

Nasal Alar SpO₂ sensor for monitoring oxygen saturation by pulse oximetry

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is the Nasal Alar SpO₂ sensor. It is used for monitoring a person's peripheral oxygen saturation (SpO₂) with a pulse oximeter.
- The **innovative aspects** are that it is currently the only sensor designed to detect SpO₂ at the nasal ala (the fleshy part of the nose). This is designed to improve accuracy and reliability in people who have poor peripheral perfusion (low blood flow).
- The intended **place in therapy** would be as an alternative to earlobe, nasal bridge and forehead sensors when conventional digit pulse oximeter sensors do not work or are inappropriate (such as in people with poor peripheral perfusion).

- The **main points from the evidence** summarised in this briefing are from 1 published US accuracy study and 2 published abstracts involving a total of 135 healthy volunteers and patients in clinical and research settings. They suggest that the Nasal Alar SpO₂ sensor is at least as accurate as digit oximetry, and may be more reliable than forehead sensors.
- **Key uncertainties** around the evidence are that the evidence base is still developing and is limited to small, non-randomised studies in non-UK settings.
- The **cost** of the Nasal Alar SpO₂ sensor is £20.62 per unit (exclusive of VAT). The **resource impact** would be that using the device would cost more than standard digit sensors. This cost may be offset if it allowed a longer duration of use, reduced nursing time or if it could provide an oximetry reading when other devices do not work.

The technology

The Nasal Alar SpO₂ sensor (Xhale Assurance) is a disposable, single patient use pulse oximetry sensor that clips onto the nasal ala, the fleshy part of the side of the nose. The sensor is indicated for use in adults and children (weighing more than 30 kg) for the continuous non-invasive monitoring of peripheral oxygen saturation (SpO₂) and pulse rate.

The Nasal Alar SpO₂ sensor includes light-emitting diodes and a photodiode pulse oximetry sensor in a plastic nasal clip, which uses photoplethysmography signals to determine a person's SpO₂ level. The sensor has soft silicone pads to hold it in place on the person's nasal alar region. It has a cable with a connector that is compatible with most pulse oximetry monitors.

The device is contraindicated for patients weighing less than 30 kg or when the sensor cannot stay in place. The device should also not be used on sites with compromised tissue or non-intact skin, or for any patient with a medical condition that decreases nasal alar blood perfusion or that increases nasal alar venous congestion or swelling.

Innovations

The Nasal Alar SpO₂ sensor is the only pulse oximetry sensor specifically designed to detect SpO₂ levels in the blood vessels of the nasal ala. This is designed to improve sensor accuracy and reliability in people who have poor peripheral perfusion (low blood flow). This is because the nasal ala is said to maintain a good blood supply from internal carotid

arteries (which supply blood to the brain). In comparison, reliable readings may not be possible in people with low peripheral perfusion using conventional digit sensors attached to a finger or toe.

Positioning of the non-adhesive sensor clip at the nasal ala is designed to allow easy and quick attachment by healthcare staff and to be better tolerated and more comfortable for patients than other sensors, especially in those who are susceptible to skin breakdown, at risk of pressure ulcers or have sensitivity to adhesives.

Current NHS pathway

Current options for continuous monitoring of SpO₂ by pulse oximetry in NHS clinical settings include: digit sensors, earlobe sensors, forehead sensors or nasal bridge sensors. These sensors may be single-use or reusable devices.

NICE's guideline on [recognising and responding to deterioration in hospital](#) states that SpO₂ should be measured as part of routine monitoring and by track and trigger systems; however, this guidance does not cover people in critical care or children. Other NICE guidance where pulse oximetry monitoring is recommended includes guidelines for [chronic obstructive pulmonary disease](#), [chest pain of recent onset](#) and [bronchiolitis in children](#).

SpO₂ monitoring by pulse oximetry is classed as essential for the safe conduct of anaesthesia or sedation in the Association of Anaesthetists of Great Britain and Ireland's [standards of monitoring during anaesthesia and recovery](#). They state that pulse oximetry monitoring should be maintained until the patient has recovered fully from anaesthesia and used for all patients who are anaesthetised or sedated, including during transfer in hospital.

