ST. JOSEPH HOSPITAL
128 STRAWBERRY HILL AVENUE
STAMFORD CONNECTICUT 06904
TELEPHONE 327-3500

Mr. John E. Bowyers
Radioisotopes Licensing Branch
Division of Fuel Cycle and
Material Safety,
Nuclear Regulatory Commission
Washington D.C. 20555

Dear Mr. Bowyers:

Our N.R.C. license, number 06-06922-02, is already amended for Xenon-133 for pulmonary ventilation studies. We have however, recently moved our radioisotope facility to new quarters on the fourth floor of the hospital and we are submitting the enclosed calculations indicating that we are in compliance with 10 CFR Part 20. We purchase the radiopharmaceutical from New England Nuclear Corp., Atomlight Place, No. Billerica, Mass. 01862. Catalog Number NRP 127 Xenon Xe-133 Gas in unit dose vials. NDA approved. Our imaging is performed on either a Searle H.P. or Large Field of View gamma camera. The following special equipment is used:

1. Delivery system - New England Nuclear Calidose Dispenser
2. Lung Function Unit - Omnimedical P.O. Box 1277, Paramount, California, 90723 - Automated Ventilation Module Model AVM-3.
3. Disposal System - Nise Inc., 20018 State Road, Cerritos, Calif. 90701 - Char-Col Xenon Gas Trap.
4. Dose Calibrator - Capintec Model CRC-6A

All personnel have whole body and wrist film badges and TLD finger badges.

Description of the Hot Lab: The Xenon-133 gas will be stored in its 1/8 inch thick lead container behind 2 inch thick lead brick in a fume hood which has an exhaust fan having a capacity of 580 cfm. The total volume of the room is 450 cu. ft. (8' x 7' x 8'). Air can enter the room through a window , a door, a ceiling vent and two pass throughs. (One to the imaging room and one to an inside hallway.) Since our weekly order is 100 m. Ci, allowing for precalibration and decay we should never have more than 180 m. Ci. in storage at any one time. Allow an escape fraction of .15.

The maximum concentration of Xenon-133 over forty hours in seven consecutive days for this restricted area has been calculated as follows:

$$C = \frac{A \times f}{v} = \frac{1.8 \times 10^5 \times .15 \text{ u. Ci.}}{580 \times 6.8 \times 10^7 \text{ ml in 40 hrs.}} = .068 \times 10^{-5} \text{ uCi/ml per 40 hrs.}$$

This is in compliance with 10 CFR Part 20 for restricted areas. In the event of accidental release of the Xenon-133 the window would be opened and the door closed after all personnel have left the room. The time required for the room air to change 20 times is

$$\frac{20 \times 450 \text{ cu. ft.}}{580 \text{ cu. ft./min.}} = 16 \text{ min.}$$

After 16 min. the room will be surveyed with a low level survey meter (0-.1mr.)

The air exhausted from the hood is released into an unrestricted area on the roof and is at least 25 feet from any air intakes. The concentration of Xenon-133 in this unrestricted area is based on our weekly order of 100 mCi. and an escape fraction of .15

$$C = \frac{10^5 \times 52 \times .15 \text{ uCi.}}{580 \times 1.5 \times 10^{10} \text{ ml/yr.}} = .89 \times 10\text{-}7 \text{ uCi./ml averaged over one year.}$$

This figure is also in compliance with 10 CFR Part 20.

Procedure: We are doing a maximum of 10 patients per week at 10 mCi per patient. The activity is assayed in the dose calibrator, the gas is transported and dispensed with Calidose Dispenser into the AVM-3 ventilation nodule and collected in the Char-Col Trap. The patient will receive instructions on the procedure, a nose clamp will be used and the study will consist of breath-hold, equilibrium and washout phases.

Description of the Imaging Room: All imaging procedures will be performed on one or the other of the gamma cameras in the imaging room. The room has 3 windows, a door, 3 air intake ducts, and a ceiling exhaust vent with a capacity of 1075 cfm. Between 20% and 100% of this air is actually exhausted on the roof which means that in the worst case the true exhaust from the room is 20% of 1075 = 215 cfm. The maximum amount of Xenon-133 used per week is 100 mCi. Assume an escape fraction of .15

$$C = \frac{10^5 \times .15 \text{ uCi.}}{215 \times 6.8 \times 10^7 \text{ ml. in 40 hrs.}} = .10 \times 10\text{-}5 \text{ uCi/ml over 40 hrs.}$$

The charcoal trap is also stored in this room and could increase this figure by no more than 50%. The air exhausted from the imaging room is released into an unrestriced area on the roof. The concentration of Xenon-133 in this unrestricted area is based on escape of .15 of our total yearly activity and an average yearly exhaust of 20% of the air leaving the room.

$$C = \frac{10^5 \times 52 \times .15 \text{ uCi}}{215 \times 1.5 \times 10^{10} \text{ ml/yr}} = 2.4 \times 10\text{-}7 \text{ uCi/ml averaged over one year}$$

In the event of an accidental release, the windows will be opened, the patient and all personnel will leave the room and the door will be closed. The door to the Hot Lab will be closed. The two rooms are connected by a pass through duct. The total volume of the imaging room is 4080 cu. ft. (34 x 15 x 8). The total volume of the two rooms is therefore 4530 cu. ft. The total air flow is at least 795 cfm. (580 + 215) The time required for the room air to change 10 times is

$$\frac{10 \times 4530 \text{ cu. ft.}}{795 \text{ cu. ft./min}} = 57 \text{ minutes}$$

After 1 hour the room will be surveyed with a low level survey meter (0-.1mr).

Disposal: The Xenon-133 gas is trapped in a charcoal trap manufactured by Nise Inc. In order to determine the escape fraction a small amount of charcoal is placed in a piece of plastic hose just before the exhaust of the trap and left in for an actual study using 10 mCi. of Xenon-133. After the study the charcoal is removed and assayed in a dose calibrator a little at a time, to reduce attenuation, and compared with the total administered activity.

This has been measured as being 1.5%. If this number should increase to 10% the cartridge will be replaced and the used one will be removed along with other radioactive waste by Nuclear Diagnostic Laboratories, Peekskill, N.Y. The desiccant in the trap will be checked weekly and replaced as needed. All exhaust vents will be checked periodically to determine their efficiency.

Cordially,

Malcolm Powell
Physicist

MP:md

CARSON, LUNDIN & THORSON, PC ARCHITECTS
880 THIRD AVENUE NEW YORK 10022

ROBERT L. THORSON

DONALD O. CHAPMAN
DONALD JEWELL
MICHAEL RUBIN
EDWARD V. FRANKLIN
BRUCE L. ALLEN

212 754 1040

June 16, 1977

St. Joseph Hospital
New Emergency APD
Addition & Alteration
Job No. 258-12 -CL&T Job No. 1275

Dr. James J. McSweeney,
Director Department of Radiology
St. Joseph Hospital
128 Strawberry Hill Avenue
Stamford, Connecticut 06904

Dear Dr. McSweeney:

In response to your telephone call regarding supply and return air quantities for Rooms 410 (Hot Lab) and 411 (Scanning), we wish to advise that the design criteria indicated on the Construction Documents is as follows:

Hot Lab. Room 410: The supply air enters the room from the supply duct at the rate of 235 CFM and is exhausted through the hood at 580 CFM. Make up air enters the room through a transfer grille at 355 CFM.

The air from the hood exhaust passes through an absolute filter and is exhausted 25'-0" from the fresh air intake of the supply fan. A distance of ten to twelve feet is usually considered acceptable.

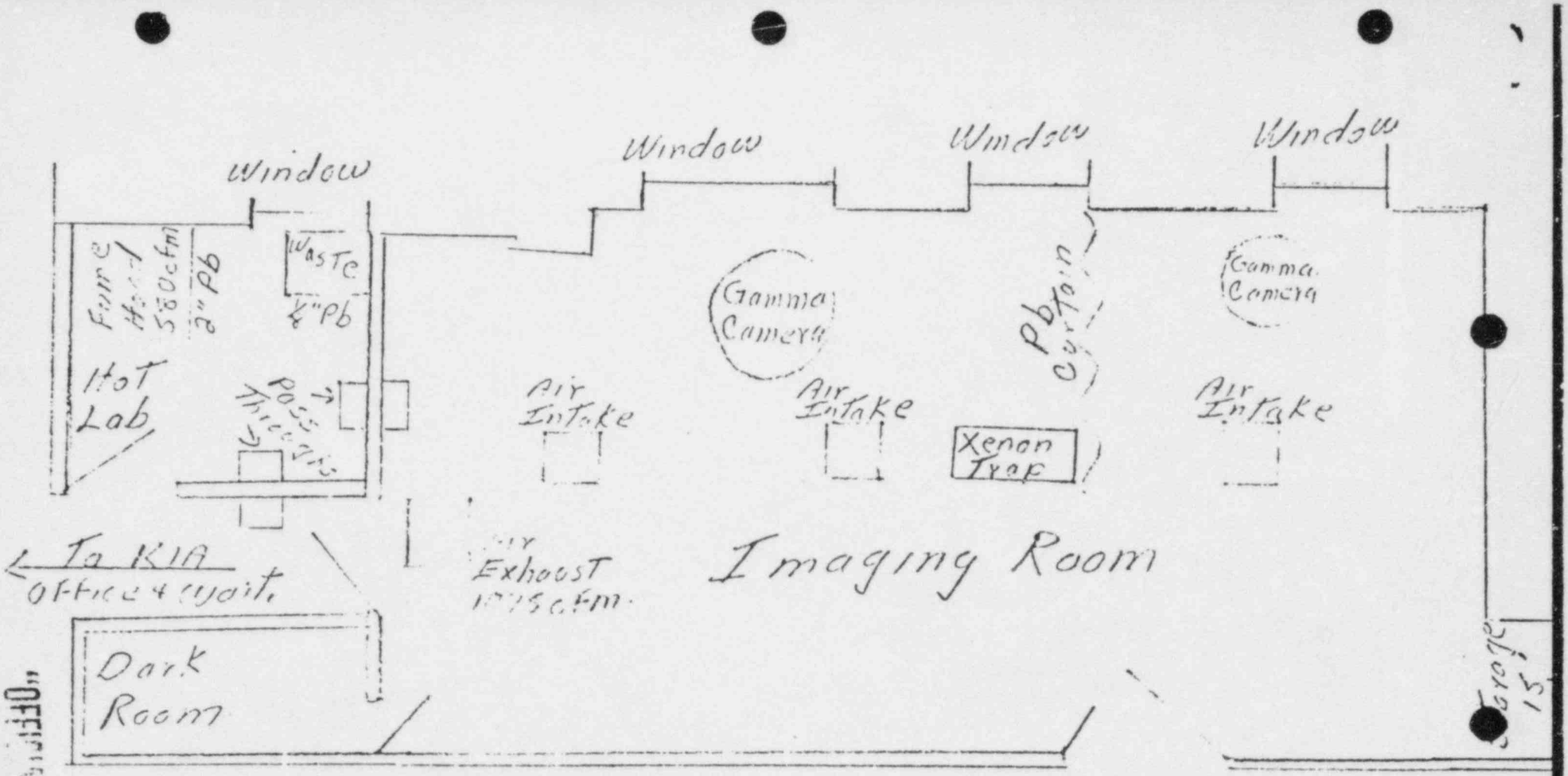
Scanning Room 411: The supply air enters the room from three registers at a total rate of 1425 CFM and is exhausted at 1075 CFM. The transfer grill to Room 410 exhausts at 355 CFM.

