MARSHFIELD CLINIC

DEPARTMENT of CLINICAL ONCOLOGY
Radiation Oncology
(715) 387-7637
Robert H. Greenlaw, M.D.
Homer H. Russ, M.D.

Medical Physics
David D. Loshek, Ph.D.

June 19, 1985

Williams J. Adams, Ph.D.
Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Dr. Adams,

Please amend our NRC license (48-10966-03) to allow us to possess and use two x 1 Curie Gadolinium -153 sealed sources. This source will be used under the jurisdiction of the Radiation Safety Committee.

The Gadolium -153 source is described as follows:
Supplier: Gulf Nuclear, Inc.
202 Medical Center Boulevard
Webster, Texas 77598
Source: 1 curie of Gd -153 as Gd_2O_3, Model GD-1
This source will be used in the Norland 2600 Dichromatic Bone Densitometer of the Lunar Radiation Corporation DP-3XT or AT. This device will be located in the Nuclear Medicine Department. Enclosed is information on both devices.

Leak testing, surveys, quarterly inventories, and other appropriate radiation safety precautions, as outlined in the conditions of our license, will be followed. The source will be sent back to the company for disposal.

Enclosed you will find a check for $120.00 for the amendment fee. It there are any questions or further information is needed, please call me at (715) 387-7637. Thank you for your cooperation.

Sincerely,

Robert E. Peterson, Jr.

Robert E. Peterson, Jr.
Health Physicist

Enc.

/dw

Applicant ...
Check No. 6138[illegible]2
Amount Fee Category $120
Type of Fee ...
Date Check Rec'd 7/5/85
Received By ...

RECEIVED
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REGION III
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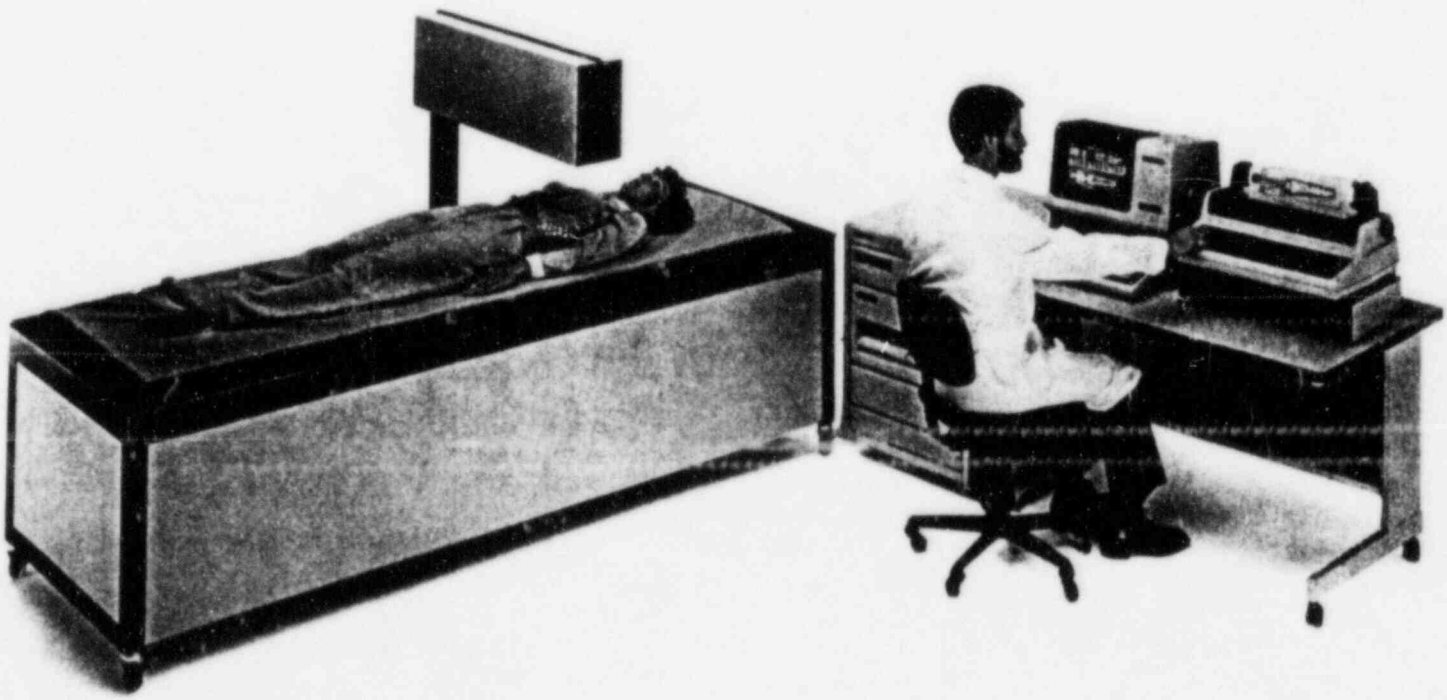
LUNAR DP4, The World's Most Advanced Instrumentation For Bone Measurement



Total Body
Lumbar Spine
Proximal Femur

LUNAR RADIATION CORPORATION

A Unique Achievement From The World Leader In Bone Measurement

The LUNAR DP4 is the only dual-photon scanner capable of measuring bone density in the entire skeleton and its constituent regions. The DP4 also measures density of the lumbar spine and proximal femur.

The LUNAR DP4 system was developed and tested at the University of Wisconsin Bone Mineral Laboratory in the 1970s by the medical physics researchers who first developed both single and dual-photon absorptiometry. LUNAR instrumentation, which has been commercially available since 1980, is now the standard of excellence in the world's leading research facilities and clinics.

