AsthmaTuner Spirometer

Before you use your AsthmaTuner Spirometer, please read this user manual, the labels and all the information provided with the product.

User Manual Rev 3.1 Issue Date 18/06/2024

CE 0476

CAUTION: FOR USA MARKET FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

CONTENTS

Thank you for choosing AsthmaTuner.

Before you use your AsthmaTuner Spirometer, please read this user manual, the labels and all the information provided with the product.

Before connecting **AsthmaTuner Spirometer** to a smartphone, install the AsthmaTuner application developed to show data measured by the device.
The package includes:

- The **AsthmaTuner Spirometer** device
- The turbine sensor
- The plastic mouthpiece
- 2 AAA batteries
- User Manual

After removing the device from its packaging, check that there is no visible damage. If there is, do not use the device and send it straight back to MediTuner, where appropriate.

Keep the original packaging!
If your product has a problem, use the original packaging to ship it back to MediTuner.

The address is as follows:
MediTuner AB
Box 3161; 103 63 Stockholm, Sweden
Webbplats: www.medituner.com E-post: info@medituner.com

Legal manufacturer:
MIR - Medical International Research S.p.A.
Viale Luigi Schiavonetti 270, 00173 ROMA (ITALY).

MediTuner cannot be held responsible for any damage caused by users failing to follow these instructions and/or the warnings contained in this manual.

1. INTRODUCTION

1.1 Intended use

AsthmaTuner Spirometer is intended for use by a physician or patient under the physician's instructions to assess lung function. The device is intended for adult patients, adolescents and children over the age of five and can be used in the home, factory, pharmacy, hospital or doctor's office.

1.1.1 Restrictions on Use

Analysis of the test results alone will not be enough to diagnose your clinical condition – you will need a medical examination which will take your clinical history into account as well as any other tests recommended by the doctor.
Diagnosis and appropriate treatments are to be given only by a qualified doctor.

The device is intended for use by one person only. If more than one person wishes to use the device, one user's measurements must not be attributed to another. If another person intends to use the device permanently, the new user needs to sign in with another AsthmaTuner account and the new user's details data (date of birth, origin, weight, height, sex) must be entered.
If you wish to use the device when it has already been used by another person, make sure to disinfect the mouthpiece and turbine, as explained in the Maintenance section.

1.1.2 Contraindications

The ATS/ERS guideline updated 2019 sets out the relative contraindications of spirometry as follows.
Due to increased myocardial demand or changes in blood pressure: Acute myocardial infarction within 1 week; Systemic hypotension or severe hypertension; Significant atrial/ventricular arrhythmia; Uncompensated heart failure; Uncontrolled pulmonary hypertension; Acute pulmonary heart; Clinically unstable pulmonary embolism; History of syncope related to forced expiration/cough.
Due to increased intracranial/intraocular pressure: Cerebral aneurysm; Brain surgery within 4 weeks; Recent concussion with persistent symptoms; Eye surgery within 1 week.
Due to increased sinus and middle ear pressure: Sinus or middle ear surgery or infection within

1 week.

Due to increased intrathoracic and intraabdominal pressure: Presence of pneumothorax; Thoracic surgery within 4 weeks; Abdominal surgery within 4 weeks; Over term pregnancy.

Due to infection control problems: Active or suspected transmissible respiratory or systemic infection, including tuberculosis; Physical conditions predisposing to transmission of infection, such as haemoptysis, significant discharge or oral injury or oral bleeding.

⚠ It is the duty of the medical professional to assess the patient's health condition before the patient undergoes spirometry.

1.2 Description of product

AsthmaTuner Spirometer is a pocket-sized system for measuring the following respiratory parameters:

- **PEF** - Peak Expiratory Flow
- **FEV1** - Forced Expiratory Volume in 1 sec
- **FVC** - Forced Vital Capacity
- **FEF2575** - Average flow between 25% and 75% of the FVC
- **FEV6** - Volume expired in the initial 6 seconds of the test
- **FEV1/FVC** - Tiffeneau index

The device connects to a smartphone via Bluetooth SMART technology. Connection is automatic once the AsthmaTuner application has been installed on the smartphone.

Measurement is performed by a turbine sensor and is based on the infrared interruption principle. This principle ensures that the measurement is accurate and reproducible.

The advantages of this type of sensor are:

- Unaffected by the humidity and density of the gas
- Shockproof and unbreakable
- Inexpensive to replace

The measurements are transferred in real time from the device to the smartphone.

1.3 Information on the parameters measured by AsthmaTuner Spirometer

PEF is the maximal flow of the air when you exhale as hard as possible after filling your lungs completely.
FEV1 is the volume of air exhaled during the first second of the same exhalation.
FVC is the volume of air exhaled during the total exhalation.
FEF2575 is the average flow between 25% and 75% of the total volume of air exhaled during the total exhalation (FVC)
FEV6 is the volume expired in the initial 6 seconds of the test.
FEV1/FVC is the Tiffeneau index

For each of these parameters, the result is a number shown on the smartphone screen.
A high number usually means that the air is moving easily through your lungs. If you have asthma (or another respiratory disease) and have an obstructive episode, the air cannot generally be expelled as forcefully as possible, so your parameters will be lower.
AsthmaTuner Spirometer thus helps you find out what sort of obstruction you have, if any, at a particular time.
By using the device on a regular basis, you can track any changes that may occur in the parameters. These changes may require appropriate treatment, as prescribed by your doctor.

