antlia Pro®

Pulmonary function test device

Antlia Pro

User Manual

iCALTECH Innovations Pvt. Ltd

ICALTECH INNOVATIONS PVT LTD

Bangalore

Table of Contents

List of Figures

Abbreviations

Rrs	Respiratory Resistance
Xrs	Respiratory Reactance
R5	Resistance at 5Hz
R11	Resistance at 11 Hz
R19	Resistance at 19Hz
X5	Reactance at 5Hz
X11	Reactance at 11 Hz
X19	Reactance at 19Hz
Z5	Respiratory impedance at 5Hz
Z19	Respiratory impedance at 19Hz
AX	Area of Reactance
Fres	Resonant frequency (Hz)
R5 COV	R5 Coefficient of Variation
Z5 COV	Z5 Coefficient of Variation
BVF	Bacterial Viral Filter
PFT	Pulmonary Function Test
NA	Not Applicable

1. Introduction and Features

1.1. Overview and Purpose of Antlia Pro

the Antlia Pro – a cutting-edge medical device utilizing the Forced Oscillation Technique (FOT) to measure respiratory system impedance. Designed for pediatric and adult patients aged 4 years and above, the Antlia Pro is an invaluable tool in evaluating and managing respiratory conditions such as asthma and chronic obstructive pulmonary disease (COPD).

By precisely measuring airway resistance, reactance, and other lung function parameters, the device aids healthcare professionals in diagnosing and treating respiratory diseases effectively in both children and adults.

1.1.1. Key Functional Features

The key features of the Antlia Pro device are designed to ensure accurate measurement and ease of use for healthcare professionals:

- Captures resistance and reactance across a frequency range of 5–37 Hz.
- Operates in two frequency modes:
    - Mono-frequency mode (5 Hz and 19 Hz).
    - Multi-frequency mode (5–37 Hz).
- Performs pulmonary function tests (PFT):
    - 12 seconds in Mono-frequency mode.
    - 24 seconds in Multi-frequency mode.
- Supports both PRE and POST test types for bronchodilator or bronchoconstrictor reversibility testing.
- Conducts system self-checks to ensure proper functionality:
    - Pressure Sensor offset.
    - USB Communication port.
- Factory-calibrated for impedance measurements in Mono-frequency mode.

1.1.2. Main Advantages

- Measures lung function with high sensitivity, capturing small and peripheral airway diseases.
- Useful for evaluating bronchodilator reversibility and distinguishing normal from abnormal lung function.
- Suitable for patients unable to perform spirometry tests (e.g., pediatric, geriatric, or severely ill patients).
- Assists in diagnosing conditions such as COPD, asthma, interstitial lung disease (ILD), fibrosis, airway clearance issues, and silicosis.
- Efficiently identifies rapid changes in impedance during the respiratory cycle, particularly in Mono-frequency mode.

1.2. Copyright and Legal information

Model Information

- **Model Name:** Antlia Pro
- **Product Code:** ANTPRO
- **Part Number:** 205-0001-000

Contact Information

For additional information or assistance, please contact the manufacturer.

Manufacturer: iCaltech Innovations Pvt Ltd.

Address: 2nd Floor, Sy no 80, Municipal No 4 & 4A (Katha no 351),
Muneshwara Layout, Service Road, Ring Road,
Laggere Bridge, Laggere,
Bengaluru, Karnataka, 560058, India.

Email: operations@iCaltech.com

Toll-Free Number: +91 9480017633

Scope of User Manual

The **Antlia Pro User Manual** provides essential guidance for the unpacking, installation, configuration, safe operation, maintenance, and troubleshooting of the device. It ensures safe and efficient usage to achieve optimal performance in clinical environments.

This manual is intended for healthcare professionals and trained personnel responsible for assessing and monitoring respiratory conditions in patients. By covering all necessary aspects of setup and usage, it enables users to maximize the device's capabilities.

About this User Manual

- **Name of Document: Antlia Pro User Manual**
- **Revision**: 05
- **Part Number**: 203-0001-004

We strongly recommend that you read the entire user manual thoroughly before using the device.

On behalf of the iCaltech team, our partners, and representatives, we sincerely thank you for placing your trust in us. We are dedicated to supporting you in maximizing the potential of this state-of-the-art technology to deliver exceptional care to your patients.

Important Notes

- Any patient or equipment data used as examples in this User Manual are entirely fictional and intended for representation purposes only.
- The actual product may vary slightly in appearance or features, depending on the model, installed options, and specific configuration.
- Any resemblance to real persons, institutions, or names is purely coincidental.

All parameters, graphs, and images shown in this User Manual are for illustrative purposes only. The parameters displayed by your device during operation are definitive.

2. Technical Specifications

2.1. Technical Specification – Antlia Pro

Technical Specification – Antlia Pro			
Flow Measurement	Calorimetric	Physical Dimensions	Height: 230 mm
Pressure range	± 2.5 kPa		Width: 140 mm
Flow Range	± 4.16 L/s		Length: 240 mm
Pressure Transducer	Piezo Resistive	Weight	2.90 Kgs

Testing Signal Mode	Mono Frequency	Mixed Frequency (5 Hz – 37 Hz)
Frequency Range	5 and 19 Hz	5, 11, 13, 17, 19, 23, 29, 31 and 37 Hz
Measurement Accuracy	For Impedance ±10%	
Calibration	Factory Calibration and Auto-Zeroing of the sensors and A calibration check with a Reference Impedance	
Connectivity	USB Port	
Applied Port	Type B	
Portability	Table Top	
Data Viewing and Storage	Desktop/ Laptop	
Support Arm	Metal	
Input Voltage	100 – 240 V AC, 1.3 – 0.6 A, 50/60Hz	
Output Voltage	12v DC, 800 milli Amps to 1 Amps	
Power Consumption	36 W	
Design Comply with IEC 60601-1, IEC 60601-1-2 and ERS Guidelines		

2.2. Device Label

3. Hardware Platform

Figure 1: Antlia Pro Device

3.1. Components Overview

3.1.1. Device Side View

Main components of the Antlia Pro Unit:

A. FOT tube enclosure

B. Source tube

C. Source Enclosure

D. LED indication Panel

E. Adjustable Arm

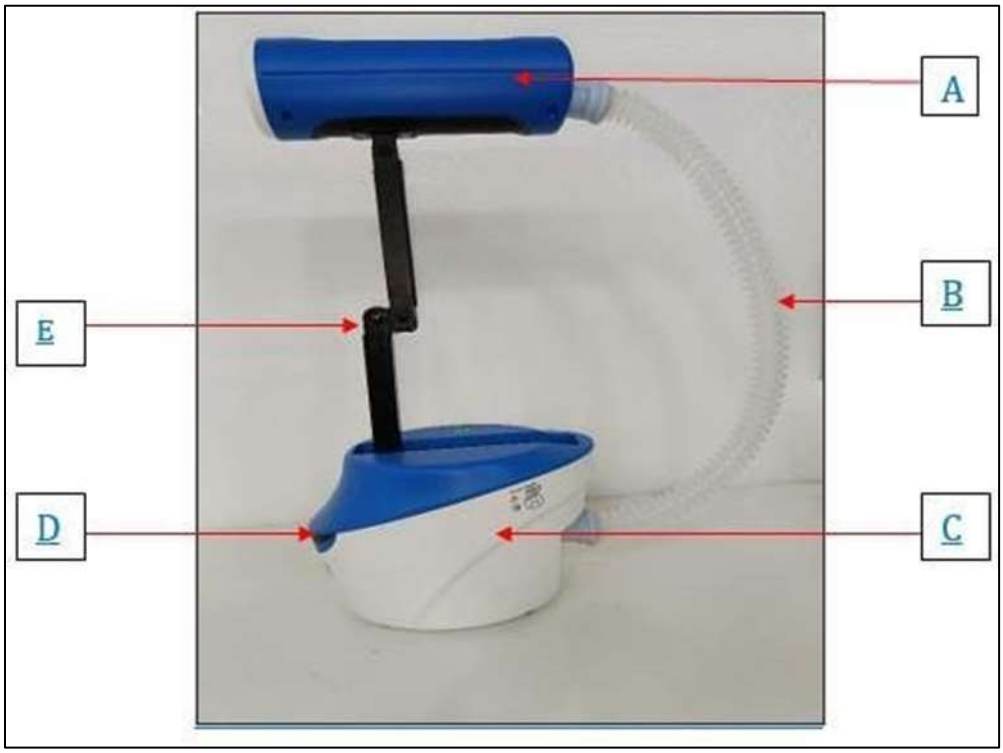


Figure 2: Rear View of Antlia Pro Device

A. FOT tube Enclosure:

The FOT tube enclosure consists of three parts: Top cover, Bottom cover, and Front cover. Any component assembled in the FOT setup can be accessed by removing the top cover.

B. Source Tube:

Antlia Pro device has a 50 cm long source tube, which is used to carry the pressure wave from Source to FOT tube.

C. Source Enclosure:

Antlia Pro includes a Source that generates pressure signals ranging from 5 Hz to 37 Hz, and a control unit that measures volume and pressure.

D. LED Indication Panel:

The source enclosure also houses the LED indication slot, which contains three LEDs: Green, Blue and Red, to notify the user in different scenarios.

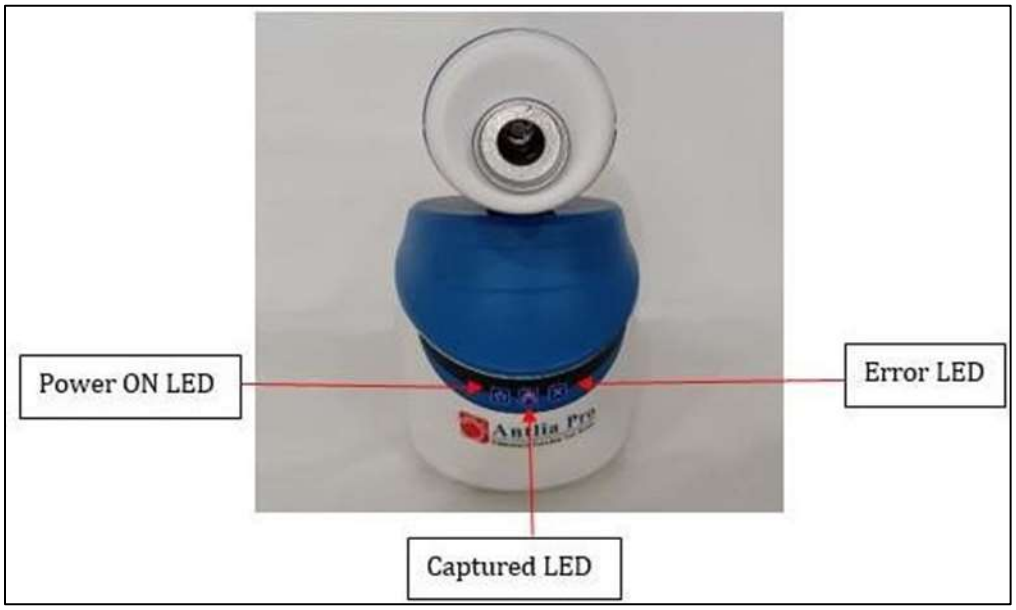


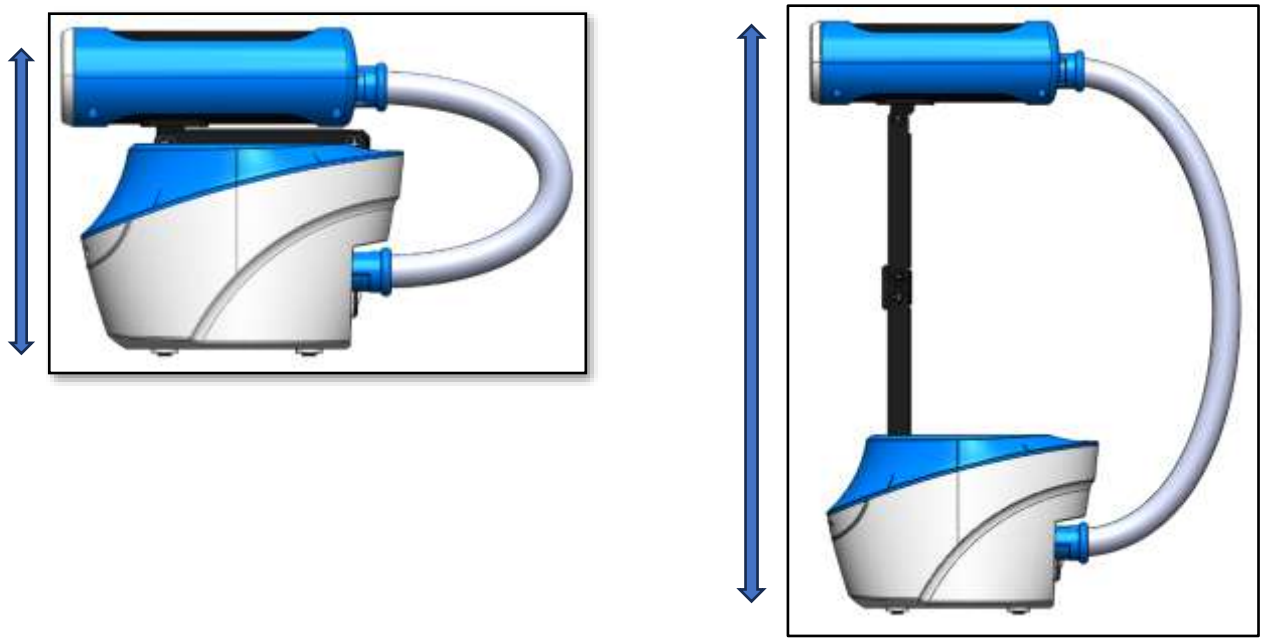
Figure 3: LED Indication Panel

LED status

Color	Status	Notification
UNLIT	OFF	The device is powered down
Green	Blinking	The device is powered up
Green	Solid state	The device is connected to App
Blue	Blinking	The device is in start mode
Blue	Solid state	Conducting test
Red	Error	The device is powered up, but a critical error has occurred, and the system is not ready for use.

