

# Smart One for measuring lung function

Medtech innovation briefing  
Published: 9 February 2017

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## Summary

- The **technology** described in this briefing is Smart One. It is a portable spirometer used for measuring lung function.
- The **innovative aspects** are that the device transmits measurements wirelessly to a smartphone (or tablet). This records results in a diary app which can be shared electronically with a healthcare professional.
- The intended **place in therapy** would be as a self-monitoring device for use at home in addition to usual care. It is for people who would benefit from home assessment of lung function, such as those with asthma, cystic fibrosis or chronic obstructive pulmonary disease.
- **Nopublished evidence** was found on Smart One. Three studies (n=496 people in total) involved similar devices from the same manufacturer, Spirotel and Spirobank, which use the same turbine as Smart One. The studies showed good reproducibility between Spirotel and a pneumotachograph and laboratory spirometer, and that Spirobank had comparable precision to other office portable spirometers.

- **Key uncertainties** around the technology are that there is no published evidence on its safety or effectiveness. The frequency of recommended use does not match guideline recommendations for spirometry, and using Smart One would not avoid the need for annual testing by a healthcare professional. More frequent spirometer measurements can worsen lung function for some conditions such as cystic fibrosis.
- The **cost** of Smart One is £99.95 per unit (exclusive of VAT). The **resource impact** overall compared with standard care (spirometry) cannot be evaluated because of the lack of evidence.

## The technology

Smart One (Medical International Research) is a spirometer that connects to a Bluetooth-enabled smartphone or tablet to monitor peak expiratory flow (PEF) and forced expiratory volume in 1 second (FEV1). PEF is the maximum speed of air as someone exhales as hard as possible after filling their lungs completely. FEV1 is the volume of air expelled during the first second of the same exhalation. Smart One connects to the smartphone or tablet through a Smart One app.

The technology includes the handheld Smart One device, the turbine sensor which is inserted into a round slot on Smart One, and a reusable plastic mouthpiece, both of which can be removed for cleaning. The mouthpiece must be disinfected after every use, and the turbine should be checked after each use and cleaned if it contains any dust or foreign bodies.

The Smart One app (available for any mobile operating system) includes an electronic diary for recording results and a message displayed on the screen to help improve test performance (for example, 'blow out fast'). When first opened, the app requests the user's date of birth, 'population origin' (ethnicity), weight, height and sex to calculate baseline PEF and FEV1 values, based on large epidemiological studies. If any of these personal details are not entered, the app issues a warning message.

To use Smart One, the user exhales into the mouthpiece. The turbine sensor measures exhalation in real time and transfers the results to the Smart One app. The app compares the measurements with the baseline PEF and FEV1 values, and displays numerical values as well as a 'traffic light' health indicator (green, yellow or red) to signify if the measurement is above or below the baseline. Alternatively, the app can store the user's 'personal best' value (based on the highest of 3 exhalations) and use it to calculate the

traffic light health indicator.

The device is intended for use by 1 person only. If the organisation issuing the device transfers it to another user, the mouthpiece and turbine must be disinfected and the previous user's data must be erased from the memory. The new user must then input their baseline data into the app.

Unless the user chooses to send measurements to a healthcare professional (see below), measurements and user data are stored only on the smartphone. The manufacturer warns users that potential threats to data collected by the app include malware installation, interception of communications, or theft of the smartphone. These could affect the integrity or confidentiality of personal data. The manufacturer recommends reducing the risk to personal data on a smartphone by using antivirus software, using a password, and backing up data periodically.

## The innovation

Smart One could enable people who need spirometry to record their PEF and FEV1 values in their own homes, allowing them to take these measurements when most needed (such as during an exacerbation of their symptoms). The app also allows the user to create and attach a PDF file to a standard email and send to their healthcare professional. The user can choose the time interval (from 1 day to 1 year) to be exported into the PDF.

## Current NHS pathway

Spirometry is a test used to help diagnose and monitor lung conditions by measuring how much air a person can breathe out in 1 forced breath. For people who have already been diagnosed with a respiratory condition, spirometry may be done to check the severity of the condition or to monitor treatment response. Each spirometry measurement is repeated at least 3 times to get a reliable result, and the maximum reading is recorded ([NHS Choices](#)).

