t. 13,1981

Director
Office of Nuclear Material Safety and Safeguard
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Letter dated October 13, 1981

Appl... 1142 B40 HB
Chec...
Amo... amendment
Type ... 10/28/81
Date ...
Rec... Brown

Re: Delnor Hospital
975 N. 5th Ave.
St. Charles, Il. 60174
NRC # 12-15842-01

Please amendour NRC license (#12-15842-01) as we have relocated our imaging room and obtained new imaging equipment. All other aspects such as storage, safety, and posting will remain the same , as previously indicated in support of our current license. Since Xe 133 will be utilized in this new room we are submitting a diagram of this room and additional data as required in support of our use of XE 133. Please refer to the following information:

1. We expect to perform approximately 5 studies per week, using approximately 10mCi/patient.

2. A facility diagram is enclosed with this correspondence indicating the ventilation, pertinent flow rates and information of equipment. Ventilation is directly to the roof with no recirculation of air. The roof exhaust is not within 100 ft. of the nearest structure. The indicated flow rates will be tested by our maintanence dept. at least semi-annually.

3. During any pulmonary study using Xe133, an area monitor will be in operation to monitor the activity levels in the room. We plan to use a ADC Medical Delivery/Trapping Unit- Model XE 400A,- information for which is enclosed. This apparatus is equipped with a charcoal trap and effluent monitor. The monitor will be calibrated along with other survey meters at least annually. Whenever there is an indication that the effluent activity exceeds limits encounteredwhen the trap is not saturated, the trap will be replaced and handeled with our normal radioactive waste. Periodic testing for trap efficiencywill be performed. This procedure is per the manufactor's operations manual.

4. The following calculation determines the minimum flow rate required to maintain concentration in restricted areas below 3×10^{-7}uCi/ml

Maximum activity per week :

$$A = \frac{10\text{mCi}}{\text{patient}} \times \frac{5\text{pts}}{\text{wk}} \times \frac{103\text{uCi}}{\text{mCi}} = 5 \times 10^{4} \frac{\text{uCi}}{\text{wk}}$$

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4. Cont'd

Assume a loss rate of 20%(f)
Therefore, the required ventilation :

$$V = \frac{5 \times 10^{4} \frac{uCi}{wk} \times 0.2}{10^{-5} \frac{uCi}{ml}} = \frac{10^{4}}{10^{-5}} = 10^{9} ml/wk \quad \text{equals=}$$

$$\frac{10^{9} ml/wk}{40 \text{ hrs/wk}} \div \frac{1.7 \times 10^{6} \text{ ml/hr}}{\text{ft}^{3}/\text{min.}} = 14.7 \text{ ft}^{3}/\text{min.}$$

5. The following calculation demonstrates that over a years time the concentration of activity released to unrestricted area will not exceed 3×10^{-7} uCi/ml. Our apparatus is equipped with a sodalime CO_2 trap which we have found to be at least 98% efficient.

Activity released per year is:

$$A = \frac{5 pts}{wk} \times \frac{10 mCi}{PT} \times \frac{10^{3} uCi}{mCi} \times .02 \times \frac{52 wks}{yr} = 5.2 \times 10^{4} \text{ uCi/yr}$$

The net negative flow rate in the room is greater than 15 cfm

This gives:

$$V = 15 cfm \times 1.49 \times 10^{10} \frac{ml/yr}{cfm} = 2.24 \times 10^{11} \text{ ml/yr}$$

Therefore the average concentration released per year is:

$$C = \frac{5.2 \times 10^{4} \text{ uCi/yr}}{2.24 \times 10^{11} \text{ ml/yr}} = 2.32 \times 10^{-7} \text{ uCi/ml}$$

6. In the event of accidental release of radioactivity, the room will be vacated and no one allowed to re enter until the area monitor indicates that background levels have been attained. We estimate that this will take approximately 15 minutes.

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7. Our new imaging equipment is :