E. Adjustable Arm

Using the adjustable arm, we can adjust the height and the inclination of the device to suit the patient's height, allowing to perform test easily. Move the arm in the upward and downward directions to adjust the height of the FOT section.



Min. height of the device - 20.3cm Max. height of the device - 49.5 cm

Figure 4: Adjustable arm of the device

3.1.2. Device Rear View

The main components of the Antlia Pro Device located on the rear side of device are as follows:

A. Power ON/OFF button

Switch to turn the device power ON or OFF.

B. Power supply connector

Insert power adaptor in to this connector to supply power to the device.

C. Type B USB port

Facilitates connection between the Antlia Pro device and the computer system.

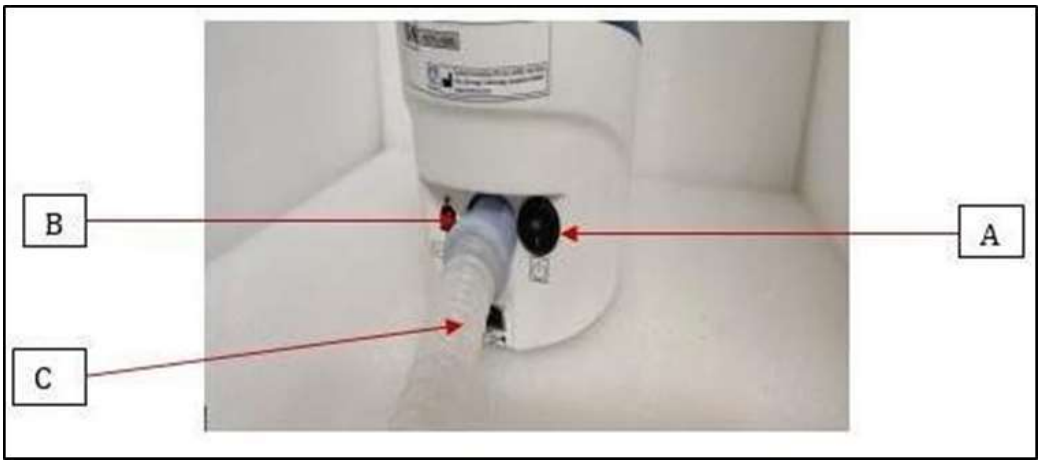


Figure 5: Rear View of Antlia Pro

3.1.3. List of Accessories

Component Description	Image
iCaltech Filter: The BVF filter recommended by iCaltech, is intended for single-patient use only.	
Nose clip: To close the nose during the test	
Power Adapter: Desktop AC Adapters 36 W, 12 V, 3A Medical.	

Reference impedance: It is used for device verification and provides a known impedance with a tolerance of ±10%.	
Device cap: It is used to cover the FOT inlet, preventing the ingress of dust and humidity into the device when not in use.	

Note: To interface the Antlia Pro device with a laptop or computer system, it is recommended to use a Type-B USB cable that is less than 1 meter in length.

3.2. Measurement Principle

The device generates pressure signals against which the patient performs tidal breathing. It provides respiratory parameters, such as resistance and reactance, at mixed and mono frequencies to assist in diagnosing respiratory disorders. The real time graphical display of respiratory volume and mouth pressure enables the user to observe and identify the subject's breathing maneuver during the test.

An electric signal is generated in the impedance analyzer and applied to a pump, which converts it into a corresponding pressure waveform. This pressure wave typically has an amplitude of approximately 0.2 kPa (peak-to-peak).

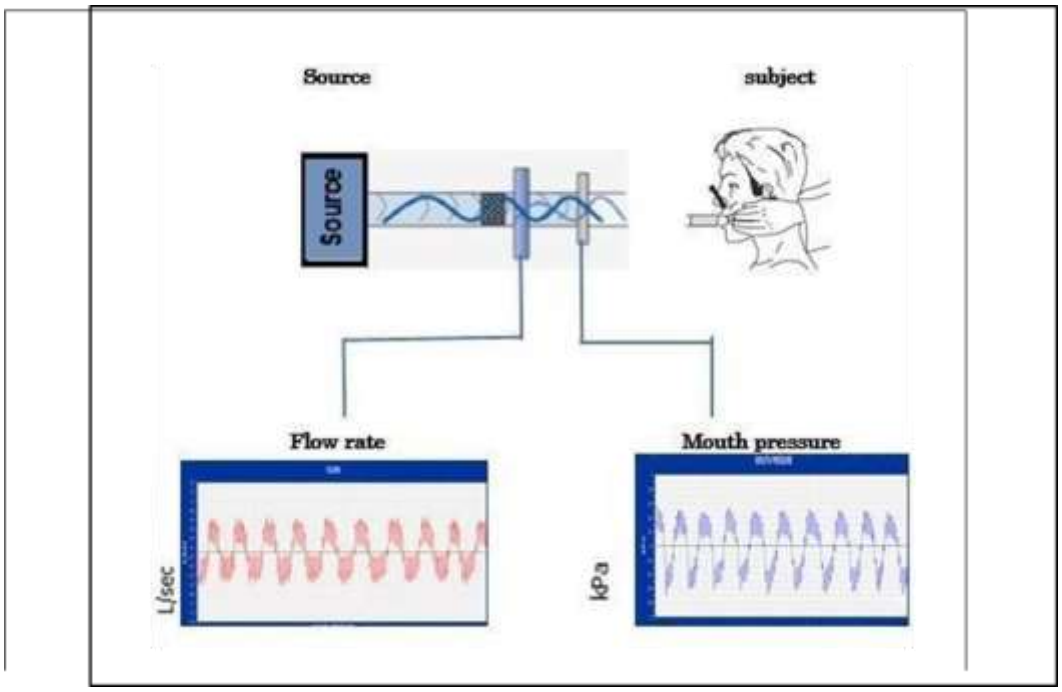


Figure 6: Graphical display of respiratory volume and mouth pressure

- This wave is directed to the patient's mouth, via iCaltech filter. The airflow (V´) is measured using pneumotachograph, and the pressure(P) is measured at the patient's airway input. The resulting signals are filtered and digitized in the impedance analyzer, which then calculates the respiratory impedance (Zrs).
- The mechanical behavior of the human respiratory system depends on the frequency of the applied oscillation. Low frequencies provide insights in to the mechanical properties of lung periphery, while high frequencies describe the properties of central and upper airways. The Antlia Pro utilizes oscillatory waveform ranging from 5 Hz to 37 Hz.

3.2.1. Resistance (R)

Resistance describes the dissipative mechanical properties of the airways, as well as the lung and chest wall tissue. Resistance mainly reflects the frictional pressure losses that occur as air moves in and out the airways, making it closely related to the overall airway's diameter.

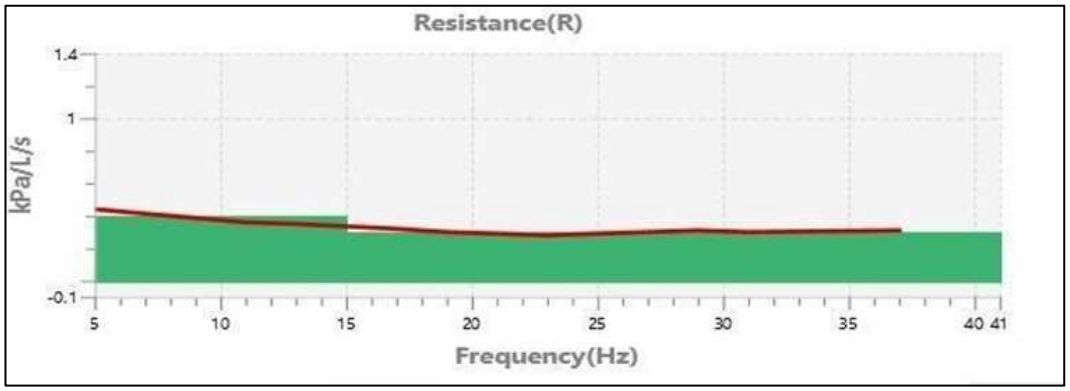


Figure 7: Resistance(R) - Graphical Representation

3.2.2. Reactance (X)

Reactance is related to the energy storage capacity of the respiratory system. It is determined jointly by the elastic properties (the relationship between pressure and volume), which are dominant at low oscillation frequencies, and the inertive properties (the relationship between pressure and volume acceleration), which are dominant at high frequencies.

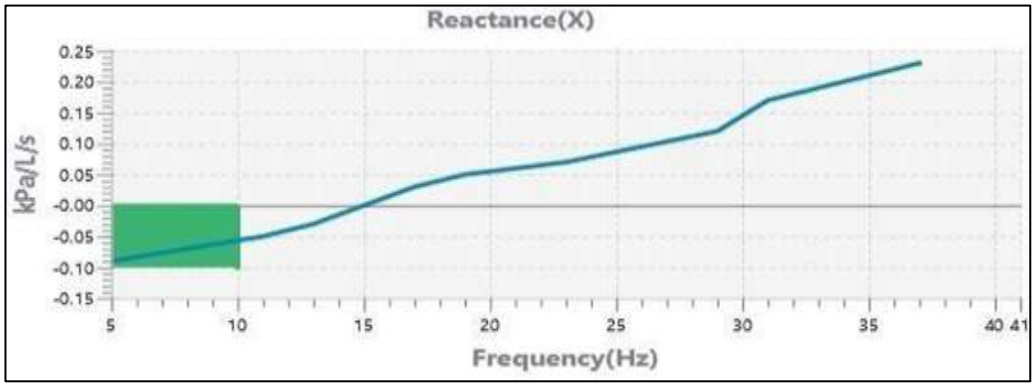


Figure 8: Reactance (X) - Graphical Representation

3.2.3. Outcome Parameters

3.2.3.1. FOT Parameters

Parameter	Abbreviation	
Resistance 5Hz	R5	Low-frequency Resistance (5 Hz) reflects total airway resistance
Resistance 19Hz	R19	Resistance (19 Hz) reflects mostly conducting airways

Frequency dep. of Resistance, 5 – 19 Hz	R5-R19	Reflects Resistance in the small airways
Reactance 5Hz	X5	Low-frequency Reactance (5Hz) reflects elastic compliance & small airways
Resonance frequency	Fres (Hz)	Resonant frequency reflects peripheral airways.
Delta X5Hz	Delta X5	Low frequency Delta (5Hz) reflects change between inspiratory reactance and expiratory reactance
Area of Reactance	AX	Area of reactance reflects elastic properties of lungs
R5 COV	R5 COV	R5 Coefficient of variation
Z5 COV	Z5 COV	Z5 Coefficient of variation

3.2.3.2. Breathing Parameters

Parameter	Abbreviation	
X5 Inspiration	X5Insp	Reactance value at inspiration cycle
X5 Expiration	X5Exp	Reactance value at expiration cycle
R5 Inspiration	R5Insp	Resistance value at inspiration cycle
R5 Expiration	R5Exp	Resistance value at expiration cycle
Tidal Volume	Tidal Volume	Amount of air that moves in or out of the lungs with each respiratory cycle
Time Inspiration	TimeInsp	Average time duration for inspiration
Time Expiration	TimeExp	Average time duration for expiration
Respiratory Rate	RR	Number of breaths per minute
R5 End Inspiration	R5EndInsp	Resistance at end of the inspiration cycle
R5 End Expiration	R5EndExp	Resistance at end of the expiration cycle
X5 End Inspiration	X5EndInsp	Reactance at end of inspiration cycle
X5 End Expiration	X5EndExp	Reactance at end of expiration cycle
Mean Inspiration Flow	Qi	Average inspiratory flow rate

Mean Expiration Flow	Qe	Average expiratory flow rate
Minutes Ventilation	Ve	Volume of gas inhaled and exhaled from a person's lungs per minute.

4. Environmental Conditions

The suitable environmental conditions for the safe operation, storage, and transport of the Antlia Pro are outlined below, ensuring accurate test results and promoting the long life of the product.

4.1. Operating Conditions

- **Air Quality:** The device should be used in a clean, dry environment free from dust and away from explosive and flammable substances.
- **Ventilation:** Ensure adequate space around the device to prevent overheating and for the patient accessibility. Keep the device away from the heat sources.
- **Electromagnetic Interference:** Do not operate the device near the strong electrical and magnetic devices such as X Ray Machines, Transformer, or Power lines to ensure accurate performance.
- **Vibration:** Do not use device near highly vibrating equipment like Generators, Large Motors, or in Rooms/Areas near to roads which has access to heavy vehicles.
- **Temperature:** +10°C to +40°C
- **Humidity:** 20% to 90% Relative Humidity (non-condensing)
- **Atmospheric Pressure:** 600 mbar (600 kPa) to 1060 mbar (106 kPa)
- **Altitude level:** Not to exceed 2,000 meters above sea level

4.2. Storage Conditions

- **Temperature:** 5°C to +40°C
- **Humidity:** 5% to 95% relative humidity (non-condensing)

4.3. Transport Conditions

- **Temperature:** 5°C to +40°C
- **Humidity:** 5% to 95% relative humidity (non-condensing)
- **Shock and Vibration:** Handle with care to avoid mechanical shock or excessive vibration during transit.
- **Protection from Exposure:** Avoid exposing the device to direct sunlight, rain, or extreme environmental conditions during transport.

5. An Overview

5.1. Device Overview

The Antlia Pro is a professional, PC-based device designed for the non-invasive measurement of the mechanical properties of the human respiratory system. It uses the Forced Oscillation Technique (FOT) to measure these properties.