Sincerely,

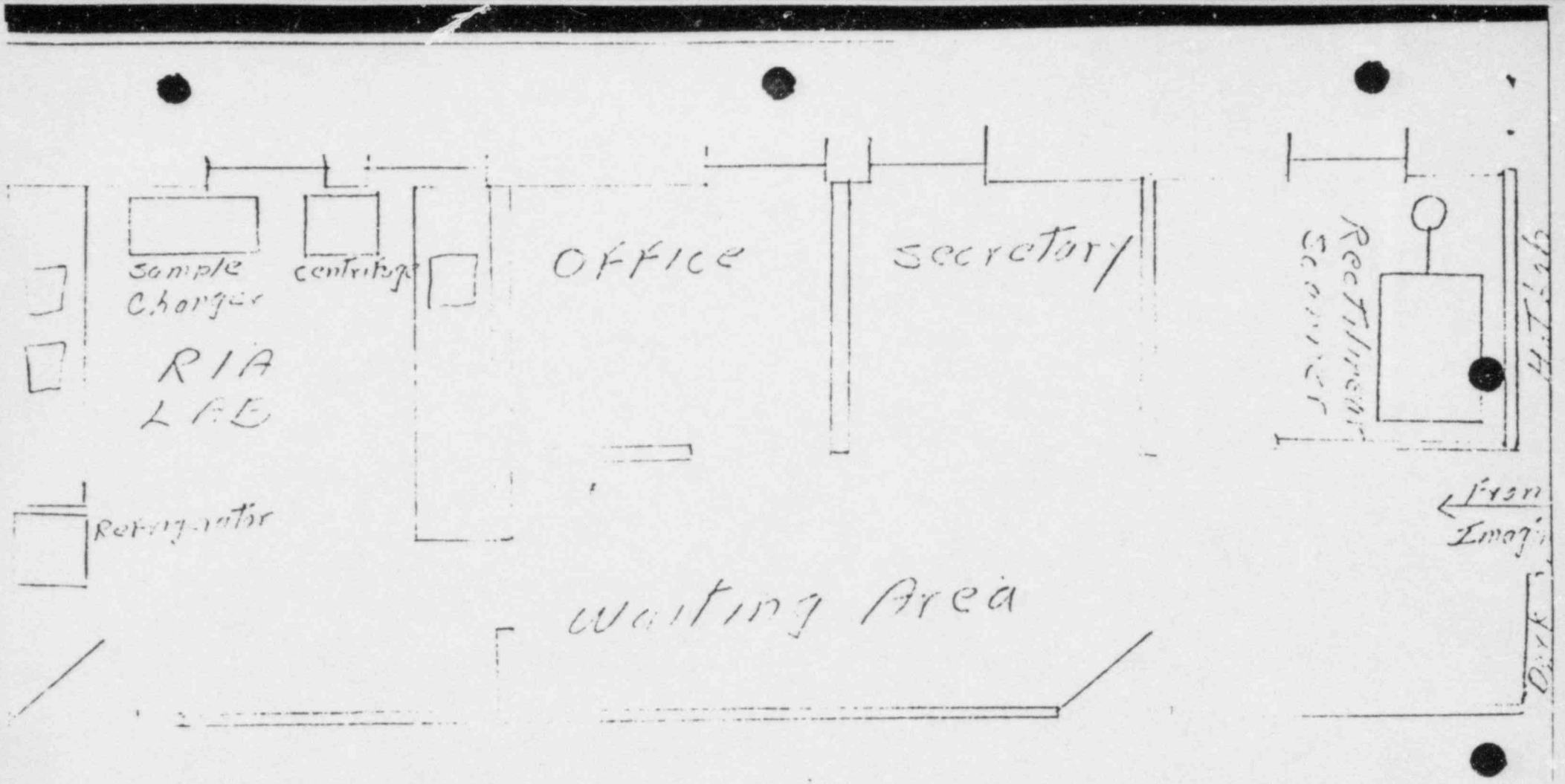
Edward V. Franklin

Edward V. Franklin
/b

CC: Sister Daniel Marie
Mr. Feyzi Bil



Radioisotope Lab
St. Joseph Hospital
Stamford, Conn.
Scale ¼" = 1'


Sample Changer
centrifuge
OFFICE
secretary
RIA LAB
Refrig-erator
waiting Area
Reception Counter
Exam

XENON Xe 133
GAS

Catalog Number NRP-127

New England Nuclear

DESCRIPTION

Xenon Xe 133 for diagnostic use is available as a gas in carbon dioxide diluents.

ACTIONS

Xenon Xe 133 is a readily diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes and freely exchanges between blood and tissues. It tends to concentrate more in body fat than in blood plasma, water or protein solutions. In the concentrations used for diagnostic purposes it is physiologically inactive. Inhaled Xenon Xe 133 gas will enter the alveolar wall and enter the pulmonary venous circulation via the capillaries. Most of the Xenon Xe 133 that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation.

INDICATIONS

Inhalation of Xenon Xe 133 gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

CONTRAINDICATIONS

To date, no known contraindications to the use of Xenon Xe 133 gas have been reported.

WARNINGS

This radiopharmaceutical should not be administered to pregnant or lactating women unless the benefits to be gained outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few days or approximately 10 days following the onset of the menses.

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactors or particle accelerators and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

PRECAUTIONS

As in the use of any other radioactive material care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. Expired Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental agency regulations.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respiratory containers. Such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic. Xenon Xe 133 gas delivery systems (i.e. respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

ADVERSE REACTIONS

To date, no adverse reactions based on the use of Xenon Xe 133 gas have been reported.

DOSAGE AND ADMINISTRATION

Xenon Xe 133 gas is administered by inhalation from

closed respirator systems or spirometers.

The suggested activity range employed for inhalation by the average adult patient (70 kg) is:

Pulmonary function including imaging: 2-30 mCi in 3 liters of air.

Cerebral blood flow: 10-30 mCi in 3 liters of air.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

PHYSICAL CHARACTERISTICS

Xenon Xe 133 decays by beta and gamma emissions with a physical half-life of 5.27 days[1]. Photons that are useful for imaging studies are listed in Table I.

Table I
Principal Radiation Emission Data Xenon Xe 133

Radiation	Mean % per Disintegration	Mean Energy (keV)
Beta-2	98.3	100.6
Gamma-2	34.60	81.0
K int. con. electrons-2	47.24	45.0
L int. con. electrons-2	7.87	76.7
M int. con. electrons-2	0.84	80.0
K x-rays	34.70	30.8
K x-rays	7.07	35.2

(1) Dillman, L. T., Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation Dose Estimation, Part 2, Supplement No. 4, MIRD pamphlet No. 6, J. Nucl. Med. p. 28, 1970.

The specific gamma ray constant for Xenon Xe 133 is 0.44 R-m(C)-hr at 1 cm. The half value layer is 1 mm of Pb.

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals before and after the date of calibration are shown in Table II.

Table II
Xenon Xe 133 Physical Decay Chart
(Half-life 5.27 days)

Day	Fraction Remaining	Day	Fraction Remaining
-5	1.830	8	.349
-4	1.693	9	.302
-3	1.483	10	.268
-2	1.300	11	.238
-1	1.140	12	.206
0*	1.000	13	.181
1	.877	14	.159
2	.769	15	.139
3	.674	16	.122
4	.591	17	.107
5	.518	18	.094
6	.454	19	.082
7	.398	20	.072

*Calibration Day

RADIATION DOSIMETRY

The estimated absorbed radiation doses[2] to an average patient (70 kg) for pulmonary perfusion and cerebral blood flow studies from a maximum dose of 30 millicuries of Xenon Xe 133 in 3 liters of air are shown in Table III.

