Surgical / Hypodermic

Needle Testing Systems

for curved and straight needles

• sharpness • strength • elasticity

Model AE-3

ACCULINE ENGINEERING, INC.

Model AE-3 is designed for ease of operation with eye-level monitor viewing and finger-tip keyboard controls. Everything needed for needle testing is within easy reach.

The Solution for Testing Surgical / Hypodermic Needles

The Model AE-3 needle tester is a turn-key fully operational machine with all the hardware and user-friendly software necessary for testing the sharpness, strength and elasticity of both straight and curved surgical / hypodermic needles. The AE-3 is designed for ease of operation with eye-level monitors and finger-tip keyboards and mouse controls. Everything needed to perform needle testing is within easy reach.

When a sharpness (penetration) test is performed, the software calculates the maximum force for that test and writes the value into an Excel spreadsheet. The raw values (load vs. angle) for the complete test are also stored in the spreadsheet for each successful test. This gives the operator the ability to recreate a load vs. angle plot for any needle tested. The data that the software puts into the spreadsheet is organized by needle number and test number (for repeated penetrations with the same needle).

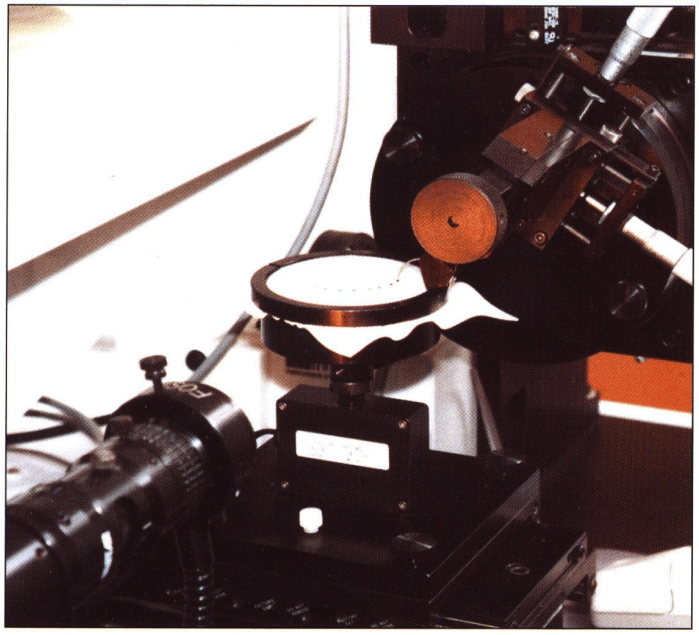
When all tests are complete for a given batch of needles, the software automatically performs some statistical analysis on the tests and saves that information on the spreadsheet **(Fig. 2)**.

When a strength (bend moment) test is performed, the software constantly calculates the slope of the load vs. angle and uses this information to determine the yield point of the needle being tested. The software then calculates the yield load, yield moment, ultimate load, ultimate moment and the stiffness and writes these values into a spreadsheet **(Fig. 4)**.

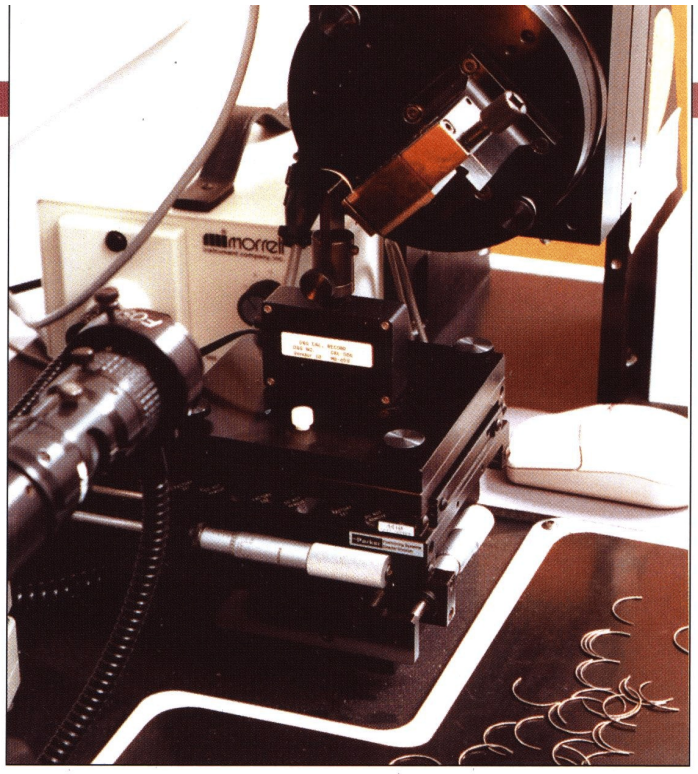
The raw values (load vs. angle) for the strength tests are also stored in the spreadsheet.

