International Standard

ISO 11608-4

Needle-based injection systems for medical use — Requirements and test methods —

Part 4: Needle-based injection systems containing electronics

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —

Partie 4: Systèmes d'injection à aiguille contenant de l'électronique

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 11608-4:2006), which has been technically revised.

The main changes are as follows:

— this document has been revised in its entirety to include requirements from the IEC 60601 series that pertain to hand-held medical injectors.

A list of all parts in the ISO 11608 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This corrected version of ISO 11608-4:2022 incorporates the following corrections:

— the value of the capacitance in Figure 4 has been corrected;

— the reference to Table 19 in 9.2.1 has been corrected to Table 21.

Introduction

Needle-based injection systems, including on-body delivery systems (OBDSs), containing electronics with or without software, are primarily intended to administer medicinal products to humans. Performance requirements regarding essential electrotechnical aspects have been selected with the intention not to restrict the Electronic Needle-based Injection System (NIS-E) design unnecessarily when applying the document.

The first edition of this document was limited to pen-injectors with electromechanical drive. Pen-injectors only equipped with electronics were covered in ISO 11608-1.

Materials used for construction are not specified in this document, as their selection will depend on the design, the intended use and the process of manufacture used by individual manufacturers.

There are other international and national standards and guidance publications and, in some countries, national regulations that are applicable to medical devices and pharmaceuticals. This document is applicable to NIS-E and specifies relevant aspects of IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-11:2015+AMD1:2020 for this particular device type.

This document does not specify non-electrotechnical requirements and test methods for NISs when specified by ISO 11608-1.

Developers and manufacturers of NIS-Es are encouraged to investigate and determine whether there are any other requirements relevant to the safety or marketability of their NIS-Es. For example, this document should be used in conjunction with IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. A risk-based approach is expected to be applied during the design, development, and manufacture of the product. Given the specific medicinal product intended use and environment, this might result in product-specific requirements and test methods that differ from what is outlined in this document.

This document is intended to be used for type testing (testing of the development result) of NIS-E. It is not intended to be used for batch release testing.

This document introduces the notion of Type X NIS-E and Type Y NIS-E. Type X NIS-E is a device type without any physical cabled connection to other devices. Type Y NIS-E has such connections. The electrical requirements in this document for Type X NIS-E is a subset of the requirements for Type Y NIS-E.

Needle-based injection systems for medical use — Requirements and test methods —

Part 4: Needle-based injection systems containing electronics

1 Scope

This document specifies requirements and test methods for needle-based injection systems (NISs) containing electronics with or without software (NIS-Es).

The needle-based injection system containing electronics can be single use or reusable and can be operated with or without electrical/conductive connections to other devices. The system is intended to deliver medication to a patient by self-administration or by administration by one other operator (e.g. caregiver or health care provider).

This document applies to electronic accessories that are intended to be physically connected to a NIS or NIS-E according to the NIS/NIS-E intended use.

This document also applies to electronic accessories that are intended to have electrical/conductive connections to a NIS or NIS-E according to the NIS/NIS-E intended use.

This document does not specify requirements for software in programmable NIS-E.

NOTE IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14 addresses software life cycle processes.

This document does not specify requirements for cybersecurity.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

CISPR 11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

CISPR 32, *Electromagnetic compatibility of multimedia equipment — Emission requirements*

ISO 11608-1:2022, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

ISO 7137, *Aircraft — Environmental conditions and test procedures for airborne equipment*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

IEC 60086-4, *Primary batteries — Part 4: Safety of lithium batteries*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014+AMD1:2020, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-11:2015+AMD1:2020, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60721-3-7:1995+AMD1:1996, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications — Part 2: Lithium systems*

IEC 62304, *Medical device software — Software life cycle processes*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 60695-11-10:2013, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods*

IEC 60950-1:2005+AMD1:2009+AMD2:2013, *Information technology equipment — Safety — Part 1: General requirements*

IEC 60747-5-5, *Semiconductor devices — Part 5-5: Optoelectronic devices — Photocouplers*

IEC 61000-3-2, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤16 A per phase)*

IEC 61000-3-3, *Electromagnetic compatibility (EMC) - Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection*

IEC 61000-4-2:2008, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) — Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test*

IEC 61000-4-5, *Electromagnetic compatibility (EMC) — Part 4-5: Testing and measurement techniques — Surge immunity test*

IEC 61000-4-6, *Electromagnetic compatibility (EMC) — Part 4-6: Testing and measurement techniques — Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-8, *Electromagnetic compatibility (EMC) — Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test*

IEC 61000-4-11, *Electromagnetic compatibility (EMC) — Part 4-11: Testing and measurement techniques — Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase*

IEC 61000-4-39, *Electromagnetic compatibility (EMC) — Part 4-39: Testing and measurement techniques — Radiated fields in close proximity—– Immunity test*

IEC 60085, *Electrical insulation — Thermal evaluation and designation*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
access cover
part of an enclosure or guard providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.1]

3.2
accessible part
part of electrical equipment other than an applied part that can be touched by means of the small test finger

Note 1 to entry: See also 8.3.2.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.2, modified — "test finger" changed to "small test finger", Note 1 to entry added.]

