

ViScope 100

USER MANUAL

CE 0197



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GERMANY**

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Congratulations and thank you for choosing the futuristic *ViScope 100* (device) - the first of its kind audio/visual auscultation device, manufactured by HD Medical Services (India) Pvt. Ltd. (HDM). *ViScope 100* brings you the following powerful features :

- Adjustable audio
- Visual display of heart's activity in real time.
Integrated chest piece for ease of use.
- Easily switchable Bell, Diaphragm and wide modes for audio.
- Distinct Visual representation of Bell and Diaphragm modes simultaneously.
- "Screen freeze" capture, save and transfer option of heart sound waveforms.
- Rechargeable Li-ion battery for continuous use.

Indications for Use

- *ViScope 100* is intended for use by trained clinicians.
- It can be used for the audio and visual output of heart sounds.
- It is intended to provide accurate detection of other body sounds while reducing environmental sounds.
- It is not intended for home use.
- It is not intended for continuous monitoring.
- It is not intended for use except as indicated.

CAUTION

GENERAL

- Go through the user manual before using the device.
- Failure to follow the directions given in this manual could result in damage to the device and/or possible injury to the user/patient.
- Failure to follow operating and maintenance instructions, listed in the manual could result in malfunction of the device.
- The device is not recommended for use in the presence of equipments producing strong electromagnetic radiation/MRI as it may affect the device functionality.
- Do not place the device over wet surfaces. Chestpiece diaphragm coming in contact with liquids will affect device functionality.
- Do not use the device on open wounds or on chest during surgeries.
- Do not allow liquids to enter into the enclosure or subject it to any sterilization processes.
- Do not use any sharp pointed tool to reset the device.

BATTERY

- ***ViScope 100*** uses custom made Li-ion battery and charger. Use of any other battery and /or charger will render the warranty void.
- Never dispose battery into fire, short the terminals or attempt to disassemble or heat the battery. Doing so could damage the battery and cause fire, injury or environmental contamination.
- Liquid leaking from battery can cause skin burns or damage to ***ViScope 100***. If battery leaks inside the instrument, return the unit to the nearest service centre.
- Remove the battery during shipment or if the device is going to be kept unused for several weeks.

Disposal of Lithium Ion Battery

For disposal of battery, follow the procedures laid down by local governing authority.

USER ASSISTANCE

If you experience any problem with *ViScope100*, do not attempt to repair it yourself.

Please notify:

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IDENTIFYING PARTS AND CONTROLS



1. LCD
2. Freeze key
3. Audio toggle key
4. Chestpiece / Diaphragm
5. Power key
6. Battery charging status indicator
7. 3 Way key
8. Reset
9. Charger connection slot (mini USB)

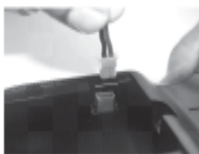
SYMBOLS	FUNCTION
	Power key to Turn the device ON/OFF
	Freeze/Unfreeze key to Freeze/Unfreeze displayed screen content
	Audio toggle key - To change the audio between bell, Dia and Wide modes
	3 way key - To increase / decrease audio/visual output
RESET	To reset the device

BATTERY INSTALLATION

Ensure that the battery is inserted into the battery compartment and has been charged for 5 hours before using the device for the first time.



Unscrew the battery compartment using suitable screw driver.



Insert the battery connector as shown in the picture.



Carefully place the battery into compartment. See that the battery leads are folded properly.



Place the battery cover as shown in the picture.



Tighten the screw.

