Document History

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<th>Date</th>
<th>Authors</th>
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1 SAFETY CONSIDERATIONS

1.1 Operator Safety

For correct and effective use of the product it is mandatory to read and to observe all instructions, WARNINGS, and CAUTION statements in this manual. If the product is not used as instructed, the safety protection provided may be impaired.

⚠️ **WARNING!**

Indicates a potentially harmful condition that can lead to personal injury.

⚠️ **CAUTION!**

Indicates a condition that may lead to equipment damage or malfunction

1.2 Intended Use

The RespiScope™ product is intended to provide realistic respiratory, heart, and bowel sounds through a modified stethoscope (SimScope™, developed originally by Cardionics). RespiScope™ is a customized version of SimScope™ for use with IngMar Medical’s RespiPatient®. It communicates with the software over a configurable Wi-Fi connection. When paired with the IngMar Medical RespiSim® System, the RespiScope™ enhances the manikin-based simulation by providing realistic auscultation linked directly to the ASL 5000 Breathing Simulator’s breath rate.
2 AN INTRODUCTION TO THE RESPISCOPE™ PRODUCT

The RespiScope™ Auscultation Option combines the Cardionics SimScope™ with the RespiScope™ software to provide realistic lung, heart, and bowel sounds on the IngMar Medical RespiPatient® manikin. RFID tags placed within the manikin at specific locations produce physiologically accurate sound responses in the following areas on the torso:

- Lung
- Right Upper
- Right Lower
- Left Upper
- Left Lower
- Heart
- Aortic
- Mitral
- Pulmonic
- Tricuspid
- Stomach
- Bowel

With the RespiScope™ software, the user has the ability to change sounds and volumes, as well as enable muting (e.g. pneumothorax). RespiScope™ can be used as a stand-alone software where the user can change the breath rate, or the software can easily be set to receive the breath rate information directly from the ASL 5000 Breathing Simulator. A visual aid is also provided for sound locations. Figure 2-1 below shows the main user interface, the Auscultation Control Center.

![RespiScope™ User Interface](image_url)

**Figure 2-1: RespiScope™ User Interface**
IngMar Medical has partnered with Cardionics and their SimScope™ product to serve as the hardware device. The SimScope™ communicates with the Software over a Wi-Fi connection. Multiple SimScope™ devices can be paired with a single RespiSim® system to enhance the simulation experience.

![Figure 2-2: Cardionics SimScope™](image)

The diaphragm of the SimScope™ incorporates an RFID sensor. When the sensor comes in range of a unique RFID tag on the manikin, a sound is played based on the settings in the RespiScope™ software.

![Figure 2-3: SimScope™ Sensor / Control](image)

Sounds are produced within the SimScope™ itself, much like in an MP3-player. Sounds therefore are not impaired by the internal workings of the manikin, but are played from pre-defined sound scenarios that act as playlists. Together with the SimScope™, the RespiScope™ software can also be controlled via the ASL 5000 RespiSim® System. Pre-designed sound scenarios can be updated based on the
Change Events within the RespiSim® Instructor Dashboard. Please refer to the ASL 5000 User’s Manual for more information.

2.1 Overview

**RespiScope™** has two major components, the **SimScope™** and the **RespiScope™ software**. The SimScope™ hardware contains all of the sound files and the RespiScope™ software controls the setting of specific sounds to physiologically correct locations on the RespiPatient® manikin. Once a sound is assigned to a specific location, placing the SimScope™ diaphragm in close proximity “plays” the sound.

RespiScope™ breath rates can be directly controlled from the ASL 5000 software. With the RespiSim® Option of the ASL 5000 software, up to five “playlists” can be configured to change disease state sounds based on the desired simulation output.

When the RespiScope™ is packaged with a RespiPatient® manikin, the software and hardware are preconfigured for use. If the software is installed separately, the RespiScope™ software provides step-by-step instructions for configuring the SimScope™.

![NOTE]

RespiScope™ is compatible with all RespiPatient® manikins in the market. No retrofit is necessary.