The Royal College of Physicians recommends the [National Early Warning Score \(NEWS\)](#) for the assessment and response to acute illness: SpO₂ monitoring by pulse oximetry is 1 of the 6 NEWS physiological parameters. The British Thoracic Society's guidance on [emergency oxygen use in adult patients](#) states that pulse oximetry must be available in all locations where emergency oxygen is used. The Resuscitation Council UK's guideline on [pre-hospital resuscitation](#) states that pulse oximetry should be used to assess SpO₂ in all patients with a cardiac output, but highlights that in the pre-hospital settings, the combination of cold peripheries and a low cardiac output can make pulse oximetry unreliable; so if a pulse oximeter sensor placed on a finger does not measure the oxygen saturation, other anatomical sites should be used (for example toes, nose, ear lobes or

tongue).

NICE is aware of the following CE-marked devices that appear to fulfil a similar function as the Nasal Alar SpO₂ sensor, however they are single-use adhesive sensors placed at different anatomical locations:

- [Nellcor OxiMaxR](#) (Medtronic/Covidien): bridge of the nose
- [Nellcor forehead sensor](#) (Medtronic/Covidien).

Population, setting and intended user

The Nasal Alar SpO₂ sensor can be used in any healthcare setting where continuous SpO₂ monitoring by pulse oximetry is done. This includes secondary care settings, such as emergency wards, intensive care units and operating theatres, as well as pre-hospital settings, such as ambulances.

The sensor can be used for any person who weighs over 30 kg. The device is most likely be used as an alternative to earlobe and forehead sensors when conventional digit pulse oximeter sensors do not work or are inappropriate, such as in people with low peripheral perfusion. This condition happens when people are critically ill, but is also associated with surgery involving large fluid shifts (liver transplants, trauma, caesarean section), shock, hypothermia and certain pre-existing conditions, such as peripheral arterial disease.

The sensor should be used by healthcare professionals who are trained in pulse oximetry monitoring. As the sensor is easy to use, minimal training should be needed, because it is compatible with standard pulse oximeter monitors.

Costs

Technology costs

Each Nasal Alar SpO₂ sensor costs £20.62 (excluding VAT) and can be used for a single patient for up to 7 days of monitoring. It can be purchased in a box of 24 sensors for £495.00 (excluding VAT).

Costs of standard care

Conventional finger or toe sensors for pulse oximeters can be reusable or single-use disposable items. Costs range from £40 to £250 each for a reusable sensor and £7 to £19 each for disposable sensors ([NHS Supply Chain](#)). Additional costs for disinfectant wipes and nursing time would be incurred for cleaning reusable items for use between patients.

Digit sensors may not provide reliable measurements in people with poor peripheral perfusion. Other single-use non-digit pulse oximeter sensors are available on [NHS Supply Chain](#):

- Nellcor forehead sensor: £16.36 each, 2 days' use (£392.59 for 24)
- Nellcor nasal bridge sensor: £16.60 each, 2 days' use (398.30 for 24).

Resource consequences

The Nasal Alar SpO₂ sensor is currently used in about 15 NHS hospitals.

Using the Nasal Alar SpO₂ sensor would incur an additional cost compared with standard digit sensors which, assuming reliable SpO₂ measurements, may be offset if it allows a longer duration of use, reduced nursing time or if it can provide an oximetry reading when other devices do not work. If the sensor can improve the accuracy and reliability of SpO₂ measurements in people with poor peripheral perfusion, it may lead to improved medical decision-making, faster intervention in response to complications, fewer false alarms and reduced nursing time, when compared with conventional digit sensors.

The Nasal Alar SpO₂ sensor can be used to monitor an individual patient for up to 7 days, compared with 2 days for single-use forehead or nasal bridge sensors. Fewer nasal alar sensors may be needed than forehead sensors for monitoring patients with low peripheral perfusion with hospital admissions over 2 days, which may lead to cost savings. Because it is a disposable single-use sensor, no nursing time or consumables are needed to disinfect it between patients, which is necessary for reusable pulse oximeter sensors to reduce the risk of healthcare-associated infections.

No changes in facilities and infrastructure would be needed to adopt the Nasal Alar SpO₂ sensor, because it is compatible with standard pulse oximetry monitors. Minimal training is needed for staff using the device. This will include being shown how to apply

the sensor and that it is disposable.

Regulatory information

The Nasal Alar SpO₂ sensor was CE marked as a class IIb device in August 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 low peripheral perfusion as a result of comorbid conditions are likely to be classed as disabled under the Equality Act 2010, as their condition may affect their ability to carry out daily activities. The device is only indicated for people over 30 kg, so is unsuitable for small children, babies and neonates.

Clinical and technical evidence

A literature search was done for this briefing in accordance with the [interim 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.

