Mecmesin

Medical device force and torque testing solutions

PHYSICAL PROPERTIES TESTERS GROUP

mecmesin.com

Explore our range of medical device testing equipment

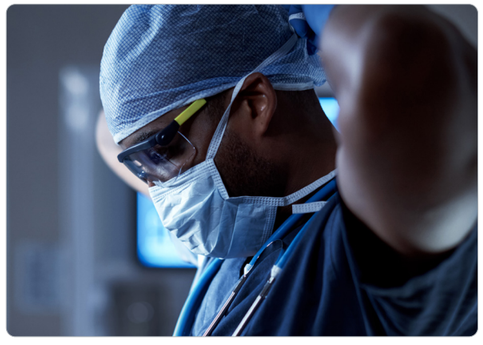
Trusted by our customers:

The medical devices and pharmaceuticals sector is highly regulated, driven by compliance and auditing processes. Safety requirements for devices are paramount since they are predominantly used on humans. This puts a heavy emphasis on quality control of devices, during the development, production and packaging phases, to ensure they meet exacting standards thereby minimising the risks to patients and users.

Testing the mechanical strength of materials, assemblies and finished medical devices is a key part of the quality assurance process.

Manufacturers of medical devices around the world have come to rely on Mecmesin force and torque testing equipment for checking medical products as diverse as pre-filled syringes, catheters, stents, inhalers as well as the medical packaging in which they are stored and distributed.

Whether it be a portable force gauge for integration into your own test rig or a complete tensile/compression testing system with software to aid your compliance to FDA 21 CFR Part 11, Mecmesin has a solution to your physical testing requirements.



Torque testing
Helixa/Vortex

The Mecmesin range of bench-top torque testing systems has been designed to measure clockwise and counter-clockwise torque from a few N.mm up to 10 N.m. The precise measurement of very low torque values in N.mm and ozf.in is often required for small medical devices and their components, which rely on a minimal friction fit for smooth operation.

The Helixa is a precision torque testing system, powered by Emperor software, which can be fitted with torque sensors from 0.1 – 6 N.m capacity thus allowing even the finest of measurements for medical devices. It features an alignment mechanism to ensure concentric measurement and a counter-balance mechanism to remove the influence of axial load – both essential when measuring extremely fine torque values.

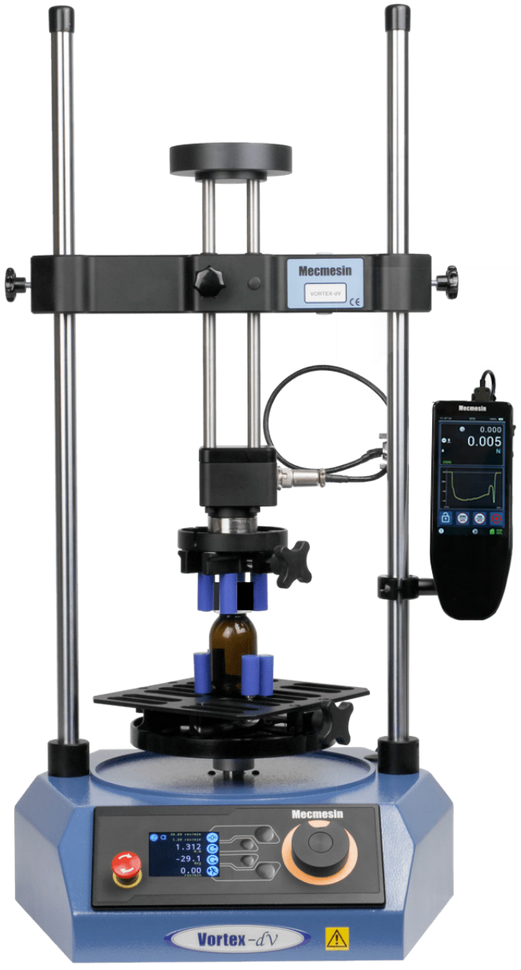
The Vortex has a higher torque rating with torque sensors from 1 – 10 N.m capacity. It's dual-column design allows for larger medical devices, surgical instruments and components to be mounted and tested for their torsional properties. Powered by either Emperor or VectorPro Lite software, the Vortex is a popular choice for use in Production, QC and R&D areas.

Both the Helixa and Vortex allow step-by-step test programmes to be created to follow the test methods described in international testing standards such as ISO and ASTM. To support and guide you with installation services a full IQ/OQ pack is available for each test system provided.

