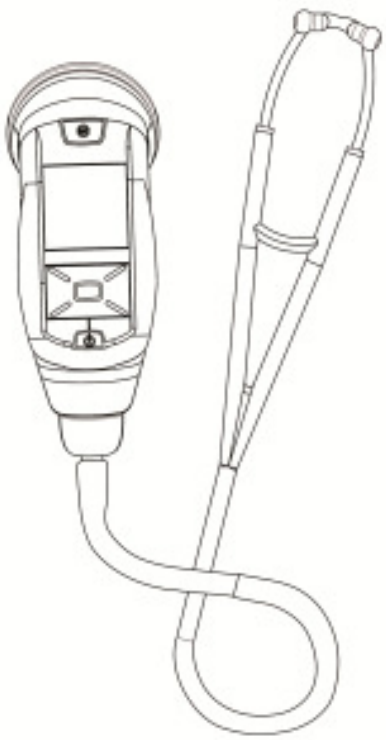
# IMEDIPLUS INC.

## Special Submission
## Electronic Stethoscope
## DS101

## Section 13

Document Title: Electronic Stethoscope DS101 User Manual
File Name: 003_Electronic Stethoscope DS101 User Manual



Model name: DS101

## 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 in one patient and up to 160 10-second auscultation sound tracks.
Clear acoustic performance.
With auscultation sound amplify ability to 27dB and 10 volume level adjustable.
Ergonomic Design.
Easy to use.
Rx only

# Content

# 1. Introduction

Thank you for choosing our Electronic Stethoscope DS101.

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

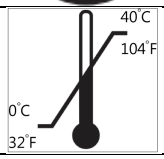
It has several smart and friendly design, which makes it easy to use and properly fit the needs for users. The design includes an easy-to-use interface that enable the users to approach the patient with one hand. The ear-tips are comfortable to wear with the soft texture. As well, it could provide a good tightness for reduction of environmental noise to offer a good sound quality for users.

Electronic Stethoscope DS101 was innovated from a group of healthcare professionals. Therefore, the user experience is an important factor of designing the stethoscope. We appreciate for your adoption of Electronic Stethoscope DS101 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 these instructions for future reference.

## 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 Limit |
|  | 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. |
|  | This product uses wireless Bluetooth communication. |
| Rx only | Federal law restricts this device to sale by or on the order of a physician. |

| **Explanation of Signal Word Consequences** | |
|---|---|
| **NOTICE** | Indicates a hazardous situation, which, if not avoided, may result in property damage. |
| **WARNING** | Indicates a hazardous situation, which, if not avoided, could result in minor injury and/or property damage. |

## 2.2 Important Safety Information

**NOTICE**

- To reduce the risks associated with environmental contamination follow applicable regulations in local when disposing of this stethoscope. Properly dispose of, or recycle, spent batteries.
- No modification of this device is allowed. Use only authorized service personal to repair this electronic stethoscope. If user modify by self, solely responsibility for the consequence.
- The Electronic Stethoscope DS101 is MR unsafe. Do not use the Electronic Stethoscope DS101 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 of ear canal,** please hold tight the device to avoid sudden falling and make sure that the soft sealing ear-tips are snapped firmly into position.

**WARNING**

- **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. 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 stethoscope's diaphragm cover in place.
- **The electronic stethoscope DS101 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 DS101 away from that device.
- **To reduce the risks associated with a damage of stethoscope,** please

put the device into the pocket of physician gowns to avoid sudden falling, when you put the device hanging on the neck.

- **Do not use the unauthorized accessories,** which would be caused hazard. The accessories use only from IMEDIPLUS provided.
- **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 DS101 in Magnetic Resonance Imaging (MRI) environment**. Because of Electronic Stethoscope DS101 contain conductive, metallic and magnetic materials. Those materials include headset, wire, connectors and inductors, which are assembled in Electronic Stethoscope.
- **Do not use for children under two years old.** Because the stethoscope chest-piece is designed for use with child, adolescent and adult patients.
- **Before first use**, battery must be charged continuously for at least 8 hours. Failure to do so may shorten the battery's lifetime.
- **To prevent causing battery leaks or damaging their terminals**, carefully follow all instructions regarding the use of batteries.
- **If battery fluid gets into your eyes**, flush your eyes immediately with clear, cold running water and seek medical attention immediately.

# 3. Product Description

When you turn on the Electronic Stethoscope DS101 for the first time, your authorization to operate this handheld electronic stethoscope is necessary for the normal mode of operation.

The Electronic Stethoscope DS101 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. When picking up the sounds, the phonogram of sounds could simultaneously display after pushing the button 'OK' or 'REC' for recording. When you auscultate with DS101, the sounds are conducted simultaneously to the user's ears bilaterally by active speaker embedded at the bottom of the DS101. At the meantime, sound processing is operated with the aid of a digital signal processor.

The one-hand users interface includes a full-color OLED display, below the OLED display, it has four way button and OK button, a tube connector for output of sounds at the inferior part, and recording button is on the top of OLED display.

After turn on the Electronic Stethoscope DS101 and connected with a wireless device by Bluetooth Class 2, the Electronic Stethoscope DS101 could transmit digital data of recorded sounds via Bluetooth. The effective range of Bluetooth transmission will be influenced when some objects blocking between The Electronic Stethoscope DS101 and the connected laptop. (Such as wall, human big objectives as barrier) Reduce the distance or allow the line of sight between The Electronic Stethoscope DS101 and the connected laptop will improve the Bluetooth connection.

The DS101 does not incorporate any off-the-shelf (OTS) software. The recorded audio data only can be replayed by The Electronic Stethoscope, and the speaker of effective range from 20 to 1000Hz. The Electronic Stethoscope DS101 operates on two AAA1.2V rechargeable battery with an include power management system to prolong the battery life.

## 4. Intended Use

The Electronic Stethoscope DS101 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. And 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 DS101 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 DS101. Additional operating training is not proposed.

## 6. Patient Privacy

The privacy of patient health information may 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 electronic patient data through the use of software. If the user becomes unable to comply with a law or restriction that applies to use and disclosure of such data, the user should not proceed to collect or save such information.

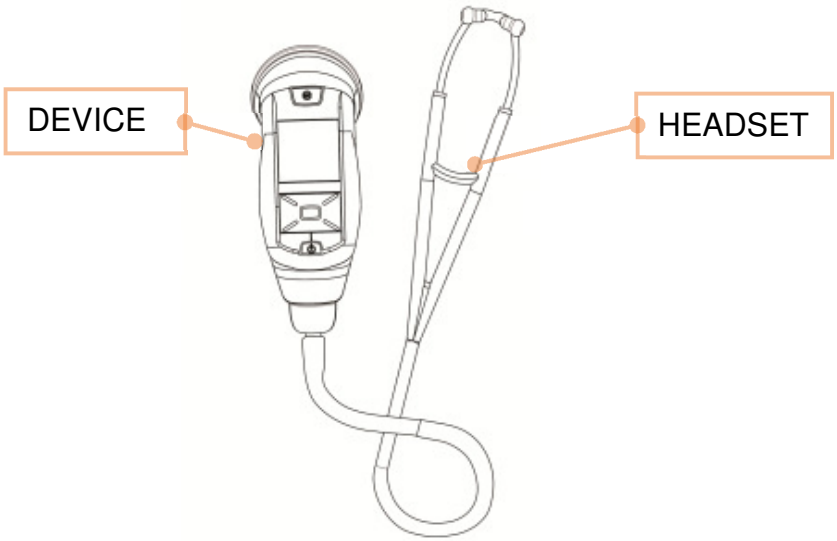
This application may require entry of individually identifiable health information in order to function. Records are stored and recalled through the

use of patient name, date of birth, and/or patient ID #. By entering this information, the user assumes any and all risks of 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 that you should keep this manual for reference anytime.

## 7.1 Stethoscope Interface




## 7.2 Replacing Battery

According to Figure 1, open the battery compartment cover by pulling down the notch on the cover, and remove the old battery by lifting it. Replace the new battery with two AAA rechargeable battery. Make sure inserting the new battery with right position that has notice marked on the inside, then remount the cover after replacing.

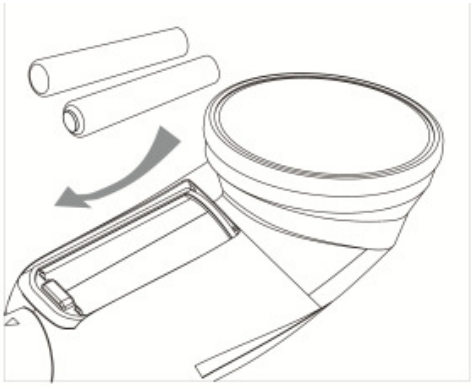


Figure 1

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

**NOTICE:**
The Electronic Stethoscope DS101 is available to install alkaline or Ni-MH batteries, the chart below is voltage that alkaline and Ni-MH battery contained. We highly recommended using rechargeable batteries which contained in the box for longer operational period.

| | 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 the Figure 2, please tightly hold the device for replacing the ear tubing. Twist the device to counter-clockwise direction to remove the ear tubing. Please put the ear tubing on the safer position in case of the unnecessary falling damage. Align the new ear tubing with the two triangle

marks on the device and directly insert it into the device. Make sure the ear tubing completely insert into the device with the arrow mark are matching.

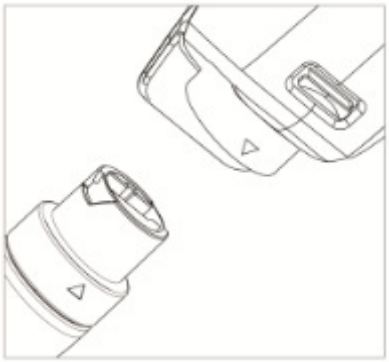


Figure 2

## 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, diaphragm will face towards your body, as shown in the Figure 3.