The respiratory system with an oscillation pressure is used to evaluate the response in terms of mechanical impedance. Impedance represents the complex relationship between flow and mouth pressure.

Minimal patient cooperation is required during the test, as the device can capture the mechanical properties of the respiratory system while the patient breathes normally. It is suitable for both adult and pediatric patients (ages 4 years and above).

The test duration is brief: the mono-frequency test lasts 12 seconds, while the multi-frequency test lasts 24 seconds. During the test, the patient should breathe normally by holding their cheeks.

The Antlia Pro device should not operate continuously. Each "Act" (patient's breathing operation) lasts approximately 24 seconds, followed by a 2-minute rest period. This cycle ensures that patients do not experience discomfort due to the forced oscillations.

5.2. Intended users

The **Antlia Pro** is designed for use by healthcare professionals with expertise in respiratory care, including:

- **Pulmonologists**
- **Chest physicians**
- **General physicians**
- **Respiratory therapists**
- **Lab technicians**
- Other trained personnel in hospitals, clinics, and healthcare facilities.

The device is intended to assist professionals in accurately diagnosing, monitoring, and managing respiratory conditions, ensuring effective treatment and care for patients.

5.3. Installation and Setup

5.3.1. Unpacking & Inspection

- Before opening, inspect the Antlia Pro packaging for damage during shipping.
- If the box appears damaged, do not open the box and immediately contact iCaltech Technical Support or your local representative.
- Open the Antlia Pro device packaging carefully without allowing sharp objects to protrude into the box.
- Remove packing foam and carefully remove all items from the box.
- Visually inspect all items, and make sure that you obtained all system components as per Antlia Pro Package list.

5.3.2. Parking Position

When device is not in use or being transported, the device must be set to the transport position as shown in the below picture.

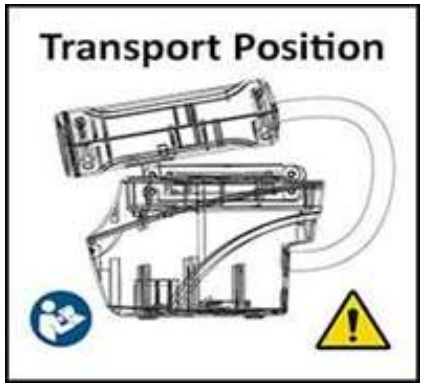


Figure 9: Transport Position of Antlia Pro

Note: During device transport, the Power Adapter cable, USB cable and Accessories shall be disconnected from the device.

5.3.3. Installation

Before starting the installation and operation of the device, make sure that the environmental condition reported in section 2.6 are met and that the laptop/ computer system configuration meets the following requirements:

a) Processor: Intel i5 processor or above
b) Operating System: Windows 10/11 - 64 bit or more
c) RAM: 16 GB or more
d) Free Space in Hard Drive: 2 GB or more
e) Display: High Definition (HD) 1280 × 720

5.3.4. Positioning

- Place the Antlia Pro Unit on a desk or other flat surface within easy reach of the intended patient location during the measurement. Position the computer in such away, that the operator can easily view both the patient and the computer screen simultaneously.

Figure 10: Positioning of the Device and Laptop

- Connect the power supply adapter to its jack connector, which is located on the rear side of the device, and plug the adapter into the power socket.

Figure 11: Connecting the power supply adaptor

- Connect the PC to the unit using Type B - USB cable and Switch on the device by pressing power ON button, which is located on rear side of the device.
- In the power ON condition, the Green LED will blink on LED panel located on the Top panel of the unit, which is on the front side of the device.

6. Operating Instructions

Before operating the device, the operator should be aware of safety information about the device, including symbols marked on the product and package. They should also understand contraindications, warnings, and cautions that may arise during operation and their potential causes

6.1. Safety Information

6.1.1. General Safety Instructions

To ensure the safety of patients, operators, and the device, follow these guidelines:

- Inspect power cords and plugs for damage before powering on the device. Replace damaged components through authorized personnel only.
- Keep this User Manual accessible for the users and adhere strictly to the instructions provided.
- Use only accessories and consumables recommended by iCaltech. Unapproved items may compromise safety and device performance.
- Protect all cables from heat, sharp objects, and rough surfaces. Regularly inspect cables for damage.
- Avoid exposing the device to direct sunlight or excessive light (over 1500 lux).
- Operate the device within the specified environmental conditions to ensure optimal performance.
- The device should not be used with other medical equipment unless explicitly approved by **iCaltech.**
- Ensure the breathing circuit is free from contaminants to prevent serious health risks, including aspiration and life-threatening conditions.
- Handle patient data as per the latest health data protection laws and regulations.

6.1.2. Equipment Safety

Improper handling of the Antlia Pro may lead to device damage, patient harm, or safety risks. **iCaltech** disclaims responsibility for:

- Operating the device in any manner other than as specified in this User Manual.
- Performing upgrades, adjustments, modifications, or repairs by personnel who are not contracted or authorized by iCaltech.
- Failing to replace components that affect the device's safe operation with original spare parts in the event of a malfunction.
- Using the device in an environment where the electrical wiring does not comply with local safety regulations.

6.1.3. Warning and Caution Notes

Warning: Indicates a potential hazard that may result in serious injury or death if ignored.

Caution: Indicates a hazard that may cause minor or moderate injury, or equipment damage if not observed.

WARNING

Do not open the device, as it contains no user serviceable parts inside.

WARNING

If any part of the device or its accessories such as Power adapter is changed, device performance may degrade performance and result in inaccurate results.

WARNING

Improper use of the device:

Do not expose the device to rain, moisture, or wet surfaces.

WARNING

If any part of the device or its accessories (e.g., power adapter, cables) is damaged or missing, discontinue use immediately. Using a damaged component could result in injury to the patient or operator.

WARNING

To mount the device, use a table of appropriate size and structure capable of supporting its weight.

WARNING

Unsuitable environmental conditions can affect the device's performance and lead to improper measurements. Use the device only under the specified environmental conditions.

WARNING

Do not modify the device in any way. Modifications can compromise safety and cause measurement errors.

WARNING

Do not position the device in a way that makes it difficult to disconnect the power cord in an emergency.

WARNING

The iCaltech filter and nose clip are intended for single use only.

WARNING

Do not perform service or maintenance activities while the device is in use with a patient.

WARNING

Do not use this device in the presence of flammable anesthetics.

CAUTION

Operation of the Device by Untrained or Unauthorized Users

Risk of incorrect measurements due to the misinterpretation of system information.

The system should only be operated by individuals with proper training.

CAUTION

Use of Unapproved Software or Hardware Components

Risk of malfunctions that could pose a hazard to patients and equipment.

Only use software or hardware components provided by iCaltech. The use of unauthorized accessories will void the warranty.

CAUTION

Modification to the System

Risk of system malfunction.

Users are not authorized to change the calibration or modify/upgrade any software. Please contact iCaltech service team for assistance.

CAUTION

Pulling/Pinching the Source Tube

Risk of incorrect measurements or results.

Users should not damage the source tube. The device should operate by trained persons, and care should be taken during transportation.

If the source tube is damaged, please contact iCaltech service team for assistance.

CAUTION

Blockage of Inertance Tube

Risk of Malfunction.

Users must not block the inertance tube opening. Before conducting tests, ensure that there is no blockage near the opening of the inertance tube.

CAUTION

Electromagnetic Disturbance

If the unit hangs or resets due to electromagnetic disturbance, the operator conducting the test must reconnect the device to the app and perform a new test with the patient. Since multiple breathing tests are required from the patient, and tidal breathing (normal breathing) is needed, this degradation is acceptable.

CAUTION

System Date and Time

The system date and time on the computer must be accurate. If not, please update it to ensure that the date and time on the report are printed correctly, as they are derived from the computer's settings.

CAUTION

Application stops the test if the device runs continuously in start mode for 60 seconds.

The Test stops, if no patient breathing is detected.

CAUTION

Use only iCaltech recommended filters. Using any other filters may lead to incorrect results and impact the safe operation of the product.

6.1.4. Contraindications

Device is not supposed to be used for patients with any of the following condition:

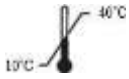
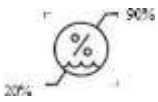
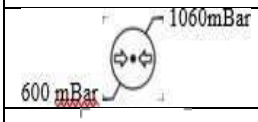
- Acute disorders affecting test performance (e.g., Vomiting, nausea, vertigo)
- Recent eye (for example, cataract), thoracic and abdominal surgery
- Oral or facial pain exacerbated by a BV Filter.

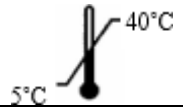
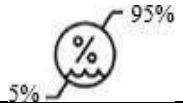
- Recent myocardial infarction

Additionally, please do not operate the device.

- In CT and MRI environment.
- In OT environment.
- Along with high surgical equipment.

6.1.5. Symbols

Symbol	Description/ Meaning of Symbol
	This symbol indicates that the device operates on DC current.
	General warning sign
	This symbol instructs the user to consult the device's instructions for proper usage information.
	Accompanied by a date, this symbol indicates the device's manufacturing date.
	Serial number. This symbol should be accompanied by the device's serial number.
	Refers the legal Manufacturer (iCaltech Innovations Pvt Ltd)
	PE B applied part: iCaltech Filter and Nose clip are applied parts
	Temperature Limitation
	Humidity Limitation
	Atmospheric pressure limitation
	Class II
	Waste must be controlled according to local regulations.
	Keep away from rain

	Non-Sterile
	Do not use if package is damaged.
IP21	Ingress Protection IP2X: Protected against solid objects over 12.5mm IPX1: Protected against vertically falling drops of water
	Universal serial bus (USB) port
	“ON” (power)
	“OFF” (power)
	DC Jack connector
Rating	⎓ 12V 3A max
	Storage and Transportability Temperature Limitation
	Storage and Transportability Humidity Limitation
	Fragile, handle with care
	This Side UP Symbol During of shipping or delivery, the carton should be kept upright.
	Stacked Boxes Maximum carton stack is 4.
	Device Transport position
℞ ONLY	A medical prescription.

6.2. Operational Training

The device should be operated by a well-trained user. An on-site training for the Antlia Pro device is provided by a Customer Service Engineer or a 3rd party service engineer assigned by iCaltech during system installation. This training covers basic system operation and safety handling.

The following training should be provided to users:

1. Device Handling: Proper techniques for handling and transporting the device.
2. FOT Tube Positioning: Adjusting the height of the FOT Tube as per the patient height.
3. Usage of Single-use Accessories: Correct use of nose clips and iCaltech filters.
4. Device Verification Procedure: Steps involved in verifying the device accuracy.
5. Patient Positioning and Device Operation
6. Connection of accessories while performing test and device verification
7. Software Operation: For the Device Verification, Patient Testing and Report Generation

Apart from the above, iCaltech will provide necessary documentation and training to service personnel for assisting in parts repair.

6.3. Operating Procedure

6.3.1. User Login and Device Connection

- First, turn on the power supply to the device. Then, connect the device to the PC in which Antlia pro application installed, by using Type B USB cable. Then open the Antlia pro application.
- Note: The Antlia Pro application is provided by iCaltech and will be installed on the user's desktop or laptop by our representative during the device installation, following the instructions outlined in Chapter 7 of this manual.

Figure 12: Device in Ready to use mode

- Enter valid Username and Password with valid credentials and click "Login."

Figure 13: Antlia Pro Application Login Page

- The Home screen will be displayed on your PC as shown in figure 14.
- Click on the “Connect” icon, located in the top right corner of the home screen.

Figure 14: Antlia Pro Home Screen

- When the device is connected to the application, the status will change to "Connected", as shown in figure 15.

Figure 15: Device Connection Status on Home Screen

6.3.2. Device Verification Test

Each Antlia Pro device undergoes rigorous quality control to ensure maximum measurement accuracy. The sensors and electronics within the Antlia Pro are designed for excellent long-term stability. However, daily field verification is crucial to maintain system accuracy and promptly detect any potential changes or damage that may have inadvertently occurred.

This verification can be conducted by comparing the device's measurement to a known impedance value. Each Antlia Pro device is supplied with a specific

reference impedance device for this verification. The measured impedance value should be within a 10% tolerance of the known reference value.

Device Verification Procedure:

- Connect the reference impedance to the FOT tube as shown in figure 16.

Figure 16 Reference Impedance connected to FOT tube

- Arrange the device and log in to the Antlia Pro application and connect the device with application as illustrated in section 6.3.1.
- Click on "Verification" button followed by the "Start" button. The device will initiate the verification process. The impedance value will begin displaying in the box on the left-hand corner under "Z(kPa/L/Sec)" after a few seconds as shown in the figure 17.

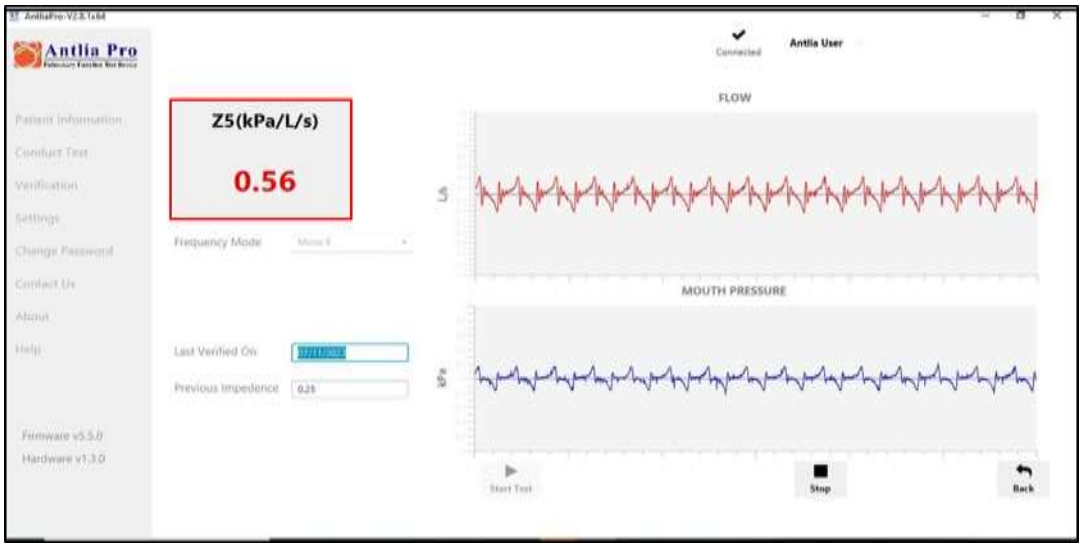


Figure 17: Device verification - Impedance Value Check

- If the value appears in "BLACK" color, it indicates that the device accuracy is within the acceptable accuracy limit. The user can then proceed with patient

testing.

