RADX

Ventil-Con

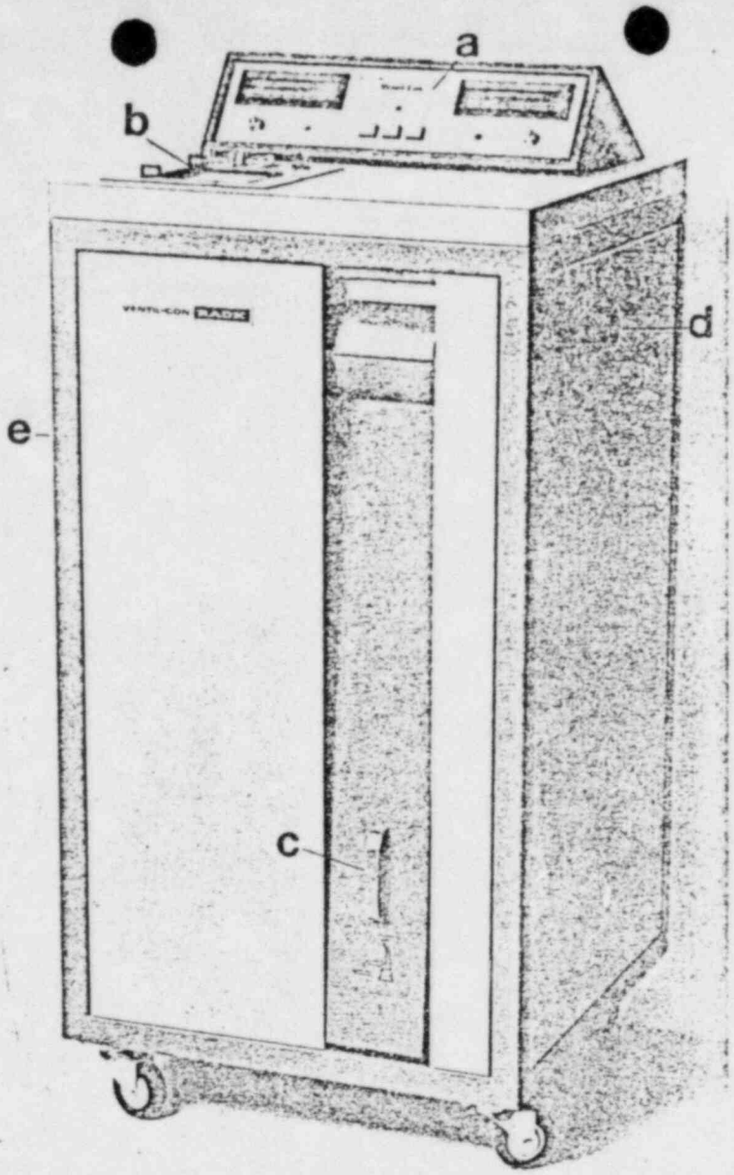

Figure 1. The Ventil-Con with dual channel strip chart recorder.
a. control panel
b. dual channel strip chart recorder
c. delivery arm
d. gas inlet valve
e. mobile console.

VENTIL-CON OPERATION MANUAL

1.0 INTRODUCTION

Since the initial application of radioactive gases for assessment of regional ventilation in 1955, the clinical utilization of this technique has rapidly expanded. Although radioactive gases such as ^{15}O, ^{11}CO, $^{11}CO_2$, ^{13}N, and ^{81m}Kr have been used, Xenon-133 is presently the most widely used for ventilation and exchange studies. Furthermore, ^{133}Xe will probably continue to be the preferred radionuclide since these other isotopes must be used near the cyclotron or reactor where produced because of their short physical half-lives.

Historically, ^{133}Xe gas ventilation studies have been performed using three basic techniques: 1) intravenous injection of ^{133}Xe dissolved in saline, 2) ^{133}Xe in air administered by a single inhalation; and 3) allowing the patient to breathe a ^{133}Xe air mixture until the lung activity reaches equilibrium and determining the rate of ^{133}Xe clearance during subsequent air breathing. Of these three methods, the third and last has been shown to produce the smallest standard error for measuring the distribution of ventilation (1).

(1). Jones, R.H., Goodrich, J.K., Sabiston, D.C.: Evaluation of ^{133}Xe techniques for measurement of regional ventilation. J Nucl Med, 7, 598-604, 1974.

1.1 Purpose

The Radx Ventil-Con Controlled Gas Delivery System has been designed to allow the clinician to perform ventilation studies using any method described above. The instrument is capable of "single breath/washout," "single breath/equilibrium/washout," or "equilibrium/washout" studies. Administration of Xenon gas may be by bolus, homogeneous mixture, or by patient injection of Xenon dissolved in saline.

1.2 Description

1.2.1 Console (Figure 1) - The Ventil-Con is completely self-contained, except for the oxygen supply, in a mobile, caster-mounted console. Each side panel and the rear panel are easily opened for convenient access to all interior components. All controls (except for the oxygen regulator valve) and information outputs are centrally located on the top of the unit. (See Figure 2.)

1.2.2 Spirometer - The ten-liter capacity dry spirometer is constructed of spun aluminum and the entire airway plumbing is fabricated of non-corrugated, smooth-surface PVC. The spirometer is mounted horizontally on extremely low friction linear roller bearings which allow the patient to breathe normally without any external inducement or resistance. Measure resistance is 0.2 inches of water under normal breathing condition. Also, since up to 70% of the total activity in the Ventil-Con will be in the spirometer it has been totally enclosed with lead sheet. (See Figure 3.)

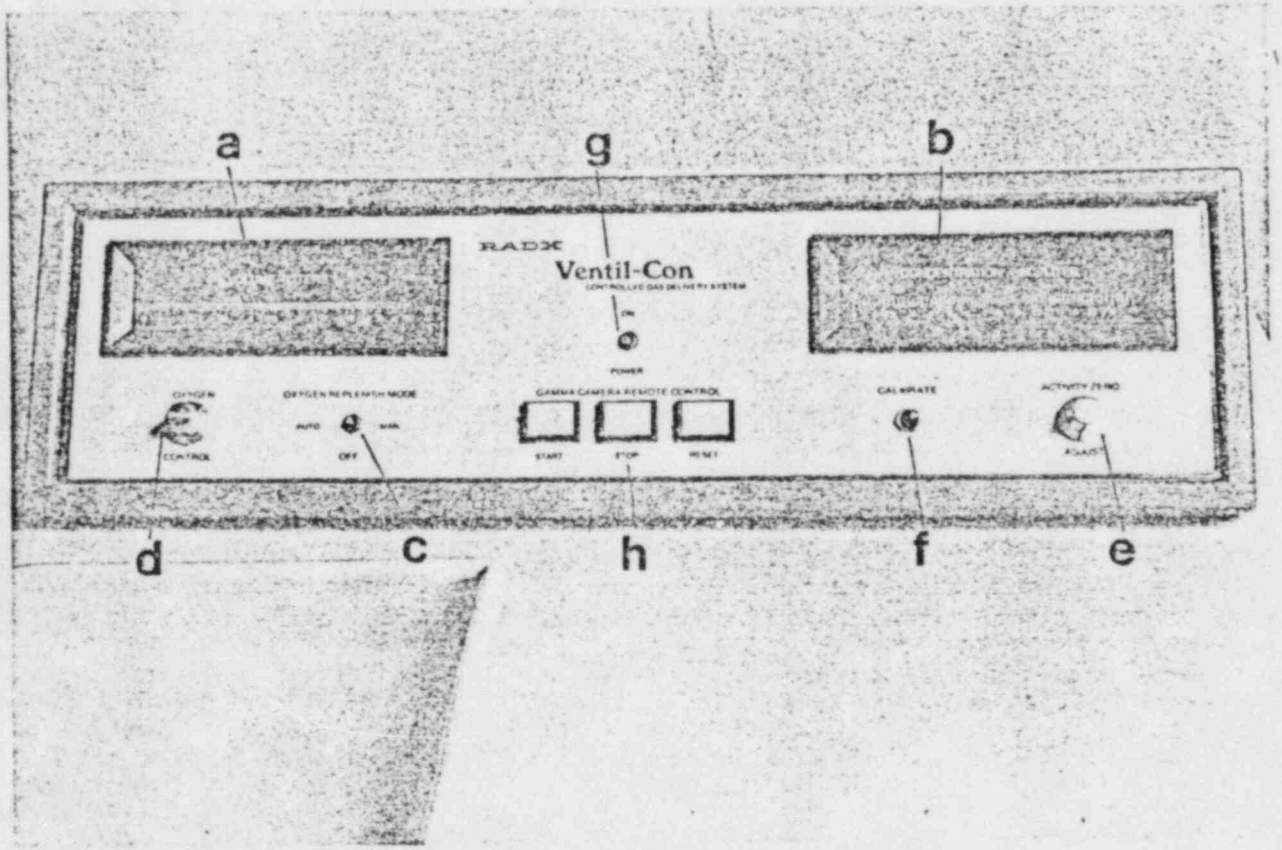

Figure 2. Control panel. a. volume meter b. concentration meter
c. oxygen replenishment mode selector d. oxygen control knob
e. activity zero adjust knob f. activity calibrate potentiometer
g. power switch h. remote control switches for gamma camera

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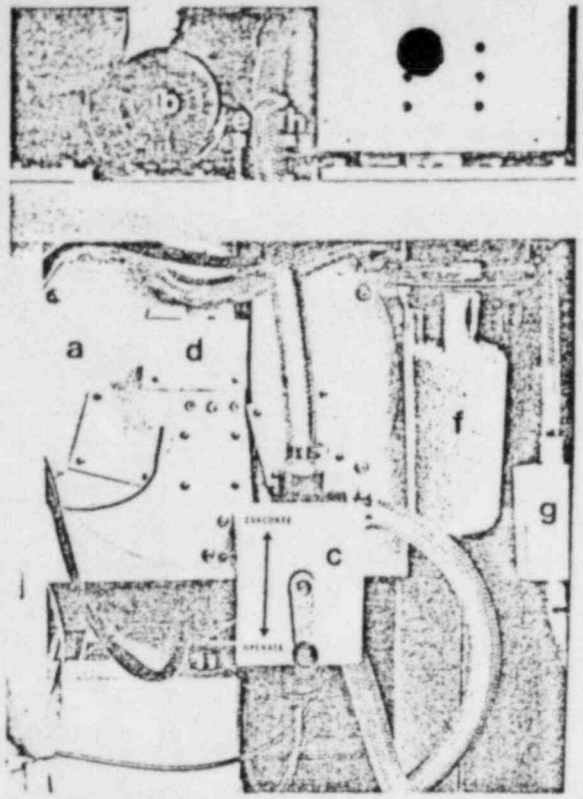

Figure 3. Ventil-Con, internal.
a. spirometer lead lined housing
b. recirculation pump
c. evacuate/operate valve
d. cable driven potentiometer housing
e. oxygen replenish solenoid
f. soda lime CO_2 trap
g. bacteriological filter
h. emergency oxygen assist solenoid

1.2.3 Recirculation Pump (Figure 3) - This is a continuous duty "flame isolated" pump motor which insures a completely homogeneous air/gas mixture. The pumping capacity and head configuration is designed in such a way as to offer no resistance to patient breathing in addition to providing gas flow direction. "Flame isolation" is necessary since O_2 is continuously added to the system during the study. It is achieved by magnetic rather than mechanical coupling between the pump and drive motor.