The user can create and save unique playlists based on the type of simulation being conducted. When a change is made to a sound location, the SimScope™ is updated in real-time. This also includes changes to the breath rate (when not driven by the ASL 5000 Breathing Simulator), volume, and mute capabilities.
3 RESPI SCOPE™ SYSTEM SETUP

3.1 Computer Requirements

- Windows 7 or Windows 10 (Windows 8 and 8.1 are not recommended)
- Intel i3 (or comparable) or better processor
- 4GB RAM
- 500 GB HD
- Also required is network connectivity either through a stand-alone router or the user network

3.2 RespiScope™ Software Setup

NOTE

If the RespiScope™ option is part of the RespiSim® Pro Package, all necessary software is already pre-installed and paired to the SimScope™. In this case, skip to section 4.1 RespiScope™ Software Interface Components.
3.2.1 Installer
The software will be provided either from a USB drive or an online download. If the installer is zipped, unzip the package by right-clicking on the file and clicking on the “Extract All...” option. Once the installer is extracted, open the folder and double-click on `setup.exe` to begin. Follow the prompts during installation and accept any license options. When the setup is complete, click Finish.

3.3 SimScope™ Setup
The first time the software is run after a fresh installation (see NOTE above), the user is prompted to configure the SimScope™ with the RespiScope™ software. The RespiScope™ software will walk the user through this process. The USB cable that comes with the SimScope™ is required for these steps. The battery in the SimScope™, however, is not necessary for the configuration process.

3.3.1 Pairing the SimScope™ to the RespiScope™ Software
- Double-click the RespiScope™ software shortcut (icon 🎮) installed on your desktop to open the user interface

A prompt states that the system must be configured for use (see Figure 3-1).

![Figure 3-1: RespiScope™ Software First Run](image)

- When prompted, click **Run setup** in the dialog window. This will open the SimScope™ Setup window as shown in Figure 3-2.
Figure 3-2: SimScope™ Setup Window

- Click the **Add New** button which opens the **Specify SimScope Name** window.

By default, the name will be populated with *SimScope 1*. You may freely change the name.

Figure 3-3: Specify SimScope Name Window

- Click **OK** to continue.

Next, install the appropriate drivers for the SimScope™.

- Click **Next** in the **Driver Installation** window.
Once the drivers are installed, the user is prompted to connect the SimScope™ to the computer.

- Using the provided USB cable, connect the SimScope™ to one of the computer’s USB ports.
NOTE

It may take up to 30 seconds before the SIMSCOPE (D:) drive appears. Close this window to continue the installation.

Figure 3-6: SimScope™ Drive Contents – Close this Window

Once the installation windows are visible again,

• click Next to continue. This opens the WiFi configuration window.

The WiFi configuration window allows the user to setup the SimScope™ on a stand-alone router or within a host network. By default, the SimScope™ is paired to an IngMar-supplied router as shown in Figure 3-7.
In order for the SimScope™ to work in a Wi-Fi environment, the following information is needed to properly configure the SimScope™:

1. Network SSID
2. Security Type
   - No Security *(Do not use this option)*
   - WPA
   - WPA2 (typical)
   - WEP (Open Key)
   - WEP (Shared Key)
3. Password (with option to show or hide characters)
4. SimScope™ Static IP Address
5. Subnet Mask
6. Gateway

**NOTE**

If help is required for setting up the IP addressing, please consult your IT specialist

- Once the SimScope™ is configured, click **Next**
- You are prompted to eject the SimScope™ and to unplug the USB cable from the computer and the SimScope™.
- Click **OK** to continue.
The **Setup Completed** window opens to confirm proper configuration.

- Click **Next** to return to the **SimScope Setup** window (see below).

![Setup Complete Window](image)

**Figure 3-9: Setup Complete Window**

Now, the **SimScope 1** (or other, user-defined name) will be present with its designated IP address.

![Updated SimScope Setup Window](image)

**Figure 3-10: Updated SimScope Setup Window**

- Close the **SimScope Setup** window by clicking the “X” in the top right of the window.