- If the value appears in "RED" color, it indicates that the device accuracy is outside the acceptable limit. In this case, don't proceed with the patient testing and contact the iCaltech Service team for assistance.

6.3.3. Performing Patient Tests

During device verification testing, if the impedance values fall within the acceptable accuracy limits, proceed to patient testing. Patient testing comprises four major steps:

1. Patient Information Entry
2. Patient Positioning
3. Performing the Test
4. Results and Reporting

6.3.3.1. Patient Information Entry

- Go to Home screen on the application page → Click 'Patient Information' → 'Add Patient' (as shown in Figure 18).

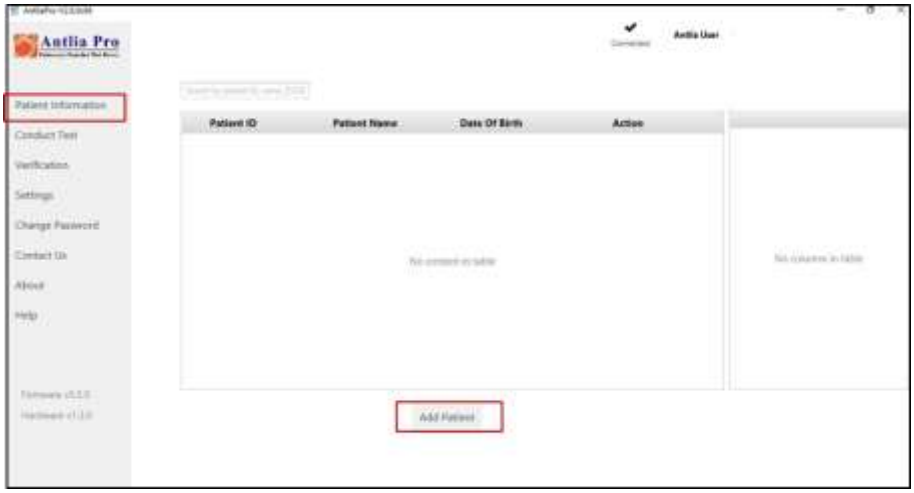


Figure 18: Patient Information Page

- Enter all patient information in the given fields, as shown in the figure 19.

Figure 19: Patient Information Entry Page

- After entering the patient details, click the "Save and Conduct Test" button to save the patient details and begin the test immediately.
- If you wish to add details for multiple patients and conduct their tests individually later, click the "Save and Add More" button to continue adding patient records. Refer to figure 19 for a visual reference.

6.3.3.2. Patient Positioning

- Proper patient posture is crucial for accurate measurements.
- Place the device on a table as shown in the figure 20.

Figure 20: Positioning of Antlia Pro for Patient Test

- To perform the test correctly, position a chair in front of the table where the device is installed.
- Seat the patient in front of the device, ensuring they maintain an upright posture.
- Connect the iCaltech filter to the FOT tube of the device as illustrated in figure 21.

Figure 21: iCaltech Filter Connection

- Adjust the position of FOT tube to the patient mouth level by using the adjustable arm of the device.
- The technician must exercise caution with the source tube while adjusting the stand to prevent damage.
- Instruct patients to wear nose clips to prevent air leakage.
- During the test run, it is essential for the patient to hold their cheeks with their hands as shown in the figure 22 to enhance the reliability of the measurement.

Figure 22: Patient Positioning

- The patient should keep their chin up and breathe normally throughout the test.
- Ensure that there are no air leaks around the lips and iCaltech filter.

6.3.3.3. Performing the Test

The Antlia Pro software is designed to assess respiratory function in accordance with the 2019 ERS guideline for Oscillometry. Therefore, a complete Antlia Pro patient test requires at least three separate, valid measurements. The overall test results are calculated as the average of these three tests.

Measurement Modes:

Mono Frequency: The PFT test should be carried out for 12 seconds at a frequency range of 5 to 19 Hz.

Multi Frequency Mode: The PFT test should be carried out in mixed frequency mode with a frequency range of 5, 11, 13, 17, 19, 23, 29, 31, and 37 Hz.

Coefficient of Variation (COV) Limits: In Mixed mode, the COV value should be less than 10% for adults and less than 15% for pediatrics for all three attempts. If the COV value exceeds these limits, the patient should repeat the test.

Test Stages:

The App supports conducting tests in two stages:

1. **Pre-test:** The Pre-test is selected when the patient is undergoing the test for the first time.
2. **Post-test:** Following the Pre-test, and based on the results, the physician may administer a bronchodilator, and then the Post-test is conducted.

Performing the Test:

- After entering the patient information and position the patient for the testing, click on “Save and Conduct the Test”.
- If patient information already exists in the database, the user has to select that patient from the conduct test screen.
- On the Home screen, Click the "Conduct test" button. This will display a list of patients added in the database. (Refer figure 23 for the visual reference).

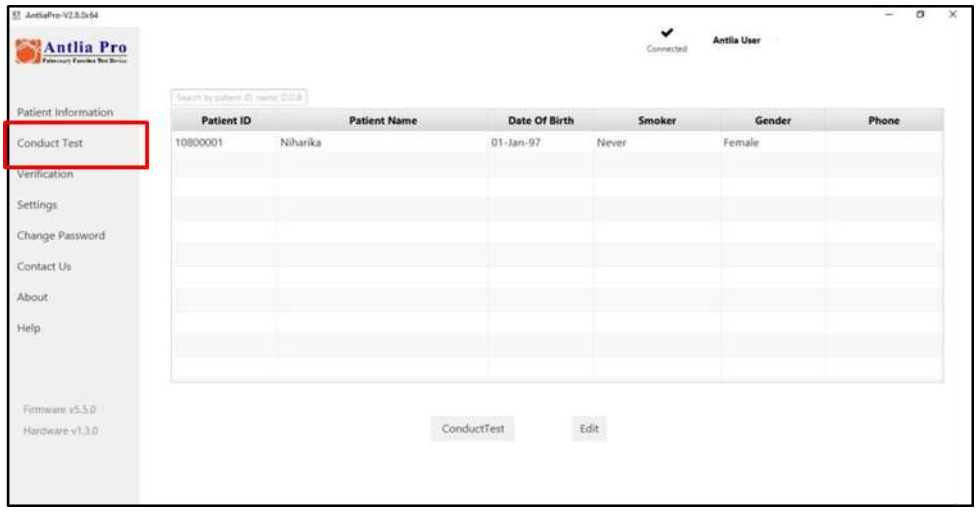


Figure 23: Patient Database on Conduct Test Page

- Select the desired patient from the list and click the "Conduct test" button located at the bottom of the page (as shown in Figure 24).

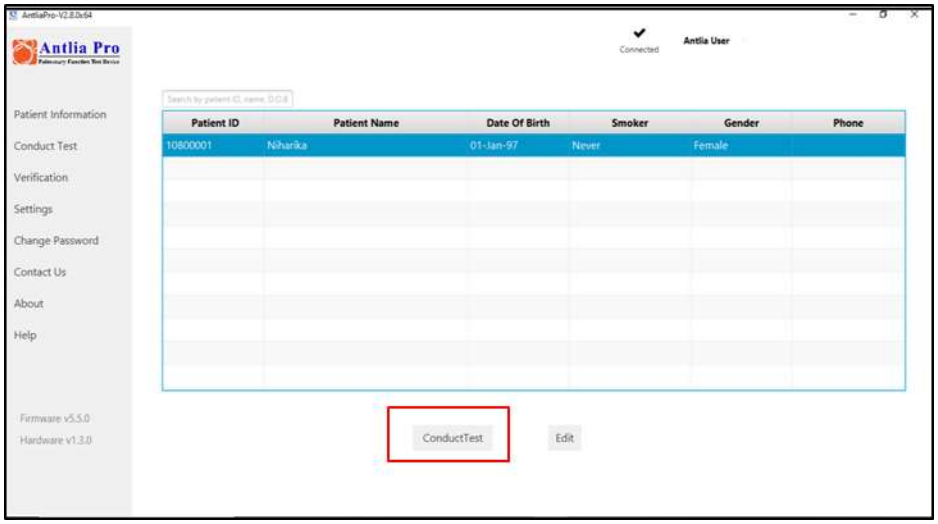


Figure 24: Selecting Patient for Testing

- By default, the app will display the Pre-test option with Multi-mode selected as shown in figure 25.

Figure 25: Conduct Test Page

- The technician can select the Pre-test or Post-test option and the Multi or Mono-mode option as per their requirements.
- Select the Frequency mode ("Multi" or "Mono") from the dropdown box as shown in the figure 26.

Figure 26: Frequency Mode Selection

- Click the "Start Test" button and wait for the "Start Breathing Test" instruction to appear on the screen.

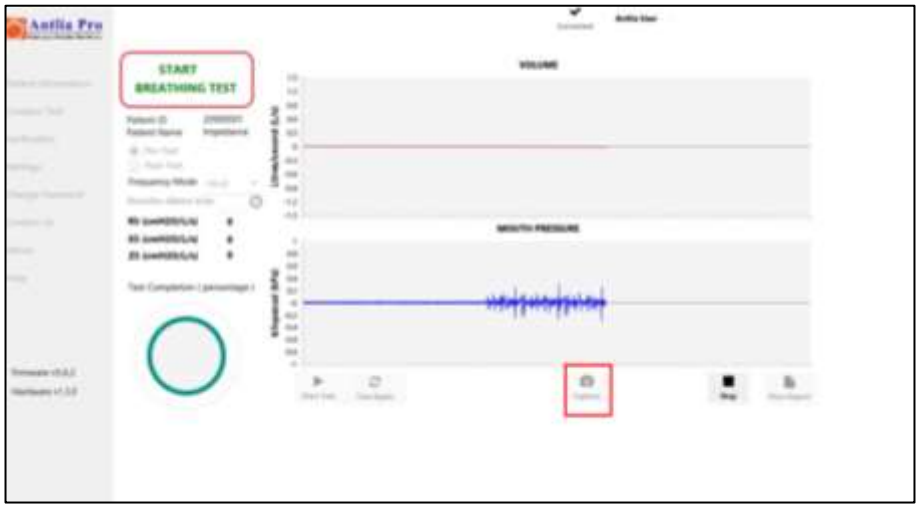


Figure 27: Start Breathing Test Instruction

- Instruct the patient to breathe through their mouth while gently holding their cheeks together to ensure a proper seal around the iCaltech filter and prevent any air leakage.
- Whenever the patient's breathing synchronizes with the waveform, click the "Capture" button.

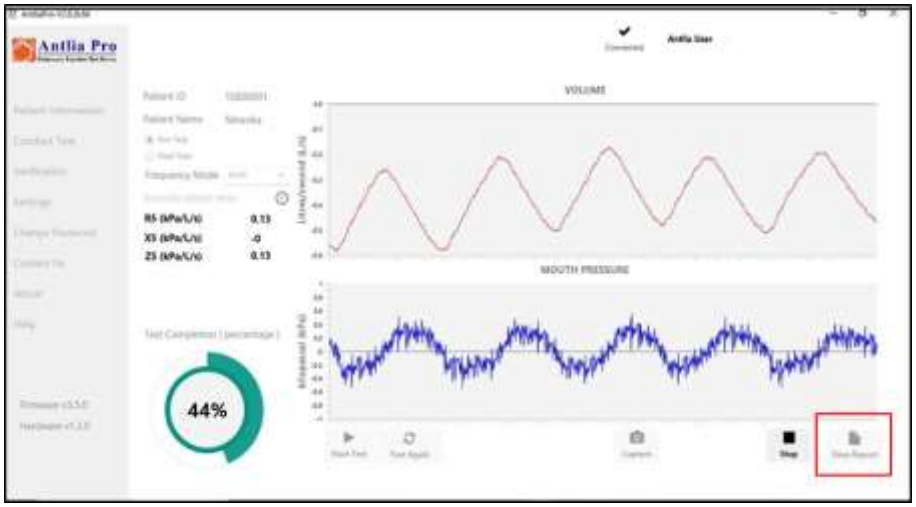


Figure 28: Volume and Mouth Pressure Measurement

- After test completion, click the "View Report" button to display the test report on the screen.

Figure 29: Test Report Page

- Click the "Save as PDF" button to save the patient report of the current test.
- By clicking the "Test again" button, perform 3 trials with a COV value less than 10% for adults or less than 15% for pediatrics.

6.3.3.4. Results and Reporting

Real time graph: When the patient is breathing, we can see volume and mouth pressure graphs in the App.

