**Package Contents**

If the upper or the lower holographic security sticker has been tampered with do not use the device. Please let us know details and send the device back for replacement.

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 for replacement.

Check if the box contains all the items shown below:

<table>
<thead>
<tr>
<th>Peak flow meter turbine</th>
<th>Plastic mouthpiece</th>
</tr>
</thead>
</table>

**HOW TO SET UP YOUR DEVICE**

Before connecting SMART PEAK FLOW to a smartphone, install the SMART ASTHMA app, which you can download for free from the App Store (for Apple) and from Google Play (for Android devices).

SMART PEAK FLOW connects to your smartphone via the 3.5 mm audio jack port. Connection is automatic once the SMART ASTHMA app has been installed on your smartphone.

**CAUTION**

When SMART PEAK FLOW is used to monitor asthma you should be under the care of a physician or other licensed healthcare professional.

According to best current evidence from scientific studies, research paper topics and clinical expertise, PEF has proven to be a good indicator of airflow function in health and illness that can indicate how well you are breathing, and can help you determine if there are changes in your airflow. Regular measurement of PEF provides evidence of disease progression.

The Guide For Asthma Management And Prevention – last updated and published in 2018 – by GINA (Global Strategy for Asthma Management and Prevention) recommends, that effective asthma self-management requires:

- Self-monitoring of symptoms and/or lung function (PEF)
- Written asthma action plan
- Regular medical review

When engaged in self-management of asthma, your lung conditions can be effectively monitored in accordance with the written action plan prepared by your physician.

**CAUTION**

A healthcare professional's advice is required to interpret the meaning and importance of the measurements reported by SMART PEAK FLOW and to decide on an appropriate action plan.

Upon first time of use the app will ask you to save your personal best (PB) peak expiratory flow (PEF) value. If you do not know your PB value, it can be estimated by entering your gender, age and height. The SMART ASTHMA app will use this data to calculate your PEF value.

**IMPORTANT INFORMATION CONCERNING INTENDED USE**

SMART PEAK FLOW is an electronic device for home use that accurately measures your peak expiratory flow (PEF). The device is designed for children (aged over 5 years), adolescents and adults.

SMART PEAK FLOW is designed for monitoring asthma. PEF is the maximum speed a person can blow air out of the lungs after taking as big a breath as possible.
baseline value, and will use it to assign a coloured marker to your test (green, yellow or red).

**CAUTION**
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 for assistance.

Each PEF measurement that you perform will be displayed on your smartphone (three blows to complete one measurement). Please use the coloured indicator (green, yellow or red) and follow your physician's advice - they will help you determine how to perform the test accurately and recommend actions when decreased values are measured.

**CAUTION**
Always take your PEF measurements with SMART PEAK FLOW before using your inhaler.

**CAUTION**
Whether you take your measurement standing or sitting straight, REMAIN CONSISTENT each time to get reliable information on the progress of your asthma condition.

A higher value of PEF usually means air is moving easily through the lungs. When asthma attacks occur air cannot move easily through the lungs and lower values of PEF will be measured. It is generally recommended to take your measurements twice a day – in the morning when you wake up and, in the evening, before you go to bed.

SMART PEAK FLOW should also be used when you are feeling symptoms of breathing problems in order to help you and your physician determine how serious the breathing problem is and how well your treatment is working. Discuss with your physician when and how often to use your SMART PEAK FLOW.

**HOW TO MEASURE YOUR PEF VALUE**

**CAUTION**
- The mouthpiece must be disinfected as shown in the CLEANING AND DISINFECTION section before the first use and periodically thereafter.
- Supervision of an adult is required for testing children and adolescents (between age 5-14) and differently-abled persons.

Take the following steps to carry out a measurement.

**Step 1.**
Attach the mouthpiece to the turbine on either side and plug it into the headphone jack port of your smartphone (in case there is no headphone jack, use a suitable adapter recommended by the manufacturer of your device).

**Step 2.**
Launch the app and allow access to your smartphone's microphone, media library and location, when asking for permission.

**Step 3.**
Insert the device into your mouth beyond your teeth and close your lips firmly around the mouthpiece. Make sure your lips form a tight seal around the mouthpiece.

**Step 4.**
Make sure that you are in a well-lit area. The device will need light (natural or electric) to go through the small window on top of the turbine to take your PEF measurements.

**CAUTION**
- DO NOT cover the window on the top with your hand or fingers during calibration or measuring. Hold the device still during calibration (normally takes 1-2 seconds).
- Never insert SMART PEAK FLOW into your mouth, in case it pierces the mucous membrane.
Step 5.