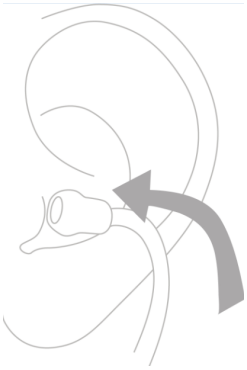


Figure 3

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 eartube to apply new ear-tips, as shown in Figure 4.

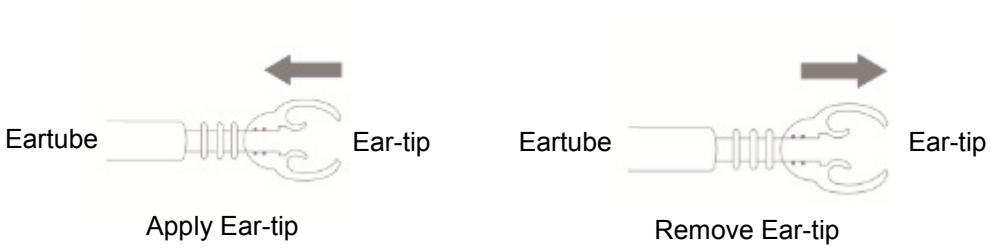



Figure 4

## 7.5 Adjust Headset for Comfort

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

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

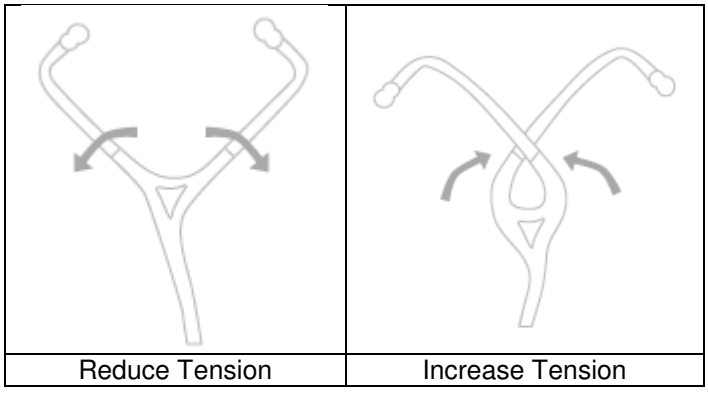



Figure 5

## 7.6 Replacing the chestpiece

As the Figure 6 shows the position of the chestpiece. Please tightly hold the device for replacing the chestpiece. Twist the device to counter-clockwise direction and remove the chestpiece. Please put the chestpiece on the safer position in case of the unnecessary falling damage. Align the new chestpiece with the two triangle marks on the device and directly insert it into the device. Make sure the chestpiece completely insert into the device until hearing the click sound.

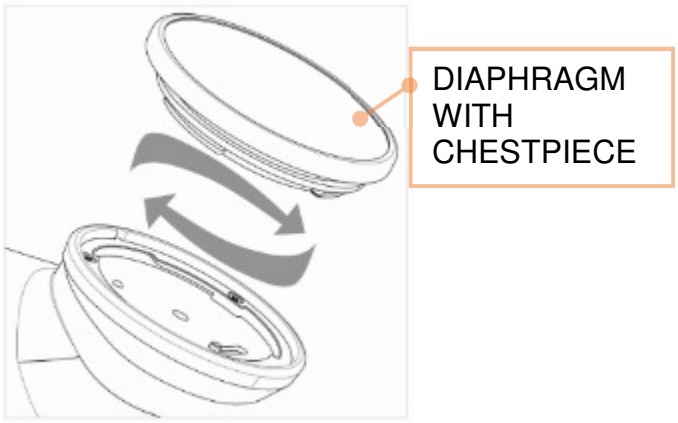



Figure 6

## 7.7 Replacing the disposable diaphragm(Silicon and PS)

As shown in the Figure 7, please hold the device and chestpiece tightly for removing the diaphragm. Pull down and remove the disposable diaphragm (Silicon) and dispose of it into medical waste bucket. To replace the new one, place the new diaphragm inside the rim, make sure the ring of the diaphragm is property and smoothly fit inside the rim groove.

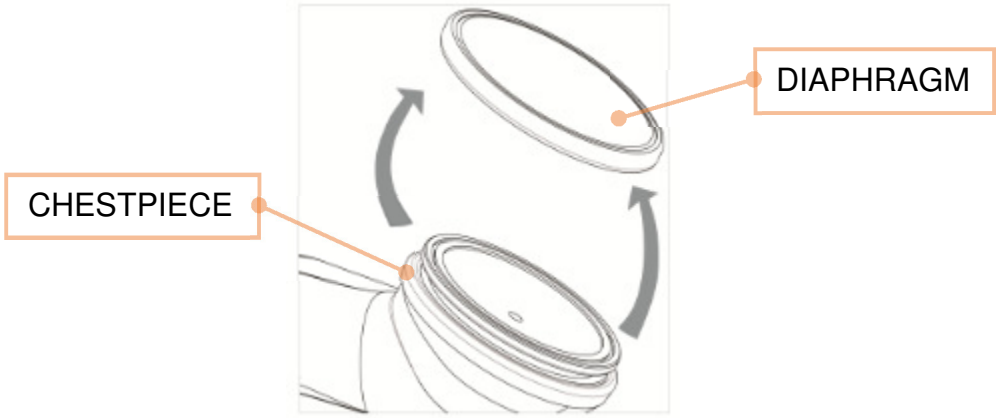



Figure 7

As shown in the Figure 8, please hold the device and chestpiece tightly for removing the diaphragm. Pull down and remove the disposable diaphragm (PS) and dispose of it into medical waste bucket. To replace the new one, tear the new diaphragm package, hold the device directly bucked up the diaphragm, and make sure the diaphragm is completely tie up with the device until hearing the click sound.

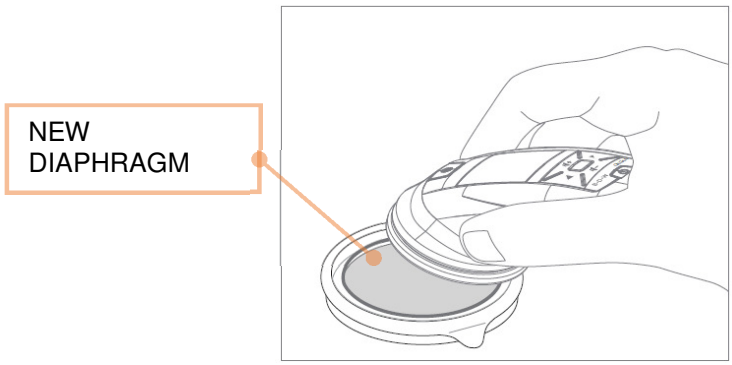
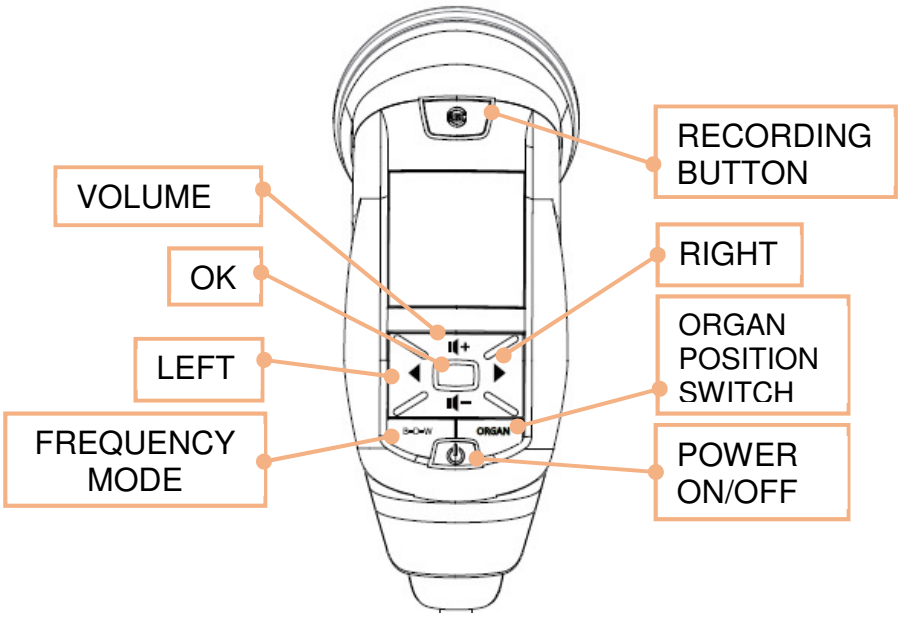