Recommendations for spirometry in people with respiratory conditions vary depending on their diagnoses. The NICE guideline on [chronic obstructive pulmonary disease in over 16s](#) states that spirometry should be done at diagnosis, and repeated to consider a second diagnosis if a person shows an exceptional response to treatment. FEV1 and forced vital capacity should be measured at least once a year in people with chronic obstructive

pulmonary disease. The guideline also states that PEF or FEV1 should not be done daily to monitor recovery from an exacerbation, because the size of changes is small compared with the variability of the measurement.

For people with asthma, the [British guideline on the management of asthma](#) states that spirometry should be quality assured and done by people with adequate training. The guideline recommends lung function assessment by spirometry or PEF to monitor adults in primary care, and PEF aids in determining asthma severity. It also states that PEF is best used to provide an estimate of variability of airflow from multiple measurements made over at least 2 weeks. Increased variability may be evident from readings twice daily and serial peak flow records may demonstrate variability in symptomatic patients, but should be interpreted with caution and with regard to the clinical context. Measuring lung function in children under 5 years is difficult so spirometry is not recommended in this population.

The guideline recommends that self-management be included in each patient's personalised asthma action plan. Self-management action plans contain information on when and how to modify treatment in response to asthma symptoms and PEF measurements. Symptom-based plans are generally preferable for children. The guideline states that the evidence of the clinical benefits of telemonitoring of asthma is mixed but is at least as good as traditionally delivered care, and states that telehealthcare may be considered as an option for supporting self-management of asthma.

The [Standards for the Clinical Care of Children and Adults with Cystic Fibrosis in the UK](#) recommend regular monitoring of lung function with spirometry in children aged 5 to 6 years, and oxygen saturation measurements with pulse oximetry at every clinic visit for outpatients. The timing of clinic visits varies based on a person's needs, but routine appointments for a stable patient should be every 2 to months. Spirometry is recommended twice weekly for inpatients.

Smart One would be used in the current clinical pathway for people needing spirometry measurements as part of their self-management plan. It would not be used to diagnose chronic obstructive pulmonary disease.

NICE is aware of 6 similar portable spirometer devices in development for use with smartphones.

## Population, setting and intended user

Smart One is intended for use as a self-monitoring tool by people with respiratory conditions. It could be used in any setting, including in the home, to measure PEF and FEV1.

## Costs

### Device costs

Smart One costs £99.95, excluding VAT. The manufacturer instructions recommend that it be used twice a day. Smart One and the mouthpiece are expected to have a lifespan of 10 years. Assuming that Smart One is purchased by the NHS and used continuously throughout the year, using a standard annuity calculation with a 3.5% discount rate, the cost per measurement would be £0.02. The manufacturer also provides an example of how quantity discounts may affect price: if 500 units are purchased together, they will cost £49.95 each (£0.01 per measurement). A suitable smartphone or tablet is needed to use Smart One.

### Costs of standard care

Standard care is spirometry. Spirometers range in cost from approximately £300 to £3,000 depending on the complexity of the device ([Barema, the Association for Anaesthetic and Respiratory Device Suppliers 2016](#), [British Thoracic Society 2005](#)). A UK cost-effectiveness analysis of treatments for chronic obstructive pulmonary disease ([Hertel et al. 2012](#)) provides a more comprehensive unit cost for an outpatient procedure of £49.98.

## Resource consequences

The manufacturer stated that Smart One is new and currently used in very few NHS trusts. However, a small number of trusts use similar spirometers from the same manufacturer.

No practical difficulties have been identified in using or adopting the device component of Smart One, and no special training is needed. Batteries and other consumables need to be replaced and it is unclear whether the NHS would be responsible for these costs.

No published evidence on the resource consequences of adopting Smart One was found. A trial-based UK economic evaluation ([Ryan et al. 2012](#)) compared conventional paper-based monitoring with a phone app for recording and transmitting peak flow readings and triggering automatic contact by a nurse. This evaluation was not directly related to Smart One, but it found no statistically significant difference in asthma control between groups and a slight increase in costs associated with this kind of app-based monitoring. The cost increase was because of the expense of the app in addition to usual health service costs, but the authors noted that this difference may decrease in clinical practice where economies of scale could reduce the cost per patient.

## Regulatory information

Smart One was CE marked as a class IIa medical device in May 2015.

A search of the Medicines and Healthcare Products Regulatory Agency website revealed that no manufacturer Field Safety Notices or Medical Device Alerts have been issued for this technology.

## Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

People with chronic respiratory conditions may be considered to have a disability if these conditions have a substantial and long-term adverse effect on their ability to carry out normal day-to-day activities. Disability is a protected characteristic defined in the Equality Act.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

### Published evidence

No publicly available evidence was found on the use of Smart One.