1.2.4 Delivery Arm (Figure 4) - The delivery arm is 31 inches long (including valve head) and is infinitely adjustable to a maximum breathing port height of 60 inches. The arm is completely lead shielded to prevent interference with the gamma camera and to minimize patient and technician exposure. The valve head employs the Radx patented three-way valve which transfers the patient from the "stabilization-washout" loop to the "closed-rebreathing" loop.

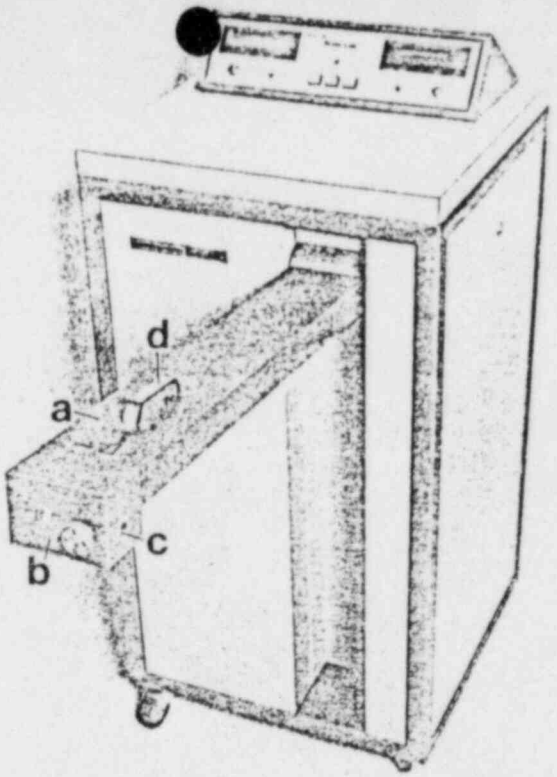

Figure 4. Ventil-Con with delivery arm extended.
a. delivery arm
b. head valve
c. breathing port
d. handle

1.2.5. Control Panel Readouts

1.2.5.1 Volume - Spirometer volume is a direct function of the rolling diaphragm position and can be related to various lung parameters through numerical analysis. Spirometer position on the Ventil-Con is determined by a cable driven potentiometer mounted to the spirometer housing above the Evacuate/Operate valve. (See Figure 3.) The signal from the potentiometer appears as volume (in liters) on the volume meter on the control panel. (See Figure 2.)

1.2.5.2 Concentration - An end-window GM tube (mounted perpendicular to the airway carrying the radioactive gas/air mixture from the spirometer to the patient) monitors the concentration of the gas mixture breathed by the patient. (See Figure 5.) The amplified signal from this GM tube appears on the concentration meter on the control panel (See Figure 2). The concentration can be increased simply by adding more radioactive gas to the system. It can be decreased by purging the system to the desired degree and then adding room air or O_2 until the desired concentration is obtained. (See also Paragraph 3.1.3)

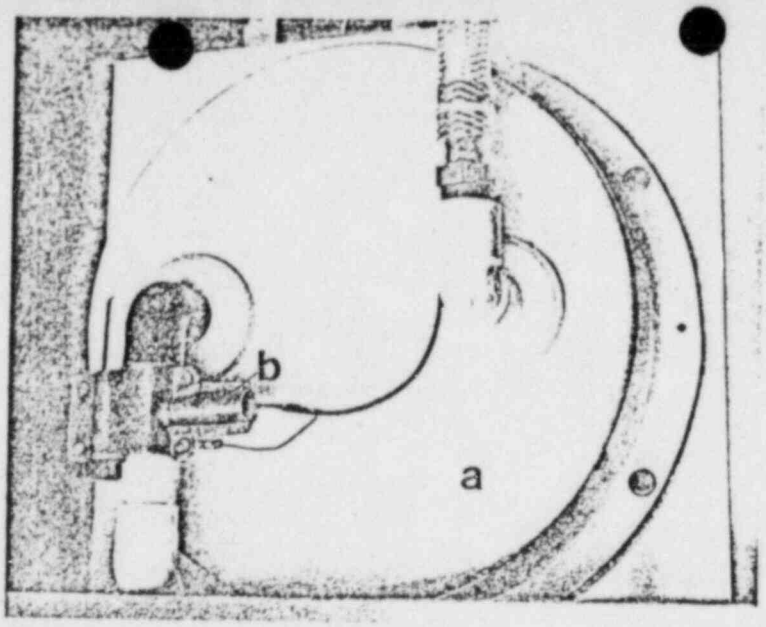

Figure 5. Ventil-Con, internal right side.
a. lead lined spirometer housing – rear
b. G-M detector

1.2.5.3. Strip Chart Recorder - An accessory to the Ventil-Con, the dual channel strip chart recorder, provides a permanent, continuous, analog record of the volumetric change of the spirometer diaphragm and the concentration of the gas/air mixture. (See Figure 1.)

1.2.6 Oxygen Replenishment Mechanism - Because O_2 is extracted from inhaled gases and replaced by CO_2, it is necessary that any closed breathing apparatus provide for the addition of sufficient O_2 to maintain the proper oxygen concentration. The Ventil-Con has three modes of oxygen replenishment, MANUAL, AUTOMATIC and EMERGENCY ASSIST. (See Figure 2.) The oxygen supply is connected to the O_2 supply tube which carries the O_2 to a solenoid. (See Figure 3.) This solenoid acts like a faucet which, when opened, releases a predetermined volume of O_2 into the airway to be homogeneously mixed with the gas/air mixture already circulating. The volume of O_2 released into the system is matched to the individual patient's consumption rate and is set by adjusting the oxygen control knob on the control panel. (See Figure 2.) The Emergency Oxygen Assist is activated by a pushbutton next to the head valve. It is an entirely separate system from the Automatic/Manual and releases O_2 directly into the head of the unit allowing immediate patient relief.

1.2.7 Carbon Dioxide Adsorber - A soda lime CO_2 trap is employed in the system to remove patient expired CO_2. The trap is rechargeable and is found to the right of the Evacuate/Operate Valve. (See Figure 3.)

1.2.8 Bacteriological Filter - The Ventil-Con is designed so that the Xenon/Air/Oxygen mixture stored in the unit may be used on successive patients without purging and refilling the system. To facilitate repeated patient use the unit is equipped with an autoclavable, removable, bacteriological filter. The filter employed is an ultra-high-efficiency low-pressure drop particulate filter. It is of the type classified by the USPHS and US Army Chemical Corps as more than 99.99% efficient on bacteria of 1 to 5 micron diameter by their standard test method. 99.97% retention of 0.3 micron particles is the minimum efficiency of a new filter. As the volume of particles deposited on the filter increases, the particles themselves may increase the effectiveness.

Diameter and length of most bacteria range from 0.3 micron up. In reproduction, they may form groups considerably larger. Bacteria in air will usually not appear singly, but rather in droplets, or attached to particles of dust, lint or skin. Filter retention of agglomerated or passenger bacteria will approach 100%.

The filter will be found attached inline directly to the right of the Evacuate/Operate Valve. (See Figure 3.)

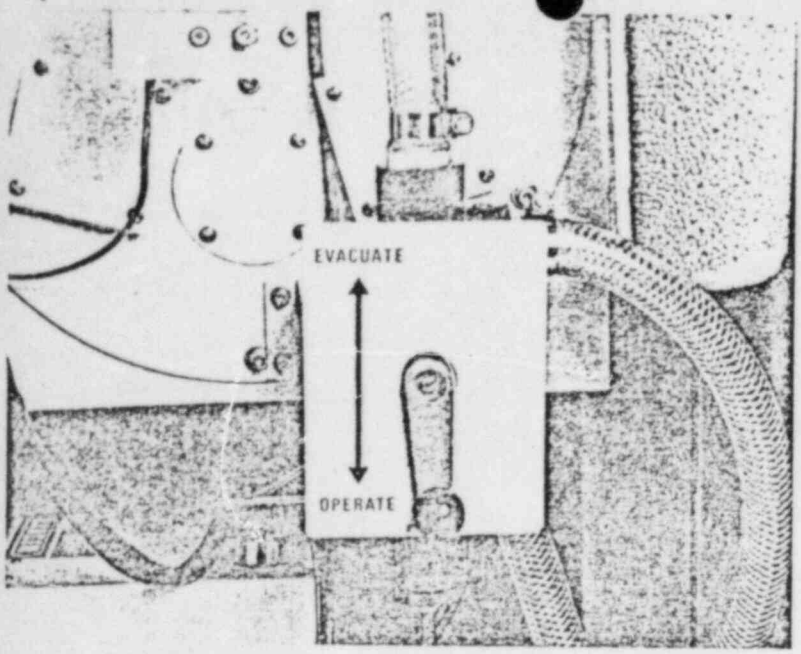

Figure 6. Flow selector valve in Operate position

2.0 INSTALLATION

BEFORE PLUGGING THE VENTIL-CON INTO AN ELECTRICAL OUTLET, PERFORM THE FOLLOWING CHECKS:

NOTE: For purposes of orientation, as you look at the Ventil-Con, the "front" of the console houses the delivery arm, the "right side" houses the Luer-lock gas inlet valve (Figure 1), and the "left side" is the access door.

2.1 Upon its arrival, carefully remove all shipping materials. Obtain and identify all items indicated on the packing slip to insure the shipment is complete.

2.2. Visually inspect the console for any indications of damage while in transit. Carefully check the control panel for any damage to switches, readout meter, knobs, etc.

2.3 Remove the CO_2 adsorber jar by turning counterclockwise. Carefully fill the trap with the quart of soda lime furnished. When replacing the trap be sure the center tube is aligned with the center hole on the cap and that the bottom is screwed securely in place.

NOTE: When the soda lime turns blue in color, it has become saturated with CO_2 and must be replaced. The soda lime color should be checked daily.

2.4 Insure that the Flow Selector Valve (Refer to Figure 6) is in the OPERATE (Vertical-Down) position. THE POSITION OF THE FLOW SELECTION VALVE IS EXTREMELY CRITICAL TO THE PROPER OPERATION OF THE VENTIL-CON!

2.4.1 When performing a study or any action on the Ventil-Con other than evacuating the system, the Flow-Selector Valve MUST BE IN THE "OPERATE" POSITION.
IMPORTANT: NEVER LEAVE THE VALVE HANDLE IN ANY POSITION EXCEPT VERTICAL. IF THE VALVE HANDLE IS LEFT IN EITHER HORIZONTAL POSITION, THE VALVE HEAD CAN BE PERMANENTLY DAMAGED AND/OR THE RECIRCULATION PUMP WILL BE OVERLOADED AND BLOW THE 5 AMP FUSE.

2.5 The Ventil-Con is designed to operate on 115 Volts AC $\pm$ 10% at 60 Hz with a maximum power requirement of less than 6 amps. If the Ventil-Con is to be used in an environment where other than 115 volts at 60 Hz is standard, the proper transformer has been installed to convert from local power conditions to those required by the electronic circuits.

