International Standard

ISO 23908

Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods

Protection contre les blessures par perforants — Mécanismes de protection des aiguilles à usage unique, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements, le contrôle et l'échantillonnage sanguins et l'administration de substances médicales — Exigences et méthodes d'essai

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Foreword

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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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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 23908:2011), which has been technically revised.

The main changes are as follows:

— the Scope has been expanded to cover single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration;

— reference has been made to medical devices standards ISO 14971, IEC 62366-1, ISO 11608-1, ISO 20417;

— a free fall test has been added, with as a pass/fail the non-access to the sharps, in order to cover a frequent misuse situation and avoid a potential increase of the risk of sharp injury;

— updates on the test methods Gauge R&R requirements for destructive testing (threshold becoming no greater than 30 % of the specification interval for destructive test, instead of 20 % for any other given measurement);

— a new requirement for A-SIPM has been introduced to include both obvious and non-obvious misuse situations in the risk assessment and to mitigate these situations as far as possible through product design;

— a new requirement has been added to apply a minimum force of 5 N to challenge access to the sharp;

— normative Annex A has been revised to include the methods for testing the access to the sharp in safe mode and after free fall;

— device and SIPM recovery has been added as a potential option to include in the device life cycle.

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

This document addresses sharps injury protection mechanism designed to protect users and others who can incidentally be exposed to such devices post-use. These sharps injury protection mechanisms are intended to prevent, or reduce the potential risk for, disease transmission which can result from accidental, post-use sharps injuries.

This document addresses devices primarily intended for human use, of a wide range of product types, including but not limited to hollow-bore needles for injection or infusion of therapeutics into the body, or sampling of fluids from the body, and hollow-bore or solid-core needles used for blood sampling (e.g. lancing devices).

Given the broad variation in product design, categories of device, and sharps protection technologies, and in order to avoid unnecessarily restricting innovation, this document has been developed to provide general design, testing and labelling requirements, rather than specific physical and prescriptive design requirements. It therefore differs from documents which list specific maximum forces, detailed test fixture designs, test systems to be used or detailed test measures, as such prescriptive details cannot cover the variety of designs and devices. Including such details can impede continuing innovation in new products, mechanisms and/or protection mechanisms that lead to future improvements in healthcare.

This document presumes that the product developer uses a risk-based approach (consistent with ISO 14971:2019) to determine the device design that best meets the needs of a target user population and expected use settings. Through this risk-based approach, the sharps injury protection mechanism would have performance requirements appropriate to the foreseeable risks associated with the intended use of the device, expected user interfaces and the settings in which these sharps injury protection mechanisms are expected to be used.

This document provides guidelines to enable the manufacturer to verify that the design of the sharps injury protection mechanism complies with the design intent spelled out in the design specification.

As part of this validation, the manufacturer is expected to demonstrate that the performance of the sharps injury protection mechanism is appropriate to the intended users and settings through the use of appropriate formative or summative user interface evaluations. These studies allow the manufacturer to demonstrate that, when used in accordance with the instructions for use, in settings representative of real-life intended use and by intended or foreseeable users, the mechanism functions as intended.

The standards ISO 23907-1 (covering single-use sharps containers, revised in 2019), and ISO 23907-2 (covering reusable sharps containers, created in 2019), have significantly improved the prevention of health risks and the safety for all the persons that manipulate post-use sharps medical devices.

However, taking into account the need to intensify the security of sharps medical devices post-use as well as the growing need to reduce their environmental impact by encouraging the possibility of allowing their recycling, this revision constitutes an additional tool for the user's health protection and the preservation of the environment.

Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods

1 Scope

This document provides requirements and test methods to evaluate the performance and usability of sharps injury protection mechanisms (SIPMs) of devices including a single use sharp, for administration and/or extraction of blood or body fluids and/or medicinal substances.

The sharps injury protection mechanisms covered by this document can be provided integral to the device or for assembly with the device prior to use.

The aim of the tests is to confirm minimization of risks of accidental sharps injury from contaminated sharps, after the period of intended use, including the path to safe disposal or recovery, where this is a legal requirement or the manufacturers' decision.

This document does not cover

— devices for medication loading and transfer, utilizing a blunt tip design, or

— invasive products whose intended use is to access small spaces, particularly ear, nose and throat, to perform ophthalmic procedures

because their SIPMs have been found to adversely affect the usability and can increase the risk for patients versus the benefit of the intended use of the device.

This document does not cover solid-core needles used for surgery (e.g. suture needles).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

ISO 16269-6:2014, *Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals*

IEC 62366-1:2015+Amd1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 https://www.electropedia.org/

3.1
activation
complete deployment of the sharp's protection mechanism

3.2
active sharp injury protection mechanism
A-SIPM
sharps protection mechanism that the user activates by performing an action (such as the deployment of a shield for the needle) separate from those actions needed to perform the primary intended function of the *device* (3.6)

3.3
accidental sharp injury
unintentional penetration of *sharp* (3.10) into a human, other than the patient, at any time including during the *path to safe disposal* (3.8) or *recovery* (3.13), after having been used to penetrate the patient's human tissue

Note 1 to entry: All sharps that have been removed from their original packaging or discarded before use are considered as potentially contaminated with blood-borne pathogens which can be transmitted to another person through the sharp's injury.

