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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.50

C 43

YY/T 0741-2018

Replacing YY/T 0741-2009

Particular Specifications for Digital X-Ray Radiography System

数字化摄影 X 射线机专用技术条件

Issued on: September 28, 2018 **Implemented on: October 01, 2019**

Issued by: National Medical Products Administration

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Particular Specifications for Digital X-Ray Radiography System

1 Scope

This Standard specifies the terms and definitions, system composition, requirements and test methods for digital X-ray radiography system (hereinafter referred to as DR system).

This Standard is applicable to the DR system for general X-ray photography. It includes but not limited to DR systems that use line scan or area scan detectors, such as:

--- DR system using flat panel detector (FPD);

--- DR system using area array CCD detector;

--- DR system using line array scanning CCD detector;

--- DR system using CMOS detector, etc.

Corresponding to the DR system using more than one digital X-ray image detector, this Standard is applicable to each digital X-ray image detector and the X-ray generating device used in its imaging.

This Standard is not applicable to system using X-ray image intensifier, system using imaging device of image plate for X-ray photography, mammary X-ray equipment, dental X-ray equipment, computed tomography equipment, mobile DR system.

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 9706.1 Medical Electrical Equipment - Part 1: General Requirements for Safety

GB 9706.3-2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators

GB 9706.11 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis

GB 9706.12-1997 Medical Electrical Equipment - Part 1: General Requirements for Safety – 3 Collateral Standard - General Requirements for Radiation Protection in Diagnostic X-Ray Equipment

GB 9706.14 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Associated Equipment of X-Ray Equipment

GB 9706.15 Medical Electrical Equipment - Part 1: General Requirements for Safety - 1. Collateral Standard: Safety Requirements for Medical Electrical Systems

GB/T 10151 Medical Diagnostic X-Ray Equipment - Specifications for High Voltage Cable Plugs and Sockets

YY/T 0291 Environmental Requirements and Test Methods for Medical X-Ray Equipment

YY 0505 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standards: Electromagnetic Compatibility Requirements and Tests

DICOM 3.0 (all parts) Digital Imaging and Communications in Medicine (Edition III)

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in Normative References and the following apply.

3.1 Digital radiography system

It uses digital X-ray image detector technology to realize the X-ray photography; generally, it consists of X-ray generating device, digital X-ray imaging device, and ancillary equipment.

3.2 Digital X-ray imaging device

The system that uses digital X-ray image detector; consists of the subsystem that can be able to perform the image processing, displaying, printing or storing; provides the projecting images in a digital format.

3.3 Digital X-ray image detector

The converter, after spatial sampling of X-ray by a line array or matrix pixel structure,

shall be less than 3mm;

c) In the image stitching function, the manual adjustment function shall be provided;

d) On the image after stitching, the stitching position shall be marked.

5.4.9 Detector calibration and stability test

a) The DR system shall have the function of supporting the user to perform conventional detector calibration;

b) The manufacturer shall provide the content and frequency of the stability test in accompanying file; the DR system shall provide a stability test procedure.

5.4.10 Quantum detection efficiency

The manufacture shall give, in the accompanying file, the quantum detection efficiency value of the used detector at the indicated standard radiation quality, irradiation dose and different spatial frequencies (at least 0.5lp/mm, 1.0lp/mm, 1.5lp/mm, 2.0lp/mm, 2.5lp/mm up to slightly lower than the maximum frequency of NYQUIST sampling frequency).

5.5 Performance of mechanical device

5.5.1 Mechanical motion range

It shall be specified in the product technical requirements for the rotation angle range of electromechanical auxiliary device, and motion range in the longitudinal, transverse and vertical directions, and their deviations.

5.5.2 Length indication value

The deviation between the length indication value and the actual value shall be within the range of ±5% indication value.

5.5.3 Angle indication value

The deviation between the angle indication value and the actual value shall be within the range of ±1 minimum division value.

