Distribution Simulation Testing

What is the industry doing?

ASTM F2 Meeting
Barcelona, Spain
September 26, 2012
Distribution Simulation Testing

What is the industry doing?
Outline

- Introduction
- What Is Distribution Simulation?
- Purpose of Distribution Simulation
- Background of Standard Writing Organizations (ASTM & ISTA)
- Identifying Test Methodologies
- Consensus Standards
- Problems in the utilization of some standards
- So what are people utilizing and why?
- Protocol Development
- Final Test Report Development
- Conclusion
- Questions
Many medical device manufactures struggle on a daily basis with what they need to do in order to comply with ISO 11607 and which procedure to utilize for performance testing (ASTM or ISTA).

Throughout this presentation, we are going to look at this situation from a different perspective. Basically, we are going to look at it from the outside in.

DDL works with MDM’s on a daily basis by helping them execute transportation simulation using various test procedures. The primarily goal is to have an effective shipping configuration that protects the product and package integrity during transit, and ultimately is in compliance with ISO 11607.
What is distribution simulation testing?

_Distribution simulation testing_ is a uniform and repeatable way of evaluating packaging systems by utilizing laboratory equipment to subject the packaging system to specific hazards that may occur within the anticipated distribution environment.
Purpose of Distribution Simulation

Transportation simulation testing is simply a conditioning element. There is no specific or variable result derived from these tests. What testing you do after 'conditioning' identifies whether the package system passes or fails.

The testing for package system validation needs to be established prior to testing.

1. Evaluate Product/Package Interaction (Sterility Maintenance)
2. Evaluate Product Functionality
3. Regulatory Compliance
Where are distribution simulation standards developed?

- **ASTM International** (American Society of Testing Materials)
  - D4169
  - D7386
- **ISTA**
  - 2 Series “Partial Simulation Performance Tests”
  - 3 Series “General Simulation Performance Tests”
- **Corporations**
  - Own protocols
  - Modified published standards.
**Standard Writing Organizations**

- **ASTM-International**
  - Public
  - Democratic Process
    - Task Group development and approval
    - Subcommittee review and approval
    - Main Committee review and approval
  - All comments and negative ballots must be resolved before approval.
  - Full ASTM membership reviews standards prior to approval.
Standard Writing Organizations

- **ISTA** (International Safe Transit Association)
  - Private industry association (Membership required to participate.)
  - Board of Directors generates new ideas for standards.
  - Standards are reviewed and approved through “test series groups” and the ISTA Technical Council. Final approval is by Board of Directors.
  - No formal ballot process for ISTA members, outside organizations, or industry experts.
Identifying Test Methodologies (ASTM)

One of the most prevalent test procedures utilized today is ASTM D4169.

“Standard Practice for Performance Testing of Shipping Containers and Systems”

First approved in 1982 and is most widely used distribution simulation standard in the world.

Ref. McKinlay, Alfred H. “Measuring Package Performance to Avoid Shipping Damage” Standardization News (October 2004)
Identifying Test Methodologies (ASTM)

**ASTM D4169-05 DC 13**

“Air & Motor Freight, Local, Single Package Up to 100#’s”
- This single standard is used quite predominately for regulatory compliance.
- Currently recognized by FDA as a consensus standard.

1. Schedule (A) Manual Handling
2. Schedule (C) Compression Testing
3. Schedule (F) Loose-Load Vibration
4. Schedule (I) Low-Pressure / High Altitude
5. Schedule (E) Random Vibration (Truck & Air)
Just Released ASTM D4169-08 (Significant Changes) from 05.

