

ASTM vs ISTA For Package Testing Which is Better?



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Definitions / Acronyms



ASTM = organization formerly known as the “American Society for Testing and Materials” that publishes many different physical testing standards, not just packaging tests.

- The acronym is now the preferred method of address.



ISTA = International Safe Transit Association focuses on physical testing of packages and package systems.

- Recently partnered with ANSI (American National Standards Institute) to achieve consensus status

Agenda

- Introduction
- Round 1: ASTM vs ISTA (1 Series tests)
- Round 2: ASTM vs ISTA (2 Series tests)
- Round 3: ASTM vs ISTA (7386 vs. 3A)
- Solution Case Study 1
- Solution Case Study 2



Single Parcel Shipments

- ASTM D4169
- ASTM D7386
- ISTA 2 Series
- ISTA 3 Series



Introduction

1. ASTM & ISTA: High-level comparison
2. Package Test Scenarios
3. Helpful Test Information
4. Test Solution Cases

Comparison: ASTM vs ISTA 1 Series

ISTA 1 Series

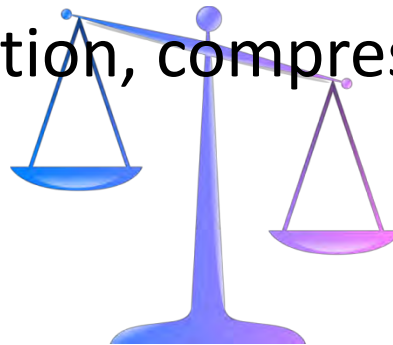
- Among the oldest package integrity tests
- Referred to as “non-simulation” test
- Not item-by-item comparable with ASTM
- ASTM D4169 Distribution Cycle 2 (DC 2) can nearly match ISTA 1 Series - if you're careful!



Comparison: ASTM vs ISTA 2 Series


ISTA 2 Series

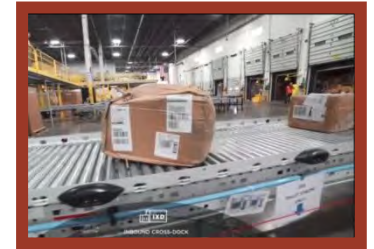
- Referred to as “partial simulation” tests
- More comprehensive than ISTA 1 Series
- Includes test input from ISTA 3 Series
- Not item-by-item comparable with ASTM
- ASTM D4169 DC 2 can get close
 - Difference in vibration, compression, drop testing



Comparison: ASTM vs ISTA 3 Series

ISTA 3 Series

- 3A: Developed in conjunction with United Parcel Service (UPS) as a pre-shipment certification test.
- Package type: Small Parcel 
- ASTM developed D7386 from ISTA 3A
 - Test results are similar
 - Vibration with Top Load: Both tests may damage cartons < 275 pound burst or 44 edge crush rating



In-Depth: ASTM vs ISTA 2 Series

ISTA 2A

- Favorite with Medical Device Manufacturers (MDMs)
 - Price of testing < ASTM D4169
- Compression Test Force Comparison

ISTA 2A	ASTM D4169	Assurance Level
359 pounds	1,146 pounds	III
	2,292 pounds	I



Example Carton
Dims: 22" x 20" x 18"
Weight: 16 pounds

In-Depth: ASTM vs ISTA 2 Series (cont.)

Recommendation

- Check the numbers before deciding the standard to use
- Only user-adjustable variable available: Safety Factor
- Understand the differences!
- Ask for help if not sure



CONTACT US



Compression Test

In-Depth: ASTM vs ISTA 2 Series (cont.)

