NICE advice

Smart Peak Flow for monitoring asthma

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Smart Peak Flow. It is a digital peak flow meter and asthma tracking tool designed for monitoring asthma.
- The **innovative aspects** are the automatic recording and charting of peak expiratory flow values in the Smart Asthma app, and calculating colour coded peak flow zones that indicate a person's asthma control.
- The intended **place in therapy** would be as an alternative to mechanical peak flow meters.
- The **main points from the evidence** summarised in this briefing are from 5 studies including 2 comparative studies, 2 observational studies, and 1 bench test study including a total of 1,181 people. They show that Smart Peak Flow passed bench tests of accuracy. Also, more people may use Smart Peak Flow compared with mechanical peak flow meters.

- **Key uncertainties** around the evidence or technology are that the evidence is limited and lacks detail. There were no studies evaluating the effect of the device on clinical or patient-reported outcomes, clinical decision making, or user satisfaction.
- **Experts advised** that Smart Peak Flow could replace mechanical peak flow meters. But evidence is needed on its validation against the current gold standard in peak flow meters, asthma-related outcomes, use and adherence, and the effect on clinical decision making and resource use.
- The **cost** of Smart Peak Flow is £9.87 per device (excluding VAT). The optional Bluetooth adapter costs £6 (excluding VAT) and the Smart Asthma app is free. Mechanical peak flow meters cost between £4.25 and £9.50 per device based on the NHS November 2021 Drug Tariff.

The technology

Smart Peak Flow (Smart Respiratory Products) is a digital peak flow meter and asthma tracking tool. It is designed for monitoring asthma. Smart Peak Flow measures peak expiratory flow (PEF). This is how fast a person can blow air out of their lungs after a deep breath and is a test of lung function. It measures airway obstruction and can show how well a person is breathing.

The technology includes the Smart Peak Flow meter and the associated Smart Asthma app, which can be downloaded from the Apple and Android app stores. The Smart Peak Flow meter has 2 parts: the peak flow meter turbine and a plastic mouthpiece. It needs a smartphone for use. The device is compatible with all smartphones using an operating system later than Android 5.0 or iOS 10. The mouthpiece is attached to the turbine and the device is plugged into the smartphone by the headphone jack port. A wireless Bluetooth adapter can be used for smartphones without a headphone jack port. Smart Peak Flow should not be connected to the smartphone while its battery is being charged. The device can be used when sitting straight or standing. It should be used in a well-lit area because the Smart Peak Flow meter needs light to go through a small window on top of the turbine to take the PEF reading. The mouthpiece and turbine should be cleaned regularly in line with the Smart Peak Flow user manual to make sure the device is functioning properly.

When first used, the app calculates a person's PEF baseline value from their known personal best PEF value or standardised scores. Future PEF readings are compared with this baseline. A person measures their PEF by taking a deep breath and blowing as hard

and fast as possible into the Smart Peak Flow mouthpiece. The PEF value is then shown in the Smart Asthma app. This process is repeated twice, with the app saving the highest (best) of the 3 values. This is compared with the baseline and colour coded green, yellow, or red based on if breathing appears to be under control or if caution or medical assistance may be needed, respectively. Healthcare professionals' advice is needed to interpret Smart Peak Flow measurements and to determine what action should be taken when PEF values change.

The Smart Asthma app records PEF measurements as well as symptoms and inhaler use. It also automatically charts the recorded measurements. People can use the device at home and share information about their asthma with their healthcare professional by email. This can be used to monitor a person's asthma control and provide care when needed.

Innovations

The company claims that Smart Peak Flow is innovative in its remote monitoring of PEF and inhaler use. It measures PEF with the Smart Peak Flow meter and automatically records and charts this data in the Smart Asthma app. The technology also calculates the colour coded peak flow zones and provides an electronic asthma action plan based on the results.

