ASTM D4169 Assurance Level Determination

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Background and Introduction

If you have ever grappled with which testing Assurance Level to use, you are not alone.

All products need some amount of protection throughout the distribution environment. An implantable medical device has different critical components and protection needs than a pillow. Package design and testing validation recognizes these differences, taking into consideration the product end use, necessary safety margins and your risk tolerance.

Product protection is vital and knowing your distribution environment and what exactly you are protecting against is equally important. Without knowing these elements, over-packaging, leading to financial and environmental waste, is likely. To assist in designing the optimal package, ASTM D4169 offers varying Assurance Levels (AL) within the package testing sequence to simulate a variety of distribution scenarios and probabilities.

> **"Just wanted to comment on how I have had multiple experiences with the WESTPAK team and am always extremely satisfied with how well everyone works together."**
>
> M.P.

Many of our customers struggle to identify what Assurance Level to specify when it comes to creating a testing protocol compliant with ISO 11607. Here is a breakdown of the different Assurance Levels and a guide to selecting the appropriate level for your product's needs.

What are the Different Assurance Levels?

ASTM D4169 offers three different Assurance Levels, conveniently named I, II, and III. These Levels pertain to drop heights, compressive loads, and the vibration intensity (Air and Rail spectra) applied within the testing sequence. Simply put, the higher the Assurance Level, the less intense the input becomes.

Based on the ASTM D4169 standard, Assurance Level is defined as "the level of test intensity based on its probability of occurring in a typical distribution cycle." Level I is a high level of test intensity and

has a low probability of occurrence. Level III is a low level of test intensity but has a correspondingly high probability of occurrence. Level II is between these extremes.

Assurance Level I (AL I)

Assurance Level I is the most severe and could be considered the most conservative approach to take. It is the most commonly used Assurance Level for sterilized medical devices due to their high-value and human end-use. If your product remains protected during Assurance Level I inputs, it will likely withstand both Assurance Levels II and III testing inputs. Successful completion of testing at Assurance Level I provides the most confidence in product protection during the normal distribution environment.

Assurance Level II (AL II)

This intermediate Assurance Level (II) provides package system confidence yet is not overly severe. This testing level imparts a decreased drop height, reduced compression load, and less intense vibration for Rail and Air profiles compared to Assurance Level I. If you are working with minimally invasive medical devices, topical products, or those with marginally robust product designs, Assurance Level II should be a strong consideration.

Assurance Level III (AL III)

This is the least severe level; it is often utilized for products with a robust design (i.e., books, clothing) or lacking components that might likely be damaged in distribution. As the level indicates, it has the lowest drop height, lightest compression load, and least intense vibration for Rail and Air spectra. This level is not recommended or recognized for medical device products.

Assurance Level Comparison

To provide some perspective on the differences, let's take a look at this example: assume you have a product weighing 10 lb contained in a one-cubic-foot carton. The Assurance Levels for Apply and Release Compression, Drop Testing and Air vibration performance tests per ASTM D4169 follow:

Test Input	Assurance Level I	Assurance Level II	Assurance Level III
Compression Testing	350 lb	245 lb	175 lb
Drop Testing	24 in	15 in	9 in
Air Vibration Testing	1.49 Grms	1.05 Grms	0.74 Grms

Basis: 1 ft³ package weighing 10 lb

Compression Test Video

Watch a compression test performed on a corrugated container using compressive forces per Assurance Level III, II, and I. The container yields prior to reaching the Assurance Level I target.

WATCH VIDEO

Compression Test Video

Westpak's ASTM D4169 Vehicle Stacking Calculator can walk you through potential compression top loads based on your package dimensions, weight and safety factors.

Which Assurance Level to Use?

To answer this question, you must know your distribution environment, product's fragility level, and the repercussions of a damaged shipment. For example, a more severe Assurance Level might be a good choice if you are seeing field damage and need to understand the failure modality.

The same severity should be considered if you are looking to determine whether the protective packaging is over or under-engineered. If your product is a small, lightweight parcel, it will likely be placed at the top of a package stack or top-shelf increasing the likelihood of a significant drop impact. Such a risk should be tested; compression testing may be less of a concern. Conversely, a larger package will likely be at the base of a package stack where compression forces are a greater concern. Your test protocol and the Assurance Levels chosen must reflect these variabilities.

> **"You have always operated at a high standard, so please keep it up. I know it's not easy."**
>
> K.K.

Distribution Hazards

The more understanding you have of your product and distribution environment, the more you can tailor the application of ASTM D4169 to correlate. If your supply chain involves either Air or Rail transports, you must consider the Assurance Level that best challenges your product.

Note that different Assurance Levels can be used for different ASTM D4169 inputs. For example, your test sequence can include Impacts (drop testing) at Assurance Level I and Compression at Assurance Level III. This mix-and-match option is handy however, be sure to document the risk assessment and justification of all decisions made.

"WESTPAK has done an excellent job of completing tests in a timely and accurate manner. The engineers are also very responsive and helpful in answering questions pertaining to shipping standards."

X.D.

Conclusion

Assurance Level determination is about making a realistic risk assessment to adequately protect your product prior to its arrival at the end-user. While we know that each distribution leg will vary, it comes down to leveraging this information to make the best decisions.

If Assurance Levels are something you need help with, WESTPAK can assist. Working together, we can assure product protection at the optimal levels for your unique parameters.