# 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 2.8 Issue Date 05 November 2021

CE 0476

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN**

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**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 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 manufacturer's address is as follows:
MediTuner AB
Box 3161; 103 63 Stockholm, Sverige
Webbplats: www.asthmatuner.com E-post: info@asthmatuner.com

Legal manufacturer:
MIR srl - Medical Inernational Research
Via del Maggiolino 125, 00155 Rome, 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 to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test lung function and can make spirometry testing in people of all ages, excluding infants and neonates.
**AsthmaTuner** can be used in any setting.

### 1.1.1 Usage environment

**AsthmaTuner** can be used in any setting. **AsthmaTuner** is used in the factory, in the hospital, in the doctor's office.

### 1.1.2 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 previous user data must be erased from the memory 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.

## 1.2 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)

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 maximum speed of the air when you exhale as hard as possible after filling your lungs completely.
**FEV1** is the volume of air expelled during the first second of the same exhalation.
**FVC** is the volume of air expelled during the total exhalation.
**FEF2575** is the average flow between 25% and 75% of the total volume of air expelled during the total exhalation (FVC)
**FEV6** is the volume expired in the initial 6 seconds of the test.
For each of these parameters, the result is a number shown on the smartphone screen.

A high number (associated with a green light) 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.

It is recommended to use the device twice a day, in the morning on waking and at bedtime.
If possible, the device should also be used as soon the first signs of respiratory problems occur, so that you can understand how serious your respiratory problem is and/or how well your current therapy is working.
In addition to displaying the PEF, FEV1 or FVC **measurement**, the device also provides a **normal baseline value**.
the Calculation of the graphic reading is an alternative to using the standard baseline value, but the best way of finding out your personal baseline value is to discuss it with your doctor.
This value is normally called the **personal best value**. Please refer to the section **determining your baseline value** for a clear understanding of the baseline value.

## 1.4 Determining your baseline values

A measure with a high value usually means that your airflow is good.
The best way to determine what are a healthy parameters for you is to discuss this with your physician or other licensed healthcare professional. In fact 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.

Your physician or other licensed healthcare professional will use one of two possible ways to identify your baseline value. The first method adopts the predicted value calculated according to the results of epidemiological studies of large groups of healthy subjects of your same age, height, sex, and origin. The second method adopts the personal best value you can reach when you are in the healthiest physical condition.

The application can calculate the predicted value, i.e. the expected value for healthy people, depending on age, height, sex, and origin. 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.

In this case, the predicted value becomes the baseline value for your treatment plan. If your physician or other licensed healthcare professional prefers this method, the application provides the calculation of the predicted value.

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.

**CAUTION: no matter which method your physician or other licensed healthcare professional prefers to use, it is important that you clearly understand the meaning of your baseline value and how it relates to your treatment plan. if you have trouble determining your baseline value, ask your physician or other licensed healthcare professional for assistance.**

# 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, FEV1or FVC you need to install application on your smartphone.

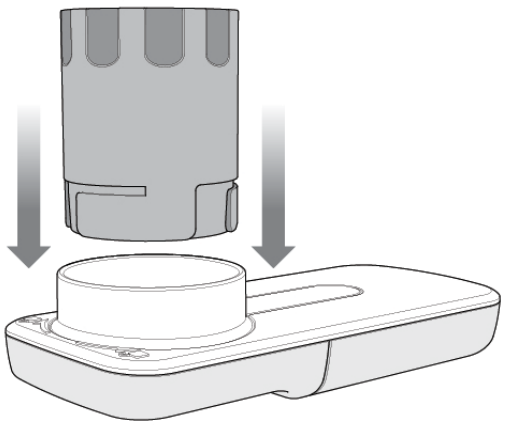
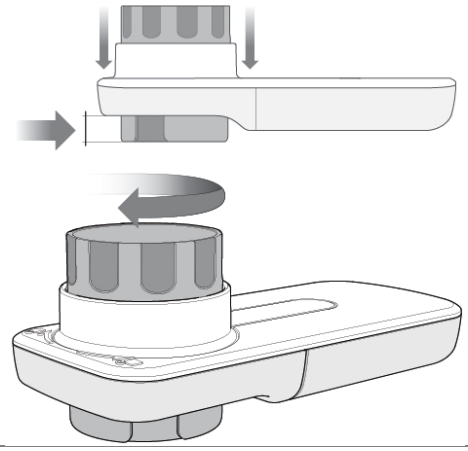
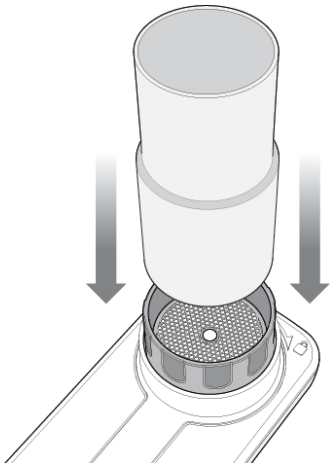
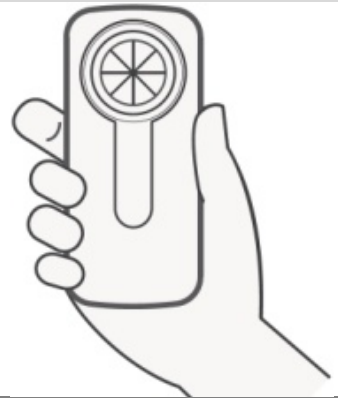
## 2.3 Connection between AsthmaTuner Spirometer and

