

Translated English of Chinese Standard: YY/T1603-2018

www.ChineseStandard.net → Buy True-PDF → Auto-delivery.

Sales@ChineseStandard.net

YY

PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.99

C 40

YY/T 1603-2018

**Medical Endoscopes - Endoscope Supply Units -
Video Camera System**

医用内窥镜 内窥镜功能供给装置 摄像系统

Issued on: January 19, 2018

Implemented on: January 01, 2019

Issued by: China Food and Drug Administration

Table of Contents

Foreword.....3

1 Scope.....4

2 Normative References4

3 Terms and Definitions4

4 requirements6

5 Test Methods7

Appendix A (Normative) Test Methods of Brightness Response Characteristic9

Appendix B (Normative) Test Methods of Signal-to-Noise Ratio..... 14

Appendix C (Normative) Test Methods of Spatial Frequency Response..... 18

Appendix D (Normative) Test Methods of Static Image Latitude..... 24

Medical Endoscopes - Endoscope Supply Units - Video Camera System

1 Scope

This Standard specifies the terms, definitions, requirements, and test methods for medical endoscopic camera system.

This Standard is applicable to medical endoscopic camera system (hereinafter referred to as camera system) that are used as endoscope supply units in endoscopy and surgery.

This Standard is not applicable to the camera system with special spectral effects and non-visible spectral imaging.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

GB 9706.19 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment

3 Terms and Definitions

For the purpose of this document, the following terms and definitions apply.

3.1 Conversion function

3.1.1 Opto-electronic conversion function; OECF

The ideal relationship between the object brightness and the corresponding output signal of the camera system.

3.1.2 Electro-optical conversion function

The inverse function of OECF.

AND the ratio of the modulation degree of the output signal calculated by the OECF inverse function to the modulation degree of the target object surface brightness.

3.7 Sine-based spatial frequency response; s-SFR

SFR when the target is a sine wave modulation diagram.

3.8 Modulation degree

The ratio BETWEEN the maximum signal value minus the minimum signal value AND the maximum signal value plus the minimum signal value.

3.9 Spectral neutrality

The reflection or transmission characteristics that is maintained constant against a certain wavelength of light.

4 requirements

4.1 Requirements for detachable lens

4.1.1 Modulation transfer function (MTF)

The manufacturer shall give the nominal value of the spatial frequency corresponding to the MTF value of the detachable lens at 50% in the attached information, the tolerance is -20%, and the upper limit is not counted.

4.1.2 Focal length

The manufacturer shall provide the focal length parameters of the detachable lens in the attached information. For the lens with a fixed focal length, the tolerance for nominal value of the focal length is $\pm 20\%$. For the lens with variable magnification, the tolerance for nominal value of the minimum focal length is +20%, and the lower limit is not counted; the tolerance for nominal value of the maximum focal length is -20%, and the upper limit is not counted.

4.2 Brightness response characteristics

The manufacturer shall provide the output brightness electro-optical conversion function or data list of the adapted monitor expressed in relative value in the technical data. The sampling points of the data list are no less than 10, and cover the entire latitude area.

The output signal of the camera system shall maintain a good linearity between the brightness calculated according to the electro-optical characteristics and the brightness of each gray scale of the actual tested target board; and the linear fitting

5.1.1 Modulation transfer function (MTF)

Place a $\Phi 10\text{mm}$ aperture in the measuring optical path, then measure by a general-purpose device with sufficient accuracy.

5.1.2 Focal length

Place a $\Phi 10\text{mm}$ aperture in the measuring optical path, then measure by a focal length meter with sufficient accuracy.

5.2 Test methods of brightness response characteristic

Check the content of the technical data provided by the manufacturer.

Measure the brightness response characteristics of the camera system according to the methods specified in Appendix A.

5.3 Test methods of signal-to-noise ratio

Check the content of the technical data provided by the manufacturer.

Measure the signal-to-noise ratio of the camera system according to the methods specified in Appendix B.

5.4 Test methods of spatial frequency response

Check the contents of the attached information provided by the manufacturer.