Published evidence

Literature searches found 3 published studies on the Nasal Alar SpO₂ sensor which are summarised in this briefing, involving 135 people in the US. These include a published accuracy and feasibility study in healthy volunteers ([Morey et al. 2014](#)), 2 published conference abstracts of an accuracy study in surgical patients ([Melker et al. 2014](#)) and a comparative study with the Nellcor forehead sensor in critical care patients ([Schallom et al. 2016](#)). Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence for the Nasal Alar SpO₂ sensor is limited in quantity and quality, and includes 1 published study and 2 conference abstracts. Most studies focussed on confirming the accuracy of the sensor using radial artery co-oximetry samples, compared with finger or forehead sensors. Other outcomes reported included the time taken to detect oxygen desaturation and the incidence of pressure ulcers. Two out of 3 studies were in clinical settings with patients, one of which studied people with low peripheral perfusion.

Because all the studies were done in the US, and some studies included healthy volunteers, this may limit their relevance to the NHS care pathway. Randomised studies comparing the Nasal Alar SpO₂ sensor with other non-digit pulse oximeters done in a UK setting would be useful to confirm its equivalence for diagnostic accuracy and effects on patient outcomes.

Table 1 Summary of published evidence on the Nasal Alar SpO₂ sensor

Morey et al. 2014	
Study size, design and location	Accuracy and feasibility study in 12 healthy volunteers in a non-clinical setting in the US.
Intervention and comparator(s)	Nasal Alar SpO ₂ sensor and conventional finger sensor. Subjects breathed hypoxic mixtures of fresh gas by a facemask to achieve SpO ₂ ranges of 70% to 100%. SpO ₂ was measured by both nasal and finger sensors and compared to the reference standard: traditional co-oximetry from radial artery samples.

Key outcomes	<p>The Nasal Alar sensor was accurate to within $\pm 2\%$ for the full range of SpO₂ levels when compared with the reference samples.</p> <p>Bias, precision and ARMS over a range of 70% to 100% were significantly better for the nasal sensor compared with the finger sensor. The mean bias for the nasal and finger sensors was 0.73% and 1.90% ($p < 0.001$) respectively, with corresponding precision values of 1.65 and 1.83 ($p = 0.015$) and ARMS values of 1.78% and 2.72% ($p = 0.047$).</p>
Strengths and limitations	<p>Single-centre non-randomised and non-blinded study.</p> <p>Small sample size in healthy volunteers in non-clinical setting.</p> <p>Manufacturer-funded study: authors were employees or held equity shares in Xhale.</p>
<u>Melker et al. 2014</u>	
Study size, design and location	Observational study in 80 surgical patients in the US.
Intervention and comparator(s)	<p>Nasal Alar SpO₂ sensor (placed on both alae) and conventional finger sensor.</p> <p>Either matched pulse oximeters were used to record data from the 2 ala and finger, or an alternative stand-alone oximeter was used on 1 ala. Simultaneous finger oximetry data was collected from a multi-parameter patient monitor.</p>
Key outcomes	<p>Desaturations were present in 15 patients (19%): alar desaturation happened on average 9 seconds (range -5 to 33) sooner than the finger with the same oximeter (physiologic delay). Alar desaturation measured with an alternative stand-alone oximeter averaged 7 seconds slower than those from the first oximeter (device delay). The multi-parameter patient monitor introduced a further 5 seconds average delay.</p> <p>In all, a combination of physiologic delay and device delay results in an average of 14 seconds delay between measurement at the finger and the first measurement at the nasal ala.</p>

Strengths and limitations	<p>Single-centre non-randomised and non-blinded study.</p> <p>Peer-reviewed accepted conference abstract, but not published as a full article so details of methodology are unclear.</p> <p>Manufacturer-funded study: authors are employees or hold equity shares in Xhale.</p>
<u>Schallom et al. 2016</u>	
Study size, design and location	Observational study in 42 critically ill patients with poor peripheral perfusion in the US. Patients were included if a peripheral signal was not able to be obtained, were on vasopressors or had a reduced temperature. All patients had arterial lines.
Intervention and comparator(s)	<p>Nasal Alar SpO₂ sensor and Nellcor forehead sensor.</p> <p>Arterial samples were measured by co-oximetry and values recorded from both sensors at time 0, 24, and 120 hours. Skin was assessed every 8 hours with relocation of the sensor to the opposite nasal ala or forehead side. sensor was removed when skin injury was seen.</p>
Key outcomes	<p>More measures were within 3% of co-oximetry values for nasal Alar (56%) compared with forehead (44%) sensors. Measurement failures were 6% for nasal ala and 21% for forehead. Mean wear time was 66.2 hours for nasal sensor and 37.4 hours for forehead sensors.</p> <p>13 patients developed a pressure injury with the forehead sensor (9 at stage 1, 3 at stage 2 and 1 deep tissue injury) and 3 with the nasal sensor (2 stage 1, 1 stage 2).</p>
Strengths and limitations	<p>Peer-reviewed accepted conference abstract, but not published as a full article so details of methodology are unclear.</p> <p>Single-centre non-randomised and non-blinded study.</p> <p>Clinical setting in a relevant patient population.</p> <p>High drop-out rate: only 14 people had all 3 measurements, as 51% died before data collection completion.</p> <p>Prevention of sensor-related pressure injury may not be possible in all critically ill patients.</p>
Abbreviations: ARMS, accuracy root mean square error: calculated as the square root of (bias ² + precision ²) with values of less than 2% to 3% considered to be acceptable.	

