NICE National Institute for Health and Care Excellence

NICE guidance

Sedaconda ACD-S for sedation with volatile anaesthetics in intensive care

HealthTech guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB229 and MTG65.

1 Recommendations

1.1 Sedaconda anaesthetic conserving device-S (Sedaconda ACD-S) is recommended as a cost-saving option for delivering inhaled sedation in an intensive care setting when the volatile anaesthetics isoflurane or sevoflurane are being considered.

1.2 Further research is recommended to identify any health conditions or groups of patients that would benefit more from inhaled sedation with Sedaconda ACD-S than from standard care. Please see the section on further research for more details.

Why the committee made these recommendations

Sedaconda ACD-S is used in intensive care settings when people need inhaled sedation. The evidence for Sedaconda ACD-S includes people with a wide range of conditions. But there were not enough people for each condition in the studies to identify who would particularly benefit from inhaled sedation with Sedaconda ACD-S. Although there is no published evidence for Sedaconda ACD-S in children, the committee accepted that the results from the adult studies will be generalisable to children. So, further research is recommended to identify the groups that could benefit from using the technology.

Cost modelling shows that, over 30 days, Sedaconda ACD-S is cost saving compared with intravenous propofol sedation by £3,833.76 per adult. In children, Sedaconda ACD-S is also cost saving compared with intravenous midazolam sedation, by £2,837.41 per child. These savings are from reduced time on mechanical ventilation, which may shorten the length of time in intensive care for the patient. Sedaconda ACD-S was cost saving when the length of time a person spent in intensive care after being taken off mechanical ventilation was reduced by only a few hours (when non-ventilated days in intensive care was only a few hours, 2.5 to 5 hours).

Evidence suggests that time to people waking up from sedation is shorter with inhaled sedation (using Sedaconda ACD-S) than with intravenous sedation, but that a reduction in

time on mechanical ventilation is uncertain. It is also uncertain if using Sedaconda ACD-S shortens a person's length of stay in intensive care. Because these are the key drivers of cost savings, the cost analysis results are also uncertain. Even with these uncertainties, Sedaconda ACD-S is still cost saving in both children and adults and shows promise as an option for use in intensive care settings for sedation with volatile anaesthetics, when sedation with isoflurane or sevoflurane is being considered.

Volatile anaesthetic drugs are potent greenhouse gases. Sedaconda ACD-S may be associated with a lower consumption of volatile drugs compared with other delivery and scavenging systems for volatile sedation.

2 The technology

Technology

2.1 The Sedaconda anaesthetic conserving device-S (Sedaconda ACD-S; Sedana Medical) is a volatile anaesthetic delivery system to give isoflurane or sevoflurane to people who are mechanically ventilated, usually in an intensive care setting. The technology conserves inhaled anaesthetics within the delivery system and any waste gas is captured by a passive or active gas scavenging system.

2.2 Sedaconda ACD-S is a single-use device (replaced every 24 hours or earlier when needed). The device can be inserted into either the breathing circuit of a ventilator between the endotracheal tube and Y piece, replacing the heat and moisture exchanger (standard placement) or in the inspiratory port of the ventilator (alternative placement). Liquid sedative is injected through the anaesthetic agent line, into a porous rod in the Sedaconda ACD-S device where the sedative is vaporised. The vaporised sedative is then inhaled by the patient with the inspiration flow from the ventilator. With continued breathing, most of the sedative agent that has not been absorbed by the lungs is exhaled and adsorbed by an active carbon filter in the device. On further inhalation, the sedative is desorbed from the filter and transported back to the lungs, reducing the amount of sedative agent wasted. The Sedaconda ACD-S device also contains a bacterial and viral filter and a gas analyser port. This port is used to measure the exhalated sedative concentration in minimal alveolar concentration, a relative measure of the level of anaesthesia; or end-tidal concentration. Side stream or mainstream gas monitors, which can measure concentrations of carbon dioxide and anaesthetic gases, must be used to continually monitor sedation. These will need to be purchased separately if not already available. Sedaconda ACD-S is also recommended to be used with a gas scavenging system. This can be either by a passive system like the manufacturer's FlurAbsorb and FlurAbsorb-S products, or by an active scavenging system. This is usually built into the hospital system to capture volatile anaesthetics in operating theatres.

