

# SOP for NDD EasyOne<sup>®</sup> Spirometer (only for WP3)

## **Practical issues**

### Calibration

- The syringe used to check the volume calibration of spirometers must have an accuracy of  $\pm 15$  mL or  $\pm 0.5\%$  of the full scale (15 mL for a 3-L syringe).
- The manufacturer must provide recommendations concerning appropriate intervals between syringe calibration checks. Calibration syringes should be periodically (e.g. monthly) leak tested at more than one volume up to their maximum (this can be done by attempting to empty them with the outlet corked).
- A dropped or damaged syringe should be considered out of calibration until it is checked.
  
- A calibration check is different from calibration and is the procedure used to validate that the device is within calibration limits, e.g.  $\pm 3\%$  of true.
- If a device fails its calibration check, a new calibration procedure or equipment maintenance is required.
- Calibration checks must be undertaken daily, or more frequently, if specified by the manufacturer.

### Quality control for volume-measuring devices

The volume accuracy of the spirometer must be checked at least daily, with a single discharge of a 3-L calibrated syringe.

More frequent checks may be required:

- 1) during industrial surveys or other studies in which a large number of subject manoeuvres are carried out, the equipment's calibration should be checked more frequently than daily
- 2) when the ambient temperature is changing, volume accuracy must be checked more frequently than daily and the BTPS correction factor appropriately updated.

Check over the entire volume range using a calibrated syringe or an equivalent volume standard. The measured volume should be within  $\pm 3.5\%$  of the reading or 65 ml, whichever is greater. This limit includes the 0.5% accuracy limit for a 3-L syringe.

### Quality control for flow-measuring devices

With regards to volume accuracy, calibration checks must be undertaken at least daily, using a 3-L syringe discharged at least three times to give a range of flows varying between 0.5 and 12 Ls<sup>-1</sup> (with 3-L injection times of  $\sim 6$  s and  $\sim 0.5$  s).

The volume at each flow should meet the accuracy requirement of  $\pm 3.5\%$ .

For devices using disposable flow sensors, a new sensor from the supply used for patient tests should be tested each day. For linearity, a volume calibration check should be performed weekly with a 3-L syringe to deliver three relatively constant flows at a low flow, then three at a mid-range flow and finally three at a high flow. The volumes achieved at each of these flows should each meet the accuracy requirement of  $\pm 3.5\%$ .

## **Test procedure**

Three distinct phases to the FVC manoeuvre:

- 1) maximal inspiration;
- 2) a “blast” of exhalation;
- 3) continued complete exhalation to the end of test (EOT).

- Check the spirometer calibration
- Wash hands
  
- Instruct and demonstrate the test to the subject, to include
  - Correct posture with head slightly elevated
  - Inhale rapidly and completely
  - Position of the mouthpiece (open circuit)
  - Exhale with maximal force
  
- Perform manoeuvre (closed circuit method)
  - Have subject assume the correct posture
  - Attach nose clip, place mouthpiece in mouth and close lips around the mouthpiece
  - Inhale completely and rapidly with a pause of <1 s at total lung capacity (TLC)
  - Exhale maximally until no more air can be expelled while maintaining an upright posture
  
  - Repeat instructions as necessary, coaching vigorously
  
- Repeat for a minimum of three manoeuvres in acceptable limits; no more than eight are usually required
- Check test repeatability and perform more manoeuvres as necessary.