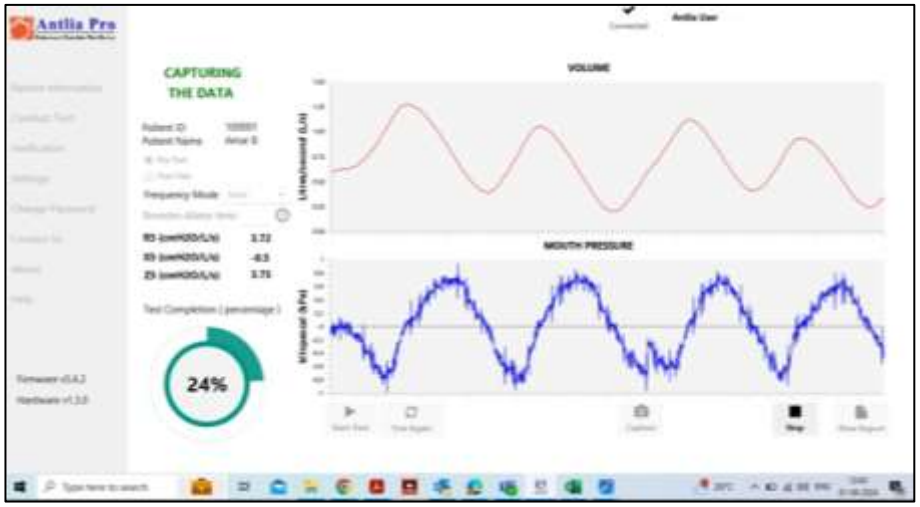


Figure 30: Real Time Graph of Volume and Mouth Pressure Measurement

After completing the pre-test, ‘Save’ button must be pressed. The report will then be stored on the PC in pdf format at user defined location. After conducting post-test for the same patient, the ‘Save’ button must be pressed again. A consolidated report of the pre-

test and post-test results for the patient will then be saved in pdf format at user defined location. Finally, a printout of post-test report, which also includes the pre-test results, can be taken.

To save the report, follow the procedure below:

- After performing the test, the screen will automatically transition to the Report screen.
- Click the 'Save to PDF' button to save the report as shown in the figure 31.

Figure 31: Report screen Page

- Save the PDF file to the desired location on the PC.

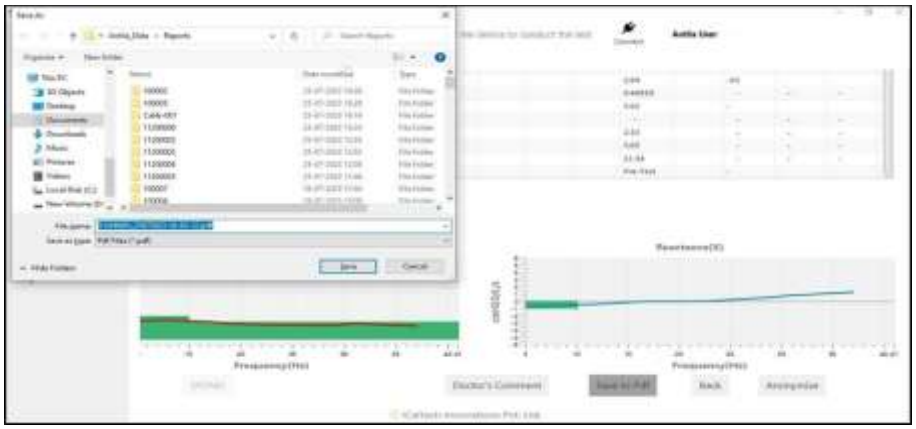


Figure 32: Saving Report Saving to the PC

- The user can take a printout of the patient report from the PC.
- Go to the location where the report was saved. Open the PDF file. The report will look as depicted below.

Device interpretation with report:

I. Patient with normal condition:

Respiratory and Healthy breath

Bangalore

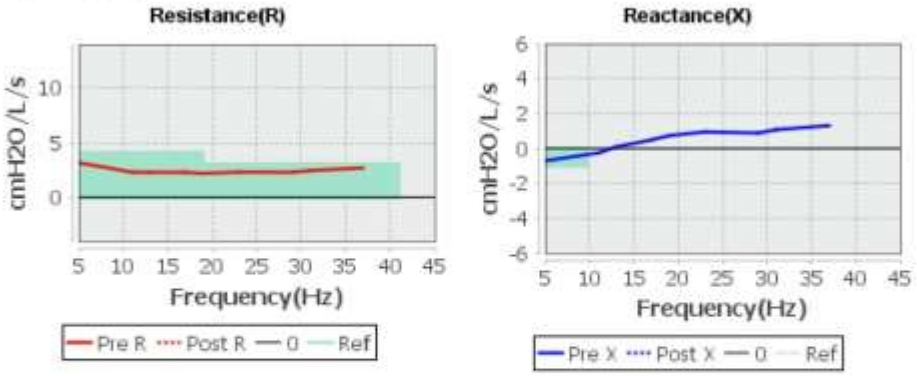
Patient Name : Test		Patient ID	: 10030	Gender: Female		Smoking status: Never	
D.O.B	: 01-Jan-99	Age	: 25 years	Height: 163.0 cm		Weight	: 72.0 kg
BMI	: 27.1	Conducted by: sri		Doctor: Dr.Latha		Test Date	: 18-Dec-24

RESPIRATORY OSCILLOMETRY

Parameters	Cut Off*	PRE	% Δ1 (pre)	POST	% Δ1 (post)	%Change
Z5 ($cmH_2O/L/s$)	4	3.22 (COV: 1.7)	-20 (n)	-	-	-
Z20 ($cmH_2O/L/s$)	-	2.27	-	-	-	-
R5 ($cmH_2O/L/s$)	4	3.14 (COV: 1.5)	-22 (n)	-	-	-
R5Insp ($cmH_2O/L/s$)	-	3.06	-	-	-	-
R5Exp ($cmH_2O/L/s$)	-	3.69	-	-	-	-
R20 ($cmH_2O/L/s$)	3	2.15	-28 (n)	-	-	-
R5-R19 ($cmH_2O/L/s$)	1	0.99	-1 (n)	-	-	-
X5 ($cmH_2O/L/s$)	-1	-0.71	29 (n)	-	-	-
X5insp ($cmH_2O/L/s$)	-	-1.27	-	-	-	-
X5exp ($cmH_2O/L/s$)	-	-0.09	-	-	-	-
AX (cmH_2O/L)	4	3.14	-	-	-	-
Fres (Hz)	<12	12.51	-	-	-	-

Bronchodilator % Change		
R5	-	-
R5-R19	-	-
X5	-	-
AX	-	-
Fres	-	-

R and X graph:



Printed on: 18/12/2024 15:47:56 with iCaltech Innovations Antlia Pro device *Sahi's etal ET AL research paper 2023

Page 1 of 3

Respiratory and Healthy breath

Bangalore

Patient Name : Srinithi One nienty four		Patient ID	: 10030	Gender : Female		Smoking status : Never	
D.O.B	: 01-Jan-99	Age	: 25 years	Height	: 163.0 cm	Weight	: 72.0 kg
BMI	: 27.1	Conducted by: sri		Doctor	: Dr.Latha	Test Date	: 18-Dec-24

Breathing Parameter	PRE	POST
Resp. Rate/min	26	-
V_T (ml)	355	-
Tinsp (s)	1	-
Texp (s)	1	-

Pre Test Table

Parameters	Cut Off	Act 1	Act 2	Act 3	Avg	%Al
R5 (cmH2O/L/s)	4	3.09	3.19	3.15	3.14(COV: 1.5)	-22 (n)
R11 (cmH2O/L/s)	4	2.24	2.28	2.26	2.26	-43 (n)
R19 (cmH2O/L/s)	3	2.18	2.15	2.13	2.15	-28 (n)
R5-19 (cmH2O/L/s)	1	0.91	1.04	1.02	0.99	-1 (n)
X5 (cmH2O/L/s)	-1	-0.66	-0.69	-0.8	-0.71	29 (n)
X11 (cmH2O/L/s)	-	-0.23	-0.3	-0.27	-0.27	-
X19 (cmH2O/L/s)	-	0.76	0.69	0.73	0.73	-
Z5 (cmH2O/L/s)	4	3.16	3.28	3.25	3.22(COV: 1.71)	-20 (n)
Z19 (cmH2O/L/s)	-	2.31	2.28	2.25	2.27	-
Delta X5 (cmH2O/L/s)	-	0.03	0.98	1.27	1.06	-
AX (cmH2O/L)	4	2.76	3.25	3.4	3.14	-
CO @ 5Hz	-	0.93	0.92	0.93	-	-
CO @ 19Hz	-	0.98	0.98	0.98	-	-
Fres (Hz)	<12	12.2	12.73	12.61	12.51	-
X5insp (cmH2O/L/s)	-	-1.13	-1.3	-1.37	-1.27	-
X5Exp (cmH2O/L/s)	-	-0.02	0.09	-0.35	-0.09	-
R5insp (cmH2O/L/s)	-	3.07	3.16	2.94	3.06	-
R5Exp (cmH2O/L/s)	-	3.46	3.67	3.96	3.69	-
X5EndInsp (cmH2O/L/s)	-	-1.2	-1.56	-1.42	-1.39	-
X5EndExp (cmH2O/L/s)	-	0.02	-0.03	-0.54	-0.18	-
R5EndInsp (cmH2O/L/s)	-	2.89	2.83	2.67	2.8	-
R5EndExp (cmH2O/L/s)	-	3.38	3.6	3.27	3.42	-
Test Time	-	15:44	15:45	15:47	-	-

Printed on: 18/12/2024 15:47:56 with iCaltech Innovations Antlia Pro device *Salvi's etal ET AL research paper 2023

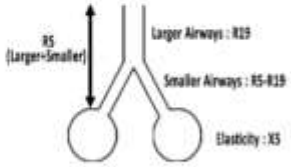
Page 2 of 3

Respiratory and Healthy breath

Bangalore

Patient Name : Srinithi One nienty four		Patient ID	: 10030	Gender : Female	Smoking status : Never
D.O.B	: 01-Jan-99	Age	: 25 years	Height : 163.0 cm	Weight : 72.0 kg
BMI	: 27.1	Conducted by: sri		Doctor : Dr.Latha	Test Date : 18-Dec-24

Device Interpretation:



*Normal

*(^) refers to Increment *(n) refers to Normal *(v) refers to Decrement * AI refers to Anomaly Index * Interpretation is done w.r.t. cut off values

Doctor's Inference:

Test conducted by

Doctor's Signature

Printed on: 18/12/2024 15:47:56 with iCaltech Innovations Antlia Pro device *Salvi's etal ET AL research paper 2023

Page 3 of 3

II. Patient with abnormal condition:

Respiratory and Healthy breath

Dr.Vinayak
MBBS

Kolkata

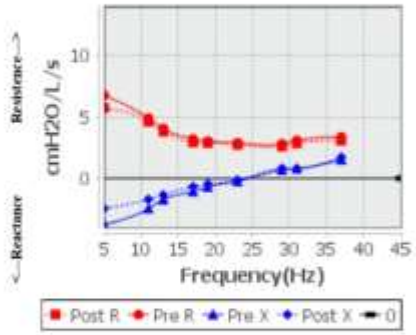
Patient Name	: Samyukta	**Patient ID**	: 700061	**Gender**	: Male	**Smoking status**	: Never
D.O.B	: 01-Jan-65	**Age**	: 58 years	**Height**	: 162.0 cm	**Weight**	: 70.0 kg
BMI	: 26.67	**Conducted by**	: Durga	**Doctor**	: Dr.Naveen	**Test Date**	: 12-Dec-23

RESPIRATORY OSCILLOMETRY

Parameters	Cut Off*	PRE	° A1 (pre)	POST	° A1 (post)	%Change
Z5 (unit: O/L/s)	4	7.75 (COV: 10.9)	94 (°)	6.23 (COV: 5.2)	58 (°)	-19.7
Z19 (unit: O/L/s)	4	5.11	-22 (n)	2.91	-27 (n)	-8.21
R5 (unit: O/L/s)	4	6.77 (COV: 7.3)	69 (°)	5.72 (COV: 5.4)	43 (°)	-15.5
R5insp (unit: O/L/s)	-	5.74	-	5.03	-	-12.3
R5Exp (unit: O/L/s)	-	8.76	-	7.52	-	-14.15
R19 (unit: O/L/s)	3	3	0 (°)	2.87	-4 (n)	-4.31
R5-R19 (unit: O/L/s)	1	3.76	276 (°)	2.84	184 (°)	-24.4
X5 (unit: O/L/s)	-1	-3.76	-276 (v)	-2.46	-146 (v)	34.52
X5insp (unit: O/L/s)	-	-4.0029	-	-3.346	-	16.41
X5exp (unit: O/L/s)	-	-3.9414	-	-1.5187	-	61.46
AX (unit: O/L)	4	32.73	-	22.23	-	-32.09
Fres (Hz)	<12	24.4	-	23.9	-	-2.02

Bronchodilator % Change		
R5	-15.5	Decr
R5-R19	-34.4	
X5	34.52	Incr
AX	-32.09	
Fres	-2.02	

R and X graph:



Printed on: 12/12/2023 16:19:29 with iCaltech Innovations Antlia Pro device*Salvi's etal ET AL research paper 2023; Only for adults > 18 years Page 1 of 4

Respiratory and Healthy breath

Kolkata

Patient Name	: Samyukta	**Patient ID**	: 700061	**Gender**	: Male	**Smoking status**	: Never
D.O.B	: 01-Jan-65	**Age**	: 58 years	**Height**	: 162.0 cm	**Weight**	: 70.0 kg
BMI	: 26.67	**Conducted by**	: Durga	**Doctor**	: Dr.Naveen	**Test Date**	: 12-Dec-23

Breathing Parameter	PRE	POST
Resp. Rate/min	22.67	24.35
V_T (ml)	624	547
T insp (s)	1.18	1.15
T exp (s)	1.44	1.31