2.3 Sedaconda ACD-S can be used with most kinds of ventilator, except high-frequency ventilators. It was launched in the UK in 2017 and is a newer version of

the Sedaconda ACD-L device (available in the UK since 2005), which is now only available on request in the UK. Sedaconda ACD-S has a lower dead space of 50 ml (compared with 100 ml in the original device) and works with tidal volumes as low as 90 ml. The lower dead space allows Sedaconda ACD-S to be used on smaller adults or children who have smaller minute or tidal ventilation.

Care pathway

2.4 Adults who need sedation in intensive care have sedation with intravenous sedatives and analgesics, primarily propofol or midazolam with alfentanil, fentanyl or morphine. Children in intensive care usually have sedation with intravenous midazolam and morphine or fentanyl.

2.5 Volatile anaesthetics are not licensed for sedation in intensive care units but are licensed for inducting and maintaining anaesthesia in operating theatres. However, clinical experts reported that sedation is a continuum to anaesthesia. The off-label use of volatile anaesthetics in sedation is widely accepted and is not considered to be harmful. The choice of type of sedation and sedative agents to be used is made by trained clinicians.

2.6 The company has submitted a marketing authorisation request to the Medicines and Healthcare products Regulatory Agency for licensing isoflurane (Sedaconda) for inhaled sedation. Sedaconda isoflurane would be indicated for sedation of mechanically ventilated adults during intensive care and should only be administered by the medical device Sedaconda ACD-S. The regulatory approval is currently under review.

2.7 Expert advice suggests the technology is being used in the NHS as an alternative to intravenous sedation in:

- people who need mechanical ventilation and who are difficult to sedate (both adults and children)
- people who have severe bronchospasms that need mechanical ventilation (both adults and children)
- people who need mechanical ventilation after cardiac surgery and cardiac

arrest

- people in whom intravenous access is difficult or not possible.

Innovative aspects

2.8 The innovative aspect is that Sedaconda ACD-S allows conserved delivery of inhaled anaesthetic in an intensive care setting in both adults and children.

Intended use

2.9 Sedaconda ACD-S is intended to be used as an alternative to intravenous sedation for people who need sedation and are mechanically ventilated in intensive care. The Sedaconda ACD-S has a tidal volume working range of 200 ml to 800 ml when used in standard placement. Small tidal volume (90 ml) can be achieved when Sedaconda ACD-S is used in the alternative placement.

2.10 Sedaconda ACD-S is for use by healthcare professionals, trained to use inhalational anaesthetic drugs and recognise and manage any adverse effects, in an intensive care setting. In the NHS this would likely be intensivists, intensive care nurses and other technical staff.

Costs

2.11 Sedaconda ACD-S is available for purchase as a pack of 6 for £2,646. This includes component materials for 6 patient set-ups and approximately 5 treatment days each (30 treatment days in total). The costs used in the economic modelling were:

- Device cost: £660 per full course per patient (10.9 days' sedation)
- Consumables (FlurAbsorb, syringes, new fill adapter, measure line, Nafion tubing, accessories kit): £347.22 per patient

- Multi-gas analyser: £36.61
- Total cost of isoflurane administration: £110.78 per patient.

For more details, see the website for Sedaconda ACD-S.

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence

The main clinical evidence comprises 21 studies

3.1 The EAC assessed 21 full text comparative studies. Twelve were randomised controlled trials, 2 cross-over studies, 5 retrospective studies, 1 prospective study, and 1 study collected data prospectively for the Sedaconda ACD-S arm but used retrospective data for the intravenous arm. Fifteen abstracts identified were not included in the evidence review. The EAC focused on primary studies only and did not extract data from 1 meta-analysis to avoid duplication of data. There was no published evidence on using Sedaconda ACD-S in children.

