

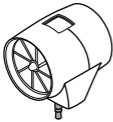
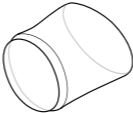



Package Contents

 Before opening the box, check that the upper and the lower holographic security stickers are not tampered. If so, do not use the device and send it straight 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:

<i>Peak flow meter turbine</i>	<i>Plastic mouthpiece</i>	<i>User's manual</i>
 A line drawing of a peak flow meter turbine. It consists of a cylindrical body with a fan-like turbine wheel on the front and a small protrusion at the bottom.	 A line drawing of a simple, cylindrical plastic mouthpiece.	 A line drawing of an open book representing a user's manual. The letter 'i' is printed on the right-hand page.

User Manual

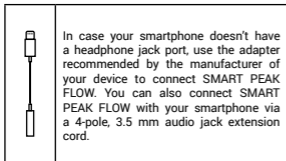
Version ENGV02. Last updated – November 2018

HOW TO SET UP YOUR DEVICE

Before connecting SMART PEAK FLOW to a smartphone, install the SMART PEAK FLOW 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 PEAK FLOW app has been installed on your phone.



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 indicated for monitoring asthma. PEF is the maximum speed a person can blow air out of the lungs after taking as big of a breath as possible.

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 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 PEAK FLOW app will use this data to calculate your

PEF 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.

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.

CAUTION

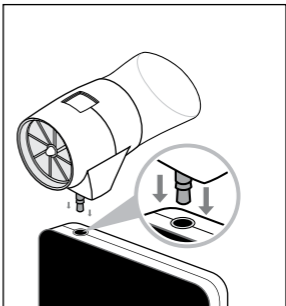
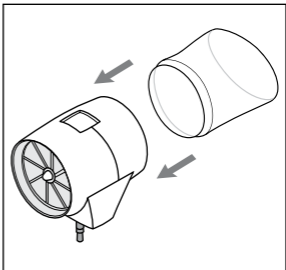


Supervision of an adult is required for testing children and adolescents (between age 5-14) and differently-abled persons.

Take the following steps to carry out a measurement.

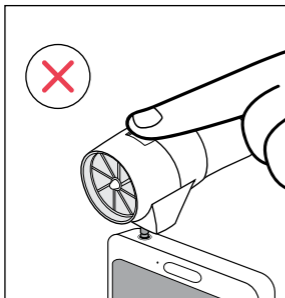
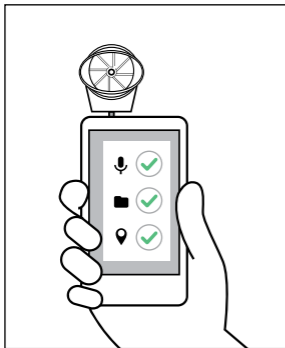
Step 1.

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.



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).

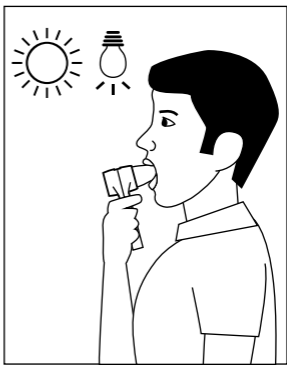
Step 3.

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



Never insert SMART PEAK FLOW into your mouth, in case the skin and/or mucosal membrane in physical contact is breached or compromised.

Step 5.

Stand up or sit upright (it makes no difference to test results). 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.

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 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.

Repeat **Step 6.** two more times, so that you will get a total of 3 values. The app will only save only 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.




INTERPRET THE RESULTS

Three tests are performed per each 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.

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 "I'm done for now" button.

You can also save notes to your results (e.g. about the circumstances or 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 below table, and are also available in the app, by tapping the ? icon under the result.

Colour	Result	Action
 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 80-60% of PB	Use caution in your activity. Refer to your Asthma Action Plan made by your physician for action to be taken.
 Red	DANGER ZONE <60% of PB	Medical alert! You should seek immediate medical attention. Act as instructed by your physician.

CAUTION



Ask your physician to watch you use your SMART PEAK FLOW before you rely on any measurements.

CAUTION



The action plan given to you by your physician will tell you what action to take when there are changes in your PEF values.

