11/29-DCS

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

October 17, 1979

John E. Bowyer
Nuclear Regulatory Commission
Region III
799 Roosevelt Rd.
Glen Ellyn, Illinois 60137

RE: License Number 34-01216-03

Dear Mr. Bowyer;

Enclosed please find the license Amendment request for Xenon-133 gas. The packet contains a letter from our hospital administrator, the amendment request information, and seven (7) attachments pertinent to that request. In addition, supplements A & B for M. Fadell, M.D. are provided so that his name may be added to our current byproducts materials license. Should you require further information regarding or clarification of the storage, use, and disposal aspects of the Xenon-133 gas system and components, please contact me at 419-259-4127.

Sincerely,

K. J. Schroader, M.S.

K.J. Schroader, M.S.
Radiation Physicist
Radiation Safety Officer

KJS/jfp

8011090390

39 pp

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

I. Amendment Request for Xenon (Xe-133) Gas Use

A. Licensee:
St. Vincent's Hospital
Department of Nuclear Medicine
2213 Cherry Street
Toledo, Ohio 43608

B. Current License Number
34-01216-03

C. Radioactive Material
Xenon Xe-133 gas

D. Type of Study
Pulmonary Ventilation Studies

E. Posession Limit Requested
300 mCi

amended in 8-21-81 letter

F. Dosage Employed
10 mCi per patient; however, higher doses may be used when professional medical judgement indicates the necessity.

G. Patient Load
10 patients per week
520 patients per year

H. Source of Radiopharmaceutical
Pharmatopes, Incorporated
2208 W. Central Avenue
Toledo, Ohio 43606
License Number: 34-16654-01MD

See Attachment 1, the manufacturer's product literature with package insert information.

Food and Drug Administration's status of the radiopharmaceutical:
IND

NDA ✓ IND _____

IND Number: N/A

FD Form 1573 completed for 'ND Product

Yes ____ No ✓

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

I. Imaging Equipment

Imaging Room #1:
General Electric Maxicamera
Model Number 46-400-321GI
Delivery Date: October, 1978

Imaging Room #2:
Searle Pho Gamma IV
Model Number: None
Deliver Date: April, 1975

and in 8-2-91 letter

J. Special Equipment

a. Xenon Delivery/Trapping System supplied by:
ADC Medical
400 Smith Street Farmingdale, N.Y. 11735
Model Number Xe-400 A

See attachment #2 for description of this system.

b. XenAlert Room Air/Trap Monitor supplied by
Nuclear Associates
100 Voice Road
Carle Place, N.Y. 11514

See Attachment #3 for description.

c. Emergency Room Air Radiodecontaminator supplied by
ADC Medical
400 Smith Street
Farmingdale, N.Y. 11735
Model Number Xe-404

See Attachment #4 for description

d. Xenon-133 Dispensers supplied by
New England Nuclear
Medical Diagnostics Division
601 Treble Cove Road
North Billerica, Maine 01862

See Attachment #5 for description

Medi Physics
5801 Christie Avenue
P.O. Box 8684
Emeryville, California 94608

See Attachment #6 for description

*NOTE: The Xe-133 dispensers will be purchased from Pharmatopes, Inc., the central radiopharmaceutical supply firm mentioned in Item H. Above. They in turn will be supplied by the above mentioned firms.

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

K. Dose Calibration
All doses for patient use will be checked immediately prior to administration with a Mediac Dose Calibrator supplied by Nuclear Chicago and described in our original license submission.

L. Personnel Safety
All personnel involved wiht the use of Xenon-133 will be monitored by film badges for whole body exposure estimates and by TLD ring badges for extremity exposure estimates. Both sets of monitoring devices are supplied by the R.S. Landauer, Jr and Co., and have a monthly exchange frequency.

M. Scale Drawing of Areas Involved with Use and Storage of Xe-133.

The scale drawing of the deparment is the same as described in Attachment F of the original license submission. However, an enlargement of this area with notations pertinent to the use of Xenon-133 is provided in Attachment #7 of this license amendment application.

N. Description of Storage Area.
The Xenon 133 gas will be stored in its 1/8 inch thick lead shipping container within the fume hood until required. The storage area within the fume hood will be surrounded with (2 inch) lead bricks. A description of this room containing the hood, in addition to the radiation monitoring equipment and radiological safety procedures are the same as described in the original license submission. The hood will operate on a continual basis with an air flow velocity of 1000 cubic feet/minute at its exhaust opening. The total volume of this room is 1536 cu ft (12' x 16' x 8') Air can enter the room through a slit under the door and two ceiling vents. All air leaves the room via the fume hood which is vented directly and exclusively to the roof. The room is under negative pressure at all times. The maximum concentration of Xenon - 133 over forty hours in seven consecutive days for this restricted area has been calculated on the following basis.

a. Maximum amount of Xenon 133 activity per week is 300 mCi, since the Xenon Delivery/Trapping system will be stored in this area when not in use.

b. Estimated escape fraction (maximum Xenon 133 activity lost due to leakage and inadvertant release) is 0.33.

c. Air flow volume is 1000 $ft.^3$/Minute.

Therefore, using the above data and appropriate conversion factors, C can be calculated.

$$C = \frac{A}{V} \times f = \frac{300 \text{ mCi} \times 1\times10^{3} \text{ uCi/mCi}}{1000 \text{ ft}^3 \text{ min} \times (6.797\times10^{7} \text{ ml/ft}^3)} \times 0.33 = 1.5 \times 10^{-6} \text{ uCi/ml per 40 hr week}$$

This calculation verifies that the MPC of 1×10^{-5} uCi/ml as stated in Section 20.103 10 CFR Part 20 and Schedule B Table I of Part 20 will not be exceeded.

In the event of an accidental release of Xenon 133 in this area, the following procedure will be implemented: All personnel will leave the room and close the door. The room will remain unoccupied for 20 minutes. Upon re-entry, the room will be surveyed with a low level survey meter to insure the radiation levels have returned to normal for the area.

The 20 minute period will insure thirteen changes of the room air based on the following calculations.

a. Total Air volume/min = 1000 cu ft/min.
b. Volume of Room 1536 cu.ft

Therefore:

$$\frac{\text{Room Volume}}{\text{Air Volume/min}} = \text{Turn over time} = \frac{1536 \text{ cu ft}}{1000 \text{ CFM}} = 1.53 \text{ min}$$

Thirteen exchanges of room air would therefore take approximately 20 minutes.

The air which is exhausted from this room is refiltered and then released directly into an Unrestricted Area located in the roof of the Hospital. The filters in this duct have an efficiency of 99.97 per cent when tested with 0.3 micron dioctylphthalate smoke. There is a solenoid switch for wash down of this duct after the filters at the base of the vertical duct. The water goes to the sanitary drainage system. This wash down system is a requirement of DHEW publication no. (HRA) 79-14500. The release point is isolated from the closest air intakes for ventilation purposes by approximately forty eight feet horizontally and twenty-eight down. There is another intake sixty feet horizontally and sixty -five feet up.

Delete per 8-21-81

*The Xenalert detector system as described in Attachment #3 will monitor the room air in the area when it is not being used during a patient procedure in the Imaging room.

O. Description of Procedure.

The Xenon 133 gas will be used in the following manner: the dose will

be measured in a ~~Medical~~ Dose Calibrator. The patient will be instructed on details of the procedure with special emphasis on the areas where his cooperation is needed. Just prior to the study, one or more practice runs will be done before the Xenon 133 gas is used. The unit dose vial will be loaded into a shielded dispenser furnished by the manufacturer and described in Attachments #5 and #6 of this amendment application. The dispenser will be taken to the imaging area where the lung ventilation procedure will be done. The dispenser will be connected to the Xenon delivery/trapping system unit (see attachment #2 of this Amendment application). A clamp or mask will be applied to the patient to prevent exhalation of Xenon 133 into the room. The Xenon 133 gas will then be administered to the patient. The lung ventilation procedure will be composed of the three standard phases of breath hold, equilibrium, and washout. These phases are accomplished automatically by the technologist as he/she operates control panel of the unit. Upon completion of the study, the used Xenon 133 will be drawn directly into the gas trap of the delivery/trapping system.