3.2 All included studies were peer-reviewed, and none were done in the UK. The included studies covered 6 population groups:

- people after cardiac surgery (8 studies, 798 people)
- people after cardiac arrest having therapeutic temperature management (3 studies, 816 people)
- people with acute respiratory distress syndrome (2 studies, 88 people)
- people with various surgical indications (2 studies, 270 people)
- people having head and neck surgery who need a tracheostomy (1 study, 29 people)
- people with pulmonary disorders (1 study, 30 people)
- people with over 12 hour (1 study, 40 people) and 24-hour sedation needs (2 studies, 361 people).

For full details of the clinical evidence, see section 3 of the assessment report in the supporting documentation on the NICE website.

Clinical experts identified 3 particularly important clinical outcomes

3.3 The EAC, after consultation with clinical experts, identified 3 outcomes of particular clinical importance: time on mechanical ventilation, wake-up time and sedation efficiency. Other outcomes reported across the 21 included studies were: intensive care and hospital length of stay; cognitive and neurological status; cardiac, renal and hepatic markers and blood gas results.

Evidence shows that inhaled sedation using Sedaconda ACD-S leads to faster wake-up time and maintains adequate sedation, but time on mechanical ventilation is uncertain

3.4 Wake-up time, usually reported as extubation time (the time from stopping the sedative infusion to taking out the endotracheal tube), was measured in 6 studies and found to be significantly shorter in the volatile sedation arms compared with the intravenous arms across all the heterogeneous populations. The EAC concluded that sedation given using Sedaconda ACD-S offers benefit over intravenous sedation in terms of wake-up time. This is likely attributed to using the volatile sedatives that Sedaconda ACD-S allows to be used rather than the device itself.

3.5 Inhaled sedation using isoflurane delivered with Sedaconda ACD-S was non-inferior to propofol in maintaining adequate sedation (time spent at the desired sedation depth) without rescue medications in a large randomised clinical trial (n=301; Meiser 2021).

3.6 Eleven publications reported time on mechanical ventilation. The difference in time on mechanical ventilation between the volatile arms and the intravenous arms was uncertain because only 3 studies reported statistically significant

differences (matched analysis of Krannich [2017], Rohm [2008] and Rohm [2009]) and the rest of the studies found non-significant differences in time on ventilation.

There is uncertainty in the evidence on length of stay for inhaled sedation and intravenous sedation

3.7 All included studies were inconclusive about the measured outcomes for length of stay. The studies looked at different sedative drug combinations, and any differences between groups are likely to be because of these drug differences as well as the variables involved in patient treatment and could not be solely attributed to using the device.

Evidence is inconclusive for other outcomes that benefit patients

3.8 Eight publications reported on cognitive and neurological outcomes, 9 studies reported on cardiac, renal and hepatic biochemical markers and 6 studies reported on patient blood gas results. Most of the studies were not statistically significant in lowering the incidence of delirium, lowering organ-specific biomarkers and improving oxygenation compared with intravenous sedatives.

Cost evidence

The company's cost analysis model compares inhaled sedation using the Sedaconda ACD-S device with intravenous sedation

3.9 The company's cost model compared inhaled isoflurane with intravenous propofol. The cost model had a 30-day time horizon and included adult patients needing mechanical ventilation for 24 hours or longer in intensive care. The clinical input parameters included the mean body weight of people having sedation in intensive care, the time on mechanical ventilation (mean, in days) and the length of stay in intensive care (mean, in days). The company also submitted a scenario analysis that compared inhaled isoflurane with intravenous midazolam.

The EAC adapted this analysis to extrapolate the cost analysis in children. The EAC inputted an average body weight of 12 kg for a child but did not change the other clinical parameters. For full details of the cost evidence, see section 4 of the assessment report in the supporting documentation on the NICE website.

