

APPENDIX 3T

LOT 20 SPECIFICATION

FLEXIBLE ENDOSCOPES AND ASSOCIATED OPTIONS AND ACCESSORIES

1. Introduction

1.1. This Lot is for the supply of flexible endoscope systems, associated options and related services to enable real-time visualisation of a body cavity including the upper and lower gastro-intestinal tracts, respiratory system and bladder. This includes Gastrosopes, Bronchoscopes, Colonoscopes, Cystoscopes, Duodenoscopes, Enteroscopes, Hysteroscopes, Sigmoidoscopes, Ureteroscopes, 3D Imaging Systems, Camera Stacks and Choledochoscopes.

1.2. The core product lines within this Lot are as follows:

Line Number	
1	Video Gastroscope System
2	Video Bronchoscope System
3	Flexible Video Cystoscope System
4	Video Colonoscope System

1.3. All product line(s) must be supplied with a minimum 7 year expected lifecycle under proper use and maintenance.

1.4. Applicants will be expected to work towards the British Society of Gastroenterology (BSG) guidelines for decontamination protocols and recommended cleaning instructions for gastrointestinal endoscopic equipment.

2. Criteria across all Endoscopy Systems

2.1. This is the core technical specification for endoscopy systems and is applicable to all core lines. An endoscopy system must include the following, all of which must be compatible with each other and interface to create a complete endoscopy system:

- 2.1.1. Camera control unit.
- 2.1.2. Light source (Optional if the light source is built into the Flexible endoscope).
- 2.1.3. Video display.
- 2.1.4. Colour video printer.
- 2.1.5. Trolley.
- 2.1.6. Flexible endoscope.

2.2. The camera control unit must have the following features:

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- 2.2.1. Must be high definition resolution (e.g. 1920x1080, 1280x1024, 1280x720 mega pixels).
 - 2.2.2. Must have either a DVI, HD-SDI, HDMI or component RGB output, a combination of these or all options.
- 2.3. The light source must have the following features:
- 2.3.1. The lamp must be halogen, LED or Xenon.
 - 2.3.2. The light intensity must have automatic control with manual override.
- 2.4. The video display must have the following features:
- 2.4.1. A medical grade LCD/LED screen.
 - 2.4.2. A minimum 18.5" screen (measured diagonally corner to corner).
 - 2.4.3. Offer a high definition resolution (e.g., 1920x1080, 1280x1024, 1280x720 mega pixels) or higher.
 - 2.4.4. Digital and analogue inputs, the use of a device to convert analogue to digital signal is acceptable.
 - 2.4.5. An aspect ratio of 16:9 or 16:10.
- 2.5. The colour video printer must have the following features:
- 2.5.1. A capture and print function that is remotely controllable from the camera head.
 - 2.5.2. The ability to provide single and multiple images per A4 sheet.
- 2.6. Endoscopy systems must be supplied with a trolley to house the equipment securely, allow power to be supplied and to enable the system to be moved as required. The trolley must have easily moveable, full swivel wheels with foot pedal-controlled swivel locks available on at least two wheels and foot pedal-controlled brakes available on at least two wheels.
- 2.7. The flexible endoscope must have the following features:
- 2.7.1. Must not be affected by reprocessing after use including disinfection and high-level cleaning.
 - 2.7.2. Must be compatible with a high definition camera control unit.
- 2.8. A charged coupled device (CCD), complementary metal oxide semi-conductor (CMOS) or equivalent image sensor must be single chip.

3. Line 1 – Video Gastroscope System

- 3.1. These are the additional requirements (along with those in section 2) for a gastroscope which is used to look inside the oesophagus (gullet), stomach and first part of the small intestine (duodenum).
- 3.2. Video gastroscopes must have the following features:
- 3.2.1. Outer diameters ranging from at least 5.4mm - 11.7mm.
 - 3.2.2. Channel diameters ranging from at least 2.2mm - 3.7mm.

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- 3.2.3. A minimum 140° field of view.
- 3.2.4. A working length from 100cm to 110cm.
- 3.2.5. 0° forward-looking.
- 3.2.6. A minimum up/down angulation of 210°/90°.
- 3.2.7. A minimum left/right angulation of 100°/100°.

3.3. A video gastroscope system also requires an air and water feeding pump that must have the following features:

- 3.3.1. A controlled supply of air for insufflation and water to enable cleaning of the endoscope lens.
- 3.3.2. A minimum of 4psi pressure for both air and water.

4. Line 2 – Video Bronchoscope System

4.1. These are the additional requirements (along with those in section 2) for a video bronchoscope system which is used look at lungs and air passages.

4.2. Video bronchoscopes must have the following features:

- 4.2.1. Outer diameters ranging from at least 3.8mm – 6.3mm.
- 4.2.2. Channel diameters ranging from at least 2.0mm – 3.2mm.
- 4.2.3. A minimum 100° field of view.
- 4.2.4. A working length from 50cm to 65cm.
- 4.2.5. 0° forward-looking.
- 4.2.6. A minimum up/down angulation of 180°/100°.

5. Line 3 – Flexible Video Cystoscope System

5.1. These are the additional requirements (along with those in section 2) for a flexible video cystoscope system which is used to look inside the bladder using a thin camera.

5.2. Flexible video cystoscopes must have the following features:

- 5.2.1. Outer diameters ranging from at least 5.1mm – 5.5mm.
- 5.2.2. Channel diameters ranging from at least 2.0mm – 2.4mm.
- 5.2.3. A minimum 100° field of view.
- 5.2.4. A working length from 35cm to 40cm.
- 5.2.5. A minimum up/down angulation of 210°/120°.

6. Line 4 – Video Colonoscope System

6.1. These are the additional requirements (along with those in section 2) for a colonoscope which is used for inspection of the colon and rectum.

6.2. Video colonoscopes must have the following features:

- 6.2.1. Insertion tube diameters ranging from at least 9.2mm – 13.7mm.

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- 6.2.2. Single instrument channel diameters ranging from at least 3.2mm – 4.2mm.
- 6.2.3. A minimum viewing angle of 140°.
- 6.2.4. 0° forward-looking.
- 6.2.5. A working length from 130cm to 170cm.
- 6.2.6. A minimum up/down angulation of 180°/180°.
- 6.2.7. A minimum left/right angulation of 160°/160°.

6.3. A video colonoscope system also requires an air and water feeding pump that must have the following features:

- 6.3.1. A controlled supply of air for insufflation and water to enable the cleaning of the endoscope lens.
- 6.3.2. A minimum of 4psi pressure for both air and water.

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