P. Description of Utilization Area (Imaging Room)

All Xenon 133 lung ventilation procedures will be performed in Imaging Rooms 1 and 2 as indicated on Attachment #7 and described in our original license submission. The Xenalert Room air monitor as described in Attachment #3 during the entire procedure will be placed near the patient. Upon completion of the procedure, the monitor will again be placed in the storage area room containing the fume hood, as described previously. Air will enter each room through the door and two ceiling vents. The air is exhausted from these rooms from a grille, in the ceiling, near the south wall approximately centered in each room. The return air system handles 816 cubic feet/min in Imaging Room #1 and 827 cubic feet/min in Imaging Room #2. Under normal (non-emergency) conditions the air from these rooms is returned to the central air handling system for recirculation. During the time in which Xe-133 will be administered to each patient, a special exhaust will be activated in the room being utilized for the study. The special system is activated from a wall switch and allows the air from the room to be exhausted through a vent in the exterior wall of the building; thus, the air is not recirculated when the special exhaust system is activated. The quantity of exhaust air in these special exhaust systems is 1002 cubic feet/min in Imaging Room #1 and 1025 cubic feet/min in Imaging Room #2. A pilot light on the switch for the special exhaust system gives positive indication that the special exhaust system is operational. The air from these two rooms under the special exhaust operation is exhausted through a vent in the sidewall of the building. The distance to the nearest building is approximately fifteen feet for Imaging Room #1 and approximately forty feet for Imaging Room #2. The distance to the nearest air intake for ventilation

purposes for Imaging Room #1 is approximately fifteen feet down and approximately six feet horizontally. There is a second air intake approximately twenty five feet up. For Imaging Room #2 the horizontal distance would be increased by an additional twenty five feet with both being approximately ninety five feet up. Both imaging rooms operate under slight negative pressure at all times.

In addition, there are two five inch round exhaust ducts that are served by one fan. The duct to Imaging Room #1 exhausts 52 cubic feet/min while the duct from Imaging Room #2 exhausts 51 cubic ft/min. There is a solenoid switch for washdown of this duct similar to that described in Section N of this license amendment application.

The maximum concentration of Xenon 133 for this Restricted area is calculated below:

	Imaging Room #1	Imaging Room #2
a. Maximum amount of Xe 133 per week, based on that resulting from patient use	100 mCi	100 mCi
b. Estimated Escape Fraction (maximum Xenon 133 activity lost due to leakage or inadvertant release)	0.33	0.33
c. Air flow volume (not including small exhaust ducts described above)	1002 CFM	1025 CFM

Therefore, using the preceding values and appropriate conversion factors, C can be calculated:

$$\text{Imaging Room \#1 } C = \frac{A}{V} \times f = \frac{(100\ \text{mCi})\ (1\times10^{3}\ \text{uCi/mCi})}{(1002\ \text{ft}^3/\text{min})\ (6.79\times10^{7}\ \text{ml/ft}^3)} \times 0.33 = 4.85\times10^{-7}\ \text{uCi/ml}$$

$$\text{Imaging Room \#2 } C = \frac{A}{V} \times f = \frac{(100\text{mCi})\ (1\times10^{3}\ \text{uCi/mCi})}{(1025\ \text{ft}^3/\text{min})\ (6.79\times10^{7}\ \text{ml/ft}^3)} \times 0.33 = 4.73\times10^{-7}\ \text{uCi/ml}$$

This verifies that the MPC of 1×10^{-5} uCi/ml as stated in Section 20.103 CFR Part 20 and Schedule B Table I of Part 20 will not be exceeded.

The maximum concentration of Xenon 133 for the unrestricted area, the sidewall outside exhaust, is calculated below:

a. Maximum amount of Xenon 133 released per year is based upon 100 mCi per week utilized for patient studies times the escape fraction of 0.33. 100mCi/wk x 0.33 x 52 weeks/yr = 1716 mCi/yr.

b. Total air flow volume from Imaging Rooms #1 and #2: 2027 CFM. These are added together because they are dumping into the same exhaust duct on the side of the building.

c. Therefore, using the preceeding values and appropriate conversion factors, C can be calculated.

$$C = \frac{A}{V} = \frac{(1716\ mCi)\ (1 \times 10^3\ uCi/mCi)}{(2027\ CFM)\ (1.484 \times 10^{10}\ ml\ min/yr\ ft^3)} = 5.7 \times 10^{-8}\ \frac{uCi/ml}{ave/yr.}$$

The maximum concentration of Xenon 133 for the unrestricted area, the roof exhaust is calculated below.

a. Maximum amount of Xenon 133 released per year is based on 200 mCi per week stored (300 mCi total - 100 mCi utilized for patient studies) times the excape fraction of 0.33.

200 mCi/wk x 0.33 x 52 weeks/yr = 3432 mCi/yr.

b. Total air flow volume 1000 cu ft/min. from hood exhaust.

c. Therefore using the preceeding values and appropriate conversion factors C becomes:

$$C = \frac{A}{V} = \frac{(3432\ mCi)\ (1 \times 10^3\ uCi/mCi)}{(1000\ ft^3/min)\ (1.484 \times 10^{10}\ ml\ min/yr\ ft^3)} = 2.3 \times 10^{-7}\ \frac{uCi/ml}{ave/yr.}$$

These calculation verify that the MPC of 3×10^{-7} uCi/ml as stated in Section 20.106 10 CFR Part 20 and Schedule B Table 2 of Part 20 will not be exceeded, and that Section 20.1(C) of 10 CFR Part 20 is being complied with.

At this point it is worthy to note that an escape fraction of 0.33 is utilized for all calculations. While an escape fraction of 0.25 is acceptable for most situations it is the desire of this institution to be as stringent as practicable on its ventilation system requirements. Therefore, although the actual escape fraction will be maintained well below 0.33, this value will still be used in all the calculations requiring its estimate

last Xenon 133 lung ventilation procedure each week, a 5 liter polyethylene bag will be placed over the exhaust port of the trapping unit, and the unit will be sealed and placed in front of the gamma camera and counted for one minute on the appropriate settings. The counts per minute will be logged in a record book and compared with previous readings. A replacement cartridge will be installed whenever there is a significant increase in the weekly counts per minute. The saturated cartridge will be placed in the fume hood behind the two inch lead blocks and will be allowed to decay to normal background levels. Spent cartridges will be disposed of by Pharmatopes, Inc., the central radiopharmaceutical service which supplies the Xenon 133.

The test bags of exhaust air which exhibit counts higher than normal will be emptied via an exhaust system in the radiation source storage room in the hospital. This system consists of a pipe with a fitted nozzle to which the bag can be directly attached. When the fan switch is turned on the bag will be evacuated and the exhaust vented directly to the roof

The bag volume is 5 liters. The air flow rate is 50 CFM. The design of the system will not allow the escape of the trace amount of Xenon 133 in the exhaust bag into the room. The outside vent is greater than 25 feet from all other air inlet vents. The maximum concentration of Xenon 133 in this Unrestricted Area on the roof is:

a. Maximum amount of Xenon 133 released per year is based on the manufacturers recommendation that the cartridge be replaced semi-annually. Therefore, twice yearly, higher activity levels should be A conservative estimate of 10 mCi per incident results in 20 mCi per year released from this special exhaust system.

b. Total air flow volume is 50 ft^3/min.

c. Therefore, using the preceeding values and appropriate conversion factors,

$$C = \frac{A}{V} = \frac{(20\ mCi) \times (1 \times 10^3\ uCi/mCi)}{(50\ ft^3/min)(1.484 \times 10^{10}\ ml\ min/ft^3\ yr)} = 2.7 \times 10^{-8}\ uCi/ml\ ave/yr$$

These calculations verify that the MPC of 3×10^{-7} uCi/ml as stated in Section 20.106 10 CFR Part 20 and Schedule B Table 2 of Part 20 will not be exceeded, and that Section 20.1 (c) of 10 CFR Part 20 is being complied with.