Stand up or sit upright – whichever position you prefer. REMAIN CONSISTENT when taking your measurements each time to get reliable information on the progress of your asthma condition. Push the "PRESS TO START" button on the screen and hold the device firmly during calibration (normally takes 1-2 seconds), making sure that the top window is not covered and is facing the direction of the light source.

If you're not satisfied with the result, press “Discard” and repeat the measurement session. If you're pleased with the result, save it by tapping the "Save" button.

You can also save notes to your results (e.g. about the circumstances of your condition at the time of the measurement).

The app shows a graphic marker behind the result – green, yellow or red. The meanings of these graphic markers are explained in the table below, and are also available in the app, by tapping the icon under the result.

<table>
<thead>
<tr>
<th>Colour</th>
<th>Result</th>
<th>Action</th>
</tr>
</thead>
</table>
| Green  | GO ZONE | >80% of PB
Your breathing condition appears under control. Your medication is working. Go ahead with your normal activities. |
| Yellow | CAUTION ZONE | 60-80% of PB
Use caution in your activity. Refer to your Asthma Action Plan made by your physician for actions to be taken. |
| Red    | DANGER ZONE | <60% of PB
Medical alert. You should seek immediate medical attention. Act as instructed by your physician. |

For a better overview, you can check your trend in a Weekly, Quarterly and Yearly view.

By tapping the button at any time to get a brief tutorial on the functions and options within the Chart view.

For an overview of the measurements reported by SMART PEAK FLOW and how to decide on an appropriate action plan.

The SMART ASTHMA app keeps a record of your highest readings of PEF for both morning and evening sessions, which you can see in the Chart view. Dots between consecutively recorded readings are connected in order to form a trend graph. This ongoing record is an important part of your asthma action plan. Your PB is indicated by a continuous, white, continuous <-> dotted line in the top level of the graph.

For better overview, you can check your trend in a Weekly, Quarterly and Yearly view.

By tapping the button at any time to get a brief tutorial on the functions and options within the Chart view.

Reviewing the measured data can help you and your physician check closely on your respiratory condition to provide the best treatment for you.

The app can measure and store an unlimited number of readings, which are also securely stored in the cloud. This can be vital to preserve your data in case you change or lose your device.

ACCOUNT AND SETTINGS

Before you first launch the app, you will be asked to set up an account, or log in, in case you already have one. Later on, you will have the option to change your account settings in the Profile section of the app. Optionally, you can also set an image as your profile picture to make your account more personalised.

Tap on the “Personal Best” button to enter your PB or estimate it by setting your height, age and gender. Press “Estimate” and then save the result.

Go to the “App settings” to set Reminders (push notifications) for yourself. It is recommended that you set two reminders a day (one for your morning and one for your evening measurement), however, you have the option to set up as many reminders as you want. Never miss a chance to keep up with your asthma tracking.

WARNINGS AND PRECAUTIONS

- Please read all the information in this user manual before using this device. If you do not understand these instructions or if you have questions about your PEF meter and its use, consult your physician.

- A healthcare professional’s advice is required to interpret the meaning and importance of the measurements reported by SMART PEAK FLOW and how to decide on an appropriate action plan.

- Self–measurement means not diagnosis or treatment. In any event, please be sure to discuss your measured values with your physician or other licensed healthcare professional. They will also explain which values are normal for you.

- No matter what your PEF measurement is, if you have signs and symptoms such as chest tightness, shortness of breath, coughing or wheezing you should contact your physician immediately.

- Follow instructions carefully in order to get an accurate reading of your PEF values. If you are unable to obtain a reading, contact your healthcare professional.

- You should never alter the dosage of any medication without talking to your physician.

INTERPRET THE RESULTS

Three tests are performed per session, after which the app automatically selects the highest PEF value and directs you instantly to the Result screen, where you can see the highest value compared to your PB. A reduction of your PEF from one measuring session to the next may mean that your asthma is getting worse.

Step 6.

Take a deep breath until your lungs are filled all the way. Hold your breath while you place the device in your mouth. Close your lips around it and DO NOT put your tongue against or inside the hole.

 Blow out as hard and fast as you can in a single blow. Your first burst of air is the most important (blowing for a longer time will not affect your result). DO NOT spit or cough into the device.

Read the result displayed on the screen of your smartphone – this is your PEF value. Tap the “How it works?” button on the home screen to review the Step-by-step guide or watch a short video on the correct use of SMART PEAK FLOW.

After your blow, the app will ask you to Wait until the rotor inside stops spinning. DO NOT blow again until the app instructs you to continue.

Repeat Step 6. two more times, so that you will get a total of three values. The app will only save the highest of the three values and this will appear on your Result screen.

Step 7.

After use, disable your SMART PEAK FLOW device by disconnecting it from the audio jack port of the smartphone.

