
Medical devices — Transfusion set and blood bag compatibility test method

Dispositifs médicaux — Méthode d'essai de compatibilité entre les appareils de transfusion et les poches de sang

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

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

The connection between a blood bag (as specified in ISO 3826-1, ISO 3826-3 and ISO 3826-4) and a transfusion set (ISO 1135-4 and ISO 1135-5) is provided by the bag port and transfusion set closure piercing device referred to in this document by the abbreviation 'spike'. The spike is a rigid structure with tightly defined dimensions whereas the blood bag port is of flexible material in order to accommodate the spike. Transfusion sets are compatible with a range of commercially available blood bags and vice versa. It is vitally important in setting up a blood transfusion that the force required to insert the spike into the port is not excessive. This can lead to difficulties in piercing the port septum, damage to the blood bag, leakage of its contents and injuries to bedside staff.

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1 Scope

This document details suitable equipment, a test method, acceptance criteria and advisable limits to help to ensure that there is compatibility (by measuring the insertion force) between a transfusion set closure piercing device (referred to in this document by the abbreviation 'spike') and a blood bag outlet port.

The test procedure in its entirety is complex and beyond the scope of each of the relevant transfusion set and blood bag standards. This document was therefore developed to support the implementation of the existing standards for blood bags and transfusion sets.

The procedure described in this document can be used by manufacturers of blood bags to test the compatibility with transfusion set spikes available on the market or by manufacturers of the transfusion set spikes to test the compatibility with blood bags available on the market.

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 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed*

ISO 1135-5, *Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus*

ISO 3826-1, *Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers*

ISO 3826-3, *Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features*

ISO 3826-4, *Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features*

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 <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

4 Materials and equipment

The following materials and equipment shall be used for the test set-up.

- Transfusion set spike in conformance with ISO 1135-4 or ISO 1135-5.
- Blood bags conforming to ISO 3826-1, ISO 3826-3 or ISO 3826-4.

— Spike insertion test equipment including standard masses.

5 Labelling

Remove each transfusion set and blood bag system from its outer packaging and mark each device with the date, the initials of tester, the Lab Test Request (LT) number and a reference number that provides traceability to the manufacturer's product code and lot number.

6 Preparation

6.1 General

The test shall be conducted at a temperature between (23 ± 2) °C. All materials and equipment shall be stored at a temperature between (23 ± 2) °C for at least 12 hours.

6.2 Insertion force equipment

An example of suitable test equipment is shown in [Figure 2](#) with dimensions given in [Annex A](#). Set up the equipment on a rigid, level surface. Ensure that the shaft/chuck assembly and standard masses have been calibrated. When no additional mass is used, the weight of the shaft, chuck and nuts is equal to 2 000 g, thus pushing the tested spike against the outlet port with a force of 20 N.

6.3 Transfusion sets

If not already isolated, remove (e.g. cut off) the spikes from 3 separate unused transfusion sets to be used in the test so that at least 5 mm of the portion above the spike, see [Figure 1](#), is available to be gripped within the chuck of the test equipment. When the spike is attached directly to the drip chamber it is alternatively possible to grip a concentric portion of the isolated drip chamber/spike assembly leaving the spike fully exposed for the insertion test.

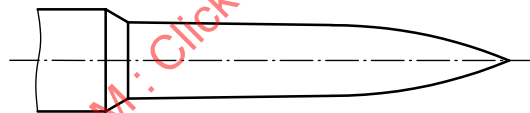


Figure 1 — Closure piercing device

NOTE [Figure 1](#) is reproduced from ISO 1135-4:2015, without dimensions.

6.4 Blood bags

Select and isolate, by heat sealing, 3 fluid filled (either anticoagulant or additive solution) blood bags.

NOTE It is important that the test is carried out on plastic in contact with aqueous fluid to simulate the condition of a bag in contact with blood or blood components. Water is an acceptable alternative to anticoagulant and additive solution.

6.5 Test worksheet

Prepare the worksheet shown in [Annex B](#) in readiness for the commencement of testing.

7 Test method

7.1 Select the equipment in Figure A.1 and set up as in 6.2.



Figure 2 — Example of test equipment

7.2 Position the shaft (3) so that the chuck (4) is 5 cm to 10 cm above the orifice (5) and rotate the lower (collar) nut (2) to lock the shaft in place in this position.

