
Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components

Implants pour neurochirurgie — Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie



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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.

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 7197 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 3, *Neurosurgical implants*.

This second edition cancels and replaces the first edition (ISO 7197:1989), which has been technically revised.

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Introduction

A hydrocephalus shunt system typically consists of three basic elements: (1) an inflow (proximal) catheter, which drains cerebrospinal fluid (CSF) from the ventricular system, lumbar subarachnoid space or extraventricular CSF space and transmits it to (2) a valve which regulates the differential pressure or controls flow through the system, and (3) an outflow (distal) catheter which drains CSF into the cardiovascular system, the peritoneal cavity or other suitable drainage site. In addition, specialized accessory devices, such as reservoirs, siphoning-preventing devices and on-off valves and filters, are added at the discretion of the physician to modify performance or adapt the basic system to the particular needs of the patient.

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Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components

1 Scope

This International Standard specifies requirements for sterile, single-use hydrocephalus shunts and components.

This International Standard is applicable to but is not limited to:

- a) complete sterile, single-use hydrocephalus shunts of the one-piece type; or
- b) complete sterile, single-use hydrocephalus shunts of the multipiece type, supplied either assembled by the manufacturer or in kit form for assembly by the physician; or
- c) sterile, single-use shunt components which (individually or in combination) comprise shunt assemblies, for example: valves, valved catheters (catheter with integral valves), inflow or outflow catheters (such as arterial, peritoneal, ventricular catheters), connectors, implantable accessory devices (such as siphoning-preventing devices, measuring devices and reservoirs/priming devices).

2 Normative references

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

ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests*.

ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*.

ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*.

ISO 11138-3:1995, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization*.

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

ASTM F640:1979, *Standard Test Method for Radiopacity of Plastics for Medical Use*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 accessory device

Component of a hydrocephalus shunt designed to perform a specific additional function (i.e. on-off valve, siphoning-preventing device, measuring device, reservoirs, connectors, retaining clips and filters).

3.2 adjustable or programmable valve

Valve with multiple functional ranges that can be set prior to or after implantation.

3.3 chambered valve

Component of a hydrocephalus shunt containing one or more valve mechanisms separated by a compartment that may be designed to allow pumping of the fluid through the shunt or accessing to the shunt.

3.4 closing pressure

Inlet pressure at which the valve closes to prevent further flow.

3.5 connector

Device intended for the joining and fixation of implantable shunt components.

3.6 environmental pressure

External pressure exerted on the valve or accessory components to mimic local tissue pressure *in vivo*.

3.7 fluid compartment

Portion of the central nervous system (CNS) including the ventricles and extraventricular structures such as subarachnoid fluid collections, cysts, hygromas and syringes.

3.8 functional range

Representative pressure/flow characteristics of a shunt or shunt element.

NOTE This is usually expressed in graphical form.

3.9 hydrocephalus

State of excessive accumulation of cerebrospinal fluid (CSF) within the ventricular system of the head due to a disturbance of secretion, flow or absorption.

3.10 hydrocephalus shunt

One-piece device or multi-piece device or combination of devices intended to be surgically implanted in the body of a patient with hydrocephalus or other disturbance of the CSF circulation and designed to divert CSF from a fluid compartment in the CNS to a internal delivery site in another part of the body or an external collection site (external shunt), for the purpose of diminishing elevated intracranial pressure (ICP) or CSF volume.

3.11 one-piece hydrocephalus shunt assembly

One-piece complete single-use hydrocephalus shunt assembled by the manufacturer, typically consisting of an inflow catheter, pressure-activated flow-controlling device or combination of devices and an outflow catheter and/or accessory devices.

3.12 inflow catheter; proximal catheter

Part of a hydrocephalus shunt that is inserted into the cerebral ventricles or any other site in the craniospinal axis to provide access to a fluid compartment of the CNS (for example, into a lateral ventricle) and therefore constitutes the inflow pathway for the diversion of fluid through a shunt system.

3.13 inlet pressure

Hydrostatic pressure at the inlet of the valve or active component.

3.14 magnetic compatibility

Characteristic of a device which can be used in environmental magnetic and electromagnetic fields of daily life without affecting the patient and/or shunt function.

3.15 magnetic resonance (MR) compatibility

Characteristic of a device which can be used in diagnostic devices using magnetic resonance techniques without affecting the patient and/or shunt function.

NOTE Adverse effects of three main types may arise from lack of compatibility:

- a) displacement of the device or device's components leading to device migration, dysfunction or change in function due to high magnetic fields;
- b) local tissue damage because of induced currents and/or temperature rise;
- c) appreciable degradation of diagnostic images.

