



LDS HOSPITAL

A Service of Intermountain Health Care

Eighth Avenue and C Street
Salt Lake City, Utah 84143
(801) 321-1100

TEST REPORT

Device: Micro Medical PulmoLife
Testing dates: November 16, 2005
Present: LDS Hospital
Heather Howell
Robert O. Crapo, M.D.
Robert L. Jensen, Ph.D.

Dynamic Waveform Testing

Dynamic testing was performed using standards published 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. The standards used were those for diagnostic devices. For forced vital capacity (FVC) and forced expired volume in one second (FEV₁), the 24 standard volume-time waveforms were used. For peak flow (PEF), the 26 standard flow-time waveforms were used. Each waveform was delivered into the device five times. Mean values were used to score performance. A 2% adjustment was made to correct measured values to ambient conditions.

The PulmoLife device only measures FEV₁. It is intended to be used as a screening device. There are no separate standards for a screening device so we used the ATS standards for a diagnostic device for this evaluation.

Dynamic waveform testing results

Forced expired volume in one second (FEV₁):

Standard: The acceptable performance criteria for accuracy are deviation from target $\pm 3\%$ or ± 0.05 liters, whichever is greater with no more than one error. The criteria were increased to $\pm 3.5\%$ or 0.100 liters to account for the estimated inaccuracy and imprecision of the waveform generator.

Precision testing: Only intra-device testing is required for diagnostic devices. The criteria for acceptable performance are that, for each waveform, the range of values must be less than 0.10 liters or range(%) less than 3.5% with no more than one error.

Results not corrected for BTPS conditions

Turbine #1

Results: See attached data sheet.

Test Report: Micro Medical PulmoLife
Test Date: 16 November 2005
Page 2

Accuracy: The average deviation from target was 0.027 liters (1.24%). No errors were observed.

Precision: The average range was 0.01 liters (0.55%). One error was observed (waveform 10).

Turbine #2

Results: See attached data sheet.

Accuracy: The average deviation from target was 0.039 liters (1.71%). No errors were observed.

Precision: The average range was 0.01 liters (0.34%). No errors were observed.

Testing with FEV₁ reported at BTPS conditions, waveforms delivered at ambient conditions

Turbine #1

Results: See attached data sheet.

Accuracy: The average deviation from target was 0.056 liters (2.26%). No errors were observed.

Precision: The average range was 0.01 liters (0.55%). One error was observed (waveform 10).

Turbine #2

Results: See attached data sheet.

Accuracy: The average deviation from target was 0.068 liters (2.74%). No errors were observed.

Precision: The average range was 0.01 liters (0.34%). No errors were observed.

Summary: The Micro Medical PulmoLife meets ATS recommendations for accuracy and precision in measuring FEV₁ for turbines #1 and #2.

Test Report: Micro Medical PulmoLife
Test Date: 16 November 2005
Page 3

Human Subject Testing

Standard: Measurements of FVC, FEV1 and peak flow from the test spirometer are compared to those from a standard spirometer in two human subjects. The largest of three trials on each spirometer is used for comparisons. For FVC and FEV1, the differences must be within 6% or 200 ml, whichever is larger. For peak flow, the differences must be less than 15% or 0.5 liters/second, whichever is larger. No errors are allowed.

Method: Two healthy subjects were tested on two devices: A standard horizontal rolling seal spirometer and on the PulmoLife spirometer. Each subject blew three times into each spirometer, alternating spirometers with each blow. One subject began blowing into the PulmoLife spirometer, the other into the "standard" rolling seal spirometer.

Results: See attached data sheets.

Turbine 1: The largest absolute difference in FEV1 was 0.15 liters and the largest percent difference was 4.39%. No errors were observed.

Turbine 2: The largest absolute difference in FEV1 was 0.14 liters and the largest percent difference was 4.17%. No errors were observed.

Summary: The Micro Medical PulmoLife meets ATS recommendations for accuracy and precision in measuring FEV₁ with turbines #1 and #2.

BTPS Testing

Standard: *The ATS recommendations require waveforms 1-4 of the 24 standard waveforms be injected with heated (temp 37 °C ± 1 °C), humidified air. Three trials are performed for each waveform. Average values for FVC and FEV1 are calculated for each waveform and compared to ATS target values. Acceptable accuracy is defined as ± 4.5% or 200 ml; no errors are allowed. Peak Flows are reported for your information only.*

Method: Heated humidified air (35.9°C; relative humidity 97.5%) was injected into the Micro Medical PulmoLife device using turbines 1 and 2. Three injections each of waveforms 1, 2, 3, and 4 were delivered into each turbine. Average measured values were compared to ATS target values.

Results: Turbine 1: The largest absolute difference in FEV₁ was 0.040 liters and the largest percent difference was 2.80%. No errors were observed.

Turbine 2: The largest absolute difference in FEV₁ was 0.046 liters and the largest percent difference was 3.28%. No errors were observed.

Summary: The Micro Medical PulmoLife meets ATS recommendations for accuracy in the measurement of FEV₁ under BTPS conditions.

Test Report: Micro Medical PulmoLife
Test Date: 16 November 2005
Page 4

OVERALL SUMMARY

Two turbines were used in the testing of the PulmoLife. Both turbines meet ATS diagnostic standards for accuracy and precision in measuring FEV₁ under ambient and BTPS conditions.

The testing done in the LDS Hospital laboratory uses criteria published by the American Thoracic Society. Meeting the criteria does not imply endorsement or acceptance by the ATS.

Sincerely yours,



Robert O. Crapo, M.D.
Medical Director, Pulmonary Laboratory



Robert L. Jensen, Ph.D.
Staff Biophysicist, Pulmonary Division

Telephone: 801-408-1610
FAX: 801-408-1671
E-mail: ldrcrapo@ihc.com
File: Micro Medical Micro PulmoLife.rpt.doc