Note 2 to entry: Unintended injury with a sharp before use presents potential hazards other than transmission of blood-borne pathogens, (i.e. infection due to contamination and/or loss of sterility before use, puncture or laceration) to the potential patient and others that should be considered in the risk assessment.

3.4
contaminated sharp
sharp (3.10) that has penetrated human tissue, usually after administration and/or extraction of blood or body fluids and/or medicinal substances

Note 1 to entry: Contaminated sharps should be considered as having the potential to carry blood-borne pathogens.

3.5
integrated sharps injury protection mechanism
built-in sharps injury protection mechanism
integrated SIPM
sharps injury protection mechanism (3.11) (active or passive) that is provided to the user pre-assembled with the *device* (3.6)

3.6
device
product for administration and/or extraction of blood or body fluids and/or medicinal substances

Note 1 to entry: For the purpose of this document, the term "device" covers products regulated as medical devices and product regulated as pharmaceutical or medicinal products.

3.7
passive sharps injury protection mechanism
self-activating sharps injury protection mechanism
P-SIPM
sharps protection mechanism which the user does not need to activate by performing a specific additional action separate from any action needed to perform the primary intended function of the *device* (3.6)

3.8
path to safe disposal
environments in which a used or discarded *sharp* (3.10) (for example time-expired) will come into contact with humans until its safe disposal or *recovery* (3.13), including potential contact immediately after use but before disposal within a sharps container

Note 1 to entry: Sharps should not be reprocessed for reuse, after a single use.

3.9
safe mode
state of the *device* (3.6) after *activation* (3.1) of the *sharps injury protection mechanism* (3.11)

3.10
sharp
part of the *device* (3.6) that can penetrate human tissue for administration and/or extraction of blood or body fluids and/or medicinal substances

3.11
sharps injury protection mechanism
SIPM
sharps safety mechanism which reduces the potential for *accidental sharps injury* (3.3)

3.12
stand-alone sharps injury protection mechanism
stand-alone SIPM
sharps safety mechanism (active or passive) which is provided to the user separate from the *device* (3.6) and which is assembled by the user prior to use of the device

3.13
recovery
separation and processing of waste to obtain materials to be recycled whilst excluding reuse for biosafety reasons

4 Symbols and abbreviated terms

n	number of measurements
$\bar{x}$	average of the sample values
s	sample standard deviation (when based on a random sample, an estimate of the true standard deviation)
k	tolerance limit factor, determined based upon the confidence level (95 %), probability content (p), and the number of measurements (n) taken according to ISO 16269-6:2014
USL	upper specification limit
LSL	lower specification limit
SIPM	sharps injury protection mechanism
A-SIPM	active sharps injury protection mechanism
P-SIPM	passive (self-activating) sharps injury protection mechanism

5 Requirements

5.1 General

5.1.1 Risk assessment: Risk analysis, risk evaluation, risk control and an evaluation of residual risk acceptability shall be performed in accordance with ISO 14971:2019, Clauses 4 to 8. The risk management process shall apply throughout the life cycle of the device.

The application of risk management as per ISO 14971:2019 shall be performed to identify risks and the control measures required to reduce the risk throughout the life cycle of the product. The application of a SIPM (active or passive) shall be considered as part of the risk control measures.

5.1.2 A usability engineering program in accordance with IEC 62366-1:2015+Amd1:2020 shall be applied and take into account the requirements from 5.1.3 to 5.1.7.

Formative or summative user interface evaluations that mimic actual human factors shall be conducted by using patient substitutes (e.g. instructional models) rather than actual patients. Devices with automated P-SIPM do not have to perform additional test if the formative or summative user interface evaluations tests from ISO 11608-5:2022 and IEC 62366-1:2015+Amd1:2020 already demonstrate compliance.

The intended users of the devices are the following: healthcare professionals, homecare patients, caregivers, lay persons, disabled persons or any other users mentioned in the device label.

Considerations of usability engineering (for devices) shall be made that assess and mitigate risks caused by usability problems associated with correct use and use errors.

The SIPM shall be integrated as part of the device before use. When applicable, any pre-use assembly shall not add any risk of failure of the SIPM.

5.1.3 Activation of the SIPM (refer to 5.2) shall permit the user's hand(s) to remain behind the exposed contaminated sharp.

SIPMs may be operated either actively or passively. If active operation is required, it is recommended that the mechanism should be able to be activated with one hand.

If appropriate given the intended use and risk associated with the use condition, passive SIPM is preferred.

5.1.4 The SIPM shall:

— not negatively affect the intended performance characteristics or proper disposal of the device;

— not impede or adversely affect the intended clinical performance of the device;

— resist inadvertent activation under expected conditions of use;

— provide protection against unintentional sharp injury until safe disposal of the sharp.

5.1.5 Once in safe mode, the SIPM of the device shall provide protection against accidental sharp injury until safe disposal of the sharp under the expected conditions of use. Protection against accidental sharp injury is demonstrated by mechanical requirements described in 6.4 and geometrically in 6.5 (refer also to Annex A).

5.1.6 It shall become apparent to the user, at least by a persistent visual indication, when the SIPM is in safe mode.

NOTE For some devices (e.g. catheters with introducers), audible and/or tactile feedback from the activation step can be adequate to substitute for this.