Multi dose drug delivery device

Luer connector

Surgical instrument



Pharma packaging

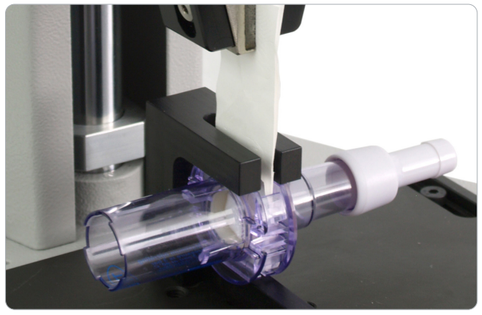
Force testing
OmniTest/MultiTest

The Mecmesin range of single-column test systems is ideal for measuring tensile/compressive forces up to 7.5 kN. They fit neatly on a workbench occupying very little space and can be fitted with interchangeable loadcells to cover precision measurements from upwards of a few grammes-force. Various models are available to suit your medical device testing applications including extended column-length versions for measuring highly elastic materials.

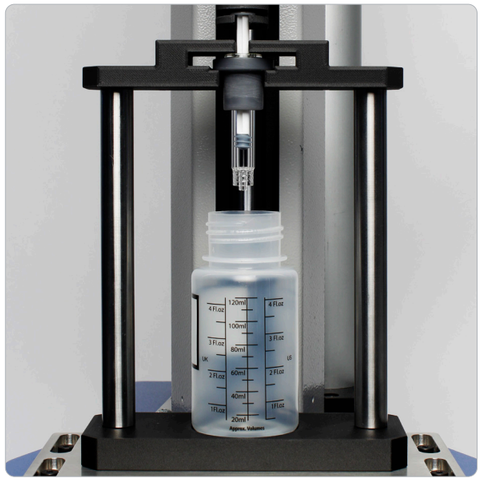
At the heart of Mecmesin test systems are 2 software platforms - the new VectorPro software and the established Emperor software. Both allow step by step test programmes to be created to follow the test methods described in international testing standards such as ISO and ASTM.

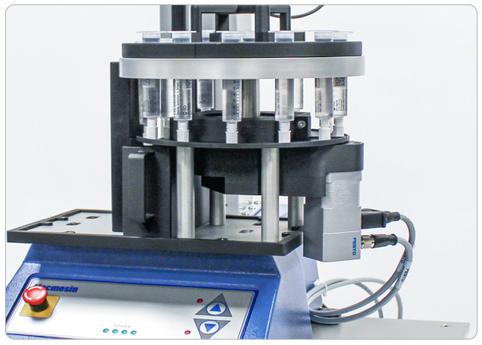
To support and guide you with installation services a full IQ/OQ pack is available for each test system provided.

Pull strength

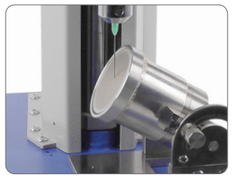


Syringe glide force

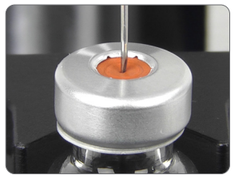




Automated test station



Needle sharpness

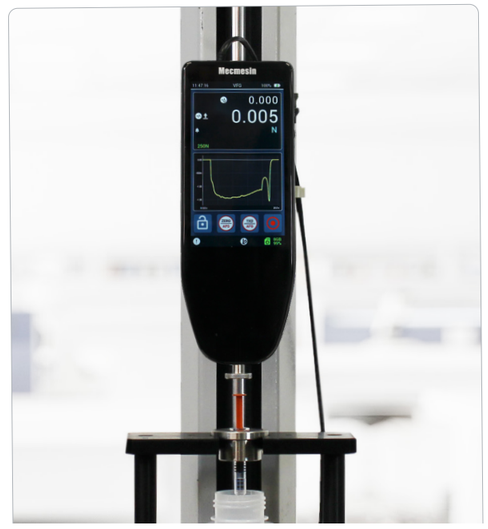


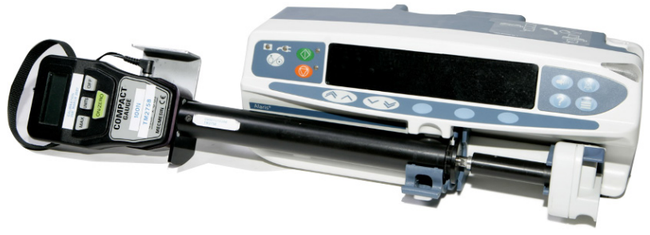
Closure penetrability

Powered by VectorPro®
Testing software

Portable force gauges are frequently used to perform a simple verification of a medical device. The gauge is used either hand-held or it is integrated into a test jig as the core measurement device. They can capture both live and peak readings in tension and compression, which can be outputted via RS232 for storage and analysis.

