

707 South Mills Street
Madison, WI 53715-0450
608 251 6100

St. Marys

Hospital Medical Center
Madison, WI

April 13, 1985

U.S. Nuclear Regulatory Commission
Region III
Radionuclide Licensing Section
799 Roosevelt Road
Glen Ellyn, IL 60137

Attn: Darrel Wiedeman, Chief

Dear Sir:

Please amend our NRC License No. 48-00919-03 to include Gadolinium-153, which will be used for bone mineral scanning.

We request a total possession limit of 1500 mCi of Gd-153. During normal use only one radionuclide source will be on site. For continuity of patient scanning, the total amount requested includes the summed activity of a newly received source and the decayed source which will be returned to the source manufacturer.

The Gd-153 source is supplied in capsule form as GdO_2 with a total activity of 1000 mCi each. The source capsule is supplied from Gulf Nuclear, Webster, TX (Model GD-1) and is shipped in a lead-lined brass holder.

The bone mineral analyzer device to be used will be a product of Lunar Radiation Corp., Madison, WI. The model number is Lunar DP3 and is registered under the NRC (Reg. No. NR-430-D-101-S) and the FDA (Reg. No. K802180A).

The Lunar bone mineral analyzer is to be installed by a qualified expert who will provide two days of installation and training. Training will cover source installation, wipe testing, scan operations, and data analysis and interpretation. Dr. R. Lindgren, Radiation Safety Officer, will be present for instruction on source replacement and wipe testing.

Product literature from Lunar Radiation Corp. on the DP3 scanner is included for your review.

RECEIVED

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REGION III

Sincerely,

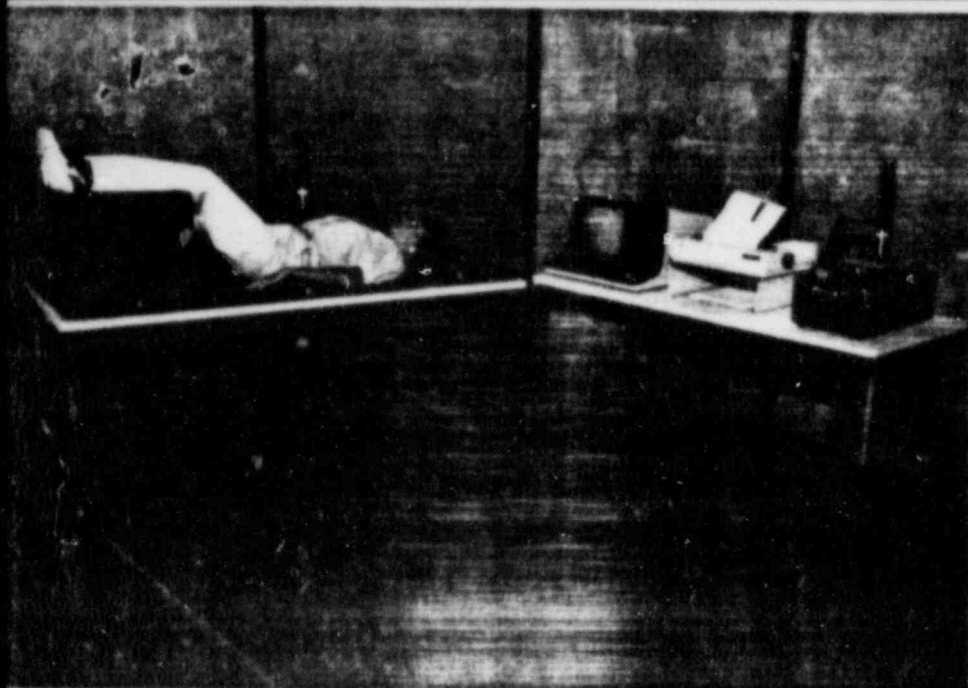
Tamnit Ansusinha

Tamnit Ansusinha, M.D.
Director, Medical Imaging

MAY 6 1985

Applicant	May 12
Check No.	0058678720
Amount/Fee Category	75
Interest Fee	april
Date Check Rec'd	2/4/85
Received By	46
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st widely used system for
ial skeleton in the world
g U.S. market the DP3 has
ements of the spine and