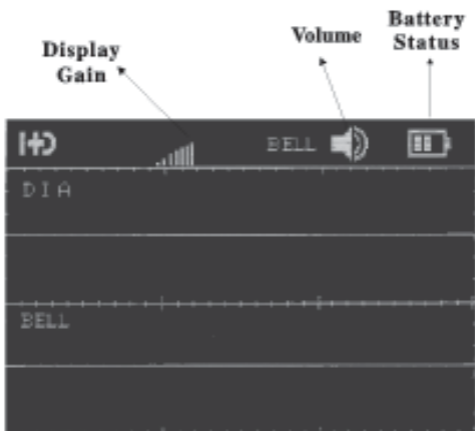















INSTRUCTION FOR USE (IFU)

ViScope100 Turn ON

1. Press and hold the power key for 3 seconds to turn *ViScope100* ON.
2. Observe that after the initial opening display, the screen shows the following icons:

Screen after Device Initialization:



Icons / Symbols	Description of Icons and Symbols
	<p>Battery charge indicator All 3 bars present – Full charge 2 bars present – Medium charge 1 bar present – Reduced Charged No bars present – Battery icon starts blinking – battery power will be available for the next 20 minutes only.</p>
	<p>Medium (default) Audio Volume</p>
	<p>Loud Audio Volume</p>
	<p>Low Audio Volume</p>
<p>BELL</p>	<p>Audio in Bell mode (All heart sounds and murmurs)</p>
<p>DIA</p>	<p>Audio in Dia mode (Lung sounds)</p>
<p>WIDE</p>	<p>Audio in Wide mode (Extended Lung sounds)</p>
	<p>Visual signal gain</p>
<p>BELL</p>	<p>Heart sound wave form processed for Bell mode frequencies</p>
<p>DIA</p>	<p>Heart sound wave form processed for Diaphragm mode frequencies</p>
	<p>Attention! Refer to the accompanying document</p>
	<p>Power Class II Internally Powered (Battery operated)</p>
	<p>Type BF Applied Part</p>
	<p>IFU - Instruction for use.</p>
	<p>Save the waveform in the device</p>
	<p>Transfer stored waveform to the PC</p>
	<p>To view the previous stored waveform</p>
	<p>To view the next stored waveform</p>

HEADSET POSITIONING



Correct

The headset of the device is specifically designed to give comfort to your ears.

The eartubes are set at an angle to fit the typical anatomy of the ear canal.



Incorrect

The position of the ear tips should be pointing towards the forward direction as you insert them into your canal.



Decrease
Tension

The tension of the spring in the headset can be reduced by holding each eartube at the bend and gradually pulling apart until fully extended.



Increase
Tension

The tension of the spring in the headset can be increased by holding the headset with one hand where the eartubes enter the plastic tubing and squeezed until the plastic tubing on one eartube touches the other.

Auscultating with *viScope 100*

1. Place the earpiece in your ears.
2. Instruct patient to assume the necessary posture for auscultating-sitting/supine/side-supine.
3. Select the appropriate audio mode, by pressing the “audio toggle” button. (By default the device is set to audio of Bell mode).
4. The BELL, DIA or WIDE appears when that particular mode is selected for audio.
5. Place the device on the patient such that the chest piece is in contact with patient’s chest at one of the four main auscultation positions. For more details on the important auscultation points, refer to page 32.
6. During auscultation, you will observe two waveforms on the display
 - Bell mode waveform (labelled as “BELL”) which displays normal heart sounds and gallops
 - Diaphragm mode waveform (Labelled as “DIA”) which displays murmurs.

Note: Minor trace of S1 & S2 appearing in “DIA” mode is normal.

7. You will also hear the heart sounds through the earpiece as you auscultate.

Note: It is a requirement that the patient should not heave heavily for 3-4 seconds during auscultation

To Adjust Audio

During auscultation, you may adjust the volume of the audio by pressing the 3 way key. Observe that when you change the volume level, the volume icon changes cyclically (Medium / Loud / Low / Medium), with every press of the key.

To Adjust Display Gain

During auscultation you may change the gain of the heart sound displayed.

1. To increase the gain, scroll the 3 way key in the direction marked by “+” symbol. The maximum gain is indicated by ten bars on the gain icon.
2. To decrease the gain, scroll the 3 way key in the direction marked by “-” symbol. The minimum gain is indicated by the single bar on the gain icon.

To Freeze / Unfreeze Display

1. Press the “Freeze/Unfreeze” key to observe the heart sound waveforms on display as a stationary trace. The contents on display are frozen and available for review.

Note: Press and hold the “freeze / unfreeze” key till you get a clear waveform and then release the key. This gives a clear stationary trace.