Table III
Radiation Doses

	Effective Half-time	Lungs*	Brain	Whole Body
		rads/30mCi		
Pulmonary Perfusion	2 min	0.2[illegible]	0.0014	0.002[illegible]
Cerebral Blood Flow	5 min	0.6[illegible]	0.003[illegible]	0.00[illegible]

*9[illegible]% of activity is in lung

(2) Method of Calculation: A Schema [illegible] Absorbed Dose Calculation for Biologically Distributed Radionuclides Supplement No. 1, MIRD pamphlet No. [illegible], J. Nucl. Med. [illegible] p. 7, 1968

HOW SUPPLIED

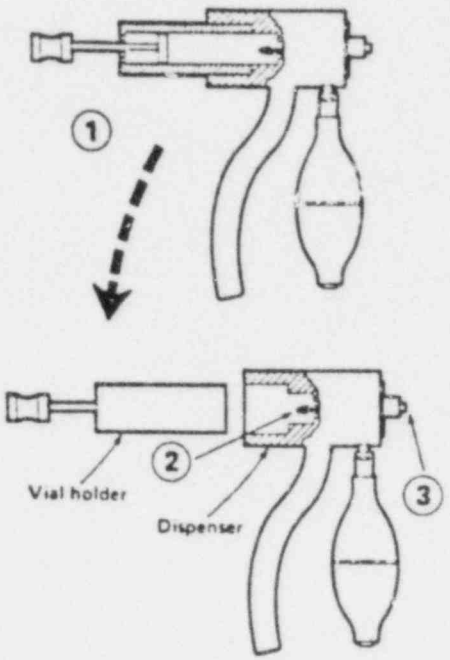
The Xenon Xe 133 gas is supplied as part of the [illegible] system consisting of [illegible] unit dose [illegible] and the [illegible] dispenser* for shielded dispensing.

Normally vials containing either [illegible] mCi [illegible] vial packed up to 5 vials per [illegible] sets containing up to 100 mCi/vial are available.

*Patent Pending

New England Nuclear
Radiopharmaceutical Division
Atomlight Place
North Billerica, Mass. 01862

Operation Instructions for NRP-186 CALIDOSE™ DISPENSER for use with NRP-127 XENON Xe 133 GAS



Loading

1 Separate shielded vial holder from dispenser.

2 Check Huber point needles inside the dispenser body to insure that they are not blocked (if necessary, clean by pushing a fine wire through needles).

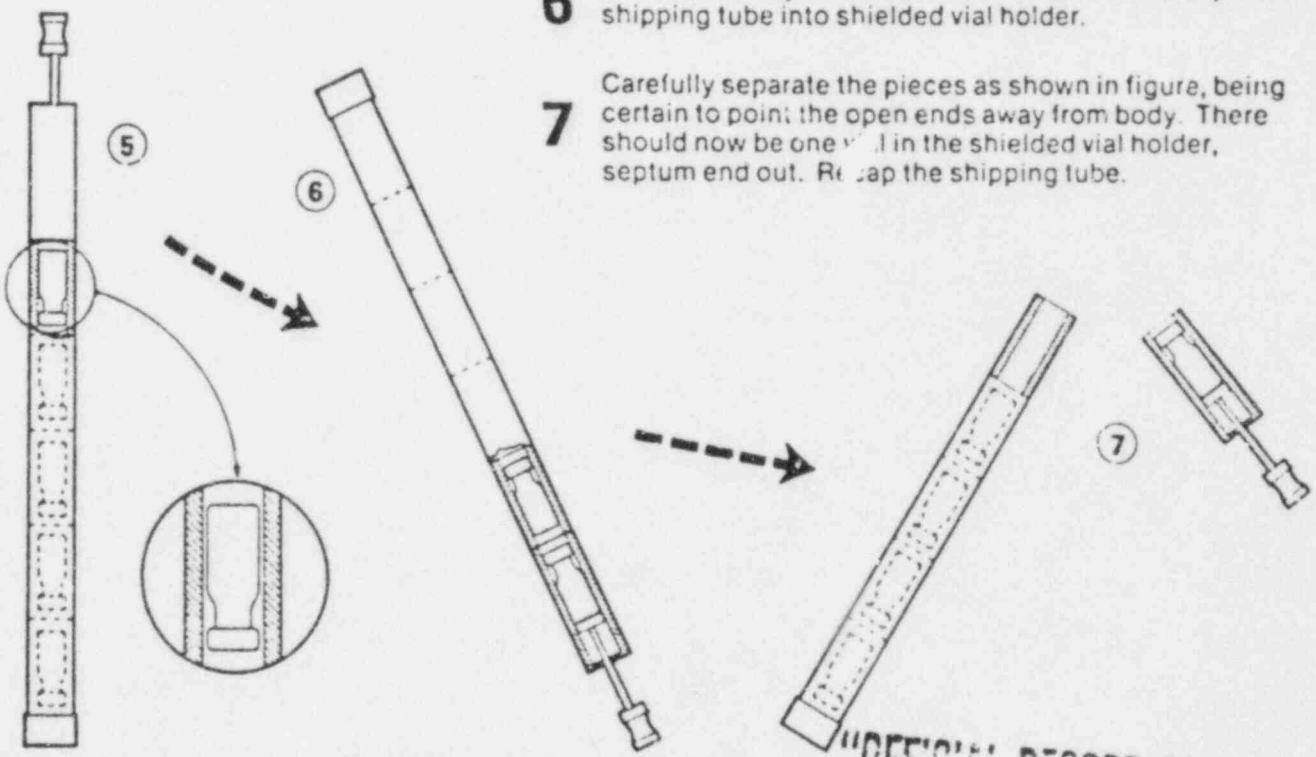
3 Attach a hypodermic needle (or other connector) securely to Luer Lock fitting on front end of dispenser.

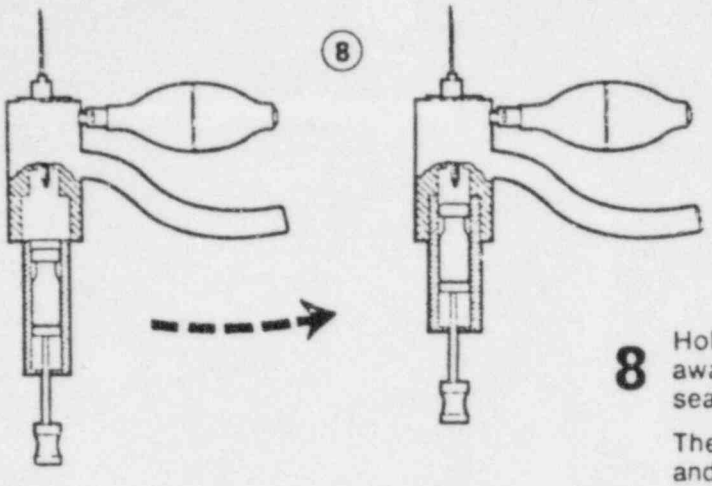
4 Remove the yellow cap of the ^{133}Xe lead shipping tube, being careful to point opened tube away from body.

5 Place the open end of the shielded vial holder tightly against the open end of the shipping tube.

6 Simultaneously invert both to allow one vial to slip from shipping tube into shielded vial holder.

7 Carefully separate the pieces as shown in figure, being certain to point the open ends away from body. There should now be one vial in the shielded vial holder, septum end out. Recap the shipping tube.

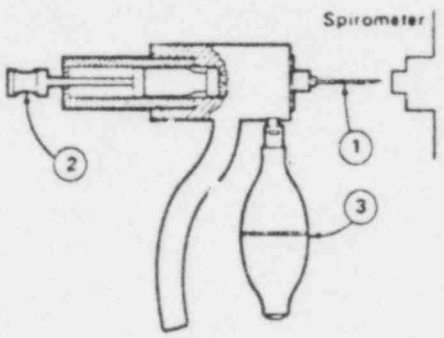




8 Holding the shielded vial holder upright (and pointed away from body), insert it into the dispenser until seated. DO NOT PUSH PLUNGER IN AT THIS TIME.

The loaded CALIDOSE Dispenser is now ready for use and can be put aside until needed. Note that appropriate radiation protection precautions must be taken since radiation can escape from the front of the unit.

Using



1 Affix the CALIDOSE Dispenser to a spirometer or related breathing apparatus.

2 Puncture septum of loaded vial by pushing plunger into dispenser.

3 Immediately squeeze the rubber bulb, and then release.

4 Detach CALIDOSE assembly from breathing apparatus.

Storing

Remove vial holder from dispenser. The previously used vial will not contain enough residual ^{133}Xe to be harmful, and may be removed by hand for disposal in the radioactive waste. Replace vial holder in dispenser for easy storage.

Statement

This CALIDOSE™ Dispenser is a device protected by U.S. Patent 3,848,773 and other patents are pending. It is to be used solely for the purposes of dispensing New England Nuclear's Xenon 133 gas Catalog Number NRP-127 as defined in New England Nuclear's NDA No. 17-284 submission. This device remains the sole property of New England Nuclear, and must be returned to New England Nuclear, Atomlight Place, North Billerica, Mass. 01862, should it cease to be used as described.

CHAR-COL INSTRUCTION MANUAL

TABLE OF CONTENTS:

INTRODUCTION

Xenon is one of the so-called rare or "inert" gases (although eight compounds have been reported in recent literature).

The density of xenon is about five times the density of air. For this reason it is difficult to dispose of xenon by means of fume hood, vented to the roof.

Xenon is slightly soluble in water, but is quite soluble in long chain hydrocarbon compounds (oil, rubber, lipids). It is easily absorbed on activated carbon through van der Waal's forces.

It is this absorbtion, coupled with the large surface area per gram of activated carbon, which permits quantitative removal of xenon from a stream of air.

Several hundred grams of activated carbon will remove over 99% of the xenon from the exhaled air, following a ventillation study. The xenon is then allowed to decay away and the chamber is ready for re-use. The process may be repeated any number of times.

THEORY OF OPERATION

The CHAR-COL is a self-contained device for the collection and containment of radioactive xenon gas.

During operation the vacuum pump draws the stream through the following components;*

A. BREATHING BAG- allows for fluctuations in flow from a breathing patient.

B. DRYING COLUMN- removes excess moisture from the expelled breath.

C. VALVE- one of six valves, one for each carbon chamber.

D. ACTIVATED CARBON CHAMBER- one of six chambers, filled with gas chromatograph grade activated carbon.

As the sample is drawn through the activated carbon the xenon is adsorbed in the lower portion of the chamber.

Adsorption is only slightly dependent upon the quantity of xenon but is directly dependent upon the volume of flow through the chamber.

Continued flow will slowly move the adsorbed xenon upward through the carbon. The physical principle is the same as that used in gas and liquid chromatography.

Each chamber is large enough to allow for thirty minutes of continuous operation.

