NICE advice

O2matic PRO 100 for optimising oxygen treatment in respiratory conditions

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is O2matic PRO 100. It is used to optimise oxygen treatment in respiratory conditions and for oxygen supplementation. It uses blood oxygen saturation (SpO_2) levels to automatically adjust the flow of oxygen delivered to a person, with the goal of achieving and maintaining target SpO_2.
- The **innovative aspects** are that it offers automatic oxygen titration to the person to reach and maintain a target SpO_2. Other automated oxygen titration devices are available in the UK.
- The intended **place in therapy** would be in a hospital setting as an alternative to fixed-dose oxygen which is manually adjusted based on pulse oximetry or arterial blood gas analysis in people with respiratory conditions and people admitted to hospital for supplemental oxygen.
- The **main points from the evidence** summarised in this briefing are from 3 studies

(1 randomised crossover trial, 1 observational study and 1 crossover trial) including a total of 69 adults (48 with chronic obstructive pulmonary disease [COPD] and 15 with COVID-19).

- **Key uncertainties** are that the evidence base is limited to small studies showing the technology can be used in some settings for people with COPD and COVID-19. None of the studies were done in the UK. More evidence is needed to understand its value in the NHS, particularly comparing its use in different groups.
- **Experts** advised that the technology has the potential to improve patient outcomes and reduce hospital stays. The technology is not yet used in the NHS and further evidence with larger sample sizes is needed to demonstrate the benefits against standard care for specific patient groups in the NHS.
- The **cost** of O2matic PRO 100 is £5,000 to £7,000 per unit (excluding VAT). The resource impact would be in addition to standard care. The expected lifespan of O2matic PRO 100 is 5 years. According to the company, no maintenance and calibration is needed.

The technology

O2matic PRO 100 (O2matic ApS) is an oxygen treatment optimisation device. The device measures blood oxygen saturation (SpO_2) and automatically adjusts the flow of oxygen to the person to achieve and maintain a target SpO_2. The company states that O2matic PRO 100 is intended for use in respiratory diseases such as chronic obstructive pulmonary disease (COPD), COVID-19, asthma, pneumonia and in people admitted to hospital for supplemental oxygen.

The device is installed on a bedside rack as a standalone unit and connected to the hospital oxygen supply. The device can also be installed on pole stands, walkers and other mobile applications. The person's oxygen saturation is measured continuously by pulse oximetry. The oxygen supply is automatically adjusted based on the person's average pulse oximetry for the last 15 seconds.

Innovations

The technology is designed to automate oxygen titration to maintain target blood oxygen saturation, helping to reduce the time the person spends in hypoxia or hyperoxia. This has

the potential to improve clinical outcomes and reduce hospital bed stays. Other automatic oxygen titration devices, FreeO2 and Airvo3, are available in the UK.

Current care pathway

The British Thoracic Society's (BTS) guideline for oxygen use in healthcare and emergency settings states that pulse oximetry must be available in all locations where emergency oxygen is used, and oxygen saturation should be checked by pulse oximetry in all patients who are breathless and acutely ill.

The BTS guideline also states that all critically ill patients outside of critical care areas (intensive care units and high dependency units) should be assessed and monitored using a recognised physiological track and trigger system such as the National Early Warning Score (NEWS). Track and trigger systems are also recommended in the NICE guideline on acutely ill adults in hospital: recognising and responding to deterioration, which notes that NEWS2 (an updated version of NEWS) is endorsed by NHS England.

The BTS guideline states that oxygen therapy should be prescribed according to a target saturation range and be monitored to remain in this range. The oxygen concentration needed depends on the condition being treated.

Standard care in the NHS usually involves the person receiving a fixed dose of oxygen which is manually monitored and adjusted by healthcare professionals (nurses, doctors, intensive care team), based on pulse oximetry or arterial blood gas analysis. The track and trigger system then dictates the frequency of observations and escalation of these observations to relevant healthcare professionals. Oxygen is delivered by a nasal cannula or face mask with a predefined flow. Oxygen saturation monitoring is then repeated as needed to assess response to the oxygen flow and the flow is further adjusted accordingly.

NICE's guideline on COPD recommends oxygen therapy as a treatment option for exacerbations of COPD. People with acute respiratory distress syndrome (ARDS), including when caused by COVID-19, may need passive oxygen therapy before further treatments such as continuous positive airway pressure (CPAP), intubation and mechanical ventilation.

