INTERNATIONAL STANDARD

ISO 28862

First edition
2018-07

Packaging — Child-resistant packaging — Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

Emballages — Emballage à l'épreuve des enfants — Exigences et méthodes d'essai pour emballages non refermables pour les produits non pharmaceutiques

Reference number
ISO 28862:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 (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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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.

This document was prepared by the European Committee for Standardization (CEN) (as EN 862) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 122, *Packaging*, Subcommittee SC 3, *Performance requirements and tests for means of packaging, packages and unit loads (as required by ISO/TC 122)*.

There are no changes to the content of the EN 862 document apart from the addition of Clause 2, Normative references.

Introduction

Child-resistant packaging is used to create a physical barrier between a child and a potentially hazardous product. Various types of packaging are recognized as being child-resistant, based on performance testing against standards for specific product categories and packaging types.

Since this type of packaging was introduced, the incidence of accidental ingestion of potentially hazardous products by children under 5 years old has fallen. The degree to which this is due to the use of child-resistant packaging as opposed to other factors, such as greater public awareness of the hazards, is not easily assessed, but there is little doubt that this packaging has made a positive contribution to the reduction.

The use of child-resistant packaging needs to be confined to those products that are potentially hazardous, or for which any legislation makes its use mandatory, since, if used in other circumstances, there could be confusion over the degree of hazard posed by the product.

In any case, proper labelling and information by the manufacturer is important for the safe use of the product in the home.

Child-resistant packaging acts as the last line of defence if other barriers separating the child and hazardous product have failed. However, it has to be recognized that it is unrealistic to expect that any functional packaging can be totally impossible for a child of 42 to 51 months inclusive to open and that child-resistant packaging cannot be a substitute for other safety precautions.

There has been an increasing use of child-resistant packaging, therefore it is desirable to achieve agreement on testing procedures in order to avoid confusion and misunderstanding in an area of great importance to the safety of young children.

This document aims to reduce the number of children “exposed to training” during panel testing. Since the introduction of performance testing, much has been learned about the use of children for testing child-resistant packaging and attention has been focused on how the number of children involved may be reduced. Future development of standards based on mechanical test methods is required to avoid unnecessary child panel testing and is essential in developing physical package attributes useable by manufacturers.

Child-resistant packaging is only the last in a series of protective measures, and does not release parents or guardians from their duty to keep potentially dangerous products out of the reach of children.

The on-going development of non-reclosable packaging offers a significant area for innovation in packaging. The styles of non-reclosable packages can be wide-ranging in design.

Mechanical test methods may be used to generate test data for comparison and demonstration that the notified packaging is as safe as the original reference one. Mechanical tests are test methods generating data by destructive or non-destructive tests of a specific reference package having shown child-resistant properties. Consequently, the development of mechanical test methods by manufacturers allied to current standards should be pursued as a means of reducing the reliance on child panel testing.

Packaging — Child-resistant packaging — Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

1 Scope

This document specifies performance requirements and methods of test for non-reclosable packaging that has been designated child-resistant and which is intended to contain non-pharmaceutical products. This document is intended for type approval only (see 2.5) and is not intended for quality assurance purposes.

This document applies to non-reclosable packages of the single-use type consisting of one or more individual units.

Non-reclosable packages for pharmaceutical products are excluded from the scope of this document. These are the subject of a separate standard, ISO 14375, *Child-resistant non-reclosable packaging for pharmaceutical products — Requirements and testing.*

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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/

3.1
child-resistant package
package which is difficult for young children to open (or gain access to the contents), but which is possible for adults to use properly

3.2
non-reclosable child-resistant package
child-resistant package or part of a child-resistant package which, when all or part of the contents have been removed, cannot be properly closed again

3.3
substitute product
inert substitute resembling the product it replaces

EXAMPLE Powder, tablets or liquids (uncoloured water), etc.

3.4
unit
discrete quantity of any product to be removed from its immediate packaging in its entirety

3.5
type approval
procedure to certify as child-resistant a specific type of non-reclosable package, formed from a specified set of materials

3.6
single use package
package of one or several units which are not only individually protected but also individually packed for single use

4 Requirements

4.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this document, shall be capable of providing a satisfactory degree of resistance to opening by children (4.2.1). Accessibility to its contents by adults can be checked according to the optional adult test (4.2.2).

