



Application : Pouch filled with liquid for parenteral use

Leaks to be detected : Integrity fault (welds, holes)

Standard : ASTM F2095-07(2021) Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates



Specifications and user requirement:

100 % Test on liquid-filled pouches. Pouches are stored at low temperature (2 to 6°C), which generates condensation on the surface when brought at ambient temperature.

Leaks to be detected : equivalent hole size 50 µm. Quantities to be tested : 100 pcs/day.

Solution : Integrity tester ASC 7400S.2 PP

The ASC 7400S.2 PP allows testing of liquid-filled pouches, even stored at low temperature.

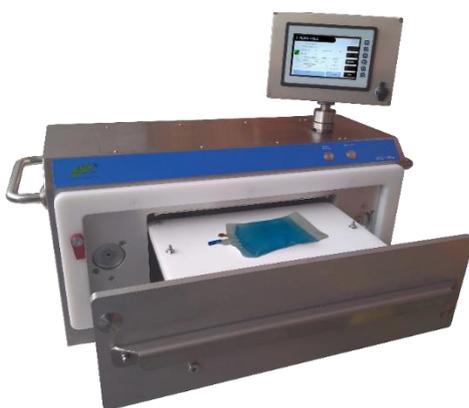
Its detection method being based on measurement of the pressure inside the pouch (ASC Instrument patent), it is unaffected by the condensation phenomenon, creating false positives with other methods.

Operation : Operator places the pouch in the drawer and closes it. This starts the cycle, which runs without further operator intervention.

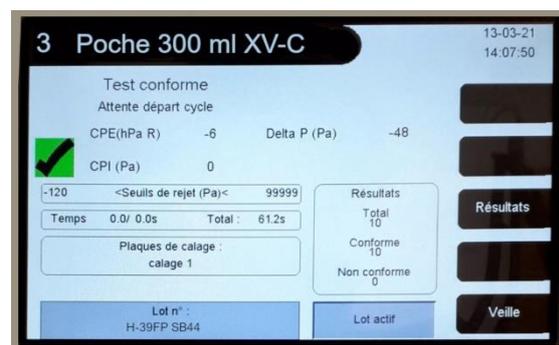
A vacuum is progressively established in the chamber, which causes the pouch to inflate. It makes contact with a pressure sensor that measures the pressure inside the pouch. If this pressure is stable during the Test stage, the pouch is leak-free and the green OK light comes on.

In case of a leak, the pressure drops off, the delta P (variation) exceeds the tolerance and the red NOK light indicates the fail result.

The operator must press an “Unlock process” button to open the drawer and remove the product.



ASC 7400S.2 PP – Non-destructive integrity tester for filled pouches



Screen showing a correct integrity result : $\Delta P = -48 Pa$ for a reject level at $-120 Pa$

Cycle time : 1 to 2 minutes depending on product to be tested.