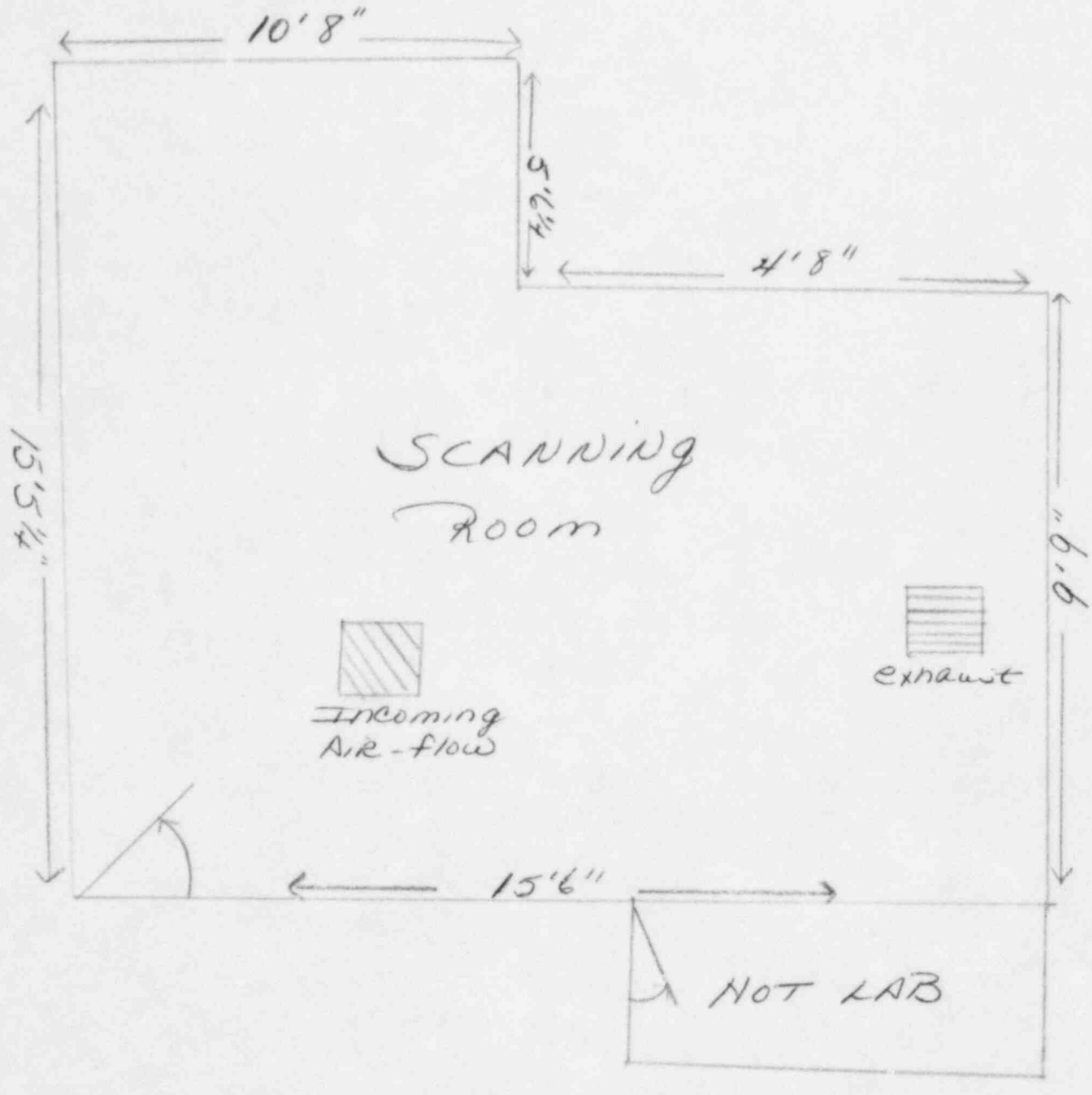
Searle/Siemens
MDL 75 017 AW
37 ZLC Basic System

ec: 3

Respectively submitted,

Alvin A. Zeman, M.D.
Chief Radiologist
Delnor Hospital
975 N. 5th Ave.
St. Charles, Il. 60174

Ro[redacted] Diagram - Refer to No#2



Air flow exhaust side 165 cfm

Air intake rate 145-150

Not recirculated

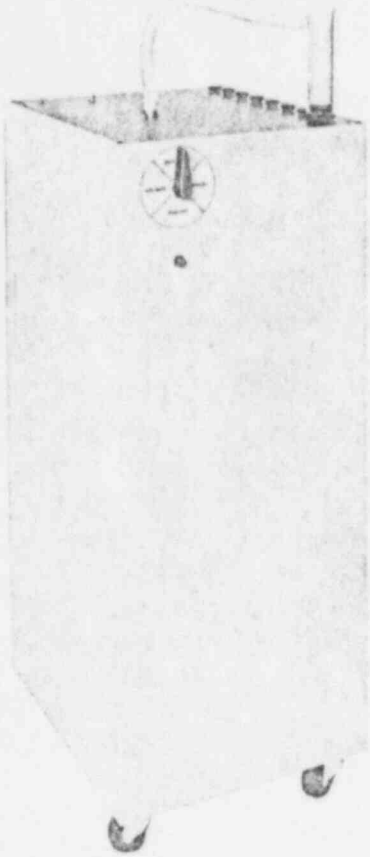
Air flow to roof and out

ADC Medical

Instruction Manual

Model No. Xe-400A

Read Rules for Operation and Instructions Carefully



XENON DELIVERY/TRAPPING SYSTEM

- Operating
- Service

WARRANTY

ADC products are warranted to be free from defects in material and workmanship for one year from date of shipment. ADC will repair or replace at its option any product that proves to be defective during the warranty period provided that it has received normal use. If product is damaged in transit, you must file claim with the carrier.

