



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1028-2023

Medical endoscopes - Fibre endoscopes

医用内窥镜 纤维内窥镜

Issued on: September 5, 2023

Implemented on: September 15, 2024

Issued by: National Medical Products Administration

Table of Contents

1	Scope
2	Normative References
3	Terms and Definitions
4	Requirements
4.6	Light Energy Transfer Efficiency
4.10	Mechanical Properties
4.10.2	Mechanical properties of flexible fiber endoscopes
5	Test Methods
5.3	Angular Resolution
5.3.1	Equipment
5.3.2	Steps
5.5	Illumination Edge Uniformity In accordance with the method of
5.6	Light Energy Transfer Efficiency
5.6.1	Equipment
5.6.2	Environmental conditions
5.6.3	Steps
5.10	Mechanical Properties
5.10.2	Mechanical properties of flexible fiber endoscopes

1 Scope

YY/T 1028 is the product standard for the fibre endoscope, the flexible scope that carries its image along a coherent fibre bundle rather than on a chip at the tip. It sets the requirements for medical fibre endoscopes and the test methods that verify them, covering the optical performance that decides what the operator actually sees: resolution, field of view, distortion, illumination and the condition of the fibre bundle, where broken fibres show as dark points that never recover. The version in circulation carries amendment 1 of 2025. Fibre scopes remain in wide use in China alongside video endoscopes, particularly in ENT and anaesthesia. For a manufacturer or an importer of flexible fibre endoscopes seeking Chinese registration, this is the standard the optical test report follows.

This document specifies the requirements for medical fiber endoscopes and describes the corresponding test methods. This document is applicable to medical fiber endoscopes.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document. JJG 245-2005 Verification Regulation of Illuminance Meter

YY 0068.1-2008 Medical Endoscopes - Rigid Endoscope - Part

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 fiber endoscope An endoscope usually consists of an objective lens system and an optical imaging / transferring system (including fiber imaging bundle), with or without an observation eyepiece system, to form an observation light path.

3.2 max vertex field angle The opening angle of the center of the fiber endoscope end to the height of the maximum field of view on the object side.

3.3 max object pupil field angle W_p The opening angle of the fiber endoscope imaging systems entrance pupil center to the height of the maximum field of view on the object side.

3.4 working distance The distance between the object being observed and the fiber endoscope end.

4 Requirements

4.1 General Requirements The optical system shall be able to ensure clear observation, and there shall be no degumming, demolding or cracks in the adhesive. The optical elements shall not have pitting, scratches, bubbles, oil spots, mold spots, dust and other attachments that may affect the observation.

4.2 Field Angle The manufacturer shall provide the design value of the endoscope field angle in the accompanying documents, with an allowable error of 15%.

4.3 Angular Resolution The manufacturer shall provide the nominal value of the angular resolution at the center of the field of view at the design optical working distance d_0 in the accompanying documents, and the allowable error of the nominal value is 10% (the upper limit is not included).

4.5 Illumination Edge Uniformity When inspecting within the depth of field range of observation, the illumination spot shall fill the effective scale of the field of view.

4.6 Light Energy Transfer Efficiency

---Effective Photometric Rate The light energy transfer efficiency of a fiber endoscope is expressed in terms of effective photometric rate. For fiber endoscopes, the effective photometric rate is expressed in the symbol DM, which is defined as the ratio of the average luminous exitance of the object surface to the average illumination of the fundus image surface. For non-visual fiber endoscopes, this effective photometric rate is defined as the lowest object surface luminance (L_{min}), at which, the image surface displays a critical discernible gray scale.

4.10 Mechanical Properties

4.10.1 Mechanical properties of rigid fiber endoscopes They shall comply with the requirements of YY/T 0068.2.

4.10.2 Mechanical properties of flexible fiber endoscopes

4.10.2.8 Dimensional deviation It shall comply with the following requirements.

4.10.2.4

a) based on the angle hand wheel controllability;

5.10.2.5 Sealing performance In accordance with the following steps, carry out the test.

a) Connect the leakage detection device attached to the product to the ventilation valve of the light guide plug part of the fiber endoscope. Press the airbag on the pressure leakage detection device, and when the barometers indication rises to 22 kPa, place the endoscope body in water, until the water is deep enough to immerse the endoscope body. Turn the angle hand wheel to bend in the upper and lower directions, and bend in each direction for 3 times. Within 3 minutes after stabilization, there shall be no bubbles emerging from the endoscope body. It shall comply with the requirements of

5.10.2.6 Matching with accessories Insert the supplied surgical instruments into the instrument channel and extend them from the outlet of the instrument channel at the tip. The surgical instruments shall be within the field of view of the fiber endoscope, and freely move without clamping stagnation. Determine whether it complies with the stipulations of

4.10.2.6

5.10.2.7 Marks In accordance with the following steps, carry out the test.

5 Test Methods

5.1 General Requirements Place a uniform white background on the end under test, observe the optical system through the eyepiece, and determine whether it complies with

the stipulations of 4.1.

5.2 Field Angle Carry out the test in accordance with the field angle determination method specified in

5.1 of YY 0068.1-2008.

5.3.1 Equipment

5.3.1.1 Resolution standard board, each group of line pairs has at least two directions, such as. horizontal direction and vertical direction, and the range is 1 lp/mm ~ 100 lp/mm.

5.3.2 Steps

5.3.2.1 Place the fiber endoscope on the optical bench.

5.3.2.2 Place the resolution standard board at the designed optical working distance d_0 of the fiber endoscope and fix it vertically to the visual axis.

5.3.2.8 Install the fiber endoscope in the endoscope fixture, and the visual axis is aligned with the measurement mark.

5.3.2.9 By observing the ring of the measurement mark, adjust the fixture of the fiber endoscope, so that the small ring of the measurement mark coincides with the field of view and perpendicular to the visual axis.

5.3.2.10 Respectively mark the position of the end apex of the fiber endoscope and the central vertical line of the measurement mark ring and use a length measuring tool to measure and record the distance between them as d_1 (mm).

5.3.2.11 In the direction of the visual axis, move the fiber endoscope or measurement mark, so that the large ring of the measurement mark coincides with the field of view and perpendicular to the visual axis.

5.3.3 Calculation In accordance with Formula (2), calculate the distance a between the entrance pupil and the vertex.

5.4 Depth of Field of Observation Fix the fiber endoscope and adjust the distance between the head end surface and the object being observed. At the two positions of the closest end and the farthest end of the nominal depth of field range, in accordance with the test method in 5.3, respectively test the angular resolution at the center of the field of view at the corresponding position. Determine whether it complies with the stipulations of 4.4.

5.5 Illumination Edge Uniformity In accordance with the method of

5.1 in YY 0068.1-2008, measure W_p . Use the test light source to illuminate an integrating sphere. The illumination light entrance of the fiber endoscope is pasted with cosine transmission material, and then, enters the small hole of the integrating sphere. The