3.16 multipiece hydrocephalus shunt assembly

Complete sterile, single-use hydrocephalus shunt, supplied either assembled by the manufacturer or in kit form for assembly by the physician, typically consisting of an inflow catheter, pressure-activated flow-controlling device or combination of devices and an outflow catheter with requisite connectors and/or accessory devices required for assembly.

3.17 on-off device

Accessory device that closes or opens the shunt system by external manipulation.

3.18 opening pressure

Inlet pressure required to initiate flow through the valve.

3.19 outflow catheter; distal catheter

Part of a hydrocephalus shunt assembly which provides an outflow pathway for the diversion of fluid from a compartment of the central nervous system to the peritoneal cavity, venous circulation or other internal or external delivery site.

3.20 outlet pressure

Hydrostatic pressure at the outlet of the valve or active components.

3.21 preassembled junction (non-modifiable junction)

Portion of a hydrocephalus shunt assembly which is assembled at the time of manufacture and is intended to be permanently fixed and not modified during a surgical procedure.

Example The site where the valve is chemically bonded to tubing is a preassembled junction.

3.22 pressure

Pressure relative to the actual ambient atmospheric pressure.

3.23 reflux

Flow of fluid within a hydrocephalus shunt towards the inflow catheter.

3.24 shunt (noun)

See hydrocephalus shunt

3.25 shunt (verb)

Act of draining CSF from the CNS.

3.26 shunt filter

Accessory device, intended to remove particulate matter from the CSF before it passes through the shunt, and designed to prevent the spread of neoplastic cells into the peritoneum or cardiovascular system following a shunting procedure.

3.27 siphoning-preventing device

Device or component of device designed to prevent reflux due to differential pressure across the shunt system occurring when the position of the patient changes from horizontal to vertical, or the reverse.

3.28 test specimen

Device, or sample of devices, representative of the population of devices.

3.29 tip valve

Outflow catheter that includes the functions of the valve.

3.30 valve

Element of a hydrocephalus shunt that (a) is intended to resist reflux and (b) functions to control the relationship between pressure and flow of cerebrospinal fluid.

NOTE Valve constructions may be based on different principles, e.g. diaphragm valve, ball-cone valve, slit valve, needle valve.

4 General requirements for hydrocephalus shunts and accessory devices**4.1 Physical requirements****4.1.1 Surface finish**

When examined with normal or corrected vision at a distance of 300 mm to 450 mm and at an illuminance of $2150 \text{ lx} \pm 215 \text{ lx}$, the surface of shunts and accessory devices that have passed through all stages of manufacture, including sterilization, shall be smooth and free from irregularities, flash, moulding and extrusion defects, and extraneous particles.

4.1.2 Radiopacity

All external parts of the shunt or accessory device shall be radiopaque or shall carry radiopaque markers.

Tests shall be carried out in accordance with ASTM F640.

4.2 Mechanical requirements**4.2.1 General**

For any given accessory device and, where appropriate, the manufacturer shall subject device(s) (test specimens) to tests of those mechanical properties which are pertinent to its intended performance.

4.2.2 Resistance to breakage of preassembled junctions

Preassembled junctions shall not break by subjecting a test specimen to an axial force of 10 N for 1 min, unless otherwise indicated by the manufacturer.

4.2.3 Leaktightness

Non-modifiable junctions of a test specimen of the assembly shall be leaktight when subjected to water pressure of 12 kPa for 5 min. Modifiable junctions shall have the same leaktightness properties as non-modifiable junctions (assembled according to the manufacturer's instructions) when tested in a similar manner.

NOTE Leakage is defined as greater than 0,025 ml of test fluid escaping from the test specimen during the test period.

4.2.4 Opening and closing pressure

If opening and/or closing pressure is specified by the manufacturer as part of the functional range of the hydrocephalus valve, testing shall be carried out according to 5.1.

4.2.5 Reflux

If reflux prevention is declared by the manufacturer as part of the functional range of the hydrocephalus valve, testing shall be carried out according to 5.4.

4.2.6 Pressure/flow characteristics

The manufacturer shall provide the functional range for each design of valve, as determined by tests in accordance with 5.3.

Sufficient valve samples shall be tested to establish the statistical confidence level for reproducibility of the pressure/flow characteristics.

4.2.6.1 Connectors and mounting clamps

If additional connectors or mounting clamps are supplied for use in conjunction with valves and catheters with integral valves, the properties of the connectors shall be such that the flow through the shunt with the connections in place shall not, when tested according to 5.3, differ by more than 5 % or more than 5 mmH₂O from the values determined for the shunt without the additional connectors in place.