1. **Schedule (A) Manual Handling**
2. **Schedule (C) Compression Testing**
3. **Schedule (F) Loose-Load Vibration**
4. **Schedule (I) Low-Pressure / High Altitude**
5. **Schedule (E) Random Vibration (Truck & Air)**
6. **Schedule (J) Concentrated Impact (<275# or 40 ECT)**
7. **Schedule (A) Manual Testing (Bridge Impact)**

---

**Schedule A Manual Handling**

**Schedule C Vehicle Stacking**

**Schedule F Loose-Load Vibration**

**Schedule I Low Pressure / High Altitude**

**Schedule E Random Vibration (Truck/Air)**

**Schedule J Concentrated Impact 32" Drop on Box Faces**

**Schedule A Manual Handling**

Bridge Impact if Needed (12")

Box Length = 3x Width or Height
Test Methodologies (ASTM)

- Newly Released **ASTM D7386-08**

- Generally developed for **ALL** types of packages moving through the single parcel shipping system (UPS, FedEx, etc.)

- This standard is dependent upon what type of package you are trying to evaluate.
  - Small Packaged-Product Bagged for Transport (**TS-1**)
  - Large Flat Packaged Product (**TS-2**)
  - Long Narrow Packaged Products (**TS-3**)
  - All Other Packaged Product (**TS-4**) (Most Typical)
- Example Situation (Standard shipper, 12”x12”x12” Containing Single Barrier Poly/Tyvek Pouch)
- This would follow into the classification of “TS-4”.

**TS-4 Test Sequence:**

2. D1. Vibration Under Compressive Load
7. L. Concentrated Impacts (36”)

This procedure can be strenuous for MDM’s because of the vibration under compressive load.
Test Methodologies (ASTM D7386-08)

Sequence D1
Vibration Under Compressive Load
Face 1 or 3 = 60 Minutes
Face 2 or 4 = 30 Minutes
Face 5 or 6 = 30 Minutes

Sequence Kc
High Altitude Testing (If Applicable)

Sequence I
Concentrated Impact
36” Drop of all faces

Sequence D3
Vibration W/O Compressive Load
Face 1 or 3 = 30 Minutes

Sequence A1
Manual Handling
Edge 3-4
Edge 4-6
Corner 2-3-5
Edge 4-6

Sequence A2
Manual Handling
Edge 2-3
Corner 2-3-6
Edge 2-5
Edge 3-5
Corner 3-4-5
Face 1
ISTA Standards (Procedures 1A – 7D)

- **ISTA 1 Series: Non-Simulation Integrity Performance Tests.**
  Challenge the strength and robustness of the product and package combination. Not designed to simulate environmental occurrences. Useful as screening tests, particularly when used as a consistent benchmark over time.

- **ISTA 2 Series: Partial Simulation Performance Tests.**
  Test with at least one element of a 3 Series type General Simulation Performance Test, such as atmospheric conditioning or mode-shaped random vibration, in addition to basic elements of a 1 Series type Non-Simulation Integrity test.

- **ISTA 3 Series: General Simulation Performance Tests.**
  Designed to provide a laboratory simulation of the damage-producing motions, forces, conditions, and sequences of transport environments. Applicable across broad sets of circumstances, such as a variety of vehicle types and routes, or a varying number of handling exposures. Characteristics will include simple shaped random vibration, different drop heights applied to the sample package, and/or atmospheric conditioning such as tropical wet or winter/frozen.

Ref: The ISTA® 2009 RESOURCE BOOK
Identifying Test Methodologies (ISTA)

ISTA Standards (Procedure 1A)

- ISTA 1 Series: Non-Simulation Integrity Performance Tests. Challenge the strength and robustness of the product and package combination. Not designed to simulate environmental occurrences. Useful as screening tests, particularly when used as a consistent benchmark over time ISTA 1 Series: Non-Simulation Integrity Performance Tests.

Many medical device manufacturers, still try to utilize ISTA Procedure 1A. This procedure was developed for a quick and easy way to evaluate a shipping configuration for drop testing and repetitive shock vibration only. For MDM’s evaluating a sterile barrier system, this is NOT the procedure that you should be utilizing for dynamic evaluation. This procedure does not take into account random vibration or atmospheric pre-conditioning and is not truly a ‘simulation’. It is also meant strictly for domestic shipment.
ISTA Standards (Procedure 2A)

- ISTA 2 Series: Partial Simulation Performance Tests. Test with at least one element of a 3 Series type General Simulation Performance Test, such as atmospheric conditioning or mode-shaped random vibration, in addition to basic elements of a 1 Series type Non-Simulation Integrity test.
- The ISTA Project 2A procedure is a widely utilized test procedure to evaluate sterile barrier system through dynamics.

