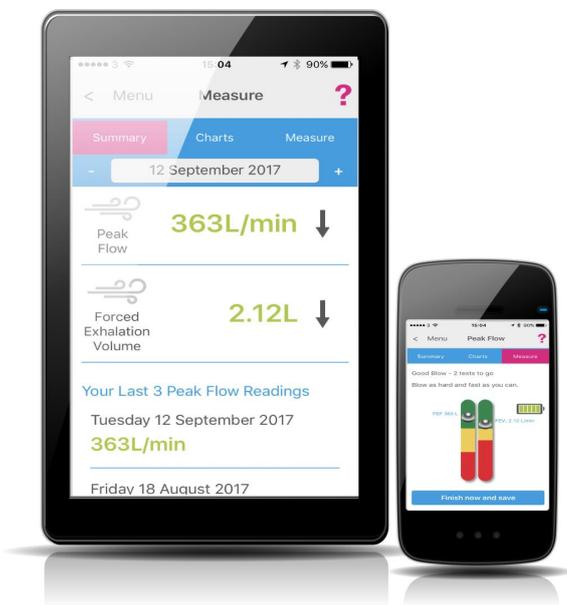


# SmartOne

Peak Flow & FEV<sub>1</sub> Meter

Lung Health



[www.activ8rlives.com](http://www.activ8rlives.com)

Peak Flow connects via Bluetooth 4.0 and uploads data to **Activ8rlives<sup>4</sup> Health+Wellness**, **Active<sup>+</sup>me REMOTE** and **Asthma<sup>+</sup>me Apps**. Works with: Bluetooth Smart Ready device (typically Bluetooth 4.0+), iOS 12+ and Android 10+. Apple Health App compatible.




We are a healthcare company. Our mission is to empower you to take care of your health and that of your family by self-care through self-monitoring.

From tracking levels of physical activity, weight, food intake, cardiovascular and lung function, to a new generation of at-home testing for long-term lung disease, we provide the devices and web-based tools to help you be active, eat well and stay healthy. Learn more at [www.activ8lives.com](http://www.activ8lives.com)

# SmartOne

Peak Flow & FEV<sub>1</sub> Meter



## Your SmartOne Peak Flow

Please read this manual carefully before you use your new device so that you do not injure yourself or others or cause damage to your new device through improper use.

## Intended Use

The **SmartOne® Peak Flow and FEV<sub>1</sub> Meter** is intended for home use by patients to monitor PEF (Peak Expiratory Flow) and FEV<sub>1</sub> (Forced Expiratory Volume in one second). The device is designed for adult and paediatric subjects when connect to the [Activ8rlives<sup>4</sup> Health+Wellness](#) (free), [Active<sup>+</sup>me REMOTE](#) or [Asthma<sup>+</sup>me](#) (subscription) **Apps**.

The **SmartOne Peak Flow and FEV<sub>1</sub> Meter** is indicated for monitoring asthma, COPD and other respiratory diseases.

 **If in any doubt about your health, please consult your medical team first and follow their advice closely.**

## Health and Safety Notices



**MEDICAL ALERT:** Seek medical advice before undertaking a strenuous exercise programme. Seek advice from your Doctor about any long-term condition. This device should not be used to make a primary diagnosis.



**WARNINGS:** The **SmartOne Peak Flow & FEV<sub>1</sub> Meter** main unit is **NOT waterproof**. Do not submerge it in water.



Do not wash the Main Unit in water. Use a soft, microfiber cloth for cleaning. Don't use harsh cleaning products as these will cause damage to your **SmartOne Peak Flow & FEV<sub>1</sub> Meter**. Don't allow sharp objects to scratch the surface as this may damage it and make it difficult to clean.



The measurement functions built into the **SmartOne Peak Flow & FEV<sub>1</sub> Meter** are not meant to substitute professional measurement or industrial precision devices. Values produced by the unit should be considered as reasonable representations only.

Do not allow your **SmartOne Peak Flow & FEV<sub>1</sub> Meter** to be subjected to excessive forces or shocks. Harsh physical treatment may stop your **SmartOne Peak Flow & FEV<sub>1</sub> Meter** from working properly.

Do not expose your **SmartOne Peak Flow & FEV<sub>1</sub> Meter** to direct sunlight for long periods of time.

Do not allow the device to be used in direct air currents (e.g. wind or fan), sources of heat or cold, humidity or other sources of light energy, dust, sand or chemical substances.



Do not immerse the Turbine or Mouthpiece in BOILING WATER, ALCOHOL or OILY CLEANING SOLUTIONS. Never try to clean the Turbine under a DIRECT JET of WATER or other liquids. Do not use a JET of HOT AIR from a HAIRDRYER or similar to dry the Turbine or Mouthpiece.

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

Only original accessories as specified by the manufacturer must be used with the device. Use of an unsuitable turbine flow sensor 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.

Use and store of 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.

Do not modify the device without authorisation from the manufacturer. All modifications, adjustments, repairs, reconfigurations must be performed by the manufacturer or by authorised personnel.



Do not remove the back cover to expose the internal electronics or tamper with the internal components. If you do, you will invalidate your warranty and may cause irreparable damage. Other than the replacement of the batteries, there are no user serviceable parts.

Take precautions when handling all battery types and dispose of batteries properly. Remove the batteries if you are planning to store the device for a long period of time. We hope you use your device for many years of course, but long periods of storage with the batteries in place may damage the device and will cause the batteries to discharge. Only use the battery type recommended in this manual. Do not touch the exposed electronic circuits, as there is a danger of electric shock.



The Mouthpiece and Turbine can be disconnected from the main unit for washing as per the instructions listed on [Page 14](#).



The technical specifications for this product and the contents of the User Manual are subject to change without notice by the manufacturer.



If you experience any serious incident that occurs in relation to this device, please report this to Aseptika Limited (Activ8rlives) and the competent authority of the Country in which you are based.

Call us 7-days-a-week, between 09:00—18:00  
t: +44 (0)1480 352 821 or [support@aseptika.com](mailto:support@aseptika.com)

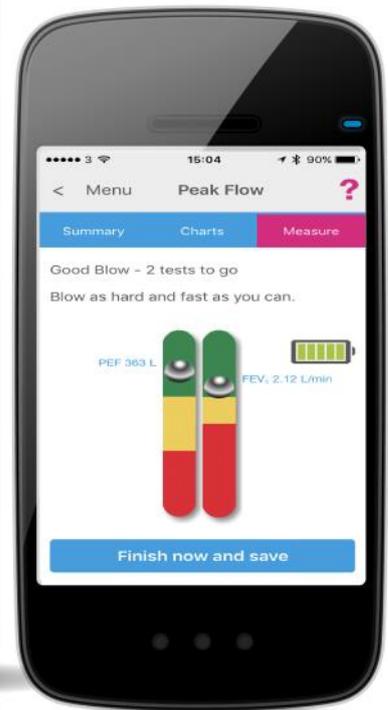
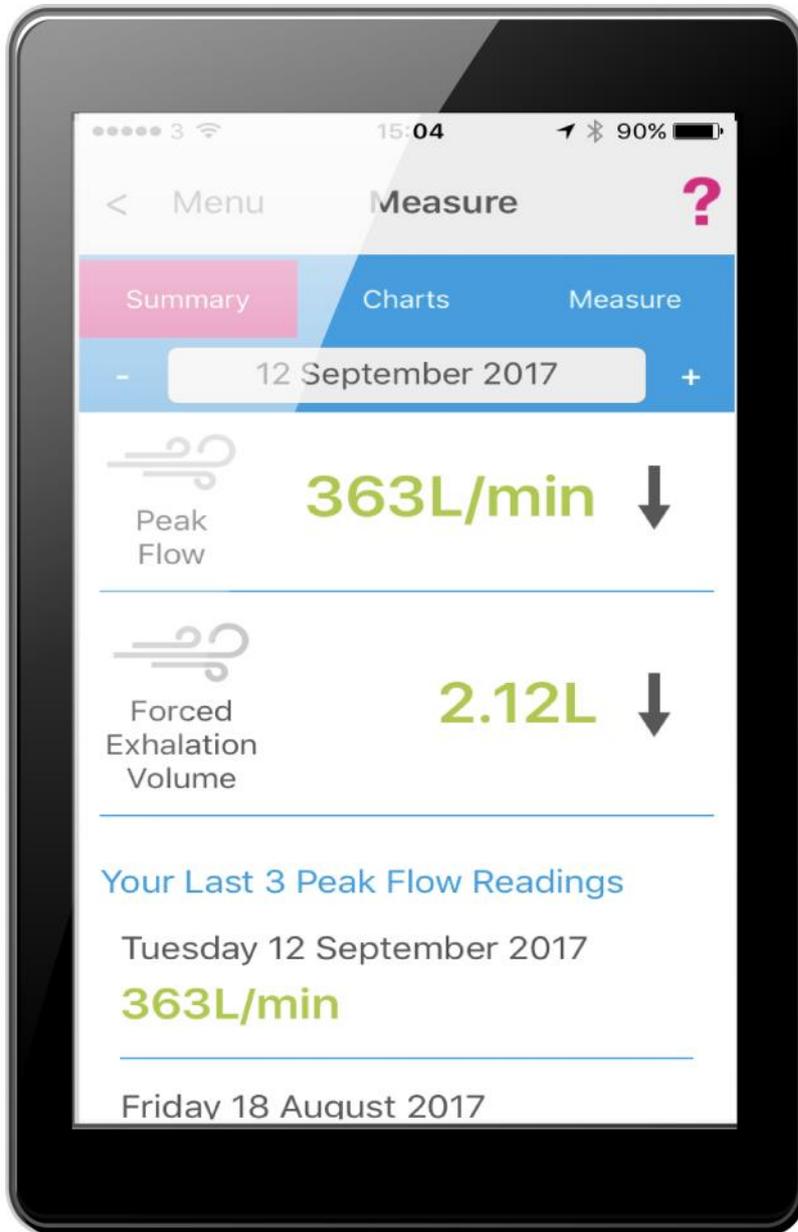
## Parts of the SmartOne Peak Flow