### **Acceptability criteria for manoeuvres**

- A satisfactory start of test and a satisfactory end of test (EOT), i.e. a plateau in the volume–time curve.
- The subject performed the manoeuvre with a maximum inspiration, a good start, a smooth continuous exhalation and maximal effort:
  - 1) without an unsatisfactory start of expiration, characterised by excessive hesitation or false start extrapolated volume or EV .5% of FVC or 0.150 L, whichever is greater;
  - 2) without coughing during the first second of the manoeuvre, thereby affecting the measured FEV<sub>1</sub> value, or any other cough that interferes with the measurement of accurate results;
  - 3) without early termination of expiration (see End of test criteria section);
  - 4) without a Valsalva manoeuvre (glottis closure) or hesitation during the manoeuvre that causes a cessation of airflow, which precludes accurate measurement of FEV<sub>1</sub> or FVC;
  - 5) without a leak;
  - 6) without an obstructed mouthpiece (e.g. obstruction due to the tongue being placed in front of the mouthpiece, or teeth in front of the mouthpiece, or mouthpiece deformation due to biting);

- 7) without evidence of an extra breath being taken during the manoeuvre.

It should be noted that a usable curve must only meet conditions 1 and 2 above, while an acceptable curve must meet all of the above seven conditions.

- The reporting format should include qualifiers indicating the acceptability of each manoeuvre.
- Records of failed such manoeuvres should be retained since they may contain useful information.

#### Between-manoevure criteria

- After three acceptable spiograms have been obtained, apply the following tests
  - The two largest values of FVC must be within 0.150 L of each other
  - The two largest values of FEV<sub>1</sub> must be within 0.150 L of each other
- If both of these criteria are met, the test session may be concluded
- If both of these criteria are not met,
  - continue testing until both of the criteria are met with analysis of additional acceptable spiograms or
  - A total of eight tests have been performed (optional) or
  - The patient/subject cannot or should not continue

## **3. Health Assessment**

### **3.1 Protocol spirometry**

#### **3.1.1 Overview**

Spirometry is one of the simplest, most effective tests available for the assessment of lung function. A spirometer measures the amount of air a subject inhales or exhales and the rate at which the air is exhaled. The most common spirometric tests require that the subject exhale with as much force as possible after taking a full, deep breath. The subject's effort is called the forced expiratory manoeuvre.

It is an important aim of this study to ensure that all centres are able to execute a common interview and examination schedule and in particular undertake uniform measures for lung function. We will therefore employ the same type of spirometer across all centres - the NDD EasyOne<sup>®</sup> Spirometer . This is a highly portable spirometer that measures flow and volume by ultra-sound transit time, is endorsed by the ERS and complies with ATS spirometry standards.

Every spirometry session must be performed according to the SOP by study staff or technicians who have undergone the study training. To ensure data integrity equipment must be regularly cleaned and the calibration checked daily according to manufacturers instructions.

### **3.1.2 Measures**

#### **During each session the following measures should be collected:**

Forced Vital Capacity (FVC)	The total volume of air exhaled in a forced expiratory manoeuvre. The FVC is useful for detecting restrictive diseases, since lower than expected results may be a sign that the lungs cannot inflate normally. FVC is reduced in people with obstructive and restrictive disorders.
Forced Expiratory Volume at One Second (FEV <sub>1</sub> )	The amount of air that a person exhales during the first second of a forced expiratory manoeuvre and is reduced in individuals with airflow obstruction.
The ratio of FEV <sub>1</sub> to the FVC (FEV <sub>1</sub> /FVC)	The most sensitive and specific index of airways obstruction measured by a spirometer. It is obtained by dividing the FEV <sub>1</sub> by the FVC, and is expressed as a percentage (100 x FEV <sub>1</sub> /FVC).
Forced Expiratory Volume at Six Seconds (FEV <sub>6</sub> )	The amount of air that a person exhales during the first six seconds of a forced expiratory manoeuvre. Increasing interest is being shown in the FEV <sub>6</sub> , and more particularly in the FEV <sub>1</sub> /FEV <sub>6</sub> ratio, as an alternative to the FEV <sub>1</sub> /FVC ratio.
The ratio of FEV <sub>1</sub> to the FEV <sub>6</sub> (FEV <sub>1</sub> /FEV <sub>6</sub> )	An alternative to the FEV <sub>1</sub> /FVC ratio.
FEF 25-75%	
MEF 50	Mid Expiratory Flow at 50% of the Vital Capacity
PEF	Peak Expiratory Flow

### **3.1.3 Location**

Spirometry testing ideally should be performed in a private, temperature-controlled room. All necessary equipment should be available in the room. Ideally the room should be well lit, preferably with a window, and in a quiet area of the school building. These conditions will improve the quality and reproducibility of the results. For safety, the participant should be seated in a chair with no wheels.