Pro’s
1. Comparable to ASTM D4169-05
2. Atmospheric Conditioning
3. Fixed Displacement Vibration and or Random Vibration
   (Both are discussed)

Con’s
1. Does not address effects of low pressure high altitude on non-porous packaging.
2. Alternative methods
**Test Methodologies (ISTA)**

**ISTA - Procedure 2A**

**Test Sequence**

*Could have many other sequences depending upon alternative methods chosen.*
Test Methodologies (ISTA 3A)

ISTA Standards (Procedure 3A)

Test Procedure 3A is a general simulation test for individual packaged products shipped through a parcel delivery system. The test is appropriate for 4 different package types commonly distributed as individual packages, either by air or ground.

Types:
- standard packages
- small packages
- flat packages
- elongated packages
Basic Requirements:

- **atmospheric pre-conditioning,**
- **random vibration with and without top load**
- **shock testing**

This test procedure is used sparingly by Medical Device Manufactures as it is severe with the utilization of top load vibration. MDM’s may encounter Damage that does not happen in the normal distribution environment.

This procedure is comparable to ASTM D7386-08.
Test Methodologies (ISTA)

ISTA - Procedure 3A
Standard Packaged Product Test
Testing Equipment Photos

- Repetitive Shock / Loose Load Vibration
- Random Vibration
- Compression Testing
- Drop Testing
In the past, Medical Device Manufacturers have only been primarily concerned with package/product interaction through dynamic testing. Dynamics play a key role in evaluating the efficacy of the shipping configuration, but most have failed to take into account the physical environmental stresses that packaging materials are subjected to in normal everyday shipment.
Test Methodologies

(Environmental Conditioning)

- Climatic extremes can have an effect on package material strength and resultant performance. By subjecting shipping units to temperature and humidity extremes prior to physical dynamic conditioning any problematic situations can be identified and corrected.

ISO 11607-1:2006 - Section 6.3:

*Note: Stability testing and performance testing are separate entities. Performance testing evaluates the interaction between the packaging system and the product units in response to the stresses imposed by the manufacturing, sterilization processes and the handling, storage and shipping environment.*
With the separation of performance testing and stability testing per ISO 11607, it is important to take environmental conditioning into consideration when setting up a performance test.
The three most popular standards that DDL utilizes for environmental conditioning are:

1. Conditioning elements in ISTA Procedures (These procedures detail a host of specific environmental conditions that can be employed.
2. ASTM D4332 (Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing.)
3. ISO 2233 (Packaging – Complete, Filled Transport Packages and Unit Loads – Conditioning For Testing.)

NOTE: ASTM Committee F2 ‘on Flexible Packaging’ is working on standard practice for environmental extremes conditioning.
## Anticipated Conditions

<table>
<thead>
<tr>
<th>Anticipated Conditions</th>
<th>Time in Hrs</th>
<th>Temperature</th>
<th>Humidity in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extreme Cold, Uncontrolled RH</td>
<td>72</td>
<td>-29°C (-20°F)</td>
<td>uncontrolled RH</td>
</tr>
<tr>
<td>Cold, Humid</td>
<td>72</td>
<td>5°C (40°F)</td>
<td>85%RH +/-5</td>
</tr>
<tr>
<td>Controlled Conditions</td>
<td>72</td>
<td>23°C (73°F)</td>
<td>50% RH +/-5</td>
</tr>
<tr>
<td>Hot, Humid</td>
<td>72</td>
<td>38°C (100°F)</td>
<td>85%RH +/-5</td>
</tr>
<tr>
<td>Hot, Humid then Extreme Heat, Moderate RH:</td>
<td>72 then 6</td>
<td>38°C (100F) then 60°C (140°F)</td>
<td>85%RH +/-5 then 30%RH +/-5</td>
</tr>
<tr>
<td>Elevated Temperature, Uncontrolled RH</td>
<td>72</td>
<td>50°C (120°F)</td>
<td>uncontrolled RH</td>
</tr>
<tr>
<td>Extreme Heat, Dry</td>
<td>72</td>
<td>60°C (140°F)</td>
<td>15% RH +/-5</td>
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<tr>
<td>Severe Cold, Uncontrolled RH</td>
<td>72</td>
<td>-18°C (0°F)</td>
<td>uncontrolled RH</td>
</tr>
<tr>
<td>User Defined (High Limit)</td>
<td>72</td>
<td>Based upon known conditions</td>
<td>Known conditions</td>
</tr>
<tr>
<td>User Defined (Low Limit)</td>
<td>72</td>
<td>Based upon known conditions</td>
<td>Known conditions</td>
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<tr>
<td>User Defined Cycle</td>
<td>72</td>
<td>Based upon known conditions</td>
<td>Known conditions</td>
</tr>
</tbody>
</table>
## Test Methodologies (Environmental Conditioning)

