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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.

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.]

3.42
single fault condition
SFC
condition of *electronic needle-based injection system* (3.13) in which a single means for reducing a risk is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.116, modified — "ME equipment" changed to "electronic needle-based injection system".]

3.43
single fault safe
characteristic of *electronic needle-based injection system* (3.13) or its parts whereby it remains free of unacceptable risk during its expected service life under *single fault conditions* (3.42)

Note 1 to entry: See 8.10.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.117, modified — "ME equipment" changed to "electronic needle-based injection system".]

3.44
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

Note 1 to entry: Supplementary insulation provides one *means of protection* (3.24).

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.119]

3.45
supply mains
source of electrical energy not forming part of *electronic needle-based injection system* (3.13)

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

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.120, modified — "ME equipment or ME system" changed to "electronic needle-based injection system".]

3.46
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

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.124]

3.47
thermal stability
condition under which the temperature of an object does not increase by more than 2 °C over a period of 1 h

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.125]

3.48
touch current
leakage current (3.19) flowing from the *enclosure* (3.12) or from parts thereof, excluding *patient connections* (3.33), accessible to any *operator* (3.29) or *patient* (3.32) in *normal use* (3.28), through an external path other than the protective earth conductor, to earth or to another part of the *enclosure* (3.12)

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.78, modified — Note to entry deleted.]

3.49
type BF applied part
F-type applied part (3.15) conforming with specific requirements to provide a higher degree of protection against electric shock than that provided by type B applied parts

Note 1 to entry: A type BF applied part is marked with symbol IEC 60417-5333 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.1, symbol 20) or, when applicable, with symbol IEC 60417-5334 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.1, symbol 26). See also 3.16.

Note 2 to entry: BF type applied parts are not suitable for *direct cardiac application* (3.9).

Note 3 to entry: See also 8.3.2.1 regarding the treatment of parts that do not fall within the definition of *applied parts* (3.4) but shall be considered as *applied parts* (3.4) as a result of applying the risk approach process.

Note 4 to entry: The specific requirements shall be in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.133, modified — "Risk management process" changed to "risk approach process" in Note 3 to entry, Note 4 to entry added.]

3.50
type CF applied part
F-type applied part (3.15) conforming with specific requirements to provide a higher degree of protection against electric shock than that provided by *type BF applied parts* (3.49)

Note 1 to entry: A type CF applied part is marked with symbol IEC 60417-5335 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.1, symbol 21) or, when applicable, with symbol IEC 60417-5336 (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table D.1, symbol 27). See also 3.16.

Note 2 to entry: See also 8.3.2.1 regarding the treatment of parts that do not fall within the definition of *applied parts* (3.4) but shall be considered as *applied parts* (3.4) as a result of applying the risk approach process.

Note 3 to entry: The specific requirements shall be in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.134, modified — "Risk management process" changed to "risk approach process" in Note 2 to entry. Note 3 to entry deleted, new Note 3 to entry added.]

3.51
type test
test on representative samples of the equipment with the objective of determining if the *electronic needle-based injection system* (3.13), as designed and manufactured, can meet specific requirements

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

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.135, modified — Note 1 to entry added]

3.52
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* (3.28)

Note 1 to entry: Overvoltages that originate outside the equipment are not taken into account.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.139, modified — Note to entry added.]

4 Abbreviated terms

EMC	Electro Magnetic Compatibility
ESD	Electrostatic Discharge
EUT	Equipment Under Test
N/A	Not applicable
NIS	Needle-based Injection System
OBDS	On-body Delivery System
RF	Radiofrequency
RMS	Root-Mean-Square
ISM	Industrial, Scientific and Medical

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.

The NIS-E shall fulfil the requirements of ISO 11608-1. In addition, the general requirements for testing specified in

— IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 5,

— IEC 60601-1-11:2015+AMD1:2020, and

— IEC 60601-1-2:2014+AMD1:2020, Clause 4

shall be considered as applicable to NIS-E.

NOTE Relevant statutory and regulatory requirements (e.g. legislation on restricting the use of hazardous substances, e.g. for flame retardants) can exist.

5.2 General design requirements

To avoid inadvertent disabling of the NIS-E containing replaceable batteries, it shall not be possible to remove the batteries unless two independent movements or an access cover openable only with tools are applied.

If the NIS-E contains software, the software shall be designed based on a life-cycle model in accordance with IEC 62304.

If the NIS-E contains an internal power source (e.g. batteries), it shall be designed to indicate to the operator by visual, tactile or audible means that it has sufficient power to operate according to its intended use. This only applies if battery depletion is considered to impact basic safety or essential performance.

The NIS-E shall maintain basic safety and essential performance after the test of IEC 60529 for, applicable IP protection level with the NIS-E placed in the least favourable position of normal use. The applicable IP levels is based on the result of the risk approach process. If an IP level different from IP22 is required based on risk assessment, the NIS-E shall fulfil that level.

An external device connected to NIS-E is not required to meet IP22.

NIS-E shall be classified as given in Table 1.

Table 1 — NIS-E type description

NIS-E type	Description
Type X	NIS-E internally powered and not electrically/conductively connected to an external device
Type Y	NIS-E that can be electrically/conductively connected to an external device. The connection can be for external supply, battery charging, data exchange, or other purposes.

Both Type X and Type Y shall fulfil the requirements given in Clauses 5 to 11. In addition, Type Y shall fulfil the requirements of 8.3.3.

5.3 Risk approach and usability engineering

Essential performance shall be determined using a risk approach process.

For NIS-E whose dose delivery function is electronically driven, the minimum essential performance shall be the dose delivery function in accordance with ISO 11608-1:2022, 10.2.1. The essential performance shall be always verified. Any failure shall be justified and documented in the risk management file.

Risk analysis, risk evaluation, risk control, evaluation of residual risk acceptability shall be performed in accordance with ISO 14971:2019, Clauses 4 to 8.

As such, risk management tools shall be used to accomplish the following:

— identify essential performance and basic safety of the system in relation to the intended use of the NIS;

— identify, establish and add requirements, specifications, methods or limits unique to each specific NIS-E (taking into account the medical condition for which the product is intended), when they are not provided in this document.

All added requirements, specifications, methods or limits shall be documented and justified.

A usability engineering program shall be developed and implemented in accordance with IEC 62366-1. It shall include addressing use risks and tests and/or assessments as part of the design verification and validation.

6 General requirements for testing

6.1 Type tests

A specified test may not be performed if analysis shows that the condition being tested has been adequately evaluated by other tests or methods.

NOTE The electrical safety tests required by this document are intended to be part of a NIS type test. They are not intended to be used for batch release.

6.2 Number of samples

For NIS-Es with mechanically driven dosing systems, the number of samples specified in ISO 11608-1 shall be used for testing for dose delivery, if supported by the risk approach process. For NIS-Es with electrically-driven dosing systems, 20 samples shall be inspected for dose delivery (i.e. dose accuracy).

Type tests shall be performed using at least one sample, considered enough to verify the basic safety after test. Pre-conditioning tests shall be performed using the sample size suitable to verify the essential performance (e.g. dose accuracy) as indicated in Tables 2 and 3.

Table 2 — Type test vs. pre-conditioning test table

Test case	Type test (T) or pre-conditioning test (P)	Type test sample size [a]	Recommendations for variable data (normal distribution or converted)				Recommendations for attribute data
			Probability content	Number of measurements (Y) [a b]	Two-sided target k	One-sided target k	Number of measurements (n) [a]
Ambient temperature, humidity, atmospheric pressure (see 6.3)	T	1	N/A	N/A	N/A	N/A	N/A
Identification and marking of NIS-E (see Clause 7)	T	1	N/A	N/A	N/A	N/A	N/A
Humidity preconditioning treatment (see 8.2)	T	1	N/A	N/A	N/A	N/A	N/A
Connection to an external DC power source (see 8.10.7)	T	1	N/A	N/A	N/A	N/A	N/A
Excessive current and voltage protection (see 8.3.3.2.5)	T	1	N/A	N/A	N/A	N/A	N/A
Patient leakage current and touch current (see 8.5)	T	1	N/A	N/A	N/A	N/A	N/A
Distance through solid insulation or use of thin sheet material (inspection, and measurement of thickness) (see 8.6.2)	T	1	N/A	N/A	N/A	N/A	N/A
Dielectric strength (see 8.6.3)	T	1	N/A	N/A	N/A	N/A	N/A
Mechanical strength and resistance to heat (Ball-pressure test) (see 8.7.1)	T	1	N/A	N/A	N/A	N/A	N/A
Creepage distances and air clearances (see 8.8)	T	1	N/A	N/A	N/A	N/A	N/A
Specific hazardous situations (see 8.9)	T	1	N/A	N/A	N/A	N/A	N/A
Pre-conditioning for the influence of fluid leakage (see 8.11)	P	N/A	0,95	20	2,760	2,396	60
Free Fall	See ISO 11608-1:2022, 10.3.1						
Shock (see 10.2)	P	N/A	0,95	20	2,760	2,396	60
Sinusoidal vibration (see 10.3.1)	See ISO 11608-1:2022, 10.3.6						
Random vibration (see 10.3.2)	P	N/A	0,95	20	2,760	2,396	60
Impact (only for OBDS) (see 10.4)	P	N/A	0,95	20	2,760	2,396	60
Push (see 10.5)	T	1	N/A	N/A	N/A	N/A	N/A

[a] Each test case can have more than one characteristic (e.g. dose accuracy or others) that needs to be tested. The sample size here is for each characteristic to be tested, although multiple characteristics can be tested on the same sample or set of samples, and potentially at the same time.

[b] Other sample sizes may be chosen. However, if smaller than 20, it shall be justified that the sample size is representative of the design.

Table 3 — Electromagnetic tests

Test case	Type test (T) or pre-conditioning test (P)	Type test sample size [a]	Recommendations for variable data (normal distribution or converted)				Recommendations for attribute data
			Probability content	Number of measurements (Y) [a b]	Two-sided target k	One-sided target k	Number of measurements (n) [a]
Mains terminal disturbance voltage (conducted emission) CISPR 11 (see 9.3) [c]	T	1	N/A	N/A	N/A	N/A	N/A
Electromagnetic radiation disturbance (radiated emissions) CISPR 11/CISPR 32 (see 9.3)	T	1	N/A	N/A	N/A	N/A	N/A
Harmonic current emissions IEC 61000-3-2 (see 9.3) [c]	T	1	N/A	N/A	N/A	N/A	N/A
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3 (see 9.3) [c]	T	1	N/A	N/A	N/A	N/A	N/A
Electrostatic discharge immunity IEC 61000-4-2 (see 9.4) [f]	P	N/A	0,95	20	2,760	2,396	60
Radiated RF electromagnetic field immunity IEC 61000-4-3 (see 9.4) [f g]	P	N/A	0,95	20	2,760	2,396	60
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method) (see 9.4) [f]	P	N/A	0,95	20	2,760	2,396	60
Electrical fast transient/burst immunity – AC mains IEC 61000-4-4 (see 9.4) [c]	T	1	N/A	N/A	N/A	N/A	N/A

[a] Each test case can have more than one characteristic (e.g. dose accuracy or others) that needs to be tested. The sample size here is for each characteristic to be tested, although multiple characteristics can be tested on the same sample or set of samples, and potentially at the same time.

[b] Other sample sizes can be chosen. However, if smaller than 20, it shall be justified that the sample size is representative of the design.

[c] Applicable only on NIS-E type Y.

