

ANTLIA

User Manual



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Model Name: ANTLIA

Product Code: ANT

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- **Welcome to the ANTLIA**

Welcome, and congratulations for the acquisition of a new ANTLIA Forced Oscillation Technique (FOT) device.

The ANTLIA is a modern medical device, and we hope that it will be able to aid and assist you in your work as you strive to provide the best possible care to your patients. On behalf of the entire iCaltech team and all our partners and representatives, we thank you for the trust you have put into us by deciding to acquire an ANTLIA system. We will work hard to continue to earn your trust and recognition, and we look forward to working with you as we support you in your use of the device.

About the User manual:

ANTLIA User Manual Revision-05

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Please read the entire user manual and understand the device before trying to operate the device. The user manual has several sections. The table of contents provided in the beginning of the chapter. The footer contains the current page number and the total number of pages. The page numbering is continuous throughout the entire manual.

- Any patient and equipment data that are used as examples in this User Manual are entirely fictional.
- Your product may differ in a few details, depending on the installed options and your configuration as well as the constant development of the product.
- Any resemblance to names of real persons and institutions is entirely coincidental.
- All parameters, graphs and images shown in this User Manual are for illustrative purposes only. Only the parameters displayed by your device are definite.

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1 INTRODUCTION

Antlia device is intended to measure the respiratory system impedance using the Forced Oscillation Technique (FOT). It is intended for use with paediatric and adult patients 4 years of age or older. The device is designed to be used by pulmonologists, chest physicians, general physicians, lab technicians, respiratory therapists and similarly trained personnel in hospitals, clinics and other healthcare facilities.

1.1 Intended Use

Antlia device is intended to measure the respiratory system impedance using the Forced Oscillation Technique (FOT). It is intended for use in paediatric and adult patients 4 years of age or older. The device is designed to be used by pulmonologists, chest physicians, general physicians, lab technicians, respiratory therapists and similarly trained personnel in hospitals, clinics and other healthcare facilities.

1.2 Contraindication:

Device is not supposed to be used in 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
- Device is not supposed to be used in CT and MRI environment.
- Device is not supposed to be used in OT environment.
- Device is not supposed to be used along with high surgical equipment.

1.3 Main Advantages:

- It is used to measure lung function of the patient.
- Useful for the patient suffering from COPD, asthma or Lung disorder, ILD/fibrosis, airway clearance and silicosis
- Captures small airways and peripheral airways diseases.
- Bronchodilator support: Efficient reversibility testing.
- Easy to distinguish normal and abnormal patients.
- Useful for patients unable to perform spirometer test such a children/ geriatric
- The method is also highly sensitive, which makes it suitable for the evaluation of bronchodilators.
- In Mono frequency mode, we can identify the rapid changes in impedance associated with changes in airway level during the respiratory cycle.

1.4 Features

- Display of Resistance and Reactance with real-time display of tidal breathing
- Predicted respiratory patterns of different age groups for easy analysis and better understanding.
- Easy test quality control by the analysis of the breathing pattern and of the quality index displayed for all the frequencies (5-20 Hz)
- Pre and Post display of bronchodilator/bronchoconstrictor test
- Comprehensive printout report

2 ENVIRONMENTAL CONDITION:

- ANTLIA units should not be operated near explosive substances.
- Equipment should not be installed near electrical or magnetic devices such as x- ray equipment, transformers, or power lines. These devices could create electrical interferences when performing testing procedures.
- Do not use the device in a highly dusty environment, highly vibrating environment.
- Do not place units near heat sources.
- Adequate floor space and easy access to the patient during exercise testing is necessary.
- Adequate ventilation should be maintained in the room when testing is performed.
- Store the device in a dry place.

2.1 Operational

Temperature range: 10 to 40°C,

Relative humidity range: 20% to 90%

Atmospheric pressure range: 600 mBar to 1060 mBar.

The device is intended to operate at an altitude $\leq 2\,000$ m.

2.2 Storage

Temperature range: 5 °C to 40 °C,

Relative humidity range: 5% to 95%

2.3 Transportability

Temperature range: 5 °C to 40°C,

Relative humidity range: 5% to 95%

3 SAFETY

3.1 General safety information:

To avoid possible damages and accidents, please pay attention to the following Safety instructions:

- Before powering ON the system, the power cords and plugs should be inspected. Damaged electrical parts must be replaced immediately by authorized personnel.
- This User Manual should always be available as a reference when testing. Only use the device according to the manual.
- Do not use any accessories not recommended for the device.
- Keep the cable away from heat source, sharp objects, rough surface and check if the cable is in good condition.
- Do not expose the device to direct sunlight or strong light (more than 1500 lux).
- Take care to ensure the current environmental conditions.
- The device should not be used in conjunction with any other medical device unless the manufacturer recommends that device.
- Residue and other contaminants in the breathing circuit pose a safety risk to the patient during testing procedures. Aspiration of contaminants can be potentially life-threatening.
- Patient data to be dealt with according to the current health data protection laws and regulations.

3.2 Equipment Safety:

Improper handling of the device may cause damage to the patient or operator. Modifications or additions to the device must be made in accordance with the legal regulations and generally accepted engineering standards.

As the manufacturer, iCaltech cannot accept responsibility for the safety features and for the reliability and performance of the equipment if improperly used:

Cases of Improper Usage of the device

- ☐ The device is used in a manner other than that specified in the Operator Manual.
- ☐ Upgrades, readjustments, modifications, or repairs are performed by personnel not contracted and authorized by iCaltech.
- ☐ Components affecting safe operation of the device are not replaced by original spare parts in the event of a malfunction.
- ☐ The electrical wiring in the room containing the system does not meet the local regulations.

4 WARNING NOTES

A **Warning** indicates a danger which if not observed, can lead to serious injury or even death.

Caution indicates a danger which if not observed, can lead to minor or moderate injury.



WARNING

Do not open the unit there are no parts that user serviceable.



WARNING

If any part of the device or its accessories such as USB Cable and Power adapter is changed, device performance will degrade and will lead to wrong results.



WARNING

Improper use of the device:

Do not expose the unit to rain or moisture.

Device should not be used in wet surface condition.



WARNING

If any part of the Antlia or its accessories and cables, appears missing or damaged, do not use the device. Usage of damaged component could cause injury to the patient or operator.



WARNING

To mount the device, using a table with size and structure that should be able to support the weight of the device



WARNING

Suitable Environmental condition not used.

Effect the performance of device, improper measurement.

Use the device in a proper environmental condition as specified.

**WARNING**

Do not modify the device in any way. Modification to the device is unsafe and cause measurement error

**WARNING**

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



CAUTION

Operation of the device by untrained users.

Risk of incorrect measurement due to misinterpretation of system information.

The system must only be used by persons with proper training.



CAUTION

Operating environmental conditions not maintained.

System is not working properly.

Maintain the allowable environmental conditions (temperature, relative humidity, altitude) as stated in user manual.



CAUTION

Use of unapproved software or hardware components.

Risk of malfunctions posing a hazard to patients and equipment.

Only use software or hardware components provided by iCaltech



CAUTION

Modification to system

Risk of system malfunction

User has no rights to change calibration or modify/upgrade any software.

Contact service person.



CAUTION

Pulling/Pinching the source tube

Risk of incorrect measurement/Results

User shall not damage the source tube. The system must only be used by persons with proper training and care should be taken during transportation.

If the source tube is damaged, Contact Service person.



CAUTION

Blockage of inertance tube

Patient will not get enough air to breath.

User shall not block the inertance tube opening. Before using/taking the trails user should ensure that there is no blockage near the inertance tube



WARNING

Vitalograph filter, and Nose clips are Single use only



WARNING

Do not perform service and maintenance activity while using device with the patient.



WARNING

System operated in Oxygen rich environment.

Danger of Explosion

The system is not designed for operation in areas where there is an explosion hazard



WARNING

Unauthorized modification of the unit.

Modifications or additions to the product must be made in accordance with the legal regulations and generally accepted engineering standards.

iCaltech cannot accept responsibility for the safety features and for the reliability and performance of the equipment as the manufacturer, assembler, installer, or importer, if:

- Installation, equipment expansions, readjustments, modifications, or repairs are not carried out by persons authorized by iCaltech.
- Components affecting safe operation of the product are not replaced by original spare parts in the event of a malfunction.

The product is not used in accordance with the Operator Manual.



WARNING

Device is not suitable for use in the presence of flammable anaesthetic.



