University of Illinois at Urbana-Champaign

Division of Environmental Health and Safety

317 McKinley Hospital
1109 South Lincoln Avenue
Urbana, Illinois 61801
(217) 333-2755

May 6, 1985

James G. Keppler
USNRC Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

85 MAY 16 A10:09

Re: License #12 00330-10 N.R.C. BRANCH

Dear Mr. Keppler:

This is to inform you that we are in the process of modifying our Norland-Cameron Model 178 Bone Densitometer in which the 200 mCi iodine-125 sealed source licensed under 12-00330-10 is used. The modification involves the installation of a "microprocessor-based computer module" and associated peripherals as described in the enclosed Norland literature.

It is our understanding that this change has received generic approval from NRC. Please contact me if there are questions.

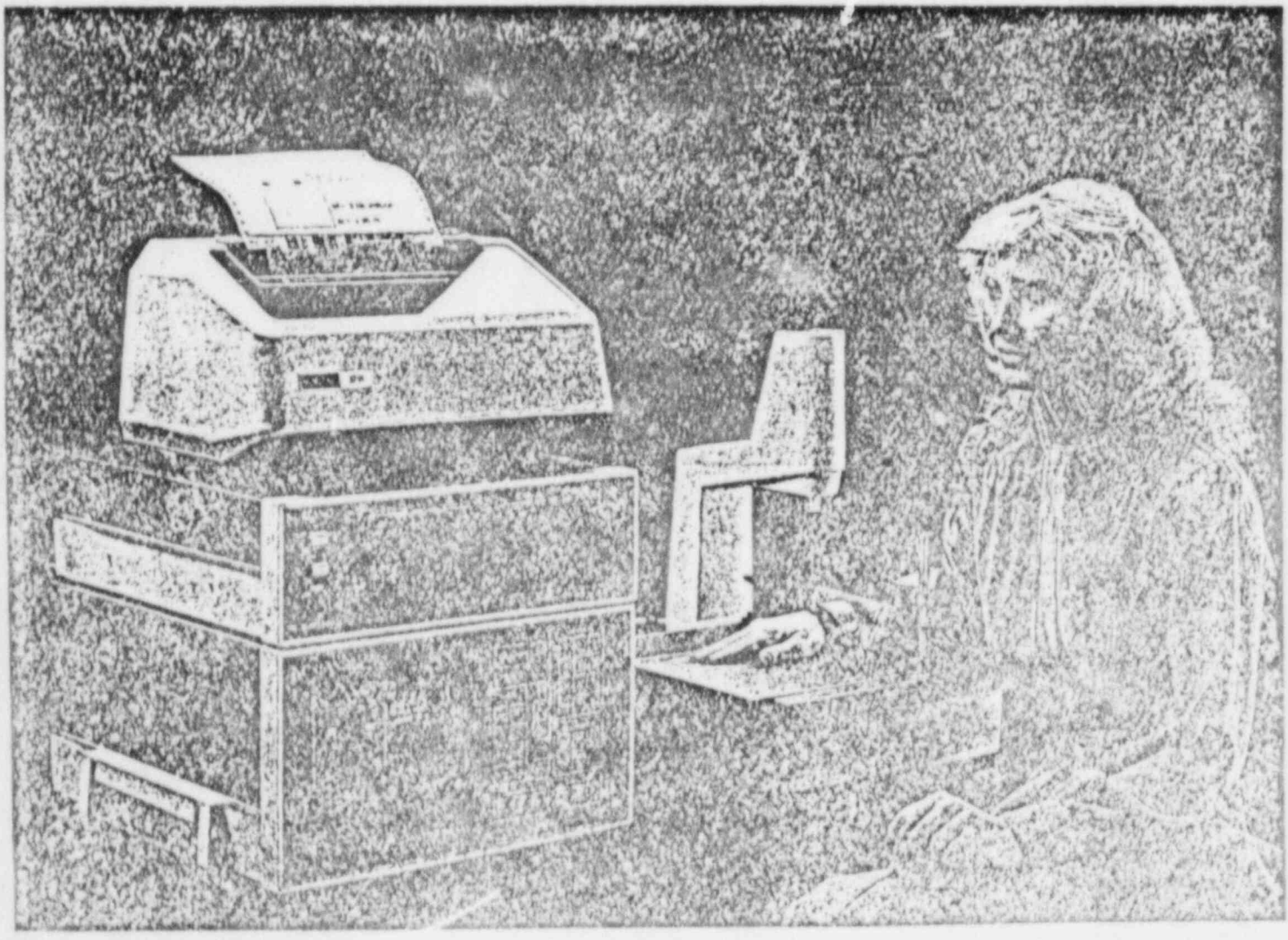
Sincerely,

Hector Mandel, Head
Health Physics

HM:la
Enclosure
cc: Samuel Kaplan, Chairman - UIUC Radiation Hazards Committee

HE NORLAND DIGITAL
BONE DENSITOMETER

MODEL 278A . . . A CRITICAL ADVANCE IN BONE QUANTIFICATION



