific patient sounds of interest. As shown in Diagram 10, press the "BDW" button to switch the frequency mode.

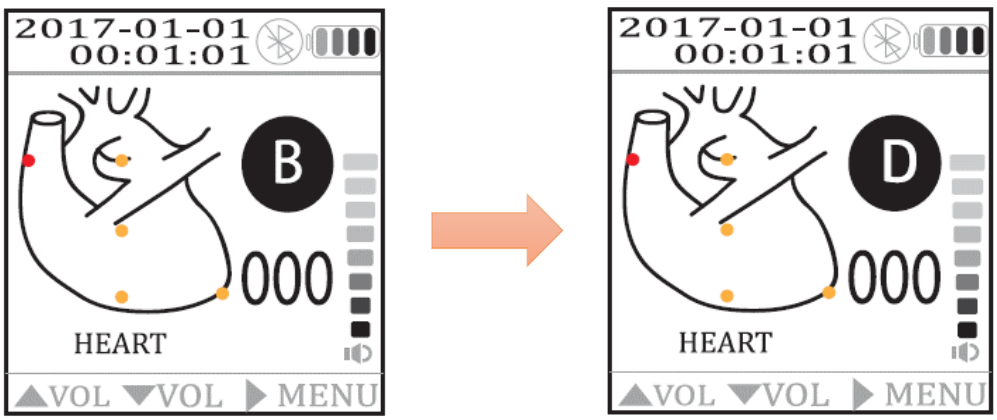


Diagram 10

- The Bell mode amplifies sounds between 20-1000Hz, but emphasizes lower frequency sounds between 20-200Hz.
- The Diaphragm mode amplifies sounds between 20-2000Hz, but emphasizes sounds between 100-500Hz.
- The Wide mode amplifies sounds between 20-2000Hz.

➢ Volume control:

As shown in Diagram 11, press “UP” to increase the sound level and press “DOWN” to decrease it. To “Mute” the device, keep pressing “DOWN”.

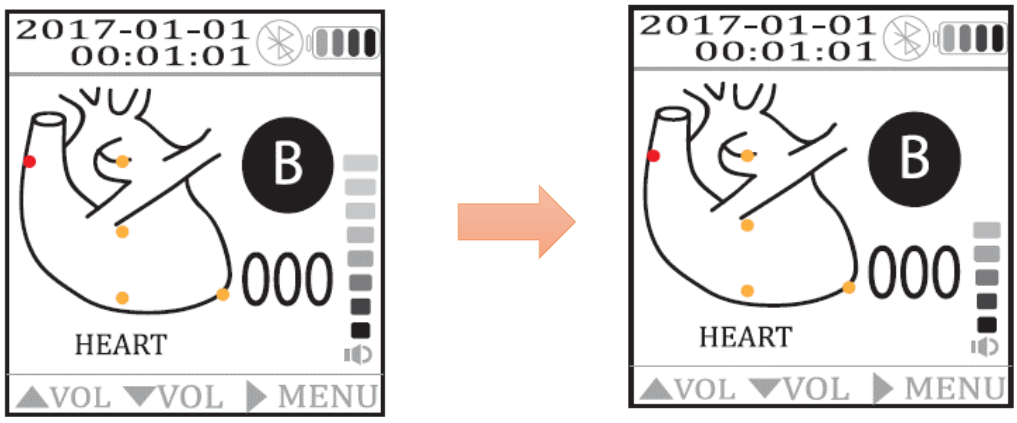


Diagram 11

➢ Bluetooth connect

As shown in Diagram 12, when Omni-Steth successfully connected with an external device, the red cross on the Bluetooth icon will disappear.

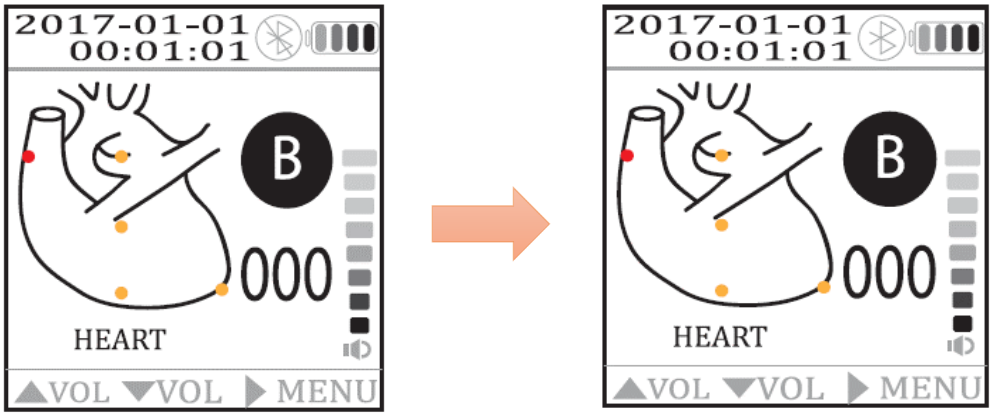


Diagram 12

➢ Recording the Auscultation Sound

The recording button is on the top of the display. Press the recording button to record the sound and the phonocardiogram will show on the screen. The red horizontal bar presents the recording time shown at the bottom on the screen. The default setting for recording time is 10 seconds and you will be automatically returned to the home page after the sound track recording is done.

⚠ **WARNING: To avoid the damage of ears, do not tap hard or scratch the chest-piece with diaphragm while wearing the ear-tips with the stethoscope powered on.**

➢ Playing Back a Sound Track

In the menu, press “UP /DOWN” button to scroll to the “PLAYBACK” then press “OK” to enter playlist. File name is “YYYYMMDD_HHMMSS” as shown in Diagram 13, press “UP/DOWN” button to scroll to” FILE NAME” and confirm with “OK” to check the organ mapping (as shown in the Diagram). Press “OK” again to play back the sound track. The phonocardiogram will be shown on the screen while a sound track is being played. Press “LEFT” to return to the menu.