Advantage Computer Module
Diagonal high resolution
CRT (640 x 240 pixel)

- | | |
|------------------------------|--------------------------------------|
| Scanner Software | |
| Statistical Analysis Package | - in-built dual sided dual density |
| Computer Console Table | disk drives |
| Calibration Standards | - 64K RAM Memory |
| Printer (optional) | - Dual Processor (Z80 CPU with Intel |
| SP2 Rectilinear Forearm | 8035 auxillary) |
| Scanner (optional) | - Scanner interface controller board |

SOFTWARE

Lunar's sophisticated software makes measurements easy and precise. Automated analysis ensures fastest results, but overrides allow the operator to interpret data if necessary. Correction factors incorporated in the software make bone measurement independent of the tissue coverage or position of the bone being scanned in the beam path. Calibration to accepted standards and reporting in common units of measure make utilization of existing normals and inter-unit comparisons possible. Intelligent software locates bones of interest and tracks them eliminating positioning problems and dependence on large scan areas. This technique allows for lower patient radiation dose, maximum precision, high anatomical resolution, and fast scan times. Results are numerically and graphically displayed on the system's 12" monitor, permanently recorded on floppy disk, and printed on 8 1/2" x 11" paper for permanent patient records.

RESULTS

All results are numerically and graphically displayed in common units of measure, stored on floppy disk for later analysis and printed for permanent patient records.

SPINE MEASUREMENTS

Calculated Values

Calibrated BMC - Bone Mineral Content Value (g)
Calibrated BMD - Bone Mineral Density Value (g/cm^2)
Calibrated BMC/W - Bone Mineral Content per unit width
Normal Comparisons - age, size, sex, and race matched for region
and individual vertebrae
Corpus Density - (mg/cc) - calculated density of vertebral body BMD
Central Density - determined in central centimeter of the centrum
and used for serial determinations
Scan Time - 15 min. (5 min. for screening scan)

ANALYSIS OF PROXIMAL FEMUR

Calculated Values

Femoral Neck - Angle of Scan - angle chosen for best
perpendicular to femoral neck
Femoral Neck BMC - Bone Mineral Content (g)
Femoral Neck Area - (cm^2)
Greater Trochanter - Trochanteric BMC - Bone Mineral Content (g)
Trochanteric Area - (cm^2)
(The trochanter is the site of 50% of all hip fractures)
Ward's Triangle - Ward's Triangle BMC - Bone Mineral Content (g)
Ward's Triangle Area - (cm^2)
(This region has the highest correlation with hip fractures)
Scan Time - 15 min.

----- WARRANTY/SERVICE -----

All system components are warranted for 1 year (parts and labor). 24-hour guaranteed service program ensures minimum downtime in operations. Service contracts are available for extension of service coverage.

----- RADIATION/LICENSING -----

- The DP3 utilizes a 1 Ci Gadolinium 153 Source (44 Kev and 100KeV). Proper licensing is required by the Nuclear Regulatory Commission or proper state agency for isotope use. Lunar's DP3 is registered with the NRC (registration number NR-430-D-101-S) and the FDA (K802180A) to facilitate licensing.
- Scan dose to patients - 12 mrem
- Dose to personnel - negligible
- Source life - 12 months for work with osteoporotics, up to 18-24 months depending on application.
- The usual source capsule is Gd-1 from Gulf Nuclear in Webster, TX and is supplied to the customer in a lead-lined brass holder.



bone assessment techniques. Let us help you choose the most effective system for your needs.