Your **SmartOne Peak Flow & FEV<sub>1</sub> Meter** has several parts, the **Main Unit** or **Device**, **Turbine**, and **Mouthpiece**. The **Main Unit** houses all the electronics and Bluetooth 4.0 component and the **Turbine** and **Mouthpiece** then slot and lock into it. The **SmartOne Peak Flow & FEV<sub>1</sub> Meter** has two replaceable and non-rechargeable batteries (instructions on [Page 14](#)).

Other than the battery compartment, the **Device** has no user-serviceable parts and opening the case to expose the electronics will void your warranty.

The **SmartOne Peak Flow & FEV<sub>1</sub> Meter** has a **non-washable Main Unit** and **washable Turbine** and **Mouthpiece**, instructions for cleaning and disinfecting are on [Page 11 and 14](#).







## How Does the SmartOne Work?

The **SmartOne Peak Flow & FEV<sub>1</sub> Meter** is a non-invasive method allowing the monitoring of the **Peak Expiratory Flow (PEF)**, also called **Peak Expiratory Flow Rate (PEFR)**, which is a person's maximum speed of expiration (breathe out). Forced Expiratory Flow at 1 second (FEV<sub>1</sub>) is also measured and is the volume of air expelled during the first second of the same exhalation.

The **SmartOne Peak Flow & FEV<sub>1</sub> Meter** is a small, hand-held device used to monitor a person's ability to breathe out air. It measures the airflow through the bronchi of the lungs and can be used to estimate the degree of obstruction in the airways. When there is an episode of obstruction the air cannot generally be expelled as forcefully as possible, so your PEF and FEV<sub>1</sub> will be lower.

Peak Flow readings are higher when we are well, and lower when the airways are constricted. From changes in recorded values, we may determine lung functionality, severity of Asthma or other respiratory symptoms and treatment, and how well our treatment is working.

Measurement of PEF requires some practise to correctly use a meter and the normal expected value depends on a patient's gender, age and height. It is classically reduced in lung disorders such as Asthma, COPD, Bronchiectasis or Cystic Fibrosis.

Due to the wide range of **Normal** values and high degree of variability, peak flow is not the recommended test to identify respiratory disease. However, it can be useful in some circumstances to monitor the severity of lung health or efficacy of treatment.

It is important to use the same peak flow meter every time to ensure consistency of the readings.

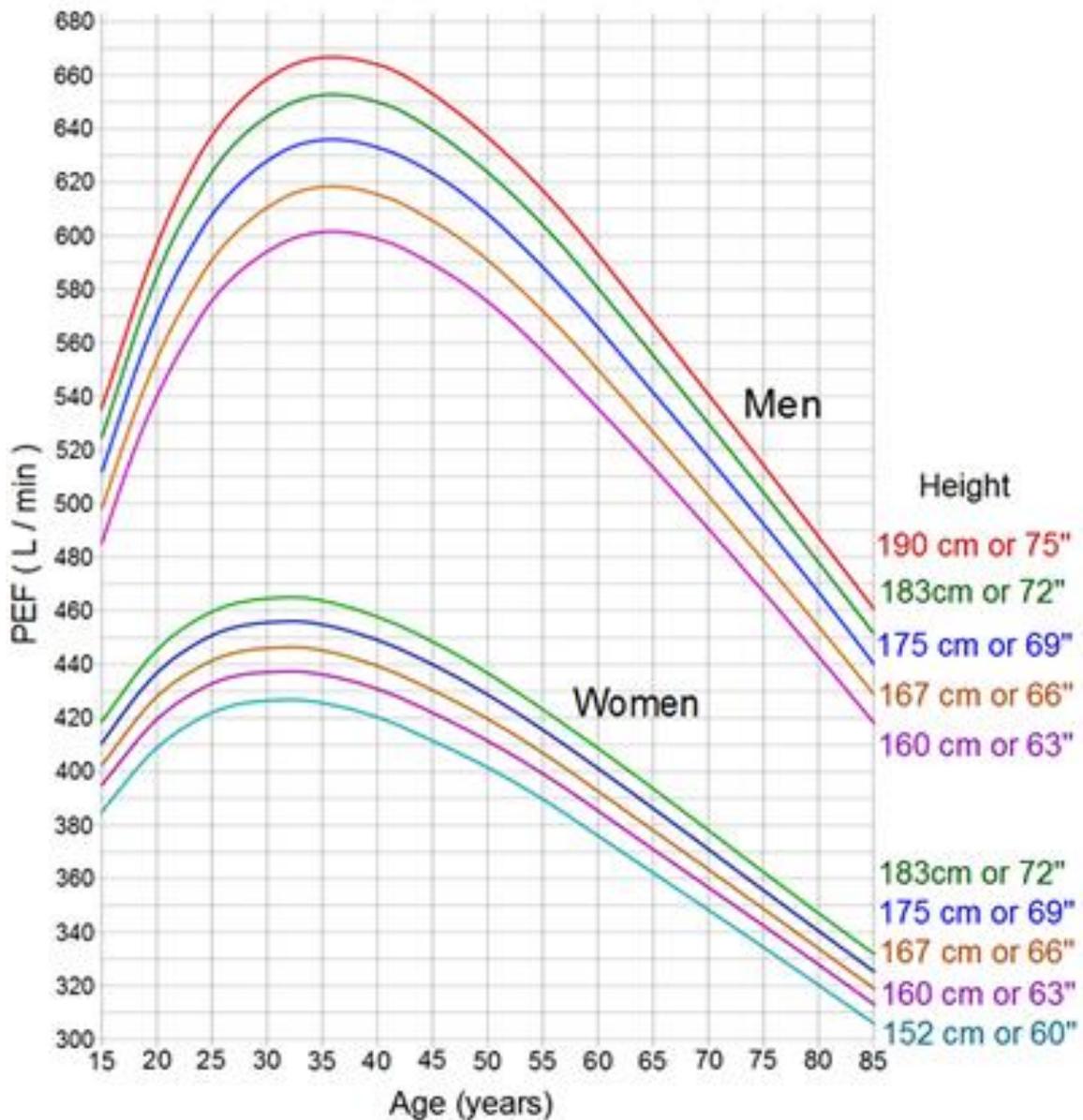
It is generally recommended to take one measurement in the morning and one in the evening, every day, before inhaling your prescribed medication. Also it is advisable to carry out additional measurements whenever you feel unwell or have a perceived shortness of breath.