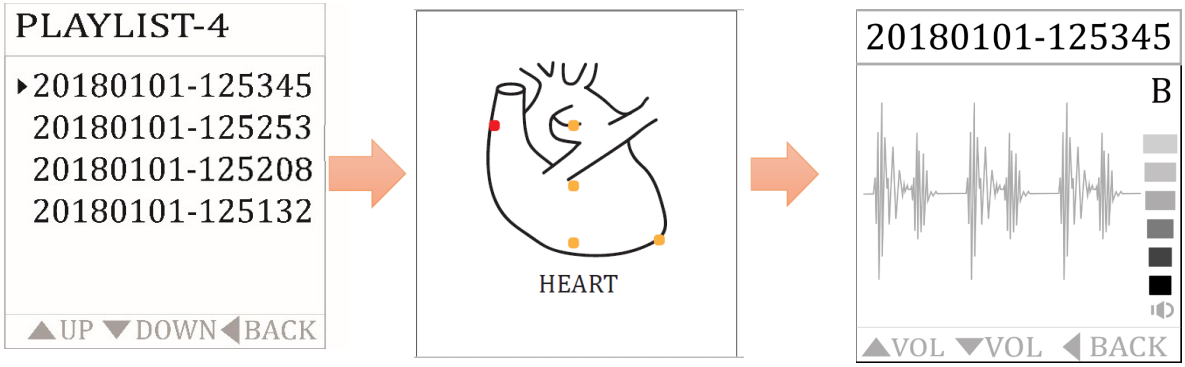


Diagram 13

➢ Heart rate detection

As shown in Diagram 14, place the electronic stethoscope where the heart rate is to be detected; the patient's heart rate would be displayed on the screen in 10 seconds, ranging from 30 to 180 bpm with the accuracy deviation of about +/-5bpm.. When the stethoscope is away from the patient, it will reset to zero within 5 seconds.

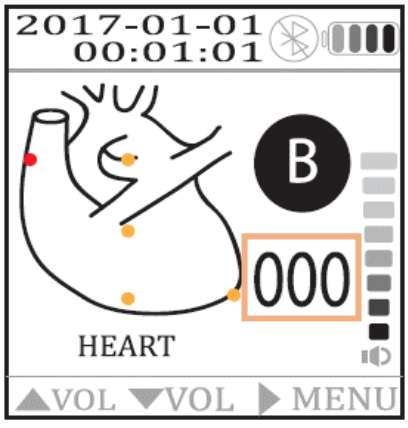


Diagram 14

IMPORTANT!

Heart rate auscultations performed in a noisy environment or by placing the electronic stethoscope in the wrong position, may yield inaccurate heart rate result.

9. App specification (Data Management)

➢ Installation for Android System

Please ensure the mobile phone or tablet for installation connects with the Internet. Enter the official website of JEDMED (https://www.jedmed.com/products/digital-stethoscope), go to TELEMEDICINE and enter Digital Stethoscope to install the app.
After the installation complete, tap on the app icon to open it.

➢ Create the first account

First, create a secure account to access the app (Data Management) and to store patient's data. Now open the app (Data Management) on the mobile

device. Enter your own user name and password.

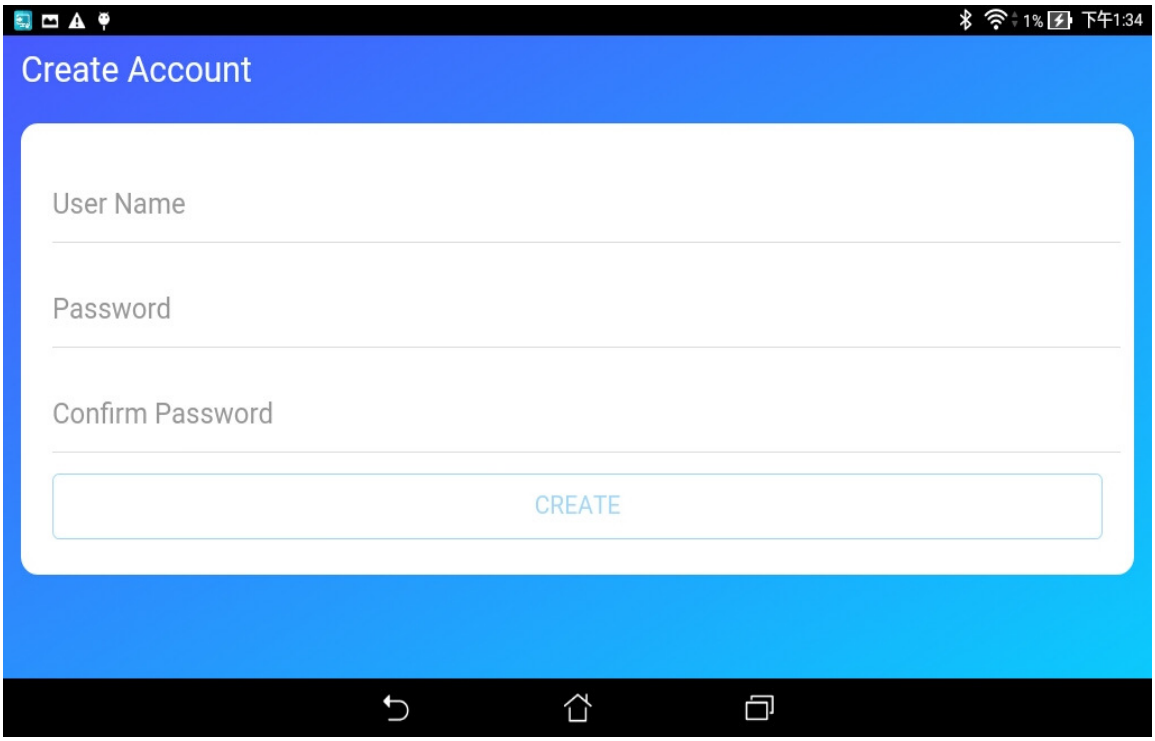


Diagram 15

➢ Sign in

After creating the first account, please sign-in with it. Please make sure to type your user name and password correctly.

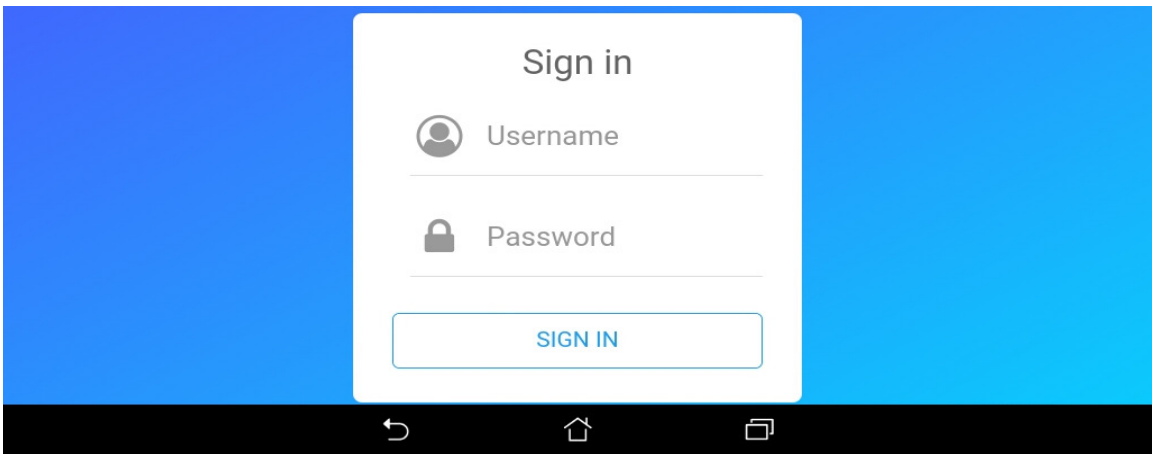


Diagram 16

➢ Bluetooth Pairing

Bluetooth must be enabled in the Bluetooth settings in the app.

