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## Standards for the Establishment of Digestive Endoscopy Centers and Equipment Configuration

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## Preface

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# Standards for the Establishment of Digestive Endoscopy Centers and Equipment Configuration

National Association of Health Industry and Enterprise Management

## 1 Scope of Application

This document specifies the medical process design, construction planning and layout, architectural design, water supply and drainage system, air conditioning and fresh air system, electrical system, medical gas configuration and requirements, intelligence and information system configuration, and medical equipment configuration for digestive endoscopy centers.

This document is applicable to the planning, new construction, renovation, expansion, or optimization of digestive endoscopy centers in medical institutions at all levels and of various types, providing standardized construction guidance and equipment configuration requirements for their design, construction, and use.

## 2 Normative References

The following normative documents contain provisions, which, through reference in this text, constitute provisions of this document. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated references, the latest edition of the normative document (including any amendments) referred to applies.

*General code for waterproofing of building and municipal engineering* (GB 55030)

*General code for energy efficiency and renewable energy application in buildings* (GB 55015)

*Code for design of general hospital* (GB 51039)

*Technical code for medical gases engineering* (GB 50751)

*Code for indoor environmental pollution control of civil building engineering* (GB 50325)

*Code for engineering design of generic cabling system* (GB 50311)

*Standard for lighting design of buildings* (GB 50034)

*Code for fire protection design of buildings* (GB 50016)

*Hygienic requirements for washer-disinfectors employing chemical disinfection for thermolabile endoscopes* (GB 30689)

*Hygienic standard for disinfection in hospitals* (GB 15982)

*Hygienic Standards for Drinking Water* (GB 5749)

*Standard for geotechnical testing method* (GB/T 50123)

*General technical requirements for medical doors of building* (GB/T 41659)

*Environmental control requirements for negative pressure isolation wards in hospitals* (GB/T 35428)

*Health Protection Standards for Medical X-ray Diagnosis* (GBZ 130)

*Welded stainless steel pipes for fluid transport* (GB/T 12771)

*Code for electrical design of medical buildings* (JGJ 312)

*Central sterile supply department (CSSD) Part 1: management standard* (WS 310.1)

*Central sterile supply department (CSSD) Part 2: Standard for operating procedure of cleaning, disinfection and sterilization* (WS 310.2)

*Central sterile supply department (CSSD) Part 3: Surveillance standard for cleaning, disinfection and sterilization* (WS 310.3)

*Hospital isolation technical standards* (WS/T 311)

*Hospital infection surveillance standards* (WS/T 312)

*Regulation of disinfection technique in healthcare settings* (WS/T 367)

*Hospital Air Purification Management Standards* (WS/T 368)

*Regulation for cleaning and disinfection technique of flexible endoscope* (WS 507)

*Evaluation standards for hospital infection prevention and control* (WS/T 592)

*Standard for Hospital Infection Control in the Operating Department (Room)* (WS/T 855)

*General Standards for Infection Prevention and Control in Key Departments of Healthcare Institutions* (WS/T 860)

*Seamless copper tubes for medical gases and vacuums* (YS/T 650—2020)

*Terminal units for medical gas pipeline systems. Part 1: Terminal units for use with compressed medical gases and vacuum* (YY 0801.1—2010)

*Low-pressure hose assemblies for use with medical gases* (YY/T 0799—2010)

ISO 13485 Medical Devices

ISO 27799 Health Informatics

## 3 Terms and definitions

The terms and definitions defined as follows apply to this document.

3.1 Digestive Endoscopy Center

A center that has the approved diagnosis and treatment specialties approved for registration by the health administrative department, which are compatible with the digestive endoscopy diagnosis and treatment techniques to be performed, and possesses relevant spaces and equipment such as pre-operative preparation rooms, diagnosis and treatment rooms, post-operative observation rooms, and endoscope cleaning and disinfection rooms for carrying out digestive endoscopy diagnosis and treatment.

3.2 Digestive Endoscopy Diagnostic and Treatment Techniques

Includes diagnostic and therapeutic techniques such as gastroscopy, colonoscopy, duodenoscopy, enteroscopy, endoscopic ultrasound, laparoscopy, mother-daughter endoscopy, and cholangioscopy.

3.3 Flexible Endoscope

Refers to a bendable endoscope used for disease diagnosis or treatment.

## 4 Medical Process Design

4.1 General requirements

4.1.1 Medical process design shall determine the medical service structure, functions, and scale, as well as related medical workflows, medical equipment, technical conditions, and parameters, based on the clinical needs of the digestive endoscopy center.

4.1.2 Digestive endoscopy centers shall be arranged and zoned according to functional use and infection control principles.

4.1.2.1 Clean zones, potentially contaminated zones, and contaminated zones shall be reasonably demarcated, with separate staff and patient pathways. Diagnosis and treatment workflows shall be properly planned, and diagnosis and treatment routes shall be clearly marked.

4.1.2.2 Digestive endoscopy centers shall emphasize the division of functional areas, mainly including appointment waiting areas, diagnosis and treatment operation areas, cleaning and disinfection areas, anesthesia recovery areas, office and teaching areas, and auxiliary living areas.

4.1.3 Patient reception, waiting, preparation, and recovery shall cover the spaces and facilities required for the entire process from appointment registration, pre-operative assessment, pre-operative preparation, post-operative recovery to discharge.

4.1.4 The endoscopy center's cleaning, disinfection, and storage shall have an independent cleaning and disinfection area and equipment that meet regulatory requirements.

4.1.5 Teaching and training: Hospitals with teaching responsibilities shall consider the configuration and spatial layout of teaching demonstration systems in their endoscopy centers.

4.1.6 Research function: Endoscopy centers undertaking research tasks shall consider the corresponding space and equipment requirements for sample processing, data storage, etc.

4.2 Medical process design parameters

4.2.1 Medical process design parameters shall be determined according to the planning require-

ments of digestive endoscopy centers in different hospitals.

4.2.1.1 The construction area of a digestive endoscopy center should be approximately 10 patient visits per square meter per year, which can be extended to 20 visits. Appropriate space for future development shall be reserved based on demand.

4.2.1.2 Common calculation method for the number of procedure rooms:

$$\text{Estimated daily number of endoscopic procedures} = \frac{\text{Total annual endoscopic procedures}}{\text{Average annual working days}}$$

$$\text{Estimated daily capacity per procedure room} = \frac{\text{Daily working hours}}{\text{Average procedure time per case} + \text{Turnaround time}}$$

$$\text{Number of endoscopic procedure rooms} = \frac{\text{Estimated daily number of endoscopic procedures}}{\text{Estimated daily capacity per room}}$$

4.3 Medical process zoning

When conducting specific functional zoning planning and design, the layout model shall be clearly centered around the diagnosis and treatment operation area, with other areas providing auxiliary coordination, and their areas shall match work requirements. For example, the appointment waiting area should be 15%, and the diagnosis and treatment operation area proportion should be ⩾50%.

