

Transit Simulation Testing for Medical Device Packaging

ISO 11607 offers three possible routes to transit simulation of single-use products. While all three methods are equally valid, the schedules differ in detail and quantity.

M. Turner, Medical Engineering Technologies Ltd, Ashford, Kent, UK

[This article is published in EMDT](#)

Packaging systems for sterile medical devices

Many medical devices are supplied to the customer in a sterile state. It is the manufacturer's responsibility to ensure that sterility of the device is maintained up to the point of use. To ensure product sterility within its packaging, three aspects require interrogation:



Seal integrity testing

- Are the seals strong and complete at the outset?
- Is the packaging stable for the claimed shelf life?
- Does the entire packaging system protect the product during carriage and storage?

This article addresses the need for protection in transit. It discusses the merits of three possible approaches to transit simulation.

Medical devices are usually sealed into their sterile barrier packaging in a cleanroom. This packaging, often a pouch or blister pack, is then removed from the clean area for loading into protective packaging. This typically consists of a presentation carton (containing single or grouped products) and a shipper (or shipping carton) with one or more presentation cartons.

Transit simulation is carried out on populated shipping cartons. There are normally two objectives: to assess the performance of the shipping carton and its robustness in transport and, more importantly for the medical device manufacturer, to subject the shipping carton's contents to the rigours of transport. This allows performance testing of the sterile barrier packaging and assessment of the product as it would arrive at the customer.

Transit testing regimes

ISO 11607¹ (5.5.1) states that protective packaging should be provided for the product during transport and storage. It defines the sterile barrier element of the packaging system and the protective element. Outer packaging protects the sterile barrier during transport. The standard offers three possible routes to transit simulation of single-use products in Appendix B: ASTM D4169², ISTA 2A³ and ISO 4180⁴.

ISO 11607 requires good documentation and a rationale for use of a particular test along with detailed conditions under which the sterile barrier must be maintained and acceptance criteria.

American Society for Testing and Materials (ASTM)

One test regime is detailed by ASTM International in ASTM D4169 - 09, Standard Practice for Performance Testing of Shipping Containers and Systems. The standard offers a variety of possible distribution cycles for transit simulation. One recommended option is to select simulated manual handling: Cycle 13, Air and Motor Freight up to 45.4 kg. Each distribution cycle has associated processes, which are further described in additional standards. In the case of Distribution Cycle 13, they are:



Vibration testing

- Initial manual handling (ASTM D5276⁵)
- Vehicle stacking (ASTM D642⁶)
- Loose load vibration (ASTM D999⁷)
- Low pressure test (ASTM D6653⁸)
- Vehicle vibration (ASTM D4728⁹)
- Concentrated impact (ASTM D6344¹⁰)
- Final manual handling (ASTM D 5276⁵)

ASTM 4169 goes on to require definition of acceptance criteria and assurance levels prior to packaging testing. With respect to a medical device, the crucial acceptance criteria are that the product is still fully functional and sterile. Of course, carton damage should be limited. In the standard this is described as Criterion 3: the package should be intact and the product damage free. Assurance levels 1 to 3 are described in the standard. These levels dictate the severity of each test such as impact mass, drop height and vibration power density. The most severe, assurance level 1 is used for medical devices. It is also recommended that real shipments be monitored to confirm the results that were found in simulated transit.



Transport System

International Safe Transit Association

The second test regime for consideration is ISTA Test Procedure 2A: ISTA Pre-shipment Testing Procedures - Combination Tests for Packaged Products Weighing 150 lbs. (68 kg) or less.

This procedure includes:

- Atmospheric preconditioning (at laboratory ambient)
- Atmospheric conditioning (ASTM D4332¹¹)
- Package compression test (ASTM D642⁶)
- Initial loose load vibration (ASTM D999¹³ or ASTM D4728⁹)
- Shock test (ASTM 5727⁵ or alternative)
- Final random vibration test (ASTM D4728⁹)



Compression testing

Again, acceptance criteria should be specified, but assurance levels are not considered. One acceptance criterion is specifically detailed for the compression test: a carton should be able to support a warehouse stack of cartons if it is to be stacked for more than 24 hours. ISTA states that testing one shipping carton is usually adequate, but that five cartons or more would be preferable. ISTA 2A offers four alternatives for the shock test: free fall, mechanical vertical impact test, incline impact test or horizontal impact test.

Both test regimes (ISTA and ASTM) recommend using a fresh carton that has not been damaged in any way prior to testing.

International Standards Organisation

Test schedules are laid out in ISO 4180 in a similar way to the ASTM system, but they are less commonly used for medical devices. The standard distinguishes between known and unknown distribution systems. In most cases, presumably, the distribution chain cannot be entirely predicted. For these products there are recommended test schedules.