Recent and ongoing studies

- Evaluation of the Xanas nasal pulse oximetry sensor during robot assisted laparoscopic prostatectomy. Primary comparator: ear sensors. Enrolment: 64. Completion date: 2017. Location: UK ([abstract presented](#)).

Specialist commentator 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.

Eight specialist commentator responses were received. Four of the specialist commentators had used the Nasal Alar SpO₂ sensor in clinical practice.

Level of innovation

Most commentators thought the Nasal Alar SpO₂ sensor was thoroughly novel, or was a significant modification of an existing technology with potential for different outcomes and impact. Three commentators thought it was a minor variation on existing technology but they had no experience of using it directly; 1 stated it was a potentially useful variation.

Commentators were not aware of similar products, apart from the nasal bridge sensor. One commentator stated that finger probes can be used on the nose, but this was not ideal. Similarly, other commentators highlighted that earlobe probes can also be used on the nose, which may yield acceptable signals. It should be noted that these applications are off-label use against manufacturers' instructions. One commentator had used paediatric probes to achieve the same aim as the Nasal Alar SpO₂ sensor, but stated that these are not designed for this purpose and do not work as well.

Potential patient impact

Some commentators thought the Nasal Alar SpO₂ sensor would improve the accuracy and reliability of continuous SpO₂ monitoring, especially in poorly perfused patients. Two commentators thought it may provide earlier detection of hypoxia, which may be beneficial: one stated it may provide an extra level of safety from earlier identification and

subsequent treatment. One commentator highlighted that the ability to measure SpO₂ continuously would be a major factor in improving the safety of healthcare. This commentator described caring for critically ill patients without a functioning pulse oximeter is extremely risky. Another highlighted that the ability to monitor SpO₂ in low output states is important because of the well-established harm from hypoxaemia and hyperoxia. Another user of the device stated that they could obtain accurate readings with the Nasal Alar SpO₂ sensor, so care for their patients is based on good clinical data. One commentator had found forehead sensors to be less accurate than this device.

Most commentators said the device would be most likely to be used in patients with poor peripheral perfusion or low output, when digit or ear readings have not worked. Other suggested situations where the device would be useful included: for very sick or shocked patients; when fingers are not accessible to check saturation (such as during surgery); patients who need their hands to be free; patients with burns or amputated limbs; older or confused patients who fidget; those who cannot tolerate finger probes or patients in the head-down position during surgery. Commentators identified that the sensor may not be able to be used in patients with nasal problems or with facial trauma.

Two commentators stated the device could be used in any scenario where pulse oximetry is used to monitor SpO₂. These included operating theatres, intensive care and high dependency units, emergency departments, wards and out of hospital critical care areas where procedural sedation is used.

Two commentators highlighted the Nasal Alar SpO₂ sensor is non-invasive, and one thought there would be less need for invasive arterial blood sampling to ensure enough oxygenation. In 1 setting, commentators used the device instead of monitoring oxygen saturation with invasive arterial lines. This commentator stated that the risks associated with invasive arterial monitoring may be removed, such as bleeding, pain and ischaemia to the hand.

Two commentators thought benefits to patients were minimal. One thought it simply increases the range of options from which to obtain oximetry readings. Another thought it may be less likely to be displaced than finger probes, but it may well be in a patient's visual field and be distracting.

One commentator highlighted that there have been pressure injuries reported from long-term use of conventional sensors.

