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Dentistry — Magnetic attachments

Médecine bucco-dentaire — Attaches magnétiques

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Foreword

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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).

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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 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*. This second edition cancels and replaces the first edition (ISO 13017:2012), which has been technically revised. It also incorporates the Amendment ISO 13017:2012/Amd.1:2015. The main changes compared to the previous edition are as follows:

— addition of ISO 14233 to Clause 2;

— addition of lead as a hazardous element;

— addition of the cleaning method of test specimens prepared for retentive force;

— change of the device for retentive force to a single shaft type;

— change of Figure 3 to the single shaft type device;

— specification of the performance of the device with respect to moving friction force and modification of specimen tables;

— change of a cross-head speed in measuring retentive force from 5,0 mm min^{-1} to 2,0 mm min^{-1};

— addition of materials for fixing a specimen on the table such as cyanoacrylate adhesive and self-curing acrylic resin;

— deletion of the description of the adhesive double sided tape to fix a specimen on the table;

— specification of the procedures to fix a specimen on the table;

— addition of detailed method of measuring retentive force;

— addition of explaining the calculation method of retentive force;

— addition of a figure that shows a retentive force curve as Figure 4;

— specification of quantitative analyses in the static immersion test using definition of determination limit and detection limit;

— addition of “quantity” to labelling.

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 early practical uses of permanent magnets were as navigational compasses. Magnets have since become firmly integrated into today's modern electronic device technology. The development of magnetic technology has generated rare earth magnets. Their excellent magnetic character properties permit predictable clinical applications and use. Dental magnetic attachments are one of the products composed of rare earth magnets, providing retention, support and stabilization of dental and maxillofacial appliances.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document, but for the assessment of possible biological or toxicological hazards, reference can be made to ISO 10993-1 and ISO 7405.

Dentistry — Magnetic attachments

1 Scope

This document specifies requirements and test methods for assessing the applicability of dental magnetic attachments that provide retention, support and stabilization of removable prostheses (crowns and bridges, partial dentures and overdentures), superstructures of dental implants and orthodontic or maxillofacial prostheses including obturators.

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 1942, *Dentistry — Vocabulary*

ISO 3585, *Borosilicate glass 3.3 — Properties*

ISO 5832-1, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*

ISO 10271, *Dentistry — Corrosion test methods for metallic materials*

ISO 14233, *Dentistry — Polymer-based die materials*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 22674, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

IEC 60404-8-1, *Magnetic materials — Part 8-1: Specifications for individual materials — Magnetically hard materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 10271 and the following apply.

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

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

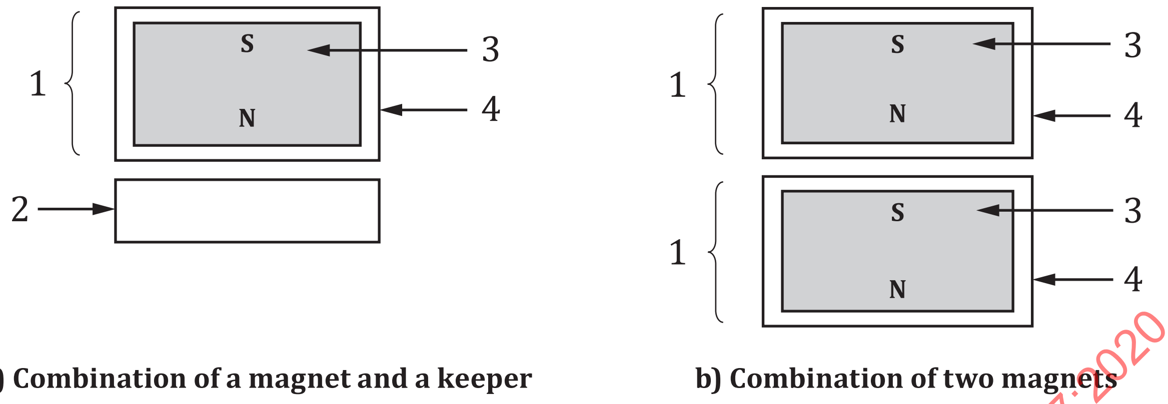
— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
magnetic attachment
device to provide retention of a prosthesis mainly utilizing magnetic attraction

