NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Report for Review Decision

Review of MTG14: Ambu aScope2 for use in unexpected difficult airways

This guidance was issued in July 2013.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However, the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Review decision

Amend the guidance to refer to the new version of the technology and to include the revised cost saving estimates and do not consult on the proposal to amend the guidance.

2. Original objective of guidance

To assess the case for adoption for Ambu ascope2 for use in unexpected difficult airways.

3. Current guidance

1.1 *The case for adopting the Ambu aScope2 for use in people with unexpected difficult airways needing emergency intubation is supported by the evidence. This shows that the Ambu aScope2 is an acceptable alternative, where a multiple-use fibre optic endoscope is unavailable. There are also advantages during replacement of dislodged tracheostomy tubes in the intensive care setting. Making the Ambu aScope2 available for use across settings is likely to improve outcomes and patient safety.*

1.2 Adoption of the Ambu aScope2 is supported by cost modelling for a range of common clinical settings in which there is no multiple-use endoscope or where

existing multiple-use endoscopes are not available. These settings are: isolated units, operating theatre units, and intensive care units, where the uses include the repositioning of displaced tracheostomy tubes. Although there were some uncertainties in the cost modelling, cost savings are likely in all settings modelled. The amount saved will depend on the number of intubations performed and on the number (if any) of existing multiple-use fibre optic endoscopes in use.

1.3 The details of the cost modelling and estimated cost savings for each clinical setting are described in sections 5.16–5.20. As an example of the clinical area where savings could be greatest, using the Ambu aScope2 in the intensive care setting is estimated to be cost saving (£3128 per year) when more than 700 intubations are conducted each year, when there are 2 or fewer existing multiple-use fibre optic endoscopes, and assuming that 5% of intubations are difficult

4. Rationale

No new evidence was identified which, if the guidance were updated, would be likely to change the recommendations. However, the Ambu ascope2 has been superseded by the third and fourth generation devices and is no longer available. We are therefore proposing to amend the guidance and, because there have been significant changes in relevant costs since the guidance was published, consult on the proposal.

5. New evidence

The search strategy from the original assessment report was re-run, including an updated search in March 2019. References from May 2012 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The Ambu ascope2 device assessed in MTG14 is no longer marketed in the UK. It was superseded by Ambu aScope 3 which was launched by the time MTG14 was published. Ascope3 was described in an adoption resource and is currently available in the NHS but no new supplies will be made.

The Ambu ascope4 is the latest version of the device and has additional features compared with Ambu aScope 2 which are summarised in appendix 2. The company

noted that these features make ascope4 suitable for a broader range of procedures than predecessor devices. All versions of Ambu aScope are CE marked.

Despite the changes, the ascope4 performs an essentially similar function to the one assessed for the indications in the scope of MTG14. The FDA considered that Ambu aScope4 is substantially the same as existing devices. The External Assessment Centre asked 4 clinical experts about the changes, 3 of whom thought that ascope2 is similar to ascope4 and 1 expert didn't respond.

5.2 Clinical practice

Clinical experts noted that Ambu aScope is currently used in some settings considered in MTG14 such as critical care areas, intensive care units, and operating theatres. They also noted its use in patients at risk of transmitted infections from reusable devices. They also confirmed that the clinical pathway for patients with unexpected difficult airways has not changed since the original NICE guidance was published.

There is no NICE pathway for patients with unexpected difficult airways was identified. The Difficult Airway Society published a guideline on the management of unanticipated difficult intubation in adults (Frerk et al. 2015). This guideline describes a 4-step plan of which laryngoscopy is 'plan A'. It notes that video laryngoscopes provide an improved view compared with conventional direct laryngoscopy and this may influence the chance of successful tracheal intubation.

5.3 NICE facilitated research

Not applicable

5.4 New studies

The EAC used the results from the NICE literature search and information from the company to assess new relevant evidence. It presented the results from 15 papers reporting 12 studies in its review. There are 6 comparative studies including 5 randomised controlled trials (Koessler et al. 2015, Lenhardt et al. 2014, Krugel et al. 2013, Kristensen and Fredensborg 2013, Chan et al. 2015) and 1 retrospective comparative review (Marshall et al. 2017). There are also 6 single arm studies (Khalifa 2015, Jacob, et al. 2016, Sowers, N. and G. Kovacs 2016, Reena, 2017, Farrant. J. 2014, Yao, J., and Rao, D. 2017). The trial reported in the Kristensen and Fredensborg (2013) study was included in the original guidance as academic in confidence and is not considered further here.

