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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.

5.1.7 The reliability of the safety feature as specified in 5.1.2 to 5.1.6 shall be established through appropriate design control specification that are verified and validated according to Clauses 5 and 6 and conducted for the expected conditions of use.

NOTE 1 Appropriate formative or summative user interface evaluations can be helpful in establishing specifications to meet the requirements of Clause 5.

NOTE 2 Local guidance for formative or summative user interface evaluations exists, such as the FDA guidance documents.[6][7]

5.2 Activation of the sharps injury protection mechanism

5.2.1 Active SIPM

It shall be possible to activate A-SIPMs immediately after intended use of the sharp.

An activation force appropriate for the intended users of the device (e.g. patients, health care professionals, lay persons or family members) shall be specified to ensure ease of activation and to avoid unintended activation. The force specification limits shall be determined from the risk assessment, including human factors considerations. The force values shall be verified using the methodology outlined in Clause 6.

The possibility of misuse situations which could lead to a mechanism malfunction (obvious or non-obvious), including failure to enter into a safe mode, shall be included in the risk assessment. Those situations shall be evaluated through a risk-based approach and be mitigated accordingly as necessary. This may lead to specific additional product requirements to be verified in design verification.

5.2.2 Passive SIPM

P-SIPM shall enter safe mode immediately after use of the sharp.

Since the user is not activating the SIPM, a successful activation of the mechanism shall be clearly indicated to the user.

5.3 Security of safe mode protection

Once in safe mode, the SIPM shall:

a) resist forces, to prevent unintended exposure to the sharp, when tested in accordance with 6.4;

b) minimize the risk of accidental access to the sharp, when tested in accordance with 6.5;

c) resist damage from a free-fall, so that that there shall be no access to the sharp, when tested in accordance with 6.4.3;

Using a risk-based approach in accordance with ISO 14971:2019, the appropriate minimum overriding forces shall be determined. These force values shall be verified using the methodology outlined in Clause 6. The forces specification limits shall be determined from the risk assessment, including human factors considerations.

For an A-SIPM, the different ways of activating the SIPM shall be included in the risk assessment, either for correct use or use-error situations. The impact of resulting associated effort on the geometrical configuration of the device (needle deformation, device components plastic deformations, etc.) or mechanical resistance of the device shall be evaluated and taken into consideration through a risk-based approach. In particular, the risk associated with needle breakage shall be mitigated for devices that cause needle deformations in their technology.

6 Test methods

6.1 General

Unless otherwise specified, all tests and test evaluations shall be performed at the following standard atmosphere conditions:

— temperature: (23 ± 5) °C;

— relative humidity: (50 ± 25) %.

Devices with an integral SIPM or a stand-alone SIPM (pre-assembled) shall be stored for at least 4 h under these conditions immediately prior to testing/evaluation.

Any suitable test system can be used for the measurement when the required accuracy (calibration) and precision (Gauge R&R) can be obtained. The repeatability and reproducibility (Gauge R&R) of the test apparatus shall be no greater than 20 % of the specification interval for any given measurement. For one-sided tolerances, an interval shall be established by adding the missing end-point (i.e. not as a specification limit). For destructive test measurements, the Gauge R&R shall be no greater than 30 % of the specification interval. If the specification interval recommended values are not applied, use case justification based on risk assessment shall be provided.

The minimum quality level proportion for each requirement asserted to meet specification needs to be established through a risk assessment. The sample size shall be consistent with specified proportion and confidence level.

Statistical tolerance intervals shall be determined according to ISO 16269-6:2014. The statistical tolerance interval shall be contained in the specification intervals.

When a SIPM is integral to a device covered by any other standard, or when combined with such a device prior to use, it shall be subjected to the same pre-conditioning requirements set out for the device by that/those other standard/s.

6.2 Test procedure and results analysis methodology

The test procedure shall be as follows.

Set up the number of devices (n) and test as follows. The number of devices to be tested (n) shall be duly statistically justified or specified in the risk management outcome.

a) Insert the device in a fixture.

b) Prepare the fixture as required.

c) Start the test cycle.

d) Record the specified results (e.g. force, pass/fail, displacement).

e) Repeat for n devices (as specified).

Attributive test results shall be assessed using appropriate statistics (see e.g. ISO 11608-1:2022).

Variable test results shall be used to calculate a statistical tolerance interval (see ISO 16269-6:2014) using the methodology outlined below.

If it is assumed that the peak force values of activation of the sharps injury protection mechanism obtained in accordance with steps a) to e) are independent from each other, and normally distributed, then the statistical tolerance around the mean of the peak force values can be evaluated. The 95 % confidence level,

two-sided statistical tolerance interval can be calculated using the average ($\bar{x}$) plus or minus the standard deviation (s) multiplied by a tolerance limit factor (k):

$$\bar{x} \pm k \times s$$

The factor (k) is determined based upon the confidence level (95 %), probability content (p), and the number of measurements (n) taken according to ISO 16269-6:2014.

