

# 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.

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## 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 11607<sup>1</sup> (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 D4169<sup>2</sup>, ISTA 2A<sup>3</sup> and ISO 4180<sup>4</sup>.

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:

- Initial manual handling (ASTM D5276<sup>5</sup>)
- Vehicle stacking (ASTM D642<sup>6</sup>)
- Loose load vibration (ASTM D999<sup>7</sup>)
- Low pressure test (ASTM D6653<sup>8</sup>)
- Vehicle vibration (ASTM D4728<sup>9</sup>)
- Concentrated impact (ASTM D6344<sup>10</sup>)
- Final manual handling (ASTM D 5276<sup>5</sup>)



Vibration testing

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 D4332<sup>11</sup>)
- Package compression test (ASTM D642<sup>6</sup>)
- Initial loose load vibration (ASTM D999<sup>13</sup> or ASTM D4728<sup>9</sup>)
- Shock test (ASTM 5727<sup>5</sup> or alternative)
- Final random vibration test (ASTM D4728<sup>9</sup>)



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 2233<sup>14</sup>)
- Shock test (ISO 2248<sup>13</sup>)
- Compression test (ISO 12048<sup>15</sup>)
- Transport vibration - vibration (ISO 13355<sup>16</sup>)
- Transport vibration - repetitive shock (ISO 13355<sup>16</sup>)
- Compression test (ISO 12048<sup>15</sup>)
- Shock test (ISO 2248<sup>13</sup>)



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](http://www.emdt.co.uk/article/product-and-package-stability-studies-application-fda-guidance) and at [www.met.uk.com/index.php?page=ageing-trials](http://www.met.uk.com/index.php?page=ageing-trials).

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