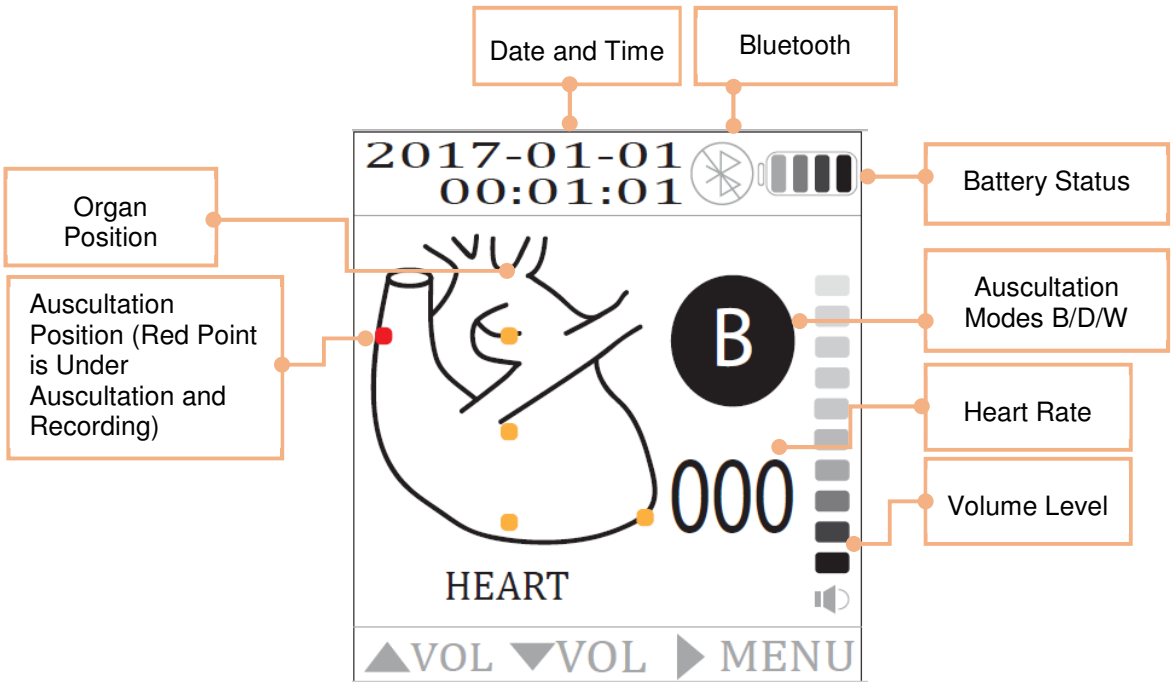

Figure 8

## 7.8 Stethoscope construction




| |
|---|
| **Power Button**<br>To turn on the device or enter the sleep mode. |
| **Recording Button**<br>During auscultation (in the HOME page), press recording button to record auscultation sounds of 10 seconds. |
| **Filter Modes Switch**<br>During auscultation (in the HOME page) and playback the recorded sound track, this button can select one of the auscultation filter mode, including “Bell”, “Diaphragm”, and “Wide” modes. |
| **Four way Button and OK Button**<br>● The “Four-way” button is used for selection.<br>● The “Right” and “Left” keys are used to enter or exit the pages.<br>● The “Up” and “Down” keys are used to adjust the sound amplification level. Using the “Up” and “Down” can move the indicator upward and downward.<br>● The “OK” button(Red key) is to set and confirm the selection item |
| **Organ Position Switch**<br>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: As the diagram 1 shows the position of power button. Depressing and releasing the power button for three seconds to turn on and off the stethoscope. The information shows up on the screen to presents the power is on. Turn off the device and the screen presents black.

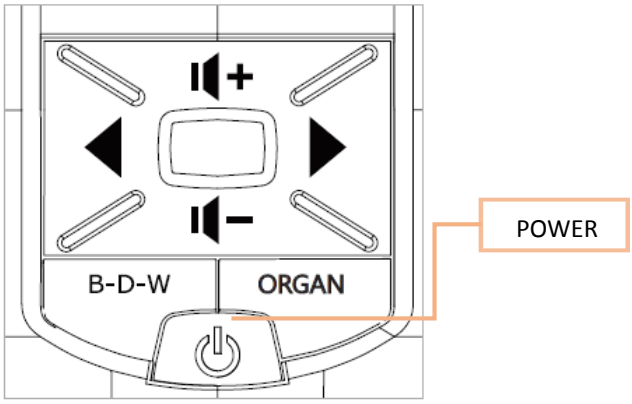



Diagram 1

## ➢ Sleep mode

- In the menu, press “UP”/”DOWN” to scroll to the “SLEEP SET”, then press the “OK” button. Here has “two minutes” , ”five minutes” and ”ten minutes” you can choose. Use “UP”/”DOWN” to choose and then press the “OK” button to confirm. The stethoscope will be in the sleep mode if you don’t use it at the certain time. Press “POWER ON/OFF” again to wake it up.

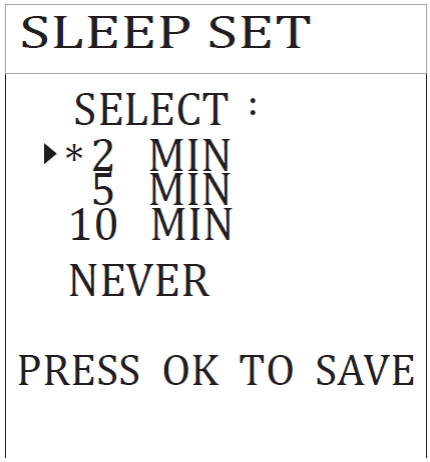



Diagram 2

## ➢ Enter the menu:

- Press “RIGHT” for 3 seconds to enter the menu. As shown in the diagram 3, play back、record time set、sleep time set、date and time set、default reset and product info.
- Product information will be displayed on the screen.

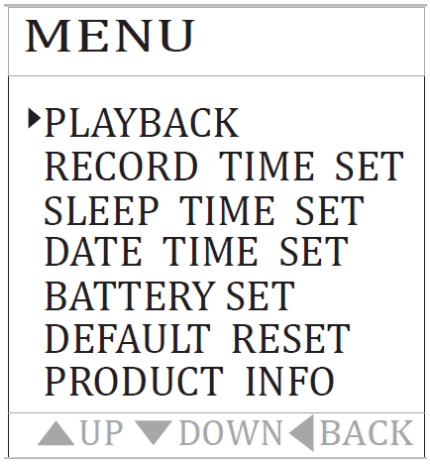


Diagram 3

## ➢ Record time set

- In the menu, press “UP /DOWN” button to scroll to the “RECORD TIME SET”. As shown in the diagram 6, then press “UP /DOWN” button to scroll to the record length then press ”OK”, as shown in the diagram 4. Here has “10 seconds”, “20 seconds”, “30 seconds” and “40 seconds”.

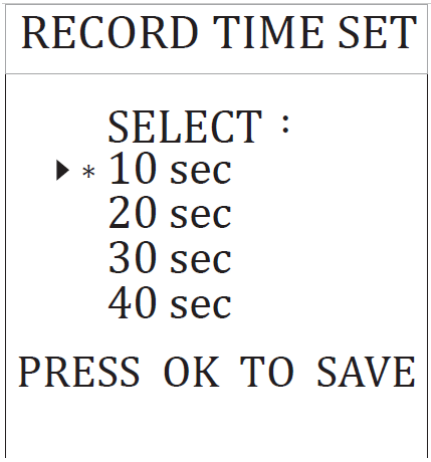



Diagram 4

## ➢ 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 the 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.

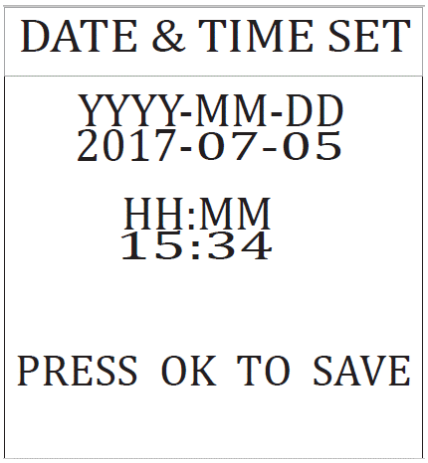



Diagram 5

## ➢ 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 the diagram 6, “UP /DOWN” buttons are used for choose two different types of battery. The user can choose “Alkaline” or “Ni-MH” based on which types of battery installed. Press “OK” to save the setting. The default batteries in the box are Ni-MH battery.

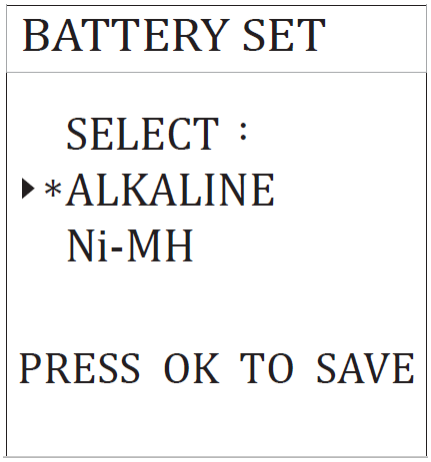



Diagram 6

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

The default setting of battery selection is Ni-MH battery. An inaccurate battery indicator will show on screen if you change with other kinds of battery without switch to the correct selection.

## ➢ 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 the diagram 7. Press “YES” if you’ve already make sure to reset to default setting. This function can help you default the unexpected condition and reset.

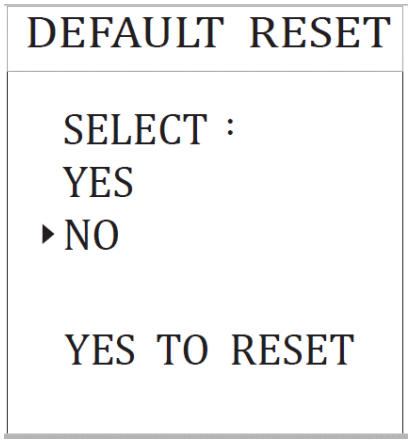



Diagram 7

Factory Default Setting Table

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

## ➢ Product Information

The stethoscope show the software version and product name on the “PRODUCT INFO” page.


