
**Aids for ostomy and incontinence —
Irrigation sets — Requirements and test
methods**

*Aides pour ostomie et incontinence — Dispositifs d'irrigation — Exigences
et méthodes d'essai*



Reference number
ISO 16391:2002(E)

© ISO 2002

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2002

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 16391 was prepared by Technical Committee ISO/TC 173, *Technical systems and aids for disabled or handicapped persons*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

...

Aids for ostomy and incontinence — Irrigation sets — Requirements and test methods

1 Scope

This International Standard specifies performance requirements and test methods for irrigation sets, used in colostomy care.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8670-2, *Ostomy collection bags — Part 2: Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply. Certain of these terms are illustrated in Figure 1.

3.1 belt

band of flexible material worn around the waist and secured to the pressure plate of drainage sleeve

3.2 colostomy

surgical opening, or stoma, created between the colon and surface of the body

3.3 connector

device that joins components of the irrigation set

3.4 drainage system

assembly of parts used to drain the colostomy, consisting of drainage sleeve, pressure plate, stoma hole, hook and belt

3.5 drainage sleeve

conduit to pass stomal effluent from the colostomy to a waste disposal container

3.6

flow controller

device that adjusts the flow rate of irrigation water

NOTE A flow controller is adjustable from the closed position to the fully opened position.

3.7

flow indicator

device that indicates the flow rate of the irrigation water

3.8

inflow system

assembly of parts used to introduce water into the colostomy, consisting of stoma adapter, connector, flow controller, flow indicator, tube, irrigation water bag, volume indicator, suspension and hanger

3.9

irrigation

introduction of water into the colon to be washed and discharged from faeces

3.10

irrigation set

assembly of all parts that are used during colostomy irrigation, consisting of inflow system and drainage system

3.11

irrigation water bag

bag that holds water for irrigation

3.12

pressure plate

device that secures the drainage sleeve on the abdomen and around the colostomy

3.13

stoma

abnormal opening established on the body surface

[ISO 8670-2]

3.14

stoma adapter

terminal part to be inserted into the stoma when irrigation water is transferred into the colon

3.15

test volume

volume of water that is added up to the maximum scale line indicated in the irrigation water bag when performing tests to verify the leakage and strength of the bag assembly

3.16

tube

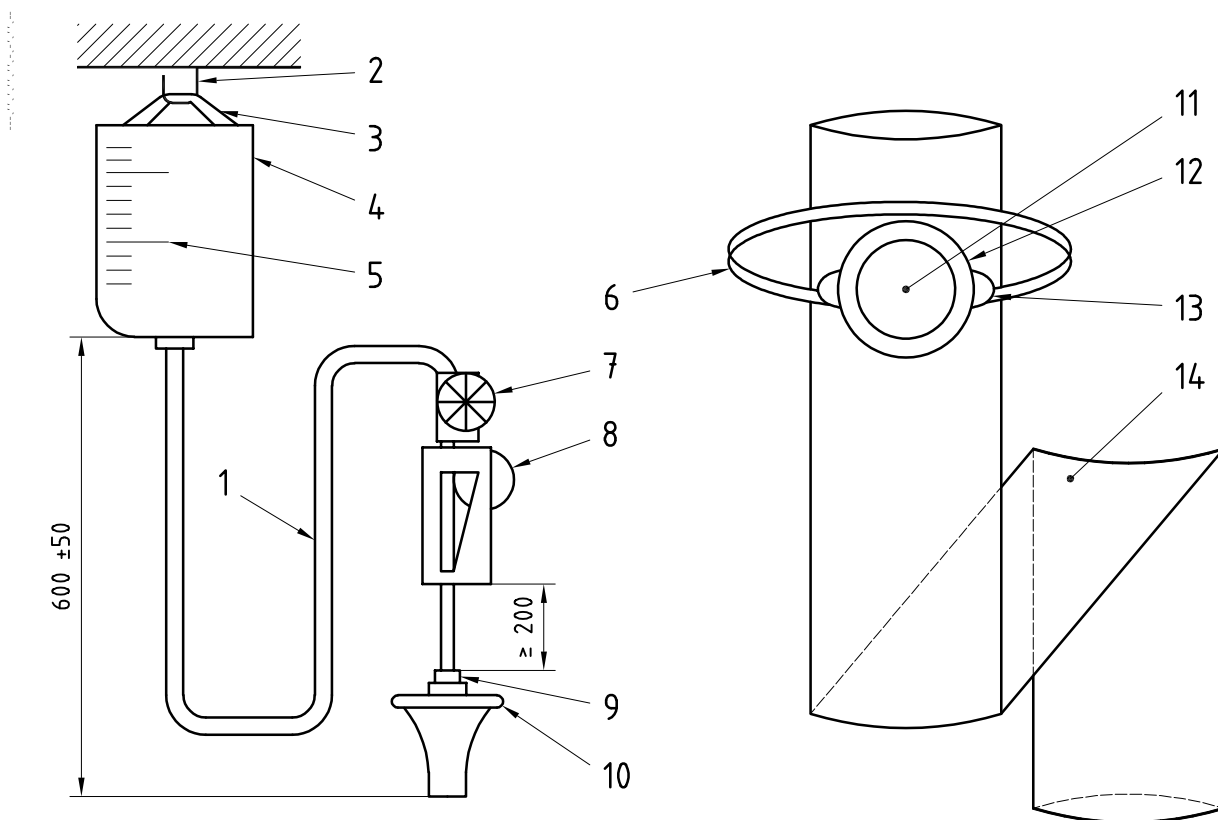
conduit which connects the irrigation water bag and the stoma adapter