2.5.1 Plug the AC power cord into a standard, three-pronged, grounded outlet. DO NOT USE A CHEATER PLUG OR ADAPTER.

2.6 Flip the Power Switch on the control panel to the ON position.

2.7 Allow the Ventil-Con to warm up at least 30 minutes before proceeding with the preoperation checks.

2.8 The Ventil-Con exhaust connectors are located in the rear of the unit and are for use with 3/4" I.D. x 1" O.D. PVC tubing (Figure 7). A screw-in hose adapter has been provided as an accessory. If 3/4" I.D. tubing is to be used from the Ventil-Con to the external trap or exhaust system, screw the male hose adapter into the female (3/4" pipe thread) fitting on the rear panel and connect the exhaust tubing. If larger I.D. tubing is desired, use a reducer adapter for the tubing I.D. desired. If the Ventil-Con is to be used with the Radx Xenon Gas Trap an interface tube is available as catalog number 127.

NOTES: 1) Use Teflon tape sealant on the threads to insure an airtight connection.
2) Use larger I.D. tubing if the distance from the Ventil-Con to the exhaust system is greater than 10 feet.

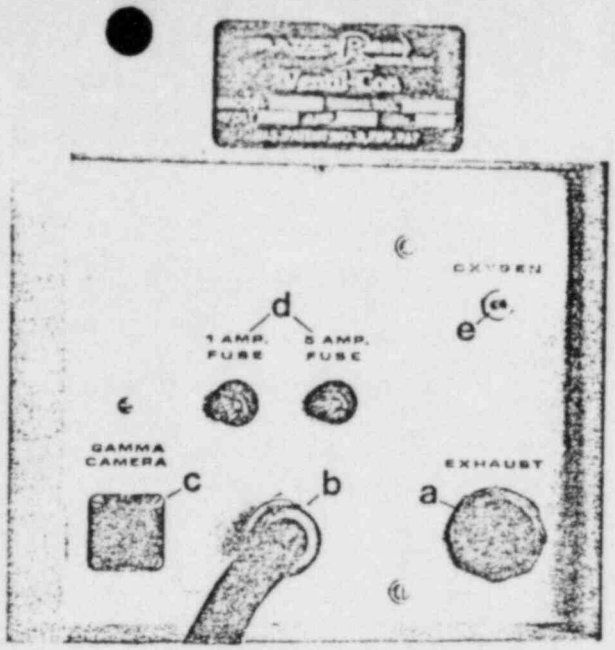

Figure 7. Connection box at rear of Ventil-Con.
a. 3/4" I.D. threaded exhaust port
b. power cable c. remote gamma camera connector
d. fuses e. 11/64" O.D. oxygen inlet connector

2.9 Oxygen Supply

The O_2 supply can be either an external wall-mounted apparatus or an external cylinder.

2.9.1 At the rear of the unit is a male connector marked "oxygen" for 11/64" I.D. tubing. (See Figure 7.) Join the O_2 supply to this connector with appropriate diameter tubing. It may be necessary to clamp the 11/64" tubing to the male hose connector of the flowmeter on the external O_2 supply.

2.9.1.1 Turn the flowmeter adjustment knob on the O_2 source to the fully closed position (zero flow).

2.9.1.2 Open the regulator valve (turn counter-clockwise) until the internal cylinder pressure appears on the pressure gauge. The maximum pressure on the outflow side of the supply valve should be 3 PSI.

2.9.1.3 Hold the Oxygen Replenish Mode switch on the control panel in the MANUAL position.

2.9.1.4 Adjust the flowmeter for a flow rate of 2 liters/min.

2.9.1.5 When the flow rate has been properly adjusted, release the Oxygen Replenish Mode switch and it will return to the OFF position. (Refer to Paragraph 3.1.4.1 for procedure precautions.)

2.10 This completes the initial installation of your Ventil-Con. If you encountered any problems or have any questions, contact RADX immediately to preclude any damage to the instrument.

3.0 CONTROLS AND ADJUSTMENTS

3.1 Control Panel (Refer to Figure 2.)

3.1.1 Power Switch - This switch controls the power to the entire Ventil-Con.

3.1.1.1 The Ventil-Con should be turned ON and allowed to warm up at least 30 minutes before any tests, calibrations, charging procedures, or studies are performed with it.

3.1.1.2 To prolong the useful lifetime of the recirculation pump, the Ventil-Con should be turned OFF during periods of nonuse.

3.1.2 Volume Meter - This meter indicates the volume of the ten-liter spirometer. (See also Paragraph 1.2.5.1.) The response time (time lag between the spirometer's achieving a new volume and the meter's indicating that new volume) is approximately 150 milliseconds and is considered insignificant.

3.1.3 Concentration Meter - This meter indicates the concentration of the radioactive gas/air mixture in units of "mCi/liter". (See also Paragraph 1.2.5.2.) The signal which drives the meter is the integral of the individual pulses from the GM tube. There is also a response time (time delay) associated with the concentration readout. Once the Ventil-Con has been allowed to warm up, the total response time of this readout is approximately eight seconds. The response time will be relatively insignificant during actual studies because the concentration will remain constant once a homogeneous gas/air mixture has been achieved.

3.1.3.1 Activity Zero Adjust - When the Ventil-Con has been purged of all gases and is free of any radioactive gas, this adjustment is used to zero the concentration readout meter to compensate for any background radioactivity being detected by the GM tube.

3.1.3.2 Calibrate - This screwdriver-adjust potentiometer is used to calibrate the concentration readout so that the meter depicts the concentration of the gas/air mixture in the system. (See Paragraph 5.3 for the correct calibration procedure.) The meter must be zero-adjusted prior to calibration.

3.1.4 Oxygen Replenish Mode - Oxygen can be selectively added to the radioactive gas/air mixture either automatically or manually.

3.1.4.1 Manual Mode - Each time the switch is placed in the MANUAL position, the oxygen replenishment solenoid is opened which causes O_2 to enter the gas/air mixture at whatever rate has been established on the oxygen supply regulator. The oxygen replenishment solenoid will remain open until the switch is released to the OFF (or center) position. Proper O_2 supply rate is 2 liters per minute at 3 PSI maximum.

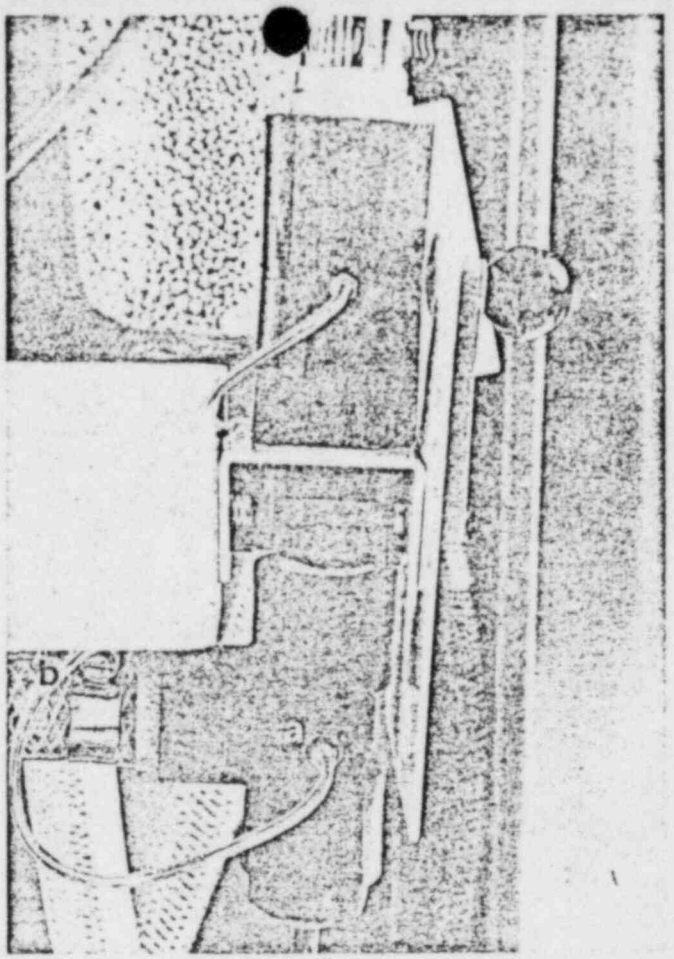

Figure 8. Side view of operate/evacuate valve showing
a. pressure relief valve
b. relief tube

NOTE: CARE MUST BE EXERCISED TO INSURE THAT THE OXYGEN REPLENISHMENT SWITCH IS NOT ALLOWED TO REMAIN IN THE MANUAL POSITION AFTER THE SPIROMETER HAS BEEN FILLED TO CAPACITY (10 LITERS). SINCE PRESSURIZATION OF THE SPIROMETER TO NORMAL REGULATOR/FLOWMETER PRESSURE (3 PSI) COULD INDUCE LEAKS, A PRESSURE RELEASE VALVE HAS BEEN INSTALLED IN THE AIRWAYS. (SEE FIGURE 8.) THIS VALVE WILL OPEN IF THE AIRWAYS PRESSURE REACHES TWO (2) INCHES OF WATER (0.5 PSI) AND RELEASE THE CONTENTS OF THE AIRWAYS INTO THE EXHAUST TUBE UNTIL THE PRESSURE DROPS BELOW TWO (2) INCHES OF WATER. THE SYSTEM WILL NOT BEGIN TO PRESSURIZE UNTIL THE SPIROMETER HAS BEEN EXPANDED TO CAPACITY.

3.1.4.2 Automatic Mode - With the switch in this position, the Ventil-Con will automatically add a predetermined volume of O_2 to the gas/air mixture. The O_2 replenishment solenoid is activated once during each respiratory cycle as the spirometer changes direction. The length of time the solenoid valve remains open is determined by the position of the Oxygen Control Knob. (See Section 3.1.5 below.)

3.1.5 Oxygen Control - The oxygen control knob is an operator adjustment which controls the length of time the solenoid valve remains open and therefore the amount of O_2 being added to the total gas/air mixture volume to replace the O_2 used by the patient during each respiration (WHEN THE OXYGEN REPLENISH MODE SWITCH IS IN THE AUTO POSITION). The proper setting for each patient must be determined individually IMMEDIATELY AFTER THE PATIENT BEGINS BREATHING THE RADIOACTIVE GAS/AIR MIXTURE DURING THE "EQUILIBRIUM" PHASE OF THE STUDY. The proper procedure for this is explained in detail in Paragraph 6.1.10. In addition, there is an emergency O_2 assist in the head of the unit. (See Section 4.5.)

3.1.6 Gamma Camera Remote Control Switches - These three switches, "START," "STOP," and "RESET," duplicate the sequence command switches on most available scintillation cameras. Once the 20' remote control cable is properly connected to the gamma camera, a single technician can perform the entire study without leaving the Ventil-Con. Connection to your gamma camera should be done by a qualified serviceman.

3.2 Strip Chart Recorder - (Figure 9)

Even though this instrument is classified as an accessory to the Ventil-Con, the application of this permanent, visual readout greatly simplifies the performance of the ventilation study and enhances the usefulness of the derived information.