The highest peak flow value is the measurement of interest. Repeat your measurement three times to get the best possible result for the moment. Take care to have sufficient relaxation time between measurements.

The **Normal** value (Target value) for PEF varies according to gender, age and height. The chart on [Page 8](#) of this manual can be used to find your **Normal** value. This is calculated for you automatically in [Activ8lives](#). Enter this value in your **Target PEF** when registering for your Free [Activ8lives](#) account.

 **If in doubt, contact your Doctor or Respiratory Nurse for advice.**

### Normal values for peak expiratory flow (PEF) EN 13826 or EU scale



Reference: Nunn A. J., Gregg I., British Med J, 1989: 298, 1068-70. For use with EN13826 / EU scale peak flow meters.



## What Your Measurements Mean

Peak flow values are often classified into 3 zones of measurement according to the **American Lung Association**: **Green**, **Amber** and **Red**.

Doctors and health practitioners develop self-management plans based on the **Green-Amber-Red** zones.

The **Activ8lives<sup>4</sup> Health+Wellness App** (or **Asthma<sup>+</sup>me** or **Active+me REMOTE**) **Apps** automatically stores the highest or best value to date, with the **Green** range being any reading above 80% of your **Target**, set when you Registered for your **Activ8lives** **account**. A reading in the **Amber** range indicates a reading between 60% and 80% of your **Target**. A reading in the **Red** range indicates a reading below 60% your target.

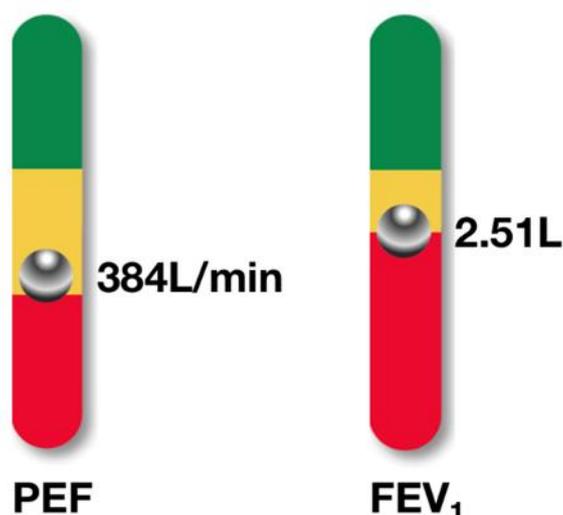
We have calculated your Peak Flow and FEV<sub>1</sub> **Targets** based on information you've already entered at Registration. If you have a different target set by your Clinician then enter it manually within the **Settings > Lung Function Targets** of the **Activ8lives<sup>4</sup> Health+Wellness** (or **Asthma<sup>+</sup>me** or **Active+me REMOTE**) **Apps**.

**Green Zone:** 80 to 100 percent of the usual or normal peak flow readings indicating that your lungs are clear. A peak flow reading in the **Green** zone indicates that the lung function management is under good control.

**Amber Zone:** 50 to 79 percent of the usual or normal peak flow readings indicates caution. It may mean respiratory airways are narrowing and additional medication may be required.

**Red Zone:** Less than 50 percent of the usual or normal peak flow readings. Indicates a medical emergency. Severe airway narrowing may be occurring and immediate action needs to be taken. This would usually involve contacting a doctor, respiratory nurse or hospital.

The readings for this female volunteer indicates that her Peak Flow (PEF) and FEV<sub>1</sub> on this reading are within the **Amber** zones and it may mean that there is narrowing of her airways and needs to seek advice from a medical professional.



 **If in doubt as to what your reading means, contact your Doctor or Respiratory Nurse.**



## Adding the Batteries

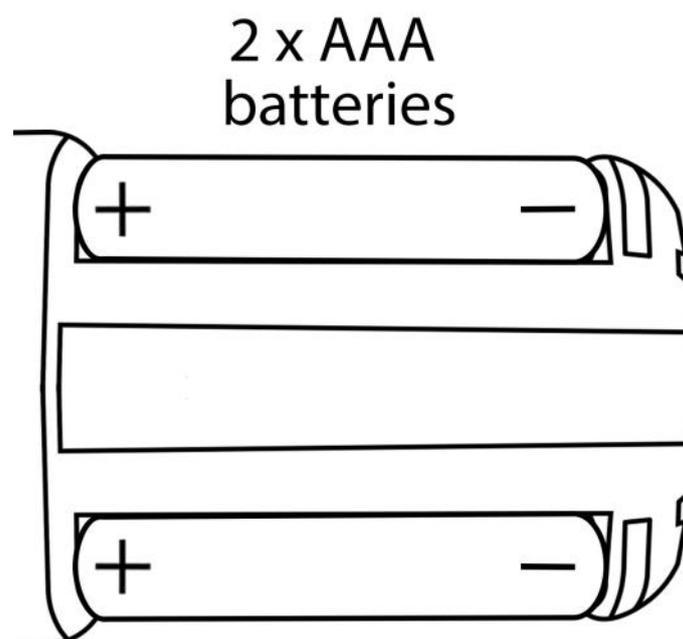
Your **SmartOne Peak Flow & FEV<sub>1</sub> Meter** uses two AAA 1.5V alkaline batteries, which are supplied. These are non-rechargeable batteries and no attempt should be made to recharge these.

Open the battery compartment from underneath and insert 2 x AAA batteries in the direction indicated. Replace the cover.

There is no DISPLAY to show whether the device is on, but once you connect the **Activ8rlives App** and Bluetooth is switched on, the device's unique Serial Number will appear on the App screen because it is within Bluetooth range.

Remove the batteries if you are planning to store the device for a long period of time. We hope you use your device for many years of course, but long periods of storage with the batteries in place may damage the device and will cause the batteries to discharge.

Replace the set of batteries (2 x 1.5V AAA) in the correct direction when the batteries are exhausted. No data is stored on the device in memory, so exchange of batteries will not affect data storage.



**Note:** Do not tamper or attempt to open the unit in which the electronics are housed, your warranty will be invalidated. Substances contained within the battery may damage the environment or human health if handled and so there is a risk to electrical shock or burns. When disposing of this product and its batteries, ensure that it is correctly disposed of for special treatment and not as normal household waste.



## Cleaning and Disinfection

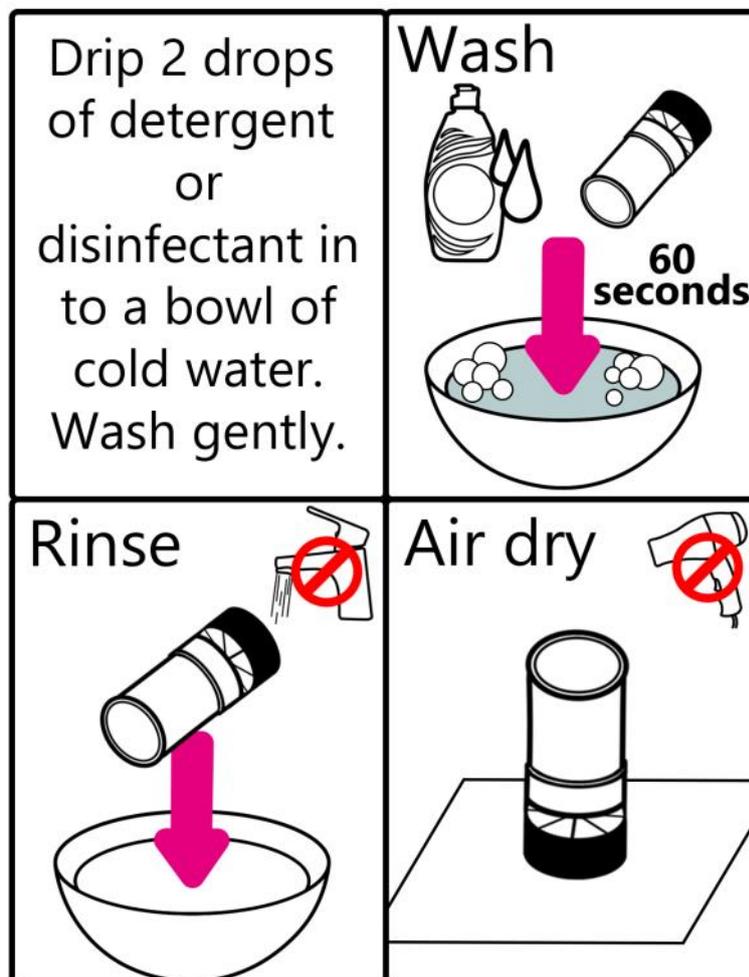
It is recommended that you disinfect the **Mouthpiece** and **Turbine** before its first use and at least once a week using the following procedures. **Never immerse** the **SmartOne Peak Flow & FEV<sub>1</sub> Meter's** main unit in water or disinfecting solution.

