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Medical endoscopes - Video endoscopes

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Table of Contents

Medical endoscopes - Video endoscopes

1 Scope

This standard specifies the terms and definitions, requirements, test methods for medical video endoscopes.

This standard applies to medical video endoscopes (hereinafter referred to as video endoscopes) for visible spectrum imaging in endoscopy and surgery.

This standard does not apply to medical video endoscopes for special spectral 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 standard.

GB 9706.19 Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment

GB/T 14233.1-2008 Test methods for infusion transfusion injection equipment for medical use - Part 1: Chemical analysis methods

GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing

YY 0068.1-2008 Medical endoscopes - Rigid endoscope - Part 1: Optical properties and test methods

YY 0068.2 Medical endoscopes - Rigid endoscope - Part 2: Mechanical properties and test methods

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Conversion function

$$SNR = 20\lg\left(\frac{S}{N}\right) \quad \cdots\cdots(1)$$

Where:

S - Output signal;

N - The root mean square of the noise signal.

3.4

Saturation value

The output signal value which further increases the brightness of the object while the output signal remains constant.

3.5

Static image tolerance

The ratio of the maximum brightness of the critical object plane to the minimum brightness of the critical object plane that the video endoscope can distinguish in a single exposure.

3.6

Spatial frequency response; SFR

In a video endoscope, the function relationship between the ratio of the modulation of the output signal which is subjected to the calculated value of the reverse function of OECF to the modulation of the brightness of the object plane of the target, and the spatial frequency of the target.

3.7

Sine-based spatial frequency response; s-SFR

The SFR when the target is a sine-wave modulation map.

3.8

Modulation transfer function

The ratio of the maximum signal value minus the minimum signal value to the maximum signal value plus the minimum signal value.

3.9

Spectral neutral

portion shall be consistent with the internal material. If it is necessary to coat the surface, the manufacturer shall provide the corresponding coating requirements and test methods.

4.1.2 Requirements for chemical composition

4.1.2.1 General

The material used in the part in contact with the patient shall be clearly indicated in any form possible by the manufacturer.

The metal material shall be marked by the designation and/or code as well as the chemical composition requirements of the material; and be verified by test.

The Chinese and English abbreviations for non-metallic materials shall be clearly indicated in any possible form.

4.1.2.2 Requirements for dissolved precipitate

The dissolved precipitates of the polymer material in contact with the patient are as follows:

a) pH: As compared with the same batch of blank control solution, the difference in pH shall be not more than 2.0;

b) Total content of soluble heavy metals: The total content of soluble heavy metals in the eluate does not exceed 5.0 μg/mL;

c) Potassium permanganate reducing substance: The difference between consumption of the same batch of blank control solution of equivalent volume shall be not more than 2.0 mL.

4.1.3 Biocompatibility

Materials in contact with patients shall be evaluated for biosafety according to the principles and requirements of GB/T 16886.1, to demonstrate good biocompatibility.

The biological evaluation may consider the results of biological tests, wherein the selection of the test items is carried out according to the guidelines of GB/T 16886.1.

For materials that have previously been proven to be applicable, if it can prove that the subsequent manufacturing process is not sufficient to create a biosafety hazard, it may not repeat the biological test.

Note 1: If the material of the device under design has an arguable history of use in a specific application; or otherwise if the information about the

well as the corresponding camera mode (if the video endoscope has multiple camera modes).

The tolerance of the signal-to-noise ratio is -20%. The upper limit is not counted.

4.6 Spatial frequency response

The manufacturer shall, in the accompanied data, give the nominal value of the angular frequency of the object space of the video endoscope corresponding to the SFR value of 50% and 30%, as well as the corresponding camera mode (if the video endoscope has multiple camera modes).

The tolerance of the angular frequency of the object space corresponding to the SFR value of 50% and 30% is -20%. The upper limit is not counted.

