

SINCE 1977



TEST-O-PAC INDUSTRIES, INC.

ENVIRONMENTAL AND PACKAGE TESTING SERVICES

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YOUR PROJECT ACCELERATION RESOURCE GUIDE

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MEDICAL PACKAGE TESTING



Your project acceleration begins with time management. In this guide we have provided you with the basic timeline for medical product design and testing.

A typical proto type requires samples of the product for R&D (Research and Development) and future production, therefore it's important for the engineering staff to understand the timing required to design custom tools for prototypes and manufacturing.

It's important for the medical device design team to get the packaging engineer involved early and to be a voice to guide the shape, appearance, texture of the product while thinking of the packaging inside out. This way you do not end up with a product design that will require costly packaging and shipping, and your product packaging will meet the FDA requirements of packaging validation testing and environment and aging effects on product and packaging.

DESIGN STAGE: Device and Packaging Design - accelerated goal to achieve in one year!

Following are our time guidelines based on our experience with design:

1. **Devise design:** The packaging engineer needs to complete design review with tooling designer and complete die (mold) and cutting sheet. This process can take 3-6 months before the customer sees any parts.
2. **Internal Packaging Part 1:** Product tray design: Packaging engineers should work on outer packaging for device (product), typical molded tray design and devolvement which require product safety, transporting, environmental aging and sterility. That process can take 3-6 month, if engineering can spare device and molded packaging it's always good to conduct aging test by stressing plastic packaging, you can determine the root cause of a problem and correct the issue before you submit the packaging for final testing
3. **Internal Packaging Part 2:** Pouch design: The packaging engineer must address all shared edges of the molded tray to make sure during transportation testing these edges will not puncture a hole in the Tyvek pouch and cause sterilization problems. When the pouch thickens peeling strength should be addressed. Typical Tyvek pouch are stock item it's safe to allow a 4-6 week window.
4. **Internal Packaging Part 3:** Chip board Box design: As a packaging engineer it's an important part of the design that functions as a marketing piece and also serves as a shell over the inner packaging and should be designed to safeguard the inner packed product. A local packaging supplier can turn around packaging products in 1-3 week window.
5. **Outer packaging:** The package engineer must consider all environmental and transportation effects on internal packaging assembly and make sure the package can withstand any abusive conditions. Packaging design can be turned around in 1-3 week.



MEDICAL PACKAGE TESTING



TESTING STAGE: Device and Package Testing - accelerated goal to achieve in one year!

Following are our time guidelines based on our experience with testing:

To help you achieve that goal we have divided Package Testing into 3 Stages!

MEDICAL PACKAGE TESTING

STAGE 1

AGING



- Accelerated Aging
- Environmental

STAGE 2

DISTRIBUTION



- Impact
- Compression
- Altitude
- Vibration

STAGE 3

STERILITY



- Gross Leak "bubble"
- Dye Penetration
- Tensile Strength
- Brust test



MEDICAL PACKAGE TESTING




STAGE 1

AGING



Aging: Depending on the device, aging test time varies. *1 year* aging for a typical part takes about *40 days* for the product stored at a test temperature of *+55 °C*. We recommend to get the “*Aging Testing*” done in the beginning stages, to determine effects of temperature on product and packaging. For further details refer to *ASTM F1980*.

Accelerated Aging

 F 1980

Q = 2.0
Ambient Temperature = 23 °C
Test Temperature = 55 °C

$$AAF = 2.0^{(55-23)/10} = 9.19$$

AAT = 365 days/9.19 = 39.7 days at accelerated aging conditions for a shelf life test of 12 month.



MEDICAL PACKAGE TESTING



ACCELERATED AGING Sterile Barrier Systems for Medical Devices


The loss of sterile barrier system integrity may occur as a result of physical properties of the materials and adhesive or cohesive bonds degrading over time and by subsequent dynamic events during shipping and handling.