Disconnect the **Mouthpiece** and **Turbine** from the main device by twisting it counterclockwise and simply pulling it out.

Soak the **Turbine** and **Mouthpiece** in a cold detergent or disinfection solution and shake it to remove any impurities inside it. Leave it to soak for the length of time suggested by the cleaning or disinfection solution manufacturers.

Rinse both the **Turbine** and **Mouthpiece** by dipping it in clean cold water. Drain the **Turbine** and **Mouthpiece** and shake it vigorously. Leave it to dry by laying it with the shaft vertical on a clean piece of paper towel. Reassemble the **Mouthpiece** onto the **Turbine** and lock into position by turning the **Turbine** in a clockwise direction and as indicated on the Main Unit.

**⚠ WARNING: Do not immerse the Turbine or Mouthpiece in BOILING WATER, ALCOHOL or OILY CLEANING SOLUTIONS. Never try to clean the Turbine under a DIRECT JET of WATER or other liquids. Do not use a JET of HOT AIR from a HAIRDRYER or similar to dry the Turbine or Mouthpiece as this will cause damage to your device.**





## Let's get started with the Set-up and Connect to the **Activ8lives<sup>4</sup> Health+Wellness App** (alternatively you may wish to subscribe to the **Asthma<sup>+</sup>me App**)

The **SmartOne Peak Flow & FEV<sub>1</sub> Meter** is programmed by and uploads information directly to and from your **Activ8lives** account each time your Bluetooth Smartphone or Tablet (not Included) is connected to it wirelessly by Bluetooth 4.0.

This guide will show you how to:

- 1 Install the **Activ8lives<sup>4</sup> Health+Wellness** (free), **Active<sup>+</sup>me REMOTE** and **Asthma<sup>+</sup>me** (subscription) **Apps** to your iOS or Android Smartphone or Tablet.
- 2 How to operate, use and take care of your **SmartOne Peak Flow & FEV<sub>1</sub> Meter** and connect to your Smartphone or Tablet.
- 3 How to take routine readings and upload directly to your **Activ8lives** account.

If you follow these directions sequentially, it will take you about 5-10 minutes to learn how to measure your lung function and connect to the **Activ8lives<sup>4</sup> Health+Wellness App**.

### Intended Use:

The **Activ8lives<sup>4</sup> Health+Wellness App** is an application software for mobile device intended for use in the home to assist people to receive and review information from connected medical and non-medical devices, track medication use, for effective health self-management. The user also can share the data via sharing functions. **Activ8lives<sup>4</sup> Health+Wellness App** is a Class I medical device designed for use with persons 5-80+ years-old, and 5-12 years-old with adult supervision, who have a health condition for which the App can be used at home for their self-care.

### Health and Safety Notices:

**Activ8lives<sup>4</sup> Health+Wellness App is not intended to monitor vital physiological parameters where variation could result in immediate danger.**

-  Long-term health conditions (LTHC) can be life-threatening. Always take medication as prescribed. If you experience any LTHC-related symptoms, refer to your **Care Plan** and follow the instructions carefully. If you continue to have symptoms, consult your medical team.
-  Do not rely on **Activ8lives<sup>4</sup> Health+Wellness App** to diagnose or treat any long-term health condition. Only recommended for children 6-years-old and over and only under adult supervision.
-  Do not rely solely on the Reminder capabilities of the **Activ8lives<sup>4</sup> Health+Wellness App** to take your prescribed medication as directed by your medical team.



## Installing the **Activ8lives<sup>4</sup>** App on Your Smartphone or Tablet

(Bluetooth 4.0 Enabled Devices are required to use the **SmartOne Peak Flow & FEV<sub>1</sub> Meter**)

Download the **Activ8lives<sup>4</sup> Health+Wellness App** from the App Store appropriate to your device. Search for **Activ8lives** in the search bar of your App Store or scan the QR code below and it will take you to the appropriate App Store for your device.



### Compatible Bluetooth 4.0 Smartphones or Tablets



Apple devices running iOS 12+ that are Bluetooth Smart Ready (typically Bluetooth 4.0+).



Android devices running Android 10+ that are Bluetooth Smart Ready (typically Bluetooth 4.0+).

**IMPORTANT NOTE:** Please adjust the screen lock function on your Smartphone or Tablet to be longer than 2 minutes to allow the SmartOne Peak Flow & FEV<sub>1</sub> Meter time to sync with your device.

Short times of less than 2 minutes cause frequent loss of connectivity.



**Help Videos** in App, follow this ?

Website [www.Activ8lives.com](http://www.Activ8lives.com)

YouTube <http://bit.ly/Activ8lives>



### Still Need Help

We are here to help you 7-days-a-week, so please call us to help you set-up your device on UK 01480 352821.

Already have an account setup?  
Skip straight to step 4

### 1. Download App

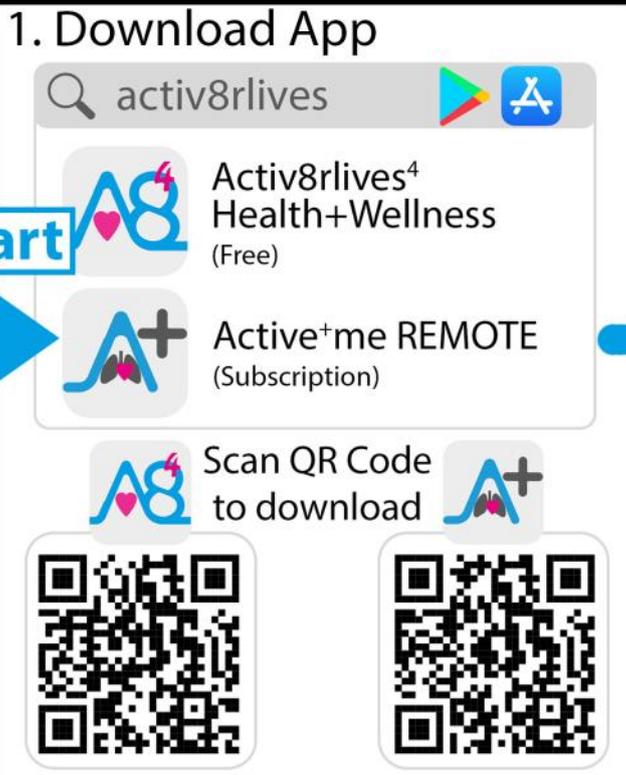
Start

Search: activ8rlives

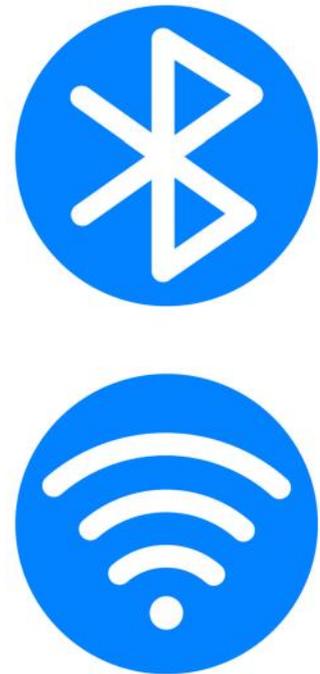
Activ8rlives<sup>4</sup> Health+Wellness (Free)

Active+me REMOTE (Subscription)

