ITT – ATTACHMENT 4B

FRAMEWORK AGREEMENT SPECIFICATION
AIRWAY MANAGEMENT PRODUCTS AND ASSOCIATED EQUIPMENT

1. Introduction

1.1. The Framework Agreement is for the supply of Airways Products and Associated Consumables and Accessories for the Airway Management of patients to ensure breathing and respiration.

1.2. The Framework Agreement is for the following Lots:

Lot Number	Lot Title
1	Laryngoscopes, Video Laryngoscopes, Tracheal Intubation Equipment, Single Use Upper Airway Devices, Single use Bronchoscopes and Single Use Flexible Intubating Endoscopes and Related Accessories
2	Endotracheal Tubes, Endobronchial Tubes and Blockers, Tracheostomy Tubes, Supraglottic Airways and Simple Airway Adjuncts
3	Breathing Systems Circuits and Accessories
4	Humidification and Filtration (HME's, HMEF's, Bacterial and Viral Filters)

1.3. Full technical specifications of the product lines awarded to the Framework Agreement (each a "**Technical Specification**" and together the "**Technical Specifications**") must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

1.3.1. Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.

1.3.2. If changes to the Technical Specification of any product line awarded to the Framework Agreement mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement.

1.3.3. NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.4. This Framework Agreement Specification makes reference to a number of standards and legislation. The list of standards and legislation is not intended to be exhaustive and any relevant standards and legislation which applies to the Framework Agreement (even if not stated) must be complied with by Applicants (together with those listed in this Framework Agreement Specification the "**Standards and Legislation**").

1.5. Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).

1.6. Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement ("**Suppliers**") to NHS Supply Chain on request during the term of the Framework Agreement; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

2. Criteria applicable across all product lines

2.1. Standards and Legislation

STANDARD AND LEGISLATION
Where products are classed as Medical Devices as per the definition under Medical Devices Regulation 2017/745 the following will apply: **Medical Devices Directive 93/42/EEC (as amended)** All products must have their CE or UKCA marking evident on the product and/or packaging. Or **Medical Devices Regulation 2017/745** (as amended) All products must have their CE marking evident on the product and/or packaging. **BS EN ISO 20417:2021 (previously BS EN 1041:2008 +A1:2013.)** Medical devices. Information to be supplied by the manufacturer **BS EN ISO 15223-1:2016 or BS EN ISO 15223-1:2021** Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. **BS EN ISO 18190:2016** Anaesthetic and respiratory equipment. General requirements for airways and related equipment. **Where applicable products must conform to;** **Units of Measurement Directive 80/181/EEC** All products must have their CE marking clearly evident on the product and/or packaging. **BS ISO 18190:2016** Anaesthetic and respiratory equipment. General requirements for airways and related equipment **BS EN ISO 18082:2014+A1:2017** Anaesthetic and respiratory equipment. Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases.

BS ISO 18562-1:2017
Biocompatibility evaluation of breathing gas pathways in healthcare applications. Evaluation and testing within a risk management process.

BS ISO 18562-2:2017
Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for emissions of particulate matter.

BS ISO 18562-3:2017
Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for emissions of volatile organic compounds (VOCs).

BS ISO 18562-4:2017
Biocompatibility evaluation of breathing gas pathways in healthcare applications. Tests for leachables in condensate.

BS ISO 18835:2015
Inhalational anaesthesia systems. Draw-over anaesthetic systems.

BS EN ISO 80369-1:2010
Small bore connectors for liquids and gasses in healthcare applications. General requirements.

BS EN ISO 80369-7:2017
Small-bore connectors for liquids and gases in healthcare applications. Connectors for intravascular or hypodermic applications.

BS EN ISO 5367:2014
Anaesthetic and respiratory equipment. Breathing sets and connectors.

BS EN ISO 5356-1:2015
Anaesthetic and respiratory equipment. Conical connectors. Cones and sockets

Where products are sterile, they must comply with either applicable standard below or equivalent international standard to designate device as sterile.

BS EN 556-1-2001
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.

BS EN556-2-2015
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for aseptically processed medical devices. Where a product is sterilised an applicable validated sterilisation and routine control process must be applied; for example

BS EN ISO 14937:2009
Sterilization of health care Sterilization of health care products.

BS EN ISO 11135:2014+A1:2019
Sterilization of health-care products. Ethylene oxide

BS EN ISO 11137 series Sterilization of health care products. Radiation **BS EN ISO 17665-1:2006** Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices

2.2. On request applicants must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) 2007 – more specifically, an SDS must be provided if a substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008.

2.3. If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).

2.4. If a product contains DEHP must be stated on the individual product packaging or IFU (instructions for use) and / or made available to NHS Supply Chain or end user on request.

2.5. Electrical product lines must comply with the requirements of the Directive on waste electrical and electronic equipment (WEEE Directive 2012/19/EU) and the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2 Directive 2011/65/EU).

2.6. All product lines and packaging should be latex free where possible. If a product line or any packaging contains or does not contain latex this must be labelled on the product line or packaging (as applicable) to inform the user.

2.7. During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.

2.8. All product line(s) must be supplied with a minimum 1 year's shelf life.

2.9. All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.

2.10. IFUs must be written in English or pictograms and included on the individual product packaging and/or within the UOI and/or made available to NHS Supply Chain or end user on request.

2.11. Any cautions / warnings / contraindications to use must be provided in IFU.

2.12. Must state details strictly necessary to identify the device for the user on the individual product packaging.

2.13. Lot number and expiry date must be stated on the individual product packaging.

2.14. For ordering purposes an identifier for example reference / manufacturing product code (MPC) must be stated on the individual product packaging and/or unit of issue packaging.

2.15. Product must be robust enough to resist breakage when used as directed by manufacturer.

2.16. Where applicable, products must be supplied sterile and individually wrapped.

2.17. Individual packaging must be of durable construction preventing product being pushed through, tampering and must not tear or rip apart during transportation and storage, to avoid damage to the product and / or breaches of product sterility and to reduce risk of plastic packaging being a foreign body when device being used.

2.18. Instructions for storage and disposal of device must be contained on the individual product packaging and/or IFU and / or made available to NHS Supply Chain or end user on request.

2.19. Where applicable, the product packaging must include a non-adherent tab which allows product packaging to be opened at one end maintaining sterility.

2.20. Where applicable, the word single use and / or symbol must be depicted on the individual product packaging to inform the user of the products single use status in line with labelling (ISO 15223).

2.21. Where applicable, products that are sterile, the transparent side of the individual packaging must allow visualisation of the contents.

2.22. If MRI compatible it must be stated on the individual product packaging and / or unit of issue packaging.

2.23. Where the product contains tubing, the packaging must be designed to minimise the risk of kinking of tubing while in storage.

2.24. All breathing system components that have a requirement for a port with a cap: the cap must be tethered to the device.

2.25. The product constituent's raw material/s must be made available to NHS Supply Chain or end user on request to support with customer recycling requirements.

2.26. Country of origin must be made available to NHS Supply Chain or end user on request.

2.27. Weight of product must be made available to NHS Supply Chain or end user on request to provide trust with weight waste information.

2.28. External product packaging must be made of recyclable material where possible.

2.29. Where packaging can be recycled this must be displayed on the packaging.

2.30. Where a product is reusable, product must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination / re-sterilisation instructions. Instructions must be stated on the individual product packaging or IFU and/or made available to NHS Supply Chain or end user on request.

2.31. Training and implementation must be provided on request and in accordance with trust requirements through mutual agreement. This could be for example, providing ongoing support including pre-implementation education, supplier support and implementation guidance, bespoke clinical training, eLearning and post-implementation support.