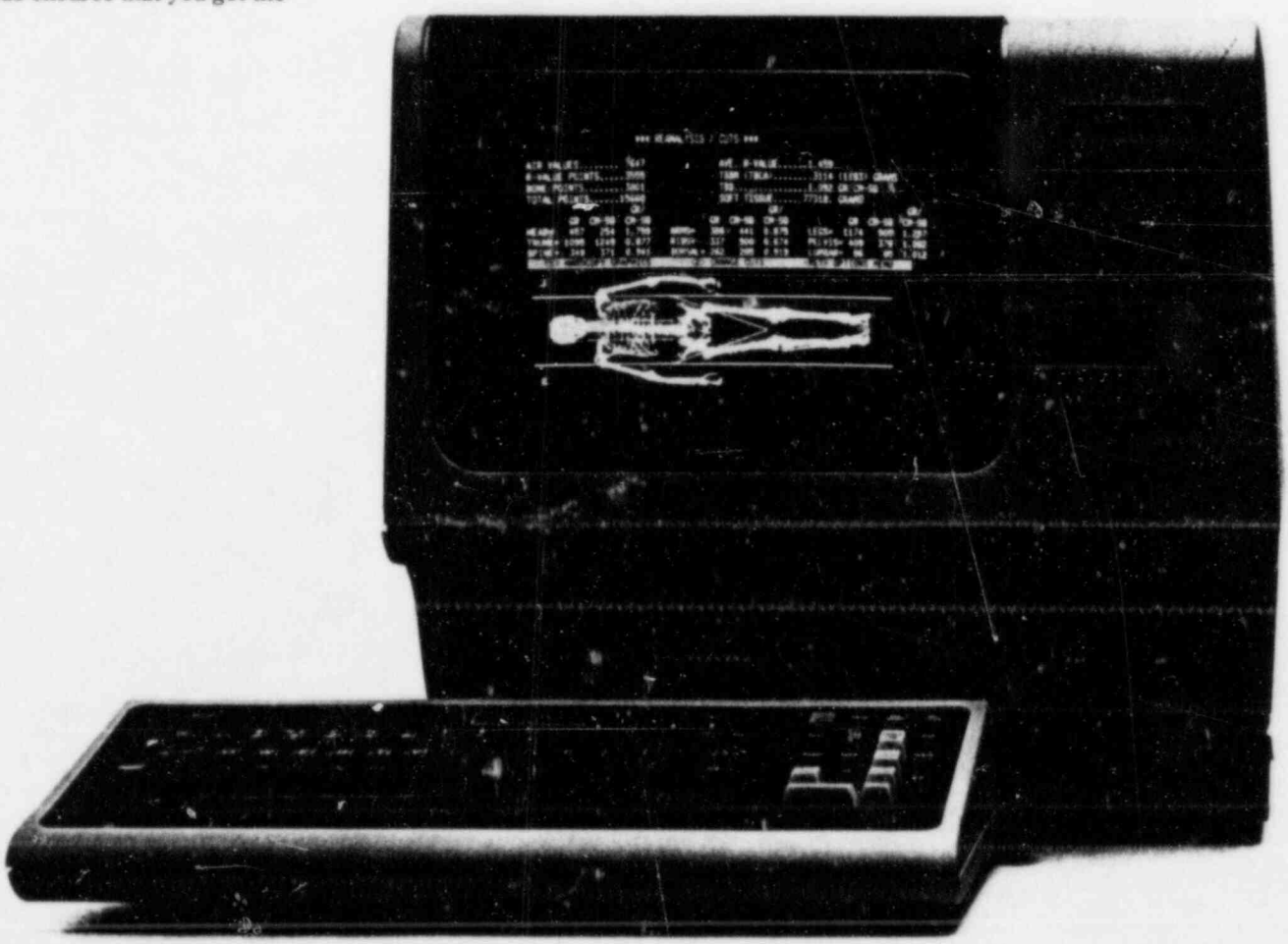
LUNAR continues to work closely with the University of Wisconsin Bone Lab and with other major research institutions. This ensures that you get the most advanced, precise and clinically relevant instrumentation. And to keep our users at the forefront, we provide them with software updates at no additional cost.

Clinically-Proven Dual-Photon Measurement

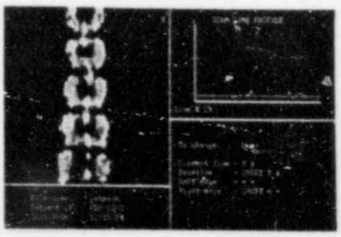
The American College of Physicians has selected *Dual-Photon Absorptiometry* as the method of choice for measuring bone density because of its low radiation dose, low cost and high sensitivity. Dual-photon scanning eliminates the need for uniform soft-tissue thickness thus allowing measurement of critical fracture locations such as the lumbar spine and proximal femur, as well as the total skeleton. Typical radiation dose from the scan procedure is one-tenth of the dose from a simple chest X-ray.

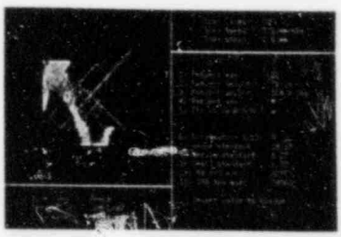
Proven Software

Over four years of clinical use have proven our software in the field. The algorithms in our software assure



LUNAR DP3-XT/AT, The Unique Clinical Solution For Bone Densitometry





Over a decade of research and clinical testing has gone into the LUNAR DP3 dual-photon spine/femur scanners. LUNAR scientists pioneered both single and dual-photon absorptiometry and helped LUNAR become the world's largest manufacturer of bone measurement instrumentation.

LUNAR now offers the IBM-XT and AT as options to our acclaimed DP3 scanner. Advanced features of the DP3-XT/AT include:

-Multi-tasking
-Automated peaking
-High-resolution color graphics
-Hard-disk storage