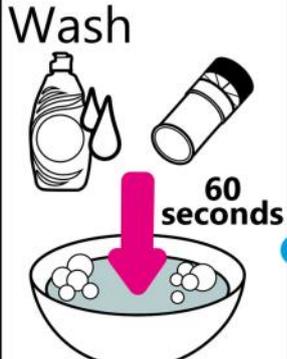
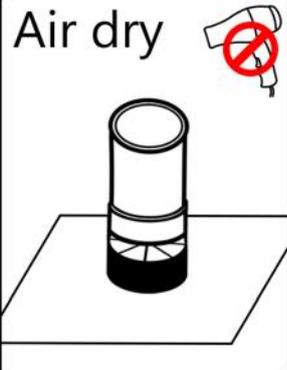
Scan QR Code to download



### 2. Turn on Bluetooth & Wi-Fi

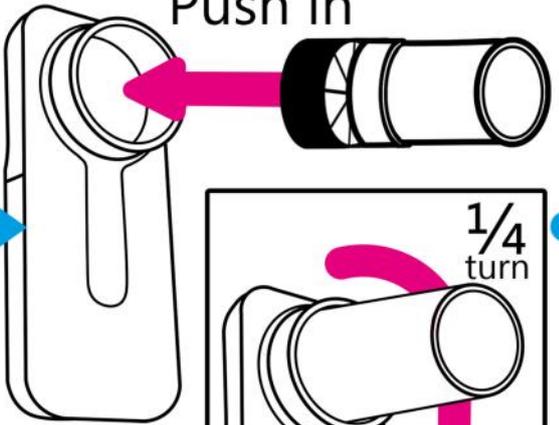


### 5. Wash the turbine / mouthpiece

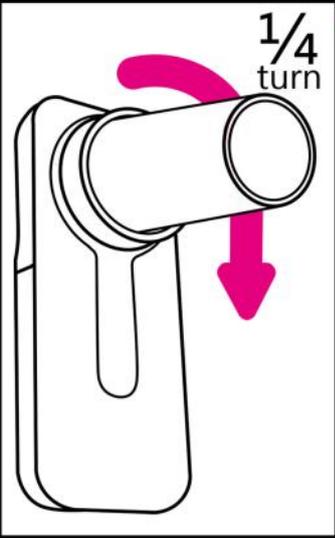
<p>Drip 2 drops of detergent or disinfectant in to a bowl of cold water. Wash gently.</p>	<p>Wash</p>  <p>60 seconds</p>
<p>Rinse</p>  <p></p>	<p>Air dry</p>  <p></p>

### 6. Install the turbine / mouthpiece

Push in



1/4 turn



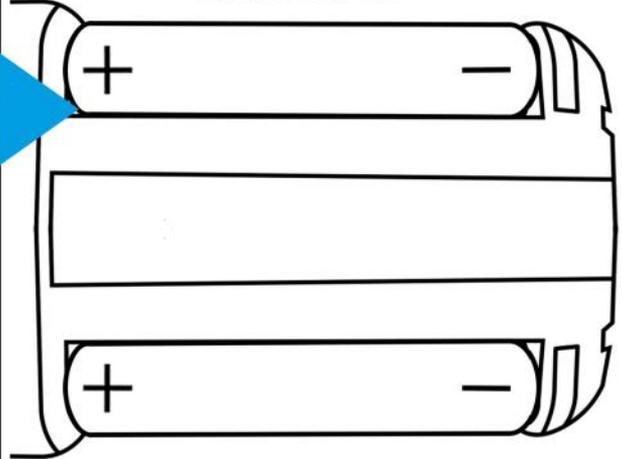
### 3. Register Account



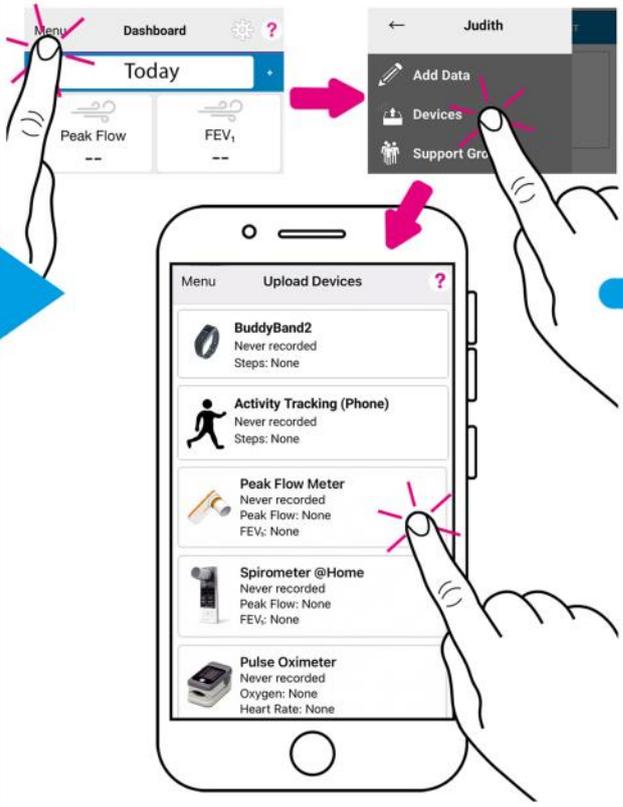
Follow registration process in App.

### 4. Insert the batteries

2 x AAA batteries

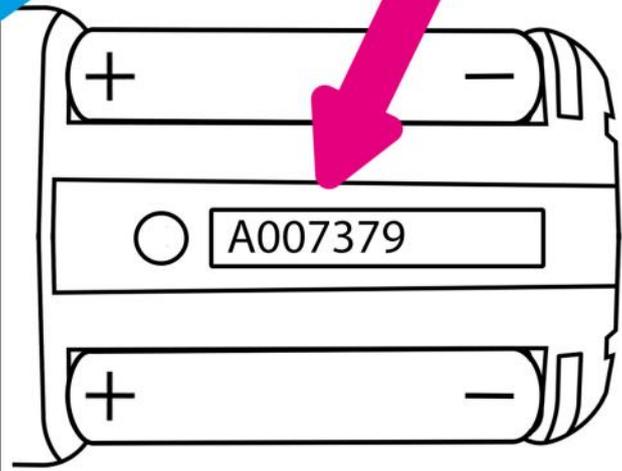


### 7. Connect in App



### 8. Find montior ID inside battery compartment

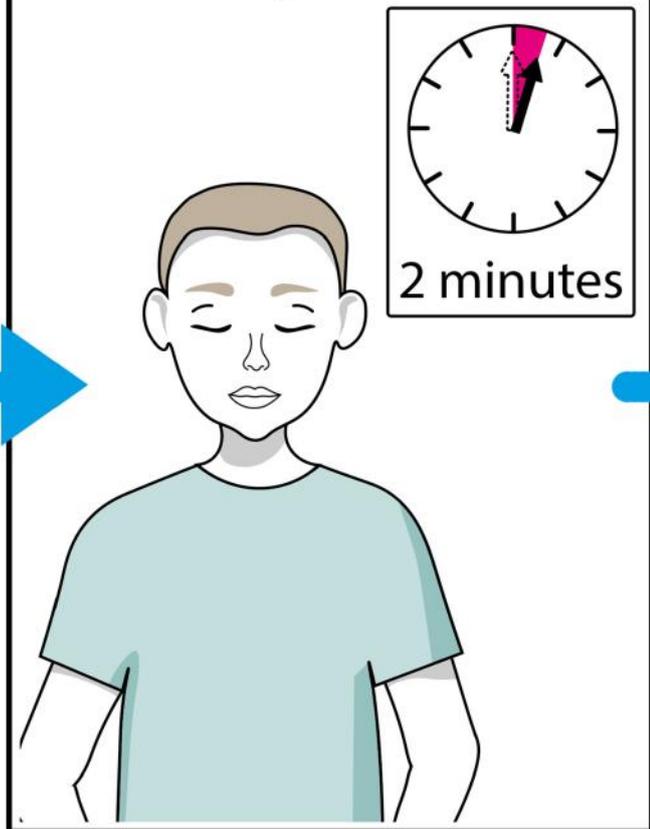
Tap on the correct serial number below to start using.