Diagram 8

## ➢ Organs setting

- "ORGAN" button is used for organs setting. As shown in diagram 9, press and release the "ORGAN" button to switch the organs pattern. For example: Heart → Lung → Prior chest → Neck → Bowel。

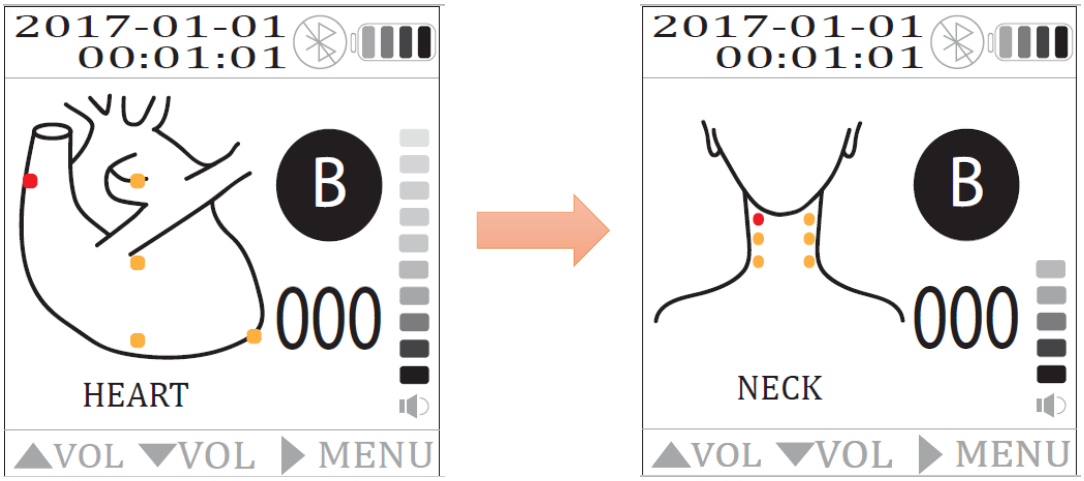



Diagram 9

## ➢ Sound frequency mode

- "BDW" is used for sound frequency mode. As shown in diagram 10, press and release the "BDW" button to switch the frequency mode. For example: B (Bell mode) → D (Diaphragm mode) → W (Wide mode)

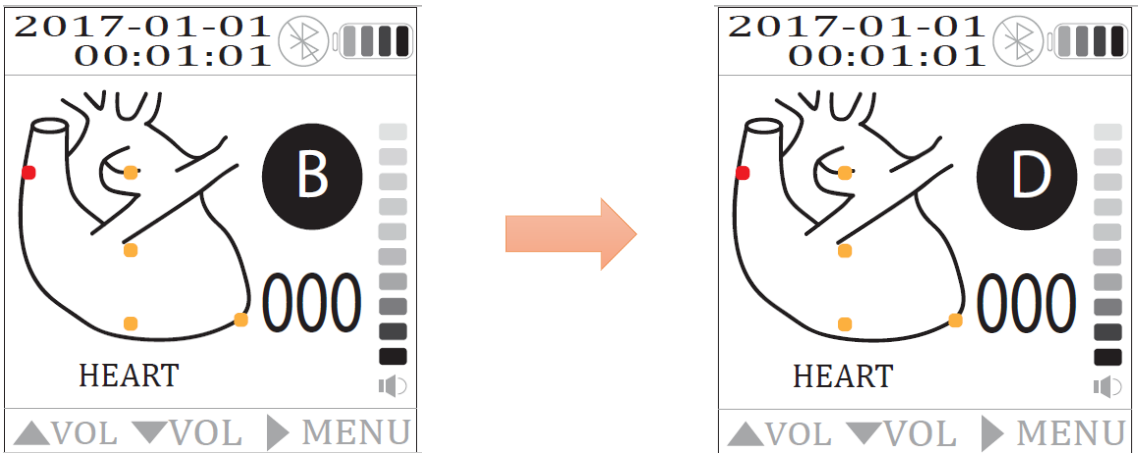



Diagram 10

## ➢ Volume control:

- As shown in diagram 11, press "UP" to increase the sound level and press "DOWN" to decrease the sound level. Keep pressing "DOWN" to decrease the volume until it turns into "MUTE" mode.

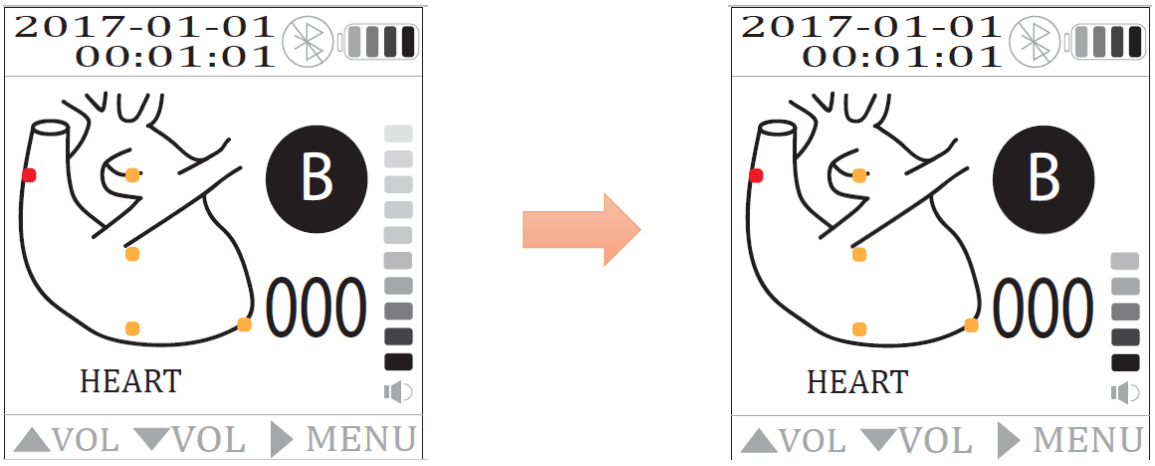



Diagram 11

## ➢ Bluetooth connect

- As shown in the diagram 12, when DS101 successfully connected with the device, the red box in the Bluetooth icon will disappear.

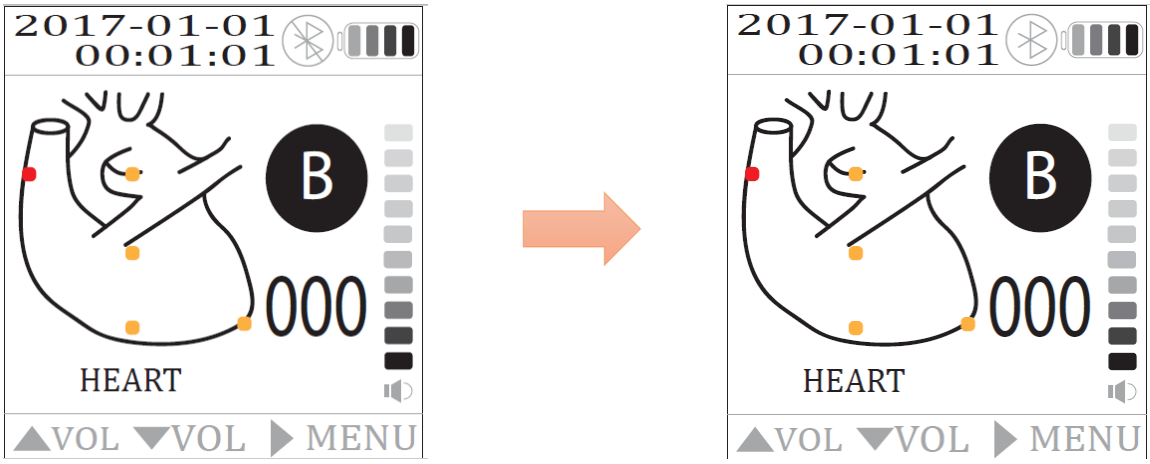



Diagram 12

## ➢ Recording the Auscultation Sound

- The recording button is on the top of the display. Press the recording button to record sound and the Phonocardiogram will show on the screen. The red horizontal red bar presents the recording time shown at the bottom on the screen. The default setting for recording time is 10 seconds, after recording the sound track the screen will go back to the home page.

⚠ **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 the 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 playing. Press “LEFT” to return to the menu.

