



INHALER DOSE COUNTER



Package Contents



After removing the device from its packaging, check that there is no visible damage. If there is any visible damage, do not use the device and return it immediately for replacement.

Check if the box contains all the items listed below:

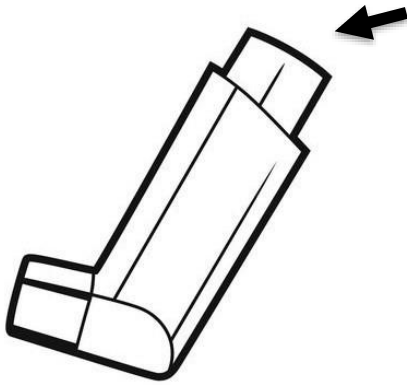
Smart Rescue device	QR code insert for eIFU website (Electronic user manual)
 A white, cylindrical inhaler dose counter with a grey top section featuring a circular array of small holes.	 A vertical grey insert with the text "Where can I find the User Manual?" at the top, a silhouette of a head with a question mark in the center, a QR code at the bottom, and the text "SCAN ME FOR EIFU" and the URL "https://smartasthma.com/sr/ifu" at the very bottom.

User Manual


Version ENGV02. Last updated December 2022


IMPORTANT INFORMATION CONCERNING INTENDED USE


The SMART RESCUE inhaler dose counter is an electronic device intended to record the number and times when its button was pressed. It is a small cap that fits over the canister of SABA inhalers, e.g. Ventolin inhaler to monitor SABA puffs taken.



SMART RESCUE is a button cell powered electronic device for home use that helps asthma patients to monitor their use of SABA inhalers more easily. Due to its design, the device fits on the top container of the inhaler and records the number of presses, meaning how many puffs the user has taken from the inhaler. The device is able to log the presses as long as they are at least 3 seconds apart. According to the correct inhaler use method, at least 10 seconds must pass between two correctly executed inhalations. The recorded presses can be read with the Smart Rescue mobile app through NFC.

CAUTION _____
 The device counts the presses if at least 3 seconds have passed between them.

CAUTION _____
 When SMART RESCUE is used to monitor the inhaler use you should be under the care of a physician or other licensed healthcare professional.

CAUTION _____
 Before using your SMART RESCUE device make sure you have read and clearly understood the contents of this User Manual. The User Manual can be found online on the website accessible from the QR code insert or from the mobile app.

HOW TO INSTALL THE SMART RESCUE MOBILE APP

Before using your SMART RESCUE device install the **SMART RESCUE Inhaler Counter mobile application** by Smart Respiratory, which you can download from the App Store (for Apple devices) and from Play Store (for Android devices).



If you are using an Android phone, turn on the NFC then simply touch the SMART RESCUE to the back of your phone and hold it there for at least 3 seconds. You will see a pop-up message from where you can open up the website and download the app. The NFC is usually near the camera, but you might need to experiment to find the best spot.

CAUTION



You can only download and install the app if your mobile phone has NFC capabilities. To be able to read the SMART RESCUE device you need an NFC capable phone since it communicates through Near-field communication.

CAUTION



The app is compatible with every smartphone with iOS 12 / Android 5.0 OS or above.

HOW TO SET UP YOUR SMART RESCUE DEVICE

Before first use you need to remove the battery pull-tab sticking out from the tiny hole located on the bottom of the device. Grab the end of the tab firmly and start pull it out slowly, making sure it is not twisted.

CAUTION



After the battery pull tab is removed make sure it has not torn apart and remained intact.

The torn part of the pull tab may prevent the device from functioning.

After the pull tab is removed the device is ready for use and can be put onto the canister of your SABA inhaler. You need to attach the Smart Rescue firmly onto the inhaler so the rubber sleeve surrounds the canister. The teal blue rubber sleeve of the device keeps it in a tight fit on the inhaler's canister, preventing it from falling.

The Smart Rescue device may fall off the inhaler when placed in a bag, pocket or other places where it is subject to physical impact, so make sure to store and transfer it properly when it is on the inhaler.

HOW TO USE YOUR SMART RESCUE DEVICE WITH THE SMART RESCUE APP

1. Put the Smart Rescue on the inhaler you would like to track
2. Turn on the NFC of your mobile phone
3. Launch the SMART RESCUE app and follow the instructions
4. When asked in the app touch the device to the back of the phone where the NFC reader is placed. It is usually located near the camera. (You might need to touch it a few times for the first time.)

To be read successfully, the Smart Rescue must be held still for at least 3 seconds in close proximity the phone's NFC reader.

5. The circular chart appears on the screen with the name you entered for your inhaler. The countdown starts from 200 puffs when you start using a new inhaler.

6. Every time you touch the Smart Rescue to your phone the remaining puffs displayed on the chart will be reduced by the number of recorded presses since the last synchronisation.