In addition to displaying the **measurement**, the device also provides a **normal baseline value**.

1.4 Determining your baseline values

The importance of any changes in airflow from one measuring to the next depends upon how much they are different from your baseline value you should reach when you are in healthy physical condition.
The AsthmaTuner application can calculate the predicted value, i.e. the expected value for healthy people, depending on age, height, sex, and origin. The AsthmaTuner application calculates the predicted value that has been endorsed by ATS (American Thoracic Society): GLI-2012 All-Age Multi-Ethnic Reference Values by Philip H. Quanjer, Sanja Stanojevic, Janet Stocks, Tim J. Cole. For PEF the predicted values are calculated according to Knudson, R. J., Slatin R. C., Lebowitz, M. D., Burrows, B., The Maximal Expiratory Flow-Volume Curve – Normal Standards, Variability, and Effects of Age, AM REV RESPIR DIS, 1976 113;587-600.

It is important to know that these predicted values are average numbers for large groups of people. You may have a higher measures than the predicted value and you may not be healthy. Or you may have a lower measures than the average and be healthy.

2. OPERATING THE ASTHMATUNER SPIROMETER

2.1 Inserting the batteries

Follow the instructions in the Maintenance section for correct battery insertion.

2.2 Installing the AsthmaTuner Spirometer application

Before measuring the PEF, FEV1 or FVC you need to install the AsthmaTuner application on your smartphone.

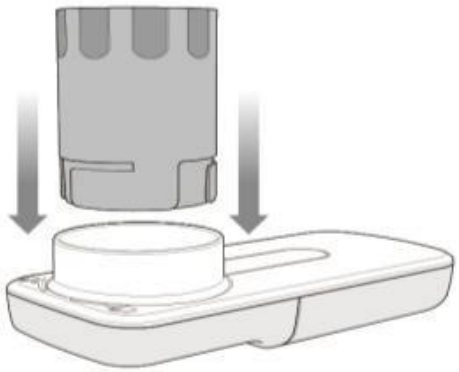
2.3 Connection between AsthmaTuner Spirometer and smartphone

Connection between the **AsthmaTuner Spirometer** and the smartphone is automatic. To check whether there is a connection, read the messages from the application.

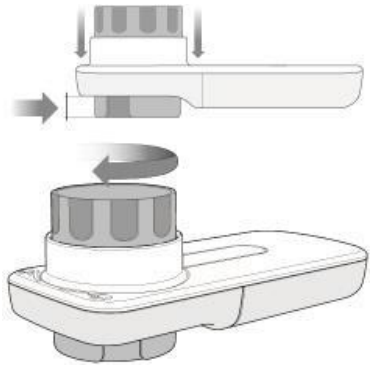
2.4 Performing a spirometry test

In order to perform a spirometry test properly, please follow the instructions below.

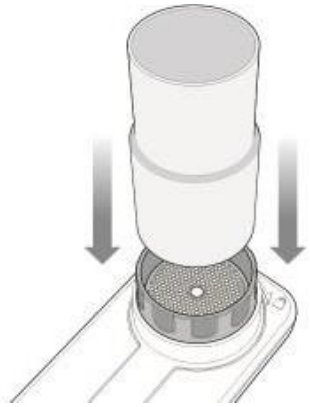
1 Push the turbine into the slot until it stops



2 Turn the turbine clockwise until it stops



3 Insert the mouthpiece at least 0.5 cm into the turbine socket.



4 Pick up the **AsthmaTuner Spirometer** with your hand as if it were a cell phone.

Make sure not to obstruct the turbine with your hand.

5 Insert the mouthpiece in your mouth beyond your teeth, and close your lips tightly over it so that the air you breathe has to pass only through the mouthpiece.

To prevent turbulence that might otherwise affect the results do not put your tongue in the mouthpiece. Do not bend your neck.

6 Press the New Spirometry Session icon under the Spirometry tab in the the application to start the test.

7 Blow out as hard as you can.

It is best to do the test standing or sitting upright. (makes no difference to test results)

8 After exhalation, slowly remove the device from the mouth and check the data on the smartphone.

When the mouthpiece is out of your mouth, avoid sudden movements because this will push air into the turbine and a flow value will be measured that may affect the test results. Repeat the test three times. The application will save the highest value.

The device shows an error message if the expiration start was not satisfactory and if the exhalation is not finished satisfactorily.

2.5 Evaluating the test

Three tests are performed per measurement session, after which the application automatically selects the highest value and compares it with the baseline value (normal or

personal best) set during configuration.