4.4 Medical process flow

Functional layout principles and requirements: Diagnosis and treatment workflows shall be reasonably planned within each functional area, with clear marking of diagnosis and treatment routes. The waiting area and examination area should be relatively independent, and controlled entrances and exits should be set up.

## 5 Construction Planning and Layout

5.1 Site selection requirements

5.1.1 The digestive endoscopy center should be located in an area convenient for the diagnosis and treatment of outpatients and inpatients. It can also be arranged in a specialist outpatient area as needed, integrated with the clinic area to form a one-stop specialized diagnosis and treatment center.

5.1.2 The digestive endoscopy center should be located on a lower floor.

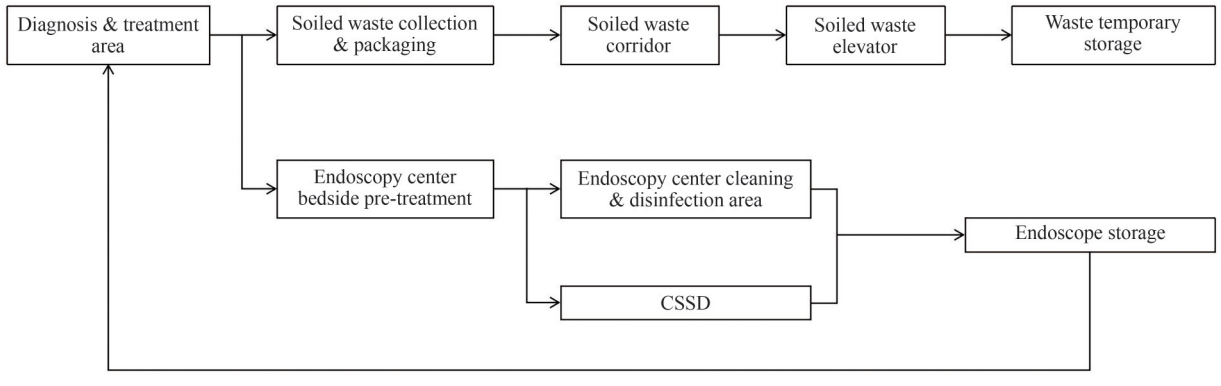
5.1.3 The digestive endoscopy center should have convenient connections with departments such as pharmacy and pathology.

5.2 Planning and layout

5.2.1 Layout requirements

5.2.1.1 The digestive endoscopy center should be in its own zone, arranged centrally. It can also be integrated with endoscopy services from other related departments, and the layout process shall meet relevant hospital infection control requirements.

5.2.1.2 The entrances and exits of the digestive endoscopy center should be closely connected with the corresponding staff/patient and clean/contaminated passages of the main building.




**Material transfer flow**

Pedestrian and material flows shall be separated to avoid cross-infection. The cleaning and disinfection room should be close to the endoscopy treatment rooms to facilitate endoscope transfer.

5.2.1.3 If the renovated endoscopy center cannot have separate clean and dirty passages, dedicated closed transfer containers, transfer bags, or covered endoscope transfer carts shall be used for closed transfer.

5.3 Flow design

5.3.1 Flow requirements

5.3.1.1 The functional flow settings for endoscopy diagnosis and treatment shall meet the principle of "separation of staff and patient flows, separation of clean and contaminated flows".

5.3.1.2 Endoscopy treatment rooms should have separate clean and contaminated passages connecting to the endoscope storage and cleaning/disinfection areas, facilitating the transfer of clean and contaminated endoscopes.

5.3.2 Medical flow design

## 6 Architectural Design

6.1 Patient and chaperone waiting area

6.1.1 General requirements

The patient and chaperone waiting area serves as a preparation area for patients before diagnosis and treatment. It should have waiting chairs and patient calling devices, etc.

6.1.2 Functional composition

The patient and chaperone waiting area mainly includes functions such as appointment registration (including pre-operative preparation guidance), patient waiting area, consultation, and restrooms.

6.2 Pre-operative preparation and anesthesia recovery area

6.2.1 General requirements

6.2.1.1 For painless endoscopy, pre-operative preparation and anesthesia recovery areas shall be reasonably set up.

6.2.1.2 The pre-operative preparation area may have changing rooms, which can be separate rooms or separated by curtains; pre-operative discussions and anesthesia risk assessments can be conducted here simultaneously.

6.2.1.3 The scale of the anesthesia recovery area shall correspond to the scale of the endoscopy procedure rooms. The ratio of procedure rooms where anesthesia/sedation endoscopy is performed to anesthesia recovery beds should be between 1∶1.5 and 1∶2.5.

6.2.2 Functional composition

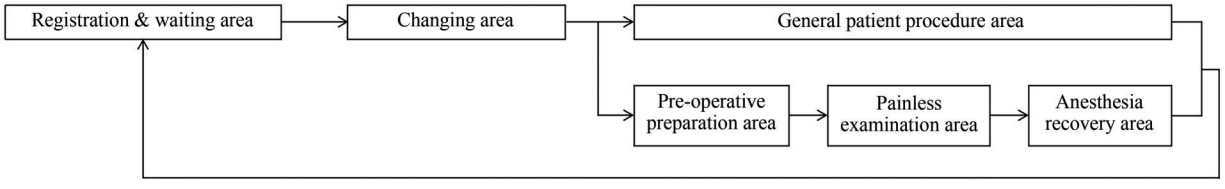
The pre-operative preparation and anesthesia recovery area mainly includes treatment preparation room, post-operative observation room, anesthesia drug management room, storage room, etc.

6.3 Diagnosis and treatment area

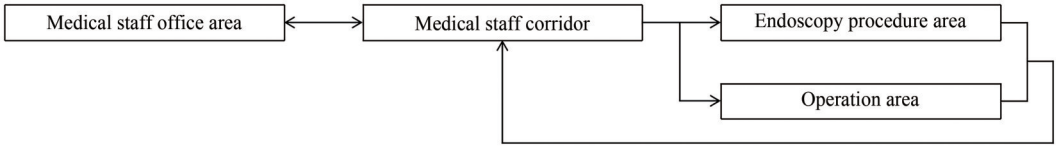
6.3.1 General requirements

6.3.1.1 The diagnosis and treatment area should have natural lighting and natural ventilation.

6.3.1.2 Level 4 endoscopic minimally invasive procedure rooms, such as those for endoscopic submucosal dissection (ESD), endoscopic retrograde cholangiopancreatography (ERCP), etc., should be located at the end of the diag-




**1. Patient consultation flow**




**2. Medical staff work flow**

nosis and treatment area. Rooms for argon breath tests and methane breath tests should be located in well-ventilated areas.