The **Auscultation Control Center** (main user interface) will now show the **SimScope 1** configured, but not connected (red line through the Wi-Fi icon).
Additional SimScope™ Wi-Fi connections can be established via the same procedure as stated above for SimScope 1. If set up correctly, the user interface screen will list a newly added SimScope™ as shown in Figure 3-12.
3.3.2 Connecting the SimScope™ to the RespiScope™

**NOTE**

Due to the Wi-Fi-based operation of the SimScope™ as part of the RespiScope™ system, batteries need to be replaced more frequently. IngMar Medical recommends using high performance batteries, e.g. Energizer Ultimate Lithium.

When a battery is inserted to the rear of the SimScope™, the system will turn on automatically with a voice in the earbuds stating, *System Activation, Mode 1* followed by several beeps. If Wi-Fi has been configured correctly, the voice will say, *Wi-Fi On*. This means that the SimScope™ has successfully connected to the network as defined by the settings shown in Figure 3-7 above.

If the SimScope™ does not turn on automatically, simultaneously press the + and – buttons on the back side of the SimScope™ diaphragm. The voice prompt will be the same as above.

- Once the Wi-Fi connection is established, click on the Auscultation Control Center. The button will change to **Connecting ...**.

During the connection process, the top left of the Auscultation Control Center shows the connection status.

![Figure 3-13: Connecting to SimScope™](image)
Once the SimScope™ is connected, the status window in the top left changes as shown in Figure 3-14. When connected, the connection button changes to , the Wi-Fi icon becomes green, and the Battery status icon becomes visible.

![Figure 3-14: SimScope™ Connected](image-url)
4 Using the RespiScope™ Software

4.1 RespiScope™ Software Interface Components

The software is comprised of five basic control / monitoring components within the main user interface.

- Connect / Disconnect / Setup

![RespiScope™ Connection](image1)

Figure 4-1: RespiScope™ Connection

- RFID Tag Guide

![RespiScope™ RFID Tag Reference](image2)

Figure 4-2: RespiScope™ RFID Tag Reference

- Playlist Control

![Playlist Control](image3)

Figure 4-3: Playlist Control

- Breath Control

![RespiScope™ Breath Control](image4)

Figure 4-4: RespiScope™ Breath Control
• Sound / Volume / Mute Control

4.1.1 Connect / Disconnect / Setup
When a SimScope™ is successfully connected to a network (Wi-Fi On voice from the device), the RespiScope™ software can be paired by clicking .

• To disconnect the software from the SimScope™, click .

• Click the setup icon to add, remove, or update a SimScope™ with the RespiScope™ software.

4.1.2 RespiScope™ RFID Tag Locations
The RespiScope™ software provides an image of the torso with each RFID tag position. When the user moves the mouse cursor over any of the sound locations, e.g. Left Upper Lobe, a GREEN dot shows the referenced location on the manikin.
4.1.3 RespiScope™ Sound Options
You can choose several available heart, lung, and bowel sounds via dropdown boxes. To access any of the sounds, click a sound name and the dropdown will show all available sounds for the tag location. The table below provides the sound locations and associated sound files available.