[d] Applicable only on NIS-E type Y with SIP/SOP only.

[e] Applicable only on NIS-E type Y not internally powered.

[f] Only 1 sample required for NIS-E equipped with mechanical (non-electrically-driven) drug delivery feature (type test).

[g] More than one sample may be required to exercise all the functions of the NIS-E (e.g. intended use plus battery charging).

[h] Also see IEC 60601-1-2:2014+AMD1:2020, 8.10 and 8.11 for specific requirements related to proximity to inductive power/heating devices.

Table 3 *(continued)*

Test case	Type test (T) or pre-conditioning test (P)	Type test sample size [a]	Recommendations for variable data (normal distribution or converted)				Recommendations for attribute data
			Probability content	Number of measurements (Y) [a b]	Two-sided target *k*	One-sided target *k*	Number of measurements (*n*) [a]
Electrical fast transient/burst immunity – I/O SIP/SOP ports IEC 61000-4-4 (see 9.4) [d]	T	1	N/A	N/A	N/A	N/A	N/A
Surge immunity IEC 61000-4-5 (see 9.3) [c]	T	1	N/A	N/A	N/A	N/A	N/A
Immunity to conducted disturbances induced by RF fields (conducted RF disturbance immunity) – AC mains IEC 61000-4-6 (see 9.4) [c]	T	1	N/A	N/A	N/A	N/A	N/A
Immunity to conducted disturbances induced by RF fields [c] (conducted disturbance immunity) – SIP/SOP ports IEC 61000-4-6 (see 9.4) [d]	T	1	N/A	N/A	N/A	N/A	N/A
Power frequency magnetic field immunity IEC 61000-4-8 (see 9.4) [f]	P	N/A	0,95	20	2,760	2,396	60

[a] Each test case can have more than one characteristic (e.g. dose accuracy or others) that needs to be tested. The sample size here is for each characteristic to be tested, although multiple characteristics can be tested on the same sample or set of samples, and potentially at the same time.

[b] Other sample sizes can be chosen. However, if smaller than 20, it shall be justified that the sample size is representative of the design.

[c] Applicable only on NIS-E type Y.

[d] Applicable only on NIS-E type Y with SIP/SOP only.

[e] Applicable only on NIS-E type Y not internally powered.

[f] Only 1 sample required for NIS-E equipped with mechanical (non-electrically-driven) drug delivery feature (type test).

[g] More than one sample may be required to exercise all the functions of the NIS-E (e.g. intended use plus battery charging).

[h] Also see IEC 60601-1-2:2014+AMD1:2020, 8.10 and 8.11 for specific requirements related to proximity to inductive power/heating devices.

Table 3 *(continued)*

Test case	Type test (T) or pre-conditioning test (P)	Type test sample size [a]	Recommendations for variable data (normal distribution or converted)				Recommendations for attribute data
			Probability content	Number of measurements (Y) [a b]	Two-sided target *k*	One-sided target *k*	Number of measurements (*n*) [a]
Voltage dips, short interruptions and voltage variations immunity IEC 61000-4-11 (see 9.4) [c]	T	1	N/A	N/A	N/A	N/A	N/A
Voltage dips immunity IEC 61000-4-11 (see 9.4) [e]	T	1	N/A	N/A	N/A	N/A	N/A
Voltage short interruptions and voltage variations immunity IEC 61000-4-11 (see 9.4) [e]	T	1	N/A	N/A	N/A	N/A	N/A
Proximity magnetic fields IEC 61000-4-39 (see 9.4) [f h]	P	N/A	0,95	20	2,760	2,396	60

[a] Each test case can have more than one characteristic (e.g. dose accuracy or others) that needs to be tested. The sample size here is for each characteristic to be tested, although multiple characteristics can be tested on the same sample or set of samples, and potentially at the same time.

[b] Other sample sizes can be chosen. However, if smaller than 20, it shall be justified that the sample size is representative of the design.

[c] Applicable only on NIS-E type Y.

[d] Applicable only on NIS-E type Y with SIP/SOP only.

[e] Applicable only on NIS-E type Y not internally powered.

[f] Only 1 sample required for NIS-E equipped with mechanical (non-electrically-driven) drug delivery feature (type test).

[g] More than one sample may be required to exercise all the functions of the NIS-E (e.g. intended use plus battery charging).

[h] Also see IEC 60601-1-2:2014+AMD1:2020, 8.10 and 8.11 for specific requirements related to proximity to inductive power/heating devices.

6.3 Ambient temperature, humidity, atmospheric pressure

After the NIS-E to be tested has been set up for use as given in the instructions for use, tests shall be performed within the range of environmental operating/transport/storage conditions given in the instructions for use, unless otherwise specified in the test methods required to be performed or justified by the risk approach process.

If the operating/transport/storage conditions given in the instructions for use are restricted compared to IEC 60601-1-11:2015+AMD1:2020, 4.2 the restrictions shall be justified and documented in the risk management file.

7 Identification and marking of NIS-E

The requirements in ISO 11608-1:2022, Clause 11 shall apply.

Additionally, the requirements specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 7, IEC 60601-1-11:2015+AMD1:2020, Clause 7 and IEC 60601-1-2:2014+AMD1:2020, Clause 5 shall be considered.

8 Protection against electrical hazards

8.1 General

When a NIS-E is energized from an internal power source only, it shall be Type X NIS-E.

NIS-E that can be electrically/conductively connected to an external device shall be Type Y NIS-E.

Type Y shall be classified as given in Table 4.

Table 4 — Classification of NIS-E, Type Y

Environment	Classification (IEC 60601-1)
	Connected to mains
Home health care	Class II
Professional health care facility only	Class II
Both home health care and professional health care facility	Class II

8.2 Humidity preconditioning treatment

The NIS-E shall be subjected to the damp heat preconditioning specified in ISO 11608-1:2022, 10.3 for 168 hours in order to fulfil the requirements for electrical safety.

NOTE The damp heat pre-conditioning is considered an acceptable way to simulate the presence of moisture.

This preconditioning shall be related only to the application of basic safety tests in terms of leakage current and dielectric strength requirements.

Prior to performing leakage current and dielectric strength tests, NIS-E or its parts shall be subjected to a humidity preconditioning treatment. The test shall be performed at damp heat or if necessary, immediately after removing the NIS-E from damp heat.

NIS-E or its parts shall be set up either completely or where necessary partially (according to the instructions for use). Covers used during transport and storage shall be detached.

Parts that can be detached without the use of a tool shall be detached but are treated simultaneously with the major part.

Access covers that can be opened or detached without the use of a tool shall be opened and detached. After the treatment, the NIS-E shall be reassembled, if necessary.

8.3 Requirements and test methods

8.3.1 General

The specified limits (see 8.5.1 and 8.6.3) for protection against electric shock shall not be exceeded for accessible parts and applied parts in normal condition or single fault condition.

Normal condition shall include the following occurring simultaneously:

— the presence on any signal input/output part of any voltage or current from other electrical equipment connected according to the instructions for use or, if the instructions for use place no restrictions on such other electrical equipment, the presence of the maximum mains voltage for internally powered equipment, maximum mains voltage shall be 240 V; this requirement applies for Type Y only;

— short circuit of insulation that does not conform with the insulation requirements;

— short circuit of creepage distances or air clearances that do not conform with the requirements of creepage distances and air clearances requirements. (Short circuit of insulation/creepage distances/air clearances may be disregarded for Type X NIS-E.)

Single fault condition includes:

— short circuit of any one insulation that conforms with the requirements for one means of protection;

— short circuit of any one creepage distance or air clearance that conforms with the requirements for one means of protection;

— unintended movement of a component;

— short circuit and open circuit of any component other than a component with high integrity characteristics that is connected in parallel with insulation, with an air clearance or with a creepage distance unless shorting can be shown not to be a failure mode for the component.

For Type Y the single fault conditions shall also include the following:

— interruption of any one supply conductor;

— transposition of supply connections, for NIS-E intended for connection to a supply mains by means of a mains plug;

— accidental detachment of conductors and connectors where breaking free could lead to a hazardous situation;

— interruption of any one power-carrying conductor between NIS-E parts in separate enclosure, if this condition can cause permitted limits to be exceeded.

Determination of which parts are accessible parts shall be performed as described in 8.3.2.2. Leakage currents shall be measured in accordance with 8.5.

8.3.2 Applied parts

8.3.2.1 General

An applied part of both Type X and Type Y NIS-E that includes a patient connection that can deliver electrical energy or an electrophysiological signal to or from the patient shall be a type BF applied part or type CF applied part (suitable for direct cardiac application).

The risk approach process shall include an assessment of whether parts that can come into contact with the patient but fall outside of the definition of applied parts need to be subject to the requirements for applied parts. If the risk approach process determines that such parts shall be subject to the requirements for applied parts, then all the relevant requirements of this document shall apply.

The requirements related to Type BF shall be applicable as a minimum.

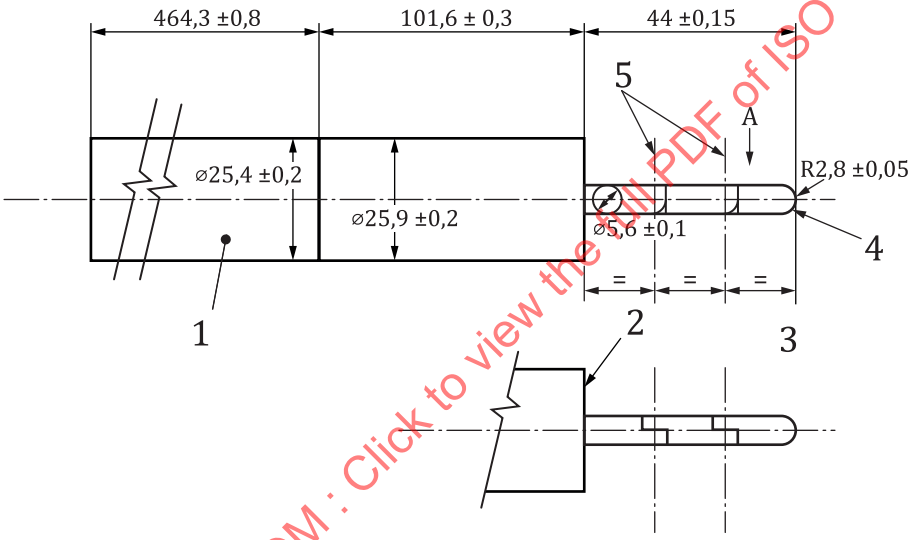
8.3.2.2 Accessible parts

Parts of Type X and Type Y NIS-E that are to be regarded as accessible parts shall be identified by inspection and where necessary, by test. In case of doubt, accessibility shall be determined by a test with the standard test finger shown in Figure 1, applied in a bent or straight position:

— for all positions of NIS-E when operated as in normal use;

— after opening of access covers and removal of parts, including, battery holders, fuses and fuse holders, without the use of a tool or according to the instructions for use.

Dimensions in millimetres



Key

A position from where the detail view (see key item 3) is viewed
1 extension of handle
2 collar
3 detail view of 'A'
4 hemispherical radius
5 axes of joints

The extension of the handle represents the arm of the child. The handle shall be provided with an extension 464,3 mm long, and the probe should be applied with or without this extension, whichever is the more onerous condition. Both joints shall permit movement in the same plane and the same direction through an angle of 90°.

NOTE This probe is intended to simulate access to hazardous parts by children of 36 months or less.

SOURCE IEC 60601-1-11:2015+AMD1:2020, Figure 1[1)].