DUAL-PHOTON ABSORPTIOMETRY (^{153}Gd)

DP3 Spine/Femur Scanner: The most sensitive tool for diagnosis and monitoring of bone disease. Features fast-scan for screening or slow-scan for precision measurements. Enables critical evaluation of trabecular bone in order to monitor therapy in serial studies. (Spine measurements have a 2-3% precision in an area that changes 15% annually rather than $\pm 1\%$ annually as in the radius.)

DP4 Total Body Scanner: A rectilinear scanner for measuring the total skeleton as well as spine and femoral neck. Offers complete skeletal coverage for clinical research.

SINGLE-PHOTON ABSORPTIOMETRY (^{125}I)

SP2 Forearm Scanner: A rectilinear scanner for high precision (1%) measurements on the limbs. For diagnosis and monitoring of all bone diseases, adult and infant studies, evaluation of the new ADFR treatment modality, and small animal studies. Capable of scanning irregular anatomical areas such as the distal radius and featuring a variety of scan speeds and step intervals.

BENEFITS OF LUNAR SYSTEMS

- Automatic Bone Location by Intelligent Scanner
- Automatic Edge and Baseline Detection
- Data Base of Normals
- Standards for System Calibration
- Sophisticated Correction Factors
- Extensive Application Support
- 24-Hour Replacement Service Program

LUNAR RADIATION CORP.

DP3 SPINE/FEMUR SCANNER and SP2 FOREARM SCANNER SPECIFICATIONS

Computer

NorthStar Advantage

Dimensions: 28x51x32cm (20kg)

Processor: Z80A CPU and INTEL 8035; option IBM compatible

Display: 28cm diagonal P31 Phosphor; 1920 character (24 lines x 80 characters);
graphics 240x640 pixels bit-mapped; screen dump to printer

Disks: Two 5-1/4" floppy diskette drives (double-sided, double density); 360K byte per
diskette (10 sector); holds 25 spine or femur scans or 55 forearm scans per diskette

Nuclear Instrumentation

High voltage: Programmable 600 to 1600V

Amplifier: High-speed (0.25 microsec shaping time)

Dual-channel analyzer: Low-drift fast analyzers

Dual-scalers: 10 MHz scalers (16-bit)

Timer: Crystal-controlled programmable

Detector: Collimated NaI (TL) scintillation detector with Bialkali Cathode

Motors and Control

Motors: 4-phase stepping motors

Control: Programmable controller; menu-driven step interval and speed

Scan Table (for DP3)

Dimensions: 183 x 81 x 69cm (50kg)

Materials: 2.5 x 5cm chrome plated steel legs; laminate covered wood top

Console Table (for both DP3 and SP2)

Dimensions: 152 x 76 x 69cm (30kg)

Materials: 2.5 x 5cm chrome plated steel legs; laminate covered wood top

Scanner Mechanism

DP3-Dimensions: 60 x 60 x 25cm metal enclosure below table (30kg)

SP2-Dimensions: 56 x 54 x 46cm metal enclosure

Source access: Through locked table top

Software

Operating system, graphics and BASIC are standard.

Compiled programs include: spinal scanning, femoral scanning, quality control;
reanalysis of data from diskette

Warranty

Ninety day complete parts and labor coverage warranty. One-year parts warranty on Lunar Radiation components (scanner and counting electronics).

Service Contracts

Extension of the complete warranty service can be obtained under a service contract. Service contracts provide for the continued operation of your systems at a predictable cost. Benefits include one-day replacement service in case of failure and on-site service if necessary.

Radionuclide sources

¹⁵³-GD (1 Ci) sources are supplied by Gulf Nuclear of Webster, Texas (713-332-3581) for approximately \$6700 and can be used for 12-18 months.