First, enable Bluetooth on the mobile device. Second, to turn on the Bluetooth, go to Settings > Bluetooth > tap the slider. Finally, search for the name of the device and tap to pair.

Then, open the app (Data Management) and tap the Bluetooth symbol icon to display the Bluetooth devices. You can tap “Scan” if the Bluetooth device to be paired is not displayed.

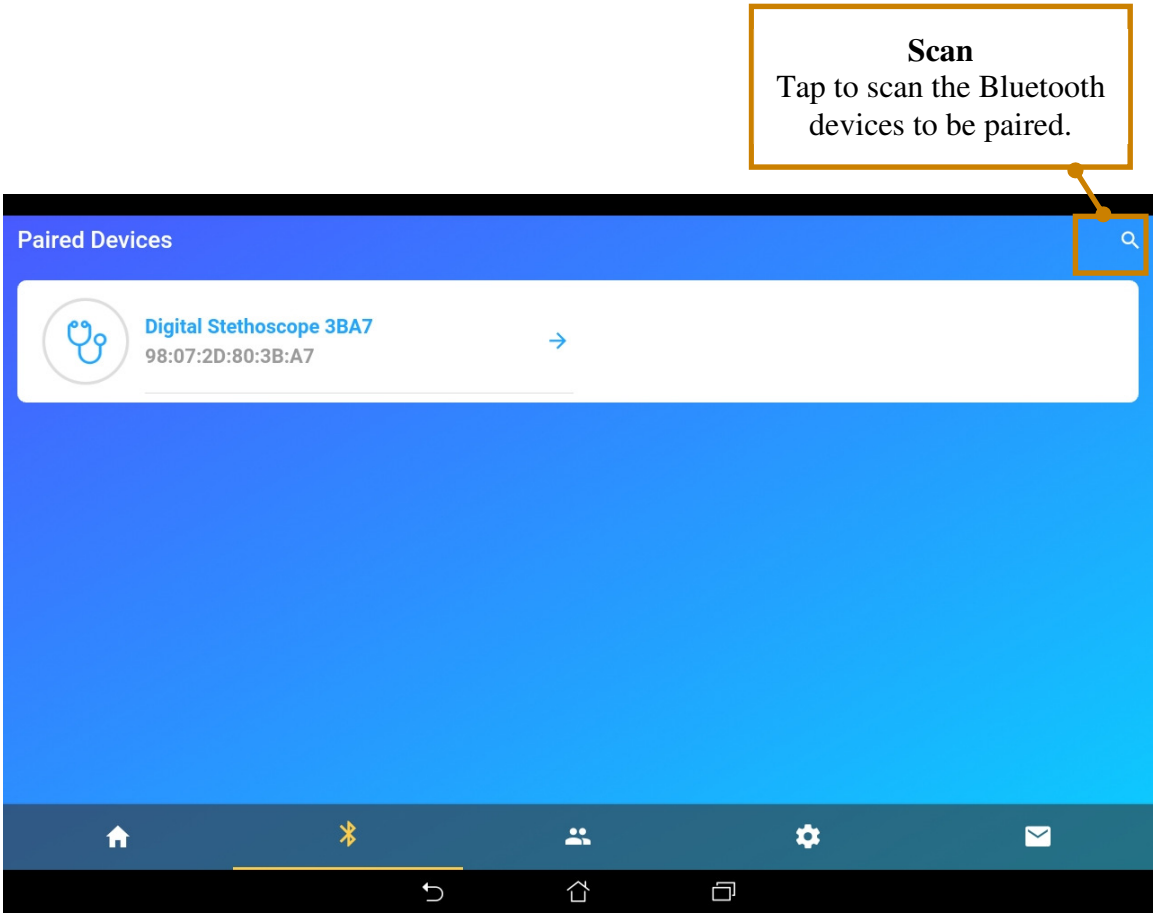


Diagram 17

After the Bluetooth device to be paired is displayed, tap on it to connect with the device.

➢ Using the app to receive recordings

After pairing with the stethoscope, users will be entering the record received page on the app (Data Management). The mobile device is now ready to receive recording data from the Omni-Steth. Tap “RECEIVE” button, and the app (Data Management) starts to receive recordings from Omni-Steth.

If Bluetooth pairing is successful, the red cross on the Bluetooth icon on the OLED screen of Omni-Steth will disappear.

