1.0 DESCRIPTION

1.1 Definition: The VMAX is a Windows 95 based device that can perform pulmonary function testing such as flow volume loops and maximal ventilatory ventilation maneuvers. Pulmonary function maneuvers are effort dependent tests that require proper instruction and patient cooperation. Inability to perform acceptable maneuvers may be due to poor subject motivation or failure to understand instructions. Physical impairment and age may also limit a patient's ability to perform these maneuvers.

1.2 Indications: The VMAX monitor will be used to perform pulmonary function testing as requested by the physician to assess work of breathing.

1.3 Contraindications

1.3.1 Do not use the VMAX in the presence of flammable anesthetics

1.3.2 Hemothysis of unknown origin (forced expiratory maneuvers may aggravate the underlying condition)

1.3.3 Pneumothorax

1.3.4 Unstable cardiovascular status (forced expiratory maneuver may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus

1.3.5 Thoracic, abdominal or cerebral aneurysms (danger of rupture due to increased thoracic pressure)

1.3.6 Recent eye surgery

1.3.7 Presence of nausea or vomiting that might interfere with test performance
1.4 Complications: Although spirometry is a safe procedure, untoward reactions may occur, and the value of the information anticipated from spirometry should be weighed against potential hazards. The following have been reported anecdotally:

1.4.1 Pneumothorax

1.4.2 Increased intracranial pressure

1.4.3 Syncope, dizziness, light-headedness

1.4.4 Chest pain

1.4.5 Paroxysmal coughing

1.4.6 Nosocomial infections

1.4.7 Oxygen desaturation due to interruption of oxygen therapy

1.4.8 Bronchospasm

NOTE: All patients should be NPO for at least 4 hours prior to any study.

1.5 Precautions

1.5.1 Do not open the monitor covers for any reason. Opening the covers has the potential for creating a significant electrical shock hazard.

1.5.2 The monitor should not be autoclaved, exposed to ethylene oxide, or immersed in any liquid.

1.5.3 The power cord should be properly connected to a grounded three-wire outlet and unplugged prior to cleaning.

1.5.4 Microbial contamination of the internal sampling system requires servicing by Sensormedics personnel.

1.5.5 Use only Sensormedics sampling tubing accessories. NOTE: Use of other tubings, accessories and any alterations of any tubings can affect accuracy of tests.

1.5.6 Allow at least 30 minutes warm-up time prior to calibration and monitoring.
1.5.7 Ensure that the correct adapters and tubings are being used prior to initiating a study.

1.5.8 Flow Volume Verification should be done once daily before testing a patient.

1.5.9 Ammonia and acetone-based cleaners should be avoided as these may damage the monitor surface.

1.6 Adverse Reactions and Interventions

1.6.1 The VMAX should be flow calibrated daily when in use. Calibration procedures must be strictly followed before any test is performed. Maintenance of the unit will be performed on an "as needed" basis upon the direction of a Sensormedics technical service representative. Refer to the operator's manual for troubleshooting guidelines.

1.6.2 Any patient that develops complications outlined in Section 1.4 will have the test aborted and the physician notified.

2.0 EQUIPMENT AND MATERIALS

2.1 VMAX Monitor with printer and sampling tubes

3.0 PROCEDURE

3.1 Turn on unit at breaker on right side of cart. Turn on laptop computer and printer.

3.2 Click on VMAX icon (If DOS display comes up on screen, type in "WIN" then press enter).

TO CALIBRATE FLOW SENSOR:

3.3 Click on flow sensor calibration.

3.4 Click on F1 to start.
   3.4.1 Attach 3L syringe to mass flow generator and zero sensor by performing two full strokes.
   3.4.2 Hit space bar and allow stabilization. The screen will automatically change to the verification screen.
   3.4.3 Perform five full strokes. The screen will automatically change to the verification screen.
   3.4.4 Perform three full strokes, then perform one full stroke between red lines, then perform one full stroke on the line.
3.4.5 Check % target at top right hand corner of the screen. If the percentage is within +/- 3% of 100%, save results by pressing F3 and proceed with test.

NOTE: A dialog box will appear if error is noted and test needs to be repeated.