Two other points must be made regarding the administration of the Xenon 133 to the patient. First, a Rad Emergency Room Air Radio Decontaminator will be kept in operation during the entire patient study. The specifications of this device may be found in Attachment #4 of this license Amendment application. The use of this device will be merely to supplement the ventilation capabilities of the room and will at no time be used as a replacement for any of the ventilation requirements described above. Secondly, the patient will be fitted with a shoulder harness to which a section of corrugated tubing is attached. This harness will position the tubing just below the patient's chin. The other end of the tubing will be fitted to a portion of the exhaust vent for the room. Much of the Xenon 133 that escapes the mouthpiece or Xenon trapping system via inadvertant patient exhalation will be suctioned out of the room via this disposable corrugated tubing system. The tubing will be surveyed by a low level survey meter following each study. Tubing exhibiting radioactive levels exceeding that of normal background for the area will be replaced in the fume hood until it no longer emits radiation levels above that of normal background.

In the event that there is an accidental release of Xenon 133 in either of the imaging rooms, the following emergency procedure will be implemented:

The patient will be removed from the room. The door will be closed. All personnel will leave the imaging room for 40 minutes. Upon re-entry, the room will be surveyed to insure that radiation levels have returned to normal for these areas. Upon verification of the above, the air exhaust for the room will be switched back to that for normal conditions.

The 40 minutes will insure 12-13 changes of the air in the rooms according to the following calculations:

		Imaging Room #1	Imaging Room #2
a.	Total air flow volume	1002 CFM	1025 CFM
b.	Total Room Volume	3078 ft^3 (19x18x9)	3402 ft^3 (21x18x9)
c.	Volume/air flow/min = turnover time	3.1 min.	3.3 min
d.	Forty minutes allows	13 changes	12 changes

Q. The Disposal Phase

The disposal of the Xenon 133 gas will be done by trapping the gas in the Xe-400 Delivery/Trapping System as described in Attachment #2 of this license Amendment Application. The potential leakage of Xenon 133 from this unit as well as other sources of leakage are included in the Escape Fraction figure. To insure that the trap is working efficiently, the exhausted air from the trap will be monitored using the following procedure: Immediately after the

ST. VINCENT HOSPITAL AND MEDICAL CENTER
TOLEDO, OHIO 43608

R. Equipment Operation and Monitoring of Leakage

a. The Xenon Dispenser Deliver System as described in Attachments #5 and #6 of this license amendment application will be checked prior to use to insure proper operation. The manufacturer's operating instructions will be followed.

b. The Delivery/Trapping Unit will be checked at the beginning of each week by filling it with oxygen and checking for leakage. Its operation will be checked during the practice runs prior to the administration of the Xenon 133 gas. The manufacturer's operating instructions will be followed and the carbon dioxide absorbers will be replaced as needed.

c. The Xenon leakage from the Xenon trap will be monitored as described above. The manufacturer's operating instructions will be followed and the dessicant in the water trap will be checked prior to the day's use and replenished as needed. The RAD Emergency Room Air Decontaminator will be monitored in a similar manner.

d. All exhaust vents will be checked twice yearly to confirm their continued efficiency. In addition, they will be checked whenever structural changes are made which could affect their efficiency. Records verifying these procedures will be maintained.

FORM NRC-313M-SUPPLEMENT A
(7-77)
10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSIO

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION PROTECTION OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION PROTECTION OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Michael F. Fadell, M.D.	Ohio

3. CERTIFICATION

SPECIALITY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Am. Board of Radiology	Radiology	June 1974

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Butterworth Hosp., Grand Rapids, Mich. July 73 – June 74	90	20
b. RADIATION PROTECTION	"	25	10
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	10	15
d. RADIATION BIOLOGY	"	25	—
e. RADIOPHARMACEUTICAL CHEMISTRY	"	10	25

Control No. 02435

FORM NRC-313M-SUPPLEMENT B
(7-77)
10 CFR 30

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME: Michael F. Fadell, M.D

STREET ADDRESS: 421 Michigan

CITY: Toledo | STATE: Ohio | ZIP CODE: 43624

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	100	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES	14	
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS	–	
I-131	THYROID IMAGING	100	
P-32	EYE TUMOR LOCALIZATION	–	
Se-75	PANCREAS IMAGING	5	
Yb-169	CISTERNOGRAPHY	8	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	–	
OTHER			
Tc-99m	BRAIN IMAGING	250	
	CARDIAC IMAGING	15	
	THYROID IMAGING	10	
	SALIVARY GLAND IMAGING	–	
	BLOOD POOL IMAGING	10	
	PLACENTA LOCALIZATION	5	
	LIVER AND SPLEEN IMAGING	–	
	LUNG IMAGING	150	
	BONE IMAGING	200	
OTHER			

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT	3	
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM AND CARDIAC CONDITION		
Au-198	INTRACAVITARY TREATMENT	—	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	—	
	INTRACAVITARY TREATMENT	—	
I-125 or Ir-192	INTERSTITIAL TREATMENT	—	
Co-60 or Cs-137	TELETHERAPY TREATMENT	-	
Sr-90	TREATMENT OF EYE DISEASE	8	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	15	
Sn-113/ In-113m	GENERATOR	—	
Tc-99m	REAGENT KITS	20	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

Jan 1 — March 31 1975

720 Hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
WILLIAM E. KINCAID, M.D.

b. NAME OF INSTITUTION
BUTTERWORTH HOSPITAL

c. MAILING ADDRESS
100 MICHIGAN N.E.

d. CITY
GRAND RAPIDS, MICH. 49503

5. MATERIALS LICENSE NUMBER(S)
21-00243-06

6. PRECEPTOR'S SIGNATURE
Wm. E. Kincaid M.D.

7. PRECEPTOR'S NAME (Please type or print)
WILLIAM E. KINCAID

8. DATE
Dec 20, 1978

FORM NRC-313M-SUPPLEMENT B
(7-77)

ATTACHMENT # 1

ST. VINCENT HOSPITAL
LICENSE AMENDMENT APPLICATION
10-17-79

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.	0.25	0.0014	0.0027
Cerebral Blood Flow	5 min.	0.63	0.0035	0.0068

*99% of activity is in lungs

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

HOW SUPPLIED

The Xenon Xe 133 gas is supplied as part of the Calidose® system, consisting of 2 ml unit dose vials and the Calidose dispenser* for shielded dispensing.

Normally vials containing either 10 or 20 mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100 mCi/vial are available.

*Patent Pending

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

JO 127 7-75 Rev 1 Printed in U.S.A.

S-73482

XENON Xe 133 GAS

Catalog Number NRP-127

New England Nuclear

Control No. 02433

DESCRIPTION

Xenon Xe 133 for diagnostic use is available as 5% gas in carbon dioxide diluent 95%.

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 tissue. 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 (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 reactor or particle accelerator, 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 respirator 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	99.3	100.6
Gamma-2	34.99	81.0
K int. con. electrons, -2	47.24	45.0
L int. con. electrons, -2	7.87	75.7
M int. con. electrons, -2	9.84	80.0
K x-rays	34.70	30.8
K x-rays	7.67	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/mCi-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	1.930	8	.349
-4	1.693	9	.302
-3	1.483	10	.268
-2	1.300	11	.235
-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