If the difference is greater, the manufacturer shall state the pressure/flow characteristics when the connector is in place.

4.2.6.2 Other components

Specialized components of shunt systems include but are not limited to reservoirs, siphoning preventing devices, filters and CSF access ports. In addition to the general requirements of 4.1 and 4.2, such specialized accessory devices of shunts shall not increase the resistance of the shunt by more than 10 %, otherwise such changes shall be stated.

4.2.7 Long-term functional stability

Valves and accessory devices shall maintain their functional range when tested according to 5.5.

4.3 Biocompatibility

Hydrocephalus shunts and components shall be demonstrated to be biocompatible when assessed according to the principles and methods recommended in 10993-1.

4.4 Sterilization

Shunt systems shall be sterilized according to ISO 11135, ISO 11137 and/or ISO 11138-3.

4.5 Type and size designation

For each designed type and size of shunt, the manufacturer shall provide the following information:

- a) function of the valve/catheter (e.g. inflow, outflow, etc.);
- b) type of valve;
- c) nominal overall length of component expressed in millimetres;
- d) nominal inside and outside diameters, expressed in millimetres, of the tubular portions of the component at connection points.

5 Test methods

5.1 General

The test shall be carried out on shunts or accessory devices that have passed through all stages of manufacture, including sterilization but not previously implanted and within the manufacturer's indicated "Use before" date, and, in the case of multipiece complete shunts, that have been assembled in accordance with the manufacturer's instructions.

5.2 Reference test method for opening and closing pressures

5.2.1 Scope

This test defines a method whereby the opening and closing pressures of any valve can be evaluated.

5.2.2 Principle

This test is intended:

- a) to provide a manufacturer with a means to collect data to determine the opening and closing pressures of a particular design of valve.
- b) as a type-test to verify that the opening and/or closing pressure of an individual valve is within the manufacturer's specification.

Alternative methods for determining the opening and closing pressures of the hydrocephalus valve may be used and may include pressure-drop detection (proximal or distal), an electronic balance or a proximal pressure transducer/manometer.

For distal slit valves, the valve shall be submerged and a proximal method of detection of the opening and closing pressures shall be used.

5.2.3 Reagents

5.2.3.1 Test fluid, consisting of deaerated and deionized or distilled water at $(37 \pm 2) ^\circ\text{C}$.

5.2.4 Apparatus

5.2.4.1 Test rig, as shown in figure 1, or a similar circuit comprising the following elements:

- a) pump, capable of maintaining a flowrate of 20 ml/h;
- b) water bath, at $(37 \pm 2) ^\circ\text{C}$ with a means of maintaining the water level constant within ± 2 mm;
- c) means of connecting the shunt or shunt component to the test rig without occluding inflow aperture(s);
- d) connecting tubing with an internal diameter consistent with tubings specified for use with the test specimen (see note 1);
- e) manometer, consisting of a water column open to air, graduated in millimetres, having a diameter of 2,5 mm and capable of being read to an accuracy of 0,5 mm (see note 2).

NOTE 1 This should include a coiled portion of sufficient length that, when immersed in the water bath, the test fluid (5.2.3.1) will reach a temperature of $(37 \pm 2) ^\circ\text{C}$ during its passage through the tubing.

NOTE 2 The reading of the manometer, h , expressed in millimetres, is converted to the pressure, p , expressed in pascals, using the following equation: $p = 9,81h$.

5.2.5 Procedure

5.2.5.1 Prepare the test specimen by performing all pre-use steps included in the manufacturer's instructions for use.

5.2.5.2 Prefill and soak the test specimen in the test fluid for a sufficient period of time to reach a state of equilibrium.

5.2.5.3 Connect the test specimen to the measuring system in such a manner as to minimize the introduction of air into the liquid pathway of the test system.

5.2.5.4 Purge all air from the liquid pathway of the test specimen and the test rig according to the manufacturer's recommendations.

5.2.5.5 Zero the pressure level of the manometer by adjusting its position so that the level of meniscus in the manometer is level with the zero graduation mark (see figure 1). The outlet of the distal catheter shall be level with the surface of the water bath.

