

Louis A. Weiss  
Memorial Hospital

4646 North Marine Drive  
Chicago, Illinois 60640  
312/878-8700

Mortimer W. Zimmerman  
Executive Director

David D. Kram, M.D.  
Medical Director

James Champer  
Administrative Director

April 16, 1979

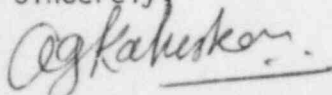
John W. Cooper, Ph.D., Chief  
Regional Licensing Section  
License Management Branch  
Division of Fuel Cycle and Material Safety  
U.S. Nuclear Regulatory Commission, Region III  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Sub: Renewal of NRC License No. 12-02418-01, your Ref. Control  
No. 01422, (Your letter of March 26, 1979)

Dear Dr. Cooper:

I am enclosing in the separate sheets all the additional  
information that you have sought and we hope that this additional  
information will enable you to complete the evaluation of applica-  
tion for renewal of the license.

Sincerely,



A.G. Kaluskar, Ph.D.  
Radiological Physicist/Radiation Safety Officer

AGK/aj

Encl.

cc: R. VanBokkelen, Associate Director  
J. Singh, M.D., Nuclear Medicine

8507230234 850702  
REG3 LIC30  
12-02418-01 PDR

APR 23 1979

Ref: NRC License No. 12-02418-01, Control No. 01422  
Your letter of March 26, 1979

- 1) Mr. W.R. VanBokkelen, Associate Director, is on the Radioisotope Committee as the member of hospital administration staff.  
Mr. VanBokkelen was a Vice President of St. Francis Hospital, Evanston, Illinois (1973-1979) administratively in charge of Radiation Therapy, Diagnostic Radiology and Nuclear Medicine Departments. He was also a member of St. Francis Hospital's Radiation Safety Committee.
- 2) We are in the process of buying the standard Co-57 and Ba-133 sources for the calibration of our dose calibrator.
- 3) Supplement I(a) attached describes the training and experience of Dr. J.B. Carter. Please note that Dr. Carter is involved only in the in vitro studies using C-14 and H-3.
- 4) We do not contemplate any animal research involving radioisotopes so please delete that clause from our license.
- 5) We will use Tc-99m PIPIDA-Tin for the hepatobiliary Scanning (Maximum amount 50mCi). We have attached photocopy of the brochure (Supplement **II**(a)) for PIPIDA-Tin kit. The form 1573 is originally submitted to Diagnostic Isotope, Inc.
- 6) We plan to use I-125 only from prepackaged kits for in vitro studies.
- 7) We would like to increase our maximum possession limit of Xe-133 for pulmonary function studies from 200 mCi to 1000 mCi. Please see the attached Supplement **III**(a) for the detailed information.

## Training and Experience of John B. Carter, M.D.

<u>Type of Training</u>	<u>Where Trained</u>	<u>Duration of Training</u>	<u>On The Job</u>	<u>Formal Course</u>
Principles and practices of Radiation protection	Univ. of Minnesota Dept. of Laboratory Medicine Dr. Ellis Benson Dr. Robert Bridges	1970-1973	no	yes
Radioactivity measurement standardization and monitoring techniques and instruments	Louis A. Weiss Mem. Hosp.	1975-	yes	no

## Experience with Radiation (actual use of isotopes or equivalent experience)

<u>Isotope</u>	<u>Max. Amount</u>	<u>Where Experience was gained</u>	<u>Duration</u>	<u>Type of Use</u>
Cr-51	2 mCi	Univ. of Minnesota Dr. E. Benson	1969-73	RBC Survival
C-14	5 mCi	L. A. Weiss Hosp. (self)	1975-79	Blood Culture
I-125	10 mCi	"	"	RIA
Co-57	10 mCi	"	"	"

**di** diagnostic  
Isotopes  
Incorporated  
225 belleville ave.  
bloomfield, n. j. 07003  
201 429 7500  
800 631 1260  
telex 133393

NUCLEAR PHARMACY  
337-2945

4388-778

5 MC  
DOSE

July, 1978  
Diagnostic Isotopes, Incorporated  
225 Belleville Avenue  
Bloomfield, New Jersey 07003

**PIPIDA (Sn) Kit****INFORMATION FOR INVESTIGATORS**

Of the several new IDA derivatives synthesized by altering the lipophilic substituents on the HIDA ring, p-isopropylacetanilidoiminodiacetic acid (PIPIDA) showed characteristics desirable for hepatobiliary scintigraphic imaging.<sup>1</sup>

Stannous chloride was used as the reducing agent in the formulation of PIPIDA Kit for preparation of Technetium Tc 99m PIPIDA-Tin and pH adjusted with NaOH and HCl.

Preclinical investigations performed at Diagnostic Isotopes showed PIPIDA-Tin to have an acute LD<sub>50</sub> in mice of 143 mg/kg.

Upon intravenous injection, Technetium Tc 99m PIPIDA-Tin was rapidly extracted from blood by the liver. Transit from liver cells to biliary tract was also rapid. The entire process took less than 5 minutes. Over 80% of the radioactivity was retained in gallbladder at 15 minutes post injection and persisted until 2 hours after injection. Little absorption from the intestine was observed. Gallbladder to intestine activity ratio remained over 10 throughout the first two hours.

Biological clearance of Technetium Tc 99m PIPIDA-Tin in mice showed an effective half-life of  $2.13 \pm 0.21$  hours and biological half-life of  $3.3 \pm 0.3$  hours.

