

E-Scan^{mc} RTX

AUTOMATED CONTAINER CLOSURE INTEGRITY TESTING OF PRE-FILLED SYRINGES

Product Overview

The *E-Scan RTX* platform is PTI's fully automated, modular container closure integrity solution for pre-filled syringes. The RTX is a practical and reliable CCI solution that features a dynamic robotic design, tailored to fit your production requirements.

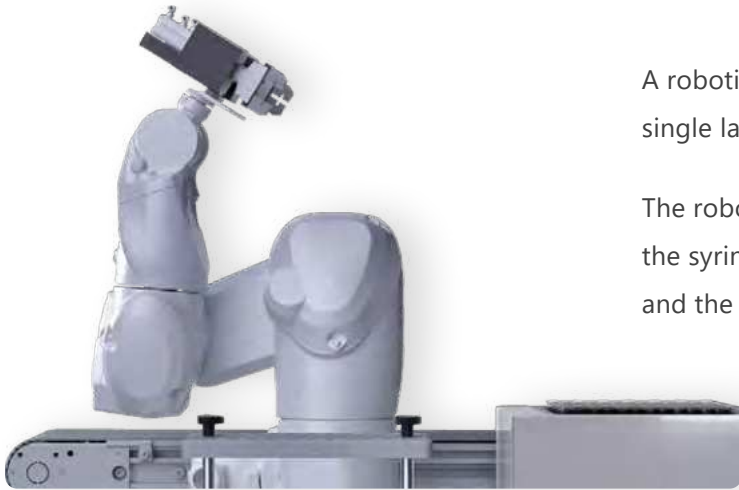
This robust, adaptable platform utilizes MicroCurrent HVLD technology, a revolutionary form of HVLD that is the ideal CCI solution for high-risk, delicate biologic liquids. It provides a rapid *PASS/FAIL* result – test cycle is only seconds – and is suitable for batch release testing, at line on production or in the lab.

BENEFITS:

- MicroCurrent HVLD technology is effective across all parenteral products, including biologics and extremely low conductivity liquids including sterile water (WFI).
- Listed in USP Chapter 1207 as recommended method for parenteral liquid package inspection.
- Robust method and good Signal-Noise-Ratio between good and defective products.
- Low voltage exposure reduces production of ozone.



E-Scan RTX Automation designed for ease of use

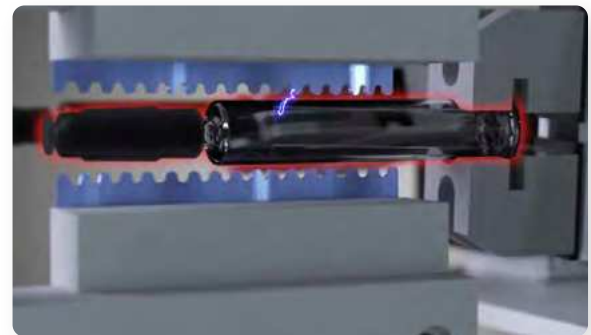
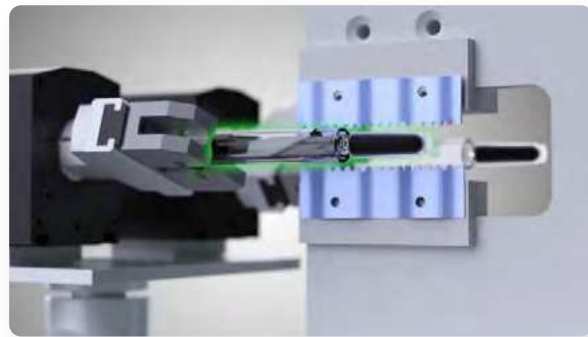


A robotic arm will track and pick-up nested syringe trays from a standard single lane conveyor.

The robot will remove the syringes from the nested tray, and will rotate the syringes through two test stations, one to find needle shield defects and the other to inspect the remainder of the syringe body.

The test is automatically initiated and will provide a definitive *PASS/FAIL* signal on test completion.

Adjustable failure reference can be set to allow for *PASS/FAIL* based on the pre-determined LOD (limit of detection) set-up in the initial recipe.



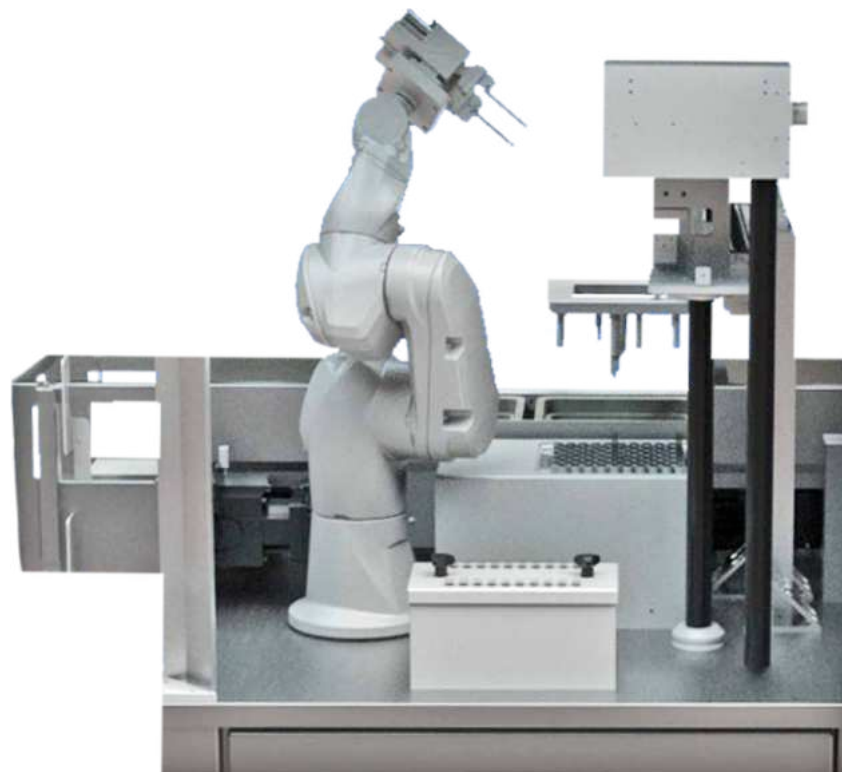
After testing, syringes will be automatically loaded back to the syringe tray or reject tray.

MicroCurrent Technology

PTI's MicroCurrent HVLD technology uses a unique mode of DC voltage, applying no more than 50% of the voltage used on conventional high voltage technologies.

The nature of the PTI solution allows for detection of leaks in packages with liquids of extreme low conductivities, including packages containing sterile water.

The low voltage and current applied to the container also reduces the voltage the product is exposed to during the test. The technological advantage makes it the ideal solution for all parenteral and biologic solutions.



The HVLD^{mc} test method ensures product seal integrity by scanning the complete package to detect small pin holes, micro cracks, and closure seal imperfections. HVLD^{mc} has proven to be a highly sensitive leak test method for various types of liquid filled pharmaceutical packaging (pre-filled syringes, vials, blow-fill-seal containers, as well as other liquid filled packages).