Measure the spatial frequency response of the camera system according to the methods specified in Appendix C.

5.5 Test methods of static image latitude

Check the contents of the attached information provided by the manufacturer.

Measure the static image latitude of the camera system according to the methods specified in Appendix D.

5.6 Electrical safety

It shall be carried out in accordance with the test method specified in GB 9706.19.

A.1.4 Image collector

It is required to be able to nondestructively collect and save image data in various encoding modes.

A.2 Procedures

A.2.1 Test conditions

The temperature of the test environment is $(23\pm 2)^\circ\text{C}$, and the relative humidity is $(50\pm 20)\%$.

The dark illumination of the test environment is no more than 1lx.

The power supply voltage stability of the control light source shall be controlled within $\pm 2\%$.

The light source shall be fully preheated and stable.

A.2.2 Test process

A.2.2.1 White balance

For the camera system with white balance function, use A.1.1 test target board to perform white balance under test conditions.

A.2.2.2 Viewfinder of camera system

Adjust the shooting distance to the desired position and record it as the measurement working distance d_0 . For a camera system suitable for visual observation of endoscopes, d_0 is 500mm; other d_0 is the design working distance. For zoomable lenses, measure at the minimum focal length.

A.2.2.3 Focus

If the camera system has an autofocus function, the focus can be slightly blurred when shooting the test target board to reduce the noise generated by the texture of the block itself. The emphasis here is "slightly", and the boundaries between blocks shall be clearly distinguished.

A.2.2.4 Set the brightness of background B on the test target board

Adjust the brightness of background B on the test target board to achieve the brightness value specified by the manufacturer. During the entire brightness adjustment process of small gray-scale block A, the brightness of background B shall keep the overall gain of the tested camera system unchanged.

A.2.2.5 Adjust the brightness of small gray scale block A on the test target board,

Appendix B

(Normative)

Test Methods of Signal-to-Noise Ratio

B.1 Device

B.1.1 Test target board

The same as A.1.1.

B.1.2 Light source

The same as A.1.2.

B.1.3 Image collector

The same as A.1.4.

B.2 Procedure

B.2.1 Test conditions

The same as A.2.1.

B.2.2 Test process

B.2.2.1 White balance

The same as A.2.2.1.

B.2.2.2 Viewfinder of camera system

The same as A.2.2.2.

B.2.2.3 Focus

The same as A.2.2.3.

B.2.2.4 Set the brightness of background B on the test target board

The same as A.2.2.4.

B.2.2.5 Change the brightness of small gray scale block A on the test target board, collect and analyze images

Gradually change the brightness of the small gray scale block A on the test target board;

proximity shall make the shape of the spectral distribution curve of the light source be similar to that of the simulated standard illuminator; and the color temperature tolerance is $\pm 10\%$.

The arrangement of the illuminance source shall make the illumination uniform in the area of the target board; and the difference between the brightness at any position in the area and the center brightness shall be within $\pm 10\%$.

C.1.3 Image collector

The same as A.1.4.

C.2 Procedures

C.2.1 Measurement conditions

C.2.1.1 Illumination conditions of the measurement target board

The brightness of the measurement target board shall enable the camera system to produce acceptable output signal levels, but not overexposed.

C.2.2 Test process

C.2.2.1 White balance

The same as A.2.2.1.

C.2.2.2 Viewfinder of camera system

Adjust the shooting distance to the desired position, record it as the measurement working distance d_0 , and center the test target board. For a camera system suitable for visual observation endoscopes, d_0 is 500mm; and other d_0 is the design working distance. For zoomable lenses, measure at the minimum focal length.

C.2.2.3 Camera system focus

If the camera system has auto-focus function, the auto-focus system of the camera system shall be used to focus at the measurement working distance d_0 . If it is manual focus, select the sharpest focus setting when the spatial frequency is about 1/4 of the Nyquist frequency of the camera system.

C.2.2.4 Camera system settings

The image compression function of the camera system may significantly affect the resolution measurement. Some camera systems may select whether to enable the image compression function by pressing the button. All setting values of the camera system may affect the measurement results, including the shooting mode, test distance, etc., which shall be reported together with the measurement results.

