

Publications and papers documenting the long term stability of ndd TrueFlow (EasyOne)

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FDA CERTIFICATION EasyOne

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MOUNT SINAI JOURNAL OF MEDICINE 75:109–114, 2008 109 STANDARDIZATION OF SPIROMETRY IN ASSESSMENT OF RESPONDERS FOLLOWING MAN-MADE DISASTERS: WORLD TRADE CENTER WORKER AND VOLUNTEER MEDICAL SCREENING PROGRAM

Paul Enright, MD,¹ Gwen Skloot, MD,² and Robin Herbert, MD,³ ¹The University of Arizona, Tucson, AZ, USA
²The Division of Pulmonary and Critical Care Medicine and
³Department of Community and Preventive Medicine, Mount Sinai School of Medicine, New York, NY, USA

Results: More than 12,000 spirometry tests were performed during the first examination. The 20 spirometers used at the 6 participating institutions maintained accuracy within 3% for more than 4 years. Overall, more than 80% of the test sessions met ATS quality goals. Spirometry abnormality rates exceeded those obtained for adults who participated in the NHANES III survey.

www.ndd.ch/UserData/Download_00186_00.pdf

THE BURDEN OF OBSTRUCTIVE LUNG DISEASE INITIATIVE (BOLD): RATIONALE AND DESIGN

A. Sonia Buists¹ (buists@ohsu.edu), William M. Vollmer² (william.vollmer@kpchr.org), Sean D. Sullivan^{3,9} (sdsull@u.washington.edu), Kevin B. Weiss^{4,5} (k-weiss@northwestern.edu), Todd A. Lee^{4,5} (toddlee@northwestern.edu), Ana M. B. Menezes⁶ (anamene@terra.com.br), Robert O. Crapo^{7,10} (ldrcrapo@ihc.com), Robert L. Jensen^{7,11} (ldrjens1@ihc.com), and Peter G. J. Burney⁹ (peter.burney@kcl.ac.uk).

To optimize quality control in the BOLD study, sites are required to use the ndd EasyOne™ Spirometer, which was chosen because it provides a high degree of accuracy, robustness, portability, and ease of storage. It can be used easily in the field and where there is no electric power available—it operates on batteries and requires no calibration with a 3-liter syringe. The ndd spirometer has been approved by the BOLD pulmonary function reading center as meeting predetermined performance criteria relating to reliability of measurement, suitability for field use, and ease of access to data.

www.ndd.ch/UserData/Download_00127_00.pdf

STABILITY OF THE EasyOne ULTRASONIC SPIROMETER FOR USE IN GENERAL PRACTICE

Julia AE Walters, Richard Wood-Baker, Justin Walls, David P Johns, Cardio-Respiratory Research Group, University of Tasmania, Hobart 7001

Conclusions: This study supports the manufacturer's claim that the EasyOne spirometer maintains its calibration during routine clinical use in general practice and does not require daily calibration as specified in international spirometry guidelines.

www.ndd.ch/UserData/Download_00173_00.pdf

THE LONG-TERM STABILITY OF PORTABLE SPIROMETERS USED IN A MULTINATIONAL STUDY OF THE PREVALENCE OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Rogelio Pérez-Padilla MD, Juan Carlos Vázquez-García MD, María Nelly Márquez MD, José Roberto B Jardin MD, Julio Pertuzé MD, Carmen Lisboa MD, Adriana Muiño MD, María Victorina López MD, Carlos Talamo MD, María Montes de Oca MD, Gonzalo Valdivia MD, Ana Maria B Menezes MD, and the Latin American COPD Prevalence Study (PLATINO) Team

Results: Ninety-seven percent of the calibration volumes were within ± 64 mL (2.1%) of the 3-L calibration signal. Excluding data from the first city studied (São Paulo), where one calibration syringe had to be replaced, 98% of the calibration checks were within ± 50 mL (1.7%). The measured volume was affected only minimally by the syringe's peak flow or emptying time.

