IMEDIPLUS INC.

510(k) Submission
Electronic Stethoscope
DS3011A

DS3011A Document For SGS Certification

Section 13

Document Title: Electronic Stethoscope DS3011A User Manual
File Name: 002_Electronic Stethoscope DS3011A User Manual

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Feature

Auscultation for heart, Anterior/Posterior chest, neck, bowel, limbs arteries, veins and internal organs.
Heart rate detection.
Built-in barcode reader for 1D (One dimensional) barcode scanning.
Real time recording and playing of auscultation sounds.
Recording multiple sounds in one patient and up to 600 10-second auscultation sound tracks.
Micro SD memory card for file transmission of auscultation sound tracks.
Friendly design for operation with organ mapping oriented interface
Clear acoustic performance
With 24X auscultation sound amplify ability and 10 volume level adjustable.
Ergonomic Design
Easy to use.

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1. Introduction

Thank you for choosing the IMEDIPLUS Electronic Stethoscope DS3011A.

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 included an easy-to-use interface that enable the users to approach the patient with one hand. Rapid identification of recording number and user's identities and 2-step operation for marking the source of the sound make the valid label while you capture the sound signals.

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.

IMEIDIPLUS Electronic Stethoscope DS3011A 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 IMEDIPLUS DS3011A 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.

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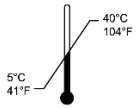
	Indicates Type BF Equipment: The equipment provides protection against electrical shock and electrical current leakage. Applied parts are considered to be the complete chest-piece with diaphragm.
	For ESD sensitivity connector the testing exemption.
	This product and packing does not contain natural 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.

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.

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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 IMEDIPLUS service personnel to repair this electric stethoscope. If user modify by self, solely responsibility for the consequence. ● The DS3011A is MR unsafe. Do not use the DS3011A 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.

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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.
- **DS3011A 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 DS3011A away from that device and/or turn the Bluetooth feature OFF.
- **To reduce the risks associated with a damage of user's eyes,** do not looking into the illumination beam of barcode reader.
- **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.
- **Before first use**, battery must be charged continuously for at least 8 hours. Failure to do so may shorten the battery's lifetime.
- **Do not use the DS3011A in Magnetic Resonance Imaging (MRI) environment**. Because of DS3011A contain conductive, metallic and magnetic materials. Those materials include headset, wire, connectors and inductors, which are assembled in DS3011A.

3. Product Description

The IMEDIPLUS Electronic Stethoscope DS3011A picks up the sounds from the heart, lung, anterior/posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs from a patient's body. After detection and amplification, the sounds are transferred to the user's ears via an active speaker and passive sound tubes. It could also identify the recording number by 1-D barcode reader, indicate the sound location by intuitive keypad, and simultaneously record the sounds from different sites.

The one-hand user interface includes a full-color OLED display and an intuitive keypad at the anterior part, a barcode reader at the posterior part, a chest-piece at the superior part, a tube connector for output of sounds at the inferior part, and a recording button at the left part. Sound processing is operated with the aid of a digital signal processor.

In order to transmit sounds to the "PhonoMagics" APP, the stethoscope and device must be connected via Bluetooth, and in order to fully use certain functions, the mobile device must be connected to the internet via cellular data connection or Wi-Fi.

The DS3011A uses a Bluetooth Class 2 wireless data link. The Bluetooth range will be reduced when objects (walls, furniture, people, etc) are between the DS3011A and a paired mobile device. To improve Bluetooth connection, reduce the distance and/or allow a line of sight between the DS3011A and mobile device.

It is highly recommended that users of the (PhonoMagics Dashboard and) PhonoMagics use device and networking security features to protect patient data created and stored using this software, in addition to security features embedded in the system. Please consult your institution's technical services to implement appropriate security measures.

The DS3011A could also exchange audio data with an external personal computing device using micro SD card. Every single audio file stored in micro SD card was labeled with the user's ID, recording number and indicated position. And the recorded audio data can only be replayed by DS3011A, but cannot be replayed by personal computing device.

The DS3011A does not incorporate any off-the-shelf (OTS) software.

The DS3011A operates on one (1) NP-120 lithium battery with an included power management system to prolong the battery life.

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4. Intended Use

The IMEDIPLUS Electronic stethoscope DS3011A is intended for the detection, amplification and recording of sounds from the heart, lung, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. The stethoscope chest-piece is designed for application to child, adolescent and adult patients. It is used for any subject undergoing a physical examination and intended only for medical diagnostic purpose in clinic or hospital.

5. Operator Profile

The IMEDIPLUS Electronic Stethoscope DS3011A is designed to be used by anyone who wishes to listen to sounds as described in the Intended Use section above. The user manual provides complete information on how to operate the DS3011A so that no additional operating training is required.

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. The IMEDIPLUS 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.

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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 Insert Battery

Insert one NP-120 lithium battery (provided in package) into the IMEDIPLUS Electronic Stethoscope DS3011A.

✧ Unlock of the battery cap, and then remove the battery cap, as follows.

✧ Insert the battery with correct direction, as follows.

✧ Remount the battery cap, as follows.

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7.3 Position Headset

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 follows.

The user can pull ear-tips away from the eartube to remove the ear-tips, as follows.

The user can push ear-tip firmly onto eartube to apply new ear-tips, as follows.

7.4 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 follows.

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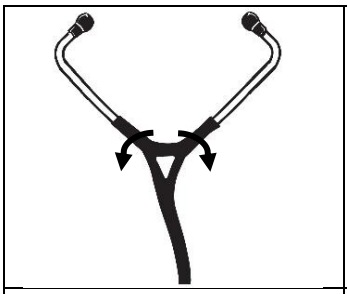
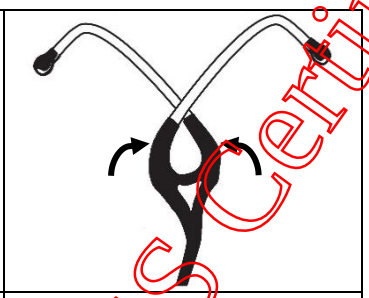
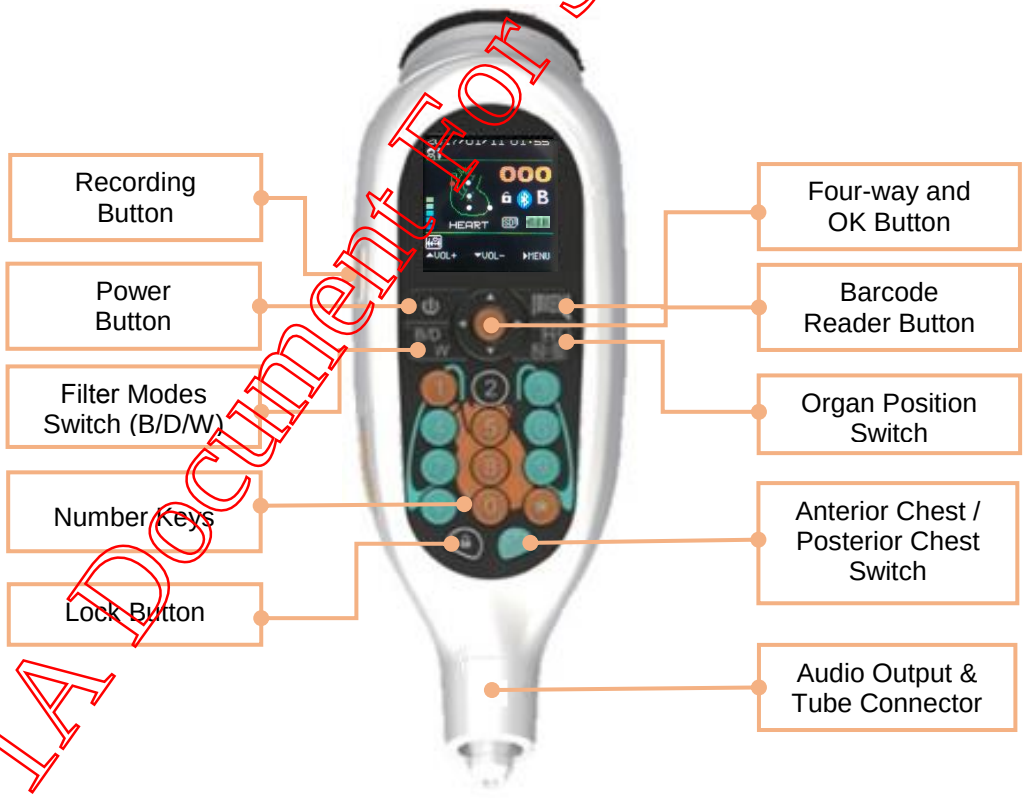
	
