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Test methods for sterile medical device package - Part 15: Performance testing of shipping containers and systems

无菌医疗器械包装试验方法

第 15 部分：运输容器和系统的性能试验

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Foreword

YY/T 0681 "Test methods for sterile medical device package" consists of the following parts:

-- Part 1: Test guide for accelerated aging;

-- Part 2: Seal strength of flexible battier materials;

-- Part 3: Internal pressurization failure resistance of unrestrained packages;

-- Part 4: Detecting seal leaks in porous packages by dye penetration;

-- Part 5: Detecting gross leaks in medical packaging by internal pressurization (bubble test);

-- Part 6: Evaluation of chemical resistance of printed inks and coatings on flexible packaging materials;

-- Part 7: Evaluating inks or coating adhesion to flexible packaging materials using tape;

-- Part 8: Coating/adhesive weight determination;

-- Part 9: Burst testing of flexible package seals using internal air pressurization weight restraining plates;

-- Part 10: Test for microbial barrier ranking of porous package material;

-- Part 11: Determining integrity of seals for medical packaging by visual inspection;

-- Part 12: Flex durability of flexible barrier films;

-- Part 13: Slow rate penetration resistance of flexible barrier films and laminates;

-- Part 14: Testing the microbial barrier for porous packaging materials under moist conditions and with passage of air;

-- Part 15: Performance testing of shipping containers and systems;

-- Part 16: Test for climatic stressing of packaging system.

This Part is Part 15 of YY/T 0681.

This Part was drafted in accordance with the rules given in GB/T 1.1-2009.

Please note that some of the contents of this document may involve patents. The issuing organization of this document is not responsible for identifying these patents.

This Part was proposed by National Medical Products Administration.

This Part shall be under the jurisdiction of National Technical Committee 106 on Medical Syringes of Standardization Administration of China (SAC/TC 106).

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Introduction

After the packaging system of sterile medical devices has withstood all the expected hazards (sources) in the transportation process, whether the performance of the devices that are delivered to the user can still meet the expected performance requirements at the factory is a problem that users are very concerned about, which gains more and more attention of producers, users and the management.

This Part of YY/T 0681 refers to ASTM D 4169-16 "Standard Practice for Performance Testing of Shipping Containers and Systems". The committee believes that the distribution cycle which is given in Table 1 of this Part (refer to DC13 in ASTM D 4169-16) represents the strictest challenge in the domestic distribution process of sterile medical device package. Therefore, it is determined to be the recommended test schedule for this Part. For sterile medical devices of special distribution cycles, the test requirements for other distribution cycles in the ASTM D 4169 standard can also be referred to.

Test methods for sterile medical device package - Part 15: Performance testing of shipping containers and systems

1 Scope

This Part of YY/T 0681 specifies a uniform method for evaluating the ability of sterile medical device shipping units to withstand the transport environment in the laboratory.

This Part is used for guiding the user to design an appropriate test plan, so that the shipping unit can withstand a series of expected hazards to be experienced in a specific distribution cycle.

This Part does not include performance testing of single parcel transport packages.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 4857.2, Packaging - Basic tests for transport packages - Part 2: Temperature and humidity conditioning

GB/T 4857.4, Packaging - Basic tests for transport packages - Part 4: Compression and Stacking tests using a compression tester

GB/T 4857.5, Packaging - Transport packages - Vertical impact test method by dropping

GB/T 4857.7-2005, Packaging - Basic tests for transport packages - Part 7: Sinusoidal vibration test method at constant frequency

GB/T 4857.10, Packaging - Basic tests for transport packages - Part 10: Sinusoidal vibration test method using at variable vibration frequency

GB/T 4857.23, Packaging - Basic tests for transport packages - Part 23: Random vibration test method

3 Terms and definitions

The following terms and definitions are applicable to this document.

3.1

Acceptance criteria

The acceptable quality level that the shipping unit must meet after being subjected to the test plan.

3.2

Assurance level

The level of test strength that is determined according to the probability of occurrence in a typical distribution cycle.

Note: The assurance level I is the highest level of test strength, but the probability of occurrence is low; the level III is the lowest level of test strength, but the corresponding probability of occurrence is high; the test strength of level II is between level I and level III.

3.3

Distribution cycle; DC

The sequence list that uses the test schedule to simulate the hazard elements that are expected to occur in the specific route of the shipping unit from production to consumption.

Note: The distribution cycle which is given in Table 1 refers to DC 13 in ASTM D 4169-16.

3.4

Feeder aircraft

The light aircraft that may not be pressurized in the warehouse, which is used to transport the packaged express.

3.5

Hazard element

A specific event that may cause hazards to the shipping unit, which is generated during a distribution cycle. This element is usually simulated through a separate test schedule.

3.6

Less than truckload; LTL

The transportation where the volume of goods is less than a truckload.

3.7

Shipping unit

The smallest complete unit that is subjected to the distribution environment, such as a shipping container and its contents.

3.8

Porous packaging material

Materials that are used in medical packaging to provide environmental and biological barriers, and which, at the same time, allow sufficient airflow to pass through in gas sterilization (such as ethylene oxide, steam, gas plasma).