⚠ **WARNING**

Ask the doctor or health care professional to see you using the AsthmaTuner before laying up any measurement.
If you use Asthmatuner to monitor a pulmonary condition for example in the case of asthma, the person must be carried by a doctor or another health care professional.
The action plan provided by your doctor or another approved health care professional will indicate which action you take if you are changed in the values you find.
Independently of what your values are, if the device is free of alarms, if you manifest signs and symptoms such as thoracic constriction, shortness of breath, cough contact your doctor or an activated healthcare professional.

2.5.1 Results diary

The test results are automatically stored and can be displayed later.

2.6 Important safety warnings

⚠ **Warning: indicates a potentially hazardous situation which, if not prevented, could result in minor or moderate injury to the user or patient or damage the device.**

⚠ The supervision of an adult is required for monitoring elderly subjects, children and disabled persons

⚠ The manufacturer cannot be held responsible for damage caused by the failure of the user to follow these instructions correctly.

⚠ Only original accessories as specified by the manufacturer must be used with the device.

⚠ Periodically check that no impurities or foreign bodies, such as skin, hairs have deposited inside the turbine. This may cause errors in measurement or compromise the correct functioning of the device.
Use of an unsuitable mouthpiece could also damage the turbine or harm the patient.

⚠ In the event of an accident of any kind arising from use of the device, you are strongly recommended to inform your doctor so that he/she can notify the authorities as required by local legislation.

⚠ The device is not designed to be used in direct air currents (e.g. wind), sources of heat or cold, direct sun rays or other sources of light or energy, dust, sand or chemical substances.

⚠ Use and store the device in compliance with the environmental conditions specified in the Technical Specifications. If the device is subjected to environmental conditions other than those specified, it may malfunction and/or display incorrect results.

⚠ The maintenance operations set out in the User Manual must be carried out with the utmost care. Failure to follow the instructions may lead to measurement errors or misinterpretation of the measured values.

⚠ Do not modify the device without authorization from the manufacturer.
All modifications, adjustments, repairs, reconfigurations must be performed by the manufacturer or by authorized personnel.
In case of problems, do not try to repair the device yourself.

2.7 Data security warnings

Your smartphone stores your personal data.
Potential threats such as the following:

- Malware installation
- Physical access to the smartphone
- Interception of communications
- Physical damage to the smartphone
- Theft of the smartphone

could have an impact on the integrity or confidentiality of such data, such as:

- Accessing data in memory by unauthorized persons
- Loss of data in memory
- Inability to use smartphone for communications
- The integrity check of the data is made automatically and in case of transmission error it will create a corruption of the data and the file will be illegible.

The following actions help reduce the risk of such events:

- Do not open or install files from suspicious sources
- Use antivirus software
- Back up your data periodically
- Do not leave your smartphone unattended
- Use a password to access the data
- Verify the correct email address where to send the test results

- When data are transmitted call the doctor to ask for confirmation of receipt

2.8 Warnings for use in electromagnetic environments

Due to the increasing number of electronic devices (computers, cordless phones, cell phones, etc.) medical devices may be susceptible to electromagnetic interference from other equipment.

Such electromagnetic interference could cause the medical device to malfunction, as a measurement accuracy lower than stated, and create a potentially unsafe situation.

AsthmaTuner Spirometer complies with EN 60601-1-2:2015 on electromagnetic compatibility (EMC for medical devices) for both immunity and emissions.

For the device to function properly, however, the following precautions must be taken:

- Make sure that the **AsthmaTuner Spirometer** and the smartphone on which the application is installed are no more than 2 meters apart.
- Do not use **AsthmaTuner Spirometer** near other devices (computers, cordless phones, cell phones, etc.) that generate strong magnetic fields. Keep these devices at a minimum distance of 30 centimeters. If it is necessary to use it at shorter distances, **AsthmaTuner Spirometer** and the other devices must be kept under observation to verify that they work normally.

2.9 Notes on FCC certification

AsthmaTuner Spirometer complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

(1) this device may not cause harmful interference

(2) this device must accept any interference received, including interference that may cause undesired operation

Any modifications not expressly approved by this company could compromise use of the device by the user.

N.B.: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated 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.
If this device does cause interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to correct the interference by taking one of the following measures:

- Reorient or relocate the antenna
- Increase the distance 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/television technician for help.

3. CARE AND CLEANING

AsthmaTuner Spirometer is a device that requires little maintenance. The following operations are to be performed regularly:

- cleaning and disinfection of the turbine
- cleaning and disinfection of the mouthpiece
- cleaning of the device
- replacing batteries

At each patient change, the reusable turbine must be cleaned.
Before each test check the inside of the turbine to ensure that there are no impurities, corpuscles, or any foreign matter like hairs which could inadvertently block or even slow down the mobile equipment in the turbine and as a consequence compromise spirometry measurement accuracy. Hold the device with one hand and move it slowly sideways, having the air pass through the turbine; check if the internal rotor spins properly. If not spins perform a calibration check, to do this please contact your physician or the local distributor.
Connect the device with a calibrated 3 Litres syringe perform a calibration check and perform a FVC test. Check the FVC value at the end. The value must be within the range 2.99-3.17; if so the turbine can be used otherwise replace it with a new one.