Reduce Tension	Increase Tension

7.5 Function Buttons



	Power Button To turn on the device or enter the sleep mode.
	Recording Button During auscultation (in the HOME page), press recording button to record auscultation sounds of 10 seconds.
	Filter Modes Switch

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	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.
	Number Keys During auscultation (in the HOME page), the “Number” keys on the intuitive keypad illustrated with heart and lung are used to choose the auscultation position. For “DATE SET” page, Number keys are used to set the date and time.
	Lock Button (Lock/Unlock Switch) During auscultation (in the HOME page), the “Lock” button is used to “lock” most of the function keys, besides Recording Button. When pressing the button again, you will “unlock” the locked status.
	Four-way Button and OK Button (Red key) ● The “Four-way” button 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” can move the indicator upward and downward. ● The “OK” button(Red key) is to set and confirm the selection item
	Barcode Reader Button For one-dimensional barcode scanning.
	Organ Position Switch The “Organ Position Switch” is used to change the organ positions among “Heart and Lung”, “Neck”, and “Bowel”.
	A/P CHEST Image Switch (Anterior and Posterior Chest) A/P CHEST Image Switch is used to change the organ images between “Anterior Chest” and “Posterior Chest”.

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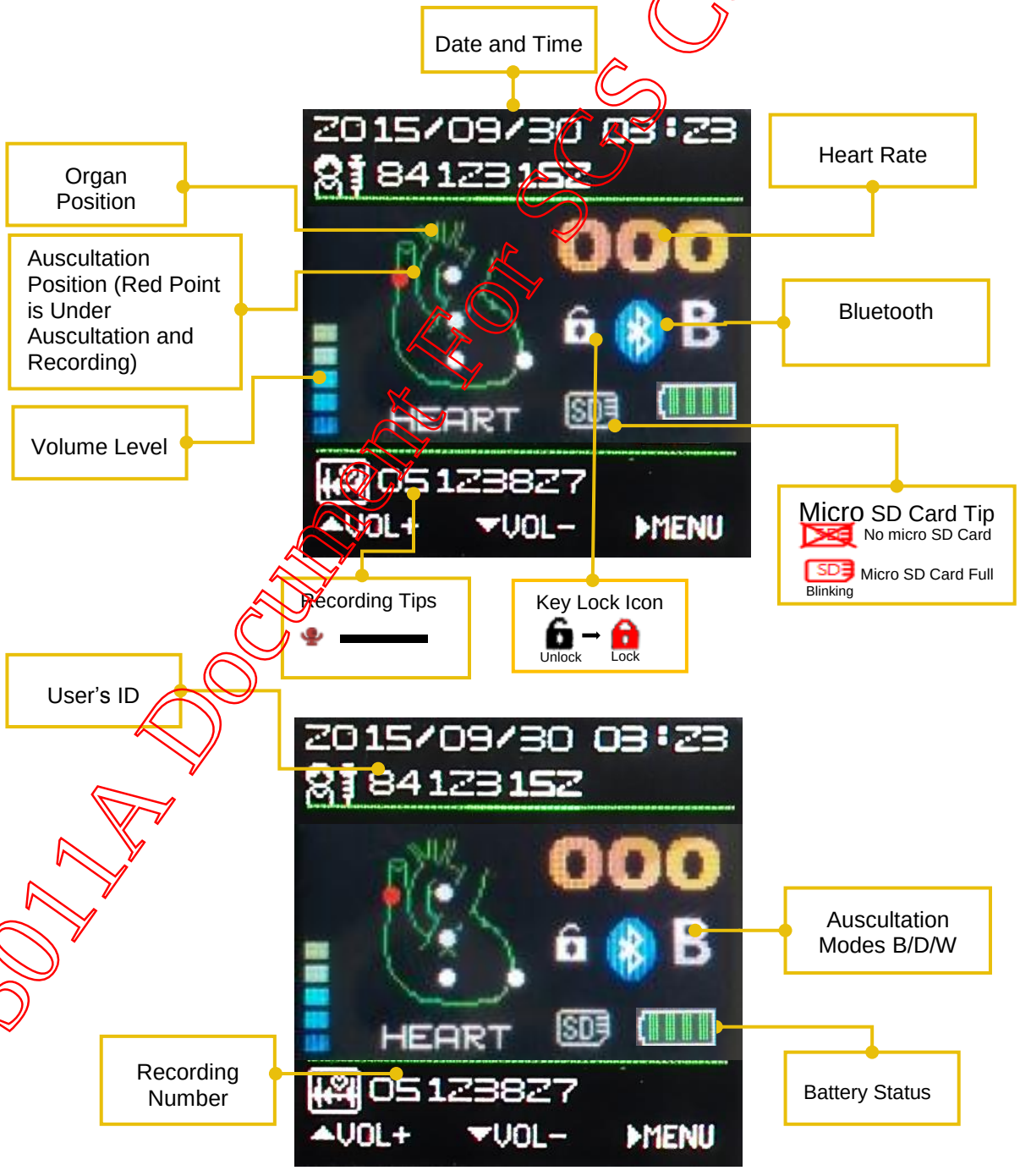
7.6 OLED display shows information



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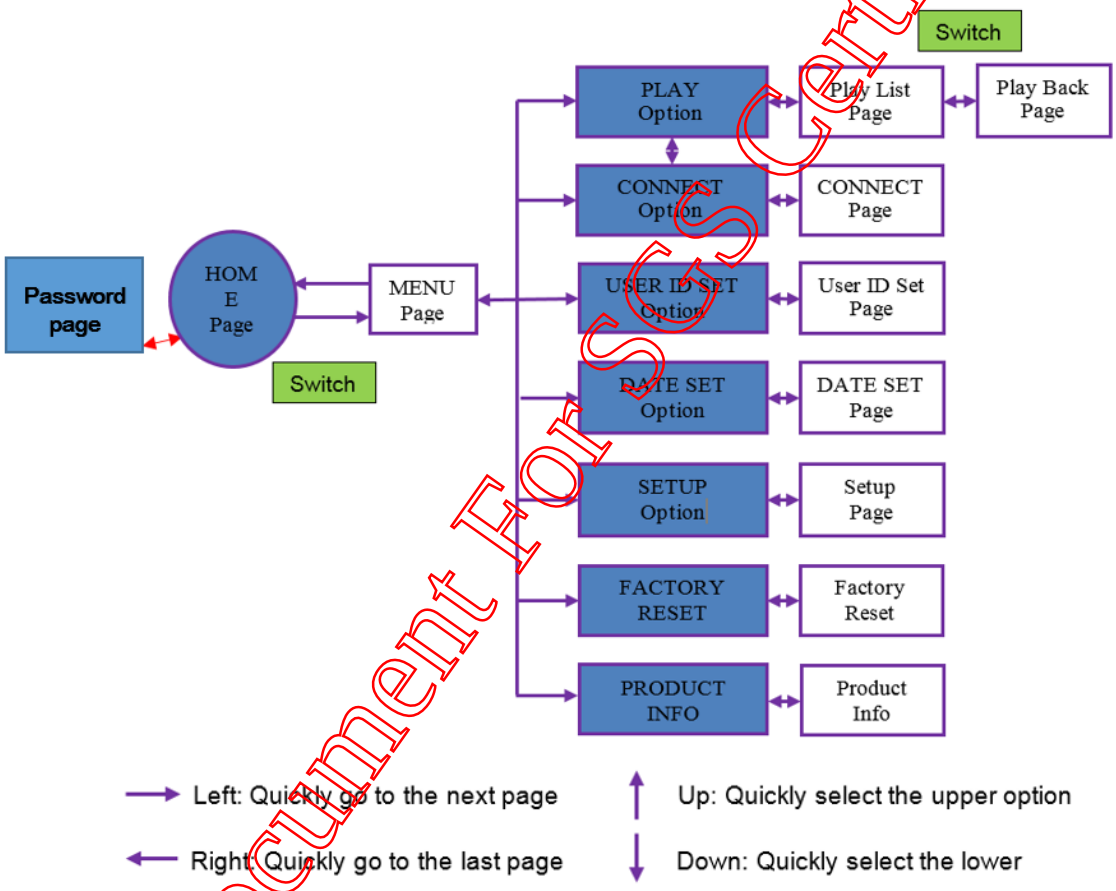
7.7 Schematic of Menu Page