3.17

volume indicator

scale lines that indicate approximate volume in the irrigation water bag

Dimensions in millimetres



Key

- | | | |
|------------------------|-------------------|--------------------|
| 1 Tube | 6 Belt | 11 Stoma hole |
| 2 Hanger | 7 Flow indicator | 12 Pressure plate |
| 3 Suspension | 8 Flow controller | 13 Hook |
| 4 Irrigation water bag | 9 Connector | 14 Drainage sleeve |
| 5 Volume indicator | 10 Stoma adapter | |

Figure 1 — Irrigation set — Inflow system (left) and drainage system (right)

4 Requirements

4.1 Accuracy of the volume indicator

When tested by the method given in 6.1, the difference in volume between any two lines of the volume indicator (3.17) shall not deviate from the actual measured difference by more than $\pm 15\%$ of the actual volume difference. The difference between the maximum indicated volume and the actual test volume (3.15) shall be less than 15 %.

4.2 Freedom from leakage

When tested by the method given in 6.2, the inflow system (3.8) of the irrigation set (3.10) shall not leak.

4.3 Flow controller

When tested by the method given in 6.3, the flow rate shall be not less than 200 ml/min.

4.4 Hanging strength of the irrigation water bag and its suspension system

When tested by the method given in 6.4, the irrigation water bag (3.11) and/or suspension shall not break.

4.5 Hanging strength of the belt hook and the pressure plate interface

When tested by the method given in 6.5, the belt (3.1) and/or pressure plate (3.12) shall not break.

4.6 Biological evaluation

When tested in accordance with ISO 10993-1, the irrigation set (3.10) shall be free from biological hazards.

5 General test conditions

5.1 Temperature

The standard testing temperature shall be $(23 \pm 2)^\circ\text{C}$. Condition the test specimens at this temperature for at least 1 h before testing.

The temperature of the coloured and uncoloured water reagent shall be $(37 \pm 2)^\circ\text{C}$ when added, and at least 32°C at the end of the test.

5.2 Reagent

5.2.1 Coloured water, comprising tap water coloured by the addition of 0,3 g/l of erythrosin (E127).

5.3 Test samples

Testing shall be carried out on product samples as supplied by the manufacturer to the end-user.

6 Test methods

6.1 Accuracy of the volume indicator

6.1.1 Principle

The irrigation water bag (3.11) is mounted vertically and filled with water to the line of the rated capacity. The volume of water accommodated by the bag is measured.

6.1.2 Apparatus

6.1.2.1 Two measuring cylinders, one of capacity 500 ml and one of minimum capacity 2 000 ml.

6.1.3 Procedure

With the flow controller (3.6) completely closed, fill the irrigation water bag (3.11) with water to the test volume line, and position the inflow system (3.8) of the irrigation set (3.10) in accordance with the manufacturer's instruction for use.

Measure the volume between every line of the volume indicator (3.17) using the 500 ml cylinder (6.1.2.1), and transfer the content of the cylinder into the 2 000 ml cylinder (6.1.2.1) between each measurement. When the water bag is empty, read the total volume on the 2 000 ml cylinder.