A non-reclosable child-resistant package, in addition to conforming to the performance requirements specified in this document (4.2), shall be appropriate for the contents, provide mechanical protection and function properly for the life of the content and packaging.

Manufacturers, component manufacturers, fillers and packers of such packages shall initiate and operate procedures to control the quality of packaging materials so that type approved packaging is in accordance with the requirements of this document.

NOTE ISO 9001 specifies requirements for quality management systems where organizations need to demonstrate their capability of supplying conforming products to customers.

4.2 Performance requirements

4.2.1 Child test

An individual child test shall be considered a failure in relation to a single use package if within 10 min, or 5 min when no demonstration has been given, the child gains access to one or more units from the packaging provided.

When tested in accordance with 5.3.2 and evaluated in accordance with 5.4.1, the packaging shall be child-resistant.

4.2.2 Adult test

This test is optional unless a tool is supplied to open the container at the point of sale.

When tested in accordance with 5.3.3 and evaluated in accordance with 5.4.2, at least 90 % of the adults shall be able to access at least 1 unit within the 1 min test period, without a demonstration.

To minimize the exposure of children to unnecessary testing, the adult test should be carried out before the child test.

5 Testing

5.1 Principle

Type approval for non-reclosable child-resistant packaging is obtained by a sequential test method for children. A test group of up to 200 children aged 42 to 51 months is divided into pairs. Each child is given a number of non-reclosable packages to be opened by whatever means they wish to use. If a

child fails to gain access within 5 min, the method of opening is demonstrated by the supervisor and the child is given a further 5 min to open the package. The results are recorded sequentially, as obtained. The package is deemed child-resistant if the trail of results on the test charts passes into the acceptance zone or if at least 80 % of the children are unable to access one or more units within 10 min and at least 85 % of the children are unable to access one or more units within the first 5 min. The package's accessibility may also be assessed by an optional full panel test for adults using a test group of 100 adults. Each adult is given a non-reclosable package, any associated opening tools and written instructions, and is allowed 5 min to familiarise themselves with the packaging. The number of adults opening the package within a 1 min test period is recorded. The package is deemed to comply with the requirements of this document if at least 90 % of the adults are able to access at least 1 unit in 1 min.

5.2 Samples and sample preparation

Sufficient packages shall be produced by the proposed manufacturing process to enable a representative sample to be selected by the supervisor for testing and to provide a reserve for reference purposes. Dangerous products shall not be used to fill the package to be tested; an appropriate substitute product shall be used. The material and design of the test samples shall conform to the technical specification and they shall be representative of an average batch of original packages.

Packages for the child panel test shall be unprinted.

In every test, a new package shall be provided for each member of the test group.

Each sample package shall be checked for integrity before the test is conducted. The packages shall be presented to the children without the outer retail packaging, giving them access to the individual units.

5.3 Procedure

5.3.1 General

The test procedure is carried out in two stages:

a) child test (5.3.2);

b) adult test (5.3.3).

5.3.2 Child test

5.3.2.1 Composition of child test group

The test group shall comprise no more than 200 children aged 42 to 51 months, inclusive, with approximately equal numbers of girls and boys. As far as possible, there shall be an even distribution of ages and sexes within the panel. The children shall be selected at random and shall have no apparent physical or mental disability that might affect manual dexterity. They shall not have taken part in more than one previous test and, in that test, a packaging of a different type and design shall have been used. If a child is used for more than one test, there shall be at least 4 weeks between tests. Parental or guardian consent shall be obtained before the child is used as a part of the test group. Any children having been involved in a reported poisoning accident shall be excluded from the test.

Children should be selected to represent, as closely as is reasonably possible, the different social, ethnic and cultural origins of the population as a whole, and not just of the immediate district in which the test is carried out.

5.3.2.2 Test procedure

Testing shall be carried out in the presence of a test supervisor. The child test shall take place in an environment familiar to the children.

Test personnel should visit the test location beforehand and become known by the children in order to gain their confidence. Only the supervisors should be present, parents being excluded from the test.