3. Lot 1 – Laryngoscopes, Video Laryngoscopes, Tracheal Intubation Equipment, Single Use Upper Airway Devices, Single use Bronchoscopes and Single Use Flexible Intubating Endoscopes and Related Accessories

3.1. This Lot is for the supply of airway equipment to aid tracheal intubation. These can be supplied sterile or non-sterile. Products within this Lot include:

3.2. Laryngoscopes and Associated Accessories

3.2.1. Complete Laryngoscopes Systems.
3.2.2. Laryngoscope Handles.
3.2.3. Laryngoscope Blades.
3.2.4. Laryngoscope Accessories.

3.3. Video Laryngoscopes and Related Accessories

3.3.1. Integrated (portable) Single Use Video Laryngoscope Systems.
3.3.2. Integrated (portable) Reusable Video Laryngoscope Monitor and Camera.
3.3.3. Non-Integrated Video Laryngoscope.
3.3.4. Standalone (cart based) Reusable Monitor.
3.3.5. Interchangeable Single Use Blades or Sheaths with or without a channel.
3.3.6. Interchangeable Reusable Blades or Sheaths with or without a channel.
3.3.7. Accessories which include replacement parts for the Video Laryngoscopes and items of equipment that are required in order for the Video Laryngoscope to be used e.g., Monitors, Modules, Battery Packs, Carry Cases, Charging Units, Connection Cables, Imagers, Batons, Wands, Blades, Stats, Stylets, Pole Mounts, Trolleys, Protection Caps, Stands, User Manuals.
3.3.8. Bougies.
3.3.9. Stylets.
3.3.10. Airway Exchange Catheters.
3.3.11. Single Use Flexible Intubating Endoscope and Related Accessories.
3.3.12. Single Use Upper Airway Devices and Single Use Bronchoscopes and Related Accessories.
3.3.13. Equipment for Difficult or Emergency Airway Management.

3.4. Standards and Legislation

STANDARD AND LEGISLATION
BS EN ISO 7376:2020 Anaesthetic and respiratory equipment. Laryngoscopes for tracheal intubation

3.5. Laryngoscopes and Associated Accessories - Laryngoscopes are devices used to perform direct laryngoscopy and to aid in tracheal intubation. They are used to visualise the larynx or pharynx for suctioning, removal of foreign body, placing of nasogastric tubes and throat packs. They can be single use, reusable, or reusable with single use blades. Laryngoscopes are handled medical instruments with

interchangeable blades of different sizes used within the throat to enable access to the vocal cords and glottis and to aid intubation.

3.6. All Laryngoscopes must meet the following:

3.6.1. Product must be robust enough to resist breakage when assembling/dismantling as directed by manufacturer.

3.6.2. Ergonomic grip design to allow end users to have a firm grip to prevent patient harm- i.e., doesn't allow hand to slip.

3.6.3. Must provide a light source to allow a direct laryngoscopy to aid tracheal intubation alongside other desired effects such as visualisation of the larynx, pharynx for suctioning and removal of foreign bodies amongst other requirements.

3.6.4. Material type must be stated on the individual product packaging and/or unit of issue packaging and / or IFUs and / or data sheets.

3.6.5. Compatibility colour coding must comply with BS EN ISO 7376:2020

3.6.6. Where products require to be assembled, the packaging must state type of light source to ensure avoidance of mismatch for example, fibreoptic.

3.6.7. The device must have the ability to accept range of blades in accordance with the BS EN ISO 7376:2020.

3.7. Complete Laryngoscope System - consists of handle and integral blade. They can be various sizes and types of blades.

3.8. Laryngoscope Handles - A clean, non-sterile, hand-held segment of a laryngoscope (i.e., non-endoscopic rigid type) designed to manipulate the laryngoscope blade during airway access and intubation. It is a cylindrical device that contains batteries / light-emitting cells to provide the energy / light for the airway-illuminating feature of the laryngoscope (e.g., small light bulb, fibreoptics), and can accommodate various blades. It is available in various sizes.. They can be single use or reusable.

3.9. Laryngoscope Blades - The segment of a laryngoscope (i.e., rigid intubation type) intended to be inserted into the oral cavity to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and / or ventilation. It is connected to the laryngoscope handle and illumination of the airway is provided by a small built-in light bulb or a fibreoptic light. This device may be curved or straight and of various designs and lengths; it may be hinged / interchanged with the handle.

3.10. Accessories - which includes equipment that is required to operate the laryngoscopes such as batteries, recharging units, battery/light containers, or bulbs.

3.11. Video Laryngoscopes, Single Use Flexible Intubation Endoscopes and Related Accessories - A collection of video laryngoscopic devices intended to be used for various procedures on the airway and respiratory tract including intubation,

lung dual-chamber positioning, suction, biopsy, drug administration and oxygen giving. It typically consists of a set of video intubation laryngoscope blades, a video intubation laryngoscope handle/monitor, a rigid non-bladed video intubation laryngoscope and a flexible video intubation laryngoscope. They can have the ability to record to support teaching and clinical audit.

3.11.1. **Integrated (portable) Single Use Video Laryngoscope Systems** - An assembly of devices enabling video imaging of the trachea during insertion of an endotracheal (ET) tube. This is a single use device.

3.11.2. **Integrated (portable) Reusable Video Laryngoscope Monitor and Camera** - An assembly of devices enabling video imaging of the trachea during insertion of an endotracheal (ET) tube. This is a reusable device.

3.11.3. **Non-Integrated Video Laryngoscope** - An assembly of devices enabling video imaging of the trachea during insertion of an endotracheal (ET) tube. This can be a single use or reusable device.

3.11.4. **Standalone (cart based) Reusable Monitor** - A monitor for the user to view anatomical images of the larynx / trachea transmitted by a video system from an electronic camera at the distal end of the blade. This is a reusable device.

3.11.5. **Interchangeable Single Use Blades or Sheaths with or without a channel** - A sterile, rigid blade-like component of a bladed video intubation laryngoscope intended to be inserted into the oral cavity to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. This is a single use device.

3.11.6. **Interchangeable Reusable Blades or Sheaths with or without a channel** - A sterile, rigid blade-like component of a bladed video intubation laryngoscope intended to be inserted into the oral cavity to manipulate the tongue, preventing it from obstructing the oropharynx and enabling a clear view of the trachea for the insertion of an endotracheal (ET) tube prior to the delivery of inhalation anaesthesia and/or ventilation. This is a reusable device.

3.11.7. **Accessories** - which include replacement parts for the video laryngoscopes and items of equipment that are required in order for the video laryngoscope to be used, for example, modules, battery packs, carry cases, charging units, connection cables, docking stations, bulbs, imagers, batons, wands, blades, stats, stylets, pole mounts, trolleys, protection caps, stands, user manuals.

3.12. Video Laryngoscopes - can vary dependent upon their intended use and some designs are unique, as a minimum they must include the following features:

3.12.1. Ergonomic grip design to allow end users to have a firm grip to prevent patient harm- i.e. doesn't allow hand to slip.

3.12.2. Provide a stable image to allow visualisation of the required anatomy.

3.12.3. The image must be able to be viewed under a variety of clinical settings.
3.12.4. Battery powered versions must run for a minimum of 2 hours on a set of fully charged batteries.
3.12.5. Must have the ability to image capture, video capture and export data as required.

