MARPOSS
TECNA

Solvent Dispensing *and* Leak Testing

FOR MEDICAL DEVICES

Guarantee the best features and performances of every device

Contact us

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Market Needs

quality

accuracy

safety

healthy

This control is essential to grant the right quality standards on the medical manufacturers production.

Medical environment has more challenge and requirements in terms of quality, reliability and safety. It is necessary to guarantee the best features and performances of every device. Complete or partial clogging of a device could have serious consequences. Each part of instruments and accessories needs to be carefully tested in order to ensure the accuracy of the tightness. This could be verified and certified through specific leak and flow testing controls that check the integrity of the manufactured product.
Most of medical disposables and devices need to respect a lot of preliminary
approvals.

Leak and flow tests are requested and performed on 100% of the medical components and sets, they allow the easier, fastest and cheaper detection of rejected products. .

COMPLIANT BALLOON

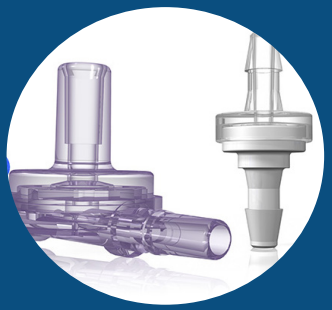
Used in enteral feeding, tracheotomy tubes, occlusion (vascular/bronchial), drainage (urinary/chest), and more. This type of medical device leak testing often uses a combination of pressure and vacuum decay for verification of inflation/deflation, ramp to burst event, and dilation curve information.

NON-COMPLIANT BALLOON

Used in stent delivery, dilation, and more. Catheter testing is often performed using positive pressure and/or vacuum decay testing and verification of inflation/deflation.

MULTI-LUMEN CATHETERS

Used in hemodialysis, diagnostics, pacing, drug delivery, etc. These catheters are often tested using both pressure decay for leak testing and mass flow using multi-port instruments for blockage testing on each individual lumen.



medical components

BAGS

Used for IV/saline, hemodialysis, blood transfer, urinary/waste collection, and more. Bag testing is often performed using pressure decay with restraining plates and bag functional testing using ramp to burst event. TECNA suggests to apply negative pressure to the bags after leak test.

CHECK VALVES

Used in drug/fluid delivery, hemodialysis, blood transfer, and more. Check valve testing is often performed using pressure decay (leak) and cracking/open pressure utilizing ramp to open event (functional). TECNA suggests air flow rate test with opening valve peak pressure control

TUBING AND FITTING SETS

Used in drug and solution delivery, blood transfer, and more. Set testing is often performed using pressure and/or vacuum decay testing and occlusion testing.

SHEATH INTRODUCERS

Used for guidewire and catheter entry into blood vessels. Testing often includes pressure and vacuum decay testing as well as occlusion testing.

MEDICAL FILTERS

- Used for eliminating or separating certain elements, as particles of certain size from a solution, or rays of certain wavelength from a stream of radiant energy.
- Test Method: Leak test, Flow Test
- Tecna Instruments: Provaset T3L, Delta TM3, Provaset T2

- Medical tubing is an important component of devices which deliver fluids to and from the body. These medical tubes, which are small and complex custom plastic extrusions, often contain multiple chambers so different fluids and drugs can be transmitted through the same fine plastic tube.
- Test Method: Solvent Dispensing System, Leak Test, Flow Test
- Tecna Instrument: Dosaset, Provaset T2, Provaset T3L

PLASTIC TUBES

MEDICAL LUER

- The Luer taper is a standardized system of small-scale fluid fittings used for making leakfree connections between a male-taper fitting and its mating female part on medical and laboratory instruments.
- Test Method: Leak test by pressure decay
- Tecna Instrument: Provaset T3L, Provaset T2

Opportunities in Biomedical

Smaller, more precise components require a higher degree of accuracy. Blood filters, catheters, diagnostic probes, syringes, ventilator tubes and other items need to meet strict criteria. Many products must undergo an intense premarket approval and validation process to ensure that they will not harm patients.

