INTERNATIONAL STANDARD

ISO 8670-2

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Ostomy collection bags —

Part 2:
Determination of freedom from leakage

Poches de recueil pour stomie —

Partie 2: Détermination de l'absence de fuites

Reference number
ISO 8670-2:1991(E)

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.

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.

International Standard ISO 8670-2 was prepared by Technical Committee ISO/TC 173, *Technical systems and aids for disabled or handicapped persons*, Sub-Committee SC 3, *Aids for ostomy and incontinence*.

ISO 8670 consists of the following parts, under the general title *Ostomy collection bags*:

— *Part 1: Vocabulary*

— *Part 2: Determination of freedom from leakage*

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Ostomy collection bags —

Part 2:
Determination of freedom from leakage

1 Scope

This part of ISO 8670 specifies a method of determining the freedom from leakage of water from ostomy collection bags. The method tests for leakage from joints and seams, for leakage through the film of which the bag is constructed, for leakage from junctions between the parts of multiple piece systems and for leakage from urostomy drain closures.

The method does not test for leakage from the closure system of open-ended bags, from vents, filters, vent or filter plugs, or from the interface between the patient's skin and the appliance. Nor is leakage from capillary action through microporous tape, if used, regarded as leakage in this test.

NOTE 1 Other methods for leakage detection will examine aspects other than those covered by this part of ISO 8670.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 8670. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8670 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8670-1:1988, *Ostomy collection bags — Part 1: Vocabulary*.

3 Definitions

For the purposes of this part of ISO 8670, the definitions given in ISO 8670-1 apply.

4 Principle

The bag is filled with coloured water and positioned horizontally to wet all internal surfaces. It is then suspended vertically and inspected visually for leakage.

5 Atmosphere for testing

Test temperature 23 °C ± 2 °C shall be used for testing.

6 Apparatus and fluid

6.1 Rigid transparent plate, e.g. glass, having a hole of 8 mm diameter to allow filling of the bag, the plate being large enough to support the whole of the bag in the horizontal position.

6.2 Test liquid, consisting of tap water at 23 °C ± 3 °C containing 0,1 g/l methylene blue.

6.3 Device(s) for sealing all openings not to be tested.

6.4 Adhesive or clamp.

7 Procedure

7.1 Seal all openings not to be tested. Attach the bag to the transparent plate by adhesive, and/or adhesive tape, and/or a clamp. A sealing material may be used around the opening for the stoma and the plate. If there is no precut opening for the stoma,

cut a centrally placed hole of 10 mm diameter. The hole of the bag is to be positioned concentrically around the hole in the plate.

NOTE 2 Ostomy bags vary in design of the means of attachment to the body. Difficulties may be encountered in attaching certain bags to the transparent plate in a manner which is strong and leak-free. For such bags more than one means of attachment may be necessary.

7.2 If the bag is a urostomy bag fitted with a drain closure, initially operate the closure ten times as follows. Pour test liquid into the bag and open and close the drain ten times ensuring that test liquid is present in the bag during the whole operation.

7.3 No matter whether a non-return valve is present or not, pour the test liquid into the bag through the inlet hole until liquid reaches the level of the bottom of the hole.

7.4 Close the inlet hole and dry the surface of the bag assembly, if any spillage has occurred. Position the bag assembly horizontally with the transparent plate underneath. Leave undisturbed for 17 h ± 1 h, and then visually inspect for leakage. Discontinue the test if leakage has occurred at any spot specified to be under test in this International Standard.

7.5 Reposition the same bag assembly in a vertical position, and leave undisturbed for 4 h. Then visually inspect for leakage, disregarding leakage from the sources not specified to be under test in this International Standard.

8 Test report

The test report shall include the following information:

a) a reference to this part of ISO 8670;

b) identity of the bag tested;

c) the test result;

d) the date and place of testing.