Potential system impact

Some commentators thought the Nasal Alar SpO₂ sensor would make it easier to monitor SpO₂. One commentator with experience of the device stated that sensor placement is easy and does not need the constant repositioning experiences with ear probes, which tend to fall off because of head movement. This commentator thought there would be less wasted nursing time when there is difficulty obtaining a reading, because the device works every time. Another commentator stated that an SpO₂ monitor which provides continuous accurate information under a wide range of conditions with minimal intervention from healthcare professionals would be a significant advantage.

One commentator thought there may be benefits relating to fewer critical hypoxic incidents (where SpO₂ is less than 90%), possibly fewer cardiac arrests because of hypoxia and decreased morbidity leading to reduced hospital stay.

Commentators highlighted that the Nasal Alar SpO₂ sensor was more expensive than other devices. Two commentators stated that as a single patient use sensor, it would be more expensive than the conventional reusable finger and ear probes. One commentator said this device would need to be provided in addition to existing technology, but additional costs could be minimised by acquiring a small number of these new devices for patients in particular need.

Two commentators thought the Nasal Alar SpO₂ sensor would lead to cost savings. Two commentators considered that it would not be necessary to order and stock other types of device for when digit probes do not work if this device were used. One of the commentators stated they have stopped using forehead sensors, nasal bridge and earlobe probes after adopting the Nasal Alar SpO₂ sensor, resulting in cost savings. Another commentator stated that it was not necessary to apply a new Nasal Alar SpO₂ sensor if it needed temporary removal, as is the case with the stick-on forehead sensors or the nasal bridge probes, thus saving costs. They added that in the setting where the Nasal Alar SpO₂ sensor is being used instead of arterial lines, the device is cheaper. Arterial lines may cost between £50 and £80, including the cost of the line and its corresponding transducer.

Most commentators did not identify any obstacles to adopting the device. One commentator stated that it offered more choice for clinicians and patients. Another user of the device had experienced no problems in changing healthcare professional working practices, as benefits were easily seen.

One commentator thought there may be infection control advantages with this device because it is single patient use.

Most commentators thought that special training to use the device was not needed. One stated the training would only take a few minutes and could be cascaded to other users very easily. Another stated that only adequate knowledge of duration of use and change of position was needed.

General comments

Most commentators stated that conventional pulse oximeters may not work in patients with poor peripheral perfusion. However, one commentator stated that in severe shock with very poor circulation the blood flow to the nasal ala will also be reduced, but not as much as in the peripheries. Another stated that it was rare not to be able to get any oximetry in patients using existing devices.

Most commentators thought the device was robust, with little or no maintenance needed. One user of the device reported no reliability problems.

One commentator thought there could be a potential disadvantage in critical care settings with nasal intubated patients or those with nasogastric tubes, and thought readings could be affected by face mask ventilation.

One commentator stated that they were currently doing a clinical evaluation of the device in patients having robotic-assisted laparoscopic prostatectomy. This type of surgery needs the patient to be in a head-down position for prolonged periods, where access to the hands maybe restricted and venous congestion in the head makes it difficult to detect a standard reading with current ear probes. Their preliminary experience of the Nasal Alar SpO₂ sensor was that they can reliably get a reading which correlates with arterial blood gas sampling, allowing an earlier response to hypoxia. This commentator said that they may reconsider their practice of routinely inserting invasive arterial lines as a result.

Specialist commentators

The following clinicians contributed to this briefing:

- Dr Ahilan Pathmanathan, consultant anaesthetist, East and North Hertfordshire NHS Trust. Personal non-financial interest declared: received 25 devices free of charge as part of an ongoing clinical evaluation.
- Mr Markku Viherlaiho, senior charge nurse, Lewisham and Greenwich NHS Trust. No conflicts of interest declared.
- Dr Richard Telford, consultant anaesthetist, Royal Devon and Exeter NHS Foundation Trust. No conflicts of interest declared.
- Prof Jaideep Pandeep, consultant anaesthetist, Oxford University Hospitals NHS Foundation Trust. No conflicts of interest declared.
- Professor Jerry Nolan, consultant in anaesthesia and intensive care medicine, Royal United Hospitals Bath NHS Foundation Trust. No conflicts of interest declared.
- Dr Martin Allen, consultant respiratory physician, University Hospitals of North Midlands NHS Trust. No conflicts of interest declared.
- Ms Manda Dunne, senior sister in anaesthetics and recovery, Lewisham and Greenwich NHS Trust. No conflicts of interest declared.
- Dr Andrew Higgs, consultant in anaesthesia and intensive care medicine, Warrington and Halton Hospitals NHS Foundation Trust. No conflicts of interest declared.

Development of this briefing

This briefing was developed by NICE. 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.

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