7.8 Operation Description

➢ Power Button (Switch On / Sleep Mode)

- Press the “Power Button” continuously for 3 seconds to turn on the device or enter the sleep mode.
- The device will automatically enter sleep mode after idling for 5 minutes.
- The idle time can be defined by the user on the “Setup Page”. (Reference to the functions of this user manual.)

➢ Password Setting

- When turn on the device, enter the password to log in to the device application. The default password for use is “000000”.
- Create a personal secure 6-digit password by selecting “SETUP” option.

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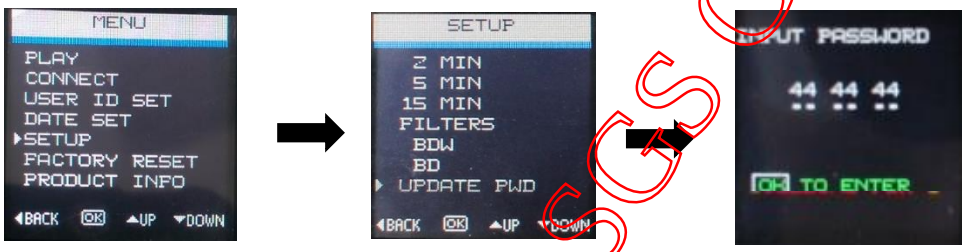
Navigate to the UPDATE PWD screen after selecting the "SETUP" option.

- Next, select "UPDATE PWD" > INPUT PASSWORD. Follow the instructions on the screen to create and save a 6 -digit password. You will need to enter your PIN twice for verification purposes.



➢ Detection of The Patient's Heart Rate

- Place the stethoscope close to the patient's heart sound positions. Within 10 seconds, the screen will display the patient's heart rate and the data will be updated every two seconds. The heart rate ranges from 30 bpm (beat per minute) to 180 bpm (beat per minute). When taking the stethoscope away from the patient, the heart rate will display 000 within 5 seconds.

IMPORTANT!

If the ambient sound is too noisy or the measuring position is incorrect, inaccurate heart rate may happen.

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

➢ Organ Position

- Using function keys to select the organ position.
- Using number keys to select the auscultation position under auscultation and recoding.
- Red point is the auscultation position under auscultation and recording (Indicated position)
- Every single audio file stored in micro SD card was labeled with the indicated position.

✧ Organ position switch among "Heart/Lung", "Neck", and "Bowel"

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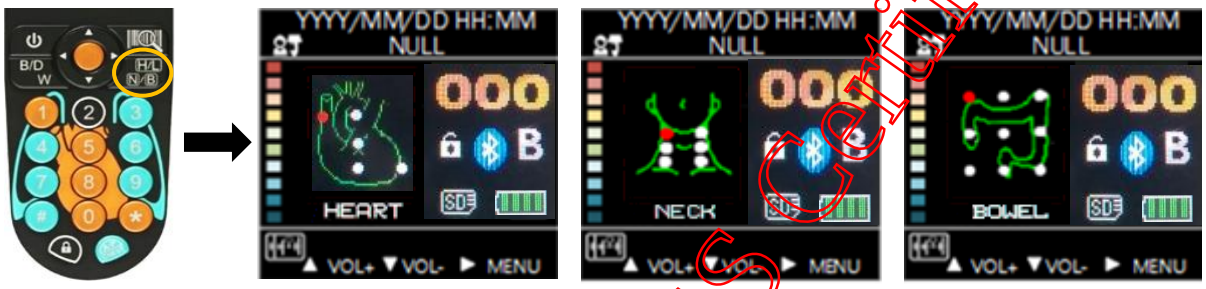
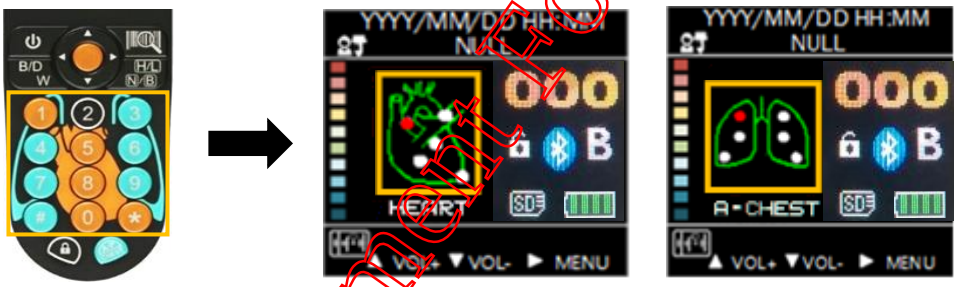


Organ Position Switch H/L N/B is used to change the organ position among “Heart and Lung”, “Neck”, and “Bowel”.

✧ **Using the “Heart /Lung” organ position, it could be quickly switched between “Heart” and “Anterior Chest” for the selection of organ position.**



Press the key with image of “Heart” or “Anterior Chest” on the keypad to switch and select organ position

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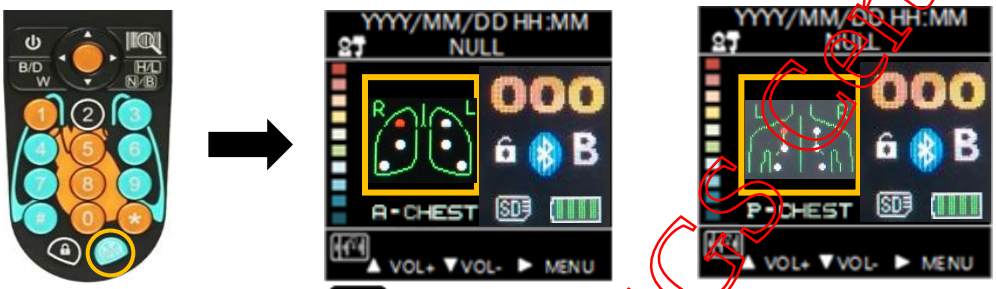
✧ Organ position switch between “Anterior Chest” and “Posterior Chest”



Press the function button A/P CHEST to switch the position to “Anterior Chest” or “Posterior Chest”.
When you pick up the sound of right upper lung filed at the front, you shall select the “Anterior Chest” area and then press the number key “4” which stands for “RUL(Right Upper Lobe) illustrated on the intuitive keypad.
When you pick up the sound of left upper lung filed at the back, you shall select the “Posterior Chest” area and then press the number key “4” which stands for “LUL(Left Upper Lobe) illustrated on the intuitive keypad.

➢ Filter Mode Selection (B/D/W Modes)

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.

- Using the “Bell” mode, the sound frequency below 390 Hz is amplified, and the sound frequency from 20 to 200 Hz is emphasized.
- Using the “Diaphragm” mode, the sound frequency below 630 Hz is amplified, and the sound frequency from 100 to 500 Hz is emphasized.
- Using the “Wide” mode, the sound frequency below 1000 Hz is amplified.

