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

YY/T 1878-2023

**Technical requirements for digitization of positron emission
tomography equipment**

正电子发射断层成像装置数字化技术要求

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1. Structure and Drafting Rules for Standardization Documents" drafting. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is prepared by the National Medical Electrical Appliances Standardization Technical Committee Radiotherapy, Nuclear Medicine and Radiation Dosimetry Equipment Standardization Sub-Technical Committee Meeting (SAC/TC10/SC3) centralized. This document was drafted by: Beijing Institute of Medical Device Inspection, Medical Device Technology Evaluation Center of the State Drug Administration, Hubei Ruishi Digital Medical Imaging Technology Co., Ltd., Shanghai United Imaging Medical Technology Co., Ltd., Huazhong University of Science and Technology, Suzhou Ruipaining Technology Co., Ltd. Ltd. The main drafters of this document. Feng Jian, Gu Xiaofang, Liu Di, Li Bingxuan, Liu Shitao, Xiao Peng, Chen Xin, Zhang Bo. Digital technical requirements for positron emission tomography devices

1 Scope

YY/T 1878 sets the technical requirements for digital positron emission tomography, the generation of PET scanners in which each detector element is read out digitally rather than through analogue photomultiplier chains. The change alters what the scanner can do: better timing resolution, better count-rate handling and time-of-flight reconstruction that improves image quality at lower dose. This document specifies what a manufacturer has to

demonstrate about a digital PET system and how, so that the claims made for a digital design can be compared between products rather than taken on trust. PET capacity is expanding quickly in Chinese oncology, and digital systems are the premium end of that market. For a manufacturer seeking Chinese registration, this is the text the performance evidence for a digital PET scanner is judged against.

This document specifies the digital technical requirements for positron emission tomography (PET) devices. This document applies to Positron Emission Tomography (hereinafter referred to as Digital PET) using digital technology.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 17857-1999 Medical Radiology Terminology (Radiation Therapy, Nuclear Medicine and Radiation Dosimetry Equipment)

GB/T 18988.1-2013 Radionuclide Imaging Equipment Performance and Test Rules Part

3 Terms and Definitions

The terms and definitions defined in GB/T 17857-1999 and GB/T 18988.1-2013 apply to this document.

4 Overview

The digitization mentioned in this document can be described as the conversion of continuous analog quantities into Process of discrete digital quantities. Digital PET can be described as the energy information, time information and position information of a single event before coincidence. All information is stored and processed in digitally coded PET. PET digitization technology is based on digital signal processing hardware as a means to achieve accurate sampling of scintillation pulses. a series of technologies. It may bring lower power consumption, more stable and superior performance, stronger scalability and adaptability. PET digital technology is embodied in the process of signal sampling, which can convert the original analog signal into digital signal and output it. According to The stage of converting the original analog signal into a digital signal in the sample circuit, the digitization of the PET signal is divided into the following two symbolic links. the electrical signal Generation link (direct digitization after photoelectric conversion), single-event signal transmission link (before event coincidence). PET signal digitization technical requirements to Meet at least one of the following.

a) Digitalization of single-event signal transmission After the electrical pulse after photoelectric conversion is processed by analog circuit, the information of single event (position, time, energy, etc.) Convert to digital signal and output.

b) Digitalization of electrical signal generation The signal output by the photoelectric conversion device is directly digitized without analog signal processing. There are 4 technical solutions as follows:

---Directly digitize the electric pulse output by the analog optoelectronic device, and obtain the position, time and energy information of a single event;

---Digital sampling of the electrical pulse output by the analog optoelectronic device to obtain the original pulse waveform of a single event;

---Digital optoelectronic devices directly output digital single-event position, time, and energy information;

---Use digital optoelectronic devices to obtain digitized single-event original pulse waveform.