YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1469-2025

Electrical infusion pump for ambulatory use

便携式电动输液泵

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1 Scope

YY/T 1469 is the product standard for the portable electrical infusion pump, the battery-powered device a patient carries rather than one that hangs on a stand. It specifies the basic requirements for ambulatory electrical infusion pumps and describes the corresponding test methods. An ambulatory pump has to hold its delivery accuracy while being carried, knocked and worn for hours, which is why it is separated from the general infusion pump requirements rather than treated as a variant. The 2025 edition takes effect on 1 November 2027, an unusually long run-in that gives manufacturers two years to bring existing models into line. For a manufacturer of patient-controlled analgesia pumps, chemotherapy pumps or insulin delivery systems intended for the Chinese market, this is the standard the registration test report is written against.

This Standard specifies the basic requirements for electrical infusion pump for ambulatory use and describes the corresponding test methods. This document applies to electrical

infusion pumps for ambulatory use in medical monitoring environments. This document does not apply to the following equipment.

---Enteral nutrition pumps;

---Insulin pumps and pumps with similar clinical applications;

---Other special-purpose electrical infusion pumps for ambulatory use with special requirements for infusion accuracy. NOTE. for explanations of the scope and related clauses, please refer to Appendix A.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 6682 Water for Analytical Laboratory Use - Specification and Test Methods

GB 9706.1 Medical Electrical Equipment - Part

3 Terms and Definitions

The terms and definitions defined in GB 9706.224-2021 and the following are applicable to this document.

3.1 electrical infusion pump for ambulatory use A portable infusion pump typically composed of a drive unit (3.2), a restoration set (3.3) and an administration set (3.4), driven by electrical energy. NOTE. the restoration set and administration set are single-use components.

3.2 drive unit A device that uses the positive pressure generated by motor drive to transfer fluid through the administration set (3.4) to the patient.

3.3 restoration set The device in the electrical infusion pump for ambulatory use (3.1) that stores the fluid.

3.4 administration set An accessory that transfers fluid from the supply point to the patient via the equipment. [Source: GB 9706.224-2021, 201.3.201, modified]

4.1 Overall Performance

4.1.1 Appearance The electrical infusion pump for ambulatory use shall have a uniform color, a clean surface, and be free of scratches, cracks, or defects. Text and markings shall be clear and durable.

4.1.2 Installation All parts of the electrical infusion pump for ambulatory use shall be securely connected, and after connection, there shall be no self-flow.

4.1.3 Infusion accuracy

4.1.3.1 The average infusion rate accuracy in continuous infusion mode shall be within the range of 10%.

4.1.3.2 The average infusion rate accuracy in non-continuous infusion mode shall be within the range of 10%.

4.1.3.3 For electrical infusion pumps for ambulatory use with patient controlled analgesia (PCA)/intended bolus infusion mode, the accuracy of infusion rate and volume shall be within the range of 10%; if a time-locking interval is present, the time error shall be within the range of 10 seconds.

4.1.3.4 For electrical infusion pumps for ambulatory use with a chronological infusion mode, the accuracy of chronological infusion shall be within the range of 10%.

4.1.4 Occlusion pressure, trigger time and resulting bolus

4.1.4.1 The alarm threshold for infusion occlusion pressure shall be specified in the accompanying documentation, with an error within 25 kPa or 20%, whichever is greater.

4.1.4.2 The time required for the occlusion alarm to trigger shall not exceed the manufacturer's claimed value.

4.1.4.3 When the electrical infusion pump for ambulatory use operates at an intermediate rate (specified by the manufacturer) and reaches the occlusion alarm threshold, the unintended bolus generated shall not exceed the manufacturer's claimed value.

4.1.5 Continuous operating time When the electrical infusion pump for ambulatory use uses a new battery and operates at an intermediate rate (specified by the manufacturer), it shall be able to continuously and normally operate for at least 25 hours or until the solution in the restoration set is depleted, whichever is

4.3.1.1 Sealing All components of the electrical infusion pump for ambulatory use that come into contact with the medication solution shall constitute a sealed, leak-free system.

4.3.1.2 Connectors The connectors of the electrical infusion pump for ambulatory use shall meet the following requirements.

a) If intended for neuraxial application connection, the connector at the dosing port (if applicable) shall be a female locking connector conforming to YY/T 0916.6, and the connector at the end of the set shall be a male locking connector conforming to YY/T 0916.6;

b) If intended for intravascular or hypodermic application connection, the connector at the

dosing port (if applicable) shall be a female locking connector conforming to YY/T 0916.7, and the connector at the end of the set shall be a male locking connector conforming to YY/T 0916.7.

4.3.1.3 Filters The system's administration set shall be equipped with filters containing membranes with a nominal pore size of 5 m or less and shall meet the filtration performance requirements for medication solution filters in YY 0286.1-2019.If the filter has an exhaust vent, it shall also meet the relevant requirements of

7.2.6 in YY 0286.1-2019.

4.3.1.4 Set If the restoration set and administration set of the electrical infusion pump for ambulatory use are separate, the connection system used shall use locking connectors. The connection between the restoration set and administration set shall be able to withstand a static tensile force of 15 N for 15 seconds.

4.3.1.5 Restoration set The restoration set of the electrical infusion pump for ambulatory use shall be designed to allow for visual inspection of foreign matter and air bubbles in the contained solution.

4.3.1.6 Particulate contamination When tested in accordance with Appendix B of YY 0451-2023 or an equivalent method, the contamination index shall not exceed 90.

4.3.1.7 Restoration set filling capacity The capacity shall not be less than the nominal capacity of the restoration set.

4.3.2 Chemical properties

4.3.2.1 Reducing substances The difference in the volume of potassium permanganate solution [c(KMnO4) =

0.002 mol/L] consumed by the test solution and the blank solution shall not exceed

4.3.2.2 Metal ions When determined by atomic absorption spectrophotometry (AAS) or an equivalent method, the total content of barium, chromium, copper, lead and tin in the extract shall not exceed 1 g/mL, and the cadmium content shall not exceed 0.1 g/mL. The color of the test solution shall not exceed that of a standard control solution with a mass concentration rho(Pb^2+) = 1 g/mL.

4.3.2.3 pH When titrating with sodium hydroxide standard solution [c(NaOH) =

0.001 mol/L] or hydrochloric acid standard solution [c(HCl) =

0.01 mol/L], the amount of either standard solution required to turn the indicator gray shall not exceed

4.3.2.4 Evaporation residue The total amount of evaporation residue shall not exceed 2 mg.

4.3.2.5 Ultraviolet absorbance When testing within the range of 220 nm to 360 nm, the