3.2.1 Gain - The recorder has a built-in volume scale expansion circuit which allows the user to increase the sensitivity of the recorder to a multiple of the Volume Meter. There are ten (10) scale dots around the Gain knob. When the indicator mark on the knob is aligned with the most counterclockwise scale dot, the "spirometer volume-to-recorder output" ratio is approximately 1:1; i.e., a one liter change in spirometer volume will result in one major division deflection on the recorder volume chart. Also, when the mark on the knob is aligned with the most clockwise of the scale dots, the ratio is approximately 1:10; that is, a one liter change in spirometer volume will appear as a 10 major division deflection on the recorder volume chart.

3.2.2 Pos. - This control allows the operator to reposition the volume stylus to compensate for variations in starting points of patient breathing excursions. The use of the Pos. knob becomes very important in high volume gain settings which would be common in pediatric patients and in cases of incipient pulmonary disorders.

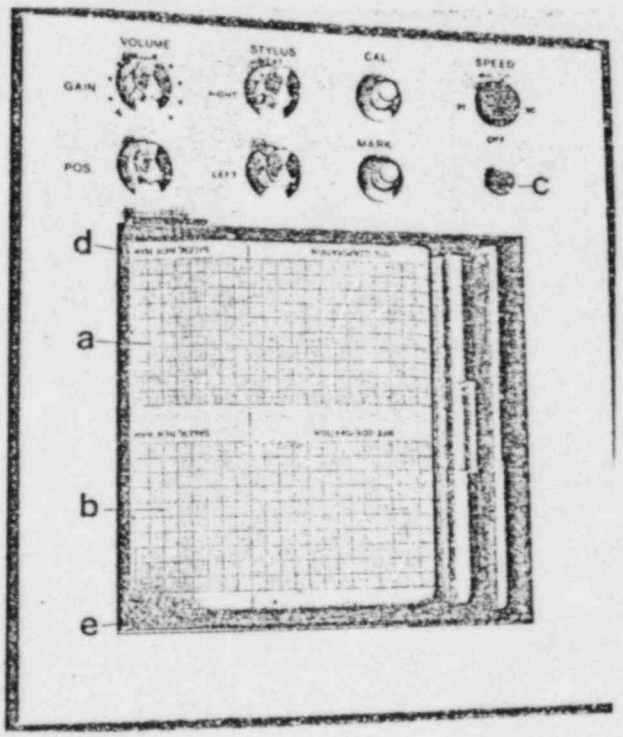

Figure 9. Dual channel strip chart recorder.
a. concentration channel
b. volume channel
c. Power On lamp
d. "Start/Stop" remote marker
e. detail marker

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3.2.3 Stylus Heat - These two controls adjust the amount of heat applied to the two styli of each recorder channel. The strip chart paper used is primarily heat sensitive.

3.2.3.1 Right - This conrols the stylus heat on the concentration channel which is the channel closest to the recorder control knobs.

3.2.3.2 Left - This controls the stylus heat on the volume channel which is farthest from the recorder controls.

CAUTION: Stylus heat can be increased to the point of actually burning the recorder paper.

3.2.4 Cal. - This pusbutton, momentary switch is primarily used for initial factory calibration. It is designed to give a 0.5 liter deflection on any gain setting but the tolerances are such (± 5% full scale) that it is only meaningful at high gain settings.

3.2.5 Mark - The recorder's two digital outputs are the two position markers, one located in each exterior margin of the chart paper. The Mark pushbutton switch is a momentary type which causes the stylus in the margin adjacent to the volume channel to place a dot on the paper. This marker is to be activated completely at the discretion of the operator. The marker stylus in the margin adjacent to the concentration channel is activated whenever the START button on the control panel is depressed. This stylus continually marks the paper until the STOP button is depressed. This gives a visual record of the length of time that data is being collected by the gamma scintillation camera.

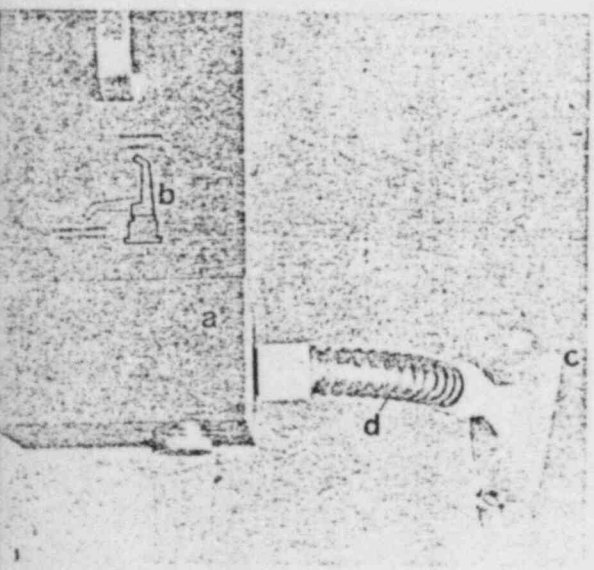
3.2.6 Speed - The chart paper speed is controlled by this three-position switch (the center is OFF). Two speeds, 25 mm/min. and 50 mm/min. are available. This is also the Power ON/OFF switch for this recorder.

3.2.7 Power ON Lamp - This red lamp indicates that power is on to the recorder.

4.0 DELIVERY ARM

4.1 Description - The delivery arm (See Figure 4) is the only part of the Ventil-Con with which the patient is concerned. It is infinitely adjustable to any breathing height up to 60 inches, completely shielded, contains the Radx patented three-way valve, and carries the gas/air mixture to the patient.

4.2 Head Valve (Figures 10a, b & c) - The Head Valve consists of the 1) room air intake port, 2) breathing port, 3) loop selector lever and 4) emergency oxygen assist button.



gure 10a.
p view of valve head with mouthpiece interfaced breathing port.
a. valve head.
b. loop selector lever position diagram
c. mouthpiece
d. interface tubing

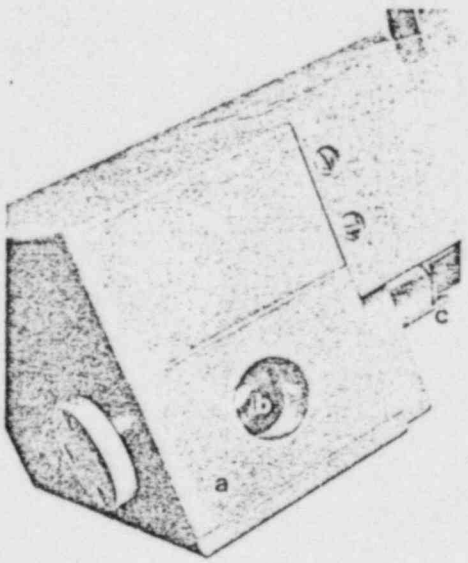


Figure 10b. Side view of valve head.
a. valve head
b. breathing port
c. loop selector lever.

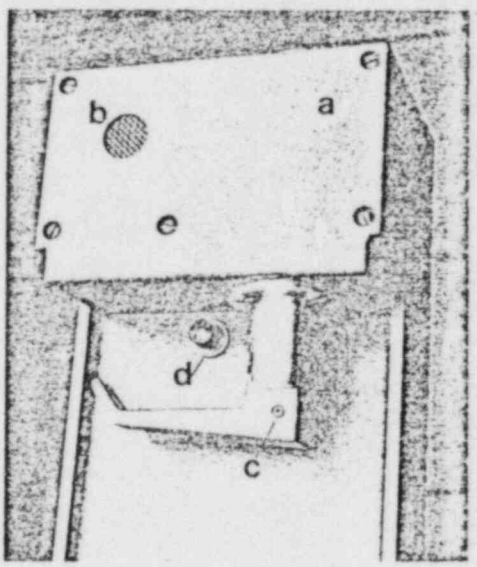


Figure 10c. Bottom view of valve head.
a. valve head
b. room air intake port
c. loop selector lever
d. emergency assist oxygen pushbutton.

4.2.1 Loop Selector Lever - This lever is used to select which of the two breathing loops the patient will be breathing on during a study.

4.2.1.1 "Stabilization/Xenon Washout" Loop - When the patient is on this loop, room air is inhaled through the intake port's one-way valve. The exhaled gases pass through a one-way exhaust valve and out through the Ventil-Con's exhaust tube (Refer to Figure 7). This loop is utilized while the patient is reaching stabilization and also during the washout phase of the study.

4.2.1.2 "Xenon Rebreathing" Loop - While on this loop, the patient rebreathes the radioactive gas/air mixture until equilibrium is reached. All exhaled gases remain in this closed loop with the CO_2 extracted from and O_2 added to the gas mixture during recirculation. "Xenon Rebreathing" position may also be used for single breath, bolus and Xenon injection studies.

4.2.2 Room Air Intake Port - Room air is inhaled through this opening. A one-way valve opens this port only during inhalation and insures no radioactive gas escapes to the atmosphere during washout

4.2.3 Breathing Port - A variety of mouthpieces are adaptable to the breathing port. To insure against any radioactive gas entering the atmosphere, the mouthpiece should 1) be easily sterilized or disposable; 2) be readily adaptable to various patient positions; 3) provide positive leak protection such as a seal over the mouth area, adjustable headstrap, etc.; and 4) be used in conjunction with a nose clamp where appropriate.

NOTE: The mouthpiece supplied with your unit is a Radx Number 109 Adult Mouthpiece with headstrap. Figure 11 shows this mouthpiece plugged into the breathing port and ready for use. The pediatric version, which covers the nose and mouth, is Number 108 Infant Mask available in three sizes, small, medium and large. Additional types are also available which interface directly with the Ventil-Con. Figure 12 shows a selection of the various types.

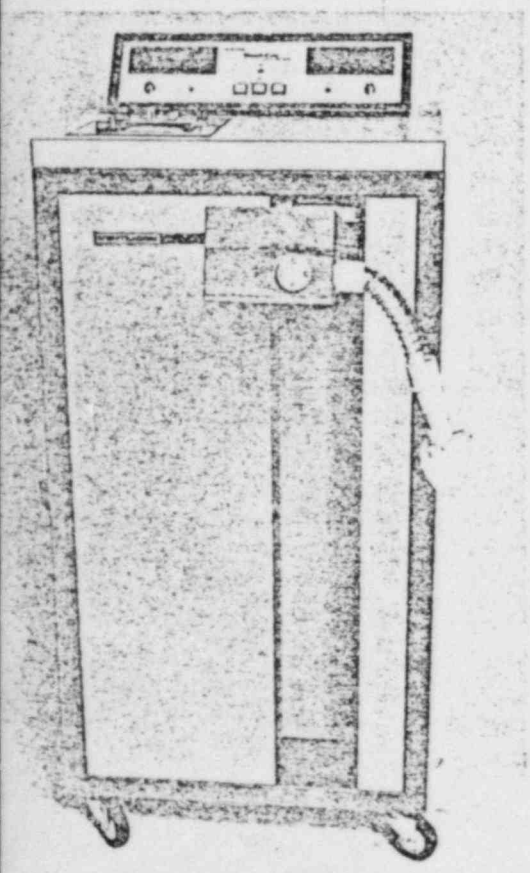


Figure 11. Ventil-Con with Radx No. 109 Adult Mouthpiece connected to breathing port ready for use.