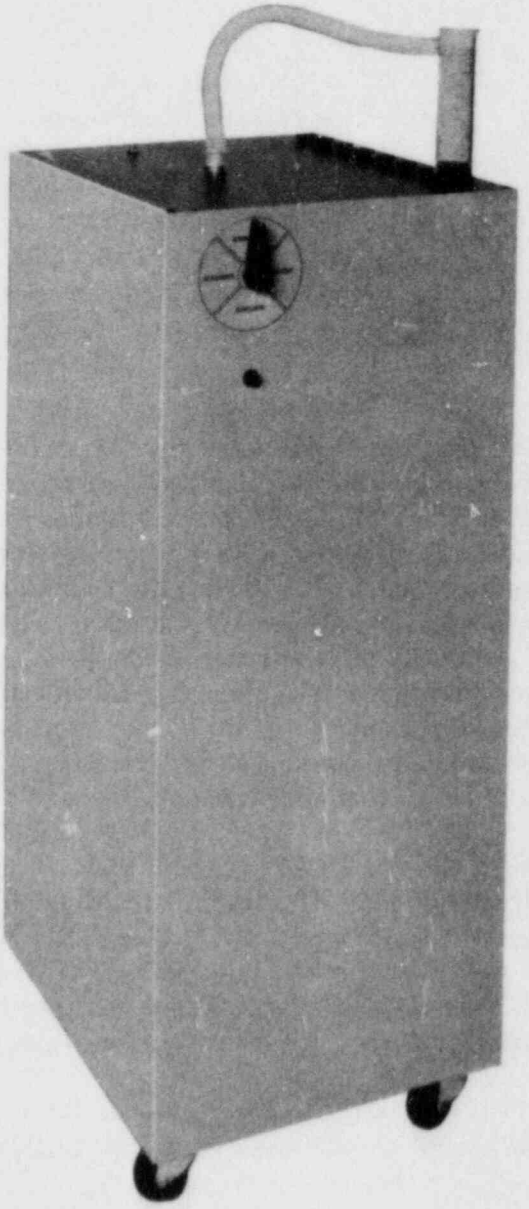
*Calibration Day

ATTACHMENT # 2

ST. VINCENT HOSPITAL
LICENSE AMENDMENT APPLICATION
10-17-79

XENON DELIVERY/TRAPPING SYSTEM

Model Xe-400A



- **Totally Integrated**
- **Exceeds NRC requirements**
- **Mobile**
- **4 year guarantee on charcoal traps**
- **Supplied with 8 charcoal xenon gas traps**
- **Simple to operate**
- **Single control knob**
- **Portable**
- **Superior to all competitive systems**
- **90 litre breathing bag**
- **Resistance free breathing**
- **Efficient**
- **Automatic shut off**
- **Fully shielded**

FOR

LESS THAN $2000.000

Control No. 02435

ADC Medical

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

XENON DELIVERY/TRAPPING SYSTEM
Model Xe-400A ONLY $1995.00

- Pump shuts off automatically upon sensing empty breathing bag
- Shielded ... Mobile ... Self-contained
- Most economical automatic system available
- Simple, easy-to-use, single dial control of all functions
- 90-liter breathing bag for resistance-free patient breathing
- Built-in CO_2 absorber and moisture trap
- In-line disposable bacteria filter, mouthpiece and tubing
- Accepts any commercially available form of Xe-133

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. The moisture trap, CO_2 absorber, O_2/air and gas trap lines are located at the top of the unit for easy access.

A 90-LITER LATEX 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. Extra-length tubing for supine patients are supplied in the relacement kits, Model MTB-327.

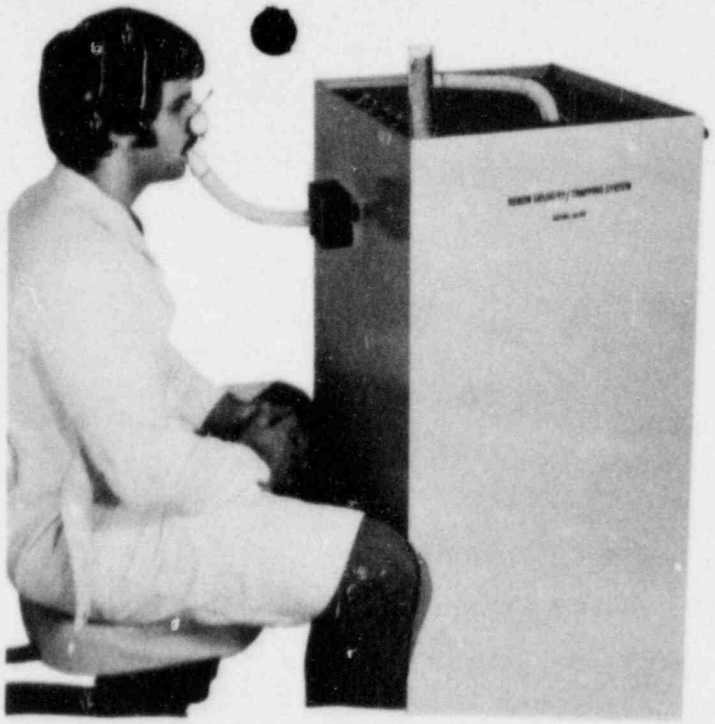
THE CO_2 ABSORBER AND MOISTURE TRAP ARE EXTERNALLY MOUNTED at the top of the unit. Each is designed for rapid twist-out/twist-in changing. The traps are made of clear plexiglass to permit observation.

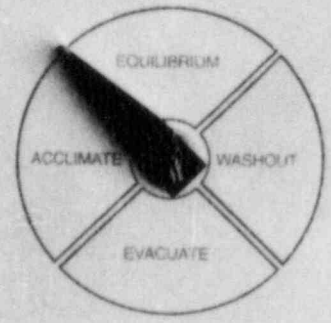
Connections for both O_2/air mixture tubing and xenon gas trap vent tubing are mounted in the top area for easy access and for routine observation.

THE SYSTEM ACCEPTS ANY COMMERCIAL FORM OF Xe-133. 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.

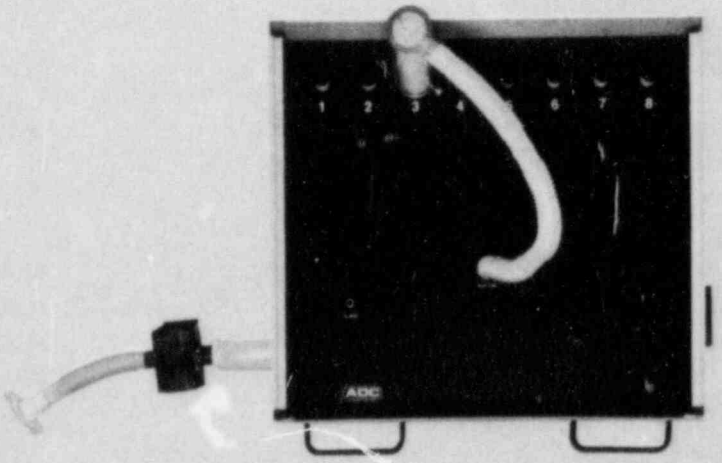
A VACCUM SWITCH assures complete system purging of xenon at the completion of a study.

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





A single knob controls each function during study. Valves automatically channel xenon gas through system by turning knob to appropriate setting.



Top view showing twist-out/twist-in moisture and CO_2 traps, connections for O_2/air and 8 xenon gas traps.

SPECIFICATIONS

MATERIAL:	Steel outer casing with lead shielding
DIMENSIONS:	20″ W x 18″ D x 46″ H
MOBILITY:	Rolls on 3″ heavy-duty casters.
SHIPPING WEIGHT:	400 lbs.

MODEL Xe-400A $1,995.00

RAD

Model Xe-404

EMERGENCY ROOM AIR RADIO DECONTAMINATOR

- Safe
- Easy to use
- Efficient
- Easy mobility
- Shielded
- Easily replaceable trap

The RAD (emergency room air radiodecontaminator), Model Xe-404, was specially developed to remove radioactive Xenon-133 from the air in the event of accidental spills from Xenon delivery systems or patients. It is ideal for the facility that is locked in and has no windows or emergency exhaust systems. The unit is a large, portable filtering system and capable of absorbing all the spilled Xenon.

A Xenon spill can occur any time a patient panics or feels discomfort, and as a result, prematurely removes the mouthpiece. It is also possible for a connection in the Xenon delivery system to break and spill Xenon into the room.

Having a RAD in the room relieves the technician of the anxiety of what to do for a Xenon spill. If such an event should occur, close all windows and doors, roll the unit in the vicinity of the spill and turn the switch on. All the room air will be sucked in from the bottom and released at the top as filtered air less the Xenon. The RAD is left on for approximately fifteen minutes, depending on the room size.