3.1 Cleaning of the turbine

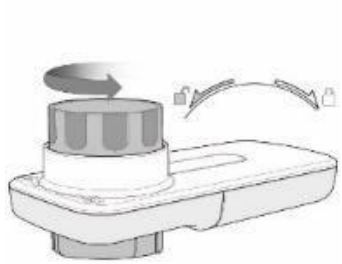
The following instructions only apply if the turbine is used.

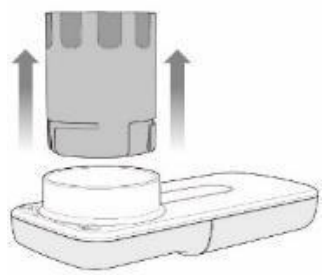
To avoid irreparable damage to the turbine, do not use any alcoholic or oily cleaning solutions, and do not immerse in hot water or solutions.
Do not try to sterilize the turbine in boiling water.
Never try to clean the turbine under a direct jet of water or other liquids. If there are no liquid detergents, the turbine must at least be washed in clean water.

Correct operation of the turbine is guaranteed only if it is "clean" and free of foreign objects that affect its movement. The presence of dust or foreign bodies (such as hairs, sputum etc.) could slow or block the moving parts of the turbine and make the result less accurate or damage the turbine itself.

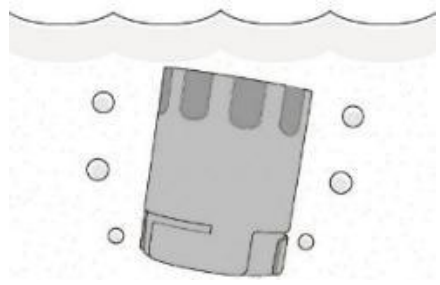
After each use, check the cleanliness of the turbine.
To clean the turbine, carry out the following steps:

1) Remove the turbine from its housing by turning counterclockwise and apply light finger pressure from the bottom of the turbine to lift it from its housing.

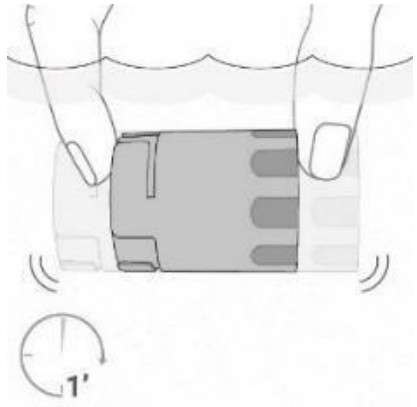




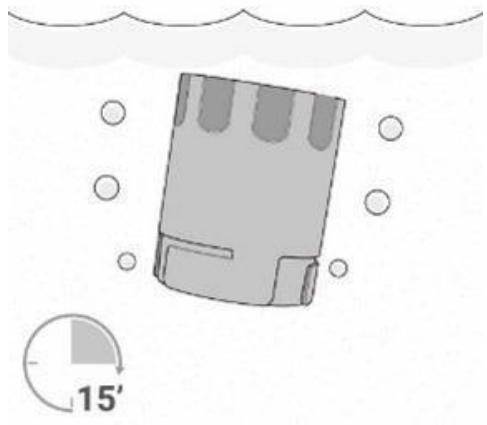
2) Use a solution of 1,15% sodium hypochlorite. Place the turbine in the solution.



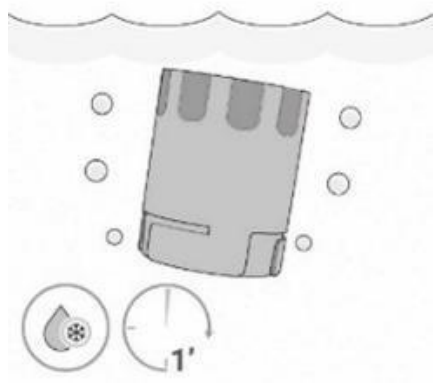
3) Shake the turbine to remove all impurities for at least 1 minute.



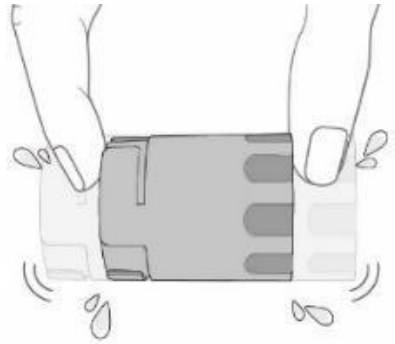
4) Let the turbine soak for 15 minutes.