- Impact Testing drop height for both ASTM D4169 & ISTA 2A is weight-dependent

Carton Weight	ASTM D4169	ISTA 2A
< 20 pounds	24 inches	38 inches
40 pounds	21 inches	32 inches
60 pounds	18 inches	26 inches
80 pounds	15 inches	20 inches

- Example

- ASTM D4169, AL I: Drop Height = 24 inches
- ISTA 2A: Drop Height = 38 inches



Drop Test

In-depth: ASTM vs ISTA 3 Series

- ASTM D4169 DC 9, DC 13
 - Top Load not required during vibration testing
 - DC 13 is one of the most commonly specified D4169 test plans



Vibration Test with Top Load

- ASTM D4169 (except DC 2, 9, & 13), ASTM D7386, ISTA 3A
 - Top Load required during Vibration Testing
 - Damage from testing inconsistent with typical Medical Device distribution environment

Summary: ASTM vs ISTA

ISTA 1 Series	ASTM D4169
<ul style="list-style-type: none">• Provides a quick, low-cost method to compare package designs	<ul style="list-style-type: none">• Almost any ISTA test can be duplicated by ASTM D4169 DC 2
<ul style="list-style-type: none">• 1 Series tests are allowed for MDMs use by ISO 11607 but are not included in the FDA “consensus standards” list	<ul style="list-style-type: none">• ASTM D4169 is recognized by both ISO 11607 and FDA
<ul style="list-style-type: none">• Vibration test time can be reduced	
<ul style="list-style-type: none">• Do not correlate well to actual field events• Can be good screening tools when properly used	
<ul style="list-style-type: none">• Many ISTA 1 Series tests can be run with only a drop tester and mechanical “rotary” shaker table	

List of FDA “Consensus Standards”

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

Summary: ASTM vs ISTA (cont.)

ISTA 2 Series	ASTM D4169
<ul style="list-style-type: none">• Frequently-specified Transit Test by MDMs• Most use ISTA 2A or proprietary	<ul style="list-style-type: none">• DC 13 is the most-used Transit Test (especially by MDMs)• Close equivalent to ISTA 2 Series
<ul style="list-style-type: none">• Low cost, less test lab time	<ul style="list-style-type: none">• Cost of testing > than ISTA
<ul style="list-style-type: none">• Grandfathered by FDA under ISO 11607	<ul style="list-style-type: none">• Listed as a consensus standard on FDA website
<ul style="list-style-type: none">• Compression test is 2-3x less difficult than ASTM D4169	<ul style="list-style-type: none">• Compression often reduced to lowest level
<ul style="list-style-type: none">• Cartons < 21 pounds dropped 10x from 38-inch drop height	<ul style="list-style-type: none">• Test can be altered to conform with your distribution environment
	<ul style="list-style-type: none">• Good correlation of lab-induced damage with actual MDM distribution environment

Summary: ASTM vs ISTA (cont.)

Example Carton: 4.5 cubic foot, 16 pounds (lbs)

Test Factor	ISTA 2A Series	ASTM D4169																		
Drop Height	10 drops @ 38 inches	11 drops at 24 inches 1 drop at 48 inches																		
Compression Force	359 pounds	<table border="1"> <thead> <tr> <th>AL I</th> <th>AL II</th> <th>AL III</th> </tr> </thead> <tbody> <tr> <td>2,292 lbs</td> <td>1,605 lbs</td> <td>1,146 lbs</td> </tr> </tbody> </table>	AL I	AL II	AL III	2,292 lbs	1,605 lbs	1,146 lbs												
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2,292 lbs	1,605 lbs	1,146 lbs																		
Random Vibration	2 hours, 1.15 Grms	<table border="1"> <thead> <tr> <th>Profile</th> <th>Minutes</th> <th>Grms</th> </tr> </thead> <tbody> <tr> <td>Truck</td> <td>40</td> <td>0.40</td> </tr> <tr> <td>Truck</td> <td>15</td> <td>0.54</td> </tr> <tr> <td>Truck</td> <td>5</td> <td>0.70</td> </tr> <tr> <td>Air</td> <td>120</td> <td>1.49</td> </tr> <tr> <td>Total</td> <td>3 hours</td> <td></td> </tr> </tbody> </table>	Profile	Minutes	Grms	Truck	40	0.40	Truck	15	0.54	Truck	5	0.70	Air	120	1.49	Total	3 hours	
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Air	120	1.49																		
Total	3 hours																			
Test Time (Excludes Conditioning)	4 – 6 hours	7 – 8 hours																		

Summary: ASTM vs ISTA (cont.)

