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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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Electronic portal imaging device using in radiotherapy – Functional performance characteristics and test methods

放射治疗中电子射野成像装置性能和试验方法

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Foreword

This Standard was drafted in accordance with the provisions given in the GB/T 1.1-2009.

Please pay attention that some contents in this Standard may involve patents. The issuing authority of this Standard does not undertake the responsibility for the identification of these patents.

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of the Technical Sub-committee of the Equipment for Radiotherapy, Nuclear Medicine and Radiation Dosimetry of the National Technical Committee for Standardization of Medical Electrical Equipment (SAC/TC 10/SC 3).

Drafting organizations of this Standard: Beijing Institute of Medical Device Testing, and Elekta BMEI (Beijing) Medical Equipment Co., Ltd.

Main drafters of this Standard: Feng Jian, Wang Peichen, Wang Huiliang, and Jiao Chunying.

Electronic portal imaging device using in radiotherapy – Functional performance characteristics and test methods

1 Scope

This Standard specifies the performance requirements and test methods for the electronic portal imaging devices.

This Standard applies to the electronic portal imaging devices using the radiation beams of medical electron accelerators as radiation source in radiotherapy.

2 Normative references

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

GB/T 17857 Medical radiology – Terminology (Equipment for radiotherapy, nuclear medicine and radiation dosimetry)

GB/T 18987 Radiotherapy equipment – Coordinates, movements and scales

3 Definitions

The terms and definitions defined in the GB/T 17857 and the following ones apply to this document.

3.1 Electronic imaging device; EID

It refers to the equipment that is composed of one or more radiation detector(s) and relevant electronic components, which can display the anatomical structures of patients in the form of digital radiation images on the viewing screen for observation.

Note: SEE also 3.2 of this edition.

3.2 Electronic portal imaging device; EPID

4.3.5.2 For the dose of 1cGy, the signal-to-noise ratio shall not be less than 5,000%.

4.3.6 Imaging device delay

The image retention shall be measured after the incentive elimination. After the exposure, the ratio of second frame signal to first frame signal shall not be greater than 5%, or the ratio of fifth frame signal to first frame signal shall not be greater than 0.3%.

4.3.7 Linearity of imaging devices

The non-linearity of images within the dynamic scope used for treatment shall be given by manufacturers.

Within the above scope, the manufacturers shall measure the linearity of video signals according to the maximum percentage deviation of the linear relation of the radiation quantity on the signals and detectors.

4.3.8 Spatial resolution of imaging devices

For a given set of imaging conditions (energy, dose monitoring count, and detector frames), when imaging a phantom with a contrast test card located on the EID surface, the distinguishable modulation transfer function (MTF) of the maximum spatial frequency function shall be given in the accompanying files by manufacturers. When using a contrast test card to conduct the above measurement, the contrast test card shall be placed at some angle relative to the *X* axis or *Y* axis of the detector. The angle shall be determined according to the specific performance of the test phantom for use (SEE the note below). The geometrical structure of the test phantom for use and the distance between X-radiation source and EID surface shall also be described.

Note: For the reason of some EID (especially those electronic components using amorphous silicon) structures, the spatial resolution might vary depending on the direction of the contrast test card relative to the *X*-*Y* axis of the detector (SEE GB/T 18987 for the coordinate system of the X-radiation imaging device). Therefore, MTF measurement shall be conducted in the direction of the contrast test card parallel with the direction of the test phantom specified by manufacturers.

For the given X-radiation energy, dose and dose rate, when the contrast test card is located on the EID surface, the spatial resolution of imaging devices under distinguished maximum frequency shall not be less than 0.6 lp/mm.

4.3.9 Low contrast resolution

The low contrast resolution shall be given in the accompanying files by manufacturers, and shall not be less than the numerical value specified by

c) The conformance test between EID image center and radiation beam axis shall be described.

5.2 Mechanical support structure

5.2.1 CHECK the accompanying files and the scope of mechanical movement for radiation field devices, which shall conform to the requirements given in the accompanying files.

5.2.2 ADJUST the accelerator rack and treatment head to 0°. REMOVE the bedplate, and OPEN the light field so that the cross lines can be projected on the maximum and minimum distances between detector and isocenter on the surface of the image detector.

MARK the projections of cross lines on the surface of the image detector.

TAKE back the image detector. STRETCH the image detector again, so as to measure the deviation of the marks for cross line projection and radiation field center. The deviation shall conform to the requirements given in the accompanying files.

When the accelerator rack rotates 90°, 180° and 270°, REPEAT the above procedures.

5.3 Electronic portal imaging

5.3.1 Detector area and pixel pitch

CHECK the accompanying files, which shall conform to the requirements specified in the Article 4.3.1.

5.3.2 Detector characteristics

CHECK the accompanying files, which shall conform to the requirements specified in the Article 4.3.2.

5.3.3 Number of visible pixels

CHECK the accompanying files, which shall conform to the requirements specified in the Article 4.3.3.

5.3.4 Detector frame time

CHECK the accompanying files, which shall conform to the requirements specified in the Article 4.3.4.

5.3.5 Signal-to-noise ratio (SNR) and dynamic scope of imaging device

images.

Analytical method 1: ADJUST the window width and window level, so as to obtain the clearest display. OBSERVE the number of distinguishable line pairs.

Analytical method 2: ADJUST the window width to the minimum. ADJUST the window level, so as to clearly display the distinguishable phantom part of the maximum number of line pairs. OBSERVE the black and white stripes of images to check whether there is an interruption. SELECT one group without any interruption as the maximum resolution.

5.3.9 Low contrast resolution

5.3.9.1 Phantom

The low-contrast phantoms are obtained by digging holes with the diameter of 0.5mm to 15mm on the aluminum or copper products with certain thickness. The hole depth shall be proportional to the material thickness.

5.3.9.2 Test methods

PLACE the low-contrast phantom at the center of radiation beams. The phantom shall be close to the image receiving surface as far as possible. OBTAIN the images.

Analytical method 1: ADJUST the window width and window level, so as to obtain the clearest display. OBSERVE the number of distinguishable holes.

Analytical method 2: ADJUST the window width to the minimum. ADJUST the window level, so as to gradually and clearly display the distinguishable holes. OBSERVE the hole edges. The holes without any clearance shall be considered as the holes with effective resolution. SELECT one minimum group without any clearance as the maximum low-contrast resolution.

5.3.10 Image distortion

5.3.10.1 Phantom

During the measurement of image distortion, the phantoms shall contain 4 points that can display the locations. The geometric positions shall constitute square or rectangle. One of the side lengths shall not be less than 1/2 of the maximum dimensions of the detector field of view.

5.3.10.2 Test methods

PLACE the phantom with image distortion in the radiation beams. The center of square or rectangle shall be placed in the central field of view. The phantom

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