Current care pathway

People aged 5 years and over who have been diagnosed with asthma are offered an asthma self-management programme. This includes a written personalised action plan and education to help self-manage their asthma. The asthma action plan should clearly outline how and when changes in treatment should happen. Asthma control is monitored at every asthma review using spirometry or peak flow variability testing. Validated questionnaires such as the Asthma Control Questionnaire or Asthma Control Test may be used to monitor asthma control in adults. Loss of asthma control may also be assessed by symptoms, particularly in children.

Peak flow readings play an important part in managing asthma. Because of this, people may be prescribed peak flow meters for self-monitoring at home. PEF should be recorded as the best of 3 readings. This value can then be compared with standardised charts or, more preferably, the person's previous measurements. People may be asked to manually record a diary or chart of PEF readings several times a day for a few weeks. This can be

used to calculate PEF variability and to detect clinical deterioration.

Peak flow readings may help to understand triggers and guide use of reliever medication in line with a person's asthma action plan. If poor asthma control is found, an assessment can be done to understand why before treatment is changed. Support and education may be provided to improve adherence and inhaler use.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on asthma: diagnosis, monitoring and chronic asthma management
- NICE's quality standard on asthma
- NICE's medtech innovation briefing on Smart One for measuring lung function
- SIGN 158 British guideline on the management of asthma

Population, setting and intended user

Smart Peak Flow is designed for people with asthma aged over 5 years. It is an alternative to mechanical peak flow meters. Peak flow meters may be offered to people with asthma in primary or secondary care. People can use Smart Peak Flow at home to monitor their asthma with the support of a healthcare professional. It is generally recommended for use twice a day; in the morning after waking and before going to bed. It should also be used when people are having symptoms of breathing problems. Smart Peak Flow should be used before an inhaler. Initial setup of the device and guidance for use should be provided by a healthcare professional. Adult supervision is needed when used by children and young people, and some disabled people.

Costs

Technology costs

The technology costs £9.87 per device (excluding VAT). The optional Bluetooth adapter costs £6 (excluding VAT) and the Smart Asthma app is free. The Smart Peak Flow device has a 2-year life expectancy.

Costs of standard care

Costs of mechanical peak flow meters range from £4.25 to £9.50 per device. Costs are taken from the NHS November 2021 Drug Tariff. Some mechanical peak flow meters are recommended to be replaced every 3 years.

Resource consequences

Smart Peak Flow is used in the NHS. The company claims that a recent survey of healthcare professionals showed consensus in the accuracy and timeliness of data collected by Smart Peak Flow. It also claims that more people are likely to use Smart Peak Flow as intended compared with traditional paper-based diaries and mechanical peak flow meters.

The company claims Smart Peak Flow had additional resource benefits during the COVID-19 pandemic because healthcare professionals could use the detailed asthma diary in remote consultations. Results of an unpublished patient survey submitted by the company suggested that most users found the device quicker and easier to use and more convenient than paper-based diaries. There was no published evidence of its use in clinical practice.

Regulatory information

Smart Peak Flow is a CE-marked class IIa medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Asthma is a common condition that affects 1 in 11 children and 1 in 12 adults. In children, asthma is more common in boys, but it is more common in women by adulthood. Incidence rates are 36% higher in communities of people who are most under served, compared with those who are least under served.

Smart Peak Flow needs to be used with a smartphone. Over 95% of people under 55 use a

smartphone, with similar use in men and women. Use decreases in people aged 55 to 64 years (77%) and 65 and older (53%). Smart Peak Flow is indicated for people aged over 5 years. Lung function tests may be unreliable in children younger than 5 as well as in people who have a learning disability or coordination difficulties. People with a learning disability or additional accessibility needs may need more support using Smart Peak Flow. Healthcare professional statements submitted by the company stated that some people had difficulties downloading and setting up the Smart Asthma app and adding data. Some people may therefore need additional guidance and support to set up and use the app. Age, sex, and disability are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. 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.