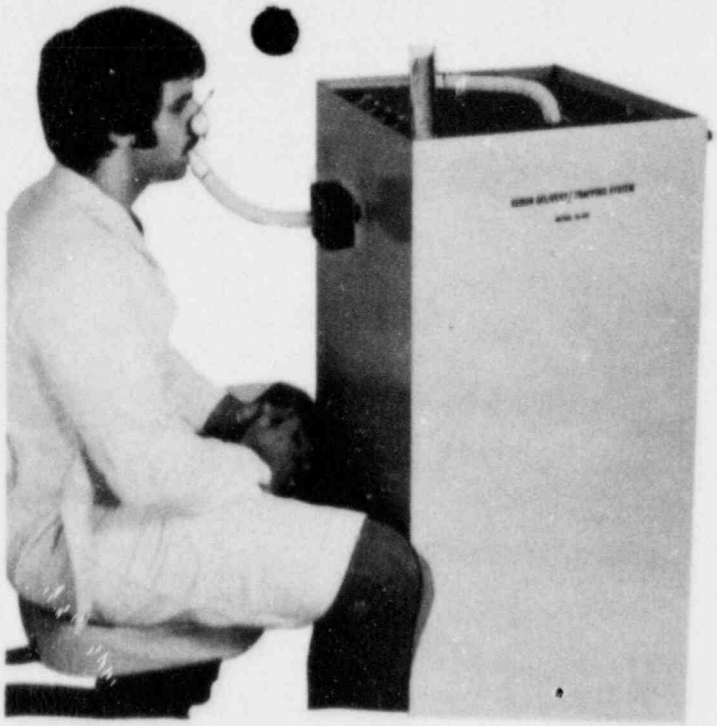
The RAD is made from a tough and durable extra heavy gauge vinyl plastic, and is mounted on four swivel ball bearing casters.

SPECIFICATION

DIMENSIONS: 24″ diameter by 28″ overall height
POWER REQUIREMENTS: 115V. 60 Hz, AC
AIR FLOW: 100 CFM
SHIELDING: ⅛″ thick lead
SHIPPING WEIGHT: 95 lbs.

Model Xe-404 .....$795.00

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



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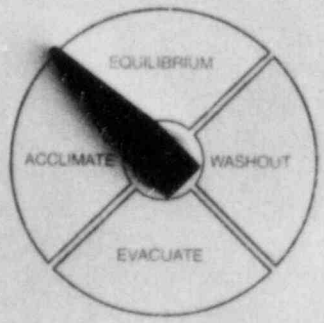

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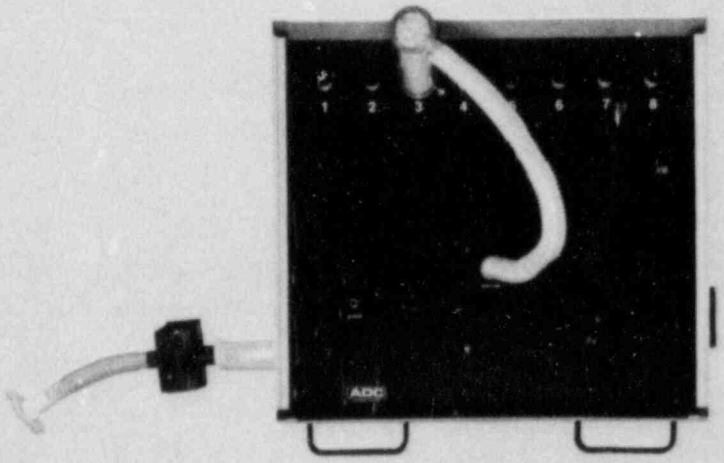

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MODEL Xe-400A $1,995.00

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Model Xe-404 .....$795.00

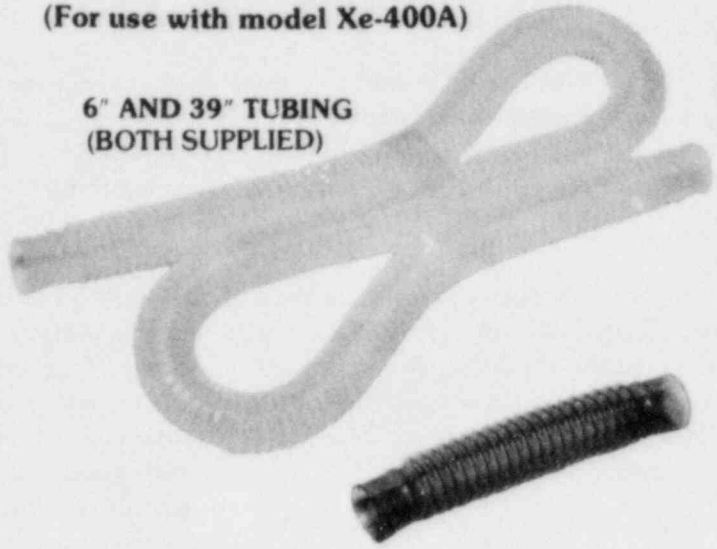
ADC Medical
400 SMITH STREET, FARMINGDALE, N.Y. 11735 • (516) 752-9686
800-645-9110

XENON ACCESSORIES

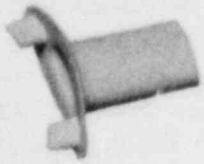
DISPOSABLE FILTER KIT
(For use with model Xe-400A)

Model MTB-327

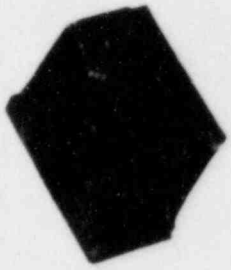
6" AND 39" TUBING
(BOTH SUPPLIED)



MOUTHPIECE



ADAPTOR



BACTERIA FILTER

Model MTB-327 .....$7.50/kit

Min. order 5 kits

Model SCP-309 **Sodalime CO_2 Absorber refill PKG of 8** $7.75

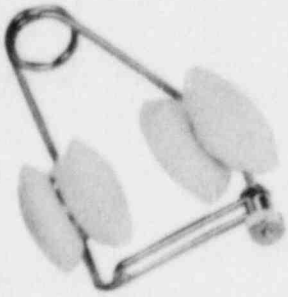
Premeasured packets for replacing CO_2 Absorber in **Model Xe-400A, DX-133 and DX-133T**

Model MA-318 **Drierite moisture absorber refill PKG of 3** $9.00

Premeasured packets for replacing moisture absorber in Model **Xe-400A** (may also be used with **Model Xe-102, Xenon Trapping System**).

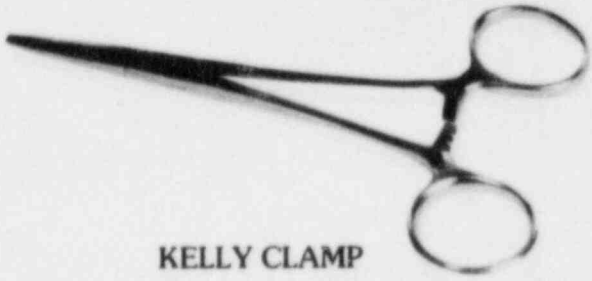
NOSE CLAMP

Model NC-12 .....$7.95



REPLACEMENT NOSE CLAMP SPONGES

Model NCS-13 .....$3.00 doz.

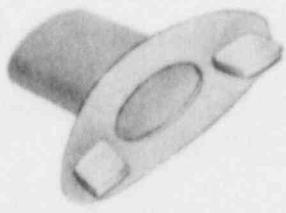


KELLY CLAMP

Model KC-11 .....$9.75

MOUTHPIECE

Model MP-15 .....$16.75 doz.