WARNING

User should have an antivirus software installed to protect the system from malicious threats. Antivirus should be licensed and regularly updated.



WARNING

The Antlia may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Antlia or shielding the location.

Electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions

The Antlia is intended for use in the electromagnetic environment specified below. The user of the Antlia should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic enforcement - guidance
RF Emissions CISPR 11	Group 1	The Antlia uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Antlia is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The Antlia is intended for use in the electromagnetic environment specified below. The user of the Antlia should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environmentGuidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile.If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines.	±2 kV for power supply lines. ±1 kV for input / output lines	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode ±2 kV common Mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles 5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles 5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical hospital environment. If the user of the Antlia requires continued operation during power mains interruptions, it is recommended that the Antlia be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			



WARNING

Regulatory compliance

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 3 Vrms 150 kHz to 80 MHz in ISM bands[a] 3 V/m 80 MHz to 2.7 GHz	3 Vrms 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Antlia, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5 / V1] \sqrt{P}$ where $V1 = 3 \text{ Vrms}$ $d = [12 / V2] \sqrt{P}$ where $V2 = 3 \text{ Vrms}$ $d = [12 / E1] \sqrt{P}$ 80 MHz to 800 MHz, where $E1 = 3 \text{ V/m}$ $d = [23 / E1] \sqrt{P}$ 80 MHz to 2.7 GHz, where $E1 = 3 \text{ V/m}$
		3 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range. [d]

			Interference may occur in the vicinity of equipment marked with the following symbol: 	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.				
a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/ portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges. c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Antlia is used exceeds the applicable RF compliance level above, the Antlia should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Antlia. d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.				
Recommended separation distances between portable and mobile RF communications equipment and the Antlia.				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.20	1.20	2.30
10	3.69	3.79	3.79	7.27
100	11.67	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3: An additional factor of $10/3$ has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



CAUTION

Due to Electromagnetic Disturbance, if the Unit hang/reset the Operator (who conducts the test) has to reconnect the device with App and take New Test with patient. As patient has to give multiple breathing tests and since Tidal Breathing (normal breathing) is required by patient, this degradation is acceptable.



CAUTION

System timing should be up to date, if it is not updated go setting and set the correct date.



CAUTION

- a. Application stops the test, if device runs continuously in start mode for 60 secs.
- b. Test get stopped, when no patient breathing is detected



CAUTION

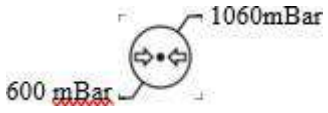
- a. The SYSTEM will blank the screen, after pressing factory default shortcut key
(Ex:  +L).
- b. To blank the screen, user shall set specified time in PC.
- c. After specified time, SYSTEM shall auto log-off when not in use. (To auto log-off the SYSTEM, user shall set the specified time in PC).



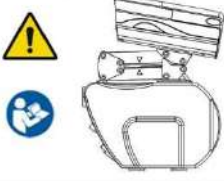
CAUTION

Federal law restricts this device For sale to or on the order of a Medical practitioner

5 Symbols

	This symbol indicates that this device is having DC current
	General warning sign
	Caution
	This symbol instructs the user to consult the instructions of the device for information on how to properly use it.
	Accompanied by a date, the symbol indicates the date when the device was manufactured.
	Serial number. The symbol should be accompanied by the serial number of the device.
	This symbol indicates the device Batch Number
	Refers the legal Manufacturer (iCaltech Innovations Pvt Ltd)
	REF No. of Product/Product Code
	Type B applied part: BV 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

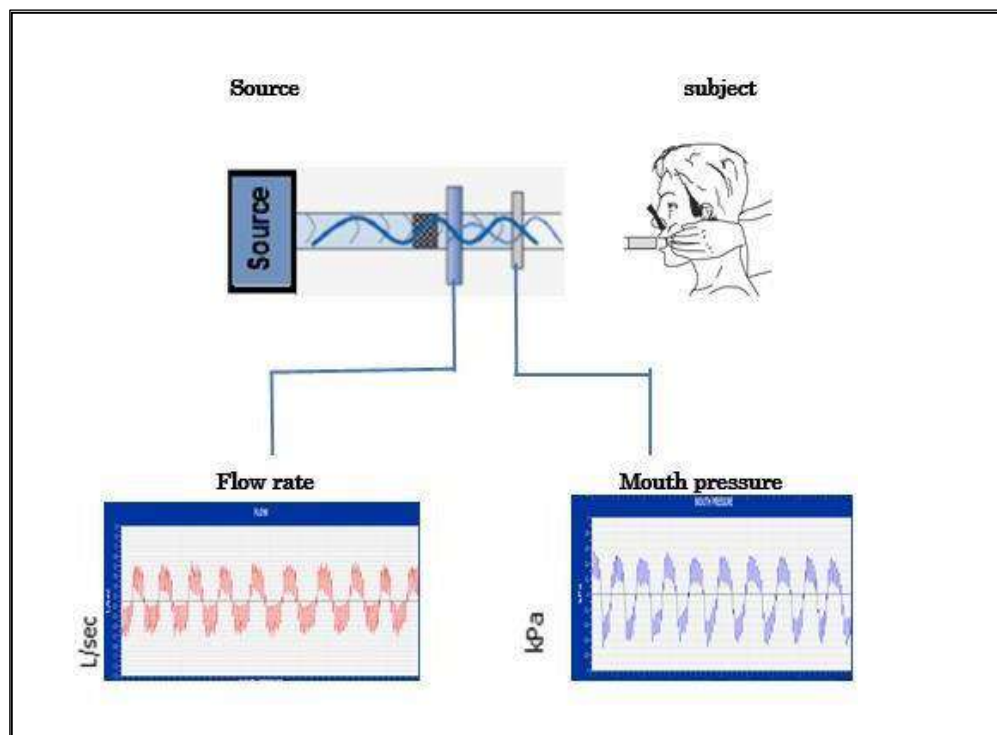
	Non-Sterile
	Do not use if package is damaged.
IP21	Ingress Protection IP2X: Protected against solid objects over 12.5mm IPX1: Protected against vertically falling drops of water
	Universal serial bus (USB) port
	"ON" (power)
	"OFF" (power)
	DC Jack connector
Rating	24V $\leq$ 1A max
	Storage and Transportability Temperature Limitation
	Storage and Transportability Humidity Limitation
	Fragile, handle with care
	This Side UP Symbol The duration of shipping/delivery, the carton should face upright.
	Stacked Boxes Maximum carton stack is 4

Transport Position 	Device Transport position
Rx ONLY	A medical prescription.

6 Measurement Principle:

Device generates the pressure signals against which tidal breathing is done. It can provide respiratory parameters such as resistance and reactance at mono and multi frequency, real time graphical display of flow rate and mouth pressure.

Through the tidal breathing of the subject, it is easy diagnose the respiratory disorders with the help of the device. Real time display allows the user to identify the manoeuvre followed by the subject during test.



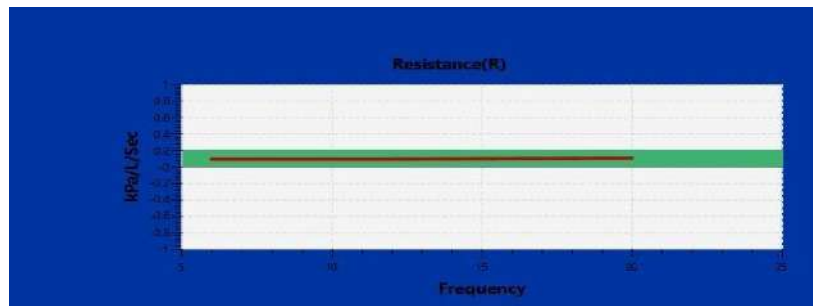
An electric signal is produced in the impedance analyser and applied to a source that Converts it to a corresponding pressure waveform. Usually, this pressure signal presents an amplitude of approximately 0.2 kPa (peak-to-peak)

This signal is directed to the airway opening of the patient, which is connected via a filter to the set-up. The airflow ($\dot{V}$) is measured using pneumotachograph and the pressure (P) is measured at the airway input of the patient. The resulting signals are filtered and digitized in the impedance analyzer. Then, the respiratory impedance (Z_{rs}) is calculated.

The mechanical behavior of the respiratory system depends on the frequency of the applied oscillation. Low frequencies better describe the mechanical properties of lung periphery, while high frequencies describe the properties of central and upper airways. The ANTLIA utilizes an oscillatory waveform ranging from 5 to 20 Hz.