CAUTION




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.

HOW TO TRACK AND SHARE YOUR RESULTS

The SMART PEAK FLOW app keeps record of your highest readings of PEF for both morning and evening session, 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, dotted line in the top level of the graph.

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

By tapping the  Export (for Apple) or  Share (for Android) button, the app can export your chart into a .PDF or .CSV file, which you can send as an attachment to your physician or yourself.

Press 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 is 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.
	When SMART PEAK FLOW is used to monitor lung conditions such as asthma you should be under the care of a physician or other licensed healthcare professional.
	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 control, 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.

IMPORTANT SAFETY WARNINGS

	Supervision of an adult is required for testing children (above age 5), adolescents (ages 5-14) and differently-abled 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.
	Never connect SMART PEAK FLOW to the smartphone while its battery is being charged.
	Periodically check that no impurities or foreign bodies, such as skin, sputum, 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.
	Do not drop the device or treat it roughly in any way. Avoid strong vibration. Do not expose the device to extreme temperature, humidity, dust, sand, or chemical substances, or direct air currents (e.g. wind), sources of heat or cold.
	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.

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.

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.

CAUTION



It is compulsory to disinfect the mouthpiece before the first use, as described in the section CLEANING AND DISINFECTION (see below).

CAUTION



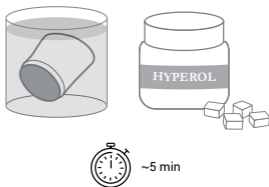
To avoid irreparable damage to the turbine, DO NOT use any alcoholic or oily cleaning solutions, and DO NOT immerse in hot water or solutions. DO NOT try to sterilize the turbine in boiling water. DO NOT try to clean the turbine under a direct jet of water or other liquids.



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 would get inside the turbine, merge and move the turbine gently in lukewarm water until the foreign object is removed. Following this, perform disinfecting on the turbine (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 after each use. Dissolve the disinfectant in lukewarm (cc. 35 Celsius degrees) water, immerse the mouthpiece and leave it in the solution for approx. 5 minutes. The disinfecting active agent tested was Carbamide peroxide. To determine the dosage and rate of dilution, follow the instructions given by the manufacturer of the disinfectant







Rinse 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.

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.



Error message	Cause of error	Action to take
 <p>No device found</p>	<p><i>The turbine got pulled out of the audio jack socket accidentally.</i></p> <p><i>The turbine is not plugged in or it is not connected properly.</i></p>	<p>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.</p> <p>To start measuring, plug your turbine all the way into the audio jack port.</p>
 <p>Hmm, something went wrong...</p>	<p><i>The smartphone is being charged.</i></p>	<p>Disconnect your phone from the charger as it may cause interference. Once disconnected, you can continue using the app.</p>
 <p>Hmm, your request seems to have timed out – please try again</p>	<p><i>After pressing START the app did not receive any data for more than 10 seconds</i></p>	<ul style="list-style-type: none"> • Make sure the device is plugged in correctly • Make sure the light conditions are optimal • Do not cover the window on top of the device with your fingers • Wrap your mouth around the device correctly <p>Press the button "OK, try again" to continue.</p>
 <p>Hmm, your measurement seems to be out of range</p>	<p><i>PEF measured is higher than 800 l/min. SMART PEAK FLOW is certified to give accurate measurement between the range of 60-800 l/min.</i></p>	<p>Make sure not to spit or cough into the device. Perform the PEF measurement as instructed by your physician.</p> <p>Press the button "OK, try again" to continue.</p>

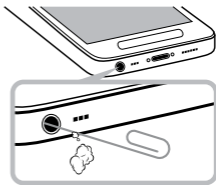
TROUBLESHOOTING

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.

