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

YY/T 1274-2025

Replacing YY/T 1274-2016, YY/T 1493-2016

Peritoneal dialysis equipment

腹膜透析设备

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Table of Contents

1.Scope	1
2 Normative References	1
3.Terms and Definitions	1
4 Requirements	1
4.1 Normal operating conditions of the equipment	1
4.2 Dialysis fluid temperature	1
4.3 Dialysis fluid volume	2
4.4 Dialysis fluid flow rate	2
4.5 Peritoneal dialysis indwelling time	2
4.6 Weighing device	2
4.7 Dialysis fluid line pressure	2
4.8 Protection against over-perfusion of dialysate	2
4.9 Insufficient Drainage Prevention	2
4.10 Pipeline blockage protection	2
4.11 Pinch valve	3
4.12 Liquid bag height	3
4.13 Operating Noise	3
4.14 Safety Requirements	3
4.15 Appearance and Structure	3
5.Test Methods	3
5.1 Test Operating Conditions	3
5.2 Dialysis fluid temperature test	3
5.3 Dialysis fluid volume test	4
5.4 Dialysis fluid flow test	4
5.5 Peritoneal dialysis indwelling time test	4
5.6 Weighing device test	4
5.7 Dialysis fluid pipeline pressure test	4
5.8 Dialysis fluid over-perfusion protection test	4
5.9 Insufficient Drainage Protection Test	4
5.10 Pipeline Blockage Protection Test	4
5.11 Pinch valve test	5
5.12 Liquid Bag Height Test	5

5.13 Operating Noise Test.....	5
5.14 Safety Requirements Test.....	5

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting. This document supersedes YY/T 1274-2016 "Pressure-Controlled Peritoneal Dialysis Equipment" and YY/T 1493-2016 "Gravity-Controlled Peritoneal Dialysis Equipment". Compared with YY/T 1274-2016 and YY/T 1493-2016, the main technical changes in the "Dialysis Equipment" standard are as follows, except for structural adjustments and editorial modifications. The following is an explanation.

---The scope has been changed (see Chapter 1, Chapter 1 of YY/T 1274-2016, and Chapter 1 of YY/T 1493-2016);

---The "Normative References" have been amended (see Chapter 2, Chapter 2 of YY/T 1274-2016, and Chapter 2 of YY/T 1493-2016);

---Terms and definitions have been revised (see Chapter 3, Chapter 3 of YY/T 1274-2016, and Chapter 3 of YY/T 1493-2016);

---The word "categorization" has been removed (see Chapter 4 of YY/T 1274-2016);

---The "Normal Operating Conditions of Equipment" have been modified (see 4.1,

5.1 of YY/T 1274-2016, and

4.1 of YY/T 1493-2016);

---The requirements and test methods for "dialysis fluid temperature" have been changed (see

6.2 of YY/T 1274-2016). YY/T 1493-2016, sections

---The requirements and test methods for "dialysis fluid volume" have been changed (see

6.3 of YY/T 1274-2016). YY/T 1493-2016, sections

---Added requirements and test methods for "dialysis fluid flow rate" (see

1 Scope

YY/T 1274 is the product standard for peritoneal dialysis equipment, the cyclor that runs automated exchanges overnight for patients dialysing at home. It specifies the requirements for peritoneal dialysis equipment and describes the corresponding test methods, and it

carries explicit exclusions for related equipment that falls outside its definition. A PD cyclor works unsupervised in a bedroom rather than in a dialysis unit, so fluid volume accuracy, warming, alarms and fail-safe behaviour matter differently than they do in a clinical machine. It takes effect on 1 January 2027. For a manufacturer or an importer of peritoneal dialysis cyclers seeking Chinese registration, this is the standard the type test is run against.

This document specifies the requirements for peritoneal dialysis equipment and describes the corresponding test methods. This document applies to peritoneal dialysis equipment (hereinafter referred to as the equipment). This document is not applicable to.

---Disposable consumables used in peritoneal dialysis (such as dialysate and dialysate tubing);

---Continuous blood purification equipment;

---Hemodialysis equipment.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 9706.1 Medical electrical equipment - Part

3 Terms and Definitions

The terms and definitions defined in GB 9706.239 apply to this document.

4 Requirements

4.1 Normal operating conditions of the equipment The equipment should meet the normal operating conditions specified by the manufacturer.

4.2 Dialysis fluid temperature

4.2.1 Temperature Control The equipment should have a dialysate heating function and meet the following requirements.

- a) The manufacturer should specify the control range and tolerance for the dialysate temperature in the accompanying documentation;
- b) The temperature control range of the dialysate should comply with the provisions of the accompanying documents.

4.2.2 Heater surface temperature protection When the heater surface is an accessible part, the maximum normal operating surface temperature of the heater should not exceed 56°C; otherwise, reasonableness and/or protection are required. Protective measures should be determined through the analysis of risk management documents.

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