### **Equipment**

The spirometry session should be carried out in a room with the following equipment:

- Sink for hand washing, soap and hand towels
- Containers of:
  - clean mouthpieces (Spirettes)
  - nose-clips
- Containers to collect:
  - used Spirettes
  - used nose clips
- Box of tissues
- Alcohol wipes
- Disposal bin
- Clinical gloves
- Chair with arms/without wheels
- Spare AA batteries
- EasyOne Spirometer
- Calibration syringe & syringe adapter

- Questionnaires

### **3.1.5 Calibration**

The EasyOne Spirometer has been designed to need no calibration. However, a calibration check should be carried out daily to ensure that the spirometer is reading accurately. Instructions for performing the calibration check are in the NDD EasyGuide technical manual. The calibration syringe and adapter should always be stored next to the spirometer so that the temperature between them is similar. If spirometry is done in the field (outside a clinical setting), it is preferable to keep the spirometer and calibration syringe together overnight to avoid temperature differences at the time of calibration.

### **3.1.6 Medication use prior to testing**

In order to provide a valid lung function assessment, volunteers should be asked about the use of bronchodilators in the last 4 hours. If the participant has used a beta-2-agonist inhaler or an antimuscarinic inhaler in the last four hours, consider waiting until four hours since last use has elapsed. If this is not possible, proceed.

If the volunteer has not been able to comply with these waiting periods, the spirometry should be done anyway (unless it is feasible that the participant be tested on another day) and medication usage in the last 24 hours should be recorded.

### **3.1.7 Reasons for rescheduling spirometry testing**

In some instances, spirometry testing may be contraindicated by a temporary condition that would affect the validity of the manoeuvre or endanger the health of the volunteer. These situations are at the discretion of the staff member but may include acute back pain, a respiratory tract infection with unresolved symptoms in the week prior to the visit, or very recent dental work.

Ideally, centres should postpone testing and should re-schedule the visit for a time when the situation could be expected to be resolved. If volunteers are brought back later for spirometry testing, but the rest of their data are collected on the first visit, then the Spirometry safety questions must be asked again.

### **3.1.8 Contraindications for testing**

Testing should not be done if the subject has or reports any of the following:

- a heart attack in the last three months
- chest or abdominal surgery in the past 3 months
- a detached retina or eye surgery in the past 1 month
- if they are a woman in the last trimester of pregnancy
- they are taking medication for tuberculosis
- any other co-morbidity (such as unstable angina or pneumonia) that, in the opinion of a local clinician, may affect the performance of the test or impact the volunteer's safety

If a volunteer has or reports any of the conditions above do not proceed with spirometry. If they agree, volunteers may be brought back for retesting at a later date.

### **3.1.9 Method**

A detailed description of the use and operation of the NDD EasyOne spirometer, together with instructions for coaching the participant, are included in the NDD EasyGuide users' manual. All

study staff who undertake the lung function tests are asked to read this document and to be familiar with its contents. A copy of this document should be kept with each spirometer in case questions about the use of the spirometer arise during testing.

Volunteer information should be entered into the spirometer as prompted. In the ID field enter the subject's unique ID. Do not enter the centre number or sample number. Do not enter the subject's name.

As prompted enter the age, height, weight, ethnic category, gender, smoking status and the ID of the lung function assistant undertaking the test.

If after safety questions it is decided to reschedule the session, document the potential safety issues in questionnaire II. Ensure that the same questionnaire is recalled for use if a second visit is arranged.