DISPOSABLE XENON-133 REBREATHING SYSTEM

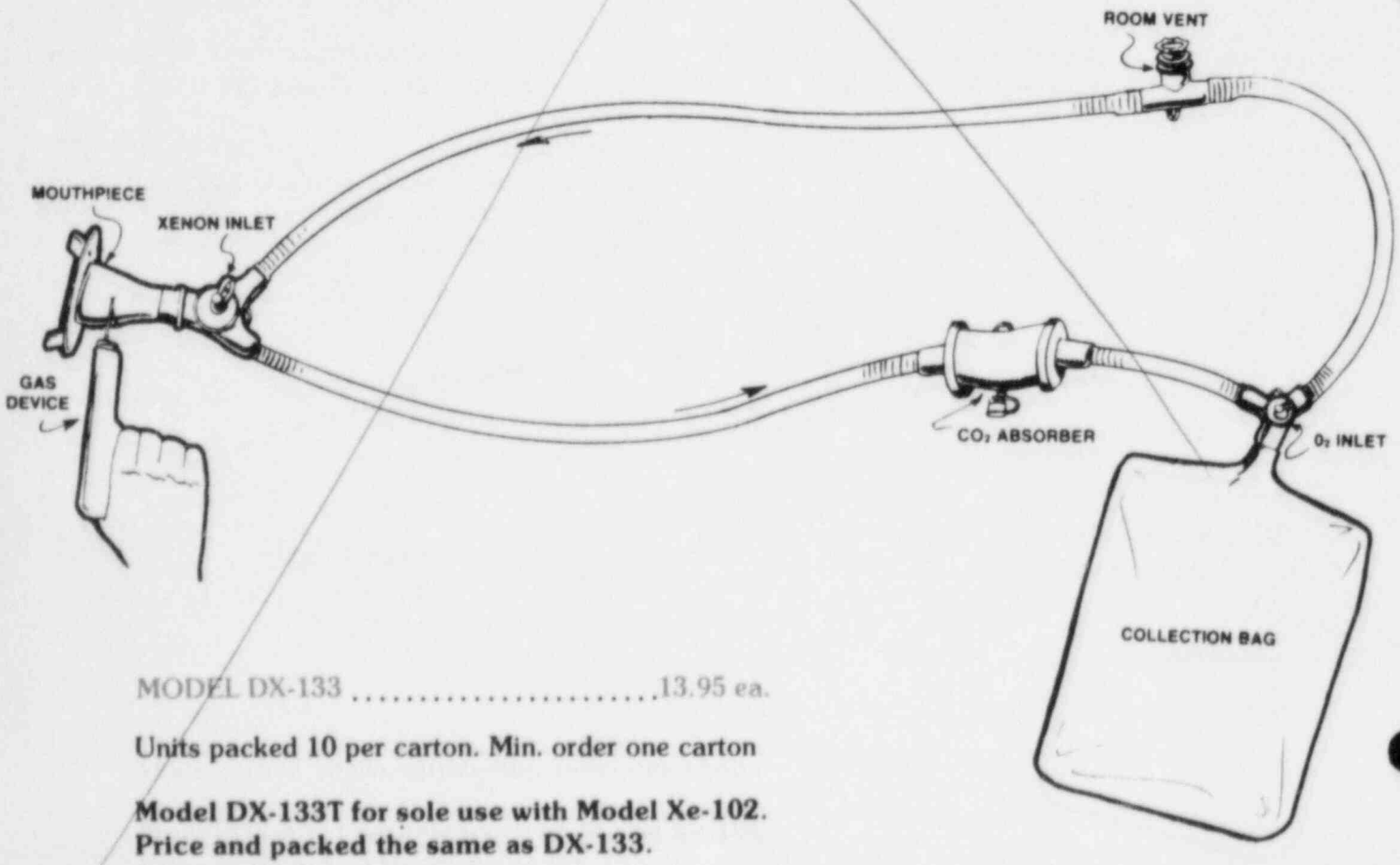
Model DX-133

- Disposable combination inhalation and trap system
- Inexpensive, easy to use
- No sterilization of mouthpiece required
- No cross-contamination between patients

This inexpensive, disposable system device is used to both administer Xenon-133 and to collect the expired gas. Made entirely of plastic, the system is used for one patient only and then discarded after the Xenon has been allowed to decay or has been exhausted from the collection bag.

The system consists of Mouthpiece, which does not require sterilization, Gas inlet valve for admission of Xenon-133, CO_2 absorber, and Gas inlet for admission of oxygen to a 35 liter collection bag.

Xenon-133 is injected into the system and inhaled by the patient when the camera is turned on. The patient then holds his breath until sufficient counts are collected or until he must breathe. While the patient is breathing through the system, "equilibrium phase" data is collected. When sufficient data has been compiled, the appropriate valves are opened, and the patient inhales outside air and exhales into the collection bag until the bag is full enough to offer resistance. The entire rebreathing apparatus is then removed and placed in a hood or other area for storage and/or release of the gas.



MODEL DX-133 .....13.95 ea.

Units packed 10 per carton. Min. order one carton

Model DX-133T for sole use with Model Xe-102. Price and packed the same as DX-133.

ATTACHMENT # 3

ST. VINCENT HOSPITAL
LICENSE AMENDMENT APPLICATION
10-17-79

UNIQUE NEW "XenAlert"™

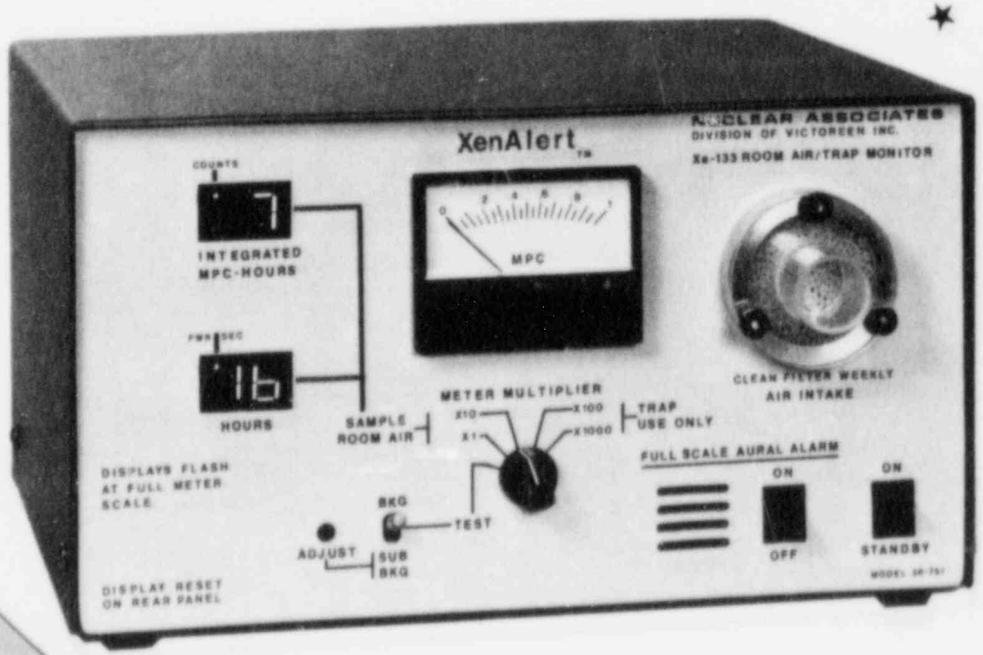
Xenon-133 Room Air/Trap Monitor*

The only instrument
that monitors exposure rate,
continuously integrates and displays the
xenon concentration of room air, in multiples of the
Maximum Permissible Concentration (MPC)[1],
and also monitors the effluent
from xenon gas traps.

- **Large meter reads directly in MPC units.**
- **Digital register shows integrated MPC-Hours.**
- **Audio and visual alarms alert personnel to hazardous xenon concentrations.**
- **Fully-shielded counting chamber.**
- **Compatible with all xenon-dispensing, administration and trapping systems.**

(1) The Code of Federal Regulations† clearly limits the permissible ^{133}Xe exposure to 1 MPC for 40 hours per week for 13 weeks. The data is continuously updated and displayed by the "XenAlert" Monitor.

† 10 CFR, Part 20, Sec. 20.103 and Appendix B, Table 1.



* Patent Pending

™ Nuclear Associates

NUCLEAR ASSOCIATES

Division of VICTOREEN, INC.