Figure 1 — Small finger probe ⌀ 5,6 mm

The small test finger shall be applied without appreciable force in every possible position. Openings preventing the entry of the small test finger of Figure 1 shall be mechanically tested by means of a straight unjointed test finger of the same dimensions, which shall be applied with a force of 30 N. If this

1) IEC 60601-1-11: ed.2.1 Copyright © 2020 IEC Geneva, Switzerland. www.iec.ch.

finger enters, the test with the small test finger of above Figure 1 shall be repeated, the finger being pushed through the opening if necessary. Any area on the NIS-E that allows contact by the test finger shall be considered accessible and the requirements for accessible parts shall apply.

8.3.3 Requirements related to power sources

8.3.3.1 Connection to an external DC power source

If a Type Y NIS-E is intended to be connected to a power supply (e.g. during charging), then a connection with the wrong polarity shall not lead to a hazardous situation. The Type Y NIS-E, when connection is subsequently made with the correct polarity, shall maintain basic safety and essential performance.

Protective devices, operating during the wrong polarity condition, that can be reset by anyone without the use of a tool shall be acceptable provided the Type Y NIS-E returns to normal condition on reset.

Conformance shall be checked by inspection and, if necessary, by functional tests.

8.3.3.2 Batteries

8.3.3.2.1 Housing

Type X and Type Y NIS-E housings containing batteries from which gases can escape during charging or discharging shall be ventilated so that there shall be no unacceptable risk from the accumulation of gases and possible ignition shall be prevented.

Battery compartments of NIS-E shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in hazardous situations described in 8.9.

Conformance shall be checked by inspection of the design documentation and the risk management file.

8.3.3.2.2 Connection

For Type X and Type Y NIS-E, if a hazardous situation can develop by the incorrect connection or replacement of a battery, NIS-E shall be fitted with a means of preventing incorrect polarity of connection.

Conformance shall be checked by inspection.

8.3.3.2.3 Protection against overcharging

For Type Y NIS-E, where overcharging of any battery of NIS-E can result in an unacceptable risk, the design shall prevent overcharging.

Conformance shall be checked by inspection of the design documentation.

8.3.3.2.4 Lithium batteries

For Type X and Type Y NIS-E, primary lithium batteries shall conform with the requirements of IEC 60086-4. Secondary lithium batteries shall conform with the requirements of IEC 62133-2.

Conformance shall be checked by inspection of the battery design documentation or by performance of the tests identified in IEC 60086-4 for primary lithium batteries and IEC 62133-2 for secondary lithium batteries.

8.3.3.2.5 Excessive current and voltage protection

An internal electrical power source in a Type X and Type Y NIS-E shall be provided with an appropriately rated device for protection against fire caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components can give rise to a fire in case of

a short circuit. Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short circuit current) which can flow. Justification for omission of fuses or over current releases shall be documented.

The short circuit test between the positive pole and the negative pole of an internal electrical power source in the area between the internal electrical power source output contacts and the subsequent protection device may be omitted if two means of operator protection are provided. Alternatively, a short-circuit test shall not result in any of the hazardous situations reported in 8.9.

Conformance shall be checked by inspection for the presence of protective means, and if necessary, by inspection of the design documentation. Alternatively, conduct the short-circuit test and none of the hazardous situation shall occur.

8.3.4 Limitation of current for accessible parts and applied parts

The currents from or to patient connections shall not exceed the limits for patient leakage current specified in 8.5. Test configurations shall be specified in 8.5.

The leakage currents from, to or between accessible parts other than patient connections shall not exceed the limits for touch current specified in 8.5. Test configurations shall be specified in 8.5. This clause applies to both Type X and Type Y NIS-E, as applicable.

8.4 Separation of parts (Type X and Type Y)

8.4.1 Means of protection (MOP)

8.4.1.1 General

Means of Patient Protection (MOPP) is a higher criteria of protection than Means of Operator Protection (MOOP) since the patient is directly connected to the NIS-E. Therefore, MOPP shall be the minimum level of protection required for Type X and Type Y NIS-E. NIS-E shall have two MOPP to prevent applied parts and other accessible parts from exceeding the values specified in 8.5.

Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds that can replasticize at temperatures to be expected during operation (including sterilization), shall not be regarded as a means of protection.

Coatings and other insulation that are intended as a means of protection and that fulfil the requirements of IEC 60950-1 or IEC 62368-1 cannot automatically be used as a means for patient protection.

NOTE For means of patient protection, considerations can arise as a result of the risk approach process.

Components and wiring forming a means of protection shall conform with the relevant components and wiring requirements.

Any insulation, creepage distance, air clearances, component that does not conform with the requirements of MOPP shall not be considered as a means of protection. Failure of any or all such parts shall be regarded as normal condition.

Conformance shall be checked according to 8.4.1.2.

8.4.1.2 Means of patient protection (MOPP)

Solid insulation forming a means of patient protection shall conform with the dielectric strength test according to 8.6.3.

Creepage distances and air clearances forming a means of patient protection shall conform with the limits specified in Table 5.

Opto-couplers conforming with IEC 60747-5-5 shall be in accordance with 8.6.2 and 8.8. All of the following shall apply:

— air clearance at the outside of the opto-coupler;

— creepage distance at the outside of the opto-coupler; and

— dielectric strength across the opto-coupler.

MOPP can also be achieved by the following:

a) Barriers providing 2 MOOP with air clearance values according to IEC 60950-1 meet the requirements for 1 MOPP according to Table 3.

b) Barriers providing reinforced insulations (2 MOOP) with air clearance values according to IEC 62368-1:2018 for working voltages up to and including 354 V direct current/250 V RMS meets the requirements for 1 MOPP according to Table 5.

c) Barriers providing reinforced insulations (2 MOOP) with creepage distances according to IEC 62368-1:2018, Table 17 and Table 18 or IEC 60950-1:2005+AMD1:2009+AMD2:2013, Table 2N meet the requirements for 1 MOPP according to Table 5."

NOTE 1 The factor of 1,6 on insulation test voltage is only used for thermal cycling tests, as also in other safety standards (e.g. IEC 62368-1, IEC 60950-1). IEC 60747-5-5 applies different test methods. Because conformance with IEC 60747-5-5 is regarded as equivalent to the thermal cycling test, the 1,6 factor is not required. This is the same approach used in IEC 62368-1:2018, 5.4.4.4.

NOTE 2 Distance through insulation (0,4 mm) and thermal cycling testing are not required because conformance with the component standards addresses the risk of pin holes and thermal effects on the insulating compound.

Table 5 — Minimum creepage distances and air clearances providing means of patient protection

Working voltage V DC up to and including	Working voltage V RMS up to and including	Spacing providing one means of patient protection		Spacing providing two means of patient protection	
		Creepage distance mm	Air clearance mm	Creepage distance mm	Air clearance mm
17	12	1,7	0,8	3,4	1,6
43	30	2	1	4	2
85	60	2,3	1,2	4,6	2,4
177	125	3	1,6	6	3,2
354	250	4	2,5	8	5
If voltage falls between limits, the higher limit shall be used.					

8.4.2 Separation of patient connection

8.4.2.1 F-type applied parts

The patient connection(s) of any F-type applied part shall be separated from all other parts, including the patient connection(s) of other applied parts, by means equivalent to one means of patient protection for a working voltage equal to the maximum mains voltage and shall conform with the specified limit for patient leakage current with 110 % of the maximum mains voltage applied (240 V for internally powered NIS-E).

A single F-type applied part may include multiple functions, in which case separation between such functions shall not be required.

If there is no electrical separation between patient connection(s) of the same or another function, then these patient connection(s) are treated as one applied part.

It shall be defined whether multiple functions are considered as all within one applied part or as multiple applied parts.

The classification as type BF, type CF applies to the whole of one applied part.

Conformance shall be checked by inspection, by the leakage current tests of 8.5, by the dielectric strength test of 8.6.3 and by measurement of relevant creepage distances and air clearances.

8.4.3 Maximum mains voltage

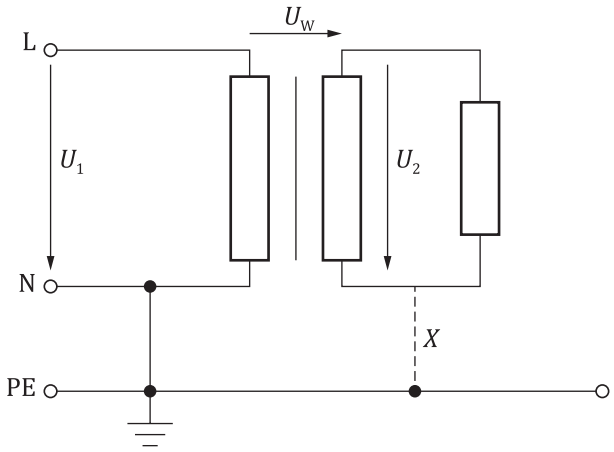
The maximum mains voltage for internally powered NIS-E shall be 240 V RMS (see also Annex B).

8.4.4 Working voltage

The working voltage for each means of protection shall be determined as follows:

— the input supply voltage to the NIS-E shall be the rated voltage or the voltage within the rated voltage range which results in the highest measured value;

— for working voltage measurement, all circuits shall be connected to earth with the exception of floating parts providing at least one means of protection to earth in which case the highest measured voltage on either side of the barrier is the working voltage (see Figure 2).



Key

X case1: $X \geq 1$ MOP

The floating circuit is isolated from earth by 1 MOP based on the floating circuit voltage U_2. The working voltage (U_w) of the mains barrier is the highest voltage of one side or the barrier, i.e. U_1 or U_2 whichever is greater in magnitude.

case2: $X < 1$ MOP

The floating circuit is not isolated by at least 1 MOP to earth based on the floating circuit voltage U_2. For the measurement of the working voltage (U_w) of the mains barrier both sides have to be earthed to obtain repeatable worst-case results.

L line terminal

N neutral terminal

PE patient enclosure

U_1 mains voltage

U_2 floating circuit voltage

U_w working voltage

reference earth (for leakage current and patient auxiliary current measurements and for testing of defibrillation-proof applied parts, not connected to protective earth of the supply mains)

Figure 2 — Working voltage measurement

— the working voltage for each means of protection forming double insulation shall be the voltage to which the double insulation as a whole is subjected;

— the working voltage between the patient connection(s) of an F-type applied part and the enclosure shall be taken as the highest voltage appearing across the insulation in normal use. See also 8.4.2.1;

— for DC voltages supplied to Type Y NIS-E (e.g. output voltage of an external AC/DC power adapter) with superimposed ripple, the working voltage shall be the average value if the peak-to-peak ripple does not exceed 10 % of the average value or the peak voltage if the peak-to-peak ripple exceeds 10 % of the average value.