Model AE-3 Surgical / Hypodermic Needle Test System

- ***DESCRIPTION:*** Entire unit mounted in mobile work station that meets clean-room requirements. Tester assists quality control in testing needle characteristics.
- ***SHARPNESS (PENETRATION):*** Test provides information on how needle geometry, needle point geometry, needle polishing and needle coating affects performance. Tests also determine how characteristics change needle performance during repeated penetration passes.
- ***STRENGTH (BEND MOMENT):*** Test provides information as to how different materials affect needle performance. It also calculates how needle geometry will change needle performance.
- ***OPERATION:*** Precision rotary and linear stages with software integrated motion control provides synchronization of needle movement and data collection.
- ***LOAD CELLS:*** Two quick change load cells provided -- a 2 lb. load cell to test for sharpness, a 20 lb. load cell for strength testing.
- ***CAMERA:*** A 1/2" CCD provides a live magnified image. A circle and line generator also displays an overlay on this image for precise needle alignment.
- ***CAPABILITIES:*** The Model AE-3 standard test system is designed to test (curved) surgical needles with a wire diameter ranging from 0.006" (0.15mm) to 0.060" (1.5mm) and (straight) hypodermic needles with tube diameters ranging from 0.012" (0.3mm) to 0.078" (2.0mm).



Precision tooling allows testing for sharpness.



Tooling is in place to test for strength.

SHARPNESS TESTING (Penetration)

A good measure of needle sharpness and other characteristics, such as coating, polishing and point geometry, is the force required to penetrate the needle into a consistent membrane (**Fig. 5**). With the Model AE-3, this is accomplished by rotating the needle into a consistent membrane, which is mounted on a load cell and collecting force data from the load cell during the penetration test. The data from the test ensures that the needle has ample sharpness so it will perform as required (**Fig. 1**).

The problem with the testing of curved needles is the addition of side loading during a penetration test, which will add error to the force profile being evaluated. The Model AE-3 has precision alignment features to allow accurate positioning of the needle to minimize the side loading. This allows the needle to rotate into and penetrate the membrane exactly perpendicular to the membrane surface. When an operator sets up a penetration test (for curved needles) he/she uses a radius generated on the monitor for alignment of the needle. This ensures that the needle radius center is aligned with the center of mechanical rotation, which is necessary in order to provide accurate and consistent test results.

STRENGTH TESTING (Bend Moment)

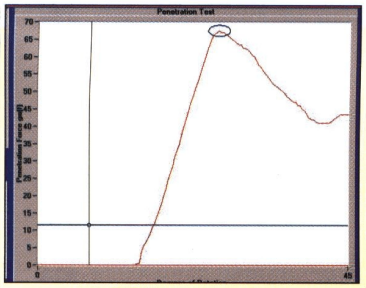
A good measure of needle strength is the force required to bend the needle around a consistent radius (**Fig. 6**).

With the Model AE-3 this is accomplished by placing the needle into a holding fixture with a carbide insert that has a .025 radius. The needle is then rotated onto a knife blade, which is mounted on a load cell, and data is collected from the load cell during the bending test (**Fig. 3**).

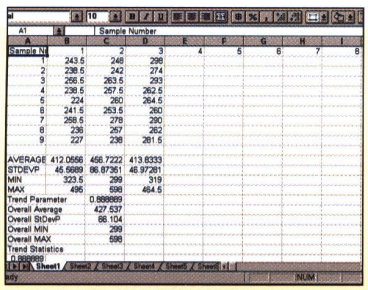
The distance from the carbide insert to the knife blade is known as the moment arm. The operator is able to measure this moment arm by using the digital micrometer slide that the camera is mounted on and then enter this value into the software. This ensures that the calculations performed by the software are accurate.

The holding fixture that the needle is placed into also has the center of the carbide insert .025 radius permanently fixed to the center of mechanical rotation. This eliminates any possible side loading from occurring during a test, which is necessary in order to provide accurate and consistent test results.