Bell Mode Diaphragm Mode Wide Mode

Press function button B/D W to select the filter mode.
The “B” mode, “D” mode, and “W” mode will cycle in turn when you press this button.

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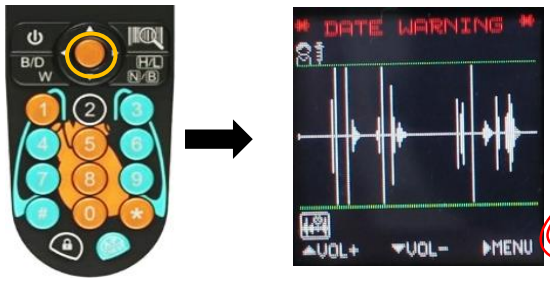
➢ Real-time monitoring sound wave

The stethoscope can show the sound wave on screen during hearing the sound in different mode.

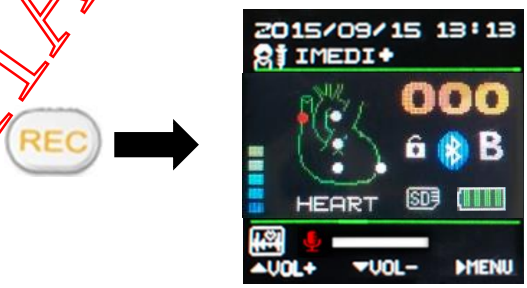


To switch the mode to show the sound wave, press the “OK” button while listening the sound.

➢ Recording the Auscultation Sound

While recording the auscultation sound, every single audio file of the sound track stored in the micro SD card will be labelled with recording number (Identity), user’s ID (Identity), and indicated position. The user could also exchange audio data with an external personal computing device using the micro SD card (Maximum to 600, 10-second sound tracks)

- Press the Recording Button to record the auscultation sound for 10 seconds after selecting the auscultation position with recording number and user’s ID.
- The recorded auscultation sound track will be saved in the micro SD card which can store up to 600 sound tracks. Don’t remove the micro SD card during recording.



10 sec Recording

Press function button REC to record the auscultation sounds.

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➢ Playing Back a Sound Track

When you enter the “MENU” page, selecting “PLAY” will help you enter the “PLAY LIST” page.

- Press the Right Button to enter the “MENU” page and then press “OK” Button to enter the “PLAY LIST” page.
- “PLAY LIST” provides the latest 50 sound tracks with auscultation position.
- Press the “Up” or “Down” button to select the sound track which you want to play back. Then press the “OK” button to play the one you select.
- The sound track you select could be transferred to the user’s ears via an active speaker and passive sound tubes. The sound track will loop continuously and demonstrate on the screen.
- While listening the sound track, the sound can be listened in different filter mode by pressing the B/D button.
- Press the “Left” button to stop playing the sound track and return to the “PLAY LIST” page.

MENU Page PLAY LIST page Playback Page

Press the “Right” button to enter the “MENU” page.
Press the “OK” button to enter the “PLAYLIST” page.
The sound track you select will loop continuously and demonstrate on the screen when you enter the “PLAYBACK” page.

➢ Adjust Sound Amplification Level

The IMEDIPLUS Electronic Stethoscope DS3011A sound level could be amplified in 10 increments up to 24X amplification of a non-electronic (Cardiology-level) stethoscope. Level 0 is equal to silent mode. Level 10 is equal to 24X amplification of a non-electronic stethoscope. The greater the amplification, the more bars you will see on the screen.

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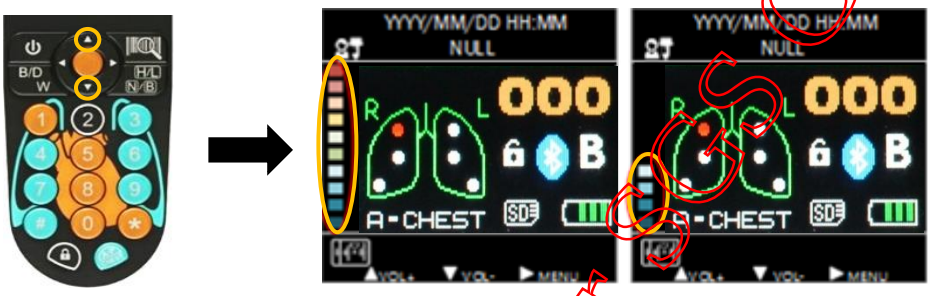
- Press the “UP” button to increase the volume level until the desired level is achieved.
- Press the “Down” button to decrease volume level until the desired level is achieved.



Volume +　　Volume -

Press the “UP” and “DOWN” button to adjust sound amplification level.
The greater the amplification, the more bars you will see on the screen.

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➢ Lock /Unlock

- Press the “Lock” Button to lock or unlock keypad to avoid inadvertently touching other keys during auscultation.
- When the keypad is locked, only the “Recording Button” can be used.

Unlocked Locked

Press function button to lock or unlock keypad.

➢ Press the “Barcode Reader” button to set the user’s ID (Identity) and recording number (Identity)

Setting the user’s ID and recording number before you select the auscultation position and pick up the sound for clinical auscultation. Every single audio file of sound track will be labelled with the recording number, user’s ID, and auscultation position for digital sound track database storage and build-up. It will be helpful to follow up your patient with valid auscultation records with lots of correlated clinical evidence for advanced study and personalized care. After your successful setting, both of the user’s ID and recording number will show on the “Home” page as following illustration.

✧ Setting the recording number

- On the “HOME” page, press the “Barcode Reader” button could identify the recording number. After your setting, the recording number will show in the screen as follows.

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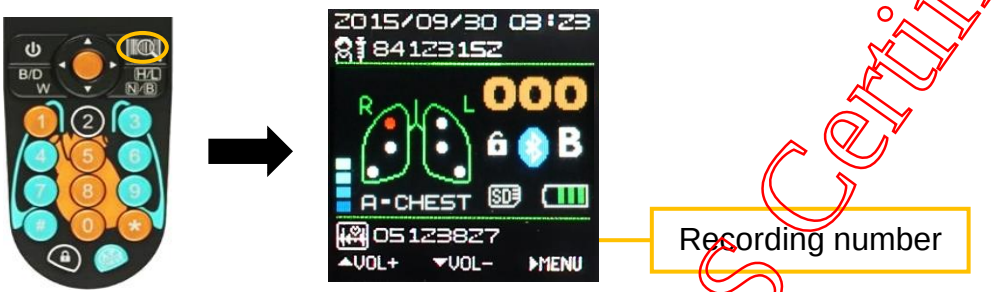


Press the "Barcode Reader" button to identify the recording number.

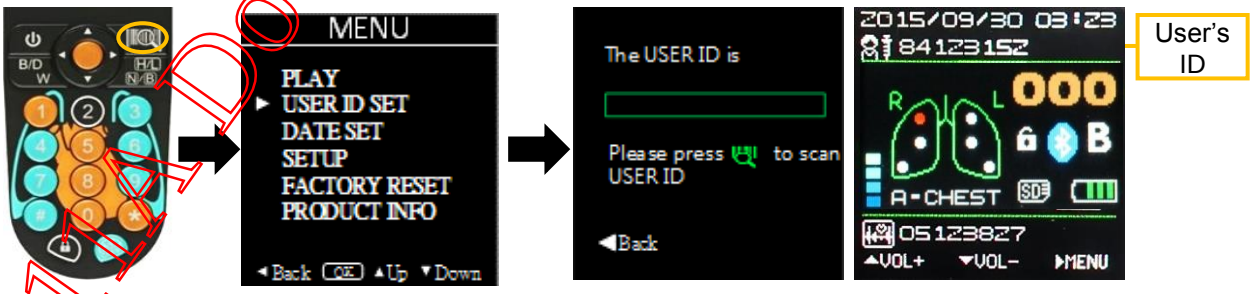
⚠WARNING: Looking at the beam light of barcode reader is prohibited to avoid damage to your eyes.

