	<b>Title:</b>	<b>Spirometry</b>		
	<b>Version Date:</b>	2014-AUG-20	<b>Document Number:</b>	SOP_DCS_0012
	<b>Effective Date:</b>	2014-OCT-15		
<b>Data Collection Site (DCS)</b>	<b>Version:</b>	2.2	<b>Number of Pages:</b>	7

**1.0 Purpose:**

The purpose of this document is to describe the standardized procedure for collecting spirometry measurements using the TruFlow Easy-On Spirometer.

**2.0 Scope:**

This document is to be used by the DCS staff when collecting participants' spirometry measurements using the TruFlow Easy-On Spirometer.

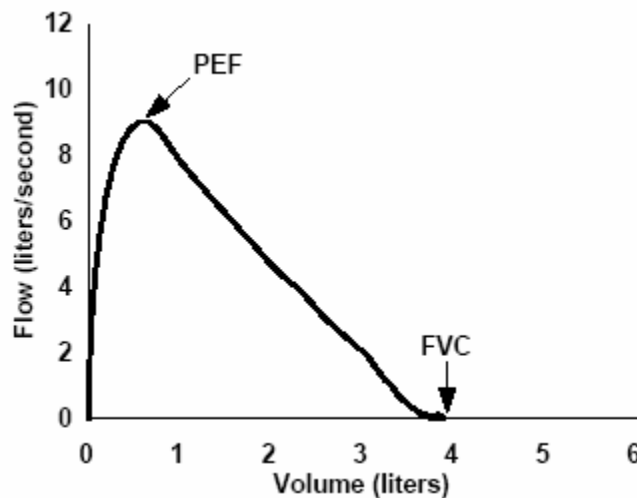
**3.0 Responsibilities:**

DCS staff are responsible for performing the procedures as described in the current and approved version of the standard operating procedure.

**4.0 Related Documents:**

Not applicable

**5.0 Definitions:**



**Figure 1:** A normal flow-volume curve

- Grading:** Quantifies the reproducibility of the measure. If the participant can master the instructions, then they should be able to have a reproducible result, even if they have lung disease. A reproducible test must have a Forced Expiratory Volume in One Second (FEV1) and Forced Vital Capacity (FVC) of less than 150 mL (Grade of B). Grading information is located below the right chart on the EasyOn screen.

Rating	Criteria
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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 100 ml (80 ml if FVC < 1.0 L) (for age <= 6: 80ml or 8% of FVC whichever is greater)
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 150 ml (100 ml if FVC < 1.0 L) (for age <= 6: 100 ml or 10% of FVC whichever is greater)
C	At least 2 acceptable tests AND the difference between the best two FEV1 and FVC values is equal to or less than 200 ml (150 ml if FVC < 1.0 L) (for age <= 6: 150 ml or 15% of FVC whichever is greater)
D (1)	At least 2 acceptable trials but the results are not reproducible according to 'C'. Quality message: "Result not reproducible" OR only one acceptable trial. Quality message: "Only one acceptable trial".
D (2)	Only one acceptable trial
F	No acceptable trial available

- **PEF:** Peak Expiratory Flow

#### 6.0 Equipment:

- TruFlow Easy-on Spirometer

#### 7.0 Supplies:

- Mouthpieces (*Spirette*)
- Nose clips



#### 8.0 Procedure Steps:

##### Contraindications:

The major contraindications for this measurement include:

- Severe acute respiratory condition (Contraindications Questionnaire);
- Pregnancy (over 27 weeks) (Contraindications Questionnaire);
- Unstable heart condition (Contraindications Questionnaire);
- Heart surgery within the last 3 months (Contraindications Questionnaire);
- Major surgery on chest or abdomen within the last 3 months (Contraindications Questionnaire);
- Detached retina or recent eye surgery in the last 3 months (Contraindications Questionnaire);
- Blood in sputum in last 3 months (Contraindications Questionnaire);
- Thoracic, abdominal or cerebral aneurysm(s) present (Contraindications Questionnaire); or
- Average blood pressure of 200/120 or above (Blood Pressure taken at DCS).