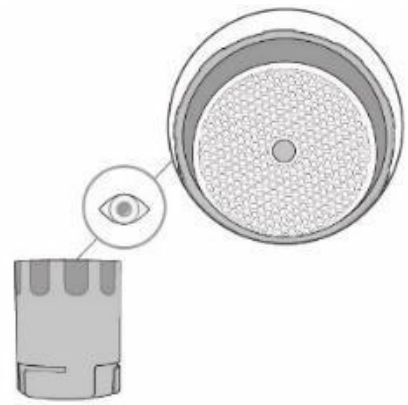
5) Clean the turbine by immersing it in clean (not hot) water for at least 1 minute.



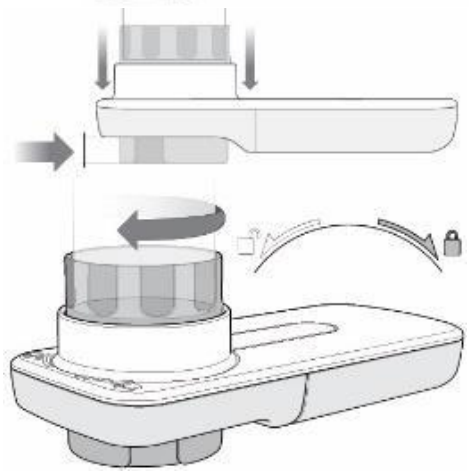
6) Remove excess water from the turbine by shaking it and let it dry by placing it vertically on a dry surface



7) Check that it is clean and free of any foreign bodies.



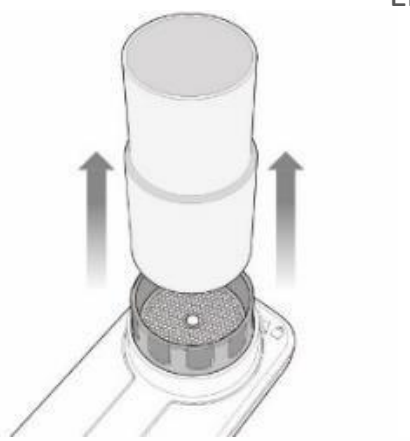
8) After cleaning, insert the turbine into the socket in the direction indicated by the closed padlock symbol screen-printed on the AsthmaTuner device. To insert the turbine correctly, push it down and turn it clockwise until it stops, to ensure that it is fully inserted into the plastic housing.



3.2 Cleaning of the mouthpiece

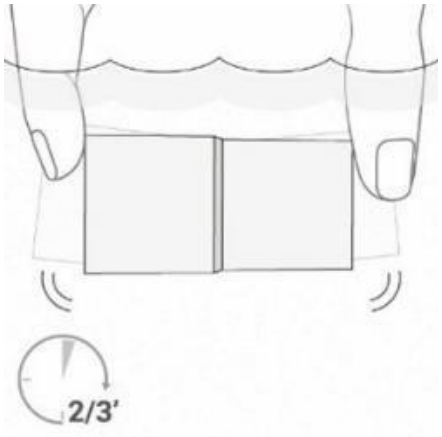
Be sure to clean the mouthpiece after each use, as outlined in the instructions below.

1) To clean the mouthpiece, simply remove it from the turbine.

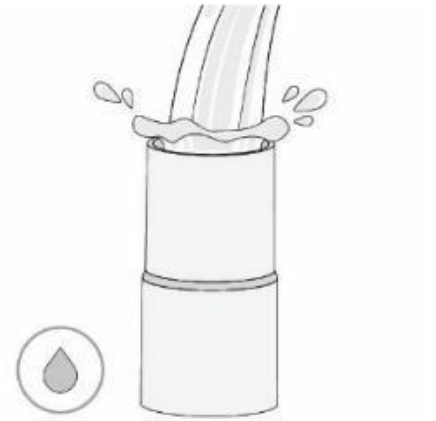


2) Immerse the mouthpiece in warm water.

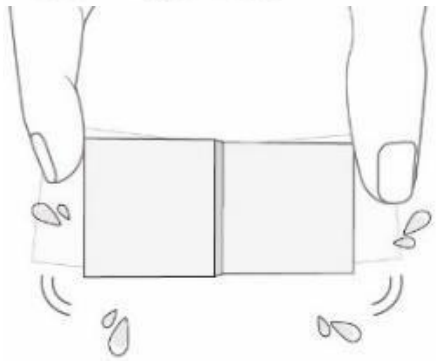
3) Shake the mouthpiece for 2-3 minutes.



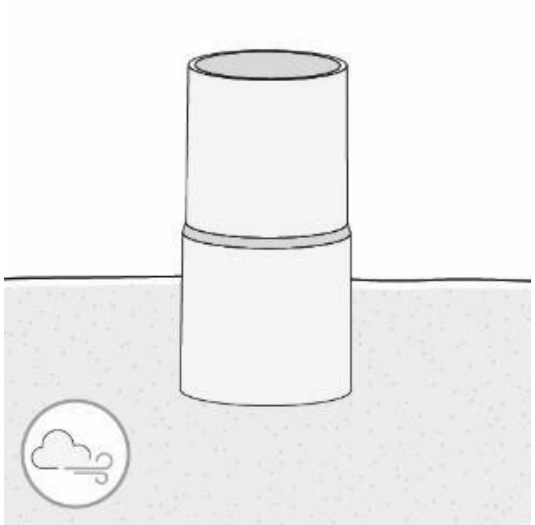
4) Rinse it in clean water.