THE 278A BONE DENSITOMETER– APPLICATIONS

CLINICAL INVESTIGATORS CALLED THE MODEL 278 DENSITOMETER "A PROMISING TOOL." NOW THE MODEL 278A CAN MEASURE A PENCIL-LEAD SIZED BONE WITH AS LITTLE AS 0.05 g/cm BONE MINERAL CONTENT. IT'S MORE PROMISING THAN EVER—AND MORE USEFUL:

- to any medical specialty concerned with bone disease or disorder . . . for diagnosis of skeletal demineralization as in advanced osteoporosis . . . and for data on response to therapy.[14,15]

- to pediatricians and neonatalogists for use in small infants . . . to measure delayed bone mineralization . . . and to investigate therapeutic measures that might correct osteopenia of prematurity.[9] (Figure 1)

- to nephrologists for the monitoring of renal osteodystrophy . . . calcification after transplant . . . and the adjustment of dialysis treatment.[8]

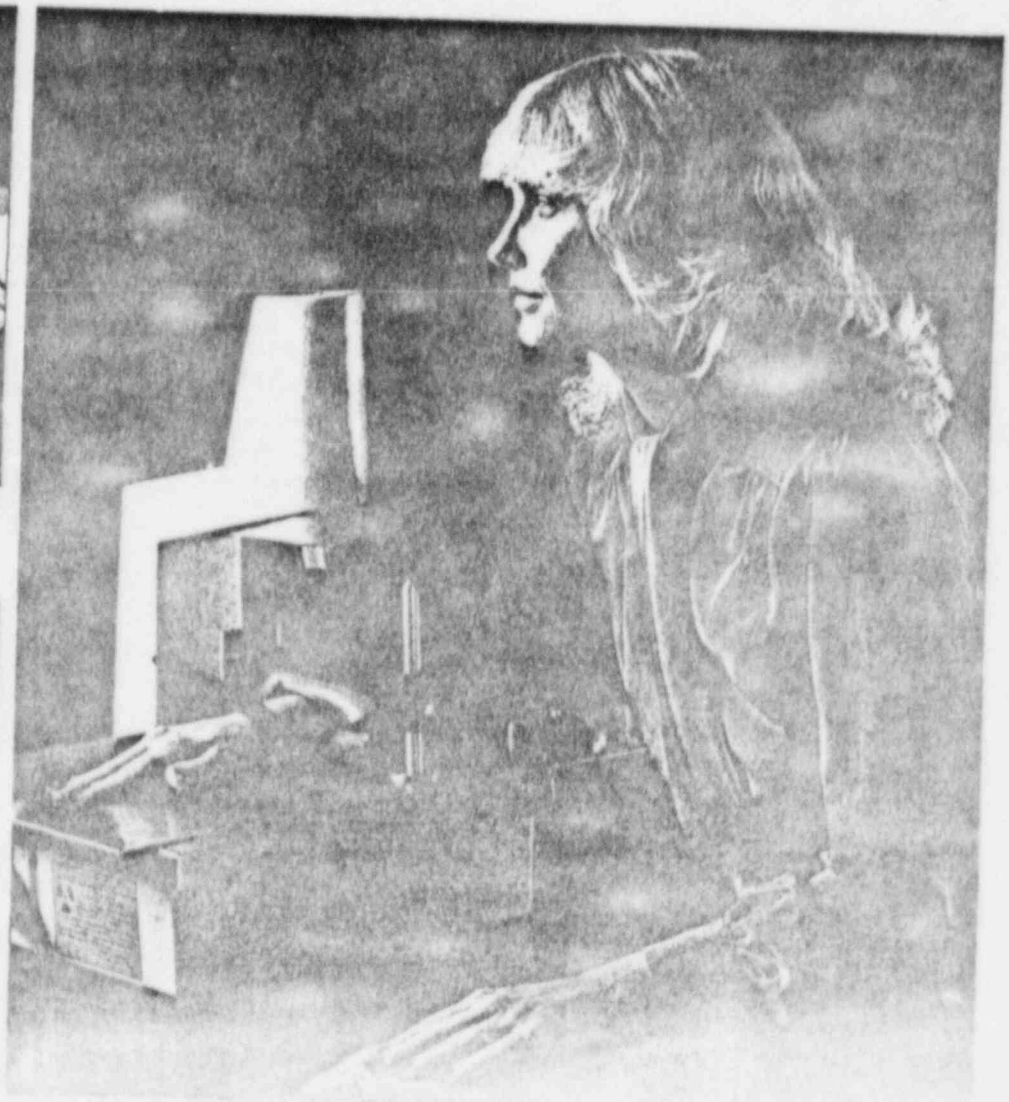
- to researchers for rapid and accurate, in vivo, non-intrusive determinations measuring bone mineral in the laboratory rat, dog or rabbit.[10,11] (Figure 2)