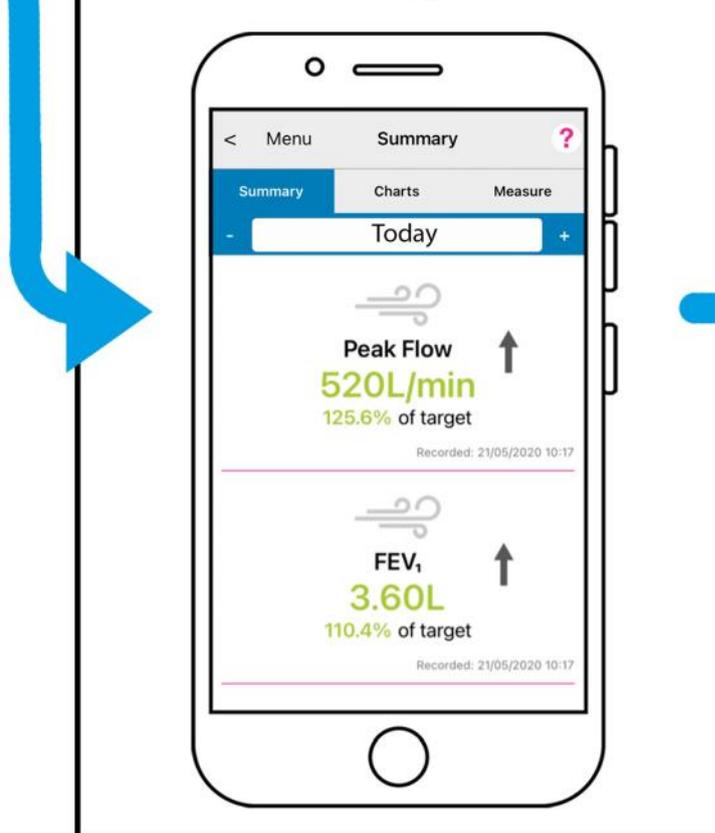
### 9. Watch the help movie



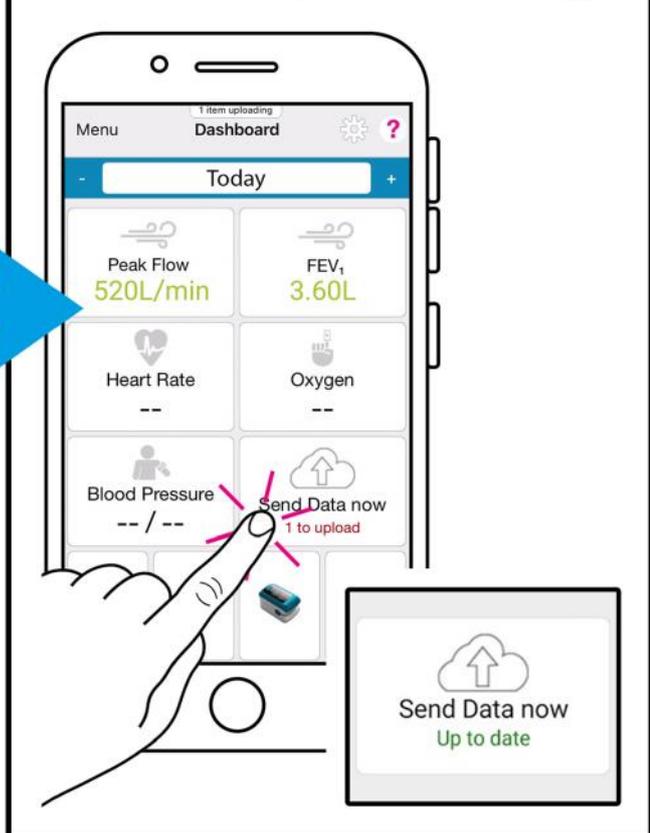
### 10. Sit calmly



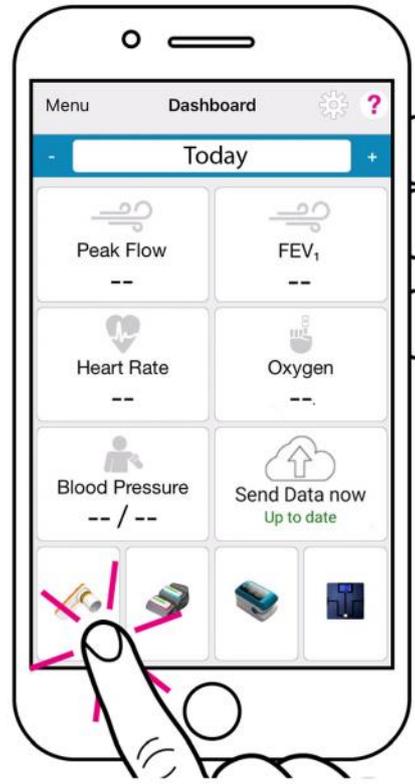
### 13. Your reading



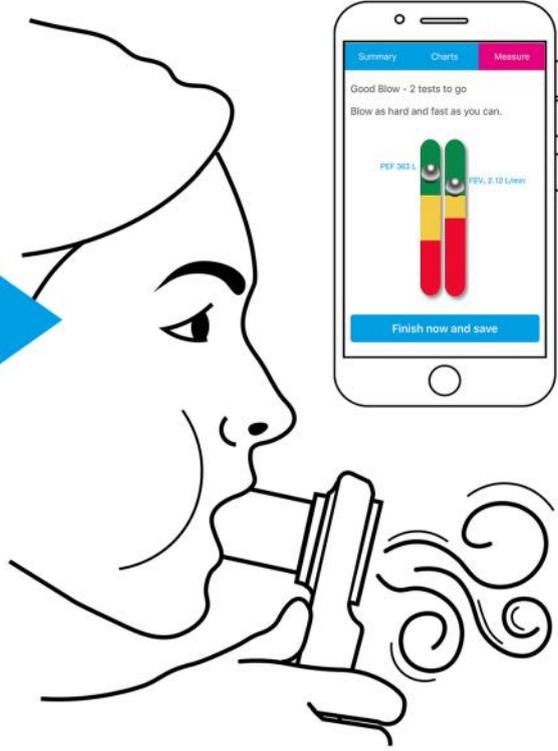
### 14. Finish & upload reading



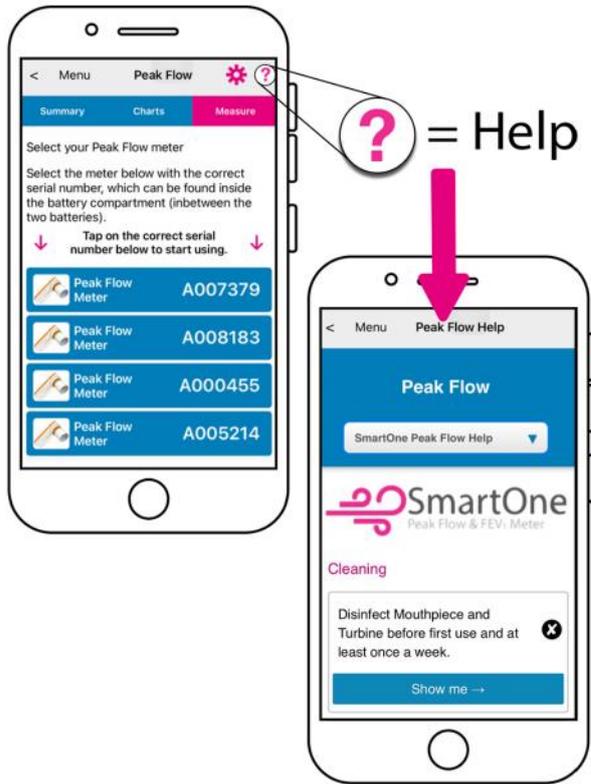
# 11. Start Measurement



# 12. Follow instructions on App to do 3 blows



# 15. Technical help



# 16. Keep this booklet safe



**WARNING**

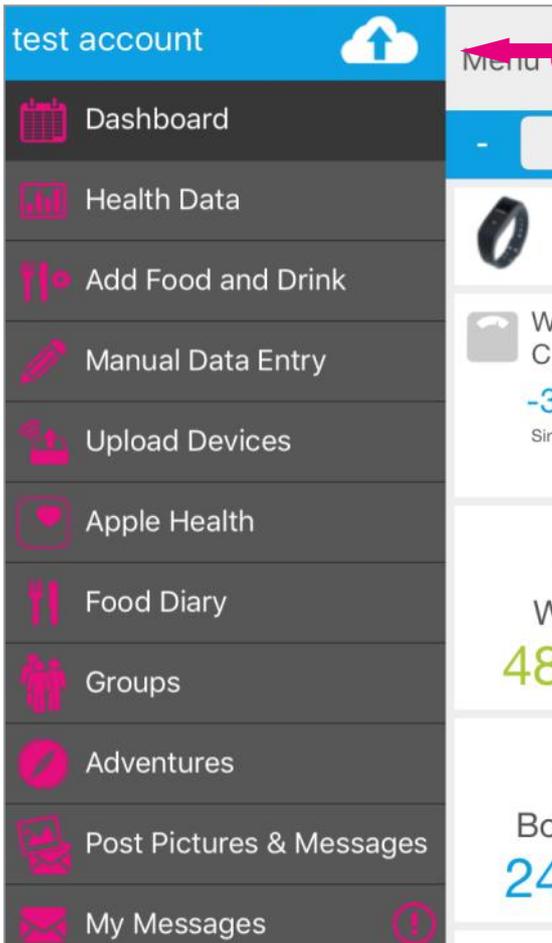
**Don't repeat reading within 5 minutes of last recording!**

**End**

**Activ8rlives Technical Support**

Phone: 01480 352 821 (UK)

Email: [support@aseptika.com](mailto:support@aseptika.com)



## Sending Your Data to Cloud

If your Smartphone or Tablet is connected to the internet by WiFi, your data will upload to your online **Activ8lives** account automatically.

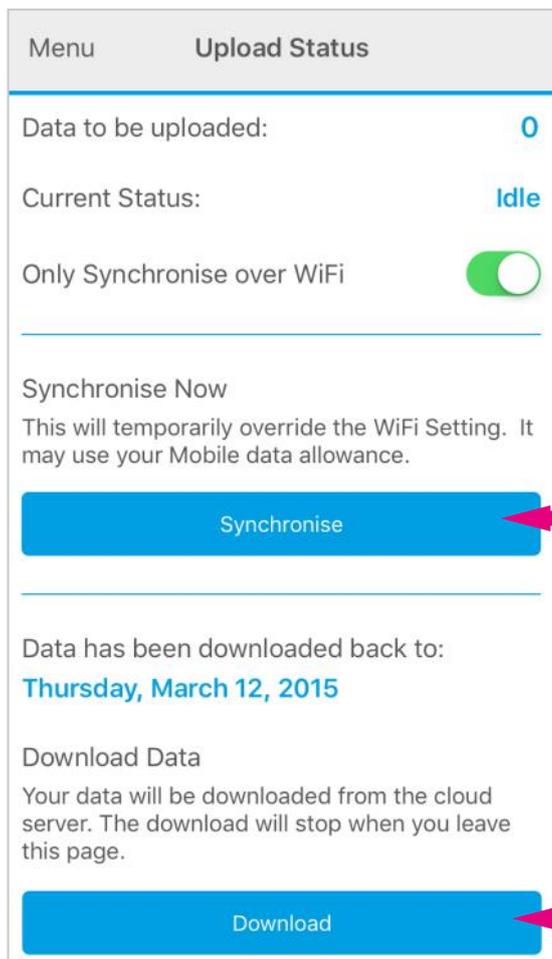
If there is an arrow in the **Cloud** in the top bar it indicates that you have data to upload to the **Cloud** Server. Touch the **Cloud** icon and it will automatically detect and synchronise if you are on WiFi.

Touch the **Synchronise** bar to upload via Cellular network to upload the data.

By touching the **Download** bar your data will download from the **Cloud** for you to view on the App.

If there are no networks available the data will be uploaded at a later time by either WiFi or Cellular when you are within range. The data is not lost and you do not have to take the reading again.

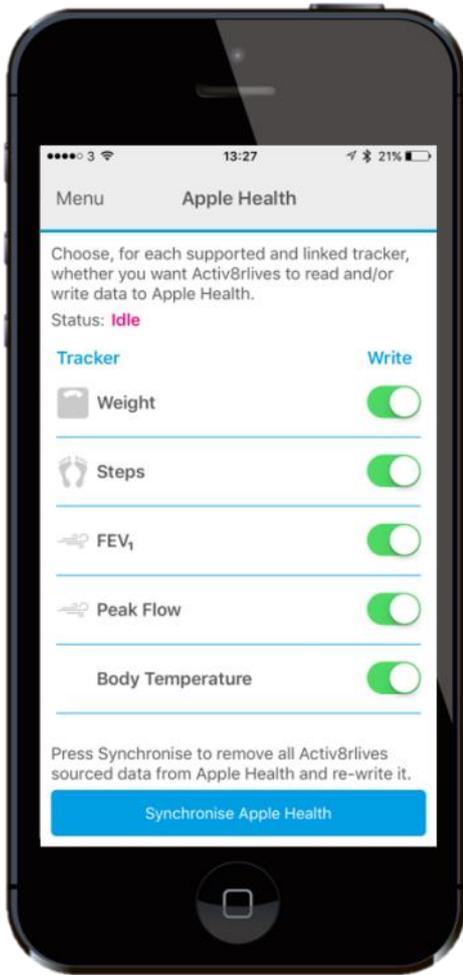
When the data is stored in the **Activ8lives** secure **Cloud**, this means that you can view your data (from today, yesterday, a week, a month or years ago) at any time via the Smartphone App or **Activ8lives** website.  
[www.activ8lives.com](http://www.activ8lives.com)



## Data Security

The storage of your data is hosted on our private **Cloud** Server operated by AWS (London, UK). No data ever leaves the UK and we work to the NHS Data Security and Protection Toolkit and Cyber Essentials Plus standards.