ISO 11607–1:2006, clause 6, states that “the packaging system shall provide physical protection and maintain integrity of the sterile barrier system. The sterile barrier system shall maintain sterility to the point of use or until the expiry date. Stability testing shall demonstrate that the sterile barrier system maintains integrity over time. Stability testing using accelerated aging protocols shall be regarded as sufficient evidence for claimed expiry date until data from real time aging studies are available.”

Real time aging programs provide the best data to ensure that sterile barrier system materials and sterile barrier system integrity do not degrade over time. However, due to market conditions in which products become obsolete in a short time, and the need to get new products to market in the shortest possible time, real time aging studies do not meet this objective. Accelerated aging studies can provide an alternative means



Accelerated Aging

 F 1980

Q = 2.0
Ambient Temperature = 23 °C
Test Temperature = 55 °C

$$AAF = 2.0^{(55-23)/10} = 9.19$$

AAT = 365 days/9.19 = 39.7 days at accelerated aging conditions for a shelf life test of 12 month.



MEDICAL PACKAGE TESTING



STAGE 2 DISTRIBUTION



Distribution: To assure your product meets transit testing requirements of *ASTM D4961* and *FDA* (Food and Drug Administration) approval for your packaging validation. Recommended distribution methods per guideline of *ASTM D4169*:

SCHEDULE A—HANDLING—MANUAL



D5276 FREE FALL DROP

DROP HEIGHT: 24 IN.

NO. OF IMPACTS: 12

- | | |
|-----------------|------------------|
| 1. Face 1 | 7. Edge 2-5 |
| 2. Edge 5-3 | 8. Face 2 |
| 3. Edge 4-3 | 9. Face 5 |
| 4. Corner 2-3-5 | 10. Corner 1-2-5 |
| 5. Corner 3-4-6 | 11. Edge 1-2 |
| 6. Face 3 | 12. Face 3 |

SCHEDULE C—VEHICLE STACKING



D642

APPLY AND RELEASE

$$W_T (S - 1) F$$

W_T Total weight of package

S No. of packages in stack (108" x H)

F Safety factor = 10

SCHEDULE F—LOOSE LOAD VIBRATION



D999

FIXED DISPLACEMENT

1 INCH PEAK TO PEAK

- | | |
|--------|----------|
| Face 3 | 30 mins. |
| Face 2 | 15 mins. |
| Face 6 | 15 mins. |

SCHEDULE I—LOW PRESSURE



D6653

ELEVATION: 14,000 ft.

DURATION: 60 min.

SCHEDULE E—VEHICLE VIBRATION



D4728 RANDOM VIBRATION

Frequency (Hz)	PSD Level, g ² /Hz
1.0	0.0001
4-16	0.02
40-80	0.002
200.0	0.00002
0.73 Grms Overall	
180 minutes	

SCHEDULE J—CONCENTRATED IMPACT



D6344

IMPACT ENERGY: 4.0 FT-LBF

VERTICAL DISTANCE: 32 IN.



MEDICAL PACKAGE TESTING



MANUAL HANDLING SCHEDULE A

The manual handling test is used for single containers, smaller packages, and any shipping container that can be handled manually (up to a weight of 200 lbs).

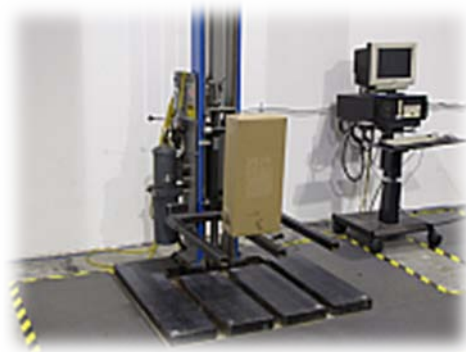
The test levels and the test method for this schedule of the distribution cycle are intended to determine the ability of the shipping unit to withstand the hazards occurring during manual handlings, such as loading, unloading, stacking, sorting, or palletizing. The main hazards from these operations are the impacts caused by dropping or throwing. The intensity of these hazards is affected by size, weight, and shape of the shipping unit. The drop heights, the number of drops, the sequence of drops, and the shipping unit orientation at impact are as follows:

SCHEDULE A—HANDLING—MANUAL

 **D 5276 FREE FALL DROP**

DROP HEIGHT: 24 IN.
NO. OF IMPACTS: 12

1. Face 1	7. Edge 2-5
2. Edge 5-3	8. Face 2
3. Edge 4-3	9. Face 5
4. Corner 2-3-5	10. Corner 1-2-5
5. Corner 3-4-6	11. Edge 1-2
6. Face 3	12. Face 3





MEDICAL PACKAGE TESTING



VEHICLE STACKING SCHEDULE C

The test levels and the test methods for these schedules of a distribution cycle are intended to determine the ability of the shipping unit to withstand the compressive loads that occur during warehouse storage or vehicle transport. The required loading must consider the effects of length of time in storage, the alignment or stacking pattern of the container, variability in container strength, moisture content, temperature, previous handling and transportation, method of load support, and vibration.

Conditioning— $73.4 \pm 2^{\circ}\text{F}$ ($23 \pm 1^{\circ}\text{C}$), $50 \pm \%$ relative humidity in accordance with Practice [D 4332](#).

SCHEDULE C—VEHICLE STACKING



APPLY AND RELEASE

$$W_T (S - 1) F$$

W_T Total weight of package

S No. of packages in stack (108" \times H)

F Safety factor = 10





MEDICAL PACKAGE TESTING



LOOSE LOAD VIBRATION SCHEDULE F

The test levels and the test method for this schedule of the distribution cycle are intended to determine the ability of the shipping unit to withstand the repetitive shocks occurring during transportation of bulk or loose loads. The test levels and test method account for amplitude, direction, and duration of the repetitive shocks.

SCHEDULE F--LOOSE LOAD VIBRATION



FIXED DISPLACEMENT
1 INCH PEAK TO PEAK

Face 3 30 mins.
Face 2 15 mins.
Face 6 15 mins





MEDICAL PACKAGE TESTING



LOW PRESSURE (ALTITUDE) SCHEDULE I

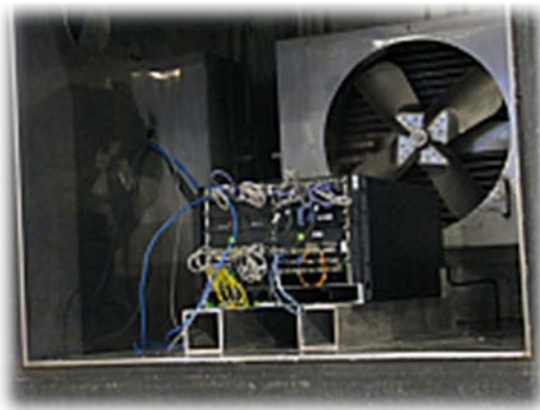
This schedule is intended to provide for the anticipated reduction in pressure when packaged products are transported via certain modes of transport, such as feeder aircraft or by ground over mountain passes. This test shall be conducted in accordance with levels described in *Test Method D 6653*. This test should be included for products and packages that could be sensitive to a low pressure environment, for example, sealed flexible non-porous packages, liquid containers, or porous packages that may be packed in such a manner as to be adversely affected by low pressure environments.

SCHEDULE I—LOW PRESSURE



ELEVATION: 14 000 ft.

DURATION: 60 min





MEDICAL PACKAGE TESTING



VEHICLE VIBRATION SCHEDULE E

The test levels and test methods for these schedules of the distribution cycle are intended to determine the ability of shipping units to withstand the vertical vibration environment during transport, and the dynamic compression forces resulting from vehicle stacking. The test levels and methods account for the magnitude, frequency range, duration, and direction of vibration. Select a **Schedule E—Vehicle Vibration** (no stacking) test as defined by the distribution cycle. Two test method options are permitted, *sine* and *random*. The two methods are not equivalent; they will not necessarily produce the same results. The *random* test method results in a better simulation of actual transport vibration environments, and is the preferred method for qualification. The *sine* test method is often used in conjunction with the random method as a means of determining and observing system resonances.