The randomised controlled trials (RCTs) were done across Europe, USA and Australia and the retrospective review was done in Singapore.

Chan et al. (2015), n= 60, compared Ambu ascope2 with a multiple-use fibre optic endoscope in anaesthetised adult patients undergoing elective surgery. Patients with known difficult airways were excluded from the study. This study reported that on a global rating scale of 1 to 5 (5 being the best) Ambu aScope2 had a rating of 3 compared to 2 for the fibre optic endoscope (p = 0.14). Ambu ascope2 was significantly easier to use (overall use score; p = 0.0003). On an image quality scale of 1 to 5 (1 being the best) Ambu ascope2 was rated worse (2 compared with 1) than the fibre optic endoscope (p = 0.05). It had a marginally higher success rate (97% vs 93% but longer total intubation time (75.4 vs 71.2 seconds) neither of which differences were statistically significant.

Koessler et al. (2015), n= 17 compared Ambu ascope2 with an Olympus multiple-use fibre optic endoscope in adult patients with not more than 2 criteria for difficult airways. Results of this study showed that fibreoptic insertion of the Ambu aScope took 64 seconds versus 42 seconds with an Olympus (p=0.26). User satisfaction was noted to be excellent in both groups.

Krugel et al. (2013), study compared Ambu aScope 2 vs the conventional fibrescope for tracheal intubation in patients (with cervical spine immobilisation by a semirigid collar undergoing elective surgery requiring general anaesthesia and tracheal intubation. Patients with known difficult airways were excluded from the study. The results reported a longer time from start to observing end-tidal CO2 on capnography with Ambu aScope2 (70 vs 50 secs with Pentax device, p = 0.0003). A jaw-thrust manoeuvre was needed significantly more often in the Ambu aScope2 group compared with the fibrescope group (32% vs 10%, p = 0.01). Fewer patients required 2 attempts in the aScope 2 arm (4 vs 8, p = 0.22). Quality of vision was significantly better with the fibrescope than with the ascope2 (p = 0.0001). Ease of intubation was ‘easy’ for 62% of procedures in the aScope 2 vs 76% with the Pentax device, p = 0.19

The Lenhardt et al. (2014) study, reported that 140 patients with anticipated difficult airways undergoing elective or urgent surgery were randomised to rigid stylet (control) or Ambu aScope2. All patients were intubated. Time to intubation was similar between groups, Ambu aScope had a median of 71 seconds and the control arm 66 seconds (p=0.35). 4 patients in the control arm could not be intubated with video laryngoscope and rigid stylet. These were successfully intubated with Ambu aScope2. Ease of intubation was similar in both groups, p = 0.5.

Marshall et al. (2017), included patients undergoing flexible bronchoscopy in the ICU were studied, comparing the Ambu aScope3, n=71, with a multiple-use fibre optic endoscope, n= 22. Ascope3 had a shorter set up time (10 mins vs 66 mins, p = 0.10) and required fewer staff.

Four of the 6 single arm studies identified were case studies which reported the successful use of the Ambu ascope3 in patients with difficult airways. Two of these studies noted that the patients had expected difficult airways.

The EAC concluded that the results from the comparative studies suggest that the Ambu aScope 2 device is as effective as its comparators in conducting procedures successfully. The main weaknesses of the Ambu aScope2 device were its visual display and absence of suction resulting in blurring and more need to clean the device. These may account for some of the slightly longer procedure times. Both considerations were noted in MTG14. The EAC noted that the Ambu ascope4 has new features to address these issues but there is no comparative evidence of the effectiveness of the Ambu ascope4.

5.5 Cost update

Background

Evidence assessment and decision making during the original guidance development were complex and challenging. At its first meeting, the committee was unable to make provisional recommendations, and asked the EAC to carry out additional work. The EAC revised the company's cost model to explore the costs in 5 scenarios with differing clinical settings and access to multiple use fibre optic endoscopes:

Scenario A: without multiple-use fibre-optic endoscopes

1. an small hospital unit

Scenario B: with multiple-usable fibre-optic scope

2. an obstetric unit
3. an operating theatre unit
4. an intensive care unit (ICU)
5. displaced tracheostomy tubes (in an intensive care unit).