<table>
<thead>
<tr>
<th>Environment (ISO 2233 Condition)</th>
<th>Temperature, °C (°F)</th>
<th>RH, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryogenic (A)</td>
<td>−55°C +/−3 (−67°F +/−6)</td>
<td>...</td>
</tr>
<tr>
<td>Frozen food storage (C)</td>
<td>−18°C +/−2 (0°F +/−4)</td>
<td>...</td>
</tr>
<tr>
<td>Refrigerated storage (D)</td>
<td>5°C +/−2 (41°F +/−4)</td>
<td>85%RH +/−5</td>
</tr>
<tr>
<td>Temperate high humidity (F)</td>
<td>20°C +/−2 (68°F +/−4)</td>
<td>90%RH +/−5</td>
</tr>
<tr>
<td>Tropical (L)</td>
<td>40°C +/−2 (104°F +/−4)</td>
<td>90%RH +/−5</td>
</tr>
<tr>
<td>Desert</td>
<td>60°C +/−2 (140°F +/−4)</td>
<td>15%RH +/−5</td>
</tr>
<tr>
<td>Condition</td>
<td>Temperature</td>
<td>Relative humidity</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>°C</td>
<td>°F</td>
</tr>
<tr>
<td>1</td>
<td>-55</td>
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<td>2</td>
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<td>104</td>
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<tr>
<td>12</td>
<td>50</td>
<td>131</td>
</tr>
</tbody>
</table>

Specified conditions for a minimum period which shall be selected from 4 h, 8 h, 16 h, 24 h, 48 h or 72 h or from 1 week, 2 weeks, 3 weeks or 4 weeks.
FDA Consensus Standards

U.S. Food and Drug Administration
Center for Devices and Radiological Health

Recent Items...
- Modification to the List of Recognized Standards (3/18/2009)
- Standards Data Report for 510(k)s - FDA 3654 [Word] [PDF] (11/20/2007)

How to use this program
- Recognition and Use of Consensus Standards
- FDA Recognized Consensus Standards Database
- Recommending Standards for CDRH Recognition
- Specialty Task Groups
- Standards Management Staff

Guidance
- Frequently Asked Questions on the Recognition of Consensus Standards
- Recognition and Use of Consensus Standards
- Use of Standards in Substantial Equivalence Determinations
- CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition
- Standards Data Report for 510(k)s - FDA 3654 [Word] [PDF]

Other Resources
- Federal Register documents
- Standards Organizations
- International issues
- International & National Center Liaison Representative Roster [PDF]

Updated March 18, 2009

http://www.fda.gov/cdrh/stdsprog.html
## Currently Recognized Standards For Medical Device Package Testing (as of Aug 2009)