IMPORTANT!

- The recording number is the series number of clinic or hospital, it did not include any patient's personal information.

✧ **Setting the user's ID**

We could set the user's ID after going to the "MENU" page and please select "USER ID SET" to go to the "USER ID SET" Page. You can use Barcode reader to set the user's ID. After your setting, the user's ID will show in the screen as follows.



Select USER ID

Press the "Barcode Reader" button to read and set the "User's ID" for the following auscultation.

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⚠WARNING: Looking at the beam light of barcode reader is prohibited to avoid damage to the eyes.

IMPORTANT!

- The 1D (one dimensional) barcode reader can only read the 1D (one dimensional) barcode.
- The barcode of the subject should be placed within the effective range of the red light emitted from the barcode reader.
- Continuously reading the barcode of the subject may lead to failure. An interval of two seconds between one scan to the next scan is recommended.
- Symbologies: 1D (one dimensional) barcode types, such as Code128, UCC/EAN 128, Code 39, UPCA, UPCE, EAN8, EAN13, Codabar, Plessey, Code 93 and ISSN etc. can be support.

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➢ Setting Date and Time

- On the “DATE SET” page, using the number keys to set the current date and time is very significant. We will label the audio file with the date and time for storage and database build-up.

Select DATE SET DATE SET page

Press the “Right” button to enter the “MENU” page.
Use the “Down” and “Up” button to control the indicator. When selecting the “Date SET” item, press the “OK” Button to enter DATE SET page.
Use the “Four-Way” button to control the indictor with number keys for setting the date and time and then press the “OK” button to save your setting.

➢ Set The Idle Time-Out before DS3011A Goes To Sleep Under the SLEEPING MODE In the SETUP Page. Set The Filter Option Group for the “BDW Switch” or the “BD Switch”.

SLEEPING MODE: To avoid the possibility of the user forgetting to turn off the DS3011A or leaving it exposed to unauthorized personnel, the user can set an idle time-out that will automatically make the DS3011A go to sleep if the DS3011A is not used for a specified amount of time, including “2 MIN (2 minutes)”. “5 MIN (5 minutes)”, and “15 MIN (15 minutes)”.

FILTER Option Group: There are two filter option group. One group is “BDW” Switch, the other one group is “BD” Switch. Under the “BDW” switch group, the “B” mode filter, “D” mode filter, and “W” mode filter will cycle in turn as you press the “B/D/W Mode Switch” button. Under the “BD” switch, the “B” mode filter and the “D” mode filter will cycle in turn as you press the “B/D/W Mode Switch” button.

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Press the “Right” button to enter the “MENU” page.

Select “SETUP” in the “MENU” page to enter the “SETUP” page.

Set up “SLEEP MODE” and “FILTER” group in the “SETUP” page.

➢ Reset To Factory Setting

The stethoscope can be reset to factory setting by using “FACTORY RESET”. After entrance the “FACTORY RESET” page, you can select to restore the factory setting if you select “YES” and press the “OK” button. This function can help you default the unexpected condition and reset to factory setting.

Press the “Right” button to go to the “MENU” page.

Using the “Up” and “Down” buttons to move the indicator to “FACTORY RESET” and press the “OK” button to go to the “FACTORY RESET” page.

If you do need to restore to factory setting, you can select “YES” to reset. If not, you can select “NO” and go back to the “HOME” page

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Factory Default Setting Table

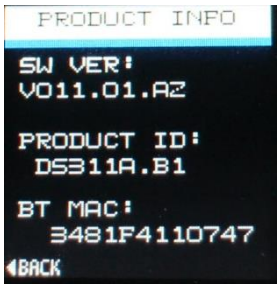
Parameters	Default
Idle time of “Sleeping Mode” before going to sleep	5MIN (5 minutes)
Filter mode group	“BDW” group
Auscultation organ position	HEART
Filter Mode	B Mode
Amplification level	Level 5
Recording number	Empty
User ID	NULL

➢ Product Information

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

Press the “Right” button to go to the “MENU” page.

Select “PRODUCT INFO” to go to the “PRODUCT INFO” page



The “PRODUCT INFO” page will show the software version, product ID and Bluetooth Media Access Control Address on the page.

➢ Connection

First, enable Bluetooth on the selected mobile device. On the Android device go to Settings > Bluetooth > and tap the slider to turn Bluetooth ON.

Then, navigate to the Menu screen by clicking on the top right tab “Connect” in the App. Navigate to Bluetooth menu, select the SSID (Bluetooth Media Access Control Address) and pair with the device.

The mobile device is now ready to record sounds from the DS3011A. If Bluetooth pairing is unsuccessful, the Bluetooth mark will flash on the OLED

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screen of DS3011A and no sounds will be recorded. If the Bluetooth connection is successful the mark will keep in bright blue of the device.

➢ System requirement

The mobile app software can be used on ASUS ZenPad10 with Android™ 6.0 and greater than 30MB of free memory.

DS3011A uses Bluetooth Class 2; mobile devices used must be compatible with Bluetooth Class 2.

*ZenPad10 are registered trademarks of ASUS, Inc.

*Bluetooth is a registered trademark of Bluetooth SIG, Inc.

➢ Using The Micro SD Card To Transfer Audio Files To An External Device

Removing the micro SD card from the electronic stethoscope can transfer auscultation sound tracks of audio files to an external device.

IMPORTANT!

- Please turn off the system before removing the micro SD card.
- Please do not delete the built-in files in the micro SD card arbitrarily.
- Having a backup of your DS3011A is helpful. When the SD card is full capacity, you need to take a copy of your SD card to an external computing device and then empty the SD card for the coming storage of audio files.
- For the stability of the operation, please backup and empty the micro SD card periodically as regular maintenance.
- In addition to audio files, do not store any other files in order to avoid unnecessary interference.

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➢ Battery Power Indication

Battery life is indicated by an icon in the screen. IMEDIPLUS Electronic Stethoscope DS3011A has a rechargeable 2300mAh NP-120 lithium-ion battery provides approximate 24 hours of continuous use. The battery power loss and the use of barcode reader are highly correlated. As the battery power decreases, the icon will change as follows:

	80~100% Battery Power
	60~80% Battery Power
	40~60% Battery Power
	15~40% Battery Power
	0~15% Low Battery Power

When the battery power is running out, the screen will display the “0~15% Low Battery Power” located on the right lower area of the screen to remind the user about the current state of the battery power. When the “0~15% Low Battery Power” displays in the screen, the user should replace the battery or charge the battery as soon as possible.

IMPORTANT!

- When the battery is completely no battery power, the IMEDIPLUS Electronic Stethoscope DS3011A will automatically turn off. All the recorded sound tracks and the settings of the DS3011A will be saved before it turns off.

➢ Charge the Battery

Taking out the Battery from the electronic stethoscope and using the battery charger, which is one of the DS3011A accessories, to charge the battery.

- Putting the adaptor plug into the battery charger, the charging indicator will display green.
- When the battery is placed in the charger, the charger will begin to charge the battery
- The charging indicator will display the charging states. Under charging states, the indicator will display red. When the battery is fully charged, the screen will show a green light.

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⚠WARNING: Do not use the unauthorized battery and charger to prevent unexpected hazards

IMPORTANT!

- Please turn off the system before taking out the battery.
- Make sure the battery is placed correctly on the battery charger before charging the battery.

➢ 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 IMEDIPLUS Electronic Stethoscope DS3011A. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the IMEDIPLUS Electronic Stethoscope DS3011A, do not attempt to repair it yourself. Please notify our customer service center for directions on shipping and receiving.