3.1.1
open magnetic circuit attachment
magnetic attachment (3.1) wherein a magnetized permanent magnet is working by itself with no high permeability material

Note 1 to entry: The magnet is encased within a corrosion-resistant metal or alloy cover of titanium, titanium alloy or stainless steel to prevent corrosion of the magnet. The attachment uses either a magnet and a ferromagnetic alloy *keeper* (3.3) or two magnets as retentive coupling components.

See Figure 1.



Key

1 magnet

2 keeper

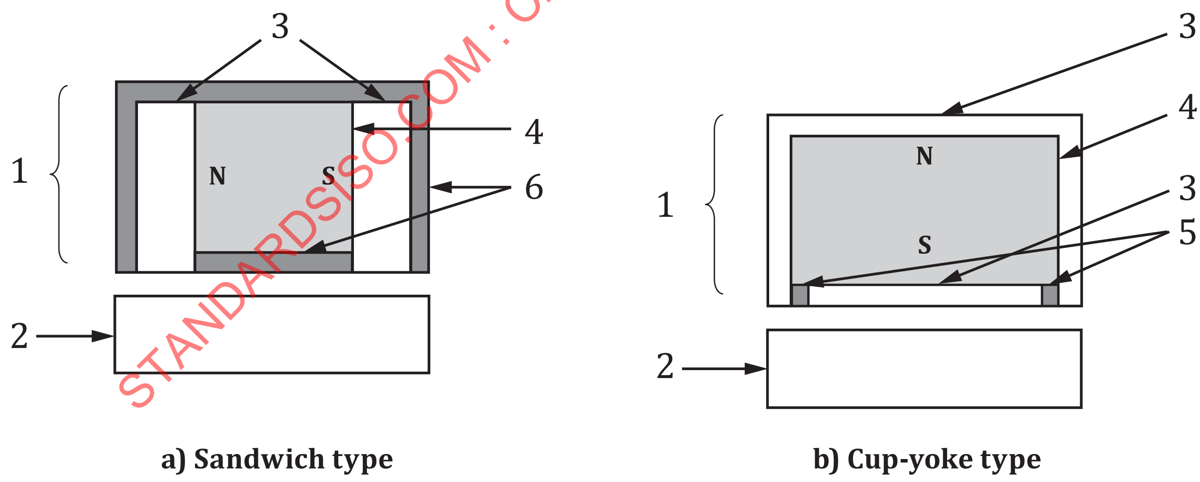
3 magnet core

4 cover

Figure 1 — Schematic diagrams of open magnetic circuit attachment

3.1.2
closed magnetic circuit attachment
magnetic attachment (3.1) wherein the external flux path of a permanent magnet is confined within a high permeability material

Note 1 to entry: The attachment consists of a combination of a *magnetic assembly* (3.2) and a *keeper* (3.3). Some examples are the sandwich type and the cup-yoke type. See Figure 2.



Key

1 magnetic assembly

2 keeper

3 yoke

4 magnet core

5 spacer

6 cover

Figure 2 — Schematic diagrams of closed magnetic circuit attachment

3.2
magnetic assembly
assembly composed of a small magnet which is sealed within ferromagnetic yokes and a non-magnetic spacer, completing a closed magnetic circuit with a *keeper* (3.3)

Note 1 to entry: The closed magnetic circuit is a complete circulating path for magnetic flux through the yoke and keeper, which are made of ferromagnetic materials. This circuit can enhance the retentive force and reduce the magnetic flux leakage.