Take a deep breath until your lungs are filled all the way. Hold your breath while you place the device in your mouth. Close your lips around it and DO NOT put your tongue against or inside the hole.

 Blow out as hard and fast as you can in a single blow. Your first burst of air is the most important (blowing for a longer time will not affect your result). DO NOT spit or cough into the device.

Read the result displayed on the screen of your smartphone – this is your PEF value. Tap the “How it works?” button on the home screen to review the Step-by-step guide or watch a short video on the correct use of SMART PEAK FLOW.

After your blow, the app will ask you to Wait until the rotor inside stops spinning. DO NOT blow again until the app instructs you to continue.

Repeat Step 6. two more times, so that you will get a total of three values. The app will only save the highest of the three values and this will appear on your Result screen.
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. In case a foreign object gets inside the turbine, immerse and move the turbine gently in lukewarm water until the foreign object is removed. Following this, perform disinfecting on the mouthpiece (see below) and let the device dry completely before use. It is recommended to perform cleaning of the turbine on a regular basis to avoid unnoticed accumulation of foreign objects inside the turbine.

**PROCEDURE OF DISINFECTION**

It is recommended to clean and disinfect the mouthpiece using a mild disinfectant. Dissolve the disinfectant in lukewarm (approximately 35 degrees Celsius) water, immerse the mouthpiece and leave it in the solution for approximately five minutes. To determine the dosage and rate of dilution, follow the instructions given by the manufacturer of the disinfectant.

**Warnings for use in electromagnetic environments**

Due to the increasing number of electronic devices (computers, smartphones, 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.

SMART PEAK FLOW complies with EN 60601–1–2: 2016 on Electromagnetic Compatibility (EMC for medical devices) for both immunity and emissions.

**CLEANING AND DISINFECTION**

Even though SMART PEAK FLOW is a device that requires little maintenance, the cleaning and disinfection of the mouthpiece should be performed after each use and should be kept safe from contamination in between uses. Rinse the device in clean water and shake gently to remove any excess water. Allow to air dry on a towel. Store in a clean, dry and safe place at home.

**CAUTION**

To avoid irreparable damage to the turbine, DO NOT use any alcoholic or oily cleaning solutions, including soapy water as they may leave residues and DO NOT immerse in hot water or solutions. The device must be allowed to dry naturally until no residue water remains. Do not dry with an electric dryer.

**ERROR MESSAGES**

If you encounter any problems when using your SMART PEAK FLOW, a message will appear on the smartphone’s display to warn you about the malfunction.
**TROUBLESHOOTING**

If you receive an unusually low reading, it could mean that your SMART PEAK FLOW 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 you have any questions regarding the use of this device, please ask your physician.

**Malfunction** | **Possible cause** | **Action to take**
---|---|---
The turbine got pulled out of the audio jack socket accidentally. | To continue taking your readings, plug your turbine into the audio jack port and press the button "OK, try again". Make sure it goes all the way into the smartphone. | Make sure that you allow the app to access the microphone. If you plugged the device all the way in and the app still does not recognize the device, check that the audio jack port is not malfunctioning.

The turbine is not plugged in or it is not connected properly. | To start measuring, plug your turbine all the way into the audio jack port. | Make sure there is not enough light to perform the measurement. Make sure that you do not cover the window with your hand or fingers.

The smartphone is being charged. | Disconnect your smartphone from the charger as it may cause interference. Once disconnected, you can continue using the app. | There is a foreign substance (fluff, dust) accumulated at the bottom of the smartphone's audio jack port, causing a blockage in signal transmission.

The SMART ASThma app does not recognise the device. | The turbine's jack is not plugged all the way into the smartphone's audio jack port. | Make sure the device is plugged in correctly.

**Possible reason** | **Action**
---|---
The turbine may be dirty. | Clean the turbine as described in the Cleaning and Disinfection section. If necessary, replace the turbine with a new one or contact the manufacturer.

The test was performed wrongly. | Repeat the test, following the directions on the screen. Avoid sudden movements when you finish exhaling. Discuss the value with your physician.

There is not enough light to perform the measurement. | Make sure there is sufficient light and that you do not cover the window with your hand or fingers.

**LABELS & SYMBOLS**

SMART PEAK FLOW complies with the Essential Requirements of Directive 93/42/EEC on Medical Devices. This statement is made on the basis of CE Certificate no. 144797-18-11-08 issued by CE Certiso Kft., Notified Body no. 2409.