The test shall be carried out by a sequential procedure (5.4.1.1 to 5.4.1.3). The number of children tested will therefore depend on the results obtained, however, the age and sex constraints specified in 5.3.2.1 shall be adhered to.

Pairs of children shall be involved in the test, each pair being monitored by one supervisor. Should a child wander off during the test, action by the supervisor shall be limited to leading the child back to its place and requesting that he or she continue the test, without any additional instruction being given concerning the opening of the package; this fact shall be included in the report (Clause 6).

If desired, a number of pairs (up to five) may undertake tests in the same room at the same time, provided that arrangements are such that they cannot distract other pairs. They may adopt any attitude or position that they find convenient and should not be restrained. During the test, children should be removed as far as possible from extraneous distractions. If other means of observation are used, the supervisor may stand at a distance from the children.

Each child shall be given sufficient packages (see 5.2) with the request that they be opened by whatever means the child wishes to use; 10 min shall be allocated for this purpose. No attempt shall be made to prevent a child using its teeth or any other method of opening the package. However, no tools or implements shall be accessible which might be used by the child, other than those supplied by the manufacturer/filler or packer at point of sale.

Children failing to open or gain access to a minimum of 1 unit in the first 5 min shall then watch a single demonstration by the test supervisor of the package being opened, with no emphasis being placed on the actions of opening and with no verbal instructions. These children then have a further 5 min to open the package or gain access to its contents.

When tools are needed to open the package, but these are not supplied by the manufacturer, there shall be no demonstration. The test is therefore limited to the first 5 min test period.

If a child leaves the test area during the test period (5 min or 10 min) or refuses to participate in the test despite encouragement, the result shall not be taken into account but the event recorded.

At the conclusion of the each test, the children should be warned not to play with, or attempt to open, these types of packages.

Annex A provides a summary of the requirements and guidance to be followed by test supervisors. If required by the regulatory body, an official observer will be present, but the guidance laid down in Annex A still applies.

5.3.3 Adult test

5.3.3.1 Composition of adult test group

The test group shall comprise 100 participants. These shall be selected using a screening procedure in which potential participants shall be asked the following question.

“Are you professionally concerned with the design, manufacture or use of child-resistant packaging?”

Only those participants responding with a negative answer shall be selected.

In order to elicit this information and, at the same time, to ascertain whether the individual is literate, this question shall be presented on a typed or printed form and given to the person to read.

Persons with obvious physical disabilities that might affect manual dexterity shall not be approached and those unable to understand the written opening instructions shall not be tested.

The purpose of the test shall be explained but no demonstration shall be given.

The 100 participants shall be randomly selected between the ages of 50 and 70 in accordance with the requirements given in Table 1. Not more than 30 of the adults tested shall be obtained from or tested at any one site. No individual supervisor shall administer the test to more than 35 adults.

Table 1 — Composition of the adult test group

	Age range years	Male number of participants	Female number of participants	Total number of participants
	50 to 54	8 or 7	17 or 18	25
	55 to 59	7 or 8	18 or 17	25
	60 to 70	15	35	50
Total	—	30	70	100

5.3.3.2 Test procedure

There is no need for the adults to be tested at any particular place or time. The test should be carried out by one person at a time and only the supervisor should be present.

Each adult shall be given a package, together with any associated opening tools that would be provided with the package at point of sale, and written instructions on how to open the package correctly, if any.

These may be printed in or on the package when supplied to a consumer.

No demonstration of how to open the package shall be given by the supervisor. A period of 5 min shall be allowed for the test participants to familiarize themselves with the package to be tested by reading the opening instructions and then attempting to open it correctly. Test participants shall not be allowed to consult either the supervisor or other participants in the test.

Participants who successfully open the test package within the 5 min period shall be given a new identical package and shall be requested to open this one as quickly as possible. A 1 min test period shall be allowed for the participants to open the new packaging.

If in this period of 5 min a panellist is unable to open the package being tested, they will be given a screening test. This screening test consists of asking the panellist to open and reclose the following two conventional non-child resistant closures in one minute each:

a) a 28 mm diameter continuous screw thread closure applied at 1,1 Nm torque onto a 25 ml to 50 ml cylindrical plastic container;

b) a 28 mm diameter “push-off” closure applied to a 25 ml to 50 ml round plastic container.