2. Press the “Freeze / Unfreeze” key again to unfreeze display and resume auscultation. The display reverts to free running and you may now continue to auscultate.

Note: Pressing “Freeze” when the device is connected to laptop / PC / enables recording of the patients waveform for the previous 10 seconds (software version 2.3 and above).

Even in the freeze mode of display, the audio can be heard.

Auscultating on Different Patients

To auscultate on difference patients, ensure that the display is free running, select your operating mode and place on the new patient.

To Transfer Data to PC

1. **ViScope100** provides the facility to connect the device to a PC for real time data transfer through a data transfer USB cable.
2. In order to use the data transfer facility, ensure that the PC is loaded with **ViScope100** software.

SYSTEM REQUIREMENTS FOR *ViScope100*

Recommended Operating System :

- Windows 2000 / Windows XP / Windows Vista

Ram Requirements

- Minimum 64 MB

Hard Disk

- Minimum 100 MB



3. The following features are available in **ViScope100** software
 - a) Display of real time heart sounds
 - b) Data acquisition and saving of acquired heart sounds of 10 seconds duration.
 - c) Caliper and zoom functions.
 - d) Audio replay of acquired and saved heart sounds.
 - e) Report generation.
4. For detailed information about **ViScope100** software, refer to the user guide in the CD provided along with this manual.

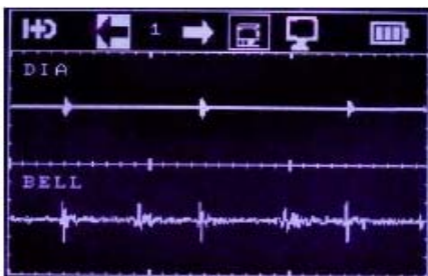
Note: The memory option feature is available only in ViScope100P

MEMORY OPTION

ViScope 100 provides the facility of saving upto 4 heart sounds heart sound waveforms during auscultation and can be transferred to the Computer.

To Store waveforms into device

1. Freeze the signal that needs to be saved.
2. The screen will appear with left arrow ←, right arrow →, save icon  transfer icon  and numbers between the arrows as shown below.



3. Number appearing between the arrows indicates the waveform getting saved.
4. Using 3 way key, scroll to the 'save icon' and to save press the 3 way key.



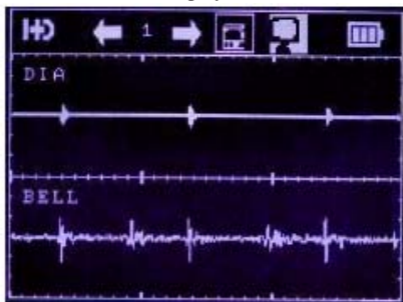
5. Unfreeze the Display.
6. Repeat the steps from 1 to 5 for saving more waveforms.

To view the saved waveforms:

1. Using “Freeze” key, freeze the display.
2. Using 3 way key select the right/left arrow.
3. The number shown between the arrows shows the memory location where the wave form is saved in device.
4. Each press of 3 way key displays the stored waveforms in the ascending / descending order if the right / left arrow is selected.
5. For going back working screen press the “Freeze” key

To transfer the waveform to a Computer.

1. By pressing the “Freeze” key, make the display freeze
2. Using the 3 way key select the **Transfer Icon** in the screen and the display will be as shown.



3. Press the 3 way key to transfer the saved heart sound waveforms to the Computer
4. Once waveforms are transferred to the Computer or Transfer icon is pressed all the saved waveforms will be erased.
5. Refer the *ViScope100* Software User guide for more details.

Battery Power Saver Features

- If there is no key press for 3 minutes (180 seconds), the display backlight turns off. To turn on the backlight again press the Power key once.
- If there is no key press for 6 minutes (360 seconds) continuously the device enters standby mode. To turn the device ON press the Power key momentarily.
- When the device is not in active use, you can turn the backlight OFF to conserve battery power, by pressing the power key once. You can re-activate the back-light by pressing the Power key once again.