For packs with a mass below 30 kg the basic schedule is:

- Atmospheric conditioning (ISO 2233¹⁴)
- Shock test (ISO 2248¹³)
- Compression test (ISO 12048¹⁵)
- Transport vibration - vibration (ISO 13355¹⁶)
- Transport vibration - repetitive shock (ISO 13355¹⁶)
- Compression test (ISO 12048¹⁵)
- Shock test (ISO 2248¹³)



Drop testing

Again, different severities of test are graded 1 to 3. The most severe is suitable for medical devices, although distance of transport should be taken into account.

ISO suggests an investigation of the transport system prior to setting up a test schedule. It also spells out in greater detail acceptable levels of carton damage as well as what is required in the test report.

Preconditioning

Each test regime also has its own indications for atmospheric conditioning of packs.

ISTA is specific about requiring climatic conditioning whereas ASTM states that it should be used in simulation if the climatic condition met in distribution will have an effect on performance of the product, container or any components.

Initial preconditioning is for six hours at laboratory ambient conditions. This must be followed (if using ISTA 2A) by the highest temperature and humidity extremes expected in normal transport. It is also recommended that the lowest extremes be used.



Atmospheric Conditioning

The anticipated pre-conditioning environments for medical devices are:

Environment	Time	Temperature	Relative Humidity (RH)
Frozen	72 hours	-29°C (-20°F)	Uncontrolled RH
Tropical	72 hours	38°C (100°F)	85% RH
Desert	72 hours	50°C (120°F)	uncontrolled RH

User defined conditions

ISO 4180 suggests 2°C at 50% RH unless other conditions are indicated. The options given differ slightly from ISTA but the goal is the same.

Conclusion

ISO, ASTM or ISTA transit simulation routes may be used for medical device packaging development with equal credibility. The schedules differ in detail and quantity. The ISTA route is usually the simplest and therefore least expensive. The ISO standard gives very good guidance on investigating the distribution process and what to include in the testing report.

ISTA 2A details a worst-case atmospheric conditioning programme, tropical (hot, humid conditions), which makes a logical choice for limiting the test programme scope.

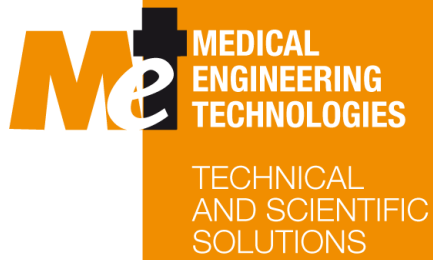
Overall, it makes sense to follow the analysis and reporting described in the ISO document as good practice, but to follow the test regime given by ISTA 2A if the analysis does not highlight any specific hazards. Validated methods are available from several qualified suppliers.

Transit simulation should be followed by package seal strength and integrity measurement as well as product QA. The package tests can be reviewed at www.emdt.co.uk/article/product-and-package-stability-studies-application-fda-guidance and at www.met.uk.com/index.php?page=ageing-trials.

References

1. ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices; Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
2. ASTM D4169 – 09, Standard Practice for Performance Testing of Shipping Containers and Systems (www.astm.org/standards/D4169.htm)
3. International Safe Transit Association. Procedure 2A: ISTA Preshipment Testing Procedures – Combination Tests for Packaged Products Weighing 150 lb (68 kg) or less. (www.ista.org/forms/2Aoverview.pdf)
4. ISO 4180:2009, Packaging – Complete, Filled Transport Packages – General Rules for the Compilation of Performance Test Schedules
5. ASTM D5276 – 98 (2009), Standard Test Method for Drop Test of Loaded Containers by Free Fall
6. ASTM D642 – 00 (2005)e1, Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
7. ASTM D999 – 08, Standard Test Methods for Vibration Testing of Shipping Containers
8. ASTM D6653 –01 (2006), Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method
9. ASTM D4728 – 06, Standard Test Method for Random Vibration Testing of Shipping Containers
10. ASTM D6344 – 04 (2009), Standard Test Method for Concentrated Impacts to Transport Packages
11. ASTM D4332 – 01 (2006), Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
12. ASTM D999 – 08, Standard Test Methods for Vibration Testing of Shipping Containers
13. ISO 2248: 1985, Packaging, Complete, Filled Transport Packages, Vertical Impact Test by Dropping
14. ISO 2233:2000, Packaging, Complete, Filled Transport Packages and Unit Loads, Conditioning for Testing
15. ISO 12048:2004, Packaging, Complete, Filled Transport Packages, Compression and Stacking Tests Using a Compression Tester
16. ISO 13355:2001 Packaging - Complete, Filled Transport Packages and Unit Loads, Vertical Random Vibration Test

Mark Turner



Sales Director

Medical Engineering Technologies Ltd,

Yew Tree Studios, Stone Street, Stanford North, Ashford, TN25 6DH, UK

tel. +44 8454 588 924

e-mail: m.turner@met.uk.com

<http://www.met.uk.com>

Medical Engineering Technologies Ltd • Yew Tree Studios, Stone Street, Stanford North, Ashford, Kent, TN25 6DH, UK
t +44 (0)8454 588924 f +44 (0)1303 813952 e solutions@met.uk.com www.met.uk.com

Registered No. 3295099 VAT No GB 6838559 76