Published evidence

This briefing summarises 5 studies including 1,181 people. The evidence includes 2 comparative studies, 2 observational studies, and 1 bench test study.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

Smart Peak Flow is a tier C digital health technology for active monitoring and self-management based on NICE's evidence standards framework for digital health technologies. The evidence is limited and lacks details of study methods and findings. Two studies included 10 people or fewer. The evidence showed that Smart Peak Flow passed bench tests of accuracy and there may be higher reported numbers of people using Smart Peak Flow compared with mechanical peak flow meters. There were no studies evaluating the effect of the device on clinical or patient-reported outcomes, clinical decision making, or user satisfaction. Further research is therefore needed.

Sakkatos and Williams (2021, brief communication)

Study size, design and location

Cross-sectional comparative study comparing the accuracy of Smart Peak Flow with spirometry in 9 adults who did not have a history of chronic lung conditions or airflow obstruction (mean age 41.9 years, standard deviation [SD] 13.1) in the UK.

Everyone in the study did 3 expiratory tasks using low, medium, and maximal effort. Acceptable limit of agreement (LOA) was set at 40 litres/minute before the start of the study based on a previous validation of peak flow meters.

Intervention and comparator

Smart Peak Flow compared with Piston PDD-301/sh spirometer.

Smart Peak Flow was tested in series connection with the spirometer. This meant that the same exhale passed through both devices at the same time.

Key outcomes

A Bland–Altman plot showed good agreement between Smart Peak Flow and the spirometer across peak expiratory flow (PEF) values ranging from 210 litres/minute to 626.4 litres/minute. The mean difference between the devices was -0.29 litres/minute with LOA ranging from -30.6 litres/minute to 30.0 litres/minute.

Strengths and limitations

This is a peer reviewed brief communication with limited detail in the reporting of results. It was a pilot study on adults who were healthy. The study set the acceptable LOA at 40 litres/minute. This differs from the American Thoracic Society and European Respiratory Society's recommendation that PEF must be measured with an accuracy of 20 litres/minute. The pilot aimed to recruit 25 people but ended early because of COVID-19 restrictions. Because of the small sample size, the authors cautioned that no firm conclusion can be made about the in vivo accuracy of Smart Peak Flow. The company was involved in the research.

Antalffy et al. (2020, brief communication)

Study size, design and location

Observational study on the Smart Peak Flow meter and app in 766 people (mean age 36.7 years, SD 17.3) who bought the device or were supplied it by a healthcare professional in the UK.

Intervention

Smart Peak Flow.

Key outcomes

A total of 766 people had the Smart Peak Flow device. Of these, 500 were offered the device by their healthcare professional during an outpatient appointment, with 133 (27%) of these patients downloading the app and recording at least 1 PEF measurement. Additionally, 266 people bought the device themselves and recorded at least 1 PEF reading. After 3 months, 32% of the 399 people using the device recorded their PEF daily and 63% measured their PEF at least twice a week. After 6 months, 28% of these people recorded their PEF daily, while 67% measured their PEF at least once a week. The authors stated that adherence is higher than traditional PEF monitoring as reported in Garrett et al. (1994), which found that 16% of people measured PEF daily at baseline which dropped to 6% after 9 months.

Strengths and limitations

This is a peer reviewed brief communication that reported real-world data of app use collected by the company. There was no information on peoples' demographics, health conditions, or treatment. The study is also limited in its reporting of results. The authors report adherence as the proportion of people who downloaded and used the app (n=399), rather than the proportion of people who had the device (n=766). This therefore makes it difficult to compare the reported levels of adherence with traditional PEF monitoring in other studies. Further research is therefore needed comparing the use of Smart Peak Flow with traditional PEF monitoring. The authors stated that no research evidence is available on factors related to usability, acceptability, and adherence of the device.

Coelho et al. (2020, abstract)

Study size, design and location

Prospective comparative study evaluating variation in PEF readings in 10 respiratory physiology staff at a university hospital in the UK.

Intervention and comparator

Smart Peak Flow and Mini-Wright peak flow meter.

Everyone recorded PEF with both devices 6 times daily for 5 days, with 3 readings taken per session for each device. The meter used for the first reading alternated between and within each session. The mean within-session coefficient of variant for each person and meter was calculated.