Instead, this briefing summarises 3 studies that used similar devices from the same manufacturer, including 496 patients. Two of the studies used Spirotel (a portable touchscreen spirometer and oximeter tool for home care and telemedicine; [Ezzahir et al. 2005](#), [Fonseca et al. 2005](#)) and 1 used Spirobank (a portable spirometer and oximeter with an option to connect with an iPad, intended for clinicians; [Liistro et al. 2006](#)). According to the manufacturer, the turbine in Smart One used to measure forced expiratory volume in 1 second (FEV1) and peak expiratory flow (PEF) is the same as that in all its spirometers.

Table 1 summarises the clinical evidence for these 2 spirometers as well as its strengths and limitations.

### Overall assessment of the evidence

The current evidence shows that the turbine technology used in the manufacturer's spirometers has good reproducibility for measuring PEF and FEV1 ([Ezzahir et al. 2005](#), [Fonseca et al. 2005](#), [Liistro et al. 2006](#)). However, there is conflicting evidence about the limits of agreement for FEV1 reported in 1 study ([Liistro et al. 2006](#)), showing that this was not acceptable based on the short-term coefficient of variability values.

As with Smart One, there is no published evidence on the effectiveness of any of these devices. App technology is a rapidly evolving area and the amount of evidence for medical device apps varies, although there is some evidence on smartphone self-management apps for asthma ([Marcano et al. 2013](#)).

Useful evidence in this area would include data on the usability of the app and device,

clinical outcomes (for example, if the device reduces emergency department or GP visits), how the app affects behaviour, and long-term cost savings.

**Table 1 Summary of evidence**

<u>Ezzahir et al. (2005)</u>	
Study size, design and location	59 children at their routine lung function tests at a hospital (with asthma, chronic cough, or sickle-cell disease), prospective comparative study, France.
Intervention and comparator(s)	Spirotel compared with a laboratory spirometer (Jeager PFT).
Key outcomes	At least 2 acceptable and intra-device reproducible curves were obtained in 88% of the laboratory and 76% of the portable spirometers. Forced expiratory flow between 25% and 75% of forced vital capacity (FVC), and forced expiratory flow at 75% of FVC were similar between spirometers, both at baseline and post-administration of a bronchodilator.
Strengths and limitations	The 2 spirometers were tested in a random order at baseline and in reverse order post-bronchodilator. The study did not evaluate the recording and transmitting functions of Spirotel. No sample size calculation was reported and thus it is unclear if the sample size was adequate to assess outcomes.
<u>Fonseca et al. (2005)</u>	
Study size, design and location	38 adults with asthma used each device and the reference instrument, randomised agreement study, Portugal.
Intervention and comparator(s)	Electronic monitoring devices: Spirotel, PiKo-1, and Mini-Wright peak-flow meter. Reference: Vitalograph (pneumotachograph).
Key outcomes	Good intra-device reproducibility and agreement between the pneumotachograph and both electronic monitoring devices.

Strengths and limitations	<p>The study included spirometers with an established flow measurement (pneumotachograph) as the reference instrument. The order in which devices were used was randomised.</p> <p>The study did not fully evaluate the measurement capabilities of Spirotel (forced expiratory flow, for example) and did not evaluate the recording and transmitting functions of the devices. There was no sample size calculation reported and thus it is unclear whether the sample size was adequate to assess outcomes.</p>
<u>Liistro et al. (2006)</u>	
Study size, design and location	399 people (300 with chronic obstructive pulmonary disease, 9 expert technicians and 90 healthy patients), multicentre comparative study at 3 hospitals, Belgium.
Intervention and comparator(s)	<p>Office spirometers: Spirobank, DatoSpir 120, DatoSpir 70, EasyOne, Microloop, OneFlow, Pneumotrac, Simplicity, SpiroPro, SpiroStar.</p> <p>Standard spirometers: Vmax 20C and Morgan TLC.</p>
Key outcomes	User-friendliness of the devices was good overall. Precision of forced expiratory volume in 1 second (FEV1) was comparable between the standard and the 10 office spirometers in most of the devices. There was no significant difference between centres in absolute values and intra-device reproducibility. The Spirobank limits of precision were acceptable, however the limits of agreement for FVC and FEV1 were not acceptable based on the short-term coefficient of variability values.
Strengths and limitations	<p>Tests were done in a random order to avoid a learning effect. People with various degrees of chronic obstructive pulmonary disease were included.</p> <p>The study assessed office spirometers only, not portable spirometers for home use. Usability was based on a questionnaire to 3 general practitioners.</p>

## Recent and ongoing studies

According to the manufacturer, studies comparing Smart One with other means of self-monitoring PEF and FEV1 in the community are in progress, but no publicly available

data are available.

## Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and from 2 relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

None of the 3 specialist commentators had used the technology.

## Level of innovation

The specialist commentators considered Smart One to be a minor innovation to existing spirometry technology. Although its ability to record measurements on a smartphone through Bluetooth is novel, there are other similar devices in development.

Spirometry is usually done by a healthcare professional and requires special training. One specialist felt that spirometry should only be done by healthcare professionals. Another specialist noted that people can use peak flow meters with little training but forced expiratory volume in 1 second (FEV1) is a more difficult measurement to take and some patients find it extremely difficult.

## Potential patient impact

Smart One may improve self-monitoring and engage people who dislike manual recording of peak flows, but it is not clear whether the device would improve outcomes. The long-term adherence, psychological benefits (for example, feeling reassured) and potential adverse effects are all unclear. The benefits of using Smart One may vary based on the patient population; for example, people with chronic obstructive pulmonary disease might have only minor benefits whereas those with cystic fibrosis or lung transplants have the potential for greater benefits. Peak expiratory flow (PEF) monitoring may be useful in patients with asthma, because there is good evidence for home monitoring and improved health outcomes in these people. All these uncertainties require a prospective, controlled investigation in differing patient populations.

The device may be useful in a clinic facility to monitor and save the results of FEV1 and PEF in patient records, but this is outside the manufacturer's recommendations for use.

Training and familiarity with smartphone apps may be a barrier for some patients, but all commentators felt that the main barrier for using Smart One at a community level would be the ability of patients to carry out the spirometry measurements. There are likely to be a small number of highly trained patients who can do spirometry independently, such as people with cystic fibrosis. However, 1 commentator highlighted that it might be especially difficult for many groups of people with chronic obstructive pulmonary disease.

## Potential system impact

Similar to the potential impact on patients, the potential system impact is unclear because of the lack of evidence. Using Smart One could lead to an increased need for healthcare professionals to download and review recordings, involving increased nurse or GP time. Nurses and GPs would need to be trained in its use and additional time would be needed to train patients.

Smart One may improve self-management in a select group of patients and therefore reduce healthcare resource use (such as emergency department attendances), but there is no evidence for this. One specialist stated that it would not lead to cost savings, because most patients do not use their inhalers as prescribed and so would be unlikely to test lung function twice daily. The cost per device is also greater than a Wright peak flow meter, which is generally recommended for home monitoring. Smart One is less costly than existing spirometers, but its functionality is more comparable to a device that monitors FEV1 alone, which is far less costly.

## General comments

One specialist commentator stated that peak flow rates and spirometry require different techniques and it may be time consuming, and potentially confusing, for patients. The specialist stated that it is important for the user to have visual feedback as to whether the correct technique is being done.

Peak flow rate is often used to monitor asthma and to support an asthma action plan (which is also based on symptoms). There are no data as to whether regular spirometry leads to better outcomes. In addition, self-management plans for chronic obstructive pulmonary disease are symptom-based and not reliant on spirometry values. One specialist stated that it is unclear how FEV1 thresholds could be individualised using an algorithm for all patients, because there are no FEV1 thresholds in clinical use as there are

for PEF.

New innovations developed with patients are important to encourage self-management, and the use of an electronic device to record peak flow rates will have a role in monitoring asthma control. The role of regular FEV1 measurement is far less clear, more difficult to implement because of the difficulties with technique, and not as clinically useful.

Another specialist agreed that FEV1 measurements may be difficult for patients compared with PEF, but that FEV1 is a more sensitive and robust measure of airflow obstruction. They explained that similar applications have had the potential to benefit patients in the past, but they have not yet been adopted because of multiple technical issues, even in highly selected patient groups. Generally, personalised asthma management plans are rarely adequate in practice. Non-adherence is a large problem for people managing asthma and introducing Smart One will not necessarily improve self-management.

PEF and FEV1 using this device are recorded from the same exhalation. However, the specialist stated that the gold-standard PEF (by meter or gauge) is recorded from a very rapid exhalation (different from the FEV1 manoeuvre) and this is just one way in which the PEF by meter or gauge is likely to numerically differ from that recorded by this device.

More data are needed to validate and justify Smart One's clinical use, preferably from large-scale controlled trials as well as well-documented real-world experiences from patients with relevant conditions.

