Diffusion Testing (DLCO)

Pre-Test Procedure

- 1. Describe the test procedure to the patient, emphasizing the following points:

 There will be 5 phases to the measurement. Demonstrate each phase visually to facilitate success. Special attention should be attributed to the importance of the 3rd phase the IVC (Inspiratory Vital Capacity) maneuver.
- 2. Instruct the patient to sit upright and comfortably in front of the MiniBox+.
- 3. Attach the handheld unit (HHU) to the main device.
- 4. Make sure the bacterial filter remains firmly attached to the HHU.
- 5. Make sure the patient's mouth aligns well with the HHU. If not, have the patient remove his/her mouth from the filter and adjust the height of the chair or the device, as needed.
- **6.** Fit a nose clip on the patient's nose.

Test Procedure:

- 1. Select **DLCO** from the menu in the left pane.
- 2. Press **Start**. A message appears indicating that the sensor zeroing process begins. Do not touch the HHU during the zeroing procedure.
- **3.** When the zeroing message clears, the test is ready to be performed. Have the patient lean towards the device and grasp the filter firmly with his/her teeth. Make sure the lips are tightly sealed and the nose clip is on securely.
- 4. Phase I have the patient perform 3 normal tidal breathing cycles;
- 5. Phase II have the patient exhale immediately to completely empty the lungs.
- **6.** Phase III Have the patient inhale deeply to completely fill the lungs. It is imperative that this phase is performed very well, since in accordance with ATS guidelines the Vital Capacity rapidly inhaled at this maneuver should be at least 85% of the Vital Capacity exhaled at the FVC test.
- 7. Phase IV Have the patient hold his/her breath until the "counter" on the top right side of the display turns green. Perform a 10-second countdown of the breath hold in order to reduce anxiety.
- **8.** Phase V When you reach 1-2 seconds, instruct the patient to exhale immediately at a slightly faster pace than normal to completely empty the lungs, until a plateau is observed on the gas%-time graph.
- 9. Press **Stop**. (See Fig. 5)



Fig. 5

Post-Test Procedure:

- 1. View the onscreen message indicating the test status (success or failure). In the event the test failed, please note the error message and proceed accordingly.
- 2. Press **Save** to save the measurement or press **Discard Test** to discard it.
- **3.** To perform an additional measurement, press **Another Test**.
- **4.** Review all "Efforts" before proceeding to the next measurement. If you wish to select different results as "Best" (override the application pick), do so now.



CONTACT INFORMATION:

PulmOne Advanced Medical Devices Ltd.

E: usinfo@pulm-one.com (USA) I
info@pulm-one.com (Global)



PUO-DOC20009 Rev. 0

Spirometry

Pre-Test Procedure

- 1. Describe the test procedure to the patient.
- 2. Instruct the patient to sit upright and comfortably in front of the MiniBox+.
- **3.** Firmly attach the viral bacterial filter on the handheld unit ("HHU").
- 4. Detach the HHU from the main device.
- **5.** Fit a nose clip on the patient's nose.

Test Procedure

- **1.** Select the appropriate measurement (FVC or SVC) from the menu in the left pane.
- 2. Press **Start** and have the patient firmly hold the HHU still. A message appears indicating that the sensor zeroing process begins.
- 3. When the zeroing message clears, the test is ready to be performed. Have the patient insert the HHU in his/her mouth. Make sure the lips are tightly sealed on the filter and the nose clip is on securely.
- **4.** Have the patient perform 2-3 normal tidal breathing cycles, to facilitate relaxation and familiarity with the device. Experienced patients can perform a single breath cycle or none at all.
- **5.** Have the patient inhale deeply to completely fill the \ lungs. Maximal inhalation typically involves a slight shrug of shoulders to expand the thorax.
- 6. For FVC: Immediately following maximal inhalation, have the patient exhale with full force to completely empty the lungs, until the "counter" on the top right side of the display turns green, or until they cannot force any more air out. This should take at least 6 seconds for adults, 3 seconds for children.
 For SVC: Immediately following maximal inhalation, have the patient exhale at a normal rate of speed to completely empty the lungs, until a plateau is observed on the flow-time graph.
- 7. During the entire measurement, make sure the patient does not lean forward or backward, but continues to sit comfortably upright. Maintain close eye contact with the patient to make sure that his/her lips are tightly sealed on the filter, and that s/he is not overly exhausted or fatigued, in order to avoid fainting or dizziness;
- 8. For FVC: Have the patient inhale deeply and then resume normal tidal breathing.
 For SVC: Have the patient resume normal tidal breathing
- **9.** Press **Stop**. (See Fig. 1 and Fig. 2)