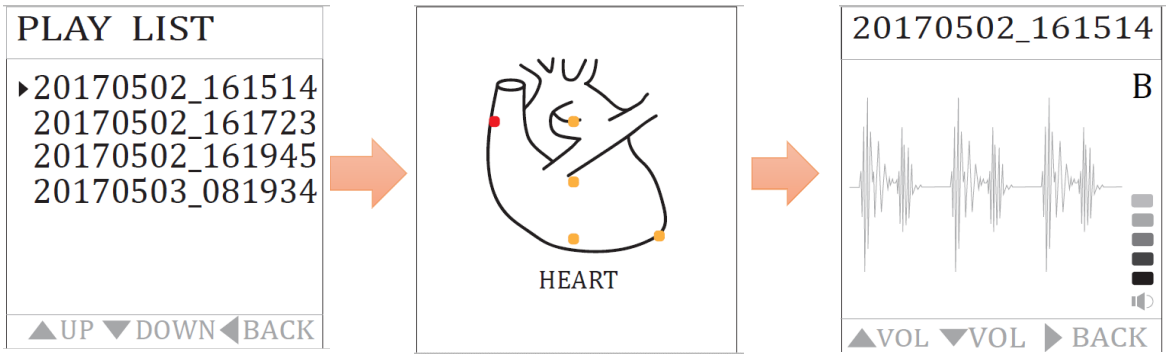



Diagram 13

## 9. DS101_DM Software (Data Management)

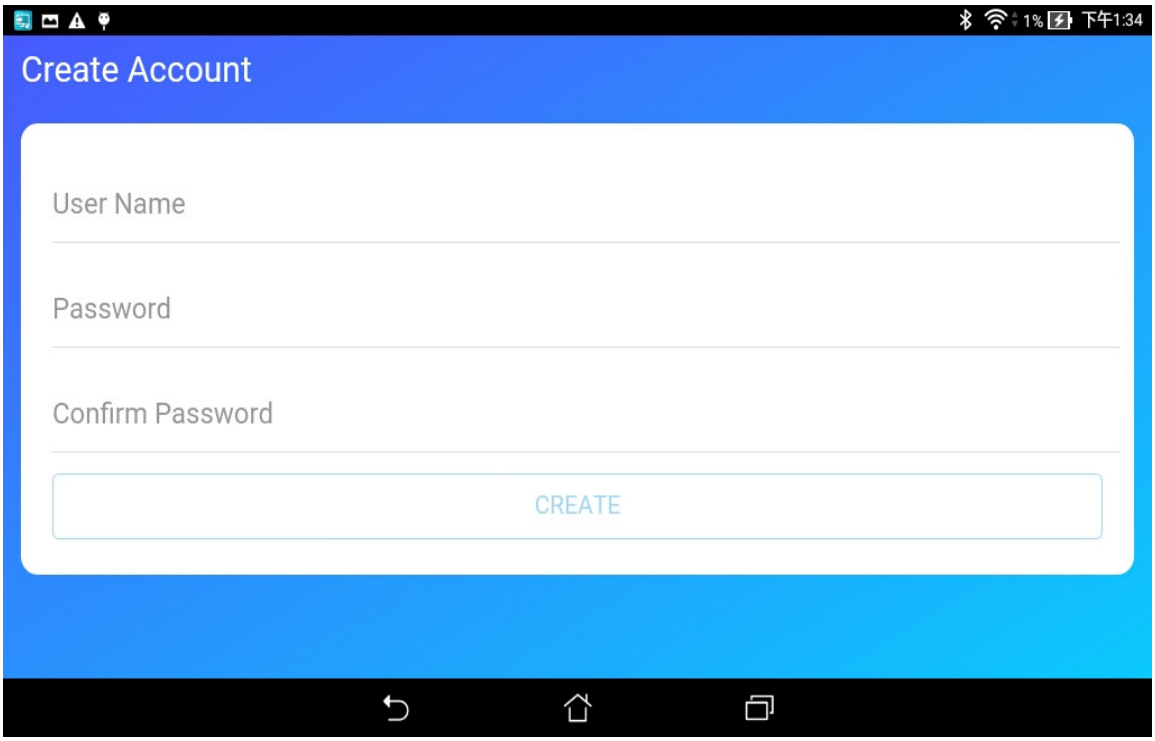
### ➢ Installation for Android System

Turn on the Android App Store using a supported mobile device. Ensure that the device is connected to the internet. Follow the instructions to download the App and wait until it has finished installing.

### ➢ Create the first account

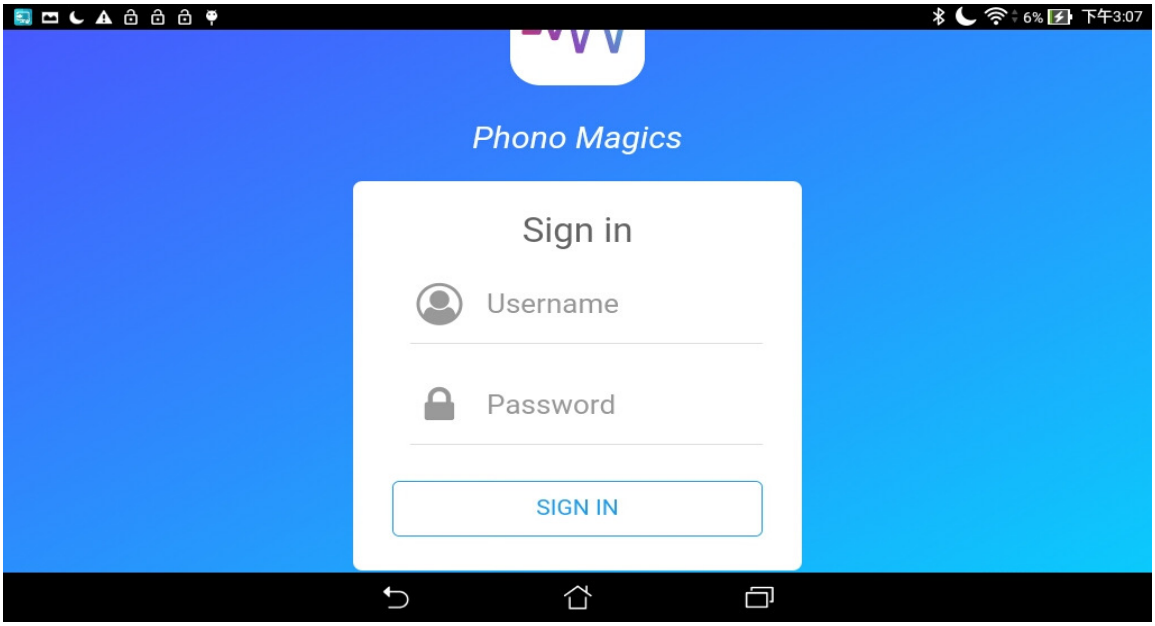
First, create the account to access the DS101_DM Software (Data Management) and also, keep patients data in your account. Now turn on the DS101_DM Software (Data Management) on the mobile device. Enter your

own user name and password.



## ➢ Sign in

After create a first account, use that account to sign-in. Please type your user name and password correctly.



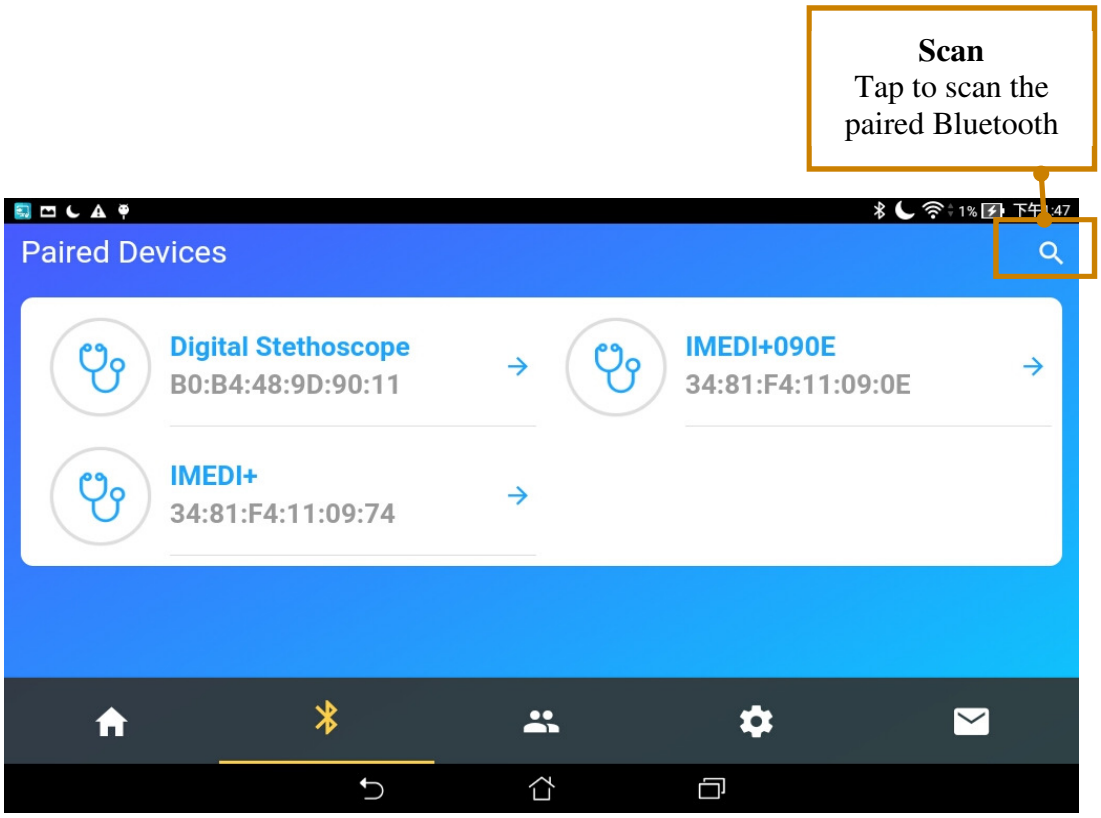
## ➢ Bluetooth Pairing

Bluetooth must be enabled in the device Bluetooth settings in the DS101_DM Software App.

First, enable Bluetooth on the selected mobile device. On the mobile device go to Settings > Bluetooth > and tap the slider to turn Bluetooth ON. Searching the mobile device's name and tap to pair.

Then, turn on the DS101_DM Software (Data Management) and tap the Bluetooth symbol icon to display the Bluetooth devices. You can tap "Scan" if the paired Bluetooth device is not displayed.

