CAVRO SCIENTIFIC INSTRUMENTS, INC. • 242 HUMBOLDT COURT, SUNNYVALE, CA 94089
TELEPHONE (408) 745-7400 • (800) 231-0711 • FAX (408) 745-0309

CAVRO.

K970616 APR 21 1997

510(k) SUMMARY

510(k) SUBMITTER INFORMATION

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SUMMARY PREPARED:	FEBRUARY 7, 1997

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510(k) SUMMARY

DEVICE IDENTIFICATION

TRADE NAME:	MINI SAMPLE PROCESSOR
MODEL NUMBER:	MSP 9500
COMMON NAME:	ROBOTIC SAMPLE PROCESSOR
CLASSIFICATION NAME:	PIPETTING AND DILUTING SYSTEM FOR CLINICAL USE
510(k) NUMBER:	

SUBSTANTIALLY EQUIVALENT DEVICE

TRADE NAME:	MINI SAMPLE PROCESSOR
MODEL:	MSP 9000
MANUFACTURER:	CAVRO SCIENTIFIC INSTRUMENTS INC.

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510(k) SUMMARY

DEVICE DESCRIPTION

The MSP 9500 Mini Sample Processor is a microprocessor controlled pipetting and diluting system. It is designed to be used for automating sample preparation or assay methods.

It is capable of aspirating, dispensing or diluting to any position on the instrument work area. An XYZ robotic positioner moves the pipetting and dispensing tip to the desired XY position then lowers it in the Z direction into the sample. A fluid pump is then used to either aspirate or dispense the desired quantity of sample or reagent.

The unit is modular, allowing customization for specific applications. It consists of an enclosure, one or two XYZ robotic modules, power supply, central controller unit, connector for interfacing with an external computer, one or more fluid pumps and may be configured with a variety of optional pumps, valves and accessories. Modular racks will accommodate many types of commonly used tubes and microwell plates. It may be private labeled to meet individual needs.

INTENDED USE OF THE DEVICE

It is intended to be used for automating sample preparation or assay methods and is capable of aspirating, dispensing or diluting fluids to any position on the instruments work area.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE.

The technology used in the MSP9500 and the MSP 9000 is the same. The racks which hold the samples and prepared samples are fixed in position on a work table. An XYZ robotic positioner moves the pipetting and dispensing tip to the desired XY position then lowers it in the Z direction into the sample. Both offer liquid detection, to allow the tip to lower the desired distance into the liquid. The fluid movement is accomplished through the use of digital controlled pumps.

Both units use robotic, XYZ, positioners and liquid detectors which were designed by Tecan AG and both use fluid pumps designed and manufactured by Cavro.

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PERFORMANCE DATA

The following data is presented to show that the device safety and effectiveness is sufficient to satisfy the needs of the intended use.

Since this device is a Sample Processor, intended to be used to automate sample preparation, there are two major performance characteristics that must be evaluated, the positioning of the sample tip and the liquid handling.

The positioning of the sample tip is evaluated by reviewing the XYZ positioning characteristics. The requirement is that the tip must be moved to the correct position on the worktable to ensure that it is over the intended test tube, micro titer plate well etc. and that it moves the correct distance in the Z direction. The summary table for Mechanical Positioning lists the specifications and test results for each of those characteristics and shows that the test results are within specification.

The liquid handling is evaluated by confirming that the volume of fluid moved is correct. The summary tables for liquid handling list the specifications and test results for each of those characteristics and show that the test results are within specification. Additional testing has been done on the unit which includes 1) linearity testing for the smallest, midsize and largest syringe, 2) imprecision testing for the same syringe sizes including both within run and between run, and 3) inaccuracy testing for all syringe sizes at full stroke. No wash carryover studies were conducted because the results are dependent upon the fluids being used. Each laboratory should verify and adjust the wash routines for their particular application.

The summary tables are on the following page.

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MECHANICAL POSITIONING

CHARACTERISTIC	SPECIFICATION	TEST RESULTS
X-AXIS TRAVEL RANGE, I ARM (MIN.)	643 mm (25.31 in)	650 mm (25.6 in)
ACCURACY	±0.20 mm (0.008 in)	±0.18 mm (0.007 in)
REPRODUCIBILITY	±0.10 mm (0.004 in)	±0.05 mm (0.002 in)
X-AXIS TRAVEL RANGE, 2 ARM (MIN.)	563 mm (22.17 in)	574 mm (22.60 in)
ACCURACY	±0.20 mm (0.008 in)	±0.18 mm (0.007 in)
REPRODUCIBILITY	±0.10 mm (0.004 in)	±0.05 mm (0.002 in)
Y-AXIS TRAVEL RANGE (MINIMUM)	300 mm (11.81 in)	303 mm (11.9 in)
ACCURACY	±0.20 mm (0.008 in)	±0.10 mm (0.004 in)
REPRODUCIBILITY	±0.10 mm (0.004 in)	±0.07 mm (0.003 in)
Z-AXIS TRAVEL RANGE (MINIMUM)	165 mm (6.50 in)	167 mm (6.6 in)
ACCURACY	±0.40 mm (0.016 in)	±0.11 mm (0.004 in)
REPRODUCIBILITY	±0.10 mm (0.004 in)	±0.06 mm (0.002 in)

LIQUID HANDLING (STANDARD UNIT, USING MODEL XL3000 PUMP)

WITHIN RUN INACCURACY AND IMPRECISION

DISPENSE VOLUME	INACCURACY SPECIFICATION	INACCURACY TEST RESULTS	IMPRECISION (CV) SPECIFICATION	IMPRECISION (CV) TEST RESULTS
250 uL Syringe				
250 uL Dispense	≤ 1.0%	0.18%	≤ 0.05%	0.05%
125 uL Dispense	≤ 1.0%	0.15%	≤ 0.25%	0.13%
2 uL Dispense	≤ 5.0%	3.69%	≤ 2.5%	2.05%
1.0 mL Syringe				
1.0 mL Dispense	≤ 1.0%	0.16%	≤ 0.05%	0.01%
500 uL Dispense	≤ 1.0%	0.50%	≤ 0.25%	0.05%
10 uL Dispense	≤ 1.0%	0.74%	≤ 1.0%	0.73%
25 mL Syringe				
25.0 mL Dispense	≤ 1.0%	0.06%	≤ 0.05%	0.04%
12.5 mL Dispense	≤ 1.0%	0.22%	≤ 0.05%	0.04%
250 uL Dispense	≤ 1.0%	0.45%	≤ 0.25%	0.23%

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RUN TO RUN IMPRECISION (at mid stroke)

Syringe Size	250uL Syringe	1mL Syringe	25mL Syringe
Coef. of Variation (%)	0.489%	0.619%	0.195%

INACCURACY (at full stroke)

Syringe Size	% Inaccuracy at Full Stroke
250uL	0.18%
500uL	0.41%
1.0mL	0.16%
2.5mL	0.23%
5.0mL	0.18%
10.0mL	0.10%
25.0mL	0.06%