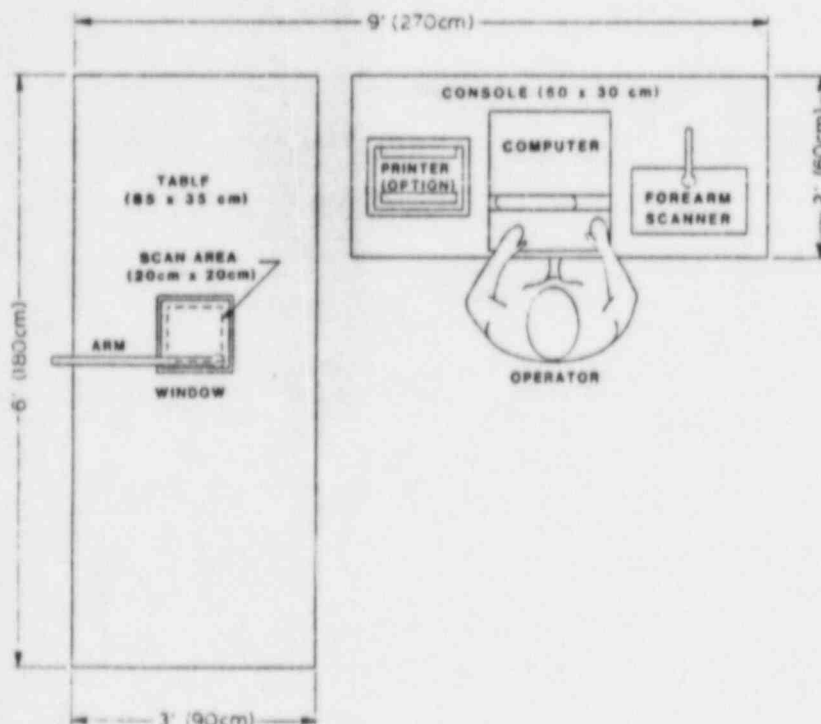
¹²⁵-I sources (200mCi) are supplied by Atomic Energy of Canada, Ltd. (613-592-2790, ext. 2048) for about \$600 and can be used for 6 months.

N.R.C. Device Registration: DP3 NR-430-D-101-S, SP2 NR-430-D-102-S. 8-hours training required for license.

Delivery

30 days ARO.

System Configuration (typical)



LUNAR RADIATION CORPORATION

916 Williamson Street—Madison, Wisconsin 53703
(608) 258-8545

LUNAR RADIATION CORPORATION CONFIGURATION/PRICE LIST

DP3	Dual-Photon Spine/Femur Scanner Epson FX-80 Printer with Memory Buffer	\$31,350 \$800
DP3/SP2	Dual-Photon Spine/Femur Scanner with Rectilinear Forearm Scanner Option (Single computer supports both systems) Epson FX-80 Printer with Memory Buffer	\$41,350 \$800
DP4	Total Body Scanning System (DEC 11/23 Computer; LA100 Printer; VT100 Terminal)	\$68,000
SP2	Single-Photon Rectilinear Forearm Scanner Epson FX-80 Printer with Memory Buffer Infant Positioning System	\$19,100 \$800 \$300
Bone Lab Package	DP3 Dual-Photon Spine/Femur Scanner with Printer and SP2 Single-Photon Rectilinear Forearm Scanner with Printer (includes two consoles)	\$49,000

TERMS:

- Prices include 2 day on-site installation and training
- FOB destination (LUNAR pays shipping costs)
- ~~• 3% discount for prompt payment within 10 days of 30 days~~

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INCOME GENERATION VERSUS COST

Income generated will offset cost of SP2 and DP3 systems even in "worst-case" situations (low patient load). At higher patient loads these systems will pay for themselves and generate a small net gain in the first year. Typical procedure charges (\$40 for a forearm determination and \$125 for a spine determination) were used; also expenses for a technician may be reduced if personnel is available on a share-time basis.

Forearm Scanner

SP2 + Printer	\$ 3,980*
50% Technician	7,000
¹²⁵ I-sources (2)	1,260

Costs	\$12,240

Annual break-even at \$40 per procedure is 306 procedures (i.e., about 6 per week). Costs are less if a technician is available on call. With a patient load of 15 per week the income generated is sufficient to break even, without amortization, in 1 year.