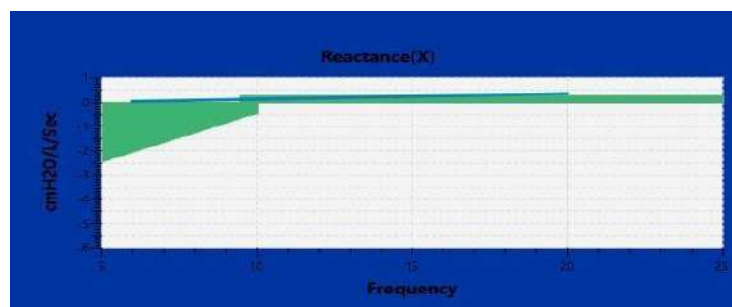
Resistance (R):

Resistance describes the dissipative mechanical properties of the airways and of the lung and chest wall tissue. Resistance mainly reflects the frictional pressure losses occurring as air travels in and out the airways and therefore it is mainly related to the overall airway's diameter.



Reactance (X):

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



Outcome Parameters

Parameter	Abbreviation	
Resistance 5Hz	R5	Low-frequency Resistance (5 Hz) reflects total airway resistance.
Resistance 20Hz	R20	Resistance (20 Hz) reflects mostly conducting airways.
Frequency dep. of Resistance, 5 – 20 Hz	R5-R20	Reflects Resistance in the small airways
Reactance at 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)
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

7 Device Overview



The ANTLIA is a professional, PC based device for non-invasive measurement of mechanical properties of the respiratory system. Technologists love the ANTLIA because it is accurate, versatile and efficient. Patients love it because it is fast and easy to use.

The ANTLIA device measures mechanical properties of the respiratory system using forced oscillation technique (FOT). Here FOT is a non-invasive technique.

The Respiratory System with an oscillation pressure is used to evaluate the response in terms of mechanical impedance. Impedance is the complex relationship between flow and mouth pressure. Here Minimum patient cooperation is required during the trials, device can capture mechanical properties of the respiratory system when patient is breathing normally. It is to be used on adult patients and children of the age four years and above. The test duration is short (Mono frequency for 12sec and Multi frequency for 36 seconds) and patient should hold his/her cheeks while breathing normally.

ANTLIA Mode of operation is non-Continuous. Device Maximum activation (ON) time is 3minutes and minimum activation (OFF) time is 2minutes.

7.1 Component Overview:

7.1.1 Device Side view



Main components of the ANTLIA Unit:

- A. FOT tube enclosure
- B. Source tube
- C. Source Enclosure
- D. LED indication Panel
- E. Adjustable Arm

A. FOT tube Enclosure:

FOT tube enclosure consists of a top cover, bottom cover and Brand panel. Brand panel it is a separate part, by removing the Brand panel we can easily change the Flow sensor, and there is no need to remove the complete assembly.

B. Source Tube:

ANTLIA device has a 75cm long Source tube, it is used to carry pressure from Source to FOT tube.

C. Source Enclosure:

ANTLIA includes a Source which generates pressure signals 5-20Hz, and Control unit which computes the pressure and flow rate

D. LED Indication Panel:

Source enclosure consisting of LED indication slot. 3 LED's i.e., Green, Blue and Red are available for user notification in different scenarios.



LED status

Colour	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 Adjustable Arm, we can adjust the height and the inclination of the device to fit the persons height so that they can perform the test easily. Move the device to upward & downward in the upward and downward direction to adjust the height of the device.

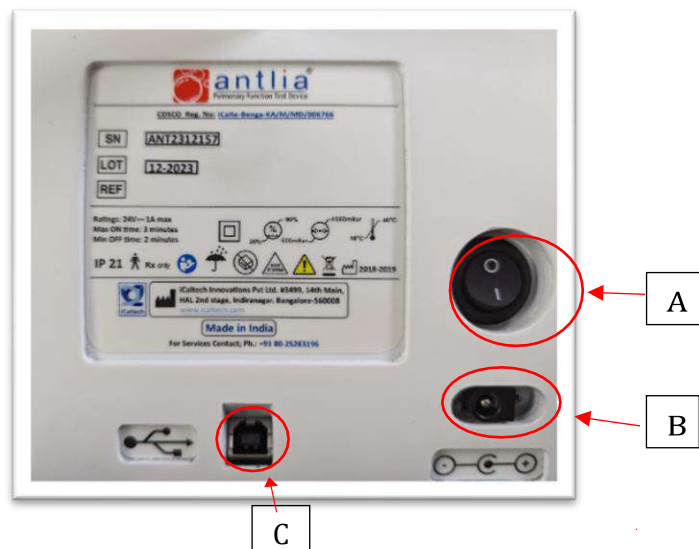


Minimum height of the device is 25cm



Maximum height of the device - 46cm

7.1.2 Device rear view:



- A. Power ON/OFF button
B. Power supply connector
C. Type B USB port

7.2 List of Accessories:

Component Description	Image
Vitalograph Filter Eco BVF BVF filter: It is only for single patient use.	
Nose clip: It is only for single patient use.	
Power Adapter: Desktop AC Adapters 90W 24V 3.75A Medical.	
USB cable: Cable USB A MALE - B MALE 3M BLK	
AC cable: Adapter power cable	

Reference impedance: It gives known impedance with tolerance $\pm 10\%$. It is used for device verification.



8 SETUP INSTRUCTIONS:

8.1 PATIENT POSITION

The proper usage of the patient circuit is necessary for the accurate measurement.

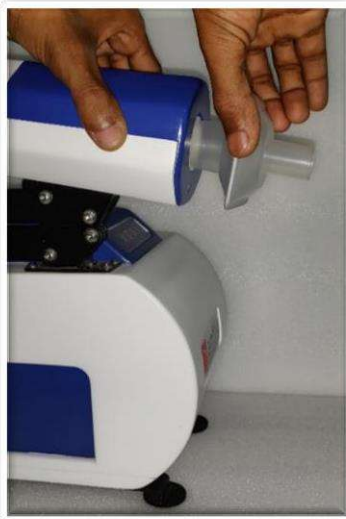
8.1.1 Install the device on a table as shown in the below picture.



8.1.2 To perform the test properly, place a chair in front of the floor where you have installed the device.

8.1.3 Seat the patient in front of the device keeping their back straight.

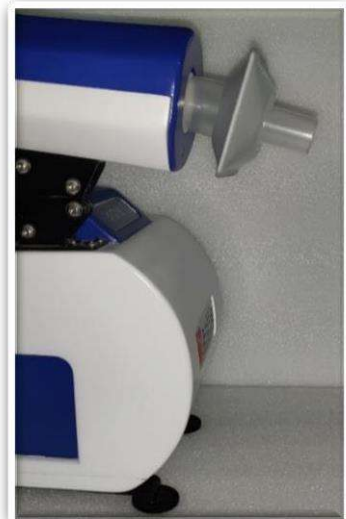
8.1.4 Connect Vitalograph filter to the device as shown in the below picture



Filter connection



Proper filter connection



Improper filter connection

- 8.1.5 Instruct patient to wear the nose clip to avoid air leakages.
- 8.1.6 Adjust the stand according to patient position and user take care of the source tube while adjusting the stand so that source tube shall not get damaged.

During the test run it is necessary for the patient to hold the cheeks with the hands as shown in the below figure to provide greater reliability of the measurement.



- 8.1.7 The patient should keep the chin up and breathe normally during the test conduction.
- 8.1.8 Ensure that there is no air leakage around the lip and BV Filter

8.2 Performing the test

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

Adding patient: Before starting the measurement, it is necessary to enter patient Information.

Selecting Existing patient: If the subject you wish to study is already in the database, Select the Patient from the **“Conduct test”** screen.

Patient Position: The proper usage of the patient circuit is necessary for the accurate measurement.

Measurement mode:

Mono frequency:

- The PFT test should be carried out 12 secs for Mono frequency with the frequency range (5,10,14,20,22) Hz
Mono-mode for a given frequency 5Hz and 20Hz, the patient should get coherence value at 5 Hz greater than 0.85 for all three acts. If the coherence value at 5 Hz is less than 0.85 the patient should repeat the test.

Multi frequency Mode:

- The PFT test should be carried out 36 secs for multi frequency mode with frequency range (5, 12, 20) Hz.