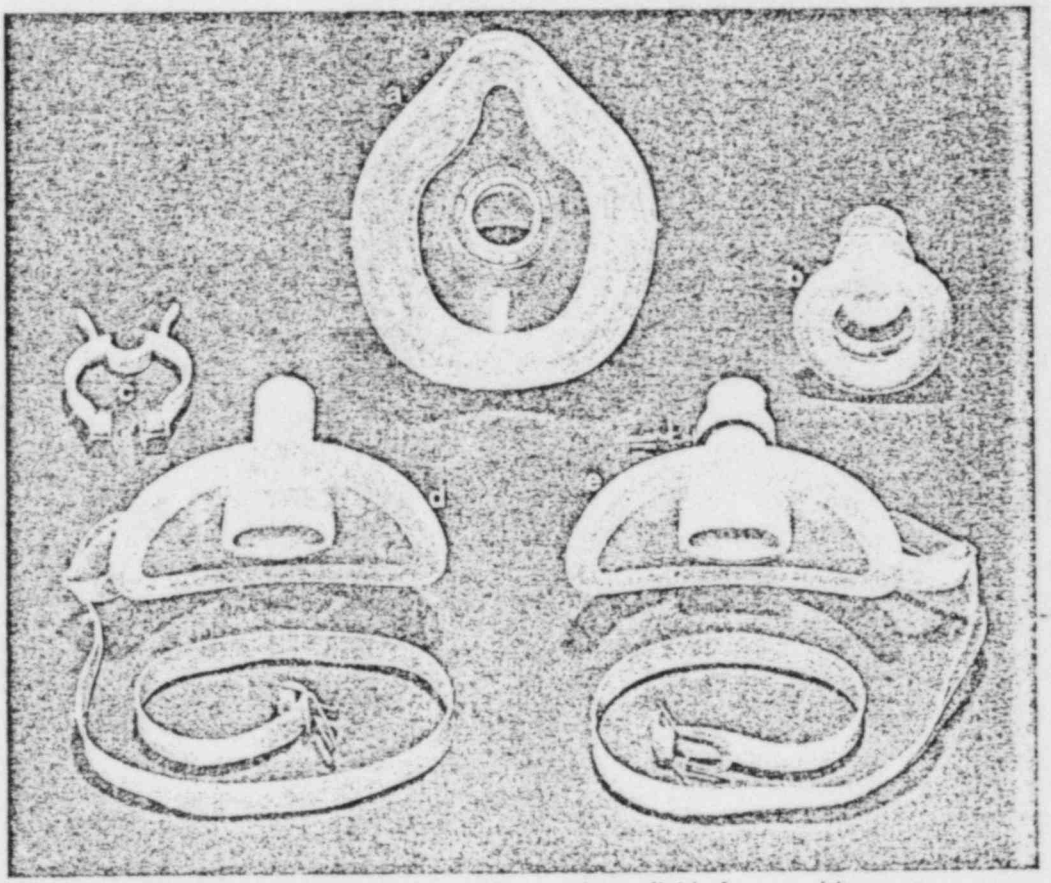


Figure 12. Various mouthpieces and face masks available for use with the Ventil-Con. a. adult face mask b. pediatric face mask c. nose clamp for mouthpieces d. adult mouthpiece e. adult mouthpiece with bolus injection valve

Multiple view lung ventilation studies in the equilibrium phase are as important as multiple view lung perfusion studies. The Ventil-Con is equipped with swivel adapter which allows patient movement without breaking the closed loop in the "Xenon Rebreathing" position. Use of the swivel requires that the patient be in a sitting position for imaging. (See Figure 13.)

4.3 Shielding - The entire delivery arm, except for the valve head, is shielded with 1.56 mm (1/16") thick lead. For ^{133}Xe photons under broad beam conditions, this is approximately equal to 5 "half-thicknesses." The total weight of the delivery arm is about 40 lbs.

4.4. Height Adjustment - The breathing port can be adjusted to the optimum height for each patient simply by raising or lowering the delivery arm. The delivery arm is held in position by two spring-loaded, self-adjusting, "fail-safe," friction brake drums. This type of positioning mechanism is 100% safe since there are no gears, handles, catches, etc., to break which could allow the delivery arm to fall and injure a patient.

4.5 Emergency Oxygen Assist - This button directly in front of the Loop Selector Lever on the underside of the Delivery Arm (See Figure 10c) allows the operator to deliver O_2 directly to the patient as required. It is a momentary pushbutton which opens a solenoid valve that allows O_2 to empty directly into the head valve.

5.0 OPERATOR CALIBRATION PROCEDURES

5.1 Volume Meter

5.1.1 With the Evacuate/Operate valve in the Operate position and the Head valve in the "Xenon Rebreathing" position, gently compress the spirometer to "O" volume by pushing in the center rod connected to cable driven potentiometer. (See Figure 14.) With the rod fully in, the volume meter should read 0 ± 0.5 liters.

5.1.2 Expand the spirometer to full capacity by gently pulling the same rod fully out. The volume meter should read 10 ± 0.5 liters. Any malfunctions should be reported immediately to Radx.

5.2 Strip Chart Recorder (Refer to Figure 9)

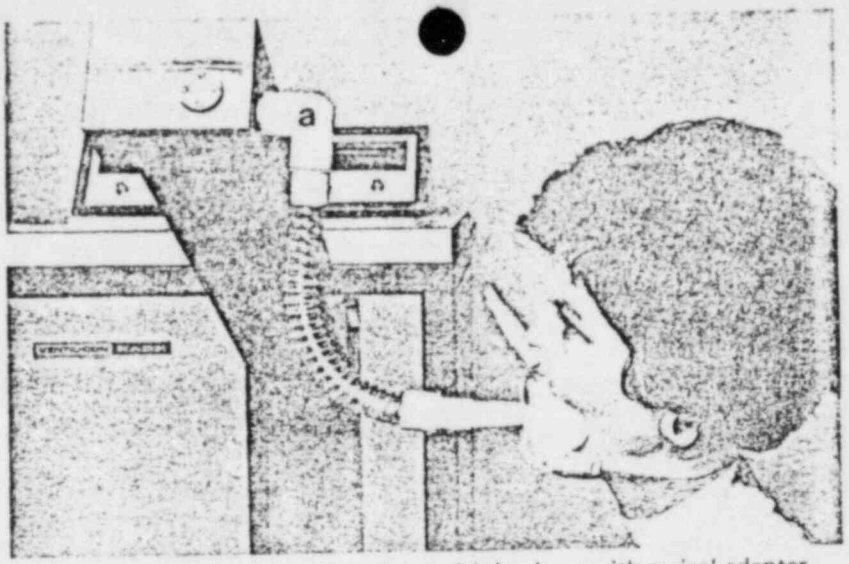


Figure 13. Patient in position for multiple views with swivel adapter. Patient may rotate 360° under the delivery arm without breaking closed loop.
a. swivel adapter.

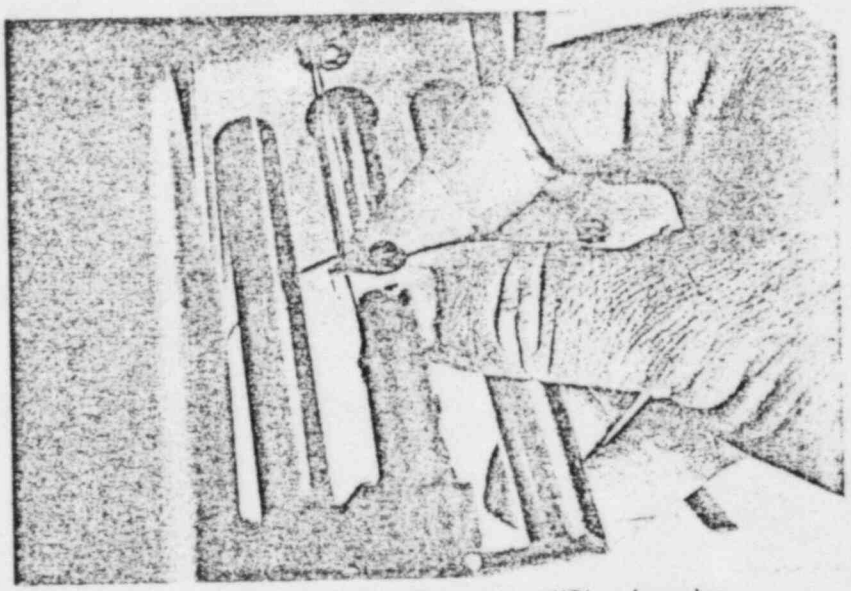


Figure 14. Compression of the spirometer to "O" volume by gently pushing the center rod completely in.

5.2.1 Volume Section

5.2.1.1 With gain control at its full counterclockwise position and the spirometer fully deflated as described in 5.1.1 above, zero the chart recorder with the POS. knob.

5.2.1.2 Inflate the spirometer to its full capacity as described in 5.1.2 above. The chart recorder should read 1:1 with the volume meter. If it does not correspond, corrections can be made by adjusting the gain control.

5.2.1.3 Whenever the gain control is changed, the recorder should be re-zeroed using the POS. knob with the spirometer fully deflated.

5.3 Concentration Meter - The Ventil-Con's minimum volume is 5 liters ± 0.5 liter and its maximum volume is 15 liters ± 0.5 liter. The values are based on the CO_2 trap being filled with soda lime crystals and correspond to a 0 to 10 liter spirometer volume and a remaining 5 liter static volume.

5.3.1 Initial Calibration

5.3.1.1 With the delivery arm in the raised position and the Head Valve in the "Xenon Rebreathing" position, inflate or deflate the spirometer by moving the center rod until the volume meter reads exactly 5 liters. Using the Zero Control knob, adjust the concentration meter to read O.

5.3.1.2 Change the Head valve to the Stabilization/Xenon Washout position.

5.3.1.3 The Ventil-Con is now completely closed to the outside and should have a total volume of 10 liters (5 in the spirometer plus 5 in the remaining static volume).

5.3.1.4 Open the stopcock on the Gas Inlet Valve and inject 30 mCi of ^{133}Xe into the Ventil-Con (See Figure 15). The resultant concentration (30 mCi/10 liters) is 3.0 mCi/Liter. Close the stopcock.

NOTE: Since ^{133}Xe readily adheres to rubber and not to glass, the use of glass syringes with glass plungers is recommended.

There is a one-way safety valve mounted inside the tubing in-line with the gas inlet valve. This safety valve prevents gas/air mixture from leaking out of the gas inlet valve if it is accidentally left open.

5.3.1.5 With a small screwdriver, adjust the calibration potentiometer so that the meter reads 3 mCi/Liter. (See Figure 16.)