3.9

Test plan

A specific list of test schedules, which is used to simulate the expected hazard of a shipping unit in the distribution cycle. It includes the test strength and the number of test items.

3.10

Test schedule

The specific procedure to be used, including the strength of three assurance levels, and a test method standard number (that is, the basis of the schedule).

Note: The purpose of the test schedule is to simulate the stress that is generated by all hazard elements in the distribution cycle.

3.11

Single parcel

A non-standard shipping unit (such as a mailing package).

4 Test schedule applicable to the distribution cycle of sterile medical devices

4.1 The recommended transport test of transport packages of sterile medical devices shall be carried out in sequence according to the test schedule that is given in Table 1.

Table 1 – Test schedule of the recommended sterile medical device shipping unit

Sequence number	1	2	3	4	5	6	7
Schedule	A	C	F	I	E	J	A
Item name	Manual handling	Carrying stacking	Unconstrained vibration	Low pressure	Carrying vibration	Concentrated impact	Manual handling
Note: This test schedule refers to DC13 of ASTM D 4169-16. If proved, other distribution cycles can be selected. For single parcel transportation test, refer to ASTM D 7386.							

4.2 The schedule which is given in Table 1 simulates the various hazards that the medical device is expected to experience during the transportation test. The test schedule is expected to be used in the following areas:

-- Used to evaluate whether the sterile medical device packaging system (including sterile barriers and protective packaging) meet the ability of the predetermined acceptance criteria after bearing the expected transportation process;

-- As a pre-test before the performance test of sterile medical devices after loading and packaging, it is used to evaluate whether all the performances of the internal devices still meet the expected clinical requirements after the expected distribution cycle.

4.3 These tests should be carried out sequentially on the same shipping unit. For performance tests, this Part requires that the shipping unit is not opened before all tests are completed. If used for other purposes, such as packaging development, the shipping unit can be opened and inspected at each time point of the series of tests, but this may not be able to evaluate the impact of closure on the performance of the container.

5 Test sample

5.1 The test sample consists of representative and complete samples of the shipping unit, including the actual contents. For valuable medical devices, if there is no need to conduct experimental research on the defects of the contents, and the defects have been recorded in the report, products of flaws

or small defects can be used. If the test on the actual product may be dangerous, a simulated device can be used as the test load. If a simulated load is used, it should be measured to determine whether it exceeds the fragility level of the actual product. The loading characteristics of actual product shall be carefully simulated and unnecessary collisions shall be avoided.

5.2 It shall be ensured that the product and packaging are not degraded when the test package arrives at the test site. If the state of the packaging is questionable, new packaging materials shall be used to repackage the product before the test.

5.3 The number of tests performed depends on the intended purpose of the test and the availability of the same product and shipping container.

6 Conditioning and test conditions

The samples shall be tested under standard atmospheric conditions; the influence of any climatic conditions shall be compensated. Unless other temperature and relative humidity conditions are considered more appropriate, the shipping unit shall be placed in the standard atmosphere, where the temperature is (23±2) °C and the relative humidity is (50±2) %, as specified in GB/T 4857.2, for conditioning. The same atmospheric conditions shall be used for all assurance levels. It is recommended to use a 72-h conditioning period, or a time sufficient for all parts of the product and packaging to reach equilibrium. The test should be performed under the conditioning atmosphere as much as possible. If not, the test shall be performed as soon as possible after the sample is taken out from the conditioning environment. If necessary, re-condition the shipping unit during the test plan.

Note: In some special transportation environments, all tests can be carried out in accordance with other atmospheric conditions that are given in GB/T 4857.2. The same atmospheric conditions shall be used for all assurance levels. The duration of the conditioning shall be sufficient to allow all parts of the product and packaging to reach equilibrium. The test should be performed under the conditioning atmosphere as much as possible. If not, the test shall be performed as soon as possible after the sample is taken out from the conditioning environment. For the non-standard conditioning atmosphere, the user shall determine the compression load factor of the corresponding vehicle stacking. The factors which are given in Table 5 of 11.2 are based on the test under the standard test atmosphere.

7 Acceptance criteria

7.1 Acceptance criteria shall be established before the test; the required state of the product should be considered when it is received. The organization that conducts the test can choose any acceptance criteria that suits its purpose. A feasible approach is to compare the type and extent of damage of the test sample with the damage that is caused in actual circulation and handling, or with the test results of similar containers of known transportation history.

7.2 In most cases, the acceptance criteria can be:

Criterion 1 – The product is undamaged;

Criterion 2 – The packaging is intact and undamaged;

Criterion 3 – Criterion 1 plus criterion 2.

In general, this means that the shipping container and its contents are suitable for normal sale and use after the test cycle is completed. Detailed acceptance criteria may allow acceptable and prescribed damage to the product or its packaging. The forms and contents of the acceptance criteria can vary greatly depending on the specific situation. The method can range from simple qualified/unqualified judgment to complex quantitative scoring or system analysis.

8 Procedure

8.1 Define the shipping unit

Use terms such as specification and dimension, weight, and structural style to describe the shipping unit.