3.13. Bougies (Endotracheal Tube Introducers) - are designed as an intubation tool; The tracheal tube introducer, known as the bougie, is typically used to aid tracheal intubation in poor laryngoscopic views or after intubation attempts fail. They can be single use or reusable. They must have the following features:

3.13.1. Material type must be stated on the individual product packaging and/or unit of issue packaging and / or IFUs and / or data sheets.
3.13.2. Size and length must be stated on the individual product packaging and / or unit of issue packaging and/or IFUs.
3.13.3. Length graduation marks must be present on the device.
3.13.4. Must have an atraumatic tip to minimise risk of patient harm.
3.13.5. Must have a smooth exterior to minimise risk of patient harm and facilitate insertion.

3.14. Stylets – are a malleable metal wire designed for pre-forming the ET tube to a desired shape to facilitate intubation. The product line must have the following features:

3.14.1. Must be designed to prevent the distal stylet tip from extending beyond the tip of the ET tube.
3.14.2. Material type must be stated on the individual product packaging and/or unit of issue packaging and / or IFUs and / or data sheets.
3.14.3. Material must allow the ET tube shape to be altered to suit the individual patient.
3.14.4. Material must allow the ET tube to be stiffened to aid passage into the trachea.
3.14.5. Size and length must be stated on the individual product packaging and/or unit of issue packaging and / or IFUs.
3.14.6. Compatibility with airway devices must be stated on the individual product packaging and /or unit of issue packaging and / or IFUs.

3.15. Airway Exchange Catheters - are specifically used for ET tube exchange and have oxygenating adaptors. They must have the following features:

3.15.1. Must have visible depth markers.
3.15.2. Adaptors must be supplied with device to provide oxygen.
3.15.3. Must have an atraumatic tip to minimise risk of patient harm.
3.15.4. Must have a smooth exterior to minimise risk of patient harm and facilitate insertion.
3.15.5. Material type must be stated on the individual product packaging and/or unit of issue packaging and / or IFUs and / or data sheets.
3.15.6. Size and length must be stated on the individual product packaging and/ or unit of issue packaging and / or IFUs.

3.15.7. Compatibility with airway devices must be stated on the individual product packaging and / or unit of issue packaging and / or IFUs.
3.15.8. These are single use.

3.16. Intubation Catheter - designed for use with a fibreoptic bronchoscope to facilitate endotracheal tube exchange.
3.16.1. Must have visible depth markers.
3.16.2. Adaptors must be supplied with device to provide oxygen.
3.16.3. Must have an atraumatic tip to minimise risk of patient harm.
3.16.4. Must have a smooth exterior to minimise risk of patient harm and facilitate insertion.
3.16.5. Material type must be stated on the individual product packaging and / or unit of issue packaging and / or IFUs and / or data sheets.
3.16.6. Size and length must be stated on the individual product packaging and / or unit of issue packaging and/or IFUs.
3.16.7. Compatibility with airway devices must be stated on the individual product packaging and / or unit of issue packaging and / or IFUs.

3.17. Single Use Flexible Intubation Video Endoscopes - designed for difficult airway procedures to visualise the airway. They connect to a live video monitor to give a clear view of the airway. As a minimum they must have the following features:
3.17.1. Ergonomic grip design to allow end users to have a firm grip to prevent patient harm - i.e., doesn't allow hand to slip.
3.17.2. Must provide suction capability.
3.17.3. Must be provided sterile.
3.17.4. Must connect to a standalone monitor.
3.17.5. The compatible monitor must have features to enable adjustment to suit different clinical settings.
3.17.6. Must have the ability to image capture, video capture and export data as required.

3.18. Single Use Upper Airway Devices and Single Use Bronchoscopes and Related Accessories - Single use upper airway devices and single use bronchoscopes are used in diagnostic and therapeutic interventions for a variety of upper airways and pulmonary disorders, they can also be used to visualise the anatomy in unexpected difficult airways. Accessories include associated equipment for the device such as monitors, cables and compatible devices. They must meet the following:
3.18.1. Must have a working channel, if size appropriate, to be used with endoscopy instruments used in diagnostic or therapeutic procedures.
3.18.2. Must have the ability to provide lavage and suction to support therapeutic interventions where applicable.
3.18.3. Must connect to a monitor to visualise the anatomy.
3.18.4. Product must achieve a neutral position to allow the clinician to accurately identify airway anatomy. The tip must be able to provide a full range of movement to visualise the anatomy through flex and

retroflex movements. Product must maintain position until the clinician dictates required movement.

3.18.5. Ergonomic grip design to allow end users to have an optimal grip to prevent patient and user harm- i.e. doesn't allow hand to slip, allows effective manipulation.

3.18.6. Device must be lightweight in order to minimise risk of endoscopy-related injury.

3.18.7. Provide a stable image to allow visualisation of the required anatomy

3.18.8. The image must be able to be viewed under a variety of clinical settings.

3.18.9. The device and/or associated accessories must have the ability to record, store, export and capture images to assist healthcare providers with auditing and training purposes.

3.18.10. Compatibility with airway devices, suctioning devices, endoscopic accessories and specimen collection devices must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs.

3.18.11. Accessories for single use Bronchoscopes.

3.19. Equipment for Difficult or Emergency Airway Management – Airway equipment that is required in an emergency situation as for "Cant Intubate, Cant Oxygenate" (CICO) situations and difficult airway management situations. This can include sets which include more than one of the product lines contained within this Framework in convenient to use packs to support management of a CICO or difficult airway management.

4. Lot 2 – Endotracheal Tubes, Endobronchial Tubes and Blockers, Tracheostomy Tubes, Supraglottic Airways and Simple Airway Adjuncts.

4.1. This Lot is Airway Devices that provide a means of access and securement of an airway. This Lot includes:

- 4.1.1. Standard Endotracheal Tubes; Cuffed and Non-Cuffed variants.
- 4.1.2. Subglottic Endotracheal Tube; Cuffed and Non-Cuffed variants.
- 4.1.3. Reinforced Endotracheal Tubes; Cuffed and Non-Cuffed variants.
- 4.1.4. Preformed Endotracheal Tubes; Cuffed and Non-Cuffed variants.
- 4.1.5. Cole Tracheal Tube.
- 4.1.6. Speciality Endotracheal Tube; Cuffed and Non-Cuffed variants.
- 4.1.7. Endotracheal Tube Holders.
- 4.1.8. Endobronchial Tubes:
  - 4.1.8.1. Single Lumen Endobronchial Tubes (SLT).
  - 4.1.8.2. Double Lumen Endobronchial Tubes, (DLT).
  - 4.1.8.3. Video Double Lumen Endobronchial Tubes (VDLT).
  - 4.1.8.4. Video Single Lumen Endobronchial Tubes.
- 4.1.9. Endobronchial Blockers (BB).
- 4.1.10. Endotracheal and Endobronchial Accessories.
- 4.1.11. Tracheostomy Tubes:
  - 4.1.11.1. Cuffed Tracheostomy Tubes.
  - 4.1.11.2. Cuffed Subglottic Tracheostomy Tubes.
  - 4.1.11.3. Fenestrated Tracheostomy Tubes (Cuffed and Uncuffed).
  - 4.1.11.4. Single Lumen Tracheostomy Tubes.
  - 4.1.11.5. Double Lumen Tube (Tube and Inner Cannula/Coaxial).
  - 4.1.11.6. Adjustable Flange Tracheostomy Tubes.
  - 4.1.11.7. Tracheostomy Inner Cannula.
  - 4.1.11.8. Speciality Tubes.
- 4.1.12. Laryngectomy Tubes.
- 4.1.13. Laryngectomy Inner Cannula.
- 4.1.14. Tracheostomy Tube Holders.
- 4.1.15. Tracheostomy Fasteners/Ties.
- 4.1.16. Percutaneous Single Stage Dilation Sets.
- 4.1.17. Tracheostomy Tube Accessories.
- 4.1.18. Standard Laryngeal Masks.
- 4.1.19. Reinforced Laryngeal Masks.
- 4.1.20. Intubating Laryngeal Masks.
- 4.1.21. Preformed Laryngeal Masks.
- 4.1.22. Speciality Laryngeal Masks.
- 4.1.23. Additional Supraglottic Devices - Additional supraglottic devices can incorporate double cuffed tubes for example.
- 4.1.24. Non inflatable Cuffed Supraglottic Device - A device where the cuff is not required to be inflated and can be inserted into the airway where it forms to the patient's anatomy.
- 4.1.25. Simple Airway Adjuncts.
- 4.1.26. Oropharyngeal Airways.