ISTA 3A	ASTM D7386
<ul style="list-style-type: none">• A frequently-used transit test (not by most MDMs)	<ul style="list-style-type: none">• A frequently-used transit test (not by most MDMs)
<ul style="list-style-type: none">• Designed in conjunction with UPS to simulate the Single Parcel distribution environment	<ul style="list-style-type: none">• Closest equivalent to ISTA 3A• Other ISTA 3 Series tests can be closely matched by some of the ASTM D4169 DCs
<ul style="list-style-type: none">• Defined as “general simulation” by ISTA	<ul style="list-style-type: none">• Cost is similar to ASTM D4169 testing
<ul style="list-style-type: none">• Stacked Vibration top-load requirement works well for most Single Parcel shipments (but not for MDMs)	<ul style="list-style-type: none">• Stacked Vibration top-load requirement is similar to ISTA 3A (therefore avoided by most MDMs)
<ul style="list-style-type: none">• ISTA 3A, 3B & 3E have been added to FDA’s list of “consensus standards”	<ul style="list-style-type: none">• Recognized both by ISO 11607 & FDA• D7386 and D4169 both listed on FDA’s list of “consensus standards”

Pros & Cons: ASTM vs ISTA

++ ISTA Advantages ++	-- ASTM Disadvantages --
<ul style="list-style-type: none">• Test prices < ASTM• Older equipment can perform the tests	<ul style="list-style-type: none">• Test prices > ISTA• Required testing takes longer• Equipment costs more than with ISTA
<ul style="list-style-type: none">• Better Impact Testing results (drop test input) because box orientation is specified	<ul style="list-style-type: none">• Box orientation during Impact Testing is less specific
<ul style="list-style-type: none">• Enables correlation of interior damage to exterior damage during Visual Inspection	<ul style="list-style-type: none">• Often difficult to correlate interior damage with exterior damage when performing Visual Inspection
<ul style="list-style-type: none">• ISTA 2A Compression Test values are less severe than ASTM D4169	<ul style="list-style-type: none">• Many MDMs will not use tests like ASTM D7386 that specify a top-load during Vibration Testing

Pros & Cons (cont.)

-- ISTA Disadvantages --	++ ASTM Advantages ++
<ul style="list-style-type: none">• ISTA 2A requires higher drop height during Impact Testing	<ul style="list-style-type: none">• Intensity of other ASTM test inputs (i.e. Drop, Compression, Vibration) can be reduced by reducing the Assurance Level (AL)
<ul style="list-style-type: none">• 3A includes Optional test combining Random Vibration Under Low Pressure (simulated High Altitude)	<ul style="list-style-type: none">• D4169 includes simulated High Altitude as a separate test
<ul style="list-style-type: none">• Vibration sequence requires higher test intensity but for a shorter time	<ul style="list-style-type: none">• D4169-16: Truck Vibration spectra is based on recent, real-world data



ASTM D4169
Webinar

www.westpak.com/page/resources/webinars



Summary: ASTM vs ISTA (cont.)

Status of Transport Test Standards within ISTA and ASTM

	ISTA 1A	ISTA 2A	ISTA 3A	D4169	D7386
FDA Consensus Standard	Not Yet (coming soon)	Not Yet (coming soon)	✓	✓	✓
FDA Grandfathered	✓	✓	n/a	n/a	n/a

List of FDA “Consensus Standards”

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

Solution Case Study #1

- Situation: Medical Device packaging sterile barrier failures resulting from ISTA 2A testing



Solution Case Study #1 (cont.)

Problem: Pouch seals were creeping to failure due to impact of the device card with the inner seal boundary

- Solution: Use ASTM D4169 (lower drop heights)
- Result: No further issues with breached sterile barriers



Solution Case Study #2

Situation: Consumer Goods client experienced repeated compression failures while using ASTM D4169

- Problem: High Loads during Compression Testing were causing defects.



Solution Case Study #2 (cont.)

Solution: Switch to ISTA 2A

- Result: No further damage issues
- Bonus: Test cost was reduced



QUESTIONS



More Questions Later?



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