3.3
keeper
ferromagnetic alloy component fixed to an abutment to retain a prosthesis mainly

Note 1 to entry: The keeper is placed across the poles of a magnet or a *magnetic assembly* (3.2) to complete the magnetic circuit.

3.4
yoke
ferromagnetic alloy component connected to a permanent magnet and used for concentrating magnetic flux

4 Requirements

4.1 Material

4.1.1 Magnet core

A magnet that is classified by principal constituents in accordance with IEC 60404-8-1 shall be used as the magnet core.

4.1.2 Components other than the magnet core

A material whose chemical composition is declared by the manufacturer shall be used for components of the dental magnetic attachment other than the magnet core.

4.1.3 Reported chemical composition

For the magnet core, the principal constituents in accordance with IEC 60404-8-1 shall be stated [see Clause 7, a)].

For the materials of the dental magnetic attachment other than the magnet core, all constituent element names that are present in excess of 1,0 % (mass fraction) shall be stated [see Clause 7, a)] by reference to the manufacturer's composition report. The manufacturer shall disclose the chemical composition of an appropriate lot production, if users request it.

4.2 Hazardous elements

4.2.1 Recognized hazardous elements

For the purpose of this document, the elements nickel, cadmium, beryllium and lead are designated hazardous elements.

4.2.2 Permitted limits for the hazardous elements cadmium, beryllium and lead

Materials of dental magnetic attachments shall not contain more than 0,02 % (mass fraction) cadmium, beryllium or lead as determined by ISO 22674.

4.2.3 Manufacturer's reported nickel content and permitted deviation

If the materials of the dental magnetic attachment other than the magnet core contain more than 0,1 % (mass fraction) nickel, the contents shall be given to an accuracy of 0,1 % (mass fraction) in the literature which accompanies the package [see Clause 7, f)] and on the package, label or insert [see 8.2, e)]. The mass fraction as determined by ISO 22674 shall not exceed the value stated in Clause 7, f) and 8.2, e).

4.3 Risk analysis

Risk analysis should be carried out and documented according to ISO 14971.

4.4 Magnetic flux leakage

If the average maximum magnetic flux density 5 mm from the surface of the magnetic attachment is over 40mT[5], when tested in accordance with 6.2, this value shall be stated in the literature accompanying the package [see Clause 7, b)].

4.5 Retentive force

The retentive force of the dental magnetic attachment shall not be less than 85 % of the value stated in the literature accompanying the package [see Clause 7, d)] when tested in accordance with 6.3.

4.6 Corrosion resistance

4.6.1 Released ions

The total metal ions released from the magnet or the magnetic assembly and from the keeper into the specified solution (see 6.4.1.3) at (37 ± 1) °C in a time period of 7 d ± 1 h shall not exceed 200 μg/cm^2 in accordance with ISO 22674 when tested in accordance with 6.4.1.

4.6.2 Breakdown potential

Breakdown potentials of the magnet or the magnetic assembly and the keeper shall be equal to, or higher than, that of wrought stainless steel in accordance with ISO 5832-1 when tested in accordance with 6.4.2.

5 Preparation of test specimens

5.1 Retentive force

Clean the mating face on the magnet or the magnetic assembly and the keeper using a cotton bud which has been soaked in acetone, ethanol or methanol just before measurement (see 6.3.4). Dry with oil- and water-free compressed air as appropriate.

5.2 Static immersion test

Prepare a sufficient number (at least three) of magnets, magnetic assemblies or keepers such that the total surface area is at least 2 cm^2. Prepare the magnets, magnetic assemblies or keepers in accordance with ISO 10271. Use these magnets, magnet assemblies or keepers for the static immersion test.

NOTE ISO 10271 requires the total surface area of the sample to be at least 10 cm^2 after preparation; however, this would require an impractical number of pieces for testing (e.g. 25 pieces to 50 pieces). Therefore, the required surface area has been reduced to at least 2 cm^2. This surface area results in a minimum volume of test solution of 2 ml when the ISO 10271 test procedure (which states "add the solution to each container sufficient to produce a ratio of 1 ml of solution per 1 cm^2 of sample surface area") is followed. These 2 ml provide an adequate volume of test solution for analysis by ICP.