5.5.4 Braking

The linear motion part of the mechanical device shall have a braking device. After the network power is turned off or the emergency stop switch is pressed, the motion parts shall be braked. (Except that the suspension is required to be balanced without the need for braking) the braking force shall be no less than 100N. The braking force of the rotating parts shall be specified by the product technical requirements.

5.10 Safety

It shall meet the requirements of GB 9706.1, GB 9706.3, GB 9706.11, GB 9706.12, GB 9706.14, GB 9706.15 and YY 0505.

6 Test Methods

6.1 Test conditions

6.1.1 Environmental conditions

It shall conform to the provisions of 5.1.1.

6.1.2 Power supply conditions

The test power supply conditions are as follows:

a) The network voltage and the number of phases shall conform to the provisions of product technical requirements; the network voltage fluctuation shall not exceed ±10% nominal value;

b) Power supply frequency: 50Hz±1Hz;

c) The power supply resistance shall conform to the provisions of 5.1.2 c);

d) The power supply capacity shall conform to the provisions of 5.1.2 d).

6.2 Electric power

6.2.1 Maximum output electric power

The DR system operating in an intermittent mode is loaded in the combination with the loading factors that cause the maximum output electric power; then observe whether there is an abnormality.

6.2.2 Nominal electric power

The DR system operating in an intermittent mode is loaded in the combination with X-ray tube voltage, X-ray tube current, loading time that cause the nominal electric power; then observe whether there is an abnormality.

6.3 Loading factor and control

6.3.1 X-ray tube voltage

It shall be performed as per the following methods:

Under the AEC mode, the repeatability of radiation output shall be performed as follows:

Set the DR system to the normal use mode specified by the manufacturer; using PMMA phantoms, the thickness of which is suitable for intended use; in the case the manufacturer does not make statement, use 20cm-thick PMMA phantom; place the dosimeter probe on the surface of PMMA phantom; set the X-ray tube voltage to be 80kV; perform 10 times AEC exposures; calculate the coefficient of variation for air kerma measurement value.

6.3.7 Correspondence between X-ray field and image receiving surface

It shall be performed as per the following methods:

a) The measurement shall, under the various normal use modes of the equipment, be performed separately at the minimum and maximum SID situations of the clinical application specified in the accompanying file;

b) For the equipment that provides automatic adjustment of radiation window, allow 5s adjustment time before measurement;

c) It shall conform to the provisions of 29.203.4 in GB 9706.12-1997.

6.3.8 Dose area product indication

It shall be performed as per the following methods:

Place the X-ray dosimeter detector in an appropriate position in the X-ray beam, such as on the image receiver surface or bed surface. Adjust the X-ray filed dimension to 15cm×15cm or other proper dimensions. Take photograph to dose area product that is displayed by the equipment is greater than 5μGy•m^2; multiply the measured dose value by the ray filed area at the air kerma dosimeter detector. It can also be measured directly by the dose area product meter. Calculate the error between displayed value and the measured value.

6.3.9 Pediatric photography requirements

Actual operation and inspection.

6.4 Imaging performance

6.4.1 Spatial resolution

Test and arrange the multi-function test card shown in Figure B.1 according to Figure A.1. Adjust SID to be the normal clinical use distance; set the visual field of the image to be the maximum effect image area of the plate; select the typically clinical protocol specified by the manufacturer; manually set the X-ray tube voltage to be 75kV±7kV; AEC automatic exposure. If required, adjust the window width and position; record the

V_i – average of gray scale of each sampling area;

V_m – average of gray scale of 9 sampling areas;

R – standard deviation of gray scale of 9 sampling areas.

6.4.5 Effect image area

The test procedures are as follows:

a) Remove the grid;

b) Place the lead scale at a position close to the image receiving surface; paralleling to the measuring direction;

1) Exposure conditions: AEC or use conditions declared by the manufacturer;

2) Directly read data x and y on the lead scale in the image formed by the exposure;

3) $dx = x/x_1$;

4) $dy = y/y_1$;

c) x_1, y_1 are the dimensions declared by the manufacturer;

d) The minimum value between dx and dy shall meet the requirements.