The Committee judged that there were likely to be cost savings in all the scenarios modelled, based on the following assumptions about the number of intubations or tracheostomies performed each year:

- Isolated hospital unit with no multiple-use endoscopes: 95 intubations.
- Obstetrics unit with no multiple-use endoscopes: 80 intubations.
- Obstetrics unit with 1 multiple-use endoscope: 500 intubations.
- Operating theatre unit with 2 multiple-use endoscopes: 1250 intubations.

- Intensive care units with 2 multiple-use endoscopes: 50 intubations (20% difficult intubation probability) and 250 intubations (5% difficult intubation probability).

- Replacement of displaced tracheostomy tubes (assuming a 15% per year displacement rate) in an intensive care unit with 2 multiple-use endoscopes: 70 tracheostomies.

Guidance review cost update

The EAC reviewed and updated the costs in the original cost modelling as described in table 1.

Table 1

Parameter	Point estimate and source in EAC's cost update (2017/18 prices)				Value in original EAC model (2010/11 prices)	% change
	Setting with no scope	Operating theatre	ICU	Obstetrics		
Cost of Ambu aScope4	**£199.80** (Ambu Ltd)				£179	12%
Cost of monitor	**£1,699.00** (Ambu Ltd)				£799	113%
Cost of litigation due to harm from intubation failure	**£214,756**				£134,000	60.3%
Mean length of stay due to intubation failure	**3.4 days** (HES 2016/7 Code T88.4)				2 days	70%
Length of stay in ICU & general ward	**50/50** (Assumption by NY EAC)				100% ICU	-50%
Mean cost per day	**£980** (NHS Reference costs 2016/17)				£1,213	-19.2%
Brain damage cost per year	**£72,711** (Turner-Stokes et al, 2016)				£36,320	100%
Life expectancy of brain damaged patients	**13.0 years** (HES 2016/7, ONS 2017 Shavelle, et al., 2007)*			**27.7 years** (same sources)	12.5 and 26.4 years	4% to 5%

The updated costs were applied to scenario A, which is a small hospital unit without re-usable fibre-optic scope provision and scenario B4, in the ICU setting with multiple use fibre-optic endoscope provision.

The original models for the other scenarios (obstetrics, operating theatres and displaced tracheostomy in an ICU setting with multiple use scopes) could not be executed because the original files could not be retrieved from the EAC authors (the University of Birmingham) whose contract with NICE ended in March 2017.

The EAC carrying out the guidance review work (YHEC) updated the cost model for these other scenarios by making informed judgements on the implications of the updated costs.

There was a substantial increase in costs of harm, specifically in the costs of managing patients with brain damage and settling claims in relation to harm caused by intubation failure The EAC explained that the 60% increase in the cost of litigation due to harm from intubation failure is based on the change in average value of NHS claims between 2010/11 and 2017/18. The 100% increase in the cost of brain damage per year is based on data from an analysis presented by Turner-Stokes et al. (2016). This analysis explored 5 years of data (2010 to 2015) from the UK Rehabilitation Outcomes Collaborative national clinical database and reported the annual cost to manage people with high dependency brain injuries as £70,341. The EAC updated this value from 2015/16 prices to 2017/18 prices for use in the cost model update. Parameters for the probability of 'more than temporary harm' given an intubation failure and the probability that such a case results in a successful litigation case against the NHS have not changed.

The EAC also increased the mean length of stay due to intubation failure to 3.4 days (originally 2 days) and changed the assumption on length of stay in ICU and general ward to a 50/50 split (previously 100% ICU) because patients are unlikely to be discharged home directly from ICU. The life expectancy of brain damaged patients was increased slightly to 13.0 years (from 12.5) for all patients other than pregnant women, for whom 27.7 years of remaining life was used (previously 26.4 years respectively).

Results

Applying the updated costs for a non-ICU setting with no multiple-use fibre optic endoscopes showed that net savings per unit doubled to £1,638 (from £749) when excluding the cost of monitor and £1,433 (£653) when the cost of monitor was included. The increased saving is largely driven by the increased cost of harms. Ambu aScope4, including cost of the monitor, is now predicted to be cost saving at a threshold of around 85 intubations per year. This is lower than the threshold of 115 reported by in the original MTG.