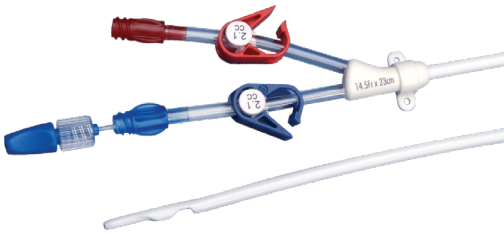
Medical device manufacturers must adhere to numerous health and safety requirements. As these demands become more stringent, test and inspection has become more critical. The accuracy, sensitivity, repeatability and reproducibility of test and inspection methods are critical.

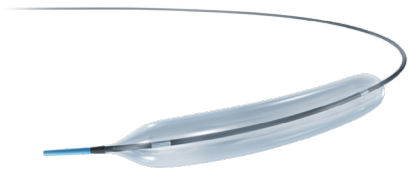
Leak testing is no exception to these demands. Because many medical devices have fluid management functions, they require complete leak testing.

Medical devices often form a barrier between fluids or gases that could create a danger for the patient if they were allowed to mix. Some devices are the route for delivery or extraction of fluids and form the pathway for the fluids.

Complete or partial blockage of medical devices could have fatal consequences, as could the failure of the device to deliver the correct dosage if required. For this reason, blockage, occlusion testing and flow measurement testing can be vital.

With medical devices, it is important to perform a leak tests on 100% of the product without adding significant costs.
This requires a nondestructive test that evaluates the integrity of the product for significant leaks, performs the tests within the cycle time of the production process, and can be integrated into the production process.





Tecna Leak tester are used on **bench or automatic systems** for various medical applications, for example:

- leak test at positive and negative pressure of luer connections to control their tightness
- pressure peak and flow measure of small medical check-valves to grant the correct opening
- flow measure of small tubes such as heparin to check that the pipe is free from occlusions
- leak and flow tests on blood-catchers to verify the compliance of the membrane
- leak test on the plastic case of the haemodialysis filters
- leak test on the plastic medical bags

LEAK TESTING METHODS and **SOLVENT DISPENSING** for **ASSEMBLY**

LEAK TEST WITH DIRECT MEASURE OF THE FLOW LEAK FLOW RATE

By using an internal volume, the instrument can measure the leak rate and also control the volume of the tested product.

INDIRECT PRESSURE MEASUREMENT IN SEALED BELL

Measurement of the pressure variation of the product under test, which is enclosed in a sealed bell.

MEASURING THE LEAKAGE FLOW

At the end of the phases of filling and settling, the pressure is maintained constant by the internal electronic controller. The flow that originates therefore corresponds to the flow required to maintain the product under test at the programmed test pressure and thus corresponds to the leakage flow.

FLOW PRESSURE LEAK TEST

A reference volume is pressurized along with the test part. A transducer reads any pressure differential that develops over time between the leaking part and the non-leaking reference.
Differential pressure testing is well-suited to high test pressures. And, it typically provides higher sensitivity, more repeatability and faster test times than pressure-decay testing.

DIRECT MEASUREMENT OF FLOW

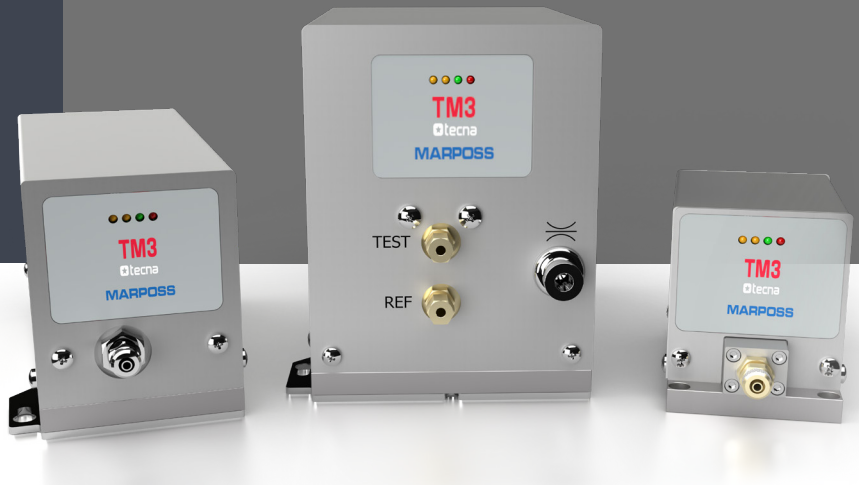
The instrument directly controls and measures pressure and flow rate on the product being tested. An electronic pressure regulator assures constant test conditions.