The estimated maximum absorbed radiation dose to an average patient (70 kg) extrapolated from mice data are as follows:

Organ	Technetium Tc 99m PIPIDA-Tin (rads, millicurie)
Whole body	0.006
Liver	0.184
Kidney	0.099
Intestines	1.408
Gallbladder	0.518

Method of Calculation - ORNL-5000.

<sup>1</sup> Subramanian, G., McAfee, J. G., Henderson, R. W., Rosenstreich, M., and Krokenberger, L. The influence of structural changes on biodistribution of Tc 99m labeled N-substituted IDA derivatives. J. Nucl. Med. 18 (6): 624, June, 1977.

*Protocol for Clinical Evaluation of PIPIDA  
as Supplied by Diagnostic Isotopes Incorporated*

**A. Purpose**

The purpose of this investigation is to evaluate the safety and efficacy of Technetium Tc 99m PIPIDA-Tin as a hepatobiliary agent. Initial studies in normal subjects will attempt to determine human side effect, if any, metabolism, excretion, whole body retention, organ distribution and other biological actions of the drug. The information derived will be used in estimation of radiation dosimetry, dose range, optimum scanning time and the investigation will be expanded to more patients to demonstrate the safety and efficacy of the drug. Patients should be fasted 6-8 hours prior to the study.

**B. Patient Consent**

Informed consent must be obtained on all participants. A sample form is attached to the clinical case report form. This, or an equivalent, may be used. When patient is unable to sign due to condition, a responsible family member may sign.

**C. Criteria proposed for patient selection.**

1. Age: Over 18 years unless unusual circumstances exist.
2. Sex: a. Male: Any meeting criterion for age.  
b. Female: Non-pregnant, non-breast feeding, meeting criterion for age.
3. Patient Selection:
  - a. Normal subjects for the initial studies.
  - b. Patients whose attending physicians request the study.
4. Clinical Indications:
  - a. Patients with history of malignancy to assess metastases or define extent of metastases.
  - b. Patient with no history of malignancy in whom malignancy is suspected.
  - c. Liver function determination.
  - d. Jaundice evaluation.
  - e. Biliary tract obstruction.
  - f. Evaluation of acute or chronic cholecystitis.
  - g. Patients with other medical conditions that, in the investigator's opinion, suggest radioisotope hepatobiliary studies would be useful.

**D. Evaluation of Scan Image**

Scanning time post-injection should be recorded and the optimum scanning time for the indication entered by the investigators based on the image quality. Evaluation of the image quality should be based on the following standards.

1. Excellent - superior quality image, diagnostically useful.
2. Good - good quality image, diagnostically useful.
3. Fair - fair quality image, diagnostically useful.
4. Poor - unacceptable image quality, diagnostically not useful.

**E. Criteria by which efficacy will be evaluated.**

1. Comparison with radiographic findings when indicated and available.
2. Correlation with surgery, biopsy, and autopsy findings when available.
3. Comparison with other imaging agent, if available.

Findings from the correlative studies will be compared with the scanning results and incidence of false-positive and false-negative ascertained.

**F. Utility of the study.**

Initial clinical impression should be compared with the final diagnosis and the utility of the procedure assessed.

**G. Adverse Reactions.**

All adverse reactions should be noted in the space provided on the case report form. In the event of a serious adverse reaction, Diagnostic Isotopes, Inc. should be notified immediately by telephone (201) 429-7590.

H. Blood clearance, urinary and stool excretion studies are to be performed in limited number of patients in the early phase of investigation only.

**I. Number of patients.**

Approximately 50 per investigator.

**J. Duration of Study.**

One year.

For other information concerning the product, please consult the product monograph.



Supplement III ( )

## Item 21 (Form NRC 313m)

## A. Quantities to be used

1. We estimate a patient load of 15 patients per week, or 780 per year with average use of 10 mCi of Xe-133 per patient.
2. Possession limit - presently 200 mCi Xe-133 increased to 1000 mCi Xe-133 with addition of model No 150 Radx-KOW II.

## B. Use and Storage Areas

Please see Fig. 2(a). Please note that this is a modified figure.

1. Storage and use areas: The unopened ampules will be stored in hot lab, which is equipped with lead lined storage module. The 1000 mCi Xe-133 ampule will be stored in a Model No. 150 Radx Xenon-KOW II which is completely lined with 3/16 inch lead. The Radx Xenon KOW II will be stored in the Xenon (Imaging) Room. The dimensions of Xenon Room are 20.5 ft. x 14 ft x 8 ft.
2. Ventillation

The air flow rate in Xenon Room is 750 cfm through the ceiling vent, the air is not recirculated. The Xenon Room is also equipped with a hood the exhaust port of which is directly exposed to the atmosphere-12 ft. above the building roof. The air flow rate through the hood is 2000 cfm. The whole area is under negative pressure as measured by an anometer.

The exhaust port of the Xenon trap will be connected to the hood.

## C. Procedures for routine use

Withdrawals of Xe-133 will be done with a lead shielded glass syringe. All personnel handling Xe-133 doses will wear finger badges in addition to their whole body badges in order to assess exposure to extremities.

Xe-133 will be administered to patients via a Radx Model 101 Ventilation in accordance with Radx instructions for use. Face masks or mouthpieces with nose clamps will be used to prevent loss of Xe-133 during patient study.

Exhaled Xe-133 will be collected in a Radx Model 120 Xenon trap. This model has a built-in saturation detector which gives an audio/visual signal when Xe-133 in the trap exhaust port reaches  $2 \times 10^{-2}$   $\mu\text{Ci/ml}$ .