Test force values satisfy the requirement when, for a given test set, the following expressions are fulfilled:

$$\bar{x} + (k \times s) \leq USL$$

and

$$\bar{x} - (k \times s) \geq LSL$$

where USL and LSL are the upper and lower specification limits, respectively.

NOTE ISO 16269-6:2014 also addresses one-sided tolerances and other non-normal distributions.

6.3 Testing activation of a sharps injury protection mechanism

6.3.1 Principle

The device shall be operated according to conditions representative[1)] of its intended use in order to activate the SIPM. In the case of a passive mechanism, this can be a sequence of events resulting in activation of the SIPM. Any applicable specified user inputs (such as forces) shall be measured and recorded. Following activation of the SIPM the device shall be inspected to confirm whether or not the SIPM has been deployed as specified. A “pass” is recorded if the deployment of the SIPM is successful and the recorded user inputs are within their specified limits.

6.3.2 Apparatus

A test apparatus shall be used that can hold the device firmly without deformation, actuate the SIPM at defined speeds and at appropriate angles, and display the resulting activation force or torque in a reproducible and repeatable manner.

6.3.3 Procedure

Perform the test and analyse results as specified in 6.2.

6.4 Challenging the SIPM in safe mode

6.4.1 General

These tests are designed to challenge the SIPM while in safe mode, to verify that the mechanism is able to protect against unintended exposure to a sharp during the time from completion of the intended use of the device to safe disposal or recovery. The tests shall be performed with the device prepared for intended use, with all packaging removed.

1) ‘Representative’ includes something different from the real use configuration, as long as rationale is provided to explain the relevance of the test conditions.

6.4.2 Overriding or unlocking test

6.4.2.1 Principle

Using a risk-based approach in accordance with ISO 14971:2019, the minimum overriding or unlocking forces shall be determined. It shall be confirmed that these force values are the values at which the SIPM cannot be overridden once in safe mode under normal conditions of use (correct use and use errors). These force values shall be obtained with the methodology outlined in 6.2, steps a) to e). These force values shall be used to calculate a statistical tolerance (see ISO 16269-6:2014) with a similar methodology to that given in 6.2. For certain design of SIPMs, it is possible that the overriding or unlocking test is not applicable. In such a case, justification shall be duly documented.

As specified in Clause 5, it shall be demonstrated that the sharps injury protection mechanism can withstand overriding forces once in safe mode, appropriate to the target population for which the device is intended and for any other individuals (e.g. health care professionals, lay persons or family members who administer the therapeutic substances) who can incidentally come in contact with the locked device prior to its safe disposal.

Test pieces are chosen and a force/torque applied to the SIPM in a manner consistent with the failure modes identified in the risk assessment. The resulting unlocking or overriding forces are then recorded in the test report.

6.4.2.2 Apparatus

The test apparatus used shall include:

— a fixture to immobilize the device but without deformation of the SIPM and its components;

— a system able to apply enough force to override the SIPM at suitable or appropriate conditions that are representative of a potential expected use;

— a system able to measure and record force and/or torque and/or other measurands as specified during the whole test in a reproducible and repeatable manner.

6.4.2.3 Procedure

Activate the SIPM on *n* devices as outlined in the instructions for use and carry out testing as specified in 6.2 to read the minimum force and/or the torque that allows overriding of the SIPM.

6.4.3 Resistance of the SIPM in safe mode to free fall

6.4.3.1 Principle

Free fall testing is intended to verify the protection performance of the needle-SIPM, while in safe mode, when subjected to a fall from a specified height onto a specified hard surface. The testing shall be performed according to the methods specified in ISO 11608-1:2022, 10.3.1.

The testing schedule includes, as pre-fall conditions, the worst-case scenario orientation identified by risk analysis or usability engineering, a 180° orientation from the worst-case, and a 90° orientation from the worst-case. The position of the sharp shall be taken into account for defining the worst-case scenario.

Chosen orientations are those to be used at the moment of dropping the parts, and are not expected to still be met at the point of landing.

A new device shall be used for each of the specified test orientations. For disposable devices, at least 30 samples shall be tested, equally distributed between the 3 orientations. Each sample shall only be dropped once. For reusable SIPM, use the same device 3 times, one for each orientation, for a total of 20 samples.

NOTE 1 If the reservoir or the container is broken during testing, the test remains successful as long as the sharp remains inaccessible.

NOTE 2 An example of equipment to perform the free fall test is given in Annex B.

6.4.3.2 Apparatus

— Use of hands or mechanical grips to hold the test device in the required orientations.

— An unobstructed path to the impact surface, 1000^{+100}_{-0} mm below the lowest part of the device under test.

— A horizontal, flat, smooth surface made from 3 mm steel plate backed by timber with a thickness of 10 mm (or more) or in stable contact to a surface (such as a concrete floor) to ensure non-elastic rigidity under the test conditions. The surface size shall be large enough to ensure that the device and its SIPM falls entirely upon the test surface.