5.2.5.6 Switch the pump on at a flowrate of 20 ml/h.

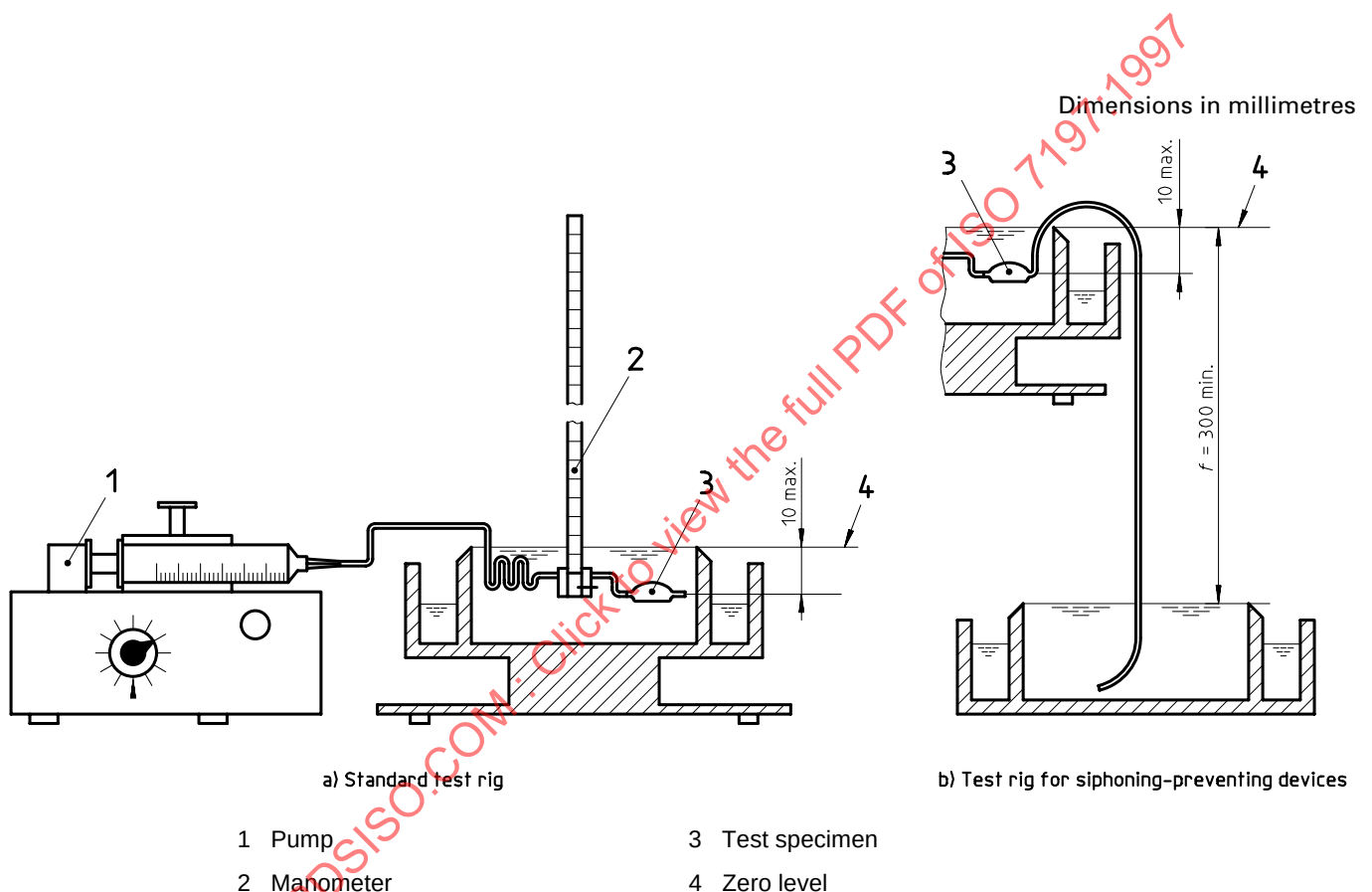


Figure 1 — Example of a test rig for determining opening and closing pressures and influence of outlet pressure

5.2.5.7 Observe the water column rise in the manometer. Record as the opening pressure the level at which the water column starts to fall.

5.2.5.8 Wait for the pressure in the manometer to stabilize and switch off the pump.

5.2.5.9 Record the pressure to which the meniscus in the manometer falls and stabilizes as closing pressure.

5.2.5.10 Repeat 5.2.5.6 to 5.2.5.9 at least six times.

5.2.5.11 For adjustable valves, repeat steps 5.2.5.6 to 5.2.5.10 for a range of representative levels including the lowest and the highest for all adjustable levels specified by the manufacturer.

5.2.5.12 For all devices specified by the manufacturer to be siphoning-preventing, the test rig shall be modified as shown in figure 1 b), with the dimension f between the water levels having a minimum value of 300 mm. Repeat steps 5.2.5.6 to 5.2.5.10 and record the value of f .

NOTE If resistance to outlet pressure is declared by the manufacturer to be dependent upon gravitational alignment, then care should be taken to ensure proper orientation of the valve within the water bath.