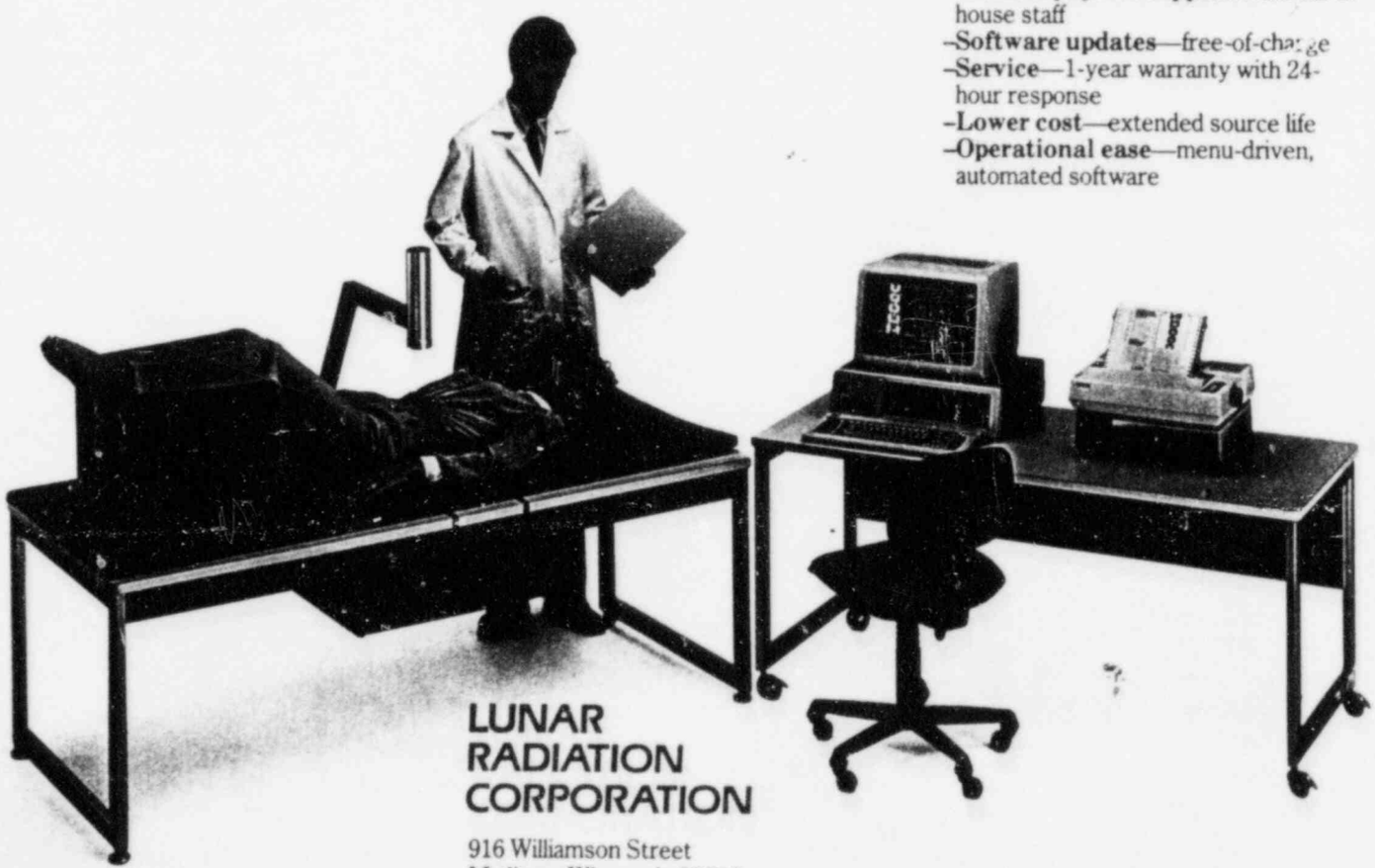
LUNAR continues to set the standard for bone measurement. These new features, plus a light-localizer and a belly-band, add to the DP3's proven capability.

Contact us to see why the clinical leaders have turned to LUNAR with confidence.

Ask A User!

Our customers comprise over 85% of all clinical facilities using dual-photon absorptiometry. They selected the DP3 because LUNAR's exclusive know-how ensures trouble-free, question-free operation and because of distinct advantages such as:

-**Intelligent scans** that reduce scan area, scan time, and patient exposure.
-**Multiple sites**—lumbar spine, proximal femur, tibia, proximal humerus and other areas
-**Graphics displays**—ultrafast, high-resolution images
-**Normal database** of US subjects
-**Accuracy/precision** based on physically correct algorithms
-**High patient throughput** with 15-minute scans
-**Sophisticated software** that takes the guesswork out of scanning
-**Medical physics support** from our in-house staff
-**Software updates**—free-of-charge
-**Service**—1-year warranty with 24-hour response
-**Lower cost**—extended source life
-**Operational ease**—menu-driven, automated software



LUNAR RADIATION CORPORATION

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

minimal technical errors by correcting for deadtime, spillover, beam hardening and scatter. LUNAR's iterative computation techniques assure the highest accuracy levels.

The operator controls the system through menu-driven options and simple keystroke commands. For normal operations, default responses to displayed queries establish appropriate scan parameters. The operator can change default parameters where needed. High-level automation reduces the possibility for errors due to operator variation, yet the overrides permit operator changes.

Real-time display of the scan image allows the operator to monitor the scan as it progresses. When data acquisition and analysis is complete, the operator can review and easily change edges, baseline and regions-of-interest if necessary.

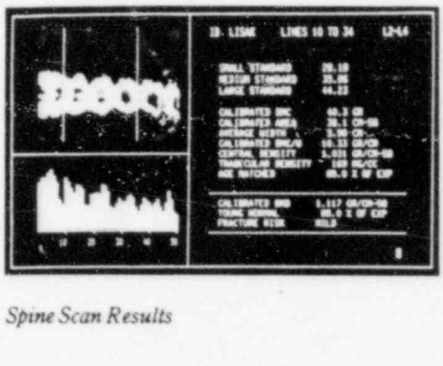
The LUNAR DP4 includes complete dedicated software for scanning, analysis, quality control and calibration, including:

–Total Body Scan
–Spine Scan
–Proximal Femur Scan
–Quality Control and Calibration
–Datafile Examination

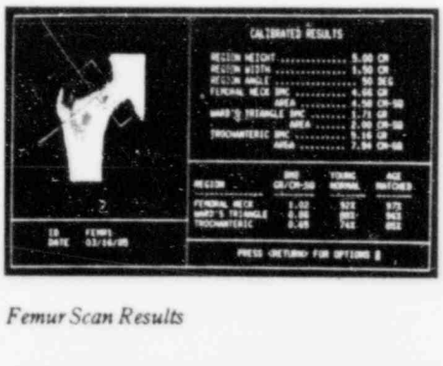
Total Body Measurement

The DP4 software automatically divides the Total Body Scan into major regions of interest: head, trunk, arms and legs. The trunk is further subdivided into dorsal spine, lumbar spine, ribs and pelvis. These divisions facilitate clinical and research measurements in which determining the magnitude of change in different skeletal regions is crucial. Total Body analysis provides the coordinates selected by the computer in determining these regions to ensure optimal reproducibility.

Since calcium is a constant fraction of bone mineral (37%), determinations of total body mineral (TBBM) are directly equivalent to total body calcium (TBCa). This has been demonstrated in skeletal series and by neutron activation in vivo. Sequential measurements will therefore directly indicate changes in calcium content and calcium balance. In order to achieve the best possible precision and to normalize for skeletal size, TBBM is expressed relative to the number of bone pixels (i.e. skeletal area). Longitudinal observations in several laboratories have shown the long-term reproducibility of total body bone density is 1 percent.