<table>
<thead>
<tr>
<th>Sound Locations</th>
<th>Sound Files</th>
</tr>
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<tbody>
<tr>
<td>Lung Sounds:</td>
<td>Bronchial</td>
</tr>
<tr>
<td>Right Upper Lobe</td>
<td>Broncho vesicular</td>
</tr>
<tr>
<td>Right Lower Lobe</td>
<td>Crackles Coarse</td>
</tr>
<tr>
<td>Left Upper Lobe</td>
<td>Crackles Fine</td>
</tr>
<tr>
<td>Left Lower Lobe</td>
<td>Vesicular Normal</td>
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<td></td>
<td>Wheeze</td>
</tr>
<tr>
<td></td>
<td>Wheeze Rhonchus</td>
</tr>
<tr>
<td>Heart Sounds:</td>
<td>Aortic Regurgitation</td>
</tr>
<tr>
<td>Aortic</td>
<td>Aortic Stenosis Mild</td>
</tr>
<tr>
<td>Pulmonic</td>
<td>Fourth Heart Sound</td>
</tr>
<tr>
<td>Tricuspid</td>
<td>Innocent Systolic Murmur</td>
</tr>
<tr>
<td>Mitral</td>
<td>Mitral Regurgitation Mild</td>
</tr>
<tr>
<td></td>
<td>Mitral Stenosis</td>
</tr>
<tr>
<td></td>
<td>Normal Heart Sound</td>
</tr>
<tr>
<td></td>
<td>Paradoxical Split S2</td>
</tr>
<tr>
<td></td>
<td>PDA Patent Ductus Arteriosus</td>
</tr>
<tr>
<td></td>
<td>Pericardial Rub</td>
</tr>
<tr>
<td></td>
<td>Physiologic Split S2</td>
</tr>
<tr>
<td></td>
<td>Systolic Ejection Clicks</td>
</tr>
<tr>
<td></td>
<td>Third Heart Sound</td>
</tr>
<tr>
<td></td>
<td>Tricuspid Regurgitation</td>
</tr>
<tr>
<td></td>
<td>Venous Hum</td>
</tr>
<tr>
<td>Bowel Sounds</td>
<td>Crohn’s Disease</td>
</tr>
<tr>
<td></td>
<td>Diarrhea</td>
</tr>
<tr>
<td></td>
<td>Irritable Bowel</td>
</tr>
<tr>
<td></td>
<td>Normal 4 Year Old</td>
</tr>
<tr>
<td></td>
<td>Normal 20 Year Old</td>
</tr>
<tr>
<td></td>
<td>Normal 60 Year Old</td>
</tr>
</tbody>
</table>

Table 1: Sound Files and Locations

Volume and mute options are also available including a Master Volume and Mute control. Volumes can be lowered for simulations where breath sounds are intended to be difficult to assess. Muting a sound can be useful for simulating, for example, a tension pneumothorax on one side of the body.
4.1.4 **RespiScope™ Breath Control**

- Breath rates from ~6 to 60 breaths per minute are possible, based on user settings. When running RespiScope™ software without the ASL 5000 Breathing Simulator, or while the **Receive Breath Rate from ASL** checkbox is not checked, a breath rate for rendering the sounds needs to be entered manually. Heart and Bowel sounds are always rendered at a fixed rate.

- Either adjust the **Breath Rate** knob or enter a value between 6 and 60 into the field provided.

![Figure 4-7: RespiScope™ Breath Control](image)

When working with the ASL 5000 Breathing Simulator, the breath rate can be driven by the lung.

- Click the **Receive Breath Rate from ASL** check box.
  Sound files will update with the ASL’s breath rate.

Figures 4-8 and 4-9 below show the ASL 5000 Real Time Analysis window next to the RespiScope™ breath control in the **Auscultation Control Center**. Breath Rates of 15 and 35 BPM, respectively, with the RespiScope™ software providing sound at the same rate.

![Figure 4-8 - RespiScope™ / ASL Breath Rate = 15BPM](image)

![Figure 4-9: RespiScope™ / ASL Breath Rate = 35BPM](image)
4.1.5 RespiScope™ Playlist Open / Save Control

The sounds, volumes, breath rates, etc. can be updated in real-time during a simulation by simply changing sound names or adjusting the volume slider. The user can also create specific combinations of sounds based on the expected simulation outcomes and save these as playlists. The playlist files (or .car files) are saved, by default, in the \Documents\IngMar Medical\RespiScope\Playlists directory. The format is tab delimited.

As an example, the playlist called Example.car is shown in the Figure 4-10 below:

![Figure 4-10: Example Loaded Playlist](image)

The same playlist file (Example.car) format is shown below as a text-based playlist file:

```
<Version>0.0.0.0</Version>
<BreathRate>12</BreathRate>
<SoundSettings>
  Location  Sound  Volume  Mute
  Right Lung Upper 0  20  1
  Right Lung Lower 1  31  0
  Left Lung Upper 3  20  0
  Left Lung Lower 6  45  0
  Aortic 0  31  0
  Pulmonic 14  11  0
  Tricuspid 13  42  1
  Mitral 4  31  0
  Bowel 2  45  0
</SoundSettings>
```
You may create multiple playlists and save them via \textit{Save Playlist}. Once saved, any playlist can be retrieved using \textit{Open Playlist}.