5.3 Anodic polarization

Prepare the magnet or the magnetic assembly, the keeper, the wrought stainless steel whose composition is stipulated in ISO 5832-1 and the working electrode in accordance with ISO 10271.

6 Test methods

6.1 Information, instructions and marking

Inspect visually to check that the requirements specified in Clauses 7 and 8 have been met.

6.2 Magnetic flux leakage

6.2.1 Apparatus

6.2.1.1 Gauss meter, using a calibrated Hall element

6.2.2 Test procedure

The maximum magnetic flux 5 mm from the surface of the dental magnetic attachment is measured with a Gauss meter (6.2.1.1) using a Hall element under conditions of use (e.g. a keeper being attached to a magnetic assembly). Report the arithmetic mean of five measurements.

6.3 Retentive force

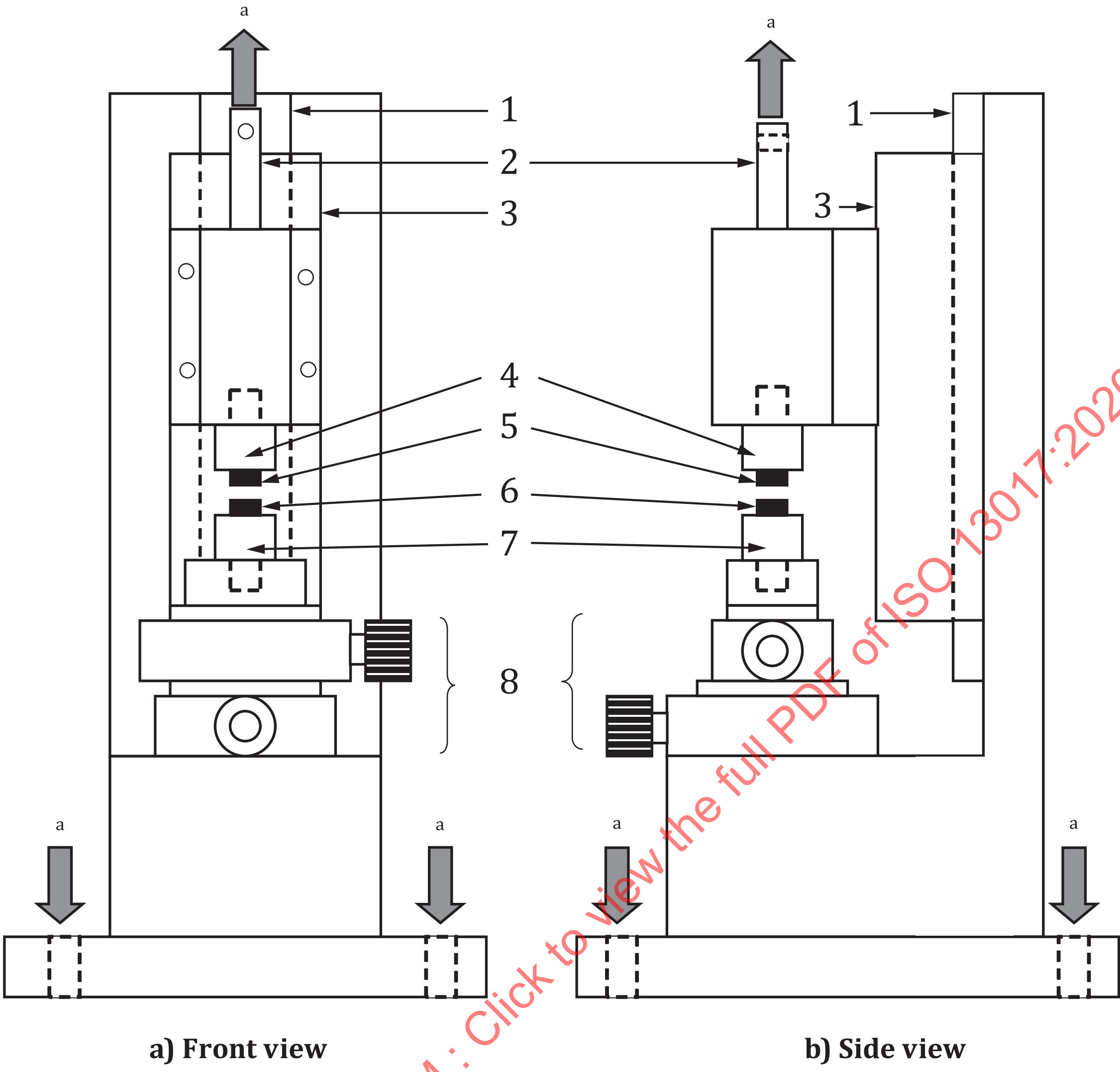
6.3.1 Apparatus

6.3.1.1 Mechanical testing machine, with an appropriate accuracy greater than 1 % of the measured value and a cross-head speed of 2,0 mm/min or less, and with an adapter appropriate for the fixing and alignment of specimens.

6.3.1.2 Device, containing a low friction ball bearing slider, for fixing and pulling the specimens vertically, installed in the mechanical testing machine.

NOTE The force required to move the shaft of the device when pulling a specimen is 0,02 N or less. The lower or upper non-magnetic table can be modified to facilitate fixation of the specimen (magnet, magnetic assembly, or keeper) in a stable manner.

See Figure 3.



Key

1 rail for a ball bearing slider
2 shaft
3 low friction ball bearing slider
4 upper non-magnetic table
5 specimen (magnet or magnetic assembly)
6 specimen (magnet or keeper)
7 lower non-magnetic table
8 x-y stage
a Connected to the mechanical testing machine.

Figure 3 — Device using a low friction ball bearing slider for fixing and pulling the specimens vertically

6.3.2 Materials

6.3.2.1 Cyanoacrylate adhesive, for fixing specimens on the lower and upper non-magnetic tables.

6.3.2.2 Self-curing acrylic resin, for embedding a non disk-shaped specimen in the embedding ring with properties in accordance with ISO 14233.