NOTE Numbers in brackets refer to keys in Annex A, Figure A.1.

7.3 Open the chuck to accommodate a spike prepared in accordance with 6.3.

7.4 Clamp the spike firmly within the chuck (see 6.3).

WARNING — Beware of the sharp spike.

7.5 Remove the protective cover from a blood bag port prepared as in 6.4 according to the manufacturer's instructions for use.

7.6 Rotate the lower (collar) nut (2) and slowly, carefully allow the spike to be introduced into the equipment orifice (5) until the chuck prevents it from entering further.

7.7 With one hand, raise the unloaded shaft (3) 15 cm to 20 cm (or greater if the spike is attached to part of the drip chamber) above the orifice (5) and with the other hand simultaneously introduce the blood bag port vertically from beneath the orifice until it can enter no further.

7.8 Holding the port securely in place within the orifice (by gripping the blood bag film adjacent to the port and without compressing the port sleeve), lower the shaft so that the spike is introduced into the port.

7.9 With the spike in the port and whilst continuing to hold the port as in 7.8, twist the shaft 5 times through 180°.

7.10 Assess if the spike has penetrated the port septum. If the septum has been completely penetrated record this on the worksheet (Annex B) at an insertion force of 20 N. If not, proceed to 7.11.

7.11 If the port septum has not been completely penetrated, lower the chuck so that it rests on the orifice with the blood bag suspended below the orifice.

7.12 Increase the loading (standard mass) on the shaft by 0,25 kg by placing the mass on the upper nut (2) which is in principle a clamp.

7.13 Repeat steps 7.7 to 7.9 and reassess whether the port septum has been completely penetrated. If so, record this on the worksheet at an insertion force of 22,5 N.

7.14 Repeat the process in step 7.12 and 7.13, increasing the loading by 0,25 kg increments until the port septum is completely penetrated and record the minimum force required to do so on the worksheet.

7.15 Carefully remove the blood bag port from the spike.

WARNING — Beware of the sharp spike.

7.16 With the shaft in position 7.7, release the used spike from the chuck and safely discard the spike and blood bag in accordance with laboratory waste disposal procedures.

7.17 Select a new blood bag port and spike and repeat the entire process from 7.2 to 7.14 for this second port/spike combination, recording the minimum insertion force on the worksheet.

7.18 Repeat step 7.15 and then steps 7.16 and 7.17 for the third and final port/spike combination.

NOTE If quantitative data is not required, the test can be abbreviated to a single test at 50 N.

8 Analysing results

8.1 Review the spike insertion forces recorded on the worksheet for each of the measurements obtained with the three combinations of spike/ port in Clause 7.

8.2 If all three results are identical report this value on the worksheet as the maximum spike insertion force and assess the outcome using the acceptance criteria in Clause 9.

8.3 If the three results are not identical, select and report the maximum insertion force and assess the outcome using the acceptance criteria in Clause 9. In this case also record the mean and minimum values obtained on the worksheet.

9 Guidance on interpretation of results

This guidance indicates typical 'state of the art' values that accord with published findings (see Reference [1]) and surveys concerning compatibility between blood bags and transfusion sets.