5.2.6 Expression of results

5.2.6.1 Calculate the mean opening and closing pressures of all replicate test shunts and accessory devices. Record the lowest and highest individual values and the standard deviations.

5.2.6.2 For adjustable valves, repeat 5.2.6.1 for a range of representative levels, including the lowest and highest settings specified by the manufacturer.

5.2.6.3 For siphoning-preventing devices, repeat 5.2.6.1 for the opening and closing pressures determined with the influence of a difference in fluid levels of 300 mm minimum.

5.2.7 Test report

The test report shall include the following information:

- a) the identity of the type of shunt or shunt component;
- b) all results from 5.2.6.1, 5.2.6.2 and 5.2.6.3, but in the latter state the difference in level f in millimetres.

5.3 Reference test method for determining functional range

5.3.1 Scope

A method is defined whereby the functional range of any valve can be evaluated by determining its pressure/flow characteristics.

Results can be used to define a graph representing the pressure/flow characteristics of a shunt or shunt component. From the individual pressure/flow data obtained, a composite graph can be plotted that describes the functional range characteristics of the product.

5.3.2 Principle

Test fluid is pumped at a number of constant rates through the test specimen, and the resultant resistive pressure is measured.

The test is intended:

- a) to provide a manufacturer with a means to collect data to determine the functional range of a particular design of valve;
- b) as a type-test to verify that the performance of an individual hydrocephalus shunt, valve, or accessory device is within the manufacturer's stated functional range.

Other methods of equal or better precision may be used, but in cases of dispute the method given in this clause shall be the reference method.

5.3.3 Reagents

5.3.3.1 Test fluid, as specified in 5.2.3.1.

5.3.4 Apparatus

5.3.4.1 Test rig, as specified in 5.2.4.1.

5.3.5 Procedure

5.3.5.1 Prepare the test specimen by performing all pre-use steps included in the manufacturer's instructions for use.

5.3.5.2 Prefill and soak the test specimen in the test fluid for a sufficient period of time to reach a state of equilibrium.

5.3.5.3 Connect the test specimen to the test rig (as shown in figure 1) in such a manner as to minimize the introduction of air into the liquid pathway of the test system.

5.3.5.4 Purge all air from the liquid pathway of the test specimen and the test rig according to the manufacturer's instructions.

5.3.5.5 Zero the pressure level of the manometer by adjusting its position so that the level of the meniscus in the manometer is level with the zero graduation mark (see figure 1). The outlet of the distal catheter shall be level with the surface of the water bath.

5.3.5.6 Adjust the pump speed to provide a flowrate of 60 ± 5 ml/h. Allow the test system to equilibrate until the change in pressure does not exceed 0,08 kPa over a period of 10 min.

5.3.5.7 Readjust the pump speed and read the manometer pressure level at the following flowrates after stabilization; 50 ml/h, 30 ml/h, 20 ml/h, 10 ml/h and 5 ml/h, in order of diminishing flowrates, then readjust the pump speed in a series of increasing flowrates at the same settings.

5.3.5.8 For adjustable valves, repeat steps 5.3.5.6 to 5.3.5.7 for all functional range settings specified by the manufacturer.

5.3.5.9 For siphoning-preventing devices, repeat steps 5.3.5.6 to 5.3.5.7 with the influence of a minimum of 300 mm difference in outlet level.

NOTE If resistance to outlet pressure is declared by the manufacturer to be dependent upon gravitational alignment, then care should be taken to ensure proper orientation of the valve within the water bath.

5.3.5.10 Repeat steps 5.3.6.1 to 5.3.6.9 for each test specimen using the same flowrates.

5.3.6 Expression of results

5.3.6.1 Determination of functional range of shunts or accessory devices

5.3.6.1.1 Calculate the mean pressure for all replicate test shunts or shunt components at a flowrate of 50 ml/h. Record the lowest and the highest individual pressures. Repeat this calculation for each of the four remaining flowrates.

5.3.6.1.2 Construct a graph of flowrate (expressed in millilitres per hour) against pressure (expressed in kilopascal) showing the average, lowest and highest pressures at each of the chosen flowrates.

NOTE The pressure may additionally be expressed in millimetres of water.

5.3.6.1.3 A composite graph shall be derived that is representative of the device population tested.

5.3.6.1.4 Representation of this composite graph shall show the typical minimum and maximum data points for each flowrate.

5.3.6.2 Verification of functional range of shunts or accessory devices

5.3.6.2.1 Calculate the mean pressure for all replicate test shunts or shunt components at a flowrate of 50 ml/h. Record the lowest and highest individual pressures. Repeat this calculation for each of the four remaining flowrates.