8.5 Patient leakage current and touch current (Type X and Type Y NIS-E)

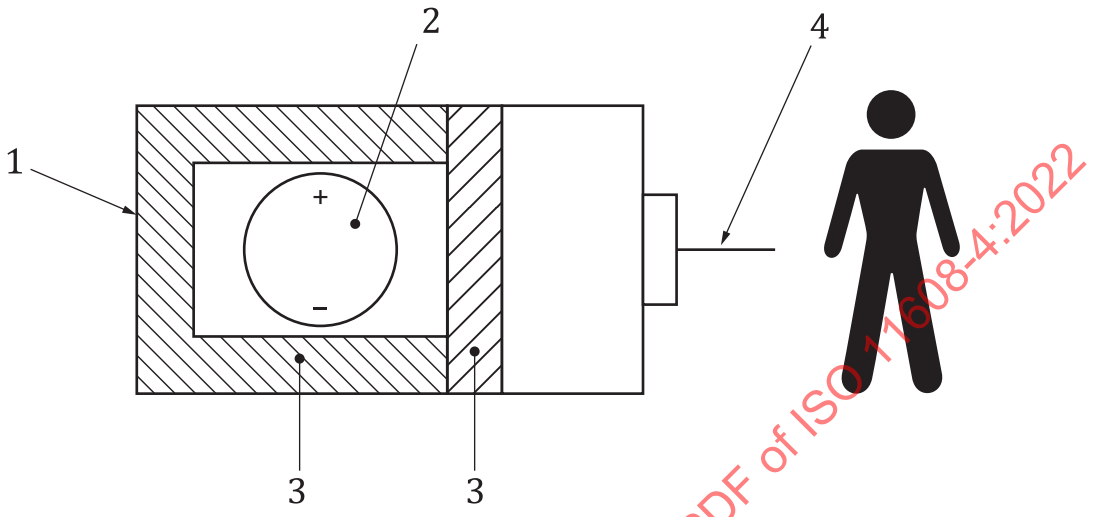
8.5.1 General

8.5.1.1 Electrical isolation providing protection against electrical shock

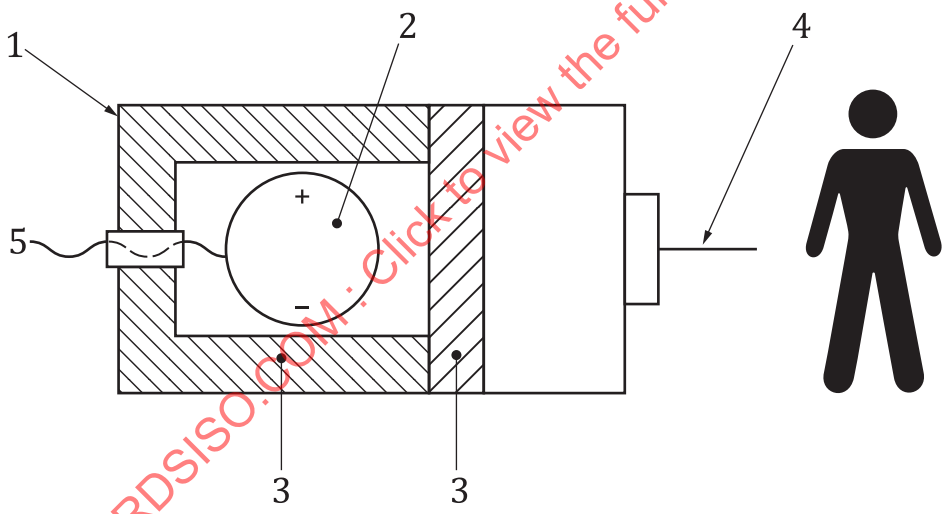
The electrical isolation providing protection against electric shock shall ensure that currents flowing through it are limited to the specified values.

Type X NIS-E shall be investigated for touch current but only between parts of the enclosure, not between the enclosure and earth. For internally powered Type Y NIS-E touch current should be investigated between parts of enclosure and between not earthed metallic accessible parts and earth considering its connection to an external electrical equipment (e.g. PC).

There shall be 2 means of patient protection (at 240 V) between 1 or 4 and both 2 and 5.



a) Electrical isolation (Type X NIS-E)



b) Electrical isolation (Type Y NIS-E)

Key

1 accessible part (enclosure)
2 internal power source (battery)
3 means of protection
4 applied part (needle)
5 external supply/wired connection

Figure 3 — Illustration of electrical isolation providing protection against electrical shock

The specified values of the touch current and the patient leakage current shall apply in any combination of the following conditions:

— at operating temperature and following the humidity preconditioning treatment, as described in 8.2;

— after any required sterilization procedure;

— in normal condition and in the single fault conditions below specified;

— with NIS-E energized in stand-by condition and fully operating;

— with the highest rated supply frequency;

— with a supply voltage equal to 110 % of the highest rated mains voltage (264 V RMS for rated mains voltage of 240 V RMS, 253 V RMS for rated mains voltage of 230 V RMS, 121 V RMS for rated mains voltage of 110 V RMS, etc).

8.5.1.2 Single fault conditions

The values given in Table 6 shall be applied in the single fault conditions specified in 8.10 except that leakage currents shall not be measured in the single fault condition of short circuiting of one constituent part of double insulation.

Single fault conditions shall not be applied at the same time as the special test conditions of maximum mains voltage on applied parts and non-protectively earthed parts of the enclosure.

8.5.1.3 Allowable values

The following allowable values specified in a), b) and c) shall be applied to currents flowing through the electrical circuit of Figure 4a or by a device measuring the frequency contents of the currents as defined in Figure 4b.

The current shall be measured as shown in the electrical circuit of Figures 4, 5, 6, 7and 8. The values shall be applied to direct current, alternating current, and composite waveforms. Unless stated otherwise they are direct current or RMS.

a) The values of the patient leakage currents shall be as given in Table 6. The values of alternating current shall be applied to currents having a frequency not less than 0,1 Hz.

Table 6 — Values of patient leakage currents

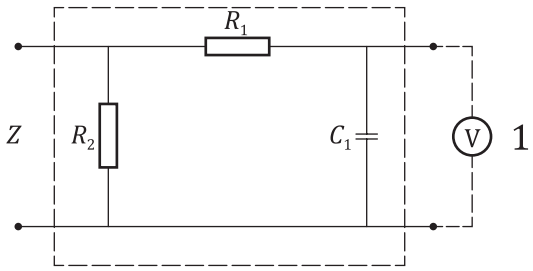
Current	Description	Measuring circuit	Current type	Type BF applied part		Type CF applied part	
				NC [a] µA	SFC [b] µA	NC [a] µA	SFC [b] µA
Patient leakage current	Patient leakage current For external powered devices: From patient connection to earth For internally powered devices: From patient connection to accessible parts and applied parts	Figure 6	Direct	10	50	10	50
			Alternating	100	500	10	50
	Caused by an external voltage on a signal input/output port	Figure 7	Direct	10	50	10	50
			Alternating	100	500	10	50
All AC values shall be applied to currents having a frequency not less than 0,1 Hz [a] Normal condition [b] Single fault condition							

b) NIS-E with a patient connection of a type F applied part and with metal accessible parts that are not protectively earthed shall be additionally tested according to Figure 8; the values are specified in Table 7.

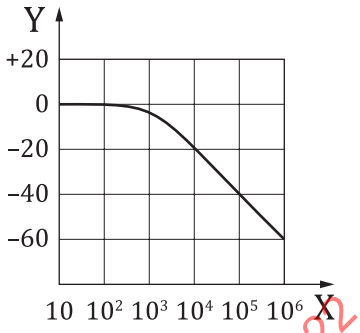
Table 7 — Values of patient leakage currents under special test

Current	Description	Type BF Applied Part µA	Type CF Applied Part µA
Patient leakage current	Caused by an external voltage on a patient of an F-type applied part	5 000	50
	Caused by an external voltage on a metal accessible part not protectively earthed	500	[a]
[a] This condition shall not be tested with type CF applied parts because it is covered by the test with maximum mains voltage on the applied part.			

c) The allowable values of the touch current are 100 µA in normal condition and 500 µA in single fault condition when measured in accordance with Figure 9. Additionally, regardless of waveform and frequency, leakage current shall not exceed 10 mA RMS in normal condition or in single fault condition when measured with a non-frequency-weighted measuring device, such as a measuring device similar to that shown in Figure 4 but without C_1 and R_1.



a) Measuring device



b) Frequency characteristics

Key

X frequency f (Hz)

Y relative magnitude[a] dB:20 $\frac{Z(f)}{Z(f=10)}$

1 voltage measuring instrument. Resistance ≥1 MΩ and capacitance ≤150 pF

R_1 (10 ± 5 %) kΩ

R_2 (1 ± 1 %) kΩ

C_1 (0,005 ± 5 %) µF

Z impedance

[a] Z(f) is the transfer impedance of the network, i.e. V_{out}/I_{in}, for a current of frequency f. (where V_{in} pertains to input voltage and I_{in} pertains to input current)

SOURCE IEC 60601-1:2005+AMD1:2012+AMD2:2020, Figure 12[2)].

Figure 4 — Example of a measuring device and its frequency characteristics

8.5.2 Measurement of patient leakage current

Measurement of patient leakage current shall be performed as follows:

a) NIS-E with an applied part shall be tested in accordance with Figures 6 to 8 and shall be tested at thermal stability. An enclosure, other than an applied part, made of insulating material shall be placed in any position of normal use upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the enclosure. For a Type Y NIS-E supplied by an external power supply, it shall be considered to be supplied by the measuring supply circuit of Figure 5. Type X NIS-E and internal powered Type Y NIS-E shall be tested without any connection to a measuring supply circuit.

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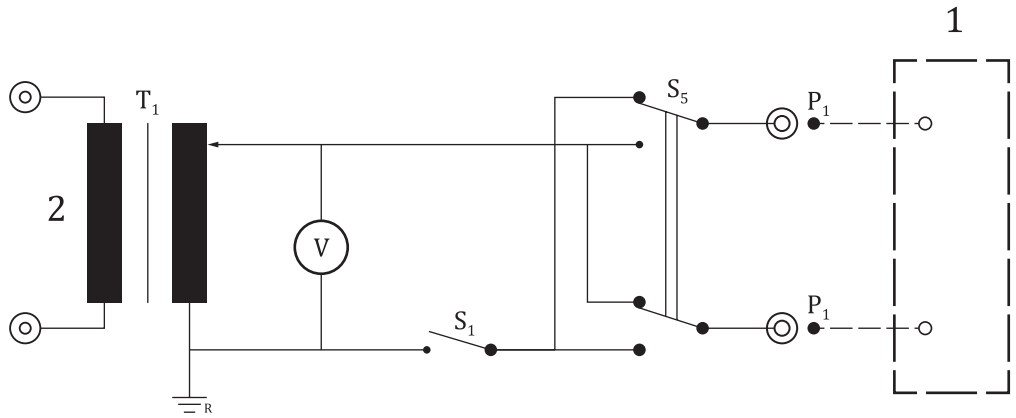


Key

1 external power source of Type Y NIS-E

2 mains

S_1 switch simulating interruption of power supply conductor

S_5 commutator switches to reverse the polarity of the mains voltage

T_1 single isolation transformers with sufficient power rating and variable output voltage

P_1 sockets, plugs or terminals for the supply connection of external power source of Type Y NIS-E

V voltmeter

R reference earth (for leakage current and patient auxiliary current measurements and for testing of defibrillation-proof applied parts, not connected to protective earth of the supply mains)

SOURCE IEC 60601-1:2005+AMD1:2012+AMD2:2020, Figure F.1[2)].