5) Shake it gently to remove any excess water.



6) Let it dry on a cloth. Next, insert the mouthpiece into the turbine with gentle pressure.



It is recommended that the mouthpiece be cleaned weekly with a solution of 1,15% sodium hypochlorite using the same method as described for the turbine.

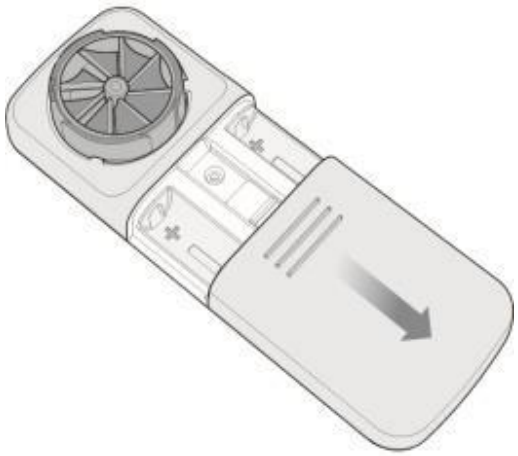
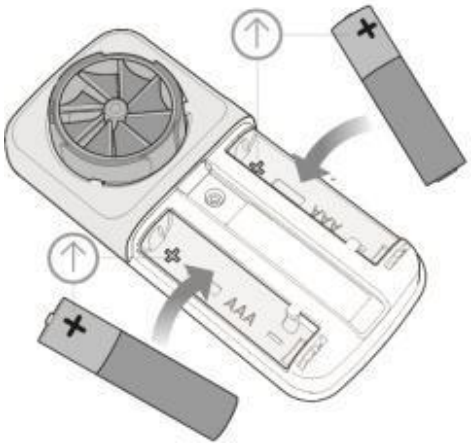
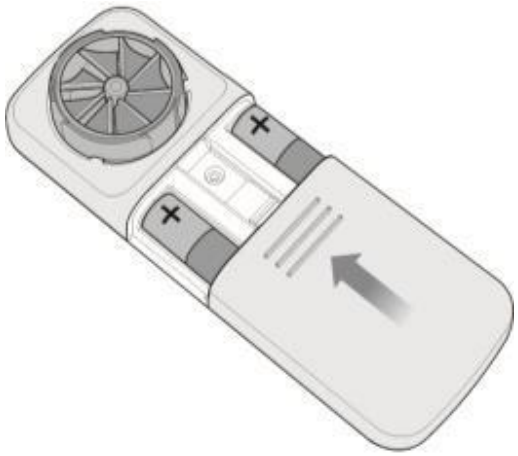
3.3 Cleaning of the device

Clean the device once a day. To clean, wipe the device's surfaces with a soft damp cloth. Dry with a soft cloth, or allow to air dry. Ensure that all surfaces are completely dry.

Never put the device into water or other fluids.

3.4 Replacing batteries

The device continuously monitors the battery level. A message on the smartphone display alerts the user when the device battery is low.

1 Remove the battery cover on the back of the **AsthmaTuner Spirometer** 	**2** Remove the two batteries and replace them with two new ones, following the polarity as indicated by the symbols in the compartment 
3 Reattach the battery cover 	

Used AsthmaTuner Spirometer batteries should only be disposed of in special containers or preferably returned to the dealer of the device or to a special collection centre.
In any case, all applicable local regulations must be complied with.

4. ERROR MESSAGES & TROUBLESHOOTING

4.1 Error messages

If you encounter any problems when using the **AsthmaTuner Spirometer**, a message will appear on the smartphone display to warn of the malfunction.

MESSAGE	POSSIBLE CAUSE	SOLUTION
Bluetooth	Bluetooth is off	To perform measurements with the device, you must activate Bluetooth on the smartphone. Exit the application and activate Bluetooth from the smartphone settings menu.
Battery low	When the **AsthmaTuner Spirometer** batteries are below 15%	Replace the **AsthmaTuner Spirometer** batteries

4.2 Troubleshooting

If you receive an unusually low reading, it could mean that your **AsthmaTuner Spirometer** the turbine is broken, or it could mean that the reading is accurate and your lung condition is getting worse.

Check to make sure that the turbine is not broken. You must follow directions exactly as instructed to obtain accurate results. If your meter is not broken, follow the instructions in your action plan for low readings and contact your physician or other licensed healthcare professional.

If problems occur when using the device, the following points should be checked.

PROBLEM	POSSIBLE CAUSE	SOLUTION
AsthmaTuner Spirometer can't connect with the smartphone	The Bluetooth connection is not working properly	Look for **AsthmaTuner Spirometer** on the list of recognized devices. For correct use, the smart phone needs Bluetooth version 4.0 or higher
	The turbine may be dirty	Clean the turbine as described in the care and cleaning section.