As previously mentioned, due to the limitations with the model, thresholds for scenario 2 can only be updated for scenario B4: with multiple-usable fibre-optic scope in an intensive care unit (ICU). The EAC estimated an annual cost saving from purchasing a 5 scope package in an ICU setting with 2 reusable fibrescopes

with and without taking the cost of the monitor into consideration. When not including the cost of the monitor the annual cost saving is estimated to be £6,632 (from £3,128). When including the cost of the monitor the annual cost savings are estimated to be £6,428 (from £3,031). The EAC concluded that in the other clinical scenarios (B2, B3 and B5), with the new cost parameters the Ambu aScope4 is very likely to also be cost saving and at lower thresholds compared with those outlined in section 5.22 of the original MTG, except in the obstetrics setting where the impact is unknown.

6. Summary of new information and implications for review

The new evidence identified since publication of the original guidance supports the recommendations made in the original guidance and highlights that more patient-based studies have been carried out with the device. The EAC and clinical experts concluded despite material changes to Ambu ascope4, the evidence on the earlier generation of the device is generalisable to the ascope4.

The revision to the cost model for scenarios with executable functionality showed that based on the cost of the new device, Ambu ascope4 remains cost saving. The review proposal is to amend the guidance to refer to the new version of the technology and to include the revised cost saving estimates. The title of the guidance will also be revised to refer to the current version of the technology Ambuascope4.

7. Implications for other guidance producing programmes

None highlighted at internal consultation.

8. Implementation

The EAC noted that a national survey of videolaryngoscopy in the UK, including Ambu aScope, which closed in January 2014, received responses from 164 units (Cook 2017). The authors stated that videolaryngoscopy was available in 91% of operating theatres, 50% of ICUs and obstetric theatres, with lower availability in emergency departments and paediatric anaesthesia units. The authors also noted that there was an increase in the incidence of difficult or failed intubation in settings where availability of videolaryngoscopy was lower.

The company advised NICE that, UK and world sales figures have shown an upward trend between 2013/14 and 2017/18.

9. Equality issues

No equality issues were identified in the original guidance.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below

Options	**Consequences**	**Selected – 'Yes/No'**
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	*Yes*
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	*No*
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	*No*
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	*No*

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below

Options	**Consequences**	**Selected – 'Yes/No'**
Transfer the guidance to the 'static guidance list'	The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review.	-
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	-
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	-

Appendix 2 – supporting information

Registered and unpublished trials

Trial name and registration number	Details
Prospective Non-interventional Evaluation of Intubation and Intensive Care Use of the New aScope™ 4 Broncho and aView NCT03294213	To assess user perception of functionality Prospective, cohort study in Germany (n= 176) Status: Completed January 2018. No results posted
Comparison of Efficiency Between I-gel Blind Intubation and I-gel Bronchoscopic Intubation During Resuscitation NCT02411422	To assess time for first intubation attempt using Ambu-aScope vs Macintosh laryngoscope. Randomised cross-over trial (n=23). Korea Status: completed April 2015
Video-Laryngoscope Alone or With Bronchoscope for Predicted Difficult Intubation (COMBO) NCT03080896	To assess time to successful intubation. Randomised study with cross over (n=80). USA Started April 2017; estimated completion December 2019
Clinical Validation Trial of a Single-use Bronchoscope (Ambu aScope 4) NCT03419546	Observational, cohort study (n=216) Status: Completed July 2018