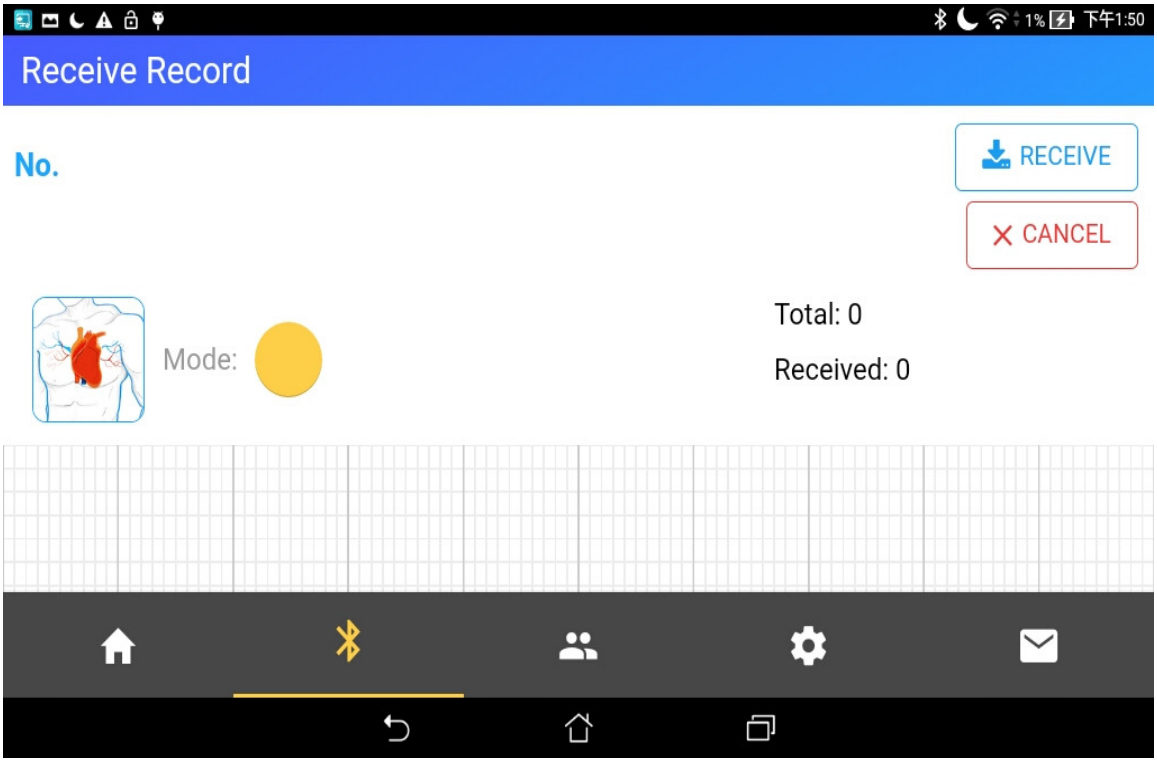
After the paired Bluetooth device is displayed, tap on it to connect with the device.



The system will pop-up, asking to pair with the stethoscope, if it is the true one, tap “Pair” to confirm.

## ➢ Using the app to receive recordings

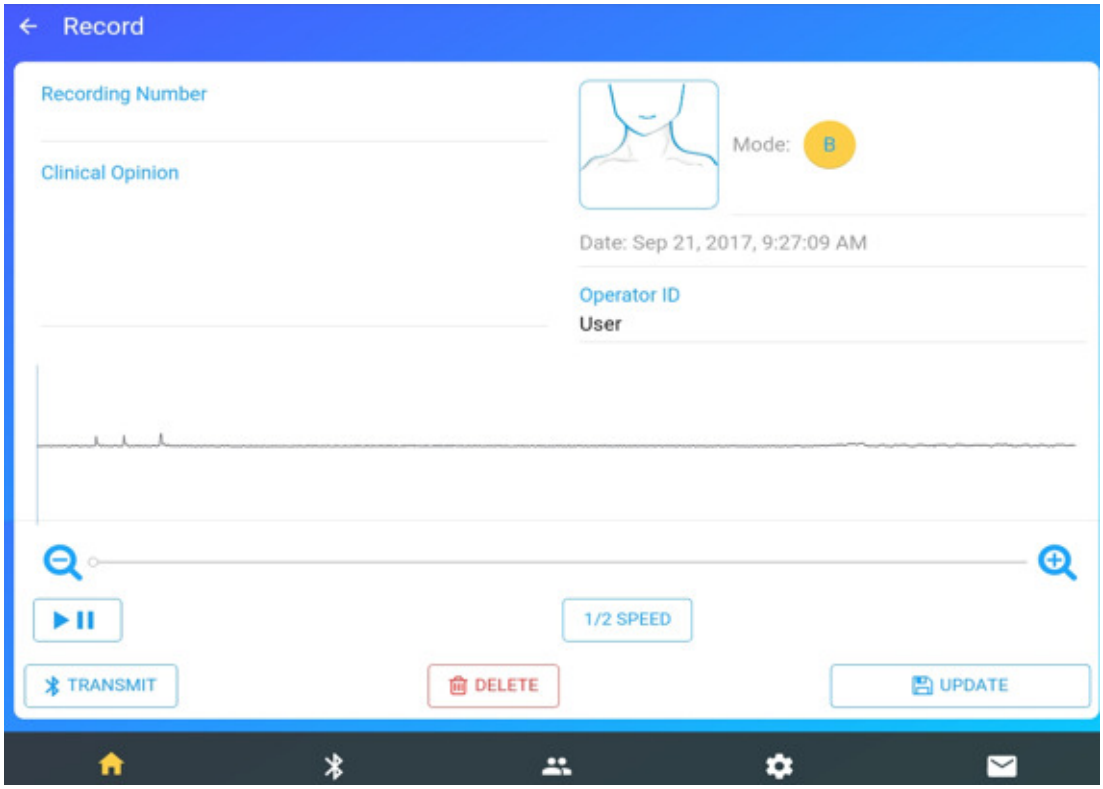
After paired with the stethoscope, the mobile device page will turn to record received page. The mobile device is now ready to receive sounds from the DS101. Tap “RECEIVE” button and the DS101_DM Software (Data Management) start to receive recordings from DS101. If Bluetooth pairing is unsuccessful, the Bluetooth mark will flash on the OLED screen of DS101 and no sounds will be recorded. If the Bluetooth connection is successful the mark will keep in bright blue of the device.



## ➢ Using the app to transmit recordings to DS101

Turn on the DS101_DM Software (Data Management) and log in. Ensure that the DS101 Device is paired to the mobile device (See Section 8).

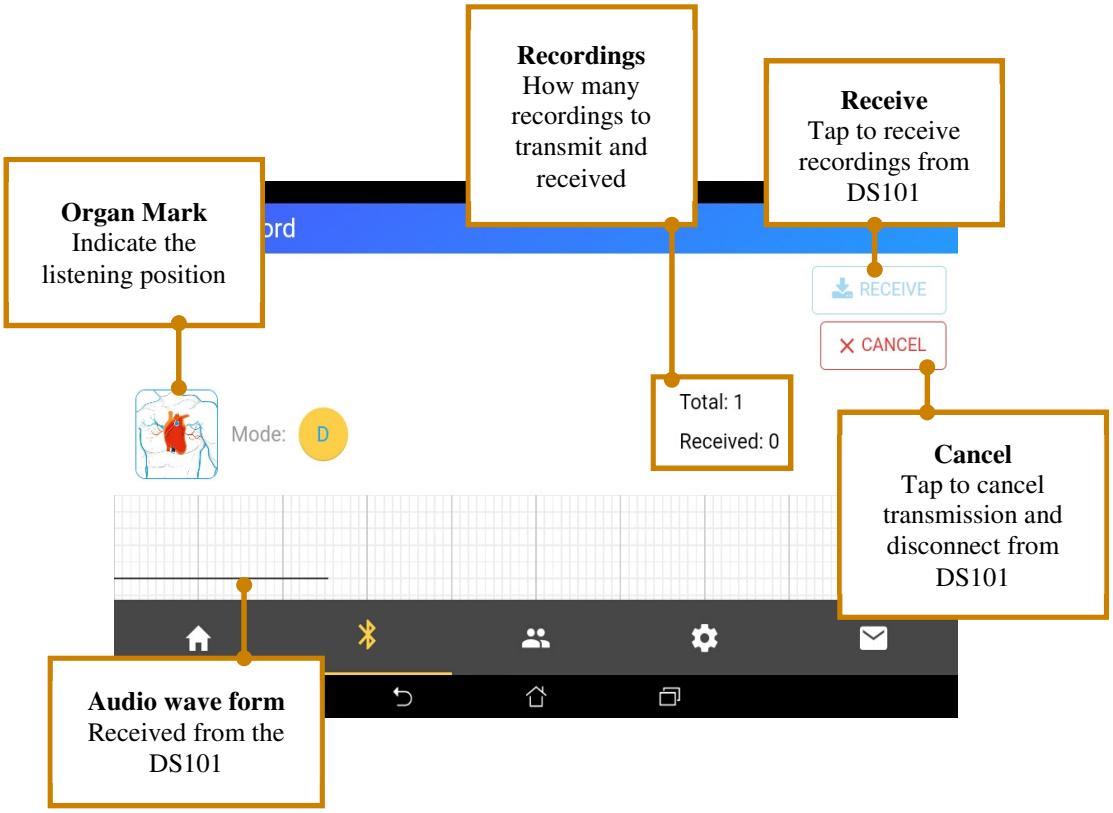
In the home screen, press “Transmit” and the original record will transmit back to DS101.




**NOTICE:** For showing better sounds quality, we highly recommend transmit recordings back to DS101 and listen with eartube.