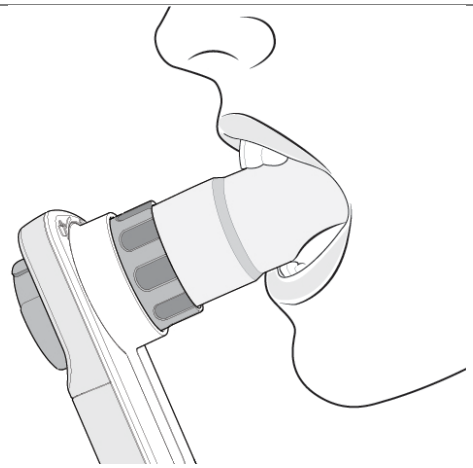
### smartphone

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 the test

In order to perform the 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 | Blow out as hard as you can.<br>**It is best to do the test standing or sitting upright. (makes no difference to test results)**<br>  | 7 | After exhalation, slowly remove the device from the mouth and check the data on the smartphone.<br><br>**When AsthmaTuner Spirometer 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.**<br><br>Repeat the test three times. **AsthmaTuner Spirometer** will save the highest value. |

## 2.4.1 Evaluating the test

Tests are performed in a measurement session, after which you select to save the value and compares it with the baseline value (personal best) set during configuration

### 2.4.2 Results diary

The test results are automatically stored on the smartphone and can be displayed later.
Medical studies have shown that if your doctor examines the test results on a regular basis, lung disease can be managed much better.

## 2.5 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.**

⚠ Special WARNING should be given to testing elderly subjects, children and differently-able 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.

## 2.6 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

## 2.7 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 and create a potentially unsafe situation.

**AsthmaTuner Spirometer** complies with EN 60601-1-2:2007 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 metres apart.
- Do not use AsthmaTuner Spirometer near other devices (computers, cordless phones, cell phones, etc.) that generate strong electromagnetic fields. Keep such equipment at a minimum distance of 7 metres.

## 2.8 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.

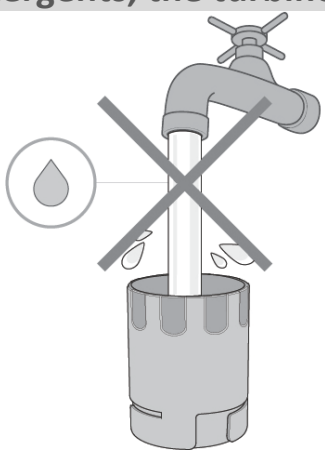
# 3. CARE AND CLEANING

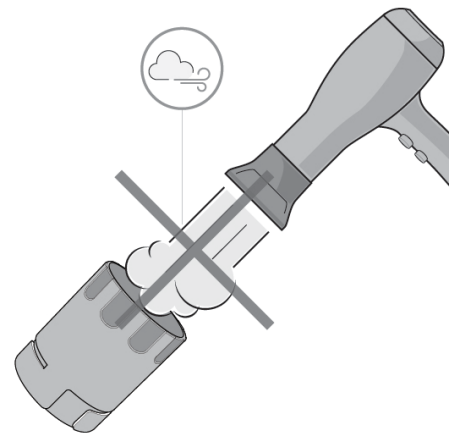
**AsthmaTuner Spirometer** is a device that requires little maintenance. The following operations are to be performed regularly:

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

## 3.1 Cleaning and disinfection of the turbine

**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, pull it out of the **AsthmaTuner Spirometer** socket by turning it counterclockwise and simply pulling it out. To make it easier to pull out, push the base of the turbine gently with a finger.

Weekly cleaning is recommended. Immerse the turbine flowmeter in warmy soapy water and agitate the turbine for 2-3 minutes.
The hand dishwashing detergent that was tested includes these ingredients: Aqua, coco glucoside, myristyl glucoside, lauryl glucoside, sodium chloride, sodium gluconate, sodium citrate, allyl caproate, ethylene brassylate, methyldihydrojasmonate).
Rinse in clean water and shake gently to remove any excess water. Allow to air dry on a towel. Store in a clean, dry place in your home.