4.1.27. Nasopharyngeal Airways (NPA).
4.1.28. Supraglottic and Airway Adjuncts Accessories.

4.2. Endotracheal Tubes - are a hollow cylinder inserted orally or nasally to provide a means of securing the patient's airway, allowing spontaneous and controlled ventilation. It is available in various diameters and lengths for adult and paediatric patients. These can be single use or reusable. They can be cuffed or uncuffed. They can be straight or curved.

4.3. Standards and Legislation – All Tracheal and Endotracheal Tubes and Connectors must conform to the below standards and legislation.

STANDARD AND LEGISLATION
BS EN ISO 5361:2016 Anaesthetic and respiratory equipment. Tracheal tubes and connectors **BS EN ISO 80369-1:2018** Small-bore connectors for liquids and gases in healthcare applications

4.4. Standard Endotracheal Tubes (ET) - must meet the following:

4.4.1. Must include a radio opaque line if not reinforced.
4.4.2. Must have indicated length of use on the individual product packaging and/or unit of issue packaging and/or IFUs and/or data sheets.
4.4.3. Must maintain its intended shape when removed from the manufacturers packaging.
4.4.4. Tracheal tube material must have sufficient rigidity with the thinnest possible wall whilst providing flexibility and resistance to collapse and kinking. NHS SC reserve the right to request the outcome of the test methods used in accordance with BS EN ISO 5361:2016.
4.4.5. Have its internal diameter marked on the outside of the tube in millimetres.
4.4.6. Have its outer diameter marked on the tube and packaging.
4.4.7. The tube must be able to be cut to size to suit the individual patient with the exception of any speciality tube not designed to be cut.
4.4.8. The length, in centimetres from the tip of the tube must be marked on the outside of the tube.
4.4.9. Must have black intubation depth marker(s) to assist in the placement of the tracheal tube within the trachea (vocal cord marker).
4.4.10. The bevel must be atraumatic to help prevent patient harm.
4.4.11. The bevel must be left facing unless other configurations are required as per clause 5.4.2 in BS EN ISO 5361.
4.4.12. Material type must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs and/or data sheets.
4.4.13. Must be provided Sterile.

4.4.14. Can be provided with or without a side hole(s) also known as Murphy Eye(s).

4.4.15. If Murphy Eye(s) present:

4.4..15..1. The Murphy Eye(s) must have a smooth surface to minimise trauma to the patient.

4.4..15..2. The Murphy Eye must be on the opposite side of the bevel. The Murphy Eye must be designed in such a manner to ensure that the patient end of the tube is not unduly prone to kinking/collapse.

4.5. For Cuffed variants - the cuff must:

4.5.1. Provide an airtight seal between the tube and the tracheal wall.

4.5.2. Cuffs can be high volume / low pressure or low volume / high pressure.

4.5.3. The cuff resting diameter must be indicated on the tube and / or packaging and / or IFUs.

4.5.4. The IFUs must contain the recommended maximum cuff inflation pressure.

4.5.5. For cuffed variants there it must have a pilot balloon and / or other device such as a pressure indicator to indicate inflation / deflation of the cuff.

4.5.6. The pilot balloon / device must indicate whether the cuff is inflated or not.

4.5.7. The pilot balloon / device must be capable of being inflated and deflated multiple times.

4.5.8. Must have a self-sealing valve for injecting air.

4.5.9. The insertion point of the pilot balloon / device inflation lumen (tubing) must not affect the ability to cut the tube to a desired length as required.

4.6. Subglottic Endotracheal Tube (ET) - A tracheal tube which has a subglottic suction; is a small hole in the shaft of the tube, just above the cuff. A channel runs up inside the endotracheal tube and is connected to a suction port to remove secretions that pool above the cuff.

4.6.1. Must meet all the requirements of paragraph 4.4 and 4.5 above.

4.6.2. Must have the ability to provide subglottic aspiration to pooled secretions from above the cuff of a tracheal tube to help prevent ventilator-associated pneumonia (VAP).

4.6.3. The lumen dedicated for suctioning must be designed in such a manner that supports prevention of occlusion.

4.6.4. The subglottic suction port line must be marked as different to the endotracheal pilot cuff line.

4.6.5. Must have the ability to flush the aspiration port and associated line.

4.7. Reinforced Endotracheal Tubes (ET) - are designed to resist kinking or compression. These tubes are frequently used during facial surgeries and neurosurgeries, and in patients in a non-supine position during surgery. Reinforced tracheal tubes contain a metal wire coil embedded in the wall of the tube shaft which keeps the lumen of the tube open when it is bent.

4.7.1. Must meet all the requirements of paragraph 4.4 above and if cuffed meet 4.5 also.
4.7.2. The metal wire must be embedded in the wall of the tube shaft.
4.7.3. The wire reinforcement must be continuous along the length of the tube to minimise the risk of kinking.

4.8. Preformed Endotracheal (ET) Tube - have a manufactured pre-formed shape to reduce the risk of kinking and obstruction and facilitate surgical access for intra oral and facial surgery. They can be "North Facing" or "South Facing". They can be reinforced or non-reinforced.

4.8.1. Must meet all the requirements of paragraph 4.4 above and if cuffed meet 4.5 also.
4.8.2. They must have a black indication mark at the point of the maximum angle of the bend.

4.9. Cole Endotracheal (ET) Tube - A Cole ET tube is a tube designed for neonates and paediatric patients due to its narrowing of the tube at the point where is passes through the larynx.

4.10. Speciality Endotracheal (ET) Tube - Speciality ET tubes are designed to maintain an airway for a variety of procedures. They include ET Tubes such as laser resistant, integrated throat / pharyngeal pack, Microlaryngoscopy Tube, Compatible ET for supraglottic devices and Evoked Potentials tracheal tubes.

4.11. Endotracheal Tube Holder - is a device designed to hold and stabilize an endotracheal (ET) tube when it has been intubated into a patient; it may also include a teeth protector to prevent damage to the teeth or tube during intubation. This is a single-use device. Available in adult, paediatric and neonatal sizes.

4.11.1. The holder must secure the airway device to minimise the risk of accidental extubation or displacement.
4.11.2. The device must have features or methods to rapidly disconnect ET tube in the event of an emergency.
4.11.3. The device must be designed that will support securement under expected conditions such as repositioning of the holder, patient secretions, patient transport.
4.11.4. The holder must enable adjustment to accommodate individual patient sizes.

4.11.5. The holder must enable securement of the ET tube and the relevant size(s) this must be stated on the individual product packaging.
4.11.6. The holder can incorporate a bite block.
4.11.7. Material type must be stated on the individual product packaging and / or unit of issue packaging and / or IFUs and / or data sheets.
4.11.8. Must be designed to minimise discomfort and potential harm to the patient particularly around known pressure areas.
4.11.9. The ET tube holder must work in conjunction with the ET tube to enable continuous securement of a definitive airway.

