QESSE

VACUUM DECAY LEAK TESTER

CCI 1000 is the new, state of the art, vacuum decay based, testing instrument capable to measure on various types of containers made of glass, plastic, metal, flexible composite.

CCI 1000

- *Liquid filled ampoules*
- *Vials (Empty, Liquid or dry filled)*
- *Pre-filled syringes (liquid filled or empty)*
- *Cartridges*
- *Pouches and Sachets*
- *Bottles, filled and sealed*
- *Bulk containers small size*
- *Ophthalmic dropper tip*
- *IV Bags*

- Vacuum decay is the most established and widely used test method for the detection of leaks from small and medium size containers and packages
- It is nondestructive, quantitative i.e. deterministic, fast, it does not require special gas
- Vacuum circuits and electronics conceived with the state of the art construction standard
- High sensitivity *(minimum size of leaks detectable in a defined container)*
- Excellent repeatability of measurements *(day-to-day, shift-to shift, sample to sample)*, i.e. the reliability of the test
- Speed of measurement, i.e. productivity

The software design and concept are intended to assure:

- **Easy to use**
- **Completeness of information, both for routine QC and for R&D**
- **Data protection and integrity, through multi-level passwords, data export capability**
- **Possibility to extend to CFR 21 part 11 standard (Audit trail and data integrity assurance)**

Key factors to run successful applications is the choice of the right measurement chamber design for the container and the help of experienced manufacturer to develop the best recipe, i.e. the optimal set of testing parameters.

The duration of each measurement can be less than 15 sec, the result is immediately displayed and requires no interpretation.

Setup of one new method can be done in one hour to one day, depending upon complexity, ample homogeneity and required sensitivity, which in turn depends upon MALL (Maximum Allowed Leakage Level).

CCI 1000 can be offered with the widest choice of measurement chambers, for different type of containers.

The capability of precise quantification of the vacuum change provides the valuable information to enable easy validation of the method.

Traceable result generation and data integrity is the key to validation and third-party qualification.

We can also provide certified defected positive samples, calibrated orifices of different diameters and dedicated adjustable calibration tools.

QESSE

CCI 1000

VACUUM DECAY LEAK TESTER

SPECIFICATIONS
Test principle: Vacuum decay in rigid or flexible chamber
Non destructive. No gas required
Reference Methods: ASTM F2338-09, USP 1207
Quantitative results (deterministic)
Adjustable limit values
UniVAcuum® Uniform Vacuum design
Vacuum measuring: Basic sensing or AddiSens®:(additional sensitivity mode)
HMI: 12” Touch screen, Windows® based, by Siemens®
Limit of detection: better than 0.05 cc/min (approx. 1,5 micron nominal hole size)
Rapid measurement cycle (No sample preparation)
Built-in suitability test before session (option)
Up to 15 different recipes easily generated and selectable
Measuring units (mBar and Pascal)
One touch button operation
Output as pass /fail with large green/red lights and number shown
Up to 100 results of the session available from HMI
Data export in csv format via USB or PC connection
Data integrity protected by multi-level password
Audit trail available for CFR 21 Part 11 (option)
Laboratory unit, extensible at production line
Easy-clean Stainless Steel case
Dimensions: 380 W x 480 L x 480 H mm | Weight: 22 kg
Power: 100-240 VAC; 50/60 Hz; 200 VA (without vacuum pump) | CE Marked

LEAFLETA4_CCI1000_ENG_SEP2022

QESSE is a trade mark of Nordtest s.r.l. | Via Liverno 11 15069 Serravalle Scrivia (AL) ITALY www.qesse.eu | info@qesse.eu | +39 014362422