6.3.1.3 The clear width of patient passages must not be less than 2.40 m.

6.3.2 Space requirements for procedure room

6.3.2.1 Endoscopy procedure rooms shall be set up as independent single rooms. Procedure rooms equipped with negative pressure isolation shall comply with the requirements of the standard GB/T 35428.

6.3.2.2 Corresponding procedure rooms shall be set up according to the endoscopic diagnosis and treatment procedures performed. The area shall be sufficient to accommodate adequate equipment and facilities while ensuring that the examination trolley can achieve a 360° rotation. See Table 6-1 for details.

6.3.3 Other configurations

6.3.3.1 The radiation protection configuration for ERCP rooms shall strictly comply with the standard GBZ 130.

6.3.3.2 Handwashing sinks should be provided.

6.4 Medical staff office area

6.4.1 General requirements

The areas of various rooms in the medical staff office area shall be set according to actual needs. The teaching/conference room should be ⩾25 $m^2$, and the main control room should be 5~15 $m^2$.

6.4.2 Functional zoning

The medical staff office area includes functional rooms such as medical staff offices, director's office, film reading room, main control room, archive/file room, teaching/conference room, staff changing rooms, shower rooms, restrooms, storage rooms, and break rooms.

6.5 Endoscope cleaning and disinfection area

6.5.1 General requirements

The cleaning and disinfection room shall comply with the relevant requirements of the standard WS 507.

6.5.2 Cleaning and disinfection area: Equipped with manual cleaning and disinfection workstations, whose configuration shall meet the requirements of the standard WS 507. Automatic endoscope washer-disinfectors should be used for disinfecting or sterilizing endoscopes, and their use and precautions shall comply with the standard GB 30689 and other relevant national regulations.

6.5.3 An independent endoscope final rinse water treatment room shall be provided, with an area preferably 1.5 times the footprint of the water treatment equipment or more.

6.5.4 Where conditions permit, an independent compressed clean gas unit may be established.

6.5.5 Drying area: The number of drying stations shall match the workload. Double-door drying cabinets should be provided.

6.5.6 Storage area

6.5.6.1 The architectural finishes of the endoscope storage room shall be smooth, dust-free, easy to clean and disinfect, and corrosion-resistant. Endoscope storage racks meeting the needs shall be provided; endoscope storage drying

**Table 6-1 Recommended areas for diagnosis and treatment area**

| Room | Recommended area | Remarks |
|---|---|---|
| Procedure room for gastroscopy/colonoscopy | >20 $m^2$ | |
| Procedure room for painless endoscopy and minimally invasive treatment | >27 $m^2$ | |
| Procedure room for endoscopic surgery under endotracheal intubation anesthesia | >30 $m^2$ | For ESD, enteroscopy, EUS-guided treatment, etc. |
| ERCP procedure room (procedure room + control room) | >50 $m^2$ | Including appropriate storage for protective equipment |
| Capsule endoscopy room and gastrointestinal motility room | >20 $m^2$ | |
| Magnetically controlled capsule endoscopy room | >25 $m^2$ | |
| Examination rooms for hydrogen breath tests, methane breath tests, etc. | >5 $m^2$/set | Set up examination rooms, and establish patient breath operation areas in close proximity outside the examination rooms |

cabinets and dedicated endoscope storage cabinets should be provided.

6.5.6.2 The endoscope storage room shall maintain good ventilation, and air disinfection devices of appropriate power shall be installed based on the room's area.

6.6 Waste disposal area

6.6.1 Mainly include a waste room and a dirty utility room.

6.6.2 Waste room: The area should meet the needs for temporary sorted storage of medical waste, domestic waste, and reusable medical textiles generated from the day's procedures.

6.6.3 Dirty utility room: Equipped with water supply and drainage, with separate cleaning sink and waste liquid disposal sink, equipped with a cleaning tool drying rack, and should have a cleaning cloth washer.

6.7 Medical auxiliary area

Include high-value consumables warehouse, low-value consumables warehouse, and dedicated dangerous goods warehouse.

6.8 Decoration and finishing

6.8.1 Decoration and finishing principles

6.8.1.1 Architectural decoration shall follow the general principles of being easy to clean, resistant to scrubbing, corrosion-resistant, impact-resistant, non-cracking, leak-proof, environmentally friendly, energy-saving, and fire-resistant.

6.8.1.2 The selection of indoor decoration materials shall comply with the requirements of current standards GB 50222 and GB 50325.

6.8.1.3 The waterproofing construction of floors, walls, and ceilings shall meet the relevant requirements of the standard GB 55030—2022. Floors shall be slip-resistant and abrasion-resistant; anti-collision measures are recommended at corridor corners.

6.8.2 Construction requirements

6.8.2.1 Building construction shall meet requirements for anti-condensation, leak prevention, and airtightness. Sealing measures shall be taken where mechanical, electrical, and plumbing (MEP) pipes pass through. Radiation shielding rooms shall meet radiation protection construction requirements.

6.8.2.2 Internal corners (Yin-Yang angles) of walls, floors, and ceilings should be finished with a rounded corner radius greater than 30 mm.

6.8.3 Doors

6.8.3.1 Doors shall comply with the relevant requirements in the standard GB/T 41659, meeting sound insulation performance, impact resistance, and resistance to scrubbing and disinfection, while also considering anti-collision devices and accessibility features.

6.8.3.2 Doors of procedure rooms should use non-contact opening/closing. The door width shall be ⩾1.4 m. If automatic sliding doors are used, they shall have automatic delayed closing and anti-collision functions, and shall have a manual function. Corridors should have necessary access control management facilities. The access control system shall be able to automatically release the lock and restore unimpeded passage during environmental emergencies.

6.8.3.3 Fire doors shall be Class A, B, or C fire doors as specified in the current standard GB 50016—2018. Steel fire doors should be selected.

6.8.3.4 Radiation shielding doors shall be selected based on the room's protection requirements for the equipment and meet radiation protection requirements.

6.8.4 Windows

6.8.4.1 Pass-through windows: Double-door, airtight, interlocked pass-through windows shall be used based on actual needs, and equipped with ultraviolet (UV) disinfection lamps.