- to race horse owners, trainers and veterinarians for assistance in determining when a horse is mature enough to start running.[12,13]

- and . . . to aid clinical investigators in population surveys[16], for the study of inheritance patterns[17], nutritional research[18], exercise programs[19], and pharmaceutical testing programs.[20]

1. Photo courtesy of Milton Werthmann, M.D., of Washington Hospital Center of Washington, D.C.

2. Photo courtesy of Brian J. Awbrey, M.D., of University of North Carolina at Chapel Hill, Chapel Hill, North Carolina



A CRITICAL ADVANCE IN BONE QUANTIFICATION

A NEED — A SOLUTION

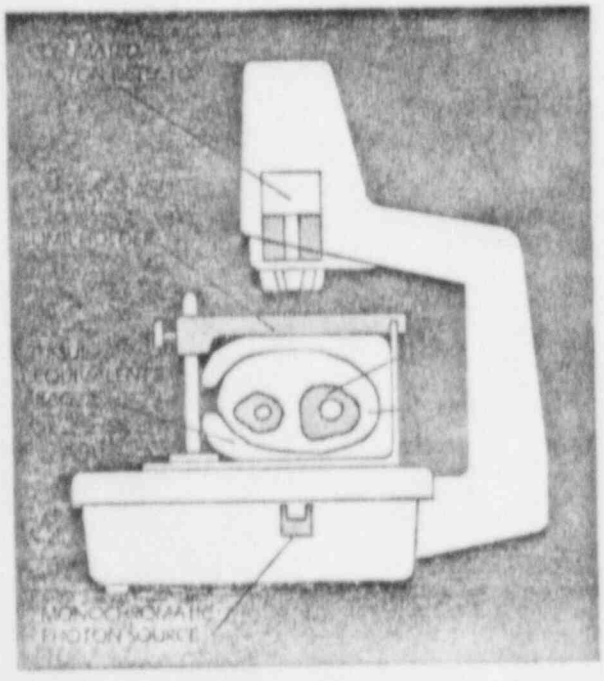
Physicians and clinicians have long recognized the shortcomings of biopsy or radiograph methods for the early detection of bone disease. In 1963, necessity once again gave birth to invention. Cameron and Sorenson reported a new in vivo, non-intrusive technique for quantifying bone mineral content—the photon absorption technique.[1] Since then, the technique has grown in sophistication and gained widespread clinical approval.[2,3]