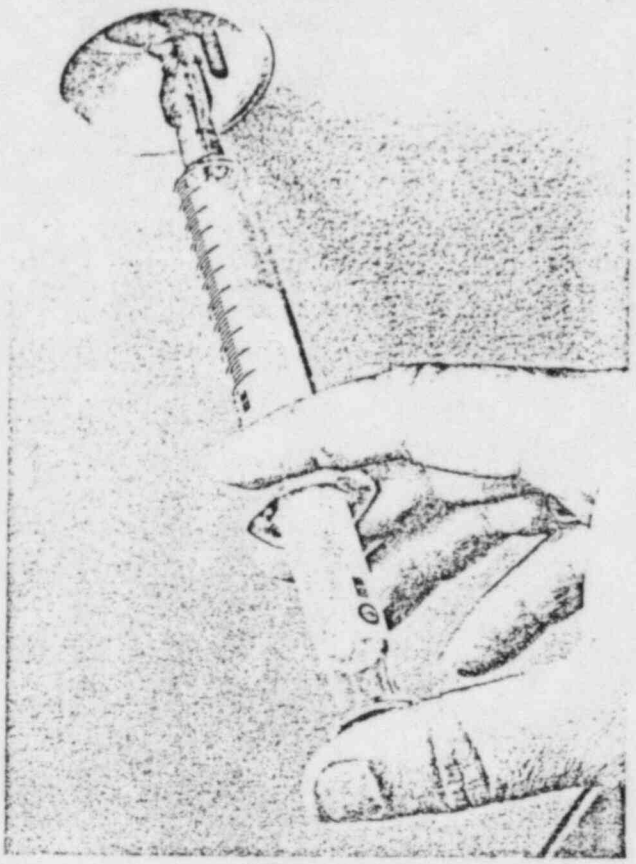


Figure 15. Injecting ^{133}Xe gas into the gas inlet valve of the Ventil-Con. Note use of an all-glass syringe.

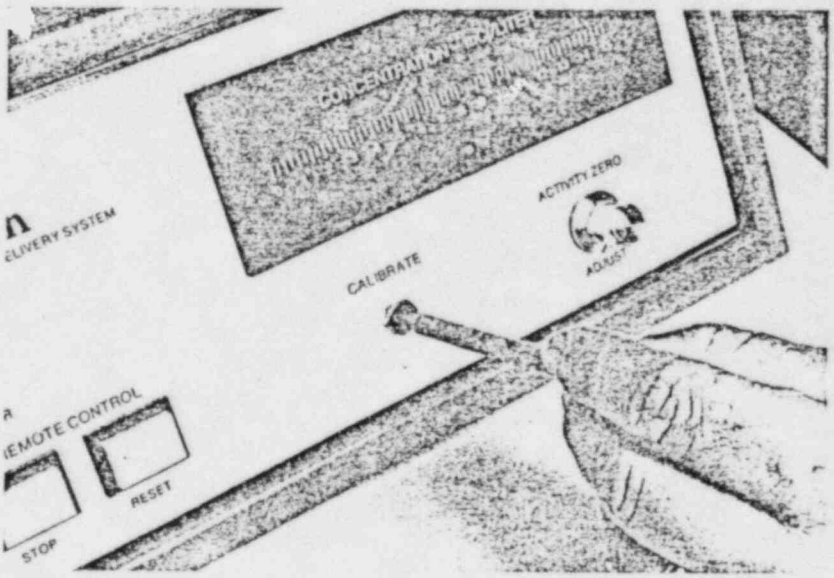


Figure 16. Calibrating the concentration meter with screw adjustment of the calibrate potentiometer.

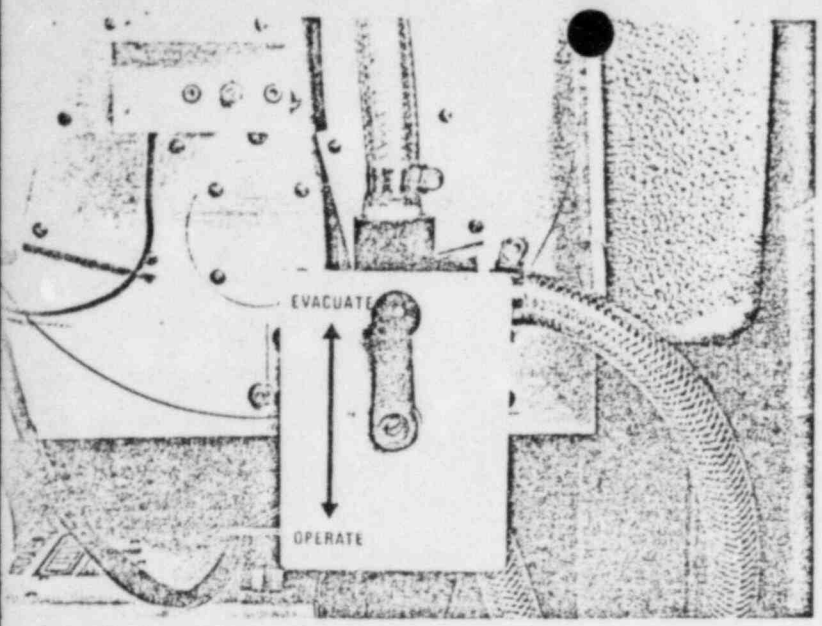


Figure 17. Flow selector valve in the Evacuate position.

5.3.2 Subsequent Calibrations - In subsequent calibrations it is necessary to first completely purge the system of all radioactivity.

5.3.2.1 With the Head Valve in the Stabilization/Xenon Washout position, turn the Operate/Evacuate valve to Evacuate. (See Figure 17.) The spirometer will automatically contract and when the volume meter reaches zero, switch back to Operate mode. In the Evacuate position the contents of the Ventil-Con are exhausted through the exhaust port.

5.3.2.2 Change the Head Valve to the Xenon Rebreathing position and inflate the spirometer to 10 liters by gently pulling the center rod to its full out position.

5.3.2.3 Change Head Valve to Stabilization/ Xenon Washout, the Operate/Evacuate valve to Evacuate and allow the spirometer to deflate to 0 volume.

Several purges may be required to remove all the radioactivity. This is accomplished by repeating steps 5.2.2.2 and 5.2.2.3.

5.3.2.4 Recalibration is accomplished by repeating steps 5.3.1.1 through 5.3.1.5.

6.0 VENTILATION STUDY PROCEDURES

6.1 Initial

6.1.1 Insure that:

1. The flow selector valve is in the "Operate" position.
2. The Ventil-Con has warmed up at least 30 minutes.
3. The soda lime crystals are not saturated with CO_2.
4. The oxygen supply regulator is open and the flow meter is adjusted to approximately 2 liters/min.

NOTE: Steps 6.1.2, 6.1.3 and 6.1.4 may be skipped if the unit has been previously loaded and calibrated as in Steps 5.3.1.1 through 5.3.1.5.

6.1.2 With the Head Valve in the Xenon Rebreathing position, move the spirometer to a position corresponding to a volume of 5 liters by moving the center rod accordingly. Switch Head Valve to the Stabilization/Washout position. It is important that at the beginning of any patient study the spirometer is in such a position that the patient's breathing cannot cause the spirometer to "bottom" or "top out." On subsequent studies when the Ventil-Con contains ^{133}Xe, the volume should be adjusted by the judicious use of the Evacuate mode (decreases volume) and/or the Manual Oxygen (increases volume).

6.1.3 Open the stopcock on Gas Inlet Valve and using a glass syringe inject 30-40 mCi of ^{133}Xe into the Ventil-Con.

6.1.4 Allow a few minutes for gas mixing and check concentration meter. The reading should correspond to the mCi added divided by the total system volume.

For example: The total system volume is 10 liters when the spirometer volume is 5 liters; therefore, if 30 mCi were added, the concentration meter should read:

$$\frac{30 \text{ mCi}}{10 \text{ liters}} = 3 \text{ mCi/liter}$$

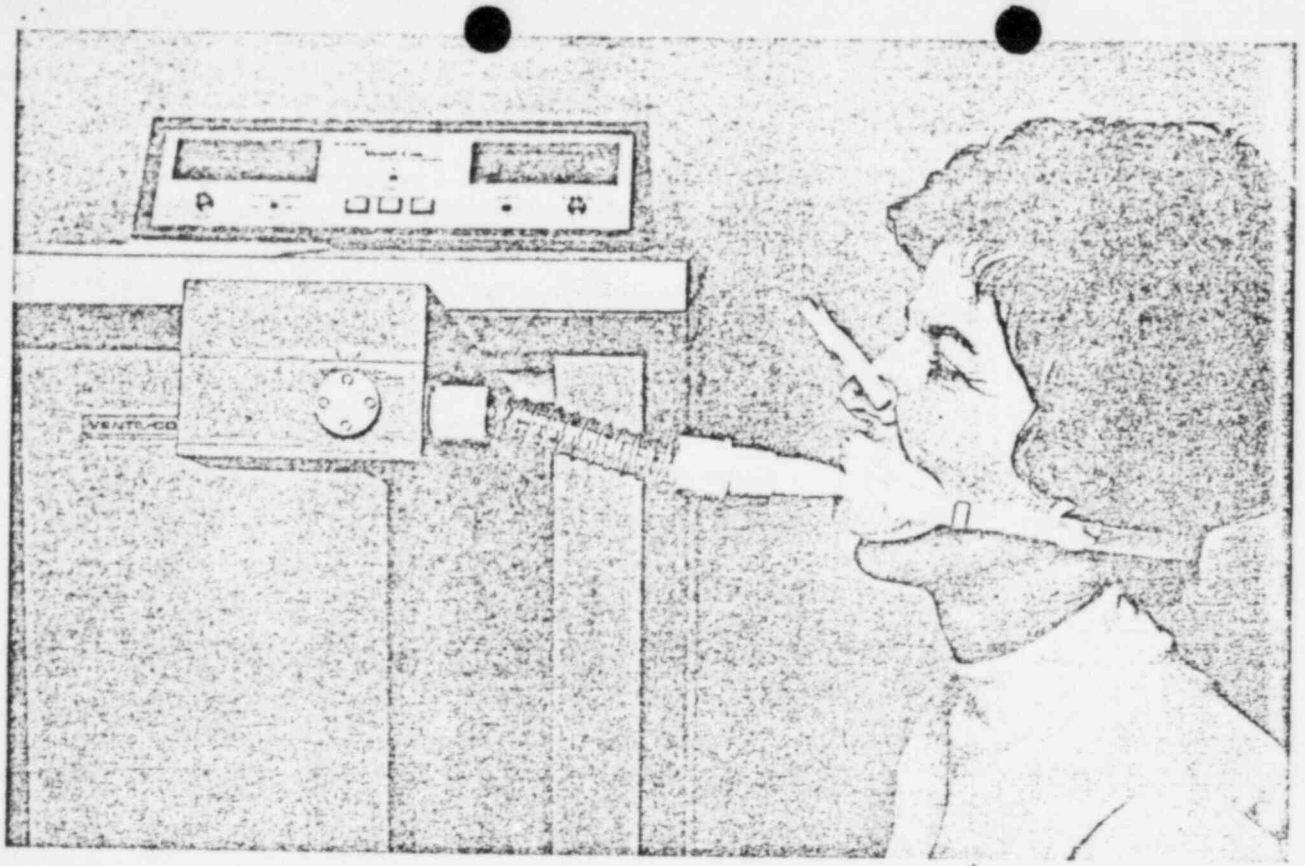


Figure 18. Proper patient position for ventilation study (sitting).
Note use of nose clamp when mouthpiece is used.