Health



## Apple Health App Integration

Included in the **Activ8lives<sup>4</sup> Health+Wellness App** is the ability to allow users to record data from **Activ8lives<sup>4</sup>** growing range of consumer-focused health monitors and store these data in both the **Activ8lives Cloud** servers and **Apple's Health App** via your iPhone.

From the **Menu** of the **Activ8lives<sup>4</sup> Health+Wellness App**, select **Apple Health** and it will guide you through step-by-step the process of set-up of **Apple Health** within the **Activ8lives<sup>4</sup> Health+Wellness App**. You must enable all related types of data in the categories to sync to **Apple Health** then touch **Synchronise Apple Health**.

**Note:** **Apple's Health App** option does not appear on iPads or on older iPhones running versions below iOS 9.



Disposable Turbine with Cardboard Mouthpiece are available in boxes of 10 via the **Activ8lives** website.

[www.activ8lives.com](http://www.activ8lives.com)



# Trouble Shooting SmartOne Peak Flow



## Help Menu?

**Help** can be found on all pages of the **Activ8lives<sup>4</sup> Health+Wellness App** in the top right-hand corner. Touch **?** to expand the page and scroll down through the **Help** information, including viewing the **Help Videos**. This symbol **!** also provides helpful hints, when found in one of the **Activ8lives Apps**.

## Will Not Connect via Bluetooth?

Requires Bluetooth Smart Ready device (typically Bluetooth 4.0+), iOS 12+ and Android 10+.

If the **SmartOne Peak Flow Metre** will not connect to Bluetooth, first check that you have Bluetooth turned on your Smartphone or Tablet. Or the batteries may be discharged and need changing.

## Changing to a Different SmartOne

If for some reason you want to change the device you measure your peak flow with, before you go through the process of **Identifying your monitor** touch the **Change Monitor** button and select the device with the correct serial number.