Pre-Test Table

Parameters	Cut Off	Act 1	Act 2	Act 3	Avg	°A.I
R5(cmH2O/L/s)	4	7.17	6.91	6.22	6.77(COV: 7.3)	69 (°)
R11(cmH2O/L/s)	4	4.67	4.99	5.01	4.89	22 (°)
R19(cmH2O/L/s)	3	2.88	3.04	3.09	3	0 (°)
R5-19(cmH2O/L/s)	1	4.29	3.87	3.13	3.76	276 (°)
X5(cmH2O/L/s)	-1	-4.66	-3.69	-2.93	-3.76	-276 (v)
Z5(cmH2O/L/s)	4	8.56	7.83	6.87	7.75(COV: 10.88)	94 (°)
Z19(cmH2O/L/s)	4	3.09	3.13	3.1	3.11	-22 (n)
AX (cmH2O/L)	4	43.96	32.81	21.42	32.73	-
CO @ 5Hz	-	0.86	0.88	0.88	-	-
CO @ 20Hz	-	0.96	0.96	0.96	-	-
Fres (Hz)	<12	26.22	24.93	22.04	24.4	-
Test Time	-	15:13	15:14	15:15	-	-
X5Insp (cmH2O/L/s)	-	-4.44	-3.67	-3.9	-4	-
X5Exp (cmH2O/L/s)	-	-6.78	-3.54	-1.5	-3.94	-
R5Insp (cmH2O/L/s)	-	6.08	5.5	5.63	5.74	-
R5Exp (cmH2O/L/s)	-	9.54	8.31	8.42	8.76	-
X5EndInsp (cmH2O/L/s)	-	-3.95	-3.31	-3.19	-3.48	-
X5EndExp (cmH2O/L/s)	-	-9.53	-5.6	-3.04	-6.06	-
R5EndInsp (cmH2O/L/s)	-	5.25	5.01	4.93	5.07	-
R5EndExp (cmH2O/L/s)	-	8.37	9	9.11	8.83	-

Respiratory and Healthy breath

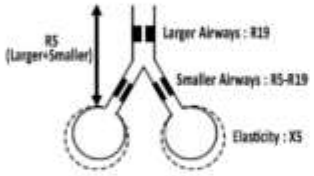
Kolkata

Patient Name : Samyukta		Patient ID	: 700061	Gender : Male		Smoking status : Never	
D.O.B	: 01-Jan-65	Age	: 58 years	Height	: 162.0 cm	Weight	: 70.0 kg
BMI	: 26.67	Conducted by: Durga		Doctor	: Dr.Naveen	Test Date	: 12-Dec-23

Post Test Table

Parameters	Cut Off	Act 1	Act 2	Act 3	Avg	*A.I	%chg
R5(cmH2O/L/s)	4	6.07	5.59	5.5	5.72(COV: 5.37)	43 (^)	-15.5
R11(cmH2O/L/s)	4	4.83	4.69	4.37	4.63	16 (^)	-5.34
R19(cmH2O/L/s)	3	2.91	2.84	2.87	2.87	-4 (n)	-4.33
R5-19(cmH2O/L/s)	1	3.16	2.74	2.63	2.84	184 (^)	-24.4
X5(cmH2O/L/s)	-1	-2.56	-2.5	-2.33	-2.46	-146 (v)	34.52
Z5(cmH2O/L/s)	4	6.59	6.12	5.97	6.23(COV: 5.18)	56 (^)	-19.7
Z19(cmH2O/L/s)	4	2.96	2.9	2.88	2.91	-27 (n)	-6.21
AX (cmH2O/L)	4	23.61	24.51	18.56	22.23	-	-32.09
CO @ 5Hz	-	0.92	0.86	0.85	-	-	-
CO @ 20Hz	-	0.97	0.97	0.97	-	-	-
Fres (Hz)	<12	24.1	24.36	23.24	23.9	-	-2.02
Test Time	-	15.39	15.40	15.41	-	-	-
X5insp (cmH2O/L/s)	-	-3.35	-3.38	-3.3	-3.35	-	16.41
X5Exp (cmH2O/L/s)	-	-2.17	-1.59	-0.6	-1.52	-	61.46
R5insp (cmH2O/L/s)	-	5.37	5.11	4.61	5.03	-	-12.3
R5Exp (cmH2O/L/s)	-	8.05	7.56	6.94	7.52	-	-14.15
X5EndInsp (cmH2O/L/s)	-	-3.1	-3.03	-2.99	-3.04	-	12.58
X5EndExp (cmH2O/L/s)	-	-3.38	-3	-1.59	-2.66	-	56.13
R5EndInsp (cmH2O/L/s)	-	4.86	4.55	3.86	4.42	-	-12.69
R5EndExp (cmH2O/L/s)	-	8.5	8.02	7.56	8.02	-	-9.07

Device Interpretation:



Larger Airway Obstruction : 100.11 %

Smaller Airway Obstruction : 376 %

Lung Elasticity : 376 %

** (^) refers to Increment * (n) refers to Normal *(v) refers to Decrement * A.I refers to Anomaly Index * Interpretation is done w.r.t. cut off values*

Printed on: 12/12/2023 16:19:29 with iCaltech Innovations Antlia Pro device*Salvi's etal ET AL research paper 2023; Only for adults > 18 years Page 3 of 4

Respiratory and Healthy breath

Kolkata

Patient Name	: Samyukta	**Patient ID**	: 700061	**Gender**	: Male	**Smoking status**	: Never
D.O.B	: 01-Jan-65	**Age**	: 58 years	**Height**	: 162.0 cm	**Weight**	: 70.0 kg
BMI	: 26.67	**Conducted by:**	Durga	**Doctor**	: Dr.Naveen	**Test Date**	: 12-Dec-23

	Pre - Post % change	Absolute Change
R5 (cmH2O/L/s)	-15.5 %	-1.1
R19 (cmH2O/L/s)	-4.33 %	-0.1
R5-R19 (cmH2O/L/s)	-24.4 %	-1
X5 (cmH2O/L/s)	34.52 %	-1.3
AX (cmH2O/L)	-32.09 %	-10.5

** - Doctor's review comments required*

Doctor's comments:

Test conducted by **Doctor's Signature**

6.4. Care And Maintenance

Accessories Disposal:

- iCaltech filters are for single-use only. Using them correctly helps prevent the transmission of diseases and infections between patients.
- Upon completion of a patient test, ensure proper disposal of single-use supplies, including the iCaltech filter, in a suitable waste collection container according to your institution's guidelines and regulations.

Storage and Transportation:

- When not in use for extended periods, cover the device with the dust cover.
- For long-term storage or transportation, use the original Antlia Pro packaging.
- After storing or transporting in cold or warm environments, allow several minutes for the device to acclimatize to room temperature before use. This ensures accurate measurement results.

Daily Maintenance:

- Perform daily device verification before each use (refer to section 6.2: Device Verification Test).

Annual Maintenance:

- The Antlia Pro device requires annual service by iCaltech-authorized service providers.
- Contact iCaltech Technical Support or your local representative to schedule service.
- Interchangeable or detachable parts specified by iCaltech must be replaced by a service engineer.
- Component or part failures must be addressed according to the iCaltech Service Protocol.

Contact Details:

- Toll-Free Number: 1800-599-3196

Expected Service Life:

- The expected service life is five years from the date of purchase.

Routine Cleaning:

- Proper use and disposal of disposable antibacterial filters and nose clips contribute to infection prevention by minimizing the risk of disease transmission between patients and reducing the need for extensive device cleaning.
- Regularly clean the exterior surfaces of the device with a mild detergent solution and a soft cloth.

⚠ **CAUTION**
Do not use harsh chemicals, abrasive cleaners, alcohol, or sterilization liquids on the device surface.

Disposal of Device Post Service Life:

- At the end of its service life, dispose of the device according to all local regulations for electrical and electronic waste.
- Improper disposal can harm the environment and human health.
- The crossed-out wheeled bin symbol indicates that the product must be taken to a designated collection point for proper disposal.

6.5. Troubleshooting

While using the device, users may encounter common operating problems or errors. Below is a list of the most frequent issues that may occur during normal use, along with their possible solutions. If you experience a problem not listed here, please contact the iCaltech Service Team for further assistance.

List of Common Problems and Solutions:

Sl. No.	Problem	Possible Cause	Solution
1	Unit fails to Power ON; all power indicators remain unlit.	Power cable not connected	Check if power cable is properly connected to the device and the power outlet
		No power at the outlet	Check if power is available at the outlet. Try plugging the device into a different outlet.
		Power button is in the OFF condition	Press the power ON button to turn on the device.
2	Device not connecting with APP	No power on outlet	Switch ON the device
		USB cable not properly connected	Disconnect and reconnect the USB cable securely.
		PC not Compatible with the software	Check if the COM port drivers are installed on your PC and confirm PC meets the specifications required for the software
3	RED LED is glowing continuously	Software error	Check error messages on screen and proceed accordingly.
		Internal error (rare)	Disconnect and connect power supply cable and Re-start the system
4	Mouth pressure and Flow rate graph is not displaying	Incorrect patient position	Check patient is in correct posture, wearing nose clip and holding their cheeks. Check if the iCaltech filter is connected properly.
		Defective Flow sensor or Pressure sensor	Replace Flow sensor or pressure sensor, if defective.

Sl. No.	Problem	Possible Cause	Solution
		Breathing circuit defective or incorrectly assembled	Verify Breathing circuit is defective and properly assembled. Check error messages on screen and proceed accordingly.
5	Device impedance is exceeding 10% accuracy during verification test by using reference impedance	Improper connection of Reference impedance to device	Connect the known resistance to FOT tube without iCaltech filter
		Incorrect Known resistance is used	Check Known resistance value and perform the test
6	Application crashes while switching from the 'Start' to the 'Capture' button	Internal error	Restart the application software
7	Unable to save the report after pre/post-test completion	Internal error	Restart the application software
8	When application is closed, the connection between device and the application is disconnected, but the device continuous to run.	Internal error	Restart the device

List of Errors and Actions

Sl. No.	Error Code	Error Type	Error message Title	Error Message	Scenario	Actions
1	NA	Text message	NA	Please enter <missing field name>	If any of the mandatory field is missing in edit/ new patient screen, hospital screen, Staff screen and user clicks on save button.	Enter all the mandatory fields with *
2	NA	Text message	NA	Phone number can contain only digits	If phone numberis entered in alphabets, alphanumeric.	On phone number field enter only Numbers

Sl. No.	Error Code	Error Type	Error message Title	Error Message	Scenario	Actions
					(Hospital information screen)	
3	NA	Text message	NA	First name Must be contained only alphabets with maximum 20 characters	If First name field is invalid. (Add new staff screen)	Enter only Alphabet's with Max.20 characters
4	NA	Text message	NA	Search not found	When user search not found in patient or staff screens. (Patient list screen)	Enter valid patient name or ID
5	NA	Text message	NA	Please enter valid username and password	If both or any one of username and Password fields are invalid. (Login screen)	Enter valid User name and password
6	NA	Text message	NA	Please enter the username. Please enter the password.	If username field or password field is blank (Login screen)	Do not keep username and password field as blank
7	NA	Text message	NA	New password and Confirm password must be same	If entered new password and confirm password are not same. (Change password screen. Admin Login)	Enter valid password
8	AS_ERR_005	Information	No reports	No patient reports are available	If user clicks on view report in home screen, when test is not conducted for patient. (View report screen)	Conduct test and click on view report screen
9	AS_ERR_006	Information	No reports for selected patient	"No reports are available for selected patient"	If no reports are available for the selected patient. (View report screen)	Conduct the test and save the Report
10	AS_ERR_102	Error	Patient not selected	Please select patient from the list	If user clicks on Begin test button without selecting patient from	Select patient and click on Begin test

Sl. No.	Error Code	Error Type	Error message Title	Error Message	Scenario	Actions
					the list. (Home screen)	
11	AS_ERR_108	Error	Problem connecting with device	Please check USB cable connection and click on "Connect" button	Without connecting device to PC. If user searches for particular device calibration values. (Calibration screen)	Connect the device with APP before calibration
12	AS_ERR_110	Warning	Hospital Information delete confirmation	"Are you sure, you want to delete Hospital information?" with "Delete" and "Cancel" options	After selecting hospital, if user clicks on delete button. (Hospital information screen)	Confirm about deletion of the filed
13	AS_ERR_111	Warning	Staff delete confirmation	"Are you sure want to delete staff <staff full name>" with "Delete" and "Cancel" options	If user clicks on delete button of particular staff information. (Staff list screen)	Confirm about deletion of the filed
14	AS_ERR_112	Warning	Cancel confirmation: Add staff	All the entered staff information will be lost	If user clicks on cancel button after entering or editing the staff details	Confirm about cancelation of the filed
15	AS_ERR_113	Warning	Cancel confirmation: Edit Staff	All the entered staff information will be lost "Are you sure want to cancel?" with "Yes" and "No" options	If user clicks on cancel button after entering or editing the staff information. (Edit staff screen)	Confirm about cancelation of the filed
16	AS_ERR_114	Warning	Delete Confirmation: Patient Informati	Are you sure want to delete patient <Patient full name> with "Delete" and	If user clicks on delete button of particular patient information. (Add patient screen)	Confirm about deletion Of the filed