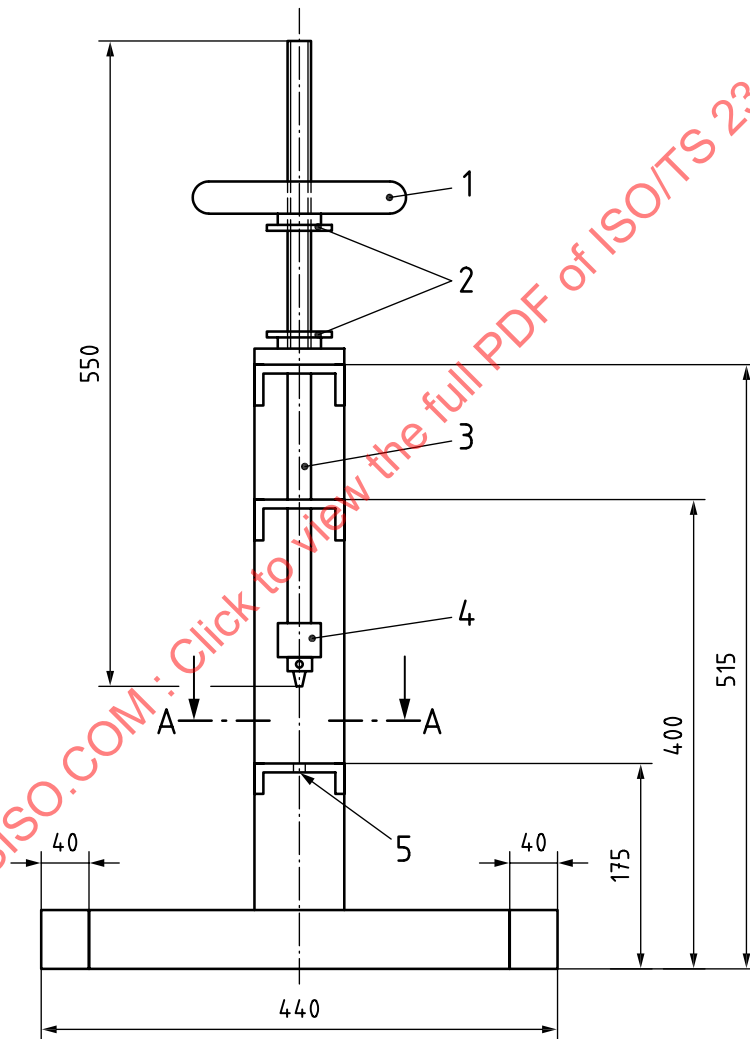
Compatibility forces between spikes and bloods bags are normally expected to be in the range of 20 N to 50 N.

Annexe A (normative)

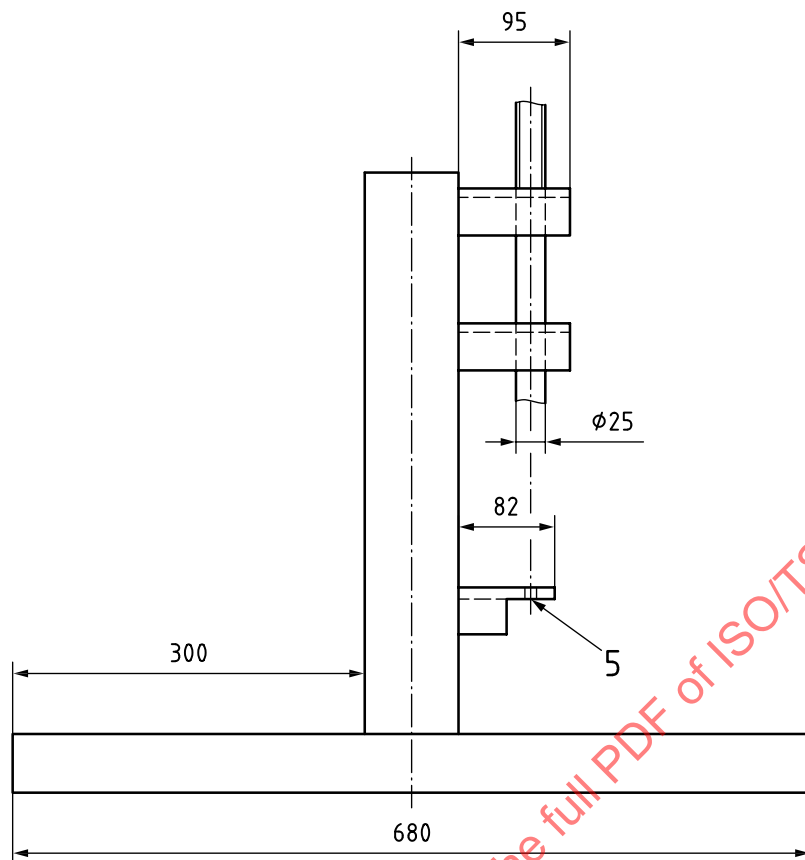
Insertion force test equipment measures

[Figure A.1](#) provides measures of the example of a suitable insertion force test equipment as shown in [Figure 2](#).

Dimensions in millimetres



a) Front view



b) Side view

