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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 9706.27-2005

**Medical electrical equipment -- Part 2-24: Particular
requirements for the safety of infusion pumps and controllers
(English Translation)**

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Foreword

There are series of standards of medical electrical equipment, which mainly consist of two parts.

- Part 1.general safety requirements for medical electrical equipment;
- Part 2.particular requirements for medical electrical equipment.

This Particular Standard is particular requirements for the safety of infusion pumps and controllers of Part 2.This Standard identically uses IEC 60601-2-

24.1998 Medical electrical equipment - Part 2-24.Particular requirements for the safety of infusion pumps and controllers (English version).

Compared with IEC 60601-2-24.1998, the editorial differences in this Particular Standard are as follows.

- for other International standards used as references in IEC 60601-2-24.1998, if they have been used in China standards, it shall replace the reference numbers of the International standards by China's;
- for easy use, added the normative Annex BB "Normative references";

modified the informative Annex L "Bibliography" and incorporated part of the standard directory into Annex BB;

- the content of Clause 36 of IEC 60601-2-24.1998 used the standard of IEC 60601-1-2.1993 but this edition (Edition 1993) has been replaced by Edition 2001, therefore Clause 36 of this Particular Standard uses requirements of YY 0505-2005;

- incorporated the relevant requirements of Amendment 2 (1995) of IEC 60601-1.1988 into corresponding terms of this Standard so as to make this Particular Standard consistent with IEC 60601-2-24.1998. to make it distinguished with particular standard, the content of Amendment 2 has been marked by double vertical line in this Particular Standard.

This Particular Standard uses GB 9706.1-1995 Medical electrical equipment--Part 1.General requirements for safety (idt IEC 60601-1.1988 + Amendment 1 (1991)) and IEC 60601-1.1998 Amendment 2 (1995) Medical electrical equipment--Part 1.General requirements for safety Amendment 2, YY 0505-

2005 Medical electrical equipment Part 1-2.General requirements for safety -

Collateral standards. Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2.2001, IDT) as references.

Annex L, Annex AA of this Particular Standard are informative; Annex BB is normative.

This Particular Standard was proposed by Sub-committee on Medical Electronic Equipment of National Technical Committee on Medical Electrical Equipment of Standardization Administration of China.

This Particular Standard shall be under the jurisdiction of Sub-committee on Medical Electronic Equipment of National Technical Committee on Medical Electrical Equipment of Standardization Administration of China.

The drafting organization of this Particular Standard. Shanghai Institute of

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Medical electrical equipment - Part 2-24. Particular requirements for the safety of infusion pumps and controllers

SECTION ONE - GENERAL

The clauses and sub-clauses of this section of the General Standard and of this section of the Collateral Standard YY 0505-2005 apply, except as follows.

1 Scope and object

The clause of the General Standard and this clause of the Collateral Standard YY 0505-2005 apply, except as follows.

1.1* Scope

Addition.

This Particular Standard specifies the requirement for infusion pumps, infusion controllers, syringe pumps and pumps for ambulatory use, as defined in 2.101 to 2.110. These devices are intended for use by medical staff and home patients as prescribed and medically indicated. These particular requirements do not apply to devices.

- specifically intended for diagnostic or similar use (e.g. angiography or other pumps permanently controlled or supervised by the operator);
- enteral infusion;
- extracorporeal circulation of blood;
- implantable or disposable devices;
- equipment specially intended for diagnostic use within urodynamics (measurement of pressure-volume relationship of the urinary bladder when filled through a catheter with water);
- equipment specially intended for diagnostic use within male impotence testing (measurement of amount of liquid infused, necessary to maintain

a preset pressure level for maintaining penile erection. cavernosometry, cavernosography).

Annex BB

(Normative)

Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (exc...

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