Recharging Batteries

1. You may operate the device uninterrupted as long as the battery icon shows at least one bar in it. Once the icon has no bar and starts blinking, charge the device.
2. Prior to charge switch OFF the device. Insert the charger unit into the USB slot in the device and plug in the charger to the AC wall point.
3. The device takes about 4 to 5 hours to get completely charged, which can be observed by the “GREEN” glow of the battery charger indicator.

CAUTION

IT IS RECOMMENDED NOT TO USE THE DEVICE FOR AUSCULTATION, WHEN THE BATTERY IS BEING CHARGED THROUGH CHARGER. ATTEMPTING TO USE THE DEVICE AT THIS TIME MAY NOT BE SAFE.

USE ONLY HDM SUPPLIED / AUTHORIZED BATTERY CHARGERS FOR CHARGING THE BATTERY.

4. In case the battery power is completely drained, the device will turn off completely. Should this happen, charge the device as described above, and restart by pressing the Power key.

Turning the device OFF

1. Turn the device OFF by pressing and holding the Power key for 3 seconds. Device enters sleep mode.

Auscultating for other body Sounds

1. *ViScope100* can also be used for auscultating other body sounds in “DIA” or “WIDE” audio modes.
2. Place the device at the other body auscultation position, and auscultate.

CLEANING INSTRUCTION

You may be using the device on a number of patients each day. Cleaning the chestpiece and the body of the device is imperative.

Failure to clean the chestpiece diaphragm and the body of the device may cause infections or allergies on susceptible patients.

Ideally the chestpiece diaphragm may be cleaned after use on each patient, and the body of the device may be cleaned at the end of each day.

Do's

- Use only a soft clean cloth or alcohol wipe to clean the diaphragm and the device.

Dont's

- Do not immerse the device in water or any other liquid for cleaning.
- Do not subject the device to any form of sterilization.

STORAGE

1. Always store the device in a cool, dry place.
2. It is advisable to place the device on a soft surface to avoid damage to the device in general and to the chestpiece in particular.

CAUTION

**DO NOT STORE THE DEVICE IN A DAMP/
HOT PLACES. THIS CAN SPOIL THE DEVICE
AND AFFECT THE FUNCTIONALITY.**

**THE DEVICE IS NOT FLUID INGRESS
PROTECTED.**

**DO NOT STORE THE DEVICE IN PLACES
PRONE TO SPRAYING LIQUIDS. INGRESS OF
LIQUID CAN RESULT IN REDUCED DEVICE
RESPONSE AND IN ACUTE CASES CAUSE
DEVICE FAILURE AND EVEN SHOCK TO
THE USER.**

ACCESSORIES



**USE OF ACCESSORIES NOT AUTHORISED
BY HDM MAY DAMAGE THE UNIT**

1. Diaphragm (VSC060-001)

Use only HDM diaphragm with the device. Use of non-HDM diaphragms can result in faulty audio and display.

Use of damaged diaphragm can also result in faulty audio and visual display.

2. USB Cable (VSC 060-002)

Mini USB Type-B Male connector to USB 4-Pin Type A Male connector can be used to connect the device to the PC.

3. Earplugs (VSC060-003)

Use only HDM earplugs.

Use of non-HDM earplugs can result in pain in ears due to material hardness and may degrade audio.

4. Battery (VSC060-004)

Rechargeable Li-Ion 3.7V, 1800 mAh

5. Battery Charger (VSC060-005)

Input: 100-230V AC, 50/60 Hz,

Output: 5V DC, 1000 mA, medical grade charger

TECHNICAL SPECIFICATION

Display

High resolution LED backlight 240 x 160 pixels
graphical monochrome (blue) LCD

Electrical

Power - 5V, 800 mA DC power supply

Battery - Rechargeable Li-Ion 3.7V, 1800 mAh

Back up of about 8 hours of continuous operation

Charger: 100-230V AC, 50/60 Hz,

5V DC, 1000 mA, medical grade charger

Environmental

Operating temperatures: 5^oC to 40^oC

Storage Temperature: -10^oC to + 60^oC

Humidity: 20% to 80%

Physical Weight: : 230 gms (approx. - including battery)

