B.O.L.T™

ONE-TOUCH WIRELESS HEALTH TRACKER

B.O.L.T Spirometer

User Manual

Model: VA08

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Document History

Version	Date	Comment
1.0	31-12-2015	Initial Release
1.1	09-02-2018	Updated with new images and contents

Review Record

Version	Reviewed by	Review Comments
1.0	Mohamed Anees, Anantharaman, Rajavel, Ketharaman, Sajith	
1.1	Mohamed Anees, Anantharaman, Rajavel, Ketharaman, Sajith	

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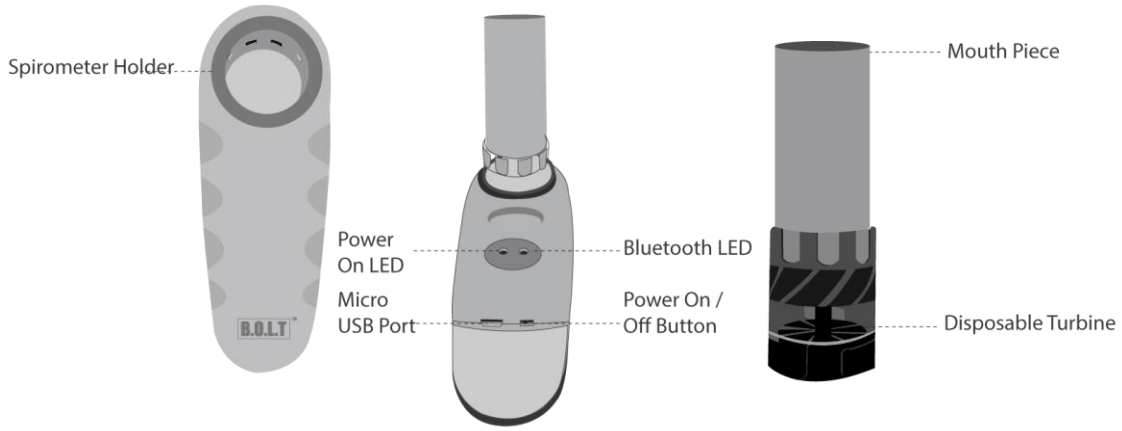
Model VA08 – B.O.L.T Spirometer

1.0 Intended Use

B.O.L.T Spirometer Device is intended to test lung function and perform spirometry testing for the people of all ages, excluding infants and neonates. The device must be used by a physician, respiratory therapist or by a patient under the instructions of a physician.

2.0 Product Description

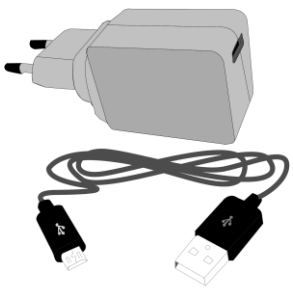
B.O.L.T Spirometer device is a portable wireless lungs monitoring system which can measure/monitor the lung function. The device is used to assess the condition of lungs by measuring the volume of air inhaled and exhaled. The system consists of the electronics part with an enclosure and a disposable turbine with mouthpiece where the user blows and sucks air. The device calculates the flow rate and other relevant parameters and sends the data wirelessly to the mobile device. The spirometer device is powered by 5V DC through a USB micro connector and also has an internal battery for power backup. The spirometer device calculates various respiratory parameters, as well as the parameter comparison after the administration of a drug (PRE/POST session) for a bronchodilator test and comparison of data made between POST (after-drug) and PRE (before drug administration). The data acquired by the spirometer device can be used to obtain clinical consultation from the doctor or healthcare practitioners.



B.O.L.T Spirometer

Disposable turbine

Nose Clip



Charging Adaptor & USB Cable

3.0 Package Contents

Package List	Packing List	Quantity
1	B.O.L.T Spirometer	1
2	Disposable turbine	3
3	Mouthpiece	3
4	Nose Clip	3
5	Power Adapter	1
6	USB Cable	1
7	Warranty Card	1
8	Quick Reference Guide	1

4.0 Product Quality Reliability and Safety

The device has been designed with an emphasis on quality, reliability and safety, but AMI can only accept responsibility for these aspects, provided the following conditions are met

- The device should be used as per the operating instructions mentioned in the user manual provided by AMI.
- All modifications and repairs to the device are carried out by authorized AMI personnel or their agents.
- The device must comply with regulation specified in warning and cautions.