PROVASET T2

Provaset T2 is the latest compact equipment for leak tests by absolute pressure decay. Its strengths are the compact size and the high performances that make this product extremely reliable and versatile.
This instrument applies the latest electronic and pneumatic technologies to offer the best performances.
Designed for manual use on bench in limited areas, especially in medical segment and in cleanrooms, it can be integrated on automatic systems managed by PLC too.

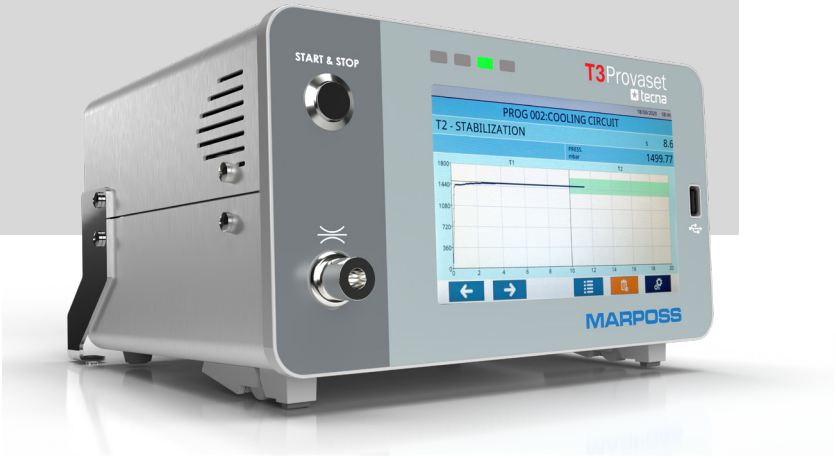
DELTA TM3

The pneumatic modules Delta TM3 concentrate the pneumatic and electronic components in a very small aluminum case, so it is possible to place the equipment too close to the component under test reducing the volume of the testing circuit.
The compact size allows also to place various modules Delta TM3 in one automation, making it possible to perform multiple tests simultaneously on a series of equal components, saving time and costs.
All these aspects are particularly significant in the medical sector: in fact, since the disposables are used in hospitals to dispense a treatment to a patient, all these one-use plastic components should be manufactured and controlled accordingly to strict quality standards, that also define the guidelines for leak and flow tests.



PROVASET T3L

T3L product line is meant for leak testing in every industrial production sector. Every instrument is designed for leak testing either by absolute or differential pressure decay, flow test or leak test with direct measure of leak flow rate. It can also perform occlusion/blockage, sealed component, volumetric, and burst testing.
T3L works great in manual stations as well as fully automatic systems interfaced with a PLC/ PC with advanced communication configurations and protocols.
Wide full scales for pressure and flow tests are available.



DOSASET

Dosaset is a dispenser for cyclohexanone or similar solvents, it is used for manual and automatic bonding of plastic components, disposables, tubes and joints.
Tecna has introduced a revolutionary dispenser that does not use pumps, capillary tubes or porous blocks to dispense the cyclohexanone.
Dosaset utilizes a rotating wheel that vibrates the correct amount of solvent every time. When a tube is placed into one of four adapters on the wheel, a short vibration is initiated, after the tube is removed the wheel rotates dipping the adapter in the solvent before presenting the next adapter ready to bond.
Dosaset is therefore nearly essential in assembly procedures, manual and automatic, programmable even from a PLC or PC.

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