

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).

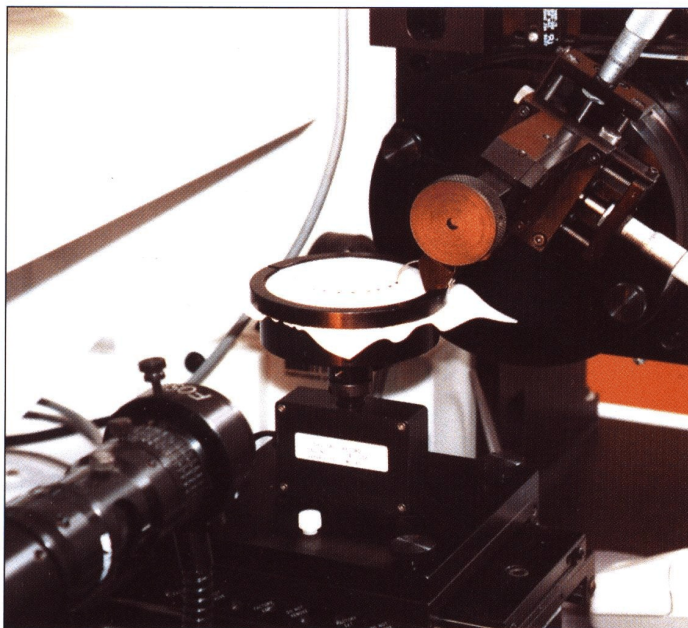
When all tests are complete for a given batch of needles, the software automatically performs some statistical analysis on the tests and saves that information on the spreadsheet (**Fig. 2**).

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).

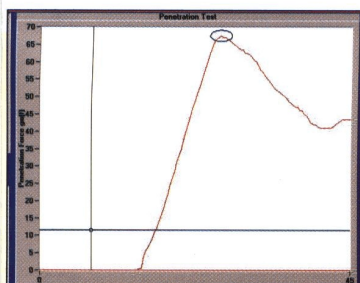


Precision tooling allows testing for sharpness.

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.



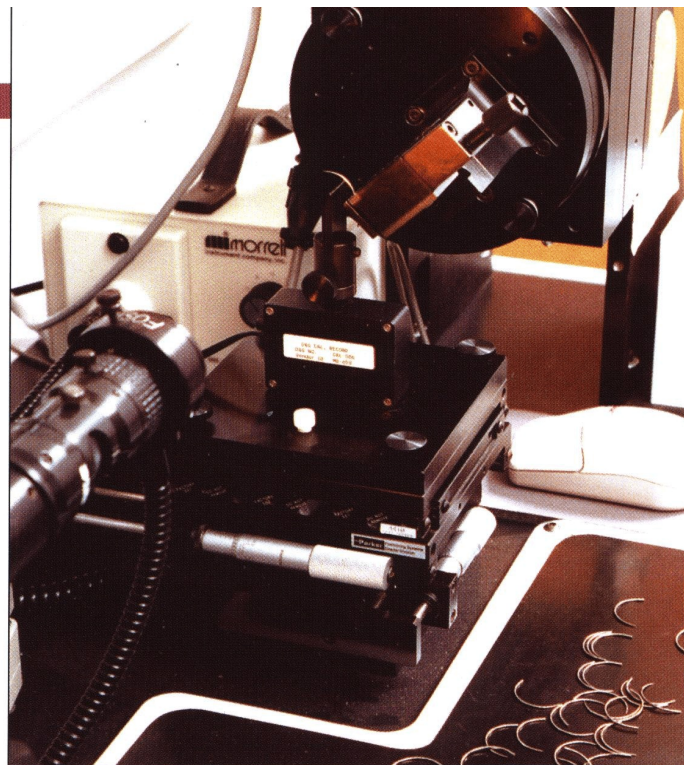
The screenshot shows an Excel spreadsheet with a data table and summary statistics. The data table has columns labeled 'Sample Number' (A1) and 'Sample No.' (B1). The data rows are numbered 1 through 9 in column A. The summary statistics are listed in column A, rows 10 through 16. The data table is as follows:

Sample No.	1	2	3
1	243.5	240	290
2	238.5	242	274
3	256.5	263.5	293
4	236.5	257.5	262.5
5	224	230	284.5
6	241.5	253.5	260
7	268.5	270	290
8	238	257	282
9	227	238	281.5