Attached is a brochure of the whole Radx System (exhibit 1)

#### D. Emergency Procedure

In case of accidental release of Xe-133, the following procedure will be followed:

The Xenon room will be evacuated. The Xenon trap and the exhaust system will be turned on, and the room closed. The room will not be reopened until a minimum of 10 complete air changes have taken place. The current exhaust system needs less than 5 minutes for one complete change of air.

The room will not be opened for use until the radiation level in the room as determined by the survey meter shows less than 0.1 mR/hr.

#### E. Air Concentration of Xe-133 in Restricted Area

- Assumptions:
- 15 patients per week
  - 10 mCi of Xe-133 per patient
  - Loss rate of 20% (maximum) due to all sources, i.e.  $f=0.2$
  - The air flow rate is 2000 cfm  
(This is due to the exhaust through the hood only. In reality there will also be a loss due to ventilation system which is not recirculated.)
  - Maximum activity used per week : A.

$$A = 10 \frac{\text{mCi}}{\text{patient}} \cdot \frac{15 \text{ patients}}{\text{week}} \times 1 \times 10^3 \frac{\mu\text{Ci}}{\text{mCi}}$$

$$\therefore A = 1.5 \times 10^5 \frac{\mu\text{Ci}}{\text{wk}}$$

$$A \cdot f = 3 \times 10^4 \mu\text{Ci/wk}$$

$$V = 2000 \text{ cfm} = 2000 \times 6.8 \times 10^7 \frac{\text{ml}}{40 \text{ Hr. wk}}$$

$$V = 1.36 \times 10^{11} \frac{\text{ml}}{40 \text{ Hr. wk}}$$

$$\frac{A \cdot f}{V} = \frac{3 \times 10^4 \mu\text{Ci/wk}}{1.36 \times 10^{11} \text{ ml/40 Hr wk}} = 2.2 \times 10^{-7} \frac{\mu\text{Ci}}{\text{ml}}$$

This concentration is well below the MPC of  $1 \times 10^{-5}$   $\mu\text{Ci/ml}$  for a restricted area as set forth in 20.103 of CFR part 20.

## F. Concentration in Unrestricted area

The Xe-133 lost in the Xenon room and from the Xenon trap will be exhausted into the atmosphere 12 feet above the roof line of the hospital. There is not any unrestricted area within a radius of at least 200 feet from the exhaust port. However, calculations are made by treating this as an unrestricted area.

- a. The Xenon trap activates a warning system when the concentration in the exhaust port exceeds  $2 \times 10^{-2} \mu\text{Ci/ml}$ . It is assumed for this calculation that the level is at this for the washout period of each patient.

Trap pumps at 5 liter/min. average washout time = 10 minutes.  
 Xenon loss per patient through trap  $= 5 \times 10^3 \text{ ml/min} \times 10 \text{ min}$   
 $\times 2 \times 10^{-2} \mu\text{Ci/ml} = 1 \times 10^3 \mu\text{Ci/pt.}$

It should be mentioned that this is a maximum figure and that the dynamics of Xe-133 adsorption on charcoal would dictate that once Xe-133 begins to pass through the system, concentration grows geometrically which would activate the alarm and the charcoal cartridge would be replaced. (The average life of the charcoal trap is approximately one year.)  
 No. of patients per week = 15 Xe-133 lost per week =  $15 \times 10^3 \mu\text{Ci/wk.}$

- b. Xe-133 exhausted to the atmosphere  $15 \times 10^3 \mu\text{Ci/wk}$  (from trap)  $+ 3 \times 10^4 \mu\text{Ci/ml}$  (loss in room, please refer E(e) ).

$$A = 4.5 \times 10^4 \mu\text{Ci/wk}$$

$$A = 4.5 \times 10^4 \frac{\mu\text{Ci}}{\text{wk}} \times \frac{52 \text{ wk}}{\text{yr.}}$$

$$\text{Volume, } V = 2000 \text{ cfm} = 2000 \times 1.48 \times 10^{10} \text{ ml/yr} = 2.96 \times 10^{13} \frac{\text{ml}}{\text{yr}}$$

$$\therefore \frac{A}{V} = 7.9 \times 10^{-8} \frac{\mu\text{Ci}}{\text{ml}}$$

This is well below the MPC of  $3 \times 10^{-7}$  and since the calculations represent worse conditions, the safety margin appears adequate.

## G. Adsorption onto Charcoal Traps

The Xenon trap from Radx has a GM detector system monitoring the exhaust port of the trap. It is designed in such a fashion that when the unit is first turned on the alarm activates for a few seconds to indicate the system is functional. The alarm is set to activate when the concentration in the exhaust port exceeds  $2 \times 10^2 \mu\text{Ci/ml}$ . The exhaust will empty into Xenon room and has been taken into account in the 20% fractional loss of Xe-133.



The proper working of the GM detector system will be checked using a standard Cs-137 source.

Saturated filters will be plugged and placed in storage in the decay room behind a minimum of  $\frac{1}{4}$  inch lead shielding for a period of not less than 15 half lives. Since the filter is plugged and completely sealed, it is not anticipated that it will contribute to the Xe-133 air concentration.