In Multi-mode the patient should get coherence value at 5 Hz greater than 0.85 for all three acts. If the coherence value at 5 Hz is less than 0.85 the patient should repeat the test.

Note: In multi-mode coherence value at 5 Hz upto 0.80 is acceptable if patient is unable to achieve the required value up to 4th Acts.

The App supports to conduct test in two stages:

- Pre-test:** Pre-test will be selected when patient is doing test for the first time.
- Post-test:** Upon Pre-test, based on the result, patient shall be broncho dilated by physician and Post-test shall be conducted.

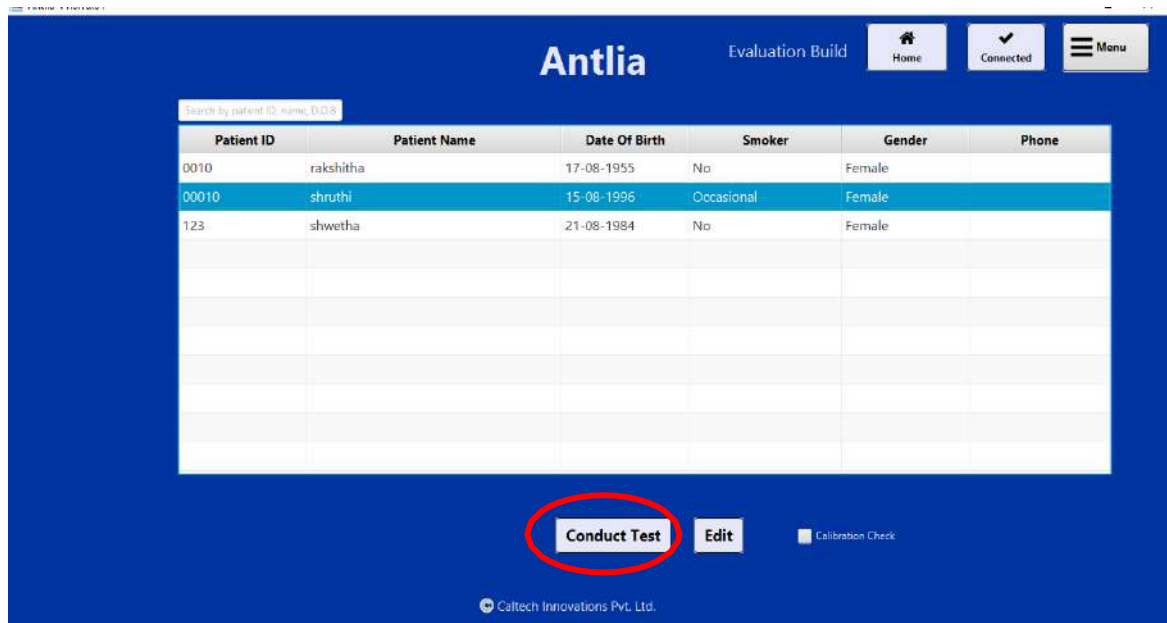
Performing Test:

If patient information is already existing in the database from Begin test screen you can directly perform the test

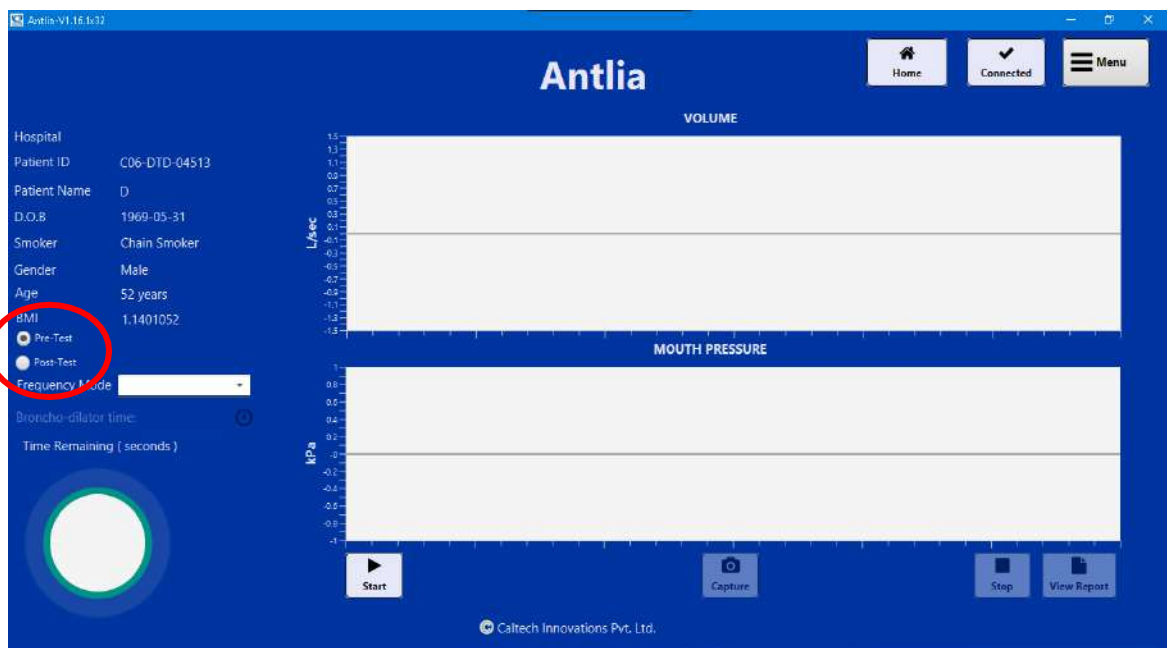
- Click on “Conduct test” option on Home screen



- Select patient from the patient list and click on “Conduct test” as shown in the below picture



