SLOVENSKI STANDARD
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»Luer« konektorji – Poročilo foruma delovne skupine za »Luer spojke« predsedujočemu CEN

Luer connectors - A report to CEN chef from the CEN forum task group "Luer fittings"

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This CEN Report was approved by CEN on 24 November 1999. It has been drawn up by the Technical Committee CEN/CS SUBSECTOR S99.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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1. SUMMARY

Luer connectors are used in medical devices with a wide range of functions, raising the possibility of accidental cross connection between devices. We assessed the hazards arising from accidental misconnection, and reviewed adverse incidents known to have involved Luer connectors.

We considered three possible strategies for reducing the risk of misconnection being made:

1) The use of different male/female sequences for different applications.
2) The use of colour coding.
3) The restriction of the applications for which the use of Luer connectors is permitted.

Only the last of these offered real benefits.

2. RECOMMENDATIONS

1) That the use of Luer connectors is **restricted** to devices intended to be connected:

   - to the **vascular system** for delivery or sampling purposes or to assist in making some sort of measurement;
   - to a **hypodermic syringe** in order for the syringe or a connected device to achieve its intended purpose.

2) That Luer connectors should **NOT** be used:

   - with devices intended to be connected to the **enteral** or **respiratory** system; specifically, they should not be used for making connections to any catheter (other than a catheter intended to be placed in the vascular system) or to components or accessories to **breathing systems**, and accessories or other devices connected to the respiratory system for the purpose of delivering gases;
   - with systems intended to deliver **compressed air** or **other gases** to medical devices e.g. driving gases;
   - for connections within medical device systems which are used to **control** or **monitor** the operation of that system;
   - with patient-connected **drainage** devices.

3) That CEN, in conjunction with ISO, develops standards for **alternative connectors** for enteral and respiratory applications, including the connection between an enteral feeding set and an enteral feed container.

4) That the scope and titles of EN 20594-1 and EN 1707 be amended to replace the phrase *"and certain other equipment"* with one that reflects the restriction to devices connected to the vascular system.

5) That CEN asks relevant Convenors to review the standards (published and under development) for which they have responsibility which permit the use of Luer connectors, amending those in which the device does not fit the revised connector standard.

3. BACKGROUND

In 1997 concern grew regarding the proliferation of devices fitted with Luer connectors and the direct consequence of patient death or injury arising from the misconnection of particular devices, or the inappropriate delivery of enteral solutions, parenteral feeds or compressed gases.

Specific concerns were raised by CEN TC 205 regarding the use of Luer connectors with enteral feeding tubes and from CEN TC 215 regarding gas sampling and gas delivery systems. Supported in principle by clinical and device experts together with a knowledge of actual and anecdotal incidents, these concerns were raised with CEN BTS 3 and the Commission through the Medical Devices Experts' Group. In November 1997 the problem was aired at the final CEN BTS 3 Healthcare Forum and the newly created CHeF steering group set up a Forum Task Group (FTG) to debate the problem.

Membership of the FTG was by invitation; CHeF ensured that there was appropriate representation drawn from users, device manufacturers, European Standards bodies and European regulators. The FTG met on three occasions between January and October 1998.

The FTG was asked to review the current evidence relating to real and potential problems arising from the misconnection of devices utilising Luer fittings, and to make recommendations regarding the application of Luer fittings to medical devices in order to reduce potential hazards arising from their misconnection.

The remit of the FTG did not cover the design of the Luer connector itself; existing standards adequately specify constructional requirements. The security of the connectors is adequate for the intended purpose providing they have been correctly manufactured and are used appropriately.

4. PROBLEMS ARISING FROM THE USE OF LUER CONNECTORS.

The increasing complexity of medical interventions, and the associated medical devices, has led to a requirement for users to connect a multiplicity of external tubes to various types of diagnostic and therapeutic devices before use.

Typically a patient in a coronary care unit will be connected to a range of devices incorporating Luer connectors. It has been estimated that there are as many as 40 connectors on the devices used with a single patient. It is not therefore surprising that misconnections are made either inadvertently or due to confusion because of the large number of potential connections or because connector sequencing has been lost.

However, whilst there are many anecdotal reports of misconnections, published evidence of serious incidents is scarce. Many clinicians will openly admit that misconnections are commonplace but go unreported either because the mistake was rectified in time or because a serious hazard did not arise from the event. Discussions with other medical device regulators reveal that commonplace but potentially serious events are not reported because users consider them as normal events.