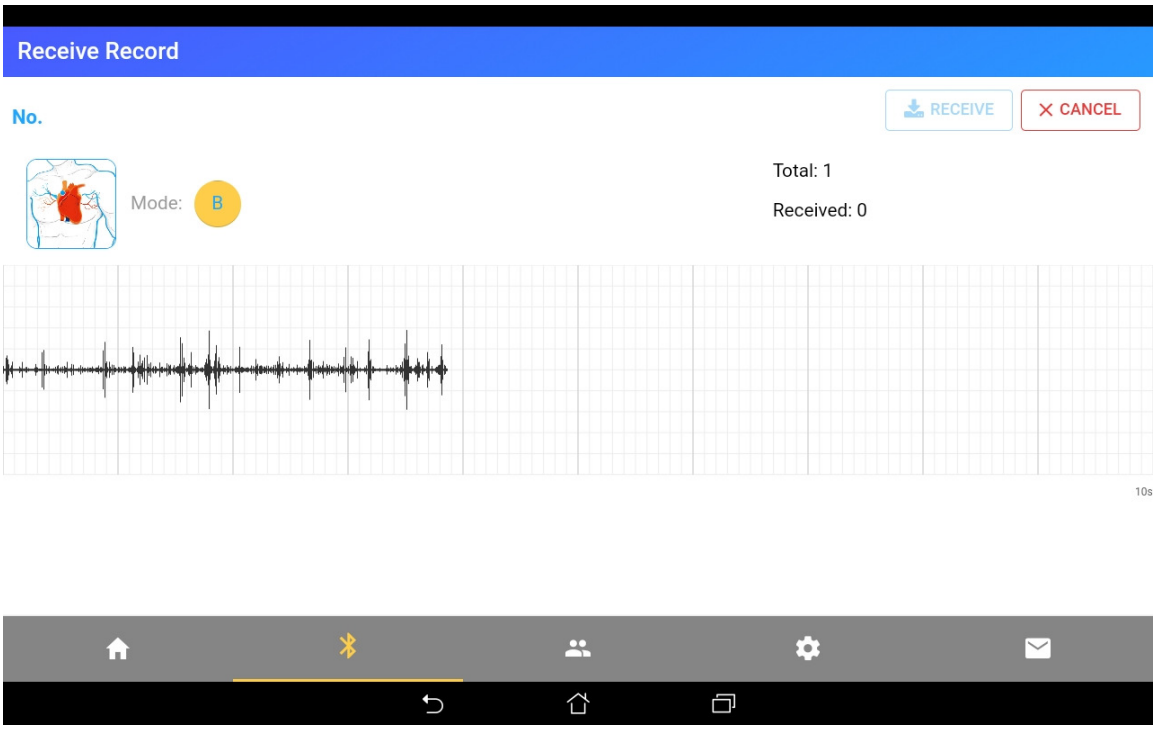


Diagram 18

➢ Using the app to transmit recordings to Omni-Steth

For better acoustic expression, the user can transmit recording data back to the Omni-Steth and play. Open the app (Data Management) and log in. Ensure that the Omni-Steth is paired to the mobile device (See Section 8).

Enter the home page, press “TRANSMIT” and the recording data will be transmitted back to Omni-Steth. The recording data won’t be saved after playing.

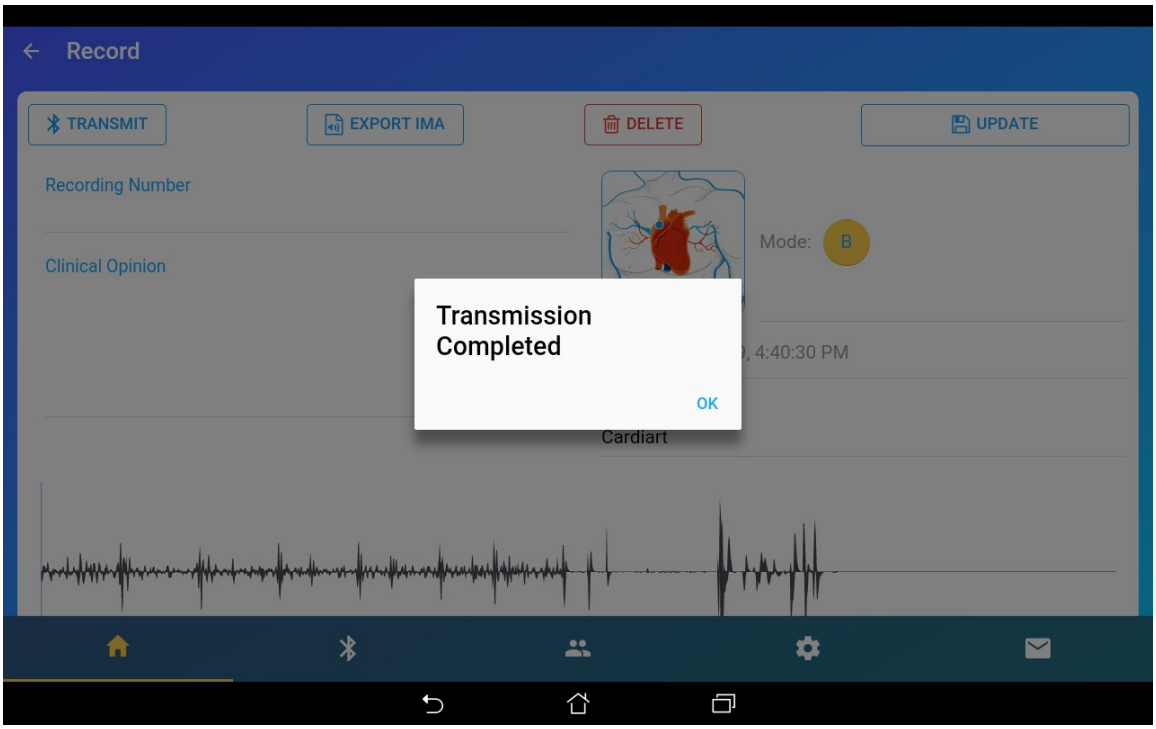


Diagram 19

NOTICE: For better sound quality, we highly recommend listening to the recordings with eartube on Omni-Steth.

9.1 The Main Recording Page

The Main Recording Page allows users to view audio data captured by Omni-Steth, conduct the recording process, retrieve specific patient data, or adjust settings. Audio data is represented in real-time phonocardiogram. The period of recording is 10-second intervals.

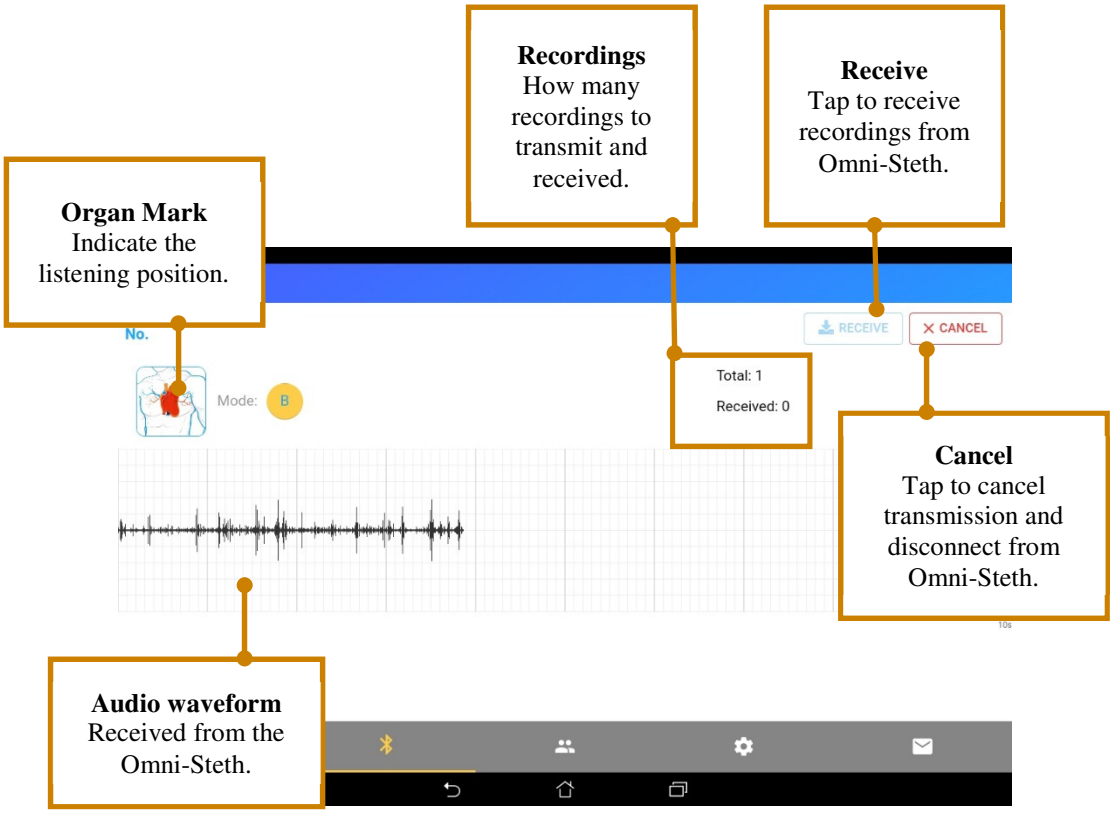


Diagram 20

9.2 Records Page

The recordings received from Omni-Steth will be saved to record page. Tap on any recording to review the detail information.