Sedaconda ACD-S device remains cost saving in the EAC's updated model

3.10 The EAC agreed with the company's cost model overall. The EAC noted that the time on mechanical ventilation and the length of stay in intensive care were based on the results of a post-hoc analysis done in a subset of people (n=177) from the original randomised clinical trial (n=301; Meiser 2021). This subgroup consisted of people that did not have their sedation approach switched after the 48-hour randomisation period. The EAC corrected some costs, added the cost of training for switching from intravenous to inhaled sedation and found that Sedaconda ACD-S remained cost saving by £3,833.76 per adult.

The company cost analysis results are robust but there is uncertainty around the clinical inputs that drive cost savings

3.11 Sensitivity analysis indicated that the cost analysis was robust to changes to drug doses, drug costs and to the addition of training costs with Sedaconda ACD-S. The EAC threshold analysis showed that, if time on mechanical ventilation is the same for both methods of sedation, inhaled sedation using Sedaconda ACD-S was cost saving compared with intravenous propofol when the duration of intensive care stay is reduced by 1.5 days. However, the length of stay in intensive care and time on mechanical ventilation were sourced from the post-hoc analysis in a subset of study patients from Meiser (2021). These outcomes were not the primary outcomes of the trial and they were not included in the publication.

Exploratory analysis suggests that inhaled sedation with Sedaconda ACD-S is cost saving in children

3.12 The EAC used the cost analysis model comparing inhaled isoflurane with intravenous midazolam to explore the economic impact of using inhaled sedation in children. Clinical parameters were informed from Krannich (2017). The cost analysis estimated a cost saving of £2,837.41 per child. The clinical experts considered it reasonable to assume that children have a similar response to intervention to adults.

4 Committee discussion

Clinical-effectiveness overview

Sedaconda ACD-S is an efficient delivery system for using inhaled sedation in an intensive care setting without needing a scavenging system

4.1 Experts explained that Sedaconda ACD-S allows delivery of inhaled sedation in an intensive care setting without the need for a gas scavenging system. The alternative would be to use an anaesthetic trolley or machine used for general anaesthesia with a gas scavenger, but the clinical experts said that intensive care units are not routinely equipped with scavenging systems. The experts also said that before Sedaconda ACD-S was implemented, patients needing inhaled sedation with vaporisers had to be transferred to operating theatres where scavenging systems for volatile anaesthetics are built into the hospital system (that is, the exhaust port of the anaesthetic circuit or ventilators are connected to the operating theatre scavenging system). The committee concluded that Sedaconda ACD-S is an efficient delivery system for inhaled sedation in an intensive care setting not equipped with scavenging systems.

No published clinical evidence is available on using Sedaconda ACD-S in children

4.2 Although no clinical evidence in children was presented to the committee, a clinical expert said that Sedaconda ACD-S has been used for 15 years in their paediatric intensive care and it is an effective way of delivering inhaled sedation. No major contraindications exist for using inhaled sedation in children, apart from malignant hyperthermia susceptibility. The EAC extrapolation of the efficacy of inhaled sedation from adults to children considered it reasonable to assume that children respond similarly to the intervention to adults. The committee accepted the assumption and concluded that Sedaconda ACD-S is a useful option for

allowing delivery of volatile sedation in children.

Evidence shows that inhaled sedation using Sedaconda ACD-S is consistently associated with faster wake-up time

4.3 Six clinical studies (5 randomised controlled trials [RCTs] and 1 comparative non-RCT) reported statistically significant differences in wake up between the intravenous sedation and the inhaled sedation using Sedaconda ACD-S. The EAC reported that the extubation time is likely dependent on the type of sedative agent used rather than using the Sedaconda ACD-S device itself. Nevertheless, the clinical experts agreed that using inhaled sedation delivered with Sedaconda ACD-S leads to more predictable wake-up time in people having sedation for a long time and this is useful when patients need to be woken quickly to make clinical assessments.