4.12. Endobronchial Tubes - A hollow cylinder that is designed for oral insertion via the trachea and into a lung to maintain airway patency and/or to deliver anaesthetic inhalation agents or other medical gases, and secure ventilation. It is typically made of plastic, rubber, or silicone and may be packaged with a connector that attaches to a breathing circuit and is available in two basic configurations: 1) a double lumen tube with independent cuffs at the distal end for ventilation of the left or right bronchi; or 2) a twin lumen tube with independent cuffs for selective lung ventilation during thoracic surgery or postoperative care when independent lung ventilation is indicated. This is a single-use device. All Endobronchial tubes must meet the following:

4.12.1. The bronchial cuff and its pilot balloon inflation must be indicated for visual identification.
4.12.2. Details for the size and use of the devices must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs, e.g., side specific use (side specific use relates to which side of the lung the product must be used on i.e. (left or right).
4.12.3. Products within this Lot must be supplied sterile.

4.13. Single Lumen Endobronchial Tubes (SLT) - are advanced into the main bronchus of the non-operative lung to selectively ventilate it, while permitting slow collapse of the contralateral lung.

4.14. Double Lumen Endobronchial Tubes (DLT) - are bifurcated tube with separate tracheal and endobronchial lumens, that can be used to ventilate either lung independently. The tracheal lumen is designed to terminate above the carina, while the bronchial lumen is angled to fit into the appropriate main-stem bronchus.

4.15. Video Double Lumen Endobronchial Tubes (VDLT) - have an integrated camera and light source between the tracheal and bronchial cuffs, thus enabling continuous airway visualization during positioning of the tube.

4.16. Video Single Lumen Endobronchial Tubes - have an embedded camera and light source between the tracheal and bronchial cuffs, thus enabling continuous airway visualization during positioning of the tube.

4.17. Endobronchial Blockers (BB) - occlude the main-stem bronchus, thereby preventing ventilation distal to the occlusion. They can also be used to provide selective lobar collapse as well. They must meet the following:

4.17.1. Details for the size and use of the devices must be stated on the individual product packaging and / or unit of issue packaging and / or IFUs, e.g., side specific use (side specific use relates to which side of the lung the product must be used on i.e. (left or right).

4.18 Endotracheal and Endobronchial Accessories - which include any product lines that would be used to connect a tube to another piece of equipment, bite guards for protection during product use, products for measuring and inflating cuffs; and Sets which include more than one of the relevant product lines contained within this Lot compiled in convenient to use.

4.18. Tracheostomy Tubes and Related Accessories - A tracheostomy tube is a sterile hollow arc shaped cylinder designed to be inserted directly into the trachea via a hole made into the neck allowing a patient to breathe without using their nose or mouth. It is available in various diameters and lengths for adults and paediatric patients. They can be cuffed or uncuffed and can be fenestrated or unfenestrated. They must be single patient use.

4.19. Standards and Legislation - All Tracheostomy Tubes and Connectors must conform to the below standards and legislation

STANDARD AND LEGISLATION
BS EN ISO 5366:2016 Anaesthetic and respiratory equipment. Tracheostomy tubes and connectors **BS EN 1282-2:2005+A1:2009** Tracheostomy tubes. Paediatric tubes

4.20. Tracheostomy Tubes - All Tracheostomy tubes must meet the following general requirements:

4.20.1. Must be single patient use.
4.20.2. Size and length must be stated on the individual product packaging and / or unit of issue packaging and / or IFUs.
4.20.3. Material type of product components must be stated on the individual product packaging and/or unit of issue packaging and /or IFUs and /or data sheets.
4.20.4. Must be stated if supplied with an obturator to aid insertion of device.
4.20.5. Device must have means of securing tracheostomy to the neck for stabilisation for example Neck flange / base plate.

4.20.6. Securement device must have tracheostomy tube size, brand, cuff type, outer diameter in mm and the inner diameter in mm on the product.

4.20.7. Include a standard 15mm male connector at end to enable connection to ventilator circuit, resuscitation bags, speaking valves and caps.

4.20.8. The size of the tracheostomy tubes without inner cannulas must be stated according to the functional internal diameter (ID) at the narrowest point. This would relate to the part of the tube which has the 15mm connector fitted to it. This information will be present on the device, the individual product packaging and / or unit of issue packaging and / or IFUs.

4.20.9. For double cannula tracheostomy tubes, the inner diameter of the tracheostomy tube with the inner cannula fitted must be stated. This information will be present on the device, the individual product packaging and / or unit of issue packaging and /or IFUs.

4.20.10. Information regard to sizing, features and benefits of the devices and associated products must be made available to NHS Supply Chain on request.

4.20.11. Must be supplied sterile.

4.21. Cuffed Tracheostomy Tubes - must meet all previous points in 4.20 plus the following:

4.21.1. The tracheostomy cuff must be connected to the pilot balloon.

4.21.2. The inflated cuff on a cuffed tracheostomy tube must provide an airtight seal when used in accordance with manufacturer's instructions.

4.21.3. Cuffed tracheostomy tubes must have a pilot balloon and / or other device such as a pressure indicator to indicate inflation / deflation of the cuff.

4.21.4. Device must have ability to connect to a cuff pressure monitoring / recording device to enable measurement of the pressure within the inflated cuff to prevent pressure on the tracheal mucosa which can lead to pressure necrosis.

4.21.5. The pilot balloon must indicate whether the cuff is inflated or deflated.

4.21.6. The pilot balloon must be capable of being inflated and deflated numerous times.

4.21.7. The pilot balloon must have a self-sealing valve for injecting air into the cuff.

4.21.8. The IFUs must contain the recommended maximum cuff inflation pressure.

4.21.9. The cuff resting diameter must be indicated on the tracheostomy tube and/or packaging and/or IFUs.

4.22. Cuffed Subglottic Tracheostomy Tubes

4.22.1. Must meet all of 4.20 and 4.21.
4.22.2. Must have the ability to provide subglottic aspiration to pooled secretions from above the cuff of a tracheal tube to help prevent ventilator-associated pneumonia (VAP).
4.22.3. Must have the ability to flush the aspiration port and associated line.
4.22.4. The lumen dedicated for suctioning must be designed in such a manner that supports prevention of occlusion.
4.22.5. The subglottic suction port line must be marked as different to the tracheostomy pilot cuff line.

4.23. Fenestrated Tracheostomy Tube - has a hole in the curvature in the posterior wall of the tracheostomy tube. Designed to allow airflow through the fenestration for better voicing, can be cuffed or uncuffed. Must meet all 4.20 plus the following:

4.23.1. The fenestration must have a surface designed that minimises trauma to the patient.
4.23.2. The fenestration must be designed in such a manner to ensure that the patient end of the tube is not unduly prone to kinking/collapse.

4.24. Single Lumen Tracheostomy Tubes - consist of only an outer tube and have no inner cannula. Must meet all 4.20 plus the following:

4.24.1. Material type must not detrimentally effect removal of secretions/prevent blocking of tube

4.25. Double Lumen Tracheostomy Tube - consists of an outer tracheostomy tube and an inner cannula, also known as coaxial tubes. These are used for one lung ventilation. Must meet all 4.20 plus the following:

4.25.1. Inner cannula must connect securely to the tracheostomy tube to prevent accidental dislodgement.
4.25.2. Single patient use inner cannulas must be able to be inserted and reinserted multiple times and remain secure once reinserted.
4.25.3. Information regarding the number of times an inner cannula can be removed, inserted and cleaned must be stated on the UOI / Individual packaging and /or IFUs.
4.25.4. Compatibility with correct tracheostomy for example, sizing, brand must be stated on the individual product packaging.