5.3.6.2.2 Compare the high, low and average pressure levels at each flowrate to the functional range specifications provided by the manufacturer, in accordance with 5.3.6.1.

5.3.7 Test report

The type test report shall include the following information:

- a) identity of the type of shunt or accessory device;
- b) functional range of the type of shunt or accessory device as provided by the manufacturer.
- c) graph of the pressure/flow performance characteristics as determined by type-testing (5.3.7.2).
- d) a statement indicating whether the performance of the individual shunt or accessory device lies within the functional range for the design (i.e. whether the values of $p_{\min}$ 5 ml/h and $p_{\max}$ 50 ml/h are higher and lower, respectively, than the corresponding values determined by type-testing as stated by the manufacturer);

5.4 Reference test method for reflux

5.4.1 Principle

The hydrocephalus valve is filled with liquid and hydrostatic pressure is applied in an attempt to induce reflux.

Other methods of equal or better precision may be used, but in cases of dispute the method given in this clause shall be the reference method.

5.4.2 Reagent

5.4.2.1 Test fluid, as specified in 5.2.3.1.

5.4.3 Apparatus

The test apparatus is shown in figure 2 a) for chambered valves and figure 2 b) for tip valves. The following equipment is also required.

5.4.3.1 Connecting tubing and connectors.

5.4.3.2 Tubing clamps.

5.4.3.3 Clock or stopwatch.

5.4.4 Procedure

5.4.4.1 Testing of chambered valves

If necessary, detach the chambered valve(s) from the shunt or shunt component. Connect lengths of tubing to both ends of the valve under test. Arrange the valve as shown in figure 2 a). Fill the assembly with test fluid, removing all air. Position the valve so that the outlet end is uppermost and press the valve chamber repeatedly until a meniscus forms in the tubing at a distance of 10 mm, 50 mm, and 500 mm above the valve, or fill the tubing using a syringe. Remove the inlet tubing from the test fluid and place it at the level of the valve unit. Stop pressing and observe the

meniscus for 1 min. If it does not remain static, measure the reflux volume issuing from the inlet tubing. No more than 0,1 ml shall reflux in 5 min at each of the specified test pressures.

5.4.4.2 Testing of tip valves

If necessary, detach the tip valve from the shunt or shunt component. Arrange the test valve as shown in figure 2 b). Hold the valve and associated tubing vertically and fill it with test fluid, keeping the outlet end under the liquid surface. Lower the inlet end of the tubing to a distance of 10 mm, 50 mm, and 500 mm below the level of the liquid in the vessel. Observe the inlet end of the tubing for 1 min at each position. If leakage occurs, measure the volume of fluid issuing from it over a 5-min period. No more than 0,1 ml may reflux in 5 min at each of the specified test pressures.

