



# Comparison of Transit Test Regimes ASTM D 4169 versus ISTA 3A

**Both ISTA 3A and ASTM D4169 are transit evaluation protocols for single parcels (this is usually the worst case for medical device distribution). Both methods are listed in ISO 11607 and both are FDA recognised.**

There are options in both protocols depending on carton configuration and any special needs. In general, the worst case is chosen for medical devices. For ASTM D4169 this usually means Distribution Cycle 13, Assurance Level II.

A transit simulation study is intended to simulate the rigours of transport and how they may damage the parcel. For medical devices the primary area of concern is whether the sterile barriers protecting the device have been compromised.

There is a secondary concern about unsightly damage to external packaging.

To this end at MET we report cosmetic damage to the cartons, but concentrate post transit testing on the sterile barrier strength and integrity.

The first stage of any transit trial is the pre-conditioning. ISTA have this as a requirement whereas ASTM D4160 does not. The pre-conditioning should be specified according to the destinations for the package. Alternatively, tropical conditions could be considered the worst case because the humidity will soften the carton material.



Test	Details	Requirement	
		ISTA 3A	ASTM D 4169
Atmospheric preconditioning / conditioning.	Temperature and humidity and time variables.	Minimum of 12 hours at ambient conditions	Not required (but is required by the Agency).
Handling / Shock	Drop test	Required	2 cycles
Vibration	Random	With top load	Loose.
Vibration	Fixed displacement	Not required	Required
Vibration	At reduced pressure	Optional	Not required
Shock	Drop onto hazard	Required	Not required
Low pressure	Mountain transport – non porous packs	Advised	Advised
Compression	Top loading crush	Not required	Required
Concentrated impact	Drop mass onto carton	Not required	Required