Figure 5 — Measuring supply circuit with one side of the supply mains at approximately earth potential to be used for Type Y NIS-E connected to an external power source

b) NIS-E with an F-type applied part shall additionally be tested according to Figure 6. Signal input/output parts shall be connected to earth, if not already permanently earthed in the NIS-E. For a Type Y NIS-E with F-type applied part and supplied by an external power supply, it shall be considered to be supplied by the supply measuring circuit of Figure 5;

— for this measurement, non-protectively earthed metal accessible parts including patient connections of other applied parts (if present) shall be connected to earth.

c) NIS-E with an applied part and a signal input/output part shall additionally be tested according to Figure 7. For a Type Y NIS-E with an applied part and supplied by an external power supply, it shall be considered to be supplied by the measuring supply circuit of Figure 5;

— the applied voltage shall be equal to 110 % of the maximum mains voltage. The specific pin configuration used when applying the external voltage shall be worst case based on testing or circuit analysis.

d) NIS-E with a patient connection of a type BF applied part and with metal accessible parts that are not protectively earthed shall additionally be tested according to Figure 8. Type X and internal powered Type Y NIS-E shall be tested without any connection to a measuring supply circuit. For a Type Y NIS-E with type BF applied part and supplied by an external power supply, it shall be considered to be supplied by the supply measuring circuit of Figure 5;

— the applied voltage shall be equal to 110 % of the maximum mains voltage. This test may not be conducted if it can be demonstrated that there is adequate separation of the parts involved, or if the risk is acceptably low.

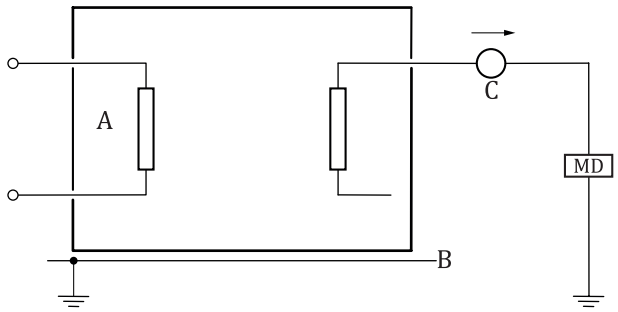
e) An applied part consisting of a surface made of insulating material shall be tested using metal foil of minimum 20 cm x 10 cm.

f) Where the surface of the applied part intended to contact the patient is considerably larger than that of a foil of 20 cm x 10 cm, the size of the foil shall be increased to correspond to the area of contact. Such metal foil shall be considered as the only patient connection for the applied part concerned.

g) The patient leakage current shall be measured:

— for type BF applied parts, from and to all patient connections of a single function either connected directly together or loaded as in normal use;

— for type CF applied parts, from and to every patient connection in turn.



Applied part type	Normal condition µA	Single fault condition µA
CF	10	50
BF	100	500

Key

A mains part

B EUT mounting surface

C patient connection(s)

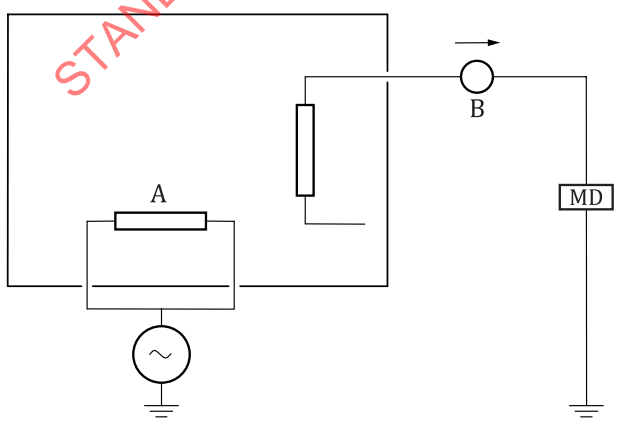
MD measuring device

reference earth (for leakage current and patient auxiliary current measurements and for testing of defibrillation-proof applied parts, not connected to protective earth of the supply mains)

Type Y NIS-E supplied by an external power supply, shall be considered to be supplied by the supply measuring circuit of Figure 5.

SOURCE IEC 60601-1:2005+AMD1:2012+AMD2:2020, Figure K.1[2)].

Figure 6 — Measuring circuit for patient leakage current from the patient connection to earth (Type Y)



Applied part type	Normal condition µA	Single fault condition µA
CF	10	50
BF	100	500

Key

A signal input/output part

B patient connection(s)

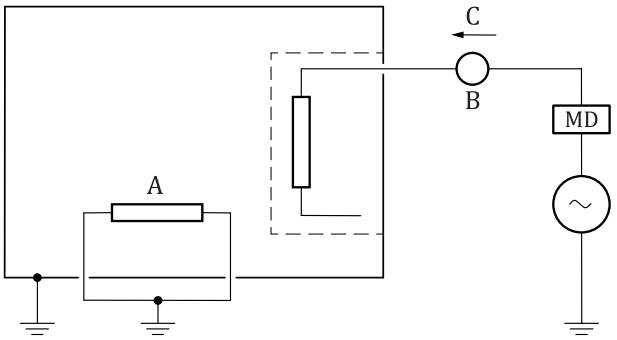
MD measuring device

supply mains voltage source

reference earth (for leakage current and patient auxiliary current measurements and for testing of defibrillation-proof applied parts, not connected to protective earth of the supply mains)

SOURCE IEC 60601 1:2005+AMD1:2012+AMD2:2020, Figure K.3[2)].

Figure 7 — NIS-E (Type Y) with an applied part and a signal input/output part



Applied part type	Single fault condition µA
CF	50
BF	500
B	--

Key

A not protectively earthed part

B patient connection(s)

MD measuring device

supply mains voltage source

reference earth (for leakage current and patient auxiliary current measurements and for testing of defibrillation-proof applied parts, not connected to protective earth of the supply mains)

SOURCE IEC 60601-1:2005+AMD1:2012+AMD2:2020, Figure K.2[2)].

Figure 8 — NIS-E (Type Y) with a patient connection of type BF applied part

8.5.3 Measurement of touch current

NIS-E shall be tested according to Figure 9, using an appropriate measuring supply circuit.

Measure with a measuring device between earth and each part of the enclosure(s) that is not protectively earthed. Measure with a measuring device between parts of the enclosure(s) that are not protectively earthed.

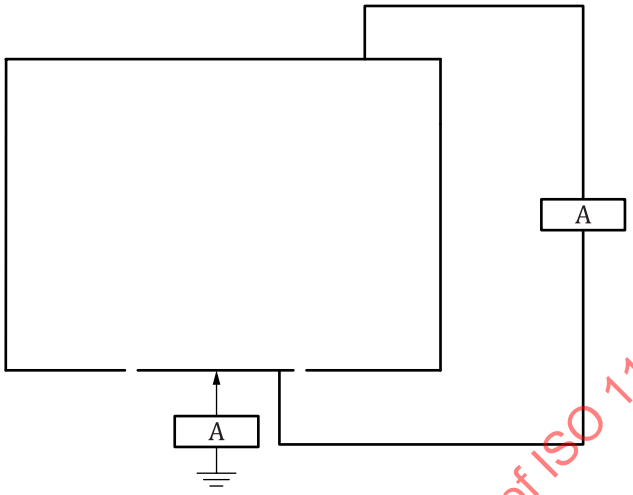
Type X shall be investigated for touch current but only between parts of the enclosure, not between the enclosure and earth.

If NIS-E has an enclosure or a part of the enclosure made of insulating material, metal foil of maximum 20 cm x 10 cm shall be applied in intimate contact with the enclosure or relevant part of the enclosure.

If the NIS-E is larger than the foil, the metal foil shall be shifted, if possible, to determine the highest value of the touch current. The metal foil should not touch any metal parts of the enclosure that are

possibly protectively earthed; however, metal parts of the enclosure that are not protectively earthed can be covered partly or totally by the metal foil.

In normal condition, the touch current from or between parts of the NIS-E within the patient environment shall not exceed 100 µA.



Key

A measuring device

reference earth (for leakage current and patient auxiliary current measurements and for testing of defibrillation-proof applied parts, not connected to protective earth of the supply mains)

For a Type Y NIS-E supplied by an external power supply, it shall be considered to be supplied by the supply measuring circuit of Figure 5.

Figure 9 — Measuring circuit for touch current

8.6 Insulation (Type X and Type Y)

8.6.1 General

Only insulation that can be relied upon as a means of protection, including reinforced insulation, shall be subject to testing.

Insulation forming means of operator protection shall be exempt from the tests of 8.6 if it conforms with the requirements and tests of IEC 60950-1:2005+AMD1:2009+AMD2:2013 or IEC 62368-1 for insulation co-ordination.

8.6.2 Distance through solid insulation or use of thin sheet material

NOTE This document does not specify requirements for minimum thickness for basic insulation and for insulation operating at working voltage below 71 V.

Solid insulation which forms supplementary insulation or reinforced insulation for a peak working voltage greater than 71 V shall either

a) have a distance through insulation of at least 0,4 mm, or

b) not form part of an enclosure and not be subject to handling or abrasion during normal use, and comprise

— at least two layers of material, each of which shall pass the appropriate dielectric strength test; or

— three layers of material, for which all combinations of two layers together shall pass the appropriate dielectric strength test.

The appropriate dielectric strength test for the one or two layers shall be the test for one means of protection in the case of supplementary insulation or the test for two means of protection in the case of reinforced insulation, respectively.

Conformance shall be checked by inspection, by measurement of thickness and by the dielectric strength test specified in 8.6.3.

The finished component shall pass routine tests for dielectric strength using the appropriate test voltages specified in 8.6.3.

8.6.3 Dielectric strength

The dielectric strength of solid electrical insulation of NIS-E shall be capable of withstanding the test voltages as specified in Table 8. Only insulation with a safety function shall be subjected to testing. For Type X it shall be treated as a secondary circuit providing 2 MOPP. For Type Y it shall be treated as protected from mains with 1 MOPP for Class I and with 2 MOPP for Class II.

Table 8 — Test voltages for solid insulation forming a means of protection

Peak working voltage (U) V peak	Peak working voltage (U) V DC	Means of patient protection			
		Protection from mains part		Protection from secondary circuits	
		One MOPP AC RMS	Two MOPP AC RMS	One MOPP AC RMS	Two MOPP AC RMS
$U \leq 42{,}4$	$U \leq 60$	1 500	3 000	500	1 000
$42{,}4 < U \leq 71$	$60 < U \leq 71$	1 500	3 000	750	1 500
$71 < U \leq 184$	$71 < U \leq 184$	1 500	3 000	1 000	2 000
$184 < U \leq 212$	$184 < U \leq 212$	1 500	3 000	1 000	2 000
$212 < U \leq 354$	$212 < U \leq 354$	1 500	4 000	1 500	3 000

Conformance shall be checked by applying the test voltage specified in Table 8 for 1 min. Alternatively, a DC test voltage equal to the peak value of the AC test voltage may be used with conformance checked by applying the test voltage specified in Table 8 for 1 min. Initially, not more than half the test voltage shall be applied, and then it shall gradually be raised over a period of 10 s to the full value, which shall be maintained for 1 min, after which it shall gradually be lowered over a period of 10 s to less than half the full value.

During the test, breakdown constitutes a failure. Insulation breakdown shall be considered to have occurred when the current which flows as a result of the application of the test voltage rapidly increases in an uncontrolled manner. Corona discharge or a single momentary flashover shall not be regarded as insulation breakdown.

Where an enclosure or part of enclosure consists of non-conductive surfaces, metal foil shall be applied. Care shall be taken that the metal foil shall be positioned in such a manner that flashover does not occur at the edges of insulation linings. If applicable, the metal foil shall be moved so as to test all parts of the surface.