Panellists unable to open or reclose both of these packages in the 1 min screening test are to be discounted from the adult panel results.

Panellists who are able to open both these packages are counted as a failure in the overall result.

5.4 Evaluation

5.4.1 Child test

5.4.1.1 General

The result of each test shall be recorded on the test charts given in Figures B.1 and B.2 in accordance with 5.4.1.2. The results shall be evaluated in accordance with 5.4.1.3.

NOTE The statistical parameters governing the sampling procedures for the test charts are given in Annex C.

The test shall be considered a failure in relation to unit, strip or blister packages if within 10 min the child removes one or more units from the packaging provided.

5.4.1.2 Test charts

As each result is obtained, plot it on either Figure B.1 or B.2 as follows.

a) Fill in a square immediately to the right of the previous result on Figure B.1 if the child failed to access one or more units in the first 5 min, and on Figure B.2 if the child failed to access one or more units by the end of the second 5 min period.

b) Fill in a square immediately above the previous result on both Figures B.1 and B.2 if the child succeeded in accessing one or more units in the first 5 min. Enter the result only on Figure B.2 if the child succeeded in accessing one or more units by the end of the second 5 min period.

NOTE In the case of the first result to be plotted, the blanked-out square is regarded as the previous result.

5.4.1.3 Expression of results

5.4.1.3.1 Sequential test procedure

The package shall be deemed to have:

— passed the test as soon as the trail of filled squares passes into the acceptance zone on both Figure B.1 and Figure B.2;

— failed the test as soon as the trail of filled squares passes into the rejection zone on either Figure B.1 or Figure B.2.

If neither occurs, the results shall be assessed in accordance with the requirements laid down in 5.4.1.3.2.

5.4.1.3.2 Full test procedure

If all 200 children are used to test the package, it shall be deemed child-resistant if the following requirements are met:

a) at least 85 % of the children in the test panel are unable to access one or more units within 5 min without a demonstration;

b) at least 80 % of the children in the test panel are unable to access one or more units within 10 min (5 min without a demonstration and 5 min after a demonstration, if appropriate).

5.4.2 Adult test

When tested in accordance with 5.3.3.2, any adult who is unsuccessful in accessing at least 1 unit during the 1 min test period is recorded as a failure.

6 Test report

6.1 General

At least the following information shall be recorded:

a) name of the body carrying out the test;

b) date(s) on which the test was carried out;

c) name and address of the manufacturer and/or supplier of the package tested;

d) name(s) of the person(s) supervising the test;

e) material specifications comprising a composite package, drawing or photographs if appropriate and a complete description of the package tested;

f) list of the exact instructions given to the adults and children during the test by the test supervisor;

g) copy of the manufacturer's instructions on opening the package given to adults during the test;

h) description of the substitute product used in the test;

i) reference to this document.

6.2 Child test

At least the following information shall be recorded:

a) test location(s);

b) number, age and sex of the children tested;

c) number of children, together with their age and sex, who successfully gained access to the contents of the package as defined in 5.4.1.1 to 5.4.1.3:

   1) before a demonstration;

   2) after a demonstration;

d) time required to open the package;

e) number of units accessed by each child;

f) method of opening used;

g) reference to this document.

6.3 Adult test

At least the following information shall be recorded:

a) number, age and sex of the adults tested;

b) number of adults who successfully opened the package during the 1 min test period;

c) number of adults who failed to open the package during the 1 min test period:

   1) number, age and sex of adults unable to open the package during the 5 min test period;

   2) time required to open the package;

d) reason for failure to open the package;

e) reference to this document.

6.4 Additional (optional) information to be recorded

Any other information deemed to be useful in assessing the interpretation of the result should be recorded.

6.5 Overall test result

It shall be recorded whether the overall result was a success or a failure.

Annex A
(informative)

Guidance for persons supervising tests with children

A.1 Parental/guardian consent

Parental or guardian consent is required to be obtained before the child is used as a part of the test group.

A.2 Surroundings and personnel

Surroundings and personnel should be familiar and friendly. For this reason, personnel should visit the test location beforehand and become known by the children in order to gain their confidence. Only the supervisors should be present, parents being excluded from the test.