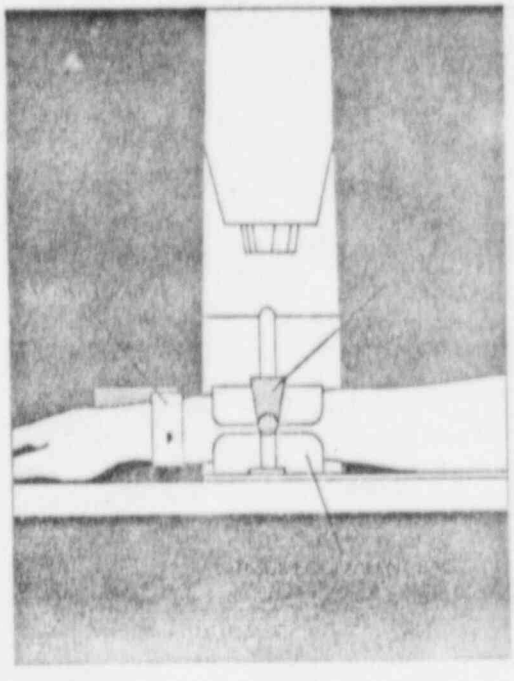
THE PHOTON ABSORPTION TECHNIQUE

This technique replaces the broad energy spectrum of the x-ray beam with a beam of monoenergetic photons. This beam passes through the soft tissue and bone of a limb, and the resulting attenuation is monitored with a photon detector. The mass of bone mineral present may be derived from the number of photons absorbed by the bone. Using a highly collimated beam from a monochromatic photon source, this measurement technique offers great advances in sensitivity, safety, accuracy, precision, and practical usefulness.

THE 278A DIGITAL BONE DENSITOMETER

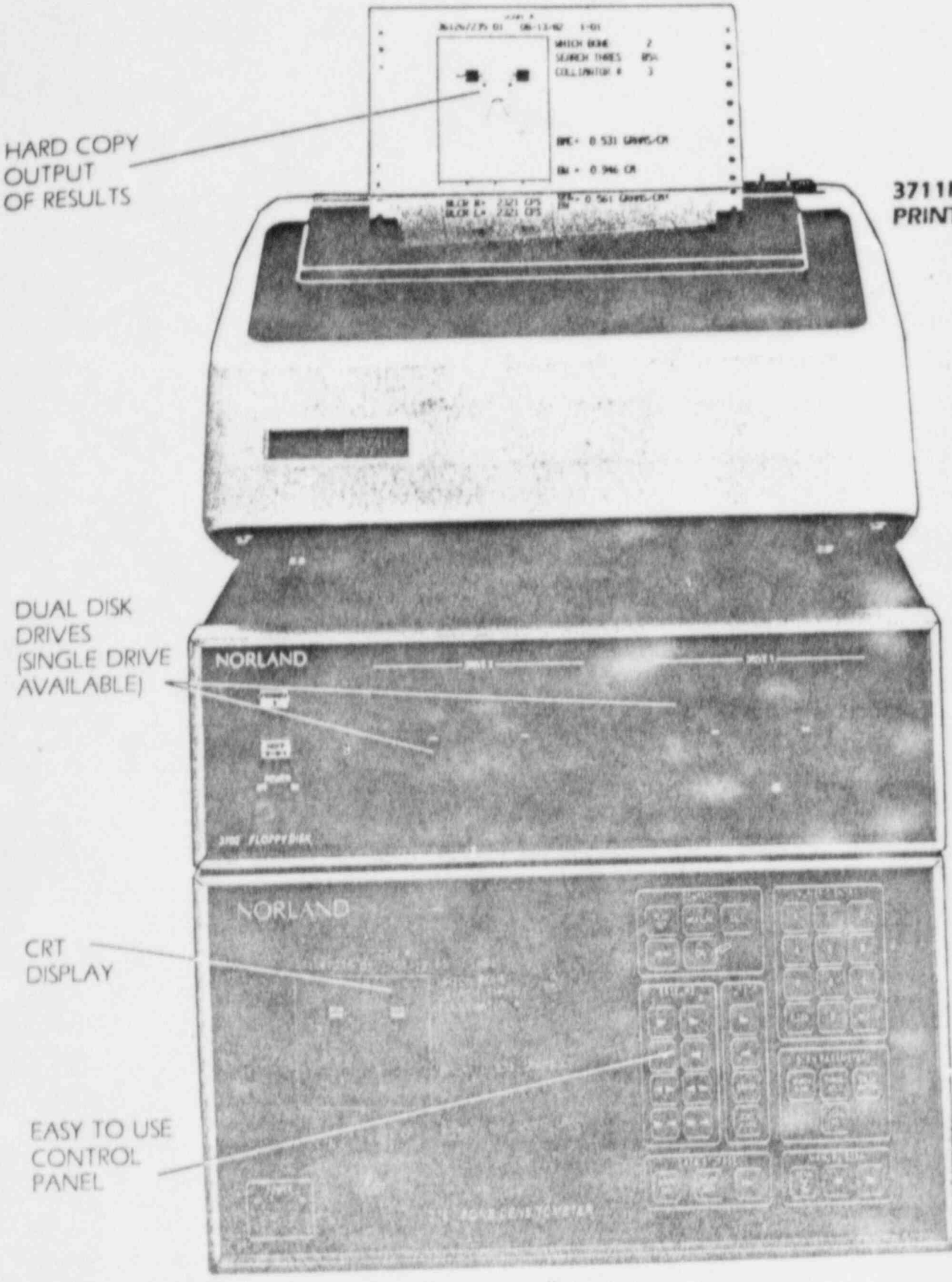
This proven instrument makes the advantages of the photon absorption technique available to you in a simple 5 minute procedure. Without causing patient discomfort, the densitometer measures bone mineral content as a linear density in grams per centimeter and bone width in centimeters. When measuring an adult radius, you can expect precision of ± 0.006 g/cm—and even better for smaller bones.[4] Compare this sensitivity to that of the radiograph, which is unable to detect anything prior to a 30-40% change in bone mass.[2]. In addition, the expanded capacity of the 278A Densitometer allows it to detect bone mineral content as low as 0.05 g/cm.