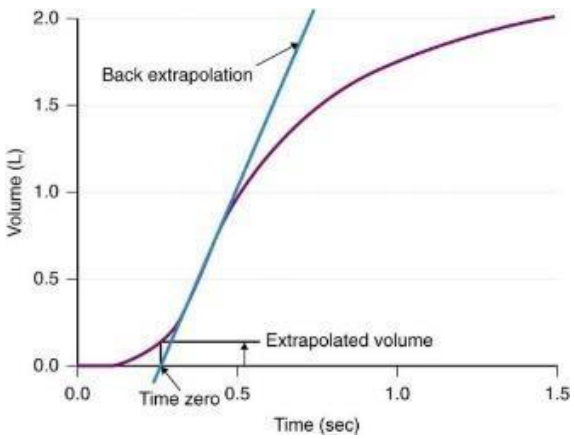
The test results are unreliable		If necessary, replace the turbine with a new one, if necessary by contacting MediTuner
	The test was performed wrongly	Repeat the test, following the directions on the screen. Avoid sudden movements when you finish exhaling
	The turbine has not been inserted properly	Insert the turbine from the front of the device by pushing it all the way down and turning it clockwise. See the *Performing the test* section

5. ACCURACY AND RELIABILITY

This device meets the requirements of the following standard:
ATS/ERS TASK FORCE: Standardization of lung function testing (volume 26/numbers 1-5: 2005)

Volume max	10 L
Volume accuracy (ATS 2019)	± 2.5% or 0.05 L whichever is greater
Flow range	960 L/minute
Flow accuracy	± 5% or ± 0.200 L/s whichever is greater
PEF accuracy	± 10% or ± 0.33 L/s whichever is greater
Time zero	

At the point of peak expiratory flow (PEF), a tangent is drawn with a slope equal to PEF and its intersection on the abscissa defines the TIME ZERO. The back extrapolated volume is the volume of gas that has already been exhaled at the point of TIME ZERO as defined by back extrapolation. The method to determine the time elapsed by TIME ZERO, t0, is given by equation:



Time zero = t_{PEF} - (V_{PEF}/PEF)

Where
PEF is the the peak expiratory flow;
t_{PEF} is the the elapsed time at PEF;
V_{PEF} is the expired volume at PEF

6. LABELS & SYMBOLS

ID label

Device labels show:

Symbol	Description
Model	Product Name
SN	Device serial number
	Manufacturer's name and address
CE 0476	This product is a certified Class IIa medical device, and complies with the requirements of Regulation (EU) 2017/745
	In accordance with **IEC 60601-1** the product and its applied parts are **type BF** and thus protected against the risks of electrical leakage.

	This symbol is required by European directive 2012/19/EEC on waste electrical and electronic equipment (WEEE). At the end of its useful life this device must not be disposed of as normal domestic waste. Instead it must be delivered to a WEEE authorised collection centre. As an alternative, the device may be returned without charge to the dealer or distributor, when it is replaced by another equivalent device. Due to the construction materials used for the device, disposal as normal waste could cause harm to the environment and/or health. Failure to observe these regulations can lead to prosecution.
IP22	Indicates the degree of resistance to liquids. The device is protected against falling drops of water if it is disposed up to +-15° from vertical.
	The symbol is used for products that include RF transmitters.
FCC ID	Identification showing traceability to FCC compliance
	Instruction for use symbol. Read this manual carefully before using the medical device
	Manufacturing date
	Temperature limits: indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation: indicates the range of humidity to which the medical device can be safely exposed
	Pressure limitation: indicates the range of pressure to which the medical device can be safely exposed
MD	The symbol indicates that the product is a medical device
UDI	The symbol indicates the Unique Device Identification

For USA market:

Rx ONLY Caution: Federal law restricts this device to sale by or on the order of a physician

7. TECHNICAL SPECIFICATIONS

Parameters measured:

FEV1	Expiratory volume in one second of testing	L
PEF	Peak expiratory flow	L/minute
FVC	Forced Vital Capacity	L
FEF2575	average flow between 25% and 75% of the total volume of air exhaled during the total exhalation (FVC)	L/s
FEV6	volume expired in the initial 6 seconds of the test	L
FEV1/FVC	Tiffeneau index	%

Flow/volume measurement system	Bi-directional turbine (rotary blade)
Measurement principle	Infrared interruption
Max Peak Expiratory Flow	PEF 960 L/min (16 L/s)
Max Volume	FEV1, FEV6, FVC: 10L
Volume accuracy (ATS 2019)	±2.5% or ± 0,05 L whichever is greater
Flow accuracy	±5% or ± 0,20 L/s whichever is greater
PEF accuracy	± 10% or ± 20 L/min (± 0,33 L/s) whichever is greater
Dynamic resistance at 12 L/s	<0,5 cm H2O/L/s
Communication interface	Bluetooth SMART (4.0 or higher)
Power supply	2 x 1,5V AAA alkaline batteries
Size	main body 109x49x21 mm
Weight	60,7 g (including batteries)
Type of electrical protection	Internally powered
Electrical protection level	BF
IP protection level	IP22