6.3.3 Fixing procedure

6.3.3.1 Fixation of specimens

Adjust the position of the lower non-magnetic table equipped with the device (6.3.1.2) using the X-Y stage so that both centres of the lower and upper non-magnetic table are aligned. Provisionally place the mating face of the magnet (or magnetic assembly) to the centre of the lower non-magnetic table. Note that the side in contact with the lower non-magnetic table will be the side that mates with the other magnet (or keeper) once this alignment procedure is completed.

Place a drop of the cyanoacrylate adhesive (6.3.2.1) on the top of the magnet (or magnetic assembly) put on the lower non-magnetic table, being careful not to let adhesive flow down the sides of the magnet (or magnetic assembly). Move the upper non-magnetic table down slowly until it makes contact with the magnet (or magnetic assembly) containing the drop of adhesive, and apply weight until adhesive sets. If necessary, reinforce the bonding area between the magnetic (or magnetic assembly) and the upper non-magnetic table with the self-curing acrylic resin (6.3.2.2).

After adhesive joining the magnet (or magnetic assembly) with the upper non-magnetic table is set, move the table upward. Put the magnet (or keeper) on the mating face of the magnet (or magnetic assembly) that is now bonded to the upper non-magnetic table. Make sure that the magnet (or keeper) is properly aligned with the magnet (or magnetic assembly). Place a drop of the cyanoacrylate adhesive (6.3.2.1) at the centre of the lower non-magnetic table. Move the upper non-magnetic table down slowly until the bottom of the magnet (or keeper) makes contact with the lower non-magnetic table containing the drop of adhesive. If necessary, reinforce the bonding area between the magnet (or keeper) and the lower non-magnetic table with the self-curing acrylic resin (6.3.2.2). Do not move the lower or upper non-magnetic table until adhesive joining the magnet (or keeper) with the lower non-magnetic table is set.