CONTROL NO. 78929

"FRIENDLY" TO USE, EASY TO READ



AN ELEGANT SYSTEM-- SCANNER AND COMPUTER MODULE

HOW THE SYSTEM WORKS

The 278A provides step by step instructions for easy and effective operation. Once the patient is positioned, the scanner module transports a collimated photon beam from a radioactive source (Iodine-125) across the chosen scan site. A search scan locates the bone of interest within the limb. Then a measurement scan collects more accurate photon absorption data. The results are computed and displayed digitally on the CRT screen.

SCAN SITE SELECTION

The densitometer primarily measures the bones of the forearm,[5] but can be adapted to measure a variety of other scan sites. Norland has recommended the forearm as the primary site because bone mineral content of the mid-distal radius has been shown to reflect with reasonable accuracy the mineralization of the entire axial skeleton.[6] The radius is also an easy bone to measure. The scanner's positioning system holds the forearm firmly but comfortably and minimizes repositioning errors.

With an accessory positioning system the densitometer can measure fingerbones,[7,8] a site often monitored in renal osteodystrophy. It can measure the ulna, tibia, fibula, and the humerus in newborn infants.[9] It can also be adapted for use with animals, ranging from the femur of the laboratory rat[10] to the tibia of the beagle[11] to the metacarpal of the horse.[12,13]

SYSTEM CAPABILITIES AND OPTIONAL COMPONENTS

THE 278A DENSITOMETER WASTES NO TIME—FOR PATIENT OR OPERATOR

- After power turn-on, the computer performs a rapid and extensive self-check; any malfunctions are indicated on the screen.
- Calibration is a simple five minute procedure which need be done only once every two weeks.
- Multiple scans are now possible with the 278A, and are performed without stopping for operator key press.

COMPLETE CRT DISPLAY

All information about a scan is presented on a large, bright CRT display:

- numeric results: BMC (bone mineral content), BW (bone width), and BMC/BW
- graphic results: bone profile showing selected baseline and bone edges
- scan number: 9-digit patient I.D., date, sequence number, and disk file number
- scan parameters: which bone, edge threshold, collimator, etc.