Spine Scan Results



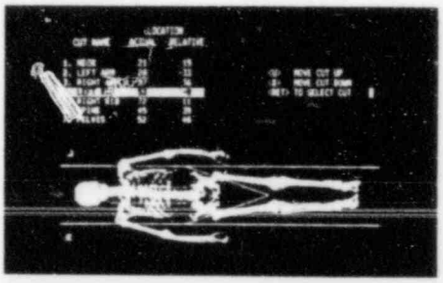
Femur Scan Results

Measurement of Critical Fracture Sites

Measurements from axial sites correlate poorly to both compact and trabecular bone loss in the appendicular skeleton. For clinical diagnosis of osteoporosis and other metabolic bone diseases, measurement of key fracture sites, such as the lumbar spine and proximal femur, are crucial in determining fracture risk. The Total Body Scan also is diagnostically sensitive even though less sensitive than measurements at each site in defining specific fracture risk.

SPINE SCANS—High-resolution spine scans of the lumbar region are readily available. The software provides automatic adjustments of the baselines and bone edges that are so critical for optimal results. Software prompting is given for identification of individual vertebrae.

PROXIMAL FEMUR—Femur scans provide a complete analysis of all the critical fracture regions: Femoral Neck, Ward's Triangle and Trochanter. LUNAR's intelligent software automatically adjusts the Femoral Neck region perpendicular to the neutral axis, providing you with an accurate, reproducible reading. Measurements of Ward's Triangle have shown the highest correlation to fracture. The low-density Trochanteric region is the site of 50 percent of hip fractures.



Total Body Scan Results

LUNAR Is Absorptiometry

Applications

The LUNAR DP4 offers an unmatched package of analysis capabilities for clinical and research applications. The Total Body Scan is suitable for cross-sectional and longitudinal studies designed to investigate loss or gain of total bone mass in patients suffering from metabolic bone diseases. Low precision error makes the DP4 ideal for clinical trials of therapeutic agents.

The lumbar and femur scans focus on key areas for diagnosing osteoporosis and monitoring its treatment. Since these regions are composed largely of trabecular bone, measurements taken here will indicate changes in bone mass which are not evident in measurements of the appendicular skeleton. Therapy for bone loss can achieve axial gains of 15 to 20% per year, which is often accompanied by a paradoxical stability or even loss of bone from the limbs. Lumbar and femur scans are also useful in diagnosis and serial monitoring of bone change stemming from renal or endocrine disorders.

Built-in Normalization

All scan output is provided in terms of departure from normality as well as in calibrated mass and density units. A large database of normal values provides a ready comparison that can be included on the screen or in the print-out if desired.

Solid Support, Reliable Service

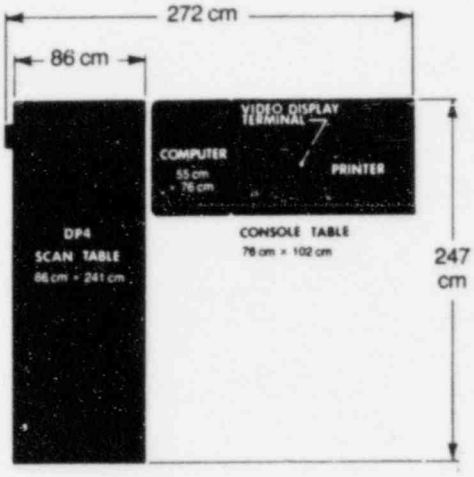
LUNAR is dedicated to the support of our customers. Our highly qualified and widely recognized staff has made LUNAR the largest manufacturer of bone densitometers. We provide our customers with extensive application support, a complete one-year warranty and 24-hour service. Our unique "Bulletin Board" offers fast assistance and information about current events and research findings via telephone.

Advanced Hardware

LUNAR's solidly crafted instrumentation assures you dependable service and maximum throughput. The DP4 utilizes the widely accepted DEC PDP 11/23 computer. This scientific computer features floppy-disc storage, high-resolution graphics display, floating-point processor and memory management. High-speed nuclear electronics reduce high deadtimes typical of systems based on multichannel analyzers. Our LA-100 printer gives high-resolution printed copies of the scan image and data.

System components include:
- –DEC PDP 11/23 system with 128 K memory, two RX-02 floppy drives, floating-point processor, memory management and RT-11 operating system
- –VT-100 monitor
- –LA-100 printer
- –Rectilinear scanner module (210 × 60 cm scan area)
- –Complete scanner software
- –Console table
- –Calibration standards

Radionuclide source is 153Gd (1Ci). Source life is 12 to 18 months. NRC or state licensing is required for handling isotopes.



System Configuration

LUNAR RADIATION CORPORATION

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LICENSING INFORMATION FOR USE OF RADIOISOTOPES IN BONE MINERAL SCANNERS

The use of I-125 and Gd-153 radionuclides for bone mineral scanning requires licensing from the appropriate authority. The Nuclear Regulatory Commission administers licenses to individuals or institutions within certain states. The remaining states, the so called "agreement states", administer licenses to their own residents. Although the following information covers only the NRC regulation, most state radiation control agencies have similar requirements. Individuals within agreement states must contact their appropriate state agency for licensing information.

Major hospitals may have broad NRC licenses that allow possession of all radionuclides with atomic number 1 to 83 for medical use. The total amount allowed for an individual radionuclide will vary with institution and requires a check of the particular institution's license. If the licensed amounts are compatible with those listed below in section A then the license need not be amended. However, since broad licenses may also have a limit on the total radioactivity, it may be prudent to amend for the specific inclusion of I-125 and Gd-153 for bone mineral analyzers.

Institutions with Group VI licensing do not have to amend for use of I-125. However, Gd-153 is currently not a Group VI isotope and its use requires a license amendment. Institutions without broad licensing or Group VI must amend their current licenses to include the use of sealed radionuclide sources for bone mineral analyzers. The institution's Radiation Safety Officer will direct the filing of an amended NRC form 313. The following information will assist in answering item 5 and 6 of form 313.

A: Radioactive materials

The appropriate source information as determined by intended clinical use should be included in item 5 of NRC form 313.

Element and mass number	chemical and/or physical form	manufacturer and model number	amount
125-I	ion exchange	AECL C324 or other NRC registered	240 mCi each 300 mCi total
153-Gd	GdO_2	Gulf Nuclear Model GD-1 or other NRC registered	1200 mCi each 1500mCi total

During normal use only one isotope per unit will be on site. For continuity of patient scanning, the total amount listed in the license must include the summed activity of a newly received source and the decayed source to be returned to the source manufacturer.

