HIGH VOLTAGE LEAK DETECTION

QESSE

VOLTA

*QESSE **VOLTA** is a nondestructive High Voltage Leak Detection (HVLD) bench top unit for package integrity testing on your liquid filled containers.*

*Listed in the USP 1207 as a deterministic method, QESSE **VOLTA** is the ideal solution for Container Closure Integrity Testing.*

*In case of defect in a container with liquid inside, a clear drop of resistivity is detected by **VOLTA** and it causes a fail response.*

It is CFR 21 PART 11 compliant.

- *Vials*
- *Pre Filled Syringes*
- *Cartridges*
- *BFS containers*
- *IV Bags*
- *Others*

- Software CFR 21 Compliant
- Test sensitivity below 1 micron
- Highest test sensitivity
- Results: PASS/FAIL
- Easy to Validate
- Nondestructive
- Minimal current = microEnergy
- Deterministic Test Method listed in the USP 1207
- Sample format change in seconds
- Customized support for any sample
- Reliable High Voltage Generator
- User friendly

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SPECIFICATIONS

Test Method: HVLD HIGH VOLTAGE LEAK DETECTION

Type: Nondestructive

Regulatory Standards:

- USP <1207> Package Integrity Evaluation – Sterile Products
- EU Guidelines to GMP Medicinal Products for Human and Veterinary Use – Annex 1, Manufacturer of Sterile Medicinal Products

Results: Deterministic PASS/FAIL

Limit: Adjustable limit values

Type: HVLD µE – micro Energy (typical below 100 mJ released to sample)

HMI: 12" Touch Screen Windows base, by Siemens®

PLC: Siemens®

Test Sensitivity: Below 1 micron*

Sample: No sample preparation or conditioning before the test

Recipe: Up to 15 different recipes

Operation: One touch button with green/red indication of PASS/FAIL

Software: CFR 21 PART 11 Compliant

Data Storage: Unlimited

Data: Data Export in .csv format via USB or PC connection

Network: RJ 45 Ethernet – OPC UA

Dimensions: 380W x 600 L X 480 H [mm]

Weight: 40Kg

Power: 100-240 VAC; 50/60Hz

Compliance: EMC 2014/30/UE, CE marked

Option:

- IQ/OQ/PQ cGMP Validation Protocols
- Tools for system suitability
- Flight Case
- Q-Data® Data Management software, CFR 21 PART 11 compliant

Services:

- Feasibility Studies on your samples
- Certified Positive Controls (Defective Samples)
- FAT Factory Acceptance Test
- IQ/OQ/PQ cGMP Validation
- Calibration & Maintenance Agreement

**test sensitivity may vary based on the combination of package/product inside*

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