The summary statistics are as follows:

AVERAGE	412.0588	456.7222	413.8333
STDEVp	45.9089	66.8771	49.7901
MIN	224	230	270
MAX	490	590	684.5
Total Parameter	0.00000		
Overall Average	427.537		
Overall StDev	68.104		
Overall Min	290		
Overall MAX	680		
Total Statistics	0.00000		

The status bar at the bottom shows 'SUMMARY' and 'Sample1: Sample2: Sample3: Sample4: Sample5: Sample6: Sample7: Sample8: Sample9: Sample10: Sample11: Sample12: Sample13: Sample14: Sample15: Sample16: Sample17: Sample18: Sample19: Sample20: Sample21: Sample22: Sample23: Sample24: Sample25: Sample26: Sample27: Sample28: Sample29: Sample30: Sample31: Sample32: Sample33: Sample34: Sample35: Sample36: Sample37: Sample38: Sample39: Sample40: Sample41: Sample42: Sample43: Sample44: Sample45: Sample46: Sample47: Sample48: Sample49: Sample50: Sample51: Sample52: Sample53: Sample54: Sample55: Sample56: Sample57: Sample58: Sample59: Sample60: Sample61: Sample62: Sample63: Sample64: Sample65: Sample66: Sample67: Sample68: Sample69: Sample70: Sample71: Sample72: Sample73: Sample74: Sample75: Sample76: Sample77: Sample78: Sample79: Sample80: Sample81: Sample82: Sample83: Sample84: Sample85: Sample86: Sample87: Sample88: Sample89: Sample90: Sample91: Sample92: Sample93: Sample94: Sample95: Sample96: Sample97: Sample98: Sample99: Sample100: Sample101: Sample102: Sample103: Sample104: Sample105: Sample106: Sample107: Sample108: Sample109: Sample110: Sample111: Sample112: Sample113: Sample114: Sample115: Sample116: Sample117: Sample118: Sample119: Sample120: Sample121: Sample122: Sample123: Sample124: Sample125: Sample126: Sample127: Sample128: Sample129: Sample130: Sample131: Sample132: Sample133: Sample134: Sample135: Sample136: Sample137: Sample138: Sample139: Sample140: Sample141: Sample142: Sample143: Sample144: Sample145: Sample146: Sample147: Sample148: Sample149: Sample150: Sample151: Sample152: Sample153: Sample154: Sample155: Sample156: Sample157: Sample158: Sample159: Sample160: Sample161: Sample162: Sample163: Sample164: Sample165: Sample166: Sample167: Sample168: Sample169: Sample170: Sample171: Sample172: Sample173: Sample174: Sample175: Sample176: Sample177: Sample178: Sample179: Sample180: Sample181: Sample182: Sample183: Sample184: Sample185: Sample186: Sample187: 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Tooling is in place to test for strength.

STRENGTH TESTING (Bend Moment)

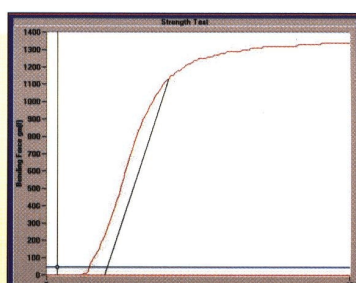
A good measure of needle strength is the force required to bend the needle around a consistent radius (**Fig. 6**).

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.



