SLOVENSKI STANDARD
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Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 4. del: Peresa za injiciranje z elektronskimi elementi (ISO/DIS 11608-4:2020)

Needle-based injection systems for medical use - Requirements and test methods - Part 4: Needle-based injection systems containing electronics (ISO/DIS 11608-4:2020)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 4: Kanülenbasierte Injektionssysteme, die elektronische Bauteile enthalten (ISO/DIS 11608-4:2020)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 4: Systèmes d'injection à aiguille électroniques (ISO/DIS 11608-4:2020)

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

Part 4: Needle-based injection systems containing electronics

Stylos-injecteurs à usage médical —

Partie 4: Exigences et méthodes d'essai pour stylos-injecteurs électroniques et électromécaniques

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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).

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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*.

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

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.

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. This document provides performance requirements regarding essential aspects of the design so that variations of such injectors are not unnecessarily restricted.

For historical reasons (ISO 11608-1 was published before ISO 11608-4), the first edition of this document was limited to pen-injectors with electromechanical drive systems. Pen-injectors only equipped with electronics were covered in ISO 11608-1. Given the set of additional tests that need to be performed on needle-based injection systems containing electronics (NIS-E) regardless of what the electronics are used for, it was decided to have all types of NIS-Es covered by this document.

Materials to be used for construction are not specified, 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 serves as a stand-alone document for NIS-E that specifies relevant aspects of the IEC 60601 series for this particular device type. This document does not specify non-electrotechnical test methods, conditions, or acceptance criteria for NISs when specified by other parts of ISO 11608.

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 products. Their requirements might supersede or complement those contained in this document.

Manufacturers are expected to follow a risk-based approach 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.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

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.

The needle-based injection system containing electronics can be single use, reusable, and/or rechargeable. It 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 which are intended to be physically connected to a NIS or NIS-E during the NIS/NIS-E intended use.

NOTE This document includes relevant requirements derived from IEC 60601 series.

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.

ISO 11608-1,[1)] *Needle-based injection systems for medical use -- Requirements and test methods -- Part 1: Needle-based injection systems*

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

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

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

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

IEC 60601-1-2:2014, *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, *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 60950-1, *Information technology equipment – Safety – Part 1: General requirements*

IEC 62133-1, *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 1: Nickel systems*

1) To be published (revises ISO 11608-1:2012). Stage at time of publication: ISO/DIS 11608-1:2020.

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*

ISO 62304, *Medical Device Software — Software Life-cycle Processes*

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

IEC 62368-1, *Audio/video, information and communication technology equipment - Part 1: Safety requirements*

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

ISO/IEC/IEEE 12207, *Systems and software engineering — Software life cycle processes*

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 terminological 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

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

Note 1 to entry: See also 8.3.2.

3.3
air clearance
shortest distance in air between two conductive parts

[SOURCE: IEC 60664-1:2007, 3.2. Modified: "path" changed to "distance"]

3.4
applied part
part of NIS-E that in *normal use* (3.30) necessarily comes into physical contact with the *patient* (3.35) for NIS-E to perform its function

Note 1 to entry: See also 8.3 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 assessment process.

Note 2 to entry: See also 3.37 for the definition of the associated term *patient connection* (3.37).

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 60601-1:2012, ed 3.1, 3.9]

3.6
basic safety
freedom from unacceptable risk directly caused by physical hazards when NIS-E is used under normal condition and *single fault condition* (3.46)

3.7
class I
electrical equipment in which protection against electric shock does not rely on *basic insulation* (3.5) only, but which includes an additional safety precaution in that means are provided for *accessible parts* (3.2) of metal or internal parts of metal to be protectively earthed

3.8
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* (3.42) are provided, there being no provision for protective earthing or reliance upon installation conditions

3.9
creepage distance
shortest distance along the surface of a solid insulating material between two conductive parts

3.10
direct cardiac application
use of *applied part* (3.4) that can come in direct contact with the patient's heart

3.11
double insulation
insulation comprising both *basic insulation* (3.5) and *supplementary insulation* (3.48)

Note 1 to entry: Double insulation provides two *means of protection* (3.26).

3.12
duty cycle
maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the NIS-E

3.13
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.

3.14
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

3.15
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: The other parts of ISO 11608 series do not apply the terms "essential performance" and "basic safety" (3.6). Instead they apply the term "primary function" which is defined as "function or operation of the NIS, which, if it does not perform to specifications during use, would result in a failure to accurately deliver the medicinal product via the correct route and/or result in unacceptable harm to the *patient*" (3.35). At a minimum, this includes the dose delivery function, achieved through assessment of dose accuracy.

3.16
F-type isolated (floating) applied part (herein F-type applied part)
applied part (3.4) in which the *patient* (3.35) connections are isolated from other parts of the *NIS-E* (3.14) to such a degree that no current higher than the allowable *patient leakage current* (3.38) flows if an unintended voltage originating from an external source is connected to the *patient* (3.35), and thereby applied between the *patient connection* (3.37) and earth

Note 1 to entry: F-type applied parts are either type BF (Body Floating) applied parts or type CF (Cardiac Floating) applied parts.

3.17
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* (3.49) socket-outlet, whether single or multiple, is not considered to result in a functional connection.

3.18
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* (3.9), *air clearances* (3.3), distance through insulation, coatings, encapsulation, environmental aspects, etc.