B: Description of use (item 6 NRC 313)

The sealed sources listed above will be used in one of two types of bone mineral analyzers. There must be a direct reference to the NRC device registration number.

source	LUNAR device	NRC device registration
125-I	SP2	NR-430-D-102-S
153-Gd	DP3	NR-430-D-101-S

C: Training and experience

By definition, broad medical licensees and Group VI licensees have users who have adequate training and experience to use radiation. Individuals planning to use LUNAR's bone mineral analyzer who lack the required training and experience must approach their institution for required training.

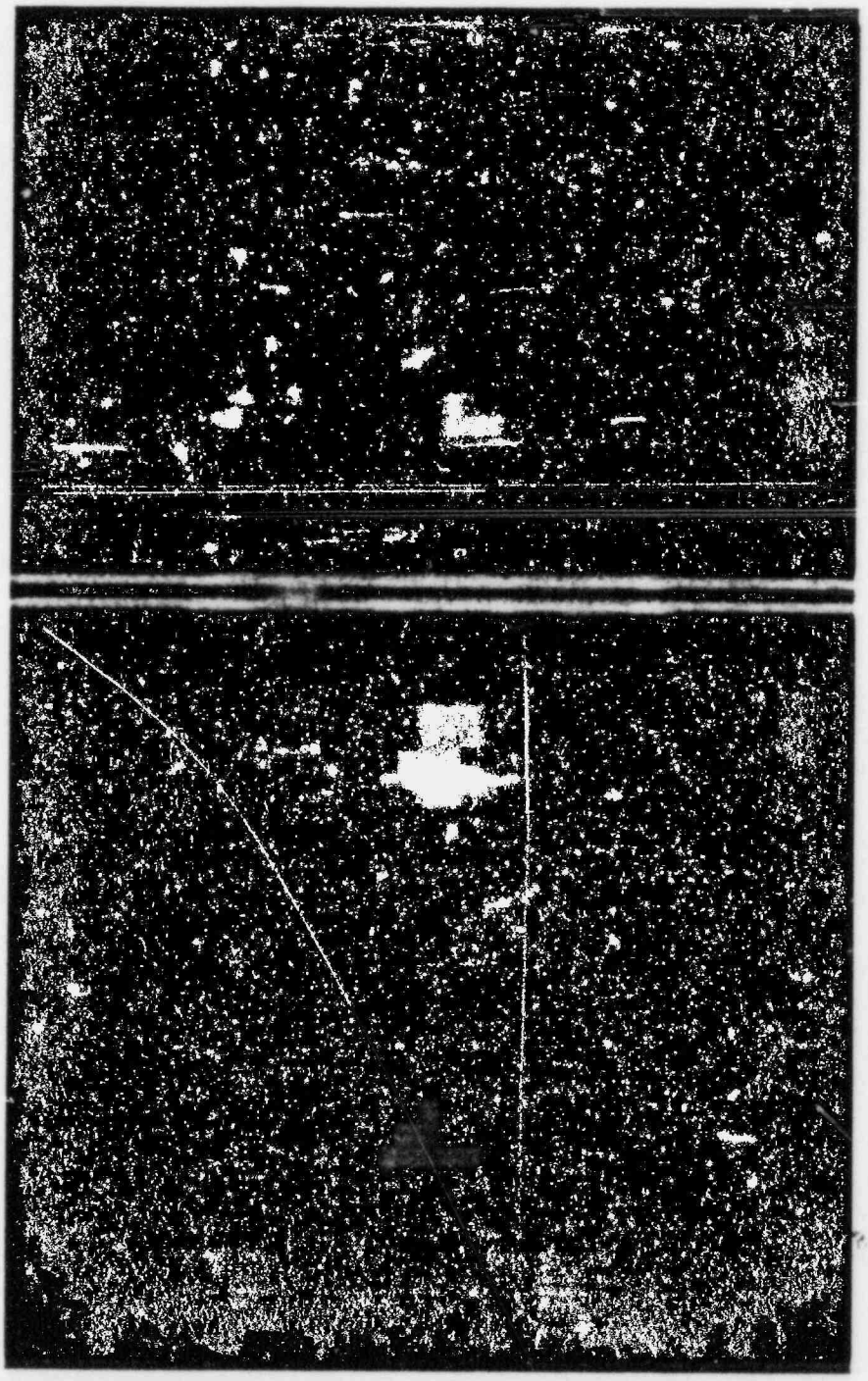
Each LUNAR bone mineral analyzer is installed by qualified LUNAR personnel who provide two days of installation and training. This training covers source installation and exchanges, wipe testing, scan operations, and data analysis and interpretation. The institutions Radiation Safety Office must be present for instruction on source replacement and wipe testing.

1985

$50,000

THE NORLAND DICHROMATIC BONE DENSITOMETER

ADVANCED TECHNOLOGY FOR AXIAL BONE ANALYSIS

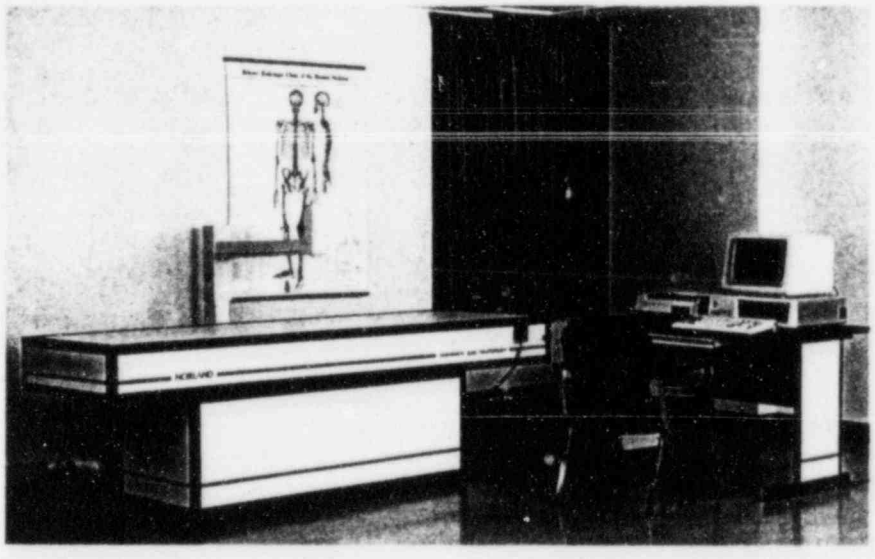


PHOTON ABSORPTION TECHNIQUE — SINGLE AND DUAL

Physicians and clinicians have long used the widely accepted photon absorption technique to quantify bone mineral content in-vivo. This technique utilizes a beam of discrete energy photons from a radioactive source instead of the broad energy spectrum of an X-ray beam in radiographic methods. The highly collimated beam passes through soft tissue and bone with its absorption monitored by a photon detector. The mass of bone mineral present is computed from the number of photons absorbed.