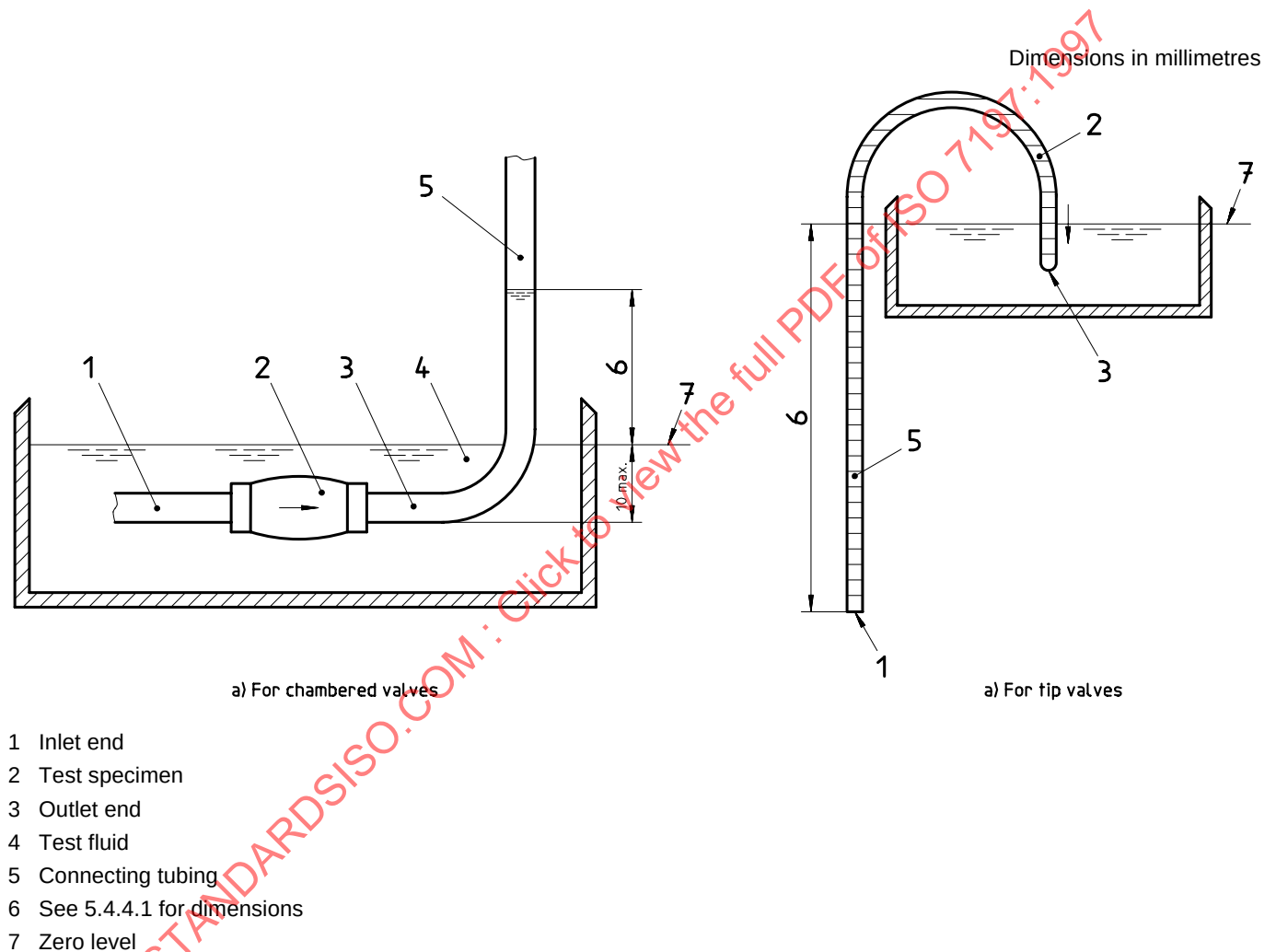


Figure 2 — Configuration for testing valves for freedom from reflux

5.5 Test for long-term functional stability

5.5.1 Scope

A method is defined whereby any shunt, valve or accessory device can be evaluated for long-term functional stability.

5.5.2 Principle

In order to simulate aging, test fluid is pulsed through the test sample for sufficient time to determine if the functionality of the test specimen is compromised due to long-term usage.

5.5.3 Reagents

5.5.3.1 Test fluid, as specified in 5.2.3.1.

5.5.4 Apparatus

5.5.4.1 Test rig (see figure 3), comprising the following elements:

- a) variable-speed pulsatile pump capable of maintaining, within $\pm 5\%$, the selected pumping rate while providing pulses at a frequency of $1 \text{ Hz} \pm 0,5 \text{ Hz}$ (see note 1 below);
- b) flowmeter, graduated in millilitres per hour;
- c) water bath, capable of being controlled at $37^\circ\text{C} \pm 2^\circ\text{C}$;
- d) means of connecting the shunt or component to the test rig without occluding inflow aperture(s);
- e) pump tubing of dimensions to produce the selected flowrate;
- f) silicone elastomer connecting tubing (see note 2 below);
- g) manometer, graduated in kilopascals (kPa), (mmHg or cmH₂O), or electrical pressure transducer.

NOTE 1 A multiple-roller peristaltic pump is suitable.

NOTE 2 This should include a coiled portion of sufficient length that, when immersed in the water bath, the test fluid (5.5.3.1) will reach a temperature of $37^\circ\text{C} \pm 2^\circ\text{C}$ during its passage through it.

5.5.5 Procedure

5.5.5.1 Soak the test specimen in the test fluid (5.5.3.1) at $37^\circ\text{C} \pm 2^\circ\text{C}$ for at least 24 h, maintaining the temperature by means of the water bath [5.5.4.1 c)].

5.5.5.2 Top up the test fluid vessel in the water bath with test fluid, and bring the contents to $37^\circ\text{C} \pm 2^\circ\text{C}$.