8.2 Determine the assurance level

Specify a level of test strength. This level shall be one of three predetermined assurance levels. The predetermined level shall be determined based on the value of the product, the expected level of expected tolerable damage, the number of shipping units, the information about the transport environment, or other criteria. When there are no other restrictions, it is recommended to use the assurance level II. Assurance level I provides a stricter test than assurance level II. The degree of strictness of the test that is provided by assurance level III is lower than assurance level II. The assurance levels of each schedule (see Chapter 10 to Chapter 13) can vary (if known differences exist); the used assurance level for the test should be reported. See Chapter 16.

8.3 Determine acceptance criteria

Acceptance criteria are related to the expected state of the product and packaging at the end of the distribution cycle. See Chapter 7.

8.4 Select the distribution cycle

For sterile medical devices, use the distribution cycle in Table 1.

8.5 Prepare the test plan

Develop a test plan for the selected distribution cycle according to the schedule that is described in Table 1. Obtain the test strength from the corresponding test schedule. When determining the specific test strength, the selected assurance level and the physical condition of the shipping unit shall be considered. In this way, Table 1 will guide the user to develop a detailed test plan, which describes the exact sequence of inputs that the shipping unit will undergo each test. Refer to the current test method standards for the instruments and techniques that are used in the test schedule related to each hazard element.

Note: See Appendix A for examples of sample test methods.

8.6 Select the test sample

See Chapter 5.

8.7 Sample conditioning

See Chapter 6.

8.8 Perform the test

Perform the test according to the test method standards that are specified in each test schedule and the changes that are given in the special instructions of each method.

8.9 Evaluate the results

Evaluate the results, so as to determine whether the shipping unit meets the acceptance criteria. See Chapter 7.

8.10 Document the test results

Document the test results by reporting each step. See Chapter 16.

8.11 Monitor the transportation

If possible, obtain feedback by monitoring the transportation of the container after the test, so as to ensure that the type and degree of damage obtained by

the laboratory is correlated with the damage that occurs during the actual distribution cycle. This information is very useful for the future preparation of test plans for similar shipping containers.

9 Test schedule corresponding to the hazard

The test schedule corresponding to the hazard is shown in Table 2.

Table 2 – Test schedule corresponding to the hazard

Schedule	Hazard	Test	Chapter
A	Manual handling	Drop (free fall or vertical impact), bridge impact (if applicable)	10
C	Carrying stacking	Compression load	11
E	Carrying vibration	Vibration (random vibration and sinusoidal resonance)	12
F	Unconstrained vibration	Subject to repeated vibrations of specified frequency in multiple directions	13
I	Low pressure hazard	Vacuum	14
J	Concentrated impact	Vertical impact	15

10 Schedule A – manual handling

10.1 Manual handling test is used for the performance test of single container, small parcel and any shipping container whose weight does not exceed 90 kg and can be handled manually.

10.2 The test level and test method of this schedule are expected to determine the ability of the shipping unit to withstand the hazards that are caused by manual handling (such as loading, unloading, stacking, sorting or pallet loading) during the distribution cycle. The main hazard of these operations is the impact caused by falling or throwing. The size, weight and shape of the shipping unit will affect the degree of these hazards. There are two drop test methods to choose from, the free fall test and the simulated drop test, both of which produce similar results.

10.3 The recommended drop height is shown in Table 3; the number of drops, the drop progress and the impact direction of the shipping unit are shown in Table 4.

For the test method, see GB/T 4857.5.

Note 1: The test can also be performed according to ASTM D 5276.

See Chapter 6 for conditioning.

Note 2: For the shipping unit, of which the long side of the packaging is at least 915 mm, and the size in the other two directions is less than or equal to 20% of the longest size, the bridge impact test shall be considered in accordance with ASTM D 5265.

Table 3 – Drop height corresponding to the shipping weight

In centimeters

Shipping weight/kg	Assurance level		
	Ⅰ	Ⅱ	Ⅲ
0～9.1	61	38	23
＞9.1～18.1	53	33	20
＞18.1～7.2	46	30	18
＞27.2～36.3	38	25	15
＞36.3～45.4	30	23	13
＞45.4～90.7	25	18	10

11 Schedule C – Carrying stacking

11.1 The test level and test method of this schedule in the distribution cycle are expected to determine the ability of the shipping unit to withstand the compression load during storage or transportation. The required load shall consider the influence of storage time, container arrangement or stacking method, container strength change, moisture content, temperature, early handling, transportation, load support method and vibration. For the minimum load of a typical shipping unit that includes the combined effects of the above factors, it is recommended to determine the F factor according to the assurance level that is given in Table 5.

For the test method, see GB/T 4857.4.

Note: The test can also be performed with reference to the method that is specified in ASTM D 642.

See Chapter 6 for conditioning.