The monochromatic photon absorption technique, utilizing photons of a single energy, provides accurate and precise quantification of the bone mineral content of the extremities such as the radius or phalanges. The dichromatic or dual photon technique evolved to expand the capabilities of quantifying bone mineral content from the extremities to the axial skeleton. This technique uses photons of two distinct energies, eliminating the need for a uniform soft tissue thickness surrounding the bone. The dichromatic photon absorption technique is suited to quantify bone mineral content in the spine and in the entire body.

THE NORLAND 2600 DICHROMATIC BONE DENSITOMETER



2600 DICHROMATIC BONE DENSITOMETER WITH SCANNER UNIT AND COMPUTER WORKSTATION

The Norland 2600 Dichromatic Bone Densitometer (DBD) employs the dichromatic photon absorption technique to quantify bone mineral content in the axial skeleton. The 2600 Dichromatic Bone Densitometer includes a Scanner Unit and a Computer Workstation.

The scan and analysis processes are directed from the Computer Workstation using the computer keyboard. The computer's color display guides the operator through the entry of patient information, initiation of a scan procedure, and analysis of the scan data. The operator may simultaneously analyze previous scan data while a new scan is being done, since the Scanner Unit has its own microprocessor control system. The operator may store scan data on the computer's disk memory for future analysis if immediate analysis is not desirable. Analysis results are displayed in color by the computer, and may also be printed out in color.

SCANNER UNIT — VERSATILE AND PRECISE

The Scanner Unit has an active scan area large enough to accommodate an adult of 195 cm height. The desired scan region is easily located by means of a Laser Positioner built into the detector head. The Scanner Unit, mounted on wheels, is easily moved from one location to another. Retractable feet provide a stable base when it is in operation.

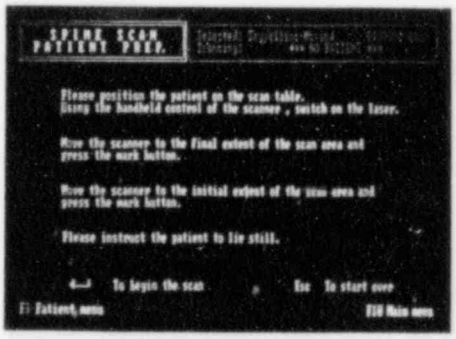
All functions of the Scanner Unit are controlled by a built-in microprocessor with initiation of the functions by the Computer. This local control of the Scanner Unit frees up the Computer for other tasks. The operator is able to make efficient use of the system's capabilities during the period of a scan.

The scanner can move in any direction (X, Y, or at any angle), at any speed from 0.1 mm/sec to 50 mm/sec, acquiring data samples at any rate. The operator may select the scanning speed and data sample rate to provide the best precision of measurement with the least time spent and lowest radiation dose to the patient.

PATIENT POSITIONING SYSTEM — EASY TO USE

Norland's 2600 is designed to orient itself to the patient. The 2600 includes a Patient Positioning System which allows the operator to direct the computer to the scan area without constantly repositioning the patient.

Scan preparation is easy using the Patient Positioning System. The patient lies down in a comfortable position on the Scanner table. The operator follows the instructions shown on the display of the Computer Workstation. The operator uses a small Handheld Remote Control to manually move the Scanner arm to positions directly over certain anatomical landmarks. The Computer prompts the operator by specifying these anatomical points, and a Laser Positioner built into the Scanner arm allows the operator to locate them with pinpoint accuracy. When all such landmarks have been located and marked, the Computer will proceed to the identified scan area and scan at the prescribed increment rate.



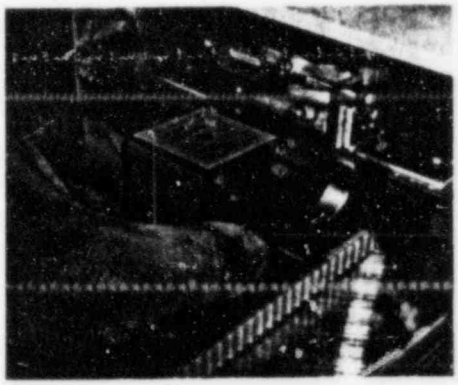
SPINE SCAN PATIENT PREPARATION INSTRUCTIONS

HANDHELD REMOTE CONTROL

SAFE SOURCE INSTALLATION

The Source Holder supplied with the Dichromatic Bone Densitometer is designed for ease and safety in handling of the Gadolinium-153 dichromatic source. Constructed of lead for maximum shielding, the Source Holder has an integral shutter which opens only upon being installed in the DBD Scanner. The shutter closes automatically when it is removed for source replacement.

A second, electrically actuated shutter is part of the Scanner System. This second shutter opens only during a scan, and closes automatically when the scan is finished. The fail-safe design of the shutter results in automatic closure of the shutter in the event of a power failure.

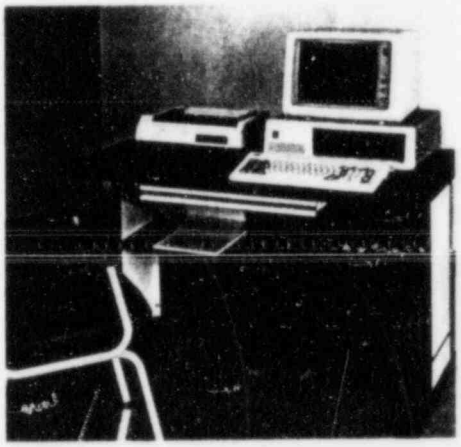


SOURCE HOLDER INSTALLATION

COMPUTER WORKSTATION

The Computer Workstation of the Model 2600 handles control of the Scanner Unit, analysis and storage of the data, display of the results, and interaction with the operator.

The nucleus of the Computer Workstation is the IBM Personal Computer XT*. The IBM PC XT utilizes the Intel 8088, a third generation 16-bit processor. The Intel 8087, a mathematics coprocessor, is incorporated in the system to speed computations. The XT features a 360K floppy disk unit with a 10 megabyte hard disk for extensive data storage and quick file retrieval. The Workstation communicates with the Scanner Unit via a standard RS-232C serial port.