<table>
<thead>
<tr>
<th>Standard Number</th>
<th>Standard Description</th>
<th>Property</th>
<th>Date</th>
<th>Applicability</th>
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</thead>
<tbody>
<tr>
<td>F1929-98 (2004)</td>
<td>standard test method for detecting seal leaks in porous medical packaging by dye penetration</td>
<td>sterility</td>
<td>09/09/2008</td>
<td>any devices that are sterilized</td>
</tr>
<tr>
<td>F2095-07</td>
<td>standard test methods for pressure decay leak test for nonporous flexible packages with and without restraining plates</td>
<td>sterility</td>
<td>09/09/2008</td>
<td>any devices that are sterilized and packaged</td>
</tr>
<tr>
<td>F2338-07</td>
<td>standard test method for nondestructive detection of leaks in packages by vacuum decay method</td>
<td>sterility</td>
<td>09/09/2008</td>
<td>any devices that are sterilized and packaged. packages that can be no ...</td>
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<tr>
<td>F2391-05</td>
<td>standard test method for measuring package and seal integrity using helium as the tracer gas</td>
<td>sterility</td>
<td>09/09/2008</td>
<td>any devices that are packaged and sterilized. this test method includ ...</td>
</tr>
<tr>
<td>F2475-05</td>
<td>standard guide for biocompatibility evaluation of medical device packaging materials</td>
<td>sterility</td>
<td>09/09/2008</td>
<td>any devices that are packaged and sterilized. this guide provides inf ...</td>
</tr>
<tr>
<td>F1608:00(2004)</td>
<td>standard test method for microbial ranking of porous packaging materials (exposure chamber method)</td>
<td>sterility</td>
<td>09/09/2008</td>
<td>any devices that are sterilized</td>
</tr>
<tr>
<td>D4169-05</td>
<td>standard practice for performance testing of shipping containers and systems</td>
<td>sterility</td>
<td>09/09/2008</td>
<td>any devices that need to maintain package integrity after undergoing s ...</td>
</tr>
</tbody>
</table>
## Currently Recognized Standards For Medical Device Package Testing (as of Aug 2009)

<table>
<thead>
<tr>
<th>Standard Number</th>
<th>Standard Title</th>
<th>Type</th>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1980-07</td>
<td>Standard guide for accelerated aging of sterile barrier systems for medical devices</td>
<td>sterility</td>
<td>09/9/08</td>
<td>any devices that are terminally sterilized.</td>
</tr>
<tr>
<td>F2097-07</td>
<td>Standard guide for design and evaluation of primary flexible packaging for medical products</td>
<td>sterility</td>
<td>09/9/08</td>
<td>any devices that are packaged and sterilized.</td>
</tr>
<tr>
<td>F1140-07</td>
<td>Standard test methods for internal pressurization failure resistance of unrestrained packages</td>
<td>sterility</td>
<td>09/9/08</td>
<td>any devices that are sterilized.</td>
</tr>
<tr>
<td>F2054-07</td>
<td>Standard test method for burst testing of flexible package seals using internal air pressurization within restraining plates</td>
<td>sterility</td>
<td>09/9/08</td>
<td>any sterilized device in a flexible package</td>
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<tr>
<td>F88-07</td>
<td>Standard test method for seal strength of flexible barrier materials</td>
<td>sterility</td>
<td>09/9/08</td>
<td>any devices that are sterilized.</td>
</tr>
<tr>
<td>D7386-08</td>
<td>Standard practice for performance testing of packages for single delivery systems</td>
<td>general</td>
<td>03/18/09</td>
<td>any devices contained in shipping units, weighing up to but not exceed ...</td>
</tr>
</tbody>
</table>
Problems in using standards with top load vibration sequences

ASTM D7386, ISTA Project 3A

- Medical device packages are not typically designed for interior packaging or products to withstand compressive loads.

- Feedback from MDM customer’s shows that actual field observations do not indicate a significant shipping box crushing problem. Test results do not correlate to actual field observations.

- Top load weights may exceed anything that is applied in actual shipments. Other boxes designed to contribute interior and/or product compressive strengths to the over-all shipping system compression strength may be able to pass this test more readily than medical device packages that only use the shipping box strength in design considerations.
What are companies using?
So what are companies using?

The primary standard that is used by the majority of DDL’s customers is ASTM D4169.