Technical specifications for aScope 2, 3 and 4

A) *Optical system*	aScope2	aScope3 Slim	aScope3 Regular	aScope3 Large	aScope4 Slim	aScope4 Regular	aScope4 Large
Field of view	80°	85°	85°	85°	85°	85°	85°
Direction of View	0° (forward viewing)	0° (forward viewing)	0° (forward viewing)	0° (forward viewing)	0° (forward viewing)	0° (forward viewing)	0° (forward viewing)
Depth of Field	9 mm ~ 18 mm (0.35 – 0.71 inch)	8-19 mm	8-19 mm	8-19 mm	6-50 mm	6-50 mm	6-50 mm
Illumination Method	LED (LTW-C28DS5-SE)	LED	LED	LED	LED	LED	LED
B) Insertion portion	aScope2	aScope3 Slim	aScope3 Regular	aScope3 Large	aScope4 Slim	aScope4 Regular	aScope4 Large
Bending section	Up/down 120° +/- 10°	130° up, 130° down°	150° up, 130° down°	140° up, 110° down°	180° up, 180° down	180° up, 180° down	180° up, 160° down
Insertion cord diameter	5.3 mm	3.8 mm (0.15")	5.0 mm (0.20")	5.8 mm (0.23")	3.8 mm (0.15")	5.0 mm (0.20")	5.8 mm (0.23")
Distal end diameter	5.3 mm	4.2 mm (0.16")	5.4 mm (0.21")	6.2 mm (0.24")	4.2 mm (0.16")	5.4 mm (0.21")	6.2 mm (0.24")
Maximum diameter of insertion portion	5.4 mm (0.21")	4.3 mm (0.17")	5.5 mm (0.22")	6.3 mm (0.25")	4.3 mm (0.17")	5.5 mm (0.22")	6.3 mm (0.25")
Minimum endotracheal tube size (inner diameter)	6.0 mm	5.0 mm	6.0 mm	7.0 mm	5.0 mm	6.0 mm	7.0 mm
Minimum double lumen tube size (inner diameter)	N/A	37 Fr	41 Fr	N/A	37 Fr	41 Fr	N/A
Working length	630 mm (24.8 „)	600 mm (23.6")	600 mm (23.6")	600 mm (23.6")	600 mm (23.6")	600 mm (23.6")	600 mm (23.6")
C) Channel	aScope2	aScope3 Slim	aScope3 Regular	aScope3 Large	aScope4 Slim	aScope4 Regular	aScope4 Large
Average inner diameter	0.8 mm	1.2 mm (0.047")	2.2 mm (0.087")	2.8 mm (0.110")	1.2 mm (0.047")	2.2 mm (0.087")	2.8 mm (0.110")
Minimum ınstrument channel width	0.8 mm (Luer channel)	1.2 mm (0.047")	2.0 mm (0.079")	2.6 mm (0.102")	1.2 mm (0.047")	2.0 mm (0.079")	2.6 mm (0.102")
D) Suction connector	aScope2	aScope3 Slim	aScope3 Regular	aScope3 Large	aScope4 Slim	aScope4 Regular	aScope4 Large
Connecting tube inner diameter range	Ø4 mm-Ø10 mm	Ø7mm +/- 1mm	Ø7mm +/- 1mm	Ø7 mm +/- 1 mm	Ø7 mm +/- 1 mm	Ø7mm +/- 1mm	Ø7mm +/- 1mm

Other changes			
	aScope2	**aScope3 Slim aScope3 regular aScope3 large**	**aScope4 Slim aScope4 Regular** aScope**4 large**
Date of availability	April 2011	April 2013	November 2017
Mode of action	It is used to visualise the airway and then to aid in the placement of an endotracheal tube directly or through an intubating laryngeal mask. It is a portable device that can be used wherever a flexible endoscope is needed for airway management. The Ambu aScope2 uses video camera technology to create the image that is displayed on the high-resolution aScope monitor.	Unchanged	Unchanged
Indications	Visual guidance during intubation	Unchanged	✓Double lumen tube (DLT) that need inspection for correct placement, ✓ Airway inspection, ✓ Percutaneous dilatory tracheostomy (PDT), ✓ Intubation, ✓ Secretion and haemorrhage management, ✓ Bronchial wash (BW) and Broncoalveolar lavage (BAL).

Appendix 3 – changes to guidance

Proposed amendments to original guidance

Section of MTG	Original MTG	Proposed amendment
Throughout the document except where reporting studies	Ambuascope2	Ambu aScope4 Broncho
1.3	The details of the cost modelling and estimated cost savings for each clinical setting are described in sections 5.16–5.20. As an example of the clinical area where savings could be greatest, using the Ambu aScope2 in the intensive care setting is estimated to be cost saving (£3128 per year) when more than 700 intubations are conducted each year, when there are 2 or fewer existing multiple-use fibre optic endoscopes, and assuming that 5% of intubations are difficult.	The details of the cost modelling and estimated cost savings for each clinical setting are described in sections 5.16–5.20. Section 5.21 presents the details of the revised cost modelling. As an example of the clinical area where savings could be greatest, using the Ambu aScope4 in the intensive care setting is estimated to be cost saving (~~£3128~~ £6,632 per year) when more than 700 intubations are conducted each year, when there are 2 or fewer existing multiple-use fibre optic endoscopes, and assuming that 5% of intubations are difficult.[2019]
Description of technology		
2.1	The Ambu aScope2 (Ambu Ltd) is a sterile, flexible, disposable device that is used to overcome difficulties with endotracheal intubation in patients with difficult airways. It is used to visualise the airway and then to aid in the placement of an endotracheal tube, either directly or through an intubating laryngeal mask. It is a portable device that can be used wherever a flexible fibre optic endoscope is needed for airway management. This may be in anaesthetic rooms, critical care or emergency departments or in other areas of hospitals where emergency airway management is undertaken. The Ambu aScope2 can also be used to aid	The Ambu aScope4 Broncho (Ambu Ltd) is a sterile, flexible, disposable device available in 3 sizes (slim, regular and large) of which the slim and regular sizes are indicated for difficulties with endotracheal intubation in patients with difficult airways. It is used to visualise the airway and then to aid in the placement of an endotracheal tube, either directly or through an intubating laryngeal mask. It is a portable device that can be used wherever a flexible fibre optic endoscope is needed for airway management. This may be in anaesthetic rooms, critical care