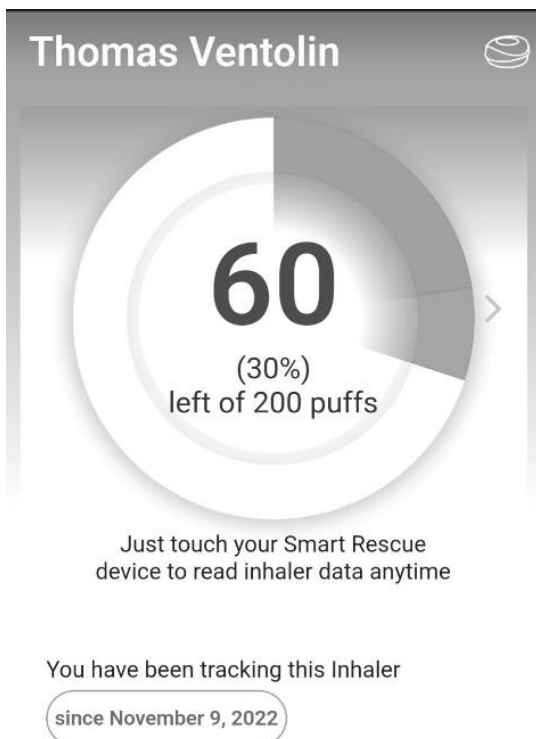
CAUTION



You might need to experiment to find out where the NFC is located in your phone.



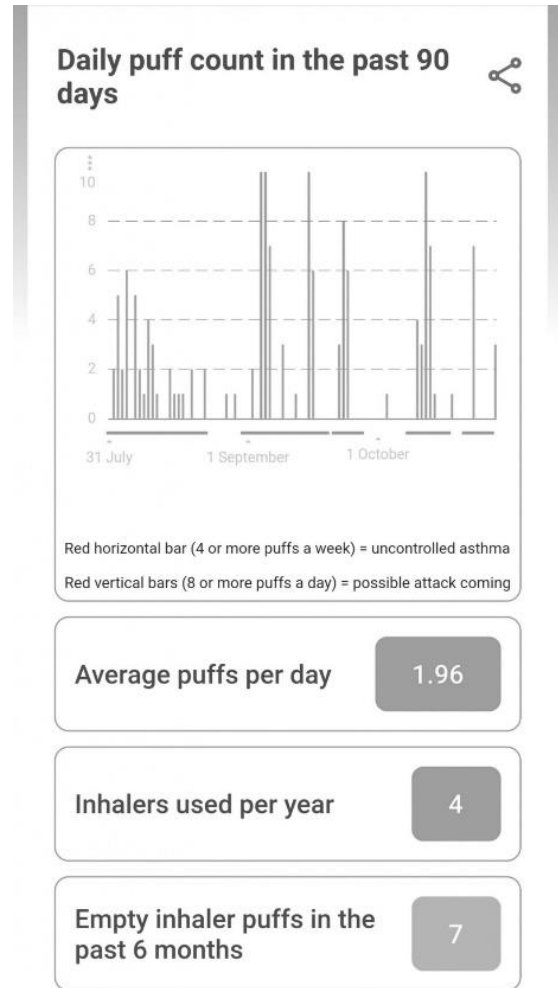
It is recommended to read the Smart Rescue device regularly to avoid exceeding the 200 puffs.



This way you can easily track your inhaler use and the number of doses left in your inhaler. By collecting this information about the tendency of your inhaler use, you or your doctor might be able to identify triggers or changes in your asthma state. When your inhaler runs out of medication you can transfer the Smart Rescue onto the next inhaler and start the counting from 200 again. The Smart Rescue automatically detects when it gets transferred onto

another inhaler and will ask about it in the app.

You can also track your inhaler use in a daily breakdown on the 90 days' chart



Red results indicate you may be overrelying on your reliever inhaler. We suggest you share this information with your doctor or asthma nurse.

THE FUNCTIONS OF THE SMART RESCUE

The device records (1) the timestamps of button presses caused by inhaler actuation and (2) the removal of the device from the inhaler. These are communicated to the smartphone via NFC (the same touch mechanism used for contactless payment).

The records allow the app to

- Calculate how many puffs are left in the inhaler. While the US mandated salbutamol inhalers to have built-in counters, in most other countries patients are in the dark as to how many puffs they have.

- Show a 90-day chart of rescue inhaler puffs per day.

- Give the users warnings on SABA overuse and inhaler depletion.

- Detect when the device has been moved to a new inhaler and start counting down from 200.

The Smart Rescue device can store up to 365 presses but it is recommended to read it with the phone regularly to be able to track the daily inhaler use and to avoid exceeding the 200 puffs.