A.3 Social circumstances of the children

Children should be selected to represent, as closely as is reasonably possible, the different social, ethnic and cultural origins of the population as a whole, and not just of the immediate district in which the test is carried out.

A.4 History of previous poisoning

Any children having been involved in a reported poisoning accident shall be excluded from the test.

A.5 Avoidance of distractions

During the test, children should be removed as far as possible from extraneous distractions.

A.6 Position of the children

Children can adopt any attitude or position they find convenient.

A.7 Behaviour of the supervisor during the test

a) The supervisor should make the request to the children to open the package in an encouraging manner.

b) No opening instructions should be given other than the visual demonstration when there is a demonstration.

c) The children should not be restrained or distracted.

d) If the children lose interest in the test object the supervisor should repeat the request to open it.

e) If other means of observation are used the supervisor may stand at a distance from the children.

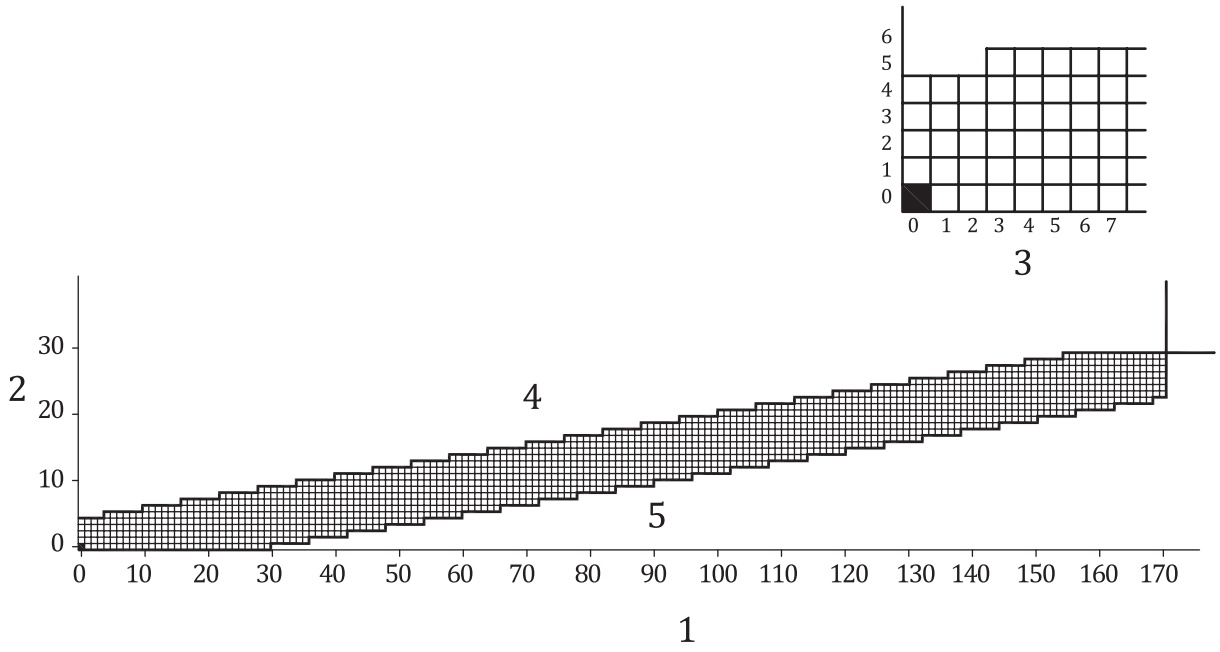
f) The supervisor should encourage the children to gain access to the contents by any means without mentioning any specific method.

g) At the conclusion of each test, the children should be warned not to play with, or attempt to open, these types of packages.