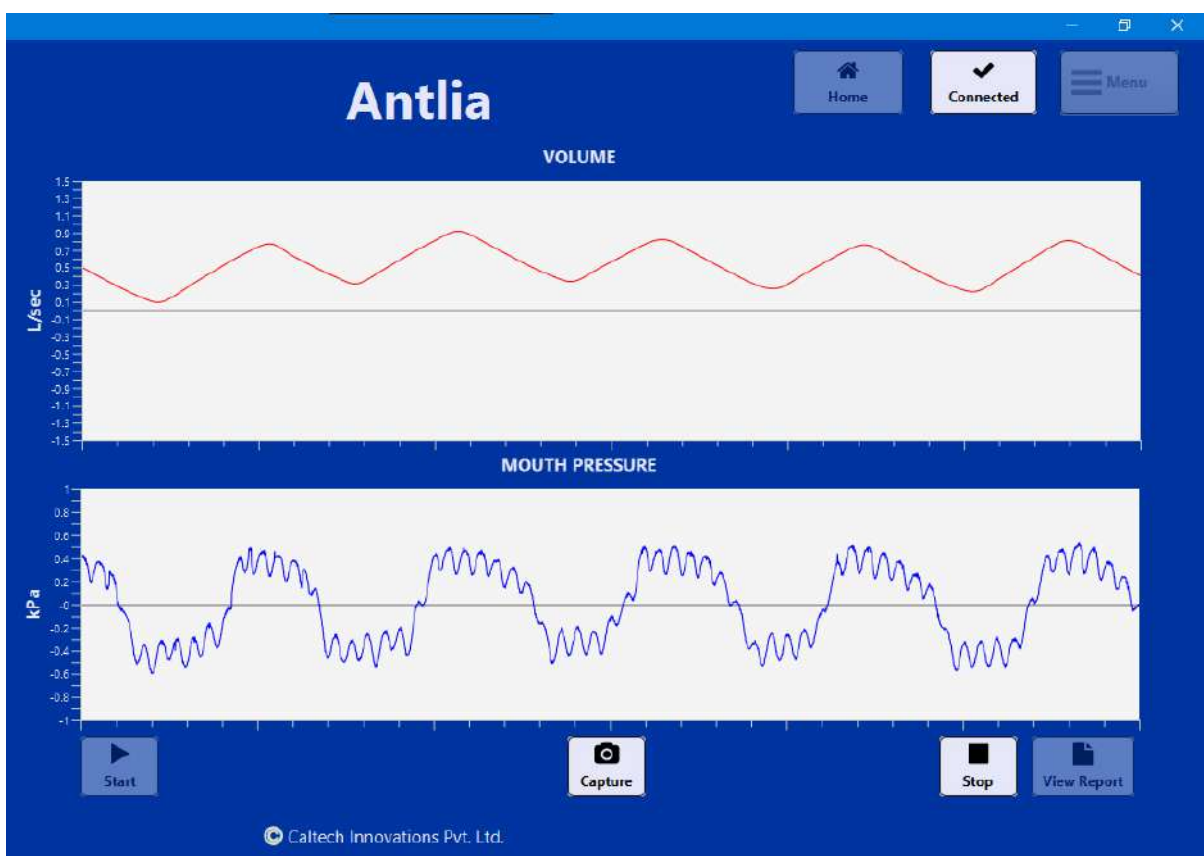
- Select Pre-test or Post-test option



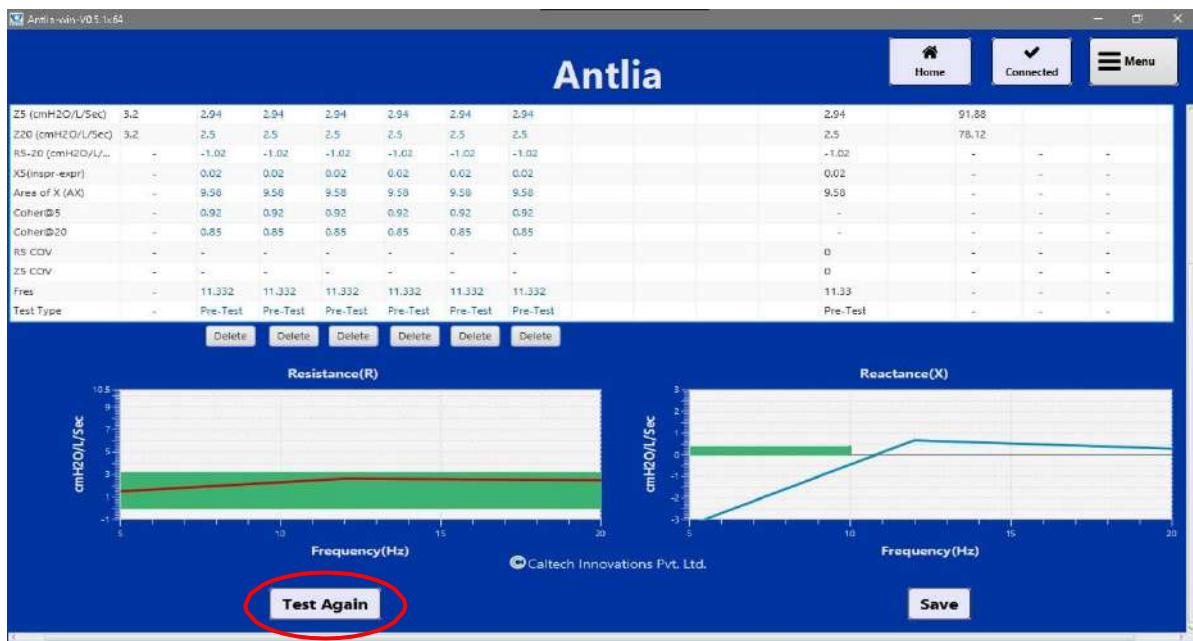
- Select Device mode “Multi” or “Mono” from the dropdown box as shown in the below picture



- Click on “Start” button, when patient breathing is synchronizing with the waveform then click on “Capture” icon



- After test completion click on “View Report ” button, test report is displayed on your screen



- Click on "Save" option to save patient report
- By clicking "Test again" option, perform 3 trials with coherence value above "0.85"

1. System Shut-Down:

Closing the Software

To close the Software, click the close(X) icon on the top right corner of the ANTLIA screen.

Auto Log-off

- 1) Application will auto log-off when not in use, after 3 minutes.
- 2) After auto log-off, user has to login.
- 3) Auto Log-off can be enabled/disabled in settings screen with admin credentials.

ANTLIA device Power Off

When you are done with your trials and after you have close down the ANTLIA software, switch off the device by pressing Power ON button on the back side of the device and switch off the Main's switch on the Mains Board. Ensure that all LED indications are turned off.

8.3 Training

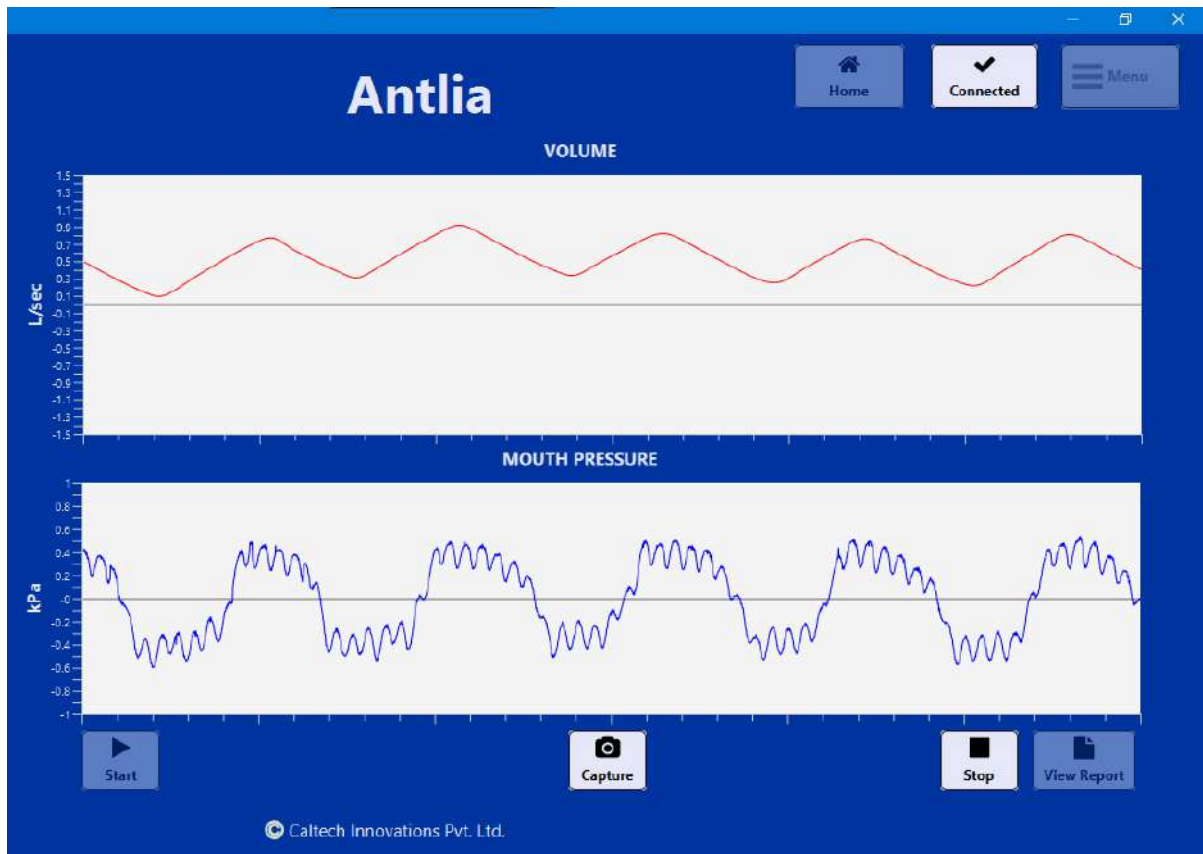
An on-site Customer Service Engineer, or a 3rd party service engineer installing the system provides the customer training for the ANTLIA device. Such training covers basic system operation and safety handling.

Following training should be given for User:

- 1) Device handling
- 2) Adjustment of stand based on patient height.
- 3) Usage of Single use accessories: Nose clip and Vitalograph filter
- 4) Device verification procedure
- 5) Patient position and Device operation
- 6) Connection of Accessories and while performing test
- 7) Result interpretation
- 8) Software operation

9 RESULTS AND REPORTING:

Real time graph: When patient is breathing we can see flow and mouth pressure graph in App



After completion of pre-Test 'Save' button must be pressed and the report will be stored in Pc at user defined location in pdf format. After carrying out post-test for the same patient the 'Save' button must be pressed again and a consolidated report of pre and post of the patient will be saved in pdf format at user defined location. Finally, we can take print-out of post-test report which includes the pre-test report also.

