Performance of the SDI Filtrette System with the ndd EasyOne Spirometer

Since the introduction of the Filtrette System ndd has been making claims that it does not perform according to ATS standards when tested with mechanical devices. Ultrasonic spirometers like the EasyOne have a well-documented problem with turbulent airflow such as produced by calibration syringes. The performance of the Filtrette when testing humans has never been questioned. Turbulence is not a problem with human testing.

In March of 2008 ndd sponsored a study at the Pulmonary Lab of LDS Hospital in Salt Lake City. The study used products supplied by ndd, not purchased on the open market, that were not of current design. Also, adapters were used to mate the Filtrette to the calibration syringe that were inappropriate to the measurement system because they failed to compensate for the turbulence. ndd widely disseminated these invalid results as "proof" that the SDI product should not be used.

In July of 2008 LDS tested current SDI Filtrettes and used proper protocols. These results are attached. The data proves, beyond any doubt, that the Filtrette will provide excellent results when used with the ndd Easyone Spirometer. It also proves that the ndd threat to void instrument warranties based on their invalid data, is totally without merit, and is nothing more than an attempt to exclude an innovative product from the marketplace by fear and coercion.

ndd has informed SDI that it "has no intention of continuing to make the statement" that the SDI Filtrette produces bad results with the EasyOne. While they did not address the bogus voiding of warranties, it is certainly implied that the basis for so doing is not valid. There is nothing in the SDI Filtrette that can harm the EasyOne or degrade its performance.

The SDI Filtrette is an excellent product that utilizes an high-efficiency filter to reduce the possibility of allowing viruses and bacteria from being spread throughout the test environment. On its website ndd actually endorses the use of the SDI Pulmoguard filter with the EasyOne. It is less expensive to use, and is packaged in a variety of configurations.

The Filtrette is being used successfully across the entire USA. Ask your dealer for samples. You'll agree that the Filtrette is a better way to test using the EasyOne.

If you are told by anyone that the Filtrette does not meet ATS standards, please call me directly at 508 238 7033 or e mail me at mjboyle@sdidiagnostics.com.

Michael J. Boyle, President

sdi DIAGNOSTICS
The Spirometry Source

10 Hampden Drive
Easton, MA 02375
800-678-5782
Fax 508-230-2752
www.sdidiagnostics.com

Test Report

ATS Standards
SDI Filtrette System
With ndd EasyOne Spirometer

EasyOne Diagnostic Spirometer Serial Number 62786/2007

SDI Diagnostics, Inc. Filtrette System, FloTube and AstraGuard Filter

Test Dates: July 14 and 15, 2008
Performed At: Pulmonary Lab, Dr. Robert Crapo, Medical Director, LDS Hospital, Salt Lake City, Utah
Performed By: Heather Gallo, Chief Pulmonary Technologist

Parameters measured were forced vital capacity (FVC), forced expired volume in one second (FEV_1), mean forced expiratory flow between 25% and 75% of FVC ($FEF_{25-75\%}$), and peak expiratory flow (PEF).

Dynamic 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), forced expired volume in one second (FEV_1), and $FEF_{25-75\%}$, the 24 standard volume-time waveforms were used. Peak flow (PEF) data from the 24 volume waveform program were also reported. PEF data for the 26 standard flow-time forms were previously reported by LDS and SDI Diagnostics. Each waveform was delivered into the spirometer five times. Mean values were used to score performance.

Dynamic waveform testing results

Forced Vital Capacity (FVC):

Standard: *The acceptable performance criteria for accuracy are deviation from target ± 3.5% of reading or ±0.100 L, whichever is greater (these include estimated inaccuracy and imprecision of the waveform generator), with no more than 1 error.*
Precision Test: *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: *See the attached data sheets*
Accuracy: *The average deviation for the target value, calculated as the value measured by the spirometer minus the ATS/ERS target value, is 0.008 liters (0.190 %) No errors were observed.*
Repeatability: *The average range was 0.062 liters (1.736%) No errors were observed.*
Summary: *The ndd EasyOne Diagnostic Spirometer using the SDI Diagnostics, Inc. Filtrette System (in place of ndd's Spirette) meets all ATS recommendations for accuracy and precision in the measurement of FVC.*

Forced Expired Volume in one Second (FEV1):

Standard: *The acceptable performance criteria for accuracy are deviation from target ± 3.5% of reading or ±0.100 L, whichever is greater (these include estimated inaccuracy and imprecision of the waveform generator), with no more than 1 error.*
Precision Test: *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: *See attached data sheets.*
Accuracy: *The average deviation from target was 0.02 liters (0.77%). No errors were observed.*
Repeatability: *The average range was 0.05 liters (2.09%). There were no errors observed.*
Summary: *The ndd EasyOne Diagnostic Spirometer using SDI Diagnostics, Inc. Filtrette System (in place of ndd's Spirette) meets the ATS recommendations for accuracy and precision in the measurement of FEV1.*

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.*
Repeatability Test: *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 ±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 0.08 liters/sec (3.22%). No errors were observed.*
Repeatability: *The average range was 0.13 liters/sec (4.99%). No errors were observed.*
Summary: *The ndd EasyOne Diagnostic Spirometer using the SDI Diagnostics, Inc. Filtrette System (in place of ndd's Spirette meets ATS recommendations for accuracy and precision in the measurement of FEF 25-75%.*

Peak Flow (PEF):

Standard: *There are no current ATS standards for performance in measurements of PEF with a diagnostic device. However, the criteria for accuracy of PEF with a peak flow meter are ±25 liters/min (0.42 liters/sec) or ± 12%.*
Repeatability Testing: *There are no ATS Standards criteria for intra-device testing of peak flow meters are ±6% or ±15 L/min, whichever is greater. The limits include allow for 1% waveform simulator variability. An error occurs if the span and percentage span exceed these limits. No more than a 5% error rate is acceptable.*

Testing by SDI using a Rudolph Waveform Simulator November 30, 2007

Accuracy: *The average range was 0.048 liters/sec (0.82%). No errors were observed.*
Precision: *The average range was 0.059 liters/sec (1.22%). No errors were observed.*

Testing done at the LDS Hospital Pulmonary Lab on March 21 and 25, 2008

Accuracy: *The average deviation from target was -0.502 liters/sec (-7.80%). One error was observed.*

Precision: *The average range was 0.09 liters/sec (1.47%). No errors were observed.*

Testing done at LDS Hospital Pulmonary lab using the PEF as part of the 24 volume protocol July 14 and 15, 2008

Accuracy: *The average deviation from target was -0.03 liters/sec (0.23%)*

Precision: *The average range was 0.15 liters/sec (2.70%)*

Summary: The ndd EasyOne Diagnostic Spirometer using the SDI Diagnostics, Inc. Filtrette System meets ATS recommendations for accuracy and precision for measuring peak flow using a peak flow meter.

A standard SDI syringe adapter was used to connect the waveform simulator to the AstraGuard filter.

In addition to the above test results, Heather Gallo, the LDS Hospital test administrator, had no difficulty with the SDI Filtrette System being aligned in the ndd easyOne Spirometer. Every insertion of the FloTube portion of the Filtrette System resulted in 100 % success.

Overall Summary

The ndd EasyOne spirometer using the SDI Diagnostics, Inc. Filtrette System (in place of ndd's Spirette) meets ATS recommendations for accuracy and repeatability in measuring FVC, FEV_1, $FEF_{25-75\%}$ and PEF under ambient 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.