Break loose force





Syringe pump calibrator

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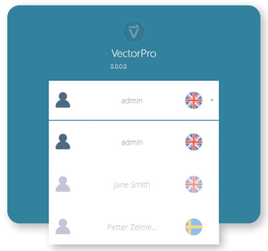
VectorPro®
Software

To assist with your organisation becoming compliant with FDA 21 CFR Part 11, Mecmesin software is packed with features and functionality to ensure data integrity. It helps a manufacturer to track who did what, when they did it, and why, in case a faulty batch of medical devices or pharmaceuticals is accidentally sent to market.



User access

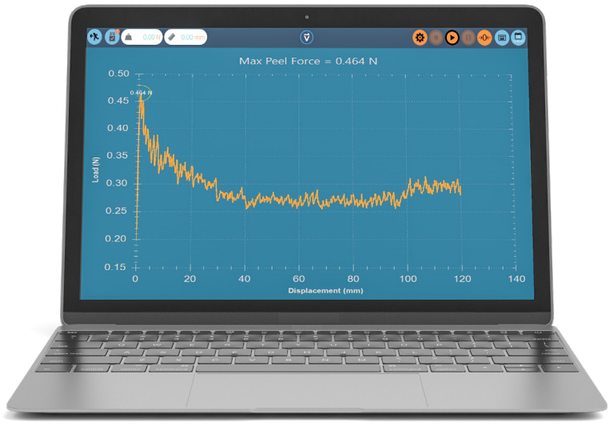
VectorPro utilises separate user accounts for individuals, enabling personalised workspaces, in the language of choice. This provides security for the organisation and simplicity for the user.

Powered by VectorPro®
Testing software

FDA 21 CFR Part 11

Core functionality of VectorPro software includes:

- SQL database - stores data for a secure audit trail of information
- Active Directory – ensures management controls around logins, User ID & password-complexity rules comply with your organisation's established procedures
- Electronic signatures- create, amend and approve test methods plus sign-off results generated from test calculations
- Test reports – use customisable templates to generate reports exactly as you and your customers wish to see them



Discover VectorPro software - visit mecmesin.com

Medical packaging
Solutions

Mecmesin force and torque testing systems are used by manufacturers and processors to optimise the design and performance of medical & pharmaceutical packaging. Performing quality control tests at regular intervals to determine the mechanical strength of medical packaging ensures ease-of-use for the medical professional and that any pack contents remain sterile, secure and undamaged throughout transportation and storage.

Specific international standards are adopted for testing medical packaging with the most common being:

Peel

ASTM F88 – Seam strength of flexible barrier materials

EN 868-5 - Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction

Torque

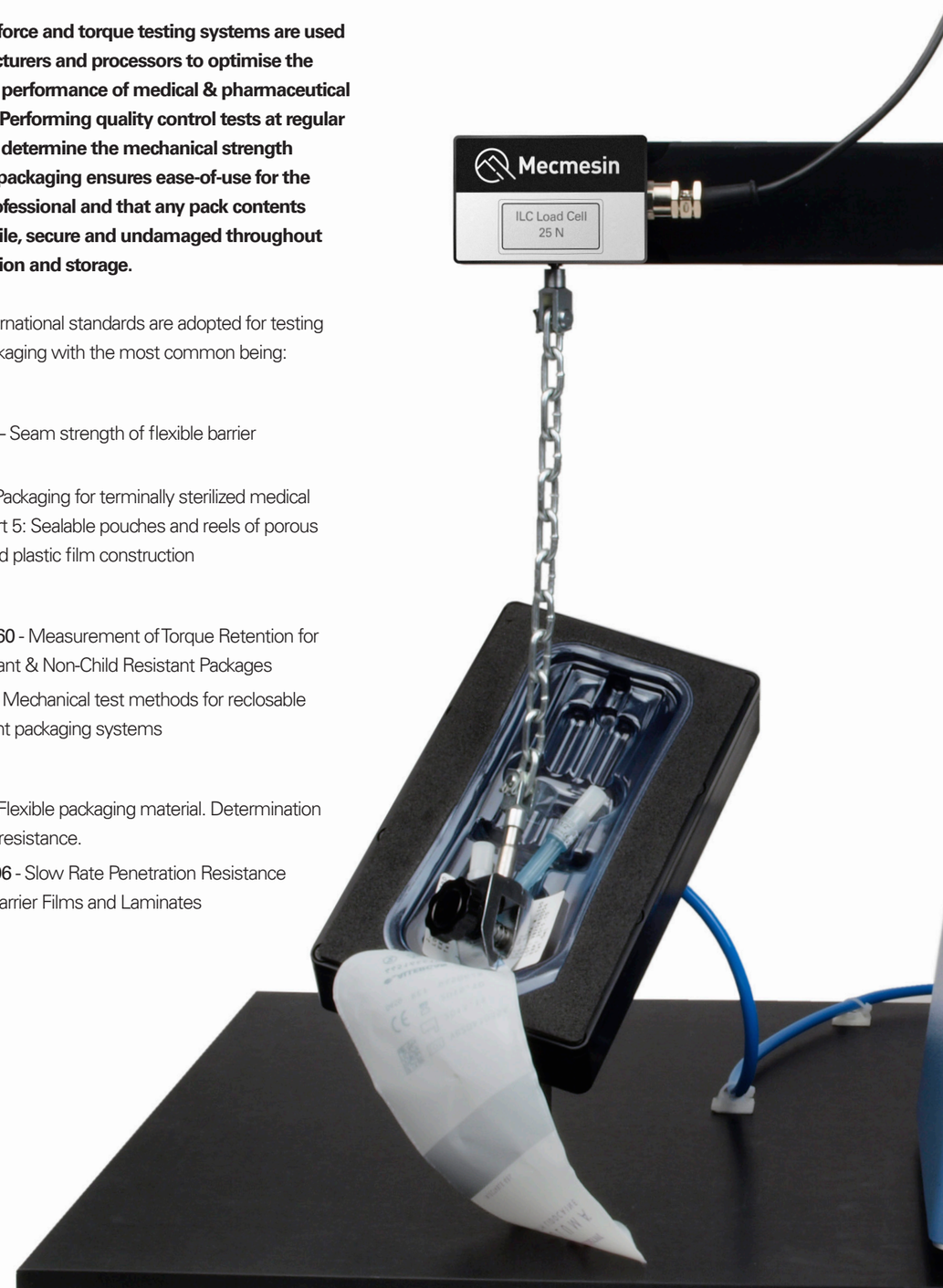
ASTM D7860 - Measurement of Torque Retention for Child Resistant & Non-Child Resistant Packages

ISO 13127 - Mechanical test methods for reclosable child resistant packaging systems

Puncture

EN 14477 - Flexible packaging material. Determination of puncture resistance.

ASTM F1306 - Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates



Medical device
Grips and fixtures

Medical devices, their components and sub-assemblies all come in various shapes, sizes and materials. To achieve repeatability when testing it is important to hold the devices consistently and securely without them slipping but also without gripping them so tightly that the material is deformed.

Mecmesin has a standard range of tensile grips and compression fixtures for the most common applications. They can be easily fitted to all test stands, force gauges and loadcells to provide the ultimate in flexibility.

For torque applications chucks and vices are available to hold medical devices, together with moulded mandrels to uniformly grip closures and connectors.

However for some medical devices and assemblies size and form is so unique that they require custom-designed fixturing. Mecmesin has an in-house design team with years of experience in creating special fixtures to meet your needs, using the latest in 3D printed materials to optimise weight and strength.

Discover your next Mecmesin medical device testing solution online - visit mecmesin.com

> We have been using Mecmesin equipment to perform retention tests on our range of lancet needles for many years. We find the system easy to use for regular in-process checks, and generally reliable with prompt servicing from Mecmesin when required.

Quality Systems Engineer, Owen Mumford Ltd

Download our free whitepaper on force and torque testing of syringes, needles and vials. Visit mecmesin.com/syringe-whitepaper

PPT Group

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Mecmesin reserves the right to alter equipment specifications without prior notice. E&OE.

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