Also, to keep the proper alignment of the magnet (or magnetic assembly) on the upper non-magnetic table with the magnet (or keeper) on the lower non-magnetic table, do not uninstall the lower and upper non-magnetic tables from the device (6.3.1.2) even after adhesive is set.

6.3.4 Test procedure

The test procedure is performed by following the steps below.

a) Install the device for fixing and pulling the specimens vertically (6.3.1.2) in the mechanical testing machine (6.3.1.1).

b) Load the test specimen in tension in the mechanical testing machine at a cross-head speed of 2,0 mm/min or less until the magnet or magnetic assembly separates completely from the keeper or the other magnet.

c) Perform the tensile force measurements until a time when the force value measured remains constant within the range of ±0,01 N, then stop the machine.

d) Reset the magnetic attachments in contact and repeat steps b) to c). Perform the procedure on the same set of magnetic attachment specimen five times.

6.3.5 Analysis

Convert the time values on X axis into distance according to the Formula (1). Speed is a constant value since the same crosshead speed is maintained throughout the experiment.

$$d = v \times t \tag{1}$$

where

d is the distance, in mm;

v is the speed, in mm/min

t is the time, in min.

From each of the force versus distance curves, obtain the force value corresponding to the peak of the curve (F_1, Figure 4). This value represents the magnetic attachments attractive force, weight of the magnet together with the movable part of the measuring device and friction during movement. It is measured when the magnetic attachments are in contact (x_1, Figure 4). Further obtain the force value (F_2, Figure 4) that corresponds to the horizontal part of the curve defined as the base line whereby no change in force is recorded with time. The value represents the weight of the movable part of measuring device and its friction during movement (beyond x_2, Figure 4). It is measured when the magnetic attachments are separated far enough to cause loss of the attractive force (s_1, Figure 4).

Subtract the force value F_2 from F_1 according to the Formula (2). The calculated difference (F_1 - F_2) is the retentive force of the magnetic attachment, F_3, which represents the attractive force between the magnet or the magnetic assembly to keeper or the other magnet.

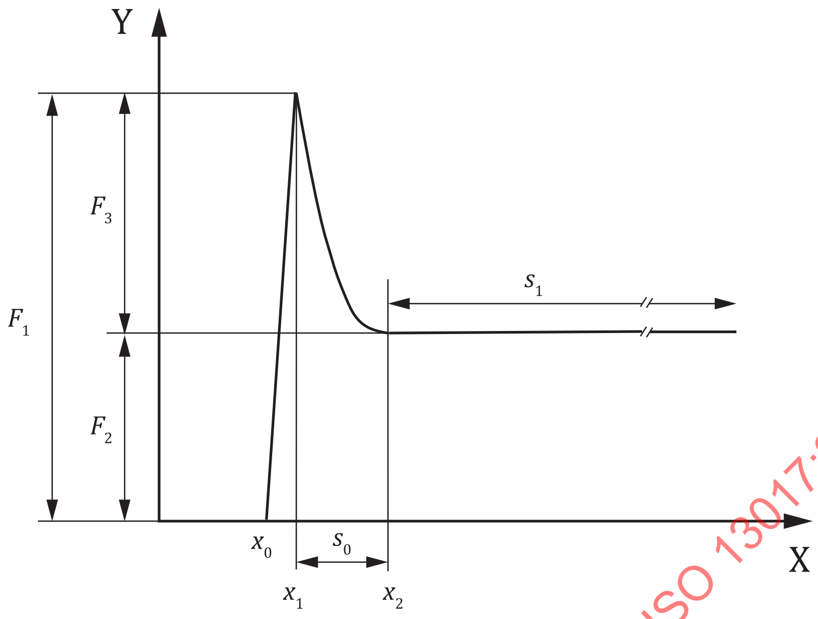
$$F_3 = F_1 - F_2 \tag{2}$$

where

F_1 is the weight of movable part of the device, its friction and magnetic attractive force;

F_2 is the weight of movable part of the device, and its friction during movement.