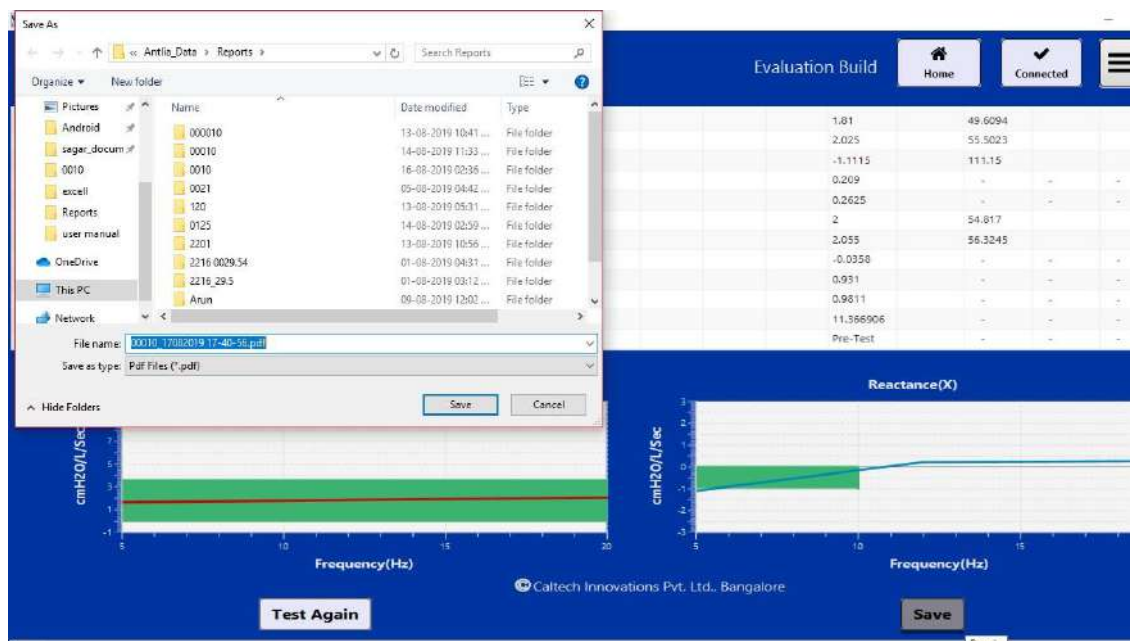
To Save report follow the below procedure:

After performing the test, automatically screen will go to Report screen.

- Click on Save option to Save Report as shown in the below picture.



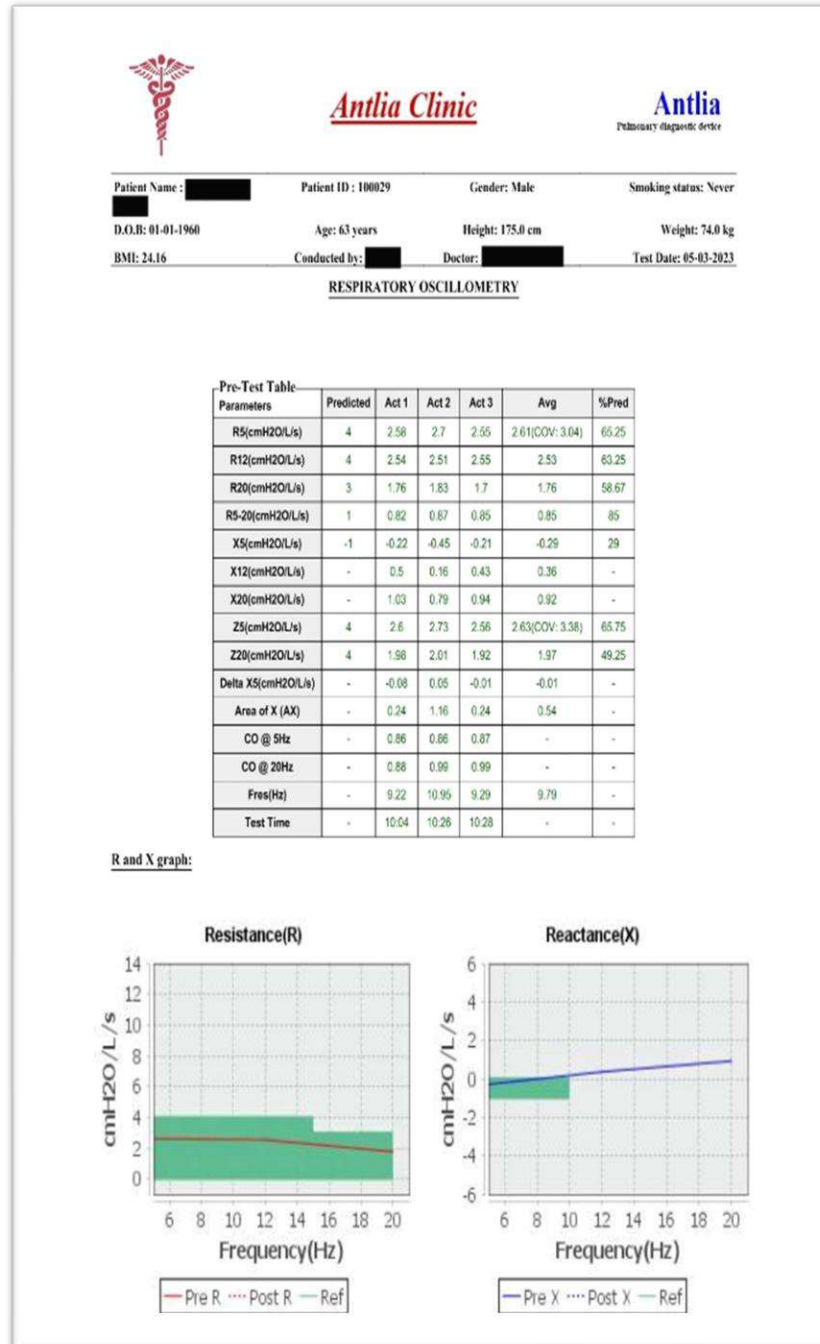
- Save the Pdf file in your PC



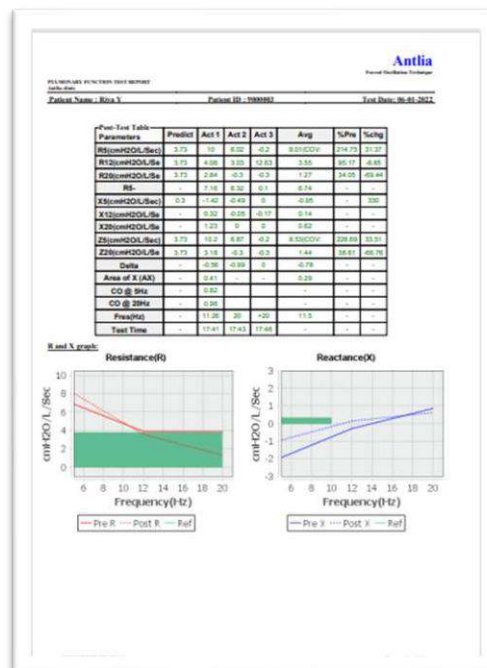
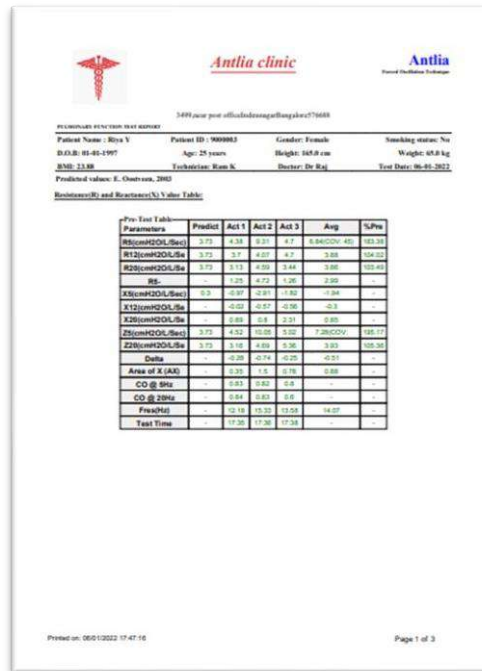
- From your PC you can print patient report
- When you open PDF file, Report will be displayed as shown in the below picture

Device interpretation with report

I. Patient with normal condition



II. Patient with abnormal condition



One page Report



Antlia clinic

Forced Oscillation Technique



3499,acae post office/inimagaftangloer576683

PULMONARY FUNCTION TEST REPORT

Patient Name : Dia KM	Patient ID : 9000001	Gender: Female	Smoking status: No
D.O.B: 01-01-1995	Age: 27 years	Height: 165.0 cm	Weight: 52.0 kg
BMI: 19.1	Technician: Ram K	Doctor: Dr Raj	Test Date: 06-01-2022