SCHEDULE E—VEHICLE VIBRATION

D 4728 RANDOM VIBRATION

Frequency (Hz)	PSD Level, g ² /Hz
1.0	0.0001
4-16	0.02
40-80	0.002
200.0	0.00002
0.73 Grms Overall	
180 minutes	





MEDICAL PACKAGE TESTING



CONCENTRATED IMPACT SCHEDULE J

This schedule provides a simulation of anticipated low level concentrated impacts as received by packages during sorting operations and in transit. The test is only applicable to lightweight single wall corrugated shipping containers (under 275 Burst or 44 ECT) and plastic film wrapped packages and unitized loads. Test the appropriate packages or unit loads according to *Test Method D 6344*.

SCHEDULE J—CONCENTRATED IMPACT

 **D 6344**

IMPACT ENERGY: 4.0 FT-LBF
VERTICAL DISTANCE:
32 IN.

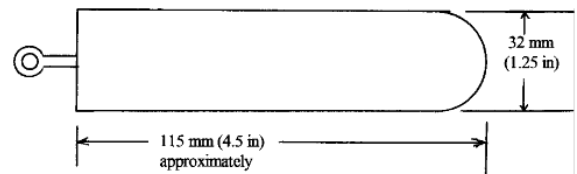


FIG. 1 Cylindrical Mass (steel rod)

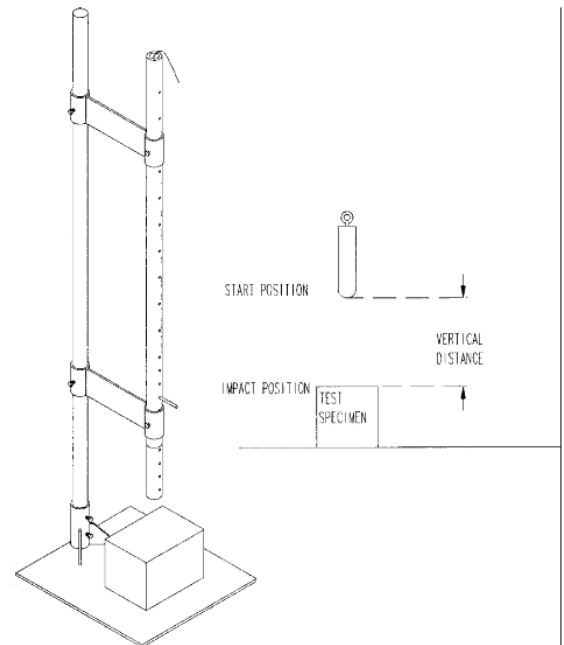
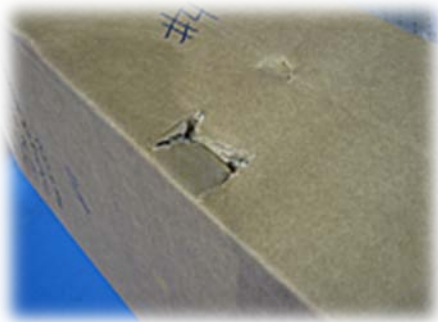


FIG. 2 Guided Free Fall



MEDICAL PACKAGE TESTING



STAGE 3 STERILITY



Sterility: To assure your packaging is meeting or exceeding the sterilization requirements of ASTM Test Standards, the following tests are recommended:

GROSS LEAK (bubble) TEST



F2096

Known defect: 250 μ m
Airflow: ~0.32 psi

DYE PENETRATION TEST



F1929

Dye penetrant solution:

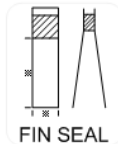
Wetting agent: TRITON X-1004 0.5%
Indicator dye: Toluidine blue 0.05%

Tensile Strength



F88

Technique A: *Unsupported*
Grip Separation Rate: 10 in./min
Fin Seal Type: Fin Seal 3" X 1"



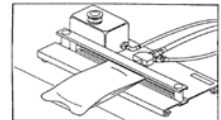
Burst Testing



F1140

Open-Package Test (Test Method A):

Position: Unsupported
Average kPa: 12.23





MEDICAL PACKAGE TESTING



DYE PENETRATION ASTM F1929

Harmful biological or particulate contaminants may enter the device through leaks. These leaks are frequently found at seals between package components of the same or dissimilar materials. Leaks may also result from a pinhole in the packaging material.