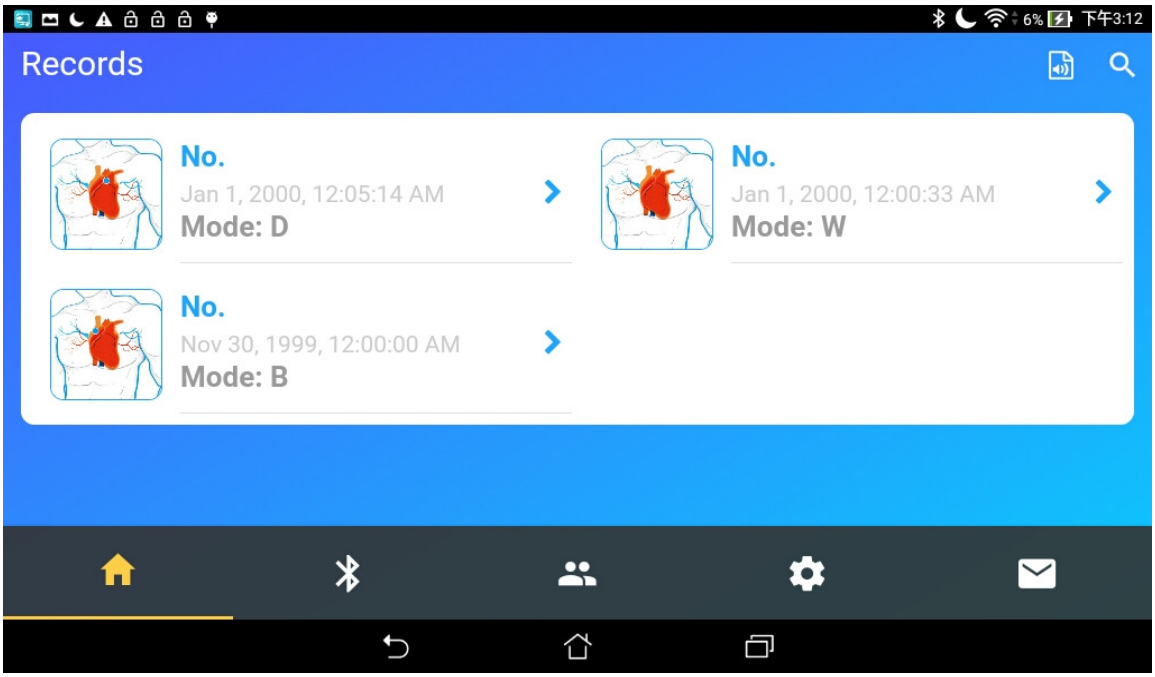
## 9.1 The Main Recording Page

The Main Recording Page allows users to view audio data captured by DS101, begin the recording process, retrieve patient specific data, or adjust settings. Audio data is represented in real-time as a phonocardiogram. A period of recording is 10-second intervals.



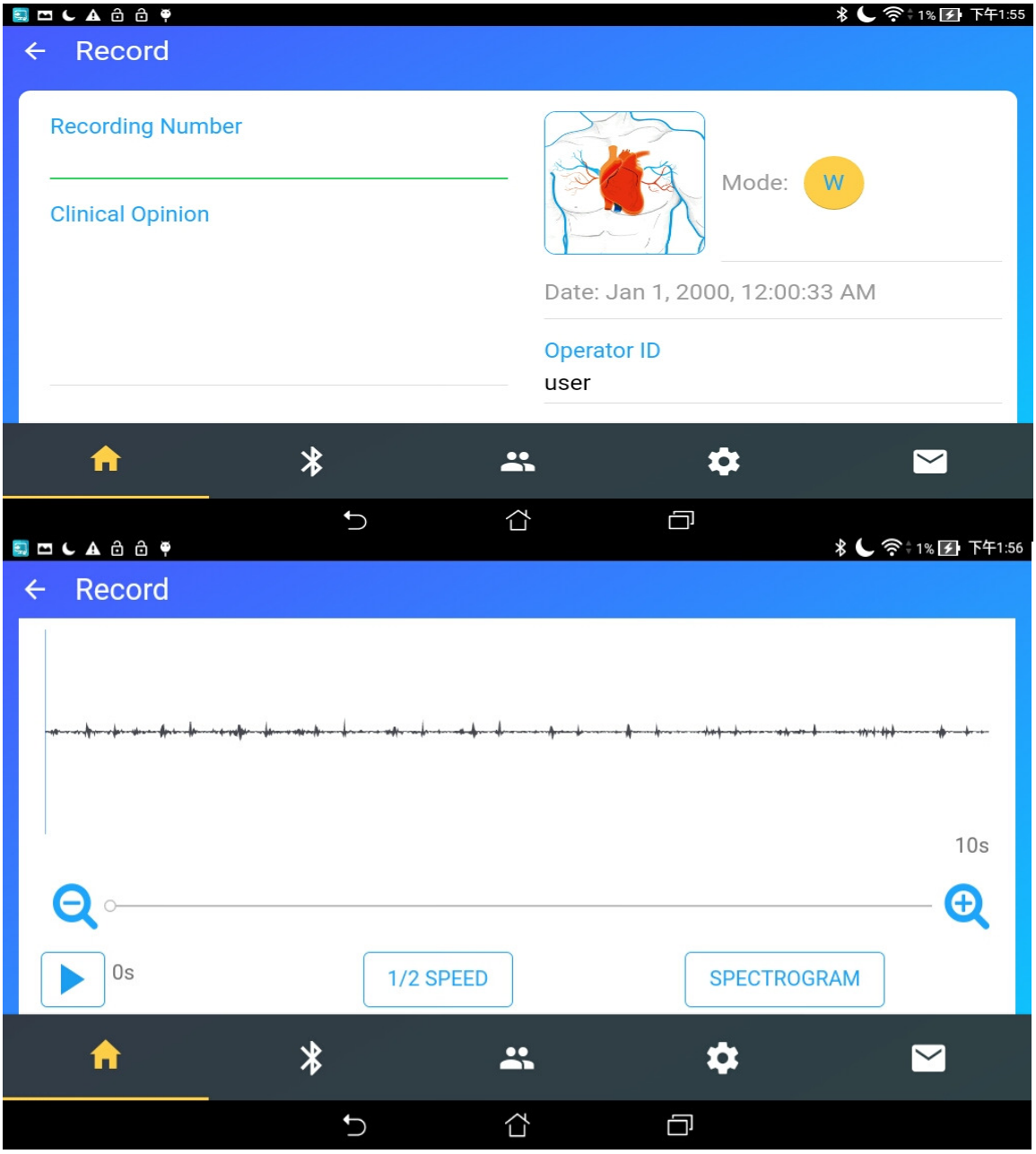
## 9.2 Records Page

The recordings received from DS101 will save to records page. Tab on any recording to review the detail information.



## 9.3 Review Page

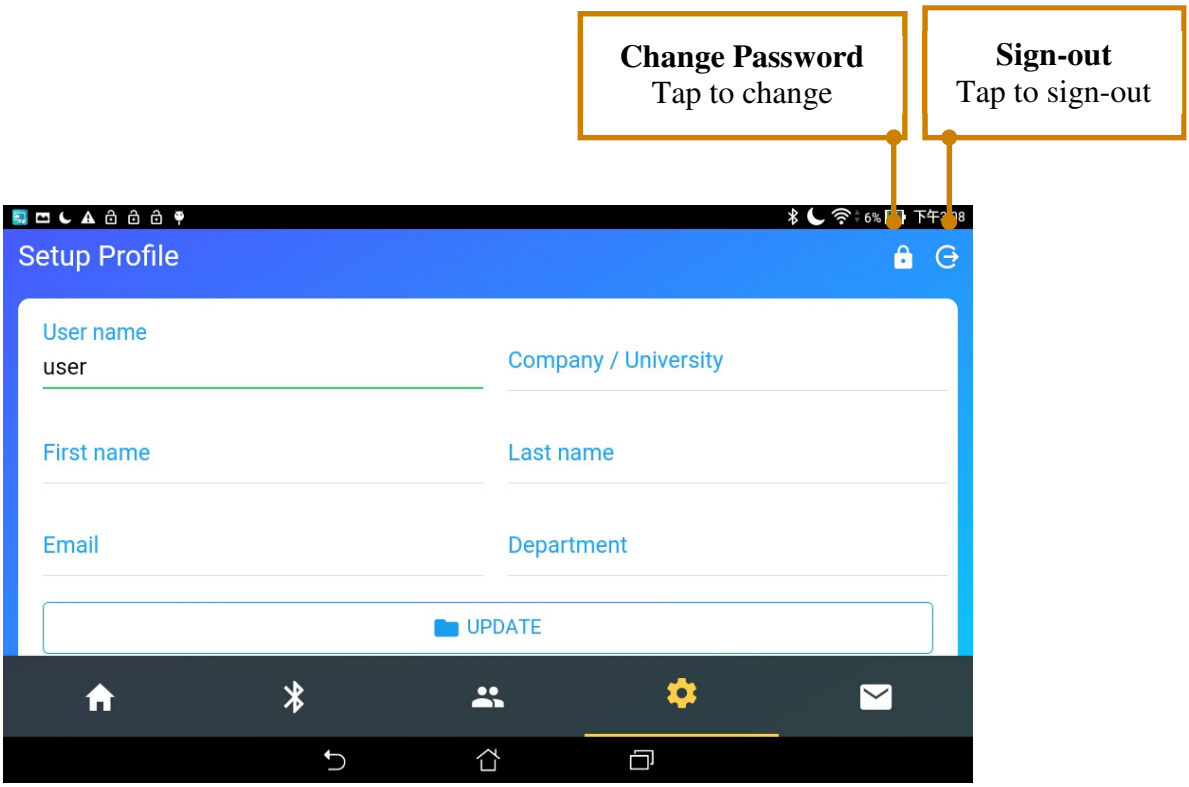
More information on a specific recording can be viewed by tapping on a recording listing. This page displays the recording number, organ mark, recording time, operator ID, and clinical opinion. User can add suggestion or diagnosis opinion on it.



This also includes a waveform of the recording with zoom in / zoom out, and playback the sound.

## 9.4 Setup Page

In setup page, it can change user name, email, belonging company, and belonging department.