6.8.4.2 Radiation shielding Windows: Shall be selected based on the room's protection requirements for the equipment.

6.8.5 Others: Patient activity corridors should use anti-collision handrails made of composite materials.

## 7 Water Supply and Drainage System

7.1 General requirements

7.1.1 Water supply and drainage pipes shall not

pass overhead through electrical (power and weak current) equipment rooms and important medical equipment rooms. Multiple drainage pipes shall be set up separately according to the endoscope cleaning volume. Sewage and disinfectant discharge shall meet national discharge standards before being discharged into the sewage treatment system.

7.2 Water supply

7.2.1 Water quality and quantity

7.2.1.1 The water supplied to the endoscopy center shall meet the requirements of the standard GB 51037.4, and the water quality shall comply with the relevant provisions of the national standard GB5747.4. The water quality for cleaning shall comply with the provisions of the current industry standard WS 507.

7.2.1.2 The water supply to the cleaning and disinfection room shall meet process requirements, and the pipe diameter and pressure shall meet the maximum inlet water flow requirements of the medical process water system.

7.2.2 Sanitary ware

Non-contact controls shall be used in public restrooms, nurse stations, treatment rooms, etc.

7.2.3 Pipe material selection

Pipe materials for water supply and hot water shall be stainless steel pipes, copper pipes, or non-toxic plastic water supply pipes that comply with current national standards.

7.3 Drainage

7.3.1 Water seal and drain pipe requirements

Equipment drainage in the cleaning and disinfection room shall adopt an indirect drainage method. The water seal height of the sink drain trap shall not be less than 50 mm. High-temperature drainage from the cleaning and disinfection room shall be collected separately and a cooling tank shall be installed. Seamless steel pipes shall be used for drainage pipes.

7.3.2 Floor drain setting requirements

For the installation of floor drains for ground drainage, floor drains shall be water-seal-free straight-through type with a strainer, plus a trap. The drainage capacity of the floor drain shall meet the requirements for ground drainage.

## 8 Air Conditioning and Fresh Air System

8.1 Indoor design parameters

8.1.1 When an air conditioning system is installed, the indoor temperature and humidity design parameters shall comply with the provisions of Table 8-1, while also meeting the environmental requirements of medical equipment.

8.1.2 The designed minimum fresh air volume for the endoscopy center should comply with the provisions of Table 8-2.

8.2 Cleaning and disinfection room

8.2.1 It shall be set up independently and maintain good ventilation.

8.2.2 If mechanical ventilation is adopted, the "upper supply, lower exhaust" method should be adopted. The air change rate should be ⩾ 10 times/h. Air hygiene requirements shall comply with the standard GB 15982.

8.3 Cooling and heating source requirements for air

**Table 8-1 Designed temperature and humidity for indoor air conditioning**

| Room | Summer | | Winter | |
|---|---|---|---|---|
| | Temperature (℃) | Relative humidity (%) | Temperature (℃) | Relative humidity (%) |
| Procedure room | 25~26 | 50~65 | 22~24 | 30~45 |
| ERCP procedure room | 23~25 | 50~65 | 22~24 | 30~45 |
| Waiting room | 25~27 | 50~65 | 18~24 | 30~45 |
| Anesthesia recovery room | 25~27 | 50~65 | 20~24 | 30~45 |
| Cleaning, disinfection, and storage area | 26~27 | 50~65 | 18~24 | 30~45 |
| Cleaning and disinfection room | 26~27 | ⩽75 | 18~24 | — |
| Office | 25~27 | ⩽65 | 18~24 | — |
| Endoscope storage area | 25~27 | ⩽65 | 18~24 | — |

**Table 8-2 Minimum fresh air volume for main rooms**

| Room | Fresh air volume | |
|---|---|---|
| | $m^3/(h \cdot person)$ | Minimum hourly fresh air changes |
| Procedure room | — | 2 |
| ERCP procedure room | — | 3 |
| Anesthesia recovery room | — | 2 |
| Cleaning, disinfection, and storage area | — | 1 |
| Cleaning and disinfection room | — | 2 |
| Waiting room | 40 | — |
| Office | 30 | — |

conditioning system

8.3.1 Endoscopy procedure rooms should have independent cooling and heating sources, which can be variable refrigerant volume (VRV) air conditioning systems or independent centralized cooling/heating source air conditioning systems. Temperature and humidity parameters shall comply with Table 8-1.

8.3.2 The centralized chilled water units and gas boilers in the hospital's central utility plant shall be able to adapt to the load demands of the endoscopy center, and a backup cooling and heating source capable of independent operation during transitional seasons shall be provided.

8.4 Air conditioning and ventilation terminal system requirements

8.4.1 The air conditioning and ventilation systems for functional rooms of different types of endoscopy rooms shall be set up independently and shall comply with the relevant requirements in the standards GB 51039 and WS/T 855.

8.5 Air distribution requirements for air conditioning and ventilation system

8.5.1 The air conditioning system shall adopt a reasonable air distribution method. Air velocity control in areas where personnel stay for long periods: Not greater than 0.3 m/s in summer and not greater than 0.2 m/s in winter.

8.5.2 To prevent toxic, harmful, and infectious gases from leaking into indoor spaces through positive pressure ducts, the exhaust fan of the ventilation system should be installed at the end of the exhaust duct to maintain negative pressure in the pipeline.

8.5.3 Air management in the endoscopy diagnosis/treatment area and cleaning/disinfection area can be carried out with reference to the standard WS/T 368.

## 9 Electrical System

9.1 Power supply and distribution design

9.1.1 The power supply and distribution system shall be designed according to the classification of the locations where medical electrical equipment is used. The distribution voltage shall be 220/380V.

9.1.2 The power supply for diagnostic and therapeutic equipment and lighting in endoscopy procedure rooms shall be classified as primary load and supplied by two independent power sources.

Electrical loads in medical buildings shall be classified according to the reliability requirements of the power supply and the impact level of power interruption on life safety, personal safety, economic loss, etc., and shall comply with the requirements of the standard JGJ 312.

9.1.3 Endoscopy procedure rooms should use multifunctional medical trunking systems to arrange various electrical devices such as sockets and grounding terminals.

9.1.4 The endoscopy center shall have sockets or outlets configured according to the functional layout of rooms to meet functional needs, and a certain number of spares shall be reserved.

9.2 Lighting design

9.2.1 Lighting design shall comply with the relevant

provisions of current national standards GB 50034 and GB 55015, and shall meet green and energy-saving requirements.

9.2.2 Lighting design shall reasonably select light sources and luminaires based on the function of the space, visual requirements, and architectural spatial characteristics, determine appropriate lighting solutions, and create a comfortable lighting environment.