Reports which have been published, or that could be otherwise substantiated include:

* misconnections resulting in enteral feed being delivered parenterally (with fatal consequences) have been reported in a number of countries including France[6], Belgium[7] and Canada [8].

* fatalities have resulted from the direct delivery of oxygen intravenously: in the UK through the use of a male-male Luer adaptor [9], and recently in France due to inadvertent connection of an oxygen "bubble" tube a Luer connector[10].

* enteral feed has been delivered into the inflation cuff of a tracheal tube resulting in total occlusion of the patient's airway [11] (the connector to the inflation cuff is a female Luer, as this is normally inflated by a syringe).

* transposition of the aspiration and actuator lines of a vitrectomy handpiece, resulting in a jet of gas entering the patient's eye, has been reported from two hospitals in the USA[12]. All the lines are fitted with Luer connectors. In addition, a stopcock may also be fitted to permit connection with another handpiece.

* liquid was inadvertently delivered into the breathing system, fitted with a female Luer connector, resulting in decreased oxygen saturation of the patient[13].

A review of reports indicates that problems can arise from two distinct events:

1) the attachment of a delivery system (parenteral fluid, enteral feed or gas) to an inappropriate device, or

2) the connection of two devices each of which is fitted with a Luer connector but are not intended to be connected in normal use.

5. RISK ASSESSMENT

Fundamentally, there are three main routes of delivery to the body: intravascular, enteral and respiratory. Some medical devices are intended to be connected to one of these routes depending upon the application or function of the device, via Luer connectors. Misconnections, which result in the delivery of a substance inappropriately to the body, create risks to the patient.

The table below shows a simple assessment of risk associated with the accidental cross-connection between these three systems.

Delivery Route ⇒ ⇓ Application	Intravascular	Enteral	Respiratory
Parenteral	-	+	++
Enteral Feed	+++	-	++
Respiratory Gases	+++	++	-
Gas Monitoring	+	-	-
Inflating Gas	+++	+++	+++
CVS Monitoring	-	-	-

KEY:

-	Intended connection, or little risk to patient foreseeable.
+	Some risk to patient.
++	Risk to patient, with fatal consequences if condition is allowed to persist.
+++	Immediate fatal risk to patient.

Table 1. Simple assessment of risk arising from misconnection between different delivery systems.

Misconnections which result in the introduction of enteral products or gas into the vascular system are likely to result in death. Serious injury results from misconnections which permit the introduction of gas into the patient's stomach or the introduction of a liquid into the breathing system, particularly if the error is not corrected.

The result of inadvertent introduction of a sterile fluid into the patient's stomach will largely depend on the nature and volume of the fluid. Whilst this event might not directly harm the patient it is a situation which should be avoided.

6. DISCUSSION

6.1 Human factors

A paper by Allnutt[5] reviews the role of human factors in accident areas such as aviation, nuclear power and marine transportation. He makes the point that all human beings, without any exceptions whatsoever, make errors and that such errors are a completely normal and necessary part of human cognitive function. He goes on to say that whilst many accidents are put down to human error (which is synonymous with user error) the guilty party may be someone else, for example the trainer, the equipment designer, the equipment purchaser etc. Well-designed equipment can prevent or at least ameliorate the effects of an error, in his opinion.

We must expect users to misconnect devices which are provided with compatible connectors, and recognise that the potential for misconnection will rise as the number of devices with similar connectors increases.

6.2 Safety under single fault conditions

Medical devices have for very many years followed the established principle of "safety under single fault conditions". Simply stated this means that a single fault should not result in a hazard. This principle is embodied in numerous medical device standards. Extending this principle to the application of Luer connectors is a logical step, i.e. that misconnection should not result in a patient hazard.

6.3 Inherent safe design

Misconnection of devices with Luer connectors is a frequent event. The widespread use of Luer connectors on a multitude of devices can therefore result in connections which have serious, or even fatal, consequences for the patient. Fundamentally, the problem results from the application of a single connector design to a number of incompatible applications.

6.4 The Medical Device Directive 93/42/EEC[14.]

The MDD addresses this type of problem in Essential Requirements 1.2. (*solutions adopted ……for the design and construction of devices must conform to safety principles, taking into account the generally acknowledged state of the art.*

In seeking the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risk as far as possible (inherently safe design and construction) etc……) and 9.1 (*If the device is intended for use in combination with other devices or equipment, the whole combination, including the connector system must be safe etc……*)

Providing alternative connectors for the applications identified earlier could significantly reduce the problem of misconnection.