3.19
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* (3.22)

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.

[SOURCE: ISO 14971:2019, 3.6]

3.20
leakage current
current that is not functional

Note 1 to entry: The following leakage currents are defined: *touch current* (3.52) and *patient leakage current* (3.38).

3.21
mains
part of electrical equipment forming a circuit that is intended to be connected to the *supply mains* (3.49)

Note 1 to entry: The mains part includes all conductive parts that are not separated from the *supply mains* (3.49) by at least one *means of protection* (3.26).

Note 2 to entry: For the purpose of this definition, the protective earth conductor is not regarded as a part of the mains part.

3.22
manufacturer
natural or legal person with responsibility for the design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name, whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

[SOURCE: ISO 14971:2019, 3.9, modified: Notes to entry deleted]

3.23
maximum mains voltage
voltage used for test purposes related to the voltage of the *supply mains* (3.49) connected to certain *medical electrical equipment* (3.27) parts

3.24
means of operator protection
[MOOP]
means of protection (3.26) for reducing the risk due to electric shock to persons other than the *patient* (3.35)

3.25
means of patient protection
[MOPP]
means of protection (3.26) for reducing the risk due to electric shock to the *patient* (3.35)

3.26
means of protection
[MOP]

means for reducing the risk due to electric shock in accordance with the requirements of this document

Note 1 to entry: Means of protection include insulation, *air clearances* (3.3), *creepage distances* (3.9), impedances, and protective earth connections.

3.27
medical electrical equipment
electrical equipment having an *applied part* (3.4) or transferring energy to or from the *patient* (3.35) or detecting such energy transfer to or from the *patient* (3.35) and which is:

a) provided with not more than one connection to a particular *supply mains* (3.49); and

b) intended by its *manufacturer* (3.22) to be used:

   1) in the diagnosis, treatment, or monitoring of a *patient* (3.35); or

   2) for compensation or alleviation of disease, injury or disability

Note 1 to entry: Medical electrical equipment includes those accessories as defined by the *manufacturer* (3.22) that are necessary to enable the *normal use* (3.30) of the medical electrical equipment.

3.28
medical electrical system
combination, as specified by its *manufacturer* (3.22), of items of equipment, at least one of which is *medical electrical equipment* (3.27) to be inter-connected by *functional connection* (3.17) 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* (3.27).

3.29
normal condition
condition in which all means provided for protection against hazards are intact

3.30
normal use
operation including routine inspection and adjustments by any *operator* (3.32), and stand-by, according to the instructions for use

Note 1 to entry: Normal use should not be confused with *intended use* (3.19). While both include the concept of use as intended by the *manufacturer* (3.22), *intended use* (3.19) focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, transport, etc. as well.

3.31
objective evidence
data supporting the existence or verity of something

Note 1 to entry: Objective evidence can be obtained through observation, measurement, test or by other means.

[SOURCE: ISO 14971:2019, 3.11]

3.32
operator
person handling equipment

Note 1 to entry: See also 3.47.

Note 2 to entry: Operator can be different from the *patient* (3.35) and can be a caregiver, health care provider or other person.

[SOURCE: IEC 60601-1:2014, 3.73. Modified: Note 2 to entry added]

3.33
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

3.34
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

3.35
patient
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A patient can be an *operator* (3.32).

[SOURCE: IEC 60601-1:2005, definition 3.76]

3.36
patient auxiliary current
current flowing in the *patient* (3.35) in *normal use* (3.30) between any *patient connection* (3.37) and all other *patient connections* (3.37) and not intended to produce a physiological effect

3.37
patient connection
individual point on the *applied part* (3.4) through which current can flow between the *patient* (3.35) and the *NIS-E* (3.14) in *normal condition* (3.29) or *single fault condition* (3.46)

3.38
patient leakage current
current:

— flowing from the *patient connections* (3.37) via the *patient* (3.35) to earth; or

— originating from the unintended appearance of a voltage from an external source on the *patient* (3.35) and flowing from the *patient* (3.35) via the *patient connections* (3.37) of an *F-type applied part* (3.16) to earth

3.39
peak working voltage
highest peak or DC value of a *working voltage* (3.57), including repetitive peak impulses generated in the electrical equipment, but not including external transients

[SOURCE: IEC 62368-1:2018]

3.40
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

3.41
rated
term referring to a value assigned by the *manufacturer* (3.22) for a specified operating condition

3.42
reinforced insulation
single insulation system that provides two *means of protection* (3.26)

3.43
responsible organization
entity accountable for the use and maintenance of a *NIS-E* (3.14)

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* (3.35), *operator* (3.32) and responsible organization can be one and the same person.

Note 2 to entry: Education and training is included in "instruction for use."

3.44
secondary circuit
circuit which is separated from the *mains* (3.21) part by at least one *means of protection* (3.26) and derives its power from a transformer, converter or equivalent isolation device, or from an internal electrical power source

3.45
signal input/output part
[sip/sop]
part of *NIS-E* (3.14), 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

3.46
single fault condition
SFC
condition of *NIS-E* (3.14) in which a single means for reducing a risk is defective or a single abnormal condition is present

3.47
single fault safe
characteristic of *NIS-E* (3.14) or its parts whereby it remains free of unacceptable risk during its expected service life under *single fault conditions* (3.46)

Note 1 to entry: See 8.10.4.