8. PhonoMagics Use

➢ Installation for Android system

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

➢ Logging in

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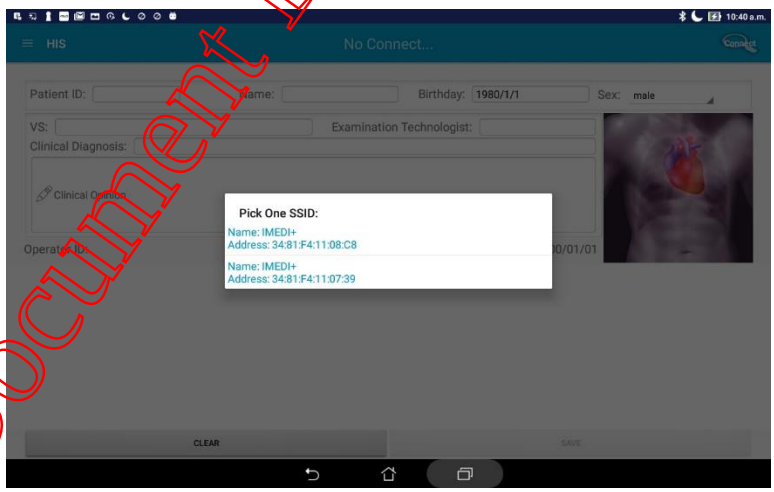
Open the PhonoMagics on the mobile device. When prompted, enter your existing password. The password is “000000” for factory setting.

➢ Bluetooth Pairing

Bluetooth must be enabled in the tablet’s Bluetooth settings in order to use Core with the PhonoMagics.

First, enable Bluetooth on the selected mobile device. On the Android device go to Settings > Bluetooth > and tap the slider to turn Bluetooth ON.

Then, open the PhonoMagics and navigate to the PhonoMagics menu screen by clicking on the top right tab “Connect” on the home screen. Navigate to Bluetooth menu, select the SSID (Bluetooth Media Access Control Address) and pair with the device.



The mobile device is now ready to record sounds from the DS3011A. If Bluetooth pairing is unsuccessful, the Bluetooth mark will flash on the OLED screen of DS3011A and no sounds will be recorded. If the Bluetooth connection is successful the mark will keep in bright blue of the device.

➢ Setting up a Password

Create a secure 6-digit password by logging in to the application. Navigate to the Menu screen by selecting the icon on the top left of the Pad App home screen.

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Next, select Change Password. Follow the instructions on the screen to create and save a 6 -digit password. You will need to enter your original password and new password twice for verification purposes.

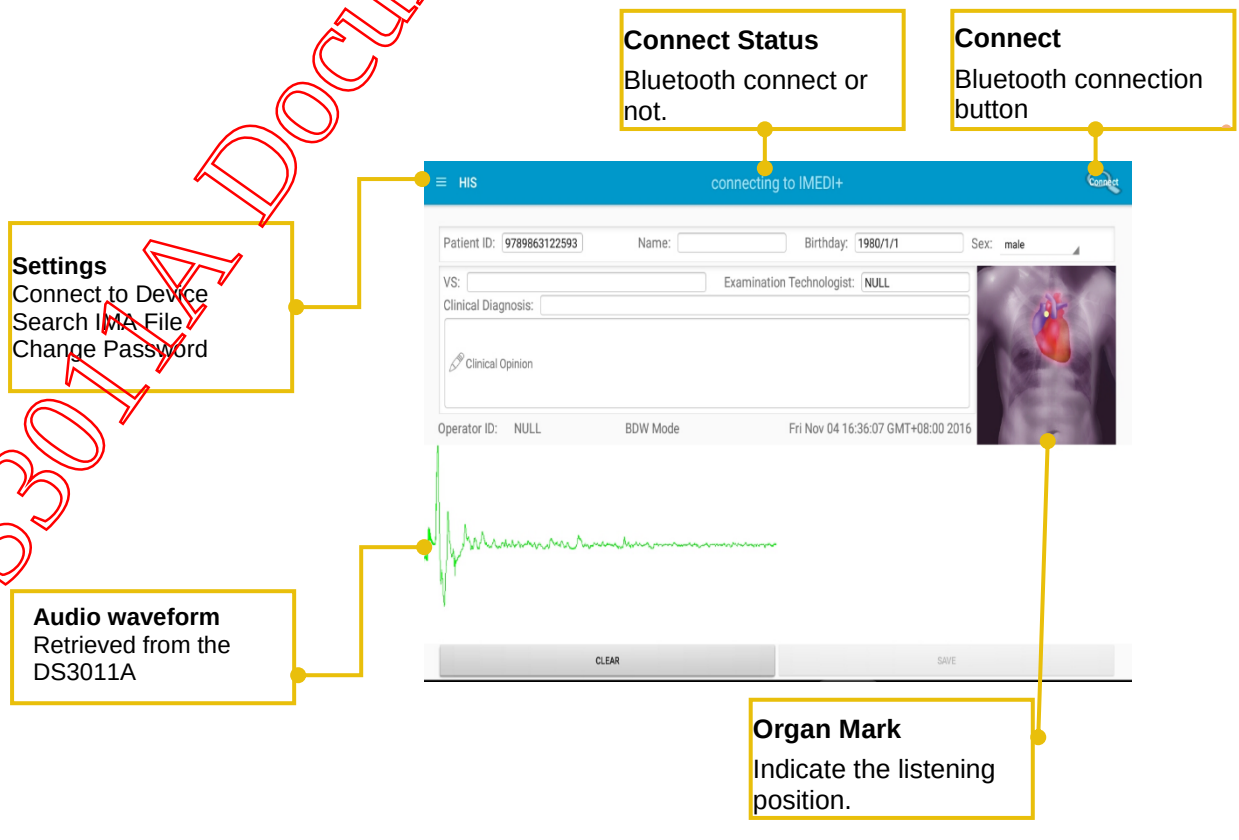
➢ **Capture & Save Recordings using the Android App**

Open the PhonoMagics and log in. Ensure that the DS3011A Device is paired to the pad device (See Section 8).

In the home screen, use DS3011A and press Recording Button to being recording. The recording process will last 10 seconds. Once it is finished, the recording process will stop automatically. When recording is finished, the home screen will appear another windows to select to save the recording or not.

8.1 Main Recording Screen

The Main Recording Screen allows users to view audio data captured by DS3011A, 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.