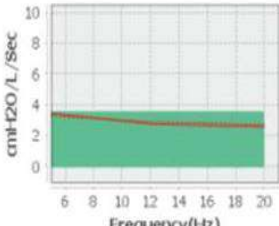
Predicted values: E. Outveen, 2003

Resistance(R) and Reactance(X) Value Table:

Parameters	Predict	Pre Avg	Pre %Pred	Post Avg	Post %Pred	%chg
RS(cmH2O/L/Sec)	3.51	3.43(COV: 7.07)	97.72	3.28(COV: 3.98)	93.45	-4.27
R20(cmH2O/L/Sec)	3.51	2.56	72.95	2.72	77.49	-4.56
RS-	-	0.87	-	0.55	-	-
X5(cmH2O/L/Sec)	0.51	-1.7	-333.33	-1.65	-323.53	9.8
Delta	-	-0.07	-	-0.03	-	-
Area of X (AX)	-	0.66	-	0.64	-	-
Fres(Hz)	-	12.77	-	12.71	-	-

R and X graph:

Resistance(R)

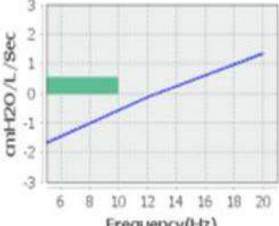


cmH2O/L/Sec

Frequency(Hz)

— Pre R — Post R — Ref

Reactance(X)



cmH2O/L/Sec

Frequency(Hz)

— Pre X — Post X — Ref

Physician's comments:

Technician's Signature

Doctor's Signature

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Page 1 of 1

Abbreviations:

Rrs	Respiratory Resistance
Xrs	Respiratory Reactance
R5	Resistance at 5Hz
R12	Resistance at 12 Hz
R20	Resistance at 20Hz
X5	Reactance at 5Hz
X12	Reactance at 12 Hz
X20	Reactance at 20Hz
Z5	Respiratory impedance at 5Hz
Z20	Respiratory impedance at 20Hz
AX	Area of Reactance
Fres	Resonant frequency (Hz)
R5 COV	R5 Coefficient Of Variation
Z5 COV	Z5 Coefficient Of Variation

10 Care and Maintenance

When the device is not used for an extended period of time, be sure to place the dust cover over the device. For long-term storage or transport, please retain and use the original ANTLIA packaging.

Upon completion of a patient test, be sure to dispose the single-use supplies, iCaltech recommended filter and the nose clip, in a suitable waste collection container as per your institution's guidelines and regulations.

After storing or transporting your device in a cold, or warm environment, allow several minutes for the device to acclimatize to room temperature before taking any measurements. This will ensure maximum accuracy of reported results.

Daily check: User should perform Device verification every day before performing the test. (Refer: 9.2 Device Verification Test).

Annual maintenance: The Antlia device should be serviced by iCaltech authorized service providers. You may contact the iCaltech Technical Support or your local representative.

Contact Details:

Contact Number: +91 94800 17633

10.1 Routine Cleaning:

The use of a disposable anti-bacterial filter prevents transmission of diseases and infection between patients during regular use of the device. Proper use and disposal the filters and nose clip means that it is not necessary to perform special cleaning procedures to the device.

However, it is important to regularly clean the exterior surfaces of the device using a mild detergent with water. Using soft cloth Wipe the exterior body and the edges of the device. Do not use harsh chemical or abrasive cleaners as these may damage your device.



CAUTION

Do not use alcohol or sterilization liquids on the surface of the device.

10.2 Disposal:

At the end of product's life dispose of the device in accordance with all local regulations regarding electrical and electronic waste. Otherwise, it can cause dangerous consequences for the environment and human health.

The crossed-out wheeled bin means that the product must be taken to a separate collection when you wish to dispose of it.

Note: iCaltech filter and nose clips are single use only.

11 Troubleshooting:

Below is a list of the most common operating problems which can occur during normal use of the device and possible actions for their solution.

Sl.no	Problem	Possible Cause	Solution
1	Unit does not turn ON; all power indicators remain unlit.	Power cable not connected	Check if power cable is connected properly
		No power on outlet	Check Power is available, try different outlet
		Power button is in OFF condition	Press the power ON button
2	Device is not connecting with APP	Device is in OFF condition	Switch ON the device
		USB cable is not connected properly	Remove the USB cable and reconnect properly
		PC is not Compatible with the software	Check COM port is installed in your PC and check specification of the PC.
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, Restart 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 Vitalograph filter is connected properly.
		Defective Flow sensor or Pressure sensor	Replace Flow sensor or pressure sensor if defective
		Breathing circuit defective or incorrectly assembled	Breathing circuit defective or incorrectly assembled *Check error messages on screen and proceed accordingly.
5	Sensor Calibration fails	Breathing circuit defective or incorrectly assembled	Breathing circuit defective or incorrectly assembled Check error messages on screen and proceed accordingly.
6	Motor stops during start mode	Power supply Fluctuation	Check voltage across mains outlet, try different outlet or provide protection circuit
		Motor wires are disconnected	Check motor wire connection and reconnect properly

7	Device impedance is above 10% accuracy using known impedance value	Known resistance is not connected properly	Connect the known resistance to FOT tube without Vitalograph filter
		Incorrect Known resistance is used	Check Known resistance value and perform the test
8	Application crashed while switching from start to capture button	Internal error	Restart the application software
9	Unable to save the report after pre/post-test completion	Internal error	Restart the application software
10	When app is closed, connection between device and app is disconnecting but, device is still running.	Internal error	Restart the device
11	Test values are not Updating properly in ACT table.	Internal error	Restart the application software
12	During breathing, app is displaying message as “device does not detect the patient” and test is stopping and sometimes it is displaying message as “Peak to Peak pressure is too high” and test is stopping. This is intermittent error	Improper connection between patient to device or High Peak to Peak pressure	Retest to be conducted

11.1 List of Errors:

Sl #	Error Code	Error Type	Error message Title	Error Message	Scenario	Actions
1	NA	Text message	N/A	Please enter <missing field name>	If any of the mandatory field is missing in edit/new patient screen and user clicks on save button. (Add patient screen)	Enter all the mandatory fields
2	NA	Text message	N/A	Please enter <missing field name>	If all fields are empty in edit/new patient screen and user clicks on save button. (Add patient screen)	Enter all the mandatory fields
3	NA	Text message	N/A	Please enter <missing field name>	If any field is missing in edit/new hospital screen and user clicks on save button. (Hospital information screen)	Enter all the mandatory fields
4	NA	Text message	N/A	Please enter mandatory (*) fields	If all fields are empty in edit/new hospital screen and user clicks on save button. (Hospital information screen)	Enter all the mandatory fields

5	NA	Text message	N/A	Enter valid Device Id	Device id is invalid. (Hospital information screen)	Enter Valid device ID
6	NA	Text message	N/A	Phone number can contain only digits	If phone Number is Entered in alphabets, alphanumeric. (Hospital information screen)	On phone number field enter only numbers
7	NA	Text message	N/A	Phone number must contain 10 to 15 digits	If entered phone number is more than 15 digits. (Hospital information screen)	Enter upto 10 to 15 Number digits
8	NA	Text message	N/A	Please enter <missing field name>	If any of the mandatory field is missing in edit/newstaff screen and user click on save button. (Add new staff screen)	Enter all the mandatory fields
9	NA	Text message	N/A	Please enter <missing field name>	If all fields are empty in edit/new staff screen and user clicks on save button. (Add new staff screen)	Enter all the mandatory fields
10	NA	Text message	N/A	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

11	NA	Text message	N/A	Last name Must be containing only alphabets with maximum 20 characters	If Last name field is invalid- (Add new staff screen)	Enter only Alphabet's with Max.20 characters
12	NA	Text message	N/A	Phone number must contain 10 to 15 digits	If Phonenumbr field is invalid - (Add new staff screen)	Enter only Digits with 10 to 15 digits
13	NA	Text message	N/A	Search not found	When user Search not Found in patient or staff screens. (Patient list screen)	Enter valid patient name or ID
14	NA	Text message	NA	Please entervlid username and password	If both or any one of username and Password fields are invalid. (Login screen)	Enter valid User name and password
15	NA	Text message	NA	Please enter username	If username field is blank (Login screen)	Do not keep user name field as blank
16	NA	Text message	NA	Please enter password	If password field is blank (Login screen)	Do not keep Password field as blank
17	NA	Text message	NA	Please enter password	If username is invalid and password field is blank (Login screen)	Enter valid User name and Password
18	NA	Text message	NA	Please enter username	If password is invalid and username field is blank. (Login screen)	Enter valid User name and Password