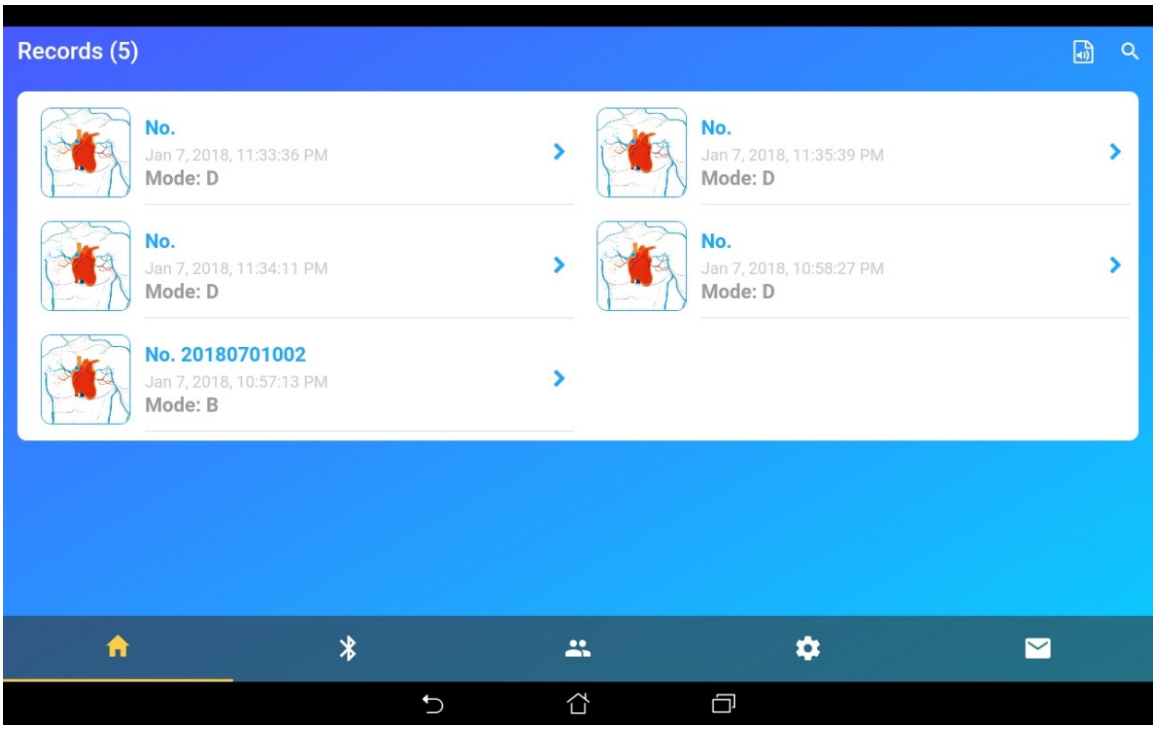


Diagram 21

9.3 Review Page

More information of a specific recording can be viewed by tapping on the recording. This page displays the recording number, organ mark, recording time, operator ID, and comments. User can add suggestion or comments on it.

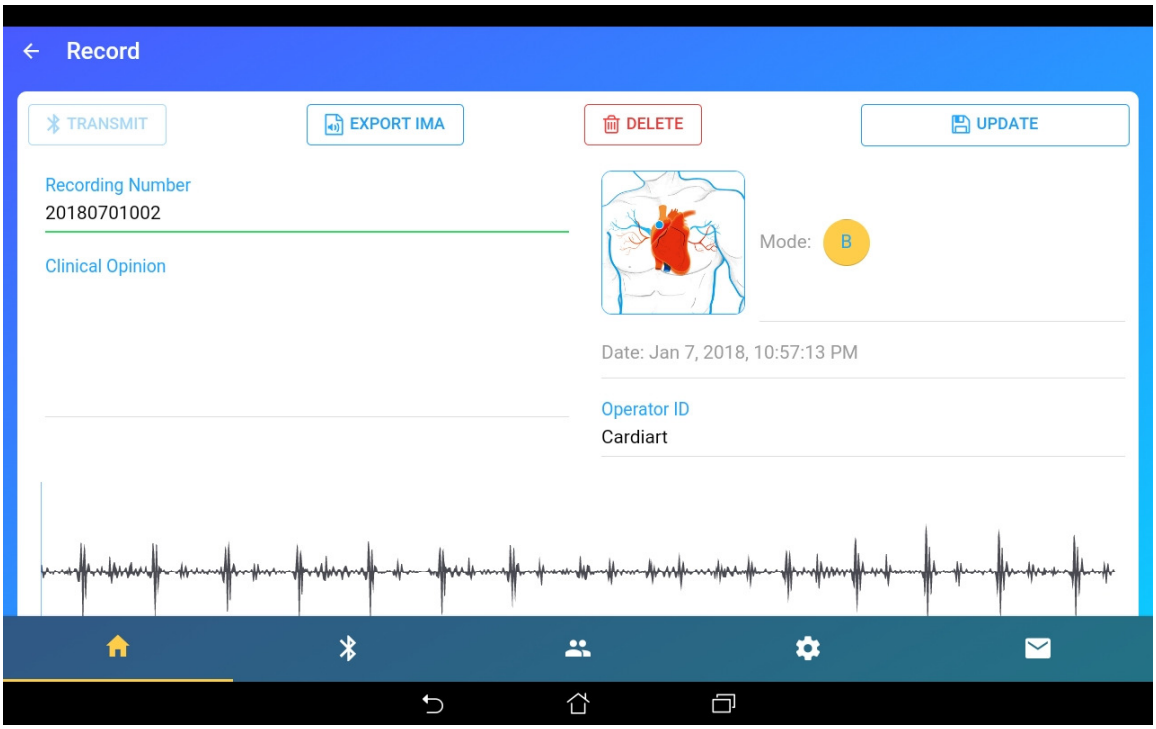


Diagram 22

A waveform of the recording with zoom in / zoom out, and playback function is also included.

