LDS HOSPITAL
IHC A Service of Intermountain Health Care

Eighth Avenue and C Street
Salt Lake City, Utah 84143
(801) 408-1100

# TEST REPORT

Device: ndd Medical Technologies EasyOne Spirometer
Testing dates: 21 April 2000
Present: LDS Hospital
Nathan Shipp
Robert O. Crapo, M.D.
Robert L. Jensen, Ph.D.
ndd Medical Technologies
Oscar Kaelin

## Dpnamic Wave Form 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 ($FEV_1$), the 24 standard volume-time wave forms were used. For peak flow (PEF), the 26 standard flow-time forms were used. Each wave form was delivered into the device five times. Mean values were used to score performance.

The ndd Medical Technologies EasyOne Spirometer tested is a developmental model.

Forced Vital Capacity (FVC):

> Standard: *The acceptable performance criteria for accuracy are deviation from target ±3% or ± 0.050 liters, whichever is greater with no more than one error. The criteria were increased to ±3.5% or 0.100 liters to account for the estimated inaccuracy and imprecision of the wave form generator.*
>
> Precision testing: *Only intradevice 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: See the attached data sheets.

Accuracy: The average deviation from target, calculated as the value measured by the spirometer minus the ATS target value, is -0.036 liters (-0.91%). No errors were observed.

Precision: The average range was 0.05 liters (1.37%). One precision error was observed (waveform 23).

Summary: The EasyOne Spirometer meets ATS recommendations for accuracy and precision in measuring FVC.

Forced exuired volume in one second ($FEV_1$):

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

Precision testing: *Only intradevice 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 ore than one error*

Results: See attached data sheets.

Accuracy: The average deviation from target was -0.014 liters (-0.58%). No errors were observed.

Precision: The average range was 0.03 liters (0.99%). The maximum range observed was 1.34%. No precision errors were observed.

Summary: The EasyOne Spirometer meets ATS recommendations for accuracy and precision in measuring $FEV_1$.

Midflows ($FEF_{25-75\%}$ or MMEF)

Standard: *The criteria for accuracy are ±5.5% or 0.250 liters/sec of target value, with no more than one* ***error.***

Precision testing: *Only intradevice testing is required* ***for*** *diagnostic devices. The criteria for acceptable performance are that, for each waveform, the range of values must be less ±5.5% or 0.250 liters/sec with no more than one error.*

Results: See attached data sheets

Accuracy: The average deviation from target was +0.029 liters/sec (+0.53%). No errors were observed.

Precision: The average range was 0.06 liters/sec (2.45%). No errors were observed.

Summary: The EasyOne spirometer meets ATS recommendations for accuracy and precision in measuring $FEF_{25-75\%}$.

Peak Flow (PEF):

Standard: *The criteria for accuracy are ± 2.5 liters/minute (0.42 liters/second) or ±12% with no more than one error.*

Precision Testing: *The ATS standards do not specifically address intradevice precision testing for peak flow measured by diagnostic devices. We therefore chose the inter-device criteria applied to peak flow meters. Specifically, range must be within 25 liters/minute (0.42 liters/second) or range (%) must be within 11%, whichever is larger. One error is allowed.*

Results: See the attached data sheets. Only the 26 standard flow-time waveforms were scored. The data sheet with results for the 24 standard volume-time wave forms is included for your information only.

Accuracy: The PEF average deviation from target was +0.014 liters/sec (+0.86%). No errors were observed.

Precision: The average range was 0.07 liters/sec (0.93%). No precision errors were observed.

Summary: The EasyOne Spirometer meets ATS recommendations for accuracy and precision in measuring peak flow.

**Human Subject Testing**

Standard: *The test spirometer is compared to a "standard" spirometer in the measurement of FVC and FEV1 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. No errors are allowed.*

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

Results: See attached data sheets. For FVC and FEV1, all differences were well within the ATS criteria.

Summary: The EasyOne Spirometer meets ATS criteria for human testing for FVC, FEV1 and PEF.

**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 made and the average used for scoring. Only FVC and FEV1 are scored. Comparisons are made with the 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 (37.0°C; relative humidity 102%) was injected into the spirometer: 3 injections each of wave forms 1, 2, 3, and 4 were made. Average measured values were compared to ATS target values.

Results: See attached data sheet. The average deviation from target for FVC was +0.136 liters (+3.2%). For FEV1, the average deviation from target was +0.109 liters (+3.5%). No errors were observed in the measurement of FVC or FEV1.

Summary: The EasyOne Spirometer meets ATS recommendations for accuracy under BTPS conditions.

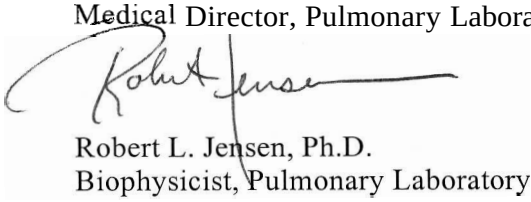
## OVERALL SUMMARY

The EasyOne Spirometer meets ATS recommendations for accuracy and precision in measuring FVC, $FEV_1$, $FEF_{25-75\%}$, and PEF.

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.
Biophysicist, Pulmonary Laboratory

Telephone: 801-408-1610
FAX: 801-408-1671
e-mail: Idrcrapo@ihc.com

F:\PULM\LDJEMBRY\ROC\ndd.rpt