19	NA	Text message	NA	Please fill Username and password fields.	If user clicks on "Login" button without username and password. (Login screen)	Enter valid User name and Password
20	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
21	NA	Text message	NA	New password	If new password is entered and must be confirmed.	Enter all the fields confirm password is blank. (Change password screen - Admin Login)
22	NA	Text message	NA	Please Enter current password Please provide a new password. New password must be confirmed	If current password, new password and confirm password fields are blank. (Change password screen - Admin Login)	Enter all the fields
23	NA	Text message	NA	Password field must contain 6 characters with at least one numeric and one alphabet	If new password and current password is invalid - Staff (Change password screen - Admin Login)	Enter valid password

24	NA	Text message	NA	Password field must contain 8 characters with at least one numeric and one alphabet.	If new password and current password is invalid - Admin (Change password screen - Admin Login)	Enter valid password
25	AS_ERR_002	Error	Unregistered Email-ID	Entered e-mail ID does not exist. Please enter Registered e-mail ID.	For Unregistered e-mail ID. (Forgot password screen - Admin Login)	Enter valid email id
26	AS_ERR_003	Error	Email-ID is missing	Please enter registered e-mail ID to get password.	If user clicks on "Submit" button without entering e-mail ID. (Forgot password Login)	Enter valid email id
27	AS_ERR_004	Error	Invalid Email-ID	Please enter valid email id	For invalid email id. (Forgot password Login)	Enter valid email id
28	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
29	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
30	AS_ERR_101	Error	Device Calibration	Please perform device calibration. Please call service engineer	If user starts the test without performing calibration. (Calibration screen)	Perform device calibration before starting the test

				to perform Calibration		
31	AS_ERR_102	Error	Patient not selected	Please select patient from the list	If user clicks on Begin test button without selecting patient from the list. (Home screen)	Select patient and click on Begin test
32	AS_ERR_103	Error	Test type and frequency mode not selected	Please select test type and frequency mode before starting the test	If user clicks on start button, without selecting pre-test/post-test &/OR Frequency mode options. (Conduct test screen)	Select patient, test type, and frequency mode before conducting the test
33	AS_ERR_104	Error	Test type not selected	Please select test type before starting the test	If user clicks on start button without selecting test-type. (Conduct test screen)	Before conducting test select test type
34	AS_ERR_105	Error	Frequency mode not selected	Please select frequency mode from the dropdown	If user clicks on start button without selecting frequency. (Conduct test screen)	Before conducting test select frequency mode
35	AS_ERR_106	Error	Invalid Device ID	Please enter valid device ID	In calibration screen, If user enters invalid device ID. (Calibration screen)	Enter valid device ID
36	AS_ERR_107	Error	Blank Device ID	Please provide a device ID	If device ID field is blank and device is not connected with the App. (Calibration screen)	Enter valid device ID, and connect the device with App

37	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
38	AS_ERR_109	Error	Problem connecting to device	Please check USB cable connection and click on "Connect" button	Unable to detect the USB COM port. (Any app screen)	Connect the USB cable to device
39	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
40	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
41	AS_ERR_112	Warning	Cancel Confirmation: Add staff	All the entered staff information will be lost. "Are you sure want to cancel?" with "Yes"	If user clicks on cancel button after entering or editing the staff information. (Add new staff screen)	Confirm about cancelation of the filed

				and "No" options		
42	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
43	AS_ERR_114	Warning	Delete Confirmation : Patient Information	"Are you sure want to delete patient <Patient full name>" with "Delete" and "Cancel" options	If user clicks on delete button of particular patient information. (Add patient screen)	Confirm about deletion of the filed
44	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
45	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
46	AS_ERR_117	Warning	Exit Confirmation	"Are you sure want to exit from the Antlia App?" with "Ok" and "Cancel" buttons	If user close(X) the application (Home screen)	Confirm about closing the application

47	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
48	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
49	AS_ERR_120	Information	Maximum trials reached	Test has Reached to maximum trials, please save thereport before continuing with new test.	While performing the 10th action in pre/post mode. (Viewreport screen)	After 10th Action save the Report
50	AS_ERR_121	Information	Maximum trials reached	Test has Reached to maximum trials, Do you want to replace thevalues?	While performing the 11th action in pre/post mode. (Viewreport screen)	After 10th Action save the Report
51	AD_ERR_201	Error	Device not found	Please check USB cable connection and click on "Connect" button	If user clicks on Begin test in home screen, without connecting device to thePC. (Homescreen)	Before starting test Connect the device with APP
52	AD_ERR_202	Error	Device Disconnect ion	Oops! Deviceis disconnected from the PC	In between if user disconnects USB cable from the PC. (Home screen)	Do not disconnect the USB cable, while performing test
53	AD_ERR_203	Error	Device disconnected	Device got disconnected.Please disconnect and reconnect	During test, if device got reset due communication slow down.	Disconnect the USB cable and reconnect

				USB cable And re- initiate the test.	(Conduct test screen)	
54	AD_ERR_204	Error	Device Disconnect ion	Oops! Device disconnected from the PC	If user power off the device when USB is connected with PC. (Home screen)	Do not power off the device while performing test
55	AD_ERR_205	Error	Device reset	Device got reset. Please disconnect and reconnect USB cable And re- Initiate the test.	Watchdog reset while communication with device in start/capture mode. (Any app screen)	Disconnect the USB cable and reconnect
56	AD_ERR_206	Error	Device stopped unexpectedly	Please test again	Motor stops during start mode. (Conduct test screen)	Ignore the trials and perform the test again
57	AD_ERR_208	Error	Device disconnected	Device got disconnecte d. Please disconnect and reconnect USB cable And re- Initiate the test.	While communicating with Device in Ideal mode	Disconnect the USB cable and reconnect and perform thetest
58	AD_ERR_209	Error	Device Accuracy Low	Requires re- calibration	Device impedance above 10% accuracy using known impedance value. (Conduct test screen – during calibration verification)	Perform Device calibration using reference resistance

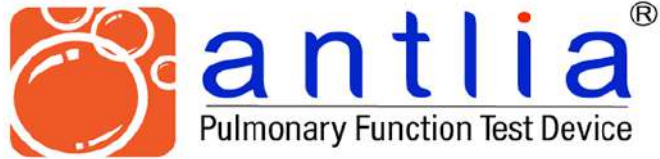
59	AD_ERR_210	Error	Device SensorFail	Please contact the service engineer	Sensor Calibration fails. (Conduct test screen – during calibration verification)	Call Service engineer
60	AD_ERR_211	Warning	Device in Idlemode	Device is Running in idle mode. Please continue or stop the test.	Start mode running more than 2mins. (Conduct test screen)	Stop the test and perform the test again
61	AD_ERR_212	Warning	Test Exit Confirmation	“Test is InProgress, test will be stopped” Are you sure want to exit?with "Ok"and "cancel" buttons	During test trial, if user close the application. (Conduct test screen)	Confirm about before closing the application

TECHNICAL SPECIFICATIONS:

Technical Specifications



Flow Measurement	Pneumotach	
Physical dimensions	Height: 287mm Width: 170mm Length: 329mm	
Mouth pressure Range	+/-2kPa	
Pressure Transducer	Piezo-Resistive	
Weight	4.5 kg	
Testing signal Mode	Mono Frequency	Multi Frequency (Composite)
	5,10,14,20,22 Hz	5,12,20 Hz
Measurement Accuracy	For Impedance +/-10%	
Calibration	Factory calibration + Auto-Zeroing of the sensors before each test. Calibration check with a test object (reference impedance) External load provided.	
Portability	Tabletop	
Data Viewing & storage	Desktop or Laptop	
Support Arm	Metal	
Power Adaptor Input Voltage	100-240V AC, 1.3-0.6A, 50/60Hz	
Output voltage	24V	
Current Ratings	3.75A (Max)	
Power Consumption	90 W	
Design is as per IEC 60601-1,1-2 and ERS Guidelines		



Manufacturing Licence Number: [MFG/MD/2025/000869](#)

SN



IP21



20% 90%

600mBar 1060mBar

10°C 40°C



MD



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