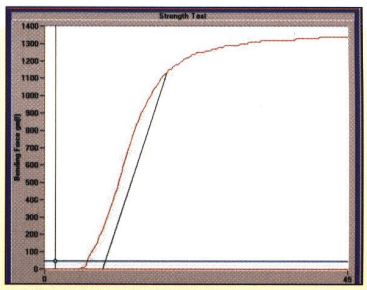
The test results will ensure that the needle has ample strength so that it will perform as required.



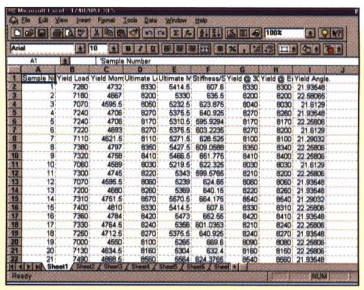
(Fig. 1) Sharpness Graph



(Fig. 2) Sharpness Spreadsheet



(Fig. 3) Bend Moment Graph



(Fig. 4) Bend Moment Spreadsheet

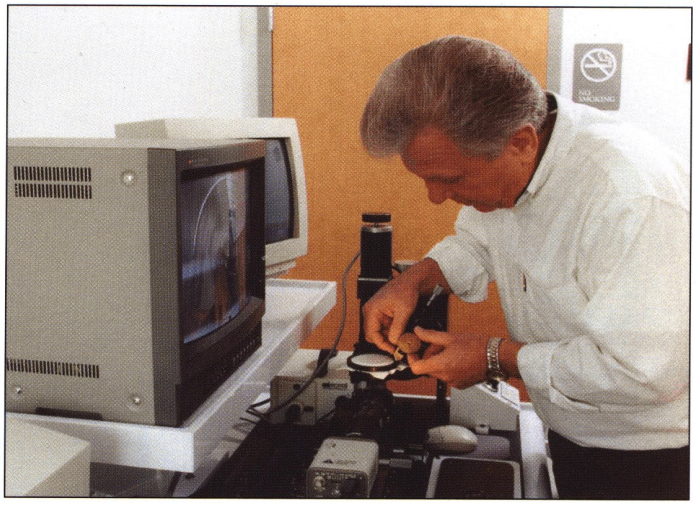
The Testing Process

The operator begins the test by placing the needle into a holding fixture (**Fig. 7**). For sharpness (penetration) testing, the precision alignment for curved needles is achieved by using the circles generated on the monitor by the graphical overlay. For strength (bend moment) testing, the alignment is fixed by the tooling with no adjustments required. However, the bending moment arm must be measured using digital micrometer stage that the camera is mounted on with that value entered into the software. This only needs to be done once for each batch of needles tested.

The Model AE-3 displays live video on one monitor so that the operator can view the needle as the test is performed, while simultaneously displaying a real-time graph on the second monitor so that the operator can view the load vs. angle plot as the test is under way (**Fig. 8**). Each test is displayed in a different color on the real-time graph so the operator can easily identify which test is for which needle. This gives the operator an immediate comparison of one test to another.

With quick-change tooling supplied, the operator can change over from one type of test to another in less than five minutes.

(Fig. 8) With side-by-side monitors, the operator is able to view the needles, left monitor, while comparing the test results on the monitor at right.

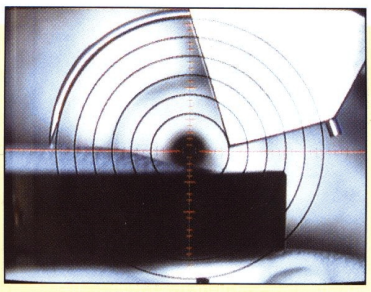


(Fig. 7) The operator, begins operation of the equipment by placing a needle into the tooling.

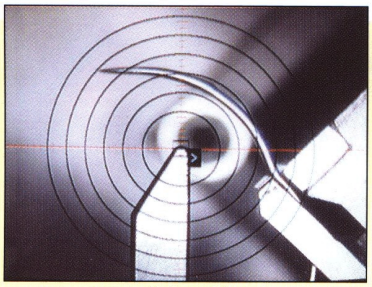
(Fig. 8)

(Fig. 7)

The AE-3 allows for elasticity testing, a test that determines the bending limits of a needle before losing its original shape.



(Fig. 5)



(Fig. 6)

CURVED NEEDLE ACCURACY

The Model AE-3 is designed for ease of use, maximum accuracy and consistency. Precision needle alignment is critical in order to achieve accurate and consistent results. The Model AE-3 has many features that allow the operator to easily and precisely align each needle to be tested.

Using a magnified live image and a graphical overlay, the operator can quickly and precisely place a needle into the tooling. The camera and all tooling are mounted on a common plate to ensure that the alignment of the camera and rotary stage do not change. This is also very critical to achieve the proper results.