If testing is to proceed offer volunteers the opportunity to use toilet facilities before testing. Instruct them to loosen any tight clothing that might restrict inspiration. Testing should be conducted with the volunteer seated, upright and with chin slightly elevated on a chair with arms but no wheels. The chair is a safety measure to support the participant in case s/he faints during the manoeuvre.

Staff should wash their hands before the start of the test and use a tissue to remove mouthpieces (the Spirette) from the storage container. If appropriate allow the volunteer to insert the clean Spirette into the spirometer. Be careful to ensure that the arrow on the Spirette is lined up with the arrow on the spirometer.

All manoeuvres should be performed with the participant wearing a nose clip. This clip prevents air from moving through the nose during the test.

Explain that the purpose of the test is to take some measurements to check on the health of the lungs. Emphasize that, although the procedure does not hurt, in order to get useful and valid results he/she must breathe out as hard and as fast and for as long as is possible when told to do so, and will need to repeat the procedure a few times.

### **3.1.9.1 The manoeuvre**

Explain that the volunteer should take in as deep a breath as possible, and when his/her lungs are totally full, quickly position the mouthpiece and BLAST out the air as hard and as fast as possible. A vigorous demonstration of the manoeuvre will help the volunteer understand the manoeuvre much more quickly. Demonstrate the correct positioning of the mouthpiece. Take a deep breath and emphasize the full depth of inhalation. Then demonstrate a dramatic blast out as fast as possible. Because the adequacy of these manoeuvres is highly dependent on volunteer effort, staff must guide the volunteer through the technique. It is extremely important to inhale as fully as possible and to exhale very forcefully, and as much as possible. Tell the volunteer when to start taking in a deep breath and to put the mouthpiece in his/her mouth. Then tell them to blast out the air and to continue exhaling for at least 6 seconds. Observe their body language as he/she attempts to follow the instructions, and encourage them to continue blowing out smoothly without re-breathing. Instruct the participant to remain erect and not to bend over during the manoeuvre.

Follow the procedures outlined in sections 5.2 to 5.4 of the NDD EasyGuide users' manual. Follow the computer prompts until a successful test session has been obtained. A successful

test session is defined as at least three acceptable manoeuvres, with both the two best FEV<sub>1,5</sub> and the two best FVCs from these manoeuvres within 200 ml of each other.

### **3.1.9.1 Acceptable and reproducible manoeuvres**

"Acceptable" is defined as a manoeuvre that is free from error. "Reproducible" is defined as being without excessive variability between manoeuvres.

Many factors will result in error, including hesitation or false starts, cough, variable effort, glottis closure, early termination and leaks.

Three acceptable manoeuvres are needed to be 'reproducible'. The two highest values for FVC and FEV<sub>1</sub> taken from acceptable forced expiratory manoeuvres should not vary more than 200 millilitres from the second highest FVC and FEV<sub>1</sub>. It is also important to monitor the volume-time curves to determine if the size and shapes of the curves are reproducible.

When errors occur, review them with the volunteer before proceeding with additional manoeuvres. You may wish to repeat a demonstration manoeuvre. Demonstrate the correct placement of the mouthpiece, emphasize the maximum depth of inhalation, and then blast out the air. If the volunteer tries again and the reproducibility criteria are not met, continue the test as needed (up to a total of five manoeuvres), assuming that the volunteer is able to continue.

Some volunteers may never be able to provide three reproducible manoeuvres. The goal of each session is to meet the acceptability and reproducibility criteria, but these are not absolute requirements for data to be used. Previous studies have shown that inability to perform reproducible spirometry, even with good coaching, is an important risk factor in predicting future health.

Centres may wish to discuss lung function results with their volunteers and will therefore wish to compare test results with predicted values. The NDD EasyOne spirometer offers a number of published predicted values, most of which were derived from studies of largely Caucasian participants. We recommend the use of the ERS/ECC's reference values.

