

Multi-use Adult Intubating Video Bronchoscope — Technical Specification (CE / FDA / India)

1) Intended use

Flexible video bronchoscope for oral/nasal endotracheal intubation and airway inspection in adult patients.

2) Regulatory & conformity (shall be met)

- European Union (CE): Device (scope and any associated processor/monitor) shall be CE-marked under Regulation (EU) 2017/745 (MDR) for bronchoscopic visualization/intubation.
- Provide EU Declaration of Conformity, Notified Body name & NB ID, valid EU certificate, and Basic UDI-DI / UDI-DI (EUDAMED details if available).
- FDA: Device (scope and any associated processor/monitor) shall be 510(k)-cleared for the same intended use.
- Provide 510(k) number (K#####), Indications for Use page, Establishment Registration & Device Listing, and UDI for all configurable components.
- India (CDSCO): Device shall be registered/licensed for import and sale under India's Medical Device Rules, 2017 (CDSCO) for the intended use.
- Provide CDSCO license/registration number(s) and Authorized Indian Agent details.
- Labeling/IFU: English IFU and reprocessing instructions supplied; UDI/CE marks visible on device/packaging; no storage of PHI without user action.

3) Physical & insertion tube

- Outer diameter (OD): Primary adult scope ≤ 5.8 mm (target 5.0–5.5 mm). Optional slim scope ≤ 4.2 mm for small ETT/nasal use.
- Working length: ≥ 600 mm (target 600–650 mm).
- Distal tip: rounded/atraumatic; distal OD not to exceed insertion OD by > 0.5 mm.
- Construction: bend protector; graduated shaft stiffness to aid railroading ETTs.

4) Working channel & suction

- Channel ID: ≥ 2.0 mm (target 2.6–3.0 mm).
- Accessory capacity: tools up to ≥ 2.0 –2.6 mm OD.
- Suction performance: at -50 kPa vacuum, open-channel water flow ≥ 200 mL/min (vendor to declare tested value).

- Suction connectors: compatible with 6–9.5 mm ID tubing; removable/cleanable suction and channel valves.

5) Imaging & illumination

- Sensor/Light: distal CMOS with LED illumination at the tip; anti-fog feature preferred.
- Field of view: $\geq 90^\circ$ (target 110–120° diagonal).
- Depth of field: approx. 5–50 mm (or wider without loss of near focus).
- Direction of view: 0° forward; minimal distortion.
- Output: live video $\geq 720p$ (target 1080p) with still capture and recording.

6) Tip articulation & controls

- Articulation (U/D): $\geq 180^\circ/160^\circ$ (target $180^\circ/180^\circ$).
- Smooth, low-hysteresis lever; articulation lock preferred.
- Durability: articulation angles remain within -10° of nominal after $\geq 1,000$ full cycles.

7) Airway device compatibility

- ETT minimum IDs: with ~ 5.0 – 5.5 mm OD scope $\rightarrow \geq 6.0$ mm ID ETT.
- ETT minimum IDs: with ~ 5.8 mm OD scope $\rightarrow \geq 7.0$ mm ID ETT.
- Optional slim ~ 4.0 – 4.2 mm OD $\rightarrow \geq 5.0$ – 5.5 mm ID ETT.
- Double-lumen tubes: compatible ≥ 35 – 41 Fr; vendor to declare tested sizes.

8) Video processor / monitor (system unit)

- Dedicated compact processor/monitor or compatibility with OR/ICU displays.
- Interfaces: ≥ 1 HDMI (or DVI) output; USB for image/video export.
- Controls: gain/brightness, freeze, snapshot, recording; on-screen watermark/time; optional patient-data entry (no PHI stored by default).

9) Reprocessing & infection prevention (multi-use)

- Leak testable before every reprocess (appropriate connector supplied).
- Validated reprocessing: detailed manual cleaning + high-level disinfection and/or AER cycle(s) provided in the IFU, including compatible chemistries and cycle parameters.
- All patient-contacting components immersible to the level stated in IFU.
- Accessories for reprocessing supplied (cleaning adapters, full-length channel brushes).
- Material durability: resists at least 500 HLD/AER cycles without loss of function (vendor to declare tested cycles).
- If sterilization is validated (e.g., low-temp hydrogen-peroxide plasma), specify method and limits.

10) Reliability, service & warranty

- Service life: ≥ 3 years or ≥ 500 full reprocessing cycles (whichever is longer) under normal use.
- Warranty: ≥ 24 months on scope; ≥ 12 months on processor/monitor & accessories.
- Availability of spare parts and loaners; state maximum repair turnaround (calendar days).

11) Safety & environmental

- Electrical safety/EMC: compliant with applicable medical electrical safety and electromagnetic compatibility requirements.
- Operating conditions: 10–40 °C, RH 30–85%, pressure 80–109 kPa (or better).
- Patient-contacting materials latex-free; disclose any phthalates.

12) Supplied accessories

Processor/monitor (if requested), power supply/cables, leak tester (manual/electronic), suction & channel valves, cleaning adapters, channel/bore brushes, bite blocks, carry/storage case, IFU and reprocessing wall chart.

Acceptance-test checklist (at delivery/commissioning)

1. Regulatory docs: EU DoC + NB certificate; FDA 510(k) letter and Indications for Use; CDSCO license/registration and Authorized Indian Agent details; UDI records.
2. Labeling: CE mark with NB number; UDI scannable on device/packaging; model/version match paperwork.
3. Leak test: pass at rated test pressure/time per IFU.
4. Articulation: verify up/down angles with gauge; within spec.
5. Optics: resolution/contrast with near-field chart; confirm FOV/DoF.
6. Illumination: no flicker/hotspot; uniform field.
7. Channel patency & suction: brush passes full length; open-flow at -50 kPa meets declared mL/min.
8. Connectivity: HDMI/USB function; still/video capture operational.
9. Compatibility: railroading through 6.0 and 7.0 mm ID ETTs (and any declared DLT sizes).
10. Reprocessing dry-run: complete one manual + one AER cycle using facility chemistry; no leaks/functional loss.
11. Training: vendor in-service delivered; wall charts provided.

Bid response (vendor to complete)

Model(s) offered	
Regulatory status	CE MDR (NB name/ID + cert); FDA 510(k) (K#); CDSCO license; UDI(s)

Scope OD / length / channel ID	
FOV / DoF / output resolution	
Articulation (U/D)	
ETT/DLT compatibility (tested)	
Suction flow at -50 kPa	
Validated reprocessing methods & chemistries/AERs	
Reprocessing durability (tested cycles)	
Warranty & service terms	
Country of origin & lead time	
Deviations from minimum	

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Reviewed

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