Hypodermic Needle Testing

The Model AE-3 is capable of performing strength (bend moment) and sharpness (penetration) tests on straight hypodermic needles. The strength test is performed by bending the needle around a consistent radius. The results from this test provide valuable information about how needle geometry affects the characteristics of the needle being tested along with important material characteristics.

Needle sharpness (penetration) tests will help ensure that the needle will perform as required in the field. The results from these tests will aid in designing a needle that produces the least amount of pain and discomfort to a patient during actual use. The real-time graph will show the operator the force profile for the penetration test. With this information, he/she can also evaluate the performance of the needle facette and eye.

The Software

The Model AE-3 has custom software that controls the motion of all powered stages while also collecting data from the load cell during needle testing. The software is user-friendly, with little training required to perform accurate and repeatable tests. The software is designed to perform strength (bend moment), sharpness (penetration) and elasticity testing.

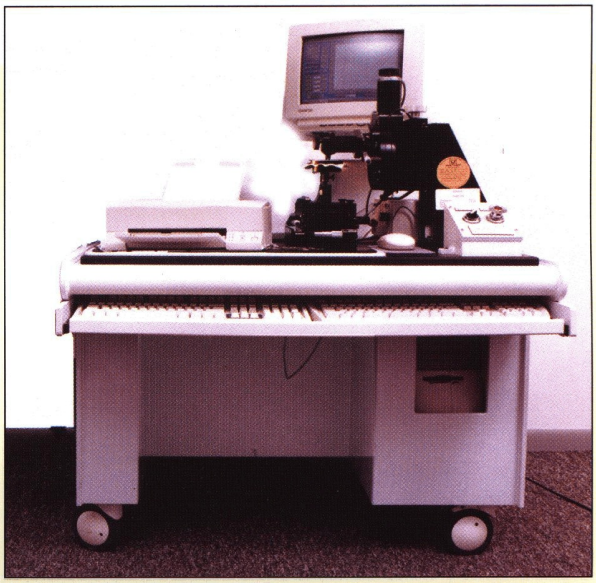
Upon initializing the software, the operator is required to go through a simple gauge calibration. When prompted, the operator simply places a 100g weight on the load cell. This enables the software to check communications with the gauge and to make sure the gauge is working properly.

Now the operator simply clicks the mouse to choose the type test desired. The operator is then prompted for test parameters (speed, degree distance, etc.). Once all the test information is entered, the operator simply clicks the mouse to begin the test.

At the end of each test, the operator can disregard the last test performed. A dialog asks if the test results should be accepted. This is useful in the event the operator has mixed, incorrect or a non-conforming needle in the batch tested, or if a quick comparison of a particular needle was requested, but not to be included in the statistical analysis of the batch.

All of the raw numbers (load vs. angle) are also stored in the spreadsheet or chart recorder for each successful test.

The Model AE-3S is needle test system designed for testing sharpness and strength for straight hypodermic and surgical needles only. This is a lower cost system with a powered linear vertical that interfaces with the load cell and custom software. This model does not have a powered rotary stage for testing curved surgical / medical needles.



Model AE-3 Highlights

NEEDLE TESTING for sharpness, strength and elasticity
CHART GENERATION software and printing
PRECISE MOTOR CONTROL for synchronization of needle movement and data collection
INTERCHANGEABLE quick change tooling for testing
FORCE INSTRUMENTATION, including two load cells
VIDEO LINE GENERATOR for needle alignment
MONITOR is a fine pitch 14" unit suitable for viewing needle alignment
COMPLETE COMPUTER HARDWARE and custom software, including pentium processor and graphics printer
COMPONENTS mounted on mobile work station
INSTALLATION and training at customer site available

Curved Needle Capabilities

WIDE DIAMETER FROM 0.006 (.15mm) to 0.060 (1.5mm)

Straight Needle Capabilities

TUBE DIAMETER FROM 0.012 (0.3mm) to 0.078 (2.0mm)

About Acculine

Acculine Engineering has a long history of building medical components and instrument test equipment. Organized in 1982, Acculine has assembled a staff of talented engineers and production workers committed to excellence and customer satisfaction. Acculine gives each order undivided attention to ensure that every product performs as intended.

Today Acculine designs and builds vacuum/pressure decay leak test systems, high-voltage dielectric testers and has CNC machinery for short and long run part fabrication.

Acculine's modern 10,000 square foot building is designed for maximum efficiency.

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