4.26. Adjustable Flange Tracheostomy tubes - are designed for patients with a deep-set trachea. The tracheostomy tube can be adjusted to the required length, when in-situ the flange can be moved to assist with cleaning. Must meet all 4.20 plus the following:

4.26.1. Once adjusted the flange must be secure and minimise risk to patient harm.

4.27. Tracheostomy Inner Cannulas (Tubes) - A sterile, hollow, cylindrical, curved device designed as an internal, independent component of a tracheostomy tube. It has precise dimensions allowing it to fit exactly into the outer tube and function as the inner cannula for tracheostomy tubes that have this kind of function. It is removed once or more times daily to facilitate the removal of phlegm, slime, and contamination build-up, thereby preventing blockage and infection of the stoma and eliminates the traumatic removal of the tracheostomy tube. There are a variety which can be single patient use or single use.

4.27.1. Compatibility with correct tracheostomy for example, sizing, brand must be stated on the individual product packaging.

4.27.2. Inner cannula must connect securely to the stated tracheostomy tube to prevent accidental dislodgement.

4.27.3. Reusable single patient use inner tubes must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions and provide to NHS SC on request.

4.27.4. Single patient use inner cannulas must be able to be inserted and reinserted multiple times and remain secure once reinserted.

4.27.5. Information regarding the number of times an inner cannula can be removed, inserted and cleaned must be stated on the UOI/Individual packaging and/or IFUs.

4.28. Speciality Tracheostomy Tube - Speciality tracheostomy tubes are designed to maintain an airway for a variety of procedures. They include tracheostomy tubes such as extra proximal length tubes, flexible reinforced tubes.

4.29. Laryngectomy Tube - is a hollow device intended to maintain tracheostoma patency immediately after laryngectomy to provide an airway for the patient and to prevent tracheostomal stenosis (narrowing) in the months following the procedure. It is a soft plastic or silicone curved/contoured tube, similar to a tracheostomy tube, and may have an inner cannula and may be fenestrated to allow simultaneous use with a tracheoesophageal speech valve. It is held in place with a strap or band around the neck and is typically regularly removed and reinserted by the patient. This is a single patient use device. They must the following points:

4.29.1. Laryngectomy tubes must have size stated on the tube to allow for identification.

4.29.2. Size and length must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs.

4.29.3. Laryngectomy tubes must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions and provide to NHS SC on request.

4.29.4. Must be supplied sterile.

4.30. Laryngectomy Inner Cannula - A sterile, hollow, cylindrical, curved device designed as an internal, independent component of a laryngectomy tube. It has precise dimensions allowing it to fit exactly into the outer tube and function as the inner cannula for laryngectomy tubes that have this kind of function. It is removed once or more times daily to facilitate the removal of phlegm, slime, and contamination build-up, thereby preventing blockage and infection of the stoma and eliminates the traumatic removal of the laryngectomy tube There are a variety which can be single patient use.

4.31. Tracheostomy tube holders - are non-invasive devices designed to be fastened around the neck of a patient to secure a tracheostomy device (tube, button) in situ. It is typically in the form of a dedicated strap / collar intended to connect to the tracheostomy device.

4.31.1. Device must be designed in such a manner to prevent airway trauma by tracheostomy tube movement whilst supporting the tracheostomy tube user to maintain movement as required. For example, touch fasteners, hook or ties.
4.31.2. Device must minimise discomfort / potential harm to the patient through use of specialised materials or design for example.
4.31.3. Must be Single patient use.
4.31.4. Sizing information must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs.
4.31.5. Must be adjustable for size to suit individual tracheostomy user.
4.31.6. Must be able to be repositioned multiple times.
4.31.7. Device must not cause damage to the tracheostomy tube through its use in accordance with manufacturer's instructions.

4.32. Tracheostomy Ties - Tracheostomy ties are the bands that go around the neck. They hold the tracheostomy tube in place. They must meet the following:

4.32.1. Device must minimise discomfort / potential harm to the patient through use of specialised materials or design for example.
4.32.2. Must be single patient use.
4.32.3. Sizing information must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs.
4.32.4. Must be adjustable for size to suit individual tracheostomy user.

4.33. Percutaneous Single Stage Dilation Set (PDT) - for placement of tracheostomy tube without direct surgical supervision of the trachea. Can contain surgical scalpel blade, an introducer needle, a guidewire, a small tracheal dilator, a protective sheath, a single-stage progressive tracheal dilator, a tracheal loading trocar, and a small slip-tip syringe. Must be supplied sterile.

4.33.1. Can contain a tracheostomy tube in the kit, the size of the tracheostomy tube must be stated on individual product packaging.

4.33.2. Training and implementation must be provided on request and in accordance with trust requirements through mutual agreement. This could be for example, providing ongoing support including pre-implementation education, supplier support and implementation guidance, bespoke clinical training, eLearning and post-implementation support.

4.33.3. Material type of product components must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs and/or data sheets.

4.34. Tracheostomy Tube Accessories - which include replacement parts for the tracheostomy tube, equipment which connects to the tracheostomy tube to enable its operation excluding breathing systems products that offer the patient comfort during the use of the tube and products for maintaining the tracheostomy tube, for example:

- products for measuring cuff pressure.
- products for inflating/deflating the cuff.
- Atomisation devices.
- Cleaning Kits that contain as a minimum one cleaning brush and two disposable trays/bowls for cleaning liquid.
- Plugs / Decannulation Cap.
- Adaptors.
- Speaking Valves.
- Atomiser Spray Bottles.
- Laryngectomy Accessories.
- Dressings.
- Bib Protectors.
- Cleaning Brushes.
- Artificial / Swedish Noses.

And sets to include more than one of the product lines contained within this Section 4.34 compiled in a convenient to use pack.

4.35. Supraglottic Devices - Supraglottic airways (SGAs) are a group of airway devices that can be inserted into the pharynx to allow ventilation, oxygenation, and administration of anaesthetic gases, without the need for endotracheal intubation. These devices are used for primary airway management, for rescue ventilation when facemask ventilation is difficult, and as a conduit for endotracheal intubation. They can be single use or reusable. Must be provided sterile.

4.36. Standards and Legislation – All Laryngeal masks and Supraglottic Devices Tubes and Connectors must conform to the below standards and legislation

STANDARD AND LEGISLATION
BS ISO 11712:2009 Anaesthetic and respiratory equipment. Supralaryngeal airways and connectors.

4.37. Standard Laryngeal Masks - must meet the following:

4.37.1. Must have a standard 15mm male connector.
4.37.2. Material type must be stated on the individual product packaging and /or unit of issue packaging and/or IFUs and/or data sheets.
4.37.3. Must have an atraumatic tip to minimise risk of patient harm.
4.37.4. Cuff must have a smooth surface to minimise trauma to the patient.
4.37.5. The connector must not accidently detach when used in expected conditions in conjunction with the manufacturer's instructions.
4.37.6. The cuff must have a pilot balloon and / or other device such as a pressure indicator to indicate inflation / deflation of the cuff.
4.37.7. Must have a self-sealing valve for injecting air into the cuff.
4.37.8. The cuff be capable of being inflated and deflated multiple times.
4.37.9. The cuff must be able to be overinflated for pre-operative checks to ensure no herniations of the cuff or pilot balloon.
4.37.10. Volumes of air for the cuff inflation must be printed on the device.
4.37.11. The airway tube must be able to bend to a 180° angle with no kinking.
4.37.12. The IFU's must state compatibility of lubricant.