Emission compliance: EN55011, CISPR 11, Group 1
Class B

Type of protection: Internally powered

Degree of Protection: Type BF

Enclosure Degree of protection: IPX0

Biocompatibility: Device is biocompatible as per ANSI/
AAMI/ISO 10993

ViScope 100 Immunity Table

Immunity Type	Basic Standard	Regulatory Acceptable Limits	Device Capability
Radiated Emission	CISPR 11 Class B :2004	30 -230MHz, 30dB μ V/m 230-1000MHz, 37dB μ V/m	30 -230MHz - 25.18dB μ V/m(Max) 230 -1000MHz - 29.93 dB μ V/m (Max)
Harmonics Current Emission	IEC 61000-3-2:2005	With in Class A Limits	With in Class A Limits
Flicker Emission	IEC 61000-3-3:2005	Short time flicker(10 Min) Pst \leq 1 Relative Steady state voltage change (dc) \leq 3% Max relative voltage change Dmax \leq 4% Value of D(t) during voltage change \leq 5%	Pass & No malfunction observed
Electro Static Discharge	IEC 61000-4-2	Contact discharge up to \pm 6KV Air discharge up to \pm 8KV	Pass & No malfunction observed
Radiated Susceptibility	IEC 61000-4-3:2006	80MHz -1000MHz .. 3V/m 1-2.5GHz .. 3V/m	Pass & No malfunction observed
Electrical Fast transient	IEC 61000-4-4:2004	Spike Voltage up to \pm 2KV for Power Line and up to \pm 1KV Signal Line	Pass & No malfunction observed
High Energy Surge	IEC 61000-4-5:2005	Pulse Amplitude up to \pm 1KV Differential Line to Neutral	Pass & No malfunction observed
Conducted RF	IEC 61000-4-6:2004	150KHz -80 MHz : 3Vrms	Pass & No malfunction observed
Power frequency magnetic Field	IEC 61000-4-8:2001	Field Strength :3A/m	Pass & No malfunction observed
Voltage Dips & Interruption	IEC 61000-4-11:2004	Short Interruption: 0% of AC mains for 5 secs Voltage dips : 40% of AC mains for 5 Cycles 70% of AC mains for 25 Cycles 0% of AC mains voltage for 0.5 Cycles	Pass & No malfunction observed

TROUBLESHOOTING

Device does not turn on when Power key is pressed.

- The battery could be completely drained. Charge the battery.
- If this does not work, it is possible that the battery is faulty; Replace with a HDM approved battery available with HDM / HDM authorized Personnel.

Unable to see anything on the LCD display

- In case the device is subjected to large mechanical shock, it is possible that the LCD may be damaged internally though it may not be readily visible. Contact HDM / HDM authorized Personnel.

Unexpected device Behaviour

- Contact HDM / HDM authorized Personnel.

Error codes, causes and solutions

Sl. No.	Error Code	Possible Reason	Solution
1.	Key Stuck Unit will Be turned OFF	You have pressed the key and held it for more than 3 seconds	Ensure that you release the Power ON keys as soon as the display turns ON Also ensure that you do not press and hold any key for more than 3 seconds.
2.	RAM failure	Failure of the processor	Contact HDM
3.	FLASH Failure	Failure of the processor	Contact HDM
4.	LOW BATTERY-UNIT WILL BE TURNED OFF	Battery is completely drained. Should be recharged	Replace the battery with a new functional one if the battery fails to get charged.

USER ASSURANCE TESTS

Test No. 1 : Device Turn ON

Pre-conditions: Device is in OFF state.

User Action: Press and hold the Power ON/OFF button for 3 seconds.

Expected Outcome: Unit will turn ON fully - you will be able to see the display go through the splash screen and then displays normal screen.

Test No. 2 : Audio Mode Change

Pre-conditions: Device is turned ON, Audio mode is in Default BELL mode

User Action: Press Audio toggle button.

Expected Outcome: Audio Mode will change to “DIA” if pressed again will change to “WIDE” mode

Test No. 3 : Volume Change

Pre-conditions: Device is turned ON, Volume icon is in Default level, showing 2 lines after speaker icon.