100 Voice Road • Carle Place, N.Y. 11514

(516) 741-6360

4-1278 266A

"XenAlert" Xenon-133 Room Air/Trap Monitor

Now, concentrations of xenon-133 in room air *and* gas trap effluent can be quantitatively monitored continuously and accurately with the unique "XenAlert" Monitor. Unlike preset, non-integrating devices, the "XenAlert" eliminates tedious and complex calculations by automatically computing total exposure (in MPC-Hours units) and exposure rate (in fractions of MPC). Xenon monitoring has never been easier!

ROOM AIR MONITORING

To continuously monitor and integrate room air concentration, the "XenAlert" is positioned near the xenon administration system and the imaging equipment. Room air is drawn into the counting chamber. Air samples are counted while the air is exchanged more than 3 times per minute. An analog meter continuously displays MPC units while two digital registers display integrated MPC-Hours and total hours (running time) respectively. When the ^{133}Xe room air concentration exceeds full scale, the digital registers flash on and off as a warning to personnel. In addition, an audible alarm can be activated.

At the end of each work day, the "XenAlert" is switched to "Stand-By." Data acquisition is suspended, but accumulated data is retained in memory. In the morning, or whenever a xenon study is to be performed, the "XenAlert" is re-activated and data accumulation resumes. At the start of each work week, the "XenAlert" is reset to zero and the process repeated.

The "XenAlert's" unique features allow personnel to assess their xenon exposure quantitatively. An accidental release of xenon, such as from a broken vial or an uncooperative patient, may temporarily raise the ^{133}Xe room air concentration well above 1 MPC. The degree to which the NRC limits have been reached, however, depends on the amount of activity released and the time required for the room's exhaust system to exchange the restricted area's air. The "XenAlert" takes these factors into account with the display of MPC-Hours. Personnel are immediately aware of both the MPC concentration to which they were exposed and the total integrated MPC-Hours, in terms of NRC regulated exposure limits.

Additional "XenAlert" Features

- ★ **Background Subtract Circuit.** Permits subtraction of background radiation to assure maximum accuracy when counting ^{133}Xe.
- ★ **Total Hours Register.** Displays total hours of xenon data accumulation.
- ★ **Power Indicator.** Light-emitting diode flashes once per second to indicate data accumulation.
- ★ **Integration Disable Circuit.** Suspends MPC-Hours and Hours data accumulation during gas trap monitoring, assuring that the digital registers will display only room air integration values.
- ★ **Emergency Alarm.** Loud alarm is activated automatically when 80 MPC-Hours have been accumulated.

Left: "XenAlert" monitors room air during ventilation study. **Right:** Gas trap output is displayed in MPC units.

GAS TRAP MONITORING

The "XenAlert" greatly simplifies the monitoring of effluent air from any xenon trap. Setting the analog meter multiplier to X100 or X1000 displays 10^{-3} μCi/ml or 10^{-2} μCi/ml full scale. Concentrations approaching the latter level at the trap's exhaust port can result in a xenon room air concentration approaching 1 MPC. Therefore, the monitor may be used periodically to verify trap performance.

Detector: Pancake thin-window GM tube.
Accuracy: ±20%.
Reproducibility: ±5%.
Calibration Factors: X1 = 10^{-5} μCi/ml; X10 = 10^{-4} μCi/ml; X100 = 10^{-3} μCi/ml; X1000 = 10^{-2} μCi/ml.
Counting Chamber: Shielded with 9.5 mm (⅜") lead.
Air Exchange System: Centrifugal blower exchanges air 3 or more times per minute.
Air Intake Port: 2.5 cm (1") diameter front-panel port with re-usable particulate-matter filter.
MPC Meter: Analog with ranges of 1, 10, 100 and 1000 MPC, full scale.
Time Constants: 40 sec on X1, 4 sec on X10, 0.4 sec on X100, and 0.04 sec on X1000.
MPC-Hours Register: 0-99; 2-digit light-emitting diode (LED).
Hours Register: 0-80; 2-digit light-emitting diode (LED).
Visual Alarm: LED registers flash at 1/sec rate at full-scale meter reading in X1 or X10 ranges.
Audio Alarm: Intermittent tone. User-selectable to alarm at full scale on all ranges.
Emergency Audio Alarm: Continuous tone on reaching 80 MPC-Hours (integration and data accumulation continue to 99 hours).
Background Subtract Circuit: Activated by moving range switch to Test position. Allows meter display of background count rate or internal subtracted background count rate. Enables user to adjust subtracted background.
Reset Function: Rear-panel pushbutton resets MPC-Hours and Hours displays to zero.
Standby Function: Switch terminates data accumulation during non-working hours. Prior accumulated data remains stored in memory.
Memory Storage Circuit: Retains accumulated data during momentary power losses.
Power: 115V, 60 Hz, 25W (230V, 50 Hz on special order).
Size: 17 cm (6.7") high x 31 cm (12.2") wide x 27 cm (10.6") deep.
Weight: Net 23 kg (50 lbs.).

36-751	"XenAlert" ^{133}Xe Room Air/Trap Monitor	**$1750.00**
36-753	Particulate-Matter Replacement Filter. Package of 25 filters	25.00
36-754	Hose for gas trap monitoring, 6-ft.	20.00

ATTACHMENT # 4

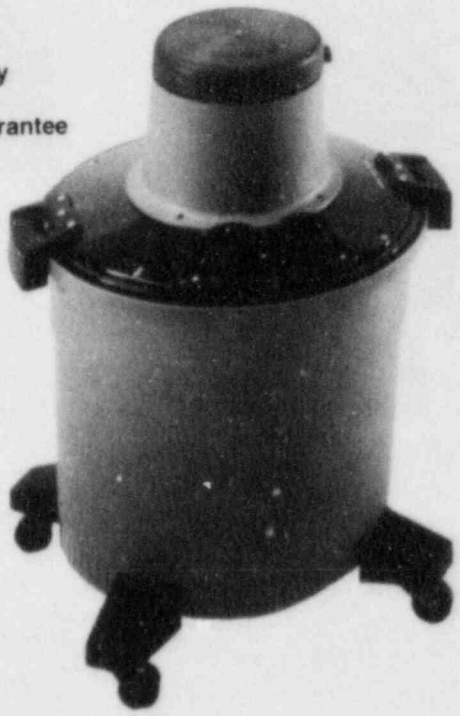
ST. VINCENT HOSPITAL
LICENSE AMENDMENT APPLICATION
10-17-79

Xenon Accessories

RAD *

Model XE-404

- **Safe**
- **Easy to use**
- **Efficient**
- **Easy mobility**
- **Shielded**
- **Lifetime guarantee on filter**



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The RAD is made from a tough and durable extra heavy gauge vinyl plastic, and is mounted on four swivel ball bearing casters.

SPECIFICATIONS

Dimensions: 24" diameter by 28" overall height
Power Requirements: 115V. 60 Hz. AC
Air Flow: 100 CFM
Shielding: 1/8" thick lead
Shipping Weight: 95 lbs.

Model XE-404 ..... **$445.00**

*Patent Pending

Control No. 02435

ATTACHMENT #6

ST. VINCENT HOSPITAL
LICENSE AMENDMENT APPLICATION
10-17-79

after initial calibration. The increased radiation absorbed doses to the thyroid that result from altered radioisotope composition of a 400 microcuries I 123 dose are shown in Table VI for time intervals of up to two half-lives after calibration, for thyroid uptakes of 5, 15, and 25%.

Table VI. Comparison of Thyroid Radiation Doses at One and Two Half-Lives of I 123

Thyroid Uptake(%)	Dose (rads/400μCi I 123)* Elapsed Time: Calibration Time	1 Half-Life	2 Half-Lives
5	4.20	6.81	11.47
15	12.47	20.60	34.66
25	21.43	34.44	57.66

*Including doses from radiocontaminants.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

How Supplied: Sodium Iodide I 123 for oral administration is supplied in glass vials and in capsules.