After this time some of the xenon will have diffused to the outlet of the chamber and will be exhausted through the vacuum pump.

For this reason a chamber should not be used for more than thirty minutes of operation at one time. The xenon should be allowed to decay away to a safe level before the chamber is reused.

One of the other chambers is selected for xenon collection during subsequent studies.

Assuming that an average ventillation study requires five minutes of collection time, one chamber should usually be sufficient for one day's case-load.

*see Block Diagram, page 6

OPERATING INSTRUCTIONS

COLLECTION ONLY:

To remove xenon from a stream of air, simply attach flexible tubing to the CHAR-COL inlet, select chamber number one, and plug the device into a standard power outlet.

The vacuum pump will draw the air stream through the various components as previously described and remove the xenon.

Do not operate for a longer period than is necessary for reasons discussed previously(ie., thirty minutes of operation is the maximum allowed for the day).

After use, shut off the valve as well as removing the power.

The xenon is now safely contained in the chamber and is shielded by the lead-lined enclosure. The device may be safely stored in the camera room if desired.

On the following day select the next chamber only and proceed as before. Use a different chamber each day and rotate the order of use in an orderly fashion.

REBREATHING AND COLLECTION:

The patient's valve and mouthpiece assembly must be such that the following conditions are satisfied;

A. If xenon gas is to be inhaled a port must be available for injection.

B. During rebreathing the patient may inhale and exhale from the bag, only.

C. During wash-out the patient may inhale room air and exhale into the bag, only.

Attach the valve and mouthpiece assembly to the CHAR-COL with the shortest possible length of flexible tubing(2-3 feet max.).

Remove the cover and fill the breathing bag with air. A valve and filling port are provided for this purpose.

All six chambers should be shut off at this time, so that the air may be contained in the breathing bag.

After injection and breath holding the patient is instructed to rebreath from the bag. During rebreathing the vacuum pump may be started.

At the conclusion of rebreathing one carbon chamber is opened, allowing the contents of the bag to be drawn through the system.

The patients valve is immediately switched so that room air is inhaled, and exhaled into the CHAR-COL.

After the wash-out phase is complete the pump is stopped and the chamber is closed.

The xenon is now safely contained in the activated carbon and is shielded by the lead-lined enclosure.

MAINTENANCE

A. Once a month check the drying agent(drying chamber is located in the back, above the vacuum pump).

   Remove the connecting tubing, hold the chamber and unscrew the cap. The agent(commercially available DRIERITE) will be blue if still useable, pink if exhausted.

   If the agent has been exhausted remove from the chamber and heat until dry(agent will again turn blue).

   Preferrably, replace the exhausted agent with fresh DRIERITE.

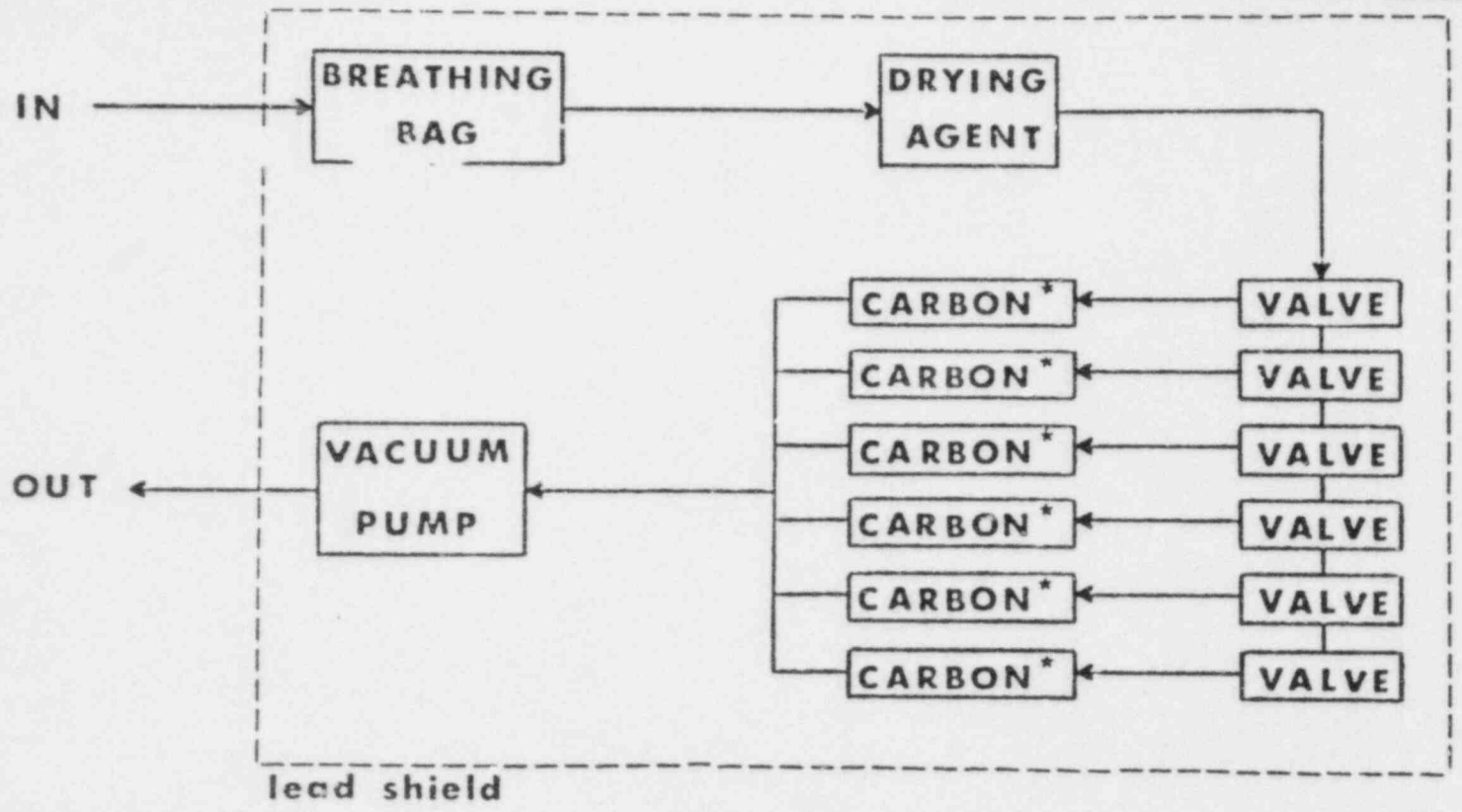
B. Periodically check the breathing bag for cracks, especially if oxygen is used in the ventillation studies.

SPECIFICATIONS

Weight.....95 pounds
DIMENSIONS.....12" wide X 24" deep X 20" high
POWER.....120 V, 60 Hz, 10 W
ADSORBANTS.....Gas chromatograph grade activated carbon for xenon; DRIERITE for moisture.
SHIELDING.....1/16" lead.

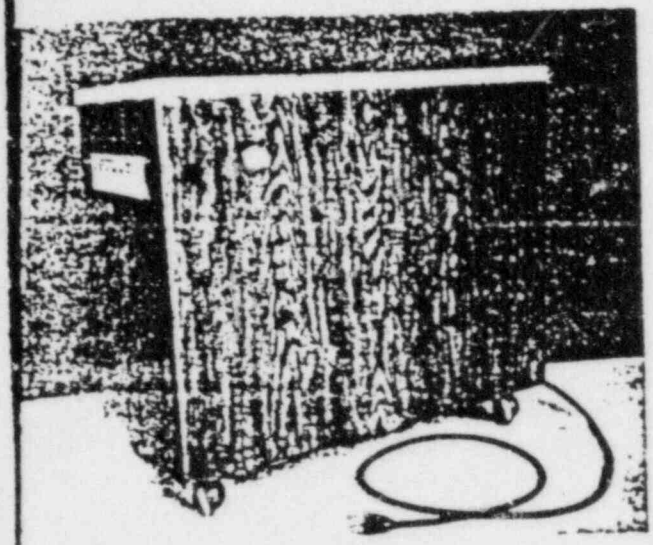
NOTE

Because of the explosive nature of oxygen it is advised that air only,is used during rebreathing from the bag. Use of oxygen during rebreathing shall be the sole responsibility of the user.



* Gas Chromatograph Grade Activated Carbon

product data



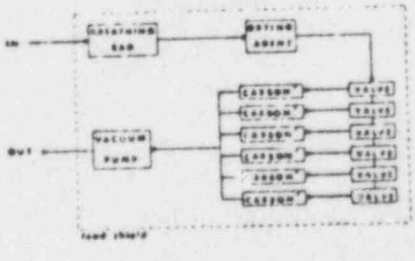
THE CHAR-COL

FOR THE COLLECTION AND CONTAINMENT

OF RADIOACTIVE XENON GAS

The Char-Col is a self-contained device for the collection of radioactive xenon. During operation a vacuum pump draws expired air through (a) a breathing bag (allows for fluctuations in flow from the breathing patient), (b) a drying column (removes excess moisture from the expired breath), (c) one of six activated carbon chambers(removes over 98 % of the radioactive xenon).
For each successive day's caseload a new chamber is selected, allowing time for xenon in previously used chambers to decay away.
If rebreathing is required the breathing bag may be filled with air by means of a separate valve and filling port.+++
The carbon chambers last indefinitely and require no maintenance. Efficiency is not impaired with use. Only the drying agent requires periodic replacement.

FLOW DIAGRAM



SPECIFICATIONS:

* Solves the serious problem of 133-Xe disposal.
* Containment of 133-Xe from a stream of air is 98 % efficient.
* May be used;
  A. During the ventillatory study (rebreathing and wash-out phases).
  B. After completion of the study (removal from spirometer or other specialized equipment).
* Each of the six chambers may be used for thirty minutes of continuous collection.
* Complete system is shielded with lead.
* Totally self-contained, portable and compact.

DIMENSIONS:
12" wide X 24" deep X 20" high(including casters).