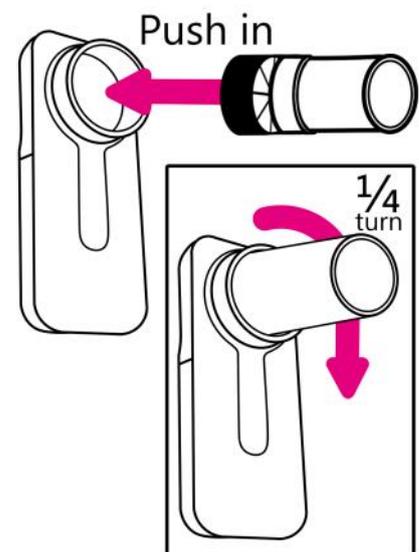
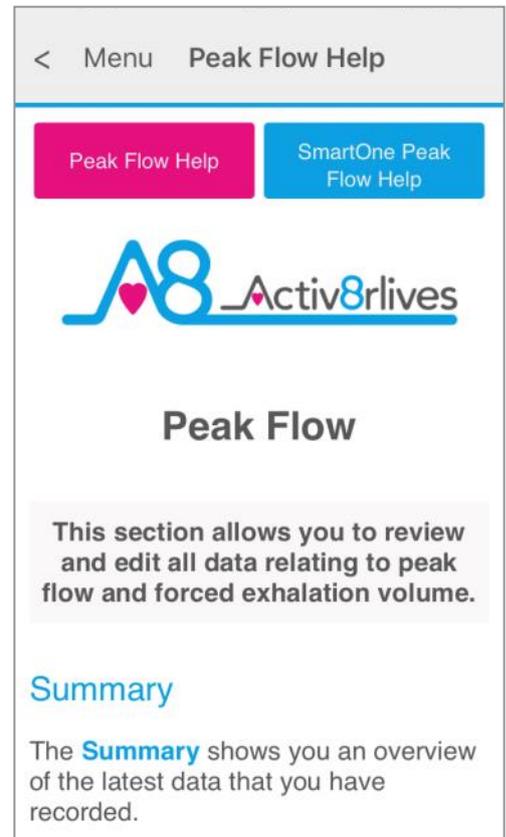
## Activ8lives App Crashes

Close other Apps open on your Smartphone or Tablet, as these may be using too much memory to allow the **Activ8lives<sup>4</sup> Health+Wellness App** to function. Rebooting the Smartphone or Tablet often helps.

## App shows no reading

If you have not taken a reading for a while or if the Smartphone or Tablet has been power cycled (i.e. turned off and then on again) you may need to reconnect the **SmartOne Peak Flow & FEV<sub>1</sub> Meter** with the Smartphone or Tablet by repeating the connection process as described on **Page 14–17**.

Ensure that the **Turbine** and **Mouthpiece** are firmly locked into position of the **Main Unit** and that the **Turbine** is protruding by 8mm out the back of the device.



Lock the Turbine by turning left or right until it is locked and firmly in place.

## Still Need Help

We are here to help you 7-days-a-week, so please call us to help you set-up your device on UK 01480 352821.



**Help Videos** in **App**, follow this **?**

Website [www.Activ8lives.com](http://www.Activ8lives.com)

YouTube <http://bit.ly/Activ8lives>



## Viewing Your Data on Your PC or Mac Computer

Login via the [Activ8lives](http://www.activ8lives.com) website, go to [www.activ8lives.com](http://www.activ8lives.com) using the same Username and Password that you used for your App Login.

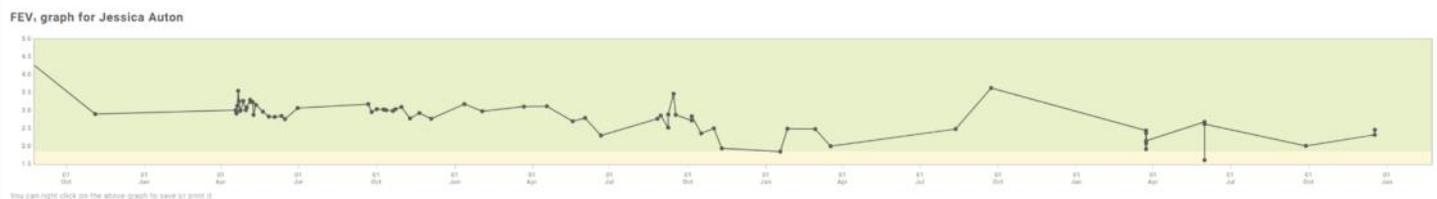
From your [Activ8lives](http://www.activ8lives.com) account you can view your **Health Data**, select the **Timeframe** and scroll down to view.

The [Activ8lives](http://www.activ8lives.com) Data website hosts an enhanced **Dashboard**. You have the choice of using either the **Simple**, **Advanced** or **Expert** settings by selecting the buttons in the top right-hand corner to switch between increasingly complex **Dashboard** layouts.

The screenshot shows the Activ8lives web dashboard. At the top, there are navigation tabs for 'Today', 'Last 7 Days', 'Last 30 Days', 'Last 90 Days', and 'Last 365 Days'. The current date is 11/2016. On the left, there is a sidebar menu with options like 'Dashboard', 'Health Data', 'Data Sync', 'Devices & Trainers', 'Settings', 'Personalize', and 'Done'. The main content area displays two line graphs: 'Peak Flow' and 'FEV1'. Both graphs show data points over time with a green shaded area representing a range. Annotations with pink arrows point to 'PRINT ALL' and 'COPY GRAPH' buttons above the Peak Flow graph, and a 'Select Trackers here to add to your Dashboard on the Web Version' button on the right side of the dashboard.

## Printing your Data

Printing your data can be achieved by going to the Web version of your [Activ8lives](http://www.activ8lives.com) account and touch the **Print All** tab or **Copy Graph**. These will be saved as a PDF file, as the example below, for easy printing or sending via email.



## Specifications

Type	Description
Dimensions of main unit	109 x 49 x 21mm
Weight	60.7g (including batteries)
Communication interface	Bluetooth Smart (4.0)
FEV <sub>1</sub> — Expiratory volume in one second	Litres (L)
PEF— Peak expiratory flow	L/minute
Flow/volume measurement systems	Bi-directional turbine
Measurement principle	Infrared interruption
Maximum volume measured	10 L
Flow range	±960 L/minute
Volume accuracy	±3%
Flow accuracy	±5%
Dynamic resistance at 12 L/s	<0.5 cm H <sub>2</sub> O/L/s
Power supply	2 x 1.5V AAA alkaline batteries
Type of electrical protection	Class II
Electrical protection level	BF
IP protection level	IP22
Regulations applicable	Electrical Safety IEC 60601-1 Electromagnetic Compatibility IEC 60601-1-2 ATS/ERS Standardisation of spirometry 2005
Conditions of use	Device for continuous use
Storage conditions	Temperature: Min -40°C, Max +70°C Humidity: Min 10% RH; Max 95% RH
Transport conditions	Temperature: Min -40°C, Max +70°C Humidity: Min 10% RH; Max 95% RH
Operating conditions	Temperature: Min +5°C, Max +40°C Humidity: Min 10% RH; Max 95% RH

## Labels and Symbols



Legal Manufacturer: This product is manufactured by MIR—Medical International Research s.r.l., Via del Maggiolino 125, Rome, 00155, Italy.



Date of Manufacture.

### Model

SMART ONE.



This product is certified Class IIa medical device and complies with the requirements of Directive 93/42/EEC, amended by 2007/47/EEC.



In accordance with IEC 60601-1 the product and its applied parts type BF and thus protected against the risks of electrical leakage.



The symbol in accordance with IEC EN 60601-1-2: 2007 in section 5.1.1 for products including RF transmitter.

### FCC

FCC Identification number TUKMIR061.

### IP22

Indicates the degree of resistance to liquids.



This symbol is required by European directive 2002/96/EC 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. Due to the construction materials used for this device, disposal as normal waste could cause harm to the environment and/or health.



Read Instructions before use. <https://www.activ8lives.com/support/manuals>

## Warranty

**Activ8lives** (Aseptika Limited) guarantees this product for one (1) year after the date of purchase. The guarantee does not cover the battery, packaging and damages of any kind due to misuse, such as: dropping or physical misuse caused by the user or water damage outside of the stipulated usage. Claimed products will be replaced when returned marked as **DAMAGED** together with the original proof-of-purchase. For any general enquiries or technical questions concerning the product or questions about the warranty, please contact **Activ8lives** — details are on the back of this User Manual.



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ASL TF-011 MAN/IFU03 SmartOne (V5.0)

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