Key outcomes

A total of 336 readings were recorded using Smart Peak Flow and 347 using Mini-Wright. This difference in the number of recordings was because of technical issues with Smart Peak Flow, including the session timing out and not enough ambient light. The mean coefficient of variation for Smart Peak Flow was 15.7 compared with 3.12 for Mini-Wright. The authors suggested several reasons for the higher variation of Smart Peak Flow. These included variation in PEF in some people, environmental factors such as lighting or background noise, and the phone and connection used (headphone jack or adapter).

Strengths and limitations

This was a small evaluation in people who are healthy. Mini-Wright is an appropriate comparator. The study was reported in abstract only and therefore lacked details on study methods and findings. Several factors were proposed to account for the higher variation in readings by Smart Peak Flow, but these were not assessed in this study with further research recommended.

Sakkatos et al. (2020, abstract)

Study size, design and location

Retrospective study exploring the use of Smart Peak Flow to predict next day PEF zones in 396 people with asthma (mean age 39.38 years, SD 19.28). Location not stated.

Intervention

Smart Peak Flow.

An algorithm based on artificial neural networks used daily PEF readings to make predictions of the colour coded PEF zone of the next day.

Key outcomes

Daily PEF readings from 21 consecutive days significantly predicted the next day PEF zone (F1 score 0.72, 95% confidence interval [CI] 0.70 to 0.76; p<0.01). Daily PEF recordings could significantly differentiate PEF zones, with receiver operating characteristic area under the curve estimated as 0.87 (95% CI 0.85 to 0.92) for green, 0.79 (95% CI 0.76 to 0.85) for yellow, and 0.90 (95% CI 0.88 to 0.95) for red zones. The authors concluded that Smart Peak Flow could be an early indicator of asthma worsening.

Strengths and limitations

This study was also reported in abstract in Sakkatos et al. (2020). Both abstracts lacked details of study methods. Data was collected retrospectively, but it was not stated if this was real-world data from the app. There was no evidence on the use of the algorithm and its effect on clinical decision making or outcomes. The research was done by the company.

VanZeller al. (2019)

Study size, design and location

Bench test study on 9 peak flow meters or spirometers with CE marking that were available in Europe.

Accuracy of the devices was tested using ISO 23747:2015 and a pulmonary waveform generator. Three tests were done on each device to determine:

- error, repeatability and resistance to peak expiratory output
- error at body temperature, ambient pressure and saturated conditions
- frequency response.

Intervention and comparators

Smart Peak Flow and 8 peak flow meters or spirometers (Air Smart Spirometer, AirZone, eMini-Wright, Medi, Mini-Wright, MIR Smart One, Philips PersonalBest, Vitalograph).

Key outcomes

Smart Peak Flow and Mini-Wright were the only devices to pass all 3 tests of accuracy. The authors concluded that these were the only 2 devices that complied with the minimum performance requirements outlined in ISO 23747:2015.

Strengths and limitations

This is a peer reviewed study that objectively tested several peak flow meters according to established accuracy standards. Tests were done in a laboratory using a pulmonary waveform generator and therefore may not reflect accuracy when used by people in real-world settings. The study reported findings as pass or fail and did not include data on the measurements taken or deviation of the readings. The study was funded and done by the company.

Sustainability

The company claims the technology uses fewer raw materials than mechanical peak flow meters because it is smaller and lighter. There is no published evidence to support these claims.

Recent and ongoing studies

Pilot voice sample collection from people with asthma. This is a prospective observational

study assessing whether changes in voice quality recorded using the Smart Asthma app are indicative of change in asthma control. ClinicalTrials.gov identifier: NCT04799678. Status: not yet recruiting. Indication: chronic asthma. Device: Smart Asthma app. Last updated: March 2021. Country: not stated.

One clinical expert who commented on this briefing reported that Smart Peak Flow is being evaluated in people with severe refractory asthma who are having dupilumab. This study is being done by researchers at the University of Dundee. There was no record of this study in the clinical trials register.