Table 4 – Number of drops, drop progress, impact position of the shipping unit

Test schedule during the distribution cycle	Number of impacts at the specified height	Impact direction		
		Box	Bag or package	Cylindrical container
	1	Top	Surface	Top

The first test schedule (schedule 1 in Table 1)	2	Two adjacent bottom edges	Two sides	Two sides separated by 90°
	2	Two opposite bottom corners	Both ends	Bottom edges separated by 90°
	1	Bottom	Opposite sides	Bottom
The second test schedule (schedule 7 in Table 1)	1	Vertical edge	Surface	Top
	2	Two adjacent sides	Both sides	Two sides separated by 90°
	2	A corner angle and an adjacent top edge	Opposite ends	Bottom edges separated by 90°
	1	See Note 1	See Note 1	See Note 1
Note 1: The last impact of the second manual handling test schedule of a distribution cycle should be twice the specified height or equivalent speed change [this is the last (6^{th}) drop in the test sequence, not an added drop]. The drop should be in the direction where the impact is most likely to fall, which is usually the largest surface or bottom. For the distribution cycle in which the drop may occur in any direction (that is, when the mechanical sorting small parcel conveyor belt is used for sorting), the most critical direction, that is, the direction that is most likely to cause damage, should be selected (refer to ASTM D 5276). **Note 2**: For the simulated drop method that uses an impact testing machine, it is recommended to take the equivalent speed change corresponding to the specified drop height according to the provisions of ASTM D 5487.				

11.2 Use the F factor that is given in Table 5.

Table 5 – F-factor assurance level of the shipping unit

Structure type	Description	Assurance level		
		I	II	III
1	Corrugated paper, fiberboard or plastic containers, with or without inner packaging that uses these materials to withstand pressure; the product does not bear any load	10.0	7.0	5.0
2	Corrugated paper, fiberboard or plastic containers, with rigid spacers (such as wood) in pressure-bearing inner packaging	6.0	4.5	3.0
3	The container structure uses materials that are not sensitive to temperature and humidity other than corrugated paper, fiberboard or plastic, or the product directly bears the load, for example, compression packaging	4.0	3.0	2.0

If the product bears a known fraction of load, calculate the F factor according to Formula (1):

$$F = P(F_P) + C(F_C) \quad \cdots\cdots(1)$$

Where:

P – the load fraction of the product;

F_P – the factor of the compression packaging that is given in Table 5 (structure type 3);

C – the load fraction of the container;

F_C – the container factor of the corresponding structure that is given in Table 5.

If a whole pallet is tested under load, the F factor can be reduced by 30%.

11.3 For carrying stacking which is composed of the same shipping unit, load the shipping unit to the load that is calculated according to Formula (2). Remove the load within 3 s after reaching the specified value.

$$L = m \times J \times \frac{H - h}{h} \times F \quad \cdots\cdots(2)$$

Where:

L – calculated load, in Newtons (N);

m – the mass of the shipping unit or a single container, in kilograms (kg);

J – 9.8 N/kg;

H – the maximum transport stacking height (if the carrying stacking height is unknown, use 2.7 m), in meters (m);

h – the height of the shipping unit or a single container, in meters (m);

F – the factor that considers the combined effect of the above-mentioned various factors.

11.4 For the delivery environment where the carrying stacking is transported by LTL that is composed of mixed goods, or small packages, load the shipping unit to the load value that is calculated according to Formula (3). Remove the load within 3 s after the load reaches the specified value. If the average transportation density factor (M_f) of a particular distribution system is not known, use 160 kg/m^3.

$$L = M_f \times J \times \frac{l \times w \times h}{K} \times \frac{H - h}{h} \times F \quad \cdots\cdots(3)$$

Where:

L – calculated load, in Newtons (N);

M_f – transportation density factor, in kilograms per cubic meter (kg/m^3);

J – 9.8 N/kg;

l – the length of the shipping unit or a single container, in meters (m);

w – the weight of the shipping unit or a single container, in meters (m);

h – the height of the shipping unit or a single container, in meters (m);

K – 1 m^3/m^3;

H – the maximum stacking height in transportation (if the carrying stacking height is unknown, use 2.7 m), in meters (m);

Note: If the H value is unknown, for packages below 13.6 kg with a volume of 0.056 m^3 or smaller, when using the less-than-truckload (LTL) transportation method, reduce the height from 2.7 m to 1.4 m when calculating the hazard element of the carrying stacking.

F – the factor that considers the combined effect of the above-mentioned various factors.

12 Schedule E – carrying vibration

12.1 Overview

The test level and test method of this schedule in the distribution cycle are expected to determine the ability of the shipping unit to withstand the vertical vibration environment and the dynamic compression force that is generated by the carrying stacking. The test level and method shall consider factors such as the amplitude, frequency range, duration and direction of the vibration. There are two vibration test methods to choose from: random vibration and sinusoidal vibration. These two methods are not equivalent and will produce different results. The random test method can better simulate the actual carrying vibration environment and is the preferred method. The sinusoidal test method, which is often used in conjunction with the random method, is a means of determining and observing system resonance. Perform the test in every possible transport direction (up to three dimensions). 12.2 gives the recommended strength and duration of the random test; 12.3 gives the recommended strength and duration of the sinusoidal test.

12.2 Random test

For the test method, see GB/T 4857.23.

See Chapter 6 for conditioning.

12.2.1 It is recommended to use the 60 min highway test plan that is given in Table 6 and Figure 1; then, use the 120 min air transport test plan that is given in Table 8 and Figure 3.