**TECHNICAL SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow measurement systems.</td>
<td>Bidirectional turbine.</td>
</tr>
<tr>
<td>Type</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Strength of illuminance</td>
<td>Min. 100 lux.</td>
</tr>
<tr>
<td>Applicable sources of</td>
<td>Tungsten, halogen, LED light bulb and natural light.</td>
</tr>
<tr>
<td>light.</td>
<td></td>
</tr>
<tr>
<td>Communication interface.</td>
<td>3.5 mm jack plug.</td>
</tr>
<tr>
<td>PEF – Peak Expiratory</td>
<td>Litre/minute.</td>
</tr>
<tr>
<td>Flow.</td>
<td></td>
</tr>
<tr>
<td>Power source.</td>
<td>Connected smartphone device's battery.</td>
</tr>
<tr>
<td>Voltage supply.</td>
<td>max. 5V DC.</td>
</tr>
<tr>
<td>Dimensions.</td>
<td>Turbine: 54 × 32 × 39 mm. Mouthpiece: 39 × 33 × 33 mm.</td>
</tr>
<tr>
<td>Weight.</td>
<td>Turbine: 15 g. Mouthpiece: 4 g.</td>
</tr>
<tr>
<td>Measurement range.</td>
<td>60-800 L/min.</td>
</tr>
<tr>
<td>Measurement accuracy.</td>
<td>10%.</td>
</tr>
<tr>
<td>IP protection level.</td>
<td>IP22.</td>
</tr>
<tr>
<td>Operating conditions.</td>
<td>Temperature: Min 0° C, Max 50° C. Humidity: Min 10% RH; Max 95% RH.</td>
</tr>
<tr>
<td>Storage conditions.</td>
<td>Temperature: Min 0° C, Max 50° C. Humidity: Min 10% RH; Max 95% RH.</td>
</tr>
<tr>
<td>Transport conditions.</td>
<td>Temperature: Min 0° C, Max 50° C. Humidity: Min 10% RH; Max 95% RH.</td>
</tr>
<tr>
<td>Life expectancy.</td>
<td>2 years.</td>
</tr>
</tbody>
</table>

This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or of the defective parts without charge for the parts or for the labour.

The product warranty shall not apply, at the discretion of the manufacturer, in the following cases:

- Improper handling, improper installation, improper operation of the device, or if the installation does not comply with local technical or safety regulations
- Use of the product for purposes other than those provided or failure to follow instructions
- Repair, adaptation, modification or tampering by third party
- Damage caused by lack of or incorrect maintenance
- Damage caused by abnormal physical or electrical stress

The repair or replacement described in this warranty is provided for goods returned at the customers’ expense to certified service centres authorised by the manufacturer. For details of these centres please contact either your local supplier or the manufacturer. Any unauthorised opening of the device invalidates all guarantee claims.

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 the manufacturer requires the written permission of the manufacturer itself.

The manufacturer – Smart Respiratory Products Ltd. – reserves the right to replace the product or make any changes deemed necessary.

Keep the original packaging! If your product has a problem, use the original packaging to ship it back to your local distributor:

Smart Respiratory Products Ltd. 4th Floor, I-Hub, Imperial College London, 84 Wood Lane London W12 0BZ United Kingdom
Tel: +44 (0)203 769 22 04
Email: info@SmartRespiratory.com
Website: www.SmartRespiratory.com

WARRANTY TERMS

SMART PEAK FLOW is guaranteed for two years of use. The warranty is effective from the first time of use and 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 the manufacturer.

The manufacturer cannot be held responsible for any damage caused by users failing to follow the instructions contained in this manual.

EC DECLARATION OF CONFORMITY

Manufacturer: Smart Respiratory Products Ltd.
Registered Office: 4th Floor, I-Hub, Imperial College London, 84 Wood Lane London W12 0BZ United Kingdom
Product Description: Peak expiratory flow meter with software application
Product Name: Smart Peak Flow is in conformity with provisions of the applied 93/42/EEC directive on Medical devices, Annex II excluding (4) (amended by 2007/47/EC of the European Parliament), as a Class II.a medical device.
EC Certificate Registration Number: 144797-18-11-08
Harmonised standards applied:
EN 60601-1
EN 60601-1-2
EN 60601-1-6
IEC 62366-1
EN ISO 10993-1
EN ISO 23747
EN 62304
EN ISO 13485
EN ISO 14971

Regarding all standards we apply the latest, valid version.
Name of Notified Body: CE Certiso Orvos- és Körháztechnikai Ellenőrző és Tanúsító Kóralótt Felelősségű Társaság
Address: Erdő u. 101., 2092 Budakeszi, Hungary
Notified Body Number: NB2409

Quality Management System CertificateRegistration Number: 144796-18-11-08 Issued: 12 January 2021 Expiry Date: 07 November 2021

Thomas Antalffy
Managing Director