The quality grades allow you to assess the reliability of the measurement result. Quality grades A to C indicate a reliable result. A quality grade between D and F indicates inadequate test quality. The result must then be interpreted with caution. The quality ratings can be activated or deactivated under "Configuration". See also Chapter 8.

The table below defines the criteria for the classification of quality grades:

<b>Rating</b>	<b>Criteria in Diagnostic mode</b>	<b>Criteria in Frontline and NLHEP mode</b>
A	At least 3 acceptable tests (for age < 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 100ml (80ml if FVC < 1.0 L; for age < 6: 80ml or 8% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 100ml
B	At least 3 acceptable tests (for age < 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 150ml (100ml if FVC < 1.0 L; for age < 6: 100ml or 10% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 150 ml
C	At least 2 acceptable tests AND the	At least 2 acceptable tests AND the

	difference between the best two FEV1 and FVC values is equal to or less than 200ml (150ml if FVC < 1.0 L; for age < 6: 150ml or 15% of FVC whichever is greater)	difference between the two FEV1 and FEV6 values is equal to or less than 200 ml
D	At least 2 acceptable trials but the results are not reproducible. Quality message "Result not reproducible" OR only one acceptable trial. Quality message: "Only one acceptable trial"	At least 2 acceptable trials but the results are not reproducible. Quality message "Result not reproducible" OR only one acceptable test. Quality message "Only one acceptable trial"
D	No acceptable test available	No acceptable test available

### **3.1.10 Reference values**

Centres may wish to discuss lung function results with their volunteers and will therefore wish to compare test results with predicted values. The NDD EasyOne spirometer offers a number of published predicted values, most of which were derived from studies of largely Caucasian participants. Four ethnic correction settings are available that allow you to customize the amount of adjustment that is made for selected racial groupings. Consult the EasyGuide users' manual, sections 8 and 12, for more information regarding the use of prediction equations.

#### **Test settings:**

<b>Related to</b>	<b>Choice</b>
Predicted	ERS/ECC
Best Value Selection "ValueSel"	Best Value
Interpretation	NONE

### **3.1.11 Spirometer Calibration, Maintenance, and Hygiene**

The EasyOne spirometer is designed to reduce the need for cleaning and maintenance (see sections 13 and 14 in the EasyGuide users' manual). The surface of the spirometer and cradle may be cleaned by wiping with a damp cloth. If a more thorough cleaning is desired, the spirometer and its spirette cavity may be cleaned with an alcohol wipe or a soft cloth that has been lightly moistened with isopropyl alcohol. Do not let liquids flow into the Spirette cavity of the spirometer while cleaning. The disposable Spirette eliminates the need for cleaning the spirometer between patients. The Spirettes are designed for single patient use only, and must be removed and disposed of after each volunteer. Nose clips should be thoroughly cleaned after each use with hot water and detergent, allowed to dry and then wiped with alcohol.

It is recommended that staff and, if possible the volunteers, wash their hands before and after testing and that proper attention be given to environmental controls in settings where tuberculosis or other diseases spread by droplet nuclei are likely occur. Volunteers with evidence of obvious upper respiratory infections should not be tested, but rather asked if they may be tested at a later date.

On each day it will be used, the spirometer should be first calibrated with a 3.00-Liter syringe that has been stored next to the spirometer. The NDD calibration adapter for connecting the syringe with the spirometer is required for calibration. Beyond battery replacement and the calibration check, no maintenance is required or recommended on the spirometer or cradle. No service should be performed on the spirometer except by manufacturer-authorized personnel.



### **3.1.12 Data Transfer**

NDD EasyWare PC-software will be used, which is compatible with a PC running Microsoft Windows 98/ME/2000/XP. EasyWare software is available in English, French, Spanish, German and Italian. Ideally data should be transferred to a local PC daily and stored in mbd format (Access). A pulmonologist of your hospital should check the data of each spirometry to ensure that the curves are nice and that spirometries are performed adequately.