WHY?

► ASTM D4169 is recognized as a consensus standard by the FDA.

► ASTM D4169 is referenced as a standard that can be used for compliance to ISO 11607 (Annex B.)

► Work to be done: update to incorporate new published field data for drop and vibration test intensities.
Scott Levy Medical
Feasibility Testing
Package Type: Single Barrier Poly/Tyvek Pouch
Product Name: Scott’s Little Widget

60 Pouch Packages
With Product

60 Pouches
(10 Shippers)
With Product

POST STERILIZATION

ISTA Project 2A (2008)
Pre Shipment Conditioning
Or
ASTM D4332-01
Pre Shipment Conditioning
Or
ISO 2223-2000
Pre Shipment Conditioning

DISTRIBUTION SIMULATION
ASTM D4169
DC 13, AL I
10 SHIPPERS
6 PKGS/SHIPPER

PACKAGE INTEGRITY TESTING
60 With Product

FUNCTIONALITY TESTING

Test Report
Protocol Development

Prior to executing a protocol a few questions need to be answered?

1. Do I have a specific shipping configuration for my product?
2. How many sterile packages are there in my shipping configuration?
3. How are my packages placed in a shipper (orientation)?
4. What type of corrugated material (wall thickness) do I have?
5. Will my sterile barrier systems be placed into the corrugated shipper without SBS cartons?
6. Will my sterile barrier systems be placed in an SBS box and then loaded into the shipper?
7. Am I folding the pouch materials to make them fit or give a false sense of protection?
8. Is my configuration robust enough to handle a stacked vibration situation?
Documentation is key...therefore, a protocol is essential to establish the plan for this phase of package validation.

<table>
<thead>
<tr>
<th>Test Protocol Title:</th>
<th>Package and Product Validation Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type:</td>
<td>Simulated Distribution Testing and Package Sterility Validation Tests</td>
</tr>
<tr>
<td>Protocol Number:</td>
<td>P99999</td>
</tr>
<tr>
<td>Revision: A</td>
<td></td>
</tr>
</tbody>
</table>

**Approvals:**

Scott Levy Medical: ___________________________ Date: ______________

DDL, Inc
Written By: ___________________________ Date: ______________

Approved By: ___________________________ Date: ______________

**Package Tested:** Single Barrier Poly/Tyvek Pouch
**Product Name:** Scott’s Little Widget
Protocol Development

What Specifics are needed?

- Purpose
- Scope
- Reference Section
- Various Materials and Equipment
- Sample Description and Preparation
- Test Procedures (List and Identify)
- Acceptance Criteria
- Documentation
- General Test Plan (Flowcharts)
After the testing is completed, a final test report must be generated to document the test results, corrective actions, or other issues found during the shipping validation.
Final Test Report

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What Specifics are needed?
FINAL TEST REPORT

STATEMENT OF CONFORMITY

DDL, Inc. has completed the above stated testing services performed in accordance to applicable standard good laboratory practices and/or standards identified within this report. Testing has been completed as described herein. The following list of exceptions occurred during testing performed at DDL, Inc.: 

- None

All materials, equipment, methods, and processes used to perform the described testing have been standardized, calibrated, and monitored in accordance with prescribed guidelines, standard operating procedures, and the supervision requirements of DDL, Inc. All raw data obtained from this testing by DDL, Inc. personnel is archived at DDL, Inc.

The signatures below are in compliance with 21 CFR Part 11.

Testing performed by: Scott Levy

Report prepared by: Packaging Engineer/Project Manager

Technical Review by: Director of Operations

Approved by: Quality Assurance
Conclusion

- Understand the specific test procedure that you will use to evaluate your shipping configuration for validation.
- Perform feasibility testing prior to executing a full blown performance test (shipping/environmental study).
- Use a test procedure that is going to best simulate your distribution environment.
- Understand the percent of defects that you are acquiring in shipping your sterile samples to the customer / end user.
- Provide adequate time to perform a thorough validation.

*This is single biggest problem that I come across.*
Questions???

Tested and Proven.