Applicable Standards	ATS/ERS Guidelines: 2005, 2019 update ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1:2005 + A1: 2012 EN 60601-1-2: 2015 EN IEC 60601-1-6: 2010+Amd2013 EN 60601-1-11: 2015 IEC 62304:2006/A1:2015 Directive 2014-53-EU-RED
Conditions of use	Device for continuous use
Storage conditions	Temperature: MIN -25°C, MAX +70°C Humidity: MIN 10% UR; MAX 93% UR Athmospheric pressure: 50kPa, 106 kPa
Transport conditions	Temperature: MIN -25°C, MAX +70°C Humidity: MIN 10% UR; MAX 93% UR Athmospheric pressure: 50kPa, 106 kPa
Operating conditions	Temperature: MIN +5 °C, MAX +40 °C Humidity: MIN 15% UR; MAX 93% UR Athmospheric pressure: 70kPa, 106 kPa

Life time - the expected life time (or service life) of the device if properly used and stored is 5 years.

8. BLUETOOTH WIRELESS TECHNOLOGY INFORMATION

Bluetooth Compliance:	Bluetooth 5-Ready
Operating Frequency:	2.4 to 2.4835 GHz
Max Output Power:	TX: 0 dBm; 1 mW
Operating Range:	10 meter radius (line of sight)
Network Topology:	Star - bus
Operation:	Server
Antenna Type:	Antenna integrated in the module

Modulation Technology:	FHSS
Modulation Type:	GFSK
Data Rate:	1 Mbit/second
Data Latency:	7 – 40 ms
Data Integrity:	Adaptive frequency hopping, Lazy Acknowledgement, 24-bit CRC, 32-bit Message Integrity Check Data
Format:	Sends data packets once per 60 ms. Includes 3 control bytes that allows the host to detect if packets are missing and the device to retransmit.
Quality of Service:	This device uses Bluetooth Smart technology for wireless communications, which allows for reliable communications in electrically noisy environments and transmits packets once per 60 ms. It includes 3 control bytes that allows the host to detect if packets are missing and the device to re-transmit. If the connection is lost, the App changes the connected status from connected to disconnected and become available for a connection immediately.
Bluetooth Profiles Supported:	GATT-based profile
Authentication and Encryption:	Supported
Encryption Key Size:	128-bit AES with Counter Mode CBC-MAC and application layer user defined

The Bluetooth® word mark and logo are registered trademarks owned by Bluetooth SIG, Inc.

8.1 Radio frequency (rf) communication

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. The following information is provided in accordance with Federal Communications Commission (FCC) regulations.

This device complies with Part 15 of the FCC Rules. 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 undesirable operation.

This device does not interfere with any radio frequency signals transmitted from outside

sources. These FCC standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference.

8.2 Radio frequency (rf) interference from other wireless devices

Common consumer electronic devices that transmit in the same frequency bands used by the AsthmaTuner Spirometer may prevent the uploader or mobile device from receiving data. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 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 to correct the interference by increasing the separation between the equipment and receiver.

9. WARRANTY TERMS

AsthmaTuner Spirometer, together with any accessories provided, is guaranteed for a period of:

- 12 months in the case of professional use (doctor, hospital, etc.)
- 24 months where the product is purchased directly by the end-user.

The warranty period is effective from the date of purchase, which must be proven by an invoice or sales receipt.

The device must be checked at the time of purchase, or upon delivery, and any claims must be made immediately in writing to MediTuner.
This warranty covers the repair or the replacement (at the discretion of MediTuner) of the product or of the defective parts without charge for the parts or for the labour.
All batteries and other consumable parts, including the turbine sensor, are specifically excluded from the terms of this guarantee.
The product warranty shall not apply, at the discretion of MediTuner, in the following cases:

- Improper installation or operation of the device, or if the installation does not comply with current technical or safety regulations in the country of purchase
- Use of the product for purposes other than those provided or failure to follow instructions
- Repair, adaptation, modification or tampering by personnel not authorised by MediTuner
- Damage caused by lack of or incorrect maintenance
- Damage caused by abnormal physical or electrical stress
- Damage caused by defects of the mains electricity supply or of equipment to which the product has been connected
- Serial number altered, deleted, removed or rendered illegible

The repair or replacement described in this warranty is provided for goods returned at the customers' expense to our certified service centres. For details of these centres please contact either your local supplier or MediTuner.
The customer shall be responsible for all transport, customs and delivery charges regarding the goods.
Each product, or accessory, sent in for repair must be accompanied by a clear and detailed explanation of the fault. Forwarding to MediTuner requires the written permission of MediTuner himself.
MediTuner reserves the right to replace the product or make any changes deemed necessary.