Warning

Warnings are intended to alert you about the importance of following the correct operating procedures to prevent the risk of injury to the patient.

- No modification of this device is allowed.
- Use only the type of power source that is indicated on the label.
- Unplug the device before servicing/cleaning.
- Don’t use a damaged power cord.
- Only trained personnel is allowed service the device.
- Check the electrical connections periodically; any defects noticed, like loose connections, damaged by insulation in the electrical wires etc., should be rectified immediately.
- Do not expose the device to strong shocks or vibrations.
- Do not disassemble, repair, or modify the device by yourself. Doing so could void the user's authority to operate the device.
- Exposure to unsuitable environmental conditions may cause the device to malfunction and provide inaccurate readings.
- The device must be used according to the indications given by the manufacturer in the User manual with particular attention to Intended use.
- Use of non-original parts such as the turbine flow sensor or the other accessories may cause errors in measurement.

- In case of any incident or malfunctioning of the device, the user is required to inform the manufacturer without any delay.
- Do not expose the turbine to a direct jet of water or air, and avoid contact with high-temperature liquids.
- Do not use any other power adaptor & USB cable with the spirometer device other than the one supplied with the package.
- The manufacturer cannot be held responsible for any damage caused by the user to the device by failing to follow the warnings and instructions mentioned in this manual.

Calibration

The turbine flow sensor does not require any calibration. Ensure that the sensor is free from the external particles like dust, hair etc. in order to avoid incorrect functioning and possible damage.

Caution

- Do not reuse the disposable turbine to perform a test for another user.
- Do not use unauthorized parts and accessories.
- Do not store or use this device in locations which are maintained above the specified temperature and humidity ranges.
- Do not use in an operating theatre nor in the presence of inflammable liquids or detergents, nor in the presence of inflammable anesthetic gases, oxygen or nitrogen.
- Do not expose the disposable turbine to a direct jet of water or air, and avoid contact with high-temperature liquids.

Care and Maintenance

- Store the device and the components in a clean and safe location.
- Charge the device for minimum two hours in case of the first-time usage.
- Do not disassemble, repair or modify the device and the components by yourself.
- Wipe the device using 70% Isopropyl alcohol and let it air dry and do not use any other hazardous solvent to clean the device.
- Do not spill any liquid into the device.
- Unexpected mechanical damage of the device must be intimate to the manufacturer immediately.

Disposal

Dispose of the instrument according to local disposal and recycling laws


This symbol is applicable for EU member countries only.

To avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of (i) for EU member countries - in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment), or (ii) for all other countries, in accordance with local disposal and recycling laws.

- Nose clip and the disposable turbine used with the spirometer device are considered as disposable products.
- The disposable turbine needs to be disposed after the single member usage to avoid cross-contamination.
- The disposable turbine is made of plastic and its disposal after use should adhere to the local authority guidelines/norms.

5.0 Contraindications

The analyzed results from the spirometry test are not by itself sufficient to make a correct diagnosis of the patient`s clinical condition. A detailed clinical history of the patient is also required together with the results of any other tests suggested by a doctor. The results depend on the person`s ability to inhale as much as possible and to exhale all of the air as fast as long as possible. If these fundamental conditions are not met then the result obtained during the spirometry testing will not be considered accurate, and therefore the test results are not acceptable.

This device is not suitable for certain age group as mentioned below or anyone who are incapable of using the device in an appropriate manner.

Age group	Suitability
Neonates (less than 4 weeks old)	Not suitable
Infants	Not suitable
Adults	Suitable

6.0 Product Features

The Spirometer provides various respiratory parameters, as well as the parameter comparison after the administration of a drug (PRE/POST) for a bronchodilator test and a comparison of data is made between POST (after-drug) and PRE (before drug administration).

Measured Parameters

Parameters	Description	Units/Percentage
FVC	Forced Vitals Capacity	L
FEV1	Volume expired in the 1st second of the test	L
FEV1/FVC	Ratio of FEV1/FVC	L
PEF	Peak Expiratory Flow	L/min
FEF 25-75%	Flow ratio at 25% and at 75%	%
FVC% Predicted	Predicted FVC	%
FEV1% Predicted	Predicted FEV1	%
FEV1 Reversibility (ml)	Reversibility in milliliter	ml
FEV1 Reversibility (%)	Reversibility in Percentage	%

7.0 Operating Environment

B.O.L.T Spirometer device has been designed for use in the hospitals, clinics or directly by the patient at home to monitor the lung conditions. The user or the physician is responsible for ensuring that the device is stored and used in appropriate environmental conditions.