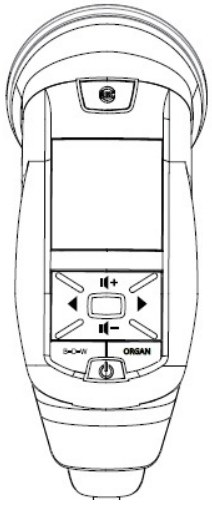
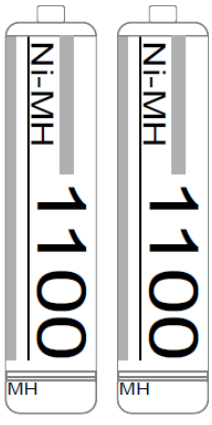


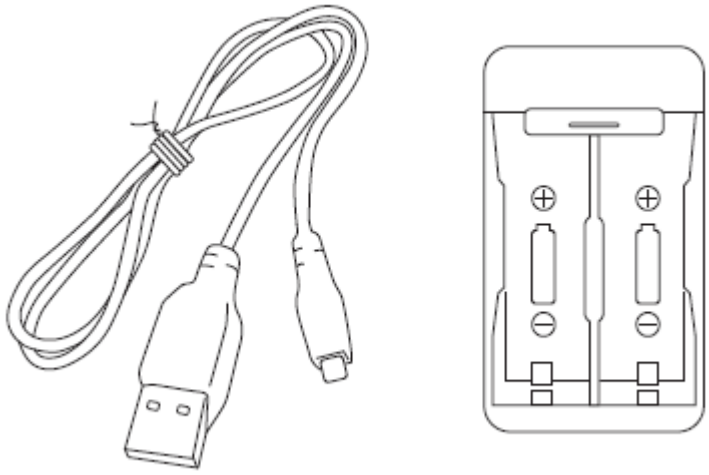
## ➢ Other Operating Considerations

- Operating range is 32ºF to 104ºF (0ºC to 40ºC), 15 to 93% relative humidity.
- Maximum operating altitude is 2000m.
- Maximum expected service life is 5 years.
- Storage and transport range is -4ºF to 158ºF (-20ºC to 70ºC), 0 to 93% relative humidity.
- To keep the life of your electronic stethoscope, please avoid operating under extremely hot and extremely cold condition.
- Don's use solvents and oils to prevent unexpected hazards.
- Remove the battery if the electronic stethoscope will not be used for several months.
- Failure to follow care and maintenance recommendations could result in damage to the internal components of the Electronic Stethoscope DS101. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

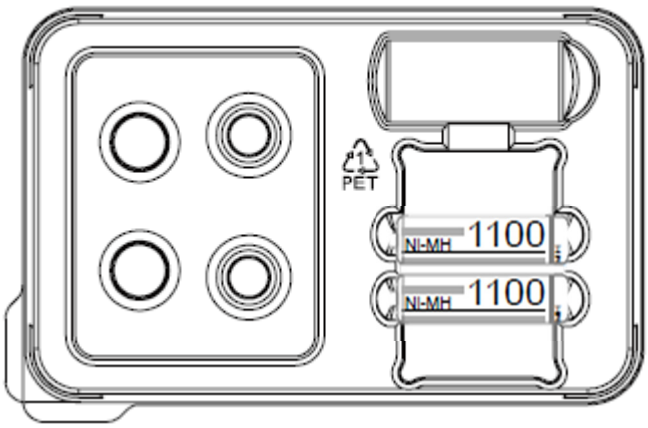
**NOTICE** ：If you experience any problems with the Electronic Stethoscope DS101, do not attempt to repair it yourself. Please notify our customer service center for directions on shipping and receiving.

# 10. Product Parts List

| | |
|---|---|
| 1. DS101 Device: It consists of chest-piece with diaphragm, screen, intuitive keypad and eartube connector of audio output. | 2. DS101 Headset: Including eartube , connector, and ear-tips |
|  |  |
| 3. Diaphragm | 4. AAA 1.2V Battery |
|  |   |
| 5. Battery Charger | |



6. Accessary Package(includes two pairs of ear tips, two AAA Alkaline rechargeable batteries)




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

## 11. Cleaning

- Electronic stethoscope:

1) Before start to cleaning, please check the tubbing connector and all structure of stethoscope are stable to avoid liquid infiltration.

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

1) Avoid directly wiping up with alcohol or detergent solution in case of the unnecessary damage, spray 70%~75% alcohol solution on the dry, clean tissue paper or cotton sheet that we highly recommended.
2) Wipe the electronic stethoscope.
3) After wiping out the dust and dirt, please check the electronic stethoscope is working as usual.

- Ear tubing and ear-tips: It can be wiped clean with alcohol. Ear-tips may be removed for the advanced cleaning and disinfection.

  Diaphragm: you can wipe the diaphragm with 70%~75% alcohol solution on the dry, clean tissue paper or cotton sheet that we highly recommended. Otherwise, replace the new diaphragms after the device is dirty or used in high contamination patient.

⚠ **WARNING: To reduce the risk of infection, cleaning of stethoscope should be done between each patient use.**

⚠ **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 a period of 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 in cases of obvious abuse or accidental damage.

## 13. Troubleshooting

| Item | Questions | Answer |
|---|---|---|
| 1. | No “Powered”, after “Turn ON”. | Please check battery whether properly installed, and then try again after reinstall the battery. |
| 2. | No “Powered”, after “Turn ON”. | Please replace a new one battery, and then try again after reinstall battery. |
| 3. | No “auscultation sound”, after “Turn ON”. | Please check headset whether properly installed, and then 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 stands for unsetting of the date and the time. Please refer to the section "Setting Date” (setting date section 6-8) to set date. |
| 6. | The device has no response when you are operating the device. | Please reinsert the battery, and then make sure the device has response when you are operating. |

**IMPORTANT!**

- If you have tried all of the solutions to the questions and that still failed to solve your problem, 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 with your Electronic Stethoscope DS101.

**NOTICE:** No modification of this device is allowed. Use only authorized service personnel to repair this electric stethoscope. If user modify by himself, the user will take all of the responsibility for the consequence.

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

**In the Taiwan (R.O.C.):**

IMEDIPLUS Inc.
Address: 2F, 12, ShengYi Rd. Sec. 2, Chupei City, Hsinchu County 30261, Taiwan (R.O.C.)
Email: service@IMEDIPLUS.com
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 DS101 needs to be sent to an authorized service center for inspection and repair. The storage environment conditions must be follow the '**Other Operating Considerations**' section of this manual.

✧ **Disposal**

You shall properly dispose of the Electronic Stethoscope and follow the local regulations. The AAA 1.2V rechargeable battery must be disposed of separately or recycled from regular waste.

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

## 16. Specification

| IMEDIPLUS Electronic Stethoscope DS101 | |
|---|---|
| Product Specification | |
| Batteries Enclosed | AAA 1.2V Alkaline/1.5V Ni-MH Battery |
| Battery indication | 100%/ 75% / 50% / 25% |
| Monitor battery level degrees | 4 degrees |
| Continuous operation with all functions | 10 hours |
| Chest-piece Technology | Changeable chest-piece |
| Device Dimension | 146x50x39.5 mm |
| Chest-piece Weight | 23g |
| Clinical Area | Auscultation |
| Water-proof requirement | IPX4 |
| Screen | OLED 1.46" Full Color 128x128 RGB |
| Flash memory | 128MB |
| 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 for Sound Track | Yes |
| Recording setting | 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 / Lung / 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 |
| phonocardiography display | Yes, 3 second display |
| Data Wireless Transfer | Bluetooth 4.0 |
| Sound Tracks Recording (Files Storage) | Save up to 160 10-second patient sound tracks |

# 17. Appendix: Guidance and Manufacturer's Declaration

| **Manufacturer's declaration-electromagnetic emissions** | | |
|---|---|---|
| The DS101 is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the DS101 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 DS101 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 DS101 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 DS101 is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the DS101 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<br>Air±2 kV,±4 kV,±8 kV,±15 kV | Contact:±8 kV<br>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<br>± 1kV for input/output lines | Not applicable<br>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)<br>± 0.5kV, ±1kV,± 2kV line(s) to earth | Not applicable<br>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:<br>0 % $U_T$; 0,5 cycle 0 % $U_T$; 1 cycle<br>70 % $U_T$; 25/30 cycles<br><br>Voltage interruptions:<br>0 % $U_T$; 250/300 cycle | Voltage dips:<br>Not applicable<br>Not applicable<br>Not applicable<br><br>Voltage interruptions:<br>Not applicable | Mains power quality should be that of a typical professional healthcare environment. If the user of the DS101 requires continued operation during power mains interruptions, it is recommended that the DS101 be powered from an uninterruptible power supply or a battery. |
| Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8 | 30 A/m<br>50 Hz or 60 Hz | 30 A/m<br>50 Hz and 60 Hz | The DS101 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 DS101 is intended for use in the electromagnetic environment (for professional healthcare) specified below.
The customer or the user of the DS101 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<br>IEC 61000-4-6 | 3 Vrms:<br>0,15 MHz – 80 MHz<br>6 Vrms:<br>in ISM bands between 0,15 MHz and 80 MHz<br><br>80 % AM at 1 kHz e) | Not applicable<br><br>Not applicable | **Portable and mobile RF communications equipment should be used no closer to any part of the** DS101 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz – 2,7 GHz b)<br>80 % AM at 1 kHz c) | 3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz | **Recommended separation distance:**<br>$d = 1,2\sqrt{P}$<br>$d = 1,2\sqrt{P}$ 80MHz to 800 MHz<br>$d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz<br><br>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 metres (m).<br><br>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]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

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 DS101 is used exceeds the applicable RF compliance level above, the DS101 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DS101

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 DS101**

The DS101 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 DS101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DS101 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 transmitter m** | | |
|---|---|---|---|
| | **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 DS101 is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the DS101 should assure that it is used in such an environment.

| **Test frequency** (MHz) | **Band** [a] (MHz) | **Service** [a] | **Modulation** [b] | **Maximum power** (W) | **Distance** (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; LTE Band 1, 3 | 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.