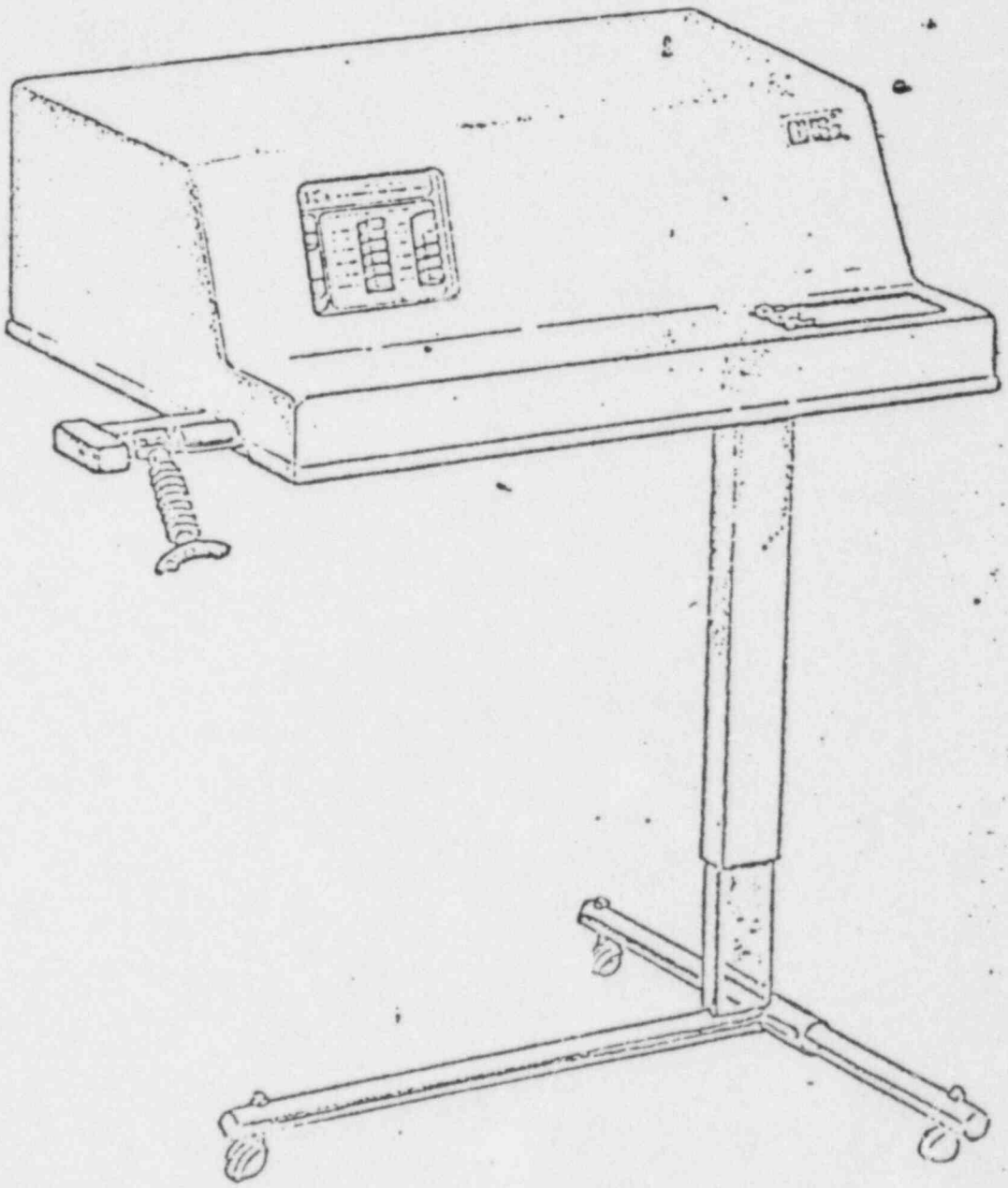
POWER:
120 V, 60 Hz, 10 W.

+++ not included, to be ordered separatly

Nise, Inc.
Nuclear Instrument Service & Engineering
20018 STATE ROAD • CERRITOS, CALIF. 90701
(714) 995-4872 (213) 860-4708

SURPRENANT/DOUGLAS

AUTOMATED VENTILATION MODULE
Model AVM-3



OPERATING MANUAL

CONTENTS

ML10

Section 1

INTRODUCTION

The Automated Ventilation Module is a highly versatile system that assists you in performing ventilation studies with a maximum amount of reproducibility between patients, and with a minimum amount of operator time and effort. The AVM consists of a series of electro-mechanical valves and electronic controls to enable the operator to automatically administer a measured amount of gas and program a series of scintiphotos in several consecutive modes of operation.

The AVM can be programmed for four basic sequences, each with at least two modes of operation, with preset time delays between scintiphotos. Since the AVM is remotely interfaced with a scintillation camera, one operator can control the entire study from the AVM console.

The complete unit is enclosed in a single molded case and mounted on an overbed table, enabling the operator to easily adjust the height of the unit. The mouthpiece is connected by flexible tubing to a rotatable breathing valve to allow studies to be performed in sitting or supine positions.

The AVM is a product of over two years of development by clinicians, physicists and electrical engineers. Omnimedical is confident that you will find the AVM to be a valuable addition to your nuclear medicine department.

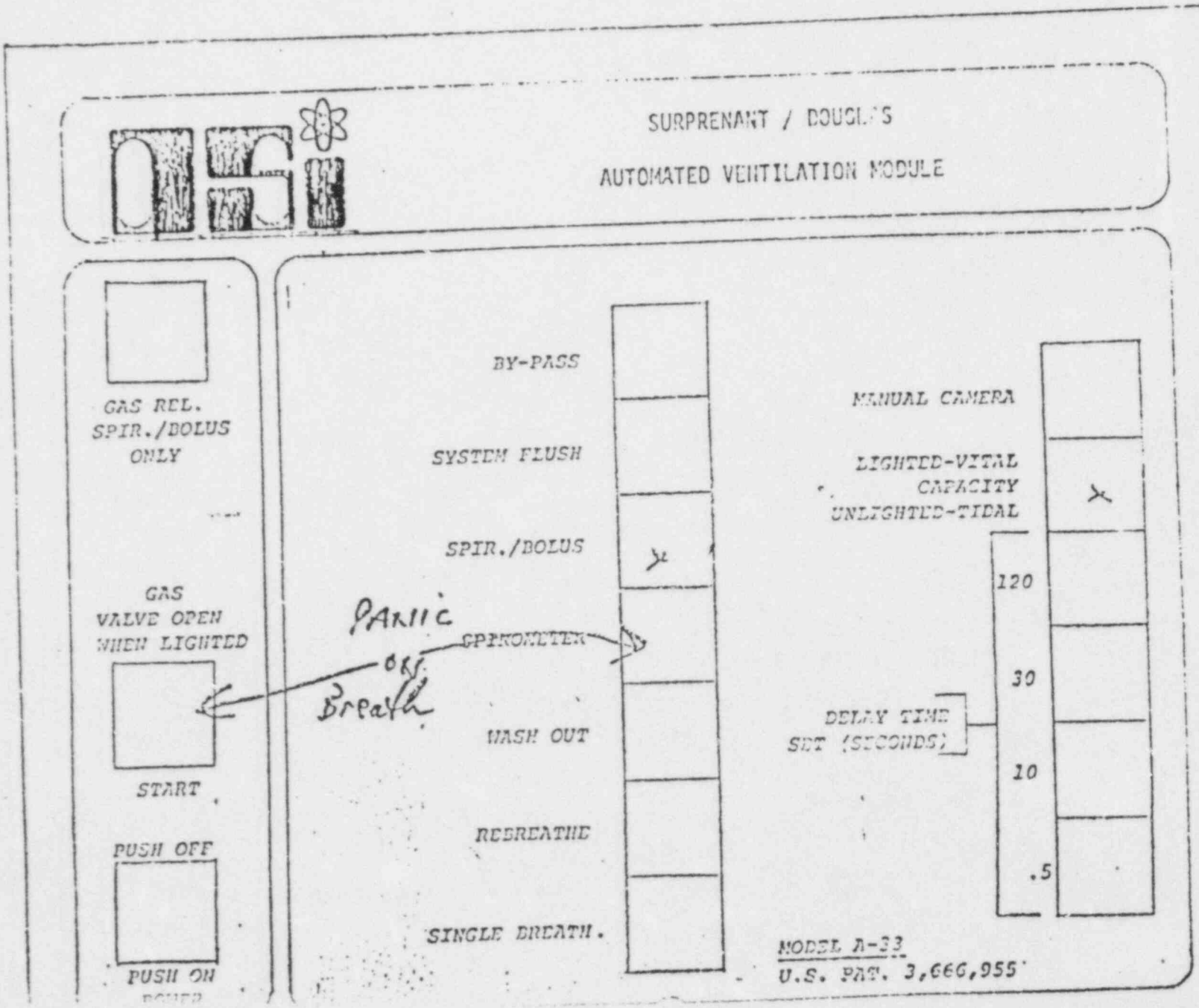
As with any instrument, the value of the AVM to you is directly proportional to how well you understand the system and how it works. For this reason, it is important that you read the manual carefully and try dry runs with the AVM to increase your familiarity of the system. Should you have any questions, call our office collect at (213) 595-1658.

WE MEASURE OUR SUCCESS BY YOUR FULL UTILIZATION OF THE AVM.

M118

CONTROL PANEL

FIGURE A



Section 2

CONTROLS AND FUNCTIONS

The controls for the Automated Ventilation Module are all located on the Control Panel, illustrated in Figure A. Before operating the AVM you should familiarize yourself with the various controls and their functions as described below. A schematic of the valves of the AVM is shown in Figure B to further your understanding of the system.

2.1 Power

The Power button controls the 115 VAC power to the system. The Power switch also opens both the Exhaust Valve and the Atmosphere Intake Valve.

The Power button is a push-on, push-off switch that glows red when the power is on. A red indicator light at the fill point of the Gas Bladder also glows when the power is on, indicating that the Gas Valve is closed. DO NOT fill the Gas Bladder if the power is on and this light is not on.

2.2 Start

The Start button is a momentary contact switch which initiates the selected program. The Start button glows red whenever the Gas Valve is open.