Conclusion: In these 70 EasyOne spirometers neither calibration nor linearity changed during the study. Such calibration stability is a valuable feature in spirometry surveys and in the clinical setting.

www.ndd.ch/UserData/Download_00176_00.pdf

STABILITY OF THE EasyOne ULTRASONIC SPIROMETER FOR USE IN GENERAL PRACTICE

Julia A. E. Walters, Richard Wood-Baker, Justin Walls, David P. Johns, Cardio-Respiratory Research Group, School of Medicine, University of Tasmania, Hobart 7001

Conclusion: These results provide strong evidence that the EasyOne spirometer is accurate and maintains its accuracy during routine clinical use for at least 26 weeks. This has practical implications in general practice, as it implies that this spirometer does not require a daily calibration check as recommended by the ATS/ERS. Spirometer guidelines may need to be reviewed to reflect this. This finding does not negate the need to regularly check overall performance using a healthy subject.

www.ndd.ch/UserData/Download_00211_00.pdf

ACCEPTABILITY AND UTILITY OF SPIROMETRY MEASUREMENT IN THE PHARMACY ASTHMA CARE PROGRAM

D Burton¹, M Simpson¹, J Wettenhall¹, C Armour², S Bosnic-Anticevich², B Saini², I Krass², L Smith², M Brilliant², L Emmerton³, J Bond³, S Johnston⁴, K Stewart⁴

¹ School of Biomedical Sciences, Charles Sturt Univ, NSW 2650, ² Faculty of Pharmacy, Univ of Sydney, NSW 2006

³ School of Pharmacy, Univ of Queensland, Qld 4072

⁴ Victorian College of Pharmacy, Monash Univ, Vic 3052

Conclusion: Spirometry measurement is a reasonable and reliable test for community pharmacists to use as a basis for referral to the physician. This project was funded by the Australian Government Department of Health and Ageing as part of the Third Community Pharmacy Agreement.

www.ndd.ch/UserData/Download_00132_00.pdf



CERTIFICATE OF STABILITY



Life time stable

The above defined instrument is based on ndd patented technologies: TrueFlow, MolMass, UPG.

It has been produced with the most stringent quality assurance procedure including the final pre delivery quality check.
www.ndd.ch/AboutUs/patents_certificates.aspx

The quality is well within the ATS/ERS standards and 2005 guide lines.

The instrument is life time stable and needs no manual calibration nor calibration checks what so ever*. This is due to the applied exclusive ndd technologies based on ultrasound transit time measurement for flow and ultrasound based molar mass measurement for He and CO:

Flow: by ndd TrueFlow as is applied in over 40'000 instruments for almost 10 years. Confirming publications include major world studies such as Platino, BOLD, WTC, IMCA, Gazlean etc.

He: by ndd MolMass, an extremely accurate measurement of Helium difference between inhalation and exhalation of DLCO test gas. This measurement is not depending on actual test gas He concentration and therefore completely calibration free.

CO: by ndd unique MolMass based 3 point calibration. Test gas; air and a test gas/air mix are measured before each DLCO measurement; adjusting both range and linearity for best results.

For proof of evidence see back of this certificate.

Use according to the manuals published at www.ndd.ch.
Use only with ndd original consumable. In case of malfunction please contact the place of purchase.

Life time free upgrade

You may upgrade free of charge the firmware or the software from our homepage to have the latest state of the art instrument suitable for the hardware capabilities of your instrument.
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ndd and our world wide dealer network wish you a very successful use and are ready to support you.
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* Some studies and/or other guide lines applicable do require frequent calibrations or checks of calibrations. This is required for spirometers not following the ndd measurement principle; for instruments that have not been long term stability confirmed. In order to comply with such rules you are able to follow these cal check procedures in the provided "calibration check" modes. Note that the ndd instrument however cannot and does not need to be calibrated since it is stable for life: much more stable than the tools used for calibration checks. And not affected by variables (temp., pressure and humidity). In case of any calibration check problem please check the calibration syringe, the tube connections, the proper procedure etc. before contacting ndd. The ndd instruments can never be miscalibrated.

| Tests | Actual Value | Target | Equipment Information |
|-------------------------------------|--------------|------------------|-----------------------------|
| Final Inspection Results | | | |
| Volume Mean Difference | exp. _____ | ± 3.5 % | EasyOne Pro _____ |
| | insp. _____ | ± 3.5 % | Device S/N _____ |
| DLCO Simulator Test Criteria | | | |
| DLCO Mean Val. | _____ | ± 1.5 DLCO Units | Test Information |
| DLCO Std Dev. | _____ | < 1 DLCO Unit | |
| DLCO Human Test | OK | | Quality Controller _____ |
| Electrical Safety Test | OK | | |


MolMass
the next step


UPG the new dimension


TrueFlow
makes the difference

Selected published documents relative to UPG, TrueFlow and MolMass

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UPG (optional R&D mode)

ULTRASONIC MEASUREMENTS OF CO₂ DURING QUIET BREATHING MAY DIAGNOSE DEGREE OF AIRWAY OBSTRUCTION

RL Jensen, C Buess, RO Crapo LDS Hospital and University of Utah, ndd, Zurich Switzerland