3.3
air clearance
shortest distance in air between two conductive parts

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.5, modified — "shortest path" changed to "shortest distance".]

3.4
applied part
part of *electronic needle-based injection system* (3.13) that, in *normal use* (3.28) ,necessarily comes into physical contact with the *patient* (3.32) for *electronic needle-based injection system* to perform its function

Note 1 to entry: See also 8.3.2.1 regarding the treatment of parts that do not fall within the definition of applied parts but need to be treated as applied parts as a result of applying the risk approach process.

Note 2 to entry: See also definition of the associated term *patient connection* (3.33).

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.8, modified — "ME equipment and ME system" changed to "electronic needle-based injection system", Note 1 to entry deleted, Note 2 changed to Note 1 to entry and amended, Note 3 changed to note 2 to entry and amended.]

3.5
basic insulation
insulation providing basic protection against electric shock

Note 1 to entry: This definition does not include insulation used exclusively for functional purposes.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.9, modified — Note 1 to entry changed.]

3.6
basic safety
freedom from unacceptable risk directly caused by physical hazards when *electronic needle-based injection system* (3.13) is used under normal condition and *single fault condition* (3.42)

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.10, modified — "ME equipment" changed to "electronic needle-based injection system".]

3.7
class II
electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or *reinforced insulation* (3.38) are provided, there being no provision for protective earthing or reliance upon installation conditions

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.14]

3.8
creepage distance
shortest distance along the surface of a solid insulating material between two conductive parts

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.19]

3.9
direct cardiac application
use of *applied part* (3.4) that can come in direct contact with the patient's heart

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.22]

3.10
double insulation
insulation comprising both *basic insulation* (3.5) and *supplementary insulation* (3.44)

Note 1 to entry: Double insulation provides two *means of protection* (3.24).

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.23]

3.11
duty cycle
maximum activation (on) time followed by minimum deactivation (off) time

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.24, modified — "necessary for the safe operation of the ME equipment" deleted.]

3.12
enclosure
exterior surface of electrical equipment or parts thereof

Note 1 to entry: For the purpose of testing to this document, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the enclosure.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.26, modified — References to figures in Note 1 to entry deleted.]

3.13
NIS-E
electronic needle-based injection system
injection system containing electronics (with or without software) intended for parenteral administration by injection of medicinal products using a needle or soft cannula and pre-filled or operator-filled, replaceable or non-replaceable containers

3.14
essential performance
performance of a clinical function, other than that related to *basic safety* (3.6), where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk

Note 1 to entry: Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

Note 2 to entry: ISO 11608-1 instead uses the term "primary function", which at a minimum, includes the dose delivery function, achieved through assessment of dose accuracy.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.27, modified — Note 2 to entry added.]

3.15
F-type applied part
applied part (3.4) in which the *patient* (3.32) connections are isolated from other parts of the *electronic needle-based injection system* (3.13) to such a degree that no current higher than the allowable *patient leakage current* (3.34) flows if an unintended voltage originating from an external source is connected to the *patient* (3.32), and thereby applied between the *patient connection* (3.33) and earth

Note 1 to entry: Also referred to as: F-type isolated (floating) applied part

Note 2 to entry: F-type applied parts are either type BF (Body Floating) applied parts or type CF (Cardiac Floating) applied parts.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.29, modified — "ME equipment" changed to "electronic needle-based injection system".]

3.16
functional connection
connection, electrical or otherwise, including those intended to transfer signals, data, power, or substances

Note 1 to entry: Connection to a fixed *supply mains* (3.45) socket-outlet, whether single or multiple, is not considered to result in a functional connection.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.33]

3.17
insulation co-ordination
mutual correlation of insulation characteristics of electrical equipment taking into account the expected micro-environment and other influencing stresses

Note 1 to entry: This includes insulation types, *creepage distances* (3.8), *air clearances* (3.3), distance through insulation, coatings, encapsulation, environmental aspects, etc.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.43]

3.18
intended use
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the *intended use* (3.18).

Note 2 to entry: Intended use should not be confused with normal use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, transport, etc. as well (IEC 60601 1:2005+AMD1:2012+AMD2:2020, 3.44).

[SOURCE: ISO 14971:2019, 3.6, modified — Note 2 to entry added]

3.19
leakage current
current that is not functional

Note 1 to entry: The following leakage currents are defined: *touch current* (3.48) and *patient leakage current* (3.34).

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.47, modified — "Earth leakage current" deleted from Note 1 to entry.]

