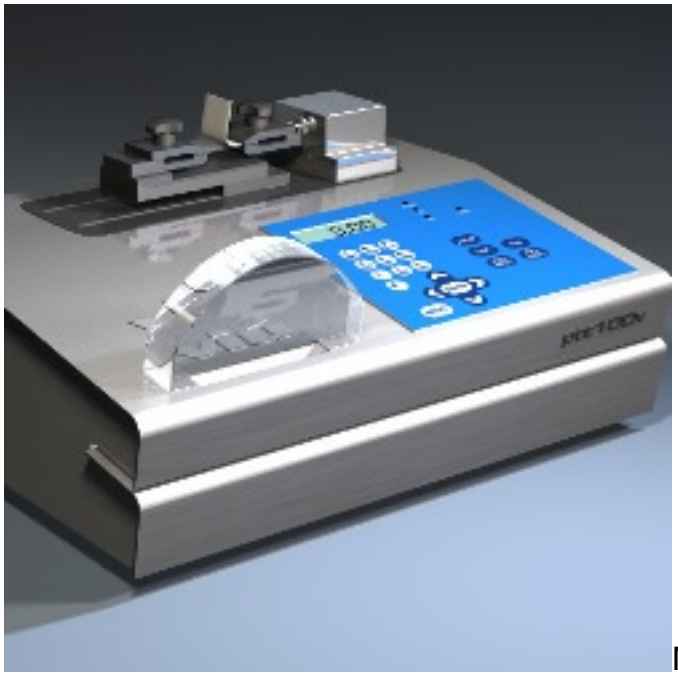
Medical Pouch Testing Unit Ensures Sterility



Non-compliant medical device packaging has been at the tip of the tongue of medical device manufacturers over this past year. Third party agencies such as the FDA and ISO are getting tough with non-compliant packaging programs.
The best way to thwart the devastating blow of a medical device product recall is regular pouch testing, claims Charlie Webb, Van der Stahl Scientific, Inc.'s president.

Webb says, "It's become increasingly apparent that many medical device companies are simply not testing pouches in process and this breach in quality assurance is a recipe for disaster."

Historically, many quality assurance groups have felt that testing machinery is cumbersome to use and because most of the tensile testing equipment is designed to pull test a variety of products and packaging, it is not finely tuned for medical device pouch peel testing.

With the new PTT-100V Testing Unit, this system incorporates a quick load fixture and has been developed and optimized to work in concert with the ASTM-F88 peel test protocol.

The unit also incorporates another important feature, the VIU system. This patented system side lights the medical pouch with a LED light wash at a low angle. With the 3X magnification lens the system allows lay packaging staff to evaluate the basic seal integrity by using this fixed magnification, fixed lighting system. The VIU includes a quick reference card in order for packagers to evaluate visual seal integrity against a known standard. The PTT-100V is a small unit that is right at home in a clean room.

The system is designed to promote regular testing through its ease of use. Perhaps most important, the system will digitally date and time stamp every inspection and testing event. Lot numbers and machine serial numbers can be included at the time of each inspection as well as the inspecting personnel's name. The PTT-100V ships with included software that allows quality teams to purge inspecting and testing data in order to archive important testing and inspection records. The firm has created a video of this unique product in order to highlight the systems ease of use, visit this URL to view. www.vanderstahl.com/medical_pouch_sealers/ptt-100v-package-testing-unit [1]

Webb says, "This is a paradigm shifting approach to medical pouch inspecting and testing. We have worked hard to include process ergonomics in order to help our medical device packaging customers stay compliant to ISO-11607. We're passionate about the movement to increase inspection intervals as we truly believe this is the pathway to total quality of a medical device packaging function."

Source URL (retrieved on *03/09/2014 - 12:15pm*):
http://www.mdtmag.com/product-releases/2011/08/medical-pouch-testing-unit-ensures-sterility?qt-recent_content=0

Links:
[1] http://www.vanderstahl.com/medical_pouch_sealers/ptt-100v-package-testing-unit