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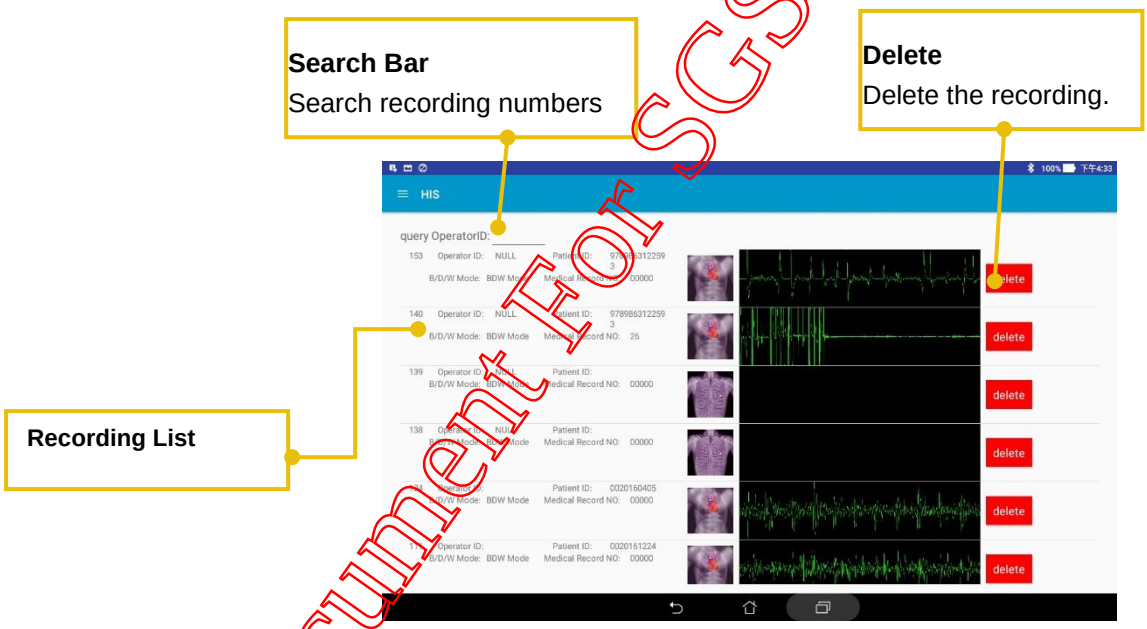
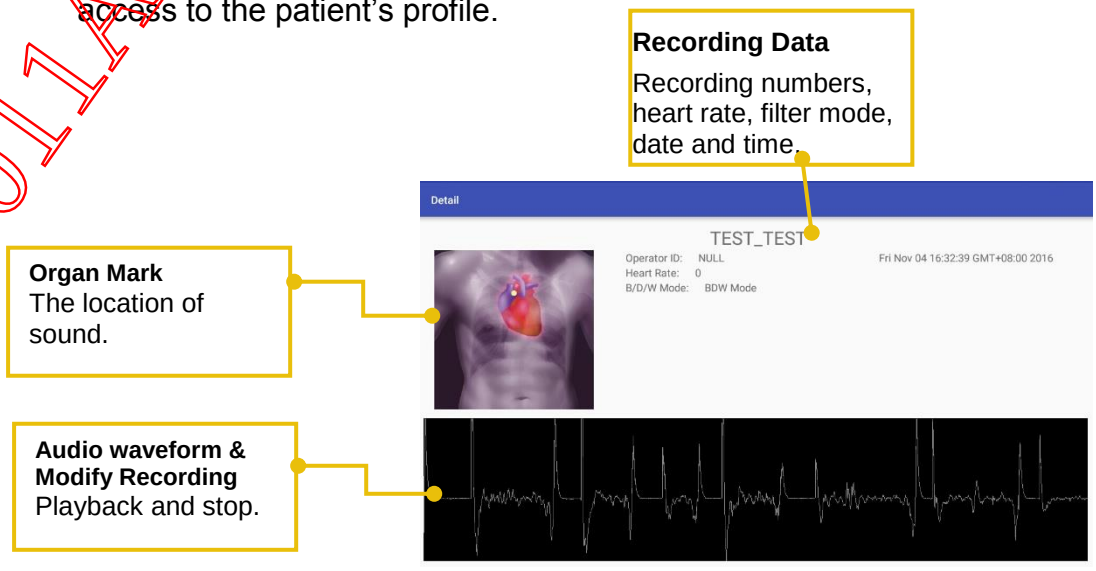
8.2 Profile Screen

Selecting the Search IMA File icon on the main screen brings up the recording list and search bar. From this page, users may access previously assigned recordings or add a new recording to the patient's record history.



8.3 Review Screen

More information on a specific recording can be viewed by tapping on a recording listing. This screen displays a waveform of the recording, options to playback the sound, and notes. Notes may be added by any user with access to the patient's profile.



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IMPORTANT!

The audio quality of the sounds play through the pad speaker or audio jack may not performed actual sounds quality, to hearing the best sounds quality, it is highly recommended that a DS3011A eartube is used to listen to the record sounds.

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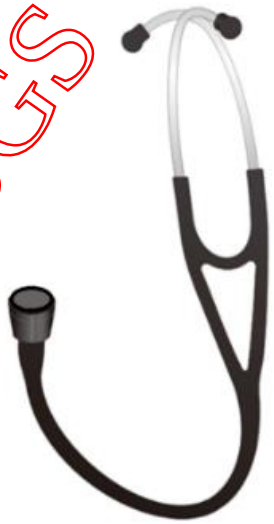
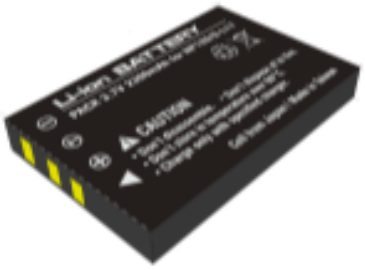
9. Assembly Parts List

1. DS3011A Device: It consists of chest-piece with diaphragm, screen, intuitive keypad and eartube connector of audio output.	2. DS3011A Headset: Including eartube , connector, and ear-tips
	
3. Micro SD Card	4. Rechargeable Lithium-ion Battery: NP-120 2300mAh
	

5. Battery Charger: Including Adaptor and Charger.

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⚠WARNING: Do not use the unauthorized accessories which would lead to unexpected hazards. All accessories only from IMEDIPLUS provided could be used. For more information, please refer to "Accessory Information section".

10. Accessory Information

The following items can be purchased as a replacement for your device. Please contact our distributors or authorized service centers for inquiries.

Part no	Part Name	Q'ty
B002011100002	Power adaptor	1 SET
B002011101003	Battery Charger	1 SET
B002028000002	Adaptor cable	1 EA
A014063001026	Sanyo Li-ion Battery UF553450Z 1S2P 3.7V 2300mAh, Model:UF553450Z	1 SET
B002032008001	SD Card	1 SET
F0002005A1S00	Headset	1 SET
B051052301016	DS301-SILICONE- Diaphragm	1 EA

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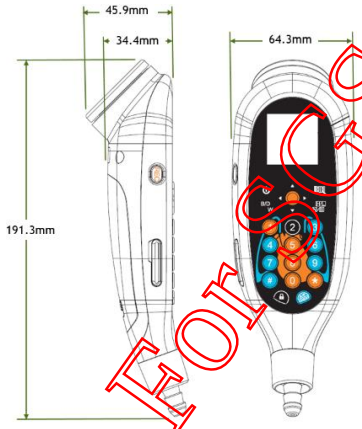
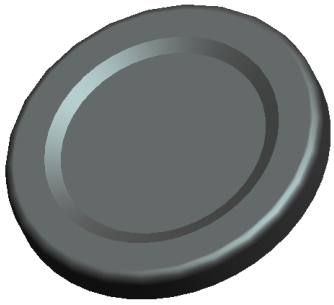
11. Mechanical Dimension

Item	Description	Outline	Dimensions (mm)			Net weight
			L	W	H	
1	Device		191.3	64.3	45.9	304
2	Rechargeable Lithium-ion Battery		53.5	35.5	11.5	55
3	Headset		660	135	25	107
4	Diaphragm		Φ 44		5	3

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12. Cleaning

Cleaning of stethoscope should be done between each patient use.

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

✧ **Cleaning the Chest-piece**

Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can be cleaned by using an alcohol wipe. If necessary, please remove the diaphragm, carefully follow the instructions mentioned bellow.

- **Diaphragm Removal:** With the diaphragm sided up, using a thumbnail to lift the underside portion of the diaphragm out of its designated groove, and peel off the chest-piece. The groove that holds the diaphragm in place can be cleaned by sliding the edge of an alcohol swab around the groove. All parts of the chest-piece can be wiped down with alcohol.
- **Diaphragm Reassembly:** Once the diaphragm is completely dry, insert the diaphragm into the groove of the rim, starting at one point, and run your finger around the diaphragm until it is seated back in the groove.

✧ **Cleaning Other Parts of the Stethoscope**

Ear-tips, eartube and chest-piece can be wiped clean with alcohol. Ear-tips may be removed for the advanced cleaning and disinfection.

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

13. Warranty

Your IMEDIPLUS Electronic Stethoscope DS3011A is warranted against any defects in material and manufacture for a period of a 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 IMEDIPLUS, except in cases of obvious abuse or accidental damage.

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14. 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 “micro SD card read error” , after “Turn ON”	Check the micro SD card is properly installed or damaged. If fails after you’re trying, please call local service for help.
6.	The screen displays “micro SD card read” blinkingly.	The micro SD card could save the maximum amount of 600 auscultation sound tracks. Please remove the micro SD card, and empty the micro SD card after backup the sound tracks. The system will work normally after insert the micro SD card into the device again.
7.	When the stethoscope is operating, the system will shut down automatically if you remove or insert the micro SD card.	In order to protect the data in the micro SD card, the stethoscope will go to sleep mode automatically when you remove or insert the micro SD card.
8.	The screen displays “FILE CHK ERR”, when the system entered PLAYBACK page.	The system can check the integrity of sound file. If the file format is incorrect, please take-out the micro SD card and format it.
9.	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”

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		(setting date section 6-8) to set date.