ADC Medical

400 SMITH STREET, FARMINGDALE, N.Y. 11735 • (516) 752-9686
800-645-9110

INSTRUCTIONS

HOW TO USE THE XENON DELIVERY/TRAPPING SYSTEM

For the first time, regional ventilation studies can be performed by turning a single control knob to index each function of the test procedure. Single breath, equilibrium, perfusion, and washout studies are accomplished simply by dialing the desired mode on the clearly marked panel. An internal valve system automatically channels the xenon/air/oxygen mixture through each cycle, fully controlled by the technician, completing the study effortlessly and evacuating the exhaled xenon to one of the eight xenon gas traps provided in this system.

THIS SYSTEM IS DESIGNED FOR OPERATOR CONVENIENCE. The single control knob is positioned opposite the patient for "one-glance" observation of both patient and controls. A clear plexiglass top-cover permits easy access to the moisture trap, CO_2 absorber, and O_2/air and gas trap lines located at the top of the unit.

A 60-LITER DOUBLE WALL BREATHING BAG provides your seated or supine patient with resistance-free breathing regardless of the extent of his pathology.

INDIVIDUAL PATIENT MOUTHPIECE INCLUDES TUBING AND IN-LINE DISPOSABLE BACTERIA FILTER preventing the need for system sterilization between studies and eliminating the possibility of cross-contamination between patients. 39" long tubing for supine patients are supplied in the replacement kits.

THE CO_2 ABSORBER AND MOISTURE TRAP ARE EXTERNALLY MOUNTED at the top of the unit. Each is designed for rapid twist-out/twist-in changing. The traps are made of clear plexiglass to permit observation. A see-through cover protects them from dust, dirt and inadvertent handling when the system is not in use.

Connections for both O_2/air mixture tubing and xenon gas trap vent tubing are mounted in the top area for easy access through the cover and for routine observation.

THE SYSTEM ACCEPTS ANY COMMERCIAL FORM OF XENON. Delivery of a bolus of xenon gas is accomplished by injecting the bolus directly into the side of the rubber patient mouthpiece, an efficient and reliable septum. Dead space is virtually eliminated as the patient inhales the bolus immediately upon command.

A PRE-PROGRAMMED TIMED EVACUATION CYCLE assures complete system purging of xenon at the completion of a study.

SYSTEM ROLLS EASILY ON HEAVY-DUTY CASTERS for convenient positioning of unit in relation to patient and gamma camera.

IMPORTANT

- DO NOT use System without a Bacteria Filter for fear of contaminating the Breathing Bag.
- DO NOT reuse Mouthpiece, Bacteria Filter or Tubing on other patients. These must be discarded and new ones used for each patient.
- DO make sure the voltage supply is 120 volts, 60 Hz.
- DO grasp plug and remove from wall socket, not by pulling on cord.

"It is possible for the Xe 400A to leak ^{133}XE, therefore, we suggest that you periodically follow the procedure for testing the efficiency of the Gas Trap."

Step 1. INSPECTION: After the packing has been removed, inspect the trap to make certain no damage has occurred in shipment. If damage is evident, file claim with carrier and notify manufacturer immediately.

Step 2. Fill both the CO_2 (Soda lime) and moisture (drierite) canisters with the samples provided. The CO_2 canister is plugged into the side. The bacteria filter is plugged into the CO_2 canister and the tube and mouth piece are attached to the bacteria filter.

Step 3. The moisture canister is located on the top. This canister is plugged into the trap #1 when starting, and is plugged into trap #2 on the following day and so on.

Step 4. Plug the system into any 120 Volt 60 H3 wall socket in close proximity to the gamma camera.

Step 5. Place an oxygen tank close to the system. Using tygon tubing, attach one end to the oxygen tank and the other end to the fitting of the system labeled "OXYGEN". This fitting is located on the top of the unit. Open the oxygen tank valve and allow about 10 litres of oxygen to enter the breathing bag.

Caution: Add oxygen if necessary during the study.

Step 6. Seat the patient with his back to the camera while making certain that both his lungs are included in the cameras field of view.