Dept. of Nuclear Medicine  
Louis A. Weiss Memorial Hospital

Radiation Survey Record

Name : \_\_\_\_\_

Date : \_\_\_\_\_

Locations	Readings	mR/hr
1) Refrigerator:	( )	
2) Pb Lined Storage Module	( )	
3) Dose Calibrator	( )	
4) Protective Barrier	( )	
5) I-131 Uptake Machine	( )	
6) BKG Scan Lab	( )	
7) Well Counter	( )	
8) Out-Side Decay Room	( )	
9) In-Side Decay Room	( )	
10) Over The Containers	( )	
a. Tc-99m		
b. All except Se-75		
c. Se-75		

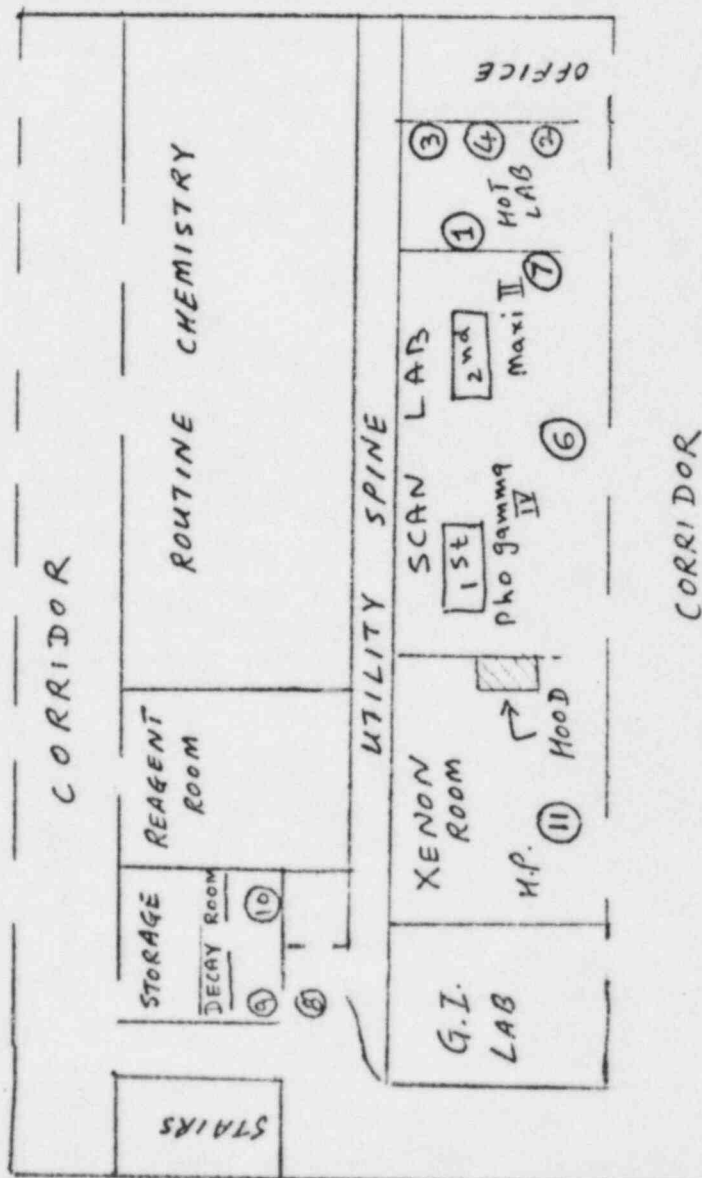
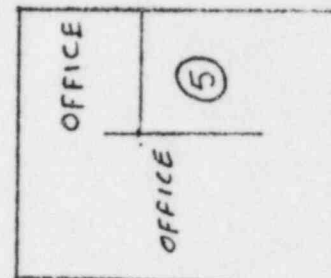
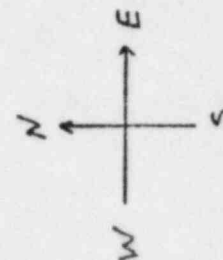
11) Xenon Room ( )

\* There are two wells for discarded needles, syringes and vials

a. For Tc-99m

b. For all other isotopes except Se-75

The Se-75 is kept in the container in one of the module drawers.



SCALE 1" = 12.4'

NUCLEAR MEDICINE (Floor Plan)  
7th Floor.

