E-Scan 655

MICROCURRENT HVLD

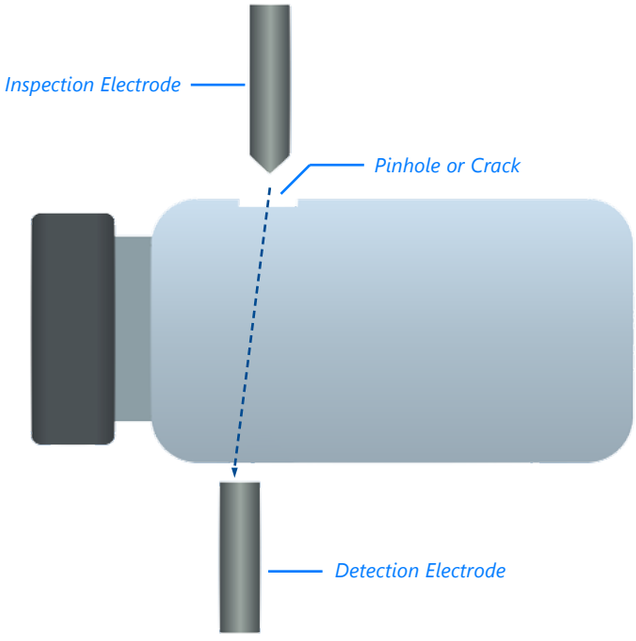
MicroCurrent HVLD technology is the optimal solution for all parenteral and biologic products.

Product Overview

The E-Scan 655 technology is a MicroCurrent conductivity test method, HVLDmc , that is completely non-destructive to the container and product; exposing the package and product to lower voltage than other conductivity based solutions. The technology uses a non-contact and non-invasive test method that requires no sample preparation. E-Scan 655 can be used with a wide range of liquid based products including low conductivity sterile water for injection (WFI) and proteinaceous products with suspensions.

The E-Scan 655 features a fast test cycle and simple operation. Additional benefits include quick changeover and easy recipe setup to accommodate a wide range of products and applications. The offline E-Scan 655 method can be migrated from laboratory to 100% inline testing applications at high production speeds.

The E-Scan testing process uses a set of electrode probes to scan a non-conductive container that is sealed. The container material can be glass, plastic, or poly laminate. The container or package must contain liquid (minimum fill 30%). If a pinhole, crack, or other defect is present, there is a resistance differential and change in current flow indicating a breach in the container. The approximate defect location can be identified.

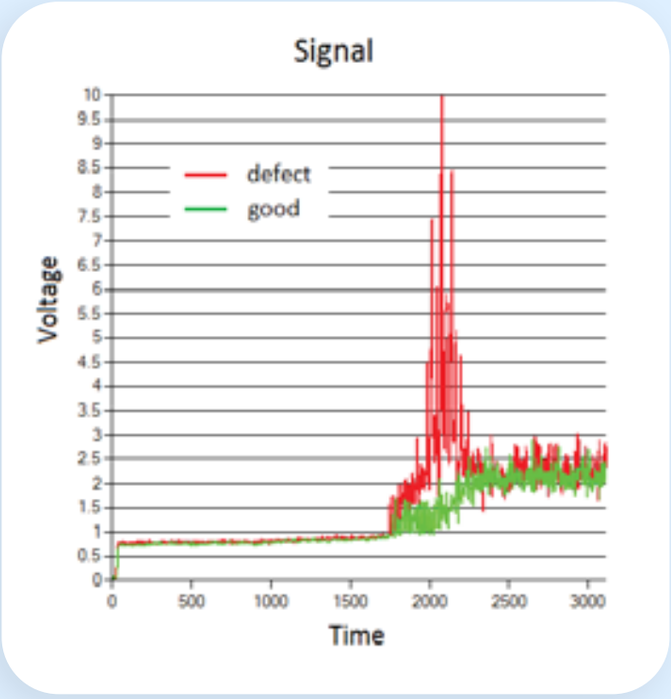


Naturally Occuring Defects

Neck Defects

Elastomer Defects

Heel Defects



BENEFITS:

- Non-destructive, non-invasive, no sample preparation
- High level of repeatability and accuracy
- Effective across all parenteral products, including extremely low conductivity liquids (WFI)
- Lower voltage exposure produces no ozone, eliminating risk to the product and environment
- Listed in USP Chapter <1207> as recommended method for parenteral liquid package inspection
- Robust method and approximate 3x Signal-Noise-Ratio for a wide range of product classes and package formats
- Simplifies the inspection and validation process

Specifications

APPLICATION	Non-destructive micro leak detection for parenteral products (liquid fill)
INSPECTION CRITERIA	◦ Detection of pinholes, cracks, and defective seals ◦ Measures & verifies container closure system integrity
PACKAGE TYPE	Pre-filled syringes, vials, cartridges, ampoules, BFS, bottles, pouches
PACKAGE MATERIAL & COMBINATIONS	Glass, plastic, poly laminate
CONTENTS	◦ Liquids including products with suspensions, emulsions and proteins ◦ Sterile Water for Injection (WFI)
TEST CONFIGURATION	◦ Offline laboratory ◦ Technology is scalable to 100% online inspection
TEST METHOD	MicroCurrent HVLD (HVLD^{mc})
OPERATOR INTERFACE	Color Touch Screen
TEST PARAMETER STORAGE	Up to 20 Products (ETHOS 21 CFR, Part 11 software provides unlimited product storage)
TEST SENSITIVITY	Approximate hole size <1 micron* (MALL)
TEST RESULTS	Voltage Reading 0-10 Volt Analog Measure
CFR SECURITY CAPABILITY	Yes (21 CFR, Part 11) PTI ETHOS Software
REMOTE INTERNET ACCESS	Yes
DATA COLLECTION	View on touch screen and electronic
TEST INSTRUMENT ENCLOSURE	Stainless steel with Lexan safety panels
SYSTEM DIMENSIONS	29" w x 23.1" D x 23.4" H
WEIGHT	160 lbs.
POWER	100-240 VAC; 50/60 cycles
OPTIONS	Validation Qualification Package (IQ/OQ)
CERTIFICATIONS	CE

*Test results may vary according to application and package specifications.