Obtain the arithmetic median of the five retentive force values established from each curve. Calculate the retentive force as the mean of the median values obtained from at least five specimens. Report the retentive force of the particular magnetic attachment to the nearest 0,1 N.



Key

X distance, in mm
Y tensile force, in N
s_0 region influenced by magnetic attraction in a diminishing manner
s_1 region of loss of magnetic attraction
x_0 initial point of load generation
x_1 point in time when the magnetic attachments are in contact just prior to separation
x_2 point in time when the elements of the magnetic attachments are separated for long enough to cause loss of magnetic attraction

Figure 4 — Retentive force curve

6.4 Corrosion resistance

6.4.1 Static immersion test

6.4.1.1 Reagents

Use reagents in accordance with ISO 10271.

6.4.1.2 Apparatus

6.4.1.2.1 pH meter, in accordance with ISO 10271.

6.4.1.2.2 Test tube, made of borosilicate glass in accordance with ISO 3585, or made of polyethylene (PE) or polypropylene (PP) for inductively-coupled plasma atomic emission spectrometry (ICP-AES) or atomic absorption (AA) analysis.

6.4.1.3 Test solution

For each test, prepare a fresh solution of lactic acid ($C_3H_6O_3$), sodium chloride (NaCl), and water mixed in accordance with ISO 10271.

6.4.1.4 Test procedure

The test procedure is performed by following the steps below.

a) Check the pH of the test solution (6.4.1.3) using a pH meter (6.4.1.2.1). The pH shall be 2,3 ± 0,1. If not, discard the solution and make a fresh one.

b) Place each specimen (at least three) in a separate glass, PE or PP test tube (6.4.1.2.2) so that the specimens do not touch the inner surface of the tube except in a minimum support line or point.

c) Add sufficient test solution to each container to produce a ratio of 1 ml of solution per 1 cm^2 of sample surface area. The specimens shall be covered completely by the solution.

d) Record the volume of solution to an accuracy of 0,1 ml. Close the container to prevent evaporation of the solution. Maintain at (37 ± 1) °C for 7 d ± 1 h.

e) Remove the specimens and use the residual test solution for analysis of released ions.

f) Prepare the reference solution to be used to establish the impurity level for each element of interest in the solution. Use an additional container to hold the reference solution that is to be maintained parallel to the test solutions containing the specimens.

g) Put reference solution of approximately the same volume as the test solution used into an empty test tube. Record the volume to an accuracy of 0,1 ml. Close the container to prevent evaporation of the solution and maintain at (37 ± 1) °C for the same time period as the solutions containing the specimens.

h) Combine all the test solutions from each test tube after retrieval of all the specimen.

i) Use chemical analysis instrumentation of adequate sensitivity, and analyse the solution qualitatively and quantitatively.

6.4.1.5 Treatment of results

Although emphasis is on those elements listed in Clause 7, a), if ions other than the elements listed in Clause 7, a) are found in a concentration greater than that of their minimum limit of determination in the test solution, each ions name and each amount of released ions in the units of "$\mu g/cm^2/7$ d" shall also be reported. For each element of interest, subtract the value obtained for the element in the reference solution from the value obtained in the test solution.

The minimum limit of determination is defined as a tenfold concentration of standard deviation in analysis of a reference solution.

6.4.2 Anodic polarization

6.4.2.1 Reagents

Use reagents in accordance with ISO 10271.

6.4.2.2 Apparatus

Use apparatus in accordance with ISO 10271.

6.4.2.3 Test solution

Prepare a fresh solution for each test in accordance with ISO 10271.