DP3 Spine Scanner

DP3 + Printer	\$ 6,430*
Technician	14,000
Source ¹⁵³ Gd	6,700

Costs	\$27,130

DP3/SP2

DP3/SP2 + Printer	\$ 8,430*
Technician	14,000
Source Gd ¹⁵³	6,700
Source I ¹²⁵	1,200

Costs	\$30,330

Annual break-even at \$125 per determination is at 217 determinations for DP3 and 242 for DP3/SP2 (4-5 weekly). With a patient load of 10 per week either system has a break-even in less than 1 year without amortization.

* amortized over 5 years

GENERAL PRODUCT WARRANTY

A) WARRANTY

Lunar Radiation Corporation warrants that all products covered hereby shall be free from defects in workmanship and materials and shall conform to published specifications or other specifications accepted in writing by Lunar for a period of one (1) year under normal use as prescribed in the operator's manual. The foregoing warranty does not apply to any products which have been subject to use other than as specified as standard operating procedure in the system manual, neglect, accident, or modification. Lunar's sole obligation to buyer hereunder for products failing to meet the aforesaid warranty shall be, at Lunar's discretion, to replace the nonconforming product (parts and labor) or issue buyer credit for the purchase price of the nonconforming product where within the warranty period: 1) Lunar has received written notice of any nonconformity and 2) after Lunar's attempts to remedy such nonconformity Lunar has determined that the products nonconformity is not a result of improper use, repair or other misuse by buyer. Any replacement product shall carry the unexpired term of the warranty which was applicable to the replaced product or a period of 30 days whichever is longest.

LUNAR MAY RETAIN THE RIGHT TO VOID ALL SYSTEM WARRANTIES IF PAYMENT IS NOT RECEIVED AS PRESCRIBED IN TERMS OF PURCHASE.

EXCEPT AS SPECIFICALLY PROVIDED HEREIN, THERE ARE NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT SHALL LUNAR BE LIABLE FOR LOSS OF PROFITS, INDIRECT, SPECIAL, CONSEQUENTIAL, OR OTHER SIMILAR DAMAGES ARISING OUT OF ANY BREACH HEREOF.

B) WARRANTY PERIOD

Warranty period is defined as one year from date of invoice (shipment) unless otherwise specified in writing by Lunar.

C) REPAIRED OR REPLACEMENT PRODUCTS (out of warranty)

Lunar Radiation for a period of 30 days warrants that its standard products repaired or replaced here under shall be free from defects in workmanship or materials under normal use as described in the system's Operator's Manual. Warranty period will begin upon shipment of repaired or replacement products. The

sole responsibility of Lunar under this warranty is, at its option, to repair or replace any defective component parts of such products. This warranty does not apply to: 1) products which have been repaired or altered other than under specific instruction from Lunar's service department, instruction as listed in systems manuals or procedures previously approved in writing by Lunar service department, or 2) products which have been subject to use other than described as standard use in the system's operator's manual, neglect, or accident.

LUNAR MAY RETAIN THE RIGHT TO VOID ALL SYSTEM WARRANTIES IF PAYMENT IS NOT RECEIVED AS PRESCRIBED IN TERMS OF PURCHASE.

PURCHASE ORDER TERMS AND CONDITIONS

The following provisions are hereby made a part of the General Purchase Order contract and seller by his acceptance of this order agrees thereto. No alterations will be effective without consent of the buyer. This order and the performance of the parties hereunder shall be controlled and governed by the law of the state shown in buyer's address on the front side hereof.

1. **PRICE:** If price exceeds the amount stipulated in the order, the seller shall notify the buyer's purchasing office immediately. If price is not stated in this order, it is agreed that the goods and services shall be billed at price last quoted, or billed at the prevailing market price, whichever is lower.