Each glass vial contains Sodium Iodide I 123 solution with a total specific concentration of 2 millicuries per ml at calibration time. Each vial is wrapped in absorbent material and then enclosed in a labeled lead shield. Each capsule contains 0.05 ml of Sodium Iodide I 123 with a total activity of 100 microcuries at calibration time. Each capsule is supplied in a plastic capsule vial that is enclosed in a labeled lead shield. One extra shield label is supplied with each glass vial and each capsule for attachment to a shielded container other than the one in which the drug product is supplied.

XENON Xe 133–V.S.S. (Ventilation Study System)
Xenon Xe 133

Description: The Xenon Xe 133-Ventilation Study System (V.S.S.) consists of a sealed plastic tube containing 10 mCi ± 20% of Xenon 133 gas at calibration time and date with less than 1% carrier Xenon in air. Xenon Xe 133 is produced by fission of Uranium-235. It is chemically and physiologically related to elemental xenon, a non-radioactive mono-atomic gas which is physiologically inert except for anesthetic properties at high doses.

Physical Characteristics

Xenon Xe 133 decays by beta emission with a physical half-life of 5.31 days[1]. Photons that are useful for detection and imaging studies are listed in Table I.

Table I. Principal Radiation Emission Data

Radiation	Mean Percent per Disintegration	Mean Energy (keV)
Beta-3	98.30	100.6
Gamma-2	36.03	80.9
K int. con. electrons, gamma-2	52.61	45.0
L int. con. electrons, gamma-2	8.48	75.6
K x rays, alpha	38.73	30.8
K x rays, beta	8.62	35.4

[1] Dillman, L. T., Von der Lage, F. C. Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation, MIRD Pamphlet No. 10, *Soc. Nucl. Med.*, (1975) p. 83.

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. Physical Decay Chart; Xenon Xe 133, half life 5.31 days

Days	Fraction Remaining	Days	Fraction Remaining
−4	1.686	9	0.309
−3	1.479	10	0.271
−2	1.298	11	0.238
−1	1.139	12	0.209
0*	1.000	13	0.183
1	0.878	14	0.161
2	0.770	15	0.141
3	0.676	16	0.124
4	0.593	17	0.109
5	0.521	18	0.095
6	0.457	19	0.084
7	0.401	20	0.073
8	0.352	21	0.065

* Calibration day.

External Radiation

The specific gamma ray constant for Xenon Xe 133 is 0.56 R/mCi hr at 1 cm. The first half value layer is 0.04 mm of Pb.

Clinical Pharmacology: Xenon Xe 133 is a readily diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes, freely exchanges between blood and tissue, and tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentrations recommended for diagnostic studies, 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 and Usage: Study of pulmonary ventilation.

Contraindications: None known.

Warnings: Xenon Xe 133 should not be administered to children or to patients who are pregnant, or to nursing mothers 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 (approximately 10) days following the onset of menses.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus.

There are no well-controlled studies in pregnant women which would allow any conclusions as to the safety of Xe 133 for the fetus. Xenon Xe 133 should be used in pregnant women only when clearly needed.

Precautions: Xenon Xe 133 as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient management.

Exhaled Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

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.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

Adverse Reactions: Adverse reactions specifically attributable to Xenon Xe 133 have not been reported.

Dosage and Administration: The recommended activity range for pulmonary ventilation studies in the average patient (70 kg) is 2 to 20 mCi (0.03 to 0.3 mCi/kg).

In order to assay the activity of the Xenon Xe 133 prior to patient administration, carefully remove the screen plug from one end of the valve-shield (B of figure I) and shake out the plastic capsule, using adequate radiation protection techniques. The capsule of Xenon Xe 133 can then be assayed in a precalibrated ionization chamber.

Preparation For Use:

- Assemble the Xenon 133-V.S.S. as shown in Figure I.
- Place the breathing-collection bag in a suitable radiation shield.
- Instill approximately 500 ml of medical grade oxygen in the bag through the Co_2 absorber canister for each minute of anticipated rebreathing time.
- Seat the patient with his back against the face of the collimator of a scintillation camera, positioned to allow imaging of the desired portion of the lungs. When a diverging collimator is used, position the patient so that both lungs are in field view.
- Clamp the patient's nose.

Use of System:

When the Key is initially turned 180°, the plastic container of xenon is broken, and the gas is released into the system. In the event that the Key is difficult to turn, gently tap the retainer ring (Figure I, E). When the Key is turned 90°, the system is closed.

Instructions are given below for single breath study followed by a rebreathing study and a washout study.

Single Breath

1. Have the patient breathe normally through the mouthpiece.
2. (a) **For a sharp dose,** have the patient exhale completely and hold his breath. Turn the Key 180°.
   (b) **For a diffuse dose,** have the patient inhale through the mouthpiece and hold his breath. Turn the key 180°. Instruct the patient to exhale maximally through the mouthpiece.
3. Following either 2(a) or 2(b), instruct the patient to take a single, smooth, deep breath through the mouthpiece and hold it.
4. Start scintigraphy while the patient is holding his breath.

Rebreathing

5. When single breath scintigraphy is complete, instruct the patient to breathe back-and-forth through the mouthpiece for at least one minute.
6. Have the patient inhale and hold his breath while a second scintigram is taken.

Washout

7. When scintigraphy is complete, instruct the patient to inhale room air deeply and exhale into the mouthpiece. Continue this washout procedure over a period of four to five minutes while taking sequential scintigrams.
8. Turn the Key 90° to close off the Xenon 133-V.S.S.
9. Dispose of the system in an appropriate manner.

These instructions may be modified to allow other types of studies.

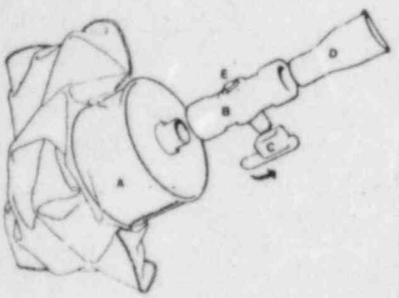
Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of the

Continued on next page

Medi-Physics—Cont.

radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

FIGURE I—ASSEMBLY OF XENON 133 VENTILATION STUDY SYSTEM (V.S.S.)



1. Remove the components from the shipping container. These components are:
   A—Breathing-collection bag with attached CO_2 absorber canister.
   B—Xenon 133 in a valve-shield with end plugs.
   C—Key.
   D—Disposable mouthpiece.
2. Remove the red cap from the CO_2 absorber canister.
3. Use the Key to remove the end plugs on the valve-shield.
4. Attach either end of the valve-shield to the canister.
5. Wedge the mouthpiece into the other end of the valve-shield.
6. Place the Key on the fitting of the valve-shield. Do not turn the Key.
7. The Ventilation Study System is now ready for use.*

*In the event that the Key is difficult to turn when the system is in use, gently tap the retaner ring (E).

Radiation Dosimetry: The estimated absorbed radiation doses[1] to an average adult (70 kg) and ten-year old child (31.8 kg) for a single breath study using 10 mCi and an equilibrium breathing study using 20 mCi are shown in Table III.
[See table below].

How Supplied: Each Ventilation Study System (V.S.S.) contains Xenon 133 in a sealed plastic tube containing 10 mCi ± 20% at calibration time and date stated on the label. The sealed plastic tube is enclosed in a metal valve-shield which is sealed with a plastic shrink band to prevent accidental loss of Xenon 133 during shipping. A Key is provided to remove the end plugs of the valve-shield and to turn the valve fitting which breaks the sealed plastic tube. The V.S.S. also includes a disposable mouthpiece and a breathing-collection bag with an attached Co_2 absorber canister.

Table III. Estimate of Radiation Absorbed Dose for Xenon 133 (in rads)

	SINGLE BREATH (10 mCi held for 30 seconds, followed by washout)		EQUILIBRIUM BREATHING (20 mCi in 2 liter spirometer for 4 minutes, followed by washout)	
Organ	Adult	Child	Adult	Child
Lung	0.050	0.1	0.300	0.36
Total Body	0.0002	0.001	0.0008	0.002
Ovaries	0.00006	0.0001	0.0001	0.0002
Testes	0.000008	0.00008	0.00002	0.0001

[1]Method of Calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, *J. Nucl. Med.*, p. 7, 1968.

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