PanVent™-OS Ventilator Test Protocol

Items needed

- IMT Medical Citrex H5 (Citrex)
- RAE Systems ppbRAE 3000 VOC analyzer
- Michigan Test Lung (MTL), one bellows, verified with volume syringe
- #8 Endotracheal tube connected to MTL
- Double-hose anesthesia breathing circuit (anticipated availability during covid crisis)
- Pressure regulator on ventilator closed fully (knob unscrewed, counterclockwise, no flow)
- Wall oxygen at 50 PSI
- Exhalation port plug
- Exhalation port to 36” hose for bubble leak test

Standard Test Configuration:

- Ventilator connected to 50 PSI gas supply
- Ventilator connected to MTL via anesthesia breathing circuit
- Citrex between Y piece and ETT
- MTL set to 0.01 L/cmH2O compliance (stiffest setting)
- no mechanical PEEP valve on exhalation limb

VOC Test

configuration: ventilator controller off, no breathing circuit connected. If ventilator has been connected non-medical shop air supply flush ventilator with medical oxygen and wait 5 min.

- VOC 0: Log background VOC measurement
- VOC 1: Log VOC measurement with VOC analyzer probe inserted 5” inside inspiratory limb at 22mm connector
- VOC 2: Log VOC measurement with VOC analyzer probe inserted 2” inside expiratory limb exit
- Join inspr and expr 22mm connections together with 16” section of breathing circuit hose, with Citrex on inspr limb for flow measurement
- Verify oxygen source reads zero VOCs
- Connect oxygen source to regulator input
- Place VOC analyzer probe inserted 2” inside expiratory limb exit
- Ventilator regulator at 0.5 LPM
- Manually open inspiratory valve for 2 minutes
- VOC 3: Log maximum transient VOC measurement and final VOC measurement

Exhalation Limb Flow Resistance Test

configuration: Citrex connected to ventilator expiratory 22mm port, Ventilator inspiratory port open to air, Ventilator connected to gas supply

- cycle expiratory valve by turning regulator to 5 PSI, turn vent on, cycle two breaths, PEEP zero
- Turn off ventilator
- Connect inspiratory limb to Citrex on expiratory limb with ventilator hose
- Manually open inspr valve by turning ¼ turn CCW
- Adjust to 60 LPM using Citrex flow sensor measurement (60 LPM +/- 1 LPM) using pressure regulator
- Verify Citrex pressure below 3.8 cmH2O
- Log pressure from Citrex

Positive pressure leak test
configuration: Standard Test Configuration

- ventilator controller off
- plug exhalation port
- Regulator to 5 PSI
- Manually adjust inspr valve to fill MTL to 35 cmH2O on Citrex, then close inspr valve
- leak test passed if airway pressure drops from 35 to 25 cmH2O in 30 sec or more
- Log pressure
- Remove exhalation port plug

Highest Flow/Pressure Test
configuration: Standard Test Configuration, MTL set to lung compliance 0.01 L/cmH2O (stiff) with Rp20 resistor

- ventilator controller off
- Disconnect breathing hose from inspr limb
- Regulator to 30 PSI
- PEEP 20, RR 30, IE 1:2, Pause ON
- Close OPR valve (60 cmH2O)
- Verify MTL pressure does not reach 70

Exhalation valve blow-by Leak Test
configuration: Standard Test Configuration, stiff lung

- Regulator to 10 PSI
- Ventilator controller to RR15, IE 1:2, PEEP 15, will generate high airway pressures
- Connect tube from exhalation limb exit to 1 cmH2O hydrostatic head (water in flask, end of tube no more than 1 cm under water)
- Verify no bubbles during inhalation cycle (some bubbles expected during the initial quarter-second of inspiratory cycle as exhalation valve fills and seals)

Ventilator Settings and Overpressure Test
configuration: Standard Test Configuration

- Verify TV is adjustable; verify measured TV error is acceptable
    - Ventilator on, RR 15, IE 1:2
    - Attempt 250 ml TV. adjust regulator pressure until 250 ml is read on vent.
        - Test measured tidal volume: Citrex should report volumes between 225 to 275 ml (+/- 10%)
        - Log 15 seconds of Citrex data
    - Attempt 450 ml TV. adjust regulator pressure until 450 ml is read on vent.
        - Test measured tidal volume: Citrex should report volumes between 405 to 495 ml (+/- 10%)
        - Log 15 seconds of Citrex data
    - Attempt 600 ml TV. adjust regulator pressure until 600 ml is read on vent.
        - Test measured tidal volume: Citrex should report volumes between 540 to 660 ml (+/- 10%)
        - Log 15 seconds of Citrex data
- Verify RR is adjustable, and RR is accurate
    - Adjust RR to 10, 20, and 30; check cycle count with stopwatch
- Verify IE is adjustable and IE timing is accurate
    - Adjust IE to 1:4, 1:3, 1:2 and 1:1; check I:E split
- Verify Inspiratory Pause is functional
    - Turn Inspiratory Pause to “on” via menu
    - Time pause at end of inspiratory cycle with stopwatch (should have no airway flow during pause)
- Verify pause length to be 1/3 of active inspiratory time
- Verify Overpressure relief valve
    - Ventilator controller off
    - Set MTL compliance to 0.02 L/cmH2O (protects MTL bellows from overtravel)
    - Plug expiratory port
    - Adjust overpressure relief valve to max
    - Manually open inspiratory valve, stop if pressures reach 100 cmH2O
    - Verify airway pressure on Citrex not over 65 cmH2O
    - Manually adjust overpressure valve to min
    - Verify airway pressure on Citrex between 35 – 45 cmH2O