4.7 Static image tolerance

The manufacturer shall, in the accompanied data, give the nominal value of the static image tolerance of the video endoscope as well as the corresponding camera mode (if the video endoscope has multiple camera modes).

The tolerance of the static image tolerance is -20%. The upper limit is not counted.

4.8 Mechanical properties

The mechanical properties of rigid video endoscopes shall comply with the requirements of YY 0068.2.

4.9 Electrical safety

It shall meet the requirements of GB 9706.19.

5 Test methods

5.1 Test of material requirements

5.1.1 Surface material

Visual inspection. For products with a surface coating, follow the appropriate test methods as provided by the manufacturer.

5.1.2 Test of chemical composition

5.1.2.1 General

Use the method which has an accuracy of better than or reaching to the tolerance or 1/3 of the limit value to carry out the test of the chemical

When testing on the plane perpendicular to the axis, use the illuminometer to measure the illuminance at the center of the filed angle. Record it as E_0.

Calculate the arithmetic mean of the above four azimuth illuminances E_1, E_2, E_3, E_4, as well as the ratio of the arithmetic mean value to the measured value of the illuminance at the center of the field angle.

The calculated ratio shall be divided by the relative effect of lambert edge light luminosity [see formula (2)], where w is the field angle corresponding to the position where $0.9w_p$ intersects the field angle.

W_p may be replaced by w.

5.4 Test method of brightness response characteristics

Check the technical data as provided by the manufacturer.

Use the method as specified in Appendix A to measure the brightness response characteristics of the video endoscope.

5.5 Test method of signal-to-noise ratio

Check the technical data as provided by the manufacturer.

Use the method as specified in Appendix B to measure the signal-to-noise ratio of the video endoscope.

5.6 Test method of spatial frequency response

Check the contents of the accompanied data as provided by the manufacturer.

Use the method as specified in Appendix C to measure the spatial frequency response of the video endoscope.

5.7 Test method of static image tolerance

Check the contents of the accompanied data as provided by the manufacturer.

Use the method as specified in Appendix D to measure the static image tolerance of the video endoscope.

5.8 Mechanical properties

The mechanical properties of the rigid video endoscope shall be carried out according to the test methods as specified in YY 0068.2.

5.9 Electrical safety

It shall be carried out according to the test method as specified in GB 9706.19.

A.2 Steps

A.2.1 Test conditions

The temperature of the test environment is 23 °C ± 2 °C; the relative humidity is 50% ± 20%.

The dark illuminance of the test environment is not more than 1 lx.

The power supply voltage's stability of the control light source shall be controlled within ±2%.

The light source shall be fully preheated and stable.

A.2.2 Test procedure

A.2.2.1 White balance

For the video endoscope which has the white balance function, use the test target of A.1.1 to carry out white balance under the test conditions.

A.2.2.2 Viewing of video endoscope

Adjust the camera distance to the desired position. Record it as the measuring working distance d_0.

A.2.2.3 Focusing

If the video endoscope has an autofocus function, when shooting the tested target, it may slightly blur the focusing, to reduce the noise as generated by the texture of the block itself. The emphasis here is "slightly". The boundaries between blocks must be kept distinct.

A.2.2.4 Setting the brightness of background B on the test target

Adjust the brightness of the background B on the test target, to achieve the brightness value L_0 as specified by the manufacturer. During the whole course of brightness change of the small gray-scale block A, the brightness of the background B shall keep the overall gain of the tested video endoscope unchanged.

A.2.2.5 Changing the brightness of the small gray-scale block A on the test target and collecting the analysis image

Gradually change the brightness of the small gray-scale block A on the test target. Within the tolerance range, select not less than 10 different brightness levels which are basic in uniform distribution. Corresponding to each brightness level, measure the brightness value and record it as L_i. Use the video endoscope to photograph the test target. Use the image collector to collect n

images and store it, wherein n is not less than 8.

