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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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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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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*.

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.

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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 (standards.iteh.ai)

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.

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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

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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.

3.48

supplementary insulation

independent insulation applied in addition to *basic insulation* (3.5) in order to provide protection against electric shock in the event of a failure of *basic insulation* (3.5)

3.49

supply mains

source of electrical energy not forming part of *NIS-E* (3.14)

Note 1 to entry: This also includes battery systems and converter systems in ambulances and the like.

Note 2 to entry: *Supplementary insulation* (3.48) provides one *means of protection* (3.26).

3.50

thermal cut-out

device that, during an abnormal condition, limits the temperature of electrical equipment or of part of it, by automatically opening the circuit or by reducing the current, and that is so constructed that its setting cannot be altered except by qualified service personnel

3.51

thermal stability

condition under which the temperature of an object does not increase by more than 2 °C over a period of 1 h

3.52

touch current

text of definition *leakage current* (3.20) flowing from the *enclosure* (3.13) or from parts thereof, excluding *patient connections* (3.37), accessible to any operator (3.32) or *patient* (3.35) in *normal use* (3.30), through an external path other than the protective earth conductor, to earth or to another part of the *enclosure* (3.13)

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3.53

type B applied part

applied part (3.4) complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable *patient leakage current* (3.38) and *patient auxiliary current* (3.36)

Note 1 to entry: A type B applied part is marked with symbol IEC 60417-5840 (2002-10) (see IEC 60601-1:2005, Table D.1, symbol 19) or, when applicable, with symbol IEC 60417-5841 (2002-10) (see IEC 60601-1:2005, Table D.1, symbol 25). See also 3.17.

Note 2 to entry: Type B applied parts are not suitable for *direct cardiac application* (3.10).

Note 3 to entry: See also 8.3 regarding the treatment of parts that do not fall within the definition of *applied parts* (3.4) but need to be considered as applied parts as a result of applying the risk assessment process.

3.54

type BF applied part

F-type applied part (3.16) complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by *type B applied parts* (3.53)

Note 1 to entry: A type BF applied part is marked with symbol IEC 60417-5333 (2002-10) (see IEC 60601-1:2005, Table D.1, symbol 20) or, when applicable, with symbol 60417-5334 (2002-10) (see IEC 60601-1:2005, Table D.1, symbol 26). See also 3.17.

Note 2 to entry: Type BF applied parts are not suitable for *direct cardiac application* (3.10).

Note 3 to entry: See also 8.3 regarding the treatment of parts that do not fall within the definition of *applied parts* (3.4) but need to be considered as *applied parts* (3.4) as a result of applying the risk assessment process.

3.55**type CF applied part**

F-type applied part (3.16) complying with the specified requirements of this document to provide a higher degree of protection against electric shock than that provided by *type BF applied parts* (3.54)

Note 1 to entry: A type CF applied part is marked with symbol IEC 60417-5335 (2002-10) (see IEC 60601-1:2005, Table D.1, symbol 21) or, when applicable, with symbol 60417-5336 (2002-10) (see IEC 60601-1:2005, Table D.1, symbol 27). See also 3.17.

Note 2 to entry: See also 8.3 regarding the treatment of parts that do not fall within the definition of *applied parts* (3.4) but need to be considered as *applied parts* (3.4) as a result of applying the risk assessment process.

3.56**type test**

test on a representative sample of the equipment with the objective of determining if the *NIS-E* (3.14), as designed and manufactured, can meet the requirements of this document

3.57**working voltage**

highest voltage to which the insulation or the component under consideration is, or can be, subjected when the electrical equipment is operating under conditions of *normal use* (3.30)

[SOURCE: IEC 60950-1:2005, 1.2.9.6]

4 Symbols and abbreviated terms

See ISO 11608-1:####, [Clause 4](#). In addition, the following symbols and abbreviated terms apply:

EMC	Electro Magnetic Compatibility
ESD	Electrostatic Discharge
IR	Infrared
OBDS	On-body delivery system
OTS	Off-the-shelf
RF	Radiofrequency
RMS	Root-mean-square
SIP	Signal Input Port
SOP	Signal Output Port

5 General requirements**5.1 Conditions for application of NIS-E**

Unless otherwise specified, the requirements of this document shall apply in normal use and reasonably foreseeable misuse.

When applying this document for NIS-E, the definitions and requirements that use the term operator shall be considered as applying to the person who operates the NIS- E to set and deliver the dose. E.g., when the operator and the patient are the same person, the requirements for the patient shall be considered (MOPP).