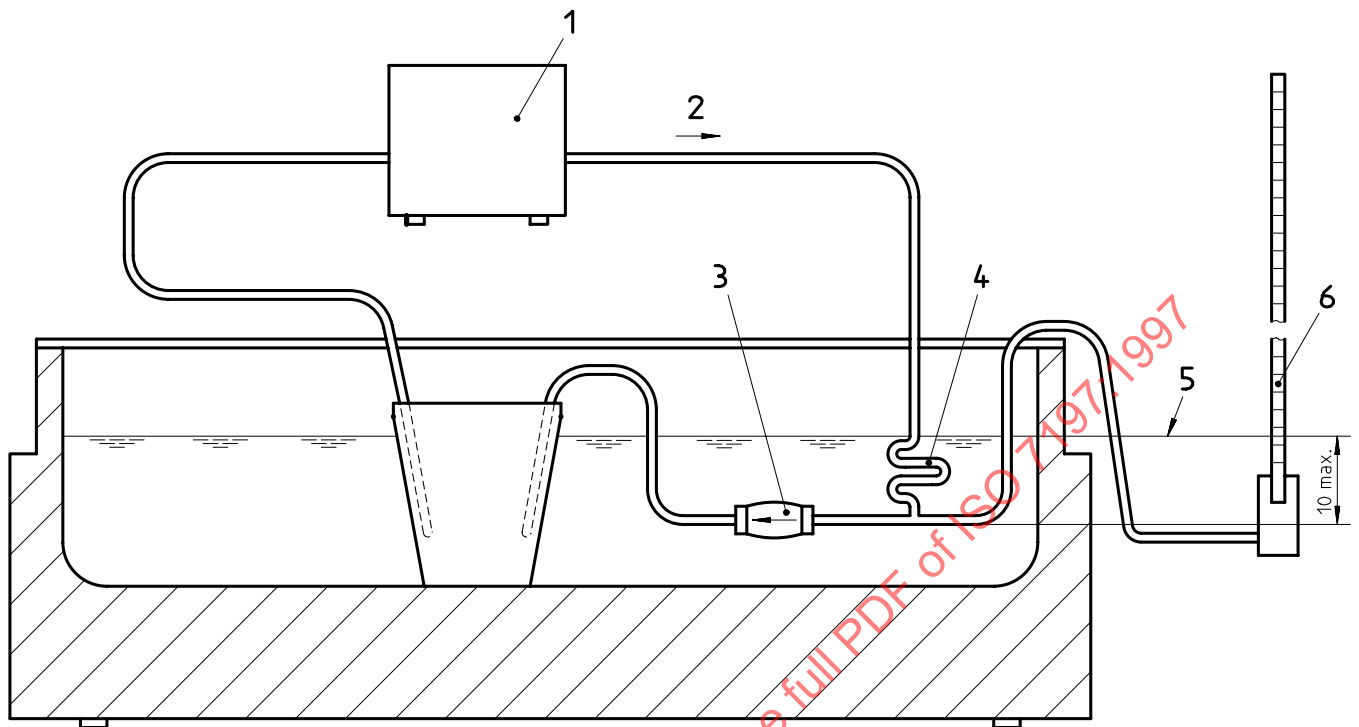
5.5.5.3 Purge all air from the liquid pathway of the test system according to the manufacturer's instructions.

5.5.5.4 Connect the test specimen as shown in figure 3, taking care not to introduce air into the liquid pathway of the test system.

5.5.5.5 Zero the manometer [5.5.4.1 g)] by adjusting its position so that the level of the meniscus in the manometer is level with the zero graduation mark or, if an electrical transducer is used, set the zero reading.

5.5.5.6 Start the pump [5.5.4.1 a)] and adjust to a flowrate of between 5 ml/h and 15 ml/h greater than the flowrate selected for the test (see 5.5.5.7) and a pulse rate of $1 \text{ Hz} \pm 0,5 \text{ Hz}$. Allow the flowrate to stabilize.

Dimensions in millimetres



- 1 Pump
- 2 Flow direction
- 3 Test specimen
- 4 Warm-up loop
- 5 Zero level
- 6 Manometer

Figure 3 — Example of test rig for determination of long-term functional stability

5.5.5.7 Adjust the pump to give a flowrate, as shown by the flowmeter [5.5.4.1 b)], either of a value selected from the upper quartile of the range of flowrates for the shunt or component stated by the manufacturer, or (if no data are available) of 50 ml/h. Maintain a pulse rate of $1 \text{ Hz} \pm 0,5 \text{ Hz}$. When the flowrate has stabilized, record the manometer reading.

5.5.5.8 Operate the pump at the rate described in 5.5.5.7 continuously for 28 days. Check the flow and pulse rates regularly and adjust if necessary. Check the manometer reading regularly. A change in pressure indicates the presence of air bubbles, which should be purged from the system. If necessary, top up the water bath regularly.

5.5.5.9 Remove the test specimen and rinse it twice with deaerated water. Examine the test specimen for breaks, loosening of unions and other evidence of mechanical damage.

5.5.5.10 Determine the pressure/flow characteristics of the test specimen according to 5.3.

5.5.5.11 Determine the reflux characteristics of the valves, if any, according to 5.4.