	A1	B1	C1	D1	E1	F1	G1	H1	I1	J1	K1	L1	M1	N1	O1	P1	Q1	R1	S1	T1	U1	V1	W1	X1	Y1	Z1	AA1	AB1	AC1	AD1	AE1	AF1	AG1	AH1	AI1	AJ1	AK1	AL1	AM1	AN1	AO1	AP1	AQ1	AR1	AS1	AT1	AU1	AV1	AW1	AX1	AY1	AZ1	BA1	BB1	BC1	BD1	BE1	BF1	BG1	BH1	BI1	BJ1	BK1	BL1	BM1	BN1	BO1	BP1	BQ1	BR1	BS1	BT1	BU1	BV1	BW1	BX1	BY1	BZ1	CA1	CB1	CC1	CD1	CE1	CF1	CG1	CH1	CI1	CJ1	CK1	CL1	CM1	CN1	CO1	CP1	CQ1	CR1	CS1	CT1	CU1	CV1	CW1	CX1	CY1	CZ1	DA1	DB1	DC1	DD1	DE1	DF1	DG1	DH1	DI1	DJ1	DK1	DL1	DM1	DN1	DO1	DP1	DQ1	DR1	DS1	DT1	DU1	DV1	DW1	DX1	DY1	DZ1	EA1	EB1	EC1	ED1	EE1	EF1	EG1	EH1	EI1	EJ1	EK1	EL1	EM1	EN1	EO1	EP1	EQ1	ER1	ES1	ET1	EU1	EV1	EW1	EX1	EY1	EZ1	FA1	FB1	FC1	FD1	FE1	FF1	FG1	FH1	FI1	FJ1	FK1	FL1	FM1	FN1	FO1	FP1	FQ1	FR1	FS1	FT1	FU1	FV1	FW1	FX1	FY1	FZ1	GA1	GB1	GC1	GD1	GE1	GF1	GG1	GH1	GI1	GJ1	GK1	GL1	GM1	GN1	GO1	GP1	GQ1	GR1	GS1	GT1	GU1	GV1	GW1	GX1	GY1	GZ1	HA1	HB1	HC1	HD1	HE1	HF1	HG1	HH1	HI1	HJ1	HK1	HL1	HM1	HN1	HO1	HP1	HQ1	HR1	HS1	HT1	HU1	HV1	HW1	HX1	HY1	HZ1	IA1	IB1	IC1	ID1	IE1	IF1	IG1	IH1	II1	IJ1	IK1	IL1	IM1	IN1	IO1	IP1	IQ1	IR1	IS1	IT1	IU1	IV1	IW1	IX1	IY1	IZ1	JA1	JB1	JC1	JD1	JE1	JF1	JG1	JH1	JI1	IJ1	JK1	KL1	JM1	JN1	JO1	JP1	JQ1	JR1	JS1	JT1	JU1	JV1	JW1	JX1	JY1	JZ1	KA1	KB1	KC1	KD1	KE1	KF1	KG1	KH1	KI1	KJ1	KK1	KL1	KM1	KN1	KO1	KP1	KQ1	KR1	KS1	KT1	KU1	KV1	KW1	KX1	KY1	KZ1	LA1	LB1	LC1	LD1	LE1	LF1	LG1	LH1	LI1	LJ1	LK1	LL1	LM1	LN1	LO1	LP1	LQ1	LR1	LS1	LT1	LU1	LV1	LW1	LX1	LY1	LZ1	MA1	MB1	MC1	MD1	ME1	MF1	MG1	MH1	MI1	MJ1	MK1	ML1	MM1	MN1	MO1	MP1	MQ1	MR1	MS1	MT1	MU1	MV1	MW1	MX1	MY1	MZ1	NA1	NB1	NC1	ND1	NE1	NF1	NG1	NH1	NI1	NJ1	NK1	NL1	NM1	NO1	NP1	NQ1	NR1	NS1	NT1	NU1	NV1	NW1	NX1	NY1	NZ1	OA1	OB1	OC1	OD1	OE1	OF1	OG1	OH1	OI1	OJ1	OK1	OL1	OM1	ON1	OO1	OP1	OQ1	OR1	OS1	OT1	OU1	OV1	OW1	OX1	OY1	OZ1	PA1	PB1	PC1	PD1	PE1	PF1	PG1	PH1	PI1	PJ1	PK1	PL1	PM1	PN1	PO1	PP1	PQ1	PR1	PS1	PT1	PU1	PV1	PW1	PX1	PY1	PZ1	QA1	QB1	QC1	QD1	QE1	QF1	QG1	QH1	QI1	QJ1	QK1	QL1	QM1	QN1	QO1	QP1	QR1	QS1	QT1	QU1	QV1	QW1	QX1	QY1	QZ1	RA1	RB1	RC1	RD1	RE1	RF1	RG1	RH1	RI1	RJ1	RK1	RL1	RM1	RN1	RO1	RP1	RQ1	RR1	RS1	RT1	RU1	RV1	RW1	RX1	RY1	RZ1	SA1	SB1	SC1	SD1	SE1	SF1	SG1	SH1	SI1	SJ1	SK1	SL1	SM1	SN1	SO1	SP1	SQ1	SR1	SS1	ST1	SU1	SV1	SW1	SX1	SY1	SZ1	TA1	TB1	TC1	TD1	TE1	TF1	TG1	TH1	TI1	TJ1	TK1	TL1	TM1	TN1	TO1	TP1	TQ1	TR1	TS1	TT1	TU1	th="" tv1=""																																																																																																									