User Action: Press the 3 way key once.

Expected Outcome: Volume icon changes showing 3 lines after speaker icon. Audio volume will be increased.

User Action: Press the 3 way key once again.

Expected Outcome: Volume icon will change showing only 1 line after speaker icon. Audio volume is decreased.

Test No. 4 : Signal Gain Change

Pre-conditions: Device is turned ON, Signal Icon is at default level, showing 5 of signal.

User Action: Scroll the 3 way key in the direction of the “+” sign.

Expected Outcome: With each scroll, the Signal icon increases by one line.

Once the number of lines reaches 10, further scrolling will have no effect.

User Action: After reaching the maximum level, scroll the key in the direction of the “-”.

Expected Outcome: With each scroll, the Signal icon decreases by one line.

Once the number of the lines reaches one, further scrolling will have no effect.

Test No. 5: Display Backlight ON/OFF

Pre-conditions: Device is turned ON, working screen is on display.

User Action: Press Power key once momentarily.

Expected Outcome: Display Backlight is turned OFF.

User Action: Press Power key once again momentarily..

Expected Outcome: Display backlight will turn ON again.

Test No. 6 : Display Freeze/Unfreeze

Pre-conditions: Device is turned ON, working screen is on display. The display will be with right and left arrows, a number between arrows, save icon and transfer icon.

User Action: Press the Freeze button once. Then perform the following one after the other and check for corresponding expected outcome.

1. Tap gently on the diaphragm
2. press the Audio toggle button
3. The display with right and left arrow, a number between the arrows, save icon and transfer icon.

Expected Outcome:

1. No change on waveform.
2. No change in mode icon and text label.

User Action: Press Freeze Button again. Perform the

following operations one after the other and check for corresponding expected outcome.

1. Tap gently on the diaphragm.
2. press the Audio toggle button
3. Press 3 way key.
4. Scroll 3 way key to “+” side and “-” side in turns.

Expected Outcome:

1. Distortion seen on displayed waveform.
2. Mode change and change in text label will be observed.
3. Change in volume icon will be observed.
4. Changes in Signal Gain icon will be observed.

Test No. 7 : Display Backlight timeout

Pre-conditions: Device is fully ON.

User Action: Allow the device to be without any key press for 3 minutes.

Expected Outcome: Backlight turns OFF.

User Action: As soon as the backlight turns OFF, press momentarily Power key.

Expected Outcome: Backlight turns On.

Test No. 8 : Device timeout to Standby mode

Pre-conditions: Device is ON.

User Action: Allow the device to be without any key press for 3 minutes.

Expected Outcome: Backlight turns OFF.

User Action: Allow the device to be without any key press for another 3 minutes.

Expected Outcome: Device displays message that it is

entering standby mode and then turns OFF.

Test No. 9 : Device transition to Sleep mode

Pre-conditions: Device is fully ON.

User Action: Press and hold Power ON/OFF key for 3 seconds.

Expected Outcome: Device displays message that it is entering Sleep mode and then turns off.

Test No. 10 : Device Battery charging mode

Pre-conditions: Device is fully OFF.

User Action: Connect the charger to the device and plug the charger into the mains.

Expected Outcome: During charging, the device battery charge indicator will glow in RED. As soon as charging is completed, charge status indicator turns GREEN.

Test No. 11 : Memory option

Pre-conditions: Device is in freeze mode.

User Action: Scroll 3 way key and see any of the arrows/ save icon transfer icon is selected when the corresponding icon is highlighted.

Expected Outcome: If the left is selected see that the number between the arrows changes in the descending order from 4 to 1, when the 3 way key pressed.