Expert comments

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

Four experts provided comments on Smart Peak Flow. One expert has used the device in clinical practice and research, while the others were familiar with Smart Peak Flow or similar devices.

Level of innovation

All experts considered Smart Peak Flow to be novel. One expert considered it to be innovative because of its small size and its connection to the Smart Asthma app, which differed from standalone digital spirometers. Other novel features included its recording of visual analogue scales for symptoms and reliever use. One expert stated that Smart Peak Flow is innovative if it works and is complemented by a personalised asthma action plan in the app.

Potential patient impact

The experts believed potential benefits of Smart Peak Flow included the automatic recording and long-term storage of asthma data, which would allow for individual level comparison of asthma control. This could help with detecting asthma worsening. One expert noted that some people do not accurately record peak expiratory flow (PEF), and many do not keep this data to share with their healthcare professional. This could delay changes to diagnosis or treatment. Smart Peak Flow may therefore help healthcare

professionals to change treatment quicker.

People may also find Smart Peak Flow convenient to use and there may be better adherence than standard care. One expert noted that despite all efforts, the uptake of self-monitoring and management in asthma remains low and is the main driver of continuing poor outcomes including preventable deaths. The experts considered that people who may particularly benefit from using the device included younger people, people with poorly controlled refractory asthma, people who have difficulty with recording or interpreting data and people with memory or dexterity problems.

Potential system impact

All experts considered that Smart Peak Flow could replace mechanical peak flow meters or standalone digital peak flow meters. One expert commented that real-time data collection and analysis would allow for more timely clinical decision making and treatment optimisation. Smart Peak Flow may also allow sharing of patient data across primary or secondary care settings. This could be used to improve the selection of people for expensive biologic therapies for asthma.

Two experts commented that monitoring asthma deterioration to facilitate treatment change could potentially reduce hospital admissions and steroid burden. This may lead to long-term cost savings. However, they noted that there is currently no evidence of this for Smart Peak Flow. One expert commented that Smart Peak Flow could be cost effective if it works and is used by more people than mechanical peak flow meters. Two experts advised that Mini-Wright is the gold standard in peak flow meters. This device is widely used in standard care and is well validated. One expert cautioned that digital devices are not necessarily better.

Smart Peak Flow needs a smartphone for use and appropriate software in clinic. One expert advised that some people may not have access to a smartphone or may have difficulty using the technology. Two experts believed healthcare professionals and patients would need training to use Smart Peak Flow. Another expert commented that healthcare professionals may need tester kits with software to explain to patients how the device is used.

General comments

Smart Peak Flow is used in asthma clinics in at least 1 NHS trust. Two experts considered that the device could be used in most or all district general hospitals if it is shown to be safe and efficacious. Most experts did not think there would be any potential harms from using the device. But 1 expert commented that there is potential for inaccurate PEF measurements because of technical failure or environmental factors such as lighting. They added that the ability of the device to accurately measure peak flow rate has not yet been proven and validation against the current gold standard in peak flow meters is needed. Another expert noted that the evidence did not show clear parity with established peak flow meters. All experts believed that more research on Smart Peak Flow is needed, including evidence of patient-reported and asthma-related outcomes, patient engagement in self-monitoring, adherence compared with mechanical peak flow meters, patient satisfaction, adverse events including device failure, and the effect on clinical decision making and resource use.

Expert commentators

The following clinicians contributed to this briefing:

- Professor Brian Lipworth, professor of allergy and pulmonology, University of Dundee and NHS Tayside. Has received funding from the company through the University of Dundee to help develop a beta app for other respiratory conditions. Has also received free Smart Peak Flow devices from the company for use in research trials.
- Dr Waseem Khan, consultant in respiratory medicine, Manchester University NHS Foundation Trust. Did not declare any interests.
- Dr Andrew Fogarty, clinical associate professor and reader in clinical epidemiology, University of Nottingham. Did not declare any interests.
- Professor Adel Mansur, consultant physician and honorary professor, University Hospitals Birmingham NHS Foundation Trust. Did not declare any interests.

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