TO PERFORM FLOW VOLUME LOOP

3.5 From the Pulmonary Function menu box, select Flow Volume Loop.

3.6 Select F1 to begin the test procedure.

3.7 Instruct the patient to put the mouthpiece in his/her mouth and attach noseclips. Record at least three stable tidal breaths.

3.8 Instruct the patient to take in a deep breath and then to forcefully exhale and completely empty their lungs.

3.9 Coach the patient to keep exhaling until the tracing crosses the vertical dotted six second line and the message "End of Test Criteria Met" is displayed at the bottom of the screen.

3.10 After maximum expiration, instruct the patient to forcefully inspire until his or her lungs are full. Select "End Test". The patient can now remove the mouthpiece from his or her mouth.

Quality Assurance Messages
If any of the following three "Quality Assurance Messages" appears, do not store the rest and repeat the above steps:

3.10.1 The patient's total expiratory time was < 6 seconds.
3.10.2 The patient's expiration did not meet the end of test criteria.
3.10.3 The test has a back-extrapolation value greater than 5% of the FVC or 150 ml, whichever is greater.

If any of the following three "Quality Assurance Messages" appears, repeat the test to obtain reproducible results:

3.10.4 There are no trials within 10% of the "best" trial for peak flow.
3.10.5 There are no trials within 0.2 liters of the "best" (largest) trial for FEV1.
3.10.6 There are no trials within 0.2 liters of the "best" (largest) trial for FVC.

NOTE: F1 restarts the FVL test routine. The latest test's results are rejected. "Esc" ignores the message and displays the test results.

TO PERFORM ENHANCED SPIROMETRY (SVC)

3.11 From the "Pulmonary Function" menu box, select "Enhanced Spirometry".
3.12 Select F1 to begin test procedure.

3.13 Instruct the patient to put the mouthpiece in his or her mouth and attach the noseclips. Instruct the patient to breathe normally on the mouth piece. After the computer detects at least three tidal breaths with a stable baseline, it will display the message: "Perform VC-F1 Start FV Loop". If you do not want to perform a flow volume loop, select "End" to terminate the test at this point.

3.14 Instruct the patient to remove the mouthpiece and noseclips.

**Quality Assurance Messages**

If any of the following Quality Assurance Messages appear, do not store latest test and repeat the above steps:

3.14.1 The vital capacity is outside physiologic range. Careful evaluation of the lung volume parameters is suggested.
3.14.2 The IC is outside physiologic range. Careful evaluation of the lung volume parameters is suggested.
3.14.3 The vital capacity CV is > 10%. Careful evaluation of the lung volume parameters is suggested.
3.14.4 The IC CV is > 10%. Careful evaluation of the lung volume parameters is suggested.

NOTE: F1 restarts the FVL test routine. The latest test's results are rejected. “Esc” ignores the message and displays test results.

**TO PERFORM MAXIMUM VOLUNTARY VENTILATION**

3.15 From the "Pulmonary Function" menu box, select "MVV".

3.16 Select F1 to begin test procedure.

3.17 Instruct the patient to put the mouthpiece in his or her mouth and attach noseclips. Instruct the patient to begin breathing fast and deep (target rate: 70-150 breaths per minute, target depth: 1/4 to 3/4 of the patient's vital capacity)

3.18 After the patient demonstrates proper technique, while attached to the system, select F1 to start collecting data.

3.19 The test automatically terminates at the end of the measurement interval.

**Quality Assurance Messages**

If any of the following "Quality Assurance Messages" appear, do not store the latest test and repeat the steps above:

3.19.1 Breathing frequency not within 70-150 breaths per minute.
3.19.2 The average tidal volume is not within 25%-75% of vital capacity.
3.19.3 The measured MVV is inconsistent with the MVV estimated from Spirometry.
3.19.4 The next best MVV is not within 10% of the best MVV.
NOTE: F1 restarts the FVL test routine. The latest test's results are rejected. “Esc” ignores the message and displays test results.

4.0 REFERENCES

4.1 VMAX Operator's Manual

4.2 AARC Clinical Practice Guideline: Spirometry, 1996 Update