For the collected image, select (M × N) pixels in the small gray-scale block-A area (recommended 32 × 32). Respectively read the output signals of the output signal matrix (M x N x 3) corresponding to each channel of red, green, blue of each image.

For a certain brightness level L_i, the average values $\overline{R}_i$, $\overline{G}_i$, $\overline{B}_i$ of the signal of each channel of red, green, blue are calculated from the arithmetic mean of the R, G, B values of (M × N × n) pixels, respectively.

A.2.2.6 Calculating the display brightness value and fitness

For the obtained L_i, corresponding to the $\overline{R}_i$, $\overline{G}_i$, $\overline{B}_i$ data sets, use the elec-opto conversion function (reverse function of OECF) of the output brightness as given by the manufacturer to calculate the displayed brightness L_{yi} (y_i represents $\overline{R}_i$, $\overline{G}_i$, $\overline{B}_i$, respectively). If the manufacturer gives a data list, the elec-opto conversion function of the output brightness may be obtained by the use of piecewise linear fitting. The result of L_{yi} corresponding to the brightness L_i of each gray-scale of the actually measured target shall be represented in the form of Table and/or graph.

Calculate the linear fit R^2 of L - L_y (effective digits to 2 digits after the decimal point). The calculation formula is as shown in formula (A.1):

$$R^2 = \frac{\left[\sum_{i=1}^{m}(L_i - \overline{L})(L_{y_i} - \overline{L}_y)\right]^2}{\sum_{i=1}^{m}(L_i - \overline{L})^2 \cdot \sum_{i=1}^{m}(L_{y_i} - \overline{L}_y)^2} \quad \text{(A.1)}$$

Where:

m - The number of gray-scales;

$\overline{L}$ - The average value of L_i;

$\overline{L}_y$ - The average value of L_{yi}.

The red, green, blue channels shall be calculated respectively.

A.3 Expression of results

Appendix B

(Normative)

Test method of signal-to-noise ratio

B.1 Equipment

B.1.1 Test target

Same as A.1.1.

B.1.2 Light source

Same as A.1.2.

B.1.3 Image collector

Same as A.1.4.

B.2 Steps

B.2.1 Test conditions

Same as A.2.1.

B.2.2 Test procedure

B.2.2.1 White balance

Same as A.2.2.1.

B.2.2.2 Viewing of video endoscope

Same as A.2.2.2.

B.2.2.3 Focusing

Same as A.2.2.3.

B.2.2.4 Setting the brightness of background B on the test target

Same as A.2.2.4.

B.2.2.5 Changing the brightness of the small gray-scale block A on the test target and collecting the analysis image

Gradually change the brightness of the small gray-scale block A on the test

target. Within the tolerance range, select not less than 10 different brightness levels which are basic in uniform distribution. Corresponding to each brightness level, use the video endoscope to photograph the test target. Use the image collector to collect n images and store it, wherein n is not less than 8.

For the collected image, select (M × N) pixels in the small gray-scale block-A area (recommended 32 × 32). Respectively read the output signals of the output signal matrix (M x N x 3) corresponding to each channel of red, green, blue of each image.

B.2.2.6 Calculating the brightness signal component based on the output signal of each channel of red, green, blue

For a certain brightness level, the average brightness signal component $\overline{Y}$ is calculated from the arithmetic mean of the Y values of (M × N × n) pixels, where Y is obtained by weighting the output signals of each channel of red, green, blue. The weight of each channel is valued according to the coding method as given by the manufacturer.

Note: The general standard code may be found in ISO 22028-1:2004.

Example: If the coding method uses the method as specified in ITU-R BT.709, the calculation of Y value may be weighted as follows:

$$Y = 0.212\ 5R + 0.715\ 4G + 0.072\ 1B \qquad \cdots\cdots (B.1)$$

Where:

R, G, B - The output signal values of each channel of red, green, blue.

B.2.2.7 Calculating noise (represented by standard deviation)

According to the Y value obtained in B.2.2.6, calculate the output signal values of the color difference channels (R - Y) and (B - Y).