The Testing Process

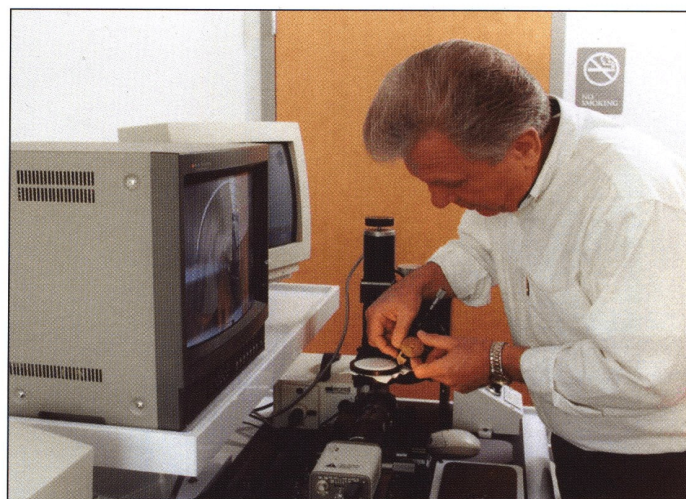
The operator begins the test by placing the needle into a holding fixture (**Fig. 7**). For sharpness (penetration) testing, the precision alignment for curved needles is achieved by using the circles generated on the monitor by the graphical overlay. For strength (bend moment) testing, the alignment 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.

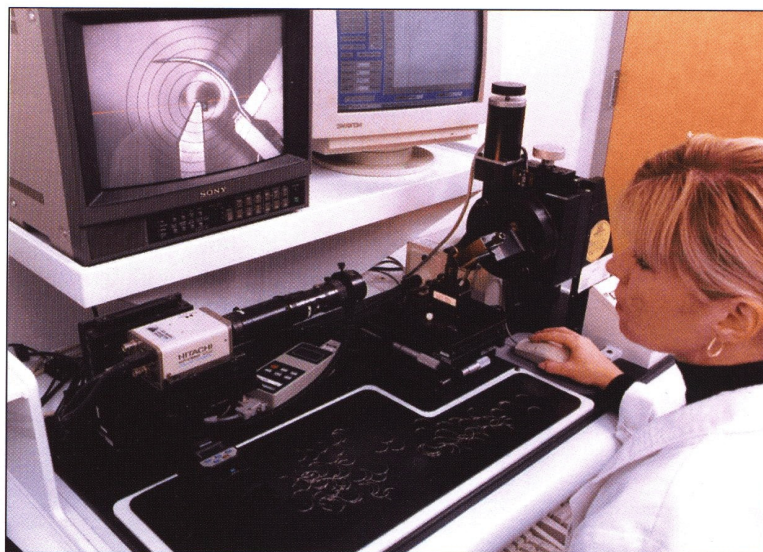
With quick-change tooling supplied, the operator can change over from one type of test to another in less than five minutes.

(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.

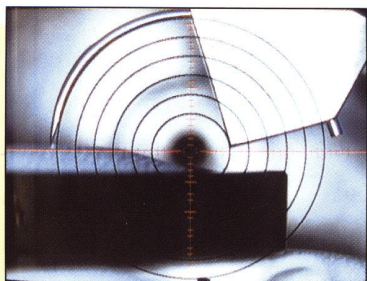


(Fig. 8)

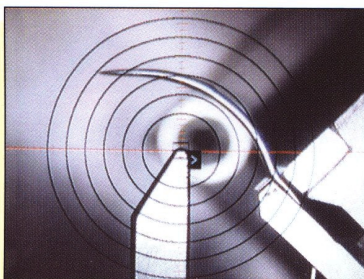


(Fig. 7)

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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