- Step 1:** At the *Interview Tab* in Onyx, look for “Spirometry” in the list of stages. Then select **Start** in that row.
- Step 2:** The “Spirometry” window will pop up.
- Step 3:** **Scan** or enter the participant ID barcode, then click on **Continue**.
- Step 4:** Insert a new Spirette in the sensor. Ensure the arrow on the spirette is lined up with the arrow on the sensor. Ensure the plastic bag protects the mouthpiece until you hand it over to the participant.
- Step 5:** Briefly explain the procedure to the participant:
- put the mouthpiece in the mouth;
  - breathe calmly;
  - fill lungs completely;
  - exhale as hard and fast as possible;
  - continue blowing out until the lungs are completely empty;
  - inhale as hard and fast as possible.
- Step 6:** Give the participant a clean nose clip. Instruct him/her to pinch his/her nostrils with the nose clip so no air is able to escape through the nose.
- Step 7:** Press **Start** in the Spirometry application launch window to open the Easy On-PC software.
- Step 8:** A window will open displaying the participant’s information. The information will be populated automatically except for ethnicity. **Do not ask** the participant this question; rather, make a best guess and fill in the information that you feel is correct. Click on **OK**. Ensure all required fields are populated. If not, enter all required fields.
- Step 9:** A window will open to ask you to “Block spirette until prompted to blast out”. Press **OK**, and block the end of the *Spirette*<sup>TM</sup> with the palm of your hand using the bag or a tissue.
- Step 10:** When the **Start Test** prompt is displayed, hand the sensor over to the participant.
- Step 11:** Instruct the participant to put the mouthpiece into his/her mouth, and to create a tight seal with his/her lips, taking care not to block the mouthpiece opening with the tongue or to bite down on the mouthpiece excessively.
- Step 12:** Ask the participant to breathe normally for 3 - 4 breaths.
- Step 13:** Tell the participant to take a **Deep Breath In** and fill his/her lungs completely.
- Step 14:** Instruct the participant to “**BLOW!**”, encouraging him/her to exhale as quickly and as hard as possible.
- Step 15:** Continue to encourage the participant to blow as hard as they can for as long as they can. Say **Keep Going, Keep Going...** for the entire 6 seconds until they can breathe in.

- Step 16:** When it is clear the participant has expelled as much air from his/her lungs as possible, tell them to take a deep breath in.
- Step 17:** “Manually End Test” will show up on the screen and click on **Test End. This is one trial.**
- Step 18:** To determine if the blow/trial is acceptable, you should observe that the subject performed the maneuver with a maximum inhalation, a strong and forceful start to the exhalation, a smooth and continued exhalation, and maximal effort. The following criteria must also be met:
- Acceptable seal between the lips and the mouthpiece;
  - Absence of false start, hesitation, or generally unsatisfactory start of expiration;
  - Absence of coughing during the maneuver;
  - Absence of glottis closure or hesitation during the maneuver;
  - Absence of mouthpiece obstruction during the maneuver by the tongue, teeth, or deformation of the mouthpiece due to biting; and
  - Exhalation for a full 6 seconds.  
See the table Quality Messages and Recommended Actions below.
- Step 19:** Provide feedback to the participant based on the results of the first blow. This can include instructions to improve the blow or positive reinforcement for a good attempt.
- Step 20:** Allow the participant to rest for 30-60 seconds between attempts.
- Step 21:** Press **Add Trial** (NOT “Add Post”)
- Step 22:** Repeat **Step 11** to **Step 20** until the three acceptable trials have been recorded and a Grading of A or B has been obtained (See definition section for more information). If you don’t have a grading of A or B, then ignore the “Session Complete! Great Job!” banner and add another trial\*.
- \*The participant can try up to eight times to get to get three acceptable trials. If three acceptable trails cannot be obtained after eight attempts, then proceed to step 23.
- If there are more than three acceptable measurements:
    - Log in as a user to be able to enter a test assessment and comments, when it asks for a password type in your user name.
    - Click the  icon on the test results screen.
    - Click on the  icon.
    - Select the *Acceptable* check box.



**NOTE:** If you are unable to get an acceptable spirometer result after attempting to complete the test for any reason, then mark the test as skipped using one of the predefined reasons. Also, make a note in the comments section that you tried to complete the test and insert the number of times you attempted to complete the test.

