LDS HOSPITAL
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TEST REPORT

Device: Microlife Peak Flow Meter
Microlife Corporation

Testing date: 25 March 2002

Present: LDS Hospital
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Dynamic Testing of Peak Flow using the 26 Flow Time Wave Forms

Dynamic testing was performed by injecting the 26 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.

Each waveform was delivered into each of two randomly selected peak flow meters five times. For this testing, Microlife meters 0132 and 0134 came up on the random selection. 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.

Accuracy

Standard: *Acceptable performance is defined as average deviation from target of less than ±12% or ±25 liters/minute, whichever is larger, for each waveform. One error is allowed.*

Results: See attached data sheets ("Accuracy Validation"). For meter 0132, the average difference from target (measured minus target) was 3.135 liters/minute (1.269%). For meter 0134, the average difference from target was –0.468 liters/minute (0.56%). No errors were observed for either meter.

Summary: The Microlife Peak Flow meter met ATS recommendations for accuracy in measuring the 26 standard flow-time waveforms.

Intradevice Precision

Standard: *Acceptable performance is defined as less than 6% intradevice variability or ±15 L/minute, whichever is greater. Note: These criteria are 1% and 5 L/minute larger than the published criteria to accommodate the imprecision of the waveform generator. An error rate of 5% is allowed.*

Method: 10 production flow meters were tested. Each of four standard waveforms (1,4, 8 and 25) was injected into each meter three times.

Results: See attached data sheet ("Intradevice Precision"). The range of measurements for all wave forms on all 10 meters was well within the recommended standard.

Summary: The Microlife Peak Flow Meter met ATS recommendations for intradevice precision.

Interdevice Precision

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 is defined as range and range% both exceeding specified limits.*

Method: 10 production peak flow meters were tested. Each of four standard waveforms (1, 4, 8 and 25) was injected into each meter three times. Interdevice variability was assessed by calculating an average peak flow for each waveform for each meter. The average values for each meter were then used to determine the range and range%.

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

Summary: The Microlife Peak Flow Meter met ATS recommendations for interdevice precision.

OVERALL SUMMARY

The Microlife Peak FlowMeter met ATS recommendations for accuracy and precision in measuring peak flow.

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.

We appreciate the opportunity of testing the Microlife Peak Flow Meter. If you have questions, please do not hesitate to ask.

Sincerely yours,

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