12.2.2 If more detailed information about the transportation vibration environment or the history of damage to the shipping unit can be obtained, it is recommended to use this information to modify the test schedule. The test time that is required to reproduce the transport damage depends on the mode of the damage and the level of vibration. The test time from 30 min to 6 h has been successfully applied to different packaging types. In the absence of specific transportation and test experience, it is reasonable to use a test time of 3 h (180 min).

12.2.3 For the highway test plan, it is recommended to use a combination of all three test levels (low, medium, and high) to better simulate the actual highway vibration environment. It is recommended to carry out the 1 h (60 min) test according to the following highway random vibration plan:

1) 40 min for low level;

2) 15 min for medium level;

3) 5 min for high level.

12.2.4 For the carrying vibration test, when there may be more than one transportation direction, the total vibration duration shall be equally distributed to each test direction.

Note: When conducting highway tests, assurance level I, assurance level II and assurance level III are not used.

Table 6 – Power spectral density level of the highway test

Frequency/Hz	Power spectral density/(g^2/Hz)		
	High level	Medium level	Low level
1	0.000 72	0.000 72	0.000 4
3	0.030	0.018	0.010
4	0.030	0.018	0.010
6	0.001 2	0.000 72	0.000 40
12	0.001 2	0.000 72	0.000 40
16	0.006 0	0.003 6	0.002 0
25	0.006 0	0.003 6	0.002 0
30	0.001 2	0.000 72	0.000 40
40	0.006 0	0.003 6	0.002 0
80	0.006 0	0.003 6	0.002 0
100	0.000 60	0.000 36	0.000 20
200	0.000 030	0.000 018	0.000 010
Root mean square of acceleration [a] (grms)	0.70	0.54	0.40
[a] GB/T 4857.23 gives the definition of the root mean square of acceleration.			

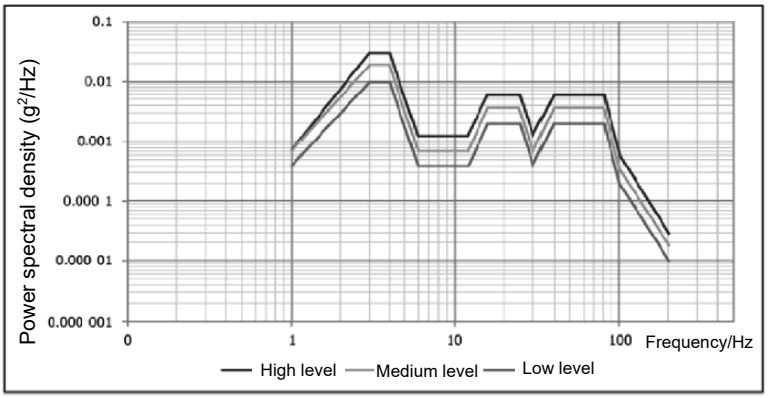

Figure 1 – Power spectral density level of the highway test

Table 7 – Power spectral density level of the railway test

Frequency/Hz	Power spectral density/(g^2/Hz)		
	Assurance level I	Assurance level II	Assurance level III
1	0.000 02	0.000 01	0.000 005
2	0.002	0.001	0.000 5
50	0.002	0.001	0.000 5
90	0.000 8	0.000 4	0.000 2
200	0.000 02	0.000 01	0.000 005
Root mean square of acceleration (grms)	0.41	0.29	0.2

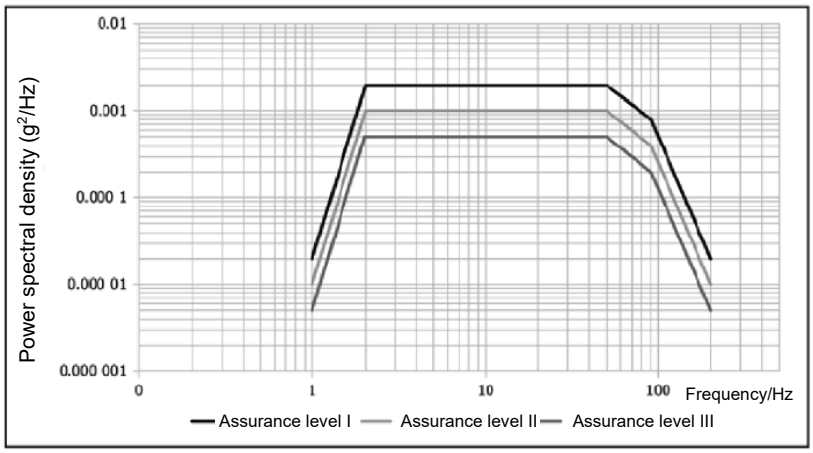

Figure 2 – Power spectral density level of the railway test

Table 8 – Power spectral density level of the aviation test

Frequency/Hz	Power spectral density/(g^2/Hz)		
	Assurance level I	Assurance level II	Assurance level III
2	0.000 4	0.000 2	0.000 1
12	0.02	0.01	0.005
100	0.02	0.01	0.005
300	0.000 02	0.000 01	0.000 005
Root mean square of acceleration (grms)	1.49	1.05	0.74