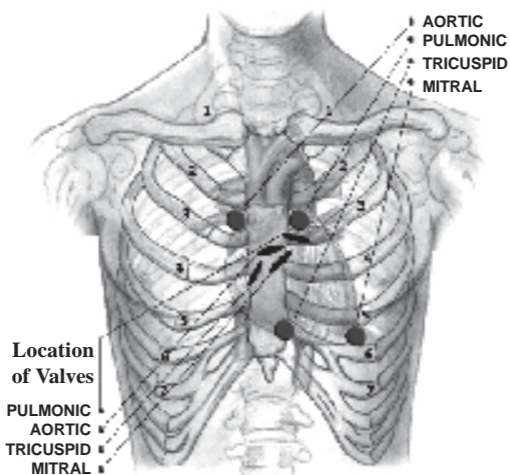
If the Right is selected see that the number between the arrows changes in the ascending order from 1 to 4, when the 3 way key pressed.

When save icon is pressed, the waveform displayed, should get saved in the position indicated by the number displayed between the arrows.





When the transfer icon is pressed, the stored 4 (four) waveforms in the device will be transferred to computer connected and erased in the device.

Auscultation Points

Auscultation Points



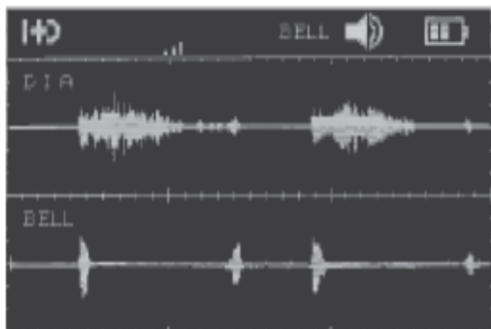
Auscultation Points for Specific abnormality

Area	Location	Auscultation Point	Abnormality
Aortic	2nd ICS R sternal border		Aortic Stenosis S2 is loudest here
Pulmonic	2nd ICS L sternal border		Pulmonary stenosis or regurgitation
Tricuspid	L. lower sternal border		Tricuspid
Mitral	5th ICS		Mitral stenosis or regurgitation S1 is loudest here

Indicative waveforms of Different Anomalies



Normal



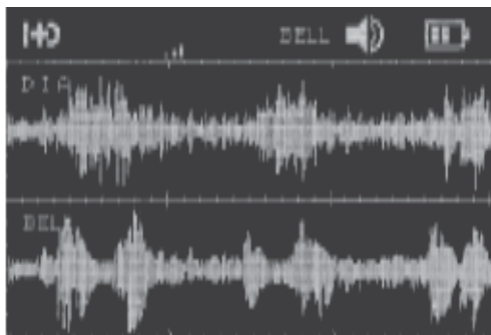
Aortic Regurgitation



Atrial Septal Defect



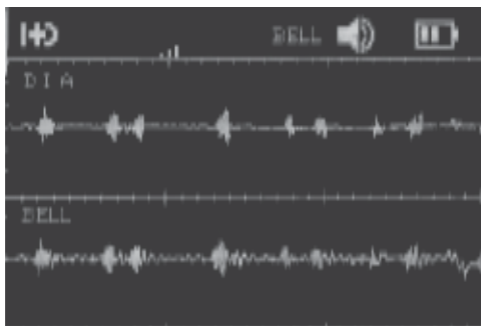
Mitral Stenosis



Patent Ductus Arteriosis



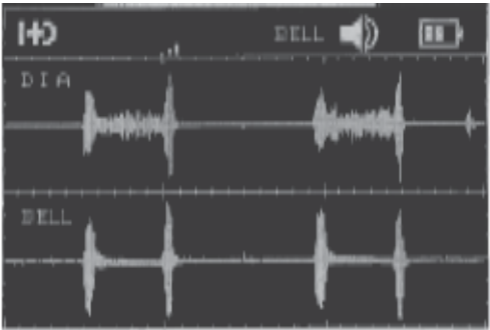
Pulmonary Stenosis



S 3



S 4



Tricuspid Regurgitation



Ventricular Septal Defect

Diaphragm Replacement



1. Remove the diaphragm from the chest piece groove as shown above.



2. Place the diaphragm over the chest piece and fix it completely to seat around the groove.

Note:

1. Do not use any sharp tool to remove the diaphragm.
2. Do not attempt to rotate the diaphragm/chest piece which might result in the chest piece alignment becoming loose.