YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1933-2024

Particular specification for MR injector

磁共振造影注射装置专用技术规范

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1 Scope

YY/T 1933 is the particular specification for the MRI contrast injector, the power injector that delivers gadolinium contrast on a timed profile during a scan. It is a device with an unusual constraint: it has to work reliably inside or beside the magnetic field of an MRI scanner, where ferromagnetic components become projectiles and ordinary motors and electronics fail or interfere with the image. Its performance requirements are the ones that govern any power injector, flow rate accuracy, volume delivery, pressure limiting and air detection, applied under those conditions. For a manufacturer or an importer of MR-compatible injection systems seeking Chinese registration, this is the particular standard the type testing follows, alongside the general medical electrical safety requirements.

This document specifies the requirements for magnetic resonance (MR) injector (hereinafter referred to as injectors) and describes the corresponding test methods. This document applies to injectors. This document does not apply to single-use high-pressure contrast syringes and their accessories dedicated to injectors.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 9706.224, Medical electrical equipment -- Part 2-

24.Particular requirements for the basic safety and essential performance of infusion pumps and controllers

YY/T 0482, Medical Magnetic Resonance Imaging Equipment -- Determination of Main Image Quality Parameters

YY/T 0935, Particular specifications for CT injector

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB 9706.224, YY/T 0935, YY/T 0482 as well as the followings apply.

3.1 MR injector A device that in the diagnosis of magnetic resonance imaging, in order to obtain the required medical images, the contrast agent is injected into the human body according to the set flow rate and injection dose in conjunction with the magnetic resonance equipment.

3.2 injector head An interface component for injection push mechanism and installation of matching syringe.

3.10 keep-vein-open rate; KVO Under specified conditions, the injector returns to a predetermined low speed state while keeping the patient line open. NOTE. The abbreviation KOR (keep open rate) is often used as a synonym for KVO. [Source: GB 9706.224-2021, 201.3.209, modified]

3.11 signal to noise ration; SNR The quotient of the signal value divided by the noise value. [Source: YY/T 0482-2022, 3.1.26]

3.12 signal-to-noise ratio change Changes in the signal-to-noise ratio of the reference image when the instrument is working and when the instrument is not working.

3.13 magnetically induced displacement force The force exerted on a magnetic object exposed to the spatial gradient of a static magnetic field. NOTE. This force is expected to cause objects to move in the spatial gradient of the static magnetic field. [Source: ASTM F2503-20, 3.1.4]

3.14 magnetically induced displacement A magnetic object in a spatial gradient magnetic field moves toward a magnetic resonance device due to the magnetically induced displacement force.

3.15 artifact What is visible in the image neither reflects the structure of the corresponding position in the object nor can it be explained by noise. [Source: YY/T 0482-2022, 3.1.2]

3.16 immunity (to a disturbance) The ability of me equipment or me system to operate without degradation in the presence of electromagnetic disturbances. [Source: YY 9706.102-2021, 3.13]

3.17 region of interest safety distance, the injector shall not produce magnetically induced displacement. If the injector has casters, verify that the casters are unlocked. NOTE. The magnetic induction value is generally regarded as the field strength value of the magnetic field, with the unit of T. Bo is the static magnetic field generated by the magnetic resonance device and its accessories. Scalars are generally represented by ordinary fonts (such as B). Bold fonts represent vectors (such as B).

5.8.2 Immunity The injector shall be able to operate normally at the applicable magnetic field strength and the safety distance claimed by the manufacturer. The basic performance of the flow rate shall not be reduced. The flow rate shall meet the requirements of 5.1.

5.8.3 Signal-to-noise ratio change amount At the applicable magnetic field strength and the claimed safety distance claimed by the manufacturer, the variation in the signal-to-noise ratio of the reference image when the injector is injecting and when there is no injector shall be less than ±10%.

5.8.4 Image artifact variation At the applicable magnetic field strength and the safety distance claimed by the manufacturer, the change in the ratio of the artifact signal value to the signal average value in the magnetic resonance imaging reference image when the injector is injecting and when there is no injector shall meet the requirements specified by the manufacturer. NOTE. The change limit is determined by the manufacturer based on the applicable magnetic field strength and the adapted magnetic resonance equipment.

5.13 Marks and accompanying documents

5.13.1 Injector marks The injector mark shall meet the following requirements.

a) Each part of the injector is provided with magnetic resonance environment safety mark; NOTE. Magnetic resonance environment safety marks shall comply with ASTM F2503-20 requirements.

b) The additional mark of magnetic resonance condition-safe products shall at least indicate the applicable magnetic field strength and safety distance.

5.13.2 Accompanying documents Injectors shall be accompanied by documentation including at least instructions for use and technical specifications. The accompanying documents shall contain at least the following information.

a) The strength of the magnetic field suitable for the injector;

b) The safety distance of injector;

c) The list of MRI devices compatible with the injector.

6 Test methods

6.1 Flow rate The test medium is distilled water or deionized water. The injection dose is set

to the maximum value. The flow rate is set to the minimum value, 50% of the maximum value, and the maximum value. Use a timer (such as a synchronized stopwatch) to record the time from the start of injection to the end of injection. Use a balance to weigh the distilled water or deionized water. Convert it to volume. Calculate the flow rate deviation.

6.2 Injection dose The test medium is distilled water or deionized water. The injection dose is set to the minimum value (flow rate is the minimum value), 50% of the maximum value (flow rate is 50% of the maximum value), and the maximum value (flow rate is the maximum value) to complete the injection. Use a balance to weigh the distilled water or deionized water. Convert it to volume. Calculate the injection dose deviation.

6.3 Fill rate The test medium is distilled water or deionized water. The fill dose is set to the maximum value, and the fill rate is set to the minimum value, 50% of the maximum value, and the maximum value. Use a timer (such as a synchronized stopwatch) to record the time from the start of fill to the end of fill. Use a balance to weigh the distilled water or deionized water. Convert it to volume. Calculate the fill rate deviation.

6.4 Maximum injection pressure Check the risk management documentation and verify the following. Set the pressure limit to the maximum value of the injector and connect the pressure gauge to the connector. Set the maximum flow rate for push injection. Read the pressure at which the injector indicates that the pressure limit has been exceeded and the push injection is stopped. It shall not be greater than the provisions of 5.4.

6.5 Pressure limit Set the pressure limit to

0.689 MPa (100 psi) and connect the pressure gauge to the connector. Set the flow rate to 2 mL/s for push injection. Read the pressure at which the injector indicates that the pressure limit has been exceeded and the push injection is stopped. Calculate the deviation between the actual pressure and the set pressure.

6.6 Injection delay time Set the injection delay time. Use a timer to record the time from when the signal is received to when the injection starts. Calculate the deviation of the injection delay time from the set value.

6.7 Scan delay time Set the scan delay time. Use a timer to record the time from the start of injection to the The test medium is distilled water or deionized water. The injection dose is set to the maximum value. The flow rate is set to 50% of the minimum value and the maximum value respectively. Under the maximum value condition, use a timer (such as a synchronized stopwatch) to record the time from the start of injection to the end of injection. Use a balance to weigh the distilled water or deionized water. Convert it to volume. Calculate the flow rate deviation. NOTE. To ensure safety, use a measuring tool to collect the injection liquid in the MR room. Immediately after the injection, go outside the MR room and weigh the volume using a balance. Calculate the flow rate.