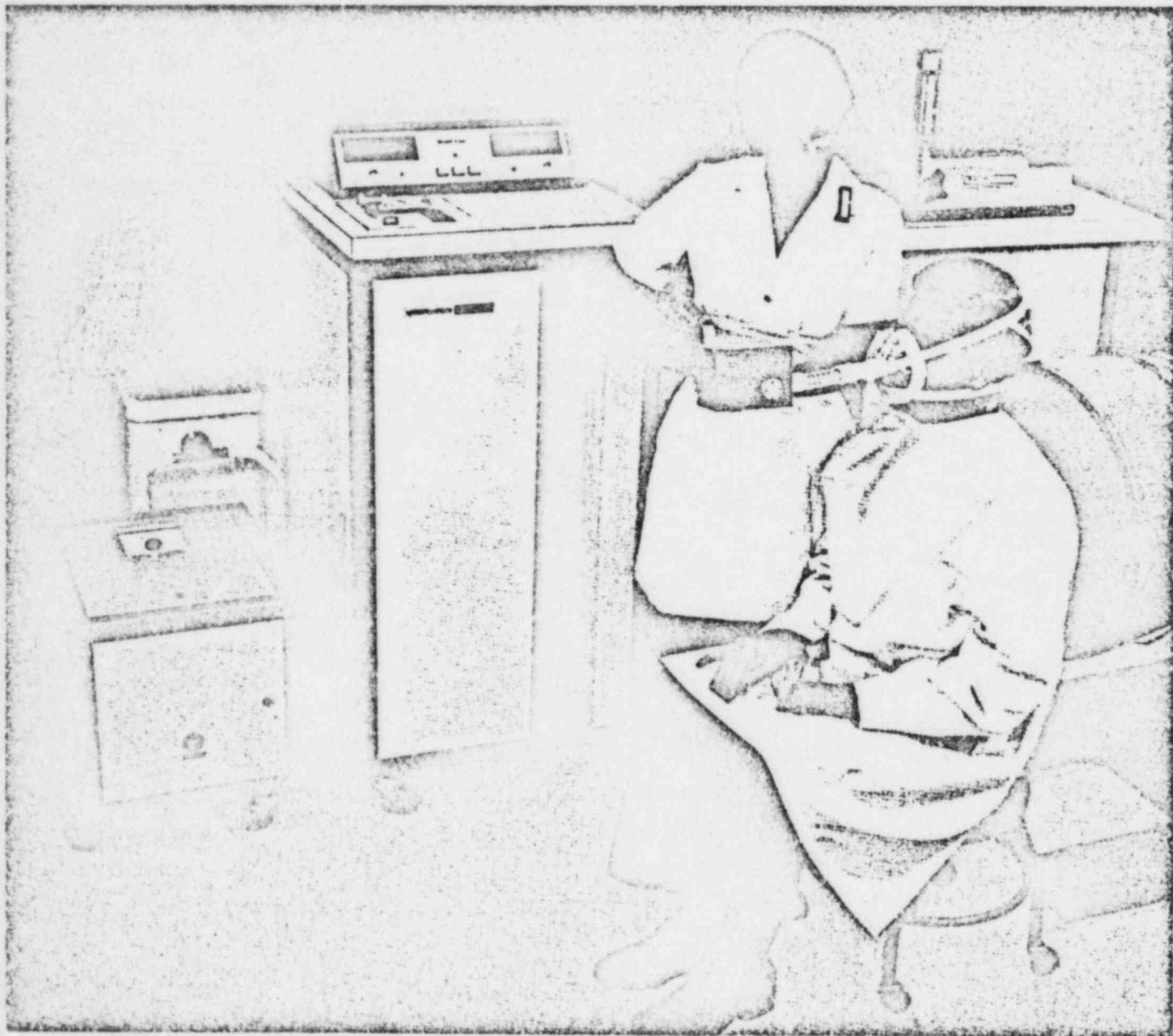
SIGNATURE: \_\_\_\_\_

Figure 2 (a)

## EXHIBIT I

# From Start to Finish...

## a $^{133}\text{Xe}$ Gas Control System from RADX



Now you can dispense, administer and dispose of  $^{133}\text{Xe}$  safely and economically under controlled conditions with a complete system from Radx.

# Economy, Safety, Efficacy, Simplicity... the criteria for the development of the Radx $^{133}\text{Xe}$ gas handling system.



Xenon Kow II safely crushes, dilutes and dispenses, using one curie "crusher" ampules.

## Economy

How can a system which costs almost \$7,000 be economical? Radx has the answers:

**First:** Design of the Ventil-Con lets you reuse the  $^{133}\text{Xe}$  gas stored within the system. An inline autoclavable bacteriological filter facilitates reuse. The only  $^{133}\text{Xe}$  lost is that in the patient's lung at the time washout is initiated. This normally represents only about 10% of the total gas in the system. Other systems, particularly those using "economical" disposable bags and "economical" homemade units, require complete dumping of  $^{133}\text{Xe}$  between patients.

**Second:** If you do five or more studies per week and if you use the new Xenon-Kow II, you can save enough in a year to pay for a Ventil-Con, Xenon Trap and the Xenon-Kow II-and have enough left over to give yourself a raise!  $^{133}\text{Xe}$  can now be purchased in one curie "crusher" ampules for less than \$200. The Xenon-Kow II allows you to crush, dilute and dispense safely from these ampules. With the inherent  $^{133}\text{Xe}$  conservation of the Ventil-Con, you should be able to get 20-25 days worth of  $^{133}\text{Xe}$  from a one curie ampule.

**Third:** When you compare the cost of the Radx Xenon Trap to the cost of running a vent system above the roofline of the hospital, the choice is obvious.

IF YOU DO FIVE OR MORE STUDIES PER WEEK THE VENTIL-CON WILL SAVE YOU ENOUGH MONEY IN ONE YEAR OVER HOMEMADE AND DISPOSABLE BAG SYSTEMS TO PAY FOR ITSELF.



## Safety

**Xenon-Kow II**—The Xenon-Kow II is completely shielded with 3/16" lead. All moving parts are precision machined. Both the crusher assembly piston and the storage vessel piston use double "O" rings for an effective seal and extra assurance against system failure if one "O" ring is damaged.

**Ventil-Con**—Some of the many built-in safety features include:

- 1/16" shielding on spirometer;
- Flame isolated circulation pump motor;
- $^{133}\text{Xe}$  concentration monitoring system;
- 3 modes of  $\text{O}_2$  replenishment: automatic, manual and emergency assist;
- Large volume  $\text{CO}_2$  trap;
- Inline, autoclavable, bacteriological filter;
- The Radx Ventil-Con uses a dry spirometer system (Some other units use a water spirometer which can serve as a bed for bacterial growth; and allows water-soluble Xenon to escape at the water/air interface).

**Xenon Trap**—The Xenon Trap activated charcoal cartridge pack is completely shielded by 3/16" lead. The unit uses a flame isolated positive displacement pump which eliminates sparks completely from the potentially  $\text{O}_2$  enriched atmosphere. The unit employs one of the largest activated charcoal pathways available which increases absorption and prevents premature leaks. The Xenon Trap Model 120 also is equipped with a

$^{133}\text{Xe}$  saturation detector warning system. When radioactivity is detected in the exhaust port an audio/visual alarm indicates the need for a cartridge change.

