pti science of quality

E-Scan 615

MicroCurrent HVLD

Product Overview

The E-Scan 615 technology is a MicroCurrent conductivity test method, HVLD^{mc}, 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 615 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 615 is a static test to inspect a non-conductive container that is sealed, providing results in seconds. The parenteral container must contain liquid. During the test cycle, the container will rotate. 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. Through advanced algorithms and technology enhancements, the E-Scan 615 simplifies the user experience as well as delivers rapid results. Additional benefits include quick changeover and easy recipe setup to accommodate a wide range of products and applications.

The E-Scan 615 is highly suitable for batch release testing, at line on the production floor or in the laboratory.

Crimp & Neck Defects

Barrel & Body Defects
Plunger Inspection

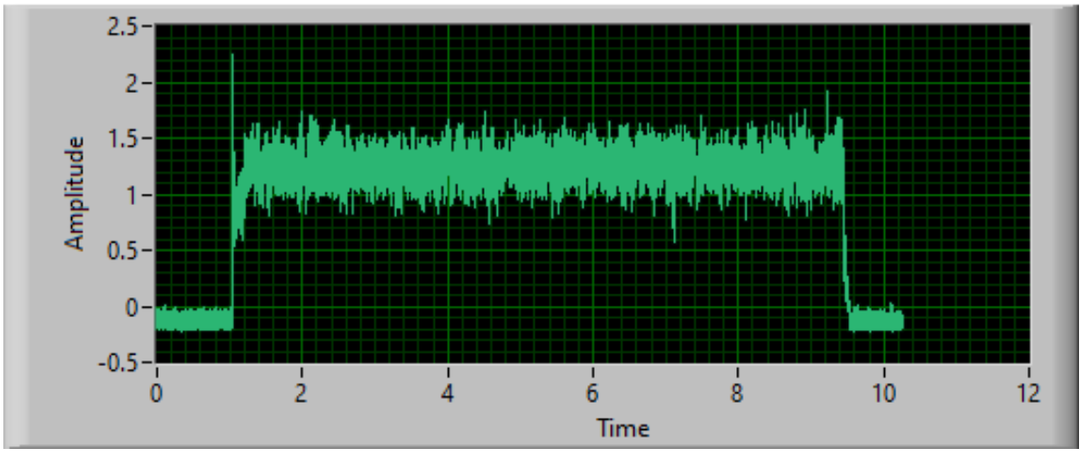
Heel Defect

Life Science
CCI Services

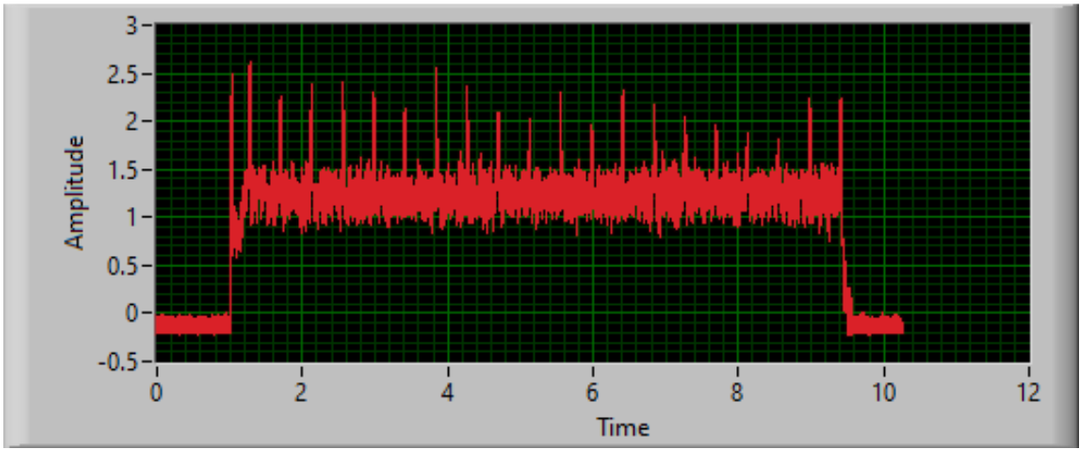
Testing, Training & Consulting Services
Test Method Development Support
Validation Support and Deployment

Our expertise and services ensure your products meet the highest standards of performance and regulatory compliance

10R Vial Negative Control Scan (Pass Result)



10R Vial Positive Control Scan 5 micron neck defect



BENEFITS:

- Non-destructive, non-invasive, no sample preparation
- High level of repeatability and accuracy
- Versatile solution as it's suitable for batch release testing, at line on the production floor, and laboratory.
- 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	◦ Pass/fail result based on detection of pinholes, cracks and other defects. ◦ Measures & verifies container closure system integrity ◦ Plunger defect inspection
PACKAGE TYPE	Vials, pre-filled syringes, cartridges
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 ◦ At line inspection
TEST METHOD	MicroCurrent HVLD (HVLD^{mc})
TEST PARAMETER STORAGE	Up to 20 Products (ETHOS 21 CFR, Part 11 software provides unlimited product storage)
TEST SENSITIVITY	Approximate defect size <1 micron* (MALL)
TEST RESULTS	Voltage Reading 0-10 Volt Analog Signal Measurement
CFR SECURITY CAPABILITY	Yes (21 CFR, Part 11) PTI ETHOS Software
REMOTE INTERNET ACCESS	Yes
DATA COLLECTION	View test result data on touch screen and electronic data collection on laptop
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.