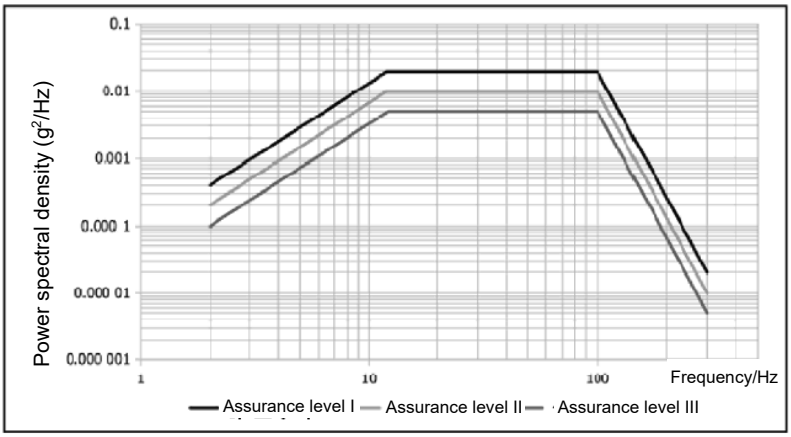

Figure 3 – Power spectral density level of the aviation test

12.3 Sinusoidal test

For the test method, see GB/T4857.10.

Note: Or refer to method B or method C in ASTM D 999-08 for testing.

See Chapter 6 for conditioning.

Special note: Duration refers to the duration of each resonance point of no more than four discrete resonances that are marked on the product or package. If there are more than four resonance points, the test shall be carried out at the four marked frequencies that produce the maximum response. In frequency scanning, the frequency ranges which are frequently encountered in the transportation type should be considered. Due to changes in the characteristics of the container system during the test, the resonance frequency may drift. It is recommended to change the continuous frequency slightly during the test to detect any drift, so that the test frequency continues at the maximum response. Use the test level that is specified in Table 9.

Table 9 – Level of sinusoidal resonance test

Assurance level	Frequency range Hz	Amplitude (0 - peak)		Duration min
		Railway	Highway	
I	3~100	0.25g	0.5g	15
II	3~100	0.25g	0.5g	10
III	3~100	0.25g	0.5g	5

13 Schedule F – Unconstrained vibration

13.1 The test level and test method of this schedule are expected to determine the ability of the shipping unit to resist revibration during bulk or unconstrained transport. The amplitude, direction and duration of revibration are considered in the test level and test method.

13.2 The following test levels are used:

For the test method, see method B in GB/T 4857.7-2005.

Note: Or refer to method A1 or method A2 in ASTM D 999-08 for testing.

See Chapter 6 for conditioning.

Special note: 50% of the duration of this test is allocated to the normal vertical transport axis, that is, the direction perpendicular to the predetermined bottom; the remaining 50% of the duration is evenly allocated to other possible transport directions.

Table 10 – Test level of the unconstrained vibration

Assurance level	Duration min
I	60
II	40
III	30

14 Schedule I – low pressure (high altitude) hazards

14.1 This schedule is expected to be used to provide the pressure drop when the packaged product is transported through certain modes of transportation (such as a feeder aircraft or through a mountain pass). This test shall be carried out at the level that is described in Appendix B. This test is suitable for products and packaging that are sensitive to low-pressure environments, such as sealed airtight flexible packages, liquid containers, or air-permeable packaging that is adversely affected by low-pressure environments due to its packaging form. When the shipping unit contains the initial packaging of air-permeable materials, this test can be cancelled from Table 1.

14.2 Use the altitude during the expected transportation period to test the package. If the precise altitude is not known, it is recommended to use the pressure (59.5 kPa) equivalent to 4 267 m in Appendix B for a duration of 60 min. The test duration and pressure can be improved according to the transportation environment, product value, expected acceptable damage level, or other criteria described in Appendix B.

15 Schedule J – Concentrated impact

This schedule provides a test method that simulates the expected low-level concentrated impact of packaging during sorting operations and transportation. This test applies only to lighter single-corrugated packaging containers whose vertical side compressive strength[1] is less than 7 700 N/m and plastic film-wrapped packaging and unitized loads.

See Chapter 6 for conditioning.

See Appendix C for the test method.

16 Report

All test schedules shall be reported; the report shall include the following:

a) The number of this Part;

b) A description of the product and the shipping unit, including the direction of the product in the shipping unit;

c) Test plan;

d) Assurance level and description;

[1] For the test method, see GB/T 6546.

e) The number of samples to be tested;

f) The used conditioning;

g) Acceptance criteria;

h) Selected vibration, random or sinusoidal;

i) Power spectral density diagram of random vibration, if used;

j) Pressure level and duration of the undergone high altitude;

k) Recommended vibration procedures;

l) State of the sample after the test.

Appendix A

(Informative)

Examples of transport test plans

A.1 General

The following examples help illustrate the use of this Part.

A.2 Examples

A.2.1 Perform a test on a packaged product; the value and volume of the shipment shall be representative of other products on the transportation line. After the test, no damage and intact packaging are acceptable conditions. The weight of the product packed in corrugated cartons is 12.7 kg; the height is 0.23 m; the yard height for storage and less than truckload (LTL) transportation is 1.6 m. The product does not bear any load.