6.1.4 Test report

The test report shall contain the general information specified in clause 7, together with the volumes measured between lines and the maximum volume.

6.2 Freedom from leakage

6.2.1 Principle

Coloured water is added to the inflow system (3.8) of the irrigation set (3.10), which is maintained in a vertical position. The irrigation set is examined for leakage.

6.2.2 Procedure

Position the inflow system (3.8) vertically with the stoma adapter (3.14) plugged and the flow controller (3.6) fully open. Fill the bag through the filling port with coloured water (5.2.1) with the total test volume determined in 6.1. Ensure that air is not incorporated.

Visually inspect the inflow system for leakage after 30 min. If leakage is observed, discontinue the test.

Close the flow controller completely. Unplug the stoma adapter.

Visually inspect the inflow system for leakage after 30 min. If leakage is observed, discontinue the test.

6.2.3 Test report

The test report shall contain the general information specified in clause 7, together with a statement detailing where leakage was observed, if any.

6.3 Flow controller

6.3.1 Principle

The volume of water that flows through the irrigation set at a determined height and time is measured.

6.3.2 Apparatus

6.3.2.1 Measuring cylinder, with a capacity above 500 ml.

6.3.2.2 Stopwatch, or similar timing device.

6.3.3 Procedure

Close the flow controller (3.6) in the irrigation set (3.10).

Hang the irrigation water bag in vertical position and fill it to the total test volume determined in 6.1 with coloured water (5.2.1).

Position the stoma adapter (3.14) so that its tip is (600 ± 50) mm below the bottom of the irrigation water bag (3.11).

Open the flow controller to the full position.

Using the measuring cylinder (6.3.2.1), measure the amount of water discharged over a period of 1 min.

6.3.4 Test report

The test report shall contain the general information specified in clause 7, together with the measured flow rate (see 6.3.3) in litres per minute.

6.4 Hanging strength of the irrigation water bag and its suspension system

6.4.1 Principle

The irrigation water bag is hung in accordance with the manufacturer's instructions for use, and a force is applied to the bag in a downward direction.

6.4.2 Procedure

Hang the irrigation water bag in a vertical position. Apply a force of 49 N to the lower end of the bag in a downward direction for 30 min. Examine the irrigation water bag for visible damage or breakage. If damage or breakage occurs, discontinue the test.

An 8 mm diameter steel wire is recommended as hanger.

NOTE The force applied is equivalent to a mass of 5 kg.

6.4.3 Test report

The test report shall contain the general information specified in clause 7, together with a statement detailing where any visible damage or breakage was observed.

6.5 Hanging strength of the belt hook and the pressure plate interface

6.5.1 Principle

The belt hook is connected to the plate interface and a force is applied for 30 min. The belt hook and pressure plate (3.12) are then inspected for visible damage or breakage.

6.5.2 Procedure

Hook the belt (3.1) to the pressure plate (3.12) and place it in a vertical position.

Fix the plate, and attach a force of 49 N to the lower end of the belt in a downward direction for 30 min.

NOTE The force applied is equivalent to a mass of 5 kg.

Inspect the belt hook and vertical plate for visible damage or breakage.

6.5.3 Test report

The test report shall contain the general information specified in clause 7, together with a statement detailing where any visible damage or breakage was observed.

6.6 Biological evaluation

6.6.1 Principle

All parts of the inflow system (3.8) which come into contact with the irrigation water are tested with respect to biological hazards in accordance with the ISO 10993 series.

6.6.2 Selection and performance of tests

Select the appropriate tests in accordance with ISO 10993-1. Carry out the selected tests, identified in ISO 10993-1.

NOTE ISO 10993-1 identifies test methods for different features of the product/material.

6.6.3 Test report

The test report shall contain the general information specified in clause 7, together with biological safety data of each part of the inflow system (3.8) of the irrigation set (3.10).

7 Test report

The test report shall contain the following information:

- a) reference to this International Standard, i.e. ISO 16391;
- b) complete identification of the irrigation sets tested;
- c) date and place of testing;
- d) number of irrigation sets tested;
- e) test results as specified in 6.1.4, 6.2.3, 6.3.4, 6.4.3, 6.5.3 and 6.6.3.

1

ICS 11.180

Price based on 7 pages

© ISO 2001 – All rights reserved