9.4 User List Page

In the user list page, users are able to identify their account in this software. Click the Add User button on the top right of screen to create a new user account.

Add User
Tap to add new user account.

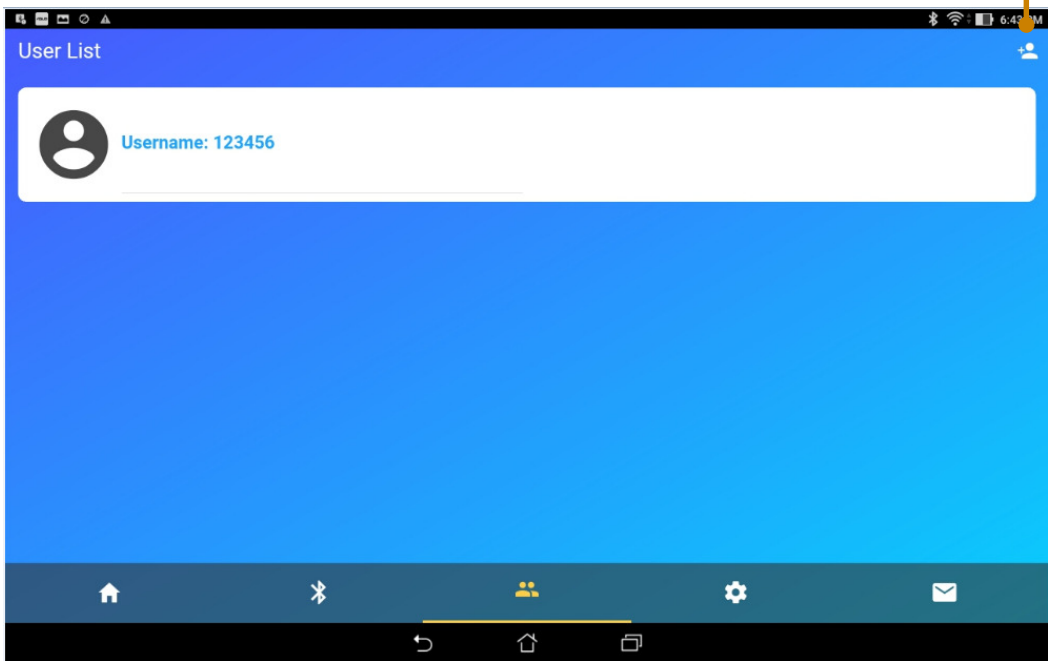


Diagram 23

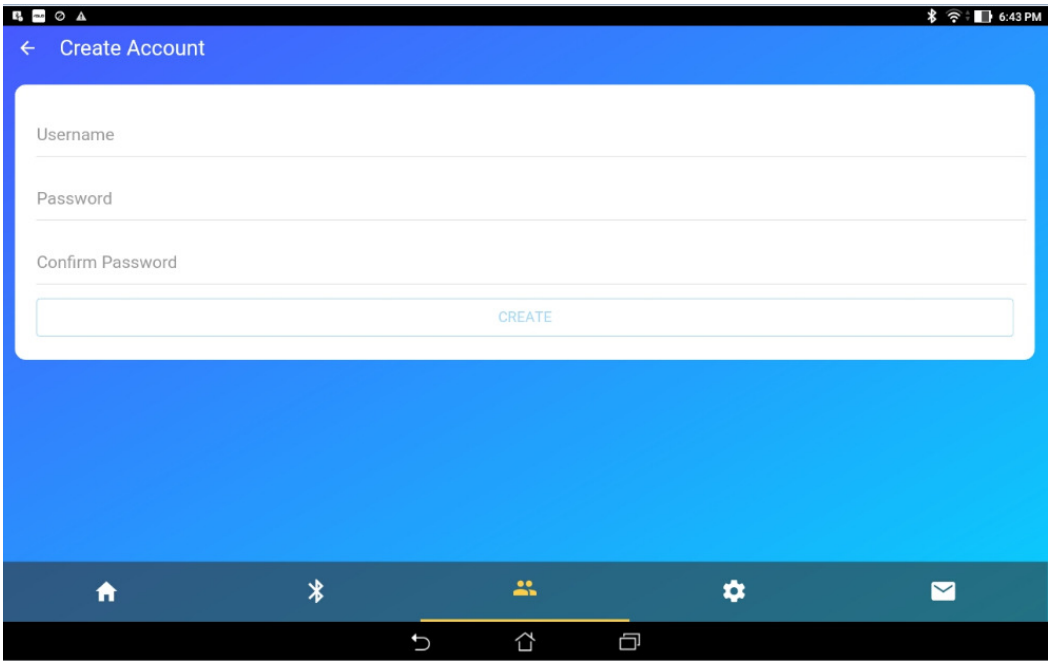


Diagram 24

9.5 Setup Page

In the setup page, users are able to change user name, email, company, and department.