Annex B
(normative)

Test charts

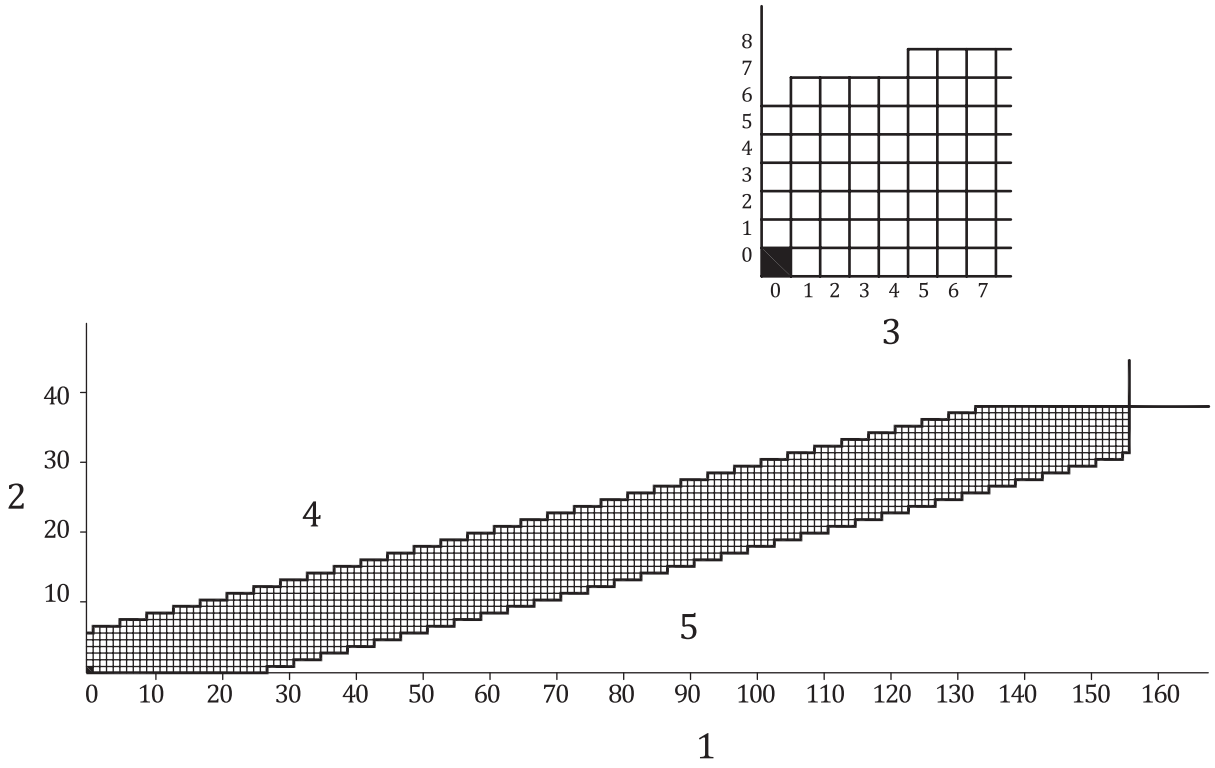
Results shall be entered on Figures B.1 and B.2 in accordance with 5.4.1.2.



Key

1 number of packages not opened (success)
2 number of packages opened (failure)
3 enlargement of chart scale
4 rejection zone
5 acceptance zone

Figure B.1 — Chart of a sequential child test procedure (after 5 min of test before demonstration)



Key

1 number of packages not opened (success)
2 number of packages opened (failure)
3 enlargement of chart scale
4 rejection zone
5 acceptance zone

Figure B.2 — Chart of a sequential child test procedure (Total test period)

Annex C
(informative)

Suitability of the sequential procedures chosen

The suitability of a sampling procedure is usually given by the coordinates of two points on its efficiency curve: the point for the producer's risk and the point for the client's risk. The two sampling procedures given in this document are the following:

— Children (before demonstration) (Figure B.1):

  Acceptable quality level $\alpha = 5\ \%$

  (AQL) = 10 %

  — Limiting quality $\beta = 5\ \%$

  (LQ) = 20 %

— Children (after demonstration) (Figure B.2):

  AQL = 15 % $\alpha = 5\ \%$

  LQ = 25 % $\beta = 5\ \%$

  where

  α is the producer's risk;

  β is the consumer's risk.

Although these values are sufficiently precise to give the sampling procedure chosen, they would not, however, be suitable for calculating a new set of acceptance and rejection figures. These figures, supplied in the charts and tables, also take into account other criteria and may, in practice, be considered to be standard.

Bibliography

[1] ISO 9001, *Quality management systems — Requirements*

[2] ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ICS 55.020
Price based on 13 pages