

AS/NZS 3770:1993

Australian/New Zealand Standard

Guide to the safe use of infusion pumps and controllers

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The following interests are represented on Committee HT/18:

Area hospital boards, New Zealand
 Australasian College of Physical Scientists and Engineers in Medicine
 Australian Nursing Federation
 Australian Society of Anaesthetists
 Australian and New Zealand Society of Nephrology
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PREFACE

This Standard was prepared by the Joint Australian/New Zealand Standards Committee HT/18 on Drug Infusion Pumps on behalf of the Joint Multitechnics Standards Policy Board and is intended as a guide to users of electrically powered infusion devices.

The Standard should be read in conjunction with AS 2500—1986, *Guide to the safe use of electricity in patient care*. General construction and other requirements for all electrically powered medical equipment are contained in AS/NZS 3200.1—1990, *Approval and test specification—Medical electrical equipment, Part 1: General requirements for safety*.

The Joint Standard emphasizes that it is the responsibility of the user to become knowledgeable about the current selection and use of infusion devices to ensure adherence to safe procedures.

As with all Standards, it is subject to automatic, periodic review. However, it is expected that this Joint Standard will need to be constantly monitored and be revised more frequently than others in order to take account of—

- (i) new developments in patient treatment techniques and equipment, and
- (ii) comments from users of the Standard.

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FOREWORD

Infusion devices are being increasingly used in hospitals for the controlled administration of drugs and parenteral fluids. Generally, they are used for intravenous administration, but they are also used for intra-arterial administration of special drugs such as cytotoxics for local cancers and epidural blocks for pain relief.

Life-saving drugs which require continuous infusion are often monitored by a pump or controller to ensure accuracy of delivery; the same devices may also be used for administration of parenteral fluids or drugs for which continuous infusion is not critical.

This Joint Standard is intended as a guide to users of such devices and it addresses safe practices specific to the type of device and its pattern of use.

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Australian/New Zealand Standard
Guide to the safe use of infusion pumps and controllers

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE This Standard provides advice on infusion pumps, infusion controllers, syringe pumps, and pumps for ambulatory use. These devices are intended to be used in hospitals for the administration of drugs or liquids to patients. In some circumstances they may be used by patients at home, under medical direction.

This Standard does not apply to devices specifically intended for angiography, enteral infusion, or infusion of blood. Devices for extracorporeal circulation of blood including haemodialysis and plasmapheresis, or which are implanted in the body, are also excluded.

In these specific cases refer to the manufacturer's operating instructions.

NOTE: Because of the wide variation in use of these devices, this Standard can only address in general terms factors affecting their reliability or their intrinsic safety. The safe use of the infusion device is primarily the responsibility of the user. The user should therefore be trained in the correct selection of devices to ensure that the characteristics of the device chosen are appropriate for the treatment. The user should also be familiar with the operation of the device in accordance with the manufacturer's instructions.

1.2 APPLICATION This Standard is intended as a guide for use by doctors, nurses and other medical personnel responsible for the safe infusion of medication and fluids to patients. The Standard is also intended for use by educators responsible for training hospital staff and patients in the fundamental principles of infusion devices.

1.3 REFERENCED DOCUMENTS The following document is referred to in this Standard:

AS

2385 Single-use (sterile) infusion sets for general medical use

1.4 DEFINITIONS For the purpose of this Joint Standard the definitions below apply:

1.4.1 Cannula—a metal or plastic tube for insertion into the body to gain access to the vascular system for the infusion of fluids.

1.4.2 Delivery tube—a length of flexible tubing connecting the adaptor and chamber of the set.

1.4.3 Device—an electronic infusion pump or controller.

1.4.4 Drop chamber—a chamber containing a drip tube and constructed so as to enable observation of the rate of flow of the infusate.

1.4.5 Drop sensor—a sensor that monitors the drops of infusate passing into the delivery tube.

1.4.6 Flow regulator—a device for controlling and stopping the flow of fluid through the set.

1.4.7 Infiltration—infusion of fluid into the tissue surrounding the infusion site.

1.4.8 Infusion controller—electrically powered equipment used to regulate the flow of liquid into the patient under positive pressure generated by gravitational force.

1.4.9 Infusion pump—electrically powered equipment used to regulate the flow of liquid into the patient under positive pressure generated by the pump. The pump may be a syringe or an in-line reciprocating piston, peristaltic or other type (see Section 3).

1.4.10 Infusion set—a single-use sterile infusion set, including any air-inlet assembly and intravenous injection device provided with the set, but excluding the end protectors.

1.4.11 Micro-bore feed tube—a tube situated in a drip chamber to ensure consistent volume of drops.

1.4.12 No flow period—the period of time during the operation of an infusion pump when it does not deliver infusate.

1.4.13 Positive pressure—the pressure applied by infusion pump to deliver infusate into the patient.

SECTION 2 PURPOSE OF INFUSION EQUIPMENT

2.1 GENERAL Infusion pumps and controllers are designed to deliver fluids directly into a patient. Electronic control and monitoring of the infusion rate and certain other parameters are provided.

2.2 MEDICATION ADMINISTRATION Administration of medication directly into the patient achieves the following:

- (a) Adequate concentration of the drug.
- (b) Direct control over pharmacological variables, such as onset of drug effects and peak serum drug concentrations.
- (c) Ability to comply with requirements of therapy and dosage in outpatients by use of specialized pumps.
- (d) Allows drug administration when the oral route is unsuitable or unavailable, for example, because of drug characteristics or the patient's mental or physical condition.

Immediacy and accuracy make this method of administration the method of choice for specific conditions, including the use of antibiotics for severe infection, chemotherapy for malignant conditions, cardiac medication in critical cases and analgesics for relief of severe pain.