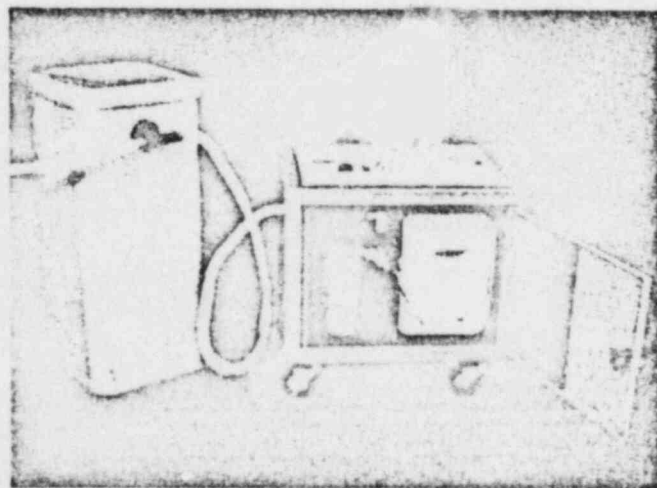
## Efficacy

The Ventil-Con allows administration of the  $^{133}\text{Xe}$  gas in two ways; as a homogeneous mixture or as a bolus, utilizing an optional mouthpiece. The three phases of lung-ventilation—washin, equilibrium and washout—can readily be performed. With the Radx automatic oxygen replenishment system the equilibrium portion may be run for as long as desired. Unlike units which require patients to sit up, the Ventil-Con allows studies to be done on patients who are bedridden.

It has become increasingly apparent that multiple view lung ventilation images are as necessary as multiple view perfusion studies. The Radx swivel adapter permits rotating the patient around a central vertical axis without disconnection from the Ventil-Con, which makes multiple view ventilation studies a reality.

The Ventil-Con also allows maximum ease of breathing. Measured resistance to normal breathing is less than 0.1 inch of water, barely noticeable even to the emphysema patient. Radx even designed the Expandable Interface because Xenon traps operate best at 5 liters per minute and people breathe best at 15 liters per minute. The interface compensates for the difference.

Optional expandable interface handles excess volume between trap operation of 5 liters per minute and normal breathing rate of 15 liters per minute.



Xenon Trap, with door open, shows lead-shielded charcoal pack (left) and flame isolated displacement pump (right).



## Simplicity

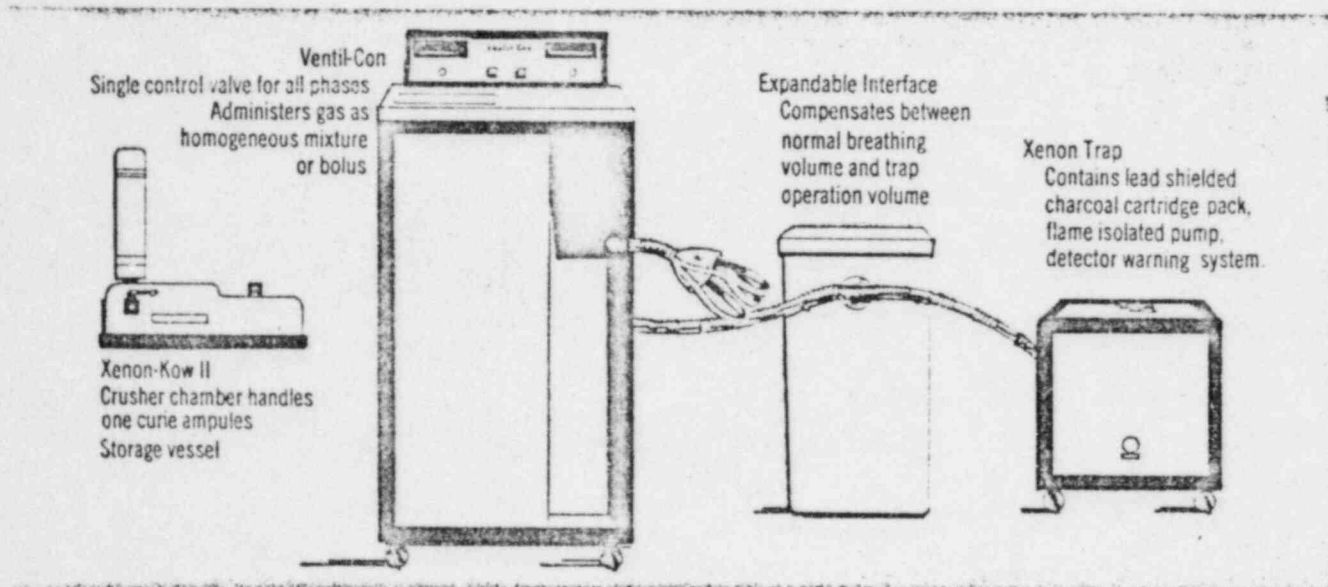
The entire system was designed for uncomplicated operation. The Ventil-Con has one control (a two-position valve) to operate the washin, equilibrium, and washout phases.

The Ventil-Con does not interfere with the patient's control of his own breathing, nor does it rely on complicated automatic sequential functioning. The Ventil-Con allows the technologist to stand next to the patient, control the administration of the  $^{133}\text{Xe}$

and operate the gamma camera with the Radx console mounted remote gamma camera start, stop, reset push-buttons.

Economy. Safety. Efficacy. Simplicity. The entire system is well planned and well designed and all three components work independently or together. Ask your Radx representative to supply the complete system or interface any one component to your existing system. Any way you elect to go it is guaranteed by Radx.