The noise may be calculated based on the standard deviation of brightness component σ (Y), the standard deviation of color difference channel σ (R - Y), and σ (B - Y) according to the formula (B.2).

$$\sigma(D) = [\sigma(Y)^2 + 0.279\sigma(R-Y)^2 + 0.088\sigma(B-Y)^2]^{1/2} \qquad \cdots\cdots (B.2)$$

Where:

σ (Y) - The standard deviation of the brightness signal component Y;

σ (R - Y) - The standard deviation of the brightness channel lack of red;

σ (B - Y) - The standard deviation of the brightness channel lack of blue.

the spectral distribution curve's shape of the light source is similar to the spectral distribution curve's shape as specified by the manufacturer. The allowable difference of color temperature tolerance is ±10%.

If the manufacturer uses the light source which is provided by itself as the test light source, the model and characteristics of the light source shall be declared in the test report.

C.1.3 Image collector

Same as A.1.4.

C.2 Steps

C.2.1 Conditions of measurement

The illumination condition of the measured target is that the brightness of the measured target shall cause the video endoscope to produce an acceptable output signal level, but not over-exposed.

C.2.2 Test procedure

C.2.2.1 White balance

Same as A.2.2.1.

C.2.2.2 Viewing of video endoscope

Adjust the photographing distance to the desired position. Record it as the measurement working distance d_0. Center the test target.

C.2.2.3 Focusing of video endoscope

If the video endoscope has an autofocus function, it shall use the video endoscope's autofocus system to focus on the measurement working distance d_0. In case of manual focus, select the sharpest focus setting when the spatial frequency is about 1/4 of video endoscope's Nyquist frequency.

C.2.2.4 Setting of video endoscope

The image compression function of the video endoscope may significantly affect the measurement of resolution. For some video endoscopes, it may select whether to enable the image compression function by pressing a button. All settings of the video endoscope which may affect the measurement results, including the shooting mode, test distance, etc., shall be reported together with the measurement results.

C.2.2.5 Collecting images

D.2.2.5 Changing the brightness of the small gray-scale block A on the test target and collecting the analysis image

The range of change of brightness level of the small gray-scale block A on the test target shall be more than the tolerance range. Meanwhile at least 5 brightness levels are lower than the cut-off critical brightness value of the dark area of the video endoscope to be tested. Near the cut-off critical brightness of the dark area and the saturated critical brightness of bright area, the ratio of adjacent brightness levels shall be not more than 1.1 times.

Gradually change the brightness of the small gray-scale block A on the test target. For each selected brightness level, measure and record the brightness value L_i. Use the video endoscope to photograph the test target of the corresponding brightness. Use the image collector to collect and save n images, wherein n is not less than 8.

For the collected image, select (M × N) pixels in the small gray-scale block-A area (recommended 32 × 32). Respectively read the output signals of the corresponding output signal (M × N × 3) matrix corresponding to each channel of red, green, blue in each image.

D.2.2.6 Calculating the brightness signal component based on the output signal values of each channel of red, green, blue

Same as B.2.2.6.

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

According to L_i and $\overline{Y}_i$ as obtained in steps D.2.2.5 and D.2.2.6A, draw the curve of the brightness and the corresponding brightness signal component.

D.2.2.8 Reading the brightness saturation threshold L_{sat} in highlight region

Read the critical brightness value L_{sat} when the brightness signal component $\overline{Y}_i$ in the highlight region on the curve is close to the saturation value.

Note: Any channel that reaches saturation is saturated.

D.2.2.9 Calculating the brightness cutoff threshold L_{min} in dark area

Read the critical brightness L_{min} when the brightness signal component $\overline{Y}_i$ in the dark area starts cutting off from the curve.

Determination of the cutoff state: Use the average value of the brightness signal component $\overline{Y}_i$ corresponding to the 5 sets of lower brightness levels as

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