9.2.3 Energy-saving light sources such as light emitting diodes (LEDs) shall be used for lighting. Under the premise of ensuring lighting quality, the lighting power density value shall be controlled.

9.2.4 Lighting switches in public areas should be centrally controlled at locations such as waiting service desks. Intelligent lighting control systems or building automation systems can be used for group and zone control based on natural lighting and usage conditions. Switch control shall be used in clinics, offices, and similar spaces.

## 10 Medical Gas Configuration and Requirements

10.1 General requirements

10.1.1 The medical gas system consists of medical gas source stations, pipeline distribution systems, monitoring and alarm systems, and terminals.

10.1.2 The endoscopy center shall have oxygen and medical vacuum systems. Compressed air and carbon dioxide systems may be installed as needed. The gas source shall meet the gas parameter requirements at the terminals.

10.1.3 Oxygen, medical vacuum, and compressed air shall be supplied by the medical institution's gas source stations. Carbon dioxide shall be supplied by a dedicated manifold room.

10.2 Medical gas pipeline system design

10.2.1 Pipes for conveying medical gases shall comply with the relevant provisions of current national standards GB 50751, GB/T 12771, and current industry standard YS/T 650.

10.2.2 The gas supply source shall be provided based on medical requirements and the availability of medical carbon dioxide supply, and should be designed to meet a usage or reserve volume for one week or more, and at least not less than 3 days.

10.3 Gas terminal system

10.3.1 Medical gas terminals should be standardized and unified where equipment and material supply permits, to avoid misconnection accidents caused by inconsistent terminal interfaces.

10.3.2 The safety performance of medical gas terminal assemblies, low-pressure hose assemblies, and supply devices shall comply with the relevant provisions of current industry standards YY 0801.1 and YY/T 0799.

10.4 Medical gas pipeline monitoring and alarm system

10.4.1 Alarm device settings

Medical gas supply under-pressure alarm devices shall be installed at the nurse station and in the manifold room. When the pressure in the supply system falls below the alarm pressure, both audible and visual alarms shall be activated. The audible alarm shall be audible within a range of 1.5 meters, and the visual alarm shall be a red indicator light.

10.4.2 The medical gas monitoring and alarm system shall include gas source alarms, area alarms, and pressure and flow monitoring. Alarm signals, pressure, and flow monitoring signals should be connected to the building automation system or a centralized medical gas monitoring and alarm system.

10.4.3 The alarm shall have a function for testing alarm indicator light failure and a self-start function after power recovery.

## 11 Intelligence and Information System Configuration

11.1 General requirements

The system shall comply with the Integrating the Healthcare Enterprise (IHE) integration pro-

files. The intelligent information system for digestive endoscopy is applicable to the entire process of basic digestive system examinations, realizing all functions of the endoscopy department from patient registration, triage management, queuing and calling, image acquisition, structured reporting, review, department management, statistical reports, to clinical image distribution. Additionally, it can be extended with subsystems for surgical teaching, research platforms, and quality control management.

11.2 System architecture

11.2.1 The system shall adopt mainstream C/S, B/S, or SaaS architecture.

11.2.2 Support DICOM 3.0 Storage SCP (image storage), SCU (image sending), and Query/Retrieve.

11.2.3 Support multiple storage architectures and storage media, including direct-attached storage (DAS), network attached storage (NAS), and storage area network (SAN); capable of easily managing massive data and supporting a large number of concurrent requests.

11.2.4 Support HL7 standard, WebService, or middleware for integration with third-party systems.

11.2.5 The system shall support 7×24-hour uninterrupted operation and support data disaster recovery.

11.2.6 Newly purchased equipment can be smoothly integrated into the system.

11.2.7 Provide detailed system logging and management functions for easy system maintenance and management.

11.2.8 Based on modular design, the entire patient diagnosis and treatment process is covered (Registration → Appointment → Triage → Calling → Examination → Diagnosis → Report → Quality Control → Review → Follow-up), supporting interoperability with hospital HIS, EMR, PACS, Pathology, and other systems (compatible with standard interfaces such as HL7, DICOM 3.0, and FHIR).

11.3 Network and information security

11.3.1 Network cabling shall comply with the standard GB 50311, with an independently partitioned endoscopy service subnet, physically isolated from the public network.

11.3.2 Core data shall be stored in the hospital's private cloud, using AES-256 encryption and dual-machine hot standby (daily full backup + real-time incremental backup). Data transmission shall comply with HTTPS protocol.

11.3.3 Conduct regular security vulnerability scans and penetration tests to prevent network attacks. Support the critical value process interfaced with clinical systems (ensuring secure and reliable transmission of emergency information).

11.3.4 Privacy and access control shall strictly comply with the *Personal Information Protection Law of the People's Republic of China*. Patient sensitive information (such as pathology results) shall be anonymized before being used for research. For special groups such as VIP patients, information access control shall be strengthened through privacy protection processes.

11.3.5 Regarding role-based access control (e. g., doctors, nurses, administrators), operation logs shall be retained for ⩾180 days (meeting audit requirements in ISO 27799).

11.3.6 The system's original security architecture design strictly follows medical information security standards. The private cloud storage and encryption solutions undergo multiple layers of verification by the original manufacturer, ensuring better data security compared to third-party integrated systems.

11.3.7 The system must strictly comply with the *Personal Information Protection Law of the People's Republic of China*, anonymize patient sensitive information, and implement role-based access control and operation log retention, meeting relevant audit requirements.

11.4 Data standardization and terminology management module

11.4.1 Terminology shall uniformly comply with the *2020 Standard Terminology Set for Digestive Endoscopy Diagnosis and Treatment* to

standardize lesion descriptions. Support ICD-11 code mapping to enhance data comparability.

11.4.2 Standardize report templates, unify report structure and fields (e.g., examination site, lesion characteristics), and support custom templates to meet the needs of different hospitals.

11.4.3 Comply with the *Medical Quality Control Indicators for Digestive Endoscopy Diagnostic and Therapeutic Techniques*, the standard WS 507, and international standards such as ISO 27799 and ISO 13485.

11.4.4 Module priorities can be adjusted according to the scale and needs of the medical institution, focusing on intelligence (such as AI assistance), quality control closed-loop, and data security, to achieve standardized and homogenized development of digestive endoscopy diagnosis and treatment.

11.5 Basic functions

11.5.1 System integration and interface module

11.5.1.1 Seamless integration with in-hospital systems such as HIS, integration platform, PACS, and EMR, enabling automation of examination orders and result transmission. Support standard interfaces such as HL7, DICOM, WebService, intermediate tables, and FHIR.

