INTERNATIONAL STANDARD

**ISO 11608-4**

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# Pen-injectors for medical use —

## Part 4: Requirements and test methods for electronic and electromechanical pen-injectors



*Stylos-injecteurs à usage médical —*

*Partie 4: Exigences et méthodes d'essai pour stylos-injecteurs électroniques et électro-mécaniques*



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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11608-4 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.



ISO 11608 consists of the following parts, under the general title *Pen-injectors for medical use*:

— *Part 1: Pen-injectors — Requirements and test methods*

— *Part 2: Needles — Requirements and test methods*



— *Part 3: Finished cartridges — Requirements and test methods*

— *Part 4: Requirements and test methods for electronic and electromechanical pen-injectors*

# Introduction

This part of ISO 11608 covers electro-mechanical driven injectors not covered by part 1 of ISO 11608. These injectors are mainly intended to administer medicinal products to humans. This part of ISO 11608 provides performance requirements regarding essential aspects of the design so that variations of such injectors are not unnecessarily restricted.

The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer's ability to manufacture one “lot” of injectors that conforms to the critical product attributes. These sampling plans for inspection do not intend to replace the more general manufacturing quality systems practices widely used in production, e.g. the ISO 9000 series.

Materials to be used for the construction of these injectors are not specified, as their selection, to some extent, will depend upon the design, the intended use and the manufacturing process selected by the manufacturer. All materials used in these injectors which come in contact with the end-user must be non-toxic and biocompatible. In some countries, national regulations may exist and their requirements may supersede or add up to this part of ISO 11608.

In relation to specification limits and dose accuracy, the ISO directives (Part 2, A3 and A13) require that the VIM[1] and GUM[2] principles are used and incorporated in all future standards and future revisions of existing standards. The reorganization to be done in relation to this will not affect the technical content of the standards, and only the terminology shall be changed to correspond to VIM, and the principles shall be changed to correspond to GUM.



However, with this part of ISO 11608, ISO/TC 84 has decided to await the revision of the ISO 11608 series where the principles will be incorporated in all parts to conform to applicable requirements.

# Pen-injectors for medical use —

# Part 4: Requirements and test methods for electronic and electromechanical pen-injectors

## 1 Scope

This part of ISO 11608 specifies requirements and test methods for electromechanically driven injectors intended to be used with needles and with replaceable or non-replaceable cartridges. The injector may be for single-use or multiple-use. The injector system is intended to deliver medication to an end-user by self-administration or with assistance.

This part of ISO 11608 is neither applicable for needle-free injectors (as covered in ISO 21649) nor infusion pumps (as covered in IEC 60601-2-24).



This part of ISO 11608 is not applicable for devices that are capable of operating while connected to an external power supply.



## 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.

ISO 11608-1:2000, *Pen-injectors for medical use — Part 1: Pen-injectors — Requirements and test methods*

IEC 60068-2-27:1987, *Environmental testing — Part 2: Tests. Test Ea and guidance: Shock*

IEC 60068-2-30:1980, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance*

IEC 60529:2001, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:1988, *Edition 2: Medical electrical equipment — Part 1: General requirements for safety* (+ AMD 1:1991 + AMD. 2: 1995)

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60721-3-7:1995, *Classification of environmental conditions — Part 3: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

IEC 61000-4-2:2001, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

## 3 Terms and definitions

For the purposes of this document the terms and definitions given in ISO 11608-1 and the following apply.

**3.1**
**drive system**
electromechanical mechanism responsible for expelling the dose

**3.2**
**pen-injector**
pen-injector with an electromechanical drive system

## 4 Symbols and abbreviated terms

See Clause 4 of ISO 11608-1:2000.



## 5 General requirements

See Clause 5 of ISO 11608-1:2000.



## 6 Test conditions

### 6.1 Standard atmosphere

See 6.1 of ISO 11608-1:2000.

### 6.2 Cool atmosphere

See 6.2 of ISO 11608-1:2000.

### 6.3 Hot atmosphere

See 6.3 of ISO 11608-1:2000.

## 7 Preconditioning of pen-injectors

### 7.1 Preconditioning in dry heat atmosphere

See 7.1 of ISO 11608-1:2000.

### 7.2 Preconditioning in cold storage atmosphere

See 7.2 of ISO 11608-1:2000.

### 7.3 Preconditioning in cyclical atmosphere

See 7.3 of ISO 11608-1:2000.

### 7.4 Preconditioning by free fall

See 7.4 of ISO 11608-1:2000.

### 7.5 Preconditioning by vibration

Instead of the vibration test as described in 7.5 of ISO 11608-1:2000, the following applies.

— Unpack and prepare 5 pen-injectors according to the instructions for use with a new cartridge.

— Place the pen-injectors in the box or pouch for transport as instructed by the manufacturer.

— Subject the pen-injectors to vibration in accordance with IEC 60068-2-64.

— Subject the pen-injectors to the conditions specified in IEC 60721-3-7:1995 Class 7M3, as follows:

  — acceleration spectral density 3 $m^2/s^3$, frequency range 10 Hz to 200 Hz;

  — acceleration spectral density 1 $m^2/s^3$, frequency range 200 Hz to 500 Hz;

  — vibrate the pen-injectors in a vertical direction and in two other directions perpendicular to one other in a horizontal plane.



The vibration time shall be 1 h.



NOTE Injectors with limited conditions for vibration shall be subjected to the test at acceptable conditions, and these acceptable conditions shall be stated in the instructions for use.

### 7.6 Preconditioning by shock

Subject the same 5 pen-injectors as used in 7.5 to the shock test in accordance with IEC 60068-2-27.

Subject the pen-injectors to the conditions specified in IEC 60721-3-7:1995 Class 7M3, as follows:

— to a shock response spectrum Type I: 300 $m/s^2$;

— to a shock response spectrum Type II: 1 000 $m/s^2$.

The number of shocks shall be 50 positive and 50 negative.

The shock response test Type II represents the device in use (without packaging).

### 7.7 Preconditioning for the influence of fluid leakage

The purpose of this test is to evaluate the influence of liquid that leaks from the cartridge (back-leakage) or leaks from a broken cartridge into the pen-injector.

— Remove the cartridge holder and pour the contents of one cartridge of the medicinal product into the pen-injector at the most likely point of entry.

— Using appropriate safety equipment, shake the pen-injector in all directions by hand for 30 s.

— Allow the medicinal product to drain from the original point of fluid entry, for 10 min.