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# Distinguishability and identifiability of products with small bore connectors according to ISO DIS 80369 series: risk analysis and summative evaluation

**Abstract:** The ISO 80369-series replace Luer-connectors in five application areas to fight misconnections. Although the standard avoids the mechanical problem of misconnections, the design of products and packages remains arbitrary. So, packages and products with same functions but different connectors could have similar designs and hence could be mixed-up.

To ascertain whether standardization is needed for marking non-distinguishable products and packages, a risk management and usability engineering process were carried out, partly.

The ensuing risk analysis created nine unacceptable risks relating to non-distinguishable packages and lookalike-products. Based on this, risk control (standardization) is needed for lookalikes with the following proposed measures: colour allocation and haptic textures for products, colour allocation and symbols for packages. Furthermore, three scenarios were planned for summative evaluation.

An additional consideration of the efficiency of proposed combinations of measures and products relying on measures would be helpful.

**Keywords:** Small Bore Connectors, SBC, ISO 80369, risk analysis, summative evaluation

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## 1 Situation

To date Luer-connectors are standard connectors for all medical purposes. Due to its universalism nearly all connections can be made, even between products which aren't intended to connect. These misconnections impair the patient safety and can lead to harms for the patient, e.g. when drugs are delivered to unintended body parts [1].

To avoid these misconnections and accompanying harms the International Organization for Standardization (ISO) defined five connectors for five relevant application areas (while the Luer-connector will only be used for intravascular and hypodermic applications anymore) [2]. The problem going along with the standards is that they only focus on the mechanical issues to prevent misconnections. The outer design of connectors and products with different Small Bore Connectors (SBCs) is the time being more or less free for every manufacturer.

The question is whether products with different SBCs can be distinguished and identified with their current free eligible design or if a possible non-distinguishability includes risks for patients and thirds, which would result in necessary marking of products and packages. So, the aim of this research project is to clarify, whether a standard is needed to determine designs for products with different SBCs and their packages to avoid mix-ups and to make unambiguous identifying possible.

## 2 Methods

The total project is geared to DIN EN ISO 14971 [3] and DIN EN 62366 [4].

In order to get a better feel for products with SBCs, an internship at St. Franziskus-Hospital and University Medical Center Muenster are made, subsequently. Respectively, one day observations regarding to the usage and storage of products are planned on intensive care units (ICU) and during operations. With these new impressions first hazardous situations can be carved out. Afterwards questionnaires are prepared for medical specialists. All addressees are summoned to consider harms relating to the machined

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hazardous situations. Beyond that they should think about additional hazardous situations, which aren't listed until now. By dint of feedbacks gotten from this interrogation the final hazardous situations and harms can be described and listed. Whereupon based on this, risks can be assessed.

Furthermore, based on prepared user interface specifications and in conjunction with results of the questionnaires possible measures can be analysed and recommended.

Last, the user interface evaluation plan with attendant summative evaluation plan will be devised, depending on the requirements in [4] and the specific information of Israelski [5].

# 3 Results

The bases for the entire project are the carved out use errors:

- sorting of products into the wrong chutes
- picking a wrong product out of the chutes and
- trying to make a connection between two products, which aren't intended to connect.

The ensuing risk analysis and assessment created nine unacceptable risks relating to possible non-distinguishability of products and especially their packages (e.g. delay of medical care, biological/chemical contamination, switch to alternative methods of treatment).

Based on this, risk control is needed, so that products and packages fulfil the following defined user interface specifications: "unambiguous and immediate sorting of products, differentiation and identification of sorted packed products and assignment of products to other products, with which it can be connected, and instant recognition of the scope of application for which the products are intended. Sorting products and making connections must be fulfilled by 100% of all users, while picking up a product must be fulfilled by only 90%, due to just economical harms."

Afterwards the risk control was considered, which contains proposes for possible measures for easing identifying and distinguishing products and packages. The recommendation for marking was to take only a subset of products (syringes, tubes, searchers and three-way stop cocks; "lookalikes") of only enteral, neuraxial, intravenous, respiratory and eventually urethral application areas, while packages of all products of all scopes of applications should be marked. For marking products colour allocation and haptic textures were advocated, and for packages coloured backs and additional application-oriented symbols of corresponding organs or body parts on the transparent front side are recommended. The colour of products and packages should be the same.

In a final step, summative evaluations were described, with which the fulfilment of user interface specifications by products can be tested. Three scenarios were brought out to evaluate packages and products itself, in which users must identify and unpack a predetermined product, sort products into labelled chutes and must find a multiplicity of product pairs on the one hand, and a single product pair on a manikin on the other hand. To simulate conditions of real usage various user groups must fulfil the tasks under different conditions, e.g. dimly light, stress or high noise levels.

# 4 Discussion

The result of the risk analysis and assessment is that there exist unacceptable risks relating to non-distinguishability of products with SBCs and their packages. Based on this, standardization would be needed to ease handling with corresponding products. Nevertheless, this result must be considered critically.

Sadly, results are just based on theoretical assumptions and few feedbacks of the questionnaire. So, only syringes and packages could be identified as lookalikes undoubtedly, for which standardization is inevitable, while the necessity of standardization for other products should be cleared up further in summative evaluations. Indeed, colour allocation (at cannulas and enteral medical devices [6]), haptic structures (at anaesthesia devices) and symbols (at root canal instruments [7]) turned out to be functional in the past, but the efficiency of combinations of measures isn't known. An additional more detailed consideration of the efficiency of proposed combinations of measures and products relying on measures would be helpful.

**Author's Statement**

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