4.38. Reinforced Laryngeal Masks - have a wire coil inside the wall of the laryngeal mask to prevent inadvertent kinking of the device when in use. Must meet all requirements of paragraph 4.37 and the following:

4.38.1. The metal wire must be embedded in the wall of the tube shaft.
4.38.2. The wire reinforcement must be continuous along the length of the tube to minimise the risk of kinking.

4.39. Intubating Laryngeal Masks - The intubating laryngeal mask may be used for blind or fibreoptic bronchoscope-guided methods to aid intubation. Must meet all requirements of paragraph 4.37 and the following:

4.39.1. Must have a circular channel to allow passage of an ET tube to support intubation in an airway rescue scenario.
4.39.2. Compatibility with airway devices must be stated on the individual product packaging and /or unit of issue packaging and /or IFUs.

4.40. Preformed Laryngeal Masks - The preformed laryngeal mask has a preformed fixed anatomically curved structure to aid insertion. Must meet all requirements of paragraph 4.37.

4.41. Speciality Laryngeal Masks - Speciality laryngeal masks include but are not limited to MRI safe devices, devices with gastric access or gastric blockage, video laryngeal masks. Must meet all requirements of paragraph 4.37.

4.42. Additional Supraglottic Devices - Additional supraglottic devices can incorporate but are not limited to, double cuffed tubes and double lumen tubes. Must meet all requirements of paragraph 4.37.

4.43. Non-Inflatable Cuffed Supraglottic Device - A device where the cuff is not required to be inflated and can be inserted into the airway where it forms to the patient's anatomy.

4.43.1. Must have a standard 15mm male connector.
4.43.2. Material type must be stated on the individual product packaging and/or unit of issue packaging and / or IFUs and / or data sheets.
4.43.3. Must have a circular channel to allow passage of an ET tube to support intubation in an airway rescue scenario.
4.43.4. Must contain an integrated bite block.
4.43.5. Must have an atraumatic tip to minimise risk of patient harm.
4.43.6. Cuff must have a smooth surface to minimise trauma to the patient.
4.43.7. If gastric channel is present, it must be designed in such a manner as to reduce risk of blockage and allow passage of an NG tube as required.
4.43.8. The IFU's must state compatibility of lubricant.

4.44. Simple Airway Adjuncts - These generally consist of two groups of devices, oral airways and nasopharyngeal airways.

4.44.1. Simple airway adjuncts are invaluable in increasing the success rate of basic airway manoeuvres, which aim to create and maintain airway patency, allowing spontaneous respiration or facilitating bag-mask ventilation.

4.45. Standards and Legislation – All Oropharyngeal and Nasopharyngeal Airways, Tubes and Connectors must confirm to the below standards and legislation.

STANDARD AND LEGISLATION
BS EN ISO 5364:2016 Anaesthetic and respiratory equipment — Oropharyngeal airways

4.46. Oropharyngeal Airways - are curved metal or plastic tube inserted through the mouth to facilitate airway patency for gas exchange or suctioning. The device prevents the tongue from obstructing airflow. This can be a reusable device or single use. The most common are guedals or Berman airways and can include other types of oropharyngeal airways such as a Williams device:

4.46.1. Must be individually packaged.
4.46.2. Must have an atraumatic tip to minimise risk of patient harm.

4.46.3. Must have a smooth exterior to minimise risk of patient harm and facilitate insertion.
4.46.4. Material type must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs and/or data sheets.
4.46.5. Size and length must be stated on the individual product packaging and/or unit of issue packaging and / or IFUs.
4.46.6. Must maintain its intended shape when removed from the manufacturers packaging.
4.46.7. Tube material must have sufficient rigidity to have resistance to collapse and kinking.
4.46.8. Must be fully compliant to the standardised colour coding guidance outlined in ISO 5364:2016.
4.46.9. Must have a straight reinforced bite block to prevent occlusion of the air channel.
4.46.10. Must have a flange to prevent it falling back into the mouth.

4.47. Nasopharyngeal Airways (NPA) - are tubes designed to maintain airway patency from the nostril and the nasopharynx, bypassing the mouth and the oropharynx. The distal end is just above the epiglottis and below the base of the tongue. The proximal end of the device may have an integral 22mm connector for oxygen delivery. They are single use.

4.47.1. Must have an atraumatic tip to minimise risk of patient harm.
4.47.2. Must have a smooth exterior to minimise risk of patient harm and facilitate insertion.
4.47.3. Material type must be stated on the individual product packaging and / or unit of issue packaging and / or IFUs and / or data sheets.
4.47.4. Size and length must be stated on the individual product packaging and / or unit of issue packaging and/or IFUs.
4.47.5. Must maintain its intended shape when removed from the manufacturers packaging.
4.47.6. Tube material must have sufficient rigidity to have resistance to collapse and kinking.
4.47.7. The size must be marked on the outside of the tube.
4.47.8. Must have a flange integral to the device to limit depth of insertion.

4.48. Supraglottic and Airway Adjuncts Accessories - includes equipment that directly connects to the airway device to enable its operation, products for measuring and inflating cuffs, atomisation devices, bite guards for protection during product use, products that directly assist in the placement, use or removal of the mask; and sets which include more than one of the relevant product lines contained within this Framework compiled in convenient to use packs.

5. Lot 3- Breathing System Circuits and Accessories

5.1. This Lot is for the supply of parts that make up the anaesthetic breathing systems / circuits and the critical care breathing systems / circuits. These systems attach to universal and specified anaesthetic machines, universal and specified ventilator machines as well as universal and specified flow drivers used within operating rooms, recovery, emergency and intensive care environments. These parts will include the components which make up the different breathing systems / circuits.

The anaesthesia breathing circuit is a non-sterile assembly of devices designed to conduct medical gases from the fresh gas supply outlet of an anaesthesia unit/workstation to the patient typically connecting the patient, a ventilator / ventilation bag, carbon dioxide (CO2) absorber, and a monitor. It may be conductive or non-conductive. This can be reusable device or single use.

Please note, Breathing Systems for non–invasive ventilation are not within the specification of this tender as there is a separate NHS SC Framework for this area.

A **non-rebreathe system** is an anaesthesia breathing system from which all the expired mixture is discharged.
A **partial rebreathing system** is an anaesthesia breathing system in which a portion of the expired mixture is retained in the system.

5.2. Breathing Systems within this Lot include but are not limited to:

5.2.1. Coaxial Breathing Systems.
5.2.2. Coaxial Breathing Systems with a Monitoring Line.
5.2.3. Coaxial Breathing Systems with a Monitoring Line and 2L Bag.
5.2.4. Coaxial Breathing Systems with a Flow Sensor.
5.2.5. Coaxial Breathing Systems with a Flow Sensor and Expiratory Valve.
5.2.6. Circle Breathing Systems.
5.2.7. Circle Breathing Systems with a Monitoring Line.
5.2.8. Circle Breathing Systems with a Monitoring Line and 2L Bag.
5.2.9. Circle Breathing Systems with a Flow Sensor.
5.2.10. Circle Breathing Systems with a Flow Sensor and Expiratory Valve.
5.2.11. Breathing Systems for Dedicated Machine.
5.2.12. Parallel Y (WYE) Breathing Systems without Rebreathing Bags and Bagging Limb.
5.2.13. Parallel Y (WYE) Breathing Systems with Bagging Limb.
5.2.14. Parallel Y (WYE) Breathing Systems with Bag and Limb.
5.2.15. Parallel Y (WYE) Breathing Systems with Bag and Limb, and Specialist Connectors.
5.2.16. Humidified Parallel Y (WYE) Breathing Systems.
5.2.17. Breathing Systems – Antimicrobial.
5.2.18. Mapleson A - Commonly used during anaesthesia.
5.2.19. Mapleson B - Commonly used during recovery and emergency situations.