11.5.1.2 The system shall be scalable, supporting multi-channel appointment capabilities (e. g., WeChat official accounts, mini-programs, hospital official platforms, self-service terminals, etc.).

11.5.1.3 Interoperate with external platforms, connect to regional medical platforms, and support data reporting and medical insurance settlement.

11.5.1.4 Provide open APIs for research institutions to analyze anonymized data; support internet services and cloud imaging services.

11.5.1.5 Shall support structured granular definition of site/lesion attributes, enabling global structured modeling of lesion feature attributes; possess multi-level indexing and drill-down statistical analysis capabilities based on lesion feature attributes, meeting the requirements for structured endoscopic management.

11.5.2 Appointment registration

a) Realize automatic reception of electronic order and return of appointment status through integration with HIS/integration platform.

b) Patients can register or be registered manually. Support registration via swiping medical cards, insurance cards, social security cards, ID cards, etc. Support quick registration by scanning barcodes on paper application forms.

c) Provide appointment resource configuration function, allowing setting of appointment dates and time slots for examination items, and customizing the maximum number of appointments per appointment queue.

d) Barcodes can be generated and printed upon appointment.

e) The software interface can be customized according to user habits. The patient list distinguishes status through different colors and marks (e. g., special marks for critical patients) to enhance operational convenience.

f) Will support integration with regional medical platforms, AI application upgrades, and medical alliance data sharing platforms to ensure system scalability. Simultaneously compatible with special process management (e. g., VIP privacy protection, priority for elderly patients, emergency priority) to meet differentiated diagnosis and treatment needs.

g) The system can call patients and chaperones by voice.

h) The system supports secondary calling (secondary waiting).

11.5.3 Image and text report

a) System UI can be personalized according to user needs.

b) The system uses structured reports. Keywords generated in structured reports comply with the *2020 Standard Terminology Set for Digestive Endoscopy Diagnosis and Treatment*.

c) Provide image acquisition function, supporting various endoscopic video signals such as SDI/YPbPr/DVI/HDMI, and supporting signals from other medical equipment such as X-ray machines, choledochoscopes, and confocal endoscopes.

d) Image acquisition includes multiple methods such as shortcut keys, handle controls, and foot switches. Images are stored in standard DICOM format.

e) Examination reports have lock and unlock functions.

f) Provide real-time report caching function, which can be automatically restored after unexpected system shutdown.

g) Provide real-time video caching function, allowing review of acquired images.

h) Provide report template maintenance function, allowing setting of personal templates, public templates, and commonly used vocabulary.

i) Support multi-terminal access (workstations/mobile devices), provide patient mobile services (report query, examination reminders, intelligent Q&A).

j) Real-time alerts for software working status (acquisition mode, room status, operation feedback information, etc.).

k) Ensure 7×24-hour business continuity, support offline working mode (can continuously acquire and write reports, automatically synchronize data after network recovery).

l) Report retrieval and statistics support multi-condition queries. Retrieval results can be exported in Excel or PDF format. Statistical functions shall include basic statistics and allow customization of statistical items based on usage.

m) Shall include follow-up management.

n) Shall include a critical value management function or interface.

11.5.4 Disinfection traceability system

11.5.4.1 Use RFID/QR codes to bind endoscope and patient information, achieving "patient-endoscope traceability" through scanning. Synchronously monitor equipment status (usage count, maintenance cycles) and automatically push maintenance reminders. Support instant communication for operators during the cleaning and disinfection process (department notifications, diagnostic discussions) to ensure efficient collaboration in key links. Data storage for ⩾ 3 years.

11.5.4.2 It shall achieve association with examination data from the reporting system.

11.5.4.3 Full-process traceability shall be implemented according to the standard WS 507.

11.6 Extended functions

11.6.1 Intelligent consumables management

11.6.1.1 Establish full lifecycle records for consumables (warehousing → requisition → patient binding → billing → write-off), monitor inventory in real-time, and provide alerts for expiration dates (e.g., automatic alarm when stock of biopsy forceps, hemostatic clips fall below 5%).

11.6.1.2 Consumable usage shall be automatically matched with electronic medical records and billing systems, linked to patient expense details, preventing missed charges and off-specification use. Support precise binding of consumables to examination items to improve billing accuracy.

11.6.2 Quality control management

11.6.2.1 Full-process quality control management

11.6.2.2 Collect 18 national quality control indicators such as examination completion rate, early cancer diagnosis rate, and complication rate, in compliance with the *Medical Quality Control Indicators for Digestive Endoscopy Diagnostic and Therapeutic Techniques*, and automatically generate a quality control dashboard.

11.6.2.3 Real-time monitoring dashboards visually display departmental operation indicators (e.g., examination volume, equipment utilization rate), supporting mobile alerts. Reg-

ularly generate quality control reports. Support interfacing with the National Digestive Endoscopy Quality Control Platform (Chinese national unified public open platform). Hospital-side quality control data shall comply with the platform's interface specification requirements to complete compliant uploads.

11.6.3 AI-assisted diagnosis and treatment applications

11.6.3.1 Real-time quality control AI: For gastroscopy, dynamically monitor the detection coverage of key gastric sites in real-time (quality control standard ⩾95%), immediately alert the operator if not met. Simultaneously monitor the observation coverage of the esophageal blind spot under dual-light mode and configure independent esophageal examination duration reminders. For colonoscopy, monitor withdrawal time (quality control standard ⩾6 minutes) and cecal intubation rate, immediately alert the operator if not met. Support bowel preparation snapshot scoring and configurable quality control parameters such as insertion/withdrawal time.

11.6.3.2 Diagnostic assistance AI: Based on deep learning algorithms, identify subtle lesions (e.g., ⩽5 mm flat early cancer) in real-time, provide preliminary judgment of lesion nature (adenoma, malignant tumor), and delivers real-time prompts on lesion identification results to reduce the risk of missed diagnosis. Its lesion localization accuracy must pass NMPA certification or FDA BDD certification.

11.6.4 AI-assisted management applications

11.6.4.1 Resource scheduling AI: Predict daily examination volume based on historical data, automatically optimize equipment and staff scheduling (error rate ⩽10%), taking into account priority configuration for special processes such as emergency and elderly patients.

11.6.4.2 Risk warning AI: Analyze anesthesia records and vital signs to predict the risk of intraoperative complications and proactively push emergency plans. Integrate patient preoperative assessment data to optimize anesthesia risk management processes.