## Schematic view of Ventil-Con System

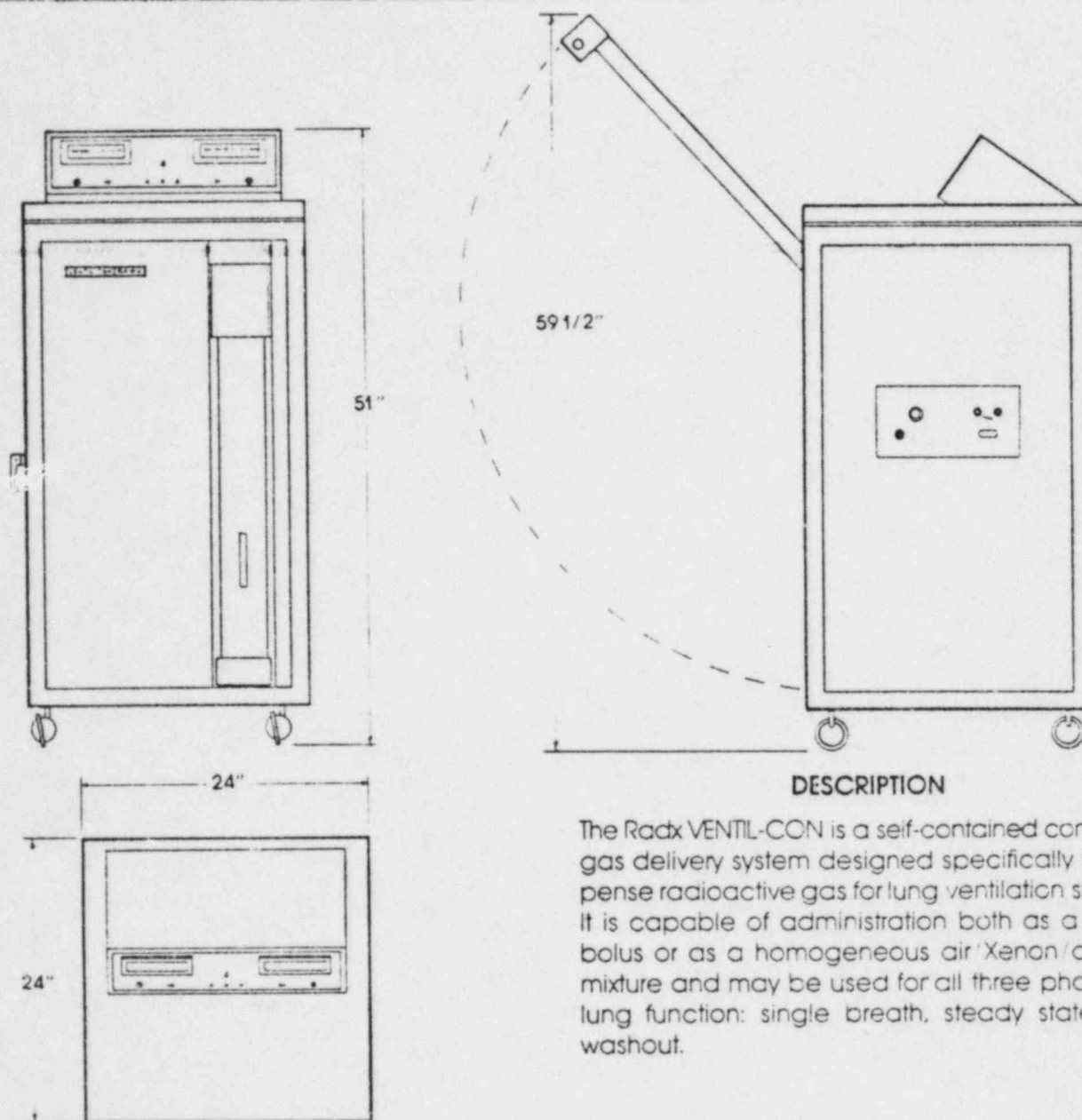


# RADX

P.O. Box 19164, Houston, Texas 77024 • (713) 468-9628

# RADX

## Ventil-Con Controlled Gas Delivery System



### DESCRIPTION

The Radx VENTIL-CON is a self-contained controlled gas delivery system designed specifically to dispense radioactive gas for lung ventilation studies. It is capable of administration both as a direct bolus or as a homogeneous air/Xenon/oxygen mixture and may be used for all three phases of lung function: single breath, steady state and washout.

### Features/Specifications

**Free Standing Mobile**—The Ventil-Con is completely self-contained in a mobile, coaster-mounted console that is easily and conveniently positioned to perform the clinical study. The Ventil-Con occupies only 4 square feet of floor space, which easily facilitates temporary storage.

**Large Volume Spirometer**—The Ventil-Con has a 10 liter capacity horizontal rolling spirometer. All airway plumbing is fabricated of non corrugated, low resistance, smooth surface reinforced PVC tubing. The expansion/contraction factor of the ball bearing mounted spirometer diaphragm is negligible, offering a resistance of 0.05 inches of water to normal breathing. The spirometer mechanism is completely shielded with  $\frac{1}{8}$  inch lead ( $\frac{1}{4}$  inch option available for  $^{127}\text{Xe}$ ) for personnel safety. The spirometer volume is displayed on the

control panel on a large scale analog meter and on one channel of a dual strip chart recorder on model 102.

**Uniform Gas Mixture**—The Ventil-Con incorporates a flame isolated motor and recirculating pump to insure a homogeneous gas mixture. Equilibrium is reached within minutes of being charged.