The evidence for replacing intravenous sedation with inhaled sedation delivered by Sedaconda ACD-S is uncertain because of heterogeneity

4.4 The 21 studies had heterogenous patient populations that included people after cardiac surgery (9 studies), people after cardiac arrest having therapeutic temperature management (3 studies), people with acute respiratory distress syndrome (2 studies), patients with various surgical indications (2 studies), people having head and neck surgery who need a tracheostomy (1 study), people with pulmonary disorders (1 study) and people with over 12 hour (1 study) and 24-hour sedation needs (2 studies). The committee concluded that there was uncertainty about which specific patient population would have the most clinical benefit from using inhaled sedation. But, based on expert advice, it agreed that Sedaconda ACD-S should be an available option for delivering inhaled sedation in intensive care settings when considered clinically appropriate.

Length of stay in intensive care and the time on mechanical ventilation depend on the underlying condition

4.5 Clinical experts said that the length of stay in intensive care and the time on mechanical ventilation are outcomes that depend on a patient's underlying condition. The committee understood that this means it is particularly challenging to show evidence of benefit for length of stay in the context of a clinical study. However, clinical experts explained that using inhaled sedation can reduce the time on mechanical ventilation and shorten the time the patient stays in intensive care after extubation by some hours. The committee concluded that type of sedation used was likely to only have a small effect on the length of stay in intensive care or time on mechanical ventilation.

Sedaconda ACD-S delivered inhaled sedation is useful for sparing intravenous agents during emergency situations

4.6 Clinical experts reported that during the SARS-CoV-2 pandemic, inhaled sedation using Sedaconda ACD-S has been used to preserve intravenous sedative agents that could potentially be in limited supply. The committee concluded that Sedaconda ACD-S is a useful option to spare intravenous sedative agents during unexpected emergency situations when a large number of people need mechanical ventilation such as in the recent SARS-CoV-2 pandemic.

Side effects and adverse events

Adverse events associated with using Sedaconda ACD-S are uncommon but inhaled sedation is contraindicated in some patients

4.7 The committee heard that there were no reported safety concerns around using the Sedaconda ACD-S device. It understood that people in intensive care have highly complex needs and as such most adverse events will be because of the different medications used to achieve sedation, rather than using the Sedaconda

ACD-S device itself. The only adverse event linked to the device is blockage, which can also happen in heat and moisture exchangers at a similar rate. There are adverse events associated with using volatile anaesthetic drugs. Volatile anaesthetics are contraindicated in patients with malignant hyperthermia susceptibility. Clinical experts said that using volatile anaesthetics in pregnant women, especially in the first trimester, involves clinical judgement in the risk/benefit balance to the unborn fetus and risk to the woman. The committee concluded that using Sedaconda ACD-S is safe.

4.8 There are other adverse events associated with using volatile anaesthesia listed in the BNF.

Other patient benefits or issues

Some evidence shows that inhaled sedation seems to be beneficial to patients

4.9 Clinical experts explained that there are benefits for patients when volatile sedatives are used, such as liver, lung and cardiac protection. The EAC reported better awareness quality (1 study) and lower incidence of delirium (1 study) in the Sedaconda ACD-S group compared with the intravenous group.

Clinical experts suggest Sedaconda ACD-S may be more beneficial in some patient subgroups

4.10 The clinical experts agreed that inhaled sedation is likely to be beneficial in the following subgroups:

- people who are difficult to sedate
- people with acute bronchospasm
- people with acute respiratory distress syndrome
- people having multiple sedative agents

- people with overdose who need a fast wake up
- people who need neurological assessment after cardiac arrest
- older people at high risk of delirium
- children with resistant status epilepticus
- people with difficult intravenous access
- people with hypoxia.

NHS considerations overview

Children and adults having sedation with inhaled volatiles using Sedaconda ACD-S can be transported for transfer within hospital

4.11 While uncommon, clinical experts said that patients can be transported for additional tests or procedures within hospitals using Sedaconda ACD-S. If transport ventilators do not have a scavenging system built in, canisters containing activated carbon, such as FlurAbsorb, can be added to the transport trolley.

Training

Only healthcare professionals trained in inhaled anaesthetic drugs can use Sedaconda ACD-S

4.12 The clinical experts said that the company offers face-to-face training and 3 accredited e-learning modules for intensive care nurses and intensivists. The clinical experts noted that the company training resources were highly effective.