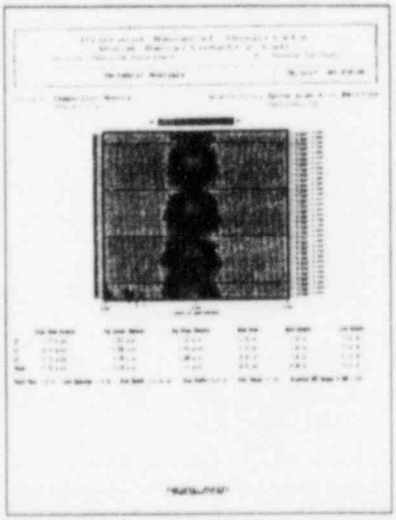


COMPUTER WORKSTATION
WITH IBM PERSONAL COMPUTER XT

USE OF COLOR

A color display monitor is provided in the system, capable of 16 color, high resolution graphic displays. Use of color makes operator interaction easier. The operator may designate the spectrum of colors used in the data displays.

A color printer is available for hard copy output of graphics data presentations, patient measurement reports, and patient lists.

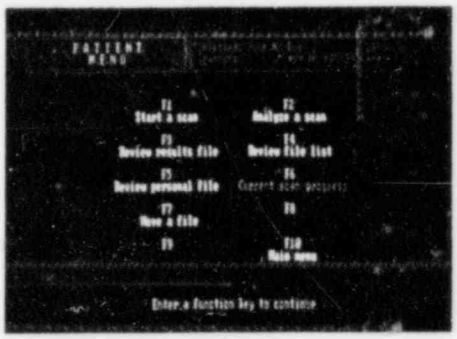


COLOR PRINTOUT OF
VERTEBRAL ANALYSIS DISPLAY

CAPABLE SOFTWARE

Norland's Bone Densitometer control and analysis software, called BoneStar, is versatile and user-friendly.

Standard BoneStar provides the foundation of the system: control of the Scanner, management of patient records and data, fundamental analysis algorithms, and the specialized ability to run and analyze spine scans. The operator selects the desired function by depressing the associated function key. Optional additions to BoneStar add the ability to run and analyze the whole body scans.



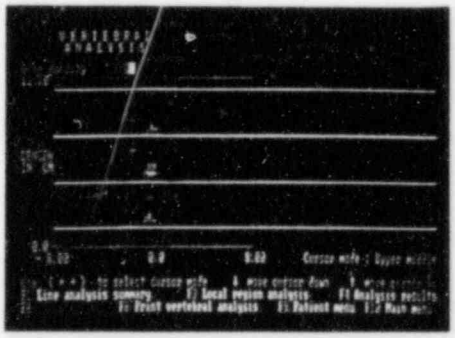
PATIENT MENU

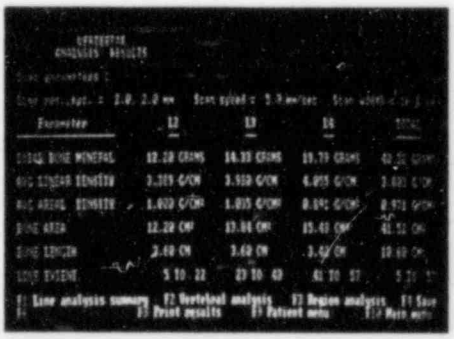
The BoneStar software is versatile because it is written largely in BASIC. Complete source code is provided allowing the DBD operator the capability to modify the BASIC program to suit his particular needs for special analysis or display format needs. Many of the BoneStar systems subprograms, such as display utilities and math routines, are written in machine code for fast execution.

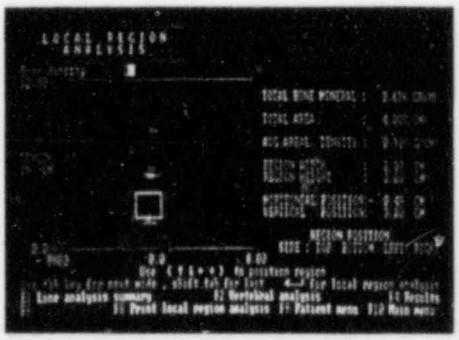
BoneStar software runs under the standard IBM PC-DOS' operating system. It is compatible with most programs which run on the IBM XT. The IBM XT can be used for other purposes when it is not functioning as part of the DBD system.

EXTENSIVE ANALYSIS AT YOUR FINGERTIPS

Scan data can be presented in several levels of analysis. The vertebral analysis provides the operator with information regarding the entire L2-L3-L4 vertebral segment. A visual representation of the scan area is displayed using a color spectrum to show the various levels of bone density. Bone measurements are calculated including the average linear density, areal density, bone area, and bone width.

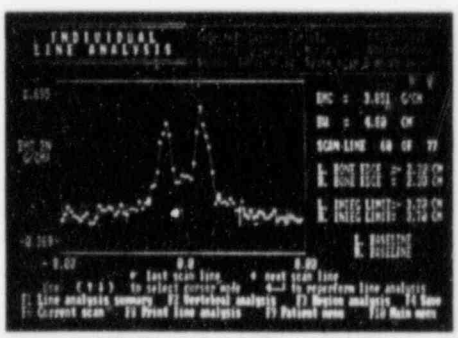

VERTEBRAL ANALYSIS


VERTEBRAL ANALYSIS RESULTS


LOCAL REGION ANALYSIS

The operator can further define an area for analysis at the level of a specific region of the bone or even a particular scan line. Selection of a specific region of the bone provides the bone density depicted using the color spectrum, total bone mineral content, total area, and average areal density for the selected region.

An individual scan line or a line analysis summary can be selected for a more detailed level of analysis. The Line Analysis Summary depicts bone density using the color spectrum with bone mineral content and bone width measurements displayed. Selection of the Individual Line Analysis allows the operator to evaluate the bone density, bone mineral content, and bone width for an individual scan line.


INDIVIDUAL LINE ANALYSIS

VERSATILITY IN SCANNING

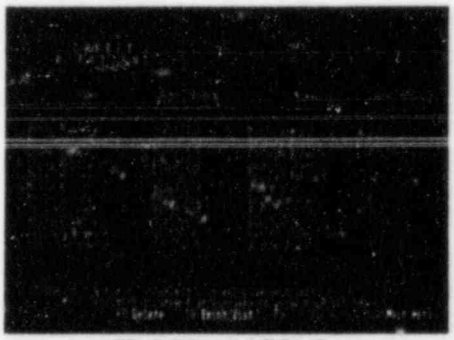
Multi-tasking and multi-processing are an integral part of Norland's Dichromatic Bone Densitometer system. With this advanced type of system, the operator is free to use the Computer for other tasks during scanning time. The operator can enter patient data, review data, or perform analysis of a previous scan.