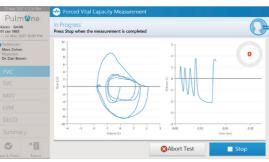


Fig. 1

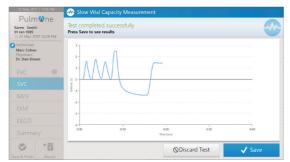


Fig. 2

Post-Test Procedure

- **1.** View the onscreen message indicating the test status (success or failure).
- Press Save to save the measurement or press Discard Test to discard it.
- **3.** To perform an additional measurement, press **Another Test**.
- 4. Review all "Efforts" before proceeding to the next measurement. If you wish to select different results as "Best" (override the application pick), do so now.
- 5. If continuing with a Post Bronchodilator FVC Study: a. Press Post Bronchodilator ON using the toggle button at the top right corner, and then Yes to confirm the selection.
 - b. Re-perform the procedure (See Fig. 3)
 - c. Warning! If continuing to a Post Bronchodilator FVC Study, you cannot perform additional LVM, SVC and DLCO tests at this point. All these other tests must be completed by now.
- **6.** To perform a non-consecutive Post Bronchodilator FVC test, after Save & Finish:
 - a. Select **Resume Session** from the main screen
 - b. Select the patient name and press **Resume Session**
 - c. Select **Post Bronchodilator** and re-perform the procedure (See Fig. 3)

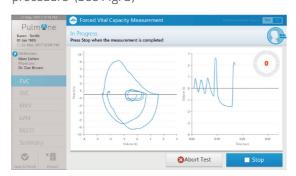


Fig. 3

Lung Volume Measurements (LVM)

Pre-Test Procedure

- 1. Describe the test procedure to the patient, emphasizing the following points:
 - a. They will hear a clicking sound from the shutter
 - b. Their lips should be kept sealed tightly on the filter until another complete breath maneuver is performed at the end of the test.
- 2. Instruct the patient to sit upright and comfortably in front of the MiniBox+.
- 3. Attach the handheld unit (HHU) to the main device.
- 4. Make sure the bacterial filter remains firmly attached to the HHU.
- 5. Make sure the patient's mouth aligns well with the HHU. If not, have the patient remove his/her mouth from the filter and adjust the height of the chair or the device, as needed.
- **6.** Fit a nose clip on the patient's nose.

Test Procedure

- 1. Select LVM from the menu in the left pane.
- 2. Press **Start**. A message appears indicating that the sensor zeroing process begins. Do not touch the HHU during the zeroing procedure.
- **3.** When the zeroing message clears, the test is ready to be performed. Have the patient lean towards the device and grasp the filter firmly with his/her teeth. Make sure the lips are tightly sealed and the nose clip is on securely.
- 4. Have the patient press his/her cheeks with both hands to avoid any trapped air.
- 5. In Automatic Mode have the patient perform normal tidal breathing cycles STEADILY, at a rate of 15-25 breaths per minute; Once the "counter" turns green at 6 qualified volume measurements of the lungs, instruct the patient to inhale deeply to completely fill the lungs, and then exhale at a normal rate of speed until the lungs are emptied.
 In Manual Mode after a stable baseline is established, turn the "valve" to ON and instruct the patient to continue normal tidal breathing even when clicks are heard, until the "counter" turns green. After 6 qualified volume measurements of the lungs with the "counter" green, turn the "valve" to OFF and instruct the patient to inhale deeply to fill the lungs, and then exhale at a normal rate of speed until the lungs are emptied.
- 6. During the entire measurement maintain close eye contact with the patient to make sure that his/her lips are tightly sealed on the filter, and that s/he is not overly exhausted or fatigued, in order to avoid fainting or dizziness;
- 7. Encourage the patient to keep the breaths even and steady (not too small or rapid).
- **8.** Press **Stop**. (See Fig. 4)



Fig. 4

Post-Test Procedure

- 1. View the onscreen message indicating the test status (success or failure). In the event the test failed, please note the error message and proceed accordingly.
- 2. Press **Save** to save the measurement or press **Discard Test** to discard it.
- 3. To perform an additional measurement, press Another Test.
- **4.** Review all "Efforts" before proceeding to the next measurement. If you wish to select different results as "Best" (override the application pick), do so now.
- 5. Post Bronchodilator LVM Studies are performed the same way as for FVC. (See Spirometry Post-Test Procedure)