3.20
mains part
part of electrical equipment forming a circuit that is intended to be connected to the *supply mains* (3.45)

Note 1 to entry: The mains part includes all conductive parts that are not separated from the *supply mains* (3.45) by at least one *means of protection* (3.24).

Note 2 to entry: The protective earth conductor is not regarded as a part of the mains part.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.49, modified — Note 2 to entry changed.]

3.21
maximum mains voltage
voltage used for test purposes related to the voltage of the *supply mains* (3.45) and connected to certain *medical electrical equipment* (3.25) parts

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.56, modified — Note to entry deleted.]

3.22
means of operator protection
MOOP
means of protection (3.24) for reducing the risk due to electric shock to persons other than the *patient* (3.32)

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.58]

3.23
means of patient protection
MOPP
means of protection (3.24) for reducing the risk due to electric shock to the *patient* (3.32)

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.59]

3.24
means of protection
MOP
means for reducing the risk due to electric shock in accordance with specific requirements

Note 1 to entry: The specific requirements shall be in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

Note 2 to entry: Means of protection include insulation, *air clearances* (3.3), *creepage distances* (3.8), impedances, and protective earth connections.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.60, modified — Note 1 to entry changed to Note 2 to entry, new Note 1 to entry added.]

3.25
medical electrical equipment
electrical equipment having an *applied part* (3.4) or transferring energy to or from the *patient* (3.32) or detecting such energy transfer to or from the *patient* (3.32)

Note 1 to entry: Medical electrical equipment includes those accessories as defined by the manufacturer that are necessary to enable the *normal use* (3.28) of the medical electrical equipment.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.63, modified — Notes 2 to 5 to entry deleted.]

3.26
medical electrical system
combination, as specified by its manufacturer, of items or equipment, at least one of which is *medical electrical equipment* (3.25) intended to be inter-connected by *functional connection* (3.16) or by use of a multiple socket-outlet

Note 1 to entry: Equipment, when mentioned in this document, should be taken to include *medical electrical equipment* (3.25).

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.64, modified — "intended" added to the definition.]

3.27
normal condition
condition in which all means provided for protection against hazards are intact

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.70]

3.28
normal use
operation including routine inspection and adjustments by any *operator* (3.29), and stand-by, according to the instructions for use

Note 1 to entry: Normal use should not be confused with *intended use* (3.18). While both include the concept of use as intended by the manufacturer, *intended use* (3.18) focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.71]

3.29
operator
person handling equipment

Note 1 to entry: The operator can be different from the *patient* (3.32) and can be a caregiver, health care provider or other person.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.73, modified — Note 1 to entry added.]

3.30
over-current release
protective device that causes a circuit to open, with or without time-delay, when the current in the device exceeds a predetermined value

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.74]

3.31
oxygen rich environment
environment in which the concentration of oxygen is

a) greater than 25 % for ambient pressures up to 110 kPa, or

b) the partial pressure of oxygen is greater than 27,5 kPa at ambient pressures exceeding 110 kPa

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.75]

3.32
patient
living being (person or animal) undergoing a medical, surgical, or dental procedure

Note 1 to entry: A patient can be an *operator* (3.29).

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.76]

3.33
patient connection
individual point on the *applied part* (3.4) through which current can flow between the *patient* (3.32) and the *electronic needle-based injection system* (3.13) in *normal condition* (3.27) or *single fault condition* (3.42)

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.78, modified — "ME equipment" changed to "electronic needle-based injection system".]

3.34
patient leakage current
current

— flowing from the *patient connections* (3.33) via the *patient* (3.32) to earth, or

— originating from the unintended appearance of a voltage from an external source on the *patient* (3.32) and flowing from the *patient* (3.32) via the *patient connections* (3.33) of an *F-type applied part* (3.15) to earth

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.80]

3.35
peak working voltage
highest peak or DC value of a *working voltage* (3.52), including repetitive peak impulses generated in the electrical equipment, but not including external transients

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.81]

3.36
potential equalization conductor
conductor other than a protective earth conductor or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.86, modified — Note to entry deleted.]

3.37
rated
referring to a value assigned by the manufacturer for a specified operating condition

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.97]

3.38
reinforced insulation
single insulation system that provides two *means of protection* (3.24)

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.99]

3.39
responsible organization
entity accountable for the use and maintenance of an *electronic needle-based injection system* (3.13)

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the *patient* (3.32), *operator* (3.29) and responsible organization can be one and the same person.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.101, modified — Note 2 to entry deleted.]

3.40
secondary circuit
circuit that is separated from the *mains part* (3.20) by at least one *means of protection* (3.24) and derives its power from a transformer, converter, or equivalent isolation device, or from an internal electrical power source

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.110, modified — Note to entry deleted.]

3.41
signal input/output part
sip/sop
part of *electronic needle-based injection system* (3.13), not being an *applied part* (3.4), intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.115, modified — "ME equipment" changed to "electronic needle-based injection system", Note to entry deleted.]