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

- BNF's treatment summary on oxygen

- NICE's medtech innovation briefing on FreeO2 automatic oxygen titration for chronic obstructive pulmonary disease and respiratory distress syndrome
- NICE's guideline on chronic obstructive pulmonary disease in over 16s: diagnosis and management
- NICE's medtech innovation briefing on OxyMask for delivering oxygen therapy
- NICE's medtech innovation briefing on myAIRVO2 for the treatment of chronic obstructive pulmonary disease
- Cochrane Library (2020) oxygen therapy in the pre-hospital setting for acute exacerbations of chronic obstructive pulmonary disease
- NICE's guideline on acutely ill adults in hospital: recognising and responding to deterioration
- NICE's medtech innovation briefing on National Early Warning Score systems that alert to deteriorating adult patients in hospital.

Population, setting and intended user

The technology is intended for people admitted to hospital for supplemental oxygen. This may include people with respiratory conditions such as COPD, COVID-19, asthma and pneumonia.

Various healthcare professionals may give oxygen therapy once appropriate training has been done. Staff who give oxygen should be trained across a range of devices to ensure oxygen is given safely, using appropriate devices and flow rates to achieve the target saturation.

Costs

Technology costs

The company states that the list price of O2matic PRO 100 in the UK will be between £5,000 and £7,000 dependent on volume discounts. The expected lifespan of O2matic PRO 100 is 5 years. The company release a new software update annually and improve the algorithm and new functions based on customer feedback at no extra cost.

According to the company, no maintenance and calibration is needed. In cases where there is no access to a mains power source, the device will need a battery replacement at an additional £70 every 2 years. The company states that there are no additional consumable costs related specifically to the use of this technology. According to the company, the device is supplied with a reusable pulse oximeter. Any other add-on consumables are similar to current standard of care.

The company states that training is needed to use the device. The company provides initial training at no extra cost. The company provides free online material such as training videos and webinars. An extra cost is charged to the purchaser for additional face to face training.

Costs of standard care

Various SpO_2 monitors are available ranging in price from £144 to £450, with separate sensors varying in price from £42 to £225.

The cost of FreeO2, another automatic system with an expected lifespan of 5 years, is £9,600 per unit (excluding VAT) with a yearly preventive maintenance and calibration cost of £450.

Resource consequences

The O2matic PRO 100 is currently used in 1 NHS Trust, the Royal Free London NHS Foundation Trust, since 2019.

Using O2matic PRO 100 in the NHS would incur an additional cost compared with standard manual delivery of oxygen. Assuming reliable SpO_2 measurements and adjustments are produced, this may be offset if the claimed benefits of reduced morbidities and length of hospital stay are seen. Automated titration may also free up nurse time because it could reduce the need for manual adjustments. There is limited published evidence to support these claimed benefits.

Regulatory information

O2matic PRO 100 is a CE marked class IIb 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.

Respiratory conditions such as chronic obstructive pulmonary disease and asthma are chronic conditions, which may mean someone is disabled if they have a substantial and long-term effect on their ability to do daily activities. Disability is a protected characteristic under the Equality Act 2010.

The Medicines and Healthcare products Regulatory Agency's guidance on the use and regulation of pulse oximeters (information for healthcare professionals), 2021 highlights a number of factors which can affect the accuracy of pulse oximeters, including skin pigmentation. It reports that darker skin pigmentation may cause an overestimation of SpO_2 saturations, so the relative changes in an individual person's readings should be considered as well as the numerical value.

Race is a protected characteristic under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with 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

There are 3 studies summarised in this briefing, including 69 adults. The studies include a multicentre randomised controlled trial, an observational study and a multicentre crossover trial.

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

Overall assessment of the evidence

None of the studies reported are based in the NHS. The available evidence is only in people with chronic obstructive pulmonary disease (COPD) and COVID-19 and is based on a very small number of people.

Further evidence is needed on the use of the device in UK-based settings across a broader range of people requiring supplemental oxygen.

Kofod et al. (2021)

Study size, design and location

Multicentre double-blinded randomised crossover trial in 33 people with COPD on home oxygen in Denmark.

Intervention and comparator

O2matic PRO 100 and fixed-dose oxygen.

Key outcomes

The study included people diagnosed with COPD based on the international criteria (hypoxemic at rest without oxygen supplement, saturation less than 88% and partial pressure of oxygen [PaO_2] less than 7.3 kPa [55 mmHg]). The study consisted of 3 separate hospital visits during which 2 different walks were performed, the endurance shuttle walk test (ESWT) or the 6-minute walk test (6MWT). Each walk was performed with both the person's usual fixed oxygen dose and with a variable oxygen dose, automatically titrated. On the first visit, the person also performed the incremental shuttle walk test (ISWT), using their usual prescribed oxygen dose. On the second visit, the patient performed an ESWT on a 10-metre course twice and in a randomised order, without the usual 2-minute warm up to avoid exhaustion. The last visit involved the person doing a 6MWT with a fixed dose and automated oxygen titration in a random order. During the ESWT, people walked 10.9 (inter-quartile range [IQR] 6.5 to 14.9) minutes with automated oxygen compared with 5.5 (IQR 3.3 to 7.9) minutes with a fixed dose. During the 6MWT, people walked an average 291.6 (standard deviation [SD] 67.4) metres with automated oxygen compared with 271.3 (SD 65.1) metres with fixed-dose oxygen. Walking

with automated oxygen titration had a statistically significant and clinically important effect on dyspnoea. People walked for a 98% longer time when hypoxemia was reduced with a more well-matched, personalised oxygen treatment.