When image receiving surface can't be accessed, a conversion method can be used.

6.4.6 Erasure thoroughness

The test procedures are as follows:

a) Remove the grid;

b) Set the SID to be normal clinical use conditions. Set X-ray tube voltage to be 80kV, 30mA•s. Place the 25mm-thick pure aluminum attenuating phantom at the center of the radiation beam; so that is covers the whole irradiation field;

c) Place the lead plate with diameter of 10mm and thickness of 2mm at the center of the irradiation field;

d) Perform the first exposure according to the set SID and loading factors. After removing the lead plate within the shortest exposure interval specified by the manufacturer, use 70kV and AEC to perform the second exposure. If not specified, it shall be performed as per 1min;

In practice, measure the range of rotation angle by the angle gauge; the minimum division scale of the angle gauge is no greater than 0.5°. The range of motion the longitudinal, lateral, and vertical directions is measured by a length gauge.

6.5.2 Length indication value

In practice, measure by the length gauge.

6.5.3 Angle indication value

In practice, measure by the angle gauge.

6.5.4 Braking

In practice, measure by a dynamometer.

6.5.5 Load bearing

The patient support device is in a horizontal state and in most unfavorable position at work; uniformly distribute 135kg load on the 168cm×37.5cm support surface for 1min; observe whether it can work normally.

For pedals and chairs, uniformly distribute 135kg load on the 0.1m^2 support surface for 1min; observe whether it can work normally.

6.5.6 Noise

When the sound level meter probe is 1m away from the DR system surface and 1.5m away from the ground, use sound level meter “Level-A” weighting network to measure; calculate according to the maximum noise value.

6.6 Network and software

6.6.1 Network communication

Check the accompanying file.

6.6.2 Information management

According to the accompanying file provided by the manufacturer, check in practice.

6.6.3 Imaging time

Place the 25mm-thick pure aluminum attenuating phantom at the center of the radiance beam; so that it covers the whole irradiation field. Expose under the AEC conditions; measure the time from the beginning of exposure to the display of normal image that meet the diagnostic requirements.

Appendix C

(Informative)

Drafting Explanation of Some Clauses

3.1 Digital radiograph system

The product name “Digital Radiography System” in this Standard is formulated according to the *Naming Rules for the Generic Names of Medical Devices* (Order No.19 of China Food and Drug Administration); and the generic name is adopted.

4.1 System composition

For the “ancillary equipment” in the DR system composition, its definition and applicable scope come from GB 9706.14-1997.

5.3.9 Pediatric photography requirements

The prompting requirements to remove the physical grid in this subclause is not to force the operator to remove the grid. In fact, the operator can judge and handle according to the patient’s situation. The relevant content of this subclause is expected to reduce the dose of pediatric photography through the requirements towards the manufacturer and the products. If the manufacturer selects “with/without grid” photography in the pediatric photography protocol, and has a prompt for inserting or removing the grid, it can be considered to comply with the requirements of this subclause.

In the IEC 60601-2-54 standard, the product is only required to be fitted with a function of at least 0.1mm-thick copper or 3.5mm-thick aluminum additional filtering function. In order to reduce the pediatric photographic dose, considering the practical application, this Standard requires the manufacturer to provide at least the above additional filtration.

5.4.8 (Long bone) image stitching performance

Different manufacturers may have their own verification phantoms and methods. If it can be proved that the image stitching performance can be effectively tested, the method specified by the manufacturer shall be preferred. In the test methods of this Standard, it is recommended to sue the lead ruler no shorter than 1m.

5.5.4 Braking

The braking force of the rotating part shall be specified by the product technical requirements. Here it is not recommended to give in the form of torque. The

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