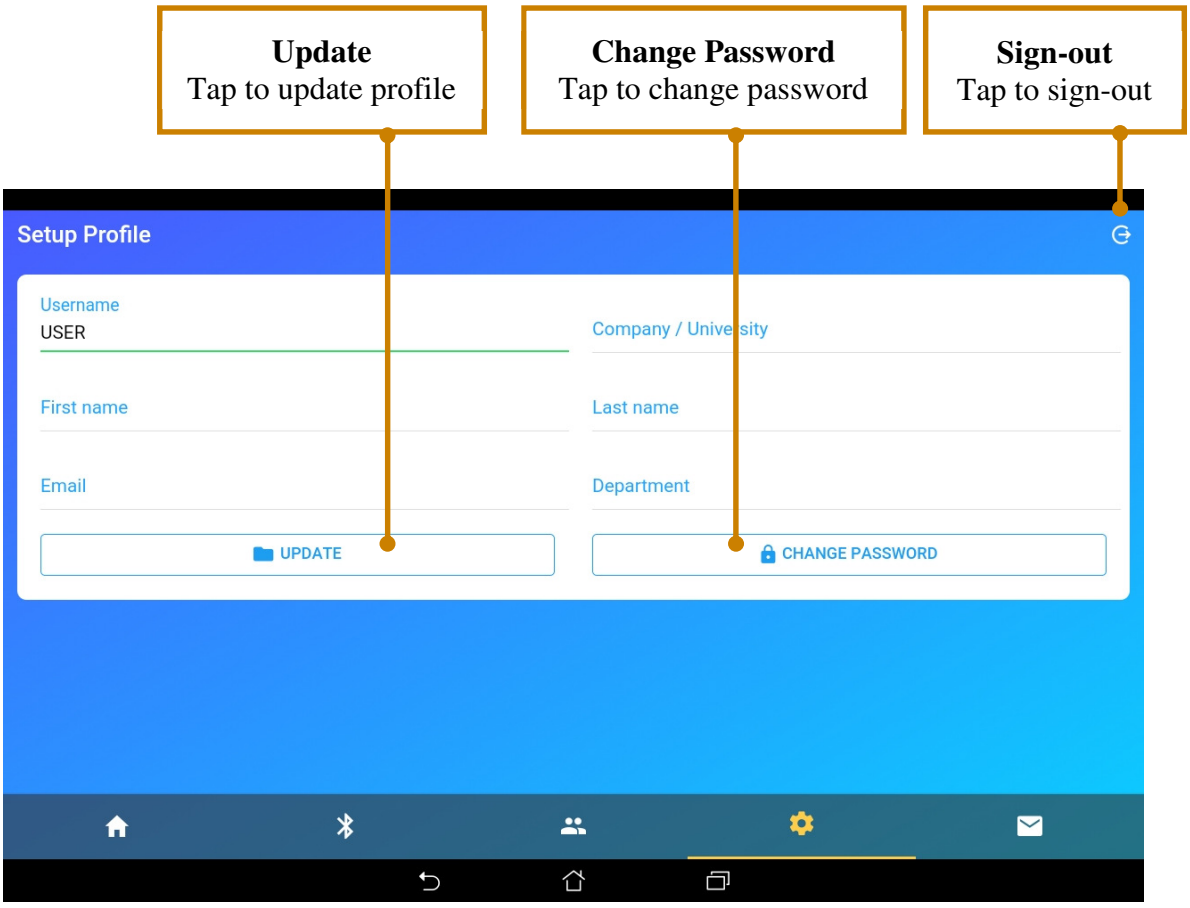


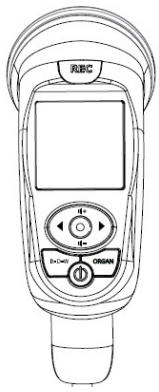
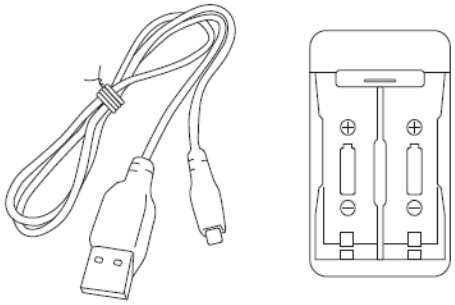
Diagram 25

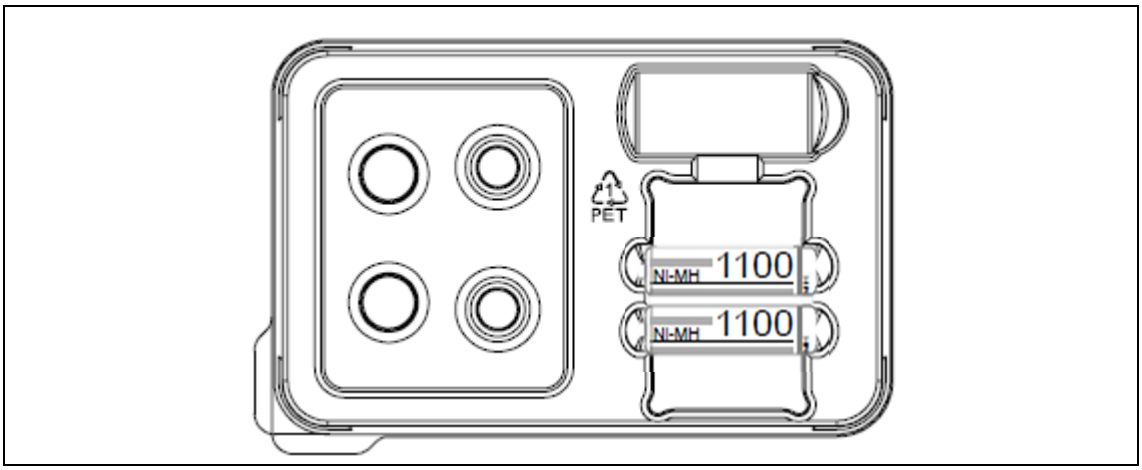
Other Operating Considerations

- Temperature ranges from 32ºF to 104ºF (0ºC to 40ºC), and 15 to 93% for relative humidity.
- Maximum operating altitude is 2000m.
- Maximum expected service life is 5 years.
- Temperature for storage and transport ranges from is -4ºF to 158ºF (-20ºC to 70ºC), and 0 to 93% for relative humidity.
- To retain the life of your electronic stethoscope, please avoid operating in an extremely hot or cold condition.
- Avoid solvents and oils to prevent unexpected hazards.
- Remove the battery if the electronic stethoscope is not expected to be used for months.
- Failure to follow care and maintenance recommendations could result in damage to the internal components of the Electronic Stethoscope Omni-Steth. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

NOTICE ：If you experience any problems with the Electronic Stethoscope Omni-Steth, do not attempt to repair it yourself. Please notify our customer service center for directions on shipping and receiving.

10. Product Parts List

1. Omni-Steth Device: It consists of chest-piece with diaphragm, screen, intuitive keypad and tubing connector.	2. Omni-Steth Headset: Includes tubing , connector, and ear-tips
	
3. Diaphragm	4. Battery charger and cable
	
5. Accessary Package(includes two pairs of ear-tips and two AAA Ni-MH rechargeable batteries)	



Consumable Information

Part Name	Part Number
Diaphragm	F000200600003

Accessory Information

Part Name	Part Number
Battery charger	B002011100005
Battery cable	B00202900002
Ear-tips	B050112T2KS01
AAA Ni-MH rechargeable batteries	A014070000003

⚠**WARNING: Do not use the unauthorized accessories which would lead to unexpected hazards.**

11. Cleaning

- Before starting to clean, please check if the tubing connector and the structure of stethoscope are intact to avoid liquid infiltration.
- Do not wipe the stethoscope directly with alcohol or detergent solution in avoidance of the unnecessary damage; we highly recommend cleaning with a dry and clean tissue paper or cotton sheet sprayed with 70%~75% alcohol solution.
- After wiping out the dust and dirt, please check if the electronic stethoscope

works as usual.

- Eartube and ear-tips: These parts could be cleaned with alcohol wipes, and the ear-tips could be removed for a more thorough cleaning.
- Diaphragm: We highly recommend cleaning the diaphragm with a dry and clean tissue paper or cotton sheet sprayed with 70%~75% alcohol solution. Alternatively, dispose of the dirty or contaminated diaphragm and mount the new diaphragms.

NOTICE : To clean the chestpiece, you may take off the diaphragm for the cleaning process.