This dye penetrate procedure is applicable only to individual leaks in a package seal. The presence of a number of small leaks, as found in porous packaging material, which could be detected by other techniques, will not be indicated. There is no general agreement concerning the level of leakage that is likely to be deleterious to a particular package. However, since these tests are designed to detect leakage, components that exhibit any indication of leakage are normally rejected. Since leaks may change in size with different ambient conditions, comparisons between test stations are not conclusive. Therefore this method is usually employed as a go, no-go test. The dye solution will wick through any porous material over time, but usually not within the maximum time suggested. If wicking does occur, it may be verified by observing the porous side of the subject seal area. The dye will have discolored the surface of the material.

When puncturing the packaging to allow injection of the dye penetrate solution, care should be taken not to puncture other package surfaces. Puncturing of the package is facilitated if it is done adjacent to a dummy device inside the package. The device will provide a tenting effect that will separate two sides of the package, reducing the chance of accidental puncture of both sides.

DYE PENETRATION TEST



F1929

Dye penetrant solution:

Wetting agent:	TRITON X-1004	0.5%
Indicator dye:	Toluidine blue	0.05%





MEDICAL PACKAGE TESTING



GROSS LEAK "BUBBLE" TEST **ASTM F2096**

The internal pressurization test method provides a practical way to examine packages for gross leaks, which may render the product non-sterile. This test method is extremely useful in a test laboratory environment where no common package material/size exists. This test method may apply to very large or long packages, which do not fit into any other package integrity test method apparatus. This test method may be used as a means to evaluate package integrity. Package integrity is crucial to consumers.

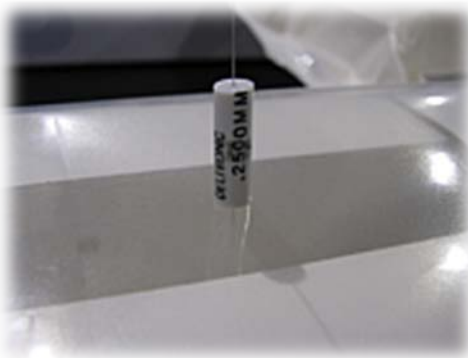
GROSS LEAK (bubble) TEST



F2096

Known defect: 250 μm

Airflow: ~ 0.32 psi





MEDICAL PACKAGE TESTING



SEAL STRENGTH OF FLEXIBLE BARRIER MATERIALS **ASTM F88**

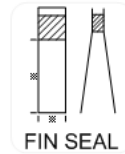
Seal strength is a quantitative measure for use in process validation, process control, and capability. Seal strength is not only relevant to opening force and package integrity, but to measuring the packaging processes' ability to produce consistent seals. Seal strength at some minimum level is a necessary strength of the seal to facilitate opening. The maximum seal force is important information, but for some applications, the average force to open the seal may be useful.

Tensile Strength



F88

Technique A: *Unsupported*
Grip Separation Rate: 10 in./min
Fin Seal Type: Fin Seal 3" X 1"





MEDICAL PACKAGE TESTING



INTERNAL PRESSURIZATION FAILURE RESISTANCE OF UNRESTRAINED PACKAGES **ASTM F1140**

These test methods provide a rapid means of evaluating tendencies for package failure when the package is exposed to a pressure differential. Pressure differentials may occur during processes such as sterilization and transportation. These test methods are frequently used to quickly evaluate packages during the manufacturing process and at various stages of the package's life cycle.

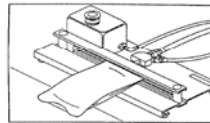
Burst Testing



F1140

Open-Package Test (Test Method A):

Position: Unsupported
Average kPa: 12.23





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