11.6.5 Healthcare-associated infection quality control

11.6.5.1 Enable traceability of the process and effectiveness of endoscope cleaning, disinfection/sterilization.

11.6.5.2 Enable traceability of information for staff involved in endoscope cleaning, disinfection/sterilization and patients using the endoscopes.

11.6.5.3 It is preferable to interface with the medical institution's healthcare-associated infection monitoring system and/or mobile client applications to provide real-time alerts for abnormal information.

11.6.6 Closed-loop anesthesia management

Support access to anesthesia-related data for preoperative, intraoperative, and post-operative phases.

## 12 Medical Equipment Configuration

12.1 Equipment classification

12.1.1 Medical equipment in endoscopy centers is classified into general endoscopy center medical equipment and special function endoscopy center medical equipment.

12.1.2 General endoscopy center's medical equipment includes four categories: basic equipment for endoscopy and treatment, anesthesia equipment, auxiliary equipment, and emergency and resuscitation equipment, see Appendix A (Table A.1).

12.1.3 This standard covers two types of special function endoscopy center medical equipment, see Appendix A (Table A.2), including: equipment for biliopancreatic duct endoscopy treatment and lithotripsy equipment. Medical institutions may reasonably configure other special function endoscopic examination and

treatment medical equipment based on their functional positioning, endoscopy center needs, and business development requirements.

12.2 Equipment configuration requirements

12.2.1 Based on the functional positioning of the medical institution's endoscopy center, the needs for endoscopic examination and treatment, and business development requirements, the configuration requirements for medical equipment are divided into three grades: A, B, and C.

a) Basic configuration (Grade A) shall be equipped by all levels of hospitals, meaning the configured quantity is at least 1.

b) Tertiary hospital add-on (Grade B) shall be equipped by tertiary hospitals, meaning tertiary hospitals shall have a configured quantity of at least 1.

c) Optional configuration (Grade C) is optional equipment for all levels of hospitals.

12.2.2 After expert assessment, qualified secondary hospitals may reasonably configure Grade B and Grade C equipment according to needs, referring to the configuration requirements for tertiary hospitals.

12.3 Equipment items

12.3.1 There are 27 types of general endoscopy center medical equipment items, including 21 Grade A items, 2 Grade B items, and 4 Grade C items. See Appendix A (Table A.1) for the specific list of items.

12.3.2 There are 16 types of special function endoscopy center medical equipment items, including 0 Grade A items, 1 Grade B item, and 15 Grade C items. See Appendix A (Table A.2) for the specific list of items.

12.3.3 Medical institutions may reasonably configure equipment items not listed in this standard based on their functional positioning, endoscopy center needs, and business development requirements.

12.4 Equipment quantity

12.4.1 Medical oxygen terminal (Appendix A, Table A.1, Item No. 1: Grade A)

Each endoscopy procedure room shall have ⩾1 medical oxygen terminal. The ratio of configured quantity to the number of beds in the endoscopy recovery room shall be ⩾1∶1, or an equivalent number of oxygen cylinders shall be provided.

12.4.2 Medical carbon dioxide gas terminal (Appendix A, Table A.1, Item No. 2: Grade B)

Each endoscopy procedure room shall have ⩾1 medical carbon dioxide gas terminal, or an equivalent number of carbon dioxide cylinders shall be provided.

12.4.3 Medical vacuum terminal (Appendix A, Table A.1, Item No. 3: Grade A)

Each endoscopy procedure room shall have ⩾1 medical vacuum terminal, or an equivalent number of vacuum aspirators shall be provided.

12.4.4 Medical transfer trolley (Appendix A, Table A.1, Item No. 4: Grade A)

The ratio of configured quantity to the number of beds in each standard endoscopy procedure room shall be ⩾1∶1. The ratio of configured quantity to the number of beds in each painless endoscopy procedure room shall be ⩾1∶2.

12.4.5 Medical cart (Appendix A, Table A.1, Item No. 5: Grade A)

Each painless procedure room shall have ⩾1 anesthesia cart (drug cart). Each procedure room shall have ⩾1 nursing treatment cart. Each anesthesia recovery room shall have ⩾1 nursing cart. Each endoscopy center shall have ⩾1 resuscitation cart.

12.4.6 Endoscopy boom (Appendix A, Table A.1, Item No. 6: Grade B)

One set of endoscopy boom shall be provided in each endoscopy procedure room.

12.4.7 Electronic endoscopy system (Appendix A, Table A.1, Item No. 7: Grade A)

One set of electronic endoscopy system shall be provided in each endoscopy procedure room (including two electronic gastroscopes, two electronic colonoscopes, two ultrasound miniprobes, one medical monitor, one auxiliary water supply device, and one carbon dioxide gas device).

12.4.8 Medical image management system (Appendix

A, Table A.1, Item No. 8: Grade A)

One set of medical image management system shall be provided in each endoscopy center.

12.4.9 Auxiliary water supply device (Appendix A, Table A.1, Item No. 9: Grade A)

One set of auxiliary water supply device shall be provided in each endoscopy center.

12.4.10 High-frequency electrosurgical workstation (Appendix A, Table A. 1, Item No. 10: Grade A)

One set of high-frequency electrosurgical workstation shall be provided in each endoscopy procedure room.

12.4.11 Medical suction unit (Appendix A, Table A.1, Item No. 11: Grade A)

One set of medical suction unit shall be provided in each endoscopy center.

12.4.12 Breath test analyzer (Appendix A, Table A.1, Item No. 12: Grade A)

One set of breath test analyzer shall be provided in each endoscopy center.

12.4.13 Air disinfection device (Appendix A, Table A.1, Item No. 13: Grade A)

One set of air disinfection device shall be provided in each endoscopy procedure room.

12.4.14 Film viewing device (Appendix A, Table A.1, Item No. 14: Grade A)

One set of film viewing device shall be provided in each endoscopy procedure room.

12.4.15 Anesthesia machine (Appendix A, Table A.1, Item No. 15: Grade A)

One set of anesthesia machine shall be provided in each painless endoscopy procedure room, and one set of anesthesia machine shall be provided in the anesthesia recovery room.

12.4.16 Patient monitor (Appendix A, Table A. 1, Item No. 16: Grade A)

One set of patient monitor shall be provided in each painless endoscopy procedure room, and one set of patient monitor shall be provided in each bed in the anesthesia recovery room.

12.4.17 Syringe pump (Appendix A, Table A. 1, Item No. 17: Grade A)

One set of syringe pump shall be provided in each painless endoscopy procedure room.

12.4.18 Endoscope cleaning & disinfection workstation (Appendix A, Table A. 1, Item No. 18: Grade A)

The cleaning and disinfection room of each endoscopy center shall have ⩾1 endoscope cleaning and disinfection workstation.