8.7 Insulation other than wire insulation

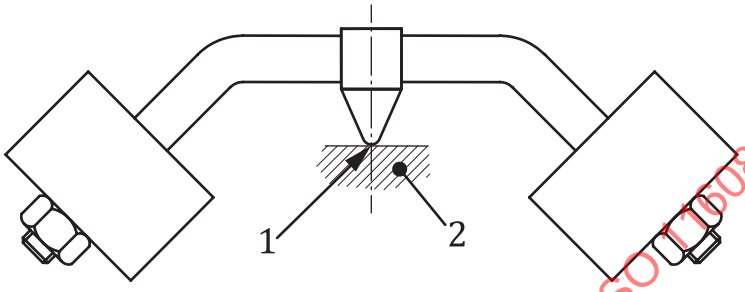
8.7.1 Mechanical strength and resistance to heat

For Type X and Type Y NIS-E, the resistance to heat shall be retained by all types of insulation, including insulating partition walls, during the expected service life of the NIS-E.

Resistance to heat shall be established by the following tests, which may not be performed if satisfactory evidence of conformance shall be provided.

For parts of the enclosure and other external insulating parts that provide protection, the deterioration of which could result in an unacceptable risk, evaluate the mechanical strength and resistance to heat using the ball-pressure test.

Enclosures and other external parts of insulating material, except the insulation of flexible cords and parts of ceramic material, shall be subjected to a ball-pressure test using the test apparatus shown in Figure 10.



Key

1 r = 2,5 mm spherical

2 test sample

SOURCE IEC 60601-1:2005+AMD1:2012+AMD2:2020, Figure 21[2].

Figure 10 — Ball-pressure test apparatus

The surface of the part to be tested shall be placed in the horizontal position and a steel ball of 5 mm diameter shall be pressed against the surface with a force of 20 N. The test shall be performed in a heating cabinet at a temperature of (75 ± 2) °C.

For parts of insulating material that support uninsulated parts of the mains part, the deterioration of which could influence the safety of the NIS-E, by the ball-pressure test a test shall be performed as specified above, but at a temperature of (125 ± 2) °C. The test shall not be performed on parts of ceramic material, insulating parts of commutators, brush-caps and the like, and on coil formers not used as reinforced insulation.

The ball shall be withdrawn after 1 h and the diameter of the impression made by the ball shall be measured. An impression greater than 2 mm in diameter constitutes a failure.

The need for ball pressure test for the NIS-E shall be determined by the risk approach process (see 5.3).

8.8 Creepage distances and air clearances (Type X and Type Y NIS-E)

8.8.1 General

Protection levels shall be in accordance with Table 5.

For creepage distances across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics, the specified minimum value of air clearance shall be applied as the minimum creepage distance.

Unless otherwise declared in the information supplied with the NIS-E, NIS-E shall be rated to operate at an altitude up to 3 000 m. Where NIS-E is intended to be operated in a pressurized environment, e.g. aircraft, the operating altitude corresponding to the air pressure concerned shall be used in determining multiplication factor from Table 9. The air clearance shall then be multiplied by this factor. Creepage distances shall not be subject to the multiplication factors but shall always be at least as large as the resulting value for air clearance.

Table 9 — Multiplication factors for air clearances for altitudes up to 5 000 m

Rated operating altitude (*a*) m	Normal barometric pressure kPa	Multiplication factor for MOPP
$a \leq 2\,000$	80,0	1,00
$2\,000 < a \leq 3\,000$	70,0	1,00
$3\,000 < a \leq 4\,000$	62,0	1,14
$4\,000 < a \leq 5\,000$	54,0	1,29

8.9 Specific hazardous situations

8.9.1 General

When applying the single fault conditions, one at a time, none of the hazardous situations listed in this document shall occur in NIS-E.

Where a single fault condition causes another single fault condition, the two failures shall be considered as one single fault condition.

During any test under single fault condition, only one fault at a time shall be applied.

8.9.2 Emissions, deformation of enclosure or exceeding maximum temperature

The following hazardous situations shall not occur in normal and single-fault condition.

— Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities.

— Deformation of enclosures to such an extent that conformance with 8.7.1 is impaired.

— Temperatures of applied parts exceeding the allowed values identified in Table 10 when the NIS-E is operated in worst-case normal use including the maximum ambient operating temperature specified in the technical description.

— Temperatures of NIS-E parts that are not applied parts but are likely to be touched, exceeding the allowable values in Table 11.

— The values identified in Table 10 and 11 shall apply when the NIS-E is operated in worst-case normal use including the maximum ambient operating temperature specified in the instruction for use.

— Temperatures exceeding 1,5 times minus 12,5 °C the allowable values for “other components and materials” identified in Table 12. Limits for windings shall be as specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Tables 26, 27 and 31. In all other cases, the values of Table 12 shall apply.

The single fault conditions with regard to the emission of flames, molten metal or ignitable substances, shall not be applied to parts and components where

— the construction or design of the supply circuit limits the power dissipation in single fault condition to less than 15 W or the energy dissipation to less than 900 J.

Conformance shall be checked by drawing 15 W from the supply circuit for 1 min. If, after 1 min. the supply circuit cannot supply 15 W, the circuit shall be considered to limit power dissipation to less than 15 W.

The related design documentation shall also be reviewed where direct measurement is not possible.

Secondary circuits shall meet the following conditions:

— mounted on material with a flammability classification of FV1 in accordance with IEC 60695-11-10:2013 or better;

— they are energized at a voltage of 60 V DC or 42,2 V peak or less in normal and single fault condition;

— they are limited to 100 VA or are limited to 6 000 J in single fault condition;

— they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide.

Table 10 — Maximum temperatures for skin contact with NIS-E applied parts

Applied parts of NIS-E		Maximum temperature [a] [b] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
Applied part having contact with the patient for a time, t	$t < 1$ min	51	56	60
	1 min ≤ t < 10 min	48	48	48
	10 min ≤ t	43	43	43

[a] These temperature limit values shall be applicable for the healthy skin of adults. They shall not be applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They shall not be applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented applying the risk approach process.

[b] Where it is necessary for applied parts to exceed the temperature limits of Table 9 in order to provide clinical benefit, the risk approach process proves that the resulting benefit exceeds any associated increase in risk.

Table 11 — Maximum temperatures for NIS-E parts that are likely to be touched

NIS-E and its parts		Maximum temperature [a] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of NIS-E that are likely to be touched for a time, t	$t < 1$ s	74	80	86
	1 s ≤ t < 10 s	56	66	71
	10 s ≤ t < 1 min	51	56	60
	1 min ≤ t	48	48	48

[a] These temperature limit values shall be applicable for touching the healthy skin of adults. They shall not be applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented applying the risk approach process.

Table 12 — Maximum temperatures of parts

Parts	Maximum temperature °C
Insulation, including winding insulation [a]	

[a] The classification of insulating materials shall be in accordance with IEC 60085. Any incompatibility of the materials of an insulating system that could reduce the maximum temperature limit of the system below the limits of the individual materials shall be considered.

[b] T marking refers to the marked maximum operating temperature.

[c] For each material and component, account shall be taken of the temperature ratings for each material or component to determine the appropriate maximum temperature. Each component shall be used in accordance with its temperature rating. Where doubt exists, the ball pressure test of 8.7.1 should be performed.

Table 12 *(continued)*

Parts	Maximum temperature °C
- of Class A Material	105
- of Class E Material	120
- of Class B Material	130
- of Class F Material	155
- of Class H Material	180
- of Class T Material	T [b]
Other components and materials	C
Parts in contact with flammable liquid with flash-point of T °C	T-25
Wood	90

[a] The classification of insulating materials shall be in accordance with IEC 60085. Any incompatibility of the materials of an insulating system that could reduce the maximum temperature limit of the system below the limits of the individual materials shall be considered.

[b] T marking refers to the marked maximum operating temperature.

[c] For each material and component, account shall be taken of the temperature ratings for each material or component to determine the appropriate maximum temperature. Each component shall be used in accordance with its temperature rating. Where doubt exists, the ball pressure test of 8.7.1 should be performed.

Conformance shall be checked by evaluation of the design documentation.

After the tests of this clause, thermal cut-outs and over-current releases shall be inspected to determine that their setting has not changed (by heating, vibration, or other causes) sufficiently to affect their safety function.

8.9.3 Exceeding leakage current or voltage limits

The following hazardous situations shall not occur:

— exceeding the limits for leakage current in single fault condition;

— exceeding the following voltage limits for parts becoming accessible parts as a consequence of fault conditions, as well as for applied parts.

For such parts, the voltage to other accessible parts (or to earth, if applicable) shall not exceed 42,4 V peak alternating current or 60 V direct current. The DC limit of 60 V applies to direct current with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The energy shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential up to 2 V.

8.9.4 Specific mechanical hazards

When tested in accordance with Clause 10, the essential performance and basic safety shall not be impacted.

8.10 Single fault conditions (Type X and Type Y)

8.10.1 General

During the application of the single fault conditions the normal conditions shall also be applied in the least favourable combination.

8.10.2 Failure of thermostats and temperature limiting devices

Thermostats shall be short circuited or interrupted, whichever is less favourable.

8.10.3 Leakage of liquid from batteries

NIS-E shall be so constructed that liquid that might escape from batteries in a single fault condition does not result in an unacceptable risk.

Since only small amounts of liquid will escape when batteries leak, rechargeable batteries should conform with IEC 62133-1 or IEC 62133-2 as appropriate. Primary lithium batteries mainly used in Type X NIS-E should conform with IEC 60086-4.

Conformance shall be checked by inspection of design documentation and the risk management file.

8.10.4 Locking of moving parts

NIS-E shall be so designed that it remains single fault safe when moving parts become jammed. Moving parts shall be locked if NIS-E

— has moving accessible parts or applied parts liable to be jammed, or

— is liable to be operated while unattended (this includes NIS-E that is automatically or remotely controlled), or

— has one or more motors with a locked rotor torque smaller than the full load torque.

If NIS-E has more than one moving part as described above, only one part at a time shall be locked. If a single fault condition can lock multiple motors, then all motors shall be locked simultaneously.

The test criteria specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 13.2.10 shall apply.

NOTE Statutory or regulatory requirements can exist.

8.10.5 Additional test criteria for motor-operated NIS-E

For every test in the single fault condition, motor-operated NIS-E shall be operated starting from cold condition, at rated voltage or at the upper limit of the rated voltage range for a period of 30 s for hand-held NIS-E.

Temperatures shall be measured when the NIS-E is operated in worst-case normal use including the maximum ambient operating temperature specified in the technical description. Temperature measured according to 8.9.2 shall not exceed the limits specified in 8.9.2.

8.10.6 NIS-E intended for used in conjunction with oxygen rich environments

If the NIS-E is intended to be used in oxygen rich environment, the appliable requirements specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 6.5, 11.2.2, 11.2.3 and Annex G shall be fulfilled. Otherwise, the instructions for use shall clearly state that the NIS-E is not intended to be used in an oxygen rich environment.

8.10.7 Power supply (Type Y)

If NIS-E is intended to receive its power from an external and separate power supply or by other equipment in a medical electrical system, the instructions for use shall specify the external and separate power supply or the other equipment sufficiently to ensure conformance with the requirements of this document and to related requirements of IEC 60601-1. If Type Y NIS-E is intended for connection to a separate power supply, either the power supply shall be specified as part of the Type Y NIS-E or the combination shall be specified as a medical electrical system. This shall be stated in the instructions for use.

Conformance shall be checked by inspection and by testing. If a particular separate power supply is specified, then the relevant tests shall be performed with the Type Y NIS-E connected to it. If a generic

separate power supply is specified, then the specification in the accompanying documents shall be inspected.