2.3 Gas Release

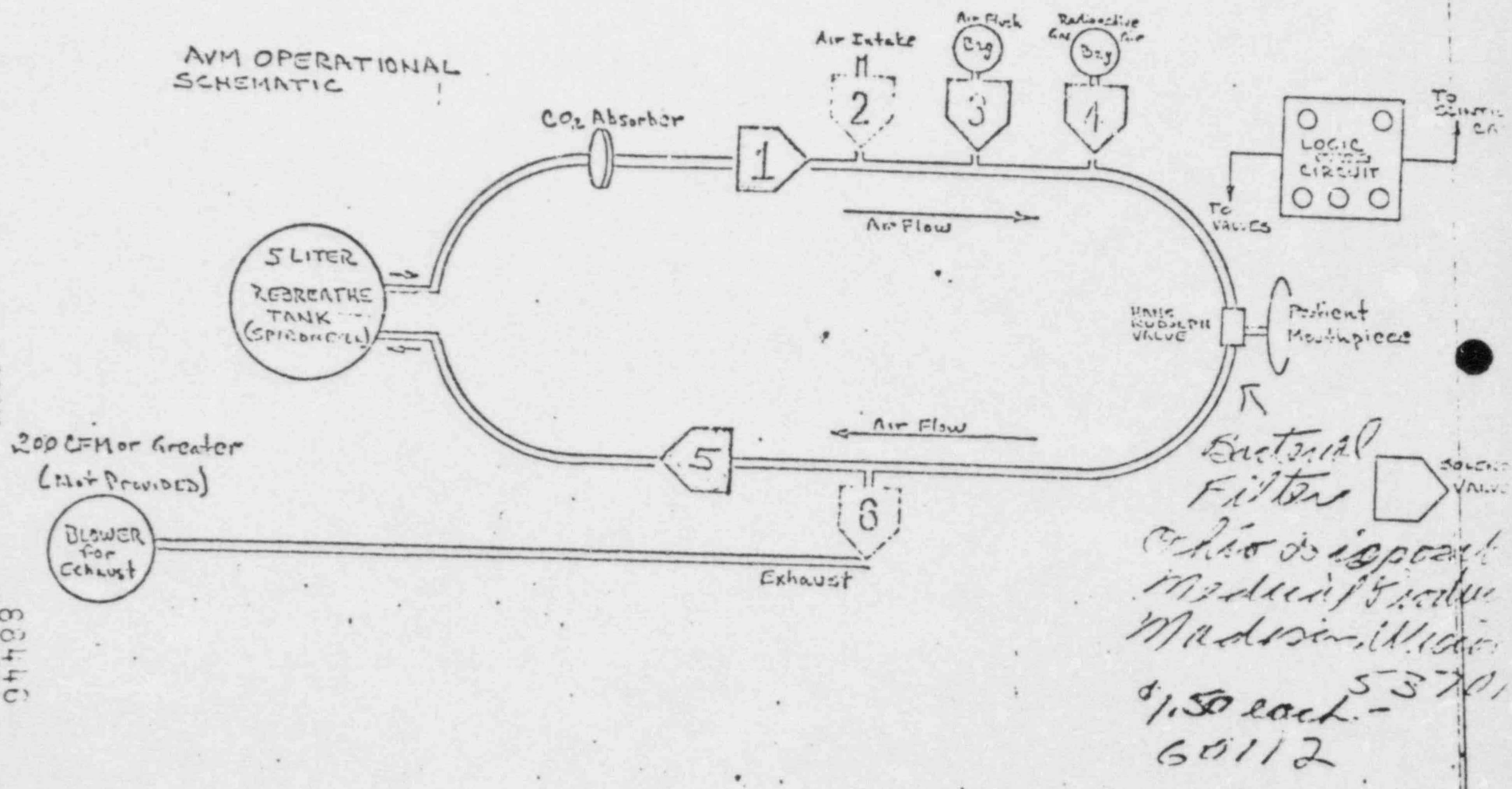
The Gas Release button opens the Gas Valve only when the Spirometer/Bolus program is selected. The Gas Release button is a momentary contact switch which glows yellow when it is depressed.

2.4 Programs

The Program buttons for the AVM are used to select Single Breath, Rebreathe, Washout, Spirometer, Spirometer/Bolus or System Flush modes of operation. All Program buttons are interlock switches preventing more than one program from being selected at one time. The functions of the various programs are discussed below.

A. SINGLE BREATH
The Single Breath mode is used when a single breath scinti, noto, without subsequent rebreathe scinti-photos, is desired. Either tidal volume or vital capacity studies may be obtained in this mode.

AVM OPERATIONAL SCHEMATIC



and Atmosphere Valves close and the Gas Valve opens. When all the gas has emptied from the Gas Bladder, a switch operated by the deflated bladder opens the Controlled Air (Tidal) or Atmosphere Intake Valve (Vital). At the end of a two second interval, after the opening of an air valve, all AVM valves close and the AVM signals the camera to reset and start accumulating data.

When the camera has completed the first scintiphoto it transmits a signal to the AVM causing the Exhaust and Atmosphere Intake Valves to open to Washout mode automatically. A preset time delay begins at this point allowing the operator to record counts/time, change film, etc. At the end of the time delay, the camera is again signaled to reset and start accumulating data. Exchanged signals between the AVM and the camera continue until sufficient Washout scintiphotos have been obtained (see Operating Instructions).

B. REBREATHE

The Rebreathe mode is used when a single breath study, followed by rebreathing in a closed system, is desired. In the Rebreathe mode, the Washout button must be pushed at the conclusion of the rebreathe study.

When the Start button is depressed, the Exhaust and Atmosphere Intake Valves close and the Gas Valve opens. When all the gas has emptied from the Gas Bladder, a switch operated by the deflated bladder opens the Controlled Air (Tidal) or Atmosphere Intake Valve (Vital). At the end of a two second interval after the opening of an air valve, all AVM valves close and the AVM signals the camera to reset and start accumulating data.

When the camera has completed the first scintiphoto, it transmits a signal to the AVM causing the Rebreathe Valves to open. This allows breathing through a closed system comprised of the 5 liter spirometer and the CO_2 absorber. The preset time delay controls time between scintiphotos. The AVM automatically signals the camera at the end of each time interval. When sufficient rebreathe scintiphotos have been obtained, the Washout button should be pushed. This will close the Rebreathe Valves and open the Exhaust and Atmosphere Intake Valves. The time delay control will continue to operate until the study is completed.

C. WASHOUT

As described earlier, the Washout mode is used following single breath or rebreathe scintiphotos to wash the gas out of the patient's lungs. The Washout mode is automatically engaged when the program is set for Single Breath. When the program is set for Rebreathe or Spirometer/Bolus, the Washout button must be pushed following rebreathe scintiphotos. When operating in the Washout mode, the Exhaust and Atmosphere Intake Valves are open.

D. SPIROMETER

The Spirometer mode is used when it is desired to administer the gas and air to the patient in a mixed volume over the entire inspiration, rather than in a bolus. When the Start button is depressed, the Exhaust and Atmosphere Intake Valves close and the Rebreathe Valves open. The time delay operates as discussed earlier. When sufficient rebreathe scintiphotos have been obtained, the Washout button should be pushed, closing the Rebreathe Valves and opening the Exhaust and Atmosphere Intake Valves.

E. SPIROMETER/BOLUS

The Spirometer/Bolus mode enables the operator to monitor the patient's respiration on the spirometer and administer the bolus of gas from the Gas Bladder at any point during the patient's inspiration. A single breath study is obtained automatically in this mode as in Single Breath or Rebreathe modes.

When programmed for Spirometer/Bolus mode, the Rebreathe Valves open when the Start button is depressed. When the Gas Release button is depressed, the Gas Valve opens followed by either Controlled Air (Tidal) or Atmosphere Intake Valve (Vital), and all valves close for the single breath study. The system will then continue operation as in the Rebreathe mode.

F. SYSTEM FLUSH

System Flush is used to open all valves after the mouthpiece has been removed from the patient, and allow the exhaust system to pull air from the atmosphere and circulate it throughout the system, thus washing out any remainder of the gas used. The Capacity button must be in Tidal position for System Flush to assure that the Controlled Air Bladder is emptied. The exhaust regulating sleeve should be adjusted to achieve maximum suction as more fully described in Section 4.

2.5 By-Pass

The By-Pass button is used to immediately open the Exhaust and Atmosphere Intake Valves in the event a problem developes during the study. The By-Pass button is interlocked to the Program switches.

2.6 Delay Time Set

Delay Time Set buttons are used to select the time between the end of one scintiphoto and the beginning of the next scintiphoto. The time setting is dependent upon the desires of the operator and the tasks to be accomplished during the delay (eg. changing film, recording counts, etc.). The timer is started by the stop count signal from the camera. At the end of the selected elapsed time a signal is given to the camera to reset and begin gathering data for the next scintiphoto.

2.7 Capacity

The Capacity button is used to select Tidal Volume (Controlled air intake) or Vital Capacity (Atmosphere air intake) studies. The amount of air available in Tidal is premeasured into a bladder by the operator. In Vital, the patient is allowed to take in an unrestricted amount of air.

The Capacity button is a green push-push switch which is lighted for Vital Capacity and unlighted for Tidal Volume.

2.8 Manual Camera

The camera may be manually reset and started at any time by depressing the Manual Camera button. The Manual Camera button is a momentary contact switch which glows blue when depressed. The Manual Camera switch is most frequently used when the Delay Time Set is programmed for 30 or 120 seconds and the operator desires an earlier scintiphoto to be started.

Section 3

SYSTEM COMPONENTS

3.1 Gas System

The Gas System consists of a rubber bladder, one end of which is connected to the Gas Valve and the other to a filling valve. The filling valve consists of two check valves which allow a syringe to be used like an air pump. In this way a measured amount of gas may be injected into the bladder. Usually 200-300 cc volume is used, but up to 1 liter may be used.