OPTIONAL COMPONENTS

Compact High Resolution Printer/Plotter

Provides four different modes of printed record ranging in complexity from:
Printing out the scan number with BMC, BW, and BMC/BW in about three seconds to printing all information shown on the CRT screen, including a plot of the bone profile, in about one minute.
All printouts done at a press of a button. Connects to the computer module with a single cable.

Flexible Disks, Permanent Storage Memory

Single or dual drive units with five diskettes included. Bone measurement information is written on a diskette for permanent storage. Data may be retrieved and displayed on the CRT for examination and/or computation. Connects to the computer module with a single cable. A valuable aid in serial patient measurement.

Scanning Positioning System

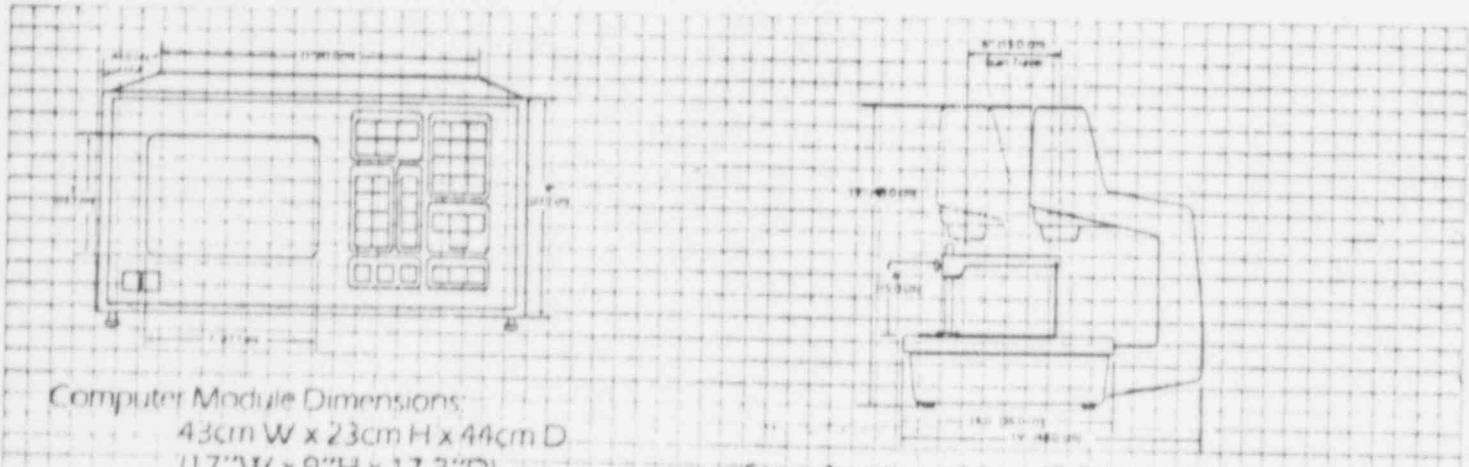
Adapts the scanner for measuring the arm bones, finger bones, infant subjects, and animals. Specific positioning systems allow accurate repositioning of the scan site.

For more information contact 1-800-558-0158

NORLAND CORPORATION

THE NORLAND BONE DENSITOMETER, MODEL 278A

PHYSICAL SPECIFICATIONS



Computer Module Dimensions:
43cm W x 23cm H x 44cm D
(17"W x 9"H x 17.3"D)
22 kg (48#)

Scanner Module Dimensions (arm retracted):
36cm W x 48cm H x 36cm D
(14"W x 19"H x 14"D)
18 kg (40#)

Scan Aperture: 14cm (5.5") vertical clearance,
15cm (6") usable scan path

Power Requirements:
100, 120, 220, 240 VAC (selectable)
50 or 60 Hz (Factory Set)
350 Watts

A NOTE ON RADIATION DOSAGE

Comparing the densitometer with radiography for radiation dosage is conceptually difficult. A radiograph exposes a large portion of the body, while the densitometer exposes a section of tissue measuring approximately five mm wide and three cm long. A rough comparison can be made by considering the total intra-tissue ionization based on relative radiation fields, exposure times, and areas exposed. The results show the total ionization produced within a patient during a set of four densitometer scans is about 1/100 of that delivered by a radiograph of the forearm.