If Type Y NIS-E is intended to receive its power from other equipment or to be connected to other equipment for data exchange in a medical electrical system, the instructions for use shall sufficiently specify such other equipment to ensure conformity with the requirements of this document (e.g. part number, rated voltage, maximum or minimum power, protection class, intermittent or continuous service) and with related requirements of IEC 60601-1.

Basic safety after assembly shall be maintained, for example, by one or more of the following measures:

— measures that are built-in within the Type Y NIS-E, for example, separation of relevant circuits;

— separation devices provided as accessories to the Type Y NIS-E (see also IEC 60601-1:2005+AMD1:2012+AMD2:2020, 16.5);

— separation devices provided as accessories to the medical electrical system;

— separating transformer.

NOTE See also IEC 60601-1:2005+AMD1:2012+AMD2:2020, Annex I.

Relevant standards for some non-medical electrical equipment can have limits for touch currents that are higher than required this clause. Therefore, a specific risk assessment to evaluate the need to reduce these touch currents shall be performed.

Leakage current reduction measures can include:

— additional protectively earthed parts;

— a separating transformer;

— an additional non-conductive enclosure.

Interconnecting cables and their connector housings are parts of the enclosure and therefore the leakage current limits as specified in this clause shall be considered for these elements.

In normal condition, the touch currents from or between parts of the medical electrical system shall not exceed 100 µA.

In the event of the interruption of any non-permanently installed protective earth conductor, the touch currents from or between parts of a medical electrical system shall not exceed 500 µA.

For the purposes of this subclause, the leakage current from accessible outer surfaces of equipment shall also be considered to be touch current.

The patient leakage current and total patient leakage current of a NIS-E in normal condition shall not exceed the values specified for the NIS-E, as given in Table 6 and Table 7. The total patient leakage current may be measured at installation.

Measurements of leakage currents on medical electrical system shall be carried out according to IEC 60601-1:2005+AMD1:2012+AMD2:2020, 16.6.

Touch current measured on accessible metal parts of a connector of an external and separate power supply to be used for its connection to Type Y NIS-E shall not exceed the limits previously mentioned in this clause in normal and single fault conditions."

8.11 Pre-conditioning for the influence of fluid leakage

The purpose of this test is to evaluate the influence of liquid that leaks from for example, but not limited to, a broken container into the NIS-E.

Perform the following test:

— remove any removable container holder and pour the contents of one container of the medicinal product into the NIS-E at the most likely point of entry;

— using appropriate safety equipment, shake the NIS-E in all directions by hand for 30 s;

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

— attach a new container, run a self-test and monitor any messages (if applicable);

— store the NIS-E in a horizontal orientation according to the instructions for use, for 24 h;

— expel all medicinal product from the container by injections and monitor the self-test and any error messages (if applicable);

— replace the used container with a new one;

— store the NIS-E in a horizontal orientation according to the instructions for use, for 96 h;

— expel all medicinal product from the container by injections and monitor the self-test and any error messages (if applicable).

An error that is obvious to the lay user is allowed if it does not influence any safety aspects in accordance with the result of the risk approach process specified in 5.3.

Means of protection (dielectric strength and leakage current as defined in 8.6.3 and leakage current as defined in 8.5) shall not be affected.

NOTE This test differs from IP22 in that the fluid source comes from within the NIS-E.

9 Electromagnetic compatibility (EMC)

9.1 General requirements

9.1.1 Risk approach process for NIS-E

NIS-E shall be tested in representative configurations, consistent with intended use, that are most likely to result in unacceptable risk as determined by the risk approach process (see 5.3).

Risks resulting from reasonably foreseeable electromagnetic disturbances shall be taken into account in the risk approach process.

Conformance shall be checked by verifying the presence of the corresponding entries in the risk management file.

NOTE For general guidance and details see the annexes in IEC 60601-1-2:2014+AMD1:2020.

9.1.2 Non-medical electrical equipment used with NIS-E

Non-medical electrical equipment (e.g. battery charging system) used with NIS-E shall conform with other EMC standards applicable to that equipment.

Non-medical electrical equipment used with NIS-E for which the intended environment could result in the loss of basic safety, essential performance, or other hazards of the NIS-E due to the non-medical electrical equipment, non-medical electrical equipment shall fulfil requirements of this document.

Conformance shall be checked by inspection of the risk management file and conformance with the respective EMC standards, or by the tests of this document.

9.1.3 General test conditions

9.1.3.1 Configurations

The applicable clauses of this document shall be identified according to the configuration of the NIS-E.

These configurations may include the following:

— rechargeable NIS-E with internal battery charging system directly connected to the mains;

— rechargeable NIS-E with external battery charging system;

— non-rechargeable NIS-E.

The intended use of the NIS-E shall be considered in determining the test configuration.

In particular:

— attachment of cables to all ports as necessary to achieve the intended use (including SIP/SOPs and, if applicable, the potential equalization conductor);

— use of cables and connectors that meet the specifications of the NIS-E;

— battery charging system connected for rechargeable NIS-E, when applicable.

During emission test, radio frequency, and power magnetic field immunity tests, the NIS-E shall be exercised simulating the intended use in the worst-case scenario identified as required by 9.1.1.

Special hardware or software might be needed to perform the emission and immunity tests. If so, this should be documented in the test plan and shall be documented in the test report.

During exposure to electrostatic discharge test the NIS-E may remain in power ON or OFF condition, whichever is deemed worst-case. Conformance shall be checked by inspection of the test report and the risk management file.

9.1.3.2 Test applicability for NIS-E

If a test is applicable, it shall be performed using the power input voltages and frequencies specified in Table 13. The test report shall list the actual voltages and frequencies used during testing.

Conformance shall be checked by inspection of the test report.

Table 13 — Power input voltages and frequencies during tests

Test	Power input voltage	Power frequency	Applicability for NIS-E
Mains terminal disturbance voltage (conducted emission) CISPR 11 [d]	Minimum and maximum rated voltage [a]	Any one frequency [b]	Only for Type Y NIS-E
Electromagnetic radiation disturbance (radiated emissions) CISPR 11 [d]	Any one voltage [a]	Any one frequency [b]	For all configurations
Harmonic current emissions IEC 61000-3-2	Only for NIS-E connected to battery charging system rated at 220 V to 240 V or 380 V to 415 V: if rated at a single voltage, that voltage; if single-phase and a range is specified, 230 V; if three-phase and a range is specified, 400 V.	50 Hz or 60 Hz	Only for Type Y NIS-E with power consumption ≥75 W
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3	Only for NIS-E connected to battery charging system rated at 220 V to 240 V or 380 V to 415 V: if rated at a single voltage, that voltage; if single-phase and a range is specified, 230 V; if three-phase and a range is specified, 400 V.	50 Hz	Only for Type Y NIS-E

NOTE “Mains terminal disturbance voltage” is a CISPR 11 phrase for what is commonly referred to as "mains conducted emissions".

[a] The test may be performed at any one power input voltage within the NIS-E voltage range including battery charging system. If the NIS- E is tested at one power input voltage, it might not be necessary to re-test at additional voltages.

[b] The test may be performed at any one line frequency within the battery charging system or power supply frequency range. If the NIS-E is tested at one line frequency, it might not be necessary to retest at additional frequencies.

Examples (Type Y):

The rated voltage range shall be 100 V a.c. to 240 V a.c.. 240 V a.c. – 100 V a.c. = 140 V a.c. (range).

25 % of 100 V a.c. is 25 V a.c. 140 V a.c. > 25 V a.c.

Therefore, the NIS-E shall be tested at the minimum and maximum rated voltage. The rated voltage range shall be 220 V a.c. to 240 V a.c.

240 V a.c. – 220 V a.c. = 20 V a.c. (range) 25 % of 220 V a.c. is 55 V a.c.

20 V a.c. < 55 V a.c.

Therefore, the NIS-E shall be tested at one voltage within the rated range.

[c] This test is in addition to the power frequency magnetic field immunity.

[d] CISPR 32 is allowed but entire system shall conform with the limits of CISPR 11.

Table 13 *(continued)*

Test	Power input voltage	Power frequency	Applicability for NIS-E
Electrostatic discharge immunity IEC 61000-4-2	Any one voltage [a]	Any one frequency [b]	For all configurations
Radiated RF electromagnetic field immunity IEC 61000-4-3	Any one voltage [a]	Any one frequency [b]	For all configurations
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3 (interim method)	Any one voltage [a]	Any one frequency [b]	For all configurations
Electrical fast transient/burst immunity – AC mains IEC 61000-4-4	Any one voltage [a]	Any one frequency [b]	Only for Type Y NIS-E
Electrical fast transient/burst immunity – I/O SIP/SOP ports IEC 61000-4-4	Only for NIS-E connected to battery charging system at any one voltage [a]	Any one frequency [b]	Only for Type Y NIS-E or Type X NIS-E equipped with Signal Input/Output port
Surge immunity IEC 61000-4-5	Only for NIS-E connected to battery charging system at any one voltage [a]	Any one frequency [b]	Only for Type Y NIS-E or Type X NIS-E equipped with Signal Input/Output port

NOTE “Mains terminal disturbance voltage” is a CISPR 11 phrase for what is commonly referred to as "mains conducted emissions".

[a] The test may be performed at any one power input voltage within the NIS-E voltage range including battery charging system. If the NIS- E is tested at one power input voltage, it might not be necessary to re-test at additional voltages.

[b] The test may be performed at any one line frequency within the battery charging system or power supply frequency range. If the NIS-E is tested at one line frequency, it might not be necessary to retest at additional frequencies.

Examples (Type Y):

The rated voltage range shall be 100 V a.c. to 240 V a.c.. 240 V a.c. – 100 V a.c. = 140 V a.c. (range).

25 % of 100 V a.c. is 25 V a.c. 140 V a.c. > 25 V a.c.

Therefore, the NIS-E shall be tested at the minimum and maximum rated voltage. The rated voltage range shall be 220 V a.c. to 240 V a.c.

240 V a.c. – 220 V a.c. = 20 V a.c. (range) 25 % of 220 V a.c. is 55 V a.c.

20 V a.c. < 55 V a.c.

Therefore, the NIS-E shall be tested at one voltage within the rated range.

[c] This test is in addition to the power frequency magnetic field immunity.

[d] CISPR 32 is allowed but entire system shall conform with the limits of CISPR 11.

Table 13 *(continued)*

Test	Power input voltage	Power frequency	Applicability for NIS-E
Immunity to conducted disturbances induced by RF fields (conducted RF disturbance immunity) – AC mains IEC 61000-4-6	Only for NIS-E connected to battery charging system at any one voltage [a]	Any one frequency [b]	Only for Type Y NIS-E
Immunity to conducted disturbances induced by RF fields (conducted disturbance immunity) – SIP/SOP ports IEC 61000-4-6	Only for NIS-E connected to battery charging system at any one voltage [a]	Any one frequency [b]	Only for Type Y NIS-E or Type X NIS-E equipped with Signal Input/output port
Power frequency magnetic field immunity IEC 61000-4-8	Any one voltage [a]	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the line frequency of battery charging system shall be the same. [b]	For all configurations
Voltage dips immunity	Minimum and maximum rated voltage	Any one frequency	Only for Type Y NIS-E

NOTE “Mains terminal disturbance voltage” is a CISPR 11 phrase for what is commonly referred to as "mains conducted emissions".

[a] The test may be performed at any one power input voltage within the NIS-E voltage range including battery charging system. If the NIS- E is tested at one power input voltage, it might not be necessary to re-test at additional voltages.