6.1.5 Position the patient and delivery arm for the study. (See Figure 18.)

6.1.6 Instruct the patient on proper breathing procedures. Fit the mouthpiece and noseclamp on the patient. Adjust the headstrap to insure a proper seal around the patient's mouth.

6.1.7 Have the patient begin breathing on the Ventil-Con until Stabilization is reached. The stabilization position is designed to decrease patient anxiety and allow him to become accustomed to the machine. In this position the patient is breathing room air through the machine.

6.1.8 Place the Oxygen Replenish Mode switch in the AUTO position, with the Oxygen Control Knob pointer set at about mid point.

6.1.9 After breathing stabilization is reached, place the Head Valve in the "Xenon Rebreathing" position. If a single breath study is desired, the valve should be switched to "Xenon Rebreathing" at the start of an inspiration and the patient instructed to take a deep breath and hold it. At completion of single breath the patient should be instructed to breathe normally for the remainder of the equilibrium and washout portion.

6.1.10 THE OXYGEN CONTROL MUST NOW BE ADJUSTED SO THAT THE O_2 ADDED DURING EACH RESPIRATION WILL EXACTLY COMPENSATE THAT USED BY THE PATIENT.

6.1.10.1 Note the maximum and minimum spirometer volume during the first several respirations and determine the average volume of each respiration. The second average should be smaller than the first since CO_2 is being removed from the total system volume.

6.1.10.2 ADJUST THE OXYGEN CONTROL KNOB UNTIL THE AVERAGE SPIROMETER VOLUME REMAINS CONSTANT.

NOTES:

1) This is most easily and accurately accomplished by using the dual strip chart recorder. The patient's normal breathing pattern will appear graphically as a sine wave. Since O_2 consumption and CO_2 adsorption will represent a net volume loss in a closed loop, unless the O_2 is resupplied at the consumption rate, this net loss will be represented by the average spirometer volume drifting toward the zero baseline. (See Figure 19.)

2) If a strip chart recorder is not used, the average volume drift must be determined visually by watching the volume meter and averaging the minimum and maximum volume during each respiration.

3) The Oxygen Control knob varies the length of time the O_2 replenishment solenoid remains open.

4) Optimum information and reproducibility are obtained when concentration remains constant during the study. The concentration may decrease somewhat, however, until equilibrium is reached, since some radioactive atoms or molecules will adhere to the lungs, trachea, etc.

6.1.11 Allow the patient to breathe until the lungs reach equilibrium. Reaching equilibrium should require about 3-5 minutes in normal subjects. If multiple views are desired, the swivel adapter should be employed and the patient positioned as in Figure 13.

6.1.12 Once equilibrium is reached and all images have been taken, switch the loop selector valve BACK to the "STABILIZATION/WASHOUT" position to BEGIN THE WASHOUT PHASE.

NOTES:

1) During WASHOUT, room air is inhaled and the exhaled radioactive gas/air mixture is exhausted through the Ventil-Con's exhaust line to the external exhaust system. It is therefore necessary that the exhausted radioactive gas either be trapped in an activated charcoal trapping device such as the Radx "Xenon Trap" or

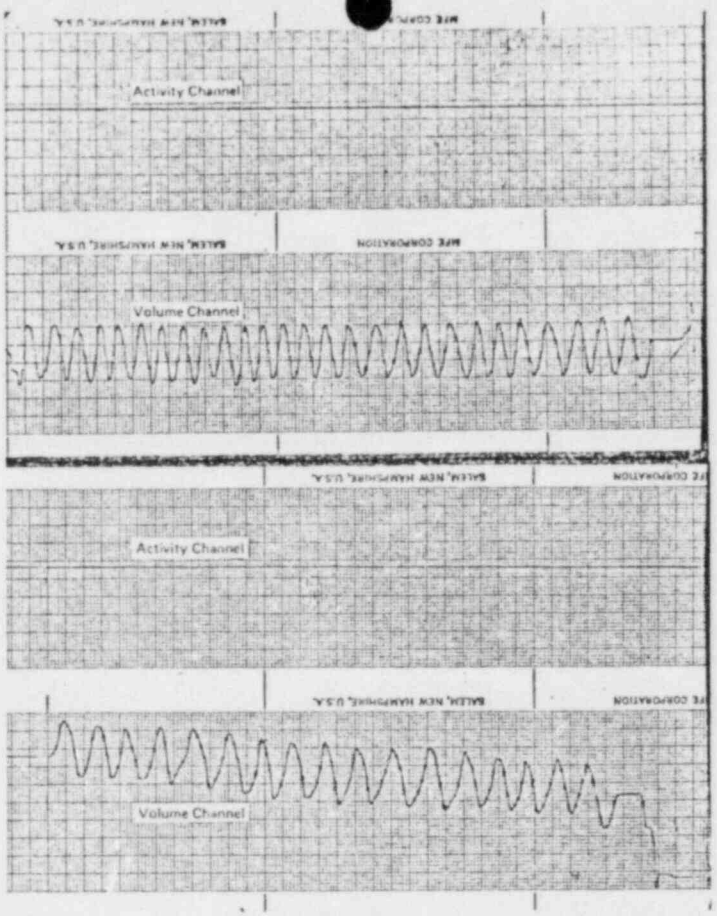


Figure 19.
Top chart recording shows proper balance between O_2 replenishment and CO_2 adsorption. Note how breathing excursions remain within a constant volume. Bottom chart recording indicates a net volume loss due to no O_2 replenishment but proper CO_2 adsorption.

exhausted in some manner above the roof line of the institution. There a. umerous ways of disposing of the gas and the method as described in your NRC (AEC) by-product material license or its equivalent should be used.

2) Adequate washout can require as long as 25 minutes in extreme cases.

6.1.13 Insure the loop selector switch is in the "Stabilization/Washout" loop position whenever no one is breathing on the Ventil-Con. Otherwise, the radioactive gas mixture can be discharged through the mouthpiece into the room.

6.2 Subsequent ventilation studies

Since the Ventil-Con is designed to store the remaining ^{133}Xe (the amount in Ventil-Con less the amount lost during patient washout), subsequent patients may use the stored radioactive gas. See Section 6.1.2 concerning spirometer position before proceeding.

6.2.1 Bring the Ventil-Con back to its original concentration by adding Xenon to the Gas Inlet Valve. This may be accomplished by adding small amounts until the concentration meter reaches the desired reading or by calculation.

6.2.2. Calculation method

Example:

Assume:
Desired concentration = 3 mCi/Liter
Concentration meter after patient washout = 2.5 mCi/Liter
Volume meter after patient washout = 6 liters

Then:
Total system volume = 6 liters (spirometer)
+ 5 liters (remainder of system)
11 liters

Total activity required to produce 3 mCi/Liter concentration = 3x11 = 33 mCi's

Total activity in system after patient washout = 2.5 mCi x 11 - 27.5 mCi's

Activity to be added = 33.0 – 27.5 - 5.5 mCi.

6.2.3 Continue as in Steps 6.1.5 through 6.1.13.

6.3 Single Breath Bolus Studies

Bolus administration studies may be done in a variety of ways depending on the clinical information required. As a no-cost option, your Ventil-Con may be equipped with a Luer-stopcock on the adult mouthpiece for direct bolus administration. (See Figure 12.)

6.3.1 Single Breath Bolus/Washout

6.3.1.1 With the Head Valve in the Stabilization/Washout position, inject the desired amount of ^{133}Xe with a glass syringe into the Luer-stopcock fitting on the side of the mouthpiece. (See Figure 20.)

6.3.1.2 Injection should be made rapidly at the beginning of the patient inspiration cycle.

6.3.1.3 Patient should be instructed to take a deep breath and hold it while the initial image is made.

6.3.1.4 Upon completion patient is instructed to breathe normally as the washout phase begins and serial washout pictures are made. As in Section 6.1.12, ^{133}Xe is exhausted through the rear port and needs to be handled accordingly.

6.3.2 Single Breath Bolus/Equilibrium/Washout

Prior to beginning a single breath bolus/equilibrium/washout study, the unit should be purged of all radioactive ^{133}Xe as described in Section 5.3.2 and the spirometer should be filled to 5 liters.

6.3.2.1 Stabilize the patient in the Stabilization/Washout position.

6.3.2.2 After stabilization, switch to Xenon Rebreathing position. (Since the unit has been purged of all radioactivity, the patient is simply breathing air in a closed loop operation.)

6.3.2.3 At the beginning of an inspiration cycle, inject the bolus of ^{133}Xe gas with a glass syringe into the Luer-stopcock fitting at the side of the mouthpiece. (See Figure 20.)

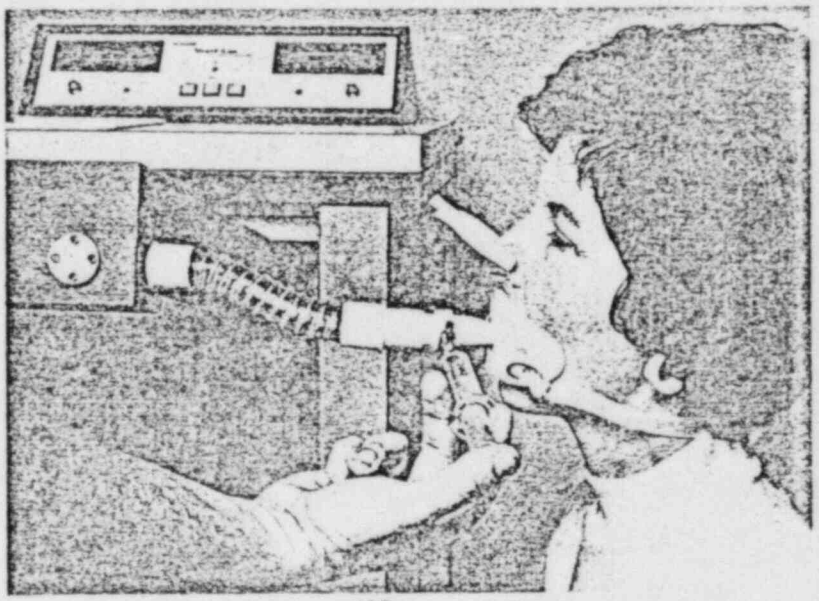


Figure 20. Injection of ^{133}Xe gas directly into the mouthpiece for bolus administration studies.

6.3.2.4 Patient should be instructed to breathe deeply and hold the breath while the single bolus image is accumulated.

6.3.2.5 When the patient begins normal breathing, the equilibrium phase is begun. The procedure should continue with auto O_2 replenishment through washout as described in Sections 6.1.8 through 6.1.13.

7.0 ROUTINE MAINTENANCE

7.1 Bacteriological Filter - The bacteriological filter should be sterilized by autoclaving at least weekly and replaced entirely yearly.

7.2 Carbon Dioxide Trap - The soda lime granules in the CO_2 trap turn blue as they become saturated and should be replaced accordingly. Prior to removing the bacteriological filter or CO_2 trap the system should be purged of all radioactivity. See Paragraph 5.3.2 for purging procedure.