- Step 23:** Remove the nose clip from the participant's nose.
- Step 24:** Dispose of the mouthpiece and nose clip in the waste bin.
- Step 25:** Press **Finish EMR**. This will return you to the Instrument application launch window.
- Step 26:** Press the **Refresh** button to see the participant's attempts.
- Step 27:** Click on **Next**. This will take you to the Conclusion page. Click on **Finish**.
- Step 28:** Indicate in the **comment** field in Onyx if there was anything that may have affected or influenced the test. Ensure that the comments do not contain any personally identifying information.
- Step 29:** Click **Continue** to return to the status page.

### Quality Messages and Recommended Actions

Message	Criterion	Recommended action
Don't hesitate ...	Back-extrapolated volume greater than 150 ml or 5% of FVC whichever is greater (for age <= 6: 80ml or 12.5% of FVC whichever is greater)	The patient must exhale all air at once and not exhale in short bursts.
Blast out faster ...	Time until peak flow greater than 160 ms	The patient must exhale more explosively and as firmly and quickly as possible.
Blow out longer ...	Expiration time less than 2 seconds OR volume in the last 0.5 seconds of the expiration larger than 100 ml	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs.
Test Abrupt End!	FVC Test only: Expiration time less than 2 seconds OR volume during last 0.5 seconds >40 ml when expiration time is <6 seconds OR volume during last second >25 ml when end-of-test was initiated by an inspiration.	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs.

Good effort, do next ...	Test meets above criteria.	Good trial. Only one to two more good trials and the test is complete.
Do not start too early!	The time to peak flow (PEFT) is less than 30 ms or flow detected before sensor was initialized (Wait until 'Start Maneuver ...' is displayed)	Instruct the patient to wait until the baseline setting is finished and the device signals that the trial can start ('Start maneuver ...')
Cough detected. Try again...	A cough has been detected (PEF or PIF > 19l/s)	Instruct the patient to avoid coughing during the first second. Repeat the test.
Message	Criterion	Recommended action
Deeper breath ...	FEV1 or FVC* not reproducible. Difference with respect to best test greater than 150 ml or 100 ml if FVC is < 1.0L (for age <= 6: 100 ml or 10% of	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
No maneuver detected!	No parameter calculation possible	Instruct the patient to perform the maneuver according to its definition.
Session complete! Great Job!	QC grade A or B reached.	The test is complete. An adequate number of good tests are available.

**NOTE:** Sometimes you might receive the message 'Test aborted by user'. This indicates that the participant removed the spirette from their mouth early. In this case, go back to **Step 11**.

#### 9.0 Documentation and Forms:

- CRF\_DCS\_0012 - Spirometry CRF

#### 10.0 References:

- Easy-on PC Operator's Manual. Version V01 Rev. A. Zurich: nnd Medizintechnik AG; [date unknown].

#### Revision History:

New Version #	Revision Date	Revision Author	Content Approval
2.2	2014-Aug-20	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
<b>Step 18:</b> Adjusted last sentence: See Easy On FVL FVC Quality Messages – the table Quality Messages and Recommended Actions below.			
<b>Step 22</b> mistakenly referred back to Step 13. It has been corrected to refer back to <b>Step 11</b> .			
<b>Step 24:</b> Dispose of the mouthpiece and nose clip in the biohazardous-waste bin.			
<b>Added NOTE below the table:</b> Sometimes you might receive the message 'Test aborted by user'. This indicates that the participant removed the spirette from their mouth early. In this case, go back to <b>Step 11</b> .			
SOP formatting updated.			
Scope, Purpose, and Responsibilities sections updated.			
New Version #	Revision Date	Revision Author	Content Approval
2.1	2013-Oct-01	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
Added Contraindication: Average blood pressure of 200/120 or above (Blood Pressure taken at DCS).			

New Version #	Revision Date	Revision Author	Content Approval
2.0	2012-Nov-13	Lorraine Moss	Mark Oremus
<b>Summary of Revisions</b>			
Added NOTE under <b>step 22</b> in section <b>6.0</b>			
Various formatting updates			
Added grading/quality messages/message tables in section <b>6.0</b>			
Added grading information into <b>step 22</b>			

Baseline