# **CCI 1000**

## VACUUM LEAK TESTER

#### Is my container leaking? | Is my packaging still airtight?

CCI 1000 is the answer



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 :

- Liquid filled ampoules
- Sealed Vials (empty, Liquid or lyo filled)
- Pre-filled syringes (liquid filled or empty)
- Pouches and sachet
- Bottles, filled and sealed
- Bulk containers small size
- Ophtalmic dropper tip

#### The measuring principle

Vacuum decay is the most established and widely used test methos for the detection of leaks from small and medium size containers and packages.

It is non-destructive, quantitative i.e. deterministic, fast, it does not require special gas

The quality of design and construction of the vacuum circuits and electronics are critical to assure

- sensitivity (minimum size of leaks detectable in a defined container),
- 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



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The software design and concept are intended to assure:

- Ease to use
- Completeness of information, both for routine QC and for RD
- 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 is always 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, sample 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.

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 <sup>®</sup> Uniform Vacuum design
Vacuum measuring: Basic sensing or AddiSens <sup>®</sup> :(additional sensitivity mode).
HMI: 12" Touch screen, Windows based, by Siemens <sup>®</sup>
Limit of detection: better than 0.05 cc/min (approx. 1,5 micron nominal hole size)
typical 10 sec or less; it depends on application
Built-in suitability test before session or when required
Up to 15 different recipes easily generated and selectable.
Different units ( mBar or 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 pw
Audit trail available for CFR 21 Part 11 (option)
Laboratory unit, extensible at production line
Easy-clean Stainless Steel case
Dimensions: 380mm W x 480 L x 480 H   Weight: 22 kg
Power: 100-240 VAC; 50/60 Hz; 200 VA (without vacuum pump)   CE Marked