3.2 Controlled Air System

The Controlled Air System, used only for Tidal Volume studies, consists of a rubber bladder, one end of which is connected to the Controlled Air Valve and the other to a filling valve. The filling valve is the same as the gas filling system and a syringe may be used like a pump to inject a measured amount of air into the system. The amount of air injected into the Controlled Air System PLUS the volume injected into the Gas System should equal the patient's tidal volume.

3.3 Spirometer System

A filling valve is used to fill the Spirometer with oxygen, air or a gas/air mixture. At the bottom of the Spirometer and near the crank which raises and lowers the AVM system, a valve is provided to drain the Spirometer when desired. A gauge at the top of the AVM case indicates the volume in the Spirometer in half liter increments. The maximum capacity of the Spirometer is 5 liters.

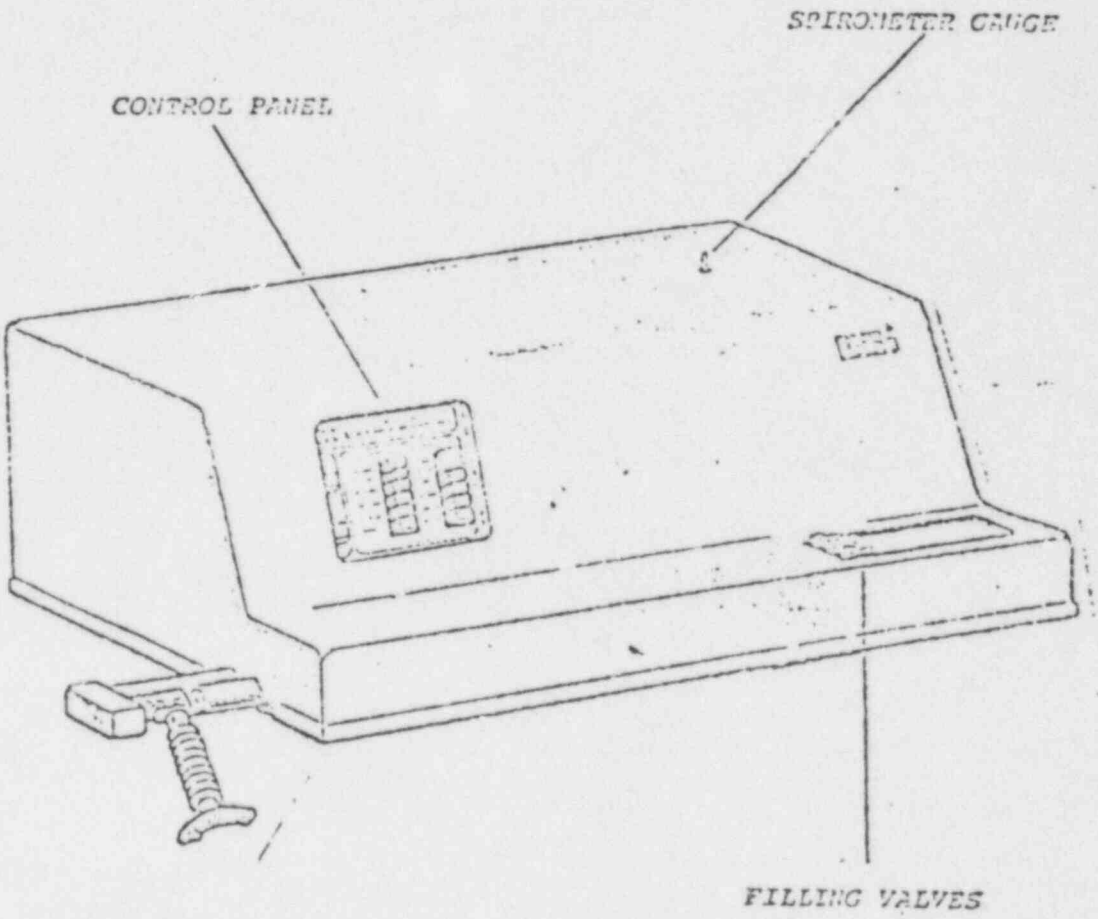
A disposable CO_2 absorber is attached to the Spirometer system. When the soda lime, visable through the window in the rear of the case, turns pink, it should be changed. For replacement, use TECO Disposable Absorber System - Full Size, manufactured by:

TECO Industries
930 5th Street
Palmetto, Florida 33561

Section 4

EXHAUST SYSTEM

Due to the type of gas which may be used in the AVM system, the AVM should be connected to an Exhaust System which will move about 200 CFM of air or to an activated charcoal gas trap. The AVM system includes 15 feet of 1¼ inch flexible hose equipped with 1½ inch rubber cuffs. The hose is connected between the AVM at the suction control pipe and the exhaust line which carries the gas outside the building. The suction control pipe has an outer sleeve which is coaxial with an inner sleeve. The outer sleeve is rotatable. Both the inner and outer sleeves have a like number of holes which, by rotating the outer sleeve, can be made to align in any number from none to all. The AVM system should be operated with the least amount of suction, ie. with all of the holes aligned. When the system is being flushed out it is recommended that the sleeve be turned to where no holes are aligned, thus applying maximum suction to the system.



AUTOMATED VENTILATION MODULE

FIGURE C

5.1 Programming the AVM

1. Press Power On button.

2. Press the appropriate program button for (a) Single Breath, (b) Rebreathe, (c) Spirometer, or (d) Spirometer/Bolus.

3. The Capacity button should be lighted if a Vital Capacity single breath study is desired, or unlighted if a Tidal Volume single breath study is desired. (Note: When programmed for Spirometer mode, the Capacity switch is not operative.)

4. Press appropriate Delay Time Set button for the desired delay between scintigrams.

5. The camera console should also be set for time/counts (eg. 12 sec./100,000).

5.2 Introducing Radiogas and Air into the AVM

1. Gas Bladder for Single Breath, Rebreathe or Spirometer/Bolus Modes.

   Introduce radiogas (eg. 10 to 20 mCi 133-Xe) into the Gas Bladder through the Gas Fill Valve (see Figure C) using a 50cc syringe. Add air to the Gas Bladder to a total volume of 100 to 300 cc.

2. Controlled Air Bladder for TIDAL VOLUME Single Breath, Rebreathe or Spirometer/Bolus Modes.

   Introduce sufficient air into the Controlled Air Bladder through the Controlled Air Fill Valve (see Figure C) to make up the difference between the patient's tidal volume and the volume in the Gas Bladder.

3. Gas and Air to Spirometer for Studies in Spirometer Mode, only.

   Introduce radiogas (eg. 10 to 20 mCi 133-Xe) and air into the Spirometer through the Spirometer Fill Valve (see Figure C) to a volume of approximately 3 to 4 liters. The supply may be enriched initially or during the study with O_2.

4. Air into Spirometer for studies in Rebreathe or Spirometer/Bolus Modes.

Tidal Volume Studies

When the AVM is programmed for Rebreathe or Spirometer/Bolus Modes, the initial single breath study may be obtained at tidal volume or vital capacity. If Tidal Volume is selected as the capacity, introduce 3 to 4 liters of air (may be O_2 enriched) into the spirometer through the Spirometer Fill Valve. When the single breath study is completed, the patient will expire his tidal volume breath into the spirometer. It is important that the patient's tidal volume plus the air introduced into the spirometer be less than the 5 liter capacity of the spirometer.

Vital Capacity Studies

If Vital Capacity is selected with the Rebreathe mode, the patient will obtain practically the entire volume of the inspiration (after emptying the Gas Bladder) from the Atmosphere Intake Valve. Therefore a minimum amount of air of O_2 should be introduced into the spirometer to prevent the 5 liter capacity of the spirometer from being exceeded upon expiration. Generally ½ liter of O_2 in the spirometer will be satisfactory.

In Spirometer/Bolus mode, the amount of air and O_2 introduced into the spirometer should be about 3 liters to allow the patient to enjoy normal breathing before the Gas Release button is depressed.

5.3 Performing Ventilation Studies

1. Position the patient's lungs in the camera field.

2. Apply the mouthpiece and noseclip to the patient. The patient is now breathing ambient air.

3. Single Breath or Rebreathe Modes, Only

   a) Observe the patient until respiration is regular. If Tidal Volume is selected depress the Start button at the conclusion of an expiration. If Vital Capacity is selected, instruct the patient to exhale completely, depress the Start button and instruct the patient to inhale as deeply as possible, even though all valves will close at the conclusion of the inspiration at either lung capacity, the patient should be instructed to hold his breath.

b) When the single breath scintiphoto is complete, the valves will reopen and the patient should be instructed to resume normal breathing.

c) In Single Breath mode, the valves open to Washout mode automatically.

d) In Rebreathe mode, the valves open to a closed system utilizing the spirometer. The operator may add O_2 as necessary through the Spirometer Fill Valve. When sufficient rebreathe scintiphotos have been obtained, depress the Washout button.

e) The AVM will continue to signal the camera for washout scintiphotos with the preset time delay between scintiphotos.

4. Spirometer Mode, Only

a) Observe the patient until respiration is regular.

b) At the conclusion of an expiration, depress the Start button. The valves will open to the closed system spirometer.

c) Although the valves remain open to the closed system, a single breath study may be obtained by instructing the patient to take a normal or vital capacity inspiration and hold his breath.

d) The operator should add O_2 to the spirometer as necessary.

e) When sufficient rebreathe scintiphotos have been obtained, depress the Washout button.

5. Spirometer/Bolus Mode, Only

a) Observe the patient until respiration is regular.

b) Depress the Start button and observe patient respiration volume on the spirometer gauge. Note: the patient has not yet received any gas and the camera has not been signaled to begin accumulating data.

c) The bolus of gas from the Gas Bladder may be administered at any time during the patient's inspiration. At the desired time, depress the Gas Release button and instruct the patient to hold his breath after he completes the inspiration for the single breath scintiphoto. (The valves will close preventing respiration during the single breath study.)

d) The remainder of the study proceeds as if the AVM was programmed for Rebreathe mode.

e) When sufficient rebreathe scintiphotos have been obtained, depress the Washout button.