Ventilator Anti-Asphyxia Test
configuration: Citrex between Y piece and 1L calibration syringe

- Ventilator controller off
- Connect 0.5L calibration syringe at Y piece in place of MTL
- Pull 0.5L calibration syringe open in one second, use stopwatch
- Check anti-asphyxia valve opens and airway pressure did not drop below – 3 cmH2O

Alarms Test

configuration: Citrex between Y piece and MTL set to normal compliance, one bellows, no PEEP, ventilator controller turned on

- Verify Patient Disconnect condition triggers alarms in low flow vent settings
    - Alarms Test base configuration
    - Vent settings: RR 12, IE 1:2, TV 250 mL, no PEEP
    - While ventilator is running, disconnect breathing circuit from 22mm inspr limb
    - Wait 4 seconds for audible alarm and UI to display "LOW AIRWAY PRES!" and "SET TV NOT DELIV"
    - Reconnect breathing circuit
    - Wait 4 seconds for audible alarm and UI display "LOW AIRWAY PRES!" and "SET TV NOT DELIV" to clear
    - Repeat test, disconnect breathing circuit from 22mm expr limb
    - Repeat test, disconnect breathing circuit Y-piece from MTL
- Verify Patient Disconnect condition triggers alarms in high flow vent settings
    - Alarms Test base configuration
    - Vent settings: RR 30, IE 1:2, TV 600 mL, no PEEP
    - While ventilator is running, disconnect breathing circuit from 22mm inspr limb
    - Wait 4 seconds for audible alarm and UI to display "LOW AIRWAY PRES!" and "SET TV NOT DELIV"
    - Reconnect breathing circuit
    - Wait 4 seconds for audible alarm and UI display "LOW AIRWAY PRES!" and "SET TV NOT DELIV" to clear
    - Repeat test, disconnect breathing circuit from 22mm expr limb
    - Repeat test, disconnect breathing circuit Y-piece from MTL
- Verify Loss of Gas Supply Pressure condition triggers alarms in low flow vent settings
    - Alarms Test base configuration
    - Vent settings: RR 12, IE 1:2, TV 250 mL, no PEEP
    - While ventilator is running, disconnect gas supply to ventilator at wall supply connection
    - Wait 4 seconds for audible alarm and UI to display "LOW AIRWAY PRES!" and "SET TV NOT DELIV"
    - Reconnect gas supply to ventilator

    - Wait 4 seconds for audible alarm and UI display "LOW AIRWAY PRES!" and "SET TV NOT DELIV" to clear
- Verify High inspiratory airway pressure alarm:
    - Alarms Test base configuration
    - Set MTL to low lung compliance (0.02 L/cmH2O)
    - Adjust high inspiratory airway pressure alarm limit to 15 mH2O
    - Ventilator on and connected to MTL
    - Vent settings: RR 15, IE 1:2, TV 600 mL, PEEP 10
    - Wait 2 seconds for audible alarm and UI to display "OVER PRES ALARM!" and "LOW VT, IT SHORTENED"
    - Inspiratory solenoid valve should close to stop inspiratory flow
    - verify pressure in the inspiratory circuit does not go above 16 cmH2O during inspiration using Citrex
    - Adjust high inspiratory airway pressure alarm limit to 35 cmH2O (default)
    - Wait 4 seconds for audible alarm and UI "OVER PRES ALARM!" and "LOW VT, IT SHORTENED" to clear
- Verify TV High alarm:
    - Alarms Test base configuration
    - Set TV high alarm limit to 400mL
    - Turn ventilator on and connect to MTL
    - Vent settings: RR 15, IE 1:2, TV 500 mL
    - Wait 4 seconds for audible alarm and UI to display "TV HIGH"
    - Set TV high alarm limit to 1000mL
    - Wait 4 seconds for audible alarm and UI display "TV HIGH" to clear
- Verify TV Low alarm:
    - Alarms Test base configuration
    - Set TV low alarm limit to 400mL
    - Turn ventilator on and connect to MTL
    - Vent settings: RR 15, IE 1:2, TV 300 mL
    - Wait 4 seconds for audible alarm and UI to display "SET TV NOT DELIV"
    - Set TV low alarm limit to 200mL
    - Wait 4 seconds for audible alarm and UI display "SET TV NOT DELIV" to clear

Backup Battery test

configuration: Citrex between Y piece and MTL set to normal compliance, one bellows, no PEEP

- Verify Ventilator can run for 30 minutes on backup battery power
    - Ventilator on, RR 30, IE 1:2
    - Set TV low alarm limit to 800mL to create constant alarm (max battery drain)
    - Attempt 500 ml TV. adjust regulator pressure until 500 ml as read on Citrex.

- Log 15 seconds of Citrex data
- Log 15 seconds of Citrex data after 30 minutes