Item	Questions	Answer
10.	The screen displays “ILLEGAL DATE” when you set the date.	Please make sure the date is legal.
11.	After the barcode reader scanning, the screen displays empty or “Invalid symbol”.	Please make sure that the subject’s barcode is placed within the range of the red light of the barcode reader. Don’t move the barcode when you are scanning. Please make sure that the barcode messages don’t have anyone of the symbols: ", *, /, :, ?, <, >, \ and |.
12.	The screen displays “KEY Scanning Err” when you press the keypad.	Please reinsert the battery, and then make sure the error message disappears.
13.	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.

15. Maintenance and Repair

For maintenance or repair Services, please register your name, physical address, e-mail address, and phone number with your IMEDIPLUS Electronic Stethoscope DS3011A.

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

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If you have any questions or comments, please feel free to contact IMEDIPLUS 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
http://www.imediplus.com

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

IMEDI PLUS 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

16. 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 IMEDIPLUS Electronic Stethoscope DS3011A 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 DS3011A and follow the local regulations. The Lithium-ion 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 Lithium-ion battery must be disposed of separately or recycled from regular waste.

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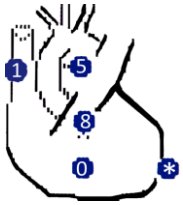
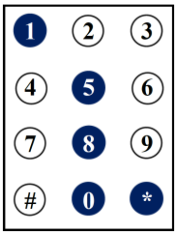
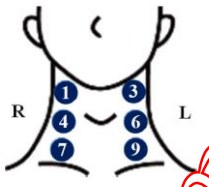
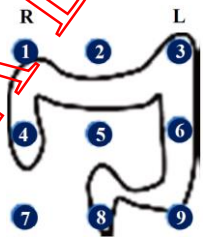
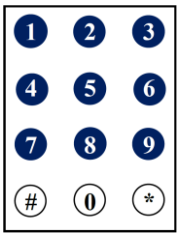
17. Organ Positions Correspond to Recorded File Name

Organ	Organ and Auscultation Position Indication		Corresponding Recorded File Name		File Name Descriptions
			Numeric Key	Saved Name	
HEART			1	##A	HEART ##A→Aortic； ##P→Pulmonic； #SA→Second Aortic； ##T→Tricuspid； ##M→Mitral
			5	##P	
			8	#SA	
			0	##T	
			*	##M	
NECK			1	RUN	NECK 1. The first character R/L means Right/Left; M means Middle. 2. The second character U/L means Upper/Lower; M means Middle. 3. The third character abbreviation “N” correspond to NECK organ.
			4	RMN	
			7	RLN	
			3	LUN	
			6	LMN	
			9	LLN	
BOWEL			1	RUB	BOWEL 1. The first character R/L means Right/Left; M means Middle. 2. The second character U/L means Upper/Lower; M means Middle. 3. The third character abbreviation “B” correspond to BOWEL organ.
			2	MUB	
			3	LUB	
			4	RMB	
			5	MMB	
			6	LMB	
			7	RLB	
			8	MLB	
			9	LLB	

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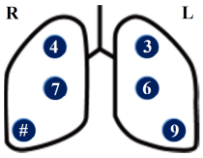
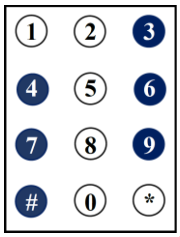
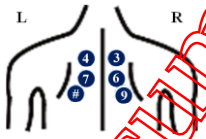
Organ	Organ and Auscultation Position Indication		Corresponding Recorded File Name		File Name Descriptions
			Numeric Key	Saved Name	
A-CHEST (Anterior-CHEST)			4	RUA	A-CHEST 1. The first character R/L means Right/Left; M means Middle. 2. The second character U/L means Upper/Lower; M means Middle. 3. The third character abbreviation “A” correspond to A-CHEST organ
			7	RMA	
			#	RLA	
			3	LUA	
			6	LMA	
			9	LLA	
P-CHEST (Posterior -CHEST)			4	LUP	P-CHEST 1. The first character R/L means Right/Left; M means Middle. 2. The second character U/L means Upper/Lower; M means Middle. 3. The third character abbreviation “P” correspond to P-CHEST organ.
			7	LMP	
			#	LLP	
			3	RUP	
			6	RMP	
			9	RLP	

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18. Appendix: Guidance and Manufacturer's Declaration

Declaration – Electromagnetic Emissions		
The IMEDIPLUS Electronic Stethoscope DS3011A is intended for use in the electromagnetic environment specified below. The customer or the user of the DS3011A should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment –guidance
RF emissions CISPR 11	Group 1	The DS3011A 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 DS3011A 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Declaration – Electromagnetic Immunity			
The IMEDIPLUS Electronic Stethoscope DS3011A is intended for use in the electromagnetic environment specified below. The customer or the user of DS3011A should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment–guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	The DS3011A power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Declaration – Electromagnetic Immunity – Continued

The IMEDIPLUS Electronic Stethoscope DS3011A is intended for use in the electromagnetic environment specified below. The customer or the user of DS3011A should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment–guidance
Voltage dips, short interruptions and voltage variations on power supply lines IEC61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle < 5% UT (>95% dip in UT) for 5 sec	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle < 5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DS3011A requires continued operation during power mains interruptions, it is recommended that the DS3011A be powered from an uninterruptible power supply or a battery.
NOTE UT is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the DS3011A, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d= 1,2 $\sqrt{P}$ d = 1,2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2,3 $\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the

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			transmitter in watts (W) according to the

Declaration – Electromagnetic Immunity – Continued

The IMEDIPLUS Electronic Stethoscope DS3011A is intended for use in the electromagnetic environment specified below. The customer or the user of DS3011A should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment–guidance
			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:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 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 DS3011A is used exceeds the applicable RF compliance level above, the DS3011A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DS3011A.

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

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Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the IMEDIPLUS Electronic Stethoscope DS3011A

The DS3011A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DS3011A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DS3011A as recommended below, according to the maximum output of the communications equipment.

Rated maximum output power of transmitter, P [W]	**Separation distance according to frequency of transmitters, d [m]**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠WARNING: To reduce the risks associated with the strong electromagnetic fields, we shall avoid using the electronic stethoscope near the strong radio frequency signals or portable and/or mobile RF devices. The electronic stethoscope might be damaged, if you hear sudden or unexpected sounds. Please immediately move away from any radio transmitting antennas to protect from damage.

19. EMC Compliance

FCC Intentional Radiator Certification

iMED+ / CaRDIaRT Electronic Stethoscope Model DS3011A

FCC ID: 2AM7NDS3011A

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

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interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

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.

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.

Industry Canada Intentional Radiator Certification

IC: 23024-DS3011A

Industry Canada Statement

This device complies with Industry Canada's licence-exempt RSSs. 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.

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Avis d'industrie Canada

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

Industry Canada Class B Emission Compliance Statement

This Class B digital apparatus complies with Canadian ICES-003.

Avis de conformite a la reglementation d'Industrie Canada.

Cet appareil numerique de la classe B est conforme a la norme NMB-003 du Canada.

Déclaration d'exposition aux radiations:

Cet équipement est conforme aux limites d'exposition aux rayonnements IC établies pour un environnement non contrôlé. Cet équipement doit être installé et utilisé avec un minimum de 20 cm de distance entre la source de rayonnement et votre corps.

NCC

根據 NCC 低功率電波輻射性電機管理辦法規定：

第十二條 經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

第十四條 低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前項合法通信，指依電信法規定作業之無線電通信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

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