⚠ **WARNING: Do not immerse the stethoscope in a liquid or subject it to any sterilization process. The device might be damaged.**

12. Warranty

Your Electronic Stethoscope is warranted against any defects in material and manufacture for one year. If a material or manufacturing defect is discovered during the warranty period, repairs will be made without charge upon the return of the instrument to vendor, except obvious abuse or accidental damage.

13. Troubleshooting

Item	Issues	Answer
1.	No “Power”, after “Turn ON”.	Please check if battery is properly installed, and try again after reinstall the battery.
2.	No “Powered”, after “Turn ON”.	Please install a new battery, and try again after installing.
3.	No “auscultation sound”, after “Turn ON”.	Please check if headset is properly installed, and try again after reassembly headset.

4.	No “auscultation sound”, after “Turn ON”.	Please use the “amplification level control” button to adjust amplification level properly.
5.	The screen displays “DATE WARNING” after “Turn ON”	This is to inform you to set the date and time. Please refer to the section "Setting Date” (setting date section 6-8) for settings.
6.	The device has no response when you are operating the device.	Please reinsert the battery, and then check if there’s any operational response.

IMPORTANT!

- If you have tried all of the suggestions to the issues listed and still failed to solve the problems, please call local service branches for assistance.

14. Maintenance and Repair

For maintenance or repair services, please register your name, physical address, e-mail address, and phone number on your Electronic Stethoscope Omni-Steth.

NOTICE: No modification of this device is allowed. Only authorized service personnel could repair this electronic stethoscope; if the device is modified by users, the user would take full responsibility for the consequences.

If you have any questions or comments, please feel free to contact Customer Service Center.

In the U.S.A:

U.S Agent Contact Name: Mr. JAMES WANG
U.S Agent Full Address: 31 Trillium Lane, San Carlos, California, 94070, UNITED STATES
U.S Agent Email: jwjwang5@gmail.com
U.S Agent Tel: +1-650-8629968

Manufactured by:
IMEDIPLUS Inc.
2F, 12 ShengYi Rd. Sec. 2, Chupei City, Hsinchu County 302, Taiwan (R.O.C.)
Tel: +886-3-658-7700
Fax: +886-3-658-9535
http://www.imediplus.com

15. Transportation, Storage, and Disposal

✧ **Transportation and Storage**

- General transportation of the unit should correspond to the conditions

outlined in the **'Other Operating Considerations'** section of this manual.

- The Electronic Stethoscope Omni-Steth needs to be sent to an authorized service center for inspection and repair. The storage environment conditions must correspond to the '**Other Operating Considerations**' section of this manual.

✧ **Disposal**

You should properly dispose of the Electronic Stethoscope in accordance with the local regulations. The AAA 1.2V rechargeable batteries must be disposed of or recycled separately from regular waste.

NOTICE: To reduce the risks associated with environmental contamination, please follow the applicable local regulations when disposing of this stethoscope. The AAA 1.2V rechargeable batteries must be disposed of separately or recycled separately from regular waste.

16. Specification

Electronic Stethoscope Omni-Steth	
Product Specification	
Batteries Enclosed	AAA 1.5V Alkaline/1.2V Ni-MH Battery
Battery indication	100%/ 75% / 50% / 25%
Monitor battery level degrees	4 degrees
Chest-piece Technology	Changeable chest-piece
Device Dimension	L127.05xW42.39xH49.74 mm
Chest-piece Weight	23g
Clinical Area	Auscultation
Waterproof requirement	IPX4
Screen	OLED 1.46” Full Color 128x128 RGB
Three Filter Modes	B/D/W
Mode Frequency Range	Bell (20-200 Hz)、Diaphragm (100-500 Hz) and Wide (20-1000Hz)
Recording Position control	← →
Volume control	↑ ↓

Volume level degree	10 level
Recording Auscultation Organ and Position of Sound Track	Yes
Record time set	10 sec, 20 sec, 30 sec, 40 sec
Recording pause	> 5 sec
Time Display	00:00:00 (hour: minutes: second)
Date Display	XXXX-XX-XX (year-month-date)
Organ Display	Heart / Anterior Chest / Posterior Chest/ Neck / Bowel
Sleep mode	2min / 5min / 10min / never
Sleep mode wake-up	2 sec
Heart Rate Detection	Yes (Heart Organ display), 30-180 bpm
Phonocardiogram display	Yes, 3 second display
Data Wireless Transfer	Bluetooth 4.0
Sound Tracks Recordings (Files Storage)	Save up to 160 10-second patient sound tracks

17. Appendix: Guidance and Manufacturer's Declaration

Manufacturer's declaration-electromagnetic emissions		
The Omni-Steth is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the Omni-Steth should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for professional healthcare environment)**
RF emissions CISPR 11	Group 1	The Omni-Steth uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Omni-Steth is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity

The Omni-Steth is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the Omni-Steth should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for professional healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 25/30 cycles Voltage interruptions: 0 % *UT*; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical professional healthcare environment. If the user of the Omni-Steth requires continued operation during power mains interruptions, it is recommended that the Omni-Steth be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The Omni-Steth power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity

The Omni-Steth is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the Omni-Steth should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz	Not applicable Not applicable	**Portable and mobile RF communications equipment should be used no closer to any part of the** Omni-Steth including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	80 % AM at 1 kHz e) 3 V/m 80 MHz – 2,7 GHz b) 80 % AM at 1 kHz c)	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Omni-Steth is used exceeds the applicable RF compliance level above, the Omni-Steth should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Omni-Steth.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the Omni-Steth

The Omni-Steth is intended for use in an electromagnetic environment (for professional healthcare) in which radiated RF disturbances are controlled.

The customer or the user of the Omni-Steth can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Omni-Steth as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmit term**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Omni-Steth is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the Omni-Steth should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Dis-tance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for professional healthcare)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

18. FCC and IC Compliance Statement

15.21
You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference and

2) This device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

1) This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2) For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

Canada, Industry Canada (IC)

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject
to the following two conditions:
(1) This device may not cause interference, and
(2) This device must accept any interference, including interference that may cause undesired operation of the device

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence.
L'exploitation est autorisée aux deux conditions suivantes:
(1) l'appareil ne doit pas produire de brouillage, et
(2) l'utilisateur de l'appareil doit accepter tout brouillage
radioélectrique subi, même si le
brouillage est susceptible d'en compromettre le fonctionnement.

RF Radiation Exposure Statement:

For body worn operation, this phone has been tested and meets RF exposure guidelines when used with an accessory that contains no metal. Use of other accessories may not ensure compliance with RF exposure guidelines.

Déclaration de l'exposition aux radiations RF:
Pour le fonctionnement du corps, ce téléphone a été testé et répond aux directives d'exposition RF lorsqu'il est utilisé avec un accessoire qui ne contient pas de métal. Utilisation d'autres accessoires peut ne pas assurer le respect des directives d'exposition RF.