**Concentration**—Concentration is continuously monitored by an in-line GM tube and displayed as mCi/liter on a large scale analog meter on the control panel and on one channel of the dual strip chart recorder on model 102. The concentration may be varied by using one or all of the following controls: the evacuate mode, oxygen replenishment, and/or Xenon charge port.

## Features/Specifications Cont.

**Oxygen Enrichment Mode**—The Ventil-Con is equipped with controls that allow the addition of oxygen in three different modes from an external supply. The three modes are:

1. Auto—replaces oxygen removed by patient during "Xenon rebreathing" phase at the spirometer.
2. Manual—allows oxygen to be added to the spirometer by manually operating the momentary oxygen solenoid switch.
3. Emergency Oxygen Assist—delivers oxygen directly to the patient and is activated by a momentary switch at the head valve.

**Delivery Arm**—The delivery arm of the Ventil-Con recesses into the cabinet during transportation or when not in use. The arm is 28 inches long, continuously adjustable up to 60 inches in height and is shielded with  $\frac{1}{8}$ " lead. An additional  $\frac{1}{8}$ " may be added on two sides as an option to provide adequate shielding for  $^{125}\text{Xe}$ .

**Valve Head**—The Ventil-Con employs the Radx patented three-way valve which transfers the patient from "Stabilization" where they breathe room air, to "Xenon Rebreathing" where they are in closed loop with the radioactive gas mixture to "Washout" where the patient inhales room air and exhales out the exhaust port. Proper use of the head valve allows for a single breath study utilizing the homogeneous mixture of the Ventil-Con.

**Masks**—A variety of masks are available for use with the Ventil-Con. The unit is supplied with one "Adult Mouthpiece" and will be supplied with an Adult Mouthpiece for Bolus Injection upon request at no additional charge.

<sup>1</sup>Obst, W.D. et al. "Determination of Regional Cerebral Blood Flow by Inhalation of Xenon-133." *Circulation Research*, XX, 124-134, January, 1967.

**Swivel Adapter**—The Ventil-Con comes equipped with a right angle swivel adapter which allows multiple views during the equilibrium phase of the study. The adapter is designed for use with the patient in the sitting position.

**Carbon Dioxide Trap**—The Ventil-Con incorporates a rechargeable  $\text{CO}_2$  trap using soda lime granules. These granules are normally pink, turn blue when saturated with  $\text{CO}_2$  and are a visual indicator that the  $\text{CO}_2$  trap needs recharging.

**Xenon Gas Storage**—The Ventil-Con is designed in such a fashion that the only Xenon loss during a study is that which is in the patient's lungs at the start of washout. This combined with the bacteriological filter allows reuse of the Xenon gas mixture on subsequent patients. The concentration may be adjusted after each patient.

**Control Functions**—The Ventil-Con control panel includes remote controls for the scintillation camera which allows the technologist to operate the gamma camera from the patient's side.

**Power Requirements**—110 volt, 60 Hz single phase 5 amp., dual-fused, chassis ground

**Dimensions**—Height—51 inches  
Width—24 inches  
Depth—24 inches  
Weight—Approximately 350 lbs.

**Special Application**—A Radx Ventil-Con has been modified for Xenon-133 gas administration to determine Regional Cerebral Blood Flow by the inhalation technique of Obrist, et al.<sup>1</sup> Modification includes a constant flow pump which draws directly from the head valve during washout.

### PRICE LIST

Radx No.	Description	Price
101	Ventil-Con Controlled Gas Delivery System	4915.00
102	Ventil-Con Controlled Gas Delivery System with Strip Chart Recorder	5915.00
Both of the above units include the following:		
(1) 12" Flex tube with Adult Mouthpiece and headstrap. Please specify Adult Mouthpiece for Bolus Injection if desired.		
(1) Nose depressor		
(1) Quart of soda lime granules		
(1) 20' remote control cable		
(1) Installation and instruction manual		
103	Single Channel Strip Chart Recorder	1,200.00
104	Soda Lime Granules — 1 Case (20 quarts case)	40.00
105	Autoclavable Bacteriological Filter	35.00
106	Remote Control Cable — 20 feet	60.00

Radx No.	Description	Price
107	Chart Recorder Paper — 12 rolls (minimum)	180.00
108	Infant Mask (small, medium or large)	15.00
109	Adult Mouthpiece	15.00
110	Adult Face Mask	20.00
111	Adult Mouthpiece for Bolus Administration	30.00
112	Face Mask Tubing (12")	8.00
113	Face Mask Tubing (6")	6.00
114	Infant Face Mask Harness	8.00
115	Swivel Adapter	25.00
116	Adult Face Mask Harness	8.00
127	Tubing — interface Ventil-Con / Xenon trap	15.00
128	Tubing — exhaust port — per foot	.75
129	Expandable interface	75.00
	Xenon-127 Additional lead shielding	200.00
	Cerebral Blood Flow Modification	400.00

Terms: Net 30 days F.O.B. Houston, Texas  
Prices effective August 1, 1976

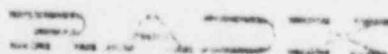
### Maintenance

Routine cleaning and replacement of the soda lime granules is all the service your Ventil-Con will require. Complete procedures for good care are outlined in the instruction manual.

### RADX Warranty

RADX warrants the Ventil-Con to be free from all defective material and workmanship for a period of one year from date of shipment. RADX Corporation's liability shall be limited to the repair or replacement of the defective material or component at its option.

Prices are subject to change without notice.



8/1/75 Printed in U.S.A.