4.1.6 \textit{RespiScope}™ Playlist \textit{RespiSim}® Control

When using the \textit{RespiScope}™ with the \textit{RespiSim}® system, playlists can be directly controlled from the \textit{RespiSim}® environment. On the \textit{RespiSim}® \textit{Instructor Dashboard}, each \textit{Change Event} can include a unique \textit{RespiScope}™ playlist. This greatly enhances the simulation by providing new sounds based on changing disease states.

\textbf{NOTE}

In order to control the \textit{RespiScope}™ from the \textit{RespiSim}® System, the \textit{RespiSim}® software MUST be running.

Prior to running a full simulation within the \textit{RespiSim}® environment, you may create up to five unique playlists that are triggered by the \textit{RespiSim}® System (\textit{Initial Conditions} and \textit{Change Events 1-4}). You may work on playlist development without the need to connect to a \textit{SimScope}™. Thus, in \textit{demo} mode (\textit{Software Only} mode), you could, for example, create \textit{Playlist1.car} ... \textit{Playlist4.car}, based on the expected simulation outcomes. (Please see the ASL 5000 User’s Manual for more details about using \textit{RespiSim}®).

Once playlists are created, you use the \textit{RespiSim}® software to load these into the simulation scenarios. Please follow the steps below to load and run \textit{RespiScope}™ from the \textit{RespiSim}® software.

- Open the \textit{RespiSim}® \textit{Instructor Dashboard} (see ASL 5000 Operator’s Manual) and right-click on \textit{Lung Sounds} or \textit{Heart Sounds} in any of the \textit{Change Event} tabs (or the \textit{Initial Conditions} tab).
  This opens the \textit{View/Edit Lung Sounds} or \textit{View/Edit Heart Sounds} window.
Click the folder icon to navigate to the appropriate sound file (xxxx.car). Once this file is loaded, click . Repeat this step for each desired Change Event. When a xxxx.car file has been loaded, the edit window will look like in Figure 4-12 below:

After all xxxx.car files have been loaded into the required Change Events, the simulation is ready for use with the RespiScope™.

- While RespiSim® is running in the ASL 5000 software and the RespiSim® Module file is loaded, connect the SimScope™ to the RespiScope™ software.
- Click after the connection has been established.
  The button will change to . This will also gray-out the sound control component removing the ability for the user to make on-the-fly changes.
Figure 4-13: RespiScope™ Controlled by RespiSim® (Initial Conditions)

Figure 4-13 shows an example of a xxxx.car file loaded with **Initial Conditions** enabled in the **Instructor Dashboard**. When you activate a column of settings on a different **Change Event** (representing another stage of the simulation), the associated changes of the sound patterns are reflected in the RespiScope™ **Auscultation Control Center** as shown in Figure 4-14 below.

![RespiScope™ Controlled by RespiSim® (Initial Conditions)](image)

Figure 4-14: RespiScope™ Controlled by RespiSim® (Change Event 1)

You can disable RespiSim® control by clicking **Stop Control from RespiSim**.
5 TROUBLESHOOTING

The following conditions are problems that can be easily identified and remedied by the user. For any help/support related to the ASL 5000 please mail to: support@ingmarmed.com.

5.1 Wi-Fi Connectivity

Problem
SimScope™ connectivity - After hearing the System Activation, Mode 1 and beeps upon inserting the battery, the voice responds with Wi-Fi System Activation Failed.

Resolution
Check the Wi-Fi settings on the SimScope™. Click the “Settings” icon and follow the steps. Click the “IP Configuration” button and verify network settings are correct.

Problem
Wi-Fi connection fails and settings are correct.

Resolution
Replace battery

5.2 File Not Found

Problem
Placing diaphragm sensor over RFID location results in File Not Found voice response.

Resolution
Disconnect RespiScope™ from SimScope™. Reconnect SimScope™ and check to see if file’s have updated. If the same message is appearing, mail SimScope™ serial number to: support@ingmarmed.com.

5.3 Verification Mode

Problem
SimScope™ voice states “Verification Mode”. This happens when the + and – buttons are pressed a second time after the Wi-Fi connection is successful or fails.

Resolution
Remove and reinsert the battery. If the SimScope™ does not turn on automatically, press the + and – buttons to enable System Activation, Mode 1.
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