6. When most of the radiogas has cleared from the patient's lungs (about 3-5 minutes), remove the mouthpiece and noseclip from the patient.

7. Depress the System Flush button and allow the system to flush for approximately 5 minutes. (Note: Capacity must be set for Tidal when the AVM is in System Flush mode.)

8. Depress the Power Off button.

Section

INSTALLATION

1. When the AVM is received and unpacked, it will be noted that the module is separated from the stand. The module should be fastened to the stand with four ¼ 20 cap screws which are provided.

2. The Exhaust suction controlling pipe should be screwed in place beneath the AVM table. Hand tight is sufficient.

3. Install the mouthpiece tube.

4. Connect the flexible exhaust hose from the AVM exhaust pipe to the exhaust system in the hospital.

5. FOR NUCLEAR CHICAGO -- PHO GAMMA CAMERAS:

   Connect the cable provided to the rear panel of the AVM and to the camera remote plug on the rear panel of the camera. The remote-manual switch on the rear of the camera should be set for manual.

6. Connect the 115 VAC power lead to the rear panel of the AVM and to a wall outlet.

7. The AVM can be tested by using air in the gas bag in order to familiarize the operator with the operating controls and program modes.

NOTE: In order to reset the system to start a new program, the power switch must be turned off and left off for at least two seconds.

ST. JOSEPH HOSPITAL
125 STRAWBERRY HILL AVENUE
STAMFORD, CONNECTICUT 06904

TELEPHONE 327-3500

Mr. John E. Bowyers
Radioisotopes Licensing Branch
Division of Fuel Cycle and
Material Safety,
Nuclear Regulatory Commission
Washington D.C. 20555

Dear Mr. Bowyers:

Our N.R.C. license, number 06-06922-02, is already amended for Xenon-133 for pulmonary ventilation studies. We have however, recently moved our radioisotope facility to new quarters on the fourth floor of the hospital and we are submitting the enclosed calculations indicating that we are in compliance with 10 CFR Part 20. We purchase the radiopharmaceutical from New England Nuclear Corp., Atomlight Place, No. Billerica, Mass. 01862. Catalog Number NRP 127 Xenon Xe-133 Gas in unit dose vials. NDA approved. Our imaging is performed on either a Searle H.P. or Large Field of View gamma camera. The following special equipment is used:

1. Delivery system - New England Nuclear Calidose Dispenser
2. Lung Function Unit - Omnimedical P.O. Box 1277, Paramount, California, 90723 - Automated Ventilation Module Model AVM-3.
3. Disposal System - Nise Inc., 20018 State Road, Cerritos, Calif. 90701 - Char-Col Xenon Gas Trap.
4. Dose Calibrator - Capintec Model CRC-6A

All personnel have whole body and wrist film badges and TLD finger badges.

Description of the Hot Lab: The Xenon-133 gas will be stored in its 1/8 inch thick lead container behind 2 inch thick lead brick in a fume hood which has an exhaust fan having a capacity of 580 cfm. The total volume of the room is 450 cu. ft. (8' x 7' x 8'). Air can enter the room through a window , a door, a ceiling vent and two pass throughs. (One to the imaging room and one to an inside hallway.) Since our weekly order is 100 m. Ci, allowing for precalibration and decay we should never have more than 180 m. Ci. in storage at any one time. Allow an escape fraction of .15.

The maximum concentration of Xenon-133 over forty hours in seven consecutive days for this restricted area has been calculated as follows:

$$C = \frac{A \times f}{V} = \frac{1.8 \times 10^5 \times .15 \text{ u. Ci.}}{580 \times 6.8 \times 10^7 \text{ ml in 40 hrs.}} = .068 \times 10^{-5} \text{ uCi/ml per 40 hrs.}$$

This is in compliance with 10 CFR Part 20 for restricted areas. In the event of accidental release of the Xenon-133 the window would be opened and the door closed after all personnel have left the room. The time required for the room air to change 20 times is

$$20 \times \frac{450 \text{ cu. ft.}}{580 \text{ cu. ft./min.}} = 16 \text{ min.}$$

After 16 min. the room will be surveyed with a low level survey meter (0-.1mr.)

The air exhausted from the hood is released into an unrestricted area on the roof and is at least 25 feet from any air intakes. The concentration of Xenon-133 in this unrestricted area is based on our weekly order of 100 mCi. and an escape fraction of .15

$$C = \frac{10^5 \times 52 \times .15 \text{ uCi.}}{580 \times 1.5 \times 1010 \text{ ml/yr.}} = .89 \times 10\text{-}7 \text{ uCi./ml averaged over one year.}$$

This figure is also in compliance with 10 CFR Part 20.

Procedure: We are doing a maximum of 10 patients per week at 10 mCi per patient. The activity is assayed in the dose calibrator, the gas is transported and dispensed with Calidose Dispenser into the AVM-3 ventilation nodule and collected in the Char-Col Trap. The patient will receive instructions on the procedure, a nose clamp will be used and the study will consist of breath-hold, equilibrium and washout phases.

Description of the Imaging Room: All imaging procedures will be performed on one or the other of the gamma cameras in the imaging room. The room has 3 windows, a door, 3 air intake ducts, and a ceiling exhaust vent with a capacity of 1075 cfm. Between 20% and 100% of this air is actually exhausted on the roof which means that in the worst case the true exhaust from the room is 20% of 1075 = 215 cfm. The maximum amount of Xenon-133 used per week is 100 mCi. Assume an escape fraction of .15

$$C = \frac{10^5 \times .15}{215 \times 6.8 \times 10^7 \text{ ml. in 40 hrs.}} \text{ uCi.} = .10 \times 10\text{-}5 \text{ uCi/ml over 40 hrs.}$$

The charcoal trap is also stored in this room and could increase this figure by no more than 50%. The air exhausted from the imaging room is released into an unrestriced area on the roof. The concentration of Xenon-133 in this unrestricted area is based on escape of .15 of our total yearly activity and an average yearly exhaust of 20% of the air leaving the room.

$$C = \frac{10^5 \times 52 \times .15 \text{ uCi}}{215 \times 1.5 \times 1010 \text{ ml/yr}} = 2.4 \times 10\text{-}7 \text{ uCi/ml averaged over one year}$$

In the event of an accidental release, the windows will be opened, the patient and all personnel will leave the room and the door will be closed. The door to the Hot Lab will be closed. The two rooms are connected by a pass through duct. The total volume of the imaging room is 4030 cu. ft. (34 x 15 x 8). The total volume of the two rooms is therefore 4530 cu. ft. The total air flow is at least 795 cfm. (580 + 215) The time required for the room air to change 10 times is

$$\frac{10 \times 4530 \text{ cu. ft.}}{795 \text{ cu. ft./min}} = 57 \text{ minutes}$$

After 1 hour the room will be surveyed with a low level survey meter (0-.1mr).

Disposal: The Xenon-133 gas is trapped in a charcoal trap manufactured by Nise Inc. In order to determine the escape fraction a small amount of charcoal is placed in a piece of plastic hose just before the exhaust of the trap and left in for an actual study using 10 mCi. of Xenon-133. After the study the charcoal is removed and assayed in a dose calibrator a little at a time, to reduce attenuation, and compared with the total administered activity.

This has been measured as being 1.5%. If this number should increase to 10% the cartridge will be replaced and the used one will be removed along with other radioactive waste by Nuclear Diagnostic Laboratories, Peekskill, N.Y. The desiccant in the trap will be checked weekly and replaced as needed. All exhaust vents will be checked periodically to determine their efficiency.

Cordially,

Malcolm Powell
Physicist

MP:md

CARSON, LUNDIN & THORSON, PC ARCHITECTS
880 THIRD AVENUE NEW YORK 10022

ROBERT L. THORSON

DONALD O. CHAPMAN
DONALD JEWELL
MICHAEL RUBIN
EDWARD V. FRANKLIN
BRUCE L. ALLEN

212-754-1040

June 16, 1977

St. Joseph Hospital
New Emergency APD
Addition & Alteration
Job No. 258-12 -CL&T Job No. 1275

Dr. James J. McSweeney,
Director Department of Radiology
St. Joseph Hospital
128 Strawberry Hill Avenue
Stamford, Connecticut 06904

Dear Dr. McSweeney:

In response to your telephone call regarding supply and return air quantities for Rooms 410 (Hot Lab) and 411 (Scanning), we wish to advise that the design criteria indicated on the Construction Documents is as follows:

Hot Lab. Room 410: The supply air enters the room from the supply duct at the rate of 235 CFM and is exhausted through the hood at 580 CFM. Make up air enters the room through a transfer grille at 355 CFM.

The air from the hood exhaust passes through an absolute filter and is exhausted 25'-0" from the fresh air intake of the supply fan. A distance of ten to twelve feet is usually considered acceptable.

Scanning Room 411: The supply air enters the room from three registers at a total rate of 1425 CFM and is exhausted at 1075 CFM. The transfer grill to Room 410 exhausts at 355 CFM.

Sincerely,

Edward V. Franklin

Edward V. Franklin
/b
CC: Sister Daniel Marie
Mr. Feyzi Bil

ML10

APPENDIX J

WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

Check as appropriate

✓ By commercial waste disposal service (See also No. 4 below)

✓ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

____ Other (specify): _____

2. Mo-99/Tc-99m generators will be:

(Check as appropriate)

____ Returned to the manufacturer for disposal

____ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants)

____ Disposed of by commercial waste disposal service (See also No. 4 below)

✓ Other (specify): Licensed salvage company- Medi-Ray Inc. Tuckahoe, N.Y. N.Y. License 2143-2157, 2077-2157

3. Other Solid Waste will be:

(Check as appropriate)

✓ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed) have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

97444

Item No. 18
Date: _____

✓ Disposed of by commerical waste disposal service (See also No. 4 below)

____ Other (Specify): _____

_____

4. The commerical waste disposal service used will be: _____

N.D.L. Peekskill N.Y.

(Name) (City, State)

NRC/Agreement State License No. 31-12000-1

Item No. 18
Date: _____