Sl. No.	Error Code	Error Type	Error message Title	Error Message	Scenario	Actions
			on	"Cancel" options		
17	AS_ERR_115	Warning	Cancel confirmation: Add Patient	All the entered patient information will be lost. "Are you sure want to cancel?" with "Yes" and "No" options	If user clicks on cancel button after entering the patient information. (Add patient screen)	Confirm about cancelation of the filed
18	AS_ERR_116	Warning	Logout Confirmation	Are you sure want to log out? with "Ok" and "Cancel" buttons	If user clicks on Log-out button (Home screen)	Confirm about Logout
19	AS_ERR_117	Warning	Exit Confirmation	Are you sure want to exit from the Antlia Pro App? With 'Ok' and 'Cancel' buttons	If user close (X) the application (Home Screen)	Confirm about closing the application
20	AS_ERR_118	Information	Duplicate staff Information	Staff information is already existing	For duplicate staff creation. (Add new staff screen)	Do not enter already Entered staff information.
21	AS_ERR_119	Information	Duplicate Patient Information	Patient information is already existing	For duplicate patient creation. (Add patient screen)	Do not enter already entered patient information
22	AS_ERR_120	Information	Maximum trials reached	Test has reached to maximum trials, please save the report before continuing with new test.	While performing the 10th action in pre/post mode. (View report screen)	After 10th Action save the Report

Sl. No.	Error Code	Error Type	Error message Title	Error Message	Scenario	Actions
23	AS_ERR_121	Information	Maximum trials reached	Test has reached to maximum trials, Do you want to replace the values?	While performing the 11th action in pre/post mode. (View report screen)	After 10th Action save the Report
24	AD_ERR_202	Error	Device Disconnection	Please connect the device to conduct the test	In between if user disconnects USB cable from the PC. (Home screen)	Do not disconnect the USB cable, while performing test
25	AD_ERR_203	Error	Device disconnected	Please connect the device to conduct the test	During test, if device got reset due communication slow down. (Conduct test screen)	Disconnect the USB cable and reconnect
26	AD_ERR_204	Error	Device Disconnection	Please connect the device to conduct the test	If user power off the device when USB is connected with PC. (Home screen)	Do not power off the device while performing test
27	AD_ERR_208	Error	Device disconnected	Please connect the device to conduct the test	While communicating with Device in Ideal mode	Disconnect the USB cable an reconnect and perform the test
28	AD_ERR_209	Error	Device Accuracy Low	Requires re- calibration	Device impedance above 10% accuracy using known impedance value. (Verification screen – during verification)	Perform Device calibration using reference impedance
29	AD_ERR_211	Warning	Timeout	Capture timeout. Please start the test again when ready	Start mode running more than 2mins. (Conduct test screen)	Stop the test and perform the test again

7. Application Software Design

7.1. Device connection with APP

7.1.1. Software Installation

Antlia Pro Desktop application will be installed by iCaltech team. Install the application software according to user's PC's configuration.

- Note: System requirements: Operating System: Windows 10.0 or later & System Architecture: 64 bits

7.1.1.1. Installation steps

Step 1: Software File

- Insert the Pen drive/CD that contains the Antlia Pro software installation .exe file.
- The contents will be as shown in Figure 33.

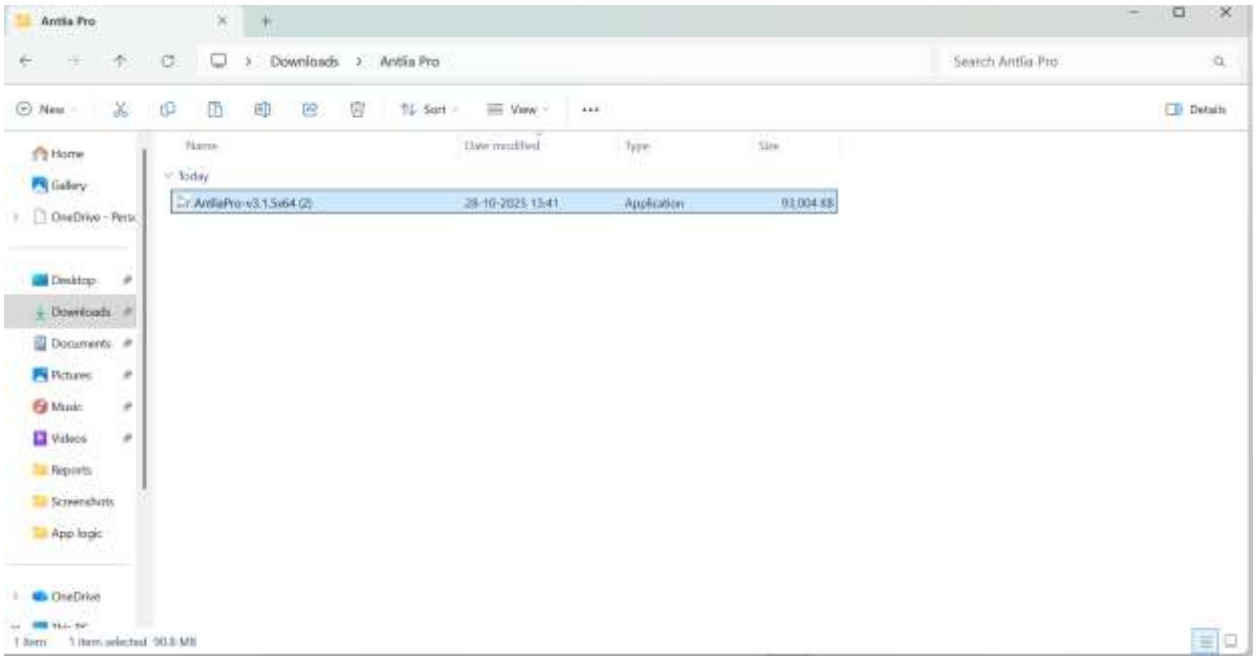


Figure 33: Antlia Pro Installation File

Step 2: Check PC's Specifications

- Right-click on "This PC" icon in your PC as shown in Figure 34 and click on "Properties."

Figure 34: PC's Properties

- This will open the system properties window and display the system information.
- In this screen, verify the operating system type (64-bit or not) as shown in Figure 35.

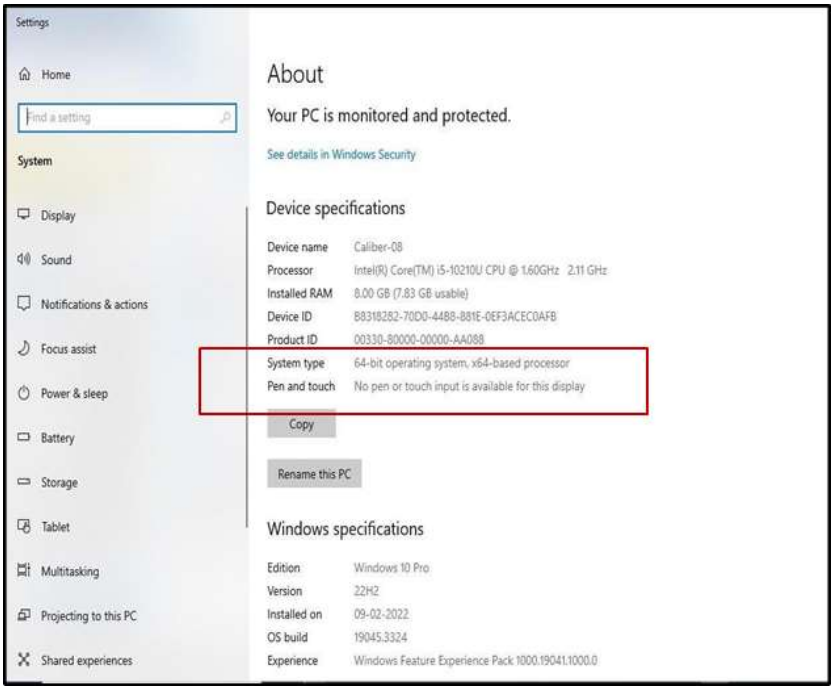


Figure 35: System Type - Verification

Step 3: Start the Installation

- Double-click on the Antlia Pro software installation .exe file.

- A dialog box will appear requesting permission to install the app. Click "Yes."

Step 4: Select the Location of Installation Files

- Select the location where you want to install the application.
- The default location is "Program Files," but you can click on "Browse" to choose a different location. Refer Figure 36 for the location of installation folder.
- After selecting the location, click "Next."

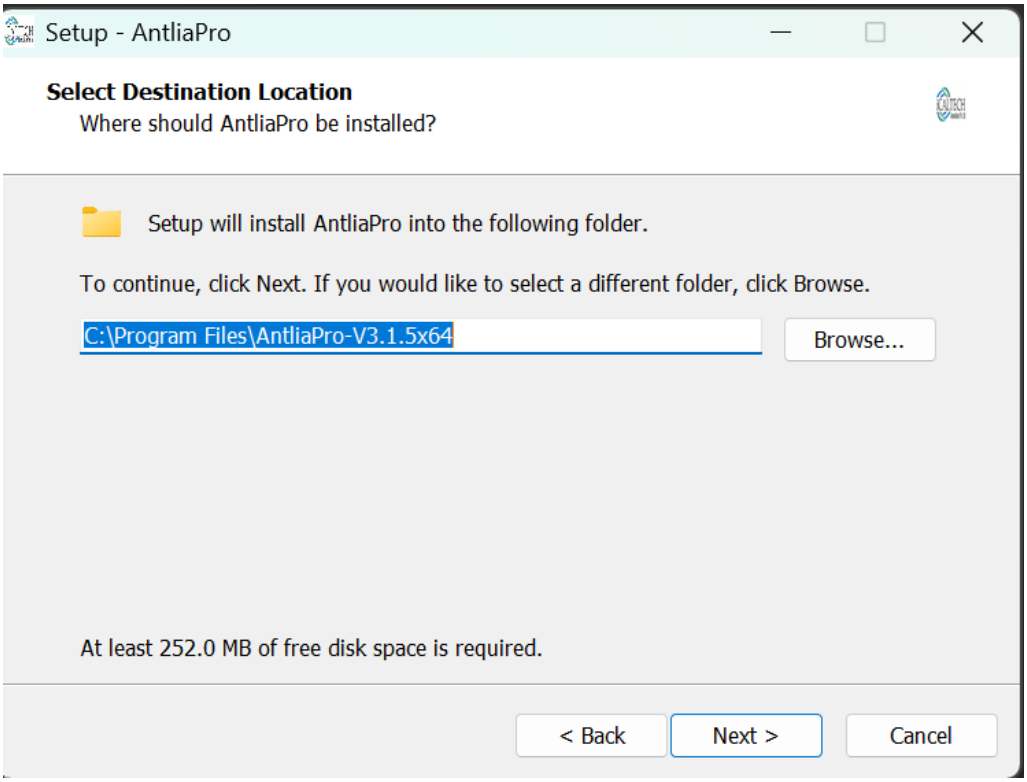


Figure 36: Installation Folder Location in PC

Step 5: Desktop Shortcut Icon

- Check the checkbox if you want to create a desktop shortcut for easy access to the application. Refer figure 37 for the details.
- Otherwise, leave the checkbox unchecked → Click "Next."
- Note: Even now, if you want to change the installation location, click on "<Back>" and repeat step 4.

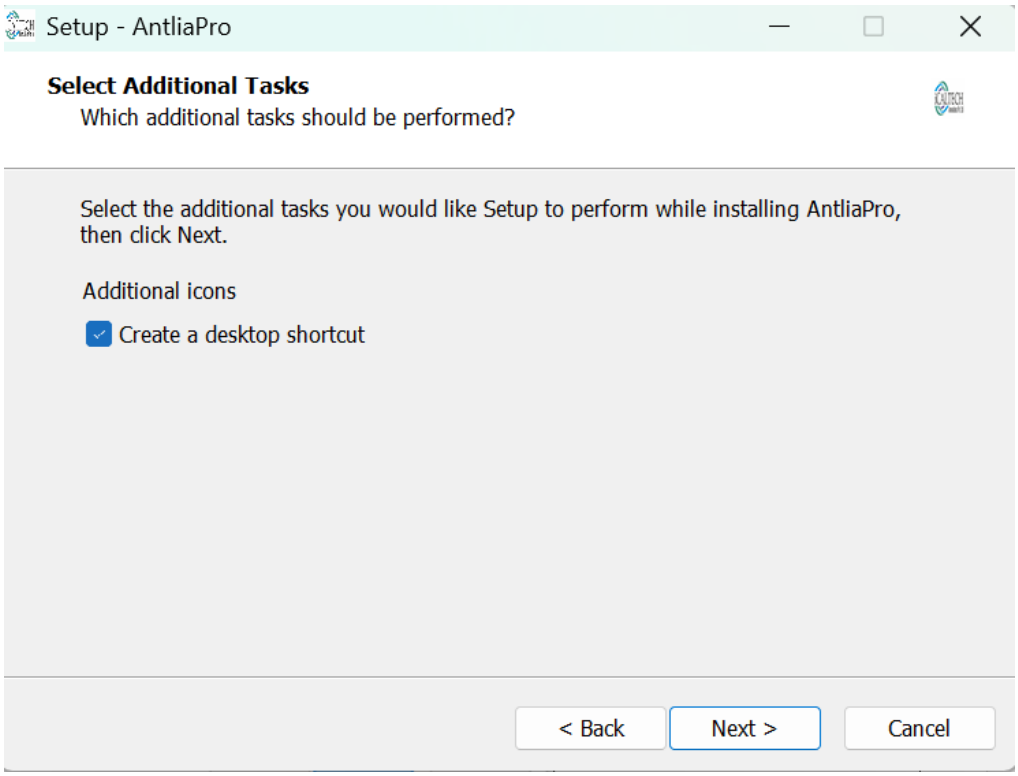


Figure 37: Selecting for Desktop Shortcut Icon

Step 7: Install the Application

- Click "Next" to proceed with the installation.
- Wait for the installer to complete the process. The dialog box will disappear when the installation is finished. (Image need to be changed)

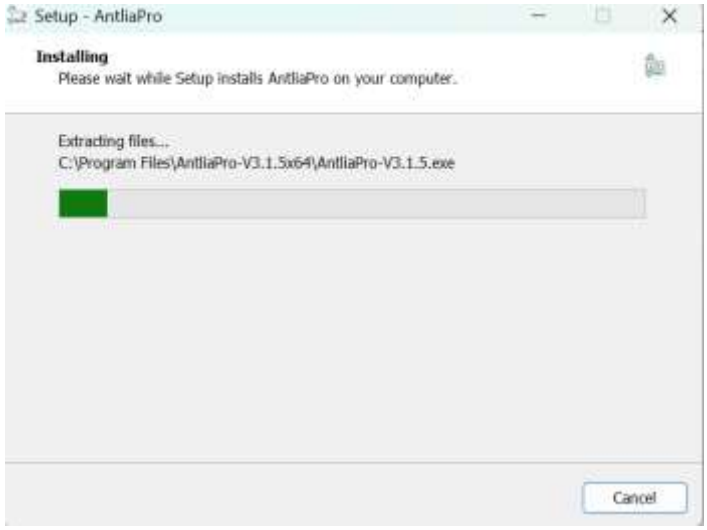


Figure 38: Installation Process - Completed

Step 8: Launch the Application

- If a desktop shortcut was created: Double-click on the Antlia Pro desktop icon.