Conclusions: 1. Molar mass measurements are simple and correlate well with traditional measures of CO₂
2. Molar mass measurements may provide an effort-independent test that will diagnose the presence and degree of airway obstruction
3. In the future, these may add additional information to traditional spirometry from the shape of the molar mass vs. volume curves
www.ndd.ch/UserData/Download_00115_00.pdf

ULTRASONIC TIDAL MOLAR MASS – VOLUME CURVES FOR ASSESSING LUNG FUNCTION IN CHILDREN WITH CYSTIC FIBROSIS

Susanne I. Fuchs¹, Christian Buess², and Monika Gappa¹

¹ Pediatric Pulmonology and Neonatology, Medizinische Hochschule Hannover, Hannover, Germany

² ndd Medizintechnik AG, Zurich, Switzerland

With this approach simple tidal molar mass vs. volume curves may become a useful screening tool to identify subjects with lung disease.

www.ndd.ch/UserData/Download_00117_00.pdf

CORRELATION OF FORCED OSCILLATION (FO) AND VENTILATORY DISTRIBUTION INDICES OF SMALL AIRWAY FUNCTION IN ASTHMA

M. Goldman (1), MD, ScD, C. Buess (2), PhD, J. Lemert (1), BA, C. Saadeh (1), MD

Conclusion: We have demonstrated that a UPG in a desktop tidal breath test is as sensitive to changes in ventilatory capacity in patients with COPD as low frequency FOT and correlates with FOT variables of small airway disease. The specificity and sensitivity of this tidal breathing test in small airway disease is at least as good as a forced Spirometry. (word count ERS)
www.ndd.ch/UserData/Download_00118_00.pdf

ELEVATED SLOPE PHASE III FROM UPG CORRELATES WITH INTRA-BREATH CHANGES IN LOW FREQUENCY REACTANCE (X₅Hz) IN PATIENTS WITH COPD.

Nolan G., Southwell K. A., Rochford P., McDonald C.F. Austin Health, Austin Hospital, Heidelberg, VIC Australia.

Conclusion: We have demonstrated that a UPG in a desktop tidal breath test is as sensitive to changes in ventilatory capacity in patients with COPD as low frequency FOT and correlates with FOT variables of small airway disease. The specificity and sensitivity of this tidal breathing test in small airway disease is at least as good as a forced Spirometry. (word count ERS)

TrueFlow

FDA CERTIFICATION EasyOne

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www.ndd.ch/UserData/Download_01816_00.pdf

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MolMass



Intermountain
LDS Hospital

8th Avenue and C Street, Salt Lake City,
Utah 84143

Device: ndd EasyOne Pro Spirometer / Testing dates: June 26 and 29, 2009 / Present: LDS Hospital, Heather Gallo, Robert O. Crapo, M.D. / Robert L. Jensen, Ph.D.

In a recent publication by Jensen, et al (Chest 2007; 132:388-395) evaluating the accuracy of DL_{CO} instruments, DL_{CO} measurement errors were defined as difference from the simulator target of +/- 2.0 ml CO/min/mmHg. This definition was based in part on the work of Punjabi et al (Chest 2003; 123:1082-1089). In the study by Jensen et al, all 5 instruments tested had error rates ranging from 2.8% to 78% during simulation testing (> 2.0 ml CO/min/mmHg from simulation target).

The differences between the simulator targets and DL_{CO} values measured by the ndd EasyOne Pro at every volume/simulator-gas combination were all less than 1.25 ml CO/min/mmHg. The device showed no errors in measurement of DL_{CO} using the above definition, performing better than the instruments tested by Jensen, et al.

Mean deviations from the target DL_{CO} values were all less than 0.75 ml CO/min/mmHg for each test level. When expressed as a percent of the average target value all were less than 2% except the low simulation gas using 3.0 Liter inspired volumes. For all testing levels, the ranges of the differences were all less than 2.0 ml CO/min/mmHg.

Overall Summary: The ndd EasyOne Pro meets ATS recommendations for accuracy and precision in measuring FVC, FEV₁, FEF₂₅₋₇₅ %, and PEF under ambient and BTPS conditions. The ndd EasyOne Pro performs acceptably in the measurement of DL_{CO}. 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.

www.ndd.ch/UserData/Download_01523_00.pdf

Sincerely yours,

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

Robert L. Jensen, Ph.D.
Biophysicist, Pulmonary Laboratory



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