Strengths and limitations

The double-blind study design and use of standard care as the comparator minimised the risk of bias. The study was done outside the NHS. This limits the translation of these findings in the NHS. One of the investigators and authors of this study is the main inventor of the technology and is the main shareholder in the company (O2matic Ltd).

Hansen et al. (2020)

Study size, design and location

Single centre prospective observational study in 15 people with COVID-19 having oxygen in Denmark.

Intervention and comparator

O2matic PRO 100, no comparator.

Key outcomes

The study measured lung function parameters in 15 people with COVID-19 having oxygen therapy controlled using O2matic PRO 100. Lung function was severely impaired with forced expiratory volume (FEV1), forced vital capacity (FVC) and peak expiratory flow (PEF) reduced to approximately 50%. The average stay on the ward was 3.2 days and O2matic PRO 100 was used on average for 66 hours, providing 987 hours of observation. O2matic PRO 100 maintained SpO_2 in the desired interval for 82.9% of the time. Time with SpO_2 more than 2% below the desired interval was 5.1% and time with SpO_2 more than 2% above the desired interval was 0.6%.

Strengths and limitations

Some limitations of this study included being a single arm study, small sample size and it was done outside the UK. This limits the generalisation of results to the UK setting.

Hansen et al. (2018)

Study size, design and location

Multicentre crossover trial comparing O2matic to manually controlled oxygen in 19 people admitted with COPD in Denmark.

Intervention and comparator

O2matic PRO 100 and standard manually controlled oxygen.

Key outcomes

People with O2matic PRO 100-controlled treatment were within the SpO_2 target interval for 85.1% of the time compared with 46.6% of the time with manually controlled treatment ($p<0.001$). Time with SpO_2 below 85% was 1.3% with O2matic PRO 100 and 17.9% with manual control ($p=0.01$). Time with SpO_2 below the target interval but not below 85% was 9.0% with O2matic PRO 100 and 25.0% with manual control ($p=0.002$). Time with SpO_2 above the target interval was not significantly different between treatments (4.6% compared with 10.5%, $p=0.2$). People using O2matic PRO 100 expressed high confidence and a sense of safety with automatic oxygen delivery.

Strengths and limitations

The study comparator was standard care. Investigators and people in the study were not blinded. This potentially introduces bias. The study was done outside the NHS. This limits the translation of these findings in the NHS. Two of the authors are co-inventors of the technology.

Sustainability

The company claims the technology will optimise oxygen use and may reduce overall oxygen consumption.

Recent and ongoing studies

- Effects of an automatic oxygen titration versus constant oxygen flow rates during daily

activities in patients after SARS-CoV-2 infection. ClinicalTrials.gov identifier: NCT04849598. Status: completed. Indication: post-COVID-19. Devices: O2matic. Completion date: 27 August 2021. Country: Germany.

- Automated oxygen control by O2matic to patients admitted with acute hypoxemia (O2MATIC-ACUT). ClinicalTrials.gov identifier: NCT04079465. Status: recruiting. Indication: hypoxemic respiratory failure, hypoxia, hypoxemia, respiratory failure, respiratory insufficiency. Devices: O2matic. Estimated completion date: 31 December 2022. Country: Denmark.

- Oxygen control and weaning by O2matic to patients admitted with an exacerbation of COPD (O2MATIC-WEAN). ClinicalTrials.gov identifier: NCT03661086. Status: completed. Indication: respiratory failure, hypoxia, hypoxemia, respiratory insufficiency, acute COPD exacerbation. Devices: O2matic. Completion date: June 2022. Country: Denmark.

- Automated oxygen titration to patients with COPD and domiciliary long-term oxygen treatment (O2matic HOT). ClinicalTrials.gov identifier: NCT04606290. Status: recruiting. Indication: chronic hypoxemic respiratory failure, COPD. Devices: O2matic. Estimated completion date: 31 December 2022. Country: Denmark.

- Does robot-administered oxygen have effect on the perception of dyspnea in patients admitted with COPD and hypoxemia? ClinicalTrials.gov identifier: NCT04370990. Status: unknown. Indication: COPD, hypoxia, Closed-Loop communication, dyspnoea, anxiety, depression. Devices: O2matic. Estimated completion date: September 2022. Country: Denmark.