Figure 39: Antlia Pro - Desktop Icon

- If no desktop shortcut was created: Navigate to the installation directory → Double-click on "Antlia Pro-Vx" to launch the application.
- Upon launching the app, a splash screen will be displayed and after that the main application screen will appear as shown in figure 40.

Figure 40: Antlia pro - Main application screen

7.1.2. Software Upgradation

- If the user wants to upgrade from the old version to new version, install the new Antlia Pro application on your PC following steps outlined in 7.1.2.
- After that, navigate to the folder where old version is installed (eg., typically C:\Program Files\AntliaPro-Va.bb.ccd-Xee\App).
- Copy the database file named “antlia_local.db” from the old application folder to the new application folder.

- Launch the newly installed Antlia pro application and proceed with testing. Refer to figure 41 for the details of data file location if needed.

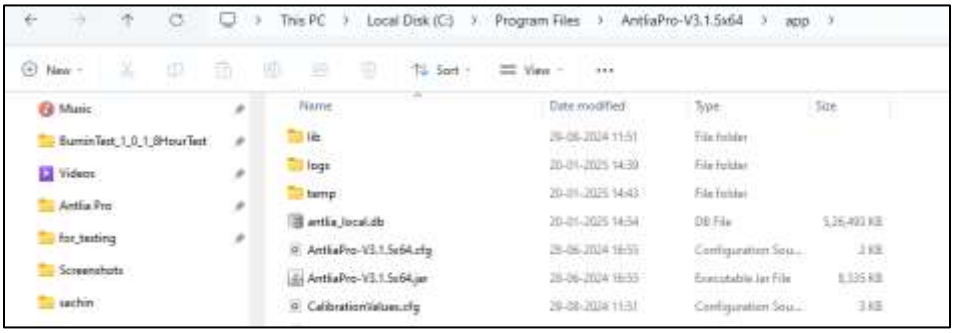


Figure 41: Data base file location in program files

7.1.3. Firmware Upgradation

- Login to the admin window and navigate to the Firmware Upgrade screen.

Figure 42: Firmware Upgradation Page

- Observe the device's LED status.
- Verify if the device is already in firmware upgrade mode (Indicated by Blue and Red light glowing on the device).
- If the device is not in firmware upgrade mode (green LED is glowing), click "NO" option in the firmware upgradation page.
- Once the "No" option is selected, the "Enter Firmware Upgrade Mode" option will appear on the page as shown in figure 43.

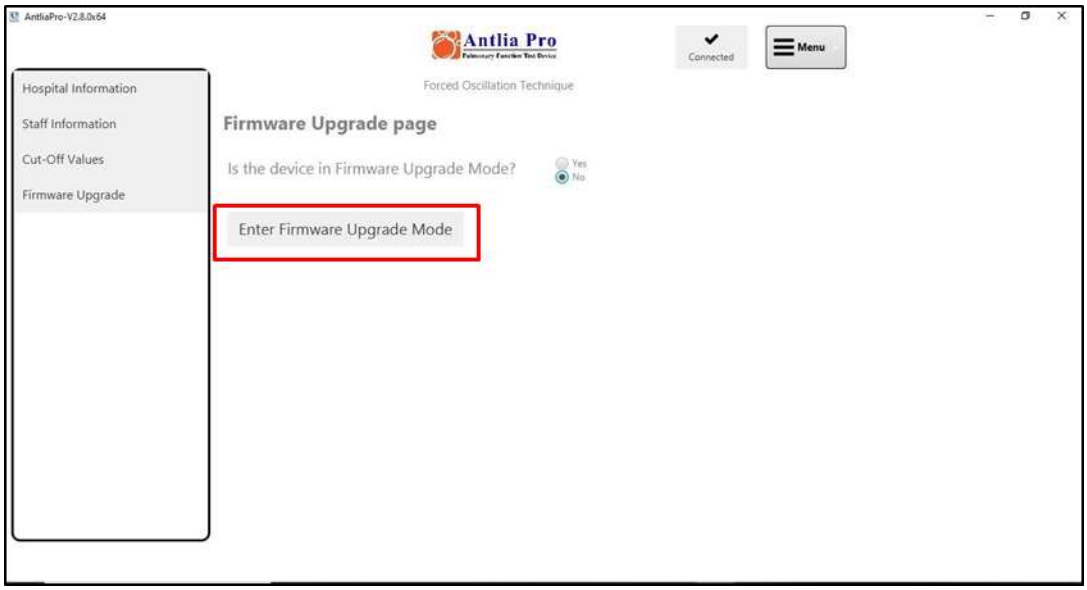


Figure 43: Firmware upgrade mode option

- Click on "Enter Firmware Upgrade Mode." The device will then enter firmware upgrade mode, and the Blue and Red LEDs will start glowing.
- Now select “Yes” for the prompt “Is the device in firmware upgrade mode?”.
- The “Choose Firmware Hex file” option will appear on the page as shown in figure 44.
- Click on it, browse to the location of the Firmware Hex File, and select it.
- After that, the "Start Upgrade” option will appear on page as shown in figure 45. Click on it.
- Wait until a “success” pop-up message is displayed as shown in figure 45, indicating that the firmware upgrade has been completed successfully.

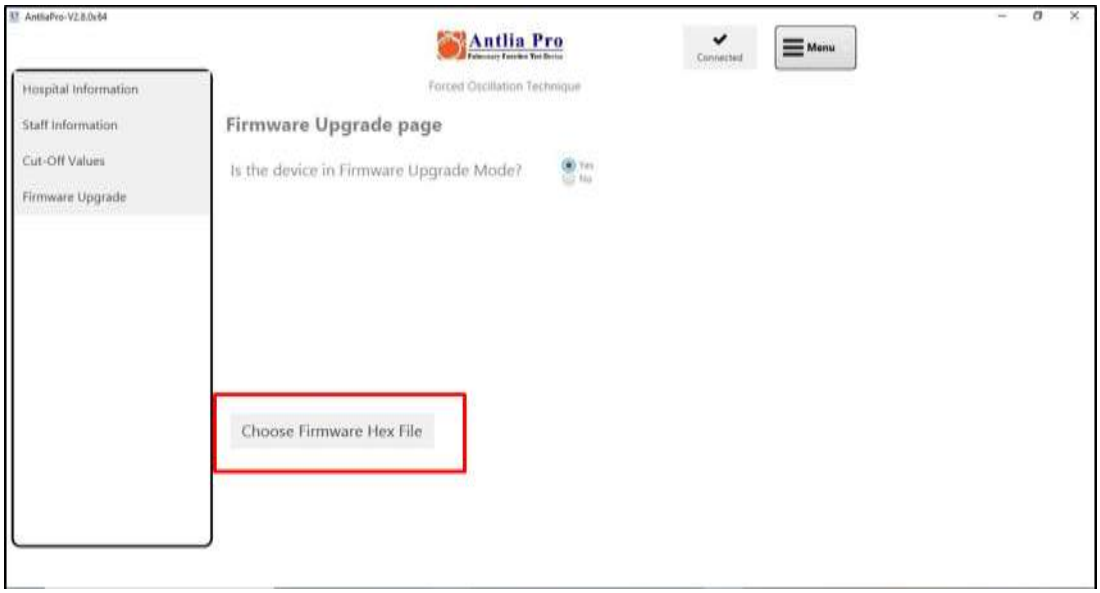


Figure 44: Choose Firmware HEX File

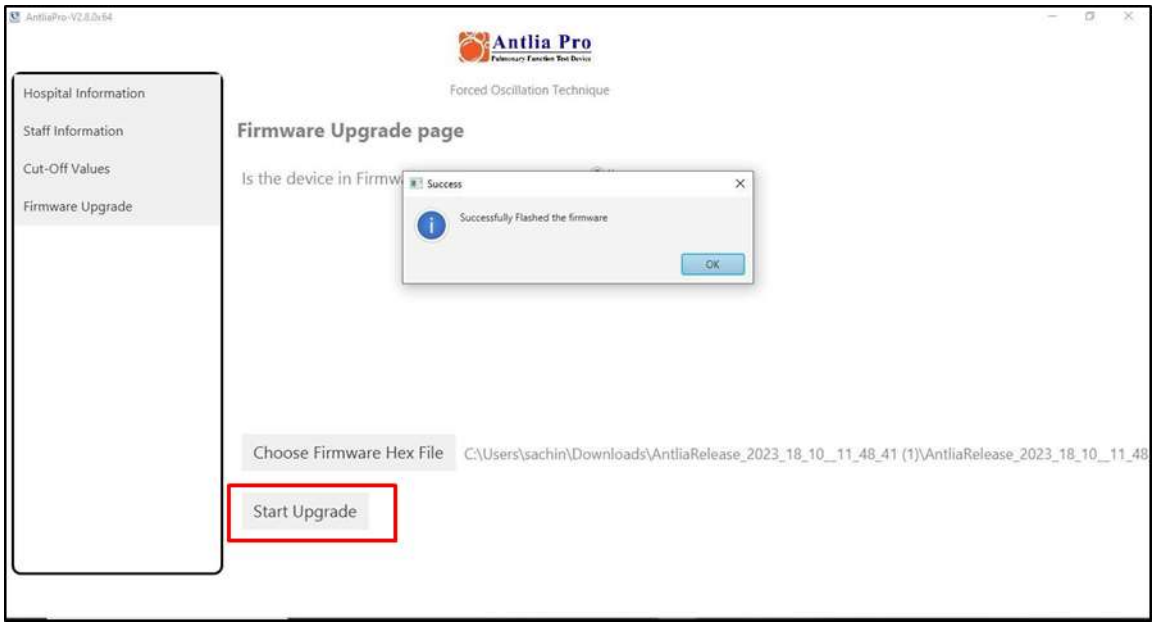


Figure 45: Start Upgrade option on firmware upgrade page

8. Exit from Application

8.1. Software Closure

To close the Antlia Pro software, click the close (X) button located in the top right corner of the Antlia Pro screen.

8.2. Antlia Pro Device Power Off

Once usage of device finished, press and hold the Power ON/OFF button on the back of the device for approximately 3 seconds. Wait for all LED indicators on the device to turn off completely. Switch off the main power supply by turning the Main's switch on the Mains Board to the "OFF" position.

Warranty Certificate

A sample Warranty card is shown below. The actual warranty card will be provided along with the device

ICALTECH INNOVATIONS PRIVATE LIMITED
2nd Floor, Sy no 80, Municipal No 4 & 4A (Katha no 351),
Muneshwara Layout, Service Road, Ring Road,
Laggere Bridge, Laggere, Bengaluru, Karnataka, 560058, India.
Ph. # +91-94800 17633; www.icaltech.com
CIN: U74999KA2016PTC094056 GST: 29AAGCC5274M1Z3

Product Warranty Certificate

Customer Name: *<Customer/Hospital/Clinic Name>*
Kind Attn:

We thank you for your recent purchase of our product detailed here under:

Product Name: Respiratory Impedance Monitoring Device **("***<Product Name>***")**
Product Sale Details:

LOT No.: *<Product Lot Number>* **; Serial No.:** *<Product Serial Number>*

Invoice No.: *<Invoice Number>*

Warranty Duration: *<MMM YYYY>* **to** *<MMM YYYY>*
AMC/CMC if any _____

We are glad to provide you this Warranty Certificate for your "*<Product Name>*" purchase. "*<Product Name>*" has passed Rigorous Tests and has been confirmed to be of Excellent Quality and Construction.
If the **"Customer"** has any issue with the purchase during the Warranty Period, they can approach **"ICaltech"** (Details provided at end of this Warranty Certificate). **"ICaltech"** will initiate necessary actions within 3 Business Days to remedy the situation. Actions may include analyzing / rectifying the issue over Phone / Emails, in person visit to **"Customer"** place, or finally replacing the product itself. **"ICaltech"** will try its best to minimize the lead time. However, all actions to rectify any issue with the Product will be at the discretion of **"ICaltech"**. The period of Warranty will be restricted to the Dates mentioned above, even if the product has been replaced in between the Warranty Period.

This Warranty does not cover damage or defects caused by:

- Improper usage (failure to follow guidelines/ Instructions on using the product)
- Negligence, accident, damage due to inefficiencies in packaging during shifting by the **"Customer"**.
- Any attempt to OPEN the device, customize the product with Modifications, use of unauthorized parts, change of Design, connections to any External products without **"ICaltech"** authorization
- Use third party filters / consumables without authorized by **"ICaltech"**.

ICaltech Innovations Private Limited has been referred to as **"ICaltech"** in this document.
Manipal Health Enterprises Pvt Ltd has been referred to as **"Customer"** in this document.

Business Days Definition:
Monday to Friday: 9 am to 6 pm
(Note: Saturday / Sunday / Government Holidays will not be considered Business Days)