A.2.2 Step 1 Define the shipping unit

The test shipping unit does not use pallet loading.

A.2.3 Step 2 Determine the assurance level

According to the loading value and loading volume, adopt the assurance level II.

A.2.4 Step 3 Determine the acceptance criteria

Criterion 1 – The product is undamaged;

Criterion 2 – All packages are in a saleable state;

Criterion 3 – The packaging meets the requirements of the ageing testing.

A.2.5 Step 4 Select the test schedule

Perform according to Table 1.

A.2.6 Step 5 Prepare the test plan (Table A.1).

A.2.7 Step 6 Select the test samples

Choose three representative samples of shipping containers.

A.2.8 Step 7 Sample conditioning

This test plan did not consider the special transportation climate.

See Chapter 6 for conditioning.

A.2.9 Step 8 Perform the test

Carry out tests in sequence according to the test plan of step 5, according to the specified standards and special instructions for each test schedule.

A.2.10 Step 9 Evaluate results

Check the product and packaging to determine whether they meet the acceptance criteria that are determined in step 3.

A.2.11 Step 10 Document the test results

According to Chapter 16, compile a test report that contains all the steps in detail.

Table A.1 – Transport test plans

Sequence	Test schedule	Test method	Test requirements
1	A Manual handling	ASTM D 5276 or GB/T 4857.5	One drop at the top, two drops at two adjacent bottom edges, two drops at the opposite bottom corners, and one drop at the bottom. The drop height is 330 mm
2	C Carrying stacking	ASTM D 642 or GB/T 4857.4	F = 7.0, pressure to 5 192 N, lasting 3 s
3	F Unconstrained vibration	Method A1 or A2 of ASTM D 999, method B in GB/T 4857.7	Double-amplitude for 25 min; the bottom surface continuously vibrates for 20 minutes; the two adjacent sides vibrate continuously for 10 minutes.
4	I Low pressure	Appendix B (ASTM D 6653)	59.5 kPa (corresponding to the atmospheric pressure at an altitude of 4 267m) for 60 min
5	E Carrying vibration	GB/T 4857.23	**Random vibration test:** It is recommended to use the highway test plan that is given in Table 6 and Figure 1 to vibrate for 40 min, 15 min and 5 min (60 min in total) at low, medium and high levels respectively; then, use the level II air transport test plan that is given in Table 8 and Figure 3 to vibrate for 120 min **Sinusoidal vibration test:**

			At no more than four resonance points (highway: amplitude of 0.5 g); the vibration duration of each resonance point is 10 minutes
6	J Concentrated impact	Appendix C (ASTM D 6344)	1 time of vertical impact at 0.8 m
7	A Manual handling	ASTM D 5276 or GB/T 4857.5	1 vertical edge drop, 2 drops from two adjacent sides, 1 drop from a top corner, 1 drop from an adjacent top edge; the height of the above 5 drops is 330 mm. A drop from the bottom; the height is 660 mm.

Appendix B

(Normative)

Vacuum test method to determine the impact of high altitude on the packaging system[2]

B.1 Significance and use

The packaging system through air transport is vulnerable to high altitude impacts and damage. When products and/or packaging systems are exposed to these altitude conditions, they will inevitably be affected by the internal and external pressure differences formed. This test method is suitable for evaluating the impact of high altitude on the packaging system.

B.2 Apparatus

B.2.1 Vacuum test chamber

Any suitable test chamber that can withstand a pressure difference of about one atmosphere and has a flat vacuum airtight cover (door). An equivalent test chamber that can provide the same function can also be used, such as an altitude test chamber.

The inner cavity of the test chamber shall be large enough to contain the to-be-tested sample, and to allow the product and/or packaging to expand in it.

B.2.2 Vacuum gauge

The inlet pipe is connected to a vacuum source; the outlet pipe is connected to the atmosphere. It shall be enclosed in a test chamber. Both the inlet pipe and the outlet pipe shall be equipped with a manually operated valve. The range of the vacuum gauge is 0 kPa ~ 100 kPa; the minimum graduation is not more than 2 kPa; the error is not more than 2%.

B.3 Sampling

When there is no sampling plan, at least three representative samples shall be selected for performance evaluation. The test sample shall contain an assembled packaging system, including primary packaging and secondary packaging.

B.4 Conditioning

[2] This Appendix refers to ASTM D 6653.

The sample shall be conditioned at 5.6 °C ± 2 °C for at least 24 h; the test shall be carried out at 5.6 °C ± 2 °C. If the conditioning before the previous test or the test conditions are not feasible, it is recommended that the sample be conditioned in the standard state of 23 °C ± 2 °C for at least 24 h.

B.5 Procedure

Put the test sample into the vacuum test chamber; close the inlet valve of the chamber; open the outlet valve and open the vacuum source; vacuum at a rate of about 305 m every 30 s ~ 60 s, until it reaches 4 267 m (59.5 kPa); the tolerance is 5%. Maintain the vacuum for 60 minutes. Then, open the inlet valve of the chamber; release the vacuum at a rate of about 305 m every 30 s ~ 60 s. Open the cover. Take out the test sample to check any damage or deformation; record the inspection result.