There is a light sensor at the bottom of the device, with its help the Smart Rescue knows if the bottom part was exposed to light, so can detect when it has been removed from an inhaler and possibly transferred to another one. The app will ask you if you have started to use a new inhaler in which case the countdown start from 200 puffs again.

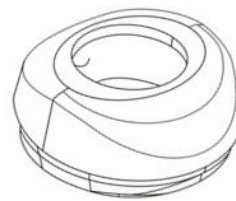
To filter out accidental button presses, the device does not record presses when it is not on the inhaler so the light sensor (located on the bottom side) is open to light.

CAUTION

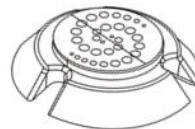


The Smart Rescue only records presses when the light sensor does not detect light so the device is probably on the inhaler.

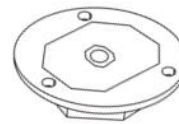
CHANGING THE BATTERY AND PARTS OF THE DEVICE



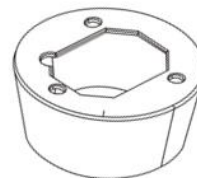
Housing



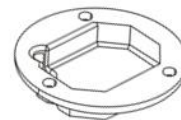
Button



PCB panel



Rubber sleeve



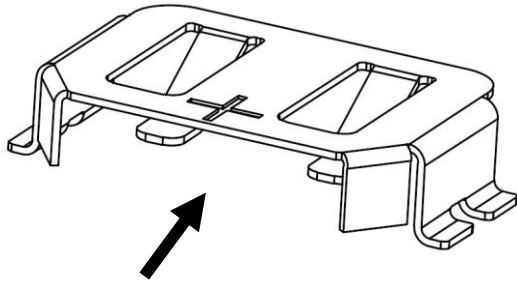
Bottom plate

The included CR1225 battery cell has a lifetime of 2 years. In any case if the battery runs out of power the battery can be changed the following way:

Turn the device upside down so the rubber sleeve is facing upwards. Now you can see 3 small screws in a triangle shape. The fourth hole belongs to the light sensor.

Use a Phillips-head #0 screwdriver to unscrew the 3 small screws from the bottom plate. Now the device can be disassembled, and the PCB panel revealed with the battery in it.

You can push the battery cell out with a screwdriver from its housing in the right direction where the metal battery holder is widely open.



Insert the new battery in the same place, with its positive side facing upwards. Make sure the battery is placed firmly in the socket before start to assemble.

First, you need to put the PCB panel in the housing. Make sure that the panel is oriented in the right direction, meaning that (1) the battery is on the upper side and (2) the 3 holes in the panel overlap with those in the housing.

Then put the 3 small screws into the 3 holes of the bottom plate (if you removed the screws) and move it above the panel placed in the housing in a way that the larger hole, cut for the light sensor, falls exactly above the larger hole in the panel. This way the 3 small screws which are sticking out from the bottom plate will fall exactly into the 3 holes of the panel.

As a last step, you need to slowly and gradually screw in the 3 small screws. The button press should feel the same as before.

CAUTION



If you have problems regarding changing the battery let us know and we will help you.

CLEANING THE DEVICE

The surface of the Smart Rescue can be cleaned from the outside with a slightly damp cloth. Make sure that no moisture gets inside the device's electric part.

WARNINGS AND PRECAUTIONS



Please read all information in this User Manual before using this device and make sure you have read and clearly understood the contents of the User Manual.



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



Do not drop the device or treat it roughly in any way. Avoid strong vibration. Do not expose the device to extreme temperature or light conditions, 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.




Do not modify the device without authorisation from the manufacturer. Apart from the described process for replacing the battery all modifications, adjustments, repairs, reconfigurations must be performed by the manufacturer or by authorised 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, smartphones, etc.) this device may be susceptible to electromagnetic interference from other equipment. Such electromagnetic interference could cause the SMART RESCUE to malfunction and create a potentially unsafe situation.

The SMART RESCUE complies with DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.


ERROR MESSAGES







Error message	Cause of error	Action to take
 <p><i>NFC read error. Try again.</i></p>	<p>The device was probably not held at least for 3 seconds to the phone's NFC reader. The NFC reading process could not be completed.</p>	<p>Find the best spot where your NFC reader is built in your phone. Try to hold the device still and at least for 3 seconds or until the result is shown on the screen.</p>

 <p><i>No supported application for this NFC tag</i></p>	<p>The app is able to read the Smart Rescue device only. If you try to read other NFC devices (e.g. bank cards) you will get this error message</p>	<p>You should only read the Smart Rescue device with the app. If you get this error message when reading the Smart Rescue please contact us.</p>
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LABELS & SYMBOLS



