

TEST REPORT

Device: Piko-1
Client: Pulmonary Data Services
Testing date: 3/4/2003
Present: LDS Hospital
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Angie Flint
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Dynamic Testing of Peak Flow using the 26 Flow Time Wave Forms

Dynamic testing is performed by injecting the standard flow time waveforms recommended by the American Thoracic Society (Crapo RO, Chair. Standardization of spirometry: 1994 Update. Official Statement of the American Thoracic Society. Am J Respir Crit Care Med 1995; 152:1107-1136) using a computer driven spirometry simulator. Monitoring standards were applied.

Accuracy for PEF

Standard: Acceptable performance is defined as average deviation from target no more than the larger of $\pm 12\%$ or ± 25 liters/minute (0.42 liters/second) for each waveform with no more than one error. The primary criterion is $\pm 10\%$, 2% is added to account for the inaccuracy of the simulator. Acceptable performance is less than three errors out of the total of 52 tests.

Method: Each of the 26 standard waveforms was delivered into each of two randomly selected Piko-1 devices five times. Average values for each waveform were used to score peak flow performance. Accuracy and precision were scored using instantaneous peak flow as calculated by piston displacement as our best estimate of target peak flow.

Results: See attached data sheets. For device B000034B, the average deviation from target was 0.479 L/min (0.181%). For device B000037B, the average deviation from target was -1.034 L/min (-0.279%). No errors were observed for either device.

Summary: The Piko-1 device meets ATS monitoring and diagnostic device recommendations for accuracy in the measurement of peak flow.

Intradvice Precision for PEF

Standard: *Acceptable performance is defined as less than 6% intradvice variability or ± 15 L/minute, whichever is greater. Note: These criteria are 1% and 5 L/minute larger than the primary criteria to accommodate the imprecision of the waveform generator. An error rate of 5% (6 errors) is allowed. An error occurs when both range and range% are outside the specified limits.*

Method: Ten production devices were tested. Each of four standard waveforms (1,4, 8 and 25) was injected into each device three times.

Results: See attached data sheet ("Intradvice Precision"). No errors were observed.

Summary: The Piko-1 device meets ATS monitoring device recommendations for intradvice precision.

Interdevice Precision for PEF

Standard: *Acceptable performance is defined as less than 11% interdevice variability or ± 25 L/minute, whichever is greater. This includes 1% or 5 L/minute for the imprecision of the waveform generator. An error occurs when both range and range% exceed the specified limits.*

Method: Same data as for PEF intradvice testing. For each waveform, all data from the ten devices are combined to calculate range and range%.

Results: See attached data sheets. No errors were observed.

Summary: The Piko-1 device meets ATS monitoring device recommendations for interdevice precision.

Accuracy for FEV1

Standard: *Acceptable performance individual waveforms is defined as average deviation from target no more than the larger of $\pm 5.5\%$ or $\pm 0.1L$ for each waveform with no more than one error. The primary criterion is $\pm 5\%$, 0.5% is added to account for the inaccuracy of the simulator. Acceptable performance for the device is less than three errors out of the total of 48 tests.*

Method: Each of the 24 standard volume-time waveforms was delivered into each of two randomly selected Piko-1 devices five times. Average values for each waveform were used to score performance.

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Results: See attached data sheet (“FEV1 Accuracy Testing”). For device B000036B, the average deviation from target was -0.028 liters (-1.333%). For device B000043B, the average deviation from target was 0.016 liters (0.603%). No errors were observed for either device.

Summary: The Piko-1 devices tested here met ATS monitoring device recommendations for intradevice precision.

Intradevice Precision for FEV1

Standard: Acceptable performance for individual waveforms is defined as less than 3.5% intradevice variability or less than 0.1 liter, whichever is greater. An error occurs when both range and range% are outside the specified limits. Acceptable performance for a device is 6 or fewer errors for the 120 trials.

Method: Ten production devices were tested. Each of four standard volume time waveforms (1, 3, 6, 11) was injected into each device three times.

Results: See attached data sheet. No errors were observed.

Summary: The Piko-1 device meets ATS monitoring device recommendations for intradevice precision in the measurement of FEV1.

Interdevice Precision for FEV1

Standard: Criterion: Less than 11% interdevice variability or ± 0.2 liters, whichever is greater. An error occurs when both range and range% exceed the specified limits. No errors are allowed.

Method: Same data as for FEV₁ intradevice testing. For each waveform, all data from the 10 devices are combined to calculate range and range percent.

Results: See attached data sheet. No errors were observed.

Summary: The Piko-1 device meets ATS monitoring device recommendations for interdevice precision in the measurement of FEV1.

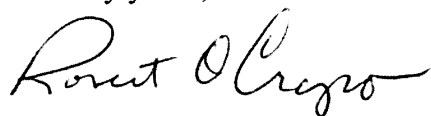
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OVERALL SUMMARY

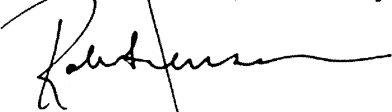
The Pulmonary Data Service Piko-1 device tested in the LDS Hospital Pulmonary Laboratory meets ATS monitoring device recommendations for accuracy and precision in the measurement of peak flow and FEV1.

Testing done at the LDS Hospital measures devices against recommendations published by the American Thoracic Society. It does not imply an endorsement or certification by the ATS.

Sincerely yours,



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Robert L. Jensen, Ph.D.
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