NOTE: Due to the high contrast of the target board, the modulation degree of the target board may be treated as 1.

If other equivalent sine wave test target boards are used, the result processing shall refer to the above method equivalently.

C.3 Presentation of results

The test report shall include the following information:

- a) The model and number of the camera system under test;
- b) Camera mode;

NOTE: It is applicable to camera systems that may adopt multiple camera modes.

- c) The characteristics of the used light source;
- d) All setting values that may affect the measurement results, such as sharpness settings (if any), lens conditions (including model, focal length, and/or zoom status of variable magnification lenses), set the number of pixels or compression mode, etc.

NOTE: The model of the non-detachable lens is often the same as the model of the camera system itself.

- e) Measurement working distance d_0 ;
- f) The number of cycles per circle of the star map; if the test board is not in the form of a star map, declare the characteristics of the test board;
- g) The angular frequency values of the corresponding object space when SFR is 30% and 50%, respectively;
- h) Response curve of spatial frequency response (SFR).

D.2.2.5 Change the brightness of small gray scale block A on the test target board, collect and analyze images

The brightness level change range of the small gray scale block A on the test target board shall exceed the latitude range; and at least 5 brightness levels shall be lower than the cut-off critical brightness value of the dark area of the camera system under test. Near the cut-off critical brightness in the dark and light areas, the ratio of adjacent brightness levels shall be no greater than 1.1 times.

Gradually change the brightness of the small gray scale block A on the test target board. For each selected brightness level, measure and record the brightness value as L_i ; use the camera system to shoot the test target board of the corresponding brightness; use the image collector to collect n images and save, n is no less than 8.

For the collected images, select $(M \times N)$ pixels (32×32 is recommended) in the area of the small gray-scale block A; and respectively read the output signals of the output signal $(M \times N \times 3)$ matrix corresponding to red, green, and blue channels in each image.

D.2.2.6 Calculate the brightness signal component according to the output signal values of each channel of red, green and blue

The same as B.2.2.6.

D.2.2.7 Draw the curve of brightness and its corresponding brightness signal output value

According to the L_i and $\bar{Y}_i$ obtained in procedures D.2.2.5 and D.2.2.6, draw the curve of brightness and its corresponding brightness signal component.

D.2.2.8 Read the brightness saturation critical value of the highlighted area L_{sat}

Read the critical brightness value L_{sat} when the brightness signal component $\bar{Y}_i$ of the highlighted area on the curve is close to the saturation value.

NOTE: When any channel reaches saturation, it is saturated.

D.2.2.9 Calculate the cut-off critical value of brightness of the dark area L_{min}

Read the critical brightness value L_{min} when the brightness signal component $\bar{Y}_i$ in the dark area on the curve starts to cut off.

Judgment of cut-off state: TAKE the 2 times of average value of random noise that is calculated according to B.2.2.7 plus average value of brightness signal component $\bar{Y}_i$ corresponding to the 5 groups of lower brightness levels obtained in D.2.2.5 AS the threshold value. Find the data whose brightness output signal value is greater than the threshold value and closest to the threshold value; the brightness corresponding to the data is the critical brightness value L_{min} .

This is an excerpt of the PDF (Some pages are marked off intentionally)

Full-copy PDF can be purchased from 1 of 2 websites:

1. <https://www.ChineseStandard.us>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Select your country (currency), for example: USA (USD); Germany (Euro).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Tax invoice can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with download links).

2. <https://www.ChineseStandard.net>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Add to cart. Only accept USD (other currencies - <https://www.ChineseStandard.us>).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with PDFs attached, invoice and download links).

Translated by: Field Test Asia Pte. Ltd. (Incorporated & taxed in Singapore. Tax ID: 201302277C)

About Us (Goodwill, Policies, Fair Trading...): <https://www.chinesestandard.net/AboutUs.aspx>

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: <https://www.linkedin.com/in/waynezhengwenrui/>

----- The End -----