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NORLAND CORPORATION

Industrial, Scientific and Medical Instrumentation
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Fort Atkinson, WI 53538

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INDUSTRIAL, SCIENTIFIC AND MEDICAL INSTRUMENTATION

DIGITAL BONE DENSITOMETER
TRADE-IN PROGRAM

July, 1983

Upgrade Your Present Model 178 Bone Mineral Analyzer to
Norland's New Model 278A Digital Bone Densitometer

ntrol your old scanner module with our ---

NEW MICROPROCESSOR-BASED COMPUTER MODULE.

atures include:

Friendly Operation - Operator is instructed on each step of the measurement procedure. Automatic Calibration (once per week).

CRT Display - 5" x 7" screen displays operation instructions, numeric results, bone profile, cursor.

All Digital Computations - Fast and accurate BMC (Bone Mineral Content), BW (Bone Width), BMC/BW (Ratio).

All Scan Parameters are Displayed for Reference - including Scan identification number, which bone number, % threshold, collimator number, baseline.

Physical Data - Color: Dark Brown, Rust, with Beige Trim
Dimensions: 17 1/2" L. x 17" W. x 9"
Height: 44.4cm x 43.2cm x 22.8cm
weight: 48 lbs. (21.7 kg.)

ncluded is a brand new Model 278A computer module with small bone scanning oftware, new 4-bone calibration standard, plus reconditioning, recalibrating nd repainting of your present scanner module so that it is completely ompatible with the 278A computer. Does not include major assemblies such as lutch, photomultiplier tube, complete circuit boards, and tissue equivalent ag. Both computer and scanner module must be returned, freight prepaid, to orland Corporation.

Cost	$12,150.00
Less Trade-In for Old Computer Module #178	- 1,200.00
Net Cost	$10,950.00

(OVER)

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• AN AFFILIATE OF CORDIS CORPORATION •

NORLAND CORPORATION

INDUSTRIAL, SCIENTIFIC AND MEDICAL INSTRUMENTATION

July 26, 1983

Dr. Tim Lohman
University of Illinois
Health Physics Office
I5309
343 McKinley Hospital
Urbana, IL 61801

Good Morning:

The enclosed literature packet has been assembled specifically for current owner of the Norland-Cameron 178 Bone Mineral Analyzer. In essence, it describes what Norland has done to insure continuing state of the art support for your important bone programs. If you are not already familiar with it, I am referring to the Norland 278A Digital Bone Densitometer, a microprocessor based, second generation instrument that is available to 178 users at a special price.

The new brochure describes the manner in which the 278A visually displays each bone profile along with BMC, BW and BMC/BW readings. Since a Microprocessor now oversees all aspects of a scan, there is less operator overhead and increased reliability. This new computer and associated software is the basis for a number of exciting enhancements.

Most significantly, the Norland Bone Densitometer has been revised to accommodate very small bones. This means that minute changes of 4-5% can be serially tracked and values as low as 0.05 g/cm BMC can be accurately measured. (Precision is $\pm$2.5%). A specially designed positioning system is now available to facilitate the special handling of infants. The response to this new development from pediatricians, neonatologists and laboratory researchers has been tremendous. The latter group is extremely enthused about our whole rat femur analysis program.

Norland has also introduced a new 5 1/4" Floppy Disk Drive system for magnetic storage of individual scans. These records are accessible in the future if further manipulation of data is required. In addition, we offer a high resolution graphics printer and associated hard copy format which is very convenient for documenting or clinically charting a subject's scan. I have included a sample for your review.

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Several new limb holders have been developed in conjunction with the Bone Densitometer.

The forearm positioning system is standard and offers a number of advantages over its predecessor including precise calibration for serial repositioning, greater patient comfort and ease of operation. To better monitor rapid changes, the phalange system is offerred for accurate hand positioning. The infant capability referenced above addresses a whole new realm of specialties and is perhaps our most critical development. Finally, a laboratory animal holder is also available if research is directed in that area.

An added bonus with the 278A is increased source life. Due to improvements in its architecture only (2) 200 mCi sources are required annually. Norland issues a discount for multiple unit orders and of course maintains a source program for an uninterrupted supply of I-125.