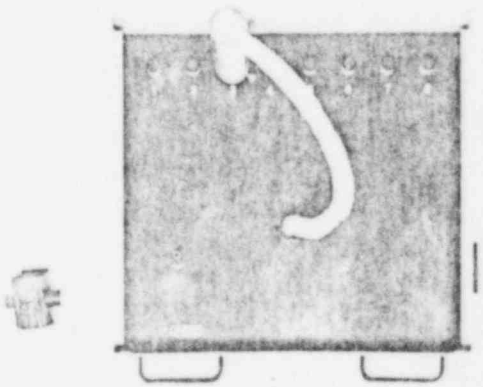
Step 7. Before introducing Xenon into the patient, it is advisable that you acclimate him with the system to gain his confidence.

Set the control knob which is located on the back of the unit, to the ACCLIMATE position. Insert the mouthpiece in the patient's mouth and attach a nose-clamp to his nose. Instruct the patient to breathe normally.

At this setting, the patient is breathing room air in and is expiring his breath into the room. This is accomplished through the unique and atuomatic valving arrangement.

Option: A face mask may be used instead of the mouthpiece if preferred.

Only after you are convinced that the patient will cooperate should you proceed with the study.



TOP VIEW

ADMINISTERING THE XENON 133

Caution: Make certain that the gamma camera is set for Xenon 133 and is on and ready.

Step 8. Set the control knob to EQUILIBRIUM and ask the patient to breathe normally. Insert the syringe needle of the gas device (NEN Gun, syringe, etc.) into the mouthpiece just outside the lips. Ask patient to exhale completely and upon inhalation, release the xenon. Have patient hold breath for as long as possible for a Single Breath Study.

Step 9. Ask patient to breathe normally until Equilibrium is reached normally taking several minutes.

Add more oxygen, if necessary.

Step 10. After sufficient data is collected for Equilibrium, set the control knob to WASHOUT. Have patient continue to breathe normally until sufficient Washout data is collected. Pictures may be taken at 15 second intervals. Three minutes is generally sufficient for Washout but continue Washout until patient is free of Xenon.

Step 11. Upon completion of Washout, set the control knob to EVACUATE and remove patient from system. At this setting, the system will automatically remove all the expired air and Xenon 133 collected in the breathing bag during the study and trap the xenon into the Xenon Gas Trap selected. It will automatically stop after evacuating the breathing bag.

Step 12. Remove and discard the mouthpiece, bacteria filter and tube assembly.

Preparation for new study:

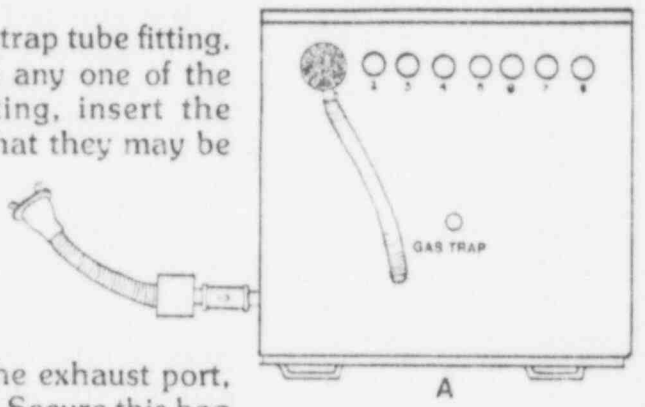
a) Attach NEW mouthpiece, bacteria filter and tube assembly.
b) Replace used soda lime with new soda lime.
c) Only replace the drierite when its color has changed to pink.
d) Select the next trap if study has been the last for this day.

Replacement parts for Xenon Delivery System Model Xe 400A

Part No.	Description
Model SCP-309	Sodalime CO_2 Absorber Pellets
Model MA-318	Drierite moisture absorber
Model MTB-327	Disposable mouthpiece, bacteria filter and tube kit. Both the 8" long tube for sitting positions and the 39" long tube for supine positions are supplied in this kit.

PROCEDURE FOR TESTING THE EFFICIENCY OF THE GAS TRAP

Step 1. Disconnect moisture trap tube at the gas trap tube fitting. The moisture trap may be inserted into any one of the eight cartridges. For subsequent testing, insert the moisture trap into other cartridges, so that they may be tested. See figure A.