8.0 Prerequisites

Some basic requirements must be adopted as mentioned below to ensure better operation of the product.

- B.O.L.T Spirometer device is designed to be operated with applications like Android, iOS or Windows.
- The Android OS version of the computer/mobile device should be 4.0 or higher.
- The iOS version of the computer/mobile device should be 7 or higher.
- The Windows OS version of the computer/mobile device should be 8 or higher.

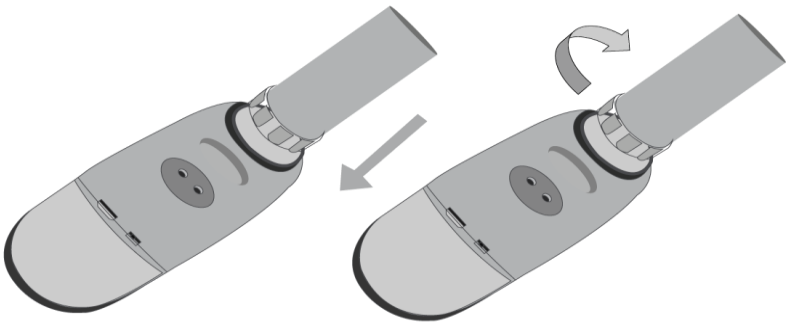
9.0 Using Mobile Application

Downloading and Installing Mobile application on your computer/mobile device

1. Download and Install the "B.O.L.T "Application from Play store/Application store/Windows application market.
2. On successful installation, launch the application on the mobile device.
3. Sign up for creating a new login or use Login as a guest. Login as guest would not allow you to save the data in cloud.

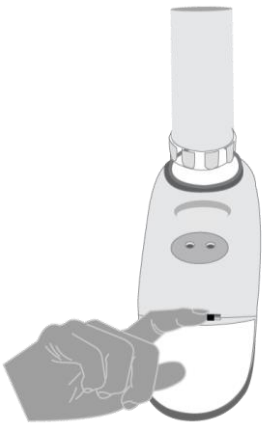
10.0 B.O.L.T Spirometer Measurement procedure

1. Insert and rotate the disposable turbine clockwise to fix with the spirometer as shown below.



Insert the disposable turbine Rotate clockwise to fix

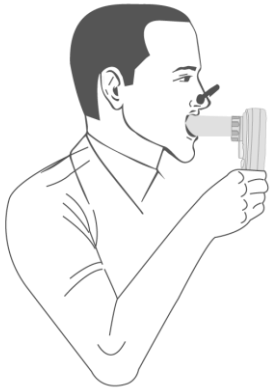
2. Switch ON the spirometer device using the slide button as shown below.



Switch ON

3. Launch the mobile application from the mobile device.
4. On successful login, Choose Check vitals menu.

5. Choose the Spirometer option from the mobile application test list.
6. Choose the Spirometer device from the available list of vitals devices.
7. Confirm the device selection and provide default pairing password 1234/0000 for pairing the spirometer device (on request for the first time pairing).
8. Ensure that the Bluetooth LED stops blinking in the spirometer device.
9. Enter the Gender, Age, Height, Weight and Ethnicity details of the user.
10. Ensure that the user is relaxed and stable during the measurement. Avoid users like recently suffered from heart attack, stroke etc.
11. Select Pre-Bronchodilator test before taking the drug provided by the doctor.
12. Holding the spirometer in one hand as the LED faces the user and also ensure that you are not covering the blow fan with your fingers.
13. Position straight and take a deep breath to fill the air in lungs.

