

Implications for Process Package Testing in ISO 11607

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The ISO 11607 Standard, Packaging for Terminally Sterilized Medical Devices, is a guidance document that describes the process for design, development, validation, process control and final qualification of packages used in the protection of sterile medical devices. Even though this document is pointed specifically at the manufacturer of sterile medical devices, it is a well thought out vehicle to guide any package designer through the complexities of specialized package production.

The ISO 11607 standard outlines the principal requirements for packaging process development, validation and process control for packages that are intended to protect the internal product. It describes methods of material qualification, section 4, process qualification, section 5 and final package qualification, section 6. In each of these sections specific reference is made to methods of testing that help to verify the overall performance of the package. Some of the paragraphs that reference these methods are discussed below.

In testing packages for their performance a distinction must be made between their ability to maintain a sterile environment and the mechanical performance properties of the package. The ability to maintain the sterile properties of the internal product is called "Integrity". The mechanical performance is more often referred to as its "strength". When evaluating the materials of the package, its "sterile barrier" properties are examined. The seals of a package, can be examined for their "seal integrity", i.e. lack of leaks, or their "seal strength", i.e. their mechanical strength.

In ISO 11607, section 4.1.5 section "c" concerning the typical peelable package materials with adhesive coatings, states that " materials shall demonstrate a minimum specified seal strength". This means in the design stage that the producer must consider the stresses of manufacture, sterilization and transportation that the package will see during its lifetime. These stresses should be transformed into a specification that will prevent package rupture in its normal life cycle. The implication for testing is that some quantitative measure needs to be made to verify this strength value. Whole package inflation tests such as burst or creep methods provide this information.

Furthermore, in section 4.1.6.2 the standard specifically states that " Packages shall meet producer's and manufacturer's specifications for seal width, burst and/or seal strength". The implication for testing is that a quantitative measure is needed to verify these parameters. The burst seal strength test provides quantitative results to meet this need.

Section 4.2.1.1.4 states " Means shall be provided to ensure that all packaging used in routine production is within the limits determined to be suitable for the sterilization process". The implication for testing is that a quantitative measure needs to be made to

check the strength and integrity of the package before and after sterilization. Burst seal strength testing and leak testing are methods to quantify this need.

Section 5 of ISO 11607 outlines the process qualification for forming and sealing packages. The intent of the requirements of this paragraph are set forth to establish appropriate upper and lower processing limits during package manufacture. Essential process controls on such things as sealer temperature, pressure and dwell must be evaluated and limits applied. A process verification must be actually performed to confirm the process limits. Furthermore, packages made at these limits need to be subjected to performance testing to prove their capability. The implication for testing is that a quantitative measure of the package strength will document the process limits. Burst, creep or creep to failure testing provides a quantitative measure of package strength.

In section 5.4.1 the standard states " Either during or after the process validation the manufacturer shall establish procedures to ensure that the package process will be under control during routine operation". The implication for testing is that a fast, easy to use method should be available to periodically check the performance of the process while it is running. Burst, creep and creep to failure testing provides a fast and effective method to gather quantitative data on the consistency of the package sealing process.

Final package product test selection must combine a series of tests to verify that the package will meet its specified requirements. Section 6 of ISO 11607 discusses these test methods. This section indicates that several tests may be required to confirm the package performance to its specification.

In section 6.3.2.2 seal strength tests are noted as methods to confirm the critical sealing process variables, and whether the process is operating under control. Furthermore, the burst/ creep pressure tests are noted to evaluate the overall minimum seal strength of the whole package as tested simultaneously. The implication for testing is that burst and creep test methods exist which will provide quantitative results that document the level of process control that the manufacturer provides. Clear documented results in graphic and numerical form or statistical data on the results are available in the BT-1000 package tester to meet the needs of both ISO 11607 and other regulatory requirements.

Section 6.4.3.3 discusses shelf life of the product. Artificial and real time aging tests are needed to verify product and package shelf life. The implication for testing is that burst and creep test methods provide quantitative performance at each life test point.

The TM Electronics, Inc. BT-1000 Automated Package Tester gives the user a simple, repeatable, reliable instrument to meet the test requirements of ISO 11607. Furthermore, its built in graphic and SQC analysis programs provide documented results of the tests for the packaging process performance. Contact T.M.E. for complete details on how the BT-1000 will meet your needs for ISO 11607 testing.