6.4.3.3 Procedure

— Condition the device as specified in 6.1.

— Activate the SIPM.

— Prepare the device for free fall by holding or lightly clamping the body of the device (not the sharp protection mechanism part of the device).

— Perform the test from a height of 1000^{+100}_{-0} mm, as measured by the distance between the lowest point on the device and the nearest point on the impact surface.

— Release the clamp or hand grip.

— Observe the unobstructed fall of the device onto the surface of the steel plate.

— Check the non-access to the sharp by using the protocol specified in Annex A, Clause A.2.

— Repeat the test for each sample and orientation.

NOTE Parts from activation test performed in 6.3 can be used for this test, provided risk analysis is performed to ensure they can be considered as representative of manually activated devices.

6.5 Testing access to the sharp in safe mode

It shall be demonstrated that, once the device is in safe mode, the risk of accidental access to the sharp is minimized.

No single test method can cover the variety of designs and working principles associated with SIPM. Based upon the individual design of the SIPM, it shall be demonstrated by an engineering study that such risk of accidental access to the sharps is minimized. This can be complemented by additional specific test method and/or computer aided design analysis.

The test methods specified in Annex A are suitable methods to demonstrate compliance with 5.3 b).

7 Information supplied with the device

7.1 General

The device with integrated SIPM or stand-alone SIPM shall be accompanied by the information needed for its safe and proper use, taking account of the training and knowledge of the potential users, including lay persons, and the information needed to identify the manufacturer.

Information needed for the safe use of the SIPM shall be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information shall be set out in the instruction for use supplied with one or more devices.

Instructions to the users for any recycling condition specific to the device or SIPM can be provided as part of the product information.

NOTE In some countries, national regulations exist whose requirements can supersede or complement the marking, labelling and information specified in this clause.

7.2 Marking/labelling

Any marking of a device with integrated SIPM or stand-alone SIPM that is essential for the safe use of the device shall be visible and easily legible after being subjected to the preconditioning specified in 6.1. This shall be checked by visual inspection according to environmental lighting conditions and reading distance defined in ISO 11608-1:2022, 11.2.

The marking/labelling of the device with integrated SIPM or stand-alone SIPM shall be done according to ISO 20417:2021.

For a reusable device, instructions shall be given to the user for reusing the device after an unintended falling situation.

NOTE Some regions can require QR code and/or specific labelling regarding the safe disposal or recovery after use in order to avoid blood exposure accident.

7.3 Instructions for use

The SIPM shall be accompanied by sufficient information on its safe use.

The instructions for use shall at least contain information on the following:

a) precautions to be taken and any warnings;

b) if the SIPM is to be assembled with the sharp before use, sufficient details to identify the correct devices and SIPM, and the assembly instructions, in order to obtain a safe combination;

c) description of the SIPM;

d) instructions for use that clearly describe how and when the SIPM is activated and that define user ergonomics, so that the user's hands remain behind the contaminated sharp;

e) instructions for disposal and, if applicable, any particular requirement for recycling of the used SIPM or the device, even if not used;

f) date of issue or the revision of the instructions for use.

Annex A
(normative)

Methods for testing access to the sharp in safe mode

A.1 Challenge the access to the sharp

Non-access to the needle point shall be demonstrated via an engineering study. This analysis shall demonstrate, based on stack-up approach, that the needle tip cannot geometrically come into contact with a virtual rigid sphere of 12 mm diameter (see NOTE 1) or appropriate. The deformations induced by the application of a 5 N load, in the worst-case orientation that can give access to the needle point, should be considered in this analysis. To support determination of physical parts deformation under load, one or a combination of the following tools can be used: bench testing measurements, finite element analysis (FEA).

NOTE 1 The diameter of the sphere is approximately equivalent to the diameter of a human finger. Depending on the intended use of the device, the environmental setting and user's profile, it can be advisable to consider a sphere of a different size, as determined by the risk assessment. Refer to Reference [5] for hand/finger sizes.

NOTE 2 The force value was chosen as a proxy for the weight of the human hand.

A.2 Physical challenge the access to the sharp after free fall

A.2.1 General

The test methods specified in this annex shall be used to test the risk of accidental access to a sharp once the SIPM, in safe mode, has undergone a free fall impact. This section provides the test procedure for assessing safety mechanisms.

A.2.2 Principle

A steel sphere with a maximum diameter of 12 mm or appropriate (see Clause A.1, NOTE 1) mounted on a steel shaft shall not contact the extremity of the needle, while positioned against the part of the SIPM covering the tip of the needle, and when a force of at least 5 N is applied to the steel shaft while orientated in the same longitudinal plane as the needle.

If this orientation is not representing the highest risk of failure of the safety mechanism, a specific orientation can be determined and presented as a replacement.

For the lumen-blunting SIPMs, the sphere shall not contact the needle extremity when the sphere is positioned in-line and in front of the extended blunting mechanism.

A.2.3 Apparatus design

Figure A.1 gives an example of apparatus design for visually testing the sharp access.