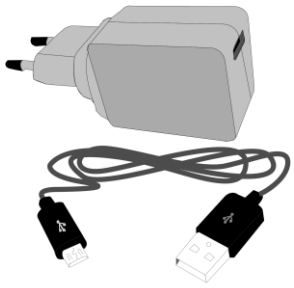


Holding the Spirometer

14. Place the nose clip over the nose to avoid air blow via the nose and Insert the mouthpiece well into the mouth beyond the teeth.
15. Exhale completely and followed by a complete inhale without any air leakage via side passage between the mouth and turbine.
16. On successful measurement, the application would display the reading successfully. If the reading was interrupted or if the user has not used full effort then restart spirometer can be opted by the user to re-take the reading.
17. Remove the mouthpiece from the mouth and then the user shall continue with the regular breathing.
18. Select Post Bronchodilator test after taking the drug provided by the doctor.
19. Post Bronchodilator test is taken again by repeating the same procedure as explained above for Pre Bronchodilator test.
20. Click to upload the result to the cloud on demand for further analysis.
21. Kindly ensure to remove the disposable turbine from the spirometer device and dispose in the disposable container after completing the test.

11.0 Charging the Spirometer

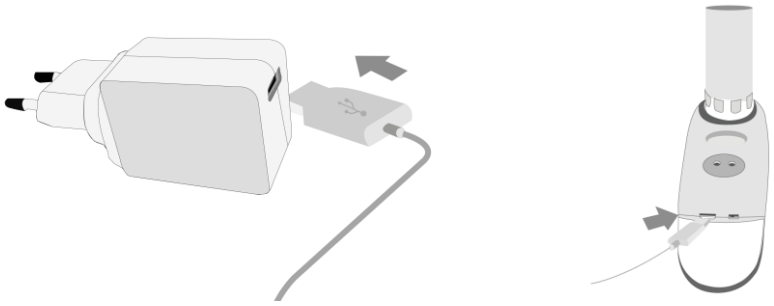
The Spirometer device is operated with an in-built rechargeable battery, which can be charged using the power adapter and USB cable as guided below. It is mandatory to charge the device for a minimum period of 2 hours before the first time usage.



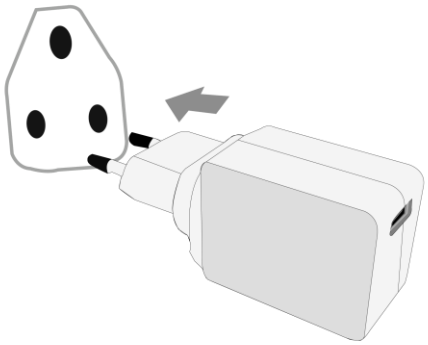
Power adapter & USB cable

Charging Procedure:-

1. Connect the USB cable to the power adapter.
2. Connect the micro USB port to the spirometer power port (USB port).



3. Plug the adapter into the AC mains (110V, 60Hz or 230V, 50Hz).



4. Switch ON the AC mains to charge the device.
5. Check whether the power indicator turns red while charging the device.

12.0 Troubleshooting

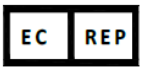
PROBLEM	POSSIBLE CAUSE	SOLUTION
Application not installing from the App store/Play store/Windows market	1. Internet/Data disconnection 2. Memory space unavailability	1. Check your Internet connectivity 2. Move some of the application from Phone storage to SD card 3. If the issue persists, delete some unwanted application and try to install B.O.L.T application
Application Login problem	Internet/Data disconnection	Enable Internet connection through mobile data or Wi-Fi and try to login
Change Password is not getting updated	Internet/Data disconnection	Enable internet connection through mobile data or Wi-Fi and try again
Device requests for Bluetooth pairing password	Bluetooth pairing permission required	Give the password as 1234/0000
Bluetooth communication disconnected while measuring vitals and Bluetooth indicator starts blinking	Bluetooth communication error	Close the application. Restart the spirometer device and restart the entire process again
Spirometer device switched ON, but not showing in List of available Bluetooth device in the application	Bluetooth pairing problem	Restart the Spirometer device, Then try to connect again
Spirometer device switched ON, but Bluetooth (Blue) LED not blinking.	Spirometer device not booted properly	Connect the respective power adaptor to the device and power ON, if still blue LED is not glowing kindly get it repaired in the authorized service center.