	percutaneous dilatational tracheostomy and to check the position and patency of airway devices such as endotracheal tubes, double lumen tubes and tracheostomy tubes. The Ambu aScope2 is too large to pass through an Aintree catheter if one is being used.	or emergency departments or in other areas of hospitals where emergency airway management is undertaken. The Ambu aScope4 can also be used to aid percutaneous dilatational tracheostomy and to check the position and patency of airway devices such as endotracheal tubes, double lumen tubes and tracheostomy tubes. The slim version of the Ambu aScope4 Broncho can pass through an Aintree intubating catheter if one is being used.
2.2	The Ambu aScope2 system consists of 2 components – a single-use aScope (endoscope) and an accompanying aScope monitor for displaying the images. These are supplied together. The Ambu aScope2 uses video camera technology to create the image which is displayed on the 640×480 pixel aScope monitor. The portable monitor indicates the rechargeable battery capacity (claimed maximum 2 hours) and also has a video output to transfer images to a larger monitor or recording device. The 2 components are used together and must therefore be available in the same location for the system to be effective. The single-use endoscopes are supplied sterile and ready for use. The monitor is re-usable. During procedures, the monitor can be powered by either battery or mains and is designed to be connected to the mains to recharge at other times.	The Ambu aScope4 Broncho system consists of 2 components – a single-use aScope (endoscope) and an accompanying aScope monitor for displaying the images. These are supplied together. The Ambu aScope4 Broncho uses video camera technology to create the image which is displayed on the 800×480 pixel aScope monitor. The portable monitor indicates the rechargeable battery capacity (claimed minimum of 3 hours) and also has a video output to transfer images to a larger monitor or recording device. The 2 components are used together and must therefore be available in the same location for the system to be effective. The single-use endoscopes are supplied sterile and ready for use. The monitor is re-usable. During procedures, the monitor can be powered by either battery or mains and is designed to be connected to the mains to recharge at other times.
2.3	The Ambu aScope2 has a Luer channel of 0.8 mm diameter that can be used for injecting topical anaesthetic or, by attaching a flow connector, to apply an air or oxygen flow. The purpose of this is to direct secretions away from the tip of the	The Ambu aScope4 Broncho has a working channel of 1.2 mm – 2.6 mm diameter, depending on size, that can be used for instillation of fluids (saline and topical anaesthesia), suction and

	Ambu aScope2; it is not designed for oxygenation or ventilation or therapeutic procedures such as biopsy. The Ambu aScope2 also has a polymer-clearing membrane (ClearLens) that covers the lens, which eases removal of secretions from the lens	insertion of endoscopic accessories. The suction port is designed to remove secretions.
Cost considerations		
5.27		For the guidance review, the external assessment centre revised the model to reflect 2018 costs. Further details of the cost parameter changes are in the cost update report. The external assessment centre applied the revised cost of the device and other costs to the cost model for settings with no multiple-use fibre optic endoscopes available and reported that net savings doubled to £1,638 (previously £749) with the cost of the monitor included and £1,433 (previously £653) when the cost of the monitor was deducted. This increase in cost savings is because of the increase in the cost of harms. It is also considered it plausible that these savings will be achieved at lower thresholds than the 95-115 intubations noted in section 5.16. The EAC also applied the revised costs to an ICU setting. It reported that that cost saving in this setting also doubled to £6,632.

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