2. **QUANTITY:** The specific quantity ordered must be delivered in full and not be changed without the buyer's consent in writing. Any unauthorized quantity is subject to buyer's rejection and return at seller's expense.

3. **PAYMENT:** It is understood that the cash discount period will date from the receipt of the goods or from the date of invoice, whichever is later. C.O.D. shipments will not be accepted. Penalties will not be paid.

4. **FREIGHT:** As indicated on the front of this purchase order, unless provided otherwise, all goods will be shipped F.O.B. Destination. Freight Prepaid. If the seller is entitled to transportation charges, these charges shall be added to the seller's invoice and supported by receipted freight bills. No charges will be allowed for containers, crating, boxing, bundling or damage, unless stated herein.

5. **PACKING:** The goods shall be packed and shipped by seller in accordance with buyer's instructions and good commercial practice and so as to insure that in domestic shipments the goods are protected from weather or transportation.

6. **IDENTIFICATION:** Purchase order numbers must appear on all packages, packing slips, and invoices. One packing slip must be included with all shipments.

7. **INVOICES:** Original copies of invoices must be mailed to B. Mar's and cash discount must be deducted on face of invoice and not amount shown. Itemized statements of account must be rendered monthly.

8. **RELEASE AUTHORIZATION:** In the absence of subsequently specified delivery dates, the goods may be shipped only in accordance with the instructions specified in the schedule and/or release forwarded to seller.

9. **ASSIGNMENT:** Seller shall not delegate any duties nor assign any rights or claims under this purchase order without the prior written consent of the buyer.

10. **APPLICABLE LAWS:** By the acceptance of this order, seller represents that the goods covered by this order were manufactured, packaged, and labeled, and if required, were registered, and are being distributed, sold, and priced in compliance with all Federal, State, and Local Laws.

OR

In the performance of this order, the seller agrees to comply at all times with all applicable Federal, State, and Local Laws, Rules, and Regulations.

11. **CANCELLATION:** Buyer reserves the right to cancel on account of defects in material, workmanship, or quality of goods, or if goods are not shipped as specified herein, or on release authorizations or schedules issued in connection herewith, time being of the essence, or if goods are not in accordance with approved samples or specifications issued in connection herewith, or if performance by seller is prevented by causes beyond seller's control, or if seller fails to comply with other terms and conditions of this order, or if seller is bankrupt, insolvent or has a receiver appointed for it.

12. **ACCEPTANCE AND INSPECTION:** All goods ordered hereunder shall be subject to buyer's right of inspection and rejection within a reasonable period of time. If goods are rejected, they will be returned at seller's risk for credit or replacement at buyer's option, and all handling and transportation expenses both ways shall be assumed by seller. When goods have been rejected, buyer shall have the right to cancel any unshipped portion of this order. Payment for goods received shall not constitute acceptance and is without prejudice to claims that the buyer may have against the seller.

13. **WARRANTY:** Seller expressly warrants that all goods covered by this order will conform to the specifications, drawings, or samples furnished by seller and shall be free from defects in material and/or workmanship and shall be merchantable. This warranty shall survive any inspection, delivery, acceptance or payment by buyer.

14. **INDEMNIFICATION:** The supplier agrees to protect, indemnify and save harmless the buyer from all attorney's fees, costs, expenses and damages arising out of (1) any infringement or claim of infringement of patents, trade-marks or copyrights in the use or resale of any goods covered by this order, unless goods hereby ordered are made specifically to the buyer's design or method, (2) liability by supplier to comply with all applicable Federal and State Laws and Regulations enacted after the date of the purchase order, and (3) all claims, suits, actions, costs, counsel fees, expenses, damages, judgments or decrees by reason of any person or persons being injured or property being damaged or destroyed because of any fault, negligence or defect, latent or otherwise, in the goods purchased or their design, or during or as a result of the work or services to be performed pursuant to this order.