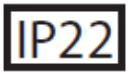
Spirometer device switched ON, but no LED is glowing	No charge for battery	Connect the respective power adaptor to the spirometer device and charge. Then power ON, if still blue LED is not glowing kindly get it repaired in authorized service center

13.0 Technical Specifications

Product Name	**B.O.L.T Spirometer**
Model	VA08
Spirometer	
Unit Dimensions	145(H) x 45(W) x 10(T) mm
Unit Weight	100 grams (Including Battery)
Power Source	DC 5V 2A
Connectivity	Bluetooth 4.0 EDR or Lower, Bluetooth Low Energy (BLE)
Operating Temperature	16°C to 35°C (60.8°F to 95.0°F)
Storage and Transport Temperature	10°C to 55°C (14°F to 131°F)
Storage Humidity	30%RH to 90%RH
Volume Accuracy	± 3% or 50mL
Flow Accuracy	± 5% or 200 mL/s
Flow Range	16 L/s
Measured parameters	FVC, FEV1, FEV1/FVC ratio, PEF, FEF25-75%, FVC % Predicted, FEV1 % Predicted, FEV1 reversibility (ml), FEV1 reversibility %
Memory capacity	Application memorizes data on the phone
Turbine	Bi-directional digital turbine
Mouthpiece	Ø 30 mm (1.18 inch)

14.0 Explanation of Indicators/Symbols

Indicators/ Symbols	Function/Description
	The indicator displays full battery power of the gadget in the computer/mobile device.
	The indicator displays low battery power of the gadget in the computer/mobile device.
(Blue)	○ Flashing of the Bluetooth light indicates that the gadget is waiting for pairing with the mobile/tab. ○ Steady Bluetooth light indicates that the gadget is paired and ready for the measurement.
(Green)	○ Steady green light indicates that the gadget is operating in battery mode. ○ Blinking of green light indicates that the gadget has low battery level.
(Red)	Steady red light indicates that the gadget is in the charging mode.
	Symbol for “DISPOSAL”
	Symbol for “KEEP DRY”
	Symbol for “MANUFACTURER”
	Symbol for “MANUFACTURED DATE”
	Symbol for “SERIAL NUMBER”
	Symbol for “EUROPEAN REPRESENTATIVE”
	Symbol for “EUROPEAN CONFORMITY”
	Symbol for “Federal Communication Commission”

	Symbol for “User Manual”
	Symbol for “Warning”
	Symbol for “Temperature limitation”
	Symbol for “Fragile”
	Symbol for protected against access to hazardous parts with a finger and against vertically falling water drops when tilted up to 15 degrees

15.0 Certifications

COUNCIL DIRECTIVE MDD/93/42/EEC of 14 June 1993 concerning medical devices.

This device complies with the following standards:

- EN ISO 10993-1:2009/AC: 2010 Biological evaluation of medical devices- Part1: Evaluation and Testing with in a risk management process.
- EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- EN 60601-1:2012 General requirements for basic safety and essential performance
- EN 60601-1-2-2007/AC: 2010 General requirements for safety -Collateral standard: Electromagnetic compatibility.
- EN 60601-1-6:2010 Collateral standard: Usability
- IEC 60601-1-4:1996 General requirements for safety- Collateral standard: Programmable electrical medical systems.

16.0 FCC compliance statements

FCC ID: 2AFV6-AMI-SPIRO-02

This device complies with Part 15 of the FCC Rules. Its operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Caution

- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Part 15B compliance statements for digital devices:

NOTE: *This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15C of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.*

This equipment generates, uses and can radiate radio frequency energy And, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no Guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television Reception, which can be determined by turning the equipment off and on,

The user is encouraged to try or to correct the interference by one or more of

The following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

For more information kindly visit our website: www.amibolt.com

Warranty Information

The B.O.L.T is warranted to be free from defects in materials and workmanship within one year from the date of purchase when used in accordance with the provided instructions. The warranty is extended only to the end user. The company will repair free of charge any part or parts of the product if the defect is due to the faulty material or workmanship.

To obtain warranty service contact customer care support by calling 1800-200-8001.

Enclose the warranty card, Proof of Purchase. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit.

The warranty shall not apply to defects resulting from:

- Unauthorized modification/misuse/mishandling of the device.
- Operation of the device outside the environmental specifications of the product (e.g.: temperature, electrical requirements etc.)
- Any other reason external to the equipment (e.g.: accidents, vibrations etc.)

Customer Care Support

AMI's flexible approach allows the customers to get Technical Support and Warranty services for B.O.L.T through our customer care support.

- Toll-free number (India): 1800–200–8001
- Customer Care Support timings: 10 am - 6 pm Monday – Friday (Except National Holidays)
- E-mail address: support@amibolt.com

Contact us

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