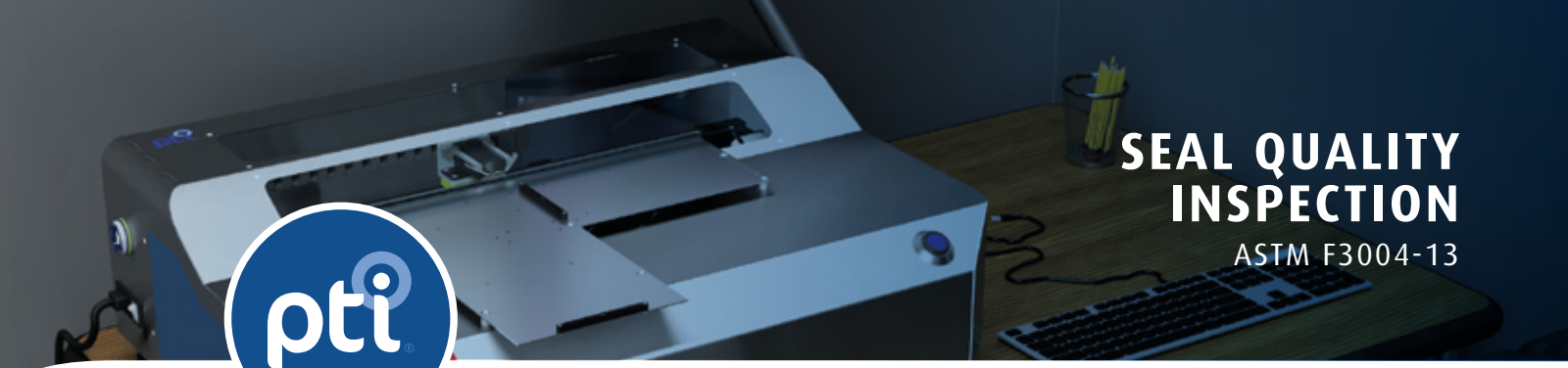

SEAL QUALITY INSPECTION

ASTM F3004-13

SEAL QUALITY TESTING AND SEAL ANALYSIS

Seal-Scan®
a PTI technology

Seal-Scan® is a semi-automatic inspection system with x-y drive, used for the detection of seal defects, seal characterization and material analysis.

Seal-Scan®

Seal-Scan® is an Airborne Ultrasonic Technology (ABUS) that inspects and analyzes pouch seals non-destructively offline. Seal-Scan® is a deterministic, quantitative, high resolution method that inspects pouch seals for defects and seal integrity for consistency.

Testing is non-destructive, non-invasive, and requires no sample preparation. Seal-Scan® provides advanced digital imaging software tools for process control which offers in-depth seal quality analysis.

Seal-Scan features two scan modes:

- Linear Scan (L-Scan) to simulate online defect detection (line graph)
- C-Scan for detailed seal analysis, producing pixel by pixel evaluation of seal (Opto-Acoustic image)

Seal-Scan systems utilize the ASTM Test Method F3004-13, non-destructive test method for "Evaluation of Seal Quality and Integrity using Airborne Ultrasound Technology." Approval of this test method was developed utilizing PTI's ABUS technology.

BENEFITS

- Deterministic inspection method producing quantitative results
- Works for any material and combinations, regardless of color, transparency, print, surface finish and porosity
- Produces high resolution Opto-Acoustic image of seal
- Characterizes overall quality and uniformity of the seal

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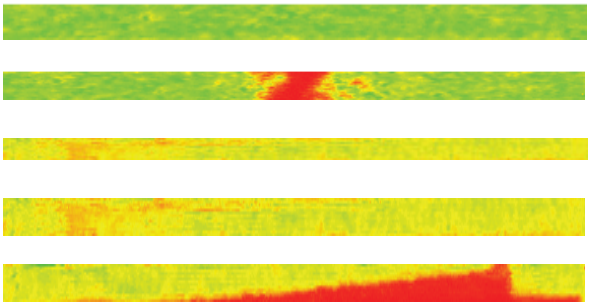
TECHNOLOGY

Pouch seal or package material is scanned between two focused ultrasonic sensors. Ultrasonic waves propagate through single or multiple layers of bonded materials. Ultrasonic propagation through different mediums causes reflection of sound waves, and reduces/eliminates signal strength. The level of signal passing through the seal is a function of the quality of the seal. Various types of defects, leaking and non-leaking, process-related and random are detectable. Seal-Scan® is capable of producing Opto-Acoustic images as well as detailed statistical analysis by either of two scan modes (L-Scan and C-Scan). An L-Scan is a single linear scan along the X-axis of the seal that provides a line graph of seal integrity and simulates online inspection. C-Scan produces multiple scans (along X and Y-axis of seal area) that provide a high-resolution ultrasonic image of the seal structure. This technology can be integrated into a pouch production line via the Seal-Sensor for 100% on-line seal defect detection.



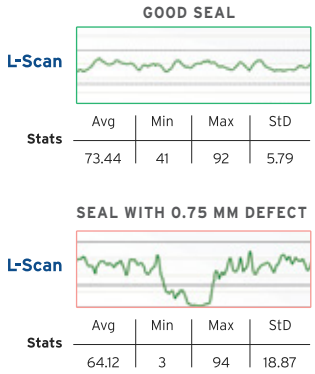
Good seal

Seal with 0.75 mm defect

Channel defect

Good side seal

Side seal with product contaminant



SEAL-SCAN® 520 SPECIFICATIONS

Application	Semi-automated offline seal quality inspection and analysis
Technology	Airborne Ultrasound Technology*
Recgonized Test Method	ASTM F3004-13, referenced in USP 1207
Package Type	Pouches, flexible packaging and laminated materials
Package Material & Combinations	Any pouch material: Tyvek®, Paper, Foil. Film, Aluminum, Plastic, Poly
Inspection Speed X-axis	Adjustable to 500mm/sec.
Inspection Rate	Up to 1,000 pulses/sec.
Pouch Placement	Manual
Scan Modes	L-Scan (X-Axis Linear Scan) C-Scan (X & Y Axes for Opto-Acoustic Image)
Seal Defects	Incomplete seal, inclusions, wrinkles, channel defect, misaligned seal, delamination or blisters. Inconsistent seal – analysis pixel by pixel
Minimum Defect Size	500 microns
Locations of Defects	Yes
Test Results	Quantitative Analysis - Opto-Acoustic Ultrasonic Images of Seal Quality
Inspection Data	Statistical results: Signal Avg/Min/Max/Standard Deviation/# of scans/Scan score and Seal Width and Seal Length
Data Collection	• ETHOS 21 CFR11 compatible for data collection and protection • Automated data collection via SQL server • Automated live imaging of scans
Statistical Sealing Trend Analysis	Yes
Operator Interface	PC Based System (Computer & monitor supplied by customer)
System Enclosure	Stainless steel workstation, with X-Y drive, operator interface, software package for seal analysis
Power	100-240 VAC 50/60 Hz.
System Dimensions	W – 32" D – 22.5" H – 9"
Options	Validation Qualification Package (IQ/OQ/PQ)
Total Seal-Scan Shipping Weight	60 lb.

*U.S. Patents 6,840,108 – 6,920,793 – 7,167,415

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