[b] The test may be performed at any one line frequency within the battery charging system or power supply frequency range. If the NIS-E is tested at one line frequency, it might not be necessary to retest at additional frequencies.

Examples (Type Y):

The rated voltage range shall be 100 V a.c. to 240 V a.c.. 240 V a.c. – 100 V a.c. = 140 V a.c. (range).

25 % of 100 V a.c. is 25 V a.c. 140 V a.c. > 25 V a.c.

Therefore, the NIS-E shall be tested at the minimum and maximum rated voltage. The rated voltage range shall be 220 V a.c. to 240 V a.c.

240 V a.c. – 220 V a.c. = 20 V a.c. (range) 25 % of 220 V a.c. is 55 V a.c.

20 V a.c. < 55 V a.c.

Therefore, the NIS-E shall be tested at one voltage within the rated range.

[c] This test is in addition to the power frequency magnetic field immunity.

[d] CISPR 32 is allowed but entire system shall conform with the limits of CISPR 11.

Table 13 *(continued)*

Test	Power input voltage	Power frequency	Applicability for NIS-E
Voltage short interruptions and voltage variations immunity IEC 61000-4-11	Only for NIS-E connected to battery charging system. If the battery charging system rated voltage range < 25 % of the lowest rated input voltage, one rated input voltage. Battery charging system rated voltage [c]	Any one frequency [b]	Only for Type Y NIS-E
Proximity magnetic field immunity IEC 61000-4-39[c]	Any one voltage	Any one frequency	Type Y

NOTE “Mains terminal disturbance voltage” is a CISPR 11 phrase for what is commonly referred to as "mains conducted emissions".

[a] The test may be performed at any one power input voltage within the NIS-E voltage range including battery charging system. If the NIS- E is tested at one power input voltage, it might not be necessary to re-test at additional voltages.

[b] The test may be performed at any one line frequency within the battery charging system or power supply frequency range. If the NIS-E is tested at one line frequency, it might not be necessary to retest at additional frequencies.

Examples (Type Y):

The rated voltage range shall be 100 V a.c. to 240 V a.c.. 240 V a.c. – 100 V a.c. = 140 V a.c. (range).

25 % of 100 V a.c. is 25 V a.c. 140 V a.c. > 25 V a.c.

Therefore, the NIS-E shall be tested at the minimum and maximum rated voltage. The rated voltage range shall be 220 V a.c. to 240 V a.c.

240 V a.c. – 220 V a.c. = 20 V a.c. (range) 25 % of 220 V a.c. is 55 V a.c.

20 V a.c. < 55 V a.c.

Therefore, the NIS-E shall be tested at one voltage within the rated range.

[c] This test is in addition to the power frequency magnetic field immunity.

[d] CISPR 32 is allowed but entire system shall conform with the limits of CISPR 11.

9.2 NIS-E identification, marking and documents

9.2.1 Instruction for use in relation to EMC

The instructions for use shall, where applicable, include the following.

a) The performance of the NIS-E that has been determined to be the essential performance and a description of what the operator can expect if the essential performance is lost or degraded due to electromagnetic disturbances. The defined term "essential performance" may not be used in the description in the instructions for use.

b) A list of all cables and maximum lengths of cables (if applicable), transducers and other accessories that are replaceable by the responsible organization and that are likely to affect conformance of the NIS-E with the requirements (emissions) and (immunity). Accessories may be specified either generically (e.g. shielded cable, load impedance, battery charging system) or specifically (e.g. by manufacturer and model or type reference).

   Transducers and cables intended to be used as replacement parts for internal components may not be listed.

c) A warning statement to the effect that "WARNING: Use of accessories, transducers and cables other than those specified in the instructions for use could result in increased electromagnetic emissions or decreased electromagnetic immunity of the [NIS-E] and result in improper operation";

d) A warning statement to the effect that: "WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [NIS-E], including cables specified for use with the [NIS-E]. Otherwise, degradation of the performance of this [NIS-E] could result".

In the above warnings, "[NIS-E]", shall be replaced with the model or type reference of the NIS-E.

If higher immunity test levels than those specified in Table 19 are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using Formula (1).

The instructions for use shall describe precautions to be taken to prevent adverse events to the patient and operator due to electromagnetic disturbances.

For NIS-E, the instructions for use shall include the following information:

1) conformance to this document, ISO 11608-4;

2) any deviations from this document and allowances used.

9.2.1.1 Requirements applicable to NIS-E that includes RF transmitters

For NIS-E that includes RF transmitters, the instructions for use shall include information on each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the effective radiated power.

NOTE Statutory or regulatory requirements can exist.

9.2.2 Documentation of the tests

9.2.2.1 General

The documentation of the tests shall contain all the information necessary to facilitate adequate planning (test plan) and execution (test report) of the tests so that they can be readily reproduced.

Conformance shall be checked by inspection of the test report.

9.2.2.2 Test plan

Prior to the start of formal testing, a detailed test plan shall be developed. Deviations from the test plan shall be documented in the test report.

NOTE IEC 60601-1-2:2014+AMD1:2020, Annex G provides guidance on development of EMC test plan.

9.3 Electromagnetic emissions requirements for NIS-E

9.3.1 Protection of radio services and other equipment

9.3.1.1 General

NIS-E shall conform with CISPR 11 Class B group 1.

NOTE 1 For further guidance on test setups, see CISPR 16-2-3.

NOTE 2 Statutory or regulatory requirements can exist.

9.3.1.2 Operating modes

During emissions testing, the NIS-E shall be tested in the modes that maximize emissions. In addition to testing for emissions in active modes, inclusion of standby mode should be considered. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.

Conformance shall be checked by inspection of the test report.

9.3.1.3 NIS-E that include radio equipment

NIS-E that includes radio equipment (e.g. RF transmitters, receivers, transceivers) shall conform with CISPR 32 and shall be tested together with the radio equipment.

NOTE National radio regulations can exist.

9.3.2 Protection of the public mains network

9.3.2.1 General

The requirements specified in 9.3.2.2 and 9.3.2.3 shall be applicable only for rechargeable NIS-E.

9.3.2.2 Harmonic distortion

Rechargeable NIS-E (with or without external battery charging system) with a rated AC mains network voltage greater than or equal to 220 V AC line-to-neutral and less than or equal to 16 A per phase and that are intended to be connected to the public mains network shall conform with the requirements of IEC 61000-3-2.

NOTE Applicable for power consumption (during intended use) ≥75 W.

Conformance shall be checked by inspection of the instructions for use and the test report.

9.3.2.3 Voltage fluctuations and flicker

Rechargeable NIS-E (with or without external battery charging system) with a rated AC mains network voltage greater than or equal to 220 V AC line-to-neutral and less than or equal to 16 A per phase and that is intended for connection to the public mains network shall conform with the requirements of IEC 61000- 3-3.

Conformance shall be checked by inspection of the instructions for use and the test report.

9.3.3 Emissions requirements summary (Type X and Type Y)

The emissions requirements are summarized in Table 14.

Table 14 — Emission limits per environment

Phenomenon	Professional healthcare facility environment	Home healthcare environment
Conducted and radiated RF emissions	CISPR 11 [c]	CISPR 11 [abc]
Harmonic distortion	IEC 61000-3-2	IEC 61000-3-2
Voltage fluctuations and flicker	IEC 61000-3-3	IEC 61000-3-3

[a] NIS-E for use in aircraft shall fulfil the RF emissions requirements specified in ISO 7137. The conducted RF emissions test shall be applicable only to NIS-E that are intended to be connected to aircraft power.

[b] Standards applicable to other modes or electromagnetic environments of transportation for which use is intended shall apply. Examples of International Standards that can be applicable include CISPR 25 and ISO 7637-2.

[c] CISPR 32 shall be allowed but entire system shall conform with the limits of CISPR 11.

9.4 Electromagnetic immunity requirements for NIS-E

9.4.1 General

Rechargeable NIS-E shall be tested as specified in this subclause, including Table 15.

Table 15 — Electromagnetic immunity requirements for rechargeable NIS-E

Phenomenon	Basic EMC standard
Electrical fast transients/bursts	IEC 61000-4-4
Surges Line-to-line Line-to-ground	IEC 61000-4-5
Conducted disturbances induced by RF fields	IEC 61000-4-6
Voltage dips Voltage interruption	IEC 61000-4-11

Electromagnetic immunity tests shall be performed:

— in a well-defined and reproducible manner;

— individually as single tests in sequence, and they may be performed in any order.

For the case in which the NIS-E is damaged by an immunity test signal, Table 16 specifies how to proceed with the remainder of the immunity test.

Table 16 — Procedure for continuing to test NIS-E that are damaged by an immunity test signal

Type of test	Reaction of NIS-E during test	How to continue with testing
Transient [a]	The NIS-E is permanently damaged. However, basic safety and essential performance continue to be provided.	The test sequence shall be repeated two times with this immunity test level and polarity. The NIS-E passes the test if it continues to provide its basic safety and essential performance. If any equipment is damaged, it can continue to be used for the immunity test for this specific phenomenon, as long as it can be proven (e.g. by the risk approach process, engineering analysis, experience, redundancy) that the ability of the NIS-E to provide its basic safety and essential performance can still be determined while using the damaged equipment. To continue with the immunity test of the next electromagnetic phenomenon, the NIS-E shall be restored to normal operation.
	The NIS-E is permanently damaged. Basic safety or essential performance does not continue to be provided (or other hazards).	The NIS-E has failed the test.
Continuous [b]	The NIS-E is permanently damaged. However, basic safety and essential performance continue to be provided (or other hazards).	The test sequence shall be repeated two times with this immunity test level and polarity or frequency. Basic safety and essential performance shall continue to be provided. To continue with the next frequency step, the NIS-E shall be restored to normal operation.
	The NIS-E is permanently damaged. Basic safety or essential performance does not continue to be provided (or other hazards).	The NIS-E has failed the test.
[a] Tests according to IEC 61000-4-2, IEC 61000-4-4, IEC 61000-4-5 and IEC 61000-4-11.		
[b] Tests according to IEC 61000-4-3, IEC 61000-4-6 and IEC 61000-4-8.		

The immunity test requirements applied to the NIS-E as specified in Table 15 specify immunity requirements and test conditions for the professional healthcare facility environment and the home healthcare environment.

NOTE 1 Immunity test levels are calculated individually for each phenomenon.

For NIS-E for which the intended use includes types of transportation (e.g. land, sea and air vehicles) or other locations in the home healthcare environment such as those that can be accessed by walking (e.g. near radiofrequency identification (RFID) systems, anti-theft systems), if additional immunity tests or immunity test levels that are higher than those specified in Table 15 shall be appropriate or shall be specified by requirements within standards applicable to a mode or electromagnetic environment of transportation, these additional tests and higher immunity test levels shall apply.

The dwell time for immunity tests shall be based on the settling time of the test system and the time required for the NIS-E to be exercised (if applicable) and adequately respond to the test signal.

The power frequency for all immunity tests may be selected at any one of the nominal power frequencies of the NIS-E, except as otherwise specified in Table 13.

Before immunity testing begins, the specific, detailed immunity pass/fail criteria shall be determined by applying the risk approach process for basic safety and essential performance (or other hazards) with regard to electromagnetic disturbances. It shall also be determined how the NIS-E shall be monitored during the tests to check for conformance with the specific pass/fail criteria. These pass/fail criteria and this monitoring specification should be included in the test plan and shall be included in the test report and the risk management file.