- Is reduced hypoxia through a robot intervention, associated with sensory and emotional descriptions of dyspnea, anxiety, depression, symptom burden and anxiolytics. ClinicalTrials.gov identifier: NCT04375917. Status: unknown. Indication: anxiety, COPD, Closed-Loop communication, dyspnoea, depressive symptoms and hypoxia. Devices: O2matic. Estimated completion date: 1 September 2022. Country: Denmark.

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.

Three experts contributed to the development of this briefing. Only 1 expert had experience of using the technology in less than 5 people. Another expert was familiar with the use of fixed oxygen delivery and monitoring devices used in acute settings, high dependency units and outpatient settings. The other expert had no experience with the technology or any similar automated oxygen titration devices. The experts were not aware of use of the technology in the NHS and only 1 has been involved in some research on this technology.

Level of innovation

The 3 experts considered the technology to be an innovative approach to maintaining oxygen saturation through automatically titrating inspired oxygen. Two experts reported that there are other similar devices available such as FreeO_2 and Airvo3. Airvo3 is a nasal high flow device that can automatically titrate delivered oxygen to a set target saturation. One of the experts added that O2matic PRO 100 differs from Airvo3 because it can be used with usual nasal oxygen and nasal high flow devices.

Potential patient impact

According to the experts, the main patient benefit would be keeping the oxygen saturation within a set range for a greater amount of time with fewer deviations. They advised that the technology may reduce the risk of harm because of uncontrolled oxygen delivery, that is, oxygen saturation levels that are too high or too low that can happen in periods between nursing observations. Experts also said the technology may help with oxygen weaning. One expert noted that the ability to download patient data to monitor flow and oxygen saturation trends over a 24-hour period may be a useful tool to help discharge people from hospital.

The experts stated that the technology has the potential to replace current standard care but it is unlikely to do so because of the high number of people who need oxygen therapy. Therefore, the experts considered it most likely to be used in specific patient groups who are at the highest risk of deviations in oxygen saturations. They advised that the technology is likely to be most beneficial for people at risk of hypercapnic respiratory failure because of oxygen sensitivity. This includes people with chronic obstructive pulmonary disease (COPD) with carbon-dioxide retention, people with neurological causes of respiratory failure, people with chest wall disease and people with obesity hypoventilation syndrome.

One expert referenced the potential benefits as shown in the study by Kofod et al. (2021) that ambulatory oxygen delivery and auto-titration may be beneficial in exercise capacity and reduction in dyspnoea.

Potential system impact

The experts noted that the technology would cost more than standard care for capital outlay but potentially offset downstream costs because of reduced nursing time needed for observations and manually adjusted oxygen flows. However, 1 expert cautioned that the resource savings for nurse time would be limited because nurses would still be needed to record other observations for acutely ill people such as pulse and blood pressure monitoring. The technology also has the potential to reduce length of hospital stay, but evidence supporting this is needed.

General comments

The experts said that adopting the technology would not need changes to the existing facilities in a hospital setting. An expert highlighted that more than 1,000 people having treatment in a mid-sized district general hospital could benefit from this technology. Furthermore, there are significant numbers of people who need emergency oxygen therapy.

The experts highlighted the lack of evidence of clinical efficacy and system impact (such as reduced length of hospital stay). They noted the need for larger studies across different patient groups to assess the benefits and safety of the technology. Important outcomes include increased time with oxygen saturation kept within a target range, reduced time of oxygen saturation kept outside of a target range, reduced length of hospital stay, reduced need for close nursing contact with people with COVID-19 therefore reduced risk of infection transmission and improvement in exercise capacity in ambulatory patients with COPD. In addition, more information is needed on technical problems with the device, saturation pick up rates and loss of signal time.

An expert raised potential issues and harms from the technology. The expert mentioned that the Kofod et al. (2021) study reported that there were episodes of loss of signal from the saturation monitoring device although this was similar in the intervention and usual care groups. This could potentially cause a risk of oxygen not being titrated accordingly and therefore too much or too little oxygen being delivered (as reported in the Hansen et

al. 2018 study). In the same study it was noted that audible and visual alarms for alerting there was no power supply were ignored and the oxygen supply shut down after 2 hours. Discomfort because of very high oxygen flow rates by nasal cannulae was reported but 1 of the experts said this could be mitigated by switching to a nasal high flow system.

Expert commentators

The following clinicians contributed to this briefing:

- Dr Amar J Shah, respiratory registrar and clinical research fellow, Royal Free London NHS Foundation Trust. The trust received 2 O2matic PRO 100 devices from the company for a trial.
- Dr Catherine Snelson, consultant in critical care and acute medicine, University Hospitals Birmingham NHS Foundation Trust. Did not declare any interests.
- Dr Stephen Scott, consultant respiratory physician, Countess of Chester Hospital NHS Foundation Trust. Did not declare any interests.

Development of this briefing

This briefing was developed for NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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