Environmental impact

Sedaconda ACD-S may minimise the release of greenhouse gases

4.13 Volatile anaesthetic drugs are potent greenhouse gases. However, the company claims that the conservation of gases within Sedaconda ACD-S and using scavenging systems can reduce the release of gases into the atmosphere. The company also claims that Sedaconda ACD-S would be associated with a lower consumption of volatile sedatives compared with other delivery systems for volatile sedation. The committee was concerned about the environmental effect of increased use of anaesthetic gases and was unsure about the company claims on the efficacy of their scavenging systems. They noted that there was a lack of evidence comparing Sedaconda ACD-S with other vaporisers used for delivering volatile sedation. Nevertheless, the committee concluded that there was potential that Sedaconda ACD-S would minimise the release of greenhouse gases.

Cost modelling overview

Economic modelling is limited by the uncertainty in some clinical inputs and its relevance to the NHS clinical pathway

4.14 The committee accepted the EAC's changes to the company model, which showed that inhaled sedation delivered with Sedaconda ACD-S was cost saving when compared with intravenous sedation. However, the committee agreed that the modelled clinical scenario comparing intravenous sedation with inhaled sedation using Sedaconda ACD-S does not reflect the average UK duration of time on mechanical ventilation in intensive care, so has limited applicability (mean time on mechanical ventilation used in the model was 10.9 days whereas experts reported 5 days to 7 days in the UK). The committee also noted that the clinical evidence used to populate the model had substantial limitations, which affected the robustness of the model and the certainty of the results.

Main cost drivers

Because of the outcomes measured in the study, the cost savings are not certain

4.15 The committee concluded that the evidence about length of stay in intensive care and the time on mechanical ventilation reported in the post-hoc analysis from the Meiser (2021) trial was weak. Because these inputs were the key drivers that led Sedaconda ACD-S to be cost saving, the conclusion of the economic modelling was uncertain. Despite these uncertainties, the committee noted that Sedaconda ACD-S has a low threshold to be cost saving. The EAC's threshold analysis found that Sedaconda ACD-S was cost saving when duration of non-ventilated days in intensive care was only a few hours shorter than that of intravenous sedation (2.5 hours to 5 hours). The committee concluded that Sedaconda ACD-S was likely to be the cost saving.

Scenario analyses

Sedaconda ACD-S remains cost saving in all analysed scenarios

4.16 The committee noted that Sedaconda ACD-S remained cost saving in all scenario analyses presented. However, the robustness of the estimates of length of stay in intensive care and time on mechanical ventilation were uncertain. The committee concluded that the uncertainty in the clinical inputs could lead to inaccuracies in the cost savings calculated.

Cost savings

Sedaconda ACD-S is likely to be cost saving compared with intravenous sedation in both adults and children

4.17 The EAC reported that in modelling, Sedaconda ACD-S is cost saving compared

with intravenous sedation by £3,833.76 per adult patient and by £2,837.41 per child. The committee concluded that Sedaconda ACD-S was likely to be cost saving compared with propofol or midazolam but recognised the limitations in the underpinning clinical evidence which made the size of the potential cost savings uncertain.

Further research

Further good quality research is needed to address uncertainties about the population for whom Sedaconda ACD-S is most appropriate

4.18 The committee recognised that Sedaconda ACD-S is an efficient and safe way of delivering volatile anaesthetics in intensive care units. It noted that, although there is clear evidence that inhaled sedation using Sedaconda ACD-S can lead to faster wake-up time, the evidence around the decrease in length of stay in intensive care and time on mechanical ventilation are more difficult to understand because of the complexity of the underlying conditions of people in the intensive care unit. The committee concluded that further research is needed to address uncertainties in the appropriate population where Sedaconda ACD-S would be recommended for use compared with standard care.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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Update information

Minor changes since publication

December 2025: Medical technologies guidance 65 has been migrated to HealthTech guidance 607. The recommendations and accompanying content remain unchanged.

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