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

YY/T 0935-2014

Particular specifications for CT contrast injectors

CT造影注射装置专用技术条件

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1 Scope

YY/T 0935 is the Chinese specification for CT contrast injectors, the powered syringes that deliver iodinated contrast at a set rate and volume in synchrony with the scan. The timing is the point: a bolus delivered a few seconds early or late produces a study in which the vessels of interest are not opacified, and the patient has taken the radiation dose and the contrast load for nothing. This document sets the requirements such an injector has to meet and the test methods that verify them, covering flow rate and volume accuracy, the pressure limits that protect the cannula and the vein, the extravasation detection, and the interface with the scanner. Contrast CT is high-volume routine work in Chinese radiology. It carries Amendment 1 of 2020, and this is the text a Chinese registration is assessed against.

This standard specifies the terms and definitions, classification and composition, requirements, and test methods of CT (X-ray computed tomography) injectors (hereinafter referred to as injectors). This standard applies to injectors. This standard does not involve accessories such as disposable syringes specially used for injectors.

2 Normative references

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

GB 9706.1-2007 Medical electrical equipment - Part 1: General requirements for safety

GB 9706.15-2008 Medical electrical equipment - Part 1: General requirements for safety -
1. Collateral standard: Safety requirements for medical electrical systems

GB/T 10149-1988 Terminology and symbol for medical X-ray equipment

GB/T 14710-2009 Environmental requirement and test methods for medical electrical

equipment

YY 0076-1992 Coating classifications for metal product - Technical conditions

YY 0505-2012 Medical electrical equipment - Part 1-2: General requirements for safety -
Collateral standard: Electromagnetic Compatibility - Requirements and tests

YY/T 0708-2009 Medical electrical equipment - Part 1-4: General requirements for safety -
Collateral standard: Programmable electrical medical systems

3 Terms and definitions

The terms and definitions defined in GB/T 10149-1988 and the followings apply to this document.

3.1 CT contrast enhanced scan A CT scan taken after a contrast agent has been injected into a blood vessel.

3.2 CT injector A device that injects a contrast agent into the body according to the set flow rate and injection volume.

3.3 injector head It refers to the injection pushing mechanism and the interface part for installing a matching syringe.

3.4 flow rate The dose of the contrast agent injected per unit of time. Unit: milliliter per second, mL/s

3.5 maximum injection pressure The maximum pressure that the injector can achieve when injecting. Unit: megapascal, MPa

3.6 pressure limit The maximum allowable pressure set for an injector during the injection. Unit: megapascal, MPa

3.7 injection delay After receiving the starting signal, the injector starts to inject after a set delay time.

3.8 scan delay After the injector starts to inject, a trigger signal is sent out after a set delay time.

3.9 inject time The time from when the injection starts to when it stops.

3.10 fill rate The dose of the contrast agent inhaled by the injector per unit of time. The setting range of the flow rate shall not be less than

0.1 mL/s~

8.0 mL/s, and the error between the measured flow rate R and the set value A shall meet the requirement: $-(0.05A+0.1) \leq R-A \leq 0.05A+0.1$.

5.3 Injection volume The setting range of the injection volume shall not be less than

6.6 Pressure limit Set the pressure limit to

1.72 MPa (250 psi), connect the connector to the syringe and pressure gauge, and set the flow rate at 2 mL/s for bolus injection; read the pressure when the injector indicates that the pressure limit is exceeded and the bolus injection is stopped, and then calculate the deviation between the actual pressure and the set pressure.

6.7 Injection delay time Set the delay time to 3 s, use a timer to record the time from the receiving of the starting signal to the start of injection, and calculate the deviation of injection delay.