After cleaning, insert the turbine into the socket in the direction indicated by the screen-printed closed padlock symbol on the **AsthmaTuner Spirometer**. To insert the turbine correctly, push it down and turn clockwise until it stops, to make sure it is fully inserted into the plastic container.

## 3.2 Cleaning and disinfection of the mouthpiece

Make sure to clean the mouthpiece after each use. To clean the mouthpiece, simply pull it apart from the turbine. Just as for the turbine, Immerse the mouthpiece in warmy soapy water and agitate the mouthpiece for 2-3 minutes . Rinse in clean water and shake gently to remove any excess water. Allow to air dry on a towel. Store in a clean, dry place in your home.

After cleaning, insert the mouthpiece in the turbine, by pressing lightly.

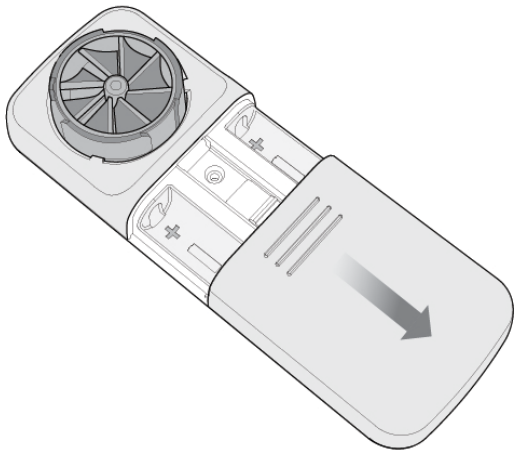
## 3.3 Cleaning of the device

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.

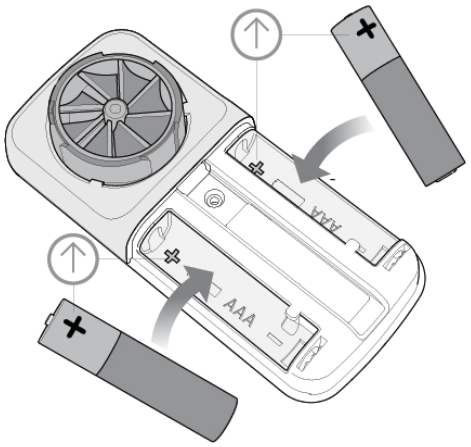
## 3.4 Replacing batteries

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

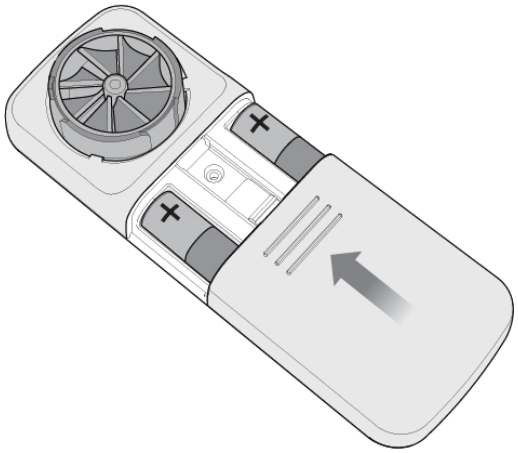
1 Remove the battery cover on the back of the **AsthmaTuner Spirometer**



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** meter is broken, or it could mean that the reading is accurate and your asthma is getting worse.

Check to make sure that the meter 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 test results are unreliable | The turbine may be dirty | Clean the turbine as described in the care and cleaning section.<br>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 |

| PROBLEM | POSSIBLE CAUSE | SOLUTION |
|---|---|---|
| | 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 |

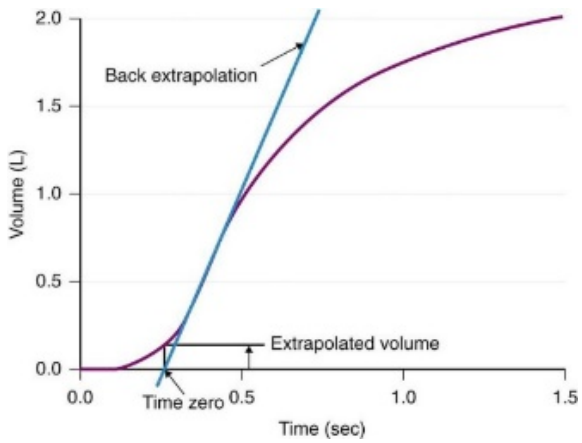
# 5. ACCURACY AND RELIABILITY

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 | ± 3% or 0.05 L |
| Flow range | 960 L/minute |
| Flow accuracy | ± 5% or 10.2 L/minute |

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:




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

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

# 6. LABELS & SYMBOLS

ID label


The label shows:

| Symbol | Description |
|---|---|
| REF | 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 Directive 93/42/EEC |
| | 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 2002/96/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.<br>As an alternative, the device may be returned without charge to the dealer or distributor, when it is replaced by another equivalent device.<br>Due to the construction materials used for the device, disposal as normal waste could cause harm to the environment and/or health.<br>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 in accordance with IEC EN 60601-1-2: 2007 in section 5.1.1 for products including 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 |

**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 |

| | |
|---|---|
| **Flow/volume measurement system** | Bi-directional turbine (rotating weel) |
| **Measurement principle** | Infrared interruption |
| **Dynamic resistance at 12 L/s** | <0.5 cm $H_2O$/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** | Class II |
| **Electrical protection level** | BF |
| **IP protection level** | IP22 |
| **Applicable Standards** | Electrical Safety IEC 60601-1<br>Electromagnetic Compatibility IEC 60601-1-2<br>ATS/ERS Standardization of spirometry 2005<br>ISO 26782, ISO 23747 |
| **Conditions of use** | Device for continuous use |
| **Storage conditions** | Temperature: MIN -40°C, MAX +70°C<br>Humidity: MIN 10% RH; MAX 95%RH |
| **Transport conditions** | Temperature: MIN -40°C, MAX +70°C<br>Humidity: MIN 10% RH; MAX 95%RH |

**Operating conditions** Temperature: MIN +5°C, MAX +40°C
Humidity: MIN 10% RH; MAX 95%RH

# 8. BLUETOOTH WIRELESS TECHNOLOGY INFORMATION

| | |
|---|---|
| Bluetooth Compliance: | Version 4.0 single mode low energy |
| Operating Frequency: | 2.4 to 2.4835 GHz |
| Max Output Power: | TX: -5.99 dBm; 0.25 mW |
| Operating Range: | 10 meter radius (line of sight) |
| Network Topology: | Star - bus |
| Operation: | Server |
| Antenna Type: | PCB antenna |
| 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.<br>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. INFORMATION FOR CORRECT USE IN AN ELECTROMAGNETIC ENVIRONMENT

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The **AsthmaTuner Spirometer** is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the **AsthmaTuner Spirometer** should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The **AsthmaTuner Spirometer** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The **AsthmaTuner Spirometer** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Not applicable | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The **AsthmaTuner Spirometer** is intended for use in the electromagnetic environment specified below. The customer<br>or the user of the **AsthmaTuner Spirometer** should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±8 kV contact<br>±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 %.<br>In the event of disruption due to ESD during oximetry test, the device recovers from any disruption within 30 s. (according to ISO 9919). |

| | | | |
|---|---|---|---|
| Electrical fast transient/burst IEC 61000-4-4 | ±1 kV for input/output lines | Not applicable | |
| Surge IEC 61000-4-5 | ±1 kV differential mode<br><br>±2 kV common mode | Not Applicable | |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % *U*T (>95 % dip in *U*T) for 0,5 cycle<br><br>40 % *U*T (60 % dip in *U*T) for 5 cycles<br><br>70 % *U*T (30 % dip in *U*T) for 25 cycles<br><br><5 % *U*T (>95 % dip in *U*T) for 5 sec | Not Applicable | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE *U*T is the a.c. mains voltage prior to application of the test level. | | | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The **AsthmaTuner Spirometer** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AsthmaTuner Spirometer** should assure that it is used in such an environment. | | | |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the **AsthmaTuner Spirometer**, including cables, than the recommended |

| | | | |
|---|---|---|---|
| | | | separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to<br>80 MHz | NA | *d not applicable* |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to<br>2,5 GHz | 20 V/m | *d*= 0,175 *√P* 80 MHz to 800 GHz<br><br>*d*=0,35 *√P* 800 MHz to 2,5 GHz<br><br>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 metres (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

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) 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 **AsthmaTuner Spirometer** is used exceeds the applicable RF compliance level above, the **AsthmaTuner Spirometer** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **AsthmaTuner Spirometer**.

b) 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 AsthmaTuner Spirometer**

The **AsthmaTuner Spirometer** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **AsthmaTuner Spirometer** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **AsthmaTuner Spirometer** as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter** | **Separation distance according to frequency of transmitter** [m] | | |
|---|---|---|---|
| | **150 kHz to 80 MHz** | **80 MHz to 800 MHz** | **800 MHz to 2,5 GHz** |
| W | *d*=not applicable | *d*=0,175 √*P* | *d*=0,35 √*P* |
| 0,01 | not applicable | 0,017 | 0,350 |
| 0,1 | not applicable | 0,055 | 0,110 |
| 1 | not applicable | 0,175 | 0,350 |
| 10 | not applicable | 0,550 | 1,100 |
| 100 | not applicable | 0,750 | 3,500 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated 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 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# 10. 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.