

**ASTM D 4169 & ISTA- Transportation/Distribution Simulation Study**

**When & How ASTM D 4169 & ISTA Applies?**

**ASTM D 4169 & ISTA series** provide guidance on testing of shipping units to verify the ability of shipping units to withstand the Transportation and Distribution hazards (i.e. shock, drop, impact, vibration, altitude pressure, temperature, humidity etc.).

**ASTM D 4169** has interpreted the simulation probability based on lifecycle of package systems and defines the possible distribution cycles (DC-1 to 18) with applicable sequential characteristics tests (Define as a Schedule A to H) to be conducted on the shipping units with respect to choice of assurance level (AL-I, II & III) based on the criticality of fragileness and integrity of product is important; which can affect by distribution environment.

ASTM recognized characteristics tests are as –

| Schedule | Test Schedule/Name             | Hazard Elements         |
|----------|--------------------------------|-------------------------|
| A        | Handling - Manual & Mechanical | Drop, impact, Stability |
| B        | Warehouse Stacking             | Compression             |
| C        | Vehicle Stacking               | Compression             |
| D        | Stacked Vibration              | Vibration               |
| E        | Vehicle Vibration              | Vibration               |
| F        | Loose Load Vibration           | Repetitive shock        |
| G        | Rail Switching                 | Longitudinal shock      |
| H        | Environmental Hazard           | Cyclic Exposure         |

**How Selection of Distribution Cycle(s) and Assurance Level with Medzus Defined Six-Q**

Understand & define the lifecycle of package system by means of following Six-Q and select DC & AL.

**Medzus Six-Q:**

- I. **What** (Product Nature)?
- II. **How** (Package System Configuration)?
- III. **Which** (Modes of Transportations)?
- IV. **When** (Environmental Conditions)?
- V. **Where** (Geographical Regions)?
- VI. **Who** (Handling Condition)?

A **Medzus** lab has developed the protocol in line with ASTM D4169 requirement and covers the complete testing solution.

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**I. What** is the Possible Product Nature?-

- Fragile/Non-Fragile
- Rigid/Flexible
- Sterile/Non-Sterile

**II. How** is the Possible Package System Configuration?-

- Bulk
- Single Package
- Load is Unitized/Non-Unitized
- Palletized/Non-Palletized

**III. Which** are the Possible Modes of Transportation?-

- Motor Vehicle
- Rail
- Air
- Sea

**IV. When** the Possible Environmental Conditions Overcomes?-

- Deep Cryogenic -65°C ± 3 (RH N/A)
- Cryogenic -55°C ± 3 (RH N/A)
- Intense cold -30°C ± 2 (RH N/A)
- Freezing -18°C ± 2 (RH N/A)
- Refrigeration 5°C ± 2 (85 ± 5% RH)
- Temperature with high humidity 20°C ± 2 (90 ± 5% RH)
- Tropical 40°C ± 2 (90 ± 5% RH)
- Desert 60°C ± 2 (15 ± 5% RH)
- Normal 23°C (50% RH)

**V. Where** are the Possible Geographical Regions to send?

- Asia
- North America
- Central America
- South America
- Eastern Europe
- Europe
- Africa
- Middle East
- Oceania
- Caribbean

**VI. Who** is the Possible Handler?-

- Man
- Machine
- Man & Machine

Categorize the risk involve in distribution process and assign to select the AL-

- High Risk: Use AL-I
- Moderate Risk, or DC is unknown or user defined: Use AL-II
- Minimal Risk: Use AL-III

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DC’s are designed in accordance with a combination of travel types and the associated risks they pose to the products being transported. For example, DC 13 simulates a distribution process that involves intercity air freight and local motor freight for a single package up to 150 lb. When there is no distribution cycle that accurately represents distribution route, then select the user defined option DC-2 and create a custom combination of distribution hazards.

| DC No. | Distribution Cycles Term                                                          |
|--------|-----------------------------------------------------------------------------------|
| 1      | General Cycle – Undefined Distribution System.                                    |
| 2      | Specially Controlled Environment, User Specified.                                 |
| 3      | Single Package Environment, up to 100 lb (45.4 kg).                               |
| 4      | Motor Freight, Single Package Over 100 lb (45.4 kg).                              |
| 5      | Motor Freight, TL Not Unitized.                                                   |
| 6      | Motor Freight, TL or LTL – Unitized.                                              |
| 7      | Rail Only, Bulk Loaded.                                                           |
| 8      | Rail Only, Unitized.                                                              |
| 9      | Rail And Motor Freight, Not Unitized.                                             |
| 10     | Rail And Motor Freight, Unitized.                                                 |
| 11     | Rail TOFC & COFC.                                                                 |
| 12     | Air (Intercity) and Motor Freight (local), Over 100 lb (45.4 kg) Unitized.        |
| 13     | Air (Intercity) and Motor Freight (local), Single Package Up to 100 lb (45.4 kg). |
| 14     | Warehousing.                                                                      |
| 15     | Export/Import Shipment for Intermodal Container or Roll-on /Roll-off Trailer.     |
| 16     | Export/Import Shipment for Palletized Cargo Ship.                                 |
| 17     | Export/Import Shipment for Break Bulk Cargo Ship.                                 |
| 18     | Non-commercial Government Shipments per MIL STD-2073-I.                           |

Medzus team helps in evaluating and validating the package system as per international standards for your product protection and keep you in market position;  
**Email us today – [mail@medzushealth.com](mailto:mail@medzushealth.com)**



We engaged in-

- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems.
- ASTM D4332-14 - Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing.
- ASTM D5276-19 - Standard Test Method for Drop Test of Loaded Containers by Free Fall.
- ASTM D642-20, Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads.
- ASTM D999-08 (2015), Standard Test Methods for Vibration Testing of Shipping Containers.
- ASTM D6653-13 - Effects of High Altitude on Packaging Systems by Vacuum Method.
- ASTM D4728-17- Standard Test Method for Random Vibration Testing of Shipping Containers.
- ISO 11607-1: 2019, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems.

**ISTA**

The primary aim of a package is to ensure the safety of the item packed inside it. And primary aim of **Medzus** is to protect our client brand loyalty by validating package system by Utilizing ISTA guidance. **Medzus** has developed testing protocols in accordance with ISTA for packages to ensure the content arrives safely at its destination. Medzus offer the following transit and packaging testing services as per ISTA:

- ISTA 1 Series: Non-Simulation Integrity Performance Tests: 1A, 1B, 1C, 1D, 1E, 1G, 1H
- ISTA 2 Series: Partial Simulation Performance Tests: 2A, 2B, 2C, 2D, 2E
- ISTA 3 Series: General Simulation Performance Tests: 3A, 3B, 3E, 3F, 3H, 3K
- ISTA 4 Series: Enhanced Simulation Performance Tests: 4AB
- ISTA 6 Series: Member Performance Tests: 6A, 6B
- ISTA 7 Series: Development Tests: 7A, 7B, 7C, 7D.