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Medical devices — Pump tube spallation test — General procedure

Dispositifs médicaux — Essai de spallation des tubes de pompes — Mode opératoire général

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

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Medical devices — Pump tube spallation test — General procedure

1 Scope

This document provides a method of measuring, analysing and assessing the particle shedding from an infusion pump set during pumping.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Materials and equipment

The following materials and equipment are needed for the test set-up.

— IV-fluid container, container or bag with IV-fluid. A container with high volume is preferable. Maybe several containers or bags are needed depending on volume, flow rate and test time. If a glass or rigid container is used, the container should be sufficiently vented. No air born particles enters the container. Recommendation for the IV-fluid is a 0,9 % NaCl solution.

— IV-filter with 0,2 µm pore size or less which is vented. Several IV-filters may be need depending on the number of IV-fluid container.

— Distributor 1, e.g. electronically driven manifold or a manually driven stopcock manifold.

— Pump set to be tested.

— Infusion pump to be tested.

— Distributor 2, e.g. electronically driven manifold or a manually driven stopcock manifold. The number of output of distributor 2 is $N = N_r + N_S + 1$, where N_r is the number of reference containers, N_S is the number of sample containers and "+1" for the waste container.

— Reference containers, container or bag to collect reference sample IV-fluid. Several containers or bags can be used to collect several reference samples. A container with a volume between 50 ml to 500 ml is preferable. If a glass or rigid container is used then the container should be sufficiently vented. No air born particles enter the container.

— Sample containers, container or bag to collect sample IV-fluid. Several containers or bags are needed depending on volume, flow rate and test time. A container with a volume between 50 ml to 500 ml is preferable. If a glass or rigid container is used then the container should be sufficiently vented. No air born particles enter the container.

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