5.2.20. Mapleson C - Commonly used during recovery and emergency situations.
5.2.21. Mapleson D - Commonly used during anaesthesia.
5.2.22. Mapleson E - Commonly used during anaesthesia.
5.2.23. Mapleson F - Jackson-Rees Modification.
5.2.24. Mapleson F - with open tail bag.
5.2.25. Mapleson F - with closed tail bag and APL valve.
5.2.26. Single Limb Breathing Systems.
5.2.27. Single Limb Breathing Systems with Heated Wire.
5.2.28. Transport Breathing Systems both dedicated machine and non-machine dedicated can be made of additional parts can include monitoring lines, filters, non-rebreathing valves, elbows, flow sensor tubing.

5.3. Standards and Legislation

STANDARD AND LEGISLATION
Where components are included in the Breathing system they must conform to the following standards, where applicable. **BS EN ISO 23328-2:2009** Breathing system filters for anaesthetic and respiratory use. Non-filtration aspects. **BS EN ISO 23328-1:2008** Breathing system filters for anaesthetic and respiratory use. Salt test method to assess filtration performance. HMEs must conform to: **International standard ISO 9360-1:2009** Anaesthetic and respiratory equipment. Heat and moisture exchangers (HMEs) for humidifying respired gases in humans. HMEs for use with minimal tidal volumes of 250 ml.

5.4. Breathing Systems and their components - All breathing systems must:
5.4.1. Must be robust, compact, and light weight.
5.4.2. Must have the ability to remove waste gases, effectively eliminate Co2.
5.4.3. Must have ability to warm and humidify inspired gas.
5.4.4. Able to deliver intended gas mixture.
5.4.5. Must permit spontaneous, controlled, or assisted ventilation in all age groups.
5.4.6. Be designed to protect patients from barotrauma.
5.4.7. Have low resistance: Should have minimal length, maximal internal diameter and be without sharp curves or sudden changes in diameter
5.4.8. Have minimal dead space within the circuit.

5.4.9. All breathing system components that have a requirement for a port with a cap: the cap must be tethered to the device.

5.4.10. Material type must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs and/or data sheets.

5.4.11. Where a product is reusable, product must be able to be cleaned to prevent cross contamination and must have available cleaning / decontamination instructions must be stated on the individual product packaging or IFU and/or made available to NHS Supply Chain or end user on request.

5.4.12. Maximum working pressure must be made available for breathing system.

5.5. Breathing Tubes - are non-rigid tubes used to convey gases and/or vapours between components of a breathing system they can be they must:

5.5.1. Tubing must have flexibility and resist kinking

5.5.2. Must have ability to act as reservoir.

5.5.3. Must have some distensibility but not enough to prevent excessive pressures from developing in the circuit.

5.5.4. Must be lightweight and have low resistance.

5.5.5. Internal diameter 22mm of tubing must be labelled on packaging and/or within IFU's.

5.5.6. The resistance to the flow of gas must be listed within the IFU's and/or made available.

5.5.7. Must be stated on individual product packaging type of tubing e.g. if coaxial, corrugated or smooth bore.

5.6. Reservoir Bag - a collapsible gas container which is a component within a breathing system and must:

5.6.1. Material type must be stated on the individual product packaging and/or unit of issue packaging and/or IFUs and/or data sheets.

5.6.2. Must have size stated on individual product packaging and/or unit of issue packaging.

5.6.3. Must be able to contain reservoir of gas without absorption.

5.6.4. Must have airtight seal when connected to breathing system.

5.6.5. Must be able to squeeze reservoir bag for assisted or controlled ventilation.

5.7. Adjustable Pressure Limiting Valve - also known as APL valve pop-off valve

5.7.1. Must allow flow of waste gas and fresh gas to leave the breathing system.

5.7.2. Provide pressure control within breathing system.

5.8. Accessories - for use on all anaesthesia and intensive care breathing systems and include all the additional connectors and parts that connect to the breathing system, accessories within this Lot include:

5.8.1. Catheter Mounts.
5.8.2. Pressure Monitoring Lines.

6. Lot 4 - Humidification and Filtration (HME's, HMEF's, Bacterial and Viral Filters)

6.1. Humidification and Filtration devices are to provide warmth, moisture and filtration manually. These devices and filters do not require the need for heated humidification circuit or cold humidification circuit and are used independently. Breathing Filters for use on all anaesthesia and intensive care breathing systems. These include the breathing filters that protect the patient, the breathing system and the equipment from bacteria and viruses. The heat and moisture exchangers (HME) that conserve expired heat and moisture and return it to the patient, as well as the combined HME and Filter options (HMEF) Filters. Breathing Filters, HME's and HMEF's can be supplied with or without a CO_2 port. This Lot includes:

6.1.1. Electrostatic Filters without HME.
6.1.2. Electrostatic Filters with HME (HMEF).
6.1.3. Pleated / Mechanical Filters without HME.
6.1.4. Pleated / Mechanical Filters with HME (HMEF).

6.2. Standards and Legislation

STANDARD AND LEGISLATION
BS EN ISO 23328-2:2009 Breathing system filters for anaesthetic and respiratory use. Non-filtration aspects. **BS EN ISO 23328-1:2008** Breathing system filters for anaesthetic and respiratory use. Salt test method to assess filtration performance. **BS EN ISO 9360-1:2009** Anaesthetic and respiratory equipment. Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - HMEs for use with minimal tidal volumes of 250 ml.

6.3. All devices within this Lot must meet the following:

6.3.1. Suppliers must be able to provide following information to NHS supply chain if required: recommended maximum duration of use, internal volume, hydrophobic filter, HME has tethered cap, Tidal volumes, if product is latex free, sterility.
6.3.2. Must have tethered cap if cap present on device.
6.3.3. Must have flow resistance of product and pressure at 30L pre/post conditioning (cmH_2O).
6.3.4. Must have flow resistance of product and pressure at 60L pre/post conditioning (cmH_2O).

6.4. Breathing Mechanical / Electrostatic Filters - are devices intended to reduce transmission of particulates, including micro-organisms, such as bacteria and viruses to prevent cross infection to and from the patient during anaesthesia or other types of ventilation. Must meet the following:

6.4.1. Filter filtration performance rate must meet ISO 23328-1 (Salt test).

6.5. Heat Moisture Exchange (HME) - conserve heat and moisture during expiration and make this available to inspired gases during subsequent inspiration. They must meet the following:

6.5.1. Must state the internal volume in millimetres on product packaging or in IFU's.
6.5.2. Must be tested against the international standard ISO 9360-1:2000(E).
6.5.3. Must state the recommended range of tidal volumes and / or flowrates on IFU's or product packaging.
6.5.4. Must state the gas leakage in millimetres per minute on product packaging or IFU's.

6.6. Heat Moisture Exchange Filters - HMEF's are a combination of an HME and Breathing Filter to achieve both clinical outcomes of filtration and heat and moisture exchange.

6.6.1. Ergonomic shape with no sharp edges reduces pressure marking
6.6.2. Must have flow resistance of product and pressure at 30L pre/post conditioning (cmH_2O).
6.6.3. Must have flow resistance of product and pressure at 60L pre/post conditioning (cmH_2O).