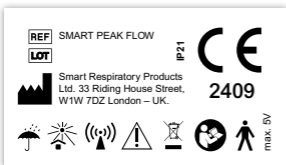
Malfunction	Possible cause	Action to take
<p>The SMART PEAK FLOW app does not recognize the device</p>	<p><i>The turbine's jack is not plugged all the way into the smartphone's audio jack port</i></p> <p><i>There is a foreign substance (fluff, dust) accumulated at the bottom of the phone's audio jack port, causing a blockage in signal transmission.</i></p>	<p>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.</p> <p>In case it is suspected that the audio jack port has been clogged up by foreign substance, gently reach inside with a suitable tool and extract the cause of blockage. Be extra gentle and very careful not to damage the audio jack port.</p>





Malfunction	Possible cause	Action to take
The test results are unreliable	<i>The turbine may be dirty</i>	Clean the turbine as described in the Cleaning and Disinfection section. If necessary, replace the turbine with a new one or contact the manufacturer.
	<i>The test was performed wrongly</i>	Repeat the test, following the directions on the screen. Avoid sudden movements when you finish exhaling. Discuss the value with your physician.
	<i>There is not enough light to perform the measurement</i>	Make sure there is sufficient light and that you do not cover the window with your hand or fingers.

	Keep away from sunlight.
	Keep dry—device needs to be protected from moisture.
	Follow operating instructions: indicates the need for the user to consult the instructions for important information.
	Type B applied part
IP21	Protected from touch by fingers and objects greater than 12 millimeters. Protected from condensation.
	In accordance with IEC EN 60601-1-2:2015 in section 5.1.1 for products including RF transmitter
	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 authorized collection centre. Due to the construction materials used for the device, disposal as normal waste could cause harm to the environment and/or health.

LABELS & SYMBOLS



	This product is manufactured by Smart Respiratory Products Ltd., 33 Riding House Street, W1W 7DZ London, United Kingdom
REF	SMART PEAK FLOW
LOT	Batch number
CE 2409	CE mark: indicates that the device is certified and that it conforms to the requirements of the 93/42/EEC medical device directive.
	Consult the instruction for use for important cautionary information.

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

Type	Description
Flow measurement systems	Bidirectional turbine
Measurement principle	Light interruption
Strength of illuminance required	100 lux minimum

Type	Description
<i>Applicable sources of light</i>	Volfram-, halogen-, LED light bulb and natural light
<i>Communication interface</i>	3.5 mm jack plug
<i>PEF – Peak Expiratory Flow</i>	Litre/minute
<i>Power source</i>	Connected smart phone device's battery
<i>Voltage supply</i>	max. 5V DC
<i>Dimensions</i>	Turbine: 54 × 32 × 39 mm Mouthpiece: 39 × 33 × 33 mm
<i>Weight</i>	Turbine: 15 g Mouthpiece: 4 g
<i>Measurement range</i>	80–600 L/min
<i>Measurement accuracy</i>	10%
<i>IP protection level</i>	IP21
<i>Operating conditions</i>	Temperature: Min 0° C, Max 50° C Humidity: Min 10% RH; Max 95% RH
<i>Storage conditions</i>	Temperature: Min 0° C, Max 50° C Humidity: Min 10% RH; Max 95% RH
<i>Transport conditions</i>	Temperature: Min 0° C, Max 50° C Humidity: Min 10% RH; Max 95% RH
<i>Life expectancy</i>	2 years

WARRANTY TERMS

SMART PEAK FLOW is guaranteed for 2 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.

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 labor.

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 authorized by manufacturer. For details of these centres please contact either your local supplier or the manufacturer. Any unauthorized opening of the device invalidates all guarantee claims.

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. 33 Riding House Street
London W1W 7DZ United Kingdom
Tel: +44 (0)203 769 22 04
Email: info@smartpeakflow.com
Website: www.smartpeakflow.com

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: **33 Riding House Street, W1W 7DZ London, 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 concerning medical devices (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 60601-1:2015;

EN 60601-1-2:2015;

EN 60601-1-6:2010;

IEC 62366-1:2015;

EN ISO 10993-1:2018;

EN ISO 23747:2015;

EN 62304:2006;

EN ISO 13485:2016;

EN ISO 14971:2013

Name of Notified Body: **CE CERTISO Kft**
Address: Gyár u. 2, 2040 Budaörs, Hungary

Notified Body Number: **NB2409**

Quality Management System Certificate
Registration Number: **14796-18-11-08**
Issued: **08 November 2018**
Expiry Date: **07 November 2021**



Thomas Antalffy
Managing Director