INDEX

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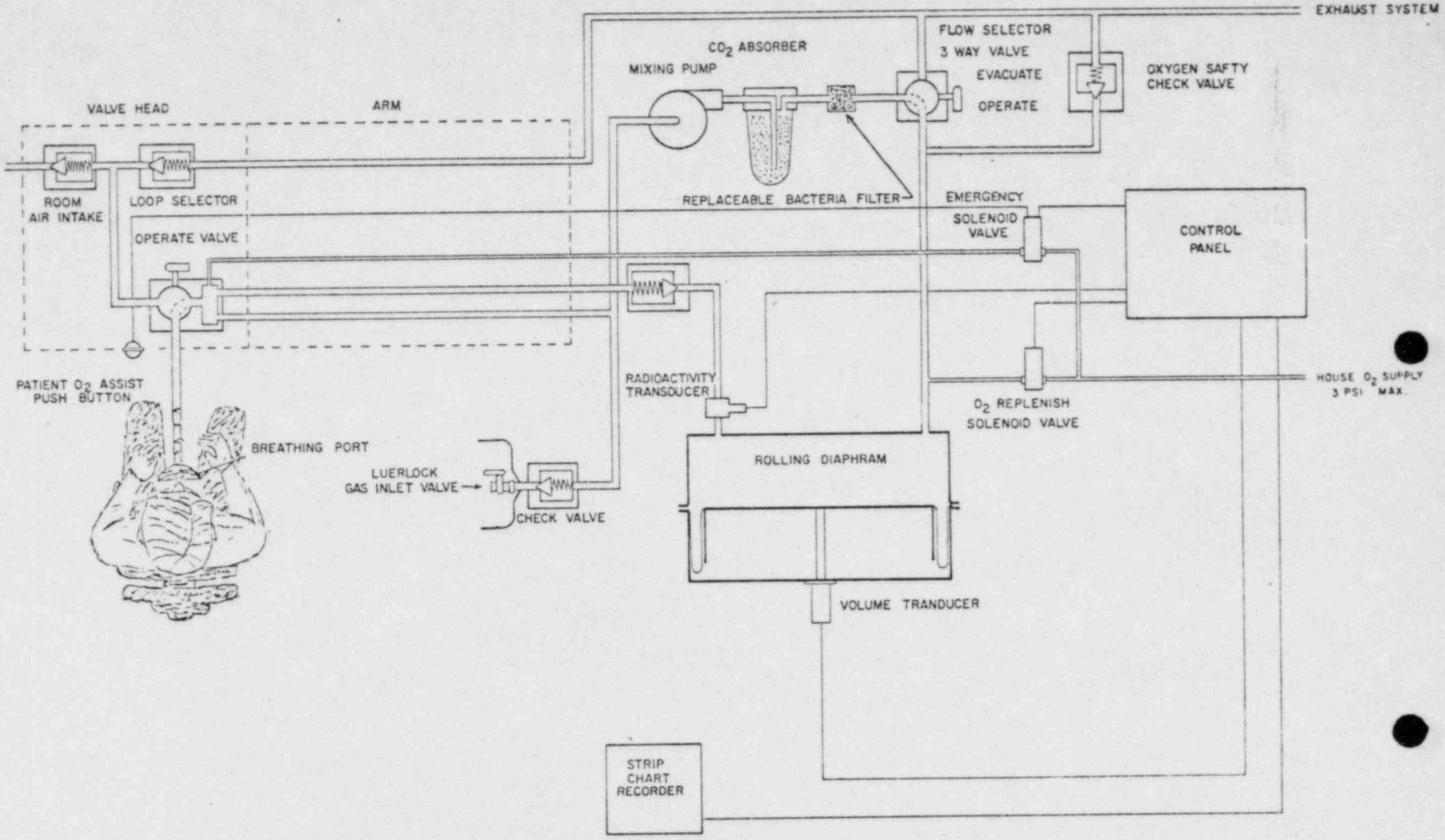

FIG. 2 GAS FLOW DIAGRAM

XENOMATIC™
XENON GAS DISPENSER

Directions for Use:

1 If required, attach needle or other appropriate connector* to the Luer-Lock fitting of the *Xenomatic* Xenon Gas Dispenser.

2 Remove plastic cap from xenon unit dose shield to expose the top of the 2.0-milliliter vial.

3 Insert vial and shield into handle of gas dispenser, impaling the vial on the needles and engaging the latch holding the shield and vial in position.

4 Connect the gas dispenser to the breathing device or spirometer.

5 Squeeze the trigger *firmly and completely* one or more times to transfer the gas from the vial into the breathing device.

6 After transfer, press shield release latch in the handle and remove the shield.

7 Pull the empty vial from the needles and discard in compliance with established requirements for the disposal of radioactive waste.

8 Replace the empty shield into the handle of the gas dispensing device, engaging the latch. This will prevent possible injury from unprotected impaling needles.

9 To clean the *Xenomatic* Xenon Gas Dispenser, simply wipe with mild detergent. DO NOT IMMERSE IN WATER.

* An adaptor is available from Mallinckrodt for use with spirometers that have a recessed xenon injection port.

Mallinckrodt® Diagnostics

Manufactured for
Mallinckrodt, Inc.
ST. LOUIS, MISSOURI 63134

Catalog No. 035

Date Issued 4/80

APPENDIX-III

RADX CORPORATION
XENON TRAP
(Preliminary Instruction Manual)

1.0 Introduction

Since the inception of inert radioactive gases, particularly ^{133}Xe, for the evaluation of lung ventilation, proper disposal has presented an interesting problem. A number of methods have been employed including venting to the atmosphere, preferential liquification of Xenon from expired air by cooling and adsorption by activated charcoal.

The latter is the method employed by Radx in our Xenon Trap. Activated charcoal is contained in six 12-inch PVC tubes which, connected in series, comprise the cartridge pack. The air/Xenon mixture is moved through the unit by a flame isolated bellows pump after first passing through a desiccant jar to remove moisture.

On units so equipped, a G-M tube constantly monitors the cartridge pack exhaust and gives an audible warning when as little as 2 uCi of activity is seen. This serves as an indication that the cartridge pack is becoming saturated and should be replaced.

1.1 Control Console

The control console is located on top of the unit and contains the power and alarm reset switch plus the audio "beeper."

When the power switch is depressed, the pump and alarm system are activated and a light comes on in the power button. Pressing the button a second time turns the power off.

1.2 Alarm System

The alarm system consists of a G-M tube monitoring the cartridge pack exhaust, an audio "beeper," an alarm reset switch, plus the associated electronics. When the power is turned on the beeper activates and the alarm reset switch light comes on for several seconds to indicate that the alarm system is operational. Sensitivity is factory set to provide an audio indication of radioactivity at around 2-4 uCi.

A sensitivity screw adjust is provided through a small hole in the side of the power box. The audio portion may be deactivated by pressing the red alarm reset button. Visual indication of the presence of radioactivity is provided by the light in the alarm reset switch. It is operational regardless of the position of the reset button.

1.3 Cartridge Pack

The activated charcoal cartridge pack consists of six 3½ x 12 inch tubes connected in series and surrounded by 3/16 inch of lead. The total pack contains approximately 4500 grams which calculations indicate will adsorb 3.5 billion curies of ^{133}Xe. Unfortunately, the life of a cartridge pack is not determined by its Xenon adsorption but by the adsorption of a wide variety of airborne contaminates. At this time we anticipate a life time of at least six months and this may be extended considerably by observing the following precautions:

1.3.1 Run the trap only during Xenon washout or when Xenon is being adsorbed.

1.3.2 Renew the desiccant whenever the color begins to change from its dark blue. (The desiccant may be reused by heating it in a pan until the dark blue color returns.)

1.4 Pump System

The air movement system used in the Xenon Trap is a positive displacement "flame isolated" bellows type pump. Our studies indicate that maximum efficiency is obtained with the charcoal pack when the air movement is less than 10 liters per minute. The Xenon Trap is set to operate at between 7 and 9 liters per minute to assure adequate dwell time for proper Xenon adsorption.

2.0 Installation

2.1 Upon its arrival, carefully remove all shipping materials. Obtain and identify all items indicated on the packing slip to insure the shipment is complete.

2.2 Visually inspect the console for any indications of damage while in transit.

2.3 Open the door and inspect the water adsorber jar. It should be filled with desiccant and the desiccant should be dark blue in color.

2.4 The Xenon Trap is equipped with two ports, one marked intake on the front of the unit and the other exhuast at the rear. The ports are equipped to handle 3/4" ID tubing.

3.0 Interfacing

Proper interfacing of the Xenon Trap to your system is critical. The main problem involved is when the patient is connected directly to the Xenon Trap. Under normal conditions a patient will breathe at a rate of approximately 15 liters per minute while movement through the trap is set for approximately half that value. Proper hookup under this condition will require an expandable interface available as Radx Expandable Interface (Item #129).

3.1 Interfacing to Radx Ventil-Con

3.1.1 Attach a length of 3/4" ID tubing to the exhaust port of the Ventil-Con with the other end attached to the Expandable Interface.

3.1.2 Attach a second length of 3/4" ID tubing between the Expandable Interface and the input of the Xenon Trap.

NOTE: The above described method should be adaptable to other Ventil-Con type devices with appropriate plumbing connections.

3.2 Interfacing to the Medi Physics Chamber

3.2.1 Since the Medi Physics system is expandable itself, an expandable interface is not required.

3.2.2 At the end of the study, close the breathing valve and attach the Xenon Trap/Medi Physics adapter.

3.2.3 Attach a length of 3/4" ID tubing to the adapter and then to the Xenon Trap.

4.0 Operation

4.1 When the power switch is pressed the audio beeper and red alarm reset light are activated for a few seconds to indicate that both are operational. They will automatically stop if no radiation is detected.

4.2 Normal background radiation will occasionally give a "beep" and a flash. An occasional alarm does not indicate that the filter is saturated. When saturation is reached, the sound alarm will activate frequently giving a steady staccato sound.

4.3 The alarm system is factory set to give the steady state at a level of 2-4 uCi. The sensitivity may be changed by adjusting the potentiometer screw adjust located on the side of the power box marked "Sensitivity."

4.4 After proper interfacing as described in Section 3.1, only run the Xenon Trap when Xenon is being adsorbed. When the Expandable Interface or the Medi Physics system is used, the Trap should be operated for sufficient time to collapse the collection bag. This will normally require about five minutes for the Expandable Interface and about ten minutes for the MPI bag.

4.5 If during a patient study the audio alarm should go off indicating saturation of the filter, the sound may be turned off by pressing the alarm reset button. Immediately upon completion of the study the saturated cartridge pack should be removed by disconnecting the input and exhaust tube at the pack and reconnecting to a fresh cartridge pack.

4.6 The saturated pack should be capped and placed in storage for a period of not less than 15 half lives (approximately 75-80 days for ^{133}Xe). Although after decaying in storage the Cartridge Pack may be reused, it should be done with caution since the expected life would be significantly reduced from a new cartridge.

5.0 Maintenance FUSE-(1 amp)

5.1 Inspect the silica gel desiccant jar frequently and replace or renew by heating when the color begins to change from a dark blue. Moisture entering the Cartridge Pack will render the charcoal ineffective for adsorbing Xenon.

5.2 Periodically inspect all hose connections to assure that they are in place.

5.3 Do not allow the pump to pull against a vacuum for any period of time.

APPENDIX - IV