12.4.19 Pure water system (Appendix A, Table A.1, Item No. 19: Grade A)

One set of pure water system shall be provided in the cleaning and disinfection room of each endoscopy center, or pure water shall be supplied by a centralized water supply device.

12.4.20 Acidic water system (Appendix A, Table A.1, Item No. 20: Grade A)

One set of acidic water system shall be provided in the cleaning and disinfection room of each endoscopy center.

12.4.21 Ultrasonic cleaning device (Appendix A, Table A.1, Item No. 21: Grade A)

One set of ultrasonic cleaning device shall be provided in the cleaning and disinfection room of each endoscopy center.

12.4.22 Automatic endoscope washer-disinfector (Appendix A, Table A. 1, Item No. 22: Grade C)

Provided as needed in the cleaning and disinfection room of each endoscopy center.

12.4.23 Endoscope transfer cart (Appendix A, Table A.1, Item No. 23: Grade A)

An appropriate number of endoscope transfer carts shall be provided in the cleaning and disinfection room of each endoscopy center.

12.4.24 Endoscope & accessory storage cabinet (room) & storage drying cabinet (Appendix A, Table A.1, Item No. 24: Grade A)

An appropriate number of storage cabinets (rooms) and storage drying cabinets shall be provided in the cleaning and disinfection room of each endoscopy center.

12.4.25 External defibrillator (Appendix A, Table A.1, Item No. 25: Grade A)

One set of external defibrillators shall be provided in each endoscopy center.

12.4.26 Manual resuscitator (Appendix A, Table A.1, Item No. 26: Grade A)

One set of manual resuscitators shall be provided in each endoscopy center.

12.4.27 Emergency and resuscitation equipment other than the above items (Appendix A, Table A.1, Item No. 27: Grade C)

Medical institutions may reasonably configure the equipment at a quantity based on their functional positioning, endoscopy center needs, and business development requirements.

## Appendix A

## （Normative）

## Items and Requirements for Medical Equipment Configuration in Endoscopy Centers

**A. 1** See Table A.1 for the items and requirements for medical equipment configuration in general endoscopy centers.

**A. 2** See Table A.2 for the items and requirements for medical equipment configuration in special function endoscopy centers.

**Table A.1 Items and requirements for medical equipment configuration in general endoscopy centers (27 types)**

| Equipment category | No. | Equipment item | Example product | Config. grade |
|---|---|---|---|---|
| Basic endoscopy equipment | 1 | Medical oxygen terminal | Medical oxygen outlet, oxygen terminal, oxygen cylinder | A |
| | 2 | Medical $CO_2$ terminal | Medical $CO_2$ outlet, $CO_2$ terminal, $CO_2$ cylinder | B |
| | 3 | Medical vacuum terminal | Medical vacuum terminal | A |
| | 4 | Medical transfer trolley | Medical transfer cart, transfer stretcher | A |
| | 5 | Medical cart | Anesthesia cart, drug cart, treatment cart, resuscitation cart | A |
| | 6 | Endoscopy boom | Endoscopy boom, laparoscopic boom | B |
| | 7 | Electronic endoscopy system | Electronic gastroscope, electronic colonoscope, ultrasound miniprobe | A |
| | 8 | Medical image management system | Endoscopy image & information system | A |
| | 9 | Auxiliary water supply device | | A |
| | 10 | High-frequency electrosurgical workstation | Electrosurgical unit, argon plasma coagulator | A |
| | 11 | Medical suction unit | Electric suction pump | A |
| | 12 | Breath test analyzer | C13 analyzer or C14 analyzer | A |
| | 13 | Air disinfection device | | A |
| | 14 | Film viewing device | Medical viewer, X-ray film viewer | C |
| | 15 | Anesthesia machine | Anesthesia workstation, anesthesia system | A |
| | 16 | Patient monitor | Patient monitor, multi-parameter monitor | A |
| | 17 | Syringe pump | Anesthesia syringe pump, micro-infusion pump, medical syringe pump | A |
| | 18 | Endoscope cleaning & disinfection workstation | Endoscope cleaning bench, disinfection station | A |
| Auxiliary equipment | 19 | Pure water system | Pure water generator, water treatment device, central water supply unit | A |
| | 20 | Acidic water system | Electrolyzed oxidized water generator | C |
| | 21 | Ultrasonic cleaning device | Ultrasonic cleaner | A |
| | 22 | Automatic endoscope washer-disinfector | Flexible endoscope reprocessor | C |
| | 23 | Endoscope transfer cart | | A |

续表

| Equipment category | No. | Equipment item | Example product | Config. grade |
|---|---|---|---|---|
| Emergency equipment | 24 | Endoscope & accessory storage cabinet (room) & storage drying cabinet | | A |
| | 25 | External defibrillator | External defibrillator, AED | A |
| | 26 | Manual resuscitator | Bag-valve mask, portable oxygen inhaler, manual ventilator | A |
| | 27 | Emergency & transport ventilator | Emergency ventilator, transport ventilator | C |

Grade A (basic configuration) shall be equipped by all levels of hospitals; Grade B (tertiary hospital add-on) shall be equipped by tertiary hospitals; Grade C (optional) are optional for all levels of hospitals.

**Table A.2 Items and requirements for medical equipment configuration in special function endoscopy centers (16 types)**

| Equipment category | No. | Equipment item | Example product | Config. grade |
|---|---|---|---|---|
| Special function endoscopy equipment | 1 | Endoscopic ultrasound system | | B |
| | 2 | Digital X-ray fluoroscopy system | Digital GI system | C |
| | 3 | Choledochoscopy system | | C |
| | 4 | Electronic magnifying gastroscope | | C |
| | 5 | Electronic magnifying colonoscope | | C |
| | 6 | Confocal endoscope | | C |
| | 7 | Endocytoscopy system | | C |
| | 8 | Electronic duodenoscope | | C |
| | 9 | Electronic colonoscope (long) | | C |
| | 10 | Electronic enteroscope | | C |
| | 11 | Transnasal electronic gastroscope | | C |
| | 12 | Esophageal motility analyzer | | C |
| | 13 | Capsule endoscopy system | | C |
| | 14 | Magnetically controlled capsule endoscopy system | | C |
| | 15 | Medical microscope | | B |
| | 16 | Single-use digestive endoscopy system | | C |

Grade A (basic configuration) shall be equipped by all levels of hospitals; Grade B (tertiary hospital add-on) shall be equipped by tertiary hospitals; Grade C (optional) are optional for all levels of hospitals.

## Appendix

## （Informative）

**Works cited:**

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