All scan data is saved by the system in its raw form before any corrections are performed and prior to analysis. The operator has the option to delay analysis of the data until a more convenient time, if necessary. The original scan data can also be accessed at a later time for analysis using different analysis procedures or algorithms. An additional advantage of storing the raw scan data is that any future changes in analysis procedures and algorithms may be applied to previous scans.

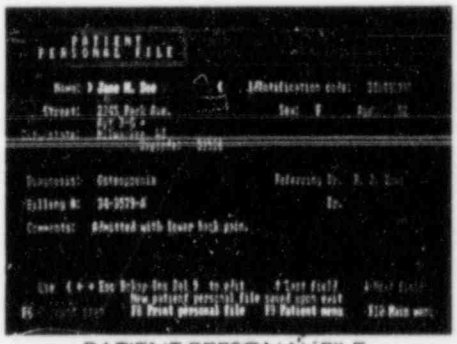
DATA BASE MANAGEMENT

Norland's BoneStar software supplied with the Dichromatic Bone Densitometer does more than just make a bone measurement, display the results, and type a report. BoneStar software also manages complete patient records and bone analysis data files for each patient.

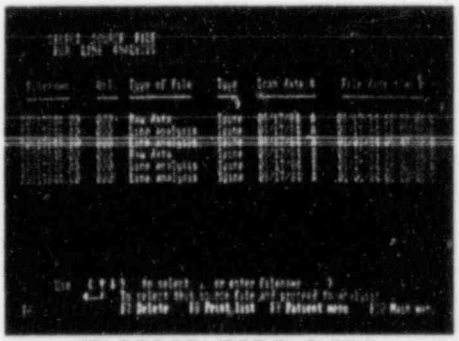
Each patient has a personal data file which is entered once by the operator and stored on the Computer's permanent hard disk for immediate reference. At the same time, a master directory for the patient is initiated. The master directory contains lists of raw scan data files, analyzed data files, and results files for each patient providing quick access. This directory is stored on the hard disk for immediate reference.



SELECT A PATIENT



PATIENT PERSONAL FILE



SELECT SOURCE FILE FOR LINE ANALYSIS

The operator can store the actual scan files on hard disk for ready reference, or on floppy diskettes for archival storage. Cross referencing of data files archived on diskettes is provided with the volume number of the diskette listed in the master directory.

NORLAND DICHROMATIC BONE DENSITOMETER

THE INSTRUMENT OF CHOICE

In its second decade as a manufacturer of bone measurement instrumentation, Norland Corporation is dedicated to bone densitometry and to making the Norland 2600 the instrument of choice for dichromatic photon absorptiometry. Contact Norland Corporation today and discover why the Norland Dichromatic Bone Densitometer is your choice for bone mineral analysis.

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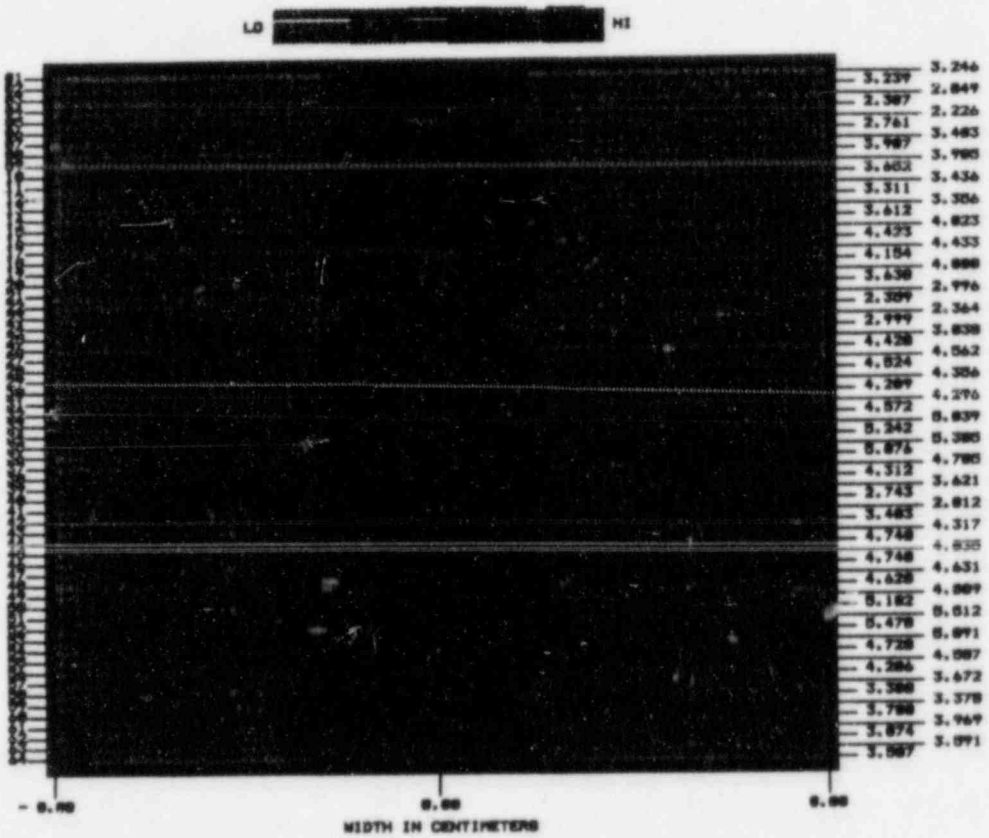
Norland General Hospitals
Dichromatic Bone Densitometer

Nuclear Medicine Department — Dr. Ferdinando Mooselini

Local Region Analysis | TIME: 00:42:26 DATE: 01-01-1985

Patient: Yohann Philibini
840000090000

Source File: Spine scan A on 08/03/84
S080384A.A0



Total Bone Mineral: 16.827 grams Total Area: 22.688 cm² Average Areal Density: 0.742 g/cm² Region Width: 5.40 cm Region Height: 4.20 cm

Horizontal Position: 0.00 cm Vertical Position: 6.40 cm Maximum Point BMC: 1.593 grams Minimum Point BMC: -.218 grams

Point Res: 2.0 mm Line Spacing: 2.0 mm Scan Speed: 5.0 mm/sec Scan Width: 16.0 cm Aver Value: 13 pts Graphics BMC Range: MIN/MAX

CONTROL NO. 79252