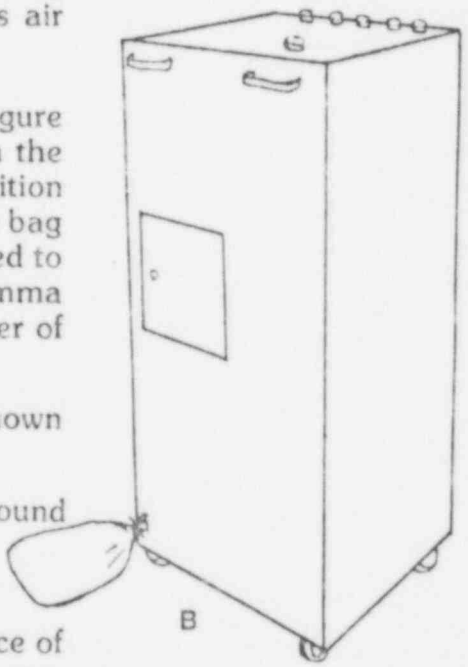
A

Step 2. Attach a soft plastic 10-25 liter bag to the exhaust port, located in the rear lower left hand corner. Secure this bag to the fitting with scotch tape, making the joint as air tight as possible. See figure B.

Step 3. Set the control knob to the evacuate position, (see figure C), to collect filtered air in the attached bag. When the bag is filled, set the control knob to the acclimate position to shut off the vacuum pump. Tie a string around the bag to contain this filtered air. Take this bag, now referred to as bag #1, and place it before the face of your gamma camera. Measure its radiation and record the number of counts. See figure D.

Step 4. Repeat step 2 with a fresh bag and leave it there as shown in figure B. We will refer to this as bag #2.

Step 5. Fill a third bag with air or oxygen and tie a string around it tightly leaving about a 4" long neck. This will be bag #3. See figure E.

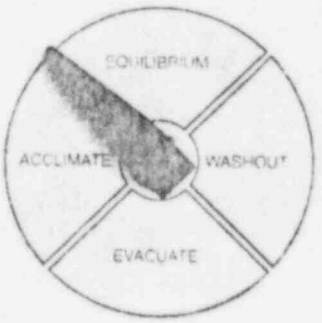


B

Step 6. Inject a bolus of Xenon into this bag and apply a piece of scotch tape over hole after removing the needle to prevent leakage. Place it before the camera to measure its radiation. Record these counts.

Step 7. Attach this bag to the moisture trap tube with tape as you did with bag #1 and untie the string. See figure F.

Step 8. Set control knob to evacuate position to allow the air and Xenon to be removed and filtered through the trap and to be collected in bag #2. Set control knob to acclimate after collecting all the contents of bag #3 into bag #2.



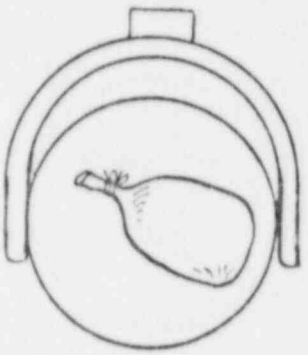
C

Step 9. Remove bag #2 exactly as in step 3 tieing the string around bag, etc. Place it before the gamma camera to measure its radiation. Record its counts.

Step 10. Solve the simple equation below to determine the percentage of untrapped Xenon.

$$P = \frac{C2 - C1}{C3}$$

P = Percentage
C = Bag Counts



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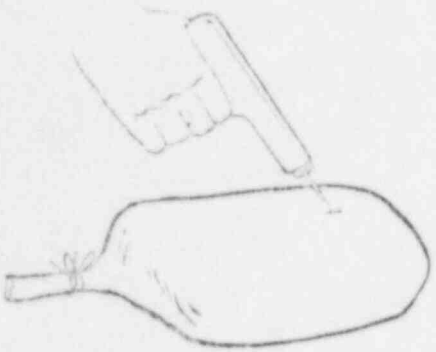
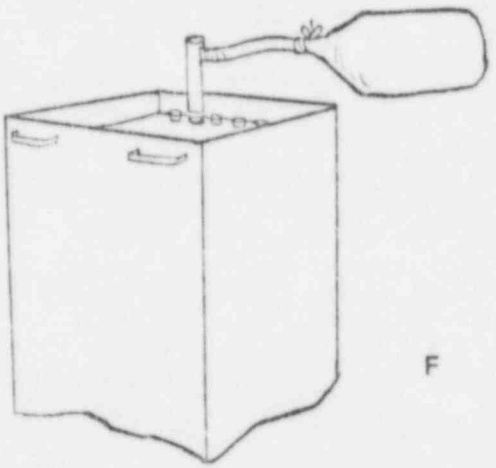


E



F

IMPORTANT

If tested traps are found to be less than 90% efficient, they should not be used for the next twelve days and then tested again. If they still are inefficient, contact your dealer or us directly to make arrangements to replace all eight traps free.