## Patient organisation comments

The Cystic Fibrosis Trust and Asthma UK provided their comments on Smart One.

## Patient benefits

Representatives from the Cystic Fibrosis Trust and Asthma UK each provided comments on Smart One, which are summarised below.

Smart One could be a useful additional tool for people with cystic fibrosis. It uses the same technique as spirometry, which many people with cystic fibrosis are familiar with after years of practice in a clinical environment.

Smart One could help reduce the number of trips needed to the nearest cystic fibrosis specialist centre, which can be a significant distance. Remote monitoring also allows patients to avoid entering an environment where they are exposed to additional bacteria

Asthma UK stated that peak flow tests are a useful monitoring tool for asthma and many people with asthma are familiar with peak flow meters. Smart One could enable easier peak flow monitoring for people with asthma, allowing them to better recognise and treat worsening asthma to avoid an attack. The device may also improve patients' experience of yearly asthma reviews by more easily providing a record of their asthma control over the year.

Asthma UK said that Smart One is a significant change in terms of linking peak flow to a smartphone and enabling data to be viewable across time. It noted that Smart One can import data from Apple Health (on iOS systems), and so may provide data to GP systems.

At an Asthma UK panel meeting, 8 UK volunteers with asthma evaluated the potential usefulness of and barriers to Smart One. The group found that the device was easily transportable and allowed for easy monitoring. Half of the group found the device and app to be clear and intuitive. They found it helpful being able to record symptoms in the app as well as having a visual trend of their lung function measurements in the form of a graph. The group felt that younger people would be more likely to use a tool connected to their smartphone, but that all patients would be able to use it.

## System benefits

Smart One may reduce unnecessary appointments in busy clinics by enabling patients to take their measurements at home and email the data to their specialist team. Emailing data to a healthcare team may make clinic visits easier and allow for earlier, preventative intervention.

Asthma UK considered that there is strong evidence that self-management support reduces hospital admissions and emergency department visits, as well as increasing the quality of life for people with asthma. Closer monitoring of peak flow data could allow more accurate management and self-management of asthma, escalating treatment sooner if lung function worsens and avoiding treatment if lung function is stable.

## Barriers to use

The Cystic Fibrosis Trust noted that the device excludes anyone without a smartphone, which may prevent equity of access. It also noted that it is important for cystic fibrosis teams to assist users in correctly interpreting results to reduce unnecessary anxiety, which may limit the usefulness of Smart One. Additional guidance would be needed for patients to learn how to use the app and who to contact in case issues arise.

Overusing the device could have adverse effects on the lungs, potentially causing soreness, coughing or haemoptysis. For this reason, using the device twice daily in people with cystic fibrosis would have negative effects without clinical benefit. The Trust also pointed out that Smart One should not be used by more than 1 person with cystic fibrosis because of the risk of cross infection.

Asthma UK noted that some of the functions of the Smart One app may not be tailored to people with severe asthma, in whom symptoms do not get better, even when usual medicines are taken regularly and correctly. People with severe asthma may have red readings on the traffic light indicator in the app, despite their readings being potentially normal for a person with severe asthma.

## Considerations for adoption

Smart One should not be used as a replacement for hospital visits and overdependence may be a problem. Cystic fibrosis teams base their decisions on more than 1 set of results and patients must be seen and assessed by their multi-disciplinary team on a regular basis.

Similar to people with cystic fibrosis, people with asthma may become overly dependent on the peak flow reading despite having worsening symptoms. It should be made clear to users that the device is a tool to help self-management, rather than replace symptom-based self-assessments.

Healthcare providers should offer initial peak flow training to ensure that Smart One is being used correctly.

## Specialist commentators

The following clinicians contributed to this briefing:

- Dr Maxine Hardinge, consultant in respiratory medicine, Oxford University Hospitals, no conflicts of interest declared.
- Dr Philip Ind, respiratory consultant, Imperial College London, conflicts of interest include: receiving occasional lecture fees, occasional participation in commissioned questionnaires, and editing a commercially funded publication. Dr Ind also sits on the Cardiology Diabetes Renal Respiratory Allergy Expert Advisory Group to the Medicines and Healthcare Products Regulatory Agency.
- Professor Raja Rajakulasingam, consultant respiratory physician, Homerton University Hospital, no conflicts of interest declared.

Representatives from the following patient organisations contributed to this briefing:

- Asthma UK.
- Cystic Fibrosis Trust.

## Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-2326-7