B.6 Interpretation of results

If after the test of the distribution packaging system, the closure, shipping container, inner packaging and product are intact and undamaged, the packaging system should be assembled again for follow-up tests, which helps to determine whether the pressure difference has affected the performance of the packaging system. It is recommended to perform the same performance test with the same packaged sample that has not been tested at high altitude.

B.7 Report

The report shall include the following information:

a) Any deviation from this test method or this test;

b) Identification of the sample;

c) A description of the product, inner packaging, transport packages and closure system, if applicable;

d) Identification of any changes in the product, inner packaging, transport packages and closure system;

e) Conditioning temperature before the test;

f) Vacuum, temperature, time and used temperature compensation factor of the test, if any.

Appendix C

(Normative)

Transport package concentrated impact test method[3]

C.1 Significance and use

This test method is expected to evaluate the ability of packaging to resist concentrated external impacts that occur during transportation and handling. These impacts can be caused by collisions between adjacent goods in the loading vehicle or during loading and unloading, conveyor belt conveying.

This test method is expected to determine the ability of the package to protect the contents from impacts, and to evaluate whether there is sufficient gap or support between the wall of the packaging box and its contents.

C.2 Apparatus

Impact test head with ball head: a solid steel rod with a diameter of (32 ± 2) mm, a length of about 115 mm, a semi-circular ball at one end, and a mass of (680 ± 15) g. The bolt which is installed in the threaded hole at the end play a role of positioning and support before the free fall of the guide; but the bolt mass is included in the range of (680 ± 15) g (see Figure C.1).

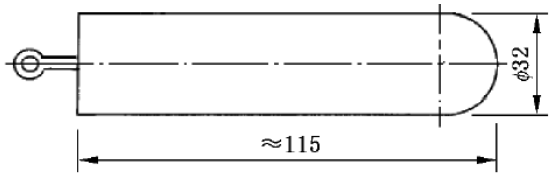

Figure C.1 – Impact test head

C.3 Sample

The sample shall preferably be designed as a package with real contents; its closing method and transportation method are the same.

Note: When the real items are valuable or dangerous, the simulated contents of the same appearance can be used; the inner packing materials should be the same as the real contents.

C.4 Procedure

C.4.1 Identification of the packaging test surface

[3] This Appendix refers to ASTM D 6344.

Normally, only test the surfaces that are most likely to receive a low level of impact during the distribution process. For large containers and containers with integrated handling platforms (such as chutes), impact the four facades and the top surface. For smaller packaging, due to the change of transportation direction in distribution, impact all sides.

C.4.2 Identification of test points on each surface of the package

C.4.2.1 If there is a specified gap between the packaging surface (wall) and the contents, and there is no support between the packaging surface and the contents, the impact position on the packaging surface should be the geometric center of the unsupported span.

C.4.2.2 If the unsupported span is greater than or equal to 50% of the width of the packaging surface or 50% of the length of the packaging surface, or the measurement exceeds 30 cm, the unsupported span is considered to be substantial. For packages that have a specified gap between the packaging surface and the contents, but have no substantial unsupported span, the impact position should be the geometric center of the surface.

C.4.2.3 If the contents of the package are in contact or within 6 mm with the packaging surface (wall), the impact position of the surface should be determined at the point where the contents are closest to the surface.

C.4.3 Establish acceptance criteria before testing

According to Chapter 17, take the vertical impact distance as 0.8 m.

Note: The impact energy under the test conditions is 5.4 J.

C.4.4 Conditioning

See Chapter 6.

C.4.5 Impact test on each surface

For small packages or any situation, take the most convenient horizontal position for the impact test head to drop as the test surface; use the free-fall method to test each identified position on the package surface.

C.5 Report

The report shall include the following information:

a) Any deviation from this test method or this test;

b) Type and size of to-be-tested packaging materials;

c) Description of the to-be-packaged contents (real or simulated);

d) The number of test samples;

e) The results of supplementary tests (such as vertical compressive strength) of the method, material and packaging of the sample conditioning;

f) Description of the used instrument (such as the impact test head free fall method);

g) Details of acceptance criteria;

h) The test surface and the test position of each surface;

i) Falling height and the energy generated by the impact of the test head;

j) Details of the test results including damage to the surface or contents of each package;

k) The name, address, date and signature of the person in charge of the test organization.

References

[1] GB/T 6546 Corrugated fibreboard - Determination of edgewise crush resistance

[2] ASTM D 642 Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads

[3] ASTM D 999-08 Standard Test Methods for Vibration Testing of Shipping Containers

[4] ASTM D 4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

[5] ASTM D 4728 Standard Test Method for Random Vibration Testing of Shipping Containers

[6] ASTM D 5265 Standard Testing Method for Bridge Impact Testing

[7] ASTM D 5276 Standard Test Method for Simulated Drop of Loaded Containers by Free Fall

[8] ASTM D 5487 Standard Test Method for Drop Test of Loaded Containers by Shock Machines

[9] ASTM D 6653 Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method

[10] ASTM D 6344 Standard Test Method for Concentrated Impacts to Transport Packages

[11] ASTM D 7386 Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems

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