	This product is manufactured by Smart Respiratory Products Ltd. - Imperial I-Hub Level 4, 84 Wood Lane, White City London, England, W12 0BZ
REF	SMART RESCUE
LOT	LOT number
EC REP	Authorised representative in the European community
CE	CE mark: indicates that the device conforms to the appropriate requirements.
UKCA	UKCA mark: indicates that the device conforms to the appropriate requirements in the UK
RoHS	In accordance with Directive 2011/65/EU with the amendments of Directive 2015/863/EU concerning the

	restriction of hazardous materials
	Consult the instructions for use for important cautionary information.
	Keep away from sunlight
	Keep dry – device needs to be protected from moisture
 eIFU	Follow instructions for use: indicates the need for the user to consult the instructions for important information. The IFU is available on our website www.SmartAsthma.com
IP21	The device is protected from touch by fingers and objects greater than 12 mm. Protected from condensation
	In accordance with Directive 2014/53/EU concerning Radio Equipment
	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. Due to the construction materials used for the device, disposal as

	normal waste could cause harm to the environment and/or health.
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TECHNICAL SPECIFICATIONS

Type	Description
Communication interface	Near Field Communication
Communication distance:	approx. 1-2 cm, depends on the reader
Working radio frequency:	13.56 MHz
Power supply	max. 5V DC (<80mA) CR1225 Lithium-ion battery
Dimensions	99 x 87 mm (diameter x height)
Weight	10 g
IP protection level	IP21
Operating conditions	Temperature: Min 0° C, Max 50° C Humidity: Min 10% RH; Max 95% RH
Storage conditions	Temperature: Min 0° C, Max 50° C

	Humidity: Min 10% RH; Max 95% RH
Transport conditions	Temperature: Min -10° C, Max 50° C Humidity: Min 10% RH; Max 95% RH
Life expectancy	2 years

WARRANTY TERMS

The SMART RESCUE 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. This warranty covers the repair or the replacement (at the discretion of the manufacturer) of the product or 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.

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. – Imperial I-Hub Level 4, 84 Wood Lane, White City London, England, W12 0BZ 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 or to the manufacturer:

Smart Respiratory Products Ltd. – Imperial I-Hub Level 4, 84 Wood Lane, White City London, England, W12 0BZ

Tel: +442032872025

Email: info@smartasthma.com

Website: www.smartasthma.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: **Imperial I-Hub Level 4, 84 Wood Lane, White City London, England, W12 0BZ**

EC rep: **Smart Respiratory Manufacturing Kft. - HU, 1113 Budapest, Ibrahim utca 14.**

Product Description: **Smart Rescue inhaler dose counter**

Product Name: **Smart Rescue**

is in conformity with provisions of the applied 2014/53/EU directive concerning Radio Equipment

and the applied Directive 2011/65/EU with the amendments of EU Directive 2015/863 concerning the Restriction of Hazardous Substances.

Harmonised standards applied:

EN 62368-1:2014+A11:2017

EN IEC 62311:2020

ETSI EN 301 489-1 V2.2.3 (2019-11)

ETSI EN 301 489-3 V2.1.1 (2019-03)

ETSI EN 300 330 V2.1.1 (2017-02)

IEC 62321-3-1:2013

IEC 62321-5:2013

IEC 62321-4:2013+AMD1:2017

IEC 62321-7-1:2015

IEC 62321-7-2:2017

IEC 62321-6:2015

IEC 62321-8:2017

UK DECLARATION OF CONFORMITY

Manufacturer: **Smart Respiratory Products Ltd.**

Registered Office: **Imperial I-Hub Level 4, 84 Wood Lane, White City London, England, W12 0BZ**

EC rep: Smart Respiratory Manufacturing Kft. - HU, 1113 Budapest, Ibrahim utca 14.

Product Description: **Smart Rescue inhaler dose counter**

Product Name: **Smart Rescue**

is in conformity with provisions of the applied Radio Equipment Regulations 2017 (S.I. 2017/1206)

and the applied Restriction of the Use of
Certain Hazardous Substances in Electrical
and Electronic Equipment Regulations
2012 (S.I. 2012/3032)

Harmonised standards applied:

BS EN IEC 62311:2020

BS EN 301 489-1 V1.9.2;

BS EN 300 330 V2.1.1;

BS EN 62368-1:2014+A11:2017;

IEC 62321-3-1:2013

IEC 62321-5:2013

IEC 62321-4:2013+AMD1:2017

IEC 62321-7-1:2015

IEC 62321-7-2:2017

IEC 62321-6:2015

IEC 62321-8:2017

Name of the testing laboratory:

**Shenzhen Anbotek Compliance
Laboratory Limited**

1/F, Building D, Sogood Science And
Technology Park, Sanwei Community,
Hangcheng Street, Bao'an District,
Shenzhen, Guangdong, China.518128

